User Manual

Exo Iris®

Made for
iPhone | iPad

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Caution U.S. federal law restricts this device to sale by or on the order of a physician.

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Introduction

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Introduction

Chapter 1

About this user manual

This user manual is intended to assist in the safe and effective operation of the Exo Iris® device and mobile Exo Iris app. It is important that all users review and understand all the instructions in this user manual before operating the device, paying careful attention to the warnings and cautions throughout this manual.

Document conventions

The user manual follows these conventions:

- A **warning** describes precautions necessary to prevent injury or loss of life.
- A **caution** describes precautions necessary to protect the products.
- A **note** provides supplemental information.
- Numbered and lettered steps must be performed in a specific order.
- Bulleted lists present information in list format but do not imply a sequence.
- Single-step procedures begin with ❖.

Getting help

In addition to the information in this user guide, you can contact us at Exo Support.

Getting Started

Getting Started

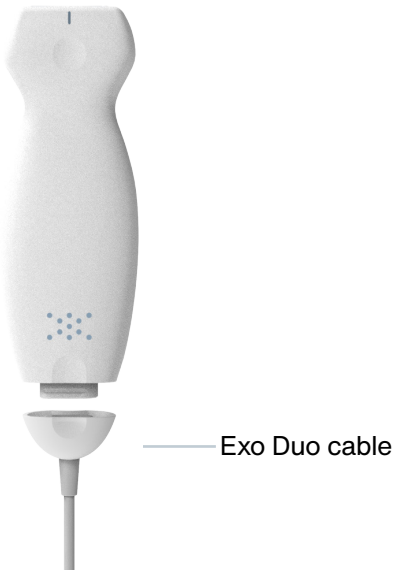
Chapter 2

This chapter provides an overview of Exo Iris device. It includes information about features, components included with the system, requirements for downloading, installing, and using Exo Iris app, and an overview of the user interface.

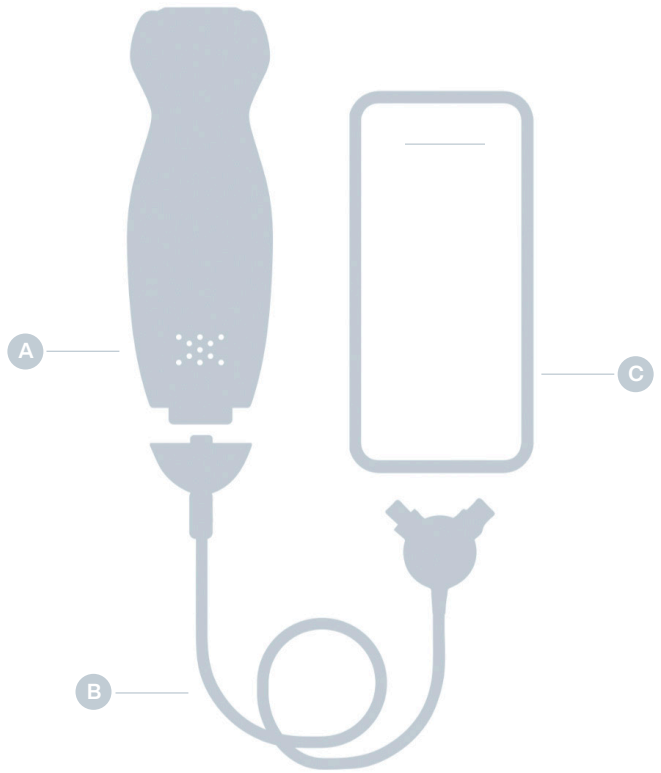
Exo Iris device components

Exo Iris device is a handheld general-purpose diagnostic ultrasound imaging device. A functional imaging system requires the following components:

- Exo Iris device
- Exo Duo Cable
- Wireless charger with USB-C Cable
- Compatible "Apple mobile device requirements"
- Exo Iris app, downloaded and installed
- USB-C Wall Power Plug



The Apple mobile device is not included with the purchase of Exo Iris device.



A Exo Iris device

B Exo Duo cable

C Apple mobile device

What's in the box

- Exo Iris device
- Exo Duo Cable
- Wireless Charger
- USB-C Cable for wireless charger
- USB-C Power plug
- Aquasonic® 100 Ultrasound Transmission Gel
- Quick start card

Note Do not place the Exo Iris device on the wireless charger when it is plugged into the Apple mobile device.

Use Exo Iris device in accordance with all safety procedures and operating instructions as outlined within this manual, and only for the purposes for which the device was intended.

A Exo Iris device

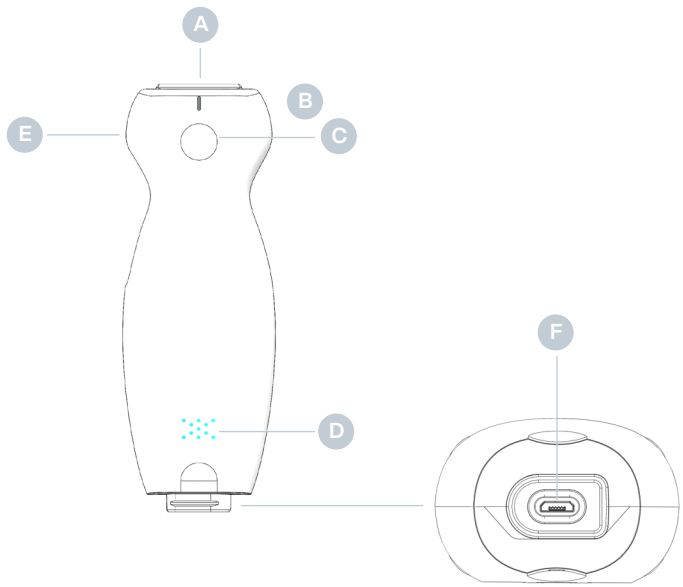
B Midline marker (located on the side of the probe)

C Finger grip

D LED battery indicator

E Orientation feature

F Exo Duo Cable Connector



Warnings

- Exo Iris device is only compatible with the approved cables and chargers listed in this user manual. Do not attempt to plug any unapproved cables or chargers into device.
- Dropping the device may cause damage. Always inspect the device before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions or leaks. To avoid the risk of electrical hazards, do not use the device if there is any sign of damage. If the device is dropped, restart the device to allow a self-check. Do not use the device if the self-check is not successful.

Caution

- An Internet connection is required to authenticate login, start the app, and send images to the Exo Works Archive. Images reside on the Apple mobile device until a connection is obtained. (For detailed instructions on using Exo Works, refer to the Exo Works user manual.)
- When your Apple mobile device battery goes into low power mode, Iris performance may be impacted.

Intended use

Exo Iris

Exo Iris device is a portable diagnostic ultrasound system intended for imaging, measurements, and analysis of anatomical structures and fluid for use by a trained and qualified healthcare professional.

The system is intended for use in environments where ultrasound is performed by healthcare professionals for clinically diagnostic purposes or for training, such as hospital departments, clinics, medical schools, or emergency services.

Caution Exo Iris is intended for use by trained and qualified healthcare professionals capable of interpreting image quality, diagnosis, and clinical utility of the system.

Exo Works

Exo Works is a cloud-based software intended to help clinicians with electronic transfer, documentation, storage, and display of medical ultrasound images.

INTENDED USERS:

Healthcare professionals trained and qualified in the collection and interpretation of ultrasound images (ex. physicians, sonographers, nurses).

INTENDED USERS FOR EXO AI TOOLS:

- **Cardiac AI:** Healthcare professionals trained and qualified to conduct echocardiography ultrasound scans in the current standard of care while acquiring ultrasound images.
- **Lung AI:** Healthcare professionals who are trained and qualified in performing lung ultrasound and routinely perform lung ultrasounds as part of their current practice in a point-of-care environment - namely Emergency Departments (EDs). The device was not designed and tested with use environments representing EMTs and military medics.

INTENDED PATIENT POPULATION:

- **Exo Iris:** Pediatrics and Adult population
- **Cardiac and Lung AI:** Patients 18 years of age and older
- **Bladder AI:** Patients aged 2 years and older.

USE ENVIRONMENT:

The system is intended for use in environments where healthcare is provided by trained healthcare professionals, such as general practitioner's office, emergency medical services, critical care, home use.

Exo Iris Indications for use

Exo Iris device and app are indicated for use by trained and qualified healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging, measurement of anatomical structures and fluids, and other tools for adult and pediatric patients for the following clinical applications:

- Peripheral vessel (including carotid, deep vein thrombosis, and arterial studies)
- Small organ (including thyroid, scrotum, and breast)
- Cardiac
- Lung
- Abdominal
- Urology
- Fetal/obstetric
- Gynecological
- Musculoskeletal (conventional)
- Musculoskeletal (superficial)
- Ophthalmic
- Procedural Guidance

Modes of operation include:

- B-mode
- B-mode + M-mode
- B-mode + Color Doppler
- B-mode + Power Doppler
- B-mode + Pulsed-Wave Doppler

Use Exo Iris device and app in accordance with all safety procedures and operating instructions as outlined within this manual and only for the purposes for which the device was intended.

Contraindications

Exo Iris device and app should not be used for indications other than the ones approved by the applicable governing agency. Exo Iris device and app is not intended for internal use.

General warnings and cautions

Please read this section before using your Exo Iris device. It provides general safety information, warnings, and cautions.

Basic safety/environment

Warnings

- Do not use Exo Iris device in a magnetic field, such as near an MRI.
- Do not use Exo Iris device in the presence of anesthetic gases.
- Do not use in the presence of flammable substances/air mixtures.
- Do not use Exo Iris device in conjunction with electrosurgical units (ESUs) and other devices where RF electromagnetic currents are introduced into patients.
- Choke/strangulation hazard: Keep all components of the device out of the reach of children, pets, and others.
- Use sterile sheath for any procedures where the device may get in contact with breached skin (ex. needle guidance, nerve blocks, etc.).

Cautions

- Federal law restricts this device to sale by or on the order of a physician.
- Exo Iris device is intended for use by trained and qualified healthcare professionals capable of interpreting image quality, diagnosis, and clinical utility of the system.
- For optimal performance, check for and download any software upgrades prior to each use.
- Ignoring the Exo Iris app alerts and messages may result in the system becoming inoperable.
- Follow all security and cybersecurity policies of your institution when using Exo Iris device.
- Your institution is responsible for securing the Apple mobile device that Exo Iris device and app resides on, and ensuring users follow the institution's policies and procedures.
- Do not allow modification or tampering of the system, such as additional components to the wired connection, as they could introduce a cybersecurity risk.
- When using AI, the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures.

Operator safety

Warnings

- Exo Iris device only compatible with the approved Duo Cable listed in this user manual.
- Do not attempt to plug any unapproved cables into Exo Iris device.
- Never attempt to modify the device; this could lead to electrical shock or other hazards.

Cautions

- Do not apply excessive force when scanning.
- Do not override or modify any safety provisions.
- Follow your institution's personal protective equipment (PPE) and infection control procedures (e.g. eye, respiratory, and hand protection) when operating, cleaning, or disinfecting the device.

Ultrasound benefits and risks

Ultrasound is widely used because it provides many clinical benefits to the patient. Ultrasound imaging has been used for over 20 years and has an excellent safety record. In over two decades of use, there has been no known long-term negative side effects associated with this technology.

BENEFITS

- Array of diagnostic uses
- Speed
- Cost-effectiveness
- Non-ionizing
- Portability
- Safety record

RISKS

- Ultrasound waves can slightly heat body tissue. Exo Iris device limits temperature exposure and will not scan at or above 43°C (109.4°F). Should Exo Iris device reach the temperature limit, it will pause scanning capabilities until the device has cooled. We recommend to allow the device to cool down for 30 minutes after use to optimize your scan time.

Before you begin

Connect to a network

Note	The hardware specification for the connection to a Wi-Fi network is in accordance with an 802.11 wireless standard.

Your Apple mobile device must have a network connection to Wi-Fi or a cellular connection to download, install or update the Exo Iris app, transfer data, or authenticate credentials.

Once authentication is complete, network connectivity is not required for scanning.

Before using Exo Iris device for the first time, complete the following steps:

1. Charge the device.
2. Download **Exo Iris app** from the Apple App Store.
3. Sign in to **Exo Iris app**.

Connect Exo Iris to Apple Mobile Device

TO CONNECT THE EXO DUO CABLE

❖ Put the connector in the device, then align the semicircles of the Duo Cable and Iris, and push them together.

TO DISCONNECT THE EXO DUO CABLE

❖ Place your thumb on the finger grip, gently pull the Exo Duo Cable away from the device, then detach the connector.

Charge Exo Iris

Fully charge your new Exo Iris device before scanning for the first time.

Warnings	▪ Do not attempt to replace the battery in the device. Only charge the battery using the chargers specified in this user manual. ▪ If any damage to the cables, remove the device from service, and contact Exo Support. ▪ If the device appears to malfunction, stop using it immediately, and contact Exo Support.

TO CHARGE THE DEVICE FROM THE WALL

1. Attach the charging end of the Exo Duo Cable to the USB-C Power plug.
2. Plug the USB-C Power plug into an electrical outlet, ensuring that the electrical outlet is easily accessible and not blocked by other objects or equipment.
3. When done charging the device, disconnect the USB-C Power plug from the electrical outlet.

TO WIRELESSLY CHARGE THE DEVICE

1. Connect the USB-C cable to the wireless charger.
2. Plug the opposite end of the wireless charger into the USB-C Power plug.
3. Plug the USB-C Power plug into an electrical outlet.
4. Detach the Exo Duo Cable from the Exo Iris device.
5. Place the flat side of Exo Iris device on the wireless charger.

LED lights on the Exo Iris device indicate the charging status.

If the Exo Iris device is...	And the LED light is...	The charge state is...
Connected to an Apple mobile device & in standby mode	White	> 10%
Connected to an Apple mobile device & in standby mode	Red	< 10%
	White	The power state is reported on your Apple mobile device & displays a warning if the power is low
Connected to an Apple mobile device & imaging		
Charging	Green	> 90%
Charging	Amber	> 10% to 90%
Charging	Red	< 10%

Wireless Charger LED light indications:

Charger Turned On	Fast pulse – Blue
Charging	Slow pulse – Blue
Charge Complete	Solid – Blue
Charging Error	Solid – Yellow

Download Exo Iris app

1. Install **Exo Iris app**  from the Apple App Store on your Apple mobile device.
2. When the Welcome page displays, tap **Get started.**
3. Type your email address and tap **Continue**.
4. Check email for Exo welcome letter, which includes a link to set up password.
5. Enter a 6-digit pin to secure your account.
6. Two options are available when accessing Exo Iris app:
   - by Face ID, then tap **Continue**, or
   - by Touch ID (if your iPad supports it), then tap **Continue**.
7. Review and agree to the Exo terms and policies; tap **Continue**.
8. To add an avatar, tap **Edit** and browse to a graphic. To proceed without an avatar, tap **Skip**.

Install updates

Always use the latest Exo Iris app and firmware for imaging. Ignoring mandatory firmware and Exo Iris app updates will disable imaging.

1. Ensure that the Exo Iris and the Apple mobile device are charged to at least 50% before updating the firmware.
2. Connect the imaging cable to Exo Iris and Apple mobile device. The Iris automatically checks for the latest available Exo Iris app and firmware updates.

Caution	For optimal performance, check for updates and download any software upgrades before each use.

Sign in and out of the Exo Iris app

SIGNING IN TO EXO IRIS APP FOR THE FIRST TIME

1. Set up your password using the link provided in the welcome email.
2. Open Exo Iris app on your Apple mobile device.
3. Enter your user name and password.
4. Enter your PIN.

Note

- If password is forgotten, enter registered email and select the password reset on the log-in screen.
- After five unsuccessful password attempts, the account is locked. An email is sent with instructions to unlock the account.

An authorized user shall receive notifications for the following authentication and onboarding events:

- User creation
- Password reset
- Account lock
- User account activation or deactivation

SIGNING OUT OF THE EXO IRIS APP

❖ Tap your user initials or profile picture in the upper right of the screen, and tap **Sign out**; at the prompt, tap **Sign out** again.

Exo Iris Tour

Exo Iris tour provides tool tips on how to use Iris, including how to adjust depth/gain, freeze the image, save clip captures/images and how to enter patient information. Access the Iris tour at anytime from the control panel.

Offline mode

If Exo Iris app is not connected to the internet, the following actions are available in offline mode (to enable offline mode, sign in to the Exo Iris app at least once):

- Scan
- Save images and clips
- Complete worksheet
- Save exam to **Drafts** folder

The following actions are not available in offline mode:

- Profile, About and Support actions.
- Cannot access any completed exams
- Cannot transfer exams to PACS or Exo Archive
- Worklist access
- Cannot Share, Favorite, or Delete exam

Profile

Access your profile page by tapping on the profile picture. To edit picture, tap again. The following options are available:

- Support: How to contact Exo Support and access to user manual
- About: Terms and conditions, privacy policy and the Exo app version
- Settings: Includes Exo Iris, PIN setup, Exo Works Archive, PACS server and modality worklists, exam policy settings
- What's New: New features/improvements in the Software version
- Sign Out

Setting up your Iris

Exo Iris Settings

ABOUT MY IRIS

- Name
- Iris Model
- Serial Number
- Iris Firmware
- UDI
- Subscription
- Log files
  - Debugging Tool to send data to customer support

SETTINGS

The Settings feature enables users to personalize imaging preferences. When a user adjusts settings on one Apple mobile device, these preferences are automatically synced to the cloud. As a result, the user's customized settings are retained and applied whenever they log in from any other Apple mobile device also when doing software upgrade.

- Toggle between TIB and TIS
- Toggle Auto Pause On/OFF
  - Conserves power by automatically pausing imaging when it detects no skin contact.
- Toggle to turn on/off Auto-Optimized Imaging
  - Automatically optimize the scanned anatomy, applies best imaging parameters, and minimizes reverberation artifacts.
- Select the % for the Maximum Occupancy Threshold
  - Alerts when vessel occupancy exceeds the threshold during catheter-to-vessel (CVR) calculation.
- Toggle Auto Freeze On/OFF
  - Enters in freeze mode after 10 seconds of continuous Pulsed Wave Doppler (PWD) imaging.
- Toggle the Probe Orientation Indicator On/OFF
  - When enabled, the probe orientation indicator is on the right side for cardiac exams.

Note Auto-Optimized Imaging is not available on the following presets:

- Ocular
- Lung
- OB1
- OB 2/3
- Thoracentesis

RESET PIN CODE

- Reset Login Pin

Subscription

EXO WORKS ESSENTIAL

- The subscription defaults to Exo Works Essential unless a different Exo Works software license has been purchased.

Exam Destination

EXO WORKS CONFIGURATION

- Exo Works Archive is ON by default
- Archives to the Cloud
- May not be turned off unless an active PACS connection

ADD PACS CONNECTION

PACS settings are accessible and modifiable only by Facility Admins.

- Add a PACS connection, configure your server
- Add a connection name
- DICOM interface

PACS SERVER DETAILS

All the following fields are mandatory:

- AE Title
- Server AE Title
- Server Name
- Port Number

> **Note** Exo Works Archive or a PACS Server must be enabled to transfer exams via Exo Iris device.

ADVANCED SETTINGS

Applies to PACS configuration only.

> **Note** Multiple PACS servers can be configured per device, but only one can be active at a time.

TEST CONNECTION

Confirms that all fields are correct and will confirm the connection is configured correctly.

MODALITY WORKLIST:

- Configure your worklist
- Add a connection name
- The following fields are mandatory:
  - AE Title
  - Server AE Title
  - Server Name
  - Port Number

TEST CONNECTION

Confirms that all fields are correct and will confirm the connection is configured correctly.

Policies

- Deleting exams from Apple mobile device:
- Storage options are set by the user:
- Exams can be stored for 1 week, 2 weeks, or 30 days.
- By default exams are stored for 30 days, then auto deleted.
- Select number of days to automatically delete exams in Drafts and Outbox folders

Logs

The retrieve logs files is a troubleshooting tool to provide additional information on the app error and fault. When contacting customer support, exporting application or DICOM log files may be required. Customer support provides guidance through the export process.

The logs do not contain any PHI information related to the patient or exam on the Iris application.

Imaging with Iris

3

Imaging with Iris

Chapter 3

Performing an Exam

- Plug **Exo Iris** into an Apple mobile device.
- Do not unplug Duo Cable during Iris Initialization.
- From the **Iris Connected** screen there are multiple ways to start an exam.

Recommended commercial ultrasound gels

For optimal transmission of acoustic energy between the patient and the device, an ultrasound transmission gel is required.

The following ultrasound gels are recommended:

- Aquasonic® 100 by Parker
- Aquasonic Clear® by Parker
- Clear Gel Image Singles by Sonotech Inc
- Kendall™ Ultrasound Gel by Covidien
- LiquaSonic Ultrasound Gel by Athena
- SCAN® Ultrasound Gel by Parker
- STERILE Aquasonic® 100 Ultrasound Transmission Gel by Parker
- Civco Sterile Latex Free CIV including the gel pack

Using sterile sheaths

Warnings

- Use market cleared, sterile device sheaths and sterile coupling gel to prevent contamination. Do not apply the device sterile sheath and coupling gel until ready to perform the procedure. After use, remove and discard the single-use sterile sheath, and clean and disinfect the device using an Exo approved disinfecting product.
- Some device sterile sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals.

Caution

After inserting the device into the sterile sheath, inspect the device sterile sheath for holes and tears.

TO INSTALL A DEVICE STERILE SHEATH

1. Place gel inside the sterile sheath. Make sure that the gel is at the end of the sterile sheath.
2. Insert the device into the sterile sheath.
3. Pull the sterile sheath over the device and cable until the sterile sheath is fully extended.
4. Secure the sterile sheath using the bands supplied, if applicable.
5. Check for and eliminate air bubbles between the face of the device and the sterile sheath. Air bubbles may affect the ultrasound image.
6. Inspect the sterile sheath to ensure that there are no holes or tears.

Recommended sterile sheath: Civco Sterile Latex Free CIV including the gel pack

BEGIN A SCAN

- Select an exam type or procedure and start scanning.

> **Note** Please refer to the following link for the correct application of the Aquasonic® 100 Ultrasound Transmission Gel: https://www.parkerlabs.com/products/aquasonic-100-ultrasound-transmission-gel/

> **Note** For procedural guidance, Exo suggest to place the mobile device on a support stand to maintain a stable position and ensure adequate image visualization.

ADD A PATIENT

1. To add a patient, choose from one of the four options below:
   - **To manually add a patient**: Tap Add new patient, add patient information. When creating a new patient there is a minimum of 4 characters required in the MRN. Tap create patient.
   - **To add a patient via barcode scan**: Tap Scan patient barcode, scan the patient's barcode and their information will populate in the MRN field only, confirm patient.
   - **To search for a patient in the Patient List**: Tap search bar, begin typing patient's name or MRN, select patient to add to exam.
   - **To add a patient from worklist**: Search the patient by either MRN, Last name, First Name, Accession# and select a patient from the list (available when the modality worklist is configured).
2. Select an exam type or procedure.
3. Begin scan.

To add a patient from the imaging screen in an ongoing exam

- Tap the **patient**  icon.
- Tap Add new patient or tap a name from the patient list.
- Type the patient information.
- Tap Create patient.

In urgent circumstances, scanning can begin immediately, and patient information can be added later. Patient information must be entered before ending the exam.

> **Note** Patient information can also be added when reviewing an ongoing exam from the Image Gallery.

Discard, pause, and end exam

Tap End, then select one of the following options:

- **Discard** - permanently removes the scan.
- **Pause** - navigates to the exam folder screen.
  Scanning can be resumed by tapping **Resume**, or the exam can be ended by tapping **End**.
- **End exam** - From here there are two options:
  - Save to Drafts, and complete and submit later
  - Complete the exam and submit immediately.

Selecting exam type/procedures

Choose your exam type from the list. Exo Iris app automatically adjusts imaging based on the selected exam.

> **Caution** Select the appropriate exam type or procedure for the anatomy being scanned. The acoustic output levels are set based on the selected exam type or procedure, and anatomical regions require lower acoustic output limits.

> **Warning** To avoid injury to the patient, use only the ocular exam when imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the ocular exam is selected.

TO SELECT A PREDEFINED EXAM OR PROCEDURE

- ❖ Tap the exam type icon.
- ❖ Choose from **Exams** or **Procedures** from the list.
- ❖ Pinning Exams (action similar to iOS devices)
  - Tap edit.
  - To Pin an exam, tap the exam type icon.
  - To remove pin, tap the exam type icon.

Understanding the control panel

Open the control panel by tapping  .

Monitoring battery life and temperature

- Battery life, the probe temperature indicator and TI/MI are displayed on the imaging screen.
- The battery life and the probe temperature indicator are also displayed in the control panel.

> **Note**
>
> - The probe temperature is displayed using four color levels, from coolest to warmest: **Blue**, **White**, **Amber**, and **Red**.
> - When the indicator reaches **Red**, a warning message appears to notify the user that the probe is warming up.

MODES

- **Flow Mode:** Enable Color Doppler and an option to select Power Doppler
- **Motion Mode:** Enable M-mode [Available for vector geometry exam type only]
- **Pulsed-Wave Doppler:** Enable Pulsed-Wave Doppler
- **AI:** Enable AI assist module for Bladder, Cardiac, IVC (Abdomen) and Lung [If licensed for AI]
- **SpotOn™:** Enable the needle visualization enhancement mode

IMAGING FEATURES

- **Mimosa:** Activate the Time Gain Compensation [TGC]
- **Flip Image:** Reverses the image orientation
- **Midline:** Activate the midline guide
- **Tour:** Access to Iris tour and tooltips
- **Hi/Low:** Toggle between high and low contrast
- **Clip timer:** Adjust the prospective clip duration from 1 to 20 seconds
- **Settings:** Access to the Iris configuration
- **ScanTutor:** An AI-powered educational assistant

CHANGING THE FIELD OF VIEW (FOV)

FOV IS ONLY AVAILABLE IN VECTOR EXAM TYPE

FOV allows configuration of the sector width based on the anatomy being viewed.

- A larger FOV is used to visualize an organ in its entirety, such as the bladder. FOV adjustments are available only in B-mode.

TO CHANGE THE FOV

1. While in B-mode, tap the degree number at the bottom of the image.
2. Use your finger to slide the wheel to the desired width; the wheel snaps to 60°, 90°, 120°, or 150°.
3. To close, tap ✕.

ACTIVATING AND DEACTIVATING SPOTON™ NEEDLE VISUALIZATION

SpotOn™ needle visualization enables more accurate guidance of needle procedures at angles up to 45-degrees. Needle entry is supported from either side in the longitudinal orientation.

The following exam types are available with needle visualization:

- MSK
- Breast
- Nerve Block
- Arterial Access
- Testicular
- Central Venous Line
- Periphereal IV

TO ACTIVATE AND DEACTIVATE SPOTON™ NEEDLE VISUALIZATION

- To activate, tap **SpotOn™**
- To deactivate, tap ✕.

CLIP DURATION

Adjust the prospective clip duration from 1 to 20 seconds.

Adjusting gain and depth

TO ADJUST GAIN

❖ Slide your finger horizontally across the image area.

TO ADJUST DEPTH

❖ Slide your finger up and down, across the image area.

TO ADJUST TIME GAIN COMPENSATION (TGC)

- Access TGC by tapping the **Control Panel** icon.
- Tap the **Mimosa** icon.
- Alternatively, swipe from the left edge of the screen to bring up the Mimosa.
- To adjust the TGC curve, slide your finger up and down the TGC on the left side of the screen.
- To return to the default, tap **Reset**.

TO REVERSE THE IMAGE ORIENTATION

❖ Tap the orientation marker.

Magnify Image on B-mode

TO MAGNIFY IMAGE ON B-MODE

❖ To magnify a specific area in B-mode, tap on the **magnify glass** icon. A magnifying glass (loupe) will appear, it can be moved anywhere within the imaging area.

❖ Tap on the **magnify glass** icon to dismiss the loupe.

Imaging Modes

Exo Iris app has five imaging modes:

- B-mode
- B-mode + M-mode
- B-mode + Color Doppler mode
- B-mode + Power Doppler mode
- B-mode + Pulsed-Wave Doppler

Depending on the exam type, the following functions are available:

B-Mode

B-mode is the default imaging mode for Exo Iris. Echoes are displayed in two dimensions by assigning a brightness level based on the echo signal amplitude.

For the eFAST exam type, when Auto-Optimized Imaging is enabled, the system automatically detects specific anatomical structures and optimizes the image quality accordingly, enhancing visualization based on the identified structures.

M-Mode

M-mode (Motion mode) is defined as time motion display of the ultrasound wave along a chosen ultrasound line.

When the Auto-Optimized Imaging is ON, the Motion Line automatically positions itself at the optimal location. For example, in a cardiac apical 4-chamber (A4C) view, the Motion Line will align with the TAPSE (Tricuspid Annular Plane Systolic Excursion). If no relevant anatomy is detected, the Motion Line will default to a centered position.

- When M-mode is turned on, the screen splits to show B-mode and M-mode.
- Depth and gain can be adjusted, similar to B-mode.
- Drag the circle on the Motion line left or right to reposition the line.

TO START AND STOP M-MODE

1. From the imaging screen, tap the **Control Panel** icon on the lower panel, and tap **Motion**.
2. To close M-Mode, tap ✕.

TO MEASURE THE HEART RATE IN M-MODE

MEASUREMENT IS ONLY AVAILABLE IN CARDIAC OB1 AND OB2/3 EXAM TYPE

1. While in the cardiac exam type, tap the **Control Panel** icon and tap **Motion**.
2. Obtain a cardiac tracing, and double tap to freeze the image.
3. Select **Edit** and then select the icon.
4. Select the heart rate measurement.
5. Adjust the calipers to measure one cardiac cycle.

Color Doppler mode

Color Doppler mode is used to visualize blood. In Color Doppler mode, there is an overlay on the image of the blood vessel to represent the speed and direction of blood flow through the vessel. The velocity scale is located on the top right corner of the image.

When Auto-Optimized Imaging is ON, the Color Flow Box will automatically adjust its position, color velocity scale, and steering angle to optimize visualization. For instance, when scanning the carotid artery, the Color Flow Box will be aligned with the vessel. If no relevant anatomy is detected, the Color Flow Box will default to a centered position.

TO START AND STOP COLOR DOPPLER MODE

1. Tap the **Control Panel** icon, and tap **Flow**.
2. To close, tap ✕.

MOVING AND RESIZING THE COLOR BOX

The color box can be moved and resized during imaging. The maximum axial and lateral size of the box may be limited depending on the organ, depth, or other settings.

- To move the color box, drag it to another position.
- To resize the color box, drag the left bottom corner to make it taller and/or wider.
- Steer the color box by dragging the ↔ symbol left or right to optimize the display for the direction of the blood flow. (Available only in Linear imaging)
  - The color scale will invert when the box is steered left.
  - Alternatively, the color box can be steered by tapping on the and selecting the desired steer direction.

INVERTING THE DOPPLER DISPLAY

Inverting changes the displayed direction of the blood flow and reduces the need to reposition the device.

❖ Tap on the INVERT icon and select the invert.

ADJUSTING COLOR DOPPLER GAIN

❖ Tap outside of the color box and slide your finger sideways across the image.

ADJUSTING COLOR SCALE VELOCITY

❖ Tap on MEDIUM icon to adjust the color velocity.

Power Doppler

Power Doppler displays the strength of the Doppler signal in color, rather than the speed and direction information. It is more sensitive than color Doppler and is particularly useful for small vessels and those with low-velocity flow.

TO START AND STOP POWER DOPPLER MODE

1. Tap the **Control Panel** icon and tap **Flow**.
2. Tap **Power**. To close, tap ✕.

MOVING AND RESIZING THE COLOR BOX

The color box can be moved and resized during imaging. The maximum axial and lateral size of the box may be limited depending on the organ, depth, or other settings.

- To move the color box, drag it to another position.
- To resize the color box, drag the left bottom corner to make it taller and/or wider.

ADJUSTING POWER DOPPLER GAIN

❖ Tap outside of the color box and slide your finger sideways across the image.

ADJUSTING COLOR SCALE VELOCITY

❖ Tap on 

icon to adjust the color velocity.

Pulsed-Wave Doppler

Pulsed-Wave Doppler Mode is used to assess velocity in a specific location within a vessel.

When Auto-Optimized Imaging is enabled, the sample volume gate, the angle correction, the velocity, and the baseline will automatically adjust itself to the optimal settings. For example, during a cardiac apical 4-chamber (A4C) scan, the sample volume will be aligned with the mitral valve. If no relevant anatomy is detected, the settings are set to default.

Note

- After 10 seconds of continuous imaging, the strip will automatically enter freeze mode.
- The auto freeze feature can be turned off in the Iris Settings.

TO START PULSED-WAVE DOPPLER

1. Tap the **Control Panel** icon and tap **Doppler**.

TO STOP PULSED-WAVE DOPPLER

2. To close, tap ✕.

Moving the PW placement indicator

The placement indicator can be moved anywhere on the B mode image. The actual gate size is 2 mm for CVL and 6 mm for Cardiac and Abdomen.

❖ Tap and hold on the placement indicator to activate the magnify glass

❖ Drag the magnifying glass to position the gate at the desired location

Adjusting the Spectral Baseline

❖ Tap on the baseline and slide finger up/down on the image.

Adjusting the Angle correct for linear exam type only

❖ Tap the 60° button and swipe up or down to modify the angle correction.

❖ The angle correction adjusts to the nearest angle in increments of ±5 degrees.

Adjusting the Spectral Sweep Speed

❖ Tap on the and select the desired sweep speed.

❖ The default sweep speed is medium.

Adjusting the Steer for linear exam type only

- Tap on the  and select the desired steer direction.
- The default steer for CVL is steer left.

Adjusting the Spectral Gain

- Tap within the viewfinder area and slide finger sideways left/right across the image.

Adjusting the Invert Spectrum

- Tap on the  and select 

.
- The spectrum and velocity scale will invert accordingly.

Adjusting the Velocity scale

- Tap on the  and select the desired scale by tapping 

.
- The velocity scale will automatically update based on your selection.

PULSED-WAVE DOPPLER MEASUREMENTS

Time Interval

- In Freeze Mode - tap Annotate and select  .
- Tap Time Interval and adjust the calipers to measure the delta in seconds.

Velocity Measurement

- In Freeze Mode - tap Annotate and select  .
- Tap PSV/EDV and adjust the calipers to measure the velocity in cm/s.

Image Management

Capturing clips

- Tap the **Shutter** button/**Record** button to start recording a clip.
- To save clip, press **Volume Up** button.

Capturing Images

- Long press the **Shutter** button/**Record** button to save an image.
- To save an image, press the **Volume Down** button.
- Tap the **Shutter** button to stop the clip.

Viewing images/clips

Image(s)/clip(s) can be viewed by expanding an image/clip to full screen or by tapping a thumbnail in the exam gallery.

TO VIEW AN IMAGE OR CLIP

1. Swipe up to open the **Exam** screen.
2. Tap the image or clip to be viewed.

TO DELETE AN IMAGE OR CLIP FROM THE EXAM SCREEN

1. Tap the scan bank to open the **Exam** screen.
2. Tap the image or clip to be deleted, then tap the Trash icon. When prompted, tap **Delete**.

Freeze and unfreeze an image

An image must be frozen to perform measurements or add annotations.

TO FREEZE AND UNFREEZE AN IMAGE

1. While scanning, double tap the screen to freeze.
2. To unfreeze and resume scanning, tap **unpause** or double tap the screen.
3. After freezing an image, the following options are available:
   - To view the retrospective clip, tap the **Play** button.
   - To select an individual frame, **scroll** frame-by-frame.

TO SAVE AN IMAGE OR CLIP

While in freeze mode, image(s) and clip(s) can be saved.

1. After freezing an image, tap **Save**.
2. When prompted, tap **Save image** or **Save clip**.
3. Tap **Close**.

Annotations

Custom annotations can be created and repositioned anywhere within the imaging area.

TO ADD AN ANNOTATION

1. On a frozen image tap **Annotate**.
2. Tap the **Text** icon.
3. Type in the text box, and tap **Return**.
4. Use a finger to drag the annotation to the desired location on the screen.
5. To save the annotation, tap **Close** and then **Save image**.

TO DELETE AN ANNOTATION

1. Tap the annotation to be deleted.
2. Tap ✕ next to the annotation name.

Tags

View and tags are pre-defined labels to add on the image. The views and tags are specific to the exam type selected.

TO ADD A VIEW OR TAGS

1. On a frozen image tap **Annotate.**
2. Tap the  icon.
3. Select the view or tags to add to the image.
4. To save the image, tap **Save** and **Close**.

The view and tags are displayed in a fixed location. Up to two tags and one view may be added to an image.

TO DELETE A VIEW OR TAGS

❖ Tap the red ✕ next to the tag to delete.

Measurements

An image must be frozen to perform measurements. Once the image is saved, measurements cannot be edited.

USING CALIPERS

- Drag caliper to the desired position and release it. Drag caliper to the end point(s) and release it. The on-screen measurement value changes as the caliper moves.

When taking measurements, there are two calipers that can be used to adjust the size of the measurement.

ADDING AND DELETING MEASUREMENTS

A maximum of four linear measurements and one ellipse measurement may be added to an image.

TO ADD A MEASUREMENT

1. Tap the **Freeze** button.
2. Tap **Annotate**.
3. Tap the **Measurements**  icon.
4. Select either the Linear or Ellipsis or an option from the list (predefined based on the exam type).
5. Using the two calipers, adjust the measurement to the desired size. The measurement value displays below the image.
   - Move the measurement by tapping anywhere inside the blue circle or line and drag it with your finger.

- Delete a measurement by tapping the red ✕ next to the measurement value.

6. When finished, do one of the following:
   - To save measurements, tap **Save**, review the measurement summary, and tap **Done**.

> **Note** Measurements can also be accessed by tapping the  icon from live imaging.

OB Measurement

MEASUREMENT AVAILABLE FOR EXAM TYPE OB1 ONLY

- **Crown Rump Length (CRL):**
  - Automatically calculates Gestational Age in weeks/days when performing CRL measurement.

MEASUREMENTS AVAILABLE FOR EXAM TYPES OB1 & OB2/3

- **Biparietal Diameter (BPD)**
- **Femur Length (FL)**
- **Abdomen Circumference (AC)**
- **Head Circumference (HC)**
  - All these measurements will calculate Gestational Age in weeks/days.
- **Estimated Fetal Weight (EFW):**
  - To calculate EFW in grams and pounds, all four measurements (BPD, FL, AC, HC) must be completed and saved.
  - When all 4 measurements are performed and saved, the EFW report is automatically generated as part of the exam.

Catheter-to-vessel ratio (CVR)

The catheter-to-vessel ratio (CVR) represents the percentage of a vessel occupied by a catheter. Select the Peripheral IV procedure to access CVR.

TO MEASURE THE RATIO

1. Tap on the  icon.
2. Adjust the ellipse to match the vessel boundary.
3. Select the catheter units (Gauge or French).
   - The catheter selection changes based on the size of the ellipse.
4. Select the desired catheter size.
5. **Save** the results. The results are saved as part of the patient exam.
6. To calculate the vessel occupancy, CVR uses the following equation:

$$\text{Vessel Occupancy } \% = \left(\frac{\text{Catheter Diameter}}{\text{Vessel Diameter}} \right) \times 100$$

$$\text{where: Vessel Diameter} = \frac{\text{Major Axis Length} + \text{Minor Axis Length}}{2}$$

> **Note** The Infusion Nurses Society (INS) Standards of Practice recommend a catheter-to-vessel ratio (CVR) lower than 45%.

ScanTutor

ScanTutor is an AI-powered educational assistant to help with the probe positioning and anatomy identification.

> **Caution** ScanTutor is for learning purposes only, not for clinical use.

ScanTutor is available for the following exam types:

- Abdomen
- Bladder
- Cardiac
- Deep Vein
- Lung
- eFAST

TO USE SCANTUTOR

1. There are 2 ways to access **ScanTutor**:
   - From the imaging screen, tap the **Control Panel** button on the lower panel, then tap the **ScanTutor** button.
   - After watching the Educational video, tap on the **ScanTutor** option (only available for **Abdomen**, **Bladder**, **Cardiac** and **Lung**)
2. The **ScanTutor** panel will appear. Follow the indication on the screen for probe placement and landmark indicator.

Exo AI

Use of Exo AI constitutes acknowledgment, understanding, and acceptance of the software use conditions.

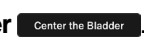
Bladder AI

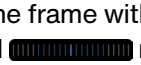
Bladder AI uses machine learning techniques to aid in the quantification of bladder volume from ultrasound images. Bladder AI is intended to be used on images of patients aged two years or older.

Cautions

- The performing provider retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures.
- The performing provider retains the ultimate responsibility for patient management.

TO USE BLADDER AI

1. From the **Exam type** screen, tap the **Bladder**  icon.
2. Place the device to begin imaging the bladder in the sagittal plane.
3. From the imaging screen, tap the **Control Panel**  button on the lower panel, then tap the **AI**  button .
4. A visual indicator will appear on-screen, prompting **Center the Bladder** 

.
5. Once the bladder is horizontally centered, the icon will prompt to begin fanning the device  .
6. Slowly fan the device towards one edge of the bladder until the icon prompts to fan the device in the opposite direction  .
7. Slowly fan the device towards the opposite edge of the bladder. Once the bladder structure is sufficiently captured, calipers and measurements will be displayed.
8. Bladder AI will automatically freeze on the frame with the largest bladder measurement. To select a different frame, use the scrubber control  near the bottom of the screen.
9. Once an appropriate frame is selected, adjust the calipers to measure bladder height and depth (see Working with Calipers).
10. Tap **Save & Return** to return to the imaging screen.
11. To capture another image with Bladder AI, repeat the above process from Step 2.
12. Tap the **Education** button to begin viewing the educational content.

Note

- Educational content is only available when the Apple mobile device is connected to the internet.
- To stop a scan in progress, tap the **End** button in the bottom-right of the screen.

Cardiac AI

Cardiac AI uses machine learning to aid users in the quantification of left ventricular ejection fraction (LVEF) during cardiac scans in the apical 4-chamber (A4C) and parasternal long-axis (PLAX) views, global longitudinal strain (GLS) from the apical 4-chamber (A4C) view, and posterior wall thickness (PWd) and interventricular septum thickness (IVSd) from the parasternal long-axis (PLAX) view.

Cardiac AI has been designed and tested to assist clinicians in analyzing cardiac ultrasound acquired according to ACEP/ASE/ AIUM guidelines shown below:

Grading Scale	Scale Definitions
1	No recognizable structures; no objective data can be gathered
2	Minimally recognizable structures but insufficient for diagnosis
3	Minimal criteria met for diagnosis; recognizable structures but with some technical or other flaws
4	Minimal criteria met for diagnosis; all structures imaged well and diagnosis easily supported
5	Minimal criteria met for diagnosis; all structures imaged with excellent image quality and diagnosis completely supported

To use Cardiac AI on Iris, the feature must first be enabled for your organization. Please contact Exo Support if Cardiac AI is not accessible.

LVEF, GLS and Wall Thickness Calculations:

- For Apical (A4C) images, Cardiac AI follows the Simpson's ejection fraction equation, also known as Method of Disks (MoD), as recommended by the American Society of Echocardiography (ASE) guidelines.

  For global longitudinal strain (GLS) $Strain(\%) = \frac{(ESL-EDL)}{EDL} \times 100$ is used, where EDL is the end-diastolic length and ESL is the end-systolic length of the myocardium contour.
- For PLAX (Parasternal Long Axis) images, the Teichholz Method is used to calculate LVEF. Additionally, Cardiac AI now includes measurements of Posterior wall thickness (PWd) and InterVentricular Septum thickness (IVSd).

Cautions

- The Cardiac AI is for use on patients 18 years and older.
- The performing provider retains the ultimate responsibility for patient management.

LIMITATIONS

- Cardiac AI has not been tested on patients with irregular heartbeat or arrhythmias.

USING CARDIAC AI

1. From the **Exam type** screen, tap the **Cardiac**  icon.
2. Adjust the Iris imaging depth and field-of-view angle (if needed).
3. There are two ways to enable Cardiac AI:

- Tap the Control Panel button on the lower panel, then tap the AI button.
- Tap the screen, then tap the AI button.

4. A Cardiac AI panel will appear. Tap the view dropdown button in this panel to select the view being acquired.
5. Once an apical 4-chamber or PLAX view of the heart is acquired, landmarks will be displayed on-screen.
6. The app automatically captures a scan when images are deemed to be of **minimally diagnostic** quality (quality grade 3 or above) in Quick mode or **Good** quality (quality grade 4 or 5) in Standard mode according to ACEP quality guidelines. Choose **Manual** mode to capture a scan manually.
7. Cardiac AI will automatically display a list of values, including the LVEF (%), Stroke Volume (mL), LVEDV (mL), and LVESV (mL) from the captured image. For images from the PLAX view, additional values for Posterior wall thickness (PWd) and Interventricular Septum thickness (IVSd) will also be displayed. Swipe up and down on these values to view them all.
8. Note that if insufficient frames are captured, results will display as Inconclusive.
9. If sufficient frames are captured, Cardiac AI will indicate the end-diastolic and end-systolic frames on the scrubber control near the bottom of the screen.
10. Use the scrubber control to view the captured frames, including the end-diastolic and end-systolic frames.
11. Tap **Save & Return** to return to the imaging screen.
12. To capture another apical 4-chamber cardiac image with Cardiac AI, repeat the above process from the beginning.
13. Tap the **Education** button to begin viewing the educational content.

Note

- Educational content is only available when the Apple mobile device is connected to the Internet.
- To stop a scan in progress, tap the **End** button in the bottom-right of the screen.

Lung AI

Lung AI uses machine learning techniques to aid users with suggestions for the presence of structures, artifacts, and lung abnormalities, like Consolidation/Atelectasis and Pleural Effusion. It has been designed and tested to assist clinicians in analyzing lung ultrasound images acquired according to ACEP/AIUM guidelines shown below:

Grading Scale	Scale Definitions
1	No recognizable structures or artifacts; no objective data can be gathered
2	Minimally recognizable structures and artifacts but insufficient for diagnosis
3	Minimal criteria met for diagnosis; recognizable structures and artifacts but with some technical or other flaws
4	Minimal criteria met for diagnosis; all structures /artifacts imaged well and diagnosis easily supported
5	Minimal criteria met for diagnosis; all structures /artifacts imaged with excellent image quality and diagnosis completely supported

To use Lung AI on Iris, the feature must first be enabled for your organization. Please contact Exo Support if Lung AI is not accessible.

Cautions

- The Lung AI is for use on patients 18 years and older.
- The performing provider retains the ultimate responsibility for patient management.

USING LUNG AI

1. From the **Exam type** screen, tap the **Lung**  icon.
2. Adjust the Iris imaging depth and field-of-view angle (if needed).
3. There are two ways to enable AI:
   - Tap the Control Panel  button on the lower panel, then tap the AI  button.
   - Tap the screen, then tap the AI  button.
4. A new AI panel will appear. Tap the view dropdown in this panel, to select the view.
5. Once a region 1, 2, or 4 of the lung is acquired, masks will be displayed on-screen.
6. The app automatically captures a scan when images are deemed to be of **minimally diagnostic** quality (quality grade 3 or above) in Quick mode or **Good** quality (quality grade 4 or 5) in Standard mode according to ACEP quality guidelines. Choose **Manual** mode to capture a scan manually.
7. Lung AI will automatically display a list of artifact suggestions (A-lines/B-lines) in all regions and lung abnormalities (Consolidation/Atelectasis and Pleural Effusion) in region 4 (PLAPS point).
8. Note that if insufficient frames are captured, results will display as "--".
9. Use the scrubber control to view the captured frames, including any highlighted frames.
10. Tap Save & Return to return to the imaging screen.

11. To capture another lung image with Lung AI, repeat the above process from the beginning.
12. Tap the **Education** button to begin viewing the educational content.

Note

- Educational content is only available when the Apple mobile device is connected to the Internet.
- To stop a scan in progress, tap the **End** button in the bottom-right of the screen.

IVC AI

IVC AI utilizes machine learning techniques to aid users in the quantification of the collapsibility index of the Inferior Vena Cava (IVC). It has been designed and tested to assist clinicians in analyzing IVC ultrasound acquired according to ACEP/ASE/AIUM guidelines.

To use IVC AI on Iris, the feature must first be enabled for your organization. Please contact Exo Support if IVC AI is not accessible.

To calculate the collapsibility Index, IVC AI uses the following equation, as recommended by the American College of Emergency Physicians (ACEP) practice guidelines.

$$IVCCI = \frac{(Dmax - Dmin)}{Dmax} \times 100$$

Where D_{max} is maximum diameter in expiration and D_{min} is minimum diameter in inspiration.

Cautions

- The IVC AI is for use on patients 18 years and older.
- The performing provider retains the ultimate responsibility for patient management.

USING IVC AI

1. There are two ways to access IVC AI, from the **Exam type** screen:
   - Tap the **Abdomen** icon.
   - Tap the **Cardiac** icon.
2. Adjust the Iris imaging depth and field-of-view angle (if needed).
3. There are two ways to enable IVC AI:
   - Tap the Control Panel button on the lower panel, then tap the AI button.
   - Tap the screen, then tap the AI button.
4. IVC AI panel will appear.
5. Once an image of IVC is acquired, landmarks will be displayed on-screen.
6. The app automatically captures a scan when images are deemed to be of **minimally diagnostic** quality (quality grade 3 or above) in Quick mode or **Good** quality (quality grade 4 or 5) in Standard mode according to ACEP quality guidelines. Choose **Manual** mode to capture a scan manually.

7. IVC AI will automatically display a list of values, including collapsibility index, maximum diameter in expiration and minimum diameter in inspiration. Swipe up and down on these values to view them all.
8. Note that if insufficient frames are captured, results will display as Inconclusive.
9. If sufficient frames are captured, IVC AI will indicate the end-diastolic and end-systolic frames on the scrubber control near the bottom of the screen.
10. Use the scrubber control to view the captured frames.
11. Tap **Save & Return** to return to the imaging screen.
12. To capture another IVC image, repeat the above process from the beginning.

> **Note** To stop a scan in progress, tap the **End** button in the bottom-right of the screen.

Exo Works

Using Exo Works

Exo Works POCUS workflow solution is an annual software subscription that enables users to scan, document, review and store ultrasound exams. Exo Iris defaults to the Exo Works Essential subscription license unless a more advanced license tier is purchased.

Please refer to your Exo Iris Settings for your Subscription status.

HOME SCREEN

The Exo Works home screen can be accessed in a variety of ways:

- Opening the Exo Iris app without the Exo Iris device being connected.
- After pausing, ending or submitting an exam.
- After connecting the Exo Iris device and swiping down the bootup screen.

The Exo Works home screen defaults to the folder structure, which provides access to the following folders that organize exams and serve different purposes.

FOLDERS

- **Drafts:** Contains exams that are in progress but not yet completed.
- **Favorites:** Includes exams marked as favorites for quick access.
- **Completed:** Contains exams that have been successfully completed.
- **Trash:** Holds deleted exams temporarily before permanent removal.
- **Outbox:** Temporarily holds exams that are being processed for transfer to PACS or Exo Works Archive.

The folder structure may change based on Exo Works license. Refer to the Exo Works user manual for additional information.

FOLDER VIEW

When a folder is selected, a summary screen is displayed showing all exams within the folder, starting with the most recent exam. Each exam is displayed as an exam card that includes an image, exam type, date and time, and patient information.

EXAM LAYOUT

When an exam is opened, the interface is structured as follows:

- The images/clips associated with the exam are shown at the top.
- Directly beneath the image(s)/clip(s), the patient data will be displayed. Additional information is displayed when the patient information or the bottom section of the exam is swiped upward:
  - A toggle to change the documentation type to a clinical or educational exam.
  - Worksheet(s) for documentation.
  - Exam destination for storage (PACS/VNA, Exo Works Archive, or both).
  - Checkbox to confirm patient information.
  - Sign off to submit the final exam.

Patient Management

This is only available in the mobile app.

UPDATING PATIENT INFORMATION

Patient information can only be edited on exams in the **Drafts** folder.

1. Select the **Edit** button within the patient information field.
2. This prompts the ability to manually edit the previously entered information.
3. There are three ways to change patient information.
   - Manually enter/edit patient information by filling out the necessary fields
   - When connected to a DICOM Modality Worklist, the Patient Worklist icon can be selected to view existing patients. Selecting the Patient Worklist icon displays a list of existing patients. Patients can be searched by MRN or patient name and then selected. The selected patient details are populated in the patient information section of the exam.
   - Alternatively, the barcode scanner can be used to populate patient information.
4. To save those changes select **Save** Changes.

Exam Documentation

This is only available in the mobile app.

PRE-DEFINED WORKSHEETS

Exo Works has twenty-two pre-defined worksheets available for documentation. Exam types are automatically linked to the pre-defined worksheet that matches the same name.

1. Abdomen
2. Aorta
3. Arterial Access
4. Biliary
5. Bladder
6. Breast
7. Cardiac
8. Central Venous Line
9. Deep Vein
10. eFAST
11. GYN
12. Lung
13. MSK
14. Nerve Block
15. OB1
16. OB2/3
17. Ocular
18. Paracentesis
19. Peripheral IV
20. Renal
21. Testicular
22. Thoracentesis

DOCUMENTING AN EXAM (MOBILE ONLY)

1. If an exam is already opened, swipe up the exam summary sheet to access the worksheet for documentation.
2. If an exam is not opened, go to Drafts folder to select an exam for documentation.
3. Update patient information as needed, see “Add Patient” section.
4. Select clinical or educational.
   - A clinical worksheet is a structured document used in healthcare to record patient data, examination findings, and treatment plans. If clinical, the exam could be sent to a PACS or VNA and/or the Exo Works Archive for storage.
   - An educational worksheet is a learning tool with exercises or questions to reinforce educational concepts. If educational, please only select Exo Works Archive for storage to avoid sending these exams to PACS or VNA.
5. Click the **Add Worksheet** icon to select desired worksheet(s).
6. Answer mandatory fields for Indications and Views.
   - Toggling **All Views** automatically populates all views.
7. Swipe left to move to the next page.
8. Complete the Findings & Interpretation section.
   - Toggling **No remarkable findings** automatically populates the associated normal findings.
9. Swipe left again to review the final report.
   - Swipe right to make edits if needed.
10. Select the **Mark as Complete** button to complete the worksheet.
11. Review exam destination and change by tapping the destination from the exam summary page (PACS/VNA, Exo Works Archive or both).
12. Review and confirm the patient by checking the box.
13. Slide to sign and submit the exam.
14. Depending on the setting, the exam destination is Exo Works Archive or PACS.
    - When Exo Works Archive is on, the exam can be found and accessed in the Completed folder on the Exo Iris mobile app or Exo Works web app.
    - When PACS server is configured, the exam will be sent to PACS.
    - If Exo Works Archive is on and the PACS server is configured, exams will be sent to PACS and also found in the Completed folder the Exo Iris mobile app or Exo Works web app.

Exam and Image Management

SELECT AND REVIEW AN EXAM (MOBILE AND WEB)

To select an exam:

1. Access the Folder View screen.
2. Navigate to any folder and **search** for the desired exam.
3. All exams within the folder can be viewed. Each exam will be displayed as an Exam Card.
4. Tap or click on the Exam Card to open the exam.
5. The following sections are displayed for review:
   - All images/clips within the exam
   - Patient information
   - Worksheet(s) for documentation
   - Exam destination
   - Patient confirmation
   - Exam sign-off

To review images/clips:

1. **Images/clips** will be displayed at the top.
2. Tap or click on a specific image or clip to **view it**.
3. Swipe left to right to review all the images and clips within an exam.
4. If applicable, **measurements** and selected **exam types** will be shown below the image or clip.

GLOBAL AI SEARCH (WEB ONLY)

Exo Works web offers a powerful global search feature to help find information quickly and efficiently. From the main screen, use the search field to locate items such as:

- Patient information such as MRN and patient name
- Exam types
- Folder names
- Exam creation dates
- Worksheet content including keywords, comments, notes, and worksheet titles
- Exam comments and clinician's NPI
- Team members involved in an exam, including non-credentialed users, credentialed users, additional performers, and QA reviewers
- AE Titles

AI MODE (WEB ONLY)

AI Mode allows a search using natural, conversational language instead of predefined filters. Simply type a question or phrase to locate exams, for example:

- "Show all cardiac exams"
- "Find kidney exams showing hydronephrosis"

TO TURN ON AI MODE:

❖ Click the **AI Mode** button in the search bar.

TO TURN OFF AI MODE:

❖ Click the **Exit** button in the same location.

SEARCH, SORT, AND FILTER EXAMS (MOBILE ONLY)

In Exo Works, an exam can be easily searched without navigating to a specific folder. Click on the search icon located at the top and use the following search options:

1. Search by patient information:
   - Patient's MRN
   - Patient Name
   - Or scan the patient MRN with the Barcode reader
2. Sort by order of entry:
   - Newest First
   - Oldest First
3. Filter by timeframe:
   - Last 24 hours
   - Last 7 days
   - Last 30 days
   - Custom Date Range

DELETE AN IMAGE OR EXAM (MOBILE AND WEB)

To delete an image:

1. From Exo Works, images or clips can only be deleted in the Drafts Folder.
2. Access the **Drafts Folder**.
3. Open the exam and tap or click on the **three-dot icon** for the exam to access and select **Select Scans**.
4. Choose the image or clip to delete, more than one may be selected. Selecting all images or clips will delete the entire exam.
5. Tap or click on **Discard** to prompt a confirmation pop-up to confirm the deletion.
6. Once confirmed, the selected image(s) or clip(s) will be permanently removed from the exam.

To delete an exam:

1. Access the desired folder view.
2. There are two ways to delete an exam:
   - Do a long-press on the exam to access and select **Discard**.
   - Tap or click on the **three-dot icon** for the exam to access and select **Discard**.
3. Deleting the exam in the **Drafts Folder** will permanently delete it.
4. Deleting the exam from the **Completed Folder** will move the exam to the Trash Folder. Exams in the **Trash folder** will be recovered within 30 days before it is automatically deleted.

RECOVER A DELETED EXAM (MOBILE AND WEB)

To recover a deleted exam:

1. Access the **Trash Folder**.
2. There are two ways to recover a deleted exam:
   - Do a long-press on the exam to access and select **Recover**.
   - Tap or click on the **three-dot icon** for the exam to access and select **Recover**.

Exporting Exams in Folders

TO EXPORT EXAMS IN FOLDERS (WEB ONLY)

1. On the Exams homepage, select the desired exam folder.
2. Click the **Export CSV** button.
3. Click **OK** to confirm.
4. Click **Exports** below the folder name to view the export list with date and time details.
5. Select the desired export entry and click the icon next to it.
6. The **CSV file** will be downloaded to your local drive.

SHARE AN IMAGE OR EXAM (MOBILE AND WEB)

De-identified images and exams can be securely shared from Exo Works.

To share an image in mobile:

1. **Select** the exam.
2. Select the image or clip and expand into full view.
3. Tap on the share icon .
4. A share window will appear.
5. Select **Continue**, and it will automatically open the IOS share kit where the selected JPEG or MP4 can be shared with any of the installed apps that allow sharing. For example, email, text, social, slack.

To share an image in web:

1. **Select** the exam.
2. Select one or all image(s) or clips(s).
3. Click on the **share** icon  .
4. A share window will appear, select **Continue**. The file size and number of files for export will be displayed.
5. Select the file type to export the image in DICOM, JPG/MP4 format, or both.
6. Select the **Export** button to save to your local Downloads folder on your PC.

To share an exam:

1. **Select** the exam to share.
2. Tap or click on the **three-dot icon** for the exam to access and select **Share Exam**.
3. A share window will appear. Select the **Share Public Link** to copy the secure URL.
4. In mobile, select **Continue**, it will automatically open the IOS share kit where the public link will be visible. The exam can be shared with any of the installed apps that allow sharing. For example, email, text, social, slack.
5. In web, paste the public link in applications installed on PC to share externally.
6. The shared public link will expire after 30 days.

To share all images and clips in mobile:

1. **Select** the exam to share.
2. Tap or click on the **three-dot icon** for the exam to access and select **Share Exam**.
3. A share window will appear. Select the **Share All Images and Clips**.
4. It will automatically open the IOS share kit where the public link will be visible. The exam can be shared with any of the installed apps that allow sharing. For example, email, text, social, slack.

FAVORITE AN EXAM (MOBILE AND WEB)

To favorite an exam:

1. Access the Completed folder view.
2. There are two ways to Favorite an exam:
   - Do a long-press on the exam to access and select **Discard**.
   - Tap or click on the **three-dot icon** for the exam to access and select **Favorite**.
3. The exam will be placed in the Favorites folder.

To unfavorite an exam:

1. Access the Completed folder view.
2. There are two ways to Favorite an exam:
   - Do a long-press on the exam to access and select **Discard**.
   - Tap or click on the **three-dot icon** for the exam to access and select **Unfavorite**.
3. The exam will be removed from the Favorites folder.

Using Exo Admin

Exo Admin is accessible from the web application only.
To access Exo Admin, please go to the top navigation and click on Admin.

Facility Management

Select Manage Facility under Facility Management to access the following information about your account:

- Organization name
- Facility name
- Language
- Country
- Organization ID
- Subscription status

User Management

Roles

Select **Facility Users** under User Management and then select **Roles** to see the types of roles available for your Exo Works license.

Role	Description
Customer Admin	▪ Serves as the primary contact for the organization. ▪ Each organization can have only one Customer Admin. ▪ Responsible for managing the facility or creating Facility Admins to manage the facility on their behalf. ▪ Can create users and assign Facility Admin and Specialty Admin roles. ▪ Do not have access to the Exo Iris mobile app. ▪ Do not have access to the Exams on the Exo Works web app.
Facility Admin	▪ Responsible for setting up and managing the facility's users. ▪ Each organization can have multiple Facility Admins. ▪ Facility Admin information can be updated by the Customer Admin. ▪ Can create users but can only assign the role of Specialty Admin. ▪ Cannot create Customer Admins or other Facility Admins. ▪ Do not have access to the Exo Iris mobile app. ▪ Do not have access to the Exams on the Exo Works web app.

Role	Description
Specialty Admin	▪ An organization can have multiple Specialty Admins. ▪ Responsible for documenting and signing off exams. ▪ Specialty Admin information updates can be managed by both the Facility Admin and the Customer Admin. ▪ Can view user information but cannot create, manage users or assign roles. ▪ Can access the Exo Iris mobile app. ▪ Can access the Exams on the Exo Works web app.

Note Accessing the Exo Iris mobile app requires a clinical role, such as Specialty Admin.

Note

- A user can be assigned multiple roles but only one clinical role.
- If a user has multiple roles, their access and permissions are dictated by the highest-level role assigned to them.

Users

Select **Facility Users** under User Management and then select **Users** to see information on the user(s) within your organization:

- Name
- Email
- Phone
- Role
- Specialty (this defaults to General for an Exo Works Essential License)
- Last time the user logged in
- Subscription status

Note Users can be created by the Customer Admin and Facility Admin via the Admin page in the Exo Works web application.

Adding a new User

1. Select **Users** under User Management and then click **+ Add User**.
2. Fill in the following required fields:
   - First Name
   - Last Name
   - Email
   - Phone number
3. Click **Add User**.
4. After the user is added, click **+Assign Role**.
5. Choose either **Facility Admin** or **Specialty Admin** from the role options.
6. Click **Save.**

> **Note** The number of clinical users that can be added to Exo Works is limited to the number of Iris devices purchased. For further details, please refer to your licensing documentation or contact us at Exo Support.

> **Note**
> - The Customer Administrator's information is read-only and cannot be modified.
> - Reassigning another user as a Customer Admin within Exo Admin is not supported via application. To request this change, please contact Exo Support.

Searching for a User

Enter the search term in the Search bar, which can be:

- Name
- Email
- Phone Number

Filtering Users

Filter the user list by selecting one of the following options:

- All
- Active
- Paused
- Deactivated
- Not provisioned

Viewing User Information

❖ Click on the **three-dot icon** and click **User Details**.

Pausing a User

❖ Click on the **three-dot icon** and click **Pause User**.

Unpausing a User

❖ Click on the **three-dot icon** and click **Un-Pause User**.

Deactivating a User

To deactivate a user, the user must first be paused. Please note that deactivation is a permanent action and cannot be reversed.

❖ Click on the **three-dot icon** and click **Un-Pause User**.

Resending the Welcome Email

❖ Click on the **three-dot icon** and click to **Resend Welcome Email**.

Device Management

Select Devices under Device Management to access information on your device(s):

- Serial number
- Order number
- Last used by is who used it last
- Last used on is the date/time it was used last

License Management

Select License under License Management to access the following information about your license:

- License type
- Catalog number
- Subscription start and end date
- Quantity of license
- Order ID
- Subscription status

Exo Iris Device Maintenance

Exo Iris Device Maintenance

Chapter 4

This chapter provides information and instructions for cleaning, disinfecting, and storing the device and cables.

General warnings and cautions

Warnings

- Avoid fluid contact with the mobile device touchscreen during scanning and when cleaning Iris. Fluid exposure may cause device damage.
- Clean and/or disinfect the mobile devise according to the manufacturer's recommendations and local regulations.
- The cleaning and disinfecting instructions contained in this chapter are based on requirements mandated by the U.S. Food and Drug Administration (FDA). Failure to follow these instructions between uses may result in cross contamination and an increased spread of pathogens.
- Creutzfeldt-Jakob disease: There is no adequate disinfection procedure if Exo Iris device is exposed to Creutzfeldt-Jakob disease.
- Do not send any device that is known to have been exposed to Creutzfeldt-Jakob disease to Exo. Adhere to the local regulation protocols.
- Ensure that cleaning and disinfecting solutions and wipes are not expired.
- Some cleaners and disinfectants can cause an allergic reaction to some individuals.
- The use of a device cover or sheath does not preclude proper cleaning and disinfecting of a device. When choosing a cleaning and disinfecting method, treat the device as if a cover was not used in the procedure.
- To avoid electrical shock, before cleaning, turn off the system and disconnect it from the power supply.
- Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as protective eyewear and gloves when cleaning and disinfecting the device.
- Use sterile sheath and sterile gel while performing procedural guidance
- Use a sheath if the device may come into contact with any of the following and use the high-level disinfection procedure.
  - Blood
  - Broken skin
  - Mucosal membranes
  - Bodily fluids

Cautions

- Use only the recommended cleaning products and wipes to clean the device and cable.
- Discontinue using the device if the housing is damaged or its lens is cracked, chipped, or torn.
- Avoid device contact with mucous membranes and non-intact areas of the skin.
- Do not allow cleaning solution, disinfectant, or moisture into the device connector.
- Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only Exo recommended cleaners and disinfectants.
- Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- Use only Exo approved cleaners and disinfectants. Using a non-approved disinfecting solution or incorrect solution strength can damage the device and void the warranty. Follow the disinfectant manufacturer's recommendations for solution strengths.
- To prevent cross-contamination, clean and disinfect the device before setting it on the wireless charger.
- As with any battery-operated device, the battery drains if the device is not used. The device must be recharged at least once every six months for proper performance.

Cleaning and disinfecting (reprocessing)

Begin reprocessing at the point of use to facilitate subsequent cleaning steps to avoid the drying of soiled material and to reduce the risk of infection. It is important to follow the steps below:

Step 1: **Clean** the Exo Iris device, (the probe and duo cable) using one of the indicated products for cleaning. Follow with one of the two disinfection methods (Step 2 or Step 3).

Step 2: If the Exo Iris device has come into contact with only unbroken skin, perform **low-level disinfection** using one of the indicated products for low-level disinfection; otherwise, proceed to Step 3.

or

Step 3: If the Exo Iris device has come into contact with blood, broken skin, or bodily fluids, perform **high-level disinfection** with one of the indicated products for high-level disinfection.

Step 1: Cleaning the Exo Iris device, Duo Cable

Cleaning should remove all visible gel, soil, bodily fluids, and particulate matter on all surfaces of the probe and duo cable. Follow the approved cleaning product manufacturing guidelines for directions of use, contact time, and precautions.

Products for cleaning

Cleaning Product	Use	Active Ingredient	Level
PDI Super Sani-Cloth® Germicidal disposable wipes (purple container)	Wipes	Alcohol, QUAT	Cleaning
Opti-Cide3	Spray/wipes	Alcohol, QUAT	Cleaning
Sani24	Spray/wipes	Alcohol, QUAT	Cleaning
CaviWipes	Wipes	Alcohol, QUAT	Cleaning
Sani-Cloth Prime	Wipes	Alcohol, QUAT	Cleaning
Super Sani-Cloth Germicidal wipes	Wipes	Alcohol, QUAT	Cleaning

TO CLEAN THE EXO IRIS DEVICE, DUO CABLE

1. Disconnect the device from the Apple mobile device.
2. Thoroughly wipe the entire device including probe and duo cable with one of the indicated cleaning products for a **minimum of one minute**, paying attention to seams, gaps, gasket material, and recessed areas. Wipe from the clean areas of the device to the soiled areas, which helps reduce cross contamination.
3. Using a new wipe each time, clean the device until it's visibly clean.
4. To dry, use a lint-free soft cloth.
5. Visually inspect the device in a well-lit area to ensure all surfaces are clean. If the device is not clean, repeat the cleaning steps above.
6. Dispose of the cleaning material in accordance with all applicable regulations.
7. Proceed with low-level or high-level disinfection.

Disinfecting Exo Iris device

There are two levels of disinfecting:

- **Low-level disinfecting** - Use this level when the device comes into contact with only unbroken skin (non-critical use).
- **High-level disinfecting** - Use this level when the device comes into contact with blood, broken skin, or bodily fluids (semi-critical use).

Step 2: Low-level disinfecting

Follow the approved disinfecting product manufacturing guidelines for directions of use, contact time, and precautions.

Products for low-level disinfection

Cleaning Product	Use	Active Ingredient	Level
PDI Super Sani-Cloth® Germicidal disposable wipes (purple container)	Wipes	Alcohol, QUAT	Low-level disinfection
Opti-Cide3	Spray/wipes	Alcohol, QUAT	Low-level disinfection
Sani24	Spray/wipes	Alcohol, QUAT	Low-level disinfection
CaviWipes	Wipes	Alcohol, QUAT	Low-level disinfection
Sani-Cloth Prime	Wipes	Alcohol, QUAT	Low-level disinfection
Super Sani-Cloth Germicidal wipes	Wipes	Alcohol, QUAT	Low-level disinfection

TO DISINFECT EXO IRIS DEVICE AT A LOW LEVEL

1. After thoroughly cleaning the device, wipe the probe and duo cable using the indicated low-level disinfection wipes, or spray the disinfection product on a lint-free cloth until it saturates and then wipe the entire device.
2. Make sure the treated surfaces remain wet for a minimum of two (2) minutes. Pay attention to seams and gaps. Use additional fresh wipes as needed to ensure continuous two minutes of contact time.
3. To dry the device, use a clean, lint-free cloth.
4. Visually inspect the device in a well-lit area to ensure all surfaces are clean. If the device is not clean, repeat the disinfecting steps above.
5. Dampen a sterile, lint-free wipe with 70% IPA, and wipe the entire device surface for a minimum of one (1) minute. Using new wipes saturated with 70% IPA, repeat wiping the device five times for a total each time of one minute.
6. Dispose of the disinfectant in accordance with all applicable regulations.
7. Examine the device for damage, such as cracks or splitting where fluid can enter.
8. If there is damage, discontinue using the device.

Step 3: High-level disinfecting

Follow the approved high-level disinfecting product manufacturing guidelines for directions of use, contact time, and precautions.

Warnings High-level disinfectants can cause harm to the patient if not completely removed from the device. Follow the manufacturer's rinse instructions to remove chemical residue.

Cautions

- Do not soak the device longer than recommended by the chemical manufacturer.
- Do not immerse the device connector in any disinfectant solution.

PRODUCTS FOR HIGH-LEVEL DISINFECTION

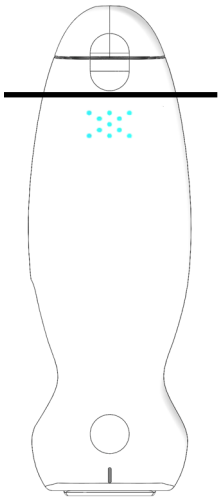
Disinfecting Product	Use	Active Ingredient	Level
Cidex OPA	Soak	Orthophthalaldehyde	High-level disinfection
MetriCide OPA Plus	Soak	Orthophthalaldehyde	High-level disinfection
RAPICIDE OPA/28	Soak	Orthophthalaldehyde	High-level disinfection
trophon®2 [see notes]	Probe reprocessing	Hydrogen Peroxide	High-level disinfection

Note Before starting the Trophon 2 disinfection cycle, ensure the probe is completely dry after cleaning and carefully inspect it for any defects.

TO DISINFECT EXO IRIS DEVICE AT A HIGH LEVEL

1. After thoroughly cleaning the device, disinfect the device with indicated products for high-level disinfection.
2. Prepare one of the indicated high-level disinfecting products in a container or bowl.
3. Immerse the device up to the line, ensuring the junction between the probe and the cable connector remain out of the fluid.

Do not immerse the device any higher than this line.



Do not immerse the device any higher than this line.

4. Soak the device in the solution for **12 minutes** at 20°C-22°C, and ensure no air bubbles to be trapped.
5. Rinse the device **three separate times** using the following procedure:
   - Rinse the device in clean, running water according to the disinfectant manufacturer's instructions (for at least one minute). Ensure that the connector remains out of the fluid.
   - Replace the rinse water before beginning the next rinse.
   - Rinse two additional times (for a total of three rinses).
6. Dry the device with a sterile, lint-free cloth.
7. Visually inspect the device in a well-lit area to ensure all surfaces are clean. If the device is not clean, repeat the disinfecting steps above.
8. Dispose of the disinfectant according to the manufacturer's guidelines.
9. Dampen a sterile, lint-free wipe with 70% IPA, and wipe/cloth the entire device surface for one minute. Using new wipes saturated with 70% IPA, repeat wiping the device five times for a total each time of one minute.
10. Examine the device for damage, such as cracks or splitting where fluid can enter.
11. If there is damage, discontinue using the device.

Recycling and disposal

Exo is an environmentally conscious company. Exo Iris device contains a lithium-ion battery and requires appropriate disposal. For proper disposal of Exo Iris device and/or any of its accessories, dispose or recycle in accordance with local, state, and federal regulations. Prior to recycling or disposal, items should be clean and contaminant free.

Storing Exo Iris device

Cautions

- Before storing, ensure that the device is dry.
- Avoid device contact with sharp objects such as scissors, scalpels, or cauterizing knives.
- Store the cleaned and disinfected device properly to prevent contamination before use.

Store the device in clean, dry, and moderate temperature conditions. Follow the guidelines for Cleaning and disinfecting (reprocessing) before storing or transporting the device.

FOLLOW THESE GUIDELINES TO PROTECT EXO IRIS DEVICE:

- Avoid storing the device in areas with temperature extremes or, in direct sunlight .
- Store the device separately from other instruments to avoid inadvertent damage to the device.
- Before storing device, make sure it is completely dry.
- Store Exo Iris device between the temperature limit : –20 °C (–4 °F) to 45 °C (113 °F), and at humidity level below 90%, non-condensing.

Troubleshooting

Situations	Recommended Actions
App crashes	Close the app and restart the app. [Note: on-going exam will be automatically saved.]
Login error	Verify username and password. Reset your password.
Can't access the Worklist	Verify the Worklist DICOM connection in the settings and the Apple mobile device network connectivity.
Can't confirm and submit an ended exam	Verify the Apple mobile device network connectivity.
Exams are not available in the Exo Works Web	Verify the Apple mobile device network connectivity.

Situations	Recommended Actions
Iris disconnects during imaging	Disconnect Iris, wait 5 seconds, and reconnect Iris.
Iris LED light not ON when connecting to the Apple mobile device	Disconnect Iris, wait 5 seconds, and reconnect Iris. Iris battery may have fully drained. Connect Iris to wired charger and allow Iris to fully charge for ~2 hours. LED lights should turn RED after a few minutes when charging has started.
Iris is not charging wirelessly [no LED light on the probe]	Verify that the wireless charger cradle is connected to the power supply and is plugged into the wall outlet. Make sure Iris is adequately settled into its cradle in the wireless charger and the LED light is blinking blue. Make sure there's no interference between the flat part of Iris and wireless charger's cradle, like a label, sticker, barcode, etc. Make sure Iris is not connected to Apple mobile device and/or wired charger with the Duo Charge Cable at the same time as being in the wireless charger. Once Iris is fully charged, wireless charge LED light turns solid blue.
Iris LED does not turn ON when connecting to wired charger	Iris battery may have fully drained. Connect Iris to wired charger and allow Iris to charge fully for ~2 hours. LED light should turn RED after few minutes when charging has started.

Iris is connected to charger but not charging [No LED light]	If the battery is fully drained, it takes up to 5 minutes to charge the battery enough to turn the LED ON. Verify that the power adapter is connected to the wall and that the cable is correctly connected to Iris.
No Imaging, blank screen, or is unresponsive	Disconnect Iris, wait 5 seconds, and reconnect Iris.
Image degradation or imaging artifact	Disconnect Iris, wait 5 seconds, and reconnect Iris and verify that the self-test passes. If Self-test failed refer to Iris self-test failure for troubleshooting.
	Contact Exo Support if the problem persists.

Alerts and Warnings	**Recommended Actions**
Iris self-test failed	Disconnect Iris, wait 5 seconds, reconnect Iris and verify that the self-test passes. If Self-test failed, contact Exo Support.
Iris is overheating	Disconnects Iris and let it cool off for ~30 minutes.
Iris Error Alert - Error during initialization	Disconnect Iris, wait 5 seconds, and reconnect Iris. Contact Exo Support if problem persists.
Iris Low battery warning	Charge Iris.
Exam failed to transfer to Cloud	Verify the internet connection.
Exam failed to transfer to PACs	Verify the Worklist DICOM connection in the Settings and retry the transfer from the Outbox folder.
FW upgrade failed	Contact Exo Support.
SW App upgrade failed	Contact Exo Support.

Safety

5

Safety

Chapter 5

This chapter contains electrical, defibrillation, biological, and equipment safety information required by regulatory agencies. The information applies to the ultrasound system, device, and accessories. This chapter also defines labeling symbols, specifications, and standards.

Exo Iris is internally powered, transportable (hand-held) equipment.

Exo Iris cannot image while charging.

Exo Iris has been tested to standards required for use in road ambulances (IEC 60601-1-12).

Electrical safety

Warnings

- To avoid the risk of electrical hazards, discontinue use of the device if the housing is damaged or its lens is cracked, chipped, or torn.
- Dropping the device may cause damage. Always inspect the device before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the device if there is any sign of damage. If the device is dropped, restart the device to allow a self- check test. Do not use the device if the self-check test is not successful.
- Do not immerse the device fully in liquid.
- Remove the device from service and contact Exo Support if cable damage is observed.
- Portable RF communications equipment (including antenna cables and external cables) should be no closer than 30 cm (12inches) to any Exo Iris device. Otherwise, performance degradation of the equipment could result.
- Use of accessories, chargers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Cautions

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas, hospitals and residential environments (CISPR 11 Class B). If the environment doesn't meet specified designation, the equipment might not offer adequate protection to radio frequency communication services and the user might need to take mitigation measures, such as relocation or re-orienting the equipment. The device can only be used by medical professionals.
- Notifications and alerts from other third-party applications running on your Apple mobile device may interfere with the study.

Defibrillation safety

Warnings

- Remove all patient-contact devices from patient before applying high- voltage defibrillation pulse.
- Device sheaths do not provide protection from defibrillation.

Biological safety

Warnings

- Always use the as low as reasonably achievable (ALARA) principle when performing an ultrasound study. Additional information on the ALARA principle can be found in AIUM's, Medical Ultrasound Safety, Third Edition publication.
- Creutzfeldt-Jakob disease: There is no adequate disinfection procedure if Exo Iris device is exposed to Creutzfeldt-Jakob disease.
- Do not send any device that is known to have been exposed to Creutzfeldt-Jakob disease to Exo for repairs. Adhere to the local regulation protocols.
- The device does not have any latex parts.

Cautions

- To avoid cross contamination, always clean the device between uses.
- Only clean the device with Exo recommended cleaning products and wipes.
- Avoid direct contact with mucous membranes and non-intact areas of the skin. Use a sheath if device contact with non-intact skin is anticipated.

Cybersecurity

Cautions

- Follow all security and cybersecurity policies of your institution when using Exo Iris device.
- Your institution is responsible for securing the Apple mobile device that Exo Iris app resides on and ensuring that their policies and procedures are followed.
- Do not modification or tamper with the device, or add components to the wired connection, as this could pose a cybersecurity risk.

Exo has taken care to prevent cybersecurity vulnerabilities throughout the product lifecycle, from production to customer delivery. However, cybersecurity threats, such as malware attacks could exist with the use of all Apple mobile devices.

Exo Works Archive stores personal health information (PHI), and Exo makes every effort to protect PHI. Security and confidentiality of patient records should be handled according to your institution's clinical procedures. If institutional policies are unclear,, contact your information technology (IT) department. It is the sole responsibility of the user that data processing or sharing follows legal standards.

Exo Iris app requires user to set a username and password to log into the program. Login is acquired through the https TLS 1.2 protocol. Contact Exo Support to obtain a valid username and password.

Exo recommends that users follow your organizations' policies for Apple mobile device security, such as setting up a PIN, application password, and logout requirements. Exo addresses cybersecurity threats by push notification, so always install the updates Exo sends. Updates to Exo Iris app are managed through the Apple App Store. Users should keep their Apple mobile device operating system and Exo Iris app up to date to guarantee they are using to most recent version.

If a user suspects a device malfunction due to a cybersecurity incident, notify the IT department, and check to make sure that the latest software updates are installed.

Equipment safety

Warnings

- Do not attempt to replace the battery. Only charge the battery using the chargers specified in this user manual.
- Do not attempt to plug any unapproved cables into Exo Iris device.
- Exo Iris device is compatible with the following approved Apple mobile device models indicated in this user manual.
- Never attempt to modify the device; this could lead to electrical shock or other hazards.

Cautions

- Remove the device from service and contact Exo Support if cable damage is observed.
- If the device appears to malfunction, stop use immediately. Contact Exo Support.
- Use only commercially available ultrasound gel.
- Only charge the battery using the charger included with Exo Iris device.
- Before storing, ensure that the device is dry.
- Avoid device contact with sharp objects, such as scissors, scalpels, and cauterizing knives.

Electromagnetic compatibility (EMC)

Exo Iris device is intended to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids by trained and qualified healthcare professionals. Electromagnetic field interference may result in artifacts, distortion, or degradation of the ultrasound image, affecting this performance.

The essential performance of Exo Iris device consists of:

- Ultrasonic image display of anatomical structures and fluid
- Freedom of image quality artifacts
- Prevention of unintended or excessive ultrasound output
- Display of correct numerical values (MI, TI, and depth)
- Prevention of excessive surface temperature

Electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

Exo Iris device is intended for use in the electromagnetic environment specified below. The operator of Exo Iris device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Exo Iris device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	Exo Iris devices in this class are suitable for use in a residential environment. If the environment doesn't meet specified designation, the equipment might not offer adequate protection to radio frequency communication services and the user might need to take mitigation measures, such as relocation or re-orienting the equipment. The device can only be used by healthcare professionals.

Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity

Exo Iris device is intended for use in the electromagnetic environment specified below.
The operator of Exo Iris device should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Same as IEC 60601-1-2 test level.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Same as IEC 60601-1-2 test level.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Same as IEC 60601-1-2 test level.	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30periods At 0° Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° Voltage Dips > 95% reduction, 1 period At 0° Voltage Interruptions > 95% reduction, 250/300 periods	Same as IEC 60601-1-2 test level.	Mains power quality should be that of a typical commercial or hospital environment. If the operator of Exo Iris device requires continued operation during power mains interruptions, it is recommended that Exo Iris device be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Same as IEC 60601-1-2 test level.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms, 0.15-80 MHz 6 Vrms in ISM and amateur radio bands within 150kHz – 80MHz	Same as IEC 60601-1-2 test level.	Portable and mobile RF communications equipment should be used no closer to any part of Exo Iris, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	Same as IEC 60601-1-2 test level.	Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range[b].

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Proximity magnetic fields IEC 61000-4-39	65A/m (RMS), PM at 2.1 kHz, 50% duty cycle, 134.2kHz; 7.5A/m (RMS), PM at 50 kHz, 50% duty cycle, 13.56MHz	Same as IEC 60601-1-2 test level.	

Note At 80 MHz and 800 MHz, the higher frequency range applies.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths 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 cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Exo Iris is used exceeds the applicable RF compliance level above, Exo Iris should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Exo Iris.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic immunity con't.

Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 - 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28

1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b)] 217 Hz	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	9

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Immunity to Proximity Magnetic Fields

Test Frequency	Modulation [b)]	Immunity Test Level (A/m)
30 kHz[a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50 kHz	7.5 [c)]

[a)] This test is applicable only to me equipment and me systems intended for use in the home healthcare environment.
[b)] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c)] r.m.s before modulation is applied.

Separation distance

Exo Iris device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. However, RF interference may still occur, as surrounding devices such as mobile devices, radio transmitters and transceivers transmit radio waves (RF) can create disturbances.

If electromagnetic disturbances are observed, the user should correct the interference by either relocating or re-orienting the system, or by increasing the separation distances between the system and the RF transmitting equipment. Separation distances are indicated in the table below.

Recommended separation distance

Recommended separation distances between portable and mobile RF communications equipment and Exo Iris device.

Exo Iris device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The operator of Exo Iris device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Exo Iris device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Labeling symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. Of those symbols, the following may be used on your product and its accessories and packaging.

Symbol	Description
	Indicates the medical device manufacturer, as EU MDR- European Medical Device Regulation- 2017/745
	Type BF applied part. Probe head (lens and surrounding area) which comes in contact with the patient is classified as Type BF applied part under the IEC 60601-1 standard.
IP67	Exo Iris device is dust-tight and is protected against temporary immersion in water.
	Federal law restricts this device to sale by or on the order of a physician.
	Do not use if damaged.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight.
	Do not throw in trash.
	Paper recycle

Symbol	Description
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Caution when cleaning and disinfecting.
	Operating instructions
http://www.exo.inc/iris/manual	Consult electronic instruction for use (e-ifu)
	Indicates the temperature limits to which the medical device can be safely exposed.
	Exo Iris device is magnetic resonance (MR) unsafe and should remain outside the MRI scanner room.
	**Medical Device** Indicates the item is a medical device.
	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information.
10 min/20 min	Exo Iris device activation time "on" is 10 minutes for Color Doppler imaging, and 20 minutes for B mode, followed by a cool down "off" time of 20 minutes for safe operation.
	The Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge and has been certified by the developer to meet Apple performance standards.

Specifications

Item	Specification
Device dimensions	143 x 53 x 36 mm
Device weight	300 g (0.66 lbs)
Power	Li-Ion Battery, rechargeable, 3.8V
Battery life	Up to 2 hrs
Languages	English
Display	See Specifications
Min/max scan depth	2 cm min / 30 cm max
Ultrasound chip	4096 individually-controlled pMUTs
Transducer	Piezoelectric micromachined ultrasonic transducer (pMUT)
Frequency range	1.5-12 MHz
Temperature scanning limits	Device head up to 43° C (109.4° F)
Dual imaging (Micro-B to lightning) /charging cable (Micro-B to USB-C)	150 cm

Apple mobile device requirements

The system should only be used with the following iOS devices:

Item	Requirement
Mobile phone	iPhone 13, iPhone 13 Pro, iPhone 13 Pro Max iPhone 14, iPhone 14 Plus, iPhone 14 Pro, iPhone 14 Pro Max iPhone 15, iPhone 15 Plus, iPhone 15 Pro, iPhone 15 Pro Max iPhone 16, iPhone 16 Plus, iPhone 16 Pro, iPhone 16 Pro Max, iPhone 16e iPhone 17, iPhone 17 Pro, iPhone 17 Pro Max, iPhone Air
Tablet	iPad Pro (13-inch) - M4 & M5 iPad Pro (12.9-inch) - 5th & 6th generation iPad Pro (11-inch) - 3rd, 4th, 5th, 6th generation, M4 & M5 iPad Air (13-inch) - M2 & M3 iPad Air (11-inch) - M2 & M3 iPad Air (10.9-inch) - 4th & 5th generation iPad (11-inch) - A16 iPad (10.9-inch) - 10th generation iPad mini - 6th & 7th generation
Operating system	iOS 18, iOS 26

Pressure, Humidity, and Temperature Limits (Exo Iris Only)

Cautions

- These limits apply exclusively to Exo Iris devices and do not apply to the Apple mobile device used to operate the Exo Iris app.
- Environmental specifications for the Apple mobile device are provided in the accompanying device documentation.

Parameter	Operating Limits	Transient Operating Limits (Not to exceed 20 minutes)	Transport and Storage Limits
Pressure	620 hPa (465 mmHg) to 1,060 hPa (795 mmHg)	—	—
Humidity	At or below 90%, non-condensing	At or below 90%, non-condensing	At or below 90%, non-condensing
Temperature	0°C (32°F) to 40°C (104°F)	0°C (32°F) to 40°C (104°F)	-20°C (-4°F) to 45°C (113°F)

Warnings

Given the Exo Iris device is handheld, it is expected that the device will be subject to various conditions and environments, including those present in the hospital, EMS, and home.

Care should still be taken to protect the Exo Iris device from extreme temperatures, shock, drop, and other extreme conditions.

Acoustic Output

6

Acoustic Output

Chapter 6

Ultrasound safety

Trained and qualified professionals should perform diagnostic ultrasound procedures safely for the intended purpose. Exo Iris device Thermal Index (TI) and Mechanical Index (MI) acoustic safety limits are set to industry standards, and as a Track 3 device, are displayed on the display screen continuously. The TI is displayed as either soft tissue (TIS) or bone (TIB), and only one of these indices is displayed at any given time, based on the clinical setting default of a selected exam. The user can change between displaying the TIS or TIB. TI and MI are displayed in increments of 0.01 over the range of 0.0 to maximum output. Thermal Index (TI) is the estimate of the temperature increase of soft tissue or bone.

Both the TI and MI are defined in the following standards:

- IEC 60601-2-37, Edition 2.1, Medical electrical equipment. Part 2-37: Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359, Edition 2.1 Ultrasonics – Field Characterization: Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasound fields.

The MI is the estimated likelihood of tissue damage due to cavitation and its limit (1.9) is set by FDA Guidance, “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.”

> **Note** The MI limit for ophthalmic is 0.23.

ISPTA.3 is the derated Spatial Peak Temporal Average Intensity and the maximum limit of ISPTA.3 is 720 mW/ cm^2 which is also set by the FDA Guidance.

> **Note** The ISPTA.3 limit is 50 mW/cm2 for ophthalmic applications.

Although the acoustic output settings have been limited in compliance with these standards, it is incumbent on the user to be trained in the use of the ultrasound and aware of the potential for ultrasound-induced bio effects and to minimize patient exposure to potential harmful effects and unnecessary risk. Ultrasound users should be knowledgeable in ultrasound procedures and be able to perform them at output levels and exposure times that are As Low As Reasonably Achievable (ALARA). ALARA is defined as ultrasound exposure kept as low as reasonably achievable while optimizing diagnostic information.

ALARA training is provided by the American Institute of Ultrasound in Medicine (AIUM) in a booklet, “Medical Ultrasound Safety.” This booklet can be accessed on the AIUM website http://aium.s3.amazonaws.com/resourceLibrary/mus4.pdf

It provides training and educational information on ultrasound bio effects and biophysics, prudent use and implementing ALARA.

An example of the ALARA principle is during abdominal ultrasound. Minimizing, for example, the use of Color Doppler, limiting dwell time, scanning only critical structures required for the study, and avoiding studies for non-medical reasons are all manifestations of a reduction in exposure to ultrasonic energy.

Output accuracy

Acoustic Quantity	Uncertainty
MI	16%
TI	33%

Mode of operation

Transducer model	Mode of operation					
	B	PWD	CWD	Color Doppler	Combined (specify)	Other* (THI)
Exo Iris Device	X	N/A	N/A	N/A	(B+CD) (B+M) (B+Power Doppler) (B + PWD)	X

*Examples of other modes of operation may include A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

Acoustic output limits

Exo Iris device maintains acoustic output below the appropriate limits for each application. The system follows the Output Display Standard (IEC 60601-2-37) and falls within the Track 3 acoustic output limits.

Non-ophthalmic application output limits

Transducer Model	Ispta.3	MI	TI
Exo Iris Device	≤ 720 mW/ cm²	≤ 1.9	≤6.0

Ophthalmic application output limits

Transducer Model	Ispta.3	MI	TI
Exo Iris Device	≤ 50 mW/ cm²	≤ 0.23	≤1.0

Acoustic output table symbols and terms

ASymbol	Term
MI	Mechanical index
TIS	Soft-tissue thermal index
TIB	Bone thermal index
TIC	Cranial-bone thermal index
$p_{r,\alpha}$ *at* z_{MI}	Attenuated peak-rarefactional acoustic pressure
P	Output power
P_{1x1}	Bounded output power
Z_s	Depth for TIS
Z_b	Depth for bone thermal index
Z_{MI}	Depth for mechanical index
$Z_{pii,\alpha}$	Depth for peak attenuated pulse intensity integral
f_{awf}	Acoustic working frequency
prr	Pulse repetition rate
srr	Scan repetition rate
n_{pps}	Number of pulses per ultrasonic scan line
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	Attenuated pulse-average intensity
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	Attenuated spatial-peak temporal-average intensity
I_{spta} *at* Z_{pii} *or* Z_{sii}	Spatial-peak temporal-average intensity
p_r *at* Z_{pii}	Attenuated rarefactional acoustic pressure

Acoustic output tables

B-mode and THI

Index label		MI	TIS		TIB		TIC
			"At surface"	Below Surface	"At surface"	Below Surface	
Maximum index value		1.062	0.007591		0.007591		0.01765
Index component value			0.007591	0.007591	0.007591	0.007591	
$p_{r,\alpha}$ *at* z_{MI}	(Mpa)	1.742					
P	(mW)		1.363		1.363		1.363
P_{1x1}	(mW)		0.592		0.592		
Z_s	(cm)			-			
Z_b	(cm)					-	
Z_{MI}	(cm)	3.8					
$Z_{pii,\alpha}$	(cm)	3.9					
f_{awf}	(MHz)	2.693	2.693		2.693		2.693
prr	(Hz)	5.4e+02					
srr	(Hz)	12					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm)	108.1					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.967					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	1.665					
p_r *at* Z_{pii}	(Mpa)	2.365					
Operating controls	Preset	abd	abd	abd	abd	abd	abd
	Display Depth (mm)	80	80	80	80	80	80

Color/Power Doppler mode (B-mode + Color/Power Doppler)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.048	0.1102		0.1102		0.3243
Index component value			0.1102	0.1102	0.1102	0.1102	
$p_{r,\alpha}$ *at* z_{MI}	(MPa)	1.715					
P	(mW)		19.09		19.09		26.71
P_{1x1}	(mW)		7.742		7.742		
Z_s	(cm)			-			
Z_b	(cm)					-	
Z_{MI}	(cm)	3.8					
$Z_{pii,\alpha}$	(cm)	3.8					
f_{awf}	(MHz)	2.674	5.883,5.143,2.936		5.883,5.143,2.936		2.674,2.064
prr	(Hz)	3.7e+02					
srr	(Hz)	12					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm2)	102.5					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.6339					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	1.081					
p_r *at* Z_{pii}	(MPa)	2.378					
Operating controls	Preset	abd	testicular	testicular	testicular	testicular	abd
	Display Depth (mm)	80	80	80	80	80	80

M-mode (B-mode + M-mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.058	0.008868		0.01813		0.0201
Index component value			0.008524	0.008868	0.008524	0.01813	
$p_{r,\alpha}$ *at* z_{MI}	(MPa)	1.733					
P	(mW)		1.538		1.538		1.538
P_{1x1}	(mW)		0.667		0.667		
Z_s	(cm)			2.7			
Z_b	(cm)					3.8	
Z_{MI}	(cm)	3.7					
$Z_{pii,\alpha}$	(cm)	3.9					
f_{awf}	(MHz)	2.684	2.684,2.683		2.684,2.683		2.684,2.683
prr	(Hz)	5.6e+02					
srr	(Hz)	12					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm2)	115.4					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.9797					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	1.688					
p_r *at* Z_{pii}	(MPa)	2.323					
Operating controls	Preset	abd	abd	abd	abd	abd	abd
	Display Depth (mm)	80	80	80	80	80	80

Pulsed-Wave Doppler (B mode + PWD)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.054	0.05927		0.4639		0.121
Index component value			0.0308	0.05927	0.03471	0.4639	
$p_{r,\alpha}$ *at* z_{MI}	(MPa)	1.725					
P	(mW)		9.477		9.023		9.023
P_{1x1}	(mW)		3.037		3.448		
Z_s	(cm)			3.1			
Z_b	(cm)					5.0	
Z_{MI}	(cm)	3.7					
$Z_{pii,\alpha}$	(cm)	3.7					
f_{awf}	(MHz)	2.677	2.677,2.064		2.697,2.071		2.697,2.071
prr	(Hz)	3.1e+02					
srr	(Hz)	9.9					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm2)	102.7					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.5073					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	0.872					
p_r *at* Z_{pii}	(MPa)	2.252					
Operating controls	Preset	abd	abd	abd	abd	abd	abd
	Display Depth (mm)	80	80	80	60	60	60

B ophthalmic (B-mode for the ocular exam)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.1719	0.003623		0.003623		0.00641
Index component value			0.003623	0.003623	0.003623	0.003623	
$p_{r,\alpha}$ *at* z_{MI}	(MPa)	0.3912					
P	(mW)		0.3077		0.3077		0.3077
P_{1x1}	(mW)		0.1359		0.1359		
Z_s	(cm)			-			
Z_b	(cm)					-	
Z_{MI}	(cm)	2.6					
$Z_{pii,\alpha}$	(cm)	2.9					
f_{awf}	(MHz)	5.179	5.998,5.179		5.998,5.179		5.998,5.179
prr	(Hz)	1.7e+03					
srr	(Hz)	43					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm2)	5.671					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.1952					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	0.5343					
p_r *at* Z_{pii}	(MPa)	0.62					
Operating controls	Preset	ophthalmic	ophthalmic	ophthalmic	ophthalmic	ophthalmic	ophthalmic
	Display Depth (mm)	50	50	50	50	50	50

Warnings To avoid injury to the patient, use only the ocular exam when imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the ocular exam is selected.

Cautions

- Do not apply excessive force when scanning.
- Do not override or modify any safety provisions.

Color/Power Doppler ophthalmic (B mode + Color/Power Doppler)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.1719	0.01371		0.01371		0.01976
Index component value			0.01371	0.01371	0.01371	0.01371	
$p_{r,\alpha}$ *at* z_{MI}	(MPa)	0.3912					
P	(mW)		0.9649		0.9649		0.9649
P_{1x1}	(mW)		0.662		0.662		
Z_s	(cm)			-			
Z_b	(cm)					-	
Z_{MI}	(cm)	2.6					
$Z_{pii,\alpha}$	(cm)	2.9					
f_{awf}	(MHz)	5.179	5.998,5.179, 4.028		5.998,5.179, 4.028		5.998,5.179, 4.028
prr	(Hz)	1.7e+03					
srr	(Hz)	43					
n_{pps}		1					
$I_{pa,\alpha}$ *at* $Z_{pii,\alpha}$	(W/cm2)	5.671					
$I_{spta,\alpha}$ *at* $Z_{pii,\alpha}$ *or* $Z_{sii,\alpha}$	(mW/cm2)	0.1952					
I_{spta} *at* Z_{pii} *or* Z_{sii}	(mW/cm2)	0.5343					
p_r *at* Z_{pii}	(MPa)	0.62					
Operating controls	Preset	ophthalmic	ophthalmic	ophthalmic	ophthalmic	ophthalmic	ophthalmic
	Display Depth (mm)	50	50	50	50	50	50

Acoustic output range summary

Mode of operation

Global maximum output levels (est.)	B	M	PWD	CWD	Color Doppler	Combined (B+CD) (B + PWD)	Other* (THI)	Ophthalmic B
max $I_{spta,\alpha 3}$	720	720	N/A	N/A	N/A	720	720	50
min$I_{spta,\alpha 3}$	0	0	N/A	N/A	N/A	0	0	0
max MI	1.9	1.9	N/A	N/A	N/A	1.9	1.9	.23
Min MI	0	0	N/A	N/A	N/A	0	0	0
Max TIS	6	6	N/A	N/A	N/A	6	6	1
Min TIS	0	0	N/A	N/A	N/A	0	0	0
Max TIB	6	6	N/A	N/A	N/A	6	6	1
Min TIB	0	0	N/A	N/A	N/A	0	0	0
Max TIC	6	6	N/A	N/A	N/A	6	6	1
Min TIC	0	0	N/A	N/A	N/A	0	0	0

* Examples of other modes of operation may include A-mode, amplitude Doppler, 3-D, imaging, harmonic imaging, tissue motion Doppler, and color velocity imaging

Measurement accuracy

B-mode images (distance and area)

- Display Depth markers accuracy shall be within **± 10%** of displayed value,
- The axial measurement accuracy shall be within **± 5%** of displayed value,
- The lateral measurement accuracy shall be within **± 5%** of displayed value,
- The diagonal measurement accuracy shall be within **± 5%** of displayed value,
- The area measurement accurate shall be within **± 5%** of displayed value,
- The circumference measurement shall be within **± 5%** of displayed value,

Color Doppler images (distance and area)

The maximum velocity indicator accuracy shall be within **± 20%** of displayed value

Time

Time measurement accuracy shall be **± 10%** of displayed value.

Appendix: OB Formula for EFW and GA

Appendix: OB Formulas for EFW and GA

Chapter 7

Crown Rump Length (CRL) Gestational Age (GA) using Hadlock method

Reference: Hadlock F.P., Shah Y.P., Kanon D.J. and Lindsey J.V. Fetal crown-rump length: reevaluation of relation to menstrual age (5-18 weeks) with high-resolution real-time US

ISSN0033-8419, Print 1992, Pages 501 - 505

Formula: $GA = e^{1.684969 + 0.315646 \times CRL - 0.049306 \times CRL^2 + 0.004057 \times CRL^3 - 0.000120456 \times CRL^4}$

Range: 0.2 cm to 12 cm

Femur Length (FL) Gestational Age (GA) using Hadlock method

Reference: Hadlock F.P., Deter R.L., Harrist R.B., Park S.K. Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters. Radiology Vol. 152 No. 2, 1984, pages 497-501

Formula: $GA = 10.35 + 2.46(FL) + 0.17(FL^2)$

Range: 0.616 cm to 8.2 cm

Abdominal Circumference (AC) Gestational Age (GA) using Hadlock method

Reference: Hadlock F.P., Deter R.L., Harrist R.B., Park S.K. Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters. Radiology Vol. 152 No. 2, 1984, pages 497-501

Formula: $GA = 8.14 + 0.753\ (AC) + 0.0036(AC^2)$

Range: 4.93 cm to 38 cm

Head Circumference (HC) Gestational Age (GA) using Hadlock method

Reference: Hadlock F.P., Deter R.L., Harrist R.B., Park S.K. Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters. Radiology Vol. 152 No. 2, 1984, pages 497-501

Formula: $GA = 8.96 + 0.54(HC) + 0.0003(HC^3)$

Range: 5.41 cm to 35.8 cm

Biparietal Diameter (BDP) Gestational Age (GA) using Hadlock method

Reference: Hadlock F.P., Deter R.L., Harrist R.B., Park S.K. Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters. Radiology Vol. 152 No. 2, 1984, pages 497-501

Formula: $GA = 9.54 + 1.482(BPD) + 0.1676(BPD^2)$

Range: 1.4 cm to 10.2 cm

Estimated Fetal Weight (EFW) with 4 (BDP, HC, AC, FL) using Hadlock method

Reference: Hadlock F.P., Harrist R.B., R.S. Sharman, R.L. Deter Park S.K. "Estimation of fetal weight with the use of head, body and femur measurements: A prospective study" Am.

J. Obstet. Gynecol. 1985; 151: 333-337

Formula: $EFW = 10^{1.3596 - 0.00386 \times AC \times FL + 0.0064 \times HC + 0.00061 \times BPD \times AC + 0.0424 \times AC + 0.174 \times FL}$

Glossary

Glossary

Chapter 8

For ultrasound terms not included in this glossary, refer to Recommended Ultrasound Terminology, Third Edition, published in 2011 by the American Institute of Ultrasound in Medicine (AIUM).

Term	Definition
ALARA	As low as reasonably achievable. The guiding principle of ultrasound use, which states that patient exposure to ultrasound energy should be kept as low as reasonably achievable for diagnostic results.
Anonymize	Remove patient identifying information from ultrasound images and other information related to the ultrasound exam.
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.
Device	A device that transforms one form of energy into another form of energy. Ultrasound devices contain piezoelectric elements, which when excited electrically, emit acoustic energy. When the acoustic energy is transmitted into the body, it travels until it encounters an interface, or change in tissue properties. At the interface, an echo is formed that returns to the device, where this acoustic energy is transformed into electrical energy, processed, and displayed as anatomical information.
DICOM	Digital Imaging and Communications in Medicine (standard for transferring medical images between systems).
EW	Stands for Exo Works point-of-care ultrasound workflow software.
Exam source	Location where the exam was performed (Emergency Department, Critical Care, Anesthesia, other).
Exam type	The type of exam performed based on the patient's indications (Ex: FAST exam, Cardiac exam, Biliary exam, DVT, other). The number of exam types includes Diagnostic and Procedural and can range from 12 types to 30 types based on the advancement of a department's ultrasound program.
FOV	Field of view, which is the dimensions of the exact anatomic region included in a scan.
HIPAA	Health Insurance Portability and Accountability Act, a 1996 Federal law that restricts access to individuals' private medical information.
MI	Mechanical index, which is an indication of the likelihood of mechanical bio effects occurring: The higher the MI, the greater the likelihood of mechanical bio effects. See Acoustic Output for a more complete description of MI.
MI/TI	Refer to mechanical index (MI) and thermal index (TI).
Notes	Ultrasound exam documentation specifying Indications, Views, Findings, Interpretation and more.
PACS	Picture Archive and Communications System - archive to store DICOM images in healthcare.

Term	Definition
PHI	Protected Health Information - under US law is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or a Business Associate of a Covered Entity such as a hospital) and can be linked to a specific individual/patient.
pMUT	Piezoelectric micromachined ultrasonic transducer.
POCUS	Point-of-Care Ultrasound (ultrasound performed at the bedside).
ROI	Region of interest
Subscription model	Pricing model whereby the customer pays a recurring fee for use of products and services.
Tags	Short text strings used to quickly locate exams of interest for teaching, presentation, research and more.
TGC	Time gain compensation happens when the signal gain is increased as time passes from the emitted wave pulse.
THI	Tissue harmonic imaging, which transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution.
TI	Thermal index, which is the ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions. See Acoustic Output for a more complete description of TI.
TIB	Bone thermal index, which is 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.
TIC	**Cranial bone thermal index**, which is 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, which is a thermal index related to soft tissues.
Unassigned exam	Exams that do not have an assigned performing physician or provider.
U/S	Short for ultrasound.
variance	Displays a variation in Color Doppler flow imaging within a given sample. Variance is mapped to the color green and is used to detect turbulence.
VNA	Vendor Neutral Archive - an archive system that stores DICOM and non-DICOM images and data.
PLAPS	Posterolateral Alveolar and/or Pleural Syndrome point
Zoom	Magnify the image to see more detail.

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