ImaCor Zura™
IMAGING SYSTEM

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New in Zura 1.5.0

Imaging Depth: 15 cm

Imaging depth has been increased from 12 cm to 15 cm. Images are life-size from 6 to 12 cm and then scaled down from 13 to 15 cm.

Depth Markers Persistence

Depth markers setting is persistent across exams and system reboots.

Encryption of DTM Data

Patient Data exported to an ImaCor Data Transfer Module (DTM) is encrypted.
An ImaCor Decryption Application is required to import DICOM files from a DTM.

ClariTEE Plug n Play

ClariTEE probe is detected and validated on the fly in the Imaging Screen. This allows for disconnect/reconnect without having to leave the Imaging Screen to validate the probe.

Communication with DICOM Servers

The Zura system can be configured to communicate with a DICOM Archiving Server and a DICOM Modality Worklist (MWL) Server.
See Zura DICOM Conformance Statement for a detailed description of the supported SOPs.

Chapter 1: Introduction

This user guide covers the set-up and operation of the ImaCor Zura system, which is intended for use only by qualified clinicians. It does not provide instruction in sonography, cardiology, or other clinical practices.

Please carefully read this guide before using the ImaCor Zura™ imaging system. Pay special attention to the information contained the Safety section, beginning on page 74, as well as text marked with the ⚠ **Caution** symbol.

This user guide covers the set-up and operation of the ImaCor Zura system, which is intended for use only by qualified clinicians. It does not provide instruction in sonography, cardiology, or other clinical practices.

User Guide Conventions

Icons

⚠ **Caution:** 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 system

Text Conventions

NUMBERED STEPS

Numbered steps are formatted as shown below. The steps **must be performed** in the order listed.
Example–
There are three steps in the process:
1 Step one
2 Step two
3 Step three

ENUMERATED LISTS

Enumerated lists are formatted as shown below. In this case, the numbers indicate quantity, not order.
Example–
The dropdown menu lists three options:
1. Option one
2. Option two
3. Option three

BULLETED LISTS

Bulleted lists are formatted as shown below. They represent a group of associated items, but do not imply quantity or order.
Example–
System features include:
- Feature
- Feature
- Feature

TERMS

Button: An onscreen software control
Key: A key found on the ECG console keyboard
Knob: A knob found on the ECG console keyboard

Special Terms and Acronyms

A glossary of terms appearing in this guide begins on page 94.
A list of acronyms and definitions begins on page 94.

Chapter 2: The ImaCor Zura Imaging System

Overview

- The ImaCor miniaturized TEE probe (ClariTEE™) 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 single-use probe 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 system is contraindicated as follows:

- It is not for pediatric use (patients less than 18 years of age).
- It is not for use on patients with stomach or esophageal varices.
- It is not for use on patients having recent stomach or esophageal surgery.
- It is not for use on patients having obstructive esophageal pathology.

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 system addresses in the critical care setting the need for a miniaturized transesophageal echocardiography (TEE) probe in assessing important cardiac parameters that influence hemodynamics. The new ultrasound probe (ImaCor ClariTEE™) provides direct visualization of cardiac size and function, allowing intensive care clinicians to conduct episodic assessments of cardiac preload and left ventricular ("LV") systolic function 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 left ventricle 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 system is not a continuous monitoring system.

The ImaCor Zura system is not a continuous monitoring device. It is intended to be used 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 dura-

tion 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	Six 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

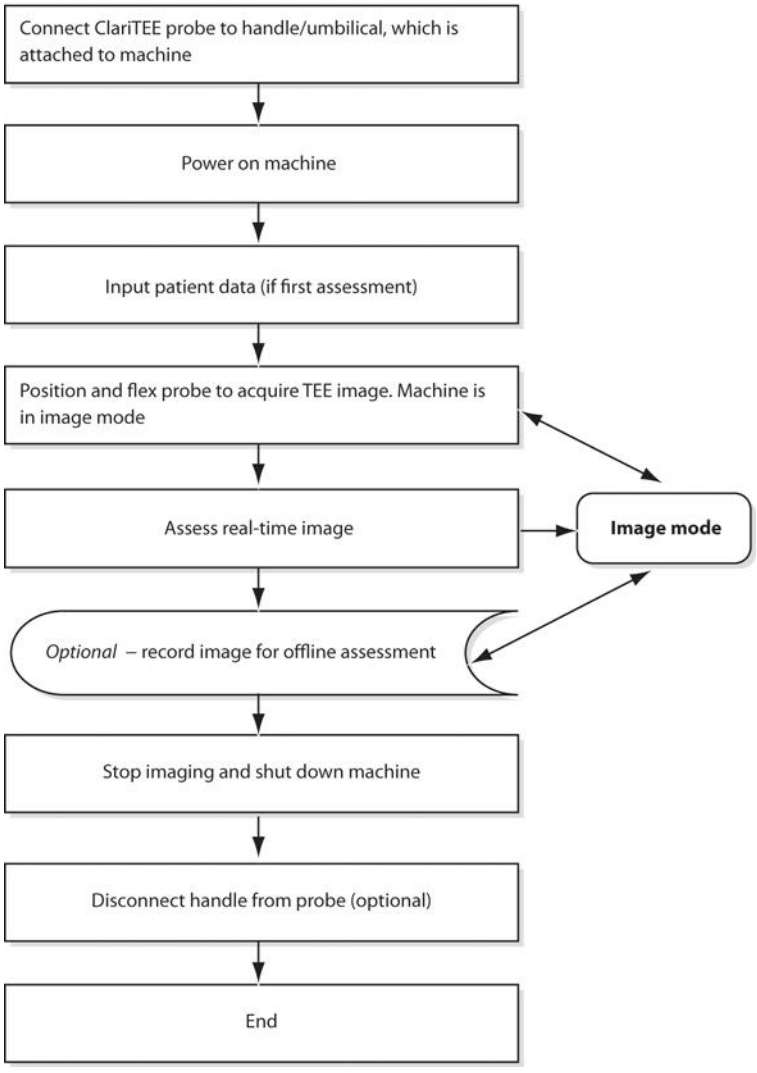


Fig. 1 Episodic assessment process flow

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 system should be in imaging mode only when an episodic assessment is being conducted.

Safety Feature
ImaCor ultrasound imaging software includes a software interlock that limits imaging time to 20 minutes per episodic assessment.

Cumulative imaging time is the total time over the course of probe dwell duration that the Zura 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. Also, only in imaging mode is the ClariTEE probe mechanically flexed to obtain the tissue contact required to capture an image.

ImaCor has included a software interlock that limits imaging time to 20 minutes per episodic assessment.

About the System

The ImaCor Zura system consists of four main components:

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

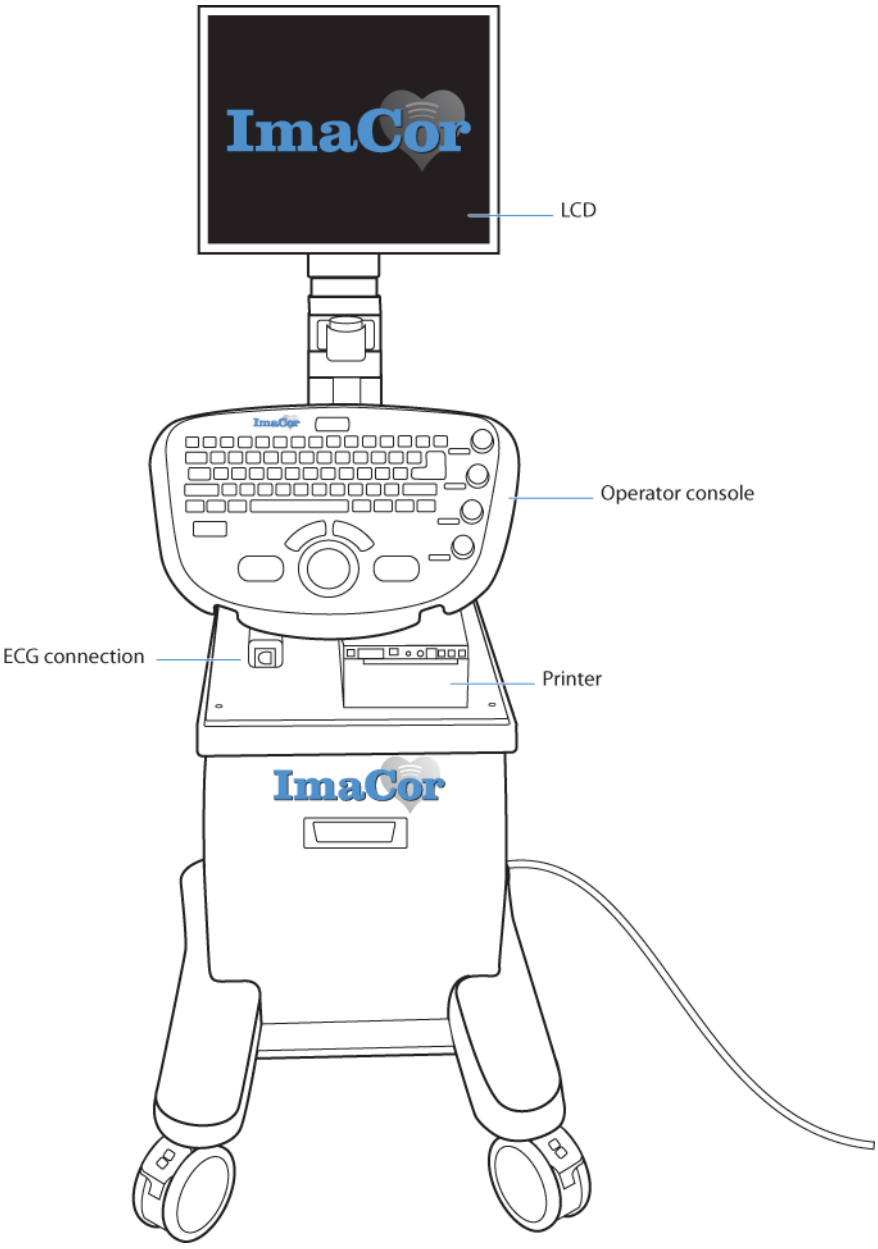


Fig. 2 ImaCor Zura Ultrasound Machine

Ultrasound Machine

The ImaCor Zura system includes an ultrasound machine optimized for use with the ImaCor ClariTEE probe (Figure 2). The machine contains a liquid crystal display (LCD), an operator console, and all the required system firmware and hardware except for the disposable ClariTEE probe.

Ultrasound Probe

The ClariTEE is a miniaturized disposable single-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.

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

⚠ Caution
The ImaCor ClariTEE is for use **only** with the ImaCor Zura 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-use only.
The maximum dwell time for the ClariTEE probe is 72 hours.

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.

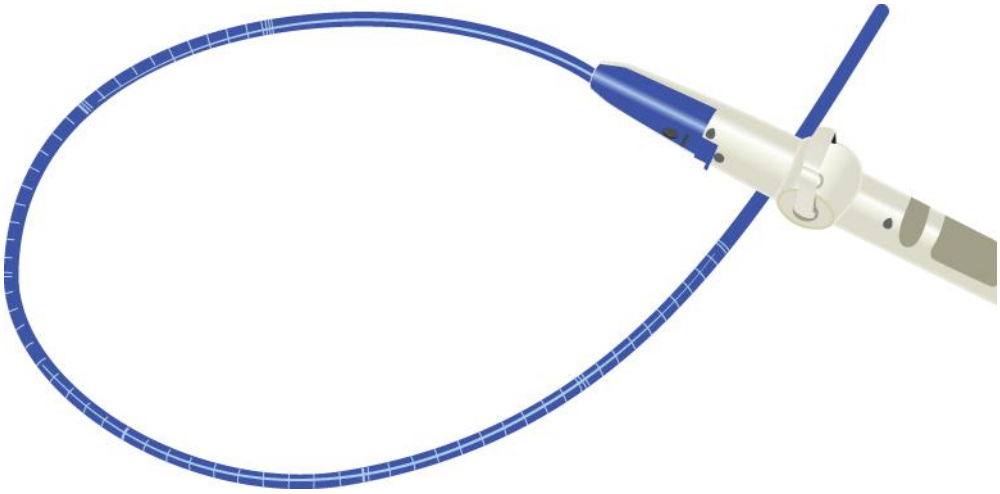


Fig. 3 ImaCor ClariTEE™ probe, umbilical, and handle

Chapter 3: Getting Started

Preparing the System

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

Connecting and Removing 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 4). The umbilical cable connector is large; you will need one hand to hold it and the other to turn the locking lever.

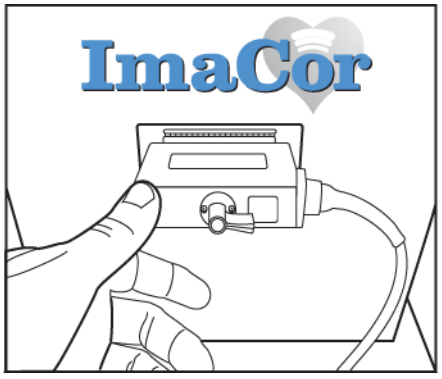


Fig. 4 Push the umbilical connector

3 When ready to attach the probe, remove it from its sterile packing. Remove the cover from the disposable probe connector as shown (Figure 5).

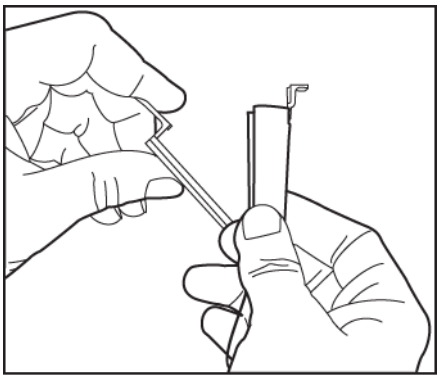


Fig. 5 Remove the cover from the disposable probe

4 Position the probe connector and handle as shown in Figure 6.

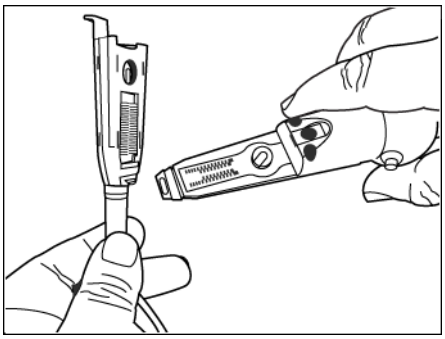


Fig. 6 Position the probe connector and handle in hand

5 Align the probe with the handle.

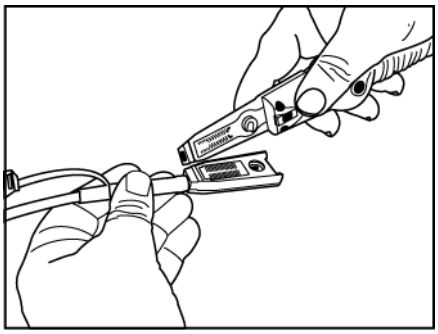


Fig. 7 Align probe and handle

6 Insert the blue connector tab into the distal end of the handle (Figure 8).

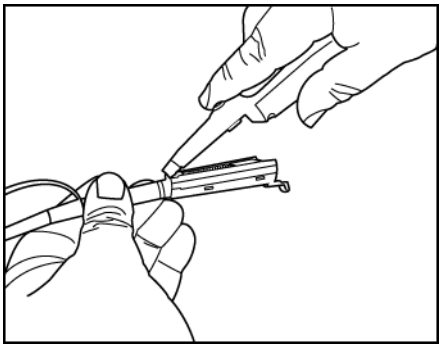


Fig. 8 Insert connector tab into distal end of the handle

7 Gently press the probe connector over the handle; press the tab on the umbilical connector to assist with engagement (Figure 9). An audible click will indicate the probe is properly connected.

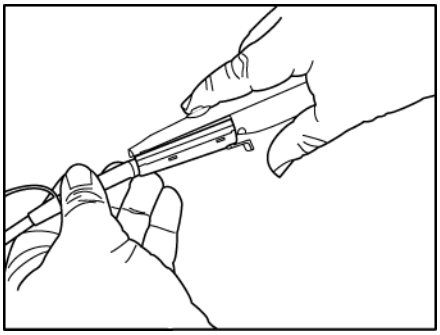


Fig. 9 Press the probe connector over the handle

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

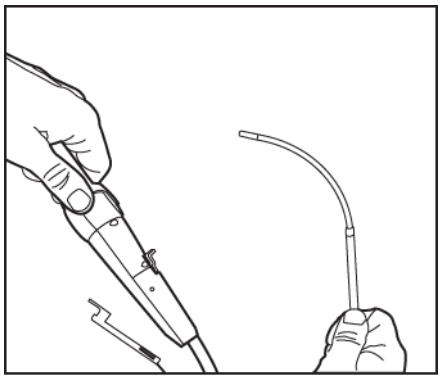


Fig. 10 Check articulation of the probe

Connecting the ECG

A three-lead ECG cable is provided for optional connection of the machine ECG to the patient. The ECG provided with the Zura is not for diagnostic purposes and is provided only to assist the detection of images at end systole and end diastole. After connecting the patient electrodes, connect the ECG cable to the machine using the circular twist-lock receptacle located next to the printer.

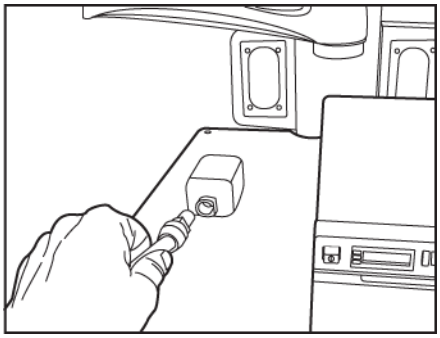


Fig. 11 Connect the ECG lead

Turning the System On/Off

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

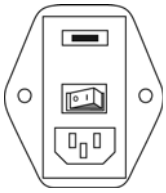


Fig. 12 ImaCor Zura on/off switch

2 Power up the computer by pressing the pushbutton switch directly behind the ECG connector shown in Figure 11 and sharing the same housing.

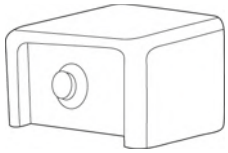


Fig. 13 Power pushbutton switch

System Software Controls

ImaCor Ultrasound imaging software 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. FAC calculation

See Figure 14 on page 17 for a detailed console drawing.

Table 2 System Software Console Controls

Control	Function
Alphanumeric keys	Enable user to enter comments or data into text boxes
View	Toggles the display view from Single View mode to split screen mode (two loops displayed side by side). For additional information, see Single View mode, page 30 and Split View Mode, page 57.
Print	Prints the displayed frozen (still) ultrasound image. See Printing, page 63.
Acquire	Stores a three-second loop of a real-time ultrasound images and ECG data (if any). See Image Acquisition, page 40.
Freeze	Toggles the Freeze/Unfreeze of a real-time image. See Freeze/Unfreeze, page 39.
Trace	Selects trace mode, which enables the user manually to trace areas. See Tracing Tool, page 46.
Measure	Selects measure mode, which enables user to measure height and width distances; e.g., in the LV cavity. See Measuring Tape Tool, page 49.
Overlay	Sustains the display of traced LVEDA and LVESA contours over other frames in a loop. See Trace Overlay Mode, page 56.
Load	Loads a cineloop into the display. See Loading a Cineloop, page 42.
GAIN	• Real-time mode: controls overall gain • Playback mode: controls brightness See Gain Control, page 35.
TGC	• Real-time mode: controls TGC • Playback mode: controls DBC See Time Gain Compensation Control (TGC), page 35.
FILTER	• Real-time mode: controls filter and contrast • Playback mode: controls contrast See Filter Control, page 36.
DEPTH	• Real-time mode: controls displayed image depth • Playback mode: controls displayed image depth See Depth Control, page 44.
“N” key	Loads the next cineloop without going through the Load Loop dialog.
“P” key	Loads the previous cineloop without going through the Load Loop dialog.

General Description of User Controls

Operator Console

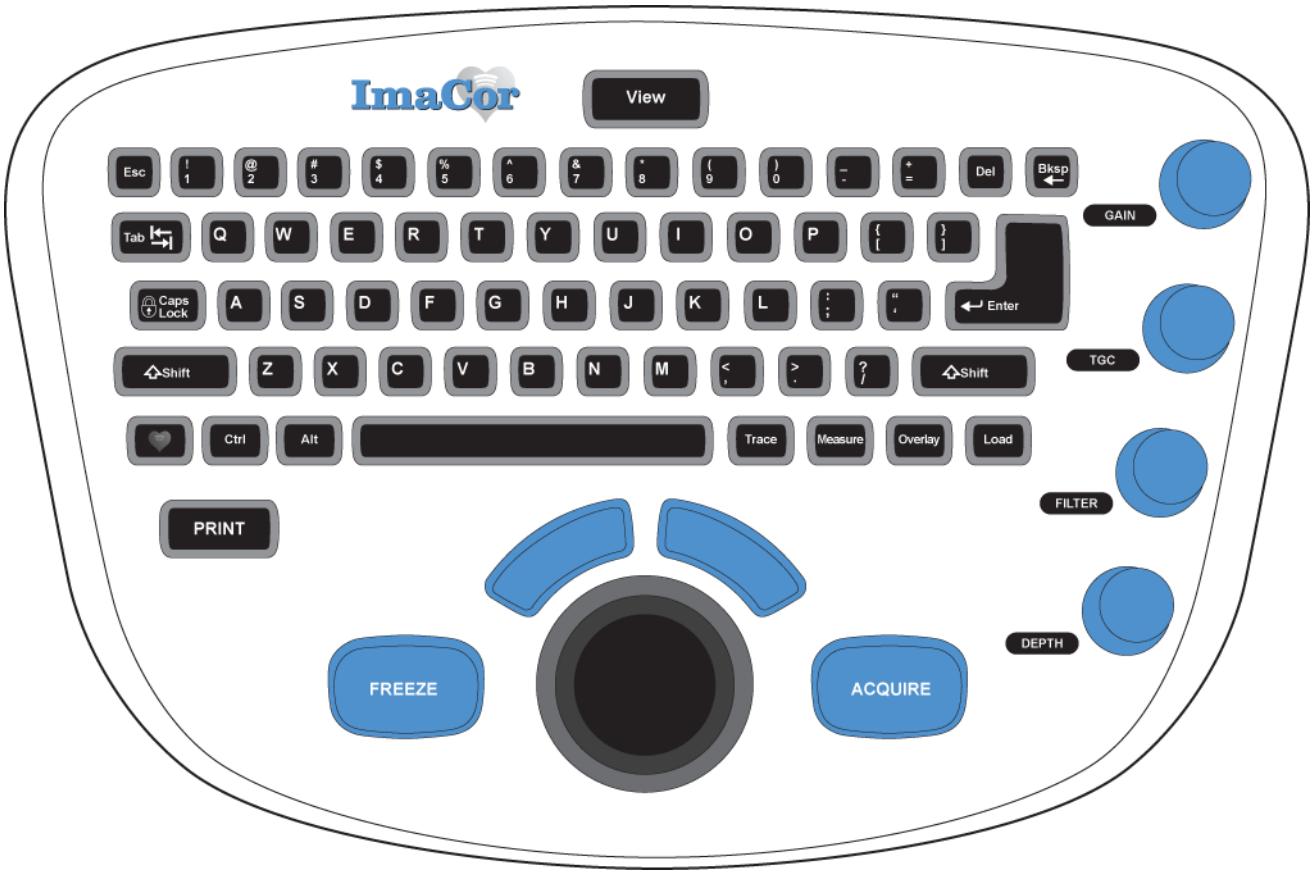


Fig. 14 ImaCor Zura operator console

Using the Trackball

The trackball is a pointing device. It serves the same functions as a mouse, but accomplishes them in different ways. A mouse must be moved from one location to another to reposition the cursor or to scroll, whereas a trackball is rotated in its socket while the device in which it is housed remains stationary. Trackballs permit fast, continuous scrolling and need not be repositioned.

Trackballs permit fast, continuous scrolling and need not be repositioned, In addition, track-balls allow for finer control than a mouse.

As a rule, trackballs are controlled with the thumb and fingertips, allowing for finer control than a mouse, which is operated with the hand and wrist.

- Roll the trackball in the direction you wish to move the cursor.
- Roll the trackball left or right to scroll

You must be in scrolling mode to scroll through images with the trackball. Left click on the image to enter scrolling mode; left click again to exit.

Like a mouse, the trackball device includes right and left buttons.

- Click the left button on the trackball to select a software button or a menu item.
- Click the right button on the trackball to view a context-sensitive menu.

Monitor

The LCD monitor contains brightness controls. These can be adjusted to the user's specifications. Other monitor controls should left at factory default settings.

Chapter 4: ImaCor Ultrasound Imaging Software

Overview

ImaCor Ultrasound Imaging Software v1.3.0 performs seven basic functions:

1. Recording and updating patient information
2. Real-time imaging
3. Cineloop acquisition
4. Cineloop enhancement
5. Cineloop playback
6. Cineloop evaluation
7. FAC calculation

Online Help System

The complete User Manual is available via electronically through the imaging software's searchable Help System. To access the Help system, press and hold the ♡ key, then press the H key.

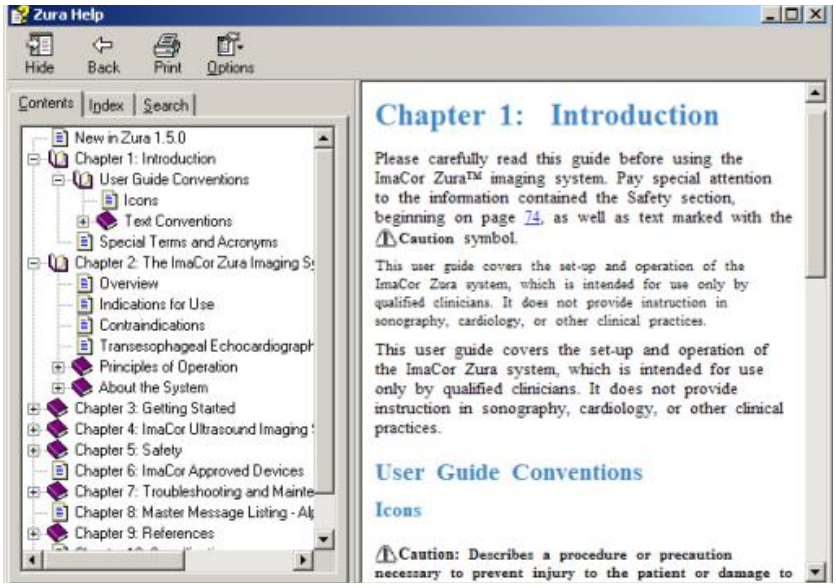


Fig. 15 Sample Help screen

Additional Help Resources

Additional assistance in the form of tooltips and live technical support is also available. See page 71 for details.

System Initialization

See Troubleshooting (page 30) and Master Message Listing (page 84) 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 Troubleshooting (page 30) and Master Message Listing (page 84) 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. 16 System initialization screen – normal initialization sequence

Patient Information

Basic patient data are entered using the Patient Information window (Figure 17). After starting the ImaCor Zura system, the Patient Information screen is the first interactive window displayed.

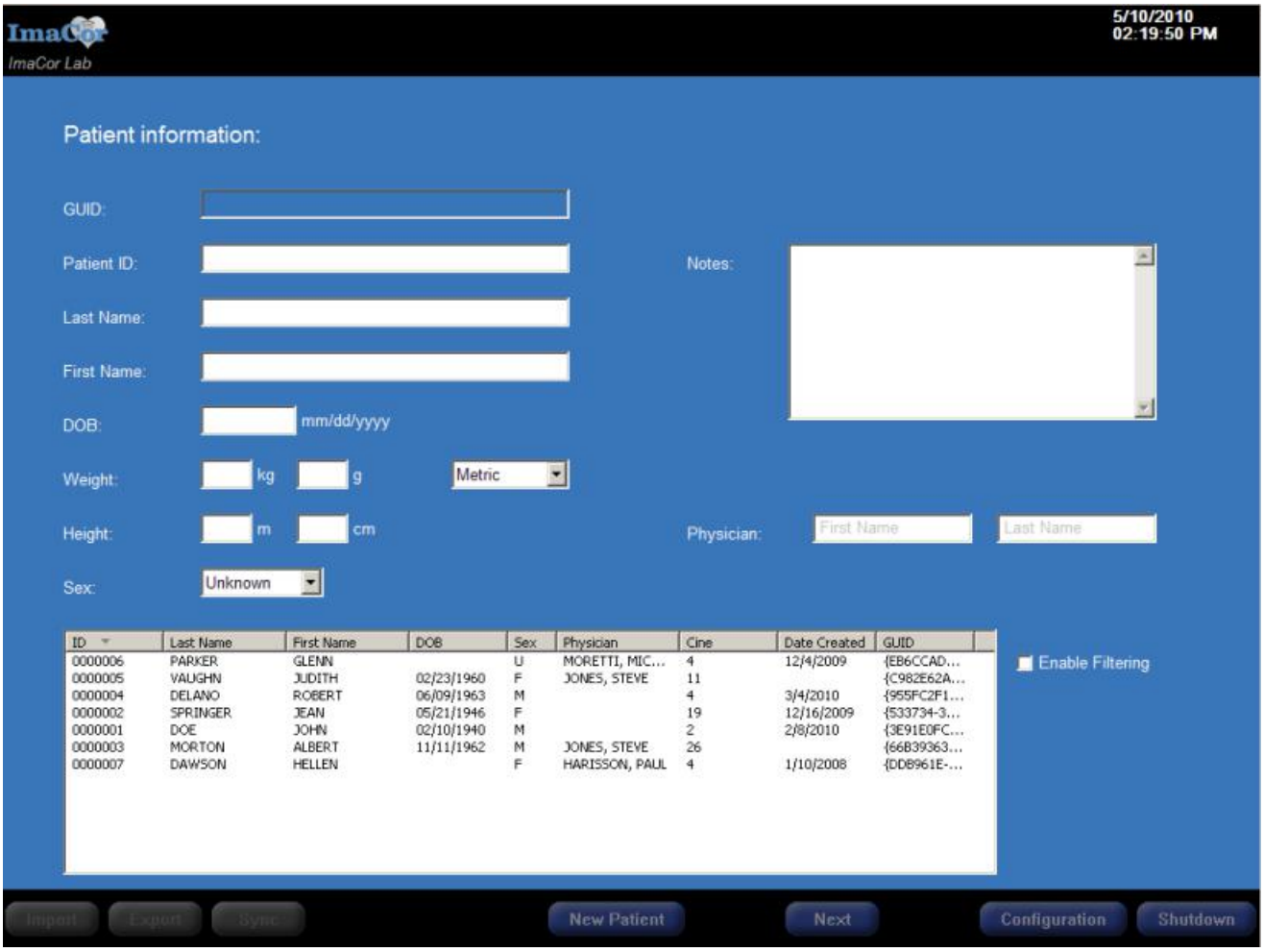


Fig. 17 Patient information screen

The fields detailed in Table 3 comprise the Patient Information screen.

Table 3 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 name information is always displayed and recorded in upper-case characters. 32 characters maximum

Table 3 Patient Information Screen Data Fields (Continued)

Field Name	Status	Function	Notes
First Name	**Mandatory**	Enter patient's first name	To ensure consistency, first and last name information is always displayed and recorded in upper-case 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.
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
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: • Smith, John • Smith, Josephine • Smithers, Joachim

Tab Order

Use the Tab key to advance through the enterable fields in the Patient Information screen. The tab order is:

- Patient ID
- Last Name
- First Name
- DOB
- Weight
- Unit System
- Height
- Sex
- Notes
- Physician First Name
- Physician Last Name

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	GUID
0000006	PARKER	GLENN		U	MORETTI, MIC...	4	12/4/2009	{EB6CCAD...
0000005	VAUGHN	JUDITH	02/23/1960	F	JONES, STEVE	11		{C982E62A...
0000004	DELANO	ROBERT	06/09/1963	M		4	3/4/2010	{955FC2F1...
0000002	SPRINGER	JEAN	05/21/1946	F		19	12/16/2009	{533734-3...
0000001	DOE	JOHN	02/10/1940	M		2	2/8/2010	{3E91E0FC...
0000003	MORTON	ALBERT	11/11/1962	M	JONES, STEVE	26		{66B39363...

Fig. 18 Sample patient list

The list includes the following information:

- 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
- Patient record creation date
- Patient GUID

PATIENT LIST SORT ORDER

You can set the sort order of the patient list by clicking on the appropriate column heading.

You can set the sort order of the patient list by clicking on the appropriate column heading. For example, click on the Last Name column heading to display the patient list alphabetically by last name. The active column is indicated with an arrow.

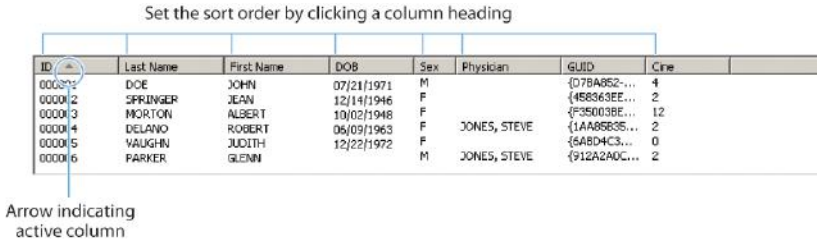


Fig. 19 Patient list column headings

Patient Information Screen Button Functions

Figure 20 shows the patient information screen buttons in their default state. The Import and Export buttons are disabled unless an ImaCor Data Transfer Module (DTM) is connected. See page 27 for information in importing and exporting patient data.

Active buttons are slightly dimmed to minimize visual distractions.

The New Patient, Next, Configuration, 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.

Fig. 20 Patient information screen buttons – default state

Table 4 Patient Information Screen Buttons and Function

Number	Button	Function
1	Import	Import patient information. Enabled only when a Data Transfer Module (DTM) is inserted in a USB port.
2	Export	Export patient information. Enabled only when a Data Transfer Module (DTM) is connected and a patient record is selected from the patient list.
3	Sync	Synchronize cineloops with a DICOM Archiving Server. See DICOM configuration.
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 imaging preparation screen. Mandatory first and last name fields must have been completed.
6	Configuration	Accesses the Configuration dialog screens; see "Configuring the System," page 65, for details.
7	Shutdown	Shuts down the system.

Table 5 Standard ImaCor Button States

Button	Button State
	Disabled
	Default
	Highlighted (rollover)
	Selected (trackball click)

When you roll the trackball over an active button, the button is highlighted as shown in Table 5. Clicking on an active button changes the color from blue to orange, also shown in Table 5. This sequence is standard throughout the ImaCor Zura system.

Patient Information Tasks

ADD A NEW PATIENT

1. If data from an existing patient are displayed in the Patient Information screen, press the New Patient button.
2. Enter the new patient information in the appropriate fields. Press the Tab key to advance from one field to the next; Press Shift-Tab to move backwards. The First Name and Last Name fields are mandatory; all others are optional.
3. When you have finished entering information, press the Next button to begin imaging preparation.

Autosave Feature

Once a single character is entered in both the First Name and the Last Name fields, the autosave feature records it and all subsequent characters in the patient data

base. No user action is required save information entered in the Patient Information screen.

Patient Information Validation

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 A PATIENT RECORD

Whenever a probe is connected to the Zura system, the system software checks to see if the probe has been used before. If the probe has been used in a previous patient exam, the system reads the patient data encoded in the probe—the GUID and the patient's first and last names—then searches for a match 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 is shown below in Figure 21.

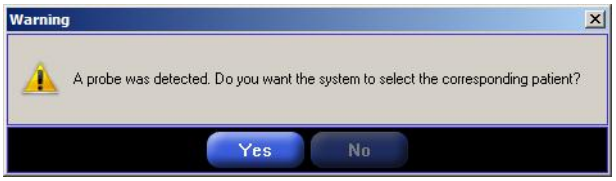


Fig. 21 Autoselect prompt

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.

Patient Records Created on a Remote System

If patient data has been encoded in the probe, but no matching record is found in the patient database, the Zura system software automatically creates a patient record based on the encoded information. The system then displays the autoselect prompt.

This situation arises when a patient's initial examination is completed on one Zura system, but a subsequent assessment uses a different Zura. For example, a patient's initial exam may take place in an emergency room setting, while later examinations are completed in the intensive care environment. These departments likely use different Zuras, and Zuras are stand-alone systems. Information entered in one patient database does not appear in databases associated with other Zura systems. This is also true for cineloops.

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 system (see "Import Patient Data," page 26). Information that is corrected in or added to a system-generated patient record will not be reflected in the original record.

UPDATE A PATIENT RECORD

Use the Patient Information screen to include additional information in a patient record or to correct existing information.

1 When the Autoselect prompt is displayed, click the Yes button; alternatively, you may manually locate the patient's record in the patient list. If you choose

the latter, click on the patient's name to select the record. The patient's personal information is displayed in the Patient Information screen data fields.

2 Tab to the field you wish to modify.

3 Enter the new information or correct the existing data.

If you access the Patient Information screen from the imaging screen during an exam, press the OK button to return to the imaging environment.

REVIEW AN EXISTING PATIENT RECORD AND ASSOCIATED CINELOOPS

You must select an existing patient record when you wish to review previously recorded cineloops or acquire new ones. A cineloop is a three-second loop of ultrasound images and ECG data.

1 When the Autoselect prompt is displayed, click the Yes button; alternatively, you may manually locate the patient's record in the patient list. If you choose the latter, click on the patient's name to select the record.

2 Press the Next button to advance to the imaging preparation environment.

3 For information on viewing an existing cineloop, see "Loading a Cineloop," page 42.

IMPORT PATIENT DATA

Patient information and cineloops can easily be exchanged between Zura 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.

Importing data into the ImaCor Zura system is a three-step process:

1 Insert the DTM into one of the two USB ports on the face of the console. When the DTM is connected, the Import button becomes active and the system displays a message indicating that the Export feature is enabled.

2 Click the Import button. The DTM Patients dialog box is displayed. Click the name of the patient whose records you wish to import. Pressing the Shift button while clicking enables you to select multiple records.

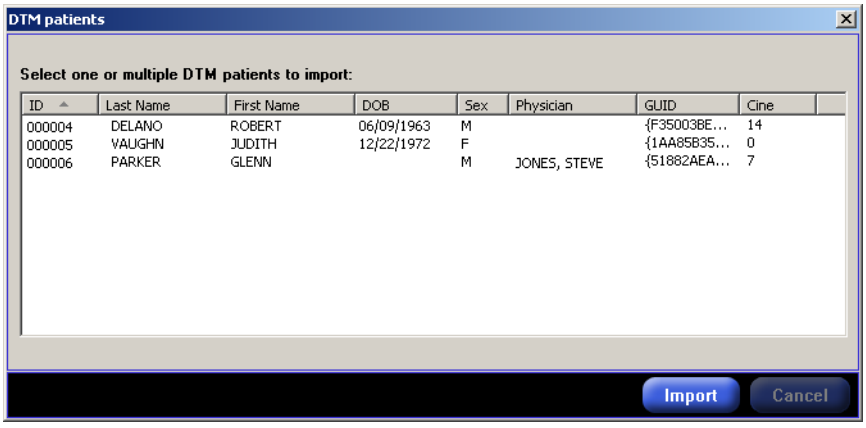


Fig. 22 DTM patient display

3 Click the Import button. Do not disconnect the DTM while the data is being imported. Figure 23 shows the Importing progress bar.

Note: Patient Data on the DTM is encrypted. A validation (checksum) of the DTM data is performed by the system when a DTM is detected.

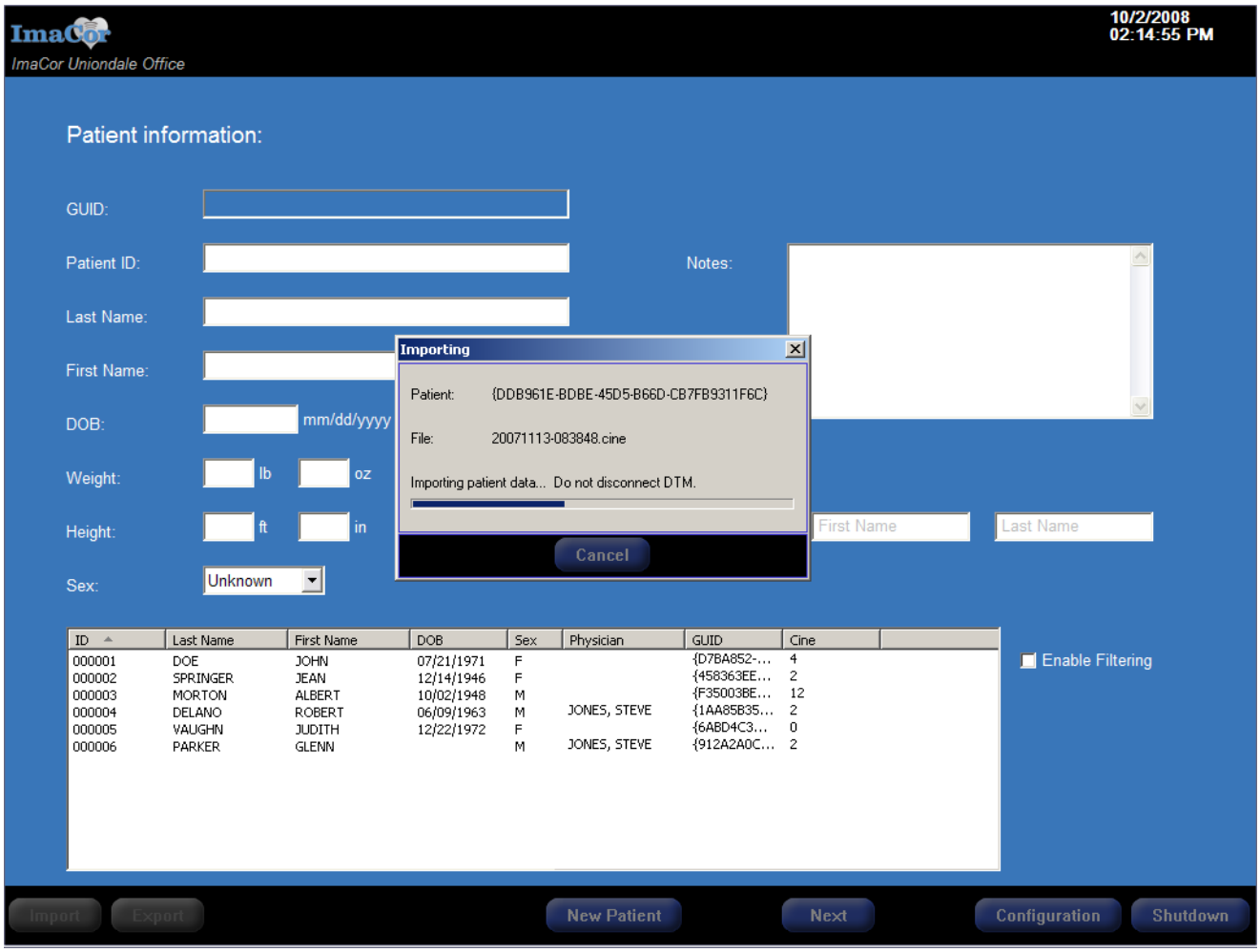


Fig. 23 Importing patient data progress bar

Duplicate Records

If you are importing a record that already exists on the target machine, a warning message is displayed, as shown in Figure 24.

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

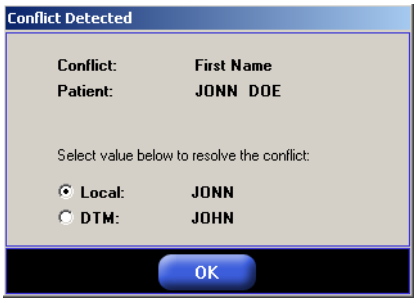


Fig. 24 Patient record overwrite warning

EXPORT PATIENT DATA

Exporting data from an ImaCor system is a three step process:

1 Insert the DTM into one of the two USB ports on the face of the console. The instructional message shown in Figure 25 is displayed.

2 Click the name of the patient whose records you wish to export. Pressing the Shift button while clicking enables you to select multiple records.

3 Click the Export button.

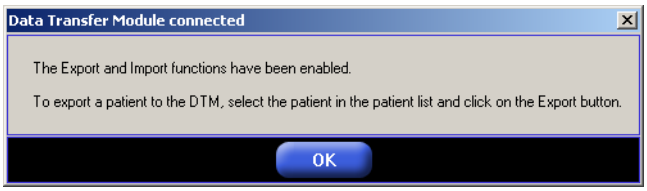


Fig. 25 DTM confirmation

Note: Patient Data is encrypted before it is stored onto a DTM.

QUERYING A MODALITY WORKLIST SERVER

If a MWL Server is configured it is possible to query it for a selected patient.

1 Select a patient from the patient list.

2 Richt-click and select “Check MWL Server...”. This requires the Zura system to be connected to the configured MWL Server via a Network.

If the MWL Server query returns at least 1 item, the user can choose to import information from a selected MWL item into the local patient record. See DICOM Conformance Statement for details of imported fields.

SYNCHRONIZING WITH A DICOM ARCHIVING SERVER

If a DICOM Archiving Server is configured it is possible to send acquired cineloops to it as multi-frame DICOM files.

This requires the Zura system to be connected to the configured Archiving Server via a Network.

Sending cineloops to the Server is done by clicking on the “Sync” button in the patient screen. After communication with the Server is verified, the Zura system will send only cineloops that have not yet been sent and that satisfy all custom rules that may have been set.

Example of Sync rules: (1) require cineloop comment, (2) require patient ID, (3) require patient DOB

DELETE A PATIENT

1 Locate the patient’s record in the patient list.

2 Click on the patient’s name to select the record.

3 Right click the trackball button.

4 Select the Delete option, as shown in Figure 26.

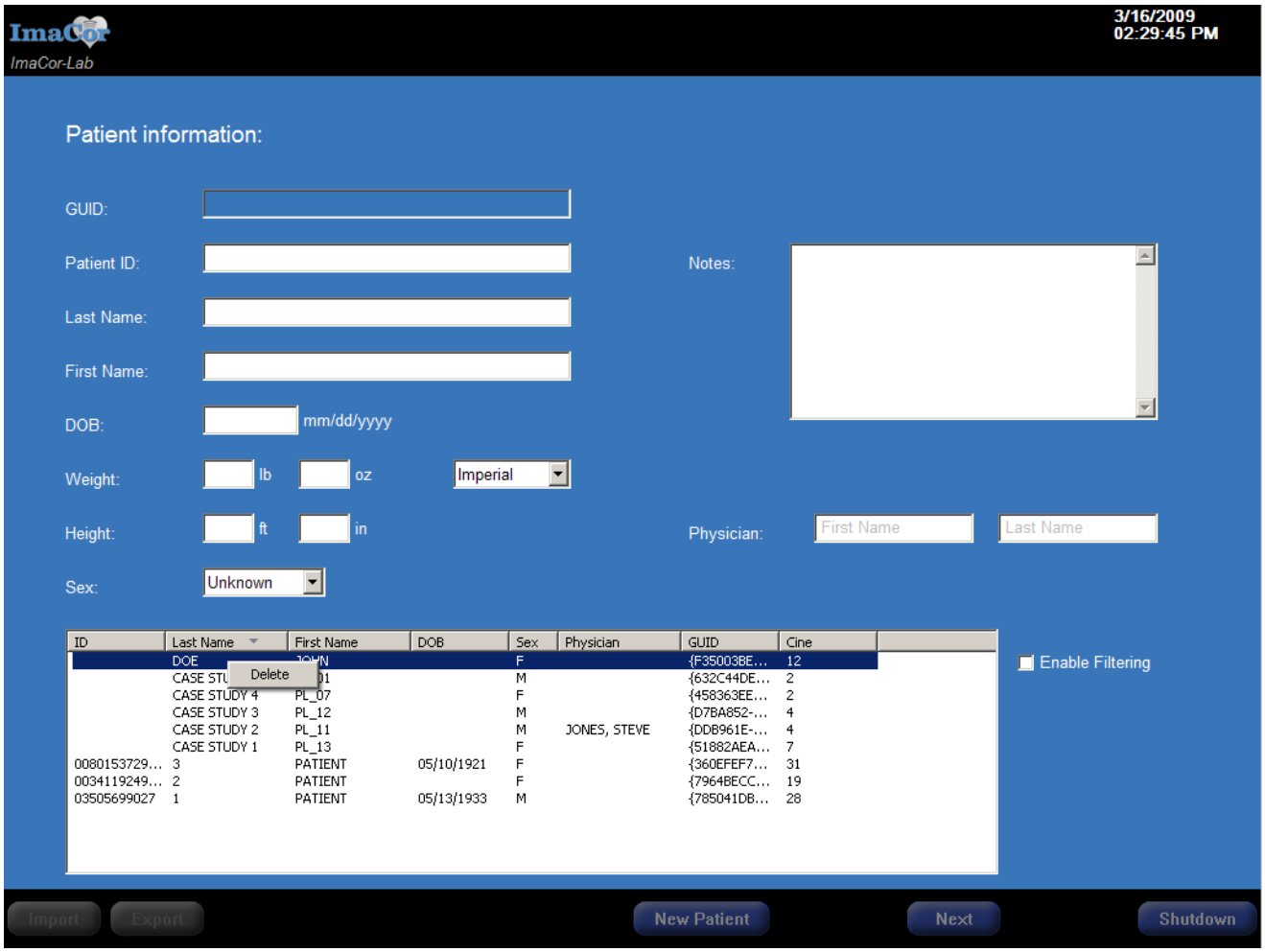


Fig. 26 Deleting a patient record

When the confirmation message is displayed (Figure 26), press the Yes button to delete the patient record. Deleted records cannot be retrieved.

Fig. 27 Deleting a patient record – confirmation message

Preparing to Image

Once you've completed the Patient Information screen, the Imacor Zura system begins a series of self checks in preparation for imaging. Most of the time the screen shown in Figure 28 will be displayed, indicating that the system encountered no errors is ready to begin imaging.

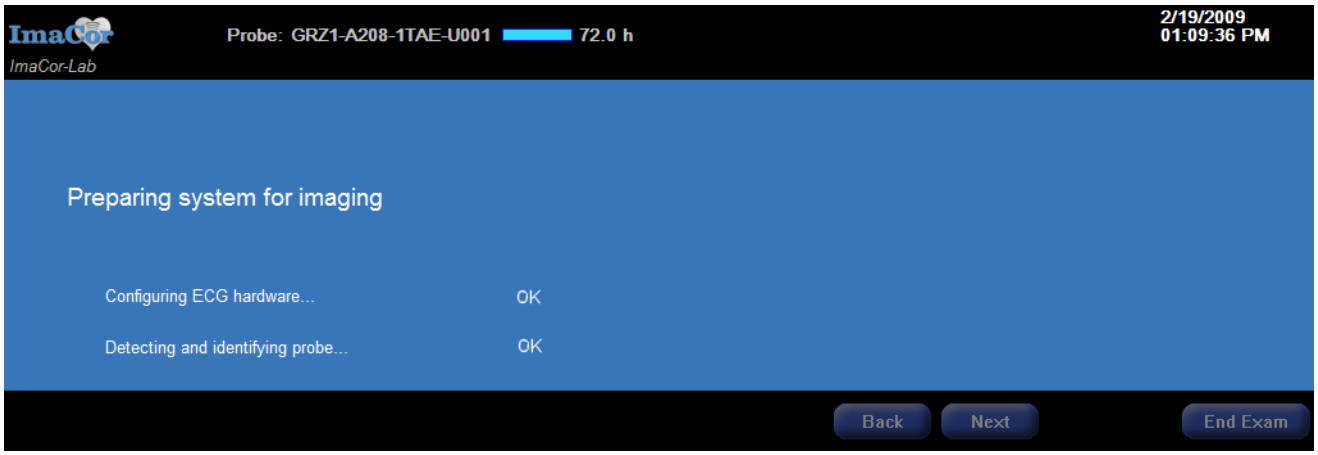


Fig. 28 ImaCor imaging preparation screen

Troubleshooting

If the ImaCor Zura system encounters a problem, an error message is displayed on the Imaging Preparation screen. See “Chapter 7: Troubleshooting and Maintenance,” page 81 for a complete listing of error messages and their meaning.

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. See page 31 for information on Single View mode. Split View mode enables you to compare two cineloops side-by-side or one cineloop beside real-time imaging. See page 57 for information on Split View mode.

Single View Mode

Single View mode is generally used for real-time monitoring and FAC calculations. To review and compare saved cineloops with live images, or to compare two saved cineloops, see “Split View Mode,” page 57.

See Table 6 on page 31 for information on Single View mode features.

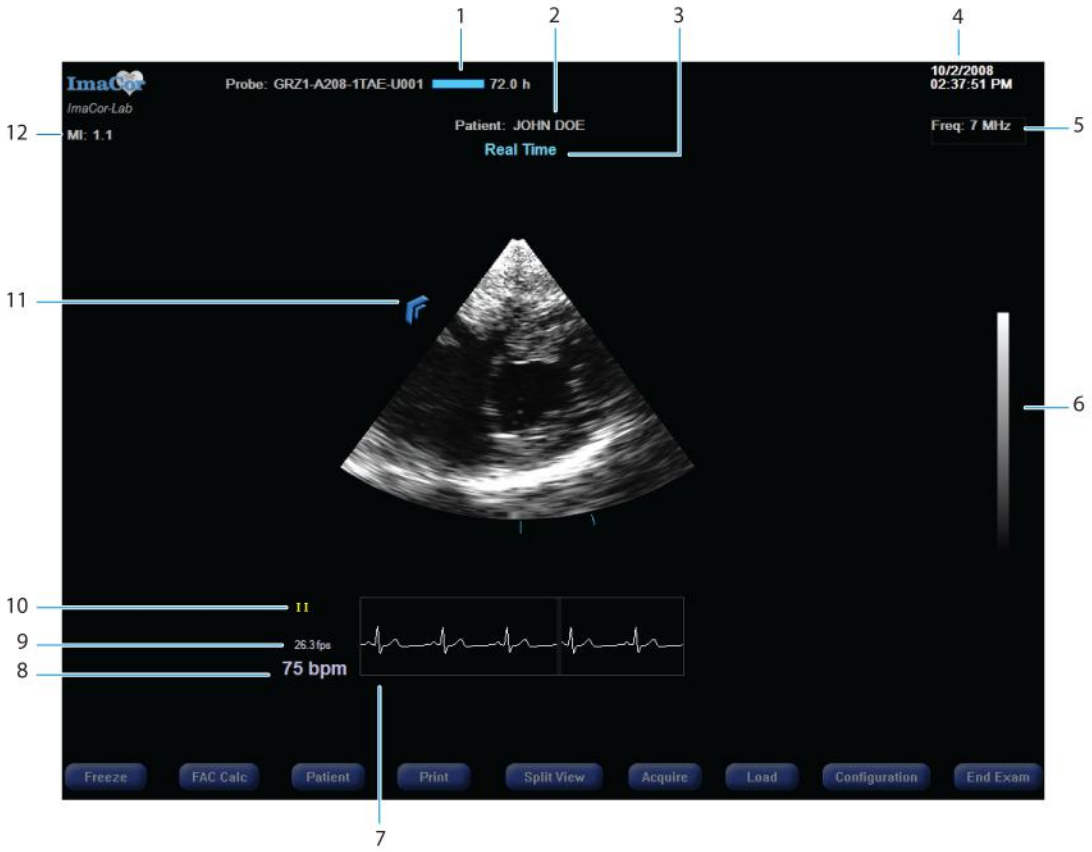


Fig. 29 Single View mode imaging screen

Table 6 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		

Table 6 Imaging Screen Features (Continued)

Number	Feature	Function	Notes
5	Tx frequency	Displays the current transmit frequency. Default is 7 MHz. The transmit frequency can be changed to 6 MHz for improved penetration with a slight decrease in resolution.	The frequency can be changed to 6 MHz in one of two ways: 1. Click within the Frequency area, bounded with a blue rectangle, to display the frequency menu. Select the desired frequency from the menu. 2. Change the frequency setting in the Configuration dialog. The new frequency value becomes the system default.
6	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.
7	ECG waveform		
8	Heart rate	Expressed in beats per minute (bpm)	
9	Frame rate	Expressed in frames per second (fps)	Standard real-time frame rate is 24 fps Acquisition frame rate is 50 fps. For more information on acquisition mode, see page 40. Recovery frame rate is 10 fps. For more information on recovery mode, see page 42. **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.
10	ECG lead	Select Lead I, II, or III	
11	Steering feature cursor	Enables the user to look 25 degrees to the left or right without physically moving the probe.	Steering is always available from the keyboard during real-time imaging. • Press ♡ > to pan right on image • Press ♡ < to pan left on image Steering also available from the trackball unless measuring or tracing mode is ON. • Left-click on the right of the image to pan right • Left-click on the left of the image to pan left The steering angle increments in five degree steps.

Fig. 30 Single View mode layout buttons

Table 7 Imaging Screen Buttons

Number	Feature	Function	Notes
1	Freeze/Unfreeze	Toggles between Freeze and Unfreeze mode	**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 trackball to scroll through the buffered frames. Use the playback buttons to click through the sequence one frame at a time. **Unfreeze:** Resumes real-time imaging. See "Freeze/Unfreeze," page 39
2	FAC Calc	Starts the FAC Wizard, which guides the user through the steps necessary to complete an FAC calculation.	See "The FAC Wizard," page 52
3	Patient	Displays the Patient Information screen, enabling you to edit patient information without ending an exam. To return to imaging view, click the OK button.	If the Patient button is 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 pressed, you are returned to the imaging screen and the exam resumes. If a cineloop was being viewed, it remains loaded. If real-time imaging was taking place, the frozen 50-frame real-time buffer is displayed.

Table 7 Imaging Screen Buttons (Continued)

Number	Feature	Function	Notes
4	Print	Sends the current image to a local printer, along with FAC data if applicable.	See "Printing," page 63
5	Single/Split View	Toggles between Single View and Split View modes.	See "Single View Mode," page 31 and "Split View Mode," page 57
6	Acquire	Starts a 3-second acquisition of real-time images and ECG.	See "Image Acquisition," page 40
7	Load	Loads a cineloop.	See "Loading a Cineloop," page 42
8	Configuration	Enables user to customize several aspects of the system configuration, including: • Application • Date-Time • DICOM • Language • Version • Help	"Configuring the System," page 65
9	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.

Real-Time Imaging

Real-Time Image Quality Controls

The real-time image quality controls enhance images that are being captured by the ultrasound hardware.

CONTRAST CONTROL

If the Filter control is displayed, press the knob once to toggle to Contrast control (Figure 31). If another control is displayed (e.g., Gain, TGC, or Depth) or if the Control display is not active, press the Filter knob twice to access Contrast control.

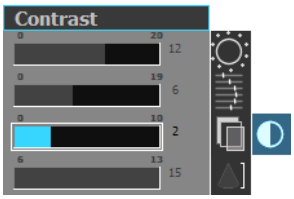


Fig. 31 Contrast control display

DEPTH CONTROL

The Depth control determines the depth in centimeters of the displayed image.

Press or rotate the Filter knob to display the Image Quality Control display with the Depth controls active (Figure 32). The Depth control range is 6–15 cm and is adjusted in 1 cm increments. From 6 to 12 cm images are life-size. From 13 to 15 cm images are scaled down.

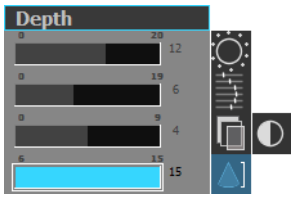


Fig. 32 Depth control display

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.

Press or rotate the Filter knob to display the Image Quality Control display with the Filter controls active (Figure 33).

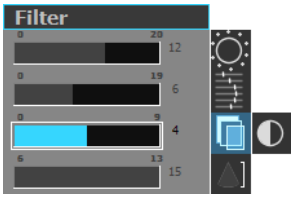


Fig. 33 Filter control display

GAIN CONTROL

The Gain Control knob, located on the console, regulates the overall gain of the ultrasound system. Gain controls the overall brightness of an image. It is used in combination with TGC, as described below.

Press or rotate the Gain Control knob to display the Image Quality Control display with the gain controls active (Figure 34).

The gain range is 0–20. The current setting is displayed on the right side of the gain gauge.

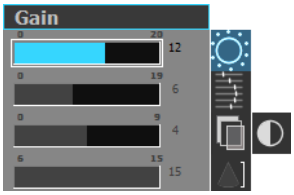


Fig. 34 Gain Control display

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.

Press or rotate the Gain Control knob to display the Image Quality Control display with the TGC controls active. The TGC range is 0–19 (Figure 35).

The current setting is displayed on the right side of the TGC gauge.

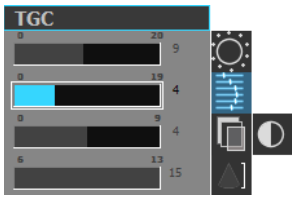


Fig. 35 TGC control display

The ECG Waveform

The ImaCor Zura system enables you to customize the ECG waveform display.

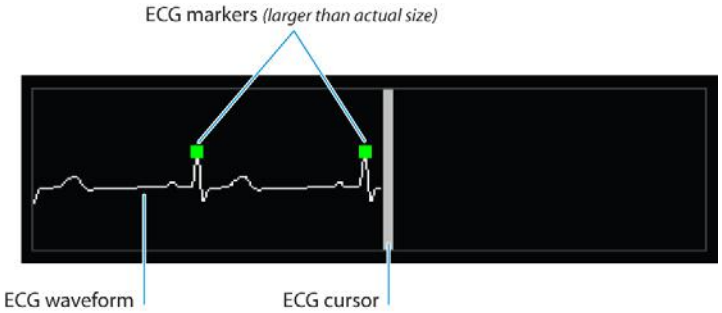


Fig. 36 Example ECG waveform with markers

ECG CURSOR

The ECG cursor is a gray vertical bar (playhead) that indicates the current frame in the waveform being viewed, as shown in Figure 36. When reviewing frames, the ECG cursor is highlighted as it passes over an ECG marker, as shown in Figure 37.

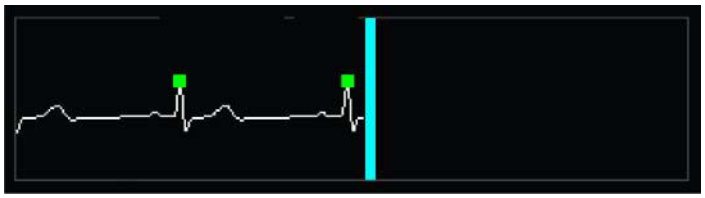


Fig. 37 ECG waveform with highlighted cursor

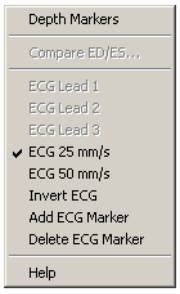


Fig. 38 Global menu

ECG MARKERS

By default, an ECG marker is automatically placed at the peak of the R wave (see Figure 36). 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.

Adding an ECG Marker

1 Move the ECG cursor to the desired position.

2 Right click the trackball button.

3 Choose the Add ECG Marker option from the pop-up menu (see Figure 41)

Deleting an ECG Marker

1 Move the ECG cursor until it is highlighted over the marker you wish to remove.

2 Right click the trackball button.

3 Choose the Delete ECG Marker option from the pop-up menu (see Figure 41)

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

1 Right click the trackball button.

2 Choose the desired ECG Lead from the pop-up menu (see Figure 39)

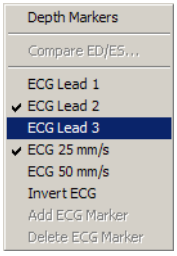


Fig. 39 Change ECG lead option

CHANGING THE ECG SWEEP SPEED

1 Right click the trackball button.

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 41.

INVERTING THE ECG WAVEFORM

1 Right click the trackball button.

2 Choose the Invert ECG option from the pop-up menu (see Figure 41).

Figure 40 below shows an inverted ECG waveform.

Fig. 40 Inverted ECG waveform with markers *(markers larger than actual size)*

Fig. 41 ECG menu options

Left Ventricle Trans-Gastric Short-Axis View (TGSAV)

In Single View mode, real-time images of the left ventricle in the TGSAV are displayed in the center of the screen (see page 41). In Split View mode, images are centered in the right and left halves of the screen, as shown on page 58. The Zura system is optimized for the TGSAV, but other views associated with TEE imaging may be obtained.

For depths from 6 to 12 cm, images are life size. A distance of 1 cm on screen represents an actual distance of 1 cm. For depths from 13 to 15 cm, images are scaled down.

The maximum image depth is 15 cm.

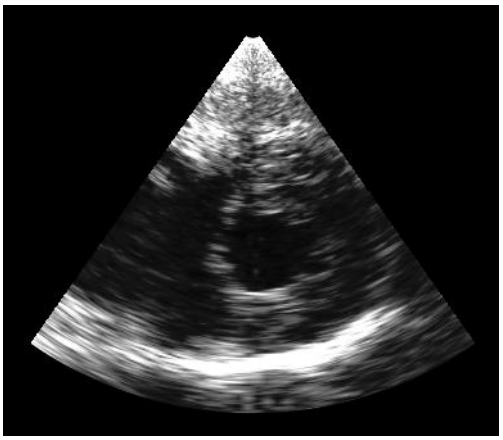


Fig. 42 Example left ventricle image in the TGSAV

DEPTH MARKERS

To display depth markers on the ultrasound image:

1 Right click the trackball button.

2 Choose the Depth Markers option from the pop-up menu (see Figure 43). The interval between two adjacent depth markers is 1 cm.

Fig. 43 Display depth marker option

Depth markers are superimposed on the ultrasound image, as shown in Figure 44. When depth markers are ON, the depth is displayed to the right of the image. Depth markers setting is persistent across Exams and System reboots.

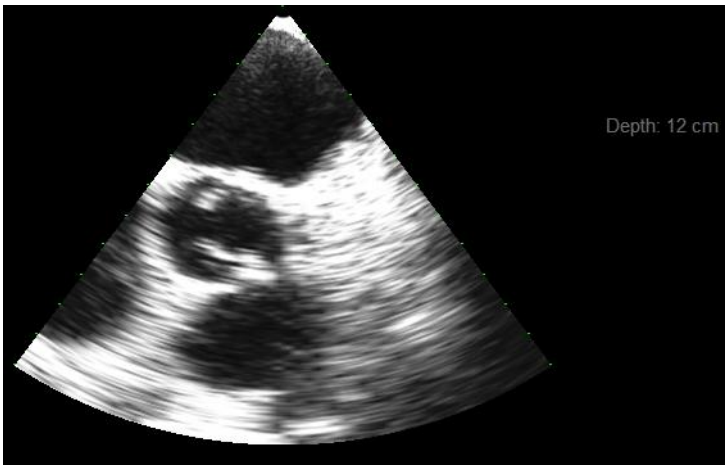


Fig. 44 Real-time image with depth markers

Freeze/Unfreeze

The Freeze/Unfreeze functions are toggled via the console button labeled Freeze and the imaging screen button, labeled Freeze or Unfreeze depending on the mode.

When in Freeze mode, there is no ultrasound imaging stream, and the Freeze/Unfreeze imaging screen button is labeled Unfreeze. Scrolling mode is automatically activated. Press the left trackball button to toggle scrolling mode on and off.

The Freeze function halts imaging on the last frame viewed and internally saves the last 50 frames imaged. The 50-frame buffer enables you to scroll backward to view previous frames. When scrolling, the fps rate displayed onscreen indicates the speed at which you are reviewing frames.

Use the trackball to scroll through the buffered frames and the playback buttons to click through the sequence one frame at a time.

When in Unfreeze mode, there is a continuous ultrasound imaging stream in real time. The Freeze/Unfreeze imaging screen button is labeled Freeze.

Steering

The steering feature enables you to pan 26 degrees to the left or right without physically moving the probe. Steering can be helpful when:

1. A structure of interest is only partially visible, but cannot be viewed in full by physically moving the probe.
2. A structure is too large to be viewed in its entirety within the Zura system's 70 degree sector.

Steering is always available from the keyboard during real-time imaging.

- Press ♡ > to pan right on image
- Press ♡ < to pan left on image

Steering also available from the trackball unless measuring or tracing mode is ON.

- Left-click on the right of the image to pan right
- Left-click on the left of the image to pan left

The steering angle advances in six steps to ±26 degrees.

When steering is activated, two visual aids appear on screen (see Figure 45):

1. A set of blue arrows pointing in the direction of motion.
2. 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—press ♡ /.

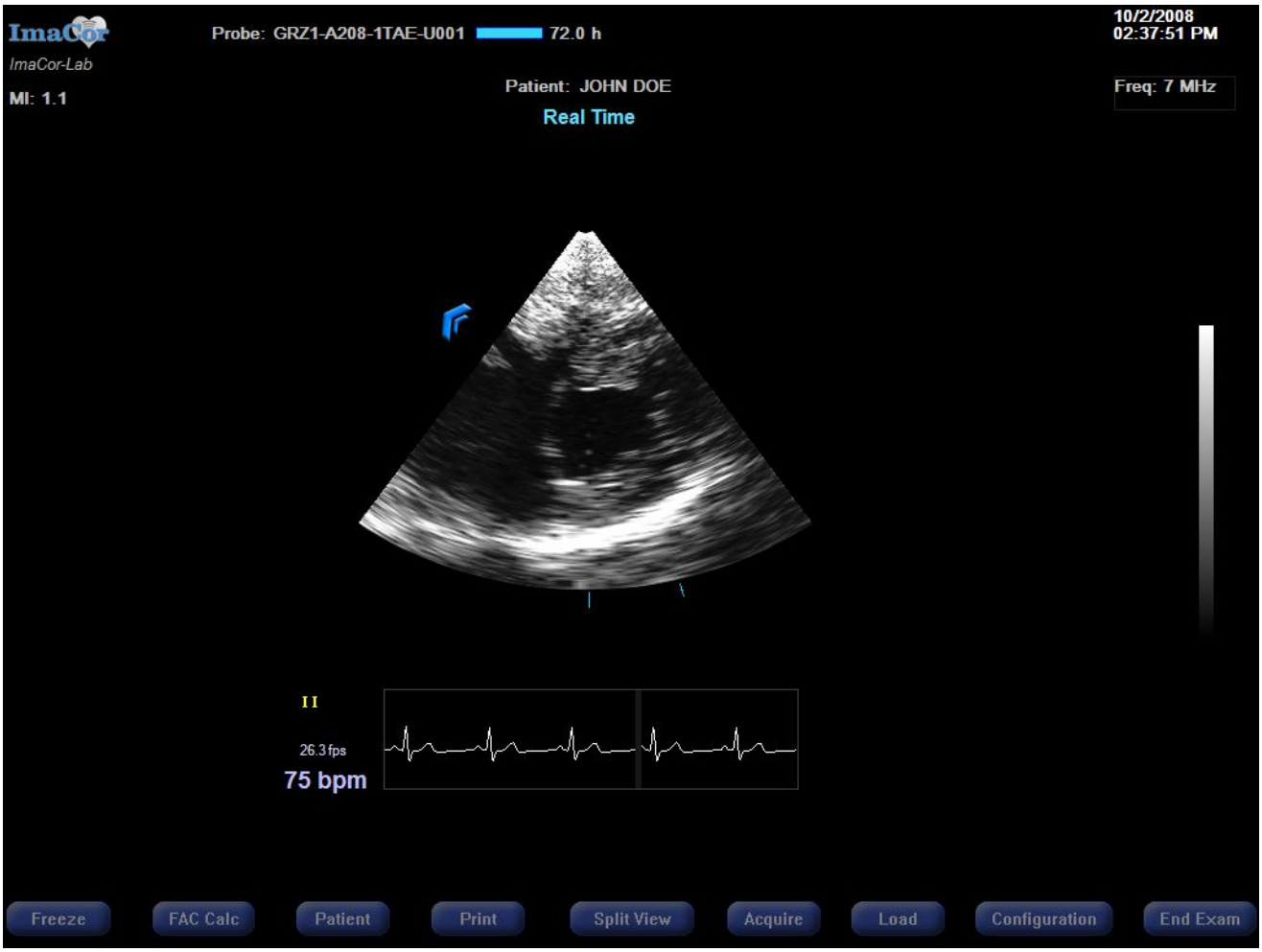


Fig. 45 Single View screen

Image Acquisition

Press the Acquire button to save real-time images and ECG data as a three-second cineloop. In acquisition mode, the frame rate accelerates from 24 fps to 50 fps and image resolution is increased. Figure 46 below shows the Single View imaging screen during acquisition.

Image acquisition can be accomplished in one of two ways:

1. pressing the Acquire key on the console
2. pressing the Acquire button on the probe handle

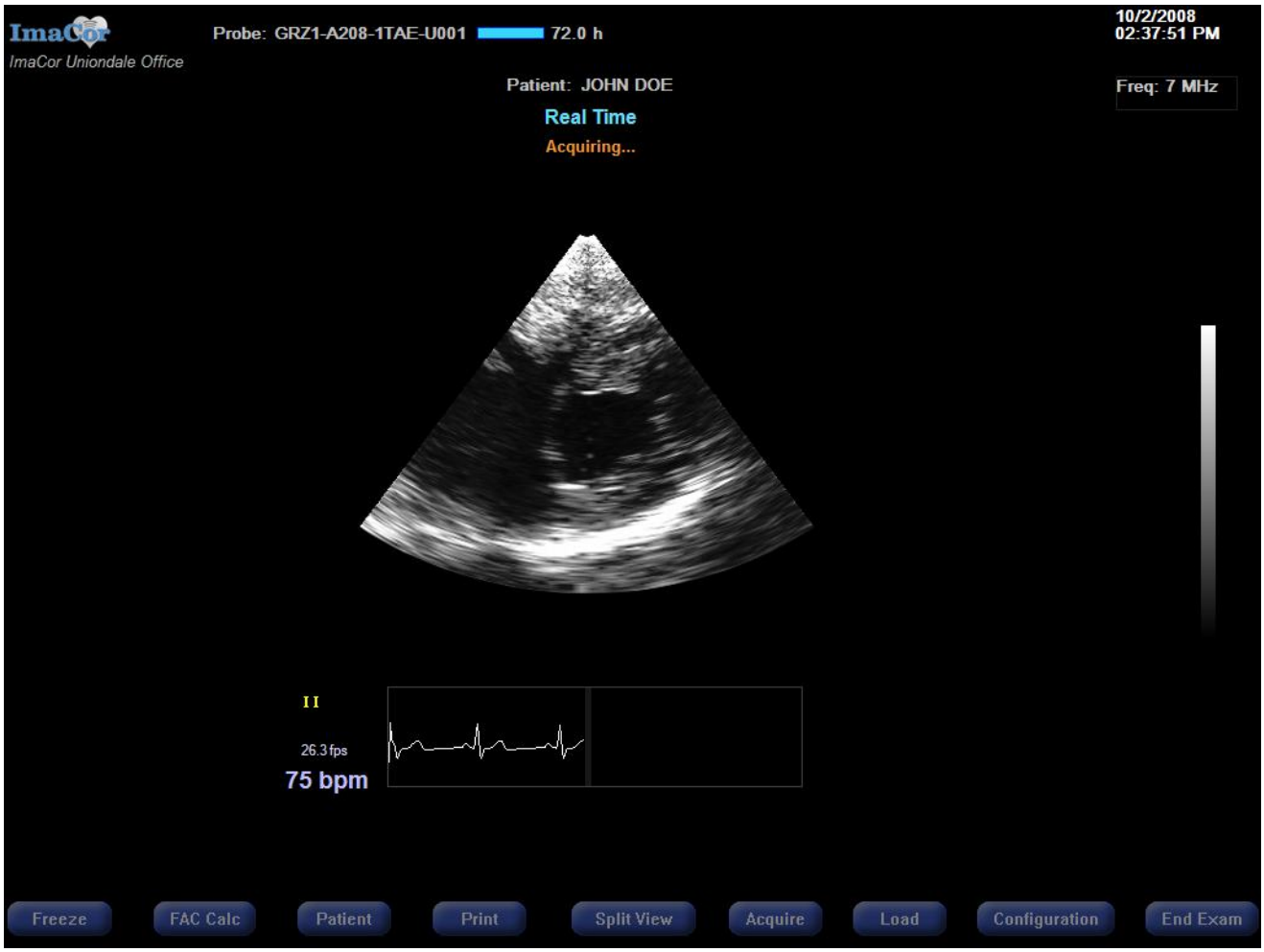


Fig. 46 Image acquisition – Single View mode

After the three-second cineloop is captured it is written to disk. Figure 47 below shows the progress bar displayed when the cineloop is saved.

Fig. 47 Cineloop save progress bar

When acquisition is complete, a comment box is displayed (see Figure 48). Comments are visible onscreen when previewing cineloops and when a cineloop is loaded.

Entering comments is optional; comments can be added or edited later. If you don't wish to enter a comment, click the OK or Cancel button to clear the dialog box. Pressing the Acquire button on the probe handle or the console will also clear the dialog box.

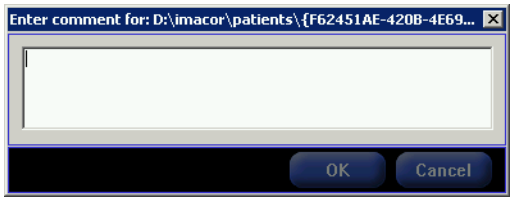


Fig. 48 Comments dialog box

After acquisition, the new cineloop is automatically loaded and ready for playback.

Recovery Mode

Safety Feature
Recovery mode allows the ClariTEE probe to cool.

While the cineloop is being written to disk, the ImaCor Zura system software enters a nine-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, but at a reduced frame rate of 10 fps. At the end of the recovery period, imaging automatically returns to the default frame rate of 24 fps and acquisition is re-enabled.

Loading a Cineloop

1 If you are starting from the Patient Information screen:
   - Select a patient name from the patient list
   - Click the Next button to enter the imaging environment

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

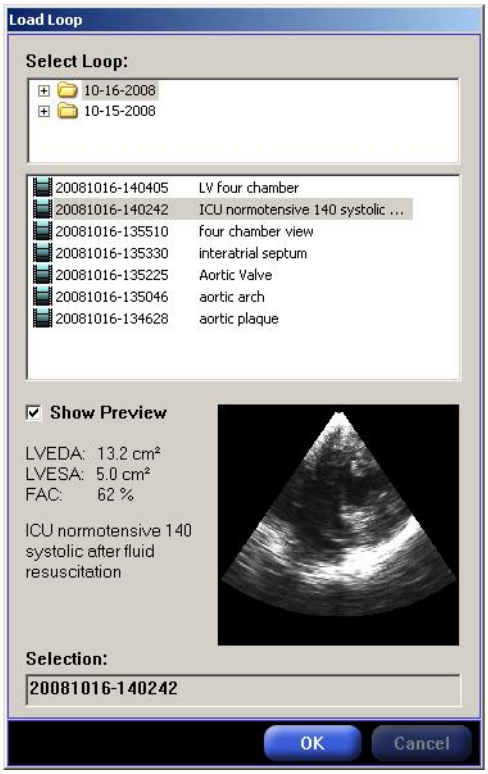


Fig. 49 Load cineloop window

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 Double click the appropriate folder to see a list of cineloops contained within it. Cineloops are labelled with the date and time of acquisition. Locate the cineloop you wish to view.

5 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 LVEDA, LVESA and FAC data, if any. See Figure 49.

6 Click the OK button to load the selected cineloop.

Note: Cineloops are automatically loaded after acquisition.

Reviewing a Cineloop

Cineloop Image Quality Control

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 knob is located on the console. It allows you to increase or decrease the brightness of your image.

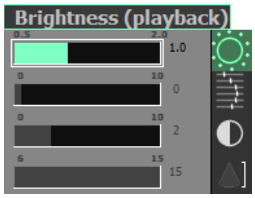


Fig. 50 Brightness control display

DEPTH BRIGHTNESS COMPENSATION (DBC)

DBC imitates TGC and applies brightness curves to the image.

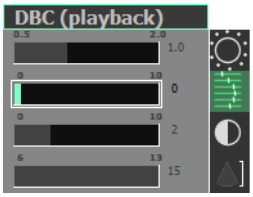


Fig. 51 Depth brightness control (DBC) display

CONTRAST CONTROL

Contrast increases or decreases the contrast between light and dark areas in an image.

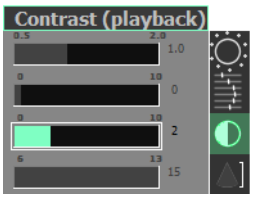


Fig. 52 Contrast control display

DEPTH CONTROL

Depth controls how much of an image you wish visible.

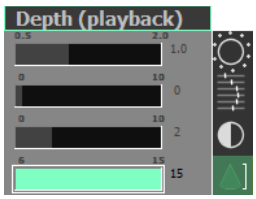


Fig. 53 Depth control display

Cineloop Control Buttons

Once the cineloop is loaded, a set of cineloop playback controls appears on screen, as shown in Figure 51.

Table 8 Cineloop Control Buttons

Button icon	Button name	Function
	Play/Pause toggle	Plays a cineloop.
	Play/Pause toggle	Pauses a cineloop.
	Forward	1. While a cineloop is paused, the Forward button advances the cineloop one frame. 2. While a cineloop is playing, the Forward button increases the playback speed. Playback speeds are: 0.250.5 0.75 1.01.5 2.0
	Backward	1. While a cineloop is paused, the Backward button reverses the cineloop one frame. 2. While a cineloop is playing, the Backward button decreases the playback speed. Playback speeds are: 0.250.5 0.75 1.01.5 2.0
	Jump	Jump to the next ECG marker

Figure 54 below shows where the cineloop controls are located on the imaging screen.

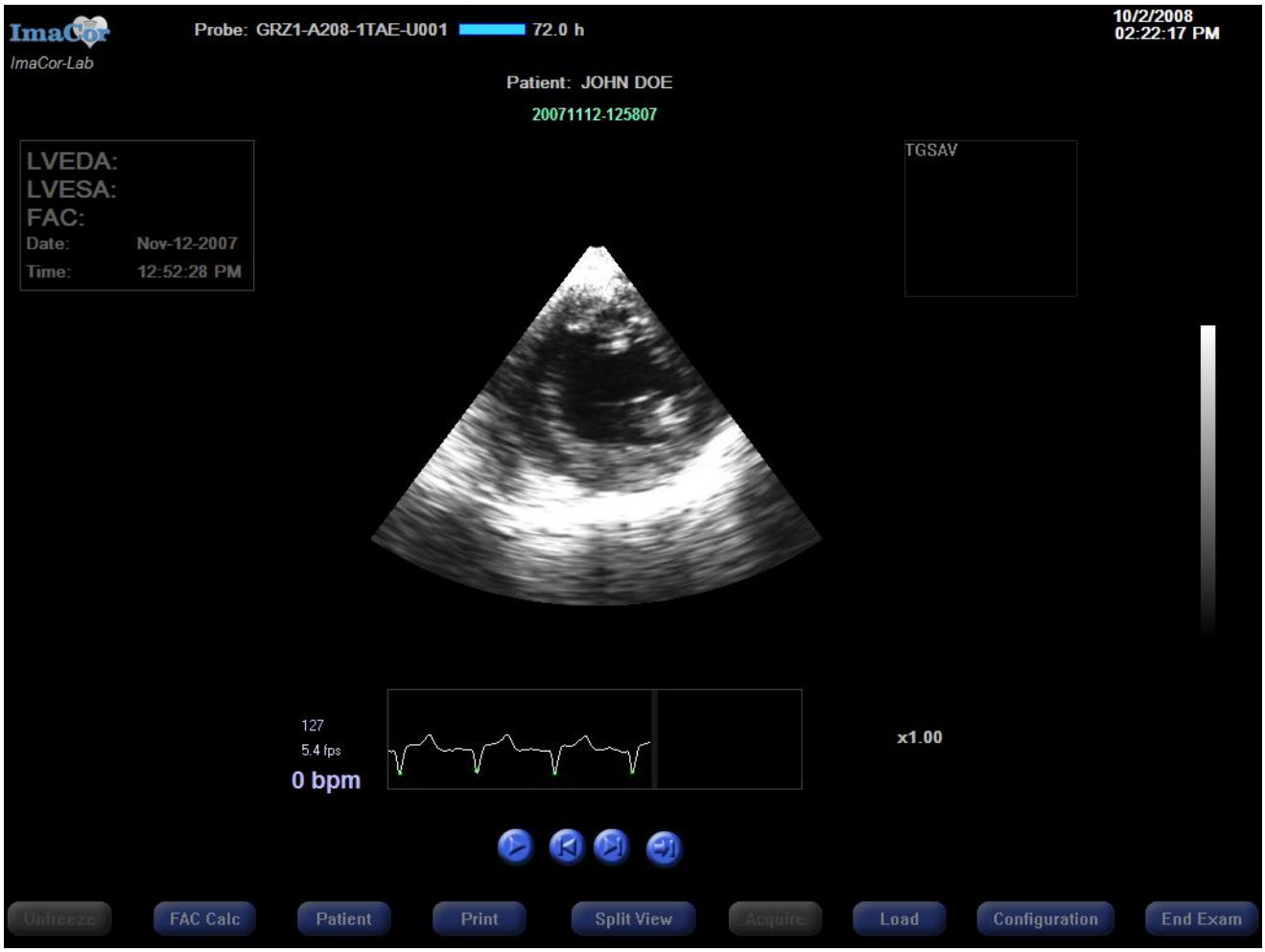


Fig. 54 Single View mode with cineloop control buttons

SCROLLING MODE

Scrolling mode enables you to scroll through frames instead of clicking frame by frame. Scrolling mode acts as a toggle; left click on the image to enable and disable scrolling.

- Roll the trackball right to scroll forward through frames
- Roll the trackball left to scroll backward through frames

Measurement Tools

The Zura system software provides two measuring tools:

1. The Tracing Tool, for area measurements. This tool is key when performing FAC calculations.
2. The Measuring Tape Tool, for distance measurements.

The Tracing Tool

Press the Trace key on the console to access the Tracing tool. If you use the FAC Wizard to guide an FAC calculation, the Tracing tool is automatically activated. When trace mode is ON, the backlit key color changes from the default blue to green. In addition, the informational message "Trace: ON" is displayed on the screen.

CREATING A TRACE

Right click the trackball to set the first anchor point and begin the trace. Once you start tracing, any movement of the trackball sets points at a fixed interval. The interval is called trace resolution and can be changed in the Configuration dialog box (see page 65).

Traces are automatically saved with the patient exam.

A new trace can be used to update a previous trace without using the FAC wizard. To substitute a new LVEDA or LVESA value:

1. Right click the desired field while Tracing or Measuring mode is on and a closed trace is displayed.
2. Select the "Use current trace" option.

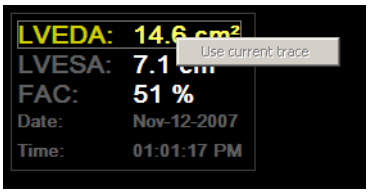


Fig. 55 Manually updating a trace value

The date and time the cineloop was acquired is also displayed in the FAC information area.

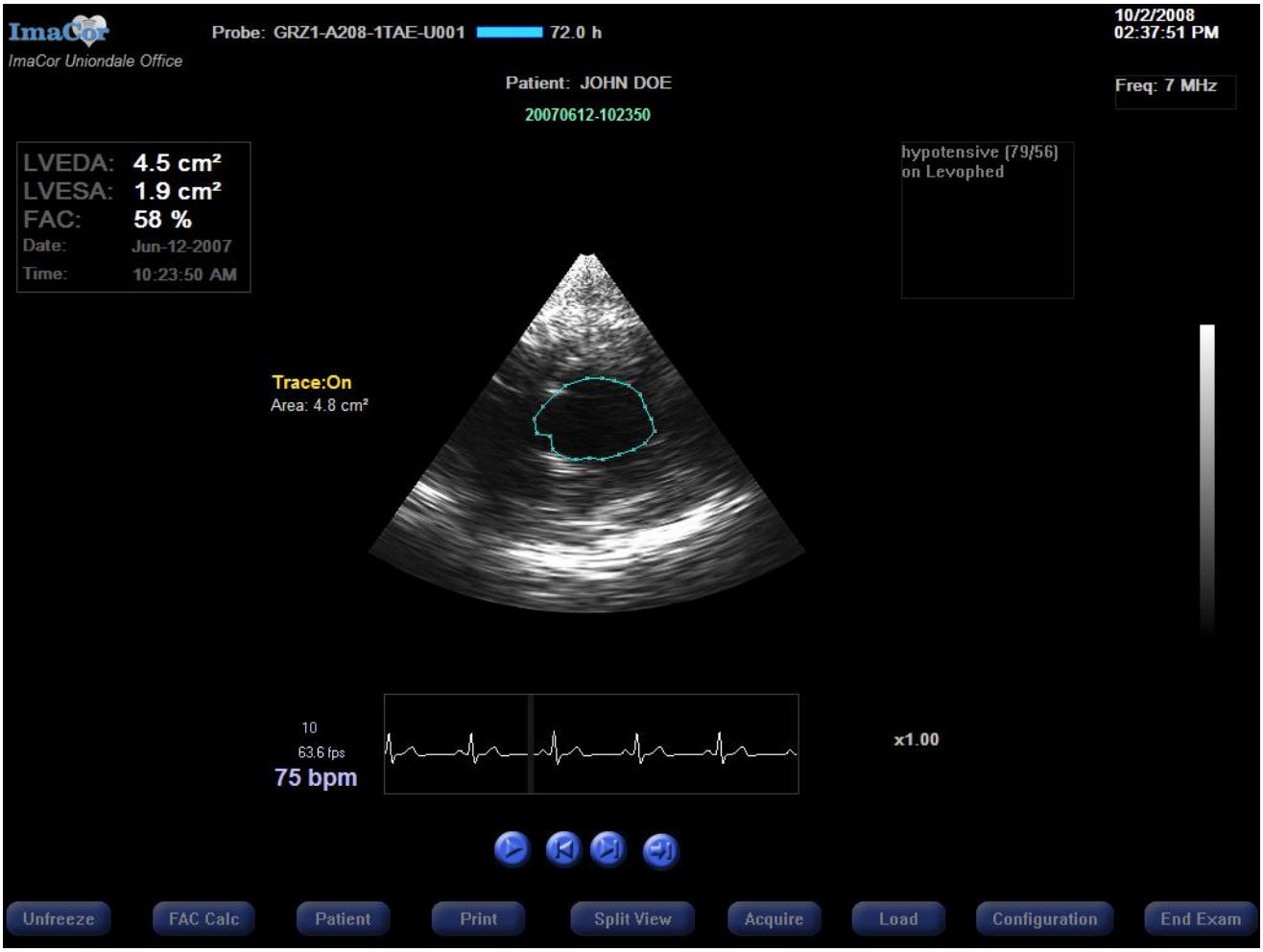


Fig. 56 Single View mode with Trace On

When tracing, the trackball is set to a lower sensitivity to reduce tracing errors. Trackball speed during tracing can be customized in the Configuration dialog box (see page 65). A low speed number indicates low sensitivity; high speed number high sensitivity.

To backtrack one point while tracing, press the Delete or Backspace key. Pressing Delete multiple times erases multiple points.

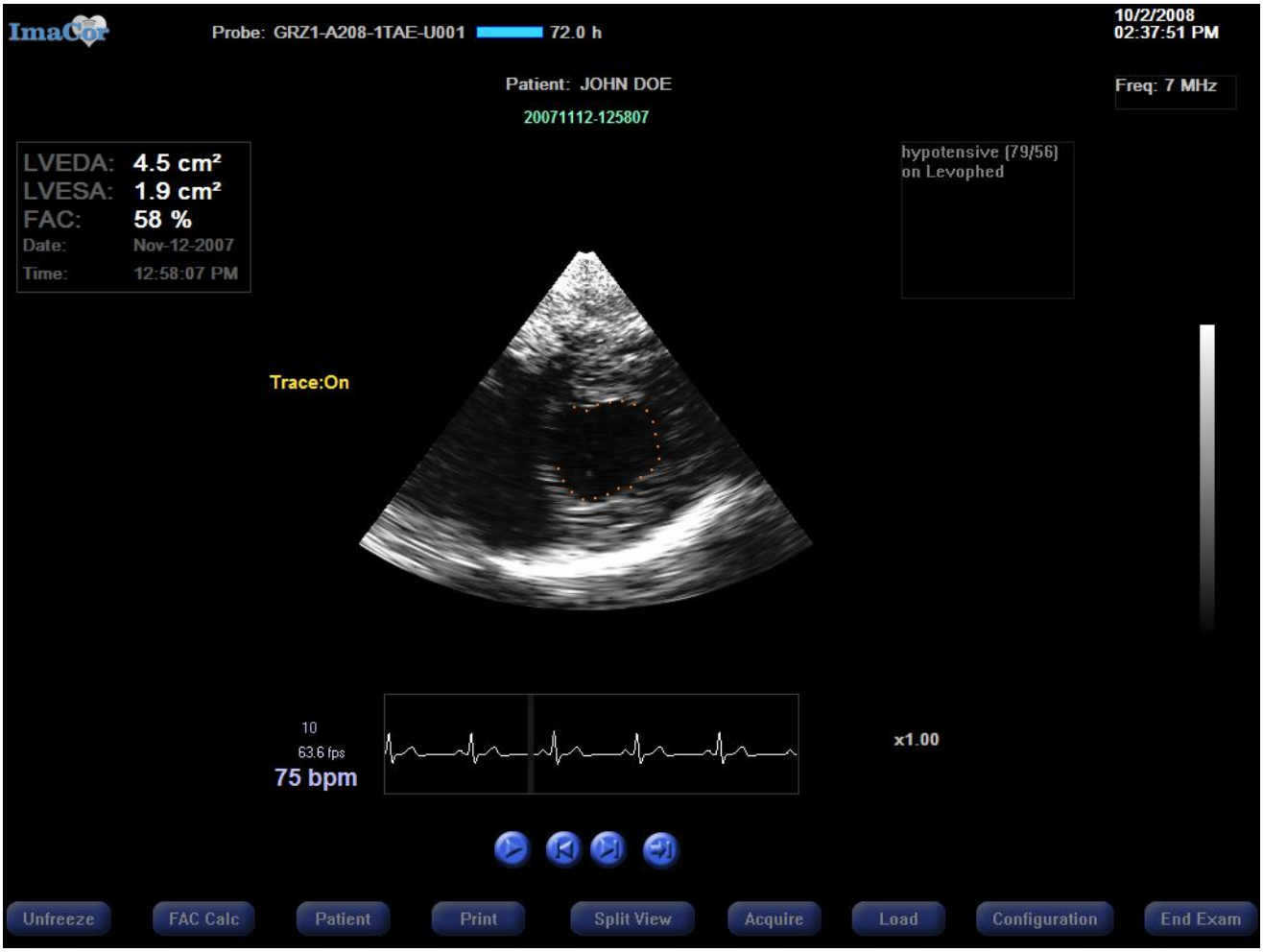


Fig. 57 Trace with multiple points deleted

Right click to close a trace.

Turning off tracing mode hides the trace until tracing mode is toggled 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.

EDITING A TRACE

When the tracing cursor is moved about an anchor point, the anchor point is highlighted and can be edited.

- Press the Delete key to erase the highlighted anchor point. This opens the trace at the location of the deleted point.
- Right click on an anchor point to open the trace at that location without deleting the point.
- Highlight multiple anchor points by holding down the Shift key and moving the trackball left or right; you need not follow the contour of the trace. Press the Delete key to erase the selected segment of the trace. You can then redraw the trace segment.

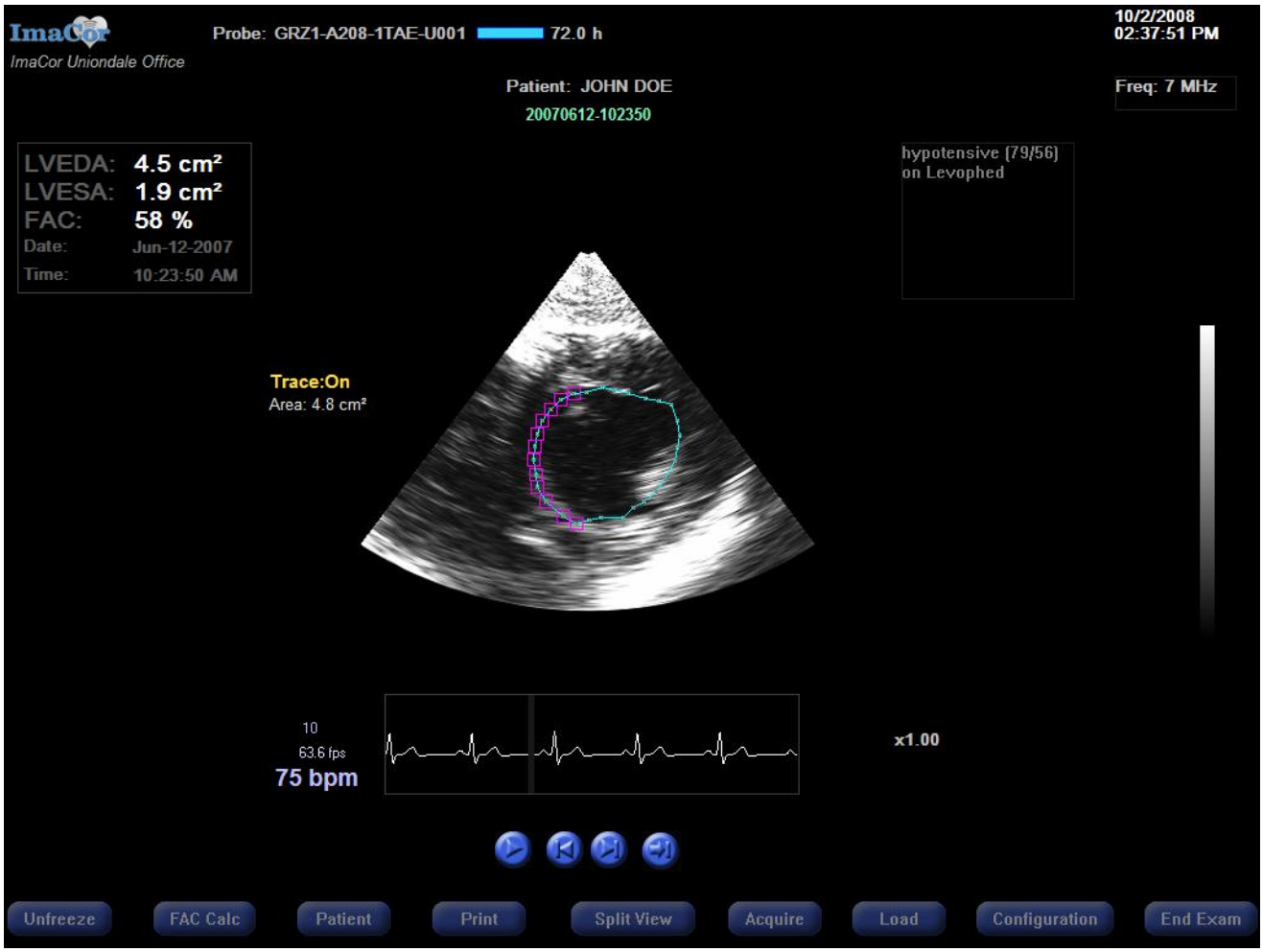


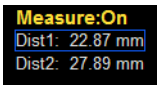
Fig. 58 Single View mode, editing multiple points

DELETING A TRACE

You must be in Trace mode to delete a trace. Be sure no points are selected, then press the Delete key.

To clear all distance and area measurements at once, press the ♡ key and the Delete key in combination.

The Measuring Tape Tool



Press the Measure key to access the measuring tape tool. When measure mode is ON, the backlit key color changes from the default blue to green. In addition, the informational message "Measure: ON" is displayed on the screen.

TAKING A MEASUREMENT

Right click the trackball to set the first end point and begin measuring. Right click again to set the second end point, completing the measurement.

To create a second measurement, right click to set a new starting point, and right click again to set the second end point. You can set a maximum of two distance measurements, which will be labeled on screen as Dist1 and Dist2. The end points are labeled 1 and 2 (see Figure 60).

If the end point of a measurement must begin on top of or very near another point, move the cursor to the desired end point location and pause until the highlight on the neighboring point disappears. Then right click to set the point in the new position.

Distance measurements are automatically saved with the patient exam.

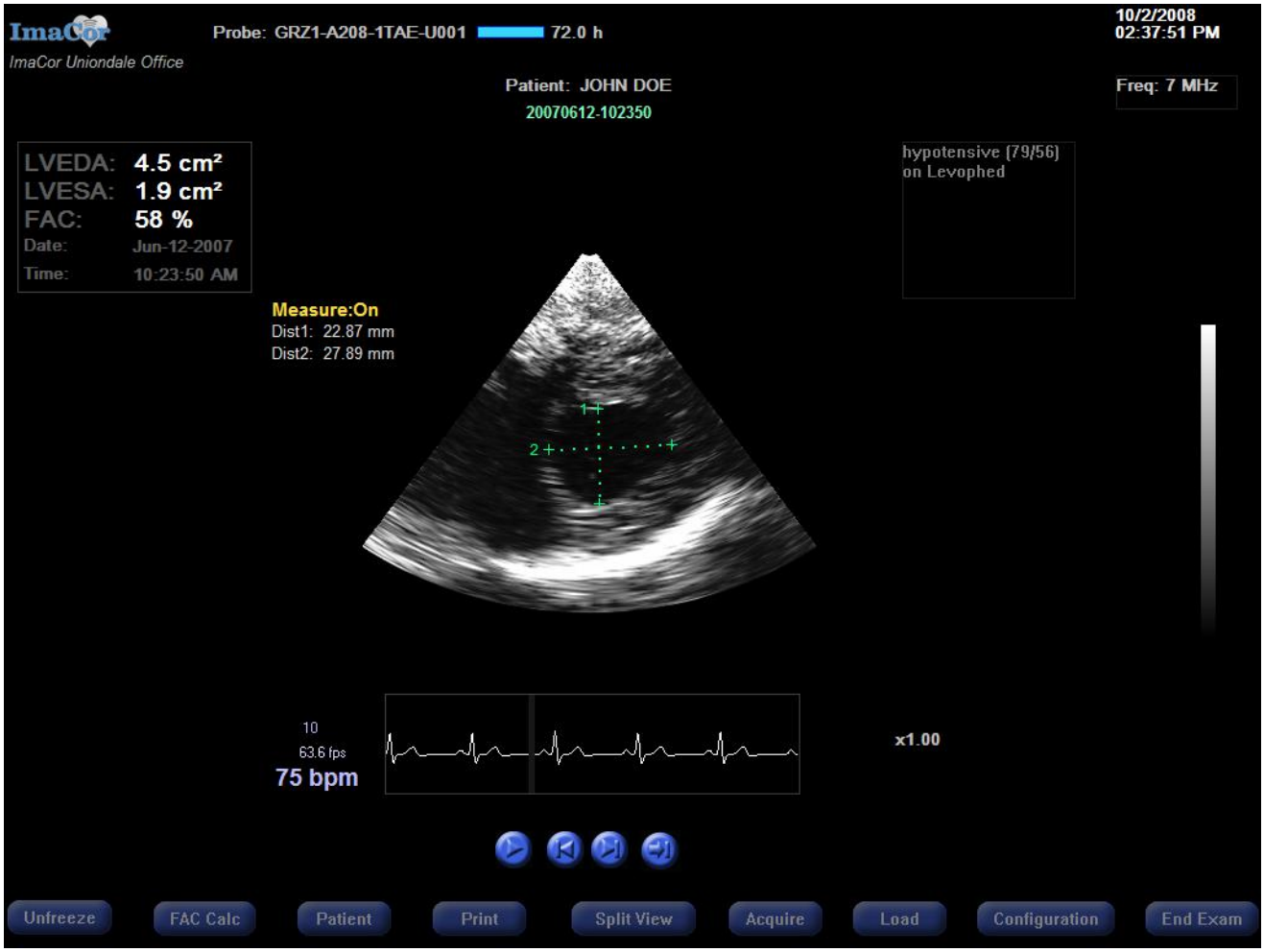


Fig. 59 Single View mode, taking distance measurements

EDITING A MEASUREMENT

Move the tape measure tool about one of the end points (caliper). When the end point is highlighted, right click. This frees the end point, which becomes a floating point. Move the floating point to the desired position, then right click again to reset the end point.

DELETING A MEASUREMENT

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

To clear all distance and area measurements at once, press the ♡ key and the Delete key in combination.

Viewing Measurements

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

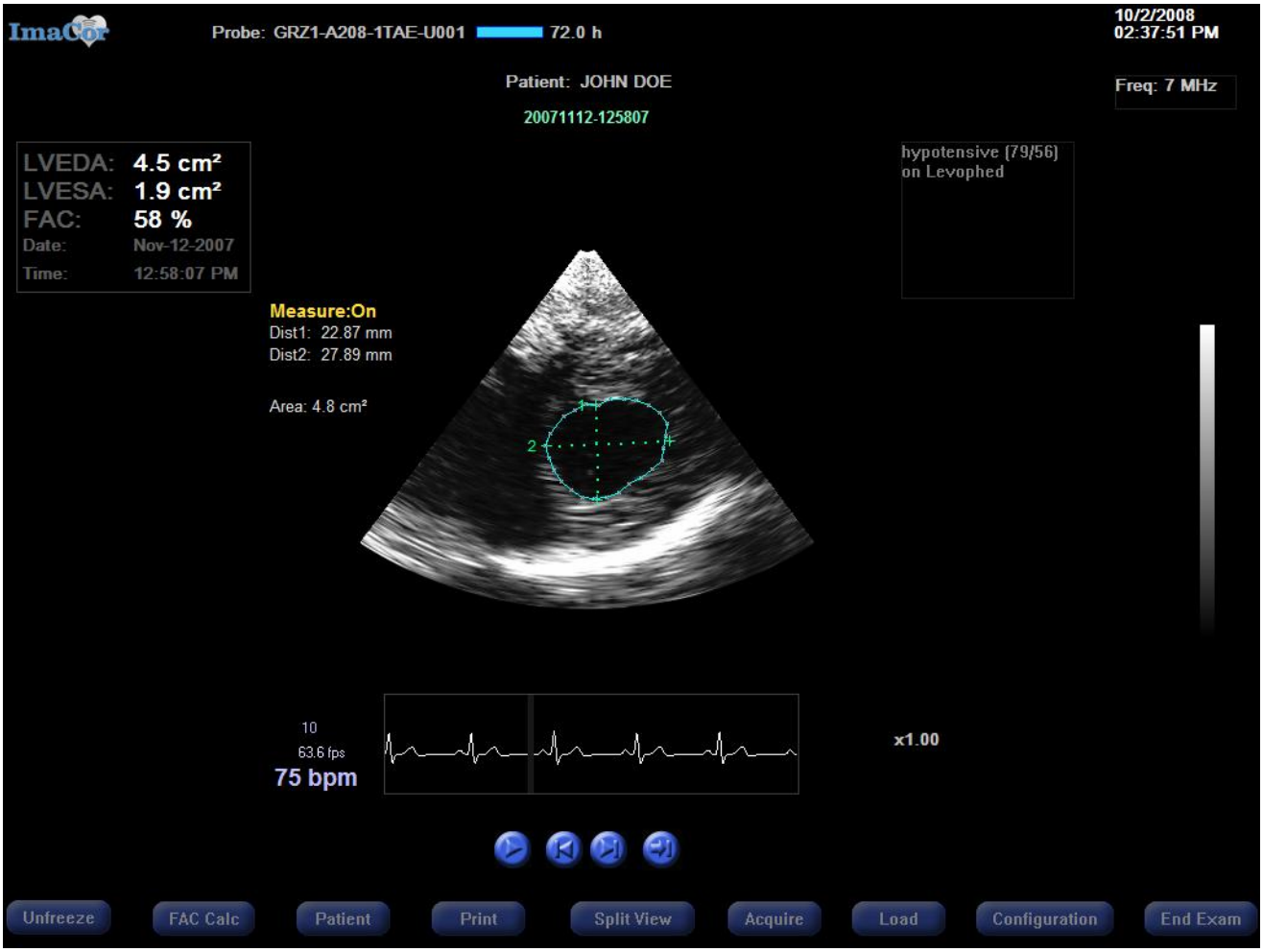


Fig. 60 Single View mode with area and distance measurements

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:

- 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.

Fractional Area Change (FAC) Calculations

Fractional area change (FAC) calculations are based on measurements of the left ventricular end-diastolic area (LVEDA) and the left ventricular end-systolic area (LVESA). The ImaCor Zura system software provides two ways to complete an FAC calculation:

1. The FAC Wizard, which guides you through the process of completing an FAC calculation. The FAC Wizard is available only in Single View mode.
2. Direct measurement by saving a current trace as the LVEDA or LVESA (see "Creating a Trace," page 46).

The FAC Wizard

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

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

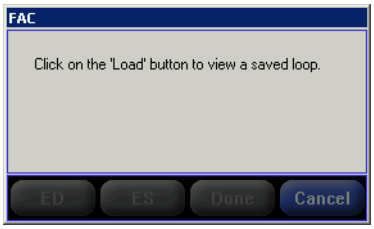


Fig. 61 Load cineloop instructional message

2 With a cineloop loaded, step or scroll through the loop and select the end-diastolic frame.

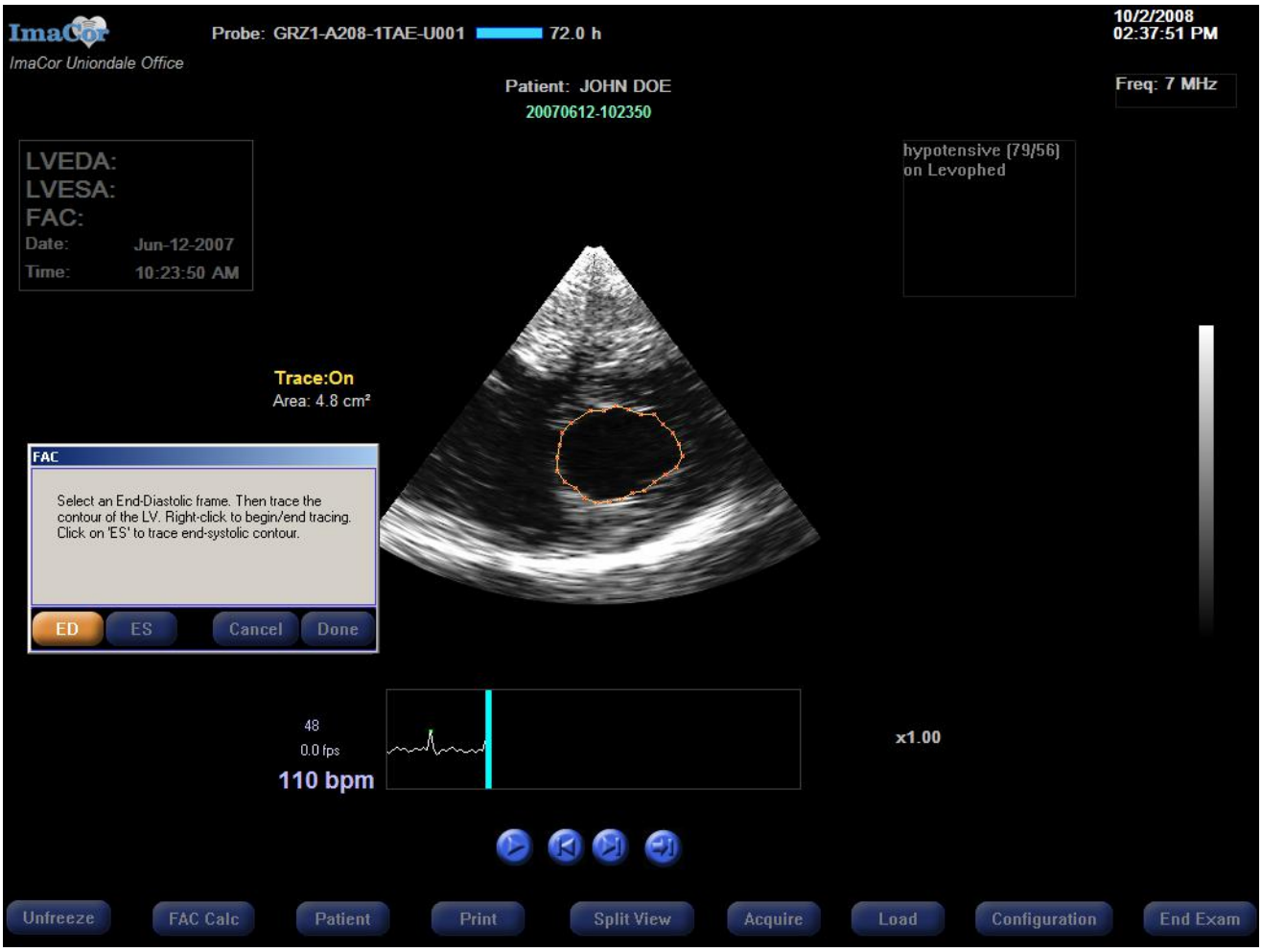


Fig. 62 FAC calculation in Single View mode – end diastolic identification and trace

3 Right click the trackball to set the first anchor point, then begin tracing. When you complete the trace, right click again to close the trace. The LVEDA value is displayed on screen, as shown in Figure 63.

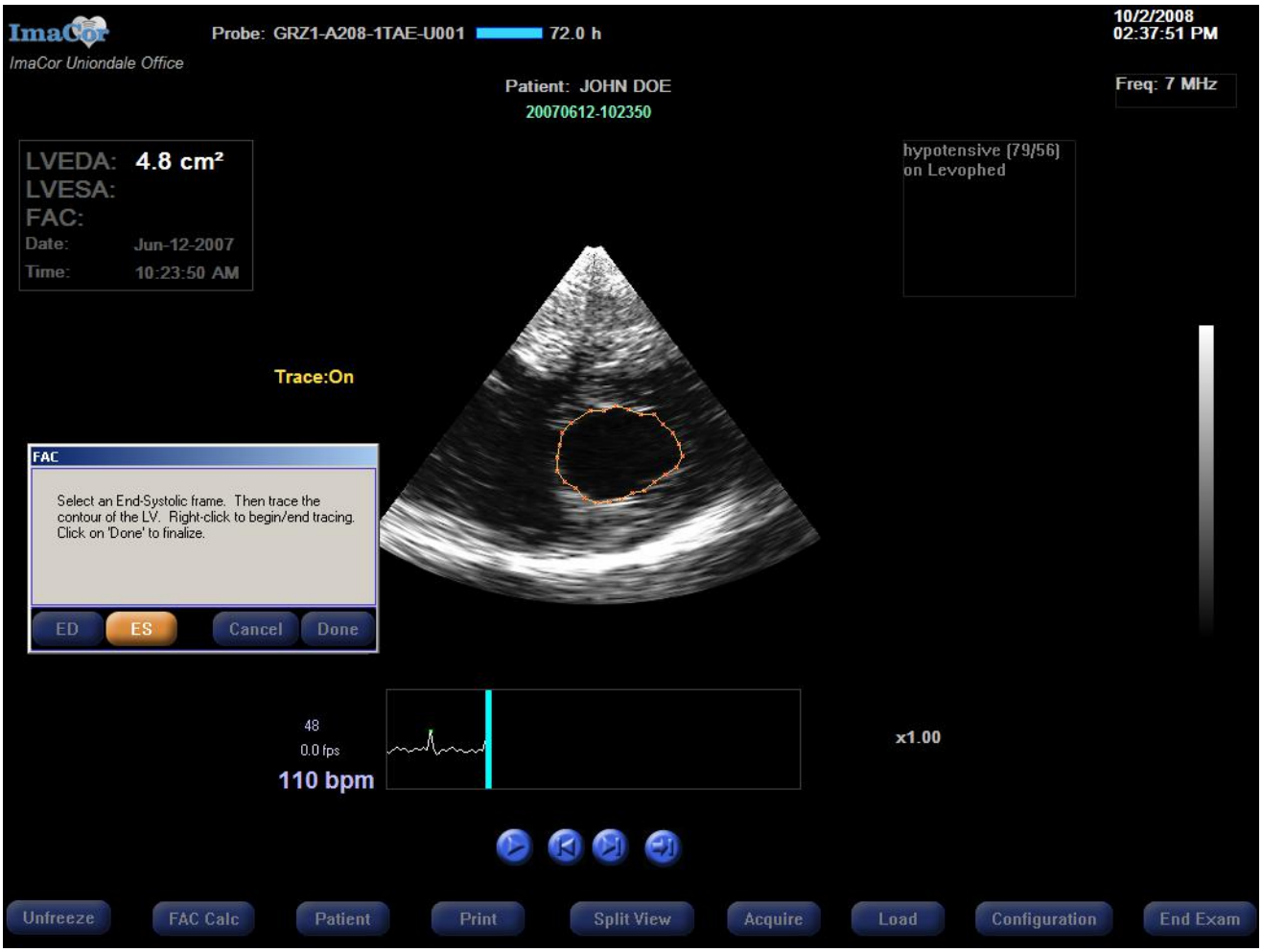


Fig. 63 FAC calculation in Single View mode – end systolic identification and trace

4 Click the ES button. Scroll or step through the frames and select an end-systolic frame.

5 Trace the LVESA.

6 When you have finished, click the Done button. The LVEDA, LVESA, and FAC values are automatically calculated and displayed, as shown inFigure 64.

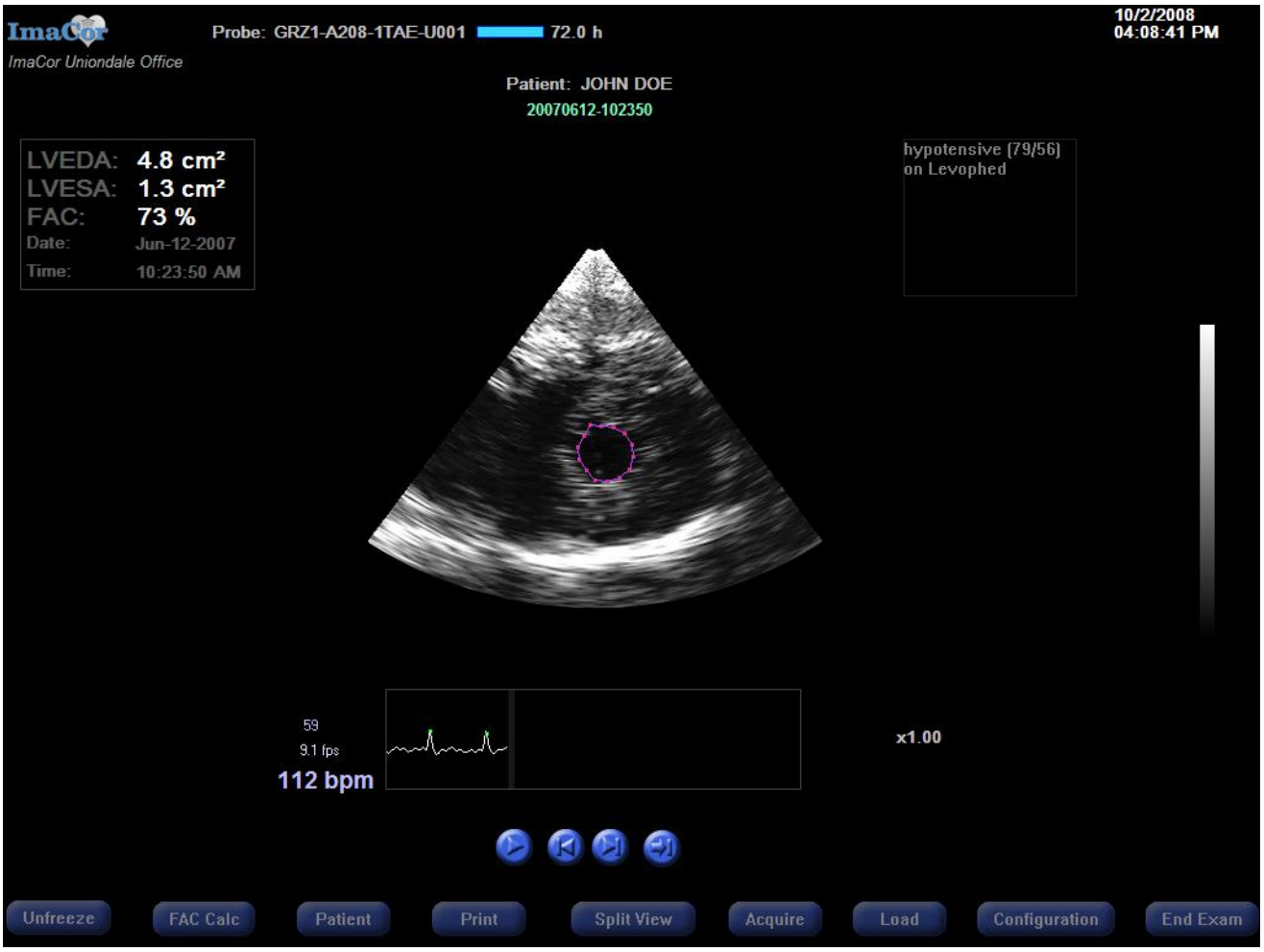


Fig. 64 Completed FAC calculation

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.

REVIEWING A TRACE

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

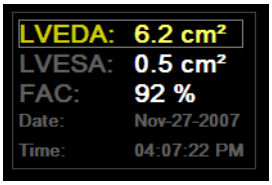


Fig. 65 FAC calculation results

TRACE OVERLAY MODE

Trace overlay mode allows you to display or hide the LVEDA and LVESA traces on cineloops. When overlay mode is active, the color of the backlit Overlay console key changes from the default blue to green.

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

1. Activate the FAC Wizard to automatically turn on trace overlay mode.
2. Left click the LVEDA or LVESA value.
3. Press the Overlay console key to toggle overlay mode on and off.

Trace overlay mode can be turned **off** by pressing the Overlay console key.

SUPERIMPOSED COMPARISON

When two cineloops are loaded in Split View mode and both have FAC calculations, traces can be compared by superimposing one on the other. See page 56 for details.

Deleting a Cineloop

You can store a maximum of 50 cineloops per patient. As you near a patient's cineloop limit, warning messages are displayed, as shown in Figure 66.

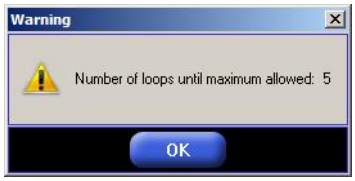


Fig. 66 Warning: cineloop limit approaching

Once 50 cineloops have been saved, you cannot acquire additional images unless you overwrite the oldest loop or delete one or more cineloops. For additional information, see the master message listing, page 84.

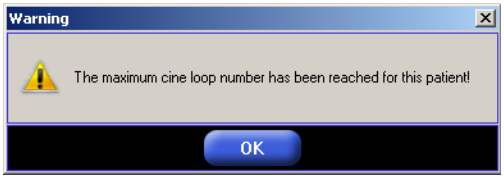


Fig. 67 Warning: cineloop limit reached

To delete a cineloop:

1. Press the Load button.
2. From within the Load Loop dialog screen, select a cineloop and right click.
3. When popup menu appears, select Delete.

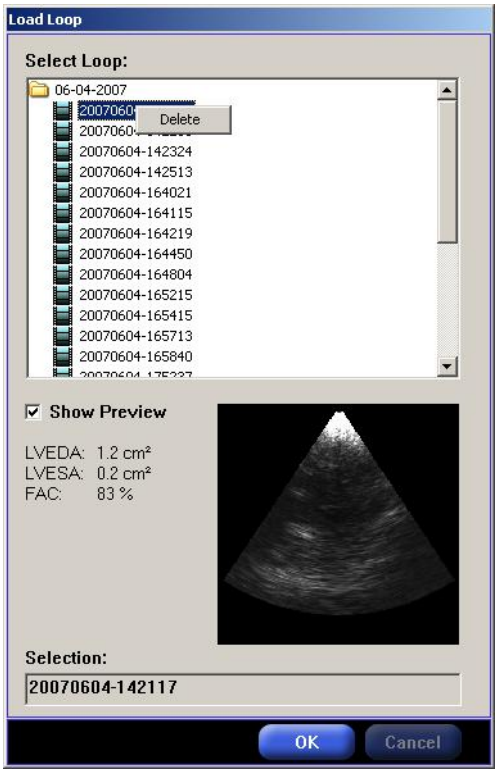


Fig. 68 Delete cineloop screen

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

Fig. 69 Delete cineloop confirmation

Split View Mode

Split View mode enables you to evaluate side by side either two cineloops (Figure 70) or a cineloop and real-time imaging (Figure 72). The Views key on your console acts as a toggle between Single and Split View.

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

Steering is available in Split View mode provided real-time imaging is taking place.

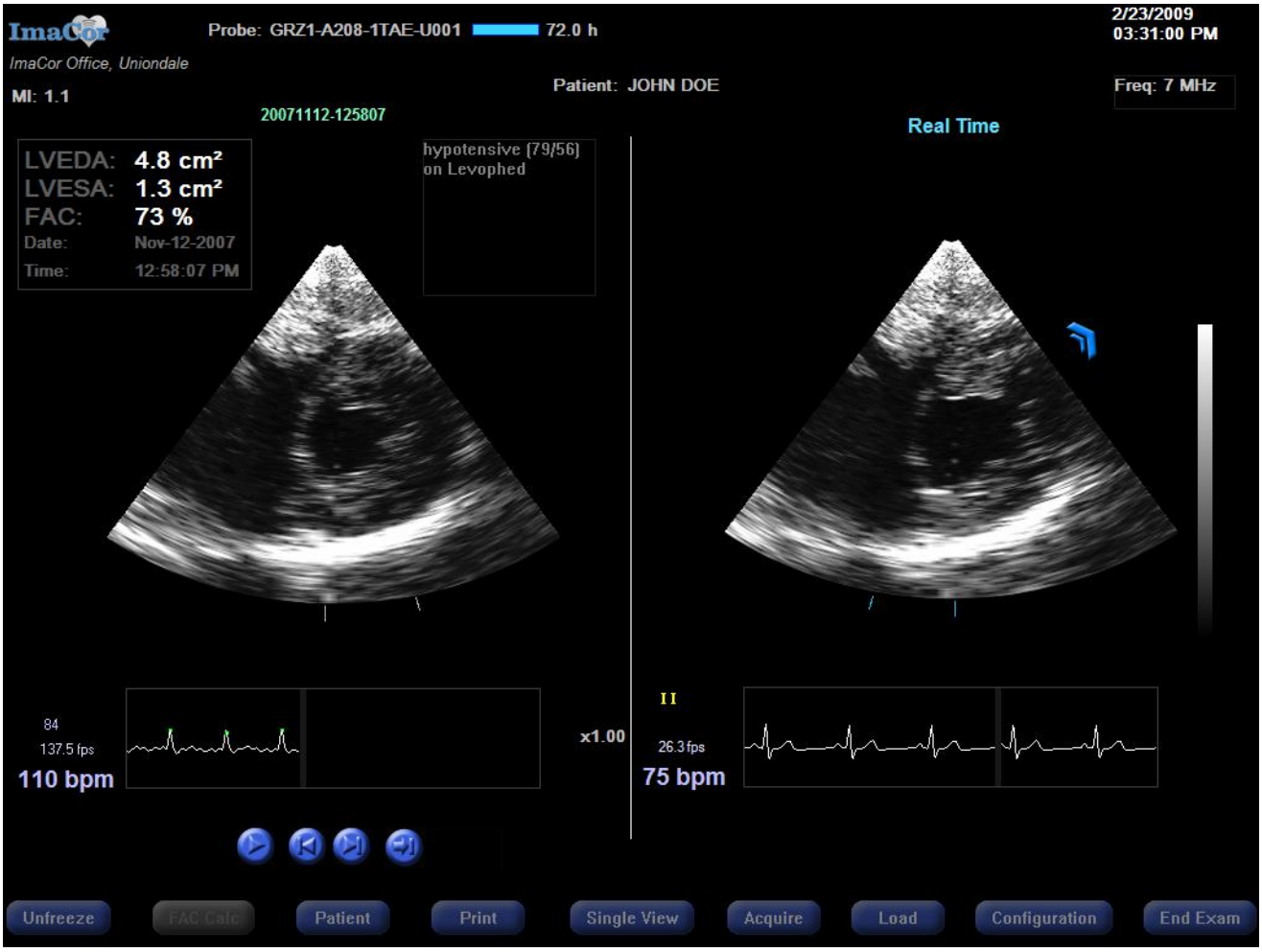


Fig. 70 Split View mode – cineloop comparison

Loading Two Cineloops in Split View Mode

1 Click the Load button.

2 When the Load Loop window is displayed, select a loop from the left and the right pane, as shown in Figure 71.

3 When the cineloops have been selected, press the OK button.

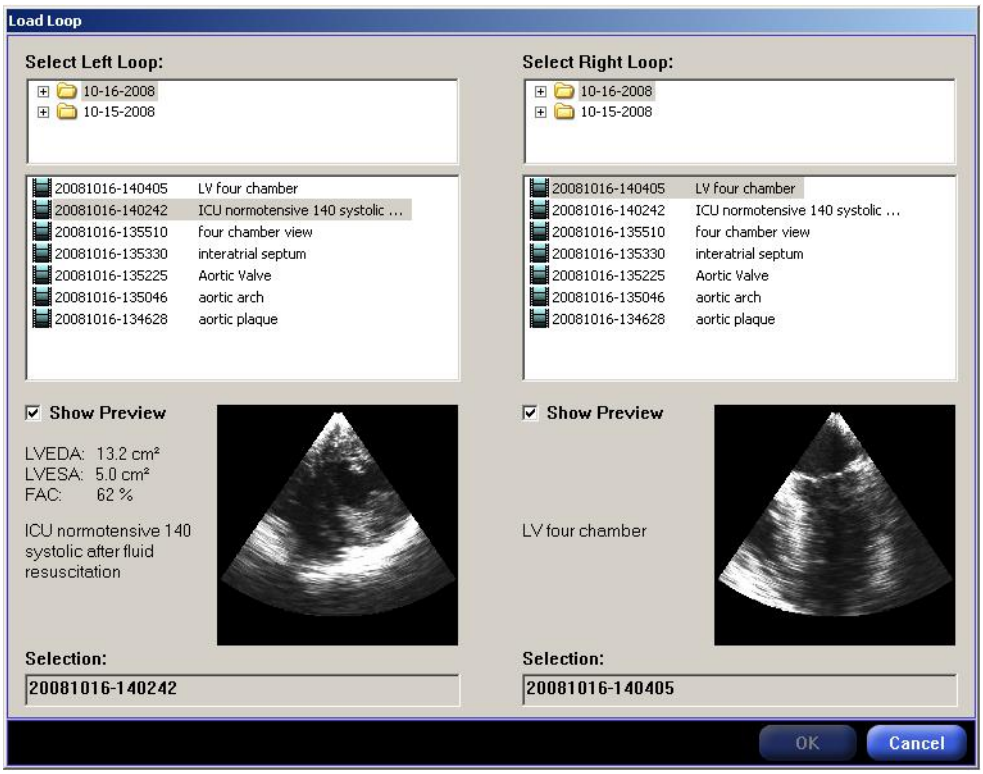


Fig. 71 Split View mode – loading two cineloops

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

1 Click the Load button.

2 When the Load Loop window is displayed, select a cineloop from the **left** pane.

3 When the cineloop has been selected, press 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. Click the Unfreeze button to resume real-time imaging.

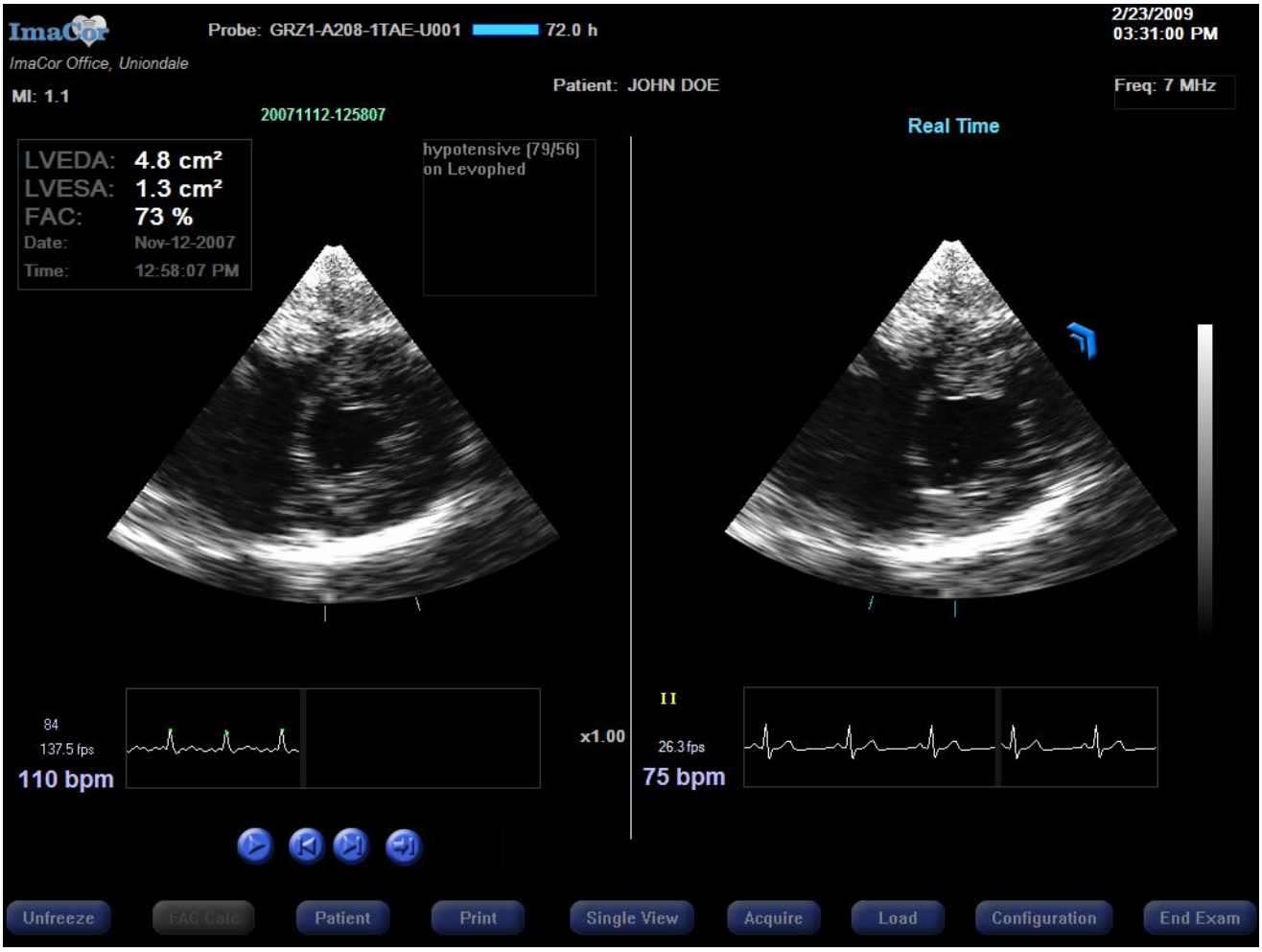


Fig. 72 Split View mode – real-time image and cineloop comparison

Synchronized 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.

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, click on the Jump to ECG marker button, located below the corresponding cineloop.

2 Repeat the process on the other cineloop, if desired.

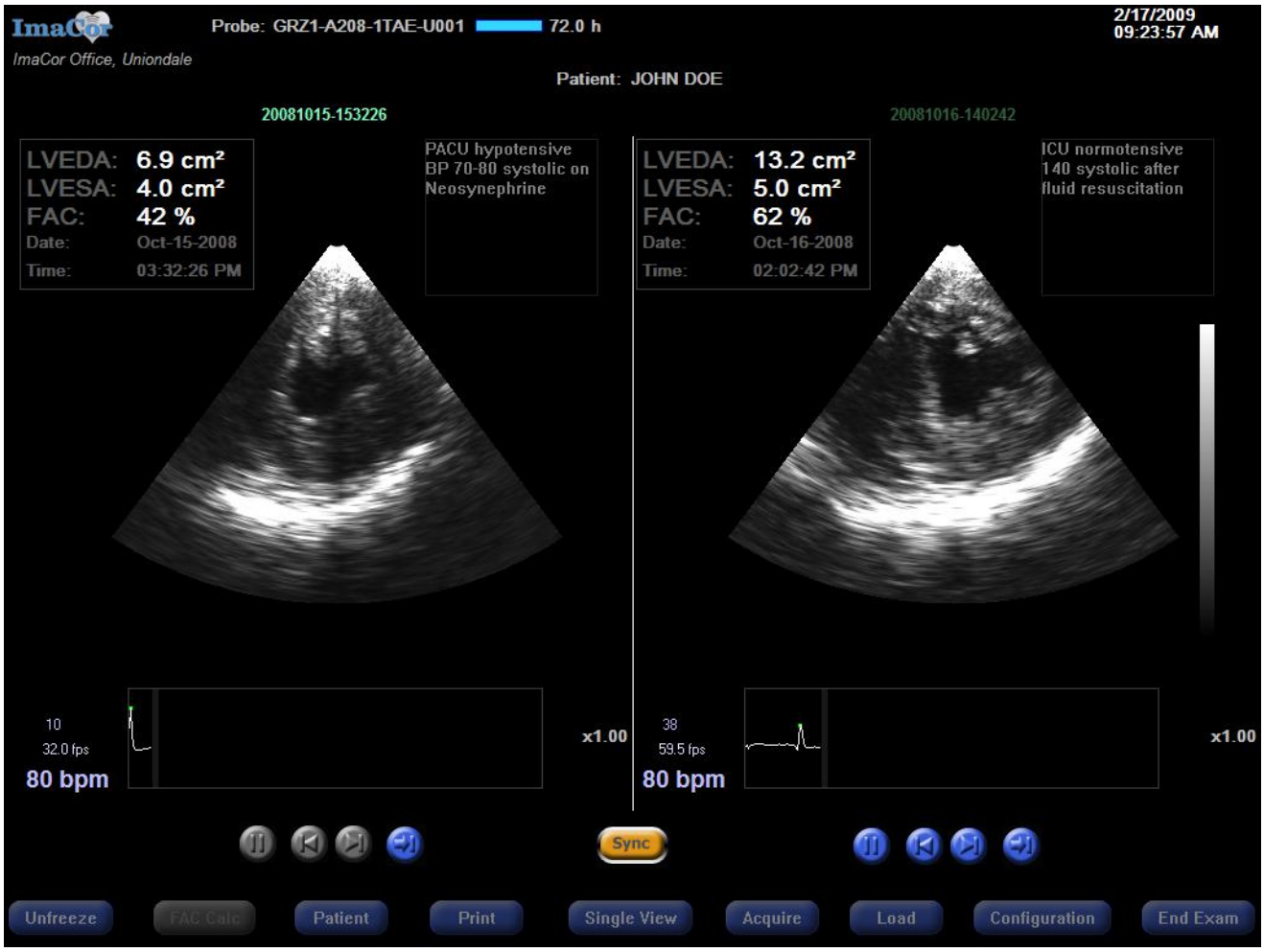


Fig. 73 Synchronized playback

ACTIVATING AND DEACTIVATING SYNCHRONIZED PLAYBACK

The Sync button, shown in Figure 74, toggles synchronized playback on and off.

Fig. 74 Playback buttons with Sync button active.

PLAYBACK SPEED CONTROLS

During playback, the Forward and Back buttons act as speed controls. Forward 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.

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

Superimposed Mode

Traces can be superimposed for comparison. The Compare ED/ES menu is enabled when two cineloops are loaded and each cineloop has FAC data.

To access the menu, right click on the image and select Compare ED/ES from the popup, as shown in Figure 75.

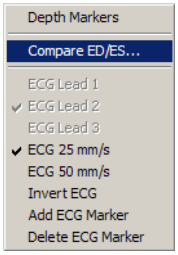


Fig. 75 Compare ED/ES menu option

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 76).

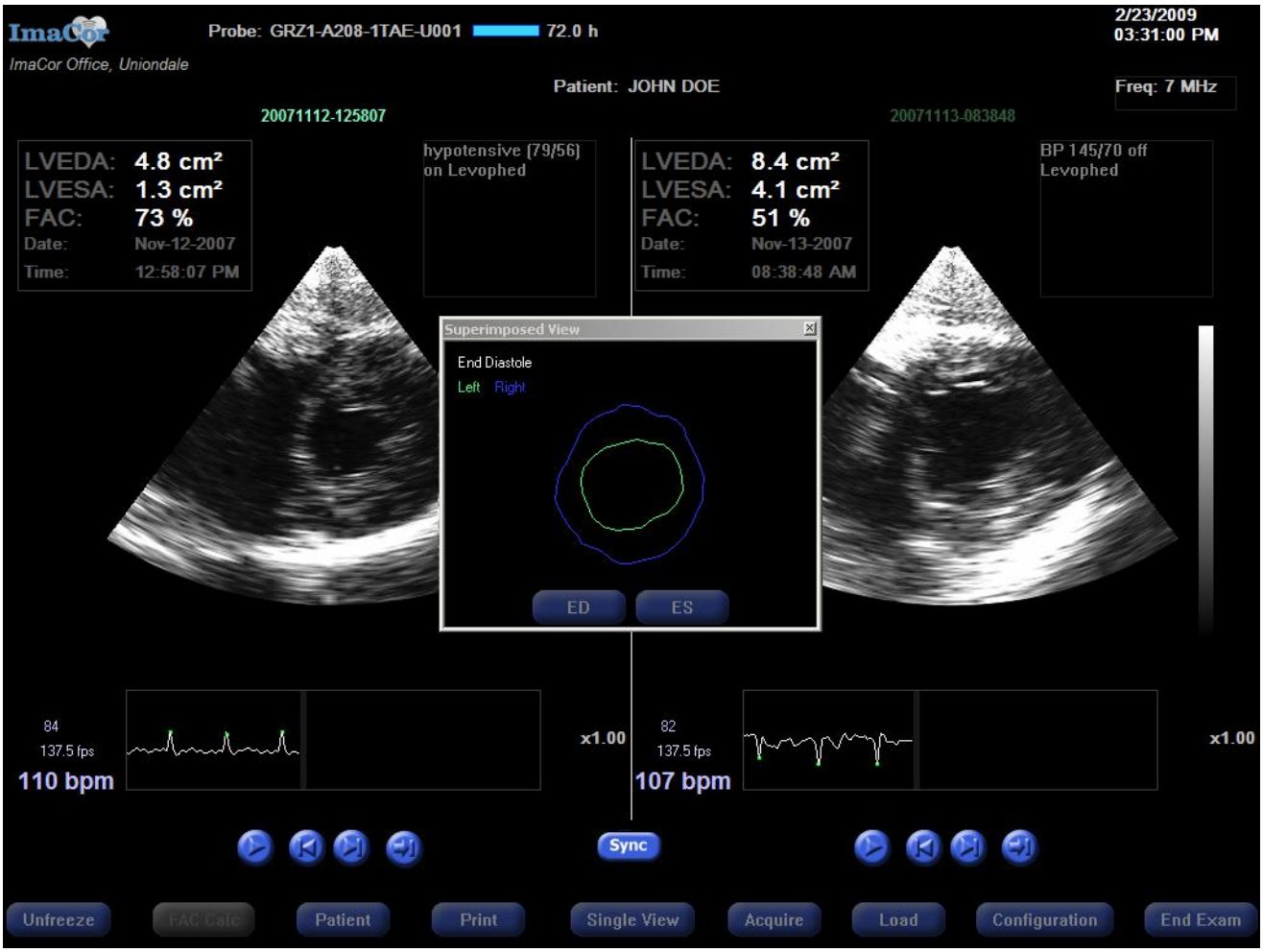


Fig. 76 Split View mode with Compare ED/ES selected

To view superimposed LVESA traces, click the ES button on the Superimposed View window.

Printing

Single View Mode

Press the Print button to produce a hardcopy of the active frame, as well as FAC measurements and comments, if applicable. The ECG waveform is not included in the printout.

Split View Mode

Press the Print button and select from the print dialog box the image you wish to print.

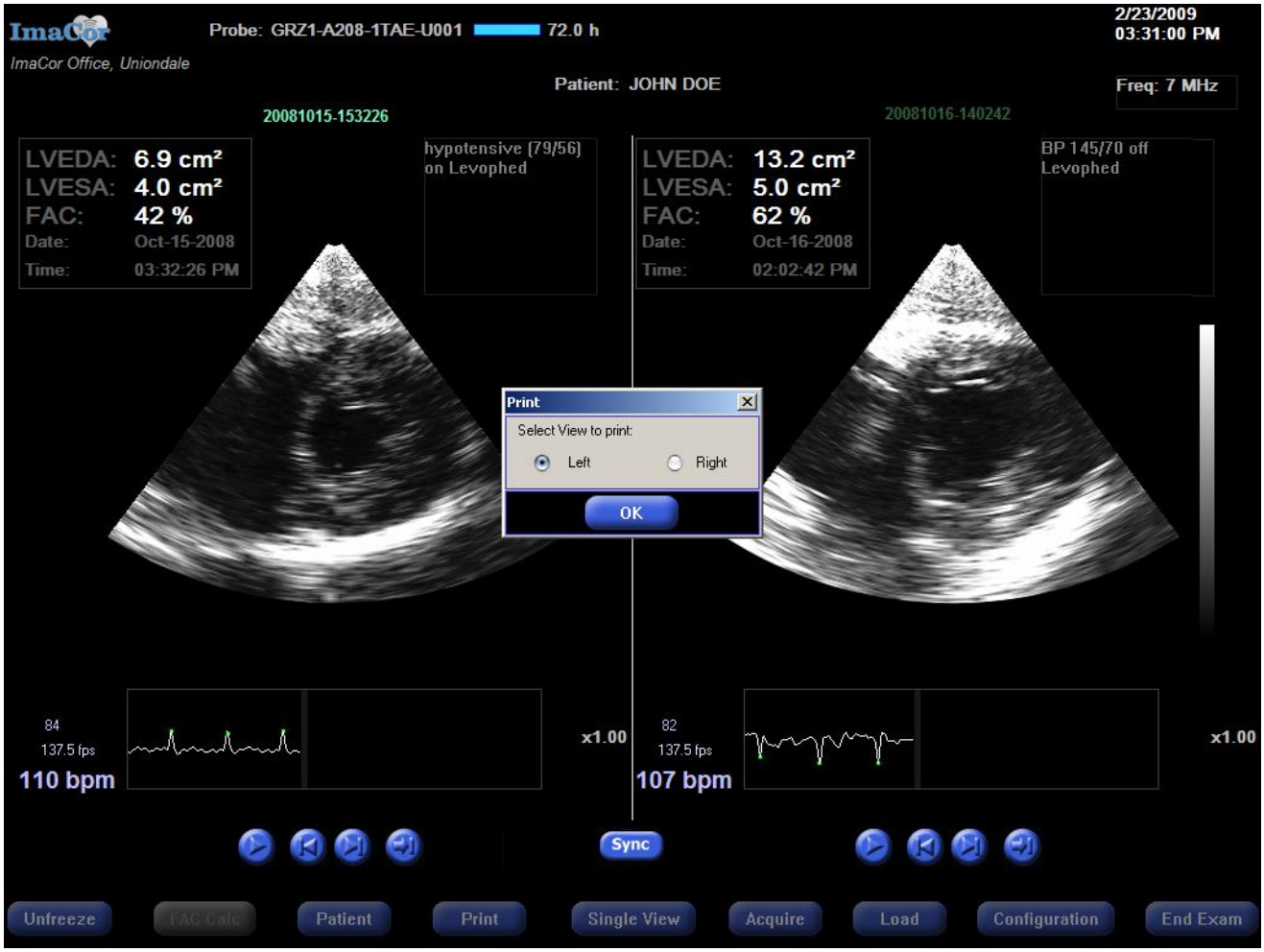


Fig. 77 Print dialog box in Split View mode

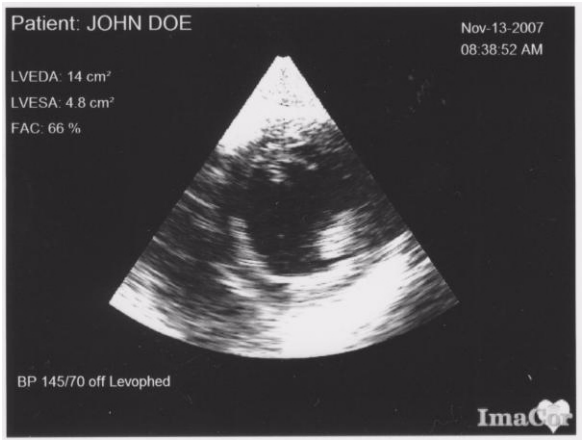


Fig. 78 Sample printed output

The warning message below is displayed if you attempt to use a printer that isn't properly connected to the system. For more information, see the master message listing on page 84.

Fig. 79 Printer connection error message

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.

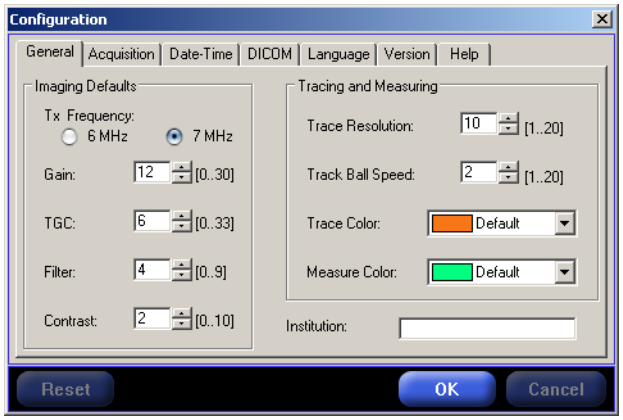


Fig. 80 Configuration > General tab

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 Trackball Speed

When tracing is enabled, the speed of the trackball is automatically lessened to reduce errors. The Trace Trackball Speed option enables you to specify a custom trace speed. The speed range is 1–20, with 1 being the lowest speed and 20 the highest.

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.

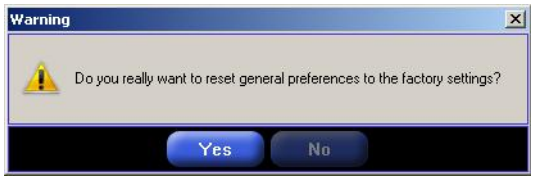


Fig. 81 Reset button confirmation screen

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.

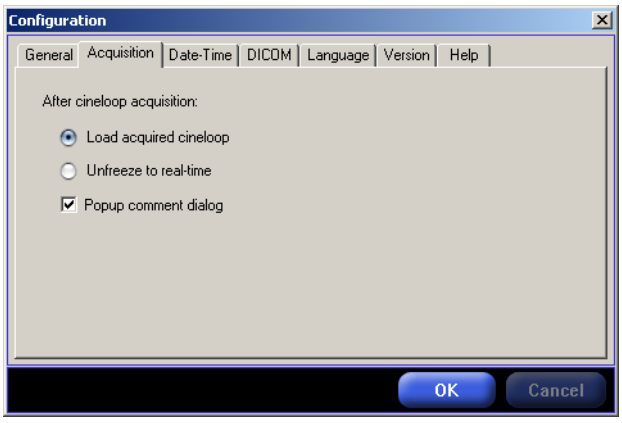


Fig. 82 Configuration >Acquisition tab

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.

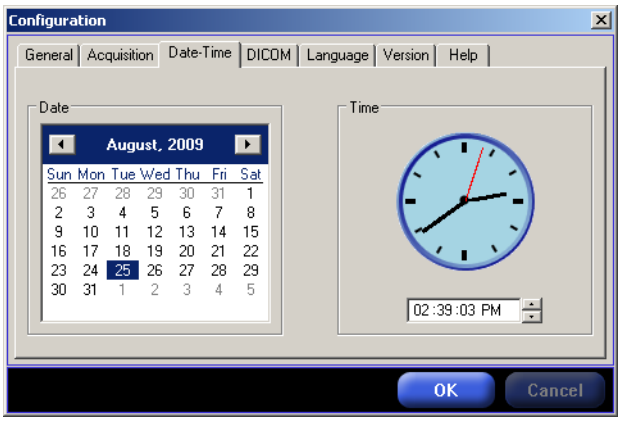


Fig. 83 Configuration > Date-Time tab

DICOM

The DICOM (Digital Imaging and Communications in Medicine) tab enables you to :

(1) specify that images (cineloops) be exported in DICOM format

(2) indicate if JPEG compression should be applied

(3) configure a DICOM Archiving Server

(4) configure a DICOM MWL Server

DICOM is the standard format for distributing and viewing all types of medical images.

DICOM files contain the following information:

- Patient information
- Cineloop
- ECG
- LVEDA, LVESA, and FAC, if present

Patient Export Option

If the Export DICOM option is selected, DICOM files are automatically created as cineloops are exported to a DTM.

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

Notes:

1-If multiple patient records are selected for export and the Overwrite DICOMDIR when Exporting option is checked, only the last patient selected will appear on the DICOMDIR.

2-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 Application Entity Title (AET)
- Host name / IP Address
- Port number

By default the client AET for Zura is ZURA. It can be changed to anything suitable by an ImaCor technician when the System is configured.

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 Screen.

Custom Synchronization Rules

The Zura System provides 3 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

For example if rules (1) and (2) are turned ON, only cineloops that have a comment and that 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.

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. Compression option applies to both exported data and data sent to the DICOM Archiving Server (if configured).

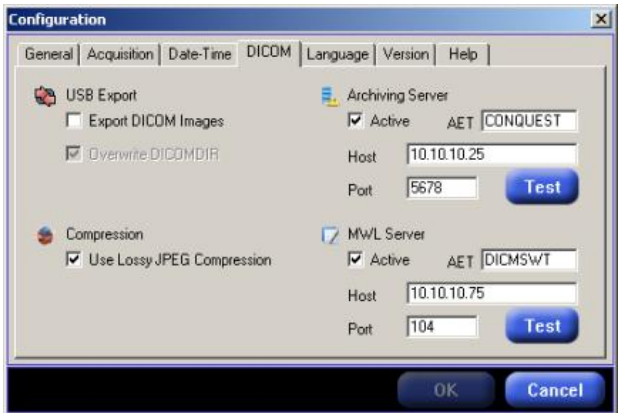


Fig. 84 Configuration > DICOM tab

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.

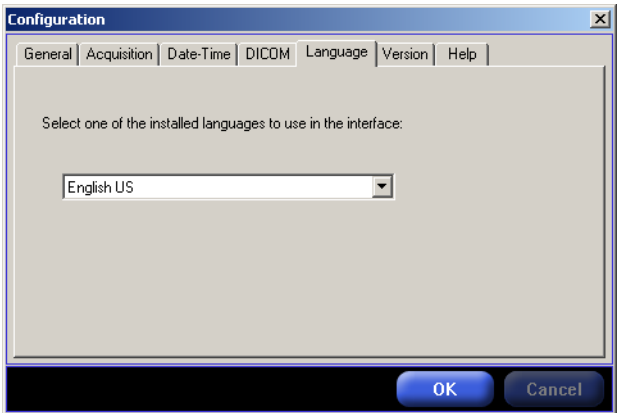


Fig. 85 Configuration > Language tab

Version

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

Fig. 86 Configuration > Version tab

Upgrade Licensing

Upgrade packages are machine-specific and require a registration code that is displayed in the Configuration Dialog >Version tab (see Figure 86).

The upgrade process requires eleven steps:

1 Insert a USB drive in one of the USB ports. You need not use a DTM.

2 With the Configuration > Version screen active, right-click on Registration Code.

3 Left-click on "Export to USB Drive..."

4 When a confirmation message is displayed, click on "OK." The registration code is saved to the USB drive under the filename "ZuraRegCode.txt"

Fig. 87 Exporting the registration code to a thumb drive and updating the software

5 Email the registration code file—ZuraRegCode.txt—to ImaCor at: support@imacormonitoring.com
ImaCor will create a custom license package and email a link where the package can be downloaded.

6 Download the upgrade package and save it to a USB thumb drive.

7 Insert the thumb drive into the console, then click the Update button on the Configuration > Version tab, shown above inFigure 87.

8 When the contents of the USB thumb drive are displayed, select the upgrade package and click "Open."

9 The upgrade Setup Wizard starts and leads you through the process of installing the upgrade package. Follow the instructions on the initial upgrade Setup Wizard, then press the Next button.

Fig. 88 Initial upgrade Setup Wizard screen

10 When the License Agreement is displayed, read the agreement carefully.

- To accept the agreement, press the I Agree button. You must accept the license agreement to proceed with the upgrade.
- To return to the initial Setup Wizard screen, press the Back button.
- To cancel the upgrade, press the Cancel button.

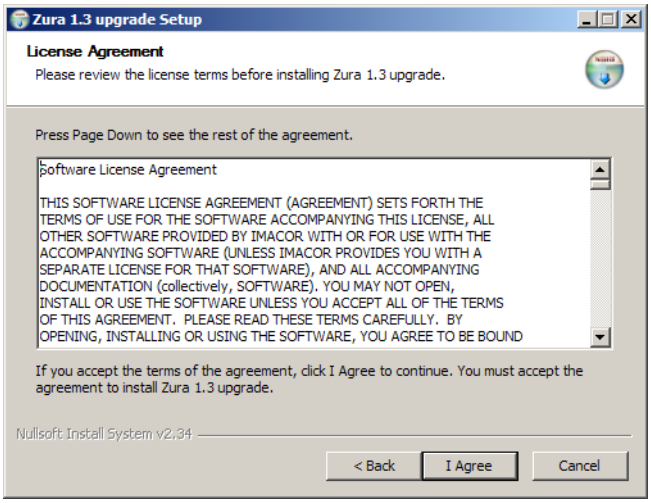


Fig. 89 License Agreement screen

11 When the final upgrade Setup screen is displayed, click the OK button. The upgrade process is complete.

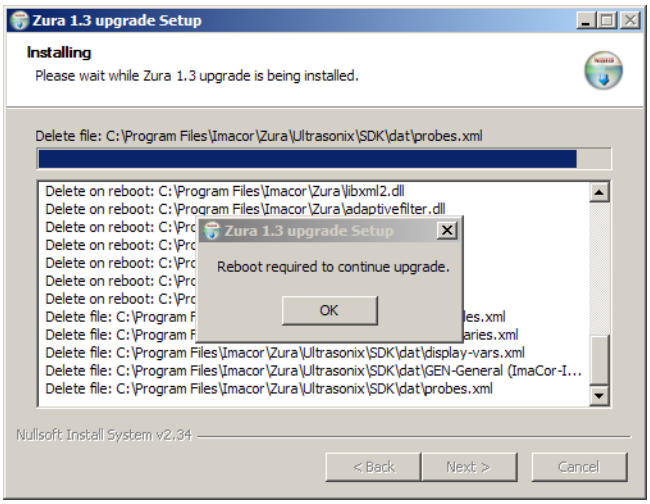


Fig. 90 Final upgrade Setup Wizard screen

Help

In addition to the online Help system (see page 19), the Zura system provides two other user assistance options:

1. ToolTips
2. Remote Assistance

Fig. 91 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 (see Figure 92 and Figure 93).

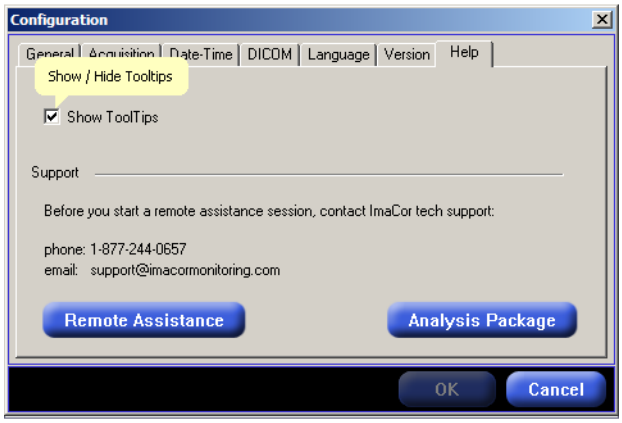


Fig. 92 ToolTips selected in Help menu

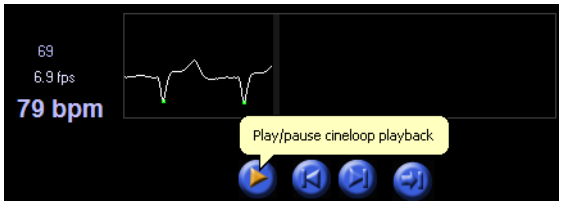


Fig. 93 ToolTips visible in imaging screen

Remote Assistance

The Remote Assistance button enables you to establish a link with an ImaCor technician who can access the Zura system remotely for troubleshooting.

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

- Enter the 6-digit PIN code provided by ImaCor tech support.
- 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:

- Select Configuration > Help
- Insert an external USB drive into the USB port in the Zura system. You need not use the special ImaCor data transfer module; any operational USB drive will work.
- Click the Analysis Package button

Email the analysis package (ZuraPkg.zip) to support@imacormonitoring.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 94 is displayed.

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

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

Fig. 94 Analysis package export error

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

Chapter 5: Safety

Read this safety information before using the ImaCor Zura system. The information applies to the entire system: machine, umbilical, disposable probe, and accessories.

Disposable ImaCor Probe

The ClariTEE probe is delivered 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**

- 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-use only.
- 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 other wised contaminated by blood, body fluids, or other biological materials. Do not sterilize or disinfect the ClariTEE disposable probe.
- Do **not** use isopropyl alcohol on the probe or umbilical cable.
- 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.

The ALARA Principle

The Zura system has been designed in accordance with the principle of ALARA. ALARA is an acronym for an important principle in ultrasound energy protection and stands for “As Low As Reasonably Achievable.” The aim is to minimize the amount of acoustic energy exposure to that which is necessary to accomplish the intended diagnostic use of the device.

Applying ALARA

The Zura 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 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 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.

Reboot the computer if the system ceases to operate or appears frozen; i.e., does not respond to keystroke commands.

Note: If a "No Coupling" message is displayed, the probe is not making adequate contact with tissue for imaging.

TWENTY MINUTE SOFTWARE INTERLOCK

If the operator leaves the Zura 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.

TEE is considered a safe procedure in that the chances of adverse events are low. In rare instances the following patient risks are associated with transesophageal echo:

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

Electrical Safety

The Zura 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 gasses 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 electromagnetic interference (EMI) in other devices in the vicinity. The Zura 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 radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the ultrasound system. Evidence of disruption may include:

- image degradation or distortion
- erratic readings
- equipment ceasing to operate
- 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 Zura 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 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 Pre-Amendments Acoustic Output Levels

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

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

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

[3]MI Mechanical Index

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

Table 10 ImaCor Zura Acoustic Output Levels (MI)

Tx Frequency	Continuous Mode		Acquisition Mode		Recovery Mode	
6 MHz	V:21	MI: 0.9	V:21	MI: 0.9	V:21	MI: 0.9
7 MHz	V:25	MI: 0.6	V:25	MI: 0.6	V:25	MI: 0.6

Global Maximum Derated ISPTA and MI 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

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 action steps. Predominate factors include the patients 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)
	"Off" (only for a part of EQUIPMENT)
	"On" (only for a part of EQUIPMENT)
	Type B equipment

Chapter 6: ImaCor Approved Devices

The ImaCor Zura has been approved for use with the following devices:

Printer Sony model UP - D897

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 system.

Chapter 7: 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: 1-516-393-0970

Technical support fax: 1-516-393-0969

Technical support email: support@imacormonitoring.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 84.***

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	1. Mains power is On if system fans are running. LCD and Printers appear to be powered up. 2. The system computer is on and booted up if the keyboard is lit
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	**Note:** If a no coupling message is displayed, the probe is not making adequate contact with tissue
No display	1. Check LCD connections 2. Confirm LCD power	2. Blue LED adjacent to LCD power switch
No ECG waveform on display	1. Check ECG connection on machine 2. Check patient ECG lead connections	
No Print function	1. Check printer connections 2. Confirm printer power	1. Consists of data and power cable 2. LCD adjacent to printer power switch should be lit.

Maintenance

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

Zura System Cleaning Recommendations

ImaCor recommends the following cleaning instructions for the Zura system.

⚠ **Caution** The ClariTEE probe is for single use only and is to be disposed after single use.

⚠ **Caution** 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 monitor.
2. Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth:
   - Water
   - Vinegar/water solution
   - Isopropyl alcohol (i.e., Windex)
   - Petroleum benzene
3. Move the cloth across the display in one direction, moving from the top of the display 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 LCD.
   - Do not scratch the LCD screen.
   - Do not use paper towels to clean the LCD screen as they may cause damage and scratches.
4. **Never** use cleaning products containing the following:
   - Acetone
   - Ethyl alcohol
   - Ethyl acid
   - Ammonia
   - Methyl chloride

OPERATOR CONSOLE CLEANING

1. Turn off the system prior to cleaning the operator console.
2. Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth:
   - Water
   - Mild detergent (PH level at or near 7) and water solution.
   - Do not apply the cleaning solution directly to the operator console.

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. Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth:
   - Water
   - Mild detergent (PH level at or near 7) and water solution.

Other Recommended Maintenance

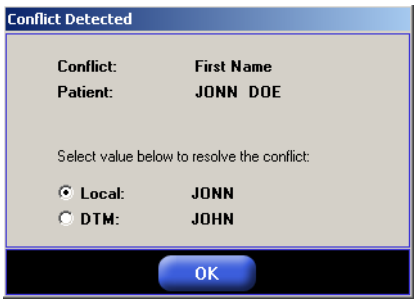
POWER SUPPLY CORD

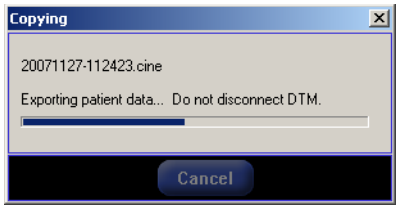
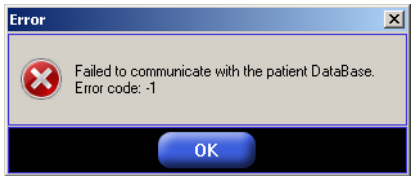
Regularly inspect the AC power cord and plug for damage.

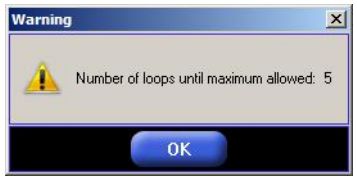
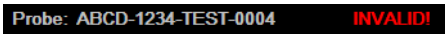
HANDLE AND UMBILICAL

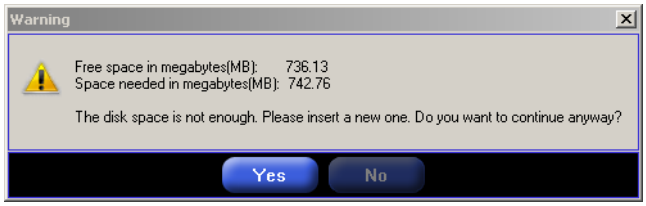
Regularly inspect the handle and umbilical for damage.

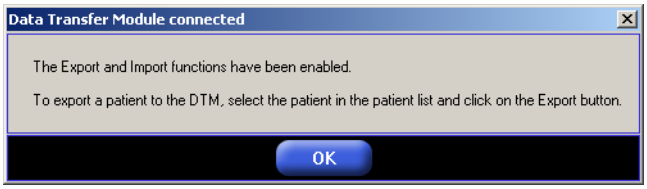
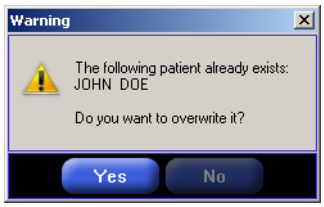
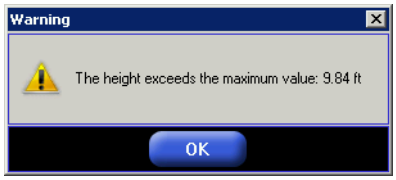
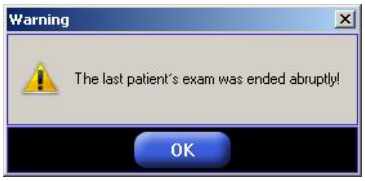
Chapter 8: Master Message Listing - Alphabetical

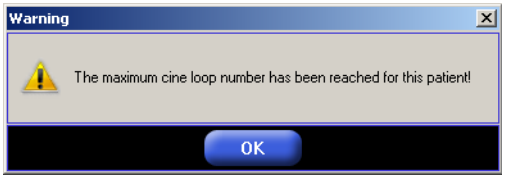
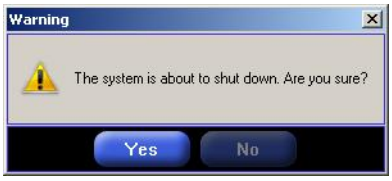
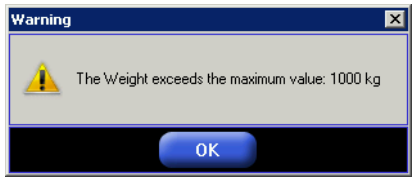
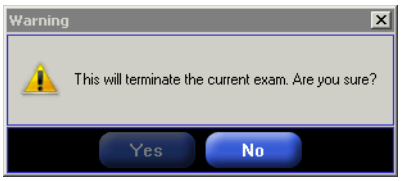
	Problem	Solution
		Restart the system. If the problem persists, contact ImaCor technical support.
	While importing or exporting patient data, the system has detected an inconsistency between the local data (that saved on the ImaCor Zura system) and the DTM.	• If the name on the main system is correct, 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 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 database server	Click the OK button and restart the system. If the error persists, contact technical support.
	Disk space for storing patient data is limited.	Delete patients or cineloops.
	Disk space for storing patient data is VERY low and the current operation cannot be completed	Delete patients or cineloops.
	1. ECG leads are not connected to the patient. 2. The placement of the ECG leads is incorrect.	1. Connect ECG leads to the patient. 2. Correct the placement of the ECG leads. Also, make sure the leads are correctly plugged into the ECG machine. 3. Click the Retry button.

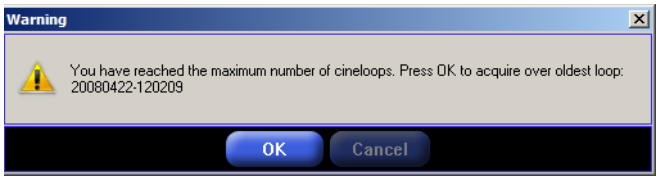
	Problem	Solution
	Informational; displayed when importing data from or exporting data to a DTM. The progress bar indicates the status of the operation, and the user is further advised against disconnecting the DTM.	
	The system isn't communicating with the patient database.	Click the OK button and restart the system. If the problems persists, contact ImaCor technical support.
	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 system. • Insert the drive in any personal computer with a USB port. • Delete unnecessary files. Files may not be deleted from the Zura 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 system. • Retry the operation.
	Review the initialization screen for the specific error.	Click the OK button and restart the system. If the problems persists, contact ImaCor technical support.
	The Unfreeze or Acquire button was pressed while an invalid probe is connected. • The probe is expired. • No probe is connected. • The probe is associated with a different patient. The wrong patient name may have been selected.	1. End the exam. 2. Connect a valid probe, or– 3. Select the correct patient name from the patient list.
	Informational message. Patient data is being imported from a DTM.	No action is necessary to continue importing patient date. To halt the transfer of patient information, press the Cancel button.

	Problem	Solution
	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 system. 3. From the Configuration > Help screen, again click the Analysis Package button.
	The ImaCor system is designed to store a maximum of 50 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 56.
	The printer and the system aren't communicating properly.	• Check that the printer is turned on. The power switch is on the front panel. • Check the data (USB) cable and power cable at the back of the printer.
	The wrong patient-probe combination has been selected.	Compare the ClariTEE probe's serial number label with the serial number displayed at the top if the imaging preparation screen. Most often, the selected patient is correct, but the wrong probe is connected to the system.
	The probe was disconnected during the patient exam.	Solution A • End patient exam • Reconnect probe to handle • Select patient and proceed to imaging screen Solution B • End patient exam • Connect new probe to handle • Select patient and proceed to imaging screen Solution C • Continue current exam; however, imaging functions will be disabled
	A probe is detected as a new probe, but the probe serial number is found in the patient database. This happens when a used probe has been reprogrammed as a new probe.	Solution A • Disconnect probe • Connect valid probe • Click Retry button • Proceed to imaging screen Solution B • Click Cancel button • Proceed to imaging screen; however, imaging functions will be disabled

	Problem	Solution
	The probe is not physically connected to the ImaCor system.	Connect the probe. • Pressing the Cancel button clears the warning. • Pressing the Next button after clearing the warning advances you to the imaging screen, but the display of real-time images and cineloop acquisition functions are disabled. • Pressing the Retry button enables you to plug in the probe. The ImaCor system will again attempt to identify the probe.
	The connected probe has been used for more than 72 hours.	The ImaCor Zura system can be used to review the patient's recorded cineloops, but not acquire new images.
	The wrong patient record has been selected for this probe. Imaging is disabled.	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 *or—* 1. Connect the correct probe. 2. Click the Retry button.
	A record has been created for a new patient, but the patient's date of birth is invalid. The patient's date of birth is entered in the following format: mm/dd/yyyy. Examples of an invalid birthdate: • 02/17/1492 invalid year • 01/25/2079 invalid year • 07/03/194 invalid year • 99/16/1939 invalid month • 11/99/1948 invalid day	1. Move the cursor to the last name field 2. Enter the patient's last name.
	1. Available disk space on the local drive is insufficient to complete an import operation, *or–* 2. Available disk space on the DTM is insufficient to complete an export operation.	1. Press No to cancel the import operation. You will be able to import records to the local disk that require less than the remaining disk space. Each cineloop requires roughly 20 MB. 2. If you are transferring data to a DTM, press No to cancel. Insert a DTM with sufficient disk space and retry the operation.

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

	Problem	Solution
	The maximum of 50 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 56.
	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.
	Non-numerical data was entered in the Weight field.	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.

	Problem	Solution
	The ImaCor system is designed to store a maximum of 50 cineloops per patient. You have reached that maximum.	Delete one or more cineloops. For more information, see Deleting a Cineloop, page 56.
	Informational only	
	The analysis package couldn't be exported to the external drive. • The external USB drive was unplugged before the analysis package export was completed. • The external USB drive is full.	• Make sure the external USB is correctly inserted. • Make sure there is at least 5 MB free space on the external USB drive.
	The analysis package must be written to an external drive, and no external drive is connected to the system.	Insert an external drive into the USB port.

Chapter 9: References

Measurements (Area and Distance)

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

Sources of Measurement Errors

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

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

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

Accuracy

METHODOLOGY OF ASSESSING ACCURACY

Phantom side-by-side measurements (area and distance) were conducted using three predicate devices and the ImaCor Zura 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 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 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 mean	4.02	4.39	13.83	5 measurements and area calculations
ImaCor Zura 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%*,**	

* 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.

Chapter 10: Specifications

Table 14 ImaCor System Specifications

Item	Specification
System dimensions	Content
Display dimensions	17-inch LCD display
Transducers	Phased array
Imaging mode	Type B 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 91
Image storage	Data transfer module (DTM)
Cables	• Power supply cord • Printer power cable • Printer data cable • ECG leads
Peripherals	A Sony printer is provided with the system
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

Chapter 11: 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™	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