KOSMOS

User Guide

EchoNous

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*Property of Cypress.

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CHAPTER 1

Getting Started

What's new in this release?

New features and changes for the 7.0 version of KOSMOS® include:

- Tissue Doppler Imaging Mode

Package contents

The KOSMOS box contains the following items:

- KOSMOS system, comprised of the Kosmos Bridge and Kosmos Torso or Kosmos Torso-One or Kosmos Lexsa
- Kosmos power supply
- Kosmos ECG patient cable (only with Kosmos Torso)
- Kosmos binaural headset (only with Kosmos Torso)
- Bridge stand
- KOSMOS Quick Start Guide
- KOSMOS Torso UI and Handle Controls Quick Guide or KOSMOS Torso-One UI and Handle Controls Quick Guide or KOSMOS Lexsa UI and Handle Controls Quick Guide
- Chemical Compatibility
- USB flash drive containing:
  - KOSMOS User Guide
  - KOSMOS Quick Start Guide

- KOSMOS Torso UI and Handle Controls Quick Guide or KOSMOS Torso-One UI and Handle Controls Quick Guide or KOSMOS Lexsa UI and Handle Controls Quick Guide
- ALARA education program (ISBN 1-932962-30-1, Medical Ultrasound Safety)
- Terms and conditions of warranty
- Manufacturer Disclosure Statement for Medical Device Security (MDS2)
- DICOM Conformance Statement

Intended users

KOSMOS is intended to be used by qualified and trained healthcare professionals that are legally authorized by law in the country, state, or other local municipality in which they practice to use the device. The list of the 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.

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 to be used by qualified and trained healthcare professionals in the clinical assessment for the following clinical applications by acquiring, processing, displaying, measuring, and storing ultrasound images, or synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms.

With respect to its ultrasound imaging capabilities, KOSMOS is a general purpose diagnostic ultrasound system used in the following clinical applications and modes of operation:

- **Clinical Applications:** Cardiac**,** Thoracic/Lung, Abdominal, Vascular/ Peripheral Vascular, Musculoskeletal, and interventional guidance (includes needle/catheter placement, fluid drainage, and nerve block)
- **Modes of Operation:** B-mode, M-mode, Color Doppler, Pulsed-Wave (PW) Doppler, Tissue Doppler Imaging (TDI), Continuous-Wave (CW) Doppler, Combined Modes of B+M, and B+CD, B+PW, B+CW, and Harmonic Imaging

KOSMOS is intended to be used in clinical care and medical education settings on adult and pediatric patient populations.

The device is non-invasive, reusable, and intended to be used on one patient at a time.

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.
	Federal (USA) law restricts this device to sale by or on the order of a physician.

General warnings and cautions

	System users are responsible for image quality and diagnosis
	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 for the Kosmos Torso, Kosmos Torso-One or Kosmos Lexsa lens and the Kosmos ECG patient cable) to touch the patient.
⚠	To avoid the risk of electrical shock or injury, do not open the Kosmos Bridge or Kosmos Torso or Kosmos Torso-One or Kosmos Lexsa 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 hazard, inspect the power supply, AC power cords, cables, and plugs on a regular basis to ensure that they are not damaged.
⚠	The KOSMOS system, including the Kosmos ECG patient cable, is not defibrillation proof. To prevent injury to the operator/bystander, Kosmos Torso, Kosmos Torso-One, Kosmos Lexsa and the Kosmos ECG patient cable/leadwires must be removed from patient contact before the application of a high-voltage defibrillation pulse.
⚠	Before using the system for interventional procedures, you must have training in the applicable interventional procedures in addition to training in the use of ultrasound imaging for needle and/or catheter guidance. Well known limitations of ultrasound physics may lead to an inability to visualize the needle/catheter or differentiate 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.
⚠	Use only with approved EchoNous Power supply (Part number P005974) in any clinical care and medical education settings.

User guide

This user guide is intended to assist you with the safe and effective operation of KOSMOS. Before attempting to operate KOSMOS, read this user guide and strictly observe all the included warnings and cautions. Also, pay special attention to the information in the chapter called **Safety**.

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

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

Symbols in this user guide

	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**.
- The word:
  - **Tap** refers to touching the screen quickly with your finger
  - **Double tap** refers to touching the screen two times in quick succession with your finger
  - **Drag** refers to touching the screen with your finger and then moving your finger across the screen
  - **Swipe** refers to moving your finger across the screen quickly
  - **Pinch** refers to moving two fingers in a pinch motion or pinch release motion across the screen
  - **Check** refers to tapping a check box to enable the associated function
  - **Clear** refers to tapping a check box to disable the associated function
  - **Select** refers to tapping a menu item from a menu list
- Links to other sections within the guide appear bold and colored, such as the cross reference, see **Imaging modes**.

-- End of section --

EchoNous customer support

Contact customer support:

Phone: 844-854-0800

Fax: 425-242-5553

Email: info@echonous.com

Web: www.echonous.com

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CHAPTER 2

KOSMOS Overview

What is KOSMOS?

KOSMOS consists of Kosmos Bridge, which runs the EchoNous system software, and is connected by cable to a Kosmos probe.

The following probes are available for the Kosmos System:

- Kosmos Torso:
  - A phased array transducer that combines ultrasound, ECG and digital auscultation in one probe.
- Kosmos Torso-One:
  - A phased array ultrasound-only probe with a smaller, more streamlined form factor to help fit in between intercostal spaces.
- Kosmos Lexsa
  - A linear array ultrasound probe.

KOSMOS provides portable ultrasound imaging and supports noninvasive Cardiac, Thoracic/lung, Abdominal, Vascular/Peripheral Vascular, Musculoskeletal and interventional guidance includes needle/catheter placement, fluid drainage, and nerve block). When Kosmos Torso is connected, KOSMOS also provides three lead, single-channel ECG and digital auscultation (DA) signals.

KOSMOS uses pulse-echo ultrasound to generate real-time ultrasound images. This process involves transmitting high-frequency acoustic pulses into the body from the probe and detecting the returned signals and processing the return echoes through analog and digital processing to form real-time images of anatomy (B-mode and M-mode) and blood flow (Color Doppler, Pulsed-Wave Doppler, and Continuous-Wave Doppler). Reference **Table 5-2 Modes of Operation by Kosmos Probe** for more information about which modes are applicable for each Kosmos Probe.

Kosmos Bridge is a custom-designed tablet approved, preconfigured, and supplied by EchoNous. Kosmos Bridge is provided with a power supply. When the display is connected to Kosmos Torso, Kosmos Torso-One or Kosmos Lexsa, the combination is configured as a medical electrical system.

KOSMOS provides optional wireless connectivity, allowing remote storage. Additionally, The Kosmos Bridge is battery powered.

KOSMOS also includes the AI-Assisted EF Workflow and Trio.

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, stroke volume (SV) and cardiac output (CO) based on the gender and age of the patient with results that you can review and adjust if you need to.

The **Algorithmic Trio** of Auto-labeling, Auto-grading and Auto-guidance can assist you with the A4C/A2C view acquisition, by annotating in real time key cardiac structures, grading your image based on the 5-level ACEP scale, and giving you directions on how to move your probe to optimize the A4C or A2C images.

The AI-assisted EF Workflow and Trio tool are not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy**.

- CO is available only with ECG when Kosmos Torso is connected and is calculated by multiplying the SV by the heart rate (HR).
- SV is calculated as ED LV volume minus ES LV volume.

For more information about calculating the EF workflow with KOSMOS, see **Using the KOSMOS AI-assisted EF workflow with Kosmos Torso or Torso-One.**

KOSMOS clinical applications

KOSMOS is for non-invasive imaging of the human body and is intended for the following applications:

- Cardiac
- Thoracic/Lung
- Abdominal
- Vascular/Peripheral Vascular
- MSK
- Nerve

Training

KOSMOS is intended to be used by clinicians with appropriate professional qualifications and clinical training.

All users should read the generic ALARA education program supplied 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 to the above, users intending to use the ultrasound imaging function must have appropriate training in ultrasound. Appropriate information on training may be obtained by contacting EchoNous or your local professional body.

KOSMOS classifications

- KOSMOS has an internal battery which allows operation when AC power is not available.
- The Kosmos power supply classification for protection against electric shock: Class II equipment.
- Kosmos Torso, Kosmos Torso-One and Kosmos Lexsa are Type BF Applied Parts. The Applied Parts include:
  - The lens (front surface) of the probe
  - ECG electrodes, as connected to the Kosmos ECG patient cable
- Kosmos Bridge is IP22

- Kosmos Torso, Kosmos Torso-One and Kosmos Lexsa are IPx7

Patient environment

KOSMOS is intended to be used in a medical facility. It is battery powered and is expected to be used in the patient environment. Scanning can also be performed when KOSMOS is plugged into the EchoNous-approved power supply. It is important to only use the EchoNous-approved power supply; if you use another power supply, scanning will be disabled (but KOSMOS will continue to charge).

- End of section -

CHAPTER 3

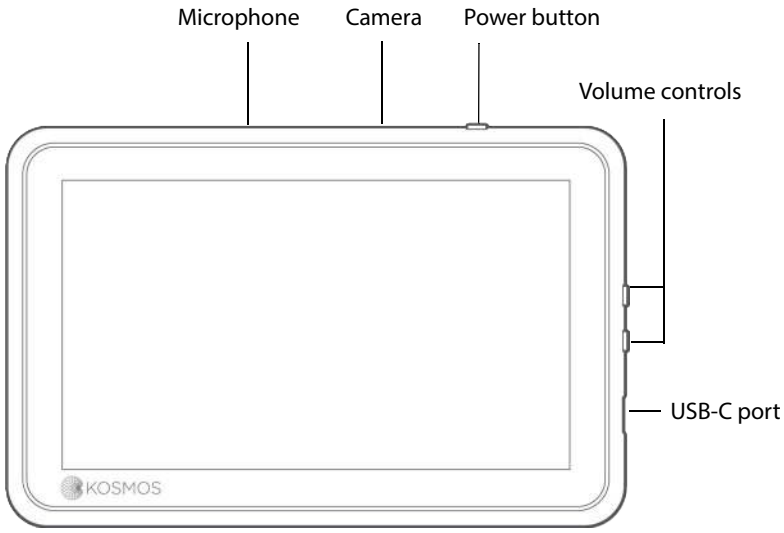
Using KOSMOS

Kosmos hardware

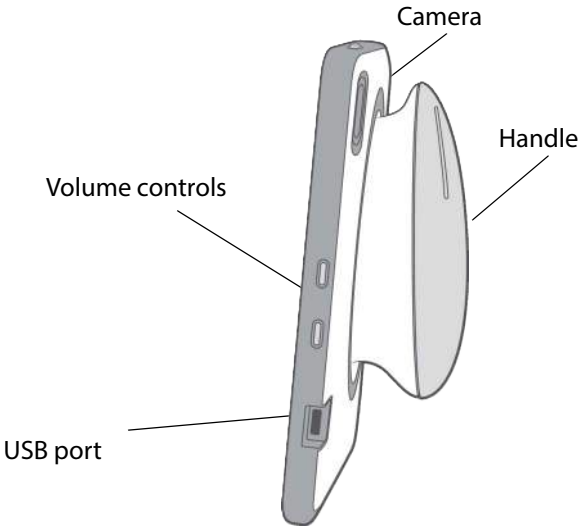
⚠	Use only accessories recommended by EchoNous. Do not connect any USB accessories to Kosmos Bridge that are not recommended by EchoNous; doing so may cause electric shock and/or compromise the security of the device. Contact EchoNous or your local representative for a list of accessories available from or recommended by EchoNous.

The following drawings point out the buttons and controls on Kosmos Bridge and Kosmos Torso.

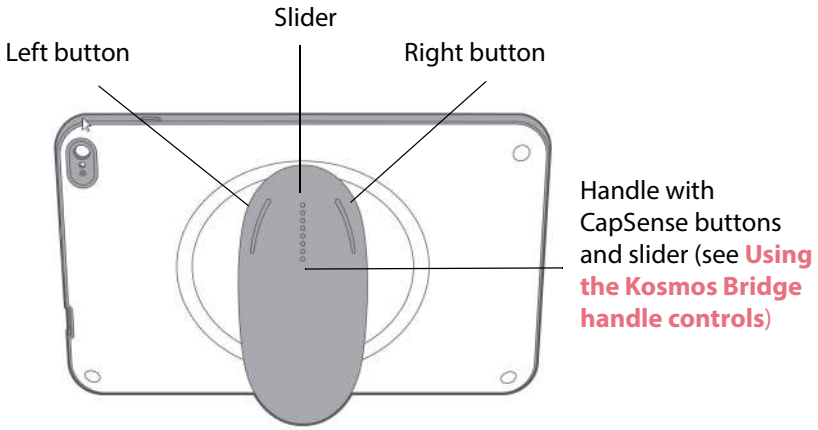
Kosmos Bridge



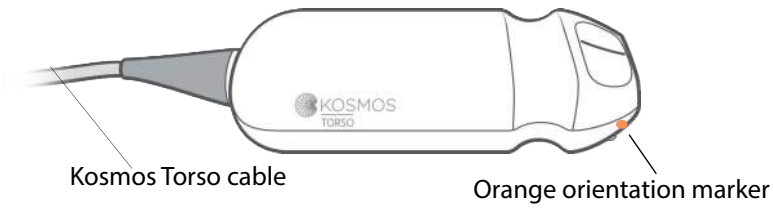
Side

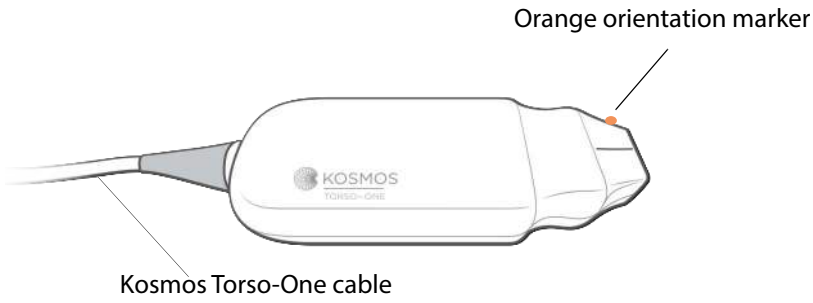

Camera
Handle
Volume controls
USB port

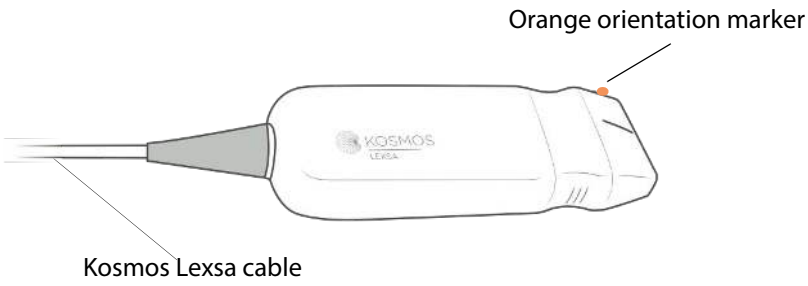
Back


Slider
Left button
Right button
Handle with CapSense buttons and slider (see Using the Kosmos Bridge handle controls)

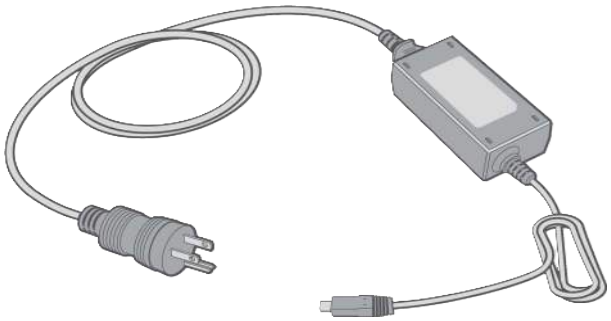
Kosmos Torso, Kosmos Torso-One and Kosmos Lexsa



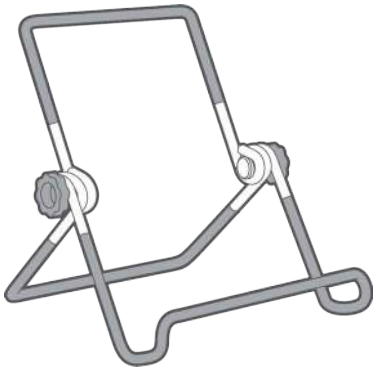




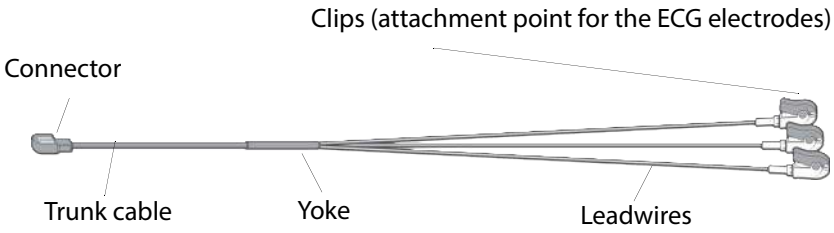
Kosmos Power Supply



Kosmos Bridge Stand

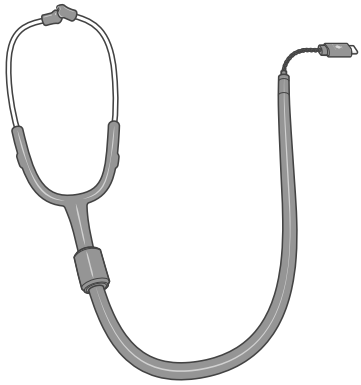


Kosmos ECG Patient Cable*



*Only applicable for Torso

Kosmos Binaural Headset*



*Only applicable for Torso

	Using a headset not approved or supplied by EchoNous may result in degraded audio performance when listening to digital auscultation signals.
	The binaural headset includes a detachable USB digital to analog converter).

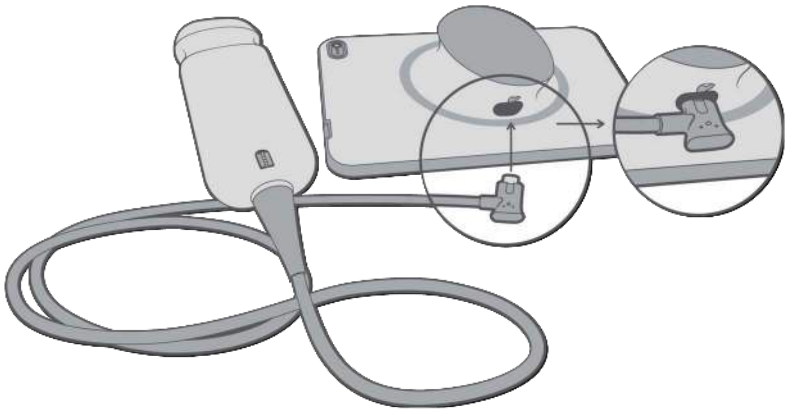
Connecting Kosmos Probes

⚠	Before each use, inspect Kosmos Torso, Kosmos Torso-One or Kosmos Lexsa for damage, such as cracks, splitting, or sharp edges. If damage is evident, discontinue using the probe, and contact your EchoNous representative.
⚠	Use only accessories recommended by EchoNous. Do not connect Kosmos Torso, Kosmos Torso-One or Kosmos Lexsa into any device other than Kosmos Bridge.
⚠	Do not attempt to plug Kosmos Torso or Kosmos Torso-One into the side USB port.
⚠	While scanning with Lexsa, do not disconnect the AC power if it is already connected.

To connect Kosmos Torso or Kosmos Torso-One to Kosmos Bridge:

✶ Plug the Kosmos Torso or Kosmos Torso-One connector into the slot below

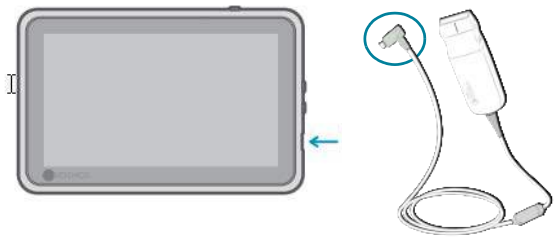
the Kosmos Bridge handle.



	If Lexsa is connected, disconnect the Lexsa probe to image with Torso or Torso-One

To connect Kosmos Lexsa to Kosmos Bridge:

✶ Plug the Kosmos Lexsa connector into the USB port on the side of the Kosmos Bridge.



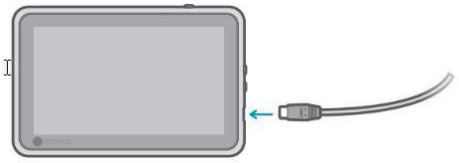
Connecting the Kosmos power supply

Kosmos Bridge contains an internal rechargeable battery. Recharge Kosmos Bridge using the power supply provided with the device.

⚠	Avoid excessive bending or twisting of the mains power cord.
⚠	Only use KOSMOS with power supplies provided by EchoNous. If you try to use a power supply not approved by EchoNous, Kosmos Bridge will continue to charge properly but will disable scanning.

To connect the power supply to Kosmos Bridge:

1. Attach the Kosmos power supply into the USB slot on Kosmos Bridge.
2. Then plug the other end into an electrical outlet.



Setting up the Kosmos Bridge stand

To set up the Kosmos Bridge stand:

1. Unfold the stand, and put it on a flat surface.
2. Place Kosmos Bridge on it.
3. Adjust the angle to the best viewing position.

4. Tighten the screws.

Turning Kosmos Bridge on and off

Turning on Kosmos Bridge

To turn on Kosmos Bridge:

1. Press the **Power** button.
2. Connect the probe (s). Select the appropriate probe on the Home screen.
3. Tap the organ of your choice to start scanning.

- If the administrator has set a PIN for security purposes, type it when prompted. However, if you need to start scanning right away, tap **EMERGENCY**.
- To save patient data after scanning, type the PIN to log on to the device, then you can save the exam.

Turning off Kosmos Bridge

To turn off Kosmos Bridge:

1. Press the **Power** button.
2. Do one of the following:
   - When prompted, tap **OK**.
   - Wait the few seconds for KOSMOS to turn itself off.

Using the Kosmos Bridge handle controls

The Kosmos Bridge handle is equipped with two buttons and one slider using CapSense technology. These buttons are protrusions on the handle that make it easier to find them while scanning. The buttons do not move when touched, but are sensitive to light touch, just like the touchscreen on the front of the Bridge.

The handle controls respond to a single tap, double tap, and up-and-down sliding gestures. Once enabled, these controls allow you to control key imaging functions, without lifting your scanning hand from the patient, such as:

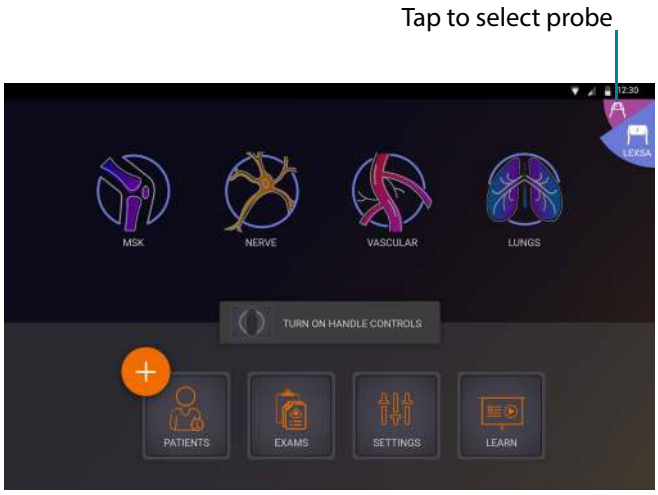
- Freezing/unfreezing an image
- Saving an image
- Saving a clip
- Adjusting the gain
- Adjusting the depth

The handle controls work only during live imaging and while an image is frozen.

If you have problems with the handle controls (such as one or more buttons not working), see **Troubleshooting**.

Switching Probes

If multiple probes are connected to the Kosmos Bridge, easily switch between the probes by tapping the desired icon in the top right corner of the Home screen. The selected probe will appear bigger than the other probe icon.



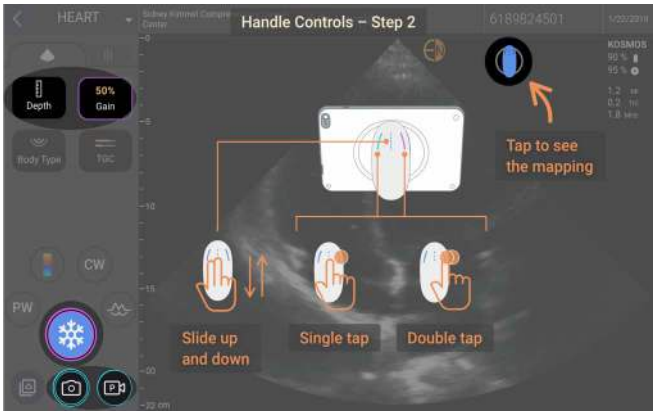
Turning on the handle controls

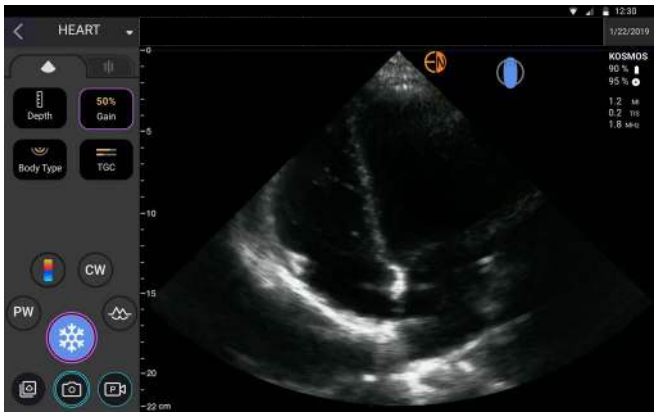
By default, the Kosmos Bridge handle controls are turned off. The handle controls are available only during imaging and that can be directed by the handle (B-mode, M-mode, B+C mode, EF workflow). The AI-assisted EF Workflow is not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy.**

To turn on the handle controls:

✶ From the Home screen, tap **TURN ON HANDLE CONTROLS** and tap **On**

✶ To see the handle control mappings from B mode imaging, tap the handle icon.

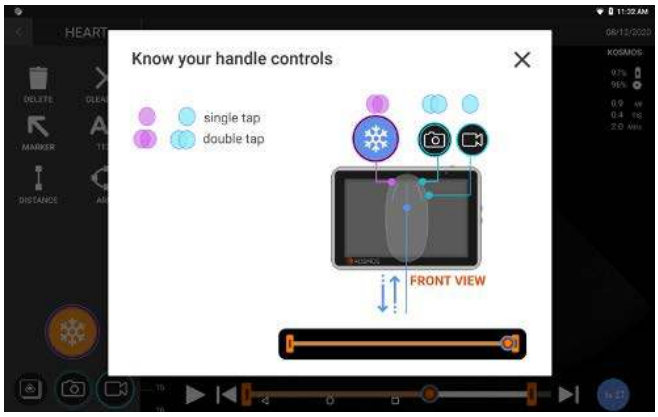




The imaging functions that can be controlled by the handle have teal and purple boundaries.

A single boundary means a single tap and double boundaries mean double tap.

In B mode imaging, single tap the left button to select between Depth and Gain. The selected control has a purple boundary. You can slide up and down to adjust the selected control.



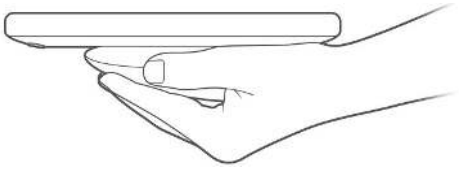
Similarly, on the cine review screen, you can use handle controls to freeze/ unfreeze, save image and save clip. Use the slider to move the cine knob between the cine fences.

Ergonomic considerations while using the handle controls

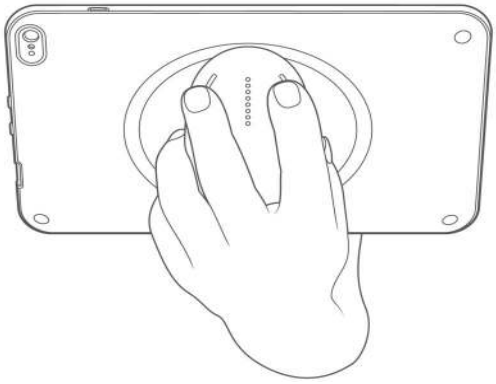
⚠	If using the handle controls cause you discomfort or pain, try adjusting your grip to a more comfortable, neutral position to minimize strain; otherwise, use the on-screen controls instead. Long-term strain can lead to a repetitive stress injury.

To hold KOSMOS Bridge so there is minimal risk of repetitive stress injury:

- Hold Kosmos Bridge in a relaxed position, so that you do not bend your wrist.

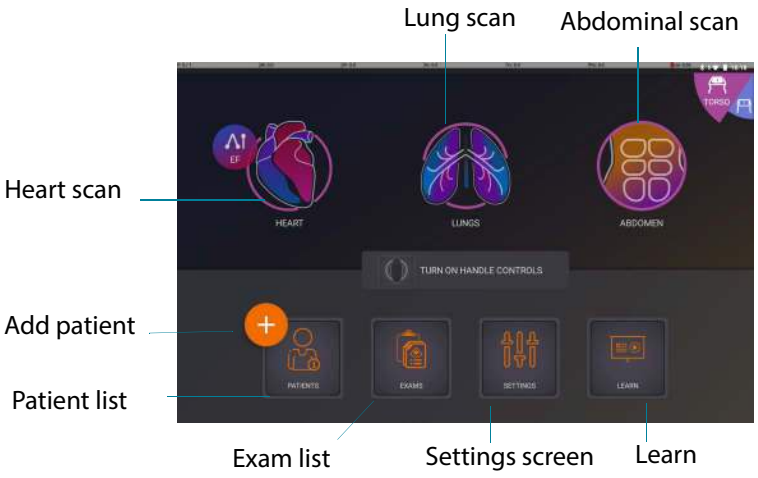


- Place your index and middle fingers on all three controls so they are easily accessible.

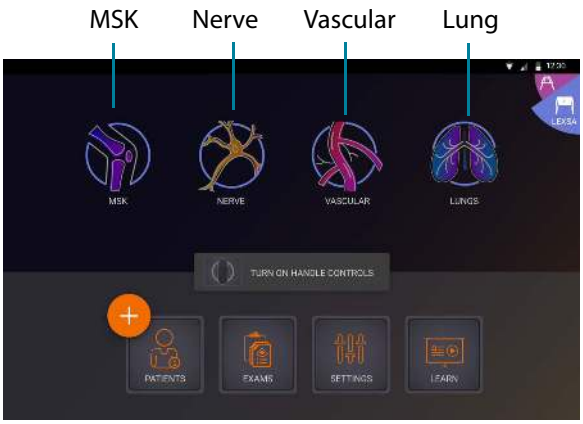


General interaction

Home Screen: Kosmos Torso and Kosmos Torso-One

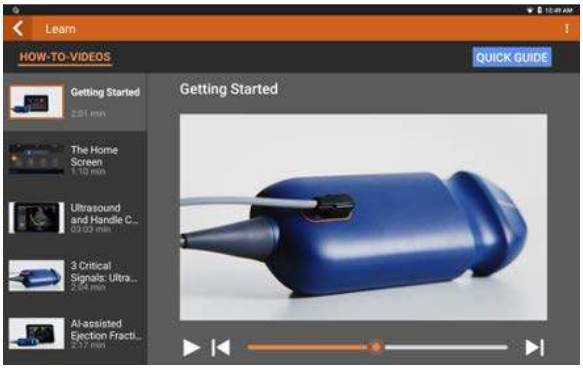


Home Screen: Kosmos Lexsa

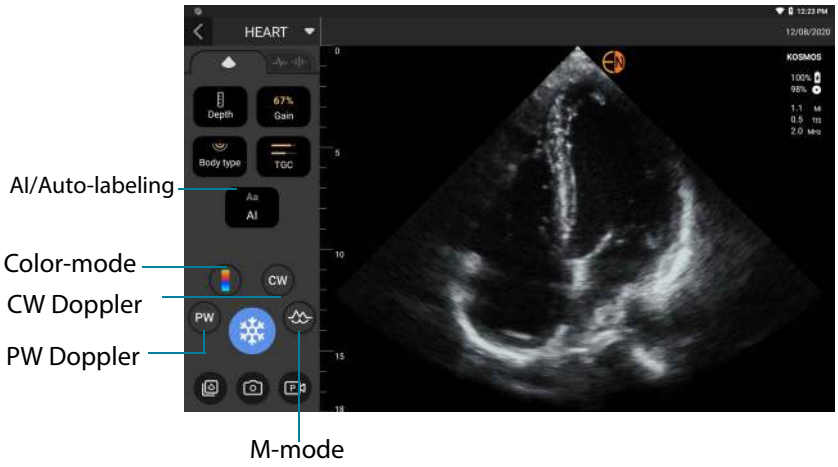


Learn

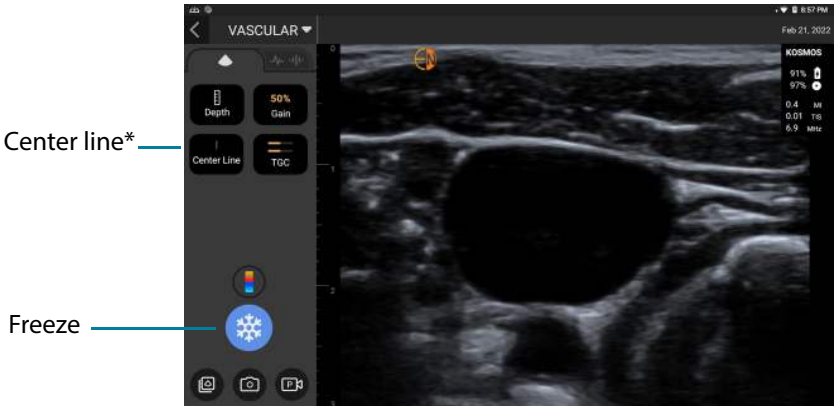
Tap **Learn** to access how-to-videos and quick guides.



Torso and Torso-One Imaging screen: Ultrasound tab (B-mode)

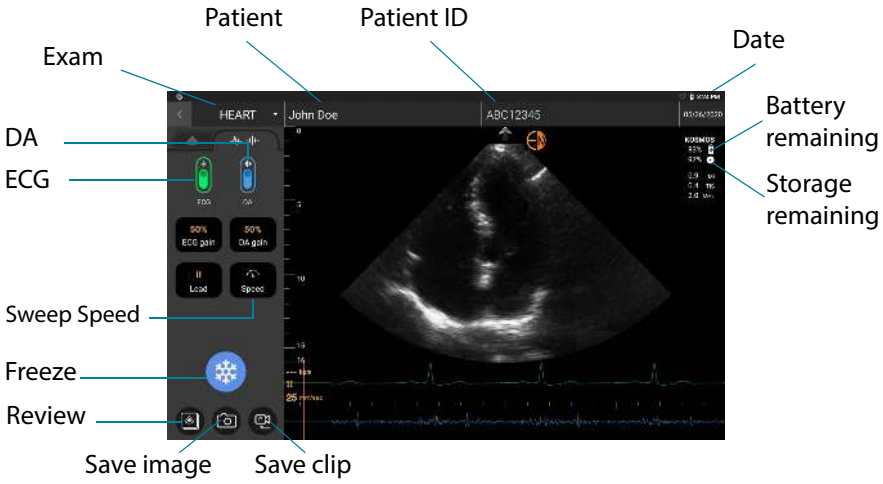


Lexsa Imaging screen: Ultrasound tab (B-mode)



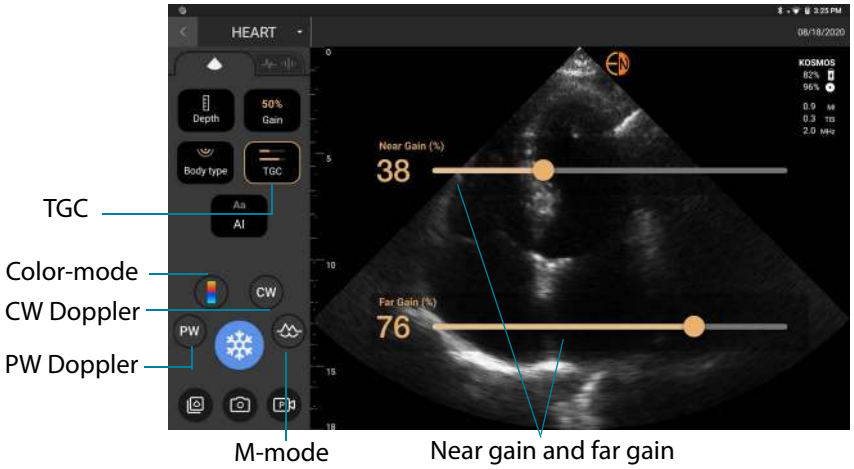
*Center line is available in MSK, Nerve and Vascular presets

Imaging screen: ECG/DA tab*



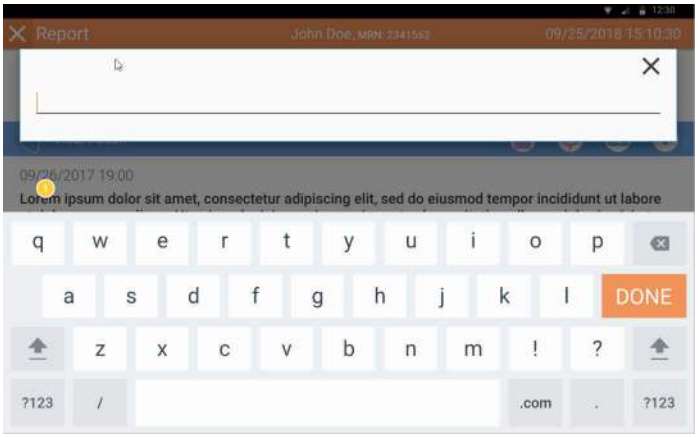
*The ECG/DA Tab will only be activated when Kosmos Torso is connected.

Ultrasound controls



On-screen keyboard

When filling out patient forms or configuring settings in KOSMOS, you can type text by tapping the text field you want to edit. An on-screen keyboard appears.

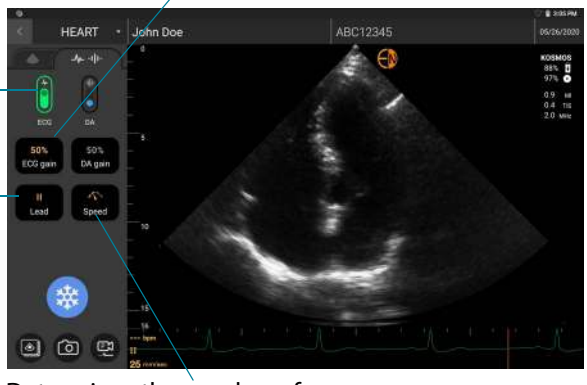


Understanding the different waveforms

ECG*

Refers to the amplitudes of the ECG waveform. Modify the amplitudes of the ECG waveform by increasing and decreasing the ECG gain.

ECG switch is turned on.



ECG lead

Determines the number of waveforms displayed. Choose the appropriate sweep speed (shared between ECG and DA). A lower sweep speed displays more waveforms, while a higher sweep speed displays fewer waveforms but provides greater details of individual waveforms.

*The ECG wave form is only available when Kosmos Torso is connected.

DA*

DA switch is turned on.

Refers to the amplitudes of the DA waveform. Modify the amplitudes of the DA waveform by increasing and decreasing the DA gain.

The DA audio plays in synchronization with the visualization of the DA waveform. You can adjust the volume of the audio (and mute the audio) with the physical buttons on Kosmos Bridge.

*The DA waveform is only available when Kosmos Torso is connected.

Configuring KOSMOS settings

Once you've configured your system settings, they remain as you set them whenever you log back on to Kosmos Bridge.

Setting imaging preferences

The Imaging Preferences screen is where you can customize the information Kosmos Bridge displays on the Imaging screen.

To set the imaging preferences:

1. From the Home screen, tap **SETTINGS**.
2. Tap **Imaging Preferences**.
3. 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.
4. 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 Clip icon. KOSMOS captures cine buffer frames for the number of seconds.
   - **Prospective**—Captures frames after you tap the Record Clip icon. KOSMOS captures frames for the number of seconds.
5. To set how long the clips record, 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.

6. 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.
7. From the **Thermal index display** area, select from the following:
   - **TIS**—Thermal index for soft tissue
   - **TIB**—Thermal index with bone near the focus
8. Select the **cardiac imaging orientation** preset
   - Select Left or Right orientation

Configuring ECG and DA signals

Ultrasound is always configured with DA, ECG or DA and ECG when Kosmos Torso is connected to Kosmos Bridge.

To configure the horizontal screen split between the ultrasound, ECG, and DA signals:

1. From the Home screen, tap **SETTINGS**.
2. Tap **ECG & DA Signals**.
3. Tap the layout that best suit your needs.

Setting the language, date, and time

Turning on the automatic date and time will not automatically select time zone. You have to manually adjust the time zone.

To set the language, date, and time for KOSMOS:

1. From the Home screen, tap **SETTINGS**.
2. Tap **Language, Date, and Time**.
3. From the **Language** list, tap the language of your choice.

4. From the **Date** list, tap the format of your choice.
5. If you would like the time to display in 24-hour format, tap to the right of the **Use 24-hour format** button to turn it on.

To turn off the automatic date and time (provided by your network), tap to the left of the **Automatic date and time** button to turn it off.

Adjusting the volume

Optionally, you can adjust the sound by sliding your finger down from the top of the screen and adjusting the sliders to the volume level you want.

To adjust the volume:

1. From the Home screen, tap **SETTINGS**.
2. Tap **Sound**.
3. Adjust the sliders to the volume level you want.

Setting brightness

To set the brightness:

1. From the Home screen, tap **SETTINGS**.
2. Tap **Brightness**.
3. Adjust the sliders to the brightness level you want.

Screen Mirroring (Miracast)

You are able to cast the Bridge screen to another supported device.

1. From the Home screen, tap **Settings**.
2. Select **Connected Devices**.
3. Select **Cast**.

	• The wifi setting must be turned **ON** to be able to cast to another screen.

Configuring administrator preferences

Only the KOSMOS Administrator can configure these settings.

Managing security settings

You have the option of setting up an administrator PIN, a clinical user PIN, or no PIN at all. If you do choose to set up PINs and then forget your PIN, you can still scan using the emergency feature (but you won't be able to save the exam).

If KOSMOS is only used by one person, then you may not want to set up a PIN. However, if the device is going to be used by more than one person, we recommend setting up both administrator and clinical user PINs. The administrator PIN provides access to all of the KOSMOS screens, and the clinical user PIN provides access to all of the KOSMOS screens, with the exception of the administration settings screens.

	It's very important to keep track of the PINs you create and store them in a safe place. If you forget your PIN, you must contact EchoNous Customer Support, and they will send you a one-use USB stick so you can change your PIN.

Setting up a PIN

	It is important to enable device PIN and Admin PIN for maximum security of patient data stored on the device.

To set up a PIN:

1. From the Home screen, tap **SETTINGS**, then **Administration**.
2. Tap **Security**.

3. Tap to select the **Enable administrator** PIN check box.
4. Type a six-digit numeric PIN, and click **OK**.
5. You now have a choice of how you would like to set up your PINs.

If you choose...	Can scan in Emergency mode?	Can save & review patient data?	Can access admin settings?
No PIN	Anyone	Anyone	Anyone
Admin PIN only	Anyone	Anyone	Administrators enter Admin PIN
Admin PIN & Restrict access to Home screen	Anyone	Administrators enter Admin PIN	Administrators enter Admin PIN
Admin PIN & basic PIN	Anyone	Administrators enter Admin PIN; users enter user PIN	Administrators enter Admin PIN

Changing a PIN

To change a PIN:

1. From the Home screen, tap **SETTINGS**, then **Administration**.
2. Tap **Security**.
3. To change the administrator PIN, tap **Change administrator PIN**, and type the new PIN number.
4. To change the user PIN, tap **Change user PIN**, and type the new PIN number.

Removing a PIN

To remove a PIN:

1. From the Home screen, tap **SETTINGS**, then **Administration**.
2. Tap **Security**.
3. Tap to clear the check box.

Managing Exam Preferences

You have the option to limit the number of patients that can be stored on the device. This also includes temporary patient records with no patient name. Once the device reaches the patient cap limit, it will ask you to delete patients to continue scanning. When you delete a patient, all associated exams associated with the patient are also deleted.

Patient Cap or Limit Patient Count

1. From the Home screen, tap **SETTINGS.**
2. Tap Admin > Exam Preferences.
3. Swipe to turn the Limit Patient Count **ON**.
4. Select the number of patients allowed on the device.

Enable Automatic Exam Deletion preference

1. From the Home screen, tap **Settings**.
2. Tap Admin > Exam Preferences > Auto Delete.
3. Swipe to turn **ON** the option.

	• Exams will only be deleted after an exam has been archived.

Managing PACS archives

	• 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 profile

To add a PACS profile:

1. From the Home screen, tap **SETTINGS**.
2. Tap Admin > DICOM > **PACS archive**.

3. Tap **ADD 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.

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.

   Kosmos Bridge displays the results 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, you have two 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.
8. In the **Auto archive** area, select from the following options:
   - **On/Off**—The auto archive is switched 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.

9. In the **SCU timeout (in seconds)** area, select **10**, **15**, or **30**.
10. In the **SCP timeout (in seconds)** area, select **10**, **15**, or **30**.
11. In the **Retry interval (in seconds)** area, select **60**, **300**, or **600**.
12. To have the system automatically retry failed jobs, keep the switch set to **On**; otherwise, slide it to **Off**.

Deactivating a profile

To activate or deactivate a profile, in the **PACS archive** list, tap the switch to toggle between **Active** and **Inactive**.

Deleting a profile

To delete 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 Admin > 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 a profile

To add a MWL profile:

1. From the Home screen, tap **SETTINGS**.
2. Tap Admin > 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** to check the availability of the active MWL server.
   - Kosmos Bridge displays the results on-screen.
6. In the **Profile nickname** box, type a unique name to display in the MWL profile list.

Deactivating a profile

To activate or deactivate a profile, in the **MWL** list, tap the switch to toggle between **Active** and **Inactive**.

Deleting a profile

To delete a MWL profile:

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

1. From the Home screen, tap **Settings**.
2. Tap Admin > 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.

Installing software updates

	Before updating the software, back up all patient data.

You can manually check for software updates or configure KOSMOS to automatically check to see if there is a new update available. You can also choose to have KOSMOS automatically download and install any updates.

To manually check to see if there is a software update available:

1. Make sure you are connected to your network (see **IT Network**).
2. From the Home screen, tap **Settings**.
3. Tap **Admin**.
4. Tap **Updates**.
5. Tap **CHECK FOR UPDATES**.

To set KOSMOS to automatically check and/or install updates:

1. From the Home screen, tap **Settings**.
2. Tap **Admin**.
3. Tap **Updates**.
4. To have KOSMOS automatically check for updates, under the Automatically check for update area, tap to select **On**.
5. Tap to select a frequency.
6. To have KOSMOS automatically update the software, under Automatically update area, tap **On**, and select a time to have any updates installed.

Managing network and internet settings

For more information about functions, security, and recovery, refer to the chapter **IT Network**.

To manage network and internet settings:

1. From the Home screen, tap **Settings**.
2. Tap **Administration**.
3. Tap **WIFI**.
4. Choose the Android settings that best suit your needs.

FIPS 140-2 Compliance

Kosmos is certified FIPS 140-2 compliant. In accordance with FIPS 140-2, Kosmos Bridge will only connect with WIFI networks that have passwords at least 14 characters long and will not support a VPN connection.

To enable FIPS 140-2 feature:

1. From the Home screen, tap **Settings**.
2. Tap **Administration**.
3. Tap **Security**

Setting the auto power off and auto sleep time interval

During periods of inactivity, KOSMOS automatically switches to sleep mode to preserve battery life.

If KOSMOS is in sleep mode, briefly press the **Power** button to wake it up; the display does not indicate activity when KOSMOS is asleep.

To change the sleep mode interval:

1. From the Home screen, tap **Settings**.
2. Tap **Auto Power off & Sleep**.
3. Tap the time period that best suits your needs.

Viewing information about KOSMOS

To view information about KOSMOS:

1. From the Home screen, tap **Settings**.
2. Tap **About**.
3. If you have not yet registered KOSMOS, tap **Register**.
4. To run the transducer element check tap **TEST.**

Registering KOSMOS

To register KOSMOS to the EchoNous cloud:

1. Make sure you are connected to your network (see **IT Network**).
2. From the Home screen, tap **Settings**.
3. Tap **About**.
4. Tap **REGISTER**.

Resetting KOSMOS to the factory settings

You can restore KOSMOS to its factory settings; however, be aware that this will erase all the data from internal storage.

To reset KOSMOS to the factory settings:

1. Make sure you are connected to your network (see **IT Network**).
2. From the Home screen, tap **Settings**.
3. Tap **Admin**.
4. Tap **Factory Reset**.
5. Tap **RESET**.

Wireless networking

Functions

You can connect KOSMOS to an IT network to perform the following:

- Storing exam data (static images and clips) acquired by KOSMOS in Picture Archiving and Communication System (PACS) by DICOM communication.
- Setting KOSMOS time correctly by inquiring the network time service.

Connection specifications

Hardware specification

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

Software Specification

KOSMOS is connected to PACS by the DICOM standard. For details, refer to the DICOM Conformance Statement that is on the USB flash drive.

-- End of Section --

Use Restriction

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

-- End of Section --

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CHAPTER 4

Incorporating ECG and DA Signals

Overview

When Kosmos Torso is connected to Kosmos Bridge, ECG and DA signals can be synchronized with ultrasound in real-time. ECG and DA signals are only available with Kosmos Torso.

ECG

Electrocardiography is the process of recording the electrical activity of the heart over a period of time using electrodes placed over the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electro physiologic pattern of depolarizing and re-polarizing during each heartbeat. The graph of voltage versus time produced by this noninvasive medical procedure is an electrocardiogram (ECG). The horizontal axis represents time, and the vertical axis represents voltage.

With respect to the KOSMOS ECG capability, the KOSMOS ECG feature uses a three-lead, single-channel ECG that allows the acquisition and display of a single ECG lead, which can be any of Lead I, Lead II, or Lead III.

The KOSMOS ECG feature is used with the Kosmos ECG patient cable. One end of the Kosmos ECG patient cable connects to Kosmos Torso, and the other end has three RA/LA/LL leadwires. The leadwires and associated clips are connected to the patient using the standard RA/LA/LL configuration. This allows, at any one time, for a single ECG lead (either Lead I, Lead II, or Lead III) to be acquired and displayed by KOSMOS. The user can select which lead to acquire and display by using Kosmos Bridge.

ECG has been traditionally used in ultrasound to provide a timing reference for the cardiac cycle, and it can do the same for digital auscultation (DA). KOSMOS ECG serves as a timing reference for both ultrasound and DA signals, and it can

also be used to look at the acquired and displayed ECG lead for HR measurement and rhythm assessment by qualified and trained healthcare professionals.

DA

Auscultation is achieved by listening to the internal sounds of the body, usually using a stethoscope, for the purpose of examining the circulatory and respiratory systems (heart and lung sounds), as well as the gastrointestinal system (bowel sounds).

When auscultating the heart, clinicians listen for abnormal sounds, including heart murmurs, gallops, and other extra sounds coinciding with heartbeats. HR is also noted. When listening to lungs, breath sounds such as wheezes, crepitation, and crackles are identified. The gastrointestinal system is auscultated to note the presence of bowel sounds. Digital auscultation (DA) is a digital form of auscultation. It includes the recording, visualization, storage, analysis, and sharing of digital recordings of heart, lung, or abdominal sounds.

The visualization of sounds in DA is accomplished with waveforms that are presented to the user in real-time while the acquisition is taking place. In the case of heart sounds, these waveforms are also known as phonocardiograms.

Benefits of using ECG and DA signals with ultrasound

Ultrasound imaging, ECG, and DA are all integrated into Kosmos Torso in a time-synchronized manner. Being able to view the real-time, synchronized signals of ultrasound, ECG, and DA is a valuable cross reference between different views of the same physiological event.

- **Ultrasound** provides an anatomical view of the motion of the heart.
- **DA** provides auditory and visual (through the phonocardiogram waveforms) feedback regarding the heart valves.
- **ECG** provides information about the electrical activity that drives the heart contractions.

Using the Kosmos ECG patient cable

⚠	The Kosmos ECG patient cable connects to Kosmos Torso by means of coupling magnets. Kosmos Torso contains a small permanent magnet where the Kosmos ECG patient cable connects. Do not use KOSMOS on patients with cardiac pacemakers or other electronic implantable devices.
⚠	The Kosmos ECG patient cable connects to Kosmos Torso by means of coupling magnets. The Kosmos ECG patient cable contains a small permanent magnet at the device connector. Do not use KOSMOS on patients with cardiac pacemakers or other electronic implantable devices.
⚠	The Kosmos ECG patient cable is not defibrillation proof.
⚠	The KOSMOS ECG functionality is a Type BF. KOSMOS ECG functionality is not for use in situations, such as patient monitoring, where the patient has exposed leadwires that are in direct cardiac contact. Conductive parts of electrodes and associated connectors for Type BF Applied Parts, including the neutral electrode, should not contact other conductive parts including earth.
⚠	KOSMOS may not accurately report HR in the case of irregular rhythms.
⚠	KOSMOS is not a substitute for diagnostic ECG. This device does not detect or measure all HR, heart rhythm, and heart waveform changes.
⚠	Conducted RF energy may cause noise in the ECG waveform. If noise is detected on the ECG waveform, disconnect KOSMOS from AC power.

To use the Kosmos ECG patient cable:

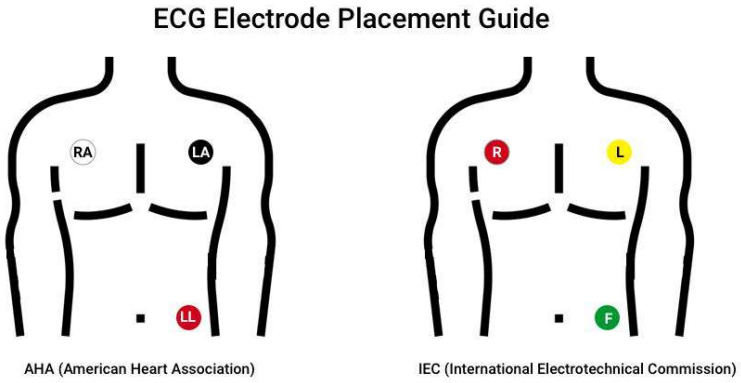
1. Place the ECG electrodes of your choice (this is where the ECG clips will be attached to) on the patient, making sure they are placed symmetrically opposite from each other and match the color coding.

   USA recommendation (American Heart Association):

   - **RA**: Right arm (white clip)
   - **LA**: Left arm (black clip)
   - **LL**: Left leg (red clip)

   IEC recommendation:

   - **R**: Right arm (red clip)
   - **L**: Left arm (yellow clip)
   - **F**: Left leg (green clip)



2. Plug the connector end of the Kosmos ECG patient cable into the magnetic slot on Kosmos Torso.

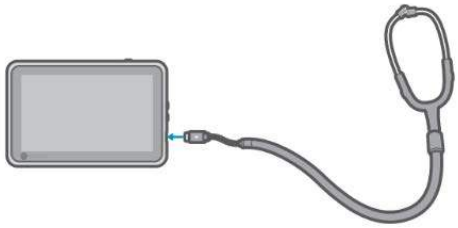
Attaching the Kosmos binaural headset

	The DA signal is built into KOSMOS; there are no external microphones/sensors to hook up.
	To listen to the DA signal, you must plug the Kosmos binaural headset into the USB port on Kosmos Bridge.

The DA microphones and signal processing are built into KOSMOS. The Kosmos binaural headset is supplied for auscultation.

To attach the Kosmos binaural headset:

1. Plug the USB end of the Kosmos binaural headset into the USB slot on Kosmos Bridge.



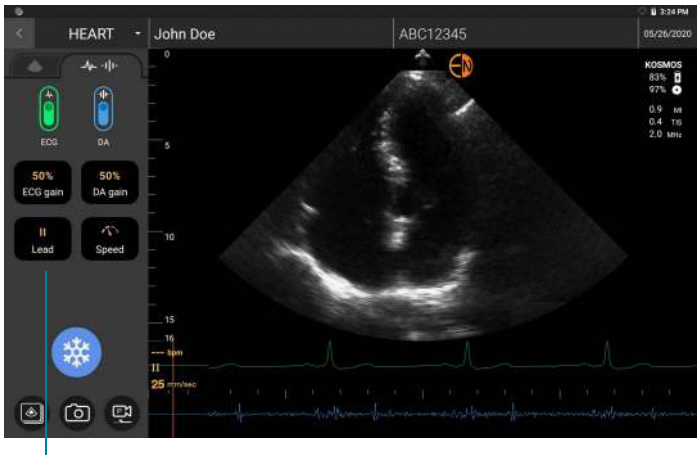
2. Put the headset on.
1. On Kosmos Bridge, tap the **ECG/DA Signals** tab.
2. Tap **DA** to turn it on.
3. From the top of the screen, slide your finger down to see the volume control.

4. Adjust the volume.

Viewing the ECG and DA signals

	The ECG and DA signals are only available in B-mode and Color-mode.

1. Tap the **ECG/DA** tab to display the two signal controls. By default, only the ultrasound image displays.
2. To view the ECG signals, tap **ECG** on; tap again to turn it off.
3. To view the DA signal, tap **DA** on; tap again to turn it off.
4. To select which ECG lead is to be acquired and displayed, tap **Lead**.



ECG lead

Signal scrolling

The ECG and DA signals scroll from left to right. The newest signals appear on the left and are indicated by the orange cursor. When the scrolling begins, the area to the right of the cursor is blank, while the new scrolling overlaps the old signals from the second round of scrolling. The DA audio is synchronized with the DA waveform scrolling.

ECG signal indicator

If the signal is weak or you cannot read it on-screen, check to make sure:

- You are holding Kosmos Torso still
- The patient is not moving
- The connection of leadwires to Kosmos Torso is not loose

Preserving the ECG and DA signals when freezing an image or taking a clip

You can freeze an image or a take a clip with the ECG and DA waveforms so you can review them in the Editing screen. What you see in the Imaging screen is what gets saved, so if you turn off any of the signals while in live imaging mode and you save an image or clip, only the signals displayed on the screen are saved.

For more information on viewing the ECG and DA signals when reviewing a saved exam or clip, refer to **Reviewing an Exam**.

Archiving and exporting ECG and DA waveforms

When you archive exams to the PACS server, the ECG and/or DA waveforms are embedded into the ultrasound image or clip.

When you export exams to a USB drive, the ECG waveform and the DA waveform and audio signals are embedded into the ultrasound image or clip. However, you cannot archive or export ECG or DA as a separate file, because the ECG and DA data is not archived separately; they are all part of the ultrasound image or clip.

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CHAPTER 5

Performing an Exam

Overview

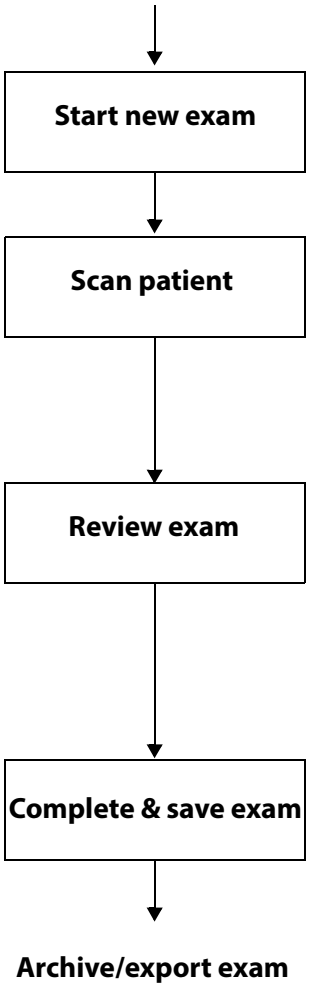
⚠	Before using Kosmos Bridge for a critical procedure, such as needle guidance, make sure it is fully charged and/or plugged into AC power. You do not want the procedure interrupted by a drained battery, which may cause harm to the patient.
⚠	Under certain circumstances, the Kosmos Bridge enclosure can reach temperatures that exceed safe (IEC 60601-1) limits for patient contact. Make sure that only the operator handles the system. Avoid placing Kosmos Bridge on the patient during use.
⚠	The maximum temperature of a Kosmos probe scan head may be greater than (41C) but is less than (43C) when in contact with the patient for normal use. Special precautions should be considered when using the transducer on children or on other patients who are 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.

With KOSMOS, there are three primary workflows; click one of the links to go to that workflow:

- **Standard workflow** starts with either creating a patient or searching for an existing patient.
- **Quick workflow** starts with scanning a patient.
- **AI-assisted EF workflow** uses AI to perform initial EF calculations. The AI-assisted EF Workflow is not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy**

Exam workflows

Standard workflow



Optional step:

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

Things you can do while scanning:

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

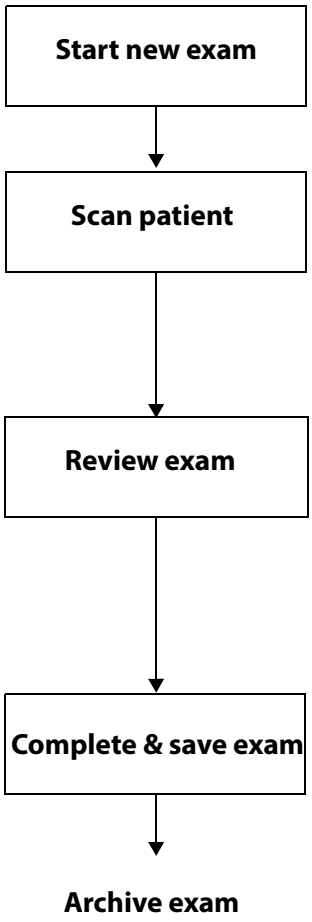
Things you can do while reviewing:

- Delete images and clips
- Add, edit, and delete annotations and notes
- Generate report

Optional steps

- Archive exam to PACS
- Export exam to USB

Quick workflow



Things you can do while scanning:

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

Things you can do while reviewing:

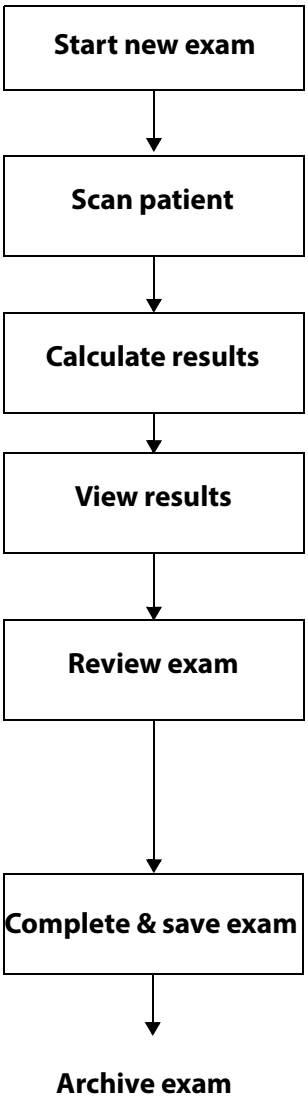
- Delete images and clips
- Add, edit, and delete annotations and notes
- Generate report

Optional steps

- Archive exam to PACS
- Export exam to USB

AI-assisted EF workflow

The AI-assisted EF Workflow is not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy**



Things you can do while scanning:

Record or retry A4C and A2C clips with or without an ECG signal, and with or without Auto-labeling, Auto-grading and Auto-guidance

Things KOSMOS does:

Uses AI to provide an initial calculation of the EF, which can be reviewed and adjusted as necessary

Things you can do while reviewing:

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

Optional steps

- Archive exam to PACS
- Export exam to USB

Managing exams

Starting an exam

There are several ways you can start an exam:

- To start scanning immediately, from the Home screen, tap a scan type.

  When you save the exam, KOSMOS automatically generates a temporary ID and saves the images/clips to the temporary ID.
- From the Home screen, tap **EXAMS**, and tap the Add icon.
- From the Patient screen, tap **SCAN**.
- From the Patient review screen, tap **START EXAM**.
- From the Exam list, tap **START EXAM**.

Searching for an exam

To search for an exam:

1. From the Exam screen, tap the Search icon.
2. Type the search criteria, such as date, patient name, DOB, or MRN.
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 in the example below. 

Deleting exams

To delete one or more exams:

1. From the list of exams, tap one or more circles to the left of the exam. The circle turns into a check mark, showing it is selected.
2. Tap the Trash icon.

3. At the prompt, tap **OK**.

To delete all the empty exams (those without images/clips):

1. From the list of exams, tap the More options ⋮ icon.
2. Tap **Delete all empty exams**.
3. At the prompt, tap **OK**.

Completing exams

To avoid mixing up images and clips saved from multiple patients, make sure to complete an exam.

To complete an exam:

1. From the Imaging screen, tap the Exam review icon.
2. Tap **Complete**.
3. At the prompt, tap **OK**.

Managing patient data

Adding a new patient

To add a new patient from the Home screen:

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.
4. Tap **SCAN** when you are done.

Accessing patient information using MWL

If you are connected to a healthcare information system and MWL is set up on your Kosmos, you can access patient information

1. From the Home screen, tap the **PATIENTS** button.

2. Tap the MWL button. Tap the icon to see the entire list.
3. Tap the icon to search for a specific patient.
4. Tap **SCAN** to start scanning

Searching for a patient

To 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**.

Changing to another patient

To change to or add a new patient when you have already started an exam:

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

Editing a patient record

To 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, and tap **SAVE** when you are done.

Merging two patient records

If you have saved multiple patients with the same name, and they are actually the same patient, you can merge all the exams of that patient into one patient record so it is easier to keep track of that patient.

	You cannot merge temporary patients.

In order to merge two patients, make sure the following fields are complete:

- First name
- Last name
- DOB
- Gender

To merge two patient records:

1. From the Home screen, tap **PATIENTS**.
2. Tap to select one of the patients.
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**.

Deleting patient records

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 patient list.
3. Tap the Trash icon.

Organ Presets

Table 5-1 provides an overview of the organ presets that are available for each Kosmos probe.

TABLE 5-1. Organ Presets by Kosmos Probe

Organ	Torso	Torso-One	Lexsa
Heart	X	X	
Lung	X	X	X
Abdomen	X	X	
Vascular			X
Nerve			X
MSK			X

Imaging modes

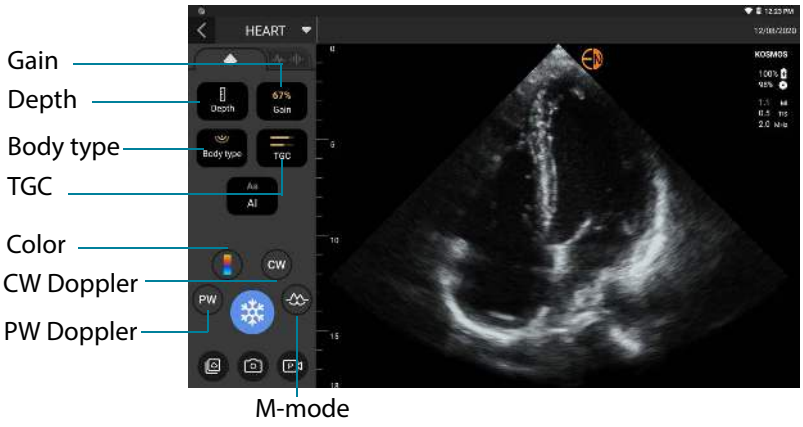
For an overview of the applicable imaging modes for each Kosmos probe, reference Table 5-2, “Modes of operation by Kosmos Probe:,” on page 66

TABLE 5-2. Modes of operation by Kosmos Probe:

Mode	Torso	Torso-One	Lexsa
B-Mode	X	X	X
M-mode	X	X	X
Color Doppler	X	X	X
CW Doppler	X	X	
PW Doppler	X	X	
Tissue Doppler (TDI)	X	X	
B+ CD	X	X	
B + PW	X	X	
B + CW	X	X	
Harmonic Imaging	X	X	

B-mode

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.

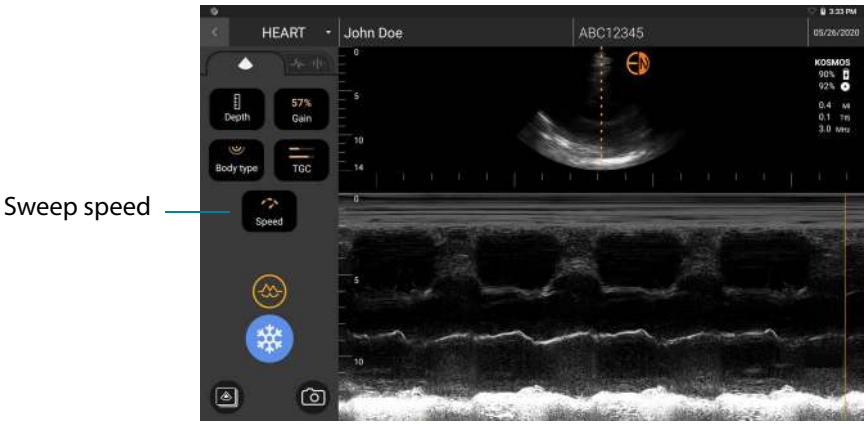


M-mode

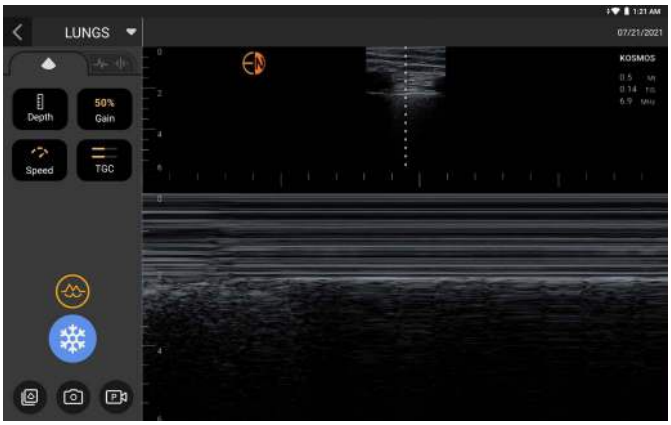
M-mode is also known as Motion Mode. It provides a trace of the image displayed over time. A single beam of ultrasound is transmitted, and reflected signals are displayed as dots of varying intensities, which create lines across the screen.

When M-mode is turned on, the screen splits to show B-mode as well as M-mode. You can adjust body type, depth, and gain (similar to B-mode) along with M-mode specific controls like M-line and sweep speed.

M-Mode: Torso/Torso-One



M-Mode: Lexsa



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, use your finger to change to M-mode, drag the M-Line to the location you want.

Sweep speed

You can change the sweep speed to isolate individual motions.

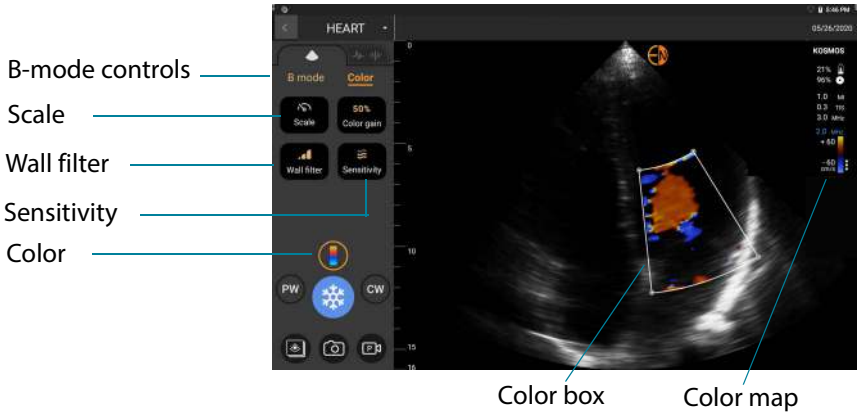
✶ To change the M-Mode sweep speed, tap **Speed**, and adjust it to your preferences.

Color-mode

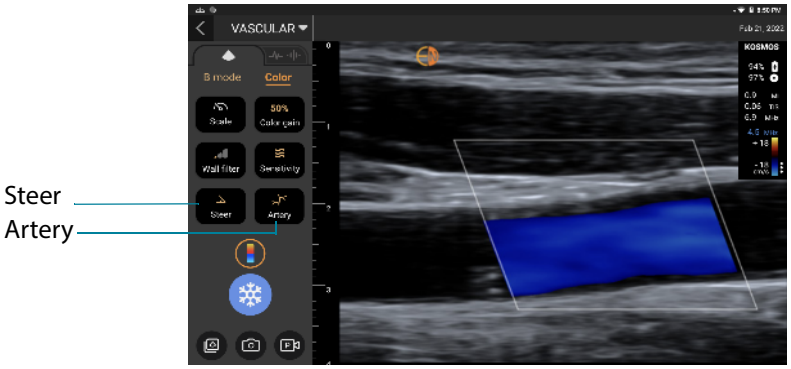
Color-mode is used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states.

When using KOSMOS, you can turn color-mode on and off without it interfering with the system's color acquisition.

Color Mode: Torso-One



Color Mode: Lexsa



✶ To turn Color-mode 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, drag it to another position.
- To resize the color box, move one of the corners to make it either taller or wider.

B-mode controls

The B-mode controls are hidden, and you can switch back and forth between the B-mode and Color-mode controls.

✶ To see the B-mode controls, tap **B-mode**.

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 range.

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

Wall filter

With the wall filter, the higher the level, the more it blocks the low-frequency flow.

✶ To change the wall filter, tap **Wall** filter, and set the appropriate low-frequency flow.

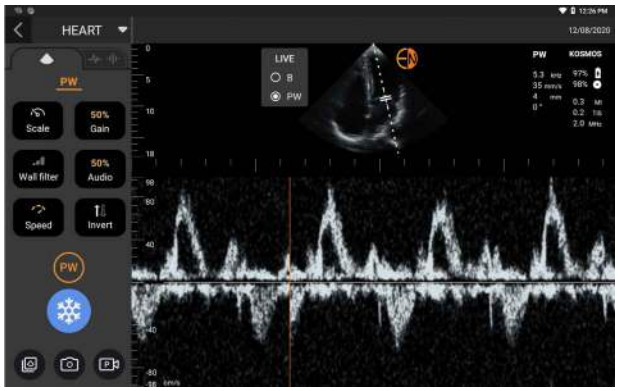
Color map

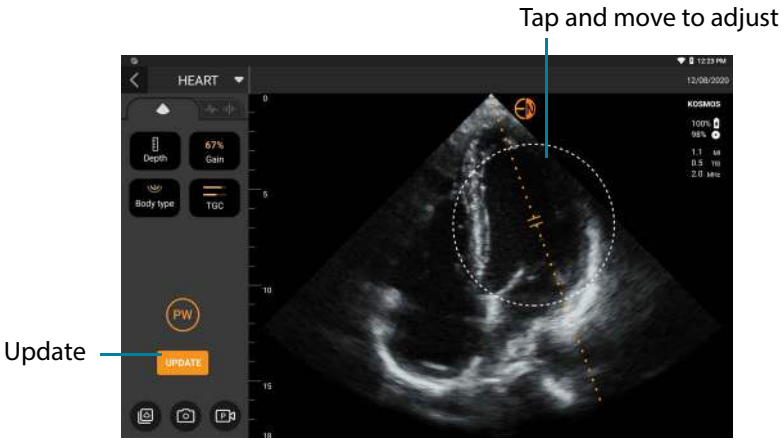
To change the heart color map:

1. Tap the ⋮ 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

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 only available in abdomen and heart presets

✶ To start PW Doppler, tap the **PW mode** **icon**. The PW mode icon is available in B-mode and Color (B+C) mode screens.

Duplex screen

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

Gate location and Doppler line

✶ Adjust the **Gate location** and the **Doppler line** by moving the dotted circle. In the abdomen preset, you can tap the Gate to see and set the angle adjust line. If Color mode is on moving the circle will also move the color box. The circle and color box can be decoupled by going to Setting > 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, Doppler trace is frozen.

Wall filter

Wall filter helps to filter out echoes from low frequency signals.

- Tap icon to select the strength of the filter: Low, Medium, High.

Invert

- To invert the Doppler spectrum, tap on the invert button.

Scale

Scale changes the velocity scale.

- 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 strength of the audio volume.

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

Sweep speed

Three sweep speed selections are available.

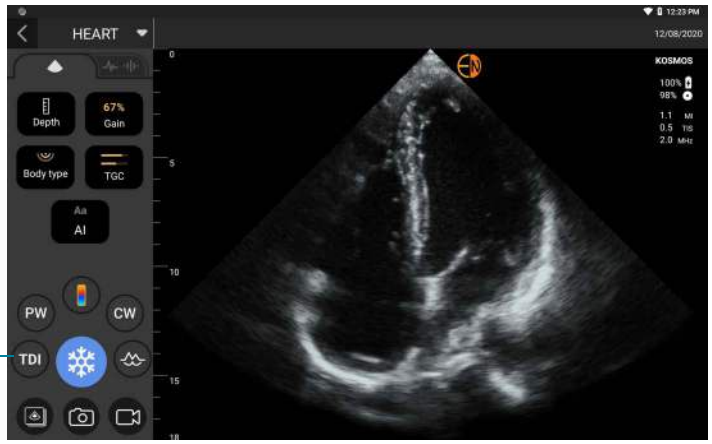
✶ To change the sweep speed, tap Sweep speed and select either low, medium or high

Save clips and images

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

Tissue Doppler Imaging

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



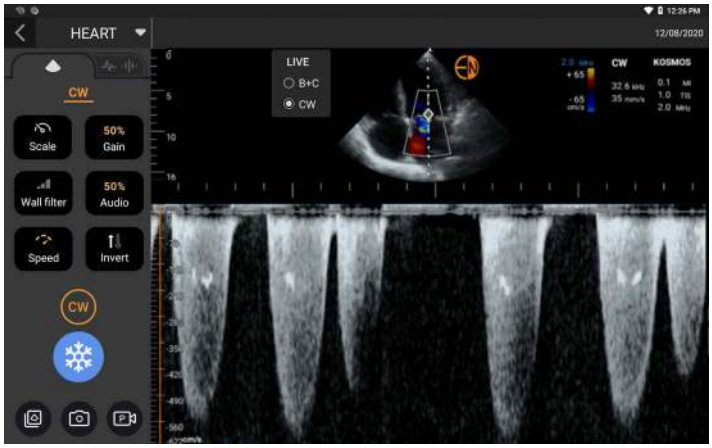
TDI

	TDI mode is only available in abdomen and heart presets

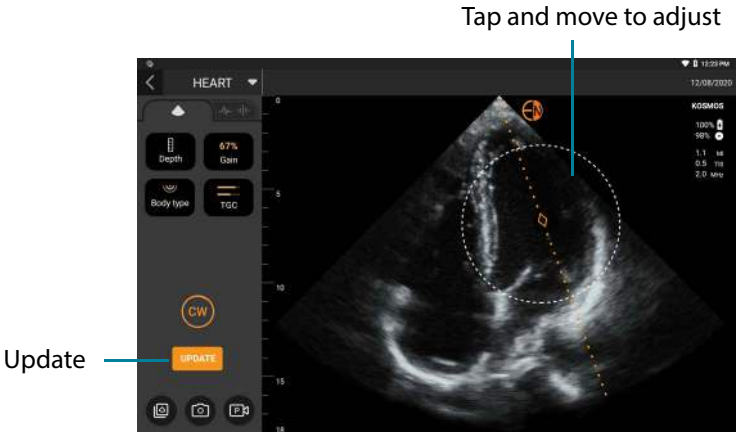
✶ To start TDI mode, tap on the **TDI mode icon**. The Tissue Doppler mode icon is available in B-mode and Color (B+C) mode screens.

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 comes into effect to manage probe temperature. A 60-second timer appears every time before the auto freeze.



	CW mode is only available in abdomen and heart presets

- To start CW Doppler, tap the **CW mode** **icon**. The CW mode icon is available in B-mode and Color (B+C) mode screens.

Duplex screen

- Tap the **Update button** for the duplex screen. The frozen B-mode image will be displayed on the 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, you can tap the focal point to see 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 CW live and B live modes. In the B live mode, Doppler trace is frozen.

Wall filter

Wall filter helps to filter out echoes from low frequency signals.

✶ Tap icon to select the strength of the filter: Low, Medium, High.

Invert

✶ To invert the Doppler spectrum, tap on the invert button.

Scale

Scale changes the velocity scale.

✶ 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 strength of the audio volume.

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

Sweep speed

Three sweep speed selections are available.

- To change the sweep speed, tap Sweep speed and select either low, medium or high

Save clips and images

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

Image mode controls

Flipping an image

You can only flip an image when you are scanning the heart.

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

Adjusting body type

In KOSMOS, body type is used to adjust the penetration level.

There are three levels of adjustment:

- Small
- Medium (default)
- Large

When you adjust the body type, it changes the penetration signal for the ultrasound parameters, so if you have a patient with a larger body mass index (BMI), you will want to set the body type to large.

- To adjust body type, tap **Body type**, and select one of the three different penetration levels.

Adjusting depth and gain

To adjust depth:

✶ To increase or decrease the displayed depth, tap **Depth**, and move the Depth wheel up and down.

To adjust gain:

- To adjust gain in Color-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.

Zooming 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.
- Notice that the zoom factor is shown near the magnifying glass as well as the orange color of the depth scale along the side image area.
- You can freeze while zoomed (and can unzoom and zoom while frozen).

Freezing an image

✶ To freeze an image, tap the Freeze  icon.
The **annotation tools** automatically display on the left side of the screen.

Using the KOSMOS AI-assisted EF workflow with Kosmos Torso or Torso-One

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 of Echocardiography (ASE)-recommended modified Simpson's method of disks (Lang 2005, 2015). The initial LV contours are produced with AI trained, expert-annotated LV contours (Ronneberger 2015). You can then review the initial AI results (which include the ED/ES frames along with the corresponding LV contours), and adjust them, as necessary.

The Trio: Auto-labeling, Auto-Grading and Auto-Guidance

The Trio of Auto-labeling, Auto-grading and Auto-guidance can assist you in real time with the acquisition of the A4C and A2C views by:

- Annotating key cardiac structures
- Grading images based on the 5-level ACEP scale
- Providing directions on how to move your probe to optimize the A4C or A2C images
- To activate any or all three of the Auto-labeling, Auto-grading or Auto-guidance functions, tap the Trio button and select the tools you would like to use as shown in **Figure 1**

	KOSMOS is an FDA-cleared medical device; however, the new AI-assisted EF Workflow and Trio tool are not yet cleared by the FDA. Instead, EchoNous® is following the *Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020* for this new feature. There are important warnings and cautions in addition to different intended users and indications for use. For detailed information, refer to **Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020**.

FIGURE 1. Trio: Auto-labeling, Auto-grading and Auto-guidance

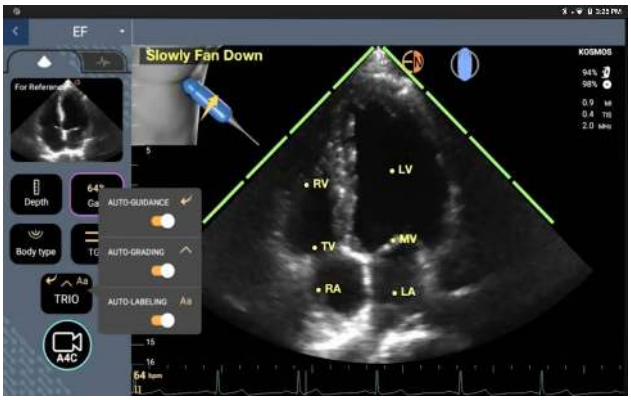


Figure 1 shows an example of Trio with all three algorithms activated.

First, key cardiac structures including the 4 heart chambers along with the mitral and tricuspid valves are provided by the Auto-labeling tool.

Second, the 4 green bars on the two sides of the sector represent the output of the Auto-grading tool and indicate an image quality of 4 out of the maximum image quality of 5 per the 5-level ACEP scale. Based on the ACEP scale, image quality of 1 and 2 is non-diagnostic, whereas image quality of 3, 4, and 5 is diagnostic.

Third, **Figure 1** features Auto-guidance by including a graphic showing the probe in the context of a patient torso and indicating probe motion for optimizing the A4C view along with the corresponding text.

The pictures indicating probe motions and the corresponding phrases provided by the Auto-guidance algorithm during A4C acquisition are shown in **Figure 2**. Note that all the pictures and corresponding phrases in **Figure 2**, can also be shown during A2C acquisition except for the one picture corresponding to the A4C view. There are three additional pictures and corresponding phrases shown in **Figure 3** that are exclusive to A2C acquisition.

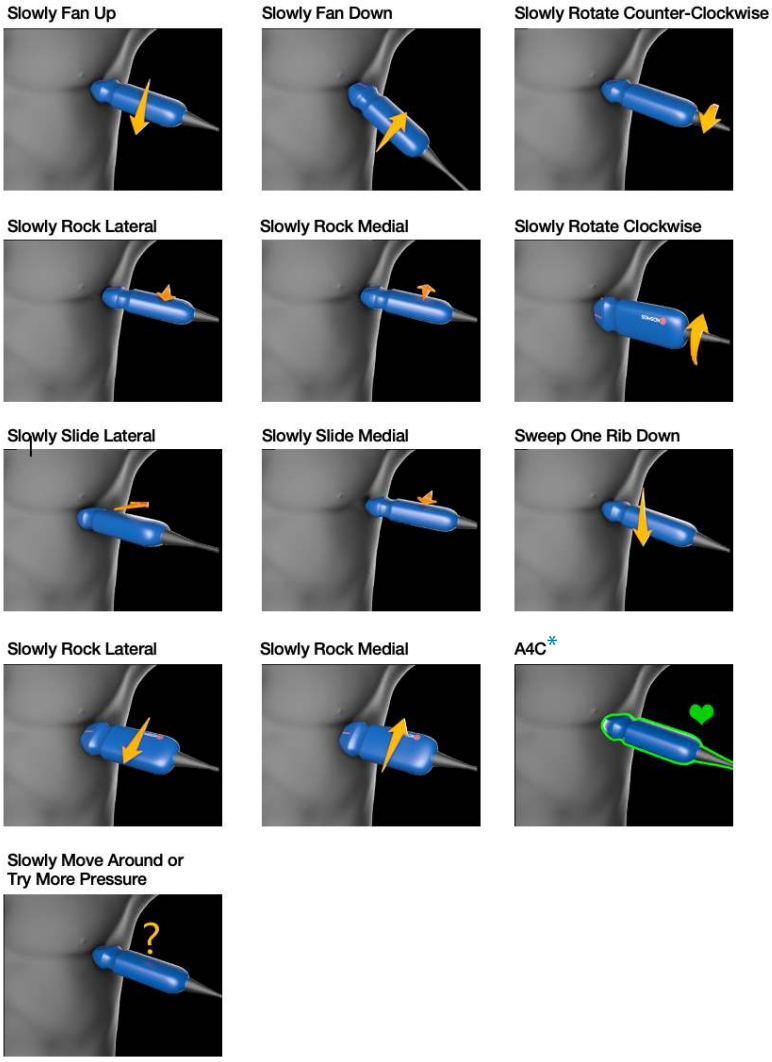
Also, note that there is one picture in **Figure 2** that can be shown with two different phrases “Slowly Move Around” and “Try More Pressure”. The two

different phrases correspond to different scenarios identified by the Auto-guidance algorithm.

- **Slowly Move Around:** You will get this message when there are no discernible cardiac structures shown in the image or when imaging the heart from non-apical windows
- **Try More Pressure:** You will get this message when there are few cardiac structures shown in the image but are not clearly visible.

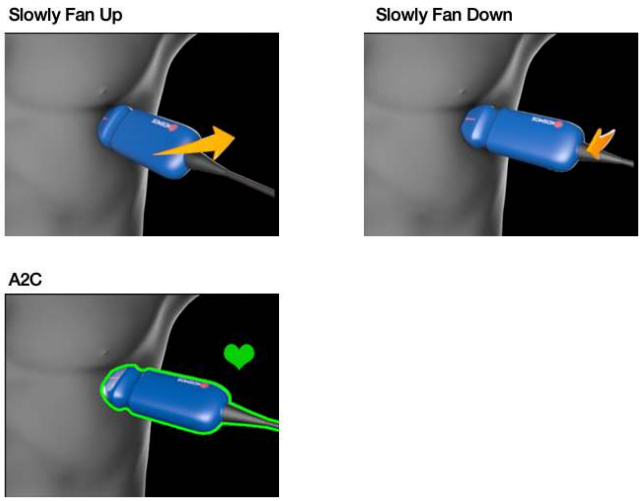
All pictures depicted in **Figure 2** and **Figure 3** are shown on the Kosmos Bridge in the form of animations to better convey probe motion.

FIGURE 2. Pictures Indicating Probe Motions and Corresponding Phrases during A4C and A2C Acquisitions



*Only for the A4C view

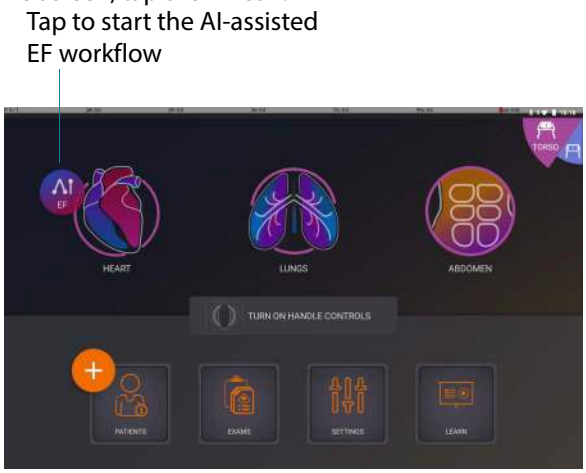
FIGURE 3. Pictures Indicating Probe Motions and Corresponding Phrases Exclusive to A2C Acquisitions



Calculating EF with the AI-assisted EF workflow

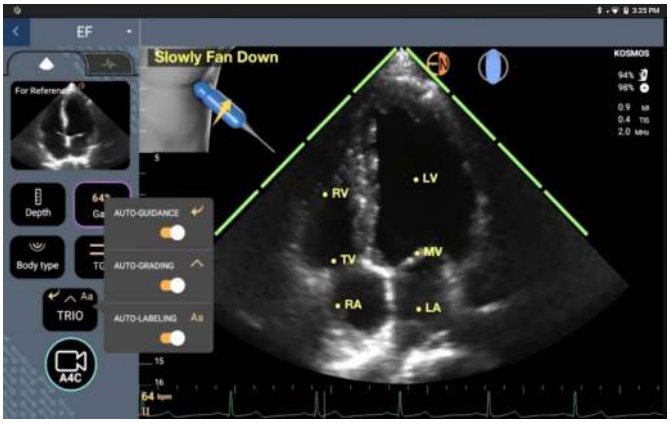
To calculate EF:

1. From the home screen, tap the AI icon.



	When you tap the Heart AI icon, KOSMOS creates a new exam that includes this EF scan.
	Do not rely upon EF calculation as the sole diagnostic criteria. Whenever possible, use EF calculation in conjunction with other clinical information.

2. After you have a good A4C view of the patient, tap **A4C** to acquire a clip. To activate any or all three of the Auto-labeling, Auto-grading and Auto-guidance tools, tap the Trio button and activate the desired tools.



3. If you are not satisfied with the recorded clip, tap **Try again** to acquire a new clip, or tap **Accept** to proceed (after four seconds, KOSMOS automatically accepts the clip).
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 more accurate calculations.

5. After you have a good A2C view of the patient, tap **A2C** to acquire a clip.
6. 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 (after four seconds, KOSMOS automatically accepts the clip).

Now that 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). Kosmos Torso must be the probe used and ECG must be connected to get the CO and HR values.

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.

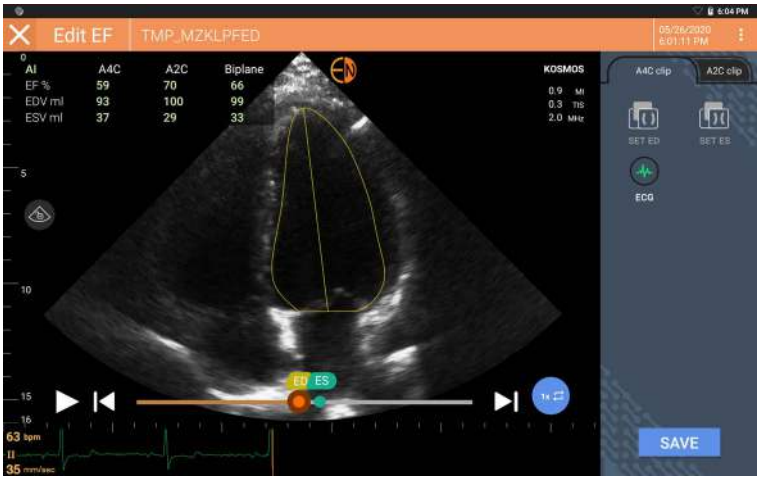
To adjust the ED/ES frames:

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

* CO and HR are only available with Kosmos Torso.

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**.



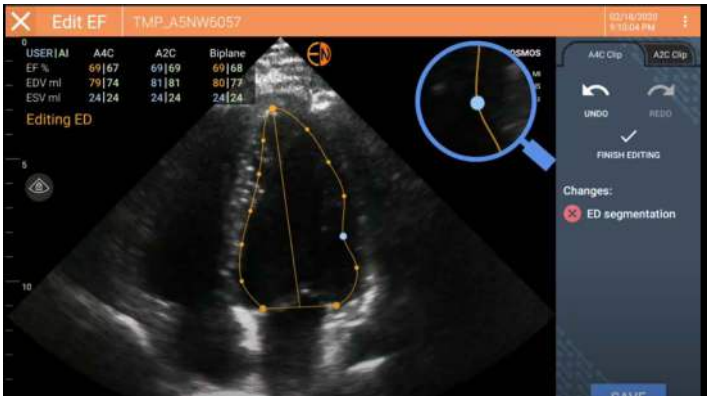
4. To return to the original AI calculations, tap the More options ⋮ icon and then **Reset**.
5. If desired, make changes to the other clip (A4C or A2C), and tap **SAVE**.

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'd like to adjust, tap the **A4C clip** or **A2C clip** tab.
3. Tap the **A4C clip** or **A2C clip** tab to select an ED or ES frame.
4. Tap the LV contour.

The LV contour becomes adjustable, and the color changes to orange.



5. Select one or more control points and move them.

   Notice the calculations are updated as you change the contour.

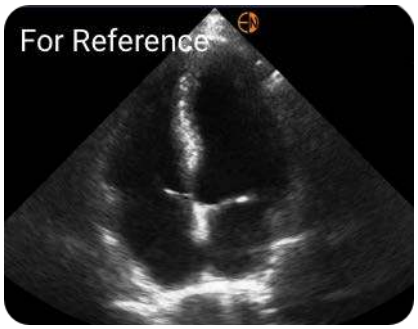
6. After you are done editing, tap **Finish editing**.
7. If desired, make more changes.
8. Tap **SAVE**.

Recommendations for acquiring optimal A4C and A2C clips for accurate EF calculations

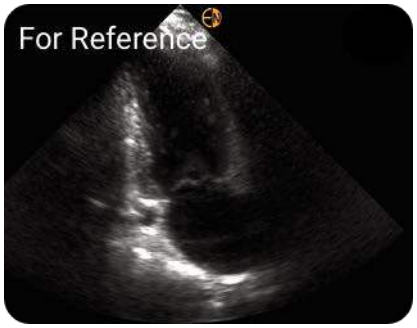
EchoNous recommends the following:

- 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:



A4C



A2C

- 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).
- Adjust the body type appropriately to the patient's body profile to obtain clear A4C and A2C images.
- Ensure the endocardial border of the LV is clearly visible with the best possible contrast. Use the Body type and 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 or 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 contours and, using the KOSMOS editing tool, adjust as needed.

Error conditions and system notifications for KOSMOS 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
  - Difference between A4C and A2C EF is more than 30%

Acquiring images and clips

To acquire an image:

✶ From the Imaging screen, tap the Save image icon.

To acquire a clip:

✶ From the Imaging screen, tap the Save clip icon.

Completing an exam

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

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 you turn off Kosmos Bridge

--End of Section --

CHAPTER 6

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.
- 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.

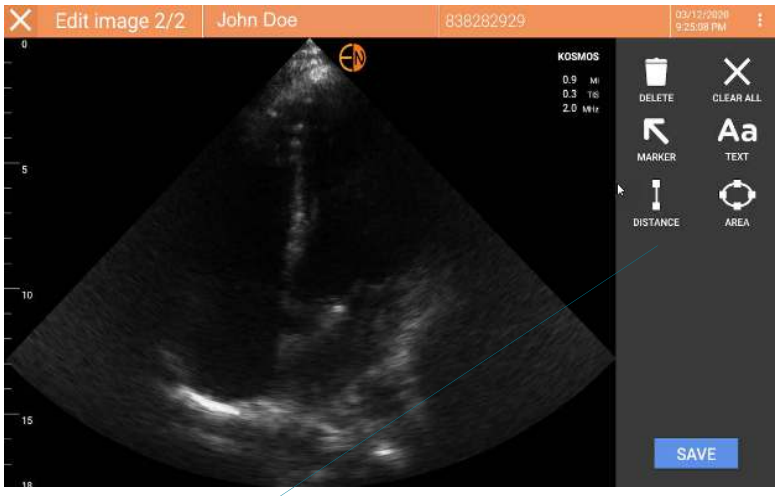
Annotating images and clips

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

To navigate to the Edit Image or Edit Clips screen:



Annotation tools

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, they persist 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.

Auto-labeling tool

When you are scanning the heart (including scanning in the AI-assisted EF workflow), there is an auto labeling tool that helps you identify parts of the

heart. The labels that appear while scanning are only there while you are scanning; after you save the image or clip, the labels will not be there.

The AI-assisted Workflow and auto-labeling tool are not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy**.

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

This feature provides real-time automated annotation/labeling of key cardiac structures in parasternal/apical cardiac views and the apical four-chamber subcostal view. Key cardiac structures include heart chambers, valves great vessels, papillary muscles, septums, and inflow/outflow ventricular tracts.

TABLE 6-1. Anatomical structures for heart Imaging screen

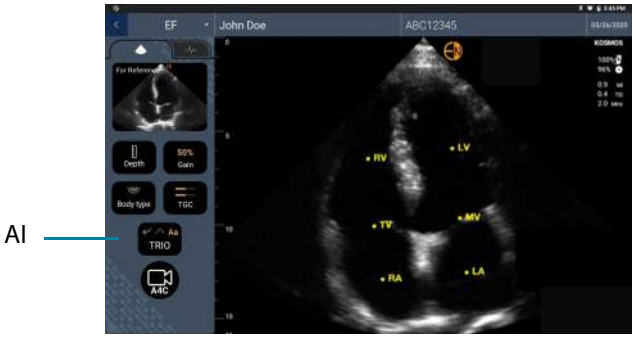
Imaging screen (heart)	Anatomical structure*
A2C	LA, LV, MV
A3C (APLAX)	AO, LA, LV, LVOT, MV
A4C	AO, LA, LV, LVOT, MV, RA, RV, TV
A5C	LA, LV, LVOT, MV, RA, RV, TV, AO
PLAX	AO, AV, IVS, LA, LV, MV, RV
RVOT	MPA, PV, RVOT
RVIT	IVC, RA, RV, TV
PSAX-AV	AV, LA, MPA, PV, RA, RV, TV
PSAX-MV	IVS, LV, MV, RV
PSAX-PM	AL-PAP, IVS, LV, PM-PAP, RV
PSAX-AP	IVS, LV, RV
Subcostal-4C	LA, Liver, LV, RA, RV

* **AL-PAP** = antereolateral papillary muscle
AO = aorta
AV = aortic valve
IVC = inferior vena cava
IVS = interventricular aeptum
LA = left atrium

LV = left ventricle
LVOT = left ventricle 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 ventricle outflow tract
TV = tricuspid valve

To turn on auto-labeling:

1. From the Imaging screen, tap the **AI** button.
2. In the pop-up window, turn on the switch.



Measuring with the caliper tool

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

When a caliper is not selected and you start dragging one of the two end points of the caliper, the caliper will become selected and will resize based on where you are dragging it.

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.

	Notice that the distance of the caliper displays in the legend on the upper left side of the screen. If you have multiple calipers, they display in different colors.

3. To resize the caliper, tap and drag one of its end points.
4. To move the caliper, tap anywhere on the caliper except the two end points.
5. To clear the caliper, tap an empty area outside it.

Zooming in and out

Use two fingers to pinch and expand the image area. To return to "normal", tap the magnifying glass. Also, zoom factor is shown near magnifying glass as well as orange color of depth scale along the side. You are able to freeze the image while zoomed (and can zoom in/out in frozen state).

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**.

PW and CW Doppler Measurements

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

While reviewing the Doppler cine, you can:

1. Perform Doppler measurements
   - VTI - The system automatically traces a peak and calculates VTI, max PG, mean PG, max velocity and mean velocity.

- Edit the VTI trace by moving the control points.
- Choose a different peak by double tapping it.

	Tip: Move either the dotted circle around the selected point or anywhere outside of the dotted circle to move the location of the selected point. As your finger moves on the screen, you will be able to see the point move, editing the trace without your finger hiding the selected point itself.

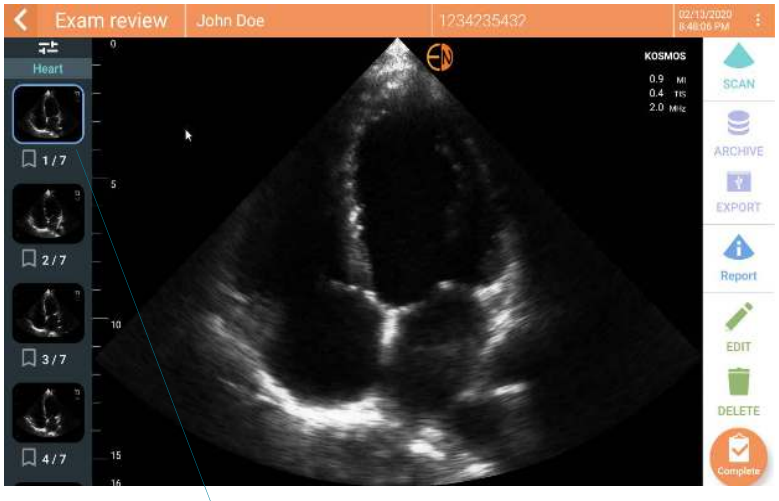
- PHT and Delta Velocity - Move the two end points of the calipers to the appropriate location on the Doppler spectrum
- Velocity and PG - move the cursor to the desired location
- You can perform 2 PHT, 2 Velocity and 1 VTI measurements per image/clip

2. Add Annotations:
   - Text
   - Marker
3. Move the baseline
4. Invert the Doppler spectrum

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.



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 on 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 shown 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 end points of the cine clip.
3. Tap the Clip icon.

To trim and save an image:

1. From the Exam Review screen, find the saved clip.
2. Tap **EDIT**.
3. Move the right and left end points 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 lets you review patient and exam information, text notes, audio notes, pictures that were taken, images, and clips in the exam report.

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 with the exception of the patient information. This is read-only and cannot be changed.

Editing exam information

The exam information section displays the exam related information that was entered before the scan.

To edit the exam information:

1. Tap the Edit icon.

2. Make any necessary updates to the section.

Adding a text note

You can add text notes that will display under each scan.

To add a text note:

1. Tap the Add text note icon. A text box, date and time label appear under the last text note.
2. Using the keyboard, type the note.
3. Tap **DONE**.

Editing a text note

To edit a text note:

1. Tap an existing text note. A text box containing the existing note and the keyboard displays.
2. Using the keyboard, edit the text note.
3. Tap **DONE**.

Deleting a text note

To delete a text note:

1. Long press an existing text note. A delete button displays.
2. Tap **DELETE** and, when prompted, tap **OK**.

Exporting images and clips to a USB drive

When exporting an 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 of the thumbnails you would like to export. (This is an optional step and only useful 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 you want all images and clips exported or only the tagged images and clips.
7. Tap **OK** to start exporting to 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 on the top of the screen. A dialog box appears.
5. Select the file type and whether you want all images and clips exported or only the tagged images and clips.
6. Tap **OK** to start exporting to USB drive.

The following table 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, you cannot edit it.

For more information about setting up a PACS server, see **Managing PACS archives**.

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

The following table 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 **Managing PACS archives**.

To archive an exam from the Exam review screen:

1. From the Exam review screen, tap **ARCHIVE**.
2. From the Archive exam to 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 Trash icon.
3. When prompted, tap **OK**.

To delete an exam while reviewing it:

1. Tap the More options ⋮ icon.
2. Tap **Delete the exam**.
3. When prompted, click **OK**.

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CHAPTER 7

Kosmos Probes

Kosmos Probe sheaths

Where fluid contamination is possible, cover the probe being used (Kosmos Torso, Kosmos Torso-One, or Kosmos Lexsa) with an appropriate sterile sheath from CIVCO, which will promote asepsis and minimize 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.

The KOSMOS battery can only be replaced at an EchoNous facility; however, for shipping/storage, the battery is Li-Ion 3.6V, 6.4 Ah.

Daily storage

KOSMOS is intended to be used and stored in normal ambient conditions inside a medical facility. In addition, the packaging provided with the device may be used for long-term storage.

Storage for transport

KOSMOS is intended to be hand held 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

To check the integrity of the transducer elements, an automatic test is run every 8 hours. 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 Kosmos Bridge boots up with a Kosmos probe connected.

This test can also be initiated by the user in Settings > Admin > About.

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CHAPTER 8

Safety

Electrical safety

References

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*

ANSI AAMI ES 60601-1: 2012 Medical electrical equipment. Part 1: *General requirements for basic safety and essential performance* – IEC 60601-1:2012, Edition 3.1

IEC 60601-1-2:2014 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*

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

ANSI AAMI EC53:2013 *ECG Trunk Cables And Patient Leadwires*

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	EchoNous Description	SDO Title Reference Number Standard
	Indicates device manufacturer. Includes 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
U.S FCC ID: 2AU8B-ECHKMOS Model P005247 	Tested to comply with FCC standards	None

	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. No. D.1-10 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	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, 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)
IPX22	Kosmos Bridge	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)
REF	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
SN	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 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 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

R-NZ	R-NZ Compliance Mark. AS/NZS 4268:2017, Radiocommunications Regulations (Radio Standards) Notice 2016.	None
	Regulatory Compliance Mark. AS/NZS 4268:2017, Radiocommunications (Short Range Devices) Standard 2014, Compilation No.2, December 2018. Radiocommunications (Electromagnetic Radiation - Human Exposure) Standard 2014, Compilation No. 1, November 2019.	None
LOT	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). 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
	Probes are tested to Type BF protection	TYPE BF APPLIED PART Refer to D1.20 IEC 60601-1 Medical Electrical Equipment - Part 1: General requirement for basic safety and essential performance

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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 which 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 nature of the imaging mode being used allows users to apply the ALARA principle with informed judgment. Additionally, the Kosmos probe frequency, Kosmos Bridge setup values, scanning techniques, and experience allow users to meet the definition of 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: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to 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 that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that 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 temperature increase.

Thermal index

TI is an estimate of the temperature increase of soft tissue or bone. There are three TI categories: TIS, TIB, and TIC. However, since KOSMOS is not intended for transcranial applications, the TI for cranial bone at the surface (TIC) is not available for display on the system. The following TI categories are available for display:

- TIS: Soft tissue thermal index. The main TI category. Used for applications that do not image bone.
- TIB: Bone thermal index (bone located in a focal region).

Mechanical index

MI is the estimated likelihood of tissue damage due to cavitation. The absolute maximum limits of 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

Output display accuracy of the bioeffect indices, MI and TI, is dependent on the uncertainty and precision of the measurement system, engineering assumptions within 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 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 Kosmos Torso and Kosmos Torso-One acoustic output tables, **TABLE 8-1.** through **TABLE 8-7.** See Kosmos Lexsa acoustic output tables **Table 8-8.** through **Table 8-12.**

Kosmos Torso and Kosmos Torso-one Acoustic output tables

See next page

TABLE 8-1. Transducer: Kosmos Torso and 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" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-2. Transducer: Kosmos Torso and 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 controls						

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in 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 8-3. Transducer: Kosmos Torso and 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 controls						

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in 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 8-4. Transducer: Kosmos Torso and Kosmos Torso-One, Operating Mode: BC-Mode (Max MI, 12cm 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	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: 1.90					
	$z_{pii,\alpha}$ (cm)	2: 2.00					
	f_{awf} (MHz)	2: 2.65	1: 2.71 2: 2.65		1: 2.71 2: 2.65		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" both in 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 8-5. Transducer: Kosmos Torso and Kosmos Torso-One, Operating Mode: BC-Mode (Max TIS/TIB, ISPTA, 12cm 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	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" both in 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 8-6. Transducer: Kosmos Torso and 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	4 mm				
	Focal Depth	20mm				

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-7. Transducer: Kosmos Torso and 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		2.43	
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	4 cm				
	CW Mode					

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-8.Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: BC-Mode (Max MI, Vascular, 4cm depth, large ROI)

Index label		MI	TIS		TIS		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	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" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-9. Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: BC-Mode (Max ISPTA, Vascular, 4cm depth, small ROI, image top)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Acoustic Parameters	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	1: 3.23E-03 2: 6.18E-02	1: 3.23E-03 2: 6.18E-02	
	$p_{r,\alpha}$ 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" both in 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 8-10.Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: BC-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	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: N/A			
	z_b (cm)					1: N/A 2: N/A	
	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" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-11. Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: B-Mode (Max MI, ISPTA, MSK, 3cm depth)

Index label		MI	TIS		TIC		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	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" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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 8-12.Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: B-Mode (Max TIS, TIB, MSK, 10cm 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	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" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an 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 or 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.

Measurement accuracy

Measurement accuracy for distance and area in B-mode images are as follows:

- Axial measurement accuracy: Axial distance measurements in 2D imaging modes shall be accurate to within +/- 2% of the displayed value (or 1 mm, whichever is larger).
- Lateral distance measurement accuracy: Lateral distance measurements in 2D imaging modes shall be accurate to within +/- 2% of the displayed value (or 1 mm, whichever is larger).
- Diagonal measurement accuracy: Diagonal distance measurements in 2D imaging modes shall be accurate to within +/- 2% of the displayed value (or 1 mm, whichever is larger).
- Area measurement accuracy: Area measurement accuracy in 2D imaging modes shall be +/-4% of the nominal value.

Measurement accuracy for distance and time in M-mode images are as follows:

- M-mode distance measurement: M-mode distance measurements shall be accurate to within +/- 3% of the displayed value.
- M-mode time measurement accuracy: M-mode time measurements shall be accurate to within +/- 2% of the displayed value.

EF measurements accuracy:

The AI-assisted EF Workflow is not yet cleared by the FDA. Instead, EchoNous is following the requirements in **Enforcement Policy.**

- The accuracy of the KOSMOS EF calculations depends on the correct selection of ED/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 AI algorithms, confirm their accuracy, and edit them, as required.
  - Ensure that the selected ED/ES frames accurately represent the corresponding end-diastolic and 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 A4C/A2C EF, which is more accurate than the single plane A4C EF.
- 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 EFs of the subjects scanned ranged from 20% to 80%. The results below include both A4C/A2C biplane and A4C 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 8-13. EF Comparison Metrics

EF Metrics	EF Percentage Units
RMSD[1]	7.12 (p-value<0.0001)
Bias	-2.94
95% limits of agreement[2]	-15.74 / 9.85
Range	-20.32 / 13.11

[1] Root-mean-square deviation (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.

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 8-14. 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 8-14. Surface temperature rise

Test	Temperature rise (^{o}C)
Still air	16.02
Simulated use	9.85

ECG supplemental information

- Recommended ECG electrodes: Use a fluid-resistant, foam-backed electrode, such as 3M™ Red Dot™ Clear Plastic Monitoring Electrode 2235.
- KOSMOS uses single ECG filter from 0.65 Hz - 47.5 Hz.

- KOSMOS, with a fully charged battery, provides about 90 minutes of continuous operation.
- The KOSMOS HR calculation is accurate to within Â±10% or Â±5/min, whichever is greater for regular HRs in the specified range per 60601-2-27 HR Accuracy Requirement.
- KOSMOS HR range (adult): 30/min to 200/min.
- KOSMOS HR range (pediatric): 30/min to 250/min.
- Noise suppression: Right leg drive max. voltage 2.12Vrms.
- Method of HR averaging: Data is analyzed for R-wave peaks in approx 2.5 seconds sampling periods. If required, two sampling periods are combined to capture a minimum of three R-wave peaks. The HR is updated after every sampling period.
- KOSMOS provides the following sweep speeds: 20 mm/sec, 25 mm/sec, 35 mm/sec, and 50 mm/sec.
- When calculating HR, KOSMOS is capable of rejecting tall T-waves (as false QRS peaks) up to amplitudes that are up to 75% of QRS amplitude.

Ergonomics

⚠	Repetitive ultrasound scanning may cause occasional discomfort in your thumbs, fingers, hands, arms, shoulders, eyes, neck, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, soreness, pain, throbbing, aching, tingling, numbness, stiffness, burning sensation, muscle fatigue/weakness, or limited range of motion, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with Work Related Musculoskeletal Disorders (WRMSDs). WRMSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of WRMSDs include bursitis, tendonitis, tenosynovitis, carpal tunnel syndrome, and De Quervain syndrome. While researchers are not able to definitively answer many questions about WRMSDs, there is a general agreement that certain factors are associated with their occurrence, including preexisting medical and physical conditions, overall health, equipment, and body position while performing work, frequency of work, and duration of work.

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, Kosmos Torso-One or Kosmos Lexsa lightly, keep your wrist straight, and minimize the pressure applied to the patient.

- Take regular breaks.

Electromagnetic compatibility

	The System complies with the Electromagnetic Compatibility requirements of AS/NZ CISPR 11:2015 and EN IEC 60601-1-2:2014. However, electronic and mobile communications equipment may transmit electromagnetic energy through air 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 re-orienting 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 the use of high-frequency electromedical devices in proximity to its systems.EchoNous equipment has not been validated for use with high-frequency electrosurgical devices or procedures. Use of high-frequency electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system. To avoid the risk of a burn hazard, do not use Kosmos probes with high-frequency surgical equipment. Such a hazard may occur in the event of 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. The user of the **System** should assure that it is used in such an environment.

Electromagnetic emissions

TABLE 8-15. 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 not likely to cause any interference in 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 and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The **System** has Class A compliance in 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 8-16. Guidance and manufacturer's declaration: electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment: guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±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 for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

TABLE 8-16. Guidance and manufacturer's declaration: electromagnetic immunity

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T[1] (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T[1] (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TABLE 8-16. Guidance and manufacturer's declaration: electromagnetic immunity

[2,3]Conducted RF IEC 61000-4-6	3 Vrms 150kHZ 80MHz	3 Vrms[6]	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 $d = 1.2\sqrt{P}$

TABLE 8-16. Guidance and manufacturer's declaration: electromagnetic immunity

Radiated RF IEC 61000-4-3	3 V/m 80MHz 2.5 GHz	3 V/m	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 separations distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be less than the compliance level in each frequency range[5]. Interference may occur in the vicinity of equipment marked with the following symbol. 

1 UT is the AC mains voltage prior to application of the test level
2 At 80MHz 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 transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system.
5 Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.
6 Conducted RF energy may cause noise in the ECG waveform. If noise is detected on the ECG waveform, disconnect the system from AC power.

⚠	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.
⚠	Conducted RF energy may cause noise in the ECG waveform. If noise is detected on the ECG waveform, disconnect KOSMOS from AC power.

Separation distances

TABLE 8-17. Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the EchoNous System

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Certificate and compliance

For details on certificate-specified and compliant mark (including number of certificate and authorization), perform the following steps:

✶ From the Home screen, tap **Settings** > **About** > **Regulatory**.

Intentional radiator

FCC Intentional Radiator Certification contains:

- FCC ID: 2AU8B-ECHKMOS
- IC ID: 25670-ECHKMOS

KOSMOS contains an intentional radiator approved by the FCC under the FCC ID numbers, as shown above. KOSMOS complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) KOSMOS may not cause harmful interference and (2) KOSMOS must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to KOSMOS shall not be made without the written consent of EchoNous, Inc. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

Operations in the 5.15-5.25GHz band are restricted to indoor usage only.

Class B device

KOSMOS has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

KOSMOS has been verified to comply with the limits for a class B computing device, pursuant to FCC rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Industry Canadian statement

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Operation in the band 5150-5250 MHz bands are restricted to indoor use to reduce potential for harmful interference to co-channel mobile satellite systems.

CAN ICES-3 (B)/NMB-3(B)

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 www.echonous.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

CHAPTER 9

KOSMOS Maintenance

Cleaning and disinfecting

General cautions

- Some reprocessing chemicals may cause an allergic reaction in some individuals.
- Ensure that cleaning and disinfecting solutions and wipes are not expired.
- Do not allow cleaning solution or disinfectant into the Kosmos Bridge or Kosmos probe connectors.
- Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as protective eye wear 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 Kosmos Bridge surfaces or on Kosmos Bridge and Kosmos probe connectors. Doing so may cause solution to leak into KOSMOS, damaging it and voiding the warranty.
- Do not attempt to clean or disinfect Kosmos Bridge, Kosmos probe or the Kosmos probe cable using a method that is not included here or 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.

Kosmos Bridge

Kosmos Bridge is not sterile when shipped; do not attempt to sterilize it.

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

Cleaning

Avoid spraying the cleaning and disinfection solutions directly onto Kosmos Bridge. 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 Kosmos Bridge.

1. After each use, disconnect the USB cable from the Kosmos probe.
2. Remove any accessories, such as the headset or power supply.
3. Using a wipe from an approved presaturated disinfectant wipe, carefully wipe the screen and all other areas of Kosmos Bridge. Choose an EchoNous-approved wipe from the list in **Presaturated wipes**.
4. If necessary, clean Kosmos Bridge with additional wipes to remove all visible contaminants.

After disinfection, examine the display for cracks, and if damage exists, discontinue use of the system and contact EchoNous Customer Support.

TABLE 9-1. Presaturated wipes

Product	Company	Active Ingredients	Contact Condition
Sani-Cloth Plus	PDI Inc.	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides. 0.125% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides. 0.125%	5 minutes wet contact time for disinfection
CaviWipes (KavoWipes)	Metrex	Diisobutylphenoxyethoxyethyld imethylbenzyl ammonium chloride (0.28%), Isopropanol (17.2%)	5 minutes wet contact time for disinfection

Kosmos Probes

Cleaning

The following cleaning instructions must be followed for Kosmos Torso, Kosmos Torso-One and Kosmos Lexsa. Kosmos probes must be cleaned after each use. Cleaning Kosmos probes is an essential step before effective disinfection.

Before cleaning Kosmos Torso, Kosmos Torso-One and Kosmos Lexsa, read the following warnings and cautions.

- Always disconnect the USB cable from the Kosmos probe before cleaning and disinfecting.
- After cleaning, you must disinfect Kosmos probes by following the appropriate instructions.
- Always wear protective eye wear and gloves when cleaning and 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.

To clean Probes:

1. After each use, disconnect the USB cable from the Kosmos probe.
2. Remove any accessories attached to, or covering the Kosmos probe, such as a sheath.
3. At point of use, wipe Kosmos probe with an approved presaturated wipe.
4. Prior to disinfecting the Kosmos probe, remove all ultrasound gel from the Kosmos probe face by using an approved presaturated disinfectant wipe. Choose an EchoNous-approved wipe from the list in **Presaturated wipes**.
5. Using a new wipe, remove any particulate matter, gel, or fluids that remain on the Kosmos probe using a new presaturated wipe from **Presaturated wipes**.
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 Kosmos probes. Before performing the following steps, read the following warnings and cautions.

Always disconnect the USB cable from 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.

To disinfect Kosmos Probes (intermediate level):

1. After cleaning, choose an intermediate-level disinfectant from the list in **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 to avoid cross-contamination.
3. Observe the required wet contact time. Monitor the Kosmos probe for wet appearance. Use at least three wipes to ensure effective disinfection.
4. Before reusing the Kosmos probe, ensure the Kosmos probe is visibly dry.

Check the Kosmos probe for damage, such as 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 it has come into contact with blood, broken skin, or bodily fluids (semi-critical use). High-level disinfection of Kosmos probes typically uses an immersion method with high-level disinfectants or chemical sterilant.

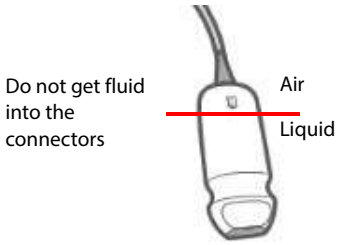
Before performing the following steps, read the following warnings and cautions.

- Always disconnect Kosmos probes from AC mains during cleaning and disinfection.
- Before disinfection, clean the Kosmos probe by following the appropriate cleaning instructions in **Cleaning** to remove all gels, fluids, and particulates that may interfere with the disinfection process.
- Always use protective eye wear and gloves when disinfecting any equipment.
- When disinfecting Kosmos probes, do not allow any fluid to enter electrical connections or metal portions of the USB or Kosmos ECG patient cable connector.
- Do not attempt to disinfect Kosmos probes using a method that is not included 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 incorrect solution strength can damage the Kosmos probe and void the warranty.
- If the Kosmos probe has come into contact with any of the following, use the high-level cleaning and disinfection procedure: Blood, broken skin, mucosal membranes, bodily fluids

To disinfect Kosmos probes (high level):

1. After cleaning, choose a high-level disinfectant that is compatible with Kosmos probes. For a list of compatible disinfectants, see **Disinfectant solutions for 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 Kosmos probe into 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 **Disinfectant solutions for Kosmos probe immersion** for duration of immersion and contact temperature.
6. Do not immerse Kosmos probe longer than the minimum time needed for semi-critical level of disinfection.
7. Rinse 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 visibly dry.
10. Wipe the strain relief and first 18 inches (45 cm) of the Kosmos probe cable with an approved wipe from the list in **Presaturated wipes**.

11. Examine the Kosmos probe for damage such as cracks, splitting, or sharp edges. If damage is evident, discontinue using the Kosmos probe, and contact your EchoNous representative.

TABLE 9-2. Disinfectant solutions for Kosmos probe immersion

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

- Check the expiration date on the bottle to ensure the disinfectant has not expired. Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- Check that the temperature of the disinfectant is within the manufacturer's recommended limits.

Kosmos ECG patient cable

Cleaning

The following cleaning instructions must be followed for the Kosmos ECG patient cable. The cable must be cleaned after each use. Cleaning the cable is an essential step before effective disinfection.

Before cleaning the Kosmos ECG patient cable, read the following warnings and cautions.

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

⚠ After cleaning, you must disinfect the cable by following the appropriate instructions.

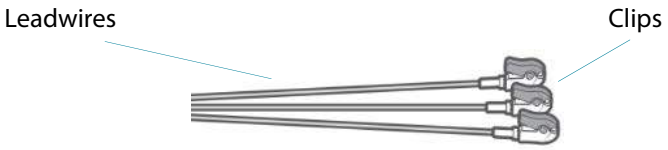
Always wear protective eye wear and gloves when cleaning and disinfecting any equipment.

Ensure cable insulation is intact before and after cleaning.

Use only EchoNous-recommended wipes and solution. Using a non-recommended wipe can damage the cable.

To clean the Kosmos ECG patient cable:

1. After each use, disconnect the cable from Kosmos Torso.
2. Remove any accessories attached to, or covering, the cable, such as electrode pads.
3. At point of use, wipe the cables with an approved presaturated wipe from the list in **Presaturated wipes** to ensure effective cleaning.
4. Immerse the ECG clips and leadwires in a cleaning solution from the list in **Cleaning detergent solution for Kosmos ECG patient cable**, and soak for at least 10 minutes. Refer to **Cleaning detergent solution for Kosmos ECG patient cable** for the solution concentration and contact time.



5. Place the cable with the solution in a ultrasonicator for at least 10 minutes.
6. Post sonicating, using a standard cleaning brush, vigorously brush all surfaces of the ECG clips while immersed in the Enzol solution until visibly clean.
7. Actuate any movable parts while immersed. In addition, flush crevices using a slip tip syringe filled with prepared cleaning detergent.
8. Remove the ECG clips from the Enzol solution, and run them under running water for 1 minute. Ensure no gel or any particulate matter is visible after this cleaning step.

9. Before continuing with disinfection, ensure the Kosmos ECG patient cable is visibly dry.

TABLE 9-3. Cleaning detergent solution for Kosmos ECG patient cable

Product	Company	Active Ingredients	Contact Condition
Enzol	Advanced Sterilization Products	Borax decahydrate >=5 - <10 Subtilisin >=1 - <5	2 oz. per gallon solution 20 minutes immersion

Disinfecting the Kosmos ECG patient cable

Use the following steps to disinfect the Kosmos ECG patient cable. Before performing the following steps, read the following warnings and cautions.

- Always disconnect the USB cable from the Kosmos probe before cleaning and disinfecting.
- Always use protective eye wear and gloves when disinfecting any equipment.
- Before disinfecting, clean the Kosmos ECG patient cable by following the appropriate instructions to remove all gels, fluids, and particulates that may interfere with the disinfection process.
- Ensure cable insulation is intact before and after disinfection.
- Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting wipe can damage the Kosmos ECG patient cable.

To disinfect the Kosmos ECG patient cable:

1. After cleaning, choose an low-level disinfectant from the list in **Presaturated wipes**, and follow the instructions on the disinfectant label for the minimum wet contact time.

2. With a new wipe, disinfect the Kosmos ECG patient cable, starting from the connector end to the clips.
3. Observe the required wet contact time. Monitor the Kosmos ECG patient cable for wet appearance.
4. Use at least three wipes to ensure effective disinfection.
5. Examine the cable for damage, such as insulation wearing or discoloration. If damage is evident, discontinue using the Kosmos ECG patient cable.
6. Before reusing the cable, ensure the cable is visibly dry.

Kosmos binaural headset

The following cleaning and disinfection method must be followed for Binaural Headset:

1. Disconnect the headset from Kosmos Bridge.
2. Using a wipe from an approved presaturated disinfectant wipe, carefully wipe all the areas of the headset. Choose an EchoNous-approved wipe from **Presaturated wipes**.
3. If necessary, clean the headset with additional wipes to remove all visible contaminants.

Recycling and disposal

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

⚠ The lithium ion battery inside Kosmos Bridge 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.

Kosmos Bridge contains lithium-polymer batteries, and the system should be disposed of in an environmentally responsible manner in compliance with federal and local regulations. EchoNous recommends taking Kosmos Bridge, and

Kosmos probes to a recycling center which specializes in the recycling and disposal of electronic equipment.

In cases where Kosmos Bridge and/or a Kosmos probe has been exposed to biologically hazardous material, EchoNous recommends using biohazard containers and in compliance with federal and local regulations. Kosmos Bridge and Kosmos probes should be taken to a waste center which specializes in the disposal of biohazard 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 battery is not replaceable.

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

Kosmos Bridge handle controls

- If you do not see the handle control checkbox on the Home screen, contact **EchoNous customer support** to get a newer version of the software/ firmware.
- If you do see the handle control checkbox on the Home screen but are not able to activate the handle controls, it is probably a firmware issue. Contact **EchoNous customer support** to get new hardware.
- If you have the updated software and firmware, but still have intermittent issues where the handle controls do not work (or one or more buttons stop responding), try one or more of the following:
  - Check to see if the **Accept** checkbox is selected on the Home screen.
  - Disable the handle controls, and enable them again
  - Restart Kosmos Bridge, and enable the handle controls.

- Try using the handle controls without gloves.
- Try using the handle controls with moisturized hands.
- Lightly tap the handle continuously for five to six seconds.
- Make sure you are tapping the handle control buttons and not doing a long press.

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CHAPTER 10

Specifications

System specifications

Feature	Height (mm)	Width (mm)	Depth (mm)	Weight (grams)	Cable (meters)
Kosmos Torso	150*	56	35	290 (with cable)	1.8
Kosmos Torso-One	150*	56	35	275 (with cable)	1.8
Kosmos Lexsa	155	56	35	280 (with cable)	1.5
Kosmos Bridge	146	216	59	652	N/A
Kosmos binaural headset	800	120	25	100	N/A
Kosmos ECG patient cable	N/A	N/A	N/A	35	0.86
Kosmos Power Supply	117.5	53.5	34.2	260	1.5

*excluding cable (the hard plastic housing length)

Environmental operating and storage conditions

Kosmos Bridge and probes are intended to be used and stored in normal ambient conditions inside a medical facility.

Operating, charging, transport, and storage condition ranges

	Operating	Transport/Storage
Temperature (°C)	0C to +40C	-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

Mode of operation

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

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

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

Kosmos Bridge enforces scanning limits to maintain safe user contact temperatures.

Power supply (charger)

Rated input: 100-240V~, 50-60Hz, 1.5A

Watts: 60

Volts out: 5V, 5.8V, 8.9V, 11.9V, 15V, 20V

Current out (Amps): 4.6A, 4.6A, 4.4A, 4A, 3.6A, 3A

Internal batteries

Kosmos Bridge

Li-Ion main battery: 3.6V, 6.4 Ah

Li-Ion coin cell battery: 3V, 5.8mAh

Battery charging time: The time to charge the battery from 0% to 90% of capacity is ~3 hours

Battery life: A fully charged battery will provide ~90 minutes of uninterrupted scanning

The performance may vary based on scanning modes used.

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CHAPTER 11

IT Network

Wireless networking

Functions

You can connect KOSMOS to an IT network to perform the following:

- Storing exam data (static images and clips) acquired by KOSMOS in Picture Archiving and Communication System (PACS) by DICOM communication.
- Setting KOSMOS time correctly by inquiring the network time service.

Connection specifications

Hardware specification

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

Software Specification

KOSMOS is connected to PACS by the DICOM standard. For details, refer to the DICOM Conformance Statement that is on the USB flash drive.

FIPS 140-2 Compliance

Kosmos is certified FIPS 140-2 compliant. In accordance with FIPS 140-2, Kosmos Bridge will only connect with WIFI networks that have passwords at least 14 characters long and will not support a VPN connection.

For further details on FIPS 140-2 compliance, please reference FIPS 140-2 Compliance section in Chapter 3 of this user guide or contact your EchoNous representative.

Network for connecting the device

⚠	It is important to configure the device on a secure network, behind a firewall with secure WIFI protocol (e.g. WPA2) to ensure security of the device and patient data transferred over the network.

Specifications for the connection

Hardware specification

802.11 a/b/g/n, Bluetooth 4.0 or later

Software specifications

KOSMOS is connected to PACS by DICOM standard. Refer to the DICOM Conformance Statement of this device for details.

When available, this device connects to the network time server at startup.

Security

This device has no listening ports open to the WLAN interface. A network entity cannot initiate a connection to KOSMOS from the WLAN. However, KOSMOS can initiate a connection to servers on the WLAN and beyond.

The KOSMOS USB port can only be used to export data to a USB memory stick. Computer access to the device through the USB port is blocked.

The following TCP/IP ports are used for outgoing communication to the WLAN:

- Port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112)

- Port 443 for encrypted traffic to HTTPS time/web servers
- Port 80 for HTTP web servers

Anti-virus software is not installed on this device.

IT network failure recovery measures

Connection to an IT network may become, at times, unreliable, and this may lead to failure to perform the functions described in **Functions**. As a result, the following hazardous situations may occur:

Network failure	Impact on equipment	Hazard	Countermeasures
IT network becomes unstable	Unable to transmit exam data to PACS Delay of transmission to a PACS	Delay of diagnosis	KOSMOS has internal memory, and exam data is stored in it. After the IT network has returned to stable, the user can reinitiate the transfer of data.
	Incorrect data transmitted to a 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 time manually.
	Incorrect time data		KOSMOS always indicates the date and the time on the main screen.

Firewall has broken down	Attack via network	Manipulation of exam data	KOSMOS closes unnecessary network ports.
	Infection by computer virus	Leak of exam data	KOSMOS prevents a user from loading software and executing it.

- Connection of equipment to an IT network that includes other systems could result in previously unidentified risks to patients, operators, or third parties. Before connecting the equipment to an uncontrolled IT Network, make sure that all potential risks resulting from such connections were identified and evaluated, and suitable countermeasures were 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, check that the change does not affect it, and take measures, if necessary. Changes to the IT network include:
  - Changing the network configuration (IP address, router, and so on)
  - Connecting additional items
  - Disconnecting items
  - Updating equipment
  - Upgrading equipment
- Any changes to the IT network could introduce new risks requiring additional evaluation to be performed.

CHAPTER 12

Glossary

Term	Description
A2C	Apical 2 chamber.
A4C	Apical 4 chamber.
ACEP	American College of Emergency Physicians
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.
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 create more room for new studies.
Arrow	An arrow is an arrow icon that a clinician may put on a certain location of an image/clip to highlight something. This displays as an overlay on the image/clip.
Auscultation	Auscultation is listening to the internal sounds of the body, usually using a stethoscope, for the purpose of examining the circulatory and respiratory systems (heart and breath sounds) as well as the gastrointestinal system (bowel sounds).
BMI	Body mass index.
B-mode	The Kosmos probe array scans a plane through the body and produces a 2D image on the screen. This is also called B-mode imaging.
Calculation	Calculations are estimations made from specific sets of measurements.
Caliper	You perform most measurements by using calipers that you drag into position. The active caliper has a round highlighted handle.

Term	Description
CapSense	The Cypress CapSense technology detects the presence of a finger on or near a touch surface. The Kosmos Bridge **handle** contains two CapSense buttons and one slider that you can feel and activate without looking.
Cine	A cine is 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 sequences of multiple frames like a movie.
CO	Cardiac output, calculated as: CO = SV x HR.
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.
CW	Continuous-Wave Doppler
DA	Digital auscultation.
DICOM	Digital Imaging and Communications in Medicine. DICOM is 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.

Term	Description
ECG	Electrocardiogram. Electrocardiography is the process of recording the electrical activity of the heart over a period of time using electrodes placed over the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electro physiologic pattern of depolarizing and re-polarizing during each heartbeat.
ED	End-diastolic.
EDV	End-diastolic volume.
EF	Ejection fraction, calculated as (a percentage): EF = (EDV-ESV)/EDV * 100
ES	End-systolic.
ESV	End-systolic volume.
Exam	An exam contains all the objects, images, clips, and reports that are saved during a clinical examination of a patient with KOSMOS, which usually maps to a patient's visit.
FOV	Field of view is the two-dimension space of B-mode image acquisition.
Frozen state	The state KOSMOS gets into when you tap the **Freeze** button in live imaging. During the frozen state, you can add annotations to one frame of the cine and save the still image. The measurements only stay on one frame of the cine, but the annotations will persist in the whole cine. When you save a clip from the cine, annotations are saved as overlays on the clip, but the measurement won't be saved in the clip. That is because usually measurements are relevant to only one frame of a cine instead of the whole series of frames.
HR	Heart rate.
Image	An image is a single frame of an ultrasound view captured by KOSMOS.
LV	Left ventricle.

Term	Description
M-line	A line that appears in B-mode for which M-mode provides the trace.
Measurement	A measurement is a distance or area measurement on images with no inference to underlying anatomy. A measurement overlay shows the tool (such as a caliper or ellipse) and the measured values.
MWL	Modality Worklist
PACS	Picture Archiving and Communication Systems. PACS refer to 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 of connecting to digital image archives.
Physical coordinates	The position in the field of view expressed in terms of physical dimensions either in millimeters or radians with respect to a designated point of reference.
Picture	You can use the KOSMOS camera to take pictures of a wound or injury as part of the exam.
PIMS	Patient Information Management Systems.
Ping test	A ping test is used to test a TCP/IP connection. If the test is successful, the connection between the KOSMOS and PACS archive is working.
PW	Pulsed-Wave Doppler
Report	A report consists of details of an exam, along with the notes entered by the clinician.
Review	This is the state of KOSMOS where you can review and edit patient data if it has not been archived.
ROI	Region of Interest. The ROI refers to the bounded region in the field of view where color flow information is depicted.

Term	Description
Scan	A scan is a system preset where system parameters are optimized for scanning a certain organ, such as heart or lungs. Scans can include multiple images, clips, and reports that you can save. The scan preset drives calculations, measurements, and reports.
Snackbar	The snackbar is a brief message that displays on the bottom of many KOSMOS screens. You don't have to act on the messages, and they automatically go away after a short period of time.
Study	A study is a collection of one or more series of medical images and presentation states that are logically related for diagnosing a patient. Each study is associated with one patient. A study may include composite Instances that are created by a single modality, multiple modalities, or by 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 that are saved during a clinical examination of a patient with KOSMOS, which usually maps to a patient's visit.
SV	Stroke volume, calculated as: SV=EDV-ESV
Verify	This is 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.

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APPENDIX A

Enforcement Policy

Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020

Indications

Intended users

The Trio tool is intended to be used by qualified healthcare professionals or under the supervision or in-person guidance of a trained or licensed healthcare professional. The Trio tool and its intended users (released under the *Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020*) have not been cleared by the FDA.

Intended use/indications for use

The Trio is a real-time automatic image labeling, grading and guidance system to enable the collection of images by healthcare practitioners, including those who are not trained in sonography, to address urgent image analysis needs during the declared COVID-19 public health emergency.

The Trio is intended to be used by qualified healthcare professionals or under the supervision or in-person guidance of a trained or licensed healthcare professional. The Trio and its intended use/indications for use (released under the *Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019*

(COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, April 2020) have not been cleared by the FDA.

Product's performance

The standards applied for the development of the device are listed below in Table 13-1.

TABLE 13-1. Standards Applied During the Development of the Device

Standards Developing Organization	Standard Designation Number and Date	Title of Standard
CISPR/CIS/B	CISPR 11:2015+ AMD1:2016+AMD2:2019 CSV Consolidated version	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
ANSI AAMI IEC	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/ (R)2012	ANSI AAMI ES60601-1:2005/ (R)2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
ANSI AAMI IEC	60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC	60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

TABLE 13-1. Standards Applied During the Development of the Device

IEC	IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO	10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO	14971	Medical devices - Application of risk management to medical devices
IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
IEC	62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
ISO	15223-1 Third Edition 2016-11-01	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
IEC	IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION	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

TABLE 13-1. Standards Applied During the Development of the Device

AIM	Standard 7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
ANSI AAMI	EC53:2013	ECG trunk cables and patient leadwires
AAMI	TIR57:2016	Principles for medical device security - Risk management.
TIR	30:2011	A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices

Potential risks and mitigations

Risk/mitigation 1

Hazard: Loss or deterioration of function

Initial cause in sequence of events: Software error

Sequence of events: User is scanning cardiac anatomy with auto-annotation active > one or more cardiac anatomic structures are incorrectly annotated.

Hazardous situation: Misinterpretation of cardiac anatomy or image orientation

Harm: User frustration

Mitigation:

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

Design requirement: The automated annotations feature shall correctly identify cardiac structures with at least 80% accuracy when a result is displayed.

Risk/mitigation 2

Hazard: Loss or deterioration of function

Initial cause in sequence of events: Software error

Sequence of events: User is scanning cardiac anatomy with auto-annotation active > automatic annotations cover anatomy important in diagnostic assessment.

Hazardous situation: Important diagnostic information in image is overlaid

Harm: User frustration

Mitigation:

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

Design requirement: The automated annotations feature shall correctly identify cardiac structures with at least 80% accuracy when a result is displayed.

Usability study: A summative usability study shall be conducted per IEC 62366. The system is free of use errors that may cause harm to patient/user.

Risk/mitigation 3

Hazard: Incorrect or inappropriate output or functionality

Initial cause in sequence of events: Software error

Sequence of events: User is in EF workflow > image grading algorithm incorrectly indicated image is low quality (1 or 2), but image quality is high quality (4 or 5)

Hazardous situation: User frustration

Harm: User frustration

Mitigation:

Clinical study: The accuracy of the grading feature based on the American College of Emergency Physicians 5-point Quality Assurance Grading Scale is verified and validated in the Grading and Guidance Algorithm, Clinical Evaluation Report.

Risk/mitigation 4

Hazard: Incorrect or inappropriate output or functionality

Initial cause in sequence of events: Use error

Sequence of events: User is in the EF workflow > image grading algorithm, incorrectly indicates image is high quality (4 or 5), but image quality is low quality (1 or 2) > acquires suboptimal image plane for A4C and/or A2C images > user trusts algorithm over expert judgment > error in image plane selection leads to an error in (EF/SV/CO) that is clinically significant

Hazardous situation: Inaccurate assessment of systolic function

Harm: Misdiagnosis

Mitigation:

Design requirement:

- After an A4C or A2C clip has been recorded, the system shall allow the user to accept or reject that clip for the calculation of the EF. If a clip is rejected, the user can re-record that clip.
- The system shall display reference A4C/A2C images for comparison in EF imaging screen.
- The system shall verify if the calculated quantities are within reasonable boundaries:
  - The system shall warn the user if the EF is out of 0%-100% range.

- The system shall disallow the user to save edits which result in EF value that is out of 0%-100% range on the Edit EF screen.
- The system shall notify the user when: 1) A4C and A2C EF difference is more that 30%; 2) ESV > 400ml; 3) EDV > 500ml.

Clinical study:

- A clinical study shall be performed demonstrating the safety and efficacy of the EF workflow feature by meeting end points.
- A summative usability study shall be conducted per IEC 62366. The system is free of use errors that may cause harm to patient/user.
- The accuracy of the grading feature based on the American College of Emergency Physicians 5-point Quality Assurance Grading Scale is verified and validated in the Grading and guidance Algorithm Clinical Evaluation Report.

Risk/mitigation 5

Hazard: Incorrect or inappropriate output or functionality

Initial cause in sequence of events: Use error

Sequence of events: User misunderstands the meaning of image grading feedback > proceeds to calculate EF with bad image (even though system has indicated it is bad) > user trusts algorithm over expert judgment > error in image plane selection leads to an error in (EV/SV/CO) that is clinically significant.

Hazardous situation: Inaccurate assessment of systolic function

Harm: Misdiagnosis

Mitigation:

Design Requirement:

- After an A4C or A2C clip has been recorded, the system shall allow the user to accept or reject that clip for the calculation of the EF. If a clip is rejected, the user can re-record that clip.
- The system shall display reference A4C/A2C images for comparison in EF imaging screen.

Risk/mitigation 6

Hazard: Incorrect or inappropriate output or functionality

Initial cause in sequence of events: Software error

Sequence of events: User is in EF workflow > image guidance instructions are incorrect > user is unable to acquire an adequate A4C/A2C view(s) based on system feedback

Hazardous situation: User frustration

Harm: User frustration

Mitigation:

Clinical study:

- A summative usability study shall be conducted per IEC 62366. The system is free of use errors that may cause harm to patient/user.
- The accuracy of the grading feature based on the American College of Emergency Physicians 5-point Quality Assurance Grading Scale is verified and validated in the Grading and Guidance Algorithm Clinical Evaluation report.

Risk/mitigation 7

Hazard: Incorrect or inappropriate output or functionality

Initial cause in sequence of events: Use Error

Sequence of events: User misunderstands the meaning of image guidance feedback > unable to acquire ad adequate view based on system feedback.

Hazardous situation: User frustration

Harm: User frustration

Mitigation:

Clinical study:

- A summative usability study shall be conducted per IEC 62366. The system is free of use errors that may cause harm to patient/user.
- The accuracy of the grading feature based on the American College of Emergency Physicians 5-point Quality Assurance Grading Scale is verified and validated in the Grading and Guidance Algorithm Clinical Evaluation Report.

General warnings and cautions

	KOSMOS is not indicated for the diagnosis of COVID-19. In vitro diagnostic testing is currently the only definitive method to diagnose COVID-19.
	All Trio recommendations provided by KOSMOS are adjunctive (supporting) and should not be solely or primarily relied upon to diagnose or treat COVID-19.
	All images should be interpreted only by a licensed healthcare practitioner with the appropriate training.
	The results from the image analysis software should not be used for screening, specific disease detection/classifications, 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 use of imaging systems.

Cleaning and disinfection

- For external procedures, low-level disinfection is effective per CDC guidelines. Refer to the *KOSMOS Chemical Compatibility* document included as part of the Kosmos Torso and Kosmos Torso-One package for a list of cleaning and disinfection agents that have been evaluated for compatibility with the device materials for use against COVID-19 (SARS-CoV2). The *KOSMOS Chemical Compatibility* document can also be found on the echonous.com

website. If low-level disinfection agents are depleted, use soap and water per CDC guidelines.

- Use market-cleared, sterile transducer sheaths to prevent cross-contamination. If no transducer covers or sheaths are available, use medical gloves or other physical barriers (such as compatible medical dressings) for COVID-19 (positive or suspected) patients.

Summary of the dataset characteristics used in the development of the auto-labeling tool

Two studies were conducted to assess the performance of the KOSMOS auto-labeling algorithm for user and system requirements validation.

The first study was a retrospective study, where 496 ultrasound images frames of 13 ultrasound views were processed and analyzed by auto-labeling in a bench testing format. Each of the image frames were curated and carefully annotated by experts for performance analysis. From the study, the expert agreed with auto-labeling for 84% of the 496 image frames, which was higher than the targeted 80% frame-level agreement threshold. Secondary structure-level statistics yielded a precision of 0.94, recall of 0.70, and F1 or F-measure of 0.80.

The second study was a prospective study, where 5 users (3 experts and 2 non-experts) scanned 6 subjects and recorded 264 clips, representing 13 ultrasound views. From this study, experts agreed with auto-labeling for 95% of the clips, which was higher than the targeted 80% clip-level agreement threshold. In addition, from the 264 clips, 794 total anatomical structures were detected, of which 98% were agreed upon by both auto-labeling and the expert. Additional analysis was performed for each user, and each user produced an auto-labeling-expert agreement percentage of 80% or higher. Similar analysis was performed for each subject and also produced 80% or higher agreement for each subject. Finally, analysis was performed for each view and yielded 80% or higher agreement for each view.

Auto-labeling reached the targeted performance threshold for validation of the user and system requirements in both the retrospective and prospective studies as part of the EchoNous evaluation of auto-labeling performance.

In general, the dataset is considered to be diverse, as it was collected on various types of devices, at various locations/countries, by multiple users with varying

degrees of skill (novice with a medical background to expert cardiologist), and on an overall diverse subject population.

Summary of the dataset characteristics used in the development of the grading and guidance tool

Two studies were conducted to assess the performance of KOSMOS Grading and Guidance algorithm for user and system requirements validation. One study was a retrospective study, where 275 ultrasound clips of A4C, A2C and suboptimal ultrasound views were processed and analyzed by the Grading and Guidance algorithm in a bench testing format. Each of the image frames were curated and carefully annotated by 4 experts for performance analysis. From the study, a consensus of experts agreed with the KOSMOS Guidance algorithm for 82.3% of the 275 clips, which was higher than the targeted 80% top-three clip-level agreement threshold. The consensus of experts also agreed with KOSMOS Grading with root mean square error of 0.80.

The second study was a prospective study, where 7 users (3 experts and 4 non-experts) scanned 5 subjects and recorded 161 A4C and A2C clips. From this study, consensus of 5 experts agreed that 95% of all the acquired images are diagnostic for visual estimation of ejection fraction, which was higher than the targeted 80% agreement threshold. Additional analysis was performed for each user, and 6 out of 7 users produced clip-level algorithm-expert agreement percentage of 80% or higher. Only one novice user acquired data that produced algorithm-expert agreement of 72.2% and this was partly because some of the data were recorded when the Grading algorithm was predicting an image quality less than 3. When these data points were removed, the novice user's clip-level algorithm-expert agreement surpassed 80%. Finally, analysis was performed for each view (A4C and A2C) and yielded 80% or higher agreement for each view. Expert's assessment of the correctness of the algorithm's predictions on the scale of 1-5 yielded an average score greater than 4.0 for both the Grading and Guidance algorithm.

Grading and Guidance algorithm reached the targeted performance threshold for validation of the user and system requirements in both the retrospective and prospective studies as part of EchoNous' internal validation of Grading and Guidance algorithm performance.

In general, the dataset is considered to be diverse as it was collected on various types of devices, at various locations/countries, by multiple users with varying

degrees of skill (novice with a medical background to expert cardiologist) and on an overall diverse subject population.