Year 7

Manual of Operations
For
Echocardiography Field Centers

CARDIOVASCULAR HEALTH STUDY

MANUAL OF OPERATIONS
FOR
ECHOCARDIOGRAPHY FIELD CENTERS

April 18, 1994

Introduction

Welcome to the echocardiography substudy of the Cardiovascular Health Study (CHS). As you probably know, the CHS is an extensive epidemiologic study of over 5,000 elderly participants, **not** patients, which was begun in June, 1988. In order to determine the factors responsible for stroke, heart failure, and other sources of cardiovascular disability the exhaustive quantities of clinical and laboratory information are being gathered. Echocardiography is a vital part of the CHS. Echocardiograms, initially performed in year 2 (June, 1989 - May, 1990) are now being repeated in the same subjects to determine which changes in cardiac structure and function have occurred, and in whom. The interval changes in cardiac status detected by echocardiography will be intensively analyzed in comparison with other measurements in the CHS protocol. As echocardiographers, you will be pioneers in a unique and important study which will likely affect health care of the elderly for decades to come. While many of you have had extensive experience with echocardiography for clinical diagnosis, the challenges in obtaining maximum information from echocardiography in an epidemiologic study of this magnitude are unlike those faced in clinical practice. Your accurate application of the techniques used in this study is essential for its success. While the demands of this study push the large-scale quantitative use of echocardiography to its limit, the rewards are great. Your participation in the echocardiography substudy has the potential of improving the quality of life of millions of people.

How to Use this Manual

We suggest that you initially browse the entire manual to become roughly familiar with its contents. However, the most important section of the manual in terms of your day-to-day activities in the CHS will be Section 5, "Procedure for Performing the Echocardiographic Examination." You should understand this section thoroughly. A summary of the echocardiographic procedure on 5 X 8 inch cards will be supplied to you (Appendix A). It may be useful to attach this to the echocardiograph for your convenience. The material in section 4, "Description of Echocardiography Equipment Features and Operation" should be referred to as needed. This may be required frequently for those who are unfamiliar with the Toshiba equipment used in the CHS.

1 Objectives

1.1 *The primary objective* of echocardiography in the Cardiovascular Health Study is to determine whether one or more echocardiographic or Doppler parameters of cardiac structure and function are useful in predicting mortality or extent of disability in subjects in the age range of 65 years and older who, during a five year follow-up, develop cardiac events (myocardial infarction, congestive heart failure, etc.) or cerebrovascular accidents. *Importantly, we will determine the importance of change in LV mass, regional wall motion, and LV function over a five year interval as a predictor of new clinical events, i.e., stroke, heart attack and death.* Cardiac structural parameters to be evaluated include left ventricular wall thickness and mass, and left ventricular and left atrial dimensions, while cardiac functional parameters include left ventricular percent fractional shortening, left ventricular global and regional wall motion, left ventricular wall stress and Doppler stroke volume, and left ventricular filling parameters.

1.2 *A second objective* of the repeat echocardiography examination is to measure the rate of progression of **aortic valve disease** in the elderly, and determine its association with clinical events such as heart failure and stroke.

1.3 *A final objective* is to develop a relevant, efficient, and cost-effective method for recording, coding and analyzing cardiac ultrasound parameters which results in data with good accuracy and reproducibility in

elderly individuals with and without clinical evidence of cardiovascular disease.

2 Rationale

2.1 Use of echocardiography for clinical and epidemiologic detection of cardiac abnormalities associated with a higher incidence of cardiovascular events or mortality

Echocardiography has been shown to be a useful tool, both clinically and epidemiologically in detecting cardiac abnormalities associated with a higher incidence of cardiovascular events or mortality. For example, Henry and associates demonstrated that patients with an echocardiographic left atrial dimension of 55 mm or greater demonstrated a much lower success rate of conversion from atrial fibrillation to normal sinus rhythm.[1] Similarly, preliminary data from the Framingham study has suggested that echocardiographic left ventricular hypertrophy in the general population is associated with an increased two-year mortality, independent of standard coronary risk factors.[2] Since echocardiography is more sensitive and specific than such indirect tools as electrocardiography in the detection of left ventricular hypertrophy and left atrial enlargement, these echocardiographic measurements may be useful as preclinical prognostic indicators of the future development of coronary artery disease, stroke, or other cardiovascular events in populations of subjects such as the elderly.[3] Furthermore, alterations in left ventricular filling have been detected by Doppler with aging and as an early marker of acute ischemia.[4,5]

The cardiac ultrasound technique (echocardiography and Doppler flow recording) has the advantage of being non-

invasive, reproducible, and without known adverse effects as used clinically.

2.2 Difficulties of Echocardiography in Epidemiologic Trials.

Consistent with the experience at Framingham, and the baseline echocardiography studies in year two with CHS, however, there is a significant learning curve present in recording technically adequate echocardiographic studies, particularly in subjects over the age of 60 years. In the Framingham report describing M-mode echocardiograms performed in over 6,000 subjects aged 17 to 90, the ability to record acceptable quality echocardiograms in subjects older than 60 years rose from a minimum of 28% during the first five months of the study to a maximum of 74% to 81% during studies two years later.[4] In the year 2 CHS echocardiography examinations the "yield" for M-mode measurements of LV mass was only 67%. Moreover, older subjects within the CHS cohort were less likely to have measurable and interpretable studies than younger subjects. Hence echocardiography "drop-outs" were not randomly distributed within the cohort leading to the possibility of bias in data interpretation. Two-dimensional echocardiographic measurements were even more problematic than M-mode.

2.3 Differences Between Field Centers

In previous large echocardiography trials major differences in echo quality have existed between field centers. For example, in a 15-center VA trial of antihypertensive monotherapy, the percent of readable echocardiograms for LV mass varied from approximately

30% to 85% (**Figure 1**). This was not due to differences between centers in the proportion of easy or difficult patients. While the use of suboptimal equipment in some cases contributed to poor studies, the intercenter differences were mostly because of variation in technical performance. Importantly, extensive previous clinical experience in echocardiography was no guarantee of studies adequate for research purposes.

A major goal of this manual is to ensure the recording in elderly patients of echocardiograms of acceptable quality and reproducibility to generate structural and functional variables which will have prognostic value for the development of coronary artery disease, and stroke, as well as for specific endpoints such as mortality and degree of disability.

2.4 Difficulties of Two-Dimensional Targeted M-Mode for LV Mass Calculation

It is easy to improperly align (**Figure 2**) the echo sector relative to anatomic axes, or improperly place the M-mode cursor during 2-D targeted recording of the LV. Such errors of acquisition technique can result in large error and variation in the measurement of LV mass. As shown in **Figure 3** a "true" LV mass calculation of 227 gm may vary between 181 gm to 448 gm based upon improper cursor or sector placement respectively.

Hence, accurate echo technique aimed at proper direction of the transducer particularly in the parasternal short axis view, is of paramount importance. In particular the echo sector must be

perpendicular to the long axis of the LV, and the M-mode cursor must pass through the center of the LV. In our experience, inability to fulfill these two conditions is the most common source of large errors in the estimation of LV mass. Additionally, optimal definition of septal and posterior wall interfaces is desirable, but usually less problematic than "angulation" errors. However, difficulty in defining the posterior wall borders, principally the border between wall and pericardium, leads to even greater variability in measuring the posterior wall, than in measuring the septum or LV cavity **(Figure 4)**.

3 Hypotheses

3.1 Echocardiographic markers of pre-clinical disease for predicting mortality and disability from cardiac or cerebrovascular events

Echocardiographic markers of pre-clinical disease (e.g., left ventricular hypertrophy, decreased left ventricular ejection fraction, or abnormalities in global or regional left ventricular systolic or diastolic function) are useful in predicting mortality and disability from cardiac or cerebrovascular events over a three-year follow-up period.

3.2 Echocardiographic markers of pre-clinical and overt disease related to traditional risk factors

Echocardiographic markers of pre-clinical and overt disease are related to traditional risk factors (e.g., smoking, high blood pressure, high cholesterol) for cardiovascular disease.

3.3 Progression in parameters related to the development of cardiovascular events or stroke detected over a three-year follow-up period

Progression in parameters such as left ventricular hypertrophy, abnormalities of left ventricular systolic or diastolic function, can be detected over a three-year follow-up period and are related to the development of cardiovascular events or stroke.

3.4 Progression of echocardiographic markers of pre-clinical disease related to baseline characteristics and to non-echocardiographic factors

The progression of echocardiographic markers of pre-clinical disease (e.g., LVH, regional or global LV dysfunction, valvular calcification and regurgitation) are related to baseline characteristics and to non-echocardiographic factors, e.g., demographic factors, blood pressure, lipid abnormality.

3.5 Predictability of aortic stenosis by echocardiographic characteristics and non-echocardiographic descriptors.

Aortic stenosis (physiologically important decrease in aortic leaflet opening) is preceded by aortosclerosis (calcification of the aortic ring). The likelihood of developing clinically important aortic stenosis is predictable by baseline echocardiographic characteristics of the aortic valve, and possibly other echocardiographic and non-echocardiographic descriptors.

4 Description of Echocardiography Equipment Features and Operation

The purpose of this section is to describe the functions and use of the Toshiba SSH-160A, with particular attention to the examination and evaluation of the heart.

4.1 Ultrasound Instrumentation

A picture of the SSH-160A is shown in **Figure 5.** Principal system features include an observation monitor, sub-panel, primary control panel and open area for mounting a camera, video cassette recorder, etc. The majority of controls influencing cardiac scanning are logically grouped on the main control panel, **Figure 6.** A detailed explanation of all controls is available in the SSH-160A Operators Manual. All users should read this manual in its entirety in order to become thoroughly familiar with the features of the system. Certain controls have a direct effect on performing cardiac studies. It is the intent of this section to describe the most commonly used functions so that the echocardiography technician may produce the most optimal studies.

The Toshiba SSH-160A is a digital ultrasound system which requires little warm-up time. The machine must be plugged into a power supply in the wall. Activation of the power switch brings the system on-line. After just a few minutes, scanning may be initiated. If it should become necessary to turn the machine off during the day, please allow at least one minute before turning the machine back on.

4.2 Transducer Selection

The SSH-160A is equipped with three electronically-focused, 96-element, phased array transducers. Echocardiographic studies in this elderly population will generally be performed with either a 2.5 MHz or a 3.75 MHz transducer. Although the 3.75 MHz transducer is theoretically preferable because of better resolution with higher ultrasound frequencies, in many

if not most cases the 2.5 MHz transducer will be required to achieve adequate tissue penetration. These transducers have the capability for performing M-mode and two-dimensional imaging, as well as pulsed, steerable continuous wave (CW), and color flow Doppler studies. These can also be done in conjunction with two-dimensional and M-mode imaging. The probes can be connected at the A and/or B probe connector port located in a protected area behind the main control panel. This panel is moved forward by releasing the lock on the underside of the left edge of the control panel to allow easy access to the probe connector ports. To activate the CW capability of a probe, the probe must be connected to port "C." Once attached, it is not necessary to disconnect probes in order to change frequencies. Probes are selected on the main control panel by pressing "B" or "C" (**Figure 6, #5**).

4.3 Initial Instrument Settings

4.3.1 Condition Presets/Programmable Menus

Each of the options in the programmable menus will be described and explained in great detail to all program participants at the three day training session (April 18-20, 1994) at the Echocardiography Reading Center at the Georgetown University Medical Center. The SSH-160A is equipped with a series of programmable menus, as well as three "Condition Preset" functions which can be used to preselect and standardize many of these programmable functions (**Figure 6, #4**). The three presets will be programmed prior to the initial

training sessions. The set of conditions felt to be the most optimal will be designated "Preset A" and will be the default mode when the machine is turned on. If "Preset A" is not felt to provide an optimal image or flow pattern for a given patient, one of the other preset patterns (B or C) may be selected. This preset will be automatically noted on the images displayed on the screen and recorded on the video tape, and should be noted by the technician in the appropriate section on the Echocardiography Technician's Worksheet (Appendix B). A detailed explanation of all menus is attached in Appendix B.

Certain controls require user interaction to optimize the quality of the image. A description of these controls is described in the following sections.

4.3.2 Mode Select

4.3.2.1 B-Mode Single

A single full-sized B-Mode image is displayed. In this format, it is possible to store two B-Mode images.

4.3.2.2 Dual 1/Dual 2

The SSH-160A permits split-screen imaging. The screen is divided down the center. Dual 1 operates the left side of the screen and Dual 2 operates the right. This format is

particularly valuable in reviewing two right-angled views of the same site.

4.3.2.3 B & M-Mode and B & D-Mode Displays

This format allows simultaneous display of B and M-mode. When Doppler mode is selected, B and D-mode are displayed.

4.3.2.4 M-Mode

Activates either an M-mode or Doppler only mode.

4.3.2.5 Depth of Field

Depth of field allows the user to select the depth of display for the anatomic part to be examined. Potential display depths are from 4 cm through 24 cm. It is recommended that the depths be set at one of four preset depths: 12 cm, 16 cm, 20 cm, or 24 cm. This will permit better standardization of image recording.

4.3.2.6 Pan/Zoom

The pan/zoom feature **(Figure 6, #17)** permits real-time enlargement of the image with no loss of image quality.

Depressing the pan zoom feature activates this function. Immediately below the pan zoom button is a digital rotary encoder knob. Clockwise movement of this knob enlarges the image. The measurement scale at the left-hand side of the image automatically adjusts.

Movement of the track ball **(Figure 6, #26)** positions the expanded image anywhere on the screen. *It is recommended that for precise measurement, the image be expanded to its fullest size.*

To turn off pan/zoom, the depth control knob must be rotated 1 setting in a clockwise or counterclockwise direction.

4.3.2.7 Gain and STC

As an ultrasound beam enters tissue, it is attenuated as it goes deeper into the body. The result is that two tissues of identical density will appear different, the one furthest from the transducer appearing the least dense. The purpose of the STC adjustments is to compensate for this natural attenuation and to allow for the

uniform appearance of similar tissue.

Receiver gain is user adjustable via the Gain knob **(Figure 6, #16)**. This controls the amount of amplification given the returning signal. As a general rule, gain should be kept as low as possible to reduce the amount of noise displayed. Gain settings are always displayed on the image as part of the lower right-hand corner alpha numerics.

4.3.3 Touch Command Screen

Most functions relating to image maximization are located in menu functions shown in the Touch Command Screen **(Figure 6)**. Any component of any menu may be activated by the user simply by placing a finger over the square of interest and applying a light pressure.

The menu functions are automatically displayed according to the mode selected, e.g., B Scan brings up the B/M Menus, PW or CW brings up the Doppler menus and Color selection activates the color flow menus. Nearly all menus have been preset, and it is not necessary for the operator to frequently change these settings. *Refer to Figure 6 and Appendix C for detailed descriptions and flow charts for all menu functions.*

5 Procedure for Performing the Echocardiographic Examination

5.1 Two-Dimensional Echocardiographic Imaging Planes and Transducer Location

5.1.1 Transducer locations to be used

The nomenclature for transducer location, as published by the American Society of Echocardiography Committee on Nomenclature and Standards in Two-Dimensional Echocardiography[6], are summarized in **Figure 7**. The transducer locations to be used in this study will be primarily the (Left) Parasternal, Apical and Subcostal.

5.1.2 Two-Dimensional Echocardiographic Imaging Planes

Figure 8 demonstrates the convention for recording two-dimensional images in the three basic orthogonal planes: Long-Axis Plane, Short-Axis Plane, and Four-Chamber Plane. In truth, each of these designated planes represents a series of tomographic slices, or planes, of the heart parallel to the labelled plane.

5.1.3 Standard imaging views

When the nomenclature for the transducer location is combined with the nomenclature for the imaging plane, a series of standard imaging views is obtained as demonstrated in **Figure 9**.

For purposes of this study, the following standard imaging views will be used: Parasternal Long-Axis and Apical Long-Axis (Two-Chamber) view **(Figures 10-12)**; Parasternal Short-Axis, (and, in some individuals) Subcostal Short-Axis view; and Apical (and, in some individuals) Subcostal Four-Chamber view .

5.2 Derivation of M-Mode Images from the Two-Dimensional Scan

Figure 13, depicts the derivation of an M-mode echocardiogram using a single scan line ("ice-pick view") derived from various positions on a two-dimensional echocardiographic image. M-mode recordings **(minimum of 20 beats for each recording)** of the left ventricle, left atrium and aorta will be derived from a cursor positioned on the two-dimensional image in the parasternal short-axis views. Additionally, M-mode recording of the aorta and LA will be made through the largest portion of the left atrium in the parasternal long axis view. M-mode measurements can not be made from M-mode recordings which were obtained with the M-mode cursor at a greater than 20° angle to the meridian of the left atrial or ventricular cavity. In addition, in the two-dimensional parasternal short-axis view, M-mode left ventricular measurements will not be made when, in the absence of wall motion abnormalities, there is an eccentricity index of 1.3, i.e., when the radius of the left ventricular cavity in one axis is $\geq$ 1.3 x the radius of the cavity in another axis.

5.2.1 American Society of Echocardiography (ASE) standards for M-mode echocardiographic measurements

M-mode echocardiographic measurements will be made using the American Society of Echocardiography (ASE) standards[8] **(Figure 14)** which include:

1) using the thinnest continuous echo lines to denote the desired interface;

2) measuring dimensions and thicknesses from the leading edge of the anterior echo line to the leading edge of the posterior echo line;

3) making diastolic measurements at the onset of the QRS complex of the electrocardiogram; and

4) measuring right and left ventricular cavities and wall thicknesses at the level of the chordae tendineae below the mitral valve. **It is of key importance to record identifiable and continuous echo lines for each of the relevant structures**, e.g., recording an identifiable endocardial and

epicardial line for the posterior wall of the left ventricle.

5.3 Two-Dimensional Echocardiographic and Tomographic Anatomy

5.3.1 Tomographic anatomic slices and diagrams, echocardiographic images, two-dimensional echocardiographic anatomy to be recorded

Figures 8-12 also illustrate tomographic anatomic slices and echocardiographic images, the two-dimensional echocardiographic anatomy to be recorded as part of this study. Specifically, these figures illustrate the parasternal long-axis view, parasternal short-axis views at the level of the aortic root, mitral valve and papillary muscles, apical four-chamber and two-chamber (long-axis) views, and subcostal four-chamber view.

5.4 Pulsed Doppler Flow Recording

5.4.1 Record beats demonstrating the highest peak velocity and narrowest spectral dispersion of the velocity spectrum

Pulsed Doppler measurements will not be performed from beats demonstrating maximum dispersion greater than 30% of the peak velocity. Therefore, the technician should attempt to record beats demonstrating the

highest peak velocity and narrowest spectral dispersion of the velocity spectrum. The next series of images demonstrates the pulsed Doppler recordings to be performed as part of this study.

5.4.1.1 Flow velocity recording in the left ventricular outflow tract

Flow velocity recording in the left ventricular outflow tract: **Figure 15** demonstrates the proper position for the sample volume and the corresponding Doppler flow velocity spectral envelope recorded in the left ventricular outflow tract from the apical long-axis view. This recording can be used to estimate stroke volume and linear cardiac output.

5.4.1.2 Mitral flow velocity:
Figure 15 demonstrates the placement of the pulsed Doppler sample volume for recording the mitral flow velocity in the apical four-chamber and long-axis views. Measurements that can be derived from the flow velocity tracing, include peak flow velocity in early and late diastole. Care must be exercised to place the sample volume at the tips of the mitral leaflets and obtain an acoustically pure signal with the

narrowest spectral envelope possible.

5.5 Color Doppler Flow Imaging

5.5.1 Basic introduction to color flow imaging

A basic introduction to color flow imaging is provided in **Appendix G**. It is important that the color gain controls be set so that the shades of blue and red displaying velocity just fill the cardiac chamber or vessel (e.g., left ventricle or aorta) without "bleeding" over onto the surrounding walls. The importance of attention to this detail cannot be overemphasized since performing color flow mapping with too much or too little gain will result in recording an erroneous color flow regurgitant (or shunt) area. The technique for proper gain and other machine factors during color flow mapping will be demonstrated during the Training Sessions at the Echocardiography Reading Center and at the Field Centers.

5.6 Continuous Wave Doppler Recording

5.6.1 Tricuspid Regurgitation: Continuous wave (CW) Doppler recordings of tricuspid regurgitation are possible from the parasternal short axis view, RV inflow tract view, and apical four chamber view. Extensive time should not be expended on this portion of the exam. The CW

interrogation should be done only if tricuspid regurgitation is identified on color flow Doppler.

5.6.2 Aortic Stenosis: CW Doppler interrogation of the aortic valve should be done **only if** the 2D exam suggests **substantial** aortic stenosis i.e. major limitation of aortic cusp separation (approx. 10 mm or less), as well as severe "thickening" and "calcification." In such cases, all three CW windows for aortic stenosis (apical, as well as suprasternal notch and right parasternal windows with stand-alone CW transducer, should be utilized.

5.7 Considerations for Optimal Echocardiographic Imaging

5.7.1 Obtaining optimal two-dimensional echocardiographic images

It is essential that the Field Center technician be meticulous in obtaining optimal two-dimensional echocardiographic images. Important data to be derived from the echocardiographic examination in the Cardiovascular Health Study will either come directly from the two-dimensional images, or be derived from the two-dimensional images, i.e., in the case of M-mode images derived from a two-dimensional image, or the pulsed Doppler and color flow Doppler information obtained with the aid of two-dimensional imaging orientation. This section summarizes some of the general considerations useful in recording

two-dimensional echocardiographic images. This discussion is based on a draft of a document entitled "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography" submitted by the Subcommittee on Quantitation of Two-Dimensional Echocardiograms of the American Society of Echocardiography (ASE) to the ASE Board of Directors[13].

5.7.1.1 Measurements from stop-frames recorded on videotape

The Echocardiography Reading Center will be making measurements from stop-frames recorded on videotape. It has been noted that optimal definition of endocardial and epicardial interfaces for making measurements at the Echo Reading Center require using higher gain than is generally optimal for displaying these interfaces on the video monitor during performance of the study at the Field Center. The necessity for using higher gain to record images of the left ventricle will be emphasized at frequent intervals to the Field Center technicians in order that optimal recordings for interpretation at the Echocardiography Reading Center are obtained.

5.7.1.2 Imaging the heart in the parasternal long-axis view

In general, when imaging the heart in the parasternal long-axis view, one should attempt to adjust the transducer position such that the aorta is not angulated at its junction with the left ventricle. Then, the transducer position should be adjusted to record the maximum vertical aspect of the left ventricle. *When imaging in the parasternal short-axis view, it is crucially important to obtain as circular an image as possible, directing the transducer away from the mitral valve (towards the feet) where the mitral valve motion is lost or where there is only minimal excursion of the leaflets. M-mode recording of at least 20 beats in made with the cursor through the center of the LV, forming a vertical diameter line.* At least twenty beats of the 2-D image without the M-mode cursor should also be recorded at this level. Parasternal short axis views which appear elliptical or egg-shaped indicate that the echo sector has intersected the left ventricle in an oblique fashion instead of perpendicular to the long axis. Use of M-mode measurements

from such oblique echo images results in large overestimations of LV mass.

The technician should virtually count out (mentally) the beats during recording. Casual attention to this aspect of echo recording often results in the "home movie" jitter effects, where disappointingly short and disjointed movie segments (e.g., 3 sec on Uncle Harry, 1.5 sec of the new baby, and back to 2 sec of Uncle Harry again!) come as an unpleasant surprise to the home movie maker who believed he/she filmed a more harmonious and informative segment. In the case of two-dimensional real time echocardiography, a nervous hand on the transducer results in recording continuously changing views of the heart which may be uninterpretable, particularly for assessment of regional wall motion. Care should be taken to also record 2-D echo of at least 20 beats of the heart in parasternal short axis view at the papillary muscle level, and at the aortic root-left atrial level.

5.7.1.3 When imaging in the apical views, the technician should attempt to maximize the left ventricular cavity

size. Specifically, apical four- and two-chamber images at end-diastole should be recorded with an effort to maximize the length of the ventricular image as well as its area. When obtaining left ventricular images from the apical four-chamber or two-chamber (long-axis) views, the imaging transducer should be applied as posterior to the apical impulse location as possible and slowly drawn anteriorly until the qualitatively maximum cardiac chamber is imaged. By starting posterior to the apical impulse, underestimation of an enlarged left ventricle will be minimized. The mattress with the "scoop" used in this study will be useful in obtaining apical images fulfilling the desired criteria for measurement. The true apical four-chamber view should be obtained through the mid-lateral wall of the left ventricle and the mid-right ventricle. The apical two-chamber view should be obtained orthogonally by rotating the transducer 90° to the four-chamber view. Although the true two-chamber view does not include the aorta and left ventricular outflow tract, these structures will also be recorded --

known as the "apical long-axis view."

5.7.1.4 M-mode and pulsed wave Doppler recordings will be performed initially in a side-by-side format with the two-dimensional update image, followed by a full-screen image of the M-mode or Doppler recording **at 50mm/sec sweep speed during quiet respiration.** Continuous wave Doppler recordings will also be performed at 50mm/sec sweep speed. Finally, a 5-second freeze-frame recording of the full-screen M-mode *and some of the Doppler images (as noted in the protocol)* will be produced at gently held-expiration, with care taken to avoid a Valsalva maneuver, or forcible exhalation.

5.7.2 Influence of Patient Position, Transducer Frequency, and Imaging Depth on Echocardiographic Images

Patients will be positioned in left lateral recumbency in order to optimize imaging of the left ventricle and also to help standardize the method for obtaining these images. The selection of transducer frequency and focal length can influence endocardial definition. As a general rule, imaging should be performed with the highest frequency transducer that

provides adequate penetration of the chest for good structural (especially endocardial) definition. In an individual with a large chest diameter, lung disease, obesity or large breasts, the lowest transducer frequency (2.5 MHz) will probably be necessary. The left ventricle should be imaged in the most magnified presentation - i.e, at the shallowest display depth - that results in good endocardial definition. This recommendation seems appropriate for the following reasons:

1) At deeper display depths, the imaging information being analyzed is represented by fewer pixels, thus resulting in potentially greater errors at the Echocardiography Reading Center in manually digitizing endocardial and epicardial borders; and

2) at deeper display depths, frame rates may be slower, potentially resulting in blurred endocardial definition.

5.8 Patient Preparation

5.8.1 Initial position

The patient should initially be positioned in the 45° left lateral decubitus position on the special "scoop" mattress using the appropriate number of foam wedges placed behind the patient's back. In addition, the initial position should include a 30° upright tilt of the patient's head.

5.8.2 Describe the examination to the patient

The echocardiography technician should briefly describe the examination to the patient while the patient is being positioned on the mattress. The explanation to the subject should include the following points:

5.8.2.1 The ultrasound examination uses sound waves

The ultrasound examination uses sound waves (similar to SONAR) to take pictures of the heart and record flow through the heart and attached blood vessels.

5.8.2.2 Length of test

The test should require approximately 20-30 minutes and be painless, except for some mild pressure from the transducer.

5.8.2.3 Patient Positions

The patient may be asked to assume slightly different positions during this ultrasound test.

5.8.2.4 Ultrasound transmission gel and electrocardiogram (ECG) electrode patches

The ultrasound transmission gel used for recording the ultrasound images may be cold; the electrocardiogram (ECG) electrode patches may cause some minor discomfort when they are removed from the skin.

5.8.3 Cable/lead/electrode connections

The electrocardiographic cable from the echocardiography machine should be connected to the 3 ECG electrodes. The cable labeled RA is connected to an electrode placed in the superior xiphoid region. The lead labeled RL is connected to the electrode pad positioned in the inferior xiphoid position. The lead labelled LA should be attached to the electrode pad positioned in the left lateral abdominal area. These ECG cable leads should then be placed laterally and attached to the waistband of the subject's gown in order to reduce spurious signals and keep them out of the way. Because it is important for the echocardiographer to have good access to the precordial, subxiphoid (subcostal) and neck areas, the subject should wear a loose-fitting gown. Of course, the echocardiographer should be careful to respect the modesty of the female subject by appropriate draping with the gown and/or a sheet.

5.8.4 Identification

The following information should be entered via the keyboard, displayed on the screen, and recorded on the video tape: *Patient's identification number and acrostic, the date of the study, technician code, and the Field Center.*

5.9 Echocardiographic Scanning Protocol
(See Appendix D)

5.9.1 Parasternal long-axis view

5.9.1.1 Two-dimensional echocardiographic imaging

Two-dimensional echocardiographic imaging will be performed in the parasternal long-axis view (with ten beats or greater recorded during quiet respiration; includes 1.2 below). Although the third or fourth intercostal space is the usual optimal position for recording in this view, the transducer should be positioned so as to maximize the left ventricular cavity area while obtaining the best definition of the ventricular septum and left ventricular posterior wall.

5.9.1.2 Ensure optimum visualization

Ensure optimum visualization of aortic valve and aortic leaflet

excursion. Record 10 beats or more of aortic leaflet excursion.

5.9.1.3 Color flow imaging for detection of aortic regurgitation.

Perform color flow imaging for detection of aortic regurgitation. Record 5 beats (even in absence of AR.)

5.9.1.4 Color flow imaging for detection of mitral regurgitation.

Perform color flow imaging for detection of mitral regurgitation. Record 5 beats (even in the absence of MR)

5.9.1.5 Placement of M-mode cursor.

Place the M-mode cursor through aorta and left atrium at the most posterior displacement of posterior aortic wall. Record 10 beats of continuous M-mode on tape during quiet respiration.

5.9.16 Transducer rotation

The transducer should be rotated 90° clockwise within the same intercostal space to begin imaging in the parasternal short-axis view.

5.9.2 Parasternal Short-Axis View

5.9.2.1 Optimal imaging

Two-dimensional echocardiographic imaging should be performed at the level of the aorta and left atrium (with 10 beats recorded during quiet respiration). Ensure optimal imaging of *aortic valve and maximum aortic leaflet excursion*. Record 10 beats or more at quiet respiration.

5.9.2.2 Placement of M-mode cursor

The M-mode cursor should be positioned perpendicular through the aorta and the maximum dimension of the left atrium (with ten beats recorded during quiet respiration). The technician should display the two-dimensional update image on the screen next to the M-mode image of the aorta and left atrium.

5.9.2.3 Two-dimensional echocardiographic imaging at the mitral leaflet tip level

Two-dimensional echocardiographic imaging should be performed at the level of the mitral leaflet tips (with **20 beats** recorded at quiet respiration).

The M-mode cursor should then be positioned perpendicularly through the ventricular septum, left ventricular cavity, and left ventricular posterior wall at or just below the mitral leaflet tips. The technician should display the two-dimensional update image on the screen next to the M-mode recording of the left ventricle (with ten beats recorded during quiet respiration). Subsequently, the technician should record twenty beats of the full-screen M-mode echocardiogram of the left ventricle during quiet respiration. Finally, the technician should record for 5 seconds in freeze-frame mode this full-screen M-mode image of the left ventricle at gently held-expiration.

5.9.2.4 Two-dimensional echocardiographic imaging at the papillary muscle level

Two-dimensional echocardiographic imaging should be performed at the level of the papillary muscles. Record 20 beats at quiet respiration without moving the transducer.

5.9.3 Apical Four-Chamber View

5.9.3.1 Two-dimensional echocardiographic imaging at quiet respiration.

Two-dimensional echocardiographic imaging should be performed at quiet respiration (with **ten** beats recorded) with the goals of maximizing chamber dimensions and areas, as well as displaying good left ventricular endocardial definition. If optimal imaging in the parasternal views was performed using the 3.75 MHz transducer, imaging from the apical views should be attempted using this transducer. If imaging in the apical four-chamber view is suboptimal using the 3.75 MHz transducer, imaging in the apical views will then be attempted using the 2.5 MHz transducer.

5.9.3.2 Pulsed Doppler recording of transmitral flow velocity

Pulsed Doppler recording of transmitral flow velocity should be performed using the 2.5 MHz transducer with the sample volume positioned parallel to the presumed direction of inflow at the tips of the mitral leaflets during diastole. An attempt should be made to record beats demonstrating the highest peak velocities and narrowest spectral

dispersion. The technician should display the two-dimensional update image on the screen next to the Doppler recording of transmitral flow velocity (with ten beats recorded during quiet respiration). Subsequently, the technician should *record ten beats of the full-screen Doppler transmitral flow velocity during quiet respiration*. Finally, the technician should record, for 5 seconds in freeze-frame mode, the full-screen Doppler image of transmitral flow velocity at held-expiration.

5.9.3.3 Doppler color flow should be performed during quiet respiration

Doppler color flow should be performed during quiet respiration using the 2.5 MHz transducer in an attempt to detect *mitral regurgitation (with ten beats recorded during quiet respiration)*.

5.9.3.4 Transducer rotation

The transducer should be rotated approximately 90° into the apical two-chamber view.

5.9.4 Apical Two-Chamber and Apical Long-Axis Views

5.9.4.1 Two-dimensional echocardiography should be performed at quiet-respiration

Two-dimensional echocardiography should be performed at quiet-respiration with a goal of recording maximum left ventricular chamber dimensions and areas, as well as obtaining good left ventricular endocardial definition. **Ten** beats should be recorded at the true apical two-chamber view - i.e., displaying only the left ventricle and the left atrium.

5.9.4.2 Apical long-axis view

An additional **ten** beats should be recorded in the apical long-axis view, which includes the left ventricle, left atrium, aorta, and right ventricle. The apical long-axis view displays slightly different portions of the left ventricle than does the apical two-chamber view.

5.9.4.3 Pulsed Doppler recording of flow velocity in the left ventricular outflow tract

Pulsed Doppler recording of flow velocity in the left ventricular

outflow tract should be performed with the Doppler sample volume positioned approximately 0.5 cm proximal to the aortic annulus. The technician should display the two-dimensional image on the screen next to the Doppler recording of left ventricular outflow flow velocity (with ten beats recorded during quiet respiration). Finally, the technician should record, for 5 seconds in freeze-frame mode, a full-screen Doppler recording of left ventricular outflow tract velocity during quiet respiration.

5.9.4.4 Doppler color flow mapping with 2.5 MHz transducer in the apical long-axis view to look for aortic regurgitation

Doppler color flow mapping should be performed using the 2.5 MHz transducer in the apical long-axis view to look for aortic regurgitation (with ten beats recorded during quiet respiration).

5.9.4.5 SUSPECTED AORTIC STENOSIS: CW DOPPLER AORTIC VALVE

Imaging 2.5 MHz **continuous wave Doppler** recordings should be performed from the apical long-axis

view or from the apical five-chamber view only if significant aortic stenosis is suspected i.e. limitation of aortic leaflet separation to approximately 10 mm or less and severe apparent "thickening and calcification" of the aortic valve. CW imaging of the aortic valve is not necessary in cases of aortosclerosis where the aortic ring may be heavily thickened and echodense but central leaflet mobility is largely preserved. The technician should display the two-dimensional updated image on the screen next to the Doppler recording of maximum aortic flow velocity (with **ten beats recorded during quiet respiration**). Finally, the technician should record, for 5 seconds in freeze-frame mode, this full-screen Doppler recording of maximum aorta flow velocity **during quiet respiration.**

Additionally, the technician should attempt to record peak aortic velocity using a non-imaging continuous wave transducer from the right parasternal and suprasternal views. Record 10 beats from each window at quiet respiration.

5.9.5 Subcostal Four-Chamber View

5.9.5.1 Subjects in whom satisfactory left ventricular images cannot be recorded from parasternal views

With subjects in whom satisfactory left ventricular images cannot be recorded from parasternal views, two-dimensional echocardiography should be performed (with ten beats recorded) at held-expiration with the goal of maximizing chamber dimensions and areas, as well as displaying good left ventricular endocardial definition. The Echocardiography Reading Center may elect to perform measurements of wall thickness and chamber dimensions from this view if imaging of the left ventricle has been suboptimal from the parasternal and apical views.

5.10 Priorities in Performance of CHS Echocardiographic Examinations

5.10.1 The most important priorities of the CHS echocardiographic examination

The most important priorities of the Cardiovascular Health Study echocardiographic examination are:

1. To obtain adequate *2-D derived M-mode recordings* for estimation of LV mass and its components;

2. To obtain excellent quality *mitral Doppler* for assessment of diastolic function;

3. To obtain stable, geometrically correct *two-dimensional images for assessment of regional wall motion;* and

4. To obtain high quality images of *aortic valve anatomy, aortic leaflet excursion* and good quality CW Doppler of aortic valve gradients when present.

Time-intensive color flow examinations are to be avoided; the color flow portion of the examination should be limited to 5 minutes or less.

5.11 Technician Review of Study

At the completion of the study the technician will **briefly** scan the tape for adequacy and completeness of the study. Additionally, from one portion of M-mode recording on tape, the technician will measure (one beat only) septal wall thickness, posterior wall thickness and LV

diastolic cavity dimension. These values will be recorded on the data transmission sheet (Appendix B) sent from the field center echo lab to the ERC. A self-report quality score (1-poor, 4-excellent) for M-mode, 2-D and Doppler portions of the exam will also be recorded on the transmittal sheet.

5.11 Echo "Alert" (Emergent) Parameters

5.11.1 "Alert" findings

"Alert" findings are those echocardiographic conditions (listed below) which will trigger an "urgent" phone call from the Echocardiography Center to the referring Field Center and, if possible, to the Field Center Echocardiography Director. The Field Center will then be responsible for calling the patient's referring physician (or physician of record) on an "urgent" basis.

Field Center echocardiography technicians will enter any of the "Alert" findings, listed below, which they identify during the examination in the computer terminal at their station and also on the Echocardiographic Technician's Worksheet (Appendix B).

Alert Findings
Aortic dissection
Vegetation
Tumor
Flail leaflet
Thrombus
Suspected pericardial tamponade

5.11.2 Suspected pericardial tamponade

Suspected pericardial tamponade will be defined echocardiographically as the presence of a pericardial effusion with right atrial and right ventricular chamber collapse and respiratory variations exceeding 30% in Doppler peak velocities recorded at any cardiac valve site.

5.12 Data Transmission

Field Center technicians will record their studies on super VHS tape, approximately six studies per 60-minute tape, and send them to the Echocardiography Reading Center weekly, each Monday The technicians will produce duplicate copies of the Echocardiographic Technician's Worksheet (Appendix B) - one copy to stay in the patient's record at the Field Center and the second copy to be sent to the Echocardiography Reading Center along with the videotape.

5.12.1 Packing and Shipping Instructions

Field Centers will package their super-VHS videotapes securely, using sufficient packing material to prevent damage to tape casements during shipment. Shipments will be sent via a secure, trackable delivery service such as Federal Express, United Parcel Service, or other secure, trackable overnight mail delivery service, to:

Retha Webb (Phone: 202/687-8977)
Cardiology Division-5 PHC (Room F5033A)
CHS Echocardiography Reading Center
Georgetown University Medical Center
3800 Reservoir Road, NW
Washington, DC 20007.

Note: Always include phone number with address in case of misrouted shipment. The outside of each package should bear the Field Center's return address, sender's name and phone number.

These videotapes should be accompanied by a packing slip listing the videotapes sent by number. In addition, copies of this packing slip should be sent by MCI mail transmission to both the Echocardiography Reading Center and to the Coordinating Center. Upon arrival at the Echocardiography Reading Center, tapes will be logged with names and code numbers for each patient study, date of arrival, name of Field Center, and tape number. The Echocardiography Reading Center will send an acknowledgement by MCI mail, both to the appropriate Field Center

and to the Coordinating Center, that a shipment of tapes has arrived from a Field Center. Tapes will then be reviewed, frames digitized, measurements made, and data entered in the data base in one operation by the reader.

6 Training and Certification Procedures for Field Center Echocardiography Technicians

6.1 Initial Training and Certification of Field Center Echocardiography Technicians

6.1.1 Orientation Visit to Echocardiography Reading Center

In March, 1994 an initial three-day orientation and training session will be scheduled for all Field Center technicians at the Echocardiography Reading Center. Prior to attending this session, each Field Center technician will fill out a questionnaire which will give the Echocardiography Reading Center staff an idea of the previous level of his/her training and experience. The initial orientation/training visit will be geared to the level of training and experience of the Field Center technician group. The orientation session will begin with a lecture-format orientation to cardiac anatomy and function, as well as basic principles of echocardiographic imaging and Doppler flow recording. Additional lectures will focus on the objectives and timetable of the Cardiovascular Health Study,

strategies for technician training and quality control, as well as details of operation of the Toshiba SSH-160A ultrasound unit and of the echocardiographic scanning protocol. Following this initial orientation, Field Center technicians will each learn how the various M-mode, two-dimensional and Doppler echocardiographic measurements will be made at the Echocardiography Reading Center using the off-line analysis system. It is extremely important that Field Center technicians are aware of constraints imposed on the echocardiography readers by limitations in reading time and by technically suboptimal studies. In addition, field center technicians will have the opportunity during this five-day training visit to perform echocardiography examinations while observed by each other and Echocardiography Reading Center personnel. This provides the opportunity to observe first hand the effects of inter-technician differences in echo acquisition on study characteristics and quality. The format for this hands-on technician training at the Echocardiography Reading Center will be the same as outlined in the next section for Field Center training.

6.1.2 Initial Training and Certification at Field Centers

One or two weeks following this initial orientation at the Echocardiography Reading Center, the principal or associate technician-reader from the Center will travel to each

Field Center to observe field center technician echocardiography performance of approximately five subjects per day. Subjects will be scanned first by the Field Center technician(s) and then the echocardiography trainer. The trainer will provide on-line supervision and instruction in the proper positioning of the transducer to record optimal two-dimensional and M-mode images--especially of the left ventricle--as well as pulsed, continuous wave and color flow Doppler studies as outlined in brief in Appendix C. At the end of this site visit, the technician-trainer will examine each of the Field Center technicians regarding their ability to do two-to-four complete echocardiograms according to the outlined protocol. The examination will be performed first by the technician-trainer, whose study will serve as the "gold standard" against which to compare examinations performed by the Field Center technicians. A scoring system will be developed for each M-mode, two-dimensional and Doppler echocardiography view in which 3 is "excellent" and corresponds to the "gold standard" recording of the technician, 2 is "good" (i.e., slightly below the technical quality achieved by the technician-trainer) 1 is satisfactory but substantially below the quality of the trainer's study, while 0 is "unacceptable." For grading M-mode and two-dimensional studies, emphasis will be placed on the ability of the Field Center technician to obtain images with appropriate spatial orientation and good endocardial and epicardial

definition. For grading pulsed and continuous wave Doppler studies, emphasis will be placed on the ability to properly position the ultrasound beam and to record beats demonstrating the highest velocity and, for pulsed wave, the least spectral dispersion. An overall average examination score of "2" will be required for each Field Center technician to be certified by the technician-trainer from the Echocardiography Center. Should any Field Center technician not qualify for certification, the technician-trainer will schedule additional time in which to train this technician at his/her Field Center.

Field Center technicians will be trained to perform the appropriate echocardiographic examination as outlined above within 30 minutes and to fill in the Echocardiography Technician's Worksheet (Appendix B). A brief synopsis of this protocol is included in Appendices A and D. If recording from the parasternal or apical views produces suboptimal images, the Field Center technician will be trained to use the subcostal view to record images and flow data.

6.2 Retraining of Field Center Echocardiography Technicians

In case of technician turnover at the field site, the Echocardiography Center technician will assist in the training of any new Field Center technicians. Whenever turnover in a Field Center technician position occurs, the same quality assurance measures used during the

pre-clinical years to certify technicians will be used, namely, a study in which the new technician performs echocardiograms in 20 subjects and repeats the echocardiogram in 20 of these subjects. These studies will be compared to the same number of studies performed in the same subjects by the remaining senior Field Center technician. Studies will then be forwarded to the Echocardiography Reading Center where all studies will be read by one reader and the coefficient of variation and re-performance variability scores calculated for inter-technician and intra-technician comparisons.

7 Quality Assurance Procedures and Monitoring of Inter- and Intra-Technician Performance Variability

(See Appendix E)

7.1 Pre-Pilot Studies

(Appendix E)

During April - May 1994, a pre-pilot series of echocardiograms will be performed on 20 subjects at each Field Center by each technician who will be involved in performing echocardiograms. The subjects will consist either of members of the CHS study cohort, or volunteer subjects in the same age group (ages 65 and over) as the CHS cohort. These studies will be performed by the Field Center technician during the two months after the initial orientation/training visit to the Echocardiography Reading Center. Because each technician (generally two) in the Center will perform echocardiograms on these same 20 subjects, we will be able to develop a measurement score (e.g., coefficient of variation) for inter-technician variability. In

addition, each technician at each Field Center will be required to repeat studies one-to-eight weeks later in these 20 subjects -- not relying on any notes as to the position of the subject or the head of the bed, the type and location of the transducer, and preset machine factors (recorded on the Echocardiography Technician's Worksheet)--to establish a measure of intra-technician performance variability. These echocardiograms will be coded by random number at the Echocardiography Reading Center. Assuming there are two technicians at each of the four centers, this will result in a series of 320 echocardiograms to be read at the Echocardiography Reading Center. **A sample of these echocardiograms will be used to certify technicians for performance of studies in the clinical year.** Appendix E outlines the schema for performing these studies at the Field Centers and interpreting them at the Echocardiography Reading Center. A sample of sets of the four echocardiograms from each of 20 subjects (selected randomly from the 80) will be read by the Director of the Echocardiography Reading Center to assess inter- and intratechnician performance variability. It is estimated that the approximate number necessary for the Director to read is 80 studies, based on maximum expected intratechnician, intertechnician, and Director reader variability of 30%, 30%, and 10%, respectively, and maximum acceptable values of 10% each. Each of four readers at the Echocardiography Reading Center will read the same sample of 40 echocardiograms, sampled from the 80 echocardiograms performed in the first round (e.g., first echocardiogram from the first technician) on the 80 patients. The same sample of 20 echocardiograms, randomly selected, will then be reread in a timely fashion to determine intra-reader

variability. These numbers are based on maximum expected inter- and intraobserver variabilities of 35% and 15%, respectively, with acceptable values of 15% and 10%, respectively.

The goal of these pre-pilot studies is to maintain a mean intra- and inter-technician performance variability (and a mean inter- and intra-reader variability) in the range of 10%. If the inter- or intra-technician variability in the pre-trial studies during Year 1 is not within 15% for technicians in any of the Field Centers, the Center will be visited by one of the echocardiography technician-readers from the Echocardiography Reading Center. The technician-reader will review the pre-pilot series of echocardiograms with the Field Center technicians in an attempt to pinpoint and correct the source of inter- or intra-technician variability. The Echocardiography Reading Center technician will have the authority, with the approval of the Director, to determine whether the problem in technician variability has been corrected after this visit, or whether further steps, such as additional training or hiring and certifying a new Field Center technician, are necessary to assure accurate data collection.

7.2 Quality Control During Clinical Examination Phase: Re-Reading of Blind Duplicate Studies and Test-Retest Replication Study

During Year 7 of the study (Examination II), an Echocardiography Center technician-reader will visit each Field Center two times (at approximately six-month intervals) to ensure that the Field Center technicians

are performing in compliance with the protocol. *Additionally, a sample of studies will be systematically repeated by the Field Center echocardiography technician to provide measurement data for assessment of inter- and intra-technician performance variability.*

For assessment of performance variability during the clinical years, a sample of 20 subjects will be asked to return for repeat echocardiography within a month of their initial examination. Consecutive subjects undergoing echocardiography at the beginning of each month of Years 2 and 5 will be asked to volunteer to return for these repeat studies. On their return visits, these 20 volunteers will include 6 with initial studies performed in June, 6 from July, 5 from August, 5 from September, 4 from October, 4 from November, 3 from December, 3 from January, 2 from February, and 2 from March. On their return visits, these 20 subjects will have one echocardiogram repeated by the technician who performed the echocardiogram at the initial study and a second repeat echocardiogram performed by a second Field Center echocardiography technician. Fifteen (75%) of these subjects should be selected from those initially studied by the principal echocardiography technician at each Field Center; the remaining five subjects will be selected from those who have had their original studies performed by the second technician. The principal technician is defined as the technician who performs most of the echocardiography studies at each Field Center. This breakdown of studies by principal and secondary technician will allow for an estimate of intra-technician performance variability for the second technician, which can be

compared to the more precise estimate of intra-technician variability obtained from the principal technician.

Temporal shift in performance of studies among Field Center technicians will be assessed by comparing means of selected echocardiographic measurements among samples of studies read each month by the same readers over time. These analyses can be done by technician and by Center to allow for detection of shifts over time in technician performance of studies. Any shifts in performance will be adjusted for any reader drift detected from re-reading samples of studies during the clinical years, as described below.

Depending on the needed sample size to assess intrareader variability, as confirmed from the pre-pilot data analysis, a 3-5% random sample of studies will be reread, blindly, on a weekly basis by each of the Echocardiography Reading Center readers, so as to track (and if necessary correct) any temporal drift in intrareader measurement variability during clinical years 2 and 5. The exact protocols for assessing intra-reader measurement variability and intra-technician performance variability will be designed and supervised by the ERC and statistical core personnel.

Additional training may be required of the technicians and/or the readers during the clinical or interim years in the event of any significant temporal shifts in accuracy or precision of echocardiography study performance and/or reading. It is the opinion of the Echocardiography Reading Center Director that Field Center technicians must perform a minimum of 4

echocardiographic studies per week according to the CHS protocol during the examination years (Years 2 and 7) to maintain sufficient proficiency to retain their certification as CHS Field Center technicians.

7.2.1 Monitoring of Field Site Technician Echo Quality Code Scores

The proportion of unreadable studies (quality code "0") for M-mode LV, and 2-D regional wall motion will be tabulated biweekly. An increase in the proportion of unreadable studies to 30% or greater will trigger a query of the field center vis-a-vis changes in personnel, study technique, echo machine performance. If helpful, a site visit will be made within one week by ERC personnel to observe study performance and offer corrective measures, if available.

7.3 Equipment Calibration

The procedure for the initial visit from the Echocardiography Reading Center technician to each Field Center, and for each subsequent visit, will include calibration of the ultrasound equipment -- including each transducer, the strip chart and video display. Equipment will be calibrated using the 100mm test object (or an equivalent phantom) to test imaging performance. The actual calibration with the imaging phantom will be performed by an Echocardiography Reading Center technician and/or a trained service representative from Toshiba, Inc., at three-month intervals.

Parameters of imaging performance which will be examined using the test object include the following[14]:

7.3.1 Relative system sensitivity
7.3.2 Longitudinal resolution
7.3.3 Lateral resolution
7.3.4 Dead zone
7.3.5 Range (depth or distance) accuracy
7.3.6 Registration accuracy
7.3.7 Compensation (sweep gain) operation
7.3.8 Gray-scale dynamic range

8 References

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9 Appendices

Appendix A: Echocardiogram Summary Card

Appendix B: Echocardiographic Technician's Worksheet

Appendix C: Description of Toshiba SSH-160A Cardiac Ultrasound Machine Menus

Appendix D: Echocardiography Scanning Protocol

Appendix E: Pre-pilot Studies

Appendix F: Basic Aspects of Doppler Color Flow Imaging

Appendix G: Echocardiographic Measurements

Appendix G: Echocardiographic Measurements for the Year 7 Study

APPENDIX A

CHS
Echocardiography Acquisition Summary

Enter Patient's Name
Enter ID Number

(Record during quiet respiration)

1. **LAX 2D: LV, Ao, AoV**: 10 beats
   C-F MR/AR: 10 beats

   LAX M-mode: LA/AO 10 beats side-by-side 2D
   M-mode: RV/LV - mitral tips: 10 beats, side-by-side,
   10 beats full-screen quiet respiration;
   5 beats held expiration

2. **SAX**
   LA/Ao
   2D: Ao/AoV/LA: 10 beats
   C-F Dopp PA (PR): 5-10 beats
   C-F Dopp TR 5-10 beats;
   If TR, CW side-by-side 2D
   M-mode: LA/Ao 10 beats side-by-side,
   10 beats full-screen

   LV
   2D: RV/LV Circular LV 10 beats MV;
   10 beats pap. m.
   M-mode: 20 beats side-by-side mitral tips;
   20 beats full screen;
   5 beats held expiration

3. **Ap 4CH:** 2D 10 beats
   PW Dopp mitral tips 10 beats side-by-side
   10 beats full screen; 5 beats held expiration

   2 minute limit
   C-F Dopp: MR/TR 10 beats
   CW Dopp: TR jet, if present

4. **Ap 2CH:** 2D - 10 beats

5. **Ap long axis**
   2D 10 beats
   C-F Dopp MR/AR : 10 beats
   P-W LVOT: 10 beats side-by-side w/2D
   Doppler sample proximate to aortic valve
   (may substitute Ap 5 Ch if necessary)
   CW Dopp AoV (*only* if AS is suspected)
   (may substitute Ap5 CH)

Subcostal 4CH/SAX: Only if no para. SAX
2D 10 beats
M-mode LV: 10 beats side-by-side
15 beats full frame

APPENDIX B

ECHOCARDIOGRAPHIC TECHNICIAN'S WORKSHEET

NAME:_____ CHEST DEFORMITIES?_____

ID #: _____ LUNG DISEASE? _____

DATE: _____

TIME: _____ _____

HEIGHT: _____ _____

WEIGHT: _____ BLOOD PRESSURE: _____

AGE:_____ SEX: _____ VIDEOCASSETTE #: _____

TECHNICIAN CODE: _____ FOOTAGE: _____

		Parasternal	Apical	Doppler
SYSTEM PRESET	A (2.5 MHz)	_____	_____	_____
SYSTEM PRESET	B (3.75 MHz)	_____	_____	_____

SAMPLE M-MODE MEASUREMENTS

LV Diastole _____ cm; Septum Diastole_____cm; Posterior Wall Diastole_____cm

QUALITY ASSESSMENT (1-4)

M-mode ____ Two-dimensional _____ Doppler ____

ALERT FINDINGS (Please check)

___ Aortic dissection ___ Vegetation ___ Tumor

___ Flail leaflet ___ Thrombosis ___ Suspected pericardial tamponade

OTHER DIAGNOSES

_____ _____

Echo Technician Field Center

APPENDIX C

DESCRIPTION OF TOSHIBA SSH-160A

CARDIAC ULTRASOUND MACHINE

MENUS AND PRESETS

FOCUS:

AUTO - The software automatically selects one appropriate focal zone according to the operating depth, or doppler sample position.

MANUAL - 20 ~ 148 (mm) any single zone or combination of focal zones.

SCAN MODE:

HIGH F - When high frame rate is selected, the sector angle decreases to 45 deg. This 45 deg. wedge can be steered by the steering controls. < >

HIGH D - The selection of high density increases the number of scan lines/frame. A corresponding frame rate reduction will occur.

PAN/ZOOM SEL:

Selects the portion of the displayed image that can be controlled by the pan/zoom function.

ECG SYNC SEL:

SINGLE - Allows only one ECG sync point to refresh the B mode image.

DUAL - Allows two ECG sync points to alternately refresh the B mode image.

B/M OTHER:

This is the control to access the B/M OTHER menu on the VFD display.

ECHO FILTER:

RESO - Selects a high center frequency characteristic of the echo filter to achieve optimum resolution.

PENE - Selects a low center frequency characteristic of the echo filter to achieve optimum penetration.

PRE-STC:

ON - Selects the user programmable STC reference waveform.

ECHO AVERAGE (B):

OFF - No averaging performed between the current and previous frames of the image.

1 - 1 New : 1 Old Ratio of averaging between frames.

2 - 1 " : 3 " Ratio

3 - 1 " : 7 " Ratio

POST PROCESS:

OFF (L) - Linear gamma response

1 - 5 - Pre-programmed gamma post processing curves.

6 - 7 - User programmable gamma post processing curves. (Access to programming area is through the registration menu).

B REAL (M+B):

ON - Allows a live B image to be displayed with a frozen image. The procedure is as follows: With live B and M mode images displayed,

1. Press FREEZE
2. Press B REAL (M+B) ON
3. Press FREEZE

M-POSI MARK:

ON - The M-direction marker is turned on or off.

D/M TIME MARK:

ON - Turns on and off the time marks for both M-mode and FFT Doppler display.

REF. FREQ:

L.M.H. - Selects low, medium or high reference clock frequency of the phase detector.

PW PROBE FREQ	L	M	H
2.5 mhZ	1.87	2.14	2.5
3.75	2.5	3.0	3.75
5.0	3.0	3.75	5.0

V RANGE MODE (P.W.):

MAN - Manual selection of the measurable PW Doppler velocity range (P.R.F.) for the depth of the sample volume.

AUTO - The system automatically selects the maximum velocity range (P.R.F.) for the depth of the sample volume.

BASE SHIFT:

Manual selection of which group of 14 adjacent data lines are used for doppler display intensity out of the 32 available data lines.

B/D EXPAND:

Gives half-screen Doppler spectrum display during M+B (real) mode.

FWD/REV CHANGE:

Inverts doppler spectrum display and velocity characters.

ANGLE MARK:

Generates angle marks which can be rotated around the sample volume by the front panel "CW/PW Angle" control. As the angle is changed, the numerical display on the spectrum velocity axis also varies.

FILTER CONDI:

Control of doppler high pass filter cut-off characteristics.

PWA (8th Order Filter)

Set	1	2	3	4	5	6	7	8	9	10	11	12	13
fc (Hz)	50	60	70	90	100	130	140	180	200	260	290	360	400

PWB (4th Order Filter)

Set	1	2	3	4	5	6	7
fc (Hz)	40	60	90	130	180	260	360

CWA (8th Order Filter)

Set	1	2	3	4	5	6	7	8	9	10	11	12	13
fc (Hz)	140	180	200	260	290	360	400	800	700	1200	1200	1400	1500

CWB (4th Order Filter)

Set	1	2	3	4	5	6	7
fc (hz)	130	180	260	360	360	700	1400

CW ACOUSTIC POWER:

Adjust acoustic (Output) CW Doppler Up/Down manually.

Max Voltages: - PSD-25RE = 13V

PC-25M = 10V

M-BLANK:

ON - Blanks the M-mode display for easy reading histograms

ECHO LEVEL:

Automatic gain control selection

ON - 23~39dB AGC amp range gain

1 - 23dB
2 - 33dB
3 - 39dB

COLOR DISPLAY:

V-T - Velocity and Turbulence display mode
P - Power display
V - Velocity only display
T - Turbulence display

DISPLAY:

C & B/W - Color & Black and White display
C - Color only
B/W - Black and White

WIDE B:

Gives a 90° wide B/W image with color sector wedge inside (30°, 45°, 60°).

CONTRAST:

Color data post-Processing

DATA NO:

N Number of samples used for color flow mapping calculation.

DENSITY:

Raster density (Spacing) in CFM Mode

COLOR FILTER:

High-pass filter characteristic control

AUTO - System automatically selects the appropriate frequency

MAN - Front panel adjustable (1~7)

C & B/W BALANCE:

Varies the threshold that the B/W image data must exceed before a color display is inhibited.

COLOR PROFILE:

Selects the type of data to be A-Mode displayed.

V - Bidirectional display
P - Undirectional display
T - Unidirectional display
B/W - A mode display

ECG AUTO DELAY:

Man — Permits manual setting of the ECG display

AUTO + 50ms — Provides a fixed 50ms delay after the RSYNC signal (peak of the R-wave + 50ms).

AUTO + 100ms — Provides a fixed 100ms delay after the RSYNC signal (peak of the R-Wave + 100ms)

BODY MARK:

For selection of body mark display.

AUTO DATA DISP:

ON - SSH-160 operating parameters are displayed.

B-LOOP HI-FRAME (COLOR):

Artificially produces a frame rate 3 times faster than that recorded, with ECG, in B-Loop playback

CONDI DATA (VCR):

AUTO - Condition data automatically decoded from tape when freeze is selected.

MAN - When operating in auto mode and condition data error is detected, change to manual mode. A green cursor will appear at the bottom of the screen, just above the line of condition data numbers. Using the keyboard, enter identical numbers to those displayed, then hit CR (carriage return) "Condition Data OK" message appears at the top of the screen. Measurements can now be performed.

REGISTRATION:

ON - Provides access to the following registration menu:

Hospital Name
Body Mark
Auto annotate
Post process
Gain correction
Correction coefficient
User function

VF READ:

FLD - Normal mode of operation, when in VTR replay mode the best image quality is achieved by selecting field read.

FRM - When replaying VTR video the characters displayed may be difficult to read. By

changing to frame read mode characters will be displayed much clearer.

MAINTENANCE:

Provides user access to 2 pages of Maintenance menu.

PRESET MENU:

Provides user access to 5 pages of Preset menu.

TIMER COR:

Adjust time and date on monitor display.

PRE STC COMP:

Stores the current overall STC curve to be used as the PRE STC reference waveform when PRE STC is selected

LSR CAL:

Selects counter as (LSR I/F) output to line scan recorder for calibration grey scale.

SERVICE FUNCTION:

Provides access to service engineers menu (4 pages).

APPENDIX D

CARDIOVASCULAR HEALTH STUDY
ECHOCARDIOGRAPHY READING CENTER

ECHOCARDIOGRAPHY/DOPPLER
SCANNING SEQUENCE

I. Parasternal Long-Axis View

A. 1. 2-D echo LV during quiet respiration: 10 beats.

2. 2-D echo aorta and aortic valve during quiet respiration, optimize aortic leaflet excursion, 10 beats

3. Color-Flow imaging, optimize MR, and/or AR if present; record 10 beats.

B. M-mode cursor through aorta and left atrium at maximum left atrial dimension; record 10 beats 2-D update image side by side with M-mode recording during quiet respiration.

B. M-mode cursor perpendicular through left ventricle just below the level of the mitral leaflet tips:

1. Record 10 beats of 2-D update image side-by-side with M-mode recording

2. Record 10 beats of full-screen M-mode during quiet respiration; finally, record a full-screen, freeze-frame M-mode image for 5 seconds at held-expiration.

3. Turn 90° into parasternal short-axis view.

II. Parasternal Short-Axis View

A. Two-dimensional echocardiography during quiet respiration at level of aorta and left atrium, optimize aortic leaflet excursion: 10 beats

B. Color Flow of pulmonary artery to optimize pulmonary regurgitation (if present). Record 10 beats at quiet respiration even if no PR is noted.

C. Color flow tricuspid regurgitation. Record 10 beats even if no TR present. If TR is noted use 2.5 Mhz transducer attempt to record 10 beats of optimal tricuspid regurgitant jet signal with best envelope and highest peak velocity side by side with 2-D image (MAX TIME 2 min):

D. M-mode cursor perpendicular through aorta and left atrium, attention to place cursor through largest "belly" of left atrium: Record 10 beats of 2-D update image side-by-side with M-mode recording, then **record 10 beats of full-screen M-mode during quiet respiration.**

E. Two-dimensional echocardiography at level of mitral leaflet tips at quiet respiration: 10 beats. **Adjust echo window to obtain**

circular cross section; avoid oval (ellipsical) cross-section

F. Two-dimensional echocardiography at level of papillary muscles at quiet respiration: **10** beats

G. ***THE FOLLOWING IS THE HIGHEST PRIORITY OF THE ECHO EXAM.*** M-mode cursor through the center of the left ventricle at the level between the mitral valve tips and papillary muscles. Take care to adjust echo window to **obtain circular cross-section.** Record 20 beats **or more** of 2-D update image side-by-side with M-mode recording during quiet respiration, then record 20 beats of full-screen M-mode during quiet respiration; finally, record a full-screen, freeze-frame M-mode image for 5 seconds at held-expiration.

III. Apical Four-Chamber View

A. Two-dimensional echocardiography at quiet respiration: Record **10** beats with maximum chamber dimensions and good LV endocardial definition.

B. Pulsed Doppler transmitral flow recording with sample volume at leaflet tips during diastole: Using a 2.5 MHz transducer, record 10 beats of 2-D update image side-by-side with Doppler recording, then display 10 beats of full-screen Doppler during quiet respiration; finally, record a full-screen,

freeze-frame Doppler image for 5 seconds at held-expiration.

C. Doppler color flow mapping during quiet respiration: Using the 2.5 MHz transducer, turn on color **Doppler** to **map** for mitral and tricuspid regurgitation: record **10** beats. TIME LIMIT: 2 minutes.

D. Imaging 2.5 MHz CW Doppler during quiet respiration: Attempt to record optimal tricuspid regurgitant jet signal with best envelope and highest peak velocity: 10 beats. TIME LIMIT: 2 minutes.

D. Turn approximately 90° into apical two-chamber view.

IV. Apical Two-Chamber and Apical Long-Axis Views

A. Two-dimensional echocardiography in the true apical two-chamber view at quiet respiration: Record **10** beats with maximum LV chamber dimensions and good LV endocardial definition

B. Two-dimensional echocardiography in the apical long-axis view **during quiet respiration:** Record **10** beats taking care to include the left ventricle, left atrium, aorta and right ventricle in the image.

C. Color flow Doppler recording in the apical long-axis view **during quiet respiration:** Record 10 beats : optimize MR and/or AR

color flow signals if present. TIME LIMIT: 2 minutes.

D. PW Doppler LV Outflow Tract: Doppler sample volume proximate to aortic valve. Record 10 beats during quiet respiration. Attention to narrow envelope, acoustically pure signal with optimal ejection contour.

E. CW Doppler Aortic Valve: **PERFORM ONLY IF AORTIC STENOSIS IS SUSPECTED**, i.e., decreased leaflet excursion (less than 10 mm) and markedly thickened/calcified aortic valve. **CW Doppler** in the apical long-axis view **during quiet respiration:** Using the 2.5 MHz imaging transducer, record 10 beats of 2-D updated image side-by-side with CW recording of maximum aortic flow velocity: 10 beats. Finally, record a full-screen, freeze-frame Doppler **image for 5 seconds.** Then, stand-alone non-imaging CW recording of maximum aortic jet from suprasternal notch and right parasternal (patient in **right** lateral decubitus position) window; 10 beats each at quiet respiration.

V. Subcostal Four-Chamber View

(Perform only On subjects in whom the left ventricle cannot be recorded from parasternal views)

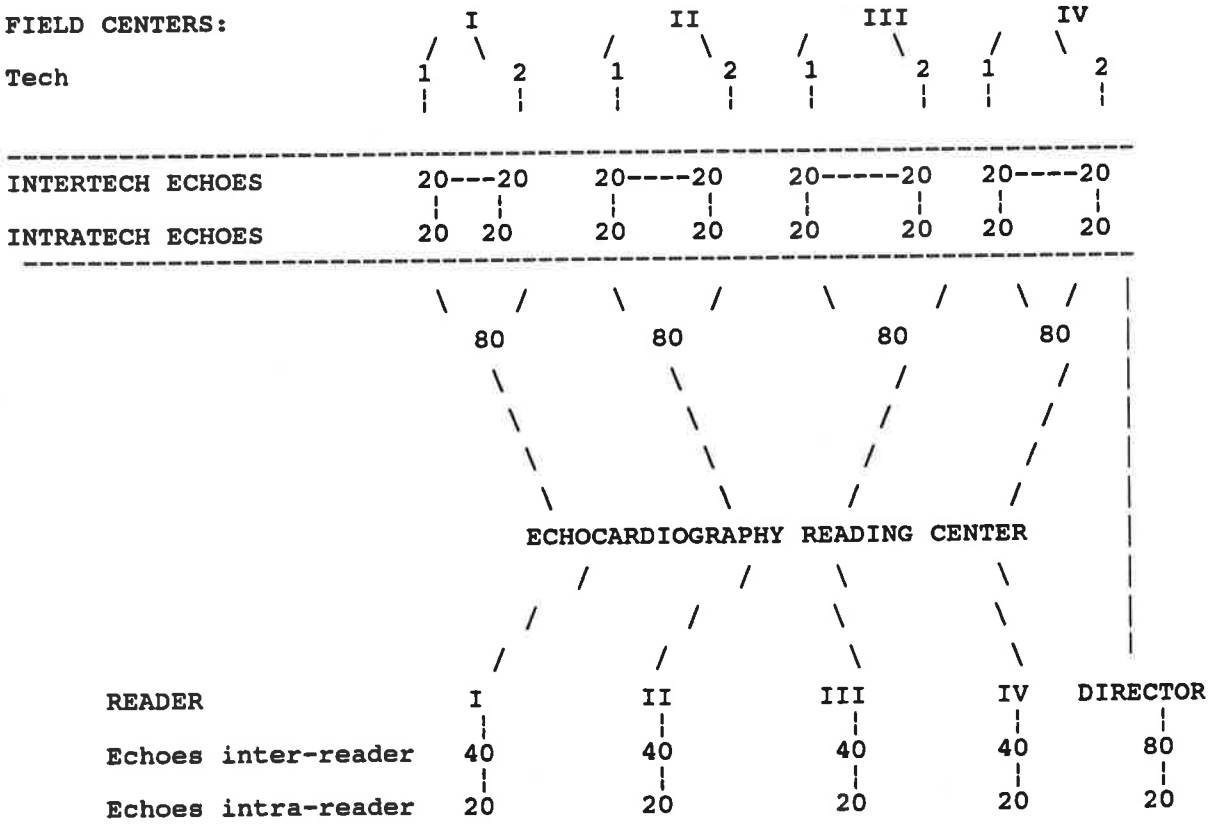
Two-dimensional echocardiography at quiet respiration: Record **10** beats with maximum chamber dimensions and good LV endocardial

definition. M-mode cursor through center of subcostal short axis; record 10 beats M-mode split screen recording side-by-side with 2-D, additional 15 beats full frame M-mode.

APPENDIX E

CARDIOVASCULAR HEALTH STUDY
ECHOCARDIOGRAPHY READING CENTER

SCHEMA FOR PERFORMING AND READING ECHOCARDIOGRAMS DURING PRE-PILOT STUDIES IN YEARS ONE AND SIX



Notes:

Each of two technicians will perform echocardiograms on the same 20 patients within each of the four centers, and will reperform the same 20 echocardiograms within a week. Therefore, a total of 80 patients will be examined four times, producing 320 echocardiograms.

Eighty echocardiograms will be read by the Director of the Echocardiography Reading Center, selected by choosing 4-echo sets (from inter- and intra-technician reperformance) from 20 patients selected by stratified randomization among the four centers (5 from each center). This is the approximate number necessary, based on maximum expected intratechnician, intertechnician, and Director reader variability (from reports in the literature, and the assumptions of intertechnician variability being at least as great as interobserver variability, and Director variability being approximately that of intraobserver variability) of 35%, 35%, and 15%, respectively, and maximum acceptable values of 10% each (the ratio of the sums of the maximum expected and acceptable variation yields a maximum R-ratio of 80%/30% = 2.67, which when multiplied by Z = 2.76, the constant needed for multiple hypothesis testing of four important parameters (LVDvol, VST, LVIDd, and LVPWT), and the product squared yields 55 cases). This analysis is conservative from the standpoint of additional hypotheses to be tested. Applying a maximum individual R of 3.5 (obtaining 93 needed cases) suggests that 25% sampling (or 80 cases total) would be appropriate. Each of four readers at the Echocardiography Reading Center will read the same sample of 40 echocardiograms, sampled from the 80 echocardiograms done in the first round (e.g., first echocardiogram from the first technician) on the 80 patients. The same sample of 20 echocardiograms, randomly selected, will be reread in a timely fashion. These numbers are based on maximum expected inter- and intraobserver variabilities of 35% and

15%, respectively, with acceptable values of 15% and 10%, respectively. All echocardiograms read by the Echocardiography Reading Center readers are the same set of 40 different patients, rather than a random set which could include duplicate patient echocardiograms, so as not to introduce a potentially attenuating factor of duplicate patients which despite being performed by different technicians or at different times, would likely display less variation than echocardiograms from different patients.

APPENDIX F

DOPPLER COLOR FLOW IMAGING - BASIC ASPECTS

I. PHYSICS AND INSTRUMENTATION

A. Multigate Pulsed Doppler:

Color flow mapping basically applies color encoding to the multi-gate pulsed Doppler technology. In a typical system, two-dimensional or M-mode echocardiographic images are is displayed in combination with color-flow velocity information. The color flow information in one commercially available system is displayed over 32 lines in a sector with each line containing 468 sample sites, or "pixels" of information, along the line. In addition, in order to obtain a representative idea of the velocities in each of these pixels at the particular instant in time, each pixel (i.e., 468 sample sites per line) may be sampled 4 to 8 times with the mean velocity displayed at each sample site and a "variance" calculated using algorithms designed to reflect the variation in velocities from this mean value.

B. Basic display:

Most color flow mapping machines display flow towards the transducer in shades of red and flow away from the transducer in shades of blue. The higher mean velocities are generally displayed in brighter shades of red (toward) or blue (away from) the transducer. However, available color flow machines generally use a technique known as "auto-correlation". In this technique, the intensity of frequency shift in the reflected signal from each pixel is displayed in color bins of various intensities of red or

blue reflecting ranges of velocities (e.g., 0-7cm/sec 8-14 cm/sec, etc).

As with pulsed Doppler, "aliasing" occurs when the Nyquist limit is exceeded for any given sample site. Basically, there is a limit on the highest velocity which can be displayed in any given sample site. This limit depends on the depth of the sample site, the angle between the Doppler beam and blood flow, and the frequency of the Doppler signal which the transducer transmits. In the color mode, aliasing is generally displayed as shades of red becoming shades of blue for higher velocities towards the transducer, and vice versa for flow away from the transducer. In most systems, aliasing will occur in the range of 0.5 meters/sec to 1.0 meters/sec if one does not shift the zero baseline. It is not uncommon with very high velocities to see three or even more "raps" of color (i.e., from red to blue to red) demonstrating multiple aliasing on color flow display.

"Aliasing" can be minimized using a number of strategies, including:

1) using a transducer with a lower Doppler transmit frequency, and
2) performing a baseline shift so that only one primary color (red or blue) is displayed.

Another variable which affects the color display is frame rate, i.e., how many times the given sector is sampled per second. Frame rate may have an important effect on the area of color displayed, e.g., in a regurgitant jet. Frame rate may be increased by:

1) Decreasing the sector depth--i.e. interrogating from a view which will allow the sampling area to be closer to the transducer;
2) using a narrower sector angle; and
3) sampling each line less times (i.e., decreasing the "packet size" from 8 to 4 lines).

The effect of the Doppler angle on flow can be seen even within a single sector of color flow information. For example, in a simple flow experiment with constant flow through a tube oriented perpendicular to the long axis of the two-dimensional transducer, constant volume flow will initially appear as red as it flows toward the mid-point of the transducer, then as black as the mid-point of the transducer is perpendicular to flow, then as blue as flow moves away from the mid- point of the transducer. It is obvious that in any of the applications of color flow mapping, it is important to know the Doppler angle for each sample site in order to derive the correct quantitative or semi-quantitative information. This admonition is true when examining for stenotic and regurgitant lesions, as well as for shunts and other volume flow applications.

C. Variance:

Non laminar blood-flow, (flow with red cells moving in various directions with a range of different velocities), is generally displayed in shades of green. The green is added to the directional color (red or blue) in an attempt to display turbulent blood flow such as is generally seen in stenotic or regurgitant lesions. In this way, turbulent blood flow toward the transducer would be displayed as yellow (red plus green) and turbulent blood away from the transducer would be displayed as cyan (blue plus green). Some instruments accentuate their "variance" displays by

appearing as a "mosaic" pattern with flecks of white or yellow, etc., displayed in the area of turbulence. It should be noted, however, that variance is not simply a display of turbulent flow, but involve other factors in their algorithms, including a minimum velocity required to trigger the variance display.

D. Artifacts

Ghosting: Ghosting is a color display which results from low velocity but intense signals returning from dense structures such as cardiac valves, septae or walls. The technology is available to eliminate these artifactual signals, e.g., by using a "moving target indicator" (MTI) filter. When working properly, the MTI filter can eliminate the high intensity, but low velocity signals which generally emanate from cardiac structures, and display only the higher velocity signals emanating from blood flow.

Reverberations: Reverberations are common in the far field, e.g., posterior to the left ventricle. These can often be eliminated by using a shallower depth of scanning.

II. COLOR FLOW EXAM

A. Survey Mode:

One important advantage of Doppler color flow mapping in experienced hands is that the color flow display can be used in conjunction with the 2-dimensional echocardiographic image to give a "quick-scan" for possible pathology, e.g., stenotic or regurgitant lesions or shunts. It should be emphasized that using color flow mapping in this manner requires much experience since small lesions

can be easily missed during "real time" color flow display. The use of a "cine loop" which allows frame-by-frame review of the color flow and 2-D imaging information can be of considerable help in this regard. In this survey mode, should any areas of "aliasing" and/or "variance" be detected, then conventional pulsed and continuous wave Doppler can be used to further investigate the lesions.

B. Basic Exam Approach:

In general, the color flow mapping should be integrated with the 2-dimensional echocardiographic examination. It should be noted that the color flow is best displayed when interrogating areas closest to the transducer. Therefore, for example, one might demonstrate the mitral regurgitant lesion better from a parasternal long axis view in individuals with a big chest in whom interrogation in the apical four-chamber view might place the relative sample volumes far away from the transducer. In addition, in patients with mechanical valves, the color display is often much better from an imaging view (e.g., the parasternal long axis view with a prosthetic mitral valve) which does not require the ultrasound beam to penetrate the mechanical valve (as would be the case from the apical four-chamber view). It is often helpful to decrease the sector size or to display color only in the near field in order to obtain the highest frame rate and the best color flow display (signal-to-noise ratio).

C. M-Q Display:

A number of applications have been outlined for a combination of M-mode echocardiographic imaging and color flow. In general, the M-Q display, as this combined

modality is known, has the advantage of better signal to noise ratio for the color display since each line in this icepick view is sampled many more times per second than would be possible over an entire 2-D sector. Therefore, enhanced signal to noise ratio and improved temporal information are advantages of this modality. This M-Q display might be helpful, for example, in delineating the temporal systolic and diastolic flow direction of a shunt or to time the onset of mitral regurgitation in a case of hypertrophic cardiomyopathy.

D. Normal color flow findings:

The basic directional color display, red or blue, of flow in the heart will depend on the position of the transducer relative to flow. It should also be noted that aliasing is not uncommon across the aortic and pulmonary valve, and is occasionally also seen across the mitral or tricuspid valves, because the Nyquist limit is so low in most instances of color flow mapping. Therefore, it is not uncommon for blood flow across the mitral valve towards the transducer to be primarily red with a small central column of blue. In addition, it should be noted that flow reversals are common in various normal situations in the heart. For example, in mid and late diastole, it is not uncommon to see flow reversal from the left ventricle, which represent eddy currents closing the mitral valve. These eddies may be displayed in shades of blue alongside the central core of red depicting flow towards the transducer.

References

1. DeMaria AN, Smith MD, Kwan OL: Doppler flow imaging: Another step in the evolution of cardiac ultrasound. Echocardiography: A review of Cardiovascular Ultrasound 2:495-500, 1985.

2. Omoto R: Color Atlas of Real-time Two-Dimensional Echocardiography. 2nd edition. Shindan-to-Chiryo and Lea & Febiger, Philadelphia, 1987.

Appendix G

ECHOCARDIOGRAPHIC MEASUREMENTS

M-MODE:

1) Left ventricular internal dimension in diastole (LVIDd)
2) Left ventricular internal dimension in systole (LVIDs)
3) Ventricular septal thickness in diastole (VSTd)
4) Ventricular septal thickness in systole (VSTs)
5) LV Posterior wall thickness in diastole (LVPWTd)
6) LV Posterior wall thickness in systole (LVPWTs)
7) Left atrial dimension (LA)
8) Aortic root dimension (Ao)
9) LV % fractional shortening (LVFS)(calculated)
10) LV end systolic stress (LVESS)(calculated)
11) LV mass (LVMASSm)(calculated)

2-D ECHO:

12) LV regional wall motion abnormality (RWMA)(qualitative)
13) LV hypertrophy (qualitative)
14) LV global systolic function (qualitative)
15) Mitral annular calcification (qualitative)
16) Aortic valve annular calcification/thickening (qualitative)
17) Aortic leaflet calcification/thickening (qualitative)
18) Aortic leaflet excursion (qualitative)

COLOR-FLOW DOPPLER:

19) Mitral regurgitation (qualitative)
20) Aortic regurgitation (qualitative)
21) Tricuspid regurgitation (qualitative)
22) Pulmonic regurgitation (qualitative)

SPECTRAL DOPPLER:

23) LV outflow tract systolic velocity integral
24) LV outflow tract peak velocity
24) Mitral peak early inflow velocity (E)
25) Mitral peak atrial inflow velocity (A)
26) Maximum aortic velocity (CW)- optional

QUALITY CODE STATEMENTS:

27) M-mode LV quality
28) LV inflow Doppler quality
29) LV outflow Doppler quality
30) 2-D RWMA quality

10 Figures

Figure 1: Site Differences in Echo Readability

Figure 1

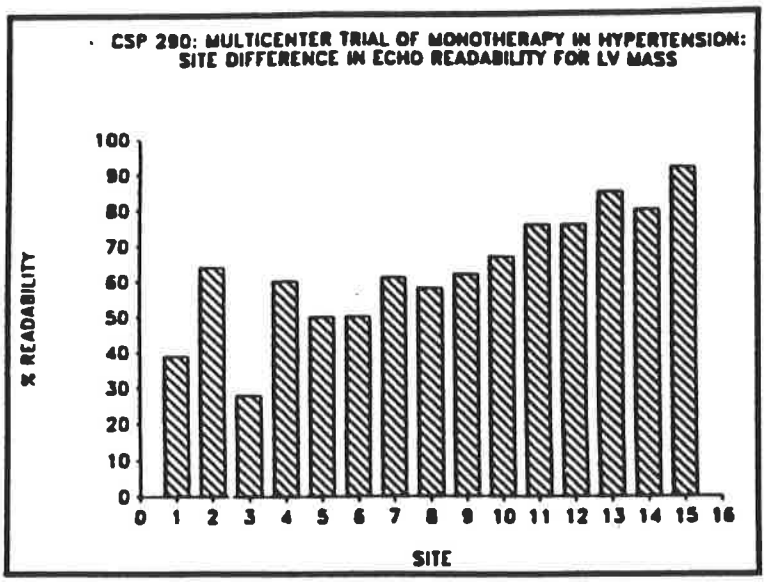


Figure 2: Variations in Placement of M-mode Cursor Through LV

Figure 2

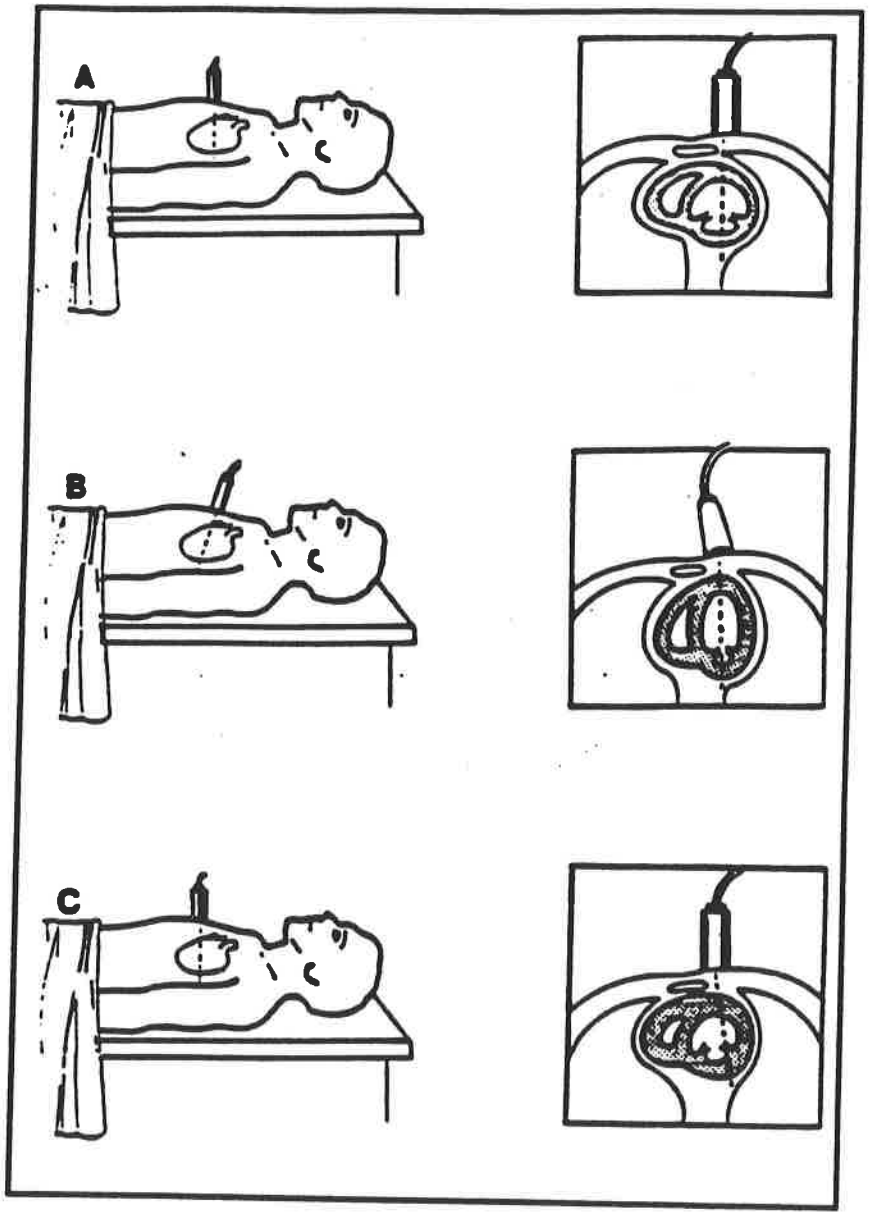
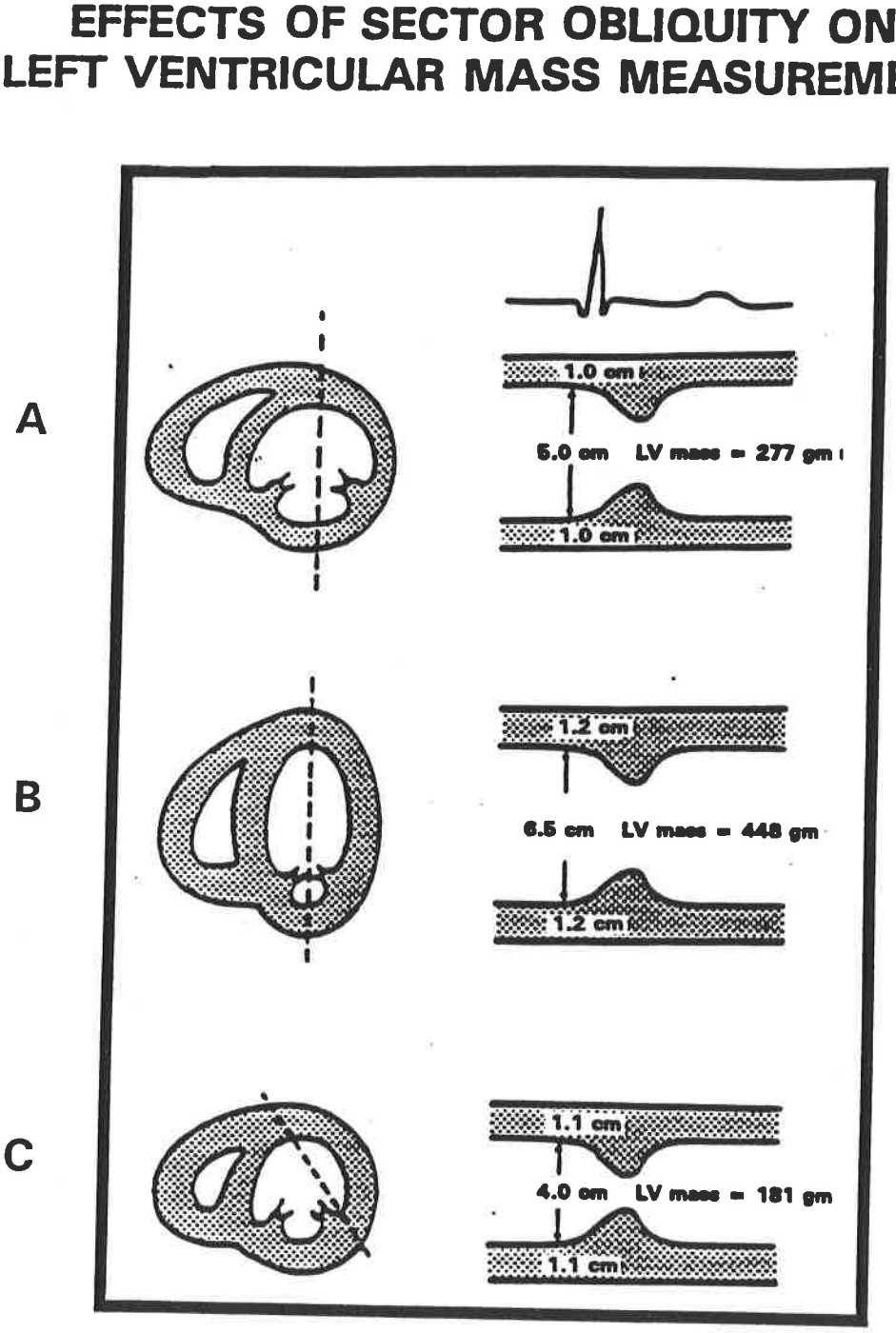


Figure 3: Effects of Sector Obliquity on LV Mass Measurement

Figure 3



Effects of beam angulation errors on 2-D targeted M-mode recordings and estimations of LV mass.

Figure 4

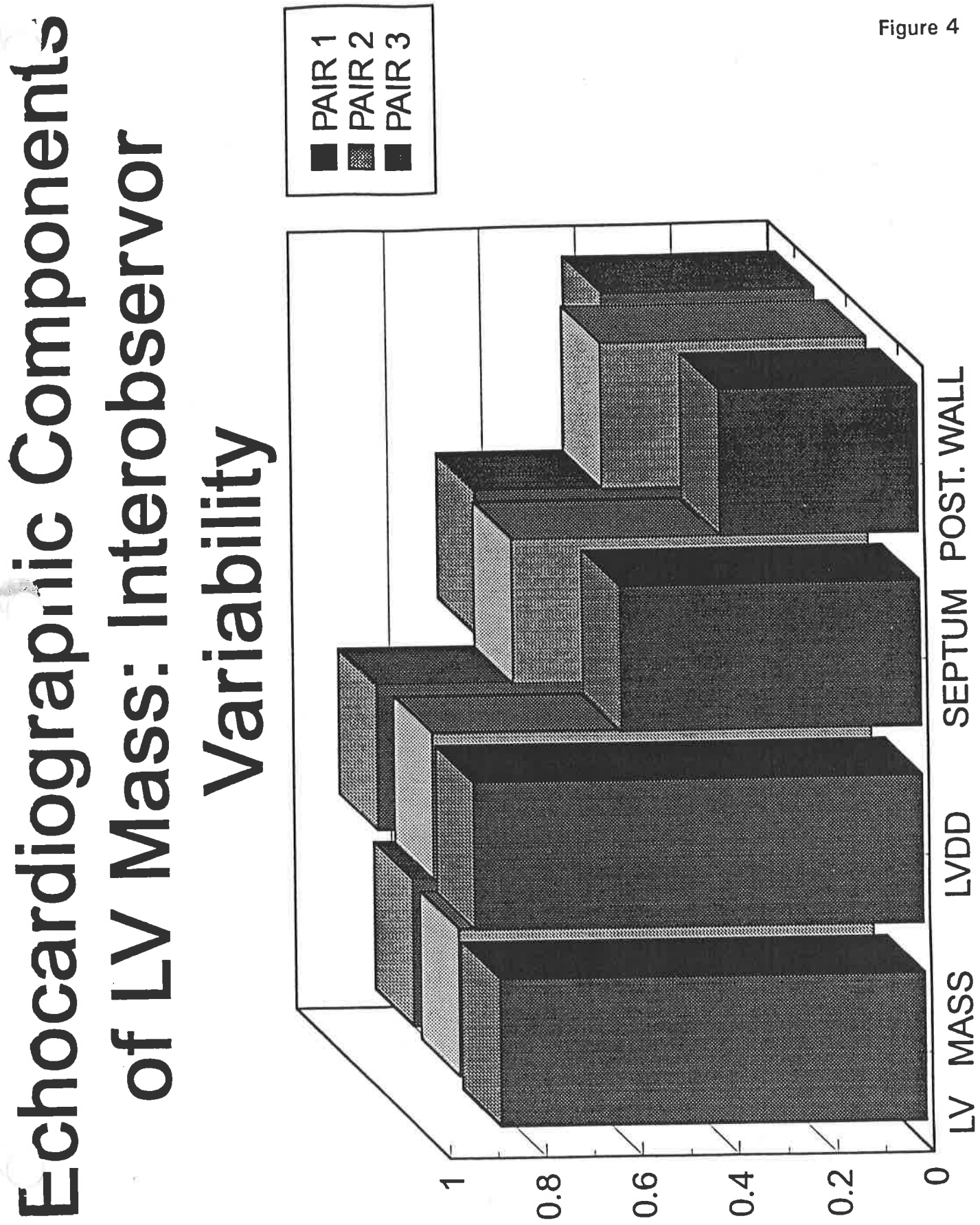


Figure 4: Echocardiographic Components of LV Mass: Interobservor Variability

Figure 5: Toshiba SSH-160 A Ultrasound Unit: Names of Components

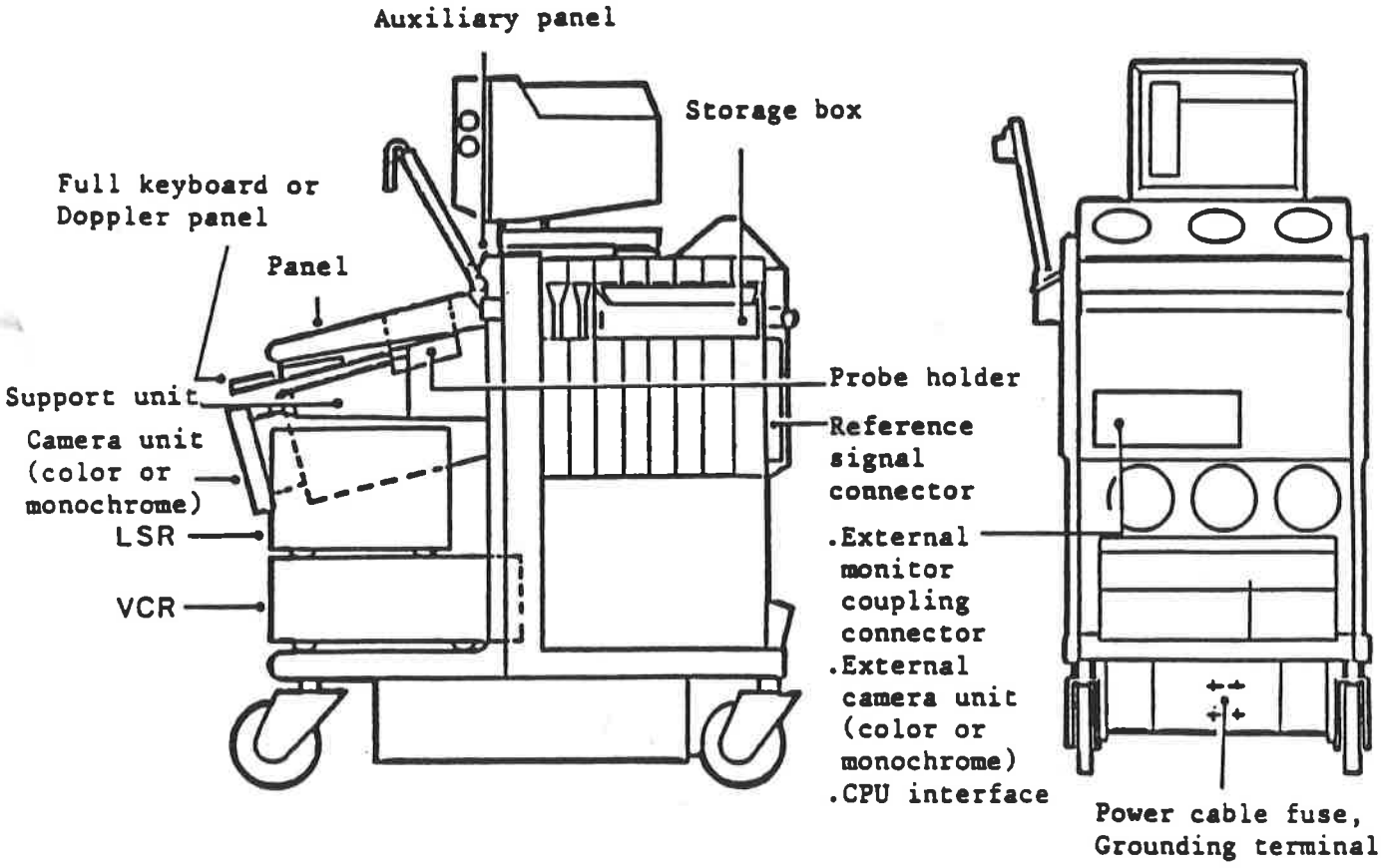


Figure 5 Names of components

Figure 6: Toshiba Ultrasound Unit: Main Panel

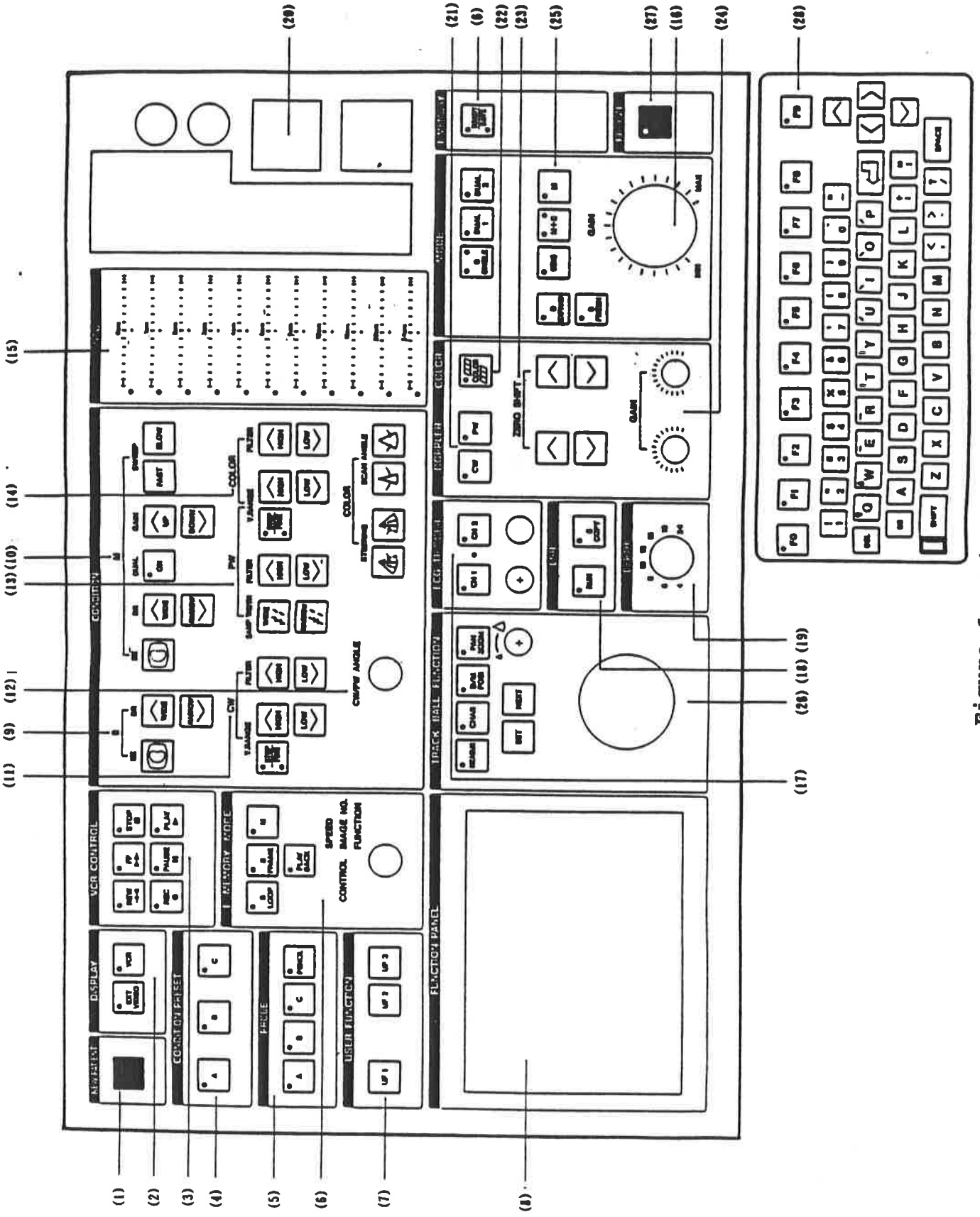


Figure 6 Main panel

Fig. 6

Figure 7: Nomenclature for Transducer Location

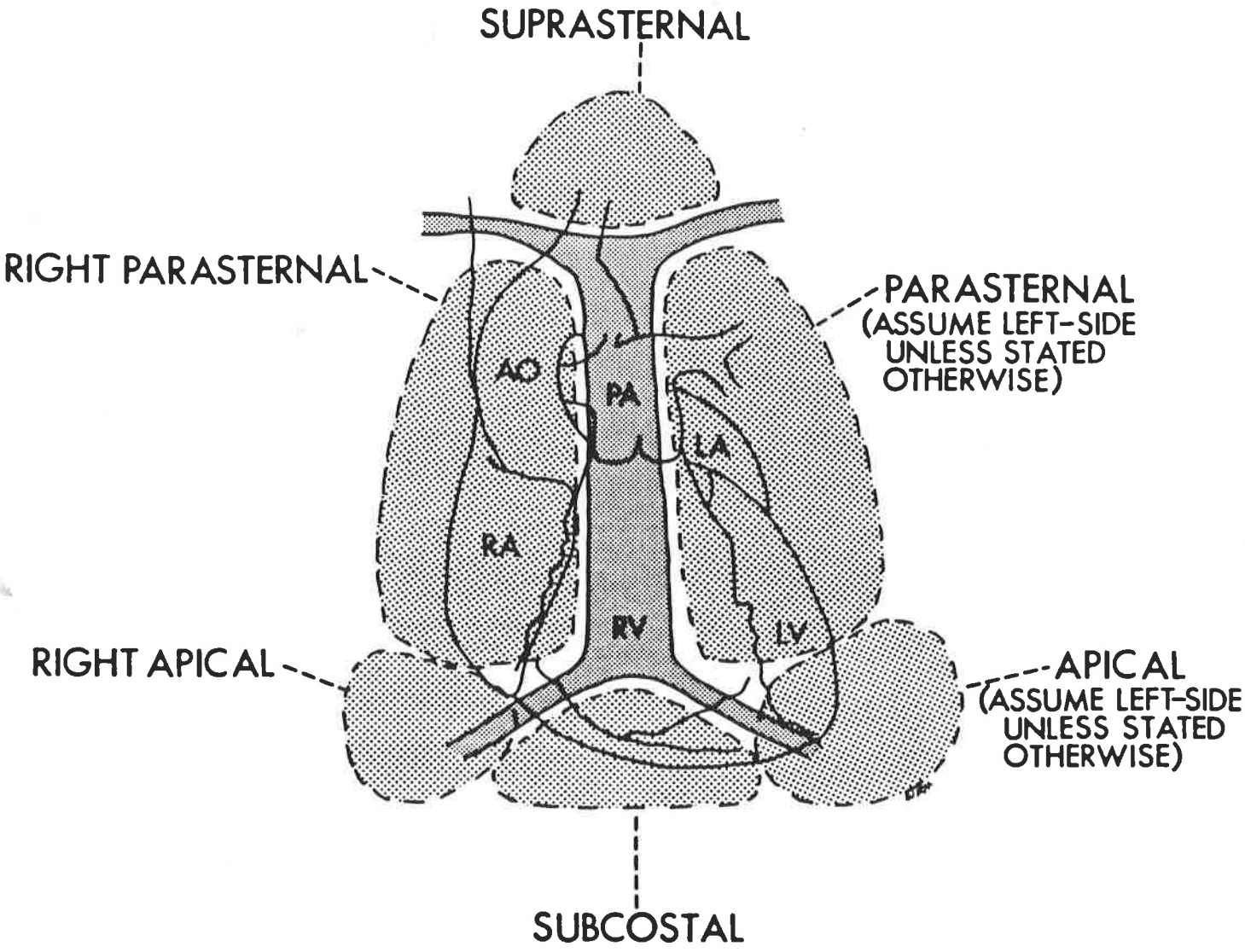


Figure 7

Diagram indicating the nomenclature to describe the locations on the body from which echocardiographic studies can be obtained.

Figure 8: Two-Dimensional Echocardiographic Imaging Planes

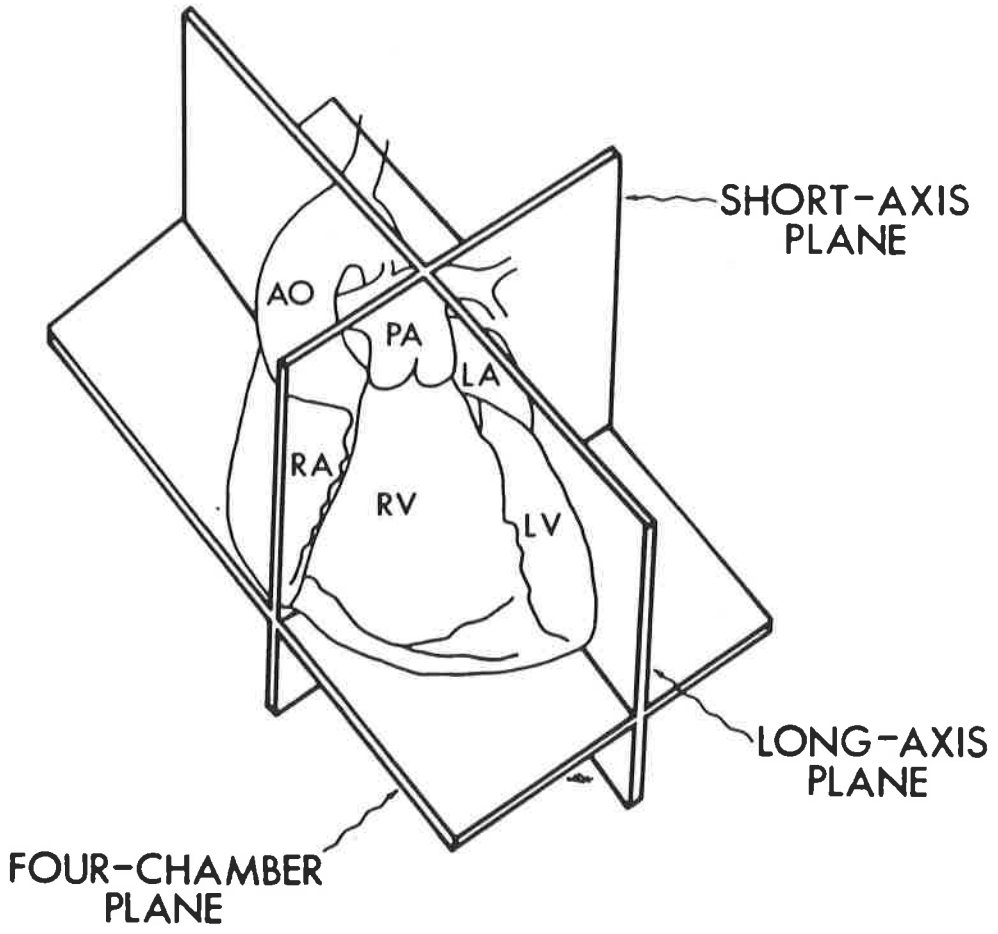


Figure 8

Diagram of the three orthogonal imaging planes used to visualize the heart with two-dimensional echocardiography.

Figure 9: Transducer Orientations

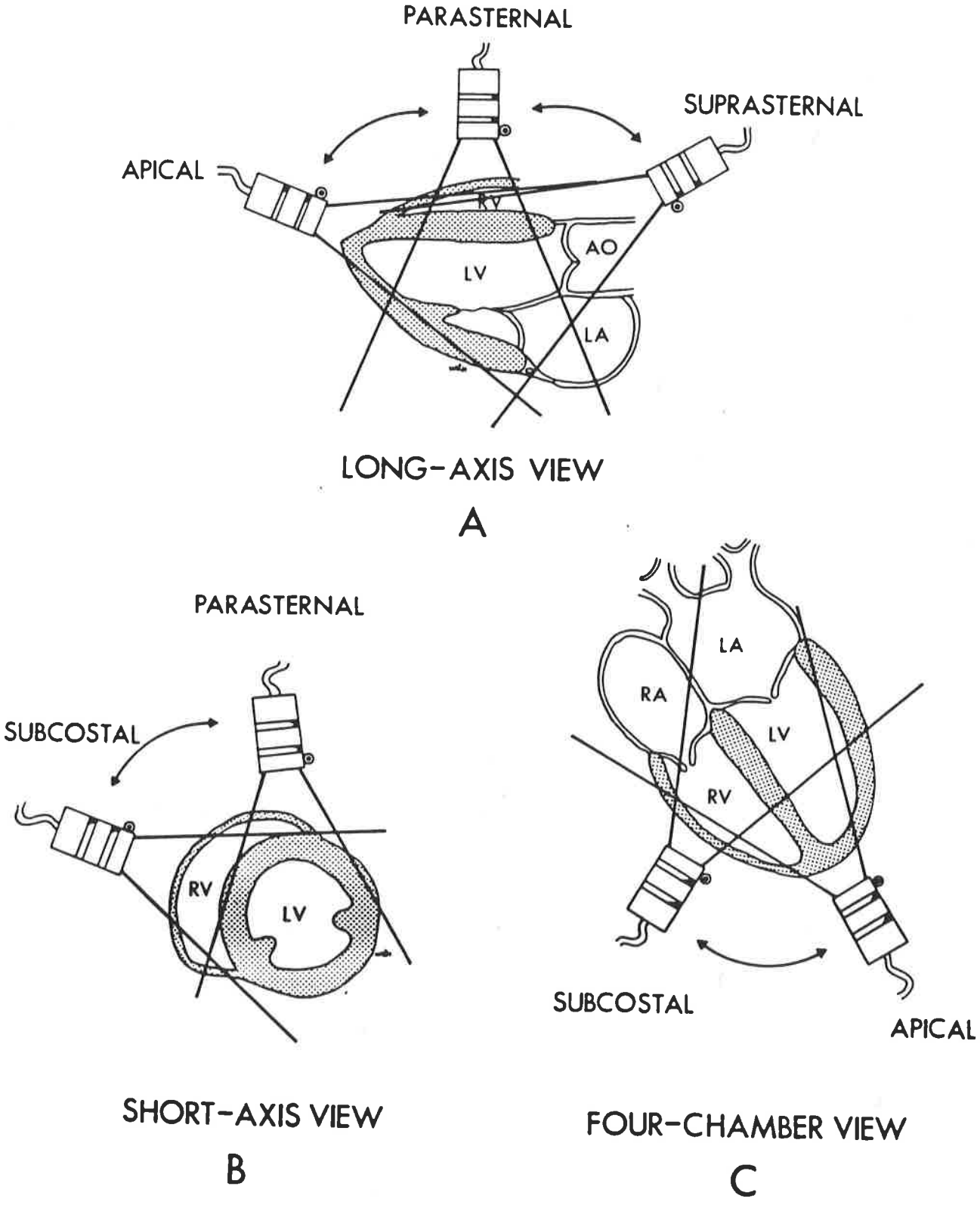


Figure 9

Diagram of the transducer orientation used to obtain long-axis views (panel A), short-axis views (panel B), and four-chamber views (panel C) of the heart. Note that the transducer index mark is always pointed either in the direction of the patient's head or the patient's left side.

Figure 10: Two-Dimensional Images and Corresponding Transducer Locations

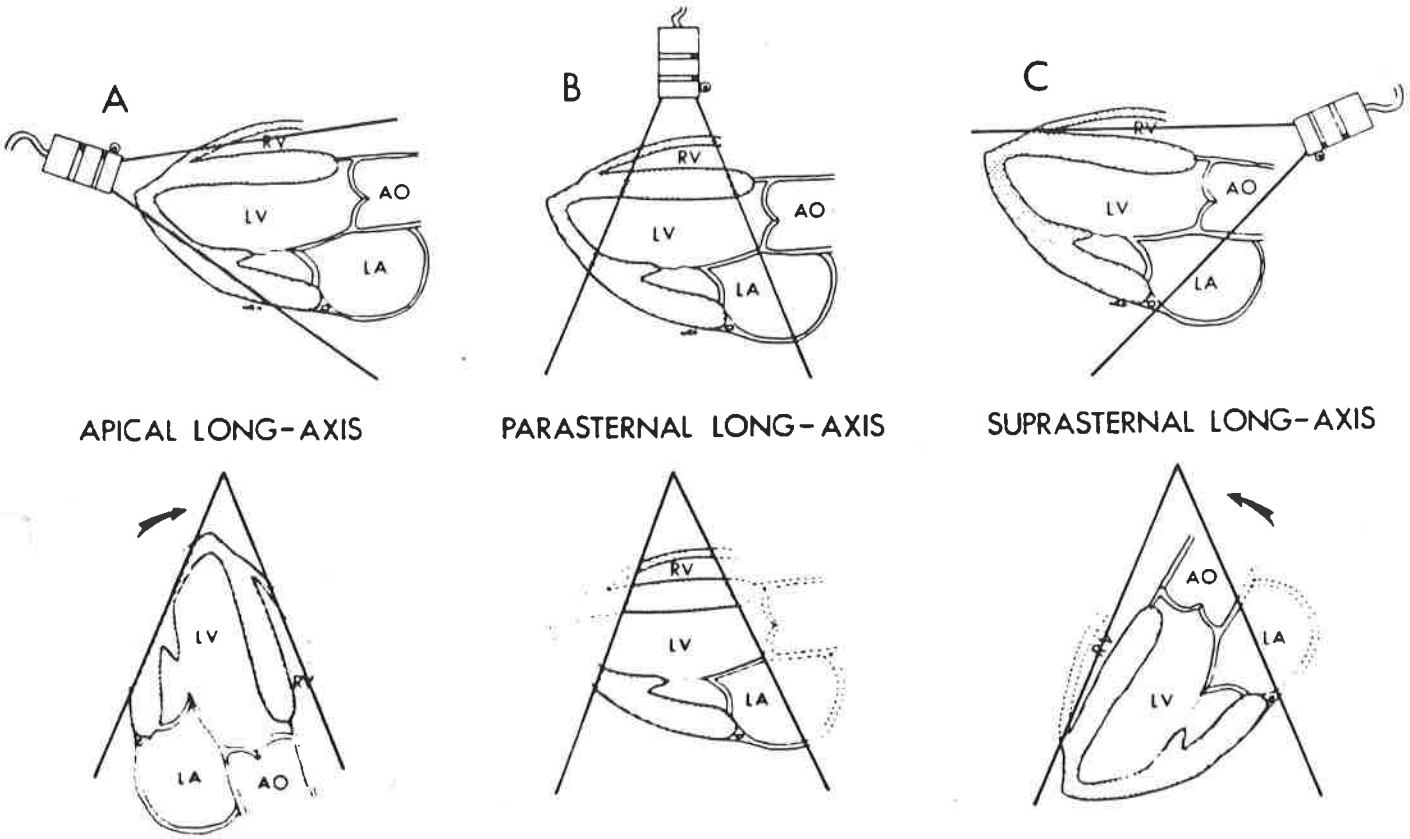


Figure 10

Illustration of the long-axis two-dimensional images that result when the transducer is used to visualize the *apical long-axis* view (panel A), *parasternal long-axis* view (panel B), and *suprasternal long-axis* view (panel C). These images were obtained with the transducer index mark pointing to the patient's head as illustrated in FIGURE 9 (panel A).

Figure 11: Short Axis Two-Dimensional Images

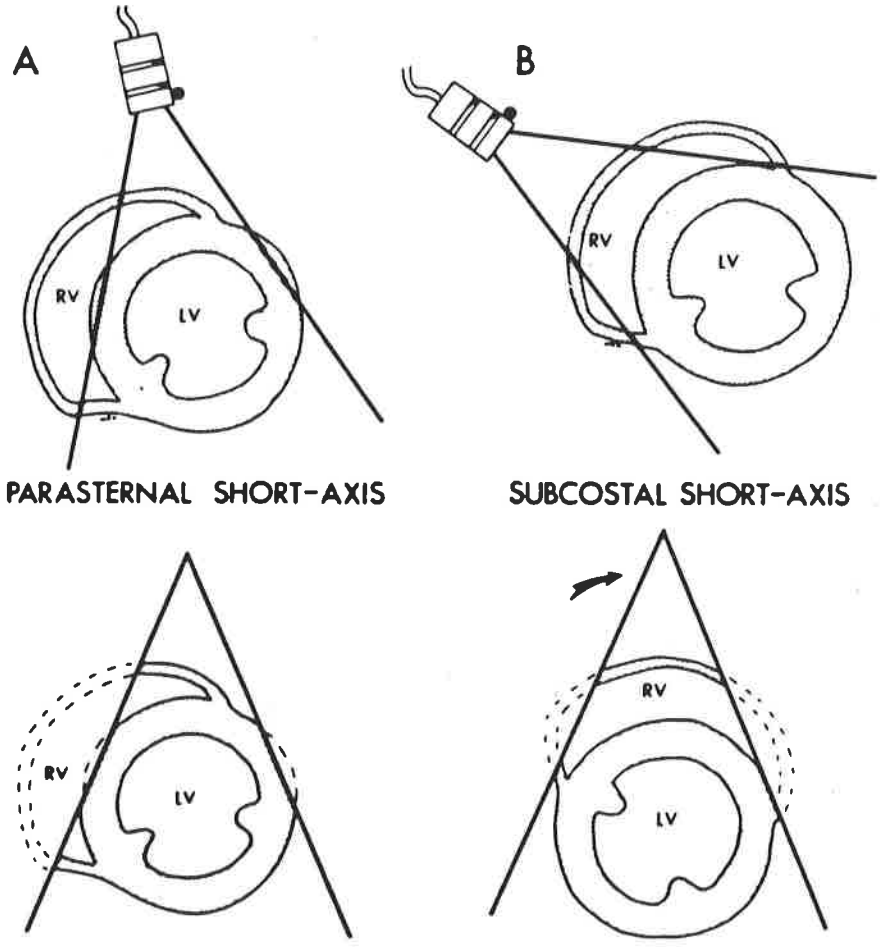


Figure 11

Diagram of the short-axis two-dimensional images that result when the transducer is used to visualize the *parasternal short-axis* view (panel A) and the *subcostal short-axis* view (panel B). These images were obtained with the transducer index mark pointing to the patient's left side as illustrated in FIGURE 9 (panel B).

Figure 12: Four Chamber Two-Dimensional Images

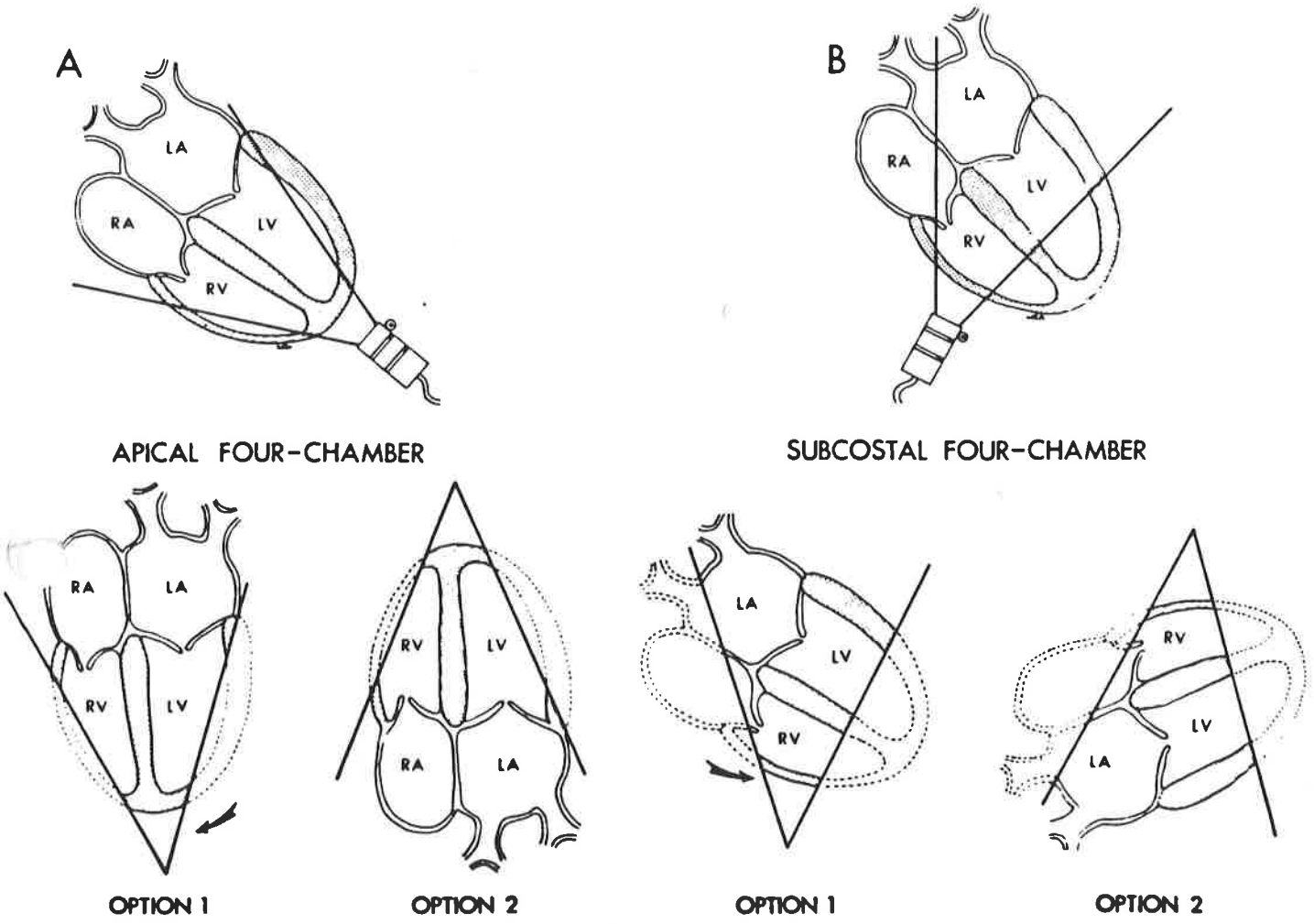


Figure 12

Illustration of the four-chamber two-dimensional images that result when the transducer is used to visualize the *apical four-chamber* view (panel A) and the *subcostal four-chamber* view (panel B). These images were obtained with the transducer index mark pointing to the patient's left side as illustrated in FIGURE 9 (panel C). Two options are included for each four-chamber view. In each case, option #1 is produced by activation of the image inversion switch which results in the near-signals of the image being inverted from the top to the bottom of the display.

Figure 13: Placement of M-mode Beam and M-mode Image

The Echocardiographic Examination

Figure 13

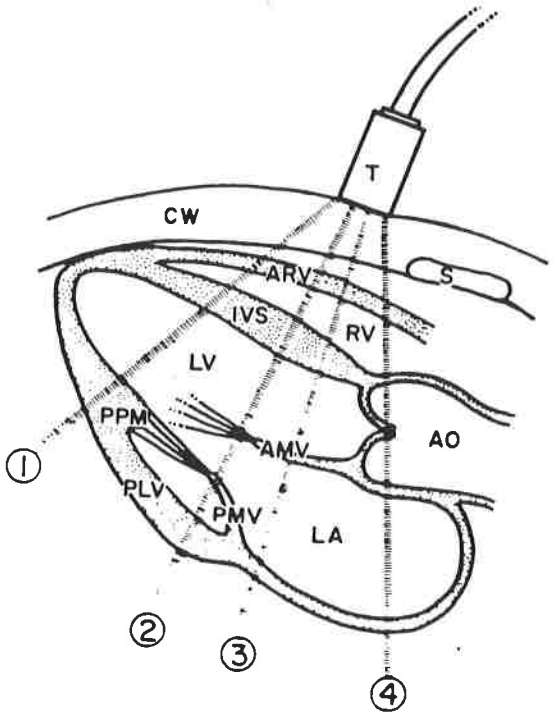
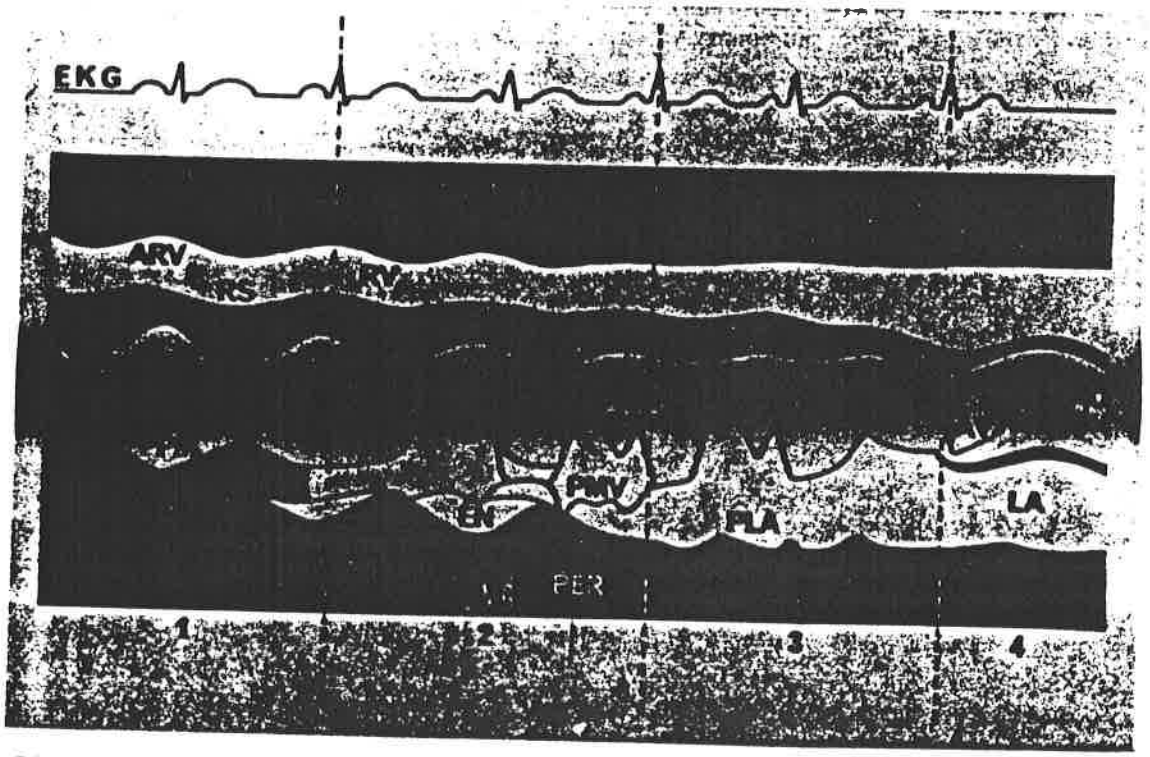


Fig. 2–57. A cross-section of the heart showing the structures through which the ultrasonic beam passes as it is directed from the apex toward the base of the heart. CW = chest wall; T = transducer; S = sternum; ARV = anterior right ventricular wall; RV = right ventricular cavity; IVS = interventricular septum; LV = left ventricle; PPM = posterior papillary muscle; PLV = posterior left ventricular wall; AMV = anterior mitral valve leaflet; PMV = posterior mitral valve leaflet; AO = aorta; LA = left atrium. (From Feigenbaum, H.: Clinical applications of echocardiography. Prog. Cardiovasc. Dis., *14*: 531, 1972.)



Diagrammatic presentation of the M-mode echocardiogram as the transducer is directed from the apex (*position 1*) th e of the heart (*position 4*). The areas between the dotted lines correspond to the transducer position as depicted in ure 2–19. LS = left septum; RS = right septum; EN = endocardium of the left ntricle; PER = pericardium; PLA = posterior left atrial wall. For explanation of other symbols see Figure 2–19. (From genbaum, H.: Clinical applications of echocardiography. Prog. Cardiovasc. Dis., *14*:531, 1972.)

Figure 14: ASE Methods of M-mode Measurement

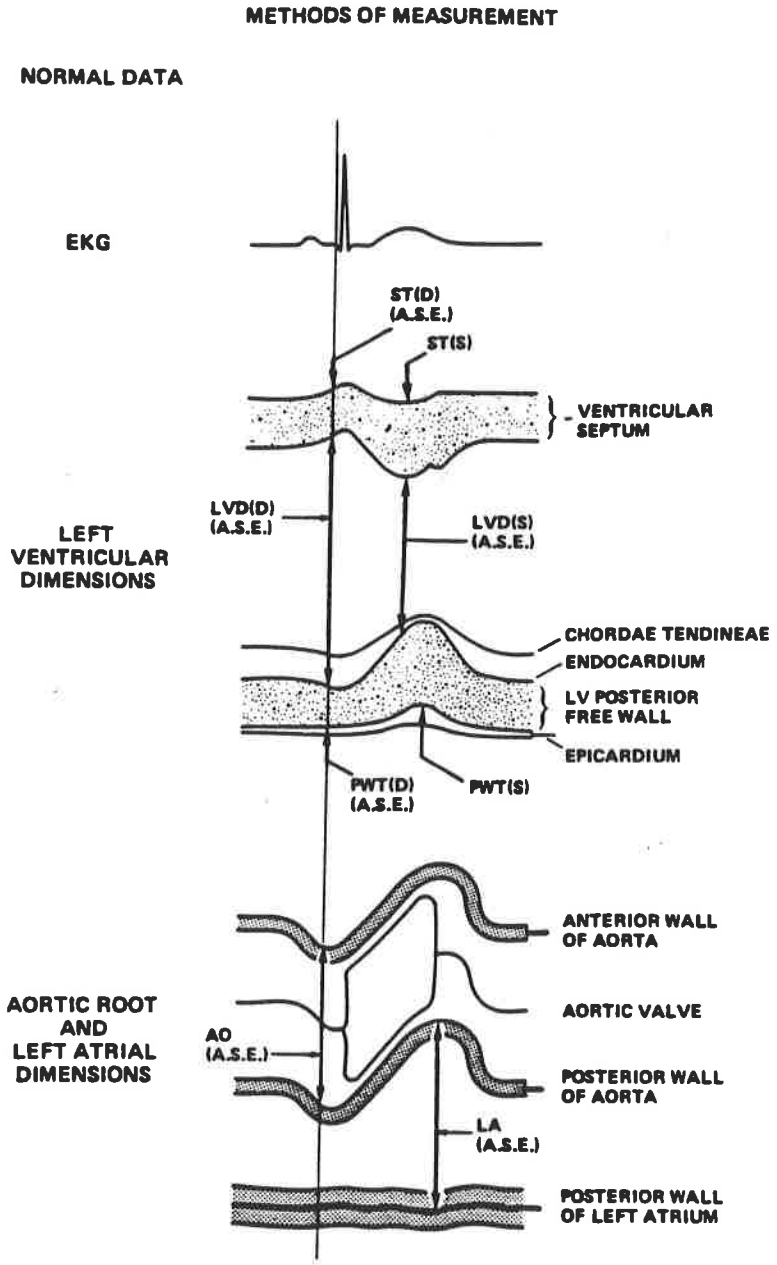


Figure 14

Figure 15: Placement of Sample Volume for LV Inflow and Outflow Tract Doppler Velocity Recording

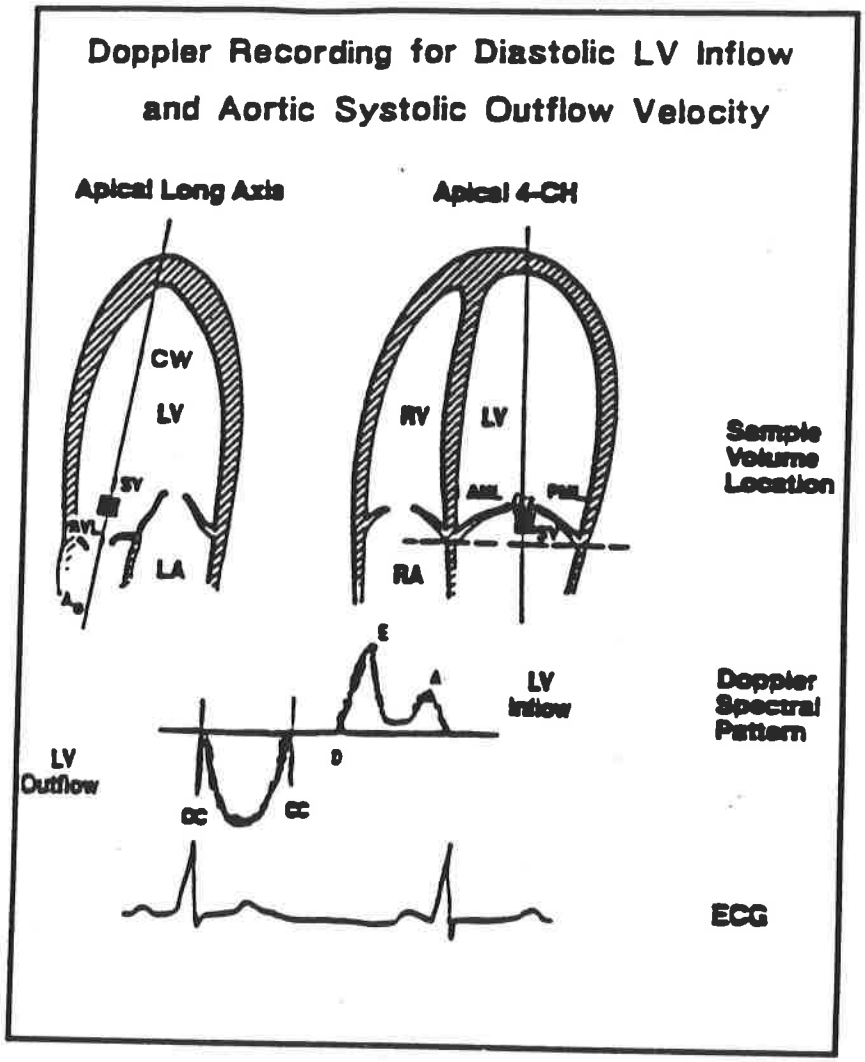


Figure 15

Year 7

Echocardiography Reading Center

Manual of Operations

CARDIOVASCULAR HEALTH STUDY

ECHOCARDIOGRAPHY READING CENTER

- MANUAL OF OPERATIONS -

(Rev. January 17, 1995)

OBJECTIVES

The primary objective of echocardiography in the Cardiovascular Health Study is to determine whether one or more echocardiographic or Doppler parameters of cardiac structure and function, and their five year interval change, are useful in predicting mortality or extent of disability in subjects in the age range of 65 years and older. *Specifically, we will determine the importance of change in LV mass, regional wall motion, and LV function over a five year interval as a predictor of new clinical events, i.e., stroke, heart attack and death.* Cardiac structural parameters to be evaluated include left ventricular wall thickness and mass, and left ventricular and left atrial dimensions, while cardiac functional parameters include left ventricular percent fractional shortening, left ventricular global and regional wall motion, left ventricular wall stress and Doppler stroke volume, and left ventricular filling parameters.

A second objective of the repeat echocardiography examination is to measure the rate of progression of **aortic valve disease** in the elderly, and determine its association with clinical events such as heart failure and stroke.

A final objective is to develop a relevant, efficient, and cost-effective method for recording, coding and analyzing cardiac ultrasound parameters which results in data with good accuracy and reproducibility in elderly individuals with and without clinical evidence of cardiovascular disease.

RATIONALE

In the past decade, echocardiography has become the technique of choice for assessment of regional and global left ventricular (LV) function, measurement of cardiac chambers and wall dimensions, and measurement of LV mass and hypertrophy (LVH). Numerous studies have used echocardiography to successfully document changes in LVH regression and LV function in hypertensive patients.[1-5] It has supplanted the use of electrocardiography and is unlikely in the proximate future to be replaced by newer technologies such as rapid CAT scan or magnetic resonance imaging (MRI). Images obtained by echocardiography provide near tomographic planes of the heart in real time thus allowing combined assessment of LV mass, architecture, and motion. Information provided by Doppler on intracardiac blood flow velocity adds substantially to the power of this technique in cardiovascular studies.

A principal use of echocardiography in cardiovascular epidemiologic studies has been the identification of LVH, a discrete variable based upon selection of a partition value of LV mass. LVH has been associated with clinically important abnormalities of diastolic, electrophysiologic[6-8] and systolic function. The importance of LVH, in itself, in the morbidity of hypertensive disease has been underscored by the number of electrocardiographic and echocardiographic studies which have convincingly demonstrated its importance as an independent predictor of morbidity and mortality.[9, 10] Not only does LVH as a dichotomous variable

predict adverse outcome, but the magnitude of LV mass as a continuous variable is also associated with cardiovascular risk,[11] even with values for LV mass within the "normal range." In the Framingham Heart Study, it was shown[10] that for each 50 grams per meter increase in LV mass (corrected for height) that there was a relative risk for mortality of 1.73, even in subjects free of clinically apparent cardiovascular disease. It was also demonstrated that this risk was independent of blood pressure, age, antihypertensive treatment and other cardiovascular risk factors. Additionally, the pattern of LV hypertrophy, as well as the magnitude of increase in LV mass, is of importance in predicting the risk of LVH for cardiovascular morbidity. It has been shown[11] that individuals with a higher relative wall thickness at any value of LV mass had greater risk of cardiovascular events. The relative wall thickness is the proportion of wall thickness to ventricular cavity size. A high number indicates "concentric" (thick wall-small cavity) LVH, as is most commonly found in hypertension, in contrast to "eccentric dilated" (thin wall-dilated cavity) hypertrophy which would be represented by a lower relative wall thickness as found in ischemic, alcoholic, and other forms of dilated cardiomyopathy. Importantly, there is an association of LVH with complex ventricular arrhythmia, a possible precursor of sudden death in hypertensive patients, even in patients without coronary artery disease on angiography.[7] In patients with reversible myocardial perfusion defects on thallium scintigraphy, both LVH and inducible ischemia are independently associated with ventricular arrhythmia.[12]

While congestive heart failure in hypertension may commonly result from the interaction of hypertension with atherosclerotic coronary disease, ischemic injury, infarction and systolic dysfunction, it also occurs in hypertensives with normal systolic function but abnormal left ventricular filling.

In addition to LVH, echocardiographic descriptors of intracardiac flow, parameters of diastolic and systolic function, left atrial size, and aortic dimension may be of importance.

Echocardiography has been shown to be a useful tool, both clinically and epidemiologically in detecting cardiac abnormalities, other than LVH, associated with a higher incidence of cardiovascular events or mortality. For example, Henry and associates demonstrated that patients with an echocardiographic left atrial dimension of 55 mm or greater demonstrated a much lower success rate of conversion from atrial fibrillation to normal sinus rhythm.[1] Similarly, preliminary data from the Framingham study has suggested that echocardiographic left ventricular hypertrophy in the general population is associated with an increased two-year mortality, independent of standard coronary risk factors.[2] Since echocardiography is more sensitive and specific than such indirect tools as electrocardiography in the detection of left ventricular hypertrophy and left atrial enlargement, these echocardiographic measurements may be useful as pre-clinical prognostic indicators of the future development of coronary artery disease, stroke, or other

cardiovascular events in populations of subjects such as the elderly.[3] Furthermore, alterations in left ventricular filling have been detected by Doppler with aging and as an early marker of acute ischemia.[4,5]

The cardiac ultrasound technique (echocardiography and Doppler flow recording) has the advantage of being non-invasive, reproducible, and without known adverse effects as used clinically.

It has been demonstrated that left atrial size is a predictor of the occurrence of atrial fibrillation and of embolic stroke.[13] Additionally, aortic dimension may reflect the sum of several pathophysiologic variables including blood pressure, aortic atherosclerosis, and connective tissue integrity. The predictive value of aortic dimension for cardiovascular outcome events, as well as those for parameters of diastolic function on Doppler echocardiography, remain to be determined.

METHODOLOGICAL AND TECHNICAL CONSIDERATIONS

Technical Limitations of Echocardiography

While echocardiography provides information on cardiac function and structure unavailable by any other means, and is free of known risks or significant discomfort, the technique confers substantial technical problems in data acquisition and interpretation. Hence, to optimize accuracy and reproducibility, careful methodology needs to be applied in training, acquisition, and interpretation of echo data.

The use of echocardiography to quantitate cardiac volumes, function and LV mass requires accurate identification of interfaces between the cardiac blood pool and walls. Additionally, measurement of LV free wall thickness (needed in quantitation of LV mass) necessitates recognition of the often subtle interface between epicardium and pericardium. Primary echocardiographic measurements of wall thickness and chamber size may be obtained from the "icepick" view of 2-D targeted M-Mode echocardiography, which provides linear dimensions, or from tracing chamber, and wall areas on still-frame two dimensional echocardiograms. The linear dimensions obtained from M-Mode echo may fail to adequately represent true cardiac chamber volume particularly when there are distortions in cardiac geometry. While area measurements from two-dimensional echo still-frames provide greater image sampling of cardiac structures than "ice pick" M-mode

dimensions, still-frames (even of technically optimal studies) suffer from image degradation, with generally greater uncertainty in identification of cardiac borders than with M-mode echo. With either means of echo display, the utilization of primary echocardiographic data to obtain cardiac volumes requires using mathematical algorithms which rely on assumptions of cardiac geometry.**(Fig. 1)** Use of these models mandate meticulous alignment of the ultrasound beam in reference to the proper anatomic axes. Variations of angulation of the manually directed echo sector between serial examinations will result in variability of primary echo measurements. Since the algorithms for LV volume estimation either square or cube primary echo measurements, test-retest reliability will suffer proportionately.

Under some circumstances, any geometric model of LV volume (**Fig. 2**) may not be true to actual LV geometry. For example, the "bullet" formula for LV volumes ($V = 5/6\ AL$; A = LV short axis area, L = LV long axis) assumes a "bullet" shape of the LV which does not exist in the case of LV aneurysm. Here, use of Simpson's Rule (method of discs), which uses integral calculus to segment an irregular LV contour into multiple cylinders, is preferable. However, a technical trade-off is incurred as apical views of the LV must be used. These views, which image the LV endocardium in lateral (poor) resolution, generally result in overestimation of LV cavity volume, in contrast to the parasternal short axis view required by the "bullet" formula which images the LV endocardium mostly in axial (good)

resolution.

While one may select the algorithm appropriate to each subject and use it on subsequent examinations, intervening clinical events, such as apical myocardial infarction, may make this difficult. Hence, the sources of variability in echocardiographic studies separated by several years may be substantial.

1. **2-D Targeted M-mode vs. 2-D Echo Measurement of LV Mass:** Some controversy exists as to specific measurement techniques used to determine left ventricular mass, with some investigators[14] suggesting that enhanced reproducibility and accuracy may be obtained using planimetry of two-dimensional echo still frames, while probably a larger experience has been obtained with the use of the M-mode and, then subsequently, 2-D targeted M-mode recordings.[15-17] While both approaches have their merits, large quantities of normal, as well as diseased population data, have been obtained using 2-D targeted M-mode recordings, and these techniques have been used by this investigator in two large echocardiography core laboratory studies in hypertension. The principal advantage of 2-D targeted M-mode recording is that it allows more certain identification of interfaces defining the endocardial and epicardial margins of the LV posterior wall, providing ready calculation of LV mass based upon certain geometric assumptions. A theoretic disadvantage is imposed by the selection of essentially three measurements for LV mass calculation while, in fact, the distribution of muscle

mass in the left ventricle is neither homogeneous nor conforms exactly to the geometric models used. While two-dimensional echocardiography, by providing multiple planes of image with essentially full visualization of LV walls and cavity, offers theoretic advantages for computation of LV mass, many of these advantages are lost by the uncertainty imposed upon measurements by the generally vague cardiac borders seen on still frame images. Additionally, subtle differences in regional LV wall thickness which can be appreciated qualitatively are difficult to measure on two-dimensional echocardiography because of resolution difficulties, principally in lateral and azimuthal image planes.

2. **Distorted LV Geometry and LV Volume Measurement:** Since patients with distorted LV geometry may not meet the assumptions necessary for the measurement of cardiac volumes using 2-D targeted M-mode echocardiography,[18] it has been suggested that two-dimensional echocardiography may provide improved accuracy and reproducibility of LV mass measurement. In addition, a good quality M-mode echocardiogram from the parasternal location may not be obtainable in all patients. However, some of these may have adequate 2-D echo images obtainable from an apical echo window.

3. **Critique of Algorithms for LV Mass Measurement:** Although 2-D echoes obtained from the apical window provide more complete interrogation of the LV than parasternal images, lateral resolution limitations of apical images require that

wall thickness be measured from parasternal short axis images. However, since the position of the echo transducer on the chest wall is relatively fixed, the circular cross-sectional image obtainable from this window cannot be iterated from base to apex to create a LV "shell" volume which would represent LV mass. Hence, even 2-D algorithms for estimation of LV mass utilize the parasternal window echo images to calculate an "average" LV wall thickness, which can then be applied to either "bullet" or apical window disc method algorithms for LV volumes, to obtain LV mass.

Unfortunately, however, LV wall thickness is not uniform even in normal ventricles, and following myocardial infarction, substantial segmental thinning of the LV wall can occur. Hence, problems in the estimation of LV mass imposed by distorted LV geometry following myocardial infarction are not completely solved by substituting 2-D echo for 2-D targeted M-mode methods.

Additionally, a principal failing of 2-D targeted M-mode echo for the estimation of LV mass is failure to obtain technically adequate parasternal window recordings, either because of unacceptable obliquity of the echo sector to the LV long axis, or because of inadequate definition of LV wall and cavity interfaces. If adequate apical window 2-D echoes are obtainable in such patients, reasonable quantitative estimation of LV volumes and ejection fraction may be obtained; however, as seen from the above, LV mass estimation will remain problematic.

Difficulties of Two-Dimensional Targeted M-Mode for LV Mass

It is easy to improperly align (**Fig 3**) the echo sector relative to anatomic axes, or improperly place the M-mode cursor during 2D-targeted recording of the LV. Such errors of acquisition technique can result in large error and variation in the measurement of LV mass. As shown in **Fig 4** a "true" LV mass calculation of 227 gm may vary between 181 gm to 448 gm based upon beam angulation errors.

Difficulties of Echocardiography in Epidemiologic Studies

However, consistent with the experience at Framingham, and the baseline echocardiography studies in year two with CHS, there is a significant learning curve present in recording technically adequate echocardiographic studies, particularly in subjects over the age of 60 years. In the Framingham report describing M-mode echocardiograms performed in over 6,000 subjects aged 17 to 90, the ability to record acceptable quality echocardiograms in subjects older than 60 years rose from a minimum of 28% during the first five months of the study to a maximum of 74% to 81% during studies two years later.[4] In the year 2 CHS echocardiography examinations the "yield" for M-mode measurements of LV mass was only 67%. Moreover, older subjects within the CHS cohort were less likely to have measurable and interpretable studies than younger subjects. Hence echocardiography "drop-outs" were not randomly distributed within the cohort leading to the possibility of bias in data interpretation. Two-dimensional echocardiographic measurements were even more problematic than M-mode.

Differences Between Field Centers

In previous large echocardiography trials major differences in echo quality have existed between field centers. For example, in a 15 center VA trial of antihypertensive monotherapy, the percent of readable echocardiograms for LV mass varied from approximately 30% to 85% **(Fig 5)**. This was not due to differences between centers in the proportion of easy or difficult patients. While the use of suboptimal equipment in some cases contributed to poor studies, the intercenter differences were mostly because of variation in technical performance. Importantly, extensive previous clinical experience in echocardiography was no guarantee of high quality echocardiograms for research purposes.

A major goal of this study is to ensure the recording in elderly patients of echocardiograms of acceptable quality and reproducibility to generate structural and functional variables which will have prognostic value for the development of coronary artery disease, and stroke, as well as for specific endpoints such as mortality and degree of disability.

HYPOTHESES

A. **Echocardiographic markers of pre-clinical disease** (e.g., left ventricular hypertrophy, decreased left ventricular ejection fraction, or abnormalities in global or regional left ventricular systolic or diastolic function) are **useful in predicting mortality and disability from** cardiac or cerebrovascular events over a three-year follow-up period.

B. **Echocardiographic markers** of pre-clinical and overt disease are **related to traditional risk factors** (e.g., smoking, high blood pressure, high cholesterol) for cardiovascular disease.

C. **Progression in parameters** such as left ventricular hypertrophy, abnormalities of left ventricular systolic or diastolic function, can be **detected over a three-year follow-up period and are related to the development of cardiovascular events** or stroke.

D. The **progression of echocardiographic markers** of pre-clinical disease (e.g., LVH, regional or global LV dysfunction, valvular calcification and regurgitation) are **related to baseline characteristics and to non-echocardiographic factors,** e.g. , demographic factors, blood pressure, lipid abnormality.

E. **Aortic stenosis** (physiologically important decrease in aortic leaflet opening) is **preceeded by aortosclerosis** (calcification of the aortic ring). The **liklihood of developing clinically important aortic stenosis is predictable by baseline echocardiographic characteristics** of the aortic valve, and possibly other echocardiographic and non-echocardiographic descriptors.

ECHOCARDIOGRAPHY MEASUREMENTS AND ASSESSMENTS IN CHS YEAR 7

Quantitative measurements and qualitative assessments utilizing the Microsonics touch pad data tablet to generate coded diagnostic statements **(Fig 6)** are summarized below:

M-MODE:

1) Left ventricular internal dimension in diastole (LVIDd)
2) Left ventricular internal dimension in systole (LVIDs)
3) Ventricular septal thickness in diastole (VSTd)
4) Ventricular septal thickness in systole (VSTs)
5) LV Posterior wall thickness in diastole (LVPWTd)
6) LV Posterior wall thickness in systole (LVPWTs)
7) Left atrial dimension (LA)
8) Aortic root dimension (Ao)
9) LV % fractional shortening (LVFS)(calculated)
10) LV end systolic stress (LVESS)(calculated)
11) LV mass (LVMASSm)(calculated)

2-D ECHO:

12) LV regional wall motion abnormality (RWMA)(qualitative)
13) LV hypertrophy (qualitative)
14) LV global systolic function (qualitative)
15) Mitral annular calcification (qualitative)
16) Aortic valve annular calcification/thickening (qualitative)
17) Aortic leaflet calcification/thickening (qualitative)
18) Aortic leaflet excursion (qualitative)

COLOR-FLOW DOPPLER

19) Mitral regurgitation (qualitative)
20) Aortic regurgitation (qualitative)
21) Tricuspid regurgitation (qualitative)
22) Pulmonic regurgitation (qualitative)

SPECTRAL DOPPLER

23) LV outflow tract systolic velocity integral
24) LV outflow tract peak velocity
24) Mitral peak early inflow velocity (E)
25) Mitral peak atrial inflow velocity (A)
26) Maximum aortic velocity (CW)- in suspected aortic stenosis only.

QUALITY CODE STATEMENTS

27) Maximum tricuspid regurgitant velocity (CW)
28) M-mode LV quality
29) LV inflow Doppler quality
30) LV outflow Doppler quality

MISCELLANEOUS

31 Heart rate (M-mode LV)

Calculated parameters derived from primary measurements listed above, e.g., fractional shortening, LV mass, relative wall thickness, septal/free-wall ratio, meridional end-systolic stress, midwall stress, M-mode cardiac output, Doppler linear cardiac output (aortic systolic velocity integral X HR) will be computed at the Coordinating Center.

Measurement Conventions

2-D Derived M-Mode:

Selection of Beats for LV Measurements: Parasternal short axis views of the LV where the M-Mode cursor traverses the center of a circular cross-sectional image at or just below the tips of the mitral leaflets will be utilized. Proper cephalad-caudad orientation of the sector will be identified by minimal motion of mitral valve structures (presumably distal mitral tips or chordae tendinae), and absence of structures consistent with the bases of the papillary muscles. Cross sectional images where the estimated eccentricity (ratio of vertical midsectional chord to horizontal midsectional chord) of greater than 1.1 will be excluded from analysis. Attempts will be made to select beats with optimal definition of the posterior wall epicardial - pericardial interface, defined by visual extension into diastole of the anterior aspect of the small systolic posterior free space. Care will be taken to exclude right ventricular muscular structures (e.g., moderator band, crista supraventricularis) from the right ventricular aspect of the septum by selecting beats where these structures do not abut against the septum within the path of

the M-mode cursor.

Selection of Beats for Left Atrial and Aortic Root Measurements:

M-mode recordings where the cursor intersects the left atrium at its most posterior displacement will be utilized for measurement. Care will be taken to avoid misinterpretation of the true posterior left atrial border by confounding of the interface by pulmonary veins, side lobe artifact, or tangential direction of the cursor.

M-Mode Measurements: American Society of Echocardiography (ASE) criteria will be used **(FIG 7)**, consistent with prior practice in the CHS. Structures are identified from leading edge to leading edge; LV measurements are made in tandem at the onset of the QRS complex; the aortic root is measured at the onset of the QRS; the left atrial dimension is measured at the peak anterior excursion of the atrial-posterior aortic interface at end-systole.

Doppler Measurements: LV inflow and outflow PW "best beats" characterized by minimal spectral dispersion and maximal velocity will be selected. Utilizing the system trackball, the LV (aortic) outflow systolic velocity integral will be contoured from the outer edge of the spectral recording, i.e., using maximum rather than modal frequency shifts. The peak aortic velocity is generated by software from the spectral contour; visual confirmation of the peak velocity is required. The mitral

peak E and A velocities will be identified and entered by trackball at the maximum excursions of the LV inflow spectral profile in early diastole, and atrial systole respectively.

Qualitative Valvular Regurgitation Statements:

Mitral and Tricuspid:

mild - maximal displacement of atrial area by the color flow jet in any view is less than 1/3.

moderate - maximal displacement is 1/3 to 1/2.

severe - maximal displacement greater than 1/2.

Aortic:

mild - Width of color flow jet in LV outflow tract (parasternal long axis, or apical long axis, or apical 5-chamber view) is less than 1/2 of the LVOT width.

moderate- Width of jet is 1/2 to 3/4 LVOT width.

severe - Width of jet is greater than 3/4 LVOT width.

Pulmonic:

mild - minimal jet extending 2.0 cm or less into RV outflow tract.

moderate - jet extends more than 2.0 cm and is 0.5 cm or less in width.

severe - jet extends more than 2.0 cm and is greater than 0.5 cm in width.

Qualitative Mitral Annular Calcification:

mild - focal, limited increased echodensity of mitral annulus.

moderate - marked echodensity involving more than 1/3 of ring

severe - marked echodensity involving 1/2 or more of ring, and with at least some compression of LV inflow tract.

Qualitative Aortic Ring Thickening/Calcification:

mild - focal, limited increased echodensity of aortic annulus

moderate - extensive echodensity involving more than 1/2 of ring circumference, but with preservation of leaflet mobility

severe - extensive echodensity involving entire circumference of aortic ring, and with limitation of leaflet excursion.

Qualitative Global LV Function Statements:

normal - Ejection fraction visually estimated at equal to or greater than 55%; vis a vis prior quantitative comparisons.

mildly depressed - Ejection fraction estimated at 45 - 54%.

moderately depressed - Ejection fraction estimated at 30 - 45%

severely depressed - Ejection fraction estimated at less than 30%.

Qualitative Regional Wall Motion Abnormality (RWMA) Statements:

can't assess - study inadequate for RWM assessment - <12 of 16 not evaluable

normal - no dyssynchronous LV wall segments; at least 75% of 16 segments evaluable.

mild - hypokinesis of 1/3 or less of evaluable segments.

moderate - hypokinesis of 1/2 to 2/3 of evaluable segments, or akinesis/dyskinesis of 1/3 of evaluable segments.

severe - akinesis/dyskinesis of 1/3 evaluable segments and hypokinesis of addition 1/3 or more.

Qualitative Aortic Leaflet Thickening:

mild - focal, limited, increased echodensity of aortic leaflets

moderate - diffuse or extensive increased echodensity; some thin leaflet echoes appreciable

severe - diffuse "white-out" of aortic valve tissue.

Qualitative Aortic Leaflet Excursion:

normal - maximal cusp separation 1.5 cm or greater.

mildly impaired - cusp separation 1.0 to 1.4 cm.

moderately impaired - cusp separation 0.5 to 0.9 cm.

severely impaired - cusp separation less than 0.5 cm.

OFFLINE IMAGE ANALYSIS SYSTEMS

The system utilized for the year 7 CHS readings is the Nova Microsonics (Mahwah, NJ) ImageVue (TM) color compact digital acquisition and analysis system. The system comprises a 80486, 66 MHz DX2 CPU and NTSC video I/O converter. The system input devices include 0.5" videotape, keyboard, trackball, and a specially configured data tablet. The system is configured with 32 MB of image memory and 16 MB of video RAM. Storage media include a 250 MB hard drive, 3.5" floppy drive, and a 650 mb optical disk drive. Optical disks are utilized for long term storage of digitized images and analyses at the ERC; the hard drive is utilized for temporary (weekly) storage of images and analyses; and 3.5" (1.44 mb) disks are used for weekly downloading and transmission (by Federal Express) of echo analyses (ASCII format) to the Seattle Coordinating Center.

The software allows M-mode LV measurements along a screen cursor which is aligned with the onset of the QRS signal on the ECG monitor trace (ASE criteria). Additional software is present for Doppler analyses. The data tablet (FIG XX) has been programmed to allow touch selection of stereotypical qualitative statements pertinent to echo technical quality, valve anatomy, valvular regurgitation, and LV regional and global function, and LV hypertrophy.

Additional system information and technical instructions are enclosed in Appendices XX, YY.

ERC PROCEDURAL DESCRIPTION

I. ERC DATA HANDLING AND PROCESSING

An outline of data throughput is presented in **Fig. 8.**

A. Handling

1. Shipping of Echocardiograms

Echocardiograms (6 studies per 0.5" super-VHS videotape) accompanied by participant identification sheets (one per subject) are mailed each Monday from the field centers. The labelled videotapes should be safely secured individually in plastic "bubble wrap" and enclosed in a large padded envelope. The packaged cassettes (ordinarily 2-7 per week) should then be placed in a sturdy cardboard box and sent via express shipment (e.g., Federal Express, or other secure, trackable service) to:

Retha Webb (Phone: 202/687-8977)
Cardiology Division; 5 PHC Room F5033A
CHS Echocardiography Reading Center
Georgetown University Medical Center
3800 Reservoir Road, NW
Washington, DC 20007

2. Receipt and Manual Log of Echocardiograms

Ms. Webb will record receipt of the tape on log sheets, maintained in a loose-leaf binder, which will contain the tape number, field site, and date of receipt. The videotape and enclosed field center subject identification sheets (refer to Appendix XX, CHS Echocardiography Field Manual) will be transferred to the reading laboratory.

3. Notification of tape receipt (FAX or E-Mail) will be transmitted within 24 hours to the field center and the Coordinating Center.

B. Processing in Reading Laboratory

1. Database Entry of Videotape I.D.: In the Reading Laboratory information from the field center subject I.D. sheets is entered by the data manager into a specially configured relational database (Foxpro) maintained on a dedicated 486 PC in the CHS ERC reading laboratory. This will facilitate subsequent participant study retrieval from videotapes. Linkage of this database with that at the Coordinating Center via I.D. numbers will be of particular use should partial re-reads be required for potential future substudies. Data entry will include field site, tape number, subject I.D number, field center technician code, and ERC reader code. The seven digit I.D. code will be verified utilizing the digit verification program supplied by the Coordinating Center. The I.D. code assigned by the Coordinating Center contains a calculated value determined from the initial I.D. digit sequence. Hence incorrect I.D. data entries can be identified and corrected.

2. Tape Assignment: Videotape cassettes containing an equal or greater number (from spillover) of studies as the weekly aliquot for a given reader are placed in the reader's inbox. Spillover from the week's reading assignment are scheduled for the following week to avoid splitting videocassettes between different readers. Readers are assigned time slots with the image analysis units.

The total time budgeted is calculated to permit a total ERC throughput of up to 120 echoes per week.

3. ERC Reading Procedure:

a. *Dual I.D. entry:* The Microsonics offline image analysis system has been configured to accept the subject I.D. in two locations. The first ("Subject I.D") is fixed, and cannot be altered after entry, except by erasure of the subject file. The second location ("Subject Title") can be edited in case of error and will be utilized for subject identification in the Coordinating Center database and for subsequent ERC database searches and queries. For clarity the subject's last and first names are entered. The reader's I.D. code is recorded.

b. *Tape Scanning and Digitization*: The tape is scanned by the ERC reader to identify appropriate segments of 2D-derived M-mode recording of LV and Ao/LA, LV outflow PW Doppler, and LV inflow PW Doppler for digitization, measurement, and storage. Two-dimensional echo segments (other than selected 2D/M-mode split screens), and color flow segments will not be digitized.

c. *Echo Measurement:* Measurement of M-mode and Doppler parameters with Microsonics offline image analysis systems will be made utilizing algorithms described in **Appendix I** and in the attached Microsonics reference manual. Three beats of each parameter will be measured. Heart rate will be obtained from

successive RR intervals of the LV M-mode recording and that value will be applied to all heart rate based calculations within the Seattle Coordinating Center database. Pre-defined qualitative statements printed on the Microsonics touch pad data tablet **(Fig 6)** will be used to score aortic valve anatomy, valvular regurgitation (color flow Doppler), mitral annular calcification, LV regional and global function, LVH, and study quality. Criteria for qualitative statements are described above, and for quality codes are provided in **Appendix II**. The qualitative statement will be based upon reading of the videotape in real time and careful inspection of all views.

d. *Save and Close:* After each measurement sequence, data are automatically saved to hard disk. After completion of the patient study the file is closed.

4. Data Storage and Transfer: Weekly, the data manager will convert the echo reports to ASCII format for downloading from hard disk to both 3.5" floppy disk and to the ERC PC-based Foxpro database. The digitized images, quantitative measurements, and qualitative statements (encoded from the data tablet) will be stored on 650 mb optical disk. The week's ASCII data on floppy disk will sent by express mail (Tuesday mailing) to the Coordinating Center in Seattle. All ERC database information will be backed up on tape weekly. The image analysis system hard disks are to be purged after data transfer to optical disk, floppy disk, and PC (database) hard disk.

The completed videocassettes will be stored, in numerical order, in special locked metal cabinets in the reading laboratory.

Prepared instructions for ERC readers summarizing the procedures described above are presented in **Appendix III.**

QUALITY CONTROL

Test-Retest Pilot Studies Before Examination Phase

During May 1994 a pre-pilot series of echocardiograms will be performed on 20 subjects at each Field Center by each technician who will be involved in performing echocardiograms. The subjects will consist either of members of the CHS study cohort, or volunteer subjects in the same age group (ages 65 and over) as the CHS cohort. These studies will be performed by the Field Center technician during the two months after the initial orientation/training visit to the Echocardiography Reading Center. Because each technician (generally two) in the Center will perform echocardiograms on these same 20 subjects, we will be able to develop a measurement score (e.g., coefficient of variation) for inter-technician variability. In addition, each technician at each Field Center will be required to repeat studies one-to-three weeks later in these 20 subjects--not relying on any notes as to the position of the subject or the head of the bed, the type and location of the transducer, and preset machine factors (recorded on the Echocardiography Technician's Worksheet)--to establish a measure of intra-technician performance variability. These echocardiograms will be coded by random number at the Echocardiography Reading Center. Assuming two technicians at each of the four centers, this will result in a series of 320 echocardiograms to be read at the Echocardiography Reading Center. **A sample of these echocardiograms will be used to certify technicians for performance of studies in the clinical year. Appendix IV** outlines the schema for performing these studies at the Field Centers and

interpreting them at the Reading Center. A sample of sets of the four echocardiograms from each of 20 subjects (selected randomly from the 80) will be read by the Director of the Reading Center to assess inter- and intratechnician performance variability. It is estimated that the approximate number necessary for the Director to read is 80 studies, based on maximum expected intratechnician, intertechnician, and Director reader variability of 30%, 30%, and 10%, respectively, and maximum acceptable values of 10% each. Each of four readers at the Echocardiography Reading Center will read the same sample of 40 echocardiograms, sampled from the 80 echocardiograms performed in the first round (e.g., first echocardiogram from the first technician) on the 80 patients. The same sample of 20 echocardiograms, randomly selected, will then be reread in a timely fashion to determine intra-reader variability. These numbers are based on maximum expected inter- and intraobserver variabilities of 35% and 15%, respectively, with acceptable values of 15% and 10%, respectively.

The goal of these pre-pilot studies will be to maintain a mean intra- and inter-technician performance variability (and a mean inter- and intra-reader variability) in the range of 10%. If the inter- or intra-technician variability in the pre-trial studies during Year 1 is not within 15% for technicians in any of the Field Centers, the Center will be visited by one of the echocardiography technician-readers from the Reading Center. The technician-reader will review the pre-pilot series of echocardiograms with the Field Center technicians in an attempt to pinpoint and

correct the source of inter- or intra-technician variability. The Echocardiography Center technician will have the authority, with the approval of the Director, to determine whether the problem in technician variability has been corrected after this visit, or whether further steps (e.g., additional training or hiring and certifying a new Field Center technician) are necessary to assure accurate data collection.

Quality Control During Clinical Examination Phase

Site Visits During Year 7 of the study an Echocardiography Center technician-reader will visit each Field Center two times (at approximately six-month intervals) to ensure that the Field Center technicians are performing in compliance with the protocol.

Inter-Technician Variability In twenty subjects, the echocardiogram performed by one technician, will be repeated by the second technician at the field center. This will allow measurement of inter-technician acquisition variability.

Test-Retest Replication Study For assessment of performance variability a sample of 20 subjects will be asked to return for repeat echocardiography within a month of their initial examination. Consecutive subjects undergoing echocardiography at the beginning of each month of Years 2 and 5 will be asked to volunteer to return for these repeat studies. On their return visits, these 20 volunteers will include 6

with initial studies performed in June, 6 from July, 5 from August, 5 from September, 4 from October, 4 from November, 3 from December, 3 from January, 2 from February, and 2 from March. On their return visits, these 20 subjects will have one echocardiogram repeated by the technician who performed the echocardiogram at the initial study and a second repeat echocardiogram performed by a second Field Center echocardiography technician. Fifteen (75%) of these subjects should be selected from those initially studied by the principal echocardiography technician at each Field Center; the remaining five subjects will be selected from those who have had their original studies performed by the second technician. The principal technician is defined as the technician who performs most of the echocardiography studies at each Field Center. This breakdown of studies by principal and secondary technician will allow for an estimate of intra-technician performance variability for the second technician, which can be compared to the more precise estimate of intra-technician variability obtained from the principal technician.

Temporal Shifts in Data Temporal shift in performance and reading of studies among Field Center technicians will be assessed by comparing means and standard deviations of selected echocardiographic measurements among samples of studies read each month by the same readers over time. These analyses can be done by technician and by Center to allow for detection of shifts over time in technician performance of studies. Any shifts in performance will be adjusted for reader drift

detected from re-reading samples of studies during the clinical years, as described below.

Depending on the needed sample size to assess intrareader variability, as confirmed from the pre-pilot data analysis, a 3-5% random sample of studies will be reread, blindly, on a weekly basis by each of the Reading Center readers, so as to track (and if necessary correct) any temporal drift in intrareader measurement variability during clinical years 2 and 5. The exact protocols for assessing intra-reader measurement variability and intra-technician performance variability will be designed and supervised by the ERC and Coordinating Center personnel.

Additional training may be required of the technicians and/or the readers during the clinical or interim years in the event of any significant temporal shifts in accuracy or precision of echocardiography study performance and/or reading. It is the opinion of the Echocardiography Reading Center Director that Field Center technicians must perform a minimum of 4 echocardiographic studies per week according to the CHS protocol during the examination years (Years 2 and 7) to maintain sufficient proficiency to retain their certification as CHS Field Center technicians.

Monitoring of Field Site Technician Echo Quality Code Scores

The proportion of unreadable studies (quality code "0") for M-mode LV, and 2D

regional wall motion will be tabulated biweekly. An increase in the proportion of unreadable studies to 30% or greater will trigger a query of the field center vis a vis changes in personnel, study technique, echo machine performance. If helpful, a site visit will be made within one week by ERC personnel to observe study performance and offer corrective measures, if available.

TRAINING AND CERTIFICATION PROCEDURES FOR FIELD CENTER ECHOCARDIOGRAPHY TECHNICIANS

Initial Training and Certification of Field Center Echocardiography Technicians

In March,1994 an initial three-day orientation and training session will be scheduled for all Field Center technicians at the Echocardiography Reading Center. Prior to attending this session, each Field Center technician will fill out a questionnaire which will give the Echocardiography Reading Center staff an idea of the previous level of his/her training and experience. The initial orientation/training visit will be geared to the level of training and experience of the Field Center technician group. The orientation session will begin with a lecture-format orientation to cardiac anatomy and function, as well as basic principles of echocardiographic imaging and Doppler flow recording. Additional lectures will focus on the objectives and timetable of the Cardiovascular Health Study, strategies for technician training and quality control, as well as details of operation of the Toshiba SSH-160A ultrasound unit and of the echocardiographic scanning protocol. Following this initial orientation, Field Center technicians will each learn how the various M-mode, two-dimensional and Doppler echocardiographic measurements will be made at the Echocardiography Reading Center using the off-line analysis system. It is extremely important that Field Center technicians are aware of constraints imposed on the echocardiography readers by limitations in reading time and by technically suboptimal studies. In addition, field center

technicians will have the opportunity during this five-day training visit to perform echocardiography examinations while observed by each other and Echocardiography Reading Center personnel. This provides the opportunity to observe first hand the effects of inter-technician differences in echo acquisition on study characteristics and quality. The format for this hands-on technician training at the Reading Center will be the same as outlined in the next section for Field Center training.

Training and Certification at Field Centers

One or two weeks following the initial training and orientation at the Echocardiography Reading Center, the principal or associate technician-reader from the Center will travel to each Field Center to observe field center technician echocardiography performance of approximately five subjects per day. Subjects will be scanned first by the Field Center technician(s) and then the echocardiography trainer. The trainer will provide on-line supervision and instruction in the proper positioning of the transducer to record optimal two-dimensional and M-mode images--especially of the left ventricle--as well as pulsed, continuous wave and color flow Doppler studies. At the end of this site visit, the technician-trainer will examine each of the Field Center technicians regarding their ability to do two-to-four complete echocardiograms according to the outlined protocol. The examination will be performed first by the technician-trainer, whose study will serve as the "gold standard" against which to compare examinations

performed by the Field Center technicians. A scoring system will be developed for each M-mode, two-dimensional and Doppler echocardiography view in which 3 is "excellent" and corresponds to the "gold standard" recording of the technician, 2 is "good" (i.e., slightly below the technical quality achieved by the technician-trainer), 1 is satisfactory but substantially below the quality of the trainer's study, while 0 is "unacceptable." For grading M-mode and two-dimensional studies, emphasis will be placed on the ability of the Field Center technician to obtain images with appropriate spatial orientation and good endocardial and epicardial definition. For grading pulsed and continuous wave Doppler studies, emphasis will be placed on the ability to properly position the ultrasound beam and to record beats demonstrating the highest velocity and, for pulsed wave, the least spectral dispersion. An overall average examination score of "2" will be required for each Field Center technician to be certified by the technician-trainer from the Echocardiography Center. Should any Field Center technician not qualify for certification, the technician-trainer will schedule additional time in which to train this technician at his/her Field Center.

Field Center technicians will be trained to perform the appropriate echocardiographic examination as outlined above within **30** minutes and to fill in the Echocardiography Technician's Worksheet. The scanning protocol is described in the CHS Echocardiography Field Center Manual.

Retraining of Field Center Echocardiography Technicians

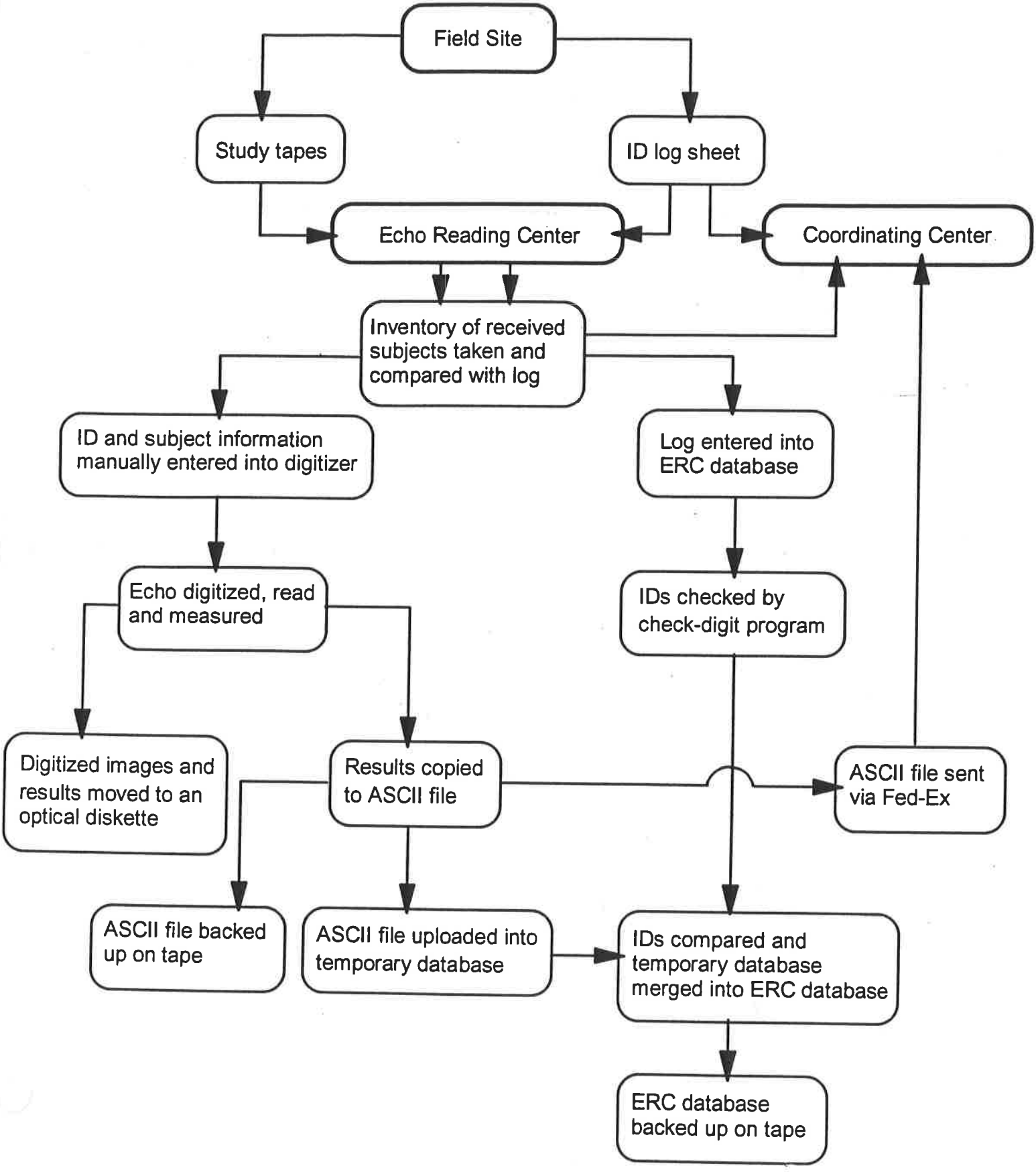
In case of technician turnover at the field site, an Echocardiography Center sonographer will assist in the training of any new Field Center technicians. Whenever turnover in a Field Center technician position occurs, the same quality assurance measures used during the pre-clinical years to certify technicians will be used--namely, a study in which the new technician performs echocardiograms in 20 subjects and repeats the echocardiogram in 20 of these subjects. These studies will be compared to the same number of studies performed in the same subjects by the remaining senior Field Center technician. Studies will then be forwarded to the Echocardiography Reading Center where all studies will be read by one reader and the coefficient of variation and re-performance variability scores calculated for inter-technician and intra-technician comparisons.

1 [illegible]node LV Qual	2 LV Inflow Doppler Qual	3 LV Outflow Doppler Qual	4 Mitral Regurg	5 Aortic Regurg	6 Tricuspid Regurg	7 Mitral Annular Ca+	8 Aortic Ring Annular Ca+	9 Aortic Leaf Thickening
Unread-able	Unread-able	Unread-able	None	None	None	None	None	None
Poor 1	Poor 1	Poor 1	Mild	Mild	Mild	Mild	Mild	Mild
Good 2	Good 2	Good 2	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Excellent 3	Excellent 3	Excellent 3	Severe	Severe	Severe	Severe	Severe	Severe
			N/A; Can't Assess	N/A; Can't Assess	N/A; Can't Assess	N/A; Can't Assess	N/A; Can't Assess	N/A; Can't Assess

10 Aortic Leaf	11 Aortic CW	12 TR CW Velocity	13 LV Function	14 LV RWMA	15 Reader ID		16 Clinical Alerts	Free Text
Normal	< 2.0 meters	< 2.0 meters	Normal	None	Falcon 1	Gay 2	No Referal	*Enter any alert comments now.*
Mildly Impaired	2.0-2.9 meters	2.0-2.4 meters	Mildly Decreased	Mild	Gottdiener 3	Hausner 4	Refer to a Physician	
Moderately Impaired	3.0-3.9 meters	2.5-2.9 meters	Moderately Decreased	Moderate	Hecht 5	Livengood 6		*Don't use commas !*
Severely Impaired	4.0-4.9 meters	3.0-3.6 meters	Severely Decreased	Severe	Banfield 7	Yohe 8		*Don't press enter!*
N/A; Can't Assess	5.0-5.9 meters	≥ 3.7 meters	N/A; Can't Assess	N/A; Can't Assess				
	≥ 6.0 meters	Not Measured						
	Not Measured							

Fig 8

CHS ECHO WEEKLY THROUGHPUT



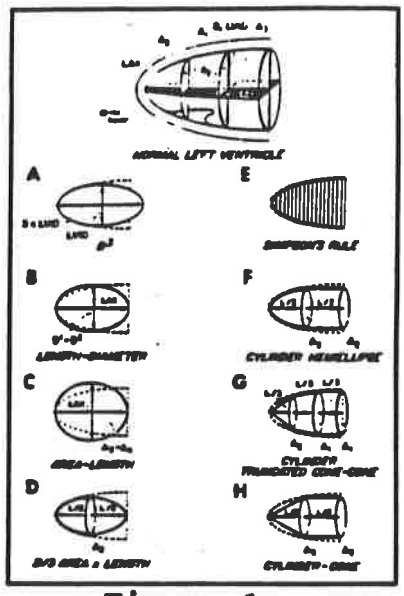


Figure 1

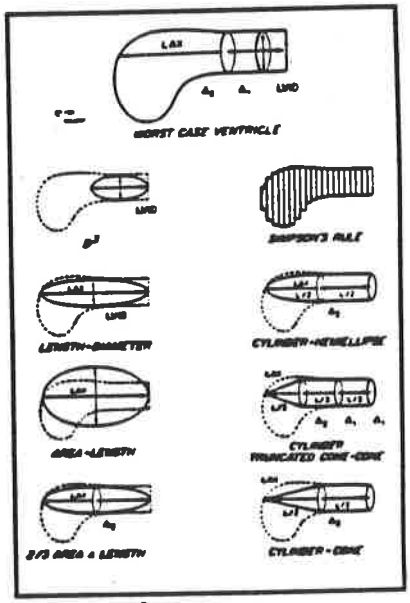


Figure 2

Fig 3

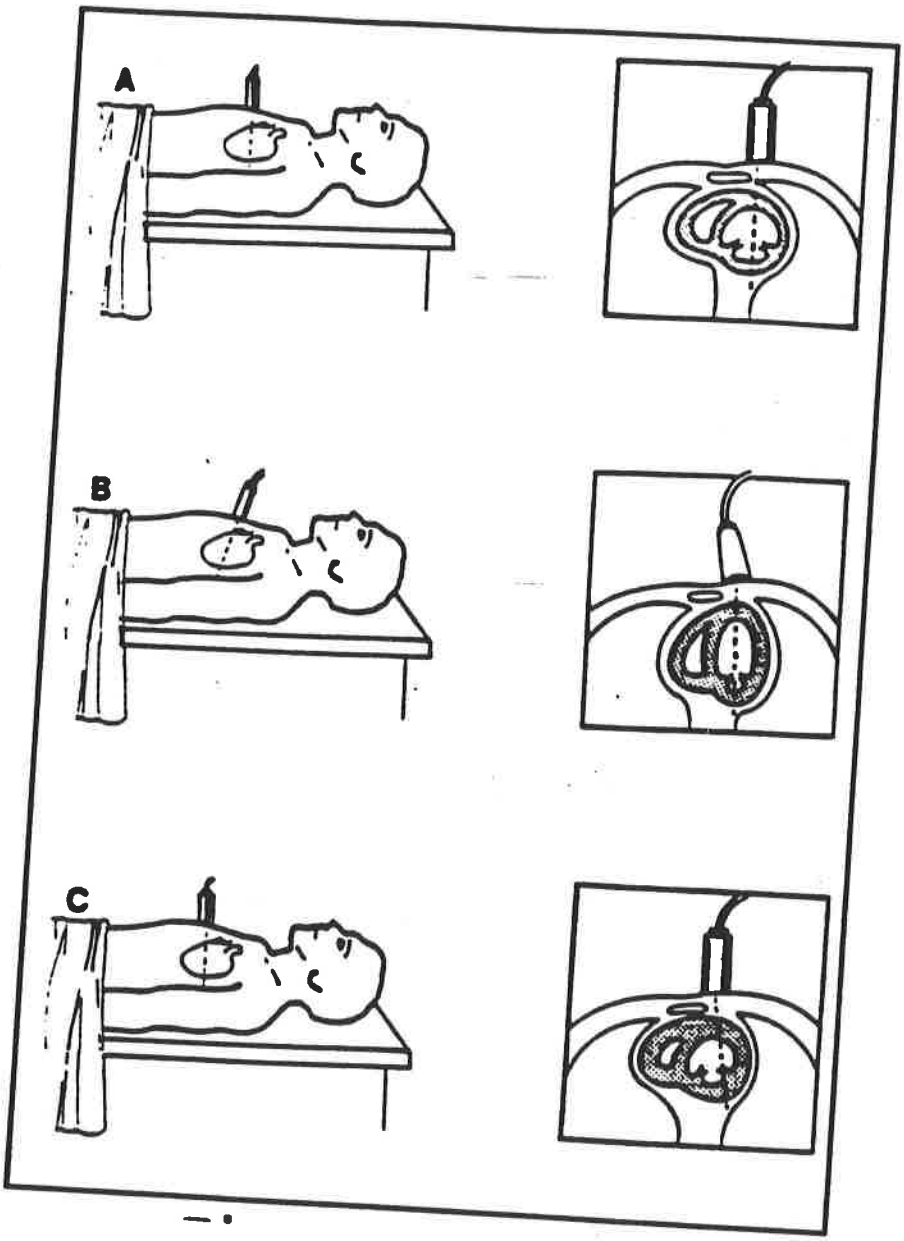
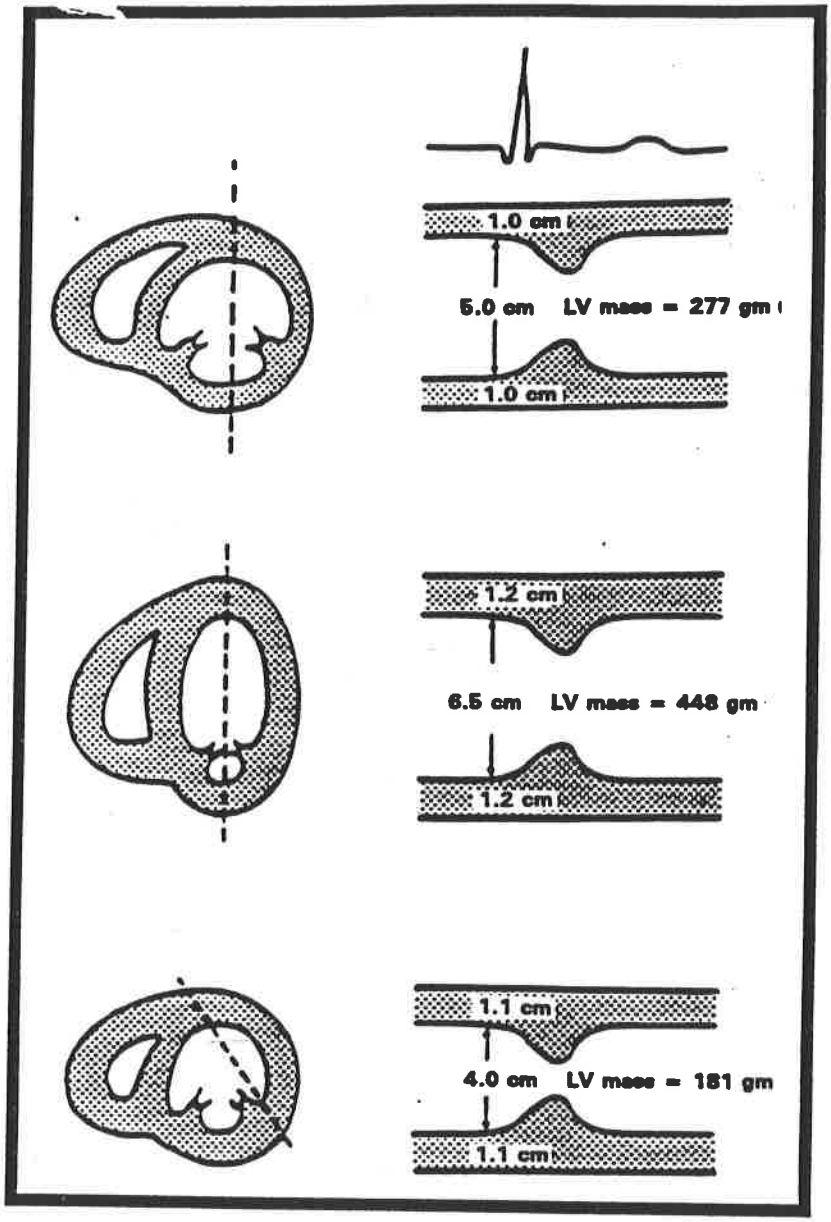


Fig 4

EFFECTS OF SECTOR OBLIQUITY ON LEFT VENTRICULAR MASS MEASUREMENT



Effects of beam angulation errors on 2-D targeted M-mode recordings and estimations of LV mass.

Fig 5

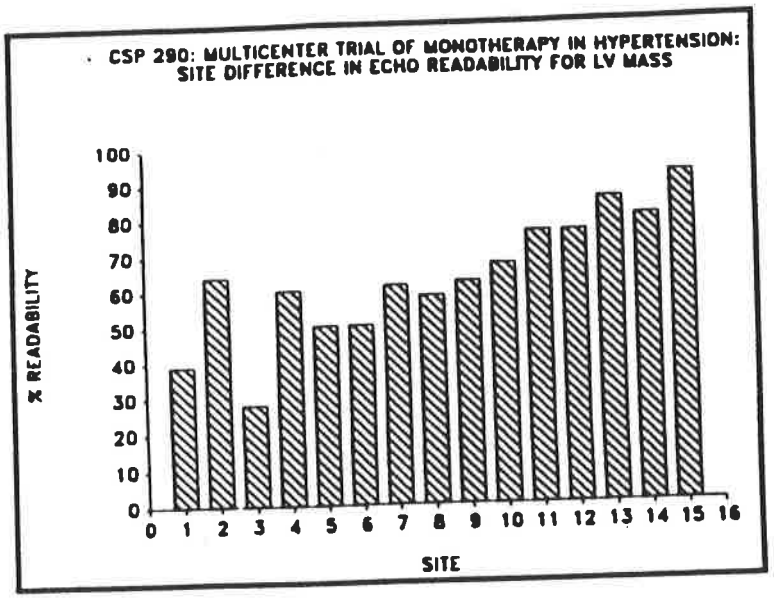
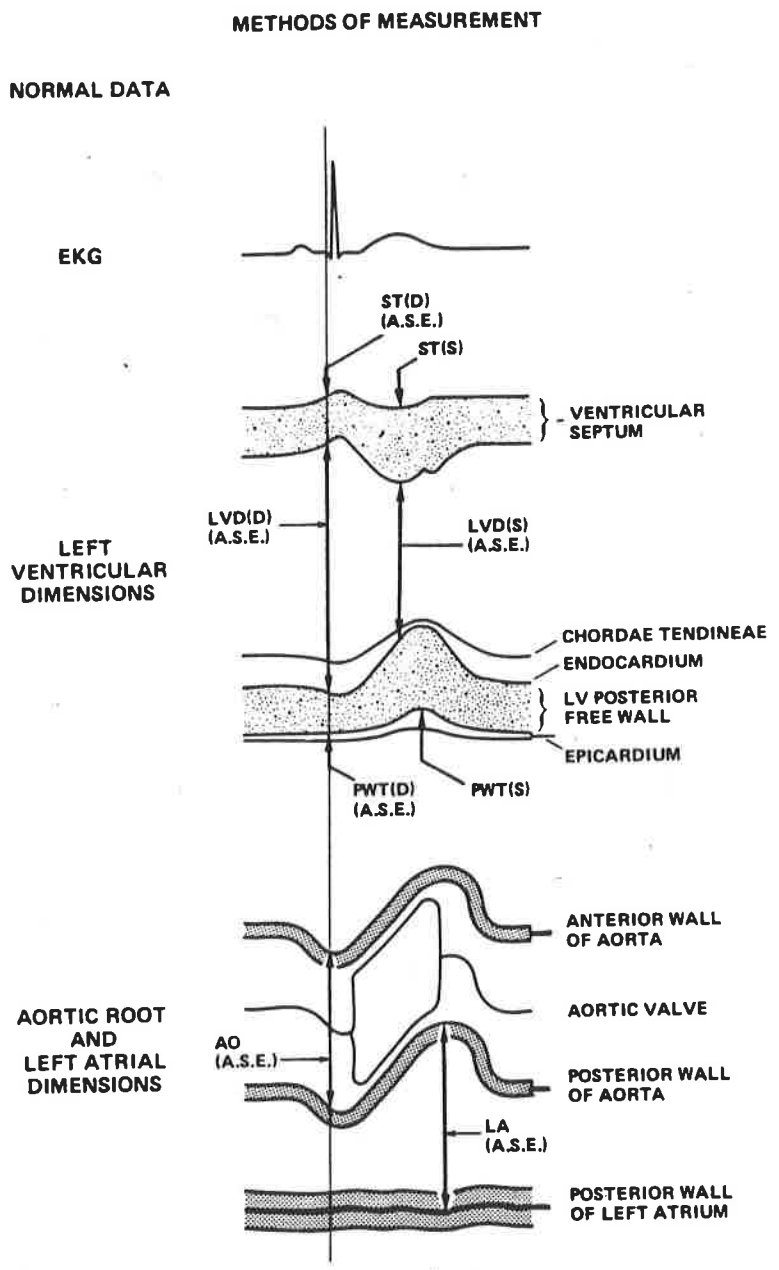

CSP 290: MULTICENTER TRIAL OF MONOTHERAPY IN HYPERTENSION:
SITE DIFFERENCE IN ECHO READABILITY FOR LV MASS
% READABILITY
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
SITE

Fig 7


METHODS OF MEASUREMENT
NORMAL DATA
EKG
ST(D)
(A.S.E.)
ST(S)
VENTRICULAR SEPTUM
LVD(D)
(A.S.E.)
LVD(S)
(A.S.E.)
LEFT VENTRICULAR DIMENSIONS
CHORDAE TENDINEAE
ENDOCARDIUM
LV POSTERIOR FREE WALL
EPICARDIUM
PWT(D)
(A.S.E.)
PWT(S)
ANTERIOR WALL OF AORTA
AORTIC VALVE
AO
(A.S.E.)
POSTERIOR WALL OF AORTA
AORTIC ROOT AND LEFT ATRIAL DIMENSIONS
LA
(A.S.E.)
POSTERIOR WALL OF LEFT ATRIUM

APPENDIX I: MICROSONICS IMAGEVUE BETA SOFTWARE ASCII EXPORT

IMAGEVUE® BETA SOFTWARE

VERSION 1.50b

RELEASE NOTES

The following features are included in the ImageVue DCR software version 1.50b which is released only to designated sites for beta testing.

CALC SETUPS

The ability to specify the results to be displayed upon the completion of each analysis procedure has been added. The operator is able to turn off undesired results so that they do not appear in the procedure results box or the final report.

VIDEO TRIGGER VERIFICATION

A mechanism for verifying the detection of ECG R-waves when setting up a video trigger has been added. This feature includes the display of a calculated heart rate and an audible beep which corresponds to detected R-waves. These devices are used to help ensure that the video trigger has been set effectively and to reduce the acquisition of improperly triggered images.

ASCII EXPORT OF ANALYSIS DATA

A utility has been added to enable the export of saved patient, exam and analysis data to an ASCII file for use with other commercially available software supporting the import of ASCII text files.

IMAGEVUE® WORKSTATION

BETA SOFTWARE VERSION 1.50b

OPERATING INSTRUCTIONS

CALC SETUP

The **CALC SETUP** function provides the ability to specify the results to be displayed for each analysis procedure so that unwanted results are not displayed. The system will still calculate all results but only those marked for display through this function will be seen. **CALC SETUP** is performed on a per procedure basis and is available for use at all times.

To define the results for multiple analysis procedures,

1. Select **CALC** in the main menu bar, then select **SETUP** in the Calc menu bar.

   or

   Select **Other** in the calc list menu bar.

2. Select **Calc Setups....** The Calc Setup Selection box is displayed.

The Calc Setup Selection box contains a list of every analysis procedure currently available on the ImageVue workstation.

3. Select the procedure to be modified in the list, then press **OK**. A procedure setup box containing all the results for the selected procedure is displayed behind the Calc Setup Selection box.

4. Repeat step 3 until all the desired procedures have been selected and a setup box is displayed for each.

5. Press the **DONE** pushbutton in the Calc Setup Selection box to dismiss the box and continue.

When multiple procedure setup boxes are opened, they appear stacked on top of one another with only their title bars visible. The most recently selected procedure setup box is on top with its contents visible.

6. Deselect the check box to the left each result you wish to turn off (ie. do not want displayed when the results box is displayed at the completion of the procedure).

7. Press the **SAVE** pushbutton in the procedure setup dialog box. The procedure setup dialog box is dismissed from the screen when the setup is saved.

If multiple procedure setup boxes had been opened, the next one in the stack will be visible.

8. Repeat steps 7 and 8 for the remaining procedures (if any).

The next time any of these calc procedures is used to analyze images, the results boxes will only display results which were preceded by a filled check box in the procedure setup box.

NOTES:

Procedure Step/Result Dependency

When Calc Setup is used for a given procedure, the ImageVue checks the procedure for the steps from which omitted results are calculated. If the procedure contains steps that correspond only to results which have been omitted, the steps are automatically excluded from the procedure box, eliminating the measurement of unnecessary steps.

Defer Calculations Check Box

The procedure setup boxes contain a selection labeled **"Defer Calculations until Results are Shown"** which may be used to speed up the actual measurement process of calculation-intensive procedures such as Centerline or Disc Biplane EF/Volume.

Typically, the system calculates results as steps are completed, causing a slight delay in the activation of the next step in the procedure. Selecting the **Defer Calculations until Results are Shown** check box will defer the calculation of results until all steps have been completed (meaning that any delay that would have occurred between procedure steps will now occur before the results box is displayed).

Additional Procedure Setup Information

The procedure setup boxes contain other information which is used by the system to perform the setup functions. This information is in the form of numbers that are either bracketed or preceded by the letter "R" and is for internal use only.

Modifying the Current Procedure

Because the ImageVue workstation always calculates all results, **CALC SETUP** can be used to modify a procedure while it is currently running. To include or exclude results from the procedure currently being used,

1. Select **OPTIONS** in the procedure box menu bar.

2. Select **Modify Setup**. The procedure setup dialog box for the current procedure is displayed.

3. Make the necessary modifications by selecting or deselecting the appropriate check boxes, then press **Save**.

The procedure box and results box (if displayed) for the current procedure will be updated to reflect the modified setup. **Modify Setup** only applies to the current procedure and can not be used to access the procedure setup boxes of other calc procedures.

Reporting Modified Calc Procedures

Reports created through the **View/Edit Current Report** function will contain only the procedure results which were included through the setup function. However, because the ImageVue always calculates all possible results for the completed measurements and because the **Calc Setup** functions are available at all times, it may be possible to display additional results in the final report without having to re-measure the image. This can be done by modifying the procedure setup through the **Calc Setup** function and then re-creating the report. The additional results will be displayed as long as the required measurements had been made originally.

The results displayed in the final report always reflect the most recent setup status. For example, if a procedure is saved and then modified and performed a second time, the first set of results for that procedure will reflect the setup of the setin the final report, even though that is not how it was originally saved. The **Calc Setup** function can be used to turn on all the results desired for both runs of the procedure and the individual check boxes in the Edit Report window can be used to tailor the actual results to be saved and/or printed in the final report.

VIDEO TRIGGER ADJUSTMENT

The ImageVue provides for various methods of triggering the acquisition of images from the R-wave of an ECG. The Video Trigger is used to trigger from the R-wave of an ECG which is displayed on the live or video taped image display. To use a Video Trigger as the ECG trigger source:

1. Select **SETUP** in the main menu bar, then select **Input Source...** on the Setup pull-down menu. The Input Source dialog box will be displayed.

2. In the section labeled "ECG Trigger", click on the radio button preceding the word **"Video"**, then press the **OK** pushbutton.

The Input Source dialog box will be dismissed from the screen.

3. Click on the **Digital/Live** icon in the system tool box.

The live video input to the ImageVue will be displayed on the full screen. A small marker in the shape of an "H" will appear over the image. This marker is used to indicate the position of the ECG on the image and hence, the setup of the video trigger.

4. Drag the video trigger marker, by clicking in between the vertical bars but not on the horizontal bar, and position it so that the R-wave of the ECG trace intersects the horizontal bar in the marker. It is important to position the marker so that only the R-wave crosses its horizontal bar; anything that crosses this bar will trigger acquisition.

5. Click on the **Digital/Live** icon in the system tool box.

The live image display will be toggled off and the video trigger marker will remain set in its last position.

NOTES: **Sweeping vs. Scrolling ECG Displays**

The setup of the Video Trigger must vary with ECG display type in order to ensure accurate triggering. A Sweeping ECG is one in which the trace is updated from the left side of the screen. On most ultrasound systems, a blank space can be seen moving along the trace from left to right as the trace gets updated. A Scrolling ECG is one in which the trace display is constantly updated. On most ultrasound systems, these traces move from right to left across the display with the most recent data occurring where the trace enters the display (the far right of the trace).

To properly position the video trigger marker for a Sweeping ECG:

1. Follow steps 1 - 4 above.

2. Drag the right vertical bar of the marker to the point at which the ECG trace enters the display.

3. Drag the left vertical bar of the marker to the point at which the ECG trace exits the display.

The width of the video trigger marker should expand the entire length of the ECG display.

4. Position the horizontal bar of the marker so that only the R-wave of the ECG touches it. This can be done by dragging only the horizontal bar (click exactly on the bar) or by moving the entire video trigger marker (click between the vertical bars but not on the horizontal bar). Because of its wide width, several R-waves should intersect the horizontal bar. *Important: The marker must not be touching any graphics or text displayed with the image.*

5. Click on the **Digital/Live** icon in the system tool box.

The live image display will be toggled off and the video trigger marker will remain set in its last position. Acquisition will be triggered each time the blank portion of the ECG trace passes through the marker, drawing a new R-wave.

To properly position the video trigger marker for a Scrolling ECG:

1. Follow steps 1 - 4 above.

2. Drag the entire video trigger marker to the right of the screen and position it so that the right vertical bar of the marker rests at the point at which the ECG trace enters the display. *Important: The marker must not be touching any graphics or text displayed with the image.*

3. Drag the left vertical bar close to the right so that the width of the marker can accommodate only a single R-Wave.

4. Position the horizontal bar of the marker so that only the R-wave of the ECG touches it. This can be done by dragging only the horizontal bar (click exactly on the bar) or by moving the entire video trigger marker (click between the vertical bars but not on the horizontal bar).

5. Click on the **Digital/Live** icon in the system tool box.

The live image display will be toggled off and the video trigger marker will remain set in its last position. Acquisition will be triggered as each R-wave enters the display.

Video Trigger Verification

The ImageVue enables you to verify the detection of the ECG R-wave when using the video trigger through the use of a calculated heart rate and, if desired, an audible "beep". These devices may be used while setting up the video trigger or any time the **Input Source** ECG Trigger is set to Video. To verify R-wave detection when using a Video Trigger:

1. Select **SETUP** in the main menu bar, then select **Video Adjustments....**

The Video Adjustments dialog box will be displayed. This box contains two sections labeled **Heart Rate** and **Audible ECG** which represent the heart rate calculated from detected R-waves and a control for enabling an audible version of each R-wave as it is detected, respectively.

2. Select the "On" radio button in the **Audible Beep** section of the Video Adjustments dialog box to hear a "beep" that corresponds to each R-wave as it is detected.

If the displayed heart rate appears to be inaccurate, or if the audible beep does not seem to correspond to the displayed ECG trace, the video trigger marker may need to be adjusted.

3. Press the **OK** pushbutton to dismiss the Video Adjustments dialog box when you feel that the system is accurately detecting the ECG R-wave.

If turned "On", the audible beep will only be heard for as long as the Video Adjustments dialog box is displayed and will not be heard after the dialog box is dismissed if left "On".

Video Trigger Marker Display

The video trigger marker is displayed whenever the **Input Source** ECG Trigger is set to "Video" and a live, full screen image is displayed. This includes the live video input image and any full screen live image displayed through an acquisition protocol. The marker will not be displayed on "full" images which are displayed as part of a multi-image display format (eg. Routine Quad-Full).

ASCII EXPORT UTILITY

The ImageVue ASCII export utility allows the export of patient information and analysis data to an ASCII text format for use with commercially available software supporting ASCII import facilities.

For definitions and operating instructions for the ASCII export utility, please refer to the attached CONFIDENTIAL document.

NOVA MICROSONICS IMAGEVUE / IMAGEVUE DCR

ASCII EXPORT UTILITY

INTERIM OPERATING INSTRUCTIONS

(Addendum to Part #'s 4700-7017-05 & 4700-7015-05)

FOR SOFTWARE VERSION 1.50b

BETA RELEASE ONLY

Distributed 8/93

Table of Contents

Table of Contents (con't)

SCOPE

This document discusses the use of the ImageVue/ImageVue DCR ASCII Export Utility and provides a detailed description of generated ASCII output.

1 INTRODUCTION

The ImageVue/ImageVue DCR ASCII export facility allows the export of patient information and analysis data stored in the ImageVue/ImageVue DCR native format to an ASCII text format. This ASCII data can then be imported into spreadsheets and other software programs that have ASCII import facilities.

1.1 OVERVIEW

The ImageVue/ImageVue DCR supports various devices for storing patient data - hard disk, floppy disk, optical disk, and ImageLAN network. The data format is different for each device because of performance considerations associated with the device and its storage medium.

ASCII export is able to read and write patient data from/to all of the supported devices, but floppy drive A is the default output drive.

1.2 DEFINITIONS

In order to understand the output data, a little background in the ImageVue/ImageVue DCR data organization is necessary.

Pertaining to ASCII Export, patient information consists of:

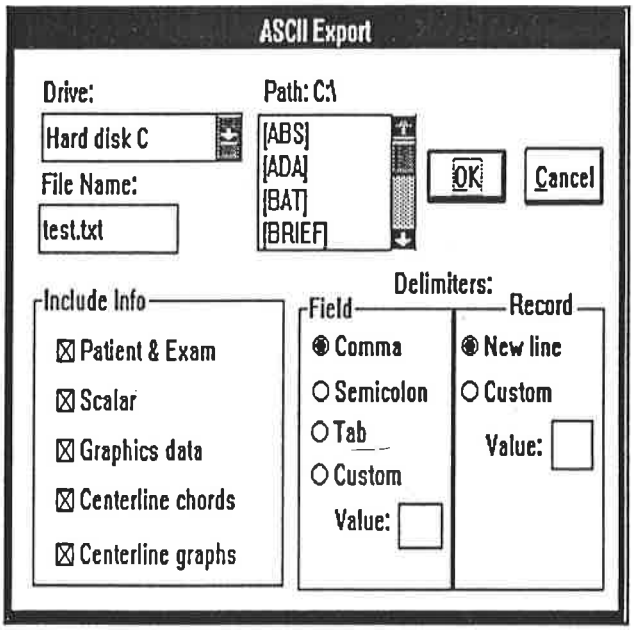
- Patient data : Constant data - eg. Name, Id, Date of Birth (DOB), etc.
- Exam data : Patient data associated with each doctor's visit.
- Comments : Doctor's comments associated with an exam.

For each Exam, patient analysis data consists of:

- Procedures : Procedure information - eg. Procedure Id, run number, date
- Results : Result information - depends on the nature of the result

2 USER-INTERFACE

ASCII export function can be accessed from the patient and exam menu via a Transfer facility. When one or more patients (or exams) are selected and then Transfer button is pressed, a dialog box comes up showing different transfer destination devices, ASCII being among them. When the user selects ASCII entry, another dialog box appears containing various selection criteria. These include: destination drive, path, and file name; characters for field and record delimiters; and the type of patient data that needs to be exported.
Below is an image of ASCII Export Dialog box:



Field delimiter character separates each field in the record. Field delimiters are usually *commas*, *semicolons*, or *tabs*. The user can select a custom field delimiter by typing in delimiter character's ASCII code (0..255).

Record delimiter character separates records in the output file. By convention each record is placed on a separate line in the output file, but the user can specify a custom delimiter in a manner described above.

The data selection parameters include:

- **Patient and Exam** - Patient record, exam record, and any comments.
- **Scalar Results** - Those results that contain one scalar value.
- **Graphics Data** - Trace and intersect arrays for Centerline and Disc Method results.
- **Centerline Chords** - Chord array for Centerline results.
- **Centerline Graphs** - Graph array for Centerline results.

At least one of these parameters must be selected.

2.1 DELIMITER RESTRICTIONS

- Custom delimiters' ASCII code must be between 0 and 255
- Field and record delimiters must be different.
- Cannot use code 34 (character ") as a custom delimiter because it is used to embrace an output string containing a delimiter character.

3 OUTPUT SPECIFICATION

The following describes output specifications for each exportable record type.
The following conventions are used:

- Block letters represent keywords or delimiters
- Entries in { } might be blank if data is missing
- Italicized entries show sample formats or sample delimiters

The following applies to all record definitions:

- Date fields for record Create and Update times will be written using the ImageVue/ImageVue DCR current date format. (eg. *mm-dd-yy* or *mm/dd/yy*)

- If the date field is undefined, it will appear as question marks (eg. *??-??-??*)

- If the field header or its contents contain user-specified delimiters, the string will be enclosed in double quotes (eg. *Comment:,"Irregular heart beat, shortness of breath"*).

- All records' fields will be placed on one line in the output ASCII file.

- All record descriptions in this document assume that *comma* is the field delimiter.

3.1 PATIENT RECORD

The patient record is the first record that will appear in the output ASCII file. It will be followed by zero or more exam records.

The format of the record is as follows:

Patient:,{Last name},{First name},{Mid.Initial},Id,{Title},{Key 1},
{Key 2},Sex,**DOB:**,date,**Created:**,date,**Updated:**,date

If the Date Of Birth (DOB) is undefined, it will be displayed as 00/00/00.

3.1.1 FIELD DESCRIPTIONS

Last name - Patient's last name
First name - Patient's first name
Mid.Initial - Patient's middle initial
Id - Patient's Id
Title - Title of the patient
Key 1 - Patient keyword 1 (currently blank)
Key 2 - Patient keyword 2 (currently blank)
Sex - Patient's sex
Units: **Gender unknown, Male, Female**
DOB - Date Of Birth date (mm/dd/yyyy) format
Created - Date of record creation
Updated - Last date record was updated

3.2 EXAM RECORD

Exam record follows a patient record in output ASCII file. If there are multiple exams for a particular patient, each exam record will be preceded by a patient's record. If an exam has any doctor's comments associated with it, the comments record will follow the exam record in the output file.

The format of the record is as follows:

Exam:,Id,{Title},{Key1},{Key2},**Height:**,number,units,**Weight:**,number,units,
Age:,number,units,**BSA:**,number,**m2**,**Resting HR:**,number,
Resting BPS:,number,**Resting BPD:**,number,**Institution:**,{name},**Dept:**,{name},
Refer.Physician:,{name},**Atten.Physician:**,{name},**Read.Physician:**,{name},
Radiologist:,{name},**Technician:**,{name},**Diagnosis:**,{string},**Procedure:**,{name},
Indications:,{comments},**Created:**,date,**Updated:**,date

3.2.1 FIELD DESCRIPTIONS

Id - Patient's Id (same Id as in patient record)
Title - Exam title
Key1 - Exam keyword 1 (currently blank)
Key2 - Exam keyword 2 (currently blank)
Height - Height of the patient
Units: **unknown** - undefined units
in - inches
cm - centimeters
Weight - Weight of the patient
Units: **unknown** - undefined units
lb - pounds
kg - kilograms

Age	- Age of the patient at the time of exam
	Units: **unknown** - undefined units
	days - days old
	weeks - weeks old
	months - months old
	years - years old
BSA	- Body Surface Area in m^2 (2 digits after decimal point)
Resting HR	- Heart Rate at rest
Resting BPS	- Systolic Blood Pressure at Rest
Resting BPD	- Diastolic Blood Pressure at Rest
Institution	- Name of the clinic or hospital
Dept	- Department name
Refer.Physician	- Name of referring physician
Atten.Physician	- Name of attending physician
Read.Physician	- Name of reading physician
Radiologist	- Name of radiologist
Technician	- Name of technician
Diagnosis	- Diagnosis string
Procedure	- Name of procedure performed during exam
Indications	- Patient indications recorded during exam
Created	- Date of record creation
Updated	- Last date record was updated

3.3 EXAM COMMENTS RECORD

If an exam has comments, the comments record will follow after the exam record. The format of the record is as follows:

Comments:,Comments string

If Comments string contains current field or record delimiters, the string will be enclosed in double quotes.

3.4 PROCEDURE RECORD

If there is analysis data associated with an exam, the procedures and results will follow the exam record. First, a procedure record will be written out, followed by all results associated with that procedure.

Each procedure has an associated Procedure Id which indicates the name of the procedure and Procedure Run number which uniquely identifies a procedure among records with same Procedure Id.

The format of the procedure record is as follows:

Procedure:,Proc#:,number**,Run#:,**number**,Done by:,**{name}**,Created:,**date**,**
Updated:,date

3.4.1 FIELD DESCRIPTIONS

Proc# - Procedure Id number (see below for Procedure Id list)
Run# - Procedure Run number
Done by - Name of the person who performed analysis procedure
Created - Date of record creation
Updated - Last date record was updated

3.4.2 PROCEDURE ID LIST

Procedure ID	Procedure Name
2	Liver
3	Right Kidney
4	Left Kidney
5	Pancreas
6	Gall Bladder
7	Abdominal Aorta
8	Bile Duct
9	A4C Disc Method Vol
11	A2C Disc Method Vol
12	A4C Area/Length Vol
13	A2C Area/Length Vol
14	A4C Disc Meth. Mass
15	A2C Disc Meth. Mass
16	SAX Area Change
17	2-Stage Qualitative Wall Motion
18	3-Stage Qualitative Upright Wall Motion
19	Routine Qualitative Wall Motion
20	Non-Exercise Qualitative Wall Score
21	LV Diastolic Funct.
22	Mitral Valve
23	AVA - Cont. Eq.
24	Aortic Valve
25	Tricuspid Valve
26	Pulmonic Valve
27	Cardiac Output
28	MV P1/2 Time
29	Disc Biplane Volume
30	Fractional Shortening
31	LAX Dimensions

32	Bullet Volume
33	LV Mass (AL)
34	Continuity Equation
35	SAX MV Area
36	RV/LV Study
37	Aortic/LA Study
38	Mitral Valve Study
39	Pulmonic Valve Study
40	Tricuspid Valve Study
41	Syst. Time Intervals
42	5-Stage Qualitative Wall Motion
44	2-Stage Exercise: A4C EF/Volume
45	Non Exercise: A4C EF/Volume
46	2-Stage Exercise: A2C EF/Volume
47	Non Exercise: A2C EF/Volume
48	2-Stage Exercise: Disc Biplane Volume
49	Non Exercise: Disc Biplane Volume
50	2-Stage Exercise: SAX Area Change
51	Non Exercise: SAX Area Change
52	3-Stage Exercise: A4C EF/Volume
53	3-Stage Exercise: A2C EF/Volume
54	3-Stage Exercise: Disc Biplane Volume
55	3-Stage Exercise: SAX Area Change
56	5-Stage Exercise: A4C EF/Volume
57	5-Stage Exercise: A2C EF/Volume
58	5-Stage Exercise: Disc Biplane Volume
59	5-Stage Exercise: SAX Area Change
60	Centerline A2C-Rest
61	Centerline A2C-Peak
62	Centerline A4C-Rest
63	Centerline A4C-Peak
64	Centerline SAX (pap. musc.)-Rest
65	Centerline SAX (pap. musc.)-Peak
66	Centerline A2C-Post
67	Centerline A4C-Post
68	Centerline SAX (pap. musc.)-Post
69	Arc Length
70	3-Stage Supine Qualitative Wall Motion
71	A4C Dimensions

3.5 RESULTS OVERVIEW

All result records follow their parent procedure record. There are various types of results that can be exported to ASCII format. Some of these result types are:

- Scalar - Results that have one value (eg. volume, index, heart rate, etc.)
- Centerline - Results that contain Intersect array, array of Chords, two wall traces, and Centerline trace.
- Disc Method - Results that contain the scalar part (volume measurement) plus an Intersects array, Area trace, and Long Axis trace.
- Normal - Results that contain normalized Centerline Graph.

Centerline, Disc Method, and Normal result types contain a lot of numerical data (eg. 200 pairs of floating point numbers) and some spreadsheets might not be able to import these long strings of numbers. In this case the numerical data will have to be manually broken down into multiple lines of text.

3.5.1 IMAGE RESOLUTIONS

To correlate trace result data to images on which these traces were performed, one needs to know the original size of the captured image. Below are the resolutions of various image sizes (in pixels):

Captured Image Size	X coordinate Resolution	Y coordinate Resolution
Full Screen	10,240	7,680
Quad Window	5,120	3,840
Vertical Dual Window	5,120	7,680
Horizontal Dual Window	10,240	3,840

The origin for all trace points lies in the lower left corner of the image.
The types of result record formats follow below.

3.6 SCALAR RESULT

The format of the record is as follows:

Scalar:,**Run#:**number,**Res#:**,number,{title},**Value:**,units,**Status:**,status,**Created:**,date,
Updated:,date

3.6.1 FIELD DESCRIPTIONS

Run# - Procedure Run Number - corresponds to parent procedure record
Res# - Result Id
Title - Title of the scalar result
Value - Floating point numerical value of the result. The default precision is six digits after decimal point.

Units: **unknown** - undefined units
mm - millimeters
cm - centimeters
% - percent
cm2 - cm^2
cm/s - cm per second
cm/s2 - cm per $second^2$
kHz - kilo Hertz
cc - volume units
whole - whole number units
score - score units
sec - seconds
msec - milliseconds
m/s2 - ms per $second^2$
ml - milliliters
l/min - liters per minute
m2 - $meter^2$
bpm - beats per minute
lb - pounds
kgs - kilograms
in - inches
g - grams
mmHg - mm of mercury
ml/m2 - ml per $meter^2$
l/min/m2 - liter per minute per $meter^2$
g/m2 - grams per $meter^2$
days
weeks
months
years

Status - Indication of result correctness

Status values: **ok** - result is valid
overflow - result is invalid (too big)
underflow - result is invalid (too small)
divide by zero - result is invalid
absent - there is no result

Created - Date of record creation
Updated - Last date record was updated

3.7 CENTERLINE RESULT

The format of the records is as follows:

Centerline:,Run#:,number,**Res#:**,number,{title},**Status:**,status,**Correction:**,name,
Created:,date,**Updated:**,date

Chords:,#Points:,number,**Lengths:**,n1,n2,...

Intersects:,#Intersects:,number,**Intersects:**,n1,n2,...

Trace #1:,#Points:,number,**Trace:**,n1,n2,...

Trace #2:,#Points:,number,**Trace:**,n1,n2,...

Centerline Trace:,#Points:,number,**Trace:**,n1,n2,...

If the user selected to transfer Centerline graphs and/or chords, the centerline header record will be exported (first format above).

3.7.1 FIELD DESCRIPTIONS

Run# - Procedure Run Number - corresponds to parent procedure record
Res# - Result Id
Title - Title of the centerline result
Status - Indication of result correctness
Status values: see status values for scalar result
Correction - Type of centerline correction
Values: **none** - no correction
automatic - automatic correction
Created - Date of record creation
Updated - Last date record was updated

For **Trace** and **Intersects** parts of centerline result, #Points corresponds to the number of trace (or intersect) points that follow. Thus, for example, if #Points = 200, there are 100 ordered pairs of X,Y coordinates. The points are integer numbers relative to the captured image size (see Image Resolutions section).

The situation with **Chords** is similar to that of traces, except that each point represents a distance in cm, and is a floating point number with six digit precision after decimal point.

3.8 DISC METHOD RESULT

This result consists of the scalar part that stores the volume, and trace results that include Intersects, Area Trace, and Long Axis line.

The format of the records is as follows:

D i s c
Method:,Run#:number,**Res#:**,number,{title},**Value:**,units,**Status:**,status,**Created:**,date,
Updated:,date

Intersects:,Thickness:,number,units,**#Intersects:**,number,**Intersects:**,n1,n2,...

Area Trace:,#Points:,number,**Trace:**,n1,n2,...

Long Axis:,#Points:,number,**Axis:**,n1,n2,...

3.8.1 FIELD DESCRIPTIONS

Run# - Procedure Run Number - corresponds to parent procedure record
Res# - Result Id
Title - Title of the scalar result
Value - Numerical value of the result
Units: See units for Scalar result
Status - Indication of result correctness
Status values: see status values for scalar result
Created - Date of record creation
Updated - Last date record was updated

For **Intersects** result:

Thickness - Thickness between intersects (a floating point number with 6-digits after decimal point)
Units: usually **cm**, but see units for Scalar result
#Intersects - Number of intersect points that follow (eg. 20 means 10 pairs of X,Y values)

For **Area Trace** and **Long Axis** result:

#Points - Number of points that follow (eg. 10 means 5 pairs of X,Y values). The points are integer numbers.

The points for Intersects, Area Trace, and Long Axis are integer numbers and are relative to captured image size (see Image Resolutions section).

3.9 NORMAL RESULT

This result consists of centerline graph information and includes the header result and the graph result records.

The format of the records is as follows:

Centerline graph:,**Run#:**,number,**Res#:**,number,{title},**Status:**,status,**View:**,view,
Stage:,stage,**Type:**,type,**Correction:**,name,
User Defs:,{name},**Created:**,date,**Updated:**,date

Graph:,**#Points:**,number,**Trace:**,n1,n2,...

3.9.1 FIELD DESCRIPTIONS

Run# - Procedure Run Number - corresponds to parent procedure record
Res# - Result Id
Title - Title of the centerline result
Status - Indication of result correctness
Status values: see status values for scalar result
View - View title
Values: **undefined**
card ap2c
card ap4c
card lax
card sax ap
card sax mv
card sax pm
Stage - Stage title
Values: **undefined**
routine
baseline
time1
time2
time3
rest
upright
midexer
peak
post

Type - Measurement title
Values: **undefined**
normalized motion
normalized thickening
% thickening

Correction - Measurement correction
Values: **none**
automatic

User Defs - User-specific measurement definitions title
Created - Date of record creation
Updated - Last date record was updated

Graph centerline result record:

#Points - Number of trace points to follow (eg. 100)
The points are displayed as floating point numbers with 6-digits after decimal point precision. The numbers represent % deviation from normal graph.

3.10 SAMPLE OUTPUT

Here is a sample output for different types of results for one patient and one exam (all result transfer options enabled). Long lines have been wrapped around for display purposes.

Patient:,Smith,Joe,A,123-45-6789,VIP,,,Male,DOB:,11/12/1963,Created:,07-10-91,Updated:,07-10-91
Exam:,123-45-6789,First Exam,,,Height:,150,in,Weight:,150.0,lb,Age:,28,years,BSA:,3.21,m2,Resting HR:,67,
Resting BPS:,90,Resting BPD:,120,Institution:,,Dept:,,Refer.Physician:,Dr.Sherry,Atten.Physician:,,

Read.Physician:,Dr.Gandolfi,Radiologist:,Dr.Vaysblat,Technician:,J.Schubert,Diagnosis:,,Procedure:,,Indications:,,
Created:,07-10-91,Updated:,07-10-91
Comments:,This was the test validation
Procedure:,Proc#:,11,Run#:,24,,Done by:,,Created:,08-01-91,Updated:,08-01-91
Disc Method:,Run#:,24,Res#:,0,Diastolic Volume,Value:,392.479758,unknown units,Status:,ok,Created:,08-01-91,
Updated:,08-01-91
Intersects:,Thickness:,0.500000,cm,#Intersects:,20,Intersects:,1840,0,1840,6016,2174,0,2174,6016,2508,0,2508,6016,

2842,0,2842,6016,3176,0,3176,6016,3510,0,3510,6016,3844,0,3844,6016,4178,0,4178,6016,4512,0,4512,6016,
4846,0,4846,6016
Area Trace:,#Points:,4,Trace:,1840,6016,1840,0,4848,0,4848,6016
Long Axis:,#Points:,2,Axis:,1840,3072,4848,3072
Scalar:,Run#:,24,Res#:,2,Ejection Fraction,Value:,35.142961,unknown units,Status:,ok,Created:,08-01-91,
Updated:,08-01-91
Scalar:,Run#:,24,Res#:,3,Stroke Volume,Value:,137.929009,cc,Status:,ok,Created:,08-01-91,Updated:,08-01-91
Scalar:,Run#:,24,Res#:,4,Stroke Volume Index,Value:,213.537320,unknown units,Status:,ok,Created:,08-01-91,
Updated:,08-01-91
Scalar:,Run#:,24,Res#:,5,Cardiac Output,Value:,24.827222,l/min,Status:,ok,Created:,08-01-91,Updated:,08-01-91
Procedure:,Proc#:,60,Run#:,63,,Done by:,,Created:,09-22-92,Updated:,09-22-92
Centerline graph:,Run#:,63,Res#:,2,Normalized Endo. Motion,Status:,ok,View:,card ap2c,Stage:,rest,Type:,normalized
motion,Correction:,automatic,User Defs:,,Created:,09-22-92,Updated:,09-22-92
Graph:,#Points:,100,Trace:,4.698974,4.537714,4.522001,4.539103,4.563213,4.507468,4.458736,4.595271,4.742348,...
Centerline:,Run#:,63,Res#:,1,Endo. Wall Motion,Status:,ok,Correction:,none,Created:,09-22-92,Updated:,09-22-92
Chords:,#Points:,100,Lengths:,0.833998,0.805377,0.802588,0.805623,0.809902,0.800008,0.791359,0.815592,0.841
696,...
Intersects:,#Intersects:,200,Intersects:,3466,118,3178,38,3443,168,3164,94,3429,220,3150,150,3418,270,3136,208,...

APPENDIX II
QUALITY CODE SCORES

2-D Targeted M-mode

0 = **Unacceptable** for reading

1 = **Acceptable:** 5mm continuous echo interface identifiable; cross-sectional eccentricity ≤ 1.2

2 = **Good:** separate full cycles readable

3 = **Very Good:** 2 continuous cycles readable

4 = **Excellent Quality:** 5 continuous cycles with distinct interfaces; minimal inter-beat variability. Distinct separation of epicardium and myocardium of LV posterior wall; perfectly perpendicular anatomic planes.

Two Dimensional Echo

0 = **Inadequate**

1 = **Acceptable:** Either circular cross-section at the papillary muscle tips and measurable long axis from apical view, or apical two- and four-chamber with minimal foreshortening of long axis; 70% endocardium recognized. Some apical echo artifact.

2 = As above, but with no apical artifact

3 = As above, but with 90-100% endocardium recognized

4 = All echo windows have optimal images

Doppler

0 = **Inadequate**

1 = **Acceptable:** distinct spectral envelope on individual beats, ECG trace present, sample volume appropriately placed. Aortic closure clicks recorded with ECG on separate tracing from LV inflow tract Doppler

2 = **Good:** 2-3 continuous cycles; narrow spectral band

3 = **Excellent:** LV inflow tract flow recording and aortic clicks on same tracing

APPENDIX III

ERC READER INSTRUCTION SHEETS

Setting up the Subject's Information for an Initial Read

i) Click on **Acquire** (located on the top menu bar).
ii) Make sure **Page-full** is selected (white letters on a black background).
iii) Click on the **Pt/Exam** button.
iv) Click the *upper* **New...** button (next to the patient name box).
v) Type the subject's **last name, first name, and ID**. Check the ID carefully because it can not be changed once you begin acquiring images. Now enter the ID again, only this timeput it in the **Patient Title** field. Pressing the **Enter** key will advance you through the entry spaces until you end up at the **Ok** button. When you press **Enter** on the **Ok** button, a new screen will appear.
vi) Press **Enter** until you get to the **Operator** blank, then type in your **reader-ID number** (use your initials until you are assigned an ID).
vii) Press **Enter** several times, until all the windows disappear and the **Foot Pedals** appear on the screen.

You are now ready to acquire the images (see *Acquiring the Images*).

Acquiring The Images

i) Scan through the tape and find the best images for each view.

ii) Play the tape and click on the **CAP** (capture) button. If you like the image click on the **ACCPT** (accept) button; the imgae is now saved. If you do not like the image, click on the **LIVE** button; the image is not saved.

iii) When you get all the images you want, press the **Page Forward** key on the keyboard (directly under the "..." key) and review your captured images.

iv) If you are satisfied that you have at least three good beats for each view, click on the **DONE** or **STORE** button. The foot pedals will disappear.

You are now ready to make your measurements (*see Measuring the Acquired Images*).

Measuring the Acquired Images

i) Make sure the subject's captured images are on the screen and in memory by paging through the images.
ii) Click on **Calc** (located on the top menu bar).
iii) Select the type of image you are measuring (M-mode or Doppler).
iv) Select the type of view you are measuring (RV/LV, LA/Ao, Mitral Doppler, or Aortic Doppler).
v) Press **Start**.
vi) Follow the measurement instructions at the bottom of the screen.
vii) When finished a results screen will appear (if it does not appear, press **results**). If you like the measurements press the **SAVE** button. If you don't like the measurements and want to change them press **CANCEL**, then press **Options, Restart**. Measurements can not be altered or deleted after the **SAVE** button has been pressed.
viii) After saving the results an hourglass will appear on the screen. When this changes back to a pointer, you may click on **Calc** and measure another beat.

If you want to see all of your measurements, click on **Results** and select **View/Edit Current Report.**

Using the Touch Pad to Add Comments

Comments can be made while acquiring the images or after measuring the images.

i) Click on **Report** (located on the top menu bar).

ii) Select either **Add Comments** or **View/Edit Current Report**. Use the **Add Comments** selection if you want to scan the tape while using the touch pad.

iii) If you want to scan the tape while you make comments, play the tape and press the **F7** key on the keyboard so that you see the live tape images.

iv) Take the **touch pad** and press the correct choice for each selection. You *must* enter a choice for **every column** (except the text column).

   a) The grey buttons are titles and have no real function.

   b) Begin at **M-mode LV Qual** and end with **Reader ID**.

   c) **Do not skip any selection** (except the text column).

v) After entering the reader ID, proof the comments and make sure the answers are correct. If they are correct, press the **Save** option which is under the Comments title bar (*Not* the large save button at the top of the report). To change the comments, press **Clear** and begin again.

vi) To close the Comments window, click on **Report** (located on the top menu bar), then click on **Add Comments** or **Edit Current Report**. The comments window should close.

General Reading Rules

1. When beginning a new session (ie. using the machine after someone else), always **turn the machine off** and then back on in order to clear any problems from a prior session.

2. Set up the patient information from the Acquire menu.

3. **Que** the tape to the correct subject and **scan** the echo. Look for:
   a) The study *quality*.
   b) From what *view* is the M-mode taken (short-axis is preferred).

4. **Acquire** no more than *three (3)* frames of each of the following views:
   a) RV/LV M-mode
   b) LA/Ao M-mode
   c) LV inflow Doppler
   d) LV outflow Doppler

Acquire the images which fill the screen, checking the split-screen display which precedes it to see if the view is off axis. If the only good images are the split-screen ones, acquire them.

Start-up:
Before You Do Anything...

i) **Restart** the machine by turning it off and then on again.
ii) Click on **Patient Files** (located on the top menu bar).
iii) Click on **Select Drives**.
iv) Make sure **Hard disk C** is *selected* (white letters on a black background) and that **every other drive** is *deselected*. Then click on the **Ok** button.

Views to Capture

1. M-mode RV/LV (short axis preferred)
2. M-mode Ao/LA
3. Doppler LV Inflow
4. Doppler LV Outflow

Calculations to Use

1. M-mode RV/LV Study
2. M-mode Aortic/LA Study
3. Doppler Mitral Valve Study
4. Doppler Aortic Valve Study

Finding a Previously Read Subject
&
Setting up the Subject's Information for a Re-read from Tape

i) Click on **Patient Files** (located on the top menu bar).
ii) Click on **Select Drives**.
iii) *Select* **Optical disk F** (white letters on a black background) and *deselect* **Hard disk C**. Then click on the **Ok** button.
iv) Look up the subject's ID in the database printout and get the optical disk indicated on the printout.
v) Click on **Acquire** (located on the top menu bar).
vi) Make sure **Page-full** is selected (white letters on a black background).
vii) Click on the **Pt/Exam** button.
viii) Click the *upper* **Choose** button.
ix) Click in the **ID#** box, type in the subject's ID and press **Enter**. The subject should appear on the screen highlighted in black. Click on the **OK** button.
x) Click on the *lower* **New...** button.
xi) Type **"Re-read"** in the **Exam Title:** box.
xii) Press **Enter** until you get to the **Operator** blank, then type in your **reader-ID number** (use your initials until you are assigned an ID).
xiii) Press **Enter** several times, until the windows disappear and the **Foot Pedals** appear on the screen.

You are now ready to acquire the images (*see Acquiring The Images).*

When you finish acquiring, you can make your measurements (*see Measuring the Acquired Images).*

Finding a Previously Read Subject
&
Setting up the Subject's Information for a Re-read from the Optical Disk

i) Click on **Patient Files** (located on the top menu bar).
ii) Click on **Select Drives**.
iii) Select **Optical disk F** (white letters on a black background) and *deselect* **Hard disk C**. Then click on the **Ok** button.
iv) Look up the subject's ID in the database printout and get the optical disk indicated on the printout.
v) Click on **Patient Files** (again).
vi) Click on **Patient Directory...**
vii) Click in the **ID#** box, type in the subject's ID and press **Enter**. The subject should appear on the screen highlighted in black. Click on the **Load** button. The images will then be loaded onto the screen.

You are now ready to make your measurements (see *Measuring the Acquired Images*).