



User Manual

EchoNous Bladder

EchoNous Vein



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www.EchoNous.com

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1. IMPORTANT INFORMATION

About the user guide

This user guide is a reference tool for users of the EchoNous™ system; it does not constitute medical advice nor provide clinical training, instruction in exam protocols, or information on how to interpret scans.

This guide should be read before the system is used. The system is intended to be used in a medical facility.

Manual conventions

The following style conventions are used in this manual:

- Buttons found on your EchoNous system are indicated in bold italics, e.g., ***Scan button***. This style is also used to describe areas of the display touch screen, e.g., ***Image name***.
- “Tap” refers to touching the screen quickly with your finger.
- “Click” refers to pressing and releasing the button on the probe unit.
- “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 checkbox to enable the associated function.
- “Uncheck” refers to tapping a checkbox to disable the associated function.
- “Select” refers to tapping a menu item from a menu list.
- New terms that describe functions for the App are introduced in italics, e.g., *exam*.
- Numbered steps must be performed in a specific order.
- Bulleted items are lists in no specific order.
- Links to other sections within the manual appear colored and underlined, e.g., see [Contact information](#).

Version information

This user guide applies to the EchoNous system with software version V4.4.x

Warnings, cautions, and contraindications

A warning describes precautions a user should take to prevent injury or loss of life.

A caution describes precautions a user should take to prevent damage to the device.

A contraindication is a specific situation in which the device should not be used because it may be harmful to the patient.

Warnings, cautions and contraindications are included throughout this manual along with the content to which they apply. In addition all warnings and cautions are listed in the [Cautions, Warnings and Contraindications](#) (page 9).

Product Description

The **EchoNous System** consists of a display running **EchoNous System** software, connected to one or two ultrasound probes (Uscan probe, EchoNous Bladder™ probe, or EchoNous Vein™ probe) via cable. The system provides portable ultrasound imaging, in either hand-held or mobile stand scenarios. The system with its two probes has been designed to support the following clinical applications:

- Non invasive urological imaging
- General ultrasound imaging
- Vascular access procedures

The **System** generates and transmits ultrasound energy in the form of pulses in the 2 to 6MHz range for the Uscan and EchoNous Bladder probes and in the 6 to 14 MHz range for the EchoNous Vein probe into a patient, detects the reflected pulses, and processes the information in order to generate ultrasound images and measure anatomical structures.

The **EchoNous System** display is an off-the-shelf Android tablet approved, pre-configured, and supplied by EchoNous. The display is provided with a power supply. When the display is connected to an ultrasound probe, the combination is configured as a medical electrical system.

The **System** supports three ultrasound probes: the Uscan probe, the EchoNous Bladder probe, and the EchoNous Vein probe. The Uscan and EchoNous Bladder probes are to be used for non-invasive urological imaging and general ultrasound imaging whilst the EchoNous Vein probe is to be used for vascular access procedures.

The EchoNous Bladder™ transducer is self contained within the EchoNous Bladder probe. The Uscan probe contains a probe assembly attached to an ultrasound transducer. The transducer shall be referenced in this manual when the patient contact part of the probe and transducer is being described.

The EchoNous Vein™ transducer is self contained within the EchoNous Vein probe.

When equipped with a bladder probe, the **System** enables the user to automatically measure bladder volume with or without a brightness mode (B-mode) image for guidance ([Fig 1.1](#)). The **System** processes data in real-time, and when the user is not scanning in the correct location to detect a bladder, the display guides the user to the correct location, reducing measurement errors.

The user can elect to scan organs beside the bladder, including the kidney and prostate, with controls to change brightness and depth in this mode.

The **System** enables the user to perform Vascular Access procedures when connected to an EchoNous Vein probe.

Images are able to be annotated by using voice or text. Examination notes can be entered.

The **System** provides optional wireless connectivity allowing remote storage and device tracking.

Accessories for wireless printing, bar code scanning, and a mobile stand are supported and available in some countries.

The **EchoNous System** display and Uscan probe are battery powered.

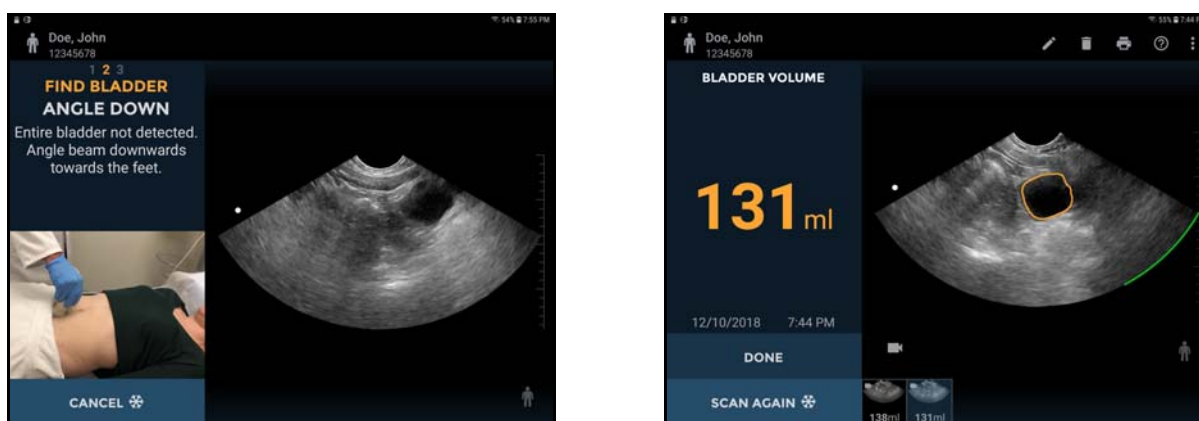


Fig 1.1 System User Interface and Display

Intended Uses

The **EchoNous System** is for non-invasive imaging of the human body and is intended for the following applications: Abdominal, Musculoskeletal, Pediatric, Small Organ, and Peripheral vessel. Users must have ultrasound training for abdominal, musculoskeletal, pediatric, small organ, and peripheral vessel imaging.

The **System** can also be used to obtain an image of the bladder that is used to automatically determine bladder volume.



Contraindications

- ✓ The **System** is designed for transcutaneous scanning only. Do not attempt intra-cavity imaging; in particular, trans-esophageal, trans-vaginal and trans-rectal scans are contraindicated.
- ✓ The **System** is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.



Cautions

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



Warning

- ✓ Show care when scanning near a wound to avoid damaging or further injuring the affected area.
- ✓ Review the ultrasound image when measuring bladder volume on pregnant or post-partum patients, and adjust the bladder outline if it has included amniotic fluid or the uterus in the measurement.

System and Transducer Applications

Table 1.1 EchoNous System Applications

Clinical Application		Mode of Operation	
General	Specific	B-mode	B-mode/ THI
Ophthalmic	Ophthalmic		
Fetal imaging & other	Fetal		
	Abdominal	✓	
	Intra-operative (specify)		
	Intra-operative (neuro)		
	Laparoscopic		
	Pediatric	✓	✓
	Small organ (specify)*	✓	
	Neonatal cephalic		
	Adult cephalic		
	Trans-rectal		
	Trans-vaginal		
	Trans-urethral		
	Trans-oesophageal (non-cardiac)		
	Musculoskeletal (conventional)	✓	
	Musculoskeletal (superficial)		
	Intravascular		
	Other (specify)		
Cardiac	Cardiac adult		
	Cardiac pediatric		
	Intravascular (cardiac)		
	Trans-esophageal (cardiac)		
	Intra-cardiac		
	Other (specify)		
Peripheral vessel	Peripheral vessel	✓	✓
	Other (specify)		

* Small organ use is prostate

Table 1.2 Applications for the Bladder Probes

Clinical Application		Mode of Operation	
General	Specific	B-mode	B-mode/ THI
Ophthalmic	Ophthalmic		
Fetal imaging & other	Fetal		
	Abdominal	✓	
	Intra-operative (specify)		
	Intra-operative (neuro)		
	Laparoscopic		
	Pediatric	✓	
	Small organ (specify)*	✓	
	Neonatal cephalic		
	Adult cephalic		
	Trans-rectal		
	Trans-vaginal		
	Trans-urethral		
	Trans-esophageal (non-cardiac)		
	Musculoskeletal (conventional)	✓	
	Musculoskeletal (superficial)		
	Intravascular		
	Other (specify)		
Cardiac	Cardiac adult		
	Cardiac pediatric		
	Intravascular (cardiac)		
	Trans-esophageal (cardiac)		
	Intra-cardiac		
	Other (specify)		
Peripheral vessel	Peripheral vessel		
	Other (specify)		

* Small organ use is prostate

Table 1.3 Applications for the EchoNous Vein Probe

Clinical Application		Mode of Operation	
General	Specific	B-mode	B-mode/ THI
Ophthalmic	Ophthalmic		
Fetal imaging & other	Fetal		
	Abdominal		
	Intra-operative (specify)		
	Intra-operative (neuro)		
	Laparoscopic		
	Pediatric	✓	✓
	Small organ (specify)*		
	Neonatal cephalic		
	Adult cephalic		
	Trans-rectal		
	Trans-vaginal		
	Trans-urethral		
	Trans-esophageal (non-cardiac)		
	Musculoskeletal (conventional)		
	Musculoskeletal (superficial)		
	Intravascular		
	Other (specify)		
Cardiac	Cardiac adult		
	Cardiac pediatric		
	Intravascular (cardiac)		
	Trans-esophageal (cardiac)		
	Intra-cardiac		
	Other (specify)		
Peripheral vessel	Peripheral vessel	✓	✓
	Other (specify)		

Training

The **EchoNous System** 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 your **EchoNous System** (see enclosed ISBN 1-93004 7-71-1, *Medical Ultrasound Safety*) 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.

For users measuring bladder volume an understanding of anatomy and location of the bladder is required. Ultrasound training is required if bladder outline adjustments are to be performed.

Users performing vascular access procedures must have appropriate training in ultrasound guided vascular access. Appropriate information on training may be obtained by contacting [EchoNous](#) or your local professional body.



Warning

- ✓ You must have appropriate ultrasound training before using the **System** for general ultrasound imaging or adjusting bladder measurement outlines.
- ✓ You must have ultrasound guided vascular access training before using the **System** for vascular access procedures.

Package Contents

The **EchoNous Bladder™ carton** contains the following:

- An EchoNous Bladder probe.
- 3 Quick Reference Guides.
- A USB Flash device containing:
 - The User Manual.
 - Training materials including:
 - A generic ALARA education program (see enclosed ISBN 1-93004 7-71-1, *Medical Ultrasound Safety*).
 - Terms and conditions of Warranty.
 - Quick Reference and Setup Guides.

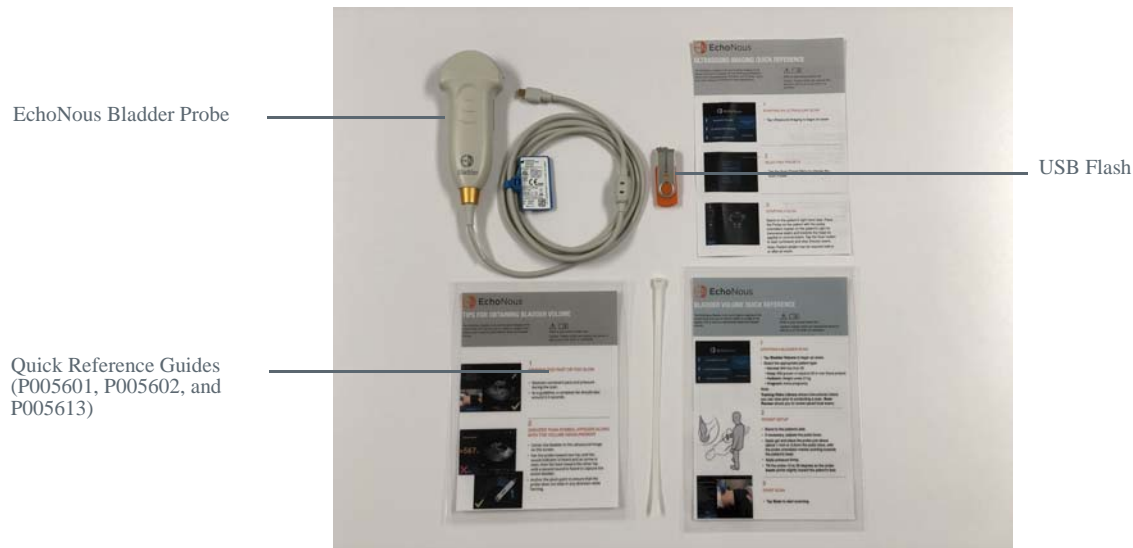


Fig 1.2 EchoNous Bladder probe package contents

The **Uscan Probe carton** contains the following:

- A Uscan probe with transducer.
- 2 Quick Reference Guides.
- An EchoNous power supply.
- A USB Flash device containing:
 - The User Manual.
 - Training materials including:
 - A generic ALARA education program (see enclosed ISBN 1-93004 7-71-1, *Medical Ultrasound Safety*).
 - Terms and conditions of Warranty.
 - Quick Reference and Setup Guides.



Fig 1.3 Uscan probe package contents

The **EchoNous Vein™ carton** contains the following:

- An EchoNous Vein probe with electronics box.
- Quick Reference Guide.
- A USB Flash device containing:
 - The User Manual.
 - Training materials including:
 - A generic ALARA education program (see enclosed ISBN 1-93004 7-71-1, *Medical Ultrasound Safety*).
 - Terms and conditions of Warranty.
 - Quick Reference and Setup Guides.



Fig 1.4 EchoNous Vein probe package contents

The **EchoNous Display carton** contains the following:

- A tablet (or handheld display) preconfigured with the **EchoNous System** software.
- A setup guide.



Fig 1.5 Uscan display package contents

System Features

The front of the **EchoNous** Samsung tablet display and probes are shown in [Fig 1.6](#).

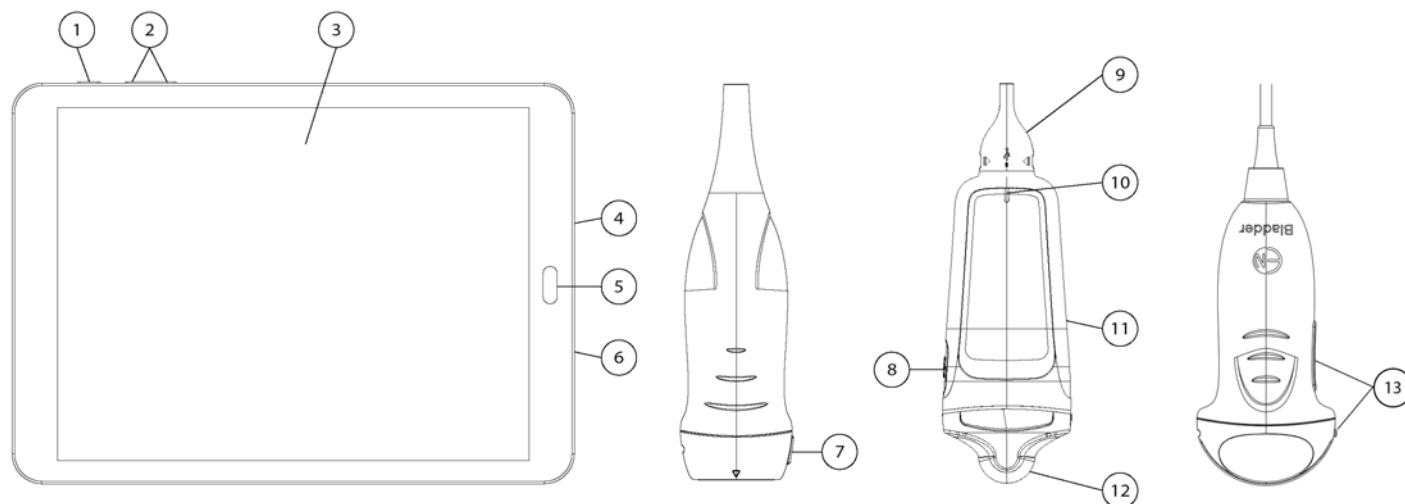


Fig 1.6 System Features

- | | |
|----------------------------|--|
| 1 Power on/off | 7 EchoNous Vein probe orientation marker |
| 2 Volume up/Volume down | 8 Uscan probe scan button and orientation marker |
| 3 Touch screen | 9 Uscan probe USB connector |
| 4 USB port | 10 Uscan probe power LED |
| 5 Home button | 11 Uscan probe over-mold |
| 6 Audio output/Audio input | 12 Uscan probe transducer |
| | 13 EchoNous Bladder probe orientation marker |

Camera for bar code scanning is on the rear of the display.

Classifications

The **System** is internally battery powered during scanning.

The EchoNous Power Supply P003198 classification for **Protection against electric shock: Class II equipment**.

The EchoNous Stand Power Supply P004016 classification for **Protection against electric shock: Class II equipment**.

The EchoNous Power Supply P005332 classification for **Protection against electric shock: Class II equipment**.

The EchoNous Type C Power Supply P005179 classification for **Protection against electric shock: Class II equipment**.

The Uscan probe is: **Type BF Applied Part**.

The EchoNous Bladder probe is: **Type BF Applied Part**.

The EchoNous Vein probe (P005134) is: **Type BF Applied Part**.

The Uscan probe is classified as **IPX1**.

The EchoNous Bladder probe is classified as **IPX4**.

The EchoNous Vein probe is classified as **IPX4**.

The **EchoNous System** is not for use within an oxygen rich environment.

Patient Environment

The **System** is intended to be used in a medical facility. It is battery powered and the user is expected to bring the system into the patient environment for use. Power supply connections for recharging are to remain outside the patient environment. See [Fig 1.7](#) for a drawing of the patient environment. When a power supply is connected, ensure the connection can be easily disconnected.

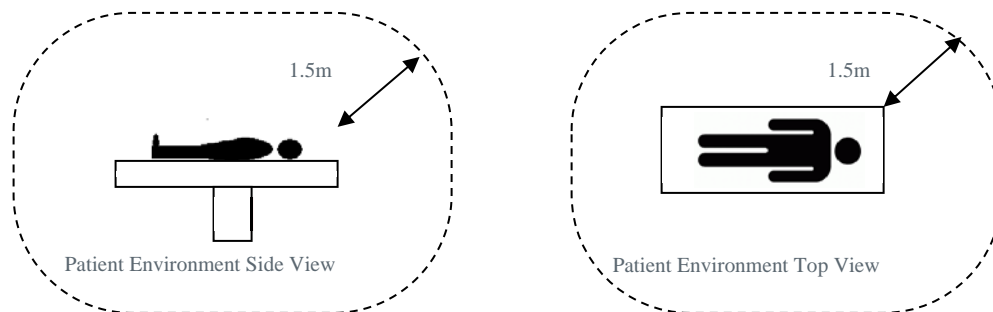


Fig 1.7 Patient Environment



Warning

- Equipment not suitable for use in the presence of a **FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE**.
- Do not use the **System** near high-frequency surgical equipment, as it could create a burn hazard.
- Do not recharge the **System** in the patient environment.



Caution

- Do not allow any fluid to enter the USB connector on the bladder probes or any connectors on the display.

If fluid is spilled on the bladder probe, display, or bladder probe cable, immediately remove the fluid with a soft dry cloth. Carefully inspect the bladder probe USB connector and display connectors for signs of fluid ingress. If there are any signs of fluid ingress or if the device exhibits any unusual behavior, do not use and contact [EchoNous](#) customer support or your EchoNous distributor immediately. If required, also follow the cleaning and disinfection instructions (see [Cleaning](#)).

Cautions, Warnings and Contraindications

To ensure the device is not damaged and user and patient safety is maintained, please read and follow the cautions and warnings below.



Warnings

- Show care when scanning near a wound to avoid damaging or further injuring the affected area.
- You must have appropriate ultrasound training before using the **System** for general ultrasound imaging or adjusting bladder measurement outlines.
- You must have appropriate ultrasound guided vascular access training before using the **System** for vascular access procedures.
- Review the ultrasound image when measuring bladder volume on pregnant or post-partum patients, and adjust the bladder outline if it has included amniotic fluid or the uterus in the measurement.
- Equipment not suitable for use in the presence of a **FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE**.
- Do not use the **System** near high-frequency surgical equipment, as it could create a burn hazard.
- Do not recharge the **System** in the patient environment.

- Recharge the **System** only with the Power Supplies (chargers) provided.
- The **EchoNous** Power Supplies are dedicated units to be used exclusively with the **EchoNous System** only.
- Only connect the Power Supplies to a mains supply rated at 100-240V and 50-60Hz.
- Do not use the device or Power Supply if there are signs of damage.
- Be aware of latex allergy. Some commercially available transducer covers contain latex.
- Check the connecting cable, connectors, and **System** housings before use for cracks or fraying. Do not use if damaged.
- No modification of this equipment is allowed.
- This device contains no user-serviceable parts. Please contact [EchoNous](#) customer support or your EchoNous distributor for maintenance or repair.
- The internal probe battery is not to be replaced by the user – doing so may create fire or explosion hazard.
- Remove all particles and other matter from crevices and surfaces when cleaning the **System** and components.
- The device is supplied unsterile.
- Clean and disinfect the patient-applied part between patients.
- Before cleaning or disinfection turn the **System** off and disconnect from the power supply.
- Do not submerge the Uscan probe, the display or the power supply (charger) as electric shock could result. The EchoNous Vein and EchoNous Bladder probes may be immersed 12mm (1/2 inch) from the cable strain relief for high level disinfection. The remainder of the probe is IPX4 which allows water splashing onto the probe. The Uscan probe is IPX1 which allows water falling vertically onto the probe. The display is IPX0 and has no protection against ingress of water.
- Clean and disinfect the **System** before placing in a bag for transport. Use the supplied EchoNous probe holder to store the probe. Clean and disinfect the probe holder regularly.
- After cleaning or disinfection examine the ultrasound probe and display as appropriate for cracks or leaks, and if damage exists discontinue use of the **System** and contact [EchoNous](#) customer support or your EchoNous distributor.
- The user must not touch any device connectors while in physical contact with the patient.
- The ultrasound probes are connected to the **EchoNous System** display running **EchoNous System** software to configure a medical system. The display has been certified by EchoNous as part of a medical system to EN IEC 60601-1: Edition 3.1.
- Do not connect the **EchoNous System** display to external computers or peripherals using the USB port unless the **System** is outside the patient area. Failure to comply with these guidelines may result in electric shock.
- Mounting the **EchoNous System** display on a mobile stand is configuring a medical system. Only use the EchoNous provided mobile stand accessory (P004013 or P005149).
- Only connect accessories that are specified as being compatible with the **EchoNous System**. Contact [EchoNous](#) customer support or your EchoNous distributor for information on compatible accessories and systems.
- If required, recharge the Uscan probe only with the EchoNous power supply (charger) provided (P003198).
- Do not open or modify the EchoNous Power Supplies (P003198, P005179) or any other supplied power supplies – Risk of electric shock
- Connecting electrical equipment to an (MSO) effectively leads to creating a medical electrical system, and can result in a reduced level of safety.
- MSOs (if provided with the medical electrical system) are to be used only for supplying power to the tablet display and optional printer in non-operating mode.
- Risk of shock or personal injury when connecting any equipment that has not been supplied as a part of the medical electrical system to the MSO.
- An additional MSO or extension cord shall not be connected to the medical electrical system.
- MSOs (if provided with the medical electrical system) shall only be used for supplying power to equipment that is intended to form part of the medical electrical system.
- Avoid any unnecessary strain on the mains power supply cord.
- When adjusting the height of the display unit on the EchoNous AI Station™ mobile stand, it is important to safely manage the DC power cord to avoid damage to the cord and risk of electric shock.
- Cord wrap must be installed as the lowest component on the AI Station Mobile Stand in order to protect the handle bar assembly against falling down into the caster base.

- When opening the collar handles for components on the AI Station Mobile Stand, it is important to support the component's weight to avoid damage or injury from falling components.
- After storage at extreme temperatures, check the transducer surface temperature before applying to a patient. A cold or hot surface may burn a patient.
- Avoid musculoskeletal strain with prolonged use of the **System**.
- Do not incinerate or discard the device in general waste at end of life. The lithium battery is a potential environmental and fire safety hazard.
- The **EchoNous System** complies with the requirements of EN IEC 60601-1 Edition 3.1. To avoid the risk of injury or electrical shock, comply with all safety instruction and warnings.
- The **EchoNous System** complies with the Electromagnetic Compatibility requirements of AS/NZ CISPR 11:2004 and EN IEC 60601-1-2:2014. However, electronic and mobile communications equipment may transmit electromagnetic energy through air and there is no guarantee that interference will not occur in a particular installation or environment. Interference may result in artifacts, distortion, or degradation of the ultrasound image. If the **System** is found to cause or respond to interference, try re-orienting the **System** or the affected device, or increasing the separation distance between the devices. Contact [EchoNous](#) customer support or your EchoNous distributor for further information.
- When using the optional mobile stand, the **EchoNous System** can be susceptible to ESD and may require manual intervention. If ESD results in an error, unplug the probe and plug back in to restore operation.
- The ALARA principle (As Low As Reasonably Achievable) should be employed for all medical ultrasound exposure.



Cautions








- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Ultrasound transducer crystals are fragile and are easily damaged if knocked, dropped or excessively vibrated.
- Avoid unnecessary bending or winding of the connecting cable.
- The **EchoNous System** display and **Uscan** probe batteries should be charged every six months at a minimum, even if you are not using your device. When storing for greater than 3 days, store at ambient or cooler temperature.
- Use only recommended disinfection methods.
- Use abrasive cleaners, isopropyl alcohol or solvents sparingly, and if used immediately clean and remove residual substances from the **System**.
- Do not heat sterilize any part of the **System**.
- Minimize application of alcohol based disinfectant to colored overmold materials. Long term use may result in material degradation. If alcohol based disinfectant is applied to the overmold, immediately remove by wiping with a damp cloth.
- Only operate, charge and store the **System** within the approved environmental parameters.
- The **System** contains sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the **System**. Any faults should be reported to [EchoNous](#) customer support or your EchoNous distributor for repair.















Contraindications

- The **System** is designed for transcutaneous scanning only. Do not attempt intra-cavity imaging; in particular, trans-esophageal, trans-vaginal and trans-rectal scans are contraindicated.
- The **System** is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Labeling

Symbol	EchoNous Description	SDO Title, Ref. No., 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
	UL Classified. Medical - General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES 60601-1 (2005) + AMD (2012) / CAN/CSA-C22.2 No. 6060-1 (2008) + (2014). E509516 Medical - Refurbished general medical equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES 60601-1 (2005) + AMD (2012) / CAN/CSA-C22.2 No. 6060-1 (2008) + (2014). E509516	None
	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
	Type BF applied part (BF = body floating)	Type BF Applied Part Ref. No. D.1-20 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	Consult instructions for use for important cautionary information such as warnings and precautions	Caution Ref. No. D.1-10 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Symbol	EchoNous Description	SDO Title, Ref. No., Standard
	Multiple socket outlet is marked with this safety sign and is visible in normal use (used in accordance with IEC 60601-1, Cl. 16.9.2.1)	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
IPX1	The probe is protected against effects of vertically falling water	IP Code for degree of protection IEC 60529 Degrees of protection provided by enclosures (IP Code)
IPX4	The probe is protected from splashing water, no matter the direction	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

Symbol	EchoNous Description	SDO Title, Ref. No., Standard
	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
	Scan button (cross-references scanning control button on probe to instructions in User Manual)	None
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or any other practitioner licensed by law of the State in which he practices to use or order the device	FDA Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements
	Equipment mass including safe working load XXX indicates specified weight (used in accordance with IEC 60601-1, Cl. 7.2.21)	None

Contact information

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2. GETTING STARTED

Unpacking the Boxes

Your **EchoNous System** is shipped in multiple boxes. Be careful not to insert anything sharp through the top of the boxes when opening. Check that you have received all of the ordered components:

- An **EchoNous System** display (with pre-installed **EchoNous System** software), associated power supply, probe connection cable, protective cover (HP tablet and mobile display only), and setup guide.
- A **Uscan** probe with EchoNous power supply, USB Flash drive, and quick reference guides.
 - And/or
- An **EchoNous Bladder** probe with USB Flash drive and quick reference guides.
 - And/or
- An **EchoNous Vein** probe, cable, USB Flash drive, and quick reference guide.

Options

- Wireless printer (Citizen Systems Model CMP-20BTU and CMP-20IIBTIUC). Not available with EchoNous AI Station Mobile Stand. Not for use in patient area.
- Wireless barcode scanner (not available in all countries. Contact [EchoNous](#) customer support or your EchoNous distributor for recommended scanners).
- Signostics Mobile Stand (P004013) with EchoNous power supply and probe connection cable.
- AI Station Mobile Stand (P005149) with EchoNous power supply and probe connection cable.

If any parts are missing or damaged then contact EchoNous customer support or your EchoNous distributor as soon as possible.

Connecting and disconnecting the Power Supply

You should fully charge the display and Uscan probe before using them for the first time (see [Fig 2.1](#)).



Warning

- ✓ Recharge the **System** only with the Power Supplies (chargers) provided.
- ✓ The **EchoNous** Power Supply is a dedicated unit to be used exclusively with the **EchoNous System** only.
- ✓ Only connect the Power Supplies to a mains supply rated at 100-240V and 50-60Hz.
- ✓ Do not use the device or Power Supply if there are signs of damage.

Recharge the display using the power supply provided with the display. The first generation display connector is magnetic and can only be connected in one orientation.

The **Uscan** probe contains an internal rechargeable battery. The probe can be directly charged using the Power Supply (P003198) as shown in [Fig 2.1](#). If the Uscan probe is connected to the HP tablet display, and the tablet display is plugged into its power supply, both the display and ultrasound probe batteries are recharged together. The Samsung tablet display does not have separate charging and USB ports, so concurrent charging is not possible.

If required, recharge the Uscan probe using the EchoNous Power Supply (P003198) (see [Fig 2.1](#)). To disconnect all mains voltages from the equipment remove the display power supply connection and (if applicable) the probe power supply connection.

Setting up the System

Two optional mobile stands are available. To setup the system with an optional mobile stand, refer to [Mobile Stand Setup](#). To configure the **System** for mobile use, follow the instructions below (and see [Fig 2.2](#)):

1. Press and hold the **Power button** for 2 seconds to turn the **EchoNous** Display on.
2. The application setup wizard will run. Setup the following:
 - 2.1 Language.
 - 2.2 Date and time.
 - 2.3 Wi-Fi connectivity.
 - 2.4 Probe selection (Samsung tablet only).
 - 2.5 Registration information.



Fig 2.1 Power Supply Connections (HP Tablet shown)

3. Insert the display into the cover (HP tablet only).
4. Insert the USB cable into the display.
5. Secure the cable in the provided cable clip (HP tablet only).
6. Insert the other end of the cable into the **Uscan** probe (**Uscan** probe only).
7. Connect the provided display charger to the display and fully charge the **System**.

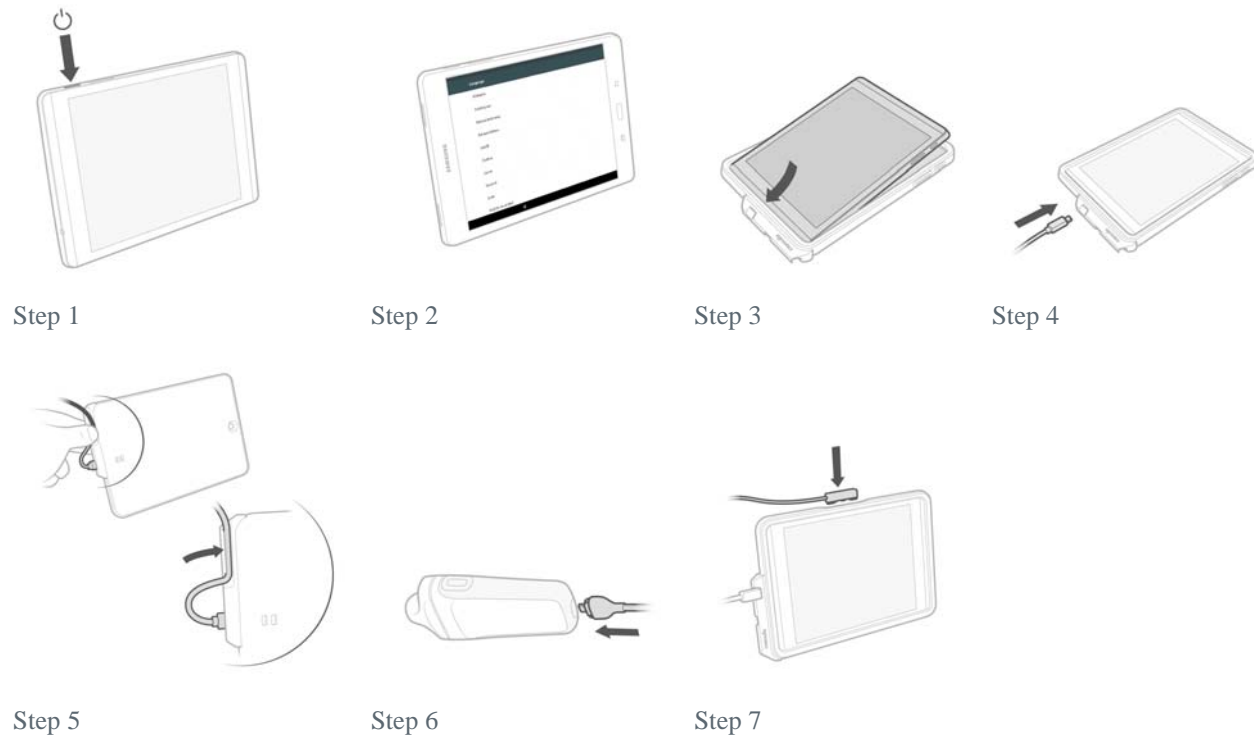


Fig 2.2 Display setup

After setup, the Home screen is displayed (see [Fig 2.2](#)) and the device is ready to use with default settings. The default settings are appropriate where there is a single user of the **System** and patient data is not saved to remote servers. The **System** can be further customized by setting preferences (see [Settings](#)).

Basic Device Control

The **System** communicates with the user in a number of ways.

- Menus
- Screens and windows
- Message boxes
- Icons

Navigate by using the touch screen, using common control gestures such as tap, drag, pinch, spread, and swipe.

The system controls and status are shown in [Fig 2.3](#).

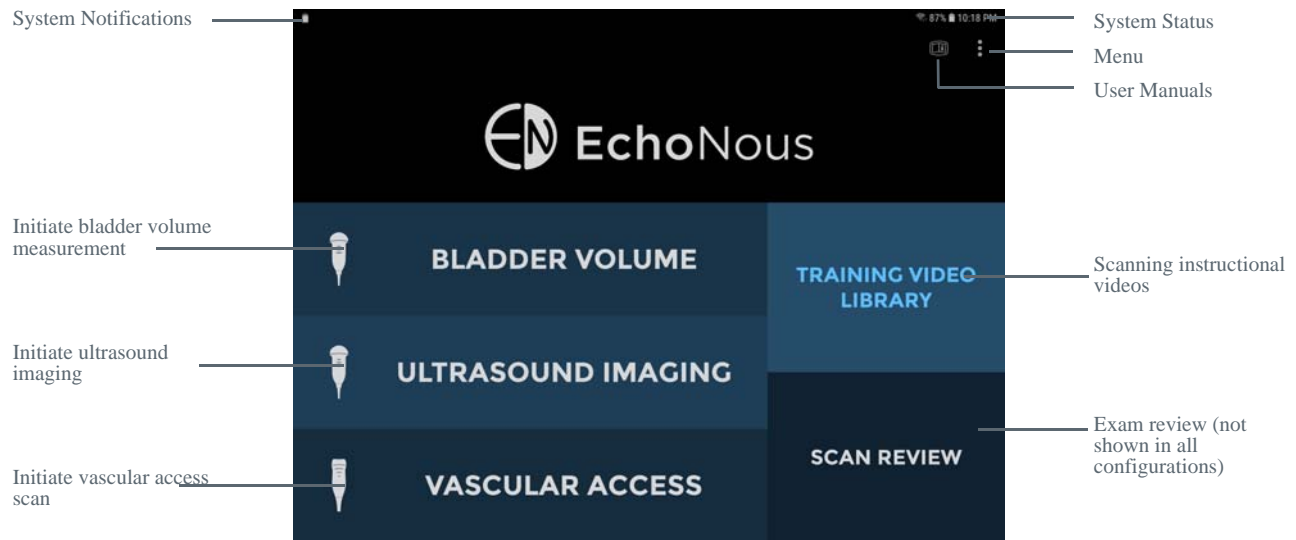


Fig 2.3 Home Screen

System Controls

Three system controls are always available at the bottom of the screen:

- **Back** – tap to return to a previous screen.
- **Home** – tap to return to the *Home screen*.
- **Tasks** – tap to display background tasks (this should not be used except by administrators or service staff).

System Status Icons

System status icons are shown at the top right of the screen:

- Tablet battery status.
- Wi-Fi status.
- Bluetooth status (used for wireless printing and bar code scanning).
- Location services – The device GPS is active and transmitting.

System Notification Icons

System notification icons are shown at the top left of the screen:

- Uscan probe battery status.
- **EchoNous System** software notification.
- The remote Device Manager has located the device.

Uscan Menu

Tap to go to the menu. The following menu items are available:

- **Settings** – provides access to all **EchoNous System** application and tablet system settings.
- **About** – displays the software version number and license keys.

Settings


To setup or change preferences or tablet system settings, tap from the Home screen and select **Settings**. The following preferences can be configured:

- **Exam Data Storage** – tap to see storage preference
 - **Local Storage** – check to automatically store patients and images on the tablet internal storage.
 - **Remote Storage** – check to automatically store patients and images to a remote server.
 - Remote Server – Select the type of remote server. Some options will only be displayed if the applicable license has been purchased and installed (see [Advanced Device and IT Setup](#)).
 - **Patient Data** – select the source for patient lists (see [Advanced Device and IT Setup](#)).

- **Exam Patient Details** – check to force users to enter patient information before starting a scan.
- **Send Anonymized Data to EchoNous** – check to send anonymized images to EchoNous to enable future product improvements. Check with your institution’s data policies or legal department before enabling this option.
- **Send data over metered connection** - check to allow data to be sent when connected to a metered (cellular) connection.
- **Organization** – tap to update registration details including organization name and address. These details are transferred to EchoNous when a network connection is available.
- **Printing** – select the Printer Type to None, Network Printer (see [Network Printer Setup \(Optional\)](#)), or Bluetooth Mobile Printer (see [Bluetooth Printer Setup \(Optional\)](#)).
- **Display** – tap to see display preferences
 - **Show Organization and Transducer Frequency** – check to display the Organization and transducer center frequency on the ultrasound image.
 - **Ruler** – check to display a cm ruler down the right side of the ultrasound screen.
 - **Hide home screen Ultrasound Imaging button** – check to remove the Ultrasound Imaging button from the home screen.
 - **Hide home screen Vascular Access button** – check to remove the disabled Vascular Access button from the home screen. If the EchoNous Vein probe was enabled during initial setup, this setting will have no effect.
- **Bladder Volume** – tap to see bladder volume preferences
 - **Default Patient Type** – tap to change the default patient type (Normal, Pediatric, Deep, Pregnant, Phantom, “Use last selected value”, or “Ask each time”).
 - **Strict Probe Positioning Rules** - check to prevent fanning for bladder volume scans unless the bladder or pubic bone is detected.
- **Vascular Access** – tap to see vascular access preferences
 - **Default Patient Type** – tap to change the default patient type (Adult, Pediatric, “Use last selected value”, or “Ask each time”).
- **Administration** – Refer to [Advanced Device and IT Setup](#) section for advanced user management and setting up several devices with the same preferences.
- **Maintenance** – provides maintenance related functionality including access to software updates.
- **System Settings** – provides access to tablet system settings, including Wi-Fi, Bluetooth, Display settings, Location services, linked accounts for device tracking, Language, and Date & time.

Network Printer Setup (Optional)

Network printing enables the Mopria Print Service. The Mopria Print Service enables printing to Mopria certified multifunction printers from many manufacturers which are on a connected WiFi network (see www.mopria.org). Follow the instructions below to setup network printing:

- Tap  **Menu** and select **Settings**.
- Tap **System Settings** then tap on **Connections**.
- Tap on **More connection settings**
- Tap on **Printing**.
- Tap **Mopria Print Service**.

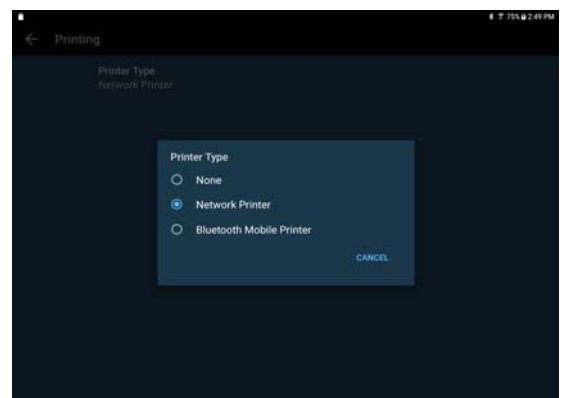






Fig 2.4 Printer Type

- Slide the on-screen button to the right  to turn *Mopria Printing* on.
- Tap *Home*  to return to *the Home Screen*.
- Tap  *Menu* and select *Settings*.
- Tap *Printing*.
- Tap *Printer Type* and select *Network Printing*.
- Tap *Home*  to return to the *Home Screen*.
- A printer icon will be shown on all bladder and ultrasound images when Network Printing is selected.

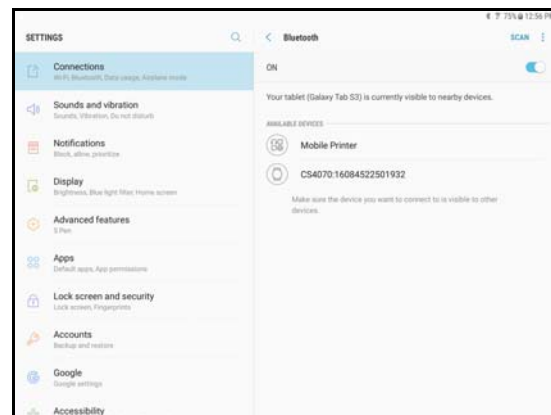







Fig 2.5 Bluetooth Pairing

Bluetooth Printer Setup (Optional)

An optional Bluetooth printer is available. Turn the wireless printer on and then follow the instructions below to setup the printer:

- From the *Home Screen* tap  *Menu* and select *Settings*. Tap *System Settings*. Tap *Bluetooth*.
- Slide the on-screen button to the right  to turn Bluetooth on.
- Select *Mobile Printer* to pair it with the system (see [Fig 2.5](#)).
- Tap *Home*  to return to *the Home Screen*.
- Tap  *Menu* and select *Settings*.
- Tap *Printing*. Tap *Printer Type* and select *Bluetooth Mobile Printer*. Tap *Bluetooth Printer*.
- Select the paired printer from the list (see [Fig 2.6](#)).
- Tap *Home*  to return to *the Home Screen*.

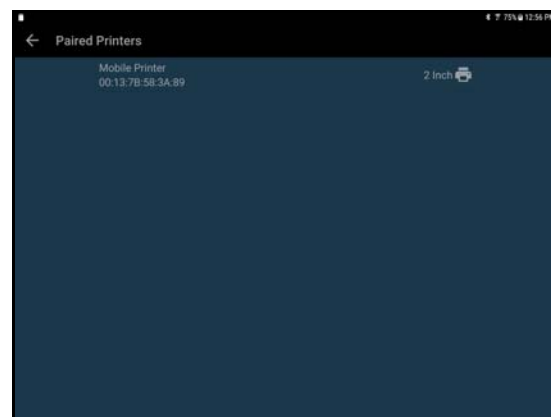





Fig 2.6 Bluetooth Printer setup

Bar Code Scanner Setup (Optional)

An optional wireless bar code scanner is supported in some countries. Bar code scanning using the device camera is also supported. To setup the wireless bar code scanner turn the bar code scanner on and follow the instructions below:

- From the *Home Screen* tap  *Menu*, select *Settings*, and select *System Settings*.
- Tap *Bluetooth*.
- Slide the on-screen button to the right  to turn Bluetooth on.
- Select the bar code scanner to pair it with the system.
- Tap *Home*  to return to *the Home Screen*.

Imaging Screens

Ultrasound Imaging Screens

Tap *Ultrasound Imaging* on the *Home Screen* to start an ultrasound exam. See [Fig 2.7](#) for ultrasound screen layouts.

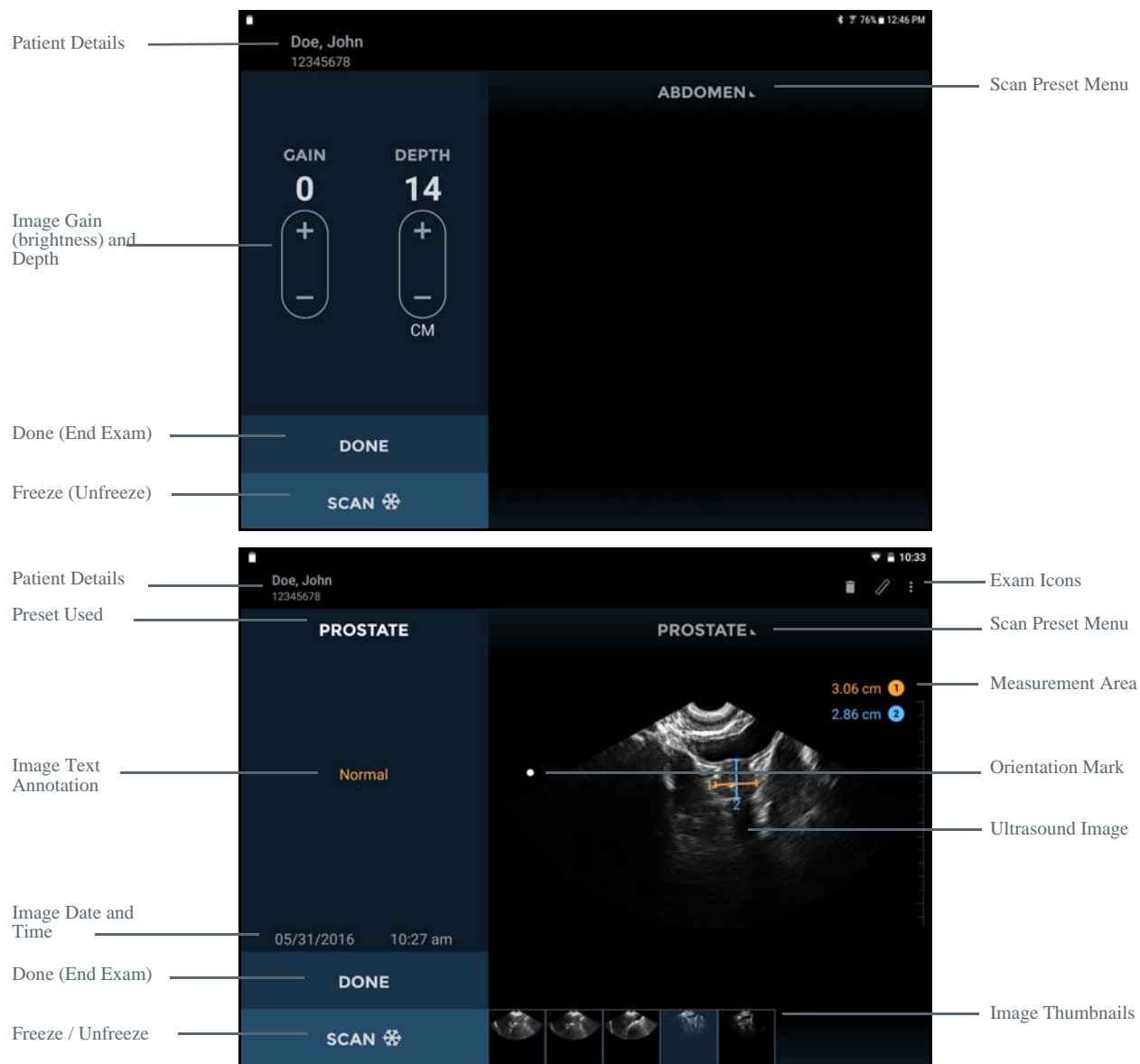


Fig 2.7 Ultrasound Imaging Screens

The ultrasound imaging screen layouts contain the following areas:

- **Patient Details** – displays patient details for the current exam. Tap to change the patient associated with the exam.
- **Preset Used** – displays the scan preset used for the current image.
- **Image Text Annotation** – displays the text annotation for the image.
- **Image Date and Time** – displays the date and time of the image.
- **Gain and Depth Controls** – adjust the gain (brightness) or the depth for the system.
- **Orientation Mark** – corresponds to the orientation marker on the probe
- **Done** – tap to end and save the exam.
- **Scan / Stop** – tap to start (unfreeze) and stop (freeze) scans.
- **Exam Icons** – are displayed depending on the context of the exam. Icons include help, print, measure, movie, delete, and a menu to access other functions (Annotations, Notes). Tap to activate the function associated with the icon.
- **Scan Preset Menu** – tap to change to a different scan preset.
- **Measurement Area** – area for displaying caliper and volume measurements.
- **Ultrasound Image** – area for displaying ultrasound images.
- **Image Thumbnails** – will be displayed for multiple images in an exam. Tap a thumbnail to view an image.



Probe Orientation Markers

Bladder Volume Screens

Tap **Bladder Volume** on the *Home screen* to start a bladder measurement. See [Fig 2.8](#) for bladder screen layouts.

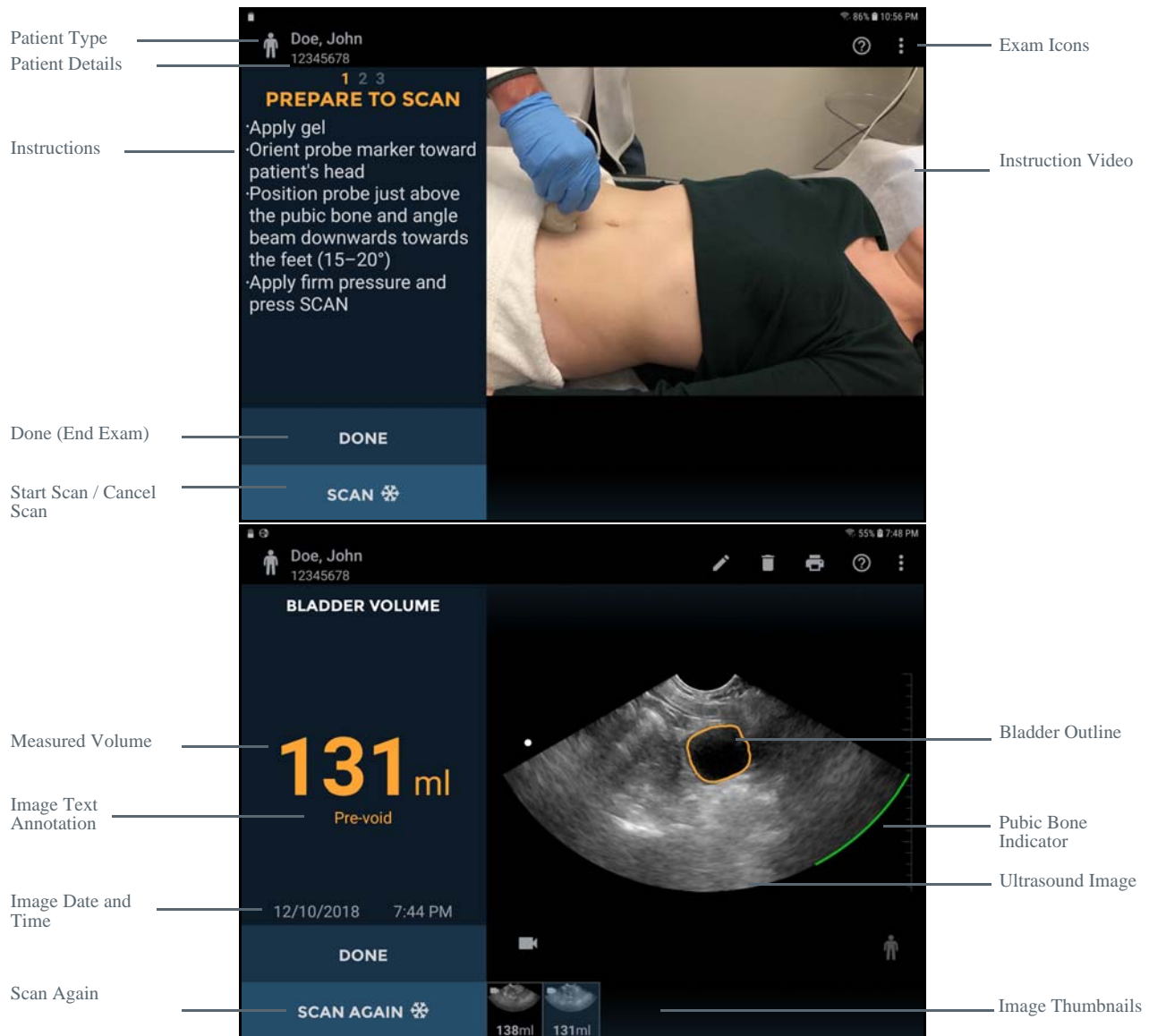


Fig 2.8 Bladder Scan Screens

The bladder screen layouts contain the following areas:

- **Patient Type** – tap to change the patient type (normal, pediatric, deep, pregnant).
- **Patient Details** – displays patient details for the current exam.
- **Instructions** – instructions of current step required for bladder measurement.
- **Instruction Video** – video showing how to perform a bladder measurement.
- **Done** – tap to end and save the exam.
- **Scan / Cancel** – tap to start a bladder volume measurement or to cancel a scan in progress.
- **Scan Again** – tap to start another bladder volume measurement.
- **Orientation Mark** – corresponds to the orientation marker on the probe.
- **Measured Volume** – measured volume in milliliters.
- **Image Text Annotation** – displays the text annotation for the image.
- **Image Date and Time** – displays the date and time of the image.
- **Exam Icons** – are displayed depending on the context of the exam. Tap to activate the function associated with the icon.
- **Ultrasound Image** – area for displaying ultrasound images.



Probe Orientation Markers

- **Bladder Outline** – indicates the area where the bladder has been detected and outlined.
- **Pubic Bone Indicator** – indicates the area where pubic bone has been detected.
- **Image Thumbnails** – will be displayed for multiple images in an exam. Tap a thumbnail to view an image.

Vascular Access Screens

Tap **Vascular Access** on the **Home screen** to start a Vascular Access exam. See [Fig 2.9](#) for vascular access screen layouts.

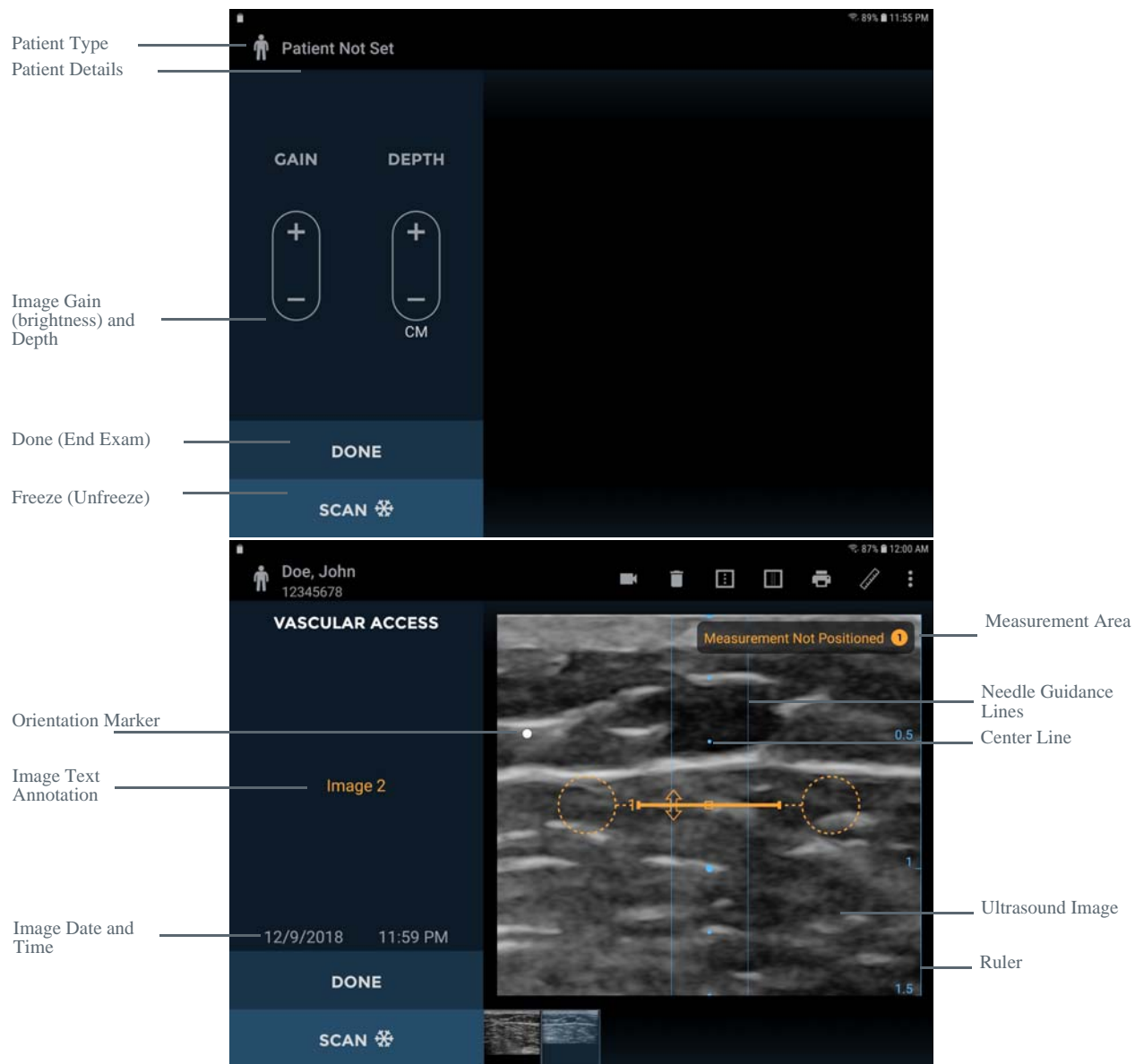





Fig 2.9 Vascular Access Screens

The vascular access screen layouts contain the following areas:

- **Patient Details** – displays patient details for the current exam.
- **Image Text Annotation** – displays the text annotation for the image.
- **Image Date and Time** – displays the date and time of the image.
- **Gain and Depth Controls** – adjust the gain (brightness) or the depth for the system.
- **Orientation Marker** – corresponds to the probe orientation marker .
- **Done** – tap to end and save the exam.
- **Scan / Stop** – tap to start (unfreeze) and stop (freeze) scans.

- **Exam Icons** – are displayed depending on the context of the exam. Icons include help, print, measure, movie, delete, toggling the center line, toggling the needle guidance lines, and a menu to access other functions (Annotations, Notes). Tap to activate the function associated with the icon.
- **Measurement Area** – area for displaying caliper measurements.
- **Ultrasound Image** – area for displaying ultrasound images.
- **Ruler** – indicates the scan depth in cm.
- **Center Line** – indication of the probe center line. Can be toggled by tapping the  icon.
- **Needle Guidance Lines** – guidance lines for needle insertion. Can be toggled by tapping the  icon.
- **Image Thumbnails** – will be displayed for multiple images in an exam. Tap a thumbnail to view an image.

Recommended ultrasound transmission gel

EchoNous recommends the use of Aquasonic 100 Ultrasound Transmission Gel manufactured by Parker Laboratories, INC. Fairfield, New Jersey 07004.

Recommended ultrasound probe sterile sheaths

Where fluid contamination is possible, the ultrasound probe shall be covered with an appropriate sterile sheath, which will promote asepsis and minimize cleaning. Refer to [EchoNous](#) website for a list of compatible probe covers in your country.



Warning

- ✓ Be aware of latex allergy. Some commercially available transducer covers contain latex.

3. SCANNING



Warning

- ✓ Check the connecting cable, connectors, and system housings before use for cracks or fraying. Do not use if damaged.
- ✓ Do not connect to the Power Supplies and AC outlets when the **System** is in the patient environment.

Preparing for the Exam

Before scanning, check you have access to everything you need and the device is ready to scan as follows:

- The **tablet display** is powered on and has battery charge available to scan (the display battery icons shows charge).
- The **ultrasound transducer** has been cleaned or disinfected as appropriate (See [Probe cleaning and disinfection](#)).
- You have suitable ultrasound transmission gel available.
- The patient is positioned appropriately.

Default Settings

Press the **Power button** to power up the **System**. Adjustable settings cannot increase acoustic output, ensuring the device always operates within safe acoustic output levels. The **Home screen** appears when the device is on ([Fig 3.1](#)), with up to five tiles:

- Tap **Bladder Volume** to perform a bladder volume examination. This option is only available when connected to a bladder probe.
- Tap **Ultrasound Imaging** to perform a general ultrasound examination. Choose the appropriate **scan preset** from the list. This option is only available when connected to a bladder probe.
- Tap **Vascular Access** to perform a vascular access scan. This option is only available when connected to an EchoNous Vein probe.
- Tap **Training Video Library** to view a series of instructional videos.
- Tap **Scan Review** to review locally stored examinations. This option is not available if **Local Storage** is disabled in [Settings](#).

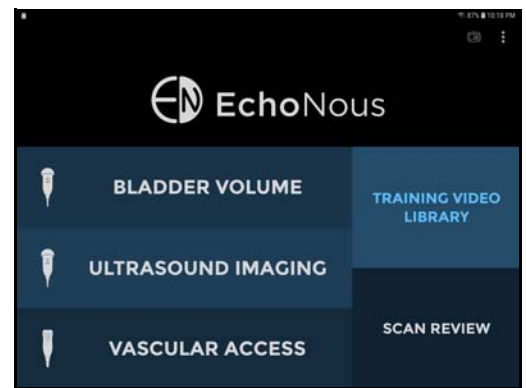


Fig 3.1 Home Screen

Bladder Scanning

Measuring Bladder Volume

On the **Home screen**, tap **Bladder Volume** to start an exam. To measure bladder volume follow the steps below:

- Select the appropriate patient type (Normal, Pediatric, Deep, or Pregnant):
 - **Normal:** BMI less than 30
 - **Deep:** BMI greater than or equal to 30 or scar tissue present
 - **Pediatric:** Weight under 27 kg
 - **Pregnant:** Active pregnancy
- Lay the patient as flat as can be tolerated.
- If necessary, palpate the patient's pubic bone, and place a generous volume of gel just above (about 1 inch or 2.5 cm) the pubic bone (see [Fig 3.2](#)).
- Place the probe just above (about 1 inch or 2.5 cm) the pubic bone with the **probe orientation marker** facing toward the patient's head.
- Apply pressure firmly.
- Tilt the probe 15 to 20 degrees so the probe beam points slightly toward the patient's feet.
- Tap the **Scan** ❄ button to start the measurement.



Probe Orientation Markers

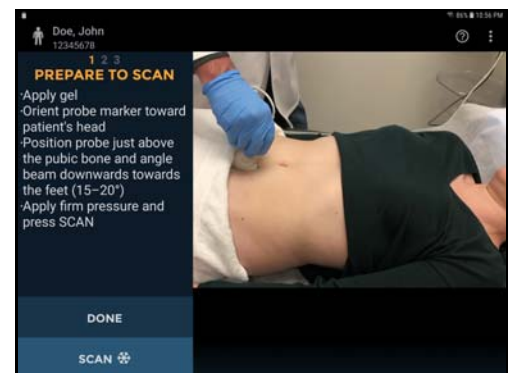


Fig 3.2 Place transducer and start scan

- If the probe is incorrectly positioned, the display will prompt the user to angle the probe ([Fig 3.3](#)).
- When the bladder has been found, an orange outline will appear around the bladder. The pubic bone indicator will appear as a green curved line ([Fig 3.4](#)).
- Maintaining pressure and angle, fan the probe towards one hip until the sound indicator is heard and an arrow is seen, then fan back towards the other hip until a second sound is heard.

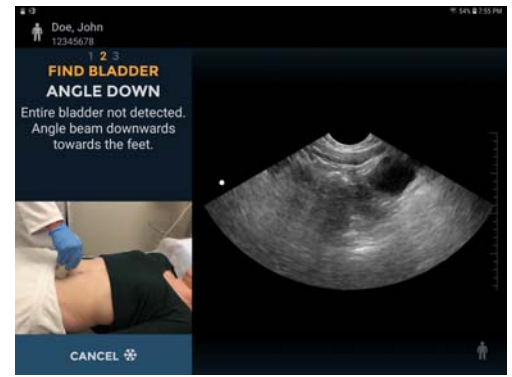


Fig 3.3 Transducer Positioning

- When fanning, consider the following:
 - Do not slide the probe.
 - Do not fan too fast or too slow. As a guideline, a complete fan should take around 3-5 seconds.
 - Do not twist the probe.
 - Angle the probe so that the bladder is in the middle of the ultrasound image.
- During acquisition, the display will show the fan position. When the three dimensional data acquisition is complete, the **System** automatically completes the scan and displays the measured volume ([Fig 3.5](#)).

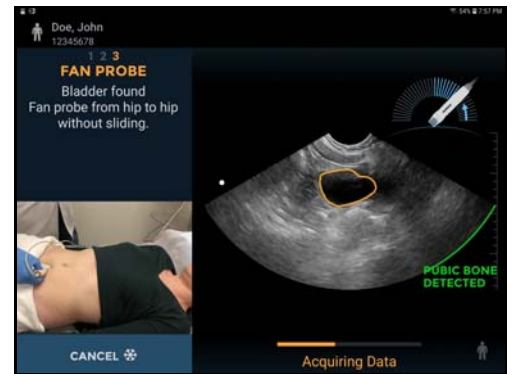


Fig 3.4 Acquire data

A movie of the complete bladder acquisition is displayed.

Bladder Measurement Correction

Correct errors outlining the bladder as follows:

- Tap the **Pencil icon** (🖋️) to start outline editing.
- Tap the **Pencil Redraw icon** (🖋️) to delete the existing outline and redraw; or
- Touch the **bladder outline** to adjust the existing outline. A drag circle will appear. Drag the outline to align with the bladder wall. The adjusted outlines change color to blue (see [Fig 3.6](#)).
- For fine adjustments, zoom in to enlarge the image before adjusting the outline.
- Tap the **Play button** (▶️) or drag the progress marker (🔵) to check other images. Every image in a measurement can be adjusted if required.
- If a bladder has been outlined where no bladder is present, then drag the progress marker (🔵) to the end of the bladder, tap (⋮) and select **Mark Bladder End**.
- Tap **End Editing** to finish.



Fig 3.5 Measured volume

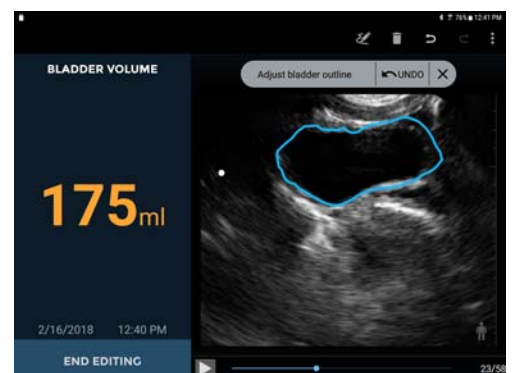


Fig 3.6 Adjusting outline

Audio Feedback

The **System** provides audio feedback during bladder measurement as follows:

- A short double beep sounds when the **System** has detected a bladder and the user can start the fan of the probe
- A short single beep sounds when the **System** has detected that more gel is required or that the user should move the probe to find the bladder.
- A buzzer sounds if a user starts fanning the probe before the **System** has found the bladder. The user should stop fanning, locate the bladder, and start fanning again when prompted by the **System**.

- A chime sounds when the **System** expects the user to change direction of the fan, and when the fanning has been completed.
- A beep sounds at the completion of a successful scan.

Tips for Obtaining Bladder Volume

If fanning too fast or too slow:

- Maintain consistent pace and pressure during the scan ([Fig 3.7](#)).
- As a guideline, a complete fan should take around 3-5 seconds.

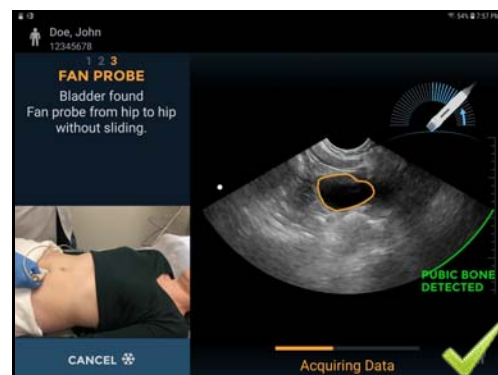


Fig 3.7 Maintain Consistent Pace

If greater than symbol appears along with the volume measurement:

- Center the bladder in the ultrasound image on the screen.
- Fan the probe toward one hip until the sound indicator is heard and an arrow is seen, then fan back toward the other hip until a second sound is heard to capture the entire bladder ([Fig 3.8](#)).
- Anchor the pivot point to ensure that the probe does not slide in any direction while fanning.

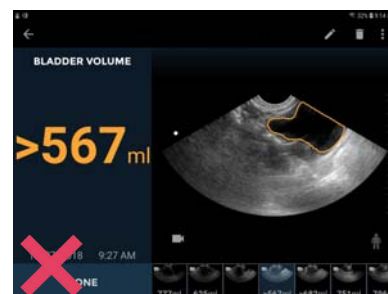


Fig 3.8 Greater Than Symbol

If twisting is detected:

- Do not rotate the probe during the fanning motion ([Fig 3.9](#)).
- Make sure that the orientation marker remains pointing toward the patient's head.



Probe Twisted

Correct Position

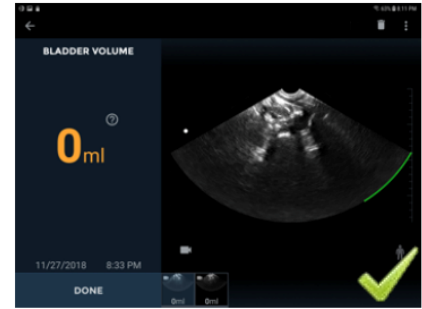
Fig 3.9 Twisting Detected

If 0 ml reading:

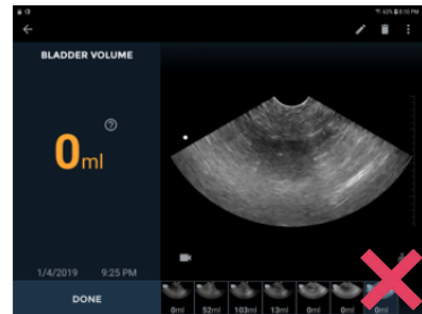
- When obtaining a measurement of 0ml, tap the (?) icon to display a message indicating possible reasons for empty result.
- A true low volume bladder scan will present with a clear pubic bone indicator and a clear visualization of a small empty bladder on the screen ([Fig 3.10](#)).

Phantom Mode

The **System** provides a special patient type for scanning ultrasound phantoms. To select the phantom patient type, tap  and select **Enable Phantom Mode**.



Bladder Found



Bladder NOT Found

Fig 3.10 Bladder Found / Not Found

Ultrasound Imaging

Tap **Ultrasound Imaging** on the **Home screen** (see [Fig 3.1](#)) to initiate an ultrasound scan.

Ultrasound Presets

Choose the appropriate preset from the **Scan Preset Menu** ([Fig 3.11](#)).

The scan presets are customized ultrasound settings for each clinical application.

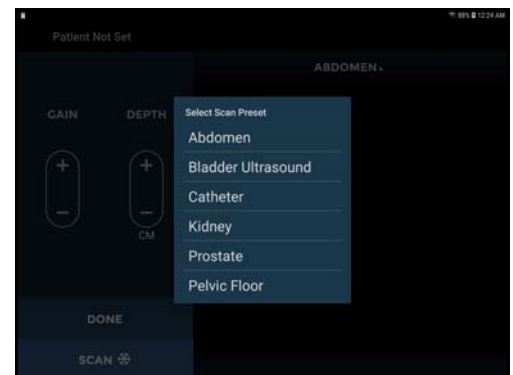



Fig 3.11 Selecting Presets

Ultrasound Scanning

The **probe orientation marker** corresponds to the **Orientation Icon**  on the display.

The convention is for the **probe orientation marker** to be on the patient's right for transverse scans, and toward the head for sagittal or coronal scans. Tap the **Scan button**  to start (unfreeze) and stop (freeze) ultrasound scans. Freezing the scan automatically captures an image that is a sector or pie shape of approximately 120° (see [Fig 3.12](#)). The user is able to save or discard the captured image/s before closing the exam. See the [Common Functions](#) section for more details on multiple scans and ending/saving exams.



Probe Orientation Markers

Controls for changing gain (brightness) and depth are provided ([Fig 3.12](#)).


Tapping the  symbol increases the gain or depth. Tapping the  symbol decreases the gain or depth.

Use a two finger pinch to zoom in or out of images.






Fig 3.12 Ultrasound Scanning

Ultrasound measurement

Tap the  **Measurement** icon to insert calipers, arrows, or volume measurements on images:

- Calipers measure a straight line distance between two points (see [Fig 3.13](#)).
- Arrows highlight part of the image, but do not perform a measurement (see [Fig 3.15](#)).
- Volume Measurements measure an ellipsoid volume using 3 caliper measurements (longitudinal, transverse, and anteroposterior) across two images (see [Fig 3.14](#)). The longitudinal and transverse measurements are positioned on the first image, and the anteroposterior measurement is positioned on the second image. The first and second images must be orthogonal.

Move the caliper or arrow using the:

-  Circular handle to position each end of the caliper in the correct place.
-  Square handle in the middle to move the entire caliper around the screen.
-  Double-arrow handle to rotate the caliper around its middle.

You can insert four measurements per image. Tap the image outside the shape to end editing that shape. Tap a shape to re-select it for editing.

The units of measurement are cm for distance and cc for volume.

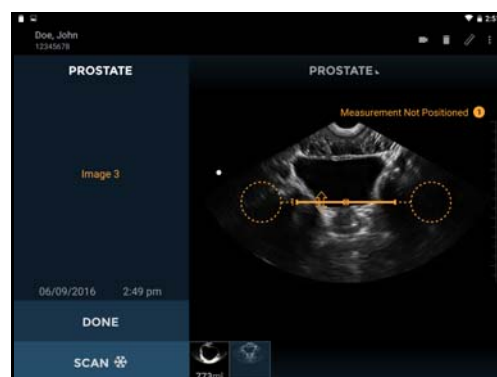


Fig 3.13 Distance Measurement

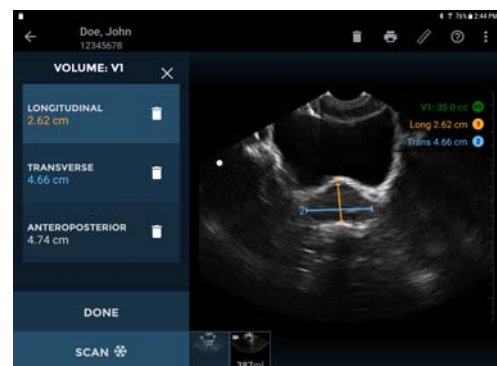


Fig 3.14 Volume Measurement

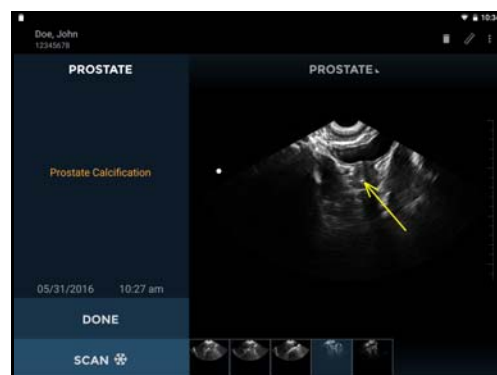



Fig 3.15 Arrow

Ultrasound Imaging Movies

Tap the  **Movie** icon to save up to 16 seconds of the ultrasound scan as a movie clip (see [Fig 3.16](#)).








- The movie clip is saved with a movie icon  in the bottom left of the image area.
- Tap the movie icon  on the image to show the movie controls.
- 
- Scroll through image frames by dragging the progress marker .
- Tap  and  to pause and play the movie clip.
- Tap the **Save Movie** button  to save the currently displayed image frame.
- Tap anywhere on the image to hide the movie controls.






Fig 3.16 Saved Movie Clip

Vascular Access

Tap **Vascular Access** on the *Home screen* (see [Fig 3.1](#)) to initiate a Vascular Access scan.

Vascular access scanning

The probe **Orientation Marker**  corresponds to the orientation marker  on the display. Tap the **Scan**  to start (unfreeze) and stop (freeze) ultrasound scans. The image automatically generated is a linear scan that is approximately 25mm wide. (see [Fig 3.17](#)).

Controls for changing gain (brightness) and depth are provided ([Fig 3.17](#)).

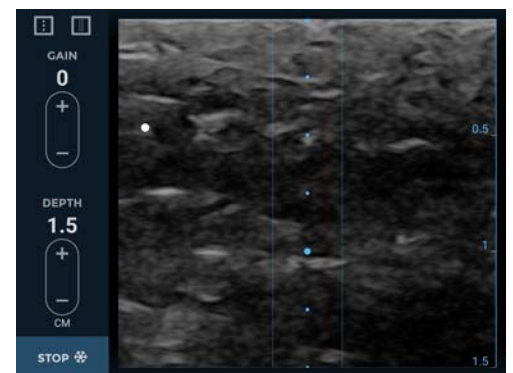





Fig 3.17 Vascular Scanning

Tapping the  symbol increases the gain or depth. Tapping the  symbol decreases the gain or depth.

Tapping the  symbol shows and hides the transducer center marker. The probe center marker corresponds to the blue circles on the display.

Tapping the  symbol shows and hides the needle guidance lines.

Use a two finger pinch to zoom in or out of images.



Fig 3.18 Distance Measurement



Enabling depths of 4 and 5 CMs

On EchoNous Vein, there are three ways of enabling depths of 4 and 5 CMs, if desired.




To enable the setting for all scans:

- From the home screen, tap the  symbol in the upper right corner.
- Tap *Settings*.
- Tap *Vascular Access*.
- Select *Enable 4 and 5 CM depth*.

To enable the setting before a scan and only for the one scan:

- Tap the  symbol in the upper right corner.
- Select *Enable 4 and 5 CM depth* (Fig 3.19).
- Tap the *Scan*  button to start the scan.

To enable the setting during the scan and only for the one scan:

- Tap the *Stop*  button to freeze the image.
- Tap the  symbol in the upper right corner.
- Select *Enable 4 and 5 CM depth*.
- Tap the *Scan*  button to continue the scan.

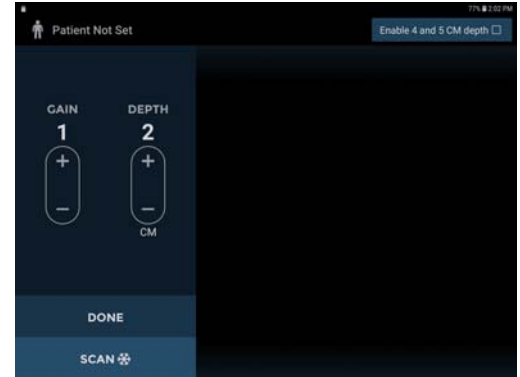





Fig 3.19 Enable 4 and 5 CM depth

Vascular access measurement

Tap the  *Measurement* icon to insert calipers, arrows, or volume measurements on images:

- Calipers measure a straight line distance between two points.
- Arrows highlight part of the image, but do not perform a measurement.

Move the caliper or arrow using the:

-  Circular handle to position each end of the caliper in the correct place.
-  Square handle in the middle to move the entire caliper around the screen.
-  Double-arrow handle to rotate the caliper around its middle.

You can insert four measurements per image. Tap the image outside the shape to end editing that shape. Tap a shape to re-select it for editing.



The units of measurement are cm.






Fig 3.20 Arrow

Vascular access Movies

Tap the  *Movie* icon to save up to 16 seconds of the vascular access scan as a movie clip.

- The movie clip is saved with a movie icon  in the bottom left of the image area.
- Tap the movie icon  on the image to show the movie controls.



- Scroll through image frames by dragging the progress marker .
- Tap  and  to pause and play the movie clip.

Tap the *Save Movie* icon  to save the currently displayed image frame.

Common Functions

Multiple Scans


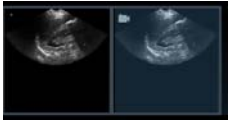
Simply tap the *Scan*  button to add more ultrasound imaging scans or vascular access scans to the exam. To perform additional bladder volume measurements, tap the *Scan Again* button.

Image thumbnails are displayed at the bottom of the image area when multiple scans have been performed. A small movie icon is embedded in movie thumbnails.



Tap a thumbnail to view an image or swipe right to left across the image area to move to the next image.


Deleting Images

Tap the *Delete* icon  to delete the displayed image.

Ending/Saving Exams

Tap *Done* to end the exam. The user will be prompted to either:

- Save all images/movies in the exam,
- Save selected images/movies in the exam,
- Discard all images.

A remote storage icon  is displayed next to *Done* when remote storage is enabled. The user is prompted to enter patient details (see [Entering Patient Details](#)) if not already entered.

After Use

After each use and between each patient, the probe and transducer must be cleaned and disinfected properly following the steps in this user manual (see [Probe cleaning and disinfection](#)).


Turning the System Off

Hold down the *Power button* of the **EchoNous System** display to turn the **System** off.

4. OTHER FUNCTIONS

Annotations

Annotations can be added to individual images.

- Tap the  menu icon to display the *Exam menu*.
- Select *Annotation* from the drop down list ([Fig 4.1](#)).
- Select from the predefined set of annotations, or select text or voice annotation for custom annotations ([Fig 4.2](#)).

Annotations are applied to individual images.

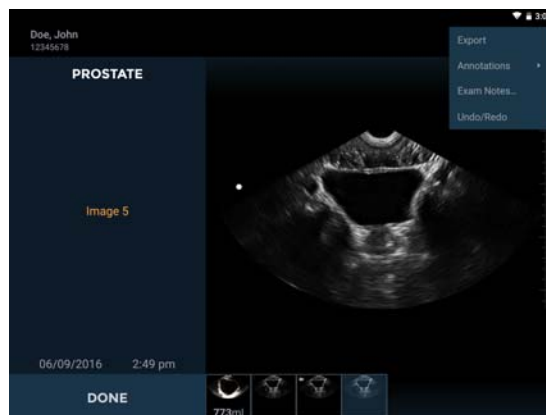


Fig 4.1 Annotating

Text Annotations

Select *Text Annotation* to enter custom annotations using the on-screen keyboard.

Voice Annotations

Select *Voice annotation* to save a recorded message with an image. The voice recording controls are displayed.

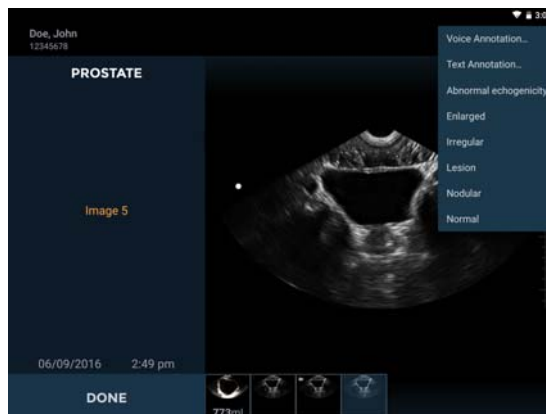
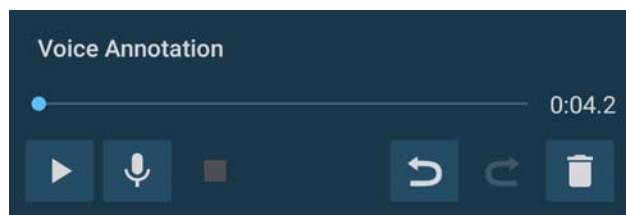



Fig 4.2 Annotation list

Press the  *Microphone button* to record. Speak clearly into the microphone.

Press the  *Stop button* to end recording. The length of the recording is displayed. Press the  *Microphone button* again to add to the end of the voice recordings.


Press the  *Play button* to play a voice recording.

Images with linked voice recordings will display a  *Voice Annotation* icon in the bottom left corner of the image. Tap this icon to launch the *Voice Annotation window* and play the existing voice annotation.

Press the  *Delete button* to delete the recording.

Exam Notes

Notes can be added for an examination.

- Tap the  menu icon to display the *Exam menu*.
- Select *Exam Notes* from the drop down list ([Fig 4.1](#)).
- Use the on-screen keyboard to type notes in the text box.

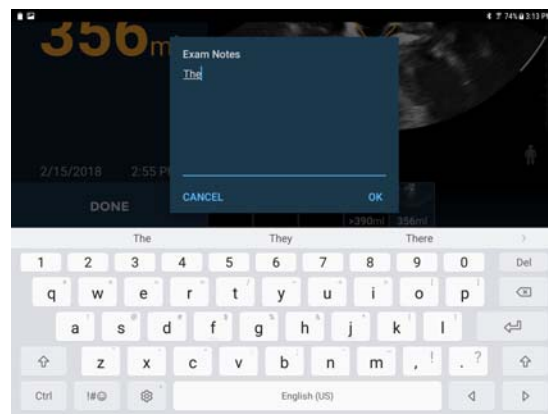


Fig 4.3 Exam notes

Entering Patient Details

Patient details will be required if data is saved. Patients may already be stored in the **System** or they may need to be entered.

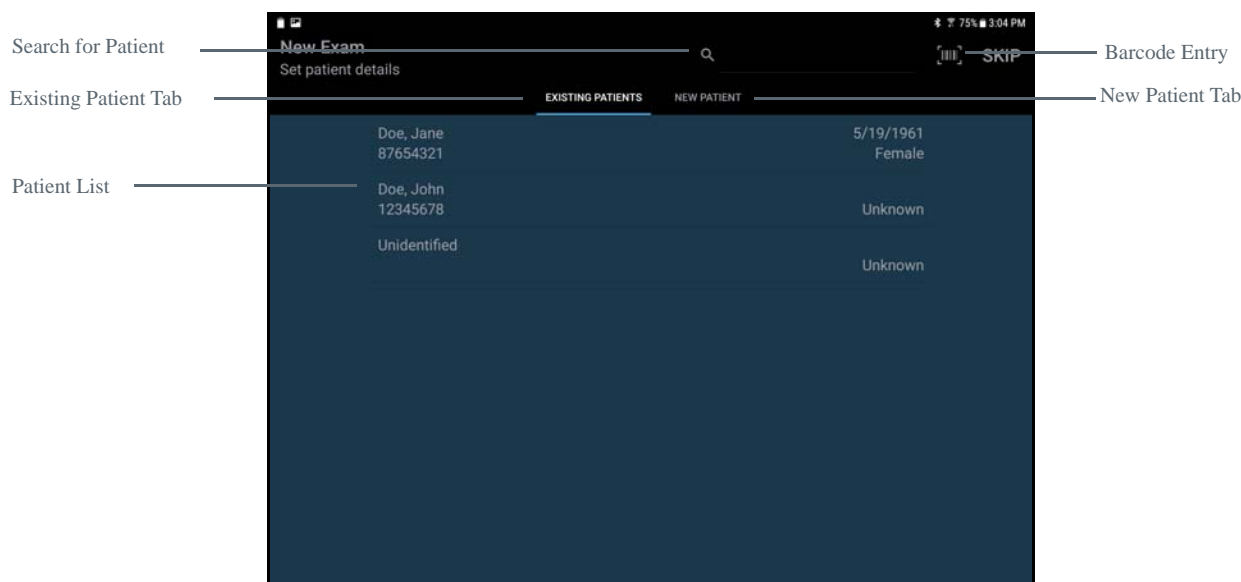


Fig 4.4 Entering Patient Details

The source for patient names is a preference setting (see [Settings](#)), and may be local storage or a remote server.

The list of patients is displayed under the *Existing Patients* tab. Tap the patient name to select a patient from the list. When querying patients from a remote server you may need to type a few letters into the search field to display patients.

The *Search field*  can be used to find an existing patient.

Tap the *Barcode icon*  or use a bar-code scanner to search using a patients bar-code.



Tap the *Skip* icon to bypass patient data entry. Note: you will be prompted to enter patient details again when saving the exam.

Tap the *New Patient* tab to enter the details for a new patient using the on-screen keyboard. Now you can enter the family name, given name, EMR identifier, sex, and date of birth.

Printing

Tap the *Printer icon*  to print to a Network (see [Network Printer Setup \(Optional\)](#)) or Bluetooth printer (see [Bluetooth Printer Setup \(Optional\)](#)).

Network printing uses the Mopria service (see www.mopria.org) enabling printing to thousands of network printer types. The **EchoNous System** display needs to be connected via WiFi to the same network as the printer. To print:

- Tap the  icon.
- Tap **PRINT ALL** to print all scans, or **PRINT SELECTION** to print only selected scans.
- Select the printer from the drop down list.
- If required, adjust the number of copies, paper size, colour, orientation, or any other options provided by the printer.
- Tap the  button to send to the printer.
- Bluetooth printing only prints the current image.

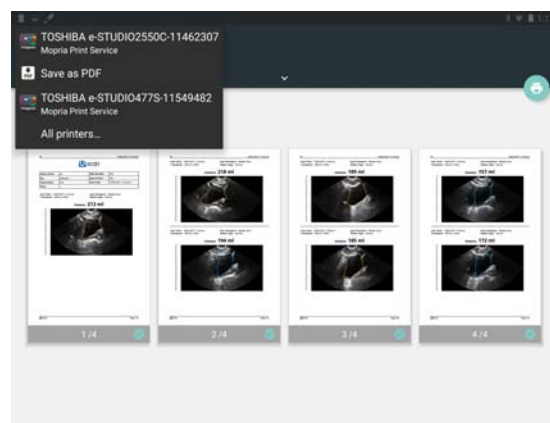


Fig 4.5 Network Printing

Export

Images, movie clips, and PDF reports can be exported to the display's internal storage for later download to a computer via USB.

- Tap the  menu icon to display the *Exam menu*.
- Select **Export** from the drop down list.
- Select **Image/Video** or **PDF Report** from the drop down list.

- Tap **EXPORT ALL** to export all scans, or **EXPORT SELECTION** to export only selected scans.

The images, videos, or PDF report are saved to the display's internal storage in a sub-folder of "EchoNous Export". The sub-folder is named using the patient name, date, and time of the exam (PatientName - YYYYMMDD_HHMMSS).

Scan Review

Scan Review is available when local storage is enabled. Tap the **Scan Review** button on the **Home screen** to review saved examinations in local storage.

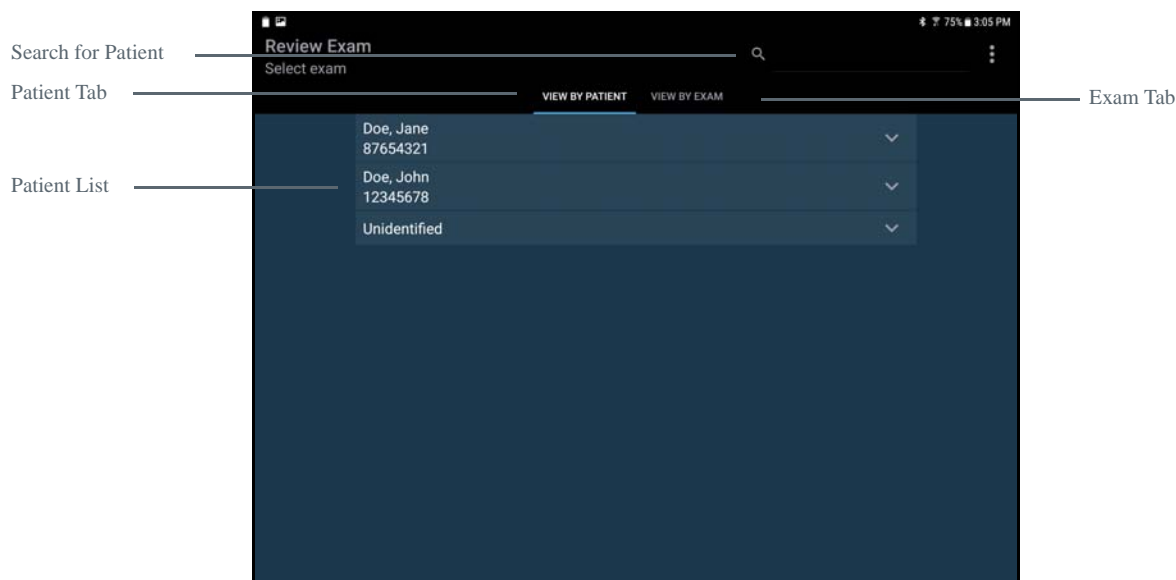


Fig 4.6 Scan Review

The data is arranged under patients, with each patient being able to link one or more examinations, and each examination containing one or more images and/or movies (an image/movie may be a bladder volume measurement or an ultrasound scan of another organ).

A list of patients will be displayed. Tap the patient to display the list of exams attached to that patient. To view all exams, tap the **View by Exam** tab.

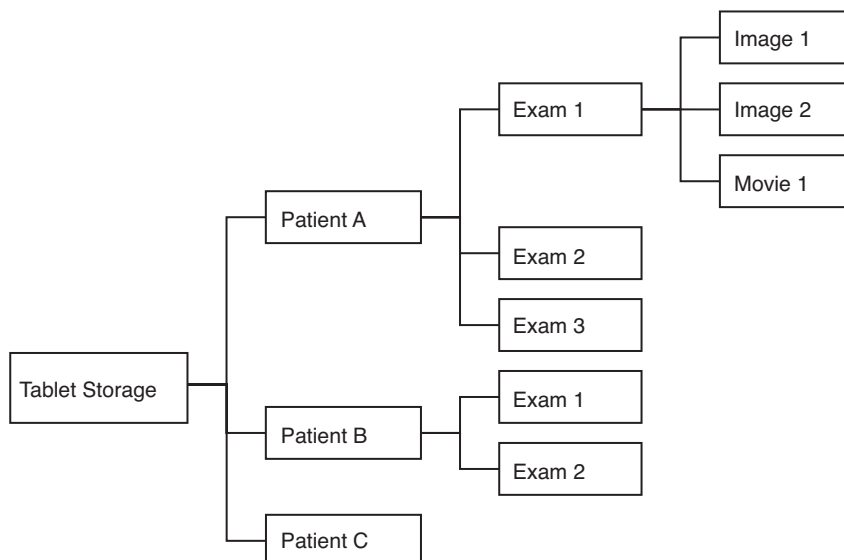





Fig 4.7 Relationship between patients, exams and images

Use the search function to find a patient and associated exams. Tap the patient arrow  to view all exams associated with a patient. Tap the exam to open and review the images.

Deleting exams and patients

To delete an exam or a patient from local storage tap *Scan Review Mode* on the *Home screen*. Tap and hold the exam or patient. The exam or patient will be checked, and check boxes appear next to other patients and exams (see [Fig 4.8](#)). Tap other patient and exam checkboxes as required, and then tap the *Trash can icon*  at the top right of the screen to delete all checked exams and patients.

Alternatively, use the menu by tapping the  icon. The following menu options are available:

- Use *Delete patients without exams* to delete any patients with no associated exams.
- Use *Delete All* to delete all but the open exam(s).
- Use *Delete Oldest* to create space on the local storage. At least 10% of the oldest exams are deleted.

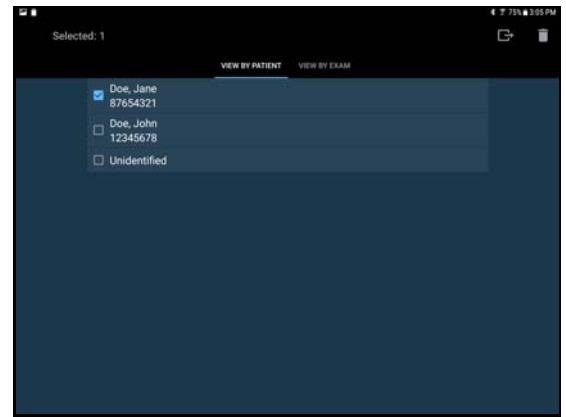


Fig 4.8 Deleting Patients



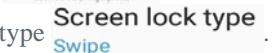
Data Security

Data security is embedded in the **System** as follows:

- The **System** can be locked by a PIN or password. No user will be able to access any data on the **System** without access to the pin or password.
- All data saved on the **System** is encrypted. Where the **System** has been stolen, no data will be accessible without the PIN or password.
- Secure Wi-Fi protocols are supported, enabling data to be securely saved to remote storage, with no local storage of patient data.
- No Internet ports are open. In the event a third party is able to access the **System**, they will not be able to access any data without the PIN or password.
- No third party applications are able to be installed or run on the **System**, preventing malware and viruses.

Setting a Device Password

To set a device PIN or password as follows:

1. From the *Home screen* tap  menu, tap *Settings*, and select *System Settings*.
2. Select Security  Lock screen and security
Lock screen, Fingerprints
3. Tap Screen lock type  Screen lock type
Swipe
4. Select PIN **PIN** or Password **Password**.
5. Enter the PIN or password.
6. Tap Continue **CONTINUE**
7. Confirm the pin or password.
8. Tap OK **OK**
9. Select your notification content preference.

Tap *Home*  to return to *Home Screen*.

5. MAINTENANCE AND TROUBLESHOOTING

Maintenance



Warning

- ✓ No modification of this equipment is allowed.
- ✓ This device contains no user-serviceable parts. Please contact [EchoNous](#) customer support or your EchoNous distributor for maintenance or repair.
- ✓ The Uscan probe's internal battery is not to be replaced by the user - doing so may create fire or explosion hazard.

The **System** requires no routine or periodic maintenance on either hardware or software components.

Inspect the transducer and display unit housings, connectors and cables prior to each use for cracks; if cracks are found, use of the device should be discontinued immediately. Contact [EchoNous](#) Customer Support or your EchoNous distributor to arrange repair or replacement.

If the **System** behaves in an abnormal manner or when damage is suspected use of the device should be discontinued immediately. Contact [Echonous](#) Customer Support or your EchoNous distributor to arrange repair or replacement.

The **System** must be returned to EchoNous Customer Support or your EchoNous distributor to arrange battery replacement. If you plan to dispose of the **System**, recycle electrical equipment and batteries where possible and abide by local disposal guidelines and directives.



Caution

- ✓ Ultrasound transducer crystals are fragile and are easily damaged if knocked, dropped or excessively vibrated.
- ✓ Avoid unnecessary bending or winding of the connecting cable.

If the **System** is dropped or suffers a heavy knock:

- Inspect the device. If you discover major damage do not use the device; report the fault to your **EchoNous** distributor for repair.
- Switch on and check normal function of all controls.
- Tap *Menu*, *Settings*, *Maintenance*, then *Bladder Probe Calibration* to check the bladder probe inertial sensors.

If there are any concerns about operation of the device, report the faults to your **EchoNous** distributor for inspection and/or repair.

Battery Maintenance

The Uscan probe and **EchoNous System** display batteries cannot be removed by the user. Precautions need to be taken if the device is not used for long periods of time. Before storage, fully charge the device. Turn the device off when placing in storage, and store at ambient or cooler temperature. Take the device out of storage at least every six months and recharge the device.



Caution

- ✓ The batteries should be charged every six months at a minimum, even if you are not using your device. When storing for greater than 3 days, store at ambient or cooler temperature.

Probe cleaning and disinfection



Warning

- ✓ Remove all particles and other matter from crevices and surfaces when cleaning the **System** and components.
- ✓ The device is supplied unsterile.
- ✓ Clean and disinfect the transducer between patients.
- ✓ Before cleaning or disinfection turn the **System** off and disconnect from the power supply.
- Always disconnect the USB cable from the display tablet before cleaning and disinfection.
- ✓ After cleaning, you must disinfect the EchoNous Vein probe by following the appropriate instructions.
- ✓ Always use protective eyewear and gloves when cleaning and disinfecting any equipment.
- ✓ Before disinfection, clean the probe by following the appropriate instructions in order to remove all gels, fluids and particulates that may interfere with the disinfection process.
- ✓ Do not submerge the probe, the display unit or the power supply (charger) as electric shock could result. The Uscan probe is IPX1 which allows water falling vertically onto the probe. The EchoNous Bladder and EchoNous Vein probes are IPX4 which

allows water splashing from all directions. The display may have no protection against ingress of water. Refer to the display user manual.

- ✓ Clean and disinfect the **System** before placing in a bag for transport. Use the supplied EchoNous probe holder to store the probe. Clean and disinfect the probe holder regularly.



Caution

- ✓ Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting wipe can damage the Probe and void the warranty.
- ✓ When cleaning and disinfecting the probe, do not allow any fluid to enter electrical connections or metal portions of the USB connector.
- ✓ Use abrasive cleaners, isopropyl alcohol or solvents sparingly, and if used immediately clean and remove residual substances from the **System**.
- ✓ Do not heat sterilize any part of the system.

Cleaning

Display

For cleaning requirements of the display refer to its user manual.

Uscan Probe

EchoNous recommends the use of a soft cloth, lightly dampened with warm water or a mild soap solution for cleaning the Uscan probe and transducer. Wipe surfaces with the moist cloth, and towel dry with a soft clean cloth.

EchoNous Vein and EchoNous Bladder Probes

The following cleaning instructions must be followed for the EchoNous Vein and EchoNous Bladder probes. The probes must be cleaned after each use. Cleaning the probes is an essential step before effective disinfection.

Cleaning Steps

After each use, disconnect the USB cable from the Display Tablet. Remove any accessories attached to, or covering the Probe, such as needle guide, needle bracket and sheath (probe cover).

Note

The needle guide is single-use disposable.

The needle bracket is reusable and must be cleaned using the same methods as the Probe.

Remove all ultrasound gel from the Probe face by using an approved pre-saturated disinfectant wipe. Choose an EchoNous approved wipe from [Table 5.1: Pre-Saturated Wipes for EchoNous Probes](#).

Obtain a new wipe. Remove any particulate matter, gel or fluids that remain on the Probe using a new pre-saturated wipe from Table 1. If necessary, clean the Probe with additional wipes to remove all visible contaminants.

Disinfection

Uscan Probe

The following disinfecting means can be used with the **Uscan** probe:

- Sani-Cloth® Active by *PDI* of Flint, UK
- Tuffie 5 Wipes by *VernaCare* of Lancashire, UK
- Protex Disinfectant Wipes by *Parker Laboratories* of New Jersey
- Any Isopropyl alcohol impregnated wipes with $\leq 70\%$ w/w alcohol
- Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes
- Oxivir® Tb Wipes by *Diversey* of North Carolina
- Any sodium hypochlorite impregnated wipes with $\leq 10\%$ w/w sodium hypochlorite

EchoNous Vein and EchoNous Bladder Probes Intermediate-Level Disinfection

Use the following steps to intermediate-level disinfect the EchoNous Vein and EchoNous Bladder probes whenever they have **not** come in contact with blood or bodily fluids (non-critical use).

After cleaning, choose an intermediate-level disinfectant that is from the list in [Table 5.1](#): Pre-Saturated Wipes for EchoNous Probes. Follow the instructions on the disinfectant label for the minimum wet contact time.

Table 5.1 Pre-Saturated Wipes for EchoNous Probes


Product	Company	Active Ingredient(s)	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%	3 min wet contact time for disinfection

With a new wipe, clean the cable and transducer, starting from the exposed cable, wiping toward the probe head to avoid cross-contamination.

Observe the required wet contact time. Monitor the probe for wet appearance. Re-apply with a new wipe if no longer wet.

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

Refer to [EchoNous](#) website for additional disinfection options.

-  **Caution**
- ✓ Minimize application of alcohol based disinfectant to colored overmold materials. Long term use may result in material degradation. If alcohol based disinfectant is applied to the overmold, immediately remove by wiping with a damp cloth.

The ultrasound probe and transducer may be disinfected using a wipe or spray method of disinfection. First clean the ultrasound probe and transducer as above. Then wipe or spray the probe and transducer with disinfectant, and leave for the disinfectant manufacturers recommended contact time. Remove any residue with a soft cloth moistened with water. Do not allow any solutions to dry on the probe and transducer.

-  **Warning**
- ✓ After cleaning or disinfection examine the ultrasound probe and display as appropriate for cracks or leaks, and if damage exists discontinue use of the system and contact [EchoNous](#) customer support or your EchoNous distributor.

Troubleshooting

Table 5.2 Troubleshooting guide

Symptom	Possible cause	Remedy
The display does not turn on	Flat battery	Connect to the display charger and turn on.
The System displays a “Probe Error” message when starting a scan or during scanning	Transducer fault. Low Probe battery.	Unplug the USB connector from the probe, wait 10 seconds, and reconnect. Check the battery status and connect the display unit to the display power supply (charger) if the display or probe battery (Uscan probe only) is low. If the Uscan probe is still not recognized, unplug the probe and connect directly to the EchoNous power supply (P003198) and leave for 2 hours to charge.
The System battery fails to recharge after a period of heavy use. The battery status indicates batteries are not recharging despite the system being connected to a power supply (charger)	Battery temperature exceeds 45°C	Allow device to cool for 10 - 15 minutes, then try charging the battery again.
The System becomes non-responsive or will not power up after recharge.	Unknown system error	Shutdown the display and reboot.
Any error message not resolved by the actions above or the action suggested on screen.	Various errors	Error messages generated by the System will be accompanied by a description of the error or an error code. If unresolved, contact EchoNous customer support or your distributor with the message and code.

Clinical Troubleshooting

Scan technique impacts the quality of the ultrasound image during a bladder measurement, and therefore impacts the accuracy of the measurement. The following tips assist in producing reliable and repeatable measurements:

- Move and angle the probe so the center of the bladder is in the center of the ultrasound image.
- Apply moderate downward pressure. On large patients, apply firm downward pressure.
- Fan the probe at a smooth speed, aiming to complete the measurement in less than five seconds.
- Pivot and do not slip or slide the tip of the probe.

EchoNous Customer Support

If problems persist or recur, contact [EchoNous](#) Customer Support or your EchoNous distributor.

For other countries, refer to EchoNous website (see [Contact information](#) page 15).

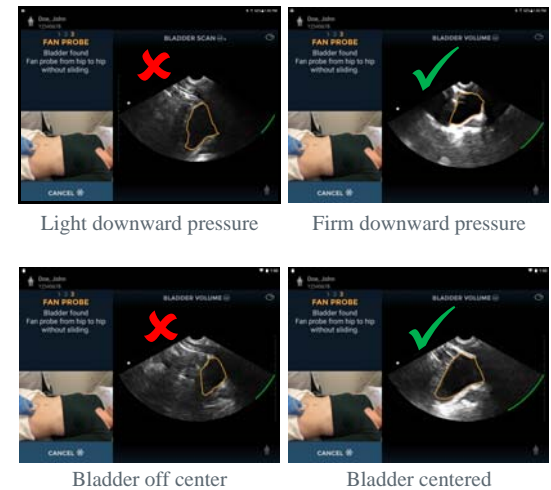


Fig 5.1 Scan Technique

6. CONNECTIVITY AND ACCESSORIES

Accessories

The following accessories are supported by the **EchoNous System**:

- Wireless printer
- Wireless bar code scanner
- Signostics Mobile Stand (P004013)
- EchoNous Power Supply (P003198)
- EchoNous Stand Power Supply (P004016)
- EchoNous Type C Power Supply (P005179)
- EchoNous AI Station Stand (P005149)
- EchoNous AI Station Stand Power Supply (P005332)
- EchoNous AI Station Stand Lower Bucket Assembly (P005181)
- System connectivity



Warning

- ✓ The user must not touch any device connectors while in physical contact with the patient.
- ✓ The ultrasound probes are connected to an Android display running **EchoNous System** software to configure a medical system. The Android display is certified as a component of a medical electrical system to EN IEC 60601-1 Edition 3.1.
- ✓ Do not connect the **EchoNous System** display to external computers or peripherals using the USB port unless the **System** is outside the patient area. Failure to comply with these guidelines may result in electric shock.
- ✓ Mounting the **EchoNous System** display on a mobile stand is configuring a medical electrical system. Only use the EchoNous provided mobile stand accessory (P004013 or P005149).
- ✓ Only connect accessories or items that are specified as being compatible with the **EchoNous System**. Contact [EchoNous](#) customer support or your EchoNous distributor for information on compatible accessories and systems.
- ✓ Connecting electrical equipment to a MSO effectively leads to creating a medical electrical system, and can result in a reduced level of safety.
- ✓ MSOs (if provided with the medical electrical system) are to be used only for supplying power to the tablet display and optional printer in non-operating mode.
- ✓ Risk of shock or personal injury when connecting any equipment that has not been supplied as a part of the medical electrical system to the MSO.
- ✓ An additional MSO or extension cord shall not be connected to the medical electrical system.
- ✓ MSOs (if provided with the medical electrical system) shall only be used for supplying power to equipment that is intended to form part of the medical electrical system.

Power sources

During operation, the **System** is electrically powered by an internal battery. The battery can be recharged by a mains-powered supply via the provided power supplies (chargers). The battery can be recharged on the AI Station Mobile Stand via the AI Station hub.

Internal battery

The **EchoNous System Display** and the **Uscan Probe** contain internal batteries.

When powered by a fully charged battery, the **System** will run for more than 12 hours with an average operating regime of 4 x 1 minute scans per hour.

From a fully discharged state, while the **System** is in sleep mode, the battery recharges to 80% capacity when connected to a display power supply (charger) for 3 hours.

Power Supplies (Charger)



Warning

- ✓ Recharge the **System** only with the power supplies (chargers) provided.
- ✓ If required, recharge the **Uscan Probe** only with the EchoNous power supply (charger) provided (P003198).
- ✓ The **EchoNous** power supplies are dedicated units to be used exclusively with the **EchoNous System** only.

- ✓ Do not open or modify the EchoNous Power Supply P003198 or any other supplied power supplies - Risk of electric shock
- ✓ Only connect to an AC supply rated at 100-240V and 50-60Hz.
- ✓ Do not use the device or power supplies (chargers) if there are signs of damage.

The EchoNous power supply (P003198 or P005332) delivers a charging power to the **UscaN Probe** of between 0-10W.

From a fully discharged state, full charge of the probe will take approximately 2-3 hours.

Mobile Stand Setup

Two optional mobile stands are available - Signostics Mobile Stand (P004013) and EchoNous AI Station™ Mobile Stand (P005149). The Signostics Mobile Stand supports the HP tablet, Samsung tablet with MSO, and Samsung tablet without the MSO. The EchoNous AI Station supports the Samsung tablet display. Setup for each stand is described in sections that follow.

Warning

- ✓ Mounting the **EchoNous System** display on a mobile stand is configuring a medical electrical system. Only use an EchoNous provided mobile stand accessory (P004013 or P005149).
- ✓ The ultrasound probes are connected to an Android display running EchoNous software to configure a medical system. The display has been certified by EchoNous as part of a medical electrical system to EN IEC 60601-1 Edition 3.1
- ✓ Do not connect the **EchoNous System** display to external computers or peripherals using the USB port unless the **System** is outside the patient area. Failure to comply with these guidelines may result in electric shock.
- ✓ Only connect accessories or items that are specified as being compatible with the **EchoNous System**. Contact [EchoNous](#) customer support or your EchoNous distributor for information on compatible accessories and systems.
- ✓ Connecting electrical equipment to an MSO effectively leads to creating a medical electrical system and can result in a reduced level of safety.
- ✓ An additional MSO or extension cord shall not be connected to the medical electrical system.
- ✓ MSOs (if provided with the medical electrical system) shall only be used for supplying power to equipment that is intended to form part of the medical electrical system.

Signostics Mobile Stand Setup

- For installation instructions on MODO Stand, follow the instructions shipped with the product.
- To configure the system for the HP tablet, refer to the Tablet Setup Guide (P004040).
- To configure the system for the Samsung tablet with MSO, refer to the Stand Upgrade Kit Guide (P005465).
- To configure the system for the Samsung tablet without the MSO, refer to the Modo Stand Upgrade Kit Guide (P006018).
- All the quick start guides are shipped with the product and available in the pen drive.

EchoNous AI Station Mobile Stand Setup

- For installation instructions on the AI station, refer to the AI Station Assembly Guide (P005339).
- To configure the system for mobile use, refer to the AI Station Tablet Setup Guide (P005447).
- Both quick start guides are shipped with the product and available in the pen drive.

Using the EchoNous AI Station Mobile Stand

Table 6.1 Safe Working Loads and Installation Heights of all components

Component	Mounting Height Range (measured from top of central column)	Safe Working Load
Tablet Holder	0" - 11" (bottom of range limited by safety stop) 0 cm - 28 cm	As configured (no storage)
Handle Bar Assembly	13" - 23" (top of range limited by safety stop) 33 cm - 58 cm	3 lbs on each side (6 lbs total) 1.3 kg on each side (2.6 kg total)
Lower Bin Assembly	30" - 36" 76 cm - 91 cm	4 lbs on each side (8 lbs total) 1.8 kg on each side (3.6 kg total)
Cord Wrap	Below lower bin	As configured (no storage)

Warning

- ✓ Cord wrap must be installed as the lowest component on the AI Station Mobile Stand in order to protect the handle bar assembly against falling down into the caster base.

Locking the Wheels

All four (4) caster wheels are capable of locking. Press the lock button with your foot. The caster is locked when the lock button is out. The caster is unlocked when the lock button is in.

Adjusting the Height of Components

All components are capable of being adjusted up or down the central column of the AI Station Mobile Stand.

1. Press the thumb button on the collar.
2. Support the weight of the component with one hand.
3. While depressing the thumb button, pull the collar handle open. The handle may be tightly engaged and required a screw driver to gently pry open.
4. With the collar handle open, use both hands to move the component to the desired position.
5. Push the collar handle closed. The thumb button on the collar should automatically fall into place.

Warning

- ✓ When opening the collar handles for components on the AI Station Mobile Stand, it is important to support the component's weight to avoid damage or injury from falling components.
- ✓ When adjusting the height of the display unit on the EchoNous AI Station mobile stand, it is important to safely manage the DC power cord to avoid damage to the cord and risk of electric shock.

When adjusting the mobile stand dock downward, ensure that enough power cord is available to reach the new height before moving. Remove the cord from the storage track and pull gently on the cord as it exits the top of the column. If the cord does not move freely, you may need to remove the plastic cap at the top of the column. After moving the dock to its new position, replace the cord in the column storage track. Push any extra cord back into the column via the top. You may need to remove the cap to push the extra cord back in.

EchoNous AI Station Power Management

Charging

The AI Station system can be fully charged using the AI Station stand power cord. To charge the system, first ensure that the tablet display is turned on, then connect the power cord to an AC source.

Sleep Mode

In order to conserve battery, the AI Station hub and attached probes go into sleep mode when the tablet display goes to sleep. The AI Station hub sleep mode is controlled by a motion sensor and will wake up when the stand is moved.

If the tablet display is turned on without moving the stand, the message shown in [Fig 6.1](#) will be displayed.

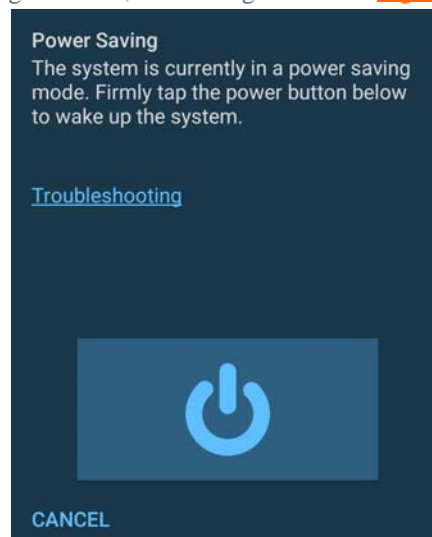


Fig 6.1 AI Stand Power Saving

To wake up the **System**, follow the instructions and firmly tap the power button displayed on the screen.

EchoNous AI Station Troubleshooting

If the **System** does not wake up after following the wake up instructions, please perform the following:

- Disconnect and then reconnect the USB cable connecting the hub to the tablet display.

If this is unsuccessful:

- Connect the AI Station power cord to an AC source.

If the **System** is still not responding:

- Restart the tablet display by holding down the power button and selecting *Restart*.

If the **System** remains unresponsive or a hub fault error is displayed, please contact [EchoNous](#) support.

Cleaning

EchoNous recommends the use of a soft cloth, lightly dampened with warm water or a mild soap solution for cleaning the mobile stand. Wipe surfaces with the moist cloth, and towel dry with a soft clean cloth.

Disinfection

Where bodily fluid or other contamination is expected, the mobile stand can be disinfected using the spray and wipe method with a variety of disinfection products. Follow the manufacturers recommended method.

The following disinfecting means can be used with the **Signostics Mobile Stand**:

- Sani-Cloth® Active by *PDI* of Flint, UK
- Tuffie 5 Wipes by *VernaCare* of Lancashire, UK
- Protex Disinfectant Wipes by *Parker Laboratories* of New Jersey
- Any Isopropyl alcohol impregnated wipes with $\leq 70\%$ w/w alcohol

The following disinfecting means can be used with the **AI Station Mobile Stand**:

- Clorox Hydrogen Peroxide wipes
- Clorox Bleach wipes
- PDI Sani-Cloth Plus

Refer to [EchoNous](#) website for additional disinfection options.

First clean the mobile stand as above. Then wipe or spray the mobile stand with disinfectant, and leave for the disinfectant manufacturers recommended contact time. Remove any residue with a soft cloth moistened with water.

7. SPECIFICATIONS

System dimensions

Table 7.1 Dimensions of probes

Component	Height	Width	Depth	Weight
Uscan probe	147mm (5.78 inches)	62mm (2.44 inches)	33mm (1.3 inches)	~200g (7.1 oz)
EchoNous Bladder probe	135mm (5.31 inches)	60mm (2.36 inches)	24mm (0.945 inches)	~181g (6.4 oz)
EchoNous Vein probe	100mm (3.94 inches)	39mm (1.54 inches)	21mm (0.827 inches)	~50g (1.76 oz)

Table 7.2 Dimensions of cable

Component	Length
EchoNous Vein USB micro to USB C	813mm (32 inches)
Connecting cable, tablet display	1800mm (70.9 inches)

Table 7.3 Dimensions of displays

Component	Height	Width	Depth	Weight
HP Tablet	207mm (8.15 inches)	137mm (5.39 inches)	8mm (0.31 inches)	350g (12.3 oz)
Samsung Tablet	237mm (9.34 inches)	169mm (6.65 inches)	6mm (0.24 inches)	429g (15.13 oz)

Environmental Operating and Storage Conditions

The **EchoNous System** is intended to be used and stored in normal ambient conditions inside a medical facility.

Table 7.4 Operating, charging, transport and storage condition ranges





	Operating	Transport and Storage
Temperature (°C)	5 (41°F) – 40°C (104°F) 	-20 (-4°F) – 50°C (122°F) 
Relative humidity (non-condensing)	15–90%	10–93%
Pressure	70–101.5 kPa (10.3-14.7 psi)	50–101.5 kPa (7.3-14.7 psi)

Table 7.5 Charging condition ranges

	Charging
Temperature (°C)	5 (41°F) – 40°C (104°F) 
Relative humidity (non-condensing)	20–80%
Pressure	70–101.5 kPa (10.3-14.7 psi)

Mode of Operation

The **System** enforces scanning limits when using the Uscan probe to maintain safe user enclosure contact temperatures.

-  **Warning**
- ✓ After storage at extreme temperatures, check the transducer surface temperature before applying to a patient. A cold or hot surface may burn a patient.



Caution

- ✓ Only operate, charge and store the **System** within the approved environmental parameters.

Power Supplies (Chargers)

For the **Uscan** probe and HP tablet, the power supply is EchoNous Power Supply P003198

- Input: 100-240V AC supply 50-60Hz
- Output: 5.0V \pm 0.25V at 2.0A maximum current

For the Samsung tablet display, the power supply is EchoNous Type C power supply P005179

- Input: 100-240V AC supply 50-60Hz
- Output: 5.0V \pm 0.25V at 2.0A maximum current

For the HP tablet display when connected to the stand, the power supply is EchoNous Power Supply P004016

- Input: 100-240V AC supply 50-60Hz
- Output: 12.0V \pm 0.25V at 1.5A maximum current

Internal battery

Uscan Probe

EchoNous Li-ion Polymer Cell

Description: Rechargeable lithium polymer battery

Rating: 3.7V 1350mAh

For the HP tablet display, the battery is a 21WHr Li-ion Polymer type.

For the Samsung tablet display, the battery is a 6000 mAh Li-ion polymer type.

The AI Station hub contains a Lithium Metal 3V / 45 mAh coin cell battery.

Measurement accuracy

Measurements reflect a physical property such as area or volume for interpretation by a clinician. They do not account for variations in acoustic speed of the body, which can vary significantly.

Table 7.6 Accuracy of measurements

Measurement	Units	Range	Accuracy	Modes
Distance				
Axial (Bladder)	cm	Full scale	$\pm 5\%$ or $\pm 0.1\text{cm}$	B-mode
Lateral (Bladder)	cm	Full scale	$\pm 5\%$ or $\pm 0.3\text{cm}$	B-mode
Axial (Vein)	cm	Full Scale	5% or $\pm 0.1\text{cm}$	B-mode
Lateral (Vein)	cm	Full Scale	5% or $\pm 0.1\text{cm}$	B-mode
Volume ¹	ml	0-999ml	$\pm 10\%$ or $\pm 10\text{ml}$	3D

¹ When used as per instructions scanning a bladder in a tissue equivalent phantom.

Degree of Protection Against Ingress of Water

The Uscan probe (P003992 or P003993) is IPX1 below the level of the USB connection. See [Fig 7.1](#)

The transducer lens can be submersed in liquid for testing purposes.

The EchoNous Bladder probe and cable assembly is IPX4. The probe is IPX7 from the probe face to the level of cable strain relief. See [Fig 7.1](#) (right).

The EchoNous Vein probe and cable assembly is IPX4. The probe is IPX7 from the probe face to the level of cable strain relief.. See [Fig 7.2](#)

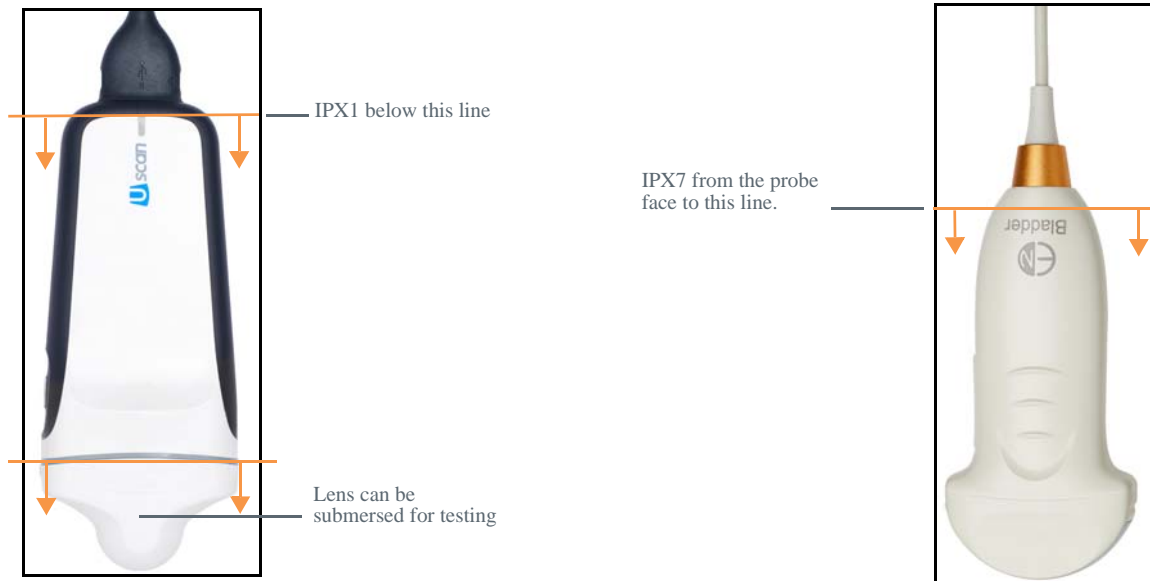


Fig 7.1 Water Protection for bladder probes

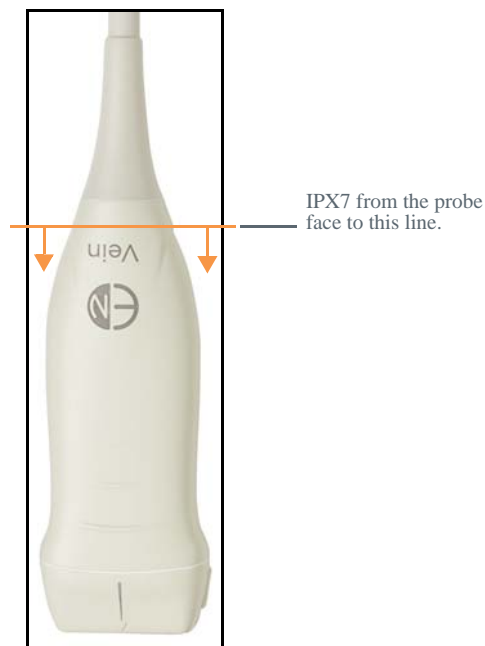


Fig 7.2 Water Protection for EchoNous Vein probe

8. SAFETY

Ergonomics



Warning

- ✓ Avoid musculoskeletal strain with prolonged use of the **System**. Follow guidelines below.

The **System** 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 the probe lightly, keep your wrist straight and minimize the pressure applied to the patient.
- Take regular breaks.

External materials

The parts of the device that come into patient contact are biocompatible as assessed in EN ISO10993-1.

Disposal



Warning

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

The **System** contains lithium-polymer batteries and the **System** should be disposed of in an environmentally responsible manner in compliance with federal and local regulations. It is recommended the **System** is taken to a recycling center which specializes in the recycling and disposal of electronic equipment.

The AI Station hub contains a lithium metal battery and should be disposed of in an environmentally responsible manner in compliance with federal and local regulations.

Where the device has been exposed to biologically hazardous material it is recommended the device be disposed of using biohazard containers and in compliance with federal and local regulations. It is recommended the **System** is taken to a waste center which specializes in the disposal of biohazard waste.

Electrical safety



Warning

- ✓ The **System** complies with the requirements of EN IEC 60601-1 Edition 3.1. To avoid the risk of injury or electrical shock, comply with all safety instruction and warnings.
- ✓ The user must not touch the any device connectors while in physical contact with the patient.
- ✓ The ultrasound probes are connected to a supplied Android display running **EchoNous System** software to configure a medical system. The Android display is certified to EN IEC 60601-1 Edition 3.1 as a component of a medical electrical system.
- ✓ Do not connect the **EchoNous System** display to external computers or peripherals using the USB port unless the **System** is outside the patient area. Failure to comply with these guidelines may result in electric shock.
- ✓ Only connect accessories that are specified as being compatible with the **EchoNous System**. Contact [EchoNous](#) customer support or your EchoNous distributor for information on compatible accessories and systems.
- ✓ Connecting electrical equipment to an MSO effectively leads to creating a medical electrical system, and can result in a reduced level of safety.
- ✓ MSOs (if provided with the medical electrical system) are to be used only for supplying power to the tablet display and optional printer in non-operating mode.
- ✓ Risk of shock or personal injury when connecting any equipment that has not been supplied as a part of the medical electrical system to the MSO.
- ✓ An additional MSO or extension cord shall not be connected to the medical electrical system.
- ✓ MSOs (if provided with the medical electrical system) shall only be used for supplying power to equipment that is intended to form part of the medical electrical system.
- ✓ Avoid any unnecessary strain on the mains power supply cord.
- ✓ When adjusting the height of the display unit on the EchoNous AI Station mobile stand, it is important to safely manage the DC power cord to avoid damage to the cord and risk of electric shock.

Electromagnetic compatibility (EMC)



Caution

- ✓ The **System** contains sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the **System**. Any faults should be reported to [EchoNous](#) or your EchoNous distributor for repair.



Warning

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

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.

Table 8.1 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	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

- ¹ 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

Table 8.2 Guidance and manufacturer's declaration: electromagnetic immunity

The user should assure the **System** is used in the electromagnetic environment specified below.

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment: guidance
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	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 $d = 1.2 \sqrt{P}$
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. 

Notes for Table 8.2

¹ U_T 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



Warning

- ✓ 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.

Table 8.3 Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the EchoNous System			
The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d=12.3 \sqrt{P}$
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.			

Power Supplies (Chargers)

The external EchoNous power supplies (chargers) comply with the requirements of EN IEC 60601-1 Edition 3.1. The HP display quick power supply (charger) complies with IEC 60950-1.



Warning

- ✓ Do not open or modify the EchoNous Power Supply P003198, the EchoNous AI Station power supply P005332, or any other supplied power supplies - Risk of electric shock

Biological safety

The device can be disinfected for re-use on immunocompromised and non-immunocompromised patients after:

- Frequent contact with healthy skin (frequent low risk).
- Occasional contact with mucous membranes or contamination with particularly virulent or readily transmissible organisms (occasional intermediate risk).

Acoustic Output



Warning

- ✓ The ALARA principle (As Low As Reasonably Achievable) should be employed for all medical ultrasound exposure

Ultrasound imaging has been in regular use for over 20 years and has an excellent safety record. Even though there are no known risks of ultrasound imaging, it heats the tissues slightly and may produce small pockets of gas in body fluids or tissues (cavitation). The long-term effects of tissue heating and cavitation are not known.

Given potential does exist for bio-effects with ultrasound exposure, any exposure should be kept As Low As Reasonably Achievable. Scans should only be performed when there is a medical benefit and in the shortest time commensurate with obtaining an adequate study. As the acoustic output of the device does not exceed an MI or TI of 1.0, visual display of MI and TI values is not required. A generic ALARA education program is supplied with your **System** (see enclosed ISBN 1-93004 7-71-1, *Medical Ultrasound Safety*).

Table 8.4 B-mode acoustic output and uncertainties

	$I_{SPTA.3}$ [mW/cm ²]	TI type	TI Value	MI	$I_{PA.3}@MI_{max}$ [W/cm ²]
Uscan Probe Output	5.69	TIS	0.09	0.823	143
Uscan Probe Uncertainties	±9.2%		±9.2%	±4.6%	±9.2%
EchoNous Bladder Probe Output	2.75	TIS	0.0366	0.925	90.1
EchoNous Bladder Probe Uncertainties	±8.4%		±8.6%	±4.3%	±8.4%
EchoNous Vein Probe (fundamental) Output	0.961	TIS	0.0088	0.411	69.2
EchoNous Vein Probe (fundamental) Uncertainties	±10.3%		±10.5%	±5.2%	±10.5%
EchoNous Vein Probe (THI) Output	4.27	TIS	0.0271	0.67	102.29
EchoNous Vein Probe (THI) Uncertainties	±10.5%		±10.6%	±5.3%	±10.4%

$I_{SPTA.3}$ Derated spatial peak, temporal average intensity (milliwatts/cm²)

TI Thermal index

MI Mechanical index

$I_{PA.3}@MI_{max}$ Derated spatial-peak pulse-average intensity (watts/cm²)


Uncertainties are the cumulative effect of measurement uncertainties.

9. ADVANCED DEVICE AND IT SETUP

The **System** provides a number of advanced configuration options to enable an institution to setup and manage the devices in their facility.


- Administrators can lock preferences with a password.
- Administrators can implement user management.
- Multiple devices can be setup with common preferences.
- Restrict ultrasound scanning and restrict viewing images during bladder scanning.
- Restrict recording of ultrasound data and bladder data.
- Restrict access to USB storage.

Administrator Setup



- From the *Home Screen*, tap  and select *Settings*.
- Select *Administration*.
- Under *Security*, tap on *Enable Administrator Password*.
- Enter an administrator password. Ensure you record the password in a secure location and do not forget or lose it.

As soon as an administrator password is setup, preferences and settings can only be changed by the administrator.

Software Updates Restrictions

- From the *Home Screen*, tap  and select *Settings*.
- Select *Administration*.
- *Automatic Updates Check* – check to automatically check for software updates (remote updates are not available in Japan).
- *Allow USB Software Updates* – check to allow installation of software updates via USB.

User Management

- From the *Home Screen*, tap  and select *Settings*.
- Select *Administration* then select *Manage Users*.
- Tap the  icon in the top right of the screen.
- Enter a Username, Family (Last) name, Given (First) name, and if required set the password (see [Fig 9.1](#)).
- Tap *Save* to finish.

The user will need to enter a user name and password to save patient data (see [Fig 9.2](#)).

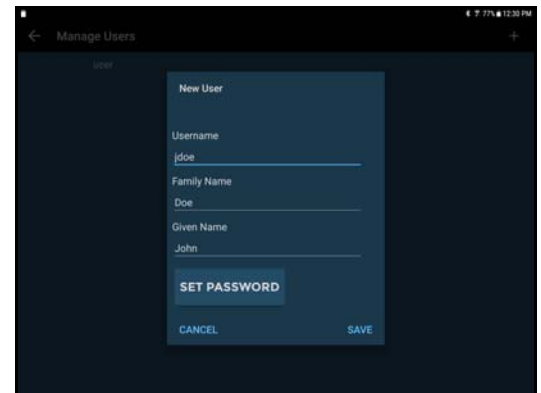


Fig 9.1 Add User

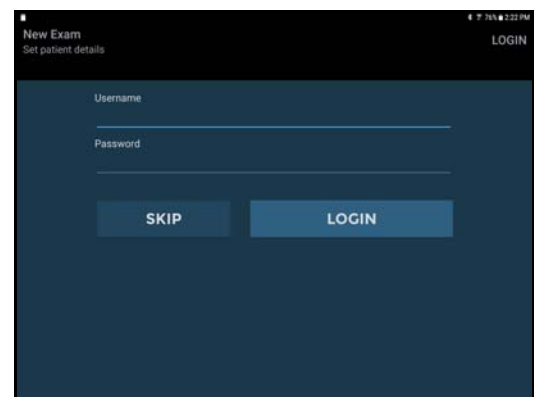



Fig 9.2 User Login

Multiple Device Setup

To setup multiple devices with identical preferences and users, first configure one device with the required settings (see [Settings](#)).

Export the settings to a file:

- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Settings Management**.
- Select **Export EchoNous System Settings**.
- Tap **SAVE** to write the settings to an XML file.
- Copy the XML file from the tablet or handheld display to a host computer (for example by connecting the tablet to a computer by a USB cable and copying the file from the tablet to the computer).

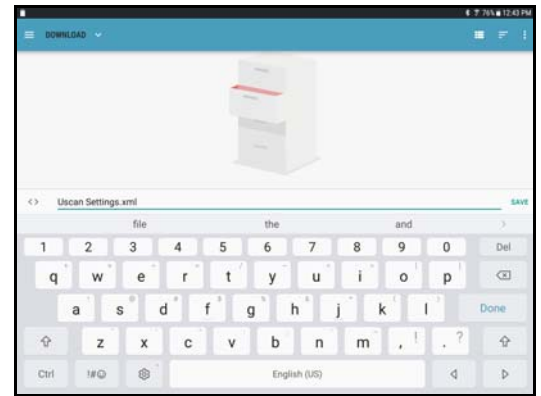




Fig 9.3 Export Settings

On each of the other systems to be setup, import the settings:


- Turn the display on and follow the initial setup instructions (see [Setting up the System](#)).
- Copy the XML file from the host computer to the display local storage.
- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Settings Management**.
- Select **Import EchoNous System Settings**.
- Select the XML file to import.

Imaging Restrictions

To setup a password for accessing Ultrasound Imaging and Vascular Access functionality:

- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Restrict Imaging**.
- Enter a password for accessing ultrasound functionality. Ensure you record the password in a secure location and do not forget or lose it.


To require ultrasound scanning password for viewing images during bladder scanning:

- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Disallow viewing images during Bladder Volume Scanning**.
- The ultrasound imaging password will be required to view images during bladder volume scanning.


Data Recording Restrictions

The **System** enables institutions to restrict saving, printing, and exporting ultrasound imaging, vascular access, and/or bladder data.

To restrict ultrasound imaging and vascular access data recording:

- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Imaging Data** under **Recording**.
- Select **Do not allow recording** to restrict recording imaging data.

To restrict bladder volume data recording:

- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Bladder Volume Data** under **Recording**.
- Select **Allow recording volume only** to restrict recording bladder volume images but allow recording volumes.
- Select **Do not allow recording** to restrict recording all bladder volume data.

Storage Access Restrictions

To restrict access to exported images via USB:


- From the **Home Screen**, tap  and select **Settings**.
- Select **Administration** then select **Restrict access to exported images via USB** under **Storage Access**.

Fig 9.4

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Glossary

<i>Bladder volume</i>	Volume of urine in the bladder.
<i>Exam</i>	A unique interaction between a clinician and patient. Up to 50 images may be saved to each exam. Exams are identified by patient name and/or by date and time of scan.
<i>MSO</i>	Multiple socket outlet.
<i>Patient</i>	A single person, with unique details such as name, gender, date of birth and EMR Id (electronic medical record).

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