

ImaCor Zura-Evo™ Imaging System



ImaCor

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User Guide Conventions	6
Icons	6
New in Zura-Evo 2.2.1	7
ImaCor Zura-Evo Imaging System Overview	8
Overview	8
Indications for Use	8
Contraindications	8
Transesophageal Echocardiography (TEE) Use in Critical Care Settings	8
Principles of Operation	9
Episodic Assessment	9
Non-Imaging Mode	10
Cumulative Imaging Time	11
About the System	12
Ultrasound Machine	13
Ultrasound Probe	13
Adaptaflex™ Technology	13
UPS (optional)	13
Getting Started	15
Preparing the System	15
Connecting the ImaCor Disposable Probe	15
Connecting the ECG	18
Turning the System On/Off	19
On-Screen Keyboard	20
ImaCor Ultrasound Imaging Software	21
Overview	21
Online Help System	21
Additional Help Resources	22
System Initialization	22
Patient Information	24
Patient Information Screen Data Fields	24
Patient Edit Lock Feature	25
Patient List	25
Patient Information Screen Button Functions	26
DICOM Synchronization Feature	26
Querying a Modality Worklist (MWL) Server	27
Synchronizing with a DICOM Archiving Server	27
Viewing the Sync Log	28
Patient Information Tasks	28
Create a New Patient Record	28
Autoselect an Existing Patient Record	28
Manually Select an Existing Patient Record	29
Select a Patient Record Created on a Remote Zura or Zura-Evo System	29
Update a Patient Record	30
Delete a Patient Record	30
Delete multiple patient records	30
Transferring Patient Records Between ImaCor Zura/Zura-Evo Systems	31
Export a Patient Record to a Data Transfer Module (DTM)	32
Import a Patient Record from a Remote Zura-Evo System	32
Duplicate Records	32
The Imaging Environment	34
Single View Mode	34
Split View Mode	38

Real-Time Imaging	41
Depth Markers	42
Freeze/Unfreeze	42
Freeze	42
Unfreeze	43
Steering	43
Activating the Steering Feature	44
Optimizing Real-Time Images	45
B-Mode Images	45
Changing Default B-Mode Image Control Parameters	45
Restoring Default B-Mode Image Control Parameters	45
Gain Control	45
Time Gain Compensation (TGC)	46
Auto-Q Feature	46
Filter Control	47
Contrast Control	47
Depth Control	48
True Depth feature	48
Color Flow Images	49
CF Gain Control	49
CF Filter Control	49
The ECG Waveform	50
Related topics	50
ECG Cursor	50
ECG Markers	50
Adding an ECG Marker	51
Deleting an ECG Marker	51
Changing the ECG Lead	51
Changing the ECG Sweep Speed	52
Inverting the ECG Waveform	52
Image Acquisition	54
Related topics	54
Acquiring Images	54
Acquisition Frame Rates	54
Adding Comments to Cineloops	55
Recovery Mode	56
Image Storage	56
Managing Cineloops	57
Loading a Cineloop	57
Reviewing a Cineloop	58
Cineloop Control Buttons	58
Color Flow Indicator Icon	59
Cineloop Image Quality Controls	60
Brightness Control	60
Depth Brightness Compensation (DBC)	60
Contrast Control	61
Depth Control	61
Saving a Cineloop as a Movie	62
Saving the Current Frame as a BMP Image	62
Deleting a Cineloop	63
Measurement Tools	65
The Tracing Tool	65
Creating a Trace	66
Updating an Existing Trace	66
Deleting Points on a Trace	67

Deleting a Trace	68
From within Trace Mode	68
From within Distance or Area Mode	68
The Measuring Tape Tool	69
Taking a Measurement	69
Taking the First Measurement	69
Taking the Second Measurement	69
Editing a Measurement	70
Deleting a Measurement	70
Viewing Measurements	71
Viewing Measurements on Cineloops	71
Zura-Evo Measurement Functions	72
Measuring Mode	72
The FAC Wizard	72
Reviewing an FAC Trace	75
FAC Trace Overlay Mode	75
Working in Split View Mode	76
Loading Two Cineloops in Split View Mode	76
Viewing a Cineloop and Real-Time Images in Split View Mode	76
Synchronized Cineloop Playback	78
Specifying ECG Markers	78
Activating and Deactivating Synchronized Playback	78
Synchronized Playback Speed Controls	79
Superimposed Mode	79
Working in Superimposed Mode	79
Color Flow Imaging	81
The Color Box	81
Repositioning the Color Box	82
Resizing the Color Box	82
B-Mode Priority	83
Setting B-Mode Priority	83
Velocities	83
Displaying the Velocities Menu	83
Changing the Velocity Setting	84
Color Maps	85
Changing Color Maps	85
Configuring the System	87
General	87
Imaging Defaults	87
Measuring and Tracing Settings	87
Trace Resolution	87
Trace Color	87
Measure Color	87
Institution	88
Reset Button	88
Acquisition	88
Date-Time	88
DICOM	89
Patient Export Options	90
Archiving Server Configuration	90
Custom Synchronization Rules	90
Modality Worklist (MWL) Server Configuration	91
Compression	91
Language	91
Version	91
Software Update	92

Download the Software Upgrade and Request a License File	92
Upgrade the Zura-Evo Software	92
Help	93
Tool Tips	93
Remote Assistance.....	93
Analysis Package	94
Safety	95
Disposable Single-Use ClariTEE.....	95
The ALARA Principle.....	95
Applying ALARA.....	96
ALARA Operator Control.....	96
Cumulative Imaging Time.....	96
Mechanical Index	96
ALARA Automatic Controls.....	96
Twenty Minute Software Interlock.....	96
Watchdog Monitor.....	97
Transesophageal Echo Imaging (TEE) Potential Complications	97
Electrical Safety	97
Electromagnetic Compatibility (EMC)	97
Biocompatibility Safety	98
Acoustic Output.....	98
Global Maximum Derated ISPTA, MI, and TI Values	99
Acoustic Measurement Precision and Uncertainty	99
Labeling Symbols	99
Transporting the Zura-Evo.....	101
ImaCor Approved Device	102
Troubleshooting and Maintenance	103
Troubleshooting	103
Maintenance	103
Zura-Evo System Cleaning Recommendations	104
LCD Monitor Cleaning	104
Handle and Umbilical	104
Other Recommended Maintenance	104
Power Supply Cord	104
Handle and Umbilical	104
Master Message Listing - Alphabetical.....	105
References.....	113
Measurements (Area and Distance)	113
Sources of Measurement Errors	113
Accuracy	113
Methodology of Assessing Accuracy.....	113
Specifications.....	115
Glossary	116
Terms	116
Acronyms	116



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DECLARATION OF CONFORMITY

(Annex II.3 of the Directive 93/42/EEC)

ImaCor Inc. declares conformance with the relevant provisions of the aforementioned EC directive. This declaration is issued under the sole responsibility of ImaCor Inc.

Manufacturer : ImaCor Inc
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USA

Product Identification : ImaCor TEE Imaging System consisting of

Ultrasound Machine Zura, Zura-EVO, EVZ100, ZT-1000 with handle model UMB-1000

ClariTEE probe

Classification : The Ultrasound Zura, Zura-EVO machine model is classified as Class IIa in accordance with rule 10 of Annex IX. The ClariTEE probe is classified as Class IIa in accordance with rule 5 of Annex IX

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Richard Lanzillotto
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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 system.

New in Zura-Evo 2.2.1

- Reduced recovery period; see page 56
- Enhanced cineloop comment capabilities; see page 55
 - Record hTEE view with cineloop comments
 - Display hTEE view information in the cineloop load window
 - Automated selection of measurement type based on hTEE view information
- Enhanced hTEE flashcards now include video clips; see page 23
- UPS monitoring for battery option; see page 13
- Improved SVC index calculation algorithm
- Still frame export (cineloop frames can be saved as BMP images on a USB thumbdrive); see page 62

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

The ImaCor system is intended for 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 period not to exceed 72 hours.

Contraindications

The ImaCor Zura-Evo 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 anaesthesia.

The ImaCor Zura-Evo 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 system is not a continuous monitoring system.

The ImaCor Zura-Evo 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 1 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

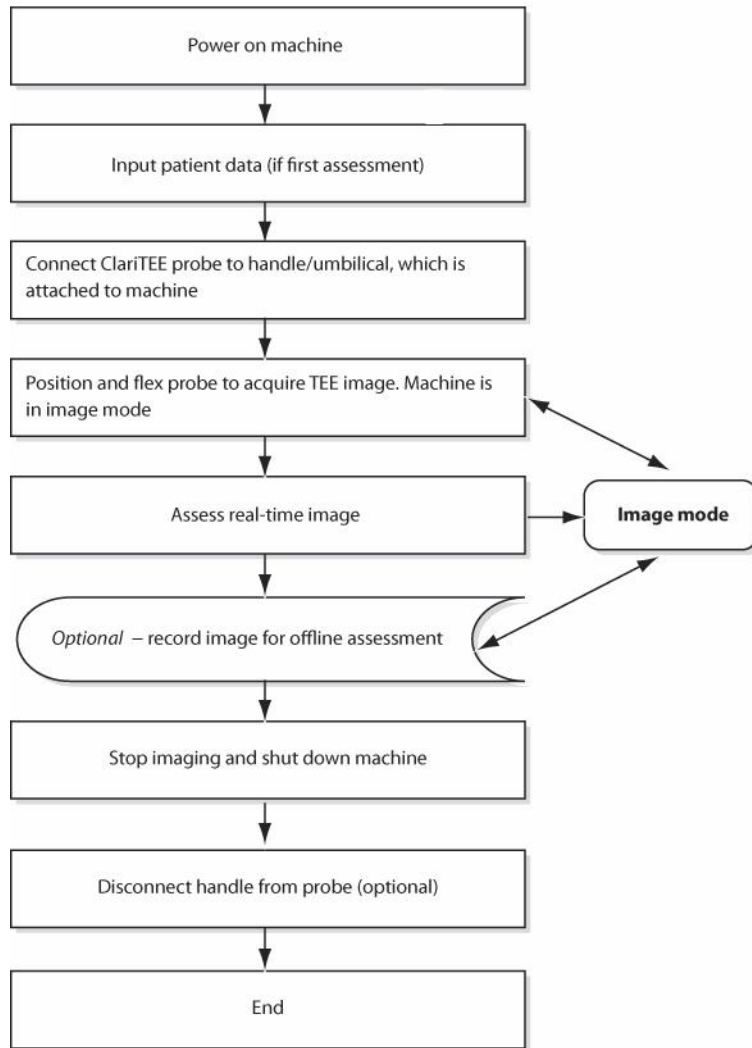


Fig. 1 Process flow of one episodic assessment

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 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 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.

About the System

The ImaCor Zura-Evo system consists of four main components:

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

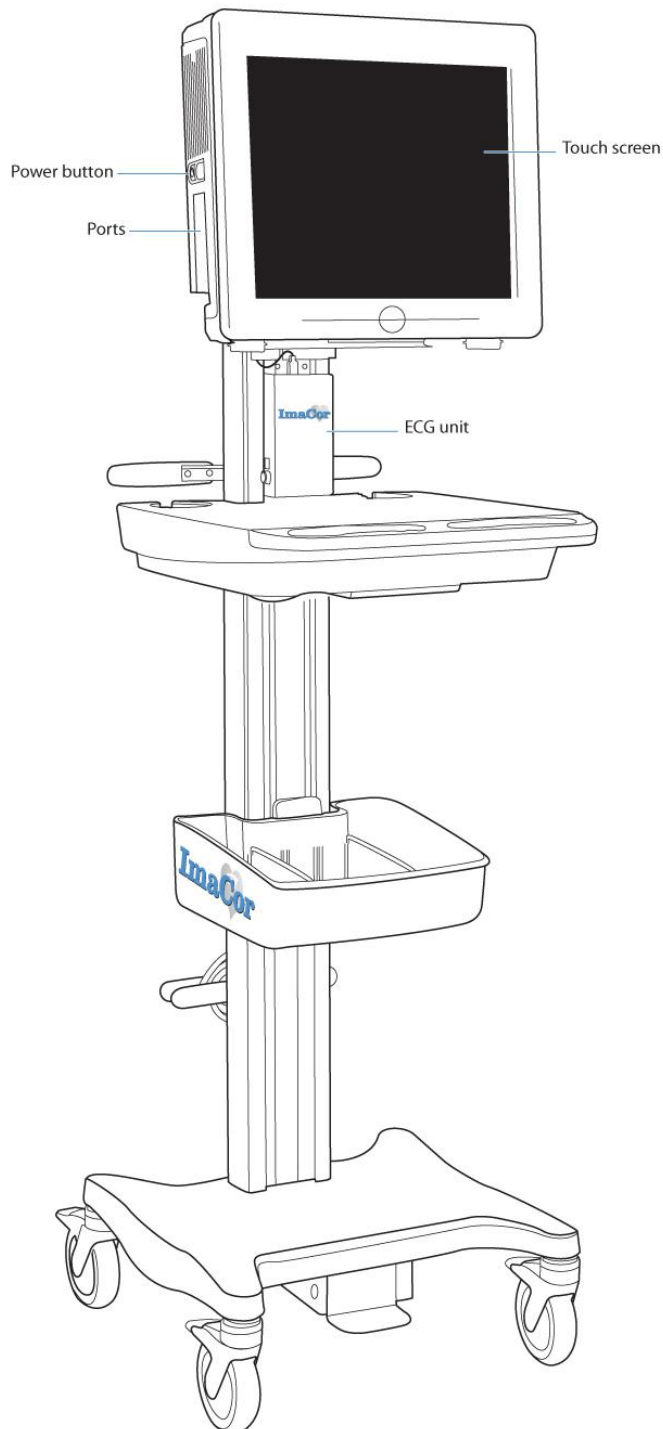


Fig. 2 ImaCor Zura-Evo Ultrasound Machine

Ultrasound Machine

The ImaCor Zura-Evo 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 Probe

 Caution
The ImaCor ClariTEE is for use only with the ImaCor Zura-Evo 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

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

Getting Started

Preparing the System

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

Connecting the ImaCor Disposable Probe

- 1 Locate the dedicated matching connector (ZIF connector) for the locking umbilical cable connector.
- 2 Push the umbilical cable connector into place (Figure 6). The umbilical cable connector is large; you will need one hand to hold it and the other to turn the locking lever.

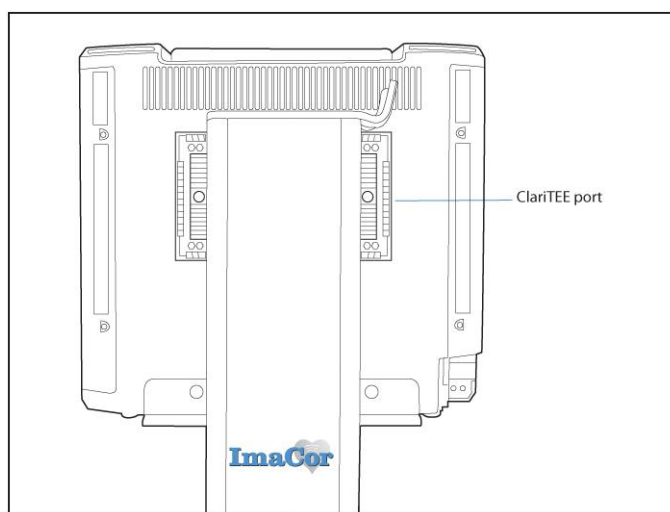


Fig. 5 ClariTEE port

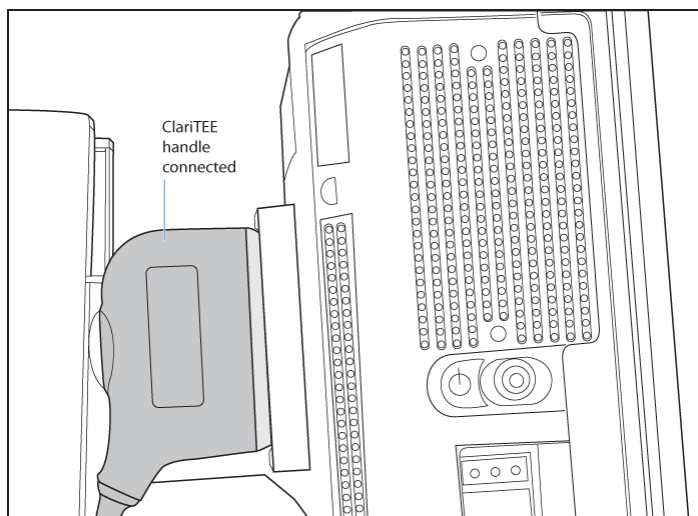


Fig. 6 Push the umbilical connector into the ClariTEE port

- 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 7).

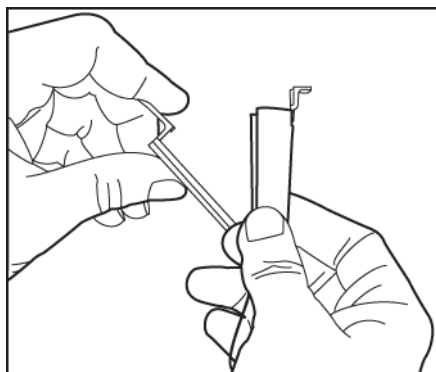


Fig. 7 Remove the cover from the disposable probe

- 4** Position the probe connector and handle as shown in Figure 8.

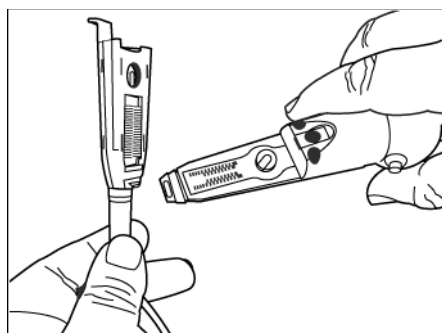


Fig. 8 Position the probe connector and handle in hand

- 5** Align the probe with the handle.

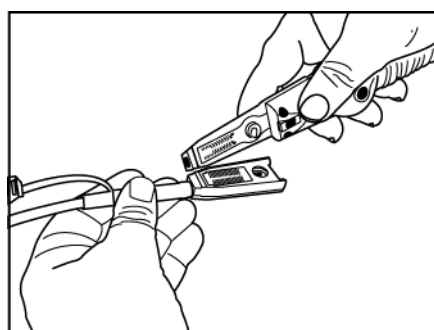


Fig. 9 Align probe and handle

- 6 Insert the blue connector tab into the distal end of the handle (Figure 10).

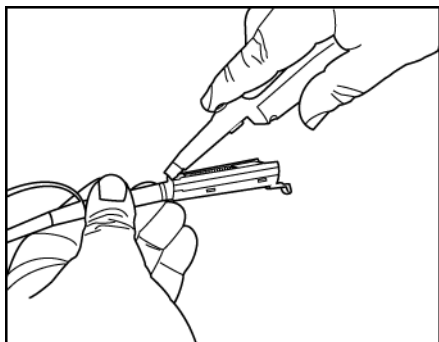


Fig. 10 Insert connector tab into distal end of the handle

- 7 Gently press the probe connector over the handle; press the tab on the umbilical connector to assist with engagement (Figure 11). An audible click will indicate the probe is properly connected.

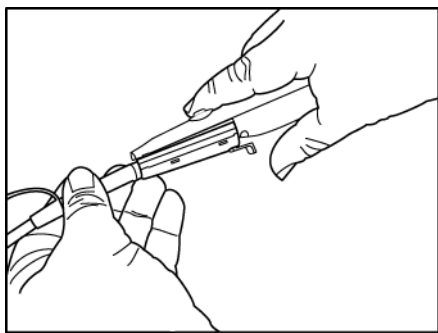


Fig. 11 Press the probe connector over the handle

- 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.

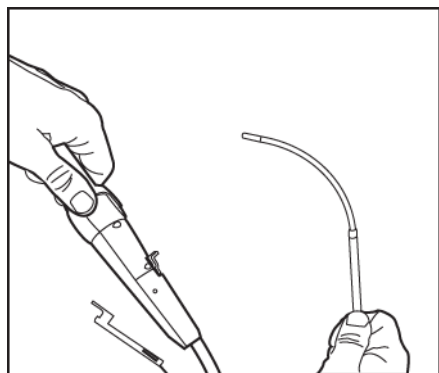


Fig. 12 Check articulation of the probe

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

Connecting the ECG

Note: The ECG provided with the Zura-Evo 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 13.

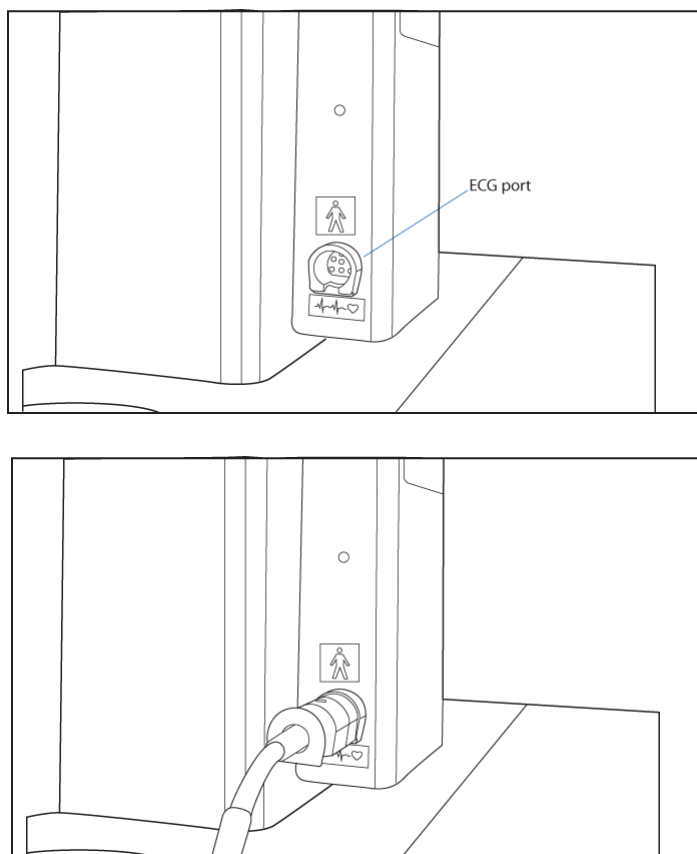


Fig. 13 Connect the ECG leads

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**.)

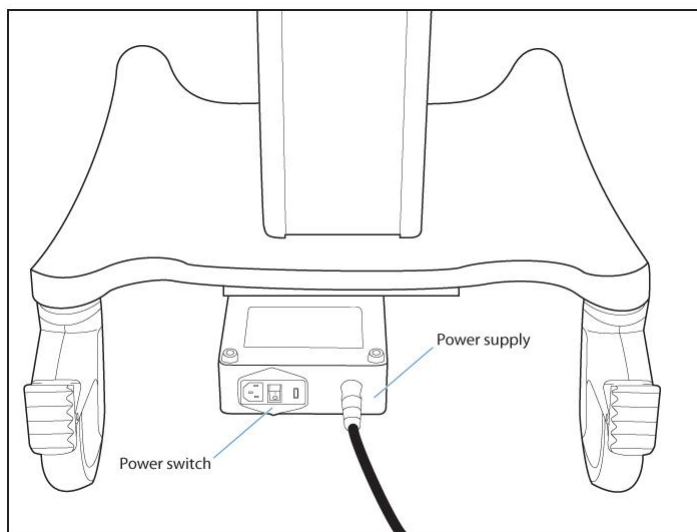


Fig. 14 Power switch

- 2 Power up the computer by pressing the power button shown in Figure 15.

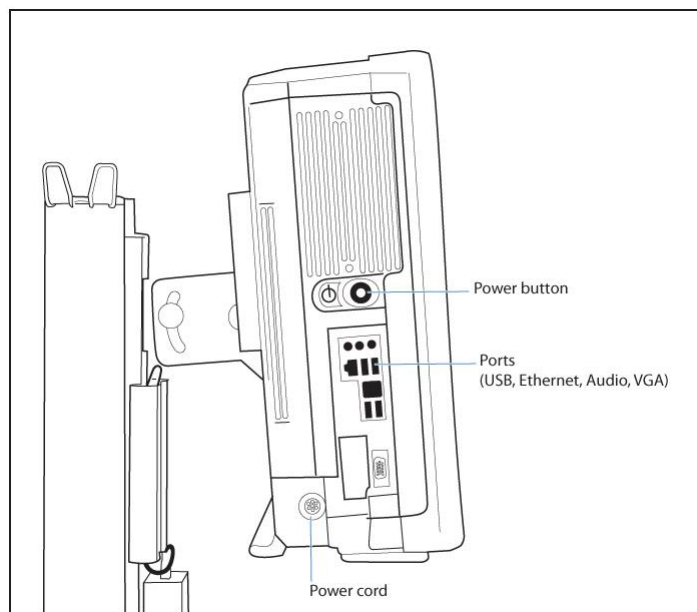


Fig. 15 Power pushbutton

On-Screen Keyboard

Whenever alphanumeric input from the user is required, the Zura-Evo system displays an onscreen keyboard, shown below. The keyboard is superimposed on the bottom of the patient information and imaging screens.



Fig. 16 Onscreen keyboard

ImaCor Ultrasound Imaging Software

Overview

ImaCor Ultrasound Imaging Software v2.2.1 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 Mouse

- 1 Right-click anywhere on the screen.
- 2 Select "Help" from the global context menu.

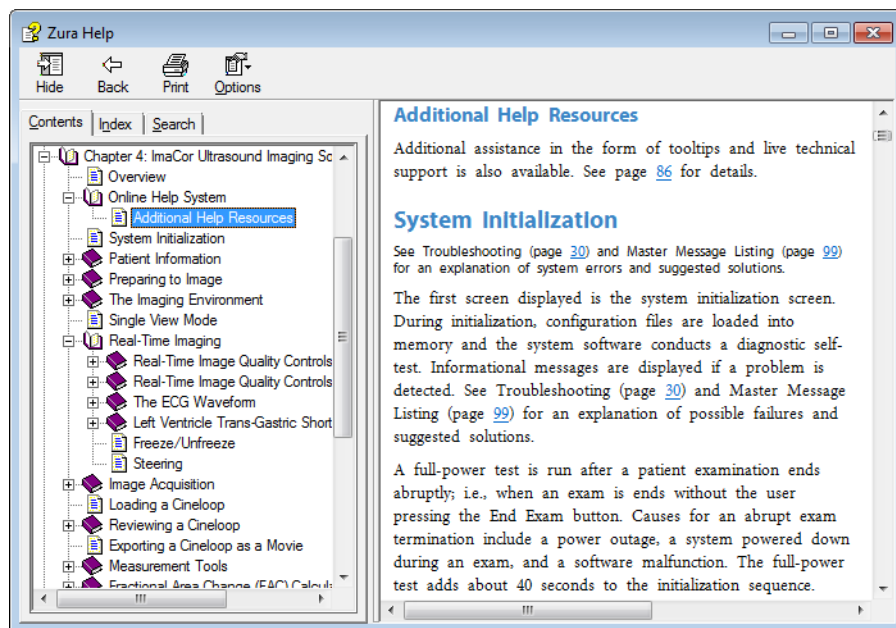


Fig. 17 Sample Help screen

Additional Help Resources

Additional assistance in the form of tooltips and live technical support is also available. See page 93 for details.

System Initialization

See the Master Message Listing (page 106) 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 106) 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. 18 Initialization screen

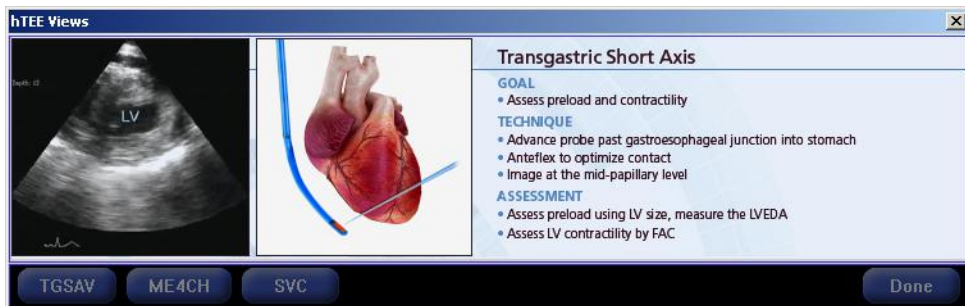


Fig. 19 System initialization screen – animated transgastric short-axis flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

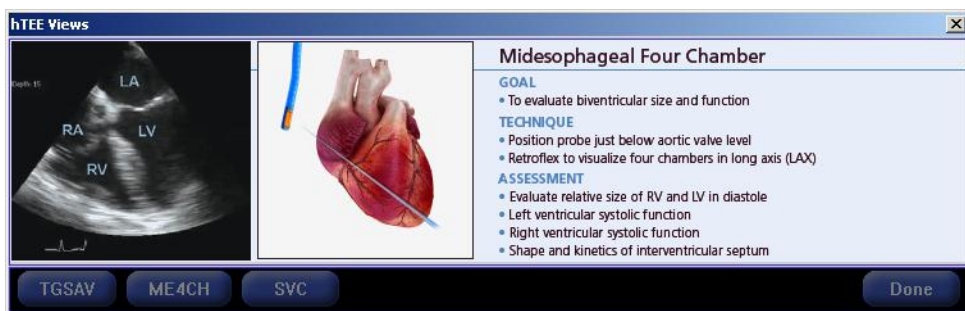


Fig. 20 System initialization screen – animated mid-esophageal four-chamber flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

Fig. 21

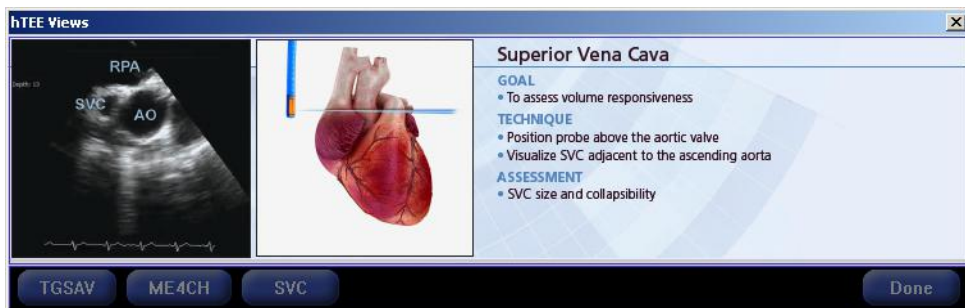


Fig. 22 System initialization screen – animated superior vena cava flash card. Click the TGSAV, ME4CH, or SVC button to view the associated hTEE view.

Patient Information

Basic patient data are entered using the Patient Information window (Figure 23). After starting the ImaCor Zura-Evo 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 26).

Patient Information Screen Data Fields

The fields detailed in Table 2 comprise the Patient Information screen.

Table 2 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	Enter local patient identification number, if applicable	32 characters maximum
Last Name	Mandatory	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	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.
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.

Table 2 Patient Information Screen Data Fields (Continued)

Field Name	Status	Function	Notes
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 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
☐		TEST	AGAIN		U		70	11/30/2011		{7EA3C7F7...
☐		R	HEATHER		U		14	12/1/2011		{2FB5EA4F...
☐		TEST	TABLETCINES		U		4	11/28/2011		{6BE2DDF3...
☒	00000003	DOE	JANE	06/11/1948	F	JESSE, JONES	1	1/10/2008		{51882AEA...
☐	00000055	MELVILLE	ROBERT	12/08/1960	U	PAUL, DAWSON	17	1/20/2011	12345678	{D657B971...
☐	00000104	VERNON	MIKE	01/02/1955	U	JON, DELERUE	0	4/28/2011		{BF67216A...
☐	AA2E37F3	G	D	10/09/1902	F		16	1/12/2011		{AA2E37F3...

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,” page 90). 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 3 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 32 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 32 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 90). 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 87, 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 system, you can query the server for a selected patient. Data elements that are already present on the Zura-Evo 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 system, the birthdate will not be imported.



Touch Screen

- 1 Select a patient from the Patient List.
- 2 Tap anywhere on the screen and hold.
- 3 Select the “Check MWL Server...” option.



Zura-Evo 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 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 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 system will not be sent to the archiving server. Cineloops can be transmitted to an archiving server only by the Zura-Evo 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

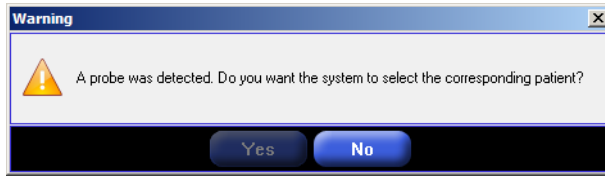
Create a New Patient Record

- 1 Access the Patient Information screen.
 - After starting the ImaCor Zura-Evo 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.
 - 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 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 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.

Manually Select an Existing Patient Record

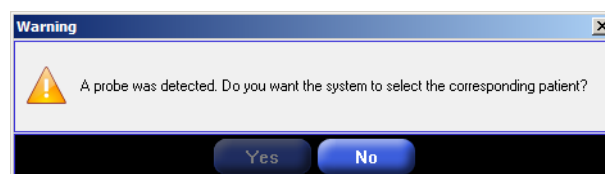
- 1 If you reject the Autoselect option, the system software turns off the probe-detection mechanism for the duration of the patient exam or until the probe is disconnected.
- 2 To maximize efficiency, make sure the Enable Filtering box is checked. When the Patient List filter is active, the characters 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 or Zura-Evo System

If patient data has been encoded in the probe but no matching record is found in the patient database, the Zura-Evo 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 system, but a subsequent assessment uses a different Zura. Zuras are stand-alone systems; information and cineloops entered in one patient database do not appear in databases associated with other Zura 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 system (see "Import a Patient Record from a Remote Zura-Evo System," page 32). 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 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 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.

Update a Patient Record

- 1** Access the Patient Information screen.
 - After starting the ImaCor Zura-Evo 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 25.
- 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 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 Mouse

- 1** Access the Patient Information screen.
 - After starting the ImaCor Zura-Evo 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 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.

ImaCor Lab 4/14/2012 02:43:03 PM

Patient information:

GUID: {1EDFC537-96CB-49DF-A3E2-E9CF857D2A25}

Patient ID:

Last Name: MEMORYCHECK

First Name: TEST

DOB: mm/dd/yyyy

Weight: lb oz Imperial

Height: ft in

Sex: Unknown

Notes:

Physician: First Name Last Name

Accession #:

ID	Last Name	First Name	DOB	Sex	Physician	Cine	Date Created	Accession #	GUID
☐	MEMORYCHECK	EXPIRATION		U		98	2/15/2012		{51667669...}
☒	MEMORYCHECK	TEST		U		40	12/28/2011		{1EDFC537...}
☒	JOHN			U		15	2/23/2012		{B4840751...}
☒	DEMO			U		2	2/24/2012		{2F70E1BD...}
☒	TT			U		8	3/1/2012		{78A9952A...}
☐	AGAIN	TEST		U		2	3/8/2012		{6AB58D83...}
☐	MEMORYCHECK	TEST		U		0	3/27/2012		{EF3345EC...}
☐	MAINTENANCE	MARCH 2012		U		0	3/29/2012		{EA9B9BA1...}
☐	PASHINT	NEW		U			4/3/2012		{421244B7...}
☐	ERASME CA2D8C	CASE 1 OCT 6 ...		M		13	10/6/2011		{CA2D8CB...}
☐	ET C60CES 4	K 5 CASE 1 OCT ...		U		17	10/7/2011		{429EE118...}

Enable Filtering

Import Export Sync New Patient Next Configure Shutdown

Fig. 26 Deleting a patient record

Transferring Patient Records Between ImaCor Zura/Zura-Evo Systems

Zura-Evos are stand-alone systems; information and cineloops entered in one patient database do not appear in databases associated with other Zura systems. Many institutions have multiple Zura/Zura-Evos in service, and it's often desirable to copy data recorded in one Zura 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/Zura-Evo 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 system records.

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

- 1 Access the Patient Information screen.
 - After starting the ImaCor Zura-Evo 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. 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 87.
- 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>

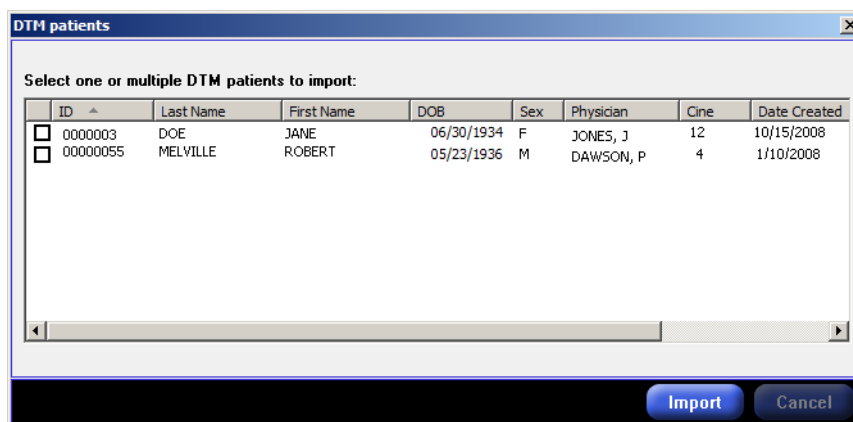
Import a Patient Record from a Remote Zura-Evo System

Related Topics

“The Imaging Environment,” page 34

“Synchronizing with a DICOM Archiving Server,” page 27

- 1 Insert a DTM into one of the USB ports on the left side of the Zura-Evo. 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,”
- **Split View mode** enables you to compare two cineloops side-by-side or one cineloop beside real-time imaging. See page 38 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 4 on page 35 summarize Single View mode features. Figure 28 and Table 5 on page 37 describe Imaging screen buttons.

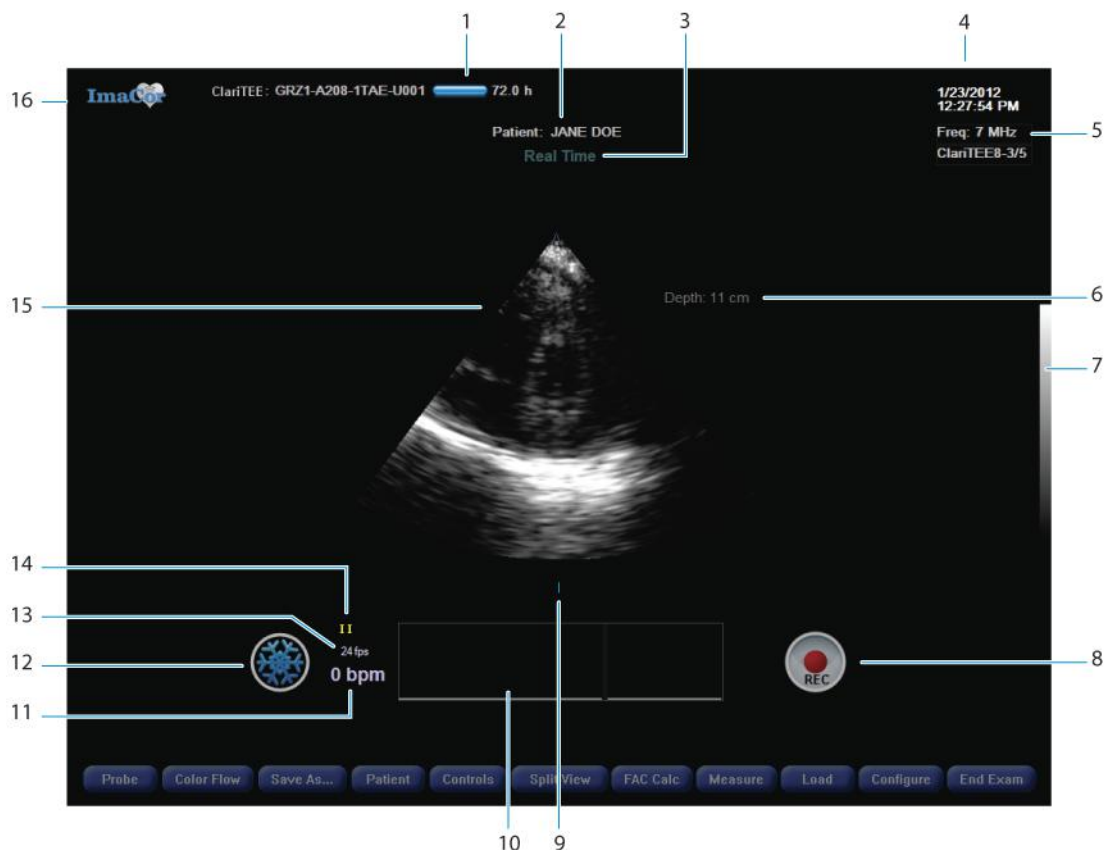


Fig. 27 Single View mode imaging screen

Table 4 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	Current date and time		
5	Tx frequency	Displays the current ultrasound transmit frequency. The values are 6 MHz and 7 MHz for B-mode imaging and 5 MHz for Color Flow imaging. The default B-mode is transmit 7 MHz. It can be changed to 6 MHz for improved penetration with a slight decrease in resolution.	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.
6	Depth display	Displays the imaging depth. The default imaging depth is 15 cm.	Always ON
7	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.
8	Acquire/Record	Acquire	Starts a 3-second acquisition of real-time images and ECG
9	Steering feature cursor	Enables the user to look left or right without physically moving the probe. For additional information, see "Steering," page 43.	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 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
10	ECG waveform		
11	Heart rate	Expressed in beats per minute (bpm)	

Table 4 Single-View Imaging Screen Features (Continued)

Number	Feature	Function	Notes
12	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 42
13	Frame rate	Expressed in frames per second (fps)	The standard frame rate for B-mode imaging is 24 fps The B-mode acquisition frame rate is 50 fps. The CF-mode imaging frame rate varies with 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 56. 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.
14	ECG lead	Select Lead I, II, or III	
15	Real-time image		
16	Institution (hospital) name and location		



Fig. 28 Single View mode layout buttons

Table 5 Imaging Screen Buttons

Number	Feature	Function	Notes
1	Probe	The probe button displays status information about the probe currently in use. - Probe in use - Probe expired - Probe does not match selected patient - Probe handle not detected - Probe not detected	 The 'Probe Information' dialog box displays the following information: - Name: ClariTEE - Type: TEE - First use: Wed May 09 14:03:00 2012 - Patient GUID: (5F02A7E9-1051-4F19-B0E8-85B6281753C3) - Status: in use Buttons: OK The dialog box also shows status messages with red exclamation marks: - Status: expired - Status: does not match selected patient - Status: handle not detected - Status: probe not detected Buttons: OK
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.
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 34 and "Split View Mode," page 38

Table 5 Imaging Screen Buttons (Continued)

Number	Feature	Function	Notes
7	FAC Calc	Starts the FAC Wizard, which guides the user through the steps necessary to complete an FAC calculation.	See "The FAC Wizard," page 72
8	Controls	Displays image quality controls.	
9	Load	Loads a cineloop.	See "Loading a Cineloop," page 57
9	Configure	Enables user to customize several aspects of the system configuration, including: • Application • Date-Time • DICOM • Language • Version • Help	"Configuring the System," page 87
10	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 78) 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.

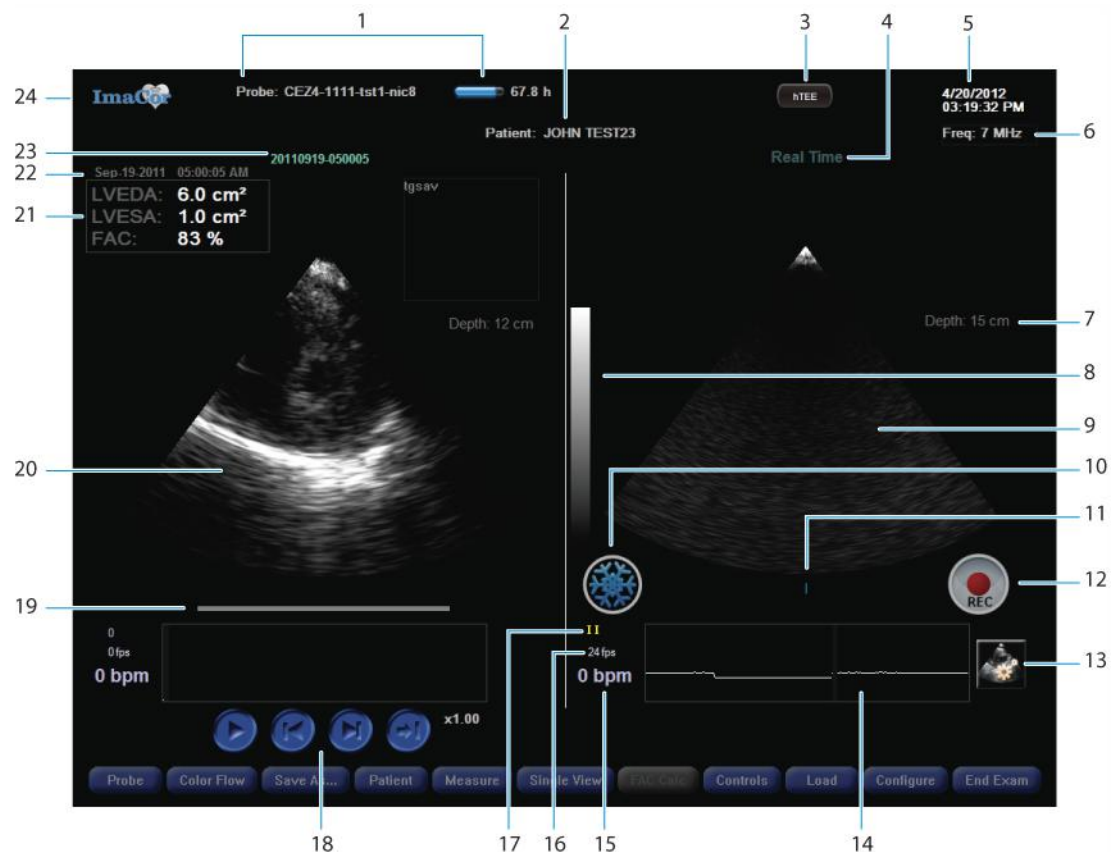


Table 6 Split View Imaging Screen

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	Status indicator	Indicates that the right side of the screen is displaying real-time images	
5	Current date and time		
6	Tx frequency	Displays the current ultrasound transmit frequency. The values are 6 MHz and 7 MHz for B-mode imaging and 5 MHz for Color Flow imaging. The default B-mode is transmit 7 MHz. It can be changed to 6 MHz for improved penetration with a slight decrease in resolution.	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.
7	Depth display	Displays the imaging depth. The default imaging depth is 15 cm.	Always ON
8	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.
9	Real-time image		
10	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 42
11	Steering marker	Enables the user to look left or right without physically moving the probe. For additional information, see "Steering," page 43.	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 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
12	Acquire/Record	Acquire	Starts a 3-second acquisition of real-time images and ECG

Table 6 Split View Imaging Screen (Continued)

Number	Feature	Function	Notes
13	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.
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 acquisition frame rate is 50 fps. The CF-mode imaging frame rate varies with 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 56. 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	Cineloop		
21	FAC information		
22	Frame title		
23	Logo and institution name		

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 29 depicts real-time imaging in Single View mode. Real-time imaging can also take place in Split View mode; see “Split View Mode,” page 38.

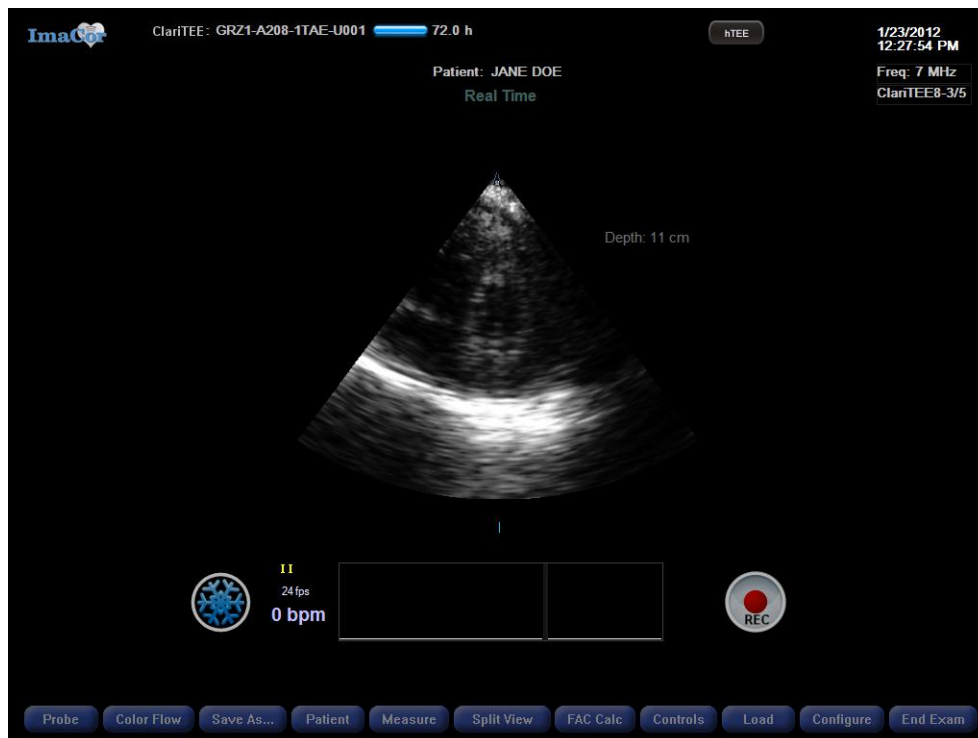


Fig. 29 Real-time imaging in single view mode

In Single View mode, real-time images are displayed in the center of the screen (see page 55).

In Split View mode, images are centered in the right and left halves of the screen, as shown on page 77. Real-time images are always displayed on the right side of the screen. The maximum image depth is 15 cm.

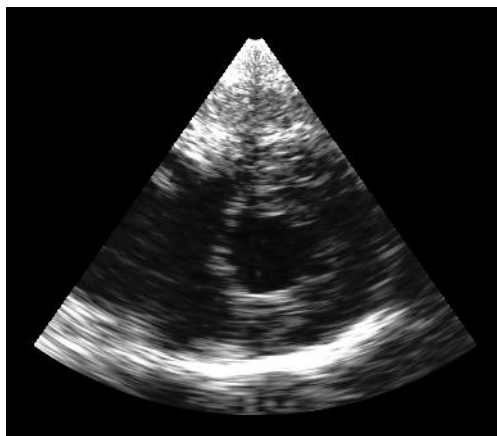


Fig. 30 Example left ventricle image in the TGS (Tissue Doppler Imaging) mode

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 31). The interval between two adjacent depth markers is 1 cm.



Zura-Evo Mouse

- 1 Right-click anywhere on the screen.
- 2 Choose the Depth Markers option from the global context menu (see Figure 31). The interval between two adjacent depth markers is 1 cm.

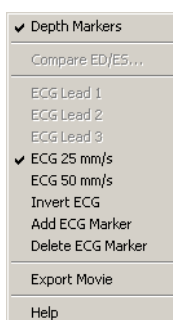


Fig. 31 Display depth marker option

Depth markers are superimposed on the ultrasound image, as shown in Figure 32. The depth marker setting is persistent across exams and system reboots.



Fig. 32 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 33).

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.

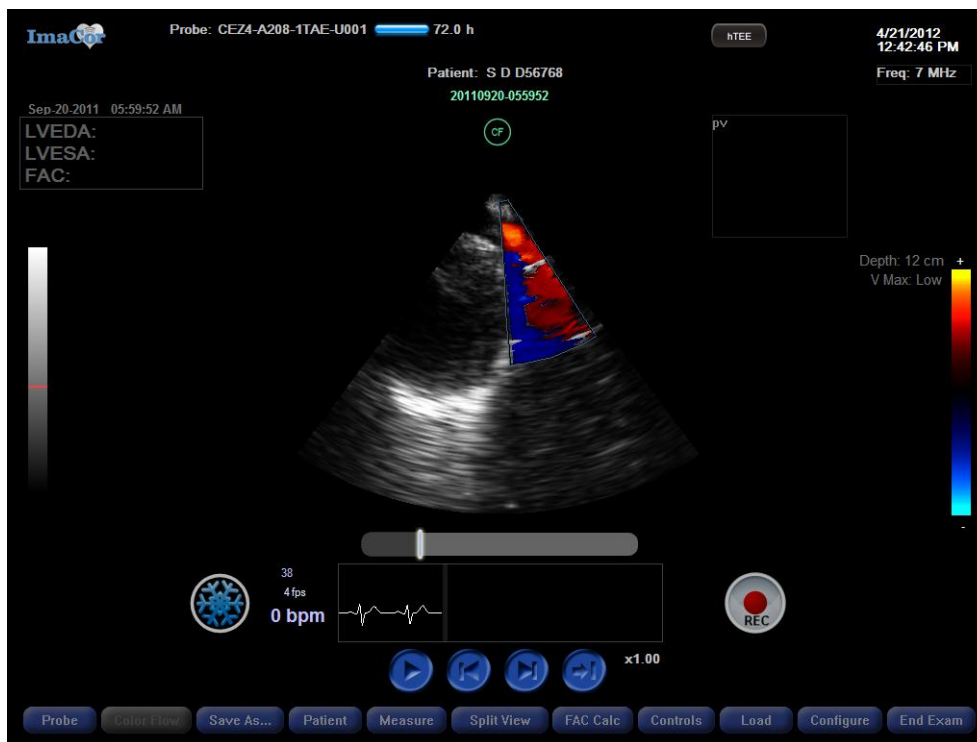


Fig. 33 Frozen single view environment scrolling enabled

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 system's 70 degree sector.

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 each side of the image to ± 26 degrees,
- At 14 cm, steering advances in five steps to ± 21 degrees.
- At 15 cm, steering advances one step on each side of the image to ± 4 degrees.

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. 34 Single View real-time screen with steering visible

Optimizing Real-Time Images

B-Mode Images

The Zura-Evo 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

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 87.

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 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 46).

- 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 35). 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.

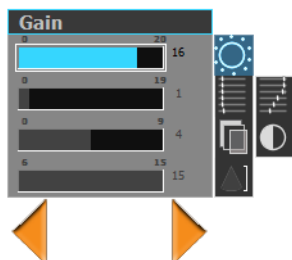


Fig. 35 Gain Control display

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 35). 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.

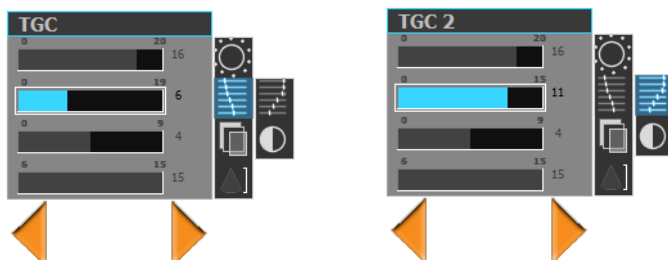


Fig. 36 TGC controls display

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 37).

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



Fig. 37 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.

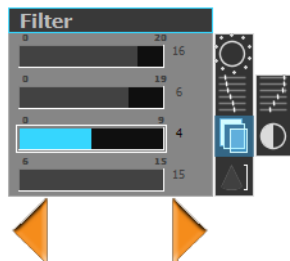


Fig. 38 Filter control display

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.

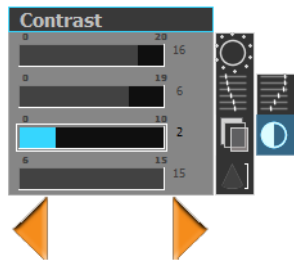


Fig. 39 Contrast control display

Depth Control

The Depth control determines the depth in centimeters of the displayed image. The Depth control range is 6–15 cm and is adjusted in 1 cm increments; the default imaging depth is 15 cm.

The Zura-Evo 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.

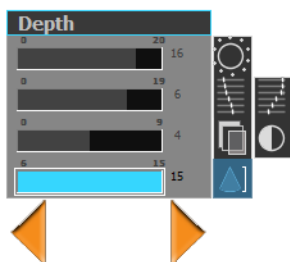


Fig. 40 Depth control display

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

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 the gauge value bar to the right or by tapping/clicking the right arrow beneath the control.

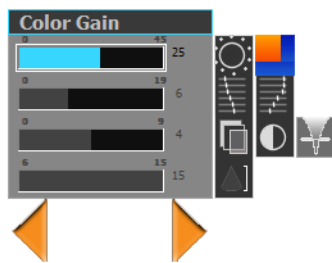


Fig. 42 CF gain control

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 CF 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.

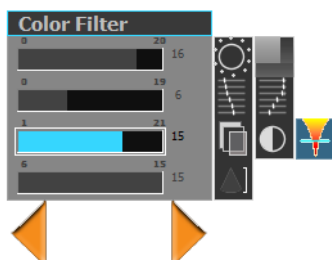


Fig. 43 CF filter control

The ECG Waveform

RELATED TOPICS

“Synchronized Cineloop Playback,” page 78

Note: The ECG provided with the Zura-Evo 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 system enables you to customize the ECG waveform display. The ECG waveform can be shown in both Single View and Split View environments.

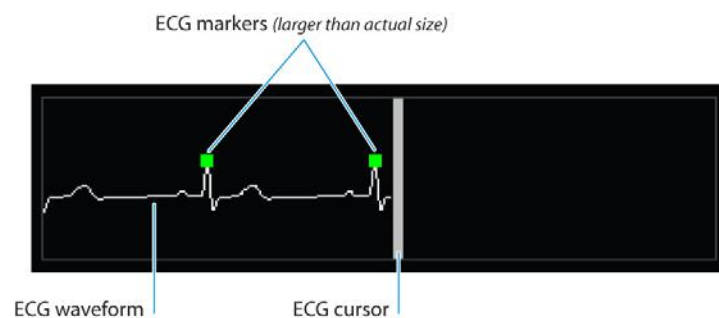


Fig. 44 Example ECG waveform with markers

ECG Cursor

The ECG cursor is a gray vertical bar (playhead) that indicates the current waveform being viewed, as shown in Figure 44. When reviewing frames, the ECG cursor is highlighted as it passes over an ECG marker, as shown in Figure 45.



Fig. 45 ECG waveform with highlighted cursor

ECG Markers

By default, an ECG marker is automatically placed at the peak of the R wave (see Figure 44). 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 51).

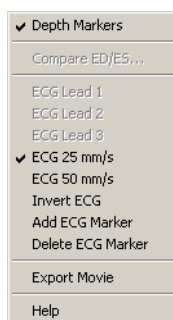


Fig. 46 Global menu

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 49).



Zura-Evo 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 49).

Deleting an ECG Marker



Touch Screen

- 1 Use the playbar to scroll through the images until the ECG cursor is 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 49).



Zura-Evo 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 49).

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 47).



Zura-Evo Mouse

- 1 Right-click anywhere on the screen.
- 2 Choose the desired ECG Lead from the pop-up menu (see Figure 47)

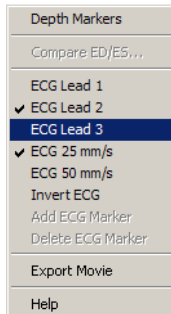


Fig. 47 Change ECG lead option

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 49.



Zura-Evo 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 49.

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 49).



Zura-Evo Mouse

- 1 Right-click anywhere on the screen.
- 2 Choose the Invert ECG option from the pop-up menu (see Figure 49).



Fig. 48 Inverted ECG waveform with markers (markers larger than actual size)

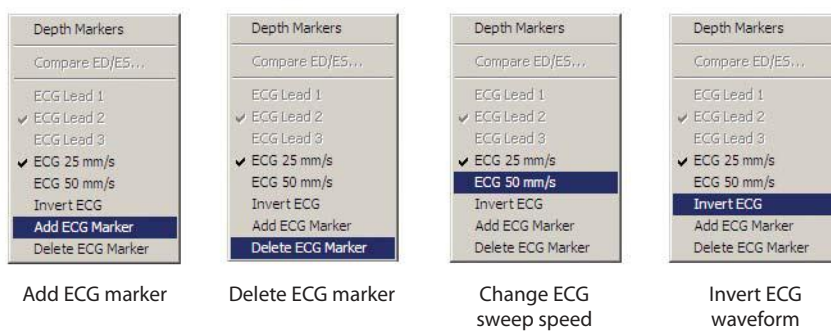


Fig. 49 ECG menu options

Image Acquisition

RELATED TOPICS

Configuring the System | “Acquisition,” page 88

“Deleting a Cineloop,” page 63

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 50 shows the Single View imaging screen during acquisition.

Image acquisition can be accomplished in one of two ways:

- 1 Tapping or clicking the onscreen Acquire button.



- 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 88.

Acquisition Frame Rates

The **B-mode acquisition frame rate** accelerates from 24 fps to 50 fps.

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.

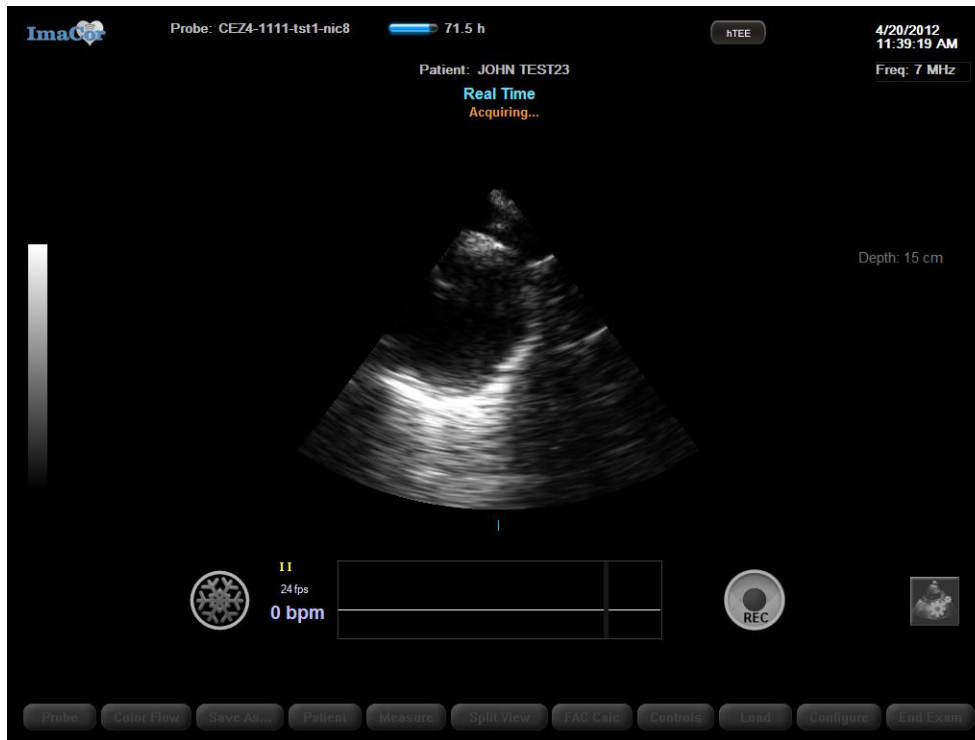


Fig. 50 Image acquisition – Single View mode

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 system begins saving the cineloop (see Figure 51). 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.

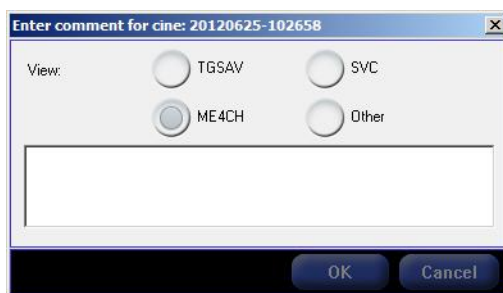


Fig. 51 Comments dialog box

Recovery Mode

Safety Feature

Recovery mode allows the ClariTEE probe to cool.

While the cineloop is being written to disk, the ImaCor Zura-Evo 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 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 63.

Managing Cineloops

Related Topics

Configuring the System | “Acquisition,” page 88

“Color Flow Images,” page 49

“Synchronized Cineloop Playback,” page 78

“Loading Two Cineloops in Split View Mode,” page 76

“Viewing a Cineloop and Real-Time Images in Split View Mode,” page 76

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 88.

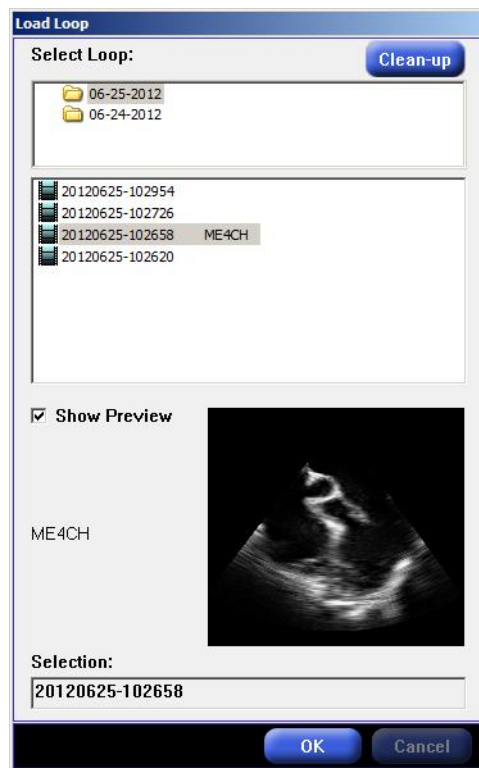


Fig. 52 Load cineloop windows

- 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 labelled 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 52.
- 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 55. Figure 53 shows where the cineloop controls are located on the imaging screen.

Table 7 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: <table> <tr> <td>0.25</td><td>0.5</td><td>0.75</td></tr> <tr> <td>1.0</td><td>1.5</td><td>2.0</td></tr> </table>	0.25	0.5	0.75	1.0	1.5	2.0
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: <table> <tr> <td>0.25</td><td>0.5</td><td>0.75</td></tr> <tr> <td>1.0</td><td>1.5</td><td>2.0</td></tr> </table>	0.25	0.5	0.75	1.0	1.5	2.0
0.25	0.5	0.75						
1.0	1.5	2.0						
	Jump	Advances to the next ECG marker						

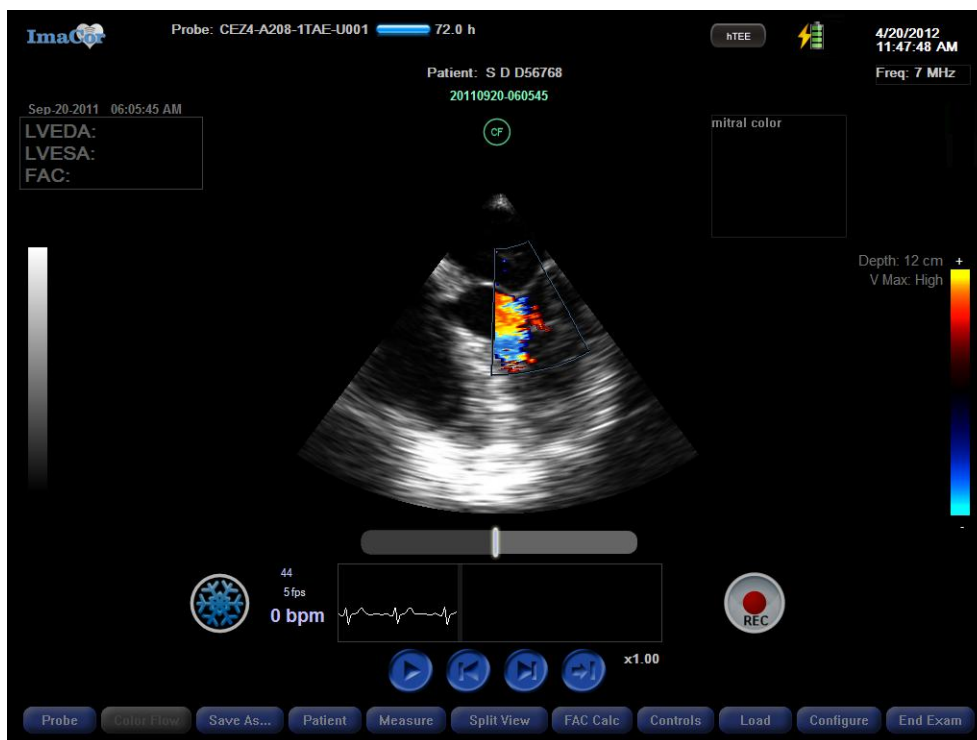


Fig. 53 Single View mode with cineloop control buttons

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 8 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.

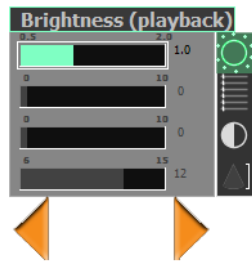


Fig. 54 Brightness control display

Depth Brightness Compensation (DBC)

Related Topic

"Time Gain Compensation (TGC)," page 46

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. 55 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.

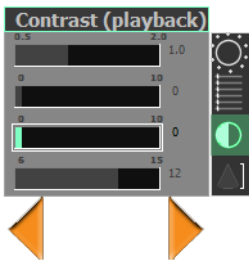


Fig. 56 Contrast control display

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.

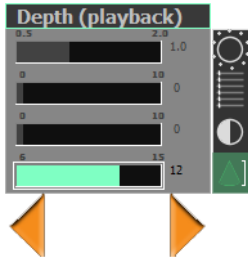


Fig. 57 Depth control display

Saving a Cineloop as a Movie

Related Topics

"Loading a Cineloop," page 57

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 57.
- 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 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 58). 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 58. 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.

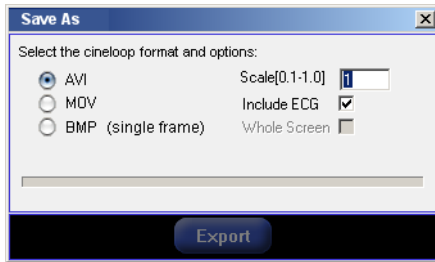


Fig. 58 Export movie format options

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 59.

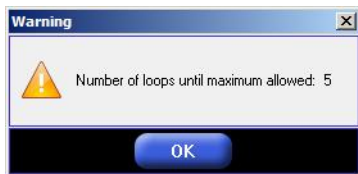


Fig. 59 Warning: cineloop limit approaching

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

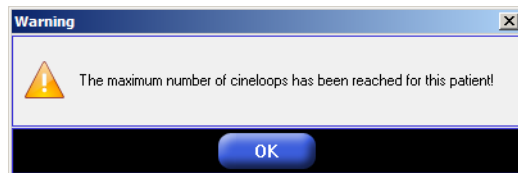


Fig. 60 Warning: cineloop limit reached

- 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.

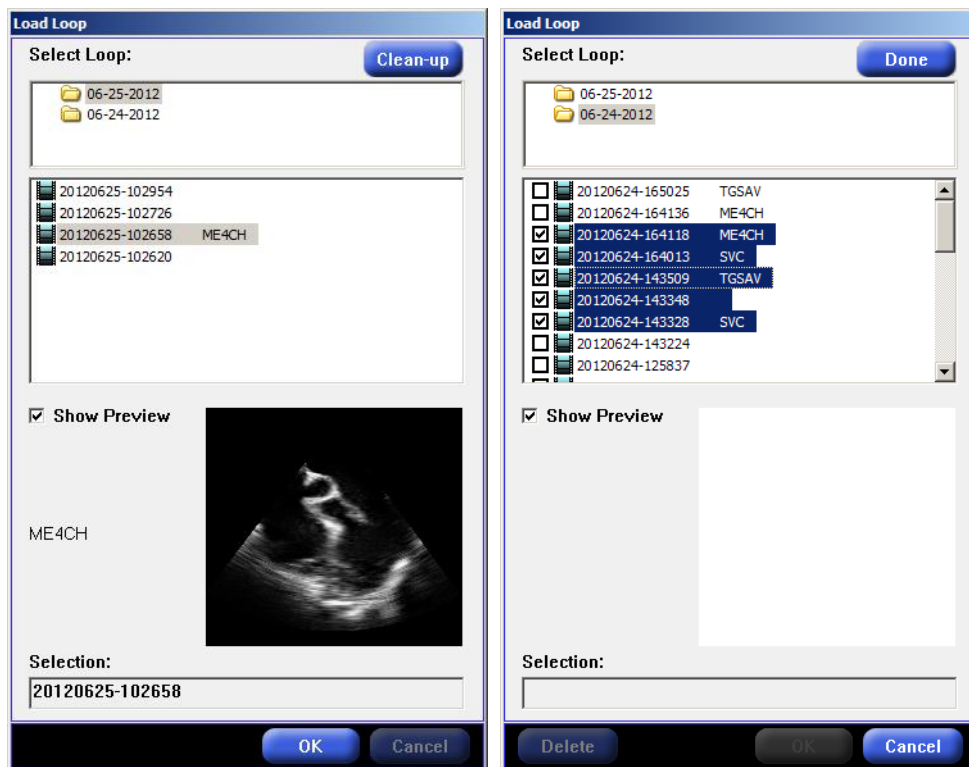


Fig. 61 Delete cineloop screen

- 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. 62 Delete cineloop confirmation

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

Measurement Tools

The ImaCor Zura-Evo 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.

When using the FAC Wizard to guide an FAC calculation, the tracing tool is automatically activated. In addition, the informational message “Trace: ON” is displayed on the screen. For information on the FAC Wizard, see page 72.

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.

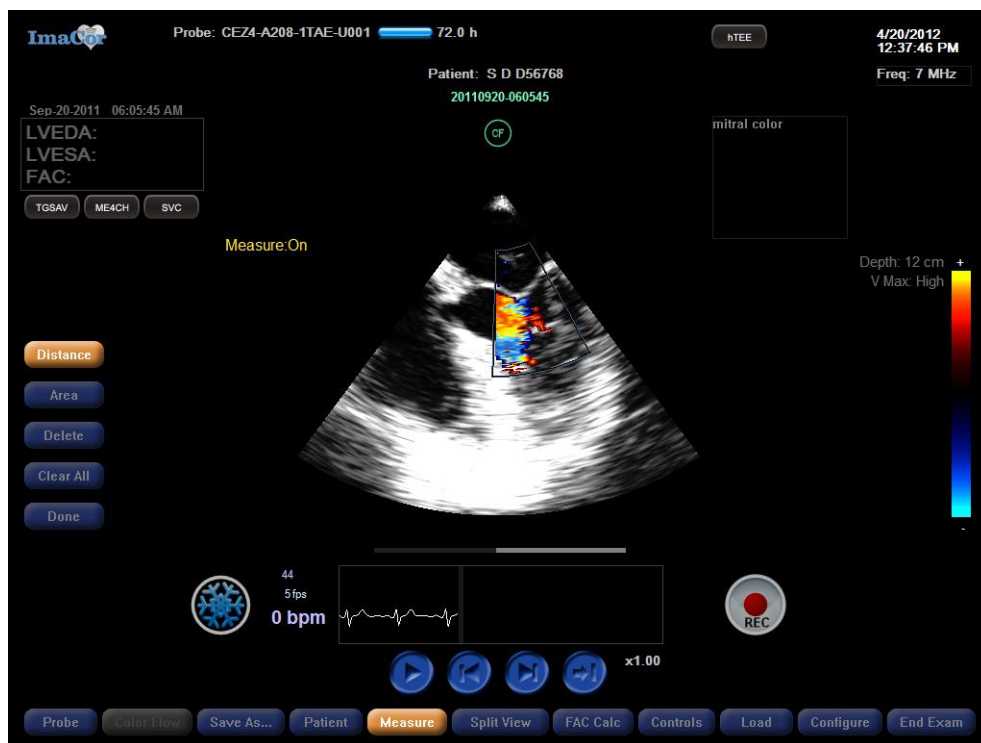


Fig. 63 Accessing the distance measuring mode with the onscreen Measure button

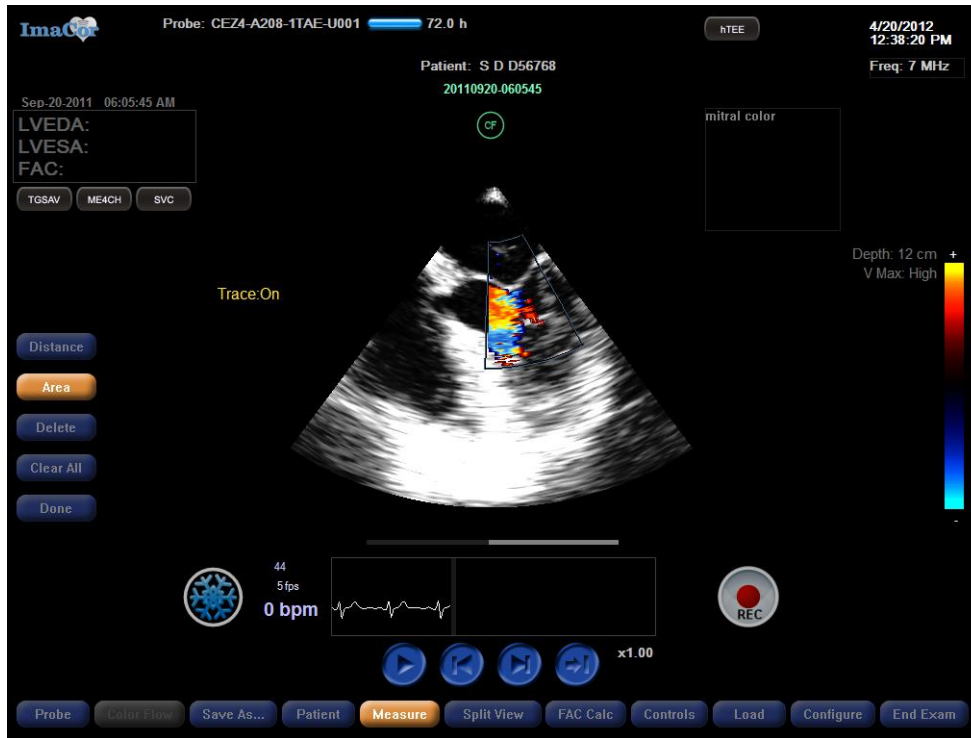


Fig. 64 Accessing the area measuring mode with the onscreen Measure button

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 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 87). 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 87).

Traces are automatically saved with the patient exam.

Updating an Existing Trace

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 65.



Zura-Evo 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 65.

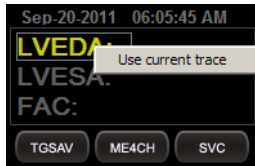


Fig. 65 Manually updating a trace value

The date and time the cineloop was acquired is also displayed above the hTEE measurement.

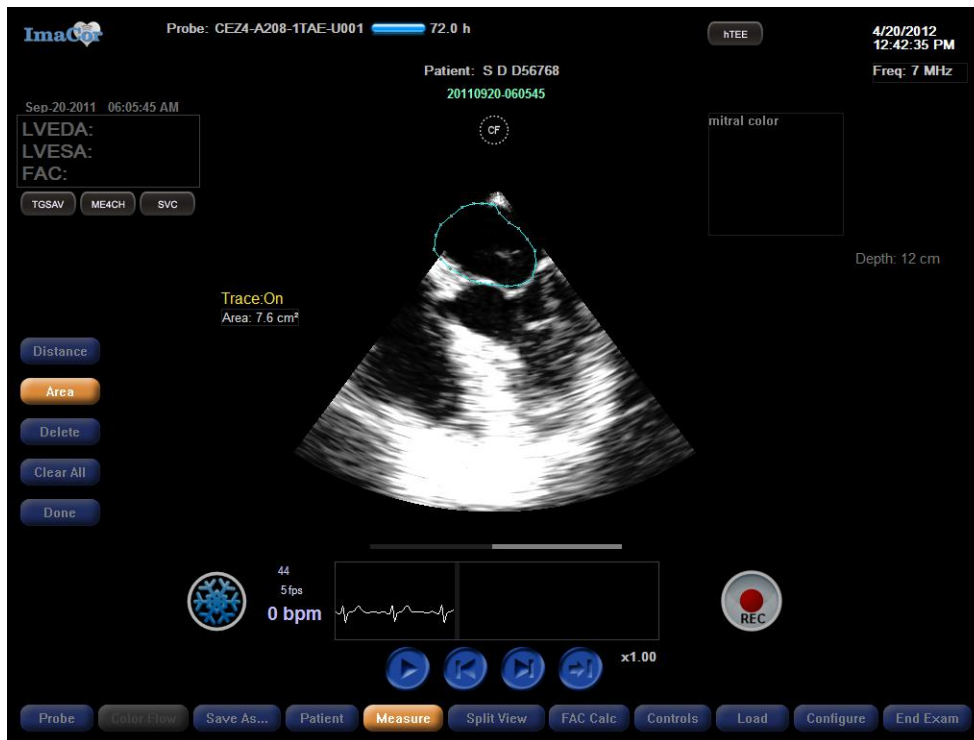


Fig. 66 Single View mode with Trace On

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.

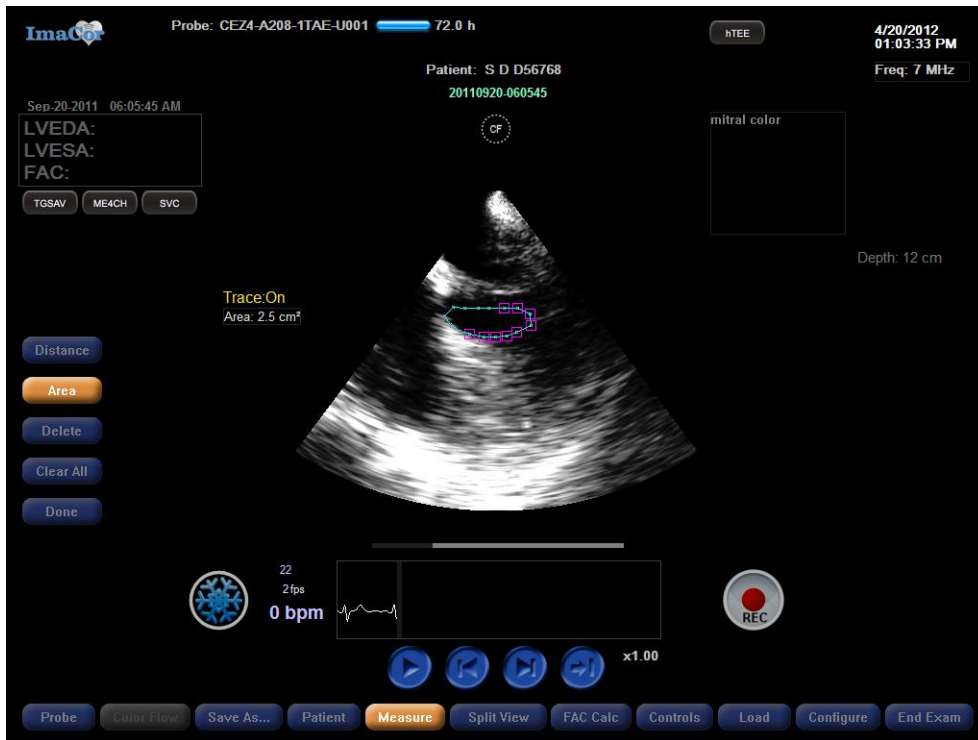


Fig. 67 Single View mode, editing multiple points

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.

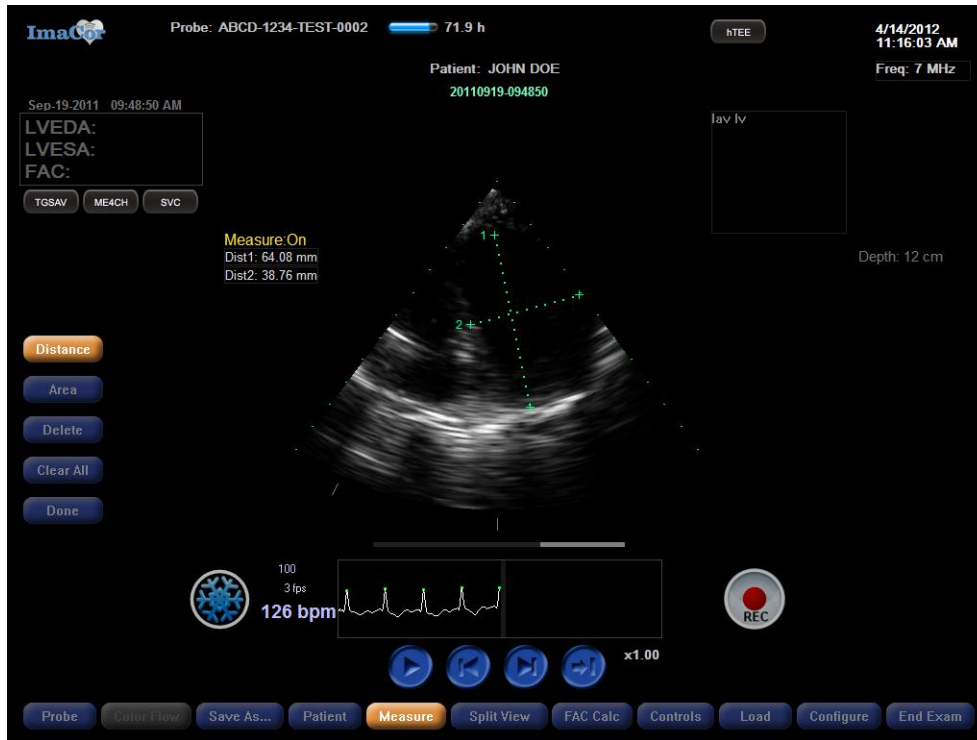


Fig. 68 Accessing the Measuring Tape tool with the onscreen Measure button.

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 70).

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 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 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.

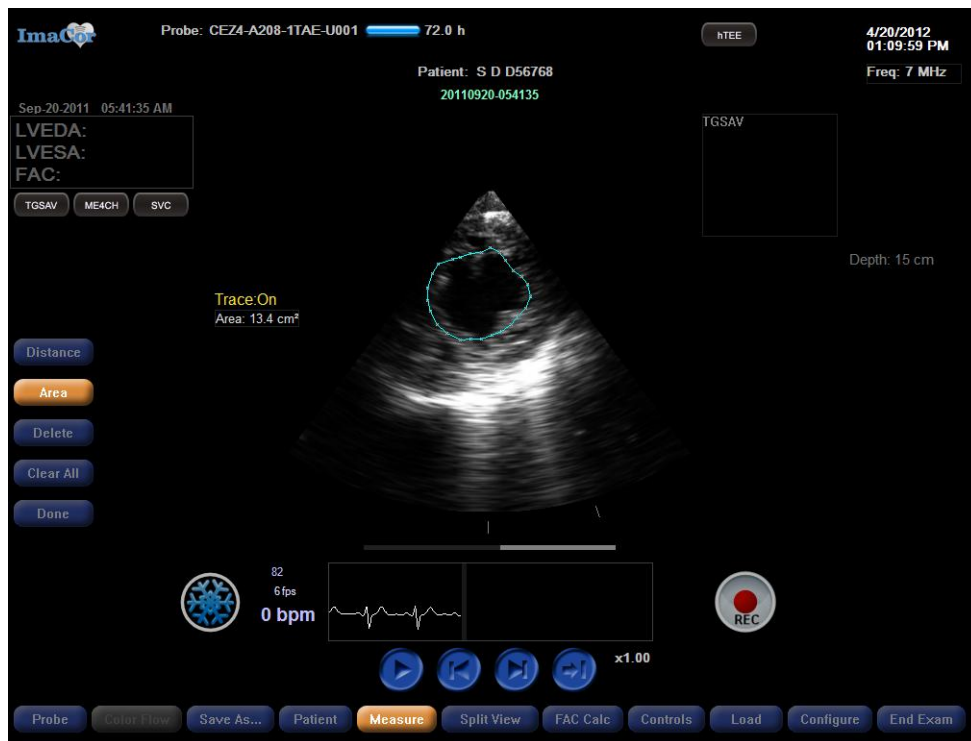


Fig. 69 Single View mode, taking area measurements (Trace: ON)

Editing a Measurement



Touch Screen

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



Zura-Evo 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 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.

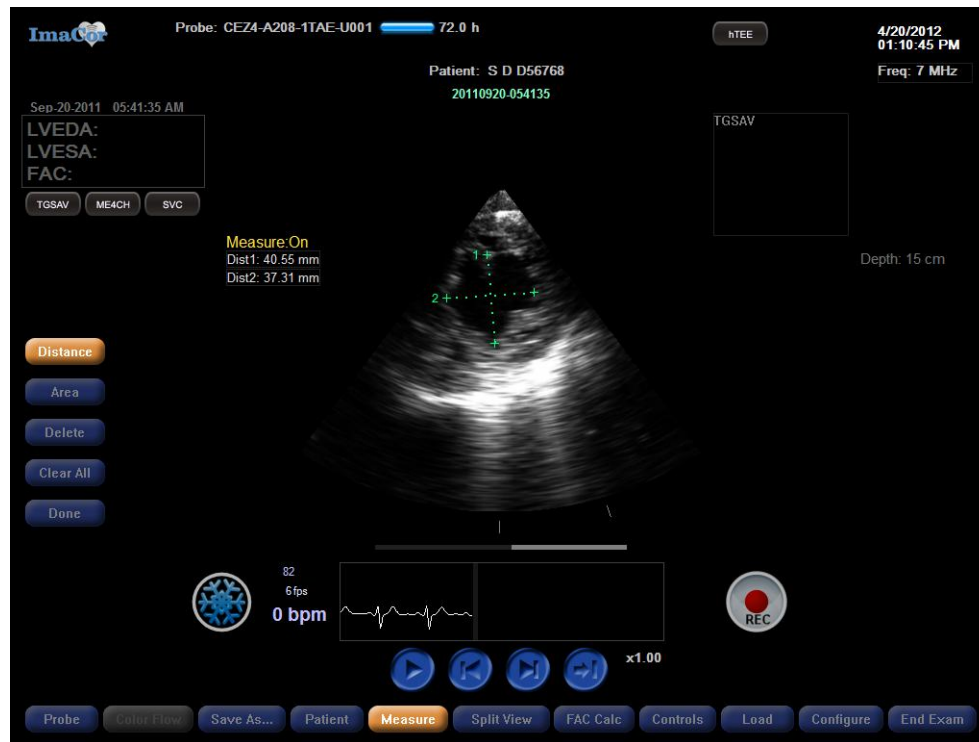


Fig. 70 Single View mode with distance measurements (Measure: ON)

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 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.

Zura-Evo Measurement Functions

Related Topic

"Loading a Cineloop," page 57

The Zura-Evo 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 51 on page 55).

The FAC Wizard

FAC calculations are based on measurements of the left ventricular end-diastolic area (LVEDA) and the left ventricular end-systolic area (LVESA). The FAC Wizard guides you through the process of completing an FAC calculation. The FAC Wizard is available only in Single View mode (see "Single View Mode," page 34).

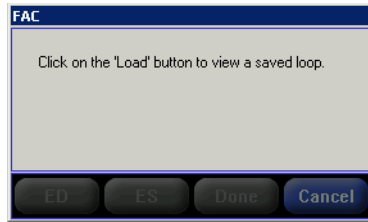
FAC data are saved with the loop and are displayed when the loop is previewed and loaded. Cineloop acquisition date and time are displayed under FAC measurements.

Using the FAC Wizard to complete a calculation is a six-step process.



Touch Screen

- 1 Tap the onscreen FAC Calc button. If you have not loaded a cineloop, a message instructing you to do so is displayed.



- 2 With a cineloop loaded, use the scroll bar to review the loop and select the end-diastolic frame.
- 3 Tap to set the first anchor point, then begin tracing. When you complete the trace, tap again to close the trace. The LVEDA value is displayed onscreen, as shown in Figure 73. For additional information on tracing, see “The Tracing Tool,” page 65.
- 4 Tap the ES button. Scroll or step through the frames and select an end-systolic frame.
- 5 Trace the LVESA.
- 6 When you have finished, tap the Done button. The LVEDA, LVESA, and FAC values are automatically calculated and displayed, as shown in Figure 74.



Zura-Evo Mouse

- 1 Click the onscreen FAC Calc button to begin. If you have not loaded a cineloop, a message instructing you to do so is displayed.

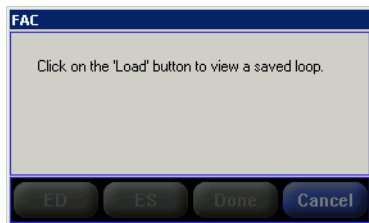


Fig. 71 Load cineloop instructional message

- 2 With a cineloop loaded, step or scroll through the loop and select the end-diastolic frame.
- 3 Follow the FAC Wizard onscreen instructions.

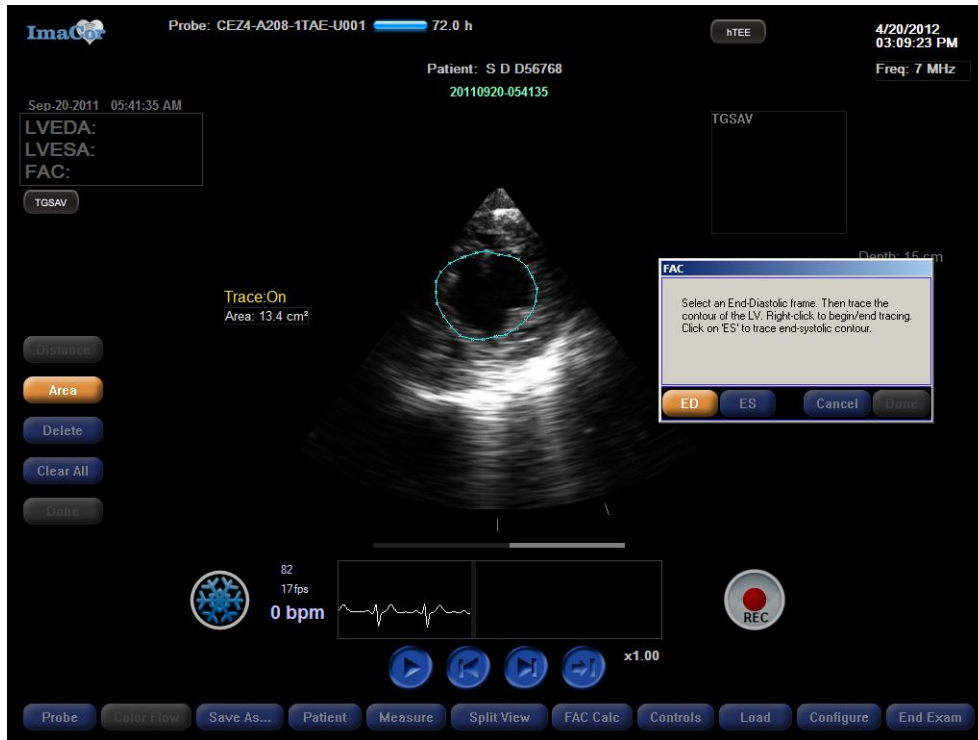


Fig. 72 FAC calculation in Single View mode – end diastolic identification and trace

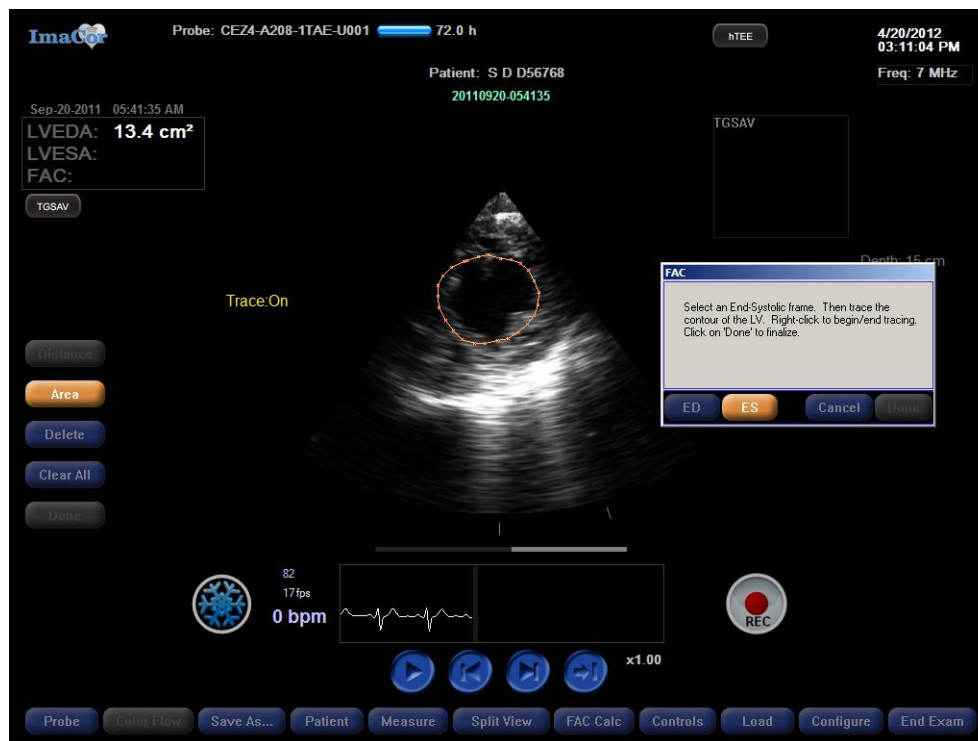


Fig. 73 FAC calculation in Single View mode – end systolic identification and trace

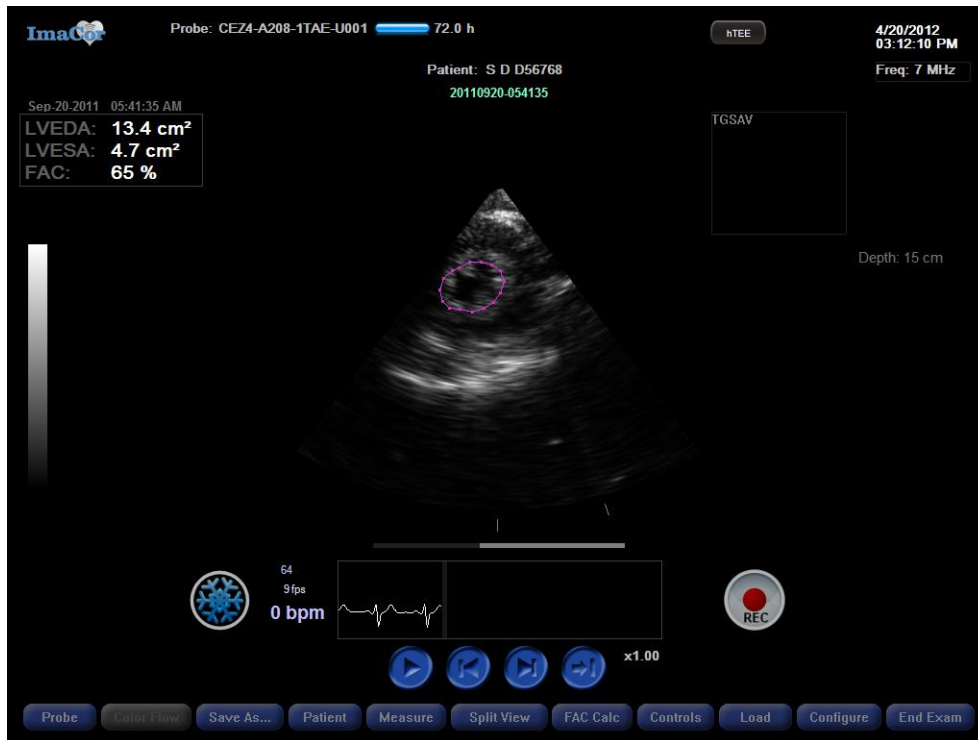


Fig. 74 Completed FAC calculation

Reviewing an FAC Trace

To review an existing FAC trace, click on the desired measurement (LVEDA or LVESA). The Zura-Evo system software automatically displays the traced frame and highlights the FAC trace value.

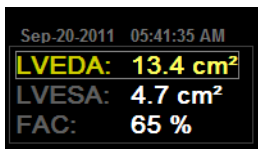


Fig. 75 FAC calculation results

FAC Trace Overlay Mode

FAC trace overlay mode allows you to display or hide the LVEDA and LVESA traces on cineloops.

Trace overlay mode can be turned **on** two ways:

1. Activate the FAC Wizard to automatically turn on trace overlay mode.
2. Left click the LVEDA or LVESA value.

FAC 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 76.
- 4 When the cineloops have been selected, tap or click the OK button.

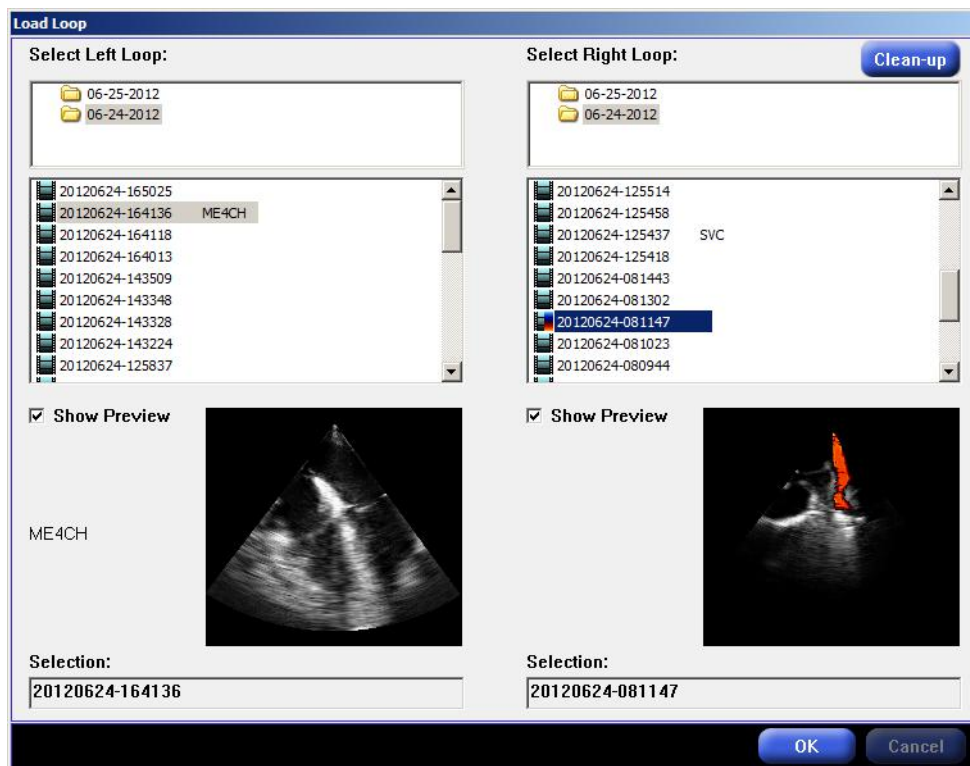


Fig. 76 Split View mode – loading two cineloops

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.

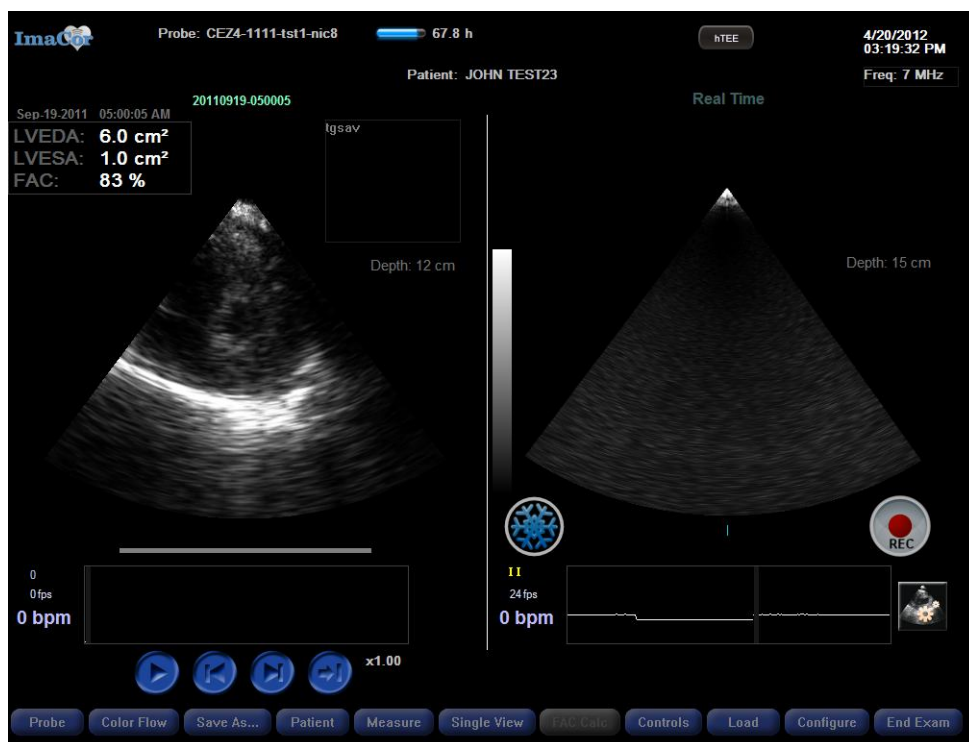


Fig. 77 Viewing a cineloop (left) and a real-time image (right) in Split View mode

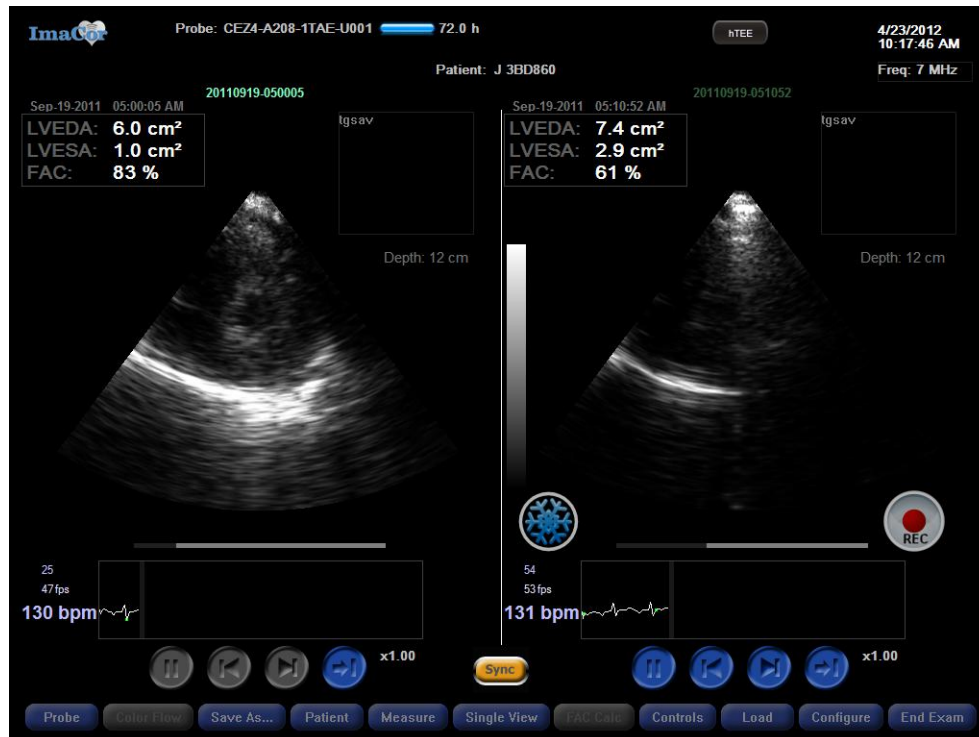


Fig. 78 Split View mode – cineloop comparison

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.

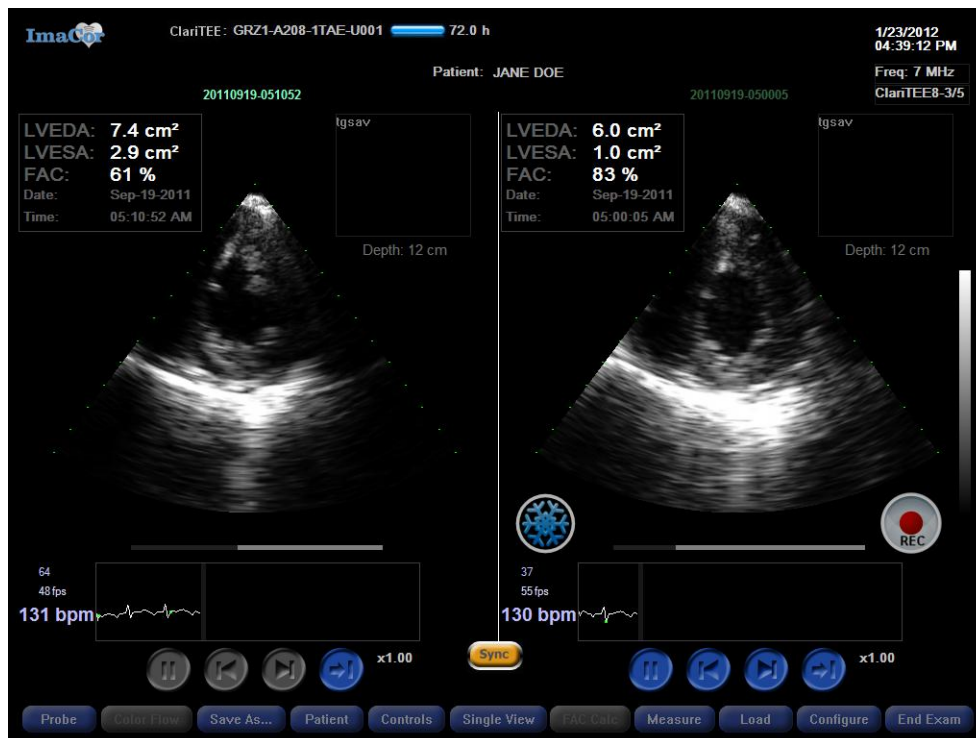


Fig. 79 Synchronized playback

Activating and Deactivating Synchronized Playback

The Sync button, shown in Figure 80, toggles synchronized playback on and off.



Fig. 80 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 81.

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

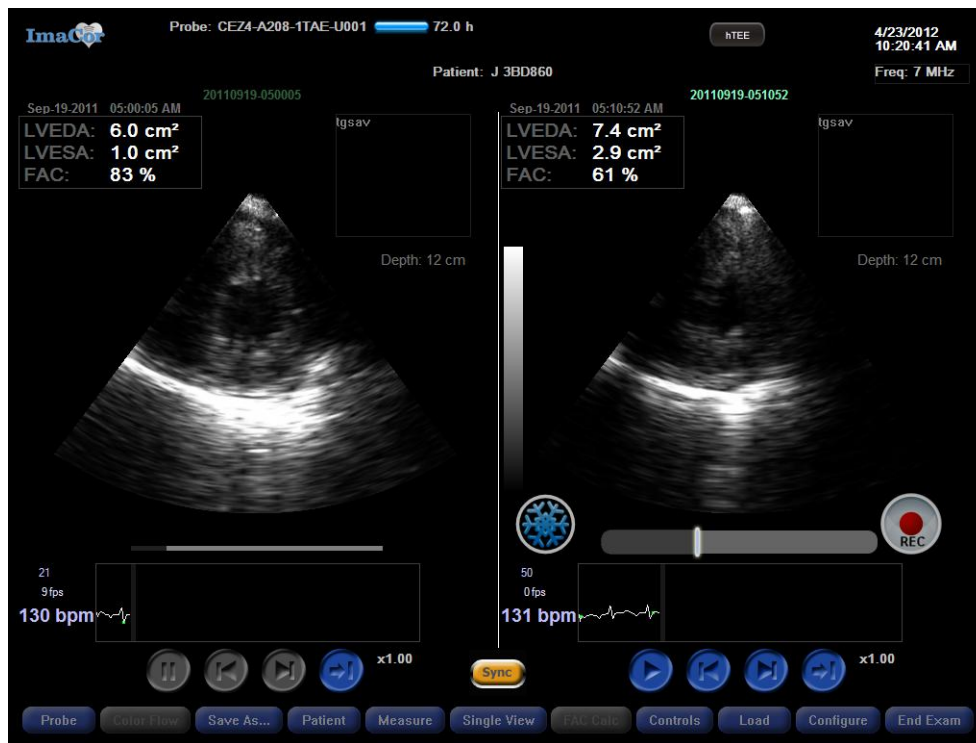


Fig. 81 Synchronized playback with scrolling enabled

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 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.

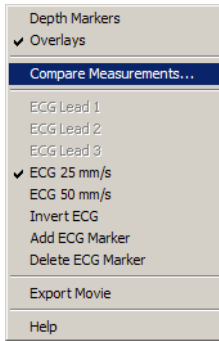


Fig. 82 Compare Measurements menu option

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.

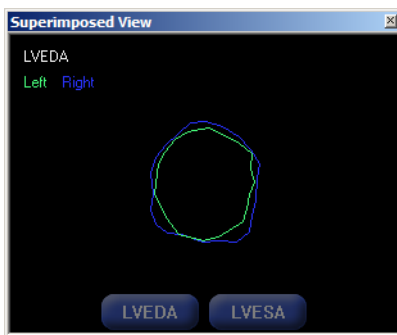


Fig. 83 Split View mode with Compare ED/ES selected

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 49.

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 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.

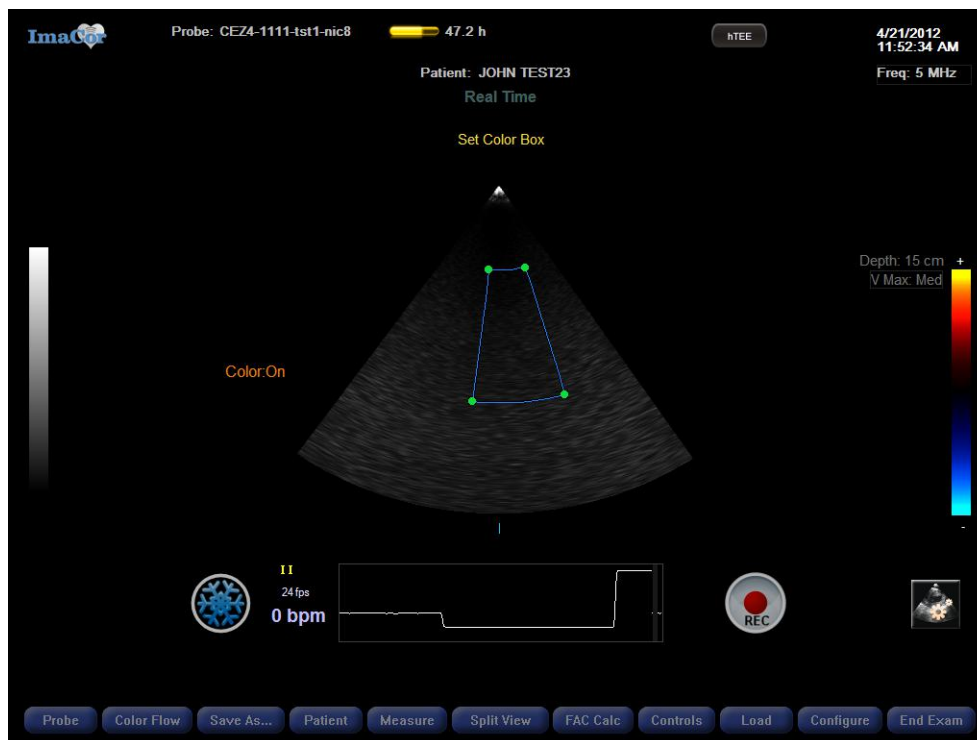


Fig. 85 Color Flow imaging with color box in edit mode

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.

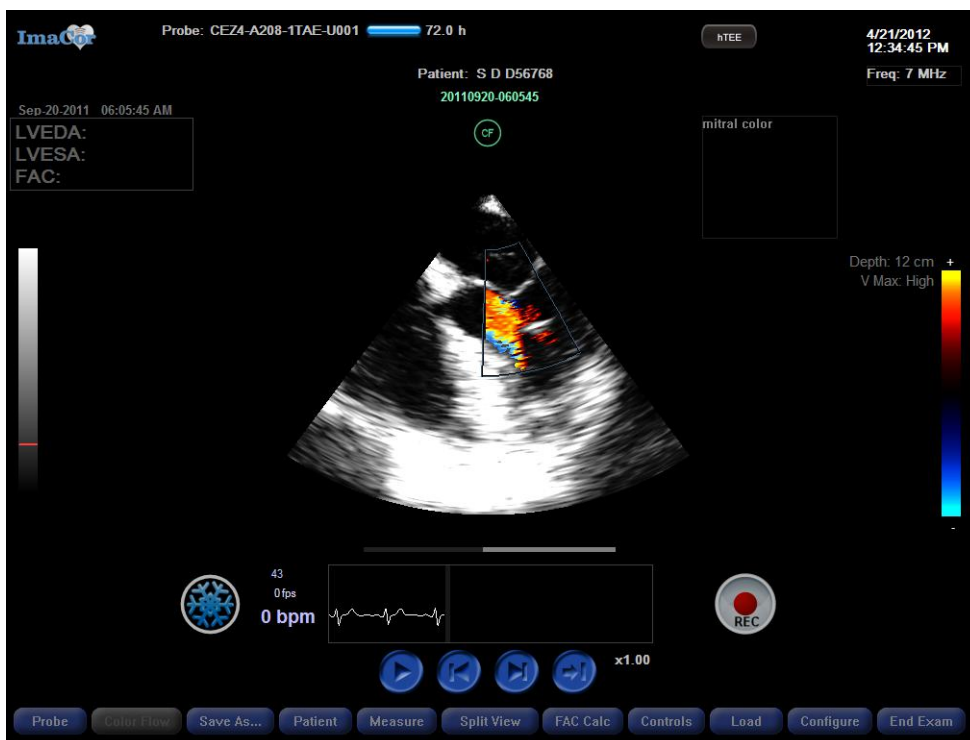


Fig. 86 Grayscale gradient bar showing priority setting

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 Mouse

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

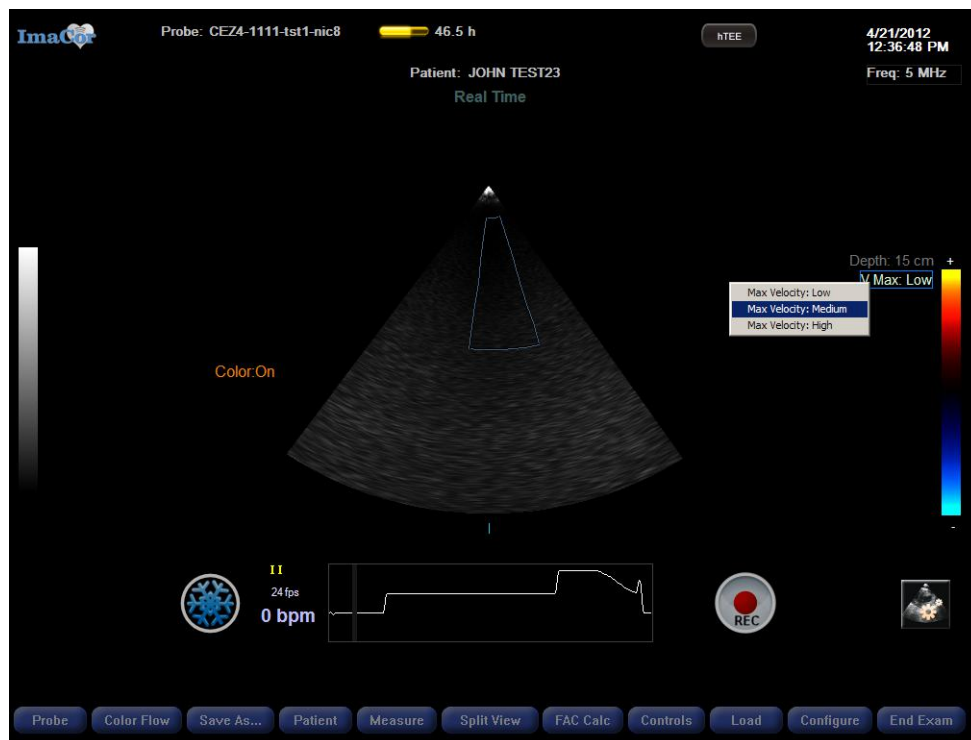


Fig. 87 Velocities menu with color box between 9 and 11 cm

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 Mouse

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

Color Maps

Five color maps are available.

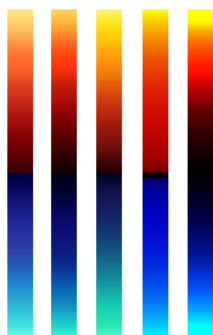


Fig. 88 Highlighted color map

Changing Color Maps



Touch Screen

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



Zura-Evo Mouse

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

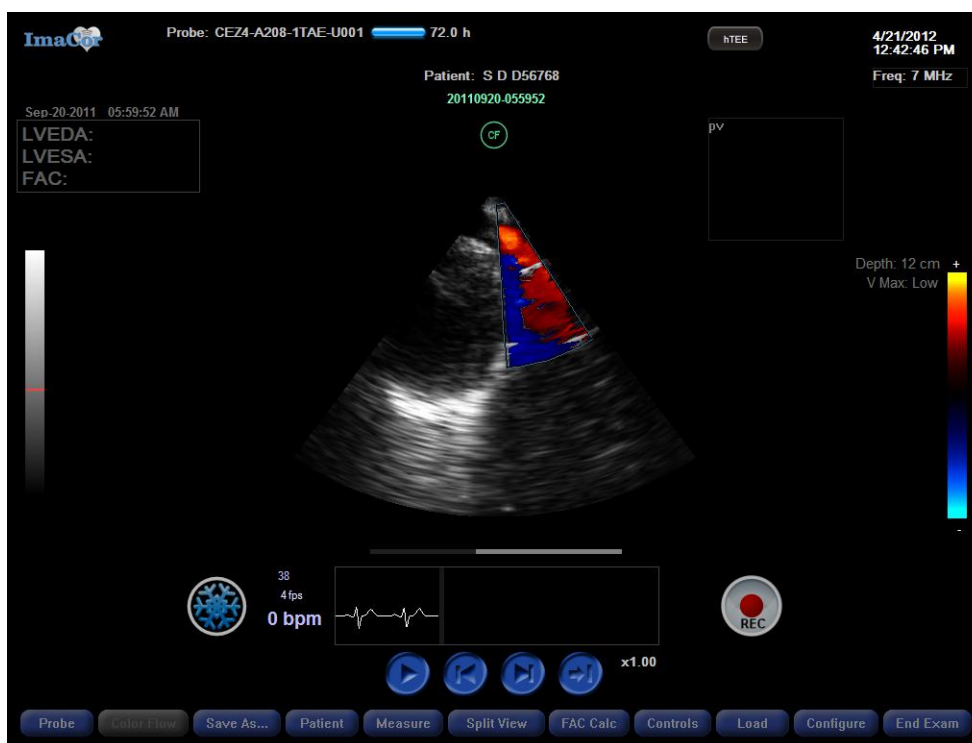


Fig. 89 CF images displayed, Color Flow

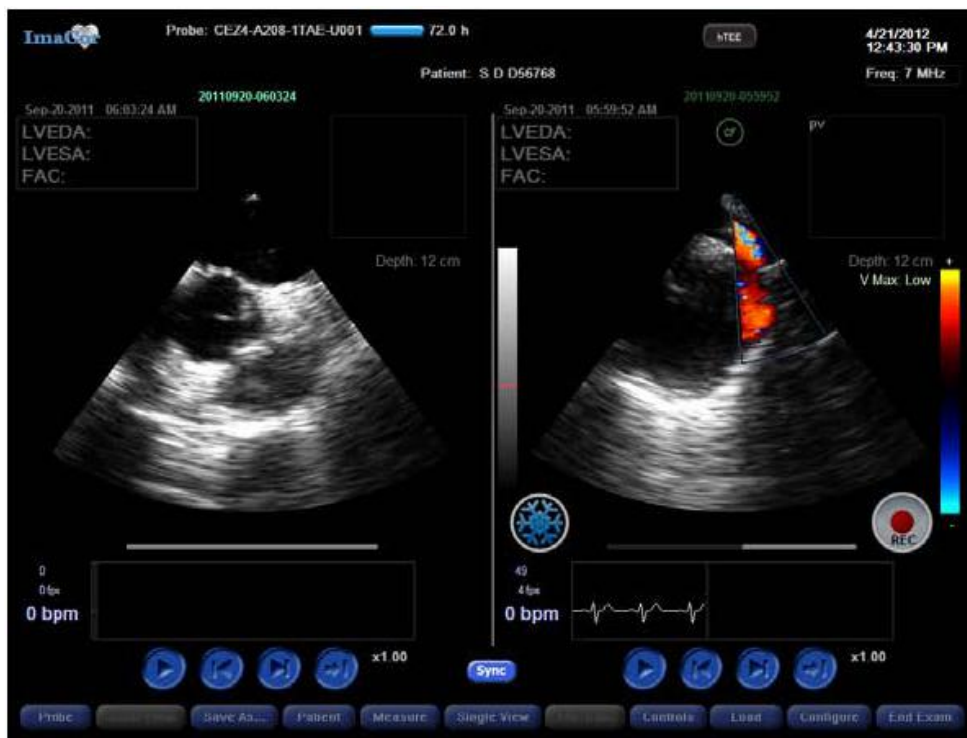


Fig. 90 CF playback in Split View mode

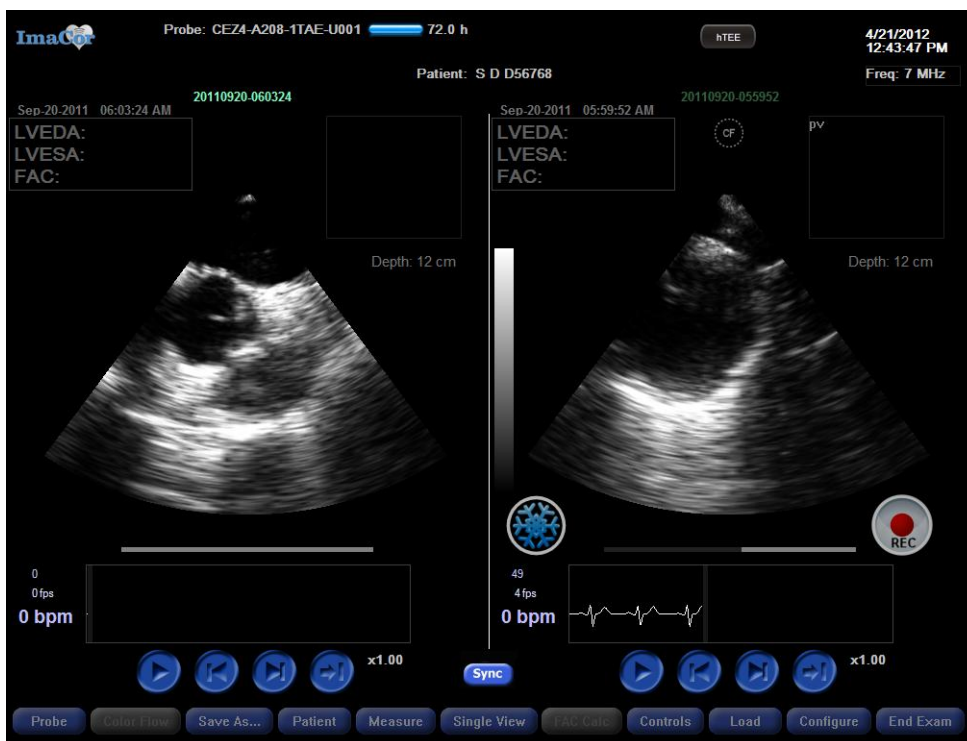


Fig. 91 CF playback in Split View mode with the righthand CF overlay turned off

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.

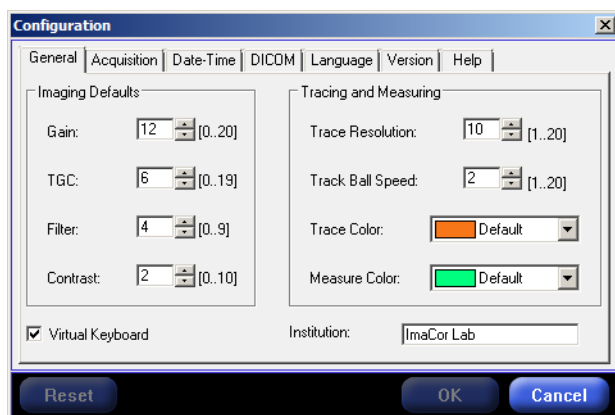


Fig. 92 Configuration > General tab

Imaging Defaults

After changing Imaging defaults, restart the system to apply the new settings.

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.

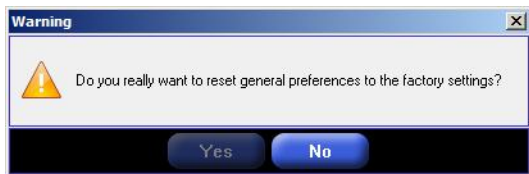


Fig. 93 Reset button confirmation screen

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.

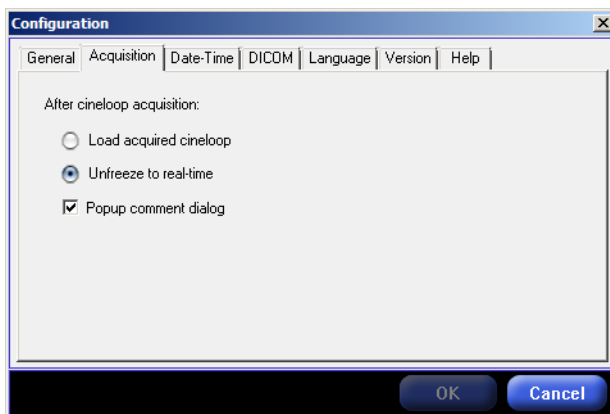


Fig. 94 Configuration >Acquisition tab

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.

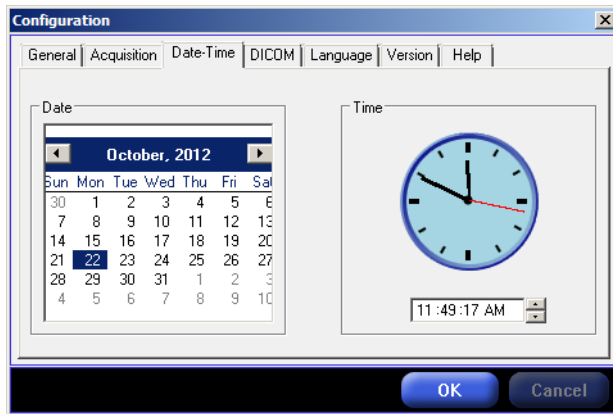


Fig. 95 Configuration > Date-Time tab

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)

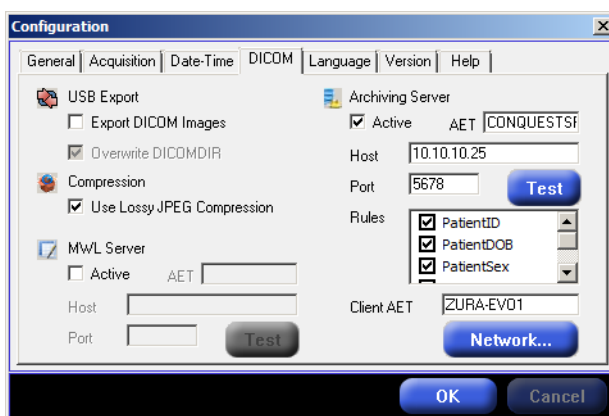


Fig. 96 Configuration > DICOM tab

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 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 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.

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 configured).

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.

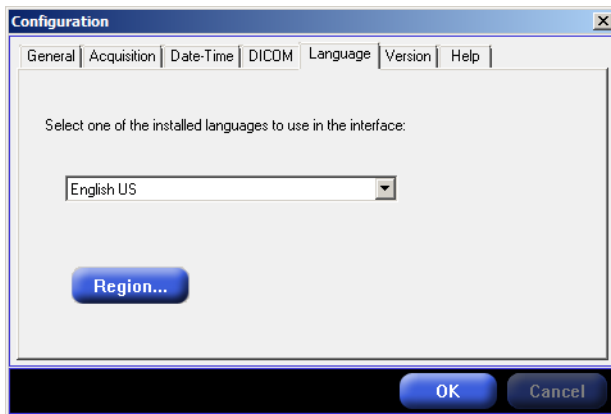


Fig. 97 Configuration > Language tab

Version

The Version tab enables you to check the version of the Zura-Evo software installed on the system.

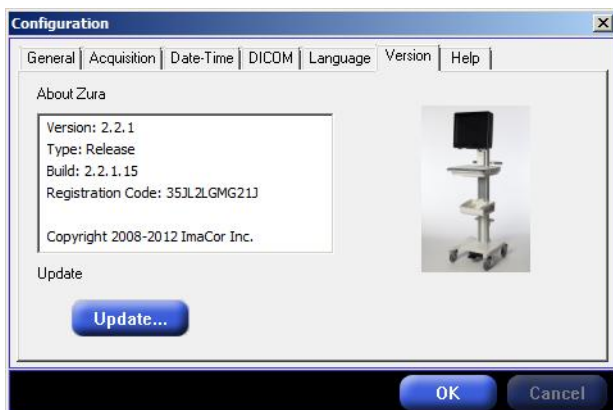


Fig. 98 Configuration > Version tab

Software Update

Upgrade packages are machine-specific and require a registration code that is displayed in the Configuration Dialog >Version tab (see Figure 98).

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 machine registration code, which can be found on the Version tab of the Zura-Evo 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 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 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 system provides three other user assistance options:

1. ToolTips
2. Remote Assistance
3. Analysis Package

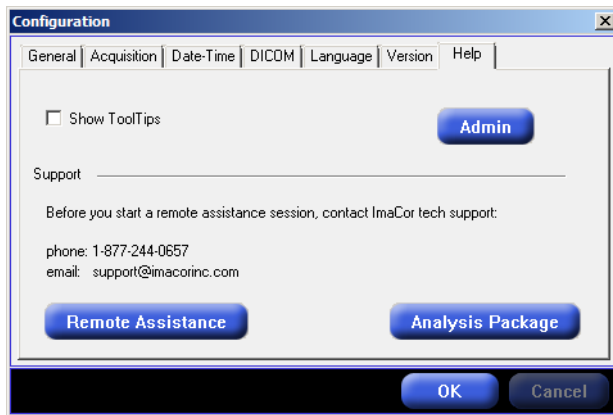


Fig. 99 Configuration > Help tab

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 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 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 100 is displayed.

- In the case of insufficient free space on the USB drive, you may:
 - Remove the drive from the Zura-Evo system.
 - Insert the drive in any personal computer with a USB port.
 - Delete unnecessary files. Files may not be deleted from the Zura-Evo 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 system.
 - Retry the operation.

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

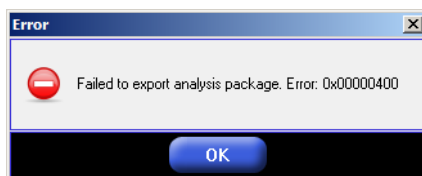


Fig. 100 Analysis package export error

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 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 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 Achiev-

able.” 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 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 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 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 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

The Zura-Evo system complies with the following safety standards.

IEC 60601-1 (1988) Medical Electrical Equipment – Part 1: General Requirements for Safety.

IEC 60601-2-37 (2001) 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 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 ClariTEE probe has 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 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 9 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

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

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

³MI 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 10 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 ($I_{pa,3@MI_{max}}$).

Table 10 Acoustic Output Parameters

Transducer Model	$I_{SPTA,3}$ (mW/cm ²)	TI Type	TI Value	MI	$I_{pa,3@MI_{max}}$ (W/cm ²)
ClariTEE – B–6 MHz	162	Tissue	0.59	0.92	159
ClariTEE– B–7 MHz	56	Tissue	0.56	0.57	98
ClariTEE– Color Flow	63	Tissue	0.45	0.35	13

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.

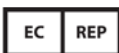
These risks are mitigated by trained echocardiographers, able to discern whether an image is technically limited or clinically useful and whether quantitative assessments, such as FAC calculations, are consistent with the images. This translates into a confidence level the physician has when making a 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 11 Labeling Symbols and Descriptions

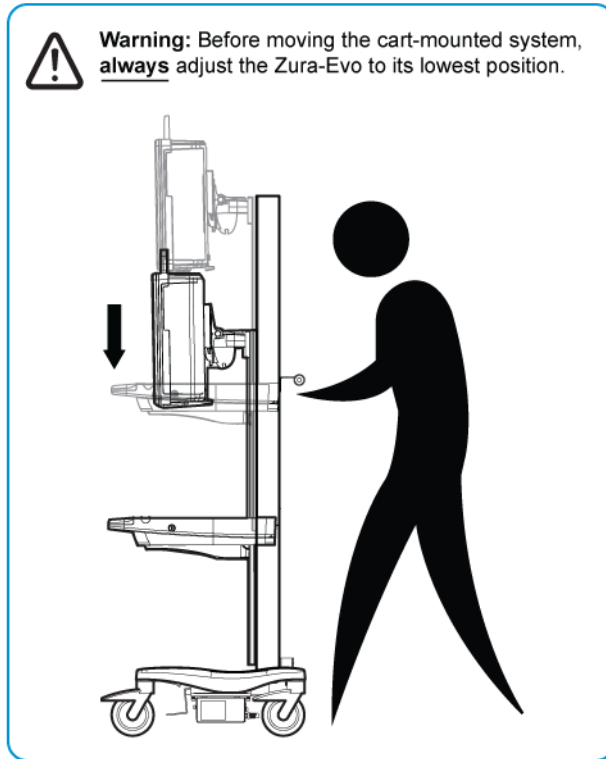
	Alternating current
	Protective earth (ground)
	Attention, consult ACCOMPANYING DOCUMENTS
	Off (power: disconnection from the mains)
	On (power: connection to the mains)

Table 11 Labeling Symbols and Descriptions (Continued)

	"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

Transporting the Zura-Evo

The Zura-Evo is mounted on a cart 64.5 inches in height (see Figure 2). The vertical position of the Zura-Evo on the cart is adjustable.



ImaCor Approved Device

The ImaCor Zura-Evo 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 system.

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@imacoric.com

Caution

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

Table 12 Troubleshooting Matrix *see also the Master Message listing on page 106.*

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 System Cleaning Recommendations

ImaCor recommends the following cleaning instructions for the Zura-Evo 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:
 - Steriplex SD 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.

Other Recommended Maintenance

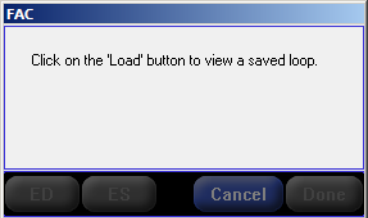
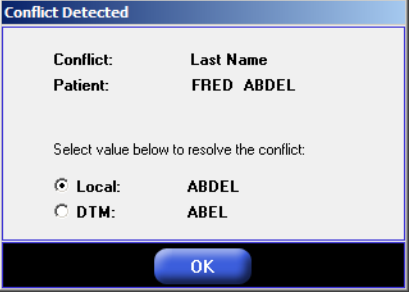
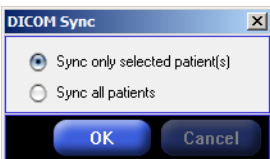
POWER SUPPLY CORD

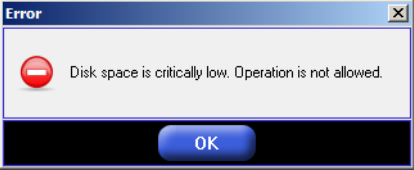
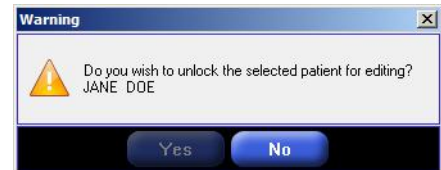
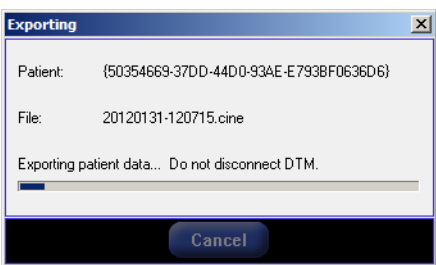
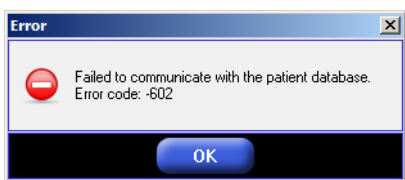
Regularly inspect the AC power cord and plug for damage.

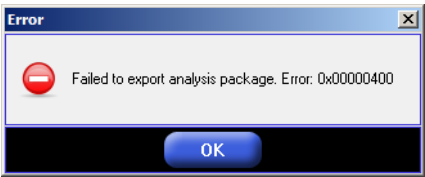
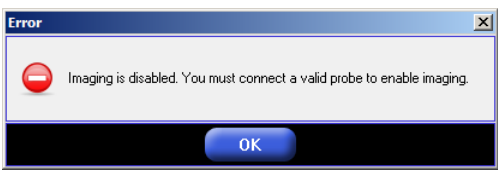
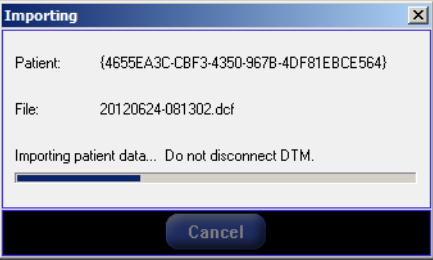
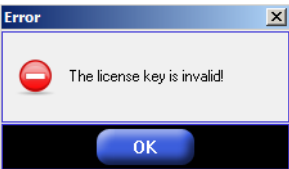
HANDLE AND UMBILICAL

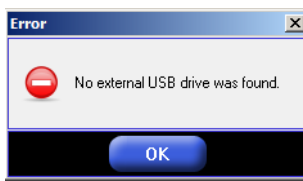
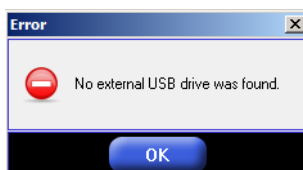
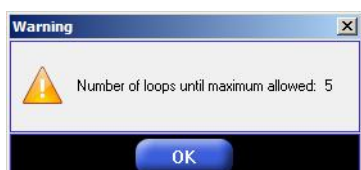
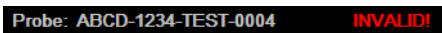
Regularly inspect the handle and umbilical for damage.

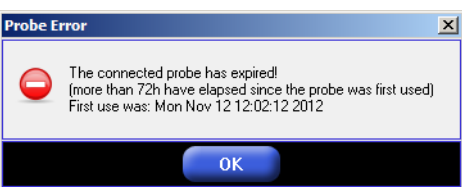
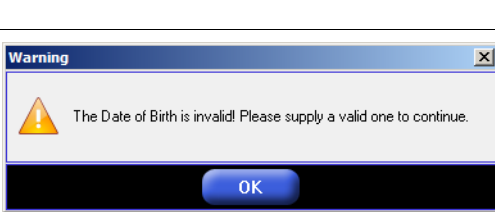
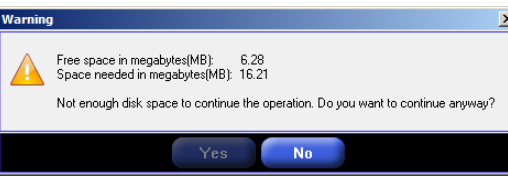
Master Message Listing - Alphabetical

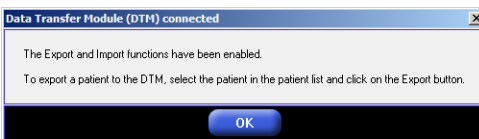
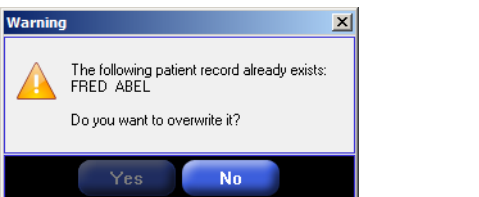
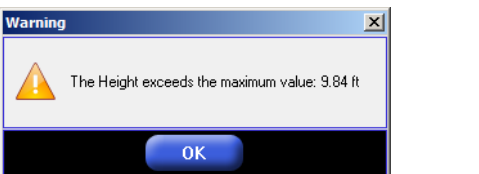
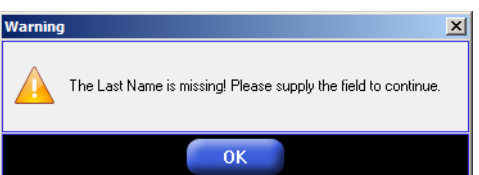
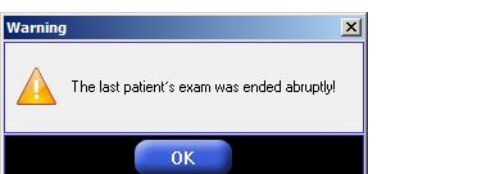
	Problem	Solution
	Informational. Zura-Evo system was able to ping archiving server.	
	Informational. When in the FAC environment, instructs you to press the Load button to view a saved cineloop.	
		Restart the system. If the problem persists, contact ImaCor technical support.
	While importing or exporting patient data, the system has detected an inconsistency between the local data (that saved on the ImaCor Zura-Evo 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 Ultrasound Machine.
	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 data-base server	Click the OK button and restart the system. If the error persists, contact technical support.
	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.

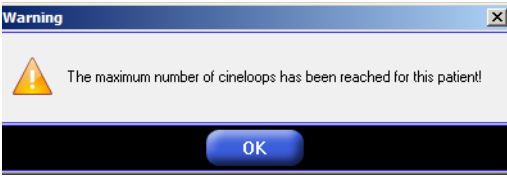
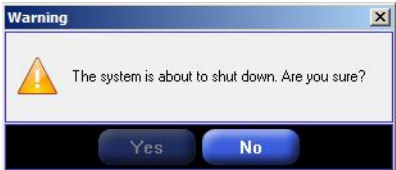
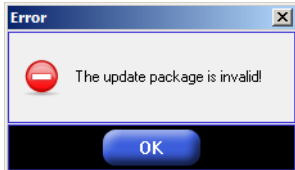
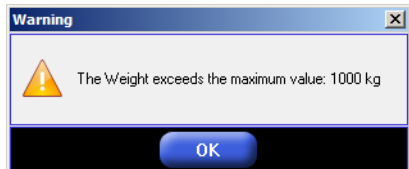
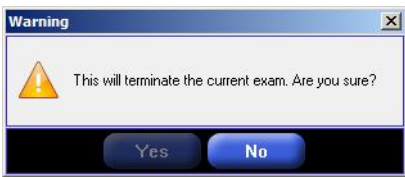
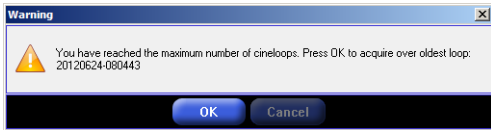
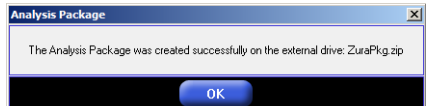
	Problem	Solution
 A warning dialog box titled "Warning" with a yellow triangle icon. The text inside says "Disk free space is low." and there is an "OK" button at the bottom.	Disk space for storing patient data is limited.	Delete patients or cineloops.
 An error dialog box titled "Error" with a red circle icon. The text inside says "Disk space is critically low. Operation is not allowed." and there is an "OK" button at the bottom.	Disk space for storing patient data is VERY low and the current operation cannot be completed	Delete patients or cineloops.
 A warning dialog box titled "Warning" with a yellow triangle icon. The text inside says "Do you wish to unlock the selected patient for editing? JANE DOE" and there are "Yes" and "No" buttons at the bottom.	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 wish to unlock the patient record, choose No.s
 An "Exporting" dialog box showing patient information and a progress bar. The text includes "Patient: (50354669-37DD-44D0-93AE-E793BF0636D6)", "File: 20120131-120715.cine", and "Exporting patient data... Do not disconnect DTM." with a "Cancel" button at the bottom.	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.	
 A "Server Test" dialog box with a yellow triangle icon. The text inside says "Failed to communicate with Archiving server." and there is an "OK" button at the bottom.	The Zura-Evo system failed to ping the archiving server.	Verify that the server is online and that the Zura-Evo system is configured to communicate with the server (AET, Host, port). Also, verify that the server allows communications from the Zura-Evo AE.
 A "Server Test" dialog box with a yellow triangle icon. The text inside says "Failed to communicate with M/WL server." and there is an "OK" button at the bottom.	The Zura-Evo system failed to ping the MWL server.	Verify that the server is online and that the Zura-Evo system is configured to communicate with the server (AET, Host, port). Also, verify that the server allows communications from the Zura-Evo AE.
 An error dialog box titled "Error" with a red circle icon. The text inside says "Failed to communicate with the patient database. Error code: -602" and there is an "OK" button at the bottom.	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.

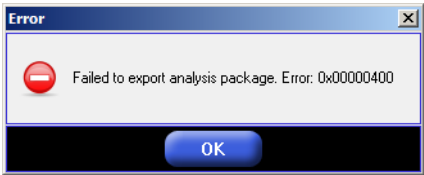
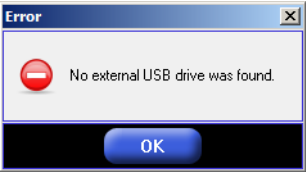
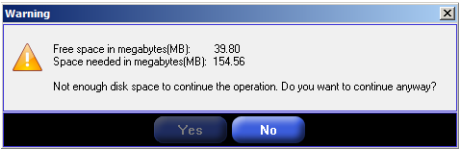
	Problem	Solution
	An analysis package was requested, but it cannot be saved to the USB drive. - There is insufficient space on the USB drive to write the analysis package. - The USB drive was removed before the analysis package was completely written. Note: the error code shown may vary and is intended 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 system. - Insert the drive in any personal computer with a USB port. - Delete unnecessary files. Files may not be deleted from the Zura-Evo 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 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.	- End the exam. - Connect a valid probe, or– - 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 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 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 63.
	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 of the imaging preparation screen. Most often, the selected patient is correct, but the wrong probe is connected to the system.

	Problem	Solution
 Probe communication error Reattach probe to enable imaging. If a probe is attached: - Try detaching and reattaching - Check for bent pins on the probe's connector - Clean handle connector pads OK	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
 Probe Error The connected probe has expired! (more than 72h have elapsed since the probe was first used) First use was: Mon Nov 12 12:02:12 2012 OK	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 system can be used to review the patient's recorded cineloops, but not acquire new images.
 Probe mismatch The connected probe does not match the selected patient. OK	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.
 Warning The Date of Birth is invalid! Please supply a valid one to continue. OK	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. 1. Move the cursor to the last name field 2. Enter the patient's last name.
 Warning Free space in megabytes(MB): 6.28 Space needed in megabytes(MB): 16.21 Not enough disk space to continue the operation. Do you want to continue anyway? Yes No	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 shut-down 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 63.
	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.
	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.
	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 63.
	Informational only	

	Problem	Solution
	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.

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 cm², representing 1% of typical LV end diastolic area (10 cm²), 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 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 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 system and 15 measurements for the control group; 5 for each predicate device.

Table 13 Accuracy of Distance Measurements and Area Calculations

Transducer	Height (cm) (measured)	Width (cm) (measured)	Area (cm ²) calculated	Comments
ImaCor Zura-Evo mean	4.02	4.39	13.83	5 measurements and area calculations
ImaCor Zura-Evo 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 accuracy	0.5%*	1.3%*	2.1%*,**	

Table 13 Accuracy of Distance Measurements and Area Calculations

Transducer	Height (cm) (measured)	Width (cm) (measured)	Area (cm²) 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.				

Specifications

Table 14 ImaCor System Specifications

Item	Specification
System dimensions	Content
Display dimensions	19-inch Touch LCD display
Transducers	Phased array
Imaging mode	Type B mode imaging Color Flow mode imaging
Application	TEE imaging. The system is optimized for the transgastric short axis view of the left ventricle
Measurement	Distance and area measurement capability. See "Measurements (Area and Distance)," page 114
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 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
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
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
USB	Universal serial bus
ZIF	Zero insertion force