Kosmos on iOS

User Guide

EchoNous

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CHAPTER 1

Getting Started

User Guide

This user guide is intended to assist you with the safe and effective operation of Kosmos. Before operating Kosmos, read this user guide and follow all the included warnings and cautions carefully. Also, pay special attention to the information in Safety (page 83).

For EU only: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Not all software versions include all the features described in this guide. Reference the software version on your device.

United States Federal law restricts this device from sale by or on the order of a physician.

User Guide Symbols

Warning: A warning describes precautions to prevent injury or loss of life.

Caution: A caution describes precautions to prevent damage to the device.

Note: A note provides supplemental information.

User Guide Conventions

The following style conventions are used in this guide:

- Numbered and lettered steps must be performed in a specific order.
- Bulleted items are lists in no specific order.
- Kosmos touch-screen icons and buttons are indicated in bold, such as **SCAN**.
- Links to other sections within the guide appear in bold and color, such as the cross-reference, see Imaging Modes & Features (page 27).
- Fundamental touch gestures for navigation and interaction:

  Tap: Touching the screen quickly with your finger

  Double-tap: Touching the screen two times in quick succession with your finger

Drag: Pressing and holding the screen with your finger, and then moving your finger across the screen to a different location.

Swipe: Moving your finger across the screen quickly

Pinch: Moving two fingers in a pinch motion or pinch release motion across the screen

Check: Tapping a check box to enable the associated function

Clear: Tapping a check box to disable the associated function

Select: Tapping a menu item from a menu list

Release Updates

New features and changes for v5.0 software for Kosmos® iOS include:

- OB/GYN preset, measurements, and calculations
- Transcranial Doppler (TCD) preset
- Vascular measurements and calculations

Features may vary between iOS and Android software. Contact your EchoNous representative for more information regarding your software.

For electronic versions of the user guides, visit the EchoNous website at echonous.com/product/resources.

Not all features are available in all markets. Please check with your local representative for availability in your region.

Intended Users

Kosmos is intended for use by qualified and trained healthcare professionals who are legally authorized to use the device in the country, state, or other local municipality where they practice. The list of potential users includes but is not limited to (based on title/geographical location): medical specialists, primary care physicians, point-of-care (POC) users, sonographers, medical healthcare technicians, nurses, nurse practitioners, physician assistants, and medical students.

Users may or may not be working under the supervision or authority of a physician.

Intended Use/Indications For Use

To help ensure the diagnostic quality of the images obtained, all patient images must be obtained by qualified and trained healthcare professionals.

Kosmos is intended for use by qualified and trained healthcare professionals in the clinical assessment of the cardiac and pulmonary systems, as well as the abdomen, by acquiring, processing, displaying, measuring, and storing ultrasound images.

Kosmos is intended for use in clinical care and medical education settings with adult and pediatric patient populations.

Kosmos includes the AI-assisted automated ejection fraction software, known as Auto EF, which is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using the Kosmos. Auto EF provides automated estimation of left ventricular ejection fraction. This measurement can assist the clinician in a cardiac evaluation. Auto EF is indicated for use on adult patients only in healthcare facilities.

Kosmos includes the Auto Anatomical Structure Labeling and View Identification, also referred to as AI FAST software, which is intended for use only by qualified and trained medical professionals for automatic real-time detection and labeling of anatomical structures during image acquisition during cardiac, thoracic/lung, or abdominal ultrasound imaging. This feature is only indicated for use on adult patients in healthcare facilities.

Kosmos includes the Bladder Biplane Caliper Volume software, also referred to as Kosmos Bladder AI, which is intended for use only by qualified and trained medical professionals to obtain ultrasound imaging of the bladder that is used to automatically determine bladder volume.

Kosmos device includes the Trio software, which is intended to assist medical professionals in the acquisition of cardiac ultrasound images. The Trio software, which includes the labeling, grading, and guidance functions, is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following cardiac standard views: parasternal long-axis (PLAX), apical 4-chamber (A4C) and apical 2- chamber (A2C).

The device is non-invasive, reusable, and designed for single-patient use.

Regarding its ultrasound imaging capabilities, Kosmos is a general-purpose diagnostic ultrasound system used for clinical applications and modes of operation.

Clinical Applications

- **Torso-One:** Cardiac, Thoracic/Lung, Abdominal (including Bladder), Obstetrics, Gynecology, and Cephalic (Adult)
- **Lexsa:** Lung, Vascular/Peripheral Vascular, Musculoskeletal, Nerve, and Image Guidance for Needle/Catheter Placement (includes needle/catheter placement, fluid drainage, and nerve block)

Modes Of Operation

Table 1. Modes of Operation

Mode	Torso-One	Lexsa	Purchasable Features
B-Mode	x	x	
M-Mode	x	x	
B + CD (Color Doppler)	x	x	
Harmonic Imaging	x		
PW Doppler	x	x	x
TDI	x		x
CW Doppler	x		x
Color Power Doppler		x	

Presets And Features

Preset/Feature	Torso-One	Lexsa	Purchasable Feature
Heart	X		
Abdomen	X		
Lung	X	X	
Vascular		X	
Nerve		X	
MSK		X	
Obstetrics	X		X
Gynecolgoy	X		X

Preset/Feature	Torso-One	Lexsa	Purchasable Feature
TCD	X		X
AI-assisted EF Workflow	X		X
AI FAST	X		X
Kosmos Bladder AI	X		X
Kosmos Trio	X		X
Auto Preset	X		X
Auto Doppler	X		X

Contraindications

Kosmos is designed for transcutaneous scanning and transthoracic echocardiography only.

Kosmos is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Show care when scanning near a wound to avoid damaging or further injuring the affected area.

United States Federal law restricts this device from sale by or on the order of a physician.

General Warnings And Cautions

System users are responsible for maintaining image quality and making accurate diagnoses.

Kosmos is not MRI compatible and should not be used in an MRI suite.

Kosmos is not for use in oxygen-rich environments.

To avoid the risk of electrical shock, do not allow any part of Kosmos (except the Kosmos probe lens) to come into contact with the patient.

To avoid the risk of electrical shock or injury, do not open the tablet or Kosmos probe enclosures for any reason. All internal adjustments and replacements, such as the battery, need to be made by a qualified Kosmos technician.

To avoid the risk of electrical shock and fire hazards, inspect the power supply, AC power cords, cables, and plugs regularly to ensure they are not damaged.

The Kosmos system is not defibrillation-proof. To prevent injury to the operator or bystander, Kosmos probes must be removed from patient contact before applying a high-voltage defibrillation pulse.

Before using Kosmos for needle guidance procedures, you must have training in the applicable interventional procedures in addition to training in the use of ultrasound imaging for needle guidance. Well-known limitations of ultrasound physics may make it difficult to visualize the needle or distinguish it from acoustic artifacts. Serious injury or complications may result from attempting an interventional procedure without proper training.

As a precaution, be careful when scanning near a wound or over a dressing.

⚠	Do not use Kosmos for intracavity imaging.
⚠	Kosmos uses Bluetooth wireless communication technology.
⚠	Keep power cords away from trafficked areas.
⚠	No modifications to this equipment shall be made without the written consent of the manufacturer, EchoNous, Inc.
⚠	Do not connect any unauthorized equipment while using the Kosmos system.
⚠	Only use tablets that have been approved as compatible by EchoNous.
⚠	All images should be interpreted only by a licensed healthcare practitioner with the appropriate training.
⚠	Results from image analysis software should not be used for screening, specific disease detection or classification, disease diagnosis, or patient management decisions.
⚠	Image analysis should only be used as an aid, and the final interpretation should be performed by a licensed healthcare practitioner with the appropriate training.
⚠	Users should be cognizant of state and local requirements regarding the use of imaging systems.

EchoNous Customer Support

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Web: echonous.com

Resources: echonous.com/product/resources

CHAPTER 2

Kosmos Overview

About Kosmos

Kosmos consists of Kosmos Torso-One or Kosmos Lexsa, connected by cable to a compatible tablet running the EchoNous Kosmos Ultrasound App. When the display is connected to a Kosmos probe, the combination is configured as a medical electrical system. The current list of compatible tablets can be found on the EchoNous website at echonous.com/product/device-compatibility.

The following probes are available for the Kosmos System:

- Kosmos Torso-One:
  - A phased array ultrasound-only probe with a smaller, more streamlined form factor to help fit in between intercostal spaces.
  - Provides portable ultrasound imaging and supports non-invasive Cardiac, Thoracic/Lung, Abdominal, Obstetrics, Gynecological, and Cephalic (Adult) imaging.

- Kosmos Lexsa:
  - A linear array ultrasound probe.
  - Provides portable ultrasound imaging and supports non-invasive Lung, Vascular/Peripheral Vascular, Nerve, Musculoskeletal, and interventional guidance (including needle/catheter placement, fluid drainage, and nerve block).

Kosmos uses pulse-echo ultrasound to generate real-time ultrasound images. This process involves transmitting high-frequency acoustic pulses from the probe into the body, detecting the returned signals, and processing the echoes using analog and digital techniques to form real-time images of anatomy and blood flow. Reference Table 4: Modes of Operation & Features for Kosmos for more information about which modes are applicable for each Kosmos Probe.

The Kosmos Link can be used as an optional accessory to provide extended scanning time for all imaging modes when used with compatible tablets. The Link also allows connecting multiple probes, which the user can select on the tablet's screen. Please visit the EchoNous website for more information.

Kosmos also includes the AI-assisted EF Workflow, Trio, AI FAST, and Kosmos Bladder AI tools.

Kosmos uses ultrasound imaging to permit a clinical assessment of the key cardiac structures, including the heart chambers, heart valves, and major heart vessels for adult and pediatric patients. As part of this clinical assessment, Kosmos permits visualization of blood flow using color Doppler technology.

The Kosmos AI-assisted EF workflow can help guide you through the calculation of left ventricular (LV) ejection fraction (EF). Kosmos uses a guided workflow to record the necessary clips. The recorded clips are then used by AI to provide an initial calculation of the EF and stroke volume (SV) with results that you can review and adjust if you need to.

More specifically, Kosmos AI provides an initial EF calculation based on identifying the end-diastolic (ED) and end-systolic (ES) frames, along with the corresponding LV contours. ED/ES frames and LV contours can then be adjusted (as necessary) or accepted as is.

While reviewing these frames, you can adjust them based on your analysis, while Kosmos (using your adjustments) computes the EF and stroke volume (SV).

Kosmos AI FAST can help guide you through a FAST exam by identifying views and labeling key anatomical structures in real time.

Kosmos Trio can assist you with A4C, A2C and PLAX view acquisition. Kosmos Trio assists with view acquisition by annotating in real time key cardiac structures, grading your image based on the 5-level ACEP-based scale, and providing directions on how to move your probe to optimize the A4C, A2C or PLAX imaging.

Kosmos Bladder AI can help determine the bladder volume by placing calipers onimages acquired during a biplane bladder exam.

SV is calculated as ED LV volume minus ES LV volume.

Features vary by software version. For more information on available features for your device, please contact you EchoNous representative.

Training

Kosmos is intended for use by clinicians with the appropriate professional qualifications and clinical training.

All users should read the generic ALARA education program provided with Kosmos (see ISBN 1-932962-30-1, "Medical Ultrasound Safety" on the USB flash drive) or the Health Canada Guidelines for the Safe Use of Diagnostic Ultrasound, available on the Health Canada website. This program outlines the guiding principle for diagnostic ultrasound, where the qualified user keeps ultrasound exposure to “as low as reasonably achievable” while performing a diagnostic examination.

In addition, users who intend to use the ultrasound imaging function must have received proper training in ultrasound. Appropriate information on training may be obtained by contacting EchoNous or your local professional body.

Kosmos Trio

Kosmos Trio training is required before first use of the software.

If you are not familiar with performing an ultrasound exam using Kosmos Trio, make sure that you receive the appropriate training before using the system, provided either by EchoNous or by a trained clinician using official Kosmos Trio training material.

It is important that you are familiar with this User Manual before use conducting an exam with Kosmos Trio.

Patient Environment

Kosmos is designed for use in a medical facility. The Link and tablet may be charged in the patient environment using the GlobTek, Inc. power supply (P005974).

Do not charge the tablet while scanning a patient unless it is connected to the Kosmos Link with the GlobTek, Inc. power supply (P005974).

Kosmos Classifications

- Kosmos Torso-One and Kosmos Lexsa are Type BF Applied Parts. The Applied Parts include the lens (front surface) of the Kosmos probe

- Kosmos Torso-One and Kosmos Lexsa are IPX7.
- Kosmos Link, with an approved power supply and a compatible tablet, is classified as a medical electrical system.
- Kosmos Link is IP32 rated.

CHAPTER 3

Using Kosmos

System Overview

Use this section to become familiar with the ultrasound system and its components.

Device Requirements

The EchoNous Kosmos Ultrasound App can only be downloaded and installed on the supported tablets listed on the EchoNous website. For a list of devices that EchoNous has tested and determined to be compatible with the Kosmos app, visit the EchoNous website at echonous.com/product/device-compatibility.

The key requirements met by the supported tablets are listed below:

- Minimum of 50 MB of storage space (plus more for patient data storage)
- Color display, minimum 203 mm (8 in)
- Touch interface
- Internally mounted speakers
- IEC 60950-1-compliant or IEC 62386-1-compliant
- Only one USB port
- Date/time configuration
- Full compliance with the USB On-The-Go standard
- 2560 x 1600 resolution (minimum)
- Wireless or cellular networking capability
- Audio capability
- Front- and rear-facing cameras

Please review all safety considerations in the Safety (page 83) section of this manual. The tablet must have the corresponding ratings to be used within the specified environmental conditions.

Kosmos Hardware

> ⚠ Contact EchoNous or your local representative for a list of accessories available from or recommended by EchoNous.

The following images highlight key features of Kosmos Torso-One, Kosmos Lexsa, and the Kosmos Link.

Figure 1. Kosmos Torso-One

Figure 2. Kosmos Lexsa

Figure 3. Kosmos Link

⚠ Charge the Kosmos Link with the included GlobTek power supply (P005974).

Getting Started

EchoNous Kosmos Ultrasound App

1. Connect the tablet to Wi-Fi.
2. If applicable, delete the previously installed version of the Kosmos App from the tablet.

   Ensure you have archived data before deleting the previously installed version of the Kosmos App from the tablet.

3. Download the newest version of the EchoNous Kosmos Ultrasound App from the Google Play Store.

   When prompted, follow on-screen instructions to ensure probe recognition.

Connecting Kosmos Probes

Before each use, inspect Kosmos Torso-One and/or Kosmos Lexsa for damage, such as cracks, splitting, or sharp edges. If damage is evident, discontinue using the Kosmos probe(s) and contact your EchoNous representative.

Only use devices and accessories recommended by EchoNous.

To connect Kosmos Torso-One or Kosmos Lexsa to compatible tablets:

1. Plug the Kosmos probe cable into the tablet's USB-C port on the side. For information on using the Kosmos Link, refer to Kosmos Link (page 11).
   - To register your transducer and licensed features for the first time, the probe must be connected to the device, and your device must be connected to the internet. This step may take a few minutes.
2. When ready to start scanning, tap the preset of your choice.

Kosmos Link

Kosmos Link, or simply Link, is a power source that allows the use of all features on compatible tablets and provides extended scanning time with Kosmos probes. Please visit echonous.com/product/device-compatibility for an updated list of compatible tablets.

Setting Up Kosmos Link

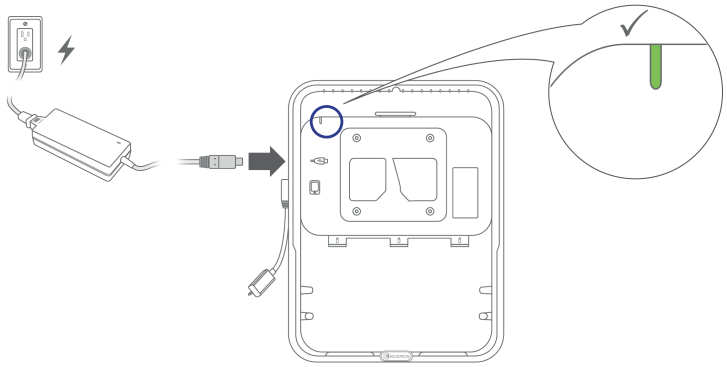
The Link is intended to be used only with compatible tablets. Please contact your EchoNous representative for additional details.

Ensure Link is placed such that the probe connection port, charging port, and wall outlet are accessible.

For more detailed Link instructions, please refer to the Kosmos Link Quick Guide (P008154).

Ensure the Kosmos Link is securely attached to the tablet before use.

Ensure Link is securely mounted on the stand or safely placed on a tabletop with the kickstand fully extended prior to use.



1. Charge the Kosmos Link until the LED turns green before use.
2. To install the tablet onto the Link, bring the tablet/bracket assembly to the front face of the Link.
3. Slide the tablet downward, ensuring it moves along the rubber seal on the front of the Link. The orange slider button (under the rubber cap) will move over, then snap back to its original position. This indicates that the tablet is securely connected to the Link.
4. Connect the Link USB-C cable to the tablet's USB-C port.

Removing The Tablet From Kosmos Link

To remove the tablet, pull the orange slider button, then lift the tablet upward until it is free of the Link.

Charging Kosmos Link

1. Probes may stay connected during charging.
2. Connect the charger to the Link. Once connected, the LED on the Link will indicate the general battery power level: white indicates low, blue indicates mid-range, and green indicates full (see Table 2: Battery Status Level).

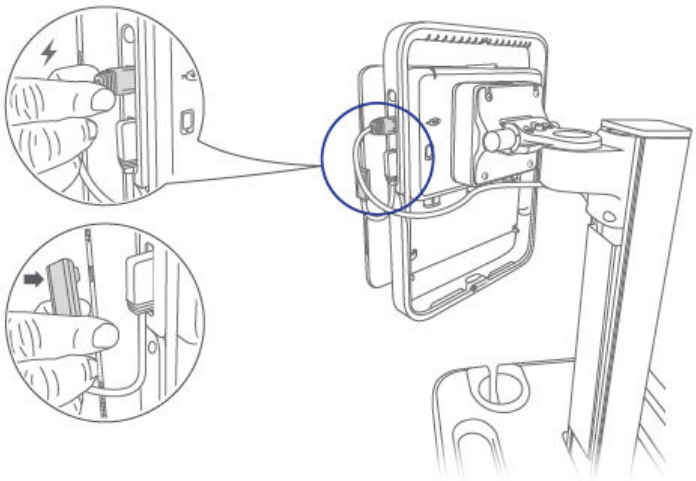
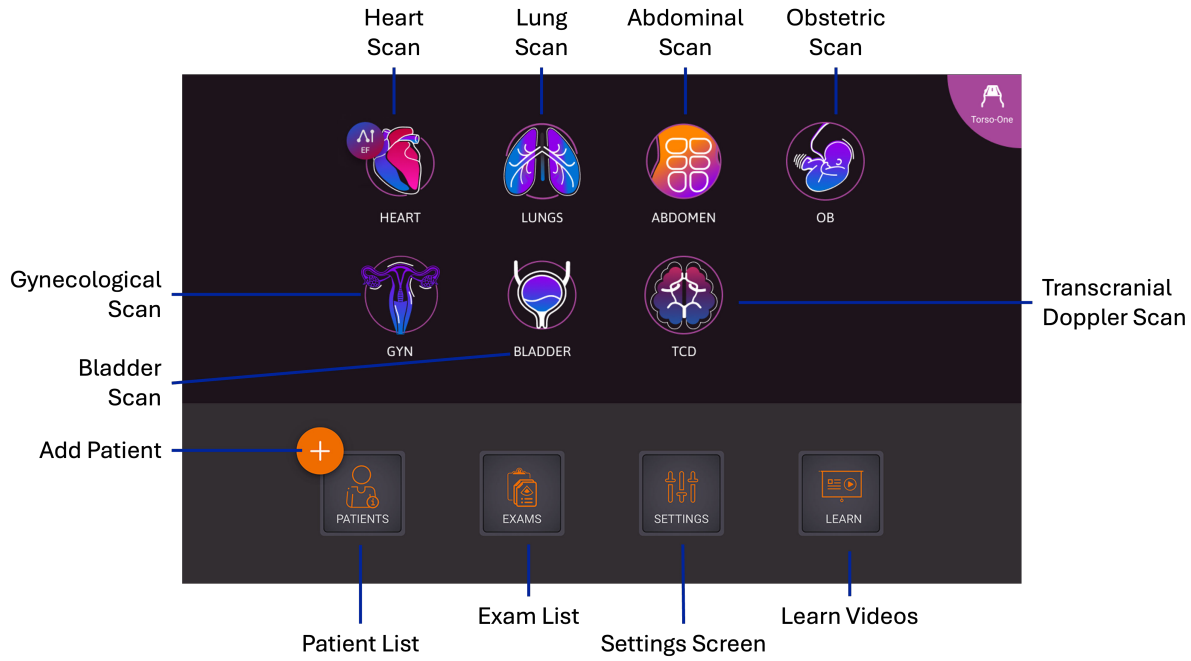


Table 2. Battery Status Level

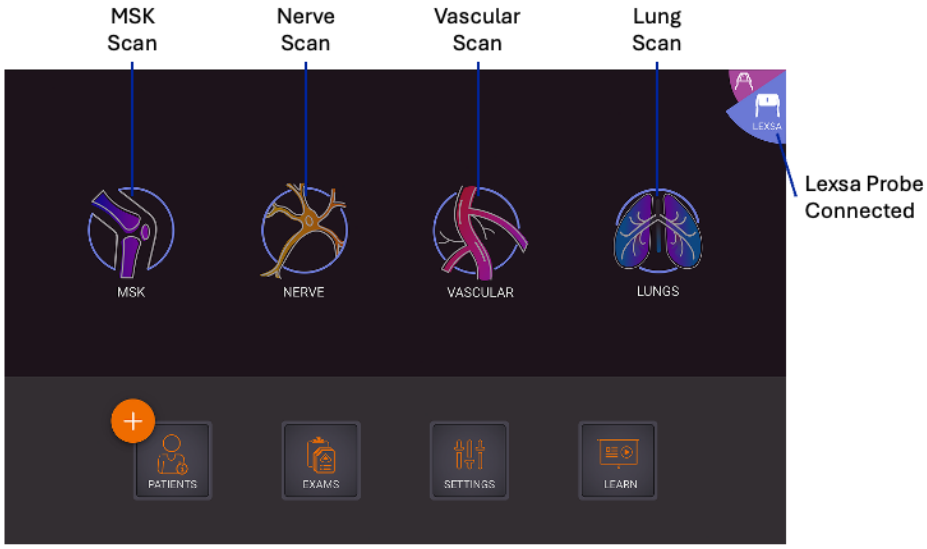
Battery Status	0%-20%	20%-80%	80%-100%
No Charging	Solid White	Solid Blue	Solid Green
Charging	Flashing White	Flashing Blue	Flashing Green

General Interaction

Home Screen: Kosmos Torso-One



Home Screen: Kosmos Lexsa



Learn

To access the how-to videos available on https://echonous.com/product/training-and-in-service-videos/, ensure your device is connected to Wi-Fi and tap **Learn**.

Settings

Once you have configured your system settings, they remain as you set them whenever you log back on to the Kosmos App.

Imaging Preferences

The Imaging Preferences screen lets you customize the information displayed on the Imaging screen.

To set the imaging preferences:

1. From the Home screen, tap **SETTINGS** → **Imaging Preferences**.
2. To have certain information display in the top bar of the Imaging screen, tap one of the following options under **Customize information**:
   - **Name of facility** —Displays the name of your organization in the top bar of the imaging screen.
   - **Patient name** —Displays the patient name in the top bar of the imaging screen.
   - **Patient ID** —Displays the patient ID in the top bar of the imaging screen.
3. To configure the way Kosmos records clips, tap one of the following options under **Record clip**:
   - **Retrospective** —Captures frames from the cine buffer when you tap the **Record Clip** icon. Kosmos captures cine buffer frames for the specified number of seconds.
   - **Prospective** —Captures frames after you tap the **Record Clip** icon. Kosmos captures frames for the specified number of seconds.
4. To set the length of the clips, select a time from the **Clip duration** area.

   During an exam, if you tap the **Record Clip** icon again, you can finish the recording earlier than the clip duration defined here.
5. To adjust the horizontal screen split between M-Mode and B-Mode, select from the following options under **M-Mode layout**:
   - **1:2** —Tap this option to adjust the screen split so the M-Mode area is twice as big as B-Mode.
   - **1:1** —Tap this option to adjust the screen split so that the M-Mode and B-Mode areas are equal.
6. From the **Thermal index display** area, select from the following:
   - **TIS** —Thermal index for soft tissue.
   - **TIB** —Thermal index with bone near the focus.
7. Select the **cardiac imaging orientation** preset:
   - Select **Left** or **Right** orientation.
8. To enable Auto Functionality features, tap the toggle to switch to the **ON** position.
   - **Auto Doppler** —When scanning in cardiac PW and TDI modes, use Auto Doppler for AI-assisted auto placement of PW and TDI sample gates.
   - **Auto Preset** —When scanning in Heart, Lung, and Abdomen presets, the AI-assisted Auto Preset feature will recognize anatomy and automatically transition to the appropriate preset.
9. For **PW** and **CW modes**, select from the following:
   - Synchronized focal point/gate and color box.
   - Decoupled focal point/gate and color box.

Configuring Connected Devices

Make sure you are connected to your network (see IT Network (page 115)) before trying to connect to another device.

Connect a Device via Bluetooth

1. From the Home screen, tap **SETTINGS** → **Connected Devices**.

2. Tap the button on the right side of the screen to turn on wireless.
3. Tap **Bluetooth** → **Pair new device**.
4. Tap the device of your choice.

Connect a Device to Cast

1. From the Home screen, tap **SETTINGS** → **Connected Devices**.
2. Tap the button on the right side of the screen to turn on wireless.
3. Tap **Cast**.
4. Tap the device of your choice.

About

The About section provides essential information about your device, including the Kosmos software version, model number, device registration status, and licensed features. You will also be able to access transducer information, perform a transducer element check, and find support contact information.

1. From the Kosmos app's Home screen, go to **SETTINGS** → **About**.
2. If you have not registered for Kosmos, tap **Register**. This will connect your Kosmos device to the EchoNous cloud. Make sure your device is connected to the internet.
3. To run the transducer element check, tap **Check**.

DICOM Settings

Manage your modality worklist (MWL) and PACS archive from the DICOM settings.

New systems do not come with any configured profiles.

You cannot have two PACS profiles active at the same time; when you add a new profile, the current one is deactivated.

Adding a PACS Profile

If you are adding a new PACS-SCP profile and already have an existing one, the system deactivates the existing profile. However, all the jobs in the existing queue and any scheduled archives must first be completed.

1. From the Home screen, tap **SETTINGS**.
2. Tap **DICOM** → **PACS archive**.
3. Tap **ADD PROFILE**.
4. Type the following information in the **DICOM connection** area:
   - **Station AE title** — Kosmos' Application Entity title
   - **Server AE title** — Archive server's Application Entity title
   - **Server IP address** — Archive server's unique identifier
   - **Server port number** — Archive server's port number
5. To make sure the connection is working on an active profile, tap one of the following:
   - **PING** to test the network connection between Kosmos and the PACS archive.
   - **Verify** to check the availability of the active PACS archive.
     The results are displayed on-screen.
6. In the **Profile nickname** box, type a unique name to display in the PACS profile list.
7. In the **Archival options** area, select from the following options:

- **Prompt options every time** — Switched on by default; each time you tap the Archive button from the Exam review screen, a pop-up menu with different options displays. If you turn the switch off, Kosmos does not display the pop-up menu.
- **Attach report** — Switched off by default. If you turn it on, Kosmos attaches a report to the archive.
- **Attach DICOM SR report** — Switched off by default. When selected, Kosmos will attach the DICOM SR report to the archive.

8. In the **Auto archive** area, select from the following options:
   - **On/Off** — The Auto archive is Off by default. This means that all the controls (except the on/off switch) are disabled and cannot be edited. If you turn the switch On, all the controls are enabled and can be edited.
   - **Archival frequency**
     - **Completion of exam** — The archival time selector is disabled.
     - **Daily** — Only the time section of the archival time selector is enabled.
     - **Weekly** — The complete archival time selector is enabled
     - **Archival time** — Select a daily time and day to archive exams.

   If you turn on Auto archive, make sure the Kosmos App is always running in the background. Closing the Kosmos App will pause the archives. Go to Job Queue to resume or retry if job(s) are not successfully archived.

9. In the **Retry interval (in seconds)** area, select **60**, **300**, or **600**.
10. In the **Maximum retries** area, select **1**,**2**, or **3**.
11. To have the system automatically retry failed jobs, keep the switch set to **On**; otherwise, slide it to **Off**.

Deactivating a PACS Profile

In the **PACS archive** list, tap the switch to toggle between **Active** and **Inactive**.

TLS Setting for DICOM

1. On the active profile page, tap**SETTINGS** → **DICOM**.
2. Scroll down to the TLS Encryption section and turn on **TLS Encryption**.
3. Select **SCU Security** option: **Anonymous** or **Authenticated**.
4. Select the SCP Certificate option: **Select TLS Certificate** or **Select TLS Certificate from Device**.

- **Select TLS Certificate** — Displays the file explorer for the user to select the certificate provided by the administrator.
- **Select TLS Certificate from Device** — Displays a list of certificates already configured in the application.

Deleting a PACS Profile

Deleting a PACS profile also deletes all configurations of the profile. There must be an active PACS profile before you can archive any exams.

1. From the Home screen, tap **SETTINGS**.
2. Tap **DICOM** → **PACS archive**.
3. From the list of profiles, tap to slide the arrow to the left of the profile you would like to delete.
4. Tap the **Delete** icon.

Managing MWL

New systems do not come with any configured profiles.

You cannot have two MWL profiles active at the same time; when you add a new profile, the current one is deactivated.

Adding an MWL Profile

1. From the Home screen, tap **SETTINGS**.
2. Tap **DICOM** → **MWL**.
3. Tap **ADD PROFILE**.

   If you are adding a new MWL profile and already have an existing one, the system deactivates the existing profile.

4. Type the following information in the **DICOM connection** area:
   - **Station AE title** —Kosmos' Application Entity title.
   - **Server AE title** —Archive server's Application Entity title.
   - **Server IP address** —Archive server's unique identifier.
   - **Server port number** —Archive server's port number.
5. To make sure the connection is working on an active profile, tap one of the following:
   - **PING** to test the network connection between Kosmos and the MWL server.
   - **Verify** the availability of the active MWL server. The results are displayed on-screen.
6. In the **Profile nickname** box, type a unique name to display in the MWL profile list.

Deactivating an MWL Profile

In the **MWL** list, tap the switch to toggle between **Active** and **Inactive**.

Deleting an MWL Profile

Deleting an MWL profile also deletes all configurations of the profile.

1. From the Home screen, tap **SETTINGS**.
2. Tap **DICOM** → **MWL**.
3. From the list of profiles, tap to slide the arrow to the left of the profile you would like to delete.
4. Tap the **Delete** icon.

Configure USB Export Preferences

1. From the Kosmos app's Home screen, go to **SETTINGS** → **USB export**.
2. Check the box to enable exporting exams to a USB drive.
3. Select the file type.

Report Settings

1. From the Kosmos app Home screen, go to **SETTINGS** → **Report Settings**.
2. Select the report type: **Cardiac**, **OB**, **GYN**, or **Abdomen**.

Wireless Networking

Functions

You can connect Kosmos to an IT network to perform the following functions:

- Store exam data (static images and clips) in a Picture Archiving and Communication System (PACS) via DICOM communication.
- Synchronize the Kosmos system time by querying the network's time service.

Connection Specifications

Hardware Specifications

- 802.11 a/b/g/n/ac
- Bluetooth 4.0 or later

Software Specifications

Kosmos communicates with PACS using the DICOM standard. For more information, refer to the DICOM Conformance Statement available on the EchoNous website.

Use Restrictions

This device is restricted to indoor use when operating in the 5150-5350 MHz frequency range.

This restriction applies in the following regions: AT, BE, BG, CH, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR, UK.

CHAPTER 4

Performing An Exam

Overview

Ensure your device is fully charged before using Kosmos for a critical procedure, such as needle guidance, to avoid interruption due to a drained battery, which could harm the patient.

The maximum temperature of a Kosmos probe scan head may be greater than 41 °C but is less than 43 °C when in contact with the patient for normal use. Special precautions should be considered when using the transducer on children or other patients sensitive to higher temperatures.

To reduce the risk of infection, use sterile sheaths when conducting needle procedures.

To avoid a mix-up of patient data, complete the exam before examining a new patient.

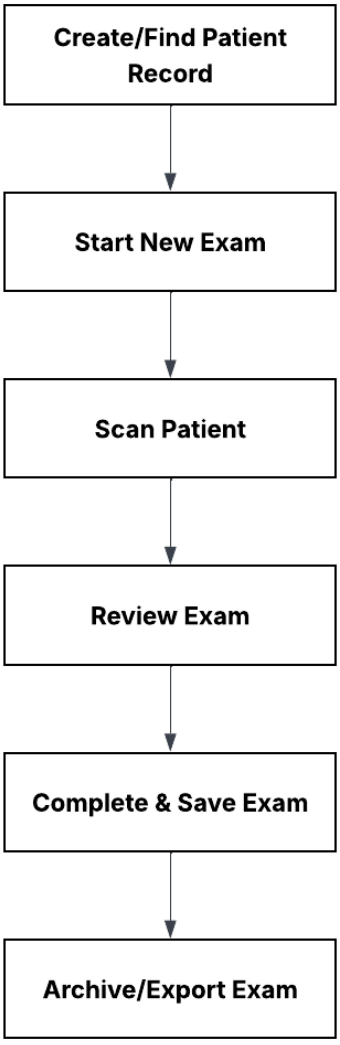
Not all features are available in every market and vary by regionally released software versions. For more information on available features for your device, contact your EchoNous representative.

Primary Exam Workflows

With Kosmos, there are two primary exam workflows; click one of the links to go to that workflow:

- Standard Workflow (page 20) starts with creating a patient or searching for an existing one.
- Quick Workflow (page 22) starts with scanning a patient.
- AI-assisted EF Workflow (page 21) uses AI to perform initial EF calculations.
- Kosmos Bladder AI Workflow (page 23) uses AI to place calipers to measure bladder volume.

Standard Workflow



Optional Step:

Start scanning immediately, then go back and connect the exam to the correct patient.

While Scanning:

You can:

- Add and delete images and clips.
- Add, edit, and delete annotations and notes.

While Reviewing:

You can:

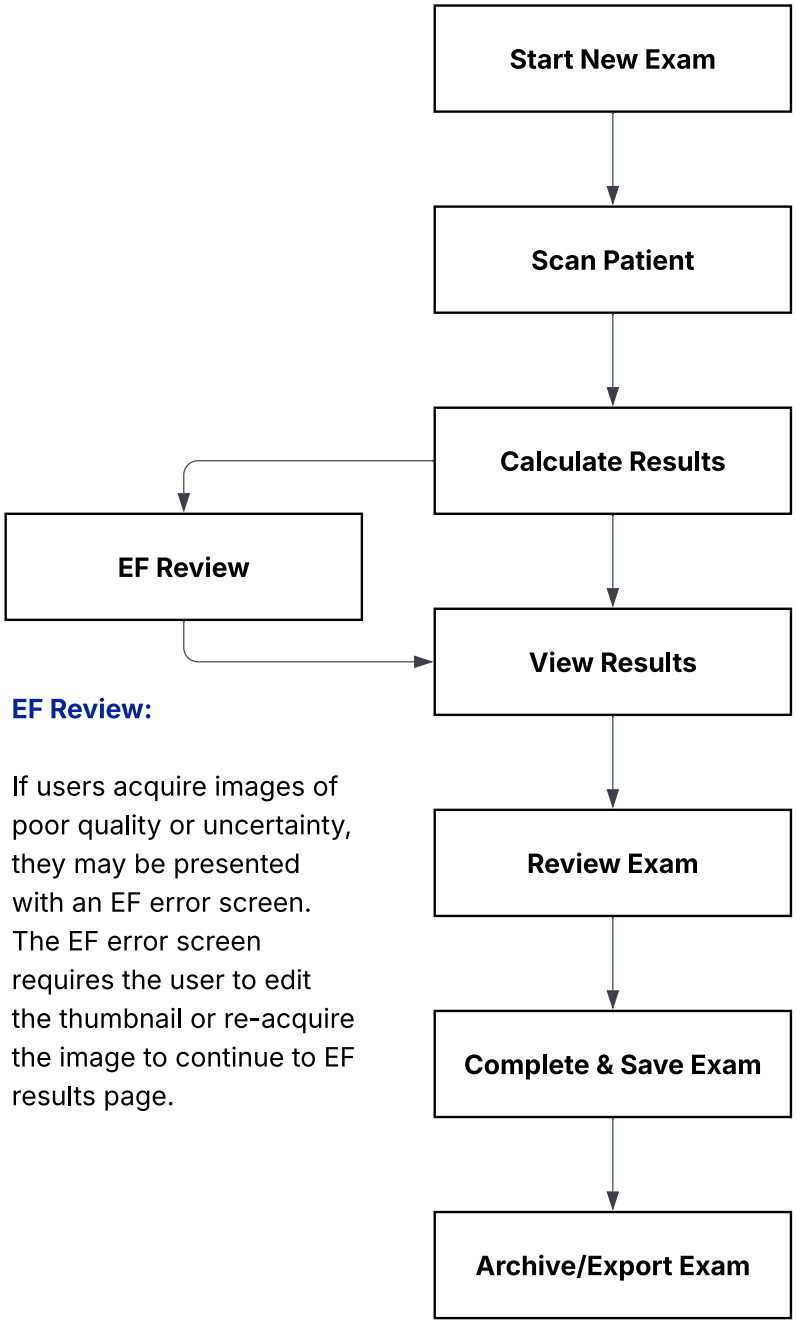
- Delete images and clips.
- Add, edit, and delete annotaitons and notes.
- Generate reports.

Optional Steps:

You can:

- Archive exam to PACS.
- Exportexam to USB.

AI-Assisted EF Workflow



While Scanning:

Record or retry A4C and A2C clips with or without Kosmos Trio (Auto-Labeling, Auto-Grading, and Auto-Guidance).

EF Review:

If users acquire images of poor quality or uncertainty, they may be presented with an EF error screen. The EF error screen requires the user to edit the thumbnail or re-acquire the image to continue to EF results page.

While Reviewing:

You can:

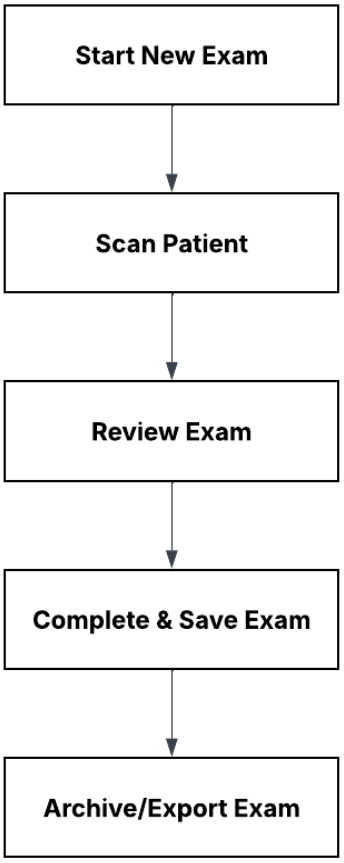
- Edit ED/ES frames and LV contours.
- Delete scans.
- Generate reports.

Optional Steps:

You can:

- Archive exam to PACS.
- Exportexam to USB.

Quick Workflow



While Scanning:

You can:

- Add and delete images and clips.
- Add, edit, and delete annotations and notes.

While Reviewing:

You can:

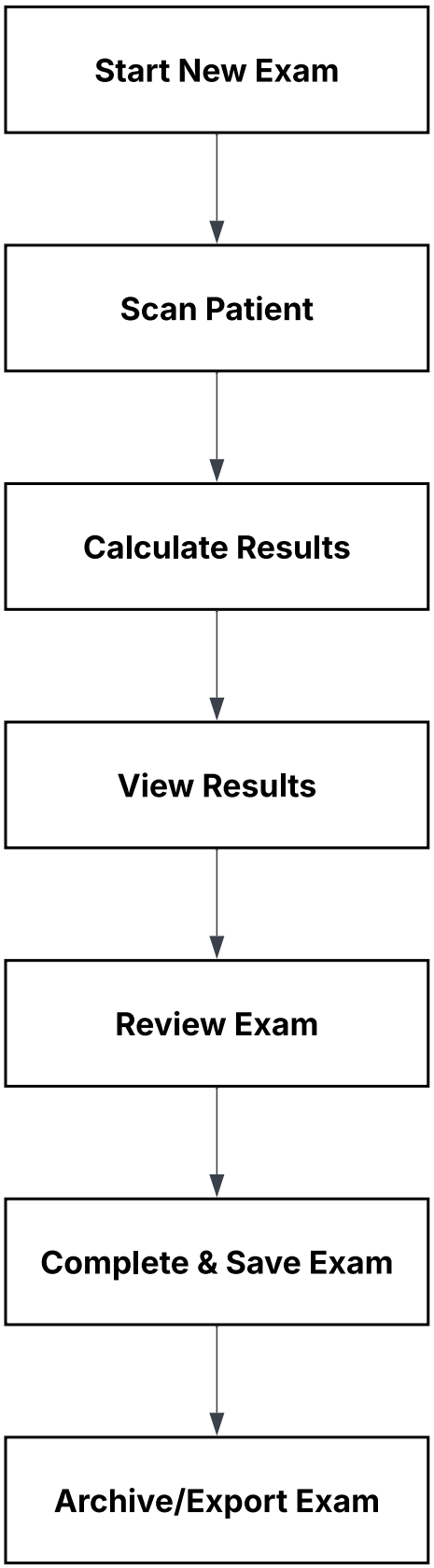
- Delete images and clips.
- Add, edit, and delete annotaitons and notes.
- Generate reports.

Optional Steps:

You can:

- Archive exam to PACS.
- Exportexam to USB.

Kosmos Bladder AI Workflow



While Scanning:

- Kosmos Bladder AI provides navigational guidance to center the bladder in the field of view.
- Provides on-screen probe placement and fanning animations for Transverse view acquisition.
- Provides on-screen probe placement and fanning animations for Sagittal view acquisition.
- Automatic placement of the calipers for measurements.

Optional Steps:

You can:

- Archive exam to PACS.
- Exportexam to USB.

Managing Exams

Start An Exam

There are several ways you can start an exam:

- To start scanning immediately, from the Home screen, tap a preset and begin scanning.

When you save the exam, Kosmos automatically generates a temporary ID and saves the images/clips to the temporary ID.

1. From the Home screen → **PATIENTS** → **NEW PATIENT** → **SCAN**.
   - Use the **Add** icon as a shortcut to add a new patient.
2. For existing patients, from the Home screen → **PATIENTS** → Select a patient from patient list → **SCAN**.
3. From the Home screen → **EXAMS** → **NEW PATIENT** or look up an existing patient → **SCAN**.

Search For An Exam

1. From the Exam screen, tap the **Search** icon.
2. Type the search criteria, such as date, patient name, date of birth, or medical record number.
3. From the list of search results, tap the exam you want to view. Each exam listed shows the number of scans taken, as shown below.

Acquire Images And Clips

- To acquire an image, tap the **Save image** icon from the Imaging screen.
- To acquire a clip, tap the **Save clip** icon from the Imaging screen.

Deleting An Exam

To delete an exam from the Exam list:

1. Tap the left icon next to the exam you would like to delete. The icon turns into a **check mark** .
2. Tap the **Delete** icon.
3. When prompted, tap **OK**.

To delete an exam while reviewing it:

1. Tap the **More options** icon.
2. Tap **Delete the exam**.

When prompted, click **OK**.

Complete An Exam

To maintain accurate patient association for all saved images and clips, complete the current exam before capturing data for a new patient.

1. From the Imaging screen, tap the **Exam review** icon.

You can only interact with this icon if there are clips or images already saved during the exam. This is indicated by the number in the upper right hand corner of the icon.

2. Tap **COMPLETE**.
3. At the prompt, tap **OK**.

If you do not tap **COMPLETE** from the Exam review screen, Kosmos automatically completes the exam:

- When you start a new exam
- When you archive the in-progress exam
- After a few minutes
- When the app is closed
- If another app is opened and the Kosmos app goes in the background

Managing Patient Data

Add A New Patient

1. From the Home screen, tap the **Add** icon on the **PATIENTS** button.
2. Enter the patient information.
3. Optionally, you can enter exam information. Additional fields become available when OB or GYN exam types are selected.
4. Tap **SCAN** when you are done.

Access Patient Information Using MWL

If Kosmos is connected to a healthcare information system with MWL capability configured, you can retrieve patient information directly from the system.

1. From the Home screen, tap the **PATIENTS** button.
2. Tap the **MWL** button. Tap the **Expand** icon to see the entire list.
3. Tap the **Filter** icon to search for a specific patient.
4. Tap **SCAN** to start scanning.

Search For A Patient

1. From the Home screen, tap **PATIENTS**.
2. Tap the **Search** icon.
3. Type the search criteria for the patient you are looking for, such as name, date of birth, or medical record number.
4. Select the patient from the search result list, and tap **DONE**.

Change To Another Patient

You can switch to a different patient or add a new patient once an exam is in progress.

1. From the New Exam screen, tap **CHANGE**.
2. Do one of the following:
   - To change to another patient, tap **ADD NEW**, then complete the patient form.
   - To look for an existing patient, tap **SEARCH HISTORY**, use the search tool to find the patient, and tap the patient's name from the list.

Edit A Patient Record

1. From the Home screen, tap **PATIENTS**.
2. From the Patient list, double-tap the patient record you want to edit.
3. Enter the patient information, then tap **SAVE** when you are done.

Merge Patient Records

If you have saved two or more patient records for a single patient, you can merge all exams for that patient into a single patient record.

> You cannot merge temporary patients.

To merge two patients, make sure the following fields are complete:

- First name
- Last name
- Date of birth
- Gender

1. From the Home screen, tap **PATIENTS**.
2. Tap to select a patient.
3. From the **Patient review** screen, tap the **More options** ⋮ icon.
4. Tap **Merge to patient**.
5. From the list, tap the other patient you want to merge.
6. Tap **NEXT**.
7. Tap the fields to keep for the patient.
8. Tap **MERGE**, then tap **OK**.

Delete A Patient Record

To delete all patient records without exams:

1. From the Home screen, tap **PATIENTS**.
2. Tap the **More options** ⋮ icon.
3. Tap **Delete all patients without exams**.

To delete selected patient records:

1. From the **Home** screen, tap **PATIENTS**.
2. Tap one or more patient names from the patient list.
3. Tap the **Delete** icon.

Organ Presets

Table 3: Organ Presets by Kosmos Probe below provides an overview of the organ presets that are available for each Kosmos probe.

Table 3. Organ Presets by Kosmos Probe

Organ	Torso-One	Lexsa
Heart	X	
Lung	X	X
Abdomen	X	
OB	X	
GYN	X	
Vascular		X
Nerve		X
MSK		X
Bladder	X	
TCD	X	

Imaging Modes & Features

For an overview of the applicable imaging modes for each Kosmos probe, reference Table 4: Modes of Operation & Features for Kosmos.

Table 4. Modes of Operation & Features for Kosmos

Mode	Torso-One	Lexsa
B-mode	X	X
M-mode	X	X
B + CD (Color Doppler)	X	X
Harmonic Imaging	X	
PW Doppler	X	X
TDI	X	
CW Doppler	X	
Color Power Doppler		X
Auto Preset	X	
Auto Doppler (Cardiac preset for PW and TDI imaging modes)	X	
AI-assisted EF Workflow	X	
AI FAST	X	
Kosmos Bladder AI	X	
Kosmos Trio	X	

Table 5. Supported Measurements and Calculations

Mode	Torso-One	Lexsa
Cardiac Calculations	X	
Vascular Calculations		X
Obstetrics Calculations	X	
Gynecology Calculations	X	
Transcranial Calculations	X	
Abdominal Calculations	X	

2D/B-Mode

2D/B-Mode is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude.

The 2D/B-Mode controls are hidden when in Doppler modes. You can switch between 2D/B-Mode and Doppler mode controls.

To view the 2D/B-Mode controls, tap **2D**.

M-Mode

M-Mode is also known as Motion Mode. It provides a trace of the image displayed over time. A single ultrasound beam is transmitted, and reflected signals are shown as dots of varying intensities, creating lines across the screen.

When M-Mode is turned on, the screen splits to show B-Mode and M-Mode. You can adjust depth and gain (similar to B-Mode), along with M-Mode-specific controls such as M-Line and Sweep Speed.

> While scanning with the Lexsa probe, M-Mode is only available in the Lung preset.

To start M-Mode, tap the **M-Mode** icon.

M-Line

To move the M-Line, tap and hold to enter M-Mode, then tap and drag it to the location you want.

Sweep Speed

You can change the Sweep Speed to isolate individual motions.

To change the M-Mode Sweep Speed, tap **Speed** and select: **25**, **50**, **75**, or **100** mm/sec.

Color Doppler

Color Doppler is used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states.

When using Kosmos, you can turn Color Doppler on and off without affecting the system's color acquisition.

To turn Color Doppler on and off, tap the **Color** icon.

Color Box

You can move and resize the color box 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, select its edge and drag it to another position.
- To resize the color box, select a corner to adjust its size.

Scale

Scale changes the pulse repetition frequency that defines the velocity scale, with the range shown at the top and bottom of the color map.

To change the scale, tap **Scale**.

Sensitivity

Three sensitivity range selections are available to optimize for low, medium, and high ranges.

To change the sensitivity, tap **Sensitivity** and select an option.

Wall Filter

The Wall Filter is set on the highest filter, which blocks low-frequency noise.

Tap the **Wall filter icon** to select the strength of the filter: **Low**, **Medium**, or **High**.

Steer

Steer changes the steering angle of the color ROI. There are five angles to choose from.

To select the desired angle, tap **Steer**.

> Steer is only available in Lexsa Color Doppler mode.

Artery

Artery enables Artery/Vein selection. **Artery** should be selected for arterial flow and **Vein** should be selected for venous flow.

For Artery/Vein selection, tap **Artery**.

> Artery is only available in Lexsa Color Doppler mode.

Color Map

To change the heart color map:

1. Tap the **More options** ⋮ icon next to the color map on the right side of the screen.
2. Select the color map you like.
3. To invert the color map, select the check box and tap **OK** to save the changes.

Color Power Doppler

Color Power Doppler (CPD) is used to measure the amplitude of blood flow. CPD is more sensitive to lower blood velocities and smaller vessels.

To turn Color Power Doppler on and off, tap the **CPD** icon.

> Color Power Doppler is available in Vascular, Nerve, and MSK presets while scanning with Kosmos Lexsa.

Pulsed-Wave Doppler

Pulsed-Wave Doppler (PW) mode uses short bursts of ultrasound with a process called range gating to facilitate signal analysis from a small area at a specified depth from the transducer.

> PW mode is available in the abdomen and heart preset while scanning with Kosmos Torso-One.

> PW mode is available in the Vascular, Nerve, and MSK presets while scanning with Kosmos Lexsa.

> Verify the sample gate depth to ensure the correct vessel is assessed. Failure to do so may lead to delay in care or misdiagnosis.

To start PW Doppler, tap the **PW mode** icon.

Baseline

Tap and move the **baseline** up and down in the Doppler trace.

Duplex Screen
Tap the **Update button** for the duplex screen. The frozen B-Mode image will be displayed on top with the live Doppler Trace on the bottom.

Focal Point and Doppler Line
Adjust the **Focal Point** and the **Doppler Line** by moving the dotted circle. In the abdomen preset, tap the focal point to see view and set the angle adjust line. If color mode is on, moving the circle will also move the color box. The circle and the color box can be decoupled by going to **SETTINGS** → **Imaging Preferences**.

Live Display
Tap the **Live display** to toggle between PW live and B live modes. In the B live mode, the Doppler trace is frozen.

Wall Filter
The Wall Filter is set on the highest filter, which blocks low-frequency noise.

Tap the **Wall filter icon** to select the strength of the filter: **Low**, **Medium**, or **High**.

Invert
To invert the Doppler spectrum, tap on the **Invert** button.

Scale
Scale changes the pulse repetition frequency that defines the velocity scale, with the range shown at the top and bottom of the color map.

To change the scale, tap **Scale**.

Doppler Gain
Gain controls the brightness/strength of the Doppler spectrum.

To adjust Doppler gain, tap **Gain**.

Audio Gain
Audio Gain controls the strength of the audio volume.

To adjust the Audio gain, tap **Audio gain**.

Sweep Speed
You can change the Sweep Speed to isolate individual motions.

To change the M-Mode Sweep Speed, tap **Speed** and select: **25**, **50**, **75**, or **100** mm/sec.

Tissue Doppler Imaging
Tissue Doppler Imaging (TDI) Mode uses Doppler to measure myocardial velocity throughout the cardiac cycle.

To start TDI Mode, tap on the **TDI Mode** icon. TDI is available in B-Mode and Color (B+C) Mode screens.

TDI Mode is only available in abdomen and heart presets while scanning with Kosmos Torso-One.

Continuous-Wave Doppler

Continuous-Wave Doppler (CW) mode uses continuous transmission and reception of ultrasound waves to measure blood velocities.

When CW is used for a prolonged period, auto-freeze goes into effect to manage probe temperature. A 60-second timer appears every time before the auto-freeze.

CW mode is only available in the abdomen preset and heart preset while scanning with Kosmos Torso-One.

To start CW Doppler, tap the **CW mode** icon.

Duplex Screen

Tap the **Update button** for the duplex screen. The frozen B-Mode image will be displayed on top with the live Doppler Trace on the bottom.

Focal Point and Doppler Line

Adjust the **Focal Point** and the **Doppler Line** by moving the dotted circle. In the abdomen preset, tap the focal point to see view and set the angle adjust line. If color mode is on, moving the circle will also move the color box. The circle and the color box can be decoupled by going to **SETTINGS → Imaging Preferences**.

Baseline

Tap and move the **baseline** up and down in the Doppler trace.

Live Display

Tap the **Live display** to toggle between PW live and B live modes. In the B live mode, the Doppler trace is frozen.

Wall Filter

The Wall Filter is set on the highest filter, which blocks low-frequency noise.

Tap the **Wall filter icon** to select the strength of the filter: **Low**, **Medium**, or **High**.

Invert

To invert the Doppler spectrum, tap on the **Invert** button.

Scale

Scale changes the pulse repetition frequency that defines the velocity scale, with the range shown at the top and bottom of the color map.

To change the scale, tap **Scale**.

Doppler Gain

Gain controls the brightness/strength of the Doppler spectrum.

To adjust Doppler gain, tap **Gain**.

Audio Gain

Audio Gain controls the strength of the audio volume.

To adjust the Audio gain, tap **Audio gain**.

Save Clips and Images

Tap **Freeze** to review or save images and clips directly. Audio will also be saved in clips.

Auto Preset

When scanning in a selected preset, the Auto Preset feature will recognize anatomy and automatically transition to the appropriate preset. This feature is only available for Torso-One.

To enable Auto Preset, go to **SETTINGS** → **Imaging Preferences** and use the toggle to enable the feature.

- Users are provided 3 seconds to reject the transition from the selected preset to the auto-adjusted preset.

  If the user rejects the transition to the auto-adjusted preset, Auto Preset will be disabled for the rest of the exam. Users can turn Auto Preset back on by selecting the Preset drop-down menu.

- Please reference Table 6: Auto Preset Scenarios for a list of Auto Preset scenarios.

Table 6. Auto Preset Scenarios

User Selected Preset	Anatomy Scanned	Kosmos Auto Adjusted Preset
Abdomen	Lung	Lung
Abdomen	PLAX, PSAX, (AV, MV, PM, Apex), A4C, A2C, A3C, A5C, SSN, RVOT, RVIT	Heart
Lung	RUQ, LUQ, SUP, Abdominal Aorta (sagittal view), Aortic Sweep	Abdomen
Lung	PLAX, PSAX, (AV, MV, PM, Apex), A4C, A2C, A3C, A5C, SSN, RVOT, RVIT, IVC, Subcostal 4C	Heart
Heart	RUQ, LUQ, SUP, Abdominal Aorta (sagittal view), Aortic Sweep	Abdomen
Heart	Lung	Lung

Auto Doppler

The Auto Doppler feature will automatically place the Doppler gate in selected views. This feature is only available in PW and TDI modes for Torso-One in the Cardiac preset.

To enable Auto Doppler, go to **SETTINGS** → **Imaging Preferences** and use the toggle to enable the feature.

- Users will still be able to place the gate manually when the Auto Doppler feature is enabled.
- Please reference Table 7: Auto Doppler Gate Placement by Mode for a list of automatic Doppler gate placements.

Table 7. Auto Doppler Gate Placement by Mode

Mode	Gate Placement	View
PW	Mitral Valve	A4C
PW	LV Outflow Tract	A5C
PW	Tricuspid Valve	A4C
PW	Pulmonary Valve	RVOT, PSAX AV
TDI	MV Septal Annulus	A4C
TDI	MV Lateral Annulus	A4C
TDI	TV Lateral Annulus	A4C

Image Mode Controls

Flip an Image

You can only flip an image from right to left when you are scanning the heart.

To flip the image, double-tap the orientation marker.

Adjust Depth and Gain

- To increase or decrease the displayed depth, tap **Depth**, and move the Depth wheel up and down.
- To adjust gain in Color Doppler Mode and B-Mode, tap **Gain**, and move the slider up and down.
- To adjust near and far gain, tap **TGC**, and move the sliders left and right. Notice the gain values automatically update as you adjust the sliders.

Zoom In and Out

- While scanning, use two fingers to pinch and expand the image area.
- To return to the default image size, tap the **magnifying glass** icon.
- Notice that the zoom factor is shown near the magnifying glass, and that the depth scale is orange in the side image area.
- You can freeze while zoomed and can zoom out and zoom in while frozen.

Freeze an Image

To freeze an image, tap the **Freeze** icon.

The Annotation Tools (page 71) automatically display on the left side of the screen.

Kosmos AI-Assisted EF Workflow (Auto EF)

Using Kosmos AI-Assisted EF Workflow

The AI-assisted EF workflow guides you through the steps of data acquisition followed by an AI-based initial EF calculation which is based on the American Society Echocardiography (ASE)-recommended modified Simpson's method of disks (Lang 2005, 2015). The initial LV contours are produced with AI algorithms that have been trained on expert-annotated LV contours (Ronneberger 2015). You can then review the initial AI results (which include the ED/ES frames along with the correspondingLV contours), and adjust them, as necessary.

Calculating LVEF Using AI-Assisted EF Workflow

After four (4) seconds, Kosmos automatically accepts the clip.

When the A4C and A2C clips are recorded and accepted, the system selects the ED and ES frames, draws the corresponding LV contours, and calculates the biplane EF using the modified Simpson's method of disks (20 disks are used in the calculation).

1. From the Home screen, tap the **AI** icon to start the AI-assisted EF Workflow.

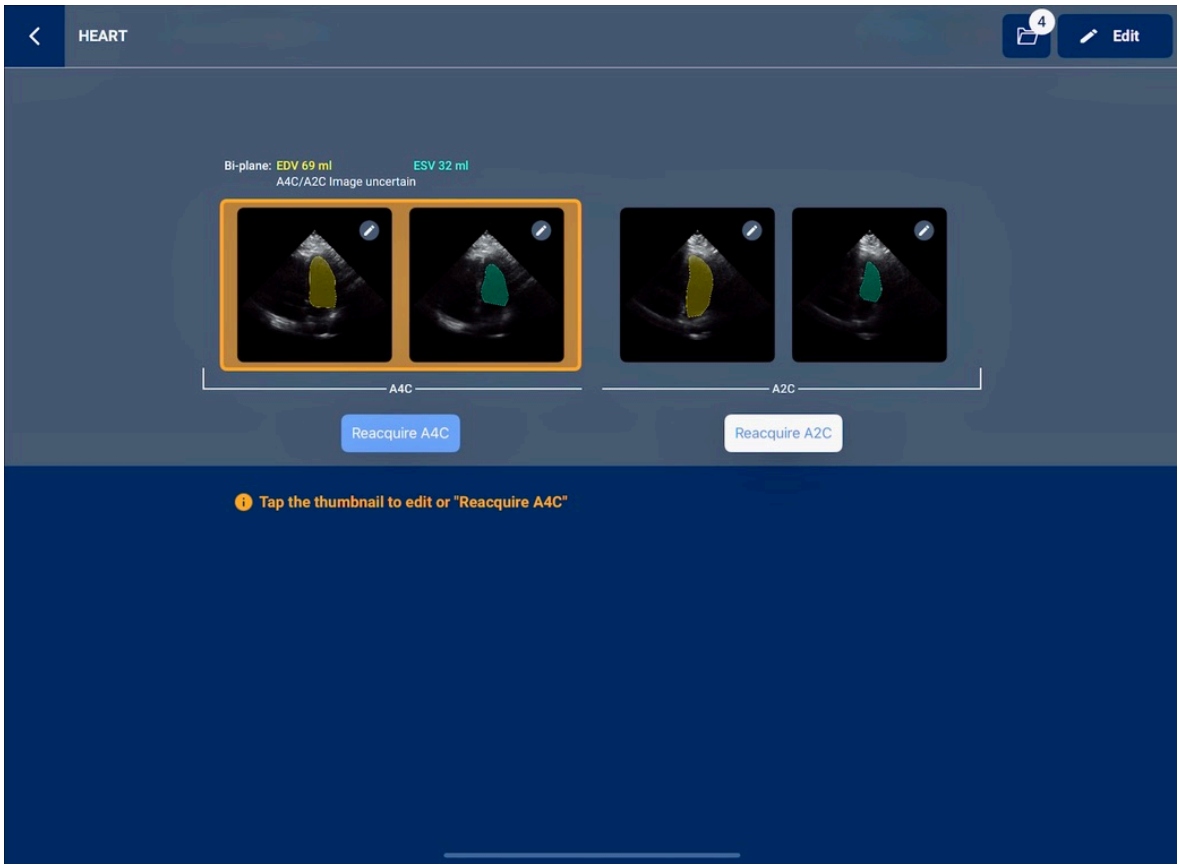
When you tap the **AI** icon, Kosmos creates a new exam that includes this EF scan.

Do not rely upon the EF calculation as the sole diagnostic criterion. Whenever possible, use the EF calculation with other clinical information.

2. After you have a good A4C view of the patient, the system will automatically record the clip. The system will then prompt you to acquire the A2C view.
3. If you are not satisfied with the recorded clip, tap **Try Again** to acquire a new clip or **Accept** to proceed.
4. Tap **SKIP** to see the A4C results, or continue with the A2C acquisition.

   We recommend that you take both A4C and A2C clips for an accurate EF calculation.

5. After you acquire images, the algorithm will assess the quality and uncertainty of the clip and users may be presented with the **EF Error** screen. To proceed to your results, the **EF Error** screen requires that you edit the thumbnail or re-acquire the image.



6. After you have a good A2C view of the patient, the system will automatically record the clip.
7. If you are not satisfied with the recorded clip, tap **Try Again** to acquire a new clip, or tap **Accept** to see the A4C/A2C (biplane) results.

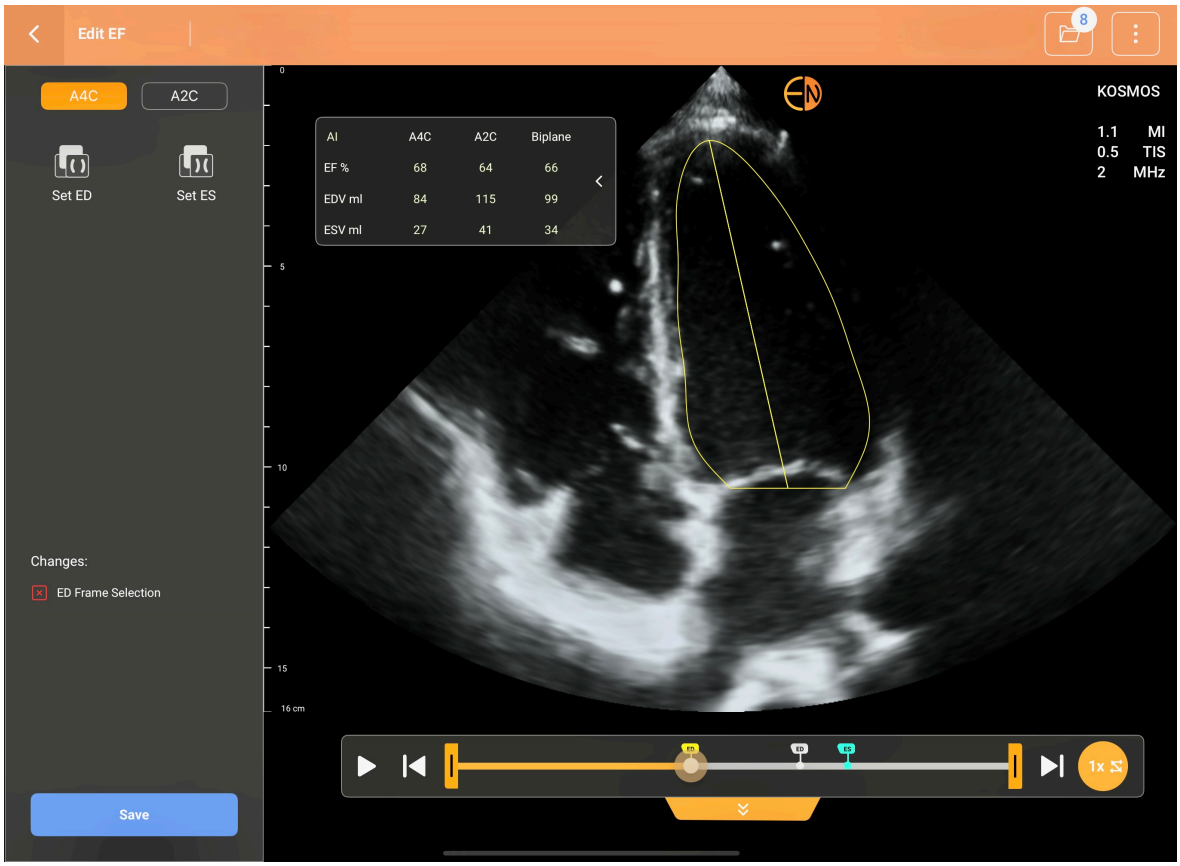
Reviewing/Adjusting The ED/ES Frames And LV Contours

When reviewing the initial AI calculations for ED/ES frames and LV contours, you can adjust just the frames, the LV contours, or both before saving the results. If you do not make any changes, the AI calculations become the final result.

Follow the instructions below to adjust the ED/ES frames.

1. From the **Results** screen, tap **Edit** or one of the thumbnail images. You can also tap **Review** to review previously acquired scans.

2. Depending on which clip you'd like to edit, tap the **A4C Clip** or **A2C Clip** tab.
3. To set a different ED or ES frame, move the orange Seek button to the desired location, and tap **SET ED** or **SET ES**.



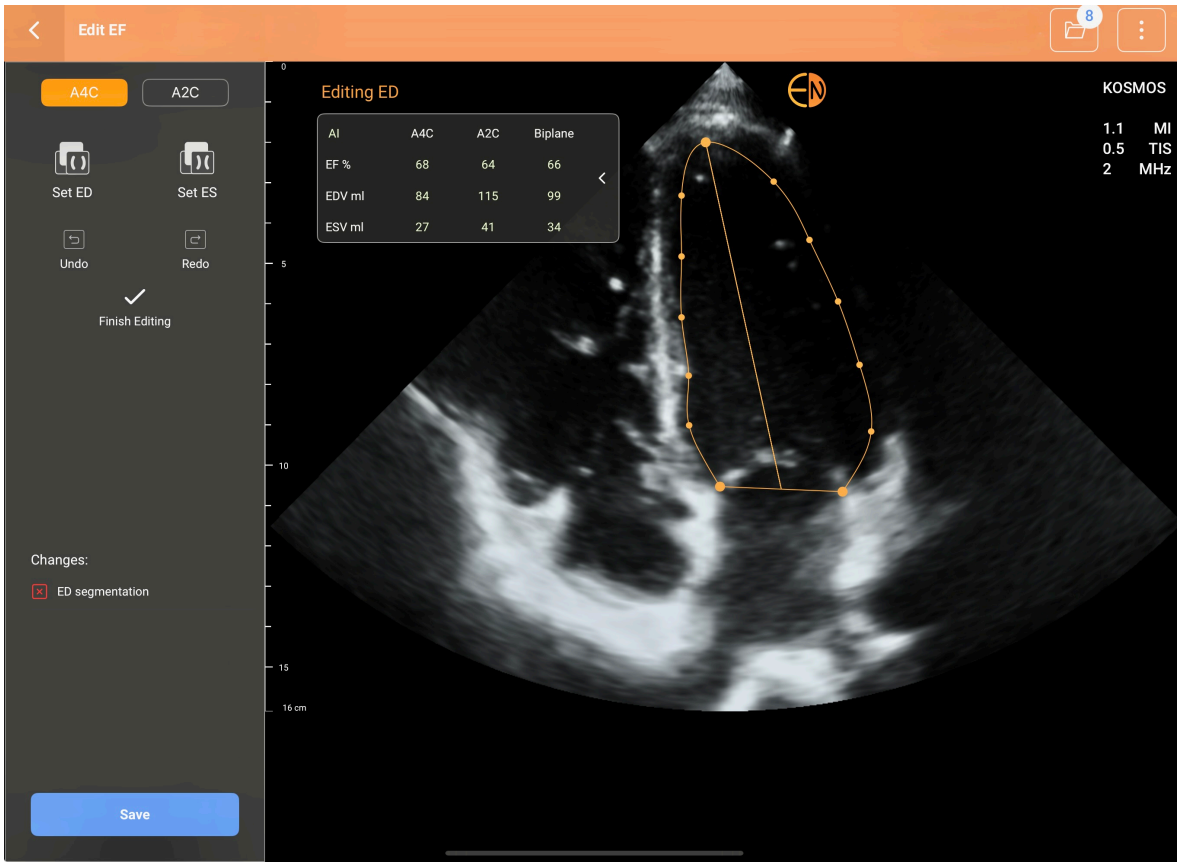
4. To return to the original AI calculations, tap the More Options icon ⋮ and then **Reset**.
5. If desired, make changes to the other clip (A4C or A2C), and tap **Save**.

Follow the instructions below to adjust the LV contours.

If you are wearing gloves while editing the LV contours, make sure they are snug against your fingertips/nails.

Having gel on your fingers may hinder using the touchscreen effectively.Make sure to wipe the touchscreen regularly.

1. From the **Results** screen, tap one of the four images to go to that image. If you don't specify which image you want, Kosmos defaults to the A4C frame.
2. Depending on which clip you would like to adjust, tap the **A4C Clip** or **A2C Clip** tab to select an ED or ES frame.
3. Tap the LV contour. This will allow the LV contour becomes adjustable, and the line color changes to orange.

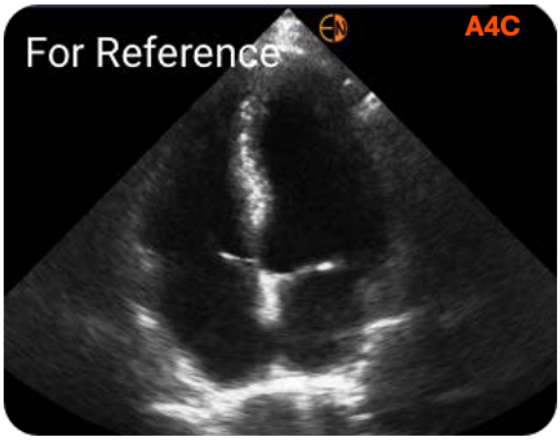


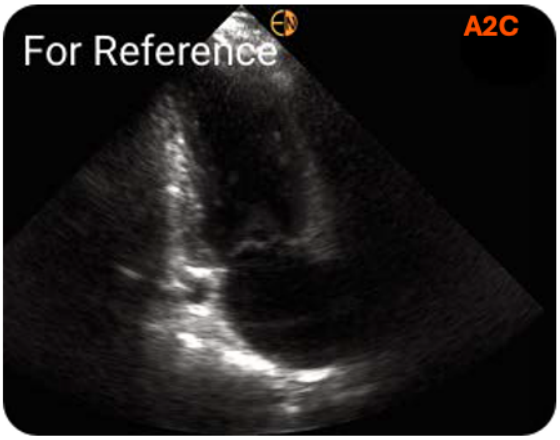
4. Select one or more control points and move them. Notice the calculations are updated as you change the contour.
5. After you are done editing, tap **Finish Editing**.
6. If desired, make more changes.
7. Tap **SAVE** to end.

Recommendations For Acquiring Optimal A4C And A2C Clips For Accurate EF Calculations

EchoNous recommends the following when using the AI-assisted EF Workflow.

- The patient should be lying on their side in the left lateral position (the left side of the patient is touching the scanning table).
  Shown below are examples of clinically acceptable A4C and A2C reference images on the top left of the Imaging screen.





- For an A4C clip, ensure all four cardiac chambers (left ventricle, left atrium, right ventricle, and right atrium) are captured in the ultrasound image (see the A4C reference image above).
- For an A2C clip, ensure both left ventricle and left atrium are captured in the ultrasound image (see the A2C reference image above).Ensure the endocardial border of the LV is clearly visible with the best possible contrast. Use the Gain settings to achieve a clear definition of the LV endocardial border.
- Adjust the depth so that the atria are near the bottom of the ultrasound image yet still visible (see the A4C and A2C reference images above).
- Avoid truncating the LV.
- Avoid foreshortening the LV.
- For an A4C clip, ensure the intraventricular septal wall (the wall between the left and right ventricles) is vertical (see the A4C reference image above).
- For an A4C clip, ensure that the orange marker on Kosmos Torso-One is pointed towards the scanning table to avoid acquiring a mirrored view.
- Once you have obtained a proper A4C view, rotate the probe 90 degrees counterclockwise to find the A2C view.
- Ask the patient to hold their breath while recording the clip.
- Make sure to review the results for correctness of ED/ES frames and LV contoursand, using the Kosmos editing tool, adjust as needed.

Error Conditions And System Notifications For AI-Assisted EF Workflow

If the resulting EF scan (initial and/or with edits) is out of the 0%-100% range, you will not be able to save the EF result in the report or export/archive the scan. You will first need to edit the ED/ES frames and corresponding LV contours to produce a valid EF. Then you will be able to save the results and export/archive the scan.

Kosmos will prompt you to edit the results or scan again if any of the following conditions are met:

- ESV > 400 ml,
- EDV > 500 ml, or
- Difference between A4C and A2C EF is more than 30%.

Kosmos AI FAST

Using Kosmos AI FAST

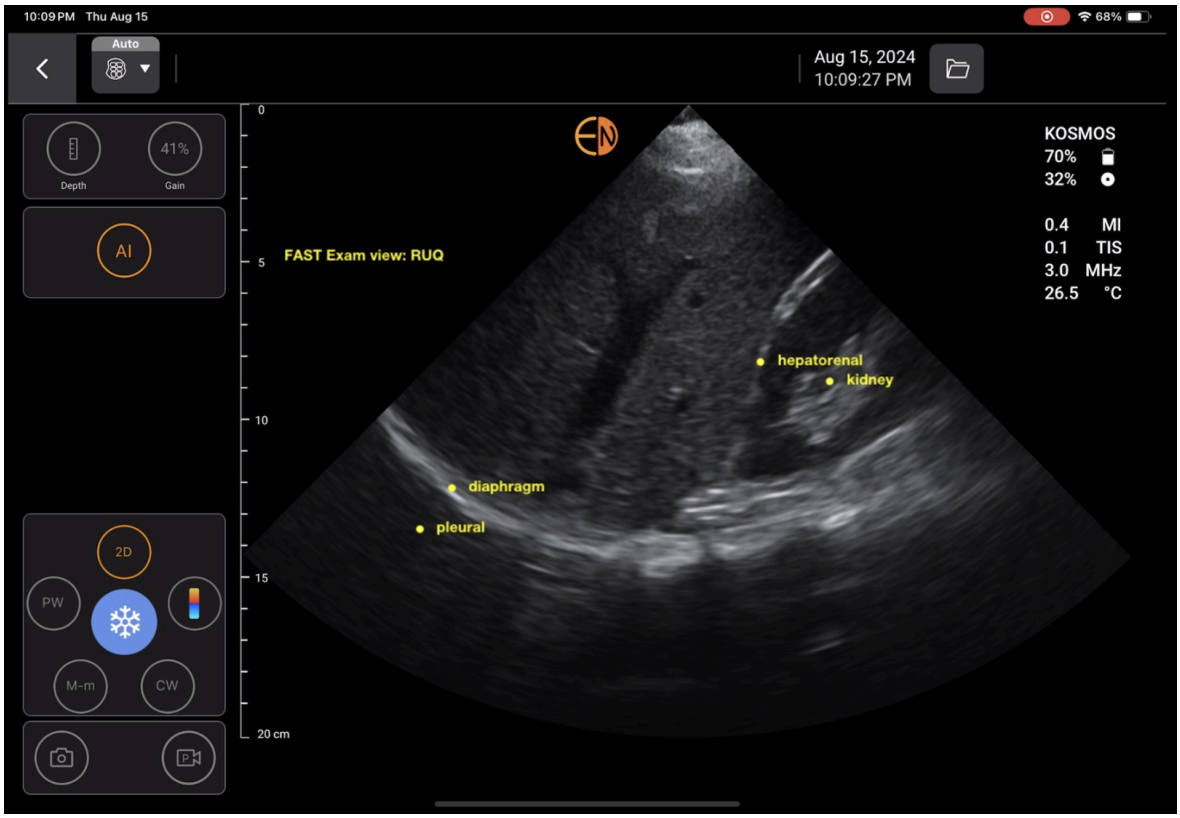
> Do not rely solely on the AI FAST tool for diagnostic purposes. Kosmos AI FAST assists users by providing a quick orientation to the anatomy of the abdomen. Users should exercise their judgment to ensure annotations are correct.

Kosmos AI FAST provides automated anatomical labeling and view identification forthe FAST exam in real time. The labels that appear while scanning are only therewhile you are scanning; after you save the image or clip, the labels will no longer be there.

Table 8. Anatomical structures for AI FAST.

FAST View	Anatomical Strucutres
RUQ	**Liver, right kidney, diaphragm, gallbladder, IVC** Potential fluid space: hepatorenal space, pleural
LUQ	**Spleen, left kidney, diaphragm** Potential fluid space: splenorenal space, pleural space
SUB	**Heart, diaphragm, liver** Potential fluid space: pericardium
AS	**Liver, transverse aorta, transverse IVC**
IVC	**Liver, sagittal IVC**
Aorta	**Liver, sagittal aorta**
A4C **A2C** **PLAX**	**Heart** Potential fluid space: pericardium
PSAX	**Heart**
SUB2	**Liver, heart, IVC, aorta** Potential fluid space: pericardium

- To enable AI FAST, tap the **Abdomen** → **AI**.



When scanning with Torso-One probe, Kosmos AI FAST feature is only available in the Abdomen preset.

Kosmos Bladder AI

Kosmos Bladder AI

Do not rely solely on Kosmos Bladder AI for diagnostic purposes.

Review the ultrasound image when measuring bladder volume on female patients. Verify the bladder is measured and does not include other organs, such as the uterus, in the measurement.

Kosmos Bladder feature assists users by automatically estimating bladder volume following Transverse and Sagittal view acquisition. Kosmos Bladder provides instructions to identify the bladder, assists users with orientation and real-time probe animations, and automatically calculates estimated bladder volume.

Using the Bladder Preset, the depth can be adjusted by tapping the **Body Type** icon located in the left hand side of the screen. The gain can also be adjusted by tapping the **Gain** icon which is next to the **Body Type** icon.

The system walks through acquiring a Transverse view, first, then a Sagittal view.

On screen directions are located at the bottom of the screen, below the live ultrasound image.

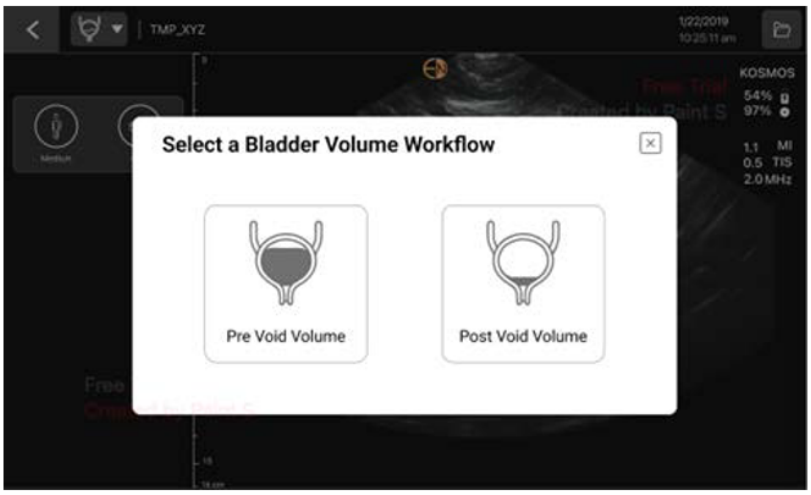
When the system is ready to move to the next step, the reference videos will automatically play then minimize to the upper left hand corner of imaging screen.

Accessing The Bladder Preset

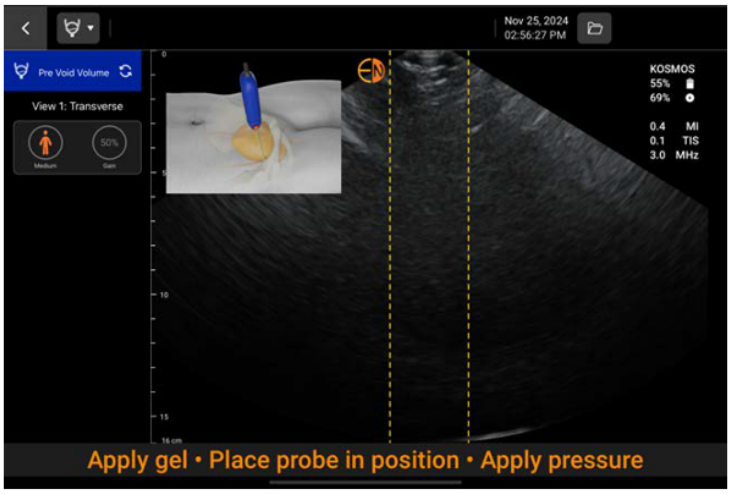
1. From the Home screen, tap the **Bladder** icon to begin the Bladder Volume Workflow.
2. When prompted, select the appropriate workflow from the dialog box by tapping on Pre Void Volume or Post Void Volume. For Pre Void Volume, follow the next set of instructions. Otherwise, skip to the Post Void Volume (page 46) section for instructions.

Pre Void Volume

1. When prompted, tap **Pre Void Volume**.

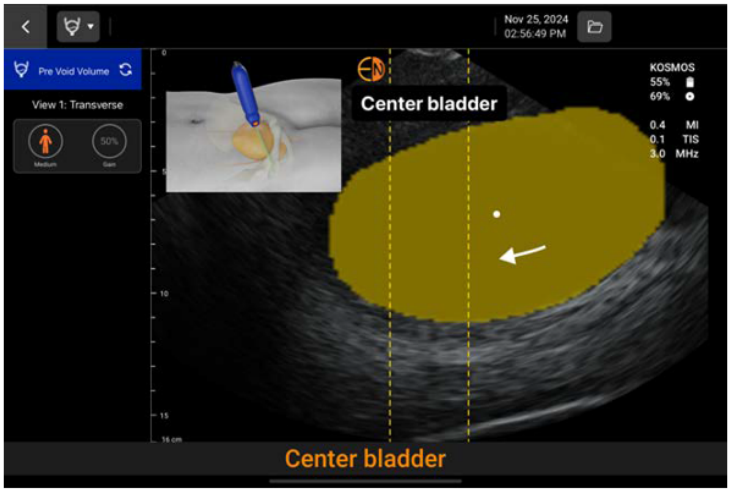


2. Following the on-screen instructions, apply ultrasound gel, place the probe intoposition, and apply pressure.



The reference video in the upper left corner of the demonstrates proper placing of the probe in relation to the patient's body position.

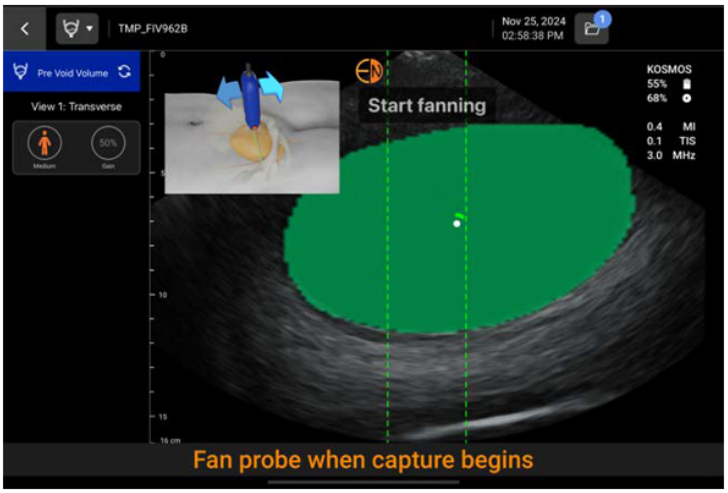
3. Once the system detects a bladder, follow the on-screen instructions and centerthe bladder. This can be done by moving the probe so the white dot lies in between the vertical lines.



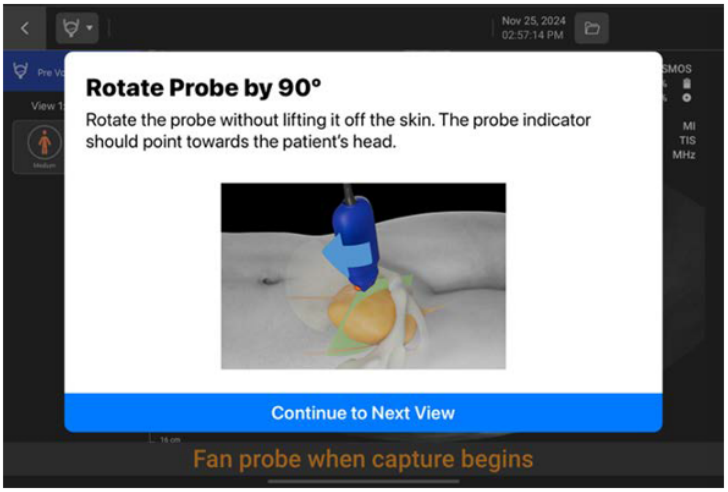
If the system cannot detect a bladder, it will prompt you to reposition the probe and try again. To keep scanning, tap **Keep Scanning**.

If the bladder cannot be detected, using the Pre Void Volume workflow, tap **Pre Void Volume** in the upper left hand side of the screen to selectPost Void Volume. Follow the instructions located in Post Void Volume.

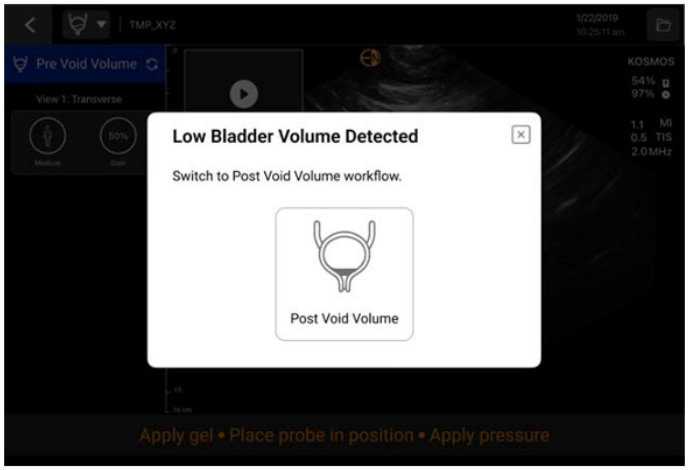
4. Once the bladder is centered, the color will change from yellow to green.
5. Follow the on screen instructions to fan the probe until the green ring completely surrounds the center white ring.



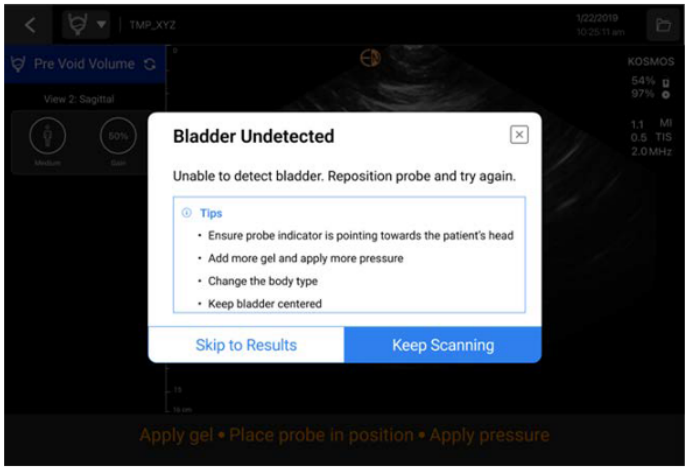
6. Once the Transverse view has been acquired, follow the video show in on-screen prompt and rotate the probe by 90 degrees.



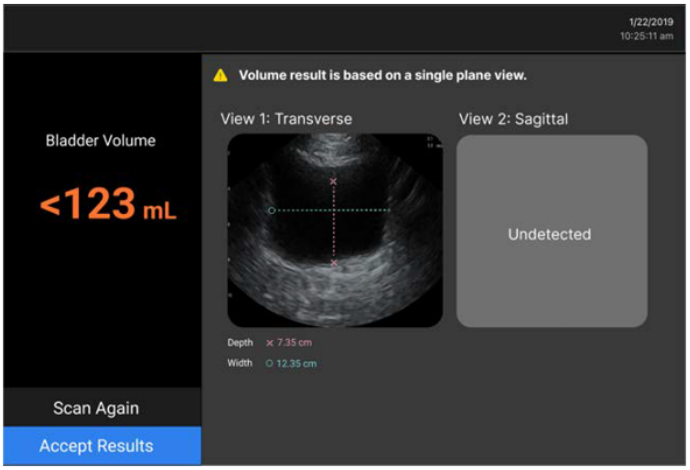
7. Repeat steps 1-6 to acquire the sagittal view.
   a. If the system detects a low Bladder volume, it will prompt you to use the Post Void Volume workflow.
      To change the workflow, tap the **Post Void Volume** icon shown in the prompt. To continue with Pre Void Volume, tap the ☒ located in the upper right hand corner of the dialog box.



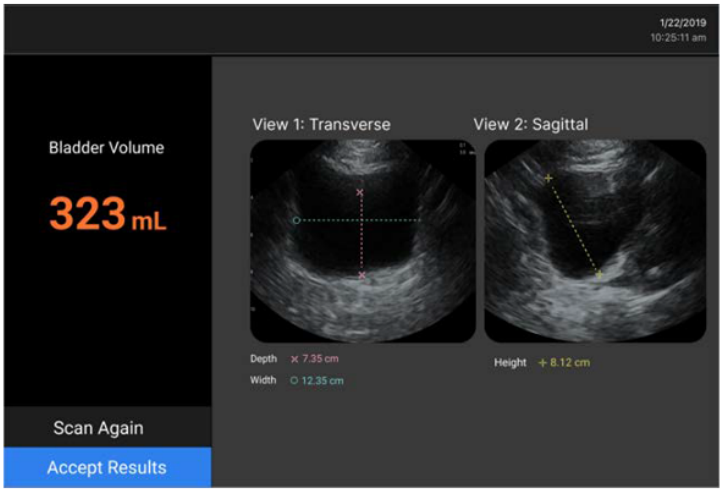
b. If the Bladder cannot be detected, the system will prompt you to skip or keep scanning. To skip, tap Skip to Results. Otherwise, tap **Keep Scanning**.



c. By skipping to the **Results** screen, the system will show the approximate volume with a caution statement indicating the result only used a single view. To save the results, tap **Accept Results** → **Save**. To repeat scanning, tap **Scan Again**.

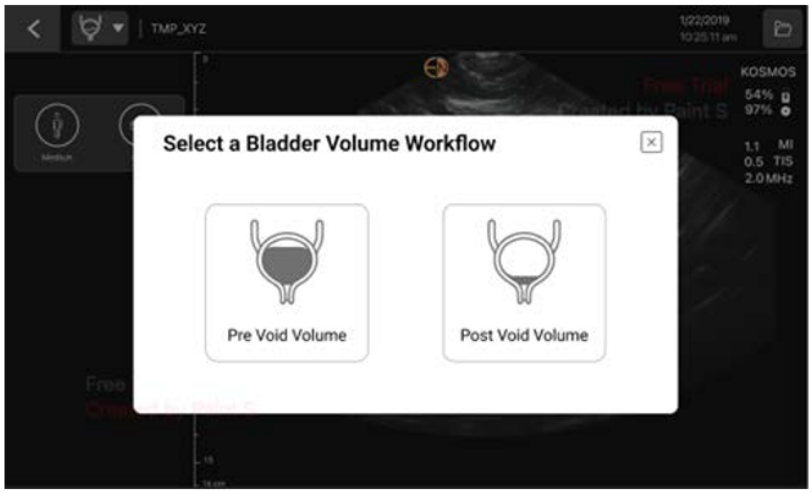


8. After acquiring the Sagittal view, the system will automatically show the **Results** screen. To save the results, tap **Accept Results** → **Save**. To repeat scanning, tap **Scan Again**.

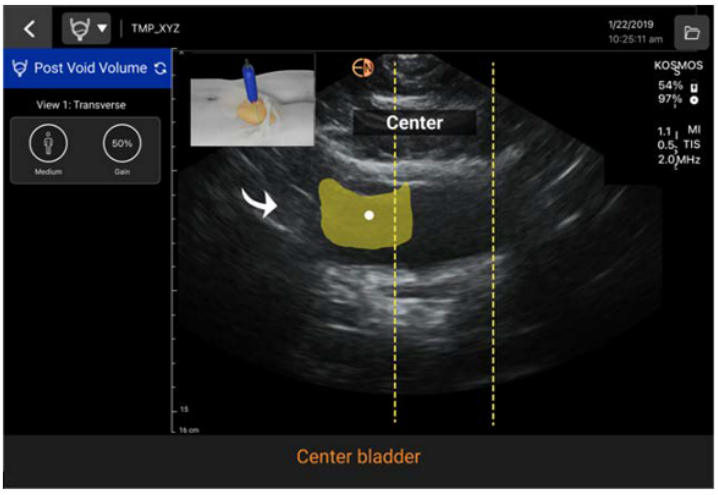


Post Void Volume

1. When prompted, tap **Post Void Volume**.

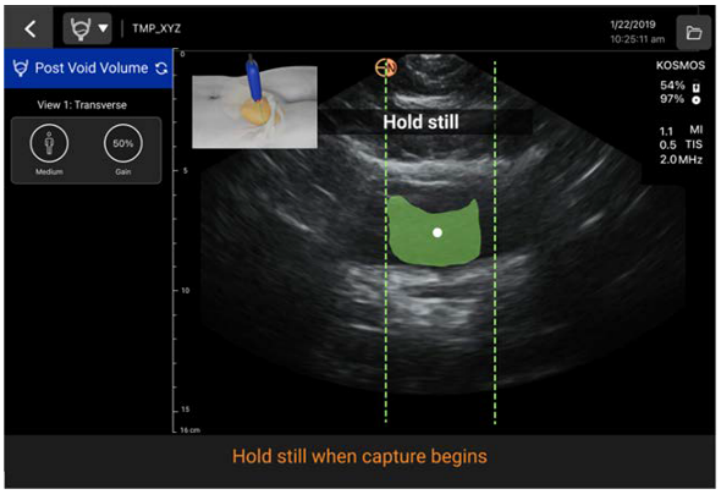


2. Following the on-screen instructions, apply ultrasound gel, place the probe intoposition, and apply pressure.



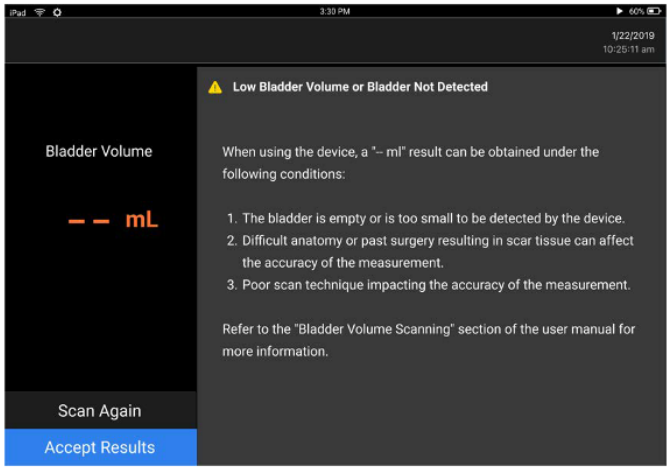
The reference video in the upper left corner of the demonstrates properplacing of the probe in relation to the patient's body position.

3. Once the system detects a bladder, follow the on-screen instructions and centerthe bladder. This can be done by moving the probe so the white dot lies inbetween the vertical lines.

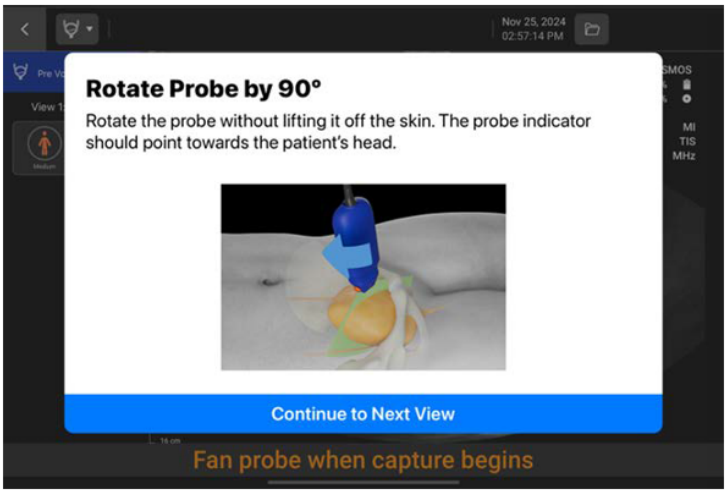


If the system cannot detect a bladder, it will prompt you to reposition the probe and try again. To skip, tap **Skip to Results**. Otherwise, tap**Keep Scanning**.

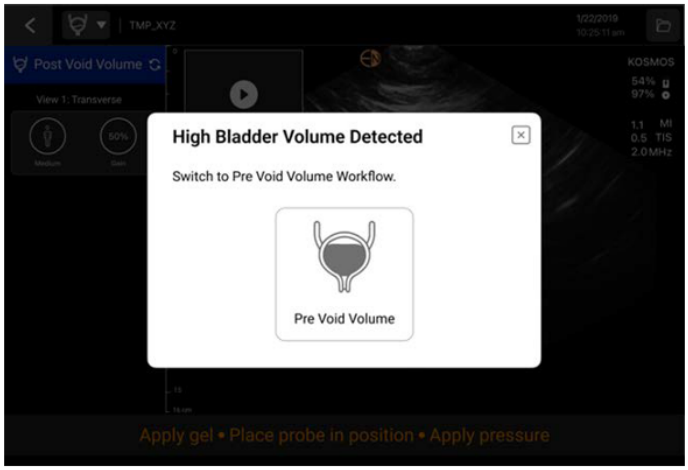
- If **Skip to Results** is tapped, the system will show the volume as “-- mL" and a caution statement indicating a low bladder volume or bladder not detected.
  To save the results, tap **Accept Results** → **Save**. To repeat scanning, tap **Scan Again**.



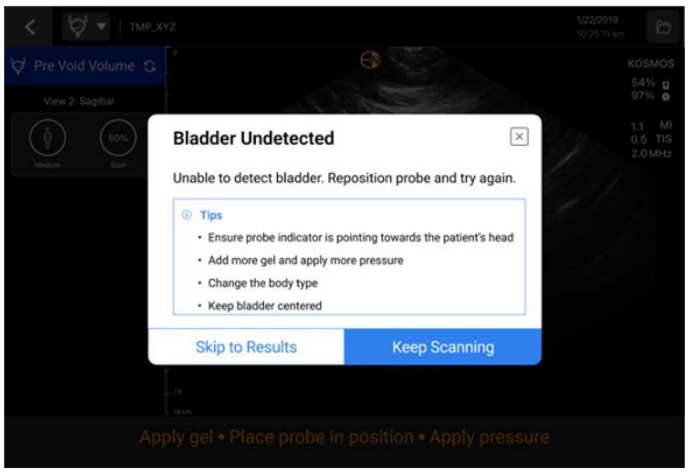
4. Once the bladder is centered, the color will change from yellow to green.
5. Follow the on-screen instructions to hold the probe until the green ring completely surrounds the center white ring..
6. Once the Transverse view has been acquired, follow the video show in on-screen prompt and rotate the probe by 90 degrees.



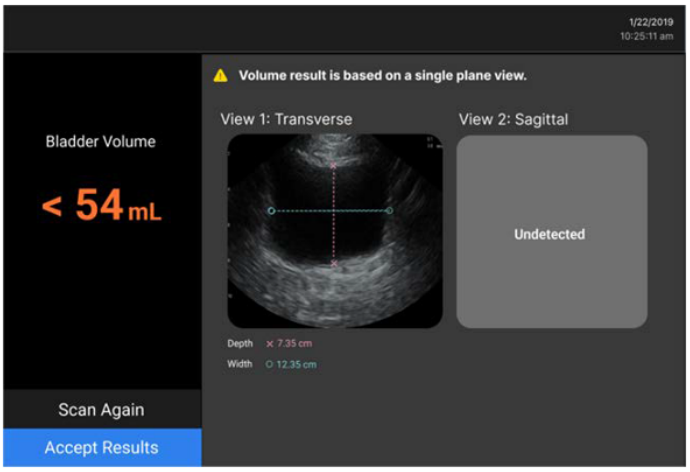
7. Repeat Steps 1-6 to acquire the Sagittal view.
   a. If the system detects a high Bladder volume, it will prompt you to use the Pre Void Volume workflow. To change the workflow, tap the **Pre Void Volume** icon shown in the prompt. To continue with Post Void Volume, tap the ⊠ located in the upper right hand corner of the dialog box.



   b. If the Bladder cannot be detected, the system will prompt you to skip or keep scanning. To skip, tap **Skip to Results**. Otherwise, tap **Keep Scanning**.



c. By skipping to the**Results** screen, the system will show the approximate volume with a caution statement indicating the result only used a single view. To save the results, tap **Accept Results** → **Save**. To repeat scanning, tap **Scan Again**.



8. After acquiring the Sagittal view, the system will automatically show the**Results** screen. To save the results, tap **Accept Results** → **Save**. To repeat scanning, tap**Scan Again**.

Kosmos Bladder AI Imaging Controls

Kosmos Bladder AI is only available in 2D/B-mode.

The Kosmos Bladder AI Workflow allows you to control two aspects of image quality.

1. Body Type: Controls the imaging depth and can be adjusted by tapping the icon on the imaging screen.

2. Gain: Controls the brightness of the image an can be adjusted by tapping the  icon on the imaging screen.

Kosmos Trio

Kosmos Trio: General Information

Kosmos Trio is an AI feature designed to assist in the acquisition of diagnostic images for echocardiography. The cardiac views supported by Kosmos Trio are **PLAX**, **A4C**, and **A2C**. The AI feature consists of the following automatic actions.

- **Auto Guidance** (Kosmos Trio: Auto Guidance (page 53)) - Displayed as **Guidance** in the Trio menu. Provides real-time predictive probe motions to acquire the optimal image while scanning.
- **Auto Grading** (Kosmos Trio: Auto-Grading (page 56)) - Displayed as **Grading** in the Trio menu. Provides real-time image grading while scanning.
- **Auto Labeling** (Kosmos Trio: Auto-Labeling (page 58)) - Displayed as **Labeling** in the Trio menu. Provides real-time anatomical labelling while scanning.

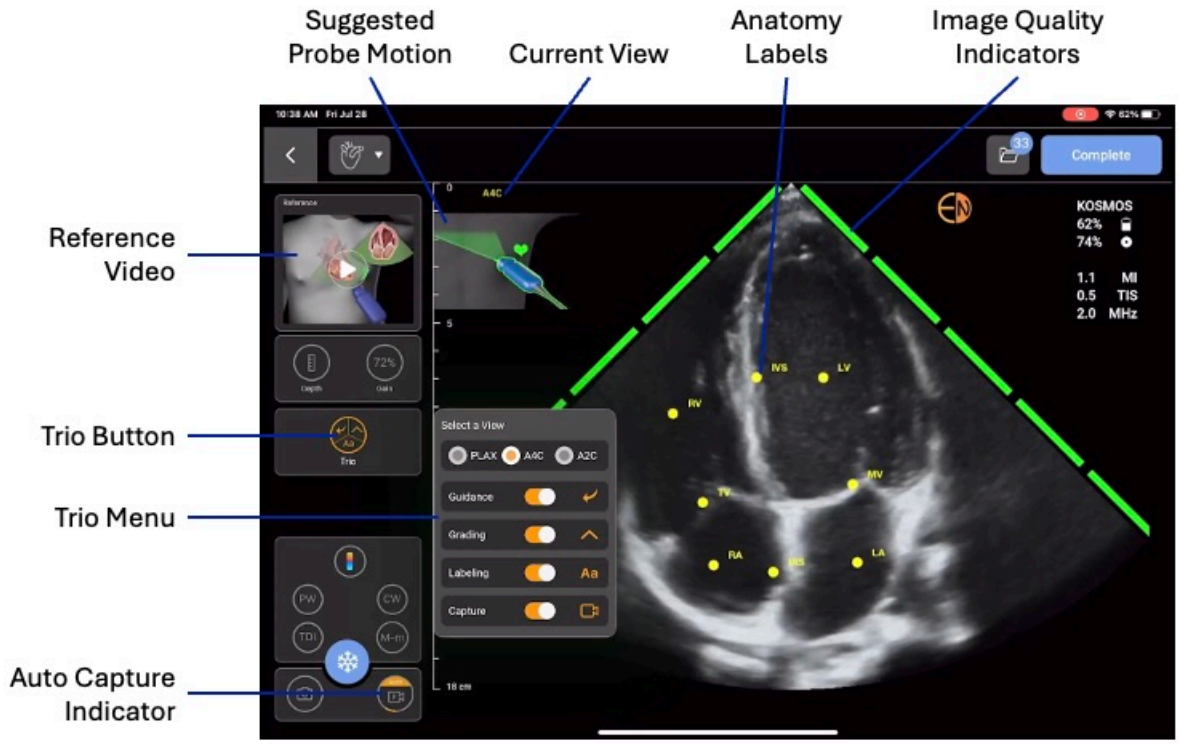
To assist in using the device, Kosmos Trio also allows for automatic clip saving using its Auto Capture and Smart Capture features.

- **Auto Capture** (Auto Capture (page 59)) - Displayed as **Capture** in the Trio menu. Provides automatic clip saving during a Trio-enabled exam.
- **Smart Capture** (Smart Capture (page 59)) - Not displayed in the Trio menu. Allows the user to save the best clip when Auto Capture requirements are not met.

> ⚠ Manual recording should be used only by those users who are able to determine, without the assistance of Kosmos Trio, that a clip is of sufficient diagnostic quality.

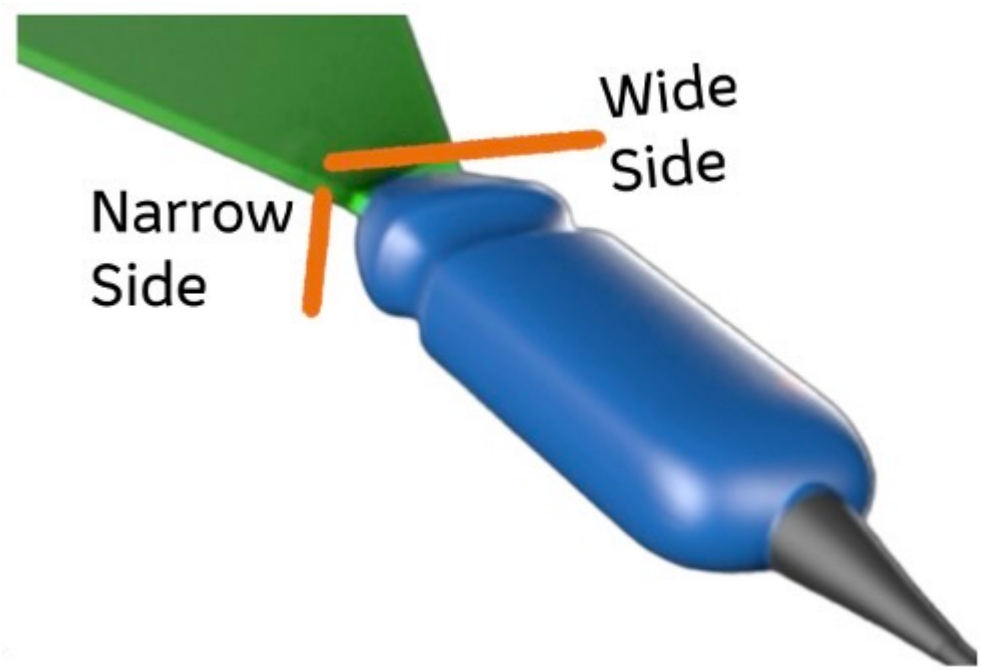
Kosmos Trio's user interface consists of the following elements which are show below.

- **Trio Button** - Activates Kosmos Trio for the current exam.
- **Trio Menu** - Allows users to select views and toggle features.
- **Reference Video** - Shows the user how to initially place the probe for a given view.
- **Image Quality Indicators** - Shows the current image's image quality.
- **Current View** - Shows the current exam view to the user.
- **Auto Capture Indicator** - Shows the status of Auto Capture. This icon turns green when Smart Capture activates when Auto Capture cannot trigger.



Probe Familiarization

Kosmos Trio's suggested probe motions use specific instructions based on the orientation of the probe and its head.



Kosmos Trio: Auto Guidance

All probe movements are in relation to the patient. For example, when the guidance says, “slowly fan down,” it means to move the probe face down away from the patient’s head. Fanning is always on the wide, non-indicator side of the probe head, whereas Rocking is always on the narrow side of the probe head.

Kosmos Trio's Auto Guidance suggests probe motions to improve image quality. The motions fall into four categories: **Rotate**, **Fan**, **Rock** and **Slide**. Each motion is animated, showing you how to move the probe. In general, these motions and their directions are in relation to the probe head, e.g., "Fan Up" means to tilt the probe head up. The **Slide** motions require the entire probe to move in the specified direction.

Follow the suggested probe motions slowly. Moving too quickly can lead to a “double movement” and will require additional prove movements to get the best image for the view. For example, if you rotate too quickly, you might accidentally rock the probe as well.

When Kosmos Trio does not detect any visual structures, it will prompt you with "Patient Positioning" or "Position At Optimal". In both cases, you can go back to the original probe placement or follow the reference video to place probe. You can also refer to the training for tips in placing the probe. Some techniques to try including rolling the patient, using respiratory prompts such as taking a slow breath in, or resetting the probe to the correct echo region.

Table 9. Description of Probe Motions Suggested by Kosmos Trio.

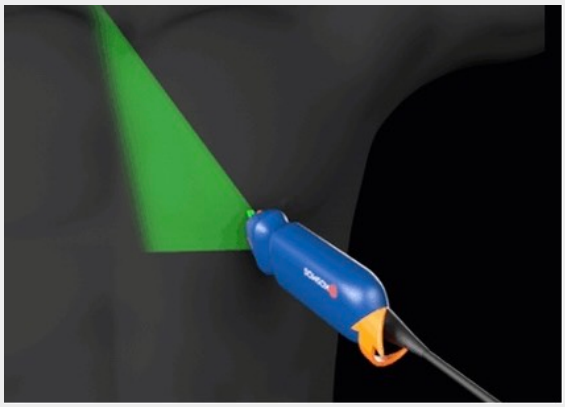
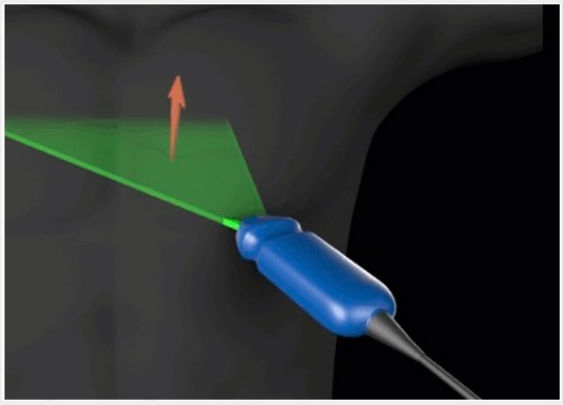
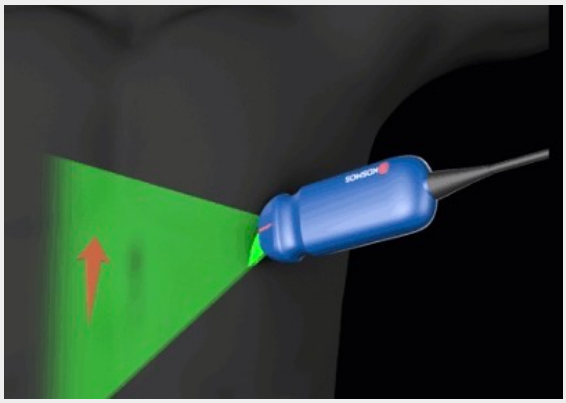
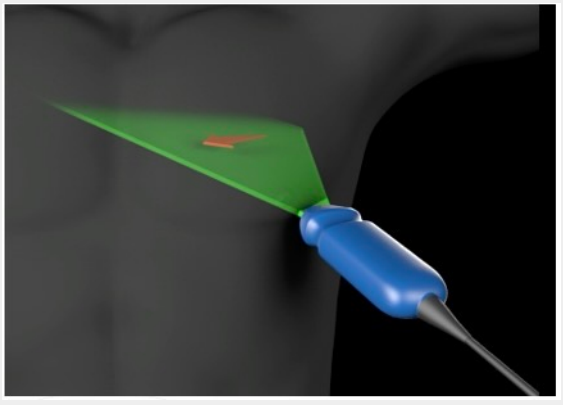
Probe Motion	Description
	**Rotate**: This motion tells the user to spin the probe around while the probe head is in contact with the body. The system will tell the user to rotate clockwise (to the right) or counterclockwise (to the left). The direction is also provided by the orange arrow.
	**Fan**: This motion tells the user to move the probe's wide side with the probe head still in contact in the body. The system will tell the user to fan up, down, toward, and away. • **Up**: Tilt the probe head up, causing the probe tail to move down. • **Down**: Tilt the probe head down, causing the probe tail to move up. • **Toward [Anatomy]**: Tilt the probe head to the specified anatomy. • **Away from [Anatomy]**: Tilt the probe head away from the specified anatomy.
	**Rock**: This motion tells the user to move the probe's narrow side with the probe head still in contact in the body. The system will tell the user to rock up, down, toward, and away. • **Medial**: Move the probe head toward the middle of the body by leaning the probe in the opposite direction. • **Lateral**: Move the probe head toward the middle of the body by leaning the probe in the opposite direction. • **Toward [Anatomy]**: Move the probe head toward the specified anatomy by leaning the prone to the opposite direction. • **Away from [Anatomy]**: Move the probe head away from the specified anatomy by leaning the prone to the opposite direction.
	**Slide**: This motion tells the user to move the entire probe along the surface of the body. • **Medial**: Move the probe towards the middle of the body. • **Lateral**: Move the probe towards the outside of the body. • **Up**: Move the probe towards the head of the patient. • **Down**: Move the probe towards the feet of the patient. • **Toward [Anatomy]**: Move the probe toward the specified anatomy. • **Away from [Anatomy]**: Move the probe away from the specified anatomy.

Figure 4. PLAX Auto Guidance Probe Motions

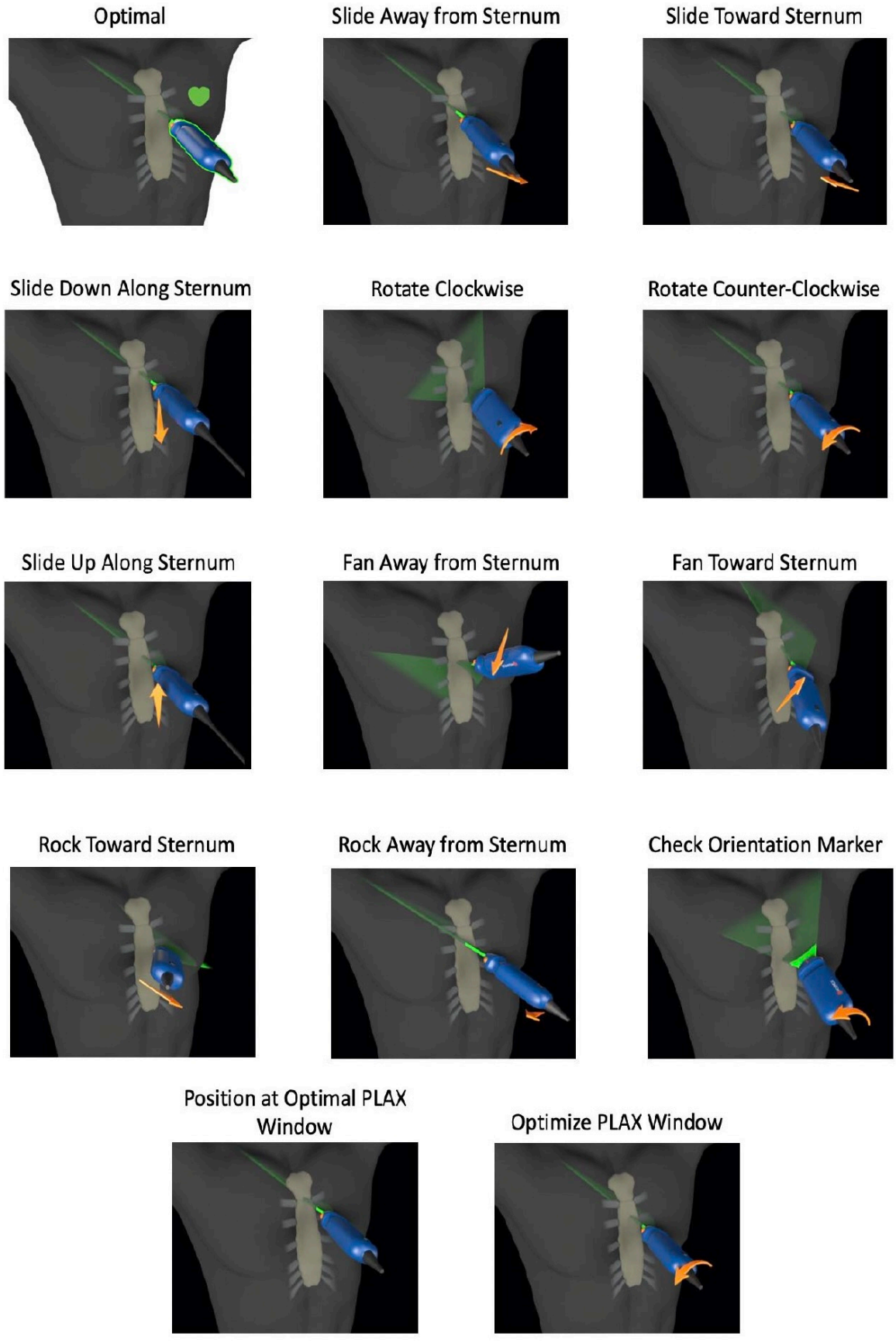


Figure 5. A4C Auto Guidance Probe Motions

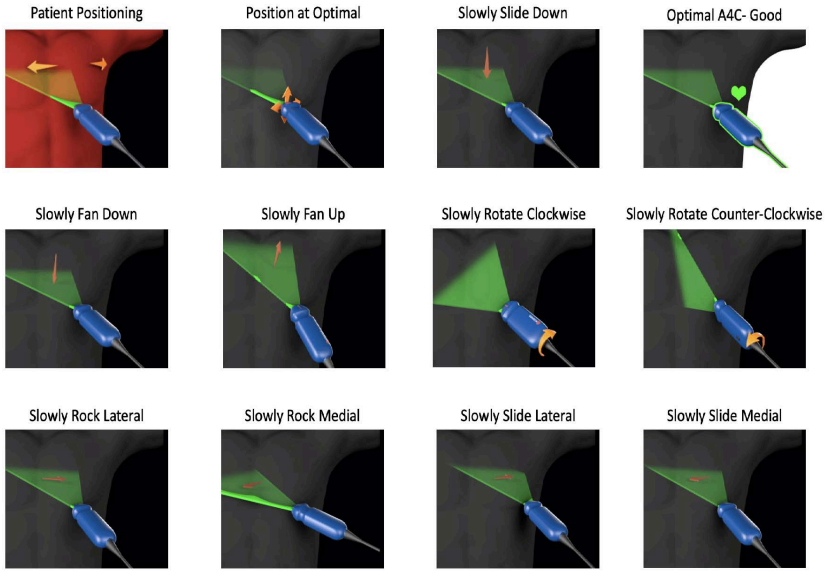
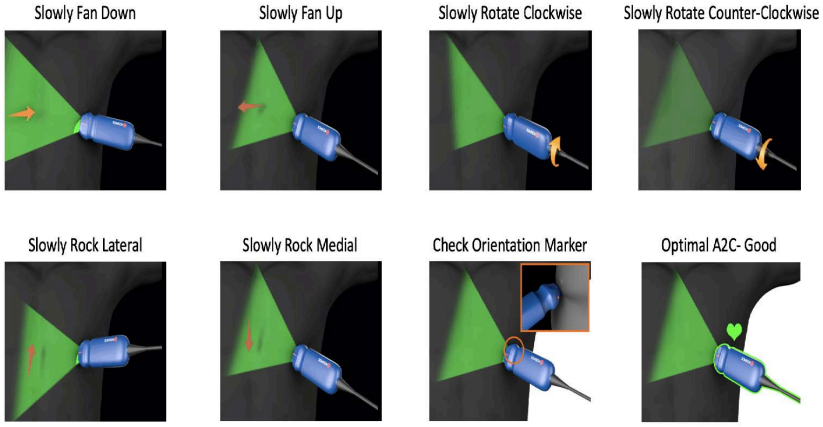


Figure 6. A2C Auto Guidance Probe Motions



Kosmos Trio: Auto-Grading

It is also possible that some images obtained during scanning may be correct and have sufficient image quality for diagnosis, but Kosmos Trio's Auto-Grading does not recognize this.

Kosmos Trio's Auto Grading provides real-time image grading using colors (green and red) and scores (one (1) through five (5) bars). The scores are based on the American College of Emergency Physicians (ACEP) 5-point scale for **PLAX**, **A4C**, and **A2C**. As the user follows the suggested probe motions provided by Auto-Guidance, the image quality improves. The system tells this to the user by increasing the number of scoring bars located around the field of view.

The system communicates the image score using bar pairs. For example, a score of 1 (one) shows one red bar on each side of the field of view and a score of 5 (five) shows five green bars on each side of the field of view.

Table 10. Image Quality Scoring System

Score	Number of Bars	Color and Meaning
1	1 Pair	Red. Considered non-diagnostic by Kosmos Trio.
2	2 Pairs	
3	3 Pairs	Green. Considered diagnostic by Kosmos Trio.
4	4 Pairs	
5	5 Pairs	

Figure 7. A Non-diagnostic A4C Image (Score 2, Red Bars)

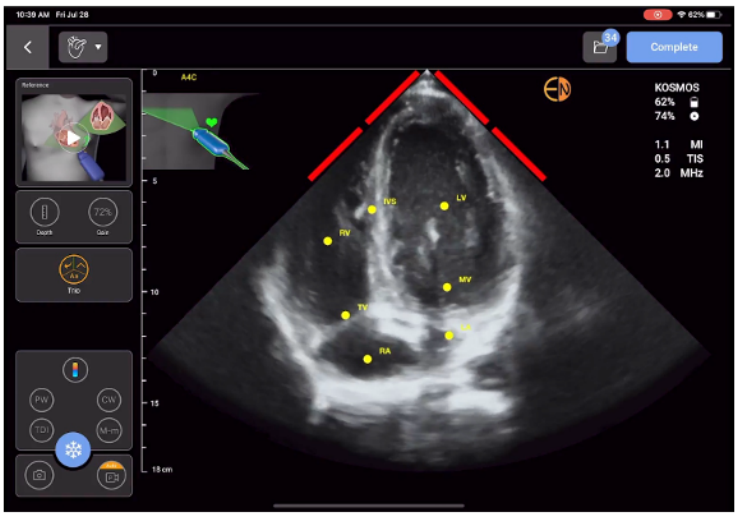
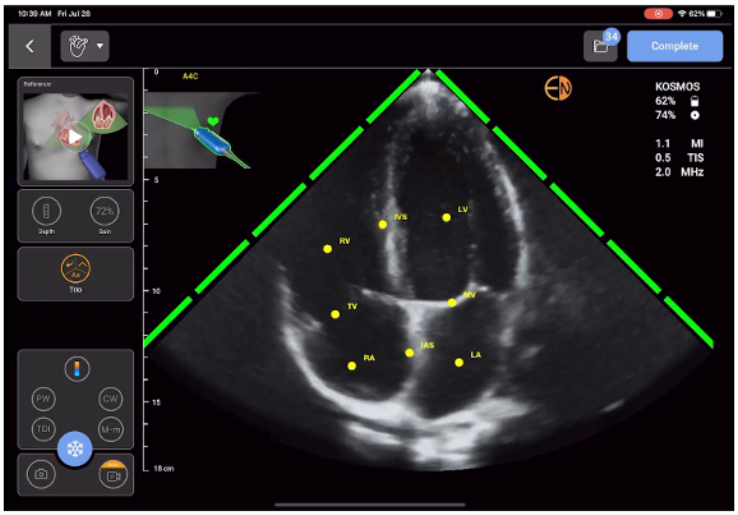


Figure 8. A Diagnostic A4C Image (Score 5, Green Bars)



Kosmos Trio: Auto-Labeling

> ⚠ Do not rely on the heart Auto-Labeling tool for diagnostic purposes. These labels help train and provide you with a quick orientation to the anatomy of the heart. Use your judgment to ensure annotations are correct.

Kosmos Trio's Auto-Labeling provides real-time cardiac structures during an exam. These labels are not saved with the exam . The anatomic labels are listed below.

Table 11. Meaning of Auto-Label Tags

Auto-Label Tag	Cardiac Structure
AL-PAP	Antereolateral Papillary Muscle
AO	Aorta
AV	Aortic Valve
IAS	Interatrial Septum
IVC	Inferior Vena Cava
IVS	Interventricular Septum
LA	Left Atrium
LV	Left Ventricle
LVOT	Left Ventricular Outflow Tract
MPA	Main Pulmonary Artery
MV	Mitral Valve
PM-PAP	Postero-Medial Papillary Muscle
PV	Pulmonary Valve
RA	Right Atrium
RV	Right Ventricle
RVOT	Right Ventricular Outflow Tract
TV	Tricuspid Valve

In addition to **PLAX**, **A4C**, and **A2C** views, the Auto-Label features can also label cardiac structures in other views, as shown below.

Table 12. Cardiac Views Supported By Auto-Label

View	Supported Structures
A2C	LA, LV, MV
A3C	AO, AV, LA, LV, LVOT, MV, RA, RV, TV
A4C	IAS, IVS, LA, LV, MV, RA, RV, TV
A5C	AO, AV, IAS, IVS, LA, LV, LVOT, MV, RA, RV, TV
PLAX	AO, AC, IVS, LA, LV, LVOT, MV, RV
RVOT	IVS, LV, MPA, PV, RVOT
RVIT	IVC, IVS, LV, RA, RV, TV
PSAX-AV	AV, LA, MPA, PV, RA, RVOT, TV
PSAX-MV	IVS, LV, MV, RV
PSAX-PM	AL-PAP, IVS, LV, PM-PAP, PV
PSAX-AP	IVS, LV, RV
Subcostal-4C	IAS, IVS, LA, Liver, LV, MV, RA, RV, TV
Subcostal-IVC	IVC, Liver
Suprasternal	AO Arch, DA

Auto Capture

Kosmos Trio's Smart Capture function allows for the automatic saving of the clip, but requires human interaction. For Smart Capture to activate, the following must be met:

- The Image Quality must be 4 or greater; and
- The Image Quality is maintained for at least 3 seconds.

Once these conditions are met, Auto Capture will save the clip and notify the user with an audible tone and deactivate. This is done to prevent the user from inadvertently saving multiple scans of the same view.

When **Capture** is activated in the Kosmos Trio menu, the **Record** icon changes (see below). Once it saves a clip using Auto Capture, the icon reverts back to its original state, i.e., the icon no longer has **Auto** shown.

The **Record** icon changes to include **Auto** indicating Auto Capture is active.

Smart Capture

Kosmos Trio's Smart Capture function allows for the automatic saving of the clip, but requires human interaction. For Smart Capture to activate, the following must be met:

- Auto Capture is enabled in the Trio menu.
- Image Quality is Grade 3 for at least 2 out of 3 seconds.

Once these conditions are met, Smart Capture will activate and notify the user by changing the **Auto Capture** icon color to green. After the icon turns green, the user can tap the icon to save the clip.

The icon changes by turning green to notify the user that Smart Capture is available.

When the icon becomes green, the user has up to 30 seconds to tap the icon before having to reacquire a new image. Capture will reset after 30 seconds, then you will have to reacquire an image of Grade 3 for at least 2 seconds

The probe does not have to maintain its position once the icon turns green. The user can remove the probe from body when tapping the green icon.

Auto Capture does not deactivate when a clip is saved using Smart Capture.

Using The Kosmos Trio Workflow

Kosmos Trio training is required before first use of the software.

Kosmos Trio is only available on Kosmos devices connected to Kosmos Torso-One probes.

If you are not familiar with performing an ultrasound exam using Kosmos Trio, make sure that you receive the appropriate training before using the system, provided either by EchoNous or by a trained clinician using official Kosmos Trio training material.

It is important that you are familiar with this User Manual before use conducting an exam with Kosmos Trio.

Users are responsible for image quality and diagnosis. The images acquired using Kosmos Trio are to be interpreted only by qualified medical professionals. A qualified medical professional must inspect the data being used for analysis and diagnosis and ensure that the data is sufficient and appropriate in anatomical correctness and both spatial and temporal resolution for the measurement being employed.

Making a diagnosis based solely on Kosmos Trio, without applying clinical judgment regarding view correctness and quality, is not recommended. Echocardiographic exams obtained using Kosmos Trio have been clinically validated. However, some cardiac pathologies, specifically those for wall motion abnormalities and left atrial enlargement, require additional clinical modalities to accurately diagnose.

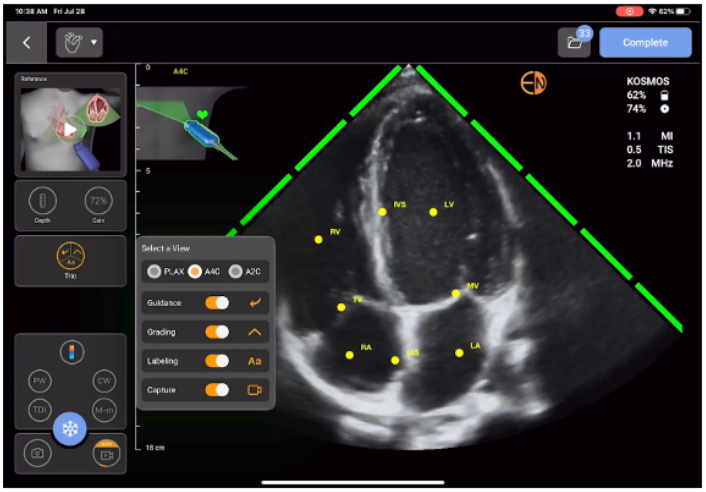
Kosmos Trio provides real-time guidance and automated capture during cardiac ultrasound (echocardiographic) examinations for three (3) standard echocardiographic views. The accuracy of Kosmos Trio in classifying correct echocardiographic views and estimating image quality has been verified and validated, but individual patient variations may introduce errors.

The automated saving functions of Kosmos Trio (Auto Capture and Smart Capture) may occasionally contain errors. It is important to review saved images independently using experienced clinical judgment prior to making a diagnosis. This may be especially important with saved clips noted as being saved through the Smart Capture function, because in these instances Kosmos Trio did not detect a clip of sufficient quality to meet the Auto Capture threshold.

Manual recording should be used only by those users who are able to determine, without the assistance of Kosmos Trio, that a clip is of sufficient diagnostic quality.

To activate Kosmos Trio, follow the steps below.

1. From the Home screen, tap the **Heart** icon .
2. Tap the **Trio** icon i on the left side of the screen. When activated, the icon will turn orange and the Trio menu will appear.



3. Select the view by tapping the radio button next to the **PLAX**, **A4C**, or **A2C**.
4. Check to see all the Trio options are activated prior to scanning.

   Each Trio option can be toggled by tapping the slider. When an option is activated, the slider color will change from gray to orange.

5. Follow the on-screen **Guidance** probe motions located in the upper left corner of the screen to move the probe to its optimal position.
6. Auto Capture will automatically save when its requirements are met.

   Auto Capture will automatically deactivate once it saves a clip. You can re-enable Auto Capture by changing the view or by tapping the **Capture** slider in the Trio menu.

7. Repeat Steps 1 though 6 to acquire additional views, if needed.
8. To review saved exams, refer to Reviewing an Exam (page 70) section of this user guide.

Kosmos Cardiac Measurements

> Do not rely upon Kosmos cardiac measurements as the sole diagnostic criteria. Whenever possible, use Kosmos cardiac measurements in conjunction with other clinical information.

Kosmos Cardiac Calculations package provides the tools to assess cardiac structure and function. Kosmos cardiac measurements are available in B-Mode, Doppler and M-Mode.

While in **Exam Review**, cardiac calculations and annotation tools can be used to perform cardiac measurements. See Annotating Images and Clips (page 70) for instructions on how to annotate images and clips.

To access the Cardiac Calculation tools from the screen, tap **Calc**.

To access the Annotation tools from the Exam Review screen, tap **Annotate**.

For a list of measurements, reference Table 13: Cardiac Measurements by Mode

While reviewing the Doppler cine, you can:

1. Perform Doppler measurements
   - VTI: When you tap on VTI, you will have the option to select Auto or Manual VTI trace.
     - If you select Auto, tap the signal that you want to trace, and the device will trace the signal automatically.
     - If you select Manual, you will be prompted to manually trace the signal with your finger.
     - Edit the VTI trace by moving the control points.
     - Choose a different peak by double-tapping it.

     > Auto trace is not available for Mitral Valve VTI in PW and CW tracing. Auto tracing is only available in Annotations or for LVOT VTI (PW) and AV VTI (CW).
   - PHT and Delta Velocity: Move to two end points of the calipers to the appropriate location on the Doppler spectrum.
   - Velocity and PG: Move the cursor to the desired location.
   - You can perform three PHT, three Velocity, and three VTI measurements per image/clip.
     - Only three frames in 2D cine loops can be placed.
     - Only three VTI measurements at a time.

     > You will receive a notification that the measurement is full in the report if you try to place a 4th measurement. You can delete a measurement in the report to make room for a new measurement.
2. Add Annotations:
   - Text
   - Marker
3. Move the baseline.
4. Invert the Doppler Spectrum.
5. View measurements by tapping the **Report** icon.
   - When viewing the report, the last measurement taken is the default measurement. However, by clicking the **Last** icon, users can choose to have the device calculate the average value or the maximum value for each measurement.

Table 13. Cardiac Measurements by Mode

2D Measurements	
PLAX	RVIDd. IVSd, LVIDd, LVPWd, LVIDS, LA diameter, LVOTd
Right Heart	RV basal, RV mid, RV length
Mitral Valve	MV Annulus diameter
Aortic Valve	Annulus, Sinus, ST junction, Ascending AO, Vena Contracta, LVOT diameter
IVC	IVC min, IVC max, RAP
Doppler Measurements	
PW	Right Heart: PV AcT (Acceleration Time) Mitral Valve: MV VTI (PW), E wave Velocity, Deceleration Time, A wave Velocity Aorta: LVOT VTI (PW) Diastology: E wave Velocity (PW), A wave Velocity, Deceleration Time (PW) Aortic Valve: LVOT VTI (PW)
CW	Right Heart: TR (CW), PAEDP (CW), PR (CW) Mitral Valve: MV VTI (CW), Pressure Half Time (CW) Aortic Valve: AV VTI (CW), Peak AV Velocity, Pressure Half Time (CW) Diastology: TR (CW)
TDI	Right Heart: TV annulus s' Mitral Valve: e' -point (m/s), a' -point (m/s) Diastology: e' -point (m/s), a' -point (m/s)
M-Mode Measurements	
M-Mode	EPSS, TAPSE, MAPSE, IVC min, IVC max, HR, RAP

Kosmos Vascular Protocol

Vascular Annotations

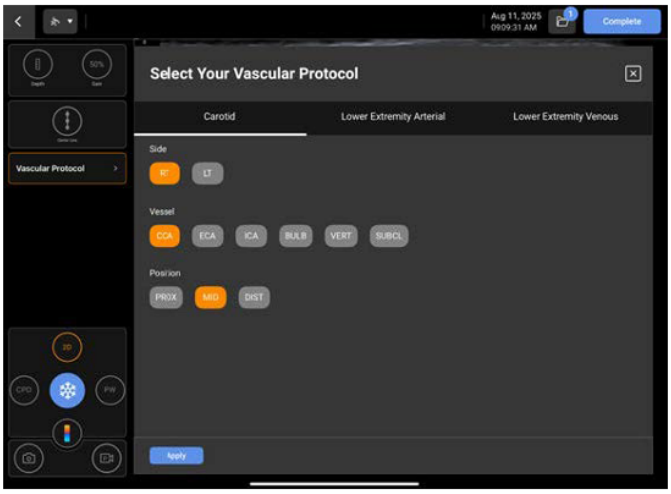
Kosmos Vascular Annotations package provides the tools to label vascular anatomy for Carotid, Lower Extremity Arterial, and Lower Extremity Venous exams. Annotations can be done during the exam when the image is frozen, during lives canning, or after you have completed the exam. Kosmos vascular annotations are available in 2D mode, PW Doppler mode, Color Power Doppler mode, and ColorDoppler mode while scanning with Kosmos Lexsa in the Vascular preset.

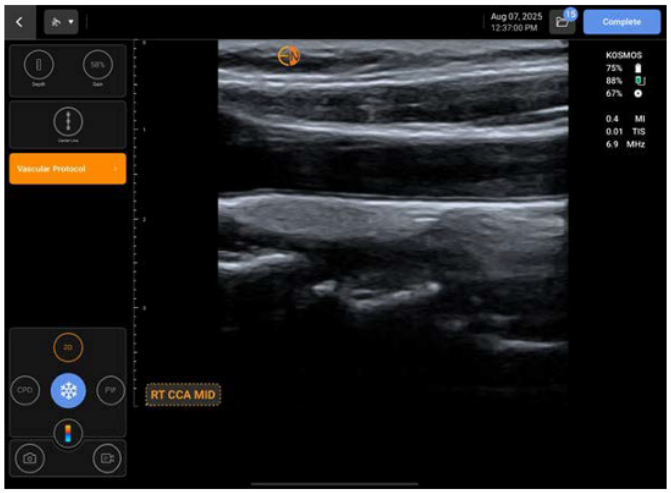
Follow the instruction below to annotate vascular anatomy.

1. Tap **Vascular Protocol** to open the protocol's menu.
2. Tap to choose from **Carotid**, **Lower Extremity Arterial**, and **Lower Extremity Venuous**.
3. Tap to select anatomical **Side**, **Vessel**, and **Position**.

> **Position** is not available for each protocol.

4. Tap **Apply** which will then show the annotation.
5. To adjust annotation location, press and hold highlighted annotation and drag to desired location within the image.



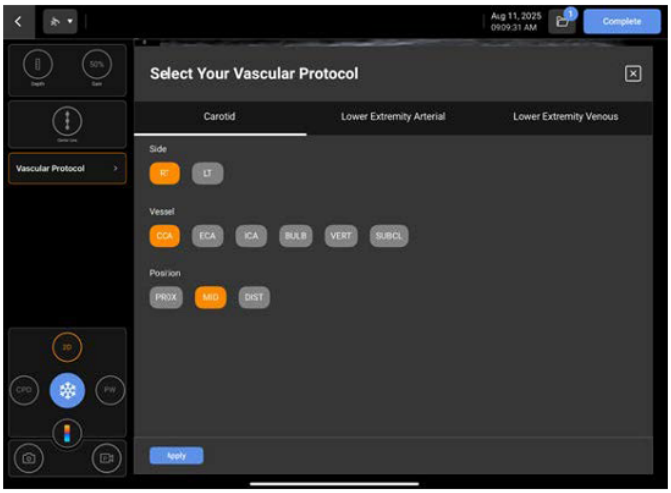


Annotations will persist until cleared. Follow the steps below to remove the annotations.

- Tap **Vascular Protocol** → **Clear**.

To exit the Vascular Protocol without annotating, follow the step below.

- Tap the ✕ icon located in the top right corner.



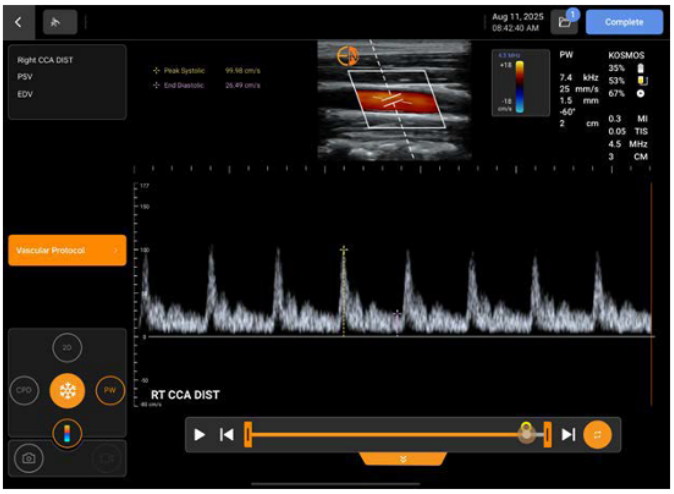
Vascular Measurements

The Kosmos Vascular Protocol package provides the tools to measure Peak Systolic Velocity (PSV) and End Diastolic Velocity (EDV). These measurements are assigned to the specific vessel selected by the user within the Vascular Protocol in PW Doppler mode and will appear in the Report.

> Only one PSV and EDV per image can be saved. A total of three PSV and EDV measurements can be assigned per vessel within an exam.

To assign PSV and EDV in PW mode within a selected Vascular Protocol, follow the step below.

1. Tap **Freeze** icon .
2. Tap **PSV** located in the top left-hand corner and manually adjust calipers.
3. Tap **EDV** located in the top left-hand corner and manually adjust calipers.
4. Tap the **Save image** icon to save measurement.
5. View measurements in the Report by tapping the **Exam Review** icon followed by the **Report & Patient Info** icon .
6. To delete a measurement in the **Report**, tap **Show All Measurements** → **Value**. Once you have selected all the values, tap → **Yes**.

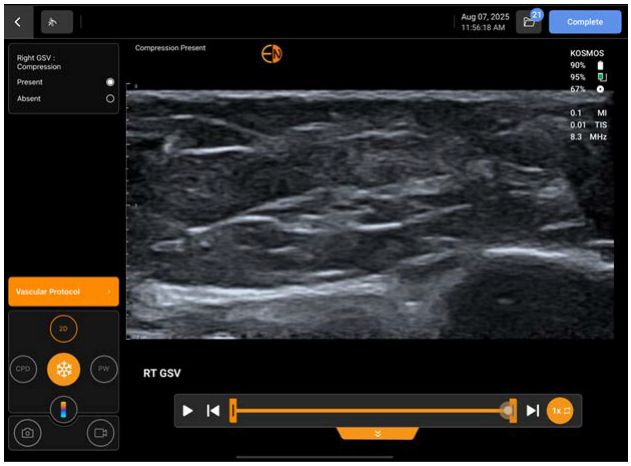


Venous Compression And Augmentation

The Kosmos Vascular Protocol package provides the tools for live documentation and reporting of the response to venous compression and augmentation.

To assign Venous Compression response in 2D or Color Doppler Mode within a selected Vascular Protocol, follow the steps below.

1. Tap the **Freeze** icon.
2. Tap next to **Present** or **Absent** to indicate the status of venous compression for a given vessel.
3. Tap **Save** image icon to save selection.



To assign Venous Augmentation response in PW Doppler Mode within a selected Vascular Protocol, follow the steps below.

1. Tap the **Freeze** icon.
2. Tap next to **Present**, **Absent**, or **Reflux** to indicate the status of venous augmentation for a given vessel.

3. Tap **Save** image icon to save selection.

Venous Compression and Augmentation comments will disappear from the top left corner of the image once out of PW Doppler mode. Each selection is stored in the Report.

Venous Compression and Augmentation comments can be edited within the Report screen while scanning or after the exam has been completed.

Kosmos Vascular Calculations

Do not rely upon Kosmos vascular measurements as the sole diagnostic criteria. Whenever possible, use Kosmos Vascular measurements in conjunction with other clinical information.

Kosmos Vascular Calculations package provides the tools to assess vascular structure and function. Kosmos vascular measurements are only available in 2D mode and PW Doppler mode while scanning with Kosmos Lexsa.

Reference Table 14: Vascular Measurements and Calculations by Mode for a list of vascular measurements.

Please note that DICOM SR is not available for the Vascular Calculations.

Table 14. Vascular Measurements and Calculations by Mode

Measurements and Calculations in 2D and PW Doppler Modes	
Venous	Peak Systolic, End Diastolic, Reflux Time, Vessel Diameter, Temporal Average Max, Temporal Average Mean, VTI (grafts)
Arterial	Peak Systolic, End Diastolic, VTI, Vessel Diameter, Temporal Average Max, Temporal Average Mean
Calculations	S/D Ratio, Pulsatility Index, Resistance Index, Flow Volumes

Obstetrics Measurements And Calculation

Obstetrics And Gynecology Warnings And Cautions

Do not perform transabdominal scans longer than 5 to 30 minutes in a scanning period.

During the first trimester, you should limit the duration of ultrasound imaging base don MI/TI. See Output Display and Display Accuracy (page 88) for more information.

CPD or Color images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool, for the diagnosis of Intrauterine Growth Retardation (IUGR).

To prevent injury or misdiagnosis, do not use this system for Percutaneous Umbilical Blood Sampling (PUBS) or in vitro Fertilization (IVF). The system has not been validated to be proven effective for these two uses.

Make sure that you have selected the obstetrics exam type and the OB author for the obstetrical calculations you intend to use. See Table 15: Obstetrics Calculations.

To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.

To avoid misdiagnosis or harming the patient outcome, make sure you end the previous study before starting a new patient study and performing calculations. Otherwise, the previous patient's data will be combined with the current patient. Tap **END STUDY** to end the previous study.

To avoid misdiagnosis or harm to the patient, do not use single calculations as the sole diagnostic criteria. Use calculations in conjunction with other clinical information.

If calipers are positioned imprecisely, the calculation result may be inaccurate.

Obstetrics Calculations

Table 15. Obstetrics Calculations

Calculation	Measurement	Authors	Mode
Yolk Sak	Yolk Sak		2D
Gestational Age (GA)	GS (Gestational Sac)	Hansmann, Rempen	2D
	CRL (Crown-Rump Length)	Hadlock, Hansmann, Jsum 2001, OsakaU, Robinson	2D
	BPD (Biparietal Distance)	Hadlock 84, Hadlock, Hansmann, Jeanty, Chitto, JSUM 2001, Osaka U, Merz, Rempen	2D
	HC (Head Circumference)	Hadlock 84, Hansmann, Chitty, Merz	2D
	AC (Abdominal Circumference)	Hadlock 84, Hansmann, Jsum 2001, Merz	2D
	FL (Femur Length)	Hadlock 84, Hansmann, Jeanty, Chitty, Jsum 2001, Osaka U, Merz	2D
	OFD (Occipital-Frontal Diameter)	Hansmann	2D
Estimated Fetal Weight (EFW)	AC, FL	Hadlock 1	2D
	AC, FL, HC	Hadlock 2	2D
	AC, FL, BPD	Hadlock 3	2D
	AC, FL, HC, BPD	Hadlock 4	2D
	BPD, AC	JSUM	2D

Obstetrics Measurements

Table 16. Obstetrics Measurements

Measurement	Type	Units	Mode
Cervical Length	Distance	cm, mm	2D
Amniotic Fluid Index 1	Distance	cm, mm	2D
Amniotic Fluid Index 2	Distance	cm, mm	2D
Amniotic Fluid Index 3	Distance	cm, mm	2D
Amniotic Fluid Index 4	Distance	cm, mm	2D
AFI Largest Pocket	Longest Distance	cm, mm	2D
AFI (Amniotic Fluid Index)	Sum of 4 Quadrant Amniotic Distance	cm, mm	2D
Fetal Heart Rate (FHR)	Distance/Time	Beats Per Minute (BPM)	M-Mode/PW
Umbilical Artery	S, D, RI,PI,S/D	m/sec, cm/s	PW

Also includes BPP using Breathing, Movement, Tone, Fluid, and Non-Stress Test (NST).

Gynecological Measurements And Calculations

Table 17. Gynecological Measurements and Calculations

Measurement Drop Down	Measurement	Type	Mode
Uterus	Uterus L, H, and W, Volume	Distance, Volume	2D
	Endometrium	Distance	2D
	Cervical Length	Distance	2D
Right Ovary	Rt Ovary L, H, and W, Volume	Distance, Volume	2D
Right Ovarian Artery	S, D, S/D, RI, PI	Velocity, VTI	PW
Left Ovary	Lt Ovary L, H, and W, Volume	Distance, Volume	2D
Left Ovarian Artery	S, D, S/D, RI, PI	Velocity, VTI	PW

Kosmos TCD Calculations

Kosmos TCD Calculations package provides the tools to use PW Doppler to assess structures within the trans-temporal window. Kosmos TCD Calculations are available in PW Doppler mode while scanning with Kosmos Torso-One in the TCD preset.

Verify the sample gate depth to ensure the correct vessel is assessed. Failure to do so may lead to delay in care or misdiagnosis.

Table 18. TCD Measurements and Calculations in PW Doppler mode.

Exam	Measurements and Calculations
TCD	Peak Systolic, End Diastolic, Time Average Max, Time AverageMean, VTI, S/D Ratio, Pulsatility Index, Resistive Index

Kosmos Abdominal Measurements

Kosmos Abdominal Measurements package provides the tools to assess the structure and function of the abdominal aorta and common iliac arteries. Kosmos vascular measurements are available in 2D mode, Color Doppler mode, and PWDoppler mode while scanning with Kosmos Torso-One in the Abdominal preset.

These measurements are assigned to the specific vessel selected by the user and will appear in the Report

Table 19. Aorta Measurements

2D Measurements	PW Doppler Measurements
Prox Aorta, Mid Aorta, Distal Aorta,RT CIA, LT CIA, Aneurysm	Prox Aorta, Mid Aorta, Distal Aorta,RT CIA, LT CIA, Aneurysm
Trans Diam, AP Diam	Peak Systolic, End Diastolic

CHAPTER 5

Reviewing An Exam

Once you have completed an exam, you cannot add any images to it; however, before archiving the exam, you can add, edit, and delete any annotations you have saved.

Once the archive process begins, you will not be able to make edits to the exam.

Starting An Exam Review

To start a review during an exam, tap the **Exam Review** icon.

> The **Exam Review** icon must indicate there are saved images or clips in order to access the **Exam Review** feature.

To start a review for a completed exam, do one of the following:

- From the Home screen, tap **EXAMS**, then tap the exam you would like to review.
- From the list of patients, find the patient, then tap the exam you would like to review.

Annotating Images And Clips

You can add annotations during the exam when the image is frozen or after you have completed the exam. All annotations are saved as overlays on the image or clip.

> Once you have archived an image or clip, you cannot annotate it.

Navigating To The Edit Image Screen

While scanning a patient:

1. Tap the **Freeze** icon.
2. Add your annotations.
3. Tap the **Save image** or **Save clip** icon.

After scanning a patient:

1. Tap the **Exam review** icon.
2. Tap the image/clip you want to annotate.
3. Tap the **Edit** icon.

From the Home screen:

1. Tap **Exam**.
2. Tap the exam row that you want to edit.
3. Tap the clip you want to annotate.
4. Tap the **Edit** icon.

From the Patient screen:

1. Tap a patient from the list.

2. Tap the exam.
3. Tap the image/clip you want to annotate.
4. Tap the **Edit** icon.

Annotation Tools

Annotations can be added to individual images and clips.

When you add an annotation (text, measurements, arrow, area) to a clip or a cine, it persists through all frames.

You can also hide the overlay of the annotations you make by tapping the **Hide overlay** icon on saved images and clips.

Measuring With The Caliper Tool

You can add up to two calipers per image/clip.

When a caliper is not selected, dragging one of its endpoints selects it and resizes it as you drag.

To place a measurement:

1. From the Edit image or Edit clip screen, tap **DISTANCE**, and a caliper appears in the center of the image or clip.
2. Tap to select the caliper.

   The caliper distance is displayed in the legend at the upper-left of the screen. If you have multiple calipers, they display in different colors.
3. To resize the caliper, tap and drag one of its endpoints.
4. To move the caliper, tap anywhere on the caliper except the two endpoints.
5. To clear the caliper, tap an empty area outside it.

Deleting Annotations

To delete one annotation, tap the annotation to select it, then tap **DELETE**.

To delete all the annotations you have made, tap **CLEAR ALL**.

Managing Images And Clips

Filtering Images And Clips

When you review an exam, all the images and clips, regardless of the scan type (lung, heart, abdomen), are visible in the thumbnail list.

You can filter images and clips in the following ways:

- Drag and pull the thumbnail list down to reveal the filter options.
- Tap the Filter icon at the top of the thumbnail list to reveal the filter options.
- Tap the **More options** icon in the title bar, and tap **Filter images and clips**. When the filter options are visible, a blue check icon will be displayed next to **Filter images and clips**.

When you select a filter, only the tagged images/clips are visible in the thumbnail list. You can tag images/clips by tapping the star icon under each image/clip in the thumbnail list so the star turns yellow.

To dismiss the filters you have selected, tap the **More options** icon, then tap the **Filter images and clips** again to remove the filters.

Selecting Images And Clips

To select images and clips:

1. Tap the **More options** ⋮ icon, and tap **Select images and clips**.
2. Select the images and clips you want. A gray check will appear in the top right corner of the thumbnail.
3. Optionally, tap the check on the thumbnail; it turns red, and a numbered circle displays to indicate how many images and clips you have selected. To clear the red check, tap it again.

To clear the selections, tap the **More options** ⋮ icon, and tap **Select images/clips**.

Trimming And Saving Images And Clips

To trim and save a clip:

1. Tap the **Freeze** icon.
2. Move the right and left endpoints of the cine clip.
3. Tap the **Clip** icon.

To trim and save an image:

1. From the Exam Review screen, locate the saved clip.
2. Tap **EDIT**.
3. Move the right and left endpoints of the image.
4. Tap **SAVE**.

Deleting Images And Clips

To delete selected images and clips:

1. Tap the **More options** ⋮ icon, and tap **Select images/clips**.
2. Select the images and clips you want to delete.
3. Tap **DELETE** and, when prompted, tap **OK**.

Reviewing And Editing A Report

Reports are not yet encapsulated in the DICOM file; you can only see images and clips at this review step.

The exam report allows you to review patient and exam information, text notes, audio notes, pictures taken during the exam, images, and clips.

Opening A Report

To open a report, tap **REPORT**.

Editing A Report

Once you've opened the report, each section is expanded for your review. You can collapse each section by tapping the arrow button. Just tap the arrow button to expand the section again.

You can edit each section of the report, except for the patient information. This is read-only and cannot be changed.

Exporting Images And Clips To A USB Drive

When exporting images and clips, use a micro USB or adapter. You can export images and clips from one exam or multiple exams.

> ⚠ To protect patient data, take appropriate precautions when exporting patient data to a USB drive.

To export images and clips from one exam to a USB drive:

1. From the Home screen, tap **EXAMS**.
2. Tap a row to select an exam.
3. Tap the bookmark icon under each thumbnail you want to export. (This is an optional step and only valid if you would like to export some but not all images and clips.)
4. Connect the USB drive using the USB-C adapter.
5. Tap **EXPORT**. A dialog box appears.
6. Select the file type and whether to export all images and clips, or only the tagged ones.
7. Tap **OK** to start exporting to the USB drive.

To export images and clips from multiple exams to a USB drive:

1. From the Home screen, tap **EXAMS**.
2. Tap the circles next to each exam you would like to export.
3. Connect the USB drive using the USB-C adapter.
4. Tap the **Export** icon at the top of the screen. A dialog box appears.
5. Select the file type and whether to export all images and clips, or only the tagged ones.
6. Tap **OK** to start exporting to the USB drive.

The following is a legend for the exporting icons.

Exam is waiting to be exported.

Export is in progress.

Export is complete.

Export failed.

Completing An Exam Review

To complete an exam:

1. Tap **COMPLETE**.
2. When prompted, click **OK**.

Archiving An Exam To A PACS Server

After completing an exam, you can archive it to a PACS server. Once an exam is archived, it cannot be edited.

For more information about setting up a PACS server, see DICOM Settings (page 15).

For each EF scan, multiple images/clips are archived and exported.

The following is a legend for the archiving icons.

 Exam is waiting to be archived.

 Archive is in progress.

 Archive is complete.

 Archive failed.

You can archive an exam either from the Exam list or the Exam review screens. To archive an exam from the Exam list screen:

1. From the Exam List screen, tap to select the completed exam(s) you want to archive.
2. Tap the **Archive** icon. The complete exam is archived according to the default archive options. For more information, see DICOM Settings (page 15).

To archive an exam:

1. From the Exam review screen, tap **ARCHIVE**.
2. From the Archive exam to the PACS server screen, select which images and clips you want to archive, and if you would like to include a report.
3. Click **OK** and, when prompted, click **OK** again.

Deleting An Exam

To delete an exam from the Exam list:

1. Tap the left icon next to the exam you would like to delete. The icon turns into a **check mark** .
2. Tap the **Delete** icon.
3. When prompted, tap **OK**.

To delete an exam while reviewing it:

1. Tap the **More options** icon.
2. Tap **Delete the exam**.

When prompted, click **OK**.

CHAPTER 6

Kosmos Probes

Kosmos Probe Sheaths

Where fluid contamination is possible, cover the probe being used (Kosmos Torso-One or Kosmos Lexsa) with an appropriate sterile sheath from CIVCO, which promotes asepsis and minimizes the need for cleaning.

Be aware that some patients have a latex allergy. Some commercially available Kosmos probe covers contain latex.

To prevent cross-contamination, use sterile transducer sheaths and sterile coupling gel for clinical applications contacting compromised skin.

Some sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals.

Use market-cleared sheaths for clinical applications when a Kosmos probe is likely to be splashed or splattered with blood or other bodily fluids.

Use market-cleared, sterile sheaths and sterile coupling gel to prevent cross-contamination. Do not apply the sheath and coupling gel until you are ready to perform the procedure. After use, remove and discard the single-use sheath, and clean and disinfect the Kosmos probe using an EchoNous-recommended high-level disinfectant.

After inserting the Kosmos probe into the sheath, inspect the sheath for holes and tears.

Ultrasound Transmission Gels

Some ultrasound gels may cause an allergic reaction in some individuals.

To prevent cross-contamination, use single-use gel packs.

EchoNous recommends the use of:

- Aquasonic 100 Ultrasound Gel, Parker
- Aquasonic Clear Ultrasound Gel, Parker
- SCAN Ultrasound Gel, Parker

Kosmos Probe Storage

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated Kosmos probes should carry an ISO biohazard label.

Storage

Kosmos is intended for use and storage in normal ambient conditions within a medical facility. Additionally, the packaging provided with the device can be used for long-term storage.

Storage For Transport

Kosmos is intended to be handheld for easy transport. Users may use the packaging supplied with the device for transport. Consult your EchoNous sales representative for information on approved bags and other accessories.

Transducer Element Check

Every time a Kosmos probe is connected, a test is run automatically to check for the integrity of the transducer elements. The test reports to the user whether all transducer elements are functioning properly (successful test) or whether failures were detected.

The same test runs automatically when the Kosmos App boots up with the Kosmos probe connected.

CHAPTER 7

Kosmos Maintenance

Cleaning And Disinfecting

General Cautions

⚠ The provided cleaning instructions are based on requirements mandated by the U.S. Food and Drug Administration. Failure to follow these instructions may result in cross-contamination and patient infection.

⚠ Cleaning and disinfection instructions must be followed when using a transducer cover or sheath.

⚠ Some reprocessing chemicals may cause allergic reactions in certain individuals.

⚠ Ensure that cleaning and disinfecting solutions and wipes are not expired.

⚠ Do not allow cleaning solutions or disinfectants to enter the tablet or Kosmos probe connectors.

⚠ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as protective eyewear and gloves.

⚠ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.

⚠ Do not spray cleaners or disinfectants directly on tablet surfaces or on the tablet and Kosmos probe connectors. Doing so may cause the solution to leak into Kosmos, damaging it and voiding the warranty.

⚠ Do not attempt to clean or disinfect the tablet, Kosmos probes, or Kosmos probe cable using a method not included in this guide or a chemical not listed in this guide. Doing so can damage Kosmos and void the warranty.

⚠ Do not pull the cable of the Kosmos probe while holding or disinfecting the device. Pulling on the cable may cause damage to the probe.

Tablet

⚠ The tablet is not sterile when shipped; do not attempt to sterilize it.

⚠ To avoid electrical shock, turn off the tablet and disconnect it from the power supply before cleaning.

Avoid spraying the cleaning and disinfection solutions directly onto the tablet. Instead, spray onto a non-abrasive cloth and then gently wipe. Ensure that all excess solution is wiped off and not left on the surface after cleaning. The following cleaning and disinfection method must be followed for the tablet.

1. Disconnect the Kosmos probe from the tablet.
2. Remove any accessories, such as the Kosmos Link or power supply.

3. Using a wipe, carefully clean the screen and all other areas of the tablet. Choose an EchoNous-approved wipe from the list in Table 20: Presaturated Wipes.
4. If necessary, clean the tablet with additional wipes to remove all visible contaminants.

Kosmos Link

The Link is not sterile when shipped; do not attempt to sterilize it.

To avoid electrical shock, disconnect the Link from the power supply before cleaning.

Do not use a chlorine dioxide-based agent, such as Tristel Duo ULT, on Kosmos Bridge or Kosmos Link because it may corrode the aluminum housing.

Avoid spraying the cleaning and disinfection solutions directly onto the Link. Instead, spray into a non-abrasive cloth and gently wipe. Ensure that all excess solution is wiped off and not left on the surface after cleaning. The following cleaning and disinfection method must be followed for the Link.

1. After each use, disconnect the USB cable from the tablet.
2. Disconnect the probes from the underside of the Link.
3. Using an approved presaturated disinfectant wipe, carefully wipe all areas of the Link. Choose an EchoNous-approved wipe from the list provided in Table 20: Presaturated Wipes.
4. If necessary, clean the Link with additional wipes to remove all visible contaminants.

After disinfection, inspect the device for cracks. If damage is found, discontinue use of the device and contact EchoNous Customer Support.

A complete guide to compatible cleaning and disinfection agents can befound online at echonous.com/resources/mediatype-chemicalcompatibility-guides/.

Table 20. Presaturated Wipes

Product	Company	Active Ingredients	Contact Condition
Sani-Cloth Super	PDI Inc.	Iso Propyl Alcohol 55.5% Quaternary Ammonium compounds, C12-18-alkyl[(ethyphenyl) methyl] dimethyl, chlorides0.25% n-alkyl dimethyl benzyl ammonium chloride 0.25%	5 minutes wet contact time for disinfection
Duo ULT	Tristel	Chlorine Dioxide 100% (Proprietary Formulation)	30 seconds wet contact time for disinfection

A complete list of approved Presaturated Wipes is available online at echonous.com/product/resources/.

Kosmos Probes

Always disconnect the probe from the Link before cleaning and disinfecting.

After cleaning, you must disinfect the Kosmos probes by following the appropriate instructions.

Always wear protective eyewear and gloves when disinfecting any equipment.

Use only EchoNous-recommended wipes. Using a non-recommended wipe can damage the Kosmos probe and void the warranty.

⚠ When cleaning and disinfecting Kosmos probes, do not allow any fluid to enter electrical connections or metal portions of the USB connector.

⚠ The use of a cover or sheath does not preclude proper cleaning and disinfecting of a Kosmos probe. When choosing a cleaning and disinfecting method, treat Kosmos probes as if a cover was not used in the procedure.

🔖 Kosmos probes must be cleaned after each use. Cleaning Kosmos probes is an essential step before effective disinfection.

1. Disconnect the Kosmos probe from the tablet.
2. Remove any accessories attached to or covering the Kosmos probe, such as a sheath.
3. At the point of use, wipe the Kosmos probe with an approved presaturated wipe.
4. Before disinfecting the Kosmos probe, remove all ultrasound gel from the Kosmos probe's face using an approved presaturated disinfectant wipe. Choose an EchoNous-approved wipe from Table 20: Presaturated Wipes.
5. Using a new presaturated wipe, remove any remaining particulate matter, gel, or fluids from the Kosmos probe.
6. If necessary, clean the Kosmos probe with additional wipes to remove all visible contaminants.
7. Before continuing with disinfection, ensure the Kosmos probe is visibly dry.

Disinfecting (Intermediate-Level)

Use the following steps to disinfect a Kosmos probe whenever it has not come into contact with non-intact skin or intact mucous membranes (non-critical use). Before proceeding with the following steps, please read the warnings and cautions carefully.

⚠ For low- and intermediate-level disinfection, EchoNous validated its disinfection with intermediate-level disinfection.

⚠ Always disconnect the USB cable from the Kosmos probes before cleaning and disinfecting.

⚠ Always use protective eye wear and gloves when disinfecting any equipment.

⚠ Before disinfecting, clean Kosmos probes by following the appropriate instructions to remove all gels, fluids, and particulates that may interfere with the disinfection process.

⚠ Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting wipe can damage the Kosmos probe and void the warranty.

1. After cleaning, select an intermediate-level disinfectant from Table 20: Presaturated Wipes and observe the recommended minimum wet contact time.
2. With a new wipe, clean the cable and the Kosmos probe, starting from the exposed cable, wiping toward the Kosmos probe head.
3. Observe the required wet contact time. Monitor the Kosmos probe for a wet appearance. Use at least three wipes to ensure effective disinfection.
4. Before reusing the Kosmos probe, ensure the Kosmos probe is visibly dry.

⚠ Inspect the Kosmos probe for damage, including cracks, splitting, or sharp edges. If damage is evident, discontinue using the Kosmos probe and contact your EchoNous representative.

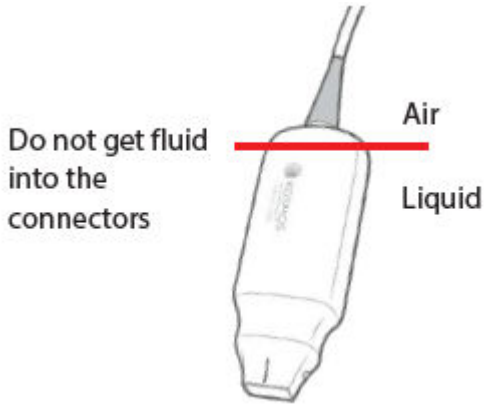
Disinfecting (High-Level)

Use the following steps to high-level disinfect the Kosmos probes whenever they have come into contact with intact mucous membranes or non-intact skin (semi-critical use). High-level disinfection of Kosmos probes typically uses an immersion method with high-level disinfectants or chemical sterilants.

Before proceeding with the following steps, please read the warnings and cautions carefully.

⚠	Always disconnect Kosmos probes from the tablet before cleaning and disinfection.
⚠	Before disinfection, clean the Kosmos probe according to the appropriate cleaning instructions in the Cleaning and Disinfecting (page 77) section to remove all gels, fluids, and particulates that may interfere with the disinfection process.
⚠	Always wear protective eyewear and gloves when disinfecting any equipment.
⚠	When disinfecting Kosmos probes, do not allow any fluid to enter the electrical connections or the metal portions of the USB.
⚠	Do not attempt to disinfect Kosmos probes using a method not specified in these instructions. This can damage the Kosmos probe and void the warranty.
⚠	Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting solution or an incorrect solution strength can damage the Kosmos probe and void the warranty.
⚠	If the Kosmos probe has come into contact with intact mucous membranes or non-intact skin (semi-critical use), use the high-level cleaning and disinfection procedure.

1. After cleaning, choose a high-level disinfectant that is compatible with Kosmos probes. For a list of compatible disinfectants, see Table 21: Disinfectant Solutions for the Kosmos Probe Immersion.
2. Test the solution strength by using a Cidex OPA test strip. Ensure that the solution is not older than 14 days (in an open container) or 75 days (from a just-opened storage container).
3. If a pre-mixed solution is used, be sure to observe the solution expiration date.
4. Immerse the Kosmos probe in the disinfectant, as shown below. Kosmos probes may be immersed only up to the immersion point shown. No other part of the Kosmos probe, such as cable, strain relief, or connectors, should be soaked or immersed in fluids.



5. Refer to Table 21: Disinfectant Solutions for the Kosmos Probe Immersion for the duration of immersion and contact temperature.

6. Do not immerse the Kosmos probe longer than the minimum time needed for a semi-critical level of disinfection.
7. Rinse the Kosmos probe for at least one minute in clean water up to the point of immersion to remove chemical residue. Do not soak or immerse any other part of the Kosmos probe, such as the cable, strain relief, or connector.
8. Repeat, rinsing three times to ensure proper rinsing.
9. Air-dry or use a soft, sterile cloth to dry the Kosmos probe until it is visibly dry.
10. Wipe the strain relief and the first 18 inches (45 cm) of the Kosmos probe cable with an approved wipe from Table 20: Presaturated Wipes.
11. Inspect the Kosmos probe for damage, including cracks, splitting, or sharp edges. If damage is evident, discontinue using the Kosmos probe and contact your EchoNous representative.

Table 21. Disinfectant Solutions for the Kosmos Probe Immersion

Product	Company	Active Ingredients	Contact Condition
Cidex OPA Solution	Advanced Sterilization Product	Products 0.55% ortho phthaldehyde	12 minutes at 20ºC

For additional compatible disinfecting agents, see echonous.com/product/resources/.

- Check the bottle's expiration date to ensure the disinfectant has not expired. Verify that the disinfection chemicals are at the manufacturer-recommended concentration (for example, using a chemical strip test).
- Verify that the disinfectant's temperature is within the manufacturer’s recommended limits.

Guidelines For Automated Reprocessors (AR)

Always disconnect the Kosmos probe before cleaning and disinfecting.

Ensure cable insulation is intact before and after cleaning.

The EMC suppressor on probes should be inside the Trophon®2 chamber below the cable clamp during disinfection.

All Kosmos probes are compatible with Nanosonic™ Trophon®2 System. Refer to the Trophon®2 user guide for detailed instructions on the disinfection of ultrasound probes.

For additional compatible disinfecting agents, see echonous.com/product/resources/.

For questions related to compatibility with other AR systems, contact EchoNous support.

Recycling And Disposal

Do not incinerate or discard Kosmos Link in general waste at end of life. The lithium-ion battery is a potential environmental and fire safety hazard.

The lithium ion battery inside Kosmos Link may explode if exposed to very high temperatures. Do not destroy this unit by incinerating or burning. Return the unit to EchoNous or your local representative for disposal.

The system should be disposed of in an environmentally responsible manner in compliance with federal and local regulations. EchoNous recommends taking Kosmos probes and Kosmos Link to a recycling center that specializes in the recycling and disposal of electronic equipment.

When a Kosmos probe or Kosmos Link has been exposed to biologically hazardous material, EchoNous recommends using biohazard containers in compliance with federal and local regulations. Kosmos probes and Kosmos Link should be taken to a waste center specializing in the disposal of biohazardous waste.

Troubleshooting

Preventive Inspection, Maintenance, And Calibration

- Kosmos does not require any preventative maintenance or calibration.
- Kosmos does not contain any serviceable parts.

The Kosmos Link battery can only be replaced by properly trained technicians.

If Kosmos is not functioning as designed and intended, contact EchoNous customer support.

Do not open the Kosmos Link enclosure.

CHAPTER 8

Safety

Electrical Safety

References

IEC 60601-2-37:2007+AMD1:2015 Medical electrical equipment – Part 2-37: *Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment. Part 1: *General requirements for basic safety and essential performance*

IEC 60601-1-2:2014:+AMD1:2020 Medical electrical equipment – Parts 1-2: *General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 62304:2015 Medical device software - *Software life-cycle processes*

ISO 14971:2019 Medical devices - *Application of risk management to medical devices*

ISO 10993-1:2018 Biological evaluation of medical devices - *Part 1: Evaluation and testing within a risk management process*

Lang, Roberto M., et al. *Recommendations for chamber quantification: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology.* Journal of the American Society of Echocardiography 18.12 (2005): 1440-1463.

Lang, Roberto M., et al. *Recommendations for cardiac chamber quantification by echocardiography in adults: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging.* European Heart Journal-Cardiovascular Imaging 16.3 (2015): 233-271.

Ronneberger, Olaf, Philipp Fischer, and Thomas Brox. *U-net: Convolutional networks for biomedical image segmentation*. International Conference on Medical image computing and computer-assisted intervention. Springer, Cham, 2015.

Labeling Symbols

Symbol	Description	SDO Title Reference Number Standard
	Indicates device manufacturer. Includes the name and address of the manufacturer	Manufacturer Ref. No. 5.1.1 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Tested to comply with FCC standards	None
	Probes are tested to Type BF protection	TYPE BF APPLIED PART Refer to D1.20 IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
	Class ii equipment	Class ii equipment Ref. No. D.1-9 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Safety cautions are identified with this mark on the device. Caution Ref	Caution Ref. No D1.10 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Symbol	Description	SDO Title Reference Number Standard
	Consult instructions for use	Operating instructions Ref. No. D.1-11 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Do not dispose of this product in normal trash or landfill; refer to local regulations for disposal	Separate collection Annex IX Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU of the European Parliament
IPX7	Kosmos Torso-One and Kosmos Lexsa are protected against temporary immersion in water.	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)
IP32	The Kosmos Link is protected against ingress of a solid foreign object greater than or equal to 2.5mm in diameter, protected against access to hazardous parts with a finger, and protected against direct sprays of water up to 15 degrees from vertical.	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)
	Part or model number	Catalog number Ref. No. 5.1.6 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Serial number	Serial number Ref. No. 5.1.7 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Date of manufacture	Date of manufacture Ref. No. 5.1.3 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Acceptable temperature range XX is generic placeholder for specified temperatures	Temperature limit Ref. No. 5.3.7 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Acceptable humidity range XX is generic placeholder for specified percentages	Humidity limitation Ref. No. 5.3.8 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Acceptable atmospheric pressure range XX is generic placeholder for the specified kPa	Atmospheric pressure limitation Ref. No. 5.3.9 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Stack the box this way up	This way up Ref. No. 13 ISO 780 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages
	Indicates direct current	Direct current Ref. No. D.1-4 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Indicates alternating current	Alternating current Ref. No. D.1-1 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Batch code	Batch code Ref. No. 5.1.5 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	UL Classified. Medical - General medical equipment as to electrical shock, fire, and mechanical hazards only in accordance with ANSI/AAMI ES 60601-1 (2005) + AMD (2012) / CAN/ CSA-C22.2 No. 6060-1 (2008) + (2014). Associated classified number E509516.	None
RX Only	Caution: Federal law restricts this device to sale by or on the order of a physician.	Reference: USA FDA 21 CFR 801.109
	Medical device	Medical Device. Ref. No. 5.7.7 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirement

Symbol	Description	SDO Title Reference Number Standard
UDI	Unique Device Identifier	Unique Device Identifier. Ref. No. 5.7.10 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirement
UK CA 0086	UK Conformity Assessed	Symbol for UK Conformity Assessed. MHRA Department of Business, Energy & Industrial Strategy December 31, 2020
CE 2797	EU Conformity Mark	Regulation EU 2017/745 Article 20 Notified Body 2797
CH REP	Switzerland Representative	Symbol for Switzerland Representative MU600_00_016e_MB
EU REP	European Authorized Representative	Authorized Representative. Ref. No. 5.1.2 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
UKRP	United Kingdom Responsible Person	The Medical Devices Regulations 2002; Article 60(2)

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外国指定高度管理医療機器製造等事業者：ECHONOUS, INC.（米国）

販売名：超音波画像診断装置 KOSMOS Series Plus

管理医療機器

特定保守管理医療機器

一般的名称：汎用超音波画像診断装置（JMDN コ ー ド：40761000)

認証番号：306AIBZI00001000

Biological Safety

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the “as low as reasonably achievable” (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel (users). No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, users are responsible for controlling total energy transmitted into the patient.

Reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, Kosmos provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound, not only in the technology but in the applications of that technology, have resulted in the need for more

and better information to guide users. The output display tables are designed to provide that important information.

There are a number of variables that affect the way in which the output display tables can be used to implement the ALARA principle. These variables include index values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

A generic ALARA education program is supplied with Kosmos (see enclosed ISBN 1-932962-30-1, Medical Ultrasound Safety).

Applying ALARA

The Kosmos imaging mode used depends upon the information needed. B-Mode imaging provides anatomical information, while Color-mode imaging provides information about blood flow.

Understanding the imaging mode being used enables users to apply the ALARA principle with informed judgment. Additionally, the Kosmos probe frequency, setup values, scanning techniques, and experience enable users to meet the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the user. This decision must be based on the following factors: patient type, exam type, patient history, ease or difficulty in obtaining diagnostically useful information, and potential localized heating of the patient due to transducer surface temperatures. Prudent use of Kosmos occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

There are several system controls the operator can use to adjust image quality and limit acoustic intensity. These controls relate to the techniques a user might use to implement ALARA.

Output Display and Display Accuracy

Output Display

Kosmos displays the two bioeffect indices prescribed by IEC 60601-2-37. Medical electrical equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

The thermal index (TI) provides a measure of the expected increase in temperature.

Thermal Index

TI is an estimate of the temperature increase of soft tissue or bone. There are three TI categories: TIS, TIB, and TIC. The following TI categories are available for display:

- TIS: Soft tissue thermal index (the main TI category), is used for applications that do not image bone.
- TIB: Bone thermal index (bone located in a focal region).
- TIC: Cranial bone thermal index (bone located directly against the transducer's face during transcranial applications).

Mechanical Index

MI is the estimated likelihood of tissue damage due to cavitation. The absolute maximum limit for the MI is 1.9, as set by the Guidance for Industry and FDA Staff - Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2019).

ISPTA

The ISPTA is the Spatial Peak Temporal Average Intensity. The absolute maximum limit of Ispta is 720 mW/cm2 as set by the Guidance for Industry and FDA Staff - Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2019).

Output Display Accuracy

The output display accuracy of the bioeffect indices, MI and TI, depends on the measurement system's uncertainty and precision, engineering assumptions in the acoustic model used to calculate the parameters, and variability in the acoustic output of the systems. EchoNous also compares both internal and third-party acoustic measurements and confirms that both measurements are within the recommended display quantization of 0.2 as outlined by the standards.

> All MI and TI values displayed on Kosmos will not exceed the maximum global values (listed in the Track 3 acoustic output tables) by more than 0.2.

The accuracy of the MI and TI indices are as follows:

- MI: accurate to within ±25% or +0.2, whichever value is larger.
- TI: accurate to within ±30% or +0.2, whichever value is larger.

See acoustic output tables in sections Kosmos Torso-One Acoustic Output Tables (page 90) and Kosmos Lexsa Acoustic Output Tables (page 100).

Kosmos Torso-One Acoustic Output Tables

Table 22. Transducer: Kosmos Torso-One, Operating Mode: B-Mode, Combined Acoustic Output Table: Reportable Mode 1 (B-Mode) Cardiac, Body Type 2, 16 cm

Index Label	MI	TIS		TIB	
		At Surface	Below Surface	At Surface	Below Surface
Maximum Index Value	1.11	0.56		0.56	
Index Component Value		1: 0.30 2: 0.26	1: 0.30 2: 0.26	1: 0.30 2: 0.26	1: 0.30 2: 0.26
Acoustic Parameters					
$p_{r,\alpha}$ at z_{MI} (MPa)	1: 1.58				
P (mW)		1: 41.03 2: 37.03		1: 41.03 2: 37.03	
P_{1x1} (mW)		1: 30.42 2: 27.46		1: 30.42 2: 27.46	
z_s (cm)			1: 4.27 2: 4.23		
z_b (cm)					1: 3.93 2: 3.87
z_{MI} (cm)	1: 4.20				
$z_{pii,\alpha}$ (cm)	1: 4.20				
f_{awf} (MHz)	1: 2.03	1: 2.03 2: 2.03		1: 2.03 2: 2.03	
Other Information					
prr (Hz)	1: 1589.5				
srr (Hz)	1: 28.4				
n_{pps}	1: 1				
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	1:91.28				
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	25.13				
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	42.50				
p_r at z_{pii} (MPa)	1: 2.13				
Operating Control Conditions					
Exam	Cardiac				
BMI Setting	2				
Depth	16 cm				

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for Transcranial or Neonatal cephalic uses.

NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 23. Transducer: Kosmos Torso-One, Operating Mode: M-Mode, Acoustic Output Reporting Table: Reportable mode 3 M-Mode (Cardiac, Body Type: Medium, 12 cm depth)

Index Label	MI	TIS		TIB	
		At Surface	Below Surface	At Surface	Below Surface
Maximum Index Value	0.43	5.32E-02		0.11	
Index Component Value		5.32E-02	2.15E-02	5.32E-02	0.11
Acoustic Parameters					
$p_{r,\alpha}$ at z_{MI} (MPa)	0.70				
P (mW)		4.55		4.55	
P_{1x1} (mW)		4.11		4.11	
z_s (cm)			5.37		
z_b (cm)					4.80
z_{MI} (cm)	5.37				
$z_{pii,\alpha}$ (cm)	5.37				
f_{awf} (MHz)	2.72	2.72		2.68	
Other Information					
prr (Hz)	800				
srr (Hz)	N/A				
n_{pps}	1				
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	52.08				
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	16.71				
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	31.29				
p_r at z_{pii} (MPa)	45.72				
Operating Control Conditions					

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 24. Transducer: Kosmos Torso-One, Operating Mode: M-Mode, Acoustic Output Reporting Table: Reportable Mode 4 M-Mode (Cardiac, Body Type: Medium, 14 cm depth)

Index Label	MI	TIS		TIB	
		At Surface	Below Surface	At Surface	Below Surface
Maximum Index Value	0.39	5.33E-02		9.70E-02	
Index Component Value		5.33E-02	2.12E-02	5.33E-02	9.70E-02
Acoustic Parameters					
$p_{r,\alpha}$ at z_{MI} (MPa)	0.63				
P (mW)		4.60		4.60	
P_{1x1} (mW)		4.14		4.14	
z_s (cm)			5.50		
z_b (cm)					4.97
z_{MI} (cm)	5.50				
$z_{pii,\alpha}$ (cm)	5.50				
f_{awf} (MHz)	2.70	2.70		2.67	
Other Information					
prr (Hz)	800				
srr (Hz)	N/A				
n_{pps}	1				
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	41.86				
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	13.64				
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	38.22				
p_r at z_{pii} (MPa)	1.06				
Operating Control Conditions					

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 25. Transducer: Kosmos Torso-One, Operating Mode: BC-Mode (Max MI, 12 cm depth, small ROI, image top)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	1.56	0.37		0.37		0.64
Index Component Value		1: 6.47E-02 2: 0.30		1: 6.47E-02 2: 0.30		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 2.50					
P (mW)		1: 5.89 2: 27.52		1: 5.89 2: 27.52		1: 5.89 2: 27.52
P_{1x1} (mW)		1: 5.02 2: 24.07		1: 5.02 2: 24.07		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 1.91					
$z_{pii,\alpha}$ (cm)	2: 2.00					
f_{awf} (MHz)	2: 2.65	1: 2.71 2: 2.65		1: 2.71 2: 2.65		
Other Information						
prr (Hz)	2: 1248.9					
srr (Hz)	2: 31.2					
n_{pps}	2: 10					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 282					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	160.04					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	233.06					
p_r at z_{pii} (MPa)	2: 2.85					
Operating Control Conditions						
Component 1: UTP 4						
Component 2: UTP 275						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 26. Transducer: Kosmos Torso-One, Operating Mode: BC-Mode (Max TIS/TIB, ISPTA, 12 cm depth, large ROI, image top)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.98	0.96		0.96		1.74
Index Component Value		1: 5.66E-02 2: 0.90		1: 5.66E-02 2: 0.90		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.58					
P (mW)		1: 5.15 2: 86.25		1: 5.15 2: 86.25		1: 5.15 2: 86.25
P_{1x1} (mW)		1: 4.39 2: 72.84		1: 4.39 2: 72.84		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 4.24					
$z_{pii,\alpha}$ (cm)	2: 4.24					
f_{awf} (MHz)	2: 2.59	1: 2.71 2: 2.59		1: 2.71 2: 2.59		1: 2.71 2: 2.59
Other Information						
prr (Hz)	2: 3824.6					
srr (Hz)	2: 25.5					
n_{pps}	2: 10					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 153					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	69.29					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	151.32					
p_r at z_{pii} (MPa)	2: 2.23					
Operating Control Conditions						
Component 1: UTP 4						
Component 2: UTP 277						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 27. Transducer: Kosmos Torso-One, Acoustic Output Reporting Table, Operating Mode: PW Doppler (Max MI, TIS, TIB)

Index Label	MI	TIS		TIB	
		At Surface	Below Surface	At Surface	Below Surface
Maximum Index Value	0.42	3.04		3.04	
Index Component Value		0.49	3.04	3.04	3.04
Acoustic Parameters					
$p_{r,\alpha}$ at z_{MI} (MPa)	0.59				
P (mW)		50.93		50.93	
P_{1x1} (mW)		37.76		37.76	
z_s (cm)			1.93		
z_b (cm)					1.87
z_{MI} (cm)	1.93				
$z_{pii,\alpha}$ (cm)	1.93				
f_{awf} (MHz)	2.03	2.03		2.03	
Other Information					
prr (Hz)	14468				
srr (Hz)	N/A				
n_{pps}	1				
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	12.14				
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	429.69				
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	553.54				
p_r at z_{pii} (MPa)	0.68				
Operating Control Conditions					
PRF	14468 Hz				
Gate Size	4mm				
Focal Depth	20mm				

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 28. Transducer: Kosmos Torso-One, Acoustic Output Reporting Table, Operating Mode: CW Doppler (Max MI, TIS, TIB)

Index Label	MI	TIS		TIB	
		At Surface	Below Surface	At Surface	Below Surface
Maximum Index Value	0.07	0.49		0.49	
Index Component Value		0.47	0.49	0.47	2.43
Acoustic Parameters					
$p_{r,\alpha}$ at z_{MI} (MPa)	0.0976				
P (mW)		62.48		62.48	
P_{1x1} (mW)		50.17		50.17	
z_s (cm)			1.27		
z_b (cm)					1.27
z_{MI} (cm)	0.9				
$z_{pii,\alpha}$ (cm)	1.27				
f_{awf} (MHz)	1.95	1.95		1.95	
Other Information					
prr (Hz)	N/A				
srr (Hz)	N/A				
n_{pps}	1				
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	N/A				
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	279.77				
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	331.51				
p_r at z_{pii} (MPa)	0.10				
Operating Control Conditions					
Focal Depth	4cm				
CW Mode					

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 29. Torso-One: Acoustic Output Reporting Table, Operating Mode: BC-Mode (TCD Preset, 10cm Depth, Smallest ROI at Top, Highest Scale)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	1.36	0.91		0.91		2.18
Index Component Value		1: 5.74E-02 2: 0.86		1: 5.74E-02 2: 0.86		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.94					
P (mW)		1: 5.86 2: 108.34		1: 5.86 2: 108.34		1: 5.86 2: 108.34
P_{1x1} (mW)		1: 4.75 2: 87.75		1: 4.75 2: 87.75		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 1.93					
$z_{pii,\alpha}$ (cm)	2: 2.00					
f_{awf} (MHz)	2: 2.05	1: 2.54 2: 2.05		1: 2.54 2: 2.05		1: 2.54 2: 2.05
Other Information						
prr (Hz)	2: 3178.6					
srr (Hz)	2: 28.4					
n_{pps}	2: 16					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 150					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	173.40					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	232.08					
p_r at z_{pii} (MPa)	2: 2.20					
Operating Control Conditions						
Component 1: 3.0MHz-60.0mm-UTP 3						
Compenent 2: 2.0MHz-20.0mm-UTP 55						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for Transcranial or Neonatal cephalic uses.

NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 30. Torso-One: Acoustic Output Reporting Table, Operating Mode: BC-Mode (TCD Preset, 10cm Depth, Highest ROI at Top, Highest Scale)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.90	1.35		1.35		3.23
Index Component Value		1: 3.83E-02 2: 1.31		1: 3.33E-02 2: 1.31		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.29					
P (mW)		1: 3.91 2: 165.15		1: 3.91 2: 165.15		1: 3.91 2: 165.15
P_{1x1} (mW)		1: 3.16 2: 133.77		1: 3.16 2: 133.77		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 4.13					
$z_{pii,\alpha}$ (cm)	2: 4.13					
f_{awf} (MHz)	2: 2.05	1: 2.54 2: 2.05		1: 2.54 2: 2.05		1: 2.54 2: 2.05
Other Information						
prr (Hz)	2: 4540.8					
srr (Hz)	2: 18.9					
n_{pps}	2: 16					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 91.8					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	92.98					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	166.13					
p_r at z_{pii} (MPa)	2: 1.65					
Operating Control Conditions						
Component 1: 3.0MHz-60.0mm-UTP 3						
Compenent 2: 2.0MHz-60.0mm-UTP 55						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for Transcranial or Neonatal cephalic uses.

NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 31. Transducer: Kosmos Torso-One Acoustic Output Reporting Table, Operating Mode: PW Doppler Mode (TCD Preset, UTP 122)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.55	0.53		2.76		1.09
Index Component Value		0.53	0.43	0.53	2.76	
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	0.81					
P (mW)		57.11		57.11		57.11
P_{1x1} (mW)		52.91		52.91		
z_s (cm)			1.97			
z_b (cm)					1.97	
z_{MI} (cm)	1.84					
$z_{pii,\alpha}$ (cm)	1.97					
f_{awf} (MHz)	2.12	2.12		2.12		2.12
Other Information						
prr (Hz)	8.68E+03					
srr (Hz)	N/A					
n_{pps}	1					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	22					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	444.46					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	593.25					
p_r at z_{pii} (MPa)	0.94					
Operating Control Conditions						
Component 1: 2.08MHz-20.0mm-UTP 122						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for Transcranial or Neonatal cephalic uses.

NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 6: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Kosmos Lexsa Acoustic Output Tables

Table 32. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: B-Mode (Max MI, ISPTA, MSK, 3 cm depth)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.77	5.39E-03		5.39E-03		1.25E-02
Index Component Value		5.39E-03		5.39E-03		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2.01					
P (mW)		0.52		0.52		0.52
P_{1x1} (mW)		0.15		0.15		
z_s (cm)			1.57			
z_b (cm)					1.57	
z_{MI} (cm)	1.43					
$z_{pii,\alpha}$ (cm)	1.57					
f_{awf} (MHz)	6.77	7.44		7.44		7.44
Other Information						
prr (Hz)	1820.0					
srr (Hz)	28.0					
n_{pps}	1					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	1.7E+02					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.62					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	3.58					
p_r at z_{pii} (MPa)	2.24					
Operating Control Conditions						
UTP 71						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 33. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: B-Mode (Max TIS, TIB, MSK, 10 cm depth)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.19	9.16E-03		9.16E-03		2.05E-02
Index Component Value		9.16E-03		9.16E-03		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	0.53					
P (mW)		0.85		0.85		0.85
P_{1x1} (mW)		0.25		0.25		
z_s (cm)			1.63			
z_b (cm)					1.63	
z_{MI} (cm)	1.63					
$z_{pii,\alpha}$ (cm)	1.63					
f_{awf} (MHz)	7.69	7.69		7.69		7.69
Other Information						
prr (Hz)	1300.0					
srr (Hz)	20.0					
n_{pps}	1					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	17.0					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.36					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	3.23					
p_r at z_{pii} (MPa)	0.82					
Operating Control Conditions						
UTP 87						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 34. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: BC, CPD-Mode (Max MI, Vascular, 4 cm depth, large)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	1.37	7.72E-02		7.72E-02		0.29
Index Component Value		1: 2.35E-03 2: 7.48E-02		1: 2.35E-03 2: 7.48E-02		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 2.88					
P (mW)		1: 0.26 2: 11.93		1: 0.26 2: 11.93		1: 0.26 2: 11.93
P_{1x1} (mW)		1:6.90E-02 2: 3.56		1:6.90E-02 2: 3.56		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 0.96					
$z_{pii,\alpha}$ (cm)	2: 1.57					
f_{awf} (MHz)	2: 4.42	1: 7.15 2: 4.42		1: 7.15 2: 4.42		1: 7.15 2: 4.42
Other Information						
prr (Hz)	2: 8236.4					
srr (Hz)	2: 21.4					
n_{pps}	2: 12					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 23.3					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	29.58					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	48.42					
p_r at z_{pii} (MPa)	2: 0.95					
Operating Control Conditions						
Component 1: UTP 225						
Component 2: UTP 339 (16V)						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 35. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: BC, CPD-Mode (Max ISPTA, Vascular, 4 cm depth, small ROI, Image top)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	1.37	6.50E-02		6.50E-02		7.98E-02
Index Component Value		1: 3.23E-03 2: 6.18E-02		1: 3.23E-03 2: 6.18E-02		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 2.88					
P (mW)		1: 0.36 2: 2.94		1: 0.36 2: 2.94		1: 0.36 2: 2.94
P_{1x1} (mW)		1: 9.49E-02 2: 2.94		1: 9.49E-02 2: 2.94		
z_s (cm)			1: N/A 2: N/A			
z_b (cm)					1: N/A 2: N/A	
z_{MI} (cm)	2: 0.96					
$z_{pii,\alpha}$ (cm)	2: 1.57					
f_{awf} (MHz)	2: 4:42	1: 7.15 2: 4.42		1: 7.15 2: 4.42		1: 7.15 2: 4.42
Other Information						
prr (Hz)	2: 2026.6					
srr (Hz)	2: 28.1					
n_{pps}	2: 12					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 23.3					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	48.65					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	79.44					
p_r at z_{pii} (MPa)	2: 0.95					
Operating Control Conditions						
Component 1: UTP 225						
Component 2: UTP 339 (16V)						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 36. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: BC, CPD-Mode (Max TIS, TIB)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.94	0.10		0.10		0.29
Index Component Value		1: 1.91E-03 2: 0.10		1: 1.91E-03 2: 0.10		
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	2: 2.34					
P (mW)		1: 0.22 2: 11.60		1: 0.22 2: 11.60		1: 0.22 2: 11.60
P_{1x1} (mW)		1: 5.62E-02 2: 3.46		1: 5.62E-02 2: 3.46		
z_s (cm)			1: N/A 2: NA			
z_b (cm)					1: N/A 2: NA	
z_{MI} (cm)	2: 0.93					
$z_{pii,\alpha}$ (cm)	2: 1.40					
f_{awf} (MHz)	2: 6.22	1: 7.15 2: 6.22		1: 7.15 2: 6.22		1: 7.15 2: 6.22
Other Information						
prr (Hz)	2: 8830.3					
srr (Hz)	2: 17.8					
n_{pps}	2: 16					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 73.7					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	29.56					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	54.39					
p_r at z_{pii} (MPa)	2: 1.51					
Operating Control Conditions						
Component 1: UTP 225						
Component 2: UTP 161						

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 37. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: PW Doppler (Max MI)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.35	0.19		0.47		0.26
Index Component Value		0.19	0.06	0.19	0.47	
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	0.88					
P (mW)		6.45		6.45		6.45
P_{1x1} (mW)		6.45		6.45		
z_s (cm)			2.6			
z_b (cm)					2.6	
z_{MI} (cm)	1.22					
$z_{pii,\alpha}$ (cm)	1.24					
f_{awf} (MHz)	6.26	6.26		6.26		6.26
Other Information						
prr (Hz)	15625					
srr (Hz)	N/A					
n_{pps}	1					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	23.9					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	338.3					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	575.2					
p_r at z_{pii} (MPa)	1.14					
Operating Control Conditions						
PRF	15625					
Gate Size	5mm					
Gate Focal Depth	10mm					

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Table 38. Transducer: Kosmos Lexsa Acoustic Output Reporting Table, Operating Mode: PW Doppler (Max TIS, TIB, TIC)

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value	0.15	0.66		1.64		0.64
Index Component Value		0.66	0.26	0.66	1.64	
Acoustic Parameters						
$p_{r,\alpha}$ at z_{MI} (MPa)	0.38					
P (mW)		22.23		22.23		22.23
P_{1x1} (mW)		22.23		22.23		
z_s (cm)			2.6			
z_b (cm)					2.6	
z_{MI} (cm)	2.58					
$z_{pii,\alpha}$ (cm)	2.58					
f_{awf} (MHz)	6.25	6.25		6.25		6.25
Other Information						
prr (Hz)	7621					
srr (Hz)	N/A					
n_{pps}	1					
$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	5.42					
$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	127.8					
I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	539.19					
p_r at z_{pii} (MPa)	0.73					
Operating Control Conditions						
PRF	7621					
Gate Size	5mm					
Gate Focal Depth	50mm					

NOTE 1: Only one operating condition per index.

NOTE 2: Data should be entered for “at surface” and “below surface” in both the columns related to TIS or TIB.

NOTE 3: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS or TIB.

NOTE 4: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

NOTE 5: Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Measurement Accuracy

Table 39. Measurement Accuracy

Measurement	Unit	Useful Range	Accuracy
Phased Array			
Axial	mm	4 - 140	± 2% or 1 mm, whichever is greater
Lateral		4 - 120	
Diagonal		2.8 - 106	
Circumference	mm	25.1 - 352	± 4% or 2 mm, whichever is greater
Area	mm^2	50 - 879.6	± 4% of displayed value
M-Mode Time	seconds (s)	0 - 1.00	± 2% or 0.1 seconds, whichever is greater
PW/CW Time	seconds (s)	0 - 1.00	± 2% or 0.1 seconds, whichever is greater
M-Mode distance	mm	0 - 300	± 3% of displayed value
PW Velocity	cm/s	-180 - 130	± 2% of full scale or 4 cm/s
CW Velocity		-90 - 280	± 2% of full scale or 4 cm/s
Linear Array			
Vertical	mm	10 - 40	± 2% or 1 mm, whichever is greater
Horizontal		4 - 18	
Diagonal		4 - 19.7	
Area	mm^2	16 - 345	± 4% of displayed value
PW/CW Time	seconds (s)	0 - 1.0	± 2% or 0.1 seconds, whichever is greater
PW Velocity	cm/s	-180 - 130	± 2% of full scale or 4 cm/s
CW Velocity		-90 - 280	± 2% of full scale or 4 cm/s

Kosmos AI-Assisted EF Workflow Measurements Accuracy

The accuracy of the Kosmos EF calculations depends on the correct selection ofED/ES frames and accurate tracing of the LV endocardial border. It is important to review the initial ED/ES frames and LV contours provided by the Kosmos Algorithms, confirm their accuracy, and edit them, as required.

Ensure that the selected ED/ES frames accurately represent the corresponding end-systolic cardiac phases in the A4C and A2C clips. Use the editing tool to select a more appropriate frame, as required.

Ensure that the LV contours accurately follows the LV endocardium. Use the editing tool to properly trace and adjust the LV contours.

When possible, acquire both A4C and A2C clips to obtain a biplane LVEF, which is more accurate than the single plane LVEF. The following table shows the results of comparing Kosmos EF calculations, without any user adjustments, to the average of manual expert measurements performed by two independent Echo Core Labs on the same A4C/A2C clips.

Subjects across a wide variety of age, gender orientation, race, body habitus, and health were scanned with Kosmos AI-assisted EF workflow in a clinical point-of-care ultrasound setting. The EF values of the subjects scanned ranged from 20% to 80%.The results below include both biplane and single-plane acquisitions, with the majority being biplane (A4C single-plane acquisition was sufficient when an adequate A2C view could not be obtained within a reasonable amount of time).

Table 40. LVEF Comparison Metrics

LVEF Metric	LVEF Percentage Units
Root Mean Squared Deviation (RMSD)[1]	6.70 (p-value > 0.0001)
Bias	-3.41
95% Limits of Agreement[2]	-14.67 / 7.91

[1]RMSD is a metric of the deviation between Kosmos EF calculations (without any user adjustments), and the average manual expert measurements.

[2]95% limits of agreement are expected to include approximately 95% of the differences between Kosmos EF calculations (without any user adjustments) and the average manual expert measurements.

Kosmos Bladder AI Workflow Volume Estimation Accuracy

± 3mL for volumes under 100mL and ± 3% for volumes between 100mL and600mL. The accuracy specification assumes the system is being used per the instructions in the Kosmos User Guide while scanning a tissue-equivalent phantom.

Control Effects

Kosmos does not provide the user with direct control of acoustic output power. Kosmos has been designed to automatically adjust the output to ensure that acoustic limits are not exceeded in any imaging mode. Since there is no direct user control for output, the user should rely on controlling exposure time and scanning technique to implement the ALARA principle.

Related References

- U.S. Dept. of Health and Human Services, Food and Drug Administration, Guidance for Industry and FDA Staff - Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2019)
- IEC 60601-2-37:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359:2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

Transducer Surface Temperature Rise

Table 41: Surface Temperature Rise summarizes the expected maximum temperature rise for Kosmos. The values are based on a statistical sample test of production-equivalent systems and were measured in accordance with IEC 60601-2-37. The values listed in the table are determined with 90% confidence, that 90% of the systems will result in a temperature rise less than or equal to that stated in the table.

Table 41. Surface Temperature Rise

Test	Temperature Rise (°C)
Still air	21.16
Simulated use	9.92

Ergonomics

Repetitive ultrasound scanning may cause occasional discomfort in the thumbs, fingers, hands, arms, shoulders, eyes, neck, back, or other parts of the body. If you experience symptoms such as persistent or recurring discomfort, soreness, pain, throbbing, aching, tingling, numbness, stiffness, burning sensations, muscle fatigue or weakness, or limited range of motion, do not ignore these warning signs. Seek prompt evaluation by a qualified healthcare professional.

Such symptoms may be associated with Work-Related Musculoskeletal Disorders (WRMSDs). WRMSDs can be painful and may result in potentially disabling injuries affecting nerves, muscles, tendons, or other soft tissues. Examples of WRMSDs include bursitis, tendonitis, tenosynovitis, carpal tunnel syndrome, and De Quervain syndrome.

Kosmos is intended for quick-look applications by qualified health professionals. It is not intended for continual use in radiology or other departments. If you need to use the device for a continual period, take the following precautions:

- Position yourself comfortably, either with a chair with appropriate lower-back support or by sitting or standing upright.
- Minimize twisting, relax your shoulders, and support your arm with a cushion.
- Hold Kosmos Torso-One or Kosmos Lexsa lightly, keep your wrist straight, and minimize pressure on the patient.
- Take regular breaks.

Basic Safety

The transducer and software, along with the Samsung SM-T860 tablet and the Lenovo TB-Q706F tablet, have been verified as compliant with IEC 60601-1. Refer to the EchoNous Tablet compatibility list available on the EchoNous website at echonous.com/product/device-compatibility for all supported configurations. For maximum safety, observe these warnings and cautions:

Devices that are compliant with IEC 60950-1 and 62368-1 have not been evaluated for compliance with IEC 60601-1 temperature limits for patient contact.

Do not operate this system in the presence of flammable gases or anesthetics. An explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

Do not bring the tablet into contact with the patient. Contact of the tablet with the patient could result in electric shock and risk of burn.

Only charge the tablet and Link with the GlobTek, Inc. power supply (P005974).

Only use devices and accessories recommended by EchoNous.

It is up to the responsible organization to check the leakage current of the tablet used with EchoNous probes in the patient environments to ensure it meets 60601-1 requirements.

Electromagnetic Compatibility

The System complies with the Electromagnetic Compatibility requirements of AS/NZ CISPR 11:2015 and EN IEC 60601-1-2:2014: AMD1:2020. However, electronic and mobile communications equipment may radiate electromagnetic energy, and there is no guarantee that interference will not occur in a particular installation or environment. Interference may result in artifacts, distortion, or degradation of the ultrasound image. If the System is found to cause or respond to interference, try reorienting the System or the affected device or increasing the separation distance between the devices. Contact EchoNous customer support or your EchoNous distributor for further information.

EchoNous does not recommend using high-frequency electromedical devices in proximity to its systems. EchoNous equipment has not been validated for use with high-frequency electrosurgical devices or procedures. The use of high-frequency electrosurgical devices in proximity to the system may lead to abnormal system behavior or system shutdown. To avoid the risk of a burn hazard, do not use Kosmos probes with high-frequency surgical equipment. Such a hazard may occur if there is a defect in the high-frequency surgical neutral electrode connection.

The System contains sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the System. Any faults should be reported to EchoNous customer support or your EchoNous distributor for repair.

The System is intended for use in the electromagnetic environment specified below.

Electromagnetic Emissions

Table 42. Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions **IEC 61000-3-2**	Class A	The System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
Voltage fluctuations & flicker emissions **IEC 61000-3-3**	Complies	

The System has Class A compliance, meaning it is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the System is found to cause or respond to interference, follow the guidelines in the warning section above.

Electromagnetic Immunity

Table 43. Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Immunity Test	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) **IEC 61000-4-2**	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	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 at 100 kHz repetition frequency on Power Supply Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	±0.5 kV, ±1 kV Line to Line, ±0.5 kV, ±1 kV, ±2, kV Line to ground	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**	0% U_T[1]; 0.5 Cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% U_T,; 1 cycle and 70% *UT* 25/30 cycles single phase at 0°	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Fields **IEC 61000-4-8**	8 A/m at 30 kHz in CW modulation 65 A/m at 134.2 kHz in 2.1 kHz pulse modulation 75 A/m at 13.56 MHz in 50 kHz Pulse modulation	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Immunity Test: Magnetic Fields - Proximity Fields **IEC 61000-4-39**	8 A/m at 30 kHz in CW modulation; 10 sec. dwell time 65 A/m at 134.2 kHz in pulse modulation, 50% square wave, 2.1 kHz; 10 sec. dwell time 7.5 A/m at 13.56 MHz in pulse modulation, 50%square wave, 50 kHz; 10 sec. dwell time	Magnetic proximity fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
[2,3]**Conducted RF** **IEC 61000-4-6**	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM and Amateur radio bands between 0.15 MHz -80 MHz, 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of **the system**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance is $d = 1.2\sqrt{P}$
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz- 2.7 GHz 80% AM at 1 kHz	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be below the compliance level at each frequency range[5]. Interference may occur in the vicinity of equipment marked with the  symbol.

[1]UT is the AC mains voltage before application of the test level.

[2]At 80 MHz and 800 MHz, the higher-frequency range applies.

[3]These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[4]Field strengths from fixed RF transmitters cannot be predicted accurately. An electromagnetic site survey is recommended. If measured field strengths exceed the applicable RF compliance level, verify normal system operation and apply mitigation measures (e.g., reorientation or relocation) if necessary.

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

When using the optional mobile stand, the System can be susceptible to ESD and may require manual intervention. If ESD results in a System error, unplug the probe and plug back in to restore operation.

Using cables, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.

Separation Distances

Table 44: Separation Distances lists the recommended separation distances between portable and mobile RF communications equipment and the EchoNous System.

Table 44. Separation Distances

Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 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 for the transmitter's frequency, where P is the transmitter's maximum output power in watts (W) as specified by the manufacturer. NOTE 1: At 80 MHz and 800 MHz, the higher-frequency separation distance applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Standards

HIPAA

Kosmos includes security settings that help you to meet the applicable security requirements listed in the HIPAA standard. Users are ultimately responsible for ensuring the security and protection of all electronic protected health information collected, stored, reviewed, and transmitted on the system.

The Health Insurance Portability and Accountability Act, Pub.L. No. 104-191 (1996). 45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy

DICOM

Kosmos conforms to the DICOM standard as specified in the Kosmos DICOM Conformance Statement, available at echonous.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

CHAPTER 9

Specifications

System Specifications

Table 45. System Specifications for Kosmos Torso-One, Lexsa, and Link

Feature	Height (mm)	Width (mm)	Depth (mm)	Weight (grams)	Cable (m)	Operating Frequency (MHz)	Scanning Depth (cm)
Kosmos Torso-One	150 [1]	56	35	267 (with ferrite-equipped cable)	1.5	1.5 - 4.5	4 - 30
Kosmos Lexsa	155	56	35	280 (with cable)	1.5	3 - 10.5	1 - 10
Kosmos Link	95	225	31	1050	0.1	-----	-----

[1]Excluding cable (the hard plastic housing length)

Environmental Operating And Storage Conditions For Kosmos Probes, Kosmos Link, And Compatible Tablets

Kosmos probes and Kosmos Link are intended for use and storage in normal ambient conditions within a medical facility.

Table 46. Kosmos Probes and Tablets: Operating, Charging, Transport, and Storage Condition Ranges

	Operating	Transport/Storage
Temperature (°C)	0°C to +40°C	-20°C to +60°C
Relative humidity (non-condensing)	15% to 95%	15% to 95%
Pressure	62 kPa to 106 kPa	62 kPa to 106 kPa

Table 47. Kosmos Link: Operating, Charging, Transport, and Storage Condition Ranges

	Operating	Transport/Storage
Temperature (°C)	0°C to +40°C	-20°C to +60°C
Relative humidity (non-condensing)	15% to 95%	15% to 95%
Pressure	70 kPa to 106 kPa	70 kPa to 106 kPa

Mode Of Operation

After storage at extreme temperatures, check the Kosmos probe surface temperature before applying it to a patient. A cold or hot surface may cause burns to the patient.

Only operate, charge, and store Kosmos within the approved environmental parameters.

When used in high ambient temperatures (such as 40°C), the Kosmos safety feature may disable scanning to maintain safe touch temperature.

Kosmos enforces scanning limits to maintain safe user contact temperatures.

Kosmos Link Electrical Specifications

Output

Tablet: USB PD 5-12Vdc @ 0-3A

Kosmos Probes: 5 Vdc ±5%, Max 2.5 A

Internal Batteries

Li-ion battery: 7.2 V, 4.04 Ah

Battery charging time: The time to charge the battery from 0% to 90% is ~2 hours.

Battery life: A fully charged Link will provide 3-8 hours of uninterrupted scanning. Performance may vary depending on the scanning modes used.

Power Supply

GlobTek, Inc. P005974

- Input: 100-240 V~, 50-60 Hz, 1.5 A
- Output: 5-11.9 Vdc, 0.4 A, 47.6 W

CHAPTER 10

IT Network

Wireless Networking Functions

Connection to the IT network is required for the following functionality.

- Storing exam data (static images and clips) acquired by Kosmos in the Picture Archiving and Communication System (PACS) using DICOM communication. For details, refer to the DICOM Conformance Statement that is on the EchoNous website.
- Setting the Kosmos time correctly by inquiring the network time service.

Security

Patient Data Protection

It is your responsibility to configure your device to comply with your local security policies and regulatory requirements. EchoNous recommends that you protect patient data by encrypting your device and setting a passcode for device access. The Kosmos app encrypts the patient database as an added layer of security.

Wireless Configuration Requirements

Refer to the documentation that accompanies the EchoNous-approved tablet for information on configuring your device for wireless networking. Consult your IT security department to ensure your device is configured in compliance with all applicable security requirements.

Network For Connecting The Device

To ensure safety, use an IT network that is isolated from the external environment by a firewall.

IT Network Failure Recovery Measures

Connection to an IT network may become unreliable at times, leading to failure to perform the functions described in Wireless Networking Functions (page 115). As a result, the following hazardous situations may occur:

Table 48. Network Failure: Impact, Hazards, and Countermeasures

Network failure	Impact on equipment	Hazard	Countermeasures
IT network becomes unstable	Unable to transmit exam data to PACS	Delay of diagnosis	Kosmos has internal memory, and exam data is stored in it. After the IT network has returned to a stable state, the user can re-initiate the transfer.
	Delay of transmission to PACS		
	Incorrect data was transmitted to PACS	Misdiagnosis	Integrity of the data is ensured by the TCP/IP and DICOM protocols used by Kosmos.
	Unable to get the time from a time server	Incorrect exam data	Kosmos has the capability of entering data and
	Incorrect time data		Kosmos always displays the date and time on the main screen.
Firewall has broken down	Attack via network	Manipulation of exam data	Kosmos closes unnecessary network ports.
	Infection by a computer virus	Leak of exam data	Kosmos prevents a user from loading software and executing it.

Connecting equipment to an IT network that includes other systems could expose previously unidentified risks to patients, operators, or third parties. Before connecting the equipment to an uncontrolled IT Network, ensure that all potential risks arising from such connections have been identified and evaluated, and that suitable countermeasures have been put in place. IEC 80001-1:2010 provides guidance for addressing these risks.

When a setting of the IT network to which Kosmos is connected has been changed, verify that the change does not affect Kosmos, and take necessary measures.

Changes to the IT network include:

- Connecting additional items
- Disconnecting items
- Updating equipment
- Upgrading equipment

Any changes to the IT network could introduce new risks, requiring additional evaluation.

Glossary

This glossary defines terms, abbreviations, and acronyms used throughout the Kosmos User Guide.

American College of Emergency Physicians (ACEP)	A professional body for emergency physicians, setting the standard for emergency medical care.
Annotation	Annotations are text notes, arrows, and/or measurements that a clinician may add to an image or clip. An annotation appears as an overlay on the image/clip.
Apical 2-chamber (A2C)	The left atrium (LA) and left ventricle (LV) in longitudinal section.
Apical 4-chamber (A4C)	A standard echocardiogram (ultrasound) perspective showing all four heart chambers (two atria and two ventricles) from the apex (tip) of the heart.
Archive	After a report is generated, the patient information is updated in the hospital's EMR/PACS system. The device needs to have a secure connection for data transfer. Once an exam is archived, it cannot be edited. At this point, it is safe to purge the exam from Kosmos to free up space for new studies.
Arrow	A clinician may place an arrow at a specific location in an image/clip to highlight a particular area. This displays as an overlay on the image/clip.
Body mass index (BMI)	A simple screening tool that compares your weight to your height to estimate body fat.
Brightness Mode (B-Mode)	The fundamental ultrasound display that shows tissue structures as different shades of gray (brightness) in a 2D image, representing echo intensity.
Calculation	Calculations are estimations made from specific sets of measurements.
Caliper	A versatile measuring tool is used by dragging it into position. The active caliper has a round, highlighted handle.
Cine	A period of images, stored digitally as a sequence of individual frames. It is recorded at high frame rates and may contain more frames than were displayed during the examination.
Clip	A clip is a short sequence of multiple frames, like a movie.
Completed exam	Once an exam is completed, you won't be able to add images to the exam. You can add/edit/delete any annotations that have been saved as overlays on images/clips until the exam is archived. Once archived, you cannot edit anything. If the clinician does not complete an exam, Kosmos will automatically complete the exam when Kosmos is turned off.

Continuous-Wave Doppler (CW)	An ultrasound technology that continuously sends and receives sound waves to measure blood flow velocities, especially high ones, along the entire path of the beam.
Digital Imaging and Communications in Medicine (DICOM)	The most universal and fundamental standard in digital medical imaging. It's an all-encompassing data transfer, storage, and display protocol built and designed to cover all functional aspects of contemporary medicine. PACS functionality is DICOM-driven.
Ejection fraction (EF)	Calculated as (a percentage): $EF = (EDV - ESV)/EDV * 100$ (1)
End-diastolic (ED)	The moment in the heart's cycle when the ventricles are fully filled with blood and stretched to their maximum volume, just before they contract (systole) to pump blood out.
End-diastolic volume (EDV)	The volume of blood in the heart's ventricles at the end of the relaxation phase (diastole), just before the heart contracts to pump blood out.
End-systolic (ES)	The state of the heart's ventricles at the end of their contraction (systole).
End-systolic volume (ESV)	The volume of blood left in the heart's ventricles after they contract (systole) and eject blood.
Exam	An exam contains all the objects, images, clips, and reports saved during a clinical examination of a patient with Kosmos, which usually corresponds to a patient's visit.
Field of view (FOV)	The two-dimensional space of B-Mode image acquisition.
Frozen state	The mode Kosmos enters when you tap the Freeze button during live imaging. In the frozen state, you can review the cine, add annotations to a selected frame, and save a still image. Measurements apply only to the specific frame on which they are placed, whereas annotations persist across the entire cine. When you save a clip from the cine, annotations are saved as overlays; however, measurements are not saved. This is because measurements typically apply to a single frame rather than to a sequence of frames within a cine.
Heart rate (HR)	The number of times your heart beats per minute (bpm).
Image	A single frame of an ultrasound view captured by Kosmos.
Left ventricle (LV)	The heart's powerful, muscular lower-left chamber receives oxygen-rich blood from the left atrium. It forcefully pumps it through the aortic valve to supply the entire body with oxygenated blood.
Measurement	A distance or area measurement on images with no inference to underlying anatomy. A measurement overlay shows the tool (e.g., a caliper or an ellipse) and the measured values.
M-Line	A user-placed cursor line used in M-Mode imaging that defines the anatomical location from which motion data are sampled over time.

	When M-Mode is activated, Kosmos tracks echoes along the M-Line and displays their motion as a time-based trace. This allows precise assessment of dynamic structures—such as cardiac wall motion, valve movement, and lung sliding—that may not be easily visualized in standard 2D (B-Mode) imaging.
Modality Worklist (MWL)	The feature on the Kosmos ultrasound system that connects to hospital IT (RIS/PACS) to automatically pull patient data (name, MRN, DOB) and scheduled exams, creating a "Patient Pick List" to prevent manual entry errors, ensure data accuracy, and streamline the workflow, all by configuring DICOM settings with server details like AE Title, IP, and Port.
Motion Mode (M-Mode)	A feature that displays anatomical movement over time as a trace, ideal for assessing cardiac function (wall motion, valve movement) and lung sliding to check for pneumothorax.
Patient Information Management Systems (PIMS)	Digital tools that centralize, store, and manage patient data.
Physical coordinates	The position in the FOV is expressed in terms of physical dimensions, either in millimeters or radians, with respect to a designated point of reference.
Picture	The Kosmos camera can be used to capture images of wounds or injuries during the exam.
Picture Archiving and Communication Systems (PACS)	Medical systems (hardware and software) built to run digital medical imaging. The main components of PACS include digital image acquisition devices, digital image archives, and workstations. The PACS settings in this document refer to the settings for connecting to digital image archives.
Ping test	Used to test a TCP/IP connection. If the ping test is successful, the connection between the Kosmos and PACS archive is working.
Region of Interest (ROI)	The bounded region in the field of view where color flow information is depicted.
Report	Details of an exam, along with the notes entered by the clinician.
Review	A Kosmos state that allows review and editing of patient data before archiving.
Scan	A system preset in which imaging parameters are optimized for scanning a specific organ, such as the heart or lungs. A scan can include multiple images, clips, and reports that can be saved and accessed later. The selected scan preset determines which calculations, measurements, and reports are available.
Snackbar	A brief message that displays at the bottom of many Kosmos screens. You don’t have to act on the messages, and they will automatically disappear after a short period of time.
Stroke volume (SV)	Calculated as:

$$SV = EDV - ESV \quad (2)$$

Study	A collection of one or more series of medical images and presentation states that are logically related for the purpose of diagnosing a patient. Each study is associated with one patient. A study may include composite Instances created by a single modality, multiple modalities, or multiple devices of the same modality. In Kosmos, the term “exam” means “study” in the DICOM world. An exam contains all the objects, images, clips, and reports saved during a clinical examination of a patient with Kosmos, which typically corresponds to a patient’s visit.
Tissue Doppler Imaging (TDI)	The Tissue Doppler Imaging feature on the portable, AI-powered EchoNous Kosmos handheld ultrasound system, used primarily in point-of-care (POCUS) settings to assess heart muscle function by measuring tissue velocity, helping clinicians evaluate myocardial movement (systolic/diastolic) and chamber function, especially in cardiology and emergency medicine.
Transcranial Doppler (TCD)	An optimized preset intended to image an adult's middle cerebral artery (MCA) using either temporal view. The supported images modes are B-mode, Color Doppler, and PW Doppler.
Transport Layer System (TLS)	The crucial Layer 4 in the OSI model, providing end-to-end communication between applications on different devices, managing data flow, ensuring reliability, and handling segmentation/reassembly, primarily through protocols like TCP (reliable, connection-oriented) and UDP (fast, connectionless).
Verify	Used to conduct a DICOM C-Echo, which sends a signal to the PACS archive using a DICOM protocol to confirm that the PACS archive is working and available on the network.

APPENDIX A

Auto EF Clinical Performance And Non-Clinical Testing

Auto EF Clinical Performance Testing

A prospective study was conducted to evaluate the difference between the left ventricle ejection fraction (LVEF; %EF) automatically generated by Kosmos' Auto EF algorithm and manually calculated by cardiologists from clips acquired by cardiac sonographers.

Study Design

The cardiac sonographers scanned one hundred and fifty-three (153) participants, and the two views were obtained using a Kosmos ultrasound system with Auto EF software. The A2C and A4C views were used to calculate the %EF, using Simpson's biplane method, at the point of care. A range of body mass index (BMI) was included in the dataset, with 22.8% of the patients overweight (25 ≤ BMI < 30 kg/m2) and 31.6% obese (BMI > 30 kg/m2). In addition, 19% of patients had reduced EF (30% ≤ EF < 53%), and 22% had severely decreased EF (EF < 30%). All studies were traced by three sonographers using the biplane Simpson's method to establish the reference standard.

The study continued enrollment until four sonographers had completed scans of 17 patients each. Enrolled patients were evenly stratified into four groups based on BMI to ensure a balanced distribution by sex and BMI. Following the patient exams, three (3) independent readers manually calculated %EF from scans containing both A4C and A2C views (N = 141), which served as the ground truth.

The performance goal is a Root Mean Square Deviation (RMSD) < 10%EF between LVEF measured manually by experts and Kosmos' Auto EF on biplane scans (A4C and A2C) acquired by cardiac sonographers.

Results

Results of the hypothesis test for the Kosmos Auto EF software, evaluating the algorithm's performance against its objective performance goal of < 10% RMSD, are shown below. The performance goal was met.

Table 49. Hypothesis Test for the Kosmos Auto EF software

Endpoint	RMSD (95% CI)	p-value	Pearson Correlation	Bias (95% CI)
LVEF Calculations	4.57%EF (5.129, 5.153)	< 0.0001	0.96	1.54%EF (6.90, -9.98)

Software Verification And Validation Testing

Software documentation generated as part of EchoNous' design process includes:

- Software/Firmware Description
- Device Hazard Analysis
- Software Requirement Specifications
- Architecture Design Chart
- Software Design Specifications
- Traceability
- Software Development Environment Description
- Verification and Validation Documentation
- Revision Level History
- Unresolved Anomalies
- Cybersecurity

A comprehensive risk analysis was conducted for the software, including a detailed description of the hazards, their causes and severity, and acceptable methods for controlling them. EchoNous developed

a description, including test protocols with pass/fail criteria and a report of results, of acceptable verification and validation activities at the unit, integration, and system levels.

Algorithm Testing

Comprehensive non-clinical performance testing of the deep-learning algorithms used in the device was performed to support their clinical performance. Specifically, the performance testing evaluated the functionality of the EF Workflow software.

Overall, the non-clinical performance testing results provide evidence in support of the functionality of Auto EF's algorithm.

APPENDIX B

AI FAST Clinical Performance And Non-Clinical Testing

AI FAST Clinical Performance Testing

A prospective study was conducted to evaluate the sensitivity and precision of AI FAST's algorithms for view identification and object labeling.

Study Design

Thirty-two (32) participants were recruited across two sites (16 participants per site). Each participants was scanned by a cardiac sonographer and a sonographer with abdominal experience using the following views: SUP (suprapubic), RUQ (right upper quadrant), LUQ (left upper quadrant), AS ([transverse] aortic sweep), IVC ([longitudinal] inferior vena cava), Aorta, SUB (subcostal 4-chamber), SUB2 (subcostal 2-chamber), A4C (apical 4-chamber), A2C (apical 2-chamber), PLAX (parasternal long axis), PSAX (parasternal short axis), and Lung.

The participants in this study represented a broad range of demographic factors, including age, gender, BMI, ethnicity, and race. Enrolled patients were evenly stratified into four groups based on BMI to ensure a balanced distribution by sex and BMI.

Five (5) radiologists, from a pool of nine, independently and collectively reviewed the algorithm's predictions on anatomical structure labeling and view identification using extracted frames. These radiologists were used to establish ground truth for comparing the algorithm's performance and were blinded to assessments by other panel members. The results from the expert panel readings were used for the statistical analysis.

Two (2) prospectively defined primary endpoints were evaluated to demonstrate the efficacy of the anatomical object labeling and view identification of AI FAST's algorithms in clinical settings.

Results

Results of hypothesis testing for the Kosmos AI FAST software, evaluating the algorithm's performance against its objective performance goal of < 20% false detection rate (FDR), are shown below. The performance goal was met.

Table 50. Hypothesis Testing of the Kosmos AI FAST Software

Endpoint	FDR (95% CI)	Recall	Precision
Object Labeling	0.9% (0.0 – 1.5%)	93.8%	99.6%
View Identification	3.4% (0.0 – 4.3%)	89.9%	96.6%

AI FAST Clinical Performance and Non-Clinical Testing

Recall is defined as how well the algorithm can identify positive instances, also known as sensitivity. Precision is how well the algorithm can correctly predict positive instance.

Software Verification And Validation Testing

Software documentation generated as part of EchoNous' design process includes:

- Software/Firmware Description
- Device Hazard Analysis
- Software Requirement Specifications
- Architecture Design Chart
- Software Design Specifications
- Traceability
- Software Development Environment Description
- Verification and Validation Documentation
- Revision Level History
- Unresolved Anomalies
- Cybersecurity

A comprehensive risk analysis was conducted for the software, including a detailed description of the hazards, their causes and severity, and acceptable methods for controlling them. EchoNous developed a description, including test protocols with pass/fail criteria and a report of results, of acceptable verification and validation activities at the unit, integration, and system levels.

Algorithm Testing

Comprehensive non-clinical performance testing of the deep-learning algorithms used in the device was performed to support their clinical performance. Specifically, the performance testing evaluated the functionality of the EF Workflow software.

Overall, the non-clinical performance testing results provide evidence in support of the functionality of Auto EF's algorithm.

APPENDIX C

Kosmos Bladder AI Clinical Performance And Non-Clinical Testing

Kosmos Bladder AI Clinical Performance Testing

A prospective study was conducted to evaluate the correlation between manual bladder volume determination and Kosmos Bladder Biplane Caliper Volume AI, also referred to as Kosmos Bladder AI, algorithm in a clinical setting.

Study Design

One hundred and forty-six (146) participants, two abdominal sonographers, and four nurses were enrolled in the study. Each participant underwent scanning by an assigned pair of healthcare professionals, comprised of a sonographer and a nurse. Three (3) independent sonographers were recruited to manually label the bladder calipers on acquired videos used to evaluate the performance of the Kosmos Bladder AI workflow. The participants in this study represented a diverse range of demographic factors, including age, gender, BMI, ethnicity, and race. This diversity enriched the dataset and provided comprehensive insights.

Three (3) sonographers labeled each acquired bladder video (transverse and sagittal). The average of these 3 measurements was considered the ground truth for assessment.

- Primary Endpoint: correlation coefficient ≥ 0.90

Table 51. Hypothesis Testing for the Kosmos Bladder AI Software

Endpoint	Result (95% CI)	p-value
Correlation Coefficient	0.988 (0.986 - 0.99)	< 0.0001

Software Verification And Validation Testing

Software documentation generated as part of EchoNous' design process includes:

- Software/Firmware Description
- Device Hazard Analysis
- Software Requirement Specifications
- Architecture Design Chart
- Software Design Specifications
- Traceability
- Software Development Environment Description
- Verification and Validation Documentation
- Revision Level History
- Unresolved Anomalies
- Cybersecurity

A comprehensive risk analysis was conducted for the software, including a detailed description of the hazards, their causes and severity, and acceptable methods for controlling them. EchoNous developed a description, including test protocols with pass/fail criteria and a report of results, of acceptable verification and validation activities at the unit, integration, and system levels.

Algorithm Testing

Comprehensive non-clinical performance testing of the deep-learning algorithms used in the device was performed to support their clinical performance. Specifically, the performance testing evaluated the functionality of the Kosmos Bladder Biplane Caliper Volume Algorithm software.

Overall, the non-clinical performance testing results provide evidence in support of the functionality of Kosmos Bladder AI’s algorithms.

APPENDIX D

Kosmos Trio Clinical Performance And Non-Clinical Testing

Kosmos Trio AI Clinical Performance Testing

A prospective non-specialist study was conducted to evaluate the use by medical professionals without specialized echocardiography training.

Study Design

A minimum of eight (8) registered nurses (RNs) were to be trained and evaluated on their performance to acquire three echocardiographic views: A2C, A4C, and PLAX. Participants were scanned by the RN (study exam), and the three (3) views were obtained using a Kosmos ultrasound system with Trio software. Additional views (including apical 3-chamber (A3C), apical 5-chamber (A5C), subcostal 4-chamber (Subcostal-4C), subcostal inferior vena cava (Subcostal-IVC), parasternal longaxis (PLAX), right ventricular inflow tract (RVIT), right ventricular outflow tract (RVOT), suprasternal, and parasternal short-axis (PSAX) views at various crucial levels such as the aortic valve (PSAX-AV), mitral valve (PSAX-MV), papillary muscle (PSAX-PM), and left ventricle apex (PSAX-AP)) were captured to evaluate the capability of the Auto Label feature.

The study continued enrollment until eight RNs and four sonographers 3 (had completed scans of 17 patients each. Enrolled patients were evenly stratified into four groups based on BMI to ensure a balanced distribution by sex and BMI. For comparison, participants were also scanned by a trained sonographer without Trio, and the same three (3) views were obtained (control exam) using the same Kosmos ultrasound system.

Following the study and control exams, a panel of five (5) expert cardiologist readers independently assessed whether the patient study, in its totality, provided sufficient information to assess four (4) clinical parameters. In addition, a panel of five (5) expert cardiologists independently assessed diagnostic image quality per clip using the ACEP scale; all five (5) cardiologists graded each clip. The readers were blinded to assessments from other panel members, as well as to the site from which the images were obtained and whether an RN or a sonographer obtained them. The results from the expert panel readings were used for the statistical analysis. To reduce possible sources of bias in the design, the RNs, sonographers, and cardiologists were all blinded to results determined by others. Four (4) prospectively defined primary endpoints were evaluated sequentially for the study, all of which assessed whether the patient study exam conducted by the RN, taken as a whole, was of sufficient image quality to make these clinical assessments. Specifically, the endpoints assessed whether, in the judgment of expert cardiologists, the studies permitted qualitative visual assessment of left ventricular (LV) size, LV function, right ventricular (RV) size, and nontrivial pericardial effusion.

Primary Endpoints And Clinical Utility Outcomes

The four primary endpoints were satisfied and demonstrated the clinical utility of Trio for non-specialist users. Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 52. Clinical Utility Outcome: Trio

Endpoint	Percent Diagnostic Quality (95% CI)
Global left ventricular function	98.5 (94.8, 99.6)
Left ventricular size	98.5 (94.8, 99.6)
Non-trivial pericardial effusion	98.5 (94.5, 99.6)
Right ventricular size	98.3 (91.7, 98.4)

The secondary endpoints presented below were evaluated at a one-sided Type I false-positive error rate of 0.025. This was controlled using a hierarchical hypothesis testing approach. These endpoints were evaluated and demonstrated the robustness of the data. Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 53. Hierarchical Hypothesis Testing

Endpoint	Outcome (95% CI)
Automatic anatomical labeling	0.72% False Discover Rate (0.54, 0.96)
Left atrial size	99.3% Sufficient Quantity (96.0%,99.9%)

Additional analyses presented below were not evaluated based on a specific hypothesis. Since the evaluation of additional analyses did not allow for control of Type I error, the study results are presented as a descriptive demonstration of Trio.

The six (6) additional patient-level clinical parameters were evaluated. Each had a high proportion of scans considered to be of sufficient image quality to support the four (4) additional patient-level clinical parameter assessments, i.e., qualitative visual assessment of RV function, aortic valve (AV), mitral valve (MV), and tricuspid valve (TV). Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 54. Descriptive Demonstration of Trio

Clinical Parameter	Percent Diagnostic Quality (95% CI)
Right ventricular function	72.1% (94.7%, 79.4%)
Aortic valve	79.4% (72.1%, 86.0%)
Mitral valve	98.5% (96.3%, 100%)
Tricuspid valve	50.0% (41.9%, 58.1%)

In addition to assessing if image quality was sufficient to make assessments, cardiologists also made specific qualitative visual assessments based on the study and control exams (e.g., presence or absence of non-trivial pericardial effusion). The proportion of scans in which the diagnostic assessment was the same between study and control exams was very high, further demonstrating the usability of Trio.

To provide a robust assessment of Trio's performance, subjects enrolled in the study included a broad range of patient characteristics representative of the intended use population. In particular, effort was made to include subjects with known cardiac abnormalities at the time of enrollment (72%), which would be expected to provide a more technically challenging scan, with the most common being a history of heart failure (27%), cardiac surgery (27%), and arrhythmia (16%). Subgroup analyses were conducted to evaluate the impact of specific baseline and demographic characteristics (i.e., BMI, presence of known cardiac abnormalities, sex, age) on the outcomes of the primary and secondary endpoints. The results demonstrated consistent performance across subgroups.

Furthermore, it was evaluated whether RN users could obtain a high proportion of diagnostic-quality clips. Specifically, the eight (8) RNs acquired echocardiographic clips of diagnostic-image quality for each of the standard views in the following proportion of study exams conducted.

Table 55. Broad Range of Patient Characteristics

View	Percent Diagnostic Quality (95% CI)
Parasternal long axis (PLAX)	95.2% (93.2%, 96.7%)
Apical 2-chamber (A2C)	97.1% (95.2%, 98.3%)
Apical 4-chamber (A4C)	67.3% (61.3%, 72.9%)

The study also demonstrated Trio's safety profile. No device-related adverse events were reported in the pivotal study. The following analysis was performed on the Pivotal Study data by an outside core lab to assess the performance of Trio using objective quantitative metrics:

- PLAX Sonographer Measurements: Three (3) registered cardiac diagnostic sonographers independently provided measurements for each of the PLAX clips acquired in the pivotal study: septal wall thickness (diastole), posterior wall thickness (diastole), left ventricular internal diameter (diastole), left ventricular internal diameter (systole), and aortic root. Measurability of study exam clips ranged from 92.5 to 96.3%, and the measurability of the control exam clips ranged from 95.6 to 97.0%. The mean absolute difference and Pearson Coefficient ranged from 0.84-3.49 mm and 0.823 to 0.925, respectively. The results demonstrate that PLAX clips acquired by nurses using Trio were highly suitable for linear measurements in clinical use.
- A2C/A4C Sonographer Measurements: Three (3) registered cardiac diagnostic sonographers independently provided measurements for each of the PLAX clips acquired in the pivotal study: septal wall thickness (diastole), posterior wall thickness (diastole), left ventricular internal diameter (diastole), left ventricular internal diameter (systole), and aortic root. Measurability of study exam clips ranged from 92.5 to 96.3%, and the measurability of the control exam clips ranged from 95.6 to 97.0%. The mean absolute difference and Pearson Coefficient ranged from 0.84-3.49 mm and 0.823 to 0.925, respectively. The results demonstrate that PLAX clips acquired by nurses using Trio were highly suitable for linear measurements in clinical use.

Summative Human Factors Evaluation

A Human Factors Validation Study was conducted with 18 participants to demonstrate the device's usability. The Kosmos Trio user interfaces. including its training materials, were developed through a series of preliminary human factors analyses. Kosmos Trio, with its training regimen, were then implemented and tested during the Human Factors Validation Study.

Evaluation Design

Eighteen (18) representative users participated in the study; none had prior training or experience with ultrasound beyond the use of a bladder scanner. These participants consisted of the following functions.

- Registered Nurse: 14
- Physician’s Assistant: 2
- Nurse Practitioner: 2

Participants received training from a Super User, who had been trained by an EchoNous Clinical Educator, in accordance with the EchoNous Super User training materials. Super User training lasted approximately 90 minutes and was followed by a minimum of one (1) hour learning decay period before the Super User delivered training to any participants.

Participant training lasted approximately three (3) hours, followed by a minimum of one (1) hour learning decay period. During each simulated use session, participants completed simulated scenarios

and tasks. Participants also navigated to sections of the User Guide, answered questions using its content, and provided feedback on their interactions with the system.

Results

Of the 496 tasks, 440 were completed successfully (88.7%), with 113 of 125 (90.4%) navigation tasks completed successfully. Participants were able to complete tasks without impacting the safety of the system. EchoNous reviewed all critical task issues and determined that the use of the system is considered acceptable.

Software Verification And Validation Testing

Software documentation generated as part of EchoNous' design process includes:

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- Software Design Specifications
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A comprehensive risk analysis was conducted for the software, including a detailed description of the hazards, their causes and severity, and acceptable methods for controlling them. EchoNous developed a description, including test protocols with pass/fail criteria and a report of results, of acceptable verification and validation activities at the unit, integration, and system levels.

Algorithm Testing

Comprehensive non-clinical performance testing of the deep-learning The algorithms used in the device were performed to support their clinical performance. Specifically, the performance testing evaluated the performance of the following software functionality:

- Probe guidance and image grading
- Auto labeling

Overall, the non-clinical performance testing results provide evidence in support of the functionality of Kosmos Bladder AI's algorithms.

Probe Guidance And Image Grading

Thirty-eight (38) participants with varying BMI, age, and gender were recruited for an in-house study to acquire echocardiographic data. Trio's probe-guidance algorithm was tested to assess its performance in predicting motions for the following tasks.

- Frame-level prediction of the probe maneuver needed to acquire an image/frame of the heart, for a specific view.
- Frame-level prediction of the automatic acquisition of a diagnostic-qualityclip for a specific view.

EchoNous assessed performance based on the positive predictive value (PPV), which signifies the ratio of accurately predicted probe motions to all predicted probe motions. Reference the overall PPV values below.

Table 56. Kosmos Trio's Probe Guidance PPV Results

View	Frame-level PPV (95% CI)
Parasternal long axis (PLAX)	0.902 (0.848, 0.938)
Apical 2-chamber (A4C)	0.904 (0.865, 0.933)
Apical 4-chamber (A2C)	0.954 (0.913, 0.976)

EchoNous also assessed the performance of its Auto Capture feature, inclusive of Smart Capture, using PPV. The overall results are shown below.

Table 57. Kosmos Trio's Auto Capture PPV Overall Results

View	Clip-level PPV (95% CI)
PLAX	0.933 (0.855, 0.97175)
A4C	0.941 (0.897, 0.967)
A2C	0.839 (0.766, 0.893)

Relative image quality prediction of the current pose of the probe, as compared to the ideal pose for a specific view of the heart at the clip and frame levels. Cohen's kappa (k) greater than 0.6 indicates the difference between the Kosmos Trio-graded image and the human-graded image are in agreement. This indicates how accurately the image grading algorithm assessed the images when compared to manual assessment by a trained sonographer.

Table 58. Kosmos Trio's Image Grading k Results

View	Frame-level *k* (95% CI)
PLAX	0.742 (0.673, 0.802)
A4C	0.694 (0.630, 0.745)
A2C	0.632 (0.579, 0.678)

Auto Labeling

The Auto-Label algorithm was validated on 6,405 frames acquired from 146 participants across varying BMI, age, and gender.

Out of 6405 frames, each annotated by five (5) truthers, 46 frames were deemed to have at least one (1) false positive, leading to the frame-level false discovery rate of 0.72% (95% C.I. 0.54%-0.96%). The ground truth number of true positives, false positives[1], false negative, and true negative structures determined by the truthers were 25737, 62, 2547, and 99754, respectively. This leads to an overall structure-level recall of 90.99% (95% C.I. 90.53% - 91.45%), a structure-level precision of 99.76% (95% C.I. 99.68% - 99.83%), and a structure-level accuracy of 97.96% (95% C.I. 97.86% - 98.06%). High levels of precision, recall and accuracy indicate that Auto-Label performs well by reducing false positive and false negative structure labels, and correctly not displaying true negative structure labels.

[1]There are more false positive structures than there are frames with false discovery. This is due to a frame may contain more than one (1) false positive structure.