FUJIFILM
SONOSITE

EN

Sonosite iLOOK Ultrasound System

User Guide

Manufacturer	EC Authorized Representative	UK Responsible Person	Australia Sponsor
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CAUTION
United States federal law restricts this device to sale by or on the order of a physician.

Patent: **www.sonosite.com/patents**

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Introduction

About the user guide

The user guide provides information on preparing and using the Sonosite iLOOK ultrasound system and on cleaning and disinfecting the system and transducer. It also provides system specifications, and safety and acoustic output information.

> **NOTE**
> We highly recommend you read the entire user guide before using the system.

This user guide is meant for users familiar with ultrasound. It does not provide training in sonography, ultrasound, or clinical practices. Before using the Sonosite iLOOK ultrasound system, you must complete such training.

For information on using accessories and peripherals, refer to the applicable accessory user guide and manufacturer's instructions.

Document conventions

The document follows these conventions:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **CAUTION** describes precautions necessary to protect the products.
- A **NOTE** provides supplemental information.
- Numbered and lettered steps must be performed in a specific order.
- Bulleted lists present information in list format but do not imply a sequence.

Symbols and terms used on the system and transducers are explained in Labeling symbols [90] and the Glossary [115].

Getting help

In addition to the system user guide, the following are available:

- On-board user guide by accessing the system menu ☰.

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Europe and Middle East	Main: +31 20 751 2020 English support: +44 14 6234 1151 French support: +33 1 8288 0702 German support: +49 69 8088 4030 Italian support: +39 02 9475 3655 Spanish support: +34 91 123 8451
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Intended Use

The intended use is: Medical Diagnostic Ultrasound. The Sonosite iLOOK ultrasound system is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

Indications for use

Diagnostic ultrasound

The Sonosite iLOOK ultrasound system is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

- Pediatric
- Peripheral vessel
- Needle Guidance

Modes of operation include: B Mode (B), Color Power Doppler, Color Velocity Doppler, Multi-beam imaging, and combined modes, including duplex imaging: B+C.

WARNING
To avoid patient injury, do not use this ultrasound system to image the eye.

This device is indicated for Prescription Use Only.

The Sonosite iLOOK system is intended to be used in medical practices, clinical environments, including healthcare facilities, hospitals, clinics, and clinical point-of-care for diagnosis of patients.

The system includes a transducer and a display connected together wirelessly. The transducer is powered by battery, while the display is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient's body where needed to obtain the desired ultrasound image.

Clinical applications

The following indications for use table displays the clinical applications and imaging modes for the system and transducer. The predefined exam types available are displayed in Selecting an exam type [43].

The indications for use table key applies to the indications for use table.

Table 1. Indications for use table key.

a	2D = B Mode; C = Color Doppler (Color Velocity Doppler or CVD, Color Power Doppler or CPD)
b	Multi-beam (MB) imaging (spatial compounding) in B Mode
c	Color Doppler includes Power/Velocity

d	Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Table 2. Sonosite iLOOK (L15-5 transducer) diagnostic ultrasound indications for use

Intended use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:			
Clinical application	Mode of operation[a]			
	2D	C	Combined (spec.)	Other (spec.)
Pediatric	✓	✓	B; B+C	b, c, d
Peripheral vessel	✓	✓	B; B+C	b, c, d

The system transmits ultrasound energy into the patient's body to obtain ultrasound images as described in the following table.

Table 3. Clinical application descriptions

Clinical application	Description	Exam types
Pediatric	You can assess the deep and superficial vessels (arteries and veins) in upper and lower extremities, central vessels, and various other small vessels for presence or absence of pathology.	Arterial, PIV, Venous
Peripheral vessel	You can assess the deep and superficial vessels (arteries and veins) in upper and lower extremities, central vessels, and various other small vessels for presence or absence of pathology.	Arterial, PIV, Venous

The Sonosite iLOOK provides ultrasound-guided vascular access as a clinical application. This includes procedures such as blood draws, peripheral intravenous (PIV) catheter insertions, peripherally inserted central catheters (PICC), midline catheter placements, central line insertions, and arterial line placements. Ultrasound guidance can help clinicians select the appropriate vessel, assess vessel patency, precisely guide needle placement, and verify successful line placement.

Biometric Measurements

You can perform distance and CVR (catheter to vessel ratio) measurements on the Sonosite iLOOK ultrasound system.

Measurement and analysis performance encompasses the accuracy of the caliper measurements as well as the accuracy of algorithms used to further analyze the measurements. The accuracy values require that the operator can place the caliper marker over one pixel. The values do not include acoustical anomalies of the body. Other limitations and assumptions for measurement performance are given in Sources of measurement errors [54].

Accuracy of each clinical measurement possible and the range over which this accuracy can be expected to be maintained are also found in Sources of measurement errors [54].

Contraindications

The ultrasound system has no known contraindications.

Getting Started

WARNING
Do not use the system if it exhibits erratic or inconsistent behavior. Such behavior could indicate a hardware failure. Contact FUJIFILM Sonosite Technical Support.

About the Sonosite iLOOK ultrasound system

The ultrasound system acquires and displays high-resolution, real-time ultrasound images and can be used in a mobile or stationary configuration. Features available depend on your system configuration, hardware and software version, transducer, and exam type.

The system consists of a display, adjustment handle, wireless L15-5 linear ultrasound transducer, and a transducer holder with built-in wireless charger. The transducer tip is placed on the human body for ultrasound scanning, and the front, rear, and sides are held by the operator.

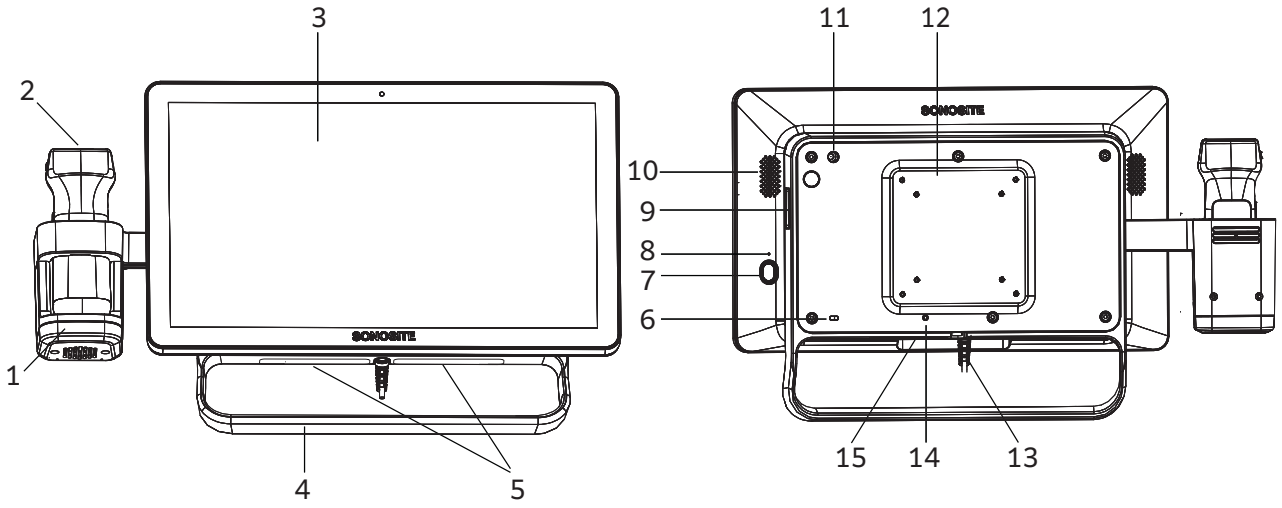
Basic operating steps

1. Charge the transducer and display. See Charging the system [11].
2. If needed, turn on the display. See Turning the display on and off [13]. The display turns on automatically when plugged in.
3. Configure the system including connecting to the wireless network. See Configuring the system for the first time [19] and Configuring application settings [33].
4. Turn on the transducer. See Turning the transducer on and off [13].
5. Start the imaging application. See General interaction [16].
6. Add and connect the transducer. See Adding and deleting transducers [34] and Connecting the transducer [42].
7. Scan. See Scanning [40].
8. End the exam. See Ending the exam [48].

Hardware features

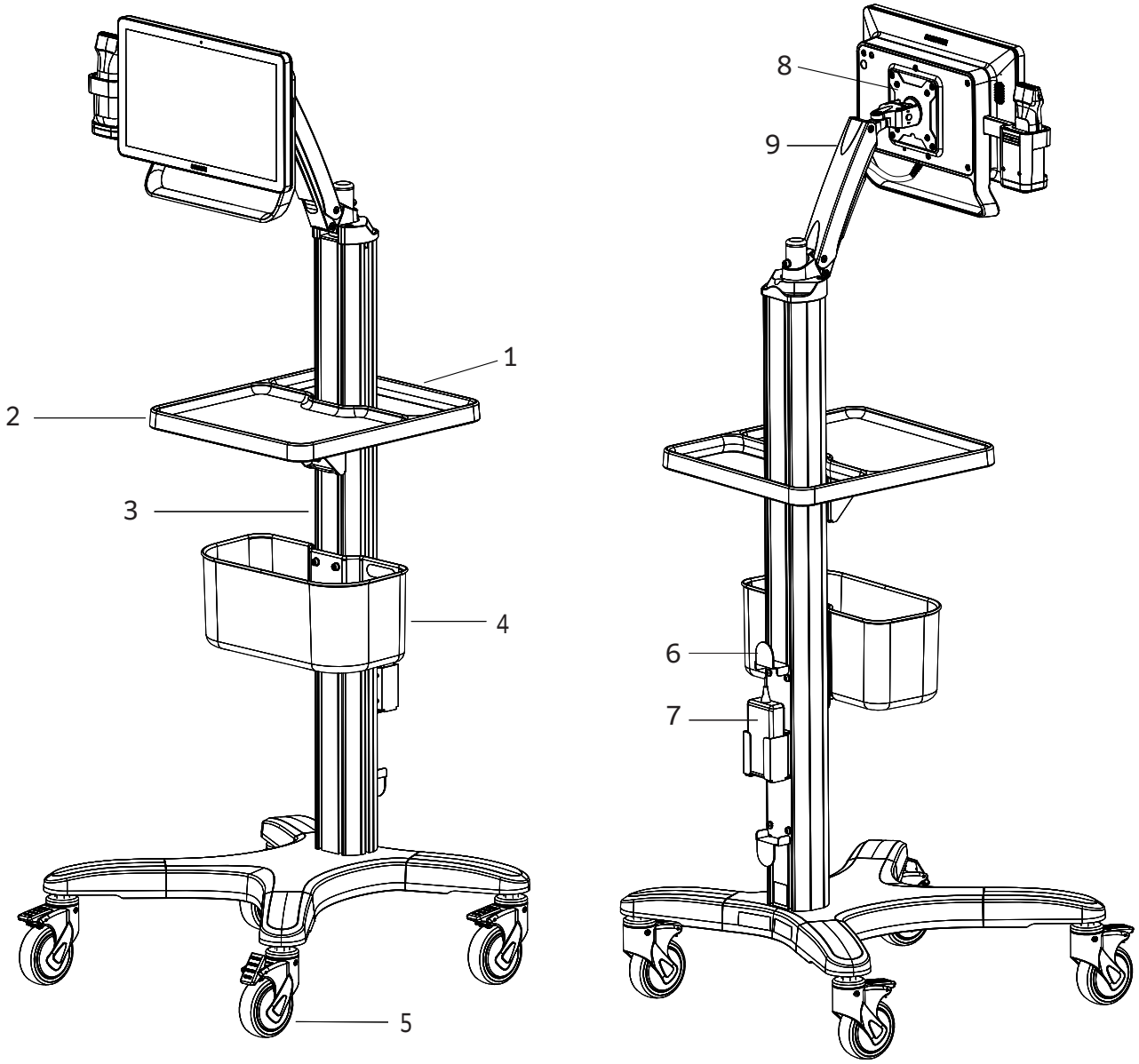
The system features a standard VESA Flat Display Mounting Interface (FDMI), MIS-D 100 mm x 100 mm with internal threads for mounting to the optional Sonosite iLOOK stand or a customer-supplied wall-mounted adjustable arm that meets the requirements described in Installing the system on a wall-mounted adjustable arm [9]. The VESA interface also includes the standard MIS-D 75 mm x 75 mm pattern. Do not attach the system to any other FUJIFILM Sonosite stand. The system must always be mounted on either the stand or an appropriate arm.

Figure 1. System



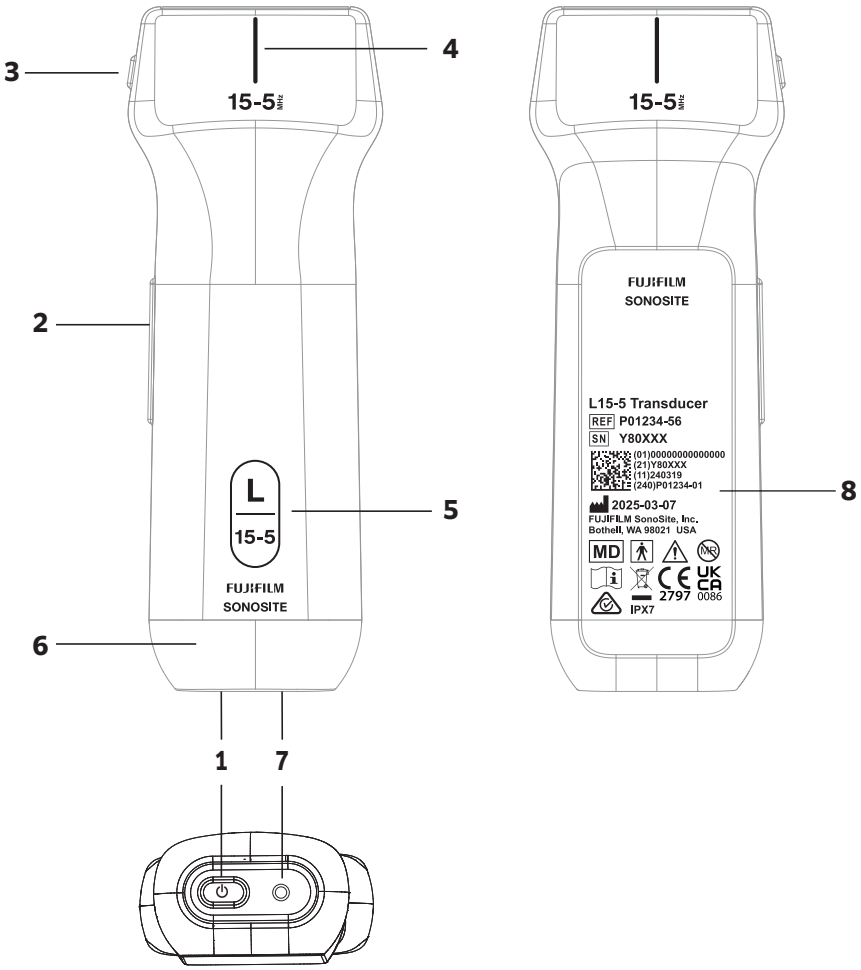
1.	Transducer holder with built-in charger and fan	4.	System handle	7.	Power button	10.	System speaker	13.	Cable connector
2.	Transducer	5.	System label	8.	Reset button	11.	Accessory port	14.	Charge indicator
3.	Clinical display with touchscreen	6.	Kensington security slot	9.	USB port	12.	VESA interface	15.	System microphone

Figure 2. System with optional FUJIFILM Sonosite stand



1.	Stand handle	4.	Storage container	7.	Power brick and holder
2.	Tray	5.	Locking wheels (4)	8.	Stand mount
3.	Stand	6.	Cord wrap	9.	Adjustable monitor arm

Transducer features



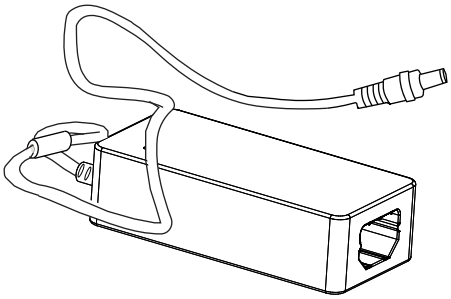
1.	Power button
2.	Power indicator
3.	Orientation marker
4.	Centerline marker
5.	Transducer type and frequency
6.	Wireless antenna location
7.	Vent
8.	Label

Accessories and peripherals

WARNING
Use only accessories and peripherals recommended by FUJIFILM Sonosite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM Sonosite could result in electrical shock and system malfunction. Contact FUJIFILM Sonosite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM Sonosite.

The ultrasound system is designed to support a variety of accessories and peripherals. For a complete list, see Compatible accessories and peripherals [85].

AC power brick



The AC power brick powers the system and charges the display battery, as well as the transducer battery via the built-in charger in the transducer holder. No preventative maintenance is required.

Installing the system on the stand

1. Loosen the four pre-installed screws on the back of the system and remove the two bottom screws. Slide the top screws into the top slots on the stand mount.
2. Re-insert the two lower screws through the bottom holes of the stand mount and into the system, then use a Phillips screwdriver to tighten all four screws securely.
3. Connect the system cable connector to the end of the power brick cable. See Hardware features [5].

Removing the system from the stand

1. Raise the stand arm to the highest position.
2. Disconnect the system cable and unscrew the bottom two screws.
3. Loosen the top two screws, then lift the system off the top slots of the stand mount.

Installing the system on a wall-mounted adjustable arm

A customer-supplied mount must meet the following specifications according to the VESA FDMI standard for safe operation. Use of any mount other than the Sonosite iLOOK stand is at your own risk.

The mount and the mounting surface should be capable of safely supporting at least four times the combined weight of the system and transducer. Refer to Specifications [94] for system and transducer weights. Follow all installation instructions and precautions provided with your mount. FUJIFILM Sonosite is not responsible for any damage or injury caused by third-party mounts.

- Mounting pad size: 115 mm (4.53 in) x 115 mm (4.53 in) (maximum)
- Number of holes: 4
- Hole spacing: 100 mm (3.94 in) x 100 mm (3.94 in) (square) or 75 mm (2.95 in) x 75 mm (2.95 in) (square)
- Hole size in pad: 5 mm (0.2 in)
- Screw thread size (4 each): 4 mm (0.16 in) diameter x 0.7 pitch
- Screw thread length: thickness of mounting pad + 6 mm (max); thickness of mounting pad + 4 mm (0.16 in) (minimum)
- Load rating: 14 kg (vertically applied)

1. Always keep one hand firmly holding the system while attaching to a wall arm or other mount.
2. Secure the power brick to the wall or wall arm near the system.
3. Make sure that the power cord attached to the system is free to move with the arm and does not cause a tripping or other hazard.

Adjusting the system or stand

WARNING
Lock the stand wheels whenever the system is unattended or stationary.

Do any of the following:

- To lock or unlock a wheel, press down the lever on the wheel or press up on the bottom of the lever.
- To raise, lower, or swivel the display, use the handle located on the front of the display mount to adjust the stand arm.

Transporting the system

1. Make sure that the system is facing forward.
2. Place the transducer in the holder.
3. Lower the stand arm to the lowest position possible.
4. Make sure that any power cords are unplugged and clear of the floor.
5. To wheel the system, unlock the stand's wheels and then push forward on the handle located on the back of the stand.

Charging the system

WARNING

- Check that the voltage of the electrical outlet is within the voltage range of the AC power brick.
- Plug the system only into a grounded hospital-grade AC mains outlet.
- Do not keep the power brick near the patient.
- If the surface of the transducer appears deformed, the battery may have failed. Do not charge or use the transducer.

CAUTION

- When using AC power, position the system to allow easy access to unplug it from the AC mains outlet.
- The batteries contain technology that requires periodic recharging to maintain optimal performance. If left uncharged for months, battery performance could degrade or the battery could become non-functional.
- Periodically check to make sure that the batteries charge. If the batteries fail to charge, contact FUJIFILM Sonosite Technical Support.

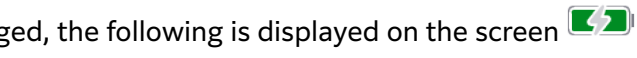
NOTE

- The display and transducer do not have AC power switches.
- The display device automatically turns on when connected to AC power.

Charge the system before using it. The display device fully charges in 2.5 hours. The transducer fully charges within 4 hours.

Charging the display device

1. Make sure that the AC power cord is connected to the power brick and that the cable on the other end of the brick is connected to the connector on the back of the system.
2. Plug the AC power cord into a hospital-grade AC mains outlet.

When the device is fully charged, the following is displayed on the screen  (plugged in) or  (unplugged).

Charging the transducer

The transducer's battery charges from the display's battery. To charge the transducer, keep the system plugged into the wall.

1. Insert the transducer into the transducer holder with the label side facing the back of the holder where the wireless charger is located.
2. The transducer indicator light is white while the battery is charging and turns off when the battery is charged.

Power and battery indicators

Battery status is shown in the upper left of the display. See Figure 4, “Main imaging screen layout” [18].

Table 4. Power and battery indicators

Indicator	Status
Transducer 1–25% 26–50% 51–75% 76–100%	The system is unplugged, and the battery is in use. The level of battery charge corresponds to the length of the bar. When the battery charge is low, the color of the bar changes to amber and the system displays a warning message.
Display 1–10% 11–30% 31–50% 51–70% 71–100%	
Transducer 0–79% 80–100%	The system is on AC power, and the batteries are charging.
Display 1–10% 11–30% 31–50% 51–70% 71–100%	

Indicator	Status
Power indicator located on the transducer's side	• Pulsing blue light: Transducer is on and ready to connect • Green light: Transducer is on, connected, and battery is above 25% • Unlit: Power is off or the transducer is sitting in the charger fully charged • Orange light: Transducer is on, connected, and battery is below 25% • Pulsing orange light: Error state. • White light: Transducer is charging (placed in the charging holder). The light turns off when the transducer is fully charged in the charger.
Charging indicator located on the back of the system	• White light: System is fully charged • Blinking white light: System is charging • Unlit: System is not charging

Turning the system on and off

WARNING
Do not use the system if it exhibits erratic or inconsistent behavior. Such behavior could indicate a hardware failure. Contact FUJIFILM Sonosite Technical Support.

CAUTION
You must charge the batteries before using the system for the first time. See Charging the system [11].

Turning the display on and off

The system powers on when connected to AC power.

- To turn on the display, press and hold the power button located on the back until the screen lights up.
- To turn off the display, press and hold the power button. Tap **Power Off** when the selection screen appears.

Turning the transducer on and off

If the system connected to the transducer powers off, the transducer will automatically power off as well. Additionally, the transducer turns off if it is fully charged and has been disconnected from the system for more than four hours.

- To turn on the transducer, press and hold the power button located on the bottom of the transducer. The power indicator flashes blue.
- To turn off the transducer, press and hold the power button for three seconds.

Putting the system into sleep mode

To conserve battery power and protect patient data, the system enters sleep mode after a period of inactivity. To specify the period of inactivity before the system goes into sleep mode or to turn off sleep mode, see Configuring sleep settings [32].

WARNING
To protect patient data, make sure that the system is configured to enter sleep mode if left unattended.

1. Briefly press the display's power button to enter sleep mode.
2. To exit sleep mode, briefly press the power button or touch the screen.

NOTE
If the system will not be used for a long period of time, turn off the power. See Turning the system on and off [13].

Inserting and removing USB devices

You can use the USB port on the system for connecting devices such as a USB storage device. Use USB storage devices to export patient data and logs. Make sure USB storage devices are formatted in exFAT (recommended) or FAT32. Devices formatted with NTFS are incompatible with the system.

WARNING
Use only accessories and peripherals recommended by FUJIFILM Sonosite. Connection of accessories and peripherals not recommended by FUJIFILM Sonosite could result in electrical shock and system malfunction. Contact FUJIFILM Sonosite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM Sonosite.

CAUTION

- To avoid losing data from or damaging the USB storage device, do not remove the USB storage device or turn off the ultrasound system while exporting. In addition, do not bump or apply pressure to the USB storage device while it is connected to the system. The connector could break.

NOTE
To protect patient confidentiality, remove all identifying information from patient images, files, or records before sending electronically.

1. Insert the USB storage device into the USB port (see Hardware features [5]).
2. If exporting, wait until the export has finished.
3. Remove the USB storage device from the port.

Disconnecting the USB storage device while the system is exporting to it may cause the exported files to be corrupted or incomplete.

Logging in and out

When a new Sonosite iLOOK ultrasound system is configured in secure mode, the login screen displays when you turn the system on. See Configuring the system for the first time [19].

Logging in and out as a user

Do the following to log in, log out or re-log into the system.

- To log into the system, type your login name and password on the login page and tap **Log in**.
- To log out of the system, tap the drop-down next to the username in the top right corner of the home screen, and tap **Log out**. See Quitting the imaging application [48] to return to the home screen.
  You are also logged out if the system enters sleep mode, is turned off, or is restarted.
- If someone else is already logged in, log them out before logging in. You might need to end an exam or study (select **End study**).
- If you have woken the system back up, re-enter your password to log back in or tap **Log out** to log the previous user out.

NOTE
If your administrator has set up a server-based login, use your server username and password to log into the ultrasound system. You can also use your server-based login if the ultrasound system is not connected to the server, provided you have already logged in at least once prior to taking the system offline. The system stores locally cached user information.

Logging in as a guest

Guests can scan, save images and clips, and manage patient data for the current study. Guests can also access on-board help and limited settings.

1. Turn on the system.
2. On the login page, tap **Guest mode**.

Changing your password

NOTE

- You can only change your password on the system if your system is using local user accounts. Server-based passwords need to be changed on the server.
- The system notifies you if your password does not meet the password requirements.

1. Sign into your account on the system.
2. Tap the drop-down next to your username in the top right corner of the screen.
3. Tap **Change password** from the menu.
4. Type your old and new passwords, confirm the new password, and then tap **Change**.

Returning to factory defaults or deleting patient data

If you have forgotten your login information, you can reset the system or contact FUJIFILM Sonosite (see Getting help [1]).

To protect patient data, deleting patient data is recommended prior to returning the system for service. To back up patient data, see Archiving studies [50] and Exporting studies to a USB storage device [50].

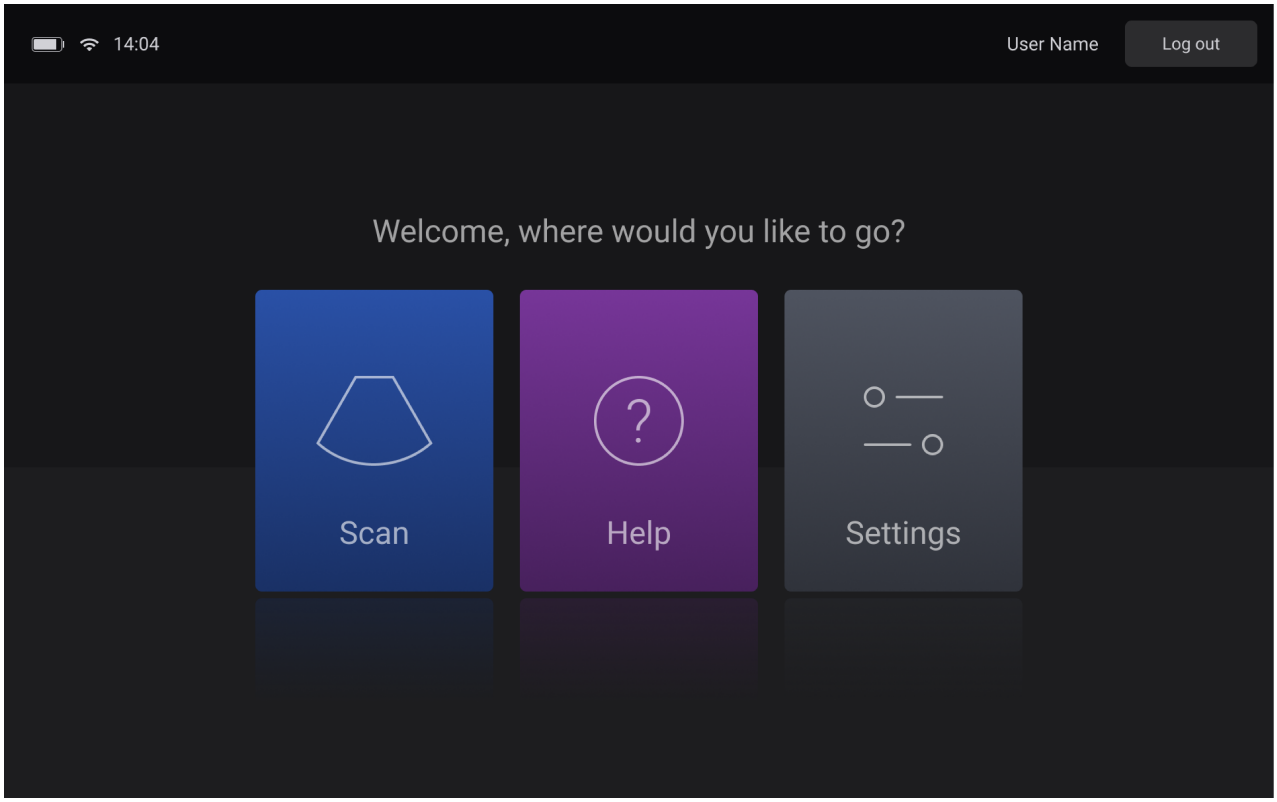
CAUTION
Restoring the system to the default settings will delete settings and data. Export patient data before performing this action.

1. On the login screen, press and hold the screen title **Log in with your user name and password** for 10 seconds.
2. Select one of the following:
   - To reset the system, select **Factory reset** then tap **Reset**.
   - To delete all patient data, select **Delete all patient data** then tap **Delete**.
   - To cancel, tap **Cancel**.

General interaction

After logging into the system, the home screen appears.

Figure 3. Home screen



The system has three main modules that are accessible from the home screen:

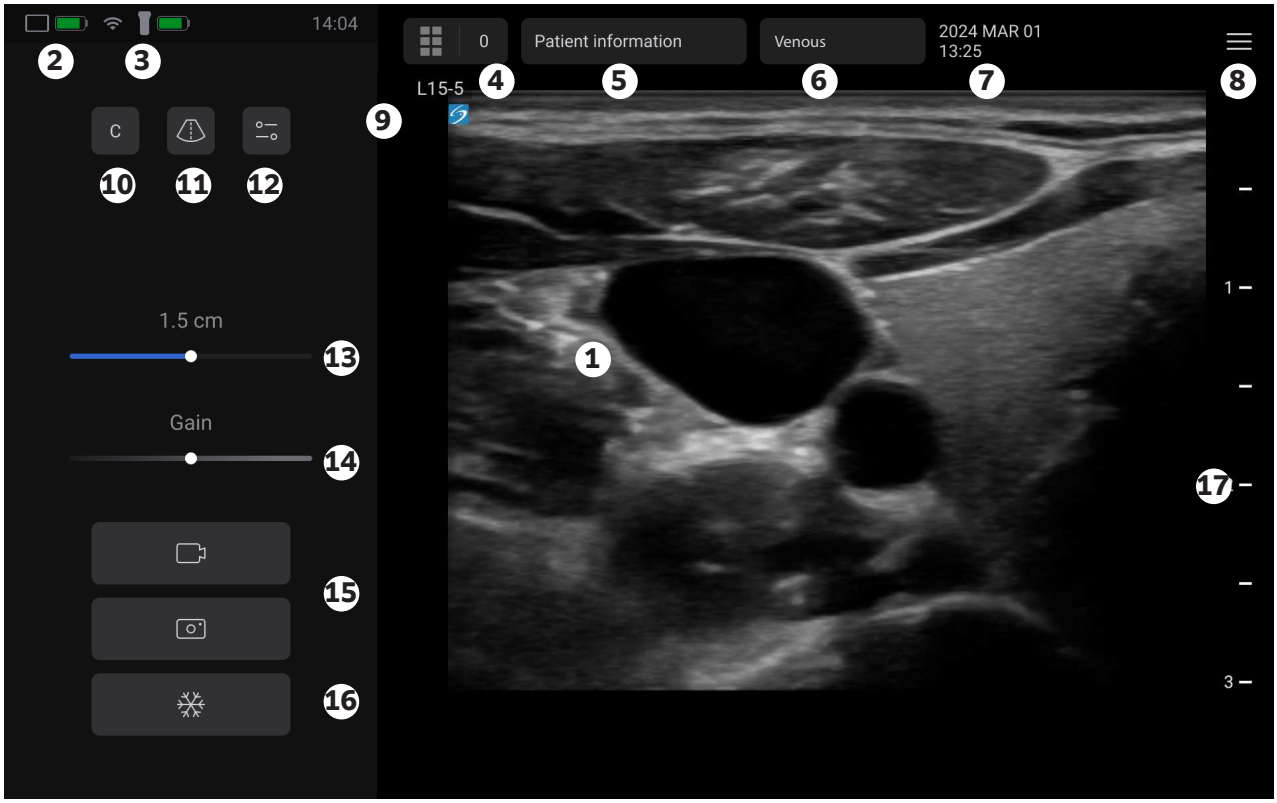
- **Scan** - This module accesses the imaging application where you can perform patient exams, enter patient information, review and export patient data, access transducer settings, and more.
- **Help** - This module accesses the on-board user guide and quick guide.
- **Settings** - This module allows you to configure settings such as date and time and connecting to a network.

An administrator has access to additional security and configuration settings that are unavailable to other users. A guest user has access to a limited number of settings.

Using the touchscreen

You can use the touchscreen on the display to interact directly with objects on the screen similar to many other touchscreen devices. Use the touchscreen to adjust settings; select the exam type, transducer, and imaging mode; enter patient information; and more.

Figure 4. Main imaging screen layout



1.	Ultrasound image	10.	Imaging modes
2.	Battery level of the display	11.	Centerline
3.	Transducer connection status and battery level	12.	Imaging control panel
4.	Review button	13.	Depth control
5.	Patient information	14.	Gain or cine controls
6.	Exam type selection	15.	Save buttons
7.	Date and time	16.	Freeze
8.	System menu	17.	Depth marker
9.	Orientation marker		

On-screen keyboard

You can enter text into text boxes (for example, on the patient form) using the on-screen keyboard.

1. Tap a text box.
2. Tap keys as needed:
   - Tap the shift key ⇧ to switch alphabet keys between uppercase and lowercase.
   - Tap **?123** to display keys for numbers, symbols, and special characters.
   - Tap **ABC** to return to the alphabet keys.
   - Tap ⌫ to delete a character on the left side of the pointer.
   - Tap ✓ or away from the keyboard to close the keyboard.

Configuring the System

Settings is where you customize the system and set preferences.

NOTE
Some settings depend on network communication and may not take effect immediately.

Configuring the system for the first time

When you first launch the imaging application on a new Sonosite iLOOK ultrasound system, an automatic configuration wizard appears. This wizard guides you through creating an administrator account and configuring the system.

1. Turn the display on by pressing the power button.
   The welcome screen appears.
2. Tap **Start setup**.
3. On the next screen, enter the administrative login information you would like to use, close the keyboard then tap **Continue**.

   NOTE
   - To ensure security, choose a password that is a minimum of eight characters, contains at least one uppercase letter, at least one number, and at least one special character.
   - You cannot use any of the following as a username: admin, administrator, root, or guest.

4. If you would like to connect the system to a wireless network, follow step 5 or 6. Otherwise, skip to step 7.
5. To connect the system to a wireless network that does not require a security certificate, do the following:
   a. Tap **Add** to search for an available wireless network.
   b. Choose an available wireless network from the list and tap **Connect** or tap **Add** to add a new network.
   c. Enter a profile name and network name.
   d. Select the appropriate security policy from the drop-down list and **Personal** under **Authentication**.
   e. Select an authentication type, for example PSK (passkey), and enter a password.
   f. Enter the name of the network location of the ultrasound system under **Alias**.

   A wireless connection is necessary to connect to an LDAP server and enable DICOM and remote software updates.
6. To connect to a network that requires a certificate, follow the same steps in step 5 except select **Enterprise** under **Authentication** and complete these additional steps.

a. Tap **Manage Certificates** then tap **+Import**.
b. Connect the USB storage device that contains the certificates to the USB port on the display device. For a list of supported certificate file types, see Managing certificates [26]. You can import your certificates for wireless, LDAP, and DICOM at the same time.
c. Tap **Yes**, then select the USB containing the certificates and tap **Import** again.
d. Tap **Install** (PFX certificates are installed automatically).
e. Fill out the network security fields as needed (for example, select **TLS** under **EAP method** and select the previously imported root certificate under **CA certificate**).

7. Tap **Continue**. On the next screen, you can choose to set the time manually or automatically, set a time zone and also select a time format.
8. Tap **Continue** and enter your institution and departmental information.
9. Tap **Continue** and select one of the following modes. You can also change modes later.

CAUTION
FUJIFILM Sonosite strongly recommends configuring the system in secure mode. Operating in non-secure mode increases the risk of being out of compliance with HIPAA regulations.

- **Secure mode:** Secure mode, the default setting, requires all users to log into the system and enables user management by an administrator including support of a directory server. Secure mode is compliant with patient privacy regulations.
- **Non-secure mode:** Non-secure mode allows any user to access all system functions, except administrative settings, without requiring a login. If you select non-secure mode, the wizard skips to the system portal configuration screen.

CAUTION
Healthcare providers who maintain or transmit health information are required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the European Union Data Protection Directive (95/46/EC) to implement appropriate procedures: to ensure the integrity and confidentiality of information and to protect against any reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosures of the information.

10. If you have selected secure mode, select **Yes** to set up the connection to the LDAP server. You can also set this up later. For details, see Configuring a connection to a directory server [21]. This allows additional users to log into the system with their server-based user accounts and use the system.
11. If you have selected secure mode, the system prompts you to add user profiles. This is recommended if you are not using LDAP server-based user accounts. For details, see Adding a new user on the system [22].
12. Continue to the next screen to enable the system portal connection. Enabling the system portal allows remote software updates and system monitoring. For details, see Remote software updates and system monitoring [25].
13. On the final screen of the setup wizard, the system prompts you to select a sleep delay setting from a drop-down menu.

14. Tap **Finish**.

Navigating system settings

You can access many of the same settings that the configuration wizard guides you through. See Configuring the system for the first time [19].

1. Log into the system as a user.
2. On the home screen, tap **Settings**.
3. Tap a setting from the list to display the settings page.
4. Do any of the following while in a settings page:
   - Tap another system setting from the list to display its settings page (any changes you have made are saved).
   - Tap **Exit settings** to leave system settings.

Using the system as an administrator

Users with administration rights have the ability to manage users and configure certain settings and security features on the system.

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

Accessing settings as an administrator

1. Log in using your administrative login information.
2. On the home screen, tap **Settings**.
3. Do any of the following while in a settings page:
   - If a system setting has multiple pages, use the breadcrumbs at the top of the page to navigate to previous pages.
   - Tap **Done** to exit the page.
   - Tap **Save** if any changes need to be saved and return to the previous page.
   - Tap **Cancel** to display a dialog that allows you to cancel your changes, save your changes, or return to the page.
   - Tap **Exit settings** to leave system settings.
4. To display the main administration settings page, tap **Administration** in the list on the left.

Configuring a connection to a directory server

In order to use server-based user accounts, you must configure the system in secure mode (see Configuring the system for the first time [19]). A network connection is required to test the connection.

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. To go to the LDAP configuration screen, tap **LDAP**.
3. In the **Remote server** field, type the Fully Qualified Domain Name (FQDN) Address or IP address of the directory server.
4. In the **Port** field, type the port number of the directory server.
   The default port for LDAP is 389. The default port for LDAPS is 636. Your directory server port number could be different.

5. To encrypt the communication between the ultrasound system and the directory server using Transport Layer Security (TLS), make sure that the checkbox next to **Secured** is selected (not checking this box could compromise any passwords used on the system).
   If using TLS with a private certificate authority (CA), you must first import the private root CA certificate (see Managing certificates [26]).
6. In the **Search root** field, type the Distinguished Name of the root directory.
   The Distinguished Name is normally the same as the domain name, expressed in X.500 "attribute=value" format per RFC-2253.
7. In the **User DN** field, type the Distinguished Name of the user directory that you wish to search.

> **NOTE**
> Normally, you read the directory path that stores the user accounts in reverse order.

8. In the **Domain name** field, type the domain name component (typically the subdomain of the DNS domain name) that should be added to the front of a user account name in order for the directory lookup to succeed.
9. In the **Delete inactive account after (days)** field, add a time period.
10. If desired, add a **Clinician search attribute**.
11. When you've finished configuring your connection, tap **Test connection**.

> **NOTE**
> If the connection fails, make sure that you have entered the correct information and that there are no issues with the network or server.

12. Tap **Save**.

Adding a new user on the system

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **User Profiles**.
3. On the user management page, tap **+ Add**. Fill in the user information fields.
4. If you want to require that the user change their password, select **Require password change on next login**, and then enter a temporary password for the new user to gain initial access.

> **NOTE**
> To ensure security, choose a password that is a minimum of eight characters, contains at least one uppercase letter, at least one number, and at least one special character.

5. If you want the user account to expire on a given date (such as accounts for students, interns, or other temporary personnel), select **Enable account expiration**, and then enter the number of days (such as 90) until the account will expire into the **Account expiration (days)** field.
6. When you have finished configuring the new user account, tap **Save**.

Editing or deleting a user

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **User Profiles**.
3. Tap the user account in the list, then tap **Edit**.
4. Make the desired changes to the user information fields.
5. When you have finished modifying the user account, tap **Save**.
6. To delete a user, select the user account from the list and tap **Delete**. Confirm the deletion in the dialog.

Managing password requirements

Administrators can define the complexity of user account passwords, including the types of required characters, length of the password, and lock-out policies after multiple unsuccessful login attempts. Password requirements defined on the system only apply to local user accounts.

1. Using your administrative login information, log into the administrative settings page.
2. Tap **Password Rules**.
3. Under **Password complexity**, select the desired combination of parameters for password complexity.
4. Use **Minimum length** and **Maximum length** to control how short or long passwords should be.
5. Enter a value into the **Min duration for password to be active (minutes)** field.
6. If you want to limit reuse of passwords, enter the number of times a person can reuse a previous password into the **Enforce password history count** field.
7. If you want passwords to be changed periodically, enter the number of days until password expiration into the **Password expires in (days)** field. To disable password expiration, enter **0**.
8. Enter the number of unsuccessful attempts a person can enter before the system prevents them from attempting to log in again into the **Account lockout threshold (unsuccessful attempts)** field.
9. Enter the length of time (in minutes) that a user will be prevented from attempting to log in after they've been locked out into the **Account lockout duration (minutes)** field.

Controlling data import and export

Administrators can control the export of data to an attached USB storage device or block access to USB storage devices and networks.

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Admin Settings**.
3. To control export to a USB storage device, do one of the following:
   - If you want to allow exporting data, select the **Enable export to USB** checkbox.
   - If you want to prevent exporting data, deselect the **Enable export to USB** checkbox.
4. To restrict access to a network or device, do any of the following under **Enabled IO devices**:
   - If you want to restrict wireless network access, deselect the **Wi-Fi** checkbox.
   - If you want to prevent any USB device from connecting to the system, deselect the **USB devices** checkbox.

Hiding patient information as an administrator

NOTE
To protect patient confidentiality, remove all identifying information from patient images, files, or records before sending electronically.

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Admin Settings**.
3. To hide patient information on the display, ensure that the **Hide patient information in imaging** checkbox is selected.
4. To hide patient information in exported data, ensure that the **Hide patient information on export** checkbox is selected.

Removing all patient data from the system

CAUTION
Back up patient data prior to performing this action.

To back up patient data, see Archiving studies [50] and Exporting studies to a USB storage device [50].

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Admin Settings**.
3. Tap **Delete all patient data**.
4. Tap **Delete** to finish the process.

NOTE
We recommend deleting all patient date on the system if you need to return it.

Resetting the system

If you have forgotten your login information and need to reset the system, see Returning to factory defaults or deleting patient data [16].

CAUTION
Restoring the system to the default settings will delete settings and data. Back up your system prior to performing this action.

To back up patient data, see Archiving studies [50] and Exporting studies to a USB storage device [50].

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Admin Settings**.
3. To return to factory defaults, tap **Factory reset** then tap **Reset**.

Creating a sign-in notification

Administrators can create a notification or other message that users will see when they log in to the system. The message can be configured to display only the first time a new user logs in, or it can be configured to appear every time users sign in.

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Admin Settings**.
3. Select the **Enable system use notification** checkbox, and then enter the text for your notification.
4. Select the appropriate option to display the notification: either each time a user logs in, or only the first time a new user logs in.
5. To display a new system notification message, select the appropriate checkbox.

Remote software updates and system monitoring

Administrators can configure and connect the system to a cloud service that allows remote software updates and system monitoring. You can download updates from the cloud and install them directly on the system or upload system logs to the cloud that allow remote service personnel to troubleshoot issues. An internet connection is required and your network firewall must be configured to allow HTTPS connection on TCP port 443 to the following URLs:

- https://system-portal.sonosite.com
- http://crl.microsoft.com
- https://system-portal-nosni.sonosite.com
- https://ffss.sac.keyscaler.io/
- http://www.microsoft.com/pkiops/crl
- https://sonositesystemportal.blob.core.windows.net

Notifications appear in your settings if the connection has not been enabled or there is a software update available. To download and install available software updates, see Installing software updates [33].

Configuring the System Portal connection

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **System Portal Connection**.
3. On the next page, tap **Configure**.
4. On the configuration page, select the checkbox to enable connection to the feature.

> **NOTE**
> If the System Portal has been enabled when the system was first configured, this checkbox should already be selected.

5. If the system is not yet connected to a network, see Selecting the system wireless network [27].
6. To use a proxy connection, select the checkbox and enter the proxy server information in the provided fields. Server address and port number are required.
   This information is maintained if the proxy connection is turned off.
7. To automatically download available updates, select the **Download new updates when available** checkbox.
8. Tap **Save** to save the proxy settings and verify the connection. Tapping **Reset** will reset all of the fields to the last time they were saved.
9. To allow non-administrative users to download and install software updates, return to the administrative settings page and tap **Admin settings**. Then tap the **Allow clinician to update software** checkbox.

NOTE
Performing a factory reset on your system will automatically disassociate the device from the System Portal.

Managing certificates

When installing wireless certificates, you may need to install either a client identity certificate, a CA certificate, or both depending on your network type. A client identity certificate is provided as a file ending in .p12 or .pfx and contains the client certificate and private key. The client identity certificate may also contain one or more CA certificates. Otherwise, the CA certificate can also be a separate PEM (Base64-encoded) or DER (binary) file.

When installing TLS certificates for DICOM, you can import PEM (Base64-encoded) certificates, which must have one of the following file extensions: .pem, .crt, .key, or .cer. Once the files are imported, they are available when configuring your DICOM settings.

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **Certificates**.
3. Connect the USB storage device that contains the certificate to the USB port on the display device.
4. Tap **Yes**, then select the USB containing the certificates and tap **Import** again.
5. Tap **Install** (PFX certificates are installed automatically).
6. To review certificate properties, select the certificate whose properties you want to review (if reviewing a .pfx, select the specific certificate within the package from the **Certificate** list), and then tap the property of interest in **Field** to review its details.
7. To delete certificates or uninstall certificates, select the certificate file or certificate, and then tap **Delete** or **Uninstall**.

NOTE
The system informs you if the certificate or certificate file is part of an active DICOM or wireless connection. Uninstalling or deleting the certificate would disrupt the connection.

Exporting and clearing log files

Logs collect information that may be useful when troubleshooting the system. You can send the information to FUJIFILM Sonosite Technical Support (see Getting help [1]).

Log contents are saved as entries are generated. The logs have limited space and overwrite existing content when full.

> **CAUTION**
> Any logs that were previously exported to the USB storage device will be deleted. If you want to keep these files, copy them to another location before continuing.

1. Using your administrative login information, log into the administrative settings page.
2. Tap **Logs**.
3. To export logs, do the following:
   a. Connect a USB storage device (see Inserting and removing USB devices [14]).
   b. Tap **Export** and confirm your selection in the dialog.
   c. Select the USB storage device in the pop-up screen. You can refresh the list if you have just connected the device.
   d. Tap **Export** again to export the logs to the USB storage device.
   e. After the export is complete, tap **OK**.
4. To clear logs, tap **Clear** and confirm your selection in the dialog.

Uploading logs

The system needs to be connected to the System Portal. See Configuring the System Portal connection [25].

1. Access the administrative settings page (see Accessing settings as an administrator [21]).
2. Tap **System Portal Connection**.
3. On the next page, tap **Upload logs**.

Selecting the system wireless network

Only administrative users can access network and internet settings.

1. Log in using your administrative login information.
2. On the home screen, tap **Settings**.
3. Make sure that the system's location is configured (see Configuring the system location [28].
4. Tap **Connectivity** from the settings menu.
5. On the connectivity page, tap **Network Setup**.
6. Select an existing network profile from the list or tap **Add** to add a network profile.
7. To connect to a network that requires a certificate, make sure the certificate is installed (see Managing certificates [26]).
8. Do the following:
   a. Enter a profile name and network name.

b. Select the appropriate security policy from the drop-down list.
c. Select **Personal** or **Enterprise** under **Authentication**. Select **Enterprise** for networks that require a certificate.
d. For enterprise networks, enter a fully qualified domain name.
e. Select an authentication type.
f. Depending on the network type, enter the password or select an installed certificate.
g. Enter the name of the network location of the ultrasound system under **Alias**.

9. Tap **Connect**.

Configuring the system for DICOM transfer

You can connect Sonosite iLOOK with storage and worklists in the DICOM (Digital Imaging and Communications in Medicine) format. For details, refer to the DICOM Conformance Statement at **www.sonosite.com**. The conformance statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

When setting up the DICOM connection, connect to the wireless network first and consult your network administrator. Follow the steps provided in the following sections to configure DICOM settings for your system, archiver, and worklist server.

Managing secure DICOM connections

FUJIFILM Sonosite recommends using TLS to secure DICOM communications. If your DICOM servers support TLS, consider using it to secure the connection.

The ultrasound system supports four levels of TLS security:

- TLS encryption only, which means that the server is implicitly trusted. No certificates are required.
- TLS encryption and client authentication. The ultrasound system's client certificate is used to authenticate the ultrasound system to the server. A client certificate and a private key are required.
- TLS encryption and server authentication. The server's certificate is verified to ensure that the server is a trusted entity. A CA certificate is required.
- TLS encryption and mutual authentication. The server's certificate is verified to ensure that the server is a trusted entity. The ultrasound system's client certificate is used to authenticate the ultrasound system to the server. A CA certificate, a client certificate, and a private key are required.

Accessing DICOM settings

1. Log in using your administrative login information.
2. On the home screen, tap **Settings**.
3. Tap **Connectivity** from the settings menu.
4. On the connectivity page, tap **DICOM Setup**.

Configuring the system location

1. On the DICOM settings page, tap **Configure**.
2. On the configuration page, tap **Location**.

3. To set up a new location, tap **New**.
4. Under **Alias***, enter a unique name that identifies the network location of the ultrasound system.
5. Under **AE title***, enter a unique DICOM application entity title.
6. Under **Wireless network**, select a wireless network from the list.
7. Select the **Prevent archive timeout** checkbox to prevent a time-out when transferring data to a DICOM server.
8. To return to the DICOM configuration page, tap **Configuration** in the navigation bar.

Configuring the DICOM archiver settings

1. On the DICOM settings page, tap **Configure**.
2. On the configuration page, tap **Archiver**.
3. To set up a new archiver, tap **New**.
4. Under **Alias***, enter the unique name of the DICOM archive server.
5. Under **AE title***, enter the unique archiver DICOM application entity title.
6. Select the image format for images that are sent to the archiver: RGB or JPEG.
7. Select **IPv4** or **IPv6** and enter the IP address of the archive server. IPv4 is selected by default.
8. Select **TLS** to encrypt and authenticate the DICOM communication between the system and the server.
9. Fill out the optional TLS fields, if you want to include a system certificate and/or authenticate the server certificate.
   - **Client certificate** Select from the list of client certificates imported into the TLS Certificates page, accessible through the Connectivity settings.
   - **Private key** Select the private key associated with the selected client certificate.
   - **Private key password** The password that unlocks the private key.
   - **Certification authority** Select the CA certificate used to validate the server's computer certificate from the list of imported wireless certificates (see Managing certificates [26]).
10. Under **Port**, enter the archiver port number. TCP port 104 is typically assigned for DICOM.
11. Tap **Ping** to determine whether the IP address is accessible. The system displays **Successful** or **Failed**.
12. To return to the DICOM configuration page, tap **Configuration** in the navigation bar.

Configuring the DICOM Modality Worklist settings

1. On the DICOM settings page, tap **Configure**.
2. On the configuration page, tap **Worklist**.
3. To set up a new worklist, tap **New**.
4. Under **Alias***, enter the unique name of the worklist server.
5. Under **AE title***, enter the unique worklist DICOM application entity title.
6. Under **Modality**, select **US** (to match orders for ultrasound) or **ALL** (to match orders for all modalities).
   You can also restrict the search by selecting **This device only**.
7. Select **IPv4** or **IPv**6 and enter the IP address of the worklist server.
8. Select **TLS** to encrypt and authenticate the DICOM communication between the system and the server.

9. Fill out the optional TLS fields, if you want to include a system certificate and/or authenticate the server certificate.
   - **Client certificate** Select from the list of client certificates imported into the TLS Certificates page, accessible through the Connectivity settings.
   - **Private key** Select the private key associated with the selected client certificate.
   - **Private key password** The password that unlocks the private key.
   - **Certification authority** Select the CA certificate used to validate the server's computer certificate from the list of imported wireless certificates (see Managing certificates [26]).
10. Under **Port**, enter the worklist server port number. TCP port 104 is typically assigned for DICOM.
11. Select the checkbox to include the placer order number in query results.
12. Tap **Ping** to determine whether the IP address is accessible. The system displays **Successful** or **Failed**.
13. To return to the DICOM configuration page, tap **Configuration** in the navigation bar.

Editing or deleting a location or device

1. On the proper configuration page, select the name from the list of locations or devices.
2. To edit, make the desired changes in the appropriate fields.
3. To delete, tap **Delete** and confirm your selection.

Setting up the connection to DICOM servers

For each location, select which devices you want to receive the data that you transfer and which worklist server you want to receive data from. Once these selections are complete, select the location you want to use.

The devices must be configured before you can associate them.

1. Tap **Connectivity** from the settings menu and select the location of the system from the **Location** list. If the system is offline, the system cannot transfer to or receive data from DICOM servers.
2. Tap **DICOM Setup** and ensure that the location of the system has been selected.
3. In the list of devices, check the box next to one or more archivers or worklist servers. Selected devices have an adjacent check mark.
4. To select a default archiver, check the default box for the archiver.
5. Complete any additional configuration tasks, and then tap **Done**.

Verifying the connection status of devices

On the DICOM settings page, tap **Verify** to confirm that the associated devices are connected. (If **Verify** is unavailable, check the wireless connections. If the problem continues, see your system administrator.)

The connection status of the devices appears in the **Status** column:

- **Failed** DICOM cannot communicate with the device.
- **Success** DICOM can communicate with the device.
- **Unknown** Configuration may have changed since the connections were last verified.
- **Busy** The DICOM manager may be working on another task such as study data being transferred to an archiver. Wait for the transfer to complete and then tap **Verify** again.

Entering institution and department

1. Tap **General** from the settings menu.
2. Enter the appropriate information under **Institution**, **Department**, and **Institution address**.

Adjusting audio and brightness levels

1. Tap **General** from the settings menu.
2. To adjust brightness levels, drag the slider right or left.
3. To adjust audio levels, drag the slider right or left.
4. To mute, select the checkbox.

You can also adjust audio and brightness levels while scanning. Tap ☰, then **Settings**, then **General** to access the audio and brightness sliders.

> **NOTE**
> Audio is not supported, so changes to the audio settings will not take effect.

Hiding patient information

1. Tap **General** from the settings menu.
   Make sure you are in the settings available from the home screen.
2. To hide patient information on the display, ensure that the **Hide patient information in imaging** checkbox is selected.

Specifying the system location

The location you specify in connectivity settings represents the active location of the system. If the system is offline, the system cannot transfer to or receive data from DICOM servers.

1. Tap **Connectivity** from the settings menu.
2. On the connectivity settings page, select a location from the **Location** list.

Setting the date and time

1. Log in using your administrative login information.
2. On the home screen, tap **Settings**.
3. Tap **Date and time** from the settings menu.
4. On the date and time settings page, do the following:
   - Choose the desired date format, and then type the current year, month, and day.
   - Type the current time in hours and minutes.
   - To obtain the system time from a time server, select **Use time on time server** and enter the **Server address**.

NOTE
If you select **Use time on time server**, you cannot manually edit the date and time.

- To specify that the system automatically adjusts for daylight savings time changes, select **Daylight savings time**.
- Select your time zone from the **Time zone** list.

Configuring sleep settings

CAUTION
To protect patient information, put the system in sleep mode when leaving it unattended.

1. Tap **Power Saving** from the settings menu.
2. Select a sleep delay setting from the drop-down menu.

USB settings

On the USB settings page, you can view information about connected USB devices and specify file formats and options for exporting data to a USB storage device.

NOTE
You can only export data to a USB storage device if your administrator has enabled this setting.

Specifying USB export options

1. Tap **USB** from the settings menu.
2. On the USB settings page, select an export type.
   - **DICOM export** creates files readable by a DICOM viewer. Video clips export in MJPEG format.
   - **Multimedia export** organizes files in a standard folder structure. Video clips export as mp4 files.
3. Select an image format for your export type.
   For optimal DICOM image quality, select RGB image format.
4. Tap **Refresh List** to refresh the list of connected USB devices.

Network status

The network status page displays the following information:

- Location
- IP connectivity and addresses (both IPv4 and IPv6)
- Subnet mask
- Default gateway
- WLAN status and active SSID
- Connected BSSID
- Wireless MAC address

System information

The system information page displays system hardware and software versions, patents, regulatory, and license information. If the system has been configured by an administrator, you can also check for and install any available software updates. If any updates are available, a notification appears on the home screen settings button and next to **System Information** in the settings list.

See also Remote software updates and system monitoring [25].

Installing software updates

To install a software update, the system needs to be connected to the Internet, System Portal, and to AC power. You can continue scanning while the update is downloading, but scanning is not possible during the installation process. The time required for the update depends on the size of the update.

> **CAUTION**
> Back up patient data prior to performing this action.

To back up patient data, see Archiving studies [50] and Exporting studies to a USB storage device [50].

1. On the system information page, tap **Check Update**.
   The system checks for an available software update.
2. Tap **Download**. The system begins downloading the update.
   You can pause or cancel the download or continue using the system during the download process.
3. Monitor the download by checking the status on the page.
4. When the download is complete, verify that the system is ready for an update by making sure it is connected to AC power and ending any exams.
5. Tap **Install**. Patient data is removed during the installation process.
6. Log back into the system and open the imaging application to check for any transducer firmware updates. See Updating the transducer [57].

Configuring application settings

In addition to the settings that are available from the home screen, more settings are available once you have accessed the imaging application from the **Scan** module.

Navigating the system menu settings

1. Tap **Scan** to access the application.
2. From the system menu ☰ in the top right corner of the screen, tap **Settings**.
3. Access the following from the settings screen.
   - Transducer settings
   - Application settings
   - Transducer information
   - General (where you can adjust brightness levels)
4. To navigate back to the system menu, tap **Menu**.
5. To exit the system menu, tap ✕.

Transducer settings

Transducer settings allow you to add a transducer to the imaging application, change a transducer name, configure transducer wireless settings, and run a diagnostic check of transducer imaging elements.

Adding and deleting transducers

See also Connecting the transducer [42] which allows you to add and connect to a transducer in one procedure. Once a transducer is added, the system will automatically connect to it as long as both the system and transducer are powered on.

1. Make sure that the transducer you want to add is turned on.
2. Tap **Transducer settings** on the system menu settings screen to open the transducer settings menu.
3. Tap **Add transducer**.
   A dialog box appears.
4. Tap **Connect**.
   A list appears that displays any transducers that are on and can be registered. Transducers are identified by the serial number located on their label.
5. From the list, tap the transducer you want to add.
6. Once the registration process is complete, the transducer appears in the transducer settings menu.
7. To display additional information, tap the transducer in the transducer settings menu.
8. To delete a transducer, make sure to disconnect it first or turn it off, then select it in the transducer settings menu and tap **Delete**.

Transducers that are on and connected, display a green check mark next to their name in the list.

Changing a transducer name

1. Tap **Transducer settings** on the system menu settings screen to open the transducer settings menu.
2. Tap **Change transducer name**.
3. Tap the input box under **Transducer name**, and use the displayed keyboard to enter a name.
4. Tap **Cancel** to cancel the changes or tap **Save**.

Switching the wireless channel

Make sure the transducer is powered on and added to the system before changing the wireless settings. See Connecting the transducer [42].

1. Tap **Transducer settings** on the system menu settings screen to open the transducer settings menu.
2. Tap **Wi-Fi channel settings**.
3. Tap the transducer name in the dialog box.
4. In the dialog, select 2.4 GHz or 5 GHz.
5. Tap the channel button to display a list of wireless channels.
6. Do one of the following:
   - Tap **Auto** to connect to a channel automatically.
   - Directly tap the channel of your choice.
7. Tap **Apply**. You can also cancel your changes at any time.
   The transducer is turned off to enable the connection.
8. To use the transducer, turn the transducer on again.

Transducer element check

To prevent false positives, make sure that the transducer is not covered in gel or touching anything when you run the transducer element check.

1. Make sure that the transducer is on and connected (see Connecting the transducer [42]).
2. Tap **Transducer settings** on the system menu settings screen to open the transducer settings menu.
3. Tap **Transducer element check**.
   The system runs a diagnostic check of the transducer imaging elements and identifies any elements that may be underperforming.
4. Tap **Close**.

Application settings

Selecting the unit for basic measurement values

1. Tap **Application settings** on the system menu settings screen.
2. Tap **Measure unit**.
3. Tap **cm** or **mm** to set the unit of measurement.

Setting the duration of saved clips

1. Tap **Application settings** on the system menu settings screen.
2. Tap **Clip time** and select a time duration from the menu.

Configuring transducer orientation settings

You can set the default on-screen orientation of the transducer. You can also select the displayed transducer orientation while scanning (see Orienting the image [44]).

1. Tap **Application settings** on the system menu settings screen.
2. Tap **Transducer orientation**.

3. Tap **Right** or **Left**.

Transducer information

The transducer information page displays the following information:

- FCC certification number
- IC certification number

Entering Patient Information

This section describes how to enter patient information, either manually or from a worklist. You can start scanning without entering any patient information. We recommend adding patient information to the exam before exporting any images or clips.

WARNING
To avoid misdiagnosis, verify that the patient information, date, and time settings are accurate.

Displaying patient information

The patient information screen is available within the imaging application. Tap **Scan** from the home page.

- To display patient information for the current exam, tap the patient information field at the top of the screen.
- To display patient information from previous exams, tap the system menu ☰ and then tap **Patient list**. Select a patient from the list and tap the patient information field.

NOTE
If you are using the system in guest mode, you cannot access previous exam information.

Creating or updating patient information

NOTE
For details on how to obtain patient information from worklists, see Entering patient information from the worklist [38].

1. While in the patient information screen, enter or update patient information:
   - To enter patient information from the patient list, tap 🔍 to display the patient list. Tap the correct patient to automatically enter that patient's information in the text fields. Entering a patient ID narrows the list to patients with matching IDs.
   - To manually enter patient information, tap each field and enter the appropriate information. The patient information form also contains fields for provider information, institution information, and performed procedures.

2. Make sure that the entered information is correct. If it is incorrect, tap **Reset** to clear the fields and enter the correct information. If patient information has been already saved, saved information is restored.
3. Tap **Save**.
4. One of the following occurs:
   - If you are entering patient information for the first time, the information is saved and the system returns to scanning.
   - If you are modifying patient information, a dialog appears. Tap **OK** to save your changes.
5. If you have not entered or changed patient information, you can tap **Close** to close the patient information screen and return to scanning.

Using the worklist

You can import patient information from a DICOM worklist.

The worklist automatically updates if set up for an automatic worklist query. You can also manually update the worklist, and you can manually search the worklist server for a matching patient procedure.

Entering patient information from the worklist

1. To display the worklist, tap the system menu ☰ and then tap **Worklist**.
2. On the next screen, enter any of the following search conditions:
   - Patient ID
   - Patient name
   - Exam date: Tap the radio button, then enter the desired range for exam dates.
   - All: Tap the radio button to search all scheduled exams.
   - Today's studies: Tap the radio button to specify the current date as the scheduled exam start date in the search conditions.
3. To clear a search term, tap ⊗.
4. Tap the 🔍 to display a list of scheduled exams that match the search conditions.
5. If you need a more detailed search, do the following:
   a. Tap the advanced search icon ☰🔍.
   b. Enter any of the previous search terms as well as the following:
      - Accession number
      - Requested procedure ID
      - Modality
   c. Tap **Search**.
6. Tap ▲▼ to sort the exam list in ascending or descending order.
7. Tap an exam row to display more details.
8. Tap the radio button to the left of the exam that you want to select.
9. Tap **Scan** to begin the exam.
10. To display patient information, tap the patient information field at the upper left of the screen.
11. Tap and check the patient information on the screen that appears.

12. Check that the patient information is correct, then tap **Scan** to return to the exam.

Scanning

This section describes scanning with the Sonosite iLOOK ultrasound system.

Understanding optimal thermal performance

As with other high-performance electronic equipment, the system generates heat during normal operation. The system software includes basic safety features to keep system temperatures within internationally recognized safety standards for the patient and the user. For optimal performance and longer scanning times, consider adopting the following temperature safety practices:

- Freeze the image when not actively scanning or exit the imaging application.
- If the system is not being used for an extended period, put the system into sleep mode or turn it off.
- Ensure proper air flow and cooling while scanning.
- During the scan, hold the transducer firmly so that it does not slip from your hand. When the transducer is being put down temporarily, freeze the image or put the system into sleep mode.
- If necessary, place the transducer in the transducer holder to enable cooling by the built-in fan.
- High ambient air temperatures can reduce the system's cooling capability. You can reduce the likelihood of exceeding the temperature in hot environments by storing the system in a cool location when not in use.

Understanding imaging modes

Sonosite iLOOK allows you to scan in several imaging modes.

- **2D** is the system's default imaging mode. The system displays echoes in two-dimensional view by assigning a brightness level based on the echo signal amplitude.
- **Color** is a form of pulse wave (PW) Doppler that uses color to show the presence, velocity, and direction of blood flow toward and away from the transducer.

Starting an exam

Tap **Scan** on the home screen. The system begins scanning as soon as the transducer and display are turned on and connected. See Turning the system on and off [13], Adding and deleting transducers [34], and Connecting the transducer [42].

If you have trouble connecting the transducer, see Unable to connect the transducer [56].

WARNING

- Needle guides are not supported on the L15-5 transducer.
- Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.

CAUTION

- Before using the system, check that the display and the transducer have enough battery power remaining.
- When not in use, place the transducer in the charging holder to keep it charged and to prevent it from falling off an unstable surface.
- Before scanning, check the status of the transducer connection. The wireless connection can take time or can fail if the wireless connection is unstable. Consider using an alternative system if the wireless connection is unavailable.
- During the exam, make sure that water and gel do not come into contact with the USB connection terminal of the display.

NOTE

- To prevent errors, do not disconnect the transducer from the display during the scan. If you need to disconnect the transducer, freeze the system first.
- Before scanning, make sure that the ambient temperature is within operating temperature limits. See Specifications [94].

Optimizing the wireless signal during a scan

Metal, water, concrete, and similar materials can interfere with wireless signals. Other wireless devices will also interfere with the signal. To obtain stable ultrasound images, consider minimizing the number of objects and wireless devices in the scan area. To optimize the wireless connection between the transducer and the display, make sure that beds, chairs, desks, and other medical instruments and electronic equipment are not blocking the signal between the transducer and the display.

The maximum distance that the transducer can connect to the system is 1.8 meters (5.9 feet).

Preparing transducers

WARNING

- Some gels and sterilants can cause an allergic reaction on some individuals.
- Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. FUJIFILM Sonosite recommends that you identify your latex and talc-sensitive patients and be prepared to treat allergic reactions promptly.

CAUTION

- To avoid damage to the transducer, use only gels recommended by FUJIFILM Sonosite. Using other gels can damage the transducer and void the warranty. If you have questions about gel compatibility, contact FUJIFILM Sonosite or your local representative.
- Clean transducers after each use.

Connecting the transducer

Before you can connect a transducer during a scan, make sure that it is on and within range of the display device (see Turning the system on and off [13]). See also Adding and deleting transducers [34].

NOTE

When using the wireless transducer, the system cannot maintain a simultaneous connection to the network. If the transducer remains in the charger for 45 minutes or longer, the system will automatically disconnect from the transducer and connect to the network instead. The system prioritizes the transducer connection except when transferring data over the hospital network. Additionally, exiting scan mode will disconnect the transducer.

1. To connect to a transducer for the first time, tap the system menu ☰ on the scan screen. While waiting to connect to the system, the transducer's indicator light should emit a pulsing blue color.
2. In the system menu, tap **Connect to transducer**.
3. Tap **Add transducer**.
   A dialog box appears.
4. Tap **Connect**.
   A list appears that displays any transducers that are on and can be registered. Transducers are identified by the serial number located on their label.
5. From the list, tap the transducer you want to add.
6. After connection, the transducer's indicator light turns green (if the battery is charged), and the scan screen appears.
7. To check the connection status of the transducer, including signal strength, view the wireless icon in the upper left corner of the screen.

   The wireless connection is not established if displays. To troubleshoot, see Unable to connect the transducer [56].
8. The system automatically tries to reconnect to the transducer when it is on the unfrozen scan screen. You can also reconnect to the transducer by tapping **Connect to transducer** in the system menu.

Once a transducer has been added to the system, the transducer appears in the system menu and in the transducer settings menu. Transducers that are on and connected, display a green check mark next to their name in the list.

Selecting an exam type

Before scanning, select an exam type. Exam types are predefined groups of scanning settings optimized for a clinical use.

WARNING
The diagnostic capability of the system differs depending on the exam type and imaging mode. Understand the system's capabilities prior to use.

1. At the top of the screen, tap on the exam type field to display a drop-down menu.
2. Select an exam type from the menu. Exam types are listed in the following table.

Table 5. Transducer imaging modes and exam types

Transducer	Exam type	Imaging mode	
		2D	Color
L15-5	PIV[a]	✓	CVD, CPD[b]
	Venous	✓	CVD, CPD
	Arterial	✓	CVD, CPD

[a]PIV = Peripheral intravenous. Use this exam type for better needle visualization during PIV procedures.
[b]CPD = Color Power Doppler, CVD = Color Velocity Doppler

Gel

Use acoustic coupling gel on the transducer during exams. Although most gels provide suitable acoustic coupling, some gels are incompatible with some transducer materials. FUJIFILM Sonosite recommends Aquasonic gel and provides a sample with the system.

For general use, apply a liberal amount of gel between the transducer and the body. For interventional use, apply a transducer sheath.

Sheaths

WARNING
Use market-cleared transducer sheaths and gel, with sterility appropriate to the procedure. Do not apply the transducer sheath and coupling gel until you are ready to perform the procedure. After use, remove and discard the single-use sheath, and clean and disinfect the transducer using a FUJIFILM Sonosite-approved disinfectant.

For detailed guidelines on cleaning and disinfecting transducers and using sheaths and gel, see "Guidelines for cleaning and preparing external- and internal-use ultrasound transducers

and equipment between patients as well as safe handling and use of ultrasound coupling gel." *American Institute of Ultrasound in Medicine | J Ultrasound Med.* 2023;42(7):E13-E22. doi:10.1002/jum.16167.

Applying a transducer sheath

1. If the sheath you are using needs gel, place the gel inside the sheath. Make sure that the gel is at the end of the sheath.
2. Insert the transducer into the sheath.
3. Pull the sheath over the transducer until the sheath is fully extended.
4. Secure the sheath using the bands supplied with the sheath.
5. Check for and eliminate air bubbles between the face of the transducer and the sheath.
   Air bubbles between the face of the transducer and the sheath may affect the ultrasound image.
6. Inspect the sheath to ensure that there are no holes or tears.

Scanning in 2D

To achieve the best possible image quality while scanning in 2D, adjust the gain, depth, and exam type, as well as the display brightness in the settings menu. Additionally, you can manually adjust the viewing angle of the display for optimal positioning.

1. From another imaging mode, tap the **2D** button (2D is the default scan mode).
2. Adjust the controls as needed.

Orienting the image

You can flip the orientation of the image horizontally. Make sure that the location of the indicator on the screen (upper left or upper right) matches up with the indicator located on the side of the transducer.

1. While scanning, tap to display the imaging control panel.
2. Tap an orientation button or .
3. Tap to exit the imaging control panel.

Zooming

Zooming is available for both live and frozen images.

1. To zoom in on an image, use a pinch-out gesture on the screen by spreading your fingers apart.
   A magnifying glass icon is displayed in the bottom-left corner of the image and the entire image is outlined by an orange frame.
2. To reduce the enlarged image, pinch in on the screen or double-tap the image to return to the original image size.
   The image cannot be reduced beyond the original size.
3. While the image is zoomed in, drag the image on the screen to adjust the position.

Scanning in Color

The color display is usually superimposed on the 2D image, allowing you to simultaneously visualize anatomy and flow dynamics. Blood flowing toward the transducer is displayed in red,

while blood flowing away from the transducer is shown in blue. Your ultrasound system has several types of color imaging available:

- Color or Color Velocity Doppler (CVD) imaging provides velocity information.
- Color Power Doppler (CPD) imaging provides amplitude strength of the Doppler signal but does not provide velocity information. You can use it to detect the presence of blood flow in very low flow states.

1. Tap the **C** button.
   The color box appears.
2. Adjust controls as needed.
3. To exit color mode, tap **2D**.

Selecting the color type

1. While scanning in color, tap to display the imaging control panel.
2. Tap **CVD** or **CPD** to scan in Color Velocity Doppler or Color Power Doppler.
3. Tap to exit the imaging control panel.

Positioning the color box

Tap one of the following buttons to move the color box vertically up, center, or down. The active position is outlined in blue.

-
-
-

You can also directly drag the box to those positions on the touchscreen.

Steering the color box

You can change the direction of the color box to optimize the display of color for the direction of the blood flow.

1. While scanning in color, tap to display the imaging control panel.
2. Tap one of the following:
   -
   -
   -
3. Tap to exit the imaging control panel.

Controlling the color scale

Changing the scale can help optimize the display for faster or slower blood flow. The scale is located in the upper left corner of the scan image.

1. While scanning in color, tap to display the imaging control panel.

2. Tap **Low**, **Med**, or **High** to adjust the scale to low, medium, or fast blood flows.
3. Tap ✕ to exit the imaging control panel.

Freezing an image

To freeze or unfreeze the image, do one of the following:

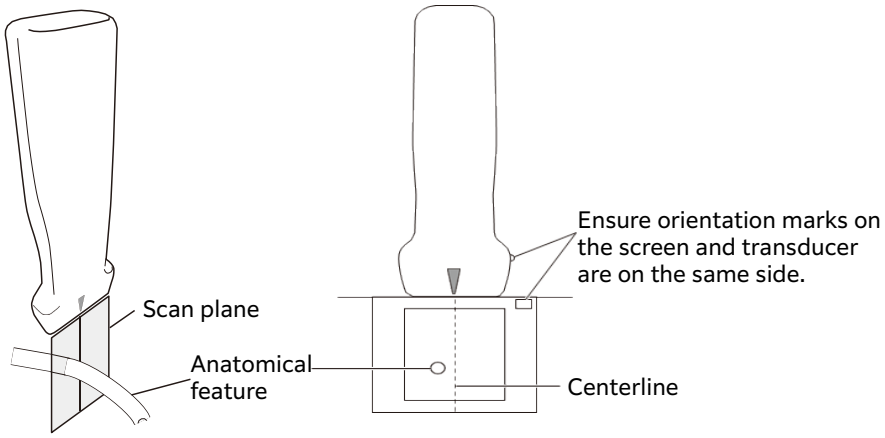
- Tap ❄.
- Briefly press the power button on the transducer.

Using the centerline

The centerline graphic aligns with the center mark of the transducer and serves as a reference mark for the center of the displayed image during live 2D imaging.

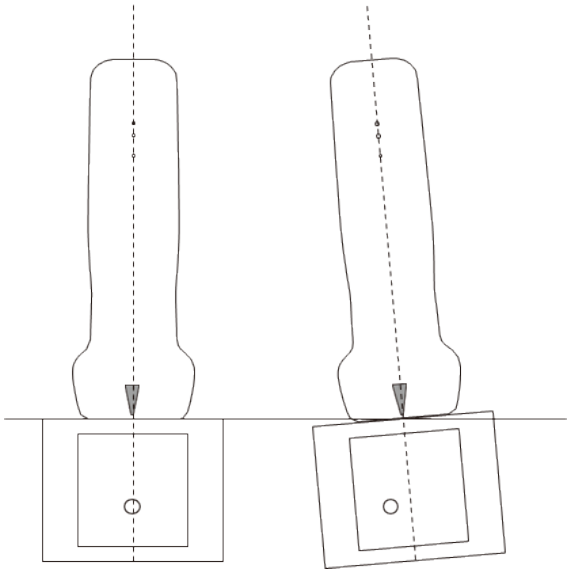
> **WARNING**
> When using the centerline feature as a reference during a freehand needle procedure, be aware that the centerline represents only the center of the ultrasound image and is not an accurate predictor of the path the needle will take.

Figure 5. Relationship of the centerline graphic to the transducer and the ultrasound image



Small tilts or rotations of the transducer can affect the relationship between any external reference points and the anatomy that appears on the ultrasound image.

Figure 6. Relationship of the ultrasound image to the transducer angle or tilt.



Turning the centerline graphic on or off

While scanning, tap to display the centerline.

Adjusting the depth

Depth refers to the depth of display. Depth controls are unavailable when the image is frozen.

The depth value is displayed above the depth slider and is always the total acquired depth of the unzoomed image. When you zoom, this value stays the same.

To decrease or increase the depth, move the slider back and forth on the touchscreen.

Adjusting the gain

Gain refers to amplifying the intensity of the returning sound waves on the display. In 2D mode, increasing the gain brightens the image. Decreasing the gain darkens the image. When you are in Color mode, the gain controls adjust the intensity of the signals within the color box.

Gain controls are unavailable when the image is frozen.

To decrease or increase the gain, move the slider back and forth on the touchscreen.

Viewing frames in the cine buffer

While imaging, the system always retains a certain number of frames in the cine buffer. You can move forward and backward in the cine buffer. The system clears the cine buffer when you unfreeze the image or change the mode or exam type.

1. Freeze the image .
   On a frozen image, the cine icon and bar appear on the left side of the monitor.
2. Move the slider on the touchscreen to scroll through the cine images.

Ending the exam

You can only end an exam if it is an active study. A study becomes active after patient information has been added or an image or clip has been saved (see Entering Patient Information [37] and Saving an image or a clip [49]).

> **NOTE**
> If you want to save images and clips to a new exam, you need to end the current exam. Before saving any images or clips to the new exam, you should enter patient information (see Entering Patient Information [37]).

To end the exam while scanning:

1. Tap the **End study** button at the top right of the screen.
2. In the dialog, tap **End study** to confirm or **Cancel** to return to the exam.

To end the exam from another screen:

1. Tap the system menu . System menu has an orange background if the study is active.
2. Tap **End study**.
3. In the dialog, tap **End study** to confirm or **Cancel** to return to the exam.

Quitting the imaging application

You can also exit the imaging application.

1. Tap the system menu .
2. Tap **Quit**.
   The home screen appears.

Managing Images and Clips

Sonosite iLOOK includes tools for saving, reviewing, and exporting your ultrasound images and clips.

Saving an image or a clip

Images and clips are saved to the current exam. The number of images and clips saved to the current exam is displayed at the top of the screen.

> **WARNING**
> To avoid mixing up images saved from multiple patients, make sure that the correct patient ID is displayed before you save an image. For more information about patient records, see Entering Patient Information [37].

1. During live imaging, tap to save an image or to start saving a clip. You can also save an image when the image is frozen.
2. To save an image from cine, see Viewing frames in the cine buffer [47] to find the image you want to save.
3. To set the duration of a clip, see Setting the duration of saved clips [35].

   You can prematurely stop the clip by tapping .

Reviewing and deleting images and clips

You can review your images and video clips after you have taken them, along with any displayed measurements.

1. Do one of the following:
   - While scanning, tap at the top of the screen to display images and clips from the current exam.
     The number of images and clips is displayed.
   - To view images and clips from a past exam, tap the menu and then tap **Patient list**. Tap to display the search screen, enter the patient ID, name, or exam date and tap to search the list. Tap the desired exam to display the review page.

     > **NOTE**
     > Guest users cannot access the patient list.
2. Tap a thumbnail image on the left to display a full-size view of the image.
3. For clips, tap or to play or pause the clip. To view the clip frame by frame tap or . You can also move the clip slider back and forth.

4. To view the previous or next image or clip, tap < or > or swipe left or right.
   You can also scroll up or down to view additional thumbnail images.
5. To delete images or clips, do the following:
   a. Tap an individual thumbnail to select it or tap **Select** and tap one or more thumbnails.
      Selected thumbnails display a checkmark.
   b. Tap 🗑.
      A dialog box appears.
   c. Tap **Delete** to delete the selected images and clips, or **Cancel** to return to the screen.
6. To return to scanning or the patient list, tap **Scan** or **Done**.

Archiving studies

If you have configured the system for DICOM transfer (see Configuring the system for DICOM transfer [28]), the system archives a study's images and video clips to a DICOM server. You cannot scan while the system is wirelessly connected to the DICOM server.

1. Tap the system menu ☰ and then tap **Patient list**.
2. Select the studies you would like to transfer by selecting the checkbox next to them.

> **NOTE**
> To select all of the studies, tap the checkbox at the top of the list.

3. If there is more than one archiver configured, tap the **Storage** box and select the desired archiver.
4. Tap **Send to** and select **Archive: DICOM Server**.
5. To exclude video clips from the transfer, tap **Settings**, deselect **Transfer clips**, and tap **OK**.
6. Tap **Send**.

A check mark in the status column of the patient list indicates whether the system has archived the study successfully. If archiving has been interrupted or cancelled, you need to manually restart the process as the system prioritizes the wireless connection to the transducer.

Exporting studies to a USB storage device

You can export exam images and clips to a USB storage device for archiving once the study has ended. Make sure you archive studies regularly.

> **CAUTION**
> Patient information might be a protected class of patient data subject to country-specific security guidelines. If you choose to include patient information when exporting or printing images and clips, be sure your information storage and handling practices comply with country-specific security guidelines.

1. To specify a default file format, see Specifying USB export options [32]).

2. Tap the system menu ☰ and then tap **Patient list**.
3. Connect a USB storage device (see Inserting and removing USB devices [14]).
4. Select the studies you would like to transfer by selecting the checkbox next to them.

> **NOTE**
> To select all of the studies, tap the checkbox at the top of the list.

5. Tap **Send to** and select **USB**.
6. If you want to show patient information, uncheck the **De-identify** box.
   By default, patient information such as names and IDs is removed from images and clips before exporting to protect patient confidentiality.
7. Tap **Send**.

To stop in-progress exporting, tap **Cancel**. A check mark in the status column of the patient list indicates whether the system has exported the study successfully.

Deleting studies

After archiving or exporting patient data, regularly delete data from the system. Low internal storage can impact system performance.

1. Tap the system menu ☰ and then tap **Patient list**.
2. Select the checkboxes next to the studies that you want to delete.
   To remove a check mark, tap the checkbox again.

> **NOTE**
> To select all of the studies, tap the checkbox at the top of the list.

3. Tap **Delete**.
4. A confirmation message appears. To delete the selected exams, tap **OK**. To cancel the deletion, tap **Cancel**.

Measurements

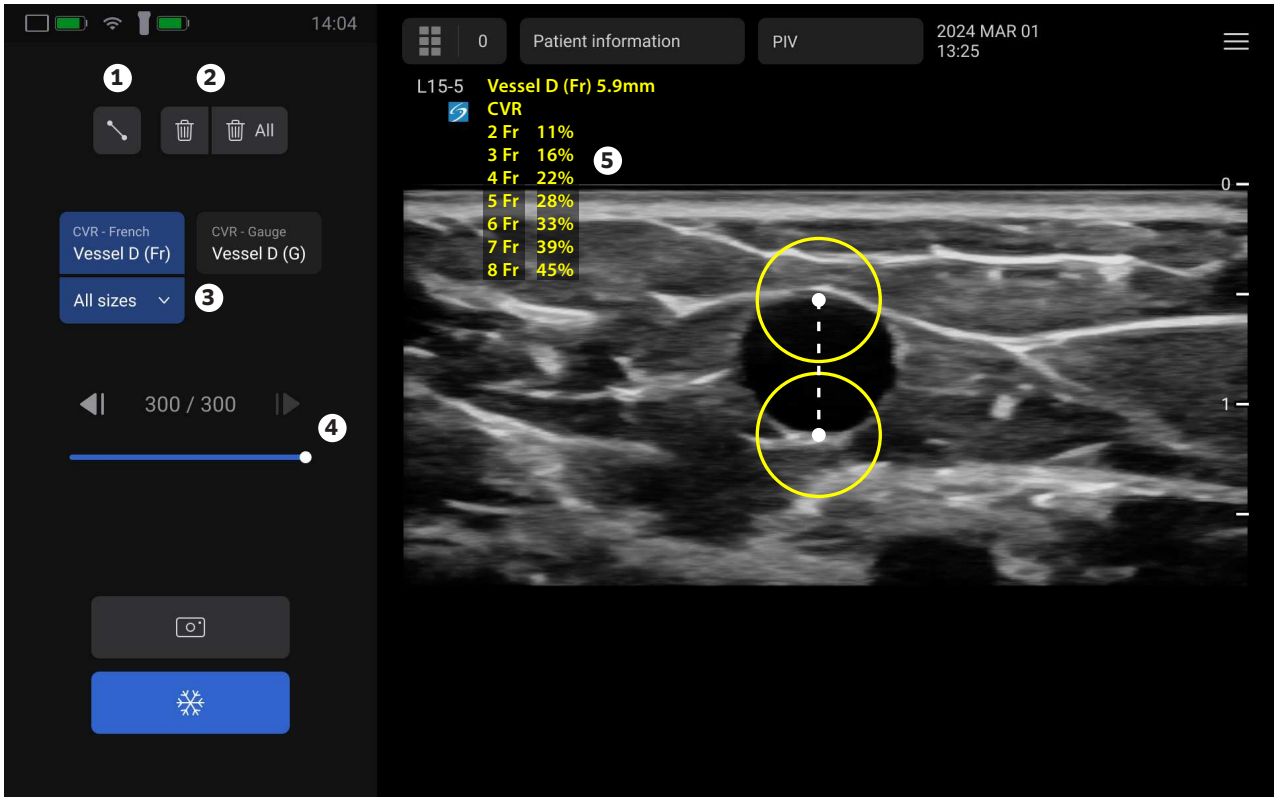
This section provides information about measurements, which are performed on frozen images.

WARNING

- To avoid misdiagnosis or harming the patient outcome, do not use single calculations as sole diagnostic criteria. Use calculations in conjunction with other clinical information.
- To help ensure the accuracy of the images obtained, all patient images must be obtained by qualified and trained individuals.

Measurements are only displayed on the screen. To save your measurements, save the images displaying the measurements before ending the exam. Measurement units can be changed. See Selecting the unit for basic measurement values [35].

The following figure displays the measurement screen.



1. Distance caliper 2. Delete buttons 3. CVR measurements 4. Cine control 5. Example of measurement results

Working with calipers

You perform measurements by dragging active, highlighted calipers into position on the touchscreen. Use the circle around the caliper to manipulate it. You can modify, delete, and save measurements.

If calipers are not positioned correctly, the calculation result will be inaccurate.

- To modify a measurement, tap the measurement value on the screen to reactivate the calipers, then drag the calipers to the desired positions. You can also directly tap the calipers on the screen.
- To delete a measurement, tap the measurement value on the screen, or directly tap a caliper to highlight it, and tap . You can also delete all the measurements. Unfreezing or switching image frames will also delete the measurements.
- To save an image with the displayed measurements, tap .

Measuring the distance between two points

1. Tap to freeze the image.
2. Tap to display the distance calipers.
3. Tap within a caliper frame and drag the caliper to the desired position on the image.
4. To finalize the edit, tap on the image outside of the caliper.
5. Tap to save an image with the measurement.
6. To take additional distance measurements, tap again. You can take up to five distance measurements per image.

CVR measurements and calculations

CVR (catheter to vessel ratio) measurements are listed in the following table. For an explanation of terms and abbreviations, see the Glossary [115].

Measurements	Procedure	Calculation results
CVR - French: Vessel D (Fr)	Distance [53]	CVR (Fr)
CVR - Gauge: Vessel D (G)	Distance [53]	CVR (G)

Calculating CVR (catheter to vessel ratio)

1. Tap to freeze the image.
2. Measure the vessel diameter depending on your workflow:
   a. Use the calipers to measure the diameter (see Measuring the distance between two points [53]). The CVR calculations for common Gauges or French catheter sizes will be displayed.
   b. To save the CVR for a specific catheter, select the **Gauge** or **French** catheter size from their respective drop-down menus.
   c. Tap to save the image.

Measurement References

This section provides information about measurement accuracy, publications, and terminology.

Measurement accuracy

The measurements from the system are of a physical property such as distance for evaluation by the clinician. The accuracy values require that you can place the calipers over one pixel. The values do not include acoustic anomalies of the body.

The 2D linear distance measurement results are displayed in centimeters or millimeters. The decimal place value depends on the measurement.

The linear distance measurement components have the accuracy and range shown in the following tables.

Sources of measurement errors

Table 6. 2D measurement and calculation accuracy and range

2D measurement	System tolerance[a]	Accuracy by:	Test method[b]
Axial distance	< ±4% plus 2% of full scale	Acquisition	Phantom
Lateral distance	< ±4% plus 2% of full scale	Acquisition	Phantom

[a]Full scale for distance implies the maximum depth of the image.

[b]A Gammex 403GS model phantom with 0.7 dB/cm/MHz attenuation was used.

In general, two types of errors can be introduced into the measurement:

- **Acquisition Error:** Includes errors introduced by the ultrasound system electronics relating to signal acquisition, signal conversion, and signal processing for display. Additionally, computational and display errors are introduced by the generation of the pixel scale factor, application of that factor to the caliper positions on the screen, and the measurement display.
- **Algorithmic Error:** The error introduced by measurements, which are input to higher order calculations. This error results from imprecision in the method used to carry out mathematical computations, usually associated with either rounding or truncation of numbers.

Measurement publications and terminology

The following are the publications and terminology used for each calculation result.

Terminology and measurements comply with American Institute of Ultrasound in Medicine (AIUM) published standards.

General references

Catheter to vessel ratio

Sharp, R., Cummings, M. et al. "The catheter to vein ratio and rates of symptomatic venous thromboembolism in patients in patients with a peripherally inserted central catheter (PICC): A prospective cohort study." *Int. J. Nurs. Stud.* 2015; 52(3): p.677-685; doi: 10.1016/j.ijnurstu.2014.12.002.

(catheter diameter/vein diameter) * 100

Troubleshooting and Maintenance

This section contains information to help correct problems with system operation and to take proper care of the system, transducer, and accessories.

Troubleshooting

If you encounter difficulty with the system, use the following list to help troubleshoot the problem. In the case of a warning dialog, perform the suggested action. If the problem persists, contact FUJIFILM Sonosite Technical Support (see Getting help [1]).

System does not turn on or is unresponsive

- Try charging the batteries. See Charging the system [11]. If the issue persists, see Batteries do not charge [55].
- If the display screen is unresponsive, press and hold the power button to turn it off then press and hold it again to restart. If you are unable to turn the display back on, contact technical support.
- If the imaging application is unresponsive, contact technical support.

Batteries do not charge

1. Make sure you are using the supplied power brick. See AC power brick [9].
2. If charging the transducer battery, make sure that the display is powered on.
3. Check all of the power connections.
4. If charging has stopped due to high temperature of the transducer or display, disconnect the power brick, wait at least 10 minutes, and then resume charging.
5. If the batteries still do not charge, contact technical support.

System image quality is poor

- Adjust the gain. See Adjusting the gain [47].
- Adjust the display brightness. See Adjusting audio and brightness levels [31].
- If adjusting the above settings does not improve image quality, assess your transducer's element status. See Transducer element check [35].

Unable to scan

Check the following if you are unable to display an ultrasound image or if scanning is erratic.

- Make sure that the display and transducer are connected properly. See Connecting the transducer [42] and Adding and deleting transducers [34].
- Make sure that the wireless connection is enabled by turning on the Wi-Fi. See Selecting the system wireless network [27].
- If the transducer is disconnected during a scan, check that the transducer has not turned off unexpectedly and check all connection settings and the environment for possible interference.

If the issue persists, contact technical support.

Unable to connect the transducer

Try each of the following until you are able to reconnect the transducer. See Connecting the transducer [42].

- Make sure that the transducer and the system are both on.
- Quit the imaging application and then restart it.
- Turn off the transducer and then turn it on again. Wait ten seconds after turning the transducer back on before attempting to reconnect to the system.
- Check that the transducer is registered. If it is, turn the transducer off, delete it from the list and register it again. See Adding and deleting transducers [34].
- Try switching the wireless channel (see Switching the wireless channel [35]).
- If the transducer remains unconnected, the surrounding radio communications could be causing interference. Relocate the system and reconnect.

Transducer is overheating

The system displays a message if the transducer is beginning to overheat and will shut down before the transducer becomes too hot. You can also place the transducer in the transducer holder to enable cooling by the built-in fan.

See Temperature safety [73] for additional guidelines on how to handle the transducer if it is overheating.

Unable to transfer data to DICOM

Try the following if you are having trouble connecting to or transferring data to DICOM.

- See Configuring the system for DICOM transfer [28] to configure DICOM settings properly.
- Make sure that the display and the DICOM server or external device are connected to the same network.
- Make sure that the **Prevent archive timeout** checkbox is selected. See Configuring the system location [28].
- Consult with your network or IT administrator if you are having issues with network and security settings.
- Check the network connection. If there are signal issues, wait a while and try transferring the data again.

Unable to export to USB

If you have issues with exporting data to a USB storage device, try the following.

- Make sure that the USB storage device has enough storage space.
- Make sure that the USB storage device is formatted in exFAT (recommended) or FAT32.
- If the USB storage device does not appear in the dialog box on the system, check that it has been properly inserted into the USB port on the system. If this does not solve the issue, try another USB storage device.

Switching transducers and displays

The transducer can only be connected to one system at a time. To switch systems, first turn off both the transducer and the current system. Since the transducer automatically attempts to reconnect to the last system, ensure the new system is powered on and properly configured before turning the transducer back on.

Multiple transducers can be connected to the same system.

Unable to find a patient name in the worklist

If you are having issues finding a patient in the worklist, try using additional search terms and use exact search terms.

Maintenance

WARNING

- No modification of this equipment, except as described in this manual, is allowed.
- Do not service or perform maintenance procedures on the system while it is in use with a patient.

No periodic or preventive maintenance, testing, or calibration is required for the system, transducer, or accessories other than cleaning and disinfecting transducers and inspecting them for cracks, adequate insulation, and other signs of damage after every use. Make sure that transducers do not have cracks or splitting that allow fluids or gel to enter. For information on cleaning and disinfecting your ultrasound system, see Cleaning and Disinfecting [60].

FUJIFILM Sonosite recommends that you periodically recharge the batteries by plugging the system in.

CAUTION

The batteries contain technology that requires periodic recharging to maintain optimal performance. If left uncharged for an extended period of time, the battery performance could degrade or become non-functional.

Performing maintenance procedures not described in this document may void the product warranty. Contact FUJIFILM Sonosite Technical Support for any maintenance questions (see Getting help [1]).

Updating the transducer

Periodically, the transducer needs firmware updates. These updates are provided along with any software updates from within the imaging application. Firmware updates may be required if you have updated the application.

If configured, updates are provided remotely (see Remote software updates and system monitoring [25]). If you are not connected to the cloud service, contact FUJIFILM Sonosite Technical Support or your customer representative.

Please be aware that scanning is not possible while installing a software or transducer update. The time required for the update depends on the size of the update.

1. After updating the imaging application, open the application.
2. Make sure that the transducer is on and within range of the display device.
   The application automatically connects to the transducer and detects if the transducer needs updating.
3. Tap **Install** in the dialog.
   Make sure to keep the transducer on and within range while the application updates the transducer.
4. To complete the update, the transducer restarts.
   Make sure to keep the transducer within range. The transducer automatically reconnects after restarting.
5. If there are multiple firmware updates needed, the application repeats the process.

System backups

To safeguard against loss of data, FUJIFILM Sonosite recommends that you routinely back up:

- Patient data

Patient data

Digital Imaging and Communications in Medicine (DICOM) provides a way to archive patient data by connecting your ultrasound system with various archivers for storage after every patient study. FUJIFILM Sonosite recommends that you configure and use DICOM transfer to prevent patient data loss in the event of a system fault. For more information, see Configuring the system for DICOM transfer [28].

If you do not use DICOM networking, then FUJIFILM Sonosite recommends that you export patient data to a USB storage device after every study. For more information, see Exporting studies to a USB storage device [50].

Servicing

Your ultrasound system may be repaired or replaced at the manufacturer's discretion. If servicing is necessary and the system is mounted on the stand, remove the system from the stand (see Removing the system from the stand [9].

Before the system is shipped to a repair facility, you must take precautions to protect patient data.

CAUTION

- To protect patient privacy, all patient procedure information must be exported to a USB storage device or archived to a secure repository via DICOM transfer and then deleted from the study list.

Preparing your system for service

1. End any in-progress procedures.
2. Export all patient procedure information to a USB storage device or archive it to a DICOM device. For complete instructions, see Archiving studies [50] and Exporting studies to a USB storage device [50].
3. Export logs to a USB storage device.
   See Exporting and clearing log files [27].
4. Factory reset your system. See Returning to factory defaults or deleting patient data [16] and End of life [113].

Cleaning and Disinfecting

Use the FUJIFILM Sonosite recommendations in this section when cleaning or disinfecting your ultrasound system, including the stand, display device, and transducer. The cleaning and disinfecting methods recommended in this chapter are based on their effectiveness and compatibility with the product.

Before getting started

- Follow the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- Inspect the system, transducer, and accessories to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM Sonosite or your local representative.
- Confirm that cleaning and disinfecting materials are appropriate for your facility's use. FUJIFILM Sonosite tests cleaners and disinfectants for use with FUJIFILM Sonosite systems and transducers.
- Disinfectants and cleaning methods listed in this section are recommended by FUJIFILM Sonosite for efficacy and material compatibility with the products.
- Ensure that the disinfectant type, concentration, and contact time are appropriate for the equipment and application.
- Follow manufacturer recommendations and local regulations, when preparing, using, and disposing of chemicals.

NOTE
Do not let contaminating material dry on the transducer. Immediately after use, wipe the transducer using an approved cleaner then follow the detailed cleaning procedures presented in this chapter.

WARNING

- Ensure that cleaners and disinfectants are not expired.
- Some cleaners and disinfectants can cause an allergic reaction in some individuals.

CAUTION

- Do not allow cleaning solution or disinfectant into any electrical connectors.
- Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM Sonosite-approved cleaners or disinfectants.

Determining the required cleaning and disinfecting level

WARNING
The cleaning instructions contained in this section are based on requirements mandated by the U.S. Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.[a]

The level of cleaning and disinfecting required for the system, stand, and transducer is determined by the type of tissue they have contacted or will contact during use. Use Table 7, "Choosing a cleaning and disinfecting method" [61] to determine the level of cleaning and disinfecting required.

Table 7. Choosing a cleaning and disinfecting method

Did, or will, any part of the system or transducer come in contact with broken skin or mucosal membranes?	
Yes	**Option A** Go to Option A: Clean and disinfect display, stand, and transducer to a high-level (semi-critical uses) [62]
No	**Option B** Go to Option B: Clean and disinfect the system, stand, and transducer to a low-level (non-critical uses) [66]

For detailed guidelines on cleaning and disinfecting transducers and using sheaths and gel, see "Guidelines for cleaning and preparing external- and internal-use ultrasound transducers and equipment between patients as well as safe handling and use of ultrasound coupling gel." *American Institute of Ultrasound in Medicine | J Ultrasound Med.* 2023;42(7):E13-E22. doi:10.1002/jum.16167.

Spaulding classifications

Spaulding classifications determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection.[b]

- **Critical devices:** Critical devices are devices that are introduced directly into the bloodstream, or which contact a normally sterile tissue or body-space during use.
- **Semi-critical devices:** Semi-critical devices are devices that contact intact mucous membranes or non-intact skin.
- **Non-critical devices:** Non-critical devices are instruments and other devices whose surfaces contact only intact skin and do not penetrate it, or do not contact the patient at all but may become contaminated during patient care.

The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

[a] *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.* Issued March 17, 2015, updated June 9, 2017.
[b] Spaulding, E.H. "The Role of chemical disinfection in the prevention of nosocomial infections". In: Brachman, P.S. and Eickof, T.C. (ed). *Proceedings of International Conference on Nosocomial Infections, (1970). Chicago, IL: American Hospital Association.* (1971), p. 254-274.

Cleaning and disinfection definitions

- **Cleaning:** Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.
- **Low-level disinfection:** A lethal process using an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.
- **Intermediate disinfection:** A lethal process using an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.
- **High-level disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

NOTE
FUJIFILM Sonosite accepts the AIUM position statement on disinfection of ultrasound transducers used for percutaneous procedures.[c,d]

Option A: Clean and disinfect display, stand, and transducer to a high-level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever they have, or will, come into contact with broken skin or mucosal membranes**.

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are both chemically compatible and the processes have been tested for efficacy with the system, stand, and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING
Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as **protective eyewear** and **gloves**.

[c]"Guidelines for cleaning and preparing external- and internal-use ultrasound transducers and equipment between patients as well as safe handling and use of ultrasound coupling gel." *American Institute of Ultrasound in Medicine | J Ultrasound Med.* 2023;42(7):E13-E22. doi:10.1002/jum.16167
[d]"Disinfection of Ultrasound Transducers Used for Percutaneous Procedures. Intersocietal Position Statement." *American Institute of Ultrasound in Medicine | J Ultrasound Med.* 2021;40(5):895-897. doi:10.1002/jum.15653

CAUTION

- Do not spray cleaners or disinfectants directly on display surfaces or connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- Do not attempt to disinfect a transducer using a method that is not included here. Do not use a chemical not listed in this guide or on **www.sonosite.com/support/cleaners-and-disinfectants**. This can damage the transducer and void the warranty.
- Use only FUJIFILM Sonosite-approved cleaners and disinfectants. Using a non-approved disinfecting solution or incorrect solution strength can damage the system and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- To prevent damage, do not use the following to clean the display device: isopropyl alcohol (>70%), methanol or ethanol (>35%), ion-based solutions such as salt water, benzene, strong solvents or alkalis, acids, abrasive cleaners or sponges, steel wool, Formula 409, detergents with fluoride, detergents with ammonia >1.6%, or steel blades.
- To avoid damaging the system, do not sterilize.

WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer's rinse instructions to remove chemical residue.

1. If your system is in secure mode, you can avoid unnecessary button presses by briefly pressing the power button to put your system into sleep mode.
2. Remove the disposable transducer sheath, if applicable.
3. Clean and disinfect the exterior surfaces of the system and stand that have been soiled or contaminated. Use the following procedure:
   a. Use either a pre-moistened wipe or a soft cloth dampened with cleaner or a low- or intermediate-level disinfectant. Choose a cleaner/disinfectant from the approved list.

Table 8. Approved cleaners/intermediate-level disinfectants for the system, stand, and transducer

Product[a,b]
PDI Sani-Cloth Prime
Chlorox Healthcare Hydrogen Peroxide

[a]For a complete list of approved cleaners and disinfectants, refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

[b]Refer to the manufacturer's instructions and safety datasheet for use concentration, temperature, duration, and appropriate rinsing methods.

   b. Remove all contaminants by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

c. Disinfect by repeating the previous step with a new wipe.

CAUTION
Do not use over-saturated wipes to clean the system. Over-saturated wipes may cause liquid to leak into the system.

d. Wipe down the transducer holder and arm with a third wipe.

e. Refer to manufacturer's instructions for the wet contact time. Monitor for wet appearance. Reapply with a new wipe if no longer wet.

NOTE
Cleaners and disinfectants can leave residues that damage the system and the transducer. Wiping with a damp cloth can remove residues and improve the longevity of the system and transducer.

f. Allow the ultrasound system to air dry in a clean, well-ventilated space.

4. Clean the transducer to remove contaminants. Use the following procedure:

a. Use either a pre-moistened wipe or a soft cloth dampened with cleaner or a low- or intermediate-level disinfectant. Choose a cleaner/disinfectant from the approved list.

Table 9. Approved cleaners/intermediate-level disinfectants for the system, stand, and transducer

Product[a,b]
PDI Sani-Cloth Prime
Chlorox Healthcare Hydrogen Peroxide

[a]For a complete list of approved cleaners and disinfectants, refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

[b]Refer to the manufacturer's instructions and safety datasheet for use concentration, temperature, duration, and appropriate rinsing methods.

CAUTION
To prevent damage to the filter, do not clean the vent with a sharp object.

b. Remove all contaminants by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

c. Repeat the previous step with a new wipe.

d. Refer to manufacturer's instructions for the wet contact time. Monitor for wet appearance. Reapply with a new wipe if no longer wet.

5. Verify that all gel and debris have been removed from the system, stand, and transducer. Ensure that the vent is free of contaminants. If necessary, repeat all cleaning steps with a new wipe.

WARNING
Failure to remove all gel and debris could leave contaminants on the transducer.

6. Prepare the high-level disinfectant for use.

a. Choose a high-level disinfectant from the list of approved disinfectants.

Table 10. High-level disinfectants compatible with the transducer:

Product[a]
Cidex OPA
Revital-Ox RESERT

[a]For a complete list of approved cleaners and disinfectants, refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

b. Refer to the manufacturer's instructions for concentration, temperature, and duration.

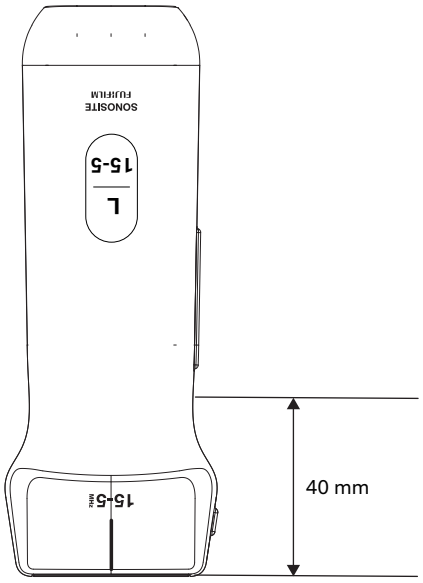
c. Check the expiration date on the bottle to ensure that the disinfectant has not expired.

d. Check that the disinfection chemical has the concentration recommended by the manufacturer (for example, use a chemical strip test).

e. Check that the temperature of the disinfectant is within the manufacturer's recommended limits.

7. Perform a high-level disinfection of the transducer by immersing only the head of the transducer in a high-level disinfectant. Do not immerse the transducer more than 40 mm from the lens surface.

Figure 7. Soaking the transducer in high-level disinfection



CAUTION

- Do not soak the transducer longer than recommended by the chemical manufacturer.
- Use only FUJIFILM Sonosite-approved cleaners and disinfectants. Using a non- recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

8. Rinse the transducer three separate times using clean water according to the disinfectant manufacturer's instructions. Do not immerse the transducer more than 40 mm from the lens surface to avoid submerging the vent on the bottom of the transducer.

9. Dry the transducer with a clean lint-free cloth.
10. Dispose of the disinfectant according to the manufacturer's guidelines.
11. Examine the system and transducer for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use and contact FUJIFILM Sonosite or your local representative.

Option B: Clean and disinfect the system, stand, and transducer to a low-level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system, stand, and transducer **if they have not, and will not, come into contact with broken skin or mucosal membranes**.

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are both chemically compatible and the processes have been tested for efficacy with the system, stand, and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING
If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure.

- Broken skin
- Mucosal membranes

WARNING
Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as **protective eyewear** and **gloves**.

CAUTION

- Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- Do not spray cleaners or disinfectants directly on display surfaces or connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- Do not attempt to disinfect a transducer using a method that is not included here. Do not use a chemical not listed in this guide or on **www.sonosite.com/support/cleaners-and-disinfectants**. This can damage the transducer and void the warranty.
- Use only FUJIFILM Sonosite-approved cleaners and disinfectants. Using a non-approved disinfecting solution or incorrect solution strength can damage the system and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- To prevent damage, 100% of the active ingredients in a cleaner used on the display device should be one or a combination of the following: isopropyl alcohol, bleach, hydrogen peroxide, ammonium chloride, and mild dish soap. Because bleach is also corrosive, we recommend wiping any bleach off using alcohol.
- To prevent damage, do not use the following to clean the display device: isopropyl alcohol (>70%), methanol or ethanol (>35%), ion-based solutions such as salt water, benzene, strong solvents or alkalis, acids, abrasive cleaners or sponges, steel wool, Formula 409, detergents with fluoride, detergents with ammonia >1.6%, or steel blades.
- To avoid damaging the system, do not sterilize.

1. If your system is in secure mode, you can avoid unnecessary button presses by briefly pressing the power button to put your system into sleep mode.
2. Remove the disposable transducer sheath, if applicable.
3. Clean and disinfect the exterior surfaces of the system and stand that have been soiled or contaminated. Use the following procedure:
   a. Use either a pre-moistened wipe or a soft cloth dampened with cleaner or a low- or intermediate-level disinfectant. Choose a cleaner/disinfectant from the approved list.

Table 11. Approved cleaners/intermediate-level disinfectants for the system, stand, and transducer

Product[a,b]
PDI Sani-Cloth Prime
Chlorox Healthcare Hydrogen Peroxide

[a]For a complete list of approved cleaners and disinfectants, refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

[b]Refer to the manufacturer's instructions and safety datasheet for use concentration, temperature, duration, and appropriate rinsing methods.

   b. Remove all contaminants by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

c. Disinfect by repeating the previous step with a new wipe.

CAUTION
Do not use over-saturated wipes to clean the system. Over-saturated wipes may cause liquid to leak into the system.

d. Wipe down the transducer holder and arm with a third wipe.

e. Refer to manufacturer's instructions for the wet contact time. Monitor for wet appearance. Reapply with a new wipe if no longer wet.

NOTE
If the cleaner leaves a residue, wipe with clean water or a clean, dry cloth.

f. Allow the ultrasound system to air dry in a clean, well-ventilated space.

4. Clean the transducer to remove contaminants. Use the following procedure:

a. Use either a pre-moistened wipe or a soft cloth dampened with cleaner or a low- or intermediate-level disinfectant. Choose a cleaner/disinfectant from the approved list.

Table 12. Approved cleaners/intermediate-level disinfectants for the system, stand, and transducer

Product[a,b]
PDI Sani-Cloth Prime
Chlorox Healthcare Hydrogen Peroxide

[a]For a complete list of approved cleaners and disinfectants, refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

[b]Refer to the manufacturer's instructions and safety datasheet for use concentration, temperature, duration, and appropriate rinsing methods.

CAUTION
To prevent damage to the filter, do not clean the vent with a sharp object.

b. Remove all contaminants by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

c. Disinfect by repeating the previous step with a new wipe.

d. Refer to manufacturer's instructions for the wet contact time. Monitor for wet appearance. Reapply with a new wipe if no longer wet.

5. Verify that all gel and debris have been removed from the system, stand, and transducer. Ensure that the vent is free of contaminants. If necessary, repeat all cleaning steps with a new wipe.

WARNING
Failure to remove all gel and debris could leave contaminants on the transducer.

6. Refer to manufacturer's instructions to remove any residual cleaner or disinfectant from the transducer.

7. Allow the ultrasound system, stand, and transducer to air dry in a clean, well-ventilated space.
8. Examine the system and transducer for damage, such as cracks or splitting where fluid can enter.
   If damage is evident, do not use. Instead, contact FUJIFILM Sonosite or your local representative.

Storing the transducer

1. Make sure the transducer has been cleaned and disinfected as detailed in the previous section.
2. Observe the following precautions:
   - Store the transducer away from any contaminated transducers.
   - Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
   - Avoid direct sunlight and exposure to X-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
   - If using a wall-mounted rack for storage, ensure that:
     - It is securely mounted.
     - The storage slots do not mar the transducer.
     - The rack is sized and positioned to prevent the transducer from inadvertently falling.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

WARNING
Avoid cross-contamination from the transducer to the transducer holders and connector or from the holders and connector to the disinfected scan head.

Cleaning and disinfecting accessories

Clean accessories prior to disinfecting. You can disinfect the exterior surface of accessories using an approved disinfectant. Refer to the cleaners and disinfectants tool available at **www.sonosite.com/support/cleaners-and-disinfectants**.

The following procedure applies to most Sonosite iLOOK ultrasound system accessories. For detailed instructions, see the accessory user guide or use the cleaning and disinfecting recommendations in the peripheral manufacturer's instructions.

1. Clean the exterior surfaces of the accessory using a pre-moistened wipe or soft cloth lightly dampened with an approved cleaner or mid-level disinfectant.
   Apply the solution to the cloth rather than the surface.
2. With a new wipe, disinfect the surfaces by wiping from clean areas to soiled areas.
3. Refer to manufacturer's instructions for the wet contact time. Monitor for wet appearance. Reapply with a new wipe if no longer wet.
4. Verify that all gel and debris have been removed. If necessary, repeat all cleaning steps with a new wipe.

5. Air dry or towel dry with a clean cloth.

Safety

This section contains general safety information that applies to the ultrasound system, transducers, accessories, and peripherals. Report any serious safety incident that occurs in relation to the ultrasound system to FUJIFILM Sonosite and to the competent authority of the country in which the user and patient are established.

Ergonomic safety

These scanning guidelines are intended to assist you in the comfortable and effective use of your ultrasound system.

WARNING

- To prevent musculoskeletal disorders, follow the guidelines in this section.
- Use of an ultrasound system may be linked to musculoskeletal disorders (MSDs).[e,f,g]
- Use of an ultrasound system is defined as the physical interaction between the operator, the ultrasound system, and the transducer.
- When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with MSDs. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

WARNING

While researchers are not able to definitively answer many questions about MSDs, there is a general agreement that certain factors are associated with their occurrence including preexisting medical and physical conditions, overall health, equipment and body position while doing work, frequency of work, duration of work, and other physical activities that may facilitate the onset of MSDs[h]. This section provides guidelines that may help you work more comfortably and may reduce your risk of MSDs.[i,j]

[e]Magnavita, N., L. Bevilacqua, P. Mirk, A. Fileni, and N. Castellino. "Work-related Musculoskeletal Complaints in Sonologists." Occupational Environmental Medicine. 41:11 (1999), p. 981-988.
[f]Craig, M. "Sonography: An Occupational Hazard?" Journal of Diagnostic Medical Sonography. 3 (1985), p.121-125.
[g]Smith, C.S., G.W. Wolf, G. Y. Xie, and M. D. Smith. "Musculoskeletal Pain in Cardiac Ultrasonographers: Results of a Random Survey." Journal of American Society of Echocardiography. (May1997), p. 357-362.
[h]Wihlidal, L.M. and S. Kumar. "An Injury Profile of Practicing Diagnostic Medical Sonographers in Alberta." International Journal of Industrial Ergonomics. 19 (1997), p.205-216.

Position the system

Minimize eye and neck strain

- If possible, position the system within reach.
- Adjust the angle of the clinical monitor to minimize glare.
- Adjust the height so that the clinical monitor is at or slightly below eye level.

Position yourself

Support your back during an exam

- Use a chair that supports your lower back, that adjusts to your work surface height, that promotes a natural body posture, and that allows quick height adjustments.
- Always sit or stand upright. Avoid bending or stooping.

Minimize reaching and twisting

- Use a bed that is height adjustable.
- Position the patient as close to you as possible.
- Face forward. Avoid twisting your head or body.
- Move your entire body front to back, and position your scanning arm next to or slightly in front of you.
- Stand for difficult exams to minimize reaching.
- Position the monitor directly in front of you.

Promote comfortable shoulder and arm postures

- Keep your elbow close to your side.
- Relax your shoulders in a level position.
- Support your arm using a support cushion or pillow, or rest it on the bed.

Promote comfortable hand, wrist, and finger postures

- Hold the transducer lightly in your fingers.
- Minimize the pressure applied on the patient.
- Keep your wrist in a straight position.

Take breaks, exercise, and vary activities

- Minimizing scanning time and taking breaks can effectively allow your body to recover from physical activity and help you avoid MSDs. Some ultrasound tasks may require longer or more frequent breaks. However, simply changing tasks can help some muscle groups relax while others remain or become active.
- Work efficiently by using the software and hardware features correctly.
- Keep moving. Avoid sustaining the same posture by varying your head, neck, body, arm, and leg positions.

[i]Habes, D.J. and S. Baron. "Health Hazard Report 99-0093-2749." University of Medicine and Dentistry of New Jersey. (1999).
[j]Vanderpool, H.E., E.A. Friis, B.S. Smith, and K.L. Harms. "Prevalence of Carpal Tunnel Syndrome and Other Work-related Musculoskeletal Problems in Cardiac Sonographers." Journal of Medicine. 35:6 (1993), p. 605-610.

- Do targeted exercises. Targeted exercises can strengthen muscle groups, which may help you avoid MSDs. Contact a qualified health professional to determine stretches and exercises that are right for you.

Temperature safety

Follow these temperature guidelines for safe storage, charging, and handling.

WARNING

- Under certain circumstances, the display can reach temperatures that exceed IEC 60601-1 (EN 60601-1) limits for patient contact. Make sure that only the operator handles the system. Avoid placing the display on the patient during use.
- The maximum temperature of the transducer scan head may be greater than 41°C (105.8°F), but is less than 43°C (109.4°F) when in contact with the patient. Special precautions should be considered when using the transducer on children or on other patients who are sensitive to higher temperatures.
- The transducer handle may reach temperatures of up to 48°C, which may be harmful to the patient. Do not touch the handle to the patient for an extended period of time.
- Do not place the system within reach of patients while charging.

CAUTION

- Except when the transducer is being charged, the system can operate when the ambient temperature is between 0°C (32°F) to 35°C (95°F). When the ambient temperature is above 35°C, the system is rated as noncontinuous (10 minutes on and 20 minutes off).
- Charge the transducer only when the ambient temperature is between 10°C (50°F) and 35°C (95°F).
- The transducer automatically shuts down before it becomes too hot. If this occurs, let the transducer cool down for 20 minutes before turning it on again. Make sure you operate the transducer at temperatures between 0°C (32°F) to 35°C (95°F). If the transducer shuts down when the ambient temperature is between 0°C (32°F) to 35°C (95°F), there could be a transducer failure. Contact technical support.

Electrical safety

This system meets EN60601-1, Class I/internally-powered equipment requirements and Type BF (transducers) isolated patient-applied parts safety requirements.

The system complies with the safety and EMC standards listed in the standards section of this document.

For maximum safety observe the following warnings and cautions.

WARNING

- To avoid discomfort or minor risk of patient injury, keep hot surfaces away from the patient.
- To avoid the risk of injury, do not operate the system in the presence of flammable gases or anesthetics. Explosion can result.
- To avoid the risk of electrical shock or injury, do not open system or accessory enclosures. All internal adjustments and replacements must be made by a qualified technician.
- For good communication quality and to prevent exposure to excessive radio frequency emissions, avoid holding the transducer where the wireless antenna is located.

WARNING

To avoid the risk of electrical shock:

- Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked “Hospital Only,” “Hospital Grade,” or the equivalent. Do not remove or defeat the grounding wire.
- Connect this equipment to a supply mains with protective earth.
- Do not allow associated connectors for applied parts to contact any other conductive parts including earth.
- When using the system in an environment where the integrity of the protective earth conductor arrangement is in doubt, operate the system on battery power only without using the power supply.
- Do not let any part of the system, including the power brick and display, touch the patient except for the transducer lens.
- Do not let the transducer touch the patient while it is charging.
- While you are touching a patient, do not touch any of the following:
  - The system, stand, or connected accessories except for transducers.
  - The signal input/output connectors on the system.
- Do not connect the system’s AC power cord to mains power using an MPSO (power strip) or extension cord.
- Before using the transducer, inspect the transducer face and housing. Do not use the transducer if the transducer is damaged.
- Do not use any transducer that has been immersed in the cleaning agent beyond the specified cleaning or disinfection level.
- Use only accessories and peripherals recommended by FUJIFILM Sonosite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM Sonosite could result in electrical shock. Contact FUJIFILM Sonosite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM Sonosite.

WARNING

- To avoid the risk of electrical shock and fire hazard:
  - Regularly inspect the power brick, including cords, for damage.
  - Use the power brick only with the Sonosite iLOOK.
- To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.
- Failures in the electrical safety design of connected devices may result in a voltage on the ultrasound system. To minimize the risk of electrical shock to the patient and/or operator:
  - Use medical-grade devices.
  - After connections are made, test the electrical safety utilizing biomedical department electrical safety procedures.

CAUTION

- Do not use the system if an error message appears on the image display: note the error code; call FUJIFILM Sonosite or your local representative; turn off the system by pressing and holding the power key until the system powers down.
- The power brick becomes hot while charging the system. To prevent burns, do not touch the power brick for an extended period of time.

Electrical safety classification

Class I equipment	The ultrasound system is classified as Class I equipment when powered from the external power supply or mounted on the stand because the external power supply is a Class I protectively earthed power supply.
Internally powered equipment	The ultrasound system is classified as internally powered equipment when it is powered by internal battery (not connected to AC power).
Type BF applied parts	Ultrasound transducers
Ingress protection IPX7	Ultrasound transducers
Handheld	Ultrasound transducers
Non AP/APG	Ultrasound system including power supply, stand elements, and connected peripherals is not suitable for use in the presence of flammable anaesthetic mixture with air or oxygen or nitrous oxide.
Mode of operation	Continuous

Isolating the ultrasound system from power

The Sonosite iLOOK ultrasound system does not become completely isolated from power by pressing the power button. Use the following procedure to completely isolate the system (including the stand) from power.

1. Press the power button on the display device to turn it off.

2. Press the power button on the transducer to turn it off.
3. If the system is connected to AC power, unplug the AC power cord from the mains outlet or from the back of the display device.

Battery safety

To prevent the batteries from bursting, igniting, or emitting fumes and causing personal injury or equipment damage, observe the following precautions.

WARNING

- The battery cannot be touched or replaced. Do not attempt to replace, disassemble, or alter the battery.
- Charge the battery only when the ambient temperature is between 10° and 35°C (50° and 95°F).
- Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.
- Do not touch battery contacts.
- Do not heat the battery or discard it in a fire.
- Do not expose the battery to temperatures over 60°C (140°F). Keep it away from fire and other heat sources.
- Do not charge the battery near a heat source, such as a fire or heater.
- Do not leave the battery in direct sunlight.
- Do not pierce the battery with a sharp object, hit it, or step on it.
- Do not use a damaged battery.
- Do not solder a battery.
- Do not connect the battery to an electrical power outlet.
- Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.
- Do not ship a damaged battery without instructions from FUJIFILM Sonosite Technical Support.
- If the battery leaks or emits an odor, remove it from all possible flammable sources.

CAUTION

- Do not immerse the battery in water or allow it to get wet.
- Do not put the battery into a microwave oven or pressurized container.
- If the battery emits an odor or heat during use, stop using the system. If you have any questions about the battery, consult FUJIFILM Sonosite or your local representative.
- Periodically, check to make sure that the battery charges fully. Contact FUJIFILM Sonosite if the battery fails to charge.
- Do not use or charge the battery with non-FUJIFILM Sonosite equipment. Only charge the system battery with the system.
- The batteries contain technology that requires periodic recharging to maintain optimal performance. If left uncharged for months, battery performance could degrade or the battery could become non-functional.

Equipment safety

To protect your ultrasound system, transducer, and accessories, follow these precautions.

WARNING

When transporting your system, to avoid possible injury from the system tipping, lower the clinical display and push forward on the stand handle instead of pushing downward on the handle, pushing the clinical display, or pushing on the tray.

Be careful of pinching your fingers when operating the monitor arm.

CAUTION

- Excessive bending or twisting of cables can cause a failure or intermittent operation.
- Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, see the cleaning and disinfecting section of this user guide.
- Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- Do not spill liquid on the system.
- Position the system to allow access to the mains power-cord connector.
- Do not remove any screws other than those described for assembling the system. Please refer to the *Sonosite iLOOK Assembly Instructions* P33248 when assembling the system. The assembly process is designed to be simple enough for the end-user or other technical personnel to complete.

Clinical safety

WARNING

- To avoid injury, inspect all fasteners and connections.
- FUJIFILM Sonosite does not recommend the use of high-frequency electromedical devices in proximity to its systems. FUJIFILM Sonosite equipment has not been validated for use with high-frequency electrosurgical devices or procedures. Use of high-frequency electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system. To avoid the risk of a burn hazard, do not use the transducer with high frequency surgical equipment. Such a hazard may occur in the event of a defect in the high frequency surgical neutral electrode connection.
- The maximum temperature of the transducer scan head may be greater than 41°C (105.8°F), but is less than 43°C (109.4°F) when in contact with the patient. Special precautions should be considered when using the transducer on children or on other patients who are sensitive to higher temperatures.
- Do not use the system if it exhibits erratic or inconsistent behavior. Discontinuities in the scanning sequence are indicative of a hardware failure that must be corrected before use.

WARNING

- Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. FUJIFILM Sonosite recommends identifying your latex- and talc-sensitive patients and being prepared to treat allergic reactions promptly.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle and follow the prudent use information concerning MI and TI.
- FUJIFILM Sonosite does not currently recommend a specific brand of acoustic standoff. If an acoustic standoff is used, it must have a minimum attenuation of 0.3dB/cm/MHz.
- Use market-cleared, sterile transducer sheaths and sterile coupling gel for guided-needle procedures. Do not apply the transducer sheath and coupling gel until you are ready to perform the procedure. After use, remove and discard the single-use sheath, and clean and disinfect the transducer using a FUJIFILM Sonosite recommended disinfectant.
- To avoid injury or reduce the risk of infection to the patient, observe the following:
  - Follow Universal Precautions when inserting and maintaining a medical device for interventional procedures.
  - Appropriate training in interventional procedures as dictated by current relevant medical practices as well as in proper operation of the ultrasound system and transducer is required. During vascular access, the potential exists for serious complications including without limitation the following: pneumothorax, arterial puncture, and guidewire misplacement.

Hazardous materials

WARNING

Products and accessories may contain hazardous materials. When disposing of products and accessories, be environmentally responsible and meet federal and local regulations for disposing hazardous materials.

Electromagnetic compatibility

The ultrasound system has been tested, evaluated, and verified to comply with the electromagnetic compatibility limits for medical devices to IEC 60601-1-2:2014 (Edition 4.0), IEC 60601-1-2:2014+A1:2020 (Edition 4.1), and IEC TS 60601-4-2:2024 (Edition 1.0). The ultrasound system is suitable for use in the professional healthcare facility environment except for near active high frequency surgical equipment or in a RF shielded room where magnetic resonance imaging is performed because both produce high electromagnetic disturbances which could result in performance disruption of the ultrasound system. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING
To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by FUJIFILM Sonosite. Connection of accessories and peripherals not recommended by FUJIFILM Sonosite could result in malfunctioning of your ultrasound system or other medical electrical devices in the area. Contact FUJIFILM Sonosite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM Sonosite. See Compatible accessories and peripherals [85].

WARNING
Do not stack other equipment on the ultrasound system or use other equipment in close proximity and adjacent to the ultrasound system. If stacking or using other equipment in close proximity is unavoidable, then you must observe the system to verify normal operation.

CAUTION
The EMC performance of the ultrasound system may be degraded if the product is used in harsh environments where the system is exposed to high humidity, elevated temperatures, high vibration, or high shock for extended durations. If the system shows symptoms of degraded EMC performance, see the precautions listed in the following section. If, after taking the listed precautions, the degraded EMC performance persists, the system may need to be serviced to maintain optimum EMC performance.

CAUTION

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency (RF) electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the sources.

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or re-orient interfering equipment.
- Increase distance between interfering equipment (or equipment being interfered with) and your ultrasound system.
- Connect the ultrasound equipment and the interfering equipment (or equipment being interfered with) to different power outlet circuits.
- Manage use of frequencies close to ultrasound system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC standards.

Wireless transmission

The transducer contains an internal IEEE 802.11 transmitter that uses the Industrial, Scientific, and Medical (ISM) frequency bands from 2.412 to 2.484 GHz and/or 5.15 to 5.825 GHz. The transmitter is capable of CCK, OFDM and MCS0-7 at HT20. The maximum transmitter power is 15 dBm. Certification numbers are displayed on the **Transducer information** screen (see Transducer information [36]).

Table 13. Transducer wireless description

Wireless specifications		
Wireless network protocols supported	IEEE 802.11a/b/g/n (for 11n, only STA mode is supported	
Frequency	2.4 GHz	FCC/ISED: 2412–2462 MHz (1–11 channels) CE/ETSI/RCM: 2412–2472 MHz (1–13 channels)
	5 GHz	5180–5240 MHz (4 channels: 36ch, 40ch, 44ch, 48ch)

Wireless specifications			
Frequency bandwidth	20 MHz		
Modulation type	DSSS OFDM (1st modulation: BPSK, QPSK, 16QAM, 64QAM)		
Maximum average power (dBM)	2.4 GHz	802.11b	16.0 dBm
		802.11g	15.0 dBm
		802.11n-HT20	11.0 dBm
	5 GHz	802.11a	13.5 dBm
Frequency tolerance	2.4 GHz	± 25 ppm	
	5 GHz	± 20 ppm	
Security/encryption	WPA2-PSK		
Antenna	Type	Chip	
	Model	M830520	
	Gain	2.4 GHz_1 dBi	
		5 GHz_2.6 dBi	

The display contains an internal IEEE 802.11 transmitter that uses the Industrial, Scientific, and Medical (ISM) frequency bands from 2.412 to 2.484 GHz and/or 5.15 to 5.825 GHz. Certification numbers are displayed in **System Information** (see System information [33]). The transmitter supports the 802.11 a/b/g/n/ac wireless communication protocol (four operational frequencies):

- WLAN 802.11b/g/n/ax 2400 MHz–2483.5 MHz ≤ 20 dBm
- WLAN 802.11a/n/ac/ax 5150 MHz–5725 MHz < 23 dBm
- WLAN 802.11a/n/ac/ax 5725 MHz–5825 MHz < 13.98 dBm
- WLAN 802.11ax 5945 MHz–6425 MHz < 23 dBm

NOTE
This device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU, the FCC, and Industry Canada.

Electrostatic discharge

WARNING
Unless following ESD precautionary procedures, do not connect to or touch (with body or hand-held tools) pins (contacts) of connectors that have the ESD Sensitive Devices label.

CAUTION
Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. ESD is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

ESD precautionary procedures include the following:

- All staff involved must receive training about ESD, including the following at a minimum: an explanation of the ESD warning symbol, ESD precautionary procedures, an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can occur to electronic components if equipment is touched by an individual who is electrostatically charged.
- Prevent the buildup of electrostatic charge. For example, use humidification, conductive floor coverings, non-synthetic clothing, ionizers, and minimizing insulating materials.
- Discharge your body to earth.
- Use a wrist strap to bond yourself to the ultrasound system or to earth.

Separation distance

Recommended separation distances between portable and mobile RF communications equipment and the Sonosite iLOOK ultrasound system

WARNING
Portable RF communications equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Sonosite iLOOK ultrasound system is intended for use in an electromagnetic environment in which radiated radio frequency (RF) disturbances are controlled. The customer or the user of the FUJIFILM Sonosite ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FUJIFILM Sonosite ultrasound system as recommended below, according to the maximum output power of the communications equipment.

Table 14. Separation distance according to frequency of transmitter (m)

Rated maximum output power of transmitter (Watts)[a]	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.7 GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

Rated maximum output power of transmitter (Watts)[a]	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.7 GHz d=2.3 √P
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

[a]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.

Compatible accessories and peripherals

FUJIFILM Sonosite has tested the Sonosite iLOOK ultrasound system with the following accessories and peripherals and has demonstrated compliance to the requirements of IEC 60601-1-2:2014 and IEC 60601-1-2:2014+A1:2020. You may use these FUJIFILM Sonosite accessories and third-party peripherals with the Sonosite iLOOK ultrasound system.

WARNING

- Use of the accessories with medical systems other than the Sonosite iLOOK ultrasound system may result in increased emissions or decreased immunity of the medical system.
- Use of accessories, transducers and cables other than those specified or provided by FUJIFILM Sonosite could result in increased emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Table 15. Compatible accessories and peripherals

Description	Model and manufacturer	Maximum cable length
L15-5 transducer	—	—
Aquasonic gel	—	—
Stand	—	—
Power brick with DC cable	—	114 cm (44.88 in)
AC power cord	—	304.8 cm (20 in)
Storage container	—	—
Tray	—	—
USB flash drive	Jetflash-890 TS128GJF890S, Transcend[a]	—

[a]Applicable EMC standards: EN 55032: 2015+A1:2020 and EN 55035:2017+A11: 2020

Manufacturer's declaration

The tables in this section document the intended use environment and EMC compliance levels of the system. For maximum performance, ensure that the system is used in the environments described in these tables.

The system is intended for use in the electromagnetic environment specified below.

Table 16. Manufacturer's Declaration - Electromagnetic Emissions per IEC 60601-1-2:2014/EN 60601-1-2:2015 and IEC 60601-1-2:2014+A1:2020/EN 60601-1-2:2015+A1:2021

Emissions test	Compliance	Electromagnetic environment
RF emissions ClSPR 11	Group 1	The Sonosite iLOOK ultrasound 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 ClSPR 11	Class B	The Sonosite iLOOK ultrasound system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	—
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	—

The system is intended for use in the electromagnetic environment specified below.

Table 17. Manufacturer's Declaration - Electromagnetic Immunity per IEC 60601-1-2:2014/EN 60601-1-2:2015, IEC 60601-1-2:2014+A1:2020/EN 60601-1-2:2015+A1:2021, and IEC TS 60601-4-2:2024

Immunity test	IEC 60601-1-2, IEC TS 60601-4-2 Test Level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8.0 kV contact, ± 2.0 kV, ± 4.0 kV, ± 8.0 kV ± 15 kV air	± 8.0 kV contact, ± 2.0 kV, ± 4.0 kV, ± 8.0 kV ± 15 kV 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 on the mains ± 1 kV on signal lines	± 2 kV on the mains ± 1 kV on signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	0% U_T 0.5 cycle Phase: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T 1 cycle Phase: 0° 70% U_T 25 cycles Phase: 0° 0% U_T 250 cycles Phase: 0°	0% U_T 0.5 cycle Phase: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T 1 cycle Phase: 0° 70% U_T 25 cycles Phase: 0° 0% U_T 250 cycles Phase: 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FUJIFILM Sonosite ultrasound system requires continued operation during power mains interruptions, it is recommended that the FUJIFILM Sonosite ultrasound system be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601-1-2, IEC TS 60601-4-2 Test Level	Compliance level	Electromagnetic environment
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the FUJIFILM Sonosite ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the Intended installation location to assure that it is sufficiently low.
Proximity Magnetic Fields IEC 61000-4-39 applicable for IEC 60601-1-2:2014+A1 :2020 (Edition 4.1) only	Per 60601-1-2:2014+A1 :2020 Table 11	Per 60601-1-2:2014+A1 :2020 Table 11	If image distortion occurs, it may be necessary to position the FUJIFILM Sonosite ultrasound system further from sources of proximity magnetic fields or to install magnetic shielding. The proximity magnetic fields should be measured in the intended installation to assure they are sufficiently low.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz\ 6 Vrms in ISM bands 6 Vrms in amateur radio band	3 Vrms 6 Vrms in ISM bands 6 Vrms in amateur radio band	Portable and mobile RF communications equipment should be used no closer to any part of the FUJIFILM Sonosite ultrasound 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	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:  (IEC 60417 No. 417-IEC-5140: “Source of non-ionizing radiation”)
Proximity fields from wireless communications equipment IEC 61000-4-3	Per 60601-1-2:2014 and IEC 60601-1-2:2014+A1 :2020 Table 9	Per 60601-1-2:2014 and IEC 60601-1-2:2014+A1 :2020 Table 9	—

[a]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 FUJIFILM Sonosite ultrasound system is used exceeds the applicable RF compliance level above, the FUJIFILM Sonosite ultrasound system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FUJIFILM Sonosite ultrasound system.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Essential performance requirements

Per 60601-2-37, the following have been determined to be essential performance for the Sonosite iLOOK ultrasound system. The Sonosite iLOOK ultrasound system must be free from the following:

- Noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value that cannot be attributed to a physiological effect and that can alter the diagnosis
- Display of incorrect numerical values associated with the diagnosis to be performed
- Display of incorrect safety related indications
- Production of unintended or excessive ultrasound output
- Production of unintended or excessive transducer assembly surface temperature

Results of EMC immunity testing show that the Sonosite iLOOK ultrasound system meets the essential performance requirements in 60601-2-37. If the operator detects unacceptable degradation of performance, they should stop using the equipment and take suitable precautions as detailed in Electromagnetic compatibility [80].

IEC TS 60601-4-2 Acceptable Degradation of Performance

Degradation of Performance During Immunity Test: Degradation is allowed. Essential performance may be affected but in a way that would not affect diagnosis. Diagnosis may be delayed if essential performance is affected in a way that prevents immediate diagnosis.

Degradation of Performance After Immunity Testing: No degradation is allowed. The ultrasound system and accessories must meet all functional and safety tests.

The Sonosite iLOOK ultrasound system was tested according to the recommendations of IEC TS 60601-4-2: Medical Electrical Equipment - Part 4-2: Guidance and interpretation - Electromagnetic Immunity Performance of Medical Electrical Equipment and Medical Electrical Systems. Results of EMC immunity testing show that the Sonosite iLOOK ultrasound system meets the performance requirements per IEC TS 60601-4-2. If the operator detects unacceptable degradation of performance, they should stop using the equipment and take suitable precautions as detailed in Electromagnetic compatibility [80].

The maximum recovery time for most transient immunity tests (Electrical Fast Transients/Burst, Surges, Voltage Dips (0%)) is 1 second or less. The maximum recovery time for Electrostatic Discharge is 3 seconds or less.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

NOTE

This equipment has been tested and found to comply with the Class B digital device limits of FCC Part 15 and the limits specified in FCC Part 18. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate harmful radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other medical or electronic equipment, take suitable precautions as detailed in Electromagnetic compatibility [80]. “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union (ITU) Radio Regulations.

This device complies with part 15 and part 18 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC compliance statement

This device complies with part 18 of the FCC Rules.

Product information:

- Product name: Sonosite iLOOK
- Model number: P35001

U.S. responsible party information:

- Company name: FUJIFILM SonoSite, Inc.
- Address: 21919 30th Drive SE Bothell, WA 98021 USA
- Telephone number: 1-888-482-9449 or 1-425-951-1200
- Internet contact information: www.sonosite.com

Canadian regulatory statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

For indoor use only (5150-5250 MHz).

NOTE
This equipment complies with FCC and ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and the RSS-102 of the ISED radio frequency (RF) Exposure rules. This equipment must be installed and operated keeping the radiator at least 20 cm or more away from a person's body.

It is only applied for "transducer holder with charger" while charging the transducer.

NOTE
"Transducer (L15-5)" has been tested and found to comply with FCC and ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and the RSS-102 of the ISED radio frequency (RF) Exposure rules.

The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power w ireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research.

Labeling symbols

The following symbols may be used on the products, packaging, and containers.

Table 18. Standards labeling symbols

Symbol	Description	Standards reference
	Manufacturer Indicates the medical device manufacturer	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.1.1
	Date of manufacture Indicates the date on which a product was manufactured	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.1.3

Symbol	Description	Standards reference
	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.1.7
	Catalog Number Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.1.6
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.4.4
	Fragile handle with care Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.3.1
	Keep dry Indicates a medical device that needs to be protected from moisture	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.3.4
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.3.7
	Atmospheric pressure limitations Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.3.9
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.3.8
	Stacking limit by number Do not stack over n high, where n represents the number on the label The number does not include the bottom package in the stack	ISO 7000 Graphical symbols for use on equipment 2403
	Refer to instruction manual/booklet	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance D.2-10
	Consult instructions for use Indicates that the operating instructions should be considered when operating the device or control close to where the symbol is placed	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements 5.4.3

Symbol	Description	Standards reference
	Corrugated recycle Shipping box is made of corrugated cardboard and should be recycled accordingly	—
	FCC—Tested to Federal Communications Commission requirements. Device complies with relevant FCC regulations for electronic devices.	Federal Communications Commission (FCC) Declaration of conformity 21 Part 15
	IC—Tested to Industry Canada requirements. Device complies with relevant IC regulations for electronic devices.	—
CAN RSS-216/ CNR-216	Complies with Canada's updated WPT safety and performance standards.	RSS-216
	In the indicated European countries, the device is restricted to indoor use only when operating in the 5150 to 5250 MHz frequency range.	Regulation (EU) 2017/1354, Article 10 of Directive 2014/53/EU of the European Parliament and of the Council.
	RESY – Recycling Symbol Paper recycle	—
	Recycle: Electronic Equipment Do Not Throw in Trash	BS EN 50419 Marking of Electrical and Electronic Equipment in accordance with Directive 2012/19/EU for the Waste of Electrical and Electronic Equipment (WEEE) and Directive 2006/66/EC on Batteries and Accumulators and Waste Batteries and Accumulators Annex IX
	CE Marking Signifies European Technical Conformity	—
	Conformité Européene Notified Body Reference No.: 2797 Indicates European technical conformity and identification of notified body responsible for implementation of the procedures set out in Annexes II, IV, V, and VI	—
	UK Conformity Assessed Mark that indicates conformity with the applicable requirements for products sold within Great Britain	The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
	UK Conformity Assessed with approved body number Mark, including the approved body number, that indicates conformity with the applicable requirements for products sold within Great Britain	The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
	Indicates the Authorized representative in the European Community	ISO 15223-1 Medical devices - symbols to be used with medical device labels, labeling and information to be supplied 5.1.2
	Medical Device Indicates the item the label is adhered to is categorized as a medical device per the MDR, Annex 1, 23.2, q.	EU MDR Annex I, 23.2 (q)

Symbol	Description	Standards reference
	UDI Unique device identifier. This symbol is optional and is used when there are multiple data carriers on a label.	ISO 15223-1:2021 5.7.10
	Regulatory Compliance Mark (RCM) Indicates C-Tick-Regulatory Compliance Mark for Australia and New Zealand. Device complies with relevant Australian and New Zealand regulations for electronic devices.	AS/NZS3820
	Alternating current Indicates on the rating plate, that the equipment is suitable for alternating current only, in order to identify appropriate terminals	IEC 60601-1
	Direct current (DC) To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IEC 60601-1
	Batch code, date code, or lot code type of control number Indicates manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements 5.1.5
	Canadian Standard Association Certification Mark CSA certification mark signifying that the product complies with the applicable CSA and ANSI/UL requirements and is authorized for use in Canada and the US	—
	TÜV SÜD certification mark for Canada and USA. The product has been independently tested and certified by TÜV SÜD.	—
	Magnetic resonance environment unsafe Indicates the system is an item that is known to pose hazards in all MR environments	ASTM International (American Society for Testing and Materials) ASTM F2503
	Degree of ingress protection provided by enclosure Protected against the effects of temporary immersion in water	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance D.3-2
	No pushing	P017 — ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs
	Type BF applied parts Identifies type BF applied part complying with IEC 60601-1	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance D.1-20
	Polarity of the DC power connector	IEC 60417: Graphical Symbols For Use On Equipment 5926
	Stand-by	IEC 60417: Graphical Symbols For Use On Equipment 5134
	For indoor use only Identifies electrical equipment designed primarily for indoor use	IEC 60417: Graphical Symbols For Use On Equipment 5957

Symbol	Description	Standards reference
	Indicates total weight of the equipment, including the safe working load	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance 7.2.21

Specifications

This section defines the technical specifications for the ultrasound system and its components. The system consists of the following:

- Wireless transducer
- System including the display, stand mount, and transducer holder with charger
- Optional stand with articulating arm, VESA mount, storage bin, and tray

For additional information on accessories and peripherals, see Compatible accessories and peripherals [85].

Table 19. L15-5 transducer

Parameter	Value
Length	151 mm (5.94 in)
Width	56.5 mm (2.22 in)
Depth	29.5 mm (1.16 in)
Weight	170 g (6 oz)
Scan depth min to max	0–6.2 cm

Table 20. System

Parameter	Value
Width	47.2 cm (14.53 in)
Height	29.2 cm (9.29 in)
Weight	5.4 kg (11.9 lbs)

Table 21. Display

Parameter	Value
Size	39.6 cm (15.6 in) diagonal
Viewing area	34.5 cm x 19.5 cm (13.65 in x 7.62 in)
Resolution	1920 x 1080 px
Rotation	180° left and right
Minimum luminance	215 cd/m^2

Table 22. System plus stand

Parameter	Value
Width range	58.4–60.9 cm (23.0–24.0 in)
Depth range	58.0–77.0 cm (22.83–31.3 in)
Height range	130.3–164.3 cm (51.3–64.7 in)
Safe working load (maximum weight with stand, system, and peripherals)	27.0 kg (59.5 lbs)

Parameter	Value
Stand base dimensions (width x depth)	• 57.9 cm x 58.4 cm (22.8 in x 23 in) wheels turned in • 69.1 cm x 70.3 cm (27.2 in x 27.7 in) wheels turned out
Storage bin capacity	2.2 kg (4.85 lbs)
Tray capacity	1.2 kg (2.65 lbs)

Table 23. Other specifications

Parameter	Value
System storage	36 GB

Environmental limits

Table 24. Operating limits

Limit type	Transducer (with battery), display (with battery), AC power brick, and stand
Temperature	0–35°C (32–95°F) continuous operation
Humidity	15–90% R.H. (no condensation)
Atmospheric pressure	700–1060 hPa (0.69–1.05 ATM)

Table 25. Charging limits

Limit type	System (display and transducer with batteries)
Temperature	10–35°C (50–95°F)
Humidity	15–90% R.H. (no condensation)
Atmospheric pressure	700–1060 hPa (0.7–1.05 ATM)

Table 26. Transportation and storage limits

Limit type	Transducer (with battery), display (with battery), and stand	AC power brick
Temperature	• -20–40°C (-4–104°F) • -20–50°C (-4–122°F) within 1 month	-20–40°C (-4–104°F)
Humidity	10–90% R.H. (no condensation)	10–90% R.H. (no condensation)
Atmospheric pressure	700–1060 hPa (0.7–1.05 ATM)	700–1060 hPa (0.7–1.05 ATM)

Electrical rating

Table 27. AC power brick

Parameter	Value
Input voltage	100–240 VAC
Input frequency	50–60 Hz
Input range	2.0–1.0 A
Output voltage	28 V DC
Output current	3.57 A
Classification	Class 1, continuous use

Table 28. Transducer charger

Parameter	Value
Input voltage	5 V DC
Maximum power	5 W max
Frequency	120–200 kHz

Table 29. Power cords

Region	Specifications	Standard
North America, 120 VAC	Rated 10 A, 125 V, 3 x 18 AWG, max 3.05 m (10 ft) length, SJT type, 105°C; provided with NEMA 5-15P Hospital Grade Plug at one end and IEC-320/C13 type socket on the other end.	UL 817, Ed.12; CSA-C22.2 No. 21-14
Other countries	Approved cord set rated min 10 A/250 V, max 3.05 m length, provided with IEC-320/C13 type socket at one end and country specific hospital grade plug at the other end, acceptable to the authorities in the country of installation.	IEC 60227-1:2007, or IEC 60245-1:2007, or equivalent acceptable in the country of installation.

Batteries

Table 30. System battery

Parameter	Value
Type	Lithium ion, integrated
Capacity	4250 mAh, 94 Wh
Lifecycle	80% capacity after 500 charges
Maximum operation time before charging	120 minutes[a]

[a]Deterioration shortens the duration after repeated charge cycles.

Table 31. Transducer battery

Parameter	Value
Type	Lithium ion, integrated
Capacity	2200 mAh, 7.92 Wh
Lifecycle	300 charges
Maximum operation time before charging	120 minutes[a]

[a]Deterioration shortens the duration after repeated charge cycles.

Imaging modes

- 2D (256 gray shades)
- Color Doppler (Color) (256 colors)
- Color Power Doppler (CPD) (256 colors)

Image and video clip storage capacity

The number of images and video clips you can save depends on imaging mode and file format.

Standards

Electromechanical safety standards

Standard	Description
ANSI/AAMI ES60601-1:2005 + A1:2012 + A2:2021 EN 60601-1:2006+A1:2013+A12:2014+A2:2021	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Edition 3.2)
CAN/CSA C22.2 No. 60601-1:14 (R2022)	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Edition 3.2)
CSA C22.2 60601-2-37:08 (R2019)	Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Adopted IEC 60601-2-37+A1:2015)
CSA C22.2 60601-1-6:11 (+A1: 2015 +A2:2021)	Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability (Adopted IEC 60601-1-6:2020, Edition 3.2)
IEC 60601-1:2020 Ed. 3.2	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Edition 3.2)
IEC 60601-2-37:2007 +A1:2015 Ed. 2.1 EN 60601-2-37:2008+A1:2015+A11:2024	Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Edition 2.1)
IEC 60601-2-37:2024 Ed. 3.0 EN IEC 60601-2-37:2024 Ed. 3.0	Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Edition 3.0)
IEC 60601-1-6:2020 Ed. 3.2 EN 60601-1-6:2010+A1:2015+A2:2021	Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability (Edition 3.2)

EMC standards classification

Standard	Description
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests (Edition 4.0).
IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests (Edition 4.1).
EN 55032: 2015+AC:2016-07	Multimedia Equipment. Electromagnetic Compatibility (EMC) Requirements for Emission.
EN 55032: 2015+A1:2020	Multimedia Equipment. Electromagnetic Compatibility (EMC) Requirements for Emission.
EN 55035: 2017+A11:2020	Multimedia Equipment. Electromagnetic Compatibility (EMC) Requirements for Immunity.

DICOM standards

Digital Imaging and Communications in Medicine (DICOM), Version 3 (NEMA).

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

Security and privacy standards

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

Standard	Description
HIPAA:1996	45 CFR Parts 160 and 164; Subparts A, C, and E, Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules
NIST SP 800-53:	Security and Privacy Controls for Federal Information Systems and Organizations

Acoustic Output

This section contains information about the ALARA (as low as reasonably achievable) principle, the output display standard, and acoustic power and intensity tables. The information applies to the ultrasound system, transducer, accessories, and peripherals.

Biological effects of ultrasound

As reported for diagnostic medical use, ultrasound has no known biological effects (bioeffects). However, you should be aware of risks associated with ultrasound to ensure its safe use. A basic understanding of ultrasound physics and the application of the ALARA principle, as described in the following sections, can help mitigate these risks.

The possible bioeffects of ultrasound occur through thermal and nonthermal mechanisms. The thermal mechanism refers to the heating of tissue and bone caused by the absorption of ultrasound energy. The nonthermal mechanism includes cavitation and other mechanical bioeffects caused by ultrasound waves passing through or near regions with gas or air pockets and inducing tissue motion. Cavitation is the expansion and contraction of bubbles caused by acoustic pressure from ultrasound. These bubbles can collapse, releasing a large amount of energy to the tissue and causing hemorrhage or capillary rupture. The risk is higher in the lungs and intestines due to the inherent presence of gas and/or air bubbles.

The likelihood of thermal bioeffects occurring is indicated by the thermal index (TI), while the likelihood of mechanical bioeffects occurring is indicated by the mechanical index (MI).

ALARA principle

ALARA is the guiding principle for the use of diagnostic ultrasound. Qualified ultrasound users, using good judgment and insight, determine the exposure that is “as low as reasonably achievable.” There are no set rules to determine the correct exposure for every situation. The qualified ultrasound user determines the most appropriate way to keep exposure low and bioeffects to a minimum, while obtaining a diagnostic examination.

A thorough knowledge of the imaging modes, transducer capability, system setup and scanning technique is necessary. The imaging mode determines the nature of the ultrasound beam. A stationary beam results in a more concentrated exposure than a scanned beam, which spreads that exposure over that area. The transducer capability depends upon the frequency, penetration, resolution, and field of view. The default system presets are reset at the start of each new patient. It is the scanning technique of the qualified ultrasound user along with patient variability that determines the system settings throughout the exam.

The variables which affect the way the qualified ultrasound user implements the ALARA principle include patient body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because the qualified ultrasound user can control it. The ability to limit the exposure over time supports the ALARA principle.

Applying the ALARA principle

The system imaging mode selected by the qualified ultrasound user is determined by the diagnostic information required. 2D imaging provides anatomical information; CPD imaging provides information about the energy or amplitude strength of the Doppler signal over time at a given anatomical location and is used for detecting the presence of blood flow; Color imaging

provides information about the energy or amplitude strength of the Doppler signal over time at a given anatomical location and is used for detecting the presence, velocity, and direction of blood flow. Understanding the nature of the imaging mode used allows the qualified ultrasound user to apply the ALARA principle.

Prudent use of ultrasound means limiting ultrasound to situations in which it is medically useful and limiting patient exposure to the lowest ultrasound output for the shortest time necessary to achieve acceptable diagnostic results. Users can directly control acoustic output as described in the next section. Decisions that support prudent use are based on the type of patient, exam type, patient history, ease or difficulty of obtaining diagnostically useful information, and potential localized heating of the patient due to transducer surface temperature. In the event of a device malfunction, there are redundant controls that limit transducer power. This is accomplished by an electrical design that limits both power supply current and voltage to the transducer.

The qualified ultrasound user uses the system controls to adjust image quality and limit ultrasound output. System controls are divided into three categories relative to output: controls that directly affect output, controls that indirectly affect output, and receiver controls.

Direct, indirect, and receiver controls

Direct controls

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 720 mW/cm^2 for all imaging modes. Also, the MI and TI do not exceed 1.0 in any situation.For more information on MI and TI, see Medical Ultrasound Safety, AIUM and IEC 60601-2-37 Annex “Guidance on the interpretation of TI and MI to be used to inform the operator.”

Indirect controls

The controls that indirectly affect output are controls affecting imaging mode, freeze, and depth. The imaging mode determines the nature of the ultrasound beam. Freeze stops all ultrasound output but keeps the last image displayed on screen. Freeze can be used by the ultrasound user to limit exposure time while studying an image and maintaining transducer position during a scan. Some controls, such as depth, show a rough correspondence with output.

Receiver controls

The receiver controls are the gain controls. Receiver controls do not affect output. They should be used, if possible, to improve image quality before using controls that directly or indirectly affect output.

Acoustic artifacts

An acoustic artifact is information, present or absent in an image, that does not properly indicate the structure or flow being imaged. There are helpful artifacts that aid in diagnosis and those that hinder proper interpretation. Examples of artifacts include shadowing, through transmission, aliasing, reverberations, and comet tails. For more information on detecting and interpreting acoustic artifacts, see the following reference:

Kremkau, Frederick W. Diagnostic Ultrasound: Principles and Instruments. 7th ed., W.B. Saunders Company, (Oct. 17, 2005).

Output display

The system meets the output display standard in IEC60601-2-37 for MI and TI (see Related guidance documents [101]). The MI and TI on the system are less than the value of 1.0, and the system does not need to display the MI and TI values.

Factors that contribute to MI and TI uncertainty

The net uncertainty of the indices is derived by combining the quantified uncertainty from two sources: measurement uncertainty and system and transducer variability.

Measurement errors of the acoustic parameters when taking the reference data are the major source of error that contributes to the display uncertainty. The measurement error is described in Acoustic measurement precision and uncertainty [106].

The MI and TI values are based on calculations that use a set of acoustic output measurements that were made using a single reference ultrasound system with a single reference transducer that is representative of the population of transducers of that type. The reference system and transducer are chosen from a sample population of systems and transducers taken from early production units, and they are selected based on having an acoustic output that is representative of the nominal expected acoustic output for all transducer-system combinations that might occur. Of course every transducer-system combination has its own unique characteristic acoustic output, and will not match the nominal output on which the display estimates are based. This variability between systems and transducers introduces an error into displayed value. By doing acoustic output sampling testing during production, the amount of error introduced by the variability is bounded. The sampling testing ensures that the acoustic output of transducers and systems being manufactured stays within a specified range of the nominal acoustic output.

Related guidance documents

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, 2023.

Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 2014.

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-2004.

IEC 60601-2-37: 2024, “Particular requirements for the basic safety and essential performance of ultrasonic diagnostic and monitoring equipment”.

Transducer surface temperature rise

The table in this section lists the measured surface temperature rise from ambient (23°C ± 3°C) of transducers used on the ultrasound system. The temperatures were measured in accordance with IEC 60601-2-37 with controls and settings positioned to give maximum temperatures.

Table 32. Maximum transducer surface temperature rise, external use (°C)

Test	L15-5
Still air	14.0
Simulated use	6.4

Acoustic output measurement

Since the initial use of diagnostic ultrasound, the possible human biological effects (bioeffects) from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, AIUM ratified a report from its Bioeffects Committee (Bioeffects Considerations

for the Safety of Diagnostic Ultrasound, J Ultrasound Med., Sept. 1988: Vol. 7, No. 9 Supplement). The report, sometimes referred to as the Stowe Report, reviewed available data on possible effects of ultrasound exposure. Another report, “Bioeffects and Safety of Diagnostic Ultrasound,” dated January 28, 1993, provides more current information.

The acoustic output for this ultrasound system has been measured and calculated in accordance with IEC 60601-2-37: 2015, Medical electrical equipment -- Part 2-37: Particular requirements for the safety and essential performance of ultrasonic diagnostic and monitoring equipment and IEC 62359: 2017, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

In Situ, derated, and water value intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount, type of tissue, and the frequency of the ultrasound passing through the tissue. The intensity value in the tissue, In Situ, has been estimated by using the following formula:

In Situ= Water [e-(0.23alf)]

where:

In Situ = In Situ intensity value

Water = Water intensity value

e = 2.7183

a = attenuation factor (dB/cm MHz)

Attenuation factor (a) for various tissue types are given below:

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

f = center frequency of the transducer/system/mode combination in MHz

Since the ultrasonic path during the exam is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true in situ intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the In Situ value commonly reported uses the formula:

In Situ (derated) = Water [e -(0.069lf)]

Since this value is not the true In Situ intensity, the term “derated” is used to qualify it.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the

In Situ (derated) formula. For example: a multi-zone array transducer that has maximum water value intensities in its deepest zone, but also has the smallest derating factor in that zone. The same transducer may have its largest derated intensity in one of its shallowest focal zones.

Tissue models and equipment survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels In Situ from measurements of acoustic output made in water. Currently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in the acoustic properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific exam types.

A homogeneous tissue model with attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the In Situ acoustic exposure when the path between the transducer and site of interest is composed entirely of soft tissue. When the path contains significant amounts of fluid, as in many first and second-trimester pregnancies scanned transabdominally, this model may underestimate the In Situ acoustic exposure. The amount of underestimation depends upon each specific situation.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate In Situ acoustic exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/cm MHz may be used during all trimesters.

Existing tissue models that are based on linear propagation may underestimate acoustic exposures when significant saturation due to non-linear distortion of beams in water is present during the output measurement.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded MI values between 0.1 and 1.0 at their highest output settings. Maximum MI values of approximately 2.0 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D and M-Mode imaging.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1° and 4°C (1.8° and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed path” tissue model and are for devices having ISPTA values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1-4.3.2.6 in “Bioeffects and Safety of Diagnostic Ultrasound” (AIUM, 1993).

Acoustic output tables

The tables in this section indicate the acoustic output for the system and transducer. For a definition of terms used in the tables, see Terminology in acoustic output tables [105].

Table 33. Acoustic output table key

(a)	This transducer is not intended for transcranial or neonatal cephalic uses.
#	No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
—	Not applicable for this transducer/mode.

L15-5 acoustic output tables

Table 34. Transducer model: L15-5 Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.80	0.02		0.02		(a)
Index component value			0.02		0.02		
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.30					
	P (mW)		1.6		1.6		—
	P_{1x1} (mW)		0.4		0.4		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.93					
	$z_{pii,\alpha}$ (cm)	0.75					
	f_{awf} (MHz)	8.19	9.05		9.05		—
Other information	prr (Hz)	1040					
	srr (Hz)	40.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	268.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	3.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	5.8					
	p_r at z_{pii} (MPa)	0.00					
Operating controls	Exam type	Venous	PIV		PIV		
	Optimization	—	—		—		
	Depth (cm)	3.16	6.31		6.31		
	MB/THI	On/off	On/off		On/off		

Table 35. Transducer model: L15-5 Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.80	0.42		0.42		(a)
Index component value			0.42		0.42		
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.30					
	P (mW)		24.3		24.3		—
	P_{1x1} (mW)		13.7		13.7		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.93					
	$z_{pii,\alpha}$ (cm)	0.93					
	f_{awf} (MHz)	8.19					—
Other information	prr (Hz)	1040					
	srr (Hz)	40.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	268.8					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	3.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	5.8					
	p_r at z_{pii} (MPa)	0.00					
Operating controls	Exam type	Venous	PIV		PIV		
	Optimization	—	—		—		
	Depth (cm)	3.16	6.31		6.31		
	MB/THI	Off/off	Off/off		Off/off		

Terminology in acoustic output tables

Table 36. Acoustic output terminology

Term	Definition
α	Attenuation coefficient used for derating. Equal to 0.3 dB/cm/MHz^2.
f_{awf}	Acoustic working frequency.
$I_{pa,\alpha}$	Attenuated pulse-average intensity.
I_{spta}	Spatial-peak temporal-average intensity.
$I_{spta,\alpha}$	Attenuated spatial-peak temporal-average intensity.
MI	Mechanical index.
P	Output power.
P_{1x1}	Bounded-square output power.
$P_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure.
P_r	Peak-rarefactional acoustic pressure.
pii	Pulse-intensity integral.
pii, α	Attenuated pulse-intensity integral.
n_{pps}	Number of pulses per ultrasonic scan line.
prr	Pulse repetition rate.
srr	Scan repetition rate.

Term	Definition
TI	Thermal index.
TIB	Bone thermal index.
TIC	Cranial-bone thermal index.
TIS	Soft-tissue thermal index.
Z_b	Depth for TIB.
Z_{MI}	Depth for mechanical index.
Z_{pii}	Depth for peak pulse-intensity integral.
$Z_{pii,\alpha}$	Depth for peak attenuated pulse-intensity integral.
Z_{sii}	Depth for peak sum of pulse-intensity integrals.
$Z_{sii,\alpha}$	Depth for peak sum of attenuated pulse-intensity integrals.
Z_s	Depth for TIS.

Acoustic measurement precision and uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first row of the table. Measurement uncertainty for power, pressure, intensity, and other quantities that are used to derive the values in the acoustic output table are shown in the table below.

Table 37. Acoustic measurement uncertainty

Parameter	Uncertainty (95% confidence)
P_r	11.1%
$P_{r.3}$	11.9%
P	22.8%
Pii	25.4%
Pii.3	26.8%

IT Network

Functions

This device can be connected to an IT network to perform the following functions:

- Storing the examination data (static images, clips) acquired by this device in Picture Archiving and Communication System (PACS) by DICOM communication.
- Querying examination orders from the Modality Worklist (MWL) server by DICOM communication and starting them.
- Setting the time of this device by inquiring the network time service.

Data backup

- Perform data backups regularly as part of your organization's disaster recovery plan. Doing so will help ensure proper system operation and data integrity. FUJIFILM Sonosite recommends that you allow only the authorized system administrator to back up the ePHI and audit log.
- Keep data backups on modern types of media to ensure data is not lost due to technology obsolescence.

Network specifications for connecting the device

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

Hardware specification

- 802.11 a/b/g/n/ac/ax

Interface and communication protocols

The following interface and communication protocols are available on the system:

- NTP
- DICOM
- DHCP
- LDAP/S
- DNS

NTP

Network Time Protocol (NTP) is widely used to synchronize the clocks of computers and network devices over a network, which is crucial for various applications and services.

Version: NTPv4 (as of RFC 5905)

Key components:

- **Timer servers:** Time servers are devices that provide accurate time information.
- **Clients:** Devices on the network that synchronize their clocks with time servers.
- **Messages:** NTP uses a series of messages exchanged between clients and servers to achieve time synchronization.

- **Stratum:** Time servers are classified into strata, with Stratum 1 servers having the most accurate time sources (e.g., atomic clocks). Stratum 2 servers synchronize with Stratum 1, and so on.
- **Time stamps:** NTP uses timestamps to represent time. Timestamps are based on a 64-bit format, which includes both seconds and fractions of a second.
- **Leap seconds:** NTP accounts for leap seconds, ensuring that devices can adjust their time accurately when leap seconds are introduced or removed.
- **Security considerations:** NTP includes security features to protect against cybersecurity attacks, such as unauthorized time adjustments.
- **Reference clocks:** Some NTP servers use reference clocks with extremely accurate time sources, like atomic clocks or GPS receivers.

NTP uses the following steps:

1. The client sends a request packet to a time server, asking for the current time.
2. The server responds with a packet containing its own notion of the current time. This packet also includes information about the server's stratum, precision, and other details.
3. The client adjusts its clock based on the received time information.
4. Continuous polling and periodic updates occur to ensure ongoing synchronization.

DICOM

DICOM (Digital Imaging and Communications in Medicine) is a standard for the communication and management of medical imaging information and related data.

Version: DICOM 3.0

Key components: For a complete description of DICOM components, please refer to the *DICOM Conformance Statement* available at **www.sonosite.com/support/connectivity**.

- **Information Object Definitions (IODs):** DICOM defines various IODs that specify the structure and semantics of information entities, such as images, patient data, and study information.
- **Service classes:** DICOM includes different service classes that define specific operations and communication patterns. Examples include the Storage Service Class for image storage and the Basic Worklist Management Service Class for accessing worklists.
- **Data elements:** DICOM uses a tag-based structure to represent data elements. Each data element has a unique tag that identifies it, and it includes information such as patient name, study date, pixel data, etc.
- **Transfer syntax:** DICOM supports different transfer syntaxes to encode and compress image and data information. Examples include JPEG and explicit VR little-endian.
- **Network communication:** DICOM uses the DICOM Application Entity (AE) as a network node. Communication between DICOM nodes involves association establishment, negotiation of capabilities, and the exchange of information.
- **DICOM file format:** DICOM defines a file format for storing medical images and related information. The files often have a ".dcm" extension.
- **Security:** DICOM includes security features to protect patient privacy and ensure the confidentiality and integrity of medical data during transmission and storage.
- **SOP classes:** DICOM defines Service-Object Pair (SOP) Classes, which are combinations of IODs and service classes. SOP classes specify how instances of information objects are manipulated in a DICOM network.
- **Modality worklist:** DICOM supports the exchange of worklists, which contain information about scheduled procedures, patient demographics, and other relevant data.

DHCP

The Dynamic Host Configuration Protocol (DHCP) is a network management protocol that dynamically assigns and manages IP addresses, subnet masks, default gateways, domain name system (DNS) servers, and other network configuration information to devices on a TCP/IP network. DHCP simplifies the process of network administration by automating the assignment of IP addresses, reducing the likelihood of conflicts, and making it easier to manage changes to the network.

Key components:

- **DHCP server:** A server responsible for dynamically assigning IP addresses and related network configuration information to DHCP clients.
- **DHCP client:** A device (such as a computer, smartphone, or network printer) that requests network configuration information from a DHCP server.
- **Lease:** DHCP operates on a lease-based system where IP addresses are assigned to clients for a specific duration (lease time). Clients must renew their leases before expiration to maintain network connectivity.
- **IP address pool:** The range of IP addresses that the DHCP server is configured to allocate to clients. DHCP assigns IP addresses from this pool to clients upon request.
- **Scope:** A scope defines the configuration options and IP address range provided by a DHCP server for a specific subnet.
- **Offer, Request, Acknowledge (ORA) process:**
  1. The DHCP server offers an available IP address and other configuration parameters to a client.
  2. The client formally requests the offered IP address from the DHCP server.
  3. The DHCP server acknowledges the client's request and finalizes the lease.
- **Renewal process:** DHCP clients periodically attempt to renew their lease before it expires by requesting an extension from the DHCP server.
- **Release process:** Clients can release their assigned IP addresses back to the DHCP server when they are done using them, freeing up addresses in the pool.
- **Broadcast communication:** DHCP initially relies on broadcast communication for discovering available DHCP servers and obtaining initial configuration information. Unicast communication can be used later for lease renewal.
- **Options:** DHCP allows for the inclusion of various configuration options, such as DNS server addresses, default gateway, subnet mask, within the DHCP messages.
- **Dynamic configuration:** DHCP allows for changes to the network configuration without manual intervention, facilitating dynamic adaptation to network changes.

LDAP/S

LDAP/S (Secure Lightweight Directory Access Protocol) is a secure form of LDAP, which is used for accessing and managing directory information services. This encryption is typically implemented using Transport Layer Security (TLS) or its predecessor, Secure Sockets Layer (SSL).

Key components:

- **Lightweight Directory Access Protocol (LDAP):** LDAP is a directory service protocol that provides a standardized way to access and manage information in a directory, which is a hierarchical structure that organizes and stores data.

- **Secure connection:** LDAP/S ensures the security of communication between LDAP clients and servers by encrypting the data exchanged during the LDAP sessions.
- **Encryption protocols:** LDAP/S uses protocols such as SSL or TLS to provide encryption for data in transit.
- **Certificate-based authentication:** LDAP/S involves certificate-based authentication, where the server presents a digital certificate to prove its identity to the client.
- **TLS handshake:** During the TLS handshake, the client and server negotiate encryption settings and exchange cryptographic keys, establishing a secure connection.
- **Directory services:** LDAP/S is used for accessing and managing directory services, which store and organize information such as user profiles.
- **Security considerations:** LDAP/S helps protect sensitive information from eavesdropping and tampering during transmission over a network, enhancing the overall security of directory services.

DNS

Domain name system (DNS) servers translate the domain names of computers, devices, and services on the Internet or other IP network into numeric IP addresses.

Key components:

- **DNS clients:** A software component built into most modern operating systems and allow web browsers to interact with DNS servers.
- **DNS recursor:** This is the component of the DNS server that receives queries from clients and interacts with other DNS servers to find the correct IP address. It queries root, TLD (top-level domain), and authoritative name servers.
- **Root name server:** The first step in translating domain names into IP addresses.
- **TLD name server:** Responds with the IP address of the domain's authoritative name server (for example, .com or .net).
- **Authoritative name server:** Provides the IP address of the origin server.
- **Origin server:** Finally, the client can query the origin server directly for website data.

Security and privacy

- The port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112) is used for outgoing communication to the network.
- Anti-virus software is not installed on this device.
- The security and privacy-related configurable controls in the Sonosite iLOOK ultrasound system are:
  - User roles and responsibilities
  - Automatic user log off
  - User authorization and authentication
  - Data encryption (at rest and in transit)
- System and department administrators should follow the suggested technical and physical safeguards listed below, as well as the detailed HIPAA guidelines to ensure HIPAA compliance:
  - **Room Access Control:** Local procedures must be put in place to limit physical access to medical equipment, to prevent accidental, casual, or deliberate contact by unauthorized individuals.
  - **System Access Controls:** Access the system only through unique user accounts. Login credentials must not be disclosed.

- **Audit Controls:** Each user action associated with patient data will be tracked through ePHI audit logs, which are accessible to and should be routinely audited by the administrator. Guest user accounts cannot be audited and should only be used when required.
- **De-identification:** Use a de-identification option before exporting patient data to removable media used for system troubleshooting or repair.
- **Transmission Security:** Clinical data transmitted over the network may not be encrypted. Add only trusted devices to the network. (We highly recommend the use of encrypted DICOM. If secure DICOM is not supported, then network security controls shall be implemented to protect integrity and confidentiality of data).
- **Data Integrity:** Cryptographic methods should be used at all times to ensure the integrity of personal data. When possible, perform integrity checks to identify unauthorized changes in personal data. In case there is suspicion of improperly altered or destroyed clinical data, notify FUJIFILM Sonosite service.
  - **Data Encryption:** Data at rest should be encrypted at the disk level as well as the database level with a FIPS 140 validated encryption method. Encryption keys should be kept secured and maintained only by system administrators.
  - **System Hardening:** The application and database hosting server(s) should be hardened according to the NIST 800-123 server security controls.
- **Software Updates:** Only FUJIFILM Sonosite authorized updates and/or patches should be applied to the medical device.

Data flow

MWL Server ——————> Sonosite iLOOK Ultrasound System ——————> PACS

Study order (DICOM MWL)——————————————Study data (DICOM Storage)

Please refer to the *DICOM Conformance Statement* for details.

CAUTION

1. Connection of equipment to an IT network that includes other systems could result in previously unidentified risks to patients, operators or third parties. Before connecting the equipment to an uncontrolled IT Network, make sure that all potential risks resulting from such connections were identified and evaluated, and suitable countermeasures were put in place. IEC 80001-1:2010 provides guidance for addressing these risks.
2. When a setting of the IT network to which this device is connected has been changed, check that the change does not affect this device and take measures if necessary. Changes to the IT network include:
   - Changes in network configuration (IP address, router etc.)
   - Connection of additional items
   - Disconnection of items
   - Update of equipment
   - Upgrade of equipment

   Any changes to the IT network could introduce new risks requiring additional evaluation to be performed as per item 1 above.

Application approved list

The application approved list prevents unauthorized use of the ultrasound system.

- The system only allows execution of software that is configured in the application approved list.
- The system blocks attempts to change, overwrite or delete all files that are included in the application approved list.
- The application approved list is not configurable by the user. This configuration is part of the FUJIFILM Sonosite software installation process.
- The system only allows a change in the application approved list when the change is initiated by a digitally signed software component, such as a FUJIFILM Sonosite update.
- The system logs any attempt to change or delete approved packages.
- The system logs any attempt to change the application approved configuration.
- The system logs any attempt to load or execute unauthorized software packages.
- System logs should be routinely audited by the administrator.

IT network failure recovery measures

Connection to an IT network may become, at times, unreliable, and this may lead to failure to perform the functions described in Functions [107]. As a result, the following hazardous situations may occur.

	Impact on equipment	Hazard	Countermeasure
IT network becomes unstable (for example, wireless communication fails)	Unable to transmit exam data to a PACS	Delay of diagnosis	The ultrasound system has internal memory, and exam data is stored in it. After the IT network has returned to stable, the user can re-initiate the transfer of data.
	Delay of transmission to a PACS		
	Incorrect data transmitted to a PACS	Misdiagnosis	Integrity of the data is ensured by the TCP/IP and DICOM Protocols used by the system.
	Unable to get order data from an MWL server	Delay of exam	The user can initiate/create a new study on the system.
	Delay of getting order from an MWL server		
	Incorrect data from a MWL server	Incorrect exam	The ultrasound system uses the TCP/IP and DICOM Protocols, which ensures data integrity.
	Unable to get the time from a time server	Incorrect exam data	The ultrasound system has the capability of entering data and time manually.
	Incorrect time data		The ultrasound system always indicates the date and the time on the main screen.
Firewall has broken down	Attack via network	Manipulation of exam data	The ultrasound system closes unnecessary network ports.
	Infection by computer virus	Leak of exam data	The ultrasound system prevents a user from loading software and executing it.

If the network connection fails due to network facility issues, the user can troubleshoot the connection (see Unable to transfer data to DICOM [56]) and re-initiate the transfer of data. There is no risk to patient safety, operator or bystander, as well as no data loss as the system buffers all data locally. The system can perform its intended clinical function even without a network connection.

Wireless connectivity

To use a wireless connection, wireless settings must be configured following instructions in Selecting the system wireless network [27]. The wireless icon on the screen indicates if the connection is lost. You do not need to take any action to reconnect to the lost wireless connection. The system automatically retries connecting to the network without having to restart the system and re-establishes the connection once the wireless signal is available again. There is no data loss in these instances as the system buffers all the data locally. Reactivation and recovery assume that the wireless profile and location settings are configured correctly, and the wireless network is working properly. When using the wireless transducer, the system cannot connect to the network simultaneously. If the transducer remains in the charger for 45 minutes or more, the system automatically disconnects the transducer and connects to the network instead.

Software bill of materials

For detailed information regarding the software components included in this device, including the software bill of materials, please contact FUJIFILM Sonosite Technical Support (see Getting help [1]). Support is available 24/7.

Implementing, detecting, and maintaining security

To ensure secure use of your system, implement **Secure mode** (see Configuring the system for the first time [19]).

To limit cybersecurity threats, the system uses industry-standard security and privacy controls, including but not limited to system hardening, an internal firewall, and an approved applications list. FUJIFILM Sonosite provides regular software updates containing the latest security patches and encourages you to maintain a high level of security by keeping the system up to date with the released software versions. Information about the latest version of the system software is made available to customers through field and service representatives, who distribute release notes for each release when the device is available for sale in the region.

Coordinated vulnerability disclosure

FUJIFILM Sonosite continuously monitors and tests the system for vulnerabilities and exploits. If a vulnerability or exploit is discovered that could impact your ultrasound system, FUJIFILM Sonosite executes its incident response plan, which includes customer notification and the implementation of preventive and corrective action plans. Additionally, the webpage **www.sonosite.com/support/security** is used to inform customers of major vulnerabilities that may affect FUJIFILM Sonosite systems. If you suspect or detect a cybersecurity event on your system, please contact FUJIFILM Sonosite Technical Support (see Getting help [1]).

End of life

At the end of the support period, the company may no longer be able to provide security patches or software updates. All end-of-life announcements are available on the company's website: **www.sonosite.com/support/security**. Customers can also receive update bulletins from the company regarding the status of their device. They are encouraged to contact their sales representative or Technical Support for additional details once their device is at the end of support.

At the end of life, we recommend completing a hard reset of the system. The hard reset completely wipes the system and removes the imaging application. See Hardware features [5] for a diagram of the system buttons.

1. Press the power button.

2. Using the end of a paper clip, press and hold the hidden reset button until **Restart** appears on the screen.
3. Keep pressing the reset button while you tap the **Restart** button that appears on the screen.
4. Keep holding down the reset button until the **Android Recovery** screen appears.
5. Tap through the menu on the screen until **Wipe data/factory reset** is selected.
6. Press the power button again and wait until the device has finished resetting.

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Third Edition*, published in 2011 by the American Institute of Ultrasound in Medicine (AIUM).

ACEP	American College of Emergency Physicians
as low as reasonably achievable (ALARA)	The guiding principle of ultrasound use, which states that you should keep patient exposure to ultrasound energy as low as reasonably achievable for diagnostic results.
bone thermal index (TIB)	A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
cranial bone thermal index (TIC)	A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
depth	Refers to the depth of the display. A constant speed of sound of 1538.5 meters/second is assumed in the calculation of echo position in the image.
in situ	In the natural or original position.
pulse repetition frequency (PRF)	Indicates the number of ultrasound pulses emitted by the transducer over a designated period of time. HPRF stands for high pulse repetition frequency.
skinline	A depth on the display that corresponds to the skin/transducer interface.
soft tissue thermal index (TIS)	A thermal index related to soft tissues.
thermal index (TI)	The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions.
Tissue Harmonic Imaging (THI)	Transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution.
transducer	A device that transforms one form of energy into another form of energy. Ultrasound transducers contain piezoelectric elements, which when excited electrically, emit acoustic energy. When the acoustic energy is transmitted into the body, it travels until it encounters an interface, or change in tissue properties. At the interface, an echo is formed that returns to the transducer, where this acoustic energy is transformed into electrical energy, processed, and displayed as anatomical information.

linear array transducer	Identified by the letter L (linear) and a number. The number corresponds to the frequency range of the transducer expressed in MHz. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, L12-3.
variance	Displays a variation in Color Doppler flow imaging within a given sample. Variance is mapped to the color green and is used to detect turbulence.

Abbreviations

Abbreviations in the user interface.

Art	Artery
Cine	Cine buffer or loop. The cine buffer stores a sequence of images recorded over a certain time frame.
CPD	Color Power Doppler
CVD	Color Velocity Doppler
CVR	Catheter to vessel ratio
D or Diam	Diameter
H	Height
L	Length
Mid	Midline catheter
Ped	Pediatric
PICC	Peripherally Inserted Central Catheter
PIV	Peripheral Intravenous
Vasc	Vascular
Ven	Venous

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