FUJIFILM

SonoSite
iViz

USER GUIDE

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Caution Federal (United States) law restricts this device to sale by or on the order of a physician.

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Chapter 1: Introduction

About the iViz User Guide

The *iViz User Guide* provides information about configuring and using the iViz ultrasound system, including:

- Managing patient data
- Performing exams
- Taking measurements and calculations
- Cleaning and disinfecting

The information and procedures in this user guide apply to the iViz system and its included accessories. Other accessories and third-party equipment are subject to their own instructions and restrictions.

The *iViz User Guide* is intended for a user familiar with ultrasound. It does not provide training in sonography, ultrasound, or clinical practices. Before using iViz, you must complete such training.

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.

Getting help

In addition to this user guide, the following resources are available:

- Instructional videos
- On-board help videos
- FUJIFILM SonoSite Technical Support:

Phone (U.S. or Canada)	877-657-8118
Phone (outside U.S. or Canada)	425-951-1330, or call your local representative
Fax	425-951-6700
Email	service@sonosite.com
Web	www.sonosite.com
Europe Service Center	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
Asia Service Center	+65 6380-5581

Chapter 2: Getting Started

Use this section to help familiarize yourself with the iViz system and its uses.

About iViz

iViz is a portable, hand-held device that acquires and displays high-resolution, real-time ultrasound images. Features available on the system include:

- 2D scanning mode with color Doppler
- Measurement and calculation support
- Image labeling
- DICOM support
- EMR system integration
- On-board help videos

Intended use

Diagnostic ultrasound

The SonoSite iViz Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use in clinical care by qualified physicians and healthcare professionals for evaluation by ultrasound imaging and fluid flow analysis.

- In the ultrasound scanning application, the iViz system with an attached transducer obtains ultrasound images as described below.
  - Abdominal imaging applications are designed to assess the liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures for the presence or absence of pathology transabdominally. Abdominal imaging can be used to evaluate and perform interventional abdominal procedures and evaluate the presence or absence of blood flow in abdominal organs.
  - Cardiac imaging applications are designed to assess the pericardial effusion or cardiac tamponade possibility, cardiac valves, the great vessels, heart size, cardiac function, lung, and surrounding anatomical structures for the presence or absence of pathology.
  - Obstetrical imaging applications are designed to assess the fetal anatomy, viability, estimated fetal weight, fetal heart rate, fetal position, gestational age, amniotic fluid, and surrounding anatomical structures for the presence or absence of pathology transabdominally.

- Color Power Doppler (CPD) and Color Velocity Doppler (CVD) imaging tools are intended to evaluate the blood flow of the fetus, placenta, umbilical cord, and surrounding maternal structures in all cases, including high-risk pregnancies. High-risk pregnancy indications include, but are not limited to, multiple pregnancies, fetal hydrops, placental abnormalities, maternal hypertension, diabetes, and lupus.

- CPD and color imaging tools are not intended as a sole means of diagnosis nor as a sole method of high-risk pregnancy screening.

Vital signs monitoring

iViz is intended for use in vital signs monitoring of the human body in a non-continuous ECG monitoring application. iViz obtains an ECG report through interaction with the Smartheart Pro software application and wireless 12-lead Smartheart Pro device.

Accessories and peripherals

Caution 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.

The iViz ultrasound system is designed to support a variety of accessories and peripherals, including:

- 2-in-1 micro USB flash drive (64 GB)
- Protective case with handle and kickstand
- iViz carry case
- Pelican case
- iViz batteries
- USB charger
- Battery bay charger with power supply
- Dual charging station

To order accessories, or to find out if a specific piece of equipment is compatible with the iViz ultrasound system, contact FUJIFILM SonoSite or your FUJIFILM SonoSite representative. See **"Getting help"** on page 2.

Hardware features

The front of the system is shown in **Figure 2-1**.

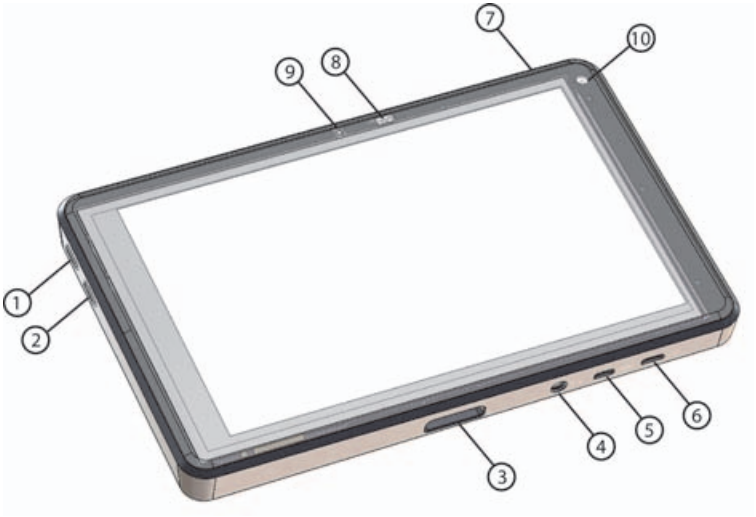


Figure 2-1 Front of the iViz ultrasound system

1	Volume up	6	Micro USB port
2	Volume down	7	Power on/off
3	Transducer socket	8	Power status LED
4	Audio out	9	Microphone
5	Micro HDMI port	10	Front camera

The back of the system is shown in **Figure 2-2**.

Figure 2-2 Back of the iViz ultrasound system

1	Battery bay	3	Speaker
2	Camera and flash		

General interaction

When you first turn on iViz, the Home screen displays, as shown in **Figure 2-3**.

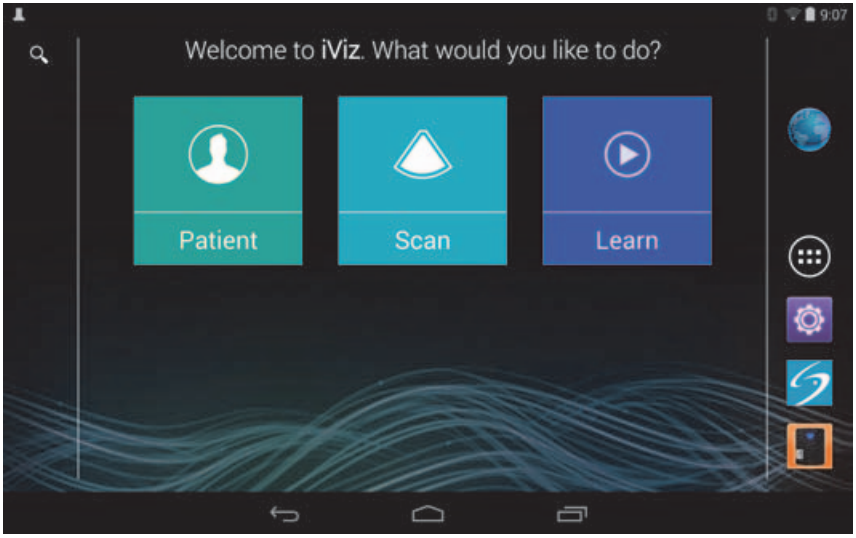


Figure 2-3 iViz Home screen

The system has three main modules that are accessible from the Home screen: Patient, Scan, and Learn.

- **Patient** - This module lets you search for a patient, view the scheduled list of patients, and select an iViz study. In addition, you can add and edit a patient form and view and share images and clips.
- **Scan** - This module is where you perform patient exams.
- **Learn** - This module contains general ultrasound training videos and iViz on-board help videos.

Using the touchscreen

When scanning, the iViz touchscreen is divided into two main areas: the left side contains your controls, and the right side is the scan area, as shown in **Figure 2-4**.

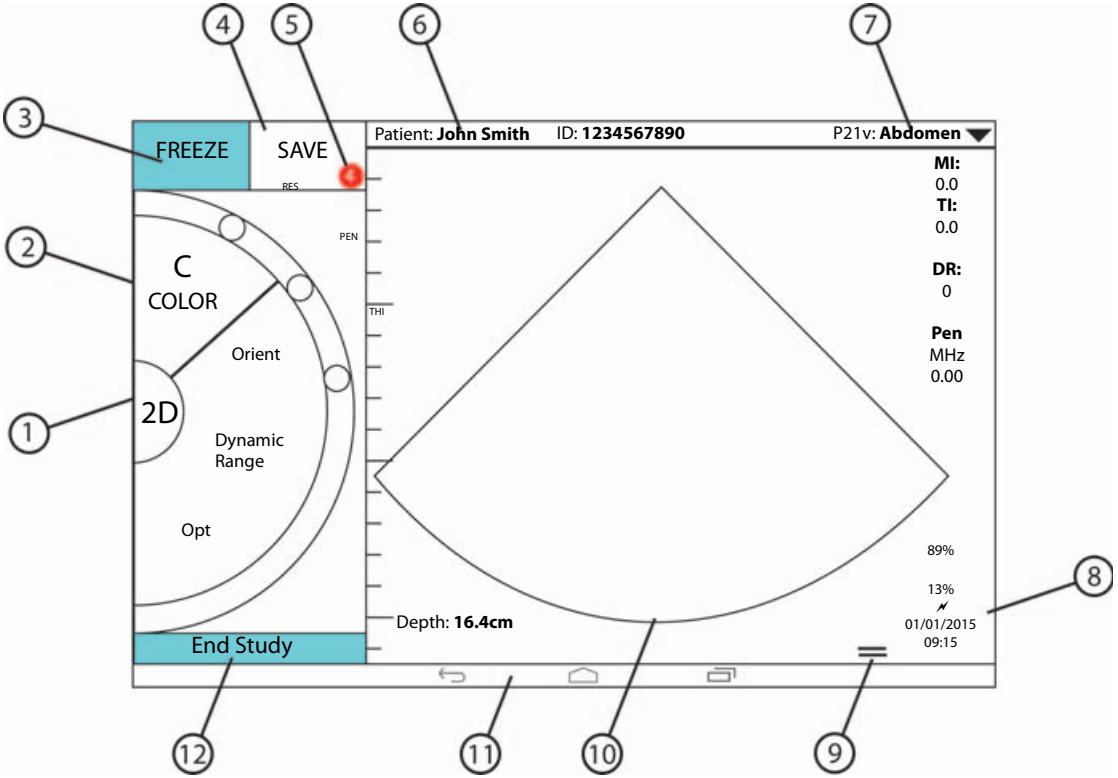


Figure 2-4 Touchscreen while in scan mode

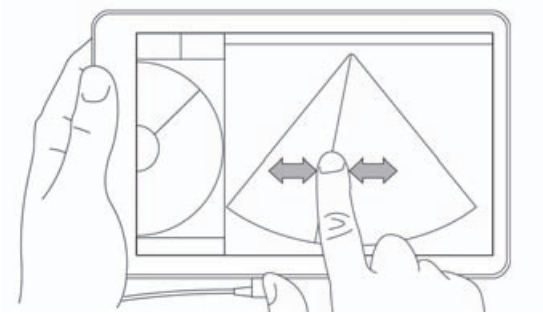
1	Scan mode selector	7	Type of exam
2	Thumb-operated control wheel	8	Time, date, and percent charged
3	Freeze an image	9	Tool drawer handle
4	Capture an image or a clip	10	Scan area
5	Number of saved images and clips in this study	11	Android controls
6	Patient name and data (tap to go to Patient module)	12	End the study and return to patient record

The system is designed so that you can use one hand to hold the system and the other hand to hold the transducer. If you're not scanning, you can always use two hands.

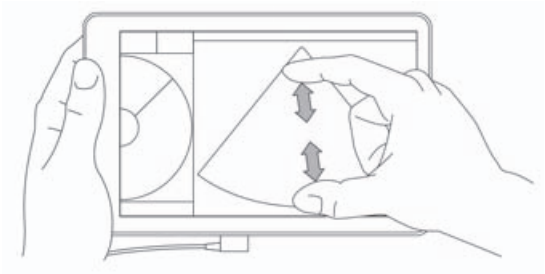
Using gestures

You interact with the touchscreen the same as with many other touchscreen devices:

- Swipe - Move your finger quickly across the screen.



- Drag - Move one or two fingers across the screen, usually to move an object from one location to another.
- Tap - Quickly touch the screen once.
- Press and hold - Touch your finger to the screen, and hold it there for about two seconds.
- Pinch or zoom - Slide two fingers together or apart on the screen.



The controls that appear on the wheel depend on the scan mode you've selected. The function of each control is discussed in detail in **Chapter 5, "Performing an Exam."**

Opening menus and tool drawers

You can access additional controls by opening menus and tool drawers.


This symbol indicates a drop-down menu. Tap or swipe this symbol to open the menu. For instance, the **Exam Type** menu allows you to choose between several preset exam types.


This symbol indicates a drawer that you can open. Swipe up on this symbol to open the tool drawer. The tool drawer contains additional options such as labels, measurements, and guided protocols.

This symbol indicates the drawer that opens the cine buffer when you are taking measurements or adding labels. Slide the drawer to the right to display the cine buffer, and slide it to the left to close it.

Entering text

When filling out forms in iViz, such as when you are updating patient records or configuring settings, you can enter text by tapping the text field you want to edit. An on-screen keyboard appears, as shown in **Figure 2-5**.

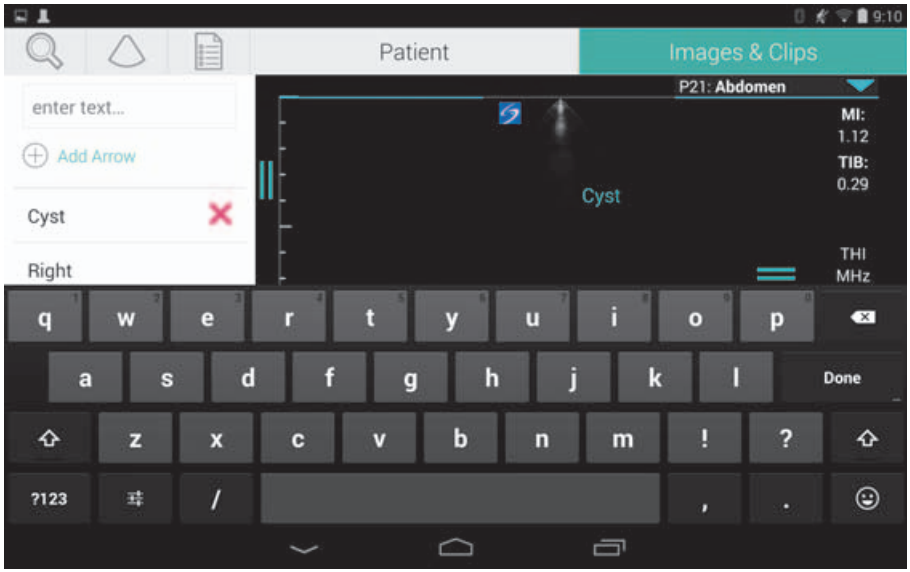


Figure 2-5 Use the keyboard to type information.

Put the system into the protective case

Caution iViz device emits RF emissions. While the system meets SAR standards, using the protective case is recommended to reduce RF exposure.

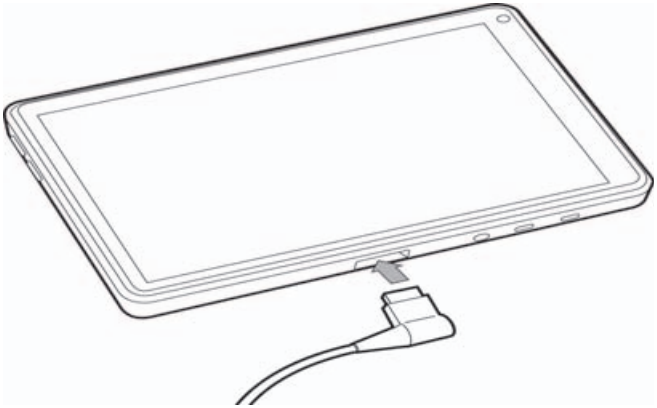
To put the system into the protective case

1 Insert the system into one end of the case.

2 Bring the opposite case ends over the system to hold it in place.

Plugging in a transducer

❖ Insert the transducer connector into the bottom of the iViz system, with the transducer connector facing away from the other connectors, until you hear it click.



Installing the battery and charging iViz

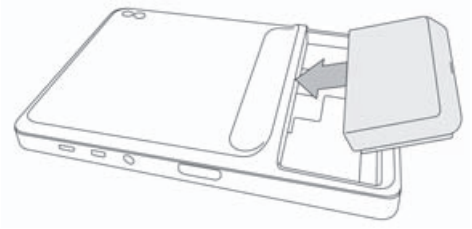
Installing the battery

Note Battery performance depends on numerous factors, such as the scanning modes used, battery age, and display brightness.

To install the battery

WARNING To avoid injury to the operator and to prevent damage to the ultrasound system, inspect the battery for leaks before installing.

1 On the back of the iViz system, position the battery in the battery slot so that the beveled edge of the battery is nearest the side of the iViz system.



2 Press the battery firmly into the back of the iViz system until it locks in place.

Charging the battery

WARNING To avoid the risk of electrical shock, burn, or fire, use only the FUJIFILM SonoSite USB charger (P19927).

Cautions

- The battery can be stored at temperatures between -20°C (-4°F) to 60°C (140°F).
- Charge batteries only when the ambient temperature is between 10°C (50°F) and 40°C (104°F).
- iViz will not operate without a battery installed, even if the USB charger is plugged in.
- Verify that the hospital supply voltage corresponds to the power supply voltage range. See **"Electrical safety standards"** on page 141.
- When the battery charge is low on your iViz system, you have the option of plugging the system in to recharge, or replacing the battery with a freshly charged one.
- To avoid risk from loss of power, plug the system into an appropriate power source or change batteries when the battery is low.

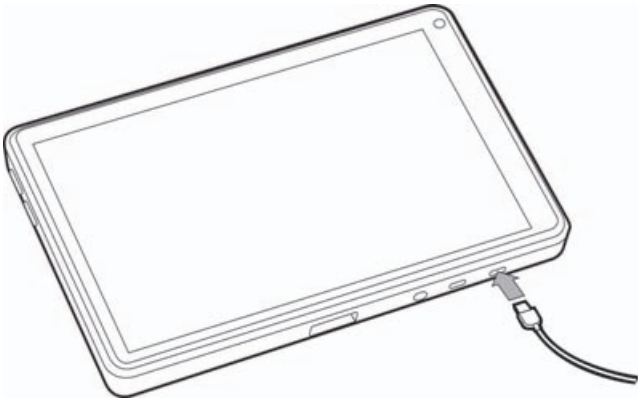
There are two ways to charge the iViz batteries; you can use the included battery charger or plug in the USB charger while a battery is installed in system.

To charge the battery while it's installed in the iViz system

1 Turn off the system. See **"Turning off iViz"** on page 15.

2 Connect the line cord of the USB power adapter to a hospital-grade electrical outlet.

3 Connect the AC power adapter to the micro-USB power receptacle on the system.



Notes

- iViz cannot perform scanning functions while the AC power adapter is attached to the system.
- Charging the battery this way may require more time than when using the battery charger.
- iViz is not provided with an AC mains power switch. To disconnect the equipment from the mains, unplug the DC adapter from the wall outlet.

4 When you are finished charging the battery, disconnect the system from AC power.

5 Turn the system on to check the battery charge.

To charge the battery using the iViz battery charger

1 Connect the line cord of the AC power adapter to a hospital-grade electrical outlet.

2 Connect the AC power adapter to the receptacle on the battery charger.

3 Remove the battery from the iViz system, and insert it in a slot on the battery charger. You can charge up to two batteries at a time.

Note

The optional iViz dual charging station allows you to charge up to four batteries at a time.

4 To determine battery charging status, check the lights on the battery charger:

Blinking green	Battery is charging.
Green	Battery is fully charged.
Amber	Battery is very low. Wait 60 seconds, then do one of the following: ▸ Remove and re-insert the battery charger. ▸ Remove and re-insert the battery. After a few seconds, the light should change to blinking or steady green. If it does not, the battery was being charged.
Red	Bad battery pack; recycle the battery.

Caution A red light on the battery charger indicates a faulty battery. Remove the battery from the charger. Do not use the battery in the iViz system. Do not try to repair the battery. Contact FUJIFILM SonoSite or your representative to get a replacement.

Removing the battery

To remove the battery

1 Turn off the system. See **"Turning off iViz"** on page 15.

2 On the back of the iViz system, press the battery lock in to unlock the battery.

3 Pull up the battery to remove it.

Turning iViz on and off

The system is battery powered.

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

Caution The battery should be charged before installing in the iViz system for the first time. For more information, see **"Charging the battery"** on page 12.

Turning on iViz

To turn on iViz

1 Check that a battery is installed in the iViz system. For more information, see **"Installing the battery"** on page 11.

2 Press the **Power** button, and wait several second for the system to power on.

The white light indicates that the system is powering up.

3 Swipe up on the **Lock** icon.

The iViz Home screen appears.

Turning off iViz

To turn off iViz

1 Press and hold the **Power** button.

2 When prompted, tap **Power off**, and then **OK**.

Caution To avoid data loss, wait for the system's "power off" message before removing the battery from the system.

Putting the system into sleep mode

To conserve battery power, the system enters sleep mode after a period of inactivity, typically about 30 seconds. You can change the length of time before it goes into sleep mode; see **"Configuring sleep mode"** on page 20.

Sleep mode turns off the display but holds the current functions in memory so that they can be recalled quickly when the system is awakened. Sleep mode is disabled during scanning.

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

To put the system into sleep mode

❖ Briefly press the **Power** button.

Chapter 3: Configuring iViz

Configuring Android settings

Google Android is the operating system (OS) that the iViz software runs on. The Android OS manages and monitors things like wireless connectivity, date and time, and battery charge. Most Android settings will be pre-configured by FUJIFILM SonoSite, but there are several Android functions that you can configure yourself.

To open the Android Settings screen

1 Tap  to open the **Home** screen.

2 From the **Home** screen, tap  to open the **Apps** menu.

3 From the **Apps** menu, tap **Settings**.

Activating security settings

For patient data privacy and security, FUJIFILM SonoSite recommends that you activate a PIN, password, or pattern from the **Security** screen. If applicable, talk to your IT Administrator.

Connecting to a wireless network

Before trying to connect to a wireless network, you must gather the following information:

- The name of the wireless network you want to join
- The security password, if any, for the wireless network

To connect to a wireless network

1 From the Android **Settings** screen, slide the **Wi-Fi** button to **ON**.

2 Tap **Wi-Fi**, and tap the wireless network you want to join.

3 Type the password for the wireless network, and then tap **Done**.

4 Tap **Connect**.

5 From the **Wi-Fi** screen, check that the word **Connected** appears under the wireless network you chose.

If the connection was not successful, check that you have the right password, and try again.

Connecting to a Bluetooth device

1 From the Android **Settings** screen, tap **Bluetooth**.

2 From the **Bluetooth** screen, slide the **Bluetooth** button to **ON**.

3 If necessary, place the target device in pairing mode.

4 From the **Bluetooth** screen, tap the Bluetooth device you want to connect to.

5 Confirm the Bluetooth pairing on both devices.

Setting the date and time

WARNING To obtain accurate calculations, an exact date and time are critical. Verify that the date and time are accurate before each use of the system.

To manually set the date and time

By default, the iViz system date and time are set automatically when you connect to a wireless network. If you choose not to connect your iViz system to a network, or if you want to use a different date and time, use the following manual procedure.

1 From the Android **Settings** screen, tap **Date & Time**.

2 From the **Date & Time** screen, clear the check box for **Automatic date & time**.

3 Tap **Set date**, choose the date you want to set, and then tap **Done**.

4 Tap **Set time**, choose the time you want to set, and then tap **Done**.

To manually set the time format

You can switch between the 24-hour clock format and the 12-hour clock format.

1 From the Android **Settings** screen, tap **Date & Time**.

2 To select the 24-hour clock mode, on the **Date &Time** screen, select the check box next to **Use 24-hour format**.

3 To select the 12-hour clock mode, on the **Date & Time** screen, clear the check box next to **Use 24-hour format**.

To manually set the date format

By default, the date format is set to <month>/<day>/<year>. This is not the standard in all areas, however. To change the way iViz presents date information, do the following:

1 From the Android **Settings** screen, tap **Choose date format**.

2 Tap the radio button next to the date format you want to use.

Adjusting the volume

To adjust the volume

1 From the Android **Settings** screen, tap **Sound**.

2 From the **Sound** screen, tap **Volumes**.

3 Adjust the sliders to the volume levels you want, and then tap **OK**.

Adjusting the screen brightness

To manually adjust the screen brightness

1 From the Android **Settings** screen, tap **Display**.

2 From the **Display** screen, tap **Brightness**.

3 If auto mode is highlighted, tap **Auto** to adjust the brightness manually.

4 Move the slider to set the brightness.

Configuring sleep mode

Changing the sleep mode interval

By default, iViz will go into sleep mode after 30 seconds of inactivity. You can manually change this interval to suit your preferences.

Note | Sleep mode is deactivated during scanning.

To change the sleep mode interval

1 From the Android **Settings** screen, tap **Display**.

2 From the **Display** screen, tap **Sleep**.

3 Tap the time period you want to change to. This is the period of inactivity before the system switches to sleep mode.

Understanding sleep mode and screen lock settings

- If system is unlocked, iViz goes into sleep mode as defined in **"Configuring sleep mode"** on page 20.
- If the system is locked:
  - if the Android settings under **Security > Screen** lock are set to anything other than **None**, after the system reboots or the system wakes from sleep mode, the system must be first be unlocked before using it.
  - If you do not unlock the system, it returns to sleep mode in 10 seconds.

Adding a wireless printer

With the **PrintHand** app, you can connect to a wireless printer. Before adding a printer, make sure the Android Wi-Fi feature is turned on; see **"Connecting to a wireless network"** on page 17.

To add a wireless printer

1 From the Android **Settings** screen, tap **Printing**.

2 From the **Printing** screen, tap **PrintHand**.

3 In the upper right corner of the screen, tap the **OFF** button.

4 At the Use PrintHand prompt, tap **OK**.

5 In the upper right corner of the screen, tap the three dots, and then tap **Add a printer**.

6 From the Nearby Printers menu, tap one of the options, such as **Nearby Wi-Fi Printers**. iViz searches for a wireless printer.

7 Tap the printer you want to add.

8 From the **Driver Needed** screen, tap **Select Manually**, and tap **Next**. You can also tap **Generic** to select a generic driver; however, you will have more print options if you select the driver for your specific printer.

9 Tap through the options to find the driver for your printer brand and model.

10 Tap **Install**.

11 When prompted to do a print test, tap **Print Test** (optional).

12 When you are done, click **Finish**.

Configuring iViz settings

iViz can be adapted to a wide variety of conditions. For example, from the iViz **Settings** screen, you can:

- Set user preferences, such as units of measure, right or left-handed operation, standard clip length and type.
- Customize the obstetrics tools the system uses to help you calculate gestational age.
- Add to or change the standard labels available in various exam types.
- Set up or change DICOM profiles for each unique location/institution and connect to the local servers.
- Modify patient search parameters, such as name, ID, date of birth, and procedure.
- Specify EMR connection settings, such as host name, IP address, and port.

Opening the iViz Settings screen

To open the Settings screen

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

Configuring preferences

To configure preferences

1 From the iViz **Settings** screen, tap **Preferences**.

2 From the **Preferences** screen, the following settings are available:

- **Units** - Select the units of measure used by iViz.

- **Thermal Index** - Select any of the following:
  - **TIB** - Thermal index in bone
  - **TIC** - Thermal index in the cranium
  - **TIS** - Thermal index in soft tissue
- **Auto Save Patient Form** - When turned on, this feature automatically saves the patient form periodically during editing to help prevent the loss of patient information.
- **Clip Recording** - Select either of the following:
  - **Prospective** - During a scan, this option records a standard length clip of the scan after tapping **Save**.
  - **Retrospective** - During a scan, this option records a standard length clip of the scan before tapping **Save**.
- **Clip Length** - From the drop-down menu, choose a standard recording length for clips.
- **Device Orientation** - Select which hand you prefer to use to hold the system.

Configuring OB measurements and calculations

1 From the iViz **Settings** screen. tap **OB Calcs**.

2 From the **OB Calculations** screen, set the author of preference for the following OB calculations and measurements:

- **GS** - Gestational Sac
- **CRL** - Crown Rump Length
- **BPD** - Biparietal Diameter
- **Cx Length** - Cervix Length
- **HC** - Head Circumference
- **Cerebellum**
- **AC** - Abdominal Circumference
- **FL** - Femur Length
- **HL** - Humerus Length

Configuring labels

You can create up to 10 custom labels for each exam type.

To view custom and default labels

1 From the iViz **Settings** screen, tap **Labels**.

2 From the **Labels** screen, tap the exam type you want to customize labels for.

- **Custom Labels** lists all of the existing custom labels for this exam type.
- **Default Labels** lists all of the labels for this exam type that are included with the system.

To create a new custom label

1 From the **Labels** screen, tap the label entry field.

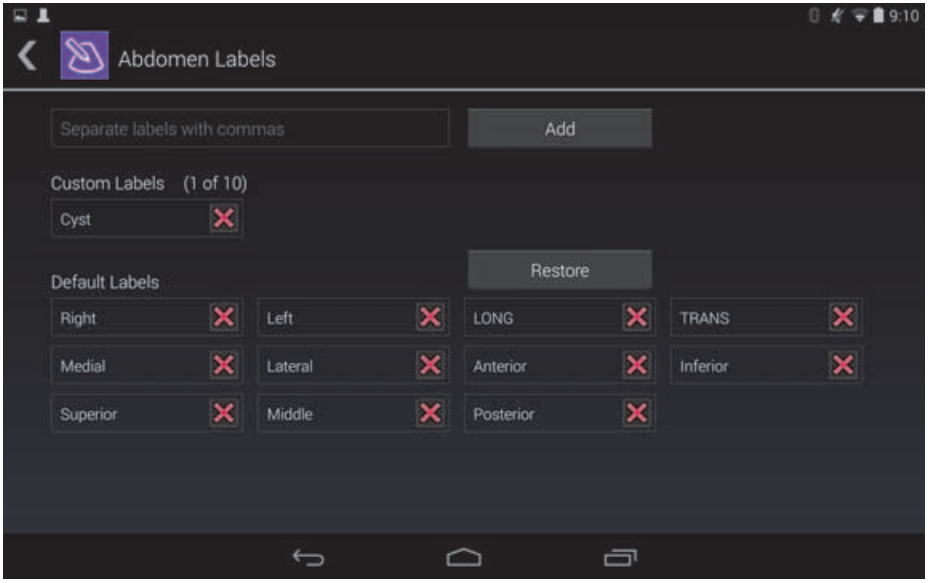
2 Type the name for the new label; if you'd like to create more than one label, separate each label name with a comma.

> **Note** | You cannot use spaces in label names.

3 Tap **Add**.

To delete a label

❖ Next to the label that you want to delete, tap . To retrieve the default list of labels, tap **Restore**.



Setting up a DICOM profile

You can create a Digital Imaging and Communications in Medicine (DICOM) profile tailored to each location or institution where iViz is used. iViz also includes a non-specific DICOM profile called Tricefy.

Note For institutions that have a Tricefy Collaboration account, the Tricefy Collaboration profile has limited editability. Most of the options in the Tricefy Collaboration profile are preset.

Adding a new DICOM profile

1 From the iViz **Settings** screen, tap **DICOM Profiles**.

2 Tap **New Profile**.

3 From the **General** tab:

- **a** In the **Profile Name** field, type a name that is easily identifiable, such as your hospital or clinic name.
- **b** In the **AE Title** field, type the application entity (AE) title. Each node needs to have a unique AE title.
- **c** In the **Institution** field, type the name of the institution for which this profile is being set up (e.g., Swedish Hospital).

Note The **IP Address, Subnet Mask**, and **Default Gateway** fields are populated automatically and cannot be edited directly. To change your system's wireless network settings, tap the **Wireless** field to open the wireless configuration window.

4 From the **Archive** tab:

- **a** In the **AE Title** field, type the application entity (AE) title. Each node needs to have a unique AE title.
- **b** In the **IP Address** field, type the IP address of the archive server.
- **c** In the **Port** field, type the archive server's port number.
- **d** In the **Transfer images** section, select one of the following options:
  - **End of Exam** - Images are uploaded automatically when the exam is complete.
  - **Manual** - Images are uploaded only when you perform a manual upload.
- **e** In the **Structured Reports** section, select **Yes** or **No** to indicate if your archive server accepts structured reports.
- **f** In the **Educational** section, select **Yes** or **No** to indicate if the archive server is used for educational purposes.
- **g** To transfer images and clips to this archiver, select **Active**. You cannot transfer images and clips if it is set to **Inactive**.
- **h** Tap **Ping** to check whether the connection to the archive server is working.

i Tap **Verify** to check whether the archive server is ready to receive uploads from your iViz system.

5 From the **Worklist** tab:

a In the **AE Title** field, type the application entity (AE) title. Each node needs to have a unique AE title.

b In the **IP Address** field, type the IP address of the archive server.

c In the **Port** field, type the archive server's port number.

d In the **Worklist** section, select the time period for retrieving worklists and schedules from the worklist server.

- **Today** - Retrieves just the current day's worklists.
- **Yesterday** - Retrieves all worklists going back one day.
- **+/- 7 days** - Retrieves all worklists for the week following and the week preceding the current day.

e In the **Auto Query** section, select **On** or **Off**.

f In the **Modality** section, select **Ultrasound** or **All** as the image modality.

g In the **Occurs Every** section, select a time from the list.

- **Duration**

h To query the worklist server, select **Active**; you cannot query the worklist server if it is set to **Inactive**.

i Tap **Ping** to check whether the connection to the worklist server is working.

j Tap **Verify** to check whether the worklist server is ready to receive uploads from your iViz system.

6 Return to the **DICOM Profiles** screen, and swipe the new profile to **On**.

Editing a DICOM profile

You can update the information for an existing DICOM profile.

To edit a DICOM profile

1 From the **DICOM** settings screen, tap the profile you want to edit.

2 Make the desired changes.

Deleting a profile from the list of DICOM profiles

To delete a profile from the list of DICOM profiles

1 From the **DICOM** settings screen, tap **Edit**.

2 Next to the DICOM profiles that you want to delete, tap  .

3 Tap **Done** to exit editing mode.

> **Note** If you have a Tricefy Collaboration account, the Tricefy Collaboration profile cannot be deleted.

Turning a DICOM profile on or off

❖ From the **DICOM** settings screen, tap the switch for the DICOM profile you want to turn on or off. Inactive profiles have a red indicator, and say **(OFF)** below the button letter.

Configuring patient search settings

When setting up the patient search settings for iViz, you can select up to three search parameters. The default parameters are **Name**, **DOB**, and **Study Dates**.

You can use any or all of these defaults or add delete/add other search parameters.

To configure patient search settings

1 From the iViz **Settings** screen, tap **Patient Search**.

2 From the **Patient Search** screen, choose up to three search parameters.

3 To delete a search parameter, tap  next to the parameter you want to remove.

To set up bar code scanning

When setting up the patient search for bar code scanning, you must select the patient ID as one of the parameters in order for the bar code scanning feature to work.

1 From the iViz **Settings** screen, tap **Patient Search**.

2 From the **Patient Search** screen, choose **ID** as one of the search parameters.

3 Now you can scan a bar code as described in **"Using bar code scanning"** on page 30.

Configuring EMR settings and preferences

Use this feature to enter FUJIFILM Synapse EMR Gateway information, such as host name, IP address, and port number for the FUJIFILM Synapse EMR Gateway that the iViz system connects to.

The FUJIFILM Synapse EMR Gateway allows ultrasound systems to connect to the EMR to obtain patient demographic information and send PDF reports to the EMR.

For more information on the FUJIFILM Synapse EMR Gateway, contact your FUJIFILM SonoSite representative.

To configure EMR settings and preferences

1 From the iViz **Settings** screen, tap **EMR**.

2 In the **Host Name** field, type the host name of the EMR system you connect to.

3 In the **IP Address** field, type the EMR system's IP address.

4 In the **Port** field, type the EMR system's port number.

Connecting to a separate display

Only connect iViz to equipment specified by SonoSite.

WARNING	Connecting to unspecified equipment may result in a safety hazard for the patient and/or operator, since the system leakage in the configuration may exceed the safety limits.
Caution	Using a display other than the one included on your iViz system may result in image distortion and degradation. The touchscreen interface functions will not be available on the secondary display.
Note	You need to use the micro HDMI connector to route the video output signal of iViz to an external display.

Chapter 4: Managing Patient Records

The Patient module offers tools for searching and managing patient exam records, which are referred to in the system as *studies*. The Patient module enables you to search the worklist server or EMR for specific studies, update patient information, create new studies, and save exams.

Each study includes basic patient data, such as name, date of birth, height, and weight, as well as exam-specific information (exam type, purpose, notes, and any saved exam images or clips).

About iViz studies

Throughout this guide, you will see references to studies. Studies are used in iViz as a way to organize and consolidate all of the data associated with an exam. The specific information contained in a study is based on the exam type. For example, the new study form for an obstetrics exam will look different from a new study form for a cardiac exam.

It is possible to add images and data to an open study, subject to the policies and procedures of your institution, but we recommend that you clearly label any updated images as coming from a different exam.

In iViz, you can start scanning without entering any patient information. iViz creates a temporary ID, and all the images are saved to that ID. Before submitting any images, you have to change the temporary ID to a patient name. See **"Creating or updating a patient study"** on page 32.

Most patient information is optional, but the more information you can provide about the patient, the easier it is to locate the exam information later.

Accessing patient information

There are two ways to open the Patient module:

- From the Home screen, tap **Patient**.
- During an exam, tap the **Patient** field at the top of the screen to open the patient study associated with that exam.

Searching for a patient record

The Search function only displays results when iViz is connected to a Worklist server and/or EMR. For more information, see **"Configuring EMR settings and preferences"** on page 26.

You cannot search for internal iViz studies.

To search for studies associated with a specific patient or date

❖ Select the **Search** tab in the **Patient** module.

- If you are in an open patient study, tap  to return to the main Patient module screen.
- Use any or all of the following parameters in your search:
  - **Name** - Search by first, last, and/or middle name of patient.
  - **Date of Birth** - Use the month, day, and year wheels to enter the patient's birth date.
  - **Study Dates** - Look for studies performed on a specific day or range of days. The **Study Dates** field has two controls:
    - **Set the date** - Tap the date, and then use the month, day, and year wheels to set the desired study date.
    - **Set the range** - Tap ⌄ in the **Study Date** field to select a range of dates.

Note Remember that the more specific you make your search criteria, the more accurate your search results will be.

To search for a patient record

1 From the **Patient Search** screen, enter all or part of the patient's name, if known.

2 Enter the patient's birth date, if known.

3 Enter the date of the study, if known.

4 Tap **Search**.

5 When the results of your search are displayed, each row represents a specific study corresponding to your search parameters. Tap a row to view the study.

Using bar code scanning

Using the integrated camera on your iViz system, you can scan the patient's ID bar code in order to search for associated studies. For information on configuring this feature, see **"To set up bar code scanning"** on page 26.

WARNING After using the bar code scanner to retrieve patient records, take a moment to verify the patient information is correct. If the patient information retrieved using the bar code scanner is incorrect, enter the information manually.

To use bar code scanning

1 Do one of the following:

- From the **Patient Search** screen, in the **Name** field, tap  .

- While scanning, tap the **Patient** field, and tap  in the **Name** field.

The camera turns on and a rectangular viewing area appears.

2 Center the patient's ID bar code in the rectangle. You may have to try several different angles and distances for the iViz system to read the bar code clearly. The patient information displays.

Managing studies

Caution When attaching a file to a report from an external sensor or other source, be sure to verify it is for the correct patient.

Viewing scheduled studies

The list of scheduled studies displays only when iViz is connected to a Worklist server and/or EMR. For more information, see **"Configuring EMR settings and preferences"** on page 26.

To view a list of scheduled studies

You can view scheduled studies one of two ways:

- To see a list of scheduled studies, tap the **Schedule** tab of the Patient module.
- If you are in an open patient study, tap the **Patient** field, and then tap the **Schedule** tab.

  The schedule list displays all scheduled studies pulled from the worklist server. By default, the list is ordered by study date and time (the earliest scheduled studies appear at the top of the list).

Browsing scheduled studies

To view a list of scheduled studies:

❖ To view the scheduled studies available on your system, tap the **Schedule** tab of the Patient module.

The list displays all the scheduled studies held in memory on the iViz system. You cannot share or delete studies.

To sort the list

❖ In the list header, tap  or  next to the item that you want to sort the list by.

To view a study

❖ Tap the study that you want to open.

To refresh the list

❖ Tap to see any new studies created since the list was last refreshed.

To share a study or studies

1 Tap **Select**.

2 Tap the box next to the study or studies that you want to share. A check mark appears.

3 Tap .

4 When asked how you would like to share, tap the box next to each sharing method you want to use.

5 Tap **Next**.

6 Depending on the option you choose, complete the remaining information on the right side of the screen (for example, the local PACS server).

7 Tap **Share**.

To delete one or more studies

1 Tap **Select**.

2 Tap the box next to the study or studies that you want to delete. A check mark appears.

3 Tap .

Creating or updating a patient study

To create or update the information in a patient study

1 Select one of the following:

- To update a patient study, locate and open the study you want to change. For more information, see **"Accessing patient information"** on page 29.
- In an open patient study, or from the **Patient Search** screen, tap **New Study**.

2 Enter the patient information.

3 To add notes, tap the **Notes** field, and use the keyboard or audio recording to enter your notes.

4 To change the exam type, tap the **Exam Type** field, and select an exam type from the menu.

> **Note** If the exam types do not appear in the menu, check that you have a transducer plugged into the system.

5 To change the exam purpose, tap the **Exam Purpose** field, and select a purpose from the menu.

6 To add or change the Procedure Code, tap the **Procedure Code** field, and use the keyboard to type a new procedure code.

7 To add or change the Procedure Meaning, tap the **Procedure Meaning** field, and use the keyboard to type a new procedure meaning.

8 To add or change the Reading Doctor, tap the **Reading Doctor** field, and use the keyboard to type a new reading doctor.

9 To add or change the Referring Doctor, tap the **Referring Doctor** field, and use the keyboard to type a new referring doctor.

10 The **Study Date** is system-generated; you cannot change this field.

11 Tap **Save**. The system saves the patient form.

Ending a study

When you have finished adding information to the current patient study, you should end the study before opening another one. You can reopen a study at any time. Opening a different study automatically ends the current one. For more information about patient studies, see **"About iViz studies"** on page 29.

To end a patient study

❖ During a scan, tap **End Study**.

If you are on a patient information or report screen, you can tap  to return to scan, or simply open a different patient study.

Sharing a study

Cautions

- Do not disclose protected patient data in email.
- To protect patient data, take appropriate precautions when exporting patient data to a USB drive.

To send or share a study

1 From the Patient module, tap the **iViz Studies** tab.

2 From the list of studies, tap the one which you would like to share.

3 Do one of the following:

- To share one study, tap the thumbnail on the left of the study you would like to share.
- To share multiple studies:

  a Tap **Select**.

  Check boxes appear next to each image.

  b Tap the studies you want to share.

  Check boxes appear next to those you have selected.

4 Tap  .

5 Tap one or more of the following check boxes:

- **Local PACS** - This option sends the study through DICOM. If you select this option, you will be asked to choose a server from the list.
- **Tricefy** - This option send the study through the Tricefy collaborative medical image-sharing tool. You must have an account set up with Tricefy to use this option. iViz comes with a free one year trial.
- **USB** - This option saves the study to the USB drive inserted in the system.

6 Click **Next**.

7 Depending on the option you choose, complete the remaining information on the right side of the screen (for example, the local PACS server).

8 Click **Share**.

Managing reports

Reports provide a summary of the information included in a study, including the study date and time, patient information, exam type, notes, and any measurements and calculations that were made. You can return to a report to add more details before you end the study.

Reports are tailored to each exam type and pre-populated with any information contained in the study.

Editing a report

Once you've ended a study, your editing options are limited. In some places, you can delete data but not add or change it.

Note You cannot edit archived reports.

To edit a report

1 Open the study that contains the report you want to edit. For more information about finding studies, see **"Accessing patient information"** on page 29.

2 In the open study, tap . The report opens.

3 To edit a measurement, tap **Edit** above the **Measurements** box.

You can delete measurements once editing is enabled, by tapping next to the measurement. To redo the measurement, return to scanning, and perform the measurement again.

4 To check a box, tap the box.

5 To select a new value in a field, tap the drop-down arrow.

6 To add a note, do one of the following:

- Tap the **Notes** field, and then type the note using the keyboard.
- Tap to record a voice note.

Note While recording, the microphone icon turns to a pause icon. You can tap pause to temporarily stop recording, and the microphone icon reappears with the playback icon next to it.

To continue recording, tap the microphone icon again. After you've ended a study, you cannot change the audio recording.

7 When you are finished editing, tap **Save**.

8 To cancel your changes, tap **Cancel**.

Printing a report

To print a report

1 Open the study that contains the report you want to edit. For more information about finding studies, see **"Accessing patient information" on page 29**.

2 In the open study, tap . The report opens.

3 Tap **Print**, and select your printer and document options.

4 Tap **Print** to print the report.

Sharing a report

You can share a report if iViz is connected to an EMR server.

To share a report

❖ Within an open report, tap **Save and Send to EMR**.

Chapter 5: Performing an Exam

This chapter describes imaging with the iViz ultrasound system.

Note If the USB charger is connected to the iViz and AC mains, you cannot perform live imaging.

Understanding optimal thermal performance

Like all high-performance electronic devices, iViz generates heat during normal operation. This is expected behavior. The system has safety features to protect it from overheating. For optimal performance and longer scanning times, here are a few recommendations.

- Do not set the transducer down while scanning; continue to hold it, and make good contact between the hand and the transducer.
- Use freeze mode when not you are not actively scanning (tap **Freeze** in the upper left corner).
- Do not lay the system down flat. Instead, use the kickstand on the protective case, or continue to hold the system.

Beginning an exam

There are two ways to begin an exam:

- From the Home screen, tap **Scan**.

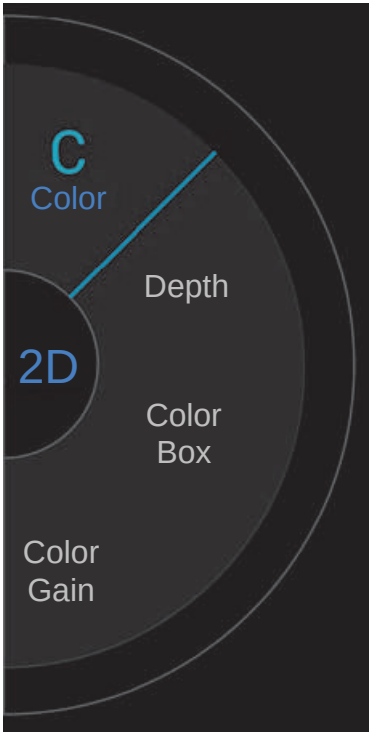
  You can return to the Home screen from anywhere in the iViz system by tapping  .

- In any patient study, tap  .

Note To prevent errors, avoid disconnecting the transducer while scanning; however, if you do need to disconnect it, first tap **Freeze**.

Understanding imaging modes

In iViz, the active imaging mode is always highlighted in blue so you can tell at a glance what imaging mode you are using. For instance, in **Color** mode, both the **2D** and **Color** buttons are highlighted in blue:



- **2D** is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. **Color Mode** is used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states.

- **M Mode** is also known as Motion Mode. It provides a trace of the image displayed over time. A single beam of ultrasound is transmitted, and reflected signals are displayed as dots of varying intensities, which create lines across the screen.

Exam overview

WARNING | Do not allow patient contact with the system other than the transducer lens.

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
- Comet tails

For more information on detecting and interpreting acoustic artifacts, see the following reference: Kremkau, Frederick W. Diagnostic Ultrasound: Principles and Instruments. 8th ed., W.B. Saunders Company, (Nov. 10, 2010).

2D imaging

2D is the system's default imaging mode. When returning to a scan, the system returns to the same imaging mode (for example, 2D or M Mode) that it was in the last time you were scanning.

- To return to 2D from M Mode, press and hold **M**.
- To return to 2D from color mode, tap **Color**.

For more information about the controls available in 2D mode, see **"Scanning in 2D"** on page 42.

M Mode

To switch from 2D to M Mode, press and hold **2D**.

For more information about the controls available in M Mode, see **"Scanning in M Mode"** on page 48.

Choosing a transducer and exam type

WARNINGS

- To prevent misdiagnosis or harm to the patient, use the correct transducer for the application. The diagnostic capability differs for each transducer, exam type, and imaging mode. Transducers are developed to specific criteria depending on their physical application. These criteria include biocompatibility requirements. Understand the system's capabilities prior to use.
- Do not use unsupported needle guides with iViz. At this time, the iViz transducers are not needle guide capable.
- Some gels and sterilants can cause an allergic reaction on some individuals.

Cautions:

- To prevent contamination, use sterile transducer sheaths and sterile coupling gel for clinical applications contacting compromised skin.
- To prevent contamination, use single-use gel packs.
- Use market-cleared transducer sheaths for clinical applications when the transducer is likely to be splashed or splattered with bodily fluids or blood.

The iViz system is capable of automating or assisting some measurements and calculations based on the exam type you choose. To ensure that the measurements and calculations you need are available, be sure to select an exam type from the menu.

The exam types available depend on the type of transducer attached to the system.

Table 5-1: Exam type by transducer

Transducer	Exam Types
P21v	Cardiac
	Abdomen
	OB
	Lung

To choose an exam type

1 When scanning, tap the **Exam Type** drop-down menu in the upper right of the screen. A list of available exam types appears.

2 Tap the exam type you want to change to.

Gels

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.

Sheaths

WARNINGS

- Use market-cleared, sterile transducer sheaths and sterile coupling gel to prevent contamination. 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 high-level disinfectant.
- Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals.
- After inserting the transducer into the sheath, inspect the transducer sheath for holes and tears.

To install a transducer sheath

1. Place 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 and cable until the sheath is fully extended.
4. Secure the sheath using the bands supplied with it.
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.

Reviewing patient information

At any time during an exam, you can tap the patient's name to review the patient's information. For more information about Patient mode, see **Chapter 4, "Managing Patient Records."**

Scanning in 2D

2D is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. To achieve the best possible image quality, properly adjust the display brightness, gain, depth settings, viewing angle, and exam type. Also, select an optimization setting that best matches your needs.

For more information about iViz controls and the touchscreen interface, see **"Using the touchscreen"** on page 7.

Scanning in color

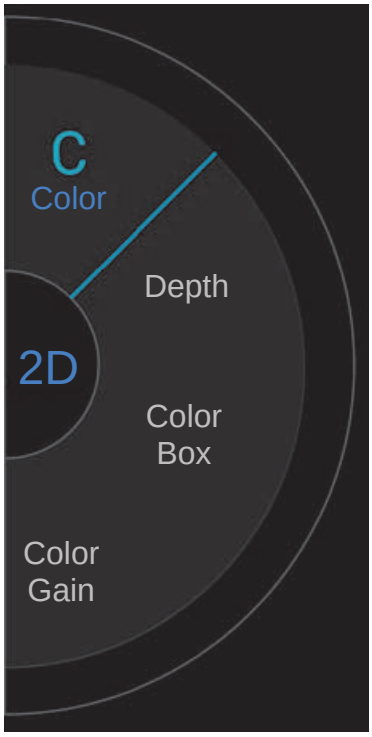
Color mode is used to display the presence and direction of blood flow overlaid on a 2D image. Typically, blood flowing toward the transducer is displayed in red, while blood flowing away from the transducer is shown in blue, although this display can be reversed or shown as color power Doppler.

Selecting Color mode

In iViz, color is included as part of the 2D scanning mode. If you are in M Mode and want to switch to color, you must change to 2D scanning mode first.

To switch from 2D to Color mode

❖ On the control wheel, tap **Color**. The system switches to Color mode.



Controlling the Color box

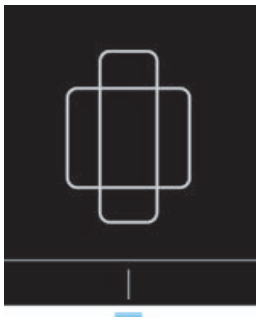
Because color images can lose some resolution and detail compared to other 2D images, the color box enables you to concentrate the scan on a particular area of interest. With iViz, you can change the location, size, and shape of the color box to achieve the best possible image.

There are two ways to control the color box. You can use your thumb in the control area or your index finger in the display area.

To control the color box using your thumb

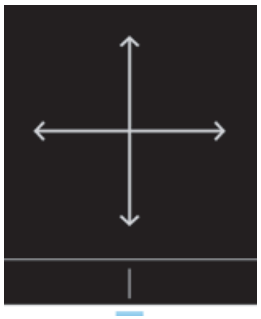
1 On the control wheel, tap **Color Box**. The color box tool drawer opens.

2 To change the size and shape of the box, tap **Resize**, and then drag your thumb in the trackpad.



- Moving to the right makes the box wider. Moving to the left makes the box narrower.
- Moving down makes the box taller. Moving up makes the box shorter.

3 To change the location of the box, tap **Move**, and drag your thumb in the trackpad.



4 When the Color box has the location, size, and shape that you want, you can close the trackpad by dragging the blue horizontal lines up.

To control the Color box using your finger

1 To change the size and shape of the box, in the main display area, drag the handle.

- Moving to the right makes the box wider. Moving to the left makes the box narrower.
- Moving down makes the box taller. Moving up makes the box shorter.

2 To change the location of the box, in the main display area, drag the box.

Switching between CVD and CPD

The iViz system offers both Color Velocity Doppler (CVD) and Color Power Doppler (CPD) modes.

- **CVD** - Uses color to differentiate between blood flow moving toward or away from the transducer. CVD is the default setting.
- **CPD** - All blood flow velocities are represented by varying intensities of one color.

> **Note** | CPD is not available for all exam types.

To switch between CVD and CPD

❖ On the control wheel, tap **CVD** or **CPD**.

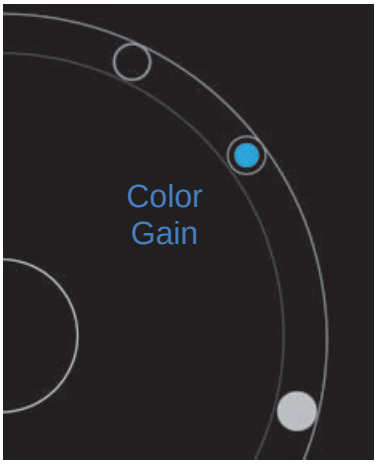
Controlling color gain

iViz lets you adjust the gain within the color box to accommodate different anatomic and flow conditions.

To control the color gain

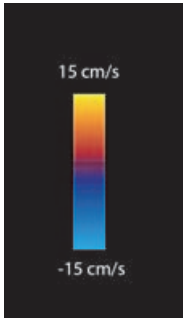
1 On the control wheel, tap **Color Gain**. The gain control appears.

2 Move the slider up or down to set the gain.



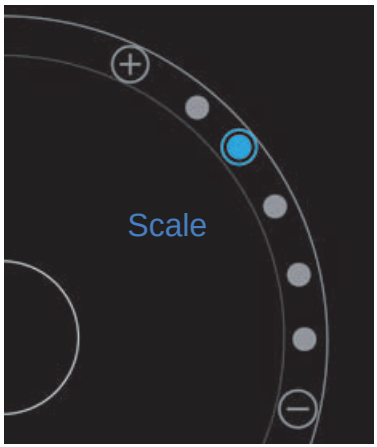
Adjusting scale

You can change the scale of the color scan to better view high or low-flow blood vessels. The current blood flow scale appears in the upper left of the scanning window:



To control the color scale

1 On the control wheel, tap **Scale**. The Scale control appears.



2 Tap ⊕ or ⊖ to change to a higher or lower blood flow scale (or tap one of the dots for specific blood flow scale index).

Inverting the blood flow colors

By default, blood flow toward the transducer is shown in red, while blood flow away from the transducer is displayed in blue. The system lets you reverse this orientation. The current blood flow orientation can be seen in the upper left of the scanning window.

Note The invert control is disabled in CPD mode.

To invert the blood flow colors

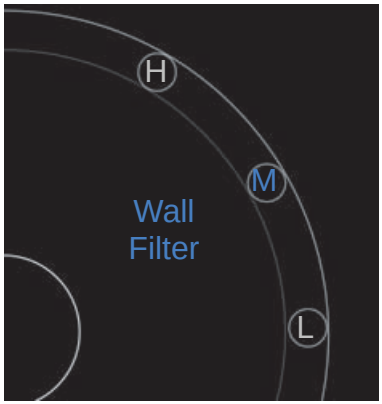
❖ On the control wheel, tap **Invert**.

Filtering

A wall filter removes return signals below certain preset frequencies. This helps eliminate low-frequency, high-intensity signals that can interfere with the quality of an image.

To control wall filtering

1 On the control wheel, tap **Wall Filter**. The Wall Filter control appears.



2 Tap the desired level of filtering:

- **H** - High
- **M** - Medium
- **L** - Low

Controlling flow

To control flow

1 On the control wheel, tap **Flow**. The Flow control appears.

2 Tap the desired level of flow.

- **H** - High
- **M** - Medium
- **L** - Low

Scanning in M Mode

M Mode shows the motion of structures in the body and can be used to measure the amplitude or frequency of that movement.

❖ To switch from 2D to M Mode, press and hold **2D**.
An **M** (representing M Mode) appears in the scan mode selector.

Moving the M Line

There are two ways to control the M Line in iViz. You can use your thumb in the control area or your index finger in the display area.

To move the M Line using your thumb

❖ Drag the slider up or down.
- Up moves the M Line to the left.
- Down moves the M Line to the right.

To move the M Line using your finger

❖ In the display area, use your finger to drag the M Line to the location you want.

Updating in M Mode

The **Update** menu initiates the M Mode sweep, which generates a linear representation of movement perpendicular to the M Line. This visualization mode is ideal for measuring the amplitude and frequency of motion.

❖ To turn on update, in M Mode, tap **Update**.

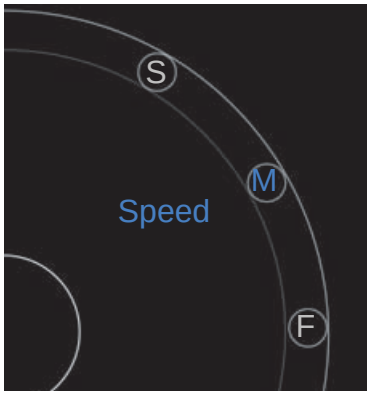
Changing the sweep speed

You can change the speed of the sweep scan to better isolate individual motions.

To change the sweep speed

1 On the control wheel, tap **Update**.

2 On the control wheel, tap **Speed**.



3 Tap one of the following:

- **S** - Slow
- **M** - Medium
- **F** - Fast

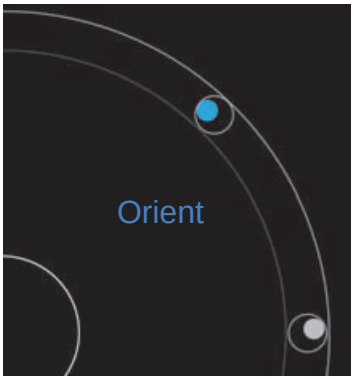
Setting the image orientation

You can determine the orientation of the image at a glance by seeing which side of the image the SonoSite logo appears. The position of the logo corresponds to the physical bump on one side of the transducer housing.

To change image orientation

1 On the control wheel, tap **Orient**. the orientation control appears.

2 Tap or to move the orientation to up/left or up/right.



Optimizing the image

The following image optimizations are available on iViz, depending on the transducer you have selected:

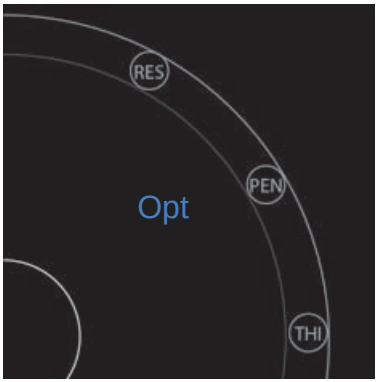
Res - Provides the best possible resolution. This is available with all transducers.

Pen - Provides the best possible penetration. This is available with all transducers.

THI - Tissue Harmonic Imaging (THI) decreases clutter and increases contrast and spatial resolution. This is only available with the P21v transducer.

To optimize the image

1 On the control wheel, tap **Opt**. The image optimization control appears.



2 Tap the image optimization option you want.

Note | THI optimization is not available for all transducers.

Adjusting depth and gain

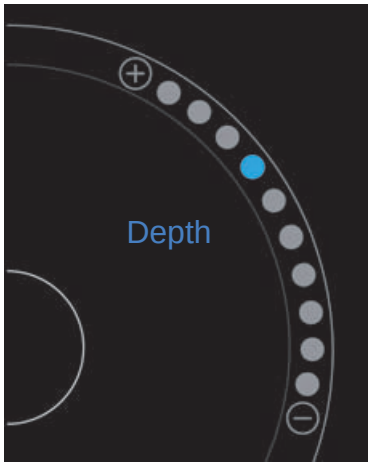
Adjusting depth

Depth refers to the depth of display. You can adjust the depth in all imaging modes. Scan depth is always displayed in the lower left of the scan window.

To adjust scan depth

1 On the control wheel, tap **Depth**. The depth control appears.

2 Tap ⊕ or ⊖ to increase or decrease the scan depth (or tap one of the dots for specific screen-depth index).



Adjusting gain

Gain refers to amplifying the intensity of the returning sound waves on the screen display. Increasing the gain brightens the image. Decreasing the gain darkens the image.

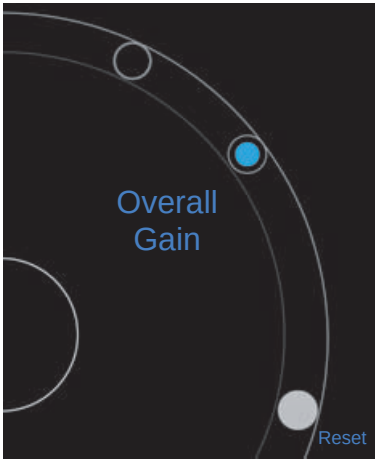
There are two types of gain that can be adjusted in iViz.

- **Overall Gain** - Adjusts the amplification of returning signals.
- **Near/Far Gain** - Adjusts the amplification of signals returning from shallow or deep depths, respectively.

To set Overall Gain

1 On the control wheel, tap **Overall Gain**. The gain control appears.

2 To set the gain, move the blue dot up and down the slider.



3 If desired, tap **Reset** to return to the default settings.

To set Near/Far Gain

1 On the control wheel, tap **Near/Far Gain**. The gain control appears.

2 Tap **Near/Far Gain** again to toggle between near gain and far gain.

3 To set the gain, move the blue dot up and down the slider.

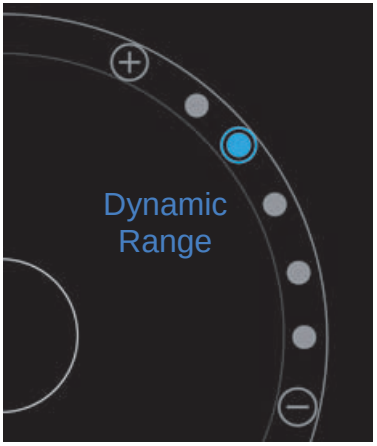
Controlling the dynamic range

Dynamic range controls the intensity of the gray scale used in the image. A lower setting increases the image contrast, making echoes appear brighter against a darker background. A higher setting broadens the gray scale, resulting in a smoother image.

To change the dynamic range

1 On the control wheel, tap **Dynamic Range**. The dynamic range control appears.

2 Tap ⊕ or ⊖ to increase or decrease the dynamic range or tap a dot; the dot in the center is marked with a **0** to indicate the midpoint.



Accessing guided protocols

iViz offers protocols that guide you through all the necessary views for that protocol and supply a reference image for that view.

To access the guided protocols

1 From an unfrozen scan, open the bottom tool drawer, and swipe upward on the tool drawer handle in the lower right of the screen.

2 Tap the class of guided protocol you want to use. A list of available protocols appears in the control area.

Physical

Assistance is available for the following types of exams:

- PLAX
- PSAX
- Apical
- Subxiphoid
- IVC
- Aorta

- Liver
- Right Kidney
- Left Kidney
- Spleen
- Bladder
- Lung (Ph.)

eFAST

Extended focused assessment with sonography for trauma (eFAST) is a rapid bedside ultrasound examination. Assistance is available for the following types of exams:

- RUQ
- LUQ
- Pelvis
- Lung (Ph.)

FATE

Focus assessed transthoracic echo (FATE) interprets echocardiographic findings. Assistance is available for the following types of exams:

- PLAX
- PSAX
- Apical
- Subxiphoid
- IVC

RUSH

Rapid ultrasound for shock and hypotension (RUSH) exam is a quick way to examine the heart, intravascular compartments, and large arteries. Assistance is available for the following types of exams:

- PLAX
- PSAX
- Apical
- Subxiphoid
- IVC
- Aorta
- RUQ
- Spleen/LUQ
- Pelvis
- Lung (Ph.)

Chapter 6: Managing Images and Clips

iViz includes tools for capturing, saving, labeling, and reviewing your ultrasound images and clips.

Be aware that images and clips can only be saved to the current study. The current study is the study that is open during the scan.

Caution 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 **"Managing Patient Records"** on page 29.

If you did not open an existing study before beginning your scan, a new blank study is created. Be sure to update the study with the necessary patient and exam information before ending it.

For more information about patient studies and how they are used in the iViz system, see **Chapter 4, "Managing Patient Records."**

All images and clips are saved to the study in the order that they were recorded. During a scan, the number of images and clips saved to the current study is displayed in the **SAVE** button 

.

Freezing an image

You must freeze an image before you can perform measurements or add labels.

To freeze an image

1 While scanning, tap **FREEZE**.

2 If desired:

- Drag the green slider up and down to scroll through the frames.

- Select the back arrow to return to the first frame or the forward arrow to go to the last frame .

Saving an image or a clip

During an exam, you can save an image or clip to the current study.

Caution To avoid mixing images saved from multiple patients, make sure that the patient ID is displayed before you save an image. For more information about finding and retrieving patient records, see **"Managing Patient Records"** on page 29.

To save an image

❖ While scanning on an active or frozen scan, tap **SAVE**.
The **SAVE** button turns red momentarily, and the image is saved to the current study.

To save a clip

1 While scanning, press and hold **SAVE** for one second.

The button shows a blue progress bar, which represents the clip recording length that was set up in Preferences (see **"Configuring preferences"** on page 21).

2 To stop recording the clip, tap **SAVE**.

The clip is saved to the current study (the clip is not saved if it was canceled).

Reviewing an image or clip

You can view an image or play back any clip saved to a study.

To view an image or clip in the current study

1 Tap the **Patient** field above the scan image.

2 In the menu area on the left, tap the image you want to view.

3

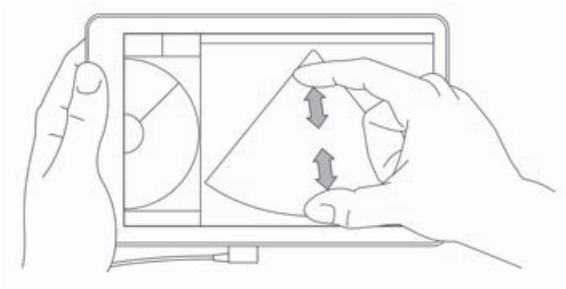
To view an image or clip in a different study

1 Open the study that contains the images and clips that you want to view. (For more information about finding specific studies, see **"Searching for a patient record"** on page 29.)

2 From the **Images and Clips** tab, tap the image or clip that you want to view.

Zooming in and out of an image

To zoom in and out of an image, make a pinching or expanding motion with your fingers on the display screen.



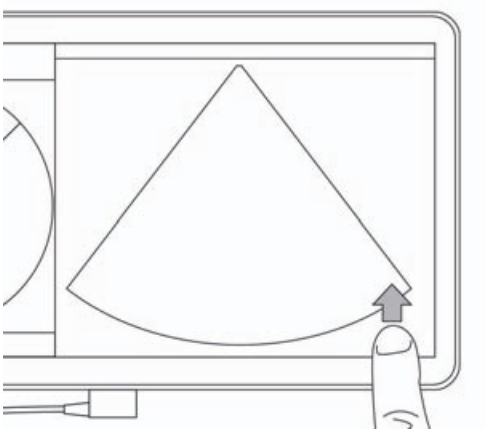
For more information about using gestures in the iViz system, see **"Using gestures"** on page 8.

Adding labels

For each exam type, there are a variety of standard labels. In addition, you can create up to 10 custom labels (with a maximum of 12 characters each).

To add labels and arrows

1 On a frozen or saved image, open the bottom tool drawer, swipe upward on the tool drawer handle in the lower right of the screen.



2 Tap **Text Labels**.

3 To add an arrow:

   a Tap **+Arrow**.

   An arrow appears on the display .

   b Using your finger, drag the arrow to a location on the screen.

   c Using your finger, drag the blue orientation arrows to rotate the center black arrow.

4 To add a standard label:

   a Tap the label you want to add, such as **Right** or **Medial**.

   b Using your finger, drag the label to a location on the screen.

5 To add a custom label (the maximum number of characters you can use for a custom label is 12; don't use spaces in the label name):

   a Tap the text box at the top of the list of labels.

   b Type the text of the label, and then tap **Done**.

   The custom label appears on the screen.

   c Using your finger, drag the label to a location on the screen.

6 Tap **Save** to keep your changes.

To delete labels and arrows

1 Tap the arrow or label that you want to delete.

2 In the label menu, tap next to the arrow or label you want to delete.

Deleting images and clips

To delete an image or clip

1 From the Patient module, tap the **iViz Studies** tab.

2 From the list of studies, tap the one from which you would like to delete the image or clip.

3 To delete one image or clip, tap the thumbnail on the left of the image or clip you would like to delete.

4 To delete multiple images or clips:

   a Tap **Select**.

   b Tap the images you want to delete.

   Check boxes appears next to those you have selected.

5 Tap , then tap **Delete** at the prompt.

Sending and sharing images and clips

Caution To protect patient data, take appropriate precautions when exporting patient data to a USB drive.

To send or share an image or clip

1 From the Patient module, tap the **iViz Studies** tab.

2 From the list of studies, tap the one from which you would like to share the image or clip.

3 To share one image or clip, tap the thumbnail on the left of the image or clip you would like to share.

4 To share multiple images or clips:

   a Tap **Select**.

   b Tap the images you want to share.

   Check boxes appear next to those you have selected.

5 Tap .

6 Tap one or more of the following check boxes:

- **Local PACS** - This option sends the image or clip through DICOM. If you select this option, you will be asked to choose a server from the list.
- **Trice** - This option sends the image or clip through the Tricefy collaborative medical image-sharing tool. You must have an account set up with Tricefy to use this option. iViz comes with a free 30-day trial, and after the 30 days, you have 500 collaboration transactions.
- **USB** - This option saves the image or clip to the USB drive inserted in the system.
- **Email** - This option sends the image or clip through the email account set up on the system.
- **Printer** - This option sends the image or clip to the printer set up on the system. For more information about setting up a printer, see **"Adding a wireless printer"** on page 20.

7 Click **Next**.

8 Depending on the option you choose, complete the remaining information on the right side of the screen (for example, the local PACS server).

9 Click **Share**.

Chapter 7: Measurements and Calculations

This chapter provides information about measurements, calculations, worksheets, and reports.

Measurements are performed on frozen images. For references used, see **Chapter 8, "Measurement References."**

WARNINGS

- 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.
- To avoid a mix-up of patient data, create a new patient study before taking any measurements.

Taking measurements

Within calculations, you can save measurement results to a patient report. You can display, repeat, and delete measurements from a calculation. Some measurements can be deleted directly from the patient report pages. See **"Ending a study"** on page 33.

Note

Except for the Abdomen exam, general measurements appear on-screen only and are not in a specific report page. Because of this, we recommend that you save the image with the measurements before ending the study.

Working with calipers

When taking measurements, each caliper appears as a white cross symbol ┼. The active caliper will be enclosed in a blue circle ⊕.

To use the calipers

1 Drag a caliper to the desired position, and release it.

2 Drag the caliper to the end point, and release it.

The on-screen measurement value changes as the caliper moves.

You can move the active caliper by touching anywhere inside the blue circle and dragging it with your finger. This method can keep you from blocking the clinical view with your finger while measuring. To make a different caliper active, simply tap it.

Viewing and deleting measurement results

The current measurement results appear on the upper left side of the scan area under the **Measurements** box. Tap the drop-down arrow to see the measurements you've taken.

To delete a measurement

❖ Select the caliper you want to delete, and then tap the red  .

Taking basic measurements

Caution: Moving the baseline, scrolling, or inverting the trace while frozen causes the cardiac output results to be cleared from the screen.

To measure the distance between two points

1 On a frozen scan, tap **Measurements**.

2 Under the **General** measurements area, tap **Distance**.

3 Drag the active caliper to the first point.

4 Drag the other caliper to the second point.

5 As needed, tap and drag each caliper until it is precisely positioned.

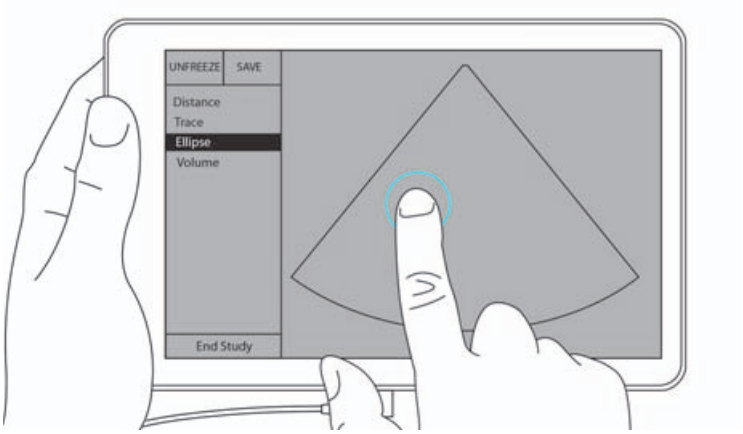
Note The **Measurements** box can be dragged around the screen to avoid blocking the clinical view. You can also minimize it by clicking  .

To measure the circumference or area using an ellipse

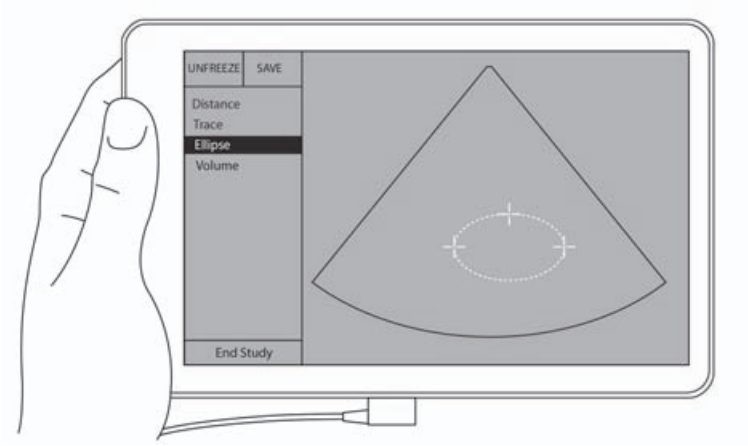
Use the ellipse measurement tool to calculate the size of a circular or oval structure, such as a blood vessel.

1 On a frozen scan, tap **Measurements**.

2 Under the **General** measurements area, tap **Ellipse**.



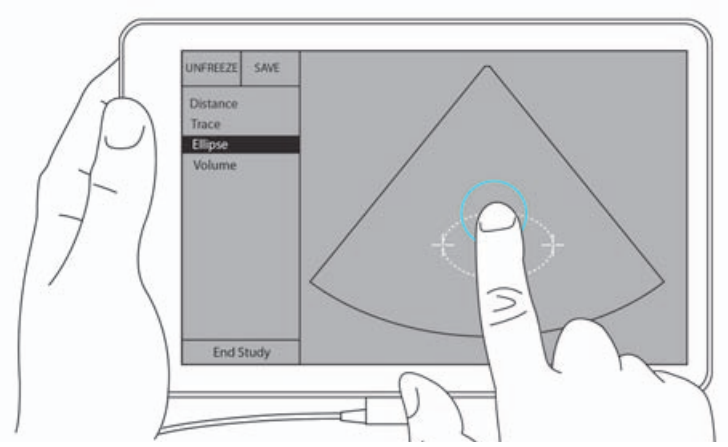
3 Drag the caliper to the boundary of the feature you want to measure. When you lift your finger, a dashed circle appears, and the ellipse is anchored at that point.



4 Drag the second caliper along the horizontal axis to align it to the rest of the feature you are measuring.

5 Tap the height caliper to make it active.

6 Drag the height caliper to the height of the feature you want to measure.



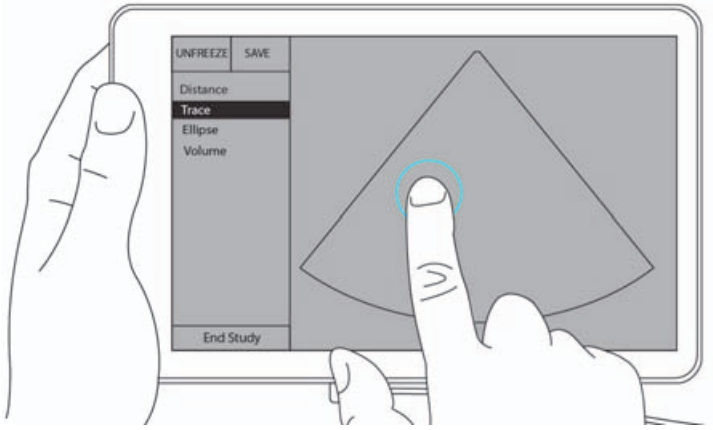
The diameter, area, and circumference measurements appear in the **Measurements** box.

To measure the circumference or area by tracing

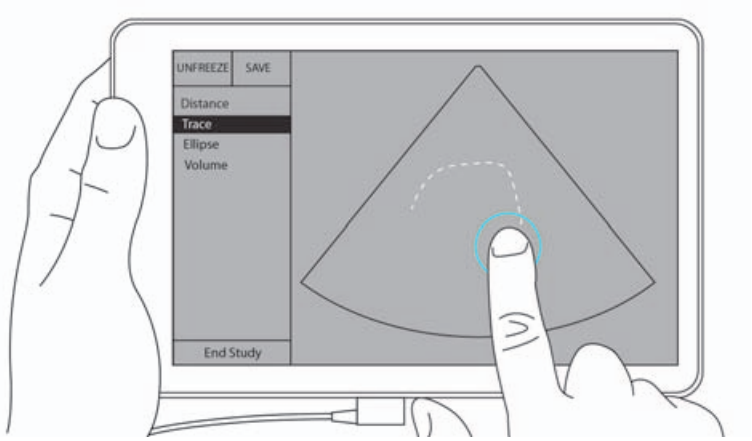
1 On a frozen scan, tap **Measurements**.

2 Under the **General** measurements area, tap **Trace**. An active caliper appears on the screen.

3 Drag the caliper to the start point of your measurement, and lift your finger.



4 Drag the caliper to outline the structure you want to measure. A dotted line shows the path of the trace.



5 Before you lift your finger, make sure the ends of the trace are close together; that way, the trace automatically closes, and the area and circumference measurement values appear in the **Measurements** box.

About calculations

In iViz, you can perform calculations that you then save to a patient report. You can display, repeat, and delete measurements from a calculation. Some measurements can be deleted directly from a patient report. See **"Ending a study"** on page 33.

There are two kinds of calculations:

- General calculations that are available for multiple exam types
- Specialized calculations that are specific to one exam type

Overview

You can access calculations from the **Exam Type** drop-down menu.

After you select an exam type, such as **OB**, the calculation list appears on the left side of the screen.

Tapping expands the list. Tapping collapses it.

After you select a measurement name, iViz highlights it, and calipers appear on the image.

Position the calipers by dragging them. The measurement result appears in the **Measurements** box beside the measurement name.

After each measurement is taken, the measurement name in the calculation menu changes color to show that it is complete.

Calculating volume

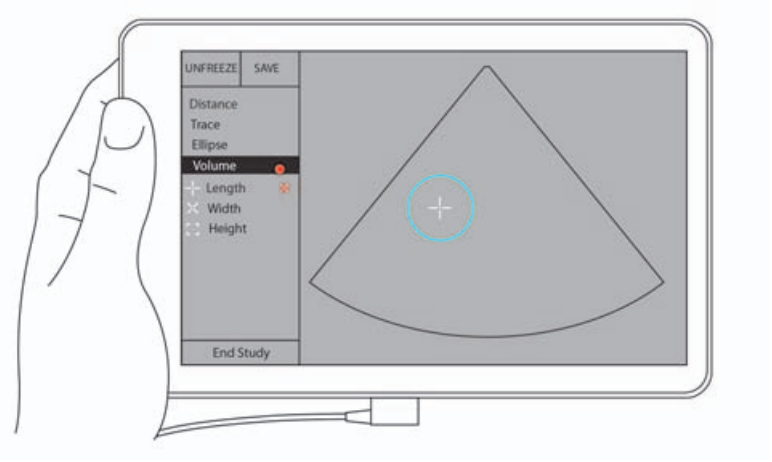
You can calculate the volume of a structure by taking up to three separate measurements: length, width, and height.

To calculate the volume of a structure

1 On a frozen scan, tap **Measurements**.

2 Under the **General** measurements area, tap **Volume**.

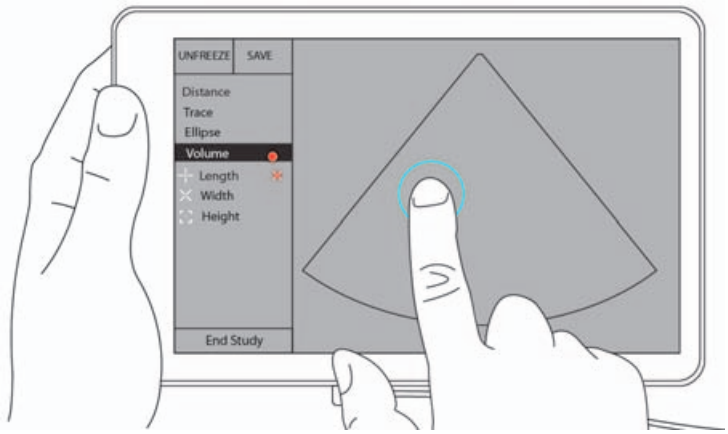
An active caliper appears. Steps 3, 4, and 5 can be performed in any order.



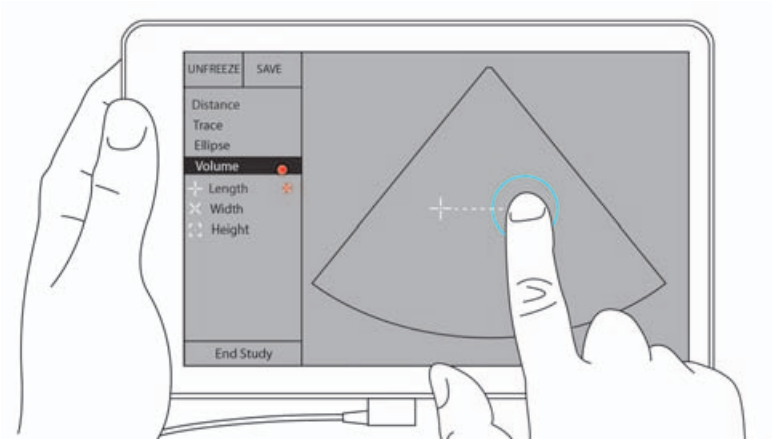
3 Measure the length of the structure.

a In the control area, tap **Length**.

b Drag the active caliper to one side of the structure. When you lift your finger, a new, active caliper appears.



c Drag the active caliper to the other side of the structure. When you lift your finger, the length value is set.



4 Measure the width of the structure.

a If necessary, unfreeze the image, reposition the transducer to show the width of the feature, freeze the image, and then tap **Measurements**.

b In the control area, tap **Width**.

c Drag the active caliper to one side of the feature. When you lift your finger, a new, active caliper appears.

d Drag the active caliper to the other side of the feature. When you lift your finger, the width value is set.

5 Measure the height of the feature.

a If necessary, unfreeze the image, reposition the transducer to show the height of the structure, freeze the image, and then tap **Measurements**.

b In the control area, tap **Height**.

c Drag the active caliper to the top of the structure. When you lift your finger, a new, active caliper appears.

d Drag the active caliper to the bottom of the structure. When you lift your finger, the height value is set.

The volume of the structure appears in the upper left portion of the screen.

Exam-based calculations

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

Cardiac calculations

WARNING Moving the baseline, scrolling, or inverting the trace while the image is frozen causes the displayed cardiac output results to be cleared.

With the **Cardiac** exam, you can perform the following calculations:

Calculation list	Measurement name (imaging mode)	Results
LV	Diastole ▸ RVWd (2D or M Mode) ▸ RVDd (2D or M Mode) ▸ IVSd (2D or M Mode) ▸ LVDd (2D or M Mode) ▸ LVPWd (2D or M Mode) Systole ▸ RVWs (2D or M Mode) ▸ RVDs (2D or M Mode) ▸ IVSs (2D or M Mode) ▸ LVDs (2D or M Mode) ▸ LVPWs (2D or M Mode)	CO CI EF SV SI LVESV LVEDV IVS LVPWFT LVDFS LV Mass (M Mode)

Calculation list	Measurement name (imaging mode)	Results
Area trace	MVA (2D) AVA (2D)	MV Area AV Area

Table 6 Cardiac calculations and results

To measure LVd and LVs

1 From the **Exam Type** drop-down menu, tap **Cardiac**.

2 On a frozen 2D image, tap **Measurements**.

3 Switch to the **Cardiac** calculation list.

4 Tap **LV**, and tap the name of the first measurement you want to take.

5 Position the calipers by dragging them.

6 If you want to take additional measurements, tap the measurement name in the calculation list.

To measure Ao, LA, ACS, and LVET

These calculations are available in M-Mode.

1 From the **Exam Type** drop-down menu, tap **Cardiac**.

2 On a frozen M-Mode trace, tap **Measurements**.

3 Switch to the **Cardiac** calculation list.

4 Under **LA/Ao**, tap the measurement name.

5 Position the calipers by dragging them.

6 If you want to take additional measurements, tap the measurement name in the calculation list.

To calculate MV or AV area

1 From the **Exam Type** drop-down menu, tap **Cardiac**.

2 On a frozen 2D image, tap **Measurements**.

3 Switch to the **Cardiac** calculation list.

4 Tap **Area**, and then tap **MVA** or **AVA**.

5 Position the caliper to where you want to begin the trace, and tap it to start the trace.

6 Using your finger, trace the desired area.

7 Complete the trace, and lift your finger off the caliper.

To measure Heart Rate (HR)

1 From the **Exam Type** drop-down menu, tap **Cardiac**.

2 On a frozen M-Mode trace, tap **Measurements**.

3 Switch to the **Cardiac** calculation list.

4 Under **HR**, tap **HR** in the calculations list.

5 Position the caliper at the peak of a heartbeat, and lift your finger from the screen.

A second caliper appears.

6 Position the second caliper at the peak of the next heartbeat, and lift your finger from the screen.

The heart rate appears.

Obstetrics calculations

WARNING Make sure that you have selected the **Obstetrics** exam type and the OB author for the Obstetrical calculation table you intend to use. See **"Obstetrical references"** on page 86.

In iViz, you can calculate gestational age, fetal heart rate, middle cerebral artery, and umbilical artery blood flow velocities. You can select authors for Obstetrical calculations. See **"Configuring OB measurements and calculations"** on page 22 and **"Measurement publications and terminology"** on page 83.

You can select authors for Obstetrical calculations. See **"Obstetrical references"** on page 86.

EFW is calculated only after the appropriate measurements are completed. If any of these parameters results in an EDD greater than what the Obstetrical calculation tables provide, the EFW is not displayed.

Note If you change the calculation author during the exam, the common measurements are retained.

Table 7-1: Results from system-defined obstetrical measurements and table authors

Calculation result	Gestational OB measurements	Available authors
Gestational Age [a]	YS	—
	GS	Hansmann, Nyberg, Tokyo U.
	CRL	Hadlock, Hansmann, Osaka, Tokyo U.
	BPD	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HC	Chitty, Hadlock, Hansmann
	AC	Hadlock, Hansmann, Tokyo U.
	FL	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HL	Jeanty
	Cereb D	—
	CM	—
	Lat Vent	—
	Cx Len	—
Estimated Fetal Weight (EFW)[c]	HC, AC, FL	Hadlock 1
	BPD, AC, FL	Hadlock 2
	AC, FL	Hadlock 3
	BPD, TTD	Hansmann
	BPD, FTA, FL	Osaka U.
	BPD, AC	Shepard
	BPD, TTD, APTD, FL	Tokyo U.
Ratios	HC/AC	Campbell
	FL/AC	Hadlock
	FL/BPD	Hohler
	FL/HC	Hadlock

Table 7-1: Results from system-defined obstetrical measurements and table authors

Calculation result	Gestational OB measurements	Available authors
Amniotic Fluid Index	Q^1, Q^2, Q^3, Q^4	Jeng
Growth Analysis Tables[d]	BPD	Chitty, Hadlock, Jeanty
	HC	Chitty, Hadlock, Jeanty
	AC	Chitty, Hadlock, Jeanty
	FL	Chitty, Hadlock, Jeanty
	EFW	Brenner, Hadlock, Jeanty
	HC/AC	Campbell

[a]The Gestational Age is automatically calculated and displayed next to the Obstetrical measurement you selected. The average of the results is the AUA. Only measurements of the same type are averaged.

[b]For Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

[c]The Estimated Fetal Weight (EFW) calculation uses an equation that consists of one or more fetal biometry measurements. The author for the Obstetrical tables, which you choose on a system setup page, determines the measurements you must perform to obtain an EFW calculation. Individual selections for Hadlock's EFW equations 1, 2, and 3 are not determined by the user. The selected equation is determined by the measurements that have been saved to the patient report with priority given to the order listed above.

[d]The Growth Analysis tables are used by the Report Graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are available only with a user-entered LMP or EDD.

To measure gestational growth (2D)

For each 2D Obstetrical measurement (except AFI), the system saves up to three individual measurements and their average. If you take more than three measurements, the earliest measurement is deleted.

1 From the **Exam Type** drop-down menu, tap **OB**.

2 On a frozen 2D image, tap **Measurements**.

3 Switch to the **OB** calculations list.

4 Do the following for each measurement you want to take:

a Select the calculation list that contains the measurement.

b Tap the measurement name.

c Position the calipers by dragging.

To measure Heart Rate (HR) in M Mode

1 From the **Exam Type** drop-down menu, tap **OB**.

2 On a frozen M-Mode trace, tap **Measurements**.

3 Switch to the **OB** calculation list.

4 Under **HR**, tap **HR** in the calculations list.

5 Position the caliper at the peak of a heartbeat, and lift your finger from the screen.

A second caliper appears.

6 Position the second caliper at the peak of the next heartbeat, and lift your finger from the screen.

The heart rate appears.

To measure gestational sacs

To make more than one gestational sac measurement on the same frozen image, tap the image to make an additional measurement, and then tap **Save**.

To make a single gestational sac measurement, tap **Save** after the measurement.

Abdomen and Lung calculations

To measure distance, see **"To measure the distance between two points"** on page 66.

To measure volume, see **"Calculating volume"** on page 70.

Working with the Smartheart Pro device

WARNING Verify the appropriate operating conditions of peripherals and external sensors, such as the SHL Smartheart Pro 12-lead ECG device, before using them with iViz.

Note Check with your local SonoSite representative to see if Smartheart Pro is approved for use in your location.

Smartheart Pro is an optional hospital-grade 12-lead ECG device that can share information with iViz. Your iViz system must be connected to Wi-Fi and paired to the Smartheart device using Bluetooth for the Smartheart app to work (see **"Connecting to a wireless network"** on page 17).

When the Smartheart monitor is paired with iViz, you can access it during a scan by selecting **ECG 12** from the **Exam Type** drop-down menu.

ECG information gathered by the Smartheart device can be either sent to your email address or imported as an image into an iViz patient study.

To clean and disinfect Smartheart, refer to the manufacturer's instructions.

To order Smartheart, contact your FUJIFILM SonoSite representative.

To set up Smartheart

Before you begin, check that the iViz system is connected to your wireless network. If it is connected, the  symbol appears in the upper right of the iViz screen. To connect to a wireless network, see **"Connecting to a wireless network"** on page 17.

1 On the iViz system, tap the **Smartheart** app to open it.

2 If necessary, follow the instructions in the **Smartheart** app for pairing your iViz system to the Smartheart device.

3 Log in to the **Smartheart** app.

To use Smartheart

1 In Scan mode, open the **Exam Type** drop-down menu, and then tap **EKG12**.

The **Smartheart** app opens.

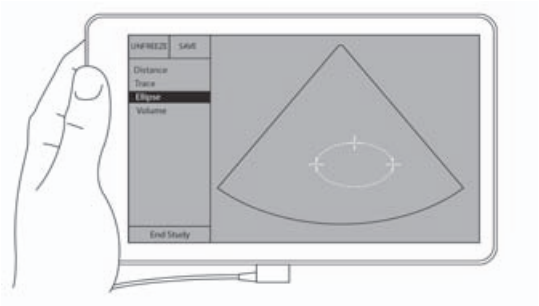
2 Follow the on-screen instructions to start the ECG.

3 When the ECG is finished, you can do one of the following:

- Use the **Smartheart** app to send the results in email.
- Save the ECG results to the iViz patient study.

To save ECG results to the patient study

1 When the ECG is complete, on the **ECG results** screen, open the **Shortcuts** drop-down menu by swiping down from the upper left corner of the iViz screen.



2 Tap  to capture an image of the results and save it to memory.

The iViz system returns to the current exam.

3 To see the ECG results, in the exam, tap the patient name above the image (see **"Reviewing an image or clip"** on page 61).

Chapter 8: Measurement References

This chapter 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 with one place past the decimal point if the measurement is 10 or greater and two places past the decimal point if the measurement is less than 10.

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

Table 8-2: 2D Measurement Accuracy and Range

2D Measurement Accuracy and Range	System Tolerance[a]	Accuracy By	Test Method[b]	Range (cm)
Axial Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-26 cm
Lateral Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-35 cm
Diagonal Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-44 cm
Area[c] The area accuracy is defined using the following equation:% tolerance = ((1 + lateral error) * (1 + axial error) – 1) * 100 + 0.5%.	< ±4% plus (2% of full scale/smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-720 cm2
Circumference[d] The circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation: % tolerance = (2 (maximum of 2 errors) * 100) + 0.5%.	< ±3% plus (1.4% of full scale/ smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-96 cm

Table 8-3: M Mode Measurement and Calculation Accuracy and Range

M Mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Distance	< +/- 2% plus 1% of full scale[a]	Acquisition	Phantom[b]	0-26 cm
Time	< +/- 2% plus 1% of full scale[c]	Acquisition	Phantom[d]	0.01-10 sec
Heart Rate	< +/- 2% plus (Full Scale[e] * Heart Rate/100)%	Acquisition	Phantom[f]	5-923 bpm

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

[b]An RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.

[c]The area accuracy is defined using the following equation:
% tolerance = ((1 + lateral error) * (1 + axial error) – 1) * 100 + 0.5%.

[d]The circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation:
% tolerance = (2 (maximum of 2 errors) * 100) + 0.5%.

[e]Full scale for time implies the total time displayed on the scrolling graphic image.

[f]FUJIFILM SonoSite special test equipment was used.

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.

Cardiac references

Body Surface Area (BSA) in m^2

Grossman, W. Cardiac *Catheterization and Angiography*. Philadelphia: Lea and Febiger, (1980), 90.

$BSA = 0.007184 * Weight^{0.425} * Height^{0.725}$
Weight = kilograms
Height = centimeters

Cardiac Index (CI) in l/min/m^2

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd Edition, Boston: Little, Brown and Company, (1999), 59.

CI = CO/BSA
where: CO = Cardiac Output
BSA = Body Surface Area

Cardiac Output (CO) in l/min

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 59.

CO = (SV * HR)/1000
where: CO = Cardiac Output
SV = Stroke Volume
HR = Heart Rate

Cross Sectional Area (CSA) in cm^2

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 383.

$CSA = 0.785 * D^2$
where: D = diameter of the anatomy of interest

Ejection Fraction (EF), percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 40.

EF = ((LVEDV – LVESV)/LVEDV) * 100%
where: EF = Ejection Fraction
LVEDV = Left Ventricular End Diastolic Volume
LVESV = Left Ventricular End Systolic Volume

Heart Rate (HR) in bpm

HR = 3 digit value input by user or measured on M Mode and Doppler image in one heart cycle

Interventricular Septum (IVS) Fractional Thickening, percent

Laurenceau, J. L., M.C. Malergue. *The Essentials of Echocardiography*. Le Hague: Martinus Nijhoff, (1981), 71.

IVSFT = ((IVSS – IVSD)/IVSD) * 100%
where: IVSS = Interventricular Septal Thickness at Systole
IVSD = Interventricular Septal Thickness at Diastole

Left Atrium/Aorta (LA/Ao)

Teichholz, L.E., T. Kreulen, M.V. Herman, et. al. "Problems in echocardiographic volume determinations: echocardiographic□angiographic correlations in the presence or absence of asynergy." *American Journal of Cardiology*, (1976), 37:7.

$LVESV = (7.0 * LVDS^3)/(2.4 + LVDS)$
where: LVESV = Left Ventricular End Systolic Volume
LVDS = Left Ventricular Dimension at Systole
LVEDV = (7.0 * LVDD3)/(2.4 + LVDD)
where: LVEDV = Left Ventricular End Diastolic Volume
LVDD = Left Ventricular Dimension at Diastole

Left Ventricular Mass in gm

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd Edition, Boston: Little, Brown and Company, (1999), 39.

LV Mass = 1.04 [(LVID + PWT + IVST)3 – LVID3] * 0.8 + 0.6
where: LVID = Internal Dimension
PWT = Posterior Wall Thickness
IVST = Interventricular Septal Thickness
1.04 = Specific gravity of the myocardium
0.8 = Correction factor

Left Ventricular Volume: Biplane Method in ml

Schiller, N.B., P.M. Shah, M. Crawford, et.al. "Recommendations for Quantitation of the Left Ventricle by Two□ Dimensional Echocardiography." *Journal of American Society of Echocardiography*. September□October 1989, 2:362.

$$V = \left(\frac{\pi}{4}\right) \sum_{i=1}^{n} a_i b_i \left(\frac{L}{n}\right)$$

where: V = Volume in ml
a = Diameter
b = Diameter
n = Number of segments (n=20)
L = Length
i = Segment

Left Ventricular Volume: Single Plane Method in ml

Schiller, N.B., P.M. Shah, M. Crawford, et.al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *Journal of American Society of Echocardiography*. September-October 1989, 2:362.

where: V = Volume
a = Diameter
n = Number of segments (n=20)
L = Length
i = Segment

Left Ventricular Dimension (LVD) Fractional Shortening, percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. Boston: Little, Brown and Company, (1994), 43-44.

LVDFS = ((LVDD – LVDS)/LVDD) * 100%

where: LVDD = Left Ventricle Dimension at Diastole
LVDS = Left Ventricle Dimension at Systole

Left Ventricular Posterior Wall Fractional Thickening (LVPWFT), percent

Laurenceau, J. L., M.C. Malergue. *The Essentials of Echocardiography*. Le Hague: Martinus Nijhoff, (1981), 71.

LVPWFT = ((LVPWS – LVPWD)/LVPWD) * 100%

where: LVPWS = Left Ventricular Posterior Wall Thickness at Systole
LVPWD = Left Ventricular Posterior Wall Thickness at Diastole

Stroke Index (SI) in cc/m^2

Mosby's Medical, Nursing, & Allied Health Dictionary, 4th ed., (1994), 1492.

SI = SV/BSA

where: SV = Stroke Volume
BSA = Body Surface Area

Stroke Volume (SV) 2D and M Mode in ml

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual.* 2nd ed., Boston: Little, Brown and Company, (1994), 44.

SV = (LVEDV – LVESV)

where: SV = Stroke Volume
LVEDV = End Diastolic Volume
LVEDSV = End Systolic Volume

Obstetrical references

Amniotic Fluid Index (AFI)

Jeng, C. J., et al. "Amniotic Fluid Index Measurement with the Four Quadrant Technique During Pregnancy." *The Journal of Reproductive Medicine*, 35:7 (July 1990), 674-677.

Average Ultrasound Age (AUA)

The system provides an AUA derived from the component measurements from the measurement tables.

Estimated Date of Delivery (EDD) by Average Ultrasound Age (AUA)

Results are displayed as month/day/year.

EDD = system date + (280 days – AUA in days)

Estimated Date of Delivery (EDD) by Last Menstrual Period (LMP)

The date entered into the patient information for LMP must precede the current date.

Results are displayed as month/day/year.

EDD = LMP date + 280 days

Estimated Fetal Weight (EFW)

Hadlock, F., et al. "Estimation of Fetal Weight with the Use of Head, Body, and Femur Measurements, A Prospective Study." *American Journal of Obstetrics and Gynecology*, 151:3 (February 1, 1985), 333-337.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 154.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 103-105.

Shepard M.J., V. A. Richards, R. L. Berkowitz, et al. "An Evaluation of Two Equations for Predicting Fetal Weight by Ultrasound." *American Journal of Obstetrics and Gynecology*, 142:1 (January 1, 1982), 47-54.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 880, Equation 1.

Gestational Age by Last Menstrual Period (LMP)

The gestational age is derived from the LMP date entered on the patient information form.

Results are displayed in weeks and days, and is calculated as follows:

GA(LMP) = System date – LMP date

Gestational Age (GA) by Last Menstrual Period (LMPd)

Same as GA by EDD.

The gestational age derived from the system derived LMP using the Established Due Date entered on the patient form.

Results are displayed in weeks and days, and is calculated as follows:

GA(LMPd) = System Date – LMPd

Gestational age tables

Abdominal Circumference (AC)

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 885.

WARNING The gestational age calculated by your FUJIFILM SonoSite system does not match the age in the aforementioned reference at the 20.0 cm and 30.0 cm abdominal circumference (AC) measurements. The implemented algorithm extrapolates the gestational age from the slope of the curve of all table measurements, rather than decreasing the gestational age for a larger AC measurement indicated in the referenced table. This results in the gestational age always increasing with an increase in AC.

Biparietal Diameter (BPD)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), 174-179, Table 3.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 440.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 98.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 885.

Cisterna Magna (CM)

Mahony, B.; P. Callen, R. Filly, and W. Hoddick. "The fetal cisterna magna." *Radiology*, 153: (December 1984), 773-776.

Crown Rump Length (CRL)

Hadlock, F., et al. "Fetal Crown-Rump Length: Re-evaluation of Relation to Menstrual Age (5-18 weeks) with High-Resolution, Real-Time Ultrasound." *Radiology*, 182: (February 1992), 501-505.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 439.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 20 and 96.

Tokyo University. "Gestational Weeks and Computation Methods." *Ultrasound Imaging Diagnostics*, 12:1 (1982-1), 24-25, Table 3.

Femur Length (FL)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), 174-179, Table 8, 186.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 101-102.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 886.

Fetal Trunk Cross-Sectional Area (FTA)

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 99-100.

Gestational Sac (GS)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986).

Nyberg, D.A., et al. "Transvaginal Ultrasound." *Mosby Yearbook*, (1992), 76.

> Gestational sac measurements provide a fetal age based on the mean of one, two, or three distance measurements; however, Nyberg's gestational age equation requires all three distance measurements for an accurate estimate.

Tokyo University. "Gestational Weeks and Computation Methods." *Ultrasound Imaging Diagnostics*, 12:1 (1982-1).

Head Circumference (HC)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), 174-191, Table 5, 182.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

Humerous (HL)

Jeanty, P.; F. Rodesch; D. Delbeke; J. E. Dumont. "Estimate of Gestational Age from Measurements of Fetal Long Bones." *Journal of Ultrasound in Medicine*. 3: (February 1984), 75-79

Occipito-Frontal Diameter (OFD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

Tibia

Jeanty, P.; F. Rodesch; D. Delbeke; J. E. Dumont. "Estimate of Gestational Age from Measurements of Fetal Long Bones." *Journal of Ultrasound in Medicine*. 3: (February 1984), 75-79.

Transverse Trunk Diameter (TTD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

Growth analysis tables

Abdominal Circumference (AC)

Chitty, Lyn S. et al. "Charts of Fetal Size: 3. Abdominal Measurements." *British Journal of Obstetrics and Gynaecology* 101: (February 1994), 131, Appendix: AC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P., E. Cousaert, and F. Cantraine. "Normal Growth of the Abdominal Perimeter." *American Journal of Perinatology*, 1: (January 1984), 129-135.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 179, Table 7.13.)

Biparietal Diameter (BPD)

Chitty, Lyn S. et al. "Charts of Fetal Size: 2. Head Measurements." *British Journal of Obstetrics and Gynaecology* 101: (January 1994), 43, Appendix: BPD-Outer-Inner.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P., E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 176, Table 7.8.)

Estimated Fetal Weight (EFW)

Brenner, William E.; D. A. Edelman; C. H. Hendricks. "A standard of fetal growth for the United States of America," *American Journal of Obstetrics and Gynecology,* 126: 5 (November 1, 1976), 555-564; Table II.

Hadlock F., et al. "In Utero Analysis of Fetal Growth: A Sonographic Weight Standard." *Radiology*, 181: (1991), 129-133.

Jeanty, Philippe, F. Cantraine, R. Romero, E. Cousaert, and J. Hobbins. "A Longitudinal Study of Fetal Weight Growth." *Journal of Ultrasound in Medicine*, 3: (July 1984), 321-328, Table 1.

(Also published in Hansmann, Hackeloer, Staudach, and Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 186, Table 7.20.)

Femur Length (FL)

Chitty, Lyn S. et al. "Charts of Fetal Size: 4. Femur Length." *British Journal of Obstetrics and Gynaecology* 101: (February 1994), 135.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 182, Table 7.17.)

Head Circumference (HC)

Chitty, Lyn S., et al. "Charts of Fetal Size: 2. Head Measurements." *British Journal of Obstetrics and Gynaecology* 101: (January 1994), 43, Appendix: HC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A longitudinal study of Fetal Head Biometry." *American J of Perinatology*, 1: (January 1984), 118-128, Table 3.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 176, Table 7.8.)

Head Circumference (HC)/Abdominal Circumference (AC)

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," *British Journal of Obstetrics and Gynaecology*, 84: (March 1977), 165-174.

Ratio calculations

FL/AC Ratio

Hadlock F.P., R. L. Deter, R. B. Harrist, E. Roecker, and S.K. Park. "A Date Independent Predictor of Intrauterine Growth Retardation: Femur Length/Abdominal Circumference Ratio," *American Journal of Roentgenology*, 141: (November 1983), 979-984.

FL/BPD Ratio

Hohler, C.W., and T.A. Quetel. "Comparison of Ultrasound Femur Length and Biparietal Diameter in Late Pregnancy," *American Journal of Obstetrics and Gynecology*, 141:7 (Dec. 1 1981), 759-762.

FL/HC Ratio

Hadlock F.P., R. B. Harrist, Y. Shah, and S. K. Park. "The Femur Length/Head Circumference Relation in Obstetric Sonography." *Journal of Ultrasound in Medicine*, 3: (October 1984), 439-442.

HC/AC Ratio

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," *British Journal of Obstetrics and Gynaecology*, 84: (March 1977), 165-174.

Chapter 9: Troubleshooting and Maintenance

Troubleshooting

Use the information in this section to help diagnose and correct problems with the system.

Common problems

Included here are some of the problems most frequently encountered by users.

- **System does not start.** Press and hold the **Power** button until the white LED illuminates (usually within five seconds). If the LED does not illuminate, replace the battery with a charged battery, and place the removed battery on the battery charger.

- **Cannot switch to M Mode.** To switch from 2D to M Mode (and back again), you need to press and hold **2D** for at least one second, or until the imaging mode changes.

  For more information about the controls available in M Mode, see **"Scanning in M Mode"** on page 48.

- **Having trouble saving a clip.** While scanning, press and hold **SAVE** for one second. The button shows a blue progress bar, which represents the clip recording length that was set up in **Preferences** (see **"Configuring preferences"** on page 21).

  To stop recording the clip, tap **SAVE**.

Understanding error messages.

There are three types of errors to help you troubleshoot problems with iViz:

- LED errors on the iViz battery charger
- LED errors on the iViz system
- Error messages displayed on the iViz screen

Battery charger LED errors

The battery charger uses its LEDs to indicate the battery charging status. There is an LED next to each battery bay.

Table 9: Battery charger behavior

LED Behavior	Condition
Blinking green	Battery is charging.
Green	Battery is fully charged.
Amber	Battery is very low. Wait 60 seconds, then do one of the following: • Press the **Power** button. • Unplug the battery charger, wait a few moments, and then reconnect the battery charger. • Remove and re-insert the battery. After a few seconds, the light should change to blinking or steady green.
Red	Bad battery pack. Replace the battery.

System LED function

When the system is not actively operating, you can check the LED to determine the status of the unit.

Table 10: System LED behavior

LED Behavior	Condition
Steady blue	Indicates that the battery very low. If the LED is blue, wait 60 seconds and then do one of the following: • Press the **Power** button. • Remove and re-insert the charger. • Remove and re-insert the battery. After a few seconds, the LED should change to blinking or steady green. If it does not, either keep it in the unit with the charger for 30 minutes, or take the battery out, place it into the battery charger, and put a charged battery in the system.
Steady white	Indicates one of the following: • The system is starting. Once the system is operating, the LED turns off. • The system is waking from sleep mode. Once the system is operating, the LED turns off. • The system is off, and the USB charger is connected to both the system and an outlet. The LED will then turn green to indicate it is charging.
Blinking green	Indicates that the system is connected to the USB charger and charging the battery.

Table 10: System LED behavior

LED Behavior	Condition
Steady green	Indicates that the system is connected to the USB charger, and the battery is fully charged.

System Error messages

The error messages displayed on the iViz screen can be classified as either hardware- or software-related.

Hardware-related errors are usually indicated by an error message. Use the following table to identify hardware-related errors and their remedies.

Table 11: System error messages

Error message	Remedy
The signal path has stopped because the transducer is not connected.	Reattach the transducer. Note that it is important to end an exam before disconnecting the transducer.
The temperature sensor is not working, either in the transducer or the system.	Disconnect and reattach the transducer, and try again.
The system temperature is too high.	Turn off the system, and allow it to cool for 10 minutes before turning it on again.
The transducer temperature is too high.	Turn off the system, and disconnect the transducer. Allow the transducer to cool for 10 minutes, and try again.

Software-related errors typically display an error message on the screen.

If the system displays a software error

1 Stop the scan, and return to the Home screen.

2 From the Home screen, tap **Scan** or **Patient** to see if the system has recovered.

If the error persists or another error appears

1 Install a fully charged battery.

2 Press the **Power** button to turn on the system.

3 If the system powers on normally, it has recovered from the fault, and you may use your system.

If the error persists

1 Write down the error message.

2 Press and hold the **Power** button.

3 When prompted, tap **Power off**, and then **OK**.

4 Contact FUJIFILM SonoSite Technical Support for assistance. See **"Getting help"** on page 2.

5 Tell Technical Support what the error message said, the conditions under which it appeared, and what actions you took as a result.

Troubleshooting connectivity problems

To troubleshoot connectivity problems

1 Verify all pertinent connectivity settings (such as wireless network, IP, and AE Title) are correct. For more information, see **"Connecting to a wireless network"** on page 17.

2 Contact your network administrator.

3 Contact FUJIFILM SonoSite Technical Support. For more information, see **"Getting help"** on page 2.

DICOM common problems

iViz DICOM FAQ

- **How do I know my exam/study was successfully transferred to the DICOM archive?** After you finish transferring the exam or study, tap the **Refresh** button in the top right corner to refresh the screen. If the transfer was successful, the word **Archived** appears in the **Status** column.

- **When transferring DICOM data to a USB storage device, how do I know when I can remove the device?** As soon as the USB transfer is complete, the message **DICOM studies transferred successfully** appears in the top left part of the screen. You may also see a message that says **Studies transferred successfully**. When either of these messages appear, you can safely remove the USB storage device.

- **How do I know if my images/clips have been emailed successfully?** The message **DICOM studies transferred successfully** appears in the upper left part of the screen as soon as the email transfer is complete.

- **How do I know if my report was successfully transferred to the EMR?** When the transfer to the EMR is complete, the message **Report sent to EMR** appears.

- **How many scheduled worklist procedures can I query and view at one time?** iViz can display up to 100 procedures.

- **Does iViz support DICOM Print?** DICOM Print is not supported at this time.

- **Does iViz support DICOM Storage Commitment service?** The DICOM Storage Commitment service is not supported at this time.

Troubleshooting DICOM connectivity

1 To check if the system can communicate on the network with the target DICOM device, on the **Archive** tab, tap **Ping**. A ping may fail even if you are connected to a DICOM device.

2 To verify that the system can communicate through DICOM messages with the target DICOM device, on the **Archive** tab, tap **Verify**.

   If you are able to successfully ping and verify the DICOM device but are still having problems, detailed troubleshooting is required. If either the **Ping** or **Verify** command fails, verify your DICOM configuration:

   a Check your iViz profile settings

      i Tap **iViz Settings**.

      ii Tap **DICOM Configuration**.

      iii Tap the current DICOM profile. The **General** tab displays.

      iv Verify that the AE title, IP address, and port number exactly match the settings specified by your administrator for iViz.

   b Check your Archiver settings.

      i Tap the **Archive** tab.

      ii Verify that the AE title, IP address, and port number exactly match the settings specified by your administrator for the desired archiver.

      iii Verify that the desired archiver is active.

      iv Repeat these verifications for each archiver that is in use.

   c Check your Worklist settings.

      i Tap the **Worklist** tab.

      ii Verify the AE title, IP address, and port number exactly match the settings specified by your administrator for the desired worklist.

      iii Verify that the desired worklist is active.

3 Contact your DICOM/ PACS/ network administrators for troubleshooting assistance. Ask the administrator for assistance with gathering a DICOM log file or network packet capture log documenting the connectivity issue between iViz and the DICOM device.

4 Contact FUJIFILM SonoSite Technical Support. For more information, see **"Getting help"** on page 2.

5 Have the following information available:

   - A description of the DICOM connectivity error

- The DICOM log file or network packet capture documenting the connectivity issue
- Configuration settings specified by your administrator for the iViz
- Configuration settings specified by your administrator for the DICOM device
- Configuration settings specified by your administrator for the wireless network connection.

Note Because iViz does not log or display detailed status information for DICOM events, the information required to perform this troubleshooting is not available on the iViz system. To further investigate and resolve the issue, your DICOM/ PACS administrator must assist you with gathering the necessary information.

Maintenance

No periodic or preventive maintenance is required for the system, transducer, or accessories other than cleaning and disinfecting the transducer after every use. (See **"Chapter 10, "Cleaning and Disinfecting."**) There are no internal components that require periodic testing or calibration. All maintenance requirements are described in this user guide. Performing maintenance procedures not described in the user guide may void the product warranty.

Contact FUJIFILM SonoSite Technical Support for any maintenance questions.

Over the air upgrades

You can upgrade your iViz system through the wireless functionality on the system (in all countries except Japan).

To upgrade iViz

1. Plug the system into the USB charger.
2. Connect to Wi-Fi; see **"Connecting to a wireless network"** on page 17.
3. From the Android **Settings** screen, tap **About iViz**.
4. Tap **Updates**.
5. To check for an update, tap **Refresh** in the upper right corner of the screen.
6. Tap the download icon next to **update**.
7. At the **Apply update** screen, tap **Update**. The system will reboot to recovery mode and apply the updates. This may take a few minutes.

   When the updates are complete, the system will automatically reboot.

8 To check the iViz version number, from the Android **Settings** screen, tap **About iViz**. The version number appears under **iViz version**.

iViz performance testing

Overview

WARNING: **Critical Test Function** - A failure of the system functions tested in this section could adversely affect safety or the effectiveness of the system. While performing the steps below, verify that the images on the system display are acceptable.

To obtain 2D images, SonoSite recommends using the Gammex 403GS Soft Tissue Phantom or the Gammex 413A Multipurpose Phantom. A .7db/cm phantom is recommend but not required.

Some features and capabilities are optional; therefore, they may be unavailable to test.

Recommended test equipment

- SonoSite ultrasound system under test
- P21v/5-1 MHz transducer
- Gammex 403 GS Multipurpose Phantom, 413A Soft Tissue Phantom, or equivalent
- Acoustic gel

Functional acceptance

To perform a functional acceptance test

1 Insert a system battery pack, and turn on the system. (See **"Turning on iViz"** on page 15.)

2 Verify that the system boots up to the normal display.

3 Verify that the system display shows the proper boot-up images and that the battery charge indicator displays the battery charge.

4 Verify that the proper date and time are displayed.

5 Connect the P21v/5-1 MHz transducer to the system.

6 Verify that the transducer connection icon appears in the upper left corner of the screen.

7 Tap **Scan**.

8 Verify that the system starts imaging.

9 Verify that the system is in **2D** mode.

10 Verify that as the Gain controls are increased and decreased, and that there is a corresponding increase and decrease in echo intensity in the sector display.

11 Verify that the scan plane orientation mark in the image located near the skin line corresponds to element #1 on the transducer.

- With the array pointing down and the orientation mark to the operator's left, element #1 corresponds with the left side of the array.
- This can be tested by putting your finger on the transducer and running it across the transducer face.
- Your finger touching the transducer face as indicated above should show up near the orientation mark in the image on the monitor.

12 Tap **SAVE** to capture an image.

13 Verify that the system shows that the image was saved.

14 Press and hold **SAVE** for one second to capture a clip.

15 Verify that the system saved the clip.

2D performance tests

2D image quality

To test for 2D image quality

1 Connect a P21v/5-1 MHz transducer in **2D** mode.

2 Adjust the position of the transducer on the phantom.

3 With the array pointing down and the orientation mark to the operator's left, ensure element #1 corresponds with the left side of the array.

4 Use the **2D** imaging mode controls to obtain a clear image that shows both the horizontal and vertical rows of pins.

5 Verify that the ultrasound image appears uniform in both the axial and lateral directions, with no dropouts or intensity variations.

6 Verify that the cystic structure at the focal zone is clearly differentiated from the surrounding tissue and is echo-free, while solid tissue with numerous echo sources appears solid.

7 Tap **Freeze**, and save the image.

8 Press **Freeze** again to return to live imaging.

Axial measurement accuracy

Note | Measurements must be performed while the image is frozen.

To perform an axial measurement accuracy test

1 Acquire the image.

2 Freeze the image.

3 Tap **Measurements**.

4 Tap **General**.

5 Tap **Distance**. A caliper appears on the image display.

6 Drag the caliper to position it over the center of the pins to be measured.

7 Measure the distance, center to center, of any two pins that are 5-12 cm apart vertically.

8 Verify that the distance measured is within the tolerance listed in **Table 12, "System measurement accuracy tolerance"** on page 102.

Lateral Measurement Accuracy

Note | Measurements must be performed while the image is frozen.

To perform a lateral measurement accuracy test

1 Acquire the image.

2 Freeze the image.

3 Tap **Measurements**.

4 Tap **General**.

5 Tap **Distance**. A caliper appears on the image display.

6 Drag the caliper to position it over the center of the pins to be measured.

7 Measure the distance, center to center, of any two pins that are 4-10 cm apart horizontally.

8 Verify that the distance measured is within the tolerance listed in **Table 12, "System measurement accuracy tolerance"** on page 102.

Table 12: System measurement accuracy tolerance

Measurements	Tolerance
Axial Distance	+/-2%
Lateral Distance	+/-2%

2D Penetration

The penetration measurement is an integral part of the quality assurance program. Penetration is defined as the deepest depth at which an ultrasound system can provide adequate image quality of small anatomical structures.

Penetration measurements should be performed and the results retained for comparison to future measurements. Penetration measurements should remain fairly consistent over time assuming use of the same system settings and scan head. Degradation of the penetration measurement in excess of 1cm may indicate a transducer or system electronics issue.

Loss of measured penetration may also be caused by degradation (dessication) of the ultrasound phantom. Ultrasound phantoms used for penetration measurements must also be part of a quality assurance program to maintain their integrity. Follow all of the phantom manufacturer recommendations for use, storage, and maintenance of the phantom.

To perform a 2D penetration test

1 Use the same scan head and system settings as previous measurements, if possible.

2 Adjust the system controls to obtain a clear image that shows the limits of echo penetration.

3 Tap **Freeze** and then **SAVE**.

4 Measure from the center of the skin line to the deepest vertical position: where the scatter echoes start to break up and tissue definition is lost.

5 Record and retain the results for future reference. Record scan head type and system settings (such as exam type, depth, and resolution mode) to ensure proper comparison with future tests.

6 Tap **Freeze** again to return to live imaging.

Additional performance tests

Color Doppler (Color)

To perform a color test

1 Start in **2D** imaging with the P21x/5-1 MHz transducer connected.

2 On the control wheel, tap **Color**. A Region of Interest (ROI) box is displayed on top of the gray scale image.

3 Touch and drag the Color ROI box to a new position.

4 Verify that the ROI box moves to the new position on the display.

5 On the control wheel, adjust the **Depth** for minimum depth in the image.

6 Adjust the **Gain** so that color speckles just appear inside the ROI box.

7 Gently tap the face of the transducer and observe that the ROI box fills with color information.

M Mode imaging

To perform an M Mode imaging test

1 Start in **2D** imaging with the P21x/5-1 MHz transducer connected.

2 Tap and hold the **2D** button to switch to **M Mode**. An M Mode sample line displays on top of the gray scale image.

3 Touch and drag the M Mode sample line to a new position.

4 Verify that the sample line moves to the new position on the display.

5 Tap **Update** to activate scrolling M Mode.

6 Verify that scrolling M Mode displays correctly.

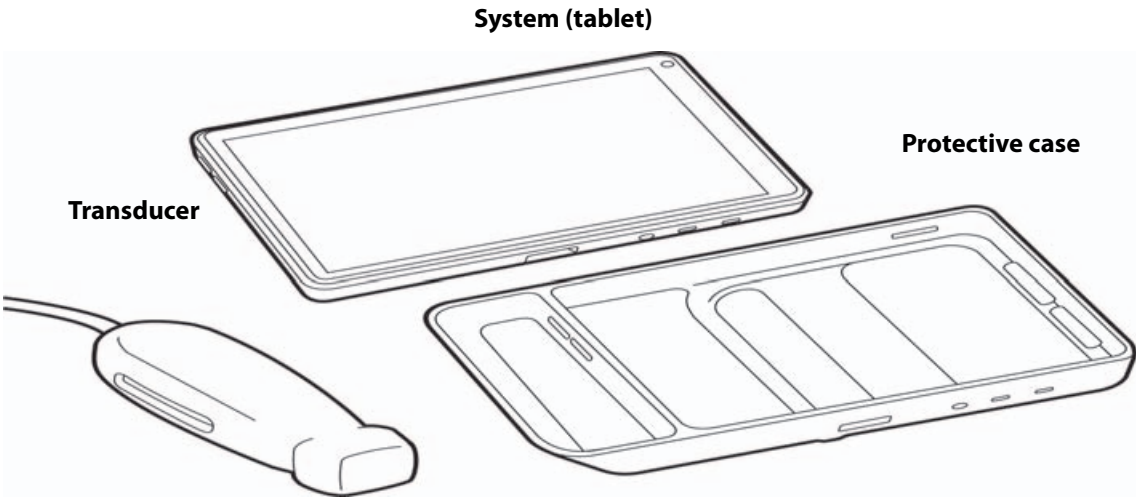
Image quality verification test/livescan

- The image quality verification test/livescan should be performed after successfully completing all applicable performance tests listed prior in this chapter.
- The test is completed before returning the system to service.
- A certified sonographer must perform the test.

- The livescan test performed is at the discretion of the sonographer and will represent their acceptance of a successful service event.

Chapter 10: Cleaning and Disinfecting

The iViz ultrasound system consists of the system (tablet), protective case, and transducer.



This section includes instructions for cleaning and disinfecting the iViz ultrasound system. The system must be cleaned and disinfected after each exam. It is important to follow this cleaning and disinfection process without shortening or skipping steps. Only use cleaners and disinfectants approved by FUJIFILM SonoSite on the iViz system. Be sure to observe the solution strength and duration requirements detailed in the cleaning and disinfection procedures.

Included in this section are instructions for two levels of cleaning and disinfection for both the transducer and the system. The level of cleaning and disinfection required depends on the type of tissue the system comes into contact with during an exam. For more information, see **"Cleaning and disinfecting the system and protective case"** on page 106.

The materials used in the iViz system are designed and tested to work with the cleaners and disinfectants listed in this chapter. The iViz system will not be damaged if cleaned according to the approved instructions and with the approved cleaners and disinfectants. Before using a disinfectant, confirm that it is appropriate for your facility's use. Verify expiration dates, concentration, and efficacy of chemicals (for example, a chemical strip test).

When preparing, using, and disposing of chemicals, be sure to follow manufacturer recommendations and local regulations.

WARNING Residual chemicals from some disinfectants can cause an allergic reaction in some individuals.

Cautions

- Follow the manufacturer's cleaning label instructions for solution strengths and disinfectant contact duration.
- Check the expiration date on all cleaning and disinfection solutions and wipes. Do not use chemicals or wipes that have expired.
- Do not allow cleaning solution or disinfectant into the battery compartment, system controls, or transducer connector.
- Do not use strong solvents, such as thinner or benzene, or abrasive cleansers since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.
- Use only a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any disinfectant on metal surfaces.

Cleaning and disinfecting the system and protective case

The following procedures can be used to clean and disinfect the system, protective case, and transducer.

Caution Do not immerse the system or the protective case in any liquid.

To clean the system and protective case

1. Make sure the system is turned off.
2. Disconnect the transducer.
3. Remove the system from the protective case.
4. Using a soft, damp cloth (dampened with cleaner or disinfectant) or a premoistened disinfectant wipe, clean any particulate matter or bodily fluids from all system and protective case surfaces.
   - Be sure to use only cleaners listed in **Table 10-2** on page 108.

- Wipe from clean areas to the soiled areas to avoid cross-contamination.

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

Cautions

- Do not spray cleaners or disinfectants directly on the system surfaces. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- Do not allow moisture to get on the transducer connector or into the connector ports on the system.
- Do not scratch the display screen.

5 Verify that all gel, particulate matter, and bodily fluids have been removed.

Note Repeat steps 4-5 with new cleaning materials, if necessary.

To disinfect the system and protective case

1 Wipe all surfaces with a premoistened wipe or a cloth moistened with a compatible disinfectant listed in **Table 10-2, "Compatible cleaners and disinfectants"** on page 108.

- Apply the disinfectant solution to the cloth rather than applying it directly to surfaces.
- Follow the chemical manufacturer's requirements for wet contact time.

Caution Use only FUJIFILM SonoSite recommended disinfectants. Using a non-recommended disinfect solution or incorrect solution strength can damage or discolor the transducer and void the transducer warranty.

2 Allow the system to air dry following the chemical manufacturer's requirements for wet contact time.

Cleaning and disinfecting the transducer

Cleaning and disinfecting the transducer requires that you chose the proper cleaning and disinfecting level.

Determining the required cleaning and disinfection level

Before cleaning, visually inspect the ultrasound system to determine that it is 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.

Spaulding classifications are a tool to help reduce cross-contamination and infection by specifying the level of cleaning and disinfecting required for your medical equipment. The Spaulding classification is based on the type of device, its usage, and the risk of infection. Based on these criteria, the iViz ultrasound system is classified as either non-critical or semi-critical, depending on how it is used.

Each Spaulding classification mandates a specific level of cleaning and disinfection of the equipment before it can be used in the next exam. Use the following guide to determine the level of cleaning and disinfection for the iViz ultrasound system according to the appropriate Spaulding classification.

Table 10-1: Cleaning and disinfection guidelines

If any part of the system came into contact with...	Then disinfect to the following level
Unbroken skin, no blood or bodily fluids (non-critical)	**"Level A: Intermediate-level disinfection (non-critical)"** on page 108
Broken skin, mucosal membranes, blood, and/or bodily fluids (semi-critical)	**"Level B: High-level disinfection (semi-critical)"** on page 112

Level A: Intermediate-level disinfection (non-critical)

Clean and disinfect the system and protective case immediately after use. Be sure to follow the manufacturer's instructions when using cleaners and disinfectants. See **"Cleaning and disinfecting the system and protective case"** on page 106.

For non-critical disinfection, clean the transducer as described in **"To clean the transducer"** on page 109, and then disinfect it as described in **"To disinfect the transducer"** on page 110.

If the transducer has come into contact with broken skin, mucosal membranes, or blood, you must then do a high-level disinfection; see **"Level B: High-level disinfection (semi-critical)"** on page 112.

The materials listed in **Table 10-2, "Compatible cleaners and disinfectants"** on page 108 are both chemically compatible and have been tested for efficacy with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

Table 10-2: Compatible cleaners and disinfectants

Product	System	Protective case	Carry case	P21 transducer
SaniCloth AF3 (Clear White Top)	✓	✓	✓	✓

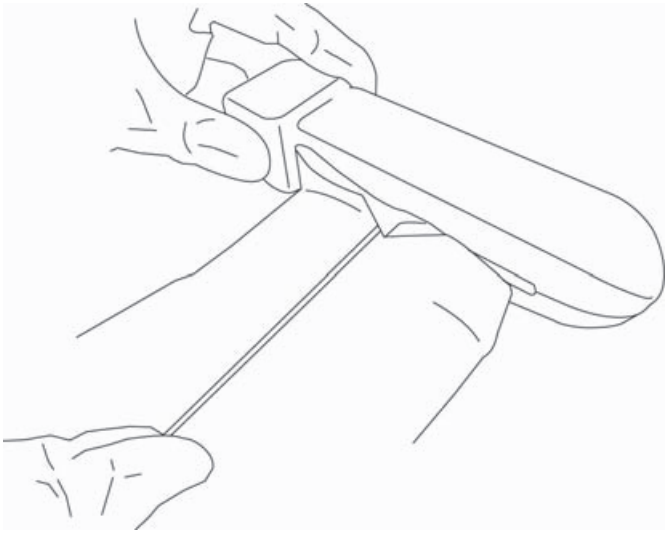
Table 10-2: Compatible cleaners and disinfectants

Product	System	Protective case	Carry case	P21 transducer
SaniCloth Bleach Wipes (Yellow Top)	✓	✓		✓
SaniCloth Plus (Red Top)	✓	✓	✓	✓
SaniCloth HB (Green Top)	✓			✓
Super SaniCloth (Purple Top)	✓		✓	
T-Spray II (PI-Spray II)	✓	✓	✓	✓

Note Proper cleaning of the slot is important because good airflow through the slot improves cooling of the transducer electronics and extends the life of the equipment.

To clean the transducer

1. Clean the transducer cord using either a soft, damp, soapy cloth or a premoistened wipe. Start at the connector and wipe toward the scan head. Do not get any water or cleaner on the connector.
2. Clean all transducer surfaces using either a soft cloth dampened with cleaner or disinfectant or a premoistened wipe. Be sure to remove any gels or particulate matter.
3. Clean the transducer cooling slot using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution or a premoistened wipe through the slot.



a Pull the cloth back and forth from one side of the slot to the other.

b Pull the cloth up and down from the transducer connector to the transducer head.

c Remove the cloth from the slot.

d Dispose of the cloth and the instrument used to insert the cloth.

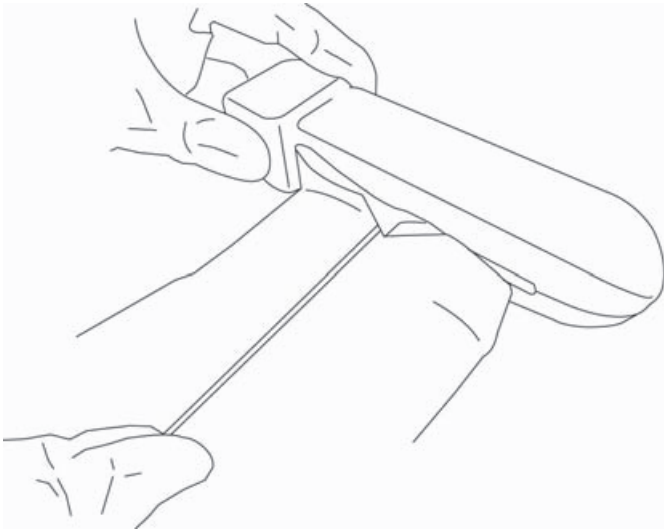
e Verify that all gel, particulate matter, and bodily fluids have been removed.

Note | Repeat Step 3 with new cleaning materials, if necessary.

To disinfect the transducer

1 Disinfect the transducer cord and body by wiping with a cloth moistened with a compatible disinfectant or premoistened disinfectant wipe. Do not get any disinfectant on the connector.

2 Disinfect the cooling slot by using a thin instrument, such as a swab, to push a disinfectant wipe into the slot.



a Pull the wipe back and forth from one side of the slot to the other.

b Pull the wipe up and down from the transducer connector to the transducer head.

c Remove the disinfecting wipe from the slot.

d Air dry.

3 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use the transducer and contact FUJIFILM SonoSite or your local representative.

Level B: High-level disinfection (semi-critical)

Clean and disinfect the transducer immediately after use.

Be sure to follow the manufacturer's instructions when using cleaners and disinfectants.

Refer to **Table 10-3, "Compatible cleaners and disinfectants"** on page 112 for a list of cleaners and disinfectants recommended for use with the transducer.

Table 10-3: Compatible cleaners and disinfectants

Product	P21 transducer
SaniCloth AF3 (Clear White Top)	✓
SaniCloth Bleach Wipes (Yellow Top)	✓
SaniCloth Plus (Red Top)	✓
Saniwipe HB (Green Top)	✓
T-Spray II (PI-Spray II)	✓

Cleaning and disinfecting the transducer

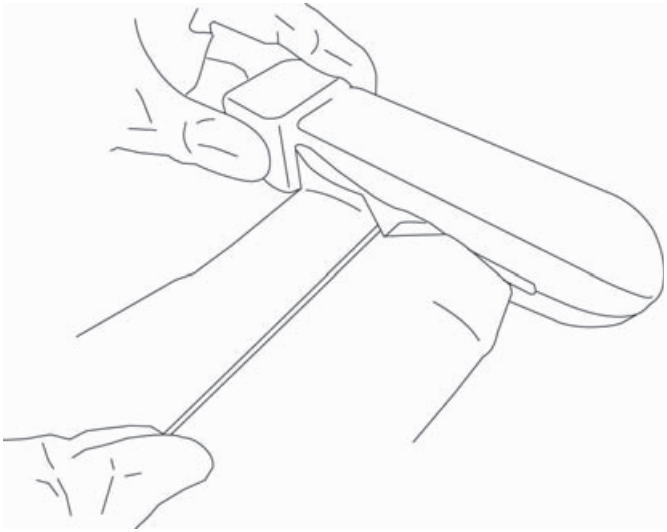
Use the following procedures to clean and disinfect the transducer.

To clean the transducer

1. Clean the transducer cord using either a cloth dampened with cleaner or disinfectant or a premoistened disinfectant wipe. Start at the connector and wipe toward the scan head. Do not get any water or cleaner on the connector.

2. Clean all transducer surfaces using either a soft, damp, soapy cloth or disinfectant wipe. Be sure to remove any gels or particulate matter.

3 Clean the transducer cooling slot using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution or premoistened wipe through the slot.



a Pull the cloth back and forth from one side of the slot to the other.

b Pull the cloth up and down from the transducer connector to the transducer head.

c Remove the cloth from the slot.

d Dispose of the cloth and the instrument used to insert the cloth.

e Verify that all gel, particulate matter, and bodily fluids have been removed.

Note Repeat Step 3 with new cleaning materials, if necessary.

To high-level disinfect the transducer

1 Mix the disinfectant solution following disinfectant label instructions for solution strengths and disinfectant contact duration.

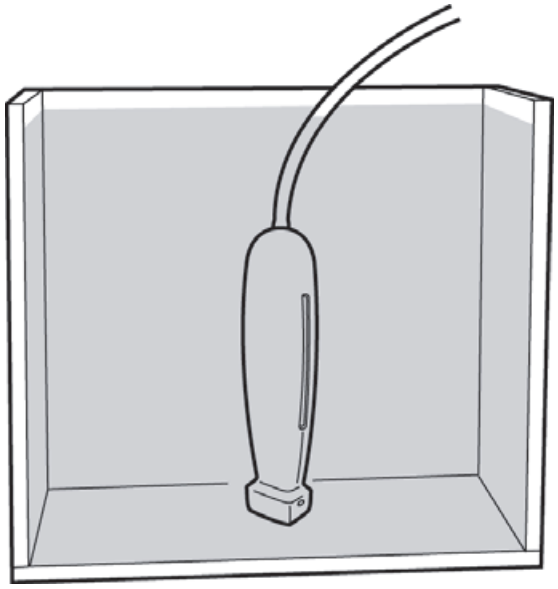
Be sure to use a compatible disinfectant as listed in **Table 10-4, "Approved high-level disinfectants and soak times"** on page 114.

Caution Use only FUJIFILM SonoSite recommended disinfectants. Using a non-recommended disinfection solution, incorrect solution strength, or immersing a transducer deeper or for a longer period of time than recommended can damage or discolor the transducer and void the transducer warranty.

2 Immerse the transducer and about two inches of the cable in the disinfectant solution.

Caution | Do not immerse the transducer connector in any liquid.

Use this diagram as a reference and then follow the instructions on the disinfectant label for the duration of the transducer immersion.



3 Using the instructions on the disinfectant label, rinse to the point of the previous immersion, and then air dry or towel dry with a clean, non-linting cloth.

4 Examine the transducer and cord for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer and contact FUJIFILM SonoSite or your local representative.

Table 10-4: Approved high-level disinfectants and soak times

Disinfectant	Temperature	Duration
Cidex	23° C, 73° F	45 minutes
Cidex OPA	23° C, 73° F	12 minutes

Cleaning the iViz carry case

To clean the iViz carry case, use mild soap and water, and wash it by hand or machine. You can also use one of the cleaners listed in the table called **"Compatible cleaners and disinfectants"** on page 108 to clean it.

Using other chemicals may cause discoloration.

Storing

Clean and disinfect the iViz ultrasound system prior to storing it.

Store the system in a clean place with good airflow. Disconnect the transducer from the system, and hang it vertically.

Transporting

When transporting the iViz ultrasound system, you must take precautions to protect the equipment from damage and avoid cross-contamination.

Clean and disinfect the system by following the instructions in **"Cleaning and disinfecting the system and protective case"** on page 106.

Be sure to transport the system in a container approved by your facility.

Disposing of the system

If the iViz ultrasound system shows damage or deterioration, such as corrosion, discoloration, pitting, or cracking, do not dispose of it. Contact FUJIFILM SonoSite or your local representative.

WARNING The battery inside this unit may explode if exposed to very high temperatures. Do not destroy this unit by incinerating or burning. Return the unit to FUJIFILM SonoSite or your local representative for disposal.

Chapter 11: Safety

This chapter contains ergonomic, electrical, and clinical safety information required by regulatory agencies. The information applies to the ultrasound system, transducer, accessories, and peripherals. This chapter also defines labeling symbols, specifications, and standards.

For safety information regarding the ALARA principle and acoustic output, see **Chapter 12, "Acoustic Output."**

Ergonomic safety

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

WARNINGS

- Use of an ultrasound system has been linked to work-related musculoskeletal disorders (WRMSDs)[1, 2, 3, 4]. To prevent musculoskeletal disorders, follow the guidelines in this section.
- When using an ultrasound system and transducer, and the transducer), you may experience occasional discomfort in your thumbs, fingers, hands, arms, shoulders, eyes, neck, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, soreness, pain, throbbing, aching, tingling, numbness, stiffness, burning sensation, muscle fatigue/ weakness, or limited range of motion, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with WRMSDs. WRMSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of WRMSDs include bursitis, tendonitis, tenosynovitis, carpal tunnel syndrome, and De Quervain syndrome.[1]
- While researchers are not able to definitively answer many questions about WRMSDs, there is a general agreement that certain factors are associated with their occurrence including preexisting medical and physical conditions, overall health, equipment and body position while performing work, frequency of work, and duration of work. This chapter provides guidelines that may help you work more comfortably and reduce your risk of WRMSDs.

Caution

To avoid injury while using the kickstand on the protective case:

- Be careful when closing the kickstand so you don't pinch yourself.
- Although the protective case is rubberized to prevent slipping, do not lean on it; the kickstand is not designed to support weight beyond the system itself.
- Be sure to place iViz on a flat surface when using the kickstand.

Minimize eye and neck strain

- Adjust the system to minimize screen glare.
- Adjust the room lighting to reduce eye strain.
- Maintain the system at chest, chin, or eye level to minimize neck strain.

Support your back during an exam

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

Minimize reaching and twisting

- Use a height-adjustable bed with controls that are readily accessible.
- Position the patient as close to you as possible.
- Locate the ultrasound system directly in front of you.
- Face forward. Avoid twisting your head or body.
- Position your scanning arm next to or slightly in front of your body.
- Stand for difficult exams to minimize reaching.

Promote comfortable shoulder and arm postures

- Keep your elbows close to your side.
- Do not hyper-extend your elbow when scanning.
- Relax your shoulders in a level position.
- Support your scanning arm using a support cushion or pillow, or rest it on the bed.
- Avoid contact stress from resting your arm on sharp corners or edges.

Employ comfortable postures

- Use a neutral wrist position when holding the ultrasound system. Avoid angling or twisting the wrist.
- Minimize thumb pressure when interacting with the thumb-operated control wheel.
- Avoid extensive use of the thumb with the control wheel. If necessary, place it on a flat surface and operate the control wheel with a finger.
- Use the handled case to reduce gripping forces needed to maintain control of the ultrasound system.

Use comfortable wrist and finger postures with transducers

- Use different grips while holding the transducer to maintain a straight (neutral) wrist position.
- Avoid excessive gripping forces by holding the transducer lightly in your fingers.
- Minimize the use of a pinch grip when holding the transducer; use a whole-hand (palmar) grip when possible.
- Minimize prolonged pressure applied to the patient.

Take breaks, exercise, and vary activities

- Minimize scanning time and take frequent breaks (at least 15 minutes for every two hours).
- Work efficiently by using the software and hardware features correctly.
- Alternate hands when holding and operating the ultrasound system.
- Keep moving. Avoid sustaining the same posture by varying your head, neck, body, arm, and leg positions.
- Do targeted exercises and stretches. Targeted exercises can strengthen muscle groups, which may help you avoid WRMSDs[5]. Contact a qualified health professional to determine stretches and exercises that are right for you.

1 Coffin, C.T. (2014). Work-related musculoskeletal disorders in sonographers: A review of causes and types of injury and best practices for reducing injury risk. *Reports in Medical Imaging, 7,* 15-26.

2 Evans, K., Roll, S., & Baker, J. (2009). Work-related musculoskeletal disorders (WRMSD) among registered diagnostic medical sonographers and vascular technologists: A representative sample. *Journal of Diagnostic Medical Sonography, 25,* 287-299.

3 National Institute for Occupational Safety and Health (2006). *Preventing work-related musculoskeletal disorders in sonography* [DHSS (NIOSH) Publication Number 2006-148]. Cincinnati, OH: Department of Health and Human Services.

4 Society of Diagnostic Medical Sonography (2003, May). *Industry standard for the prevention of work-related musculoskeletal disorders in sonography.* Plano, TX.

5 Alaniz, J, & Veile, B.L. (2013). Stretching for sonographers: A literature review of sonographer-reported musculoskeletal injuries. *Journal of Diagnostic Medical Sonography*, 29, 188-190.

System and transducer temperatures

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

WARNINGS

- Under certain circumstances, the system enclosure can reach temperatures that exceed IEC 60601-1 limits for patient contact. Make sure that only the operator handles the system. Avoid placing the iViz base unit 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 (118.4 °F), which may be harmful to the patient. Avoid touching the handle to the patient skin for extended periods of time.

Cautions

- Except for battery charging, the entire system (including the case) can operate when the ambient temperature is between 10°C (50°F) to 40°C (104°F).
- The battery can be stored at ambient temperatures between -20°C (-4°F) to 60°C (140°F).
- Charge batteries only when the ambient temperature is between 10°C (50°F) and 40°C (104°F).
- If the system shuts down because it is too hot, wait 10 minutes before turning it on again.

Electrical safety

The system meets IEC 60601-1, Class II / internally powered equipment requirements, with type BF patent applied parts.

The system complies with the standards as listed in the Standards section of this document; refer to **"Standards"** on page 141.

For maximum safety observe the following warnings and cautions.

WARNINGS

- 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 the system enclosures. All internal adjustments and replacements, except battery replacement, must be made by a qualified technician.
- To avoid the risk of electrical shock:
  - Do not allow any part of the iViz system (except for the transducer) to touch the patient.
  - Do not simultaneously touch the system battery contacts and the patient when the power supply is connected to the system.
- When connecting commercial grade peripherals to the iViz system, use only battery-powered peripherals. To avoid electric shock hazard, do not connect any AC mains powered peripherals to the system, except as recommended by FUJIFILM SonoSite. Contact FUJIFILM SonoSite or your local representative for a list of commercial grade peripherals available from or recommended by FUJIFILM SonoSite.
- To avoid the risk of electrical shock and fire hazard, inspect the power supply, AC power cords, cables, and plugs on a regular basis. Ensure that they are not damaged.
- To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.

Cautions

- 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.
- Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if there are any signs of damage.
- Only use with power supplies provided by FUJIFILM SonoSite.
- Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See **"Cleaning and disinfecting the transducer"** on page 105.
- Keep power cords away from trafficked areas.

Electrical safety classification

Class II equipment	The ultrasound system is classified as Class II equipment when powered from the external power supply, and internally powered equipment when powered from the internal battery (not connected to the power supply).
Type BF applied parts	Ultrasound transducers

Equipment safety

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

Cautions

- Excessive bending or twisting of cables can cause a failure or intermittent operation.
- To avoid the risk of overheating, avoid blocking the air vents in the transducer.
- Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, see **"Contact FUJIFILM SonoSite Technical Support for any maintenance questions."** on page 96.
- Do not submerge the transducer connector or cable in solution.
- Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- Remove the battery from the system if the system is not likely to be used for an extended period of time.
- Do not spill liquid on the system.
- The iViz system, including all internal adjustments and replacements (except battery replacement) can only be serviced by a qualified FUJIFILM SonoSite technician.

Battery safety

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

WARNINGS

- Periodically check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.
- Do not ship a damaged battery without instructions from FUJIFILM SonoSite Technical Support.
- 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 below -20°C (-4°F) or 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.
- The polarity of the battery terminals are fixed and cannot be switched or reversed. Do not force the battery into the system.
- Do not connect the battery to an electrical power outlet.
- Do not continue recharging the battery if the red light appears on the charger.
- If the battery leaks or emits an odor, remove it from all possible flammable sources.

To avoid the battery becoming damaged and causing equipment damage, observe the following precautions:

Cautions

- 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, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult FUJIFILM SonoSite or your local representative.
- Use only FUJIFILM SonoSite batteries.
- Do not use or charge the battery with non-FUJIFILM SonoSite equipment. Only charge the battery in the iViz system or in the battery charger provided by FUJIFILM SonoSite.

Clinical safety

WARNINGS

- To avoid injury, inspect all fasteners and connections.
- Non-medical (commercial) grade peripheral display monitors have not been verified or validated by FUJIFILM SonoSite as being suitable for diagnosis.
- Using a display monitor other than the one provided by FUJIFILM SonoSite may result in distortion of the image and degradation of image quality.
- 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.
- 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.
- Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Inspect the labeling for **Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions** or a similar statement.
- 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 .3dB/cm/MHz.

Hazardous materials

WARNINGS

- Products and accessories may contain hazardous materials. Ensure that products and accessories are disposed of in an environmentally responsible manner and meet federal and local regulations for disposing hazardous materials.
- The liquid crystal display (LCD) contains mercury. Dispose of the LCD properly in accordance with local regulations.

Electromagnetic compatibility

The ultrasound system has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2007 and IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The iViz ultrasound system is suitable for the professional healthcare environment per 60601-1-2:2014. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except near HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging or other environments where the intensity of electromagnetic disturbances is high.

WARNINGS

- The iViz ultrasound system should not be used adjacent to or stacked with other equipment. If such use occurs, verify that the iViz ultrasound system operates normally in that configuration.
- The iViz ultrasound system is intended for use by healthcare professionals only. The system/equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting, shielding, or relocating the system.

Cautions

- Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. Portable and mobile RF communications equipment can affect the ultrasound system. Electromagnetic interference (EMI) from other equipment or interference 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 source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or re-orient interfering equipment.
- Increase distance between interfering equipment and your ultrasound system.
- 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.

- 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 to the ultrasound system may result in malfunction of the 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 the FUJIFILM SonoSite accessories user guide.

Wireless transmission

iViz is designed and tested in conformity with the essential requirements and other relevant requirements of the R&TTE Directive (1999/5/EC).

This device complies with part 15 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.

The iViz ultrasound system contains a IEEE 802.11 a/b/g/n wireless LAN plus Bluetooth 4.0 combo transmitter. The transmitter is capable of transmitting in the bands 2.412-2.484 GHz and 5.180-5.925 GHz. In the 2.412-2.484 GHz band, the transmitter is capable of CCK, OFDM, MCS0, MCS3, MCS5, MCS7, MCS8, MCS11, MCS11, MCS13, and MCS15 at HT20 modulations. For the 5.180-5.925 GHz bands, the transmitter is capable of OFDM, MCS0, MCS3, MCS5, MCS7, MCS8, MCS11, MCS13, and MCS15 at HT20. The maximum ERP is 17.9 dBm.

Electrostatic discharge

WARNING If running on battery power, the iViz system can be susceptible to ESD and may power off at reduced immunity levels (for air discharge). Although this behavior does not damage the system or cause data loss, you must turn the system back on, a task that can interrupt or delay patient therapy.

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.

Separation distance

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 iViz ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The iViz 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 iViz ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iViz ultrasound system as recommended below, according to the maximum output power of the communications equipment.

Table 11-5: Separation distance

Rated maximum output power of transmitter *Watts*	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Compatible accessories and peripherals

FUJIFILM SonoSite has tested the iViz ultrasound system with the following accessories and peripherals and has demonstrated compliance to the requirements of IEC60601-1-2:2007 and IEC60601-1-2:2014.

You may use these FUJIFILM SonoSite accessories and third-party peripherals with the iViz ultrasound system.

WARNINGS

- Use of the accessories with medical systems other than the iViz ultrasound system may result in increased emissions or decreased immunity of the medical system.

- Use of accessories other than those specified may result in increased emissions or decreased immunity of the ultrasound system.

Accessories and peripherals compatible with iViz ultrasound system

Description	Maximum Cable Length
iViz base unit	No cable
iViz battery	No cable
iViz USB charger	4.9 ft/1.5 m
iViz protective case	No cable
P21v transducer	4 ft/1.2 m
Battery bay charger	No cable
iViz dual charging station	No cable
AC/DC battery supply for battery charger	AC cord length=5.7 ft/1.8 m DC cable length=6.1 ft/1.9 m
Micro USB drive	No cable

Guidance and manufacturer's declaration

WARNING Other equipment, even equipment that complies with CISPR emission requirements, can interfere with the iViz ultrasound system.

Table 11-6: Manufacturer's Declaration - Electromagnetic Emissions (IEC60601-1-2:2007, IEC 60601-1-2:2014)

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The iViz 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 CISPR 11	Class A (iViz battery charger)	The iViz battery charger is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.

Table 11-6: Manufacturer's Declaration - Electromagnetic Emissions (IEC60601-1-2:2007, IEC 60601-1-2:2014)

Emissions Test	Compliance	Electromagnetic Environment
	Class B (iViz ultrasound system excluding battery charger)	The iViz ultrasound system (excluding the battery charger) 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 11-7: Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2:2007)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 2.0KV, ± 4.0KV, ± 6.0KV contact ± 2.0KV, ± 4.0KV, ± 8.0KV air	± 2.0KV, ± 4.0KV, ± 6.0KV contact ± 2.0KV, ± 4.0KV, ± 8.0KV 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	N/A	N/A	See footnote[1]
Surge IEC 61000-4-5	N/A	N/A	See footnote[1]
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	See footnote[1]
Power Frequency Magnetic Field IEC 61000-4-8	3 A/m	3 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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 $d = 1.2\sqrt{P}$

Table 11-7: Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2:2007)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3	3 Vim 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 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, should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol:  (IEC 60417 No. 417-IEC-5140: "Source of non-ionizing radiation")

1. The iViz system only provides essential performance during diagnostic ultrasound imaging and, by design, this is only possible with battery power. The iViz system does not allow scanning when it is connected to AC power via a wall wart power supply. Since there is no essential performance provided while the iViz system is AC powered, the criteria to assess degradation of essential performance is not applicable. Therefore, immunity testing on the iViz system is not applicable for the following AC powered immunity tests (Electrical Fast Transients (EFT)/Burst, Surge, Voltage Dips, Short Interruptions, and Variations).
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 11-8: Manufacturer's Declarations - Electromagnetic Immunity (IEC 60601-1-2:2014)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	+8 kV contact +2 kV, +4 kV, +8 kV, +15 kV air	+2 kV, +4 kV, +8 kV contact +2 kV, +4 kV, +8 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	N/A[1]	N/A[1]	N/A[1]
Surge IEC 61000-4-5	N/A[1]	N/A[1]	N/A[1]
Voltage dips IEC 61000-4-11	N/A[1]	N/A[1]	N/A[1]
Voltage Interruptions IEC 61000-4-11	N/A[1]	N/A[1]	N/A[1]
Power frequency (50/60 Hz) 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 iViz ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic filed should be measured in the intended installation location to assure that it is sufficiently low.

Table 11-8: Manufacturer's Declarations - Electromagnetic Immunity (IEC 60601-1-2:2014)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz Outside ISM bands	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FUJIFILM SonoSite iViz ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation Distance $D=1.2\sqrt{P}$
	6Vrms 150 kHz to 80 MHz ISM Bands	6Vrms	$D=2.0\sqrt{P}$
	6Vrms 150 kHz to 80 MHz Amateur Radio Bands	6Vrms	$D=2.0\sqrt{P}$ Home healthcare environment

Table 11-8: Manufacturer's Declarations - Electromagnetic Immunity (IEC 60601-1-2:2014)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m	$D=1.2\sqrt{P}$ 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, should be less than the compliance level in each frequency range[2]. 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	Per 60601-1-2:2014, Table 9	Per 60601-1-2:2014, Table 9	

1. The iViz system only provides essential performance during diagnostic ultrasound imaging and, by design, this is only possible with battery power. The iViz system does not allow scanning when it is connected to AC power via a wall wart power supply. Since there is no essential performance provided while the iViz system is AC powered, the criteria to assess degradation of essential performance is not applicable. Therefore, immunity testing on the iViz system is not applicable for the following AC powered immunity tests (Electrical Fast Transients (EFT)/Burst, Surge, Voltage Dips, Short Interruptions, and Variations).
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

This device complies with 15.247 802.11 bgn Bluetooth LE of the FCC Rules. Operation is subject to the following two conditions:

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

Immunity testing requirements

The iViz ultrasound system complies with the essential performance requirements specified in IEC 60601-1-2 and IEC 60601-2-37. Results of immunity testing show that the iViz ultrasound system meets these requirements and is 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 may 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
- Production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use

WARNING The iViz system has been tested to the stated immunity requirements; however, electromagnetic disturbances in excess of the tested levels may cause essential performance to be lost or degraded. Any of the previous six listed items may be observed if excessive electromagnetic disturbances occur (in other words, the iViz system may not be free of the six listed items).

iViz labeling symbols

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

Symbol	Definition
CE 0086	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC.
	Attention, see the user guide.

Symbol	Definition
	Device complies with relevant Australian regulations for electronic devices.
REF	Catalog number.
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Corrugated recycle.
	Manufacturer.
	Do not get wet.
	Do not stack over 10 high.
	Device complies with relevant FCC regulations for electronic devices.
	Fragile.
	Paper recycle.
SN	Serial number type of control number.
	Temperature limitation.

Symbol	Definition
	Atmospheric pressure limitation.
	Humidity limitation.
	Contains mercury. LCMs contain a small amount of Liquid Crystal and Mercury. Please follow local ordinances or regulations for disposal.
	Follow instructions for use.
	A mandatory action that the user shall read the accompanying documentation for more information.
	UL Product Certification. The product or company has successfully met stringent standards for product safety.
	Non-ionizing electromagnetic radiation. To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems (e.g., in the electrical medical area) that include RF transmitters or that intentionally apply electromagnetic energy for diagnosis or treatment. Note: In case of application in a warning sign, the rules according to ISO 3864 shall be adhered to.

Specifications

Dimensions

System (without the case)

- **Length:** 7.21 in. (183.1 mm)
- **Width:** 4.59 in. (116.5 mm)
- **Height:** 1.06 in (26.9 mm)

System (with the case)

- **Length**: 9.5 in. (241.3 mm)

- **Width**: 4.8 in. (123.0 mm)
- **Height**: 1.12 in. (28.6 mm)

Display

- **Length:** 6.37 in. (161.87 mm)
- **Width:** 4.11 in. (104.52 mm)
- **Diagonal:** 7.0 in. (177.8 mm)

Environmental limits

Note The temperature, pressure, and humidity limits apply only to the ultrasound system, transducers, and battery.

Operating (system, battery, and transducer)

10–40°C (50–104°F), 15–95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Mode of Operation:

Continuous

Shipping and storage (system and transducer)

-20–60°C (-4–140°F), 15–95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Shipping and storage (battery)

-20–60°C (-4–140°F), 15–95% R.H. (For storage longer than 30 days, store at or below room temperature.)

500 to 1060hPa (0.5 to 1.05 ATM)

Electrical specifications

USB power charger PN P19927

Input: 100-240 Vac, 0.1 - 0.3 A, 50/60 Hz;

Output: 5 V dc, 2 A max; 10 W max.

Class II, continuous operation.

Battery specifications

Battery Pack: Li-Ion rechargeable, 7.4 V, 2.0 Ah (14.8 Wh).

Run time varies, depending on imaging mode and display brightness.

Equipment specifications

IPX-7 (watertight equipment)	Ultrasound transducers (except the connector)
Non AP/APG	Ultrasound system, including the power supply and peripherals are not suitable for use in the presence of flammable anesthetics.

Standards

Electrical safety standards

ANSI/AAMI ES60601-1:2005/(R) 2012, and A1:2012 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Consolidated Edition 3.1);

CAN/CSA C22.2 No. 60601-1:2014 (Edition 3.1) - Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1:2012 (Edition 3.1) - Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-37:2007 - Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 61157:1992 – Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment.

JIS T0601-1:2013 (3rd Edition), Japanese Industrial Standard, General Requirements for Safety of Medical Electrical Equipment.

EMC standards classification

CISPR 11, International Electrotechnical Commission, International Special Committee on Radio Interference. Industrial, Scientific, and Medical (ISM) Equipment—Radio-Frequency Disturbance Characteristics—Limits and Methods of Measurement. Classification for the ultrasound system and accessories when configured together: Group 1, Class B.

IEC 60601-1-2: 2007 – Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and Tests.

Acoustic standards

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

IEC 60601-2-37: 2007, Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

IEC 62359:2010 - Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

Biocompatibility standards

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices—Part 1: Evaluation and testing (2009).

AAMI/ANSI/ISO 10993-5, Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity (2009).

AAMI/ANSI/ISO 10993-10, Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (2002).

Airborne equipment standards

RTCA DO-160G, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B. 118.

DICOM standard

NEMA PS 3.15, Digital Imaging and Communications in Medicine (DICOM)—Part 15: Security and System Management Profiles.

Security and privacy standards

Health Insurance and Portability and Accountability Act (HIPAA).

45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy.

IEC TR 80001-2-2, Application of risk management for it networks incorporating medical devices - part 2-2: guidance for the disclosure and communication of medical device security needs, risks and controls (2012).

Wireless standards

U.S.

- FCC15.247:2015
- FCC2.1093:2015

Europe

- EN 301 893
- EN 300 328
- EN 62311:2008
- EN 62209-2

Australia/New Zealand

AS/NZS 4268 - RCM

Chapter 12: Acoustic Output

This chapter 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.

ALARA principle

ALARA is the guiding principle for the use of diagnostic ultrasound. Sonographers and other 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; Tissue Harmonic Imaging uses higher received frequencies to reduce clutter, artifact, and improve resolution on the 2D image. 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. Although there are no direct user controls for acoustic output, users can indirectly control output by varying depth. 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. See **"Transducer surface temperature rise"**

on page 149. 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 sonographer uses the system controls to adjust image quality and limit ultrasound output. The 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 have a direct user control for output. Rather, the system has been designed to automatically adjust output to ensure that acoustic and thermal limits are not exceeded for all imaging modes. Since there is no direct user control for output, the sonographer should rely on controlling exposure time and scanning technique to implement the ALARA principle.

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 720 mW/cm2 for all imaging modes. The mechanical index (MI) and thermal index (TI) may exceed values greater than 1.0 on some transducers in some imaging modes. Ultrasound users can monitor the MI and TI values on the right side of the clinical monitor and implement the ALARA principle accordingly. For more information on MI and TI, see BS EN 60601-2-37:2001: Annex HH.

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 probe position during a scan. Some controls, such as depth, show a rough correspondence with output, and may be used as a general means for indirectly reducing MI or TI. For more information on MI and TI, see **"Guidelines for reducing MI and TI"** on page 147 or AIUM Medical Ultrasound Safety, 3rd Edition.

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).

Guidelines for reducing MI and TI

The following are general guidelines for reducing MI or TI. If multiple parameters are given, the best results may be achieved by minimizing these parameters simultaneously. In some modes changing these parameters does not affect MI or TI. Changes to other parameters may also result in MI and TI reductions. Please note the MI and TI values on the right side of the screen.

Table 12-9: Guidelines for Reducing MI

Transducer	To reduce MI
P21v	Increase depth

Table 12-10: Guidelines for Reducing TI (TIS, TIC, TIB)

Transducer	CPD Settings					
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize
P21v						

 Decrease or lower setting of parameter to reduce MI.

 Increase or raise setting of parameter to reduce MI.

Output display

The system meets the AIUM (American Institute of Ultrasound in Medicine) output display standard for MI and TI (see **"Related guidance documents"** on page 149). The following table indicates for each transducer and operating mode when either the TI or MI is greater than or equal to a value of 1.0, thus requiring display.

Table 12-11: TI or MI ≥ 1.0

Transducer Model	Index	2D/ M Mode	CPD/Color
P21v	MI	Yes	Yes
	TIC, TIB, or TIS	No	No

Even if MI is less than 1.0, the system provides a continuous real-time display of MI in all imaging modes, in increments of 0.1.

The system meets the output display standard for TI and provides a continuous real-time display of TI in all imaging modes, in increments of 0.1.

The TI consists of three user-selectable indices, and only one of these is displayed at any one time. In order to display TI properly and meet the ALARA principle, the user selects an appropriate TI based on the specific exam being performed. FUJIFILM SonoSite provides a copy of *AIUM Medical Ultrasound Safety*, which contains guidance on determining which TI is appropriate.

MI and TI output display accuracy

The accuracy result for the MI is stated statistically. With 95% confidence, 95% of the measured MI values will be within +17% to -25% of the displayed MI value, or +0.2 of the displayed value, whichever value is larger.

The accuracy result for the TI is stated statistically. With 95% confidence, 95% of the measured TI values will be within +29% to -42% of the displayed TI value, or +0.2 of the displayed value, whichever value is larger.

A displayed value of 0.0 for MI or TI means that the calculated estimate for the index is less than 0.05.

Factors that contribute to display uncertainty

The net uncertainty of the displayed indices is derived by combining the quantified uncertainty from three sources: measurement uncertainty, system and transducer variability, and engineering assumptions and approximations made when calculating the display values.

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"** on page 156.

The displayed 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.

Another source of error arises from the assumptions and approximations that are made when deriving the estimates for the display indices. Chief among these assumptions is that the acoustic output, and thus the derived display indices, are linearly correlated with the transmit drive voltage of the transducer. Generally, this assumption is very good, but it is not exact, and thus some error in the display can be attributed to the assumption of voltage linearity.

Related guidance documents

Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, 2008.

Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 2014. (A copy is included with each system.)

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

Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993.

Transducer surface temperature rise

The tables in this section list 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 EN 60601-2-37 with controls and settings positioned to give maximum temperatures.

Table 12-12: Transducer Surface Temperature Rise, External Use (°C)

Test	P21v
Still air	20.4 (≤27°C)
Simulated use	9.2 (≤10°C)

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, "American Institute of Ultrasound in Medicine (AIUM)," published in the April 2008 edition of the Journal of Ultrasound in Medicine, provides more current information.

The acoustic output for this ultrasound system has been measured and calculated in accordance with "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD2-2004), IEC 60601-2-37: 2007, Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, and IEC 62359:2010 - 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:

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:

$$\textit{In Situ}\ (\text{derated}) = \text{Water}\ e^{-(0.069 f)}]$$

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/cm2. 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 combinations with a TI or MI equal to or greater than one. These tables are organized by transducer model and imaging mode. For a definition of terms used in the tables, see **"Terminology in acoustic output tables"** on page 156.

Table 12-13: Transducer Model: P21v, Operating Mode: 2D

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.83					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	4.5					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.81	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.919					
	PRF	(Hz)	2580					
	p_r@PII_{max}	(MPa)	2.43					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	299					
Operating Control Conditions	Control 1: Exam Type		OB					
	Control 2: Optimization		THI					
	Control 3: Depth		Index 3					
	Control 4:							

(a) This index is not required for this operating mode; value is <1.
(b) 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.)
- Data are not applicable for this transducer/mode.

Table 12-14: Transducer Model: P21v, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	-	(a)	-	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.83					
	W_0	(mW)		-	#		#	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.5	-	#	-	#	#
	$d_{eq}(z_{sp})$	(cm)		-	#	-	#	#
	f_c	(MHz)	1.81	-	#	-	#	#
	Dim of A_{aprt}	X (cm)		-	#	-	#	#
		Y (cm)		-	#	-	1.30	#
Other Information	PD	(µsec)	0.919					
	PRF	(Hz)	600					
	$p_r@PII_{max}$	(MPa)	2.43					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	229					
Operating Control Conditions	Control 1: Exam Type		Abd					
	Control 2: Optimization		THI					
	Control 3: Depth		Index 3					
	Control 4:							

(a) This index is not required for this operating mode; value is <1.
(b) 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.)
- Data are not applicable for this transducer/mode.

Table 12-15: Transducer Model: P21v, Operating Mode: Color/CPD

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.70					
	W_0	(mW)		-	#		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	$z@PII_{.3max}$	(cm)	4.4					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.81	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.938					
	PRF	(Hz)	640					
	$p_r@PII_{max}$	(MPa)	2.24					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	174					
Operating Control Conditions	Control 1: Exam Type		Abd					
	Control 2: Mode		CVD					
	Control 3: 2D Optimization/ Depth		THI/ Index 3					
	Control 4: Color Optimization/ PRF		Low/ Index 0					
	Control 5: Color Box Position/ Size		Middle/ Default					

(a) This index is not required for this operating mode; value is <1.
(b) 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.)
- Data are not applicable for this transducer/mode.

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 column of the table. Measurement precision and 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. In accordance with Section 6.4 of the Output Display Standard, the following measurement precision and uncertainty values are determined by making repeat measurements and stating the standard deviation as a percentage.

Table 12-16: Acoustic Measurement Precision and Uncertainty

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
Pr	1.9%	±11.2%
$Pr_{.3}$	1.9%	±12.2%
Wo	3.4%	±10%
fc	0.1%	±4.7%
PII	3.2%	+12.5 to -16.8%
$PII_{.3}$	3.2%	+13.47 to -17.5%

Terminology in acoustic output tables

A_{aprt}	Area of the active aperture measured in cm^2.
$d_{eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((Wo)/(I_{TA}(z)))}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z in centimeters.
$d_{eq}@PII_{max}$	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
Dim. of A_{aprt}	Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
fc	Center frequency in MHz.
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters.
$I_{pa.3}@_{MImax}$	Derated pulse average intensity at the maximum MI in units of W/cm^2.
$I_{SPTA.3}$	Derated spatial peak, temporal average intensity in units of $milliwatts/cm^2$.

$I_{SPTA.3}z_1$	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
MI	Mechanical index.
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
$P_{r.3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
$p_r@PII_{max}$	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
TI type	Applicable thermal index for the transducer, imaging mode, and exam type.
TI value	Thermal index value for the transducer, imaging mode, and exam type.
TIB	(Bone thermal index) is 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. TIB non-scan is the bone thermal index in the non-autoscanning mode.
TIC	(Cranial bone thermal index) is the thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
TIS	(Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode.
$W_3(z_1)$	Derated ultrasonic power at axial distance z_1 in units of milliwatts.
Wo	Ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
z_1	Axial distance corresponding to the location of maximum $\min(W_3(z_1), I_{TA.3}(z) \times 1\ cm^2)]$, where $z \geq zbp$ in centimeters.
z_{bp}	1.69 (A_{aprt}) in centimeters.
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b.3}$) in centimeters.

Glossary

General terms

For ultrasound terms not included in this glossary, refer to Recommended Ultrasound Terminology, Third Edition, published in 2008 by AIUM.

AIUM	American Institute of Ultrasound in Medicine
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.
curved array transducer	Identified by the letter C (curved or curvilinear) and a number (60). The number corresponds to the radius of curvature of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, C60xp.
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.
LCD	liquid crystal display
linear array transducer	Identified by the letter L (linear) and a number (38). The number corresponds to the radius of width of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam.
mechanical index (MI)	An indication of the likelihood of mechanical bioeffects occurring: the higher the MI, the greater the likelihood of mechanical bioeffects. See **"Direct, indirect, and receiver controls"** on page 146 for a more complete description of MI and how to manage it.
MI/TI	See mechanical index (MI) and thermal index (TI).
phased array	A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus.
SonoMB technology	A subset of the 2D imaging mode in which the 2D image is enhanced by looking at a target from multiple angles and then merging or averaging the scanned data together to improve overall image quality and, in parallel, reducing noise and artifacts.
target depth	A depth on the display that corresponds to the skin/transducer interface.

thermal index (TI)	The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions. See **"Direct, indirect, and receiver controls"** on page 146 for a more complete description of TI and how to manage it.
TIB (bone thermal index)	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.
TIC (cranial bone thermal index)	A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
TIS (soft tissue thermal index)	A thermal index related to soft tissues.
Tissue Doppler Imaging (TDI)	A pulsed wave Doppler technique used to detect myocardial motion.
Tissue Harmonic Imaging	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.
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.

Chapter 13: IT Network

Functions

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

- The examination data (static images, clips) acquired by this device can be stored in Picture Archiving and Communication System (PACS) by DICOM communication.
- This device can query examination orders from the Modality Worklist (MWL) server by DICOM communication and start them.
- The time of this device can be set correctly by inquiring the network time service.

Network for connecting the device

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

Specifications for the connection

Hardware specification

802.11 a/b/g/n, Bluetooth 4.0

Software specifications

- This device is connected to PACS and MWL by DICOM standard. Refer to the DICOM Conformance Statement of this device for details.
- When available, this device connects to the network time server at startup.

Security

- This device has no listening ports open to the WLAN interface. A network entity cannot initiate a connection to the iViz system from the WLAN. However, iViz can initiate a connection to servers on the WLAN and beyond.
- The iViz USB port can only be used to export data to a USB memory stick. Computer access to the iViz through the USB port is blocked.
- The following TCP/IP ports are used for outgoing communication to the WLAN:
  - Port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112)
  - Port 443 for encrypted traffic to Tricefy, HTTPS time / web servers

- Port 80 for HTTP web servers

- Anti-virus software is not installed on this device.

Data flow

DICOM

MWL Server ----------> iViz ----------> PACS
Study order Study data
(DICOM MWL) (DICOM Storage)

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

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"** on page 161. As a result, the following hazardous situations may occur:

Table 13-17: IT network failure recovery

Network failure	Impact on equipment	Hazard	iViz countermeasures
IT network becomes unstable	Unable to transmit exam data to a PACS	Delay of diagnosis	iViz 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 iViz.
	Unable to get order data from an MWL server	Delay of exam	On iViz, the user can initiate/create a new study.
	Delay of getting order from an MWL server		
	Incorrect data from a MWL server	Incorrect exam	iViz uses the TCP/IP and DICOM Protocols. Integrity of the data is ensured by them.
	Unable to get the time from a time server.	Incorrect exam data	iViz has the capability of entering data and time manually.
	Incorrect time data		iViz always indicates the date and the time on the main screen.
Firewall has broken down	Attack via network	Manipulation of exam data	iViz closes unnecessary network ports.

Table 13-17: IT network failure recovery

Network failure	Impact on equipment	Hazard	iViz countermeasures
	Infection by computer virus	Leak of exam data	iViz prevents a user from loading software and executing it.

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.

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