GE Vingmed Ultrasound

System FiVe
User Manual for
Software Version 1.9.x

GEVU P.No.: FA092423

GEVU Revision:L

GEMS Cat.No.: H44701VA

CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

Verify the System Software version as shown on page 35

System FiVe

Caution:

Product Name labels, Colors, Options, Specifications and Configurations described in this manual may vary in different geographical markets.
Please contact the local representative for more details.

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COMPANY DATA:	
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INTRODUCTION

GE Vingmed Ultrasound

GE Vingmed Ultrasound is ISO 9001 (1994) and EN 46001 certified. Copies of the certificates are available on request.

System FiVe

System FiVe is an Ultrasound Diagnostic System for applications such as Adult, Pediatric and Neonatal Cardiac, Peripheral Vascular, Abdominal and Ob-Gyn. (See: Indications for use, page 207.)

Probes

The System FiVe allows the use of various probes. Refer to a Probe / Application overview list on page 208.

User Interface

The System FiVe has an intuitive yet flexible user interface philosophy. All the tools are readily available when needed.

Operating Modes

The system controls operate the following modes: Color Flow, 2-D Image, Color M-Mode, M-Mode, HPRF Doppler, LPRF Doppler and CW Doppler, or a combination of these, positioned on the operating panel.

System FiVe's User Manual

Using this manual:

- The TOC of this manual contains, in the order from front to rear, the heading on each page of the manual from Chapter A and backwards.
- The manual has continuous numbering from Chapter A and backwards.
- The manual has an index at the very rear which contains minimum 1, maximum 3 entries from each pageof this manual.

IMPORTANT.

This manual is periodically revised. Changes, typographic errors and technical inaccuracies, which may be included, will be corrected in future revisions.

FEEDBACK.

Any views and comments concerning the product (including its manuals) should be forwarded to the local GE Vingmed Ultrasound product representative or GE Vingmed Ultrasound Head office in Horten, Norway. The official address, is found on page 3 of this chapter.

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Chapter A

System Preparations 1

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Chapter A

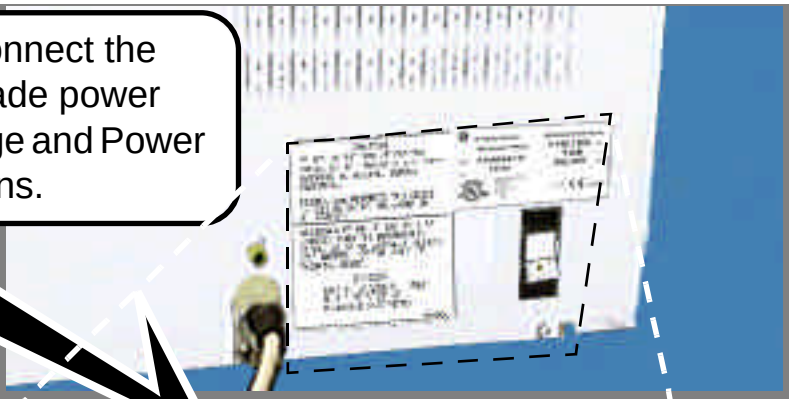
System Preparations

This chapter tells you about, and how to:

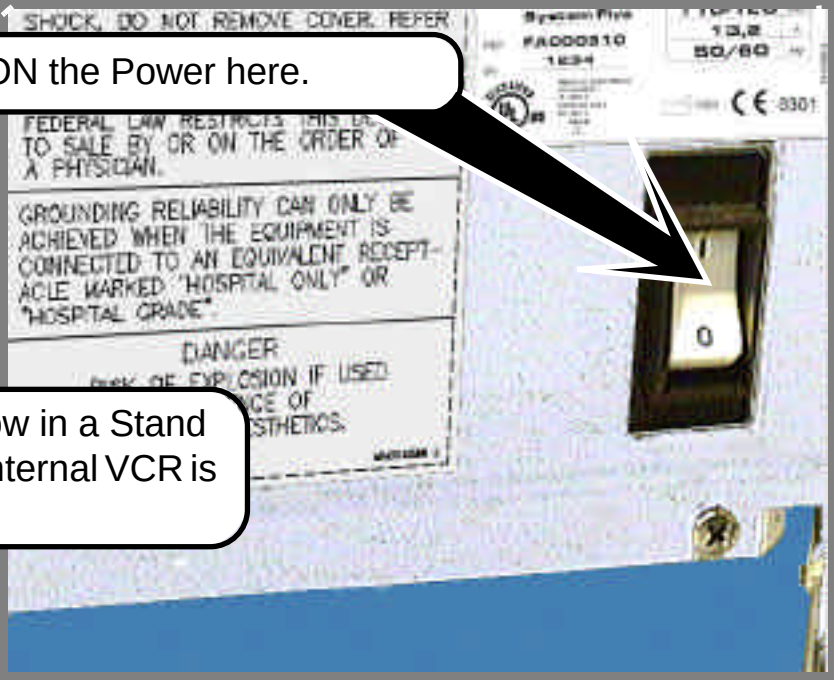
Turn ON the system

Connect Power cable and locate Power switches

Unwind this cable and connect the plug end to a hospital grade power source with correct Voltage and Power consumption specifications.



Switch ON the Power here.



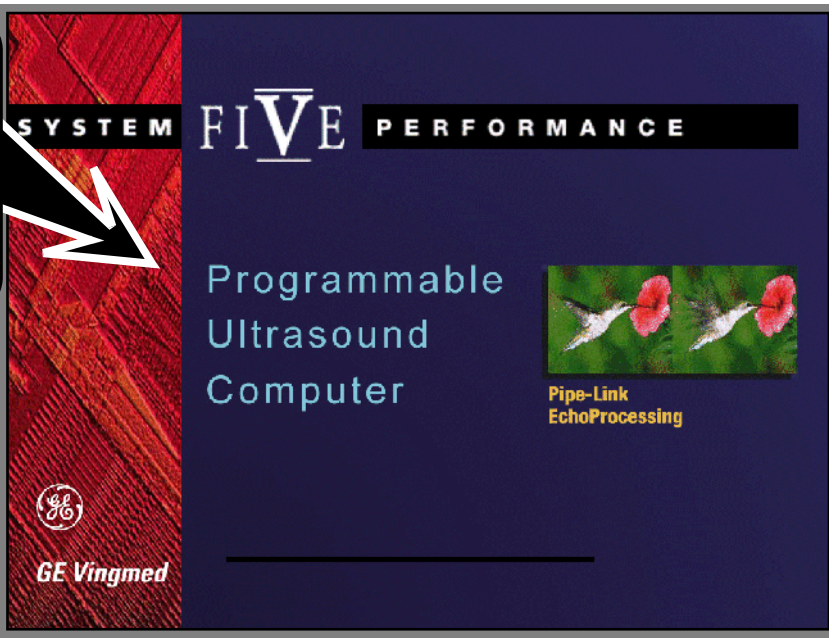
System FiVe is now in a Stand by situation. The internal VCR is ON.

To start System FiVe, press this Stand by/ ON key once.

Turn On the system

The Power-Up process

The actions on the previous page start the power-up process, including self-tests. During this, the start-screen picture appears on the monitor.



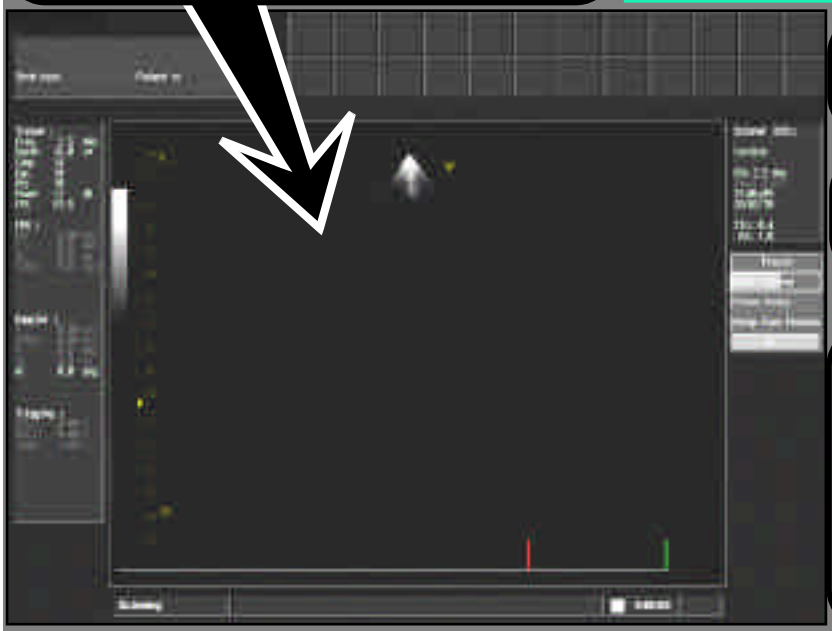
IMPORTANT

Color unstableness on the monitor picture at power up may last as long as 10 minutes. Do not try to correct this or do any other monitor adjustments during this period.

HINT

All connected GE Vingmed Ultrasound probes have unique identities that the system reads at boot-up. The system chooses the one with the lowest number as default probe.

When done, the screen picture changes, the default probe, if connected, calibrates and the machine opens in the 2D scan mode.



For scanning information, go to Chapter B.

To change settings, enter ID etc., go to Chapter B.

The ultrasound area has a depth scale, a 2D sector, a tilt indicator, a grey-scale bar, a time/motion line with 1second apart markers.

At the top left hand side of the screen, the Location name is found and below it, the Patient ID window. Find the Clipboard area for image captures to the right of patient I/O input. Down the left edge you see scan parameters. Down the right edge, we have the scanner info window and the paddle menu controls.

System Probes

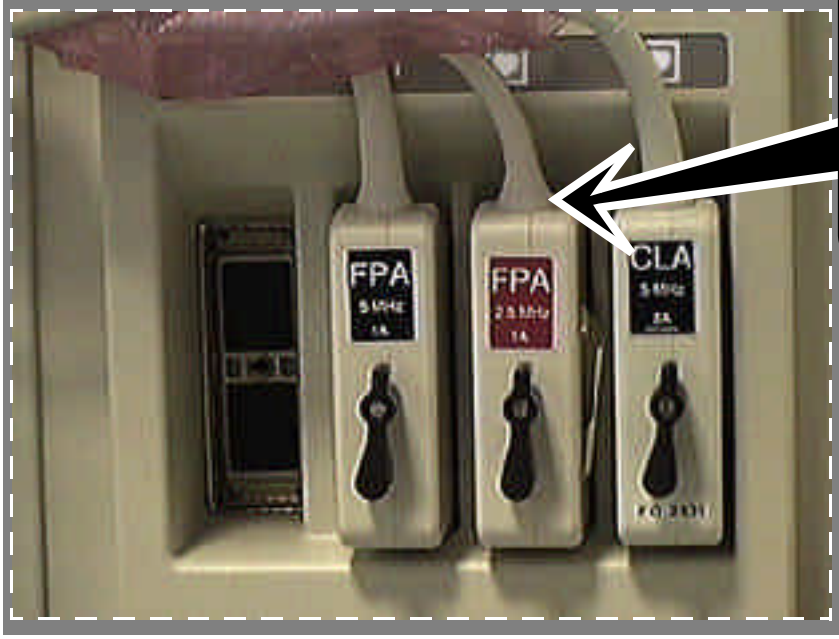
Probe connections

Before the scanner can be used, it is necessary to mount the Probes that are to be used. Let connected but unused Probes rest in the Probe holders at each side of the system.

Organize all probe cabling so that it runs via the hooks under the control panel and avoids getting run over when the System is moved.

Connect either 1 or 2 APAT Probes, or 1 or 2 MPTE Probes and one Doppler Probe on this connector panel.

HINT
Available Probes are listed on **page 208**.



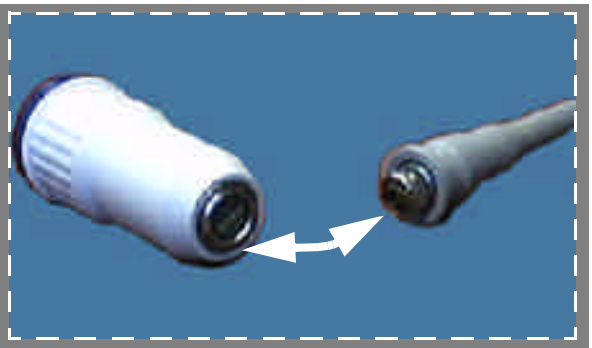
Connect Phased Array Probes (maximum 3) on this connector panel. An extra Phased array Probe connector may be lodged in the dummy slot.

CAUTION
Malfunctioning or non-working probes that show any signs of mis-handled use will not be replaced by GE Vingmed Ultrasound A/S.

System Probes

Change APAT Probes at Cable end

Study the connector section of the Probe and Probe cable, and notice how they can fit together.

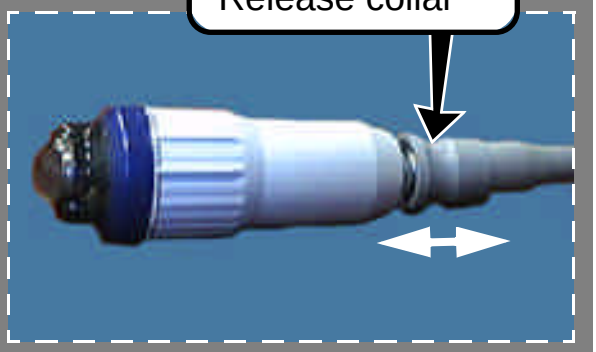


To connect an APAT Probe to its cable, align the connector and receptacle and connect the cable.

After connections, the system senses the Probe's presence, notes its imaging frequency and calibrates it.

The activated Probe frequency is on the screen.

To disconnect the APAT Probe from the cable, hold the probe, take a grip of the cable release collar and gently free it from the Probe housing.



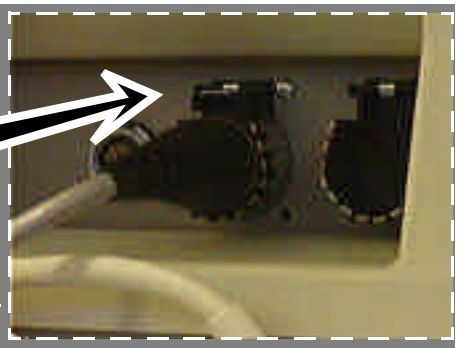
HINT!
Find the Probe's part number and frequency on the colored Probe collar and the serial number on the grey housing near the ring.

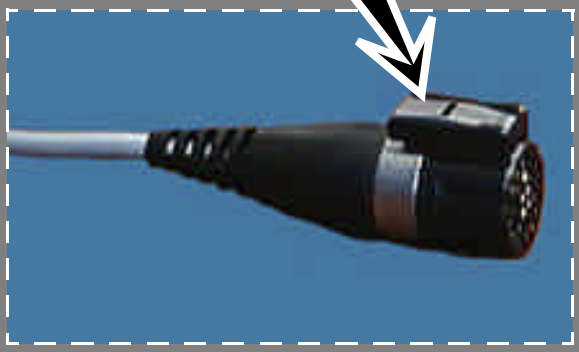
CAUTION
Use ultrasound gel during all NON-INVASIVE investigations to get the best image views at the lowest possible Acoustic power output. For Invasive probes consult each invasive probes manual.

System Probes

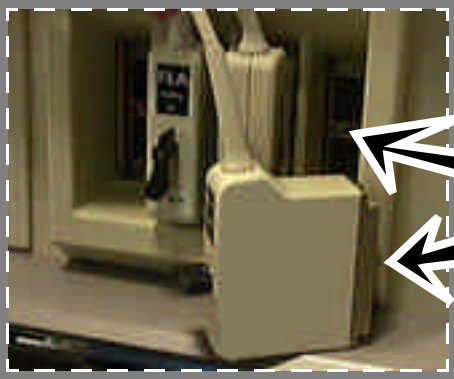
System-Connect Probe cabling

To connect APAT or MPTE Probes, align the connector with the socket and insert it.
To disconnect one of these, press this part of the connector gently downwards and extract the connector from the socket.





HINT1
You may change APAT Probe types at the Probe end of the cable, without removing the socket end. See previous page.



To connect a Phased Array Probe, align the connector with the socket, insert the connector into the socket so that the connector center pin centers on the socket center. To fasten the connector, rotate the lock handle 90° clockwise.

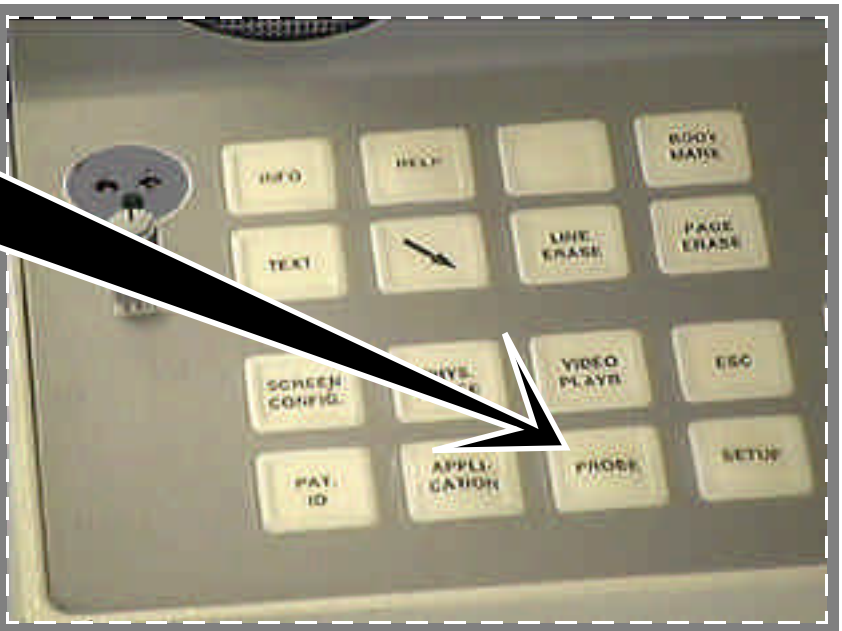
Disconnect a probe connector in the reverse order.

HINT2
After Probe changing at these locations, always select the (new) activated Probe on the PROBE MENU. See next page.

System Probes

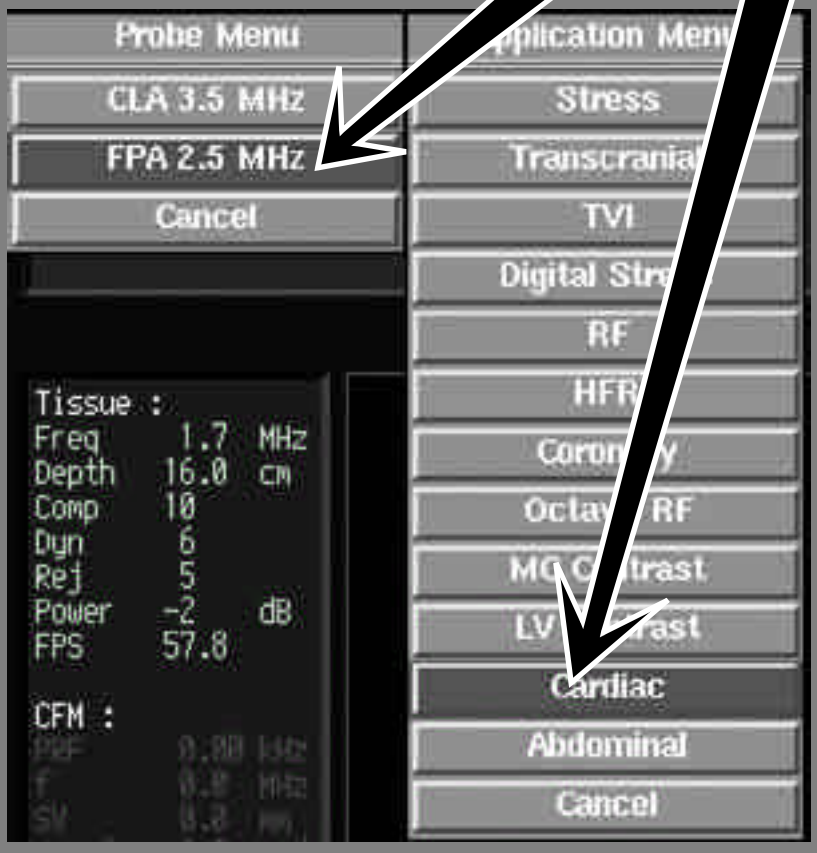
Active Probe and Application Selection

Press this key to display the Probe menu which contains an overview of the connected Probes.



This **Probe menu** appears on the screen. Its setup contents are Probe type dependent.

With the trackball, move activity onto the menu and onto the desired Probe. Beside the **Probe menu**, an **Application menu** appears shortly after.



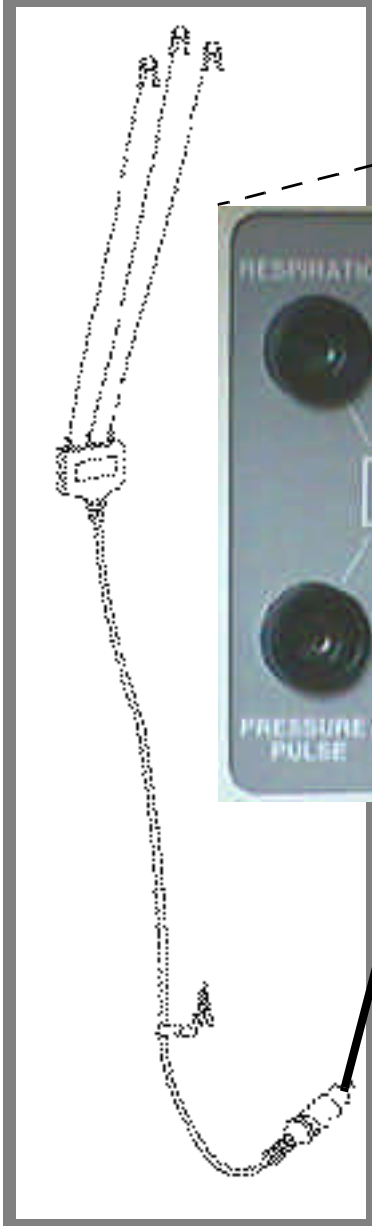
To select a Probe and Application, highlight it and press the Select key.

Exit from **Probe** and **Application Menus** with **Cancel**.

Patient I/O & traces setup

Connect ECG harness

The Patient I/O panel is here. You may connect four different patient Input/ Output sources. These appear as traces on the screen.



Connect the ECG harness here. There are two types, either Blue or Grey.

ECG Electrode placement table

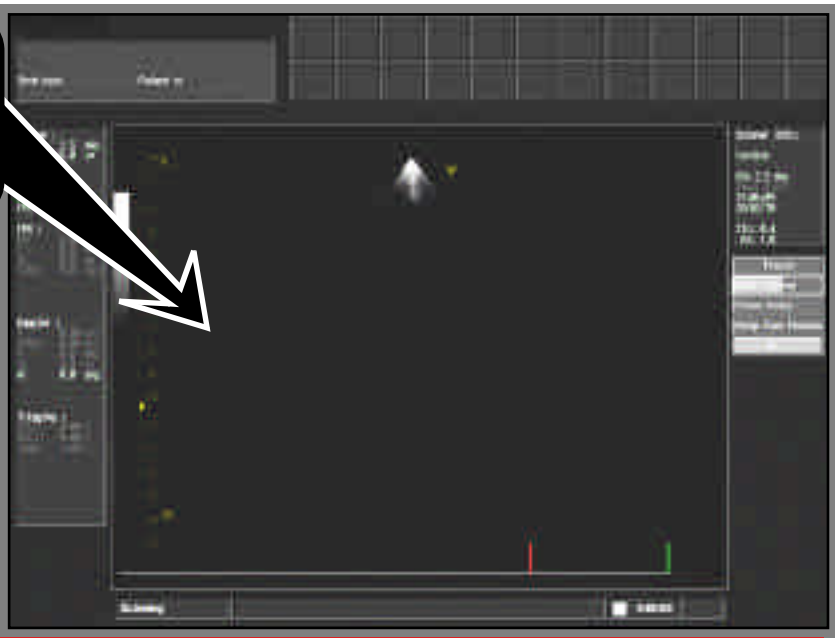
Physical placement	“Blue cable”	“Grey cable”
Right arm	RA	R
Left leg	LL	L
Left arm *)	LA	N

*) The left arm ECG pad connection is the reference electrode. Use it as this in order to remove unwanted electrical noise that is detected in the ECG signal.

Patient I/O & traces setup

Screen changes after ECG connection

In **2D** tissue mode, with no **ECG** trace, the screen may look like this.



WARNING!
To obtain the correct isolation on the patient I/O only one connection (i.e.ECG, Phono, Pulse pressure or Respiration) must be used on the Scanner at a time.This means that in normal use the Scanner will have three open connectors. The System User must ensure that the patient cannot touch the open connectors.

In Cardiac **2D** Acquisition, when **ECG** wiring is strapped to a patient and connected to the system, a trace from it appears as shown here.

Hint
In Peripheral Vascular acquisition, the display of traces is off but may be reconfigured to be on.

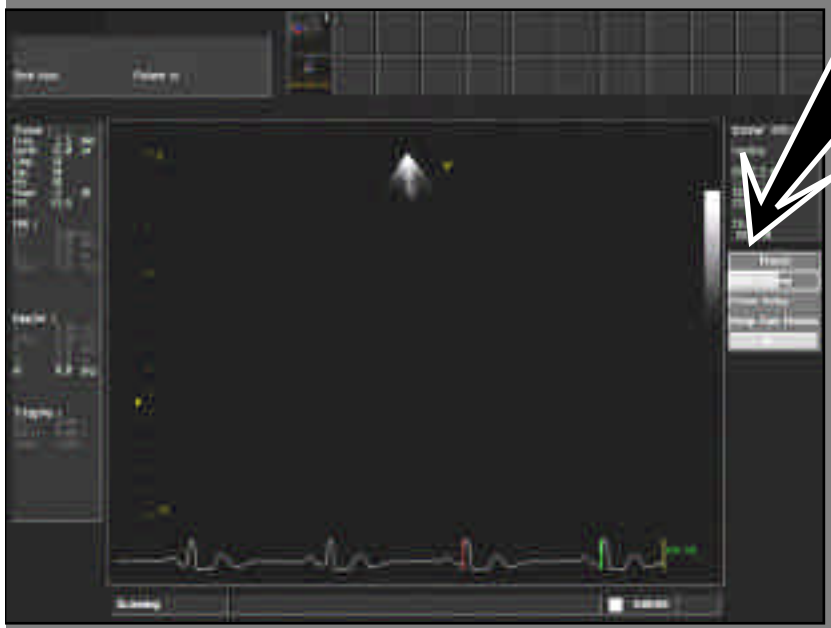
Patient I/O & traces setup

ECG trace control

To access the Physiological trace controls, including ECG, press this key.

At the re-programmables on the control panel these functions appear.

The screen is redrawn, and some Trace controls are available on the Paddle-controlled menu.

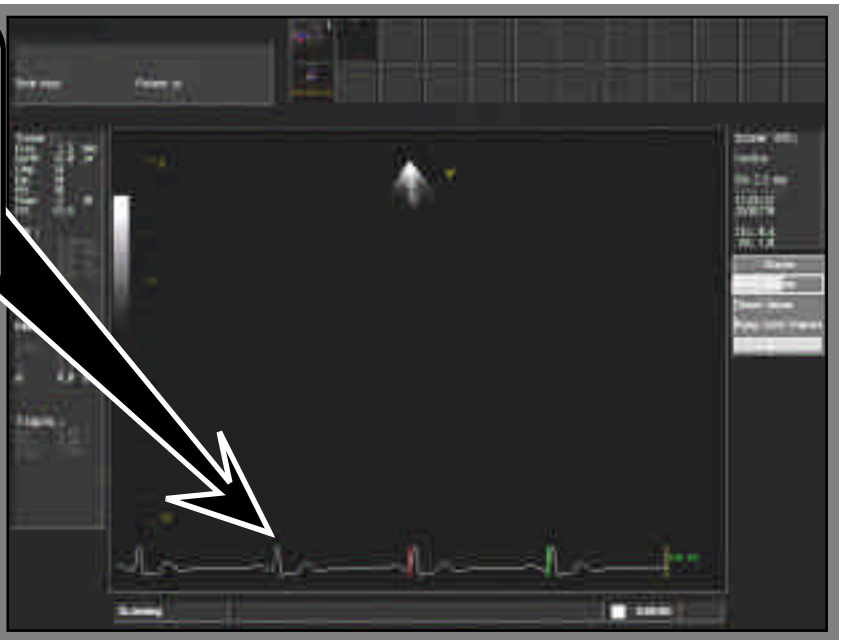


Hint
Screen Functions are:
- **Timer Delay**, Each step to the right lengthens time between triggers, when on.
- **Keep Cont.frames**, On/Off, for keeping the continually memory stored frames before switching to triggered scan or just overwriting the stored data.

Patient I/O & traces setup

ECG GAIN Adjustment

When the ECG trace appears on the screen, it has a setting of maximum gain and the waveform height looks similar to this.



To reduce the waveform height, turn this rotary counterclockwise.

Reducing ECG GAIN also reduces the waveform height shown.

Patient I/O & traces setup

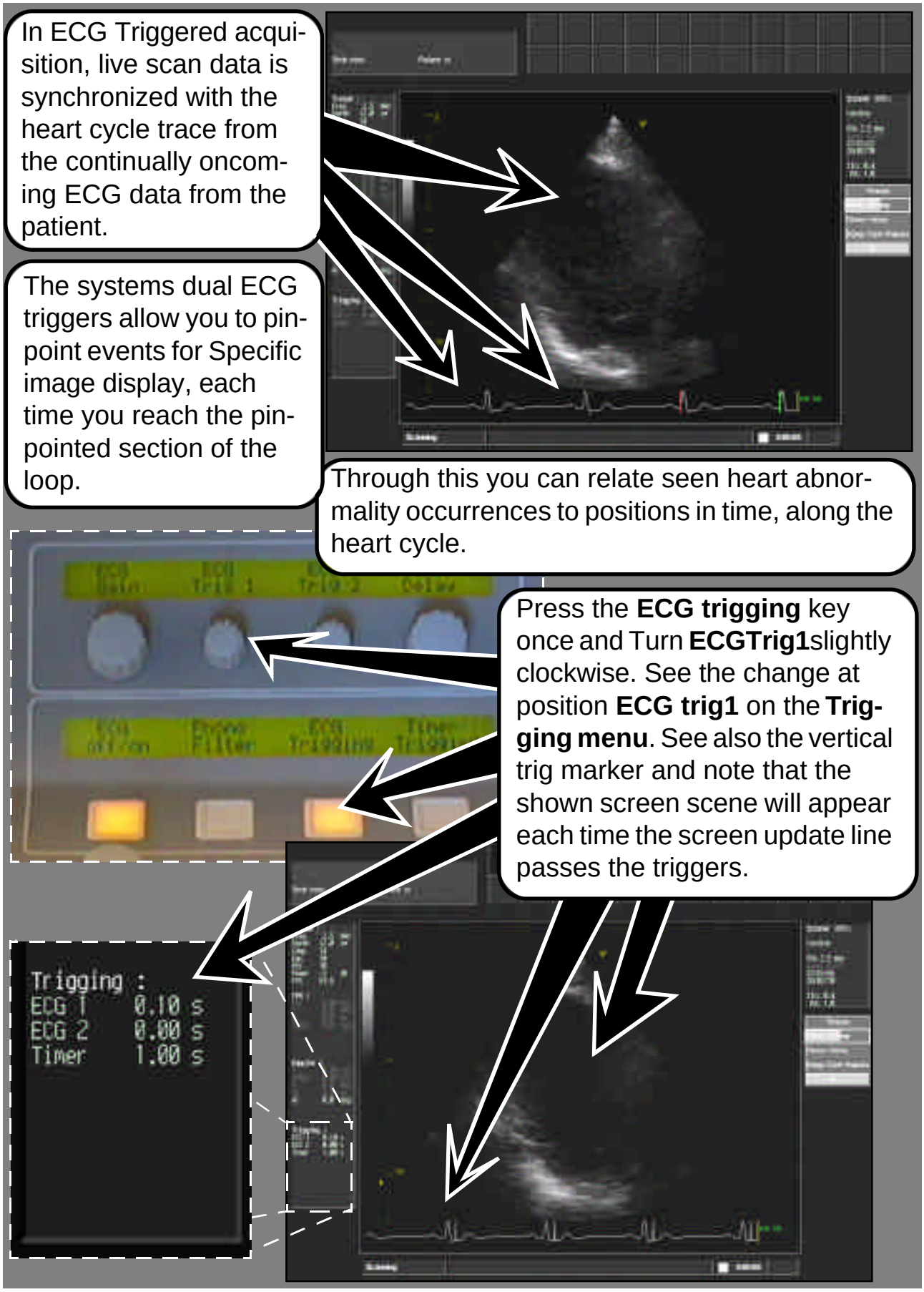
Set ECG trigger one

In ECG Triggered acquisition, live scan data is synchronized with the heart cycle trace from the continually oncoming ECG data from the patient.

The systems dual ECG triggers allow you to pinpoint events for Specific image display, each time you reach the pinpointed section of the loop.

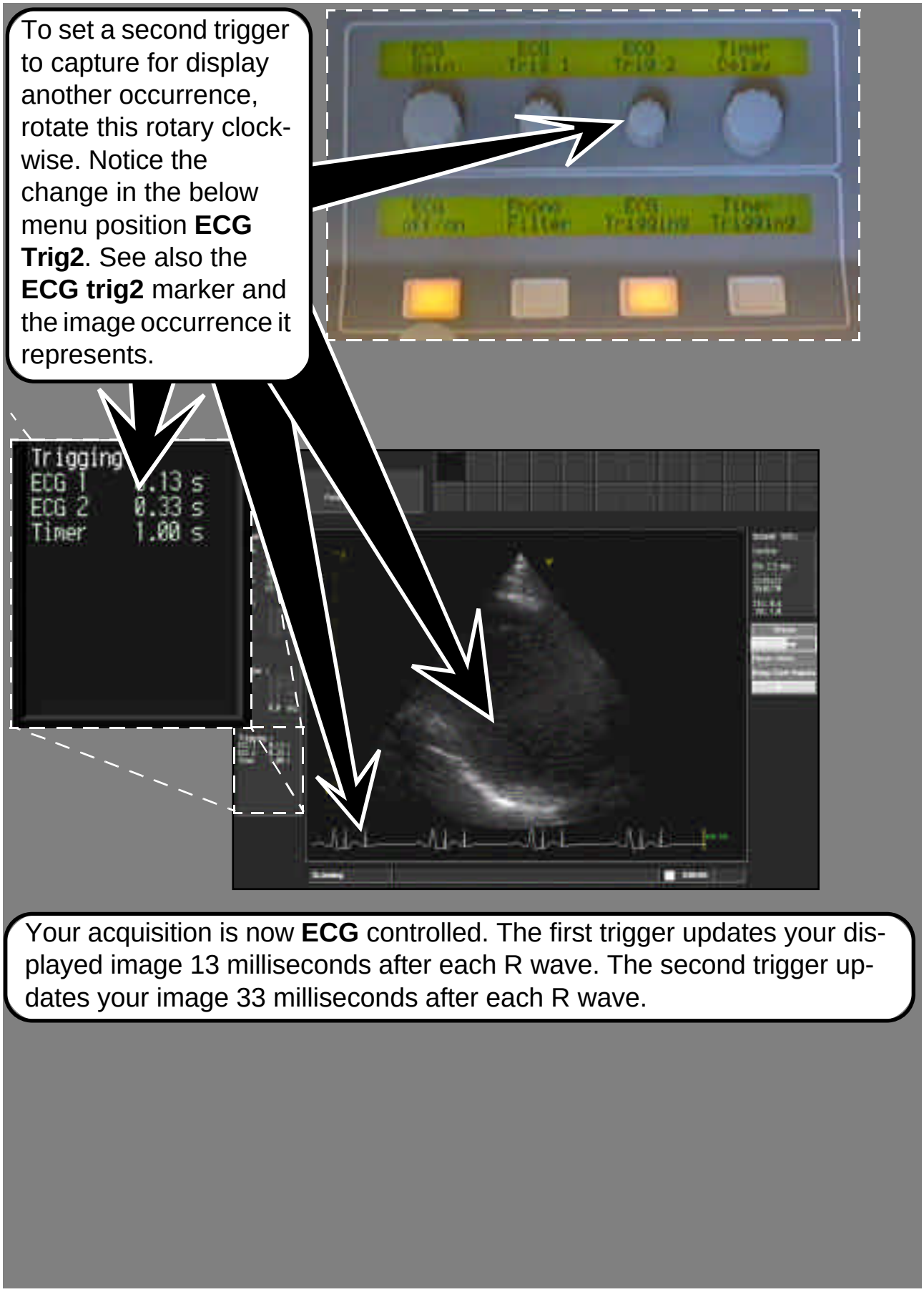
Through this you can relate seen heart abnormality occurrences to positions in time, along the heart cycle.

Press the **ECG trigging** key once and Turn **ECGTrig1**slightly clockwise. See the change at position **ECG trig1** on the **Trigging menu**. See also the vertical trig marker and note that the shown screen scene will appear each time the screen update line passes the triggers.



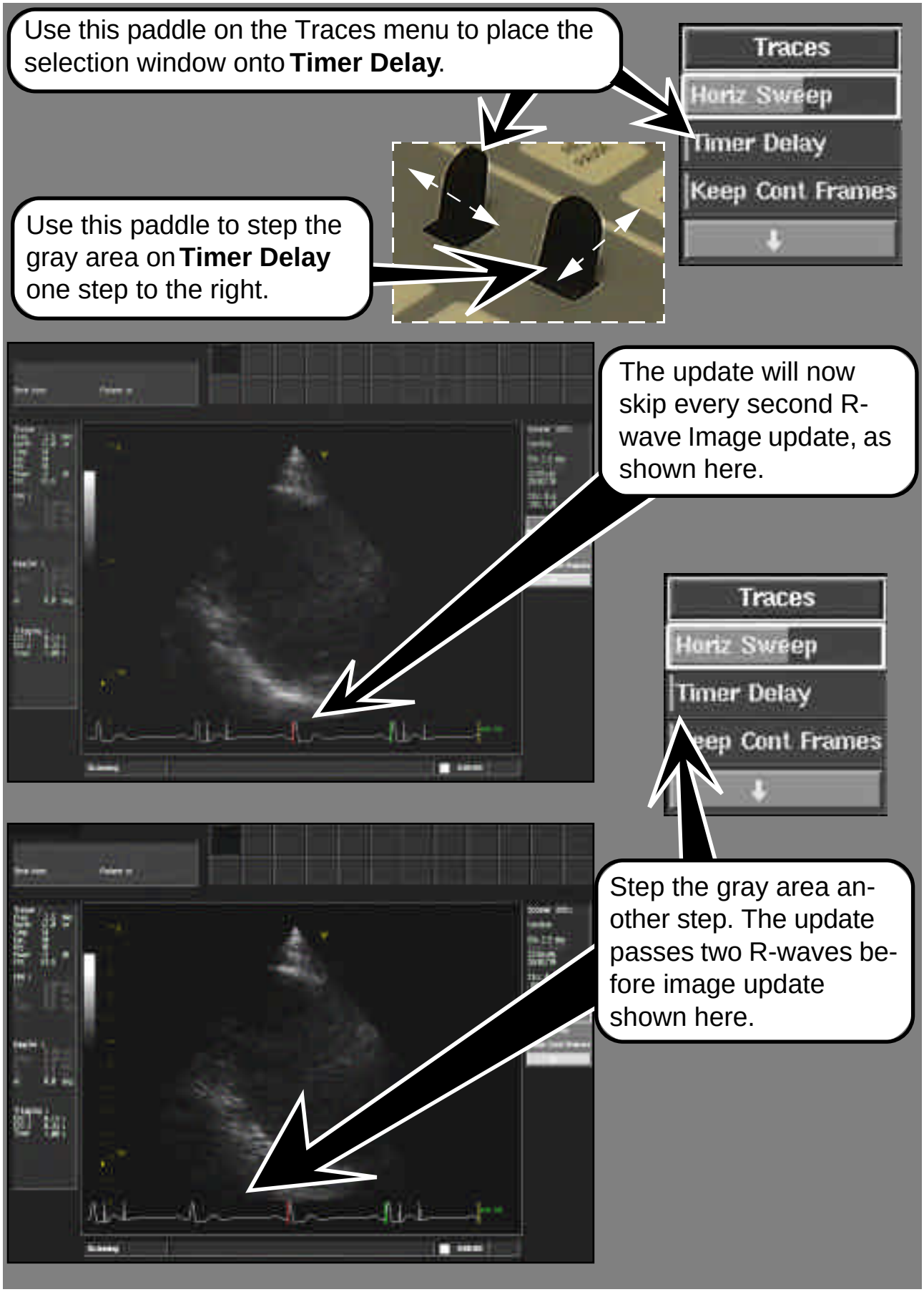
Patient I/O & traces setup

Set ECG trigger two



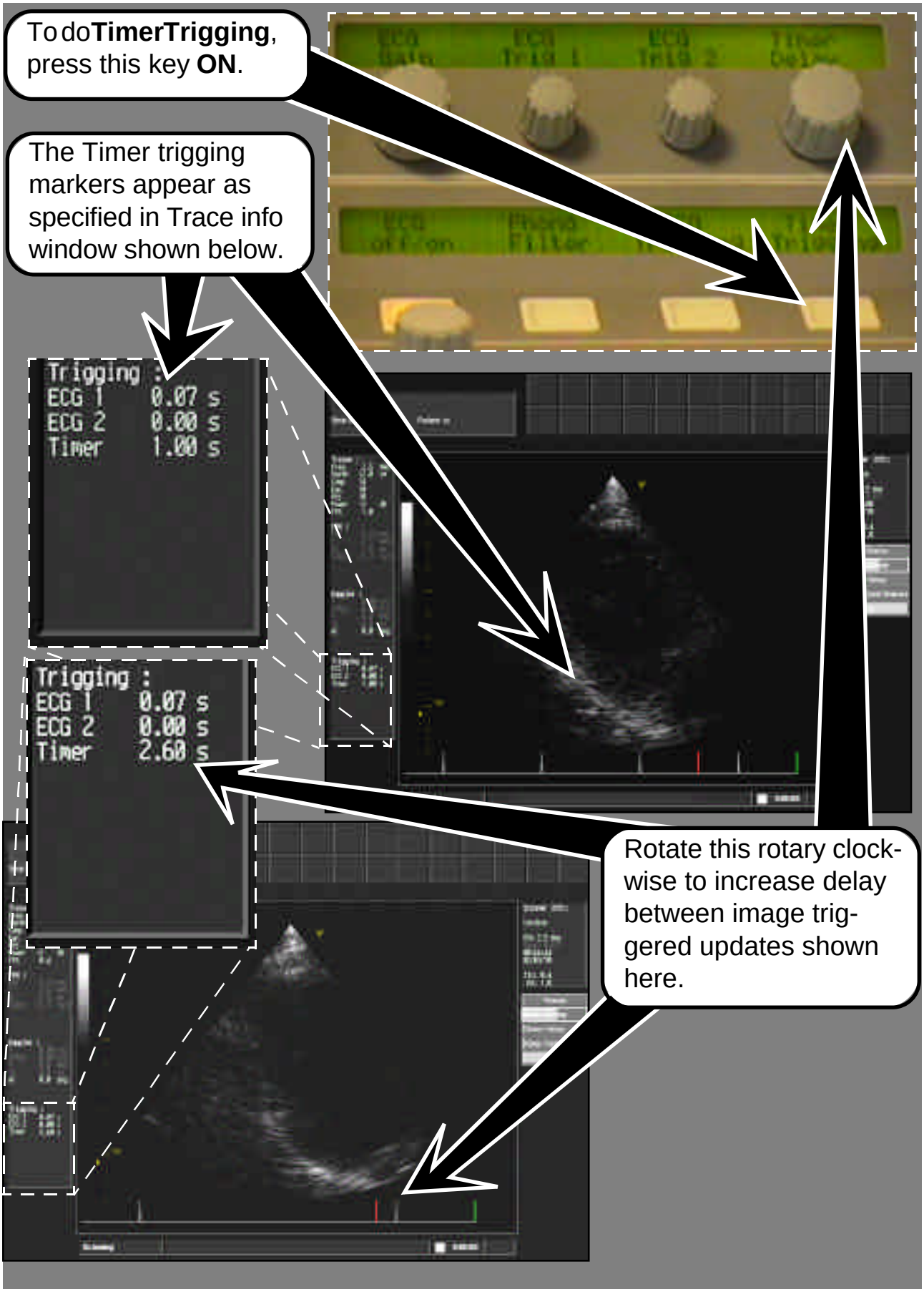
Patient I/O & traces setup

Timer Delay



Patient I/O & traces setup

Timer Trigging

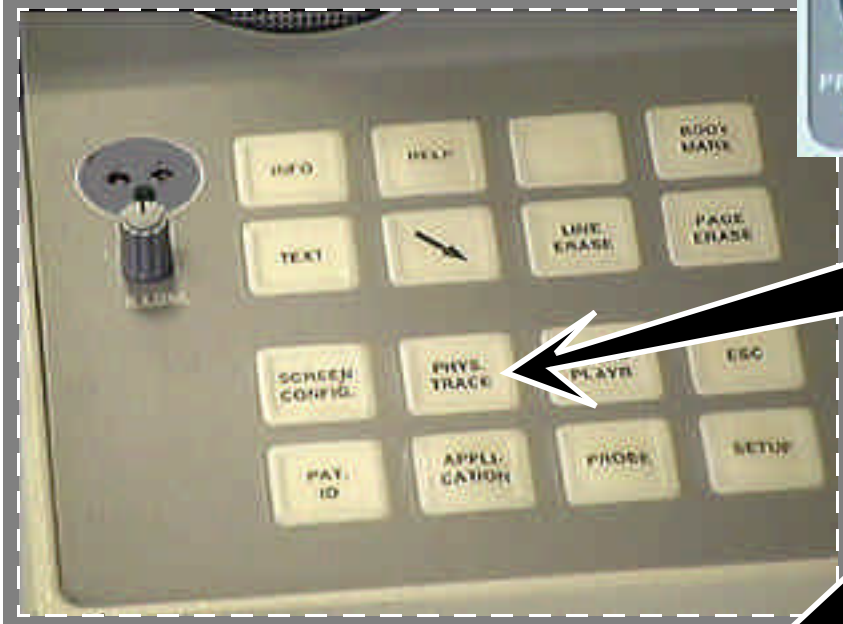


Patient I/O & traces setup

Connect other trace sources

Besides the ECG source, connect a Heart microphone source, a Breath indicator source and one Pressure/Pulse device source at the other sockets.

Heart microphones, Breath indicators and Pressure/Pulse devices are available options from the manufacturer.

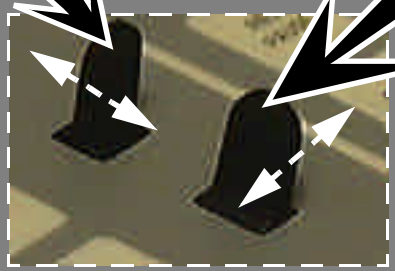


Press this key to select a trace from a connected source for display on the image.

A Trace menu appears somewhere on the screen. Here, it appears in the Paddle (see below) controlled area.

Moves select-window Up and Down the Menu.

Switches traces On-Off, sets gain levels and positions traces on screen.



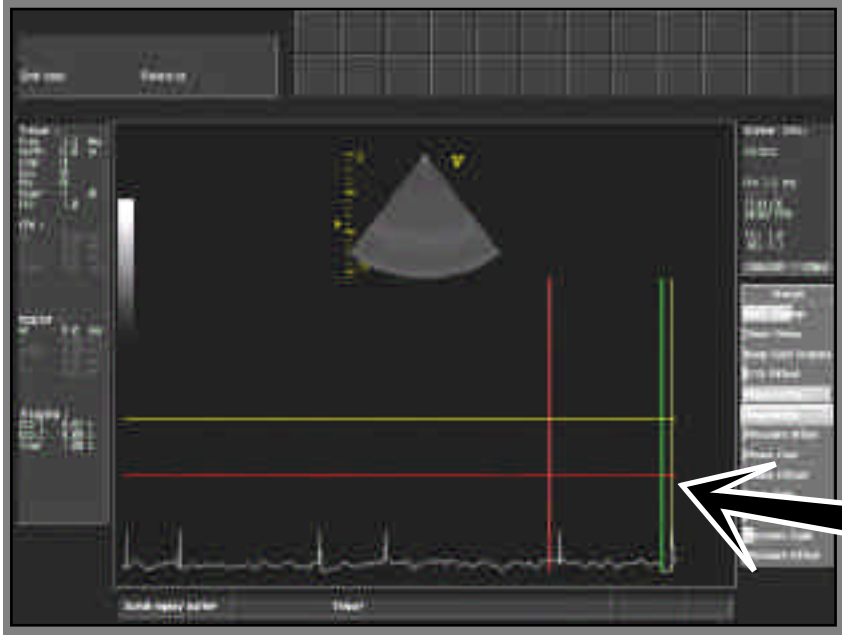
Patient I/O & traces setup

Trace area size

To set or change the Trace area size on the screen, click ON/OFF Small, Mediur, Large or Full.

With **Large** area chosen the **Traces** menu has these additional setting options, the same as the Small Area.

Using paddle controls, connect and switch **ON Phono** and **Resp** traces.

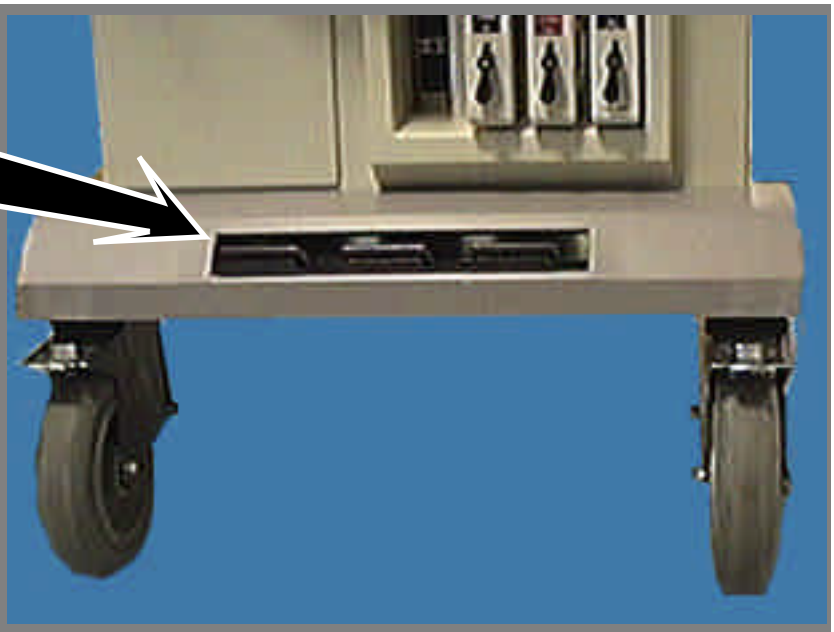


Adjust their settings, still using the Paddle controls, and the result will resemble the screen situation shown here.

Footswitch

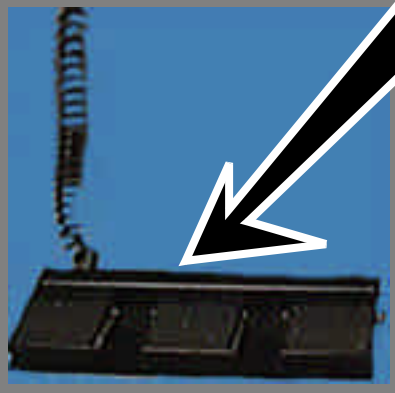
Mount the System Footswitch

The system contains an internally connected Footswitch located in this slot.



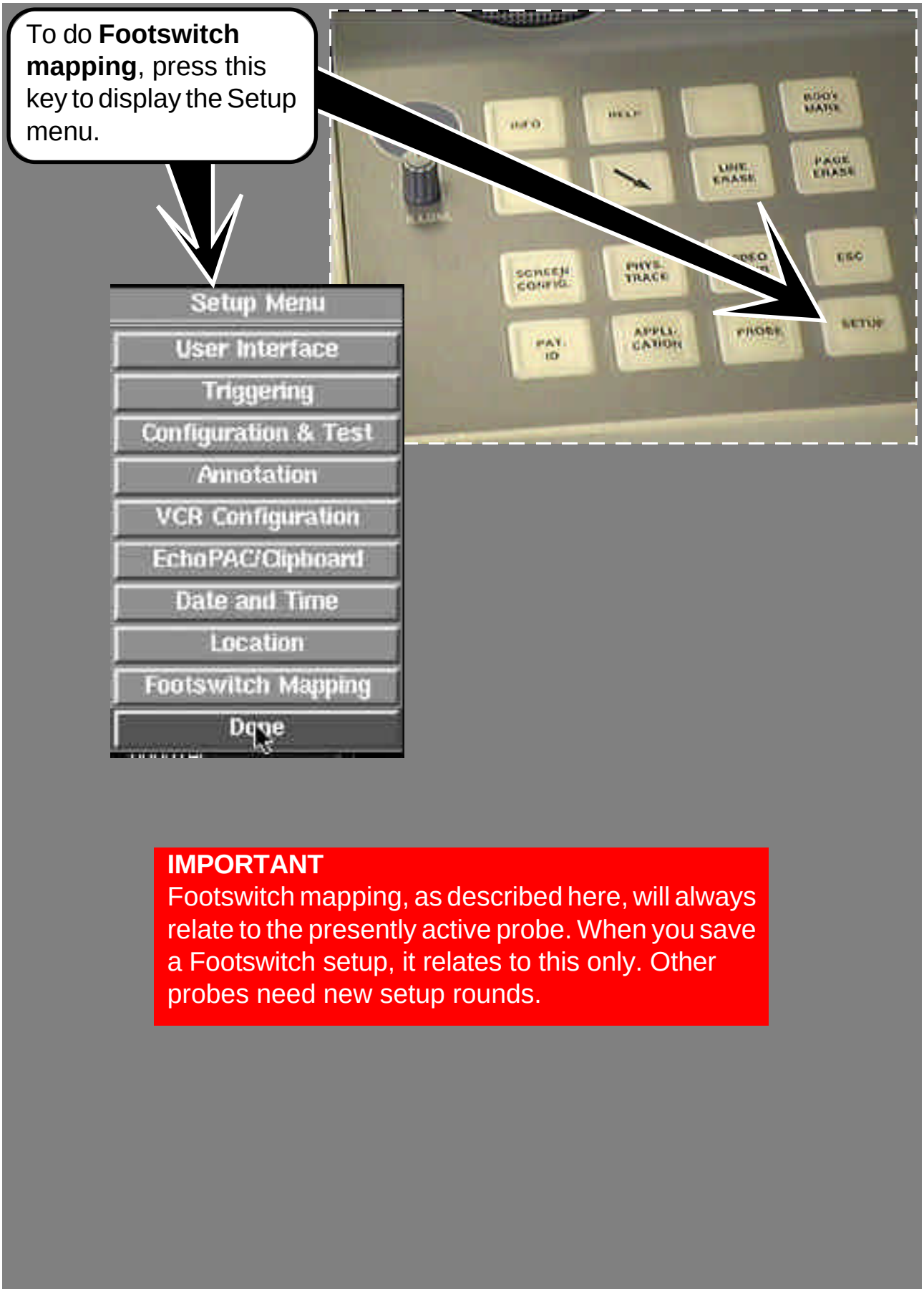
WARNING
The standard footswitch is not submersible. Do not use the standard footswitch in operating rooms or other locations where fluids might be present on the floor. If you need a submersible footswitch in your environment, contact your local GEVU distributor.

To prepare it for use, pull it out of this opening and place it on the floor where you need it.



Footswitch

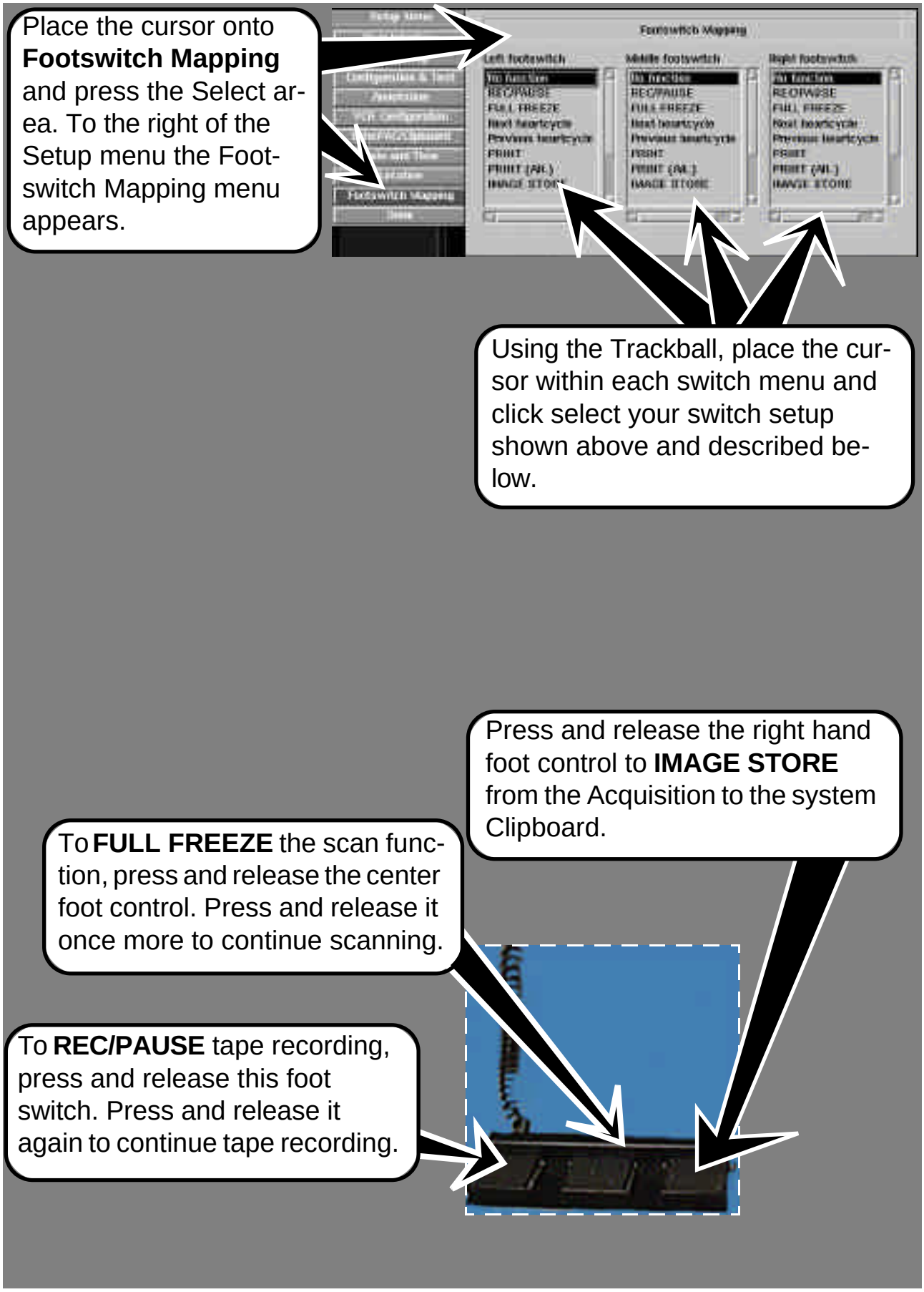
Finding the Footswitch Mapping option



IMPORTANT
Footswitch mapping, as described here, will always relate to the presently active probe. When you save a Footswitch setup, it relates to this only. Other probes need new setup rounds.

Footswitch

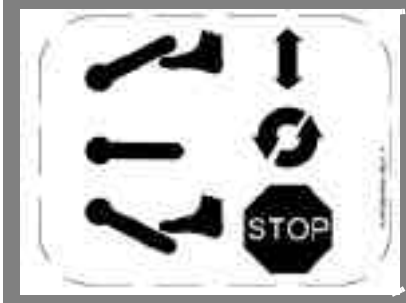
Footswitch Mapping

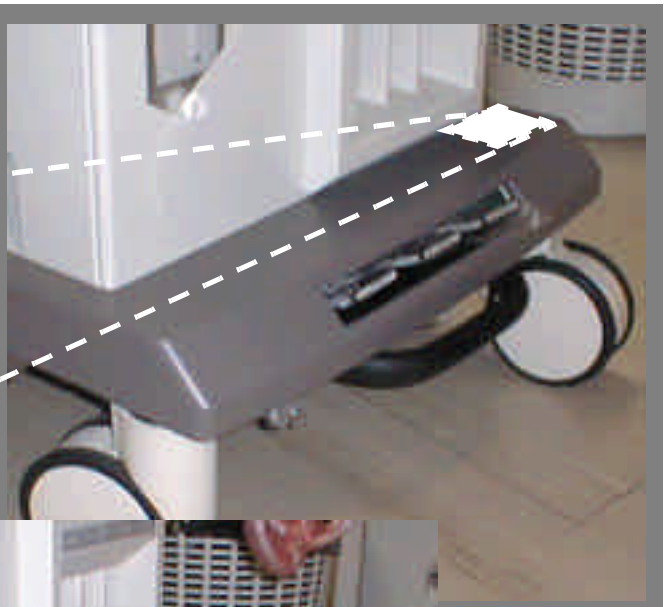


Wheel locking

Lock, Unlock scanner wheels

In upper position the rear wheels are direction locked but rotate freely



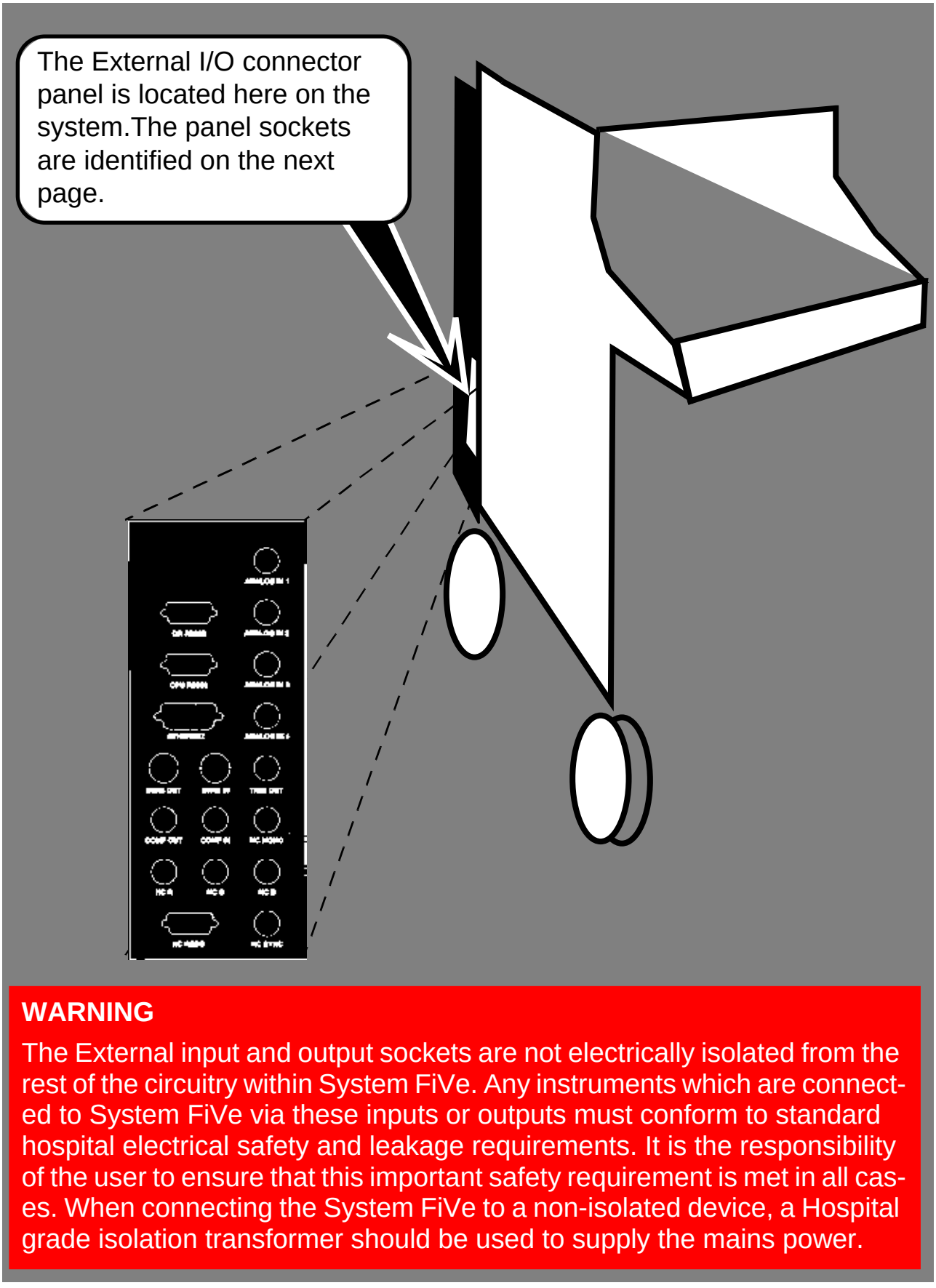


At half way down position all wheels turn and rotate freely.

At the lowest position the system is parked and breaks are active on both-rear wheels.

External I/O Panel

System I/O panel location



WARNING

The External input and output sockets are not electrically isolated from the rest of the circuitry within System FiVe. Any instruments which are connected to System FiVe via these inputs or outputs must conform to standard hospital electrical safety and leakage requirements. It is the responsibility of the user to ensure that this important safety requirement is met in all cases. When connecting the System FiVe to a non-isolated device, a Hospital grade isolation transformer should be used to supply the mains power.

External I/O Panel

Socket identifications

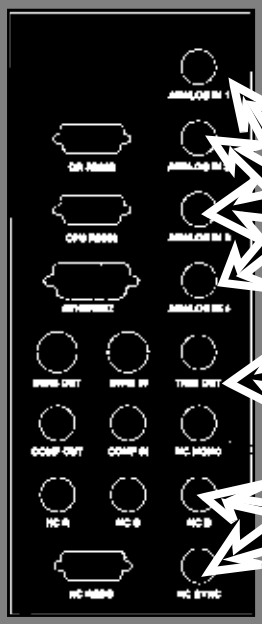
GR(aphic) **RS232** and **CPU RS232** sockets.

ETHERNET** socket. Used for communication with EchoPAC stand-alone.

SVHS OUT and **SVHS IN** sockets for Super VHS VCR connection.

COMP OUT and **COMP IN** connectors. **COMP OUT** is used by EchoPAC. **COMP IN** can be used by a great variety of sources, such as display of an X-Ray picture etc.

****IMPORTANT**
Connect the Ethernet interface cable (FA200460) between the External I/O socket and the Ethernet adapter and slide latch these together. Arrange cabling to avoid any possible damages. When a patient is connected to the System, always use the Ethernet Isolation Box (P/N:EP200032, as shown to the right) to obtain correct isolation.



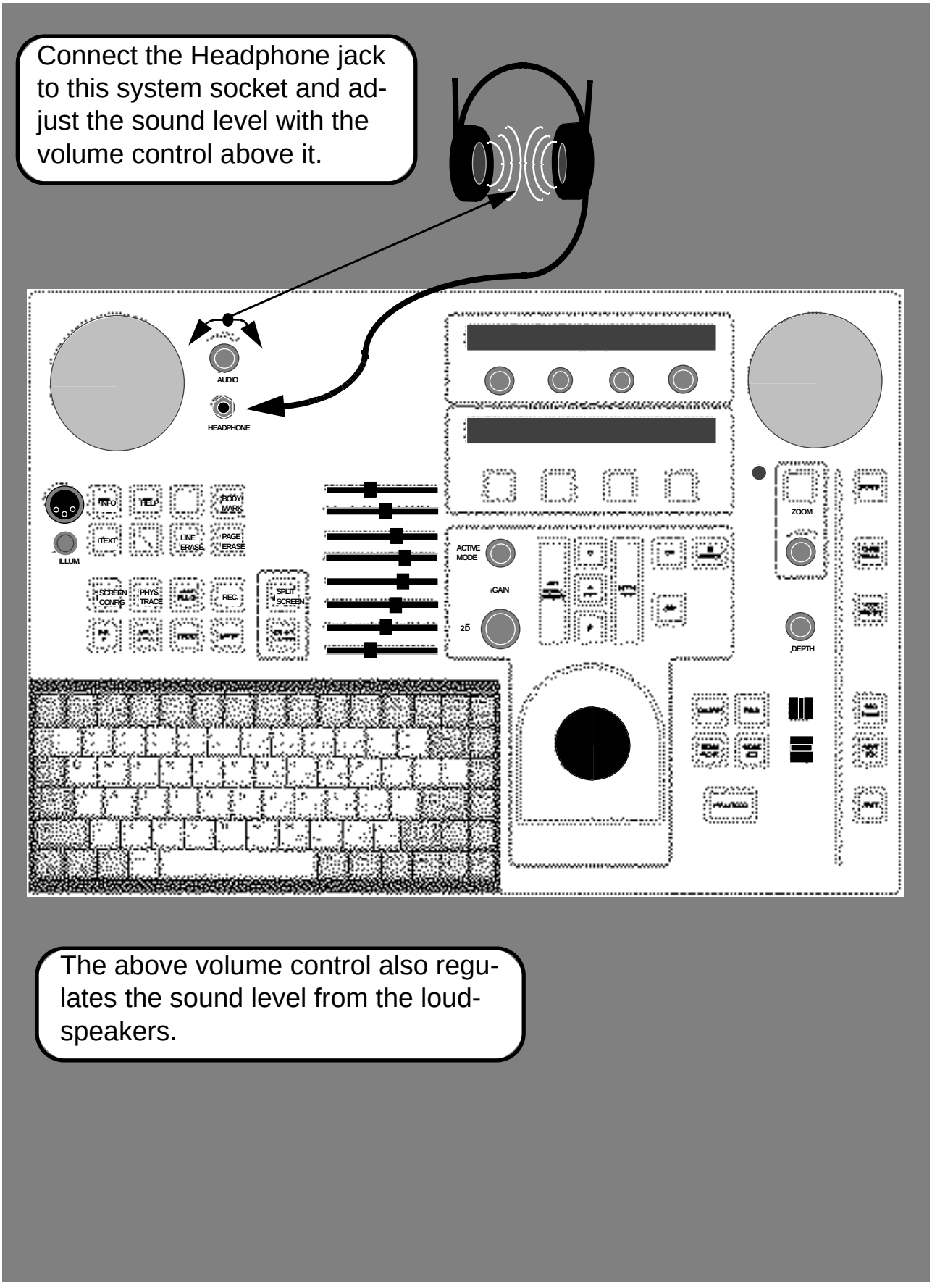
Four Analog input sockets. Can be used for auxiliary traces.

ECG TRIG OUT socket.

Output sockets for color printers.

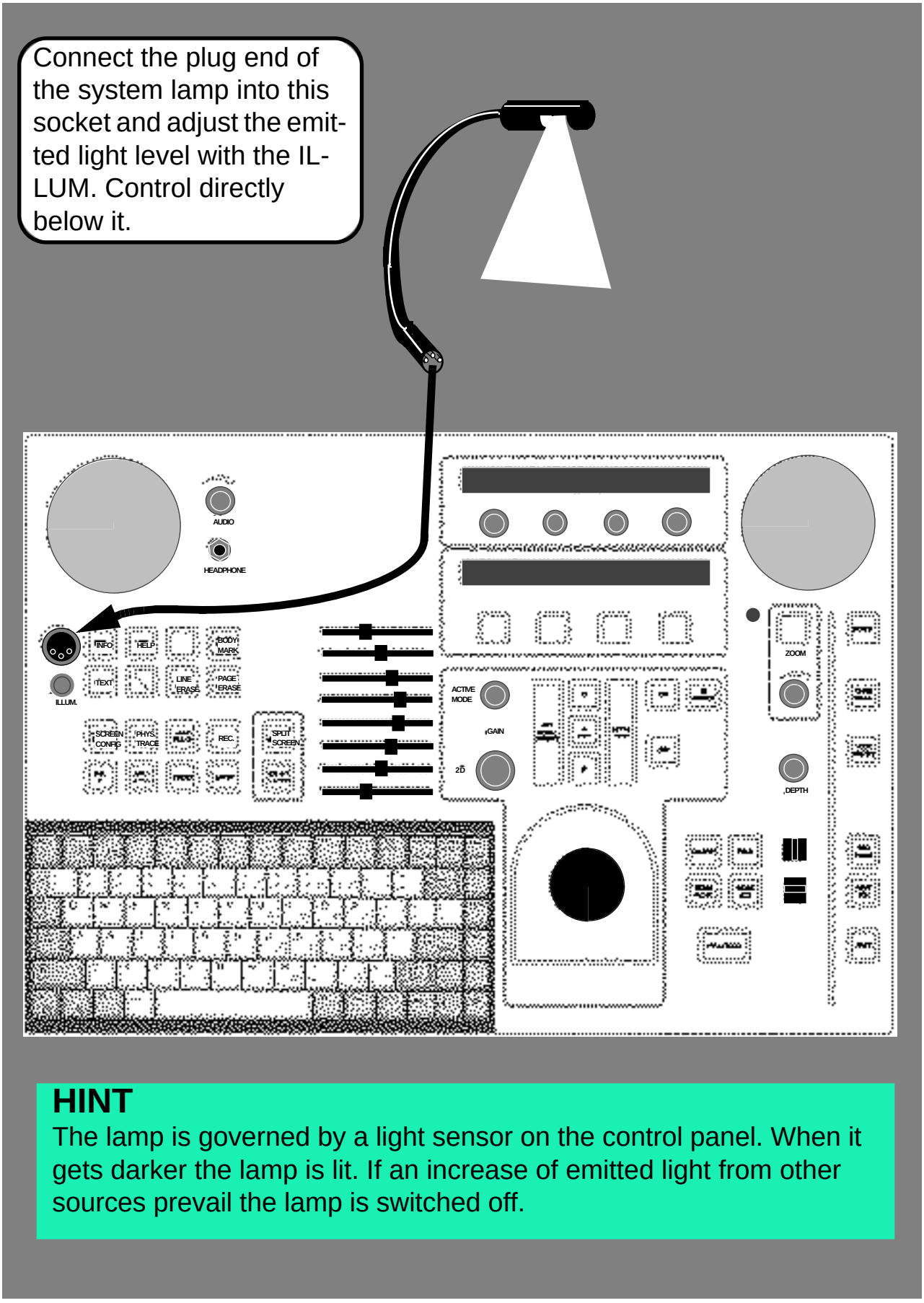
Control Panel Equipment

Headphone connection and volume adjustment



Control Panel Equipment

Lamp Connection

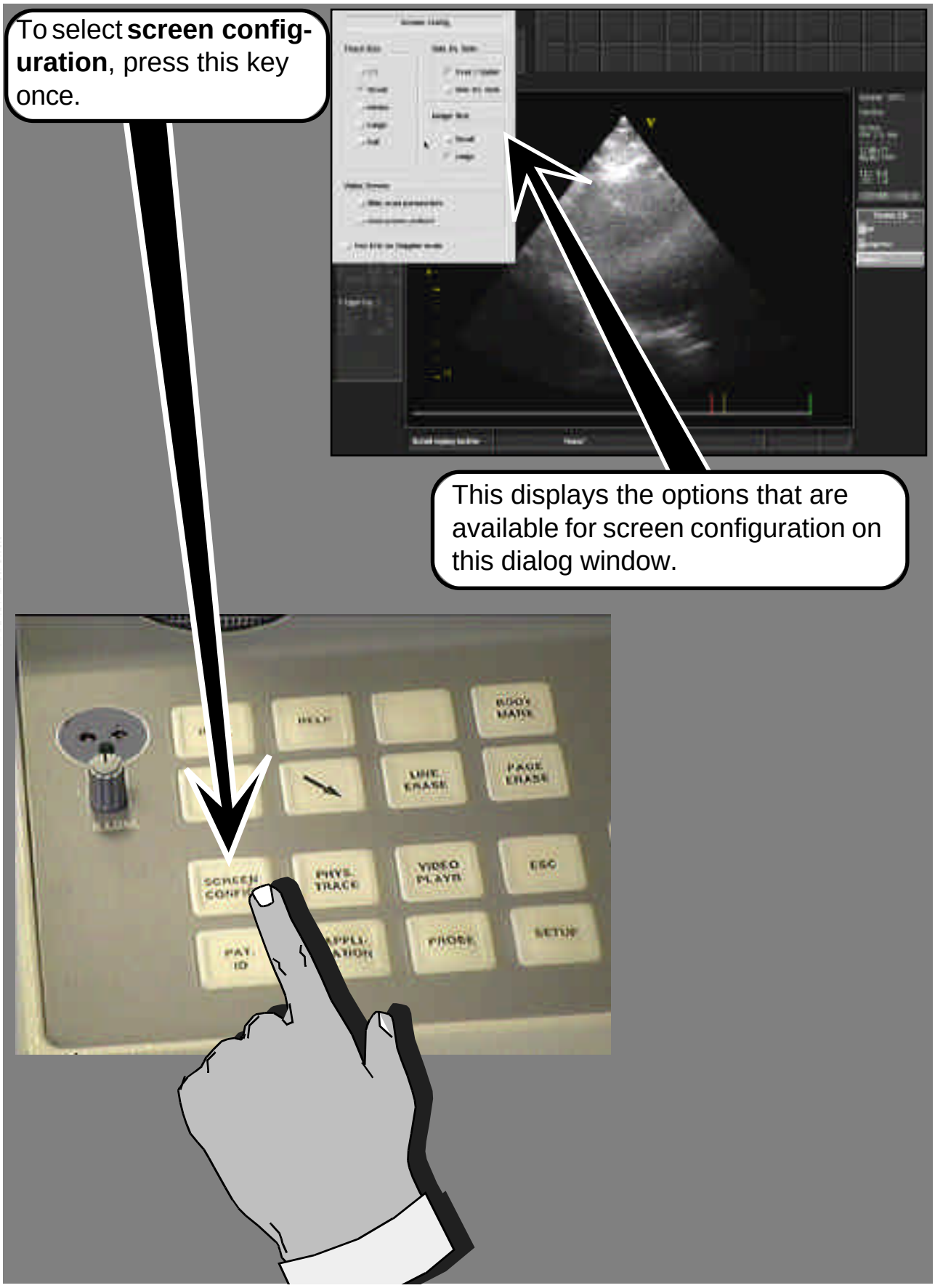


HINT

The lamp is governed by a light sensor on the control panel. When it gets darker the lamp is lit. If an increase of emitted light from other sources prevail the lamp is switched off.

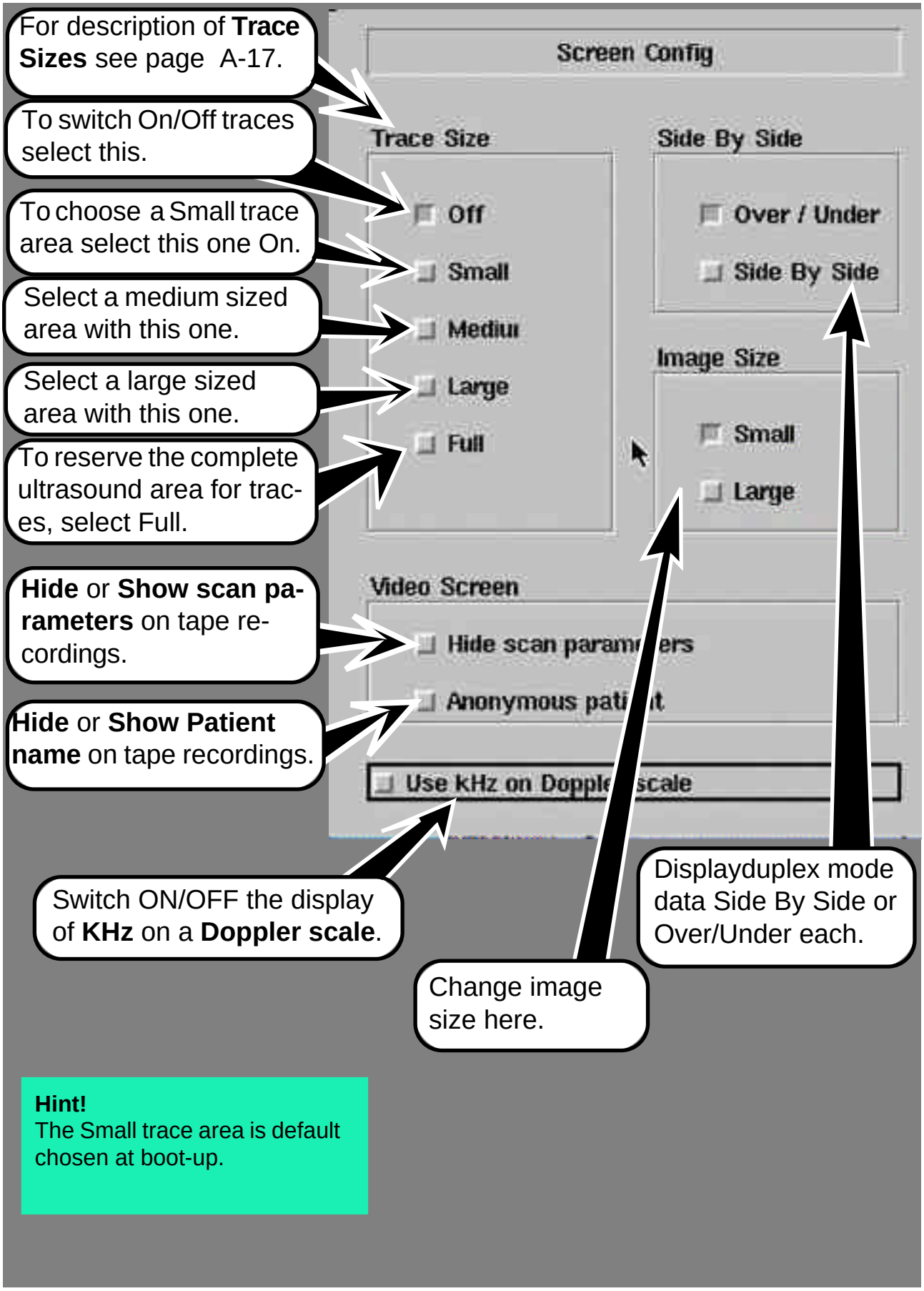
Screen Configuration

Start screen configuration



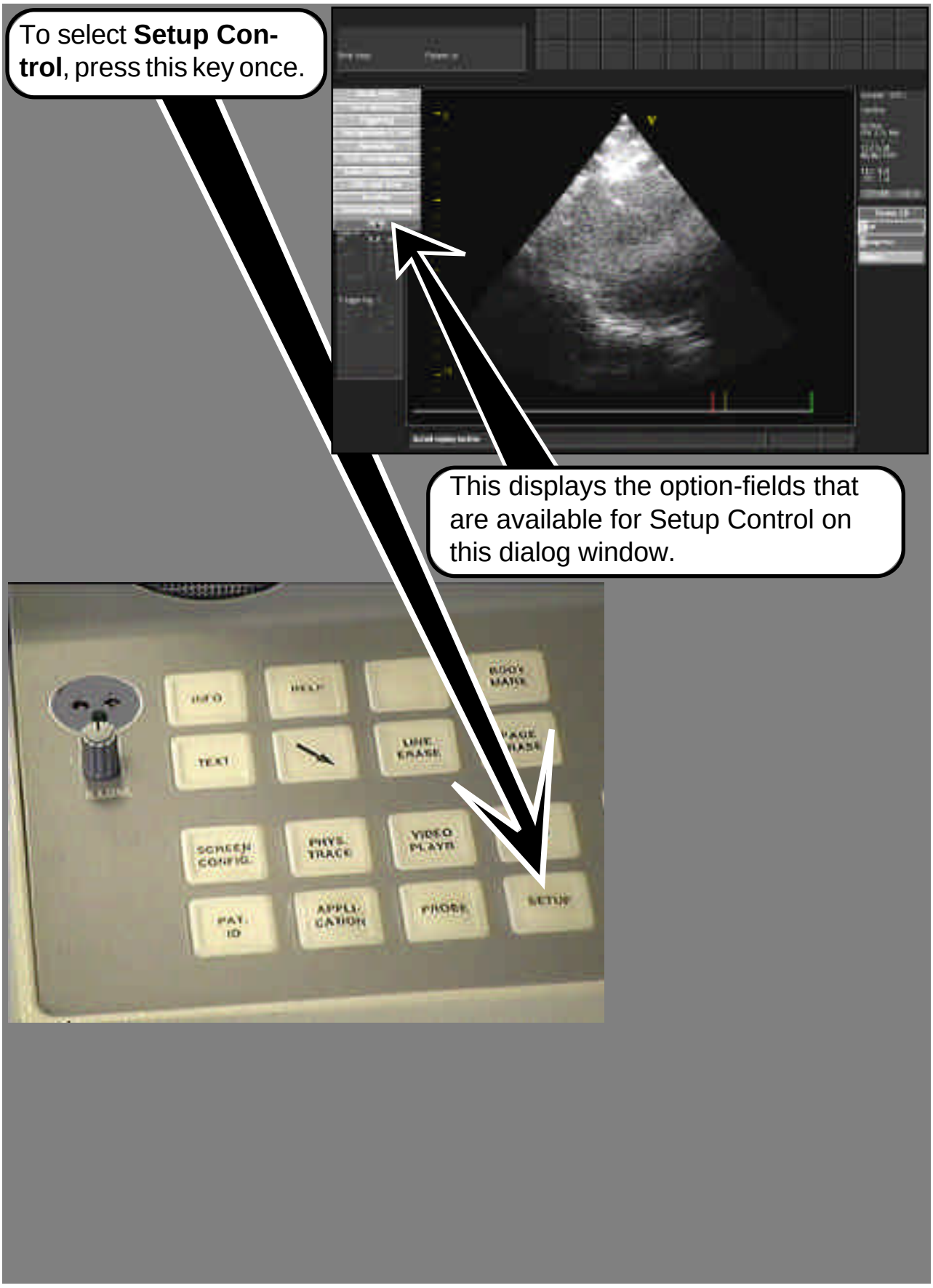
Screen Configurations

Configure Scanner Screen and VCR recording



Setup

Start System Setup



Setup

Get a Setup Menu overview

Here, you have an overview of the options on the Setup menu. Change the setup whenever you change probes or application.

Done exits you from the setup menu. Changes are automatically saved on exit by **Done.**

Most of these options have their own separate descriptions on the following pages.

Footswitch mapping is described in the Footswitch mounting description found **on page 20.**

Setup

User Interface

Do your User Interface setups on this configuration screen. It allows you to configure Freeze and Autofreeze functionality.

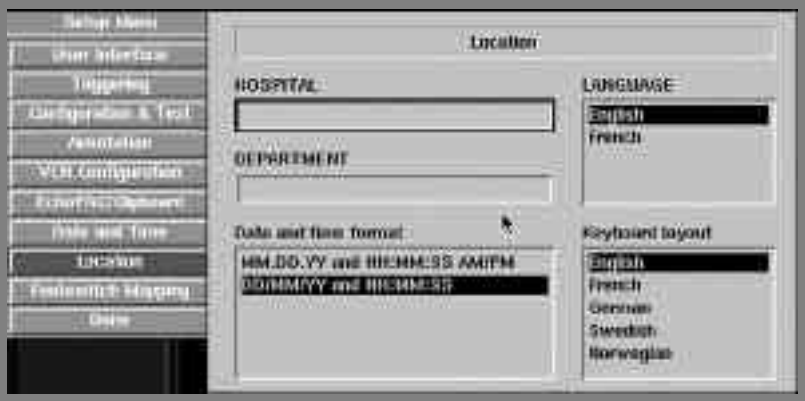
Setup

Do Date & Time and Location setup

On the **Date and Time** Setup dialog set the Date and time of day in a format that is selectable on the Location dialog, described below.

To set date, make **New Date** area active, erase contents within, enter new date in same format as removed contents and click-select **Set date** to start it at **Current Date**.

To set time, make **New Time** area active, erase contents within, enter new date in same format as removed contents and click-select **Set time** to start it at **Current Time**.



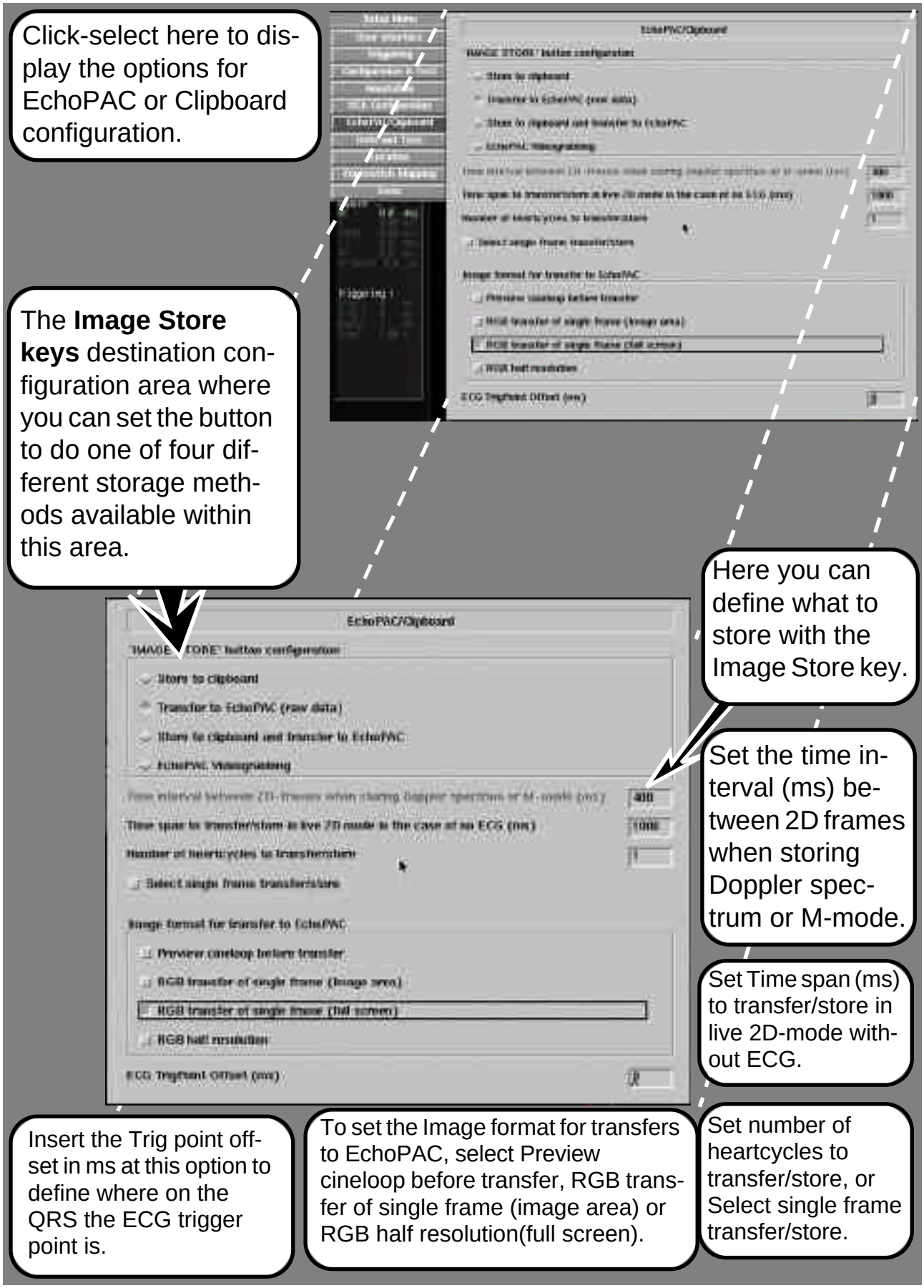
On the **Location Setup** dialog, enter the **Hospital** name. Enter the Hospital **Department** name where the system is to be used. Choose the native **Language** of the country that the hospital is located in and choose a **Date** and **time** format.

To enter **Hospital** and **Department** names, make each area active, erase any wrong contents, type the correct names at each.

To choose a **Language** or **Date and Time Format** for system display, place the cursor within each area and click-select the correct **language** and **Date and Time format**.

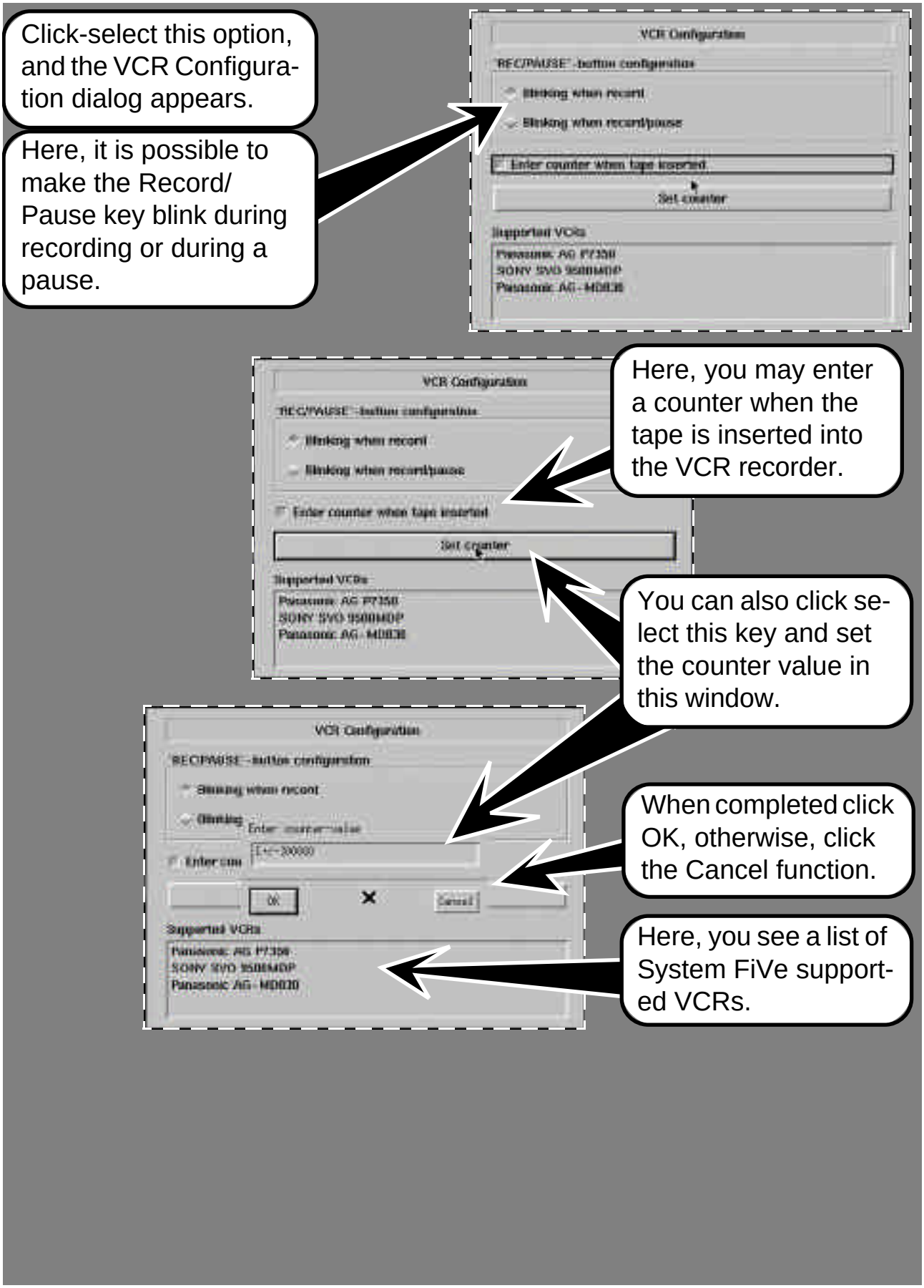
Setup

Do EchoPAC/Clipboard setup



Setup

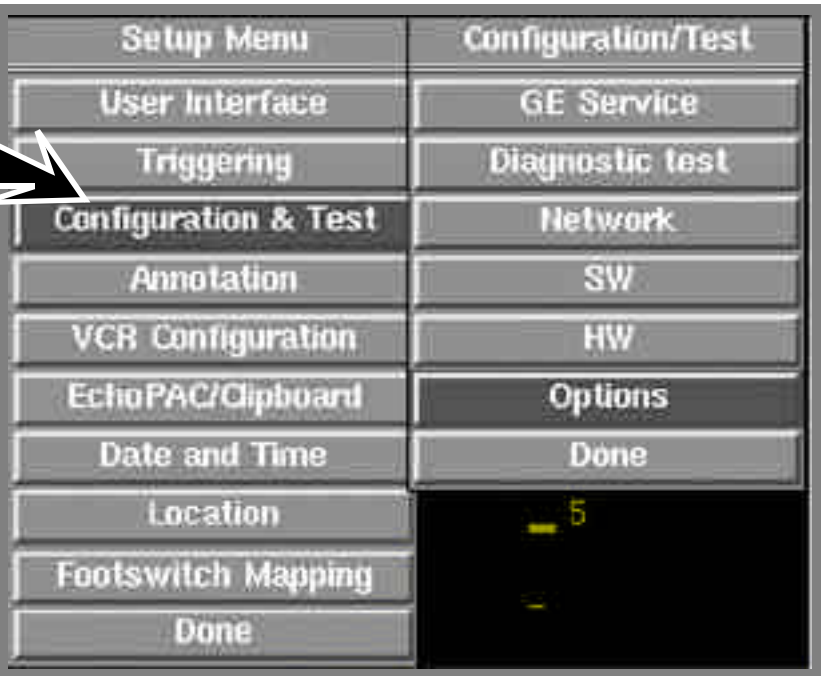
VCR Configuration



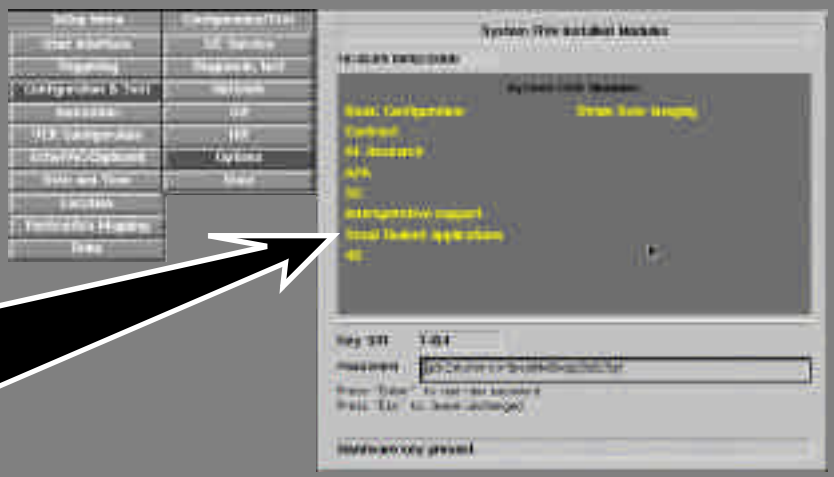
Setup

Configuration and Test

This function gives access to Password input for GE service and System Options, tests, and Software and Hardware overviews.



The System options and password input example is displayed when you select Options. Yellow text reflects the installed, Black text displays the available.

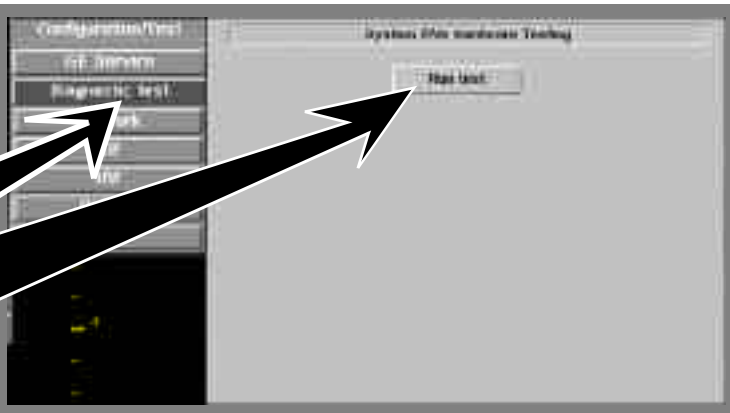


This is the Hardware Module overview. Actives you module names, part numbers and their revisions levels, Master Control Document revision, Factory Order number and production series number.

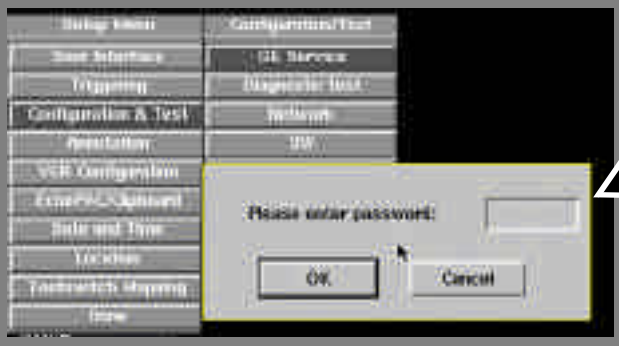
Setup

Diagnostic Tests, Software versions, GE Service

Select this key to start a Diagnostics test. The test proceeds automatically when you select Run test. When completed, a list of results is displayed in the grey area.



Select SW to display the system sw versions.



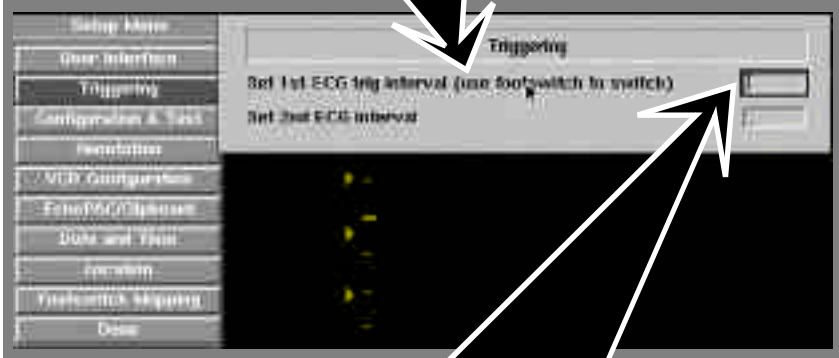
This is the password access to the system for GE Service personnel only.

Enter the password to gain access to this set of service functions

Setup

ECG Triggering

Triggering is a special function for the Contrast Option in ECG triggered acquisition.



It allows you to set two individual ECG trigger intervals. Configure one of the pedals on the Footswitch to quickly toggle between the intervals.

In our example let's enter 3 in the first input box and 5 in the next which means that we want the system to trigger at the third or fifth heartcycle.

To make the left pedal toggle between the two, switch ON the ECG trig Interval sw.

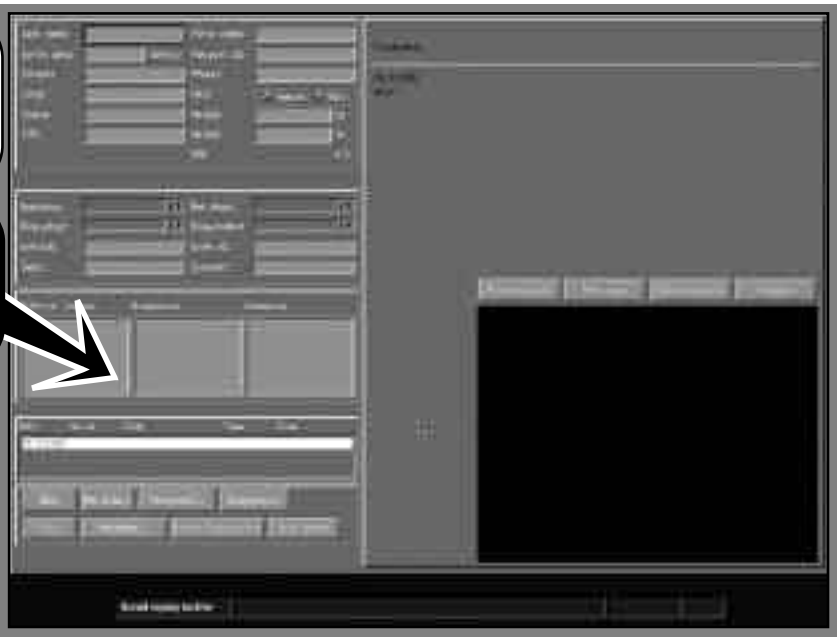
The left switch pedal will now trigger at the third heartcycle one time you press it and on the fifth the next time in accordance with our example.

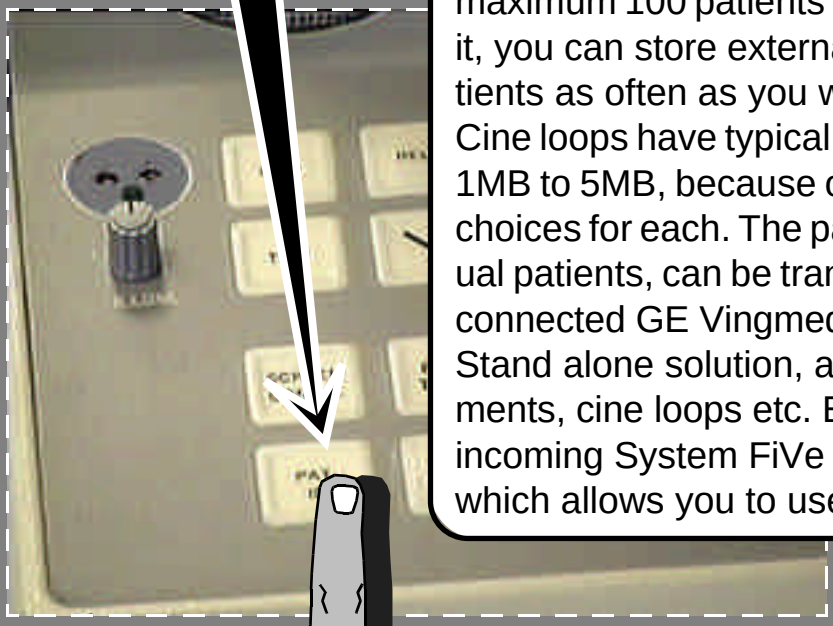
Internal Patient Archive*

Open the internal Patient Archive

*The Internal Patient archive is only available on Systems without an integrated EchoPAC.

To start the internal patient archive for patient ID entries, press this key.





Internally, the system is designed to handle maximum 100 patients at a time. Within this limit, you can store externally, delete and add patients as often as you wish. Internally Stored, Cine loops have typical data sizes ranging from 1MB to 5MB, because of probe and application choices for each. The patient archive, or individual patients, can be transferred to an externally connected GE Vingmed Ultrasound EchoPAC Stand alone solution, along with measurements, cine loops etc. EchoPAC converts the incoming System FiVe data to its own format which allows you to use it at a later stage.

Hint
You may scan a patient without entering Patient ID. To store this however, in a retrievable manner, you should always do ID entries prior to storage. Scanning is described in **Chapter B**. Id entry and storage descriptions continue here.

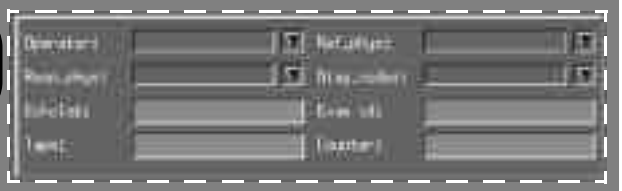
Internal Patient Archive

Do Patient information storage

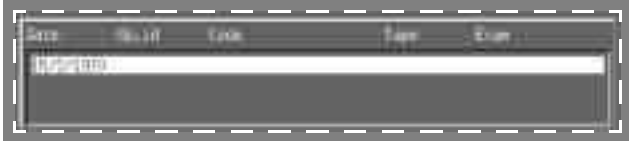
The area for Patient ID entries where Minimum accepted input is the Last Name.

Hints:
Maximum number of characters in text entries:
Last name: 30
First name: 30
Birthdate: 10
Patient ID: 30
Street: 20
Phone:20
City:20
State: 20
Weight:15
height:15
Zip:20

The area for examination background entries.



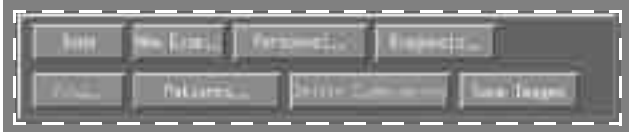
Hints:
Max.Characters & entries:
4 Pop-up menus: 8 user entries each.
Operator:16
Resp Phys:16
Rep Phys:16
Diag codes:16
Echolab:20
Tape:20
ExamID:20
Counter:20



This is the Examinations overview area. Its displayed contents, also dependent on the input from the above areas.

Area for free text input as Referral reasons, Diagnosis and Comments.

INFO
All text input from keyboard. Delete text input with Backspace key.



Screen function keys described separately on following pages.

Internal Patient Archive

New Exam

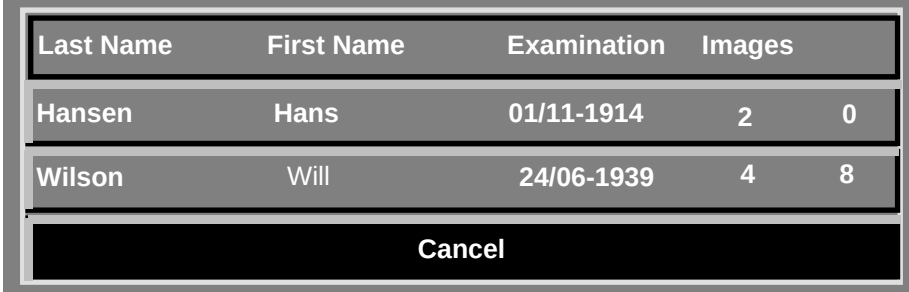
To tell the system that you are going to do a New Examination, click-select this screen function.

On the New Exam menu that appears, use the Trackball and the Select function to choose one of the menu alternatives or Cancel the activity.

Find patient

To find a patient name stored on your system, click-select this function.

On the patient list that appears, use the Trackball and Select function to choose the correct patient or cancel to exit.



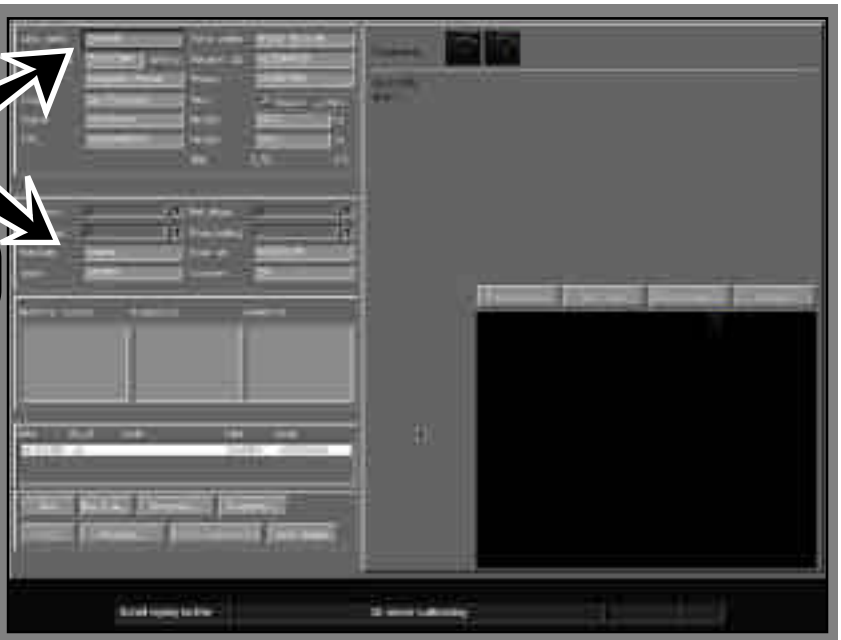
A patient file similar to the one shown on the next page, regarding your selected patient, is displayed.

Note!
If you are going to do a new examination, find the patient via the **New Exam** function.

Internal Patient Archive

Complete an Exam entry

A complete ID entry, prior to an exam, will resemble this.



Minimum input is the last name.

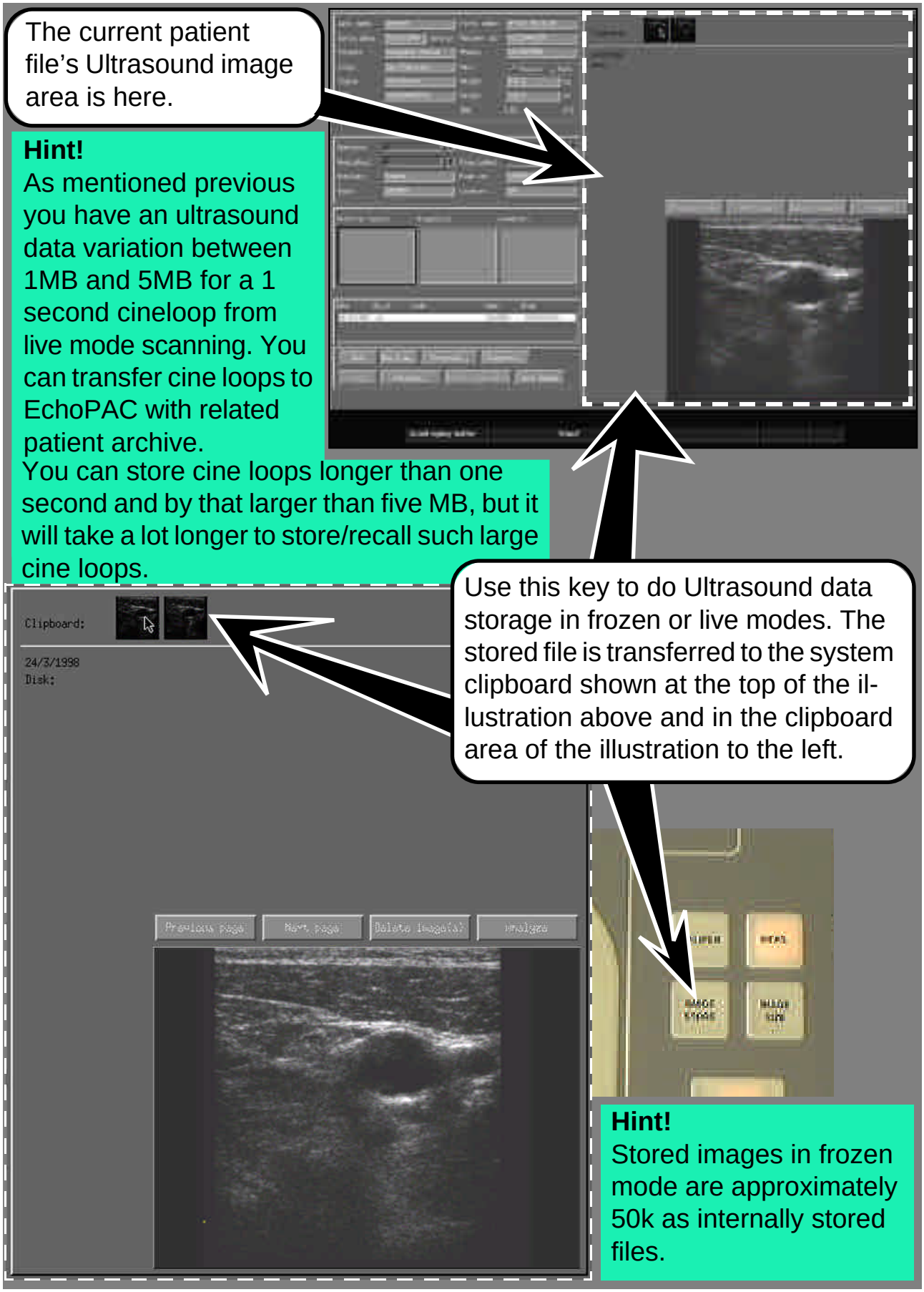
Exit from patient archive with **Done** or **Cancel**.

If EchoPAC is on-line with System FiVe, EchoPAC will also automatically create a home screen for your patient, shown to the left.

If you shut down EchoPAC, and restart it, it automatically comes up again with the same home screen.

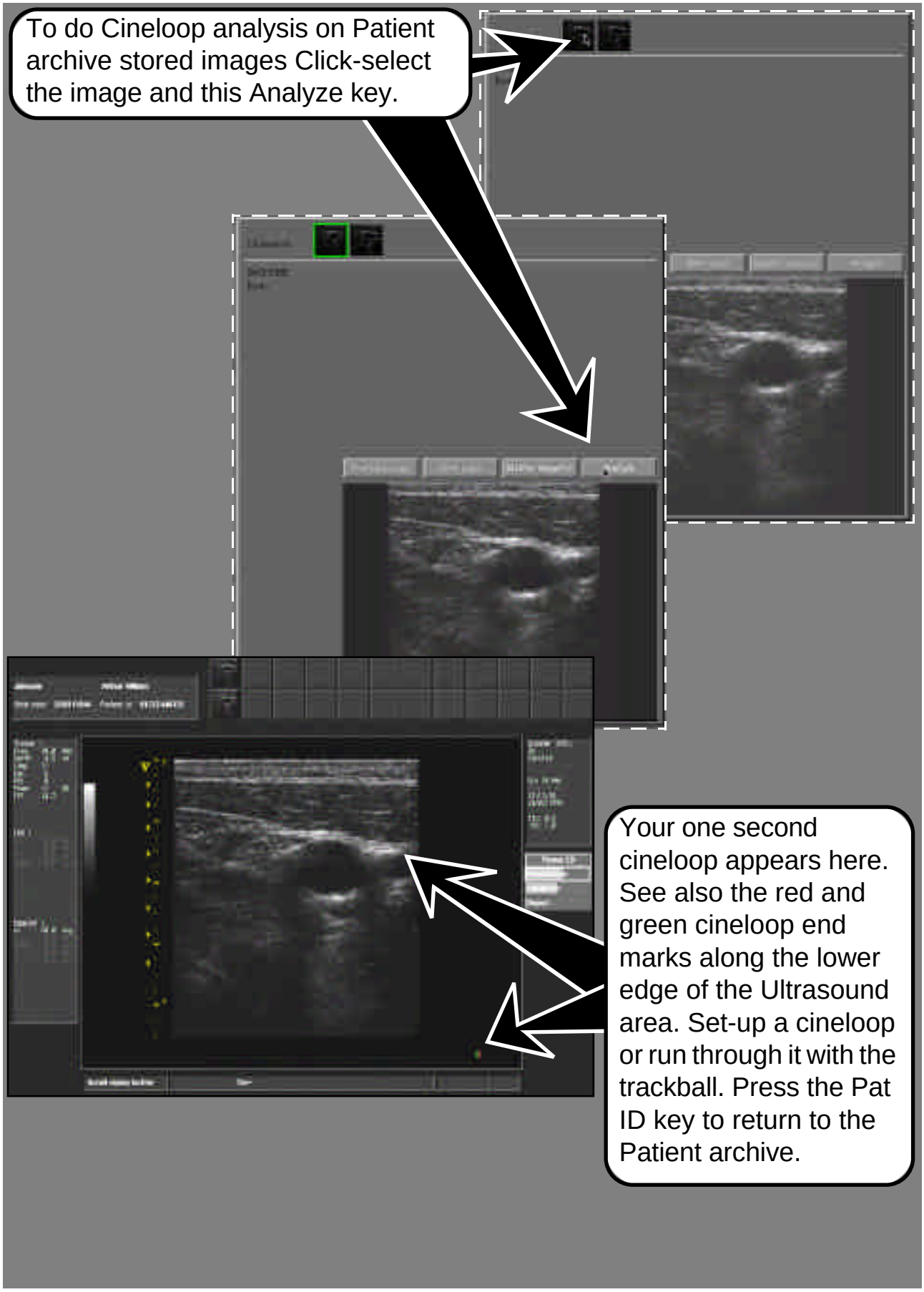
Internal Patient Archive

Do Ultrasound Image storage



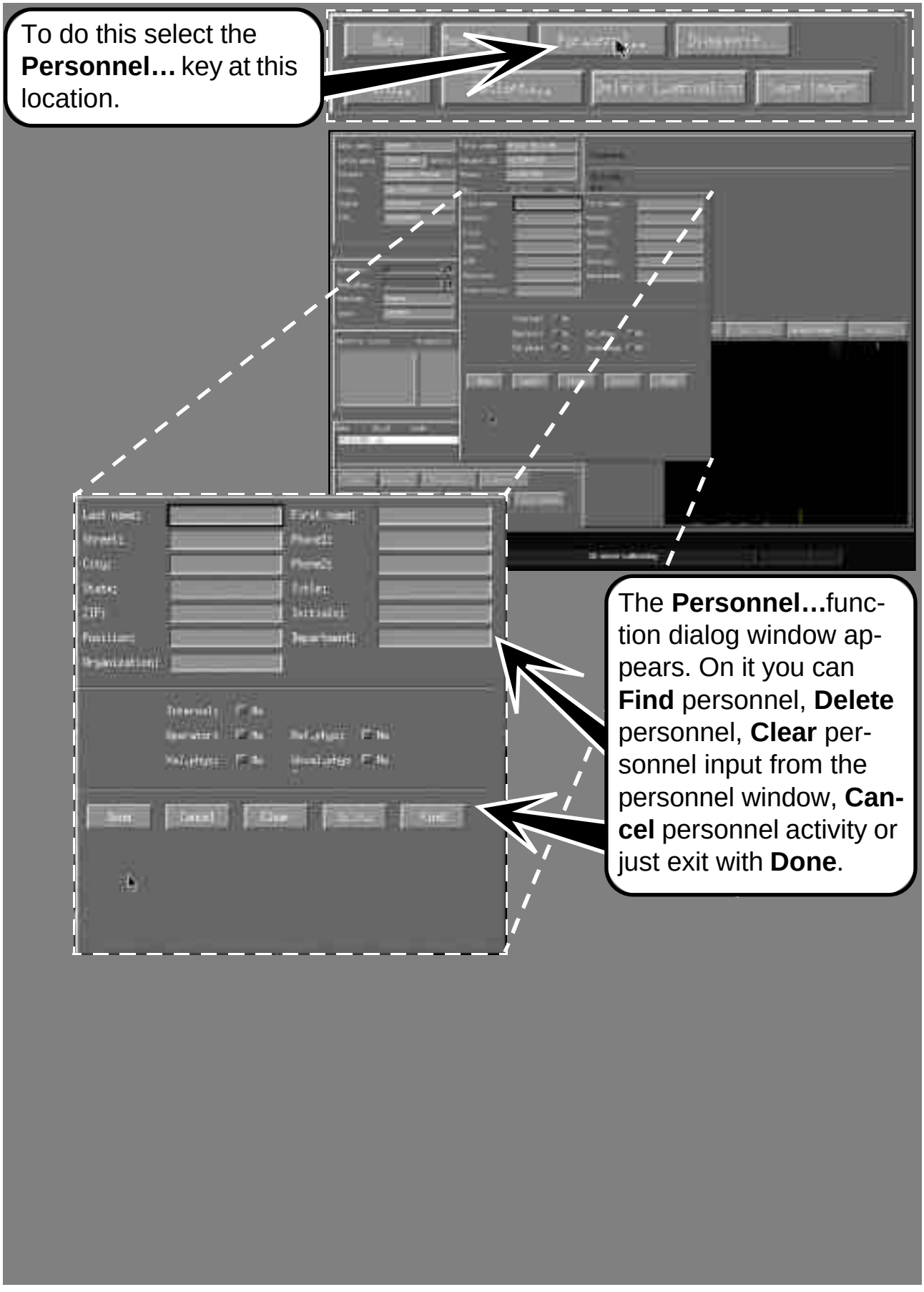
Internal Patient Archive

Cineloop Analysis



Internal Patient Archive

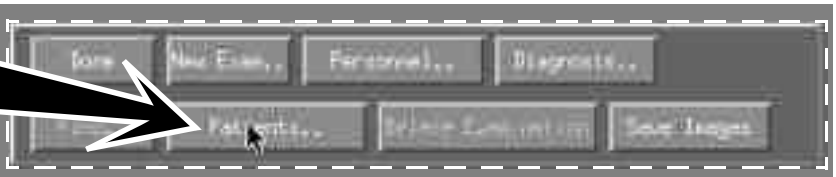
Add, Find, Edit, Delete Personnel…



Internal Patient Archive

Patients list handling

To display the Archive Patients list click-Select this key.



Use this function to handle patient file storage limits within the system (Thirty Patients). With it you can select the current, any individual or all files, transfer the current file, any file or all files to EchoPAC. After the transfer to EchoPAC, you can Delete current, any individual or all patient files, plus their images etc., from the internal storage area.

The thirty patient files, are stored here when the scanner is not in any way connected to EchoPAC.

Hint
The system can be configured so that all patient files established on the system go directly to EchoPAC storage and never land here.

To **Select all** in archive list, press this key.

Press this key to **Save** the **current** patient **to** the intern **Disk**

Press this key to **Delete** a **selection**. It deletes your patient selection and its images etc.

Press this key to Save the current patient to the on-line EchoPAC solution. Images etc. are in the transfer.

To Transfer all selected, or just a selected patient, to an on-line EchoPAC, press this key. Images etc., are in the transfer.

Exit from this with **done**.

Internal Patient Archive

Diagnosis entry

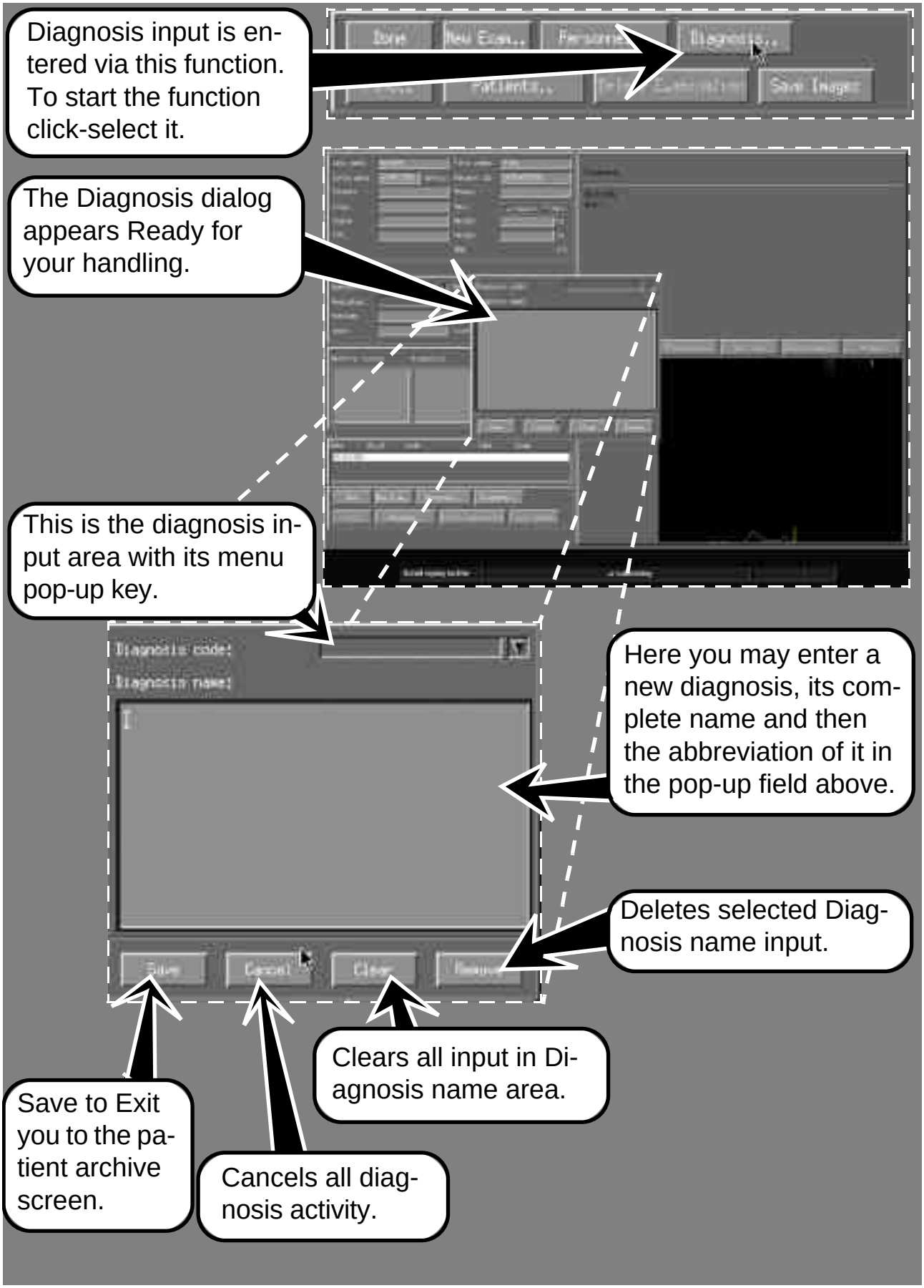
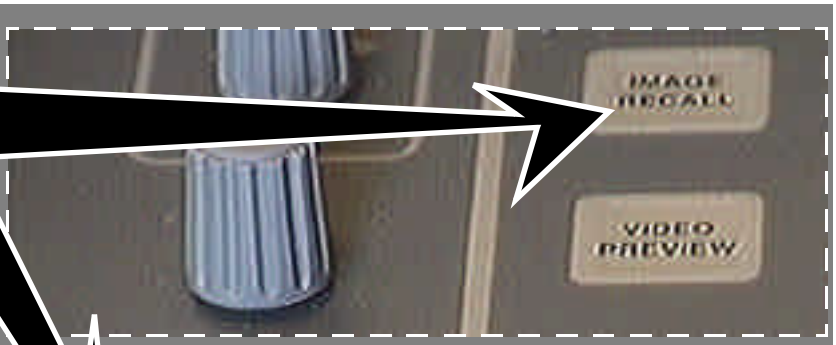


Image Recall

Recall the clipboard image

To recall Clipboard stored images, press this key. You are then asked to click-select one of the icons on the clipboard area. Click-select it.

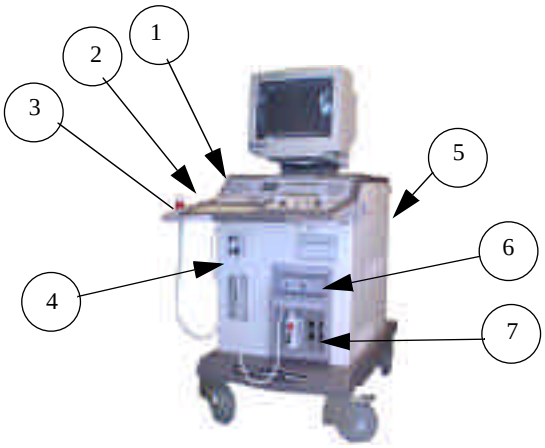


Your selected image recall is then displayed as shown here.

System Quick Reference

System connections

Note
Study mobility warnings on pageF-193 before you start using the systems mobility.

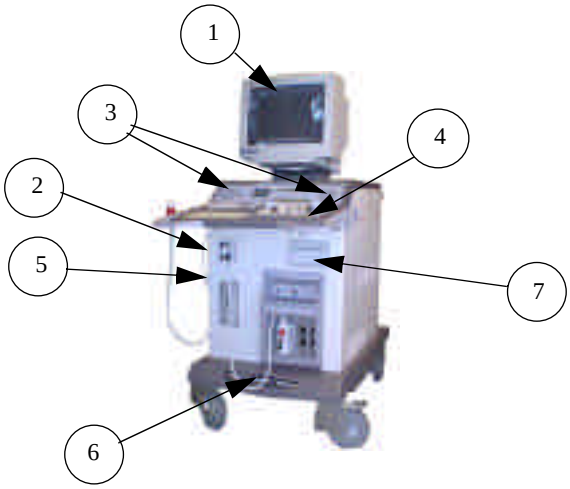


Warning:
Even though they may look and feel alright afterwards, never continue using any Vingmed Probes that have been dropped onto or bashed against hard surfac-es . Such probes must be disconnected and tested by qualified personnel.

Number label	Title	Contents
1	Headphone	- Headphone connector with vol-ume control
2	Illum.	- One lamp connector with Intensity adjustment
3	External I/O panel, (Left side, rear) **See warning text on pageF-193**	- Two RS232 interface sockets - One ECG TRIG socket - One Ethernet interface socket - One SVHS OUT socket - One SVHS IN socket - One Composite Video output socket - One Composite video input socket - One B/W Video output socket - Four Analog input sockets - Output sockets for color printers
4	Patient I/O panel	- One pressure sockets(option) - One Respiration socket(option) - One Phono socket(option) - One ECG socket
5	Rear wall	- One mains cable - One Power ON/OFF switch - Protective earth
6	Upper Front End panel	- Two Annular Phased Array probe sockets - One Doppler probe socket - One system Standby-ON switch
7	Lower Front End panel	- Sockets for three Phased Array probes - A parking socket for an unused Phased Array probe P.S.A Phased Array probes must be connected at position 1 before Power Up.

System Quick Reference

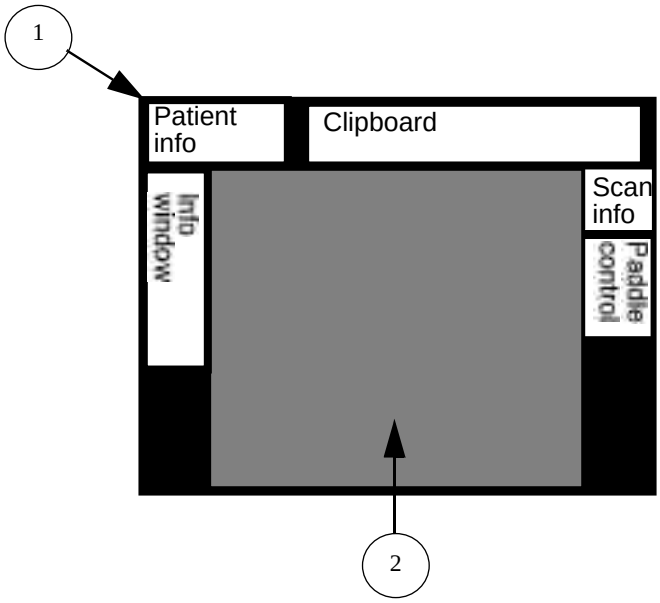
System communication



Number label	Unit	Communication type
1	Screen	- Visual
2	Video Cassette Recorder	- Taped
3	Loudspeakers	- Sound
4	Control Panel	- Key
5	Printer	- Paper
6	Footswitch	- Pedal switches
7	Printer	- Paper

System Quick Reference

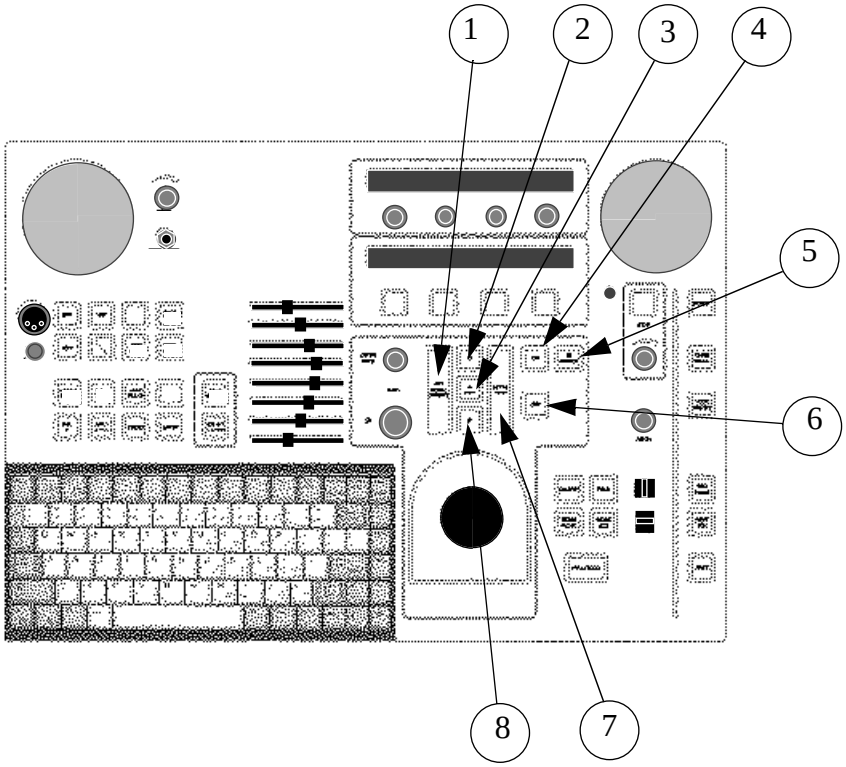
Screen areas



Number label	Title	Contents
1	Information display area	- Patient ID - Clipboard - Current clinical application icon - Date and Time - Operator ID - Replay indicator - Thermal index - VCR Status - Active mode - Paddle report window - System messages - Warnings - User adjustable parameters - Performed measurements - Measurements list
2	Ultrasound display area	

System Quick Reference

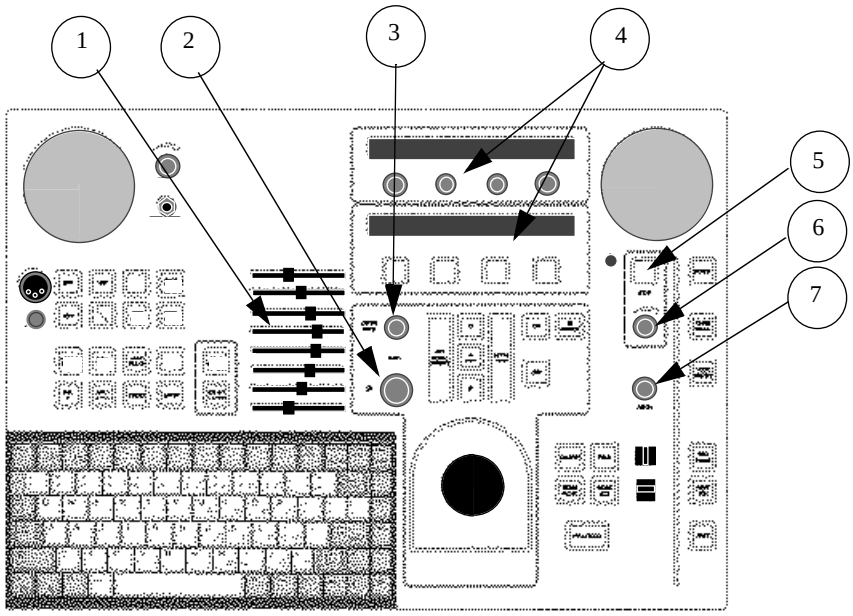
Scan mode selection



Number label	Title	Activity
1	ADD MODECURSOR/	- Adds a non-displayed mode to a Simplex mode or Duplex mode situation in combination with the specific mode key - Adds a screen cursor to desktop activities and displayed communication windows
2	DOPPL.	- Starts the default Doppler Mode
3	M-MODE	- Starts the M-Mode
4	CW|PW	- Starts the CW and PW Doppler Modes
5	2D FREEZE	- Halts activity in 2D mode
6	CFM	- Adds Color Flow to 2D Mode and M-Mode
7	ACTIVE MODE	- Switches active mode in Duplex and Triplex mode situations.
8	2D	- Starts the 2D mode

System Quick Reference

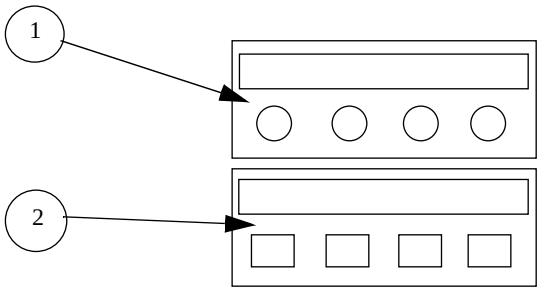
Basic mode adjustments



Number label	Title	Activity
1	TGC slides	- Adjust the amount of echo brightness at specific depths in the 2D sector
2	GAIN, 2D	- Adjusts the overall amount of echo brightness within the 2D sector
3	GAIN, ACTIVE MODE	- Increases or decreases echo brightness within the active mode window
4	Assigned keys and rotaries	- See next page.
5	ZOOM, Step variable.	- Enables step variable zoom.
6	Continuously variable ZOOM	- Enables continuously variable zoom.
7	Depth, 2D sector	- In 2D, 2D/color, M-Mode and Color M-Mode it adjusts the depth of the data sampling area which is displayed. - In PW Doppler it adjusts the depth of the measuring point.

System Quick Reference

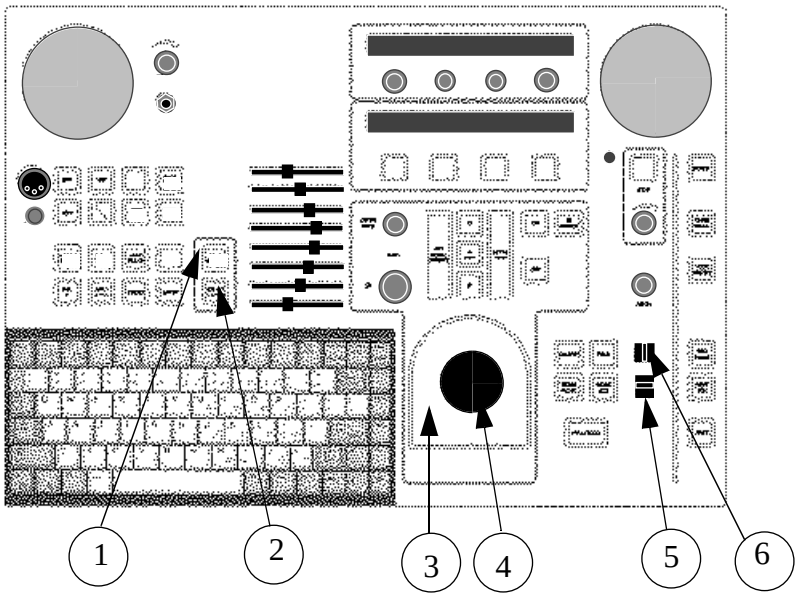
Assigned Keys and Rotaries



Number label	Title	Contents
1	Upper assign panel	- A continually mode updated rotary function label window - A row of mode assigned rotaries
2	Lower assign panel	- A continually mode updated key function label window - Mode assigned keys

System Quick Reference

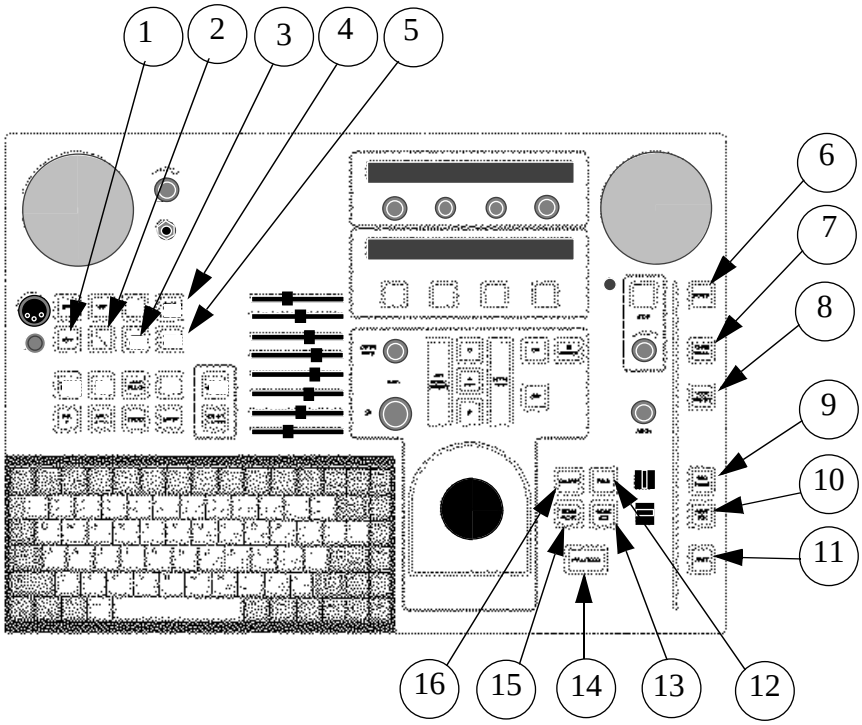
System screen tools



Number label	Title	Activity
1	SPLIT SCREEN	- Divides the acquisition area into two halves, horizontally or vertically.
2	SELECT SCREEN	- selects active screen
3	Select key	- confirms selections
4	Trackball	- steers the Pointing device
5	Vertical paddle switch	- moves activity between menu fields vertically.
6	Horizontal Paddle switch	- moves activity between menu fields horizontally.

System Quick Reference

Post-processing functions



Number label	Title	Activity
1	TEXT	- starts the text annotations function.
2	ARROW	- allows arrow annotation with trackball and select key.
3	LINE ERASE	- removes a selected text line.
4	BODY MARK	- starts body marking function.
5	PAGE ERASE	- erases all annotation arrows on active screen.
6	REPORT	- starts the report generator function.
7	IMAGE RECALL	- recalls stored image from clipboard.
8	VIDEO PREVIEW	- displays video preview before VCR storage.
9	REC/PAUSE	- remote VCR control.
10	PRINT (ALT.)	- prints on alternative printer.
11	PRINT	- prints on default printer.
12	MEAS.	- starts M&A.
13	IMAGE SIZE	-changes size of displayed image .
14	FULL FREEZE	- halts active scanning
15	IMAGE STORE	- saves single images or cineloops to clipboard.
16	CALIPERS	- starts calipers M&A

Chapter B

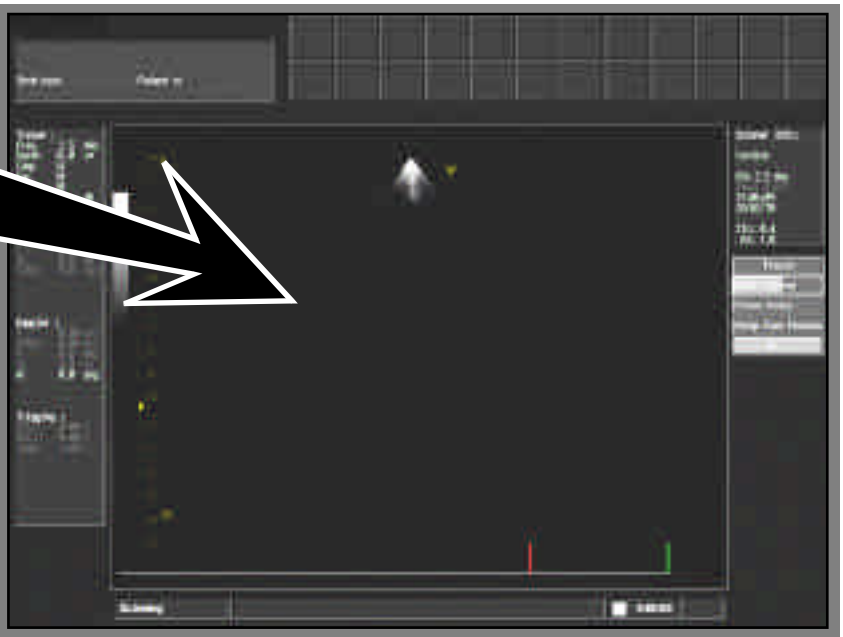
Scanning

This section tells you about:

2D Mode

Start 2D scanning

At every boot-up, the System Five starts in the previous shut-down mode.Here, It is 2D-Mode.



About 2D Mode -1
2d mode gives a 2-Dimensional ultrasound-generated view of the heart where you perfect its presentation with mode - available tools.

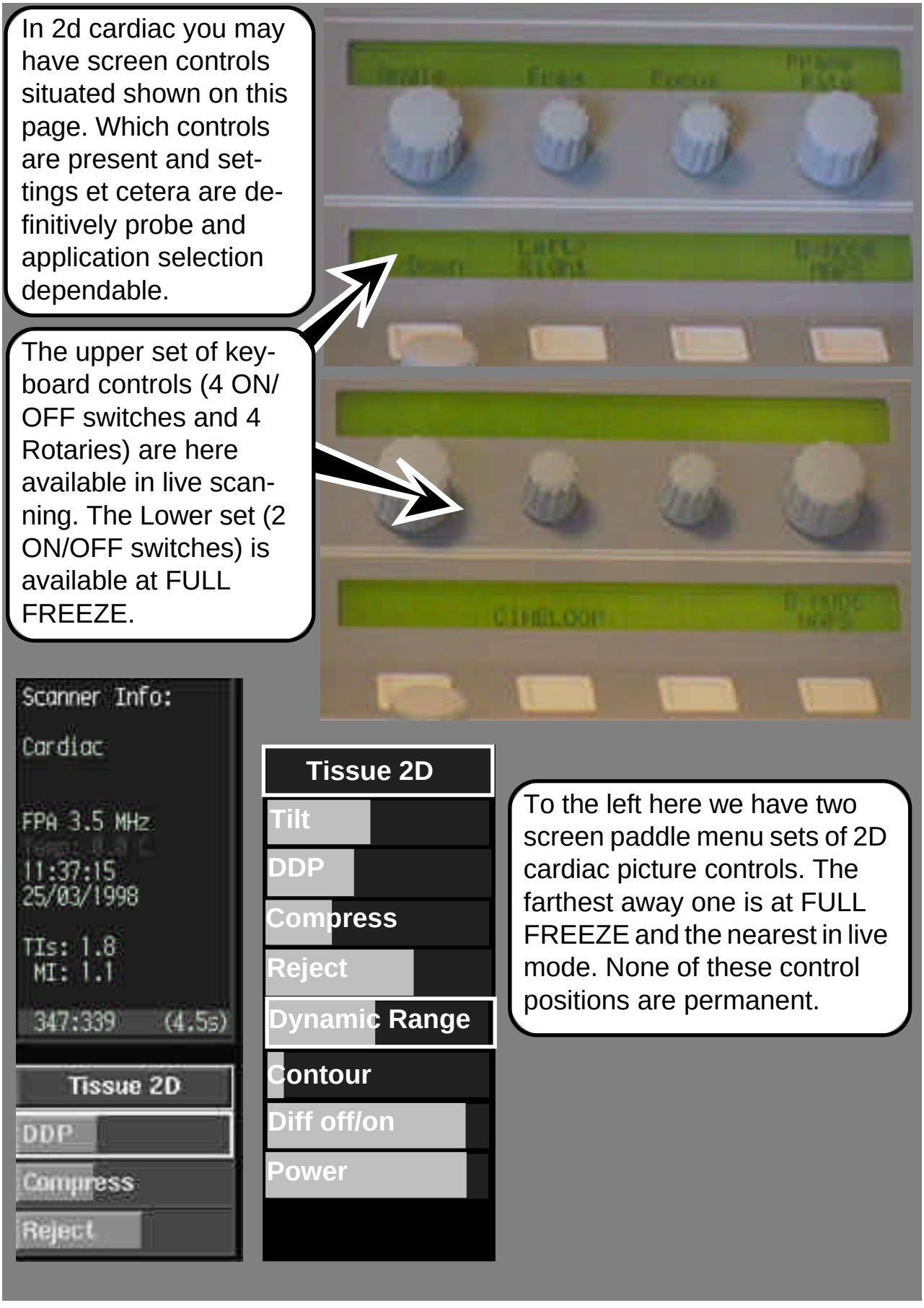
About 2D mode - 2
The gotten views allow you to study tissue behavior and valve functioning primarily.

Place the probe onto the patient, start scanning and image adjustment.

In this case the patient is also connected with ECG cabling where trace handling etc., is described in chapter A, under section for Patient I/O & traces setup.

2D Mode

Ultrasound picture Controls



2D Mode

Control Panel Re-programmable Rotaries & keys

Angle
Controls the scan sector angle.

Frequency
Frequency is the transmitted frequency that your acquisition scan has. Frequency variations, depends on probe and application selections.
-Increase the frequency value to improve resolution.
-Reduce thefrequency value to improve penetration.
There is often a tradeoff situation between the two.
Frequency adjustment in 2D imaging changes the display framerate and moves the focal marker to a new position on the screen depth scale.

Cineloop (FULL FREEZE only) is a group of functions that you to create and run a mini movie from the stack of scan data found in the systems replay memory.

Up/Down
Theseflip the ultrasound image upside down or downside up.

Left/Right
These flip the ultrasound Image right or left

Focus
Focus positions the transmit focus point(s) within the transmitted sector depth, indicated by a focal marker on the screen depth scale. Available focal regions overlap, and make it possible to focus on any part of the image.
If you use ZOOM in live 2D, the focal point(s) move to within the zoomed part of the image. If you exit from zooming, without touching the focal control, the focus returns to the position it had before you activated ZOOM.

Framerate
Framerate controls the resolution in image movement and detail.
Increase the framerate to get frames with less focal points and made up of wider beams, which in turn gives images with poor detail resolution but high temporal resolution.
A framerate reduction does the exact opposite.
The control is not available for APAT (annular array) probes.

B-Mode maps (Live and FREEZE)
This function Displays a menu of alternative color maps for displayed tissue, selectable from the trackball and Select key area.

The Cineloop Re-programmables

2D Mode

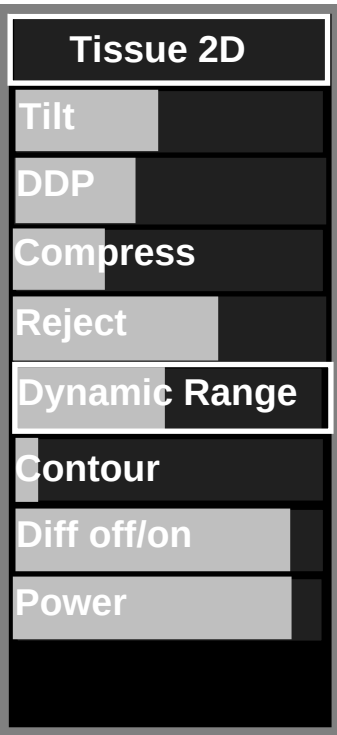
Screen commands, Cardiac, Live & Full freeze

DDP (Data Dependent Processing)

In cases where normal scan adjustments are not enough, cases where random artifacts, appear as bright speckles, in your image, try DDP. Increase DDP to remove the speckle without effecting moving structures such as valve flaps etc.

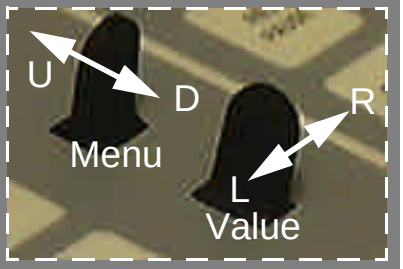
Compress

Compress adjusts the greyscale range of your image. No Compress hardens your image, giving it a black and white appearance. Increased Compress tends to make your image grayish, and in turn softer.



Reject

Reject removes low amplitude unwanted noise echoes in your image. Increased Reject darkens your image and removes more and more of the low amplitude echoes. Avoid removing relevant low amplitude echoes. After Compress & Reject, readjust Gain, if necessary.



2D Mode

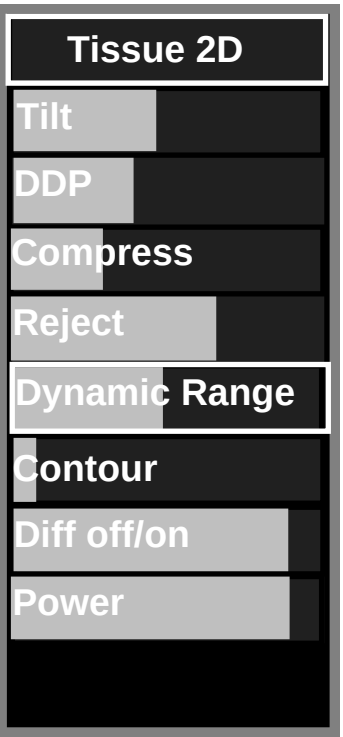
Screen commands, Cardiac, live only

Dynamic range
This function gives shades of gray to the various intensities of the incoming image data. It differs from Compress, Reject, postprocessing or screen adjustment controls because it actually preprocesses the grayscale range of the incoming data. Dynamic Range is a live mode function which is unavailable in Full Freeze mode.

Contour
Contour adjusts the **edges** enhancement in an image. Adjustments towards minimum give minimum enhancement.

Diff OFF/ON
This affects reverberations in the image. If turned on the frame rate (or focal zones) will decrease, while the reverberations attenuate

Power
Power adjusts penetration effectiveness. It does not increase the background noise that makes unwanted artifacts in doing so. Power increase improves penetration.



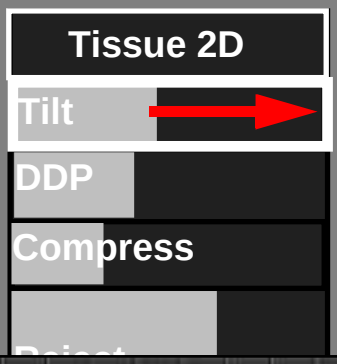
2D Mode

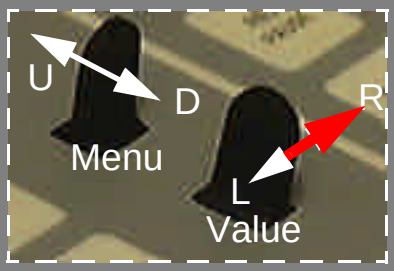
Sector Tilt

Tilt is active, whenever there is a 2D image present on the screen, without a Time motion cursor. When the cursor is displayed, tilt adjustment is disabled.

The Yellow marker that is visible at the top of the sector, marks the probe diode light's position.

On this System a less than 90°sector is tiltable in any direction, left and right, within the probes 90° scan range, by merely stepping the paddle.

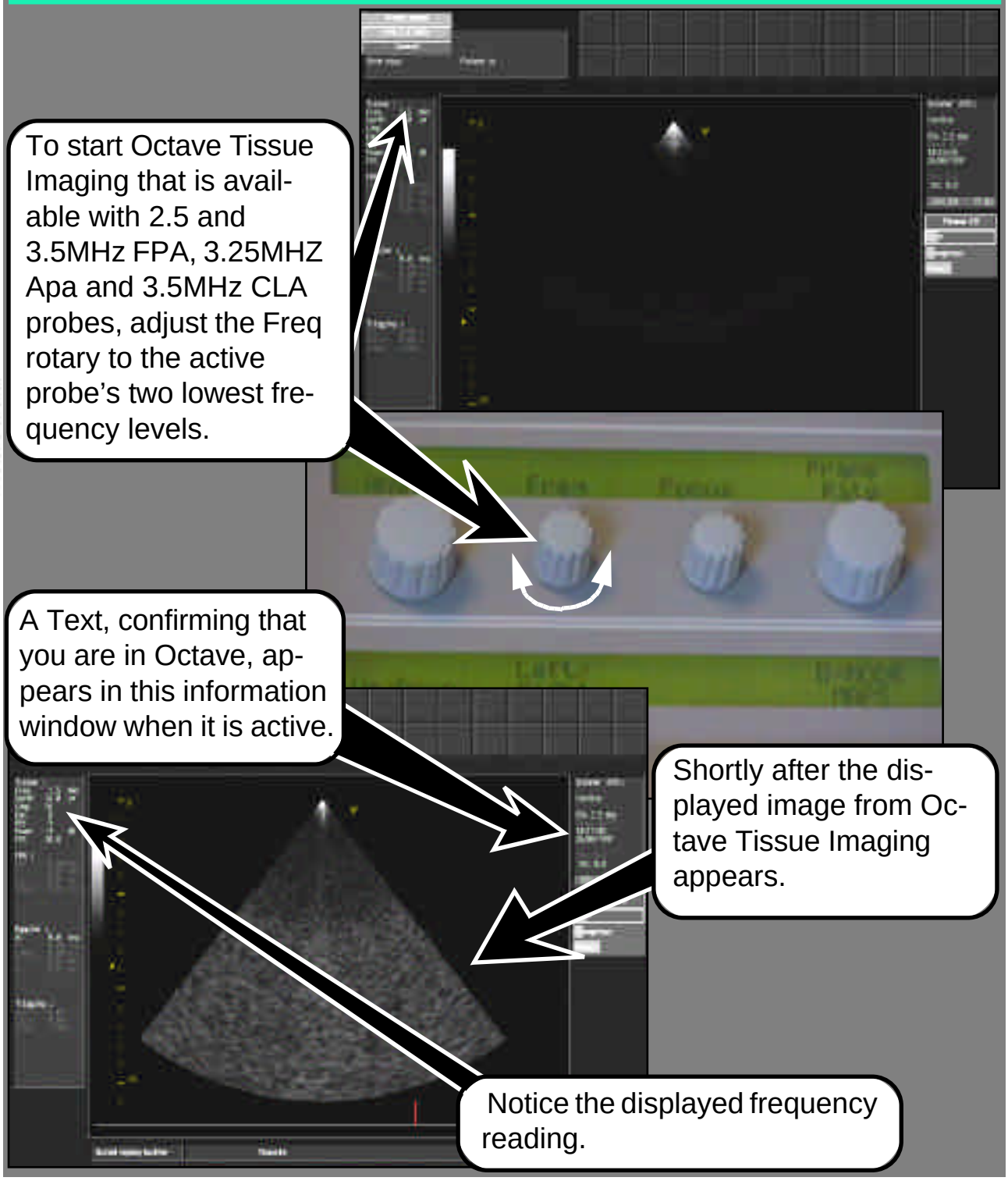




2D-Mode

Octave Tissue Imaging

Standard B-mode (2D) imaging transmits and receives ultrasound at roughly the same frequency. At higher power levels, return echoes from tissue are generated not only at the original frequency but also at twice the frequency transmitted. This frequency, known as the second harmonic, is one octave higher than the original frequency. These echoes are mixed with normal echoes when they return to the transducere but are much weaker. Within the System Five the second harmonic, from the received spectrum is separated, amplified and processed for display.



2D-Mode

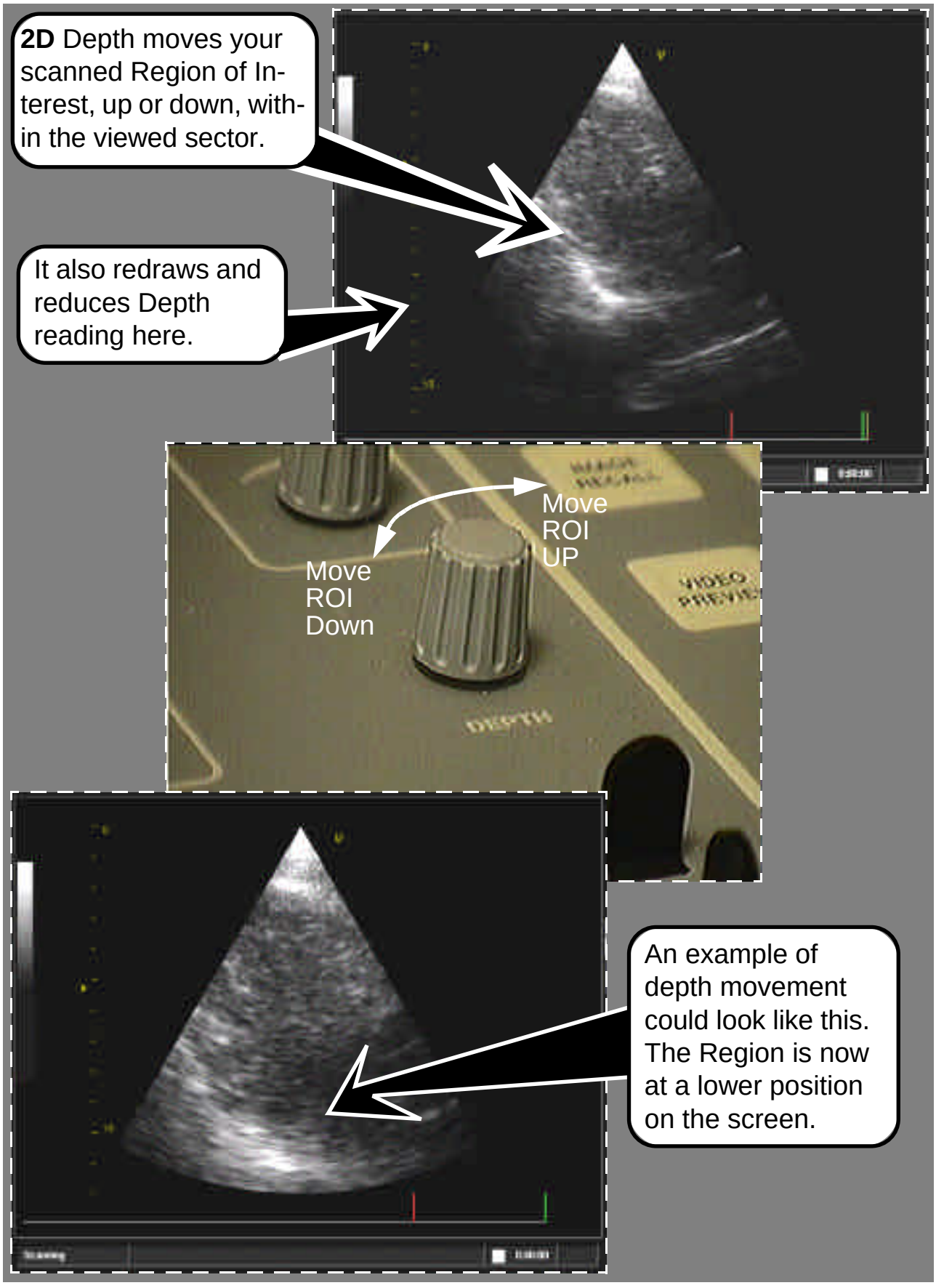
How does Octave Imaging improve image quality?

When Octave Imaging is active, the transmitted frequency is lowered, fully utilizing the high bandwidth of the transducer. At lower frequency the ultrasound beam becomes less sensitive to the non-linear characteristics of tissue; it also penetrates further into the tissue before losing signal strength.Thus with lower transmit frequency more signal energy reaches the region of interest.

The harmonic ultrasound signal is then reflected from the organ and back to the transducer, just like the original(fundamental frequency) ultrasound signal. Very little harmonic signal is generated from “noise echoes” often seen in the blood pools and as general noise; therefore the returned signal provides better contrast separation betweentissue and blood pools. Since the frequency is doubled,Octave Tissue Imaging also provides twice the lateral resolution due to the increased effective aperture.

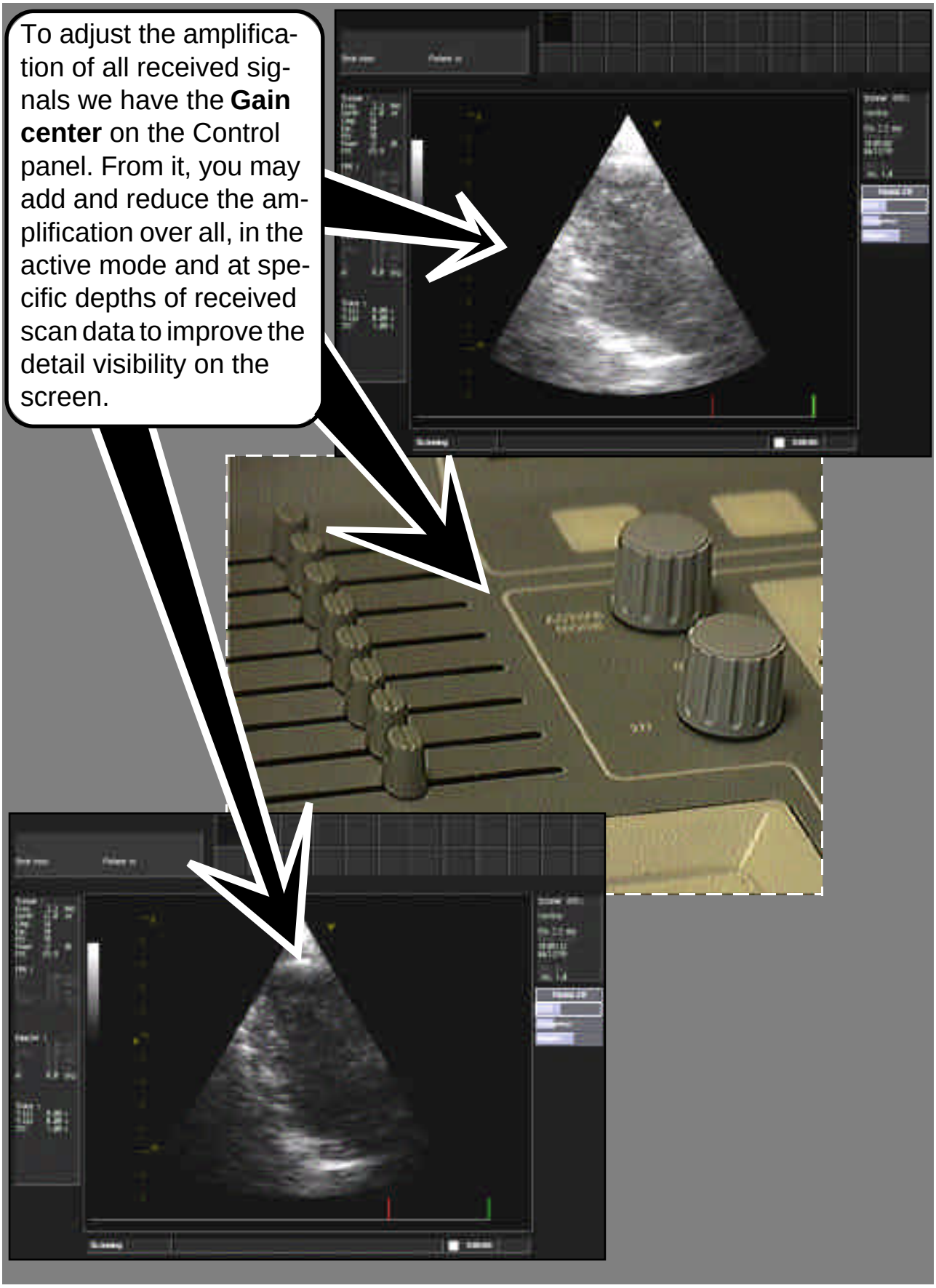
Depth Control

Adjust Region of Interest DEPTH



GAIN

Gain Location



Gain

Adjust Gains

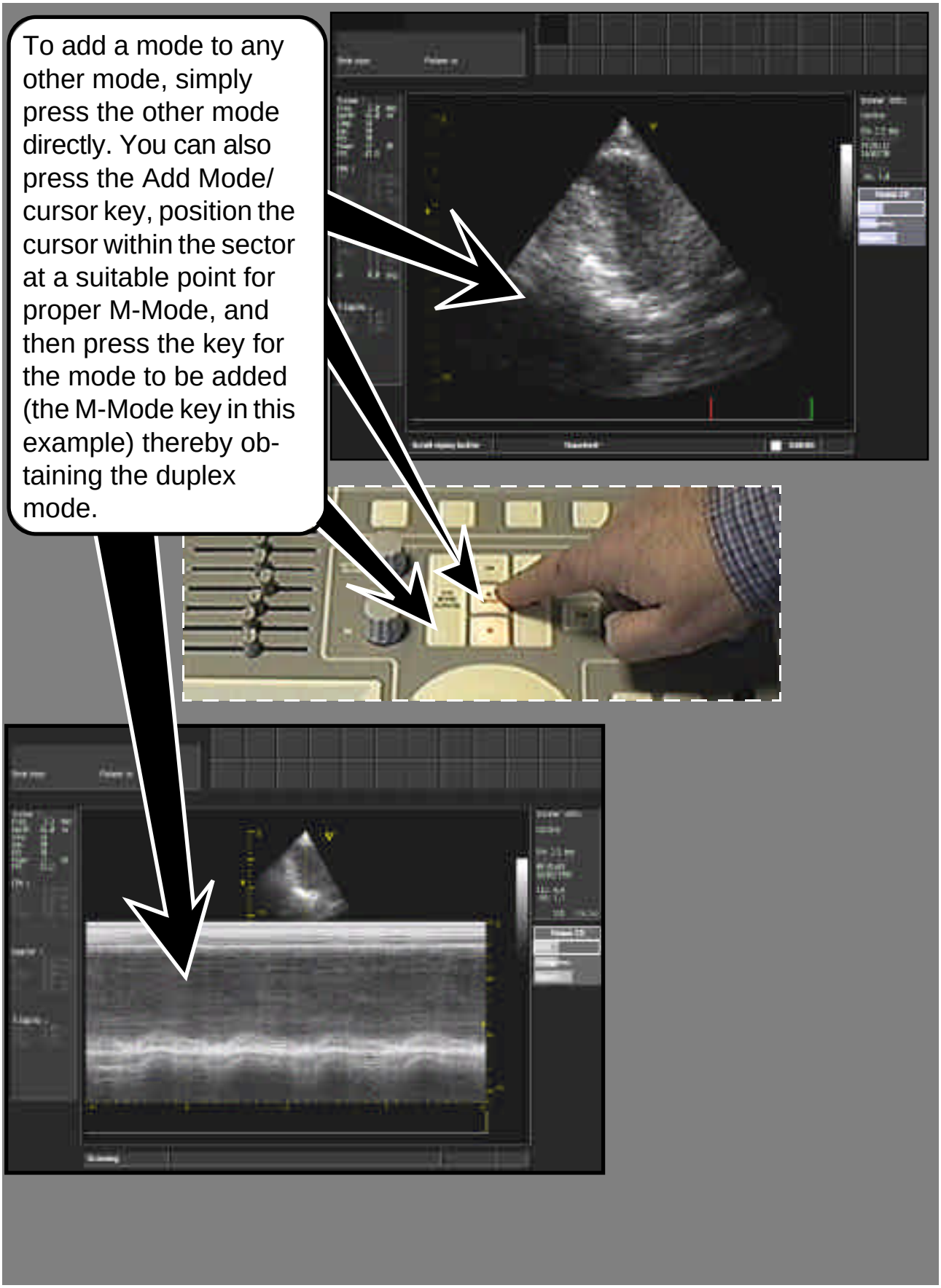
TGC has eight slide-potentiometers. Each of these allow you to separately adjust the amplification of displayed data at eight specific depths on the displayed 2D sector. The mid-positioning of all, shown here should give correct TGC for the normal patient.

Active Mode Gain adjusts, as it states, Gain in the mode that is active. In 2D mode it does the same as the 2D gain rotary. In color flow it adjusts the color flow etc.

2D Gain adjust the amplification of tissue in tissue in the displayed 2D sector.

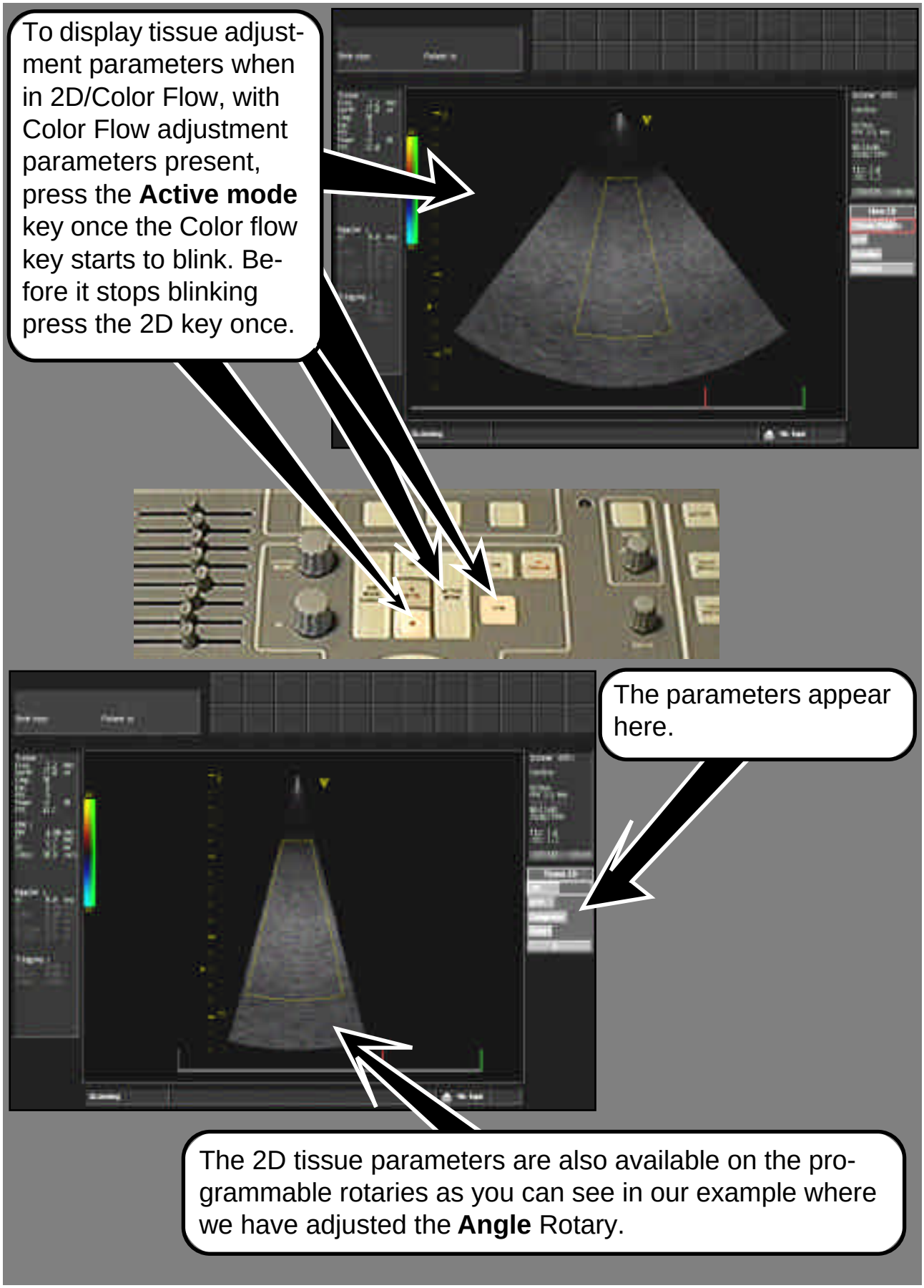
Acquisition mode handling

Add modes



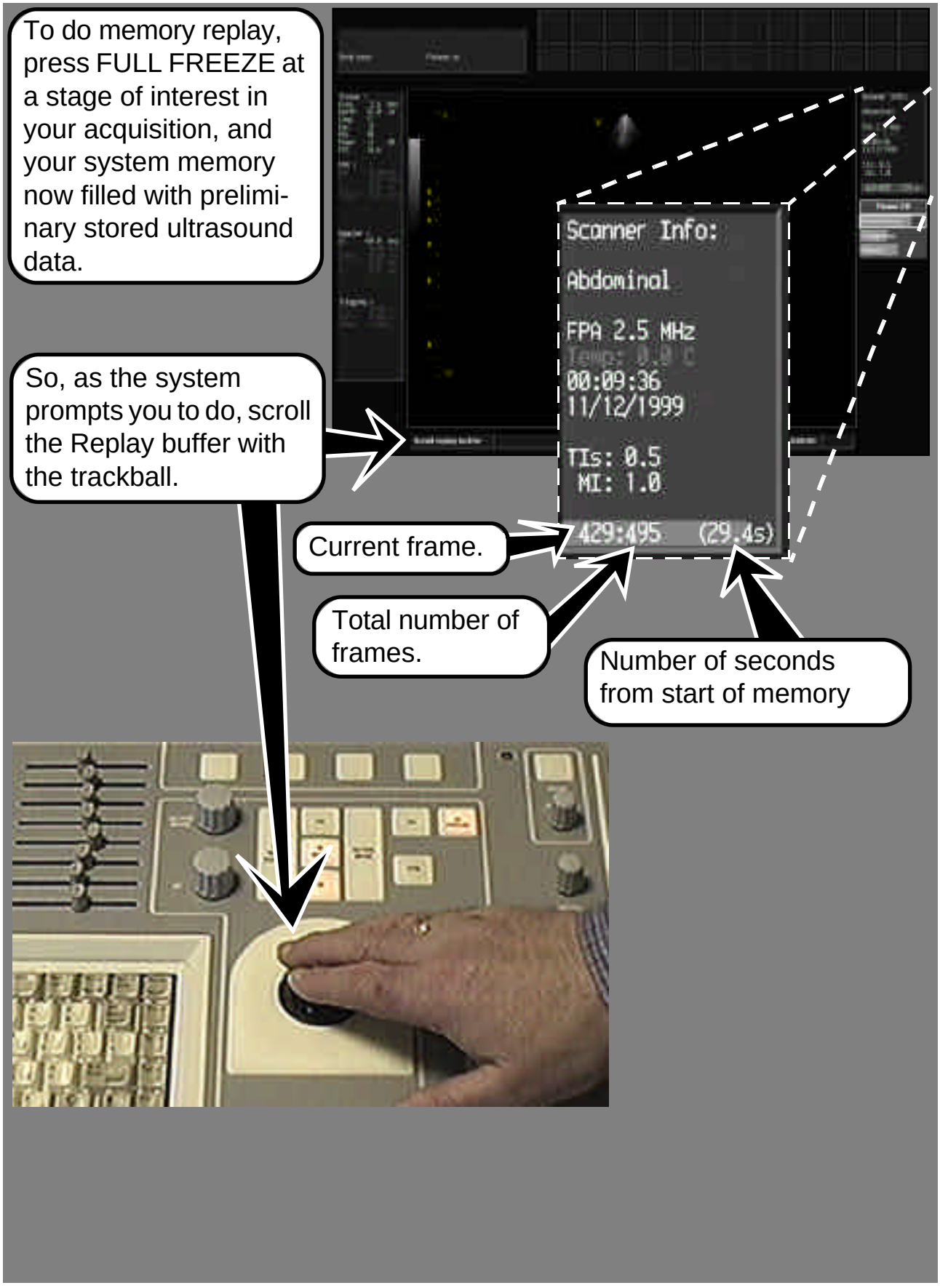
Acquisition mode handling

Use the Active Mode key to change Parameters



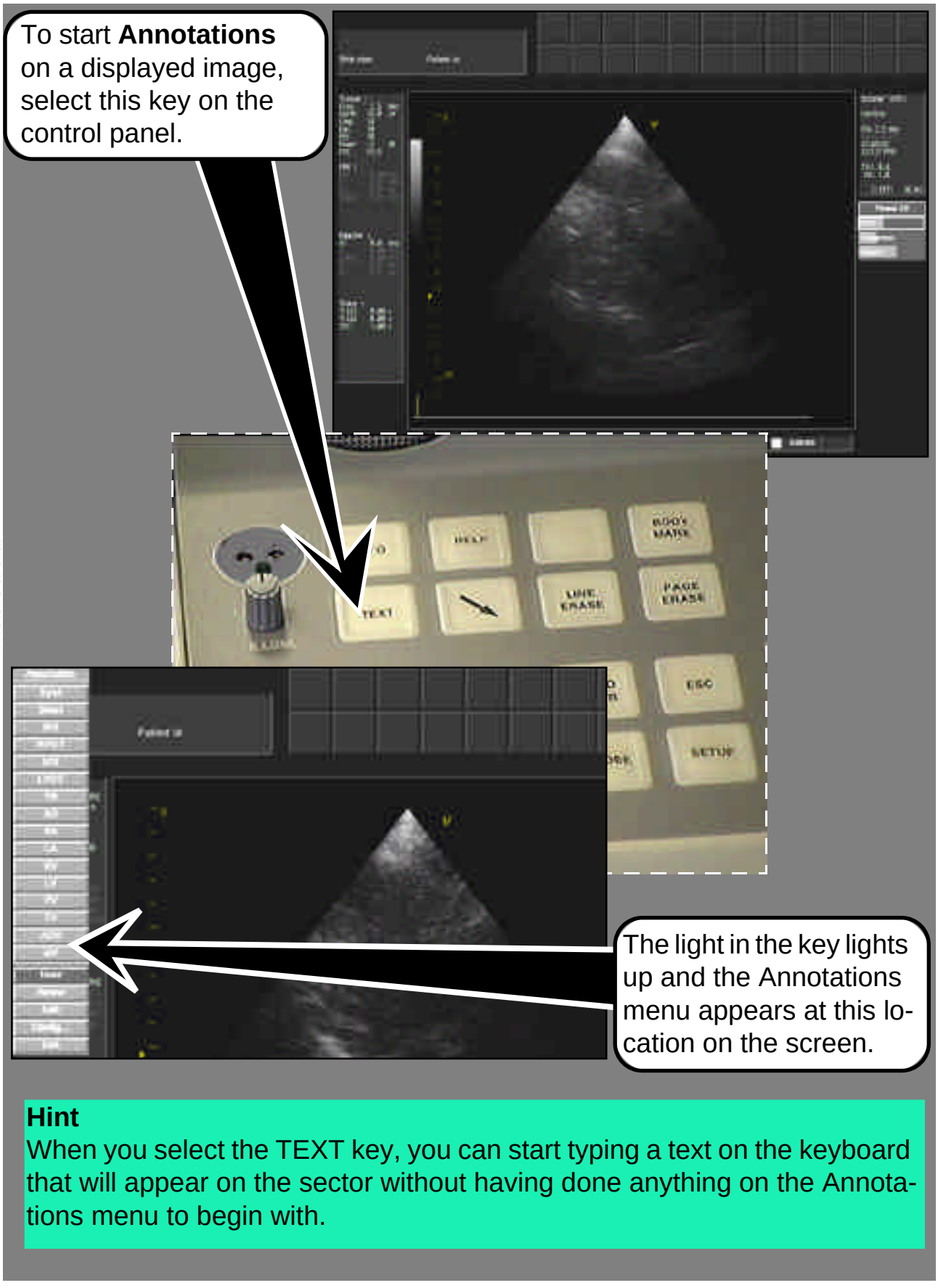
Memory Replay

Replay memory handling



Annotations

Start Annotation



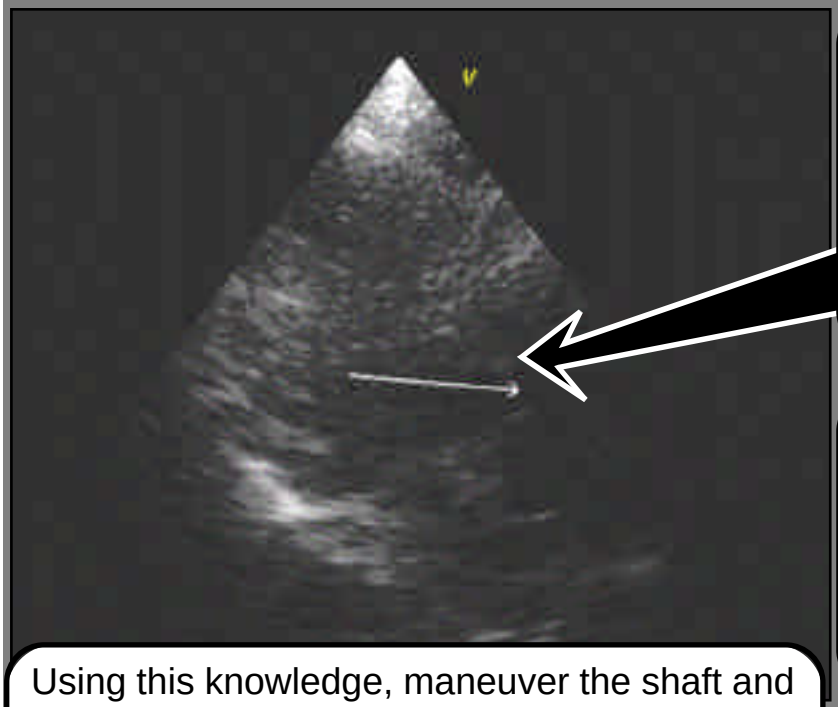
Hint
When you select the TEXT key, you can start typing a text on the keyboard that will appear on the sector without having done anything on the Annotations menu to begin with.

Annotations

Add a menu Arrow

To add a menu arrow select this menu position.

A quite different arrow pointer key is also available on the control panel. When selected its key lights up and the arrow pointer pops onto the screen. It is also maneuvered, positioned as if fastened to the trackball and select key.



An arrowhead appears on the screen. Using the trackball, maneuver it onto the location you want to anchor its shaft at and press the select key.

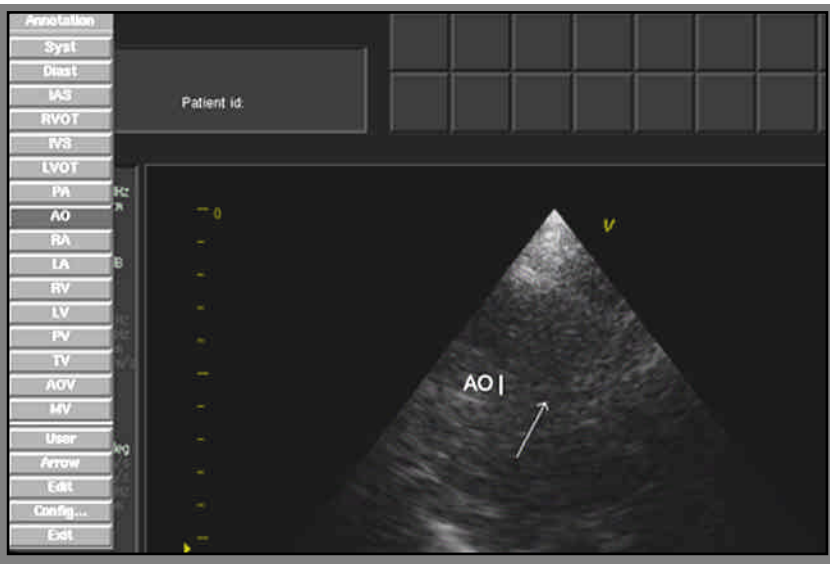
Move the trackball again and now the arrow shaft stretches, or crimps or the whole arrow and shaft rotate around the anchor.

Using this knowledge, maneuver the shaft and arrowhead so that it points at its target and press select to anchor it completely.

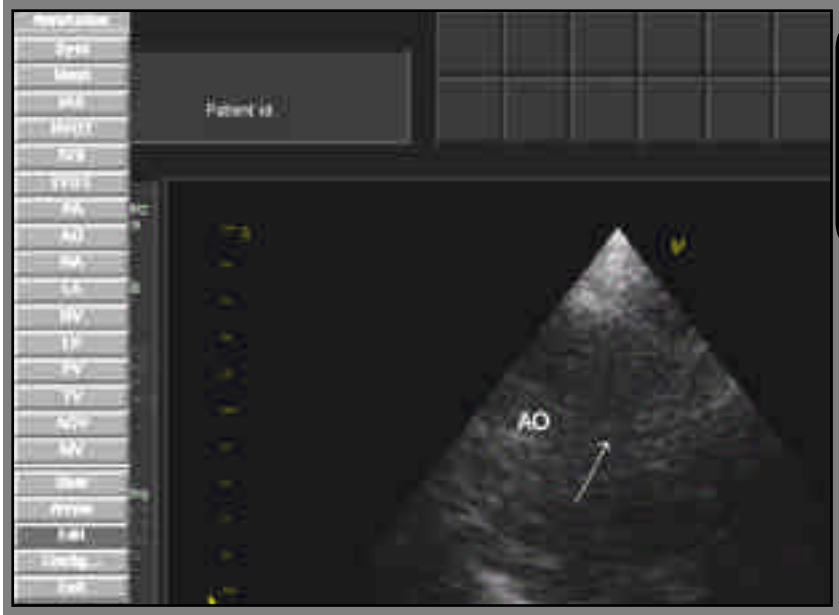
Annotations

Enter an menu text abbreviation

Highlight and choose **AO** with the Select key, and your input appears with a text input cursor behind it. If necessary, you can edit or add text from system keyboard.



Maneuver the input to its planned position with the trackball.



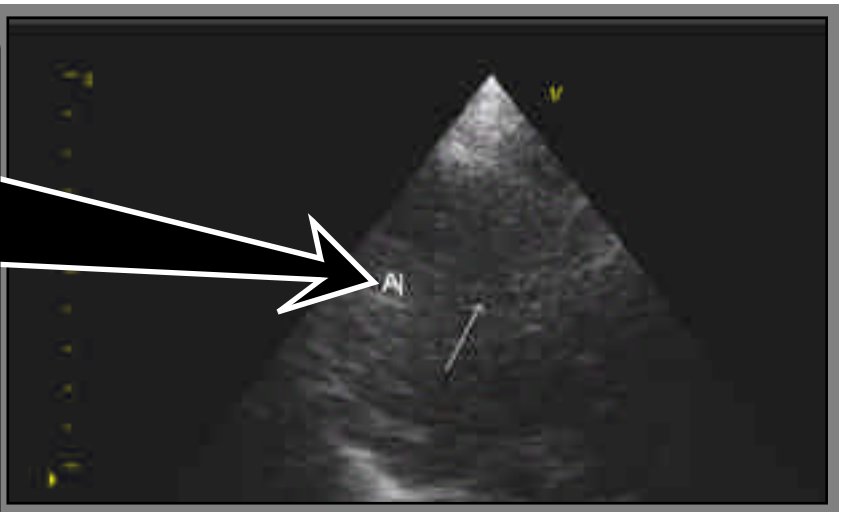
To anchor it at this location, press the select key. Use Line Erase to delete the selected input.

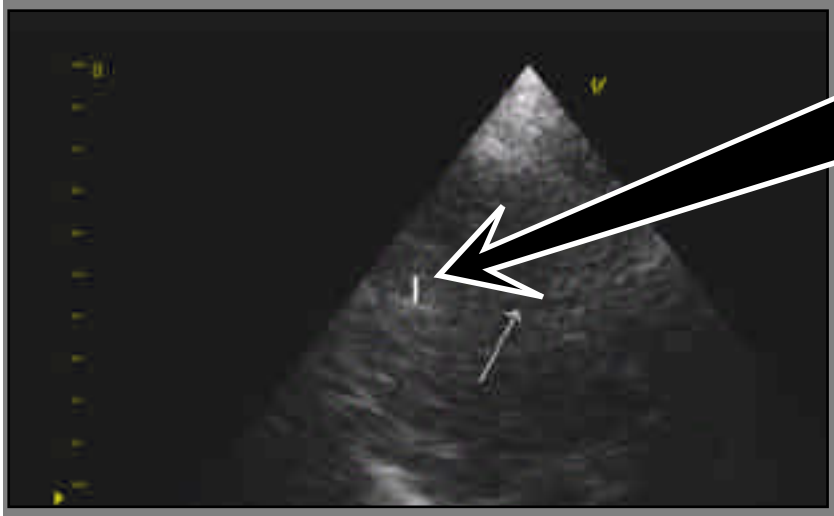
Use Edit to change a text input or to move it to another location.

Annotations

Change a text entry

To Change a text entry, choose **Edit** on the menu, place the Cross cursor that appears on the screen, onto **AO**, and press Select. A short and vertical line cursor, replaces the cross, and places itself behind the **AO** text. Press the Backspace key once, and **O** disappears.

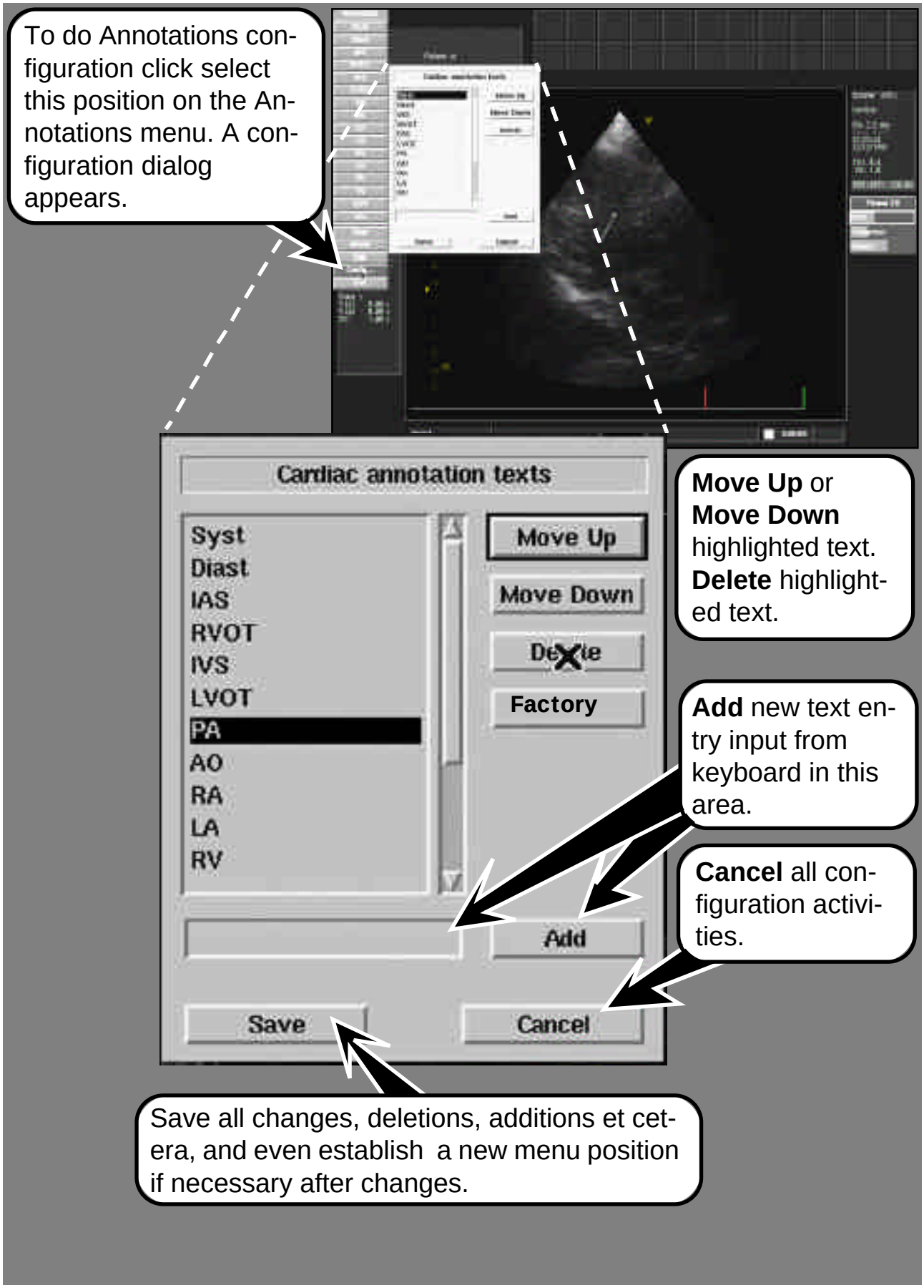




You can also use the **LINE ERASE**, and the **PAGE ERASE** keys to erase single entries, one by one, or all entries in one selection.

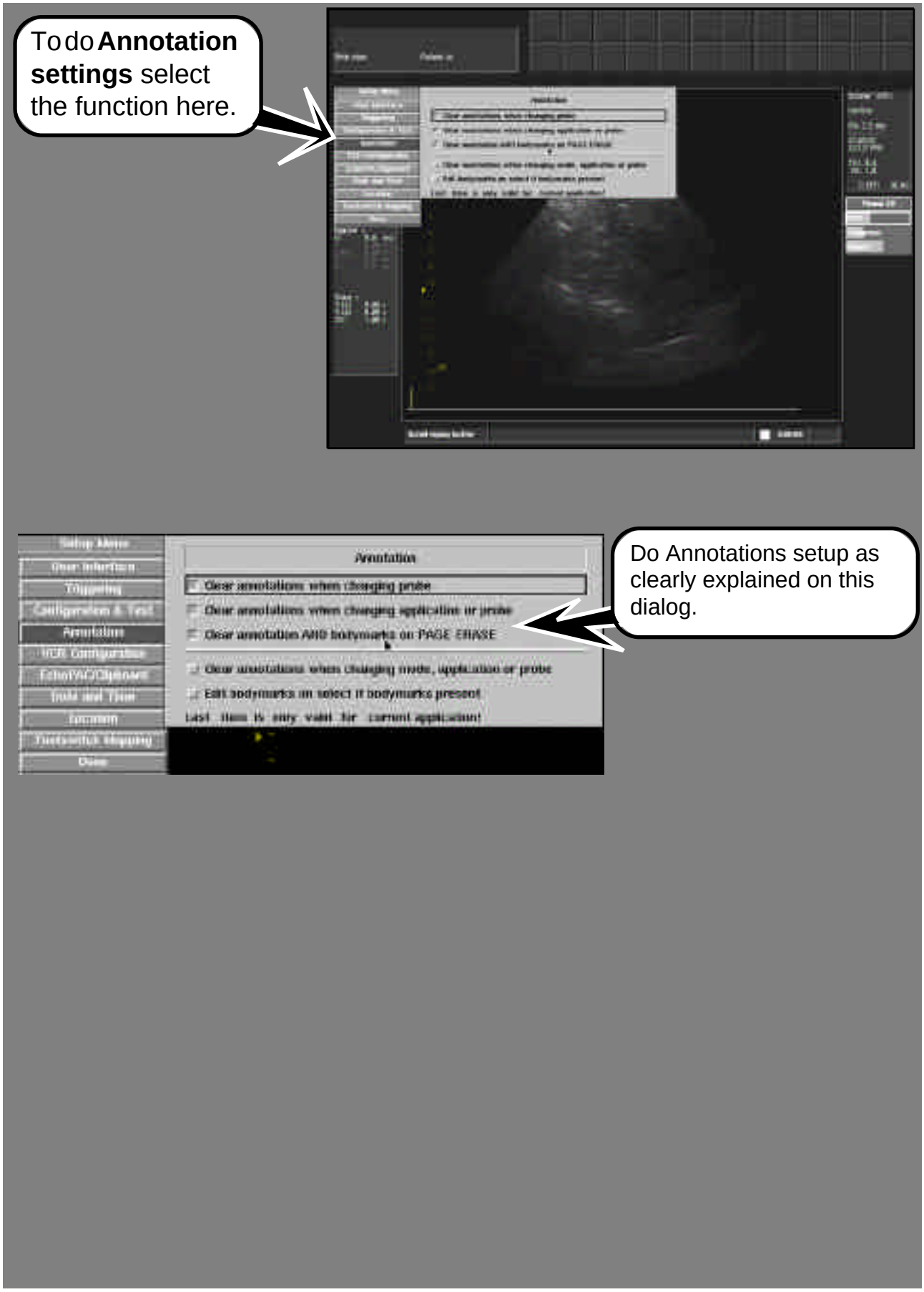
Annotations

Configuration



Annotations

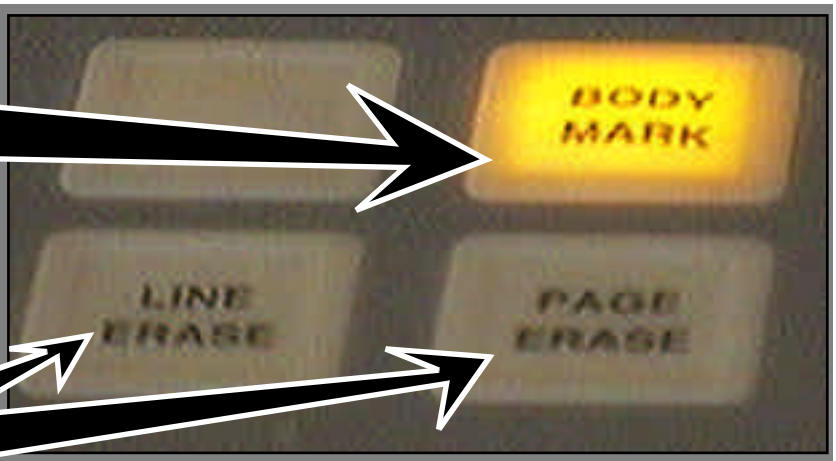
Setup



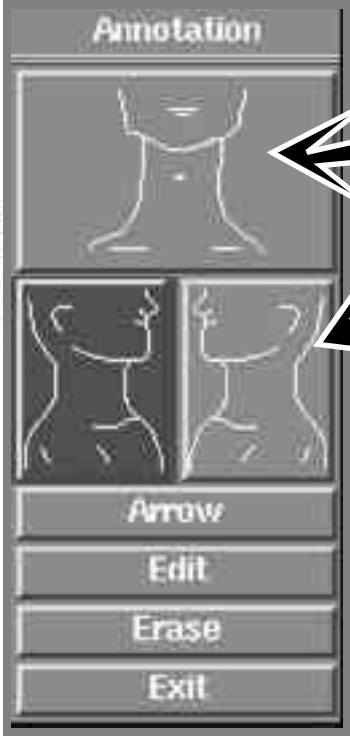
Body Marks

Start the Body mark function

To add **BODY MARKS** to your displayed ultrasound picture, press this key on the control panel.



Page Erase removes all Body marks and **Annotation** inputs. **Line Erase** takes the click-selected ones only.

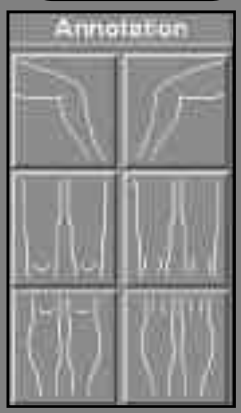


Body marks appear on the Annotations menu. The body mark selection that appears is application-dependent. These are the Carotid application ones. See Body marks for other application below. They function as described here.

Aorta Iliac

Pelvic and Gyn.

LegArt and LegVein



Abdo,PedAbdo and Renal.

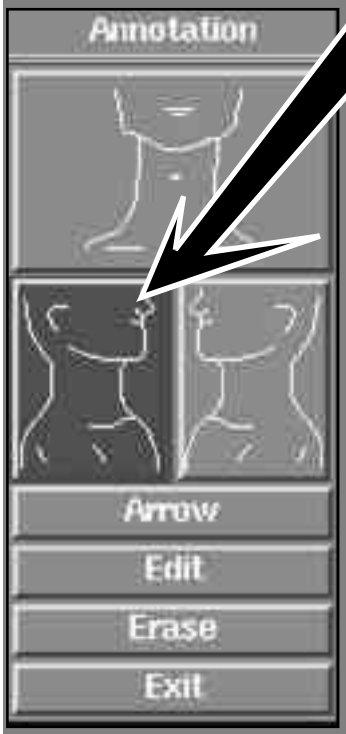
Small Parts

Body Mark

Select a body mark

Whenever you need to add a body mark during ultrasound scanning start the body marking function, decide which mark view suits your needs and click select it shown below.

The Annotations menu always appears in a ready for editing status.



By default setup, the selected Body mark pops onto your ultrasound situation, shown here.The Probe Indicator is active and locked to all Trackball movement, ready to be moved around the Body mark.

Key operators are:
Del to go Backwards one step, at each entry, to previous activity.
Select to go forward one step to next activity.

Body Mark

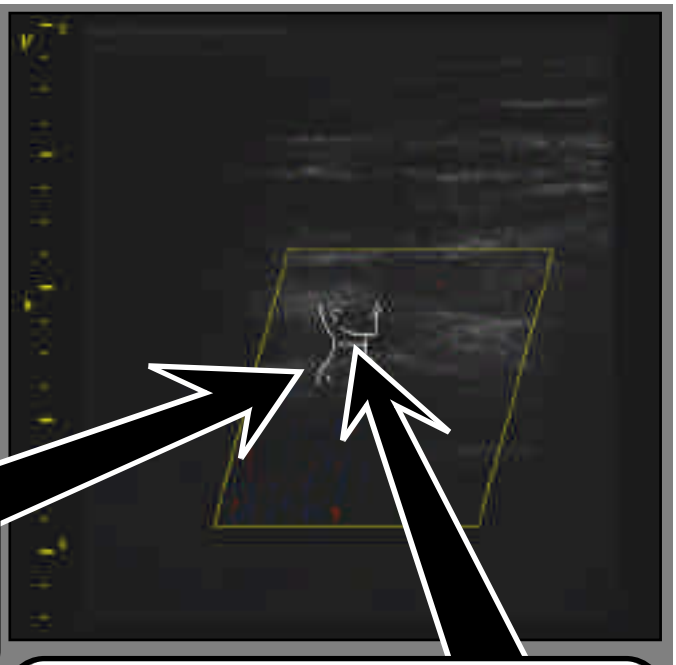
Move the Body mark and Probe Indicator

To move the Body mark around your ultrasound situation, press the **Del** key and the Body Mark is now locked to all trackball movement.

The **Del** key input exits you from **Probe Indicator** movement to **Body mark** movement.

Use the **Trackball**, move the **Body Mark** to a desired position on the ultrasound sector and press **Select** to lock it there.

The **Select** input also exits you from **Body mark** movement to **Probe Indicator** movement.



To move the **Probe indicator** on the **Body mark**, roll the **Trackball** in the desired direction. When satisfactory, press **Select** to lock it at the position.

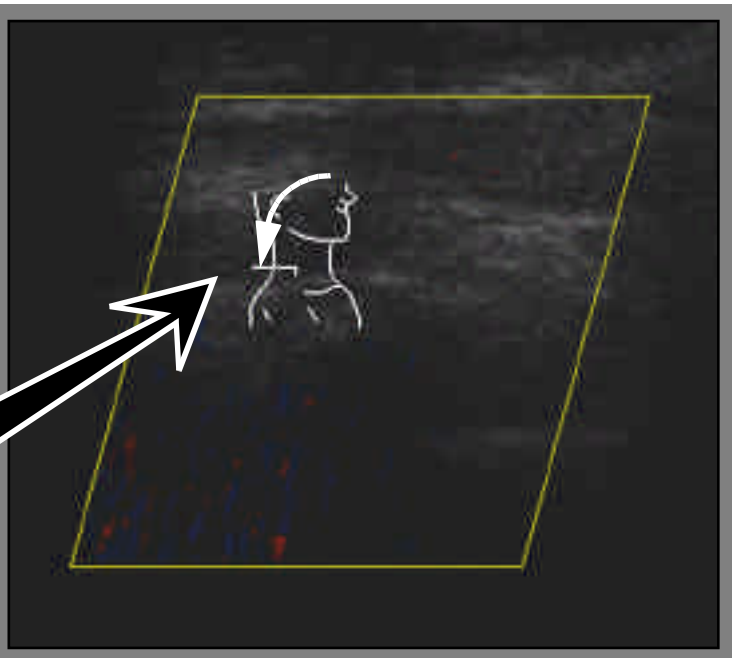
The **Select** key input also exits you to the next activity which is **Turn** or **Rotate** the **Probe indicator** at the locked position. For more on this see the next page.

A **Del** key input returns you to Move **Body mark** mode, if you need to adjust it.

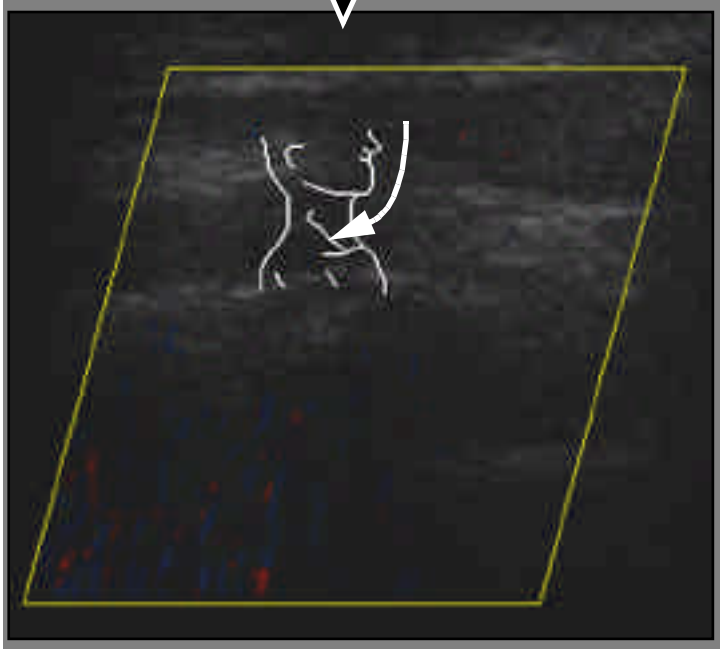
Body Mark

Turn or Rotate Probe Indicator

The Indicator's short and right-angled line is the probe head. The rest of it is the probe body. Trackball rotation rotates the body around the locked in place head.



Roll the **Trackball** to the left or right and the **Probe Indicator** turns or rotates leftward or rightward.



At the new angle, press the Select key once to lock it at this position.

Select also exits you to the next activity.

A **Del** input returns you to the previous situation where you can move the **Probe Indicator** on the **Body mark**.

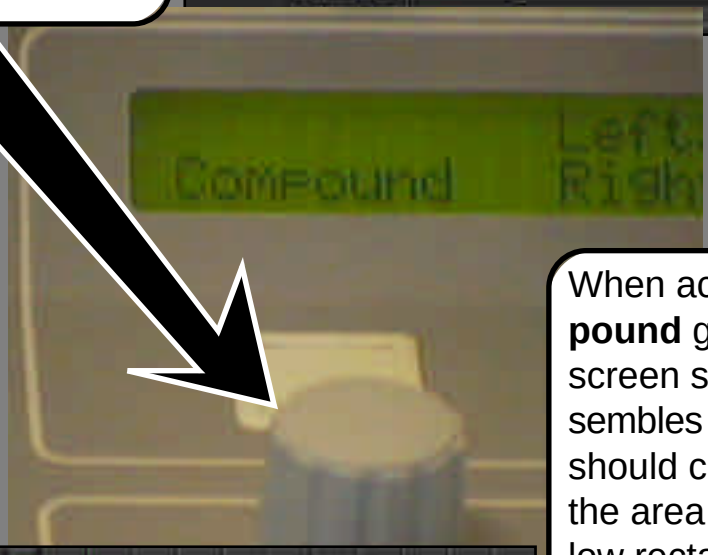
Compound

Start Compound

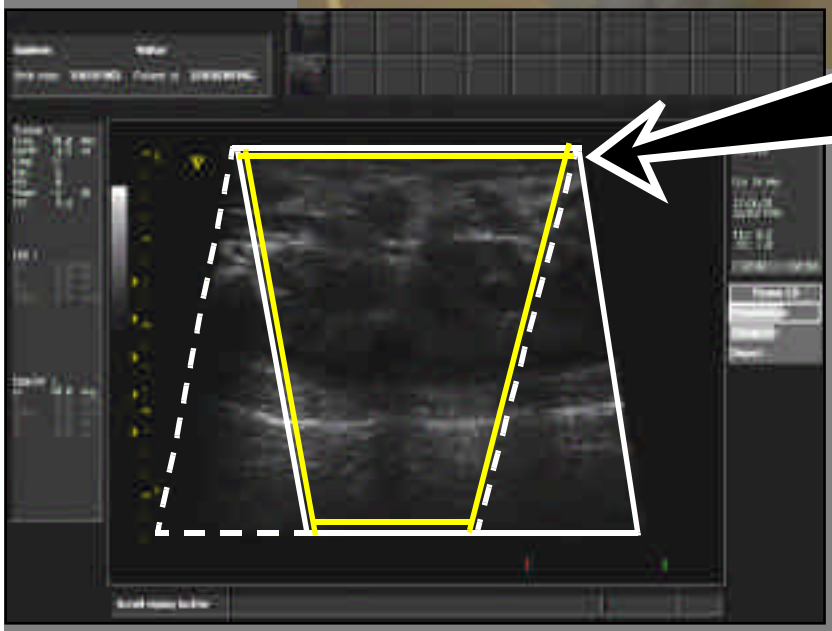
Some probes for System five have the Compound function.

Traditional PV scanning will normally give you a screened image situation similar to this.

Select the Compound function here.



When activated **Compound** gives you a screen situation that resembles this. You should clearly see that the area within the yellow rectangle is much clearer than in the image above.

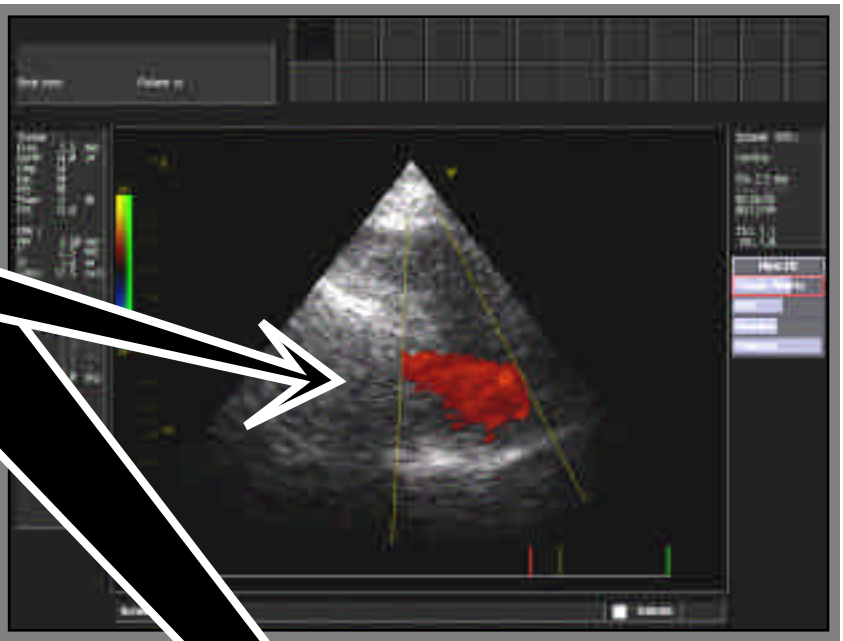


The reason for this is that with Compound one scan is “shot” within the dot- rimmed area and the next one within the Line-rimmed area. This gives the Yellow marked area double coverage which results in a better picture.

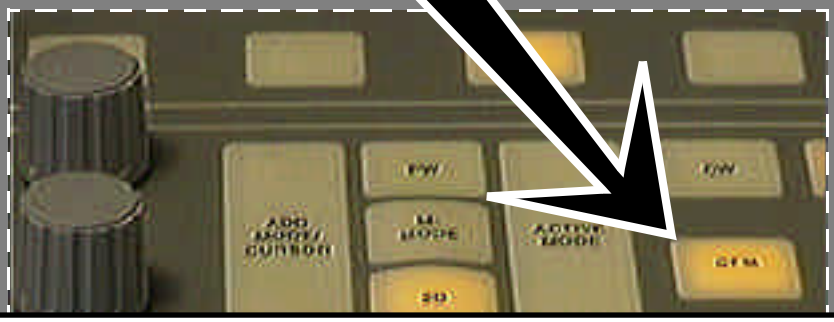
Color Flow Mapping

Start Color Flow in 2D mode

To start Color Flow in 2D mode, press this key directly or go via the Add Mode/Cursor key. Two clearly seen lines appear on the 2D sector that mark the color limits.



As you scan in live mode you will see color flow appear within this sector. You may need to adjust the Active Mode gain rotary.



Note that the term Color Flow is a generic term which includes the three Color Flow modes that are available in the system:

*** Conventional Color Flow Mapping**

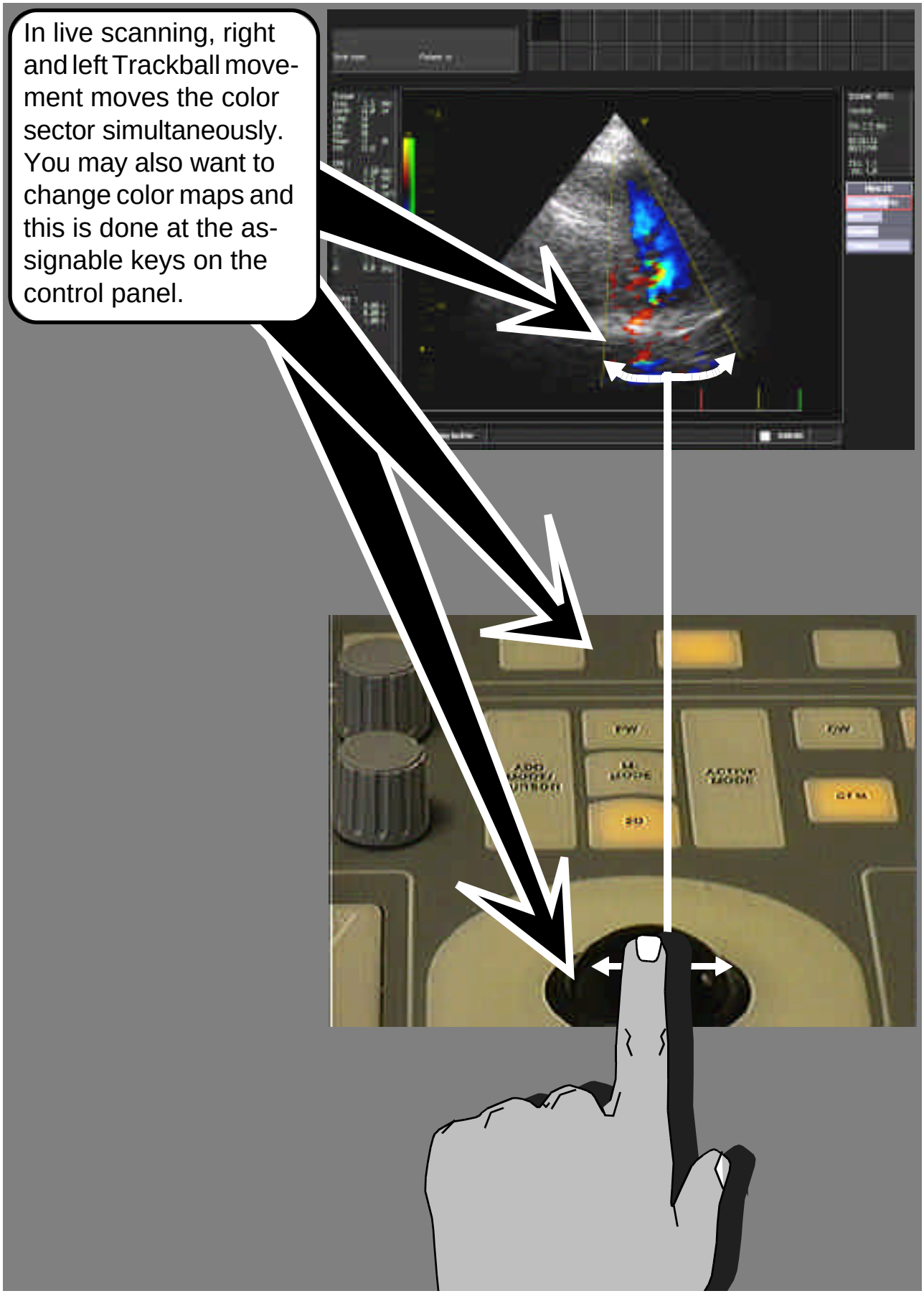
* Power Amplitude Doppler (Ref: page 96.)

* Tissue Velocity Imaging (optional).See separate Manual.

Conventional Color Flow Mapping provides information (bandwidth and direction) about the velocity, bandwidth and direction of blood flowing in the Region of Interest box. Blood flowing towards the transducer is mapped in red, while blood flowing away from the transducer is mapped in blue. Blood flow that contains a variety of velocities which often appear where there is turbulence or a jet mapped in green.**Tissue Velocity Imaging** maps velocities from tissue motion to colors in accordance with a color map.

Color Flow Mapping

Move the color sector within the 2D sector

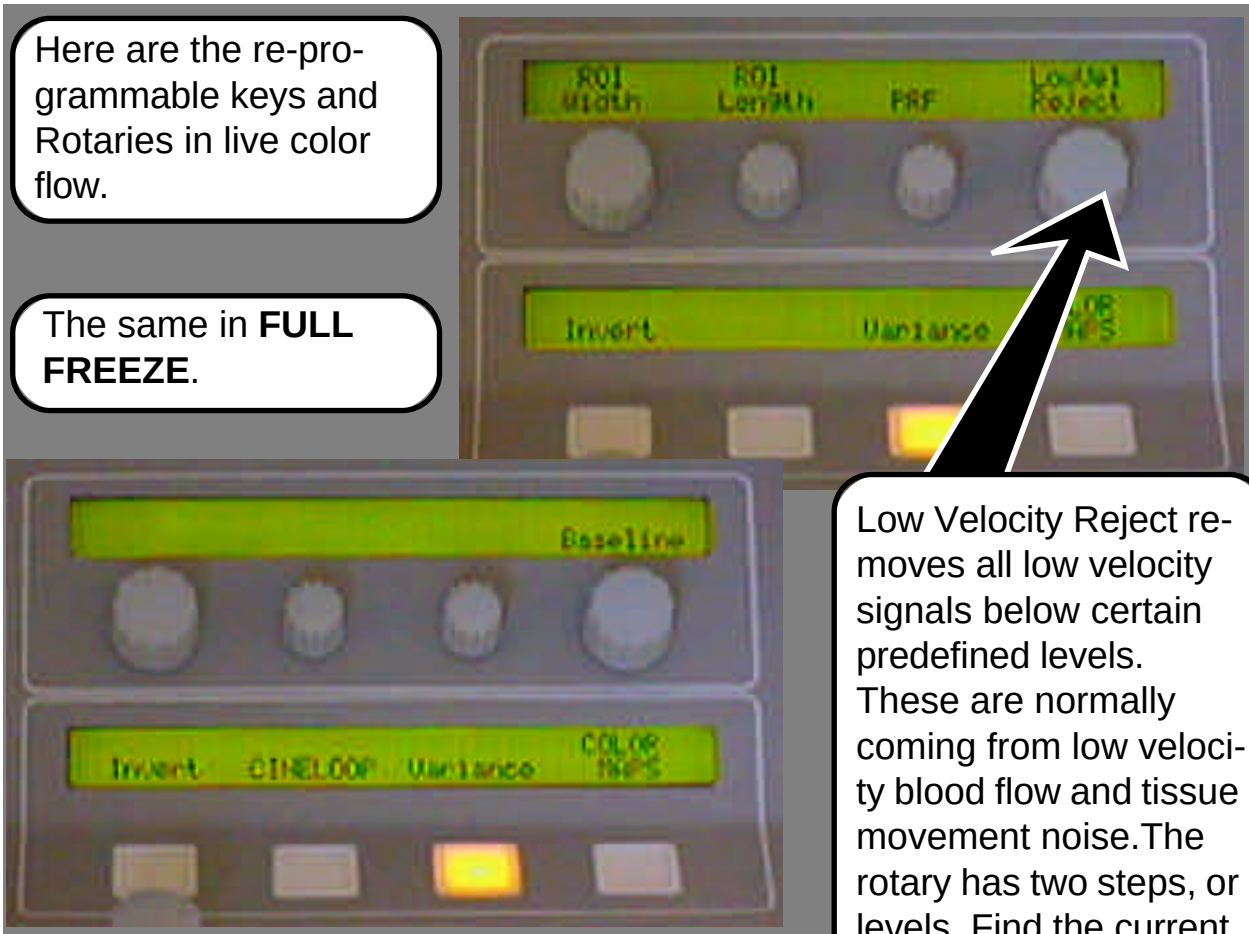


Color Flow Mapping

Programmable Keys and Rotaries

Here are the re-programmable keys and Rotaries in live color flow.

The same in **FULL FREEZE**.

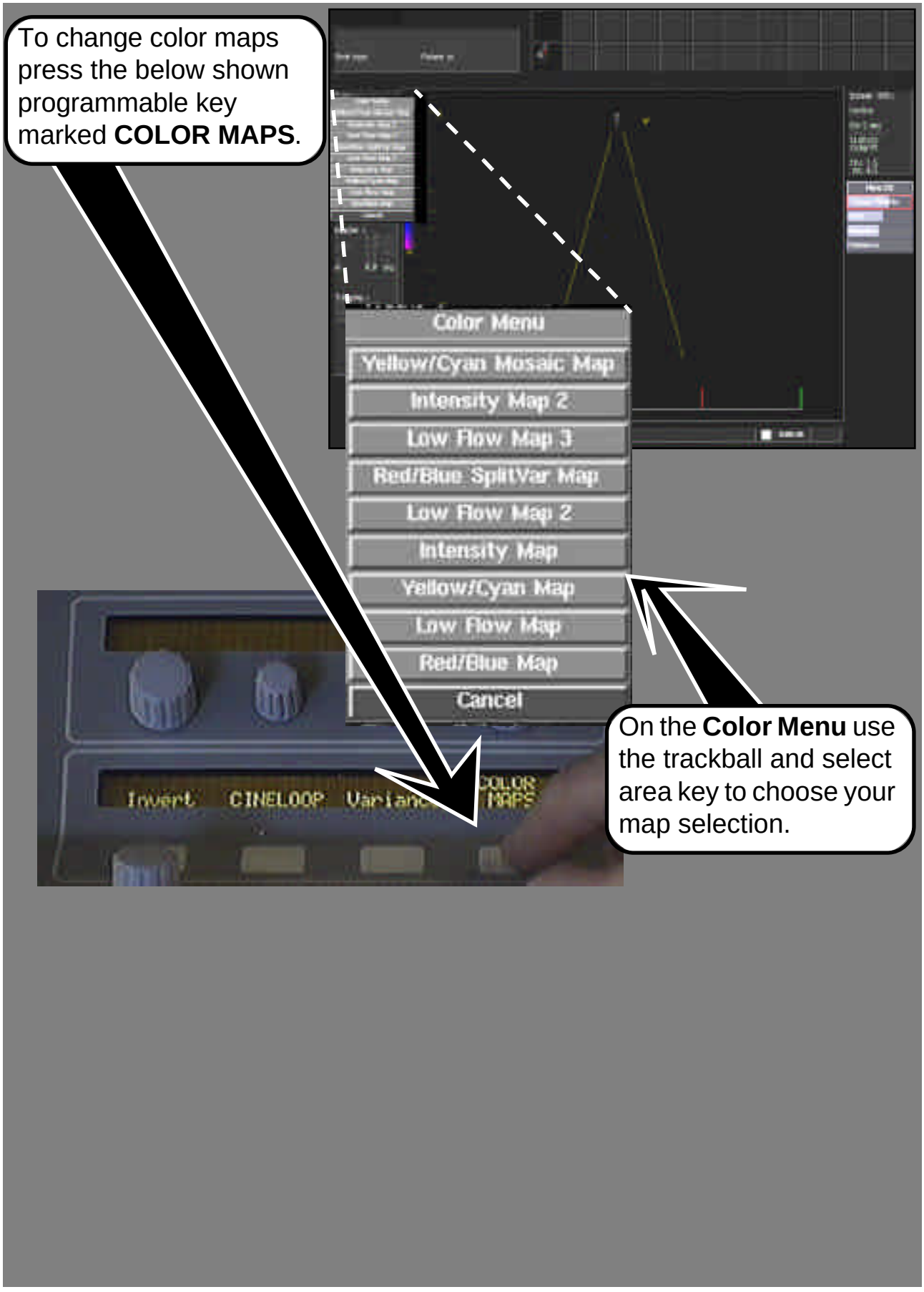


Low Velocity Reject removes all low velocity signals below certain predefined levels. These are normally coming from low velocity blood flow and tissue movement noise.The rotary has two steps, or levels. Find the current level at this position on the Tissue/Color Flow Mapping settings information window.

WARNING
Frequency adjustment In Doppler or Color Flow modes affects the maximum size of the available velocity range. (Frequency increase lowers the maximum).

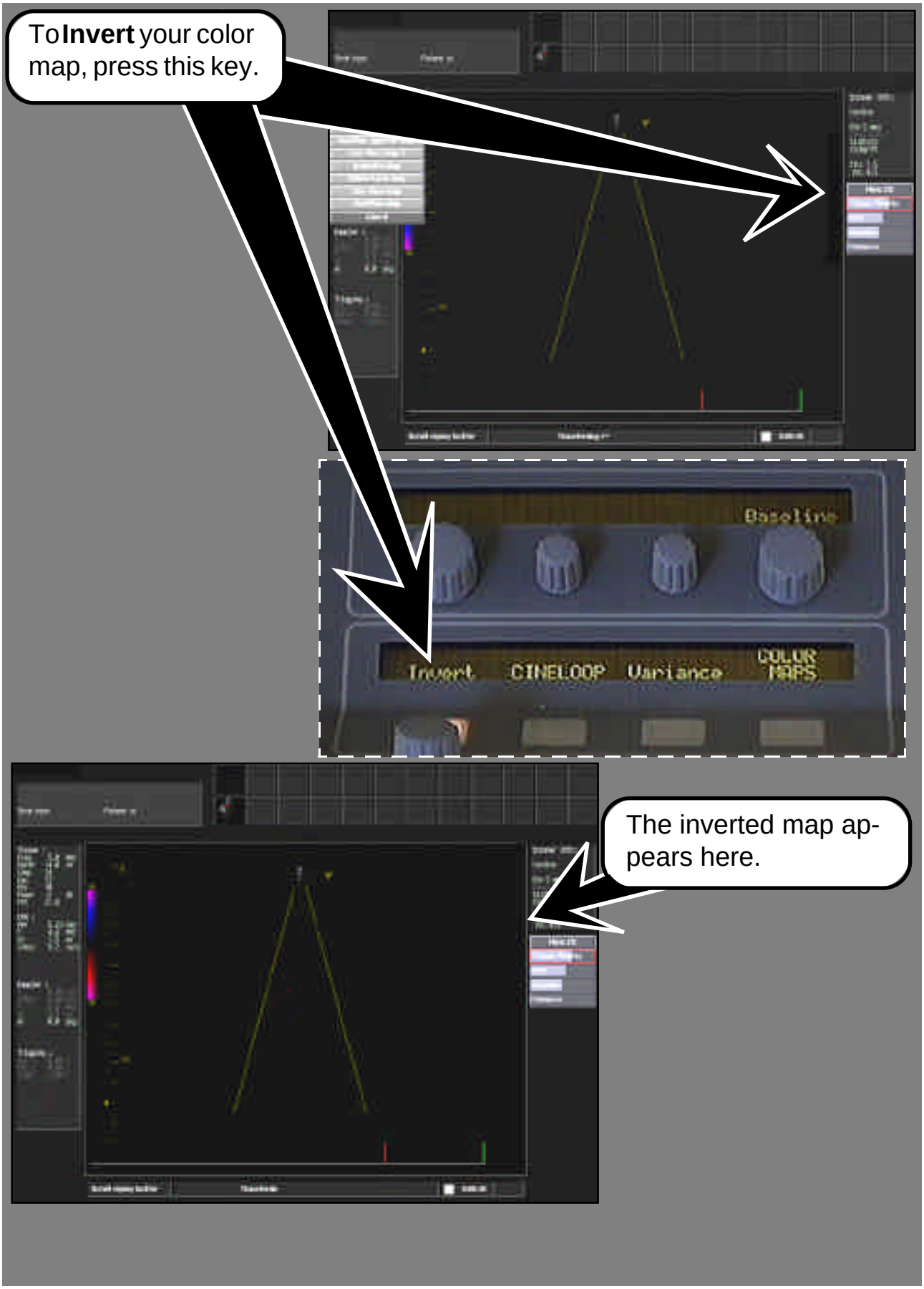
Color Flow Mapping

Color map selection



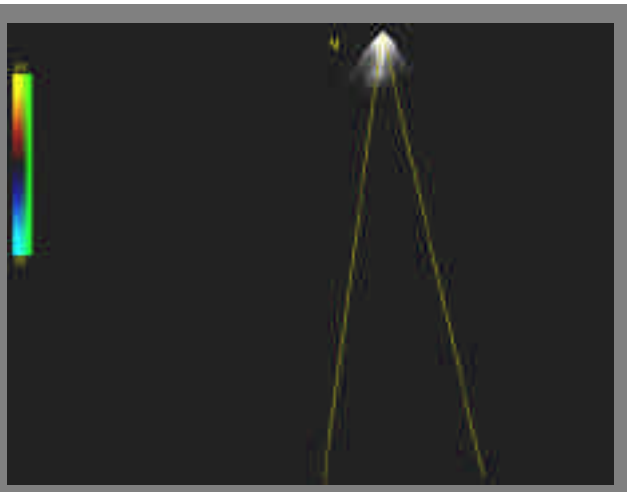
Color Flow Mapping

Invert color map

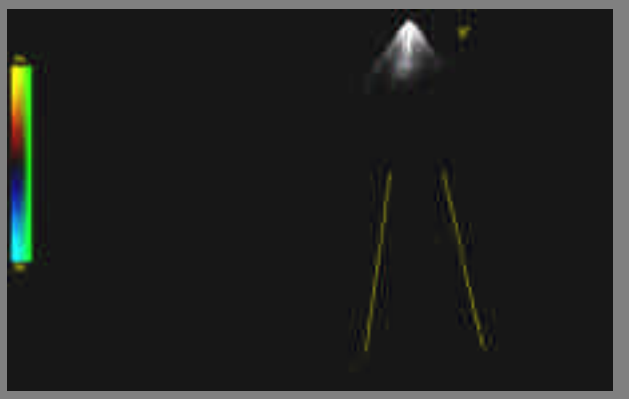


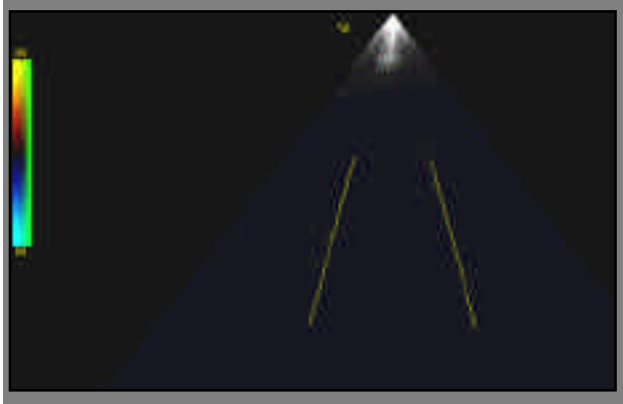
Color Flow Mapping

Region of interest handling



Adjust ROI Span shown above to achieve situations to the right and adjust ROI Width shown below to the Right, to achieve situations shown direct below. Trackball adjusts the angle of ROI.

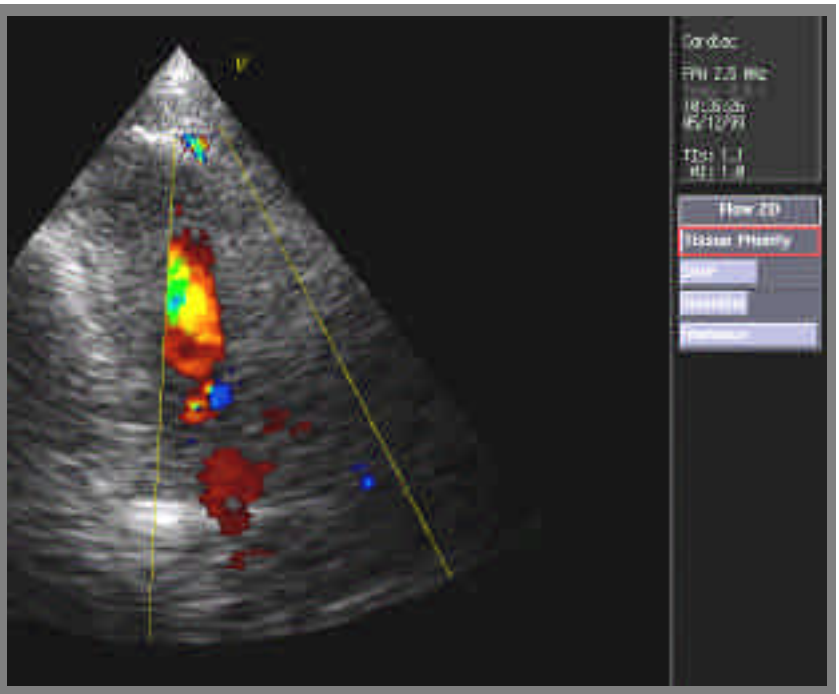




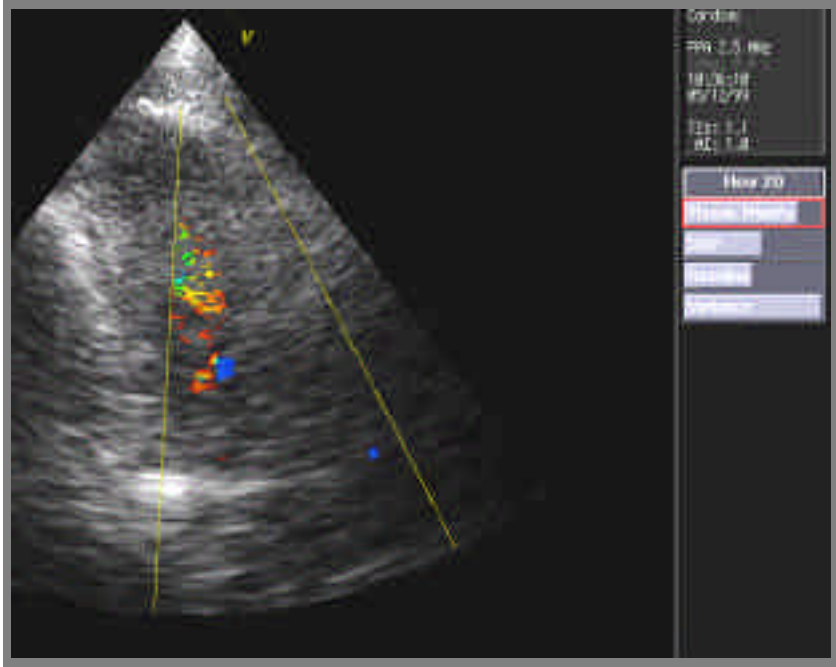
Color Flow Mapping

Tissue priority

While you are scanning or in FULL FREEZE Move onto Tissue Priority on the paddle menu and pace it at a minimum value with the right/left paddle. The color on your image has now the priority shown to the right. You may here have tissue detail that is not visible because of flow. Continue with the investigation shown below.



Hint
The paddles govern the right hand menu as described earlier.

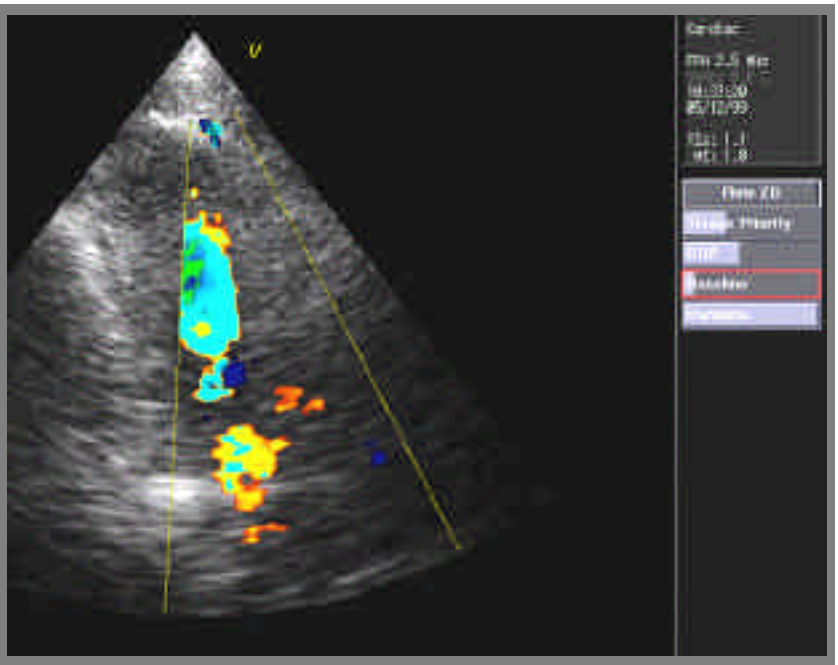


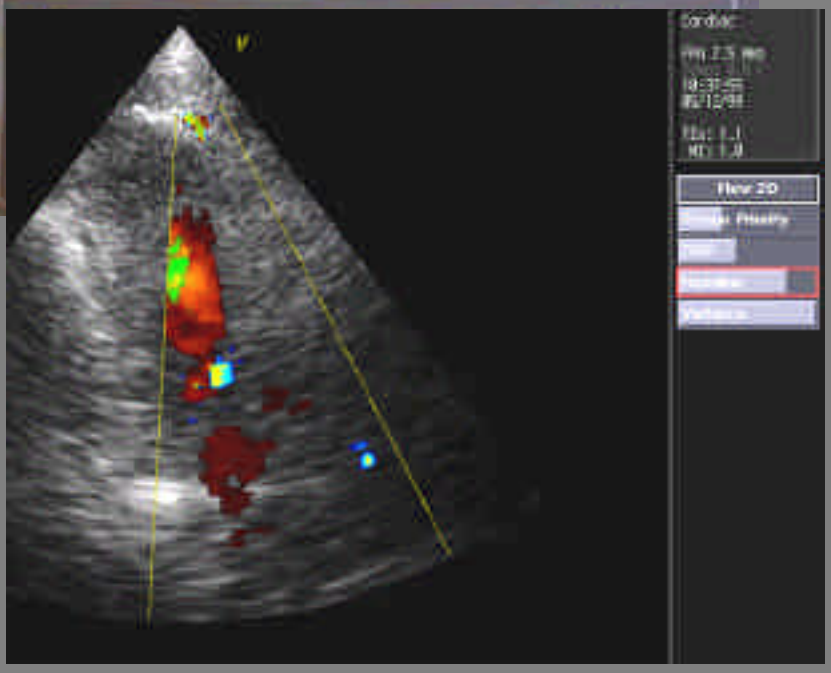
Using the same paddle and in live or frozen status and adjust Tissue priority to the approximately same level shown to the left. Color is hardly visible, and tissue has the priority. It is now possible to view structures that were not visible when color had the priority.

Color Flow Mapping

Baseline

In color flow, find Baseline on the re-programmable rotaries shown below and on the paddle menu. It allows you to view suspecting flow velocities shown in examples to the right and below.



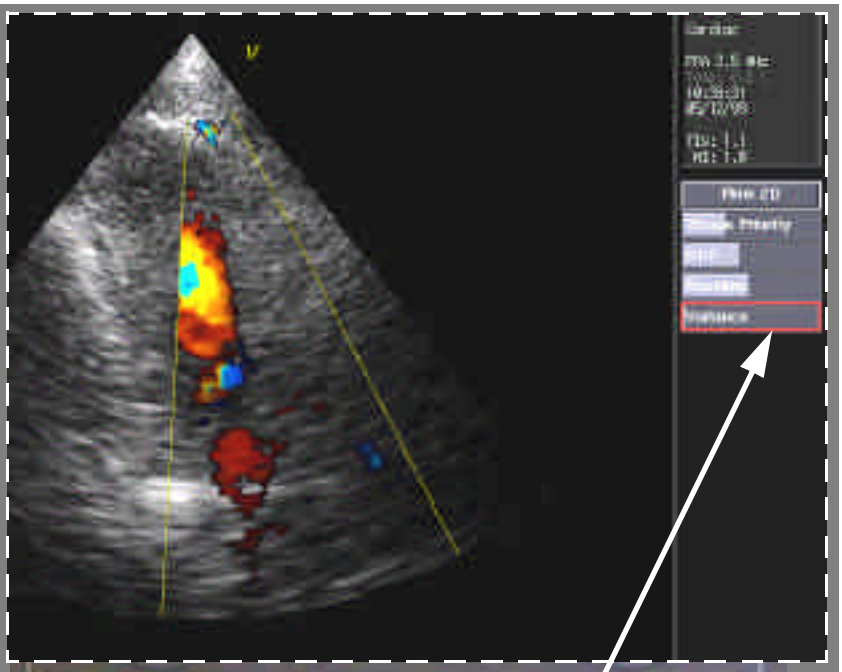


Above we adjust Baseline to a minimum, to study the negative velocities. Notice the color bar. To the left we adjust Baseline towards maximum to look at positive velocities. Notice also the color bar change and variance is present in both.

Color Flow Mapping

Variance

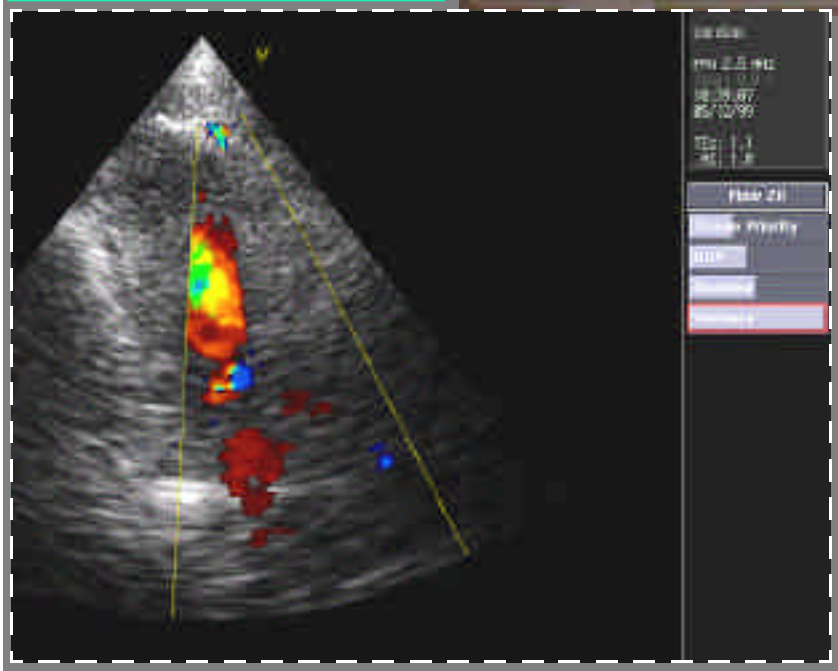
At a minimum setting or, when switched off at the re-programmables the Variance function is not present on the color bar or in the displayed flow of the right hand view.



About Variance - 1

Variance selection, is available in both live scanning and full freeze

Variance is a measure of how disturbed, or non-luminary the flow is at the given sample volume. From a technical point of view, it is the bandwidth of the velocity information.



Whereas when you paddle onto or switch On Variance it is present on the image and in the color bar.

About Variance - 2

Use Variance maps when you look at disturbed flows. Such flows include jets of all sorts, regurgitations, leaks, ASDs, VSDs and the like. Intensity is a measure of the amplitude of the echoes coming back from the sample volume. Intensity maps are best suited when you are looking at slower flows, ventricle filling, Carotids etc.

Color Flow Mapping

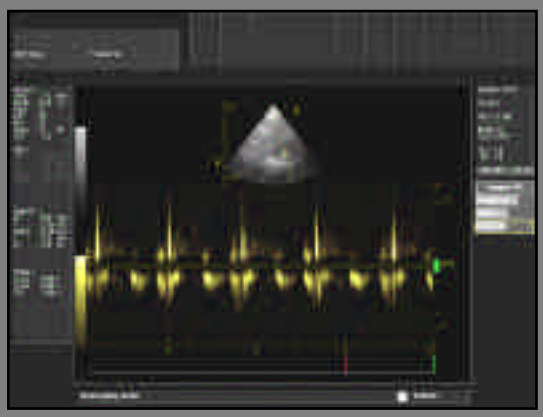
How Color Flow Mapping works

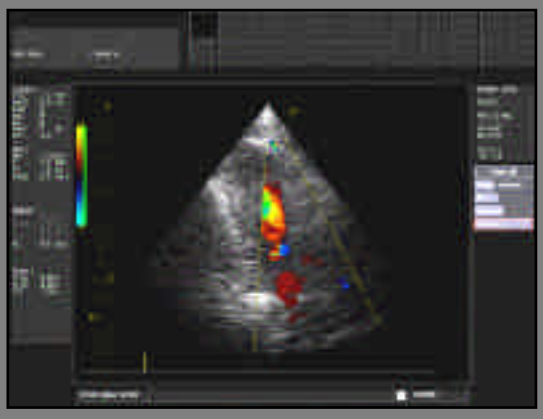
Understanding the basic processes for Color Flow images is how to get the best color flow images possible from striking the optimal balance between frame rate, mapping angle, quality (“packet size”) and Low Velocity Reject.

This section will establish a basic understanding of what color flow mapping is, and briefly describe the complex series of events that must happen to build a color flow map in real time.

In Doppler Spectrum Analysis (pulsed) a large mathematically transformed data set from a given sample volume is to yield the spectrum of velocities present in that sample volume over the time. Because the interrogation of one specific sample volume at a time is typical, there is a continuous stream of data available from that location, and time or frame rate is not a factor.

In Color Flow Mapping, a limited set of data from a given sample volume is collected over an interval of time which is as short as possible. Mathematically manipulated data produce the Color Flow outputs for this sample volume. The outputs obtained are an estimate of the mean velocity, the intensity or power of the signal, and a measure of the statistical variance of the velocities in the sample.





Color Flow Mapping

Color Map construction

A color flow map construction enhanced from an array of a variable amount of independent color flow lines, each of which is taken from a variable amount of independent sample volumes, obtained as described on the previous page. Although all the sample volumes on a given flow line are evaluated and obtained simultaneously, each line requires many ultrasound pulses to make velocity estimates.

The flow information from the array of lines combined with 2D information, collected on an independent 2D scan, to yield the whole color flow map. At each location in the displayed sector you have either an echo intensity or a mean velocity.Constructing a color flow image, therefore, can take a considerable length of time.

The key to understanding the velocities being mapped is understanding the color bar. This is a pictorial translation table that will allow you to associate a color on the flow map with a particular flow state. To understand what the color bar represents, one must first understand what information is available from the color flow mapping process.

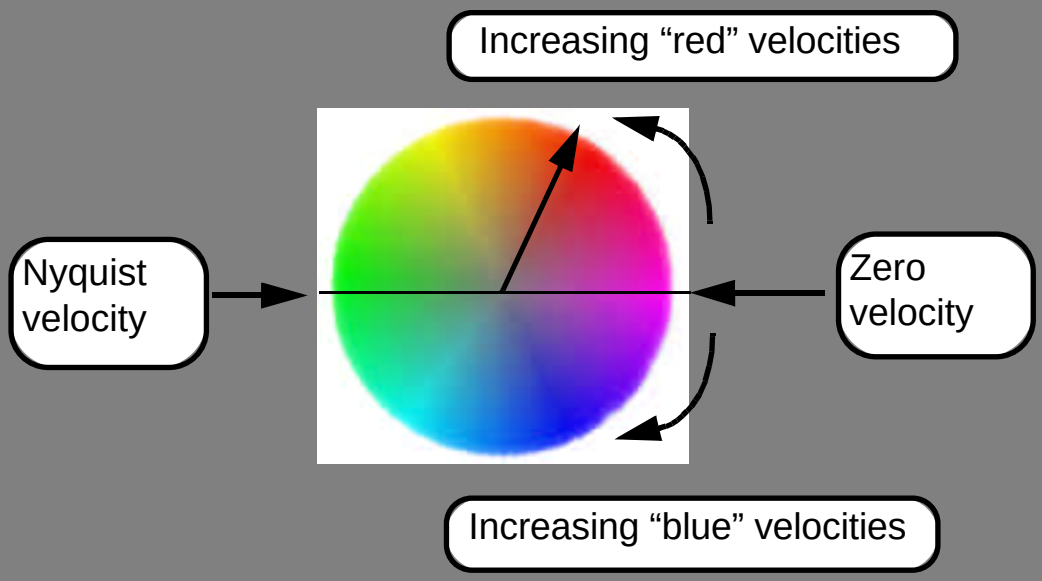
Color Flow Mapping

The Spectral Estimate

Spectral estimation is the process in which the CFM extracts velocity information from the returning Doppler shifted ultrasound data. Thethree parameters, mean velocity, signal intensity, and the variance of velocity determines each pixel on the flow map, i.e., each range gate along each flow vector. The mean velocity is the statistically determined average velocity. Variance is a measure of the bandwidth of the velocity spectrum. It tells how much the velocity typically deviates from the average velocity. The intensity is a measure of the returning signal strength.

Spectral estimation depends on a mathematical process called auto-correlation to convert the Doppler shifted echoes into velocity information. The raw outputs of the auto-correlation process are a set of rays, each having an angle and a length. The angle of the ray corresponds to the velocity, and can range from O to 1 Nyquist Velocity covering the span of O to 180°. The length of the ray is proportional to the signal intensity.

Spectral estimate rays can be drawn on the wheel shown here. On this wheel one ray is drawn, although for the spectral estimate there will be at least three (Application dependent) generated in the Color Flow Mode. One thing to notice is that for any given ray there is no way to deduce whether the velocity detected is flowing to or from the transducer. Inference from observed hemodynamics, determine the flow direction in clinical situations.

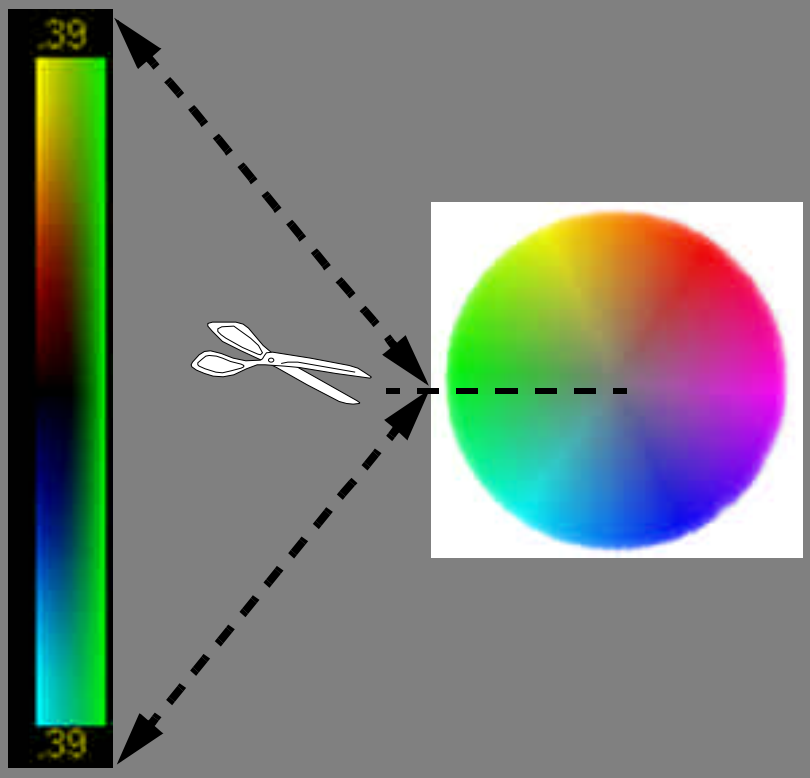


Color Flow Mapping

Assigning Colors and unwrapping the Color Wheel

Locations on the wheel shown on the previous page have assigned colors in red/blue flow maps. This type of color assignment is the core of most manufacturer's red/blue maps. In the Vingmed map, intensity is an additional factor. This will appear on the color wheel as concentric rings, growing brighter as the diameter grows. Adding intensity to the color assignments helps to give the mapped velocities a more flow-like appearance.

Although the flow wheel represents a continuous process, in color flow mapping systems the wheel is always "cut" at some point to be unwrapped and displayed on the monitor. The exact cut location on the wheel is arbitrary. The cut location is similar to the position of the baseline in a Doppler spectrum display.



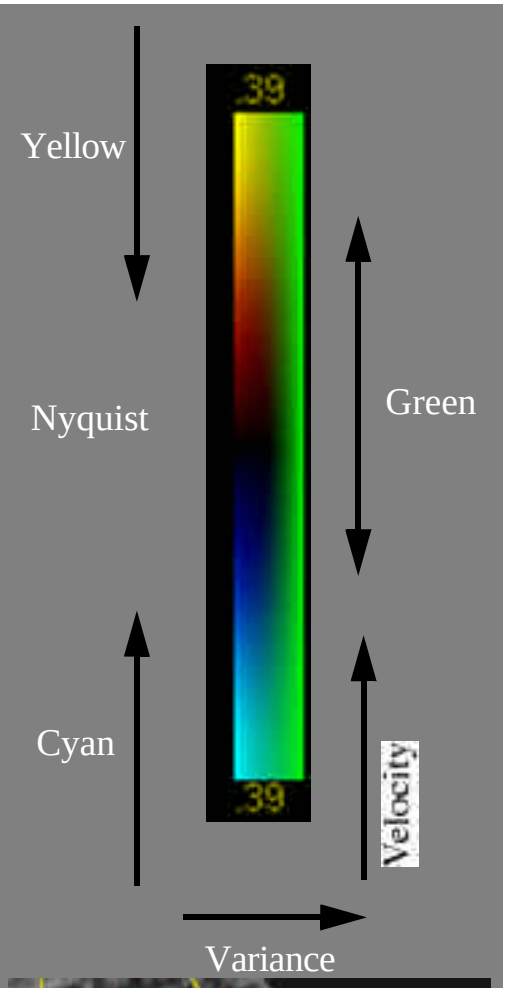
Color Flow Mapping

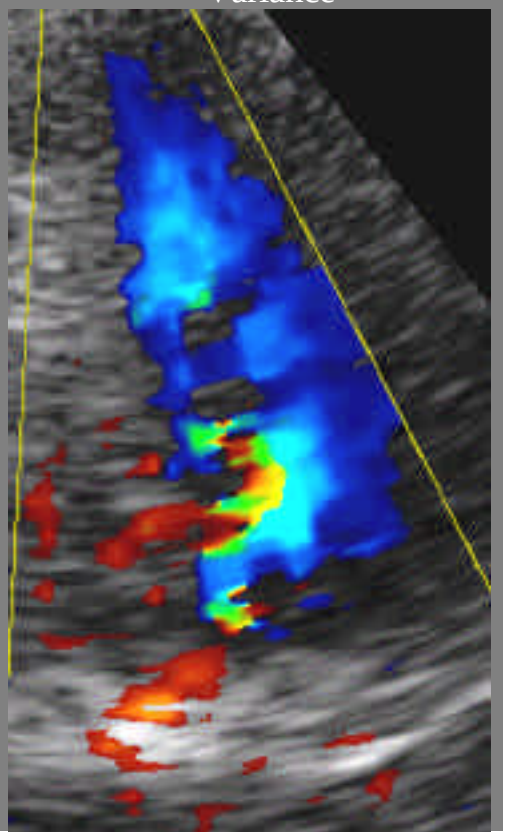
Disturbed Flow Indicator

The Disturbed Flow Indicators purpose is to help in the visualization and delineation of turbulent flows and jets. A set of color maps is available for selection on the Color Map menu. In cardiac Yellow/Cyan is the normally used map. Disturbed Flow describes a variety of flow conditions that are not well defined by a flow map that incorporates only the velocity and intensity parameters into the color assignment process.

The turbulence causes the presence of a broad range of velocities so that the mean velocity statistic is not very significant. This is the classic example of Disturbed Flow. The variance display allows you to see variation from normal velocities or turbulent flow. This type of turbulent flow ids associated with doppler data with a broad bandwidth such as signals generated by valvular regurgitation, valvular stenosis and intercavity shunts.

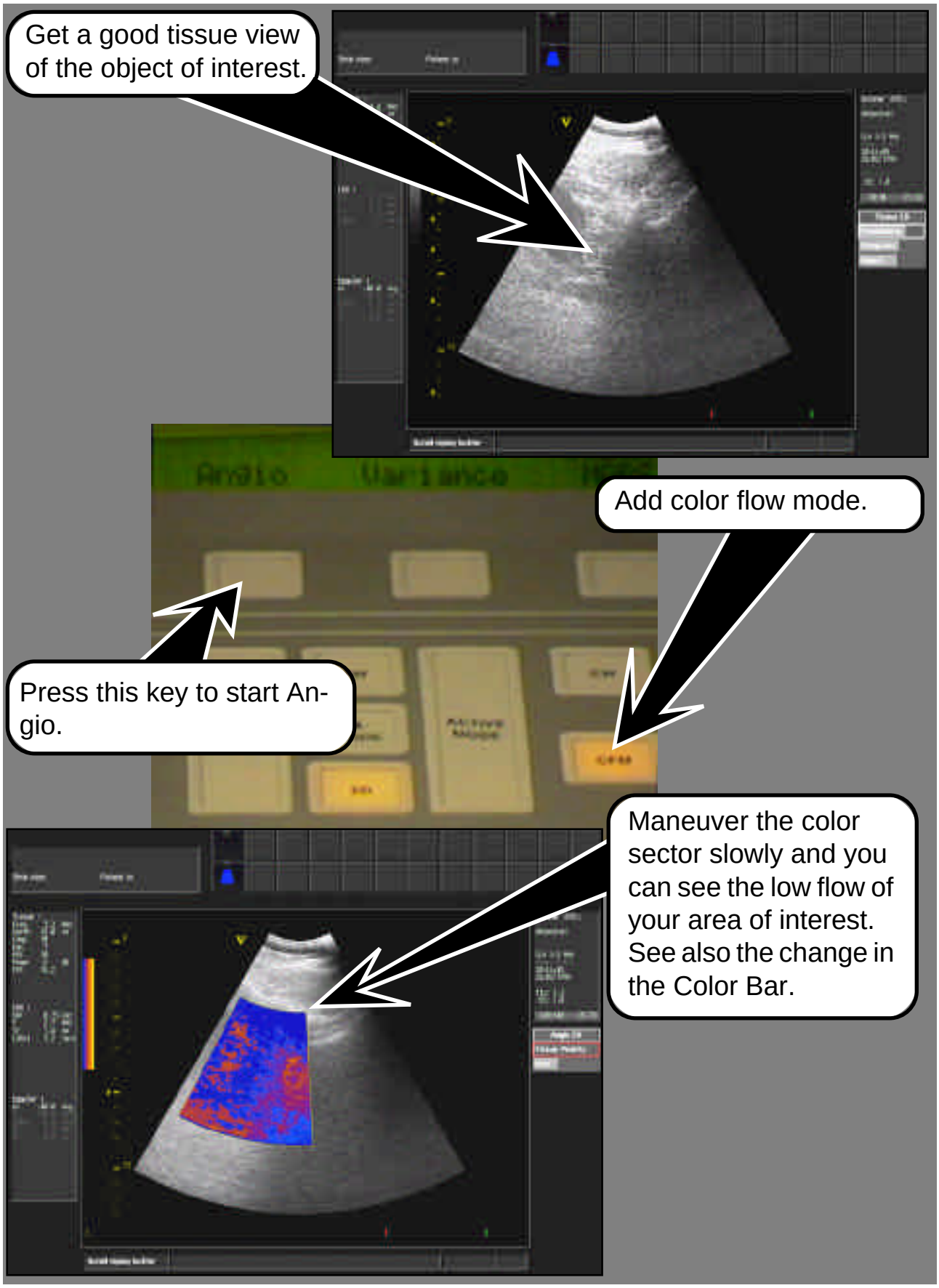
With the Disturbed Flow Indicator system, when the system determines that the given combination of intensity, mean velocity and variance will not yield meaningful mean velocity data, a shade of green substitution, not addition, forthe mean velocity color. These green areas stand out from the other flow areas, and catch the eye's attention as often brief phenomena pass by. The heart of the Disturbed Flow system is Deciding exactly when to substituted mean velocity for the Disturbed Flow green. This is what provides the outstanding jet and turbulent flow visualization in the CFM.





Angio

Start Angio



Angio

Power amplitude Doppler, Angio

Note that the term **Color Flow** is a generic term which includes the three **Color Flow** modes that are available in the system:

* Conventional Color Flow Mapping (Ref: page 81.)
*** Power Amplitude Doppler**
* Tissue Velocity Imaging (optional). See separate Manual.

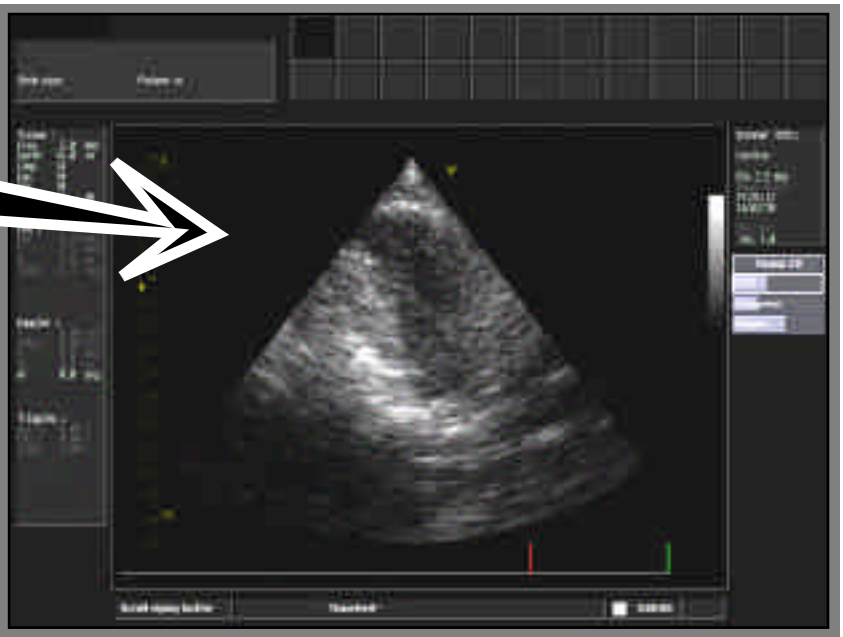
Power Amplitude Doppler, also known as Ultrasound Angio or Doppler Energy, uses the same data as acquired using Conventional Color Flow Mapping. In Power Amplitude Doppler it is the of the doppler signal amplitude that represents the intensity which is mapped to a color instead of the velocity, bandwidth and direction. Undesired signals from slowly moving tissue structures are surpressed by the same type of wall filter. Power Amplitude Doppler provides noticeably higher sensitivity because of much lower pulse repetition frequency and extensive temporal processing.

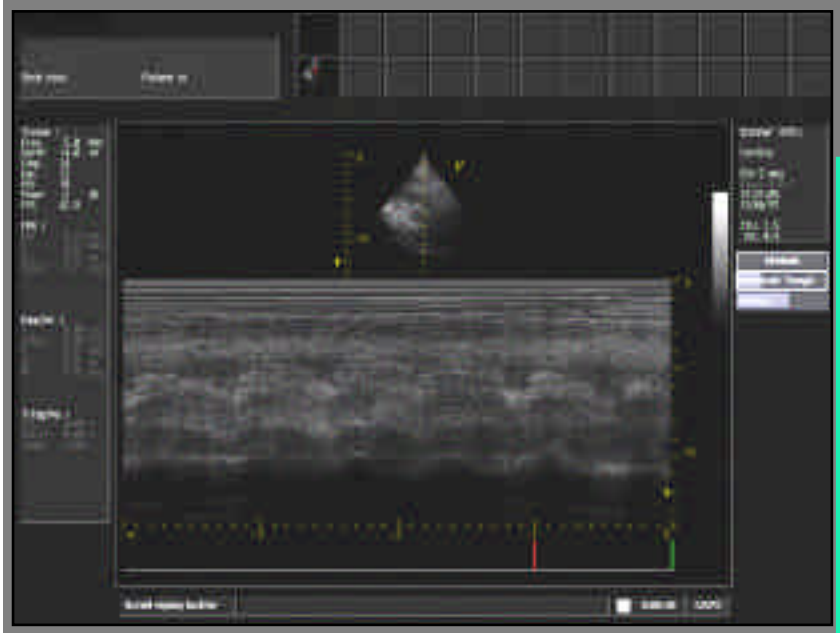
Tissue Velocity Imaging maps velocities from tissue motion to colors in accordance with a color map.

Traditional M-Mode

Start M-Mode, duplex view

In **2D** mode, press the **ADD CURSOR/MODE** key and position the cursor line on a tissue area of interest. Press this key to start 2D/M-Mode.





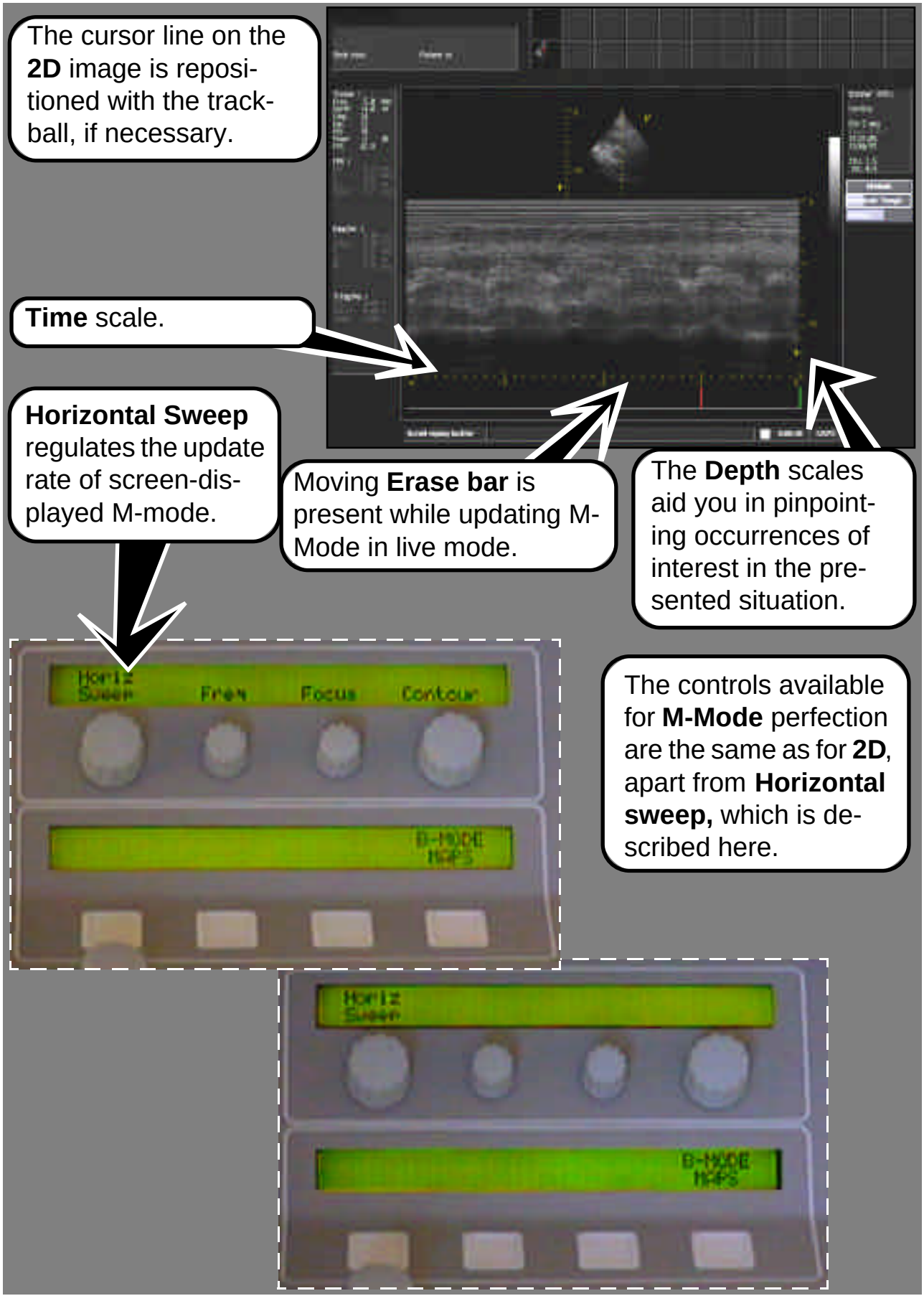
Shortly after, **Duplex M-Mode** replaces **2D**.

About M-Mode

In Traditional M-Mode, Tissue Data is continually gathered along the cursor line on the 2D image. Each recorded pulse is joined together and presented horizontally within a rectangle which has a horizontal time scale and a vertical depth scale. It is normally used to scrutinize found tissue abnormalities on the 2D image.

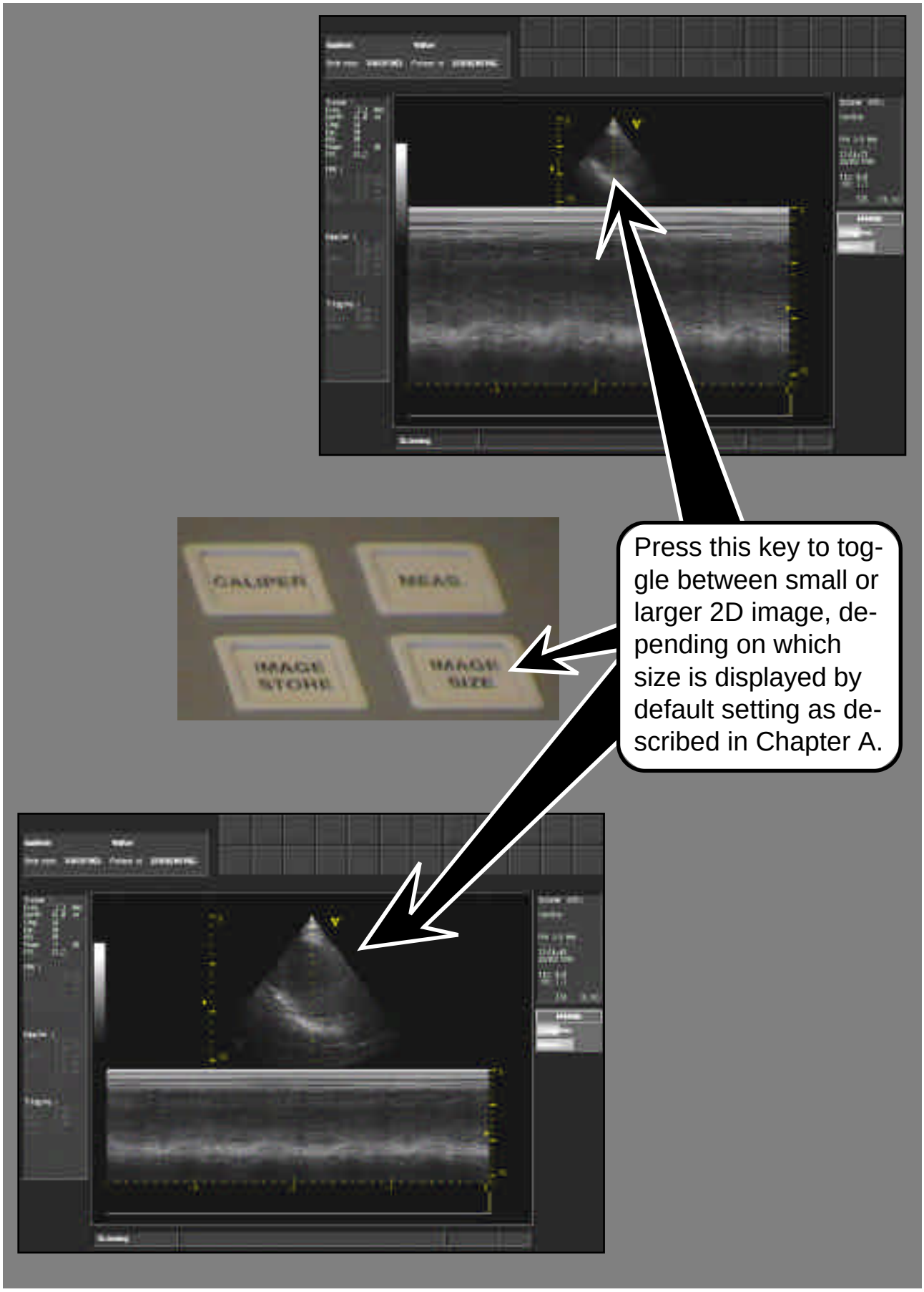
Traditional M-Mode

Elements in duplex M-Mode display



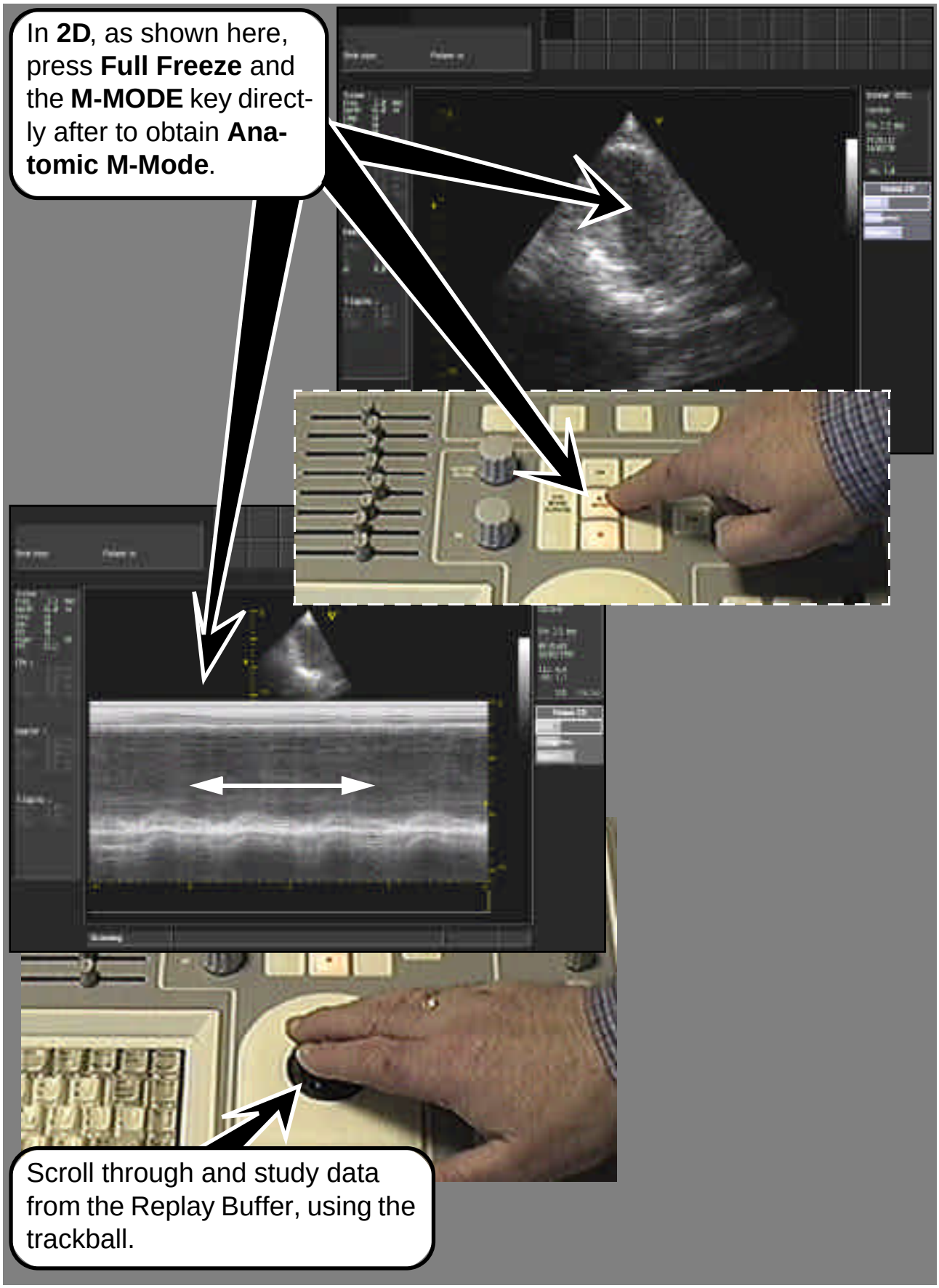
Traditional M-Mode

Image size



Anatomic M-Mode

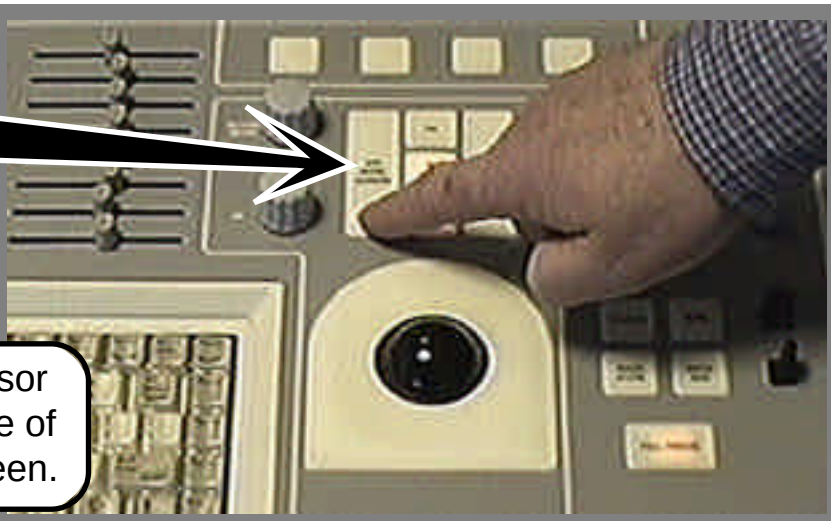
Prepare for Anatomic M-Mode



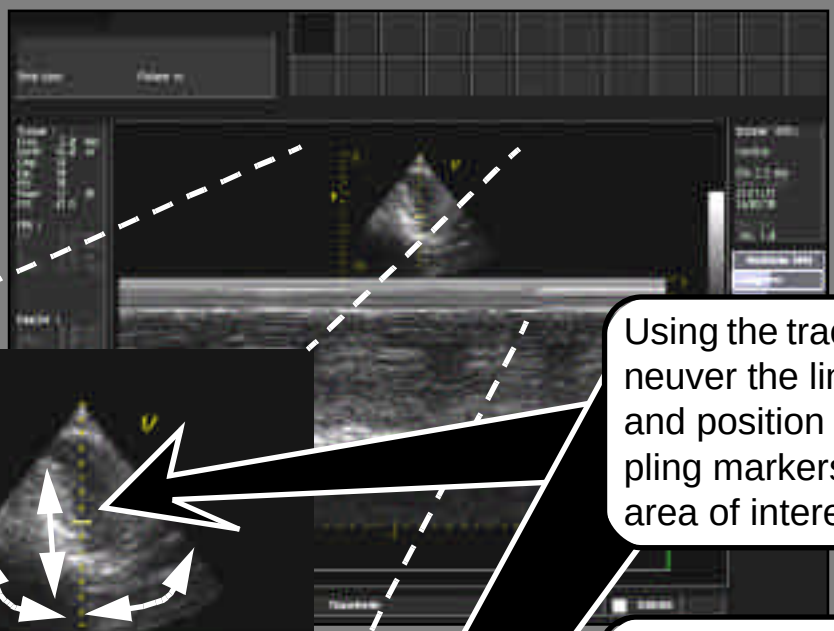
Anatomic M-Mode

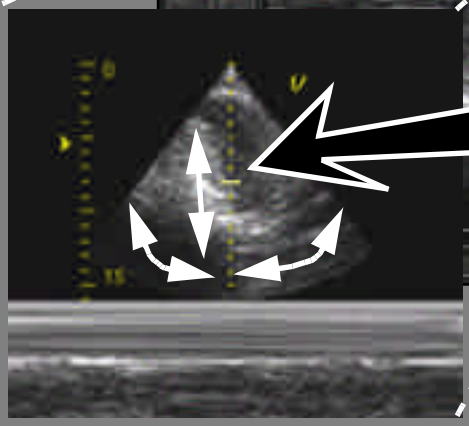
Maneuvering the cursor line

Still in full freeze status, press **ADD CURSOR/ MODE** once to move activity to the 2D image and thereby access to cursor line maneuver.



The Instruction Move Cursor is displayed at the left side of the lower edge of the screen.





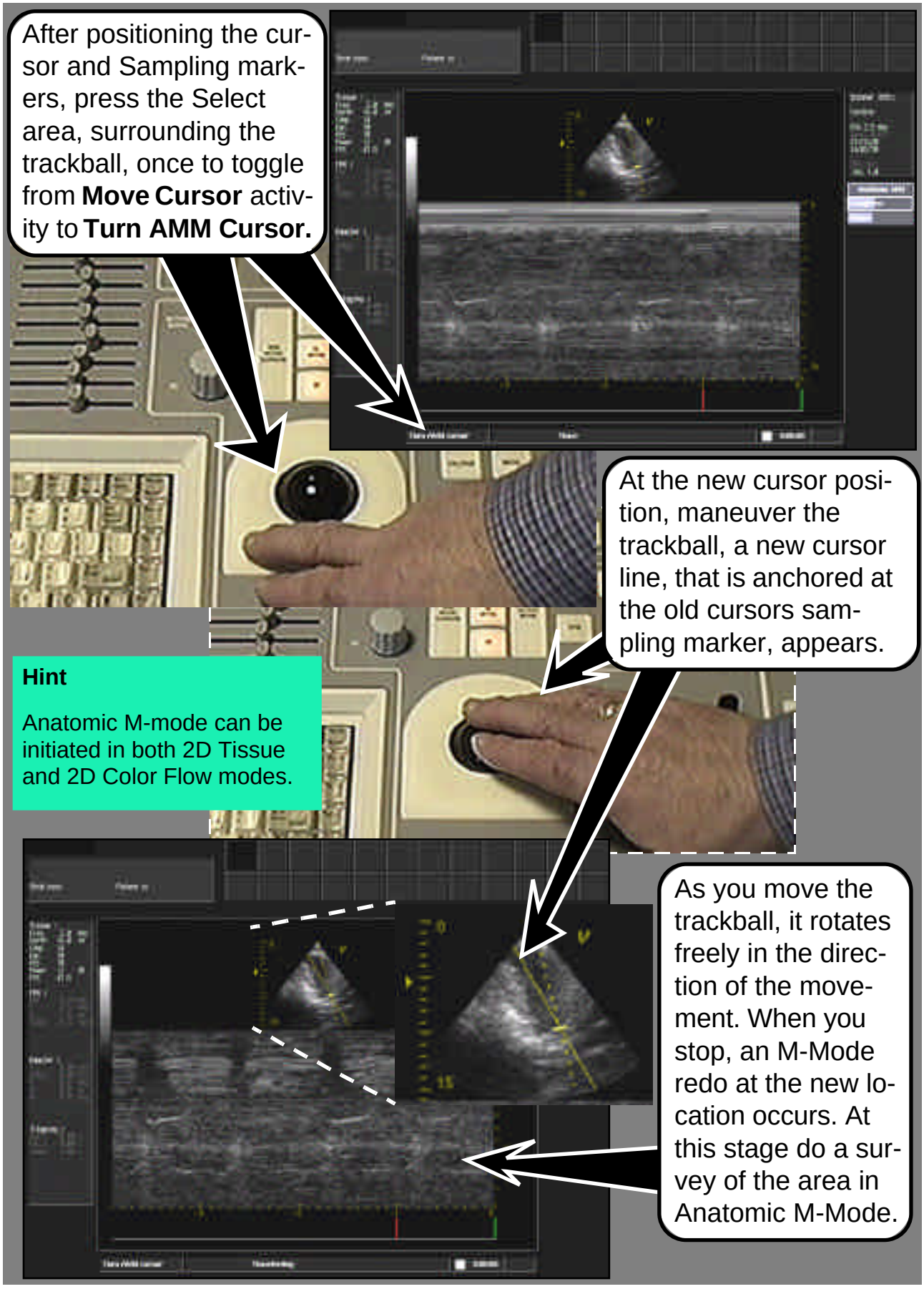
Using the trackball, maneuver the line cursor, and position its sampling markers on an area of interest.

When you stop maneuvering these a display update of the M-Mode view at the new location of interest occurs.

Press **ADD CURSOR/ MODE** once more to return to normal M-Mode Replay buffer scrolling.

Anatomic M-Mode

Anatomic M-Mode viewing



Anatomic M-Mode

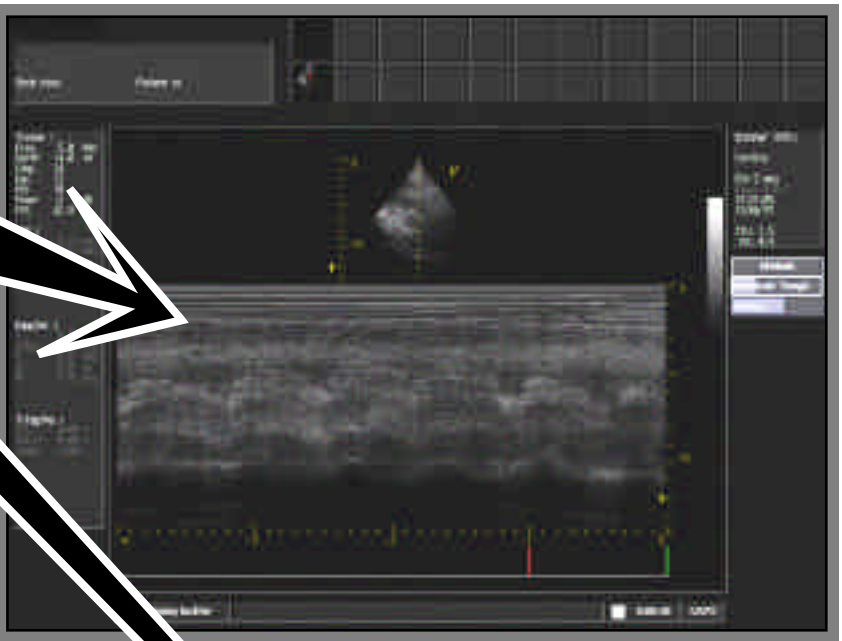
About...

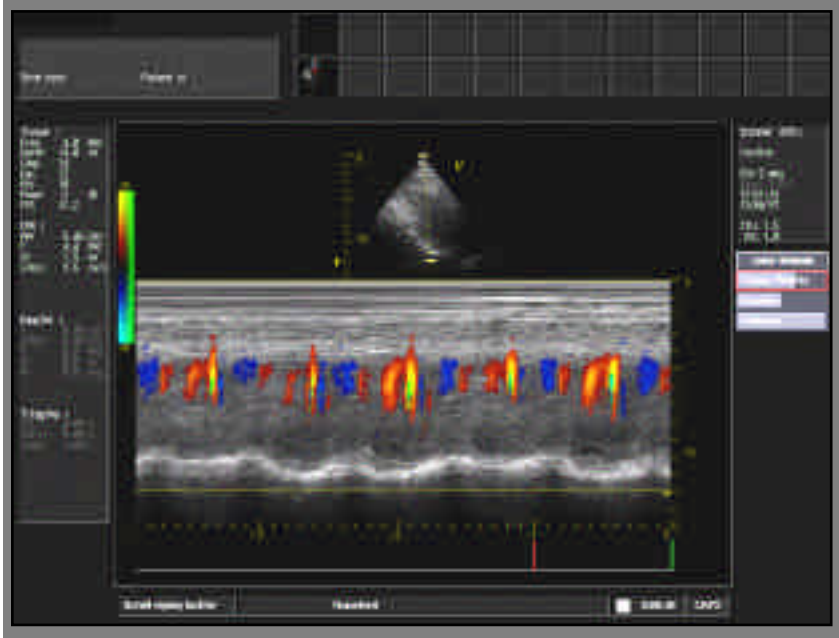
Anatomical M-Mode is a most useful tool for the validation and quantification of tissue movement and thickening. It is for instance possible to measure wall thickening in locations where the wall boundary is parallel with the acoustic beams. The anatomical M-Mode applied to tissue velocity data provides the tool that resolves the complex motion characteristics of myocardial wall movement. The Anatomical M-Mode lines are sampled with the same temporal and spatial resolution as done with the 2D tissue or 2D color flow images, making it possible to produce high quality M-Mode images from high framerate 2D acquisitions.

Color M-Mode

Select Color M-Mode

In 2D/M-Mode, press this key, to select Color M-Mode, and below shown color information, representing speed (movement), appears.



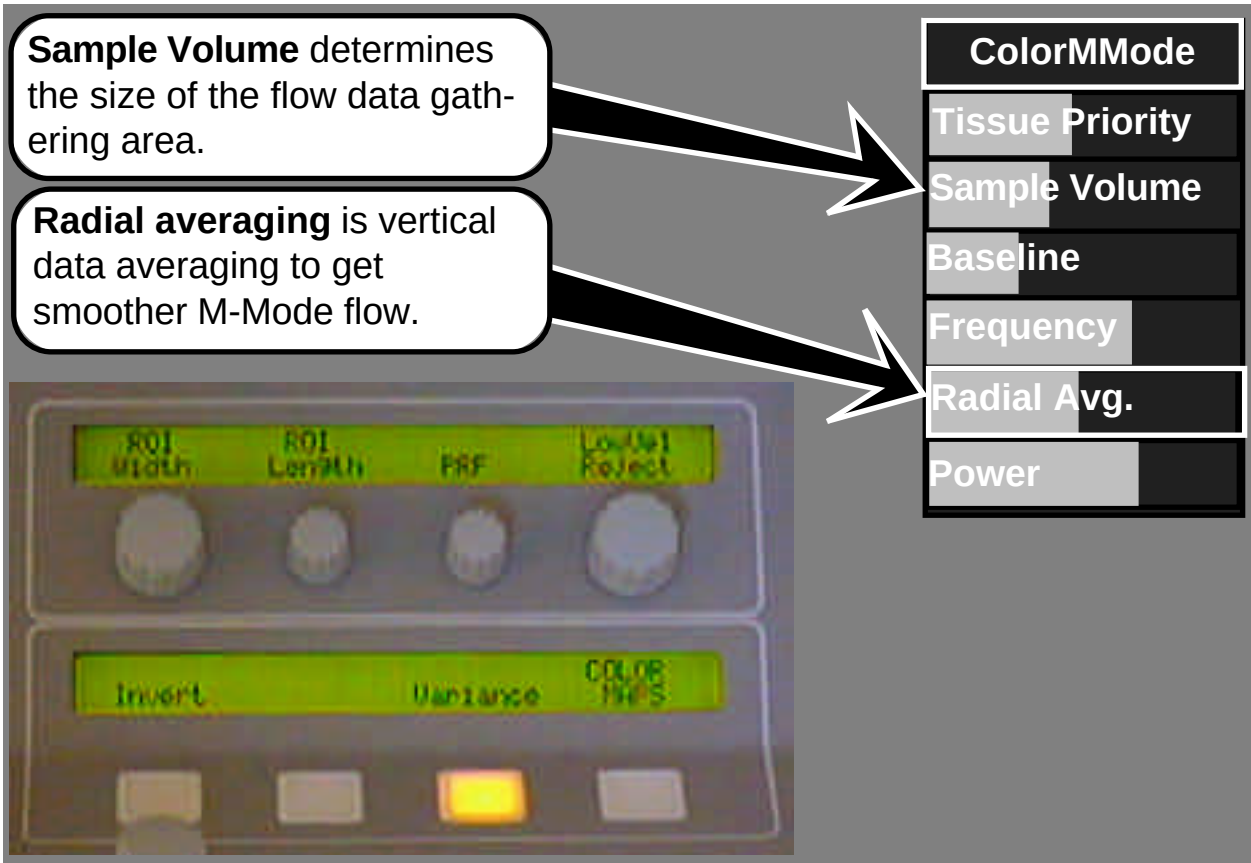


Color M-Mode

Assignables, screen functions, live

Sample Volume determines the size of the flow data gathering area.

Radial averaging is vertical data averaging to get smoother M-Mode flow.



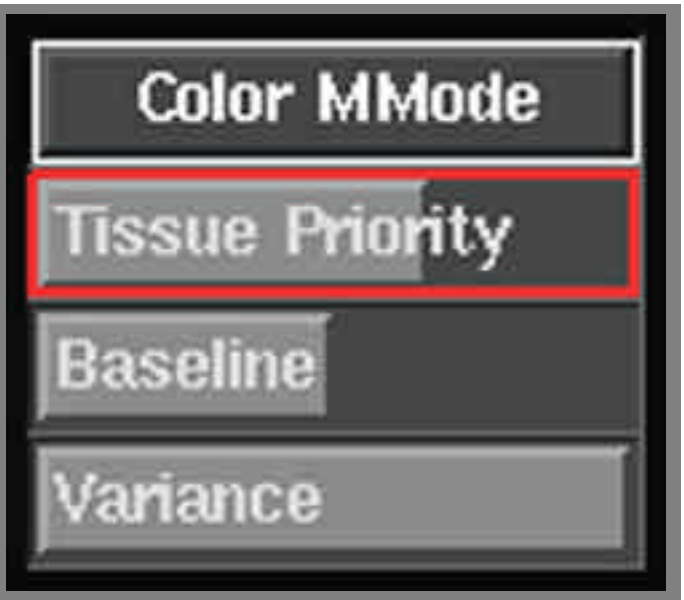
WARNING
Frequency adjustment In Doppler or Color or Flow modes affects the maximum size of the available velocity range. (Frequency increase lowers the maximum.

Information
Find missing Color M-Mode commands and adjustment descriptions in 2D, M-Mode and Color flow descriptions.

Color M-Mode

Assignables, screen functions, FULL FREEZE

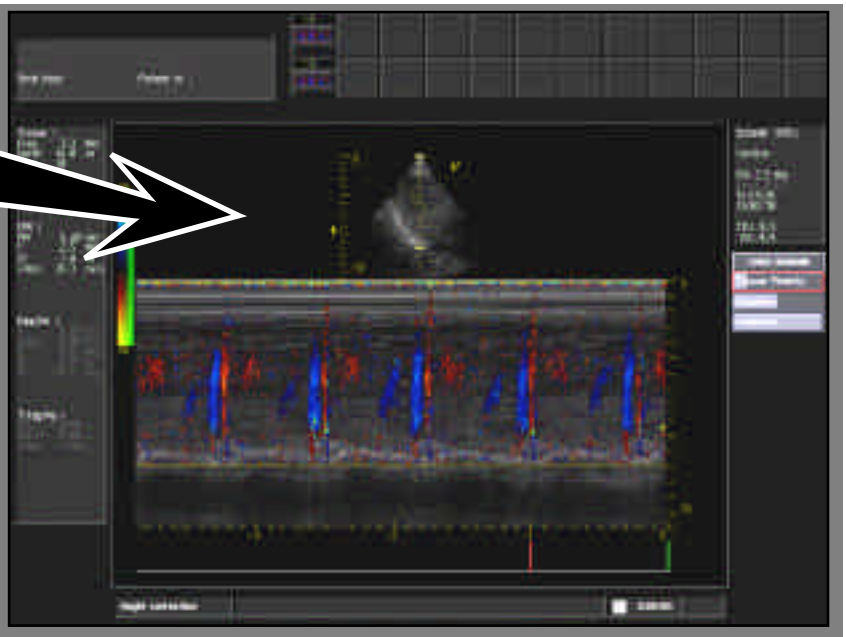
Information
Find missing Color M-Mode commands and adjustment descriptions in 2D, M-Mode and Color flow descriptions.

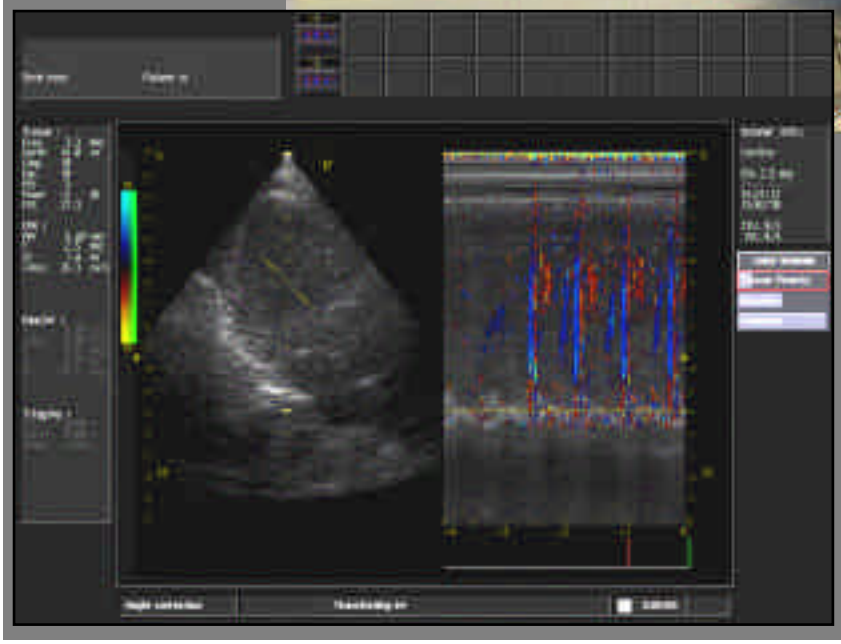


Side by side viewing

Choose side by side view

The default setting on the screen configuration menu, over/under, is the automatic choice when selecting duplex modes.





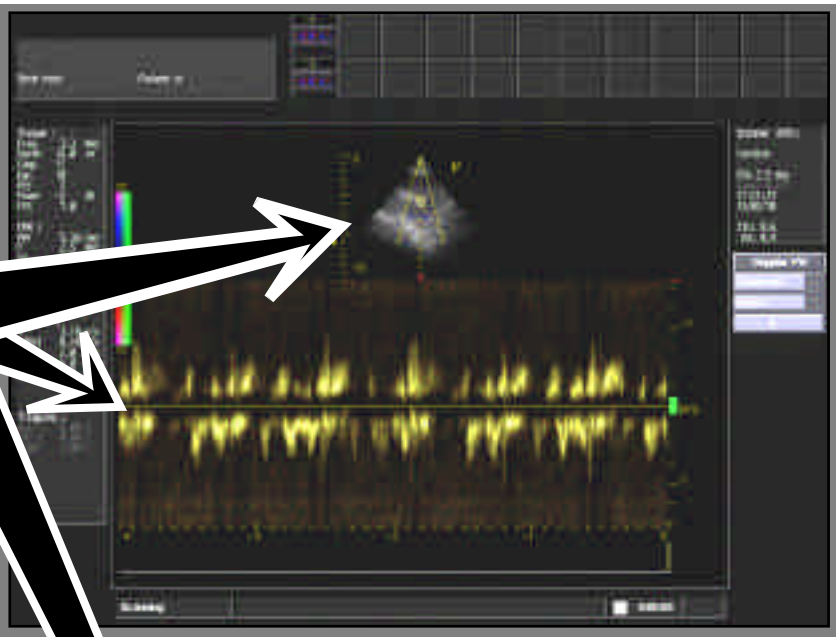
To present the new view, shown to the left, press the SELECT SCREEN key.

Repeat the above to return the default view.

Doppler

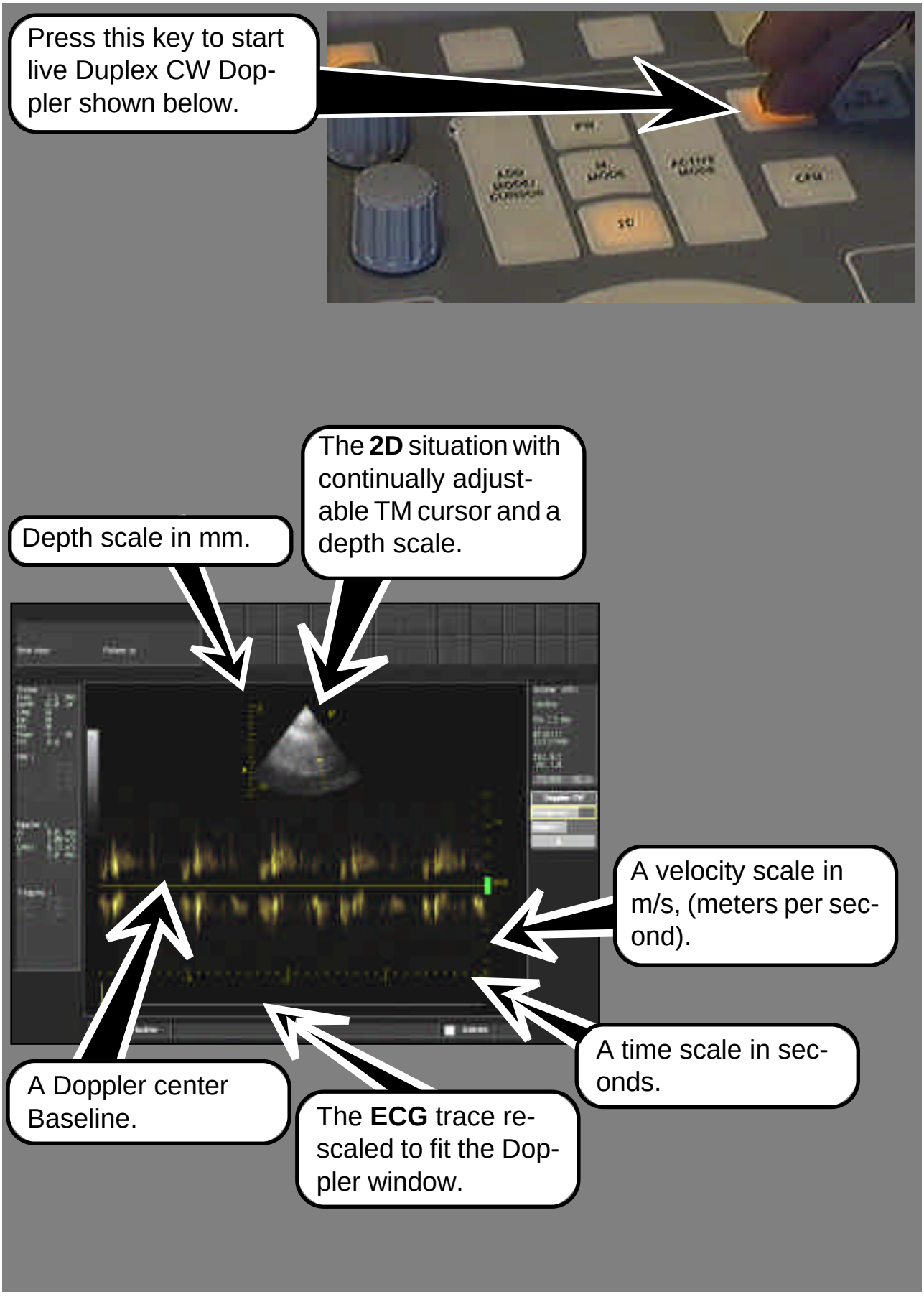
Start PW Doppler Mode

From 2D mode, press this key to add Doppler from the region of interest marked by the TM cursor. The 2D picture is rescaled, and the Doppler Window appears below it.



Doppler

Start Duplex CW Doppler



Doppler

Carotid Angle Correction

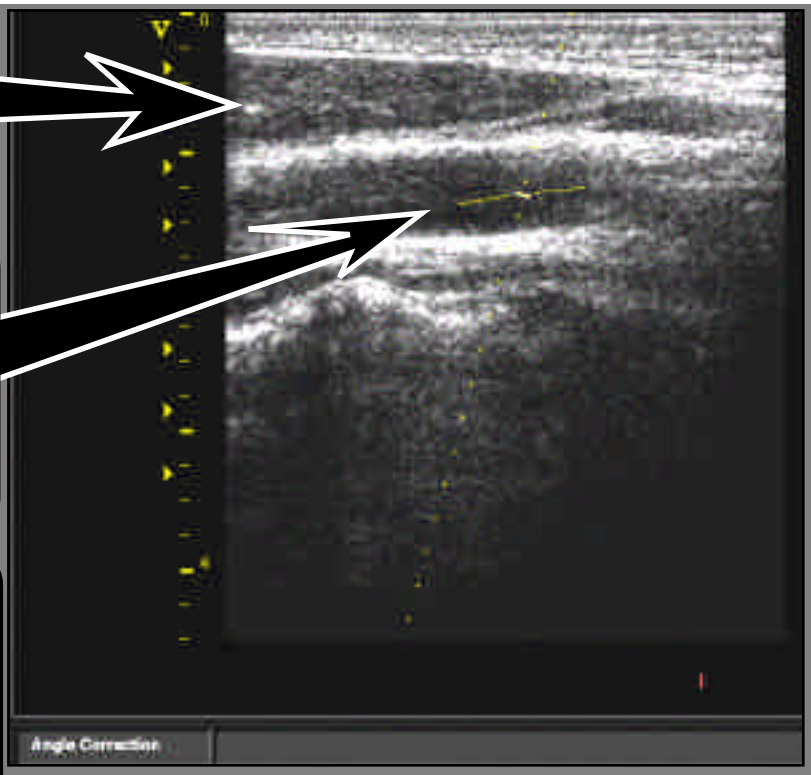
Obtain a good image and engage the Cursor with the **Add Mode/ Cursor** key.

Move the Cursor with the Trackball and place the Angle Correction marker, on the cursor sample volume, in the center of vessel.

Press the **Select** key once, adjust the angle until the yellow line is parallel with the vessel wall or the assumed direction of flow.

Press one of the Doppler Mode keys and continue the investigation.

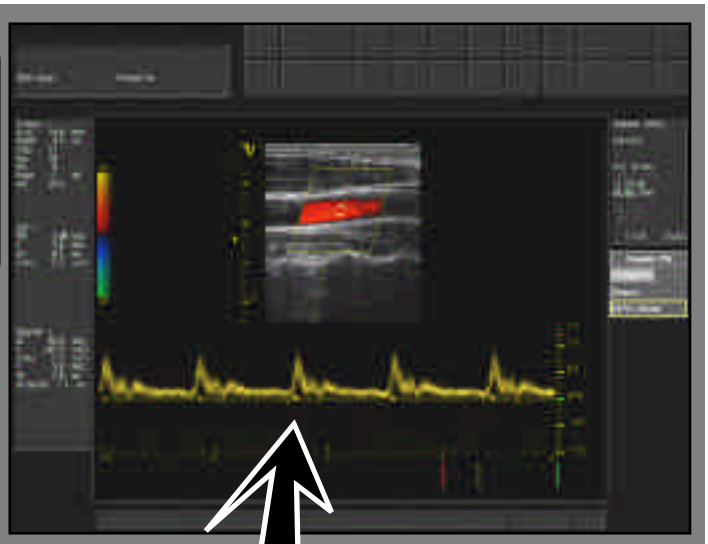
To move the cursor to another position press the Select key once more.



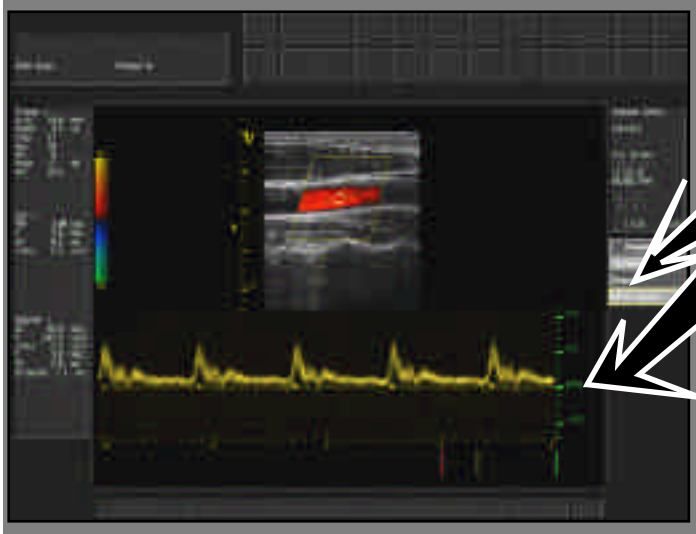
Doppler

Peak Velocity Correction

Peak velocity Correction is used for finding a more correct maximum velocity reading as a function of Tilt Angle Correction, Sample Volume and Depth.



With the above situation the Automatic Peak Velocity Correction is switched ON/OFF here.



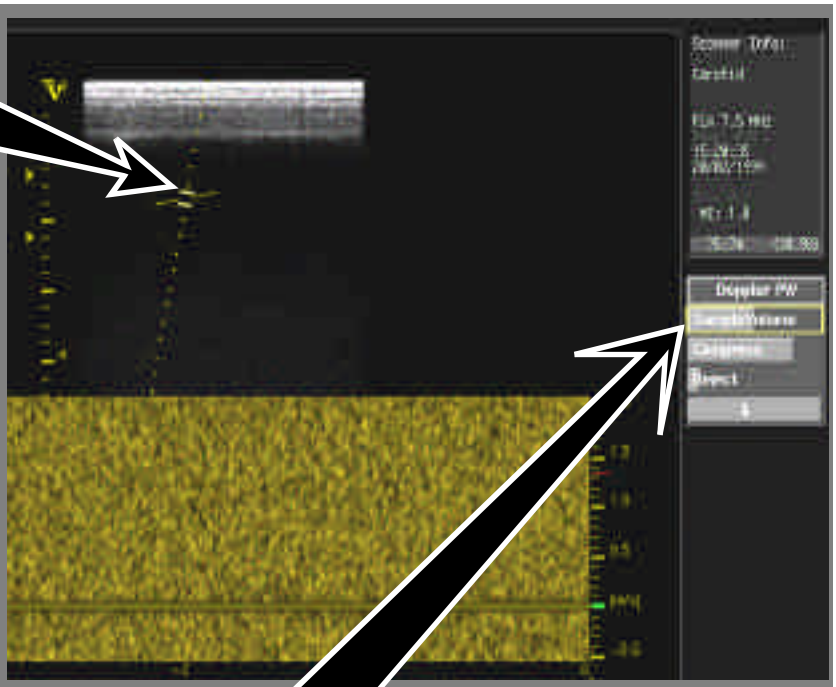
When switched ON the Velocity is corrected and the Doppler scale is Green.

Doppler

Sample Volume size change

Sample Volume Controls size of the doppler Sample Volume (Gate).

The horizontal paddle adjusts the Sample Volume. The vertical paddle finds the Sample Volume



Increasing the sample volume size improves sensitivity but reduces spatial resolution.

This also reduces the achievable maximum velocity range.

Doppler

Assignables, screen commands, live

Doppler PW

- Sample Volume
- Compress
- Reject
- Frequency
- Framerate
- Tracking
- Overrange
- Power
- Angle Corr.

Baseline
Controls position of the zero velocity baseline of the spectral display. To be used to help avoid aliasing of the doppler display.

Doppler CW

- Compress
- Reject
- Frequency
- Framerate
- Power
- Angle Corr.

WARNING
Frequency adjustment In Doppler or Color Flow modes affect the maximum size of the available velocity range. Frequency increase lowers the maximum.

Doppler

Doppler Control descriptions

Velocity Range

Control the velocity range of the spectrum display.The requested velocity range will not necessarily be achievable. The available range depends on parameters like frequency, sample volume position and sample volume size. If the required range is not achievable reducing the sample volume size might help.When measuring high velocities one might get unlikely sample volumes. To get rid of these use either the LPRF control (this will lower the velocity range) or the Overrange control. The displayed velocity range depends on the setting of the Angle Correction.

Tracking

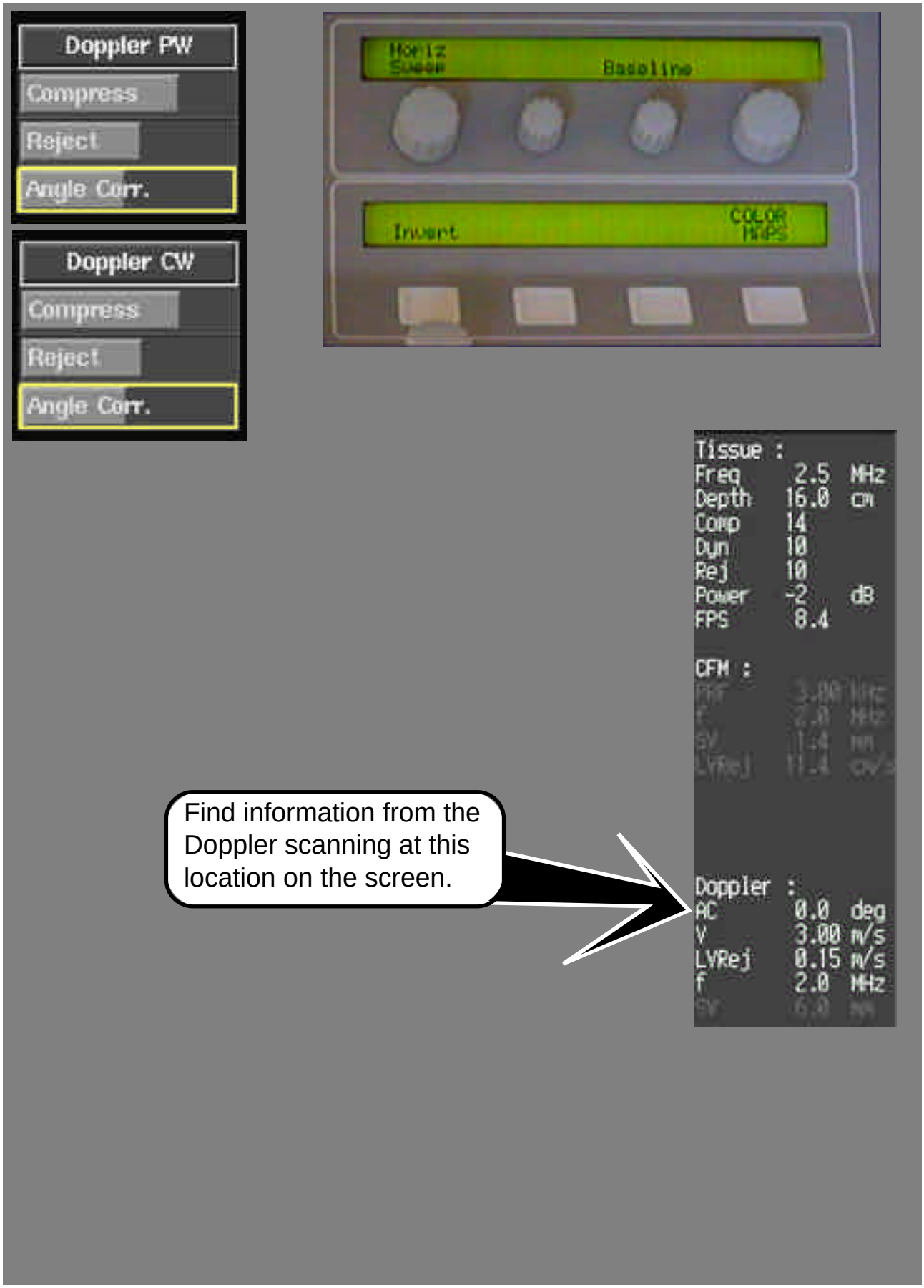
Controls the spectral analyzers “tracking” of blood cells. When tracking is off (set to minimum value) the analyzer will work in the traditional way. Increasing the tracking will make the analyzer to try to “track” the blood cells. This will improve the resolution of the spectral display, and it makes it possible to measure velocity above the Nyquist velocity. But increasing the tracking will also reduce the sensitivity of the doppler. See also Overrange control.

Overrange

If overrange is on (value higher than minimum) the spectral analyzer analyzes velocities beyond the Nyquist velocity. This will make the measurement of high velocities possible without the drawback of unlikely sample volumes. To make it possible to distinguish the signal from blood moving with velocities beyond Nyquist velocities from ghosts from lower velocity signals tracking must be on (see Tracking control).

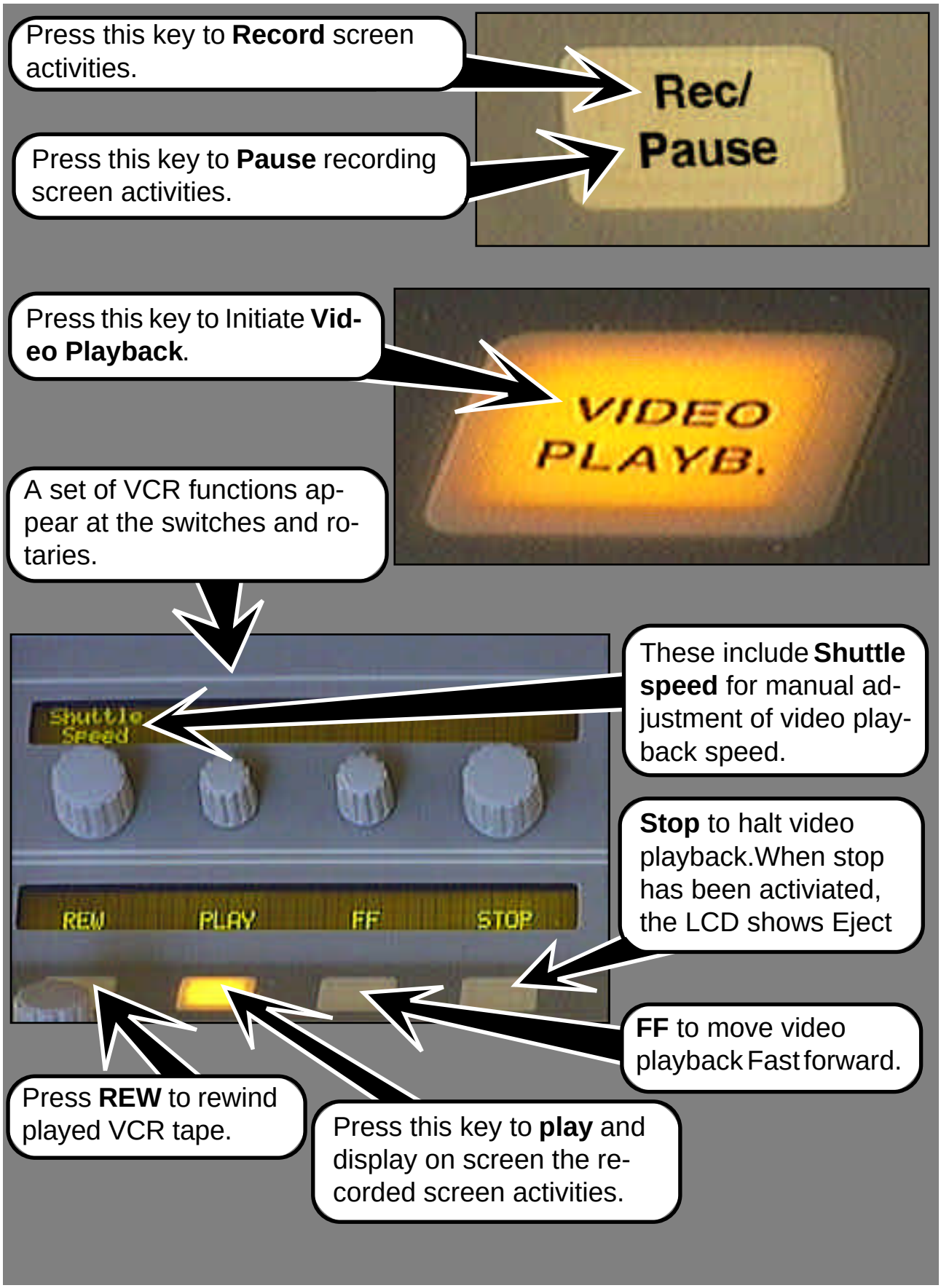
Doppler

Assignables, screen commands, FULL FREEZE



Tape Recording

Control Panel VCR controls



Chapter C

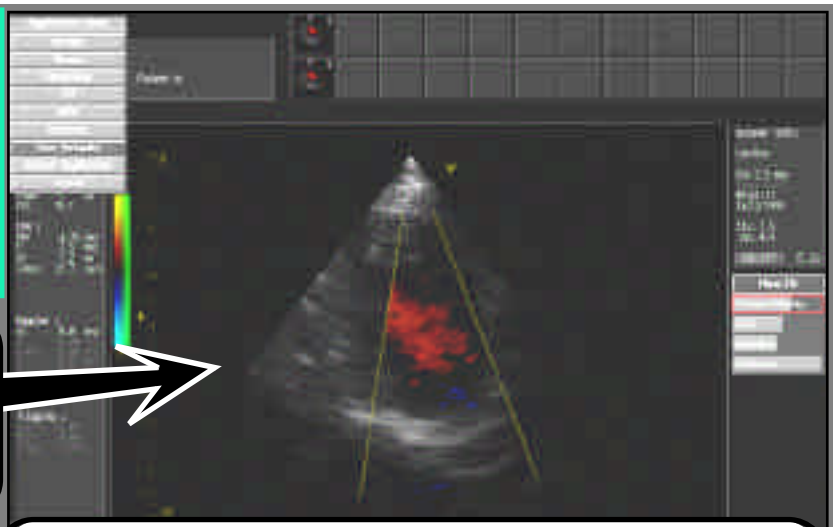
Applications

This section tells you about:

User Defaults storage

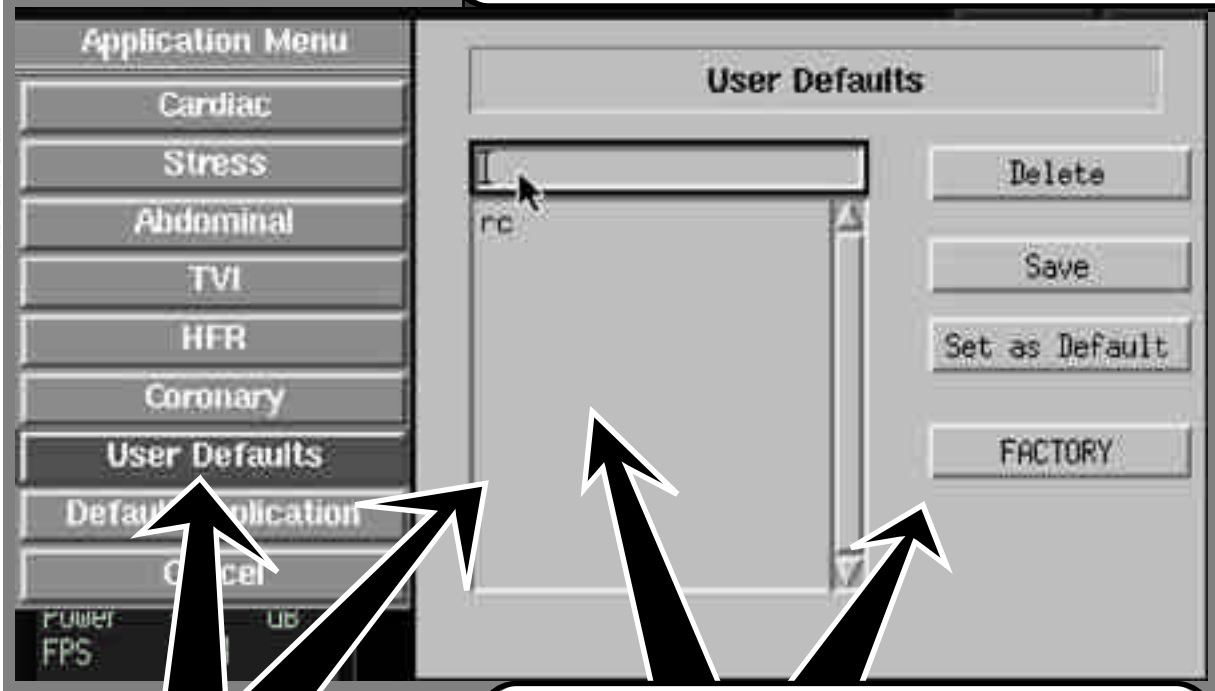
User Defaults selection

This function allows you to save and recall system adjustments and setups to add effectivity to your acquisition routines. How to do this follows.



Select the Probe, Scan the patient and adjust the system to optimize the scan.

To gain access to the **Applications menu,** press the APPLICATION key.



To open the **User Defaults** setup dialog, click-select **User Defaults** on the displayed **Applications Menu**.

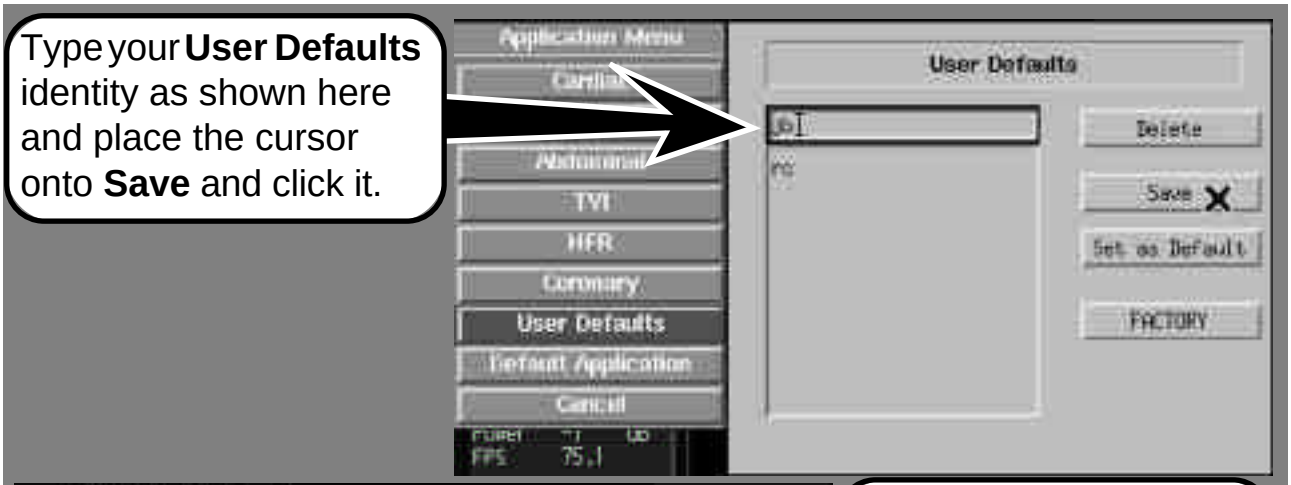
Here, you can Save settings under a file-name, Set as Default for present acquisition, Deleted altogether or you can use FACTORY set instead.

IMPORTANT
Your POWER control setting is not stored with your saved user default.

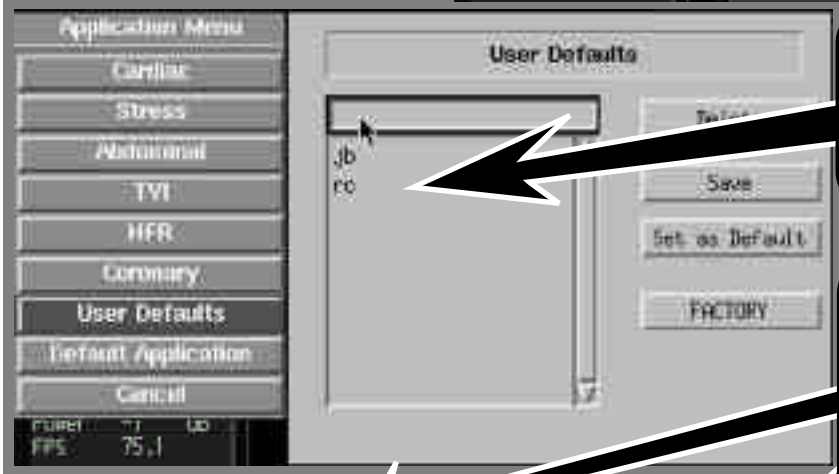
User Defaults Storage

Save and Recall your user default

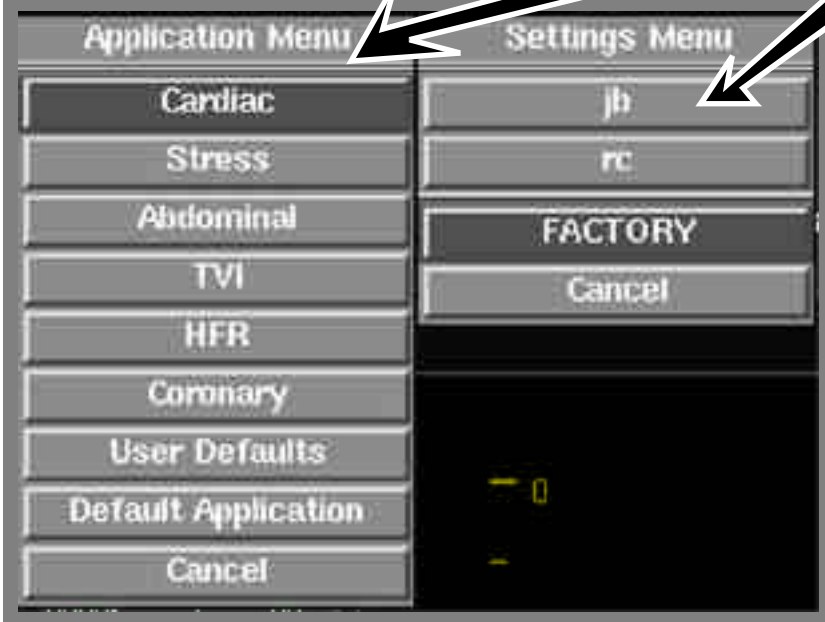
Type your **User Defaults** identity as shown here and place the cursor onto **Save** and click it.



Your entered setup file-name appears on the list below the naming window.



To recall your default set-up, which in our example was in Cardiac acquisition you can find your saved defaults file on the Settings Menu that appears when you highlight Cardiac shown here. Otherwise, you must find it via the User Defaults menu.



To return to the Users Defaults menu and click Set as Default which will make this setting the automatic choice the next time you choose Cardiac on the Application Menu.

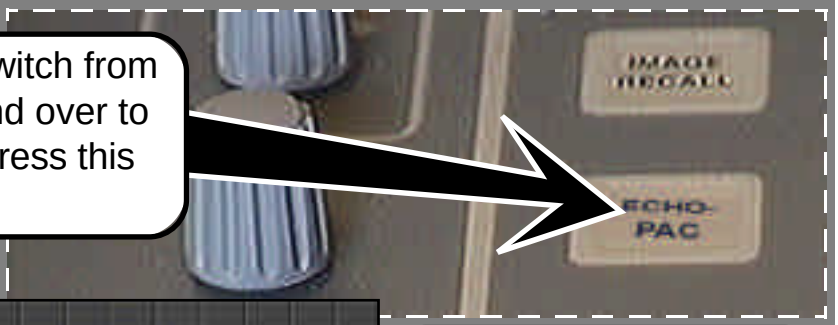
Note
If you have chosen your own setting its filename appears on the scanner info window, under the chosen application.

System Five, SuperVision

Handle EchoPAC on System FiVe

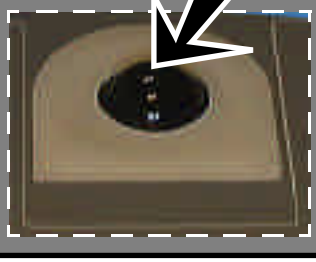
Some System Fives are shipped with an EchoPAC integration. These have added functionality within and SuperVision added to their product names. The following section describes how the integration affects normal System Five use. The EchoPAC integration boots at system boot-up.

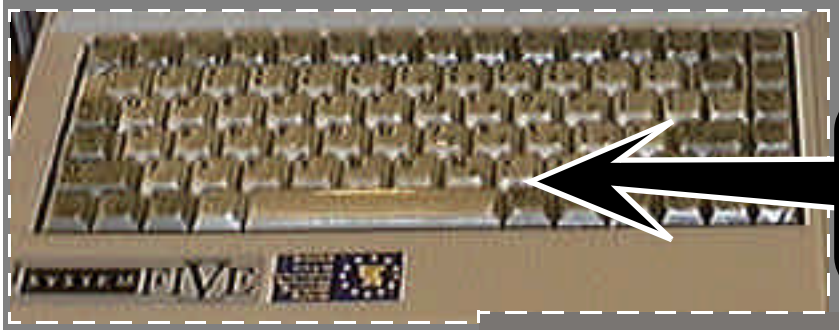
Whenever you need to switch from System Five scanning and over to the EchoPAC program, press this key.



After selection, Echo-PAC display covers this area.

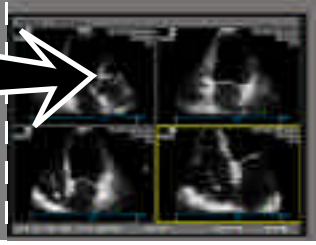
The Trackball and Select area function as your stand-alone mouse, and it's Select key when EchoPAC is active.





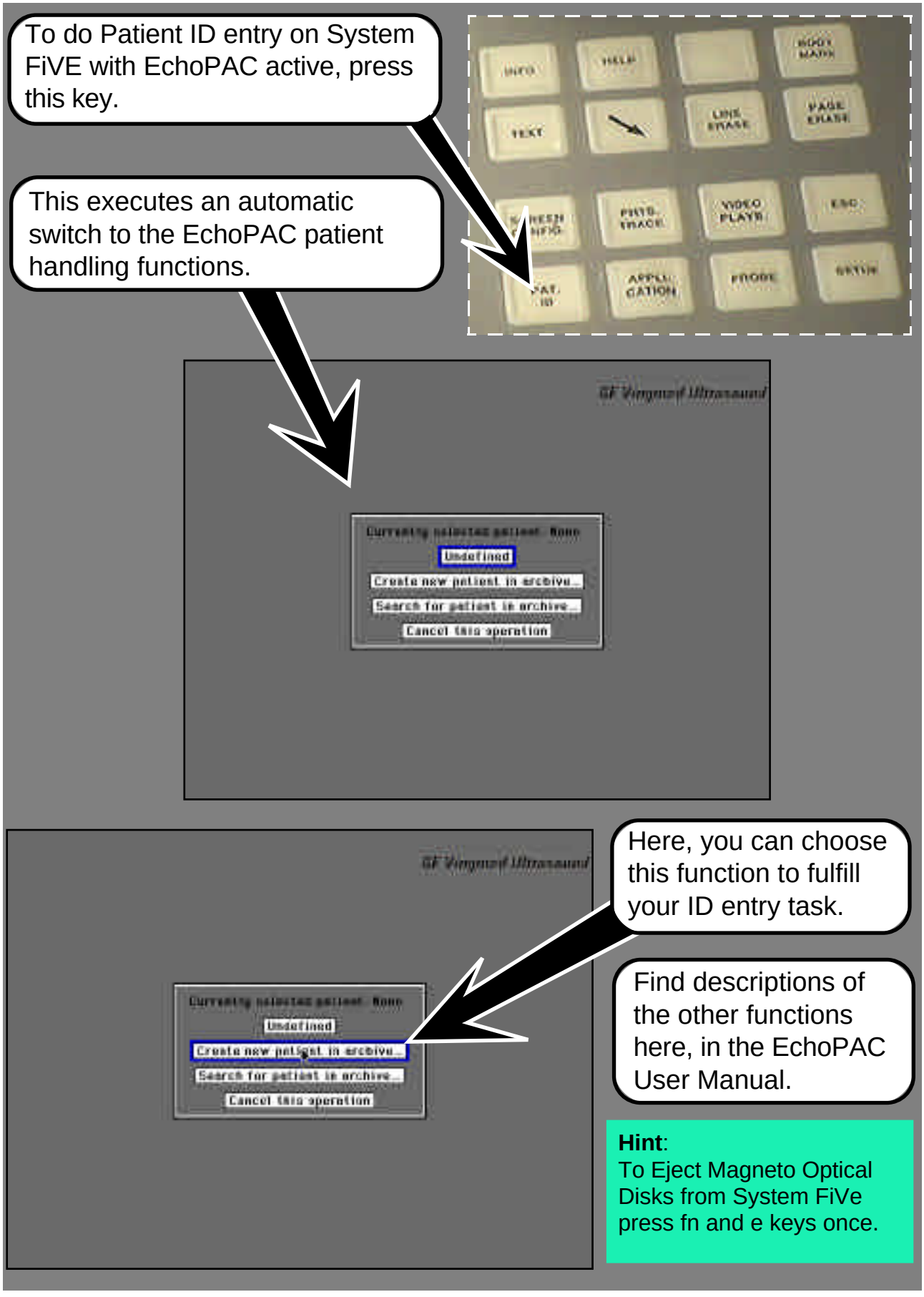
This keyboard covers most of your normal **EchoPAC** needs but some shortcuts may fail.

This miniature monitor, found just above the key-board, continuously dis-plays the current EchoPAC situation.



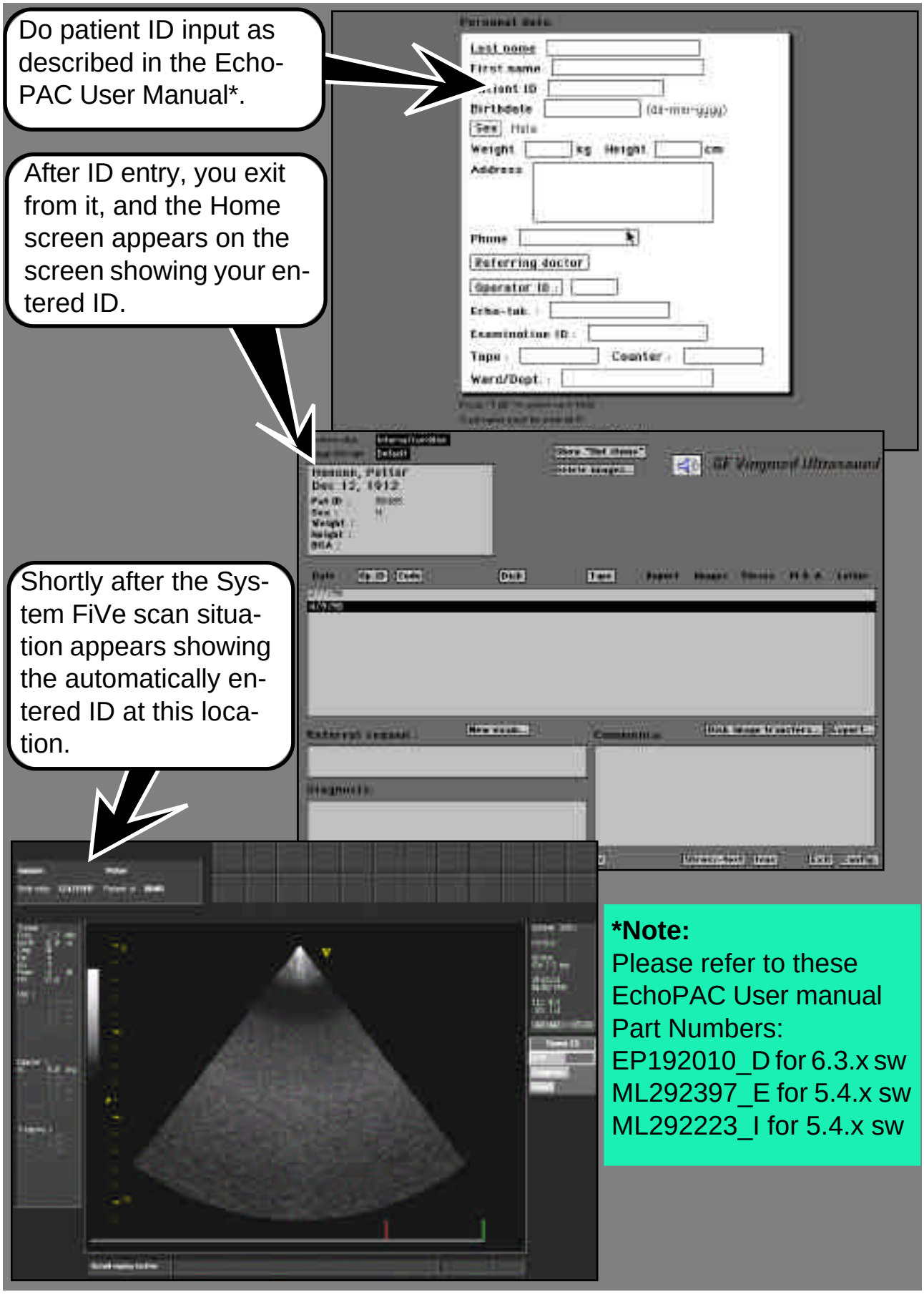
System Five, SuperVision

Patient ID entry selection



System Five, SuperVision

Patient ID input



System Five, SuperVision

Special Setup functions

Switch EchoPAC Video Grabbing ON when you want to do video grabbing from the System Five video signal and transfer it to EchoPAC.

The Transfer in detail is also dependent on other setups on this menu.

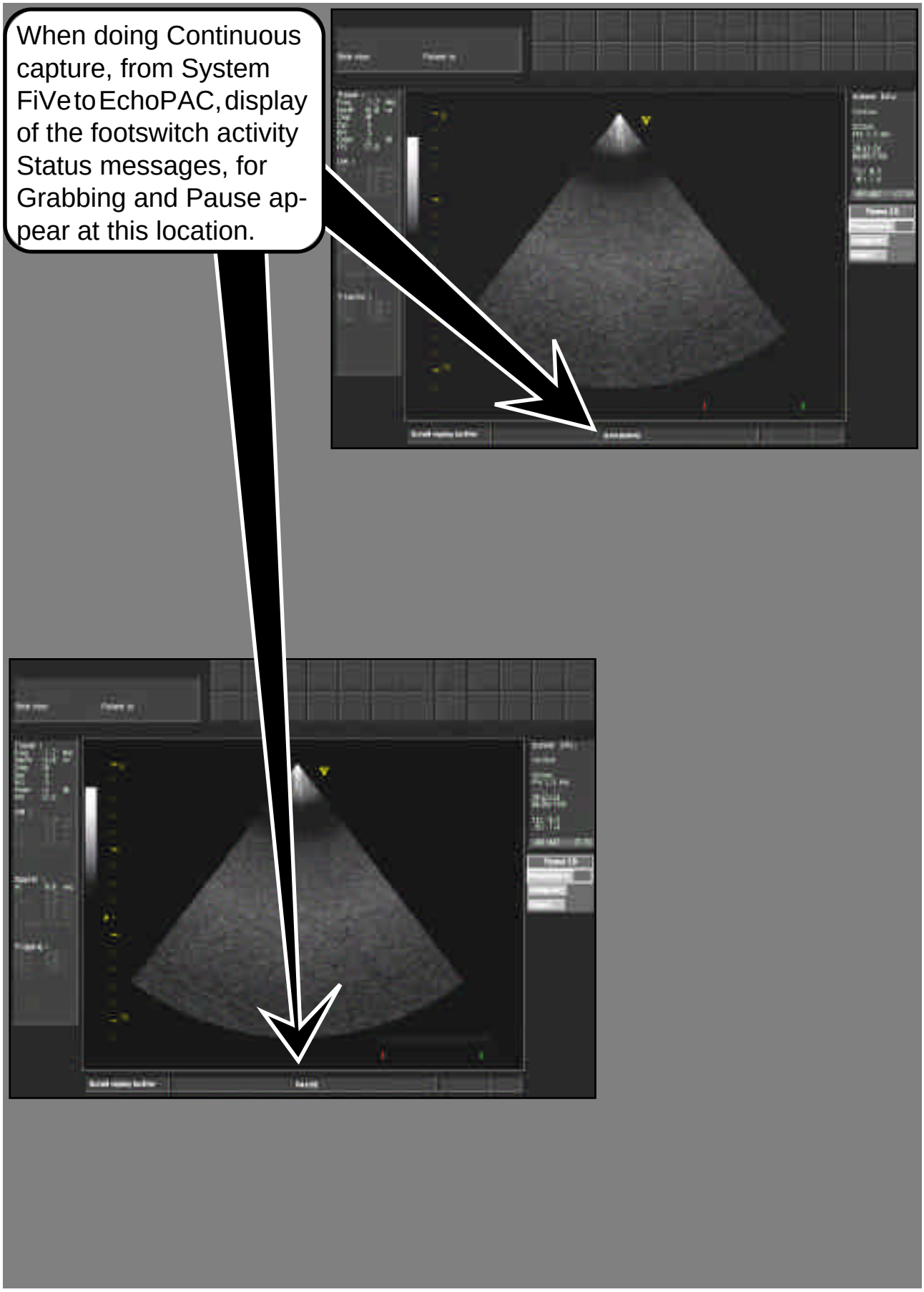
In live mode you get a raw data transfer of the scan activity on the screen.

At full freeze you transfer the amount of rawdata memorized by the System FiVe, or a normal copy of the present screen picture or a high resolution copy of the screen picture.

Select these to make the Footswitch work in EchoPAC only. Then the footswitch acts as it does on the EchoPAC stand-alone. See the EchoPAC User Manual for details.

System Five, SuperVision

Footswitch activity messages



System FiVe SuperVision

Willful System shut-Down with integrated Mac™

During normal everyday conditions, always use following shut-down routine:

-Set in standby-mode with Standby/ON key.

-Allow time for computer to clear up and organize it’s data and allow the system to come to rest in Stand-by mode.

-After this, switch power off with the Power ON/OFFswitch at the system rear.

Biopsy Option

Introduction

Intended use

The biopsy option is intended for use by a duly licensed physician who has received the appropriate training in biopsy techniques as dictated by current relevant practices, as well as in proper operation of the System FiVe Ultrasound Scanner.

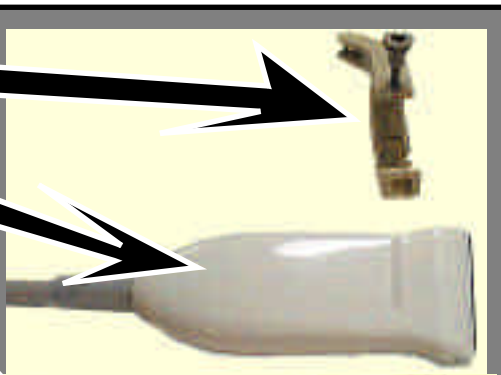
This device provides a mechanical means for doing needle / instrument guided procedures with the use of a diagnostic ultrasound probe. A reusable bracket is securely positioned over the probe body allowing attachment and use of disposable needle guides. This device provides a fixed path for the needle or instrument that, when coupled by the ultrasound system software, corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures. Furnish the CIVCO Biopsy Needle Guide includes transducer cover, which are disposable for single patient / procedure use, sterile. The single use, disposable feature helps to prevent transfer of microorganisms, body fluids, and particulate material to the patient and health care worker during reuse of the transducer. Furnish the reusable Biopsy bracket non-sterile, and clean it before each use to the user-required disinfection level.

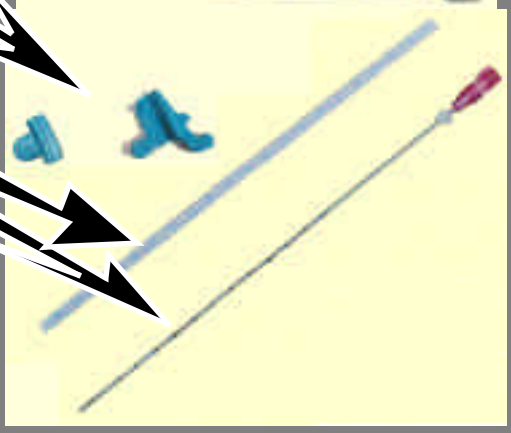
A **Biopsy Bracket**

A **Probe**.

A **Needle Guide** with reversible snap-on, snap-off, hole-channel piece.

A **Biopsy Needle** with protection sheath.





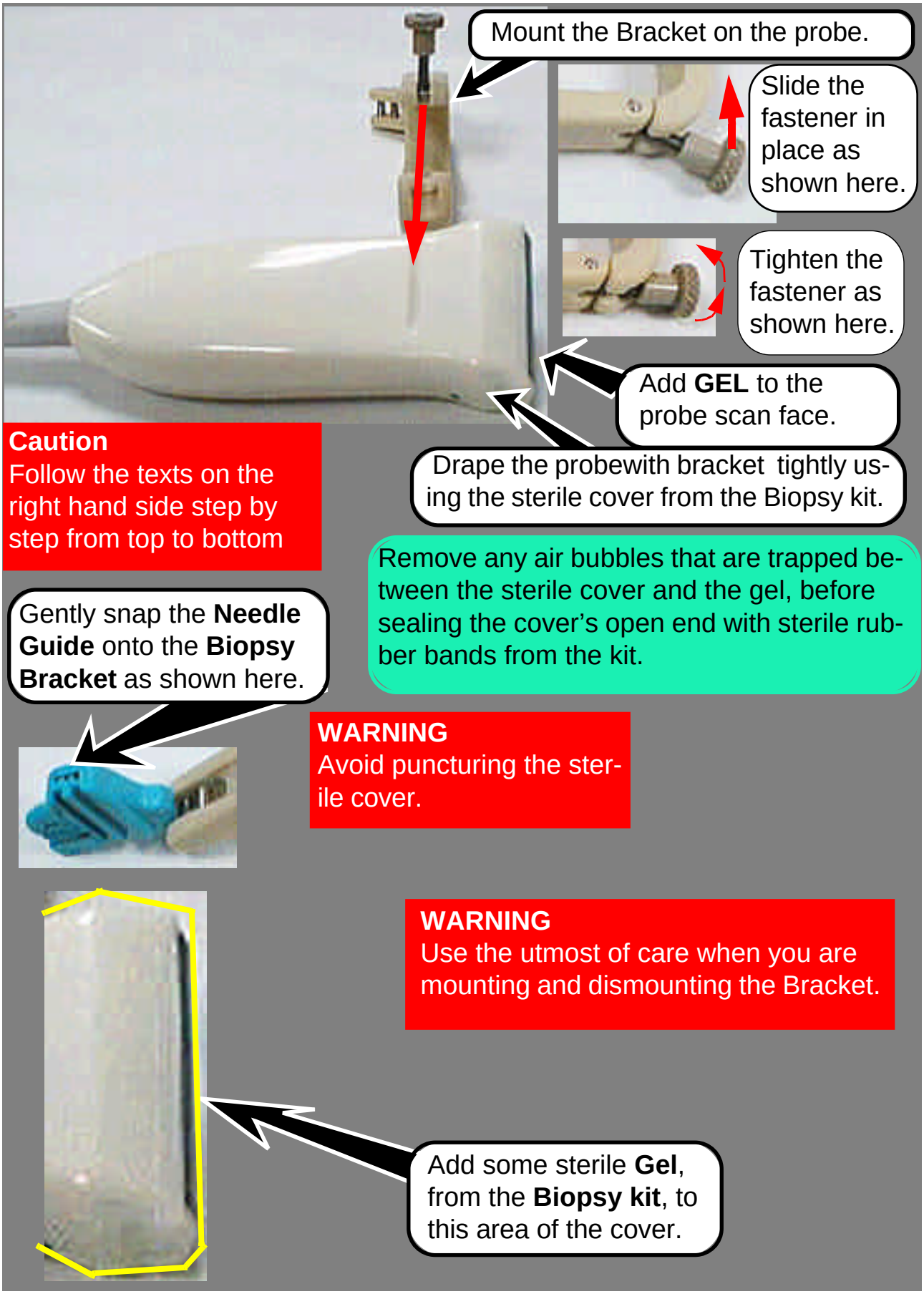
Sterile GEL sachet and **Sterile Cover**.

Sterile Kit packaging.

Rubber Bands.

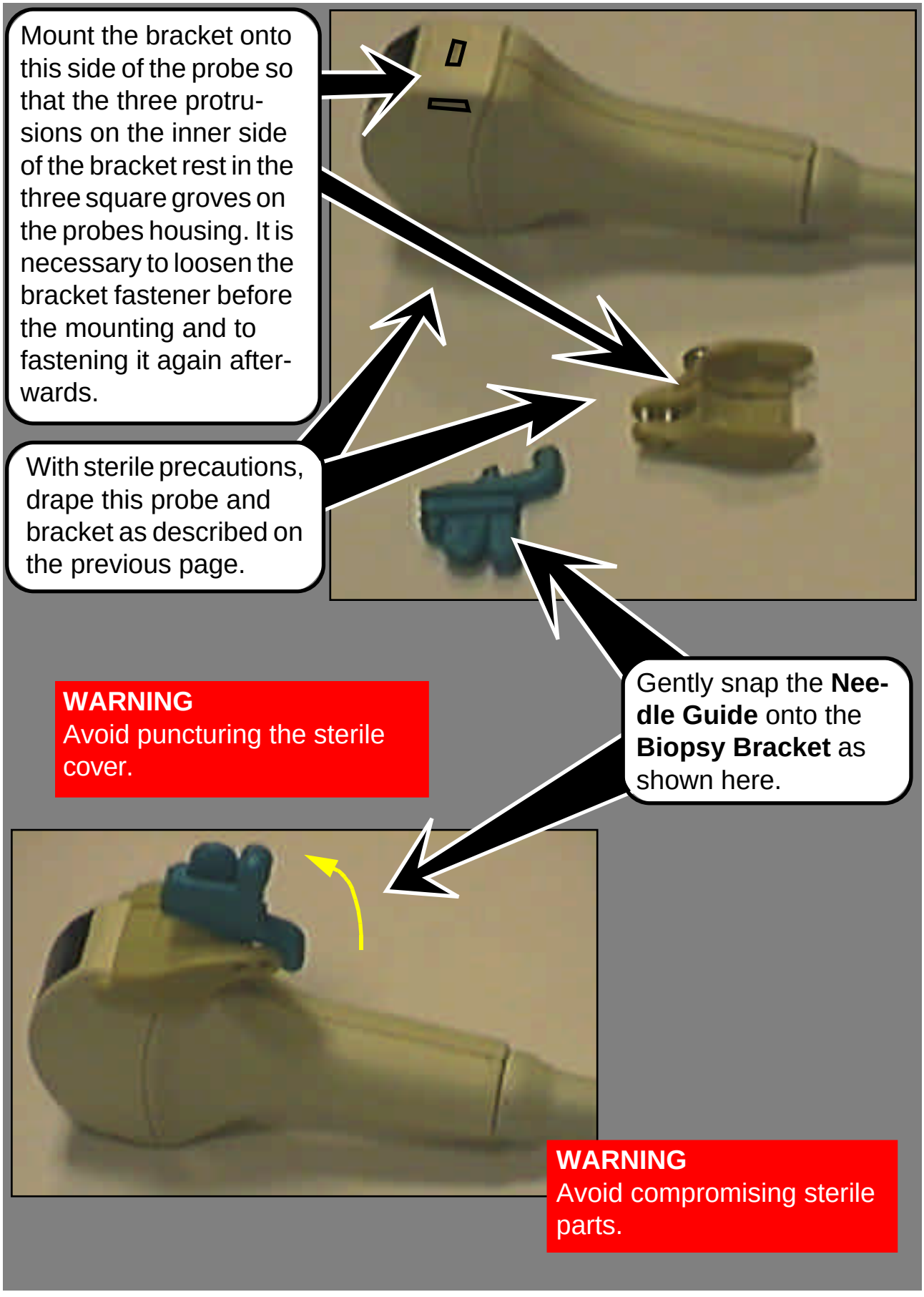
Biopsy option

Bracket and Needle guide mounting (10MHz FLA-Feb.99)



Biopsy option

Bracket and Needle Guide mounting (3.5MHz CLA)



Biopsy option

Start the Biopsy Option

To start the Biopsy Option, press this key on the Control Panel.

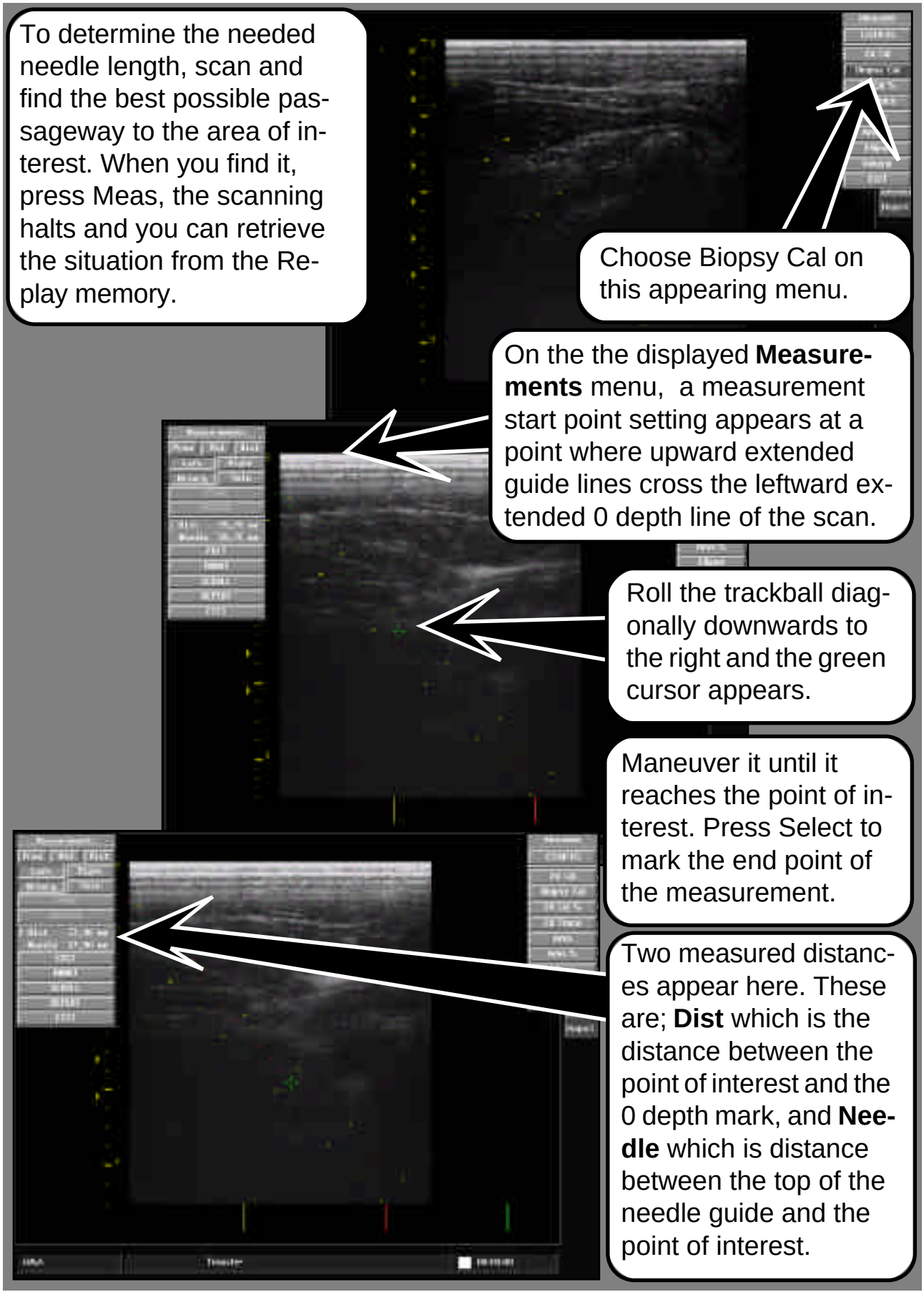
A **Biopsy** menu appears on the screen. It consists of click-selectable keys for Probe type/Needle thickness selection.

Choose a needle with an appropriate gauge (14, 16, 18, 20 or 22) for the job.
Press the appropriate needle key as input for the system.

The Biopsy guide lines replace the menu on the screen's ultrasound area. (1.0cm between large yellow dots, 0.5cm from large yellow dots to small yellow dots and 5.0cm between red dots).

Biopsy option

Determine Biopsy needle length



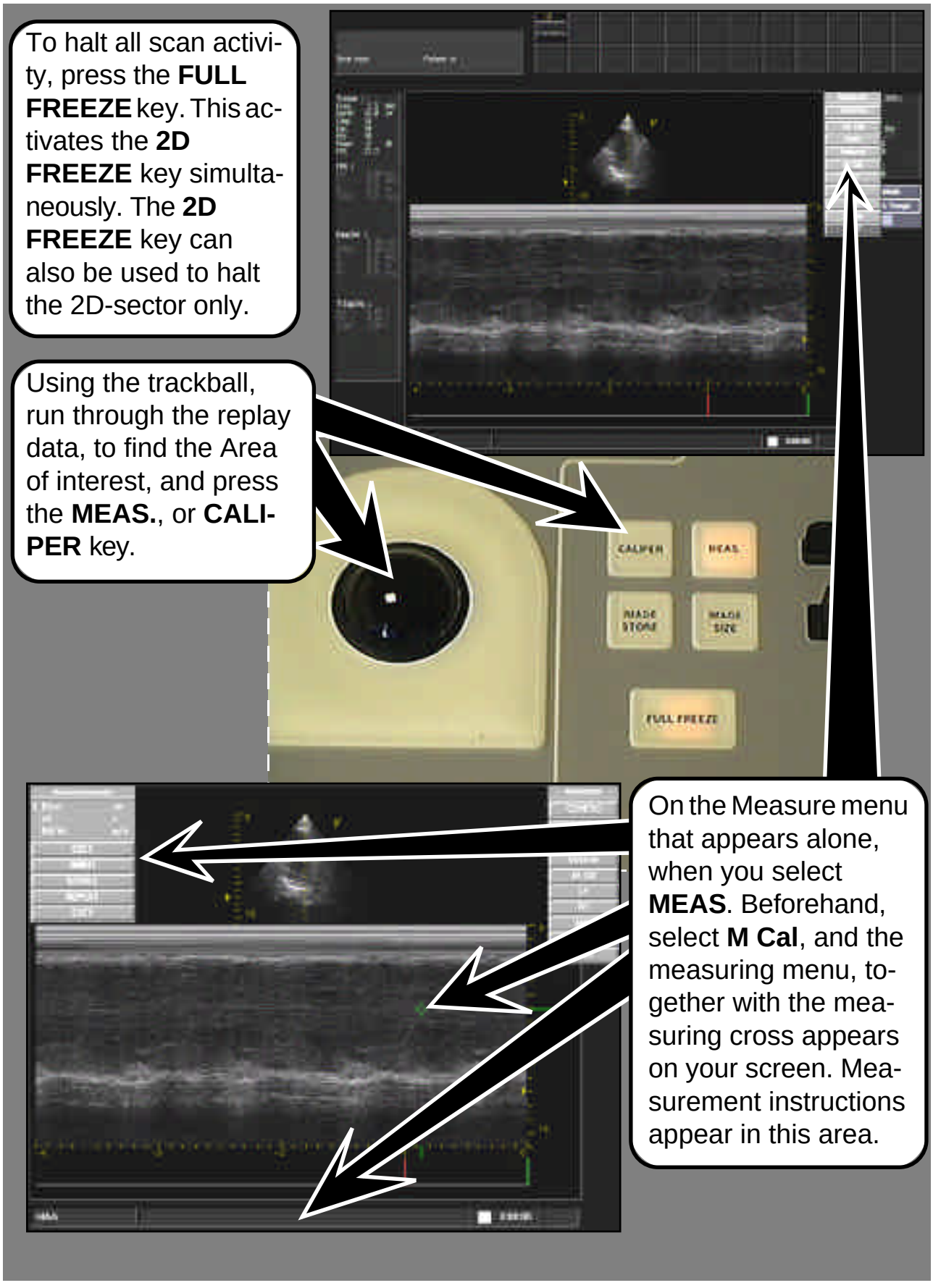
Chapter D

Using M&A

This section tells you how to:

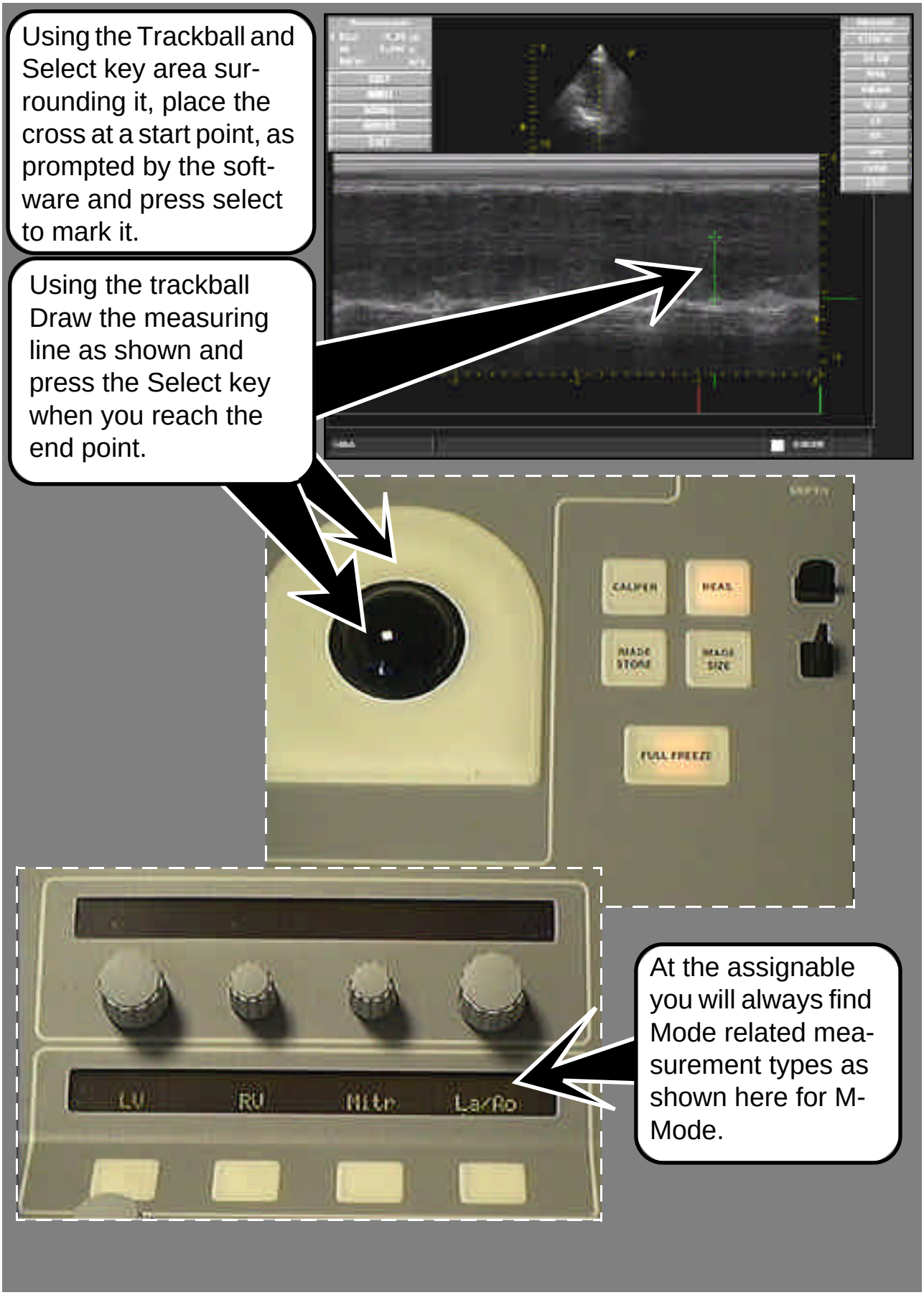
M&A examples

M-Mode M&A



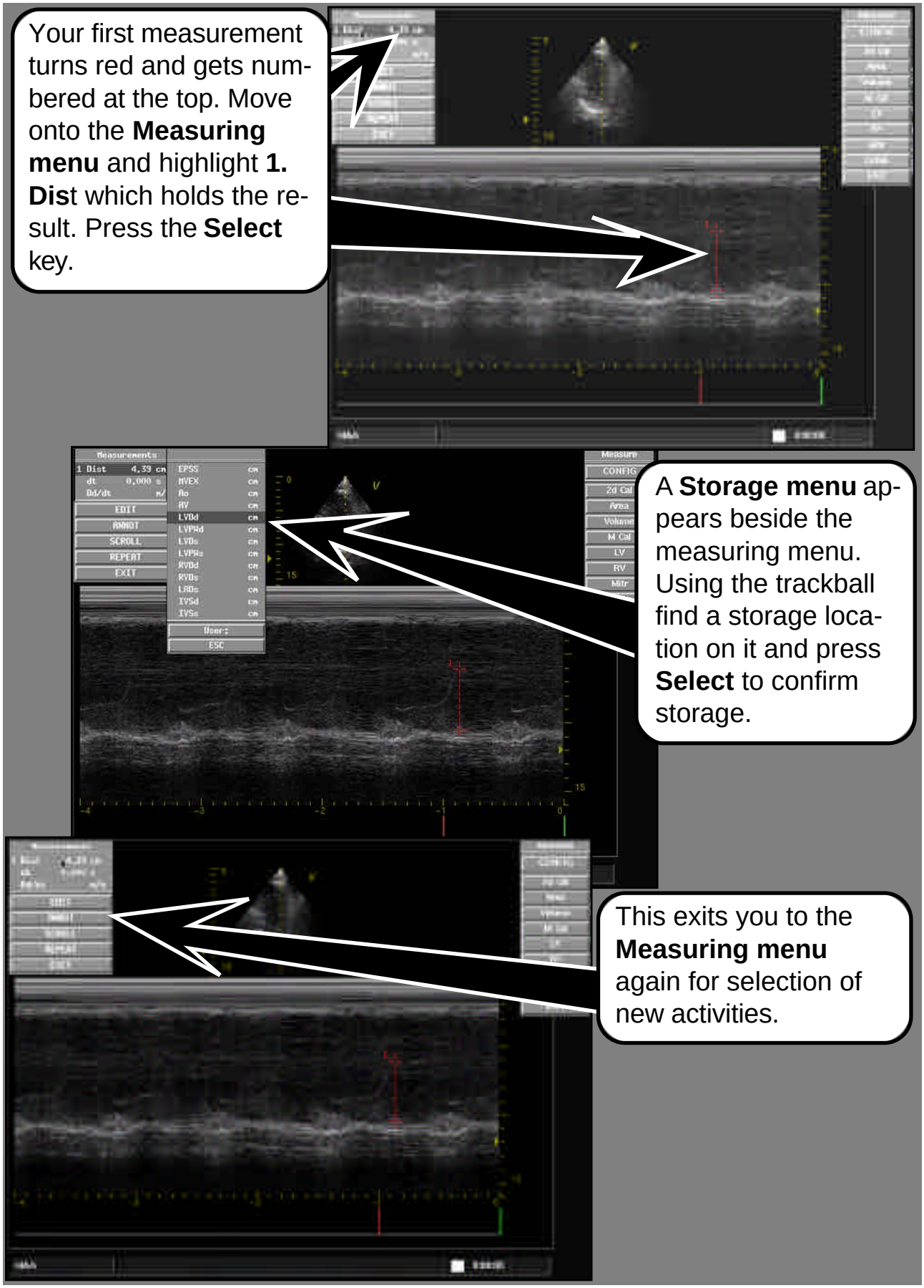
M&A examples

Draw the first distance measurement



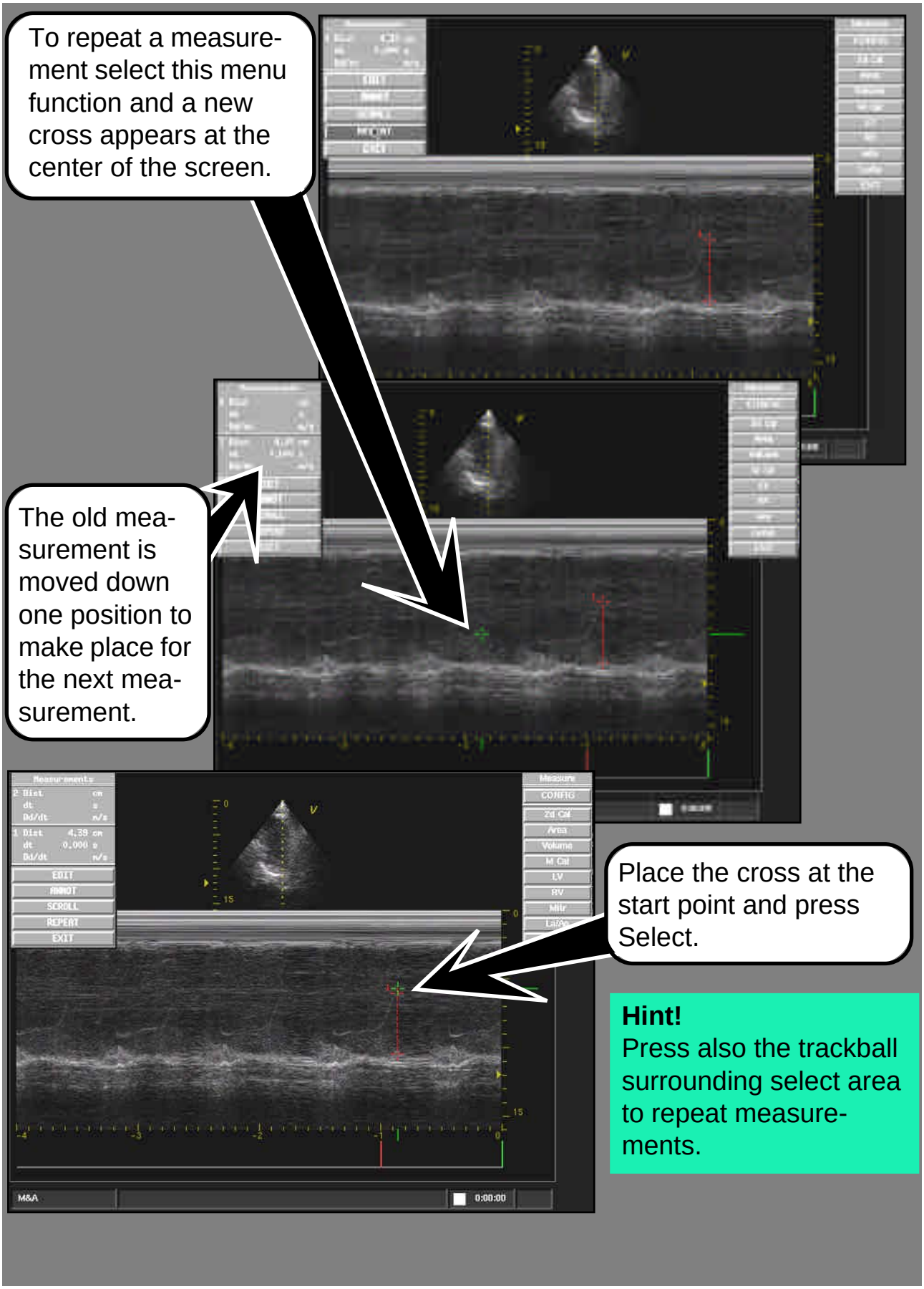
M&A examples

Store measurement number one



M&A examples

Repeat a measurement

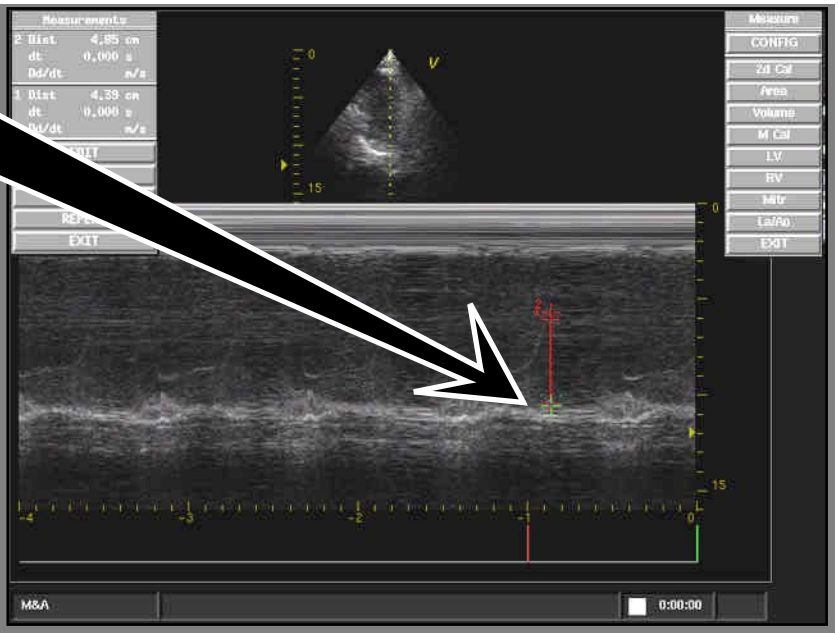


Hint!
Press also the trackball surrounding select area to repeat measurements.

M&A examples

Store the repeated measurement

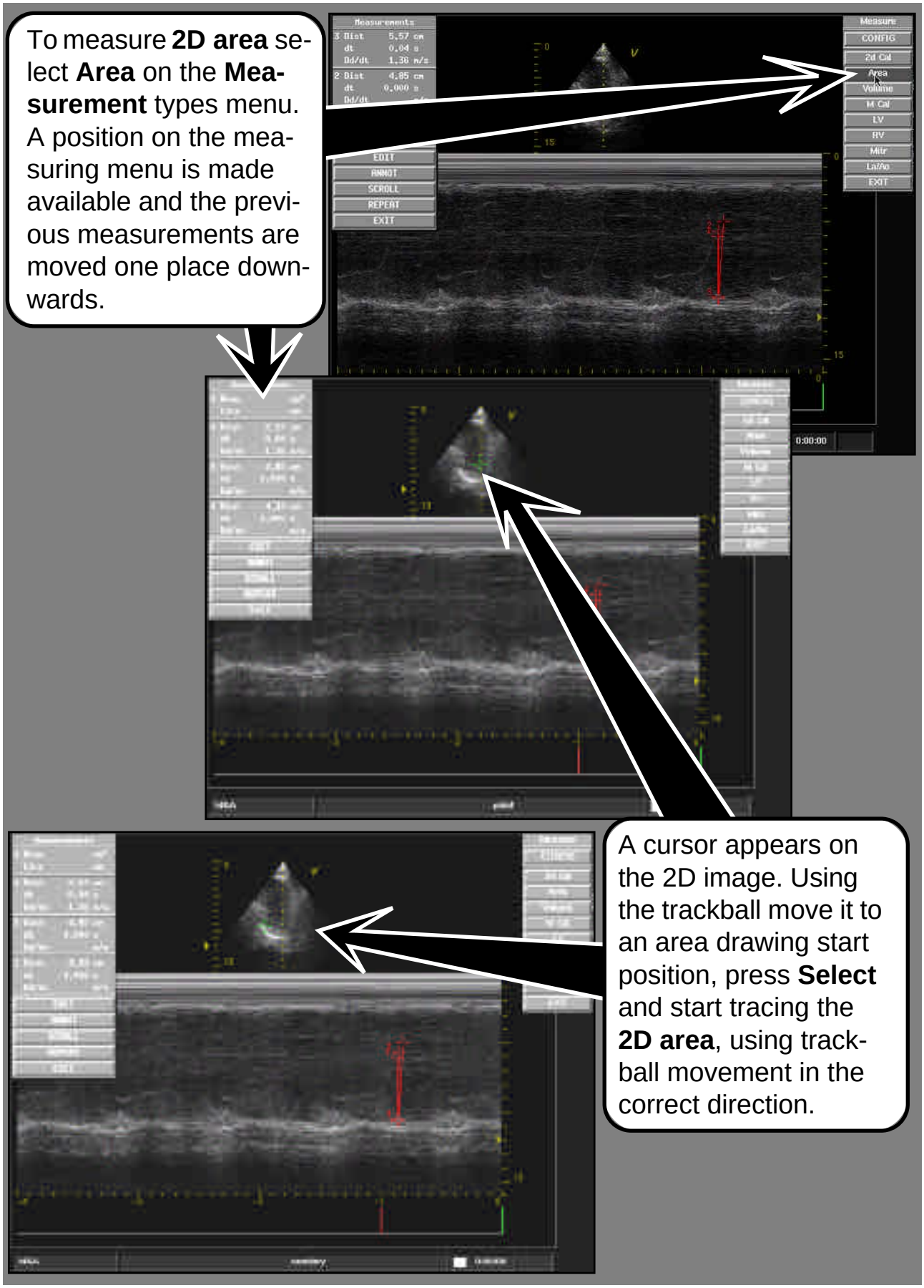
As you arrive at the end point of your second measurement press the trackball**Select** area.



The result is available on the **Measuring menu**. Store it as described previously.

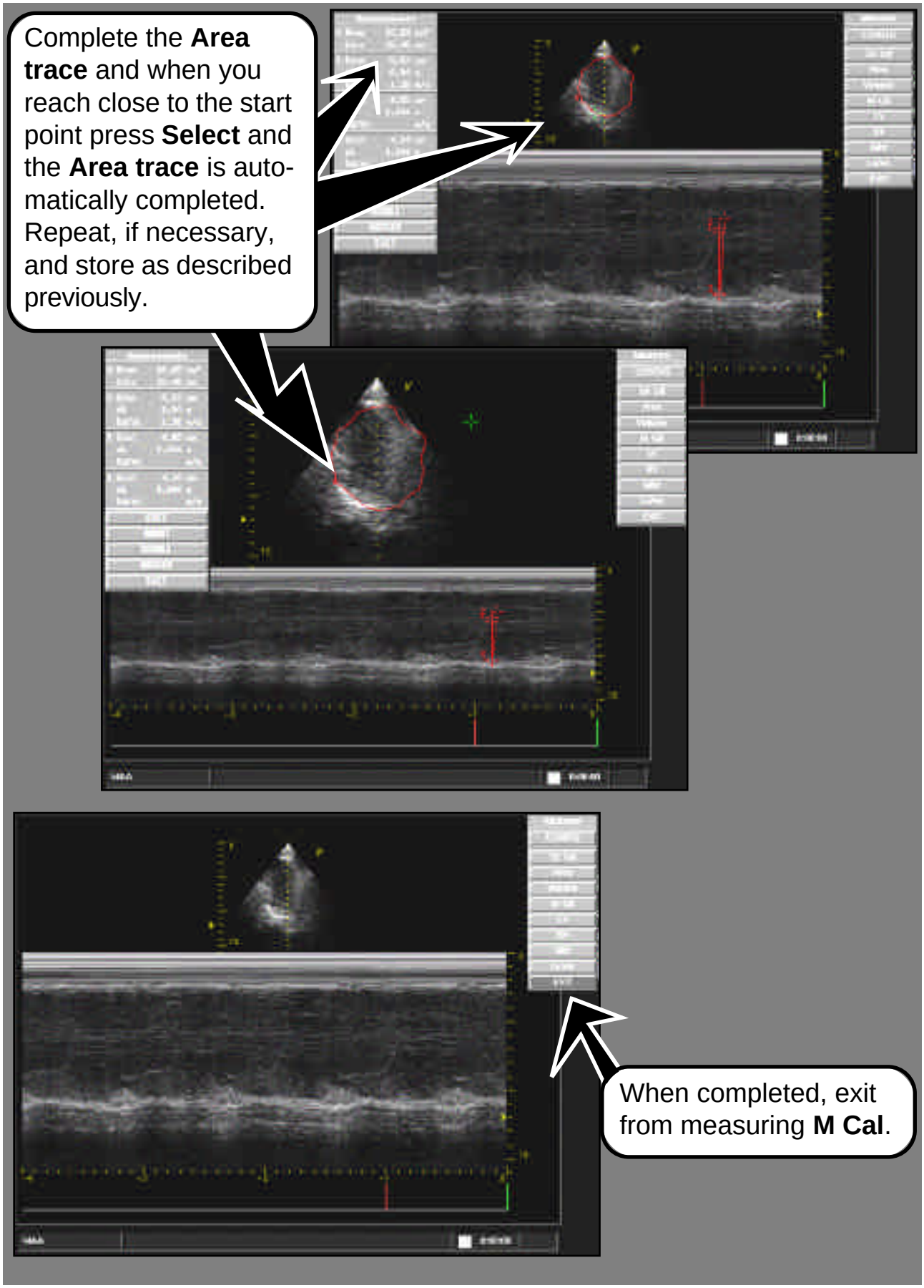
M&A examples

Measure 2D Area in duplex M-Mode



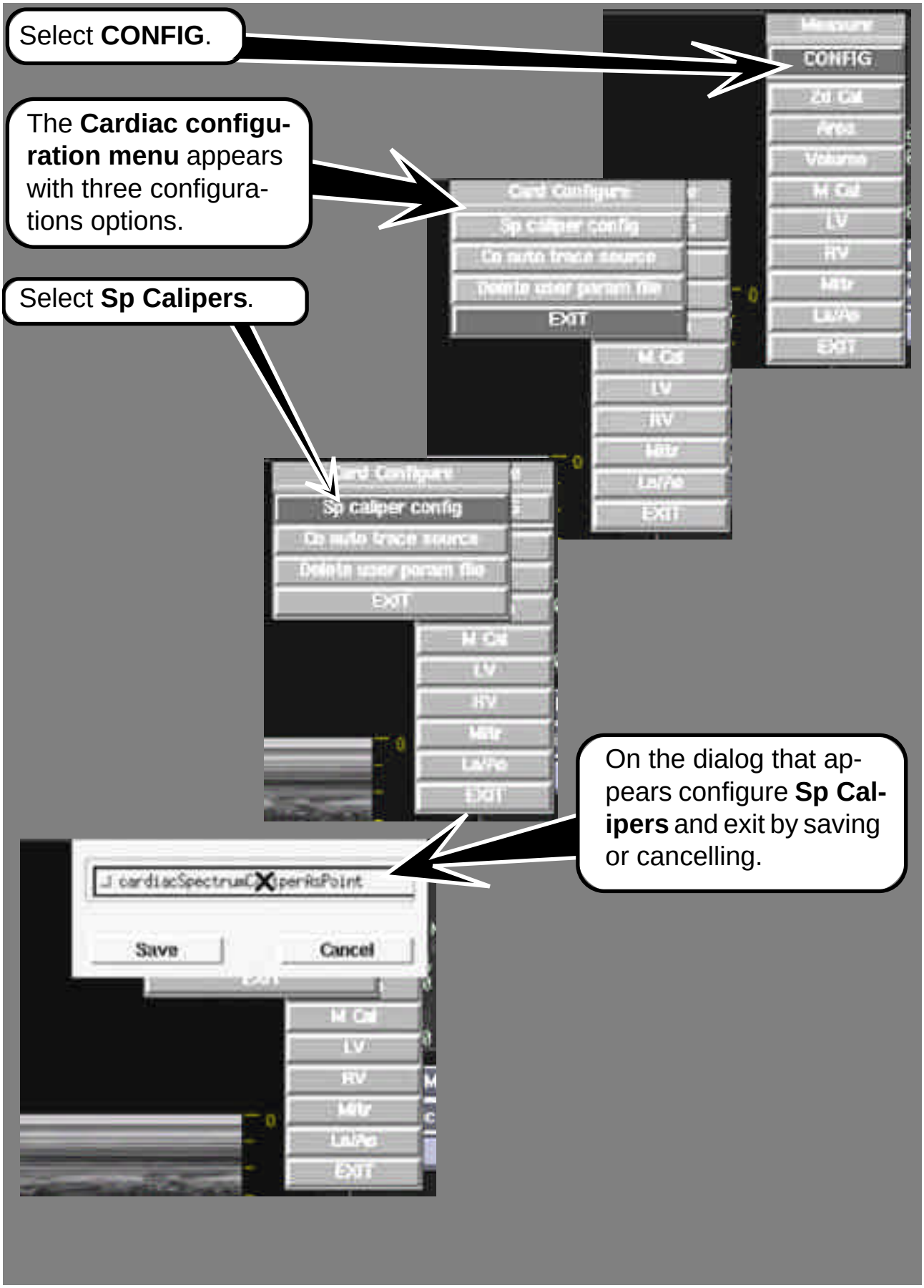
M&A examples

Complete and store 2D area measurements



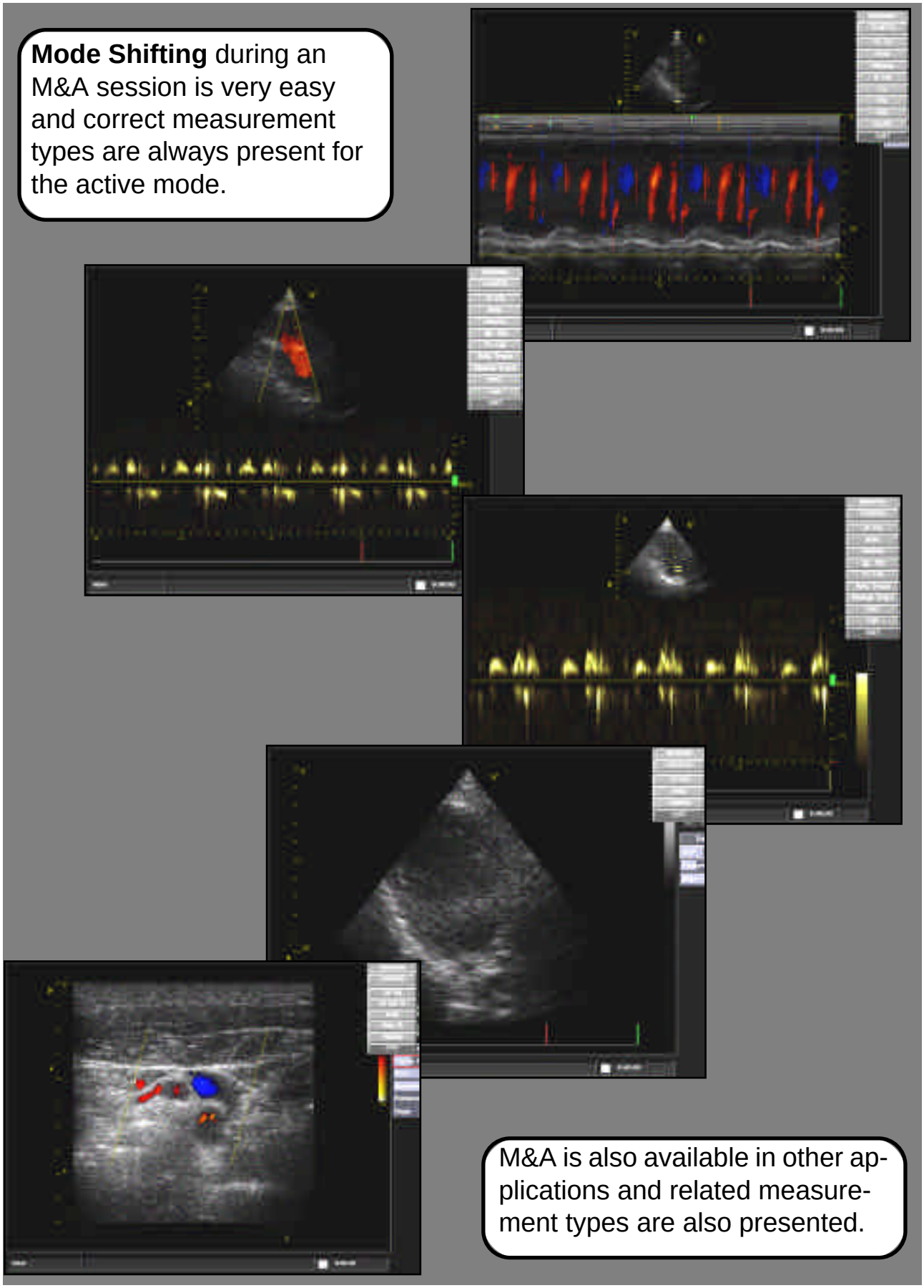
M&A examples

Cardiac M&A Configuration



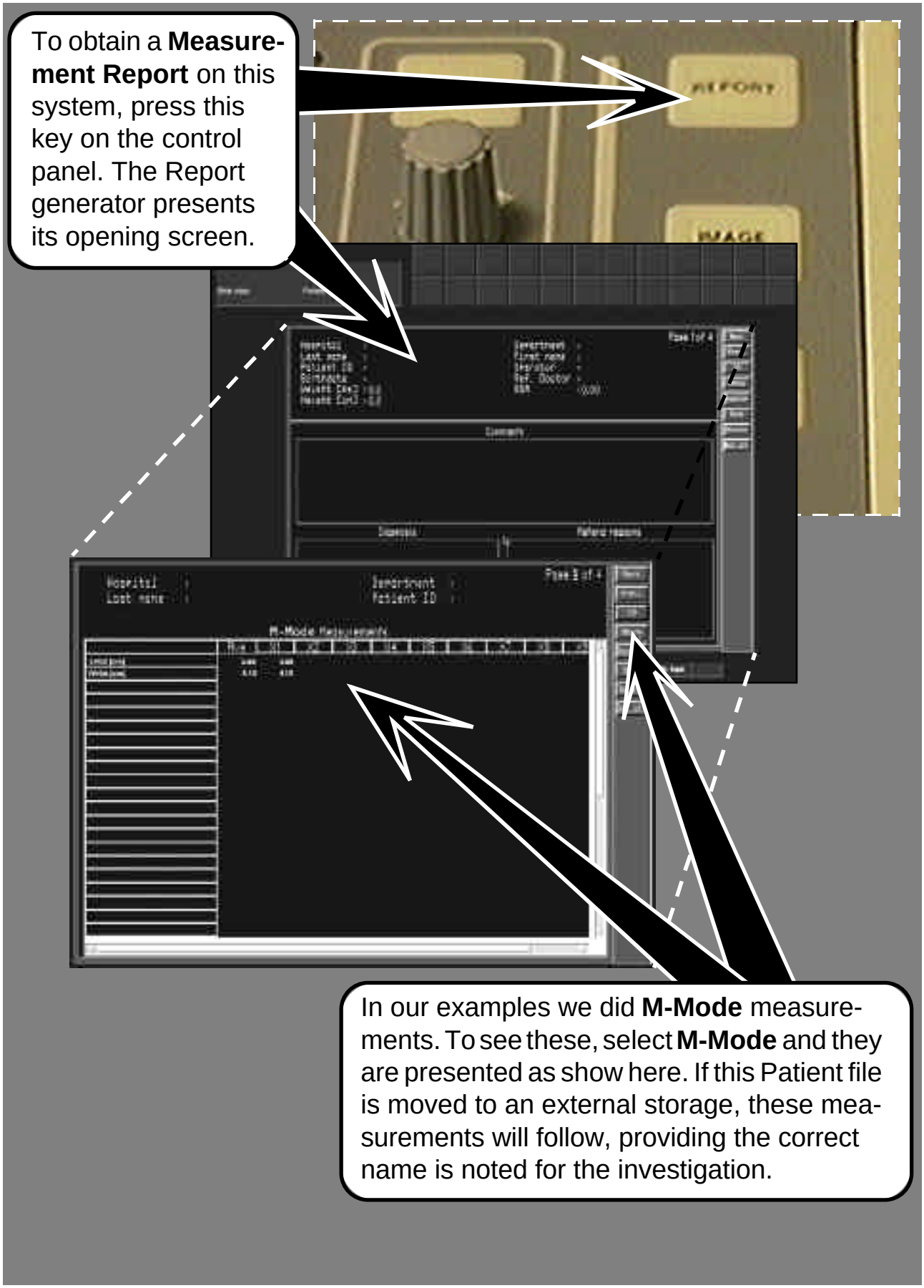
M&A examples

Mode shifting during M&A



M&A examples

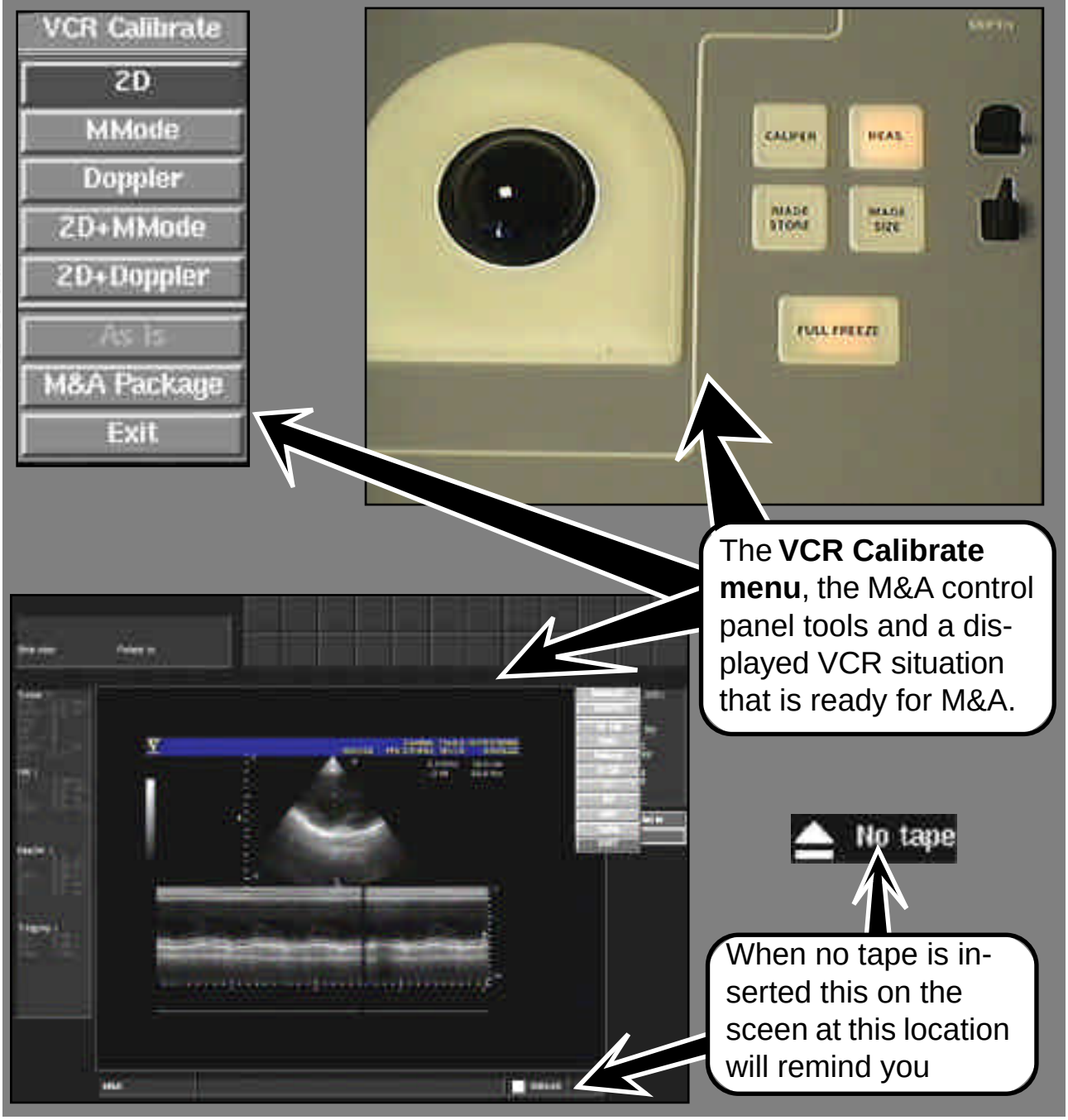
Report



VCR M&A

About VCR M&A

On System FiVe you can do M&A on VCR recorded scan data from single or duplex modes. You are automatically asked to calibrate VCR scan data from single or duplex modes. You can choose to use existing calibrations from single or duplex modes. The M&A Function, when used on VCR data, is always related to the systems active probe and selected application and not the ones that were used during this particular vcr recording. You may however change application and gain access to the measurement types that you intended to use.



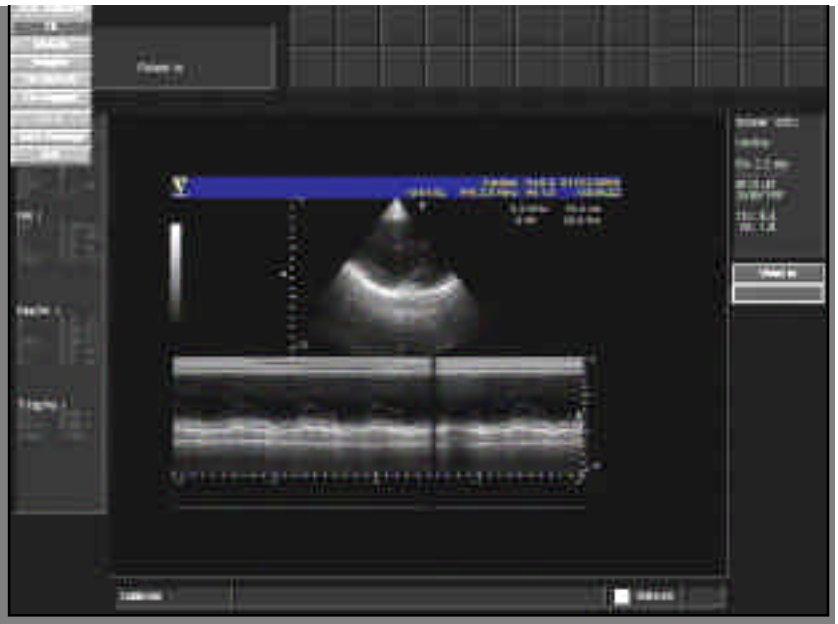
The **VCR Calibrate menu**, the M&A control panel tools and a displayed VCR situation that is ready for M&A.

When no tape is inserted this on the sceen at this location will remind you

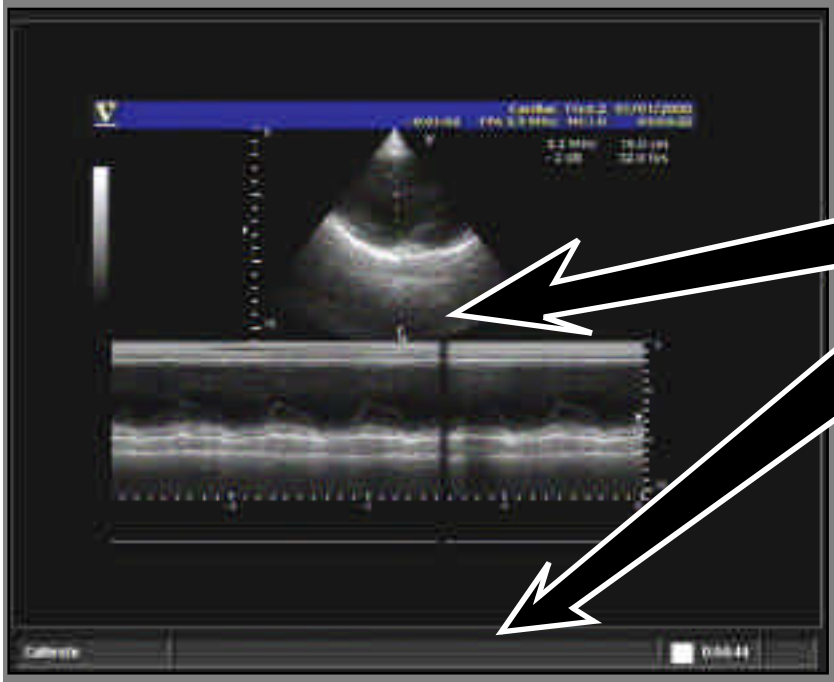
VCR M&A

2D VCR Calibrate

After initiating a video replay of VCR recorded data, press the **MEAS**., or **Calipers** key on the control panel.



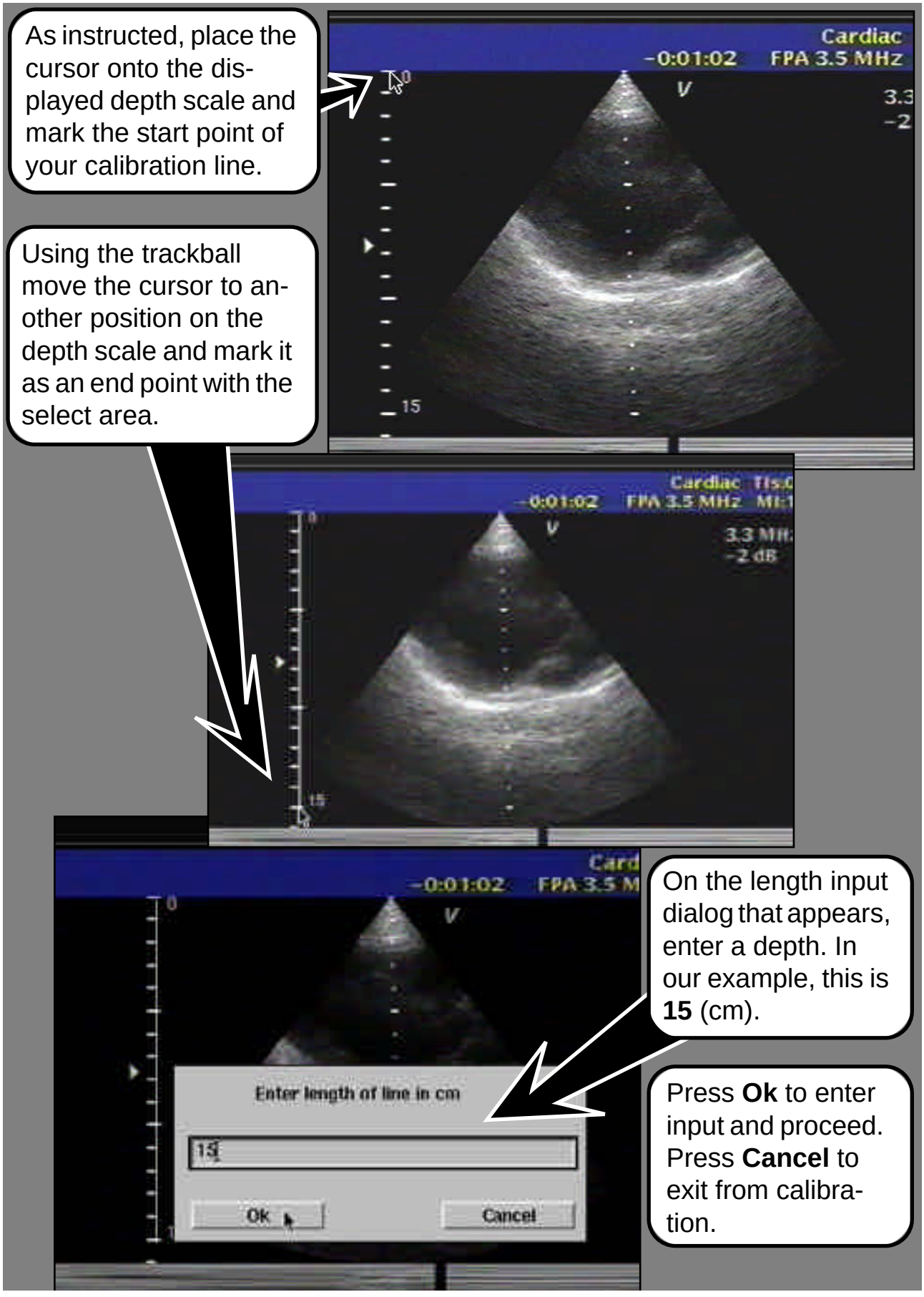
On the **VCR Calibrate** menu select the **2D** position with the Trackball and the Select area surrounding it.



The menu is removed, a cursor appears on the 2D situation and what to do next is continually updated at this location, as you proceed.

VCR M&A

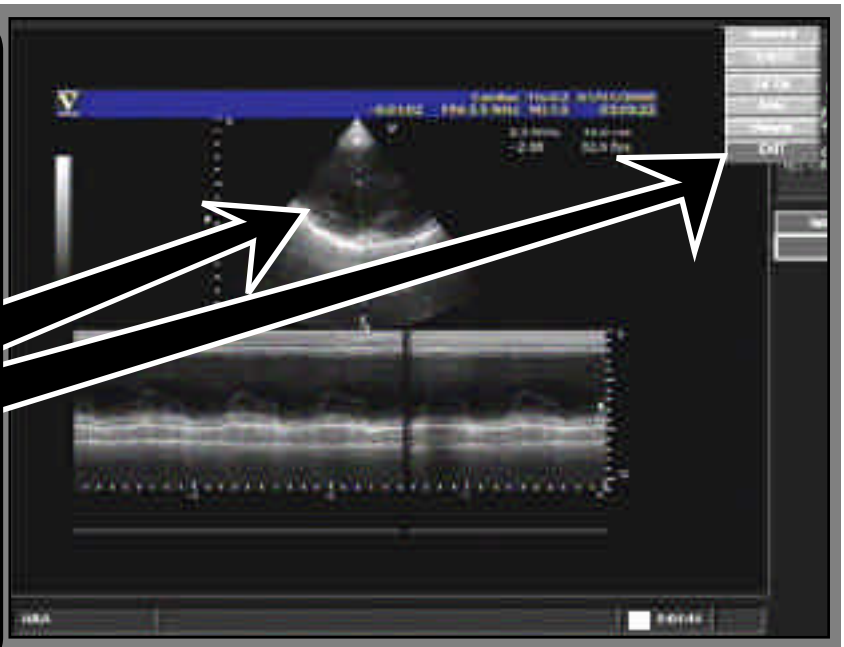
Enter the 2D calibration data



VCR M&A

Ready for 2D M&A

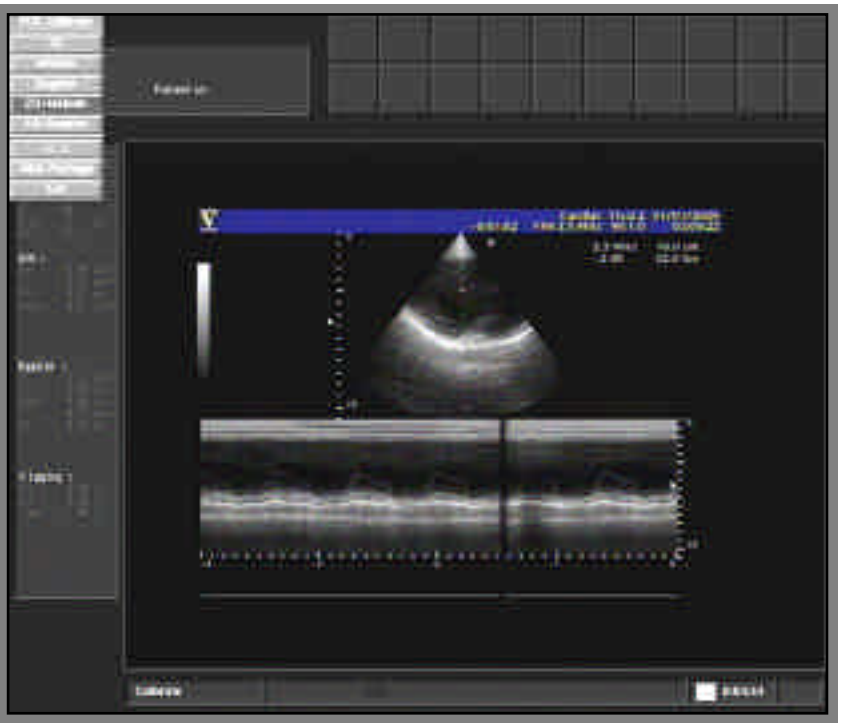
The **Ok** input leads you to proceed with M&A using the measurement types that are forwarded by the system. If the application and displayed measurement types are wrong for the displayed data, recall the **VCR Calibrate** menu, select **M&A Package** and proceed as described on **page D1-151**.

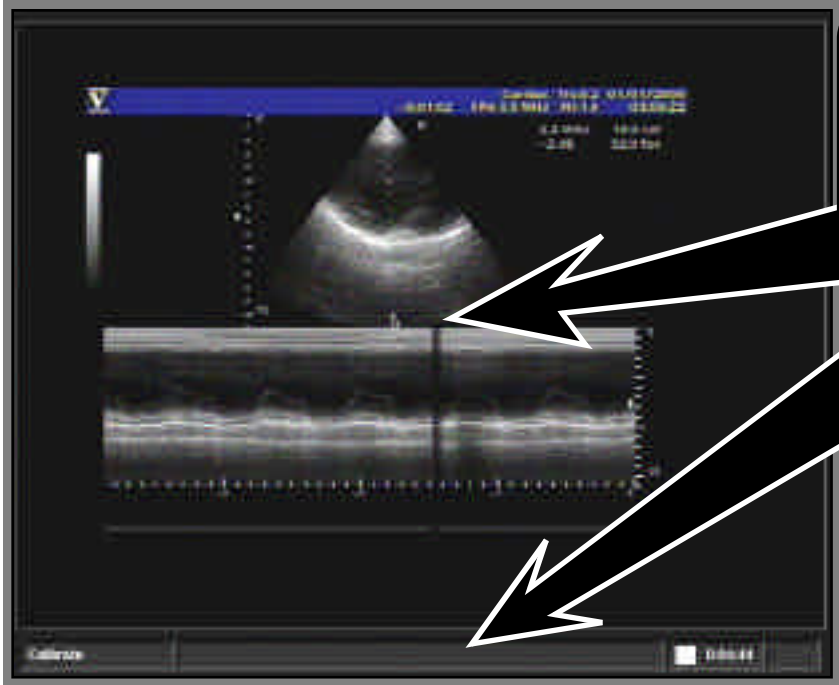


VCR M&A

2D/M-Mode calibration

In Duplex mode calibration, which in our example is **2D/M-Mode**, select either **2D/M-Mode** or **2D/Doppler** on the menu.

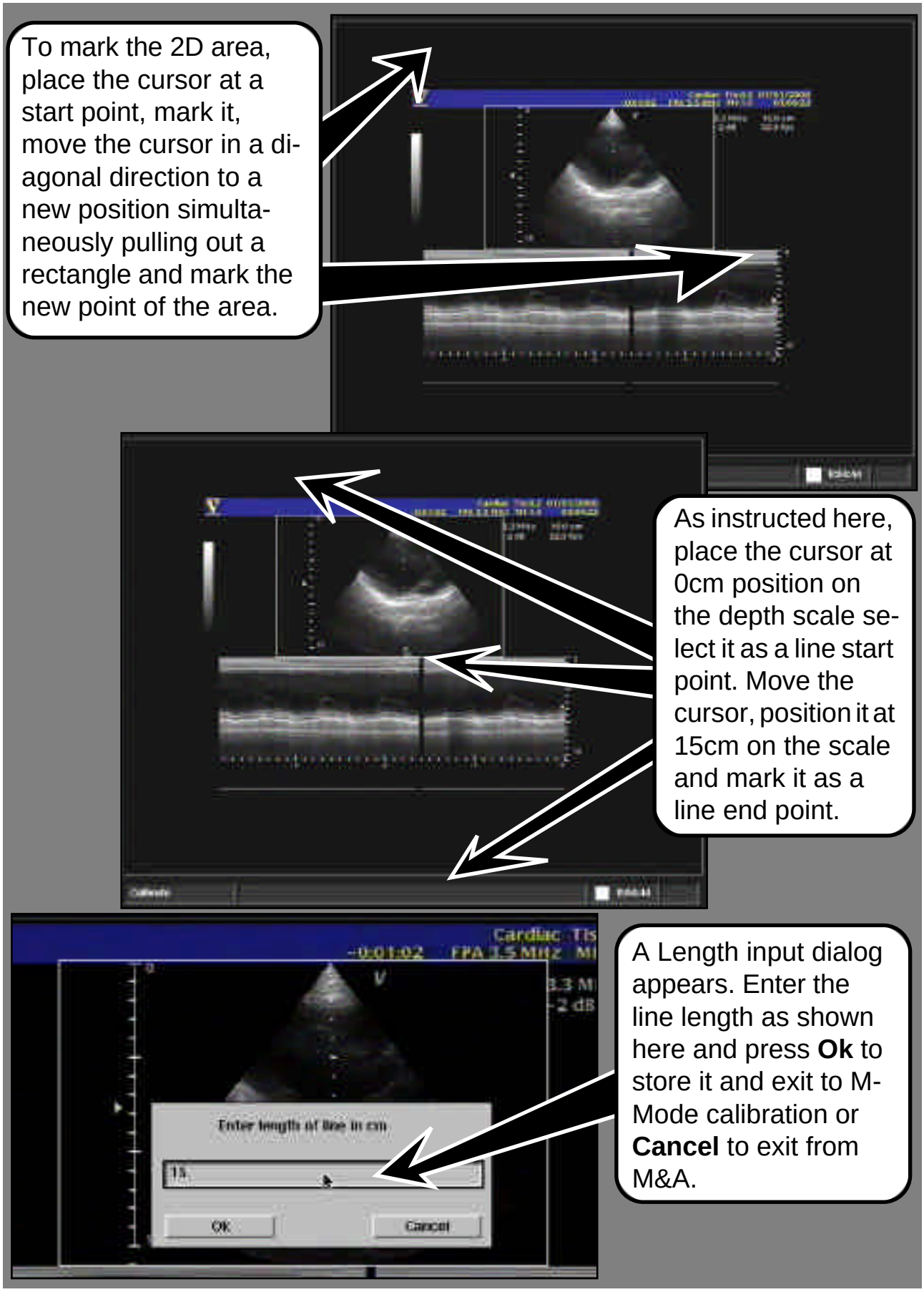




The system cursor appears once again on the 2D part of the scene and the system asks you to use it to draw a rectangle to mark the 2D area.

VCR M&A

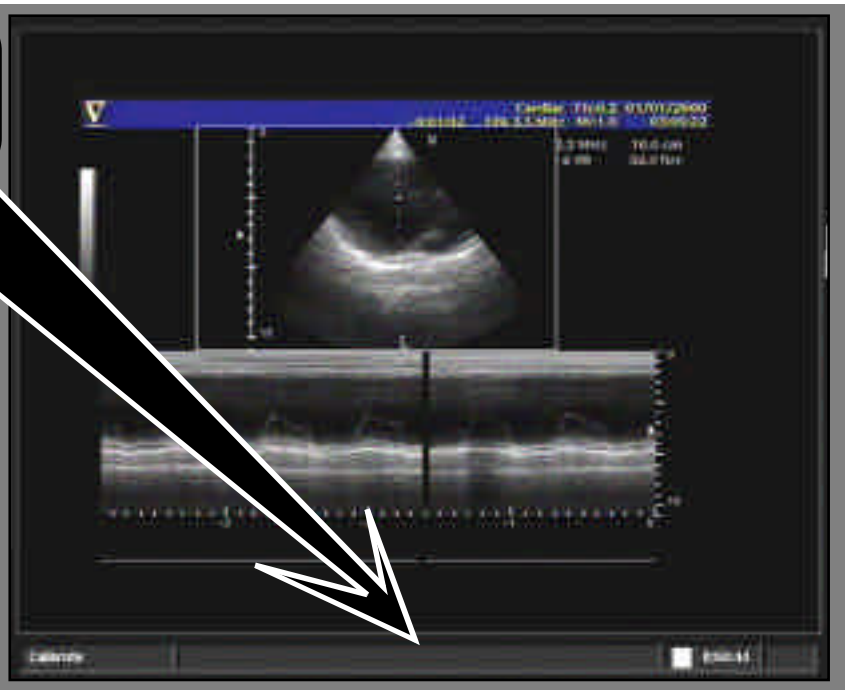
Calibrate the 2D area

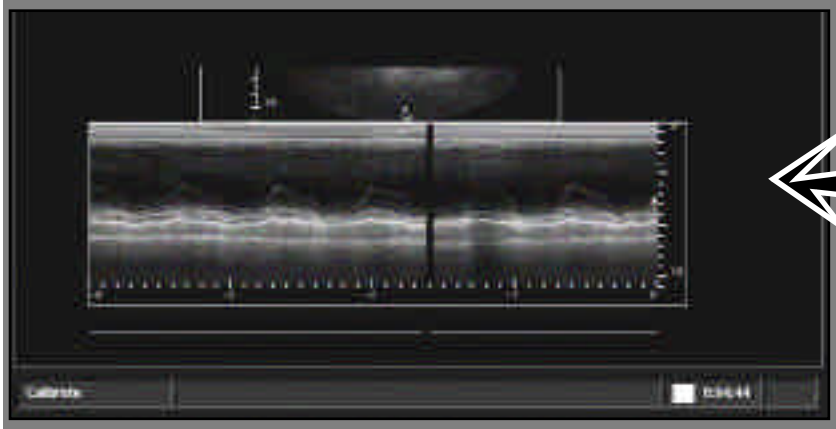


VCR M&A

Mark the M-Mode area

When **2D** sector is calibrated you are asked to mark the **M-Mode area**.



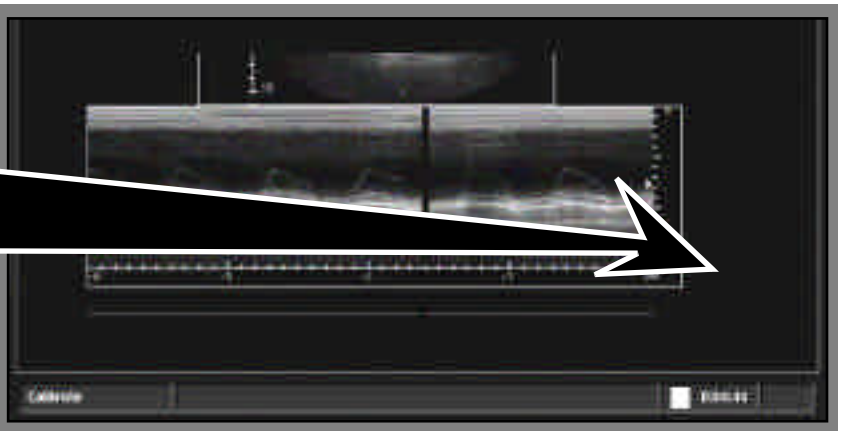


Do this in the exact same manner as described for marking the **2D area** and end up with a rectangle that resembles this.

VCR M&A

Calibrate the M-Mode area Time scale

The next step is to calibrate the M-Mode time lapse. To do this place the cursor onto 0 secs and press select. Move the cursor onto 4 secs mark and press select again. A white line is now drawn along the time scale.

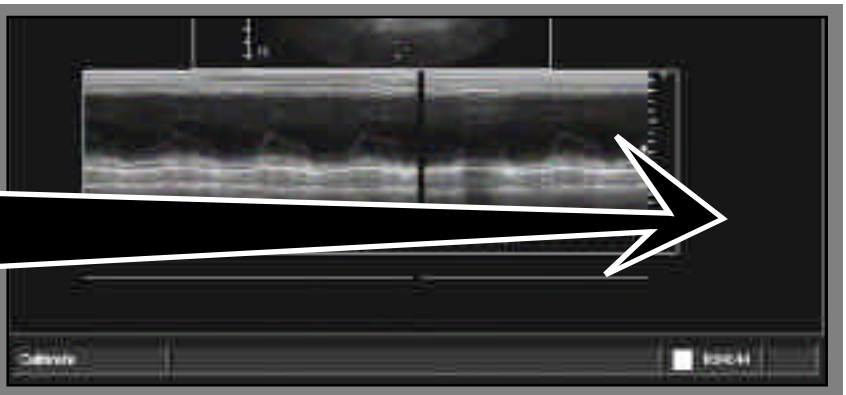


The seconds entry dialog appears for you to enter the specific number.

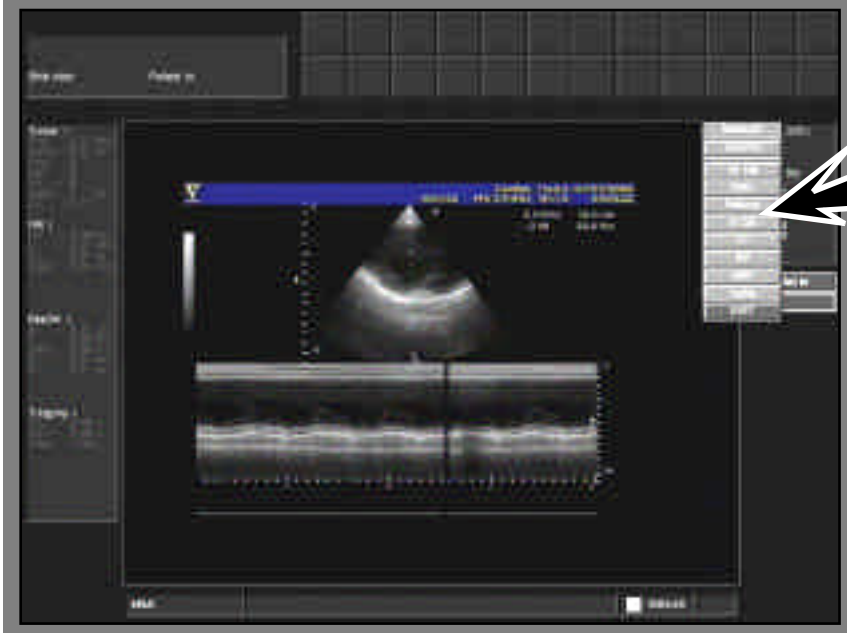
VCR M&A

Calibrate the M-Mode area depth scale

Once more you are asked to measure depth but this time it concerns the M/Mode view. So place the cursor on 0cm marker and press select. Repeat this at the 15cm marker.



On the entry dialog enter **15** and select **Ok** to do M&A or **Cancel** to exit.



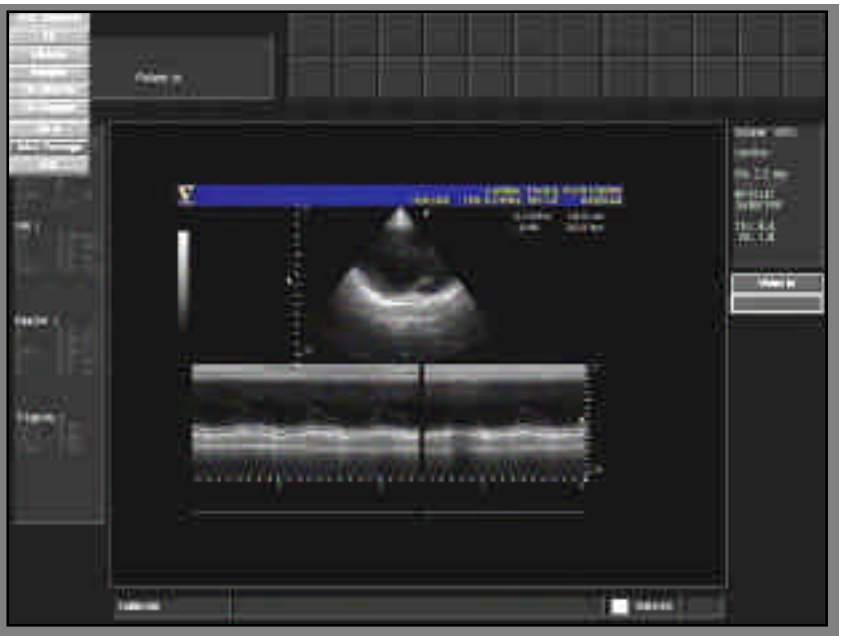
The M&A options for in this case **2D/M-Mode** are displayed and you can continue.

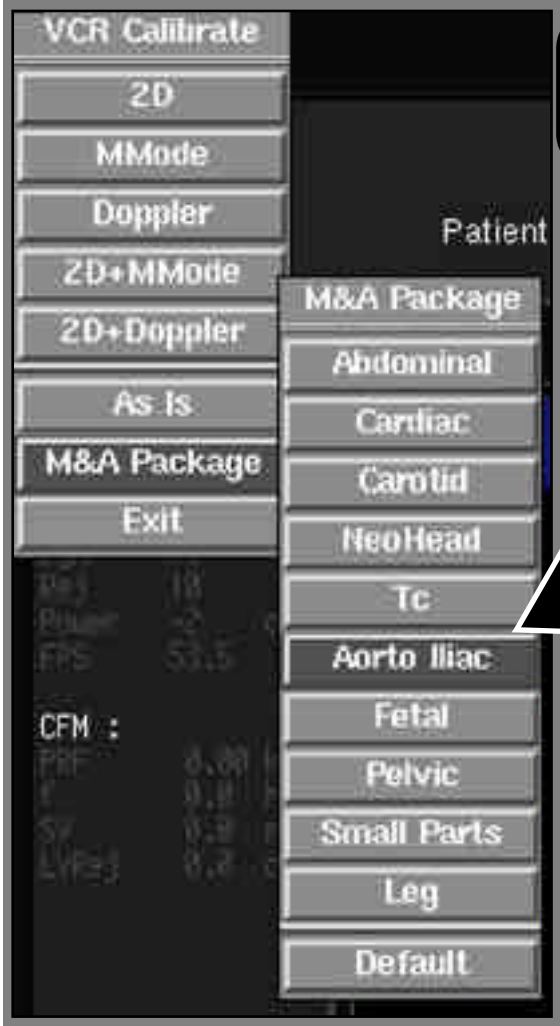
Hint!
Autotrace is not available in VCR M&A.

VCR M&A

M&A Package for application change

To change application in VCR M&A, click-select **M&A Package** on the **VCR Calibrate** menu.

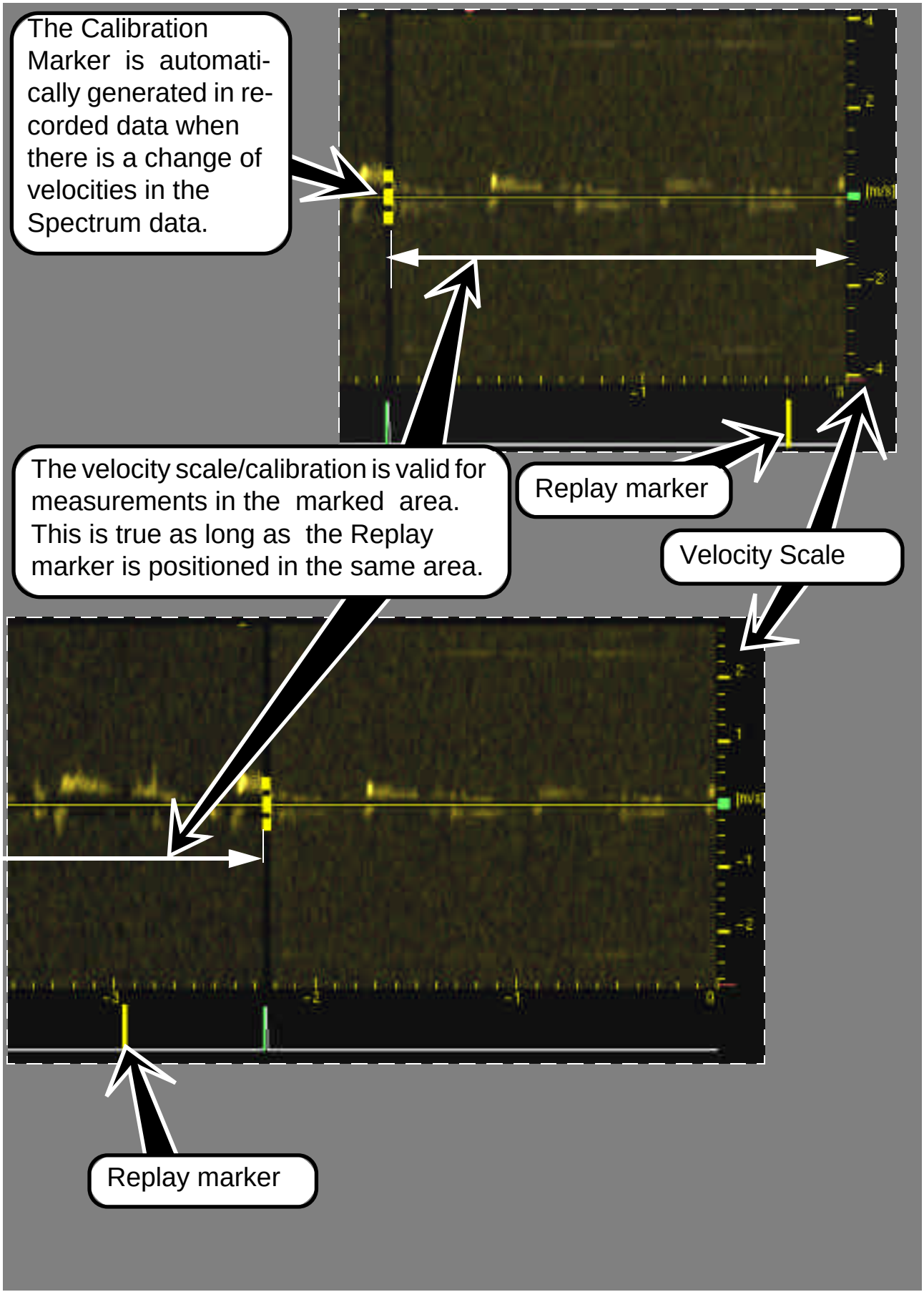




On this input the system presents a set of applications. Highlight and select one that suits your displayed VCR recorded data.

VCR M&A

The Calibration Marker



Cardiac Acquisition Formulas

In addition to the parameters that are directly measured by a user, the System FiVe has a number of Formulas which are automatically calculated as soon as all of the parameters in the Formulas have been assigned. The labels in the formulas below, are the same as the labels listed in the parameter menus for assignment.

Body Surface Area

$$\mathbf{BSA}[m^2] = 0.007184 \times (Height[cm]^{0.725}) \times (Weight[kg]^{0.425})$$ (Patient Browser Entry)

BSA

$$Basedonweight = (\sqrt[3]{Weight}[kg])^2 \cdot 0.1$$

(Patient Browser Entry)

2D - measurements

Volume

Volume by length-area $[cm^3] = \frac{8 \times (Area[cm^2])^2}{3 \times \Pi \times Dist[cm]}$

Volume by Simpson $[cm^3] = \sum_{1}^{20} \frac{\Pi \times h[cm] \times D[cm]^2}{4}$

When calculating volume by Simpson, the Volume is sliced up in 20 slices perpendicular to the long-axis. The h in the formula is the thickness of the slice, and D is the diameter.

Left Ventricular study

2D-Left Ventricular Ejection Fraction =

$$\frac{LeftVentricularVolumeEndDiastole[cm^3] - LeftVentricularVolumeEndSystole[cm^3]}{LeftVentricularVolumeEndDiastole[cm^3]}$$

Cardiac Acquisition Formulas

LV Mass

$$a1 = LeftVentricleEpcardialArea$$

$$a2 = LeftVentricleEndocardialArea$$

$$b = \sqrt{\frac{a2}{\pi}} \qquad t = \sqrt{\frac{a1}{\pi}} - b$$

$$DLVMass = 1.05 \times \frac{5}{6}[\{a1 \times (LeftVentricalEndocardialLength + t)\} - \{a2 \times LeftVentricaleEndocardialLength\}]$$

M - Mode measurements

Left Ventricular-study

M-Mode Left Ventricular Ejection Fraction =

$$\frac{LeftVentricularDiameterEndDiastole[cm]^3 - (LeftVentricularDiameterEndSystole[cm])^3}{LeftVentricularDiameterEndDiastole[cm]^3}$$

Fractional Shortening[%] =

$$100 \times \frac{LeftVentricularDiameterEndDiastole[cm] - LeftVentricularDiameterEndSystole[cm]}{LeftVentricularDiameterEndDiastole[cm]}$$

LV MASS

$$LVMass = 1.04x((IVSd + LVPWd + LVDd)^3 - LVDd^3) - 13.6$$

(Report)

LA/AO ratio = $\frac{LeftAtrialDiameterEndSystole[cm]}{AorticDimensionEndDiastole[cm]}$ (Report)

E/A ratio =

$$\frac{MVe(Evelocity)[m/s]}{MVa(Avelocity)[m/s]}$$

Cardiac Acquisition Formulas

Teich holz:

$$EDVtz[cm^3] = \frac{7.0}{2.4 + LVDd[cm]} \cdot LVDd^3$$

$$ESVtz[cm^3] = \frac{7.0}{2.4 + LVDs[cm]} \cdot LVDs[cm]^3$$

$$SVtz[cm^3] = EDVtz - ESVtz$$

$$EFtz = \frac{ESVtz}{EDVtz}$$

$$COtz = SVtz \cdot HR$$

Doppler Spectrum measurements

Calipers

The pressure is calculated as follows:

$$\text{P[mmHg]} = 4 \times V\left[\frac{m}{s}\right]^2$$

Cardiac Output

$$\text{Pmax[mmHg]} = 4 \times Vmax\left[\frac{m}{s}\right]^2 .$$

$$\text{Vmean}\left[\frac{m}{s}\right] = \frac{1}{TimeOfEnvelope[s]} \times \int_0^{TimeOfEnvelope[s]} V\left[\frac{m}{s}\right] dt$$

$$\text{Pmean[mmHg]} = \frac{1}{TimeOfEnvelope[s]} \times \int_0^{TimeOfEnvelope[s]} 4 \times v\left[\frac{m}{s}\right]^2 dt$$

$$\text{Velocity Trace Integral } [cm] = \int_0^{TimeOfEnvelope[s]} V\left[\frac{m}{s}\right] dt$$

$$\text{Heart Rate[BPM]} = \frac{60}{TimeBetweenBeats[s]}$$

$$\text{Cardiac Output}\left[\frac{l}{min}\right] = 6 \times \Pi \times \left(\frac{Diameter[cm]}{2}\right)^2 \times Vavg\left[\frac{m}{s}\right]$$

where Vavg = vti/TBB (vti i [m])

Cardiac Acquisition Formulas

Shunt Ratio:

$$ShuntRatio = \frac{PVvti \cdot (\pi \cdot (PA/2)^2}{AVvti \cdot \pi \cdot (Ao/2)^2}$$

Pressure Half Time

Pressure Half Time is calculated automatically.

PHT[s] = time to reach $\frac{1}{\sqrt{2} \times Vmax\left[\frac{m}{s}\right]}$

Mitral Valve Area $[cm^2]$ = $\frac{0.22}{MitralValvePressureHalfTime[s]}$

Mitral Valve Area By Continuity Equation $[cm^2]$ =

$$\Pi \times \left(\frac{LeftVentrOutflowTractDiam[cm]}{2}\right)^2 \times \frac{LeftVentOutflowTractVelocityTraceIntegral[cm]}{MitralValveVelocityTimeIntegral[cm]}$$

(Report)

Aortic Valve Area By Continuity Equation $[cm^2]$ =

$$\Pi \times \left(\frac{LeftVentrOutflowTractDiam[cm]}{2}\right)^2 \times \frac{LeftVentrOutflowTractVelocityTraceIntegral[cm]}{AorticValveVelocityTimeIntegral[cm]}$$

(Report)

Aortic Valve Area From Vmax $[cm^2]$ =

$$\Pi \times \left(\frac{LeftVentrOutflowTractDiam[cm]}{2}\right)^2 \times \frac{LeftVentrOutflowTractPeakVelocity\left[\frac{m}{s}\right]}{AorticValvePeakVelocity\left[\frac{m}{s}\right]}$$

(Report)

Cardiac Acquisition Parameters

Mitral Valve

Name	Label	Unit	Description	Mode
MVVMX	MV	m/s	Mitral Valve Peak Velocity	
MVVME	MVmn	m/s	Mitral Valve Mean Velocity	
MVVR	MR	m/s	Mitral Valve Regurgitant Velocity	
MVVMER	MRmn	m/s	Mitral Valve Mean Regurg. Velocity	
MVACF	MV	m/s2	Mitral Valve Flow Acceleration	
MVPMX	MV	mmHg	Mitral Valve Peak Pressure	
MVPME	MVmn	mmHg	Mitral Valve Mean Pressure	
MVPR	MRp	mmHg	Mitral Valve Regurgitant Pressure	
MVPMER	MRpmn	mmHg	Mitral Valve Mean Regurg. Pressure	
SMVA	MVA	cm^2	Mitral Valve Area (from Spectrum)	
2MVA	MVA	cm^2	Mitral Valve Area (from 2d)	
MVAVTI	MVAvti	cm^2	Mitral Valve Area (from VTI)	
MVPHT	MVpht	ms	Mitral Valve Pressure Halftime	
MVVTI	MVvti	cm	Mitral Valve Velocity Time Integral	
MVCO	MV	l/min	Mitral Valve Cardiac Output	
MVTTP	MVtpk	sec	Mitral Valve Time To Peak	
MVDSE	EPSS	cm	Mitral Valve S-E distance	
MVE	MVEX	cm	Mitral Valve Excursion	
MVSEF	MVe-f	cm/s	Mitral Valve E-F Slope	
MVD	MV	cm	Mitral Valve Diameter	

Tricuspid Valve

Name	Label	Unit	Description	Mode
TVVMX	TV	m/s	Tricuspid Valve Peak Velocity	
TVVME	TVmn	m/s	Tricuspid Valve Mean Velocity	
TVVR	TR	m/s	Tricuspid Valve Regurgitant Velocity	
TVVMER	TRmn	m/s	Tricuspid Valve Mean Regurg. Velocity	
TVACF	TV	m/s2	Tricuspid Valve Flow Acceleration	
TVPMX	TV	mmHg	Tricuspid Valve Peak Pressure	
TVPME	TV	mmHg	Tricuspid Valve Mean Pressure	
TVPR	TRp	mmHg	Tricuspid Valve Regurgitant Pressure	
TVPMER	TRpmn	mmHg	Tricuspid Valve Mean Regurg. Pressure	
TVPHT	TVpht	ms	Tricusp Valve Pressure Halftime	
TVVTI	TVvti	cm	Tricuspid Valve Velocity Time Integral	
TVCO	TV	l/min	Tricuspid Valve Cardiac Output	
TVTTP	TVtpk	sec	Tricuspid Valve Time To Peak	
TVD	TV	cm	Tricuspid Valve Diameter	

Pulmonic Valve

Name	Label	Unit	Description	Mode
PVVMX	PV	m/s	Pulmonic Valve Peak Velocity	
PVVME	PVmn	m/s	Pulmonic Valve Mean Velocity	
PVVI	PI	m/s	Pulmonic Valve Insufficience Velocity	
PVVMER	PImn	m/s	Pulmonic Valve Mean Insufficience Velocity	
PVACF	PV	m/s^2	Pulmonic Valve Flow Acceleration	
PVPMX	PV	mmHg	Pulmonic Valve Peak Pressure	
PVPME	PVmn	mmHg	Pulmonic Valve Mean Pressure	
PVPI	PIp	mmHg	Pulmonic Valve Insufficience Pressure	
PVPMEI	PIpmn	mmHg	Pulmonic Valve Mean Insuff. Pressure	
PVVTI	PVvti	cm	Pulmonic Valve Velocity Time Integral	
PVCO	PV	l/min	Pulmonic Valve Cardiac Output	
PVTTP	PVtpk	sec	Pulmonic Valve Time To Peak	
PVD	PV	cm	Pulmonic Valve Diameter	

Aortic Valve

Name	Label	Unit	Description	Mode
AVVMX	AV	m/s	Aortic Valve Peak Velocity	
AVVME	AVmn	m/s	Aortic Valve Mean Velocity	
AVVI	AI	m/s	Aortic Valve Insuff. Velocity	
AVVMER	AImn	m/s	Aortic Valve Mean Insufficience Velocity	
AOPHTR	ARpht	ms	Aortic Valve Regurg. Pressure Halftime	
AVACF	AV	m/s^2	Aortic Valve Flow Acceleration	
AVPMX	AV	mmHg	Aortic Valve Peak Pressure	
AVPME	AVmn	mmHg	Aortic Valve Mean Pressure	
AVPI	AIp	mmHg	Aortic Valve Insuff. Pressure	
AVPMEI	AIpmn	mmHg	Aortic Valve Mean Insuff. Pressure	
AVVTI	AVvti	cm	Aortic Valve Velocity Time Integral	
AVCO	AV	l/min	Aortic Valve Cardiac Output	
AVTTP	AVtpk	sec	Aortic Valve Time To Peak	
MAVDED	Ao	cm	Aortic Dimension (ed) (from M-mode)	
2AVD	Ao	cm	Aortic Dimension (from 2d)	
MAVD	AV	cm	Aortic Valve Diameter (from M-mode)	
AVA	AVA	cm^2	Aortic Valve Area	
AVAVTI	AVAvti	cm	Aortic Valve Area (from VTI)	
AVAVMX	AVAvmx	cm	Aortic Valve Area (from Vmax)	

Left Ventricular

Name	Label	Unit	Description	Mode
LVOTVMX	LVOT	m/s	Left Ventricular Outflow Tract Peak Velocity	
LVOTD	LVOT	cm	Left Ventricular Outflow Tract Diameter	
LVOTVTI	LVOTvt	cm	Left Ventricular Outflow Tract Velocity Trace Integral	
LVOTVME	LVOTmn	m/s	Left Ventricular Outflow Tract Mean Velocity	
LVOTCO	LVOT	l/min	Left Ventricular Outflow Tract Cardiac Output	
LVOTPMX	LVOT	mmHg	LVOT Peak Pressure	
LVOTPME	LVOTmn	mmHg	LVOT Mean Pressure	

LVET	LVET	sec	Left Ventricular Ejection Time
MLVDED	LVDd	cm	Left Ventricular Diameter (ed) (from M-mode)
2LVDED	LVDd	cm	Left Ventricular Diameter (ed) (from 2d)
LVPWED	LVPWd	cm	Left Ventricular Posterior Wall (ed)
LVAED	LVAd	cm^2	Left Ventricular Area (ed)
LVAEN	LVAend	cm^2	Left Ventricular Area (endo) in LVmass(2d)
LVAEP	LVAepi	cm^2	Left Ventricular Area (epi) in LVmass(2d)
LVVED	LVVd	ml	Left Ventricular Volume (ed)
MLVDES	LVDs	cm	Left Ventricular Diameter (es) (from M-mode)
2LVDES	LVDs	cm	Left Ventricular Diameter (es) (from 2d)
LVVES	LVVs	ml	Left Ventricular Volume (es)
LVPWES	LVPWs	cm	Left Ventricular Posterior Wall (es)
LVAES	LVAs	cm^2	Left Ventricular Area (es)
LVPW	LVPW	cm	Left Ventricular Posterior Wall
2LVEF	LVEF		Left Ventricle Ejec Frac (from 2d)
MLVEF	LVEF		Left Ventricle Ejec Frac (from M-mode)
LVFS	%FS	%	Left Ventricle Fractional Shortening
LVM	LVmass	g	Left Ventricle Mass
2LVM	LVmass(AL)	g	Left Ventricle Mass 2D Area-Length Method
LVDEN	LVDend	cm	Left Ventricular Length (endo)(from2D)

Right Ventricular

Name	Label	Unit	Description	Mode
RVET	RVET	sec	Right Ventricular Ejection Time	
MRVDED	RVDd	cm	Right Ventricular Dimension (ed) (from M-mode)	
2RVDED	RVDd	cm	Right Ventricular Dimension (ed) (from 2d)	
RVVED	RVVd	ml	Right Ventricular Volume (ed)	
2RVDES	RVDs	cm	Right Ventricular Dimension (es) (from 2d)	
MRVDES	RVDs	cm	Right Ventricular Dimension (es) (from M-mode)	
RVVES	RVVs	ml	Right Ventricular Volume (es)	

Left Atrial

Name	Label	Unit	Description	Mode
LAD	LAD	cm	Left Atrial Dimension	
LADES	LADs	cm	Left Atrial Dimension (es)	
LAV	LAV	ml	Left Atrial Volume	

Right Atrial

Name	Label	Unit	Description	Mode
RAV R	AV	ml	Right Atrial Volume	

E/A

Name	Label	Unit	Description	Mode
MVVE	MVe	m/s	E Velocity in E/A	
MVVA	MVa	m/s	A Velocity in E/A	
IVRT	IVRT	[ms]	ISO Volumetric Relaxation Time	
MVTAC	aT	[ms]	Mitral Valve Acceleration Time	

MVTDC	DT	[ms]	Mitral Valve Deceleration Time
MVEAR	E/A		MVe/MVa Dimension Ratio

??

Name	Label	Unit	Description	Mode
TBB	Tb-b	sec	Time Between Heartbeats	
HR	HR	BPM	Heart Rate	

Inter Ventricular

Index	Name	Label	Unit	Description	Mode
IVSDED	IVSd	cm	Inter Ventricular Septum (ed) M-mode		
IVSDES	IVSs	cm	Inter Ventricular Septum (es) M-mode		
IVSD	IVS	cm	Inter Ventricular Septum 2D		
TQAV	AVq-o	sec	Time from Q-wave to Aortic Valve opens		
TQPV	PVq-o	sec	Time from Q-wave to Pulmonic Valve opens		

LA/AO

Name	Label	Unit	Description	Mode
LAAOR	LA/AO		LA/AO Dimension Ratio	

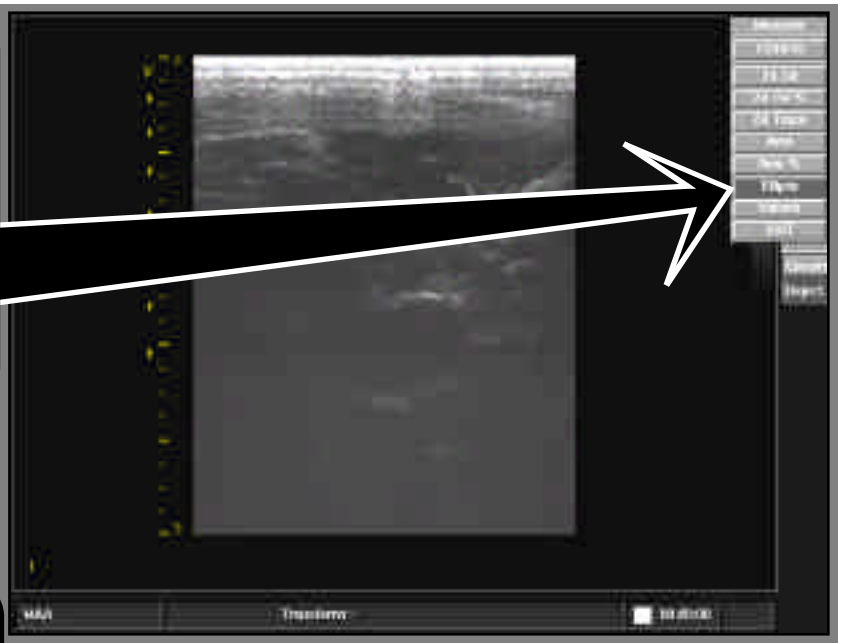
WEIGHT, HEIGHT, BSA (Pat. browser)

Name	Label	Unit	Description	Mode
WEIGHT	Weight	kg	Patient Weight	
HEIGHT	Height	cm	Patient Height	
BSA	B.S.A	m^2	Body Surface Area	

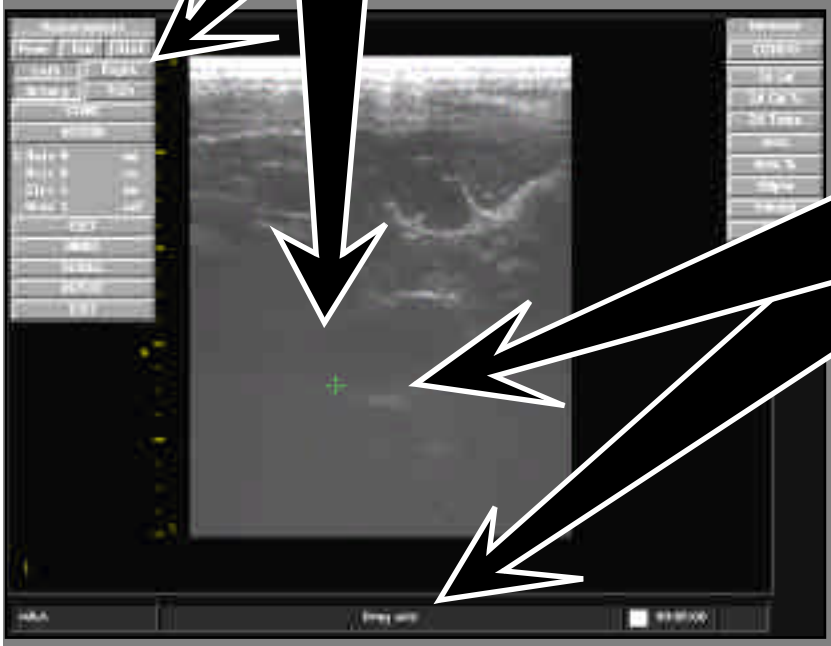
PV M&A:

Start Ellipse measuring

To start Ellipse measuring in PV M&A, when you have found a scan view of interest, press **FULL FREEZE** then **MEAS** and the measuring menu appears for you to select **Ellipse.**



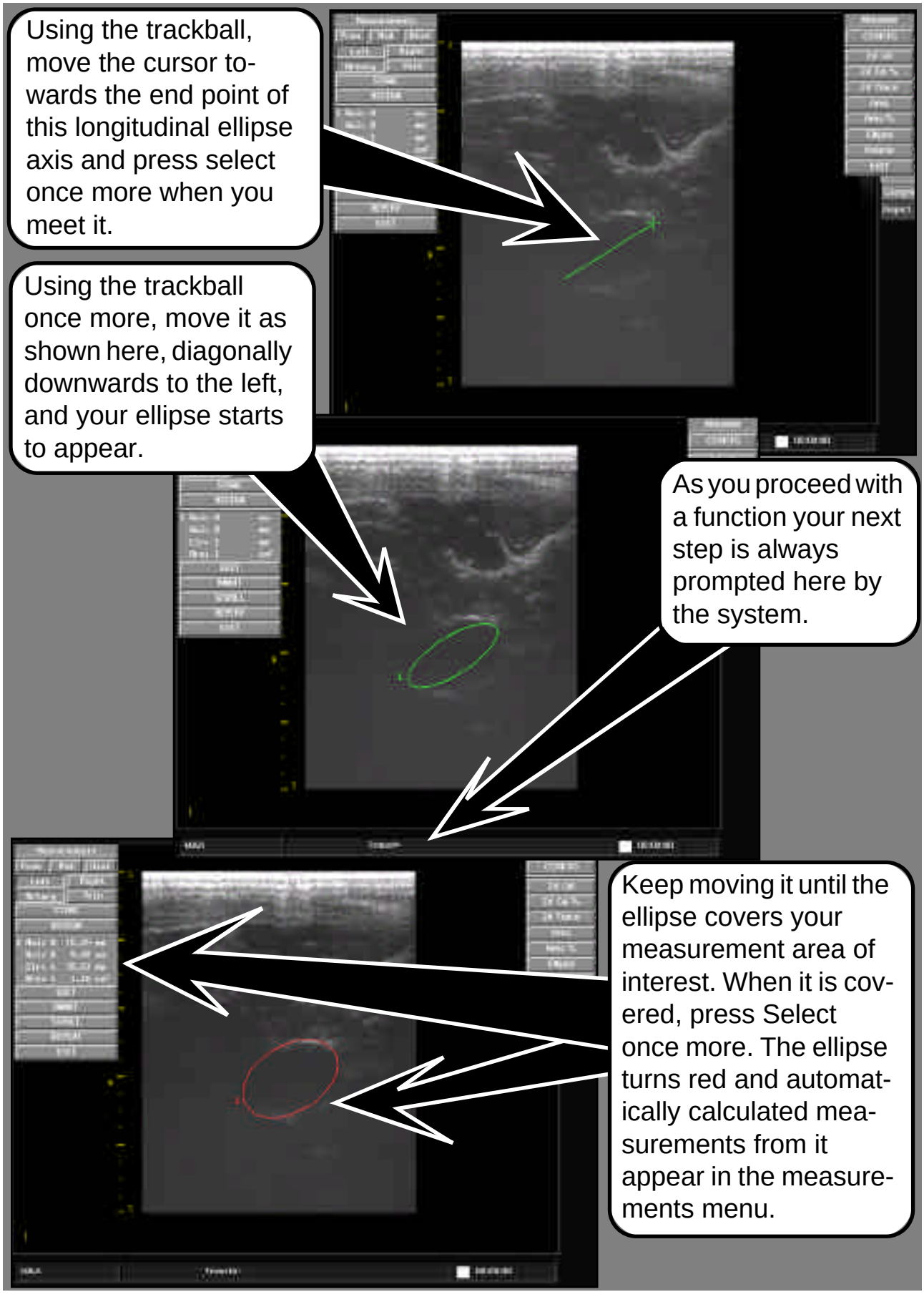
The Measurements menu, for the Ellipse measurement, appears, together with a green cursor, in the scan area.



Place the cursor at a position on your area of interest from where you can start drawing an ellipse axis and press Select to mark the start point of it.

PV M&A

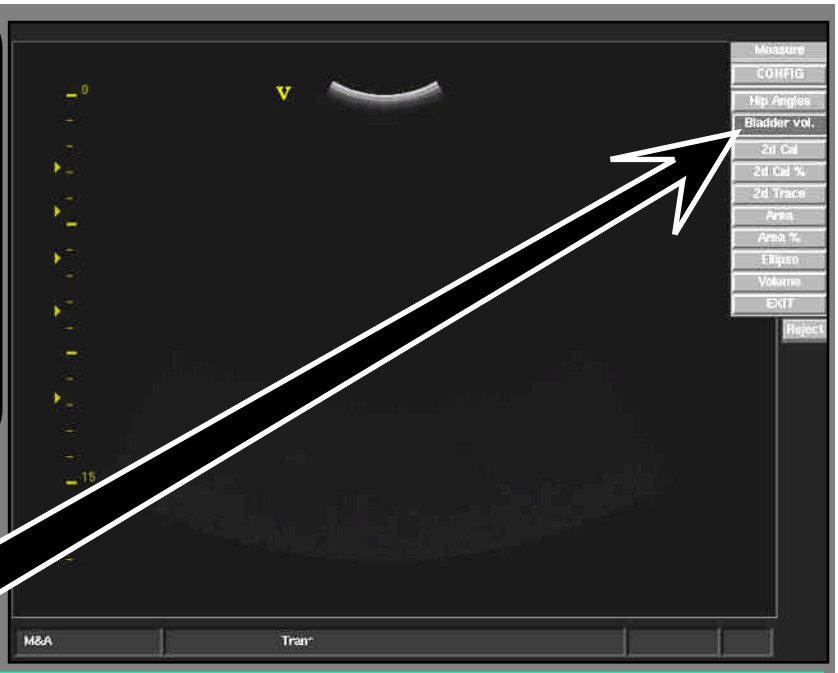
Make the ellipse



Volume M&A, Tissue, Bladder and Thyroid

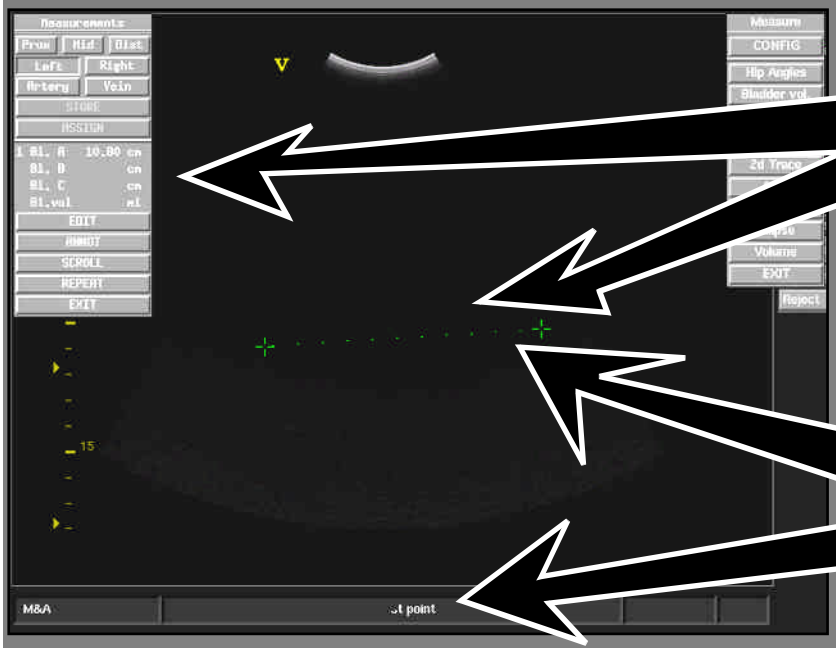
Start Volume M&A

The Volume M&A's are very much alike and similar to use. To prepare for any one of them, obtain the correct probe, scan the patient and press **FULL FREEZE** and then **MEAS** keys, at a sight of interest



Start them from this menu that appears.

Hint
Volume M&A is independent of continuous measuring. You may start measuring, measure length and width, exit from M&A and continue scanning. If you then re-enter M&A and measure the height your volume calculation will be completed.



A measuring cursor appears on the screen along with a measurements menu to the left where three are shown vacant and awaiting entries from your measurements.

Place the cursor in accordance with instructions here, press Select to choose a start point and do the measurement.

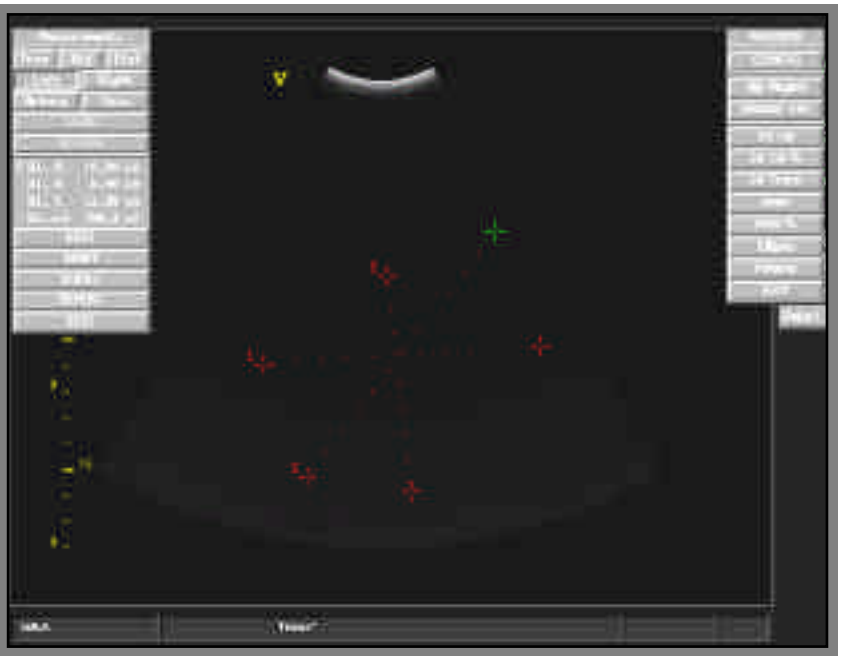
Continue in this manner until all are measured.

Volume M&A, Tissue, Bladder and Thyroid

Save Volume M&A Results

When completed, the volume is presented below the measurements on the measuring menu.

Save these to the report.



Volume Formulas:

These are as shown below

$$TissueVolume = \frac{\pi}{6} \times length \times width \times height$$

$$BladderVolume = 0.7 \times length \times width \times height$$

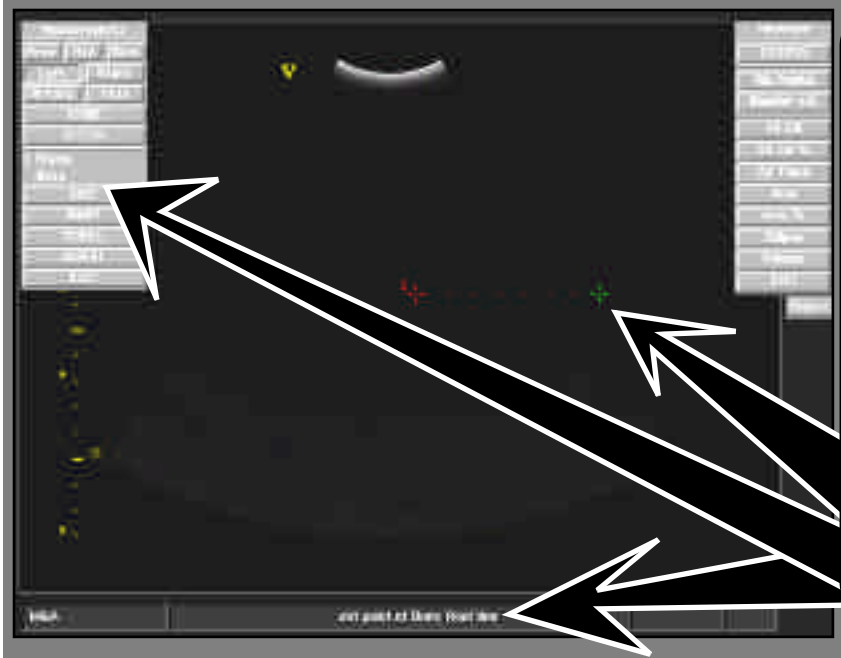
$$ThyroidVolume = 0.479 \times length \times width \times height$$

Hip Angle M&A

Start Hip Angle M&A

This is Fetal M&A with ultrasound. It allows you to uncover fetal abnormalities.at an early stage. Scan your patient with the correct probe, obtain and study a good fetal view before selecting to start Measurements.

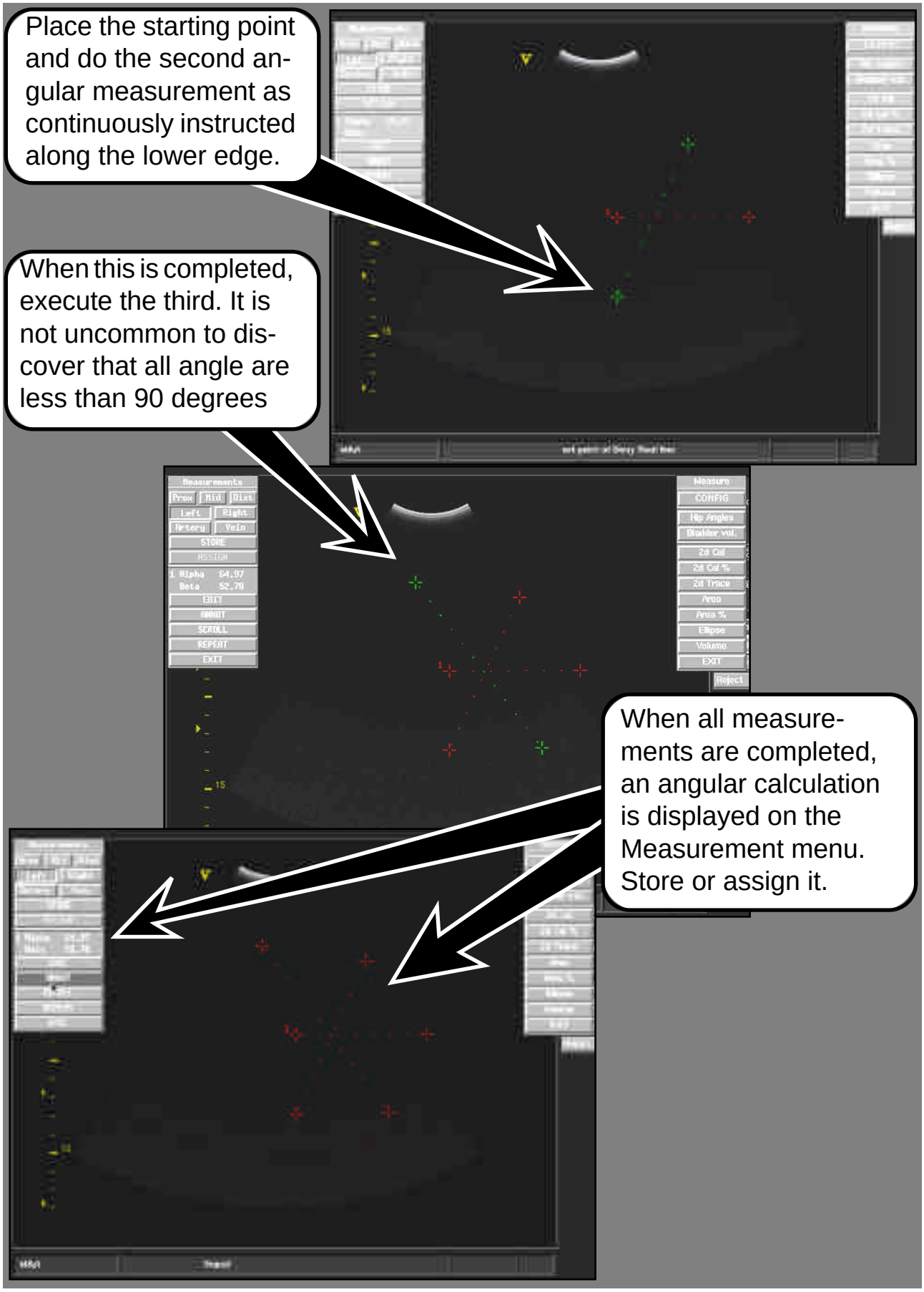
The **Hip Angle** Function is located on this menu. To start hip angle M&A highlight and choose it on the menu using the Trackball and Select key



Place the appearing cursor onto the starting point of the first angular measurement, as instructed along the lower edge of the screen and press select to mark it. With trackball movement, direct the cursor at the instructed angle. The reading appears on the left hand measurement menu.

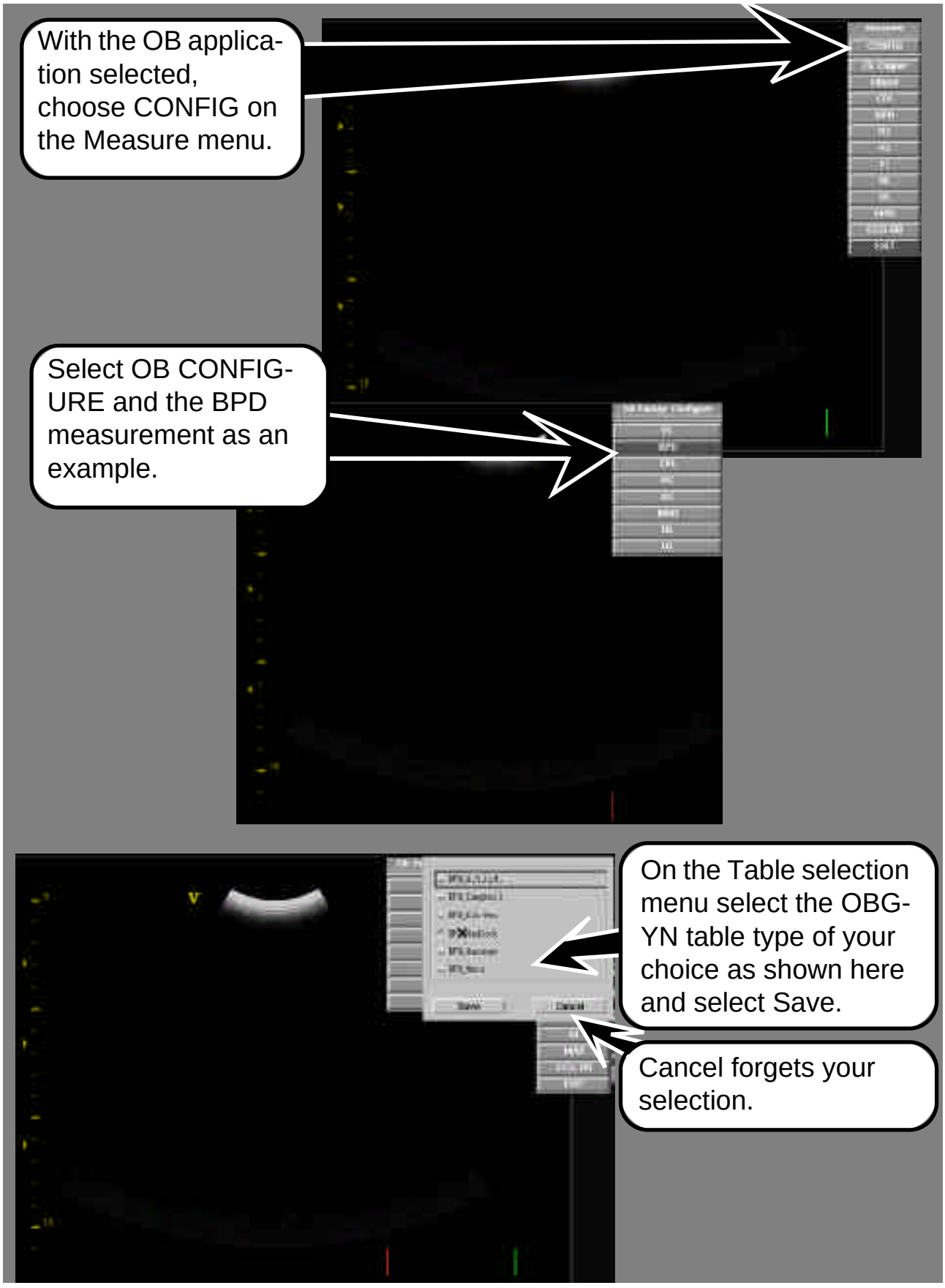
Hip Angle M&A

Complete Measurements and Save results



OBGYN M&A Setup

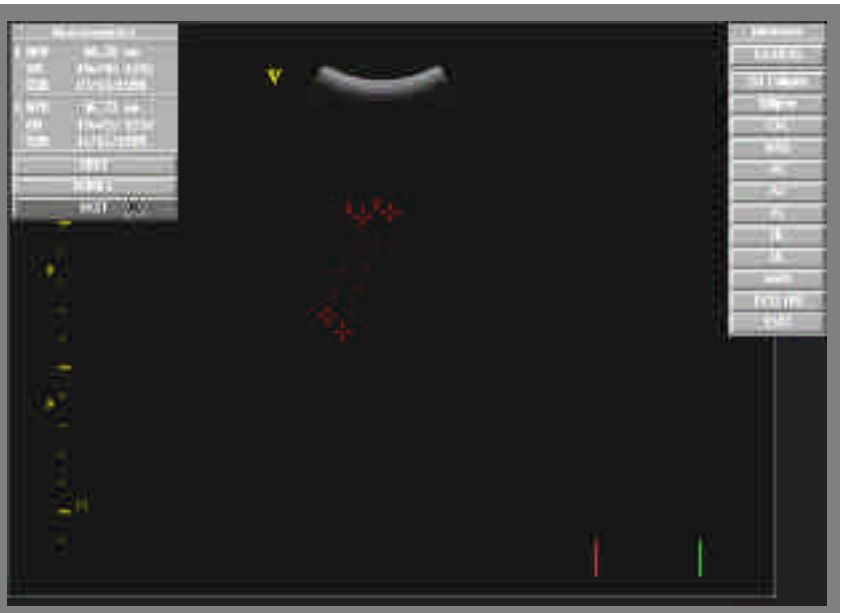
Select the Measurement type



OBGYN M&A Setup

Do the Measurement

Do Biparietal Diameter measurements as decided previously and repeat if necessary. This gives automatic calculation of Gestational Age GA and Estimated Date of Delivery EDD.



This is included on the OBGYN report Page- where you can see that our two measurements have been averaged to give safer age and closer date of delivery.

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Femur Length

FL(GA) via ASUM
FL range: 1.0 –7.9 cm

$$Ga = 10.38 + 2.262 * \mathrm{FL} + 0.1912 * \mathrm{FL}^2 + 0.0008605 * \mathrm{FL}^3 - 0.00009128 * \mathrm{FL}^4 + 0.000003583 * \mathrm{FL}^5$$

Assosiated standard deviation:

$$Sd = 0.19 + 0.42 * \mathrm{FL}$$

FL(GA) via Hadlock
FL range: 0.7 –8.2 cm

$$Ga = 10.35 + 2.46 * \mathrm{FL} + 0.17 * \mathrm{FL}^2$$

Assosiated standard deviation:

$$Sd = 1.0 + 0.26 * \mathrm{FL}$$

FL(GA) via Hansman
FL range: 2.0 –7.5 cm

$$Ga = 10.79 + 3.728 * \mathrm{FL} - 0.6631 * \mathrm{FL}^2 + 0.2492 * \mathrm{FL}^3 - 0.3495 * \mathrm{FL}^4 + 0.001861 * \mathrm{FL}^5$$

Assosiated standard deviation:

$$Sd = 0.19 + 0.412 * \mathrm{FL}$$

FL(GA) via Hohler
FL range: 0.1 –8.7 cm

$$Ga = 9.174068 + 2.670895 * \mathrm{FL} + 0.159947 * \mathrm{FL}^2$$

Assosiated standard deviation:

$$Sd = 0.19 + 0.42 * \mathrm{FL}$$

FL(GA) via Jeanty
FL range: 1.0 –8.0 cm

$$Ga = 9.421153 + 3.05168 * \mathrm{FL} + 0.0890988 * \mathrm{FL}^2 + 0.0009513 * \mathrm{FL}^3$$

OBGYN M&A Calculation Formulas

Assosiated standard deviation:

$$Sd = 2.70$$

FL(GA) via O'Brien
FL range: 1.0 –7.9 cm

$$Ga = 5.184726 + 9.844899 * \mathrm{FL} - 3.99398 * \mathrm{FL}^2 + 1.041302 * \mathrm{FL}^3 - 0.116949 * \mathrm{FL}^4 + 0.004815 * \mathrm{FL}^5$$

Assosiated standard deviation:

$$Sd = 0.19 + 0.42 * \mathrm{FL}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Biparietal Diameter

BPD(GA) via ASUM
BPD range: 2.0 –9.8 cm

$$Ga = -5.269 + 17.03 * \mathrm{BPD} - 6.492 * \mathrm{BPD}^2 + 1.377 * \mathrm{BPD}^3 - 0.1359 * \mathrm{BPD}^4 + 0.005114 * \mathrm{BPD}^5$$

Assosiated standard deviation:

$$Sd = -0.125 + 0.331 * \mathrm{BPD}$$

BPD(GA) via Campbell
BPD range: 2.1 –9.4 cm

$$Ga = 9.363446 + 2.4510590 * \mathrm{BPD} - 0.9873671 * \mathrm{BPD}^2 + 0.387842 * \mathrm{BPD}^3 - 0.0522160 * \mathrm{BPD}^4 + 0.002448 * \mathrm{BPD}^5$$

Assosiated standard deviation:

$$Sd = 0.643 + 0.253 * \mathrm{BPD}$$

BPD(GA) via Eik-Nes
BPD range: 2.5 –10.1 cm

$$Ga = 2.035 + 3.522 * \mathrm{BPD} + 0.2468 * \mathrm{BPD}^2 - 0.0709 * \mathrm{BPD}^3 - 0.004395 * \mathrm{BPD}^4 + 0.00004305 * \mathrm{BPD}^5$$

Assosiated standard deviation:

$$Sd = -0.125 + 0.33 * \mathrm{BPD}$$

BPD(GA) via Hadlock
BPD range: 1.5 –10.1 cm

$$Ga = 6.8954 + 0.26345 * \mathrm{BPD} + 0.000008771 * \mathrm{BPD}^3$$

Assosiated standard deviation:

$$Sd = 0.643 + 0.253 * \mathrm{BPD}$$

OBGYN M&A Calculation Formulas

BPD(GA) via Hansman
BPD range: 2.0 –10.0 cm

$$Ga = -3.542 + 6.972 * \mathrm{BPD} \ -1.91 * \mathrm{BPD}^2 + 0.4055 * \mathrm{BPD}^3 - 0.0406 * \mathrm{BPD}^4 + 0.001596 * \mathrm{BPD}^5$$

Assosiated standard deviation:

$$Sd = 0.643 + 0.253 * \mathrm{BPD}$$

BPD(GA) via Merz
BPD range: 2.0 –9.9 cm

$$Ga = 7.739 + 1.683 * \mathrm{BPD} \ + 0.306 * \mathrm{BPD}^2 - 0.04438 * \mathrm{BPD}^3 - 0.002958 * \mathrm{BPD}^4$$

Assosiated standard deviation:

$$Sd = 1.3 + 0.117 * \mathrm{BPD}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Crown Rump Length

CRL(GA) via Hansman
CRL range: 0.6 –15.0 cm

$$Ga = -4.555 + 2.822 * \mathrm{CRL} - 0.3868 * \mathrm{CRL}^2 + 0.02904 * \mathrm{CRL}^3 - 0.0007966 * \mathrm{CRL}^4 + 0.000005078 * \mathrm{CRL}^5$$

Assosiated standard deviation:

$$Sd = 0.81 + 0.098 * \mathrm{CRL}$$

CRL(GA) via Robinson
CRL range: 0.6 –7.8 cm

$$Ga = -4.933912 + 2.8007 * \mathrm{CRL} - 0.6356975 * \mathrm{CRL}^2 + 0.117067 * \mathrm{CRL}^3 - 0.011622 * \mathrm{CRL}^4 + 0.0004623 * \mathrm{CRL}^5$$

Assosiated standard deviation:

$$Sd = 0.81 + 0.098 * \mathrm{CRL}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Head Circumference

HC(GA) via Campbell
HC range: 11.0 –34.8 cm

$$Ga = 11.83 - 0.8894 * \mathrm{HC} + 0.1546 * \mathrm{HC}^2 - 0.005916 * \mathrm{HC}^3 + 0.00008253 * \mathrm{HC}^4$$

Assosiated standard deviation:

$$Sd = 1.2 + 0.4 * \mathrm{HC}$$

HC(GA) via Hadlock
HC range: 6.7 –35.0 cm

$$Ga = 8.96 + 0.54 * \mathrm{HC} + 0.0003 * \mathrm{HC}^2$$

Assosiated standard deviation:

$$Sd = 3.10 - 0.008 * \mathrm{HC}$$

HC(GA) via Hansman
HC range: 14.0 –35.0 cm

Assosiated standard deviation:

$$Ga = 22.37 - 3.033 * \mathrm{HC} + 0.3522 * \mathrm{HC}^2 - 0.01505 * \mathrm{HC}^3 + 0.0002935 * \mathrm{HC}^4 + 0.000001944 * \mathrm{HC}^5$$

Assosiated standard deviation:

$$Sd = 3.10 - 0.008 * \mathrm{HC}$$

HC(GA) via Merz
HC range: 7.6 –36.1 cm

$$Ga = 7.779 + 0.4014 * \mathrm{HC} + 0.02711 * \mathrm{HC}^2 - 0.0009649 * \mathrm{HC}^3 + 0.00001634 * \mathrm{HC}^4$$

Assosiated standard deviation:

$$Sd = 0.4 + 0.3 * \mathrm{HC}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Abdominal Circumference

AC(GA) via ASUM
AC range: 3.5 –37.7 cm

$$Ga = 6.958 + 0.8784 * \mathrm{AC} - 0.0001584 * \mathrm{AC}^2 + 0.000009226 * \mathrm{AC}^3 + 0.0000002614 * \mathrm{AC}^4 + 0.000000002801 * \mathrm{AC}^5$$

Assosiated standard deviation:

$$Sd = 0.6129 + 0.06155 * \mathrm{AC}$$

AC(GA) via Campbell
AC range: 8.6 –36.0 cm

$$Ga = 4.490188 + 1.277832 * \mathrm{AC} - 0.022174 * \mathrm{AC}^2 + 0.0003847 * \mathrm{AC}^3$$

Assosiated standard deviation:

$$Sd = 1.31 + 0.048 * \mathrm{AC}$$

AC(GA) via Hadlock
AC range: 5.1 –40.0cm

$$Ga = 8.14 + 0.753 * \mathrm{AC} + 0.0036 * \mathrm{AC}^2$$

Assosiated standard deviation:

$$Sd = 1.31 + 0.048 * \mathrm{AC}$$

AC(GA) via Hansman
AC range: 5.3 –32.0 cm

$$Ga = 7.427 + 0.9061 * \mathrm{AC} - 0.01746 * \mathrm{AC}^2 + 0.002514 * \mathrm{AC}^3 + 0.0001004 * \mathrm{AC}^4 + 0.000001314 * \mathrm{AC}^5$$

Assosiated standard deviation:

$$Sd = 1.31 + 0.048 * \mathrm{AC}$$

OBGYN M&A Calculation Formulas

AC(GA) via Jeanty
AC range: 5.7 –31.6 cm

$$Ga = 4.467561 + 1.494606 * \mathrm{AC} - 0.040213 * \mathrm{AC}^2 + 0.0008904 * \mathrm{AC}^3$$

Assosiated standard deviation:

$$Sd = 1.31 + 0.048 * \mathrm{AC}$$

AC(GA) via Merz
AC range: 5.8 –34.6 cm

$$Ga = 6.445 + 0.9519 * \mathrm{AC} + 0.00137 * \mathrm{AC}^2 - 0.00003561 * \mathrm{AC}^3 + 0.0000003159 * \mathrm{AC}^4$$

Assosiated standard deviation:

$$Sd = 1.5 + 0.02 * \mathrm{AC}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Humerus Length

HL(GA) via Jeanty
HL range: 1.0 –6.9 cm

$$Ga = 9.814957 + 2.454296 * \mathrm{HL} + 0.315232 * \mathrm{HL}^2 - 0.006896 * \mathrm{HL}^3 + 0.0002902 * \mathrm{HL}^4$$

Assosiated standard deviation

$$Sd = 1.283 + 0.00983 * \mathrm{HL}$$

OBGYN M&A Calculation Formulas

Gestational Age (week+days) using Ulna Length

UL(GA) via Jeanty
UL range: 1.0 –6.4 cm

$$Ga = 9.797318 + 3.253571 * \mathrm{UL} + 0.042887 * \mathrm{UL}^2 + 0.071384 * \mathrm{UL}^3 - 0.009265 * \mathrm{UL}^4 + 0.0004399 * \mathrm{UL}^5$$

Assosiated standard deviation

$$Sd = 1.52 + 0.0013 * \mathrm{UL}$$

PV M&A

Measurements & Ratios

Calculated Ratios

ICA/CCA (Internal Carotid Artery to common Carotid artery - Carotid Application)

CFA/EIA(Common Femoral Artery to External Line Artery-Lower Limbs)

SFA/CFA(Superficial Femoral Artery to Common Femoral Artery-Lower Limbs)

Renal Artery/Aorta (Abdomen and Renal applications)

Two Ratios are calculated-from **Peak Systolic Velocities** and **End Diastolic velocities**. For the first three ratios, the two vessels must be on the same side and labelled Right or Left.

Cardiovascular Acquisition Formulas

In addition to the parameters that are directly measured by a user, the System FiVe has a number of Formulas which are automatically calculated as soon as all of the parameters in the Formulas have been assigned. The labels in the Formulas below, are the same as the labels listed in the parameter menus for assignment.

2D-measurements

Body Surface Area (Patient Browser Input)

BSA = 0.007184 x Height (cm) $^{0.725}$ x Weight (Kg) $^{0.425}$

(US units are internally converted to metric units and used in the same formula.

Distance stenosis

Stenosis = $100.0 \times \left(1.0 - \frac{SmallestDistance[mm]}{LargestDistance[mm]}\right)$

Area stenosis

.

Stenosis = $100.0 \times \left(1.0 - \frac{SmallestArea[mm^2]}{LargestArea[mm^2]}\right)$

Spectrum measurements

RI = $\frac{VMax\left[\frac{cm}{s}\right] - VMin\left[\frac{cm}{s}\right]}{VMax\left[\frac{cm}{s}\right]}$ ---->If Triphasic, then RI=1.

S/D = $\frac{VMax\left[\frac{cm}{s}\right]}{VMin\left[\frac{cm}{s}\right]}$

Cardiovascular Acquisition Formulas

Vmax and Vmin is the larger/lesser value when we compare absolute values but in the Formulas we use the measurement assigned values. i.e. V1 = -5, V2 = -3 where Vmax is assigned the value of -5 and Vmin -3.

$$RI = \frac{-5-(-3)}{-5}$$

Automatic trace

$$Flow\left[\frac{ml}{min}\right] = \text{Cross Sectional Area x Vavg}$$

$$TimeAverageVelocity \times CrossSectionalArea = 60 \times \Pi \times \left(\frac{Diameter[cm]}{2}\right)^2 \times AverageVelocity\left[\frac{cm}{s}\right]$$

PI

$$PI = \frac{SystoleVelocity\left[\frac{cm}{s}\right] - DiastoleVelocity\left[\frac{cm}{s}\right]}{AverageVelocity\left[\frac{cm}{s}\right]}$$

Chapter E

Installation & Maintenance

This chapter provides you with maintenance procedures for your system and its probes and contains some advice on installation.

Chapter E explains how to:

System FiVe Installation

System FiVe

Shipments:

• System FiVe should be unpacked, installed and cleared for operation by an authorized service representative. Packing /Unpacking instructions are found on the outside of the transport package. System FiVe must be mains-connected to a **HOSPITAL GRADE** power source. DO NOT attempt to assemble the system or connect it to a power source until qualified approval for operation has been given.

Preventive User Maintenance

Cleaning the System

• DO NOT pour water on System FiVe or immerse any part of it, in any liquid. Avoid spilling liquids into ventilation grates.

Weekly: • The exterior surface of the System FiVe should be cleaned with a dry cloth. When more extensive cleaning is required, the unit should first be powered down and then wiped with a soft cloth that has been dampened with either water or a very mild detergent. NEVER use abrasive cleaners or steel wool.

After use: • Wipe away gel stains from the control panel and keyboard as soon as possible, because some ultrasound gels are mildly aggressive towards plastics.

Cleaning the Probes

Patient exams and the appropriate level of cleaning or disinfection are categorized by the nature of patient contact (location or type of tissue):

- Scanning on intact surface skin is considered non-critical and usually requires a low or intermediate level disinfection. Cleaning with soap and water is usually sufficient.
- Invasive scanning involving contact with mucous membranes (TR, TV or TE probes) is considered semi-critical and requires a cleaned and High-Level Disinfected probe or a probe having been intermediate level disinfected and fitted with a sanitary probe sheath. A sanitary sheath is recommended for all TV and TR exams.
- Invasive scanning involving contact with re-circulating blood (surgical probes) is considered critical and requires sterile technique using a cleaned and sterilized probe or a probe having been High Level Disinfected with a fully enclosing sterile sheath. Sterile technique and sterile sheath are indicated with any probe involving biopsy procedures.

After each patient investigation:

Note: Disinfection of Invasive probes (Transesophageal or Tranvaginal) is described in the specific probe manuals. The description below is for non-invasive probes only

Probes and their cables should be cleaned using a soft cloth dampened with a mild detergent. We recommend that this be done in accordance with site rules and regulations.

DO NOT AUTOCLAVE ANY PROBES OR ATTEMPT TO STERILIZE THE PROBES USING ETO GAS OR AGGRESIVE FLUIDS.

Do NOT submerge any system probes or connectors in cleaning / disinfection fluids. Use caution when cleaning probes and avoid spilling liquids into connector recep-tacles.

If probes are to be used in potential contamination situations, cover the probe WITH A STERILE SHEATH

Visual Inspection & Maintenance

- Prior to all system maintenance tasks, disconnect the mains cable.

Monthly:

- The user is advised to inspect all external cables and connectors for signs of wear. If cables or connectors appear to be damaged, contact your service representative for repair or replacement.
- Two Air filters are situated under the system. These are easily removed by using a cross-point screwdriver. These should be vacuume cleand or washed in water to remove dust particals

Always:

- If the bulb in the control panel lamp is defect or used up, disconnect the lamp from the front panel, remove and replace the bulb and reconnect the lamp on the control panel.

More extensive maintenance should be performed by trained Service personnel.

Chapter F

Warnings

The use of the System FiVe requires a high regard for patient and operator safety. The System FiVe was designed to meet or exceed all applicable electrical and mechanical safety standards. However, design alone cannot eliminate the possibility of unsafe operation. The operator must be aware of the types of procedures or actions that could result in unsafe conditions. It is recommended that you carefully review the following information before attempting to operate the unit.

These Warnings inform you about:

System safety

Electrical Power Safety

System FiVe is factory-wired to operate at 115-120 (Hospital graded mains circuit), or 230-240VAC, or as appropriate for the original destination. Verify the correct voltage at your location before mains connection of the unit. All connections must be made with the plug provided with the unit.

The system grounding point is clearly marked provided at the rear. The system must be grounded when the three- pronged plug from the System FiVe is plugged into a grounded (Hospital graded, where applicable) wall receptacle.

Electrical Shock Hazards

- DO NOT try to open any of the System FiVe panels or remove any covers or wires. Refer all servicing or questions regarding system function, to qualified service personnel.
- The System FiVe external input and output protection cover may be removed by the user, using an appropriate screwdriver. This gives access to a location for legal connection of accessory devices. All external connectivity at this location must be carried out when the system is switched off.
- The System FiVe external input and output connectors are not electrically isolated from the rest of the circuitry inside System FiVe. Any instruments connected to the System FiVe via these inputsor outputs must conform to standard hospital electrical safety and leakage requirements. It is the responsibility of the user to ensure that he meets the important safety requirement in all cases. When connecting the System FiVe to a non-isolated device, use a Hospital grade isolation transformer for all mains power supply..

Explosion Hazards

- If System Five use is in the vicinity of flammable anesthetics, the risk of explosion exists.

Mechanical Safety

The System FiVe is a compact and mobile system. To ensure user and patient safety, take the following precautions when moving the system.

- Make sure that all loose wires, such as transducer cables, are out of the way so that they will not snag on wheels, doorknobs or other protruding objects.
- Place all loose objects such as bottles of gel, ECG leads and cable, extra video tapes, film or paper in the storage drawer or bins provided.
- Both front wheels have locks. Be sure to unlock each wheel before attempting to move the system. Once you move the unit to a new location, we recommended that the front wheels are locked to prevent it from rolling during use.

Statements on the safety of Ultrasound

AIUM statement on clinical safety.

October 1982, Revised March 1983 and October 1983.

Diagnostic ultrasound has been in use for over 35 years. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound In Medicine herein addresses the clinical safety of such use:

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

AIUM Statement on Mammalian in Vivo Ultrasonic Biological Effects

August 1976, Revised October 1978: Reaffirmed October 1982 and October 1983

In the low megahertz frequency range there have been (as of this date) no independently confirmed significant biological effects in mammalian tissues exposed to intensities ”a” below 100 mW/cm^2. For ultrasound exposure times “b” less than 500 seconds and greater than 1 second, such effects have not been demonstrated even at higher intensities when the product of intensity “a” and exposure time “b” is less than 50 joules/cm^2.

1 Spatial peak, temporal average as measured in a free field in water.

2 Total time, this includes off-time as well as on-time for a repeated pulse regime.

GE Vingmed Ultrasound Safety statement

May 1994

Although no harmful biological effects have been demonstrated for ultrasound frequencies, intensities and exposure times used in examination with the VINGMED System FiVe systems, VINGMED SOUND recommends using the lowest acoustic output settings which will produce diagnostically acceptable information.

The GE Vingmed Ultrasound Patent Rights

Below you will find a valid list of approved patents which are fully or partly used in GE Vingmed Ultrasound System FiVe. In addition, the product comprises pending patents.

List of GE Vingmed Ultrasound's Patents

REVISED 31.03.00/Rba

*** new patent**

CASE NO.1 ULTRASONICS TRANSDUCER PROBE WITH LINEAR MOTION DRIVE MECHANISM

PATENT NO.	4,757,818	US		(1988)
PATENT NO.	2.512,461	JAPAN		(1996)
PATENT NO.	235.969	FRANCE	EURO	(1997)
PATENT NO.	235.969	GERMANY	EURO	(1997)
PATENT NO.	235.969	ITALY	EURO	(1997)
PATENT NO.	235.969	UK	EURO	(1998)

CASE NO.5/6 MINI PROBE: A MINIATURIZED MECHANICALLY-STEERABLE ULTRASONIC PROBE

PATENT NO.	4,972,839	US		(1990)
PATENT NO.	375.132	EUROPA		(1995)
PATENT NO.	375.132	GERMANY	EURO	(1995)
PATENT NO.	375.132	ITALY	EURO	(1995)
PATENT NO.	375.132	FRANCE	EURO	(1995)

CASE NO. 7 COLOR CODES: A METHOD OF COLOR CODING TWO DIMENSIONAL ULTRASONIC DOPPLER VELOCITY IMAGES OF BLOOD FLOW ON A DISPLAY

PATENT NO.	4,932,415	US	(1990)

CASE NO 8 ULTRASONIC IMAGING PROBE

PATENT NO.	5,085,221	US	(1992)

CASE NO 13 MULTIGATED DOPPLER: METHOD FOR ESTIMATING BLOOD FLOW VELOCITY

PATENT NO.	5.560.363	US	(1996)
PATENT NO	1277233	ITALY	(1998)
PATENT NO.	2 727 851	FRANCE (	1998)

CASE NO 14 MATCHED SPECTRUM

PATENT NO	5.662.115	US	(1997)
PATENT NO	1.279.010	ITALY	(1998)
PATENT NO	2 720 922	FRANCE	(1999)

CASE NO 15 WALL MOVEMENT

	5.568.811	US	(1996)

CASE NO 16 POSITION INDICATION

PATENT NO	5.617.858	US	(1997)
PATENT NO	300.407	NORWAY	(1997)
PATENT NO	1277510	ITALY	(1998)
PATENT NO	95.101.30	FRANCE	(1997)
PATENT NO	689724	SWITZERLAND	(1999)

CASE NO 17 M-MODE: A METHOD FOR GENERATING ANATOMICAL M-MODE DISPLAYS

PATENT NO	5,515,856	US	(1996)
PATENT NO	1277511	ITALY	(1998)
PATENT NO	2.723.835	FRANCE	(1998)

CASE NO. 18 TISSUE ANALYSIS: A METHOD FOR REAL-TIME ANALYSIS

PATENT NO	5,467,096	US	(1996)
PATENT NO	1277512	ITALY	(1998)
PATENT NO	2.724.245	FRANCE	(1998)

CASE NO 19 TISSUE VELOCITY: A METHOD FOR ANALYSIS AND MEASUREMENT OF TEMPORAL TISSUE VELOCITY INFORMATION

PATENT NO	5,820,561	US	(1998)
PATENT NO	1293746	ITALY	(1999)

CASE NO.114/115 METHOD OF ULTRASONICALLY MEASURING BLOOD FLOW VELOCITY

PATENT NO.	4,559,952	US	(1985)
PATENT NO.	2,112,937	UK	(1982)
PATENT NO.	PV 82 18 993	FRANCE	(1988)
PATENT NO.	1,210,951	ITALY	(1990)
PATENT NO.	1,595,636	JAPAN	(1991)
PATENT NO.	32 41 670	GERMANY	(1995)

CASE NO. 118 METHOD AND APPARATUS FOR GENERATING A MULTIDIMENSIONALMAP OF BLOOD VELOCITIES USING BACKSCATTERED ULTRASOUND AND THE DOPPLER EFFECT

PATENT NO.	4,848,354	US	(1989)
PATENT NO.	2,142,142	UK	(1989)
PATENT NO.	2545715	FRANCE	(1992)
PATENT NO.	1,174,091	ITALY	(1988)
PATENT NO.	1887967	JAPAN	(1995)
PATENT NO.	4317660.80	GERMANY	(1995)

CASE NO. 121 METHOD AND APPARATUS FOR SYNTHESIZING A CONTINUOUS ESTIMATE SIGNAL FROM SEGMENTS OF A GAUSSIAN SIGNAL PROVIDED BY ULTRASONIC DOPPLER MEASUREMENT ON A FLUID FLOW

PATENT NO.	4,934,373	US	(1990)

PATENT NO.	2,142,753	UK	(1988)
PATENT NO.	3,417,568	GERMANY	(1993)
PATENT NO	2,549,957	FRANCE	(1990)
PATENT NO.	1,173,985	ITALY	(1987)
PATENT NO.	1887966	JAPAN	(1995)

CASE NO. x METHOD AND APPARATUS FOR ULTRASOUND IMAGING

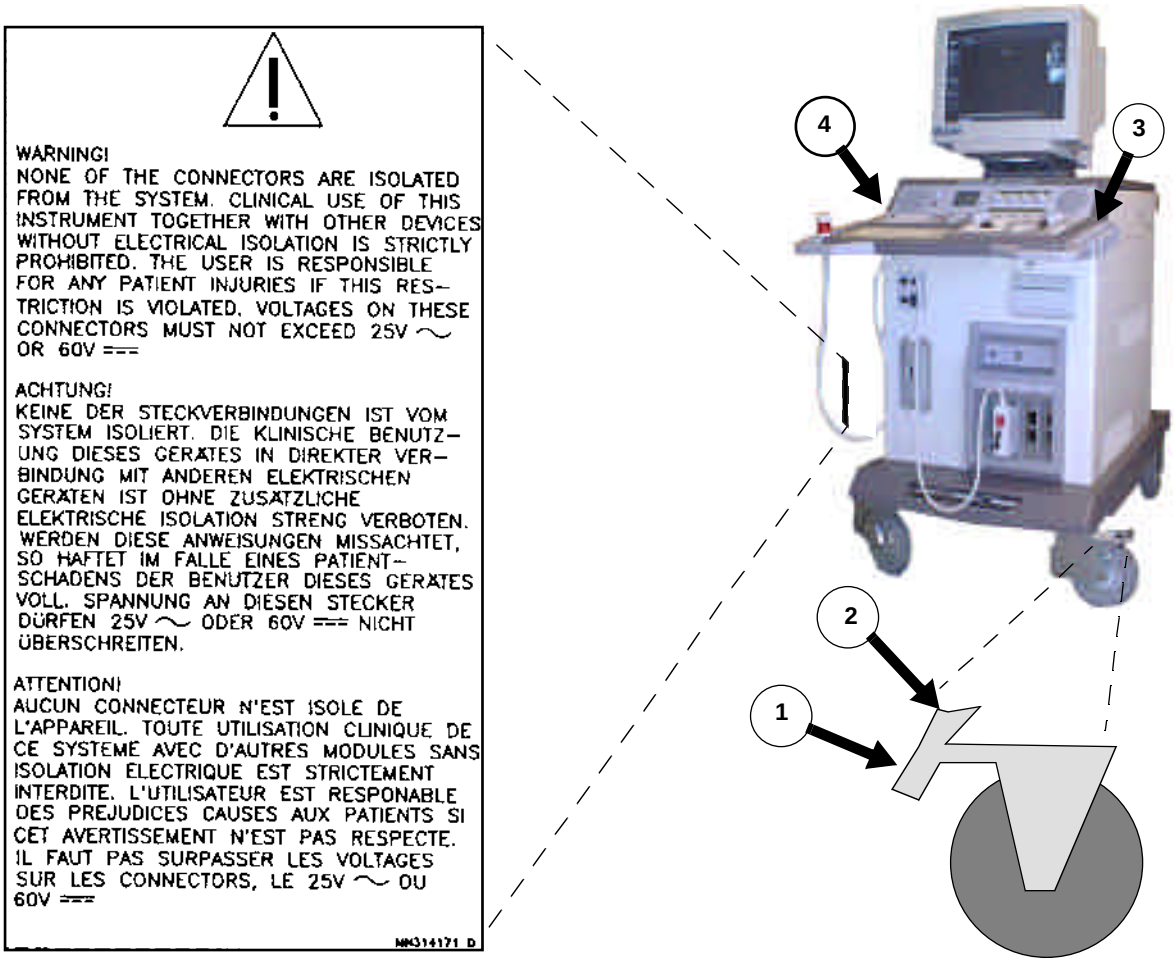
PATENT NO.	5,465,723	US	(1998)

REGISTRATED TRADE MARK: SONOTRON ULTRASOUND SOLUTIONS
FRANCE 97 667 911

REGISTRATED TRADE MARK: (VALID UNTIL 08.04.2008)	ECHOPAC	FRANCE	98/727/129
	ECHOPAC	GERMANY	398 20 510
	ECHOPAC	US	2,281,514
	ECHOPAC	UK	obs avventer bevis pr 13.03.00
	ECHOPAC	JAPAN *	4365760

Warnings and Caution labels

External I/O Warning label



Mobility Warnings

Never leave a mobile device such as the System FiVe unattended on a slanted surface.To lock front wheels, press edge marked (1). To unlock front wheels press edge marked (2).

Do not carry System FiVe by the front handles (3) or rear bumper (4). These are designed for tilting, pushing and guiding the system.

Probe Warning

Although they may look and feel OK afterwards, never continue using any Vingmed Probe that has been dropped onto, or been bashed against hard surfaces. Disconnect such probes and get them tested by qualified personnel.

ECG Warning

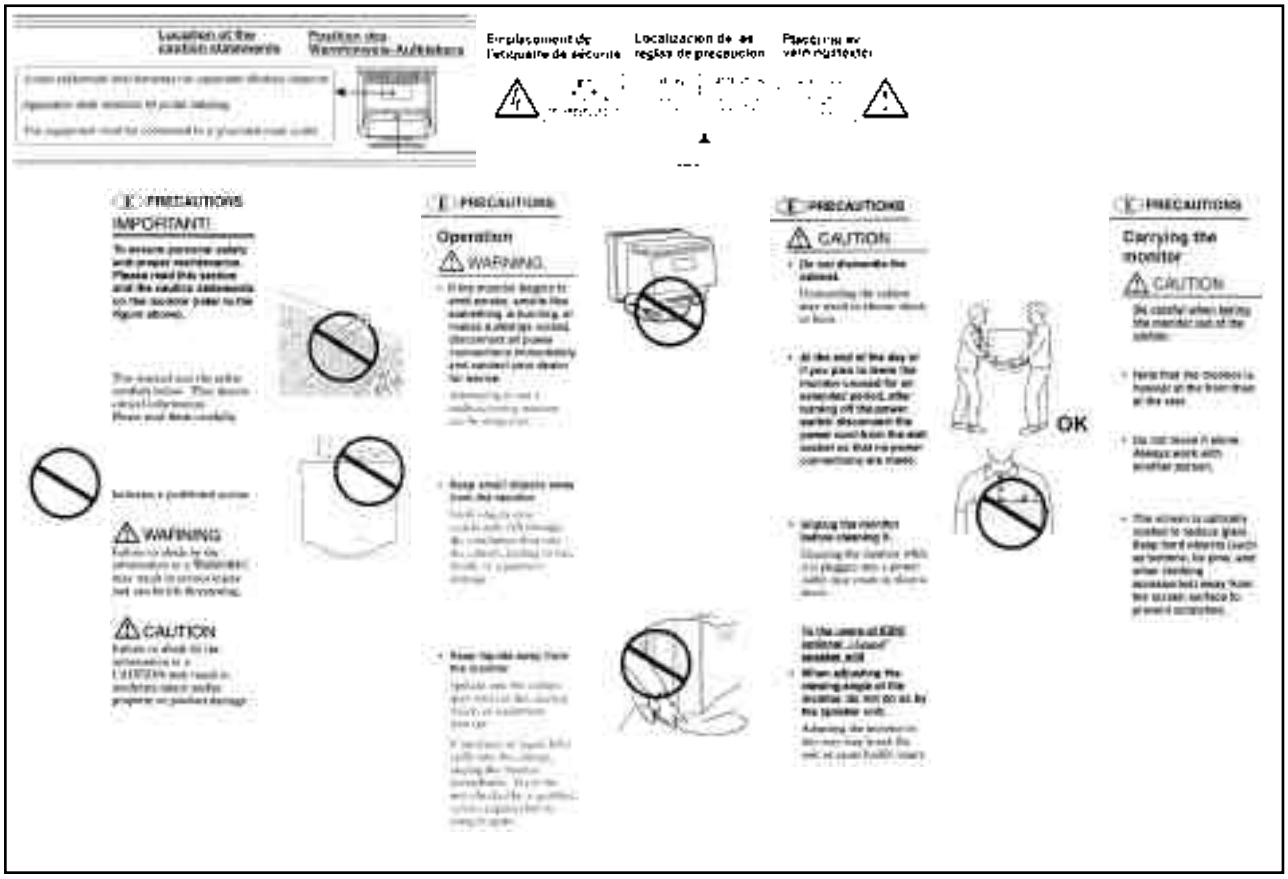
Conductive parts of the electrodes and the ECG cables, including the neutral electrode must not come into contact with other conductive parts, including ground

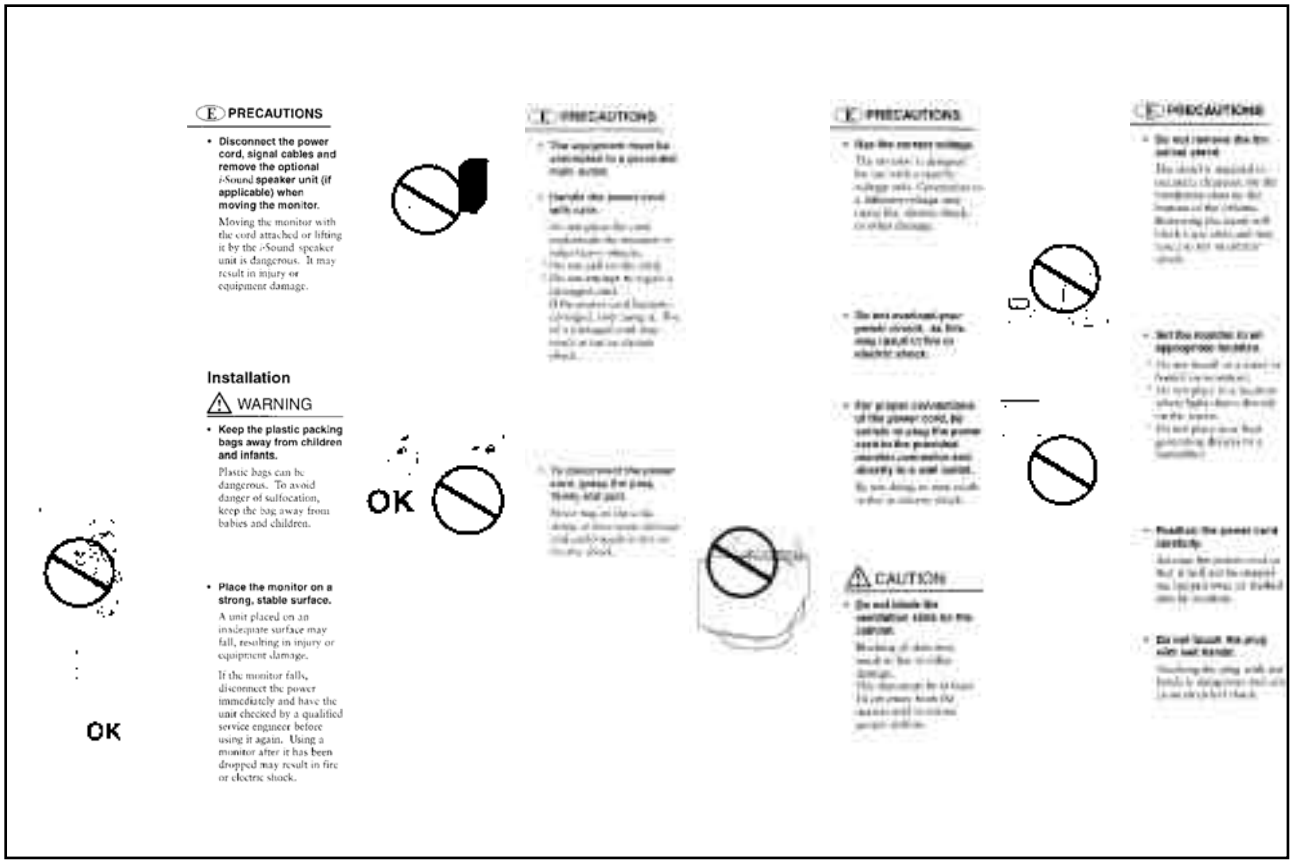
FDA’s Prescription Device Label

Federal law restricts this device to sale by or on the order of a physician.

Warnings and Caution labels

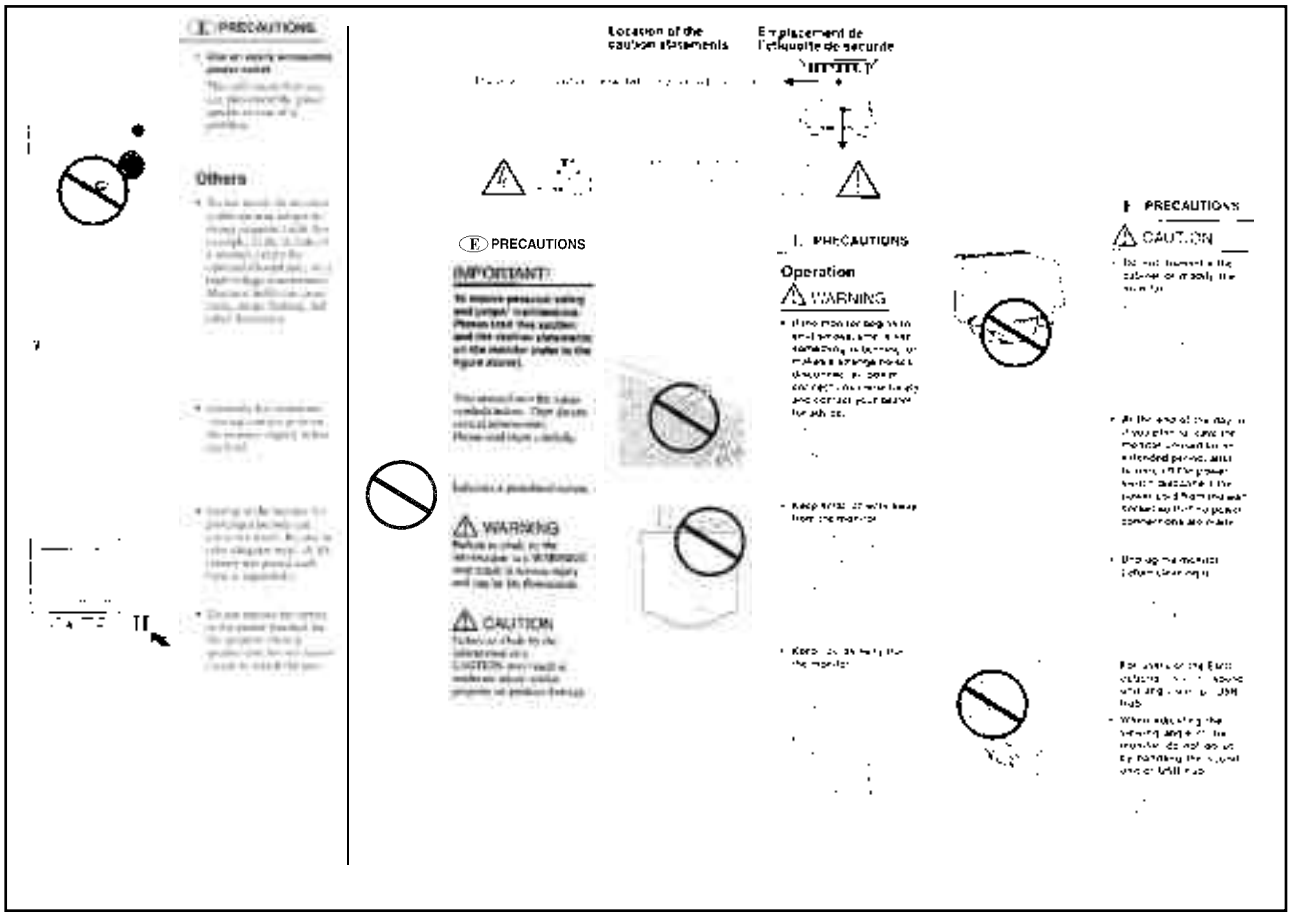
Monitors

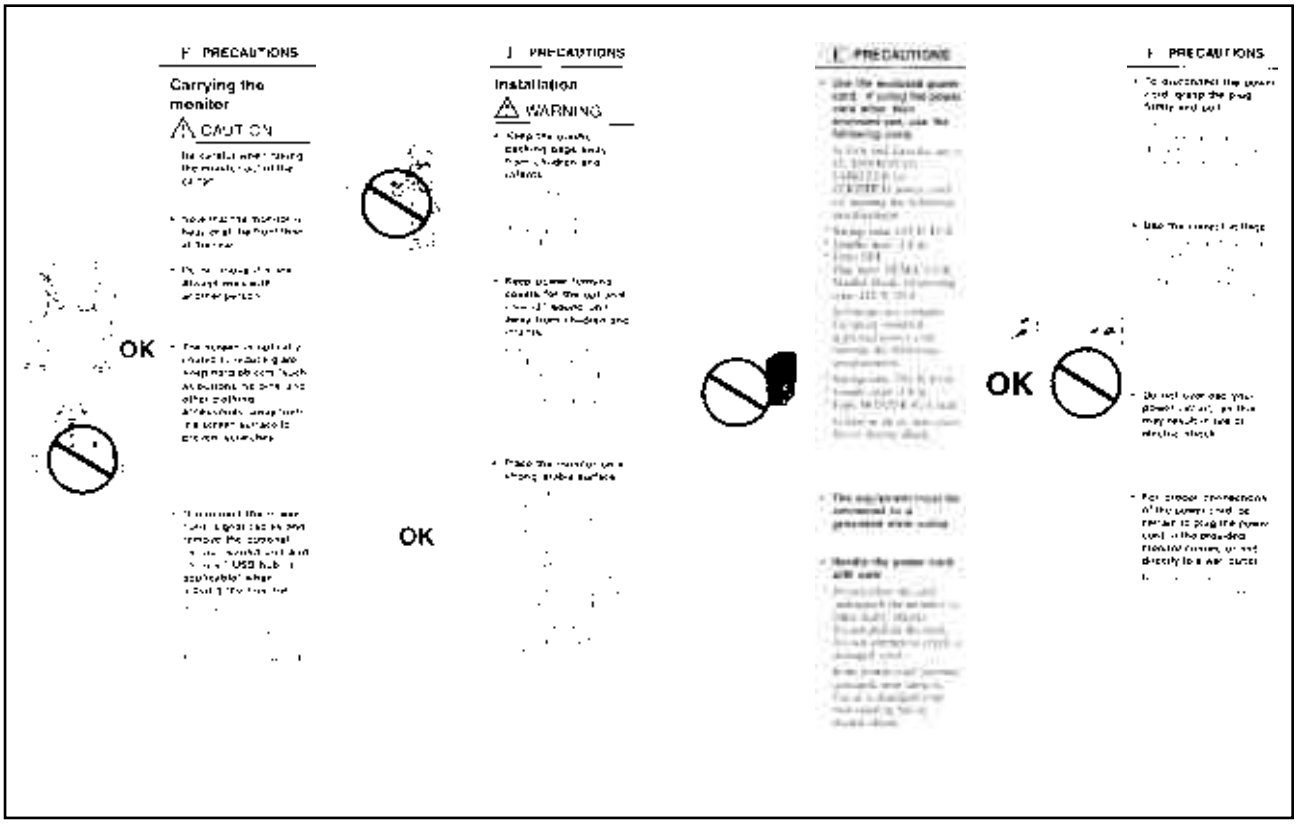




Warnings and Caution labels

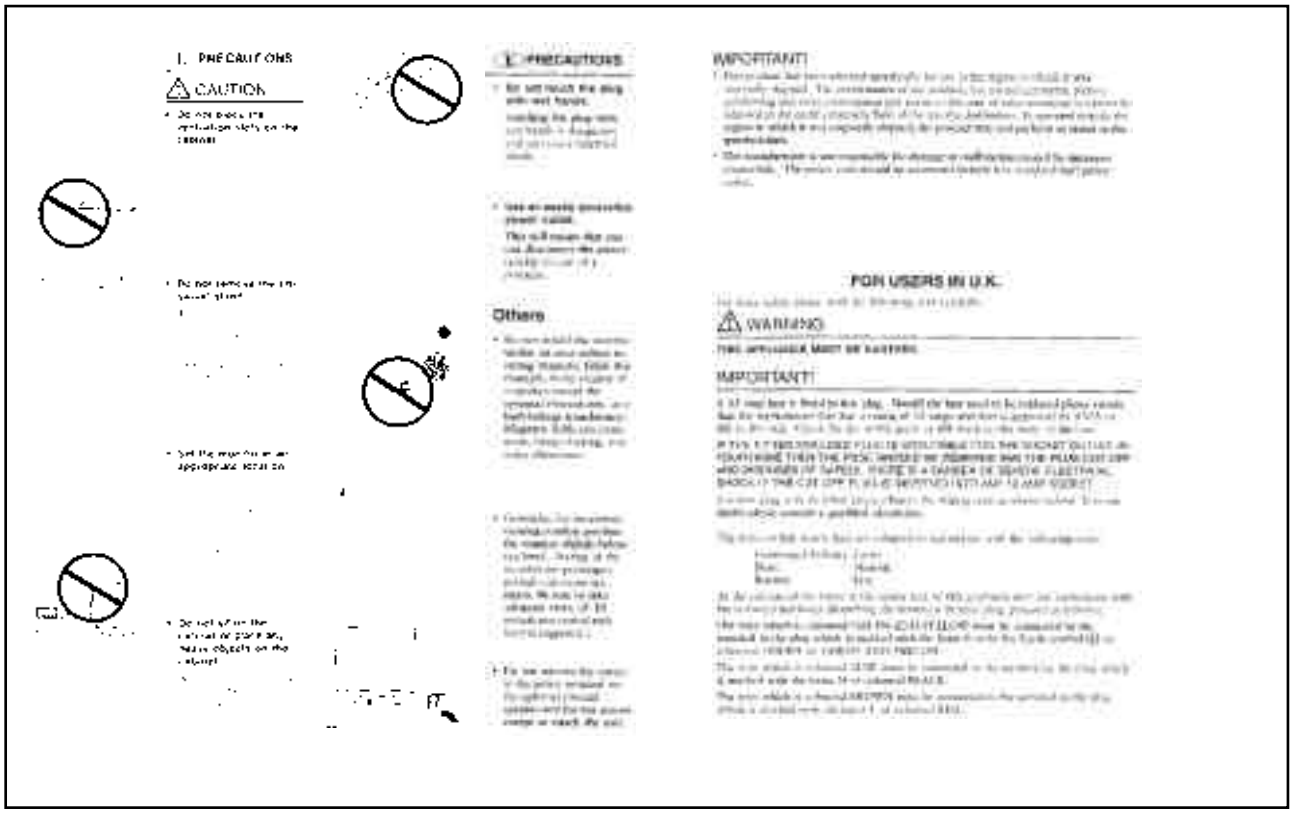
Monitors





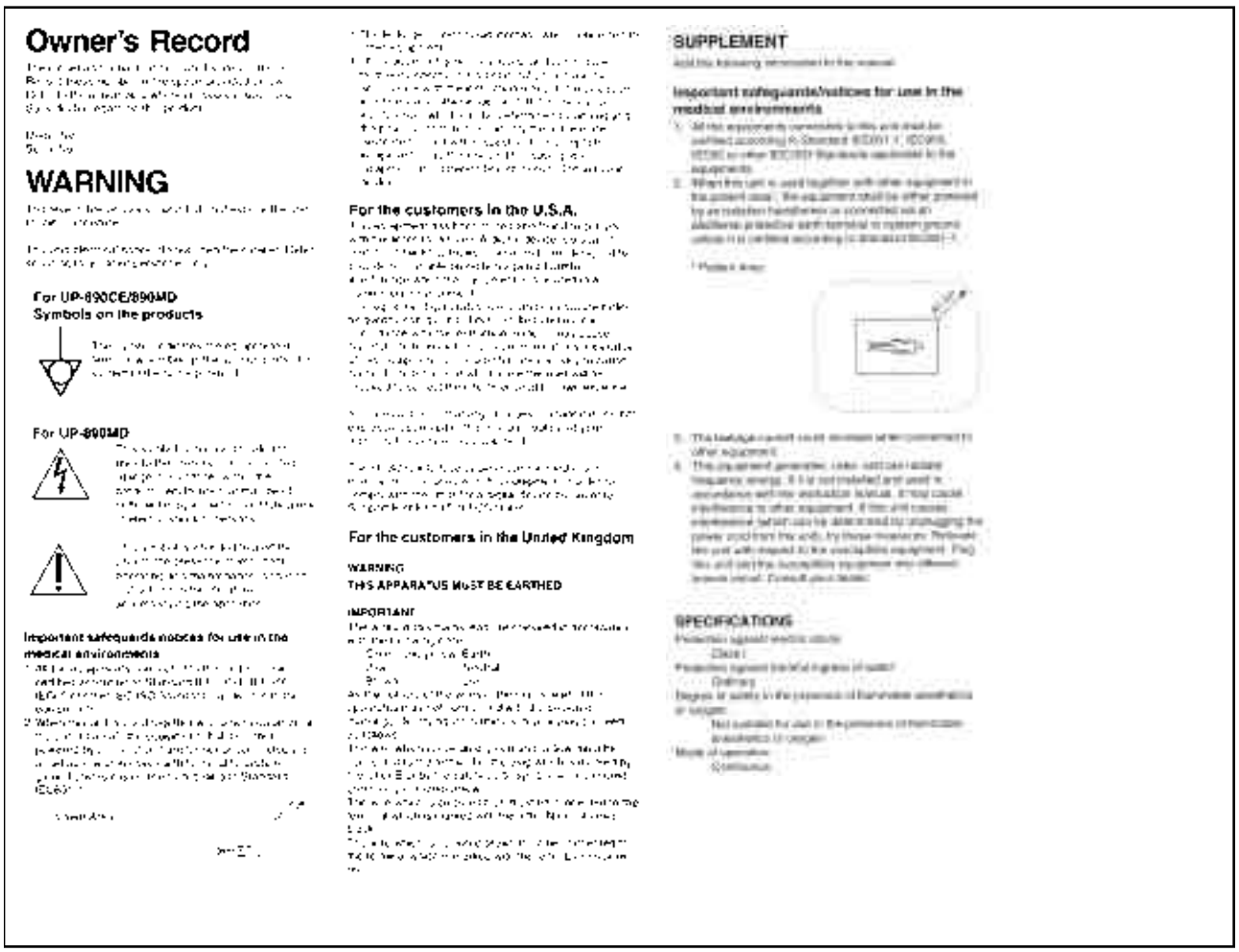
Warnings and Caution labels

Monitors



Warnings and Caution labels

Printers, B/W and Color



Owner's Record

WARNING

For UP-890CE/890MD
Symbols on the products

For UP-890MD

Important safeguards notices for use in the medical environments

For the customers in the U.S.A.

For the customers in the United Kingdom

WARNING
THIS APPARATUS MUST BE EARTHED

IMPORTANT

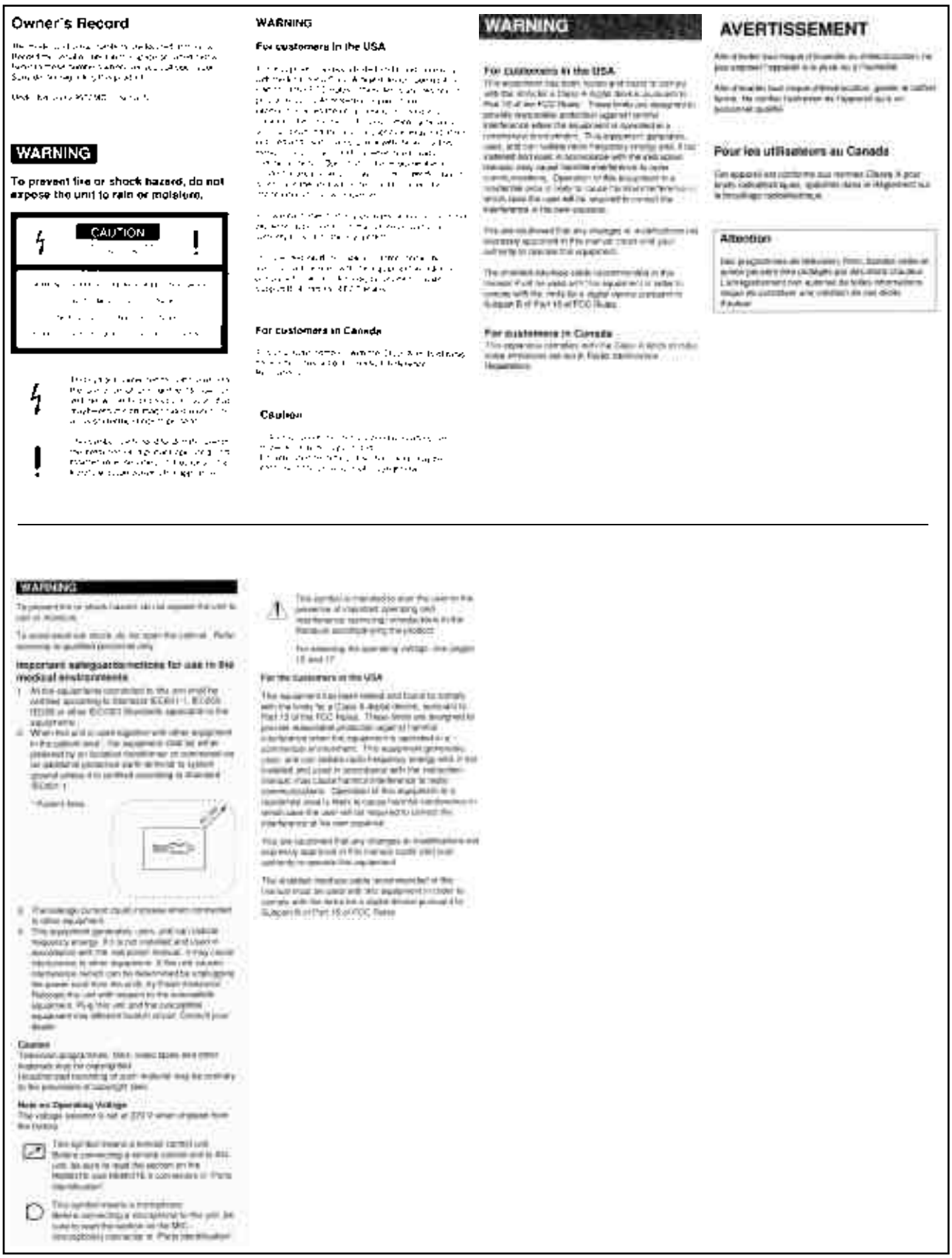
SUPPLEMENT

Important safeguards/notices for use in the medical environments

SPECIFICATIONS

Warnings and Caution labels

Video Cassette Recorders



Chapter G

Specifications

Regulatory Information

The GE Vingmed Ultrasound product families are tested to meet all applicable requirements in relevant EU Directives and European/International standards. (See “Standards used” below.) Any changes to accessories, peripheral units or any other part of the system must be approved by the manufacturer; GE Vingmed Ultrasound. **Ignoring this advice may compromise the regulatory approvals obtained for the product.**

Please consult your local GE Vingmed Ultrasound representative for further details.

Standards used

Our ultrasound scanners are class I devices, according to Clause 14 of IEC 60601-1 (1988).

To fulfill the requirements of relevant EC directives and/or European Harmonized/International standards, the following documents/standards have been used:

STANDARD/DIRECTIVE	SCOPE
93/42/EEC	Medical Devices Directive (MDD)
IEC 801-2/ 4.1991	Electrostatic Discharge
IEC 801-3/ 1984	Radiated Electromagnetic Field
IEC 801-4/ 1988	Electrical Fast Transient/Burst
IEC 801-5/ 1.1993(draft)	Surge
EN 55011/CISPR 11/ 3.1991	Emitted noise according to Class B requirements + Electromagnetic Susceptibility
IEC 60601-1 (1988) EN 60601-1/ 1990 UL2601-1/ 8.1994	Medical Electrical Equipment, Part 1; General Requirements for Safety “CLASSIFIED BY UNDERWRITERS LABORATARIES INC WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL2601-1 AND CAN/CSA C22.2 NO.601.1”
IEC 1157/ EN 61157/ 1994	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment.
IEC EN 60601-1-2 /1993	Medical Electrical Equipment - part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.

NOTE:
1) Any rest energy within our scanners or their components will be below 60V DC or 2 mJ.
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CE 0301

System Five

System Architecture

- All-modality digital Front-End for excellent cardiovascular performance with high frame rate and advanced research capabilities

Data Acquisition

- High precision data acquisition
- Programmable open-ended system architecture
- 12 bit A/D converters per physical channel
- Application specific Digital Beam Forming algorithms for each mode
- Supports Curved Linear, Phased Array and Doppler transducers
- Receive focusing, aperture, apodization, and frequency response are all continuously variable as a function of depth

Data Processing

- PipeLink™ technology: high speed echo data processing
- Echo data processing of phase, amplitude and frequency
- Easily upgraded for future expansions
- Raw data digital replay for retro and looping. Allows for adjustment of all major display parameters and M & A

Display Replay™

- High resolution, flicker-free SVGA 17 inch computer graphics monitor, tilt and swivel
- Resolution of main display 1024 * 768. 16.7 Million simultaneous colors available
- VCR input is played back through Digital Replay™, allowing VCR images to be looped during review
- Scanplane position indicator and probe temperature are displayed with all multiplane TEE probes.
- Image orientation marker
- Selectable display configuration of duplex and triplex modes: side-by-side or top-bottom, during live, Digital Replay™ and clipboard image recall

Display Annotations

- On-screen display of Mechanical Index (MI)
- On-screen display of Thermal Index (TIB, TIS, TIC)
- Patient name/ID
- Hospital name
- Time/date
- Trackball driven annotation arrows
- Scanning parameters
- Active mode display

Tissue Imaging

General

- Variable transmit frequencies for resolution/penetration optimization
- Variable Acquisition Zoom concentrates all image acquisition power into selected Region of Interest ROI)
- Proprietary Confocal Imaging™
- Variable Contour filtering for edge enhancement
- Depth range up to 30 cm, transducer specific
- Selectable grayscale parameters: Gain, Reject, Compress can be adjusted in Live, Digital Replay™ or image clipboard recall
- Predefined TGC curves require minimal operator interaction - application specific

2D-mode

- Sector tilt capability
- Frame Rate in excess of 600 fps, depending on transducer, settings and applications
- Coded Octave Imaging™ 2nd generation harmonic tissue imaging providing improved lateral and contrast resolution over conventional imaging. Features reduced noise and improved wall definition. COI™ gives improved axial resolution without sacrificing frame rate, making it the tissue modality of choice for all patient groups.
- Confocal Imaging™ allows for multiple focal zones over range of view and a high vector density, probes dependent.
- Variable image width: a reduction either increases frame rate or increases the number of focal zones while maintaining the frame rate, application dependent
- L/R and Up/Down invert, in live, Digital Replay™ or image clipboard recall
- Digital Replay™ for retrospective review or automatic looping of images, allowing for adjustment of parameters such as gain, color, reject, Anatomical M-Mode (optional), persistence and replay speed.
- Data Dependent Processing™ performs temporal

processing which reduces random noise but leaves motion of significant tissue structures largely unaffected. Can be adjusted even in Digital Replay™
- Colorized 2D-mode, user selectable in real-time, Digital Replay™

M-mode

- Trackball Steerable M-Mode line available with all imaging transducers, max steering angle is transducer dependent.
- Simultaneous Real Time 2D- and M-mode.
- M-mode PRF 1 kHz, all image data acquired are combined to give high quality recording regardless of display scroll speed.
- Digital Replay™ for retrospective review of spectral data
- 1/3 - 2/3, 2/3 - 1/3, 1/2 - 1/2, side-by-side or top-bottom duplex display formats. Can be adjusted in Live or Digital Replay™.
- Selectable horizontal scroll speed:
  1, 2, 4, 8, 16 seconds across display.
  Can be adjusted in Live or Digital Replay™.

Color Doppler

General

- Steerable Color Doppler available with all imaging transducers, max steering angle is transducer dependent
- Trackball-controlled ROI
- Removal of color map from the tissue during Digital Replay™
- Digital Replay™ for retrospective review of Color M-mode data allowing for adjustment of parameters such as encoding principle, Color Priority and Color Gain even on frozen data
- Mosaic and variance maps to delineate disturbed flow and high velocity jets, user selectable in Digital Replay™ and image clipboard recall
- PRF settings, user selectable
- Advanced Regression Wall Filter gives efficient suppression of wall clutter
- For each encoding principle multiple color maps can be selected, in live and Digital Replay™
- More than 65,000 simultaneous colors processed, providing a smooth display two-dimensional color maps containing a multitude of color hues
- Color Invert, user selectable in Live and Digital Replay™
- Variable color baseline, user selectable in Live & Digital Replay™
- Multivariate Color Priority function gives reliable delineation of disturbed flows even across bright areas of the 2D-mode image
- Selection of color maps
- Color Doppler freq. can be changed independently from 2D for optimal flow

Color Doppler Imaging

- Frame Rate in excess of 100 fps, depending on transducer and settings
- Variable ROI size in width and depth
- Very high digital signal processing power, maintaining high frame rates with large ROIs even for very low PRF settings
- Advanced Regression Wall Filter
- User selectable Radial and Lateral Averaging for reduction of statistical uncertainty in the color velocity and variance estimates
- Data Dependent Processing™ (DDP) performs temporal processing and display smoothing with reduced possibility for loss of transient events of hemodynamic significance.
- Digital Replay™ for retrospective review or automatic looping of color images, allowing for adjustment of parameters such as DDP, encoding principle, baseline shift, color maps, color priority and color gain even on frozen/recalled data
- Application dependent Multivariate Motion Discriminator reduces flash artifacts
- Same controls and functions available as in standard 2D color Doppler
- Dedicated coronary flow application

Color Angio (Color Intensity Imaging)

- Angle independent mode for visualization of small vessels with increased sensitivity compared to standard color flow

Color M-mode

- Variable ROI size, user selectable
- User selectable Radial Averaging for reduction of statistical uncertainty in the color velocity and variance estimates
- Selectable horizontal scroll speed: 1, 2, 4, 8, 16 seconds across display. Can be adjusted during Live, Digital Replay™ or image clipboard recall.
- Real-time 2D image while in color M-mode
- Same controls and functions available as in standard 2D color Doppler

Spectral Doppler

General

- Operates in PW, HPRF, and CW modes
- Trackball Steerable Doppler available with all imaging transducers, max steering angle is transducer dependent
- Selectable Doppler frequency for better optimization
- High-Quality Real Time Duplex or Triplex operation in all Doppler modes, CW and PW and for all velocity settings
- Frame Rate control for optimized use of acquisition power between spectrum, 2D, and Color Doppler modes in duplex or triplex modes
- Very fast and flexible spectrum analysis with an equivalent DFT rate of 0.2 ms
- Dynamic Gain Compensation™ for display of flows with varying signal strengths over the cardiac cycle and improved ease-of-use
- Dynamic Reject™ gives consistent suppression of background, user selectable, in real-time, Digital Replay™ or image clipboard recall
- Digital Replay™ for retrospective review of spectral Doppler data.
- 1/3 - 2/3, 2/3 - 1/3, 1/2 - 1/2 duplex display formats, side-by-side or top-bottom. Can be adjusted in Live or Digital Replay™.
- Selectable horizontal scroll speed:

  1, 2, 4, 8, 16 seconds across display. Can be adjusted in Live or Digital Replay™.
- Adjustable spectral Doppler display parameters: Gain, Reject, Compress, color maps, can be adjusted in Live or Digital Replay™
- User adjustable baseline shift, in Live, Digital Replay™ and image clipboard recall
- Adjustable velocity scale
- Wall filters with range 10 - 2000 Hz (velocity scale dependent)
- Angle correction with automatic adjustment of velocity scale, in Live, Digital Replay™ and image clipboard recall
- Stereo speakers mounted in the front panel
- Display annotations of frequency, mode, scales, Nyquist limit, wall filter setting, angle correction, acoustic power indices.

PW / HPRF Doppler

- Automatic HPRF Doppler maintains its sensitivity even for shallow depths and with the highest PRFs
- Digital Velocity Tracking Doppler™ employs processing in range and time for high quality spectral displays
- Frequency Over-range control allows analysis and display of narrowband velocities exceeding the Nyquist limit.
- Adjustable sample volume size of 1-20 mm (transducer dependent).
- Maximum sample volume depth 30 cm.

CW Doppler

- Highly sensitive steerable CW available with all phased array probes.

Physiological Traces

- Up to 4 traces display simultaneously.
- ECG trigger.
- High-resolution display of the following traces: ECG, Respiration, Pressure, Phono.

Analysis Program

- Bodymark icons for loca-

tion and position of transducer
- Cardiac calculation package including extensive measurements, and display of multiple repeated measurements.
- Vascular measurements package
- Measurements assignable to report generator
- Doppler auto trace function with automatic calculations
- Possibility of performing Measure and Analysis on video playback
- User assignable parameters

User Interface
- Easy-to-learn user interface with intelligent keyboard
- Front Panel with assignable rotaries and push buttons for primary controls, application specific
- Application specific secondary controls available through slidebars operated by paddles
- Slide pot TGC curve with 8 pots
- Overall gain for 2D-mode, Depth and Zoom Span on dedicated rotaries
- Digital harvesting of images and loops into Image Clipboard
- Patient Browser screen for registration of demographic data and quick review of Image Clipboard contents
- Fully programmable user presets for probe/application default settings
- Support for international (European) keyboard character sets (ISO 8859)

Image Memory

- 2D, CFM or TVI data at maximum framerate may be reviewed by scrolling or by running cineloops.
- “Image Clipboard” for stamp-size storage and review of stored images and loops.
- Built-in patient archive with images/loops, patient information and measurements
- Internal archive can be exported to Removable Image Storage through Magneto-Optical Disk of EchoPAC™.
- Internal hard-disk: storing Programs, Application defaults, Ultrasound Images and patient archive.
- All ultrasound data storage is digital RF data based, allowing to change gain, baseline, color maps, sweepspeeds etc., for recalled images and loops.

Advanced Options

Compound Imaging
- Real-time Compound Imaging mode with linear arrays for improved delineation of curved structures and speckle reduction without loss of any image resolution.

Anatomical M-mode™
- M-mode generated from the cursor independent from the axial plane, can be activated from Digital Replay™ or image clipboard recall
- M & A Capability

Tissue Velocity Imaging™
- Myocardial Doppler Imaging with color overlay on tissue image
- Digital Velocity profile analysis allowing velocity and time quantification at any point and at any time during the heart cycle from Digital Replay™ or image clipboard recall.
- Quantitative Segmental wall motion analysis can be obtained with use of Anatomical M-mode, from Digital Replay™ or image clipboard recall
- The velocity of all myocardial segments after entire heart cycle can be displayed in one single image.
- Tissue color overlay can be removed to show just the 2D image, still retaining the tissue velocity information.
- Tissue Tracking: real time integrated TVI display.

Contrast Option*
- Myocardial Contrast (MC) Application:
  - Based on 2 nd harmonic Imaging, optimized for detection of contrast specific signals within the myocardium in ECG-triggered mode
  - Available in 2D Tissue harmonic imaging and Color Angio
  - Probe dependent: 2.5 MHz FPA, 3.5MHz FPA and 5.0 MHz MPTE
- Left Ventricular Contrast (LVC):

- Based on 2nd harmonic imaging, optimized for LV edge detection and LV thrombus detection.
- Probe dependent: 2.5 MHz FPA, 3.5 MHz FPA and 5.0 MHz MPTE.

Digital RF (Radio Frequency) output (Research option)

- Features acquisition and export of ultrasound RF data
- Special EchoPAC™ module: EchoResearch available to translate to MATLAB® file format, allowing for complex and extensive signal processing to the imported data
- Probe dependent
- Echo densitometry
- RF Spectroscopy

Biopsy Support

- Biopsy needle probe attachment for the following transducers:
  - 3.5 MHz Convex Array
  - 10.0 MHz Linear Array
- On-screen biopsy guideline display

Continuous capture option

- Small rodents option
- Special applications option to optimize performance when scanning small animals. For high frequency probes.

EchoPAC™

- EchoPAC™ adds post-processing and data archiving capabilities to System FiVe™. It takes special advantage of the easy access to ultrasound raw data provided by the system.
- EchoPAC™ is available as a fully integrated module into the ultrasound system or as a standalone review station
- EchoPAC™ captures scan data from basic ultrasound application such as adult and pediatric cardiac, stress echo

echo-cardiography, transesophageal and intra-operative imaging.

- The software is available as application related modules:

Echo Basic:

- Raw data acquisition at original frame rate and resolution from scanner or video grabbing image capture and storage.
- Complete patient and image archive database.
- Advanced Post processing analysis.
- Anatomical M-Mode
- Complete M&A and Reporting capabilities
- Clinical data, PICT or JPEG files from one or several studies can be stored into a common repository. The files may then be loaded into the computer memory for quick recall during presentation or peer-reviews.
- DICOM Media Interchange: storage to removable media and import from removable media of DICOM images (single or multiframe).
- Magneto-optical disk drive.

Echo Stress

- Advanced and flexible stress-echo capabilities

EchoResearch

- Advanced analysis features such as:
  - -Quantitative TVI
  - -RF analysis
  - -3D casting Echo3D (research option)
- Post-processing of scan data captured with an attached position sensing device for 3D scanning
- Volume visualization and measurements
- 3D color flow visualization.

Echo Client

- Enables System FiVe for communication with a central database.
- Optional HL7 Communicator for export and import of data going to or coming from HIS.

Echo Contrast

- This module lets the user perform analysis and post processing on Contrast Harmonic images (2D and Angio data) such as:
  - -Time-Intensity analysis (densitometry).
  - -Backscatter analysis
  - -Baseline Image Substraction.
  - -Arbitrary straight Anatomical M-Mode
  - -Arbitrary curved Anatomical M-Mode
  - -Caliper
  - -Area

Echo DICOM

- Enables the user to store DICOM images (single and multiframe) and verify connection to any DICOM device

Echo Import

- Enables EchoPAC™ to read, display and import images and measurements from MO-disks from HP Sonos ultra-

sound systems.

PDF Creator

- enables user to create PDF (Portable Document Format) reports directly from EchoPAC.

Peripherals (options)

- Integrated VCR controls (VCR peripheral option)
- Recommended VCR: Sony 9500.
- Hard-copy devices: Any Video-based device using Composite, S-Video or RGB format PAL video.

Cart

- Low rolling resistance casters
- Brakes on front casters
- Direction of rear casters can be locked for improved maneuverability
- Intelligent Fans: revolution speed is automatically adapted to the system’s internal operating temperature, reducing audible fan noise

Indications for use

System FiVe is intended for the forllowing applications:

Abdominal, Cardiac, Small Organ, Pediatric, Fetal, Intra-Operative, Transesophageal, Transvaginal, Transrectal, Peripheral Vascular, Neonatal and Adult Cephalic.

Contraindication:

"System FiVe is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye."

CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

Technical Specifications

Probe / Application / System overview(Max.Configuration)

Name: CLA 3.5MHz	**Type:** Curved Linear Array probe		**Part Number:** KK 100004
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Aorto-Iliac	y	y	Not intended for fetal use
Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Fetal Heart	y	y	
Obstetrics	y	y	
Pelvic	y	y	Not intended for fetal use
Renal	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use

Name: CLA 5.0MHz	**Type:** Curved Linear Array probe		**Part Number:** KN 100008
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Aorto-Iliac	y	y	Not intended for fetal use
Fetal Heart	y	y	
Obstetrics	y	y	
Pelvic	y	y	Not intended for fetal use
Renal	y	y	Not intended for fetal use

Name: ECLA 6.25MHz	**Type:** Curved Linear Array (Endocavity) probe		**Part Number:** KQ 100002
System Five Application	**System Five**	**System FiveUS**	**Note**
Obstetrics	y	y	
Pelvic	y	y	Not intended for fetal use
Prostate	y	y	Not intended for fetal use

Technical Specifications
Probe / Application / System overview(Max.Configuration) Cont..d

Name: FLA 5.0MHz	**Type:** Flat Linear Array probe		**Part Number:** KN 100003
System Five Application	**System Five**	**System Five US**	**Note**
Carotid	y	y	Not intended for fetal use
Limbs-Arterial	y	y	Not intended for fetal use
Limbs-Veneous	y	y	Not intended for fetal use
Superficial	y	y	Not intended for fetal use
Breast	y	y	Not intended for fetal use

Name: FLA 7.5MHz	**Type:** Flat Linear Array probe		**Part Number:** KT 100001
System Five Application	**System Five**	**System Five US**	**Note**
Breast	y	n	Not intended for fetal use
Carotid	y	n	Not intended for fetal use
Limbs-Arterial	y	n	Not intended for fetal use
Limbs-Veneous	y	n	Not intended for fetal use
Long acquisition	y	n	Not intended for fetal use
RF (Research Option)	y	n	Not intended for fetal use
Superficial	y	n	Not intended for fetal use

Name: FLA10MHz	**Type**: Flat Linear Array probe		**Part Number:** KW 100001
System Five Application	**System Five**	**System Five US**	**Note**
Breast	y	y	Not intended for fetal use
Carotid	y	y	Not intended for fetal use
Limbs-Arterial	y	y	Not intended for fetal use
Limbs-Veneous	y	y	Not intended for fetal use
Long acquisition	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Superficial	y	y	Not intended for fetal use

Technical Specifications

Probe / Application / System overview(Max.Configuration) Cont..d

Name: FPA 2.5MHz	**Type:** Flat Phased Array probe		**Part Number:** KG 100001/A
System Five Application	**System Five**	**System Five US**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
Transcranial	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Technical Specifications
Probe / Application / System overview(Max.Configuration) Cont..d

Name: FPA 2.5MHz	**Type**: Flat Phased Array probe		**Part Number**: KG 100001/B
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
Transcranial	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Name: FPA 2.5MHz	**Type**: Flat Phased Array probe		**Part Number**: KG 100001/C
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
Transcranial	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Technical Specifications

Probe / Application / System overview(Max.Configuration) Cont..d

Name: FPA 3.5MHz	**Type**: Flat Phased Array probe		**Part Number:** KK 100001/A
System Five Application	**System Five**	**System Five US**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Name: FPA 3.5MHz	**Type**:Flat Phased Array probe		**Part Number**: KK 100001/BC
System Five Application	**System Five**	**System Five US**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Technical Specifications
Probe / Application / System overview(Max.Configuration) Cont..d

Name: FPA 3.5MHz	**Type:** Flat Phased Array probe		**Part Number**: KK 100005
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
Octave RF (Research Option)	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
RF (Research Option)	y	y	Not intended for fetal use
Digital Stress	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Stress	y	y	Not intended for fetal use

Name: FPA 5MHz	**Type:** Flat Phased Array probe		**Part Number:** KN 100001
System Five Application	**System Five**	**System FiveUS**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
Fetal Heart	y	y	
HFR	y	y	Not intended for fetal use
Neonatal Head	y	y	Not intended for fetal use
Pediatric heart	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Obstetrics	y	y	

Technical Specifications

Probe / Application / System overview(Max.Configuration) Cont..d

Name: FPA 5MHz Ped	**Type**:Flat Phased Array probe		**Part Number**: KN 100002/A
System Five Application	**System Five.**	**System Five US**	**Note**
Abdominal	y	n	Not intended for fetal use
Cardiac	y	n	Not intended for fetal use
Coronary	y	n	Not intended for fetal use
HFR	y	n	Not intended for fetal use
Neonatal Head	y	n	Not intended for fetal use
Pediatric heart	y	n	Not intended for fetal use
TVI	y	n	Not intended for fetal use

Name: FPA 5MHz Ped	**Type**: Flat Phased Array probe		**Part Number**: KN 100002/B
System Five Application	**System Five.**	**System Five US**	**Note**
Abdominal	y	y	Not intended for fetal use
Cardiac	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
Neonatal Head	y	y	Not intended for fetal use
Pediatric heart	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use

Name: FPA 10MHz Ped	**Type**: Flat Phased Array probe		**Part Number**: KW100002
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use
Pediatric Heart	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
Neonatal Head	y	y	Not intended for fetal use

Technical Specifications
Probe / Application / System overview(Max.Configuration) Cont..d

Name: DOP 2MHz	**Type:** Doppler probe		**Part Number:** TE 100024
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use

Name: DOP TC 2MHz	**Type**: Doppler Transcranial probe		**Part Number**: KE 100001
System Five Application	**System Five**	**System FiveUS**	**Note**
Transcranial	y	n	Not intended for fetal use

Name: DOP 6MHz	**Type**: Doppler probe		**Part Number**: TQ 100001
System Five Application	**System Five**	**System FiveUS**	**Note**
Carotid	y	y	Not intended for fetal use

Name: DOP 6MHz	**Type**: Doppler probe		**Part Number**: TQ 100002
System Five Application	**System Five**	**System FiveUS**	**Note**
Carotid	y	y	Not intended for fetal use

Name: APA 2.5MHz	**Type**: Annular Array probe		**Part Number**: TG 100102
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use

Name: APA 3.25MHz	**Type**: Annular Array probe		**Part Number:** TK 100104
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use

Technical Specifications

Probe / Application / System overview (Max.Configuration) Cont..d

Name: APA 5MHz	**Type**: Annular Array probe		**Part Number**: TN 100119
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use

Name: APA 7.5MHz	**Type**:Annular Array probe		**Part Number**: TT 100101
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use
Carotid	y	y	Not intended for fetal use

Name: APA TE 5MHz	**Type**: Annular Array Transe-sophageal probe		**Part Number**: TN 100047
System Five Application	**System Five**	**System FiveUS**	**Note**
Cardiac	y	n	Not intended for fetal use

NameAPA MPTE 5MHz	**Type**: Annular Array Transe-sophageal (Multiplane)		**Part Number**: TN 100053
System Five Application	**System Five.**	**System FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use

Name: APA MPTE Ped	**Type**: Annular Array Transe-sophageal (Multiplane)		**Part Number** : TN 100065
System Five Application	**System Five**	**System FiveUS**	**Note**
Pediatric heart	y	y	Not intended for fetal use

Name:PA MPTE 5MHz	**Type**: Phased Array Transe-sophageal (Multiplane)		**Part Number**: KN 100006
System Five Application	**System Five.**	**PSystem FiveUS**	**Note**
Cardiac	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
MC Contrast	y	y	Not intended for fetal use
LV Contrast	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use

Technical Specifications

Probe / Application / System overview(Max.Configuration) Cont..d

Name: PA MPTE 5MHz	**Type**: Phased Array Transesophageal (Multiplane)		**Part Number:** KN 100007/A
System Five Application	**System Five**	**System Five US**	**Note**
Cardiac	y	n	Not intended for fetal use
Coronary	y	n	Not intended for fetal use
HFR	y	n	Not intended for fetal use
TVI	y	n	Not intended for fetal use

Name: PA MPTE 5MHz	**Type**: Phased Array Transesophageal (Multiplane)		**Part Number**: KN 100007/B
System Five Application	**System Five**	**System Five US**	**Note**
Cardiac	y	y	Not intended for fetal use
Coronary	y	y	Not intended for fetal use
HFR	y	y	Not intended for fetal use
TVI	y	y	Not intended for fetal use

Name: PA MPTE Ped	**Type**: Phased Array Transesophageal (Multiplane)		**Part Number** : KN 100010
System Five Application	**System Five**	**System FiveUS**	**Note**
Pediatric heart	y	y	Not intended for fetal use

Options

See page 204 for the options for this product version

Technical Specifications

Guidelines for Fetal use

Ultrasound Energy Exposure

Ultrasonic energy, propagated via mechanical compressions and rarefactions of the media through which it travels. These compressions and rarefactions happen at the transducer’s natural frequency. If the acoustic intensities are great enough, i.e. the compressions and rarefactions are large enough, an effect called cavitation (or micro-cavitation) may occur.

This cavitation can cause physical damage or disruption at the cellular level. No reports of bio-effects caused by ultrasonic energy in the intensity ranges used on System FiVe are documented to this date. This lack of bio-effects not with standing - IT IS PRUDENT TO KEEP ULTRASOUND EXPOSURE AS LOW AS POSSIBLE, within the constraints of getting the data necessary and enough to develop a meaningful and clinical diagnosis.

Fetal Exposure to Ultrasonic Energy

- The fetus is particularly sensitive to cavitation because of, among other factors, its embryological growth and the cell division/differentiation that is constantly happening.

Technical Specifications

Physical Dimensions

***Size: (With monitor and without peripherals)**

Height	Width	Depth
142cm	68.5cm	112cm
55.9 ins	27.0 ins	44.1 ins

Weight without Monitor: System Five196Kg (432 lbs).+Computer +10Kg

Electrical Specifications

Power requirements:

P/N:	Voltage	Tolerances	Current	Frequency
FB000226	230-240VAC	±10%	8 A	50-60 Hz
FB000228	100VAC	±10%	13,5 A	50-60 Hz
FB000227	110-120VAC	±5%	13,2 A	50-60 Hz

REM

Power requirements:

P/N:	Voltage	Tolerances	Current	Frequency
FB000717	230VAC	±10%	8 A	50-60 Hz
FB000715	115VAC	±5%	13,2 A	50-60 Hz
FB000718*	230VAC	±10%	8 A	50-60 Hz
FB000716*	115VAC	±5%	13,2 A	50-60 Hz

*+EchoPAC.

WARNING!
Be absolutely sure that your power source fits the power requirements of your system.

Radiated audio noise level:

Less than 70dB(A) according to DIN 45635 - 19 - 01 - KL2

Technical Specifications

Environmental conditions

SYSTEMS:	
Operating temperature	10 - 35 deg C (50 - 95 deg F)
Storage temperature	-20 - 50 deg C (- 4 - 122 deg F)
Humidity	< 90% non-condensing
Heath dissipation	4500 BTU pr hour

PROBES:				
	Electronic	TE/MPTE	PAMPTE	APAT
Operation	10 - 40	15 - 41,3	15 - 42,7	10 - 35
Storage	-20 - 50	0 - 45	-20 - 50	0 - 50

(all temperatures in deg C, conversion to deg F = deg C*(9/5) + 32)

WARNING:
SYSTEMS AND ELECTRONIC PROBES ARE DESIGNED FOR STORAGE TEMPERATURES OF -20 TO + 50 deg C. WHEN EXPOSED TO LARGE TEMPERATURE VARIATIONS, THE PRODUCT SHOULD BE KEPT IN ROOM TEMPERATURE FOR 10 HOURS BEFORE USE.

MECHANICAL PROBES MAY BE STORED BETWEEN ZERO AND +50 deg C DUE TO CONTENTS OF LIQUID. FACTORY PACKAGING ALLOWS TRANSPORTATION FOR SHORTER PERIODS (LESS THAN 6 HOURS) AT TEMPEREATURES DOWN TO -20 deg C.

MECHANICAL PROBES WITH AIR BUBBLES, A RESULT OF LOW TEMPERATURE STORAGE/TRANSPORTATION, SHOULD BE KEPT IN AN UPRIGHT POSITION UNDER TEMPERATURES BETWEEN + 20 and + 40 deg C UNTIL THE AIR BUBBLES DISSAPEAR.

Specifications are subject to change without notice.

Measurement Accuracy

General

When using the Measurement and Analysis (M&A) package, it is important to keep in mind the different aspects that affect the accuracy of the measurements. These include acoustical properties, patient echogenicity, measurement tools and algorithms, scanner setup (especially Field-of-view or Range settings), probe type used, and operator inputs.

Sources of error

Image Quality

The accuracy of each measurement is highly dependent on image quality. Image quality is highly dependent on system design, operator variability, and patient echogenicity. The operator variability and patient echogenicity are independent of the ultrasound system.

Operator variability

One of the largest potential sources of error is operator variability. A skilled operator can reduce this by optimizing the image quality for each type of measurement. Clear identification of structures, good probe alignment and correct cursor placement is important. Because of pixel resolution, the accuracy of a measurement decreases with decreasing distance on screen. Therefore it is important when scaling the object on the screen to avoid measuring objects that are too small. See also “Optimizing Measurement Accuracy” below for recommended techniques.

Image measurement

The accuracy in lateral direction is limited by the beam width and the beam positioning (especially mechanical positioning for APA probes). The radial accuracy is mainly limited by the acoustic pulse length. Best accuracy is obtained by measuring distances along the beam axis.

Doppler alignment

Errors in velocity measurements increase with the cosine of the angle between the measured flow and the ultrasound beam. For example, an alignment error of 20 degrees, will give a 6% under-estimation of the velocities, while an error of 40 degrees will cause the under-estimation to be 24%.Optimize transducer position to align the beam with the flow direction. If alignment is not possible, you may use the ANgle CORRection control to compensate if the flow direction is known.

Measurement Accuracy

Screen pixel resolution

The display screen is composed of an array of square picture elements (pixels). The smallest resolvable unit is +/- 1pixel. This pixel error is only significant when measuring short distances on the screen. By observing good scanning practices, the settings of the field of view should be such that the measured distance covers a relatively large portion of the screen. When such scaling is impossible, the pixel error may come into play. The pixel error is +/- 0.2 % (or better) of the full ultrasound area in the User Screen.

Algorithms

Some formulae used in clinical calculations are based on assumptions or approximations. For example the volume calculations from 2D or M-mode assume a certain, ‘ideal’ shape of the heart chamber, while the actual shape can vary quite much between individuals. Also, formulae taking several “raw” measurements as inputs are prone to increased errors, depending on the combination of input variable accuracies. For example, the Cardiac Output formula from Doppler is sensitive to errors in the entered Diameter, since this will be squared in the formula.

Speed of Sound in Tissue

The average value 1540 meters / second is used for all calculations. Depending on the tissue structures, this generalization may give errors from 2% (typical) to 5% (much fatty tissue layers present).

Optimizing Measurement Accuracy

Probe selection

Select a transducer appropriate for the application, and optimize the transducer frequencies used. Higher imaging frequencies give better resolution, but less penetration than lower frequencies. Lower Doppler frequencies can measure higher max velocities, and at greater depths, but with less velocity resolution than higher Doppler frequencies.

Field of View

All display modes should be adjusted so that the area of interest covers as large portion of the display as possible. Use DEPTH, ANGLE, ZOOM, HORizontal SWEEP and VELOCITY controls to optimize the different modes.

Cursor Placement

All measurements are dependent on the accuracy of their “input” data. Consistency and precision in placing cursors and drawing traces correctly on the images are important.

Please notice that on curved and linear probes system sensitivity is optimized if cursor placement near the array edges is avoided.

Measurement Accuracy

Measurement Uncertainties

The accuracy percentages reported below are based on data taken with optimum control setings, using calibrated phantoms and test equipment. The tables below does not include sources of error other than system uncertainties, measured under these conditions.

The calibration is done for the measurement primitives: Distance, Time and Velocity. All measurements are based on these, and mathematical formulae are used to calculate the expected accuracy for derived masurements and calculations.

Independent sources of uncertainty contribute to a total uncertainty by a RMS (Root Mean Square) combination of the sources .

Please refer to the discussions above regarding measurement accuracy and sources of error when reading the tables below.

.

Table 1: Cardiac Measurement Uncertainties

Measurement	Typ. Range	Accuracy	Comments
2D			
Distance	1 - 10 cm	7%	Typical range 1 to 10 cm
	> 10 cm	5%	
Area	1 - 300 cm^2	10%	Typical range 1 to 50 cm^2
	> 300 cm^2	7%	
Circumference	6 - 10 cm	10%	Typical Range: 6 - 20 cm
	> 10 cm	7%	
Volume	20 - 150 cm^3	15 - 35%	Length area method
	20 - 150 cm^3	12 - 20%	Method of discs
M-mode			
Calipers			
Distance	1 - 10 cm	5 - 7%	
dt	0.5 - 1.5 s	0.5% - 10%	At low and high sweep rate, resp.
dD/dt	2 - 14 cm/s	5 - 15%	
Left Ventricular study			
Left Ventricular Ejection Fraction	0.4 - 0.7	15 - 20%	
Fractional Shortening	25 - 50%	7 - 10%	
Right Ventricular study			
Right Ventricular Dimension diastole/systole	1 - 10 cm	5 - 7%	

Table 1: Cardiac Measurement Uncertainties

Measurement	Typ. Range	Accuracy	Comments
Left Atrium-Aortic opening study			
Mitral Valve Excursion	1 - 10 cm	5 - 7%	
Mitral Valve EF slope	2 - 14 cm/s	5 - 15%	
Spectrum			
Calipers			
Velocity (v1 - v2)	0.5 - 1.0 m/s	6%	
dt	0.5 - 1.5 s	0.5% - 10%	At low and high sweep rate, resp.
dv	0 - 1.0 m/s	8.5%	Accuracy of dv decreases when v1 and v2 approach each other
dv/dt	0.1 - 10 m/s^2	8 - 14%	
P (pressure gradient)	40 - 200 mmHg	12 - 20%	Simplified Bernoulli equation
Envelope Tracing			
Vmax	0.5 - 1.0 m/s	6%	
Pmax	0.1 - 10 m/s^2	12 - 20%	
Vmean	0 - 1.0 m/s	6 - 12%	
Pmean	60 - 180 mmHg	12 - 16%	
Velocity Time Integral (VTI)	8 - 20 cm	6 - 10%	
Heart Rate	40 - 200 BPM	0.5 - 10%	
Cardiac Output	3.0 - 6.0 l/min	14 - 25%	The accuracy of the manually entered diameter is significant since the value is squared in the equation
Pressure Half-Time (PHT)	40 - 500 ms	6 - 12%	Accuracy increases with the distance between the two points
Derived Measurements displayed in Report			
M-mode derived			
LV Ejection Fraction	0.4 - 0.7	15 - 20%	
Fractional Shortening	25 - 50%	7 - 10%	
LA/AO Ratio	1.2 - 1.7	7 - 14%	
Spectrum derived			
Mitral Valve Area	0.5 - 5.0 cm^2	6 - 12%	
Mitral Valve Area by Continuity Equation	0.5 - 5.0 cm^2	13 - 25%	

Table 1: Cardiac Measurement Uncertainties

Measurement	Typ. Range	Accuracy	Comments
Aortic Valve Area by Continuity Equation	0.5 - 5.0 cm^2	13 - 25%	
Aortic Valve Area from Vmax	0.5 - 3.0 cm^2	13 - 20%	

Table 2: Peripheral/Vascular Measurement Uncertainties

Measurement	Typ. Range	Accuracy	Comments
2D			
Distance	1 - 10 cm	7%	Typical range 1 to 10 cm
	> 10 cm	5%	
Distance Stenosis	20 - 80%	7 - 14%	
Area	5 - 30 cm^2	10%	
Area Stenosis	20 - 80%	15 - 25%	
M-mode			
Distance	1 - 10	5 - 10%	
Spectrum			Alignment error < 20% assumed
Calipers			
Velocity (v1 - v2)	0.2 - 1.5 m/s	6%	
dt	0.5 - 1.5 s	0.5% - 10%	At low and high sweep rate, resp.
dv	0 - 1.0 m/s	8.5%	Accuracy of dv decreases when v1 and v2 approach each other
Resistance Index	0.2 - 0.8	9%	
S/D (Vmax/Vmin)	3 - 7	9%	
Automatic Tracing			Best on a clean, strong Doppler signal
Flow	3 - 5 l/min	13 - 20%	
Manual Tracing	3 - 5 l/min	13 - 20%	
Pulsatility Index (PI)	2 - 10	10%	
TAV ratio	2 - 8	9%	
Automatic Average Velocity Calc.		17%	
Bandwidth		17%	

Chapter H

Symbols

This chapter provides you with an overview of the International symbols that are used by GE Vingmed Ultrasound.

Chapter H shows you:

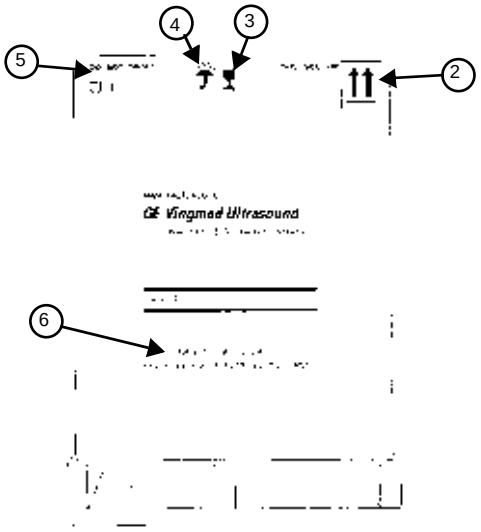
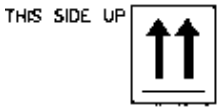
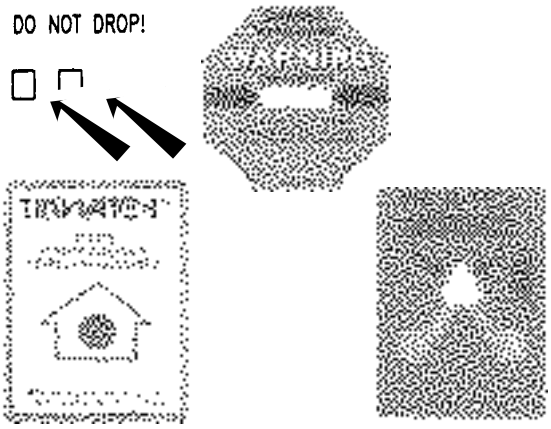
System Symbols

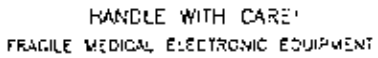
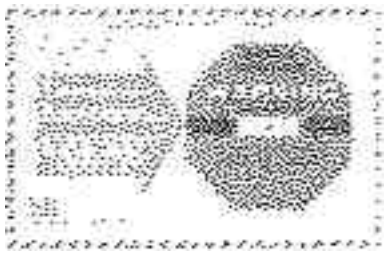
Symbols used by Vingmed Sound are described below, together with reference to international publication(s).

No.	Symbol	IEC publication	Description
1		417-5032	Alternating current
2		417-5019	Protective earth (ground)
3		417-5017	Earth (ground)
4		417-5021	Equipotentiality
5		348	Attention, consult ACCOMPANYING DOCUMENTS
6		417-5008	Off (power: disconnection from the mains)
7		417-5007	On (power: connection to the mains)

No.	Symbol	IEC pub-lication	Description
8		417-5065	“Off” (only for a part of EQUIPMENT)
9		417-5064	“On” (only for a part of EQUIPMENT)
10		878-02-02	TYPE B EQUIPMENT
11		878-02-03	TYPE BF EQUIPMENT
12			TYPE CF EQUIPMENT
13		878-03-01	Dangerous voltage
14			Freeze
15			Screen Cursor

Shipment Symbols

No.	Symbol	Ref.	Description
1			Extract of Symbols from a VINGMED shipment
2			Transport Placeing instructions: **THIS SIDE UP**
3			Fragile, handle with **utmost** care symbol
4			Avoid **all** wetness symbol
5			**TILT-N-TIP** or **TILT-WATCH** and **SHOCK-WATCH** positionining area. Tilt-n-tip is not used so often as Tilt-watch. See also 7 and 8.

No.	Symbol	Ref.	Description
6			**HANDLE WITH CARE** and **FRAGILE MEDICAL ELECTRONIC EQUIPTMENT** warnings text in english
7			**TILTWATCH**, Detects and reports system-fatal shipment-tilting that may happen during transport. Color dye is visible in the round hole in the middle of the arrow, when this occurs
8			**SHOCKWATCH**, Detects and reports system-fatal shipment shock-movements that may happen during transport. Color dye is visible in the tube side-view between two arrows, when this occurs.

Keyboard Symbols

Symbol	Meaning	Language
AUDIO	AUDIO ACOUSTIQUE AUDIO AUDIO ÁUDIO AUDIO	English French German Italien Portuguese Spanish
HEAD-PHONE	HEADPHONE ÉCOUTEUR KOPFHÖRER CUFFIA HEADPHONE AURICULAR	English French German Italien Portuguese Spanish
ILLUM.	ILLUMINATION ILLUMINATION ABLICHTUNG ILLUMINAZIONE ILUMINAÇÃO ILUMINACIÓN	English French German Italien Portuguese Spanish
INFO	INFORMATION L'cInformation INFORMATIONEN Le INFORMAZIONI INFORMAÇÃO INFORMACIÓN	English French German Italien Portuguese Spanish
	Annotation Annotation Anmerkung Annotazione Anotação Anotación	English French German Italien Portuguese Spanish
HELP	HELP AIDE HILFE AIUTO AJUDA AYUDA	English French German Italien Portuguese Spanish
BIOPSY	BIOPSY BIOPSIE BIOPSIE BIOPSIA BIOPSY BIOPSIA	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
BODY MARK	BODY MARK MARQUE DE CORPS KÖRPER Markierung CONTRASSEGNO DEL CORPO MARCA DO CORPO MARCA DEL CUERPO	English French German Italien Portuguese Spanish
TEXT	TEXT TEXTE TEXT TESTO TEXTO TEXTO	English French German Italien Portuguese Spanish
LINE ERASE	LINE ERASE LA LIGNE EFFACENT ZEILE LÖSCHEN LA RIGA CANCELLA A LINHA APAGA LA LÍNEA BORRA	English French German Italien Portuguese Spanish
PAGE ERASE	PAGE ERASE LA PAGE EFFACENT SEITE LÖSCHEN LA PAGINA CANCELLA A PÁGINA APAGA LA PAGINACIÓN BORRA	English French German Italien Portuguese Spanish
SCREEN CONFIG	SCREEN CONFIG CONFIGURATION D'CÉcran BILDSCHIRM Konfiguration CONFIGURAZIONE DELLO SCHERMO CONFIGURAÇÃO DA TELA CONFIGURACIÓN DE LA PANTALLA	English French German Italien Portuguese Spanish
PHYS. TRACE	PHYSIOLOGICAL TRACE PHYSIOLOGIQUE TRACE PHYSIOLOGISCHE SPUR FISIOLOGICA TRACCIA PHYSIOLOGICAL TRAÇO FISIOLÓGICO RASTRO	English French German Italien Portuguese Spanish
VIDEO PLAY-BACK	VIDEO PLAYBACK VISUEL PLAYBACK VIDEO Playback VIDEO PLAYBACK VIDEO PLAYBACK VIDEO APARATO DE LECTURA	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
ESC	ESCAPE ÉVASION ENTWEICHEN FUGA ESCAPE ESCAPE	English French German Italien Portuguese Spanish
SPLIT SCREEN	SPLIT SCREEN DIVISÉ ÉCRAN AUFGETEILTER BILDSCHIRM SPACCATO SCHERMO RACHADA TELA DIVIDIDA PANTALLA	English French German Italien Portuguese Spanish
SELECT SCREEN	SELECT SCREEN CHOISISSEZ L'CÉcran WÄHLEN SIE BILDSCHIRM AUS SELEZIONARE LO SCHERMO SELECIONE A TELA SELECCIONE LA PANTALLA	English French German Italien Portuguese Spanish
SETUP	SETUP INSTALLATION SETUP MESSA A PUNTO INSTALAÇÃO DISPOSICIÓN	English French German Italien Portuguese Spanish
PROBE	PROBE SONDE SONDE SONDA PONTA DE PROVA PUNTA DE PRUEBA	English French German Italien Portuguese Spanish
APPLICA-TION	APPLICATION APPLICATION ANWENDUNG APPLICAZIONE APLICAÇÃO APLICACIÓN	English French German Italien Portuguese Spanish
PAT.ID.	PATIENT IDENTITY PATIENTE IDENTITÉ GEDULDIGE IDENTITÄT PAZIENTE IDENTITÀ PACIENTE IDENTIDADE PACIENTE IDENTIDAD	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
ADD MODE/ CURSOR	ADD MODE/CURSOR AJOUTEZ MODE/CURSOR FÜGEN SIE MODE/CURSOR HINZU AGGIUNGERE MODE/CURSOR ADICIONE MODE/CURSOR AGREGUE MODE/CURSOR	English French German Italien Portuguese Spanish
PW	PULSED WAVE PULSÉE VAGUE PULSIERTE WELLE PULSATA ONDA PULSADA ONDA PULSADA ONDA	English French German Italien Portuguese Spanish
M-MODE	M-MODE M-MODE M-MODE M-MODE M-MODE M-MODE	English French German Italien Portuguese Spanish
2D	2 DIMENSIONAL 2 DIMENSIONNEL 2 DIMENSIONAL 2 DIMENSIONALE 2 DIMENSIONAL 2 DIMENSIONAL	English French German Italien Portuguese Spanish
ACTIVE MODE	ACTIVE MODE ACTIF MODE AKTIVER MODUS ATTIVO MODO ATIVA MODALIDADE ACTIVO MODO	English French German Italien Portuguese Spanish
CW	CONTINUOUS WAVE CONTINUE VAGUE UNUNTERBROCHENE WELLE CONTINUA ONDA CONTÍNUA ONDA CONTINUA ONDA	English French German Italien Portuguese Spanish
CFM	COLOR FLOW MODE MODE D'CÉcoulement DE COULEUR FARBE FLUSS Modus MODO DI FLUSSO DI COLORE MODALIDADE DO FLUXO DA COR MODO DEL FLUJO DEL COLOR	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
GAIN	GAIN GAIN GEWINN GUADAGNO GANHO AUMENTO	English French German Italien Portuguese Spanish
DEPTH	DEPTH PROFONDEUR TIEFE PROFONDITÀ PROFUNDIDADE PROFUNDIDAD	English French German Italien Portuguese Spanish
ZOOM	ZOOM ZOOM ZOOM ZOOM ZOOM ZOOM	English French German Italien Portuguese Spanish
SPLIT SCREEN SELECT	SPLIT SCREEN SELECT ÉCRAN DIVISÉ CHOISI AUFGETEILTER BILDSCHIRM AUSERWÄHLT SCHERMO SPACCATO PRESCELTO TELA RACHADA SELETA PANTALLA DIVIDIDA SELECTA	English French German Italien Portuguese Spanish
2D FREEZE	2D FREEZE 2D GEL 2D FREEZE 2D FREEZE 2D FREEZE 2.O HELADA	English French German Italien Portuguese Spanish
REPORT	REPORT ENREGISTRENT BERICHTEN SEGNALANO RELATÓRIO SEÑALAN	English French German Italien Portuguese Spanish
IMAGE RECALL	IMAGE RECALL RAPPEL D'CImage BILD Rückruf RICHIAMO DI IMMAGINE RECORDAÇÃO DA IMAGEM MEMORIA DE LA IMAGEN	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
VIDEO PREVIEW	VIDEO PREVIEW VISUELLE PRÉVISION VIDEO Vorbetrachtung VIDEO PREVISIONE VIDEO INSPECÇÃO PRÉVIA VIDEO INSPECCIÓN PREVIO	English French German Italien Portuguese Spanish
EchoPAC	EchoPAC EchoPAC EchoPAC EchoPAC EchoPAC EchoPAC	English French German Italien Portuguese Spanish
REC./ PAUSE	REC./PAUSE ENREGISTRENT/PAUSE SATZ/PAUSE REGISTRANO/PAUSA GRAVAM/PAUSA REGISTRAN/PAUSA	English French German Italien Portuguese Spanish
PRINT (Alt)	PRINT (Alternative) Copie (Alternative) Druck (Alternative) Stampa (Alternativa) Cópia (Alternativa) Impresión (Alternativa)	English French German Italien Portuguese Spanish
PRINT	PRINT Copie Druck Stampa Cópia Impresión	English French German Italien Portuguese Spanish
MEAS.	MEASURE MESURE MASS MISURA MEDIDA MEDIDA	English French German Italien Portuguese Spanish
IMAGE SIZE	IMAGE SIZE TAILLE D'CImage BILD Größe FORMATO DI IMMAGINE TAMANHO DA IMAGEM TALLA DE LA IMAGEN	English French German Italien Portuguese Spanish

Symbol	Meaning	Language
FULL FREEZE	FULL FREEZE PLEIN GEL VOLLER FREEZE PIENO FREEZE CHEIO FREEZE LLENA HELADA	English French German Italien Portuguese Spanish
IMAGE STORE	IMAGE STORE MÉMOIRE D'CImage BILD Speicher DEPOSITO DI IMMAGINE LOJA DA IMAGEM ALMACÉN DE LA IMAGEN	English French German Italien Portuguese Spanish
CALIPER	CALIPER ÉTRIER SCHIEBER COMPASSO COMPASSO DE CALIBRE CALIBRADOR	English French German Italien Portuguese Spanish

Chapter L

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Numerics

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ADDENDUM

The following warning on the cover page should be modified from:

“Caution: Federal law restricts this device to sale by or on the order of a physician”

to

Pages 193 to198 should be removed because they are nearly unreadable.

“Caution for USA only: US Federal law restricts this device to sale by or on the order of a physician”

References to ALARA text (As Low As Reasonably Achieveable) in this manual should be removed.

The following sentence is to be added on page 217:

“All probes sold with System FiVe/Vivid FiVe are type CF, except PAMPTE Adult which is type BF.”

The following sentence is to be added on page 200:

“The system meets Class A EMC requirements. Electromagnetic interference between the equipment and other devices may occur.”

The following recycling information is to be added after page 193:

LABEL for locating DISASSEMBLY PROCEDURE

The following small sticker label is found on the system rear plate.

DISASSEMBLY PROCEDURE
Please find disassembly procedure attached to the inside of lower right side panel. To access the procedure remove the panel by unscrewing the 4 screws on the rear side of the panel.

The following sentence is added on page 200:

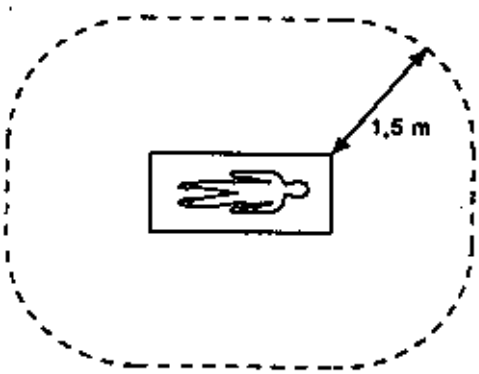
“Circuit diagrams, parts lists etc. will be provided upon request.

The following sentence referring to Packing/Unpacking instructions which accompanies every system, is to be edited into the Warnings Chapter F page 193:

To safeguard the system during all external transportation use the systems original delivery casing with safeguards etc. and follow instructions in the Vivid/System Five Packing/ Unpacking procedure P.No: FA050431.

To be inserted into Warnings Chapter F page 193:

The area inside the dotted line shows the patient environment (refer to local regulations and EN 60601-1-1).



In Chapter F - Warnings, the following sentence should be modified:
“When connecting the System FiVe to a non-insolated device, use a Hospital grade isolation transformer for all mains power supply”

to

“When connecting the System FiVe to a non-insolated device, refer to IEC- EN 60601-1-1 **must be adhered to** (EU) or use a Hospital grade isolation transformer for all mains power supply (USA).”

The following street address should be added to the company data on page 3:

Strandprommenaden 45

Subject: Recommended Liquid Chemical Germicides, To be added to chapter E
In order to provide users with options in choosing a germicide for processing their ultrasound transducer between uses, GE Medical Systems routinely reviews new medical germicides for compatibility with the materials used in the transducer enclosure, cable and lens. Although a necessary step in protecting your patients and employees from disease transmission, liquid chemical germicides must also be selected to minimize potential damage to the transducer.

For cleaning and low-level disinfection, we recommend washing the probe and cable in a warm soap and water solution (<80∞F / 27∞C), removing all visible residue by scrubbing with a soft bristle brush or gauze and using a mild, nonabrasive soap. Rinse with clean water and wipe dry with a soft towel. Check the instructions provided with each probe so as not to exceed the depth to which the probe can be safely immersed in liquid. Do not immerse the electrical connector. Use additional precautions (e.g., gloves and gown) when decontaminating an infected probe.

Low-level disinfection is intended to destroy vegetative bacteria and lipid or medium sized viruses and is somewhat effective on fungi. This is usually sufficient when scanning on intact surface skin.

For high-level disinfection, it is necessary to soak the thoroughly cleaned probe in a suitable liquid chemical germicide for an extended period. Check the instructions provided with each probe so as not to exceed the depth to which the probe can be safely immersed in liquid. Do

not immerse the electrical connector. Use additional precautions (e.g., gloves and gown) when decontaminating an infected probe. The following germicides have been evaluated as being compatible only with the probe type listed:

Table 3:

Probe	P/N	DISINFECTANT			
		Cidex™	Cidex PA™	Cidex OPA™	Sporox™
FPA 2.5 -64	KG100001	YES	YES	YES	YES
FPA 3.5 -96	KK100005	YES	YES	YES	YES
FPA 5.0 -96	KN100002	YES	YES	YES	YES
FLA 5.0-192	KN100003	YES	YES	YES	YES
FPA 10.0	KW100002	YES	YES	YES	YES
FPA 5.0 - 128	KN100001	YES	No	YES	No
CLA 3.5 - 192	KK100004	YES	No	YES	No
CLA 5.0 - 192	KK100008	YES	No	YES	No
ECLA 6.5 -128	KQ100002	YES	No	No	No
FLA 10.0	KW100001	YES	No	No	No
2MHz Doppler	TE100024	YES	No	No	No
6MHz Doppler	TQ100002	YES	No	No	No
Transesoph-ageal probes		YES	YES	YES	No

Be sure to follow the germicide manufacturer's instructions for storage, handling, preparation, time of exposure and disposal. Use only disinfectants that are approved according to local / national regulations.

High-level Disinfection destroys vegetative bacteria; lipid & non-lipid viruses, fungi and, depending highly on time of contact, is effective on bacterial spores. This is required for cavity (TV,TR,TE) scanning when in contact with mucosal membrane.

CAUTION - Improper handling can lead to early probe failure and electric shock hazards:

- DO NOT disinfect or sterilize probes by autoclaving or ethylene oxide gas process.

- DO NOT soak or wipe the probe face with methanol, ethanol, isopropanol or any other alcohol based cleaner. Doing so could result in irreversible damage to the probe’s lens.

- DO follow the specific cleaning, disinfection procedures provided with the documentation of your product, as well as the germicide manufacturer's instructions.

Failure to do so will void probe warranty.

Addition to chapter C:

Special note regarding vascular or abdominal measurements with integrated EchoPAC:

If the user makes several vascularor abdominal measurements on the system, saves the data to EchoPAC (measurements viewable in EchoPAC report), and then goes back to the scanner to make additional measurements and saves them, these last measurements will delete all of the previous measurements already stored in EchoPAC for the current examination.

Workaround: If it is necessary to make additional measurements, start a new exam for that patient

Addition to chapter A

System FiVe Phono/Heart Microphone

Instructions for use

1. Plug transducer into connector in front of system marked Phono.

2. Select the button on the keyboard marked Phys. Trace.

3. Use the up/down toggle switch on the keyboard to select Phono off/on. This selection is located on the lower part of the menu to the right of the ultrasound image. The Phono off/on selection is not visible until the down pointing arrow on the menu is activated. Click to the right to turn the trace on.

4. The trace will be displayed on top of the ECG trace on the System FiVe monitor.

5. To adjust the position of the trace on the screen, select Phono Offset on the menu using the up/down toggle. The trace is moved upwards and downwards using the left/right toggle. (CAUTION: Adjusting the trace baseline too far from the ECG can cause the trace to be a flat line)

6. The size of the trace window is adjustable. The default size is small. The window size can be changed by pressing the Screen Config button. The options are small, medium, large and full.

7. To adjust the gain of the trace, use the up/down toggle switch and select Phono Gain. The gain is increased by clicking the left/right toggle to the right and decreased clicking the left/right toggle to the left (CAUTION: The gain should be adjusted in very small increments).

8. The heart microphone is placed on the chest of the patient. The heart microphone is equivalent to a stethoscope and should be used in the same way.

9. The heart sound trace will be displayed on the screen.

Heart sound filtering

1. It is possible to process the phono signal by passing it through a filter. You can choose between six different filters. The filters are accessible by first pressing Phys. Trace, then the Phono Filter button. A menu with the different filters will pop up. The default filter is highlighted.

2. The characteristics of each filter are shown in the table below:

Table 4:

	Lower frequency	Higher frequency	Comment
BP LOW	50Hz	100Hz	Bandpass filter located in a lower frequency range
BP MED	65Hz	105Hz	Bandpass filter located in a medium frequency range
BP HIGH	75Hz	150Hz	Bandpass filter located in a high frequency range
HP50	50Hz	•	Highpass filter attenuating frequency content lower than 50Hz in the signal
HP30	30Hz	•	Highpass filter attenuating frequency content lower than 30Hz in the signal
STANDARD			At the moment, the same as HP30

Table 1 - The characteristics of the different phono filters

The different filter characteristics are shown in the figure below:

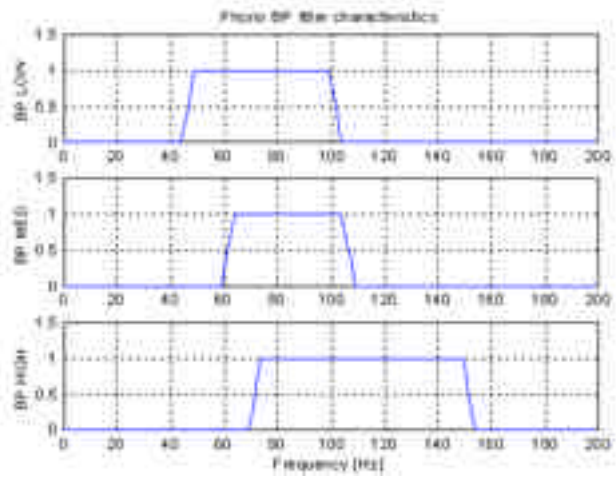


Figure 1 - Phono filter characteristics

Proper filter is chosen based on what heart sound you want to listen to. The BP-LOW is used for heart sounds with low pitch, BP-MED is used for heart sounds with medium pitch while the BP-HIGH is used for heart sounds with high pitch.

It is also possible to only have low pass characteristics. This might be desirable in cases where you don't want to limit the higher frequency content of the signal. The two filters using this characteristics are the HP30 and the HP50 filter. The filter characteristics are shown in the figure below:

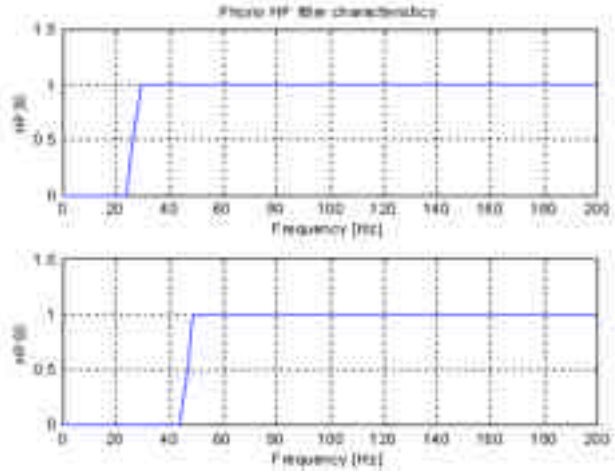


Figure 2 - Phono filter characteristics

Reported Edit misses

Page 86 - "Adjust ROI Span shown above..." however the picture shows "ROI

Length"?__ It is a undetected menu name change. ROI span has become ROI length since last update.

To be added under Chapter F: Warnings

Important regulatory information for use in Germany:

Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the system standard EN 60601-1-1:1993. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 601-1-1:1993. If in doubt, consult the technical service department or your local representative.

To be added under Chapter G: Specifications

ACCESSORY	PART NUMBER	COMMENT	TYPE/ CLASS
ECG lead wire	164L0027	AHA cable US	Type CF
ECG patient cable	164L0025	AHA cable US	Type CF
ECG lead wire	164L0028	IEC cable EU	Type CF
ECG patient cable	164L0026	ECG patient cable	Type CF
Foot pedal, general use	FB200723		Class IP20
Foot pedal, operating room	FB200734		Class IP68

The following table to be inserted under Chapter A, System Probes.

The probes listed in the table below in bolded letters are tested with Vivid Five. The remaining previously approved System Five probes are supported by Vivid Five.

PROBE TYPE	GE VINGMED P/N	CAT NO	SYSTEM FIVE	VIVID FIVE
CLA 3.5 MHz	**KK 100004**	**H4830KL**	**X**	**X**
CLA 5.0 MHz	**KN 100008**	**H4830KM**	**X**	**X**
ECLA 6.25 MHz	**KQ 100002**	**H4830KN**	**X**	**X**
FLA 5.0 MHz	**KN100003**	**H4830KJ**	**X**	**X**

PROBE TYPE	GE VINGMED P/N	CAT NO	SYSTEM FIVE	VIVID FIVE
FLA 10.0 MHz	**KW 100001**	**H4830JZ**	**X**	**X**
I13LV, flat linear array	KW 100003	H45001KC	X	X
I18LV, flat linear array	**KQ 100005**	**H45001KB**	**X**	**X**
FPA 2.5 MHz	**KG 100001/C**	**H4830JS**	**X**	**X**
FPA 2.5 MHz	KK 100001/ BC	H4830JT	X	X
FPA 3.5 MHz	**KK 100005**	**H4830JW**	**X**	**X**
FPA 5.0 MHz	**KN 100001**	**H4830JX**	**X**	**X**
FPA 5.0 MHz Ped	**KN 100002/B**	**H4830JY**	**X**	**X**
FPA 10.0 MHz Ped	**KW 100002**	**H4501AE**	**X**	**X**
Dop 2.0 MHz (dop-pler)	**TE 100024**	**H4830JE**	**X**	**X**
Dop TC 2 MHz (TC – transcranial)	KE 100001	H4830KP	X	X
PA MPTE 5.0 MHz	**KN 100006**	**H4830KK**	**X**	**X**
PA MPTE 5.0 MHz	**KN 100007/B**	**H45001A**	**X**	**X**
PA MPTE Ped	**KN 100010**	**H45001JJ**	**X**	**X**

To be added under Chapter E, Installation & Maintenance

The user must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard IEC-EN 60601-1.

Only trained persons are allowed to perform the safety inspections mentioned above.