ImaCor®

The hemodynamic ultrasound company.™

ImaCor Zura-EVO™ Imaging Systems

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User Guide Conventions

Icons

⚠ **Caution or Warning:** Describes a procedure or precaution necessary to prevent injury to the patient or damage to the system.

Safety Feature: Highlights a safety feature.

ImaCor Innovation: Highlights a feature unique to the ImaCor ZURA-EVO Imaging System.

RoHS Compliance Statement

We declare that our product complies with The European RoHS Directive 2002/95/EC

(Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment), which restricts the following substances in electrical and electronic medical equipment:

- Lead (Pb) < 1000 ppm
- Mercury (Hg) < 1000 ppm
- Cadmium (Cd) < 100 ppm
- Polybrominated Biphenyls (PBB) < 1000 ppm
- Hexavalent Chrome (Cr VI) < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE) < 1000 ppm

Exemption:

COMMISSION DELEGATED DIRECTIVE, Council of the EU of 18.10.2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards to an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators.

ImaCor ZURA-EVO Imaging System Overview

Overview

- The ImaCor ClariTEE™ miniaturized transesophageal echocardiography (TEE) probe enables direct visualization of cardiac size and function, and is designed specifically for episodic assessment in the critical care environment.
- Miniaturization of the probe permits an extended maximum dwell time of 72 hours.
- The probe is intended for single patient use only and is provided sterile and is disposable.

Prescription use: For use by qualified clinicians only.

Indications for Use

1. The ZURA-EVO Imaging System is intended for the following applications: cardiac and transesophageal measurement and calculation packages that provide information of anatomical structures that may be used by a physician for clinical diagnosis purposes.
2. When used with the ClariTEE probe -- The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hours.
3. When used with the TTE probe -- Intended for imaging and assessment of cardiac anatomy and function.

Diagnostic Ultrasound Indication for Use Forms

ClariTEE PROBE

Intended Use: When used with the ClariTEE probe – The episodic assessment of cardiac function using transesophageal echocardiography (TEE). It is indicated for use in clinical settings including long term settings such as the ICU for an indwelling time not to exceed 72 hours.

Table 1 ClariTEE Probe Indications

	Mode of Operation							
Clinical Application	**B**	**M**	**PW Doppler**	**CW Doppler**	**Color Doppler**	**Power Doppler**	**Combined Modes**	**Other (Notes)**
Opthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								

Table 1 ClariTEE Probe Indications (Continued)

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Transesophageal	P				P			
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New Indication; P = Previously cleared under K080223, K100989

SA4-2/24 PHASED-ARRAY TRANSDUCER (TTE PROBE)

Intended Use: Diagnostic Ultrasound imagining or fluid analysis of the human body as follows:

Table 2 TTE Probe Indications

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Opthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	N				N			
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								

Table 2 TTE Probe Indications (Continued)

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other (Notes)
Nerve Block								
Other								

N = New Indication; P = Previously cleared under K080223, K100989

Contraindications

The ImaCor ZURA-EVO Imaging System is contraindicated as follows: *It is not for pediatric use (patients less than 18 years of age).*

⚠ **Warning:** Patients with known issues such as esophageal or stomach varices, obstructive esophageal pathology, recent surgery, or radiation therapy in the esophageal or gastric area, should be evaluated by a physician prior to having a TEE procedure.

Transesophageal Echocardiography (TEE) Use in Critical Care Settings

ImaCor Innovation
Miniaturization of the TEE probe permits assessment of cardiac function episodically over an extended period of time, as the smaller probe should not require the use of general anesthesia.

The ImaCor ZURA-EVO Imaging System addresses the need in the critical care setting for a miniaturized TEE probe to assess important cardiac parameters that influence hemodynamics. The ImaCor ClariTEE ultrasound probe provides direct visualization of cardiac size and function, allowing intensive care clinicians to conduct episodic assessments of cardiac performance over an extended period.

Principles of Operation

ImaCor Innovation
The ImaCor single-use disposable probe can remain in place for up to 72 hours, enabling episodic assessment of the patient's cardiac function over that period at intervals determined by the physician.

Miniaturization of the ClariTEE probe enables direct visualization of the cardiac structures episodically over time. Direct visualization of the left ventricle permits improved assessment of intravascular volume status and cardiac function.

The ClariTEE disposable probe can remain in place for up to 72 hours, enabling episodic assessment of the patient's cardiac function over that period at intervals determined by the physician. Episodic assessments typically occur up to six times over a 24-hour period.

Episodic Assessment

Important: The ZURA-EVO Imaging System is not a continuous monitoring system.

The ImaCor ZURA-EVO Imaging System is not a continuous monitoring device. It is intended to conduct episodic assessments of the patient's cardiac function. Normal use in this setting should consist of a maximum of six episodic assessments over a 24-hour period with maximum intubation time not to exceed 72 hours. The duration of a typical assessment will be in the range of 5–15 minutes. Hence, the typical cumulative imaging time for each patient is in the range of 1.5 hours to 4.5 hours during a 72-hour indwelling time period.

Table 3 Episodic Assessment Overview

Anticipated episodic assessment frequency	6 episodic assessments per 24 hours
Typical episodic assessment time	5–15 minutes
Maximum probe dwell time	72 hours
Typical cumulative imaging time during a 72-hour indwelling time period	1.5–4.5 hours
Maximum cumulative imaging time during 72-hour time period	6 hours

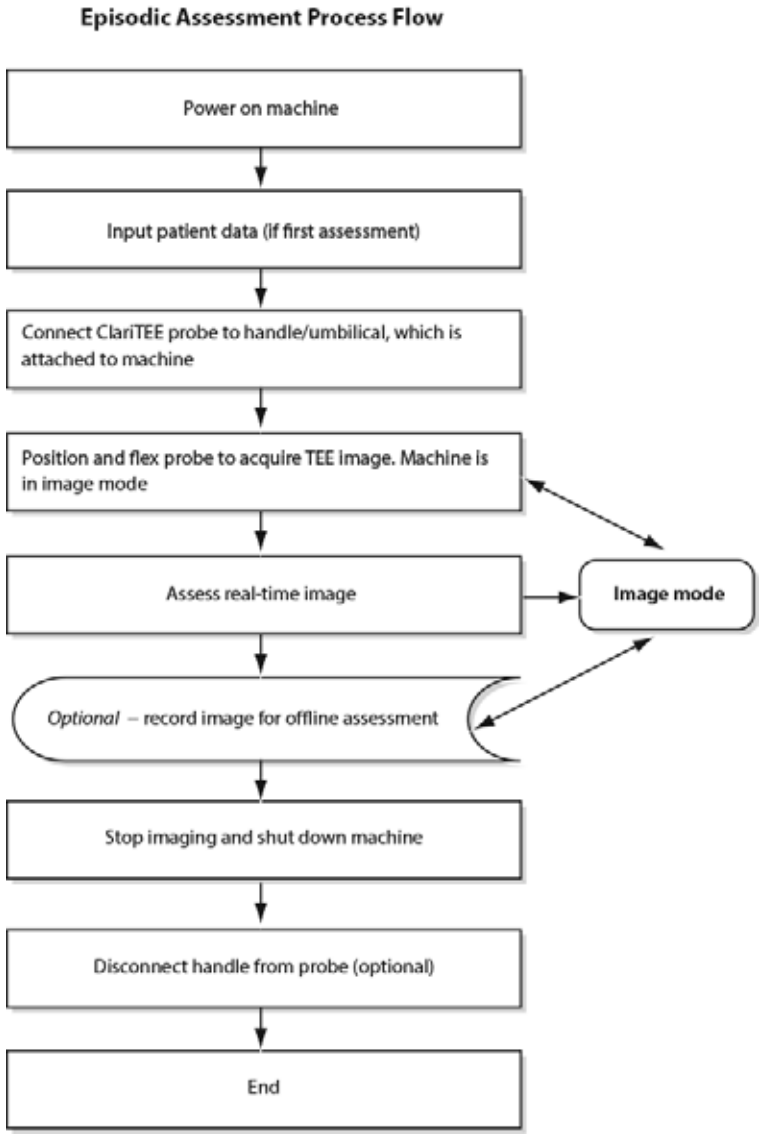


Fig. 1 Process flow of one episodic assessment

Non-Imaging Mode

Safety Feature
During non-imaging intervals, no energy is delivered to the patient and the probe remains in a relaxed, unflexed position. As a result, the mucosal tissue is not subject to any mechanical or thermal stress.

The ClariTEE probe is designed for a maximum dwell time of 72 hours. Episodic assessments typically account for a fraction of total dwell time; therefore, during the majority of probe dwell time no imaging is taking place. During non-imaging intervals, no energy is delivered to the patient and the probe remains in a relaxed, unflexed position.

Cumulative Imaging Time

⚠ **Caution**
The ZURA-EVO Imaging System should be in imaging mode only when an episodic assessment is being conducted.

Cumulative imaging time is the total time over the course of probe dwell duration that the ZURA-EVO Imaging System is in imaging mode for the purpose of episodic assessment. The ClariTEE probe delivers energy to the patient only while in the imaging mode. Only in imaging mode is the ClariTEE probe mechanically flexed to obtain the tissue contact required for imaging.

⚠ **Warning:** NEVER allow water or other liquids onto the power pack or interior of the system case.

About the System

The ImaCor ZURA-EVO Imaging System consists of five main components:

1. Ultrasound machine
2. ClariTEE probe
3. TTE probe
4. Ultrasound handle
5. ImaCor ultrasound imaging software

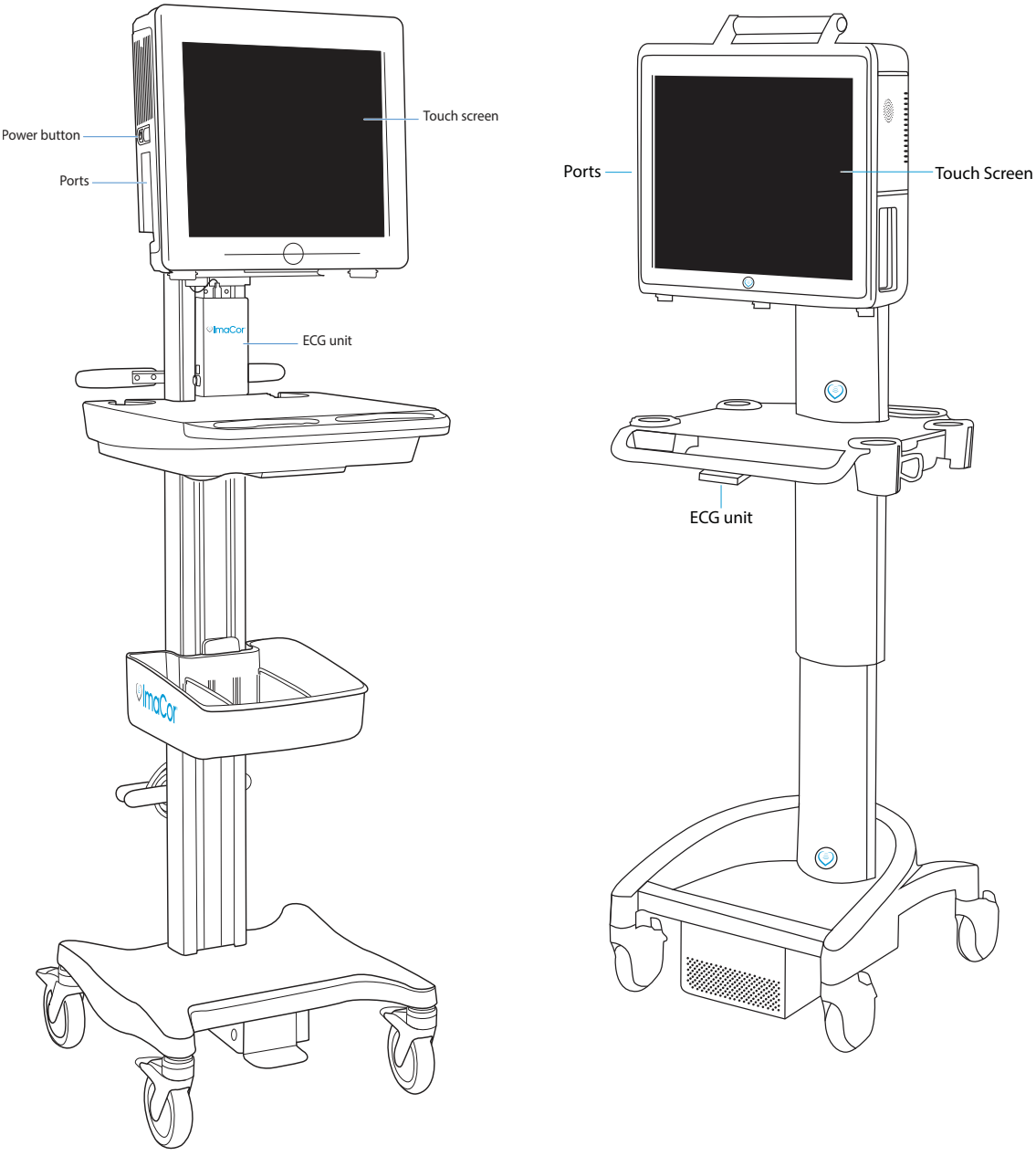


Fig. 2 ImaCor Zura-EVO and Zura-EVO 1 Imaging Systems

Ultrasound Machine

The ImaCor ZURA-EVO Imaging System includes an ultrasound machine optimized for use with the ImaCor ClariTEE probe (Figure 2). The machine contains a liquid crystal (LCD) touch screen and all the required system firmware and hardware except for the disposable ClariTEE probe.

Ultrasound TEE Probe

⚠ **Caution**
The ImaCor ClariTEE is for use **only** with the ImaCor ZURA-EVO Imaging System
Flex the probe only when imaging.
Disconnect the probe from the handle when not conducting an episodic assessment.
The ClariTEE probe is designed for single patient use.
The maximum dwell time for the ClariTEE probe is 72 hours.

The ClariTEE is a miniaturized disposable single patient use probe optimized for extended dwell-time, making it ideal for use in longer-term clinical settings such as the ICU. During episodic assessments, the probe tip is flexed upward (anteflexed) or downward (retroflexed).

The indwelling portion of the ClariTEE probe is detachable from the control handle. The detachable handle enables one machine to serve multiple patients.

ADAPTAFLEX™ TECHNOLOGY

The ClariTEE probe features ImaCor AdaptaFlex technology. This technology changes the flex point of the probe's adaptive section to accommodate the patient's anatomy. AdaptaFlex technology enables the operator to obtain an optimal view across patients of varying sizes.

Fig. 3 ImaCor ClariTEE™ probe, umbilical, and handle

Ultrasound TTE Probe

The ZURA-EVO Imaging System TTE probe is provided as an optional for those instances where trans-thoracic imaging is the preferred method of cardiac imaging. The imaging modes available are identical to the ClariTEE: B-mode (2-D) and color flow.

UPS (optional)

Battery monitoring is now available on systems using the optional uninterruptible power supply (UPS). The icons shown in Figure 4 indicate two basic states: UPS charging or discharging. The icons that include a lightning bolt indicate the UPS is connected to a power outlet and is charging; the others show that the UPS is not connected to a power outlet and therefore is discharging.

The battery monitoring icon is displayed in the upper right corner of the screen, just left of the date and time. Click the battery icon for detailed information about the status of the UPS.

Fig. 4 Battery monitoring icons

1-D Barcode Scanner (optional)

The 1-D barcode scanner scans information from patient wristbands directly into the EVO system. The barcode scanner is optional and can be purchased separately.

Fig. 5 Optional 1-D barcode scanners

Getting Started

Preparing the System

Plug the system into a hospital grade or equivalent receptacle (outlet).

Connecting the Ultrasound Probe

1 Locate the dedicated matching connector (ZIF connector) for the locking umbilical cable connector.

2 Push the umbilical cable connector into place (Figure 7). The umbilical cable connector is large; you will need one hand to hold it and the other to turn the locking lever.

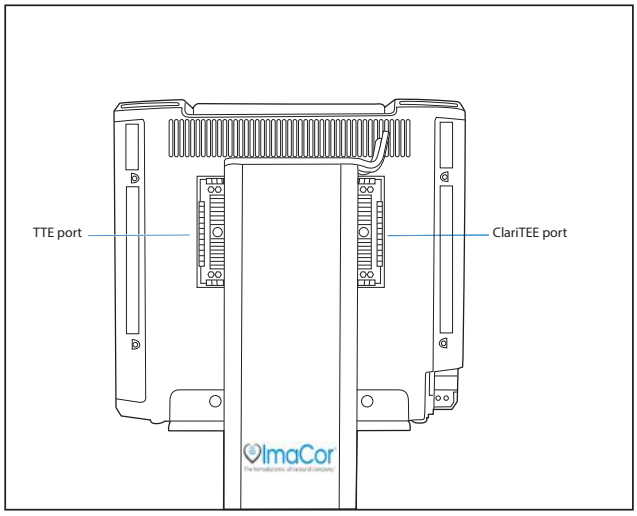


Fig. 6 ClariTEE and TTE ports

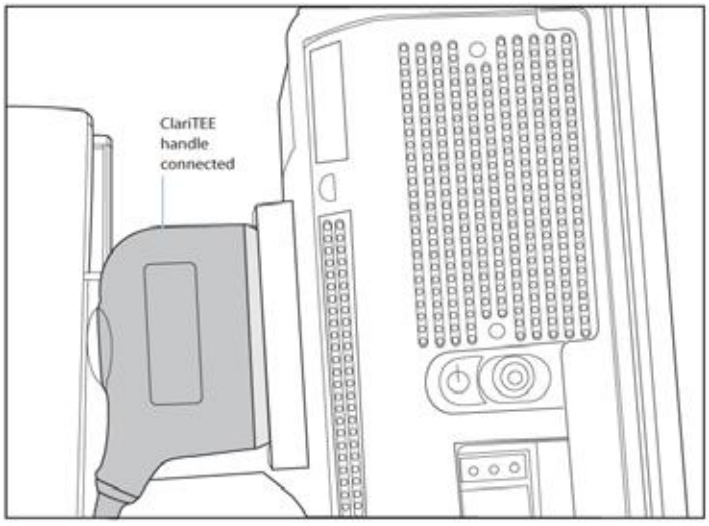


Fig. 7 Push the umbilical connector into the ClariTEE port

3 When ready to attach the probe, take the probe from its sterile packing. Remove the cover from the disposable probe connector as shown (Figure 8).

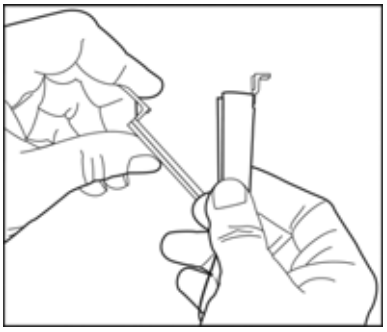


Fig. 8 Remove the cover from the disposable probe

4 Position the probe connector and handle as shown in Figure 9.

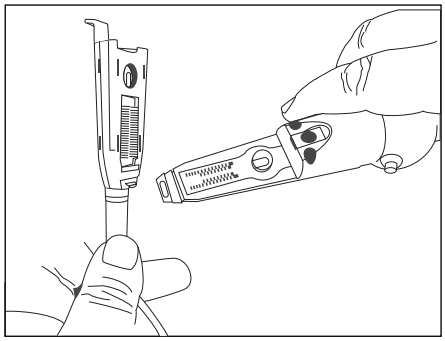


Fig. 9 Position the probe connector and handle in hand

5 Align the probe with the handle.

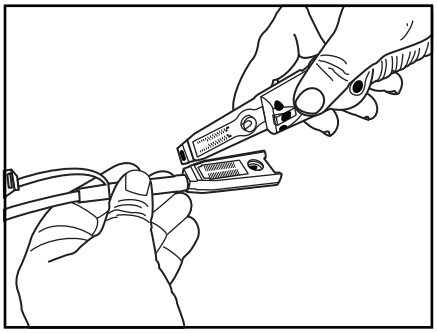


Fig. 10 Align probe and handle

6 Insert the blue connector tab into the distal end of the handle (Figure 11).

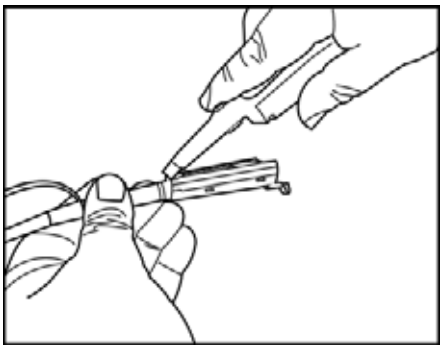


Fig. 11 Insert connector tab into distal end of the handle

7 Gently press the probe connector over the handle; press the tab on the umbilical connector to assist with engagement (Figure 12). An audible click will indicate the probe is properly connected.

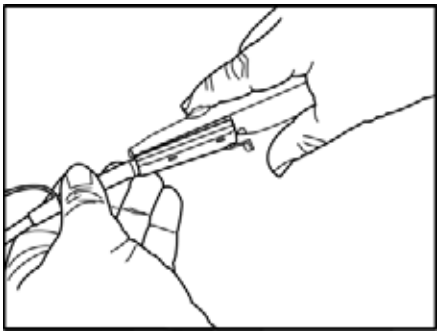


Fig. 12 Press the probe connector over the handle

8 With the disposable probe locked into place, check articulation by moving level in each direction. The distal tip of the probe should flex in either direction.

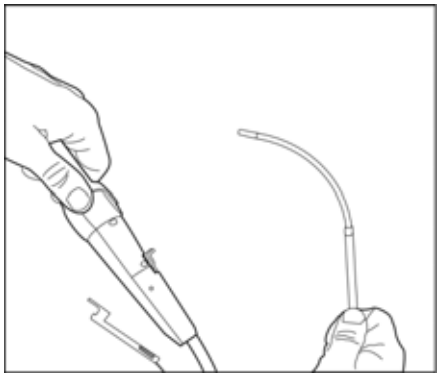


Fig. 13 Check articulation of the probe

Note: Expect flex of 90 degrees in the forward direction (anteflex) and 20 degrees minimum in reverse direction (retroflex)

Connecting Other Transducers

Use the port not labeled ClariTEE for the other transducers; i.e TTE.

Connecting the ECG

Note: The ECG provided with the ZURA-EVO Imaging System is not for diagnostic purposes and is provided only to assist the detection of images at end systole and end diastole.

A three-lead ECG cable is provided for optional connection of the machine ECG to the patient. After connecting the patient electrodes, connect the ECG cable to the machine using the circular twist-lock receptacle shown in Figure 14.

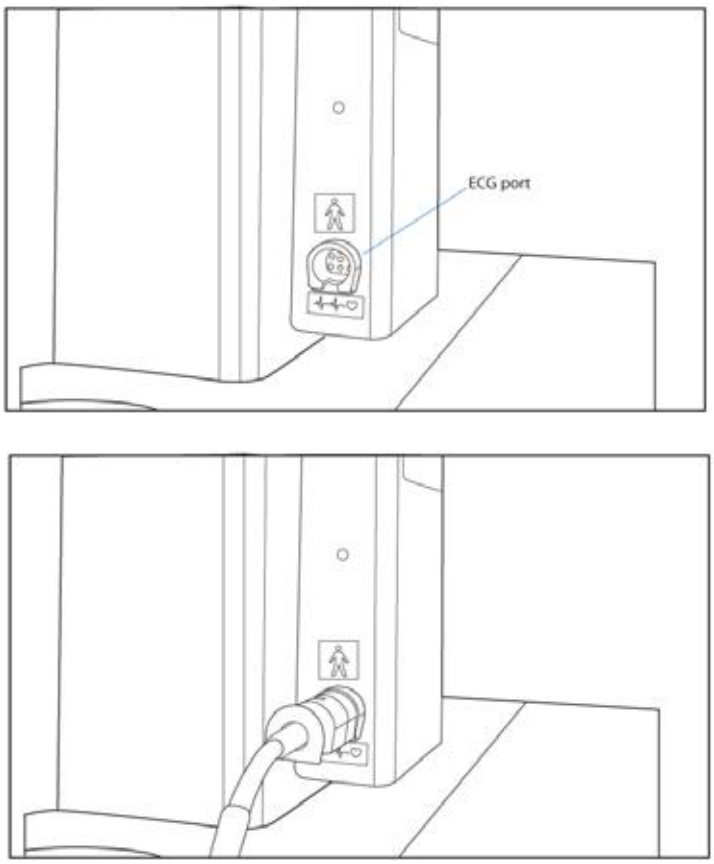


Fig. 14 Connect the ECG leads

Turning the System On/Off

1 Turn on the power supply by pressing the rocker switch at the bottom of the unit to the ON position, marked **I**. (The OFF position is marked **O**.)

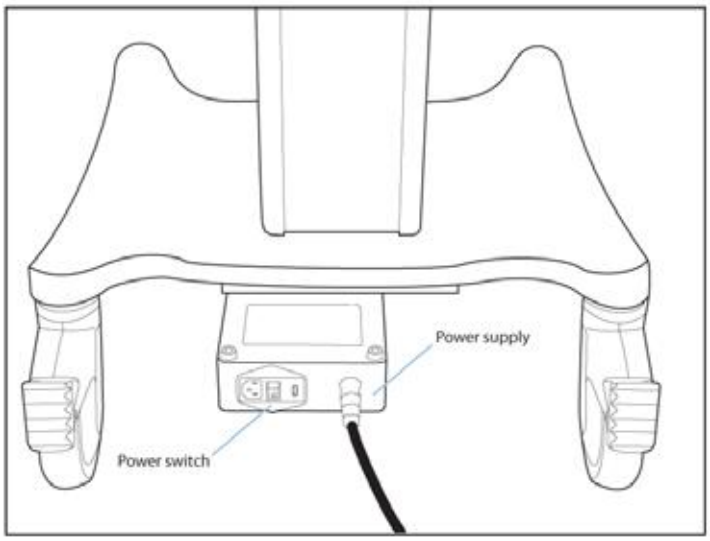


Fig. 15 Power switch

2 Power up the computer by pressing the power button shown in Figure 16.

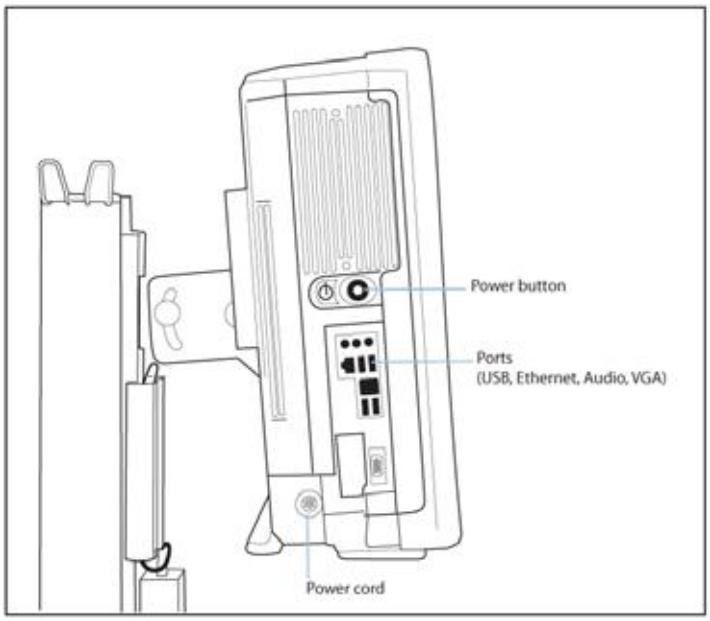


Fig. 16 Power pushbutton - located on back left side of EVO 1 system (not shown)

On-Screen Keyboard

Whenever alphanumerical input from the user is required, the ZURA-EVO Imaging System displays an onscreen keyboard, shown below. The keyboard is superimposed on the bottom of the patient information and imaging screens.

Fig. 17 Onscreen keyboard

ImaCor Ultrasound Imaging Software

Overview

ImaCor Ultrasound Imaging Software v3.0.0 performs seven basic functions:

1. Recording and updating patient information
2. Real-time imaging
3. Cineloop acquisition
4. Cineloop enhancement
5. Cineloop playback
6. Cineloop evaluation
7. hTEE measurements: FAC, RV/LV, SVC

Online Help System

The complete User Manual is available electronically through the imaging software's searchable Help system. To access the Help system:

Touch Screen

1 Tap anywhere on the touch screen and hold.

2 Select "Help" from the global context menu.

ZURA-EVO Imaging System Mouse

1 Right-click anywhere on the screen.

2 Select "Help" from the global context menu.

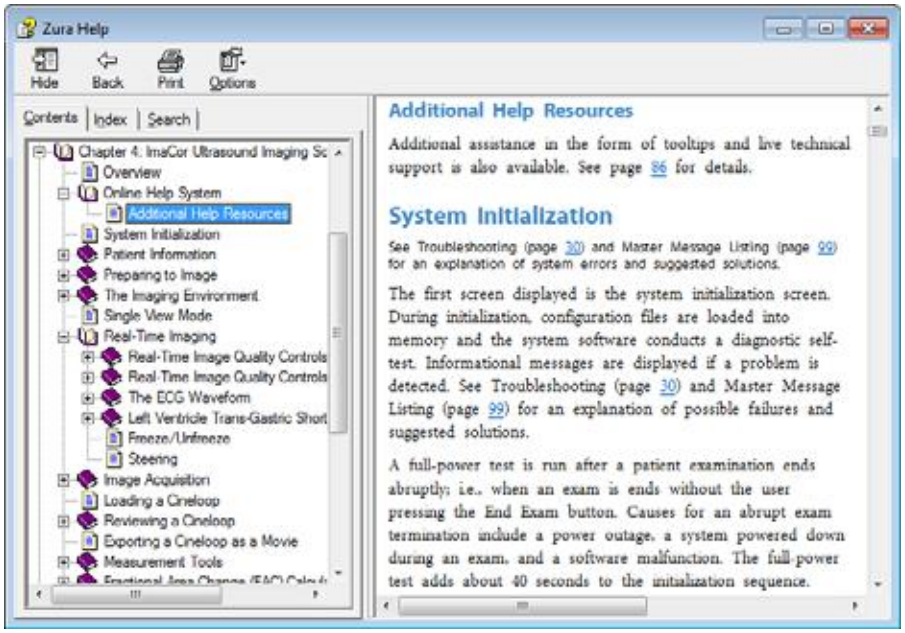


Fig. 18 Help Screen PDF

Additional Help Resources

Additional assistance in the form of tooltips and live technical support is also available. See page 97 for details.

System Initialization

See the Master Message Listing (page 110) for an explanation of system errors and suggested solutions.

The first screen displayed is the system initialization screen. During initialization, configuration files are loaded into memory and the system software conducts a diagnostic self-test. Informational messages are displayed if a problem is detected. See the Master Message Listing (page 110) for an explanation of possible failures and suggested solutions.

A full-power test is run after a patient examination ends abruptly; i.e., when an exam is ends without the user pressing the End Exam button. Causes for an abrupt exam termination include a power outage, a system powered down during an exam, and a software malfunction. The full-power test adds about 40 seconds to the initialization sequence.

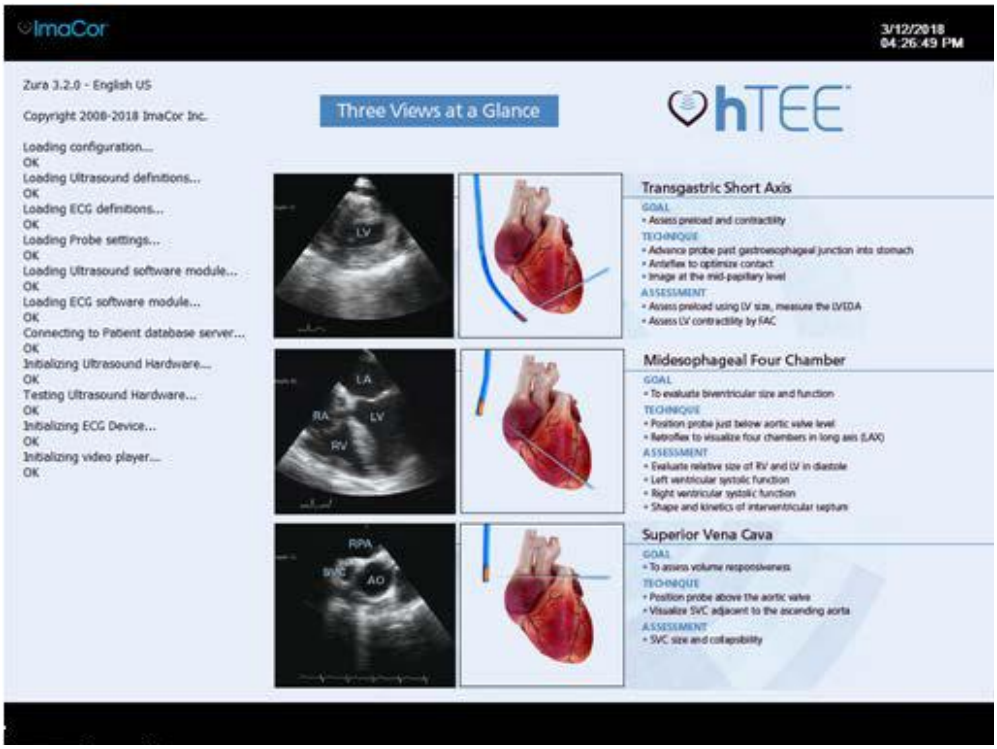


Fig. 19 Initialization screen

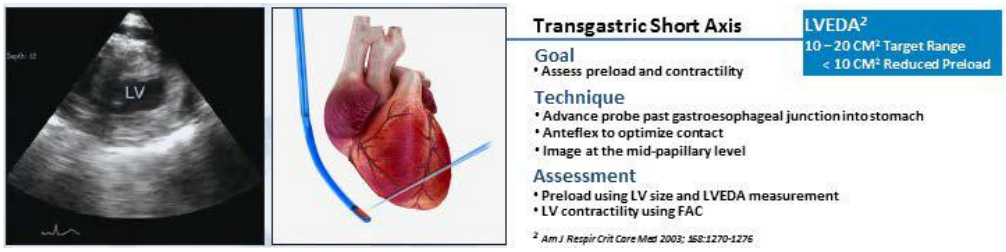


Fig. 20 System initialization screen – animated transgastric short-axis flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

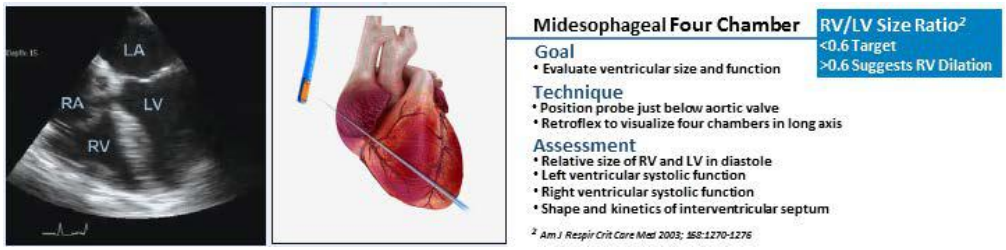


Fig. 21 System initialization screen – animated mid-esophageal four-chamber flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

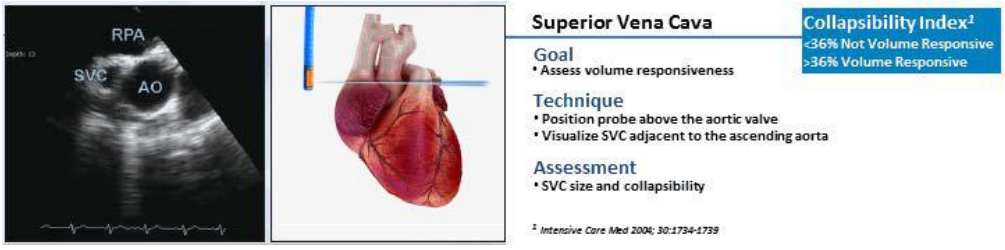


Fig. 22 System initialization screen – animated superior vena cava flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

Patient Information

Basic patient data are entered using the Patient Information window (Figure 23). After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.

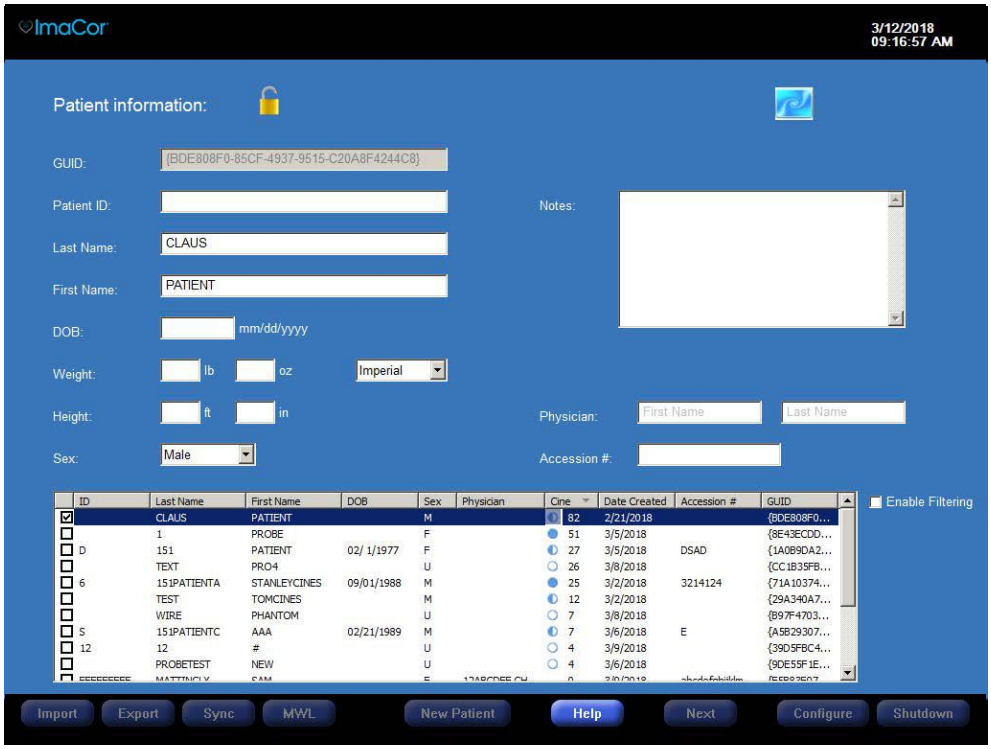


Fig. 23 Patient Information screen, information editing enabled (see "Patient Information Screen Button Functions," page 27).

Patient Information Screen Data Fields

The fields detailed in Table 4 comprise the Patient Information screen.

Table 4 Patient Information Screen Data Fields

Field Name	Status	Function	Notes
GUID	System generated	A unique patient identifier	Read-only; i.e., the information in this field is displayed but cannot be changed
Patient ID	Optional; can be configured as mandatory. See page 83	Enter local patient identification number, if applicable	32 characters maximum
Last Name	Mandatory by default.See page 83 for information on changing patient information defaults	Enter patient's last name	To ensure consistency, first and last names are always displayed and recorded in uppercase characters. 32 characters maximum
First Name	Mandatory by default. See page 83 for information on changing patient information defaults	Enter patient's first name	To ensure consistency, first and last names are always displayed and recorded in uppercase characters. 32 characters maximum
DOB	Optional	Enter patient's date of birth	Format is mm/dd/yyyy; e.g., 06/02/1956.

Table 4 Patient Information Screen Data Fields (Continued)

Field Name	Status	Function	Notes
Weight	Optional	Enter patient's weight	The drop-down menu to the right of the Weight field enables you to select Imperial or metric units. If you change units after entering the patient's weight, the measurement is converted. The option you select becomes the system default.
Height	Optional	Enter patient's height	The drop-down menu to the right of the Height field enables you to select Imperial or metric units. If you change units after entering the patient's height, the measurement is converted. The option you select becomes the system default.
Physician	Optional	Enter the physician's first and last name	Each field can accommodate 32 characters.
Sex	Optional	Enter patient's sex	The drop-down menu provides three choices: 1. Male 2. Female 3. Unknown
Accession #	Optional	Enter accession number (can also be imported from an MWL server)	The accession number is an identifier for an Imaging Service Request. The ZURA-EVO Imaging System allows one accession number per patient. The accession number is embedded in DICOM files that are sent to the archiving server (when configured).
Notes	Optional	Enter additional comments	This freeform text field can accommodate 256 characters.
Enable filtering	Optional	Enable/disable Patient List filtering	When the Patient List filter is turned on (the option box is checked), the characters you type in the first and last name fields limit the names displayed in the Patient List to those with matching character strings. For example, if you type "Sm" in the last name field and "J" in the first name field, only patients whose last name begins with the string "Sm" and first name begins with "J" will be displayed, e.g.: • Smith, John • Smith, Josephine • Smithers, Joachim

Patient Edit Lock Feature

The Patient Edit Lock feature prevents unintentional changes to critical patient data fields. Once a patient record is created, the patient ID, last name, and first name fields are locked. To edit these fields in an existing record, you must unlock them.The lock icon next to the Patient Information screen title displays the current state of a selected record.

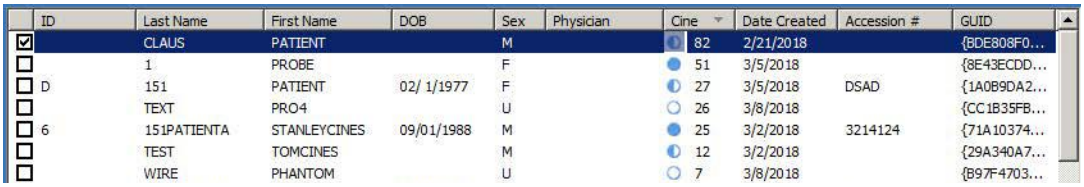
The icon on the left indicates that a selected patient record is unlocked and that all fields are available for editing. The icon on the right indicates that patient records are locked and editing of the patient ID, last name, and first name fields is disabled.

The lock icon works like a toggle switch.

1. Tap or click the icon to lock and unlock a selected patient record.
2. When you unlock a record, a confirmation message is displayed.

Patient List

A list of patient records appears at the bottom of the Patient Information screen.



	ID	Last Name	First Name	DOB	Sex	Physician	Cine	Date Created	Accession #	GUID
☑		CLAUS	PATIENT		M		82	2/21/2018		{BDE808F0...
☐		1	PROBE		F		51	3/5/2018		{8E43ECDD...
☐	D	151	PATIENT	02/ 1/1977	F		27	3/5/2018	DSAD	{1A0B9DA2...
☐		TEXT	PRO4		U		26	3/8/2018		{CC1B35FB...
☐	6	151PATIENTA	STANLEYCINES	09/01/1988	M		25	3/2/2018	3214124	{71A10374...
☐		TEST	TOMCINES		M		12	3/2/2018		{29A340A7...
☐		WIRE	PHANTOM		U		7	3/8/2018		{B97F4703...

Fig. 24 Sample Patient List

The Patient List includes the information listed below. You can set the sort order of the Patient List by tapping or clicking the appropriate column heading.

- Local identification number, if applicable
- Patient's last name
- Patient's first name
- Patient's date of birth
- Patient's sex
- Physician name
- Cine
  - The number of cineloops recorded for the patient (maximum 100)
  - Synchronization state icon (under Cine) – indicates the state of synchronization with the archiving server, if configured. There are three states:
    - ○ No sync (no cineloop for the selected patient has been sent to the DICOM server)
    - ◐ Partial sync (at least one cineloop for the selected patient has been sent to the DICOM server)
    - ● Complete sync (all cineloops for the selected patient have been sent to the DICOM server)
- Patient record creation date
- Accession #
- Patient GUID

Patient Information Screen Button Functions

Figure 25 shows the Patient Information screen buttons in their default state.

Fig. 25 Patient Information screen buttons – default state

The New Patient, Next, Configure, and Shutdown buttons are active but slightly dimmed. This is the default state of active buttons in the ImaCor system; it is intended to minimize visual distractions.

The Sync button is enabled when a DICOM Archiving Server is active (see "Archiving Server Configuration," page94). The Sync button allows you to send cineloops as DICOM files to a DICOM server via a network connection. Tap and hold the Sync button to view a server synchronization log.

DICOM Synchronization Feature

The atomic DICOM synchronization feature permits you to send selected patient records to the archiving server.

Table 5 Patient Information Screen Buttons and Function

Number	Button	Function
1	Import	Import patient information. Enabled only when an ImaCor Data Transfer Module (DTM) is inserted in a USB port. See page 34 for information in importing patient data.
2	Export	Export patient information. Enabled only when an ImaCor Data Transfer Module (DTM) is connected and a patient record is selected from the Patient List. See page 33 for information on exporting patient data.
3	Sync	The Sync button is enabled when a DICOM Archiving Server is active (see "Archiving Server Configuration," page 94). The Sync button allows you to send cineloops as DICOM files to a DICOM server via a network connection. The server synchronization log can be viewed by tapping or right-clicking the Sync button.
4	New Patient	Clears the Patient Information screen, including the GUID, enabling the user to create a new patient record. The New Patient button is the **only** way to clear the GUID.
5	Next	Advances to the single-view imaging environment. The mandatory first and last name fields must have been completed.
6	Configure	Accesses the Configuration screens; see "Configuring the System," page 91, for details.
7	Shutdown	Shuts down the system.

Querying a Modality Worklist (MWL) Server

If an MWL server is configured and networked to a ZURA-EVO Imaging System, you can query the server for a selected patient. Data elements that are already present on the ZURA-EVO Imaging System are not imported from the MWL server. For example, if the date of birth for a selected patient is already recorded on the ZURA-EVO Imaging System, the birthdate will not be imported.

Touch Screen

1. Select a patient from the Patient List.
2. Tap the MWL button.

ZURA-EVO Imaging System Mouse

1. Select a patient from the Patient List.
2. Right-click and select the "Check MWL Server..." option.

If the MWL server query returns at least one item, you can import the information from a selected MWL item into the local patient record. See the DICOM Conformance Statement for details of imported fields. The DICOM Conformance Statement is available to registered customers for download from the ImaCor support web page: http://www.imacorinc.com/support.html

Note: The accession number can be imported from the MWL server.

Synchronizing with a DICOM Archiving Server

If a DICOM archiving server is configured and networked to a ZURA-EVO Imaging System, you can send acquired cineloops to it as multiframe DICOM files.

To transmit cineloops to the server, tap or click the Sync button in the Patient Information screen.

After communication with the server is verified, the ZURA-EVO Imaging System sends cineloops that do not yet reside on the server and that satisfy user-defined Sync rules, if any. Examples of user-defined rules follow:

- Cineloop comment required
- Patient ID required
- Patient DOB required
- Accession number required
- Patient sex required; ("unknown" not acceptable)

Note: Cineloops imported from another ZURA-EVO Imaging System will not be sent to the archiving server. Cineloops can be transmitted to an archiving server only by the ZURA-EVO Imaging System that acquired them.

VIEWING THE SYNC LOG

The Sync Log feature enables you to check the status of the last synchronization operation, displaying transmission errors and the count of cineloops not transmitted because of rule noncompliance.

To view the Sync Log, tap or right-click the Sync button, which displays the Show Synchronization Log menu.

Patient Information Tasks

Create a New Patient Record

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
2. If an existing patient record is displayed, tap or click the New Patient button to clear the data fields.
3. Enter the new patient information in the appropriate fields. You may choose from three options for "mandatory fields required" before creating a new patient profile: FName + LName, Patient ID, or FName + LName and Patient ID.
   - Tap or click to advance from one field to the next. The First Name and Last Name fields are mandatory; all others are optional.
   - No user action is required to save information entered in the Patient Information screen.
4. When you have finished entering information, tap or click the Next button to begin imaging preparation.
   - Information entered in the Patient Information screen is validated before you enter the imaging environment. If an error is detected, the field is highlighted.

Autoselect an Existing Patient Record

1. Access the Patient Information screen.

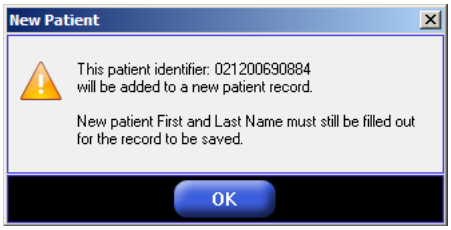
– After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
– If you are in the imaging environment, tap or click the Patient button.

2 If a probe used in a previous patient exam is connected to the ZURA-EVO Imaging System, the system checks to see if data for the patient exists in the patient database. If a match is found, the system will, at your direction, automatically select the record and populate the data fields. The user prompt below is displayed:

If you reject the Autoselect option, the system software turns off the probe-detection mechanism for the duration of the patient exam or until the probe is disconnected.

New in Version 2.3.0: The optional 1-D barcode scanner enables you to scan the patient's wristband. If the patient is in the ZURA-EVO Imaging System, the patient record is automatically selected.

Otherwise, the ZURA-EVO Imaging System will automatically create a new patient record and complete the Patient ID field using information from the barcode.



Manually Select an Existing Patient Record

1 If you reject the Autoselect option, the system software turns off the probe-detection mechanism for the duration of the patient exam or until the probe is disconnected.

2 To maximize efficiency, make sure the Enable Filtering box is checked. When the Patient List filter is active, the characters you type in the first and last name fields limit the names displayed in the Patient List to those with matching character strings.

3 Insert your cursor in the Last Name field and enter the first few characters of the patient's last name. The Patient List will display only those patients whose last names begin with the same characters.

4 Because patients may share the same or similar names, check the GUID to make certain you are choosing the correct patient.

5 Tap or click to select the desired patient name.

Select a Patient Record Created on a Remote ZURA-EVO Imaging System

If patient data has been encoded in the probe but no matching record is found in the patient database, the ZURA-EVO Imaging System software automatically creates a patient record based on the encoded information. This situation arises when a patient's initial examination is completed on one ZURA-EVO Imaging System, but a subsequent assessment uses a different ZURA-EVO Imaging System. ZURA-EVO Imaging System are stand-alone systems; information and cineloops entered in one patient database do not appear in databases associated with other ZURA-EVO Imaging Systems.

A system-generated patient record will contain just the patient's GUID and first and last names. Other patient information, as well as associated cineloops, must be imported from the remote ZURA-EVO Imaging System (see "Import a Patient Record from a Remote ZURA-EVO Imaging System," page 34). Information that is corrected in or added to a system-generated patient record will not be reflected in the original record.

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
2. If a probe used in a previous patient exam is connected to the ZURA-EVO Imaging System, the system checks to see if data for the patient exists in the patient database. If a match is found, the system will, at your direction, automatically select the record and populate the data fields. The user prompt below is displayed:

   Tap or click the Yes button to load the patient's GUID and first and last names.

   New in Version 2.3.0: If the probe currently in use was first employed on a different ZURA-EVO Imaging System, a patient record (First Name and Last Name) is automatically created on the current system. Unlock the patient record for editing, then use the barcode scanner to scan the patient's wristband. This action automatically fills the Patient ID field.

Update a Patient Record

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
   - If the first or last name fields will be edited, unlock the patient record. For information on locking and unlocking and unlocking records, see "Patient Edit Lock Feature," page 26.
1. When the Autoselect prompt is displayed, tap or click the Yes button; alternatively, you may manually locate the patient's record in the Patient List.
2. Tap or click to the field you wish to modify.
3. Enter the new information or correct the existing data. Your changes are autosaved.
4. If you access the Patient Information screen from the Imaging screen during an exam, press the OK button to return to the imaging environment.

Delete a Patient Record

Touch Screen

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
2. Locate the patient's record in the Patient List.
3. Tap and hold the patient's name.
4. Choose the Delete option, as shown in Figure 26.
5. When the confirmation message is displayed (Figure 26), press the Yes button to delete the patient record. *Deleted records cannot be retrieved.*

ZURA-EVO Imaging System Mouse

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
2. Locate the patient's record in the Patient List.
3. Right-click the patient name.
4. Choose the Delete option, as shown in Figure 26.
5. When the confirmation message is displayed (Figure 26), click the Yes button to delete the patient record. *Deleted records cannot be retrieved.*

DELETE MULTIPLE PATIENT RECORDS

Touch Screen

1. Check each patient name you wish to delete.
2. Tap and hold the patient name and select the Delete menu option.
3. When the confirmation message is displayed (Figure 26), tap the Yes button to delete the patient record. *Deleted records cannot be retrieved.*

ZURA-EVO Imaging System Mouse

1. Check each patient name you wish to delete.
2. Right-click the patient name and select the Delete menu option.
3. Choose the Delete option as shown in Figure 26.
4. When the confirmation message is displayed (Figure 26), click the Yes button to delete the patient record. *Deleted records cannot be retrieved.*

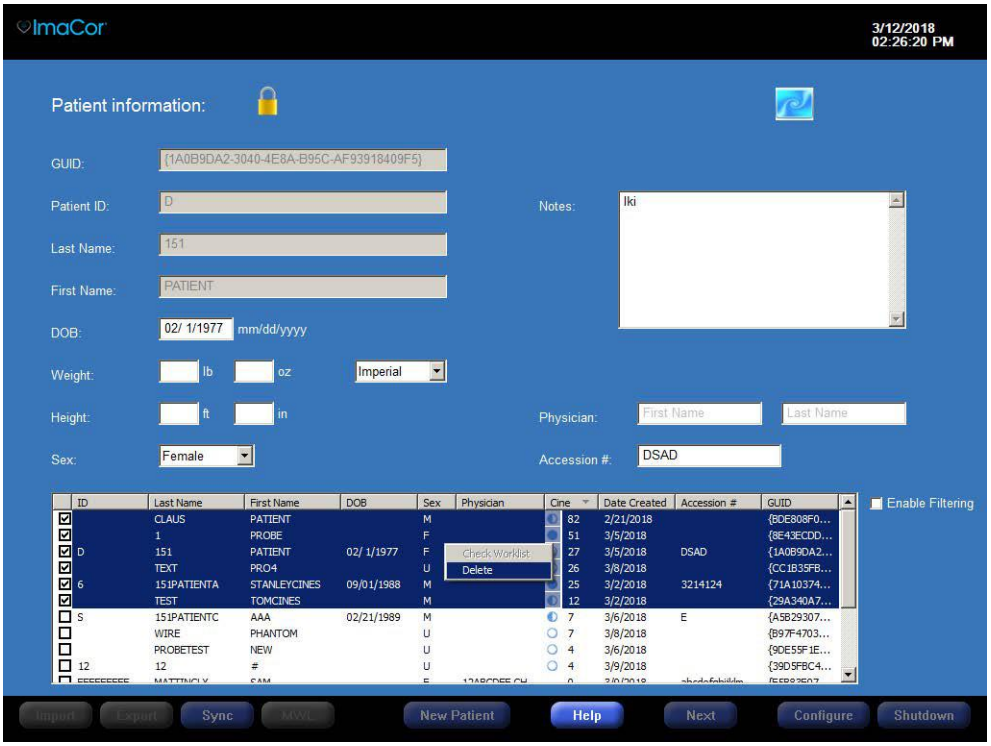


Fig. 26 Deleting a patient record

Transferring Patient Records Between ImaCor ZURA-EVO Imaging System

ZURA-EVO Imaging Systems are stand-alone systems; information and cineloops entered in one patient database do not appear in databases associated with other ZURA-EVO Imaging Systems. Many institutions have multiple ZURA-EVO Imaging Systems in service, and it's often desirable to copy data recorded in one ZURA-EVO Imaging System database and import it into another. For example, a patient's initial exam may take place in an operating room setting, while later examinations are completed in the intensive care environment.

Patient information and cineloops can easily be exchanged between ZURA-EVO Imaging Systems. To import or export information, you must have a Data Transfer Module (DTM), which is a jump drive specially formatted for transferring ImaCor ZURA-EVO Imaging System records.

Export a Patient Record to a Data Transfer Module (DTM)

1. Access the Patient Information screen.
   - After starting the ImaCor ZURA-EVO Imaging System, the Patient Information screen is the first interactive window displayed.
   - If you are in the imaging environment, tap or click the Patient button.
2. Insert the DTM into one of the USB ports on the left side of the ZURA-EVO Imaging System. The DTM Patients dialog box is displayed.
3. Tap or click the name of the patient whose records you wish to export. Check the GUID to make certain you are selecting the correct patient.
4. Tap or click the Export button.

Notes:

- If the "Export DICOM Images" option is enabled in the Configuration window, the operation will export ImaCor cine files as well as DICOM multiframe images. For more information, see "Configuring the System," page 91.
- The ImaCor decryption utility must be used before DICOM images can be imported and viewed on a DICOM workstation. The decryption utility is available to registered customers for download from the ImaCor support web page: http://www.imacorinc.com/support.html

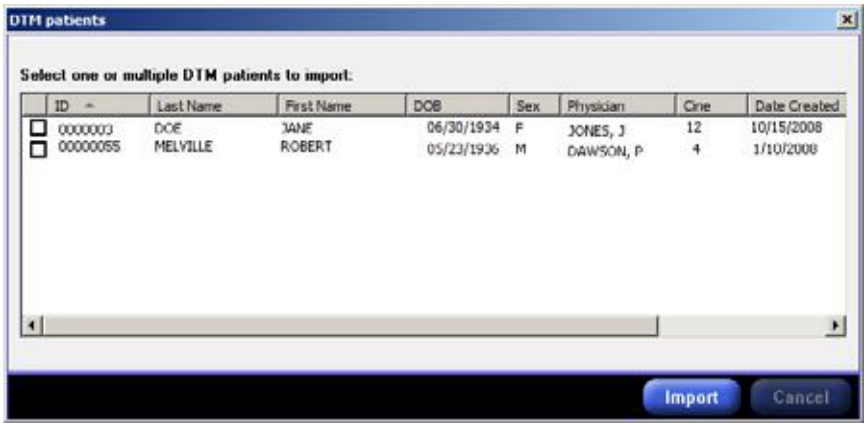
Import a Patient Record from a Remote ZURA-EVO Imaging System

Related Topics

"The Imaging Environment," page 34
"Synchronizing with a DICOM Archiving Server," page 29

1 Insert a DTM into one of the USB ports on the left side of the ZURA-EVO Imaging System. When the DTM is connected, the Import button becomes active and the system displays a message indicating that the import/export features are enabled.

2 The DTM Patients dialog box is displayed. Tap or click the name of the patient whose records you wish to import. Check the GUID to make certain you are selecting the correct patient.



3 Tap or click the Import button. While data is being transferred, a progress bar is displayed.
Do not disconnect the DTM while the data is being imported.

DUPLICATE RECORDS

If you are importing a record that already exists on the target machine, a warning message is displayed.

- If you wish to overwrite the record on the target machine, tap or click the Yes button.
Overwritten records cannot be retrieved.
- If you wish to retain the record on the target machine, tap or click the No button. The patient record on the DTM will not be transferred.

The Imaging Environment

The imaging environment is where you will view, acquire, optimize, and compare real-time images and cineloops.

There are two basic screen modes in the imaging environment: Single View and Split View:

- **Single View mode** displays one real-time or cineloop view. For more information, see "Single View Mode," below.
- **Split View mode** enables you to compare two cineloops side-by-side or one cineloop beside real-time imaging. See page 39 for information on working in Split View mode.

After leaving the Patient Information screen, you enter the imaging environment at the Single View screen. If a valid probe is connected, real-time imaging automatically begins.

The ClariTEE probe is detected and validated from within the imaging environment. This enables you to disconnect/reconnect without having to exit the imaging environment to validate the reconnected probe.

Single View Mode

The Single View screen is generally used for real-time monitoring, cineloop acquisition, and FAC calculations. Figure 27 and Table 6 on page 36 summarize Single View mode features. Figure 28 and Table 7 on page 38 describe Imaging screen buttons.

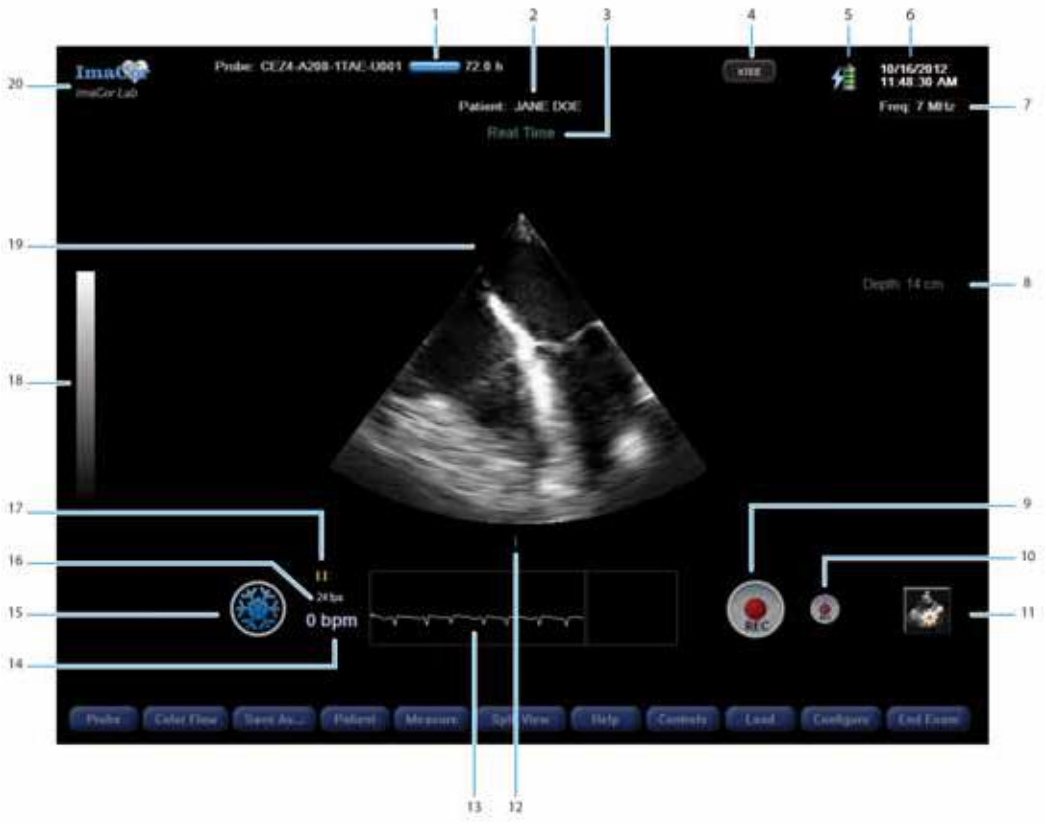


Fig. 27 Single View mode imaging screen

Table 6 Single-View Imaging Screen Features

Number	Feature	Function	Notes
1	Probe meter	Displays the probe's unique serial number and a progress bar indicating the time remaining on the probe (0–72 hours).	
2	Patient name	Patient's first and last name.	
3	Frame title	Alerts user that real-time imaging is taking place.	Indicates current view. Displays Real Time when viewing real-time images. When a cineloop is loaded, displays the cineloop title(i.e., the date and time of acquisition).
4	hTEE	Displays the hTEE Views tutorial	
5	Battery monitoring icon		
6	Current date and time		
7	Tx frequency	Displays the current ultrasound transmit frequency. The values are 5MHz, 6 MHz and 7 MHz for B-mode imaging and 5 MHz for Color Flow imaging. The default B-mode is transmit 7 MHz - High Definition. It can be changed to 6 MHz for improved penetration with a slight decrease in resolution, and 5 MHz for even further penetration.	To toggle between B-mode frequencies, tap or click within the Frequency area, bounded with a blue rectangle, to display the frequency context menu. Select the desired frequency from the menu. The default B-mode frequency setting can be changed in the Configuration dialog box. The Color Flow frequency cannot be changed.
8	Depth display	Displays the imaging depth. The default imaging depth is 15 cm.	Always ON
9	Acquire/Record – 3 second	Acquire	Starts a 3-second acquisition of real-time images and ECG.
10	Acquire/Record – 6 second	Acquire	This button starts an extended, 6-second cineloop acquisition.
11	Auto-Q	Auto-Q is a "smart" Gain+TGC function that automatically adjusts the Gain, TGC1, and TGC2 settings until an optimal image is obtained.	Image quality is subjective. You may prefer Gain and TGC settings other than those selected by Auto-Q.
12	Steering feature cursor	Enables the user to look left or right without physically moving the probe. For additional information, see "Steering," page 42.	**Touch Screen** • Tap on the right side of the ultrasound image to pan right on image • Tap on the left side of the ultrasound image to pan left on image **ZURA-EVO Imaging System Mouse** • Left-click on the right of the image to pan right on the image • Left-click on the left of the image to pan left on the image
13	ECG waveform		
14	Heart rate	Expressed in beats per minute (bpm)	

Table 6 Single-View Imaging Screen Features (Continued)

Number	Feature	Function	Notes
15	Freeze/Unfreeze	Toggle that starts or stops the acquisition of real-time images.	**Freeze:** Halts imaging on the last frame viewed and internally saves the last 50 frames. The 50-frame buffer enables you to scroll backward to view previous frames. When scrolling, the fps rate display indicates the speed at which you are reviewing frames.Use the play bar to scroll through the buffered frames. Use the playback buttons to tap or click through the sequence one frame at a time. **Unfreeze:** Resumes real-time imaging. See "Freeze/Unfreeze," page 47
16	Frame rate	Expressed in frames per second (fps)	The standard frame rate for B-mode imaging is 24 fps. The B-mode 3-second acquisition frame rate is greater than 24 fps; the 6-second acquisition frame rate is 24 fps. The CF-mode imaging frame rate varies with depth and colorbox width. The CF acquisition frame rate is double the standard CF frame rate with a maximum of 30 fps. Recovery frame rate is 6 fps. For more information on recovery mode, see page 63. **Note:** The frame rate shown represents the number of frames per second displayed on screen. This number is lower than the fps captured during acquisition due to the time required to process and render images on screen.
17	ECG lead	Select Lead I, II, or III	
18	Grayscale	Used in adjusting monitor brightness and contrast.	The grayscale is a vertical gradient bar on the imaging screen that allows the user to adjust the LCD's brightness to an optimal setting for the ambient lighting. The monitor should be adjusted to display as much of the grayscale range as possible. Grayscale is also used to set the Color/B-Mode Priority when imaging with CF or replaying a CF cineloop.
19	Real-time image		
20	Institution (hospital) name and location		

Fig. 28 Single View mode layout buttons

Table 7 Imaging Screen Buttons

Number	Feature	Function	Notes
1	Probe	The probe button displays status information about the probe currently in use. • User can select the ClariTEE probe or another; i.e., TTE. **ClariTEE Probe** • Probe expired • Probe does not match selected patient • Probe handle not detected • Probe not detected	
2	Color Flow	Toggles Color Flow imaging on and off	During real-time imaging, toggles Color Flow imaging mode on and off.
3	Save As	Enables user to save loaded cineloop onto a USB drive as an .AVI or .MOV video clip.	Same as the "Export Movie..." menu item.
4	Patient	Displays the Patient Information screen, enabling you to edit patient information without ending an exam. To return to imaging view, tap or click the OK button.	If the Patient button is tapped or clicked during an exam, real-time imaging is automatically frozen although the exam is still in progress. After patient information is edited and the OK button is tapped or clicked, you are returned to the imaging screen and the exam resumes. If a cineloop was being viewed, it remains loaded. If real-time imaging was taking place, the frozen 50-frame real-time buffer is displayed.

Table 7 Imaging Screen Buttons (Continued)

Number	Feature	Function	Notes
5	Measure	Displays Measure buttons that allow user to select Area, Distance, or Off option.	
6	Single/Split View	Toggles between Single View and Split View modes.	See "Single View Mode," page 35 and "Split View Mode," page 39
7	Help	Opens the ZURA-EVO Imaging System user manual/help system.	See Online Help, page 22
8	Controls	Displays image quality controls.	
9	Load	Loads a cineloop.	See "Loading a Cineloop," page 64
10	Configure	Enables user to customize several aspects of the system configuration, including: • Application • Date-Time • DICOM • Language • Version • Help	"Configuring the System," page 91
11	End Exam	Terminates patient exam and returns the user to the Patient Information screen.	A patient exam is completed by clicking the End Exam button or by selecting a different name from the Patient List.

Split View Mode

Split View mode enables you to evaluate side by side either two cineloops (Figure 79) or a cineloop and a real-time image. The Single/Split View button at the bottom of the screen enables you to toggle between imaging screen modes.

Real-time imaging is always displayed on the right of the screen. The active loop name is highlighted.

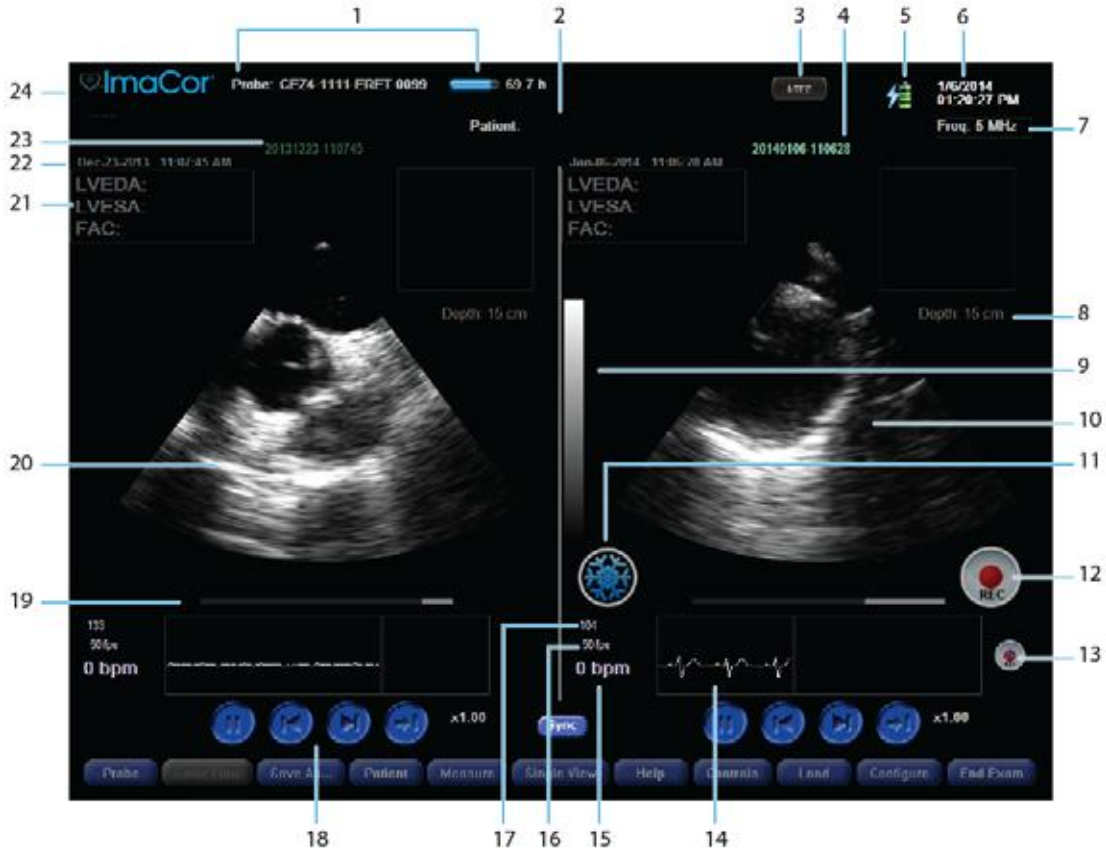


Fig. 29 Split View mode imaging screen

Table 8 Split View Imaging Screen

Number	Feature	Function	Notes
1	Probe meter	Displays the probe's unique serial number and a progress bar indicating the time remaining on the probe (0–72 hours)	
2	Patient name	Patient's first and last name	
3	hTEE	Displays the hTEE Views tutorial	
4	Name of loaded cineloop		
5	UPS battery monitoring icon	Indicates the status of the UPS battery	
6	Current date and time		
7	Tx frequency	Displays the current ultrasound transmit frequency. The values are 5MHz, 6 MHz and 7 MHz for B-mode imaging and 5 MHz for Color Flow imaging. The default B-mode is transmit 7 MHz - High Definition. It can be changed to 6 MHz for improved penetration with slight resolution decrease, and 5 MHz for more penetration.	To toggle between B-mode frequencies, tap or click within the Frequency area, bounded with a blue rectangle, to display the frequency context menu. Select the desired frequency from the menu. The default B-mode frequency setting can be changed in the Configuration dialog box. The Color Flow frequency cannot be changed.
8	Depth display	Displays the imaging depth. The default imaging depth is 15 cm.	Always ON

Table 8 Split View Imaging Screen (Continued)

Number	Feature	Function	Notes
9	Grayscale	Used in adjusting monitor brightness and contrast	The grayscale is a vertical gradient bar on the imaging screen that allows the user to adjust the LCD's brightness to an optimal setting for the ambient lighting. The monitor should be adjusted to display as much of the grayscale range as possible. Grayscale is also used to set the Color/B-Mode Priority when imaging with CF or replaying a CF cineloop.
10	Image		
11	Freeze/Unfreeze	Toggle that starts or stops the acquisition of real-time images.	**Freeze:** Halts imaging on the last frame viewed and internally saves the last 50 frames. The 50-frame buffer enables you to scroll backward to view previous frames. When scrolling, the fps rate display indicates the speed at which you are reviewing frames.Use the play bar to scroll through the buffered frames. Use the playback buttons to tap or click through the sequence one frame at a time. **Unfreeze:** Resumes real-time imaging. See "Freeze/Unfreeze," page 47
12	Acquire/Record	Acquire	The large Acquire button starts a 3-second acquisition of real-time images and ECG.
13	Acquire/Record	Acquire	**New in Version 2.3.0:** The small Acquire button starts an extended, 6-second cineloop acquisition.
14	ECG waveform		
15	Heart rate	Expressed in beats per minute (bpm)	
16	Frame rate	Expressed in frames per second (fps)	The standard frame rate for B-mode imaging is 24 fps The B-mode 3-second acquisition frame rate is 50 fps; the 6-second acquisition frame rate is 24 fps. The CF-mode imaging frame rate varies with depth and colorbox width. The CF acquisition frame rate is double the standard CF frame rate with a maximum of 30 fps. Recovery frame rate is 6 fps. For more information on recovery mode, see page 63. **Note:** The frame rate shown represents the number of frames per second displayed on screen. This number is lower than the fps captured during acquisition due to the time required to process and render images on screen.
17	ECG lead	Select Lead I, II, or III	
18	Playback controls		
19	Playback scroll bar		
20	Image		
21	FAC information		
22	Date and time in readable format		

Table 8 Split View Imaging Screen (Continued)

Number	Feature	Function	Notes
23	Date and time		
24	Logo and institution name		

Probe Selection

The EVO and EVO 1 systems support both the ClariTEE and TTE probes. The Imaging window provides a probe dialog box for the user to select a probe. It displays information of the probes currently connected to either of the two connector ports in the back of the system.

For each probe, the probe information includes the name, type, time of first use, patient GUID and probe status. It also contains a list of probe presets which a user can choose for better imaging quality.

Note that the EVO Systems require a TTE license to support the TTE probe. If no license is present on the system, the TTE probe information will not be visible to the user.

Switching Probes

1. To select a probe, tap or click Probe button on bottom of screen to bring up the probe dialog box.
2. In probe dialog box, tap or click the radio button to choose a probe.
3. Tap or click **OK** in the probe dialog box. The probe is selected and real-time imaging resumes.

Note that if a probe is not connected, the radio button will be disabled.

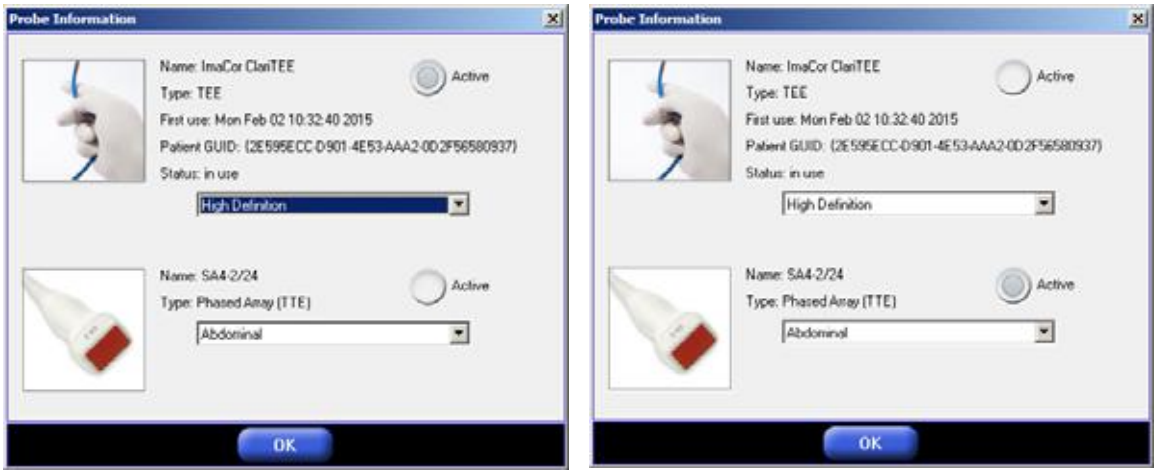


Fig. 30 Probe Dialog box depicting TEE probe is "Active" (left) and TTE probe is "Active" (right).

Loading Probe Settings

To load a probe setting for better imaging quality, you may use the probe dialog box or use the setting menu.

1. Using the probe dialog box - tap or click Probe button on bottom of screen to bring up the probe dialog box.
2. Each probe has a list of settings in the probe dialog box. Tap or click the drop-down menu and choose one setting from the following list for the "active" probe:
   - **ClariTEE probe:**
     - Resolution (Transmit frequency 7MHz, 128 B line density)
     - High Definition (default setting) (Transmit frequency 6MHz, 128 B line density)
     - Penetration (Transmit frequency 5MHz, 128 B line density)
   - **TTE probe:**
     - TTE 1.6 MHz

- TTE 2.0 MHz
- TTE 3.3 MHz

1 Using the setting menu - Tap or Click the setting menu in the upper right corner of the screen.

2 The “active” probe type is indicated by the tutorial button on the upper right corner of the screen.

3 The setting menu list will reflect the “active” probe settings - tab or click the probe setting.

Fig. 31 Setting menu list for TEE probe

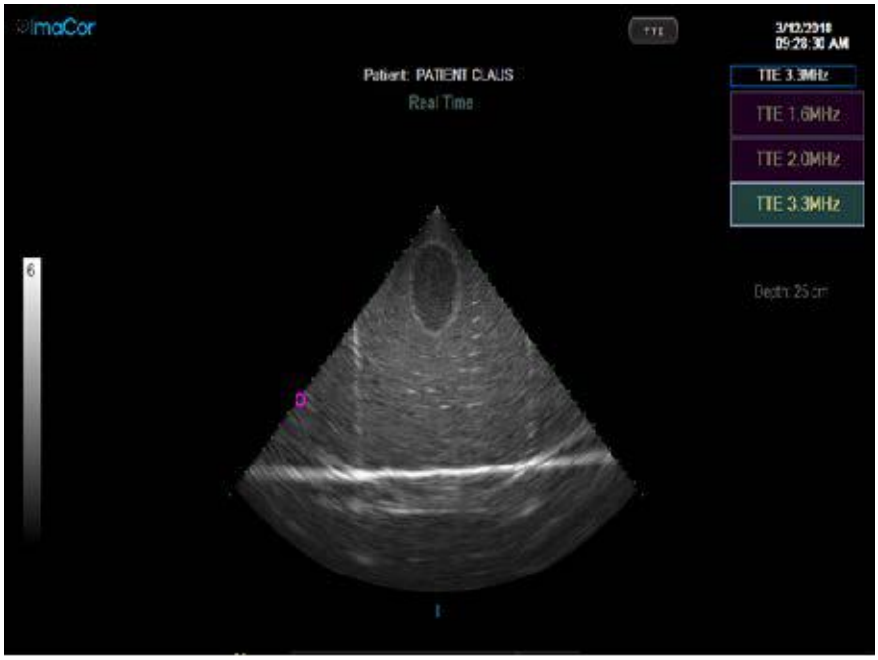


Fig. 32 Setting menu list for TTE probe

Real-Time Imaging

After leaving the Patient Information screen, you enter the imaging environment at the Single View screen. If a valid probe is connected, real-time imaging automatically begins. Figure 33 depicts real-time imaging in Single View mode. Real-time imaging can also take place in Split View mode; see “Split View Mode,” page 34. The maximum image depth is 18 cm.

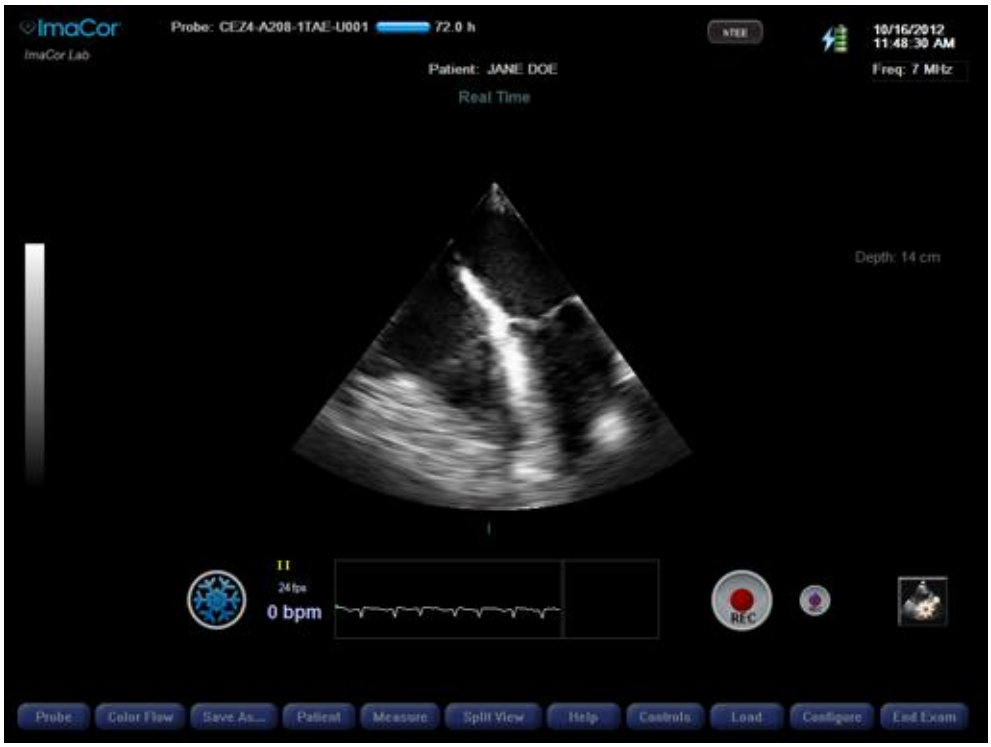


Fig. 33 Real-time imaging in single view mode

In Single View mode, real-time images are displayed in the center of the screen (see above).

In Split View mode, images are centered in the right and left halves of the screen, as shown on page Figure 78 on page 82. Real-time images are always displayed on the right side of the screen.

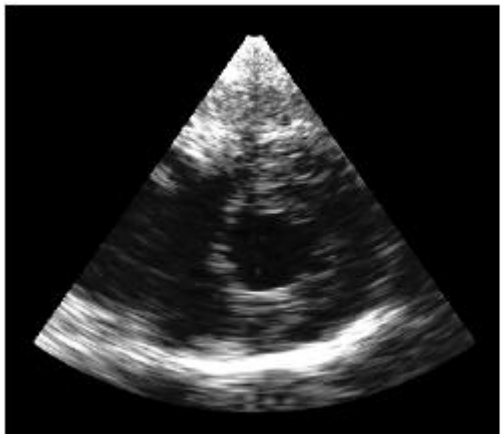


Fig. 34 Example left ventricle image in the TGSAV

Depth Markers

To display depth markers on a real-time ultrasound image:

Touch Screen

1 Tap anywhere on the screen and hold.

2 Choose the Depth Markers option from the global context menu (see Figure 35). The interval between two adjacent depth markers is 1 cm.

ZURA-EVO Imaging System Mouse

1 Right-click anywhere on the screen.

2 Choose the Depth Markers option from the global context menu (see Figure 35). The interval between two adjacent depth markers is 1 cm.

Fig. 35 Display depth marker option

Depth markers are superimposed on the ultrasound image, as shown in Figure 36. The depth marker setting is persistent across exams and system reboots.

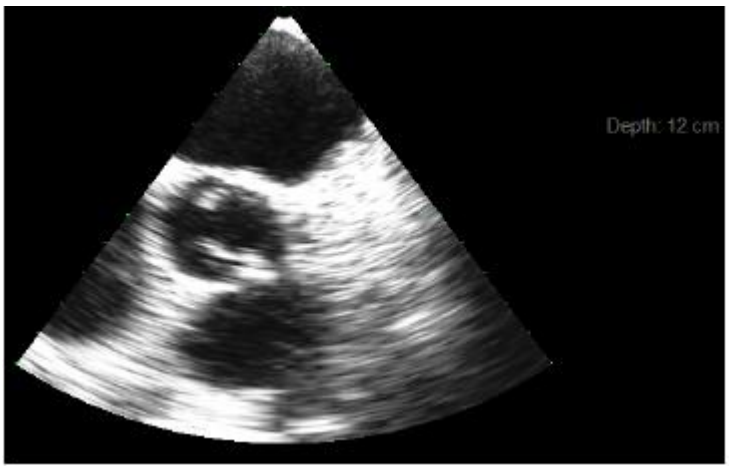


Fig. 36 Real-time image with depth markers

Freeze/Unfreeze

Freeze

The Freeze/Unfreeze functions are toggled via the imaging screen button labeled with the snowflake icon. The Freeze function halts imaging on the last frame viewed and internally saves the last 50 frames imaged. When in Frozen mode, no ultrasound imaging takes place.

The 50-frame buffer enables you to scroll backward to review previous frames and select the best one captured around the time the freeze was requested. When scrolling, the fps rate displayed onscreen indicates the speed at which you are reviewing frames. Scrolling is accomplished by dragging the horizontal scroll bar to the right or left, depending on whether you wish to advance or review previous frames (see Figure 37).

The playback buttons enable you to tap or click through the buffered frames one at a time.

Unfreeze

When in Unfreeze mode, there is continuous, real-time ultrasound imaging.

Fig. 37 Frozen single view environment scrolling enabled

Steering

The steering feature enables you to pan left or right without physically moving the probe. Steering can be helpful when:

- A structure of interest is only partially visible, but cannot be viewed in full by physically moving the probe.
- A structure is too large to be viewed in its entirety within the ZURA-EVO Imaging System's imaging sector.
  New in Version 2.3.0: The default sector angle is 90 degrees. In previous versions, the default sector angle was 70 degrees. If desired, the default can be reset to 70 degrees. See Configuration > General > Sector, page 91.

The degree of pan is dependent on the image depth:

- At image depths of 6 cm to 13 cm, the steering angle advances in six steps on either side of the image to ±26 degrees,
- At 14 cm, steering advances in five steps to ±21 degrees.

- At 15, 16, 17, and 18 cm, steering advances one step on either side of the image to ±4 degrees.
- For a 90 degree sector:
  - From 6–14 cm, steering is three steps on either side of the image
  - From 15–18 cm, steering is one step on either side of the image.

Activating the Steering Feature

Steering is available unless measuring or tracing modes are ON.

- Tap or click the right side of the ultrasound frames to pan right
- Tap or click the left side of the ultrasound frames to pan left

When steering is activated, two visual aids appear on screen:

- A set of blue arrows pointing in the direction of motion.
- Blue tick marks beneath the image. One mark is positioned on the centerline of the image and is stationary; the other indicates the incremental movement of the steering.

To reset steering to the center position (i.e., angle = 0) tap or click the centerline icon beneath the ultrasound image.

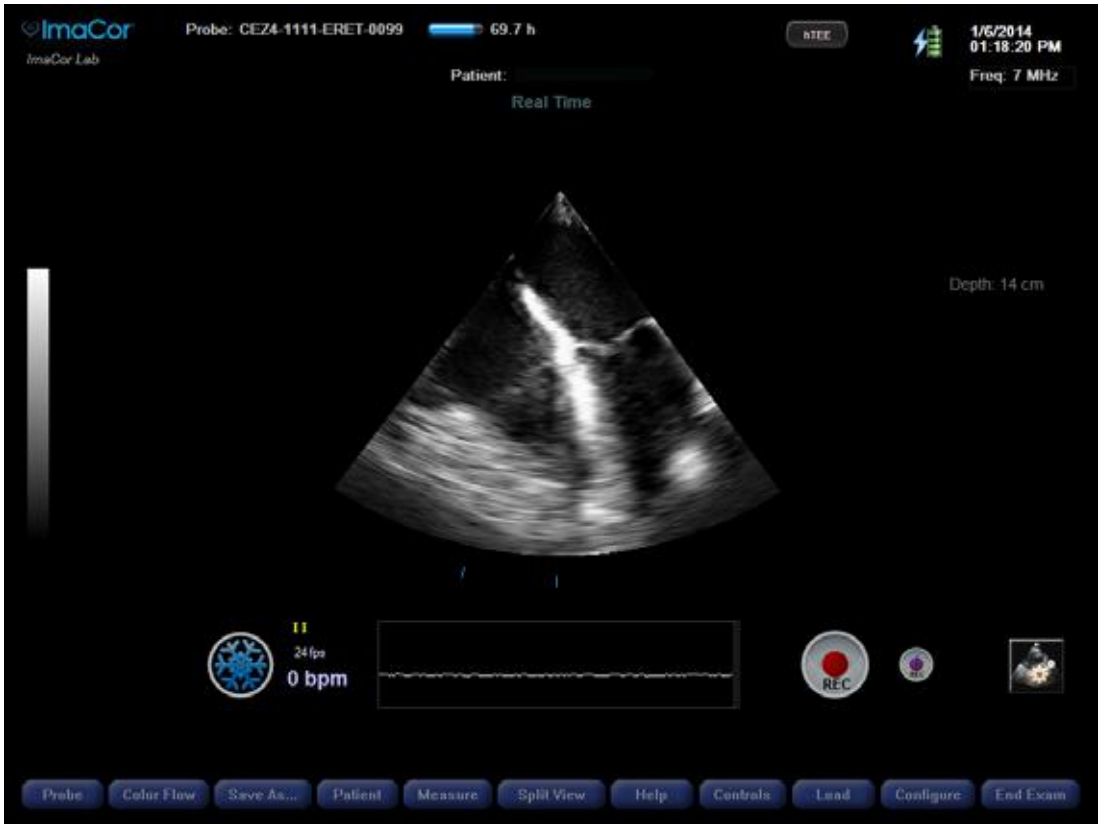


Fig. 38 Single View real-time screen with steering visible

Optimizing Real-Time Images

B-Mode Images

The ZURA-EVO Imaging System provides a wide range of controls to optimize real-time B-mode images captured by the ultrasound hardware.

- Gain control
- Time Gain Compensation (TGC)
- Auto-Q feature
- Filter control
- Contrast control
- Depth control
- B-Map control
- Focus control
- Dynamic control
- Reject control

The real-time control parameters are automatically saved when a patient is being imaged and are restored when the patient is re-examined.

Changing Default B-Mode Image Control Parameters

Default values can be customized in the Configuration window; choose the General tab. See page 91.

Restoring Default B-Mode Image Control Parameters

To restore default values for each control:

Touch Screen

1. Tap and hold the control,
2. Choose the Reset to Default menu.

ZURA-EVO Imaging System Mouse

1. Right-click the control.
2. Choose the Reset to Default menu.

Gain Control

Gain control regulates the gain of the ultrasound system. Gain determines the overall brightness of an image and is used in combination with TGC (see "Time Gain Compensation (TGC)," page 51).

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the image quality control display.
2. Tap or click the Gain control icon to activate the control (Figure 39). The current gain control setting is displayed on the right side of the gain gauge. The gain range is 0–20; the default setting is 10.
3. Set the desired value.
   - Decrease the gain value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.

– Increase the gain value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

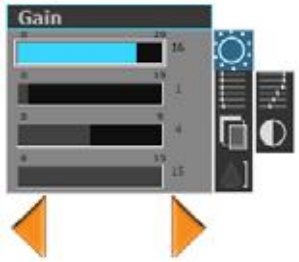


Fig. 39 Gain Control display

Time Gain Compensation (TGC)

TGC control is an index in a family of preset TGC curves. It simplifies the usual TGC slider controls.

Since ultrasound waves are attenuated, or absorbed, as they pass through tissue, the waves reflected from distant areas are weaker than those from the areas near the transducer. Without TGC, the image would have a light-to-dark gradient from the near field to the far field. TGC enables you to compensate for the loss of ultrasound waves in the far field by amplifying their signal. The result is even brightness across the entire field of view.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the image quality control display.
2. Tap or click the TGC control icon to activate the control, The TGC range is 0–19:
   – The TGC1 default setting is 5.
   – The TGC2 control is similar but controls the rolloff on the TGC curve. This is useful to attenuate the brightness in the far field. The TGC2 range is 0–15.
3. Tap the TGC control icon to activate the control (Figure 39). The current TGC control setting is displayed on the right side of the gain gauge.
4. To toggle between TGC1 and TGC2, tap or click the appropriate icon.
5. Set the desired value(s).
   – Decrease the TCG value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   – Increase the TGC value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

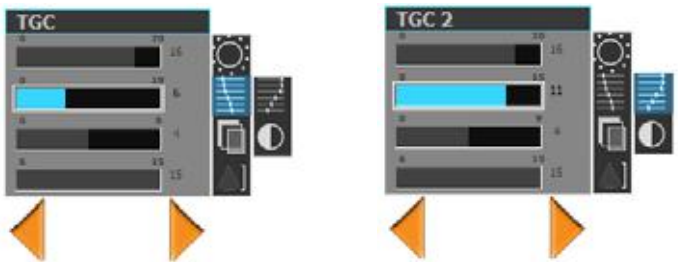


Fig. 40 TGC controls display

AUTO-Q FEATURE

Auto-Q is a "smart" Gain+TGC function that automatically adjusts the Gain, TGC1, and TGC2 settings until an optimal image is obtained.

To activate the Auto-Q feature, tap or left-click the onscreen Auto-Q button during live imaging (Figure 41).

Note: Image quality is subjective; you may prefer Gain and TGC settings other than those selected by Auto-Q.

Fig. 41 Auto-Q feature

Filter Control

The Filter control is a despeckling (noise reduction) filter that enhances the contrast of the preprocessed ultrasound images. The Filter control range is 0–9, with 0 specifying no filtering, and is adjusted in one-step increments.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the image quality control display.
2. Tap or click the Filter control icon to activate the control, The Filter control range is 0– 9; the default setting is 4.
3. Set the desired value.
   - Decrease the Filter value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Filter value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

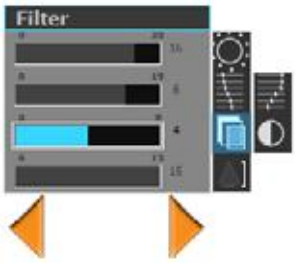


Fig. 42 Filter control display

Contrast Control

Contrast is a post-processing step applied to B-mode images. Increasing the contrast value brightens light portions of an images and deepens dark areas.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the image quality control display.
2. Tap or click the Contrast control icon to activate the control. The Contrast range is 0–10; the default setting is 2.
3. Set the desired value.
   - Decrease the Contrast value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Contrast value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

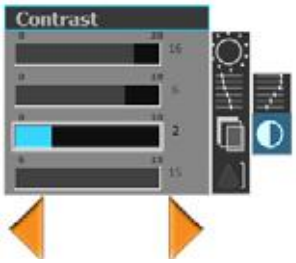


Fig. 43 Contrast control display

Depth Control

The Depth control determines the depth in centimeters of the displayed image. The Depth control range is 6–18 cm for TEE and 6-25 for TTE. It is adjusted in 1 cm increments.

The ZURA-EVO Imaging System automatically saves the last imaging depth for the selected patient and restores that depth when the patient is again selected for imaging.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the image quality control display.
2. Tap or click the Depth control icon to activate the control,
3. Set the desired value.
   - Decrease the Depth control value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Depth control value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

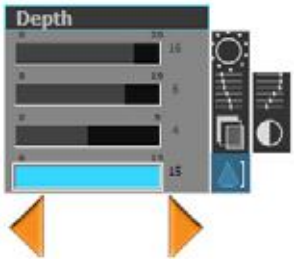


Fig. 44 Depth control display

TRUE DEPTH FEATURE

Images captured at depths less than 12 cm are magnified to fill the same display area as those obtained at depths ≥ 12 cm.

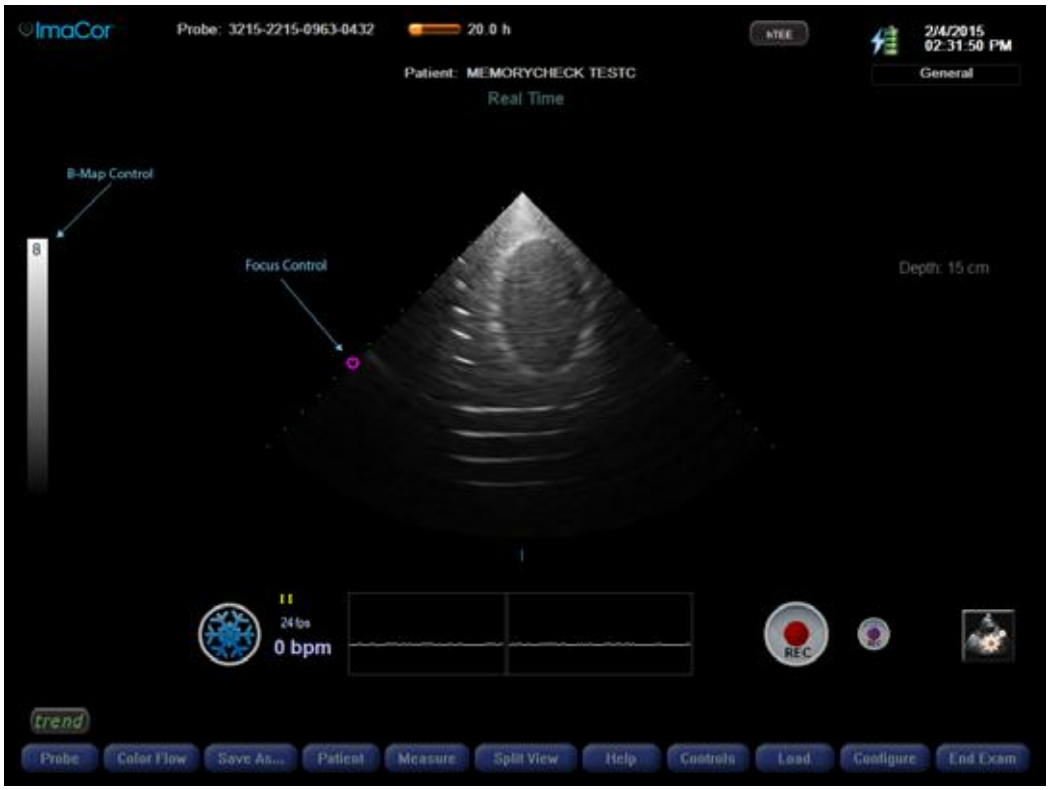
Fig. 45 True Depth feature—the same image at depths of 7 cm, 10 cm, and 12 cm (left to right)

B-Map Control

To change the B-map for better imaging quality, Tap or click the gray bar on the left side of the screen. The current B-map index number will be shown on the top of the gray bar with a range from 1 to 17.

Focus Control

To change the probe focus for better imaging quality, Tap or click inside the live imaging sector. The current focus depth marker is shown on the imaging sector and only appears during real-time imaging.



Dynamic Control

Dynamic range is the ratio of highest echo signal to lowest echo signal in dB.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; tap or click again to clear the image quality control display.
2. Tap or click the Dynamic control icon to activate the control. The Dynamic control range is 50–75; the default Dynamic range setting is 60.
3. Set the desired value.
   - Decrease the Dynamic value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Dynamic value by dragging he gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 46 Dynamic control

Reject Control

Reject range is the lowest echo signal in dB below which to discard.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; tap or click again to clear the image quality control display.
2. Tap or click the Reject control icon to activate the control. The CG Filter control range is 0–20; the default Reject setting is 10.
3. Set the desired value(s).
   - Decrease the Reject value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Reject value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 47 Reject control

Color Flow Images

Color flow imaging quality is managed by two real-time image quality controls: CF Gain and CF Filter. B-mode controls continue to be available in CF mode.

CF Gain Control

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; tap or click again to clear the image quality control display. To toggle between B-mode and CF gain, tap or click the appropriate icon.
2. Tap or click the Color Gain control icon to activate the control. The CG Gain control range is 0–45; the default CF gain setting is 25.
3. Set the desired value.
   - Decrease the CF Gain value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the CF Gain value by dragging he gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 48 CF gain control

CF Filter Control

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; tap or click again to clear the image quality control display. To toggle between B-mode and CF filter, tap or click the appropriate icon.
2. Tap or click the Color Filter control icon to activate the control. The CG Filter control range is 1–21 and is adjusted in one-step increments; the default CF filter setting is 15.
3. Set the desired value(s).
   - Decrease the CF Filter value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the CF Filter value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

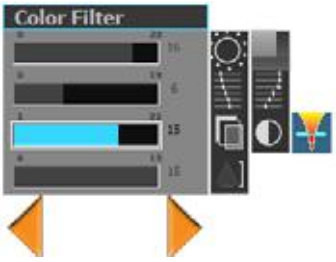


Fig. 49 CF filter control

The ECG Waveform

RELATED TOPICS

"Synchronized Cineloop Playback," page 83

Note: The ECG provided with the ZURA-EVO Imaging System is *not* for diagnostic purposes and is provided only to assist the detection of images at end systole and end diastole.

The ECG waveform display consists of three elements:

- ECG waveform
- ECG cursor
- ECG markers

The ImaCor ZURA-EVO Imaging System enables you to customize the ECG waveform display. The ECG waveform can be shown in both Single View and Split View environments.

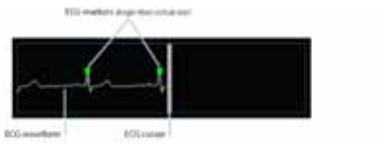


Fig. 50 Example ECG waveform with markers

ECG Cursor

The ECG cursor is a gray vertical bar (playhead) that indicates the current waveform being viewed, as shown in Figure 50. When reviewing frames, the ECG cursor is highlighted as it passes over an ECG marker, as shown in Figure 51.

Fig. 51 ECG waveform with highlighted cursor

ECG Markers

By default, an ECG marker is automatically placed at the peak of the R wave (see Figure 50). Marker placement is usually reliable, but can be inaccurate if:

- There is no ECG signal
- The signal is too low for R-wave detection
- The R-wave detection software misidentifies the R wave, which can occur with extremely atypical ECG waveforms

In these instances, ECG markers can be entered and edited manually (see page 58).

Fig. 52 Global menu

Adding an ECG Marker

Touch Screen

1. Use the playbar to scroll through the images until the ECG cursor is in the desired position.
2. Tap anywhere on the screen and hold.
3. Choose the Add ECG Marker option from the pop-up menu (see Figure 55).

ZURA-EVO Imaging System Mouse

1. Use the playbar to scroll through the images until the ECG cursor is in the desired position.
2. Right-click anywhere on the screen.
3. Choose the Add ECG Marker option from the pop-up menu (see Figure 55).

Deleting an ECG Marker

Touch Screen

1. Use the playbar to scroll through the images until the ECG cursor s highlighted over the marker you wish to remove.
2. Tap anywhere on the screen and hold.
3. Choose the Delete ECG Marker option from the pop-up menu (see Figure 55).

ZURA-EVO Imaging System Mouse

1. Use the playbar to scroll through the images until the ECG cursor is highlighted over the marker you wish to remove.
2. Right-click anywhere on the screen.
3. Choose the Delete ECG Marker option from the pop-up menu (see Figure 55).

If you delete all ECG markers on a cineloop, the ImaCor System software will attempt to detect the R-wave peaks and place ECG markers accordingly the next time the cineloop is loaded.

Changing the ECG Lead

Touch Screen

1. Tap anywhere on the screen and hold.
2. Choose the desired ECG Lead from the pop-up menu (see Figure 53).

ZURA-EVO Imaging System Mouse

1. Right-click anywhere on the screen.
2. Choose the desired ECG Lead from the pop-up menu (see Figure 53)

Fig. 53 Change ECG lead option

Changing the ECG Sweep Speed

Touch Screen

1. Tap anywhere on the screen and hold.
2. When the pop-up menu opens, choose from the two sweep-speed options: 25 mm/s and 50 mm/s, as shown in Figure 55.

ZURA-EVO Imaging System Mouse

1. Right-click anywhere on the screen.
2. When the pop-up menu opens, choose from the two sweep-speed options: 25 mm/s and 50 mm/s, as shown in Figure 55.

Inverting the ECG Waveform

Touch Screen

1. Tap anywhere on the screen and hold.
2. Choose the Invert ECG option from the pop-up menu (see Figure 55).

ZURA-EVO Imaging System Mouse

1. Right-click anywhere on the screen.
2. Choose the Invert ECG option from the pop-up menu (see Figure 55).

Fig. 54 Inverted ECG waveform with markers *(markers larger than actual size)*

Add ECG marker | Delete ECG marker | Change ECG sweep speed | Invert ECG waveform

Fig. 55 ECG menu options

Image Acquisition

RELATED TOPICS

Configuring the System | "Acquisition," page 92

"Deleting a Cineloop," page 70

Acquiring Images

Real-time images and ECG data can be acquired and saved as a three-second cineloop. Images can be acquired in both Single View and Split View modes. Figure 56 shows the Single View imaging screen during acquisition.

New in Version 2.3.0: A six-second cineloop acquisition option is available

Image acquisition can be accomplished in one of two ways:

1 Tapping or clicking the onscreen Acquire button
   - Tap the large Acquire button to initiate a 3-second acquisition.
   - Tap the small Acquire button to initiate a 6-second acquisition.

2 Pressing the Acquire button on the probe handle

By default, the new cineloop is automatically loaded and ready for playback after acquisition. This behavior can be changed in the Acquisitions tab of the Configuration window. For additional information, see "Acquisition," page 92.

Acquisition Frame Rates

The **B-mode 3-second acquisition frame rate** accelerates from 24 fps for increased resolution.

The **CF acquisition frame rate** is twice the CF frame rate in continuous imaging up to a maximum of 30 fps. For example, if the CF frame rate is 13 fps, the acquisition rate is 26 fps. However, if the CF frame rate is 20 fps, acquisition is 30 fps.

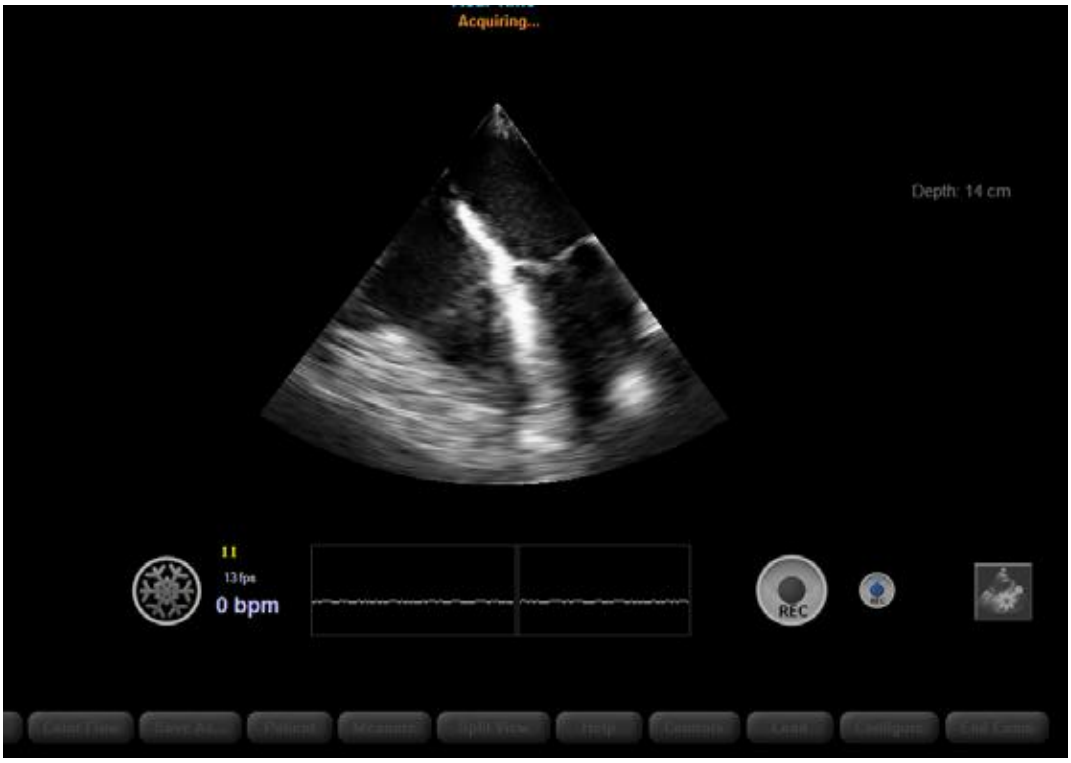


Fig. 56 Image acquisition – Single View mode

Adding Comments to Cineloops

While the cineloop is being saved to disk, you may enter a comment in the cineloop comment window. The Comment window appears as soon as the ZURA-EVO Imaging System begins saving the cineloop (see Figure 57). Comments are visible onscreen when previewing cineloops and when a cineloop is loaded.

Entering comments is optional; comments can be added or edited later. Click the appropriate radio button to indicate the hTEE view type of the acquired cineloop. If you don't wish to enter a comment, tap or click the OK or Cancel button to clear the dialog box.

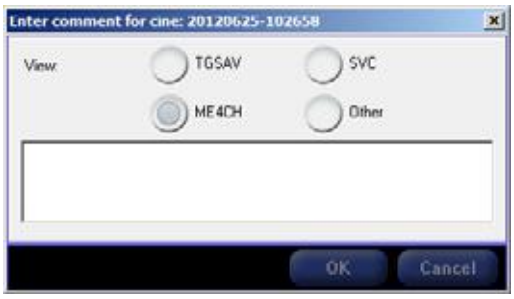


Fig. 57 Comments dialog box

Recovery Mode

Safety Feature
Recovery mode allows the ClariTEE probe to cool.

While the cineloop is being written to disk, the ImaCor ZURA-EVO Imaging System software enters a 3.3-second recovery mode to allow the probe to cool. During the recovery period, the acquisition function is disabled.

Imaging is allowed after the cineloop has been saved to disk. At the end of the recovery period, acquisition is re-enabled.

Image Storage

The ZURA-EVO Imaging System stores up to 100 cineloops per patient. If a cineloop is acquired after the limit has been reached, you will be prompted to overwrite the oldest cineloop with the new acquisition. If desired, you can cancel the operation and manually delete selected cineloops. For additional information, see “Deleting a Cineloop,” page 70.

Managing Cineloops

Related Topics

Configuring the System | "Acquisition," page 92
"Color Flow Imaging," page 86
"Synchronized Cineloop Playback," page 83
"Loading Two Cineloops in Split View Mode," page 81
"Viewing a Cineloop and Real-Time Images in Split View Mode," page 81

Loading a Cineloop

1 **From the Patient Information screen:**
   – Select a patient name from the Patient List
   – Tap or click the Next button to enter the imaging environment

2 **From the imaging environment,** tap or click the Load button. The Load Loop window is displayed.

   Note: Cineloops are automatically loaded after acquisition. This behavior can be changed in the Acquisitions tab of the Configuration window. For additional information, see "Acquisition," page 92.

Fig. 58 Load cineloop windows

3 Folders containing cineloops are listed in the Select Loop section. The folders are labeled with the date the cineloops were acquired. Locate the folder containing the cineloop you wish to view.

4 Tap or click the appropriate folder to see a list of cineloops contained within it. Each cineloop name is preceded by an icon that indicates whether it is a B-mode or Color Flow cineloop, as follows.
   – B mode icon:
   – CF mode icon:

5 To assist with cineloop identification, the first 32 characters of the cineloop comment are displayed. Cineloops are also labeled with the date and time of acquisition and hTEE view type, if available. Locate the cineloop you wish to view.

6 Tap or click once on the desired cineloop. If the Show Preview option is checked, the cineloop is displayed in the lower right of the Load Loop dialog window, along with comments and hTEE measurements. See Figure 58.

7 Tap or click the OK button to load the selected cineloop.

Reviewing a Cineloop

Cineloop Control Buttons

Once the cineloop is loaded, a set of cineloop playback controls appears onscreen, as shown in Figure 61. Figure 59 shows where the cineloop controls are located on the imaging screen.

Table 9 Cineloop Control Buttons

Button icon	Button name	Function
	Play/Pause toggle	Plays a cineloop
	Play/Pause toggle	Pauses a cineloop
	Forward	• **While a cineloop is paused**, the Forward button advances the cineloop one frame. • **While a cineloop is playing**, the Forward button increases the playback speed. Playback speeds are: 0.25 0.5 0.75 1.0 1.5 2.0
	Backward	• **While a cineloop is paused**, the Backward button reverses the cineloop one frame. • **While a cineloop is playing**, the Backward button decreases the playback speed. Playback speeds are: 0.25 0.5 0.75 1.0 1.5 2.0
	Jump	Advances to the next ECG marker

Fig. 59 Single View mode with cineloop control buttons

Color Flow Indicator Icon

When Color Flow (CF) images are available for a cineloop, the CF indicator icon is displayed. Tap or click the CF indicator icon to toggle on and off the display of Color Flow images during cineloop playback and when viewing frozen real-time images.

Table 10 Color Flow Indicator Icons

Icon	Function
	Indicates that color flow images are available and are displayed.
	Indicates that color flow images are available but are not displayed.

Cineloop Image Quality Controls

Cineloop image quality controls enhance existing loops for review purposes. Changes to the image control settings are not saved with the cineloop.

Brightness Control

The Brightness control allows you to increase or decrease the brightness of your cineloop.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the cineloop image quality control display.
2. Tap or click the Brightness control icon to activate the control. The Brightness control range is 0.5–2; the default setting is 1.0.
3. Set the desired value.
   - Decrease the Brightness value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Brightness value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 60 Brightness control display

Depth Brightness Compensation (DBC)

Related Topic
"Time Gain Compensation (TGC)," page 51

Similar to the TGC, the DBC applies brightness curves to the image.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the cineloop image quality control display.
2. Tap or click the Depth Brightness Compensation icon to activate the control. The Depth Brightness Compensation range is 0–10; the default setting is 0.
3. Set the desired value.
   - Decrease the Depth Brightness Compensation value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Depth Brightness Compensation by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 61 Depth brightness compensation control (DBC) display

Contrast Control

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the cineloop image quality control display.
2. Tap or click the Contrast control icon to activate the control. The Contrast control range is 0–10; the default setting is 2.
3. Set the desired value.
   - Decrease the Contrast control value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Contrast control by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 62 Contrast control display

Depth Control

The Depth control regulates visible area of an image.

1. Tap or click the Controls button at the bottom of the screen to display the image quality controls. The Controls button acts as a toggle; press it again to clear the cineloop image quality control display.
2. Tap or click the Depth control icon to activate the control. The Depth control range is 0–15; the default depth for playback is the depth at which the cineloop was acquired.
3. Set the desired value.
   - Decrease the Depth control value by dragging the gauge value bar to the left or by tapping/clicking the left arrow beneath the control.
   - Increase the Depth control value by dragging the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

Fig. 63 Depth control display

Saving a Cineloop as a Movie

Related Topics
"Loading a Cineloop," page 64

Cineloops can be exported as movies that can be viewed on standard video (.AVI and .MOV) players. Exported movies must be saved to a USB thumb drive. You need not use an ImaCor-formatted DTM for this operation. Cineloops are watermarked with the ImaCor logo.

1 From within the imaging environment, tap or click the Load button to load the cineloop. For information on loading a cineloop, see page 64.

2 Insert a USB thumb drive.

3 Tap or click the Save As button, or select the Save As option from the global context menu.

Touch Screen

- Tap anywhere on the screen and hold to bring up the global context menu.
- Select the Save As option.

ZURA-EVO Imaging System Mouse

- Right-click anywhere on the screen to bring up the global context menu.
- Select the Save As option.

4 When the Save As window opens, specify the following:

- Desired movie format (AVI or MOV)
- Scaling, if desired
- Inclusion of ECG trace, if desired

5 Click the Export button (see Figure 64). A progress bar is displayed while the movie is exporting.

Saving the Current Frame as a BMP Image

The current frame can also be saved as a BMP image, as shown in Figure 64. Follow the steps for saving a cineloop as a movie, but select the BMP (single-frame) option from the Save As window. Like cineloops, single-frame BMP images are also watermarked with the ImaCor logo.

Fig. 64 Export movie format options

Deleting a Cineloop

You can store a maximum of 100 cineloops per patient. As you near a patient's cineloop limit, warning messages are displayed, as shown in Figure 65.

Fig. 65 Warning: cineloop limit approaching

Once 100 cineloops have been saved, you cannot acquire additional images unless you overwrite the oldest loop or delete one or more cineloops.

Fig. 66 Warning: cineloop limit reached

1. From within the imaging environment, tap or click the Load button.
2. Tap or click the Clean Up button.
3. From within the Load Loop dialog screen, tap or click to select the cineloop(s) you wish to delete.
4. Tap or click the Delete button.

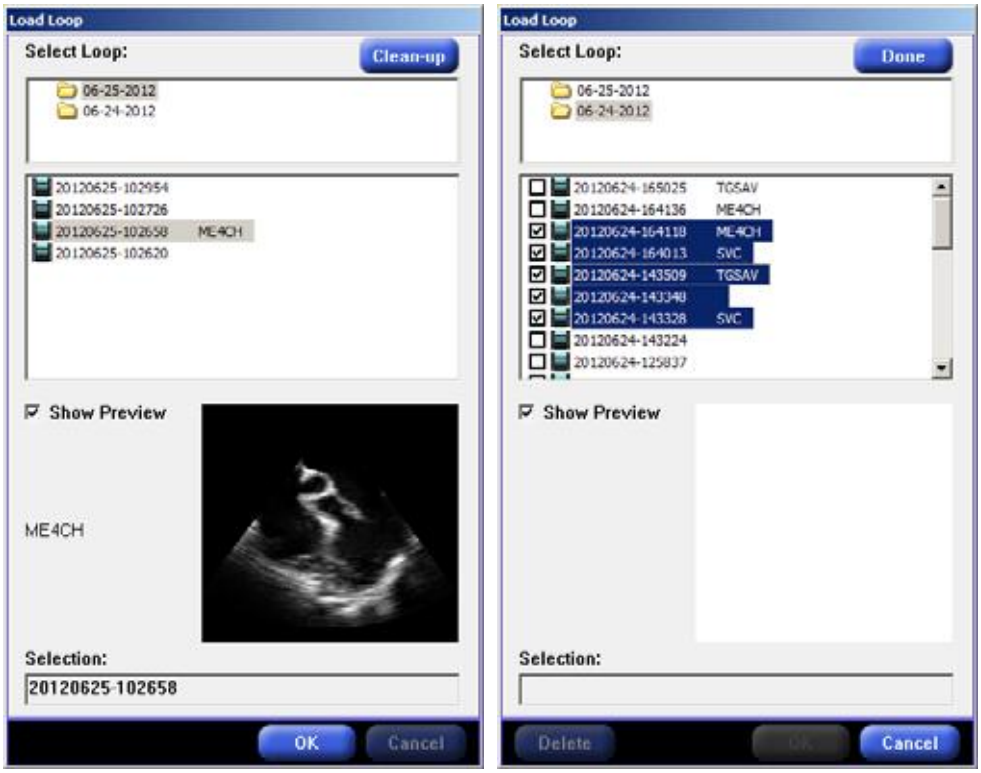


Fig. 67 Delete cineloop screen

5 When the warning message appears, tap or click the Yes button to delete the cineloop or No to cancel the operation. *Once a cineloop has been deleted, it cannot be retrieved.*

Fig. 68 Delete cineloop confirmation

6 Tap or click the Done button to exit Clean-up mode.

Measurement Tools

The ImaCor ZURA-EVO Imaging System software provides two measuring tools:

- The **Tracing Tool**, for area measurements. This tool is key when performing hTEE calculations:
  - FAC
  - RV/LV ratio
  - SVC collapsibility index

  Area measurement is the default measuring mode.
- The **Measuring Tape Tool**, for distance measurements.

The Tracing Tool

To access tracing tool, tap or click the onscreen Measure button, Area measuring is activated by default.

Turning off tracing mode hides the trace until you turn tracing mode back on; it does not delete the trace.

You can have only one trace onscreen at a time. If you wish to create a new measurement, you must delete the existing trace.

Fig. 69 Accessing the area measuring mode with the onscreen Measure button

Creating a Trace

Touch Screen

1 Tap the screen to set the first anchor point and begin the trace.

2 Drag your finger to draw the trace.

3 To close the trace, end your trace near the starting point. The trace closes automatically.

ZURA-EVO Imaging System Mouse

1. Right or left-click to set first anchor point and begin the trace.
2. Use the mouse to draw the trace. When tracing, the mouse is set to a lower sensitivity to reduce tracing errors. Mouse speed can be customized in the in the Configuration dialog box (see page 91). A low speed number indicates low sensitivity; high speed number high sensitivity.
3. To close the trace, end your trace near the starting point. The trace closes automatically.

Once you start tracing, any movement sets points at a fixed interval. The interval is called trace resolution and can be changed in the Configuration dialog box (see page 91).

Traces are automatically saved with the patient exam.

Deleting Points on a Trace

1. To backtrack one point while tracing, tap or click the onscreen Delete button.
2. Tapping or clicking the Delete button multiple times erases multiple points.
3. To clear all points at once, tap or click the onscreen Clear All button.

Fig. 70 Single View mode, editing multiple points

Deleting a Trace

FROM WITHIN TRACE MODE

1. Be sure no points are selected.
2. Tap or click the onscreen Delete button.

FROM WITHIN DISTANCE OR AREA MODE

1. Tap or click the onscreen Clear All button.

To clear all distance and area measurements at once, tap or click the Clear All button.

The Measuring Tape Tool

The measuring tape tool can be accessed by tapping or clicking the onscreen Measure button and selecting Distance. The informational message "Measure: ON" is displayed on the screen.

Fig. 71 Accessing the Measuring Tape tool with the onscreen Measure button.

Taking a Measurement

Distance measurements are automatically saved with the patient exam. You can set two distance measurements, which will be labeled onscreen as Dist1 and Dist2. The end points are labeled 1 and 2 (see Figure 72).

TAKING THE FIRST MEASUREMENT

Touch Screen

1. Tap to set the first end point
2. Tap again to set the second end point, completing the measurement.
3. Alternatively, you can tap to set the start point, then drag and watch the end point stretch as you drag. Lift your finger off the screen to drop the end point.

ZURA-EVO Imaging System Mouse

1. Right or left click to set the first end point.
2. Click again to complete the measurement.

TAKING THE SECOND MEASUREMENT

To create a second measurement, set a second starting point and a second end point.

If the end point of a measurement must begin on top of or very near another point:

Touch Screen

1. Create a second measurement.
2. Drag and drop the point(s) to the desired location.

ZURA-EVO Imaging System Mouse

1. Move the cursor to the desired end point location and pause until the highlight on the neighboring point disappears.
2. Right-click to set the point in the new position.

Editing a Measurement

Touch Screen

1. Tap one of the end points.
2. Drag and drop the point to a new position.

ZURA-EVO Imaging System Mouse

1. Click or right-click one of the end points.
2. Right-click to set the point in a new location.

Deleting a Measurement

Touch Screen

1. Tap either of the end points.
2. When an end point is highlighted, tap the onscreen Delete button.

ZURA-EVO Imaging System Mouse

1. Move the tape measure tool about either of the end points.
2. When an end point is highlighted, press the Delete key.

To clear all distance and area measurements at once, tap or click the Clear All button.

Viewing Measurements

You can view distance and area measurements at the same time. Select both modes, and both measurements are displayed simultaneously.

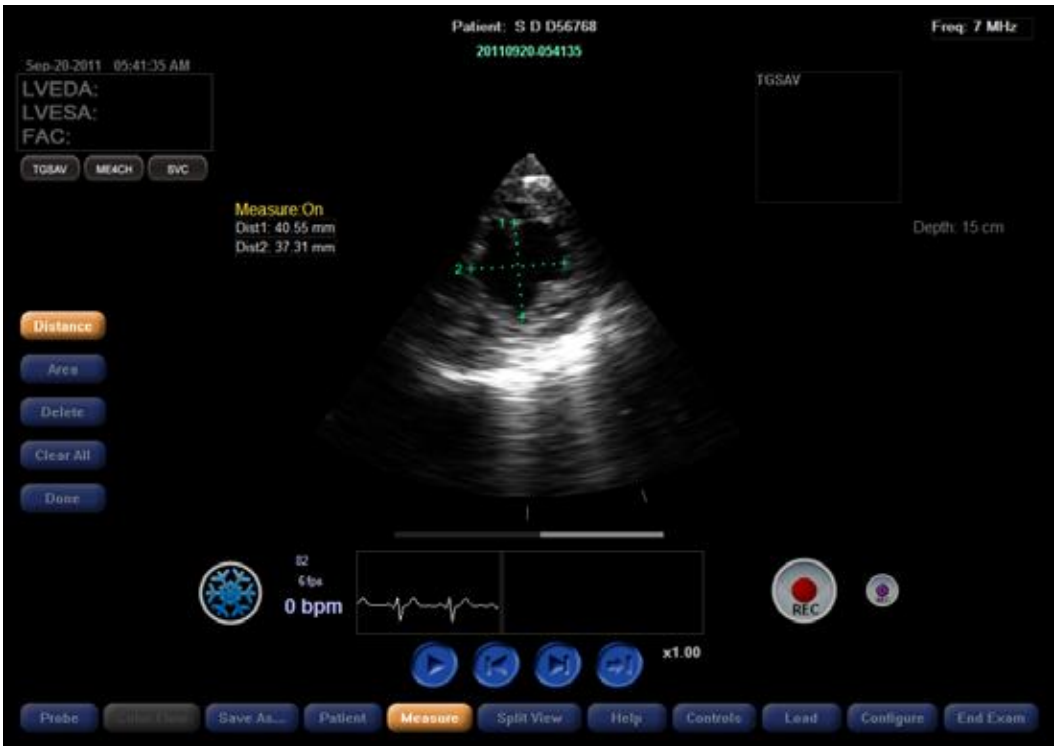


Fig. 72 Single View mode with distance measurements (Measure: ON)

If you turn off either trace or measure mode, both measurements are hidden. Reactivating one mode will display only the measurement associated with it. The second measurement can be turned on separately, if desired.

Viewing Measurements on Cineloops

When a cineloop containing distance and/or area measurements is loaded, the measurements are visible only if measure mode is ON. *The measurements displayed may not apply to the current frame.* To view the frame on which the measurements were based:

Touch Screen

- Tap the distance or area value. A blue rectangle appears around the value.
- Tap the measurement value to jump to the corresponding frame.

ZURA-EVO Imaging System Mouse

- Move your mouse over the distance or area value. A blue rectangle appears around the value.
- Left-click the measurement value to jump to the corresponding frame.

Trending

The hemodynamic trending displays cardiac filling and function data over time in a dashboard format. There are three types of cardiac measurements to trend: TGSAV, FAC and ME4CH Ratio and SVC index.

To create a trending measurement:

1 Create the trace measurements from existing cineloops of the current patient in the Imaging screen. The trace measurements can be any desired type among the TGSAV, FAC and ME4CH Ratio or SVC index.

2 Tap or click the ***trend*** button to display the trending graph. The trend button changes to an **OK** button.

3 To close the trending graph, tap the **OK** button.

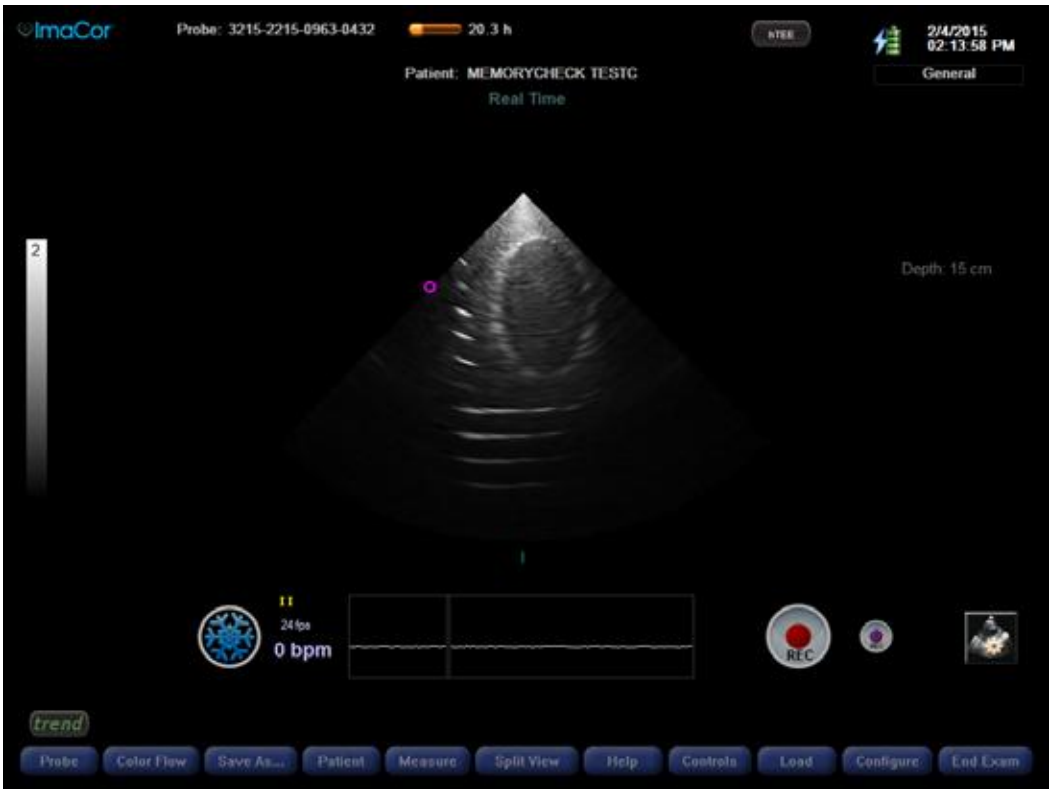


Fig. 73 Trending button.

The system collects existing measurements for the current patient and displays the trending curves on top of the Imaging screen.

Fig. 74 Trending measurements.

ZURA-EVO Imaging System hTEE Measurement Functions

Related Topic
"Loading a Cineloop," page 64

The ZURA-EVO Imaging System enables you to perform three types of hTEE measurements:

- FAC (LVEDA, LVESA)
- RV/LV ratio (RVEDA, LVEDA)
- SVC collapsibility index (SVC max, SVC min)

All three measurement types can be taken directly. Fractional area change (FAC) calculations can also be performed with the assistance of the FAC Wizard, which guides you through the process of completing FAC calculations.

Measuring Mode

hTEE measurements are performed in Measuring mode.

1 Load a cineloop.

2 Tap or click the Measure button to activate Measuring mode.

3 Tap or click to select the desired measurement type:
   - **TGSAV** displays the LVEDA, LVESA, and FAC measurements
   - **ME4CH** displays the LVEDA, RVEDA, and ratio
   - **SVC** displays the SVCmin, SVCmax, and index

   Only one type of hTEE measurement can be applied to a cineloop. If you switch from one measurement type to another the previous measurements are lost. You are prompted about the potential loss when switching between measuring modes.

Note: If the hTEE view type has been specified, the corresponding measurement type is automatically selected. The hTEE view type can be indicated by selecting the appropriate radio button in the cineloop Comments window (see Figure 52 on page 58).

Using a Trace for hTEE Measurement

A new trace can be used to update an existing hTEE measurement. To substitute a new area value:

Touch Screen

1 Tap the desired field (LVEDA, RVEDA, LVESA, SVCmin or SVCmax) and hold while Tracing or Measuring mode is on and a closed trace is displayed.

2 Select the "Use current trace" option, as shown in Figure 75.

ZURA-EVO Imaging System Mouse

1 Right-click the desired field (LVEDA OR LVESA) while Tracing or Measuring mode is on and a closed trace is displayed.

2 Select the "Use current trace" option, as shown in Figure 75.

Fig. 75 Manually updating a trace value

Reviewing an hTEE Trace

To review an existing hTEE trace, click on the desired measurement (LVEDA, LVESA, RVEDA, SVCMin, SVCMax). The ZURA-EVO Imaging System software automatically displays the traced frame and highlights the selected measurement.

Fig. 76 FAC calculation results

Trace Overlay Mode

Trace overlay mode allows you to display or hide the hTEE traces on cineloops.

To turn **on** trace overlay mode, left click on any hTEE measurement value (LVEDA, LVESA, RVEDA, SVCMin, SVCMax).

Trace overlay mode can be turned **off** by accessing the global context menu and selecting the Overlays option.

Working in Split View Mode

Loading Two Cineloops in Split View Mode

1 Access the Split View screen.

2 Tap or click the Load button.

3 When the Load Loop window is displayed, select a loop from the left and one from the right pane, as shown in Figure 77.

4 When the cineloops have been selected, tap or click the OK button.

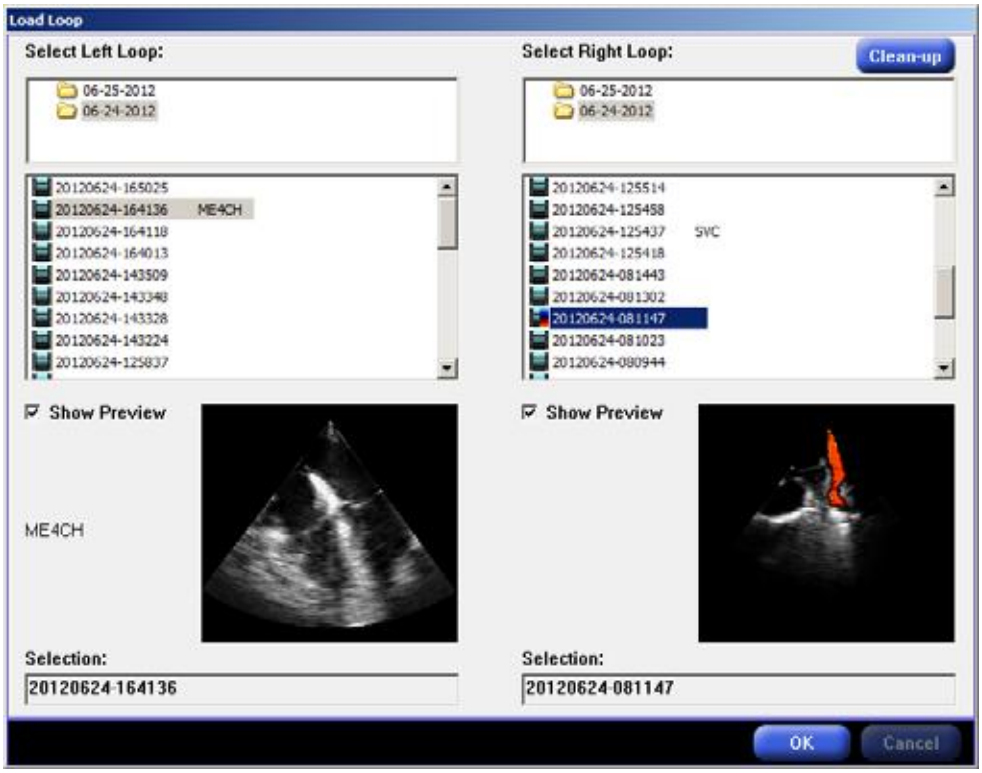


Fig. 77 Split View mode – loading two cineloops

Viewing a Cineloop and Real-Time Images in Split View Mode

1 Access the Split View screen.

2 Tap or click the Load button.

3 When the Load Loop window is displayed, tap or click to select a cineloop from the **left** pane.

4 When the cineloop has been selected, tap or click the OK button. The cineloop is displayed on the left of the Split View screen, real-time imaging on the right.

Note: If you load a cineloop from the right pane during real-time imaging, the cineloop replaces the real-time view. Tap or click the Unfreeze button to resume real-time imaging.

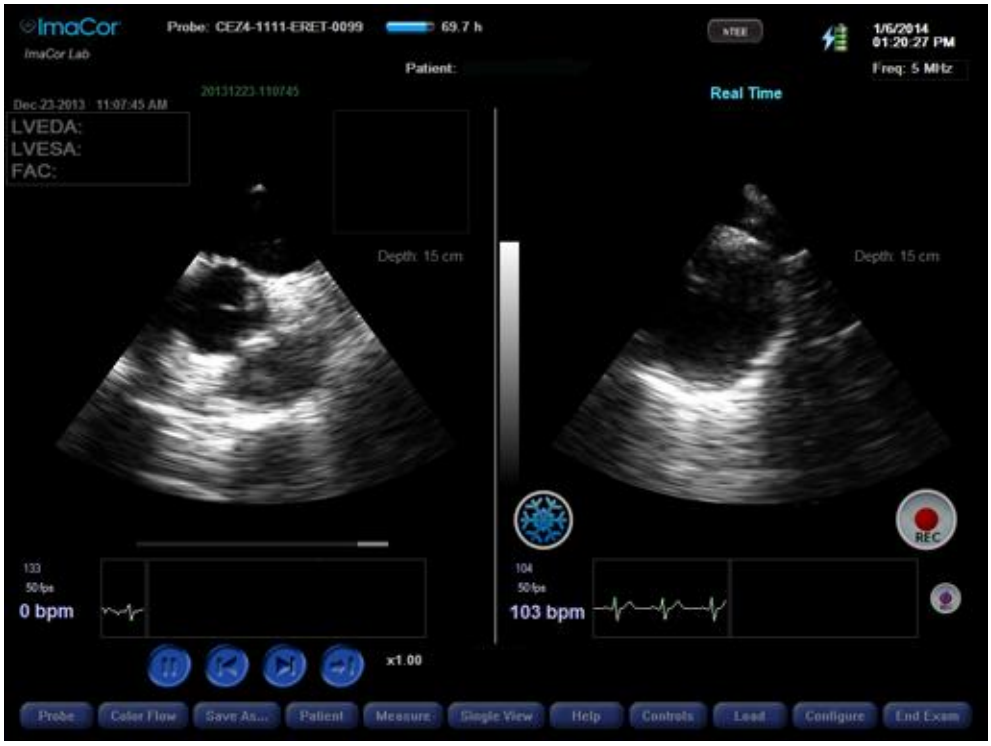


Fig. 78 Viewing a cineloop (left) and a real-time image (right) in Split View mode

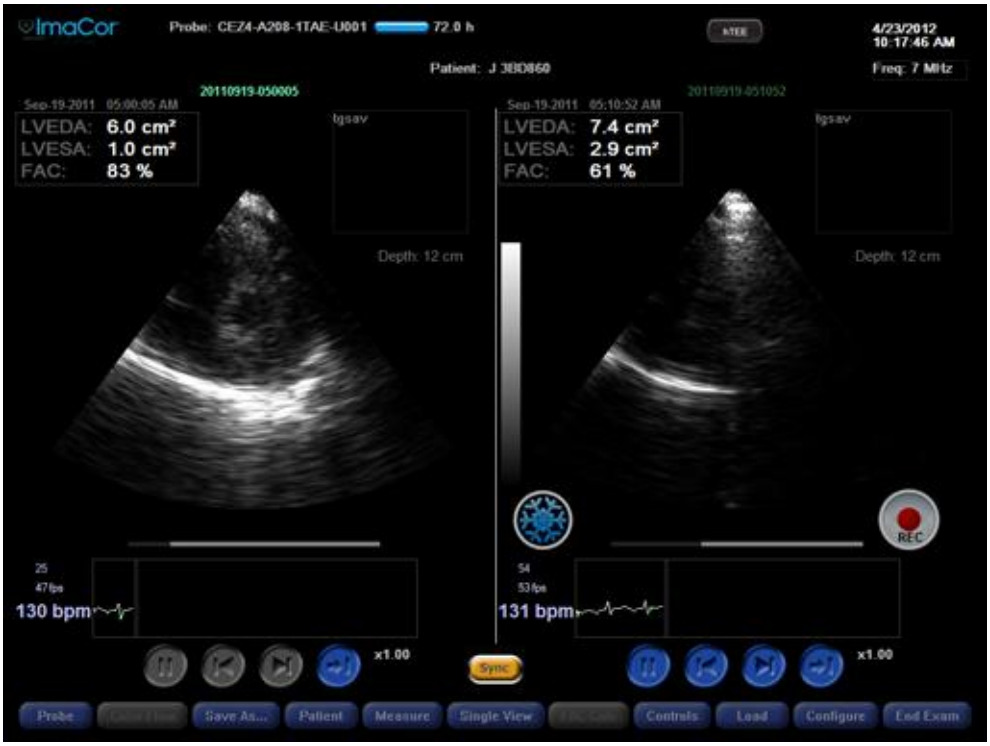


Fig. 79 Split View mode – cineloop comparison

Synchronized Cineloop Playback

The synchronized playback function enables you to review a full cardiac cycle from two different cineloops in a synchronized fashion. You must view cineloops—the function is unavailable during real-time imaging—and each loop must have at least two ECG markers.

The software synchronizes the playback using the first two consecutive ECG markers it encounters on each cineloop. If the cineloop frames were not advanced after being loaded, these will be the first two ECG markers in the cineloop.

Specifying ECG Markers

If one or both cineloops contain more than two ECG markers, you can specify which marker should be used to begin the synchronization.

1. To advance to the next ECG marker, tap or click on the Jump to ECG marker button, located below the corresponding cineloop.
2. Repeat the process on the other cineloop, if desired.

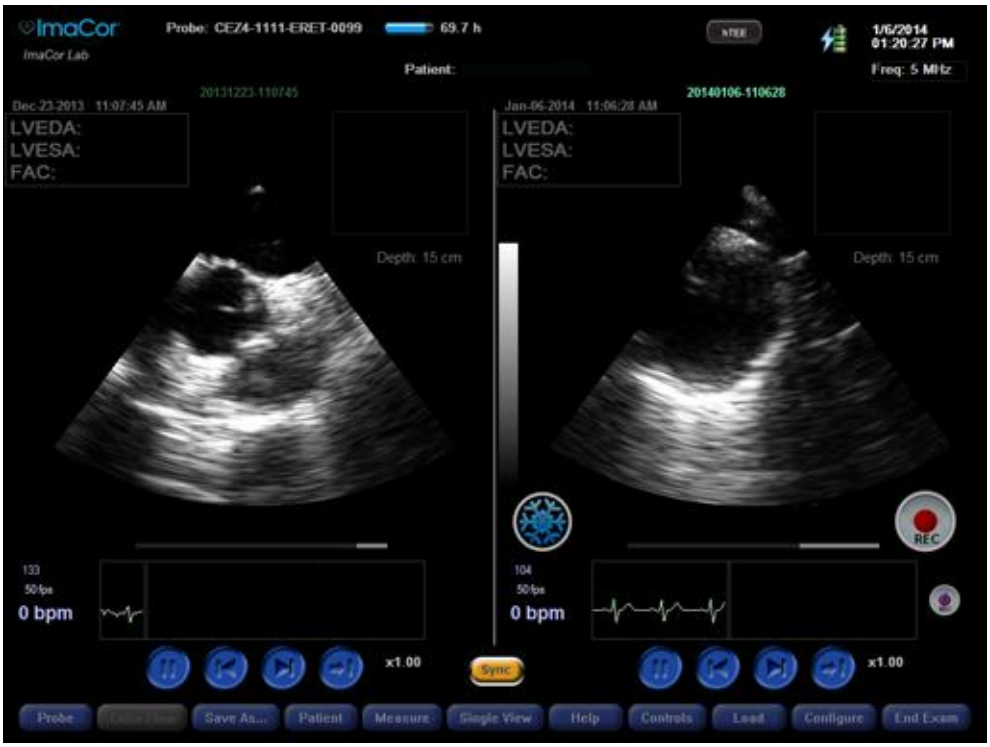


Fig. 80 Synchronized playback

Activating and Deactivating Synchronized Playback

The Sync button, shown in Figure 81, toggles synchronized playback on and off.

Fig. 81 Playback buttons with Sync button active.

Synchronized Playback Speed Controls

During synchronized playback, the Forward and Back buttons act as speed controls. The Forward button increases the frame rate and Back slows the playback. Playback speeds are: 0.25, 0.5, 0.75, 1.0, 1.5, 2.0.

To view a frame-by-frame synchronized playback, you must scroll on the master (right) side of the display, as shown in Figure 80.

When in pause mode, the Forward and Back buttons enable you to step forward and backward one frame at a time.

Superimposed Mode

In Split View mode, traces can be superimposed for comparison. The Compare Measurements menu is enabled when two cineloops are loaded and both have hTEE measurements of the same type.

Working in Superimposed Mode

Touch Screen

1. To access the Context menu, tap anywhere on the image and hold.
2. When the Context menu is displayed, select the Compare Measurements option from the popup, as shown in Figure 82.

ZURA-EVO Imaging System Mouse

1. To access the Context menu, right click anywhere on the image.
2. When the Context menu is displayed, select Compare Measurements from the popup, as shown in Figure 82.

Fig. 82 Compare Measurements menu option

The Superimposed View window is displayed in the center of the screen. By default, the LVEDA trace of each loop is superimposed on a black background. The LVEDA trace from the left panel is in green, and the right in blue (see Figure 83). To view superimposed LVESA traces, click the ES button on the Superimposed View window.

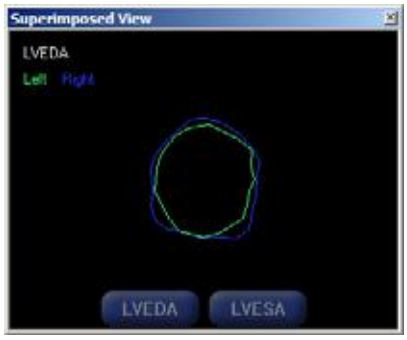


Fig. 83 Split View mode with Compare ED/ES selected

Color Flow Imaging

Color flow (CF) imaging, also known as Color Doppler, uses color to detect blood flow and determine flow direction. Colors in the middle to the top of the Color Map indicate positive blood-flow velocities; i.e., blood flow toward the transducer. Colors in the middle to the bottom of the range show negative blood-flow velocities; i.e., blood flow away from the transducer.

Color Flow mode can be activated during real-time imaging mode. Activate CF imaging mode by tapping or clicking the Color Flow button in the button bar.

When Color Flow imaging is on the "Color ON" indicator is displayed, as shown in Figure 84.

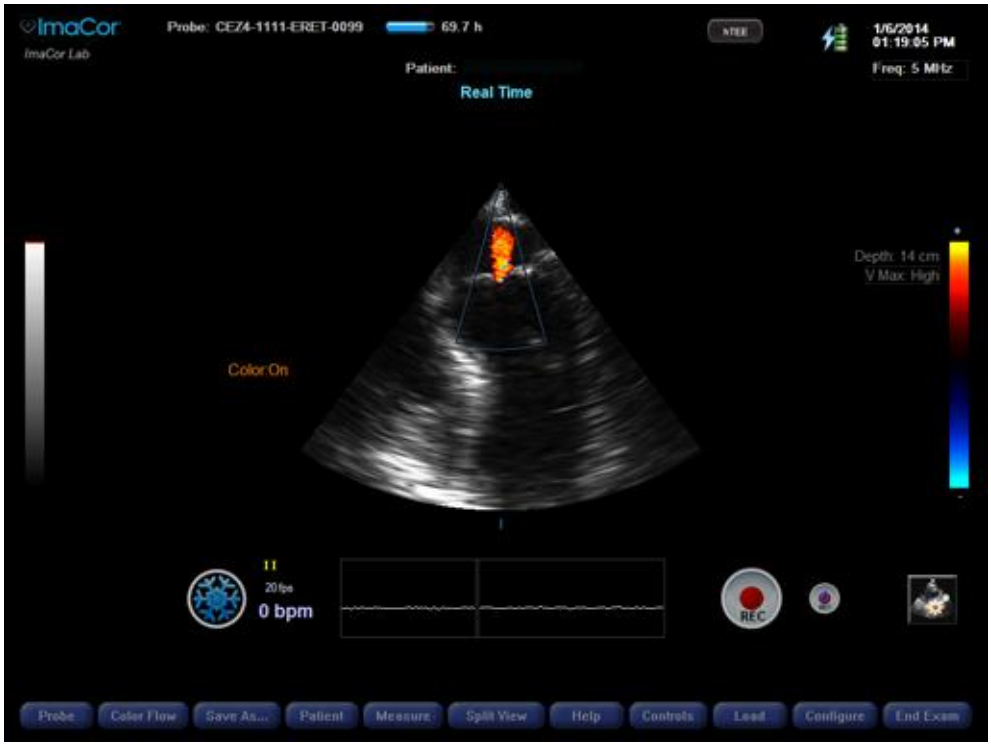


Fig. 84 Real-time imaging with Color Flow imaging active

The Color Box

The color box, shown in Figure 85, defines the region where CF data is displayed. The color box is visible when viewing:

- real-time images
- frozen buffer images
- cine playback images

The color box is not displayed when CF overlay is turned off.

When color flow imaging is activated, the color box appears in edit mode (see Figure 85). The color box can be resized and repositioned.

Color flow image quality controls are explained in "Color Flow Images," page 56.

Repositioning the Color Box

Note: Changes to the position of the color box take effect in 1.5 seconds.

Touch Screen

1. With color flow imaging active, tap inside the color box.
2. Drag the box to the desired position, *or*—

1. With color flow imaging active, tap inside the color box.
2. Tap anywhere outside the color box to set the new center position of the box.

ZURA-EVO Imaging System Mouse

1. With color flow imaging active, left-click inside the color box.
2. Drag the box to the desired position
3. Left-click to restore the mouse cursor.

Resizing the Color Box

Note: Changes to the position of the color box take effect in 1.5 seconds.

1. With color flow imaging active, tap or click any color box corner.
2. Drag the box to the desired size.

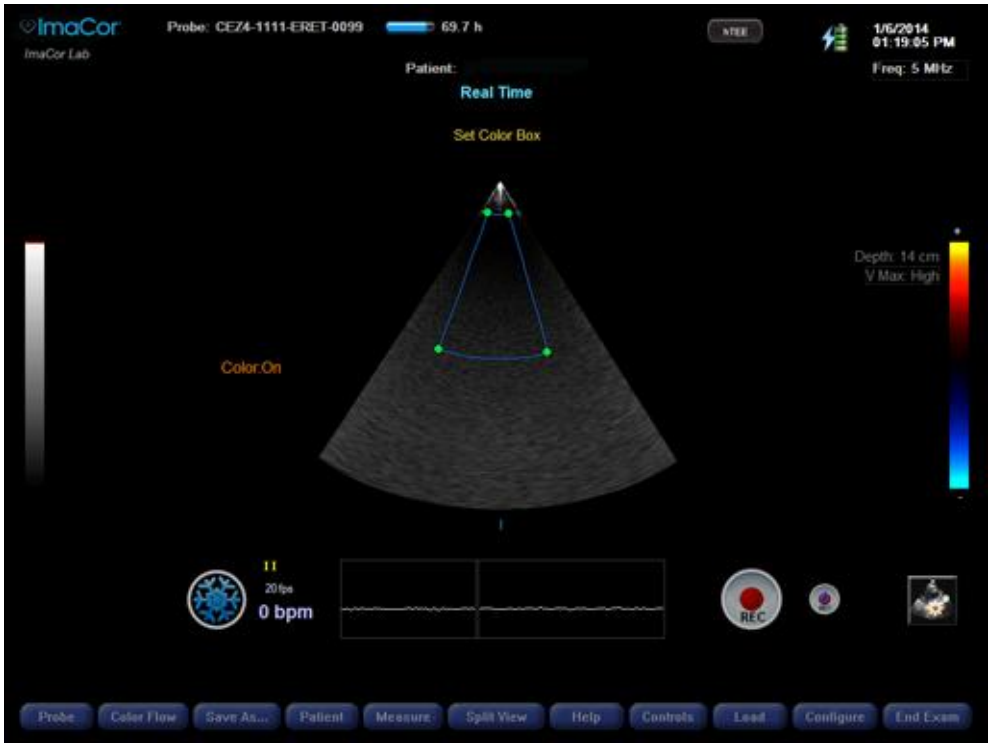


Fig. 85 Color Flow imaging with color box in edit mode

B-Mode Priority

B-mode priority is a user-adjustable grayscale value between 10 and 255. B-mode data takes priority when the grayscale value is greater (brighter) than the user-set priority value. For example, if you set a priority level of 150, B-mode data are shown instead of CF data when the B-mode data value is greater than 150. This prevents the display of CF data with no clinical benefit, such as in tissue.

- B-mode data values range from 0 (black) to 255 (white).
- Priority is also available on cineloop playback.

Like other image quality parameters, the priority setting is saved as a part of the patient record and restored when the patient is again imaged.

Setting B-Mode Priority

1. Tap or click the grayscale gradient bar on the left of the screen. A red horizontal bar appears indicating the position on the scale where priority has been set, as shown in Figure 86.
2. Tap or click on the scale to change the location of the bar and priority setting.

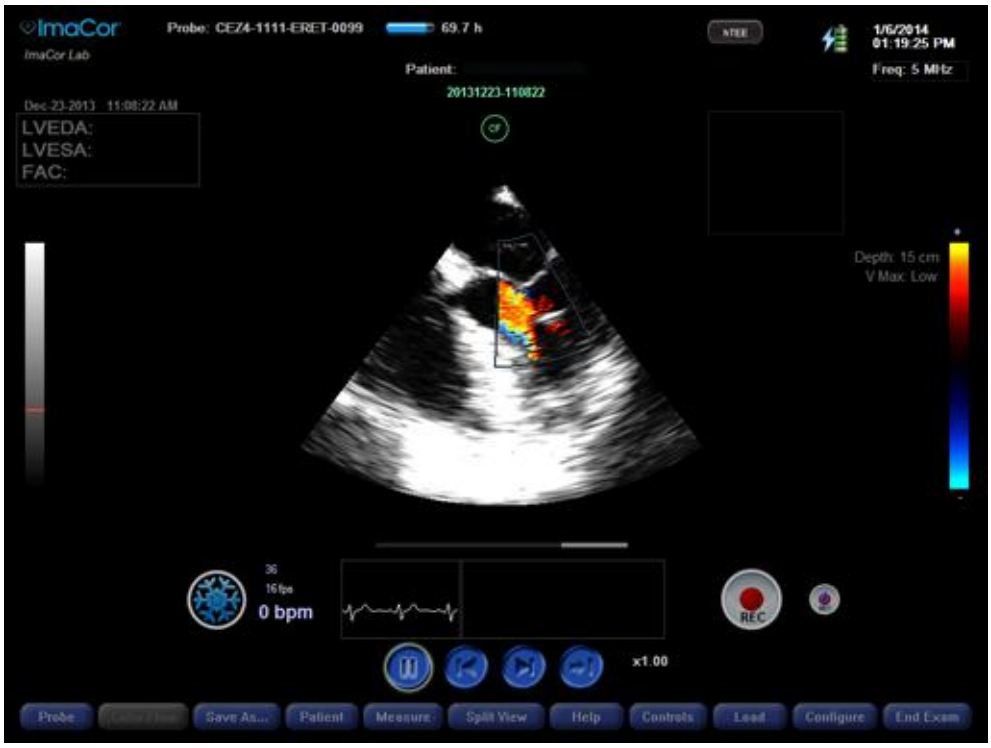


Fig. 86 Grayscale gradient bar showing priority setting

Velocities

There are three velocity modes to choose from: Low, Medium, and High.

Displaying the Velocities Menu

Touch Screen

Tap the velocity display (V Max) during Color Flow imaging.

ZURA-EVO Imaging System Mouse

Right or left click the velocity display (V Max) during Color Flow imaging.

Fig. 87 Velocities menu

Changing the Velocity Setting

Velocity setting availability is associated with the depth of the color box. When the bottom edge of the color box exceeds 9 cm, the velocity setting automatically changes from High to Medium. When the image depth exceeds 11 cm, the velocity settings automatically shifts from Medium to Low.

In low velocity mode, the velocity text display flashes as a reminder that you are operating in low velocity mode, which is not the primary velocity mode.

Touch Screen

To manually select a velocity setting, tap the velocity display and choose from the velocity pop-up menu.

ZURA-EVO Imaging System Mouse

To manually select a velocity setting, right-click the velocity display and choose from the velocity pop-up menu.

Color Velocity Maps

Five color maps are available.

Fig. 88 Highlighted color map

Changing Color Maps

Touch Screen

Tap the onscreen color map to advance to the next color map.

ZURA-EVO Imaging System Mouse

Left-click the onscreen color map to advance to the next color map.

Configuring the System

The Configuration dialog window consists of seven tabbed sections:

- General
- Acquisition
- Date-Time
- DICOM
- Language
- Version
- Help

The Configuration dialog can be accessed from either the Patient Information screen or the imaging environment. Imaging-related options can be configured only from the imaging environment.

General

The General tab enables you to change the Imaging and Tracing/Measuring default parameters.

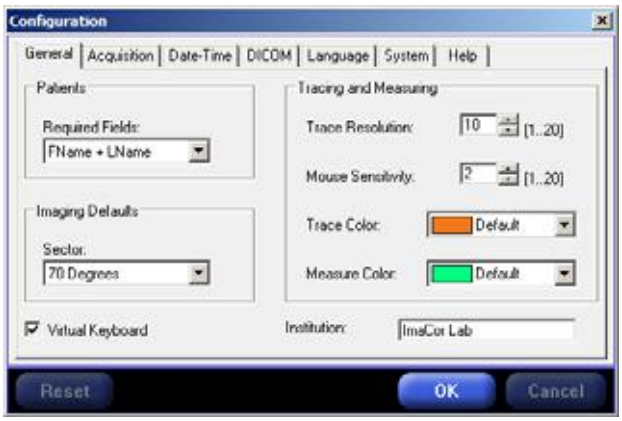


Fig. 89 Configuration > General tab

Patients

REQUIRED FIELDS

Enables user to specify which patient identification fields are mandatory. Options are:

- First and last names
- Patient ID
- Patient ID and First and last names

IMAGING DEFAULTS

ClariTEE probe

Enables user to specify as the default either a 70 degree or 90 degree B-mode sector angle

TTE probe

90 degree angle only

Measuring and Tracing Settings

TRACE RESOLUTION

Trace resolution is the interval between two consecutive anchor points. This interval is expressed in pixels, so a smaller resolution value results in a larger number of anchor points. The range is 1–20.

TRACE COLOR

The Trace Color option enables you to specify anchor point color.

MEASURE COLOR

The Measure Color option enables you to specify the color of measurement lines drawn with the Tape Measure tool.

Institution

Enter the name of your institution (hospital, medical center, etc.) in this field. Your institution name will be displayed on all screens. Limited to 30 characters.

Reset Button

Press the Reset button to restore the manufacturer's default values. If you press the Reset button, the confirmation shown below is displayed.

Fig. 90 Reset button confirmation screen

Acquisition

The acquisition tab lets you select one of the following cineloop acquisition options.

- The "Load acquired cineloop" option directs the system to load a newly acquired cineloop after it has been acquired. This is the default option.
- The "Unfreeze to real-time" option returns the system to real-time operation after a cineloop has been acquired.

Selecting the "Popup comment dialog" option directs the system to display a cineloop comment dialog pop-up after cineloop acquisition. This is the default setting; it can be specified with either of the above options.

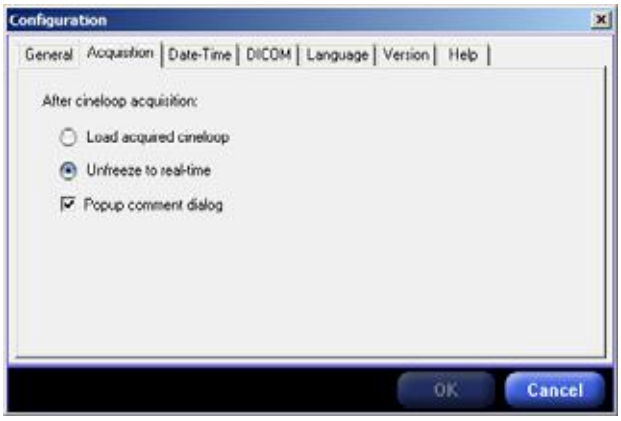


Fig. 91 Configuration >Acquisition tab

Date-Time

The Date-Time tab enables you to set the current date and time.

Changing the system date and time has no effect on probe life.

Fig. 92 Configuration > Date-Time tab

DICOM

Digital Imaging and Communications in Medicine (DICOM) is the standard format for distributing and viewing all types of medical images. DICOM files contain the following information:

- Patient information
- Cineloop
- ECG
- hTEE measurements, if present

The DICOM tab in the Configuration menu enables you to:

- Specify that cineloops be exported in DICOM format
- Indicate if JPEG compression should be applied
- Configure a DICOM Archiving Server (application entity title [AET], Host, Port)
- Configure a DICOM MWL Server (AET, Host, Port)
- Customize DICOM synchronization rules

- Customize system network properties
- Edit the client application entity title (AET)

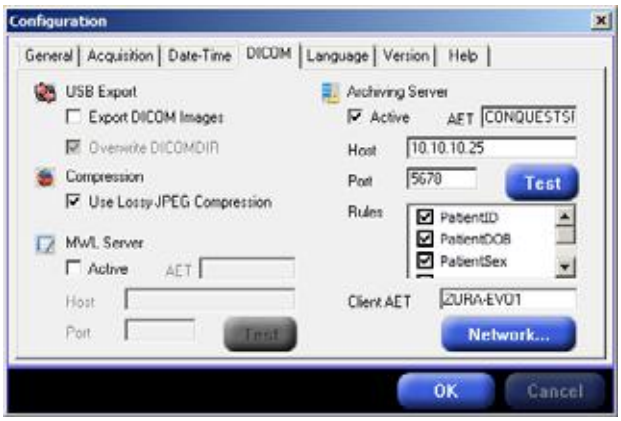


Fig. 93 Configuration > DICOM tab

Patient Export Options

If the Export DICOM option is selected, DICOM files are automatically created as cineloops are exported to the DTM. If Color Flow images are available, they are embedded in the DICOM file.

If the Overwrite DICOMDIR when Exporting option is checked, the DICOMDIR file is overwritten with each patient export.

Notes:

- If multiple patient records are selected for export and the Overwrite DICOMDIR when Exporting option is checked, only the last record selected will appear on the DICOMDIR.
- DICOMDIR and DICOM files are encrypted before they are saved onto a DTM. An ImaCor decryption application is provided to import DTM data into a DICOM workstation.

Archiving Server Configuration

To configure the Archiving Server, the "Active" box must be checked. The server configuration parameters are:

- Target AET
- Host name / IP Address
- Port number

By default the client AET for ZURA-EVO Imaging System is ZURA. It can be changed by entering an appropriate name in the Client AET field.

The Network configuration parameters are those exposed by the Windows XP operating system and will require an ImaCor technician (locally or with remote access) to set up.

Once the server has been configured the user can click on the Test button to check communication with the server.

Checking the Archiving Server "Active" checkbox will enable the Sync button on the Patient Information screen.

Custom Synchronization Rules

The ZURA-EVO Imaging System provides six basic rules that can be turned ON or OFF independently to customize the synchronization process. These rules are:

1. Require Cineloop Comment
2. Require Patient ID
3. Require Patient DOB
4. Require Patient Accession Number
5. Require Patient Sex
6. Max Daily Cine

For example if rules (1) and (2) are turned ON, only cineloops that have a comment and are for a patient whose ID is not empty will be sent to the Archiving Server. The rules can only be turned ON/OFF by an ImaCor technician.

If the Require Patient Accession Number rule is ON, cineloops are sent to the server only if the accession number field in the Patient Information screen is completed for the corresponding patient.

The Max Daily Cine rule enables you to specify the maximum number of cineloops in a daily folder that may be sent to the archiving server.

Synchronization operations occur when the Sync button is clicked. A synchronization log provides information about the last Synchronization operation that was performed. To view the Log, simply right-click on the "Sync" button and choose "Show Synchronization Log."

Modality Worklist (MWL) Server Configuration

To configure the MWL Server, the "Active" box must be checked. The MWL Server configuration parameters are similar to those required by an Archiving Server.

Once the server has been configured the user can click on the Test button to check communication with the server.

Checking the MWL Server "Active" checkbox will enable the Check Worklist menu in the Patient list.

⚠ **Warning:** Connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties. The responsible user should identify, analyze, evaluate, and control these risks.

Compression

If the Compression option is selected, JPEG compression is automatically applied to the DICOM files. The compression option applies to both exported data and data sent to the DICOM Archiving Server (if con-figured).

Language

The Language tab enables you to select from a drop-down menu the language used in the software interface. Only languages appropriate for your location will be present on the menu.

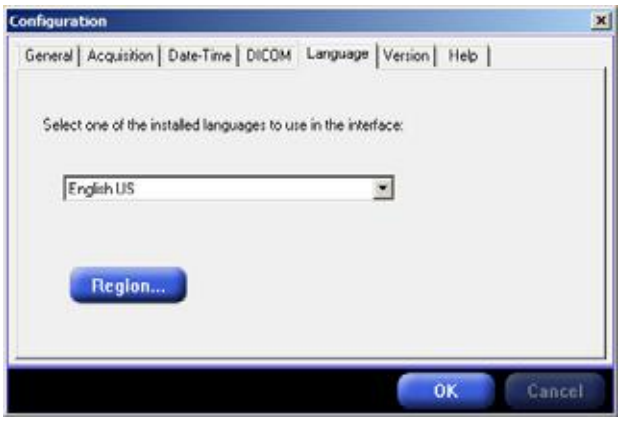


Fig. 94 Configuration > Language tab

System

The System tab enables you to check the version of the ZURA-EVO Imaging System software installed on the system.

Fig. 95 Configuration > System tab

Software Update

Upgrade packages are machine-specific and require a registration code that is displayed in the Configuration Dialog >Version tab (see Figure 95).

Download the Software Upgrade and Request a License File

1. Log into the ImaCor support web page: http://www.imacorinc.com/support.html
2. Tap or click on the software upgrade you wish to download.
3. Enter the ZURA-EVO Imaging System machine registration code, which can found on the Version tab of the ZURA-EVO Imaging System Configuration window.
4. Tap or click on the Go button. A license request is automatically sent to the ImaCor support team.
5. Tap or click on the "Download File" option.
6. Navigate to the location on your computer where you wish the file saved.

Upgrade the ZURA-EVO Imaging System Software

1. Save the .icm file that was emailed to you onto a USB thumb drive. For example, if your thumb drive is the F: drive, save the .icm file to F:
2. Unzip the software downloaded upgrade and move the .exe file inside the zip folder to your USB thumb drive. The .icm and .exe files must be placed at the same location.
3. Plug your USB key into the ZURA-EVO Imaging System you are upgrading.
4. Go to Configuration > Version tab and tap or click the Update button. You can accomplish this from either the Patient Information screen or the Imaging screen.
5. Select the .icm file on your thumb drive and tap or click "OK."
6. When the Upgrade Wizard appears (it may take up to 5 seconds), follow the instructions.
7. Do not disconnect the USB thumb drive until a message is displayed instructing you to reboot the system.
8. After the system reboots you will be prompted by the Upgrade Wizard to tap or click on "Finish." Once you've clicked Finish, the upgrade is complete.

Help

In addition to the online Help system (see page 21), the ZURA-EVO Imaging System provides three other user assistance options:

1. ToolTips
2. Remote Assistance
3. Analysis Package

Fig. 96 Configuration > Help tab

Tool Tips

If the Show ToolTips option is selected, informational pop-ups are displayed when you hover the mouse over interactive features like software buttons and dialog box elements.

Remote Assistance

The Remote Assistance button enables you to establish a link with an ImaCor technician who can access the ZURA-EVO Imaging System remotely for troubleshooting.

Once the Remote Assistance button is clicked, the Support Internet Explorer window is displayed.

1. Enter the 6-digit PIN code provided by ImaCor tech support.
2. Tap or click the "Connect to technician" option to establish a secure connection with a technician's console.

Configuration > Support tab

Analysis Package

The support technician may request an analysis package, which is a file that provides information about your system and assists in troubleshooting.

To create an analysis package:

1. Select Configuration > Help
2. Insert an external USB drive into the USB port in the ZURA-EVO Imaging System. You need not use the special ImaCor data transfer module; any operational USB drive will work.
3. Tap or click the Analysis Package button
4. Email the analysis package (ZuraPkg.zip) to support@imacorinc.com.

If there is insufficient free space on the USB drive to accommodate the analysis package, or if the USB drive is removed prematurely, the error message shown in Figure 97 is displayed.

- In the case of insufficient free space on the USB drive, you may:
  - Remove the drive from the ZURA-EVO Imaging System.
  - Insert the drive in any personal computer with a USB port.
  - Delete unnecessary files. Files may not be deleted from the ZURA-EVO Imaging System.
  - Retry the operation
- If the USB drive was removed prematurely — i.e., before the analysis package is completely written to the drive — you may:
  - Reinsert the drive in the ZURA-EVO Imaging System.
  - Retry the operation.

The error code shown in the message may vary and is for the use of ImaCor technicians only.

Fig. 97 Analysis package export error

If no USB drive is present when the Analysis Package button is pressed, the error message below is displayed.

Safety

Read this safety information before using the ImaCor ZURA-EVO Imaging Systems. The information applies to the entire system: machine, umbilical, disposable probe, and accessories.

Disposable Single-Use ClariTEE

The ClariTEE is a single-use probe provided in sterile packs.

During episodic assessments, the probe tip is flexed upward via the articulation lever on the handle. Probe pressure on mucosal tissue during flexing requires continuous operator action; there is no locking mechanism in handle.

The indwelling portion of the ClariTEE probe is detachable from the control handle. Detaching the control handle allows for improved patient mobility and comfort during probe dwell time.

The distal end of the ClariTEE probe may be immersed in water or other gastric liquids. The ClariTEE probe's distal end and insertion tube meets the requirements of WATERTIGHT, (IPX7 rating) per ingress protection standard IEC 60529

⚠ **Caution**

- The ClariTEE probe is designed for single patient use only. If the probe is reused there are known characteristics and technical factors that could pose safety risks as follows:
  - The probe is not designed to survive Cydex disinfection. Cydex disinfection of the ImaCor ClariTEE probe could present a toxicological and electric shock risk to the patient
  - The electrical insulating properties of the ClariTEE probe are unknown if the probe is reused. Reuse of the ClariTEE single-use probe could present an electric shock risk to the patient.
  - The biocompatibility properties of the ClariTEE probe are unknown if the probe is reused. Reuse of the ClariTEE single-use probe could present safety risks due to material incompatibility with the patient.
  - The mechanical integrity of the ClariTEE probe is unknown if the probe is reused. Reuse of the ClariTEE single-use probe could present a mechanical risk to the patient; i.e sharp edges.
- Flex the probe only when imaging.
- Disconnect the probe from the handle when not conducting an episodic assessment.
- The maximum dwell time for the ClariTEE probe is 72 hours.
- The ClariTEE probe is for single use only and is to be disposed after single use or if otherwise contaminated by blood, body fluids, or other biological materials. Do not sterilize or disinfect the ClariTEE disposable probe.
- Handle the probe carefully.
- Do **not** drop the disposable probe.
- Do **not** pinch or kink the disposable probe.
- Do **not** use probe if cracked, broken, or damaged.
- Do **not** force the probe during intubation. If resistance is met during intubation, gently withdraw the probe.
- Separate disposed probe(s) from normal waste. Refer to local regulations.

The ALARA Principle

The ZURA-EVO Imaging System has been designed in accordance with the principle of ALARA. ALARA is an acronym for an important principle in ultrasound energy protection and stands for "As Low As

Reasonably Achievable." The aim is to minimize the amount of acoustic energy exposure to that which is necessary to accomplish the intended diagnostic use of the device.

Applying ALARA

The ZURA-EVO Imaging System is a track 1 ultrasound imaging device. This means that acoustic output levels do not exceed FDA limits established in 1976. Further, the output power has been set as low as reasonable to produce an image in the area of interest. Every appropriate design effort has been made to use the minimum acoustic output required to obtain clinically adequate image.

ALARA Operator Control

CUMULATIVE IMAGING TIME

The ZURA-EVO Imaging System is intended to be used episodically. It is not a continuous monitoring device. The device should be in imaging mode only while conducting episodic assessments of patient cardiac function.

⚠ **Caution**
The ImaCor ZURA-EVO Imaging System should not be used beyond a maximum cumulative imaging time per patient of 6 hours.

Normal use should consist of a maximum of six episodic assessments over a 24-hour period with maximum intubation time (the probe dwells within the patient) not to exceed 72 hours. The duration of a typical assessment will be in the range of 5–15 minutes. Hence, the typical cumulative imaging time for each patient is in the range of 1.5 hours to 4.5 hours during a 72-hour indwelling time period.

⚠ **Caution**
Disconnect probe from handle when not conducting an episodic assessment.

When not conducting an episodic assessment the device should not be imaging; no acoustic energy shall be delivered to the patient. In order to terminate imaging mode:

- Click Freeze button, or
- Exit patient application

MECHANICAL INDEX

The Mechanical Index (MI) is an index derived from the acoustic output of ultrasound diagnostic systems. The lower MI is achievable at the 7 MHz frequency setting. The operator is advised to use the 7 MHz setting where reasonable to achieve the desired image.

ALARA Automatic Controls

Important: To restore imaging, the user should toggle the Freeze/Unfreeze command button.

TWENTY MINUTE SOFTWARE INTERLOCK

If the operator leaves the ZURA-EVO Imaging System in imaging mode while not conducting a bedside episodic assessment, the acoustic output automatically times out after 20 minutes. This limits the acoustic energy unnecessarily delivered to the patient.

WATCHDOG MONITOR

In the event of a software or operating system failure, the watchdog monitor limits burst mode duration to three seconds.

Transesophageal Echo Imaging (TEE) Potential Complications

⚠ Caution
TEE procedures shall be conducted by a qualified physician.

- Dental injury
- Bleeding or tearing of the esophagus or stomach
- Difficulty swallowing after the procedure
- Respiratory distress

Electrical Safety

TheZURA-EVO Imaging System complies with the following safety standards.

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety.

IEC 60601-2-37 Medical Electrical Equipment – Particular Requirements for the Safety of Ultrasonic Medical Diagnostic Equipment.

- To reduce the risk of electric shock, do not open system enclosures.
- To reduce the risk of injury, do not operate the system in the presence of flammable gases or anesthetics. Explosion can result.
- To reduce the risk of electrical shock, use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.
- To reduce the risk of electrical shock, inspect the transducer face, housing, and cable before using the transducer. Do not use the transducer if the transducer or cable is damaged.
- To reduce the risk of electrical shock, always disconnect the power supply from the system before cleaning the system.
- To reduce the risk of electrical shock and fire hazard, regularly inspect the power supply, AC power cord, and plug for damage.
- To reduce the risk of electrical shock, use only accessories and peripherals recommended or supplied with the system by ImaCor. Use of accessories and peripherals not recommended by ImaCor could result in electrical shock. Contact ImaCor or your local representative for a list of accessories and peripherals available from or recommend by ImaCor.
- To reduce the risk of electrical shock, regularly inspect the interconnect cables for damage.
- To reduce injury to the operator/bystander, the ClariTEE must be removed from patient contact before the application of a high-voltage defibrillation pulse.

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility, or EMC, means that the device will accept interference caused by its electromagnetic environment and does not emit levels of electromagnetic energy that cause electromag-

netic interference (EMI) in other devices in the vicinity. The ZURA-EVO Imaging System complies with *IEC 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*.

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radiofrequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radiofrequency 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
- 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 reorient 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

Biocompatibility Safety

Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The patient contact materials have been designed and tested in accordance with the applicable requirements contained in ISO 10993. This is the internationally-recognized standard for the biocompatible evaluation of medical devices.

Acoustic Output

The ZURA-EVO Imaging System is a Track 1 device. This means the acoustic output does not exceed the highest levels known by the Food and Drug Administration as of 1976. This is in contrast with Track 3 ultrasound diagnostic devices that contain higher acoustic output levels.

Table 11 Accepted Acoustic Output Levels for Track 1 Devices

Use	ISPTA.3 (mW/cm^2)[1]	ISPPA.3 (mW/cm^2)[2]	MI[3]
Cardiac	430	190	1.9

[1]ISPTA.3 Derated Spatial-Peak Temporal-Average Intensity

[2]ISPPA.3 Derated Spatial-Peak Pulse-Average Intensity

[3]MI Mechanical Index

Note: Cardiac use includes transesophageal use for visualization of the heart.

Global Maximum Derated ISPTA, MI, and TI Values

ISPTA is the intensity, spatial-peak temporal-average defined as the value of the temporal-average state that ISPTA and MI are defined parameters in the FDA guidance document for ultrasound systems. TI is a temperature index defined in IEC60601-2-37, an internally recognized standard for ultrasound diagnostic equipment.

Table 12 indicates for each operating mode the values of the Thermal Index (TI), Mechanical Index (MI), derated spatial-peak temporal-average Intensity ($I_{SPTA.3}$), and derated peak average Intensity at peak MI (Ipa .3@MI_{max}).

Table 12 Acoustic Output Parameters

Transducer	Imaging Mode	MI	$I_{SPTA.3}$ (mW/cm^2)	TI	Type
ClariTEE	Resolution	0.92	251	0.98	Tissue
ClariTEE	Penetration	0.98	353	0.70	Tissue
ClariTEE	Hi Definition	0.69	251	0.90	Tissue
ClariTEE	Color Flow	0.67	150	0.54	Tissue
SA4-2-24	B mode	0.88	35	< 1.0	Tissue
SA4-2-24	Color Flow	0.85	135	< 1.0	Tissue

The global maximum values for MI and TI are never greater than 1.0. As a TI or MI greater than 1.0 never occurs, neither is displayed. The user cannot directly adjust the power output. The device is inherently limited to the track 1 limits and the global maximum values.

Acoustic Measurement Precision and Uncertainty

All ultrasound diagnostic devices contain a residual risk that:

- images obtained will not be clinically useful due to a lack of image quality, and
- numerical calculations such as Fractional Area Change (FAC) will be inaccurate.

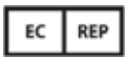
These risks are mitigated by trained echocardiographers, able to discern whether an image is technically limited or clinically useful and whether quantitative assessments, such as FAC calculations, are consistent with the images. This translates into a confidence level the physician has when making a diagnosis which is reflected in his or her action steps. Predominate factors include the patient's acoustic window quality, RFI interference, and operator technique. For the physician, the software measurement quantitative tools serve a supporting role behind the qualitative image assessment.

Labeling Symbols

Table 13 Labeling Symbols and Descriptions

	Alternating current
	Protective earth (ground)
	Attention, consult ACCOMPANYING DOCUMENTS
	Off (power: disconnection from the mains)

Table 13 Labeling Symbols and Descriptions (Continued)

	On (power: connection to the mains)
	"Off" (only for a part of EQUIPMENT)
	"On" (only for a part of EQUIPMENT)
	Type B equipment
	Type BF equipment
	Keep away from sunlight
	Keep dry
	Manufacturer
	Authorized representative in the European Community
	Sterilized using ethylene oxide
	Date of manufacture
	Contains or presence of natural rubber latex

ImaCor Approved Device

The ImaCor ZURA-EVO Imaging System has been approved for use with the following device:

Data Transfer Module (DTM) ImaCor-supplied thumb drive for transferring image files, patient information, cineloops, and measurements. The drive is also used to export cineloops as DICOM files.

Note: Only thumb drives provided by ImaCor can be used. General purpose thumb drives will not function with the ImaCor ZURA-EVO Imaging System.

⚠ **Warning:** All configurations shall comply with the system standard IEC 60601-1. Accessory devices connected to an EVO-1's interface must be certified to their respective IEC standards (IEC 60950 for data processing equipment, IEC 60601-1 for medical equipment, etc.). Anyone who connects equipment to a signal input or output configures a new medical system and is therefore responsible for ensuring that the system complies with the requirements of the system specified in clause 16 of IEC 60601-1.

Troubleshooting and Maintenance

Troubleshooting

If you encounter difficulty with the system refer to the troubleshooting guide below, if you are unable to resolve the issue, contact ImaCor technical support at the following numbers and addresses:

Technical support: 1-877-244-0657

Technical support email: support@imacorinc.com

⚠ Caution
To reduce the risk of electric shock, do not open system enclosures.

Table 14 Troubleshooting Matrix ***see also the Master Message listing on page 110.***

Problem	Solution	Comments
Unit does not turn on	1. Check that On/Off rocker switch is on 2. Check that power cord is connected to equipment 3. Check that power cord is connected to building receptacle 4. Check building supply 5. Check main fuse of machine	5. Fuse holder is located integral to Power inlet. Refer to ratings on fuse holder
System computer does not boot up	1. Refer to solutions for above, "Unit does not turn on" 2. Press pushbutton switch adjacent to ecg connector to boot computer	Mains power is On if system fans are running. LCD appears to be powered up.
System software freezes; does not respond to user actions	Reboot computer	
System does not image	1. Toggle freeze/unfreeze command button 2. Reposition probe 3. Reboot computer 4. Check umbilical connection 5. Check probe connection to handle	
No display	1. Check LCD connections 2. Confirm LCD power	2. Blue LED adjacent to LCD power switch
No ECG on display	1. Check ECG connection on machine 2. Check patient ECG lead connections	

Maintenance

ImaCor Inc. offers a preventive maintenance plan. Contact ImaCor for further information. The following user maintenance is recommended.

ZURA-EVO Imaging System Cleaning Recommendations

ImaCor recommends the following cleaning instructions for the ZURA-EVO Imaging System.

⚠ Caution

- The ClariTEE probe is for single use only and is to be disposed after single use.
- To reduce the risk of electrical shock, always disconnect the power supply from the system before cleaning the system.

LCD MONITOR CLEANING

1. Turn off the system prior to cleaning the touch screen.
2. Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth:
   - NoroxyCdiff for high-level disinfection
   - Water
   - Vinegar/water solution
   - Isopropyl alcohol (i.e., Windex)
   - Petroleum benzene
3. Move the cloth across the touch screen in one direction, moving from the top of the screen to the bottom. Computer wipes may be used only if they specifically state they are designed for LCD screens.
   - Do not apply the cleaning solution directly to the touch screen.
   - Do not scratch the touch screen.
   - Do not use paper towels to clean the touch screen as they may cause damage and scratches.
4. *Never* use cleaning products containing the following:
   - Acetone
   - Ethyl alcohol
   - Ethyl acid
   - Ammonia
   - Methyl chloride

HANDLE AND UMBILICAL

⚠ Caution Do not immerse any part of the handle and umbilical in any cleaning solution.

1. Disconnect from the machine prior to cleaning.
2. Routinely clean the handle with special emphasis on the pads that make the connection to the probe cartridge. Any smudge or dirt on these pads could affect EEPROM communication or image quality. Use an alcohol-based cleaner; we recommend alcohol and dionized water, 70% IPA. Other types of cleaner may leave a residue that could affect performance.

ULTRASOUND TRANSDUCERS

The ClariTEE is a single-use disposable probe provided sterile.

FOR OTHER TRANSDUCERS

See “Maintenance and Cleaning of TTE Probe,” page 118

Other Recommended Maintenance

POWER SUPPLY CORD

Regularly inspect the AC power cord and plug for damage.

HANDLE AND UMBILICAL

Regularly inspect the handle and umbilical for damage.

⚠ **Warning:** Do not actively connect to a patient while performing maintenance on any part of the system.

Master Message Listing - Alphabetical

	Problem	Solution
	Informational. ZURA-EVO Imaging System was able to ping archiving server.	
	Lithium ion chemistry prefers partial discharge to deep discharge, so it's best to avoid taking the battery below 50%. Running repeatedly with the battery below 50% will reduce its life.	When the battery level reaches 50% the system will display a warning on the screen every minute reminding the user he/she should connect the battery to AC power.
	Informational. When in the FAC environment, instructs you to press the Load button to view a saved cineloop.	
		Restart the system. If the problem persists, contact ImaCor technical support.
	While importing or exporting patient data, the system has detected an inconsistency between the local data (that saved on the ImaCor ZURA-EVO Imaging System) and the DTM.	• If the name on the main system is correct, select the Local option and click the OK button. This will append the information being transferred from the DTM to the patient record on the local system. • If the name on the DTM is correct, select the DTM option and click the OK button. This will change the name on the Local system to match that on the DTM *The local system is the one that resides within the ImaCor ZURA-EVO Imaging System.
	The failure of one of the following initialization steps failed: • Loading configuration • Loading ultrasound definitions • Loading ECG definitions • Loading probe settings • Loading ultrasound software module • Loading ECG software module • Connecting to the patient database server	Click the OK button and restart the system. If the error persists, contact technical support.

	Problem	Solution
	Prompt. If at least one patient record is selected in the Patient List when the Sync button is pressed, you are prompted to indicate whether to sync only the selected patient(s) or all patients.	Make the appropriate choice and press the OK button.
	Disk space for storing patient data is limited.	Delete patients or cineloops.
	Disk space for storing patient data is VERY low and the current operation cannot be completed	Delete patients or cineloops.
	The user is trying to change a locked patient record.	If you wish to unlock the patient record so that it can be change, click Yes. If you do not with to unlock the patient record, choose No.s
	Informational; displayed when importing data from or exporting data to a DTM. The progress bar indicates the status of the operation, and the user is further advised against disconnecting the DTM.	
	The ZURA-EVO Imaging System failed to ping the archiving server.	Verify that the server is online and that the ZURA-EVO Imaging System is configured to communicate with the server (AET, Host, port). Also, verify that the server allows communications from the ZURA-EVO Imaging System AE.
	The ZURA-EVO Imaging System failed to ping the MWL server.	Verify that the server is online and that the ZURA-EVO Imaging System is configured to communicate with the server (AET, Host, port). Also, verify that the server allows communications from the ZURA-EVO Imaging System AE.
	The system isn't communicating with the patient database.	Click the OK button and restart the system. If the problems persists, contact ImaCor technical support.

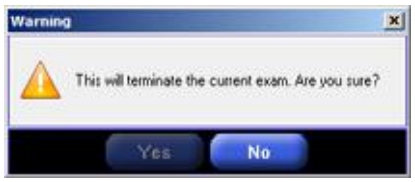
	Problem	Solution
	An analysis package was requested, but it cannot be saved to the USB drive. • There is insufficient space on the USB drive to write the analysis package. • The USB drive was removed before the analysis package was completely written. **Note:** the error code shown may vary and is intended for use by an ImaCor technician.	If there is insufficient free space on the USB drive to accommodate the analysis package: • Remove the drive from the ZURA-EVO Imaging System. • Insert the drive in any personal computer with a USB port. • Delete unnecessary files. Files may not be deleted from the ZURA-EVO Imaging System. • Retry the operation If the USB drive was removed prematurely – i.e., before the analysis package is completely written to the drive: • Reinsert the drive in the ZURA-EVO Imaging System. • Retry the operation.
	Review the Initialization screen for the specific error.	Click the OK button and restart the system. If the problems persists, contact ImaCor technical support.
	The Unfreeze or Acquire button was pressed while an invalid probe is connected. • The probe is expired. • No probe is connected. • The probe is associated with a different patient. The wrong patient name may have been selected.	1. End the exam. 2. Connect a valid probe, or– 3. Select the correct patient name from the Patient List.
	Informational message. Patient data is being exported to a DTM.	No action is necessary to continue exporting patient data. To halt the transfer of patient information, press the Cancel button.
	Informational message. Patient data is being imported from a DTM.	No action is necessary to continue importing patient data. To halt the transfer of patient information, press the Cancel button.
	The selected license file is invalid. • There is there is no matching upgrade file for this license file (both license and upgrade files must be in the same folder). • The license file does not match the upgrade file. • The license file is corrupted.	Contact ImaCor technical support.

	Problem	Solution
	Informational. ZURA-EVO Imaging System was able to ping the MWL server.	
	The Analysis Package button was pressed, but no USB drive is present.	1. Click the OK button. 2. Connect a USB drive to the USB port in the ZURA-EVO Imaging System. 3. From the Configuration > Help screen, again click the Analysis Package button.
	You are attempting to export cineloop(s) as a movie, but no USB drive is detected.	1. Insert a USB thumb drive. 2. Press the Retry button.
	A probe is not connected to the system.	Connect a probe and select it with the Probe button.
	The ImaCor system is designed to store a maximum of 100 cineloops per patient. This informational message is displayed when you near the storage limit.	No immediate action is necessary. For more information, see Deleting a Cineloop, page 70.
	Warning message displayed when user attempts to delete a patient.	
	Warning message displayed when user attempts to delete a patient whose cineloops have not all been sent to the archiving server. Note: This message is only displayed if the archiving server is active in the configuration window.	
	The wrong patient-probe combination has been selected.	Compare the ClariTEE probe's serial number label with the serial number displayed at the top if the imaging preparation screen. Most often, the selected patient is correct, but the wrong probe is connected to the system.

	Problem	Solution
	The probe was disconnected during the patient exam or the connected probe is not achieving proper contact with the handle pads.	Solution A • Check for bent pins on the probe's connector • Clean handle connector pads • Reconnect probe to handle • Select patient and proceed to imaging screen Solution B • Connect new probe to handle • Select patient and proceed to imaging screen Solution C • Continue current exam; however, imaging functions will be disabled
	The connected probe has been used for more than 72 hours. The message includes the date the probe was first used.	The ImaCor ZURA-EVO Imaging System can be used to review the patient's recorded cineloops, but not acquire new images.
	The patient-probe combination is invalid. Either the wrong probe has been used or an incorrect patient record has been selected.	1. Click the Cancel button to clear the error message. 2. Press the Back button to return to the Patient Information screen and select the correct patient record. 3. Press the Next button to advance to the imaging screen.
		1.
	A record has been created for a new patient, but the patient's date of birth is invalid. The patient's date of birth is entered in the following format: mm/dd/yyyy. Examples of an invalid birthdate: • 02/17/1492 invalid year • 01/25/2079 invalid year • 07/03/194 invalid year • 99/16/1939 invalid month • 11/99/1948 invalid day	1. Move the cursor to the last name field 2. Enter the patient's last name.
	1. Available disk space on the local drive is insufficient to complete an import operation, *or*– 2. Available disk space on the DTM is insufficient to complete an export operation.	1. Press No to cancel the import operation. You will be able to import records to the local disk that require less than the remaining disk space. Each cineloop requires roughly 20 MB. 2. If you are transferring data to a DTM, press No to cancel. Insert a DTM with sufficient disk space and retry the operation.

	Problem	Solution
	Informational message. The data transport module is properly connected, enabling patient data import and export functions.	
	A record has been created for a new patient, but the patient's first name hasn't been entered.	1. Move the cursor to the first name field 2. Enter the patient's first name.
	The current patient already exists on the destination drive.	• Press No to return to the imaging screen. • Press Yes to replace the existing patient record with the current record.
	The height entered for the patient exceeds the maximum value. • 9.84 ft (if Imperial) • 3 m (if metric)	Enter a valid height value.
	A record has been created for a new patient, but the patient's last name hasn't been entered.	1. Move the cursor to the last name field 2. Enter the patient's last name.
	A variety of actions that can produce in this error message. Generally speaking, this means that the operation underway was interrupted.	Repeat the operation that was in progress when the abrupt shutdown occurred.

	Problem	Solution
	The maximum of 100 cineloops has been saved for this patient.	An additional cineloop cannot be acquired unless an existing cineloop is overwritten. By default, the oldest existing cineloop will be overwritten. • If you wish to overwrite the oldest cineloop for this patient and record a new one, press the OK button. • If you wish to retain the oldest cineloop, press the Cancel button. Cineloop acquisition is cancelled, but the exam is not ended. • If you wish to delete a cineloop other than the oldest: - Press Cancel to end the acquisition in progress. - Delete one or more of the patient's cineloops. For more information, see Deleting a Cineloop, page 70.
	Informational. Informs user of a system shutdown and asks for confirmation.	• Click the Yes button to continue with the shutdown. • Click the No button to continue the patient exam.
	The UPS battery level is at 20% and is not connected to the AC power. The machine will shutdown in the specified number of seconds.	Connect to an AC power supply and recharge the UPS battery.
	1. An ImaCor update package has been corrupted, *or*– 2. You have attempted to run another executable as if it were an ImaCor update package.	Obtain and run a valid ImaCor update package.
	The weight entered for the patient exceeds the maximum value. • 1000 kg (if metric) • 2204.62 lb (if Imperial)	Enter a valid weight value.
	The scanned bar code exists in the patient database.	Informational; no action necessary.

	Problem	Solution
	The scanned bar code was not found in the patient database.	Enter the patient's first and last names to create a new record.
	While examining a patient, you return to the patient information screen and select another patient name from the Patient List – Or, while examining a patient, you return to the patient information screen and create a new patient record.	• If you wish to continue the exam in progress, press the No button. • If you wish to end the current exam, press the Yes button.
	The ImaCor system is designed to store a maximum of 100 cineloops per patient. You have reached that maximum.	Delete one or more cineloops. For more information, see Deleting a Cineloop, page 70.
	Informational only	
	The analysis package couldn't be exported to the external drive. • The external USB drive was unplugged before the analysis package export was completed. • The external USB drive is full.	• Make sure the external USB is correctly inserted. • Make sure there is at least 5 MB free space on the external USB drive.
	The analysis package must be written to an external drive, and no external drive is connected to the system.	Insert an external drive into the USB port.
	The space available on the DTM is insufficient for the operation you are attempting.	• Delete unnecessary files from the DTM and retry the operation. • Use another DTM with sufficient available space. • Cancel the operation. Should you choose to continue, the system will attempt to export patient data onto the DTM until the DTM is full. However, as stated in the warning message, the system will not be able to export all the data.

Maintenance and Cleaning of TTE Probe

Transducers

Overview

- Read all documentation accompanying the transducer. Make certain you are familiar with the procedures for using, maintaining, and cleaning the transducer.
- **Always** follow the manufacturer's instructions on cleaning and disinfection procedures.
- Prior to each use, inspect the transducer for:
  - cracks or other damage
  - debris
  - film
  - ultrasound gel from previous use

⚠ **Warning:** Do not use a transducer that is cracked or damaged in any way. Do not use a transducer if the cable is damaged and wiring is exposed.

Ultrasound Coupling Gel

The following coupling gel is recommended. Use of another produce may damage the transducer and void the warranty.

Table 15 Recommended Coupling Gel

Product	Manufacturer	Manufacturer phone	Manufacturer website
Aquasonic 100	Parker Laboratories, Inc.	800.631.8888	www.parkerlabs.com

General Maintenance

- **Do not** drop or strike the transducer against a surface that could cause damage.
- **Do not** tangle or kink the transducer cable.
- **Do not** clean or disinfect with phenol, benzothonium chloride, pHisohex, hydrogen peroxide, or benzoyl peroxide. Use only chemicals or cleaning agents recommended by the manufacturer.
- **Do not** use disinfection procedures other than those recommended by the manufacturer.
- **Do not** immerse the transducer for an extended period.
- **Do not** immerse the scan head past the first seam.
- **Do not** rinse or immerse near the strain relief.
- Use **only** a soft cloth to clean the transducer.
- **Before immersing or soaking** the transducer, read carefully the manufacturer's recommendations.

Cleaning and Disinfecting a Transducer

Thorough cleaning of the transducer is required for successful disinfection. Before cleaning, remove accessory, attachments, and covers.

⚠ **Warning:**

- **Do not** use sterilize using an autoclave, ultraviolet, gamma radiation, gas steam, or heat sterilization techniques.
- **Do not** clean or disinfect with phenol, benzothonium chloride, pHisohex, hydrogen peroxide, benzoyl peroxide, acetone, freon, or other industrial cleansers. Use only chemicals or cleaning agents recommended by the manufacturer.
- **Do not** attempt to clean, sterilize, or dispose of a transducer suspected of being contaminated with Creutzfeld Jacob disease. Contact the manufacturer for instructions on disposal.
- **Do not** permit biological materials to dry on the transducer.
- **Make certain** that cleaning and sterilization processes are completed by trained personnel.
- **Follow all** manufacturer's recommendations and regulatory requirements regarding cleaning products (including expiration dates), sterilization processes. disposal techniques
- **Follow all** safety and infection control practices established by your organization.
- Refer to all relevant FDA, EPA, Health Canada, and CE documentation.

Table 16 Recommended Cleaning and Disinfecting Agents for Noninvasive Transducers

	Cleaning and Disinfecting Agents													
Noninvasive Transducer	**75% IPA**	**Akazyme**	**Cidex Activated Dialdehyde Solution 14 day**	**Cidex Plus 28 day**	**Cidex OPA**	**Cidezyme**	**Klenzyme**	**McKesson Brand**	**Metrizime**	**Milton Disinfecting Liquid**	**Nuclean**	**Omnicide - FG2**	**Steranios 2%**	**T-Spray**
SA4-2/24				•	•					•				•

CLEANING THE TRANSDUCER

1. After each use, wipe the ultrasound gel off the transducer with a soft cloth moistened with water.
2. Following the manufacturer's instructions, clean with an appropriate agent from Table 16.
3. Wipe dry with a clean, dry cloth.

Note: Where any transducer (including, but not limited to, an intracavity transducer) is used in a clinical application of a semi-critical nature (including, but not limited to intraoperative transrectal, transvaginal, transesophageal, etc.) ensure the transducer is covered with the appropriate STERILE transducer cover/sheath that has received regulatory clearance for use.

Caution: Do not allow cleaning solutions to air dry on the transducer.

Disinfecting Noninvasive Transducers

Following the manufacturer's instructions, disinfect with appropriate agent from Table 16.

Sterilization

Transducers cannot be sterilized. Follow the instructions for cleaning and disinfecting.

Storing and Packaging

To help avoid contamination, ensure the transducer is clean/disinfected and dry before storing and/or packing it.

Store transducers:

- in one of the transducer holders
- separately, in a protected environment to avoid inadvertent transducer damage
- in the original case (recommended)
- away from direct sunlight dust and extreme temperatures

After placing a transducer in its carrying case, pack the case in bubble wrap and place the wrapped case in a cardboard box.

Packaging and Shipping Transducers for Servicing

- The transducer must be disinfected prior to shipping, see “Cleaning and Disinfecting a Transducer,” page 118
- The transducer must be properly packaged, see “Storing and Packaging,” page 120
- All relevant paperwork must be completed in compliance with regulations and laws.

Cleaning the Transducer Holders and Cable Hooks

⚠ **Caution:**

- Power off and unplug the system prior to cleaning.
- **Do not** apply cleaning solutions directly to the transducer holders and cable hooks.
- For best results, remove the transducer holders and cable hooks before cleaning.

Wipe down the transducer holders and cable hooks using a soft, nonabrasive cloth moistened with either of the following:

- water
- solution of a mild detergent (pH about 7) and water.

References

Measurements (Area and Distance)

The measurement tools provided are for use by a qualified clinician. Measurements do not translate into specific physiological parameters. The ability to obtain accurate measurements is affected by complexities of cardiac geometry, the ultrasound window presented by the patient, clarity of image, operator identification of features, operator placement of calipers, and tracing.

Sources of Measurement Errors

Measurement error can result from acoustic anomalies of the body, placement of markers by the operator and machine processing, signal acquisition, conversion, processing for display, and limitations of the monitor. The monitor pixel size is approximately 0.03 cm.

Linear data is presented in cm, rounded to the nearest 0.01 cm, representing 0.2 to 0.5% of the linear dimension of a typical LV (2 cm to 5 cm).

Area data is rounded to the nearest 0.1 cm^2, representing 1% of typical LV end diastolic area (10 cm^2), appropriate since the relative bound error in area is twice the relative error bound in length.

Accuracy

METHODOLOGY OF ASSESSING ACCURACY

Phantom side-by-side measurements (area and distance) were conducted using three predicate devices and the ImaCor ZURA-EVO Imaging System. A CE tissue mimicking wire target phantom was used (ATS model 535). Areas were calculated based using the height and width measurements and based on the area formula for an ellipse
($A = \pi hw/4$). The control data used as the basis for the ImaCor ZURA-EVO Imaging System measurement accuracy determination were the mean height and width measurements, along with the calculated areas of three predicate systems combined.

Predicate 1– Acuson Aspen (K934915)

Predicate 2– Philips Sonos 7500 (K980687)

Predicate 3– GE Vivid 7 (K051449)

The mean data entered into the below table were based on 5 measurements for the ImaCor ZURA-EVO Imaging System and 15 measurements for the control group; 5 for each predicate device.

Table 17 Accuracy of Distance Measurements and Area Calculations

Transducer	Height (cm) (measured)	Width (cm) (measured)	Area (cm^2) calculated	Comments
ImaCor ZURA-EVO Imaging System mean	4.02	4.39	13.83	5 measurements and area calculations
ImaCor ZURA-EVO Imaging System SD	0.02	0.03	0.07	
Predicate mean	4.04	4.45	14.12	Control group – 15 measurements and area calculations
Predicate SD	0.02	0.03	0.14	
ImaCor ZURA-EVO Imaging System accuracy	0.5%*	1.3%*	2.1%*,**	

Table 17 Accuracy of Distance Measurements and Area Calculations

Transducer	Height (cm) (measured)	Width (cm) (measured)	Area (cm^2) calculated	Comments
* Assumes that the control data averages of 15 measurements by the three predicate systems, represent the actual dimensions. Does not include rounding or monitor limitations. If these limitations were included, then the relative error bounds would be approximately 2%, 3%, and 5%, respectively.				
** Need not equal 0.5% + 1.3% because errors in height and width measurement may be correlated.				

Table 18 Accuracy Measurements for TTE Probe Model SA4-2-224

Parameters	Axial Distance (AD) (mm)
Trial 1	20.07
Trial 2	19.97
Trial 3	20.18
Trial 4	19.81
Trial 5	20.1
AD_{ave}	20.03
AD_{ref}	20
AD_{ERR}	0.03
$AD_{\%ERR}$	0.13
AD_{max}	359.86
AD_{min}	0.12

Parameters	Axial Distance (LD) (mm)
Trial 1	29.7
Trial 2	29.93
Trial 3	29.7
Trial 4	29.82
Trial 5	29.81
LD_{ave}	29.79
LD_{ref}	30
LD_{ERR}	–0.21
$LD_{\%ERR}$	–0.69
LD_{max}	502.32
LD_{min}	0.12

Table 19 Test Results (Area)

Parameters	Area (AREA) (cm)
Trial 1	0.81
Trial 2	0.73
Trial 3	0.77
Trial 4	0.73
Trial 5	0.77
$AREA_{ave}$	0.76
$AREA_{ref}$	0.79
$AREA_{ERR}$	–0.03
$AREA_{\%ERR}$	–3.5

Table 19 Test Results (Area)

Parameters	Area (AREA) (cm)
$AREA_{max}$	1005.97
$AREA_{min}$	0.01

Specifications

Table 20 ImaCor System Specifications

Item	Specification
System dimensions	Content
Display dimensions	19-inch LCD display
Transducers (probes) TEE TTE	Phased array Single-use, disposable, provided sterile Multi-use
Imaging mode	Type B mode imaging Color Flow mode imaging
Sector Angle	70° and 90°
Application	TEE imaging. The system is optimized for three views: • Transgastric short axis view of left ventricle • Midesophageal four chamber view to evaluate size and function • Super Vena Cava view to assess volume responsiveness TTE imaging: The system is optimized for transthoracic view
Resolution	128 Lines
Measurement	Distance and area measurement capability. See “Measurements (Area and Distance),” page 121
Image storage	Data transfer module (DTM)
Cables	• Power supply cord • ECG leads
Probe	Single use, TEE, disposable, provided sterile
Temperature, pressure, & humidity limits	Operating limits: system • 10–40°C (50–104°F), 15–95% R.H. noncondensing • 700 to 1060 hPa (0.7 to 1.05 ATM)
	Shipping/storage limits: system • -35–65°C (-31–149°F), 15–95% R.H. noncondensing • 500 to 1060 hPa (0.5 to 1.05 ATM) • For storage longer than 30 days store at room temperature.
	Operating limits: Probe • 10–40°C (50–104°F), 15–95% R.H. noncondensing • 700 to 1060 hPa (0.7 to 1.05 ATM)
	Shipping/storage limits: Probe • -20–60°C (-4–140°F), 0–95% R.H. noncondensing • 500 to 1060 hPa (0.5 to 1.05 ATM) • For storage longer than 30 days, store at room temperature
Supply source	100–120 Vac, 7A, 50/60 Hz 200–240 Vac, 4A, 50/60 Hz Slide switch provided to adjust voltage to either 120 Vac or 240 Vac range
Mains fuse	3 AG Slo-Blo, 7A/250 V Fuse drawer style compartment located adjacent to Mains power inlet. Screwdriver needed to access fuses for replacement

Glossary

Terms

ClariTEE™	ImaCor miniature disposable TEE probe
Cineloop	Recorded ultrasound image file
Fractional area change	Change in ventricular area at end diastole to end systole
ICU	Intensive Care Unit
ImaCor ZURA-EVO™	ImaCor ZURA-EVO Imaging System
R-wave	First upward deflection of the electrocardiogram
Real-time imaging	Imaging occurring in the present moment
TEE	Transesophageal echo where ultrasound transducer is placed in esophagus or stomach
TTE	Transthoracic echo where ultrasound transducer is placed on the surface.
Umbilical	Cable extending from probe handle and terminating in ZIF connector for machine connection

Acronyms

AC	Alternating current
ALARA	As low as reasonably achievable
BPM	Beats per minute
DBC	Depth brightness compensation
DTM	Data transfer module
ECG	Echocardiogram
ED	End diastolic
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ES	End systolic
FAC	Fractional area change
FDA	Food and Drug Administration
FPS	Frames per second
hTEE	Hemodynamic transesophageal echo
ICU	Intensive care unit
ISPPA	Intensity spatial-peak pulse-average
ISPTA	Intensity spatial-peak temporal-average
LCD	Liquid crystal display

LV	Left ventricular
LVEDA	Left ventricular end-diastolic area
LVESA	Left ventricular end-systolic area
MI	Mechanical index
RFI	Radiofrequency interference
TEE	Transesophageal echocardiography
TGC	Time gain compensation
TGSAV	Trans-gastric short-axis view
TTE	Transthoracic echocardiography
USB	Universal serial bus
ZIF	Zero insertion force