INFRASCAN
HANDHELD BRAIN DIAGNOSTICS

Infrascanner Model 2000

Operation Manual

InfraScan Inc.
3508 Market Street
Philadelphia PA 19104
USA

R_x ONLY

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.

CAUTION

The Infrascanner contains a near infrared laser and should be handled carefully.

May cause interference to other infrared devices when the Measurement Button is depressed.

Class 1 Laser Product

The Infrascanner is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

REVISION RECORD

Rev.	Issue Date	CRR No.	CRR Incorporation Approved	
			Date	Initials
1.1	07-25-11	11-067	07-25-11	D. Solt
1.2	08-12-11	11-072	08-12-11	D.Solt
1.3	01-17-12	12-034	01-17-12	D.Solt
1.4	02-21-12	12-064	02-21-12	D.Solt
1.5	06-01-12	12-117	06-01-12	D.Solt
1.6	06-22-12	12-140	06-22-12	D.Solt
1.7	01-17-13	13-008	01-17-13	D.Solt
1.8	06-06-13	13-074	06-06-13	D.Solt
1.9	07-02-13	13-076	07-02-13	D.Solt
2.0	12-18-13	13-116	12-18-13	D.Solt
3	05-08-15	15-044	05-08-15	D.Solt
4	07-30-15	15-050	07-30-15	D.Solt
5	04-28-16	16-014	04-28-16	D.Solt
6	09-08-16	16-030	09-08-16	D.Solt
7	02-26-18	18-025	02-26-18	T.Groch
8	04-23-19	19-036	04-23-19	I.Shipway
9	01-03-20	20-001	01-03-20	D.Solt
10	11-16-20	20-107	11-16-20	D.Solt
11	05-03-21	21-032	05-03-21	D.Solt
12	06-07-21	21-052	06-07-21	D.Solt
13	11-11-21	21-075	11-11-21	D.Solt
14	01-25-21	21-001	01-25-21	D.Solt
15	03-02-22	22-018	03-02-22	D.Solt
16	01-06-23	23-004	01-06-23	D.Solt
17	03-17-23	23-019	03-17-23	D.Solt
18	07-06-23	23-044	07-06-23	D.Solt
19	02-21-24	24-005	02-21-24	T.Groch

Symbol Information

Manufacturer	Caution, see Operation manual. Attention, voir manuel d'utilisation
EC REP European Authorized Representative	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
CE 2797 CE Mark	
Date of manufacture	Attention, see Operation Manual for use. Attention, voir manuel d'utilisation
Single Patient – Multiple Use (for disposable shield only). Usage multiple pour seul patient (seulement pour protecteur jetable)	5VDC Cradle Power Adapter is 5 VDC. Le bloc d'alimentation du support est de 5 V
LOT Batch Code	REF Catalog Number
SN Serial Number	NON STERILE Non Sterile
MD Medical Device	4.8V/6Vdc Rechargeable / AA Battery Voltage
R_x ONLY Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	Electrical and electronic equipment; return waste to recycling facilities

TABLE OF CONTENTS

Classification

Equipment Function:	Detection of superficial supratentorial traumatic intracranial hematomas
Type of protection against electrical shock:	Internally powered/battery operated
Degree of protection against electrical shock:	Type BF applied part.
Supply connection:	Internal rechargeable or disposable battery
Cradle Power Adapter:	Medical Grade 5 VDC at >1.2 Amp
Mode of Operation:	Continuous with intermittent loading
Degree of mobility:	Handheld
Laser Classification:	Class 1 Laser Product
	Not suitable for operation in presence of flammable anesthesia

Warnings and Cautions

WARNINGS

- The Infrascanner is a screening device intended as an adjunct to the standard clinical assessment of 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 adult clinical study of the device, patients were to be scanned with the Infrascanner within 30 minutes before or after CT scan. Since an adult 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.
- In the pediatric clinical study of the device, patients were to be scanned with the Infrascanner within 6 hours before or after CT scan. Since a pediatric traumatic hematoma may evolve rapidly the Infrascanner result is not predictive of the absence of a hematoma when longer than 6 hours have elapsed since the test was completed.
- Complete the Training and read the entire Instruction manual before attempting to operate the Infrascanner.
- Only connect the Cradle Power Adapter to the Cradle, otherwise hazards may exist.
- Only 60950-1 approved devices may be connected to the cradle.
- 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.
- Do not allow light from the laser diode to enter the eye.
- Use caution in exercising pressure on the head when using Infrascanner since excessive pressure might exacerbate an underlying skull injury.

PRECAUTIONS

- The safety and efficacy of this device in subjects less than 2 years of age have not been evaluated.
- The accuracy of Infrascanner in detecting subarachnoid hemorrhage has not been established.
- Device safety and effectiveness have not been established in a pre-hospital setting.
- The Infrascanner should be operated by a physician or by a nurse, 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 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.
- Because Infrascanner result is based on the difference in infrared light absorption on homologous left and right regions of the skull:
    - The Infrascanner result may be negative in the presence of bilateral hematomas of similar size and location.
    - The Infrascanner may only detect the larger of bilateral hematomas in a similar location.
    - The performance of Infrascanner may be affected by the presence of blood within or under the scalp and by the presence of scalp edema.
    - The performance of Infrascanner may be affected by increased skull thickness.
    - The Infrascanner cannot detect chronic (non-acute) hematomas.
- Do not re-use the Disposable Fiber Optic Shield on another 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 Disposable Fiber Optic Shield reaches a maximum temperature of 52°C at the highest operating temperature specified. For safe contact with the patient, the Shield fiber contact time is 10 Seconds, at the 8 head locations (Total of 80 Seconds).
- The Infrascanner should not be used on patients for whom the use of an unsterilized device might pose a risk of infection.
- If excessive power is input to the Infrascanner model 2000 Cradle, the scanner can be turned on and the cradle can be turned on. However, this is not an adverse reaction (malfunction), and it is a safe state that only the power of the equipment is turned on and the laser is not emitted, and there is no problem in using the device after charging.
- USB connection of Cradle to a Computer that includes other equipment could result in previously unidentified risks to patients or operators. Consult with your computer department to identify, analyze, and control any risks. Disconnect Cradle from Computer if making any Computer upgrades or changes. USB supports serial connection only to download data.

Training

Read Operator's Manual and watch the training DVD before attempting to operate the Infrascanner. Although, not necessary for proper operation, additional in-service training can be provided by an InfraScan representative. Training is available when the system is purchased or a later time.

Operator Profile

The operator of this equipment must be a physician, intern, resident, nurse, or other medical professional who is under the direction of a physician who has been trained in the use of the device.

Operator Position

The operator of this equipment shall be holding the equipment where the display is easily visible. They shall be able to easily hold the device and press button while contacting the patient.

INTENDED USE/INDICATIONS

The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of as small as 3.5 mL and as deep as 2.5 cm from brain surface, but not both at the same time,

as an adjunctive device to the clinical evaluation in the acute hospital setting of adult patients and pediatric patients aged 2 years and older with suspected traumatic supratentorial intracranial hematoma. The device is indicated to assess patients for CT scans but should not serve as a substitute for these scans, the device should only be used to rule in subjects for the presence of hematoma, never to rule out. 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.

CLINICAL BENEFITS

Clinical benefit is the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

The benefit of the Infrascanner is based on the intended use which is the detection of brain hematomas. The main benefit of the Infrascanner NIR device is the detection of intracranial hematomas, specifically for early identification of traumatic brain injury (TBI) which results in expedited care for the patient in terms of the neurological assessment and/or CT Scan. The clinical benefit is supported by the clinical studies performed by InfraScan and published in the clinical literature and is based on the sensitivity and specificity of the device.

CLINICAL DATA

Study	Patients (N)	Intracranial Hematomas	Results
Xu et al. (2017) (China)	85	45	• Sensitivity = 95.6% • Specificity = 92.5%
Tan et al. (2017) (Nederlands)	25	14	• Sensitivity = 93.3% • Specificity = 78.6%
Liang et al. (2018) (China)	102	24	• Sensitivity = 100% • Specificity = 93.6%
Kontojannis et al. (2019) (UK)	205	45	• Sensitivity = 89.4% • Specificity = 48.7%
Yuksen et al. (2020) (Thailand)	47	11	• Sensitivity = 100% • Specificity = 44.4%
Gramer et al. (2022) (USA)	500	104	• Sensitivity = 94% • Specificity = 96%

Infrascanner Performance in Pediatric Subgroup		
	2-12 Years Old	12-18 Years Old
Total	220	146
No Hematomas	202	139
Hematomas	18	7

Sensitivity	88.9%	85.7%
Specificity	72.3%	73.4%

Controls and Indicators

A. Measure Buttons

Located on the back of the Infrascanner are two buttons, depressing and releasing either one of them initiates a measurement.

B. 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.

C. Power and USB Receptacles

Located on the back of the Cradle are the receptacles that accept the 5.5mm by 2.5mm Cradle Power Adapter connector and the mini-USB connector to connect to a personal computer.

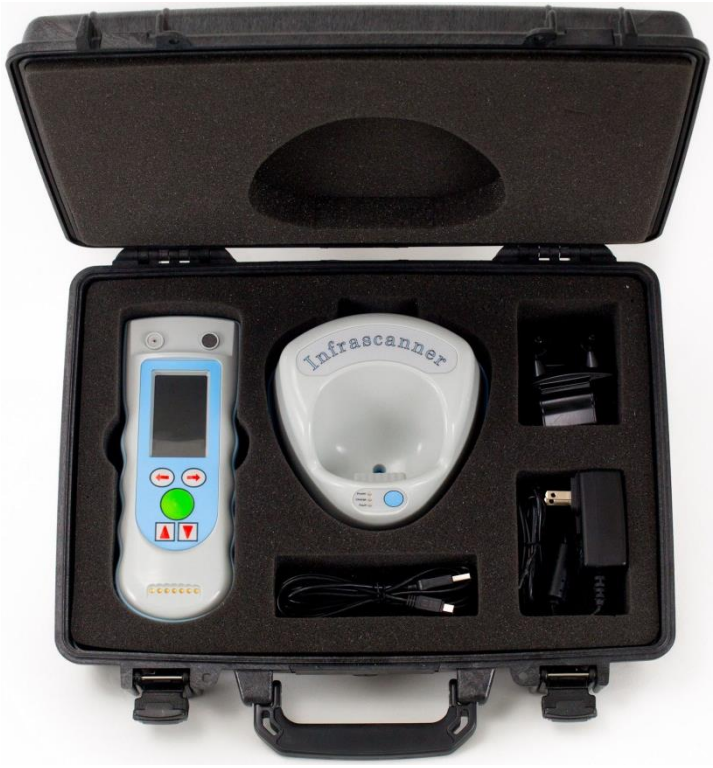
D. Charging LEDs and Cradle ON/OFF switch

Figure 1-1: Model 2000 in Cradle

The blue cradle ON/OFF switch is used to turn on the Infrascanner, when the Infrascanner is placed in the Cradle, instead of using a Disposable Fiber Optic Shield to turn it on. When the Infrascanner is being charged in the Cradle, an amber LED will illuminate behind the power switch. When disposable batteries are used in the Infrascanner, the orange Fault LED will illuminate, to indicate that the Infrascanner is not charging. Disposable batteries cannot be charged by the Cradle.

1.0 SYSTEM COMPONENTS

The InfraScan Model 2000 Infrascanner is a handheld Near InfraRed (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 are:



- The Infrascanner Model 2000
- The Infrascanner Model 2000 Cradle
- An Infrascanner Model 2000 Disposable Shield
- The Infrascanner Model 2000 Transport Case
- The USB Cable to connect the Cradle with a PC computer
- The Cradle Power Adapter, 5VDC
- Rechargeable Battery

A computer running Microsoft Windows 7, or later, is required to download the Infrascanner's data.

Figure 1-2: Transport Case with system components

2.0 THEORY OF OPERATION

2.1 BASIC NEAR INFRARED 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, Computed Tomography (CT), and Near InfraRed (NIR) imaging. From the principles of spectroscopy, it is also known that different molecules absorb different wavelengths of EM radiation (which is synonymously referred to as light at smaller wavelengths). Similarly, tissue scatters EM radiation to different degrees. The Infrascanner is concerned with NIR imaging of the hemoglobin molecule.

From any light source, photons follow a characteristic path through the target tissue back to a detector on the same approximate plane as the source. While the light is severely attenuated due to the scattering and absorption process, it is nonetheless encoded with the spectroscopic signatures of the molecules encountered en route to the detector. By carefully choosing the wavelengths that are produced by the source, it is possible to detect the relative concentration of hemoglobin in the target tissue. By comparing these levels to tissue in a "baseline" state, and using some basic knowledge about "interesting" conditions for the tissue, it is possible

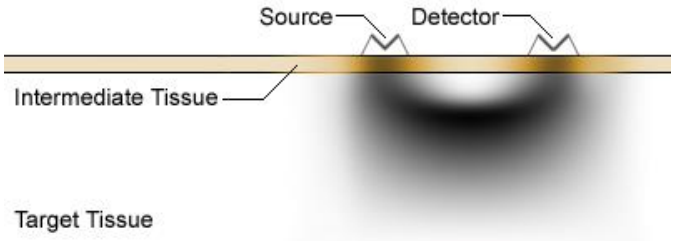


Figure 2-1: Simulated Photon Diffusion Path

to draw conclusions from these levels. Figure 2-1 shows the simulated diffusion path through target tissue from source to detector. This simulation shows the photon path density, not the overall transmission level.

The principle used in identifying intracranial hematomas with the Infrascanner is that extravascular blood absorbs NIR light more than intravascular blood. This is because 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, than on the uninjured side.

The wavelength of 805nm is sensitive only to blood volume, not to oxygen saturation in the blood. 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.

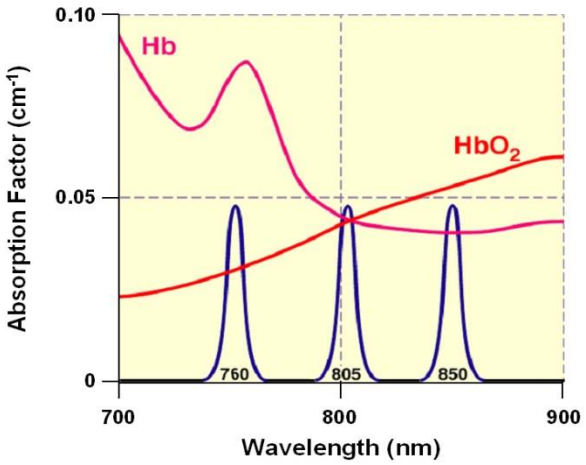


Figure 2-2: Absorption of light by hemoglobin

Frontal Left/Right forehead, above the frontal sinus
Temporal In the Left/Right temporal fossa in front of the top of the Left/Right ear
Parietal Above the Left/Right ear, midway between the ear and the midline of the skull
Occipital Behind the top of the Left/Right ear, midway between the ear and the occipital protuberance

The difference in optical density (ΔOD) in the different areas is calculated from the following formula:

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

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

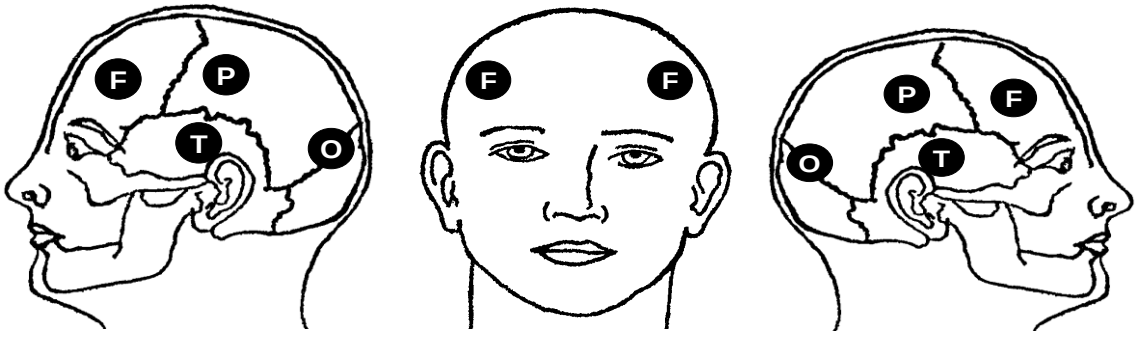


Figure 2-3: Head locations of NIR measurement

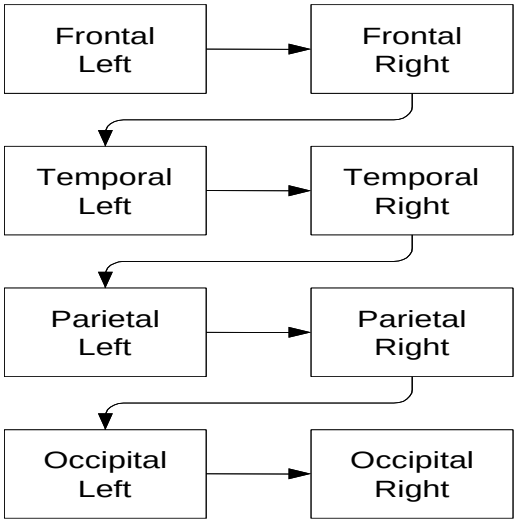


Figure 2-4: Infrascanner head scanning sequence

2.2 THE INFRASCANNER SYSTEM

The system includes two components: the Infrascanner and the Cradle. The Infrascanner includes a safe Class 1 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 and turned off by removing the Disposable Shield. After approximately 10 minutes of inactivity, if the shield is not removed, the Infrascanner starts beeping until the Disposable Shield is removed. When the Infrascanner is in the Measurement screen, pressing and releasing one of the Measure Buttons activates a measurement sequence at a given head location. While the measurement is in process, the amber Measure LED (not available on older units) will illuminate. When a successful measurement is finished, the Measure LED will blink green. If there is an error message, the Measure LED will blink amber. 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.

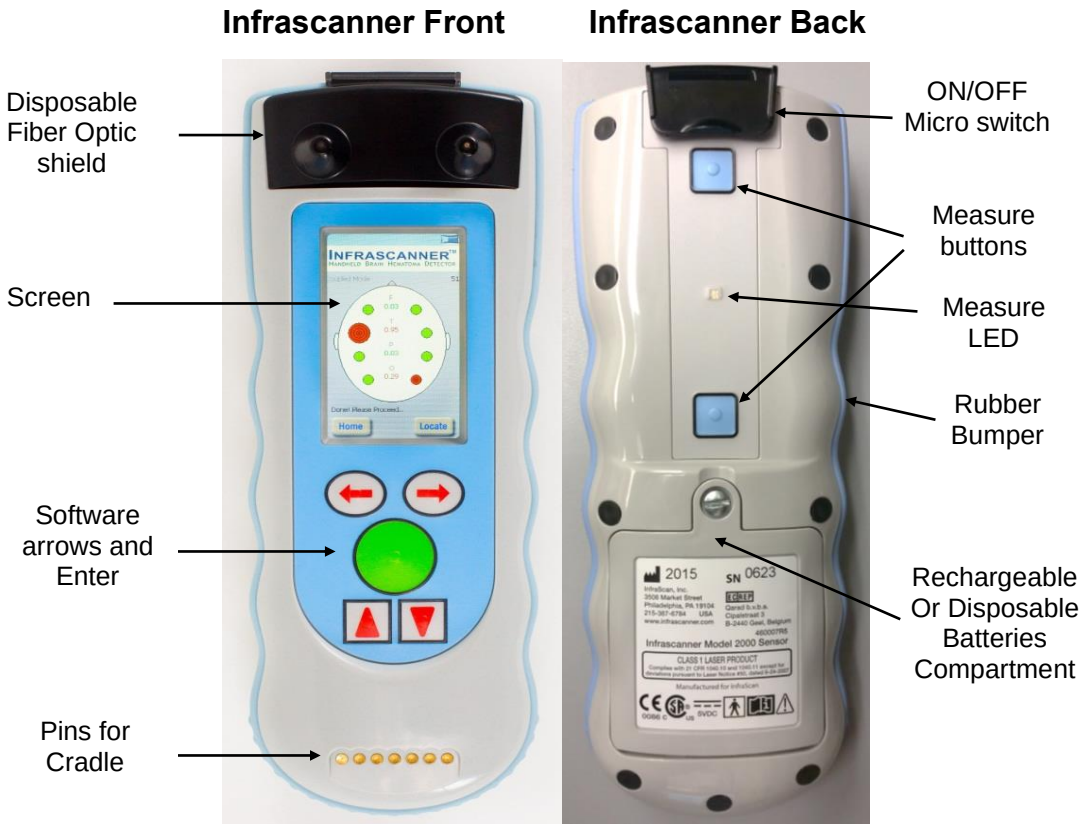


Figure 2-5: Model 2000 Infrascanner

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 is used to charge the rechargeable battery pack, if it is used in the Infrascanner, and to transfer data from the Infrascanner to a Personal Computer (PC) or printer.

Figure 2-6: Model 2000 Cradle

The Disposable Fiber Optic Shield is used to couple the light to the patient's head. Attaching the Shield turns the Infrascanner on, and removing the Shield turns the Infrascanner off.

Caution: Select a Shield for each patient. 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.

Note: The Shield is non-sterile and should not be sterilized.
Note: When reusing on same patient, the Shield can be cleaned by wiping with a soft tissue damp with alcohol.

Caution: Dispose of used Shields in accordance with local regulations.

Figure 2-7: Model 2000 Disposable Shield

3.0 OPERATING PROCEDURE

3.1 SETTING UP THE SYSTEM

3.1.1. Battery Installation. Use a ¼" flat blade screwdriver (or a coin) to release the battery door latch by turning one half turn counter clockwise.

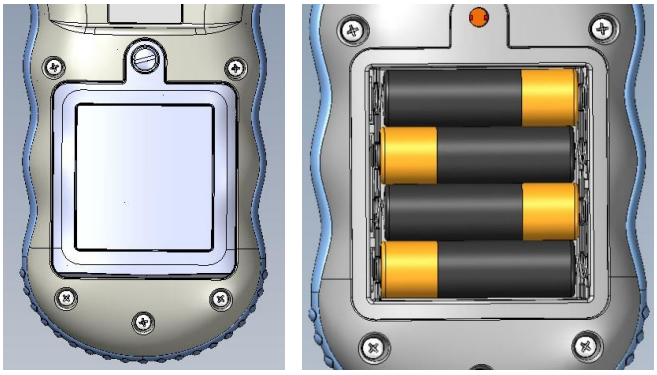


Figure 3-1: Installing Disposable Batteries

3.1.1.1. If using disposable AA batteries, ensure that proper polarity is observed when inserting the new batteries.

3.1.1.2. If using rechargeable battery, plug in the leads from the battery pack to the connector in the battery compartment assuring proper polarity. Place the battery pack against the left wall of the compartment with the edge towards the bottom inserted against the battery springs. Press on the battery to compress the two springs and push the top edge against the case. The single spring on the top side should be moved if necessary to be pressed against the middle of the battery pack. Verify that the leads are positioned as indicated in the picture, and not pinched or compressed in any way.

Figure 3-2: Installing Rechargeable Battery

3.1.2. Install the battery door and use the screwdriver to turn one half turn clockwise. You may need to press downwards with the screwdriver while turning to engage the latch.

3.1.3. Charging. Attach the Cradle Power Adapter to the Cradle and connect it to the AC Power Mains. 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. 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 slowly for several hours). Do not place the Infrascanner into the Cradle with the Disposable Shield installed. If the

Infrascanner turns on when the Infrascanner is placed in the Cradle, disconnect the mains power briefly and reconnect.

3.1.3.1 If the disposable batteries are installed, the amber Charge LED will not illuminate continuously. 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, neither the Charge LED nor the Fault LED will illuminate.

3.1.3.2 The Infrascanner requires approximately 6 hours to charge, and is fully charged when the amber “Charge” LED on the Cradle extinguishes. The Infrascanner battery will not charge if the Infrascanner is ON or if the battery temperature is below 0 degrees Celsius or above 50 degrees Celsius. The Infrascanner detects when disposable batteries are in the Infrascanner and will not charge them. There is no hazard under this condition. If the orange Fault LED illuminates replace the rechargeable battery pack.

3.1.4. Fiber Optic Disposable Shield. Press fibers outward so that don’t get bent against the windows during installation, as shown in Figure 3-3.

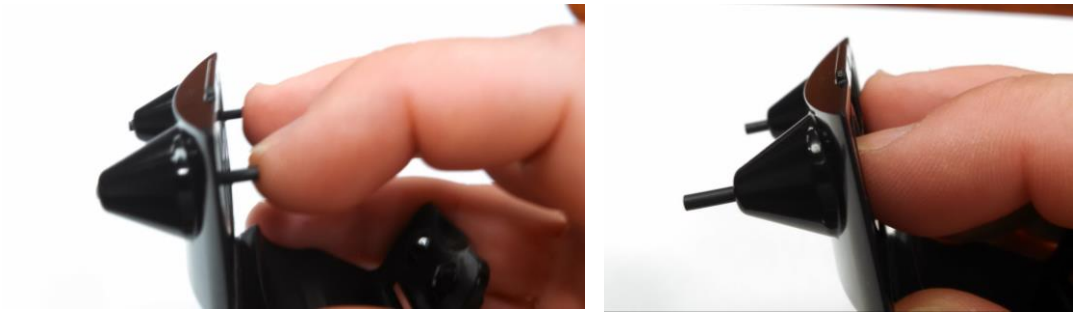


Figure 3-3: Proper Placement of Fibers

3.1.5. Attach the Disposable Shield to the Infrascanner as shown in Fig. 3-4. 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. Once the disposable Shield is installed press the fibers inward so that they are up against the windows.

Note: Attachment of the Fiber Optic Disposable Shield turns on the Infrascanner.

Caution: Select a new Disposable for each patient. Do not reuse the Disposable Fiber Optic Shields on a different patient. Disposable Shields contact the patient and may be contaminated. The Disposable Shield is Single Patient Use.

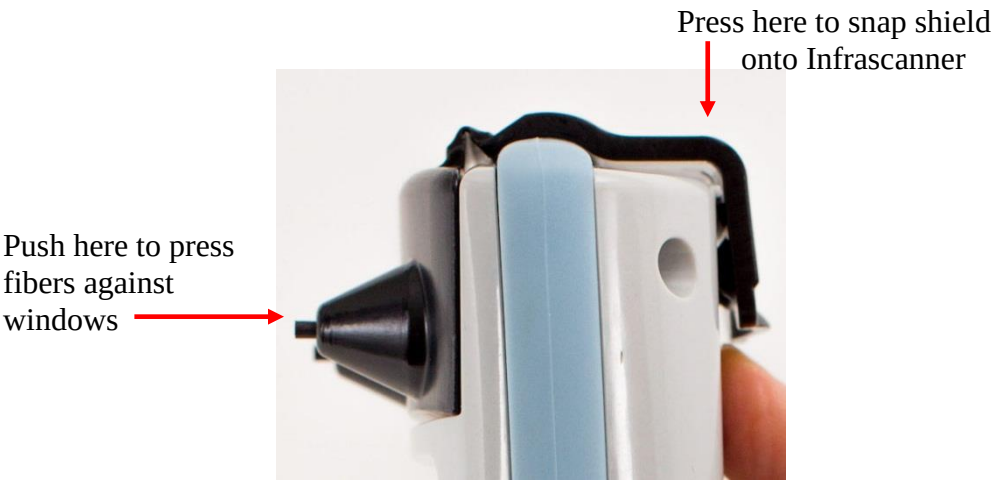


Figure 3-4: Attaching the Disposable Fiber Optic Shield

3.1.6. 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.

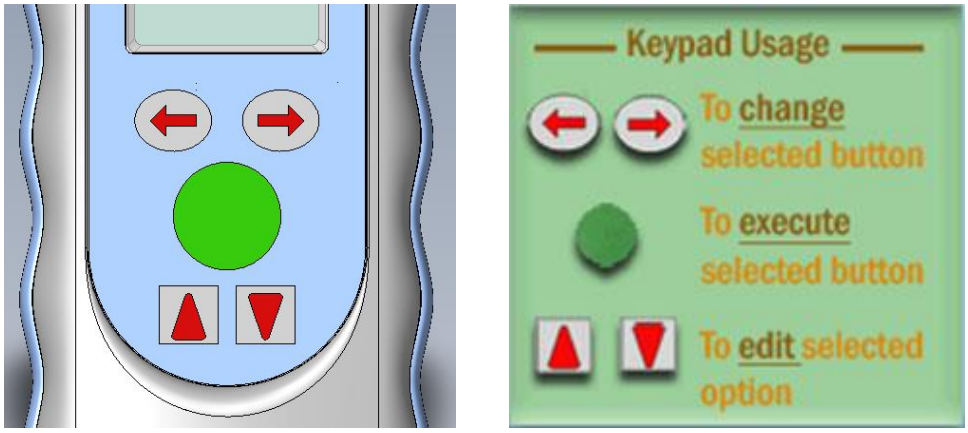
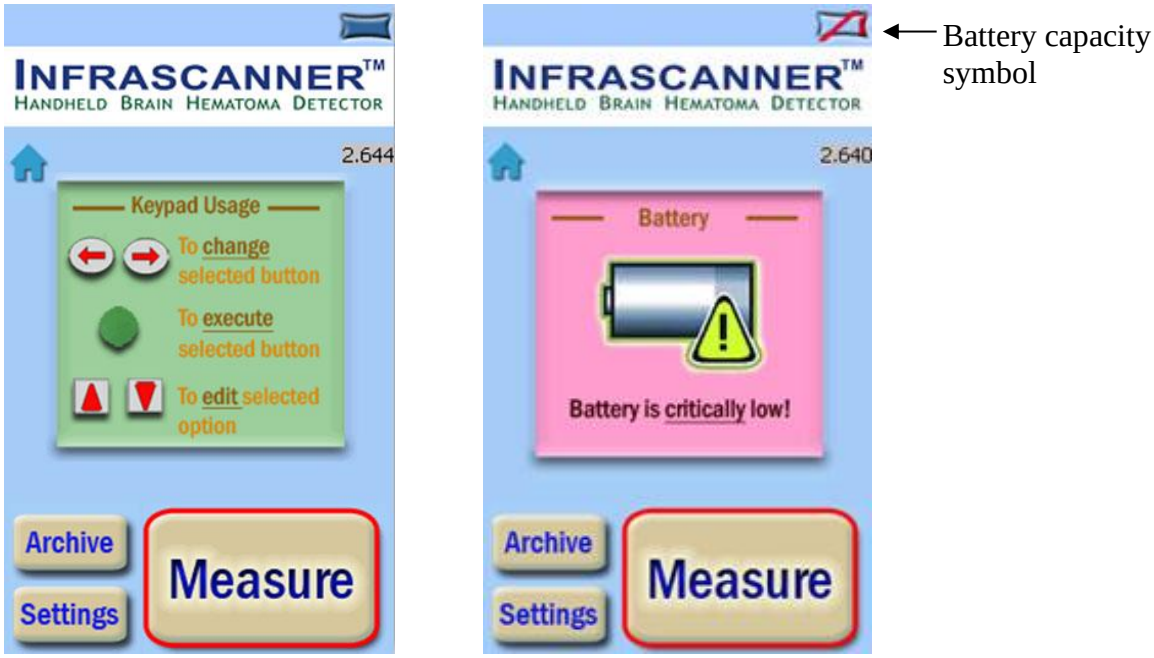


Figure 3-5: Software Navigation Buttons of the Infrascanner and their use

3.2 MEASUREMENTS WITH THE SYSTEM – GUIDED MODE

1. Attach a Disposable Fiber Optic Shield to turn on the Infrascanner.
2. Press the “Measure” button, as shown in Figure 3-6. The indicator in the upper right corner of the screen shows the battery capacity status.



(a) (b)

Fig 3-6: Main Screen (a – standard, b – when the battery is low)

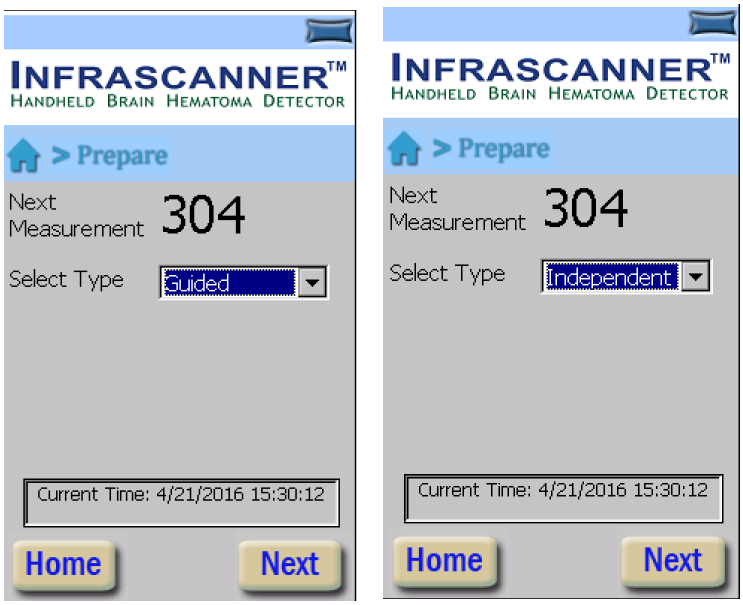


Figure 3-7: Select Study ID Screen

3. The Select Study ID screen (Figure 3-7) displays the next sequential number of the measurement. Please record this number (or the patient ID number) in your notes, if you are interested in a later analysis of the data. If the Infrascanner clock was reset, due to battery depletion or removal, a yellow triangle will ask the user to set the Infrascanner real-time clock.

4. Select Guided Mode on the Select Study ID screen (Figure 3-7). Guided Mode helps the user through the measurement process by displaying tutorial screens and guiding the user to repeat measurements when a potential hematoma is detected.

Guided mode is intended for novice users. Once the user is more experienced with the use of the Infrascanner, Independent Mode can be selected (see Section 3.3).

CAUTION: new users should use Guided Mode when initially learning to use the Infrascanner.

5. Guided Mode helps the user through the measurement process by displaying tutorial screens (Figure 3-8) and guiding the user to repeat measurements when a potential hematoma is detected. Guided mode is intended for novice users. Once the user is more experienced with the use of the Infrascanner, Independent Mode can be selected.

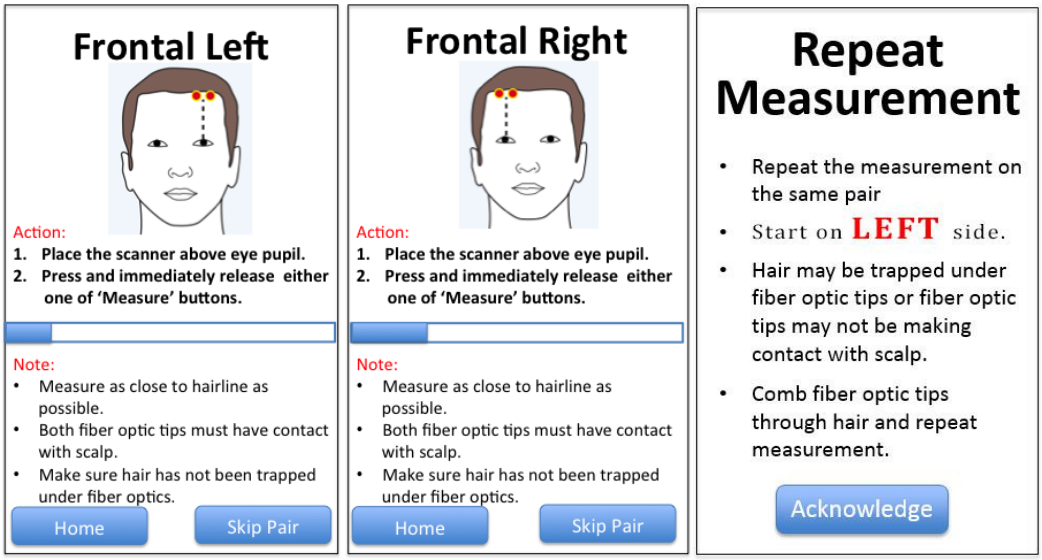


Figure 3-8: Guided Mode Measurement Windows

6. 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 2-4. Follow the guidance on the screens to complete a full head measurement.

7. To skip a head location, press the "Skip Pair" button to move to the next head location. To cancel the measurement sequence, press the "Home" button.

8. 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 on the rear of the Infrascanner. 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.

9. If a suspected hematoma is detected, the system will automatically guide the user to repeat the head location (up to two times) to confirm the measurement.

10. The results of measurements (Figure 3-10) will not be displayed until the user completes the occipital measurements (or if they are skipped).

11. The Infrascanner will display the relative optical density difference between left and right sides of the head with a relative measurement uncertainty of 0.02, left vs. right.

The green circle in the display changes to red when the OD difference exceeds 0.2. The OD is a logarithmic scale and represents about a 50% difference between the light intensity from one side to the other.

12. 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. Feel the measurement area with your fingers to verify that you are not measuring over a subcutaneous scalp injury ("head bump"). This condition could adversely affect the results of the measurement. If a softer and more mobile scalp area is identified during this scalp palpation, try to find a non-injured area nearby for the measurement location and make sure to shift the contralateral measurement accordingly.

13. 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 to detect.

14. If it is desired to re-take data, press the "Home" button for a new head scan.

3.3 MEASUREMENTS WITH THE SYSTEM – INDEPENDENT MODE

1. Attach a Disposable Fiber Optic Shield to turn on the Infrascanner.

2. Press the "Measure" button, as shown in Figure 3-6. The indicator in the upper right corner of the screen shows the battery capacity status.

3. The Select Study ID screen (Figure 3-7) displays the next sequential number of the measurement. Please record this number (or the patient ID number) in your notes, if you are interested in a later analysis of the data. If the Infrascanner clock was reset, due to battery depletion or removal, a yellow triangle will ask the user to set the Infrascanner real-time clock.

4. The Select Study ID screen (Figure 3-7) allows the user to select Independent Mode or Guided Mode. Select Independent Mode. Guided Mode helps the user through the measurement process by displaying tutorial screens and guiding the user to repeat measurements when a potential hematoma is detected. Guided mode is intended for novice users (see Section 3.3). Once the user is more experienced with the use of the Infrascanner, Independent Mode can be selected.

CAUTION: new users should use Guided Mode when initially learning to use the Infrascanner.

5. Click on the “Next” button to start patient measurement. After the appearance of the Measurement Screen (Figure 3-9) 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. If not, contact the factory. 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.

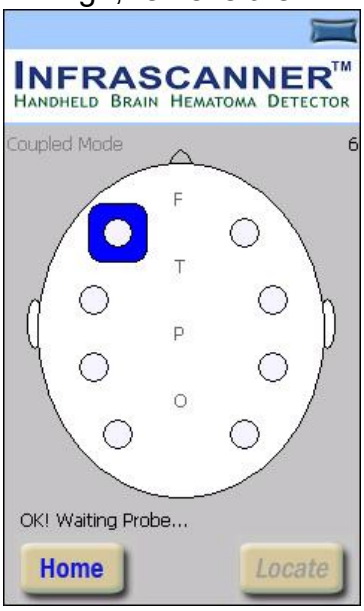


Figure 3-9: Measurement Screen

6. 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 2-4. The blue square on the screen in Figure 3-9 indicates the current measurement location.

7. 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 on the rear of the Infrascanner. 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.

8. 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 Infrascanner will display the relative optical density difference between left and right sides of the head with a relative measurement uncertainty of 0.02, left vs. right. The green circle in the display changes to red when the OD difference exceeds 0.2. The OD is a logarithmic scale and represents about a 50% difference between the light intensity from one side to the other.

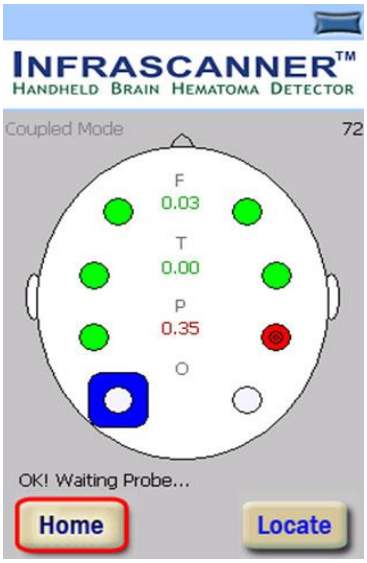


Figure 3-10: Measurement Screen with results

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. Feel the measurement area with your fingers to verify that you are not measuring over a subcutaneous scalp injury (“head bump”). This condition could adversely affect the results of the measurement. If a softer and more mobile scalp area is identified during this scalp palpation, try to find

a non-injured area nearby for the measurement location and make sure to shift the contralateral measurement accordingly.

10. After completing each data pair, review the screen. If one of the locations is red, use the arrow keys to navigate to that location and repeat the measurement of the pair (up to two more times), to confirm the findings and reduce the chances of a false indication due to a trapped hair under the light guides. Continue testing until the entire head scan is complete. 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 to detect.

11. If it is desired to re-take data, press the “Home” button for a new head scan.

3.4 TURNING OFF THE SCANNER

1. To turn off the Infrascanner, remove the Disposable Fiber Optic Shield.

2. The same Disposable Fiber Optic Shield can be re-installed to turn on the Infrascanner for reuse on the same patient or for viewing archived measurements.

3. Select a new Disposable for each patient. Do not reuse the Disposable Fiber Optic Shields on a different patient. Disposable Shields contact the patient and may be contaminated. The Disposable Shield is Single Patient Use.

4. If the Infrascanner is not turned off by removing the Disposable Fiber Optic Shield and no buttons are pressed for approximately 8 minutes, a reminder tone will sound and a message will be displayed on the screen to remove the Disposable Shield (Figure 3-11).

Figure 3-11: Remove Shield Screen

3.5 DATABASE, ARCHIVE, AND PRINTING

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).

To view archived measurements on the Infrascanner:

1. In the Main Screen (Figure 3-6), click on “Archive” button.
2. To view archived measurements click on “View” button, as shown in Figure 3-12.
3. In the list of all the measurements select the required serial number of the measurement and click on “View” button, as shown in Figure 3-13.
4. The next screen (Archived Measurement screen, Figure 3-14 is the same as the Measurement Screen (Figure 3-10) shown at the end of a measurement.
5. 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 repeat the depressing the button for two seconds.

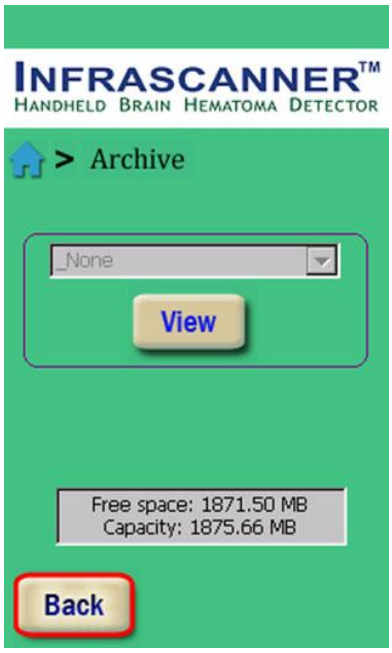


Figure 3-12: Archive Screen

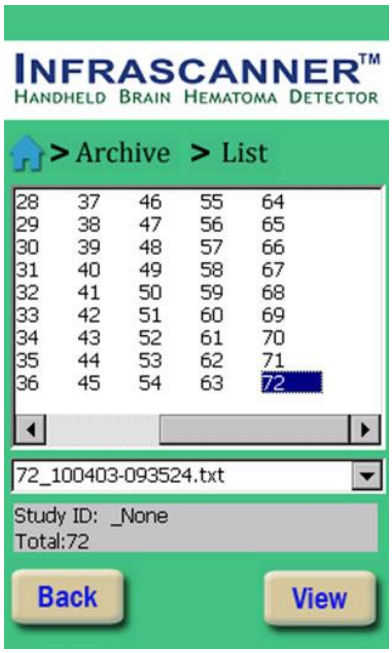


Figure 3-13: List of Measurements

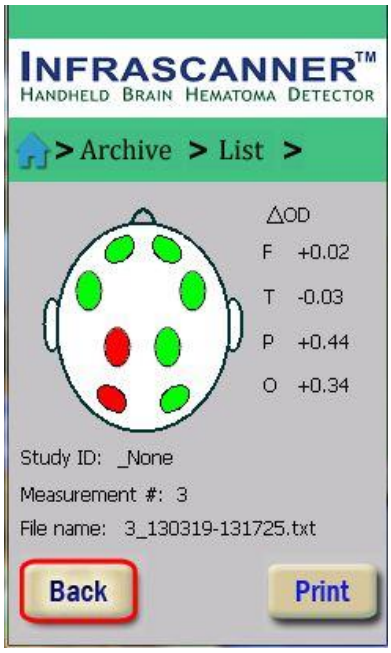


Figure 3-14: Archived Measurement

6. In order to print a data file to the optional label printer, go to the Archive Screen and view the data file that you wish to print. Then, select the Print button. It will take about 10 seconds to transfer the data to the printer and print the label. Printing is only possible when the Infrascanner is in the Cradle and is connected to power and the optional label printer.

3.6 SETTINGS

In the Main Screen (Figure 3-6) click on “Settings” button to reach the Settings Screen (Figure 3-15), which allows changing some of the different parameters of the Infrascanner. Users will not need to access most of the technical parameters of the Infrascanner, and they exist for use by technical support personnel. Technical parameters can be accessed by selecting the “Technical” button.

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

1. In the Settings Screen click on a relevant button.
2. Use the Left/Right arrows to move between various fields and the Up/down arrows to edit the selected field values.
3. Click on Save to store the new parameters and Back to return to the main screen.

Figure 3-15 Settings Screen

Figure 3-16: Date/Time Setup Screen

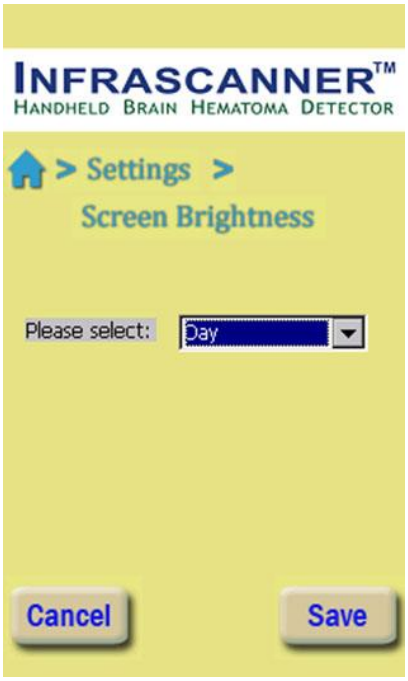


Figure 3-17: Screen Brightness Setup

Figure 3-18: Battery Status info

3.7 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.	
Disposable batteries are installed in Infrascanner	The Cradle does not charge disposable AA batteries.

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.	
Disposable batteries are installed in the Infrascanner.	The Infrascanner will only charge if the rechargeable battery pack is installed in the Infrascanner.
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 real 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 Infrascanner starts beeping in the middle of a scan	
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.
Problem: The printer does not print	
Corrupt serial connection	Disconnect and reconnect power to the Cradle. Re-start the Infrascanner and the printer. Make certain that the serial cable is connected to the printer and the Cradle. When starting a printing session, always feed a label by pressing the advance paper button on the printer. Make sure that the printer status LED is not amber, orange, or blinking.
Cradle loses sync with the Infrascanner	If the Infrascanner turns off before the Cradle does, the Cradle loses sync. The Infrascanner can print about 4 labels before it turns itself off. If this happens, power both off and then turn both back on.

3.8 ERROR MESSAGES

Must be cleared by pressing the Green navigation button

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.

3.9 DOWLOADING DATA FILES TO A COMPUTER

To review the stored data, follow the steps below

1. 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).

2. Data files can downloaded to a computer by using Windows Mobile Device Center (embedded in Windows 7 and above) while the Infrascanner is installed in a Cradle connected via USB to a computer running Windows.

3. Plug the power supply adapter into a power outlet, then plug the other end into the Cradle.

4. Plug the USB Cable provided with the system to the Cradle and to a computer (PC). The connector to the Cradle has to be firmly pushed into the Cradle to ensure a good contact.

5. 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. Press the blue ON button on the Cradle to turn on the Infrascanner.

6. The Infrascanner automatically turns OFF after ~8 minutes, so the blue ON button may have to be pressed again.

7. After the Infrascanner boots up, Windows Mobile Device Center should appear on the PC as shown in Figure 3-19.

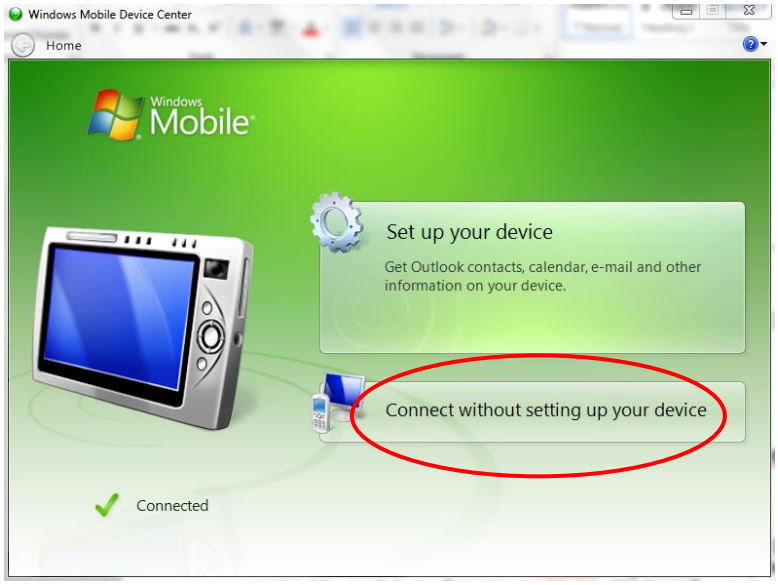


Figure 3-19: Windows Mobile Device Center

8. Move the PC cursor to select the “Connect without setting up your device”.

9. Move the PC cursor to select the “File Management”, then select “Browse the contents of your device” as shown in Figure 3-20.

Figure 3-20: File Management

10. The Windows File Explorer will open and show the contents of the Infrascanner 2000. Click on the Storage Card to browse the Infrascanner SD memory card and the data files in the HSData folder. Drag and drop the “HSData” folder located on the Storage Card, to the PC to copy the data files.

11. Use a text editor or Excel to view and analyze the data on your PC.

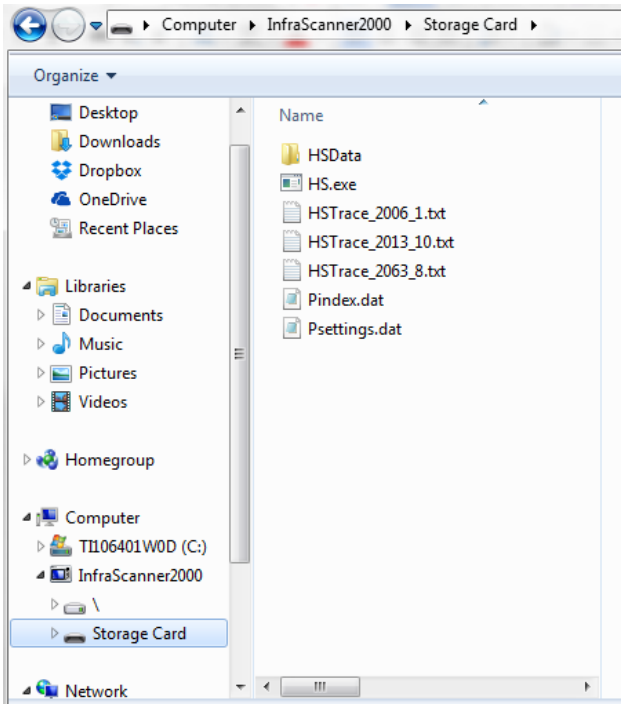


Figure 3-21: Storage Card Files

12. 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 ID counter. The Infrascanner will regenerate the necessary files the next time it is turned on.

    Minimum Desktop Computer Requirements (Internet connection is helpful):

    - Microsoft Windows 7 or later.
    - Microsoft Internet Explorer 6.0 or later
    - 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)
    - Available USB port
    - VGA graphics card or compatible video graphics adapter at 256 color or better
    - Keyboard
    - A Mouse or compatible input pointer device

4.0 CLEANING, PREVENTIVE INSPECTION AND MAINTENANCE

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. DO NOT immerse the Infrascanner in any solution. Subjecting the Infrascanner to excessive moisture may damage the electronic components and nullify the warranty. Always ensure that the cradle pins are clean of debris in order to communicate properly with the Cradle.

Preventive Inspection and 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. Always use the provided medical grade Cradle Power Adapter for connecting to the Cradle. Any other power supply could damage the charging circuitry and/or the Nickel Metal Hydride rechargeable battery.

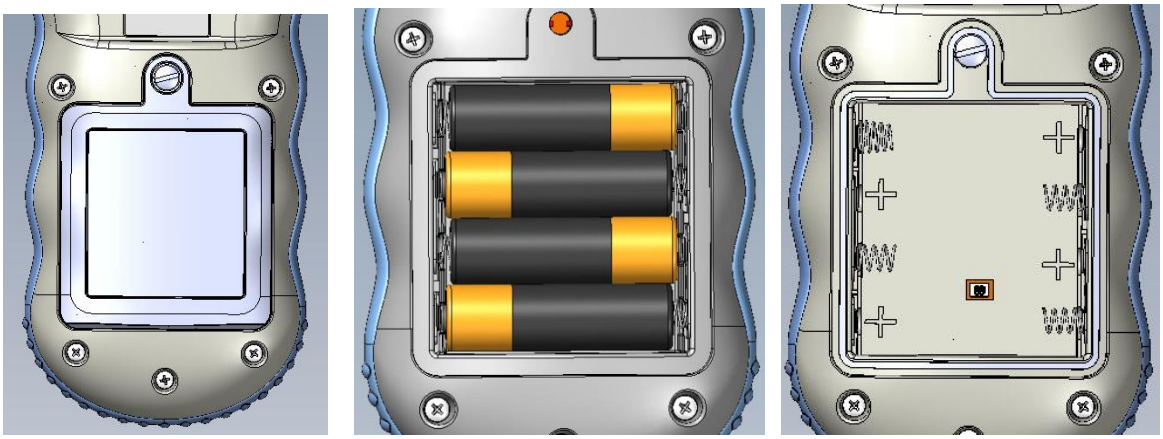
Sterilization

Never sterilize the Infrascanner or the Disposable Fiber Optic Shields.

Replacement of Batteries

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 below. Ensure that proper polarity is observed when inserting the new batteries. Replace the battery door and engage the latch.



(a) (b) (c)

Figure 4-1: (a) Battery compartment; (b) Door removed and disposable batteries shown; (c) Batteries removed, showing the rechargeable battery pack connector.

Rechargeable Battery Pack Installation

The battery pack needs to be installed with caution to ascertain that the wires are not pinched. Follow the steps below and place the battery leads as indicated in the picture.

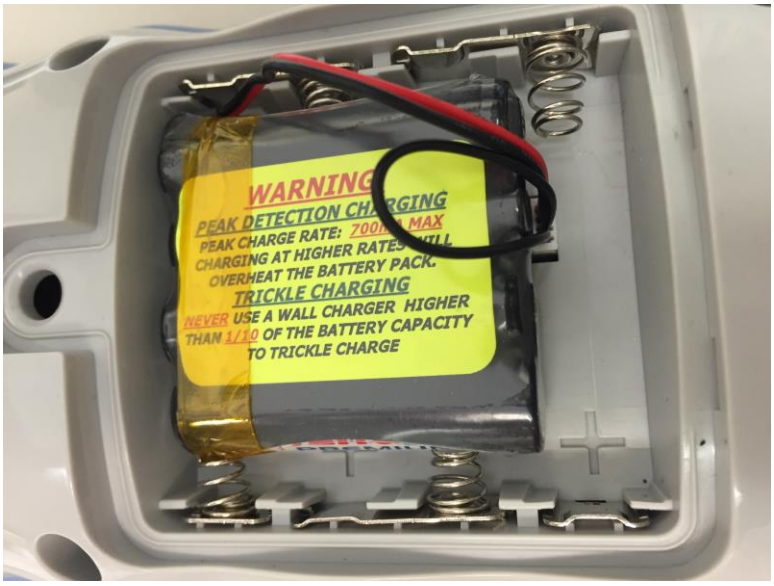


Figure 4-2: Battery compartment with the rechargeable battery pack installed

1. Remove the battery compartment door with a ¼ inch straight screwdriver.
2. Orient the Infrascanner as shown.
3. Inspect the battery leads and ascertain that there is no bare wire exposed going into the connector. If there are, discard the battery pack and use disposable batteries, or contact InfraScan to obtain a new battery pack.
4. Plug in the leads from the battery pack to the connector in the battery compartment assuring proper polarity.
5. Place the battery pack against the left wall of the compartment with the edge towards the bottom inserted against the battery springs
6. Press on the battery to compress the two springs and push the top edge against the case. The single spring on the top side should be moved if necessary to be pressed against the middle of the battery pack.
7. Verify that the leads are positioned as indicated in the picture, and not pinched or compressed in any way.
8. Replace the battery compartment door.

If the system will not be used for 2 weeks or more, remove the batteries.

Caution: Dispose of the Infrascanner, or the batteries, in accordance with local regulations.

5.0 SUPPORT

The Infrascanner 2000 has an expected service life of 7 years and will be supported for 7 years from the date of manufacture.

Parts List

There are no field serviceable components in the Infrascanner. The Parts' List and additional Operation Manuals are available upon request. The Infrascanner can be powered by 4 disposable AA batteries. The Infrascanner can also be powered by a 4.8 volt Nickel Metal Hydride rechargeable battery. This battery is not serviceable by the user. When recharging the Infrascanner, make sure that only the supplied medical grade 5 VDC regulated >1.2 Amp Cradle Power Adapter is used.

Caution: The Infrascanner contains electronic components. Consider recycling at the end of service life. Dispose of the equipment in accordance with local regulations.

Catalog Numbers

Description	Catalog Number
Infrascanner Model 2000 System	2000
Disposable Shields, Infrascanner 2000 (box of 25)	2000-1
Rechargeable Battery	720005
Cradle Power Adapter, 5VDC	000018
Brother Label Printer	RJ-4030

Attenuator Shield Test

Attenuator Shields **(Part Number 000036)** are available for purchase for service personnel to do periodic testing of the Infrascanner. The Attenuator Shields are calibrated by the factory and can be used on a periodic basis (e.g. annually) to check that the Infrascanner is functioning properly. To verify that the Infrascanner functioning properly, place the Attenuator Shield on the Infrascanner. Navigate to the Measurement Screen and take two frontal measurements. Record the Attenuator Shield nominal attenuation and the data file number. Remove the Attenuator Shield.

Figure 5-1 Attenuator Shield

Place the Infrascanner in a Cradle connected to a PC running Windows 7 or later. Turn on the Infrascanner by depressing the Cradle "ON" button. When the PC recognizes the Infrascanner with the Windows Mobile Device Center, download the data file created above from the HS Data folder on the SD Storage Card, and open it. The file name includes a measurement number, date, and time.

Record the actual OD measured. It must be within ±0.3 of the nominal attenuation marked on the Attenuator Shield.

Electromagnetic Interference

The product has been designed and tested to meet the essential performance under Electromagnetic Interference. The essential performance is pulsing the laser to perform a measurement.

Radio-frequency transmitting equipment and other sources of electrical noise may result in disruption of performance of this device and an increase in error messages.

In the event of degradations of essential performance due to electromagnetic interference, remove the shield from the scanner and replace.

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 1	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 A	The Model 2000 is suitable for use in all establishments other than 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity test	**Test Level**	**Compliance**	**Electromagnetic environment - guidance**
ESD IEC 61000-4-2	±8KV Contact ±15KV Air	±8KV Contact ±15KV Air Passed: Criteria C	Floors should be wood, concrete or ceramic tile. If floors are synthetic the relative humidity should be a least 30%.
EFT IEC 61000-4-4	Not Applicable	Not Applicable	Not Applicable
SURGE IEC 61000-4-5	Not Applicable	Not Applicable	Not Applicable
Voltage Dips/Dropout IEC 61000-4-11	Not Applicable	Not Applicable	Not Applicable
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity **Not Life Supporting**			
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.			
Immunity test	**Test Level**	**Compliance**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Not Applicable 10V/m 80 MHz to 2.7 GHz	Not Applicable 10 V/m	Portable and mobile communications equipment should be used no closer to any part of Model 2000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=[3.5/V1]√P d=[3.5/E1]√P 80-800MHz d=[7/E1]√P 800MHz-2.7GHz Where P is the max power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
a) Field strengths from fixed transmitters such as base stations for radios, (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. b) Over the frequency range of 150KHz – 80MHz field strengths should be less than (V1) volts per meter			
Note 1: At 80MHz and 800MHz the higher range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			

Recommended Separation Distances between Portable and RF Communications Equipment **Not Life Supporting**
$$d = \frac{6}{E}\sqrt{P}$$ **30cm**

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

Warning: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the tables above. The system should not be used adjacent to other equipment. If adjacent use is necessary, the system should be observed to verify normal operation in the configuration in which it is used.

Caution: This device 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.

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 the Infrascanner will not be used for 2 weeks, remove the batteries.

6.0 INFRASCANNER MODEL 2000 TECHNICAL SPECIFICATIONS

1. Physical Specifications:

1.1. Scanner

1.1.1. Dimensions with Disposable: 9.0H x 3.4W x 2.4D inch (23H x 8.5W x 6.1D cm)

1.1.2. Dimensions without the Disposable Fiber Optic Shield: 9.0H x 3.4W x 1.8D inch (23H x 8.5W x 4.6D cm)

1.1.3. Weight of Infrascanner: 14oz (400g)

1.1.4. Number of detectors: 1

1.1.5. Number of light sources: 1

1.1.6. Light Source - Detector Separation: 4 cm

1.2. Cradle

1.2.1. Dimensions: 3.0H x 6.4W x 6.4D inch (7.6H x 16.3W x 16.3D cm)

1.2.2. Weight: 11oz (312g)

1.3. Shield

1.3.1. Dimensions: 0.9H x 2.9W x 3.2D inch (2.3H x 7.4W x 8.1D cm)

1.3.2. Weight: 0.6oz (17g)

2. Functional Specifications

2.1. Power 4.8Vdc Rechargeable NiMH Battery pack (1AH) or 6Vdc four AA disposable batteries

2.2. Operating time on new fully charged batteries: >60 minutes

2.3. Operating time on new AA batteries: >90 minutes

2.4. Hematoma indication: $\Delta OD > 0.2 +/-0.02$

3. Laser Diode Specifications:

3.1. Wavelength: 808nm (±4nm)

3.2. Maximum peak pulsed power: 100 milliwatt

3.3. Safety: Class 1 Laser Product

4. Cradle Power Adapter Specification:

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.

5. Environmental:	**Operational**	**Storage**
Temperature	-10°C to 50°C	-10°C to 70°C
Relative Humidity (non-cond)	40% to 88%	40% to 88%

Atmospheric Pressure	70-101 kPa	50-101 kPa

6. Computer Requirements for Data Download:

6.1. Microsoft Windows 7 or later
6.2. Windows Mobile Device Center installed
6.3. USB port

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

7.0 INCIDENCE REPORTING

Warning: any serious incident that has occurred in relation to the Model 2000 Infrascanner should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. InfraScan can be notified by phone (215.387.6784) or e-mail (service@infrascanner.com).

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.

7.2.1 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.

7.2.2 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.