Infrascanner Model 2500

Operation Manual

InfraScan Inc.
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USA

EC REP

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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.

WARNING

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
0	06-04-21	21-050	06-04-21	D.Solt
1	08-03-22	22-039	08-03-22	D.Solt
2	01-25-23	23-006	01-25-23	D.Solt
3	12-07-23	23-115	12-07-23	T.Groch
4	05-13-24	24-059	05-13-24	T.Groch
5	10-21-24	24-083	10-21-24	T.Groch
6	12-04-24	24-112	12-04-24	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 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	3V/3.7Vdc AA/Rechargeable Battery Voltage
R_x ONLY Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	Follow operating instructions
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 when battery operated Class II when using Power Adapter to charge
Degree of protection against electrical shock:	Type BF applied part.
Supply connection:	Internal rechargeable and/or disposable battery 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 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 adult clinical study of the device, patients were to be scanned with the Infrascanner within 30 minutes before or after 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.
- 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 supplied Power Adapter to the system, otherwise hazards may exist.
- Only IEC 62368 approved devices may be connected to the Scanner.
- If connected to personnel computer to download Infrascanner data, regularly ensure that the computer is free of viruses or malware and is updated with the latest security patches.
- 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.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Model 2500 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use only the 6 foot cable provided to charge the device. Cables lengths different than what is provided may result in different EMC test results than that reported in the EMC table.
- Do not operate the Infrascanner when it is plugged in and charging.
- If entering a Medical Record Number for measurements, the user should avoid entering patient identifiable numbers for IDs (e.g., social security number, military ID number).
- Do not keep the Disposable Shield touching the patient for longer than 80 seconds as the surface temperature of the Shield may exceed 41°C.
- The Infrascanner performance may degrade or malfunction if subjected to radiated electromagnetic fields at 2.44 MHz - 2.7 GHz, at 80% AM, 1 kHz modulation.

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 Infrascanner should not be used on patients for whom the use of an unsterilized device might pose a risk of infection.
- USB connection 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 scanner from Computer if making any Computer upgrades or changes.
- Be alert against exposure to potential electromagnetic disturbance sources. If anomalies are observed, move the Infrascanner away from the source of the electromagnetic disturbance source and remove and replace the shield.

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.

The Infrascanner is used to provide patient care in emergency situations where time to therapy delivery can be critical. Its portability and simplified user interface enable use in professional healthcare facilities (ex. hospital, clinic, medical office) and emergency medical services environment (ex. road ambulance and pre-hospital environments).

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%

Controls and Indicators

A. Measure Buttons

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

B. Software Arrows, Menu and Enter Buttons

Located on the front of the Infrascanner, are 6 buttons that are used to control the software of the Infrascanner.

C. USB Receptacle

Located on the side of the Infrascanner is the receptacle that accept the USB-C connector to charge the scanner or to connect to a personal computer.

Figure 1-1: Infrascanner Model 2500

1.0 SYSTEM COMPONENTS

The InfraScan Model 2500 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 2500
- An Infrascanner Model 2500 Disposable Shield
- The Infrascanner Model 2500 Transport Case
- The Infrascanner Model 2500 Operation Manual
- The USB Cable to connect the Scanner with a charger or a PC computer
- The Infrascanner Model 2500 Power Adapter, 5VDC

A computer running Microsoft Windows 10, or later, is required to download the Infrascanner's data.

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 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.

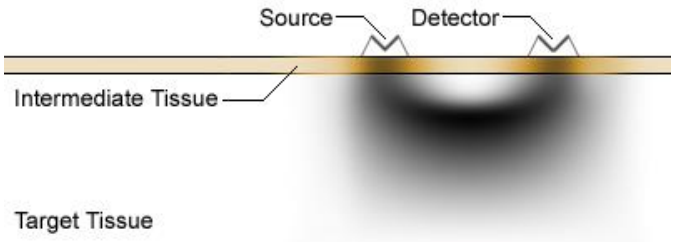

Figure 2-1: Simulated Photon Diffusion Path

The principle used in identifying intracranial hematomas with the Infrascanner is that extravascular blood absorbs NIR light more than intravascular blood. 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.

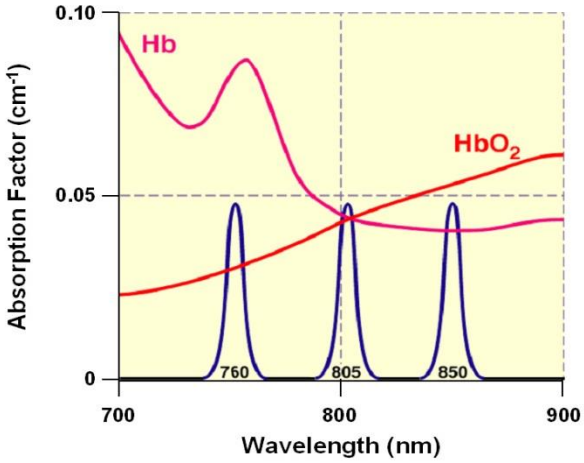

Figure 2-2: Absorption of light by hemoglobin

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.

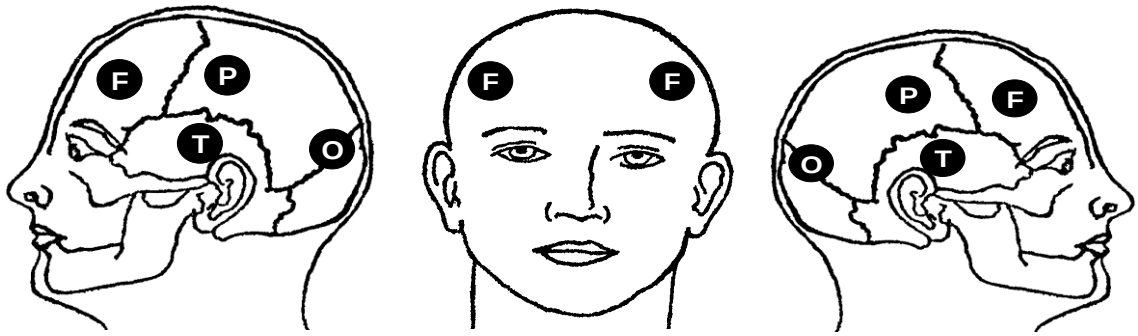

Figure 2-3: Head locations of NIR measurement

Frontal	Left/Right forehead, above the frontal sinus
Temporal	In the Left/Right temporal fossa above 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, about an inch above the top of the ear

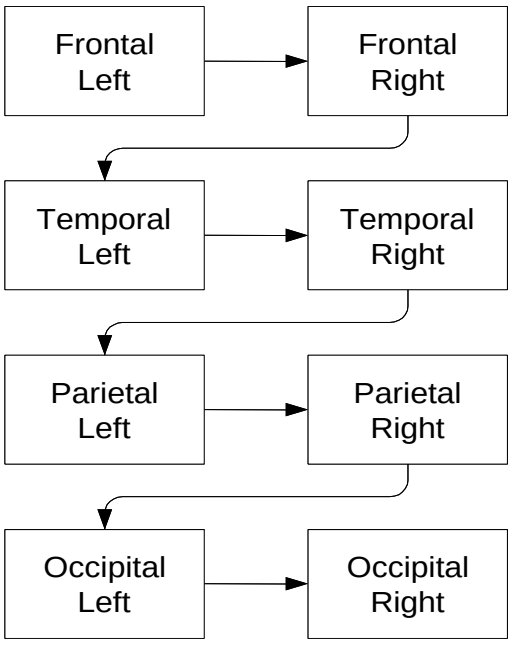

Figure 2-4: Infrascanner head scanning sequence

2.2 THE INFRASCANNER SYSTEM

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 microprocessor in the Infrascanner. The microprocessor 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 microprocessor 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 8 minutes of inactivity, if the shield is not removed, the Infrascanner starts beeping until the Disposable Shield is removed. When the Infrascanner is in one of the measurement screens, pressing and releasing one of the Measure Buttons activates a measurement sequence at a given head location. When the measurement is starting, the amber Measure LEDs will blink. When a successful measurement is finished, the Measure LEDs will blink green. If there is an error message, the Measure LEDs 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 completing head scan, the screen will display the differential optical densities for the measured pairs. The absolute value of optical density is not relevant, just the relative difference between left and right sides of the head.

Audible signals indicate when the measurement is done. A first short beep indicates when the measurement button is pressed and the measurement begins and two consecutive short beeps indicate a completed measurement. An elongated beep indicates an error message. The error message must be cleared by pressing the enter 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 by a- built-in rechargeable LiPo battery and by 2 disposable AA batteries.

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 new 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.

Infrascanner Front **Infrascanner Back**

Figure 2-5: Infrascanner Model 2500

Figure 2-6: Infrascanner Model 2500 Membrane Keypad

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.

3.0 OPERATING PROCEDURE

3.1 SETTING UP THE SYSTEM

3.1.1. Battery Installation. Release the battery door by lifting the latch at the bottom of the scanner.

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

3.1.2. Install the battery door and snap it into its location.

3.1.3. Charging. Attach the USB Power Adapter to the USB port of the scanner and connect it to the AC Power Mains. The charging symbol should appear on the LiPo battery indicator.

3.1.3.1 The Infrascanner requires approximately 2 hours to charge from AC charger, and is fully charged when the LiPo battery indicates 100%. The Infrascanner will not charge disposable batteries when they are in the Infrascanner. There is no hazard under this condition.

3.1.3.2 Note: the Infrascanner cannot be used to make a measurement when it is being charged (from the AC charger or a personal computer).

3.1.3.3 Note: the Infrascanner will not charge the LiPo battery if the temperature of the battery is less than 0C or greater than 45C. If the battery does not charge properly, move the Infrascanner to an environment greater than 0C or less than 45C, then try charging again.

Figure 3-1: Installing Disposable Batteries

3.1.4. Fiber Optic Disposable Shield. Press the fibers outward from the cone so that don't get bent against the windows during installation, as shown in Figure 3-2.

Figure 3-2: Pressing the Fibers

3.1.5. Attach the Disposable Shield to the Infrascanner. Insert the Shield into the slot on the back of the Infrascanner so the fibers sit over the optical towers. Push firmly at the top/back of the disposable, until you feel the disposable snap onto the Infrascanner, as shown in Figure 3-3. Once the disposable Shield is installed press the fibers inward so that they are up against the windows.

Figure 3-3: Attaching the Disposable Shield

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.

3.1.6. Software Navigation. Use the Left/Right arrows to change which button is selected. Use the central “Enter” button to execute the selected button in the software. Use the Up/Down arrows to edit the selected field values. Use the Menu button to open case sensitive menus. Use the Back button to return to previous screen.

3.2 MEASUREMENTS WITH THE SYSTEM

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

3.2.2 Select the “Scan” option, as shown in Figure 3-4. The status bar at the top of the screen shows the current date, time and the active battery charge level. At the bottom of the screen the status of the different batteries is presented:

3.2.2.1 The scanner includes a built-in rechargeable Lithium Polymer (LiPo) battery and can accommodate, in addition, 2 AA disposable alkaline batteries.

3.2.2.2 If disposable batteries are present, the internal rechargeable battery is used first and once it is depleted, the scanner switches automatically to the disposable batteries.

3.2.2.3 When the disposable shield is removed and the system is off, the disposable batteries are used to charge the rechargeable battery.

3.2.2.4 The status bar at the top of the screen shows the charge level of the actively used battery and in the bottom of the home screen the status of all batteries is shown.

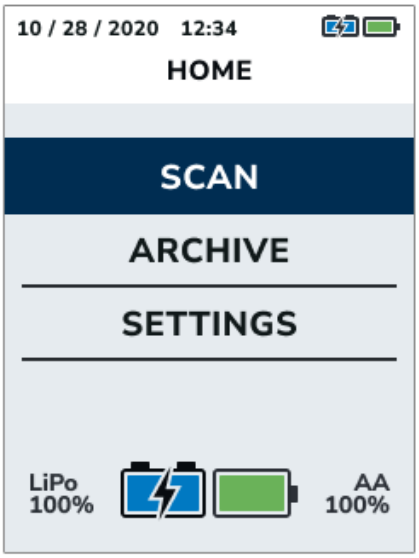

Fig 3-4: Home Screen

3.2.3 The New Scan screen (Figure 3-5) gives the operator an option to scan without Medical Record Number (MRN), to attached the scan to an existing MRN, to create a new MRN in the system or to perform a Monitoring Scan (future use). After selecting the MRN option (and setting it up, if selected) the operator is reminded to keep good contact with the skin before continuing.

CAUTION: if entering an MRN, the user should avoid entering patient identifiable numbers for IDs (e.g., social security number, military ID number).

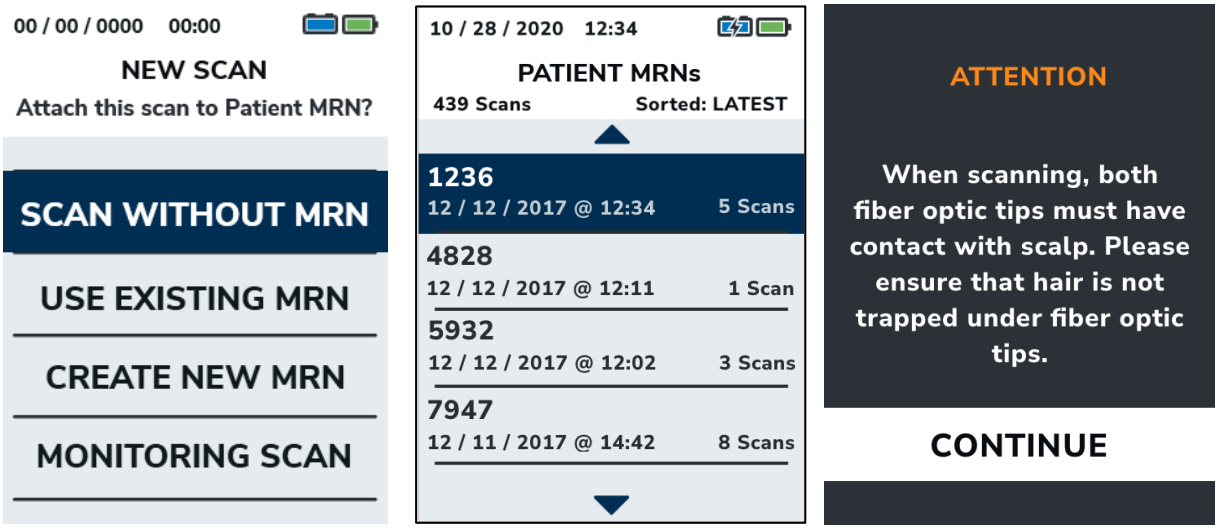

Figure 3-5: New Scan Screen

3.2.4 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 system helps the user through the measurement process by displaying tutorial screens (Figure 3-6) and guiding the user to repeat measurements when a potential hematoma is detected. If the operator wishes to skip head lobe, Menu button is pressed to bring a menu for skipping a lobe.

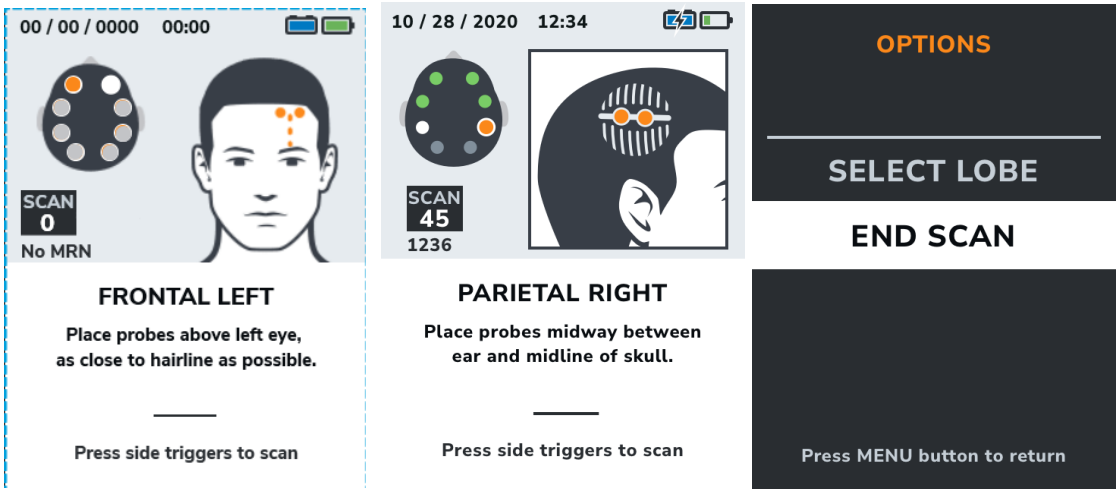

Figure 3-6: Scanning screens

3.2.5 In each location wiggle the light guides so they will be in clear contact with the scalp. Confirm that no hair is between the light guides and the scalp. After establishing firm contact press and release one of the two “Measure” triggers on the sides of the Infrascanner. Either one of the triggers can be used, depending on which is more convenient. The measurement begins after the trigger 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.

3.2.6 After each successful measurement, the Infrascanner will beep and the screen will prompt the user to move to the next head location. An error will be indicated by three beeps. When an error occurs look at the screen to read the error message. Then clear the message by pressing the enter button. Repeat the measurement in the same location (or in the contralateral side – depending on the error message).

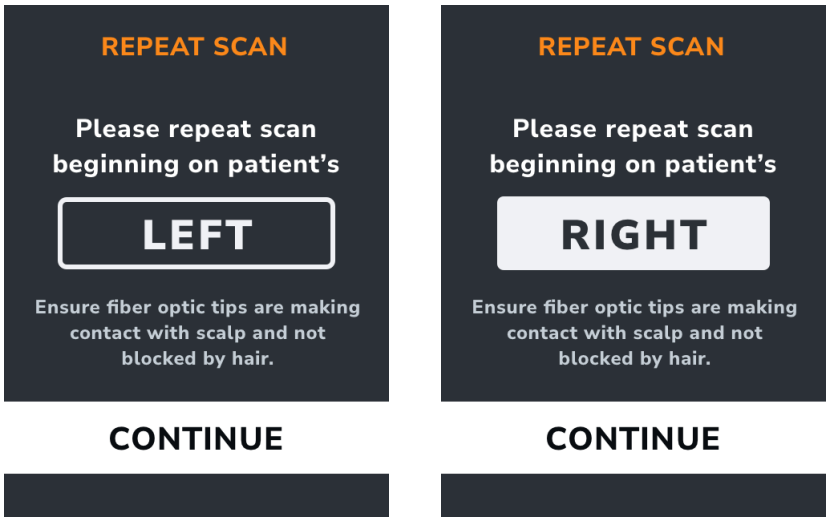

Figure 3-7: Repeat screens

3.2.7 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.

3.2.8 After completing each data pair, review the screen. If a brain hematoma is suspected, the scanner will ask to 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. 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. After successful measurement of the head 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. To assist color blind users, the red locations have different pattern than green locations.

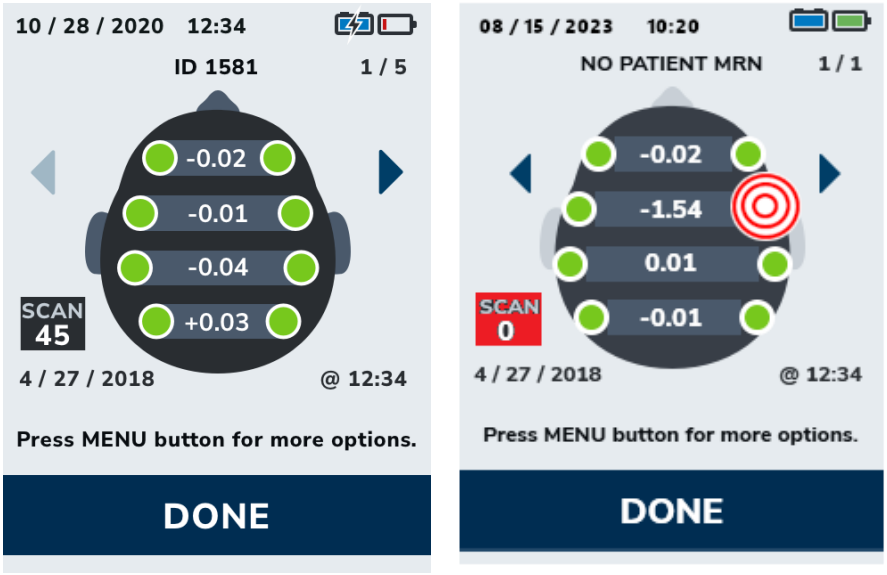

Figure 3-8: Diagnosis Screens

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

3.3 TURNING OFF THE SCANNER

3.3.1 To turn off the Infrascanner, remove the Disposable Fiber Optic Shield by pulling back at the top of the Shield (at the top of the Infrascanner).

3.3.2 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.

3.3.3 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.

3.3.4 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 3-9).

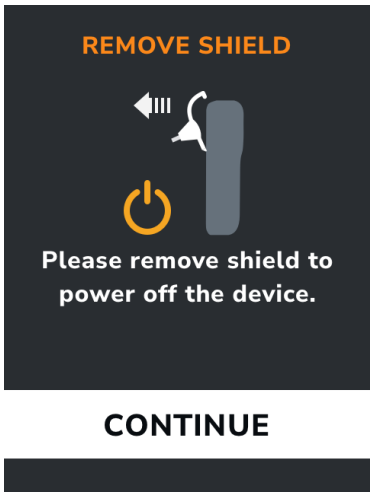

Figure 3-9: Remove Shield Screen

3.3.5 If the Infrascanner is not going to be used for an extended period of time (more than 3 weeks, the AA batteries should be removed.

3.4 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: “HSyymmdd-hhmmss-xxxx.txt” (year, month, date, hour, minutes, seconds and measurement number).

To view archived measurements on the Infrascanner:

1. In the Home Screen (Figure 3-4), click on “Archive” button.
2. To view archived measurements organized by measurement number click on “All Scans” button or select “Patient MRNs” to view archived measurements organized by MRN, as shown in Figure 3-10.
3. In the list of all the scans select the required scan number of the measurement and click on enter button to view a specific measurement, as shown in Figure 3-11.
4. In the list of patient MRNs select the required patient and click on enter button to view the measurements of that patient, as shown in Figure 3-12.
5. The next screen (Archived Measurement screen) is the same as the Diagnosis Screen (Figure 3-8) shown at the end of a measurement. To scroll through measurements of the same patient use the left and right arrows.
6. In the Archive List, the way to jump a page forward or backward in the list is to use the left and right arrows instead the up and down arrows.

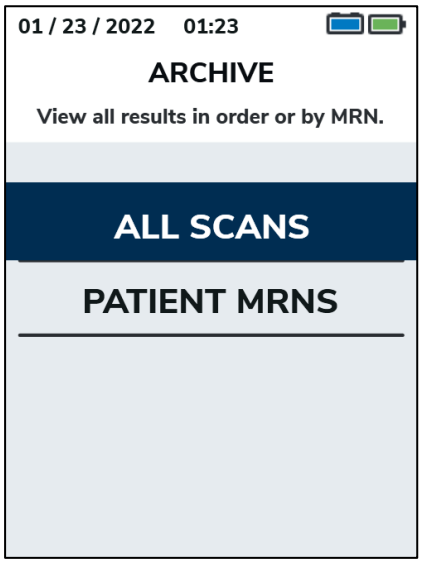

Figure 3-10: Archive Screen

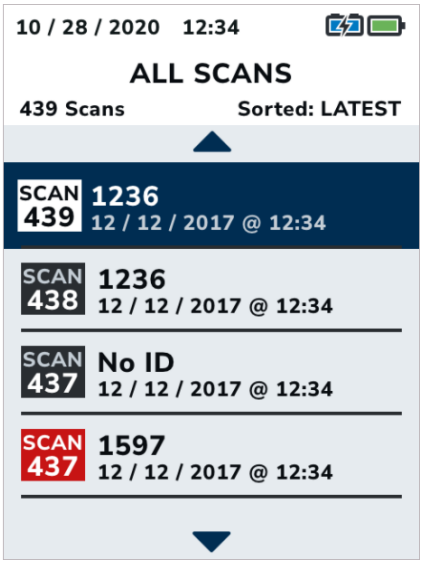

Figure 3-11: List of all scans

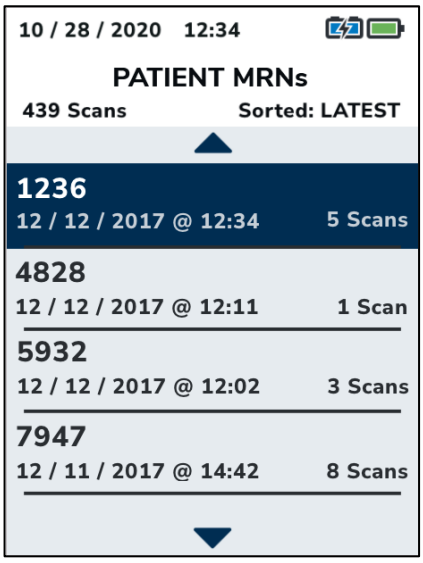

Figure 3-12: List of all MRNs

7. In the scans list it is possible to find a specific patient or to sort the list by pressing the menu button, which opens a popup menu allowing searching and sorting, as in Figure 3-13.

   a. Enter a number or numbers then select Search to search for saved MRN that contains that number.

   b. To sort archived files by date/time select Latest or Earliest. To sort by MRN select MRN-Low or MRN-High.

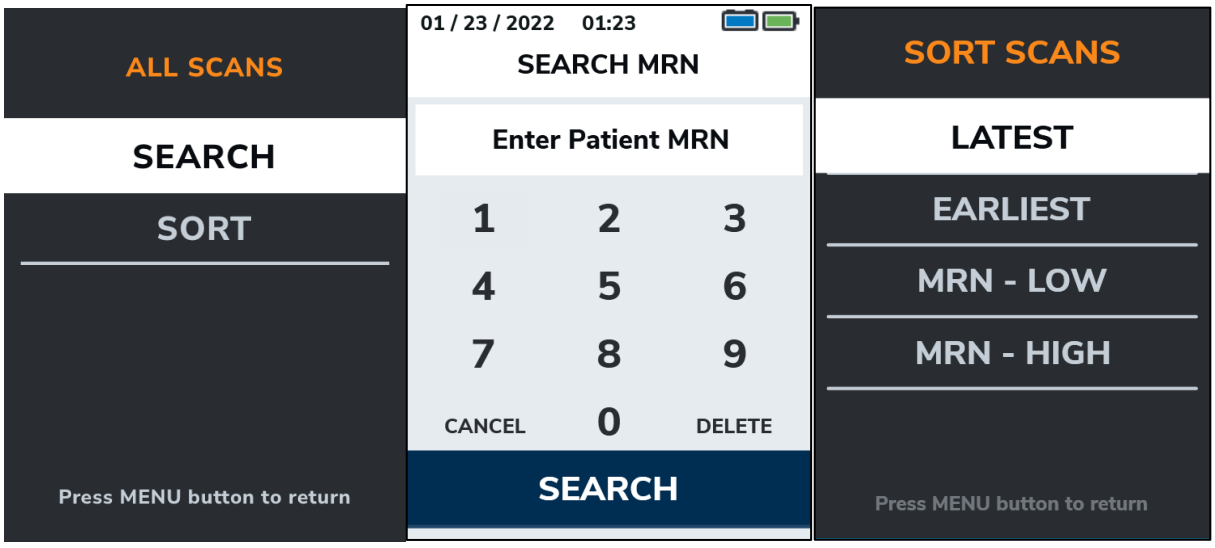

Figure 3-13: Searching and sorting popup menus

Data File Download to a Computer: steps to review stored patient data.

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 number of that

measurement: “HSyymmdd-hhmmss-xxxx.txt” (xxxx = four digits of the measurement number).

2. Data files can be downloaded to a computer by using the PC Connect application while the Infrascanner is connected via USB to a computer running Windows.
3. Plug the USB-A to USB-C Cable provided with the system to a computer (PC), then plug the other end into the scanner. The connector to the scanner has to be firmly pushed into the scanner to ensure a good contact.
4. Install and run the PC Connect application. Enter a user name and click on Connect. Click on Skip. Click on the File Download icon. PC Connect will show the contents of the Infrascanner. Check the box next to the files that you want to download. Click the Download button and select a location on the PC to save the file(s).
5. Use Windows Explorer to locate the downloaded file(s). Use a text editor or Excel to view and analyze the data on your PC.

Minimum Desktop Computer Requirements (Internet connection is helpful):

- Microsoft Windows 10 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

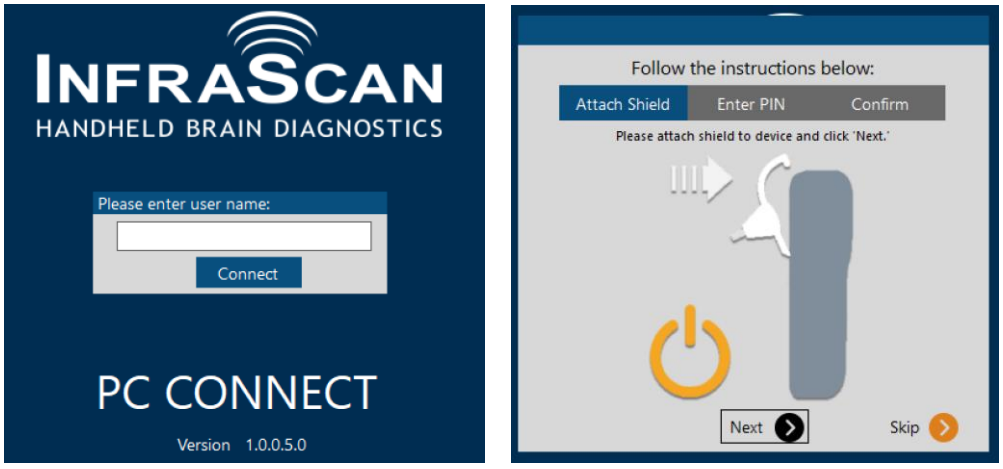

Figure 3-14: PC Connect

3.5 SETTINGS

In the Home Screen (Figure 3-4) click on “Settings” option to reach the Settings Screen (Figure 3-15), which allows changing some of the different parameters of the Infrascanner.

To change the most common options:

1. In the Settings Screen click on a relevant option.
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 OK to store the new parameters and to return back to the Settings screen.

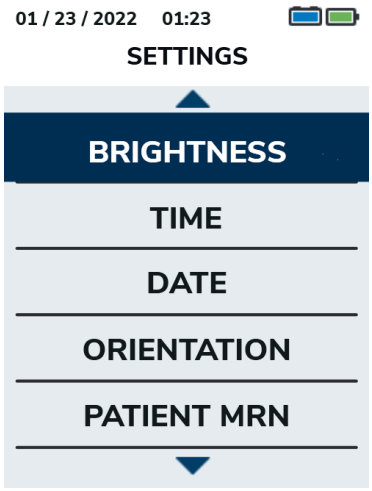

Figure 3-15: Settings Screen

Figure 3-16: Date Format Setup Screen

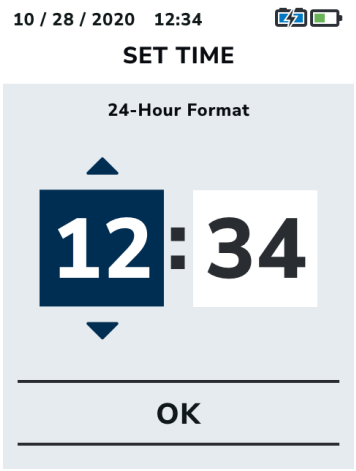

Figure 3-17: Time Setup Screen

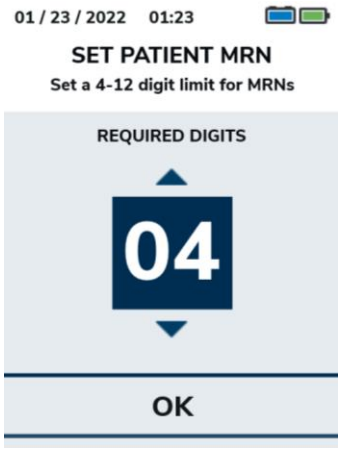

Figure 3-18: Patient MRN Length

Figure 3-19: Language Selection

NOTE: 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 “Technician” option.

3.6 TROUBLESHOOTING

For help with troubleshooting the device, please email us at support@infrascanner.com.

Cause	Solution
Problem: The Infrascanner screen does not turn on when Disposable Fiber Optic Shield is placed on.	
The battery of the Infrascanner is drained.	Recharge the Infrascanner and/or use fresh 2 AA disposable batteries
The disposable batteries are inserted incorrectly	Ensure that the 2 AA 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 and/or use 2 fresh AA disposable batteries.
Problem: Infrascanner does not communicate with PC	
There is dirt in the USB plug of the Infrascanner.	Ensure that the USB plug is clean and free of debris on the Infrascanner.
Problem: The system shows an incorrect date or time	
The batteries were automatically disconnected during prolonged storage or was shipped from another time zone.	Set the date and time in the Settings section of the software.
Problem: The error tone was heard and there is an error message on the screen.	
The algorithm detected a problem with the incoming data.	Clear the error message by pressing the enter button and then follow the recommended corrective action on the screen.
Problem: A measurement head location is Red.	
A real hematoma.	No further action.
A bad measurement	Hair is trapped under the light guides - Scan again. 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 continuously	
More than ~8 minutes elapsed from the previous measurement and the Infrascanner reminds to remove the shield.	Take off the disposable fiber optic shield and put it back on, to reset the Infrascanner.

3.7 ERROR MESSAGES

Must be cleared by pressing the Enter button.

High Signal – Caused by too much ambient light, Infrascanner is especially sensitive to infrared lamps, bright incandescent bulbs and bright sunlight. Try shielding the light guide area with hands and repeat the measurement.

Repeat Measurement (Start on Left) – Infrascanner has detected a potential hematoma and needs to re-take the data (left side first) to confirm or the light on one side of the patient's head is brighter than the other. Re-take the data of the pair.

Repeat Measurement (Start on Right) – 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).

Unstable Signal – Caused by variations in the signal level. Hair may be trapped under the light guide or light guide might not be making contact with scalp. Repeat the measurement at the site taking care to hold Infrascanner steady.

Battery is Low – Charge the Infrascanner or replace AA batteries.

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 USB plug of debris in order to charge properly.

Preventive Inspection and Maintenance

Ensure that the windows over the detector and laser are clear of debris, lint or dust. 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 Power Adapter for connecting to power outlet. Any other power supply could damage the charging circuitry and/or the Lithium Polymer rechargeable battery.

Sterilization

Never sterilize the Infrascanner or the Disposable Fiber Optic Shields.

Replacement of Batteries

Use your finger to release the battery door latch. To change the AA disposable batteries, remove the used disposable batteries. Ensure that proper polarity is observed when inserting the new batteries. Replace the battery door and engage the latch. When disposing of the Infrascanner, or the batteries, ensure that environmental regulations are followed.

Test Shield

Test Shields (part number 000210) are available for purchase for service personnel to do periodic testing of the Infrascanner. The Test Shields are set up by the factory and can be used on a periodic basis (e.g. annually) to check that the Infrascanner is functioning properly. Inspect the laser and detector windows for cleanliness. Clean with alcohol if necessary. Place the Test Shield (part number 000210) over the Infrascanner windows. Push firmly at the top/back of the shield until you feel the shield snap. This will turn on the Infrascanner. Press **Continue** to go to the operational check.

Figure 4-1: Test Shield (000210)

Figure 4-2: Optical Windows

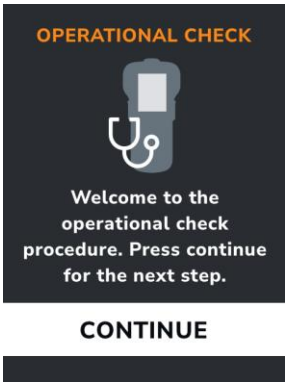

Figure 4-3: First Screen

Press a Measure button on the left or right sides. The scanner will perform a self-test and display a Pass or Fail result. Remove the Test Shield.

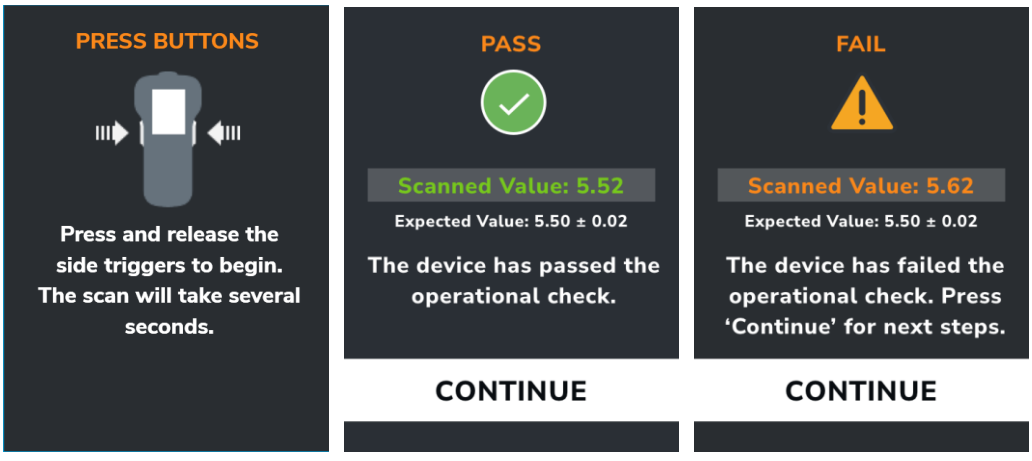

Figure 4-4: Test Measurement with Pass and Fail Screens

If the device **Fails** the test, please contact InfraScan support.

5.0 SUPPORT

The Infrascanner 2500 has an expected service life of 7 years and will be supported for 7 years from the date of manufacture. For support, please email us at support@infrascanner.com.

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 2 disposable AA batteries. The Infrascanner can also be powered by an internal Lithium Polymer 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 Power Adapter is used.

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

Catalog Numbers

Description	Catalog Number
Infrascanner Model 2500 System	2500
Disposable Shields, Infrascanner 2500 (box of 25)	2500-1
USB-C to USB-A Cable	000214
Power Supply, 5 Vdc	000212

Electromagnetic Interference

The product has been designed and tested to meet the essential performance under Electromagnetic Interference. The essential performance is pulsing the laser and to accurately 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 2500 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2500 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 2500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 2500 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. • Professional healthcare facility environment • Emergency medical services environment
Harmonic emissions IEC 60601-3-2	Complies	
Voltage fluctuations /flicker emissions IEC 60601-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 2500 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2500 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%. • Professional healthcare facility environment • Emergency medical services environment
EFT IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical home, commercial or hospital environment. • Professional healthcare facility environment • Emergency medical services environment
SURGE IEC 61000-4-5	±2 kV line(s) to earth ±1 kV line(s) to line(s)	Not Applicable ±1 kV line(s) to line(s)	Mains power quality should be that of a typical home, commercial or hospital environment. • Professional healthcare facility environment • Emergency medical services environment
Voltage Dips/Dropout IEC 61000-4-11	0% U_T (95% dip in U_T for 0.5 cycle) 0% U_T; 1 cycle 70% U_T (30% dip in U_T for 25 cycles) 0% U_T for 5 seconds	0% U_T; 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles 0% U_T; 250/300 cycles	Mains power quality should be that of a typical home, commercial or hospital environment. • Professional healthcare facility environment • Emergency medical services environment
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 home, commercial or hospital environment. • Professional healthcare facility environment • Emergency medical services environment

Guidance and manufacturer's declaration – electromagnetic immunity

Not Life Supporting

The Model 2500 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2500 should assure that it is used in such an environment.

Immunity test	Test Level	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, 80% amplitude modulation with 1 kHz sine wave and 6 V rms in the ISM Band	3 Vrms 150 kHz to 80 MHz, 80% amplitude modulation with 1 kHz sine wave and 6 V rms in the ISM Band	Portable and mobile communications equipment should be used no closer to any part of Model 2500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[3.5/V1]\sqrt{P}$ $d=[3.5/E1]\sqrt{P}$ 80-800MHz $d=[7/E1]\sqrt{P}$ 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. • Professional healthcare facility environment • Emergency medical services environment
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10 V/m 1.00 kHz sine (from 80 MHz to 500 MHz) 1.01 kHz sine (from 500 MHz to 2.7 GHz) ⚠ Warning: The Infrascanner performance may degrade or malfunction if subjected to radiated electromagnetic fields at 2.44 MHz - 2.7 GHz, at 80% AM, 1 kHz modulation.	

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 for 30 minutes before use.

6.0 INFRASCANNER MODEL 2500 TECHNICAL SPECIFICATIONS

1. Physical Specifications:

1.1. Dimensions with Disposable: 6.65H x 2.99W x 2.25D inch

1.2. Dimensions without the Disposable Fiber Optic Shield: 6.5H x 2.99W x 1.47D inch

1.3. Weight of Infrascanner: 9.1oz (257g)

1.4. Number of detectors: 1

1.5. Number of light sources: 1

1.6. Light Source - Detector Separation: 4 cm

2. Functional Specifications

2.1. Power: 3.7Vdc Rechargeable LiPo Battery (0.73Ah) or 3Vdc two AA disposable batteries

2.2. Operating time on new fully charged LiPo battery: >1.5 hours

2.3. Operating time on new AA batteries: >1.5 hours

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

2.5. The internal, rechargeable LiPo battery needs to be replaced after 500 discharge cycle

3. Laser Diode Specifications:

3.1. Wavelength: 808nm (±4nm)

3.2. Maximum peak pulsed power: 200 milliwatt

3.3. Safety: Class 1 Laser Product

4. Power Adapter Specification:

Input voltage: 100-240 volt AC. Input current: 0.3 Amps. Input frequency: 50-60 Hz. Output: 5 VDC @ 1.2 amps.

5. Environmental:	Operational	Storage
Temperature	-20°C to 50°C	-40°C to 70°C
Relative Humidity (non-cond)	0% to 90%	0% to 90%
Atmospheric Pressure	62-106 kPa	50-101 kPa

6. Transient Operating Conditions:

The Infrascanner meets all specifications for 20 minutes during transient operating conditions of a temperature range of –20°C to 50°C and a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa.

7. Ingress Protection

IP33 3 = Protected against solid objects of 2.5mm and greater
3 = Protected against direct sprays of water up to 60 degrees from vertical

8. Computer Requirements for Data Download:

8.1. Microsoft Windows 10 or later

8.2. USB port

8.3. PC Connect application

Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-12

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 2500 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.