KOSMOS on Android

User Guide

EchoNous

P006631-007, Rev A

April 2022

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CHAPTER 1

Getting Started

What's new in this release?

New features and changes for the 3.0 version of KOSMOS® include:

- Addition of Color Doppler imaging on Kosmos Lexsa
- Expansion of compatible tablets. Please visit the EchoNous website for a current list of compatible tablets.

Package contents

The KOSMOS box contains the following items:

- Kosmos Torso-One and/or Kosmos Lexsa
- KOSMOS App for Android™ Quick Start Guide
- Kosmos Lexsa on Android UI Quick Guide
- Chemical Compatibility
- USB flash drive containing:
  - KOSMOS on Android User Guide
  - KOSMOS App for Android Quick Start Guide
  - Kosmos Lexsa UI Quick Guide for Bridge and Android
  - 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.

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

Intended use/indications for use

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

KOSMOS is intended to be used by qualified and trained healthcare professionals in the clinical assessment of the cardiac and pulmonary systems and the abdomen by acquiring, processing, displaying, measuring, and storing ultrasound images.

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 Image Guidance for Needle/ Catheter Placement (includes needle/catheter placement, fluid drainage, and nerve block)
- **Modes of operation:** B-mode, M-mode, Color Doppler, combined modes of B+M and B+CD, 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 Kosmos probe lens) to touch the patient.
⚠	To avoid the risk of electrical shock or injury, do not open the tablet or Kosmos probe enclosures for any reason. All internal adjustments and replacements (such as the battery) need to be made by a qualified KOSMOS technician.
⚠	To avoid the risk of electrical shock and fire 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 is not defibrillation proof. To prevent injury to the operator/bystander, Kosmos probes must be removed from patient contact before the application of a high-voltage defibrillation pulse.
⚠	Before using KOSMOS for needle guidance procedures, you must have training in the applicable interventional procedures in addition to training in the use of ultrasound imaging for needle guidance. Well known limitations of ultrasound physics may lead to an inability to visualize the needle or differentiate the needle from acoustic artifacts. Serious injury or complications may result from attempting an interventional procedure without proper training.
⚠	As a precaution, be careful when scanning near a wound or over a dressing.
⚠	Do not use KOSMOS for intracavity imaging.
⚠	KOSMOS uses Bluetooth wireless communication technology.
⚠	Keep power cords away from trafficked areas.
⚠	No modifications to this equipment shall be made without written consent of manufacturer, EchoNous, Inc.
⚠	Do not charge the tablet inside the patient area.
⚠	Do not connect any unauthorized equipment while using the Kosmos system.
⚠	Only use tablets that have been approved compatible by EchoNous.

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**.

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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:

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CHAPTER 2

KOSMOS Overview

What is KOSMOS?

KOSMOS consists of Kosmos Torso-One or Kosmos Lexsa connected by cable to an EchoNous approved tablet which runs the EchoNous Kosmos: Ultrasound App. When the display is connected to a Kosmos probe, the combination is configured as a medical electrical system. The current list of compatible tablets can be found on the EchoNous website.

The following probes are available for the Kosmos System:

- Kosmos Torso-One:
  - A phased array ultrasound-only probe with a smaller, more streamlined form factor to help fit in between intercostal spaces.
- 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).

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). Reference **Modes of operation by Kosmos Probe:** for more information about which modes are applicable for each Kosmos Probe.

KOSMOS provides optional wireless connectivity, allowing remote storage.

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 Torso-One and Kosmos Lexsa are Type BF Applied Parts. The Applied Parts include:
  - The lens (front surface) of the Kosmos probe
- Kosmos Torso-One and Kosmos Lexsa are IPx7

Patient environment

KOSMOS is intended to be used in a medical facility. The tablet must not be charged in the patient environment.

⚠	Do not charge device while scanning a patient

KOSMOS capabilities

Overview

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

Using AI-assisted EF workflow to calculate ejection fraction

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

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

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

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**.

	• 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-One.**

--End of Section--

CHAPTER 3

Using KOSMOS

System Overview

Use this section to acquaint yourself with the ultrasound system and components.

Device requirements

For a list of devices that EchoNous has tested and determined to be compatible with the Kosmos app, visit the Kosmos website.

The EchoNous Kosmos Ultrasound App can only be downloaded and installed on the supported tablets listed on the Kosmos Website, and the key requirements met by the supported tablets are listed below:

- Minimum of 50 MB of storage space (plus more for patient data storage)
- Color display, minimum 267mm (10.5 in)
- Touch interface
- Internally mounted speakers
- IEC 60950-1-compliant or IEC 62386-1 compliant
- Only one USB port
- Date/time configuration
- Full compliance with USB On-The-Go standard1
- 2560 x 1600 resolution (minimum)
- Android 10.0 or later operating system
- Qualcomm 855, or faster equivalent
- Wireless or cellular networking capability
- Audio capability
- Front- and rear- facing cameras

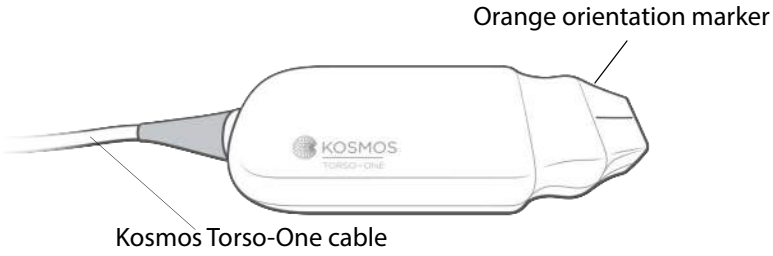
Please review all safety considerations in the safety section of this manual. The tablet must have the corresponding ratings to be used within specified environmental conditions.

Kosmos hardware

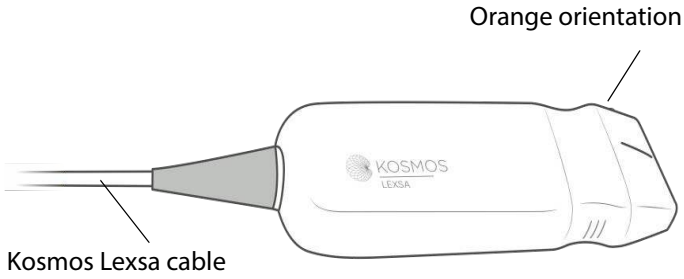
⚠	Contact EchoNous or your local representative for a list of accessories available from or recommended by EchoNous.

The following drawing points out key features on Kosmos Torso-One and Kosmos Lexsa.

Kosmos Torso-One



Kosmos Lexsa



Downloading the Kosmos App

✶ To begin using Kosmos on Android, download the EchoNous Kosmos: Ultrasound App from the Google Play Store using the QR code below.

Connecting Kosmos Probes

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

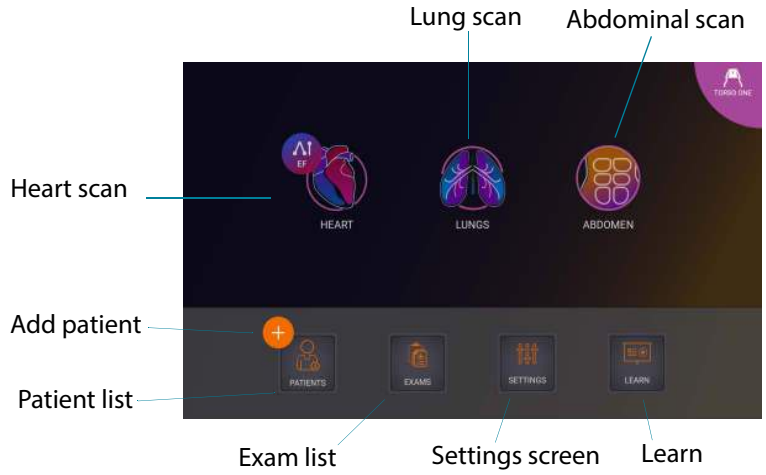
To connect Kosmos Torso-One or Kosmos Lexsa to approved tablets

✶ Connect Kosmos probe via the USB port to the tablet

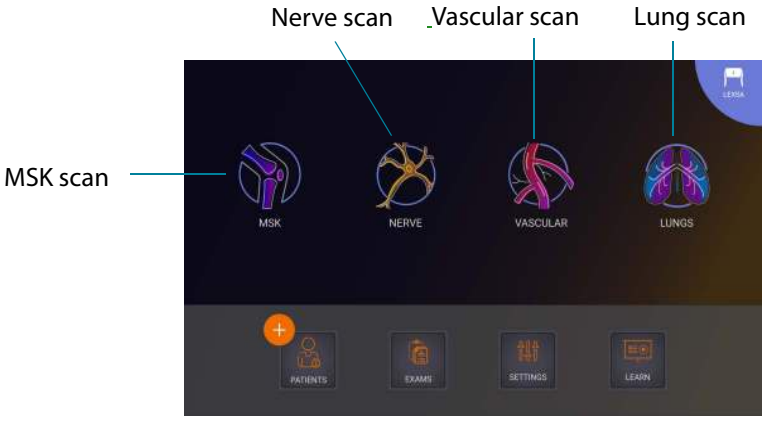
✶ When ready to start scanning, tap the organ of your choice to begin.

General interaction

Home screen: Kosmos Torso-One



Home screen: Kosmos Lexsa



Learn

To access the how-to-videos available on YouTube, ensure your device is connected to Wi-fi and tap **Learn**.

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.

Configuring KOSMOS settings

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

Setting imaging preferences

The Imaging Preferences screen is where you can customize the information displayed 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 administrator preferences

Only the KOSMOS Administrator can configure these settings.

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.

   The results are displayed on-screen.
6. In the **Profile nickname** box, type a unique name to display in the PACS profile list.
7. In the **Archival options** area, 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.

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

9. In the **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.
   - The results are displayed 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.

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**.

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.

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 --

CHAPTER 4

Performing an Exam

Overview

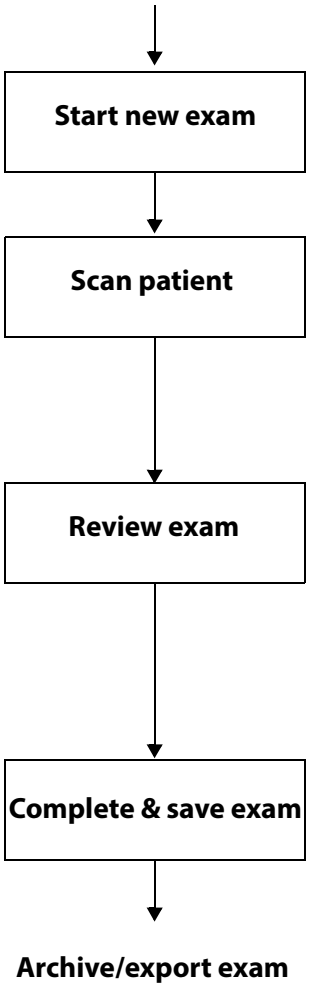
⚠	Before using KOSMOS for a critical procedure, such as needle guidance, make sure it is fully charged. You do not want the procedure interrupted by a drained battery, which may cause harm to the patient.
⚠	The maximum temperature of a Kosmos probe scan head may be greater than (41C) but is less than (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

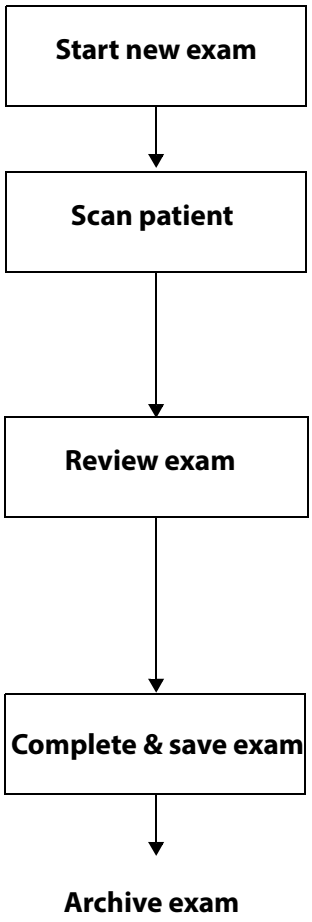
Things you can do while reviewing:

- 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:

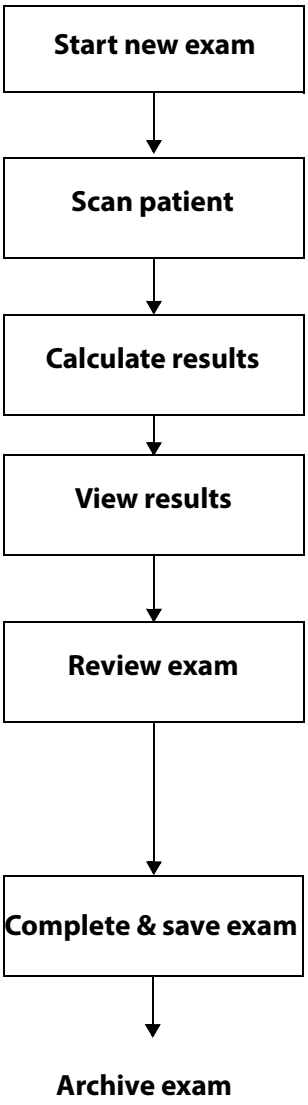
- Delete images and clips
- Add, edit, and delete annotations and notes
- Generate report

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 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 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 4-1 provides an overview of the organ presets that are available for each Kosmos probe.

TABLE 4-1. Organ Presets by Kosmos Probe

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

Imaging modes

For an overview of the applicable imaging modes for each Kosmos probe, reference Table 4-2 Modes of operation by Kosmos Probe:

TABLE 4-2. Modes of operation by Kosmos Probe:

Mode	Torso-One	Lexsa
B-mode	x	x
M-mode	x	x
B + CD (Color Doppler)	x	x
Harmonic Imaging	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.

	While scanning with Lexsa probe, M-mode is only available in the Lung preset

✶ To start M-mode, tap the M-mode  icon.

M-Line

✶ To move the M-Line, use your finger to change to M-mode, tap the M 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.

✶ 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.

Steer

Steer changes the steering angle of the color ROI. There are 5 angles to choose from.

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

Artery

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

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

	Steer and Artery are only available in Lexsa Color-mode

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

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 zoom out 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-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

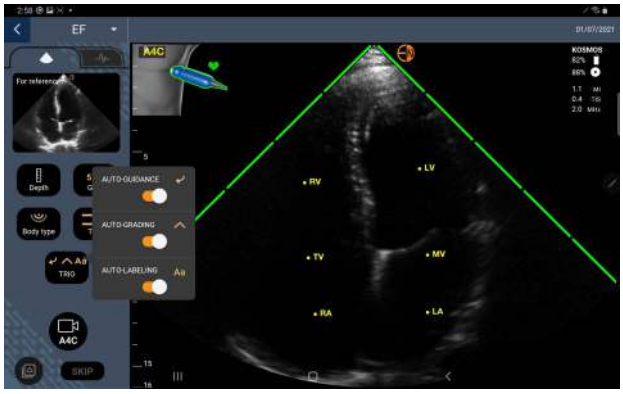


Figure 1 shows an example of Trio with all three algorithms activated.

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.

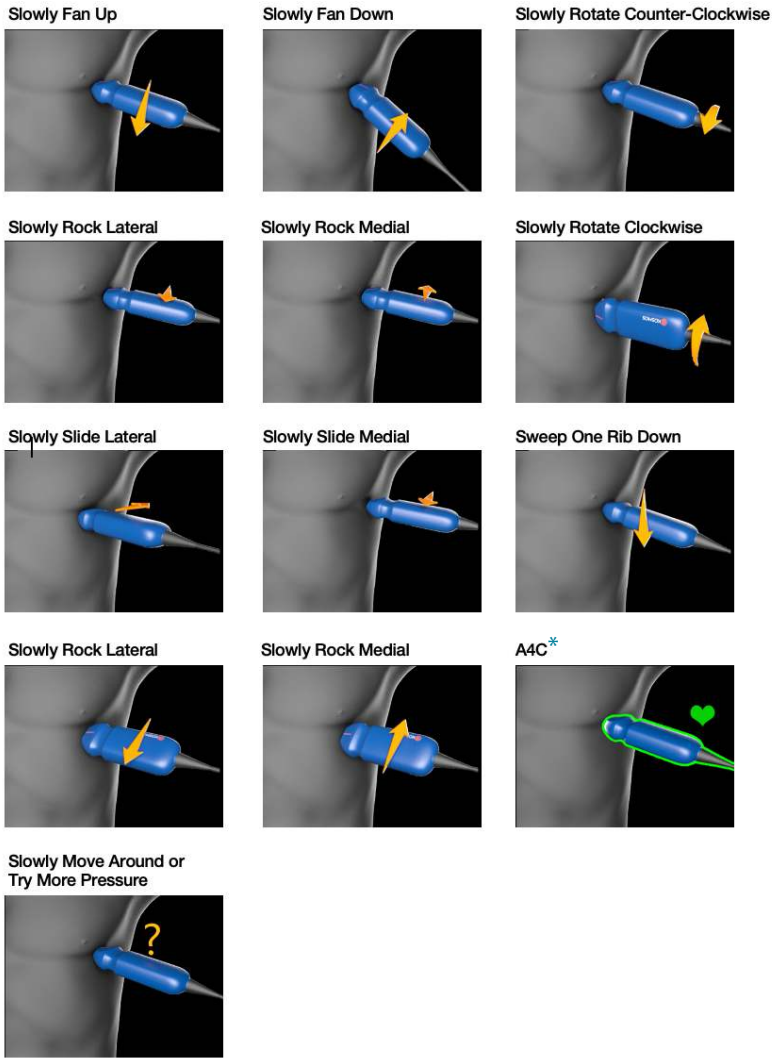
The pictures indicating probe motions and the corresponding phrases provided by the Auto-guidance algorithm during A4C acquisition are shown in **Figure 2**. Note that all the pictures and corresponding phrases in **Figure 2**, can also be shown during A2C acquisition except for the one picture corresponding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

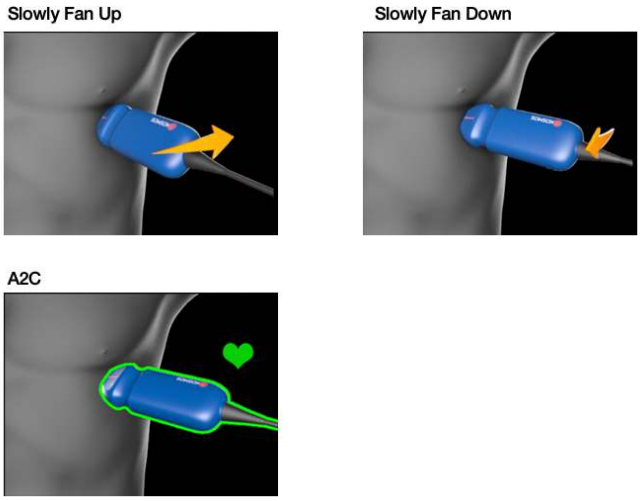
All pictures depicted in **Figure 2** and **Figure 3** are shown on the Kosmos Bridge in the form of animations to better convey probe motion.

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



*Only for the A4C view

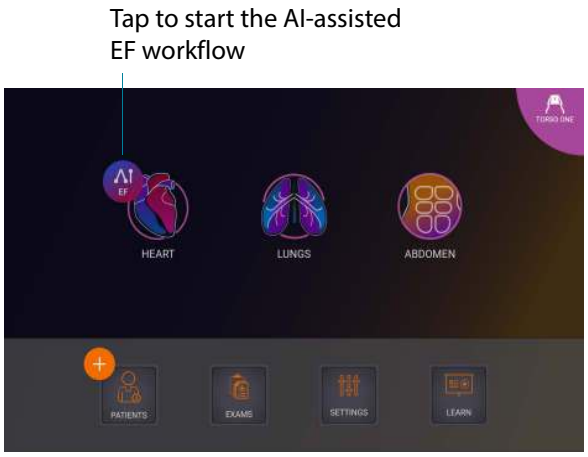
FIGURE 3. Pictures Indicating Probe Motions and Corresponding Phrases Exclusive to A2C Acquisitions



Calculating EF with the AI-assisted EF workflow

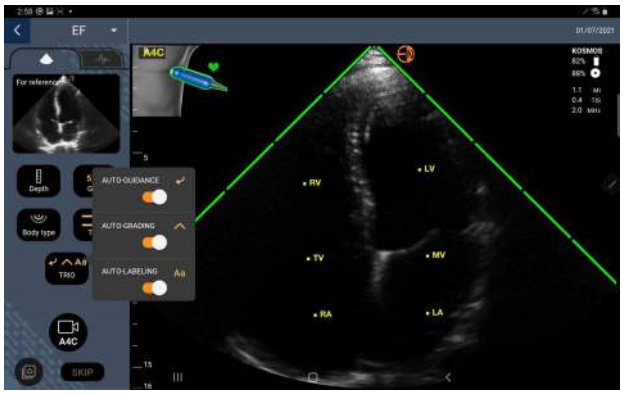
To calculate EF:

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).

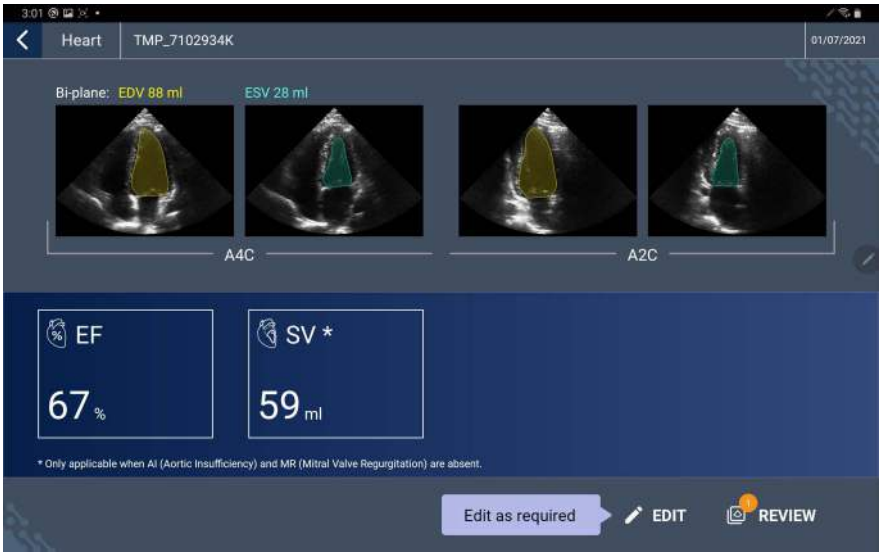
Now that when the A4C and A2C clips are recorded and accepted, the system selects the ED and ES frames, draws the corresponding LV contours, and calculates the biplane EF using the modified Simpson's method of disks (20 disks are used in the calculation).

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.

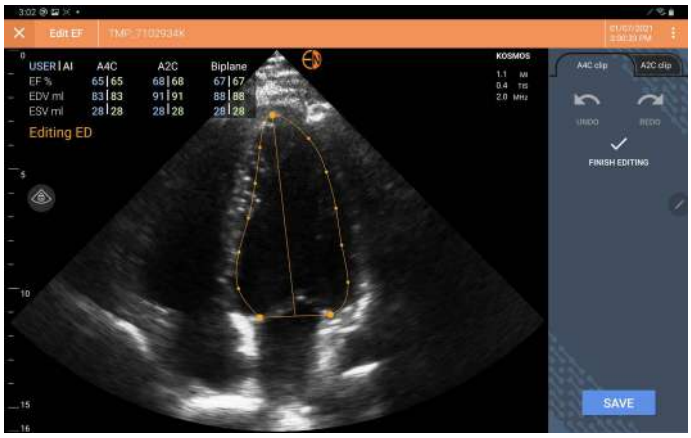
To adjust the ED/ES frames:

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



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**.



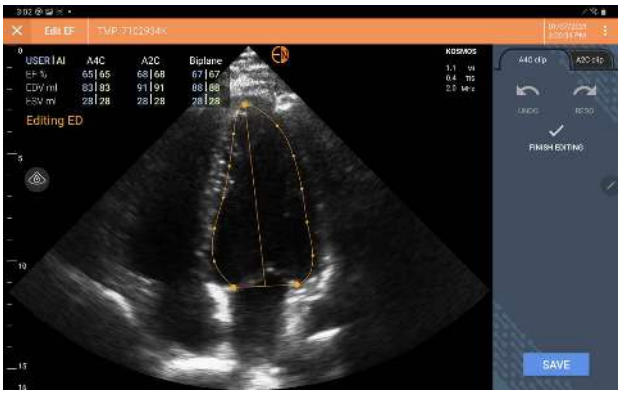
4. To return to the original AI calculations, tap the More options ⋮ icon and then **Reset**.
5. If desired, make changes to the other clip (A4C or A2C), and tap **SAVE**.

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.

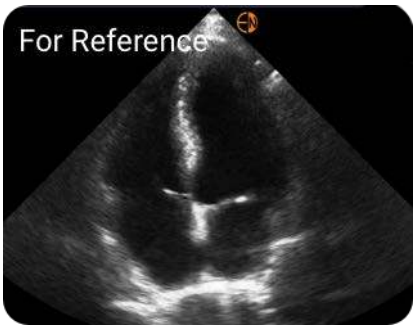
6. After you are done editing, tap **Finish editing**.
7. If desired, make more changes.
8. Tap **SAVE**.

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

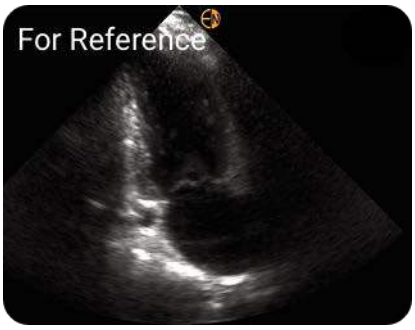
EchoNous recommends the following:

- 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-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 the app is closed
- If another app is open and the Kosmos app goes in the background

-- End of section --

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CHAPTER 5

Reviewing an Exam

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

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

Starting an exam review

- To start a review during an exam, tap the Exam review  icon.
- To start a review for a completed exam, do one of the following:
  - From the Home screen, tap **EXAMS**, then tap the exam you would like to review.
  - From the list of patients, find the patient, then tap the exam you would like to review.

Annotating images and clips

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

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

Navigating to the Edit Image screen

While scanning a patient:

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

After scanning a patient:

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

From the Home screen:

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

From the Patient screen:

1. Tap a patient from the list.
2. Tap the exam.

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

Annotation tools

Annotations can be added to individual images and clips.

When you add an annotation (text, measurements, arrow, area) to a clip or a cine, 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 EF 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 5-1. Anatomical structures for heart Imaging screen

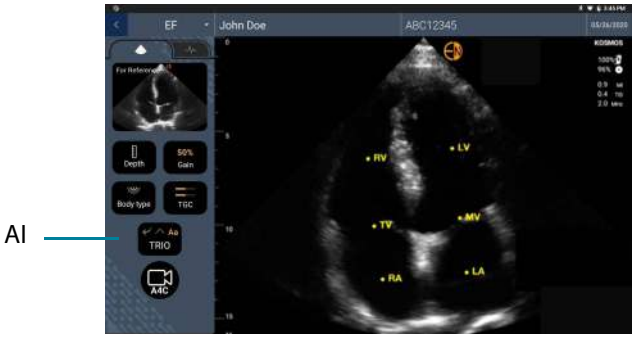
Imaging screen (heart)	Anatomical structure*
A2C	LA, LV, MV
A3C (APLAX)	AO, LA, LV, LVOT, MV
A4C	AO, LA, LV, LVOT, MV, RA, RV, TV
A5C	LA, LV, LVOT, MV, RA, RV, TV, AO
PLAX	AO, AV, IVS, LA, LV, MV, RV
RVOT	MPA, PV, RVOT
RVIT	IVC, RA, RV, TV
PSAX-AV	AV, LA, MPA, PV, RA, RV, TV
PSAX-MV	IVS, LV, MV, RV
PSAX-PM	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. Can freeze while zoomed (and can zoom out and zoom 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**.

Managing images and clips

Filtering images and clips

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

You can filter images and clips in the following ways:

- Drag and pull the thumbnail list down to reveal the filter options.
- Tap the Filter icon 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 6

Kosmos Probes

Kosmos Probe sheaths

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

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

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

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

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

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CHAPTER 7

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

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

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

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

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

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

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

Labeling symbols

Symbol	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
	Tested to comply with FCC standards	None
	Probes are tested to Type BF protection	TYPE BF APPLIED PART Refer to D1.20 IEC 60601-1 Medical Electrical Equipment - Part 1: General requirement for basic safety and essential performance

	Class II equipment	Class II equipment Ref. No. D.1-9 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Safety cautions are identified with this mark on the device.	Caution Ref. No D1.10 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-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)
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
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

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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, 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 acoustic output tables, **TABLE 7-1.** through **Table 7-10**

Kosmos Torso-One Acoustic Output Tables

See next page

TABLE 7-1. Transducer: Kosmos Torso-One, Operating Mode: B-Mode, Combined acoustic output table: Reportable mode 1 (B-mode) Cardiac, body type 2, 16 cm

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

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" 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 7-2. Transducer: Kosmos Torso-One, Operating Mode: M-Mode, Acoustic output reporting table: Reportable mode 3 M-mode (Cardiac, Body type: medium, 12 cm Depth)

Index label		MI	TIS		TIB	
			At surface	Below surface	At surface	Below surface
Maximum index value		0.43	5.32E-02		0.11	
Index component value			5.32E-02	2.15E-02	5.32E-02	0.11
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.70				
	P (mW)		4.55		4.55	
	P_{1x1} (mW)		4.11		4.11	
	z_s (cm)			5.37		
	z_b (cm)					4.80
	z_{MI} (cm)	5.37				
	$z_{pii,\alpha}$ (cm)	5.37				
	f_{awf} (MHz)	2.72	2.72		2.68	
Other information	prr (Hz)	800				
	srr (Hz)	N/A				
	n_{pps}	1				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	52.08				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	16.71				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	31.29				
	p_r at z_{pii} (MPa)	45.72				
Operating 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 7-3. Transducer: Kosmos Torso-One, Operating Mode: M-Mode, Acoustic output reporting table: Reportable mode 4 M-mode (Cardiac, Body type: medium, 14 cm Depth)

Index label		MI	TIS		TIB	
			At surface	Below surface	At surface	Below surface
Maximum index value		0.39	5.33E-02		9.70E-02	
Index component value			5.33E-02	2.12E-02	5.33E-02	9.70E-02
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.63				
	P (mW)		4.60		4.60	
	P_{1x1} (mW)		4.14		4.14	
	z_s (cm)			5.50		
	z_b (cm)					4.97
	z_{MI} (cm)	5.50				
	$z_{pii,\alpha}$ (cm)	5.50				
	f_{awf} (MHz)	2.70	2.70		2.67	
Other information	prr (Hz)	800				
	srr (Hz)	N/A				
	n_{pps}	1				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	41.86				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	13.64				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	38.22				
	p_r at z_{pii} (MPa)	1.06				
Operating 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 7-4. Transducer: Kosmos Torso and 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: 1.91					
	$z_{pii,\alpha}$ (cm)	2: 2.00					
	f_{awf} (MHz)	2: 2.65	1: 2.71 2: 2.65		1: 2.71 2: 2.65		
Other information	*prr* (Hz)	2: 1248.9					
	srr (Hz)	2: 31.2					
	n_{pps}	2: 10					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 282					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	160.04					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	233.06					
	p_r at z_{pii} (MPa)	2: 2.85					
Operating Control Conditions							
	Component 1: UTP 4						
	Component 2: UTP 275						

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" 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 7-5. Transducer: Kosmos Torso and 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.

Kosmos Lexsa Maximum Acoustic Output Summary

Table 7-6 Transducer: Kosmos Lexsa Acoustic output reporting table, Operating Mode: B-Mode (Max MI, ISPTA, MSK, 3cm depth)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
	Maximum index value	0.77	5.39E-03		5.39E-03		1.25E-02
	Index component value		5.39E-03	5.39E-03	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 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 7-7 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 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 7-8 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 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 7-9 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	
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	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2: 2.88					
	P (mW)		1: 0.36 2: 2.94		1: 0.36 2: 2.94		1: 0.36 2: 2.94
	P_{1x1} (mW)		1: 9.49E-02 2: 2.94		1: 9.49E-02 2: 2.94		
	z_s (cm)			1: N/A 2: N/A			
	z_b (cm)					1: N/A 2: N/A	
	z_{MI} (cm)	2: 0.96					
	$z_{pii,\alpha}$ (cm)	2: 1.57					
	f_{awf} (MHz)	2: 4:42	1: 7.15 2: 4.42		1: 7.15 2: 4.42		1: 7.15 2: 4.42
Other Information	prr (Hz)	2: 2026.6					
	srr (Hz)	2: 28.1					
	n_{pps}	2: 12					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 23.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	48.65					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	79.44					
	p_r at z_{pii} (MPa)	2: 0.95					
Operating Control Conditions							
	Component 1: UTP 225						
	Component 2: UTP 339 (16V)						

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" 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 7-10 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: NA			
	z_b (cm)					1: N/A 2: NA	
	z_{MI} (cm)	2: 0.93					
	$z_{pii,\alpha}$ (cm)	2: 1.40					
	f_{awf} (MHz)	2: 6.22	1: 7.15 2: 6.22		1: 7.15 2: 6.22		1: 7.15 2: 6.22
Other Information	prr (Hz)	2: 8830.3					
	srr (Hz)	2: 17.8					
	n_{pps}	2: 16					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 73.7					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	29.56					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	54.39					
	p_r at z_{pii} (MPa)	2: 1.51					
Operating Control Conditions	Component 1: UTP 225						
	Component 2: UTP 161						

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" 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.

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 7-11. 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 7-12. 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 7-12. Surface temperature rise

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

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

Basic Safety

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

⚠	Devices that are compliant with IEC 60950-1 and 62368-1 have not been evaluated for compliance with IEC 60601-1 temperature limits for patient contact.
⚠	Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.
⚠	Do not bring the tablet into contact with the patient. Contact of the tablet with the patient could result in electric shock and risk of burn.
⚠	Do not charge the tablet while an EchoNous probe is plugged into the tablet.
⚠	Only use devices and accessories recommended by EchoNous

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

Electromagnetic Compatibility

	The System complies with the Electromagnetic Compatibility requirements of AS/NZ CISPR 11:2015 and EN IEC 60601-1-2:2014: AMD1:2020. However, electronic and mobile communications equipment may 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 7-13. 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 7-14. 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 7-14. 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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TABLE 7-14. 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 7-14. 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.

⚠	When using the optional mobile stand, the **System** can be susceptible to ESD and may require manual intervention. If ESD results in a **System** error, unplug the probe and plug back in to restore operation.
⚠	Using cables, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system

Separation distances

TABLE 7-15. 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.

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.

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CHAPTER 8

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 tablet 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 tablet surfaces or on the tablet 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 the tablet, Kosmos probes, or 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.

Tablet

⚠	The tablet is not sterile when shipped; do not attempt to sterilize it.
⚠	To avoid electrical shock, before cleaning, turn off the tablet and disconnect it from the power supply.

Cleaning

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

1. 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 the tablet. Choose an EchoNous-approved wipe from the list in **Presaturated wipes**.
4. If necessary, clean the tablet 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 8-1. 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

Kosmos Probes

Cleaning

The following cleaning instructions must be followed for 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-One and Kosmos Lexsa, read the following warnings and cautions.

	Always disconnect the USB cable from 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.

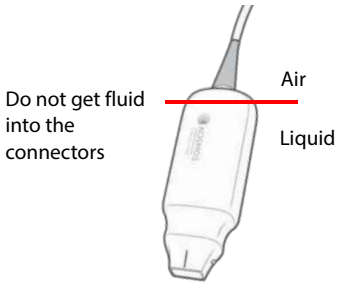
Before performing the following steps, read the following warnings and cautions.

⚠	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.
⚠	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 8-2. 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.

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

In cases where a Kosmos probe has been exposed to biologically hazardous material, EchoNous recommends using biohazard containers and in compliance with federal and local regulations. 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.

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

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CHAPTER 9

Specifications

System specifications

Feature	Height (mm)	Width (mm)	Depth (mm)	Weight (grams)	Cable (meters)
Kosmos Torso-One	150 *	56	35	267 (with ferrite equipped cable)	1.5
Kosmos Lexsa	155	56	35	280 (with cable)	1.5

*excluding cable (the hard plastic housing length)

Samsung S6 Tablet (SM-T860)

Height: 244.5 mm

Width: 159.5 mm

Depth: 5.7 mm

Weight: 420 g

Internally Powered (5V, 2A max)

Fully charged battery will provide 120 minutes of continuous scanning. The performance may vary based on scanning modes used.

Lenovo Tab P12 Pro

Height: 285.6 mm

Width: 184.5 mm

Depth: 5.6 mm

Weight: 565 g

Internally Powered (5V, 2A max)

Environmental operating and storage conditions for Kosmos probes

Kosmos 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 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 enforces scanning limits to maintain safe user contact temperatures.

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CHAPTER 10

IT Network

Wireless Networking

Functions

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

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

Security

Patient Data Protection

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

Wireless Networking

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

Network for connecting the device

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

IT network failure recovery measures

Connection to an IT network may become, 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 re-initiate 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.

-- End of section --

CHAPTER 11

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.
BMI	Body mass index.
B-mode	Kosmos Torso-One 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.
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.

Term	Description
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.
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.
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.

Term	Description
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.
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.

Term	Description
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.
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.
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.

Term	Description
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

KOSMOS has been designed and evaluated to comply with the following applicable FDA-recognized consensus standards. All verification and validation testing for KOSMOS confirms that product specifications are met.

- ANSI AAMI ES60601-1:2005/(R)2012 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/®2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- ANSI AAMI IEC 60601-2-27:2011(R)2016 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (limited set of test requirements)
- ANSI AAMI IEC 60601-1-2:2014: AMD1:2020 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
- ANSI AAMI IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- 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
- NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- 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
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to 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.

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