Infrascanner Model 2000

Operator Manual

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DISCLAIMER

Neither InfraScan nor any of its worldwide subsidiaries shall be liable in any manner in respect to bodily injury and/or property damage arising from this product or the use thereof if the Infrascanner is not operated and maintained in strict compliance with instructions and safety precautions contained herein, in all supplements hereto and according to all terms of warranty and sale relevant to this product.

DEPARTMENT OF THE NAVY
Headquarters, U.S. Marine Corps
Washington, DC 20380-0001

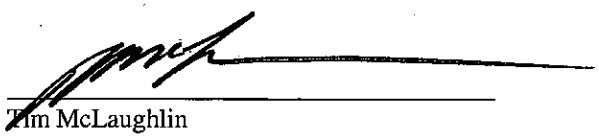
04 February 2015

1. This Technical Manual (TM), authenticated for Marine Corps use and effective upon receipt, provides operations and levels of maintenance as determined by the OPERATOR'S MANUAL FOR THE INFRASCANNER MODEL 2000, National Stock Number (NSN): 6515-01-626-6441.

2. Safety issues related to the information contained in this manual should be reported to the Marine Corps Systems Command Safety Office at MCSC Safety@usmc.mil. All significant safety hazards that have the potential to affect other commands and require widespread dissemination shall be reported via a Hazard Report per MCO P5102.1B.

BY DIRECTION OF THE COMMANDANT OF THE MARINE CORPS

OFFICIAL:



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REVISION RECORD

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Table of Contents

Table of Figures

1.0 System Information

1.1 Classification.

- **Equipment Function:** Detection of superficial supratentorial traumatic intracranial hematomas
- **Degree of protect against elec. Shock:** Type BF applied part.
- **Supply connection:** Internal rechargeable or disposable battery
- **Cradle Power Adapter:** Medical Grade 5 VDC at >1 Amp
- **Mode of Operation:** Continuous with intermittent loading
- **Degree of mobility:** Handheld
- **Laser Classification:** Class 1 Laser Product

1.2 Intended Use / Indications.

The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of greater than 3.5 mL in volume that are less than 2.5 cm from the brain surface, as an adjunctive device to the clinical evaluation in the acute hospital setting of patients 18 years old or greater with suspected traumatic supratentorial intracranial hematoma. The device is indicated to assess patients for Computed Tomography (CT) Scans but should not serve as a substitute for these scans. The Infrascanner is indicated for use by physicians, or under the direction of a physician, who has been trained in the use of the device.

1.3 Specifications.

1.3.1 Physical Specifications:

a. Dimensions with Disposable: 9.0H x 3.4W x 2.4D inch (23H x 8.5W x 6.1D cm).
b. Dimensions without the Disposable Fiber Optic Shield: 9.0H x 3.4W x 1.8D inch (23H x 8.5W x 4.6D cm).
c. Weight of Infrascanner: 14oz (400g).
d. Number of detectors: 1.
e. Number of light sources: 1.
f. Light Source - Detector Separation: 4 cm.

1.3.2 Functional Specifications:

a. Power 4.8V, Rechargeable NiMH Battery pack (1AH) or 4 AA disposable batteries.
b. Standby time 2 weeks.
c. Operating time on new fully charged batteries: >60 minutes.

1.3.3 Laser Diode Specifications:

a. Wavelength: 808nm (±3nm).
b. Maximum peak pulsed power: 100 milliwatt.
c. Safety: Class 1 Laser Product.

1.3.4 Cradle Power Adapter Specification:

a. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647, 201.784.1000. Model Number: WR9QA1200LCP-N-MED (R). Input voltage: 100-240 volt AC. Input current: < 0.5 Amps. Input frequency: 50-60 Hz. Output: 5 VDC @ 1.2 amps.

1.3.5 Operational Limits:

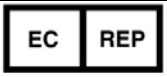
	Environmental:	Operational	Storage
a	Temperature	14°F to 122°F	-40°F to 158°F
b	Relative Humidity (non-cond)	0% to 90%	0% to 90%
c.	Barometric Pressure	0.7 – 1.01 BAR	0.5 – 1.06 BAR

	***NOTE:*** *Complies with IEC 60601-1 3rd Edition, C22.2 No 601.1-M90 and UL Std. No 60601-1.*

1.4 Regulatory Compliance.

Regulatory symbols have been added to indicate regulatory compliance. These symbols, along with a brief description, are shown in the following table.

Figure 1.1: Regulatory Compliance Symbols

SYMBOL	DESCRIPTION
	Qarad b.v.b.a. Cipalstraat 3 B-2440 Geel Belgium
	"Conformite Europeen" Mark 2008
	Single Patient Use (for disposable shield only) Usage unique (seulement pour protecteur jetable)

	CSA Canada and USA Safety Testing IEC60601-1 CSA Canada et vérification de sécurité Américaine IEC60601-1
	Type BF equipment -having an applied part with or without an intentional electrical path to the patient Équipement de type BF - partie appliqué avec ou sans chemin conducteur intentionnel vers le patient
	Attention, see Operation Manual for use Attention, voir manuel d'utilisation
	Cradle Power Adapter is 5 volts DC Le bloc d'alimentation du support est de 5 VDC
	WEEE

2.0 Safety Information

2.1 Symbols and Messages.

2.1.1 Cautions, Warnings and Notes.

a. This manual contains important messages with symbols labeled **NOTE, CAUTION** and **WARNING**. These messages have the following format and meaning:

Figure 2.1: Safety Symbols and Messages Used in Manual

 **NOTE:**	**SUPPLIES ADDITIONAL INFORMATION THAT WILL HELP COMPLETE, OFFER AN ALTERNATIVE TO, OR EXPLAIN A PORTION OF A GIVEN PROCEDURE.**
 **CAUTION!**	**PROVIDES INFORMATION TO PREVENT ERRORS OR INDISCRETIONS THAT COULD RESULT IN EQUIPMENT, SYSTEM, OR COMPONENT DAMAGE.**
 **WARNING!**	**INDICATES AREAS WHERE INSUFFICIENT KNOWLEDGE OF A GIVEN PROCEDURE, IMPROPER HANDLING, OR LACK OF ATTENTION COULD RESULT IN PERSONAL INJURY OR LOSS OF LIFE!**

b. Read each labeled message carefully, and follow its instructions during operation to reduce the risk of system or component damage and/or personal injury.

	**WARNING! IMPROPER OPERATION OF THE INFRASCANNER COULD ENDANGER THE OPERATOR AND/OR A PATIENT!**

c. Since it is virtually impossible to foresee all of the possible consequences resulting from the failure to follow instructions and adhere to safety procedures, the **NOTES, CAUTIONS** and **WARNINGS** contained in this manual are not exhaustive. It is the responsibility of the individual operating the Infrascanner to make safety the number one priority during operating procedures.

2.1.2 General Warnings

SYMBOL	GENERAL WARNING
	THE INFRASCANNER CONTAINS A NEAR INFRARED LASER (CLASS 1). DO NOT ALLOW THE LASER LIGHT TO ENTER THE EYES.
	THE INFRASCANNER IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE. A FIRE MAY RESULT. KEEP THE INFRASCANNER AWAY FROM FLAMMABLE SOURCES.
	THE INFRASCANNER IS A SCREENING DEVICE INTENDED AS AN ADJUNCT TO THE STANDARD CLINICAL ASSESSMENT OF ADULT PATIENTS WITH SUSPECTED TRAUMATIC INTRACRANIAL HEMATOMA. A “NEGATIVE” INFRASCANNER RESULT SHOULD BE INTERPRETED WITH CAUTION SINCE SUCH A RESULT DOES NOT ADEQUATELY EXCLUDE THE PRESENCE OF SERIOUS UNDERLYING INTRACRANIAL HEMATOMA.
	IN THE CLINICAL STUDY OF THE DEVICE, PATIENTS WERE TO BE SCANNED WITH THE INFRASCANNER WITHIN 30 MINUTES BEFORE OR AFTER A CT SCAN. SINCE A TRAUMATIC HEMATOMA MAY EVOLVE RAPIDLY THE INFRASCANNER RESULT IS NOT PREDICTIVE OF THE ABSENCE OF A HEMATOMA WHEN LONGER THAN 30 MINUTES HAVE ELAPSED SINCE THE TEST WAS COMPLETED.
	COMPLETE THE TRAINING AND READ THE ENTIRE OPERATOR MANUAL BEFORE ATTEMPTING TO OPERATE THE INFRASCANNER.
	ONLY CONNECT THE CRADLE POWER ADAPTER TO THE CRADLE, OTHERWISE HAZARDS MAY EXIST.
	THE INFRASCANNER SHOULD NOT BE MODIFIED IN ANY WAY OR BY ANY USER. UNAUTHORIZED MODIFICATIONS TO THE INFRASCANNER MAY CAUSE IT TO MALFUNCTION OR FAIL IN USE.
	USE CAUTION IN EXERCISING PRESSURE ON THE HEAD WHEN USING INFRASCANNER, SINCE EXCESSIVE PRESSURE MIGHT EXACERBATE AN UNDERLYING SKULL INJURY.
	THE SAFETY/EFFICACY OF THE INFRASCANNER IN SUBJECTS <18 YEARS OLD HAS NOT BEEN EVALUATED.

	**THE ACCURACY OF THE INFRASCANNER IN DETECTING SUBARACHNOID HEMORRHAGE HAS NOT BEEN ESTABLISHED.**
	**THE INFRASCANNER SAFETY AND EFFECTIVENESS HAS NOT BEEN ESTABLISHED IN A PRE-HOSPITAL SETTING.**
	**THE PERFORMANCE OF THE INFRASCANNER HAS NOT BEEN ESTABLISHED FOR THE DETECTION OF HEMATOMAS LESS THAN 3.5 CC IN VOLUME OR MORE THAN 2.5 CM FROM THE BRAIN SURFACE INCLUDING INTRAVENTRICULAR HEMORRHAGE. THE PERFORMANCE OF THE INFRASCANNER HAS NOT BEEN ESTABLISHED FOR THE DETECTION OF POSTERIOR FOSSA HEMORRHAGE.**
	**THE PERFORMANCE OF THE INFRASCANNER IN DETECTING SUBARACHNOID HEMORRHAGE ALONE OR WITH OTHER TYPES OF HEMORRHAGE HAS NOT BEEN ESTABLISHED.**
	**THE INFRASCANNER RESULT IS BASED ON THE DIFFERENCE IN INFRARED LIGHT ABSORPTION ON HOMOLOGOUS LEFT AND RIGHT REGIONS OF THE SKULL. BECAUSE OF THIS:** **1. The result may be negative in the presence of bilateral hematomas of similar size and location.** **2. The Infrascanner may only detect the larger of bilateral hematomas in a similar location.** **3. The performance of Infrascanner may be affected by the presence of blood within or under the scalp and by the presence of scalp edema.** **4. The performance of Infrascanner may be affected by increased skull thickness.** **5. The Infrascanner cannot detect chronic (non-acute) hematomas.**
	**DO NOT RE-USE THE DISPOSABLE FIBER OPTIC SHIELD ON A DIFFERENT PATIENT. THE DISPOSABLE SHIELD IS FOR SINGLE PATIENT USE ONLY. WHEN THE DISPOSABLE SHIELD CONTACTS THE PATIENT, IT IS CAPABLE OF TRANSFERRING INFECTIOUS AGENTS.**
	**THE INFRASCANNER SHOULD NOT BE USED ON PATIENTS FOR WHOM THE USE OF AN UNSTERILIZED DEVICE MIGHT POSE A RISK OF INFECTION.**

	**FEEL THE MEASUREMENT AREA WITH YOUR FINGERS TO VERIFY THAT THERE IS NOT A SUBCUTANEOUS SCALP INJURY AT THE MEASUREMENT SITE. THIS CONDITION COULD ADVERSELY AFFECT THE RESULTS.**

2.1.3 General Cautions.

SYMBOL	GENERAL CAUTIONS
	**THE INFRASCANNER MAY CAUSE INTERFERENCE TO OTHER INFRARED DEVICES WHEN THE MEASUREMENT BUTTON IS DEPRESSED.**
	**DO NOT IMMERSE THE INFRASCANNER IN ANY LIQUID. SUBJECTING THE INFRASCANNER TO EXCESSIVE MOISTURE MAY DAMAGE THE ELECTRONIC COMPONENTS AND NULLIFY THE WARRANTY.**
	**ALWAYS USE THE PROVIDED CRADLE MEDICAL POWER ADAPTER FOR CONNECTING TO THE CRADLE. ANY OTHER POWER SUPPLY MAY DAMAGE THE CHARGING CIRCUITRY AND/OR THE NIMH RECHARGEABLE PACK.**
	**NEVER STERILIZE THE INFRASCANNER OR THE DISPOSABLE FIBER OPTIC SHIELD OR IT WILL BE DAMAGED.**
	**THE BATTERY PACK NEEDS TO BE INSTALLED WITH CARE TO ASCERTAIN THAT THE WIRES ARE NOT PINCHED OR COMPRESSED IN ANY WAY, OR THE BATTERY PACK CAN BE DAMAGED. VERIFY THAT THE LEADS ARE POSITIONED AS INDICATED IN THE FIGURE 6-2, AND NOT PINCHED OR COMPRESSED IN ANY WAY OR THE BATTERY PACK CAN BE DAMAGED.**
	**ELECTROMAGNETIC INTERFERENCE CAN DISRUPT INFRASCANNER OPERATION.**

2.1.4 General Notes.

SYMBOL	GENERAL NOTES
	***The Infrascanner should be operated by trained Health Service Support personnel on order of a physician. Any user of the Infrascanner must be trained on the use of the Infrascanner. The Infrascanner should not be operated by users who were not trained on its use.***
	***The Infrascanner battery will not charge if the battery temperature is <0˚ C or >50˚ C.***
	***To assist color blind users, the red locations have different pattern than green locations.***
	***Taking measurements with dark skinned, dark haired subjects is more difficult than light haired, light skinned subjects, because the dark pigment in skin, hair, and hair follicles is very absorbent of Near Infrared (NIR) light resulting in a weaker signal for the Infrascanner.***
	***Read each labeled message carefully, and follow its instructions during removal or replacement to reduce the risk of system or component damage and/or personal injury.***

2.1.5 Tool Symbol.

SYMBOL	GENERAL NOTES
	Tool requirements are indicated by this symbol and have this format. This symbol and the accompanying text indicate that a specific tool and/or material is required to perform a specific part of a procedure. Always use the tool recommended in the repair procedures of this service manual. Substitutions, or using the improper size drive, could damage the hardware. Use of an improper tool could also result in personal injury. **ALWAYS USE THE RIGHT TOOL FOR THE JOB!**

3.0 System Components

The InfraScan Model 2000 Infrascanner is a handheld NIR brain hematoma detector. This manual familiarizes the operator with the Infrascanner operation, the technology of the Infrascanner, and the software used in its operation. Items that are included in the system (see Figure 3-1), are:

- The Infrascanner Model 2000.
- The Infrascanner Model 2000 Cradle.
- An Infrascanner Model 2000 Disposable Shield.
- Transport Case.
- The Infrascanner Model 2000 Operation Manual.
- The USB Cable to connect the Cradle with a PC Computer.
- The Cradle Power Adapter, 5VDC.
- OPTIONAL, Brother RJ4030-K printer, (not included in kit).
- An Infrascanner Rechargeable Battery Pack.

!	***NOTE: A computer running Microsoft Windows XP (with Active Sync installed) or later, is required to download the Infrascanner's data.***

Figure 3-1: Transport Case with System Components

3.1 Control *and* Indicators.

3.1.1 Measure Buttons.

Located on the back of the Infrascanner are two blue buttons (see Figure 3-2), depressing and releasing either one of them initiates a measurement.

Figure 3-2: Blue Buttons

3.1.2 Software Arrows and Enter Button.

Located on the front of the Infrascanner, are 5 buttons that are used to control the software of the Infrascanner (see Figure 3-3).

Figure 3-3: Control Buttons

3.1.3 Power and USB Receptacles.

Located on the back of the Cradle are three connectors. They are the 5.5mm by 2.5mm Cradle Power Adapter connector, the optional printer RS-232 serial port connector, and the mini-USB connector for connecting to a personal computer (See Figure 3-4).

Figure 3-4: Cradle Connectors

3.1.4 Charging Light-Emitting Diode (LED)s and Cradle ON/OFF switch.

The blue Cradle ON/OFF switch is used to turn ON the Infrascanner, while the Infrascanner is in the cradle (see Figure 3-5). When the Cradle is connected to the main power, a green Power LED will illuminate. When the Infrascanner is set in the cradle and being charged, an amber LED will illuminate. When no batteries are present in the Infrascanner both the amber charge LED and the orange fault LED will be extinguished. When disposable batteries are placed in the Infrascanner, both the amber charge LED and the orange fault LED will be extinguished to indicate that the Cradle is not charging the disposable batteries. Disposable batteries cannot be charged by the Cradle.

Figure 3-5: Cradle LED and ON/OFF

4.0 Theory of Operation

4.1 Basic Near Infrared Light Theory.

- All biological tissue is, to differing extent, permeable to electromagnetic (EM) radiation of different frequencies and intensities. This can also be considered permeability to photons of different energy levels. This permeability to EM energy is the basis of all imaging based on transmission/scattering characteristics such as x-ray, CT Scan, and NIR imaging. From the principles of spectroscopy, it is also known that different tissues absorb different wavelengths of light. The Infrascanner is concerned with NIR imaging of the hemoglobin molecule.

- Photons follow a characteristic path through tissue when the source is on the same plane as the detector. While the light is severely attenuated due to the scattering and absorption process, it is encoded with the spectroscopic signatures of the molecules encountered en route to the detector. By choosing the wavelengths that are produced by the source, it is possible to detect the relative concentration of haemoglobin in the target tissue. Figure 4-1 shows the simulated diffusion path through target tissue from source to detector.

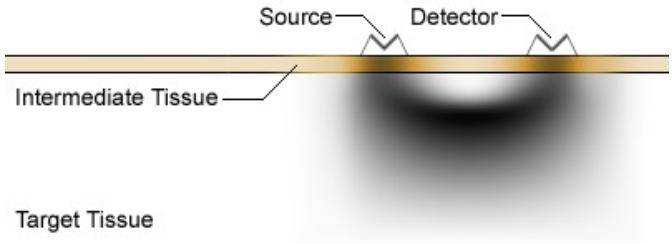


Figure 4-1: Simulated Photon Diffusion Path

- The principle used in identifying intracranial hematomas with the Infrascanner is that extravascular blood absorbs NIR light more than intravascular blood. There is a greater (usually 10-fold) concentration of hemoglobin in an acute hematoma than in normal brain tissue where blood is contained within vessels. The Infrascanner compares left and right side of the brain in four different areas. The absorbance of NIR light is greater (and therefore the reflected light less) on the side of the brain containing a hematoma.

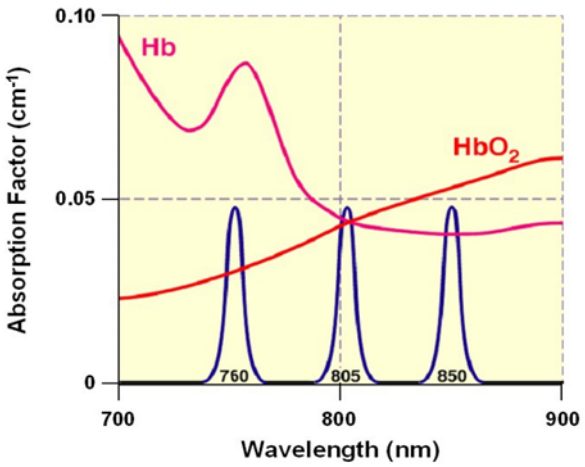


Figure 4-2: Absorption of light by hemoglobin

- The wavelength of 805nm is sensitive only to blood volume, not to oxygen saturation in the blood (see Figure 4-2). The Infrascanner is placed successively in the left and right frontal, temporal, parietal, and occipital areas of the head and the absorbance of light at 805 nm is recorded and compared.

- The frontal sites are on the left and right sides of the forehead, above the frontal sinus. The temporal sites are on the left and right sides of the temporal fossa in front of the top of the ear. The parietal sites are on the left and right sides midway between the ear and the midline of the skull. The occipital sites are on the left and right sides behind the top of the ear, midway between the ear and the occipital protuberance, (see Figure 4-3). The sites are scanned in a predetermined sequence as shown in Figure 4-4. The difference in optical density (ΔOD) in the different areas is calculated from the following formula:

$$\Delta OD = \log_{10}\left(\frac{I_N}{I_{H(1)}}\right)$$

Where I_N = the intensity of reflected light on the normal side, I_H = the intensity of reflected light on the hematoma side.

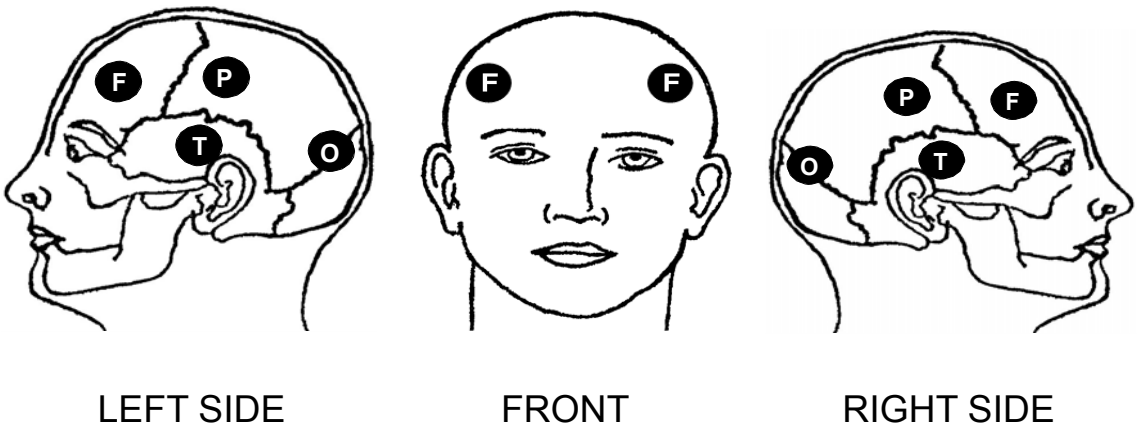


Figure 4-3: Head locations of NIR measurement

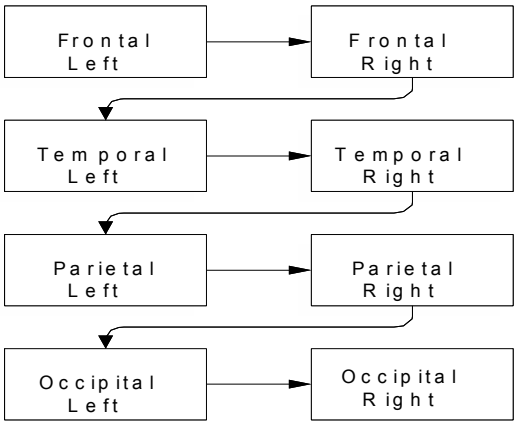


Figure 4-4: Infrascanner head scanning sequence

4.2 The Infrascanner System.

- The Infrascanner includes a safe Class I NIR 808nm diode laser and a silicon detector. The light to and from the laser and detector are optically coupled to the patient's head through two short disposable light guides. The light guides are long enough to reach through hair and contact the scalp. The light guides are placed 4 cm apart allowing optimal detection of hematomas. The detector light passes through an optical bandpass filter centered at 808nm in order to minimize background light interference. Electronic circuitry is included to control laser power and the detector signal amplifier gain. The detector signal is digitized and analyzed by a Single Board Computer (SBC) in the Infrascanner. The SBC receives the data from the detector and automatically adjusts the settings of the Infrascanner to ensure good data quality. The data is further processed by the SBC and the results are displayed on the screen.

- The Infrascanner is turned on by placing a Disposable Fiber Optic Shield on the Infrascanner (see Figure 4-5) and turned off by removing the Disposable Fiber Optic Shield. If the Disposable Fiber Optic Shield is not removed after approximately 8 minutes of inactivity, the Infrascanner goes into a sleep mode and starts' beeping until the Disposable Fiber Optic Shield is removed. Since the Infrascanner is still on, this will drain the battery.

- When the Infrascanner is turned on and set to the Measurement screen, pressing and releasing one of the Measure Buttons activates a measurement sequence at a given head location. The measurement includes an initial adjustment phase and then the data collection. The adjustment of laser power and detector signal gains is only done at the first head location of a pair. The contra-lateral location uses the same Infrascanner hardware parameters as the ipsi-lateral location. After a measurement pair, the screen will display the differential optical density for that pair. The absolute value of optical density is not relevant, just the relative difference between left and right sides of the head.

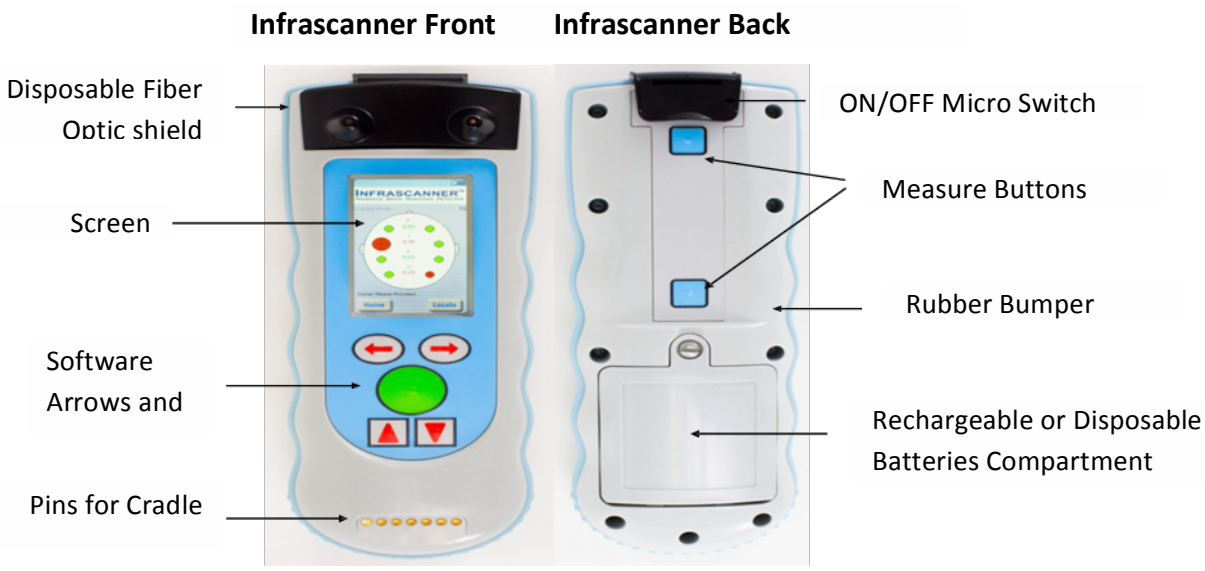


Figure 4-5: Model 2000 Infrascanner

- Audible signals indicate when the measurement is done. A first short beep indicates when the measurement button is pressed and the measurement begins and a second short beep indicates a completed measurement. Four short beeps indicate a time out message. An elongated beep indicates an error message. The error message must be cleared by pressing the green button. If the data is unacceptable, the measurement pair is to be repeated before proceeding to the next head pair. The Infrascanner can be powered either by a rechargeable NiMH battery pack or by 4 disposable AA batteries.

- The Cradle, Figure 4-6, is used to charge the rechargeable battery pack, if it is used in the Infrascanner, to connect to the optional printer, and to transfer data from the Infrascanner to a Personal Computer (PC).

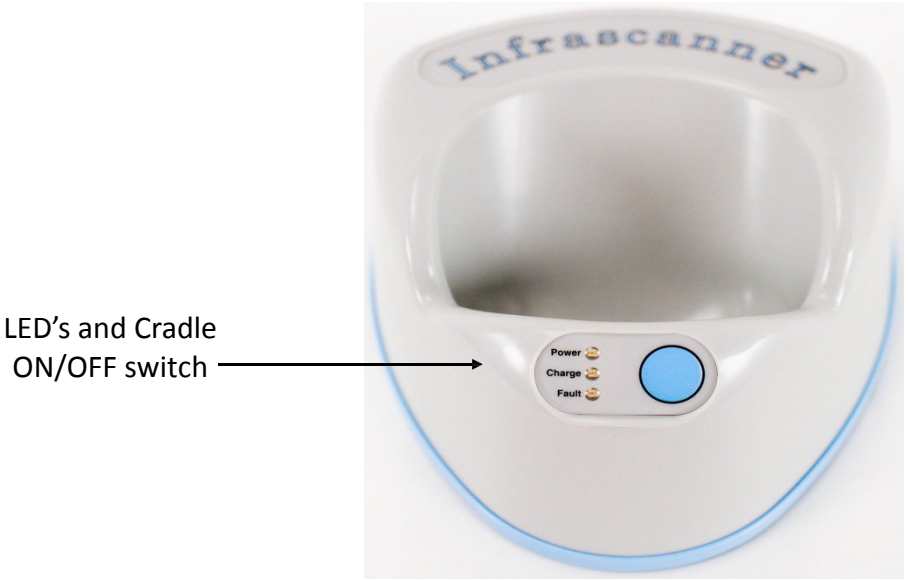


Figure 4-6: Model 2000 Cradle

Summary of Audio and Visual Feedback	
Task	**Audio/Visual Feedback**
Initiate Measurement with button.	Short Beep and screen dark.
Finish Measurement.	Short Beep and screen flash.
Error during measurement.	Long Beep and screen message.
Forgot to remove the disposable shield.	Constant short beeping until dead battery.

5.0 Operating Procedure

5.1 Setting Up the System.

- Attach the Cradle Power Adapter to the Cradle (see Figures 5-1 and 5-2), and connect it to the AC Main Power. The green “Power” LED on the cradle should illuminate. Place the Infrascanner in the Cradle, taking care to insert the Infrascanner vertically and then let the Infrascanner lean backwards pushing the contacts against the spring loaded cradle pins. When removing the Infrascanner from the Cradle tilt it back to vertical, to first disengage the pins, and then pull it out vertically.

Figure 5-1: Power Adapter

- Do not place the Infrascanner in the cradle with the disposable shield installed. If the Infrascanner turns on when placed in the cradle, disconnect main power for 10 seconds. When the cradle “ON” button is pressed, the Infrascanner turns on and the charging function is stopped until the Infrascanner turns itself off in about 10 minutes. If the orange “Fault” LED illuminates, replace the rechargeable battery pack.

- When the Infrascanner is placed in the Cradle, the amber Charge LED will blink for 10 seconds, (unless the rechargeable battery pack is severely depleted at which point it can blink for longer). If the disposable batteries are installed, after the 10 seconds of blinking, the amber Charge LED and the orange Fault LED will be extinguished. If the rechargeable battery pack is installed, after the variable time of blinking, the amber Charge LED will illuminate continuously. If no batteries are installed, after the 10 seconds of blinking amber LED, neither the amber Charge LED nor the orange Fault LED will illuminate. The Infrascanner can require up to 6 hours to charge, and is fully charged when the amber Charge LED extinguishes. The Infrascanner detects when disposable batteries are in the Infrascanner and will not charge them. There is no hazard under this condition.

- When the Infrascanner is placed in the Cradle, the amber Charge LED will blink for 10 seconds, (unless the rechargeable battery pack is severely depleted at which point it can blink for longer). If the disposable batteries are installed, after the 10 seconds of blinking, the amber Charge LED and the orange Fault LED will be extinguished.

- If the rechargeable battery pack is installed, after the variable time of blinking, the amber Charge LED will illuminate continuously. If no batteries are installed, after the 10 seconds of blinking amber LED, neither the amber Charge LED nor the orange Fault LED will illuminate. The Infrascanner can require up to 6 hours to charge, and is fully charged when the amber Charge LED extinguishes. The Infrascanner detects when disposable batteries are in the Infrascanner and will not charge them. There is no hazard under this condition.

Figure 5-2: Cables Connected

!	***NOTE:*** *The Infrascanner battery will not charge if the battery temperature is <0˚ C or >50˚ C.*

5.2 To Review the Data.

- Connect the Cradle to a Windows PC with the USB cable.
- Connect the power supply to the Cradle (see Figure 5-2).
- Insert the Infrascanner into the cradle.
- Turn on the Infrascanner by depressing the blue cradle ON button. In Windows 7 and newer operating systems, the “Windows Mobile Device Center” will automatically start, connect and query what to do. Select, Connect without Syncing.
- Browse the Infrascanner SD memory card and download the data files in the data folder which is called HSData.

5.2.1 Minimum PC Computer Requirements.

a. Microsoft Windows XP with Microsoft ActiveSync or Windows 7 or later.
b. Microsoft Internet Explorer 6.0 or later.
c. Hard-disk drive with 65 MB of available hard-disk space (actual requirements will vary based on selection of features and user's current system configuration)
d. Available USB port.
e. VGA graphics card or compatible video graphics adapter at 256 color or better
f. Keyboard.
g. A Mouse or compatible input pointer device.
h. Internet connection is optional.

5.3 The Disposable Fiber Optic Shield.

- Attach the Disposable Shield to the Infrascanner as shown in Figure 5-3. Place the fibers over the optical towers and push firmly at the top/back of the disposable, until you feel the disposable snap onto the Infrascanner. This turns on the Infrascanner.

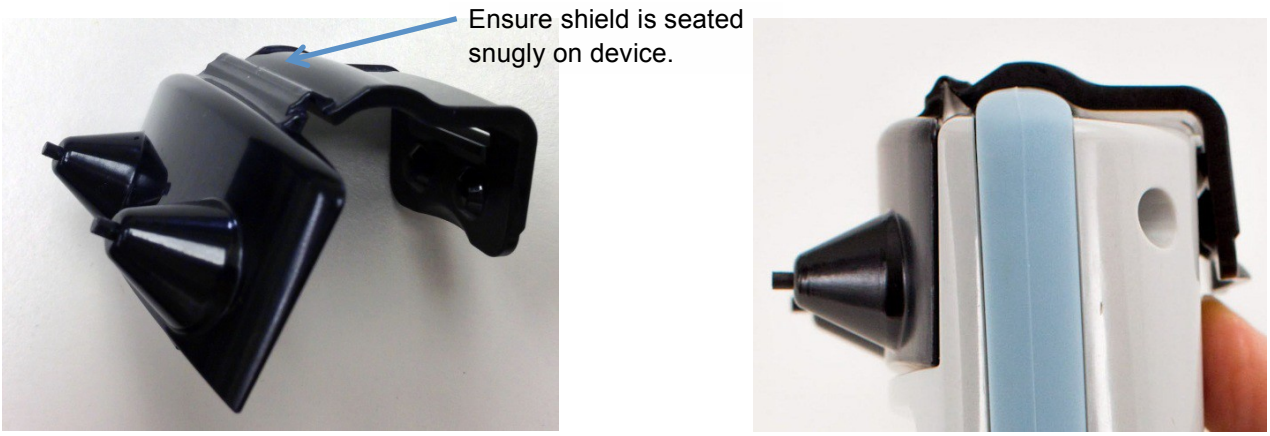


Figure 5-3: Attaching the Disposable Fiber Optic Shield

5.4 Software Navigation.

- Use the Left/Right arrows to change which button is selected. Use the Green central "Enter" button to execute the selected button in the software. Use the Up/Down arrows to edit the selected field values (See Figure 5-4).

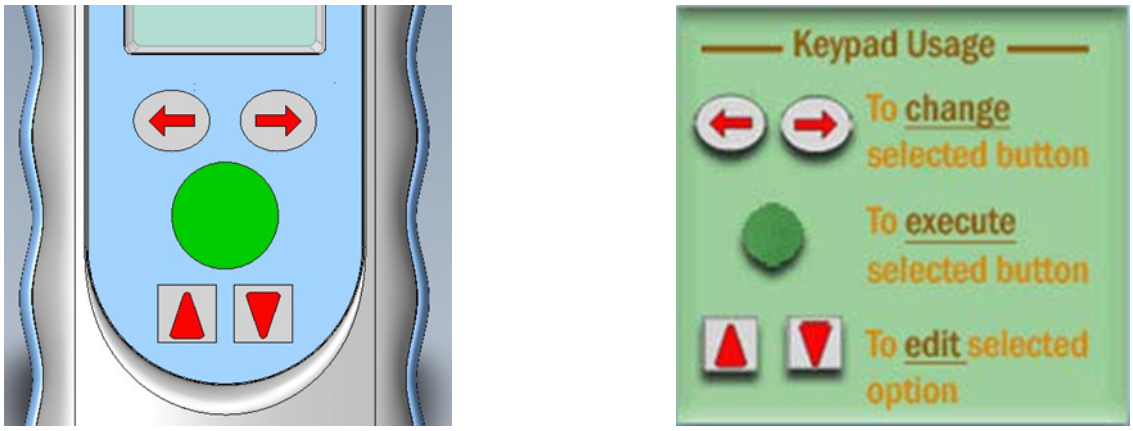
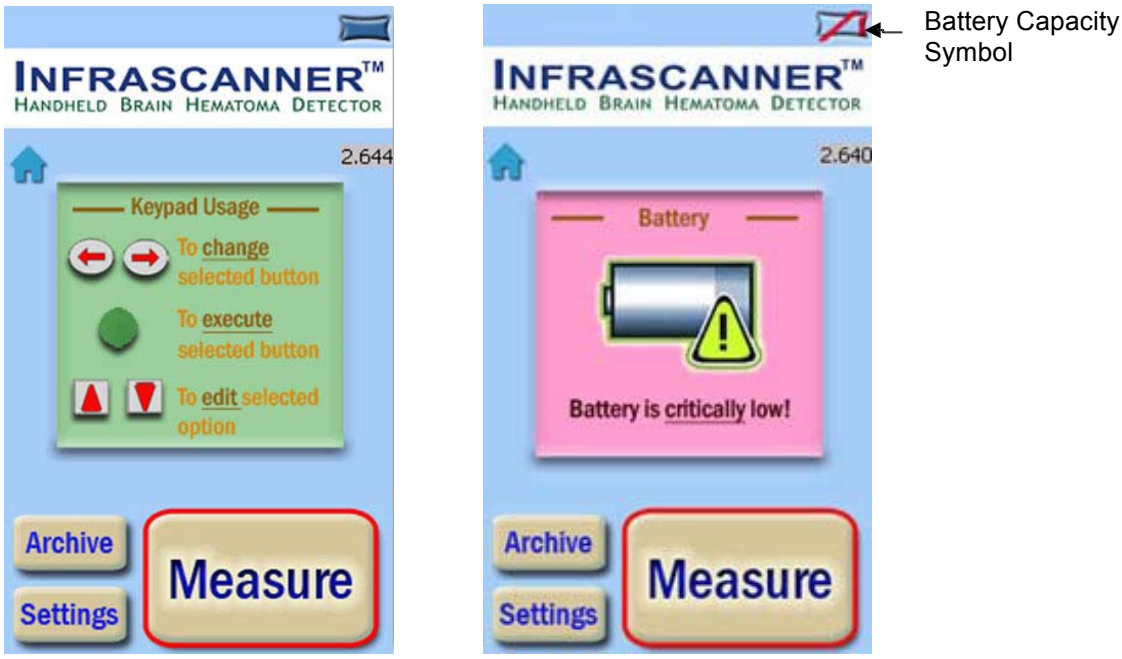


Figure 5-4: Software Navigation Buttons of the Infrascanner and their use

5.5 Measurements with the System.

- Attach a Disposable Fiber Optic Shield to turn on the Infrascanner.
- Press the Measure button, see Figure 5-5. The Select Study ID screen appears, (see Figure 5-6). The Select Study ID window is de-activated, but the screen indicates a sequential file number (Next Measurement #) for the patient. Record this number in the notes, if interested in a later analysis of the patient's data.
- Press the Measure button again to go to the Measurement screen. The file number appears in the upper right corner, (see Figure 5-7).
- The indicator in the upper right corner of the screen shows the battery capacity status, See Figure 5-7.



(a) (b)

Figure 5-5: Main Screen (a – standard, b – when the battery is low)

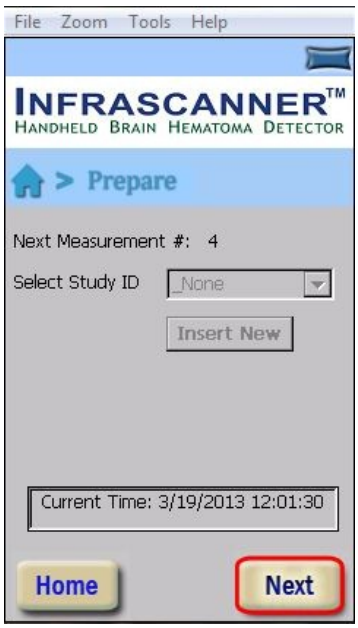


Figure 5-6: Select Study ID Window

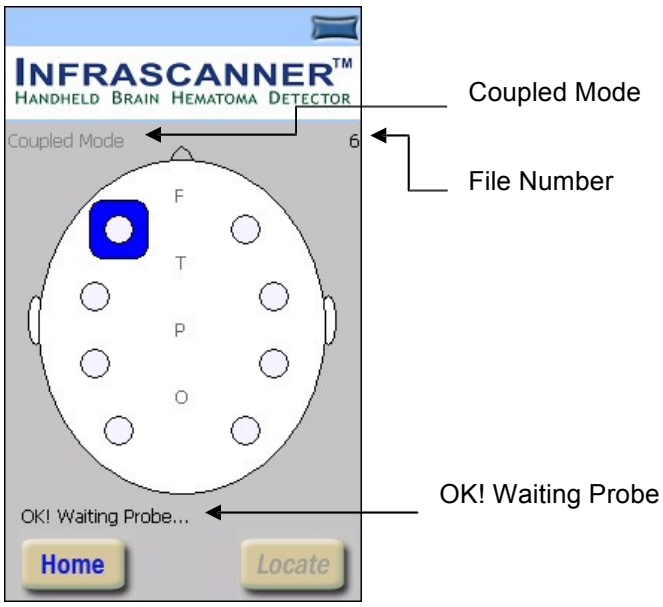


Figure 5-7: Measurement Screen

- If the battery was removed, or is dead, the Infrascanner clock will need to be reset. A yellow triangle popup will ask the user to set the Infrascanner clock. See Section 5.8 of the Operator Manual to set the clock.
- Verify that the “OK, Waiting probe” message appears on the bottom left of the screen. Verify that “Coupled Mode” is indicated on the top left of the screen (see Figure 5-7). If a “communications error” message is indicated instead of the “OK, Waiting probe” message, remove the Disposable Fiber Optic Shield and put it back on to reset the Infrascanner. Re-initiate the data collection.

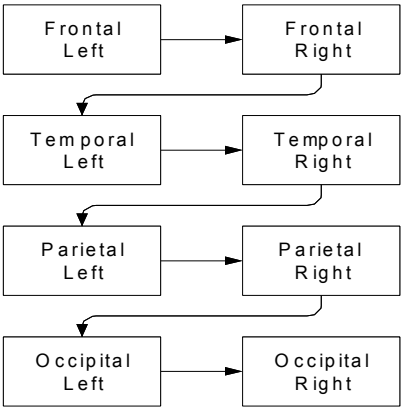


Figure 5-8: Scanning sequence

- The Infrascanner is ready to begin measuring. Take the Infrascanner and start the head scan, alternating between left and right positions according to the head scanning sequence in Figure 5-8. The blue square on the screen in Figure 5-9 indicates the current measurement location.
- In each location wiggle the light guides so they will be in clear contact with the scalp. Ascertain that no hair is between the light guides and the scalp. After establishing firm contact press and release one of the two Measure buttons. Either one of the buttons can be used, depending on which is more convenient. The measurement begins after the button is released and an audible beep is sounded. Use your free hand to support patient’s head, by placing it on the contra-lateral side of the measurement site. Ensure that the light guides are perpendicular to the scalp.

- After each successful measurement, the Infrascanner will beep and the blue square indicator will prompt the user to move to the next head location. An error will be indicated by an elongated beep. When an error occurs, look at the screen to read the error message. Then, clear the message by pressing the green button. Repeat the measurement in the same location (or in the contralateral side – depending on the error message). After successful measurement of two contralateral head locations the scanner will display the relative optical density difference between left and right sides of the pair, (see Figure 5-9).
- The Infrascanner may be used on patients with open wounds but is placed adjacent to, not in, the wound. Wipe away any residual blood before placing the light guides on the scalp.

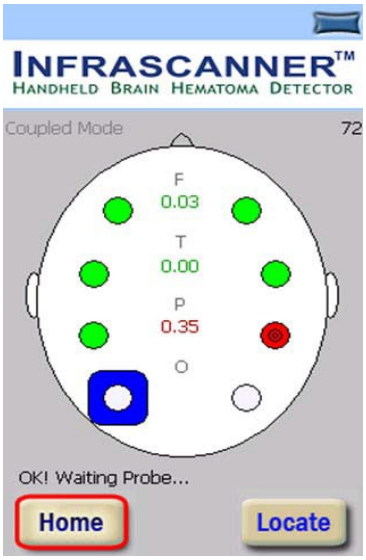


Figure 5-9: Measurement Screen with results

	**WARNING! FEEL THE MEASUREMENT AREA WITH YOUR FINGERS TO VERIFY THAT THERE IS NOT A SUBCUTANEOUS SCALP INJURY AT THE MEASUREMENT SITE. THIS CONDITION COULD ADVERSELY AFFECT THE RESULTS.**

- After completing each data pair, review the screen. If one of the locations is red, touch the right location and repeat the measurement of the pair (up to two more times), to confirm the findings and reduce the chances of a false alarm due to a trapped hair under the light guides. Continue testing until the entire head scan is complete.

	***NOTE:*** *To assist color blind users, the red locations have different pattern than green locations.*
	***NOTE:*** *Taking measurements with dark skinned, dark haired subjects is more difficult than light haired, light skinned subjects, because the dark pigment in skin, hair, and hair follicles is very absorbent of NIR light resulting in a weaker signal for the Infrascanner.*

- If it is desired to re-take data, press the “Home” button for a new head scan. Otherwise, remove the Disposable Fiber Optic Shield to turn off the Infrascanner.

5.6 Database and Archive.

All measurements are automatically saved on the Infrascanner. Each measurement is saved as a text file. The name of each data file is the date and time of that measurement: “n_yymmdd-hhmmss.txt” (measurement serial number, year, month, date, hour, minutes and seconds).

5.6.1 To copy the files to your PC.

a. Connect the Cradle's USB port to the PC's USB port with the provided cable.

b. Place the Infrascanner in the Cradle, taking care to insert the Infrascanner vertically and then let the Infrascanner lean backwards pushing the contacts against the spring loaded cradle pins. When removing the Infrascanner from the cradle tilt it back to vertical, to first disengage the pins, and then pull it out vertically. Press the blue Cradle ON button to turn on the Infrascanner. The ActiveSync or Device Center window will pop up automatically, (see Figures 5-10, 5-11).

Figure 5-10: Mobile Device Center

c. Click on the "Explore" icon in ActiveSync tool bar (Win XP) or "Browse the content of your device" under "File Management" (Win7). A Windows Explorer window will open.

d. Double-click on "My Windows Mobile-Based Device". Drag and drop the "HSData" folder located on the Storage Card, to the PC. This folder contains both the data files and the patient database. You can also copy individual data files from the "HSData" folder. To make more storage space available for patient data, delete the HSData folder, the Pindex.dat file, the Psettings.dat file, and the HSTrace file(s) in the root directory. This resets the sequential patient counter.

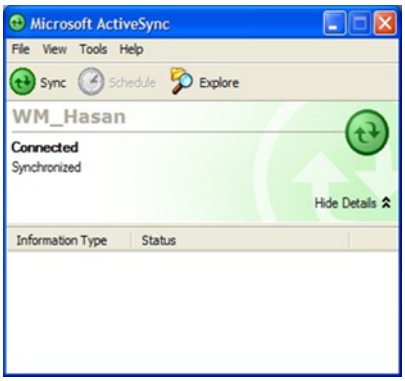


Figure 5-11: Active Sync View

e. Use any text editor or Excel to view and analyze the data on your PC.

f. The text file will indicate the unique file number and time stamp. It will indicate the software versions loaded onto the Infrascanner. The optional Study ID number will be entered into the comment field. The calculated OD's, raw voltages, light power, and gains will be indicated for each measurement site.

5.6.2 To view archived measurements on the Infrascanner.

a. In the Main Screen (Figure 5-5), click on "Archive" button.

b. To view archived measurements click on "View" button, as shown in Figure 5-12.

c. In the list of all the measurements select the required serial number of the measurement and click on “View” button, as shown in Figure 5-13.

d. The next screen, the Archived Measurement screen, Figure 5-14, is the same as the Measurement Screen (Figure 5-9) shown at the end of a measurement.

e. In the Archive List, the way to jump a page forward or backward in the list is to depress the up or down button for 2 seconds. Upon release it will page up or page down. It will revert to single step after that, so if you need to jump another page, you need to re-press the button for two seconds.

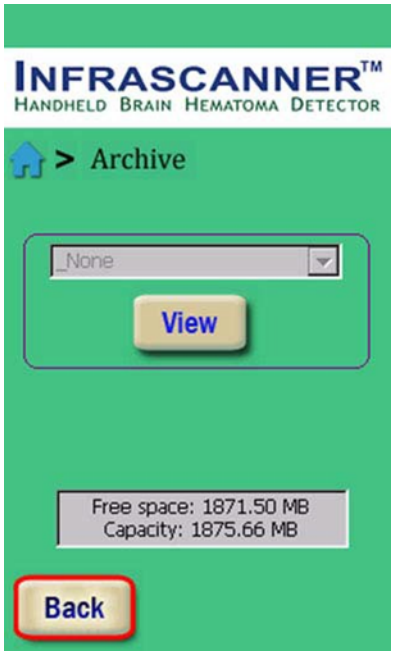


Figure 5-12: Archive Screen

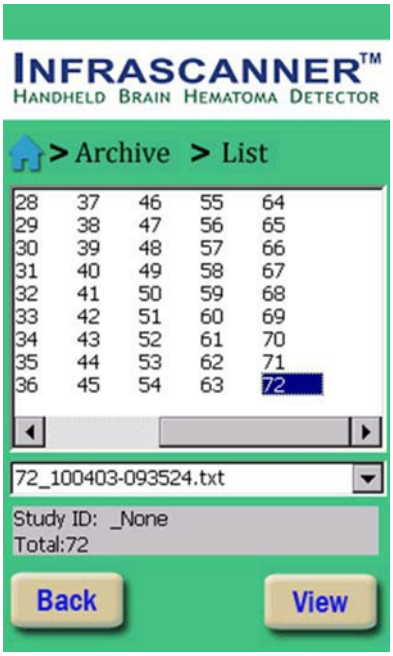


Figure 5-13: List of Measurements

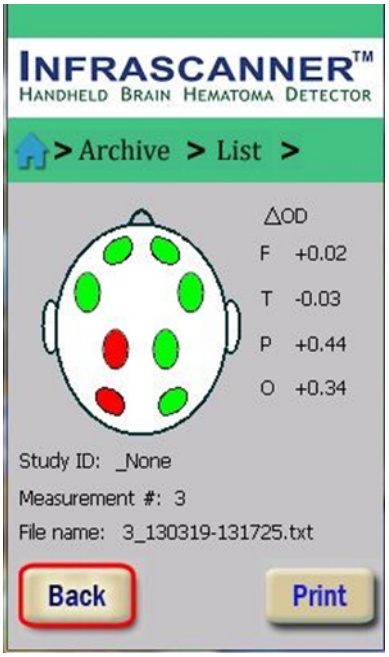


Figure 5-14: Archived Measurement

5.7 Settings.

In the Main Screen (Figure 5-15) click on the Settings button to reach the Settings Screen (Figure 5-16), which allows changing some of the different parameters of the scanner.

To change the most common options (Date/Time, screen Brightness, and to see the Battery status):

- In the Settings Screen (see Figure 5-16) click on a relevant button.
- Use the Left/Right arrows to move between various fields and the Up/down arrows to edit the selected field values.
- For example, to change the date and time, press the Date/Time button (see Figure 5-16 and 5-17). Then, use the Left/Right arrow to navigate to Year and use the Up/Down arrows to set the correct year. Similarly, navigate to the other fields and set the correct date and time.
- Click on Save to store the new parameters and Back to return to the main screen.
- Similarly, the Brightness button allows the selection of Night or Day, Figure 5-18.
- The Battery button allows the battery status to be observed, Figure 5-19. By navigating to the "mv" (milli-volt) window and selecting update, a real time milli-volt reading of the battery voltage can be obtained.

Figure 5-15: Main Screen

Figure 5-16
Settings Screen

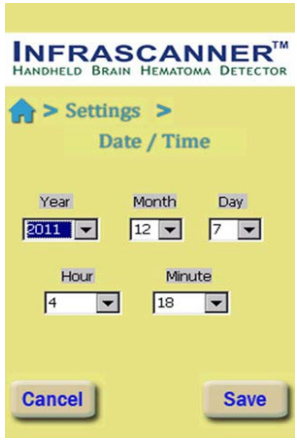


Figure 5-17
Date/Time Setup Screen

Figure 5-18:
Screen Brightness

Figure 5-19:
Battery Status

5.8 Troubleshooting.

Cause	Solution
Problem: The Infrascanner screen does not turn on when Disposable Fiber Optic Shield is placed on.	
There are no batteries installed.	Install either the rechargeable battery pack or use fresh 4 AA disposable batteries.
The battery of the Infrascanner is drained.	Recharge the Infrascanner or use fresh 4 AA disposable batteries.
The disposable batteries are inserted incorrectly.	Ensure that the batteries are installed with the correct polarity as marked on the case.
Problem: The Infrascanner screen flashes or the Infrascanner continuously restarts when the Disposable Fiber Optic Shield is placed on.	
The battery of the Infrascanner is low.	Recharge the Infrascanner or use 4 fresh AA disposable batteries.
Problem: The Cradle amber Charge indicator does not illuminate when charging.	
The battery charging temperature range is exceeded.	The battery will only charge if the battery temperature is between 0-50 degrees Celsius.
The spring loaded cradle pins are dirty or damaged.	Ensure that the cradle pins are clean and free of debris on the Infrascanner and the Cradle. Ensure that the cradle pins press in and extend freely.
The Infrascanner ON button has been depressed.	The cradle does not charge the battery when the Infrascanner ON button is pressed.
Problem: The Cradle Orange Fault indicator illuminates.	
There is a problem with the rechargeable battery pack.	Replace the rechargeable battery pack.

Problem: Infrascanner does not communicate with PC.	
There is dirt on the cradle pins of either the Infrascanner or the Cradle.	Ensure that the cradle pins are clean and free of debris on the Infrascanner and the Cradle. Ensure that the cradle pins press in and extend freely.
Problem: The date resets to an incorrect date.	
The batteries were removed for more than 5 minutes and the clock backup battery was drained.	Set the date and time in the Settings section of the software.
Problem: After selecting the "Next" button to start a measurement, there is a "communications error" message instead of the "waiting probe" message in the bottom left of the Measurement screen.	
Software error.	Take off the Disposable Fiber Optic Shield and put it back on to reset the Infrascanner.
Problem: The error tone was heard and there is an error message on the screen.	
The Infrascanner is low/out of memory.	Delete the HSData folder, the Pindex.dat, the Psettings.dat, and the HSTrace files when connected to a PC. This will reset the sequential file counter to 1.
The optical density algorithm detected a problem with the incoming data.	Clear the error message by pressing the green button and then follow the recommended corrective action on the screen.

Problem: A measurement head location is Red.	
A possible hematoma.	Click on the site of the Red location and repeat the measurement of the pair, up to 3 times, to confirm the findings.
A bad measurement.	Hair is trapped under the light guides. Re-position the light guides taking care to wiggle through hair and repeat measurement up to 3 times.
A bad measurement.	Placement of the light guides is not done in a symmetrical manner on the patient's head.

Problem: The scanner starts beeping.	
More than ~8 minutes elapsed from the previous measurement and the Infrascanner went into the "Sleep" mode.	Take off the disposable fiber optic shield and put it back on, to reset the Infrascanner.

5.9 Error Messages.

Must be cleared by pressing the GREEN navigation button.

Error Message	Causes
High Signal.	Caused by too much ambient light, Infrascanner is especially sensitive to infrared lamps or bright incandescent bulbs. Try shielding the light guide area with hands and repeat the measurement.
Low Signal.	Hair may be trapped under the light guide or light guide might not be making contact with scalp, Repeat the measurement.
Repeat Measurement.	The light on one side of the patient's head is brighter than the other and the amplifiers need to begin the measurement with a lower gain. Re-take the data of the pair.
Saturated, Start in Reverse Order.	The Infrascanner has detected a potential hematoma and needs to re-take the data in the reverse order (right side first) to confirm. The message always occurs when a hematoma is present on the left side (first side of pair to be measured).
Timeout.	Infrascanner gains unable to converge quickly enough. Move the light guides 5mm and repeat the measurement.
Unstable Signal.	Caused by variations in the signal level. Repeat the measurement at the site taking care to hold Infrascanner steady.
Communications Error.	Software error. Take off the Disposable Fiber Optic Shield and put it back on to reset the Infrascanner.
Battery is Low.	Charge the Infrascanner or replace the AA disposable batteries.

6.0 Cleaning, Inspection, and Preventive Maintenance

6.1 Cleaning.

Clean the Infrascanner exterior surfaces monthly (or more frequently if necessary) with a damp cloth or sponge. Use alcohol or mild cleaning solutions to remove stains or adhesives that may stick to the surface. Always ensure that the cradle pins are clean of debris in order to communicate properly with the cradle.

	**CAUTION! DO NOT IMMERSE THE INFRASCANNER IN ANY LIQUID. SUBJECTING THE INFRASCANNER TO EXCESSIVE MOISTURE MAY DAMAGE THE ELECTRONIC COMPONENTS AND NULLIFY THE WARRANTY.**

6.2 Inspection and Preventive Maintenance.

Ensure that the windows over the detector and laser are clear of debris. No special cleaning solutions are required. If necessary, wipe with a soft tissue damp with alcohol. View through the Disposable Fiber Optic Shield's light guides and verify that there are no obstructions to the light path through them.

	**CAUTION! ALWAYS USE THE PROVIDED CRADLE MEDICAL POWER ADAPTER FOR CONNECTING TO THE CRADLE. ANY OTHER POWER SUPPLY MAY DAMAGE THE CHARGING CIRCUITRY AND/OR THE NIMH RECHARGEABLE PACK.**

6.2.1 Sterilization.

	**CAUTION! NEVER STERILIZE THE INFRASCANNER OR THE DISPOSABLE FIBER OPTIC SHIELD OR IT WILL BE DAMAGED.**

6.3 Replacement of AA Batteries.

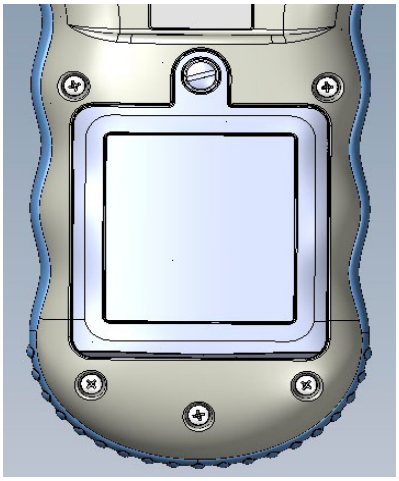
Tool Required.

¼" flat blade screwdriver.

Procedures.

- Use a ¼" flat blade screwdriver to release the battery door latch by turning one half turn counter clockwise.
- To change the AA disposable batteries, remove the used disposable batteries per the image to right.
- Replace the battery door and engage the latch, (see Figure 6-1).
- Follow the polarity markings on the floor of the battery compartment.

!	***NOTE:*** *Ensure proper polarity is observed when inserting the new batteries", and then this should be added to the safety section up top.*



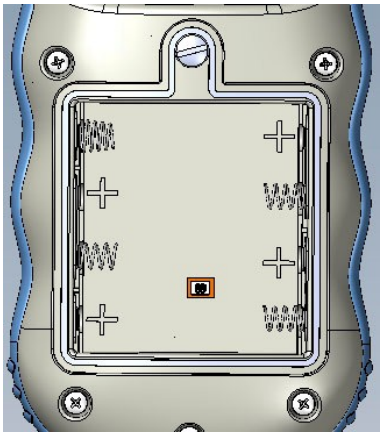


Figure 6-1

6.4 Rechargeable Battery Pack Installation.

Tool Required.

¼" flat blade screwdriver.

Procedures.

- Remove the battery door by loosening the screw with a large flat blade screwdriver.
  - Sometimes the door sticks shut. When this happens do not pull on the screw to open the door, pry on the top of the door with the screwdriver to open.
- Check that the battery pack leads have no bare wire exposed going into the plug. If there are bare wires exposed, switch to disposable batteries, and/or get a replacement battery pack.
- Insert the battery pack plug into the connector inside the battery compartment, making sure that the orientation (polarity) is correct.
- Place the battery pack against the top edge of the battery compartment (see picture to right) as far away from the battery connector as possible.
- Insert the battery, compressing the two springs on the left side as in the picture, and compress the single spring on the right side, if necessary. The battery pack should sit flush against the top of the compartment.
- Verify that the leads are positioned as indicated in the picture, and not pinched or compressed in any way.
- Replace the battery compartment door.

Figure 6-2

NOTE: *Remove the battery if the Infrascanner will not be used for 2 weeks.*

CAUTION! THE BATTERY PACK NEEDS TO BE INSTALLED WITH CARE TO ASCERTAIN THAT THE WIRES ARE NOT PINCHED OR COMPRESSED IN ANY WAY OR THE BATTERY PACK CAN BE DAMAGED. VERIFY THAT THE LEADS ARE POSITIONED AS INDICATED IN THE FIGURE 6-2, AND NOT PINCHED OR COMPRESSED IN ANY WAY OR THE BATTERY PACK CAN BE DAMAGED.

CAUTION! WHEN DISPOSING OF THE INFRASCANNER, OR THE BATTERIES, ENSURE THAT ENVIRONMENTAL REGULATIONS ARE FOLLOWED.

7.0 Support

- The Infrascanner Model 2000 will be supported for 7 years from the date of manufacture. InfraScan will repair the device (for free during the first year), as long as the components are commercially available (for years 2-7). If the Infrascanner is unable to be serviced and repaired due to obsolete or unavailable components, the system will not be repaired and serviced.

- Should the Infrascanner fail to operate or fail to operate properly, the operator should refer to Troubleshooting, Section 5.8, to find the cause and solution required to correct the problem. If the operator is unable to fix the problem, the operator should turn the Infrascanner in for repair to the supporting biomedical equipment repair activity.

7.1 Electromagnetic Interference.

- All radiated emissions as recorded at a distance of 10 meters from the Infrascanner Model 2000 are below the 10 meter limit specified by CISPR11, Class B products by a margin of at least 4 dB. The Infrascanner complies with the requirements for radiated power in IEC 60601-1-2 making interference to other devices well within the IEC guidelines.

!	***NOTE**: The Infrascanner Model 2000 operated satisfactorily during and after exposure to electromagnetic fields and can be considered compliant to the requirements of EN 61000-4-3.*

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Model 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 2	The Model 2000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Model 2000 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-3-2	Not Applicable	
Voltage fluctuations /flicker emissions IEC60601-3-2	Not Applicable	

- The Infrascanner has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

  However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two- way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device. This Infrascanner is not designed for use in environments in which its operation can be disrupted by electromagnetic interference.

	**CAUTION! ELECTROMAGNETIC INTERFERENCE CAN DISRUPT INFRASCANNER OPERATION.**

7.2 Transport and Storage.

- The Infrascanner should always be transported in the manufacturer provided shock absorbent transport case. Always allow the Infrascanner to acclimate to ambient temperatures. If the operating temperatures have been exceeded during storage or transport, allow the Infrascanner to acclimate to an operating temperature.

- If long term storage or shipment (greater than 2 weeks) is envisioned remove the batteries from the battery compartment.

8.0 Warranty

8.1 Limited Warranty.

The Infrascanner 2000 is distributed with a one year (from the date of shipment from the manufacturer) full replacement warranty provided the integrity of the device has not been compromised by the user.

This warranty does not apply to:

- Regular wear and tear items.
- Consumable or single use items.

8.2 Limitation of Warranty.

InfraScan does not warrant that the operation of the Infrascanner will be uninterrupted or error free. For this LIMITED WARRANTY to be valid, the purchaser must use and maintain the Infrascanner according to the procedures set out in this Operator Manual. Routine maintenance, as specified in the Operator Manual, is not covered under this LIMITED WARRANTY.

8.2.1 This LIMITED WARRANTY does not apply to defects or damage to the Infrascanner resulting from, as determined solely at the discretion of InfraScan:

a. Improper use or misuse.
b. Neglect, fire, flood, loss, theft.
c. Normal wear and tear.
d. Improper or inadequate maintenance.
e. Unauthorized modifications or repairs.
f. Use of any Infrascanner with unauthorized accessories or consumables.
g. Use or storage outside the Infrascanner specifications.

8.2.2 This Limited Warranty is Void if:

a. Any part of the Infrascanner is repaired or opened by a repair person not authorized in writing by InfraScan.
b. Any part of the Infrascanner is used with an incompatible accessory or part.
c. The Infrascanner is not maintained as set out in this Operator or Maintenance Manual.
d. The Infrascanner is used in a manner, or for a use, not set out in the intended use section of the Operator Manual.

8.3 Limitation of Liability.

IN NO EVENT SHALL INFRASCAN BE LIABLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, EXEMPLARY DAMAGES, COMMERCIAL LOSS FROM ANY CAUSE, PERSONAL INJURY, BUSINESS INTERRUPTION, LOSS OF USE, OR OTHER DAMAGES, WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY AND WHETHER ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

The remedies provided in this **LIMITED WARRANTY** are the sole and exclusive remedies. To the extent allowed by law, there are no other warranties expressed or implied, including without limitation any expressed or implied warranties or conditions of merchantability, satisfactory quality, and fitness for a particular purpose. InfraScan liability for damages of any kind shall, in any event, be limited to the purchase price of the defective Infrascanner.

For warranty service or repair, the InfraScan Service Department must be contacted by phone (215.387.6784) or e-mail (service@infrascanner.com). The Service Department will first attempt to resolve the issue by phone or email. If InfraScan determines, at its sole discretion, that the product is in need of repair, InfraScan will provide a returned merchandise authorization (RMA) to return the unit. The product must be returned to InfraScan or a service facility designated by InfraScan. Shipping to the InfraScan service facility will be paid for by the customer. Return of the Infrascanner to the customer will be paid for by InfraScan.

Products must be shipped back in their original shipping containers. Once the returned product is inspected by InfraScan, InfraScan will determine, in its sole discretion, whether this LIMITED WARRANTY applies. If InfraScan determines that the **LIMITED WARRANTY** applies, InfraScan will repair or replace the defective product and ship the Infrascanner back to the customer, with a method of InfraScan's choosing, and at InfraScan's cost.

If InfraScan determines, in its sole discretion, that this **LIMITED WARRANTY** does not apply, the customer will be requested to authorize the repairs, and upon authorization, will be billed for the repair. Regardless if the repairs are authorized or not, InfraScan will pay shipping to return the Infrascanner to the unit.