EchoNous

USER GUIDE

KOSMOS

P005794-001, Rev B
March 2020

CHAPTER 1

Getting Started

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.

Package contents

The KOSMOS box contains the following items:

- KOSMOS system, comprised of the Kosmos Bridge and Kosmos Torso
- Kosmos power supply
- Kosmos ECG patient cable
- Kosmos binaural headset
- Bridge stand
- KOSMOS Quick Start Guide
- KOSMOS UI Quick Guide
- USB flash drive containing:

- KOSMOS User Guide
- KOSMOS Quick Start Guide
- KOSMOS UI Quick Guide
- ALARA education program (ISBN 1-932962-30-1, Medical Ultrasound Safety)
- "How To" and clinical videos
- 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 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 synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms.

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

- Clinical applications: Cardiac, Thoracic/Lung, Abdominal, Peripheral Vascular, and Image Guidance for Needle/Catheter Placement
- 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

	KOSMOS is not MRI compatible and should not be used in an MRI suite.
	KOSMOS is not for use in oxygen-rich environments.
	To avoid the risk of electrical shock, do not allow any part of KOSMOS (except for the Kosmos Torso lens and the Kosmos ECG patient cable) to touch the patient.

	To avoid the risk of electrical shock or injury, do not open the Kosmos Bridge or Kosmos Torso enclosures for any reason. All internal adjustments and replacements (such as the battery) need to be made by a qualified KOSMOS technician.
	To avoid the risk of electrical shock and fire hazard, inspect the power supply, AC power cords, cables, and plugs on a regular basis to ensure that they are not damaged.
	The KOSMOS system, including the Kosmos ECG patient cable, is not defibrillation proof. To prevent injury to the operator/bystander, Kosmos Torso and the Kosmos ECG patient cable/leadwires 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. During fluid removal procedures of the pericardium, pleural cavity and abdomen, the potential exists for serious complications including, without limitation, the following: pneumothorax, arterial puncture, cardiac puncture, or damage to other organs.
	As a precaution, be careful when scanning near a wound or over a dressing.
	Do not use KOSMOS for intracavity imaging.
	Federal law restricts this device to sale by or on the order of a physician.
	KOSMOS uses Bluetooth wireless communication technology.
	Keep power cords away from trafficked areas.

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
  - **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**.

Customer support

In addition to this user guide, you can find clinical videos, how-to videos, and on-board help in Kosmos Bridge.

You can also contact customer support:

Phone: 844-854-0800

Fax: 425-242-5553

Email: info@echonous.com

Web: www.echonous.com

CHAPTER 2

KOSMOS Overview

What is KOSMOS?

KOSMOS consists of Kosmos Bridge, which runs the EchoNous system software, and is connected by cable to Kosmos Torso. KOSMOS provides portable ultrasound imaging and supports the following:

- Noninvasive heart, lungs, and abdominal ultrasound imaging
- Three lead, single-channel ECG
- Digital auscultation (DA) signals

KOSMOS uses pulse-echo ultrasound to generate real-time ultrasound images. This process involves transmitting high-frequency acoustic pulses into the body with Kosmos Torso, detecting the returned signals with Kosmos Torso 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).

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

KOSMOS provides optional wireless connectivity, allowing remote storage. Both the Kosmos Bridge and the Kosmos Torso are battery powered.

KOSMOS clinical applications

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

- Cardiac
- Lung

- Abdominal

Training

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

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

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

KOSMOS classifications

- KOSMOS has an internal battery which allows operation when AC power is not available.
- The Kosmos power supply classification for protection against electric shock: Class II equipment.
- Kosmos Torso is a Type BF Applied Part. The Applied Parts include:
  - The lens (front surface) of Kosmos Torso
  - ECG electrodes, as connected to the Kosmos ECG patient cable
- Kosmos Bridge is IP22
- Kosmos Torso is IPx7
- ECG is type BF

Patient environment

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

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 ultrasound, ECG, and DA signals simultaneously

In most situations, ultrasound, auscultation, and ECG are a few of the most valuable signals used in medicine for assessing the heart. KOSMOS seamlessly integrates these three signals to acquire, visualize, and analyze the results with a single device.

To properly capture and analyze the dynamic anatomic and physiological information associated with the signals, KOSMOS acquires, stores, and displays these signals in synchronization. As a user, you can add DA, ECG, or both signals to the ultrasound exam.

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CHAPTER 3

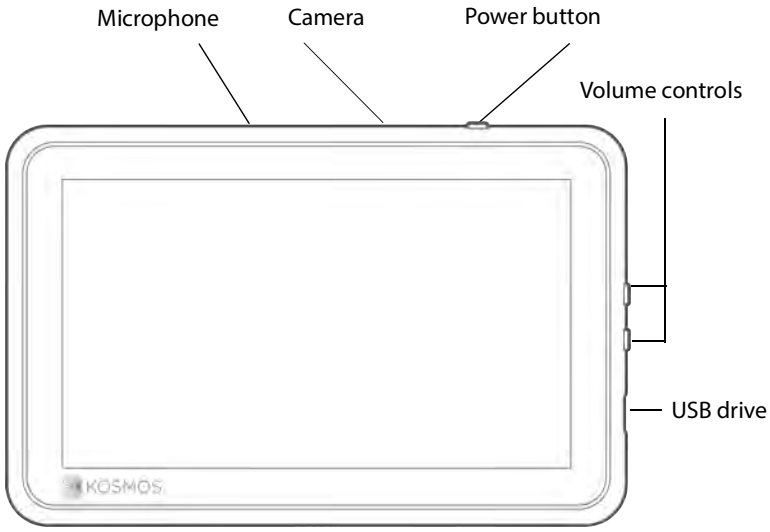
Using KOSMOS

Kosmos hardware

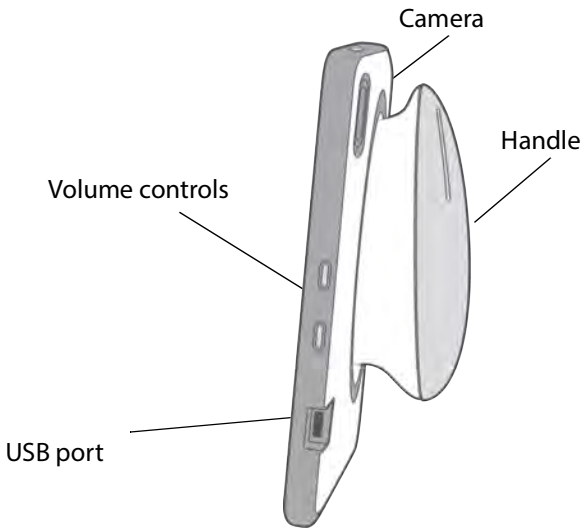
⚠	Use only accessories recommended by EchnoNous. Do not connect any USB accessories to Kosmos Bridge that are not recommended by EchoNous; doing so may cause electric shock and/or compromise the security of the device. Contact EchoNous or your local representative for a list of accessories available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

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

Kosmos Bridge

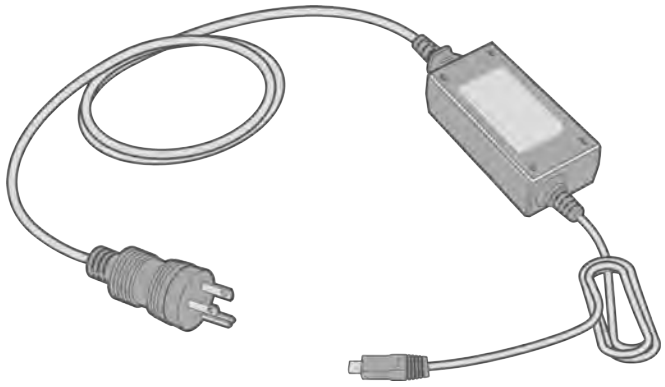


Side

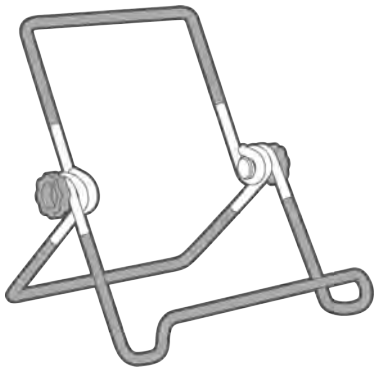


Kosmos Torso

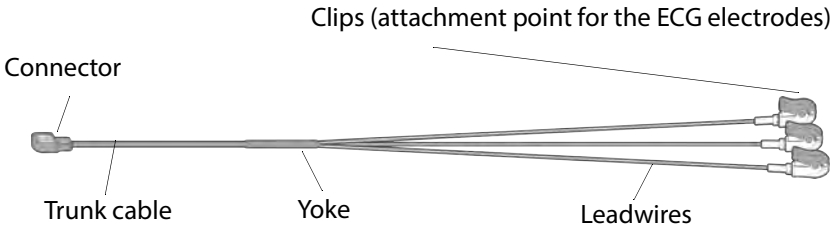
KOSMOS power supply



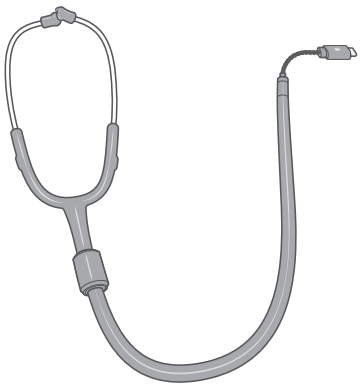
KOSMOS Bridge stand



Kosmos ECG patient cable



Binaural headset



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

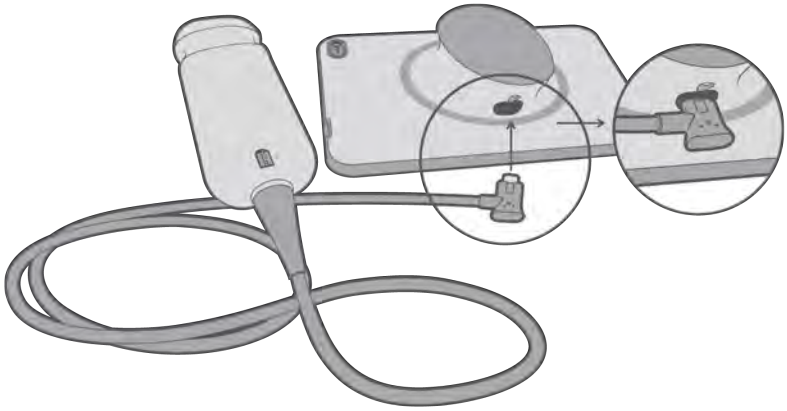
Connecting Kosmos Torso

⚠	Before each use, inspect Kosmos Torso for damage, such as cracks, splitting, or sharp edges. If damage is evident, discontinue using Kosmos Torso, and contact your EchoNous representative.
⚠	Use only accessories recommended by EchnoNous. Do not connect Kosmos Torso into any device other than Kosmos Bridge.
⚠	Do not attempt to plug Kosmos Torso into the side USB port.

To connect Kosmos Torso to Kosmos Bridge:

✶ Plug the Kosmos Torso connector into the slot below the Kosmos Bridge

handle.



Connecting the power supply

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

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

To connect the power supply to Kosmos Bridge:

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

Setting up the Kosmos Bridge stand

To set up the Kosmos Bridge stand:

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

Turning Kosmos Bridge on and off

Turning on Kosmos Bridge and Kosmos Torso

To turn on Kosmos Bridge and Kosmos Torso:

1. Press the **Power** button.

2. Tap the organ of your choice to start scanning.

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

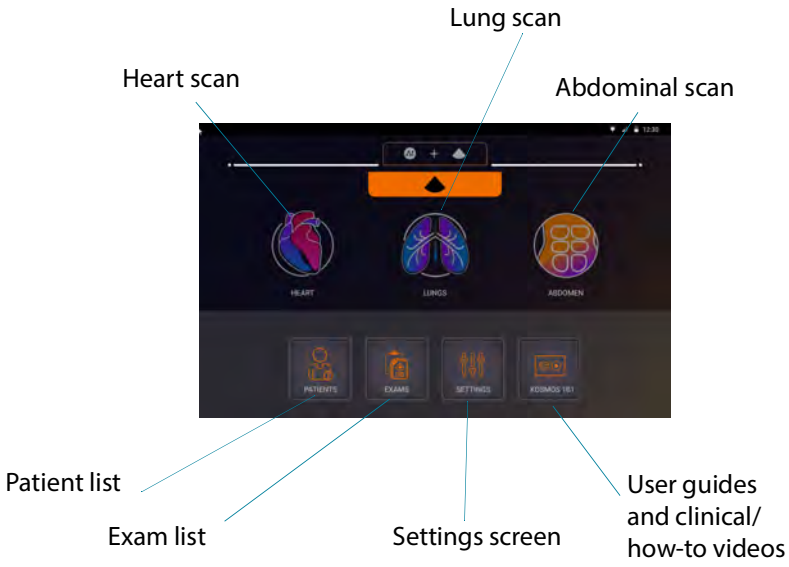
Turning off Kosmos Bridge

To turn off Kosmos Bridge:

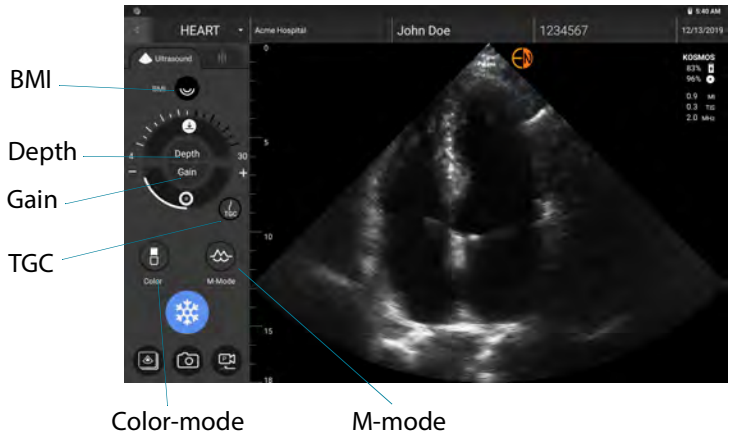
1. Press the **Power** button.
2. Do one of the following:
   - When prompted, tap **OK**.
   - Wait the few seconds for KOSMOS to turn itself off.

General interaction

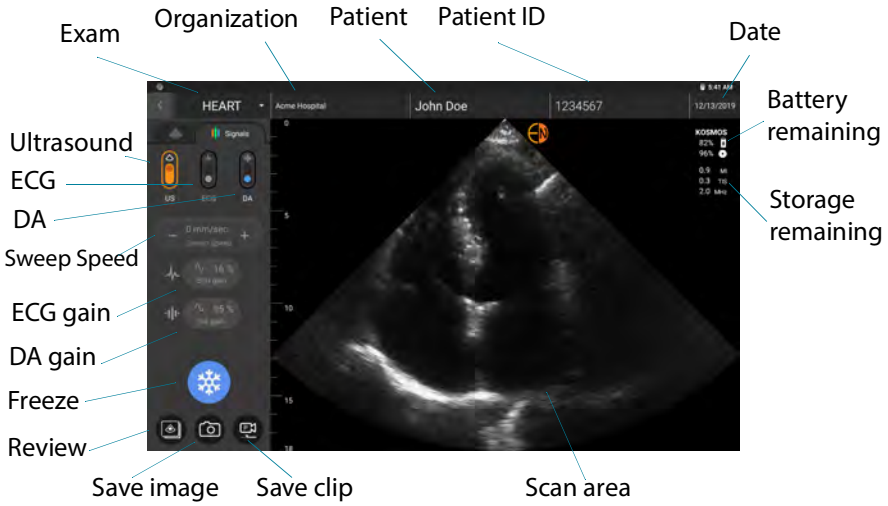
Home screen



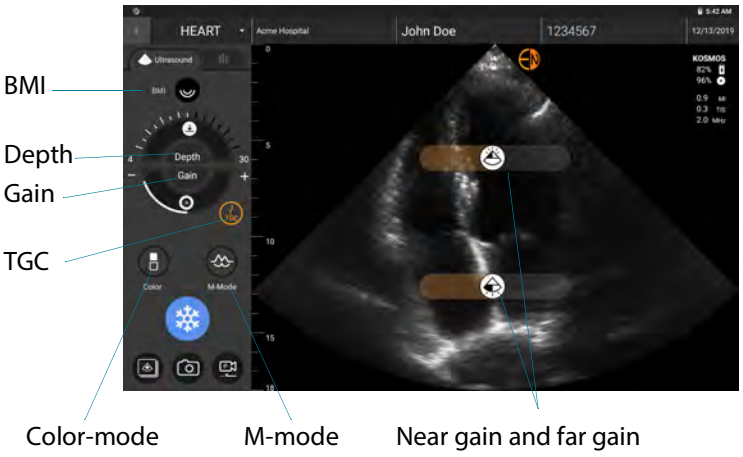
Imaging screen: Ultrasound tab (B-mode)



Imaging screen: Three-signal tab

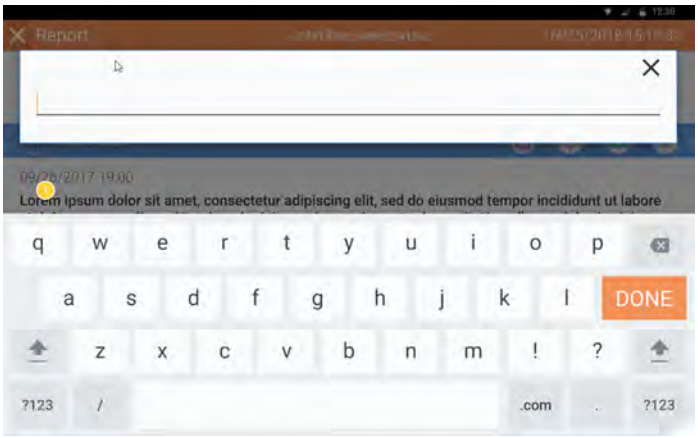


Ultrasound controls



On-screen keyboard

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

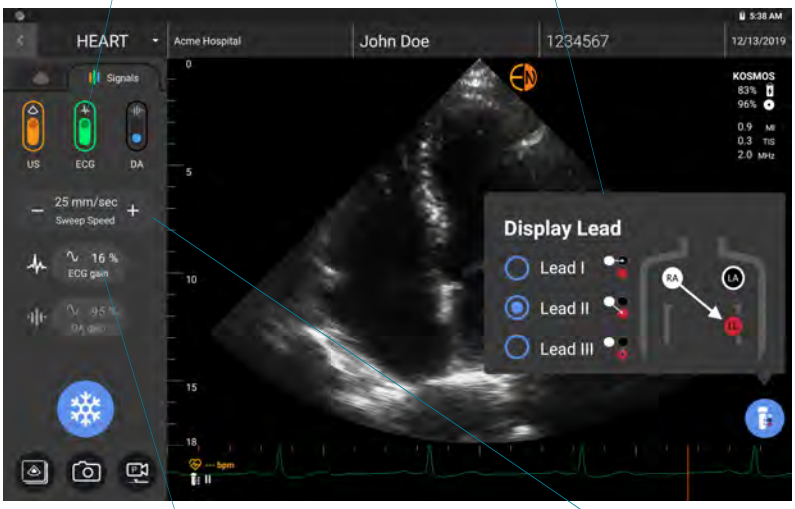


Understanding the different waveforms

ECG

ECG slider is turned on.

Display lead

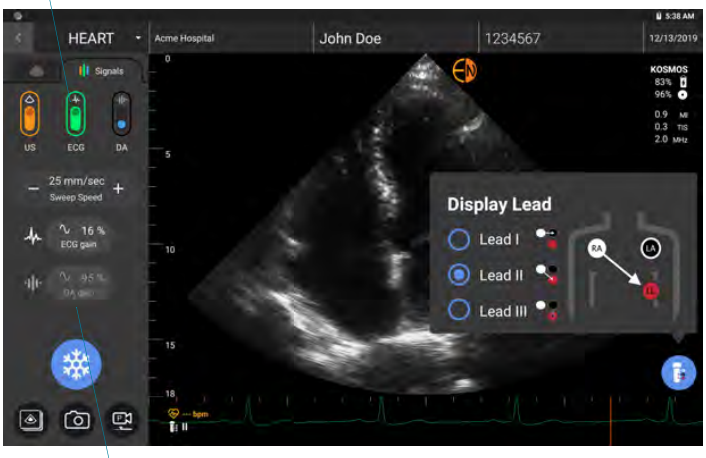


Refers to the amplitudes of the ECG waveform. Modify the amplitudes of the ECG waveform by increasing and decreasing the ECG gain.

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

DA

DA slider is turned on.



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

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

Configuring KOSMOS settings

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

Setting imaging preferences

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

To set the imaging preferences:

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

> During an exam, if you tap the Record Clip icon again, you can finish the recording earlier than the clip duration defined here.

6. To adjust the horizontal screen split between M-Mode and B-mode, select from the following options under **M-Mode layout**:

- **1:2**—Tap this option to adjust the screen split so the M-Mode area is twice as big as B-mode.
- **1:1**—Tap this option to adjust the screen split so that the M-Mode and B-mode areas are equal.

7. From the **Thermal index display** area, select from the following:
   - **TIS**—Thermal index for soft tissue
   - **TIB**—Thermal index with bone near the focus

Configuring ECG and DA signals

Ultrasound is always configured with DA, ECG or DA and ECG.

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

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

Setting the language, date, and time

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

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

1. From the Home screen, tap **SETTINGS**.
2. Tap **Language, Date, and Time**.
3. From the **Language** list, tap the language of your choice.
4. From the **Date** list, tap the format of your choice.
5. If you would like the time to display in 24-hour format, tap to the right of the **Use 24-hour format** button to turn it on.
6. To turn off the automatic date and time (provided by your network), tap to the left of the **Automatic date and time** button to turn it off.

Adjusting the volume

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

To adjust the volume:

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

Setting brightness

To set the brightness:

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

Configuring administrator preferences

Only the KOSMOS Administrator can configure these settings.

Managing security settings

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

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

user PIN provides access to all of the KOSMOS screens, with the exception of the administration settings screens.

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

Setting up a PIN

To set up a PIN:

1. From the Home screen, tap **SETTINGS**, then **Administration**.
2. Tap **Security**.
3. Tap to select the **Enable administrator** PIN check box.
4. Type a six-digit numeric PIN, and click **OK**.
5. You now have a choice of how you would like to set up your PINs.

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

Changing a PIN

To change a PIN:

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

3. To change the administrator PIN, tap **Change administrator PIN**, and type the new PIN number.
4. To change the user PIN, tap **Change user PIN**, and type the new PIN number.

Removing a PIN

To remove a PIN:

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

Managing 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 **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:
   - **KOSMOS AE title**—KOSMOS' Application Entity title
   - **PACS AE title**—Archive server's Application Entity title
   - **PACS IP address**—Archive server's unique identifier
   - **PACS port number**—Archive server's port number
5. To make sure the connection is working on an active profile, tap one of the following:

- **PING** to test the network connection between KOSMOS and the PACS archive
- **Verify** to check the availability of the active PACS archive.

  Kosmos Bridge displays the results on-screen.

6. In the **Profile nickname** box, type a unique name to display in the PACS profile list.
7. In the **Archival options** area, you have two options:
   - **Prompt options every time** - Switched on by default; each time you tap the **Archive** button from the Exam review screen, a pop-up menu with different options displays. If you turn the switch off, KOSMOS does not display the pop-up menu.
   - **Attach report**—Switched off by default. If you turn it on, KOSMOS attaches a report to the archive.
8. In the **Auto archive** area, select from the following options:
   - **On/Off**—The auto archive is switched off by default. This means that all the controls (except the on/off switch) are disabled and cannot be edited. If you turn the switch on, all the controls are enabled and can be edited.
   - **Archival frequency**
     - **Completion of exam**—The archival time selector is disabled.
     - **Daily**—Only the time section of the archival time selector is enabled.
     - **Weekly**—The complete archival time selector is enabled.
   - **Archival time**—Select a daily time and day to archive exams.
9. In the **SCU timeout (in seconds)** area, select **10**, **15**, or **30**.
10. In the **SCP timeout (in seconds)** area, select **10**, **15**, or **30**.
11. In the **Retry interval (in seconds)** area, select **60**, **300**, or **600**.
12. To have the system automatically retry failed jobs, keep the switch set to **On**; otherwise, slide it to **Off**.

Deactivating a profile

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

Deleting a profile

To delete a PACS profile:

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

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

Installing software updates

	Before updating the software, back up all patient data.

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

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

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

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

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

4. To have KOSMOS automatically check for updates, under the Automatically check for update area, tap to select **On**.
5. Tap to select a frequency.
6. To have KOSMOS automatically update the software, under Automatically update area, tap **On**, and select a time to have any updates installed.

Managing network and internet settings

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

To manage network and internet settings:

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

Setting the sleep mode interval

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

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

To change the sleep mode interval:

1. From the Home screen, tap **Settings**.
2. Tap **Administration**.
3. Tap **Sleep**.
4. Tap the time period that best suits your needs.

Changing privacy settings

To enable and disable the setting to manually send image data to the EchoNous Cloud:

1. From the Home screen, tap **Settings**.

2. Tap **Administration**.
3. Tap **Privacy**.
4. Do one of the following:
   - To turn off the setting, tap to deselect the **Enable buttons to manually send image data to EchoNous Cloud** check box.
   - To turn on the setting, tap to select the **Enable buttons to manually send image data to EchoNous Cloud** check box.

Viewing information about KOSMOS

To view information about KOSMOS:

1. From the Home screen, tap **Settings**.
2. Tap **Administration**.
3. Tap **About**.
4. If you have not yet registered KOSMOS, tap **Register**.

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 **Admin**.
4. Tap **About**.
5. Tap **REGISTER**.

Resetting KOSMOS to the factory settings

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

To reset KOSMOS to the factory settings:

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

4. Tap **Factory Reset**.
5. Tap **RESET**.

Wireless networking

Functions

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

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

Connection specifications

Hardware specification

802.11 a/b/g/n/ac, Bluetooth 4.2 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.

EU Compliance

EchoNous, Inc. hereby declares that this wireless device is in compliance with Directives 2014/53/EU and 93/42/EEC. A copy of the EchoNous EU Declaration of Conformity for KOSMOS, including device frequency bands and maximum radio-frequency power, is available at www.echonous.com/en_us/regulatory. The EchoNous EU Authorized Representative can be found **here**.

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.

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CHAPTER 4

Incorporating ECG and DA Signals

Overview

ECG

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

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

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

ECG has been traditionally used in ultrasound to provide a timing reference for the cardiac cycle, and it can do the same for digital auscultation (DA). KOSMOS ECG serves as a timing reference for both ultrasound and DA signals, and it can also be used to look at the acquired and displayed ECG lead for heart rate measurement and rhythm assessment by qualified and trained healthcare professionals.

DA

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

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

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

Benefits of using ECG and DA signals with ultrasound

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

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

Using the Kosmos ECG patient cable

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

To use the Kosmos ECG patient cable:

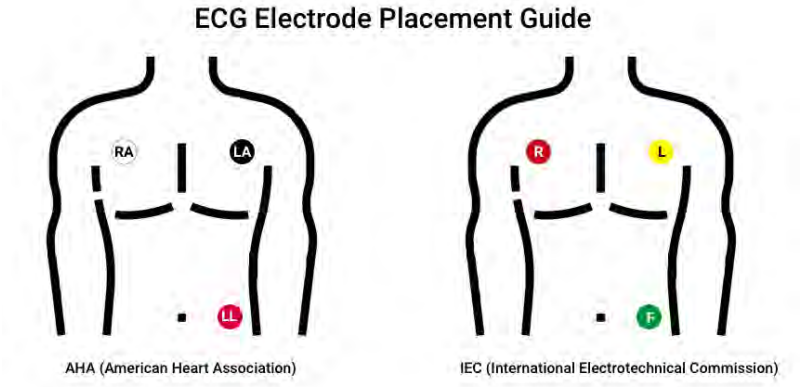
1. Place the ECG electrodes of your choice (this is where the ECG clips will be attached to) on the patient, making sure they are placed symmetrically opposite from each other and match the color coding.

   USA recommendation (American Heart Association):

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

   IEC recommendation:

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



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

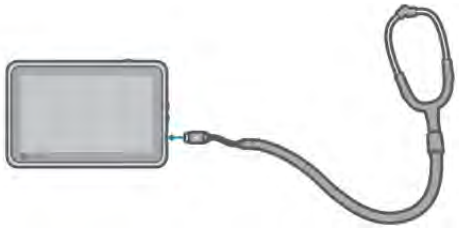
Attaching the Kosmos binaural headset

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

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

To attach the Kosmos binaural headset:

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

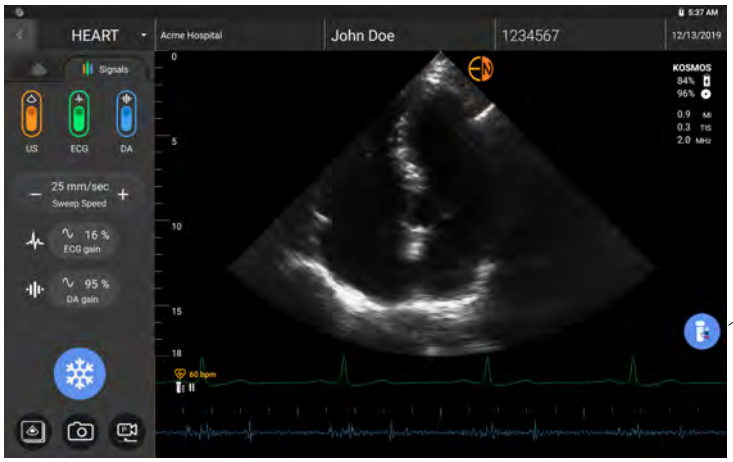


2. Put the headset on.
1. On Kosmos Bridge, tap the **Signals** tab.
2. Tap **DA** to turn it on.
3. From the top of the screen, slide your finger down to see the volume control.
4. Adjust the volume.

Viewing the ECG and DA signals

	• When the **Signal** tab is inactive, it is grayed out. Just tap the Signal icon to bring up the ultrasound controls.
	• The ECG and DA signals are only available in B-mode and Color-mode.

1. Tap the **Signal** tab to display the three signal controls. By default, only the ultrasound image displays.
2. To view the ECG signals, tap **ECG** on; tap again to turn it off.
3. To view the DA signal, tap **DA** on; tap again to turn it off.
4. To select which ECG lead is to be acquired and displayed, tap the **ECG** button on the bottom right side of the screen.



Signal scrolling

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

ECG signal indicator

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

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

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

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

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

Archiving and exporting ECG and DA waveforms

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

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

CHAPTER 5

Performing an Exam

Overview

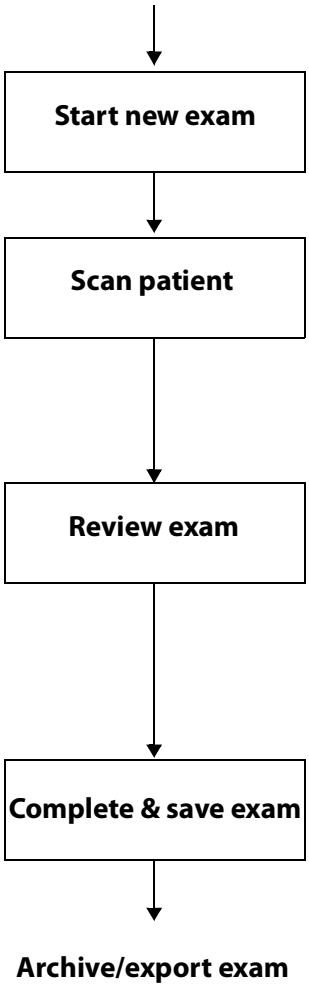
	Under certain circumstances, the Kosmos Bridge enclosure can reach temperatures that exceed safe (IEC 60601-1) limits for patient contact. Make sure that only the operator handles the system. Avoid placing Kosmos Bridge on the patient during use.
	The maximum temperature of the Kosmos Torso scan head 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:

- **Recommended workflow**
- **Quick workflow**
- **Managing exams**

Exam workflows

Recommended workflow



Optional step:

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

Things you can do while scanning:

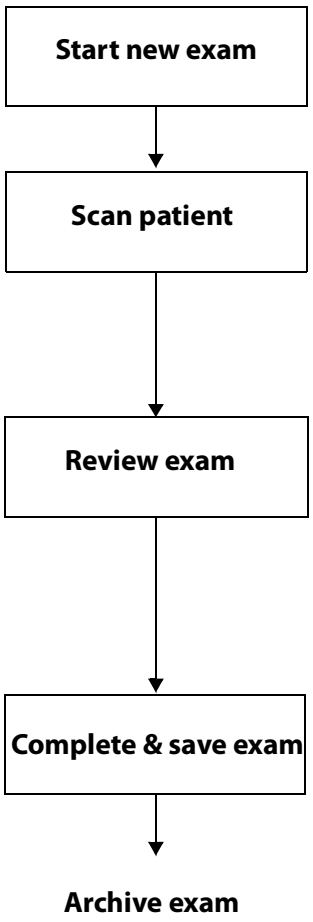
- Add and delete images and clips
- Add, edit, and delete annotations and notes

Things you can do while reviewing:

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

Optional step

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
- Archive exam to PACS
- Export exam to USB

Optional step

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 **NEW EXAM**, and then tap **SCAN**.
- From the Exam list, tap the Add icon, and then tap **SCAN**.

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 **PATIENTS**.
2. Tap the Add icon.
3. Enter the patient information, and tap **SAVE** when you are done.

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 patient~~s~~, 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**.

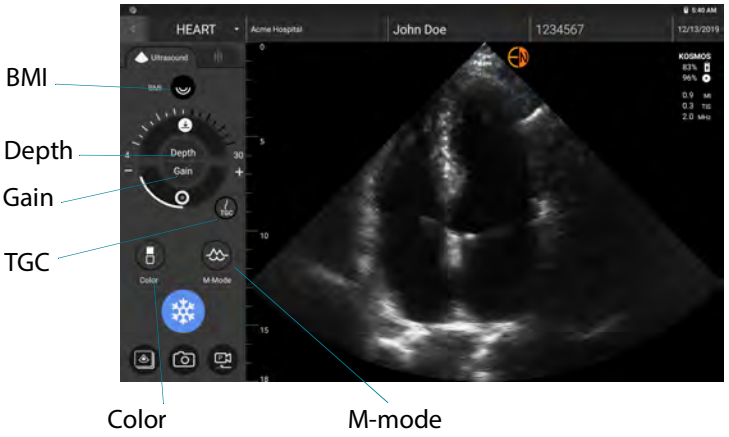
To delete selected patient records:

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

Imaging modes

B-mode

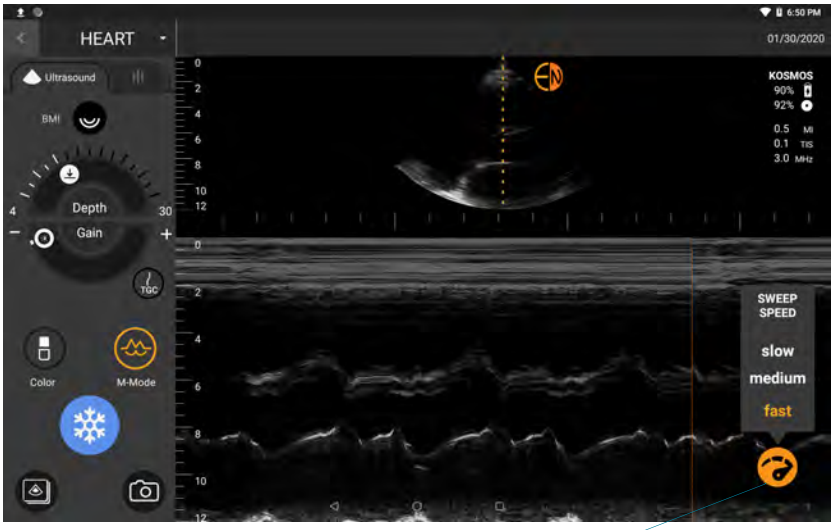
B-mode is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude.



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 BMI, depth, and gain (similar to B-mode) along with M-mode specific controls like M-line and sweep speed.



✶ To change to M-mode, tap **M-Mode**.

M-Line

✶ To move the M-Line, use your finger to drag the M-Line to the location you want.

Sweep speed

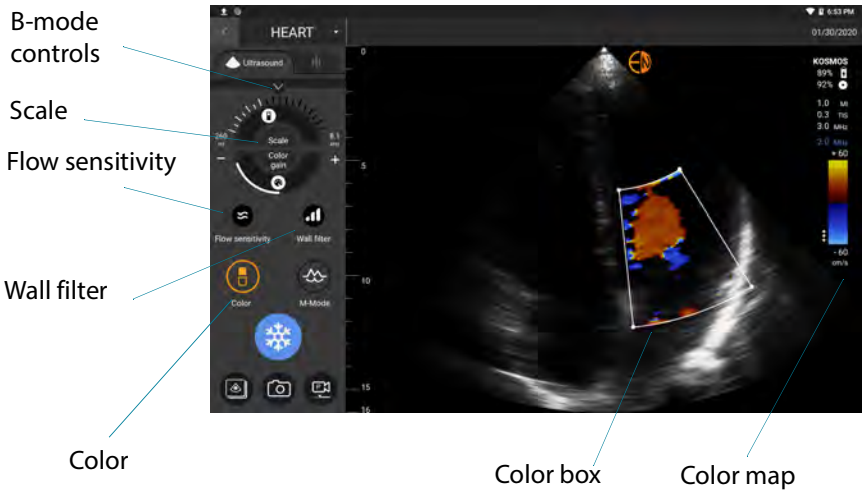
You can change the sweep speed to isolate individual motions.

✶ To change the M-Mode sweep speed, tap the Sweep speed icon, 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 **Color**.

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 two modes.

- To see the B-mode controls, tap the down arrow, and tap the up arrow to close 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, move the slider.

Flow sensitivity

Three flow sensitivity selections are available to optimize for low, medium, or high velocity flow.

- To change the flow sensitivity, tap the Flow sensitivity  icon one, two, or three times to set the appropriate velocity flow.

Wall filter

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

- To change the wall filter, tap the Wall filter  icon one, two, or three times to set the appropriate low-frequency flow.

Color map

When you open the color map, it shows seven color indexes. By default, it's set to index 5, and the first one is 0.

To change the heart color map:

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

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 mass index (BMI)

In KOSMOS, BMI is used to adjust the penetration level. BMI is not calculated or supplied from the patient's height or weight entry.

There are three levels of adjustment:

- Low (default)
- Medium
- High

When you adjust the BMI, it changes the penetration signal for the ultrasound parameters, so if you have a patient with a high BMI, you will want to increase the BMI (and vice versa).

✶ To adjust BMI, tap **BMI**, and select one of the three different penetration levels.

Adjusting depth and gain

To adjust depth:

- To increase the displayed depth, turn the Depth knob clockwise.
- To decrease the displayed depth, turn the Depth knob counter-clockwise.

To adjust gain:

- To manually adjust gain in Color-mode and B-mode, turn the Gain knob clockwise to raise the gain and counter-clockwise to lower the gain.
- To switch between near or far gain, tap **Gain**.
- To adjust near and far gain, tap **TGC**.

Zooming in and out

- While scanning, use two fingers to pinch and expand the image area.
- To return to the default image size, tap the magnifying glass.
- Notice that the zoom factor is shown near the magnifying glass as well as the orange color of the depth scale along the side image area.
- You can freeze while zoomed (and can unzoom and zoom while frozen).

Freezing an image

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

Acquiring images and clips

To acquire an image:

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

To acquire a clip:

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

Completing an exam

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

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

- When you start a new exam
- When you archive the in-progress exam
- After a few minutes
- When you turn off Kosmos Bridge

CHAPTER 6

Reviewing an Exam

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

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

Starting an exam review

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

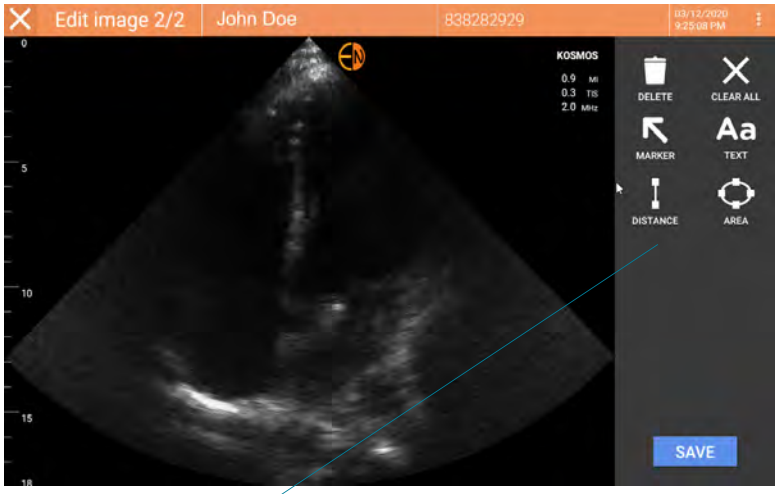
Annotating images and clips

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

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

Navigating to the Edit Image screen

To navigate to the Edit Image or Edit Clips screen:



Annotation tools

While scanning a patient:

1. Tap the Freeze icon.
2. Add your annotations.
3. Tap the Save image or Save clip icon.
4. Move the image or clip <?>

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.

Measuring with the caliper tool

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 endpoints.
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 unzoom and zoom in frozen state).

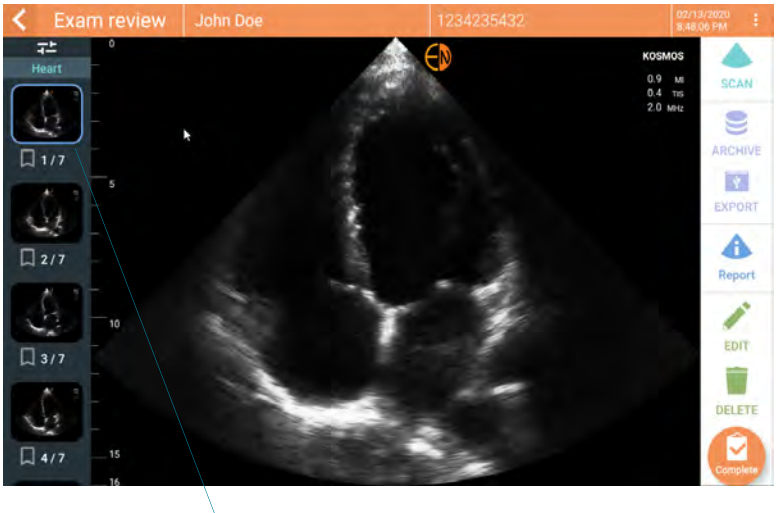
Deleting annotations

- 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.



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.


Exam is waiting to be exported.


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**.

The following table is a legend for the archiving icons.


Exam is waiting to be archived.


Archive is in progress.


Archive is complete.


Archive failed.

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

To archive an exam from the Exam list screen:

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

To archive an exam from the Exam review screen:

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

Deleting an exam

To delete an exam from the Exam list:

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

To delete an exam while reviewing it:

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

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CHAPTER 7

Kosmos Torso

Kosmos Torso sheaths

Where fluid contamination is possible, cover Kosmos Torso 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 Torso 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 Kosmos Torso 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 Kosmos Torso using an EchoNous-recommended high-level disinfectant.
- After inserting Kosmos Torso 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 Torso storage

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

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

Daily storage

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

Storage for transport

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

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 Kosmos Bridge or Kosmos Torso connectors.
- Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as protective eye wear and gloves.
- Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- Do not spray cleaners or disinfectants directly on Kosmos Bridge surfaces or on Kosmos Bridge and Kosmos Torso connectors. Doing so may cause solution to leak into KOSMOS, damaging it and voiding the warranty.
- Do not attempt to clean or disinfect Kosmos Bridge, Kosmos Torso, or the Kosmos Torso cable using a method that is not included here or chemical not listed in this guide. Doing so can damage Kosmos Torso and void the warranty.

Kosmos Bridge

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

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

Cleaning

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

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

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

TABLE 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 Torso

Cleaning

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

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

- Always disconnect the USB cable from Kosmos Torso before cleaning and disinfecting.
- After cleaning, you must disinfect Kosmos Torso 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 Kosmos Torso and void the warranty.
- When cleaning and disinfecting Kosmos Torso, 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 Kosmos Torso. When choosing a cleaning and disinfecting method, treat Kosmos Torso as if a cover was not used in the procedure.

To clean Kosmos Torso:

1. After each use, disconnect the USB cable from Kosmos Torso.
2. Remove any accessories attached to, or covering Kosmos Torso, such as a sheath.
3. At point of use, wipe Kosmos Torso with an approved presaturated wipe.
4. Prior to disinfecting Kosmos Torso, remove all ultrasound gel from Kosmos Torso 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 Kosmos Torso using a new presaturated wipe from **Presaturated wipes**.
6. If necessary, clean Kosmos Torso with additional wipes to remove all visible contaminants.
7. Before continuing with disinfection, ensure Kosmos Torso is visibly dry.

Disinfecting (intermediate-level)

Use the following steps to disinfect Kosmos Torso. Before performing the following steps, read the following warnings and cautions.

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

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

Before disinfecting, clean Kosmos Torso 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 Kosmos Torso and void the warranty.

To disinfect the Kosmos Torso (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 Kosmos Torso, starting from the exposed cable, wiping toward the Kosmos Torso head to avoid cross-contamination.
3. Observe the required wet contact time. Monitor Kosmos Torso for wet appearance. Use at least three wipes to ensure effective disinfection.
4. Before reusing Kosmos Torso, ensure Kosmos Torso is visibly dry.

Check Kosmos Torso for damage, such as cracks, splitting, or sharp edges. If damage is evident, discontinue using Kosmos Torso, and contact your EchoNous representative.

Disinfecting (high-level)

Use the following steps to high-level disinfect Kosmos Torso whenever it has come into contact with blood, broken skin, or bodily fluids (semi-critical use). High-level disinfection of Kosmos Torso typically uses an immersion method with high-level disinfectants or chemical sterilant.

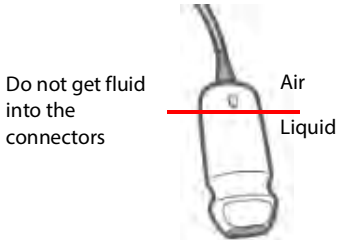
Before performing the following steps, read the following warnings and cautions.

- Always disconnect Kosmos Torso from AC mains during cleaning and disinfection.
- Before disinfection, clean Kosmos Torso 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 Torso, do not allow any fluid to enter electrical connections or metal portions of the USB or Kosmos ECG patient cable connector.
- Do not attempt to disinfect Kosmos Torso using a method that is not included in these instructions. This can damage Kosmos Torso and void the warranty.
- Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage Kosmos Torso and void the warranty.
- If Kosmos Torso 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 Torso (high level):

1. After cleaning, choose a high-level disinfectant that is compatible with Kosmos Torso. For a list of compatible disinfectants, see **Disinfectant solutions for Kosmos Torso 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 Torso into the disinfectant as shown below. Kosmos Torso may be immersed only up to the immersion point shown. No other part of Kosmos Torso, such as cable, strain relief, or connectors should be soaked or immersed in fluids.



5. Refer to **Disinfectant solutions for Kosmos Torso immersion** for duration of immersion and contact temperature.
6. Do not immerse Kosmos Torso longer than the minimum time needed for semi-critical level of disinfection.
7. Rinse Kosmos Torso 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 Kosmos Torso, 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 Kosmos Torso until visibly dry.
10. Wipe the strain relief and first 18 inches (45 cm) of the Kosmos Torso cable with an approved wipe from the list in **Presaturated wipes**.
11. Examine Kosmos Torso for damage such as cracks, splitting, or sharp edges. If damage is evident, discontinue using Kosmos Torso, and contact your EchoNous representative.

TABLE 8-2. Disinfectant solutions for Kosmos Torso immersion

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

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

Kosmos ECG patient cable

Cleaning

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

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

Always disconnect the cable from Kosmos Torso before cleaning and disinfecting.

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

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

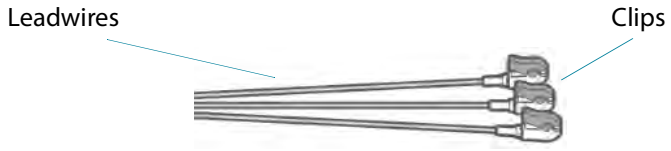
Ensure cable insulation is intact before and after cleaning.

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

To clean the Kosmos ECG patient cable:

1. After each use, disconnect the cable from Kosmos Torso.
2. Remove any accessories attached to, or covering, the cable, such as electrode pads.

3. At point of use, wipe the cables with an approved presaturated wipe from the list in **Presaturated wipes** to ensure effective cleaning.
4. Immerse the ECG clips and leadwires in a cleaning solution from the list in **Cleaning detergent solution for Kosmos ECG patient cable**, and soak for at least 10 minutes. Refer to **Cleaning detergent solution for Kosmos ECG patient cable** for the solution concentration and contact time.



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

TABLE 8-3. Cleaning detergent solution for Kosmos ECG patient cable

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

Disinfecting the Kosmos ECG patient cable

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

Always disconnect the USB cable from KOSMOS Torso before cleaning and disinfecting.

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

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

Ensure cable insulation is intact before and after disinfection.

Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting wipe can damage the Kosmos ECG patient cable.

To disinfect the Kosmos ECG patient cable:

1. After cleaning, choose an low-level disinfectant from the list in **Presaturated wipes**, and follow the instructions on the disinfectant label for the minimum wet contact time.
2. With a new wipe, disinfect the Kosmos ECG patient cable, starting from the connector end to the clips.
3. Observe the required wet contact time. Monitor the Kosmos ECG patient cable for wet appearance.
4. Use at least three wipes to ensure effective disinfection.
5. Examine the cable for damage, such as insulation wearing or discoloration. If damage is evident, discontinue using the Kosmos ECG patient cable.
6. Before reusing the cable, ensure the cable is visibly dry.

Binaural Headset

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

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

Recycling and disposal

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

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

Kosmos Bridge contains lithium-polymer batteries, and the system should be disposed of in an environmentally responsible manner in compliance with federal and local regulations. EchoNous recommends taking Kosmos Bridge and Kosmos Torso to a recycling center which specializes in the recycling and disposal of electronic equipment.

In cases where Kosmos Bridge and/or Kosmos Torso has been exposed to biologically hazardous material, EchoNous recommends using biohazard containers and in compliance with federal and local regulations. Kosmos Bridge and Kosmos Torso should be taken to a waste center which specializes in the disposal of biohazard waste.

Troubleshooting

Preventive inspection, maintenance, and calibration

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

- The KOSMOS battery is not replaceable.

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

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CHAPTER 9

Safety

Electrical safety

References

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

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

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

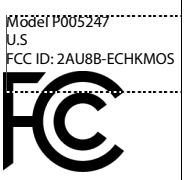
IEC 62304:2015 Medical device software - *Software life-cycle processes*

ISO 14971:2007/(R)2010 Medical devices - *Application of risk management to medical devices*

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

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

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
	Manufacturer's declaration of product compliance with applicable EEC directives and the Notified Body reference number	CE Marking Ref. Appendix 12 93/42/EEC EU Medical Device Directive
	Tested to comply with FCC standards	None
	Class II equipment	Class II equipment Ref. No. D.1-9 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

	Safety warnings are identified with this mark on the device.	General warning sign Ref. No. D.2-2 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 is protected against temporary immersion in water.	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)
IPX22	Kosmos Bridge	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)

REF	Part or model number	Catalog number Ref. No. 5.1.6 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
SN	Serial number	Serial number Ref. No. 5.1.7 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Date of manufacture	Date of manufacture Ref. No. 5.1.3 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Acceptable temperature range XX is generic placeholder for specified temperatures	Temperature limit Ref. No. 5.3.7 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

	Acceptable humidity range XX is generic placeholder for specified percentages	Humidity limitation Ref. No. 5.3.8 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Acceptable atmospheric pressure range XX is generic placeholder for specified kPa	Atmospheric pressure limitation Ref. No. 5.3.9 ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	Stack box this way up	This way up Ref. No. 13 ISO 780 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages

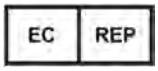
	Indicates direct current	Direct current Ref. No. D.1-4 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Indicates alternating current	Alternating current Ref. No. D.1-1 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Contact information

United States

EchoNous Inc.
8310 154th Avenue NE
Building B, Suite 200
Redmond, WA 98052
Technical Support (toll free): (844) 854 0800
Sales (toll free): (844) 854 0800
Email: support@EchoNous.com
Website: www.EchoNous.com

European Economic Area



Authorized Representative:
Advena Ltd
Tower Business Centre
2nd Flr, Tower Street
Swatar, BKR 4013
Malta

CE
2797

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 Torso frequency, Kosmos Bridge setup values, scanning techniques, and experience allow users to meet the definition of the ALARA principle.

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

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

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

Output display and display accuracy

OUTPUT DISPLAY

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

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

Thermal index

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

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

Mechanical index

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

Ispta

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

Output Display Accuracy

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

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

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

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

See acoustic output tables, **TABLE 9-1** through **TABLE 9-6**.

Acoustic output tables

TABLE 9-1 Combined acoustic output reporting table: Reportable mode 1 B-mode (Cardiac, BMI1, 12 cm Depth)

Index label		MI	TIS		TIB	
			At surface	Below surface	At surface	Below surface
Maximum index value		0.69	0.34		0.34	
Index component value			1: 0.17 2: 0.17	1: 0.17 2: 0.17	1: 0.17 2: 0.17	1: 0.17 2: 0.17
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.01				
	P (mW)		1: 19.10 2: 18.60		1: 19.10 2: 18.60	
	P_{1x1} (mW)		1: 16.91 2: 16.48		1: 16.91 2: 16.48	
	z_s (cm)			1: 4.33 2: 4.30		
	z_b (cm)					1: 4.33 2: 4.30
	z_{MI} (cm)	2: 4.30				
	$z_{pii,\alpha}$ (cm)	2: 4.30				
	f_{awf} (MHz)	2: 2.14	1: 2.14 2: 2.14		1: 2.14 2: 2.14	
Other information	prr (Hz)	2: 1589				
	srr (Hz)	2: 28				
	n_{pps}	2: 1				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 48.99				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	10.38				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	19.64				
	p_r at z_{pii} (MPa)	2: 1.38				
Operating controls	Component 1: UTP21					
	Component 2: UTP22					

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 9-2 Combined acoustic output reporting table: Reportable mode 2 B-mode (Cardiac, BMI2, 12 cm Depth)

Index label		MI	TIS		TIB	
			At surface	Below surface	Atsurface	Below surface
Maximum index value		0.74	0.50		0.50	
Index component value			1: 0.25 2: 0.25	1: 0.25 2: 0.25	1: 0.25 2: 0.25	1: 0.25 2: 0.25
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.06				
	P (mW)		1: 30.68 2: 30.23		1: 30.68 2: 30.23	
	P_{1x1} (mW)		1: 25.49 2: 25.10		1: 25.49 2: 25.10	
	z_s (cm)			1: 4.13 2: 4.20		
	z_b (cm)					1: 4.13 2: 4.20
	z_{MI} (cm)	2: 4.20				
	$z_{pii,\alpha}$ (cm)	2: 4.20				
	f_{awf} (MHz)	2: 2.07	1: 2.07 2: 2.07		1: 2.07 2: 2.07	
Other information	*prr* (Hz)	2: 1589				
	srr (Hz)	2: 28				
	n_{pps}	2: 1				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 54.17				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	17.24				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	31.29				
	p_r at z_{pii} (MPa)	2: 1.43				
Operating controls	Component 1: UTP73					
	Component 2: UTP74					

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 9-3 Acoustic output reporting table: Reportable mode 3 M-mode (Cardiac, BMI2, 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	UTP4					

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 9-4 Acoustic output reporting table: Reportable mode 4
M-mode (Cardiac, BMI2, 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	UTP5					

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 9-5 Combined acoustic output reporting table: Reportable mode 5 B+C-mode (Abdominal, BMI1, 12 cm depth, smallest color ROI at top)

Index label		MI	TIS		TIB	
			At surface	Below surface	At surface	Below surface
Maximum index value		1.09	1.31		1.31	
Index component value			1: 5.47E-02 2: 1.25	1: 5.47E-02 2: 1.25	1: 5.47E-02 2: 1.25	1: 5.47E-02 2: 1.25
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.56				
	P (mW)		1: 4.68 2: 144.87		1: 4.68 2: 144.87	
	P_{1x1} (mW)		1: 4.23 2: 128.26		1: 4.23 2: 128.26	
	z_s (cm)			1: 5.37 2: 2.30		
	z_b (cm)					1: 4.80 2: 2.30
	z_{MI} (cm)	2: 1.97				
	$z_{pii,\alpha}$ (cm)	2: 2.30				
	f_{awf} (MHz)	2: 2.04	1: 2.72 2: 2.05		1: 2.72 2: 2.05	
Other information	prr (Hz)	2: 4882				
	srr (Hz)	2: 28				
	n_{pps}	2: 16				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 82.58				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	108.55				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	152.01				
	p_r at z_{pii} (MPa)	2: 1.59				
Operating controls	Component 1: UTP4					
	Component 2: UTP55					

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 9-6 Combined acoustic output reporting table: Reportable mode 6 B+C-mode (Abdominal, BMI1, 12 cm depth, largest color ROI at top)

Index label		MI	TIS		TIB	
			At surface	Below surface	At surface	Below surface
Maximum index value		0.76	1.14		1.14	
Index component value			1: 2.84E-02 2: 1.11	1: 2.84E-02 2: 1.11	1: 2.84E-02 2: 1.11	1: 2.84E-02 2: 1.11
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2: 1.09				
	P (mW)		1: 2.43 2: 134.94		1: 2.43 2: 134.94	
	P_{1x1} (mW)		1: 2.19 2: 113.82		1: 2.19 2: 113.82	
	z_s (cm)			1: 5.37 2: 3.97		
	z_b (cm)					1: 4.80 2: 3.97
	z_{MI} (cm)	2: 3.97				
	$z_{pii,\alpha}$ (cm)	2: 3.97				
	f_{awf} (MHz)	2: 2.05	1: 2.72 2: 2.05		1: 2.72 2: 2.05	
Other information	prr (Hz)	2: 5283				
	srr (Hz)	2: 15				
	n_{pps}	2: 16				
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	2: 59.28				
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	57.37				
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	101.13				
	p_r at z_{pii} (MPa)	2: 1.44				
Operating controls	Component 1: UTP4					
	Component 2: UTP57					

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.

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 9-7 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 9-7 Surface temperature rise

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

ECG supplemental information

- Recommended ECG electrodes: Use a fluid-resistant, foam-backed electrode, such as 3M™ Red Dot™ Clear Plastic Monitoring Electrode 2235.
- KOSMOS uses single ECG filter from 0.65 Hz - 47.5 Hz.
- KOSMOS, with a fully charged battery, provides about two hours of continuous operation.
- The KOSMOS heart rate calculation is accurate to within Â±10% or Â±5/min, whichever is greater for regular heart rates in the specified range per 60601-2-27 Heart Rate Accuracy Requirement.
- KOSMOS heart rate range (adult): 30/min to 200/min.
- KOSMOS heart rate range (pediatric): 30/min to 250/min.
- Noise suppression: Right leg drive max. voltage 2.12Vrms.
- Method of heart rate (HR) averaging: Data is analyzed for R-wave peaks in approx 2.5 seconds sampling periods. If required, two sampling periods are combined to capture a minimum of three R-wave peaks. The HR is updated after every sampling period.

- KOSMOS provides the following sweep speeds: 20 mm/sec, 25 mm/sec, 35 mm/sec, and 50 mm/sec.
- When calculating heart rate, KOSMOS is capable of rejecting tall T-waves (as false QRS peaks) up to amplitudes that are up to 75% of QRS amplitude.

Ergonomics

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

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

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

- Take regular breaks.

Electromagnetic compatibility

	The System complies with the Electromagnetic Compatibility requirements of AS/NZ CISPR 11:2015 and EN IEC 60601-1-2:2014. However, electronic and mobile communications equipment may transmit electromagnetic energy through air and there is no guarantee that interference will not occur in a particular installation or environment. Interference may result in artifacts, distortion, or degradation of the ultrasound image. If the System is found to cause or respond to interference, try re-orienting the System or the affected device, or increasing the separation distance between the devices. Contact <hyperlink>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 Torso 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 <hyperlink>EchoNous 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 9-8 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 9-9 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.
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.

TABLE 9-9 Guidance and manufacturer's declaration: electromagnetic immunity

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
[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 9-9 Guidance and manufacturer's declaration: electromagnetic immunity

Radiated RF IEC 61000-4-3	3 V/m 80MHz 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separations distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be less than the compliance level in each frequency range[5]. Interference may occur in the vicinity of equipment marked with the following symbol. 

1 UT is the AC mains voltage prior to application of the test level
2 At 80MHz and 800 MHz, the higher frequency range applies
3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
4 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system.
5 Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.
6 Conducted RF energy may cause noise in the ECG waveform. If noise is detected on the ECG waveform, disconnect the system from AC power.

⚠	When using the optional mobile stand, the **System** can be susceptible to ESD and may require manual intervention. If ESD results in a **System** error, unplug the probe and plug back in to restore operation.
⚠	Conducted RF energy may cause noise in the ECG waveform. If noise is detected on the ECG waveform, disconnect KOSMOS from AC power.

Separation distances

TABLE 9-10 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
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=12.3\sqrt{P}$
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.

Intentional radiator

FCC Intentional Radiator Certification contains:

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

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

NO MODIFICATION: Modifications to KOSMOS shall not be made without the written consent of EchoNous, Inc. Unauthorized modifications may void the

authority granted under Federal Communications Commission rules permitting the operation of this device.

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

Class B device

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

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

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

Industry Canadian statement

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

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

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

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

Standards

HIPAA

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

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

45 CFR 164, Security and Privacy

DICOM

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

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CHAPTER 10

Specifications

System specifications

Kosmos Torso dimensions

Height: 150mm (excluding cable (the hard plastic housing length))

Width: 56mm

Depth: 35mm

Weight: 260 grams (with ferrite-equipped cable)

Cable dimensions: 1.8 meters

Kosmos Bridge dimensions

Height: 146mm

Width: 216mm

Depth: 59mm

Weight: 657 grams

Binaural headset

Length: 800mm

Width: 120mm

Depth: 25mm

Weight: 100 grams

ECG cable

Cable length: 860mm

Weight: 35 grams

Power supply

Length: 117.5mm

Width: 53.5mm

Depth: 34.2mm

Weight: 260 grams

DC cable dimension: 1 meter

Environmental operating and storage conditions

Kosmos Bridge and Kosmos Torso 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 Torso surface temperature before applying to a patient. A cold or hot surface may burn the patient.

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

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

Kosmos Bridge enforces scanning limits when using Kosmos Torso to maintain safe user enclosurecontact temperatures.

Power supply (charger)

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

Watts: 60

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

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

Internal batteries

Kosmos Bridge

Li-Ion main battery: 3.6V, 6.4 Ah

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

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

Battery life: A fully charged battery will provide ~2 hours of uninterrupted scanning

CHAPTER 11

IT Network

Wireless networking

Functions

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

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

Connection specifications

Hardware specification

802.11 a/b/g/n/ac, Bluetooth 4.2 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.

Network for connecting the device

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

Specifications for the connection

Hardware specification

802.11 a/b/g/n, Bluetooth 4.0

Software specifications

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

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

Security

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

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

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

- Port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112)
- Port 443 for encrypted traffic to HTTPS time/web servers
- Port 80 for HTTP web servers

Anti-virus software is not installed on this device.

IT network failure recovery measures

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

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

- Connection of equipment to an IT network that includes other systems could result in previously unidentified risks to patients, operators, or third parties. Before connecting the equipment to an uncontrolled IT Network, make sure that all potential risks resulting from such connections were identified and evaluated, and suitable countermeasures were put in place. IEC 80001-1:2010 provides guidance for addressing these risks.

- When a setting of the IT network to which KOSMOS is connected has been changed, check that the change does not affect it, and take measures, if necessary. Changes to the IT network include:
  - Changing the network configuration (IP address, router, and so on)
  - Connecting additional items
  - Disconnecting items
  - Updating equipment
  - Upgrading equipment
- Any changes to the IT network could introduce new risks requiring additional evaluation to be performed.

CHAPTER 12

Glossary

Term	Description
Annotation	Annotations are text notes, arrows, and/or measurements that a clinician may add to an image or clip. An annotation appears as an overlay on the image/clip.
Archive	After a report is generated, the patient information is updated in the hospital's EMR/PACS system. The device needs to have a secure connection for data transfer. Once an exam is archived, it cannot be edited. At this point, it is safe to purge the exam from KOSMOS to create more room for new studies.
Arrow	An arrow is an arrow icon that a clinician may put on a certain location of an image/clip to highlight something. This displays as an overlay on the image/clip.
Auscultation	Auscultation is listening to the internal sounds of the body, usually using a stethoscope, for the purpose of examining the circulatory and respiratory systems (heart and breath sounds) as well as the gastrointestinal system (bowel sounds).
BMI	Body mass index.
B-mode	The Kosmos Torso 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.

Term	Description
Clip	A clip is a short sequences of multiple frames like a movie.
CO	Cardiac output.
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.
DA	Digital auscultation.
DICOM	Digital Imaging and Communications in Medicine. DICOM is the most universal and fundamental standard in digital medical imaging. It's an all-encompassing data transfer, storage, and display protocol built and designed to cover all functional aspects of contemporary medicine. PACS functionality is DICOM driven.
ECG	Electrocardiogram. Electrocardiography is the process of recording the electrical activity of the heart over a period of time using electrodes placed over the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electro physiologic pattern of depolarizing and re-polarizing during each heartbeat.
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.
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.
PACS	Picture Archiving and Communication Systems. PACS refer to medical systems (hardware and software) built to run digital medical imaging. The main components of PACS include digital image acquisition devices, digital image archives, and workstations. The PACS settings in this document refer to the settings of connecting to digital image archives.
Physical coordinates	The position in the field of view expressed in terms of physical dimensions either in millimeters or radians with respect to a designated point of reference.
Picture	You can use the KOSMOS camera to take pictures of a wound or injury as part of the exam.
PIMS	Patient Information Management Systems.

Term	Description
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.
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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