Zura Handheld Scanner
User Manual
Model UML-ZHH-011

Table of Contents

Disclaimer:

This disclaimer extends to all printed matter accompanying the ImaCor Zura Handheld Scanner.

The information contained in these materials is proprietary and confidential to ImaCor Inc. ("ImaCor") and is provided for the sole use of the individual or entity to whom it is addressed and therefore these materials must be kept in the strictest confidence. No portion of this manual may be copied, reproduced, republished, modified, sold, disclosed, or distributed without the prior written permission of ImaCor. Unauthorized copying or distribution of this manual, in addition to infringing copyright, may reduce the ability of ImaCor to provide updates and current information to users.

ImaCor has taken care to ensure the accuracy of this document, however, revisions may not be possible in all situations. Information in this document may be subject to change without notice, and ImaCor assumes no liability for errors or omissions. ImaCor reserves the right to make changes without further notice to any products herein to improve reliability, function, or design. ImaCor may make improvements or changes in the products or programs described in this document at any time.

These materials may contain third-party copyright and/or trademark materials, the use of which has not always been specifically authorized by the intellectual property owner. All copyrights and/or trademarks contained in these materials are the sole and exclusive property of their respective owners.

ImaCor Zura, ClariTEE Probe, and the ImaCor logo are trademarks or registered trademarks, and are the sole and exclusive property of ImaCor.

© 2022 ImaCor Inc.

All rights are reserved. Reproduction or transmission in whole or in part, in any form or by any means, electronic, mechanical, or otherwise, is prohibited without the prior written consent of the copyright owner.

Published in USA.

About This Manual $\qquad$ 1

This manual provides instructions for use of the ImaCor Zura Handheld Scanner.

This document is licensed as part of the purchase of the ImaCor Zura Handheld Scanner and meets applicable regulatory requirements. Use of this document by unauthorized persons is strictly prohibited.

This document contains the following information:

- About the ImaCor Zura Handheld Scanner: Describes the product, and lists technical specifications, and its intended use.

- Using the ImaCor Zura Handheld Scanner: Shows you how to get started and begin scanning, introduces you to the features and concepts, and helps you set up your system.

- Accessories: Describes additional accessories you can purchase for use with your ImaCor Zura Handheld Scanner.

- Cleaning & Disinfecting: Explains how to clean and disinfect your scanner and its accessories.

- Safety: Outlines important safety standards, principles, and policies to follow when using the product.

- References: Offers information such as product standards, regulatory requirements, terms and conditions, glossary of terms, and acoustic output data.

Access to user documentation may be affected by: Internet availability and accessibility, website availability, and local electromagnetic interference.

Target Audience

This document is written for trained medical professionals who operate and maintain your ImaCor Zura Handheld Scanner. It contains instructions and reference material pertaining to the usage and maintenance of the product.

Document Conventions

Icons

Icon	Title of Icon	Description
	Alert	Possible risks beyond the reasonable control of ImaCor.
	Do not do this	This icon indicates actions to avoid.
	Note	This icon indicates informative material or helpful suggestions.

Symbols Glossary

The symbols shown in this document and on the ImaCor Zura Handheld Scanner are compliant with current versions of the following standards: ISO 7000, ISO 7010, IEC 6417, (EN) ISO 15223-1, and EN 15986.

STANDARD: ISO 7000 — GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

Symbol	Reference	Title	Description
	3082	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/ 385/EEC, 93/42/EEC and 98/79/EC.
	2497	Date of manufacture	Indicates the date when the medical device was manufactured.
REF	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.

STANDARD: ISO 7000 — GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

SN	2498	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
NON STERILE	2609	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	0621	Fragile; handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	0626	Keep away from rain	Indicates a medical device that needs to be protected from moisture.
	0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
%	0224	Measure humidity	Indicates the range of humidity to which the medical device can be safely exposed.
	1641	Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use.
	0434A	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	1135	General symbol for recovery/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process.

You may see some of these standard symbols on your ImaCor Zura Handheld Scanner, accessories, and packaging:

OTHER STANDARDS— GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS
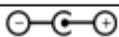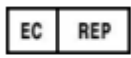
Symbol	Standard	Reference	Title	Description
	ISO 7010	M002	Refer to instruction manual/booklet	Indicates to read the instruction manual/booklet before starting work or before operating equipment or machinery.
	IEC 6417	5172	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 60536.

OTHER STANDARDS— GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT — REGISTERED SYMBOLS

	IEC 6417	5957	For indoor use only	To identify electrical equipment designed primarily for indoor use.
	IEC 6417	5333	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.

You may see these other symbols on your ImaCor Zura Handheld Scanner, accessories, and packaging:

OTHER GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT

Symbol	Title	Description
⊖—Ⓒ—⊕	Power connector	Indicates a barrel-type power connector.
RoHS 2	RoHS compliant	Identifies electrical and electronic equipment that meets the Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU.
CE	European Conformity	Conforms to European Council Directive 93/42/EEC.
FCC	FCC	Conforms to US Federal Communications Commission.
CSA	CSA certification	Certified by the Canadian Standards Association. The number below this symbol indicates the contract number.
	Waste Electrical and Electronic Equipment	Requires separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE). Directive. When accompanied by (Pb) or (Hg), components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD system monitor contain mercury.
IPX4	Ingress protection rating	The equipment inside the enclosure is resistant to water splashes
===	DC	Direct current.
GS1	GS1 DataMatrix	Identifies GS1 encoded DataMatrix.
GMDN	Global Medical Device Nomenclature Code	A system of internationally agreed generic descriptors used to identify all medical device products.
EC REP	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	n/a	Do not stack boxes.

	n/a	Do not use knife to open.
	n/a	Recycle Li-ion battery in accordance with local, state, and federal regulation

About the ImaCor Zura Handheld Scanner 2

Install, operate, and maintain this product according to the safety and operating procedures in this manual, and only for its intended purpose. Always use the information in this document with sound clinical judgment and best clinical procedures. This product is subject to the law in the jurisdiction that the product is used. Install, use, and operate the product only in ways that adhere to applicable laws or regulations, which have the force of law.

⚠

- Product package must be maintained with medical device. Do not dispose.
- Using the product incorrectly, or for purposes other than those intended and expressly stated by ImaCor, may relieve ImaCor or its agents from all or some responsibility for resultant noncompliance, damage, or injury.
- Using portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.
- Operating this system in the presence of flammable gases or anesthetics can cause an explosion.
- Install and operate medical equipment according to electromagnetic compatibility (EMC) guidelines.
- Users are responsible for image quality and diagnosis.
- This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices. It is important that you use compliant peripheral 1 CSA Reference No.: 246340 - 80061297, Attachment 2 User Manual, Page 11 of 79 ImaCor Zura Handheld Scanner Device Description revision A 7 devices to reduce the possibility of causing interference to radios, televisions, and other electronic devices.

🔔

- Circumstances in the patient's environment may negatively impact the scanner and the exam. For example: (1) Chemicals and gases in the operating room. (2) Altitudes below -382 m or above 4000 m.
- Vulnerable patients, such as children and pregnant/nursing women, may be more prone to the exposure of acoustic energy when the scanner is used for prolonged periods.
- Biological incompatibility may exist between the scanner materials used and the biological tissues, cells, and body fluids of the patient/user, taking account of the intended purpose of the scanner.
- Using the scanner in the patient environment may be unsafe if the following conditions exist: (1) Extremes in humidity (RH<15% and RH>90%). (2) Ambient temperatures that are excessively high (>35°C / 95°F) or excessively low (<0°C / 32°F).
- Unqualified/untrained personnel purchasing and using the ImaCor Zura Handheld Scanner may be unable to attain quality images.

Users will be trained medical professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound or with access to ultrasound professionals. Images produced by the scanner are transmitted wirelessly to the user's smart device (tablet or smart phone).

Caution: Federal law restricts this device to sale by or on the order of a physician.

Device Description

The ImaCor Zura Handheld Scanner (ZHH) is a portable, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) Apple iOS or Android™ device. The ImaCor Zura Handheld Scanner is a Bluetooth and Wi-Fi-based scanner that communicates with a traditional tablet/smartphone via direct Wi-Fi to allow users to export ultrasound images and display in different modes of operation. The ImaCor Zura Handheld Scanner houses a battery and internal power supplies, multichannel beamformer, pre-scan converter and Wi-Fi components.

The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals. The ImaCor Zura Handheld Scanner is not to be used in a fixed- or rotary-winged air ambulance.

The system is for use with the ImaCor ClariTEE probe. The ClariTEE probe is a miniaturized Trans esophageal Echo (TEE) Probe used for cardiac imaging.
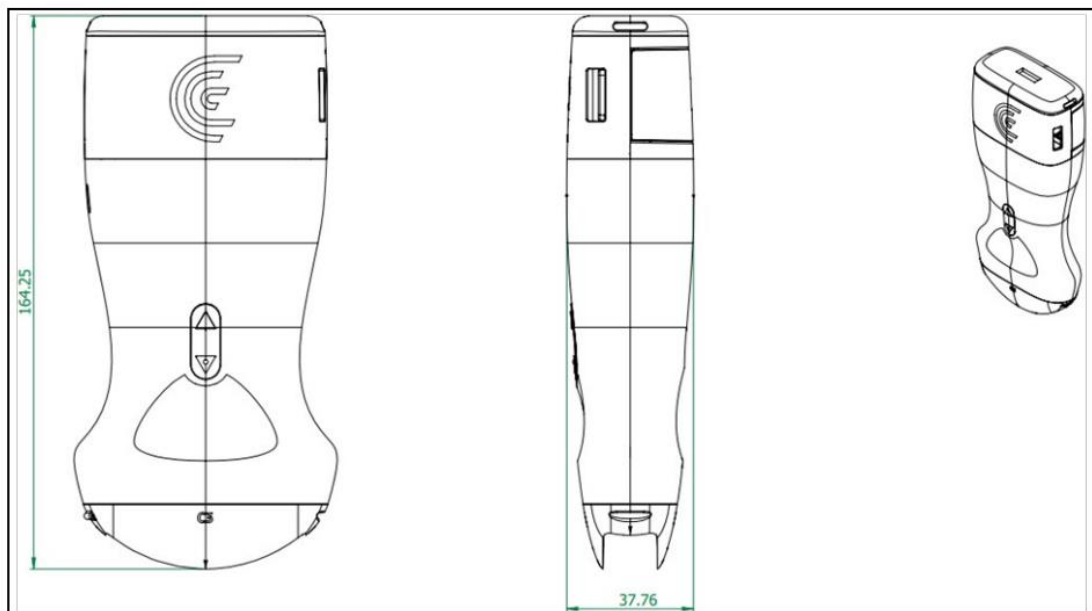
FIGURE 3-1: ImaCor Zura Handheld Scanner (ZHH)
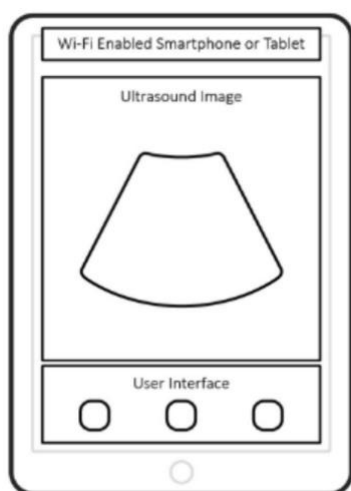
FIGURE 3-2: User Interface/Display

Scanner Dimensions

Item	Length (in/mm)	Width (in/mm)	Height (in/mm)	Weight (oz/g)
ImaCor Zura Handheld Scanner	6.5/164	3.1/78	1.5/38	16/453

Product Usage

Indications for Use

The ImaCor Zura Handheld Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging cardiac (adult) applications:

The system is intended for use in critical care environments where healthcare is provided by trained healthcare professionals.

It is not for pediatric use (Less than 18 years of age)

It is not for use in EMS clinical settings

Indications for Use Table

SYSTEM: IMACOR ZURA HANDHELD SCANNER
INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	PW Doppler	Combined (Specify)	Other*
Cardiac	Cardiac Adult	N						
	Trans-esophageal (Cardiac)	N						
N = new indication; P = previously cleared by FDA								
Note 1: Needle Enhancement in B-Mode.								

Precautions

For Use in Surgical Environments

Before you use the ImaCor Zura Handheld Scanner for intra-operative procedures or in a surgical environment, follow the instructions for high-level disinfection (for instructions see *High-Level Disinfection)* then cover the ImaCor Zura Handheld Scanner with a sheath:

- Use only CIVCO REF 610-1212, Safersonic DAN-33803-WG, and Safersonic DAN-33803-NT.
- Follow the usage instructions provided by the manufacturer.

When you have finished using the ImaCor Zura Handheld Scanner, immediately clean it (for instructions see *Cleaning the ImaCor Zura Handheld Scanner*), followed by another high-level disinfection.

If the sheath breaks during the intra-operative procedure, dispose the sheath and follow the same cleaning and high-level disinfecting process as above, then cover the ImaCor Zura Handheld Scanner with a new sheath before continuing to use it.

Hardware

Warranty

Your ImaCor Zura Handheld Scanner includes a one-year warranty. For full warranty details, go to https://imacorinc.com/contact/contact-us/ and click the Support tab.

Disposal

For proper disposal of the ImaCor Zura Handheld Scanner or any of its accessories, dispose it in accordance with local, state, and federal regulations. Alternatively, you can return it to ImaCor.

The improper disposal of the ImaCor Zura Handheld Scanner (when the battery is no longer working, or the scanner has exceeded its shelf life), or any of its accessories, adds hazardous materials to our landfills.

Security

Information Security

When entering data using the ImaCor App, it is the user responsibility to protect security credentials (e.g. passwords) and the personal information of patients (e.g. names). The user is responsible for ensuring that patient health information is protected when using features in the ImaCor App that may expose identifying information to other viewers.

Network Security

When connecting your smart device, use a network that supports Wi-Fi 802.11n. We recommend that you secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as your security protocol.

For information on setting up your wireless network security, refer to your network equipment's documentation.

You may run into situations where no wireless access point is available. Using an untrusted wireless access point may allow malicious parties to see your Wi-Fi signals, perform harmful actions, and view communications between the two smart devices. When no secure access point is available, operate the ImaCor App in Wi-Fi Direct mode, and it will automatically set up encryption.

For security purposes:

• Use secure passwords.
• Use secure wireless equipment using the latest firmware and software, and secure protocols.
• Lock your smart devices.

The following actions could introduce new risks to patients, operators, and third parties. It is your organization's responsibility to identify, analyze, evaluate, and control these risks:
• Changing network configurations.
• Connecting to additional networks or disconnecting from existing networks.

- Upgrading to new equipment or updating existing equipment.

Confidentiality

Confidentiality of information is assured as follows:

- The scanner contains no patient-identifying information.
- When the scanner connects to a wireless network, it encrypts and stores the Wi-Fi password.
- The data transferred between the ImaCor Zura Handheld Scanner and the ImaCor App is encrypted.
- Image data contains no patient- or user-identifying information and is transmitted in unencrypted form. If you want this data encrypted, connect to a:
  o Wi-Fi network where only trusted parties are permitted. The Wi-Fi network encrypts all image data sent from other Wi-Fi networks.
  o Wi-Fi Direct network. The Wi-Fi Direct network encrypts all image data, and because no other users are on the Wi-Fi Direct network, the image data is confidential.
- If no images are exported to ImaCor Zura ImaCor Cloud or DICOM, the ImaCor App stores them indefinitely. If images are exported, these images will be deleted from the device 10 days after export by default. You can change this default in the ImaCor App's Settings page.

Integrity

Integrity of the data transmitted between the ImaCor Zura Handheld Scanner and the ImaCor App is assured as follows:

- Authenticated encryption prevents malicious users from intercepting and modifying data.
- Integrity checks ensure completion and validity of data received. If any data is incomplete or invalid, it is discarded.
- TCP channels used over Wi-Fi ensures that data is delivered correctly. For transmitting image data, a UDP channel is used.

Availability

If Wi-Fi connection is unattainable (e.g. Wi-Fi access points are unavailable, or the network is down), use Wi-Fi Direct network, which is managed by the smart device. Because Wi-Fi Direct network is a peer-to-peer connection using the Wi-Fi protocol, it disallows other users from connecting, thereby reducing DDOS (Distributed Denial of Service) attacks.

If the Wi-Fi Direct network is disrupted, the ImaCor Zura Handheld Scanner continues to monitor itself and shuts down after a period of inactivity. This reduces acoustic energy transmission and battery usage.

Accountability

The concept of accountability does not apply to the ImaCor Zura Handheld Scanner. However, ownership (i.e. the active user) of a smart device is assigned to one user at a time. Once you begin using the smart device, no other user can connect to the same smart device. All data transmitted between the smart device and the ImaCor App is owned by the active user.

System Requirements

Using the ImaCor Zura Handheld Scanner on a smart device that does not meet the minimum requirements may result in low-quality images, unexpected results, and possible misdiagnoses.

To run the ImaCor App, a smart device must meet or exceed the following minimum specifications:

Technical Features:

- Supports Bluetooth LE v4.0+
- Supports Wi-Fi 802.11n and Wi-Fi Direct
- 8 GB of storage (on-board)
- 512 MB of memory

Operating System:

- Android™ 4.4.2 (API 19)+ or Apple iOS 11.0+

Processor:

- Dual core processor (CPU)
- ARM-based CPU architecture (for Android™-based devices)

Display:

- Resolution (in pixels) of 960x640 (or 640x960)
- Contrast ratio of 800:1
- Supports OpenGL ES 2.0
- A smart device that is too small may not have the necessary resolution for viewing small structures.

Using the ImaCor Zura Handheld Scanner 3

This chapter explains how to install and use your ImaCor Zura Handheld Scanner safely and effectively. Refer to section on Safety before handling the ImaCor Zura Handheld Scanner. Your ImaCor Zura Handheld Scanner is already activated and ready for use. You just need to download the ImaCor App on an Apple iOS device or an Android™-based device

Downloading the ImaCor App

Whether you are using Apple iOS or Android™, you must have an account and password set up with them. Before installing the ImaCor App, make sure your smart device meets the minimum requirements.

▼ To download the ImaCor App:
1. Go to the Apple App Store or Google Play Store.
2. Search for the ImaCor App. If you cannot find the ImaCor App, your smart device may not be meeting minimum specifications.
3. Tap the Install button and follow the instructions on your screen.
   This downloads the application.
4. Tap the Open button.
   This opens the ImaCor App.

Turning the System On & Off

Starting the ImaCor App

Before you begin using the ImaCor Zura Handheld Scanner, make sure you have the ImaCor Zura Handheld Scanner, and your smart device with the ImaCor App installed on it.

To open the ImaCor App on your smart device:

1. Go to your smart device's home screen and tap
   .

2. The ImaCor App opens to the sign-in screen.

   For information on using the ImaCor App and scanner, go to https://imacorinc.com/contact/contact-us/#support-tab.

Exiting the ImaCor App

▼ To close the ImaCor App:
Refer to your smart device's user manual.

Managing Exams

• Notifications and alerts from third-party applications may interrupt you or the ImaCor App, thereby interfering with the exam. Configure your smart device in accordance with your institution's security policies.
• Vibration range that is too high for the scanner may cause the scanner to malfunction during an exam.

Error Messages

The ImaCor Zura Handheld Scanner does not display error messages. Instead, the ImaCor Zura Handheld Scanner presents visual notifications in the form of status lights, and audible notifications in the form of status alerts.

Status Lights
The following table defines the ImaCor Zura Handheld Scanner's status lights:

Color	Display	Meaning
Blue	Flashing	Scanner is booting up.
Blue	Solid	Scanner is ready for a Wi-Fi connection, or has a connection and is not imaging.
Green	Solid	Scanner is imaging.
Orange	Flashing	Battery is low.
Orange	Solid	Internal communications error.[a]
Red	Flashing	Battery is critically low.
Red	Solid	Critical boot-up error has occurred. [a]
Purple	Flashing	Software/firmware is updating. Do not remove battery.

a. Remove the battery from the scanner, wait 10 seconds, re-insert the battery, and re-connect it to your smart device. If symptoms persist, contact ImaCor.

Audible Notifications
The following table defines the audible indicators the ImaCor Zura Handheld Scanner emits:

Sounds	Meaning
1 short beep	Wi-Fi Network Connected
2 short beeps	Wi-Fi Direct Enabled
2 quick beeps	Scanner Components are Ready
3 quick beeps	Bluetooth is Ready
2 tone-increasing pitches	Power On
2 tone-decreasing pitches	Power Off
1 beep every few seconds	Critically Low Battery
4 long alerts	Embedded Processor is Preparing for Software Update
4 short beeps	No Network Connected
4 quick beeps	App Find Request (based on Selected Ring Tone)
8 long alerts	App Find Request (Important)

Imaging

Scanner Buttons	Description
Up	Press this button to turn on the scanner. Press this button while scanning an image.
Down	Press this button while scanning to freeze or unfreeze an image.

The ImaCor Zura Handheld Scanner can take up to 30 seconds to power up and prepare for imaging.

When scanning for more than 15 consecutive minutes, the fan must be used. For information on the fan, see *Cooling Fan*.

When you go to the image acquisition page to begin an exam, the ImaCor Zura Handheld Scanner automatically switches from standby mode to scanning mode. For instructions on using the imaging tools, go to https://imacorinc.com/contact/contact-us/#support-tab.

A typical use of the **ImaCor Zura Handheld Scanner** is described as five continuous scanning minutes followed by 10 minutes in standby mode (or turned off).

Using the Measuring Tools

Measurement Accuracy

You can use the ultrasound system to make measurements on ultrasound images. The measurements are then used with other clinical data to make a diagnosis.

Never make a diagnosis based solely on measurements. When quantifying data, consider other factors. The accuracy of each measurement is highly dependent on image quality, which in turn is highly dependent on system design, operator scanning technique, familiarity with system controls, and patient echogenicity.

You are responsible for image quality and diagnosis. Ensure that the data used for inspection and diagnosis is sufficient, both spatially and temporally, for the measurement method.

Measurement Accuracy Table

Each figure below is derived from the sum of all parts of the ImaCor Zura Handheld Scanner when used with its dedicated probe.

2D MEASUREMENT ACCURACY			
Scanner	Measurement	System Tolerance	Range
ImaCor Zura Handheld Scanner	Axial Distance	± 2%	0 – 32 cm
	Lateral Distance	± 2%	0 – 32 cm
All Scanners	Axial Distance	± 2%	0 – 32 cm
	Lateral Distance	± 2%	0 – 32 cm

Inaccurate measurements or misinterpretation of results taken from an exam may lead to mis-diagnosis.

Updating the ImaCor Zura Handheld Scanner

Software Updates

▼ To update the software:
Go to the Apple App Store or the Google Play store.

Firmware Updates

If an ImaCor Zura Handheld Scanner software update is required, the ImaCor App will notify you.

▼ To update the firmware:
Tap **Update**.

During the update, the ImaCor Zura Handheld Scanner emits a purple flashing light. Also, a purple indicator displays at the top right of the screen. Once the update is complete, the ImaCor Zura Handheld Scanner light turns blue.

Maintenance

The scanner routinely performs automated maintenance of the scanner itself. Perform maintenance regularly and as needed. The system must be serviced by trained personnel only.

Failing to regularly maintain or verify the ImaCor Zura Handheld Scanner may lead to undetected performance errors.

Hardware Maintenance

Testing Scanners

When you turn on the system, the scanner powers up and automatically tests its internal components. The ImaCor Zura Handheld Scanner's LED will light up and you will hear a two-tone beep. The table below defines these conditions:

Battery Condition	Priority	Visual Indication	Audible Indication
Low Battery	Low	Orange Flashing Status Led	None
Critically Low Battery	Low	Red Flashing Status Led	1 Beep Every Few Seconds

Also, the system runs a series of tests in the background. If your smart device is not connected to a wireless or cellular network, the logs are queued until you have network connectivity. For more information, go to https://imacorinc.com/contact/contact-us/ and contact ImaCor.

Recharging ImaCor Zura Handheld Scanner
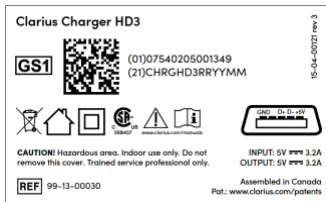
Because the ImaCor Zura Handheld Scanner is battery-operated, you must recharge it when battery gets low or empty. An empty battery takes approximately 1½ hours to fully charge. A full battery has approximately 45 minutes of continuous scanning time and multiple hours of episodic scanning time. The battery charge can last up to two weeks in sleep mode. Charge the battery at least once a month to ensure proper functionality.

Charge the ImaCor Zura Handheld Scanner using its dedicated charging dock (Clarius Ref 99-13-00030). Its charging dock supports various USB-dedicated adapters and USB ports; however, these products may cause the charger to fail or vary in charging time.

The battery power level is displayed on the screen. Battery warning notifications from ImaCor Zura Handheld Scanner in sleep mode via BLE are displayed to the user using the standard notification services of the smart device running the ImaCor App.

⚠ Charge the ZHH scanner using only its dedicated charging dock.

If you turn on the ImaCor Zura Handheld Scanner and leave it untouched, it will go through the following modes to help reduce temperature and battery power:

1. After three seconds, it decreases frame rate.
2. After 30 seconds of decreased frame rate, it freezes.
3. After 10 seconds in freeze mode, it goes idle.
4. After 15 minutes of idle time, it shuts down.

Do not use other chargers for the ImaCor Zura Handheld Scanner when in air ambulances, regular ambulances, or the EMS environment in general. Instead, use only its dedicated charger dock.

When charging the ImaCor Zura Handheld Scanner, it displays the following status lights:

• Orange: Battery is currently charging.

• Green: Battery is fully charged.

Storing Scanners

To protect your ImaCor Zura Handheld Scanner:

- Dry them thoroughly before storage.
- Avoid storing them in extreme temperatures.
- Avoid placing them under direct sunlight for prolonged periods of time. This will not impact the ImaCor Zura Handheld Scanner's safety and performance but may discolor the housing's finish.
- Store them separately from other equipment.
- Make sure stored batteries have at least 40% charge.

The scanner may degrade in performance or become unusable if stored or transported in ambient temperatures below-20°C (-4°F) or above 50°C (122°F).

System Maintenance

Sending Activity Logs

Select the Support menu option to go to the Support page and select the Submit Logs button. This downloads logs from the ImaCor Zura Handheld Scanner, then combines them with the logs from the ImaCor App. This bundle is then sent to the ImaCor Cloud where they can be retrieved by ImaCor Support staff. The log files contain diagnostic information.

If the log files grow too large, you may want to delete them to save space on your smart device. To delete the log files, go to the Settings menu.

Accessories 4

To order these additional accessories, go to https://imacorinc.com/contact/contact-us/#support-tab.

- ImaCor Stand: A roll stand with a basket.
  - ➢ assembly (CIDN 50-02-00040)
  - ➢ package (CIDN 99-03-00012)

- Cooling Fan (Clarius 50-02-00077): Attaching this fan to the ImaCor Zura ImaCor Handheld Scanner allows for longer scanning time.
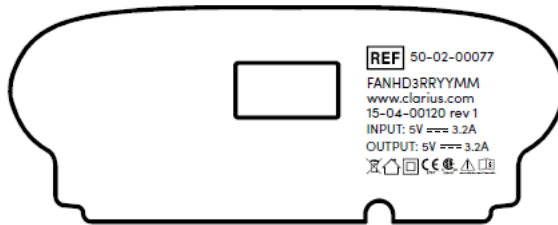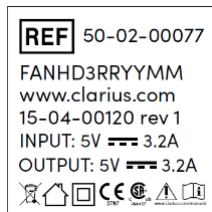
Cooling Fan

The Cooling Fan attaches to the built-in heatsink of the ImaCor Zura Handheld Scanner. Use the ImaCor Fan to extend scanning time.

Fans are designed differently for different scanners. Use only fans that match your scanner type.

▼To attach the Fan:

1. Align the top of the fan with the top of the scanner.
   Make sure the fan's logo is facing towards you. Press the top of the fan onto the top of the scanner until the fan snaps into place.
   When the scanner reaches a temperature of 35°C (95°F), the fan automatically activates.

▼To remove the Fan:
1. Pull on the latch located on either side of the fan. This loosens the fan from the scanner.
2. Lift the fan off the scanner.

Clean and disinfect the Fan after each use. For cleaning instructions, see *Cleaning the Fan*. For disinfecting instructions, see *Disinfecting the Fan.*

Cleaning & Disinfecting 5

It is important to clean and disinfect the ImaCor Zura Handheld Scanner immediately after use. This chapter will guide you through the cleaning and disinfecting process.

The classification of cleaning and disinfecting you select will depend on the type of tissue that gets into contact with the ImaCor Zura Handheld Scanner. To find the correct classification, refer to Spaulding Classification.

When cleaning and disinfecting:

- Follow the procedures in the order they are described in this guide, without skipping steps.
- Use only solutions approved by ImaCor Mobile Health. Other solutions may be incompatible with the system and could damage the scanner.
- Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations.
- Check expiry dates, concentration, and efficacy of the chemicals used.
- Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.
- Due to repeated use and cleaning, the cleanliness and sterility of the hardware deteriorates over its service life (five years for the scanner and fan).
- Using incompatible solutions to clean the scanner may damage its surface.
- The scanner and its parts (including accessories) may not withstand the cleaning or disinfecting processes (including repetitive process) specified in this manual, and may damage or deteriorate its safety provisions.
- Cleaning or disinfecting the scanner using IPA (isopropyl alcohol) may damage it.
- The ImaCor Zura Handheld Scanner is not intended to come in direct contact with the patient. The patient contact probe (ClariTEE) is single use and provided Sterile in a sterile pouch.

Cleaning

Cleaning the ImaCor Zura Handheld Scanner

Before cleaning, visually inspect the scanner to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use and contact ImaCor support.

Cleaning the scanner requires that you select the proper cleaning level. Before you begin, determine the level of cleaning by referring to *Spaulding Classification*. Once you have determined the level, have the cleaning solution ready and follow the procedure below.

▼To clean the ImaCor Zura Handheld Scanner:

1. Make sure the ImaCor Zura Handheld Scanner is turned off.
2. Remove the fan from the scanner.
   It is important that you clean the two pieces separately.
3. To clean the scanner, dampen a soft cloth using a compatible cleaner. Alternatively, use a pre-moistened disinfectant wipe.

   For a list of compatible cleaners, see *Cleaners & Disinfectants*.

4. Start at the top of the scanner and wipe toward the scan/probe interface. Be sure to remove any gels or particulate matter.
5. Clean the heat sink (the grooves along the body of the scanner) using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution (or use a pre-moistened wipe) across the slot. Move the cloth back and forth from one side of the heat sink to the other.
6. Dispose the cloth and the instrument used to insert the cloth.
7. Verify that all gel, particulate matter, and bodily fluids have been removed.
8. Repeat with new cleaning material if necessary.

When you are done, keep the two parts separate. You will be disinfecting them individually. For disinfecting instructions, see *Disinfecting the ImaCor Zura Handheld Scanner*.

Cleaning the Cooling Fan

▼ To clean the Cooling Fan:

1. Remove the fan from the ImaCor Zura Handheld Scanner.
2. Wipe down all surfaces using a premoistened disinfectant wipe.
   For a list of compatible cleaners, see *Cleaners & Disinfectants*.
3. Repeat with new cleaning material if necessary.
4. Air-dry the fan.

Alternatively, towel-dry with a clean, non-linting cloth.
When you are done, keep the two parts separate. You will be disinfecting them individually.

Disinfecting

Disinfecting the ImaCor Zura Handheld Scanner

Before you begin disinfecting, make sure you have cleaned the scanner (see *Cleaning*).

Disinfecting requires that you choose the proper disinfecting level. Determine the necessary disinfection level by referring to *Spaulding Classification*. Once you have determined the required disinfecting level, have the disinfectant ready and follow one of the appropriate procedures below. Note that different levels of disinfection require different steps, not just different solutions.

Intermediate Disinfection

Refer to *Cleaners & Disinfectants* for a list of disinfectants recommended for intermediate disinfection of the scanner.

If the scanner gets into contact with broken skin, mucosal membranes, or blood, it is classified as semi-critical, and you must perform a high-level disinfection. See *High-Level Disinfection* for steps.

1. Disinfect the scanner by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a pre-moistened disinfectant wipe.
2. Disinfect the heat sink (the grooves along the body of the scanner) using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a disinfectant (or use a pre-

moistened wipe) across the slot. Move the cloth back and forth from one side of the slot to the other.

3. Remove the disinfecting wipe from the slot.
4. Air-dry. Alternatively, towel-dry with a clean, non-linting cloth.
5. Examine the scanner for damage, such as cracks or splitting where fluid can enter.
   If damage is evident, do not use the scanner and contact ImaCor Mobile Health.

High-Level Disinfection

Refer to *Cleaners & Disinfectants* for a list of disinfectants recommended for high- level disinfection of the scanner.

1. Mix the disinfectant solution by following the disinfectant label instructions for solution strength and disinfectant contact duration.
2. Disinfect the Scanner by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a pre-moistened disinfectant wipe
3. Air-dry. Alternatively, towel-dry with a clean, non-linting cloth.
4. Examine the parts for damage, such as cracks or splitting where fluid can enter. If damage is evident, discontinue use of the scanner, and contact ImaCor.

Disinfecting the Cooling Fan

Before you begin disinfecting, make sure you have cleaned the fan (see *cleaning the ImaCor Fan)*.

Class	Use	Method
Non-Critical Class Disinfection	Touches intact skin	Cleaning followed by intermediate
Semi-Critical Class Membranes and Non-Intact Skin	Touches mucous	Cleaning followed by High-Level Disinfection (HLD)

Because the fan cannot be submerged in liquid, you must always use intermediate-level disinfection. Refer to *Cleaners & Disinfectants* for a list of disinfectants recommended for intermediate disinfection of the fan.

1. Make sure that the fan is detached from the scanner.
2. Disinfect the fan by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a pre-moistened disinfectant wipe.
3. Air-dry. Alternatively, towel-dry with a clean, non-linting cloth.
4. Examine the fan for damage, such as cracks or splitting. If damage is evident, do not use the fan and contact ImaCor Support.

Spaulding Classification

The level of cleaning and disinfecting required for your ImaCor Zura Handheld Scanner is based on the Spaulding classification system. Following the correct classification will help reduce cross- contamination and infection.

Each Spaulding classification mandates a specific level of cleaning and disinfecting of the equipment before it can be used in the next exam. Determine the Spaulding classification based on your scanner's usage.

Safety 6

This chapter provides instructions on the product's safe usage and offers information on safety guidelines. Pay special attention to warnings and cautions, and follow them before, during, and after operating the product:

- Warnings indicate information vital to the safety of you, the operator, and the patient.
- Cautions highlight possible damages to the product that may void your warranty or service contract, or lose patient or system data.

About Diagnostic Ultrasounds

Interactions with Matter

When using diagnostic ultrasound, the sound waves are directed towards an area of interest, which then interacts with any matter along its path. This interaction is determined by the characteristics of the ultrasound wave, as well as the physical properties of the matter through which the sound wave passes. Diagnostic ultrasound frequencies range from 2 MHz to 15 MHz.

Studies

Exposure-effect studies have been performed at intensity levels much higher than those in diagnostic ultrasound practice, which revealed two mechanisms known to alter biological systems:

- Thermal mechanism: Heating of soft tissue and bone.
- Non-thermal mechanism: Mechanical phenomena, such as cavitation.
  These mechanisms are discussed later.

Benefits & Risks

Ultrasound is widely used because it provides many clinical benefits to the patient and has an outstanding safety record. In more than three decades of use, there has been no known long- term negative side-effects associated to this technology.

More questions of safety are being discussed because more applications are being discovered, and the industry is producing technically sophisticated scanners that provide more diagnostic information. Dialogue among the medical community, manufacturers, and the FDA has resulted in a standard that allows higher outputs for greater diagnostic capability.

Ultrasound benefits:

- Multiple diagnostic uses
- Immediate results with high-quality information
- Replacement or complimentary or used with other procedures
- Cost-effectiveness
- Portability
- Patient acceptance
- Safety record

Ultrasound risks:

The potential for adverse bio-effects caused by heating or cavitation.

"… the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present." -- AIUM

Safety Topics

Use the ImaCor Zura Handheld Scanner only if you have read and understood all the information in this section. Operating the system without proper safety awareness could lead to fatal or serious personal injury.

This section covers general safety information. Safety information applicable to specific tasks are noted in the procedure. The ImaCor Zura Handheld Scanner is intended for use by a trained medical professional, or by the direction and supervision of a licensed physician qualified to instruct its usage.

"Diagnostic ultrasound is recognized as a safe, effective, and highly flexible imaging modality capable of providing clinically relevant information about most parts of the body in a rapid and cost-effective fashion." -- WHO (World Health Organization)

Product Safety

ImaCor is responsible for the safety of the scanners. The safety of your smart device is your responsibility. Always follow the safety guidelines provided with your smart device before, during, and after use.

Product Warnings

The following actions may cause fatal or other serious injury:

- Using the system without adequate training on its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, do not use it.
- Attempting to remove, modify, override, or frustrate any safety provisions on the system.
- Using the system with any product that ImaCor does not recognize as compatible with the system, or operate the product for unintended purposes

- If the system, scanner, appears to be malfunctioning, stop use immediately and contact ImaCor.
- To avoid exposing you and the patient to safety hazards, if any part of the system is known or suspected to be defective or incorrectly adjusted, do not use the system until it is repaired.
- To avoid compromising the effectiveness of the system and the safety of the patient, the user, and others, do not operate the system with patients unless you have an adequate understanding of its capabilities and functions.
- Configure your smart device in compliance with your institution's security policies. For example, notifications and alerts from third-party applications may interfere with an exam.

- Selecting an incorrect or hazardous imaging mode may deliver excessive acoustic energy to the patient during the exam.
- Heat dissipates through the heatsink and the metal portion of the scanner enclosure.
  Do not touch these parts or apply them against the patient for longer than one minute.
  Hold the scanner using the rubber handle.

Product Compatibility

The ImaCor Zura Handheld Scanner comes with a charging dock for the scanner. Components and accessories of models are not compatible with non- models and are not interchangeable. Do not use your system in combination with other products or components not provided by ImaCor, unless ImaCor expressly recognizes those other products or components as compatible.

Changes and additions to the system can be made only by ImaCor or by third parties expressly authorized by ImaCor to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices. System changes and additions that are made without the appropriate training or by using unapproved spare parts may carry risks of system damage and personal injury.

Thermal Safety

⚠ The ZHH enclosure can reach temperatures of 48 degrees C. This is considered safe for the patient contact materials of medical devices (of which the ZHH enclosure is not). At approximately this temperature a thermal cut-off is activated shutting down the scanner output. However to reduce the risk of thermal harm as far as possible it is recommended to take these additional steps.

Keep the scanner away from the patient so that it is not in contact. One way of accomplishing this is by using the bed rail clip to mount the scanner.
Use the accessory cooling fan to reduce ZHH enclosure temperature below 48 degrees C and increase scanning time.

Cleaning Safety

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is particularly important for pieces of peripheral equipment because they contain electromechanical parts. If exposed to constant and excessive sunlight and humidity, the scanner will suffer in both performance and reliability.

It is your responsibility to clean and disinfect your scanner in accordance with the cleaning and disinfecting instructions in this manual. For instructions on cleaning and disinfecting the ImaCor Zura Handheld Scanner, refer to *Cleaning*.

Cleaners & Disinfectants

- Use only cleaners and disinfectants recommended by ImaCor. Avoid acetone, Methyl ethyl ketone (MEK), paint thinner, or other strong solvents and abrasive cleaners.
- Always use protective eyewear and gloves when cleaning and disinfecting equipment.
- Disinfectants are recommended based on their chemical compatibility (not their biological effectiveness) with product materials. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- If a pre-mixed solution is used, check the expiry date.
- The level of disinfection required for a scanner is determined by the type of tissue it contacts. Ensure the disinfectant is appropriate for the scanner and its application.
  Also, read the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- Clean the scanner after each use. This is an essential step before disinfection.

- When disinfecting the scanner, ensure that the solution's strength and duration of contact are appropriate for disinfection.
- Selecting a non-recommended solution, using an incorrect solution strength, or immersing a scanner deeper or longer than recommended can damage the scanner and will void warranty.
- Follow the manufacturer's recommendations and instructions when using cleaners and disinfectants.

Minimizing the Effects of Residual Disinfectant

If you use an OPA-based disinfectant, residual solution may remain on your scanners if you do not carefully follow the manufacturer's instructions.

To minimize the effects from residual OPA, or any other disinfectant, ImaCor recommends the following:

- Follow the disinfectant manufacturer's instructions very carefully.
- Limit the time that scanners are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer.

Factors Affecting Disinfectant Efficacy
The following factors will affect the efficacy of a disinfectant solution:

- Number and location of microorganisms
- Innate resistance of microorganisms
- Concentration and potency of disinfectants
- Physical and chemical factors
- Organic and inorganic matter
- Duration of exposure
- Biofilms

Scanner Care

Lint, dust, and light (including sunlight) have no effect on the scanner's basic safety and essential performance.

- Avoid sharp objects, such as scissors, scalpels, or cauterizing knives, from touching the scanners.
- Avoid bumping the scanner on hard surfaces.
- Avoid surgeon's brushes when cleaning scanners. Even soft brushes can damage scanners.
- Before storing scanners, make sure they are completely dry. If it is necessary to dry the scanner lens or acoustic window, apply a soft cloth to the area, and blot rather than wipe.
- Use only liquid solutions to disinfect scanners.

The following actions may damage your scanner:
- Cleaning or disinfecting a scanner using methods unapproved by ImaCor.

Clinical Safety

Defibrillator Safety

If you are using the ImaCor Zura Handheld Scanner and defibrillation is required, use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Before defibrillation, remove any part of the system that is in contact with the patient.

Biological Safety

⚠ • Do not use a system that exhibits erratic or inconsistent image updates. This indicates a hardware failure that must be corrected before continuing use.
• Follow the ALARA (as low as reasonably achievable) principle.
• Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle. For information on ALARA, see *ALARA Principle*.

Latex

The ImaCor Zura Handheld Scanners or dedicated probe (ClariTEE) do not contain natural rubber latex. The following are FDA recommendations on latex awareness:

• When taking general histories of patients, include questions about latex sensitivity.
  For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rashes, or wheezing after wearing latex gloves or inflating a toy balloon may be useful. For patients with positive histories, flag their charts.
• If latex sensitivity is suspected, consider wearing a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)
• Whenever latex gets in contact with mucous membranes, be alert to the possibility of an allergic reaction.
• If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
• Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

Bio effects

Thermal

Thermal bio-effects refers to heat generated whenever ultrasound energy is absorbed. The amount of heat produced depends on the ultrasound's intensity, exposure time, and the tissue's absorption characteristics.

Tissue absorbs ultrasound energy to varying degrees depending on the tissue's absorption characteristics. Absorption characteristics are quantified by the absorption coefficient:

• Fluids: Their absorption coefficient is almost zero. Fluids such as amniotic fluid, blood, and urine absorb very little ultrasonic energy. That means the ultrasound goes through the fluid with very little decrease. And there's little temperature elevation in the fluid.

- Bone: Its absorption coefficient is very high. Dense bone absorbs the energy very quickly and causes the temperature to rise rapidly. Adult bone absorbs nearly all acoustic energy impinging on it. Fetal bone absorption coefficients vary greatly depending on the degree of ossification.

- Soft tissue: Soft tissue varies in density depending on the organ, but the density does not vary much within an organ. We call it soft tissue to distinguish it from hard tissue such as bone. Also, the tissue density within a particular organ is not always the same. But for our purposes, we assume that attenuation is uniform throughout the organ. We call this a homogeneous soft tissue model.

Attenuation is caused by:

- Absorption: Energy converted to heat.
- Scattering: Redirection of ultrasound.

Mechanical (Non-Thermal)

Mechanical bio-effects are threshold phenomena, such as cavitation, that occur when the output exceeds a certain level. This threshold varies by tissue type.

Cavitation is the interaction of ultrasound with gas bubbles, causing rapid and potentially large changes in bubble size. These bubbles originate within materials at locations termed nucleation sites, the exact nature and source of which are not well understood in a complex medium such as tissue or blood. The change in bubble size may increase temperature and pressure within the bubble, causing mechanical stress on surrounding tissues, precipitate fluid micro-jet formation, and generate free radicals. Gas-containing structures, such as lungs, are most susceptible to the effects of acoustic cavitation; however, such higher frequency ultrasounds do not provide sufficient time for significant bubble growth; therefore, cavitation is unlikely to occur under these circumstances. Factors that produce cavitation include pressure(compressional, rare-factional), frequency, focused/unfocused beam, pulsed/ continuous waves, degree of standing waves, boundaries, and the nature and state of material.

Scientific evidence suggests that the onset of transient cavitation is a threshold phenomenon. There is a combination of rare-factional pressure values, ultrasonic frequency, and cavitation nuclei that are required for inertial cavitation to occur. If inertial cavitation is a threshold phenomenon, then exposure to pressure levels below the threshold will never induce such events, regardless of the length of exposure.

There are two categories of cavitation:

- Stable: Stable cavitation is associated with vibrating gas bodies. In stable cavitation, a gas body oscillates or pulsates continuously around its equilibrium size. As the oscillations become established, the liquid-like medium around the gas body begins to flow or stream; we call this microstreaming. Microstreaming has been shown to produce stress sufficient to disrupt cell membranes.

- Inertial: During inertial (transient) cavitation, pre-existing bubbles or cavitation nuclei expand because of the rare-factional pressure of the ultrasonic field and then collapse in a violent implosion. The whole process takes place in a time span on the order of microseconds. The implosion can produce huge local temperature rises that may be thousands of degrees Celsius and pressures equal to hundreds of atmospheres, all in a volume of less than $1 \ \mu m^3$. The implosion can damage cells and tissue, ultimately leading to cell death. In addition, bubble implosion can generate highly reactive chemical species. All these effects, microstreaming, implosion, and generation of reactive chemicals, occur in a very small space around the bubble, affecting only a few cells.

Exposure of the lung can produce small, localized hemorrhages under some conditions in laboratory animals. These lesions resolve naturally and are without lasting effects in normal subjects, but their possible significance in compromised individuals has not been studied.

ALARA Principle

The guiding principle for the use of diagnostic ultrasound is defined by the ALARA (as low as reasonably achievable) principle. The threshold for diagnostic ultrasound bio-effects is undetermined, and the definition of "reasonable" is left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as reasonably achievable as you obtain diagnostic images, you can minimize ultrasonic bio-effects.

Output display indices are designed to provide more quality information, to help guide the sonographers using ultrasound technology, in applying the ALARA principle. Some variables that affect the way output display indices can be used to implement the ALARA principle:

- index values
- body size
- location of the bone relative to the focal point
- attenuation in the body
- ultrasound exposure time (an especially useful variable, as it is controlled by the user)

Applying ALARA

The system's imaging mode you select depends on the information needed. Understanding the nature of the imaging mode used, the scanner frequency, system setup values, scanning techniques, exposure time, system and scanner capabilities, and operator experience allows the sonographer to apply the ALARA principle with informed judgment and meet the definition of the ALARA principle.

The amount of acoustic output is up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to scanner surface temperatures. The objective is to limit patient exposure to the lowest index reading for the shortest amount of time achieving acceptable diagnostic results.

A high index reading does not necessarily indicate the occurrence of a bio-effect; however, it must be taken seriously. It is your responsibility to make every effort to reduce the possible effects of a high index reading by limiting exposure time.

System controls (direct, indirect, and receiver) can be used to adjust the image quality and limit the acoustic intensity and are related to the techniques that an operator could use to implement ALARA.

Using System Controls to Implement ALARA

Direct Controls

The system has no direct control for output, therefore the sonographer must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not

exceeded for all imaging modes, the ImaCor Zura Handheld Scanner is designed to automatically adjust output.

The system does not exceed a spatial peak temporal average intensity (I_{SPTA}) of 720 mW/cm^2 for all imaging modes. The system follows the Output Display Standard (IEC 60601-2-37) and falls within the Track 3 acoustic output limits.

Indirect Controls

Controls affecting imaging mode, freeze, and depth indirectly affect output. The imaging mode determines the nature of the ultrasound beam. Because freeze stops all ultrasound output but keeps the last image displayed on screen, you can use it to limit exposure time while studying an image and maintaining scanner position during a scan. Some controls, such as depth, show a rough correspondence with output, and may be used as a general means for indirectly reducing MI or TI.

Controls indirectly affecting intensity:

- Pulse repetition frequency: The higher the PRF, the more output pulses per second, increasing the temporal-average intensity.
- Focusing depth: Setting the scanner focus at the proper depth improves the resolution of that structure, without the need to increase intensity to see it better.
- Pulse length: Generally, the longer the pulse, the greater the temporal-average intensity value, which both raises the temperature in the tissue and slightly increases the likelihood for cavitation.
- Dwell time: Scanned modes, such as B-Mode imaging, distribute the energy over a large volume. In scanned modes (equipment keeps the beam stationary), the highest temperature is frequently at the surface where the ultrasound enters the body.

Receiver Controls

The receiver controls have no output effect. The following receiver controls affect images only:

- Gain or time-gain control (TGC)
- Dynamic range
- Post-processing User Responsibility

The various operating modes and output levels mean that more responsibility must be assumed by the users. This is a point that is very often neglected: many assume that if an instrument is "FDA cleared," then there is no risk of bio-effects. This notion is inaccurate because changing the mode of operation or manipulating controls has the potential to cause major changes in output and hence in exposure. In other words, there is a shift in responsibility for patient safety from the manufacturer to the user.

To obtain good diagnostic information, a high return signal amplitude is needed. This can be attained either by higher output, like talking louder, or by higher receiver gain, like a hearing aid with a volume control. You must attain the best diagnostic information with minimal exposure to the patient. The threshold at which ultrasound energy causes bio-effects for each individual patient is unknown, therefore, you must get the most information at the lowest possible output level by adjusting the output intensity of the equipment.

As a general guideline:

1. Select the correct scanner frequency and application.
2. Start with a low output level.
3. Optimize the image by using focus, receiver gain, and other imaging controls.
4. If the image is still not diagnostically useful, increase output.

Additional considerations:

- Minimize scan time by performing only medically required ones.

- Use diagnostic ultrasounds efficiently and effectively, as all other medical tools.
- Compromising the exam's quality by rushing the exam could result in a poor exam, which could require follow-up exams, which then adds exposure time.
- Select the appropriate TI and MI range for the task at hand.
- Note that output is affected by frequency, focus, pulse length, and dwell time.

Output Display

The output display provides the user with an indication of the potential for bio effects that might be caused by the ultrasound energy being emitted. With this information, users can better control the diagnostic ultrasound equipment and examination to ensure that needed diagnostic information is obtained with a minimum of risk to the patient.

Display Standards

The system output display consists of the following exposure indices to indicate the potential thermal and mechanical effects:

- TI: This is continuously displayed over the range of 0.0 to maximum output, based on the scanner and application, in increments of 0.1, and consists of the following indices:
    - thermal index for soft tissue (TIS)
    - thermal index for bone (TIB)
    - thermal index for cranial bone (TIC)

    Keep output display indices to a minimum. Select a TI based on:

    - Approximate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface (for example, a cranial exam).
    - Mitigating factors that might create artificially high or low TI readings: Location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the TI displays?
    - Scanned modes versus un-scanned modes of operation that affect the TI: For scanned modes (such as B-Mode), heating tends to be near the surface. For un-scanned modes (such as M-Mode or Doppler-type modes), the potential for heating tends to be deeper in the focal zone.
    - MI: This is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

TI Display

The TI indicates any conditions that may lead to temperature increase on the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. TI informs you of a potential rise in temperature of body tissue, by estimating temperature increases in those body tissue with specific properties. The actual temperature increase is influenced by factors such as tissue type, vascularity, and mode of operation. Use the TI as a guide for implementing the ALARA principle.

You can choose to display one of the following types of TI indices:

- TIS: Indicates potential for heating within soft homogeneous tissue.
- TIB: Indicates potential for heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid. For example, at or near second- or third-trimester fetal bone.
- TIC: Indicates potential for heating of bone at or near the surface. For example, cranial bone.

MI Display

The higher the MI value, the greater the likelihood of mechanical bio-effects occurring. The potential for mechanical bio-effects varies by peak rare-factional pressure and ultrasound frequency. The MI accounts

for these two factors. There is no specific MI value that indicates the occurrence of a mechanical effect. Use the MI as a guide for implementing the ALARA principle.

When interpreting the MI, remember that it is intended to estimate the potential for mechanical bio-effects. The higher the index reading, the greater the potential. However, neither MI = 1 nor any other level indicates that a bio-effect is occurring. We should not be alarmed by the reading, but we should use it to implement the ALARA principle.

Display Accuracy

The MI and TI have a precision of 0.1 unit on the system.

Estimates of the MI and TI display accuracies is shown in the Acoustic Output Table. The following factors are considered when estimating the accuracy of the displayed values:

- Hardware Variations
  Variability among scanners and systems is a result of piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations.

- Estimation Algorithm Accuracy
  Differences in system pulser voltage control and efficiencies are also contributor to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages.

- Measurement Variability
  Inaccuracies in laboratory measurements can be caused by hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

Controls Affecting Display Indices

Use system controls to change the TI and MI values. Power Controls

Two real-time output values are on the display: TI and MI. These change as the system responds to power-control adjustments. TI and/or MI values will be displayed whenever the Index values exceeds 0.4 (dimensionless).

B-Mode Controls

- Focus:
  When the focal depth is near the natural focus of the scanner, the MI may be higher.

Other Control Effects

- B-Mode Depth:
  An increase in two-dimensional depth will automatically decrease the B-Mode frame rate, thereby decreasing the TI. The system may also automatically choose a deeper two-dimensional focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.

- Application:
  Acoustic output defaults are set when you select an application. Factory defaults vary with scanner, application, and mode. Defaults have been chosen below the FDA limits for intended use.

- Imaging Mode Controls:
  When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

- Scanner:
  Each scanner type has unique specifications for contact area, beam shape, and center frequency. Selecting a scanner initializes its default settings, which varies by scanner, application, and selected mode. These defaults are set below the FDA limits for intended use.

Example of reducing output:
Imagine we are getting ready to do a liver scan. The first thing we need to do is select the appropriate scanner frequency. Next, we adjust the output intensity (or power) transmit setting. We check to make sure that it is positioned at the lowest possible setting to produce an image. We adjust the focus to the area of interest and then increase the receiver gain to produce a uniform representation of the tissue. If we can obtain a good image by increasing the gain, we can lower the output and continue to increase the gain. Only after making these adjustments and if tissue penetration or echo amplitude levels are inadequate should we increase the output to the next higher level.

Acoustics
The scanner is the most important factor in image quality. Optimal imaging cannot be obtained without the correct scanner. The system is optimized for use based on your scanner selection.

The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the scanner is shut off immediately, preventing overheating of the scanner surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

A temperature elevation of less than 1.5°C (2.7°F) is considered harmless to human tissue (including embryo or fetus). Temperatures in excess of this may cause harm, depending on the length of time maintained. A temperature elevation of 4°C (7.2°F), maintained for five minutes or more, is potentially hazardous to a fetus or embryo.

Acoustic Artifacts
An acoustic artifact is information, present or absent in an image, which does not properly indicate the structure or flow being imaged. Examples of acoustic artifacts that hinder proper interpretation:

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, or ring down.
- Missing objects due to poor resolution.
- Incorrect object brightness due to shadowing or enhancement.
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes, speed error, or range ambiguity.
- Incorrect object size due to poor resolution, refraction, or speed error.
- Incorrect object shape due to poor resolution, refraction, or speed error.

Acoustic Output & Measurement
The acoustic output for this system has been measured and calculated in accordance with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (Revision 3, AIUM, NEMA, 2004),

the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (Revision 2, AIUM, NEMA, 2004), and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Scanners."

In Situ, Derated, & Water Value Intensities

All intensity parameters are measured in water. Because water absorbs very little acoustic energy, these water measurements represent a worst-case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, in situ, has been estimated by using the following formula:

In situ = Water [e-(0.23alf)] Where:

Variable	Value
In situ	In situ intensity value
Water	Water value intensity
e	2.7183
a	Attenuation factor
Tissue	A(dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
L	Skin line to measurement depth (cm)
f	Center frequency of the scanner/system/mode combination (MHz)

Because this value is not the true in situ intensity, the term "derated" is used.

Mathematical derating of water-based measurements using the 0.3 dB/cm MHz coefficient may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/ cm MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions. Therefore, the reported maximum water and derated values may not be related by the in situ (derated) formula. For example: A multi-zone array scanner that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models & Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels in situ from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm MHz through out the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the in situ acoustic exposure when the path between the scanner and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cmMHz.

When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned trans-abdominally, this model may underestimate the in situ acoustical exposure. The amount of underestimation depends on each specific situation. For example, when the beam path is longer than 3 cm and the propagation medium is predominantly fluid (conditions that may exist during transabdominal OB scans), a more accurate value for the derating term is 0.1 dB/ cm MHz.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate in situ acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/cm MHz may be used during all trimesters.

The maximum acoustic output levels of diagnostic ultrasound scanners extend over a broad range of values:

- A survey of 1990-equipment models yielded MI values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment. Maximum MI values are similar for real-time B-Mode, M-mode, and PW Doppler.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C (1.8°F and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively.
  The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a "fixed-path" tissue model and are for scanners having I_{spta} (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bio-effects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28, 1993).

Acoustic Measurement Precision & Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

Measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

ACOUSTIC MEASUREMENT PRECISION

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rare factional pressure measured in megapascals (MPa)	Pr: 5.4%
Wo is the ultrasonic power in milliwatts (mW)	6.2%
f_c is the center frequency in megahertz (MHz) (NEMA UD-2 definition)	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2)	PII.3: 3.2%
Pr is the underated peak rare factional pressure measured in megapascals (MPa)	Pr: ±11.3%
Wo is the ultrasonic power in milliwatts (mW)	±10%

Fire & Electrical Safety

Fire Safety

Always have fire extinguishers available for both electrical and non-electrical fires. In the event of an electrical or chemical fire, use only extinguishers that are specifically labeled for such purposes. Using water or other liquids can cause fatal or other serious personal injury. To reduce the risk of electrical shock, try isolating the product, if safe to do so.

Using electrical products in an environment for which they were not designed to be used can lead to fire or explosion. Apply, observe, and enforce appropriate fire regulations for the type of medical area being used.

Electrical Safety

- To reduce electrical shock hazards, inspect the scanner face and housing before use. Discontinue use if the housing is damaged, or if the face is cracked, chipped, or torn.
- All patient-contact scanners not specifically indicated as defibrillation-proof must be removed from the patient before applying high-voltage defibrillation pulse.
- High-frequency electrical signals from an ultrasound can interfere with pacemaker operation. Be alert to this unlikely but potential hazard and stop using the system if you notice it is interfering with a pacemaker.
- Connecting accessories not supplied or approved by ImaCor could result in electrical shock.
- Electrosurgical units (ESUs) and other scanners intentionally introduce RF electromagnetic fields (currents) into patients. Because imaging ultrasound frequencies are within the RF range, ultrasound scanner circuits are susceptible to RF interference.
- A burn hazard may result from a surgical equipment with a defect in the high-frequency surgical neutral electrode connection. Do not use scanners with high-frequency surgical equipment.
- Using accessories other than those specified for use with the ImaCor Zura Handheld Scanner may result in increased emissions of the system.

Electromagnetic Safety

The ImaCor Zura Handheld Scanner uses wireless technology to communicate with your smart device. Wireless communication can be affected by severe weather conditions and radio frequency interference. Such environments will not cause the safety of the ImaCor Zura Handheld Scanner to deteriorate, but the captured image may show signs of unwanted noise and/or artifacts. The technology used in the ImaCor Zura Handheld Scanner is designed to minimize these affects but may not eliminate them entirely.

Electromagnetic Compatibility

The ImaCor Zura Handheld Scanner has been manufactured with existing electromagnetic compatibility requirements and have been tested and found to comply with electromagnetic compatibility standards to provide reasonable protection against harmful interference in a typical medical installation.

Use of this system in the presence of an electromagnetic field can cause momentarily degraded image quality. If this occurs frequently, review the environment surrounding the system and identify possible sources of radiated emissions. These emissions could be caused by other electrical equipment from:

- The same or adjacent room.
- Portable or mobile RF communications equipment (such as cellular phones and pagers).
- Radio, TV, or microwave transmission equipment located nearby.

The scanner's built-in radio operates in the 2.4 GHz and 5 GHz bands, and supports:

- Bluetooth 4.1 as well as CSA2.
- IEEE Std 802.11a, 802.11b/g, and IEEE Std 802.11n data rates with 20 MHz or 40 MHz SISO and 20 MHz MIMO.

⚠

- Using parts and accessories not recommended by ImaCor may result in increased emissions or decreased immunity of the system. Use only accessories and peripherals recommended by ImaCor.
- EMC precautions for medical equipment must be followed according to the EMC information provided in that system's accompanying documents.
- The ImaCor Zura Handheld Scanner's AC power supply cable is limited to 1.5 m (4.9 feet).

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), or static shock, results from the flow of an electrical charge from a person or object of a higher charge to that of a lower charge. ESD is most prevalent in low- humidity environments, often caused by heating or air-conditioning.

To reduce ESD:

- Use anti-static spray on carpets, linoleum, and mats. Or use a ground wire connection between the system and the patient table or bed.

Electromagnetic Emissions

Ensure that the ImaCor Zura Handheld Scanner is used only in those operating environments indicated in the following table. Operating the system in an environment that does not meet these conditions may degrade system performance.

DECLARATION OF ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Electromagnetic Environment
RF emissions, CISPR 11	Group 1	The system 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 A	The system is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker	Complies emissions, IEC 61000-3-3	

Electromagnetic Immunity

Immunity Test Level	IEC 60601-1-2 Test Level	Compliance
ESD @ mode transmitting and charge mode* EN/IEC 61000-4-2	+/-2kV, +/-4kV, +/-8kV Contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air	+/-2kV, +/-4kV, +/-8kV contact +/-2kV, +/-4kV, +/-8kV, +/-15kV Air
Radiated, radio frequency electromagnetic field immunity - transmitting and charge mode (1 kHz 80% AM for ETSI 2 Hz modulation 2 Hz modulation 301 489-1 and -17 only for IEC 60601-1-2)* EN/IEC 61000-4-3	3 V/M 2 Hz modulation	3 V/M 2 Hz modulation
Electrical fast transient @ charge mode IEC 61000-4-4	+/-0.5kV, +/-1.0kV	+/-0.5kV, +/-1.0kV
Immunity to surge @ charge mode IEC 61000-4-5	0.5kV, 1.0kV, 2.0kV common mode 0.5kV, 1.0kV differential mode	0.5kV, 1.0kV, 2.0kV common mode 0.5kV, 1.0kV differential mode
Conducted, radio-frequency electromagnetic immunity test @ charge mode (2 Hz modulation) mode (2 Hz modulation) IEC 61000-4-6	3 VRMS-6VRMS in ISM bands 2 Hz modulation	3 VRMS-6VRMS in ISM bands 2 Hz modulation
Power frequency magnetic field immunity test charge mode IEC 61000-4-8	30A/M	30A/M
Voltage dips/ interruptions @ charge mode IEC 61000-4-11	0% for 0.5 cycle @ 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0% for 1 cycle @ 0º 70% for 25/30 cycles (50/60 Hz) @ 0º 0% for 250/300 cycles @ 0º	0% for 0.5 cycle @ 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0% for 1 cycle @ 0º 70% for 25/30 cycles (50/60 Hz) @ 0º 0% for 250/300 cycles @ 0º

*For ETSI 301 489-1 and ETSI 301 489-17: Tested in transmit mode only, no idle mode exists for this product.

Electromagnetic Interference

The way an electromagnetic interference (EMI) from other equipment affects the ImaCor Zura Handheld Scanner depends on the system's operation mode, image control settings, and the type and level of electromagnetic phenomena. Electromagnetic phenomena may be intermittent, making it difficult to identify the source.

If you experience EMI, use caution if you continue using the system, or consider relocating your system.

The following table describes typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference because it depends on many parameters of the transmitting equipment, for example, the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the imaging system's performance and become invisible on the image. If the diagnostic results are suspicious, confirm the diagnosis using other methods.

Imaging Mode	ESD[a]	RF[b]	Power Line[c]
B-Mode	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging scanners, white radial bands or flashes in the center lines of the image. For linear imaging scanners, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, or diagonal lines near the center of the image.
	a. Electrostatic discharge caused by discharging of electric charge buildup on insulated surfaces or persons. b. Radio frequency energy from RF transmitting equipment such as portable phones, hand-held radios, wireless devices, commercial radio and TV stations, and soon. c. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning		

Separation Distance

Recommended Separation Distance

The following table shows recommended separation distances for the system to be kept away from any RF-transmitting equipment. To reduce the risk of interference, when using portable and mobile RF communications equipment, follow the recommended separation distance (calculated from the equation applicable to the frequency of the transmitter). Ensure that field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, are less than the compliance level in each frequency range as noted in the table.

Field strength is difficult to predict theoretically with accuracy if they come from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast. To assess the electromagnetic environment from fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, observe the system to verify normal operation. If abnormal performance is observed, apply additional measures, such as reorienting or relocating the system.

At 80 MHz and 800 MHz, the higher frequency range applies.

The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The table here provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

RECOMMENDED SEPARATION DISTANCES BY TRANSMITTER FREQUENCY

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
0.01	0.35 m (13.8 in)	0.12 m (4.7 in)	0.23 m (9.1 in)
0.1	1.1 m (3.6 ft)	0.38 m (15 in)	0.73 m (28.7 in)
1	3.5 m (11.5 ft)	1.2 m (3.9 ft)	2.3 m (7.5 ft)
10	11 m (36.1 ft)	3.8 m (12.5 ft)	7.3 m (24 ft)
100	35 m (114.8 ft)	12 m (39.4 ft)	23 m (75.5 ft)

For example, if a portable transmitter has a maximum radiated power of 1 W and an operating frequency of 156 MHz, it can be operated at distances greater than 1.2 m (3.9 ft) from the system. Similarly, a 0.01 W Bluetooth wireless LAN smart device operating at 2.4 GHz should be placed no closer than 0.24 m (9.5 in) from any part of the system.

Avoiding Electromagnetic Interference

An ultrasound system is designed to receive signals at radio frequencies, making them susceptible to interference generated by RF energy sources. Other examples of interference are medical equipment, information technology products, and radio and television transmission towers.

To locate the source, find out if the problem resides with the system or the scanning environment:

- Is the interference intermittent or constant?
- Does the interference show up only with one scanner or with several scanners?
- Do two different scanners operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a scanner or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the scanner or printer can result in reduced electromagnetic interference.

If you find the interference's source, go to https://imacorinc.com/contact/contact-us and contact ImaCor Support.

References

7

Compliance Statement

ImaCor products comply with international and national standards and laws. Users are responsible for ensuring that the chosen smart device and scanner are compliant with the law in the jurisdiction where the product is used. ImaCor meets all regulatory standards listed in this chapter.

The ImaCor Zura Handheld Scanner

Product Classification

Classification:

- Device with scanners (internally powered ME equipment):
- Health Canada: Class III
- US FDA: Class II
- EU: Class IIa
- Scanner:
- Type BF applied parts,
- IPX7
- Charger: IP00
- Ordinary Equipment/Continuous Operation
- Non-AP/APG
- ClariTEE Probe:
- IPX7 excluding connector
- Type BF applied parts

Product Serial Number

ImaCor has assigned a unique serial number on each scanner to track quality control.

ImaCor Zura Handheld Scanners uses the format NNNHDXXYYMMAZZZZ. We will use the serial number L7HD011812A0004 as an example to explain how to interpret this.

NNN
Scanner type. In our example, this is "L7".

XX
Two-digit assembly revision number. In our example, this is "01".

YY
Two-digit year of manufacture. In our example, this is "18" meaning the year 2018.

MM

Two-digit month of manufacture. In our example, this is "12" meaning the month of December.

A

Alphabetical counter, from A to Z. In our example, this is "A".

ZZZZ

Four-digit numerical counter. In our example, this is "0004" meaning the fourth scanner manufactured in this series.

System Specifications

The ImaCor Zura Handheld Scanner conforms to the following specifications:

- Gray shades: 256 in B-Mode
- Scan lines: Up to 1,024 scan lines
- Pressure, humidity, and temperature limits: These limits apply only to the ImaCor Zura Handheld Scanner, not to the smart device. It is your responsibility to select an ImaCor- compatible smart device that meets the needs of your clinical environment.

	Operating Limits	Storage Limits	Transient Operating Conditions
Pressure	620 hPa to 1060 hPa	n/a	n/a
Humidity	15% to 95%	0% to 95%	15% to 95%.
Temperature	0°C (32°F) to 35°C (95°F)	-20°C (-4°F) to 50°C (122°F)	-20°C (-4°F) to 35°C (95°F)

a. The conditions under which the scanner can operate, for at least 20 minutes, immediately after being removed from an environment of 20°C (60°F).

To reach an operating temperature of 20°C (68°F), the ImaCor Zura Handheld Scanner requires approximately 30 minutes to:

- Warm up from a storage temperature of-20°C (-4°F).
- Cool down from a storage temperature of 50°C (122°F).

Maximum scanner surface temperatures are:

- 48°C at an maximum ambient temperature of 35°C

For information on storage temperatures see *Storing Scanners*.

Scanner Specifications

ImaCor Zura Handheld Scanner

Scanner	Clinical Usage	Probe	Frequency Range
ImaCor Zura Scanner	Cardiac, TEE (adult,)	ClariTEE	5-7 MHz

Standards

Biocompatibility

Not Applicable - The scanner is not in patient contact - Refer to ClariTEE probe IFU.

Chemical

REACH 02006R1907-20181017 - REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

The ImaCor Zura Handheld Scanner meets the minimum requirements for compliance with the European Union's Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU and its amendments.

Electrical Safety

Reference No.	Year	Title
IEC 61157	2013	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
IEC 62133	2012	Secondary cells and batteries containing alkaline or other non-acid electrolyte - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ST/SG/AC.10/11/Rev.5	2009 U N38.3	Transport of Dangerous Goods.

Labeling

ISO 60417:2014 - Graphical symbols for use on equipment. See *Symbols Glossary*.

Quality

Performance

Reference No.	Year	Title
AIUM/NEMA UD 2-2004	2009	NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. (Radiology)
AIUM/NEMA UD 3-2004	2009	NEMA Standards Publication UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
ANSI/AAMI ES60601-1	2005/(R)2012 A1:2012 C1:2009(R)201 2 A2:2010(R)201 2	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
ANSI/AAMI/IEC 62304	2006	Medical device software – Software life cycle processes.
CAN/CSA-C22.2 No. 60601-1- 6:11	2011	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (Adopted IEC 60601-1- 6:2010, third edition, 2010-01)
CAN/CSAC22.2 No. 60601-1:14	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
IEC 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
GB 9706.1	2007	Medical electrical equipment - Part 1: General requirements for safety
GB 9706.9	2008	Medical electrical equipment - Part 1: General requirements for safety
GB 10152	2009	B-Mode ultrasonic diagnostic equipment
GB/T 14710	2009	Environmental requirement and test methods for medical electrical equipment.
GB/T 16846	2008	Requirements for the declaration of acoustic output of medical diagnostic ultrasonic equipment
GB/T 191	2008	Packaging and pictorial marking for handling of goods
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Capability - Requirements and tests
IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-12	2014	Medical electrical equipment - Part 1-12: Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended For Use in the Emergency Medical Services Environment
IEC 60601-2-37+ AMDI	2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
YY 0076	1992	Classification of metal parts coating technology
YY 0505	2012	Medical electrical equipment - Part 1-2: General requirements for safety Collateral standards: EMC requirements and tests
YY 0767	2009	Ultrasound color flow imaging system
YY/T 1420	2016	Environmental requirement and test methods for medical ultrasonic equipment

Security & Privacy

IEC TR 80002-3:2014 - Medical device software - Part 3: Process reference model of medical device software life cycle processes.

Wireless

U.S.

- FCC 47CFR PT 15.247

Cleaners & Disinfectants

Cleaner & Disinfectant Usage

The following table lists the cleaners and disinfectants compatible with your ImaCor Zura Handheld Scanner and accessories. The products listed in the following table are chemically compatible and have been tested for efficacy.

Product	Qualified Use[a]	ImaCor- Zura Handheld Scanner	Fan	Scanner Dock Charger
Accel® PREVention™ Wipes	LLD, ILD	✓	✓	✓
Accel® TB Wipes	LLD, ILD	✓	✓	✓
CaviWipes	LLD, ILD	✓	✓	✓
CIDEX® OPA	HLD	✓	✓	
McKesson OPA/ 28 High-Level Disinfectant Solution	HLD	✓	✓	
Sani-Cloth® HB Germicidal Disposable Wipe	LLD, ILD	✓	✓	✓
Sani-Cloth® Plus Germicidal Disposable Cloth	LLD, ILD	✓	✓	✓
Tristel Trio Wipes System	HLD[b]	✓	✓	
Virox™ AHP® 5 RTU Wipes	LLD, ILD	✓	✓	✓

You may also use products not specifically listed in the compatibility table but with similar active ingredients, as indicated in this list, and marketed for medical use.

Because of the large number of available cleaners and disinfectants, it is impossible to have an all-inclusive list. If you are unsure of the suitability of a particular product, contact ImaCor for more information.

Cleaner & Disinfectant Details

Solution	Origin[a]	Usage	Active Ingredients
Accel® PREVention™ Wipes	CA	Wipe	Hydrogen Peroxide
Accel® TB Wipes	CA	Wipe	Hydrogen Peroxide
CaviWipes	US	Wipe	Alcohol, Quaternary Ammonia
CIDEX® OPA	US	Soak	Ortho-phthalaldehyde
McKesson OPA/28 High-Level Disinfectant Solution	US	Soak	Ortho-phthalaldehyde
Sani-Cloth® HB Germicidal Disposable Wipe	US	Wipe	Alcohol, Quaternary Ammonia
Sani-Cloth® Plus Germicidal Disposable Cloth	US	Wipe	Alcohol, Quaternary Ammonia
Tristel Trio Wipes System	UK	Pre-clean wipe, Sporicidal wipe, Rinse wipe	Enzymes, Chlorine Dioxide
Virox™ AHP® 5 RTU Wipes Peroxide	CA	Wipe	Hydrogen

a. AU = Australia, CA = Canada, US = United States, UK = United Kingdom

Sterilization Systems

The following sterilization systems are approved for use with the ImaCor Zura Handheld Scanner and its batteries:

Sterilization System	For general reprocessing instructions, including proper cleaning, and drying, and packaging information prior to reprocessing any medical device using this system, refer to:	For specific sterilization efficacy questions, contact:
STERRAD® 100S (Short Cycle)	STERRAD® System User's Guides	STERRAD® Advanced Sterilization Products 1-888-STERRAD

Glossary of Terms

For ultrasound terms not included in this glossary, refer to Recommended Ultrasound Terminology, Third Edition, published by AIUM.

Acoustic Outputs

A_{aprt}

Area of the active aperture measured in cm^2.

$d_{eq}(z)$

Equivalent beam diameter as a function of axial distance z, and is equal to $[(4/\pi)(W_o/I_{TA}(z))]^{0.5}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z in centimeters.

$d_{eq}@PII_{max}$

Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.

depth

Refers to the depth of the display. A constant speed of sound of 1538.5 meters/second is assumed in the calculation of echo position in the image.

Dim. of A_{aprt}

Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.

f_c

The center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.

in situ

In the natural or original position.

FL

Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters. $I_{pa.3@MI max}$ Derated pulse average intensity at the maximum MI in units of W/cm^2.

$I_{SPTA.3}$

Derated spatial peak, temporal average intensity in units of $milliwatts/cm^2$.

$I_{SPTA.3z1}$

Derated spatial-peak temporal-average intensity at axial distance z_1 in units of $milliwatts/cm^2$.

$I_{TA.3}(z_1)$

The derated spatial-peak temporal-average intensity at axial distance in units of $milliwatts/cm^2$.

MI (mechanical index)

An indication of the likelihood of mechanical bio effects occurring. The higher the MI, the greater the likelihood of mechanical bio effects.

PD

Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.

$P_{r.3}$

Derated peak rare factional pressure associated with the transmit pattern giving rise to the value reported under MI in units of megapascals.

$p_r@PII_{max}$

Peak rare factional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in units of megapascals.

PRF

Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.

TI (thermal index)

The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C (1.8°F) under defined assumptions.

TI type

Applicable thermal index for the scanner, imaging mode, and exam type.

TI value

Thermal index value for the scanner, imaging mode, and exam type.

TIB (bone thermal index)

A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. TIB non-scan is the bone thermal index in the non-auto scanning mode.

TIC (cranial bone thermal index)

A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.

TIS (soft tissue thermal index)

A thermal index related to soft tissues.

TIS^{scan}

The soft tissue thermal index in an auto-scanning mode.

$TIS^{non-scan}$

The soft tissue thermal index in the non auto-scanning mode.

$W_3(z_1)$

Derated ultrasonic power at axial distance z1 in units of milliwatts.

Wo

Ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one-centimeter window in units of milliwatts.

z_1

Axial distance corresponding to the location of maximum $[\min(W_3(z), I_{TA.3}(z) \times 1 \text{ cm}^2)]$, where $z \geq$ zbp in centimeters.

Zbp

$1.69\ A_{aprt}$ in centimeters

zsp

For MI, the axial distance at which pr.3 is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b.3}$) in centimeters.

z@PII.3max

The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).

Acoustic Artifacts

Acoustic saturation

Occurs when received signals reach a system's high-amplitude limit. At that point the system becomes unable to distinguish or display signal intensities. At the point of saturation, increased input will not increase output.

Aliasing

Occurs when the detected Doppler frequency exceeds the Nyquist limit. It is characterized on the spectral display by the Doppler peaks going off the display, top or bottom, and then continuing on the other side of the baseline. On the Color display an immediate change in color from one Nyquist limit to the other is seen.

Comet tail

A form of reverberation artifact produced when two or more strong reflectors are close together and have a high propagation speed. In this case, sound does not travel directly to a reflector and back to the scanner, and a strong linear echo appears at the reflector and extends deeper than the reflector.

Enhancement

An increased relative amplitude of echoes caused by an intervening structure of low attenuation.

Focal enhancement (focal banding)

The increased intensity in the focal region that appears as a brightening of the echoes on the display.

Mirror imaging artifact

Most commonly seen around the diaphragm. This artifact results from sound reflecting off another reflector and back.

Mirroring

The appearance of artifacts on a spectral display when there is improper separation of forward and reverse signal processing channels. Consequently, strong signals from one channel mirror into the other.

Multi-path positioning and refraction

Artifacts that describe the situation in which the paths to and from a reflector are different. The longer the sound takes traveling to or from a reflector, the greater the axial error in reflector positioning (increased range). Refraction and multi-path positioning errors are normally relatively small and contribute to general degradation of the image rather than to gross errors in object location.

Propagation speed errors

Occur when the assumed value for propagation speed by the ultrasound system is incorrect. If the actual speed is greater than that assumed, the calculated distance to a reflector is too small, and the reflector will be displayed too far from the scanner. Speed error can cause a structure to be displayed with incorrect size and shape.

Range ambiguity

Can occur when reflections are received after the next pulse is transmitted. In ultrasound imaging, it is assumed that for each pulse produced, all reflections are received before the next pulse is sent out. The ultrasound system calculates the distance to a reflector from the echo arrival time assuming that all echoes were generated by the last emitted pulse. The maximum depth to be imaged unambiguously by the system determines its maximum pulse repetition frequency.

Reverberation

The continuing reception of a particular signal because of reverberation rather than reflection from a particular acoustic interface. This phenomenon is analogous to the effect created by mirrors positioned on opposite walls when an object, a head for instance, is placed between the mirrors. The image of the head is reflected back and forth infinitely between the two mirrors, creating the optical illusion of multiple heads. Reverberations are easily identifiable because they are equally spaced on the display.

Scattering

Is the diffuse, low-amplitude sound waves that occur when acoustic energy reflects off tissue interfaces smaller than a wavelength. In diagnostic ultrasound, Doppler signals come primarily from acoustic energy back-scattered from red blood cells.

Shadowing

Is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the display. This cloud, or shadow, is useful as a diagnostic clue.

Side lobes (from single-element scanners) and grating lobes (from array scanners)

Cause objects that are not directly in front of the scanner to be displayed incorrectly in lateral position.

Speckle

Appears as tissue texture close to the scanner but does not correspond to the scatterers in the tissue. It is produced by ultrasound wave interference and results in general image degradation.

Spectral broadening

A display phenomenon that occurs when the number of energy-bearing Fourier frequency components increases at any given point in time. Consequently, the spectral display is broadened. Spectral broadening can indicate the disturbed flow caused by a lesion, and therefore it is important diagnostically. However, broadening can also result from interaction between flow and sample volume size, in which case it is an artifact.

Speed of sound artifacts

Occur if the sound propagation path to a reflector is partially through bone, and the speed of sound is greater than in the average soft tissue. Echo position registration artifacts will be produced. Reflectors appear closer to the scanner than their actual distance because of this greater speed of sound, resulting in a shorter echo transit time than for paths not containing bone.

Acoustic Output Table

ImaCor Zura Handheld Scanner

ACOUSTIC OUTPUT REPORTING TABLE

Transducer Model: ClariTEE   **Operating Mode:** B-Mode

Index Label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1$ cm²	TIS Non-scan $A_{aprt} > 1$ cm²	TIB Non-scan	TIC
Maximum index value			1.20	0.792	-	-	-	#
Associated acoustic parameter	$p_{r.3}$	(MPa)	2.69					
	W_0	(mW)		33.0	-		-	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.00				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	5.04	5.04	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.00	-	-	-	#
		Y (cm)		1.30	-	-	-	#
Other Information	PD	(μsec)	0.368					
	PRF	(Hz)	3840					
	p_r @ PII_{max}	(MPa)	3.20					
	d_{eq} @ PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		0.106	-	-		
		Fl_y (cm)		0.862	-	-		
	$I_{PA.3}$ @ MI_{max}	(W/cm²)	318					
Operating Control Conditions								

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

(a)   Intended use does not include cephalic so TIC is not computed
\#   No data reported.

Revision History

User Manual Revision	Revision Date	Description
A		First official release.

Headquarters:
ImaCor, Inc.
50 Jericho Turnpike, Suite 105, Jericho, NY 11753
516.393.0970