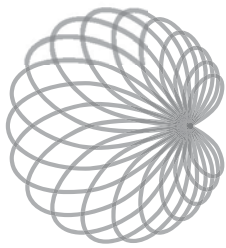


USER GUIDE



KOSMOS



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CHAPTER 1	Getting Started	1
	Package contents	1
	Intended users	2
	Intended use/indications for use	2
	<i>Contraindications</i>	3
	General warnings and cautions	3
	Symbols in this user guide	5
	User guide conventions	5
	Customer support	6
CHAPTER 2	KOSMOS Overview	7
	What is KOSMOS?	7
	KOSMOS clinical applications	7
	Training	8
	KOSMOS classifications	8
	Patient environment	9
	KOSMOS capabilities	9
	<i>Overview</i>	9
	<i>Using ultrasound, ECG, and DA signals simultaneously</i>	9
CHAPTER 3	Using KOSMOS	11
	Kosmos hardware	11
	<i>Kosmos Bridge</i>	11
	<i>Kosmos Torso</i>	12
	<i>KOSMOS power supply</i>	13
	<i>KOSMOS Bridge stand</i>	13
	<i>Kosmos ECG patient cable</i>	13
	<i>Binaural headset</i>	14
	Connecting Kosmos Torso	14
	Connecting the power supply	15
	Setting up the Kosmos Bridge stand	16
	Turning Kosmos Bridge on and off	16
	<i>Turning on Kosmos Bridge and Kosmos Torso</i>	16

Turning off Kosmos Bridge	17
General interaction	18
Home screen	18
Imaging screen: Ultrasound tab (B-mode)	19
Imaging screen: Three-signal tab	19
Ultrasound controls	20
On-screen keyboard	20
Understanding the different waveforms	21
ECG	21
DA	22
Configuring KOSMOS settings	23
Setting imaging preferences	23
Configuring ECG and DA signals	24
Setting the language, date, and time	24
Adjusting the volume	25
Setting brightness	25
Configuring administrator preferences	25
Managing security settings	25
Managing PACS archives	27
Installing software updates	29
Managing network and internet settings	30
Setting the sleep mode interval	30
Changing privacy settings	30
Viewing information about KOSMOS	31
Registering KOSMOS	31
Resetting KOSMOS to the factory settings	31
Wireless networking	32
Functions	32
Connection specifications	32

CHAPTER 4 **Incorporating ECG and DA Signals** **35**

Overview	35
ECG	35
DA	36
Benefits of using ECG and DA signals with ultrasound	36
Using the Kosmos ECG patient cable	37
Attaching the Kosmos binaural headset	39

Viewing the ECG and DA signals	40
<i>Signal scrolling</i>	40
<i>ECG signal indicator</i>	41
Preserving the ECG and DA signals when freezing an image or taking a clip	41
Archiving and exporting ECG and DA waveforms	41

CHAPTER 5 Performing an Exam 43

Overview	43
Exam workflows	44
<i>Recommended workflow</i>	44
<i>Quick workflow</i>	45
Managing exams	46
<i>Starting an exam</i>	46
<i>Searching for an exam</i>	46
<i>Deleting exams</i>	46
<i>Completing exams</i>	47
Managing patient data	47
<i>Adding a new patient</i>	47
<i>Searching for a patient</i>	47
<i>Changing to another patient</i>	48
<i>Editing a patient record</i>	48
<i>Merging two patient records</i>	48
<i>Deleting patient records</i>	49
Imaging modes	50
<i>B-mode</i>	50
<i>M-mode</i>	50
<i>Color-mode</i>	52
<i>Image mode controls</i>	54
Acquiring images and clips	55
Completing an exam	55

CHAPTER 6 Reviewing an Exam 57

Starting an exam review	57
Annotating images and clips	57

<i>Navigating to the Edit Image screen</i>	58
<i>Annotation tools</i>	59
<i>Measuring with the caliper tool</i>	59
<i>Deleting annotations</i>	60
Managing images and clips	61
<i>Filtering images and clips</i>	61
<i>Selecting images and clips</i>	62
<i>Trimming and saving images and clips</i>	62
<i>Deleting images and clips</i>	62
Reviewing and editing a report	63
<i>Opening a report</i>	63
<i>Editing a report</i>	63
Exporting images and clips to a USB drive	64
Completing an exam review	65
Archiving an exam to a PACS server	65
Deleting an exam	66

CHAPTER 7 **Kosmos Torso 69**

Kosmos Torso sheaths	69
Ultrasound transmission gels	70
Kosmos Torso storage	70
<i>Daily storage</i>	70
<i>Storage for transport</i>	70

CHAPTER 8 **KOSMOS Maintenance 71**

Cleaning and disinfecting	71
<i>General cautions</i>	71
<i>Kosmos Bridge</i>	72
<i>Kosmos Torso</i>	73
<i>Kosmos ECG patient cable</i>	77
<i>Binaural Headset</i>	79
Recycling and disposal	80
Troubleshooting	80
<i>Preventive inspection, maintenance, and calibration</i>	80

CHAPTER 9	Safety	83
	Electrical safety	83
	<i>References</i>	83
	Labeling symbols	84
	<i>Contact information</i>	89
	Biological safety	90
	<i>ALARA education program</i>	90
	<i>Acoustic output tables</i>	92
	<i>Measurement accuracy</i>	99
	<i>Control effects</i>	99
	<i>Related references</i>	99
	<i>Transducer surface temperature rise</i>	100
	<i>ECG supplemental information</i>	100
	Ergonomics	101
	Electromagnetic compatibility	102
	<i>Electromagnetic emissions</i>	103
	<i>Electromagnetic immunity</i>	104
	<i>Separation distances</i>	107
	<i>Intentional radiator</i>	107
	<i>Class B device</i>	108
	<i>Industry Canadian statement</i>	108
	Standards	109
	<i>HIPAA</i>	109
	<i>DICOM</i>	109

CHAPTER 10	Specifications	111
	System specifications	111
	<i>Kosmos Torso dimensions</i>	111
	<i>Kosmos Bridge dimensions</i>	111
	<i>Binaural headset</i>	111
	<i>ECG cable</i>	112
	<i>Power supply</i>	112
	Environmental operating and storage conditions	112
	<i>Operating, charging, transport, and storage condition ranges</i>	113
	<i>Mode of operation</i>	113
	<i>Power supply (charger)</i>	113

Internal batteries 114

CHAPTER 11 IT Network 115

Wireless networking 115

Functions 115

Connection specifications 115

Network for connecting the device 115

Specifications for the connection 116

Hardware specification 116

Software specifications 116

Security 116


IT network failure recovery measures 117

CHAPTER 12 Glossary 119

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.
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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:

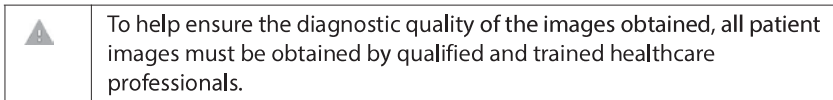
- KOSMOS User Guide
- KOSMOS Quick Start Guide
- KOSMOS UI Quick Guide
- ALARA education program (ISBN 1-932962-30-1, Medical Ultrasound Safety)
- “How To” and clinical videos
- Terms and conditions of warranty
- Manufacturer Disclosure Statement for Medical Device Security (MDS2)
- DICOM Conformance 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



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:

General warnings and cautions

- 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

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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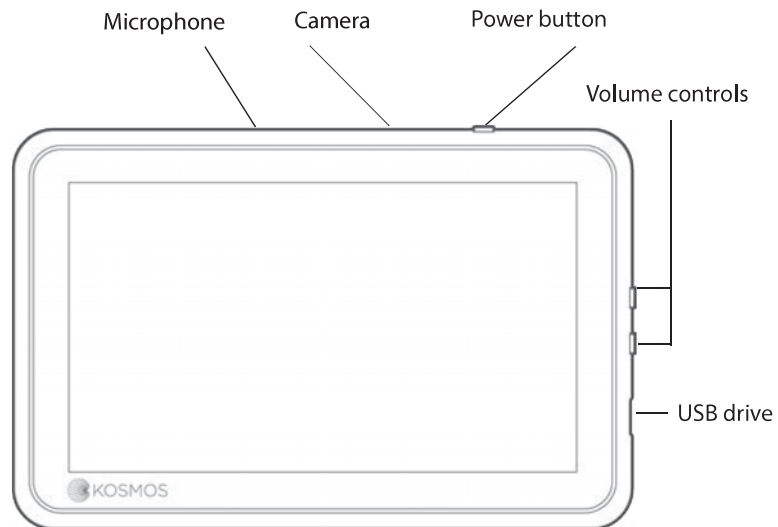
Using KOSMOS

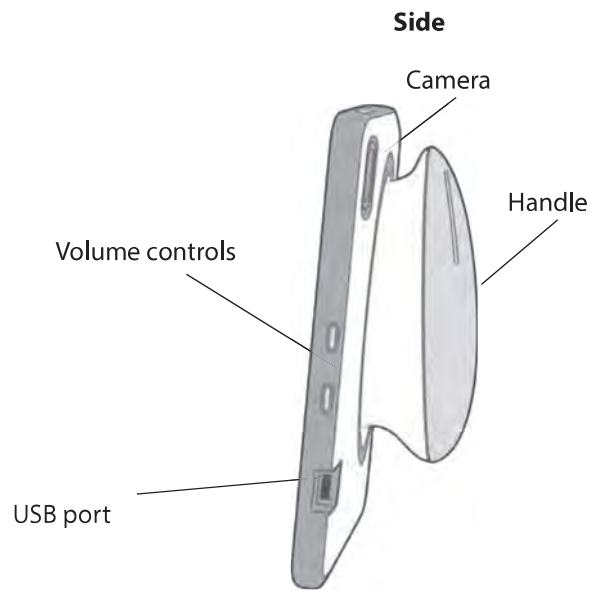
Kosmos hardware

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

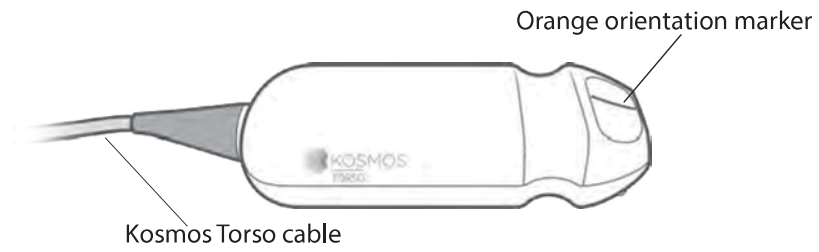
The following drawings point out the buttons and controls on Kosmos Bridge and Kosmos Torso.

Kosmos Bridge

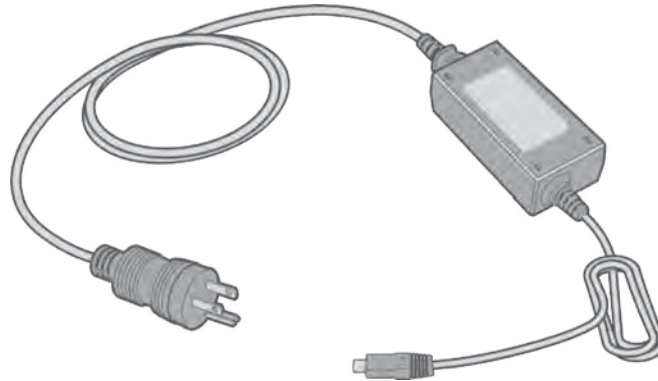




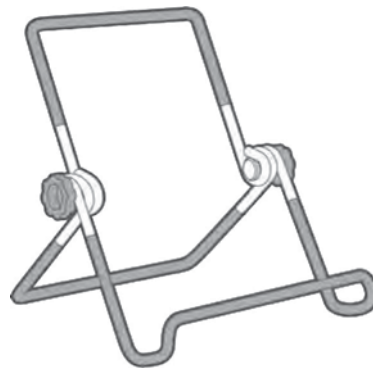
Kosmos Torso



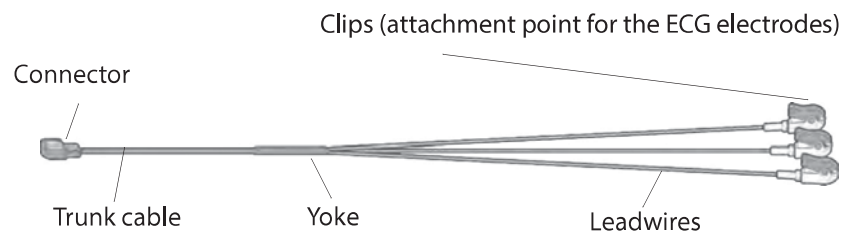
KOSMOS power supply



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).

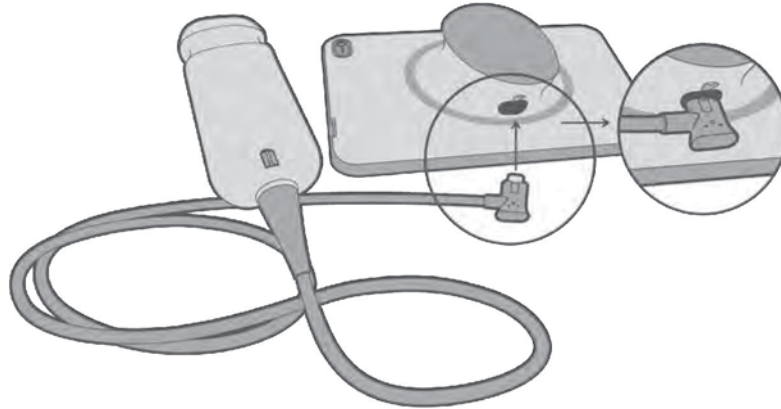
Connecting Kosmos Torso

⚠	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 EchoNous. 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.

	<ul style="list-style-type: none">• 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.
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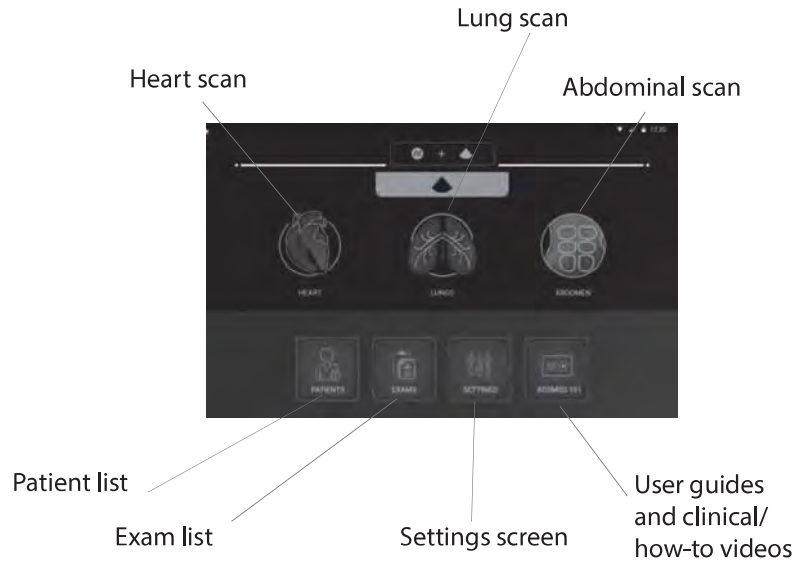
Turning off Kosmos Bridge

To turn off Kosmos Bridge:

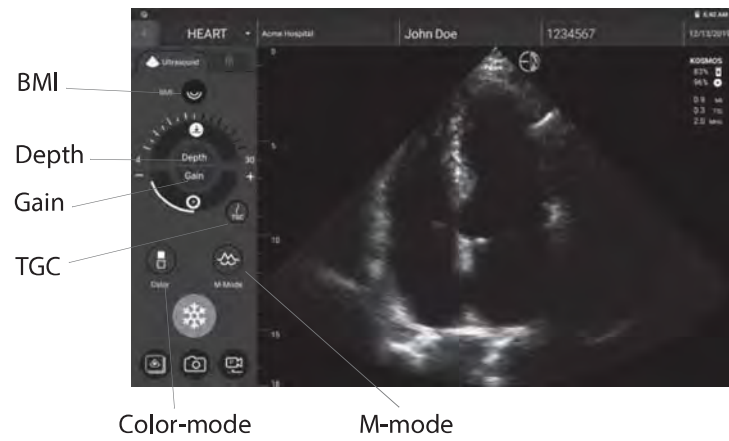
1. Press the **Power** button.
2. Do one of the following:
 - When prompted, tap **OK**.
 - Wait the few seconds for KOSMOS to turn itself off.

General interaction

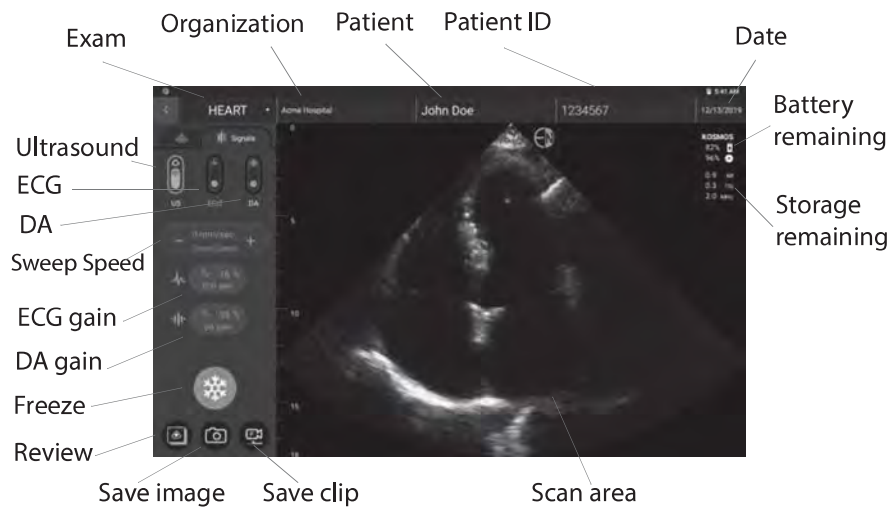
Home screen



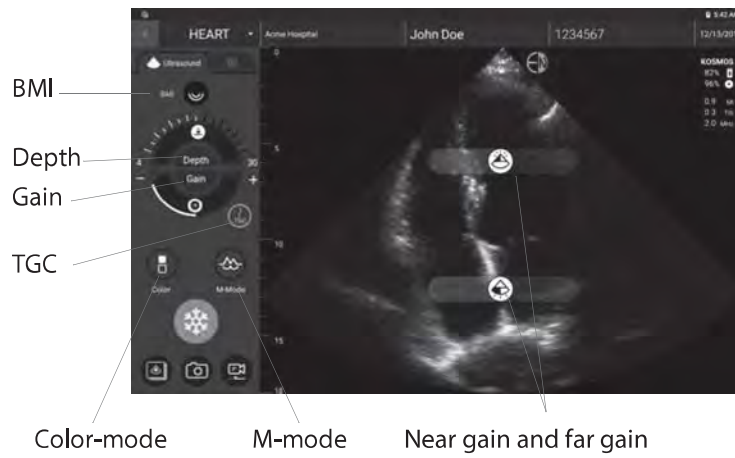
Imaging screen: Ultrasound tab (B-mode)



Imaging screen: Three-signal tab

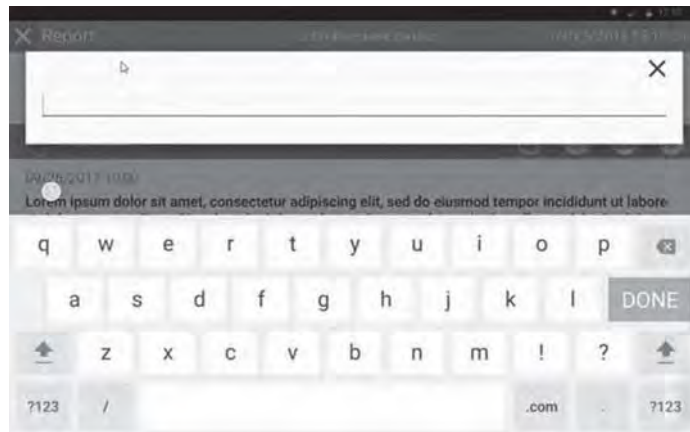


Ultrasound controls



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.

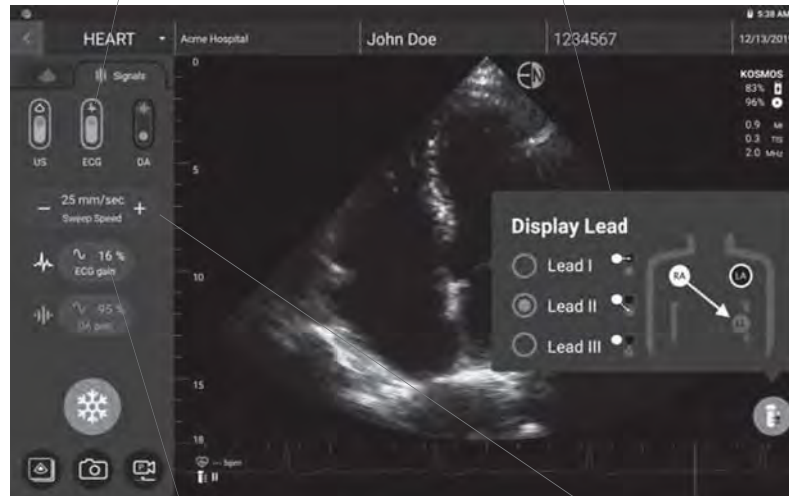


Understanding the different waveforms

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

	<ul style="list-style-type: none">• 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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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.

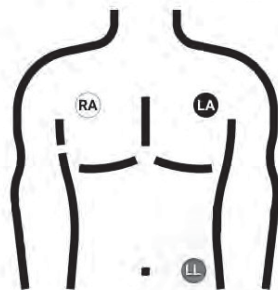
USA recommendation (American Heart Association):

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

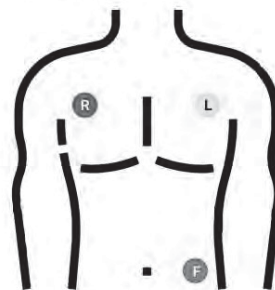
IEC recommendation:

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

ECG Electrode Placement Guide



AHA (American Heart Association)



IEC (International Electrotechnical Commission)

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

	<ul style="list-style-type: none"> When the Signal tab is inactive, it is grayed out. Just tap the Signal  icon to bring up the ultrasound controls.
	<ul style="list-style-type: none"> 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 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.

Performing an Exam

Overview

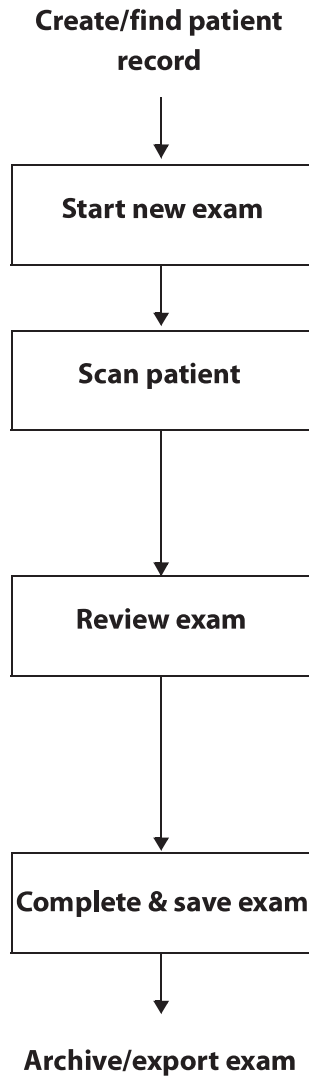
	Under certain circumstances, the Kosmos Bridge enclosure can reach temperatures that exceed safe (IEC 60601-1) limits for patient contact. Make sure that only the operator handles the system. Avoid placing Kosmos Bridge on the patient during use.
	The maximum temperature of the Kosmos Torso scan head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

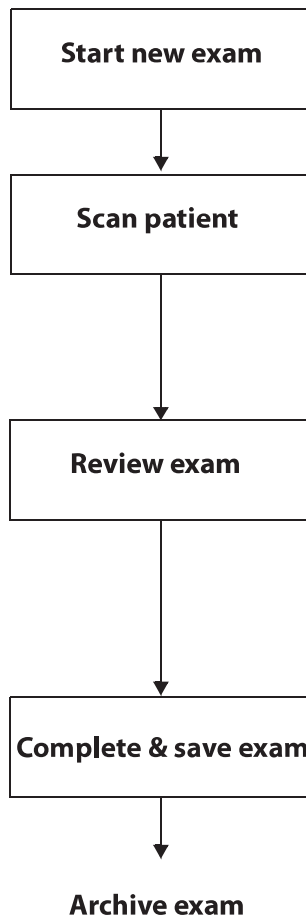
- Add and delete images and clips
- Add, edit, and delete annotations and notes

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

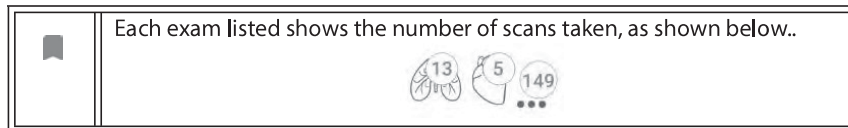
There are several ways you can start an exam:

- 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.




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 patients, tap **SEARCH HISTORY**, use the search tool to find the patient, and tap the patient name from the list.

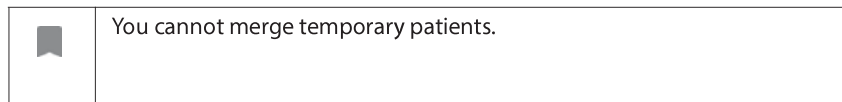
Editing a patient record

To edit a patient record:

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

Merging two patient records

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




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**.

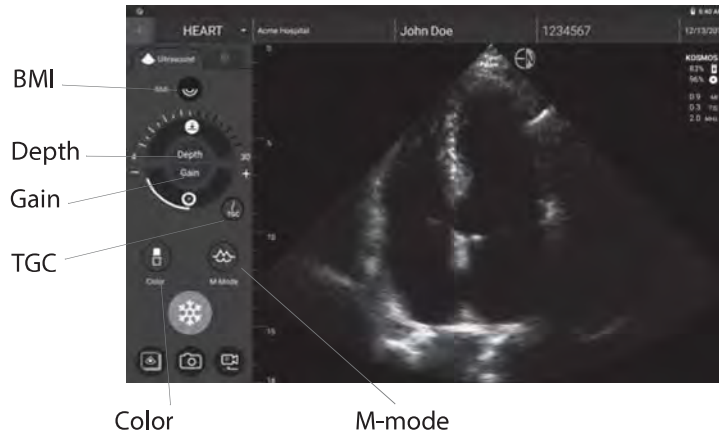
To delete selected patient records:

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

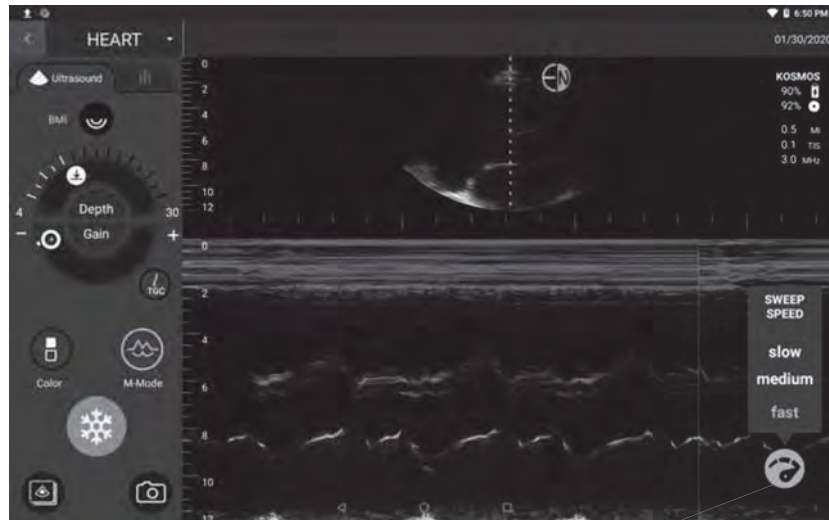
B-mode is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude.



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.



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

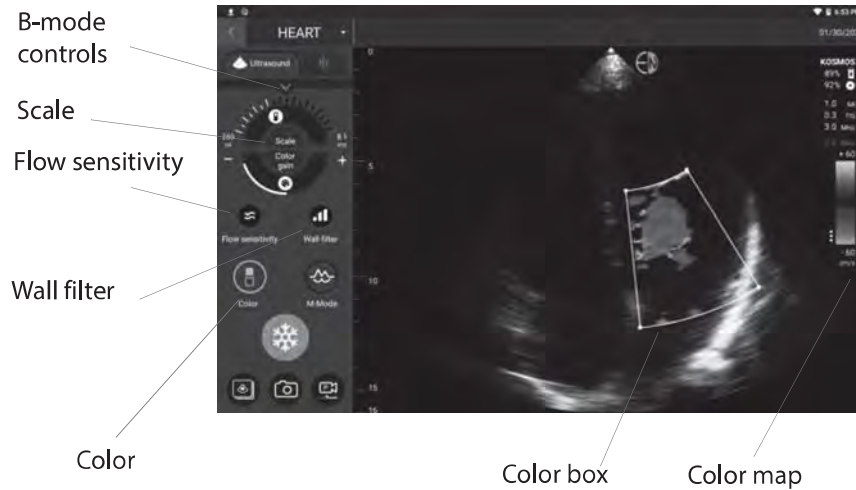
You can change the sweep speed to isolate individual motions.

- ★ 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

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**.