ST3 Digital Transcranial Doppler System

Model PMD150

Operator's Manual

SPENCER TECHNOLOGIES
FOR THE BRAIN

CERTIFICATION STANDARDS:

Classified with respect to electric shock, fire, mechanical hazards only in accordance with
UL 60601-1 Edition 1
CSA C22.2-601.1-M90

ADDITIONAL STANDARDS:

IEC 60601-1
IEC 60601-1-2 Edition 2
IEC 60601-2-37 Edition 1.1
IEC 60601-1-1

Table of Contents

List of Figures

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Chapter 1 – Introduction

DESCRIPTION OF ST3 / PMD150

The ST3 / PMD150 (referred to as "System" throughout this Operator's Manual) is a digital transcranial Doppler (TCD) pulsed wave ultrasound system with digital Power M-Mode™ technology. This next generation transcranial Doppler has been designed with both the novice and the expert user in mind. Through digital Power M-Mode™ aiming technology, the advanced embolus detection algorithm, and the flexible data collection system, the System is much easier to use than previously existing TCD devices. These features provide increased information about transtemporal window location and intracranial blood flow when utilized in the clinic and the operating room.

In addition to this increased information, the data can be easily reviewed and analyzed. All data is stored internally and can be replayed immediately. This eliminates the need for an external recording device and allows data segments to be reviewed with a greater level of flexibility. If data archiving is desired, the System has data export capabilities and removable CD/DVD storage. It is possible to export screen images and reports, which can be utilized by a desktop application.

For long term monitoring, the System is used in conjunction with the Spencer Technologies Marc Series Headframe. This fixation device provides a stable platform to assure good signal quality. It may be used for bilateral or unilateral monitoring of cerebral blood velocities.

INTENDED USE

The System is designed to perform two primary functions: 1) to measure cerebral arterial blood flow velocity and 2) to monitor cerebral arterial blood flow for the occurrence of microembolic signals. Both of these functions can take place in the clinical, preoperative, or intraoperative settings.

The primary vessels intended for examination with the System are the middle, anterior and posterior cerebral arteries via the temporal windows, the vertebral and basilar arteries via the foramen magnum, and the ophthalmic artery and intracranial internal carotid artery via the orbit.

In measuring cerebral arterial velocity, the System monitors five main parameters: the mean peak systolic velocity (PEAK, cm/s), the mean velocity (MEAN), the mean end diastolic velocity (DIAS, cm/s), the pulsatility index (PI), and the relative change in mean peak systolic velocity over time (Δ%). Changes in these parameters, along with spectral analysis of the blood flow, allow determinations to be made about hemodynamically significant deviations from baseline values.

When the System is used to determine the presence of microembolic signals, the patented advanced embolic detection algorithm identifies an embolic signature using the Power M-Mode™ information base. This allows the System to isolate microembolic signals from background noise and to reject artifacts.

The System is NOT intended to replace any means of evaluating vital patient physiological processes.

INTENDED USERS

For clinical or surgical assessment, the System is to be used by a technologist or physician qualified by education and experience in the use of Doppler ultrasound. The user will:

- Locate the vessels to be examined.
- Make findings regarding blood flow velocities, changes therein, and the presence of emboli.
- Report these results to the attending physician for interpretation.

INDICATIONS FOR USE

The System is intended for use to monitor adult patients both clinically and intraoperatively.

Clinically, the System can be used to evaluate intracranial blood flow velocities, analyze blood velocity spectrally, and monitor for the occurrence of microembolic signals.

Intraoperatively, the System can be used to monitor intracranial blood flow during different phases of surgery and can be compared to baseline values to provide the surgeon with better information regarding changes in cerebral perfusion and microembolic activity.

CONTRAINDICATIONS

There are no known contraindications for adult cephalic evaluation with Doppler ultrasound devices such as the System. A small fraction of patients may not be suitable for standard evaluation for lack of a transcranial 'ultrasound window,' usually because of temporal bone thickness.

This device is not indicated for fetal use.

This device is not indicated for evaluating vital patient physiological processes.

CONVENTIONS

Warnings: Alerts you to safety issues with the System. You must read these warnings before using the System.

Cautions: Contain important information about the operation and maintenance of the System. Read these carefully in order to avoid any problems.

Notes: Notes contain information for help with operation of the System.

HOW TO USE THIS MANUAL

Caution: Before you set up or operate the ST3 / PMD150 it is important to read and understand all the material in this manual.

Once you are familiar with the contents of the manual, you can use it as needed for reference. To help you find things quickly, here is a description of the manual's organization:

Getting Started

Chapter 1 "Introduction" introduces the product.
Chapter 2 "System Overview" explains the System and components.
Chapter 3 "Quick Start" gives an overview of the tasks required to set up and use the System.

System Setup

Chapter 4 "System Setup" explains cable connections and startup.
Chapter 5 "System Operation" explains user options and how to choose setup screens.

System Operation

Chapter 6 "Diagnostics and Monitoring a Patient" describes how to perform diagnostic exams and review data.
Chapter 7 "Data and File Management" shows how to store patient data, organize files, and create reports.

Appendices & Specification References

Appendix "A" "Technical Information and Specifications" contains acoustic output reporting and specifies measurement limitations.
Appendix "B" "Ultrasound Safety" addresses Ultrasound Safety issues.
Appendix "C" "Troubleshooting" describes troubleshooting the System.
Appendix "D" "Maintenance and Care" contains instructions for system maintenance.
Appendix "E" "Product Specifications" is a list of specifications for the product.
Appendix "F" "List of System Components" is a list of System parts and contact information.
Appendix "G" "List of Replacement Parts" is a list of replacement parts and contact information.
Appendix "H" "Warranty and Service Policy" contains information about the Spencer Technologies product warranty, the service agreement policy, and the software license.
Appendix "I" "Glossary of Terms" and product symbols
Appendix "J" "Patents"

If, upon reading this manual, you find that you need clarification or additional information, you can direct questions to your local sales representative or to the contact listed on the back cover of this manual.

PRECAUTIONS

Warning: Electrical Shock Hazard. Do not open the System console casing.

Warning: To avoid the risk of electric shock, the equipment should only be connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.

Warning: Inspect power cord for damage prior to use. Using a damaged cord may result in electrical shock.

Warning: To avoid the risk of electrical shock, do not use extension cords to connect the system to mains power.

Warning: Disconnect the System console from the power source prior to cleaning. Failure to do so may result in electrical shock.

Warning: Inspect transducer housing and cable for damage before use. Using a damaged transducer assembly could result in electrical shock.

Warning: Remove transducer from patient contact before the application of a high-voltage defibrillation pulse. Failure to do so may result in electrical shock to the user.

Warning: Do not operate the system in the presence of flammable gasses or anesthetics. Explosion may result.

Warning: To avoid the risk of electric shock, do not connect non-medical (commercial) grade OEM accessories to AC mains power when monitoring/examining the patient.

Warning: To avoid the risk of electric shock, assure protective cap covers VGA connector when VGA connector is not in use.

Warning: To avoid the risk of electric shock, connect only medical grade equipment with medical grade power cords, conforming to UL/EN 60601-1, and a UL approved interconnection cable to the VGA connector.

Warning: Although the system meets EMI / EMC standards, this device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating this device or shielding the location.

Caution: Do not exceed 10% power through the eye, foramen magnum, burrholes, or fontanelles.

Caution: In determining the correct ultrasound power setting to use, always follow the ALARA principle: As Low As Reasonably Achievable.

Caution: Carefully read operator's manual before using the System.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Caution: Do not submerge the unit in water. Submerging the unit in water may damage the unit.

Caution: Do not submerge the transducer assembly in water. Submerging the transducer assembly in water may damage the transducer.

Caution: Do not subject the transducer assembly to rough handling. Dropping or striking the transducer may damage the probe crystal or insulation.

Caution: Do not use Betadine® to clean transducers or transducer connectors.

Caution: Read, follow all cleaning, and disinfection instructions. Failure to do so may damage the System.

Caution: This device is for adult use only. This device is not intended for fetal use.

Caution: Unit overheating may result if cooling fan on rear of unit is blocked.

Caution: This device cannot be sterilized, and is not intended for use inside the sterile field.

Caution: Use of this device in the presence of active electrocautery may result in distorted signal display.

Caution: Although the system meets current EMI / EMC standards, strong electromagnetic fields from non-compliant devices may cause degradation of the system display. If this occurs, identify and remove the source of the emission or move the system equipment.

Caution: Portable and mobile RF communications equipment can affect medical electrical equipment.

Caution: Any patient contact materials must be properly cleaned to prevent the transmission of infectious diseases.

Caution: Patient contact materials are only intended for limited duration (less than 24 hours), non-invasive direct contact with intact human skin.

Caution: This device is manufactured to operate properly at national voltage requirements 100-240V~, 50-60Hz, 1.5A. For Korea: 220V~, 60 Hz, 1.5A.

Caution: This device is manufactured to operate within the following conditions:

Humidity:	30 to 90% (non-condensing)
Operating temperature:	10° C to + 40° C (50° F to +104° F)
Storage temperature:	0° C to 50° C (32° F to 122° F)

Caution: Do not connect any accessory to this product that is not specified in this ST3 / PMD150 Operators Manual. Connection of non-specified accessories may cause the system to malfunction.

Caution: Inspect the System console for damage before use. A cracked or chipped surface may cause user discomfort, skin irritation, or abrasion, upon contact.

Caution: Do not use a transducer with a damaged probe face. A cracked or chipped transducer face may cause patient discomfort, skin irritation, or abrasion, upon contact.

Caution: Do not interfere with the CD/DVD drive during disk insertion or ejection. Forced or interrupted insertion or removal may damage the drive.

Caution: Do not ship the system in packaging that is not approved by Spencer Technologies. Shipping the system in an unapproved container may damage the equipment.

Note: **Figures pictured in this manual are typical and may not represent the most current appearance.**

Note: **Data Compatibility. Data recorded with v1.5.2 or above is not playable on earlier software versions of the PMD150 or PMD100. Data recorded on all earlier versions of the PMD150 and PMD100 is playable with v1.5.2.**

Note: **Blue Screen. A blue screen error occasionally occurs after hours of continuous acquisition with the analog output feature enabled. The device is not intended for continuous long-term use greater than 12 hours. To reset the device, simply turn it off and back on.**

CLINICAL SAFETY

There are no confirmed biological effects on patients or instrument operators caused by exposure from present diagnostic ultrasound instruments.

Chapter 2 – Overview

The System offers Power M-Mode™ in all TCD applications. The Power M-Mode™ provides 33 gates of continuous Doppler information across a 66mm depth range. The Power M-Mode™ information facilitates rapid vessel location and rapid acquisition of Doppler images.

In addition to this increased information, the data can be easily reviewed and analyzed. All data is stored internally and can be replayed immediately. This eliminates the need for an external recording device and allows data segments to be reviewed with a greater level of flexibility. If data archiving is desired, the System has data export capabilities and removable CD/DVD storage. It is possible to export screen images and reports, which can be utilized by a desktop application.

For long term monitoring (up to 12 hours), the System is used in conjunction with the Spencer Technologies Marc Series Headframe. This fixation device provides a stable platform to assure good signal quality. It may be used for bilateral or unilateral monitoring of cerebral blood velocities.

Physical Description

Note: The pictures shown below are typical of the Model PMD150. Your System may have differences including branding (ST3 colors are shown).

FRONT PANEL

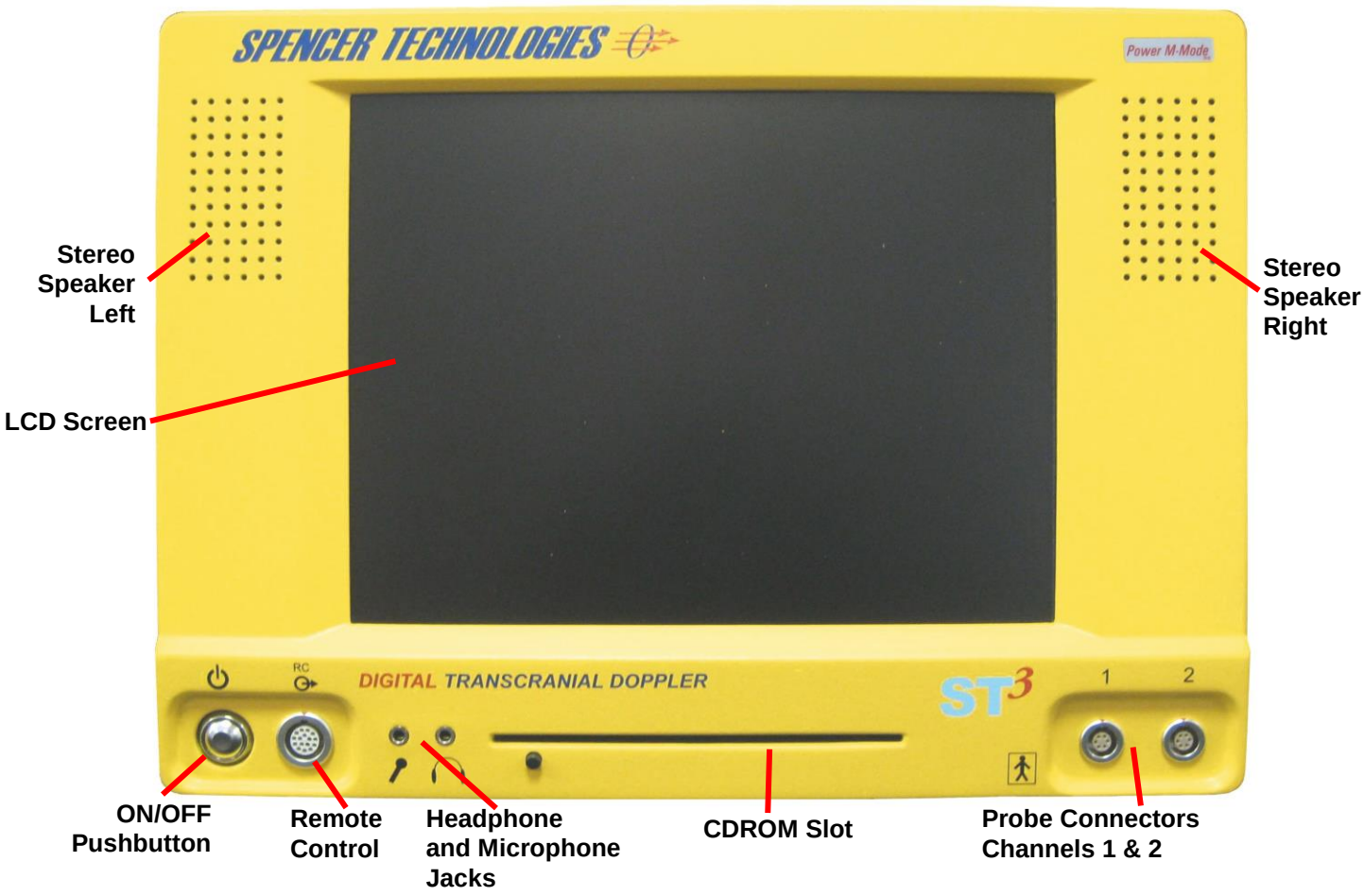


Figure 1 – Front Panel

The front panel includes the following:

- Probe connectors, channel 1 and 2.
- CD insertion slot and CD eject button.
- Headphone and microphone jacks.
- Remote Control (RC) connector.
- Power button.
- LCD screen.
- Stereo speaker grilles.
- Feet (2, bottom, not shown here).

Caution: Always elevate both feet to the same height. Inappropriate use of extended feet may result in damage to the system console.

REAR PANEL

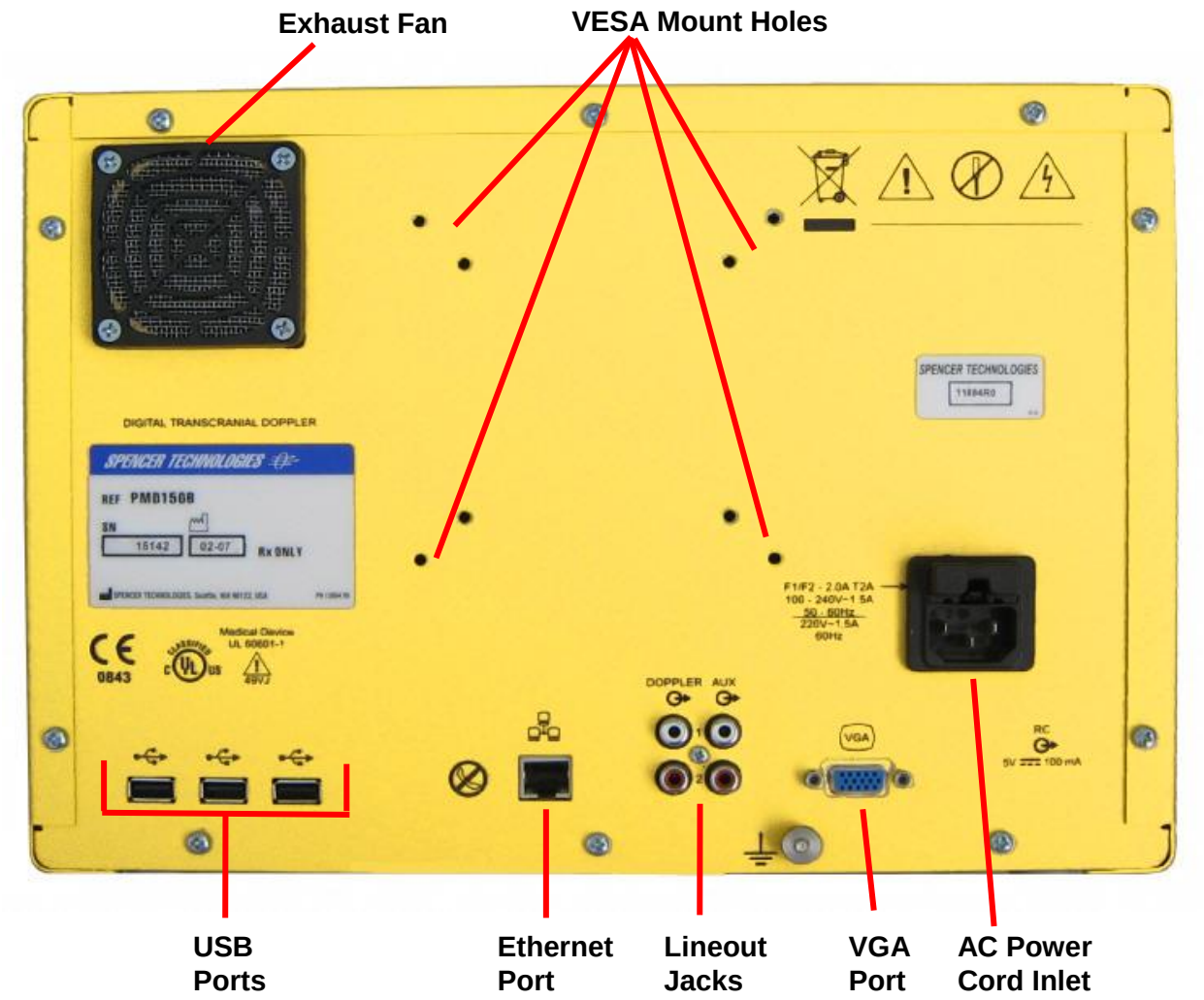


Figure 2 – Rear Panel

The rear panel includes the following:

- Three USB 2.0 ports.
- Ethernet port.
- "DOPPLER" lineout jacks for channel 1, 2.
- "AUX" line out jacks for channel 1, 2.
- VGA port for secondary display.
- AC power cord inlet.
- Fan exhaust port.
- VESA mounting holes, 75mm and 100mm spacing.

SIDE PANEL

The side panel includes two USB 2.0 ports. (Not shown here)

REMOTE CONTROL

Functions of the System are controlled by the Remote Control (Figure 3), and four categories are denoted by color coding:

- Doppler Controls — Light Blue (ST3 remote) or Yellow (PMD150 remote)
- Power M-Mode™ controls — Green
- Screen Controls — Blue
- Data Files and Setup — Yellow (ST3 remote) or no color (PMD150 remote)

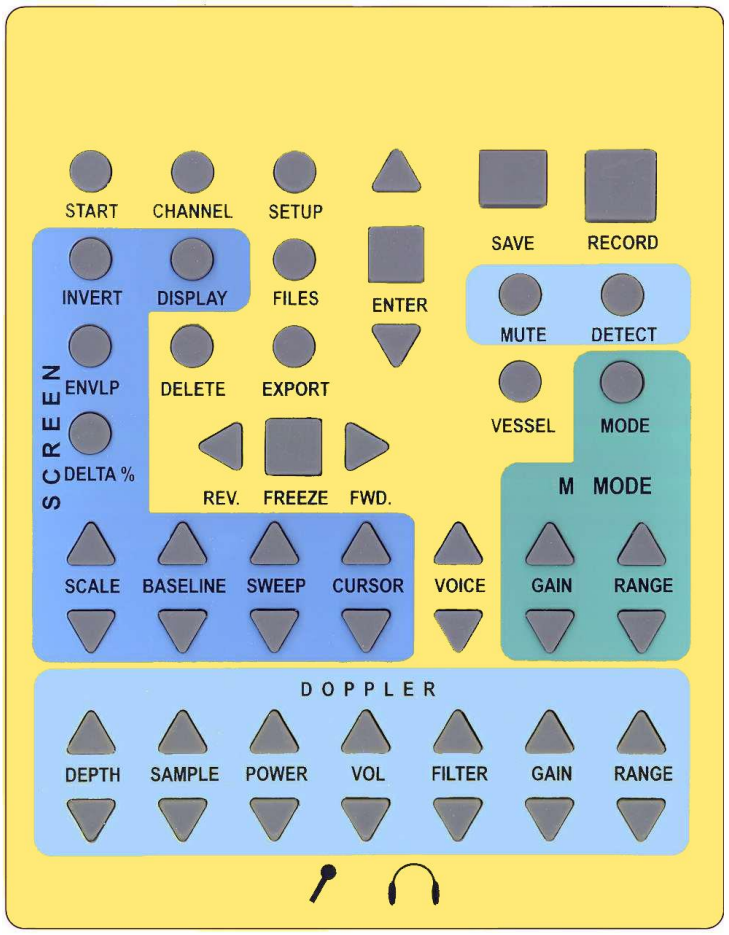


Figure 3 – Remote Control

Note: The remote control must be connected to the System at power-on in order to function.

The **ENTER** and arrow (▲ ▼ ◄ ►) buttons are widely used in operation of the System. Generally the ▲ (up) and ▼ (down) buttons are used to move up and down in a list, and the **ENTER** button confirms the selection action. On a Keyboard, the arrow keys and ENTER key can be used for these same functions.

Remote Control Buttons

Table 1 – Remote Control buttons

D O P P L E R	
⬍ **DEPTH**	Adjust the depth of the spectrogram and audio signal
⬍ **SAMPLE**	Adjust the sample length for signal acquisition
⬍ **POWER**	Adjust the acoustic output intensity
⬍ **VOL**	Adjust the Doppler audio volume
⬍ **FILTER**	Adjust the Doppler low-frequency filter cutoff
⬍ **GAIN**	Adjust the Doppler spectrogram display gain
⬍ **RANGE**	Adjust the Doppler spectrogram display range
MUTE	Set the audio mute on or off.
DETECT	Set the embolus event detection counter on or off.
M – M O D E	
⬍ **GAIN**	Adjust the M-Mode display gain
⬍ **RANGE**	Adjust the M-Mode display range
MODE	Set the display mode to emphasize M-Mode
S C R E E N	
INVERT	Invert the displayed spectrogram
DISPLAY	Select the channel display format
ENVLP	Set the envelope on or off
DELTA %	Set the reference for Delta % calculations
⬍ **SCALE**	Adjust the spectrogram velocity scale
⬍ **BASELINE**	Adjust the spectrogram zero-velocity baseline
⬍ **SWEEP**	Adjust the sweep period
⬍ **CURSOR**	Adjust the cursor positions on a frozen spectrogram
(OTHER)	
START	Access the exam start and patient information functions
SETUP	Access the setup functions
FILES	Access the files
▲ , ▼	Move up or down in a list
CHANNEL	Select the channel for adjustments
ENTER	Press ENTER to confirm a selection or action
◄ REV	Move reverse
► FWD	Move forward
FREEZE	Freeze the graph sweep
SAVE	Save the on-screen data to disk
RECORD	Record the new Doppler data to disk
DELETE	Delete the selected information
EXPORT	Export or import the selected information
⬍ **VOICE**	Adjust the voice audio volume during playback

KEYBOARD

A Keyboard can be attached to the System for entry of text information:

- Enter patient information.
- Edit the list of vessel labels.
- Edit Clinic Information shown on reports.
- Enter text to be printed on the report.
- Enter a note for each Save File, displayed when the Save File is reviewed.
- Text entry on reports or protocol customization.

MOUSE

The basics steps of a PMD exam can be performed with a mouse. When used with the System, the mouse can be hand-held. The simple rule for control is click to select, wheel to adjust. Click the left or right mouse button to select a parameter, and rotate the mouse wheel to adjust the selected parameter. The controllable parameters are listed below.

Table 2 - Mouse controls - standard wheel mouse

Control	***Function***
Left button	Select Parameter for adjustment
Right button	Select parameter for adjustment: DEPTH, M-GAIN, BASELINE, DOPPLER-GAIN, SCALE, INVERT, CURSORS (when frozen)
Left+ right button	Start new exam (if Start menu visible) FREEZE (if sweep active)
Right button - hold	To stop an exam and display the Start Menu, hold down the right button for 1 second. (software version 1.5.1+)
Wheel scroll ⬍	Adjust selected parameter
Wheel button	Press and release for SAVE, hold 1 second for RECORD

Chapter 3 – Quick Start

HARDWARE SETUP

1. Connect the power cord between the System console and standard AC power outlet.
2. Connect Remote Control.
3. Connect USB keyboard if desired for text entry.
4. Connect USB mouse if desired for control of an examination.
5. If connecting a USB storage device or printer, connect it before operating the System.
6. Plug six-pin transducer connector into the front panel. On bilateral systems either channel 1 or 2 may be used.

See Chapter 4 – System Setup on page 15 for details on this procedure.

SYSTEM STARTUP

1. To turn on the System
   - Press the power button ⏻.
2. To turn off the System
   - Press the power button momentarily.

If the System does not shut down normally:

- Press the power button and hold it down for 5 seconds.

START THE PATIENT EXAM

Patient Information Screen

After system startup, a Start Menu should appear on the display.

To begin an exam with patient information:

1. Press **START** to show the patient information / begin exam screen.
2. To create a new patient entry, select **New Patient**. To use a previous patient entry, select **Recall**.
3. To start a new exam, press **Begin.** A new exam can be started on a new patient or a recalled patient.
4. To continue any exam started within the previous 24 hours, select **Recall** followed by **Continue**.

Or, to very quickly begin an exam without entering patient information:

1. If using a remote control, Press **START** to open the patient info screen and then press **START** again to begin the exam.
2. If using a mouse, view the Start Menu, and simply click both the left and right mouse buttons to begin the exam.

PERFORM EXAM

1. Locate the desired cerebral vessel by aiming the probe. Adjust the **DEPTH** to obtain a signal in the Spectrogram.
2. Press the **VESSEL** button to label the displayed blood flow data.
3. To save the displayed blood flow data, press the **SAVE** button. A message will confirm that the data has been saved.
4. Repeat the steps for each vessel included in the exam.

CONCLUSION

Review the blood flow data and generate a report

1. After collecting all data, press **FILES** to open the Files List. Press **ENTER** to open the exam folder**.**
2. Press **RECORD** to exclude or include each saved image in the report.
3. Press ▸ to go from the Exam Files list to the report screen.
4. Select **Preview Report** to view the report. To change the report content, return to the Exam Files list.
5. Select **Save Report** to save a copy of the report (PDF file) to the Reports folder.
6. View and export or print the PDF report.

Chapter 4 – System Setup

HARDWARE SETUP

Warning: Inspect power cord for damage before use. Using a damaged power cord could result in electrical shock.

Warning: To avoid the risk of electrical shock, the equipment should only be connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.

1. Connect the power cord between the System and standard AC power outlet.
2. Connect Remote Control.
3. Connect USB keyboard if desired for text entry.
4. Connect USB mouse if desired for control of an examination.
5. If connecting a USB storage device or printer, connect it before operating the System.
6. Plug six-pin transducer connector into the front panel. On bilateral systems, either channel 1 or 2 may be used.
7. Press the monitor ⏻ ON/OFF pushbutton to turn the monitor on.

Warning: Inspect transducer housing and cable for damage before use. Using a damaged transducer assembly could result in electrical shock.

SYSTEM STARTUP

On/Off ⏻

Power on/off is controlled by a push button switch located on the front panel.

To turn on the System

- Press the **POWER** button.
  The monitor will display identification screens during boot-up. When boot-up is complete, a startup menu is displayed as shown in Figure 4.

To turn off the System

- Press the **POWER** button momentarily.
  After releasing the power button, it may take a few seconds for the System to shut down.

If the System does not shut down normally:

- Press the **POWER** button and hold it down for 5 seconds.
  The System should turn off.

To completely remove power from the System, after turning off the System unplug the AC power cord.

Note: Always use the front panel power button to power the System on or off.

Note: **If AC line power is disconnected while the system is on, the System typically recovers by automatic restart.**

Note: **If the System fails to start, press the power button and hold it down for 5 seconds to ensure power is switched off. Then momentarily press the power button to start the system normally.**

Note: **If at any time there is some difficulty preventing normal operation of the System, wait for the display to stabilize and turn power off. This action generally will clear the problem.**

START MENU

The Start Menu shown below in Figure 4, appears on the screen at power on. To return to the Start Menu during an exam or data review, press **START**.

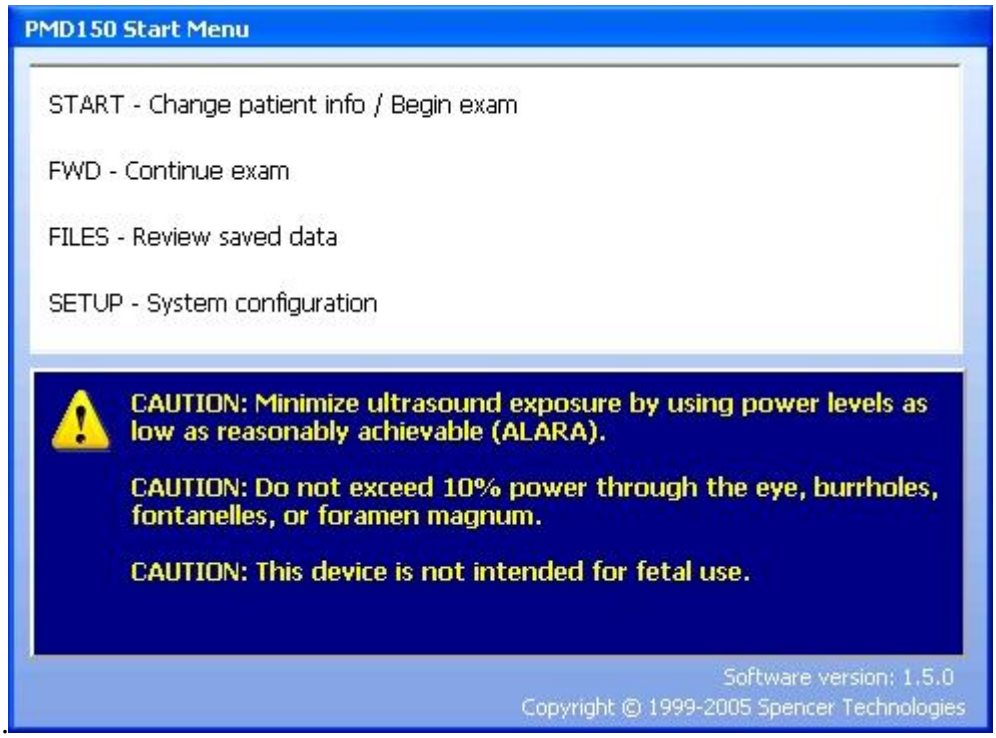


Figure 4 – Start Menu

When the Start Menu is active, pressing **START** opens the Patient Information screen so that patient information can be entered prior to starting an exam. See "Start the Exam" on page 27.

FILES

Patient data can be recorded to files for later review.

- Press the **FILES** button for access to the list of stored files.

See Files List on page 32 for additional instructions.

SETUP

The SETUP button accesses menus for viewing or adjustment of the system configuration settings:

- Default Doppler settings.
- Time/Date.
- Display and printing preferences.
- System Information, such as software version.

Using Digital Power M-Mode™ and Spectrogram Screens

There are two sections on the System standard screen display, which indicate Doppler information, digital Power M-Mode™ and Spectrogram screen as shown in Figure 5.

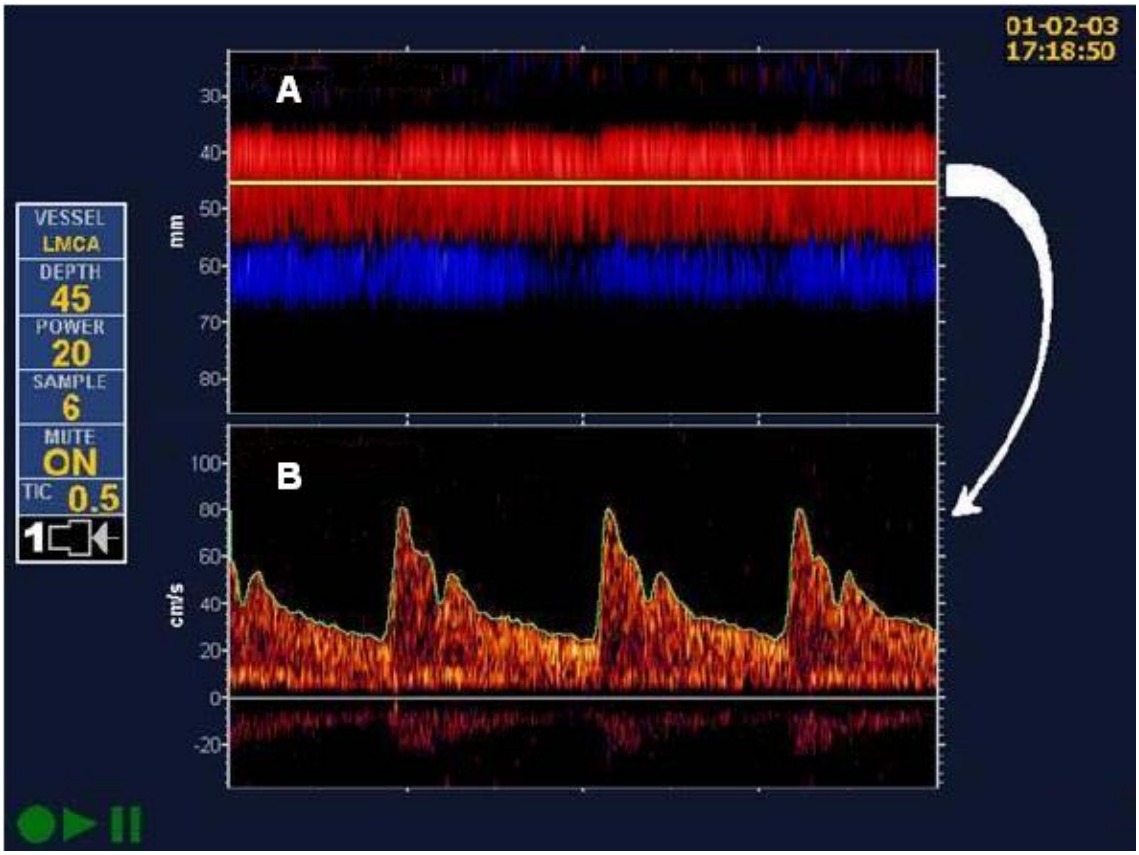


Figure 5 – Power M-Mode™ (A) and Spectrogram (B) screen layout

POWER M-MODE™ SCREEN

The Power M-Mode™ screen shows all blood flow within a depth range, as seen in the upper section of Figure 5. In the Power M-Mode™, blue represents blood flow away from the transducer, and red represents blood flow toward the transducer. Brighter color intensity corresponds to stronger signals. The blood flow signals, when located, make a horizontal streak across the M-Mode screen. In Figure 5, a depth of 45mm (LMCA) is selected as the basis for the velocity waveform seen in the Spectrogram screen. The selected sample depth is seen as a yellow bar in the Power M-Mode™ screen.

SPECTROGRAM SCREEN

The Spectrogram screen shows a Doppler spectral waveform that indicates the velocity profile of blood flow at the selected depth. The flow waveform shown in the spectrogram screen corresponds to the depth selected in the M-Mode screen. When the depth is adjusted, the spectrogram waveform changes to show flow at the new depth.

SCREEN DISPLAY FORMATS

There are two screen display formats: Standard and M-Mode

Standard Display Figure 6 shows M-Mode and Spectrogram screens of equal size. It displays the M-Mode screen at the top half of the display and the spectrogram at the lower half of the display. This mode is recommended for patient monitoring.

M-Mode Display Figure 7 emphasizes Power M-Mode™ data. The M-Mode screen is expanded, and the spectrogram screen is hidden. This display mode simplifies location of blood flow.

To switch Screen Display Mode:

- Press **MODE** to switch between Standard and M-Mode display formats. This change affects the display only, and not the format of recorded data.

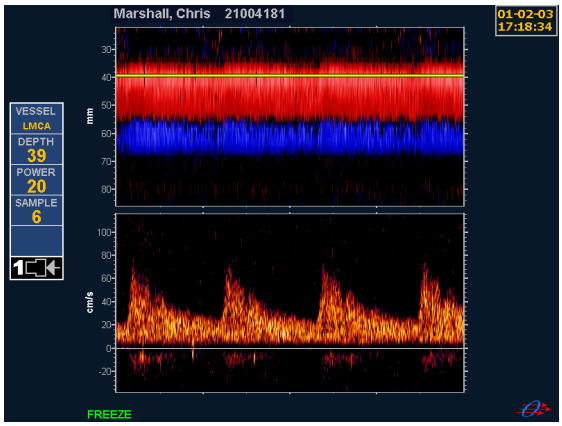


Figure 6 – Standard Display

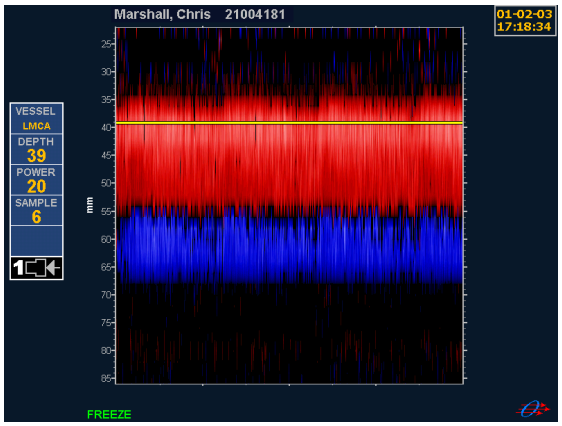


Figure 7 – M-Mode Display

COLOR SCALE AND DOPPLER GAIN ADJUSTMENTS

Adjust The Displayed Color Intensity Of The Signal Using The Gain ⬍⬎ Buttons.

DOPPLER GAIN ⬍⬎ adjusts the Doppler Spectrogram color scale. **M-MODE GAIN** ⬍⬎ adjusts the M-Mode color scale. The adjustments can be performed on either dynamic or frozen signals.

If background speckle is excessive, press **GAIN ▼** until the speckle is barely visible.

If the background is completely black, press **GAIN ▲** until the signal is clear or the speckle is barely visible.

The **GAIN** adjustment affects the display only, not the ultrasound power or receiver gain.

The signal colors are displayed on a dB (logarithmic) power scale. The **GAIN (NOISE)** and **RANGE** adjustments are in steps of dB. Higher signal intensity is indicated by lighter colors.

The **GAIN (NOISE)** adjustment sets the threshold (minimum level) for signals to appear on the display.

The **RANGE** adjustment sets the range of signal strength represented by the display color scale. Range adjustment is rarely necessary. Optimize the display signals by first adjusting **GAIN** and then adjusting **RANGE** if needed.

Figure 8 – Doppler Spectrogram Color Scale

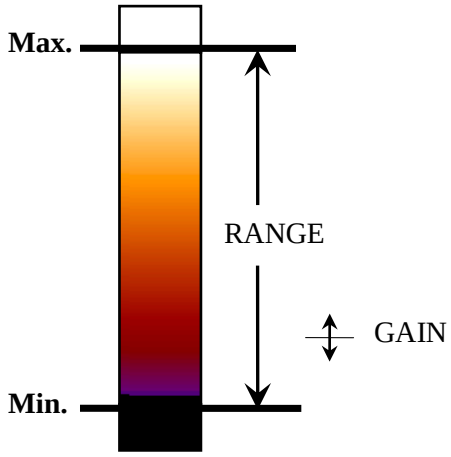
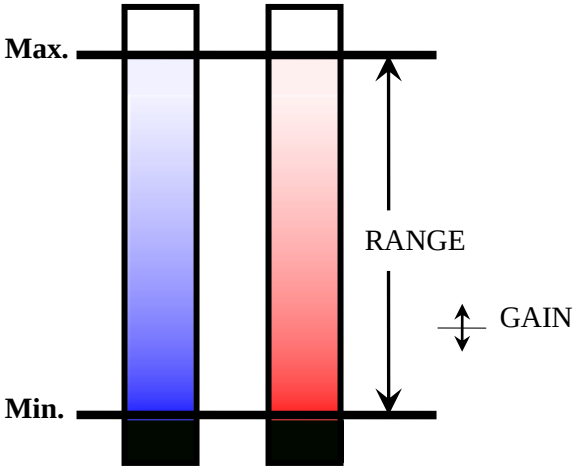


Figure 9 – Power M-Mode™ Color Scale



KEY:		
	Max.	Maximum intensity of color scale
	Min.	Minimum intensity, no color
	RANGE	Range (dB)
	GAIN	Adjustable offset (dB) of displayed color scale

Using the Remote Control

CHANNEL

The CHANNEL button is used to select between Channel 1 and Channel 2 for remote control adjustments. Each channel is associated with a transducer. This control will only function when two transducers are connected, or when playing a two-channel recording.

To switch channels:

- Press **CHANNEL**.
- The boxes at left of display are highlighted for the selected channel.
- Other buttons now can make adjustments for the selected channel.

EXPORT

The **EXPORT** button will copy selected exam folders to internal or external disks or drives.

DELETE

The DELETE button removes selected files from the internal disk. Files can be deleted at the Patient folder, Exam Folder, or Exam Files level.

FREEZE

The **FREEZE** button stops the display sweep. When the sweep is frozen, Doppler transmit power is turned off. For that reason, FREEZE is disallowed while recording new exam data.

While the screen is frozen, a screen image can be saved or printed. See “Screen Image Capture” on page 32.

To review up to 20 seconds of recent data during an exam, press **FREEZE** and ◂ and ▸ to move through recent data.

ENTER

The **ENTER** ⬍ button confirms a selection action activated by other keys.

SAVE

The **SAVE** button is used to capture one screen sweep of blood flow signals. The data captured is backward in time from when **SAVE** is pressed; essentially, it is the same data seen on the screen when **SAVE** is pressed.

RECORD

The **RECORD** button is used to start and stop continuous recording of the blood flow signals for all active channels, and the voice annotation.

VESSEL

A vessel label can be selected for each Doppler channel. The vessel label can be selected while acquiring data or when reviewing static S-files.

To advance the vessel label

1. Press **VESSEL**. The next vessel label in the list will be applied.

To select a vessel label from the list

1. Press and hold **VESSEL**. A list of vessel labels is presented.
2. Scroll to a label in the list using ▲/▼.
3. Press **ENTER** to select the highlighted label, or press **VESSEL** to exit without selecting a new label.

The list of vessel labels can be customized using **SETUP**.

STATUS ICONS

A group of icons are displayed in the bottom left of the screen.

	**RECORD**	Highlighted when **RECORD** is active.
	**PLAY**	Highlighted when previously recorded data is replayed; indicates direction of playback, also indicates end-of-file states.
	**FREEZE**	Highlighted when sweep is paused.
	**MIC**	Appears when microphone activity is detected*
		**Not provided in all configurations of the product*.

Screen Controls

INVERT

Use the **INVERT** button to vertically flip the spectrogram display. This function is normally utilized to provide better viewing of blood flowing away from the probe.

When inverted, the selected spectrogram display flips vertically. The vertical axes are appropriately relabeled. For example: a –1 to +3 kHz setting inverts to +1 to –3kHz.

DISPLAY

The **DISPLAY** button is active when two transducers are plugged into the System or when reviewing data recorded with two transducers. The **DISPLAY** button is used to select among types of display: Channel 1 and Channel 2, Channel 1, or Channel 2.

The displayed number of channels determines the configuration of audio channels.

AUDIO CHANNELS

Table 4 – The audio output convention

Displayed Channel	*Audio Channel*
Ch1 + Ch2	Ch1 mono left, Ch2 mono right
Ch1	Ch1 stereo
Ch2	Ch2 stereo

When only one channel is displayed, the controls are active for that channel, and the audio output is the stereo separated signal for that channel. When Channels 1 and 2 are displayed at the same time, the audio outputs are monaural; sound reproduction using a single channel to carry and reproduce sound from each channel. The audio can be heard on the internal speakers or through headphones. Audio line outputs are also provided from two jacks, labeled DOPPLER, on the rear panel.

ENVELOPE CONTROL

The **ENVLP** control is used to activate an envelope trace on the spectrogram display. The envelope tracks the maximum blood flow velocity in the spectrogram. When the envelope is activated, five additional parameters are displayed on the right hand side of the display:

- **PEAK** velocity (average peak systolic velocity) in centimeters per second (cm/s)
- **MEAN** velocity (average velocity) in cm/s
- **DIAS** velocity (average velocity at end of diastole) in cm/s
- **P.I.** – Pulsatility Index = (Peak-Dias)/Mean
- **Δ%** – Delta % (see explanation on page 23)

All of the above displayed values reflect averages over the most recent four seconds of spectrogram data.

Press the **ENVLP** button to select the top or bottom envelope. See “Velocity Accuracy” on page 52 for display of envelope parameters.

DELTA PERCENT (Δ%)

The Delta % value is a relative measure of Mean velocity.

- Delta % = 100 x (Current Mean / Reference Mean).
- The reference Mean value is established when the user presses the **DELTA**% button.

To establish a reference for the Δ% calculation:

- Confirm that the envelope trace is active. (see **ENVLP**)
- Press **DELTA**%.

The value in the Δ% box at the right of the display shows 100% and will track changes in the mean velocity. For example: if Mean = 80 cm/s when the user presses the **DELTA**% button the displayed value starts at 100%, and if the Mean falls to 60 cm/s the displayed value becomes 75%. This button can be pushed as often as a new reference is desired.

SCALE

The SCALE ⬍ buttons adjust the spectrogram velocity scale. The scale is displayed on the vertical axis along the left edge of the spectrogram.

The maximum velocity scale depends on the PRF (Pulse Repetition Frequency), which can vary depending on the selected depth. For a given PRF at 8000 Hz or less, the velocity scale can be set to full, half, or quarter PRF. (See "PRF" on page 24.) With a single active probe, at depth settings of 70mm or less, a high PRF is available for high velocity measurements. Scales from 48 cm/s up to 480 cm/s are possible, depending on the current PRF.

Table 5 – Scale adjustment ranges

M-Mode display range	*PRF*	*Scale*	*Spectrogram range*
22mm to 87mm	8000 Hz	Full	308 cm/s
		Half	154 cm/s
		Quarter	77 cm/s
52mm to 117mm	6250 Hz	Full	240 cm/s
		Half	120 cm/s
		Quarter	60 cm/s
82mm to 147mm	5000 Hz	Full	192 cm/s
		Half	96 cm/s
		Quarter	48 cm/s
22mm to 55mm	12500 Hz*	Full	480 cm/s*
22mm to 73mm	10000 Hz*	Full	385 cm/s*

** Not provided in all configurations of the product.*

BASELINE

The **BASELINE** ⬍ buttons adjust the position of the spectrogram zero-velocity line.

SWEEP

The **SWEEP** ⬍ buttons are used to adjust the sweep period of the data in the M-Mode and spectrogram screens. The sweep periods available are 4 seconds, 8 seconds, and 16 seconds.

CURSOR

The **CURSOR** ⬍ buttons are used to make velocity measurements in a frozen image of the Doppler spectrogram. One cursor line is positioned at peak velocity and the second at diastolic velocity. The derived PEAK, MEAN, DIAS and P.I. values are displayed at the right side of the display.

To measure velocity using the cursors:

1. Press **CHANNEL** to select a channel for cursor measurements.
2. Press **FREEZE** to obtain a still image of the desired spectrogram.
3. Press **CURSOR ▲** or **CURSOR ▼** to begin cursor adjustment.
4. Use **ENTER /▲/▼** to position one cursor at PEAK and the second cursor at DIAS. Press **ENTER** to toggle between the upper and lower cursor.

Note: Mean = Dias + 0.4* [Peak-Dias] when cursors are in use.

Doppler Controls

DEPTH

The **DEPTH** ⬍ buttons are used to set the depth (distance from transducer) of the Doppler sample volume. The depth in millimeters is displayed for each active channel on the left side of the display. The depth adjustment range is 23mm to 145mm. The selected depth is shown as a yellow line within the M-Mode display. A blood flow velocity waveform for the selected depth is displayed in the spectrogram portion of the display.

To adjust the depth of the Doppler signal:

- Press **DEPTH ▲** to decrease the **DEPTH** value (decreases distance from the transducer).
- Press **DEPTH ▼** to increase the **DEPTH** value (increases distance from transducer).
- The **DEPTH** ⬍ arrows point in the direction of movement of the depth line in the M-Mode screen.

PRF

The pulsed Doppler PRF (Pulse Repetition Frequency) is controlled indirectly by the Doppler depth setting, and affects the displayed depth range, as shown in the table below. When two channels are active, the channel with a deeper depth selection determines the PRF setting for both channels.

Table 6 – Doppler PRF depth range settings

Selected depth	*Normal PRF*	*High PRF**	*M-Mode display range*	*Spectrogram velocity range (baseline at bottom)*
23mm to 85mm	8000 Hz	-	22mm to 87mm	308 cm/s
53mm to 115mm	6250 Hz	-	52mm to 117mm	240 cm/s
83mm to 145mm	5000 Hz	-	82mm to 147mm	192 cm/s
23mm to 54mm	-	12500 Hz*	22mm to 55mm	480 cm/s*
60mm to 70mm	-	10000 Hz*	22mm to 73mm	385 cm/s*

** Not provided in all configurations of the product.*

When using a high PRF (greater than 8000 Hz), the filter values are increased to optimize the high velocity signals. At any PRF, when the **FILTER** setting is 500Hz or higher the high-frequency audio is unattenuated.

SAMPLE

The **SAMPLE** ⬍ buttons adjust the Doppler sample length, which determines the sample volume. Sample length is adjustable from 3 mm to 9 mm, in 3 mm steps. Larger sample volumes include a larger region of depth (surrounding the selected depth) over which the M-Mode and spectrogram measurements are made. Smaller sample volumes improve the M-Mode depth resolution. At a larger sample volume setting a larger region of flow is presented in the spectrogram. The sample volume setting does not affect the total acoustic output power. The sample setting is shown in a box at the left of the display.

POWER

The POWER ⬍ buttons are used to adjust the transmit power level for the selected channel.

The power setting is shown in the box labeled POWER at the left of the channel display.

Cranial bone thermal index is displayed in a box below the power setting display.

Adjustments are made in steps of percentage of available power. Power can be increased when Doppler signals are deemed too weak, and decreased when signals are satisfactory at lower power levels.

Caution: Ultrasound power should always be adjusted using the ALARA principle (As Low As Reasonably Achievable).

Caution: Do not exceed 10% power through the eye, foramen magnum, burrholes, or fontanelles.

To adjust the power:

- Press **POWER ▲** to increase the transmit power.
- Press **POWER ▼** to decrease the transmit power.

Adjustment of **GAIN** may be appropriate after adjusting power.

While transmit power is on, a Cranium Thermal Index (TIC) is displayed in a box below the power setting display. The TIC value is proportional to the selected power setting, and indicates the probe's bone heating effect for the selected power setting. The TIC value is further explained in Appendix A, "Technical Information and Specifications" on page 47.

VOLUME (DOPPLER AUDIO)

The **VOL** ⬍ buttons are used to adjust the volume level of the Doppler audio signal output from the speakers or headphones. When pressing the **VOL** buttons, the value of the Doppler volume (in dB) is shown in the box labeled VOLUME at the left of the display.

FILTER

The **FILTER** ⬍ buttons are used to adjust the level of frequency noise rejection for the selected channel. When pressing either **FILTER** ⬍ button, the filter value in Hz is shown in a box at the left of the selected display. The filter removes low frequency noise below the selected frequency. Low-frequency noise is low-velocity noise. The filter removes low-velocity signals such as tissue motion.

GAIN

DOPPLER GAIN ⬍ adjusts the Doppler Spectrogram color scale. The GAIN adjustment sets the threshold (minimum level) for signals to appear on the display. Optimize the display signals first by adjusting the **GAIN** followed by the use of the **RANGE** if needed.

RANGE

DOPPLER RANGE ⬍ adjusts the Doppler Spectrogram color scale. The RANGE adjustment sets the range of signal strength represented by the display color scale. The RANGE adjustment is used to optimize the GAIN adjustment if needed.

MUTE

The **MUTE** button is used to deactivate audio output to the speakers and the headphones.

Note: Plugging in the headphones will also turn off audio output to the speakers.

DETECT

The **DETECT** button controls Automatic embolus detection independently for each channel.

M-Mode Controls

MODE

The **MODE** button toggles between the Standard display and the M-Mode display.

M-MODE GAIN

The **GAIN** ⬍ button is used to adjust the appearance of the spectrogram or M-Mode signals. The GAIN adjustment sets the threshold (minimum level) for signals to appear on the display.

M-MODE RANGE

The **RANGE** ⬍ button is used along with the **GAIN** button to adjust the appearance of the spectrogram or M-Mode signals. The RANGE adjustment sets the range of signal strength represented by the display color scale.

Chapter 6 – Diagnostics and Monitoring a Patient

PERFORMING A NEUROVASCULAR DIAGNOSTIC EXAM

Start the Exam

1. Press **START** to enter the Patient Info screen.
    - If patient was previously examined, select Recall Patient, and select the previous patient.
    - If patient is new, select New Patient and press **ENTER**.
    - Type in the patient information.
2. Press **ENTER** when finished entering patient information.
3. Select Begin Exam to leave the Patient Info screen and begin the new exam.

Locate the blood vessel

4. Position the transducer to see flow in the M-Mode window.
5. Adjust **DEPTH** ⬍ into the desired flow color band.

For more detailed information, refer to "Using Power M-Mode™ and Spectrogram Screens" on page 18.

Label the vessel

6. Press **VESSEL** button to select the desired vessel label.

See "Vessel Label" on page 30 for more detailed instructions about selecting vessel labels.

Save the blood flow data

7. When you see a flow tracing that you want to save, press **SAVE**. Save at least one tracing per vessel.
8. Repeat Locate - Label - Save (steps 4 to 7) for each vessel to be included in the exam.
    - For one-hand mouse control of these steps, see "Mouse Controls" on page 11.

Review the blood flow data and select for report

9. After collecting all data, press **FILES** to open the Files List.
    - Use arrow keys to open the exam folder (under the current patient folder) and browse through images of the Exam Files.
10. If necessary, adjust the images and press **SAVE** to store changes.
11. Press **RECORD** to exclude or include the image in the report.

See "Data Storage" on page 31 for more detailed instructions.

Generate a report

12. Press ▸ to go from the Exam Files list to the report screen.
13. Preview the report by selecting Report Preview from the menu in the report screen.
    - To change the report content, return to the Exam Files list.

14. Select Save Report to save a copy of the report (PDF file) to the Reports folder.
    - From the Reports folder you can view the PDF report and export or print the report.

See "Generating a Report" on page 36 for more detailed instructions.

PERFORMING A MONITORING EXAM

Start the Exam

1. Press **START** to enter the Patient Info screen, select New Patient and press **ENTER**.
    - Type in the patient and exam information.
2. Select Begin New Exam to leave the Patient Info screen and begin the new exam.

Locate the blood vessel

3. Position the transducer to see flow in the M-Mode window.
4. Adjust **DEPTH** ⬍ into the desired flow color band.

For more detailed information, refer to "Using Power M-Mode™ and Spectrogram Screens" on page 18.

Label the vessel

5. Press **VESSEL** button to select the desired vessel label. If monitoring two channels, press **CHANNEL** to select each channel for labeling. The active channel will be highlighted

See "Vessel Label" on page 31 for more detailed instructions about selecting vessel labels.

Save the blood flow data

6. Press **SAVE** to save a displayed blood flow image, or press **RECORD** to start / stop continuous recording of all data.
    - The green status indicator is highlighted during recording.
    - Any saved or recorded data can be played back after the exam.

Note: Remember that recorded data will eventually fill up the internal disk. To monitor what percentage of the internal disk is full, see the first level of the FILES list.

Review the blood flow data

7. After collecting all data, press **FILES** to open the Files List.
    - Use arrow keys to open the exam folder (under the current patient folder) and browse through images of the exam files.
    - Press **ENTER** to begin playback of an exam file.
8. A report can be generated in the same manner described above in the Diagnostic Exam procedure.

See page 36 for more instructions about generating a report.

USING DIGITAL POWER M-MODE™

For identification of Spectrogram and M-Mode screens see Figure 5 on page 18.

M-Mode

To locate desired cerebral vessel:

1. Begin exam, if an exam is not already started. (See "Performing a Neurovascular Diagnostic Exam" on page 27.)
2. Place an adequate layer of ultrasound gel on the transducer face. Manipulate the transducer position and direction within the temporal area on the patient, until signals appear in the M-Mode window. Red indicates flow toward the transducer and a blue indicates flow away from the transducer.
3. Use **POWER** ⬍ to adjust signal strength. Use **GAIN** ⬍ to adjust brightness. (See "Doppler Controls" on page 24.)
4. While maintaining the blood flow signal, adjust **DEPTH** ⬍ until the Doppler depth indicator (yellow line) is centered on the blood flow signal of interest. As the depth is adjusted into a blood flow region seen in the Power M-Mode™ window, the corresponding blood flow velocity waveform will appear in the Spectrogram window.

USING EMBOLUS DETECTION*

** Not provided in all configurations of the product.*

When automatic detection is enabled, the count of emboli detected is displayed at the right side of the display (see Figure 10 below). Detection is controlled independently for each channel. The System will separate embolic events from artifact or noise signals and will also count the emboli at all depths between 30mm and 81mm. Each automatic embolus detection event is marked in the spectrogram by an "A" marker.

The System can be configured to automatically save a screen-width Save-file for each detected event. This auto-save feature can be turned on or off in the SETUP menu.

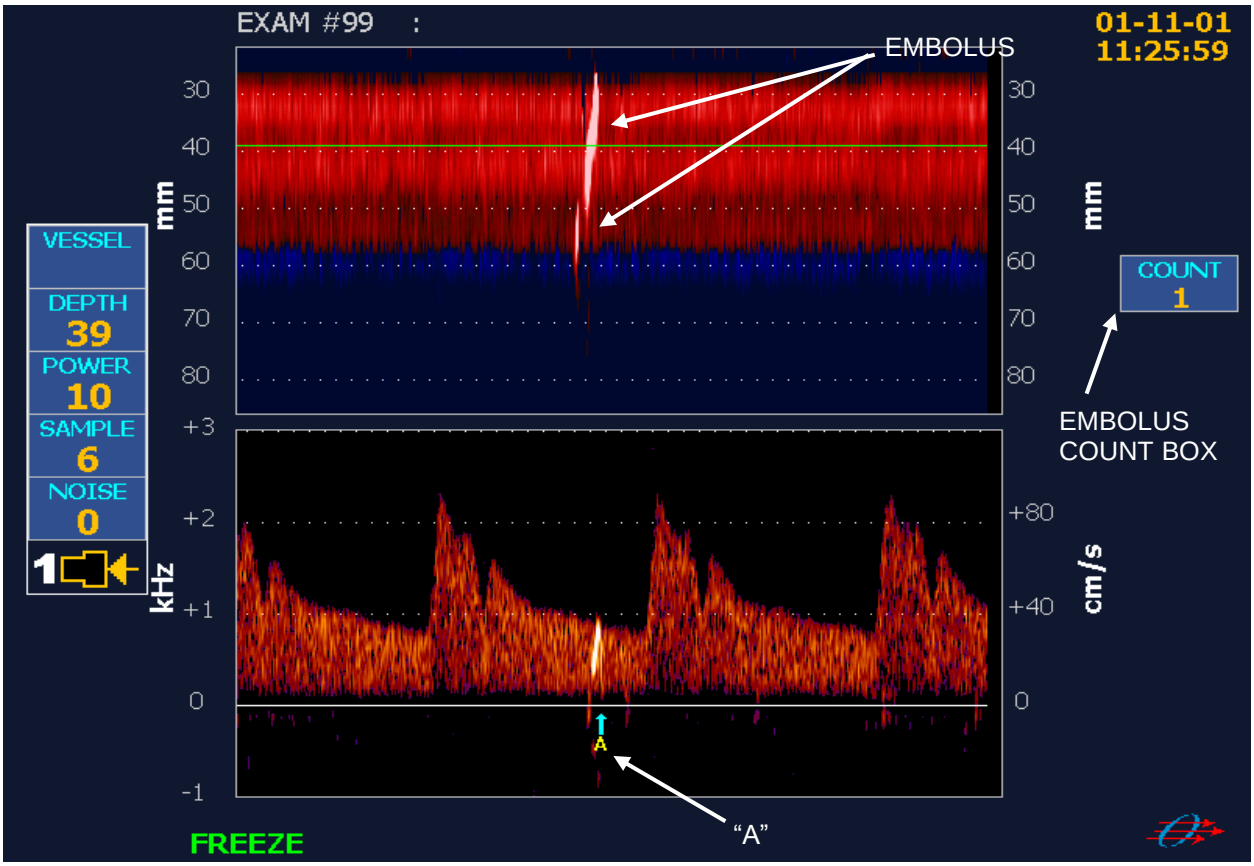


Figure 10 – Embolus Detection Display

To activate embolus detection

1. Select the channel. Press **DETECT**.
   A count box will be updated every time a microembolic signal is detected. The count box will only appear if both channels are showing a 22-87 mm depth range in the M-Mode screen. If the box does not appear, reduce the depth in each channel into the 22-87 mm depth range, and then activate detection.
2. Press **DETECT** again to turn off embolus detection.

Note: In software versions 1.5.0 and earlier, the System has been observed to falsely indicate emboli during systolic flow in cases where the end diastolic flow is weak or of very low velocity. Where this has been observed, it occurs in a small percentage of patient cases.

Chapter 7 – Data and File Management

Data Storage

Two functions are provided for storing Doppler data: SAVE and RECORD.

SAVE

Press the **SAVE** button to capture the currently displayed screen width of blood flow data into a "Save File". An entry is added to the exam files list for each Save File.

The manual SAVE event is marked in the spectrogram by an arrow and 'M' marker.

If **SAVE** is pressed several times during one sweep period, no more than two overlapping Save Files are created per screen period.

The screen sweep period is selectable as 4, 8, or 16 seconds using the **SWEEP** ⬍ buttons. Save Files generated by auto-detection (enabled with **DETECT** button) are the same length as segments generated with the **SAVE** button.

RECORD

The **RECORD** button is used to start and stop continuous recording of the blood flow signals for all active channels, and the voice annotation. When recording is active, an indicator (●) is highlighted on the display.

Note: During long-term recording, the system automatically segments the data file at 10-minute intervals. Each segment will be shown as "REC" entry in the Exam Files listing.

Note: The System holds a limited amount of data internally. The System will notify the user when less than 60 minutes of recording time remains. When there is no time remaining, the System will stop storing new data.

VESSEL LABEL

A vessel label can be assigned to each Doppler channel while acquiring data or when reviewing static Save Files.

To advance the vessel label:

- Press **VESSEL** button. The next vessel label in the list will be applied.

To select a vessel label from the list:

1. Press and hold VESSEL button. A list of vessel labels is presented.
2. Scroll to a label in the list using ▲/▼.
3. Press ENTER to select the highlighted label, or press VESSEL to exit without selecting a new label.

The list of vessel labels can be customized in the system Setup Menu under Doppler Defaults.

SCREEN IMAGE CAPTURE

To capture a screen image:

- If the Files list is visible, press the **FILES** button to hide it.
- If the screen is not frozen, first press **FREEZE**.
- Press **EXPORT** to capture the frozen screen image and export to "**INTERNAL**".

Captured screen images appear in a Screens folder within the Exam Folder. From there, an image can be exported or printed. The exported screen image files can be viewed on any personal computer. If a printer is attached, the screen image can also be printed. Print options and the size and format of the exported image can be selected from the Setup menu in the Display and Printing Preferences. A screen image is different than a "Save File"; a Save File can be dynamically replayed on the System.

Note: Images must be in JPEG format for DICOM export.

Files List

FILES ORGANIZATION

The Files list has four levels:

1. A **Patient folder** appears for each patient that is entered in the system.
2. **Exam folders** appear within patient folders. The exam folder is labeled with the date and time that the exam started.
3. **Exam Files** appear within each exam folder. The files contain data that was recorded during that exam. Subfolders may contain Reports, Screen images, and Trend data.
4. Reports can be accessed from the Exam Files level. See Figure 11, Files List Levels, below.

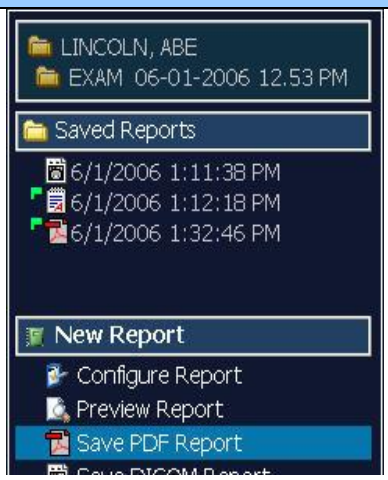
Patient Folders *Exam Folders*	*Exam Files*	*Reports*
		

Figure 11 – Files List Levels

FILES FOLDER NAVIGATION

Press the **FILES** button to enter or leave the files list.

1. Use the **ENTER** and up/down navigation buttons to move up and down the folder list. A blue highlighted box will identify your location.
2. Use the left/right navigation buttons to move between folder levels.
3. To select the drive (hard drive, CD/DVD or external drive), move to the top of the patient folder list and continue up using the up navigation button. Then select the drive using the left/right navigation buttons.

Note: Slow response may be observed when the user performs the following:

-Starts a new exam when there are many patient folders.
-Continues an exam that has many Save Files within it.
-Opens or modifies an exam folder that has many Save Files within it.

Note: There is a limit of 2000 files per exam folder.

FILES FOLDER PRESENTATION

To change the sort sequence of the patient folder list, use the navigation arrow buttons to move the blue highlighted box to the "Sort by" section. Use left/right navigation buttons to select Name, Time or Size of patient folder.

Folders that contain new or modified files are marked with a green flag until those files have been archived to CD/DVD or external storage.

EXAM FOLDER PRESENTATION

In the Exam Files list, each Save File includes a vessel label for each channel. If no vessel label has been selected then the sample depth is displayed.

When playing back a selected Save File, the Files list narrows to allow partial viewing of the recorded data. To re-expand the Save File list, use the up/down navigation arrows to move within the exam folder.

To view a full screen Save File recording, press the **FILES** button and the Files listing will be removed from the display. To view the Save File list, press the **FILES** button and the listing will be displayed.

EMBOLUS DETECTION COUNT

Press **DETECT** while viewing the files to show or hide the detected event count found in the files. When automatic detected events are shown, they appear in the Exam Files list under column "A1" for channel 1 and "A2" for channel 2.

A '*' symbol in the A1 or A2 column represents 1 or more detected events within the corresponding segment. The total number of events within a recording is shown next to entry at the end of the REC file.

INCLUDING AND EXCLUDING DATA IN A REPORT

In the Exam Save Files list, an icon 🗎 indicates when a Save File is selected for inclusion in the report. To include or exclude a Save File in the report, highlight the Save File item and then press **RECORD** to toggle the report inclusion state. Up to 100 items can be included, however a report with many items will be slower to generate and print. Press ▸ to enter the Reports screen.

VIEWING AND ADJUSTMENT OF SAVE SEGMENTS

- To view a Save File image simply browse to it in the Exam Files list.
- Some of the settings of the static image are adjustable. See Table 7 – Adjustments to "Save Files" on page 35.
- After making adjustments to a Save File image, it can be resaved by pressing **SAVE**. The data that appears on the screen will appear in the report

Note: During two-channel operation, if only one channel is viewed on the display when SAVE is pressed, then only that one channel appears later when the Save File is browsed as a static image.

DYNAMIC PLAYBACK OF SAVE AND RECORD FILES

Initiating Dynamic Playback

1. To play back a segment, move to the item in the Exam Save Files list and press **ENTER**.
2. Playback can be restarted by pressing **ENTER** again.
3. Press **FILES** to show or hide the Exam Save Files list.

Freeze/Playback of exam data

1. Press **FREEZE** to pause playback of data.
2. Press ◂ and ▸ to move through the data.
3. To fast-forward, hold down the ▸ button.
4. To fast-reverse, hold down the ◂ button.

Note: Files must be played forward at normal speed for accurate viewing of data. After reverse playback, perform forward playback for at least one screen-width before interpreting or resaving the data.

VOICE VOLUME

The **VOICE** ▲▼ buttons are used to adjust the playback volume level of voice annotations in recorded files. This control is active only during playback of previously recorded data. As the voice volume is increased, the relative Doppler audio volume is decreased.

ADJUSTMENTS TO PREVIOUSLY SAVED IMAGES

Most adjustments that can be made during image acquisition can also be made during later review of the Save File or Recording. A Save File can be resaved after the adjustment.

The adjustment and resave capability is outlined below.

Note: "Static Adjust" means that the adjustment is made on the Save File during a static preview. The SAVE button must be pressed after the adjustment is made to capture the changes.

Note: "Dynamic adjust" means that the adjustment is made while the Save File is being played back dynamically. The adjusted image can be resaved after playback.

Table 7 – Adjustments to "Save Files"

Parameter	*Adjustable*	*Static Adjust And Save*	*Dynamic Adjust And Save*
VESSEL	Yes	Yes	No
GAIN	Yes	Yes	Yes
RANGE	Yes	Yes	Yes
ENVELOPE ON/OFF	Yes	Yes	Yes
CURSORS	Yes	Yes	No
INVERT	Yes	No	Yes
BASELINE	Yes	No	Yes
SCALE	Yes	No	Yes
SWEEP	Yes	No	No
FILTER	Yes	No	Yes
POWER	No	No	No
DEPTH	No	No	No
SAMPLE	No	No	No

*After Dynamic Adjustment, the SAVE segment should be replayed in its entirety before pressing the **SAVE** button to store the adjusted image.

Annotating saved images

To annotate (enter brief notes about) an image during acquisition or during post-exam review of a Save File:

- When viewing a frozen image, press the space bar on the USB keyboard to show a single-line text entry box.
- Type in a short note and press **ENTER**.
- If the image was not previously stored, press **SAVE** to store it.

Note: Whenever you view the image, the associated note is briefly displayed with it.

Generating a Report

Types of reports*:

- **Neurovascular diagnostic report** – designed for general neurovascular exams. See Fig 12, page 37.
- **Velocity Trend report** – designed for daily trending of velocities in selected vessels, such as for vasospasm evaluation. See Figure 13 on page 38.
- **RLS / PFO report** – designed specifically for RLS / PFO diagnostic exams. See Figure 14, page 39.

To choose the type of report, open the report screen and select 'Configure Report'.

** Not provided in all configurations of the product.*

THE REPORT SCREEN

The report screen displays a menu allowing the user to configure, preview, compose or save an exam report.

To open the report screen:

1. Press **FILES** to open the Files List.
2. Navigate to the desired exam folder. Open the exam folder.
3. Press ▸ to go from the Exam Files list to the report screen.

See "Files List" on page 32 for additional instructions.

Note: Always review entire report contents before saving or publishing a report.

PREVIEW, SAVE, AND EXPORT REPORTS

The report can be previewed on the screen of the System. This is a convenient way to see the data included in the report so adjustments can be made before printing or exporting the report. The report can be saved and exported as a PDF file.

1. Preview an exam report by selecting Report Preview from the menu in the report screen.
2. Select Save Report to save a copy of the report to the Reports folder.
3. From the Reports folder you can export or print the report.

See "Files List" on page 32 for additional instructions.

CLINIC INFORMATION

The clinic information printed on reports can be edited with a USB keyboard from the Report Heading option of the exam Reports menu. After editing this information, preview or print a report to make sure that the new information fits within the printable area of the report heading.

ENTERING REPORT COMMENTS

Text comments can be entered in a Neurovascular Diagnostic report using a keyboard.

1. In the report screen, select Report Preview.
2. When the preview of the report is displayed, press the spacebar on your keyboard (a text box will pop up), enter your comments, and save the text.
    - The saved comments will appear at the bottom of the report.
    - Separate comments may be added to the summary and graphical sections of the report.

NEUROVASCULAR DIAGNOSTIC REPORT

The report can be customized with these options:

- Include graphical images in the report, or show only the flow velocity summary.
- Show a black or white background on included graphical images.
- Include or exclude a vasospasm index.

If included, the vasospasm index will be calculated from the (L or R) ICA-EC and (L or R) MCA images with the highest mean velocities on the report.

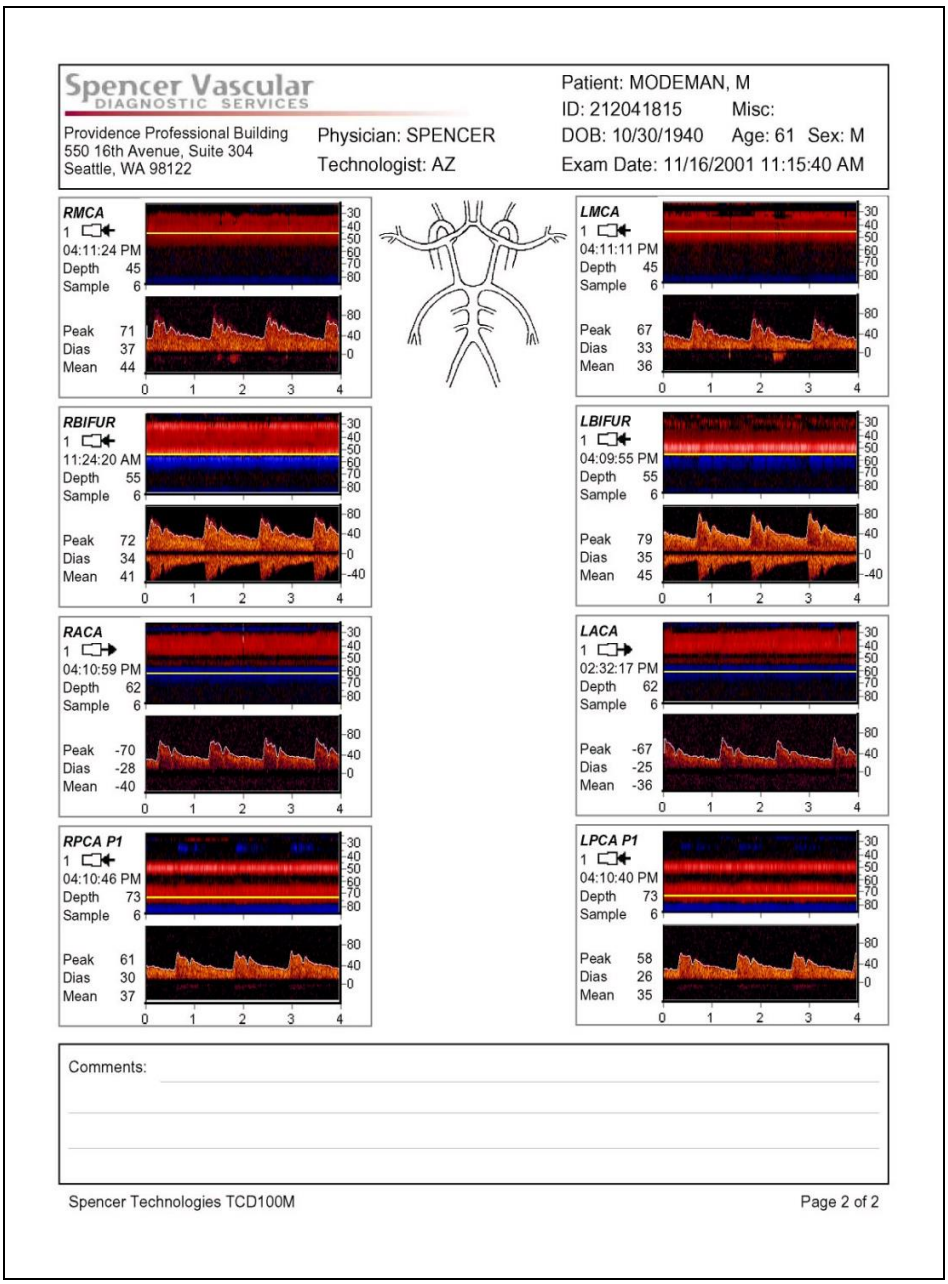


Figure 12 – Sample of a Neurovascular Diagnostic Report

VELOCITY TREND REPORT

The Velocity Trend Report provides trend plots of velocity data that is acquired across multiple days. The vessels used for trending are user-selectable. The report automatically extracts data from multiple exams within a patient folder and plots the vessel velocities versus time (days). The magnitude of the maximum mean velocity is extracted for each selected vessel. A velocity ratio – for example, the Lindegaard ratio – can be included in the report. The trend numerical data is also exportable for use in a spreadsheet.

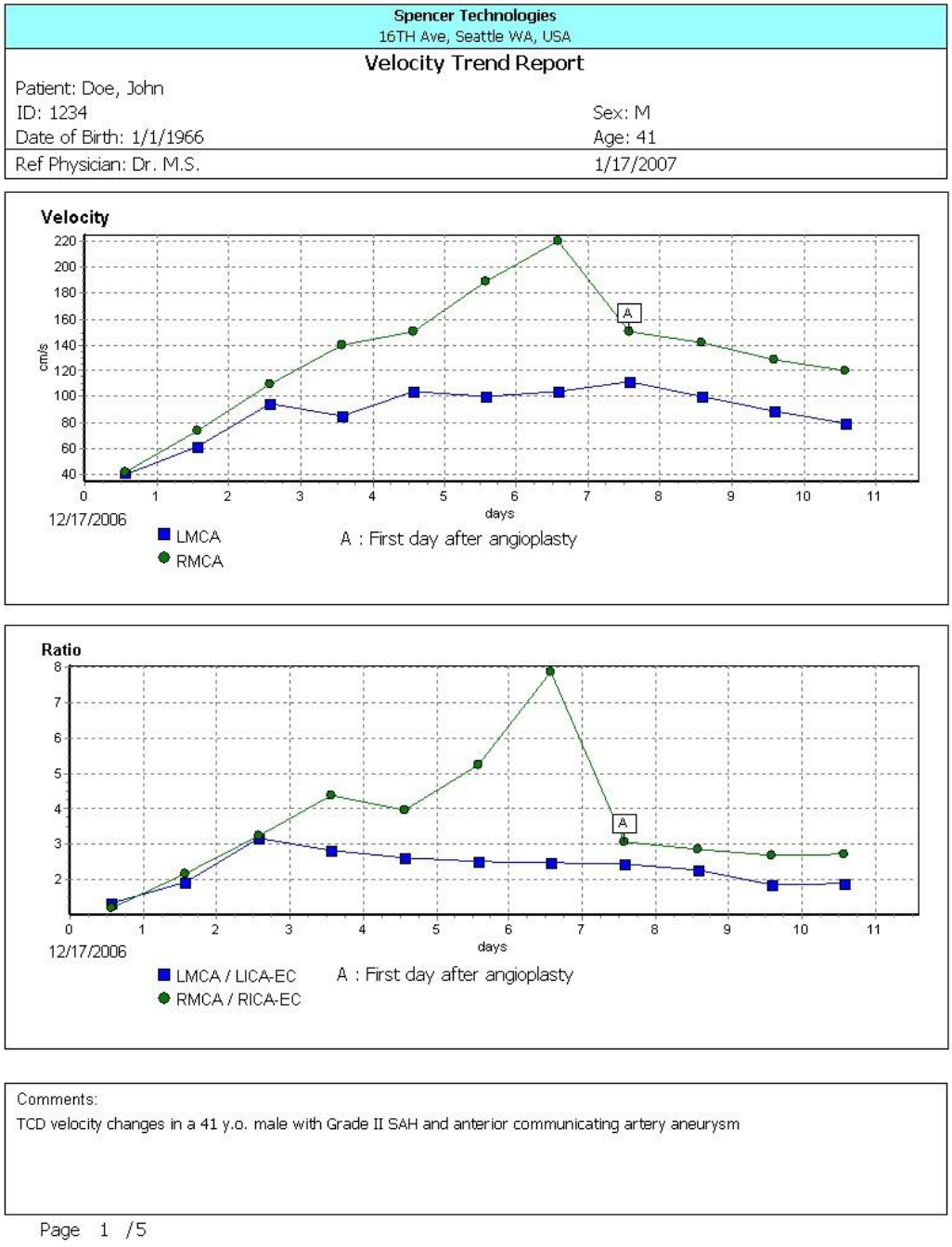
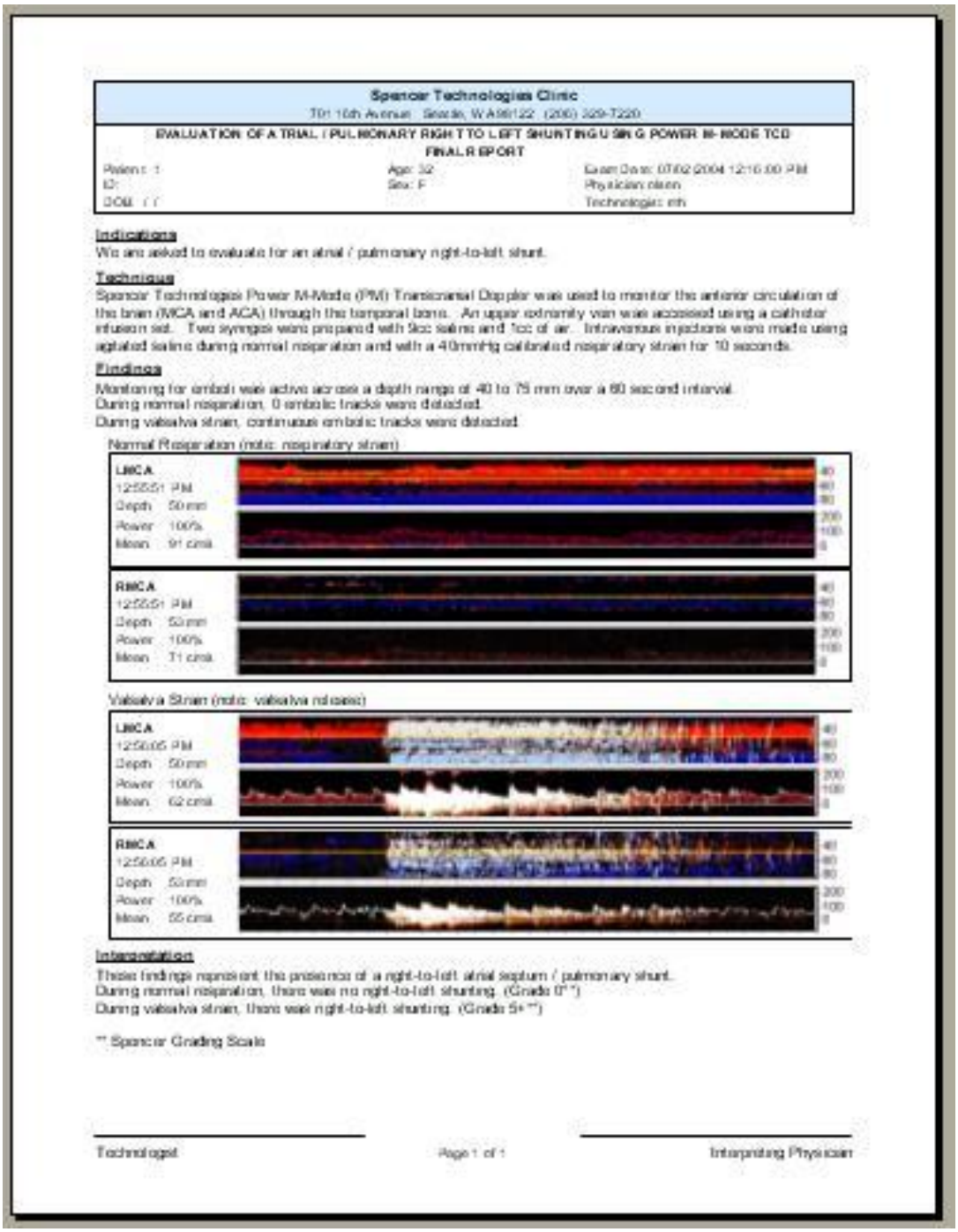


Figure 13 – Sample of a Velocity Trend Report

RLS / PFO EXAM REPORT

The RLS/PFO report can be easily generated after an RLS/PFO exam. Much of the report text is automatically inserted during report generation based on pre-defined report templates. The report templates can be customized to conform to your institution's medical documentation standard practices and unique procedural protocols.



Spencer Technologies Clinic
701 10th Avenue Seattle, WA 98122 (206) 329-7220

EVALUATION OF A TRIAL / PULMONARY RIGHT TO LEFT SHUNTING USING POWER M-MODE TCD
FINAL REPORT

Patient: 1 Age: 32 Exam Date: 07/02/2004 12:16:00 PM
ID: Sex: F Physician: olson
DOB: / / Technologist: mh

Indications
We are asked to evaluate for an atrial / pulmonary right-to-left shunt.

Technique
Spencer Technologies Power M-Mode (PM) Transcranial Doppler was used to monitor the anterior circulation of the brain (MCA and ACA) through the temporal bone. An upper extremity vein was accessed using a catheter infusion set. Two syringes were prepared with 9cc saline and 1cc of air. Intravenous injections were made using agitated saline during normal respiration and with a 40mmHg calibrated respiratory strain for 10 seconds.

Findings
Monitoring for emboli was active across a depth range of 40 to 75 mm over a 60 second interval.
During normal respiration, 0 embolic tracks were detected.
During valsalva strain, continuous embolic tracks were detected.

Normal Respiration (note: respiratory strain)

LMCA
12:55:51 PM
Depth 50 mm
Power 100%
Mean 91 cm/s

RMCA
12:55:51 PM
Depth 53 mm
Power 100%
Mean 71 cm/s

Valsalva Strain (note: valsalva release)

LMCA
12:56:05 PM
Depth 50 mm
Power 100%
Mean 62 cm/s

RMCA
12:56:05 PM
Depth 53 mm
Power 100%
Mean 55 cm/s

Interpretation
These findings represent the presence of a right-to-left atrial septum / pulmonary shunt.
During normal respiration, there was no right-to-left shunting. (Grade 0**)
During valsalva strain, there was right-to-left shunting. (Grade 5+**)

** Spencer Grading Scale

Technologist Page 1 of 1 Interpreting Physician

Figure 14 – Sample of a Right-to-Left Shunt Grading Report

Note: Up to two saves may be included in an RLS/PFO exam report. Refer to "Including and Excluding Data In A Report" for instructions on how to select saves. If more than two saves are selected, the unit will give a "Too Many Items" error message. Once up to two saves are selected, users may enter information for emboli count and select with or without valsava under "Compose Report" to generate image representations to be displayed within the report.

Note: Always review the entire report contents before saving or publishing a report.

Note: A keyboard and mouse are necessary to accomplish the creation, customization and editing of an RLS / PFO report.

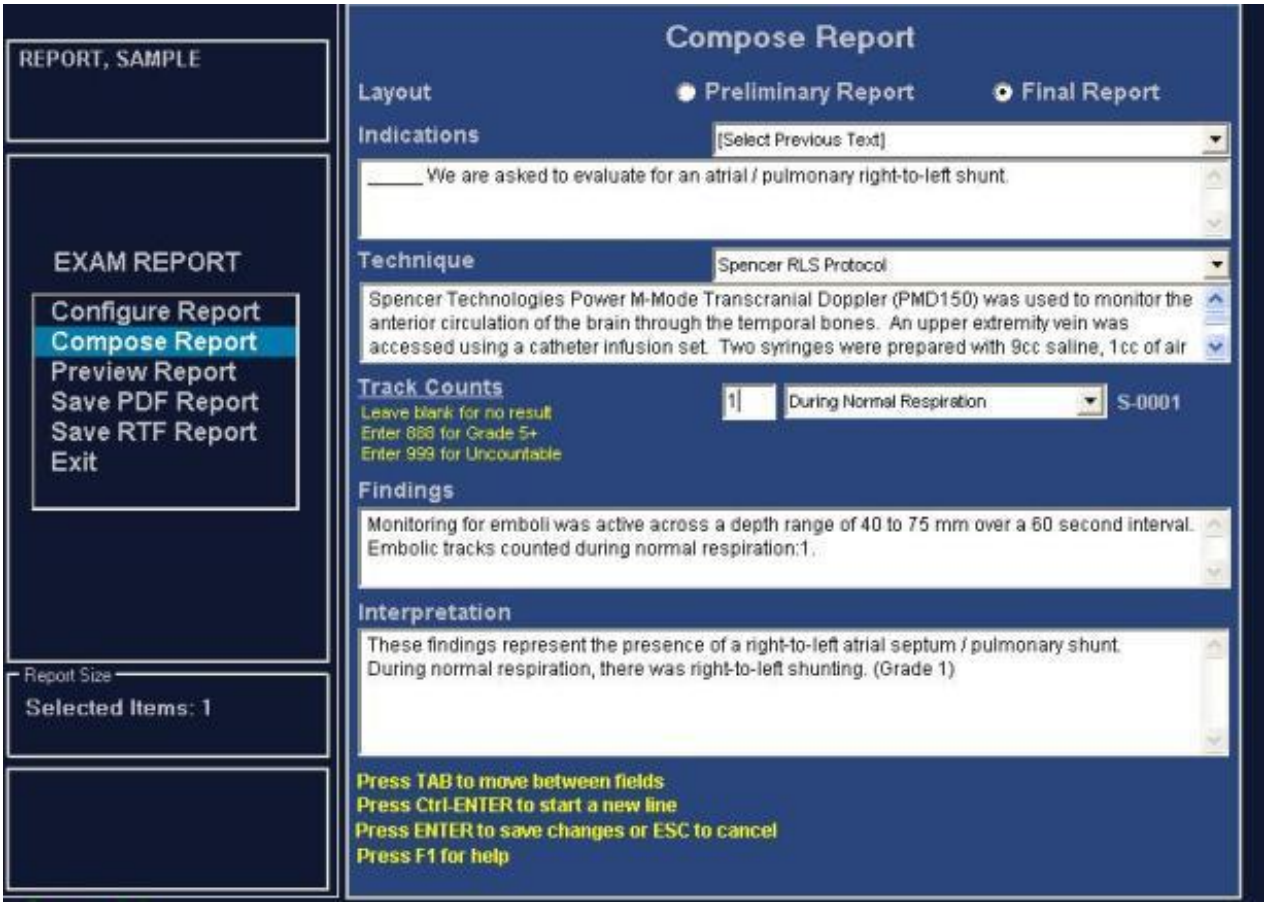


Figure 15 – Compose RLS /PFO Report

REPORT TEMPLATES

The templates for the RLS / PFO Report provide the following customization capabilities:

- Inclusion, exclusion or renaming of any section of the report.
- Entry of phrases to be automatically inserted in the report for positive and negative results.

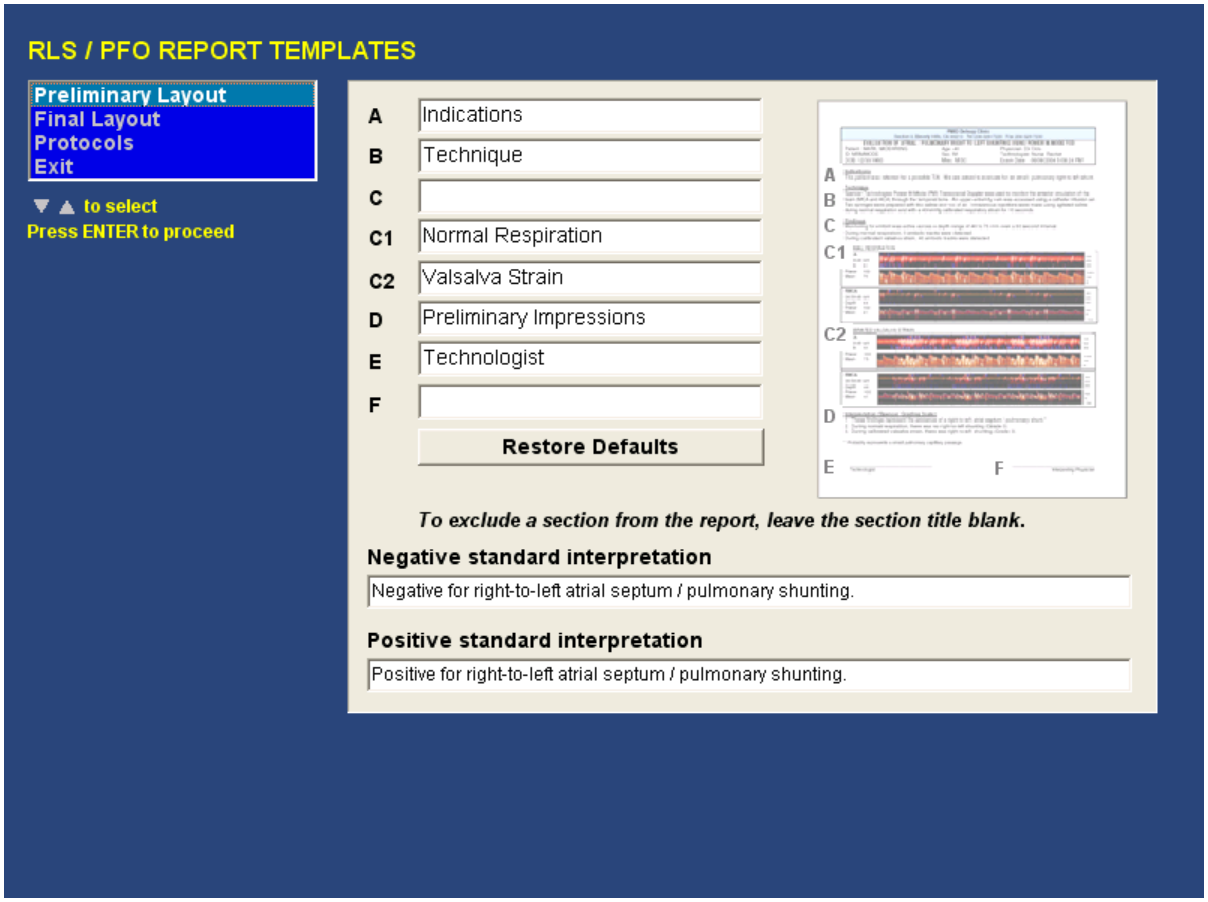


Figure 16 – RLS / PFO Report Template Menu

Exam Protocols

An exam protocol template consists of an exam technique description and a set of grading criteria. The grading criteria are applied to the track counts entered by the user, resulting in automatic insertion of text in the report. A user can add customized exam protocols. The ***Spencer RLS Protocol*** is well suited to the System.

Note: The Spencer RLS Protocol and International Consensus Protocol (1999) are read-only and cannot be edited.

Managing Data Files

EXAM FILES EXPORT / IMPORT

Screen images, reports, and exam data files can be exported to an external disk drive, other external USB mass storage devices such as a USB flash drive or removable optical media (internal DVD/CD drive). The DVD/CD drive supports media types: CD-R, CD-RW, DVD+R, and DVD+RW. In addition, previously exported files can be imported into the internal disk drive.

Note: Only PDF report files, JPEG files, and Trend data files can be viewed on a PC.

When the Files list is shown and the internal disk is highlighted, pressing **EXPORT** will copy the selected exam folders from the internal disk to an external disk. If the external drive is highlighted, **EXPORT** performs an import of files from the external disk to the internal disk.

To begin an export or import, highlight a patient or a patient exam folder and press **EXPORT**. The System will present instructions for selecting additional folders and initiating the export or import operation.

Exported raw data files (named with extension .BIN) can only be reviewed on an ST3 or PMD150 System.

EXTERNAL DRIVE

Caution: Do not connect or disconnect an external drive while acquiring new patient data.

Export / import is intended for use with a removable CD/DVD, or with an external USB storage device.

See the "Replacement Parts" on page 66 for a partial list of storage devices that are compatible with the System.

When exporting data to an external drive, do not power down the equipment until at least 15 seconds after disk activity stops on the external disk.

EXAM ARCHIVAL

A set of exam folders created within a specified date range can be archived to a CD/DVD or external drive. These file folders can be copied or moved to the destination drive.

Press Export, then Mode on the remote. Choosing the "Move" option for the file folders causes the file folders to be moved to the destination drive and removed from the internal drive. This action will remove exam folders, not patient folders. Pressing the **FREEZE** button will cancel the archiving process.

Import, export and archival operations will replace exams on the destination drive with the selected revisions on the source drive. For example, an EXAM123 that has previously been exported will have its contents overwritten (replaced) by updated EXAM123 folder content if it is again exported to the same external drive. Similarly, an imported exam replaces the existing exam content (if any) on the internal drive.

DELETING FILES

The **DELETE** button removes selected files from the internal disk, freeing space for new exam data. Files can be deleted at the Patient Folder, Exam Folder, or Exam Files level.

To delete an item from the Files list:

- Navigate to the item.
- Press the **DELETE** button when the item is highlighted.

The System allows the user to select additional exams to be deleted at the same time.

Note: After patient or exam data has been deleted, it cannot be "undeleted" or recovered.

DATA STREAM OUTPUT

A portion of the data acquired by the System can be streamed to an output for external analysis by a custom designed software program.

The streamed data includes the following:

- Data time stamps.
- Doppler settings: Vessel label, Depth, Power, Sample.
- Numeric values for each Doppler channel, updated once per second.
- Spectrogram envelope derived PEAK, DIAS, MEAN velocities.
- Emboli count (cumulative per exam).
- Emboli count per minute.
- Annotation messages.
- Spectrogram envelope data at 125 points per channel per second.

The stream output destination can be either or both of:

- A file in the current exam folder on the System internal hard disk.
- A serial port connected between the System and an external computer.
- The data stream options can be enabled or disabled via the SETUP menu and "Analog Output and Data Stream Output" submenu.

Serial Output

The System's serial output feature provides a stream of data to an external computer. This feature can be utilized only with the optional Serial Output Kit.

To utilize Data Stream to Serial Output follow the instructions in the Serial Output Kit.

Trends and CSV File Output

The Data Stream output to file is a standard feature of the System. When enabled, this feature produces a file containing a data stream for the entire exam. The file is in a comma-separated-value (CSV) text file format (*.csv) that can be read directly into a spreadsheet application such as Microsoft Excel™. The data fields are identified by text headings within the file. The CSV files are stored in a TRENDS folder in the exam files list, and can be viewed on an external computer after export.

To utilize Data Stream to File:

1. Enable the "CSV File Output" feature via Setup / Analog Output and Data Stream Output submenu. The feature remains enabled until you disable it.
2. Perform an exam as usual. Export the exam folder to an external disk.
3. The exported CSV file data can be plotted and manipulated directly by a PC-based spreadsheet application.

ANALOG OUTPUT

The System has a pair of configurable analog outputs. These are RCA jacks labeled 'AUX.' on the rear panel. The channel number (1 or 2) is labeled next to each jack. Each analog output can be configured to output one of several parameters:

- Envelope - peak velocity envelope.
- Peak Trend - peak velocity trend (based on envelope "Peak" value).
- Dias Trend - diastolic velocity trend (based on envelope "Dias" value).
- Mean Trend - mean velocity trend (based on envelope "Mean" value).

The velocity values will match displayed envelope values.

Table 8 – Analog Scaling for Velocity Output

Range	***-5V to +5V***
DAC Resolution	12 bits
Scale factor	1 volt = 100 cm/s
Examples	0.85 V = 85 cm/s -1.37 V = -137 cm/s

To use the analog output for monitoring flow velocities:

1. Configure the analog output using the SETUP menu.
2. Connect a transducer and obtain a Doppler signal.
3. Activate the spectrogram envelope by pressing **ENVLP** button on the System's Remote Control.
4. To monitor flow away from the probe (negative flow velocity), press **INVERT**. When an inverted flow signal is monitored, the analog output for the flow velocities will be a negative voltage.

Printer

Supported printers are listed in this manual on page 66. Installation of drivers for unsupported printers must be made by authorized service personnel.
Connect the printer to a USB port and turn it on before powering on the System.

Note: When connecting a printer for the first time or after a new software installation, allow two minutes before using the System. During this period the System loads the printer driver.

Network Connectivity

NETWORK ACCESS

When the System is connected to a network, the user can exercise these functions.

- Optional DICOM features (see DICOM Setup section)
- Use an external computer to copy files from the System to the external computer.
- Use an external computer to remotely browse reports and screen images.

Data on the System is password-protected against externally initiated network access.

To connect the System to a network, attach a network cable to the Ethernet port on the rear panel before powering on the system.

Caution: Do not connect a phone to the Ethernet port. Damage to the Ethernet port could result.

Note: Consult your network administrator for help in using a remote computer for network access to the System.

The remote access method will depend on the type of remote computer and its operating system. For example, on a remote Windows XP computer, enter the System's network computer name (e.g. '\\PMD-xxxxxxx') on the address bar of Windows Explorer, or simply browse 'My Network Places' \ 'Entire Network' \ 'Microsoft Windows Network' \ 'Workgroup' \ [computer name].

The System's network computer name is displayed in the Setup menu under 'System Information'. The default user name and password are shown in Table 9 below. To change the password, go to the Setup menu and select 'System Options' - 'Set Network Password'.

Table 9 – The default network configuration

Description	*Default setting*
Network Workgroup name	"WORKGROUP"
Network computer name	PMD-xxxxxxxx (see Setup menu / System Information)
Network - guest user name	"PMDNET"
Password	"netpass"
IP Address (obtained from DHCP server)	(see Setup menu / System Information)
Network protocol	TCP/IP and NetBIOS
Firewall	Windows XP firewall enabled

DICOM

About DICOM

The DICOM standard specifies many possible methods for medical devices to exchange information with external information systems. A medical device may conform to any appropriate portion of the standard. A "DICOM Conformance Statement" defines the level of conformance for a specific medical device.

DICOM Features

The System supports the "DICOM Store" and "DICOM MWL" functions, as summarized in Table 10 below. The "DICOM Conformance Statement" document fully specifies its support of DICOM functions, including many technical details.

Note: DICOM features are optional and not provided in all configurations of the product. The DICOM features are available beginning with software version 1.5.1.

Table 10 – DICOM Function descriptions

Function	*Description*
DICOM Store	Send reports and screen images across a network directly to a DICOM server. The external server must support DICOM Store.
DICOM MWL	Obtain a list of scheduled exams and patient information from an external DICOM server. The external server must support DICOM MWL. (MWL = "Modality Work List". The modality of interest is ultrasound; a work list is a list of scheduled exams)

DICOM Setup

Note: Before using DICOM for the first time, obtain assistance from the administrator of the external DICOM server. Administrators may contact Spencer Technologies for a copy of the System Administration Guide which contains information for DICOM installation.

To use DICOM functions, connect the System to a network where a DICOM server is accessible. Before using DICOM for the first time, obtain assistance from the administrator of the external DICOM server. Open the Setup menu and navigate to DICOM setup to configure network connection. For more information about setup of the network connection, see on-screen help found in the DICOM setup menu.

Using DICOM Functions

DICOM Store:

1. Save a screen image or DICOM report. Note: Saved screen captures located within the SCREENS folder cannot be exported to DICOM unless they are in JPEG format.
2. Navigate to the folder containing the report or screen image and open image.
3. Click the DICOM Store button to send the image. The System sends patient and exam information along with the image.

To Store multiple screen images: highlight the screen images folder, press **EXPORT**, and select DICOM as the export destination.

DICOM MWL:

1. From the Start Menu, open the Patient Information menu.
2. Select the MWL function to obtain today's patient list from the server.

Note: If the System cannot retrieve the patient list from the server then it will display the most recently retrieved list for that day.

Appendix A – Technical Information and Specifications

MEASUREMENTS, FORMULAS, AND TERMS FOR ACOUSTIC INTENSITY

Methods for the calculation of spatial peak temporal average intensity (ISPTA.3), mechanical index (MI), spatial peak pulse average intensity (ISPPA.3), and thermal index cranium (TIC) were carried out using calibrated PVDF hydrophone probes following the recommendations of the American Institute of Ultrasound in Medicine, 'AIUM'. Standard for the Real-time Display of Thermal & Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, NEMA UD-3 Rev. 2 and Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD-2 Rev. 3.

The following definitions apply:

d_{eq} at max. I_{pi}	The equivalent beam diameter in cm at the location of the maximum pulse-intensity integral.
d_{eq} (z_b)	The equivalent beam diameter in cm at the location of the depth for TIB.
Dim of A_{aprt}	The diameter of a circle whose area is the Output Beam Area in cm^2. For the bone at surface model (adult cephalic), it is given as the area of the transducer.
GMV	The Global Maximum Value, defined as GMV = μs + U[μs(n)]
where μ_s=	measurement mean
U =	expanded uncertainty
n =	number of systems in sample
$I_{pa,3}$ at max. MI	The derated pulse-average intensity at the settings yielding the maximum MI in mW/cm2.
I_{SPTA}.3	The derated spatial-peak, temporal-average intensity in mW/cm^2.
ISPPA. 3	The derated spatial-peak, pulse-average intensity in W/cm^2.
$I_{ta,\alpha}$(zs)	The attenuated temporal-average intensity in mW/cm^2 at the depth for TIS, used to determine TIS, non-scanning mode.
MI	The Mechanical Index, an estimate of the probability that mechanical damage by non-thermal processes, e.g. cavitation, might occur within tissue, defined as (P_{ra} / ($f_{awf}^{1/2}$))/C_{MI} (for f_{awf} < 4MHz).
where p_{ra} =	The attenuated peak-rare factional pressure @ the position of $I_{SPPA.3}$ in MPa.
f_{awf} =	Center frequency (acoustic working frequency) in MHz.
C_{MI} =	1 MPa $MHz^{-1/2}$.
$P_\alpha(z_s)$	The attenuated output power in mW at the depth for TIS, used to determine TIS, non-scanning mode.

prr	The pulse repetition rate in Hz.
p_r at max. I_{pi}	The peak-rarefactional acoustic pressure at the maximum pulse-intensity integral in MPa.
t_d	The pulse duration in s.
TI	Thermal Index, the ratio of the attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1^o C (dimensionless).
TIB (non-scan)	Thermal Index Bone at focus (not used in applications intended only for adult cephalic).
TIC	Thermal Index bone at surface, an estimate of the rise in surface (cranial) bone temperature (dimensionless). It is defined as $(P/D_{eq})/C_{TIC}$.
where P =	the time average acoustic power at the source in mW.
Deq=	the equivalent aperture diameter in cm. For the bone at surface model it is given as the size (diameter) of the transducer.
CTIC=	40 mW cm^{-1}.
TIS (non-scan)	Thermal Index Soft tissue, non-scanning mode (not used in applications intended only for adult cephalic).
TIS (scan)	Thermal Index Soft Tissue, scanning mode (not used in non-scanning applications or applications intend only for adult cephalic).
z	The distance from the source to a specified point in cm.
z at max. $I_{pi,3}$	The depth of the maximum attenuated pulse-average intensity in cm.
z_b	The depth for the bone at focus thermal index in cm.
z_{bp}	The break-point depth in cm.
z_s	The depth for the soft tissue thermal index (scanning and non-scanning modes) in cm.
Units: mW	= milliwatts
W	= Watts
cm	= centimeters
MPa	= megapascals
mm	= millimeters
MHz	= megahertz
s	= seconds

ACOUSTIC OUTPUT TABLES

PN 11714, 11981, 11717, 12035, 12069, 12246, 12248

2 MHz Transducer Global Maximum ISPTA.3, MI, and ISPPA.3 Values*

Mode = Pulse Doppler		***MI***	***$I_{SPTA.3}$ [mW/cm^2]***	***$I_{SPPA.3}$ [W/cm^2]***
Global Maximum Value:		0.56	587	26.9
Operating Conditions:	Power	100%	100%	100%
	Sample	Short	Long	Short
	Depth	Deep	Shallow	Deep

2 MHz Transducer Acoustic Output Reporting Table*
Scanning Mode: Pulsed Doppler

Index Label				***MI***	***TIS^2***			***TIB2 Non-scan***	***TIC***
					Scan	***Non-scan***			
						A_{aprt} ≤1 cm^2	***A_{aprt} >1 cm^2***		
Maximum Index Value:				***Note[1]***	***N/A[2]***	***N/A[2]***	***N/A[2]***	***N/A[2]***	2.2
Associated Acoustic Parameters	P_{ra}		[MPa]	Note[1]					
	P		[mW]		Note[2]	Note[2]		Note[2]	152
	Min of [$P_{,3}(z_s)$, $I_{ta,3}(z_s)$]						Note[2]		
	z_s		[cm]				Note[2]		
	z_{bp}		[cm]				Note[2]		
	z_b		[cm]					Note[2]	
	z at max. $I_{pi,3}$		[cm]	Note[1]					
	deq(z_b)		[cm]					Note[2]	
	f_{awf}		[MHz]	Note[1]	Note[2]	Note[2]	Note[2]	Note[2]	2.0
	Dim of A_{aprt}	X	[cm]		Note[2]	Note[2]	Note[2]	Note[2]	1.6
		Y	[cm]		Note[2]	Note[2]	Note[2]	Note[2]	1.6
Other Information	t_d		[s]	Note[1]					
	prr		[Hz]	Note[1]					
	p_r at max. I_{pi}		[MPa]	Note[1]					
	d_{eq} at max. I_{pi}		[MPa]					Note[2]	
	$I_{pa,3}$ at max. MI		[mW/cm2]	Note[1]					
Operating Control Conditions	Power			Note[1]	Note2	Note2	Note2	Note2	100%
	Sample			Note[1]	Note2	Note2	Note2	Note2	-
	Depth			Note[1]	Note2	Note2	Note2	Note2	-

[1]MI < 1, all settings.
[2]System intended for adult cephalic only.

*Values calculated per Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD-2 Rev 3, at a level of confidence of 95%.

2 MHz Transducer Global Maximum ISPTA.3, MI, and ISPPA.3 Values*

Mode=Pulse Doppler		***MI***	***$I_{SPTA.3}$ [mW/cm^2]***	***$I_{SPPA.3}$ [W/cm^2]***
Global Maximum Value:		0.64	681	31.2
Operating Conditions:	Power	100%	100%	100%
	Sample Depth	Short	Long	Short
		Deep	Shallow	Deep

2 MHz Transducer Acoustic Output Reporting Table*
Scanning Mode: Pulsed Doppler

Index Label				***MI***	***TIS^2***			***TIB2 Non-scan***	***TIC***
					Scan	***Non-scan***			
						A_{aprt} ≤1 cm^2	***A_{aprt} >1 cm^2***		
Maximum Index Value:				***Note[1]***	***N/A[2]***	***N/A[2]***	***N/A[2]***	***N/A[2]***	2.5
Associated Acoustic Parameters	P_{ra}		[MPa]	Note[1]					
	P		[mW]		Note[2]	Note[2]		Note[2]	190
	Min of [$P_{,3}(z_s)$, $I_{ta,3}(z_s)$]						Note[2]		
	z_s		[cm]				Note[2]		
	z_{bp}		[cm]				Note[2]		
	z_b		[cm]					Note[2]	
	z at max. $I_{pi,3}$		[cm]	Note[1]					
	deq(z_b)		[cm]					Note[2]	
	f_{awf}		[MHz]	Note[1]	Note[2]	Note[2]	Note[2]	Note[2]	2.0
	Dim of A_{aprt}	X	[cm]		Note[2]	Note[2]	Note[2]	Note[2]	1.6
		Y	[cm]		Note[2]	Note[2]	Note[2]	Note[2]	1.6
Other Information	t_d	[s]		Note[1]					
	prr	[Hz]		Note[1]					
	p_r at max. I_{pi}	[MPa]		Note[1]					
	d_{eq} at max. I_{pi}	[MPa]						Note[2]	
	$I_{pa,3}$ at max. MI	[mW/cm2]		Note[1]					
Operating Control Conditions	Power			Note[1]	Note2	Note2	Note2	Note2	100%
	Sample			Note[1]	Note2	Note2	Note2	Note2	-
	Depth			Note[1]	Note2	Note2	Note2	Note2	-

[1]MI < 1, all settings.
[2]System intended for adult cephalic only.

*Values calculated per Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD-2 Rev 3, at a level of confidence of 95%.

Acoustic Measurement Uncertainty

Measurement precision and uncertainty for pressure, intensity, power and frequency that are used to derive the above global maximum values are shown in the table below. All values below have been obtained at the operating conditions that give rise to the maximum parameter value.
The following measurement precision and uncertainty values were determined by making repeat measurements in accordance with Section 6.4 of Standard for the Real-time Display of Thermal & Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Output Display Standard, NEMA UD-3 Rev. 2, at a level of confidence of 95%.

Parameter	PN 11714, 11981, 11717, 12035, 12069, 12246, 12248 ***Uncertainty (U)***	PN 12286, 12288 ***Uncertainty (U)***
P_{ra}	±15.7%	±10.4%
$I_{SPTA.3}$	±16.9%	±11.0%
$I_{SPPA.3}$	±16.8%	±11.8%
W_o	±16.6%	±18.0%
f_{awf}	±0.002%	±0.002%

TRANSDUCER ASSEMBLY FACE TEMPERATURE

2 MHz PWD16 Transducer Face Temperature. Value calculated per section 201.11 of Medical electrical equipment-Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, IEC 60601-2-37, Edition 2.0 and the ISO Guide to the expression of Uncertainty in measurement, 1995, at a level of confidence of 95%. The maximum temperature rise of the transducer face occurs with the system power at 100% with the bare probe suspended in still air.

Temperature Measurement	***Temp Rise [^{o}C]***
PN 11714, 11981, 11717, 12035, 12069, 12246, 12248	13.9
PN 12286, 12288	16.2

Temperature Measurement Uncertainty

Measurement uncertainty is expressed at a level of confidence of 95%.

Transducer	***Parameter***	***Uncertainty (U)***
PN 11714, 11981, 11717, 12035, 12069, 12246, 12248	Temp	±59.8%
PN 12286, 12288	Temp	±8.5%

EMBOLUS DETECTION CAPABILITY/LIMITATIONS

The Bilateral System has automatic embolus detection capability, but not all emboli moving in blood are easily detectable with ultrasound. Emboli traveling in blood distinguish themselves ultrasonically by two physically detectable phenomena: their movement and how well they reflect ultrasound relative to the surrounding blood. The latter factor of relative reflectivity is critical in order to assess the embolus for motion characteristics. If the embolus is a weak scatterer compared to the blood flowing in the Doppler sample volume, then it may not appear in either the Power M-Mode™ display or the spectrogram. For example, a 20µ diameter embolus made of a clump of red cells moving through the center of a 6mm sample volume in the middle cerebral artery will not stand out against the background blood flow signature, while a 20µ diameter bubble will stand out dramatically because of its higher backscatter capability. Further, position of an embolus in weaker areas of the ultrasound beam can make it less visible against the background blood flow. The sensitivity of the system is therefore context dependent on the type of emboli that are being observed, both in size and in composition, and false negative events may occur associated with very small emboli composed of fresh clot. False positives have also been observed when somewhere in the System display (at a fixed depth) there is a blood flow signal which disappears during diastole. This is a rare occurrence because the brain is a low resistance organ. The appearance of such lack of blood flow signal is in some cases due to a steep Doppler angle, and again this is not common because of the temporal approach being roughly coaxial with the lay of the middle cerebral artery.

The power drop and restoration under this scenario of disappearing diagnostic flow signal and reappearance during systole in some cases will produce a false positive embolic detection.

For further reading on this subject, the user is referred to:

MA Moehring, "Fundamental concepts regarding sizing and discrimination of air bubbles and red cell aggregates using pulse Doppler ultrasound", *Echocardiography*, 13(5): 567-571, 1996.

MA Moehring, JR Klepper, "Pulse Doppler Ultrasound Detection, Characterization and Size estimation of emboli in Flowing Blood", *IEEE Trans. Biomed. Eng.*, 41 (1): 35-44, 1994.

VELOCITY ACCURACY

Lab Accuracy

Accuracy and ranges of velocity measurements were tested with a string phantom (Mark IV Doppler Phantom, JJ&A Instruments). The input test signal was a string moving at constant velocity.

The result was measured as the center of the spectral tone in the spectrogram. The accuracy result is summarized in the following table:

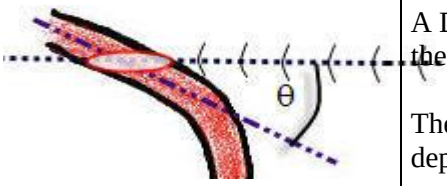
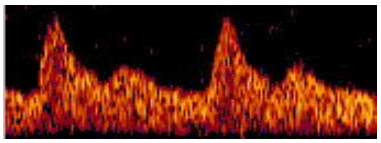
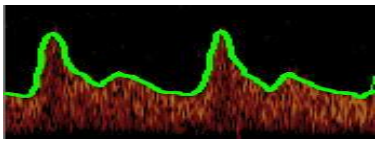
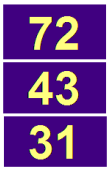
Velocity Range	***Tested Range***	***Accuracy***
10 – 480 cm/s	10 – 160 cm/s (10 cm/s steps)	± 1% or ± 1 cm/s

The velocity accuracy is expressed as a percentage of the measured velocity. The resolution of measured values is ±1 cm/s. Resolution uncertainty dominates at low velocities. For example, the accuracy at 20 cm/s can be determined within ±1 cm/s, or ±5%.

Envelope Velocity Numbers

Velocity measurement numbers provided by a transcranial Doppler instrument are derived from computational analysis of the spectrogram. The sequence of computation is: Sampled Blood Flow Signal → Spectrogram → Envelope Trace → Envelope Velocity Numbers, as shown in Table 11 below.

Table 11 – Stages of velocity measurement

(a) Blood Flow Signal		A Doppler signal is received from regions where the ultrasound beam intersects blood flow. The sample volume is determined by the Doppler depth and sample settings.
(b) Spectrogram		The spectrogram represents blood flow velocity, shown along the vertical axis of the graph. The spectrogram velocity accuracy, assuming zero Doppler angle is ±1% (or ±1 cm/s).
(c) Envelope Trace		An envelope trace is computed from the spectrogram data. It is intended to track the maximum flow velocity in a blood vessel. Envelope tracking accuracy is subject to clinical interpretation.
(d) Envelope Velocity Numbers		The velocity numbers are derived from the envelope trace minimum, maximum and mean. These numbers are as accurate as the envelope trace from which they are derived.

Because blood flow is never uniform across a vessel, the distribution of associated velocities shown on the spectrogram can be complex and the velocity measurement result remains subject to clinical interpretation. The maximum flow velocity is usually of clinical interest, and is recognizable as an edge of a spectrogram waveform (Table 11-b). The System performs a computational analysis of the spectrogram to continuously track the waveform edge, which it draws as an envelope waveform trace (Table 11-c). It then derives peak-systolic, end-diastolic, and mean velocity numbers from this waveform, and displays those as PEAK, DIAS, and MEAN velocity values (Table 11-d).

Note: Please note that System velocity calculations are made with the assumption of a zero degree Doppler angle.

Note: Always confirm that the envelope is properly tracing the edge (flow signal maximum velocity) of the spectrogram before interpreting the derived velocity numbers. Use manual cursors when the envelope is not tracing the edge.

Note: The envelope does not support heart rates below 30 beats per minute or above 150 beats per minute.

Uncertainties in Envelope Parameters

The envelope is intended to follow the maximum velocity edge of the flow signal in the spectrogram display. When interpreting envelope values, confirm that the envelope trace properly follows the edge of the spectrogram. If the envelope does not properly trace the edge, use the CURSORS function to manually locate the PEAK and DIAS velocity of the spectrogram edge.

Velocity measurement numbers provided by a transcranial Doppler instrument are derived from computational analysis of the spectrogram. Because the spectrogram waveform may depict blood flow that is complex, the numerical results remain subject to clinical interpretation.

The velocity measurement is affected by multiple factors:

The Doppler angle — The Doppler angle is a measure of alignment between the ultrasound beam and the flow direction, which depends on probe position and blood vessel orientation. The Doppler velocity is computed with the assumption of no Doppler angle (i.e. flow straight toward or straight away from the transducer). The measured velocity is always affected by the angle of the ultrasound beam with respect to the direction of flow. The measured velocity is reduced by a factor of $\cos(\theta)$, where θ is the Doppler angle. For example, a flow of 100 cm/s measured at 30 degree Doppler angle produces a measurement of $100 \cdot \cos(30) = 87$ cm/s. The Doppler angle is the dominant variable causing a difference between measured and actual flow velocity.

Envelope edge uncertainty — The System's envelope is intended to follow the instantaneous maximum velocity of the flow signal waveform in the spectrogram. For a complex blood flow, the spectral edge of the waveform is subject to interpretation.

Beat-to-beat variation — The peak-systolic (PEAK), end-diastolic (DIAS), and MEAN velocity values are computed on a cardiac cycle basis, and are averaged over time as described in "Envelope Control" on page 22.

Velocity scale variables — The maximum measurable envelope velocity is affected by PRF and baseline settings. The upper limit is indicated by the vertical scale of the spectrogram. The range is reduced at lower PRF settings and when the baseline is set at a higher position in the spectrogram. User depth setting determines PRF, as indicated on page 24.

Filter setting — The minimum measurable envelope velocity is affected by the Filter (clutter filter cutoff frequency) setting. The higher the filter setting, the higher the minimum measurable velocity. For FILTER=200 Hz (manufacturer default), the minimum envelope velocity is about 10 cm/s.

Calculations — Calculations are based on a nominal acoustic velocity of 1540 m/s through tissue.

Appendix B – Ultrasound Safety

INTERACTIVE CONTROL OF ACOUSTIC OUTPUT

The System provides only one parameter that affects acoustic output. This parameter is the system power level, which is displayed as a percentage of total power and is controllable from 10% to 100%, in 10% increments. There are also lower power settings available of 1%, 2%, and 5%. The System controls the acoustic output to operate at the selected percentage of acoustic power independent of changes in sample volume or depth.

When the user adjusts sample volume size, or when the user makes a depth adjustment that affects the Doppler PRF (pulse repetition frequency), the system automatically changes the acoustic output pulse amplitude in order to maintain the specified power level.

Acoustic output should be adjusted in accordance with the ALARA ('As Low As Reasonably Achievable') principle which simply stated means that you should keep the total ultrasound exposure as low as possible while obtaining optimal diagnostic information. This is accomplished by starting the exam at a low power level (10-50%, the factory default is set at 10% power) and then increasing the power level as necessary to accomplish the desired acquisition of blood flow signals.

For the eye, foramen magnum, burrholes and fontanelles, the user is directed by the device to always use the 10% or lower power level, which sets the power level at or below 72mW/cm².

ULTRASOUND BIOEFFECTS

When ultrasound is propagated into the body there exists a potential for tissue damage to occur. There are two known mechanisms by which tissue damage may occur, a Thermal Mechanism-heating of soft tissue and bone and a Nonthermal Mechanism-mechanical phenomena including but not limited to cavitation. By following the principles of ALARA the operator will reduce the possibility of these occurring.

To aid the user in applying the ALARA principle models representing a relative measure of the potential tissue damage due to heating (thermal index) or mechanical (mechanical index) have been developed and are displayed when appropriate with the Doppler power information.

The following indices are used to describe potential sources of harm resulting from exposure to ultrasound:

TI - Thermal Index, the ratio of the attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1^{o}C (dimensionless).

TIB - (non scan) Thermal Index Bone at focus (not used in applications intended only for adult cephalic).

TIC - Cranial-Bone Thermal Index, an estimate of the rise in surface (cranial) bone temperature (dimensionless). It is defined as $(P/D_{eq})/C_{TIC}$. See page 48.

TIS - (non scan) Thermal Index Soft tissue, non-scanning mode (not used in applications intended only for adult cephalic).

MI - The Mechanical Index, an estimate of the probability that mechanical damage by non-thermal processes, e.g. cavitation, might occur within tissue, defined as $(P_{ra} / (f_{awf}^{1/2}))/C_{MI}$ (for fawf < 4MHz). See page 47.

To assist in setting power by the ALARA principle the System shows the Cranial Bone Thermal Index (TIC) in the display boxes containing acoustic output parameters. The TIC is calculated based on a tissue heating model, which follows the *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment*, NEMA UD-2, Revision 2 (the "Output Display Standard" or ODS). The TIC is an estimate for increase in tissue (cranial bone) temperature which increases with power, that is, the higher the power setting the higher the TIC. TIC does not represent a literal increase in temperature in degrees Celsius but provides an estimate of the potential for increased temperature that can be used when adhering to the ALARA principal. The actual temperature rise will be influenced by such factors as the tissue (bone) characteristics, blood perfusion, and exposure time. The estimated TIC for the system is 2.5 at 100% power. Decreasing the acoustic power lowers the estimated TIC proportionally. The other indices discussed above (MI, TIB, TIS) are not displayed because their maximum values when using the System are below values for which there is a potential safety concern (all are < 1), or they are not applicable for a system intended only for adult cephalic usage.

EXPOSURE DURATION

Note: Always read and follow the instructions included with a Marc Series Headframe when performing patient monitoring with the System.

The safety index models established in the Output Display Standard do not currently take into account the duration of exposure but provide relative indications for the potential for mechanical or thermal damage due to ultrasound. Scientific evidence suggests that both effects are threshold phenomena and damage is only likely to occur when a certain level of output is exceeded. Thus indices which are <1 are not required to be displayed under the standard as the risk of harm is very low.

For the ST3 / PMD150 System, the only index that is greater than 1 is the TIC, the estimate of the potential for increased cranial bone temperature. It is generally accepted for all tissues that temperature increases above normal body temperature, of 1.5º C or less, do not present a safety concern. Further, there have been no significant, adverse biological effects observed, associated with temperature increases above normal body temperature of 2.0º C or less, and for up to 50 hours duration (AIUM Declaration Concerning Heat).

The Output Display Standard thermal index that models potential thermal heating in soft tissue such as the brain is the soft tissue thermal index (non-scanning), otherwise known as TIS. For the ST3 / PMD150 System, the TIS is both less than the TIC at all settings and is uniformly less than 1.0 even without adjusting for absorption of the ultrasound energy by the cranial bone. Furthermore, the TIS model does not include the potential for absorption of ultrasound energy by the temporal bone, and therefore it an inappropriate index to use in the context of transcranial (adult cephalic) ultrasound devices. The TIS is accordingly not displayed by the System. The index having the maximum and the appropriate information for transcranial ultrasound devices is the TIC.

Mechanical Index (MI), a value derived from the peak negative pressure associated with the ultrasound pulse, is also uniformly < 1.0 for the System. MI is therefore not required by the Output Display Standard to be displayed. Like TIS, the MI is also calculated without the attenuating effect of the skull, and so the actual value of MI in the brain can be expected to be considerably lower than the estimated value.

TIC is the only parameter describing the System operation that reflects a possible temperature increase for which display to the user is required, and should especially be considered when performing long term monitoring. Importantly, this parameter reflects heating within temporal bone, and not within underlying brain tissue as the absorption is within the bone itself. While the TIC estimate is not affected by duration,

the ALARA principle should always be applied and the TIC reduced to the minimum required to obtain the appropriate monitoring information. For transcranial Doppler exams this may be accomplished by initially exploring the patient's cranial windows to find the thinnest window available and performing the examination at this location following the ALARA principle.

Additional explanation is found in the *American Institute of Ultrasound in Medicine* (AIUM) booklet "Medical Ultrasound Safety" which may be ordered from AIUM, 14750 Sweitzer Lane, Suite 100, Laurel, Maryland, USA 20707-5906 or through the AIUM website www.aium.org.

Appendix C – Troubleshooting

This manual outlines those repair items that could normally be expected to be accomplished without sending the device to an Authorized Service Agent.

To maintain international regulatory requirements, any service requiring removal of the product cover must be accomplished by an Authorized Service Agency.

REMOVAL OF THE PRODUCT COVER WILL VOID WARRANTY.

Customer Troubleshooting Guide

The following table provides a guide to resolving potential problems with the System. If the actions suggested here don't resolve the problem, contact an Authorized Service Agent. If disassembly is required, service must always be accomplished by an Authorized Service Agent.

CATEGORY – NOT FUNCTIONING

Observation	***Possible reason***	***Action***
Unit does nothing when power is turned on; fan does not operate.	No power	Check AC power source. Verify power at wall outlet, power cable plugged into unit
	Blown fuse	Check fuse
Fan operates, but display remains dark	Power-on sequence fault	Push and hold power button for at least 5 seconds for power off. Then push the button momentarily for power on
Fan operates, but display remains dark	Defective display back light	Look for dim display activity. Repair required if backlight defective.
When unit is turned on, screen stays white	Computer or LCD malfunction	Power off/on to reset computer. Connect external VGA monitor to check display function.
The unit takes longer to boot	Software or internal problem.	Turn unit off. Wait up to 1 minute, try again.
	Slow network connection.	Disconnect network.
No response to pressing button on remote	Remote not connected	Connect the remote cable
	Remote was connected after power-on	Connect the remote, then turn power on
	Button has no function in current mode	Try other buttons
	One button is malfunctioning	Try other buttons
	Button stuck	Jiggle the buttons, check if any button is stuck down.
	Software glitch	Reboot and try again
	Remote defective	Try another remote.
	Cable damaged	Inspect cable and its connector pins. Replace cable if damaged.
	Panel connector on remote is damaged	Inspect pins. Replace remote if damaged.

Observation	*Possible reason*	*Action*
Unit stops operating after a period of time	System overheating	Check that fan is operating. If airflow is normal but unit is hot, turn off system and contact service.
	Check AC power quality	Check AC voltage is 100 to 240 VAC
	Defective fan	Assure air is moving at fan
	Airflow is blocked	Make sure system is installed in an open area on hard level surface
Does not power off	Computer halted	Hold power button down for more than 5 seconds

CATEGORY – SIGNAL AND OUTPUT RESPONSE

Observation	*Possible reason*	*Action*
No Doppler waveform or weak signal	Probe is not aimed at blood vessel.	Adjust probe position or direction.
	DEPTH setting incorrect	Position DEPTH in flow signal
	Power setting is too low	Adjust POWER setting up
	Gain level is too low	Adjust GAIN setting up
	Very low flow or no acoustic window	Gently tap end of probe, look for signal on display
	Defective probe/cable	Replace probe / cable
Displayed signal looks noisy or erratic	Defective probe/cable	Replace probe / cable and retest
	Inadequate amount of gel	Clean the probe face and apply plenty of gel
	Electrical noise	Check for source of noise such as electrocautery. Remove or turn off noise source.
	Interference on probe cable.	Reposition cable or interfering device.
Audio "pop" in Doppler signal	A pop with DEPTH adjustment is normal.	Press DEPTH control to verify
	Worn or defective probe/ cable	Replace probe/ cable and retest
Two-channel unit does not have CH2 function	Invalid license key	
Channel information does not appear when a probe is connected	Incorrect channel selection	Press CHANNEL button and see if the channel appears
	Doppler acquisition must be active.	Press START to begin acquiring data
No waveform sweep during an exam	FREEZE function in effect.	Press FREEZE to unfreeze
	Internal error	Turn system off and on
Unstable graph sweep, repeated pause, blank and restart of sweep	Unsupported software applications or device drivers are interfering with data collection.	Use System Restore function to reset System software. Field-installed drivers must be reinstalled after system restore.

Observation	*Possible reason*	*Action*
"Probe disconnected" displayed while probe is connected	Probe / cable or connector problem. Possible incompatible probe.	Inspect cable and connector pins.
No Doppler audio	MUTE is on	Press the MUTE button to un-mute
	Doppler volume too low	Adjust Doppler VOLUME up
No Doppler audio From speakers	Headphones plugged in	Check for audio on headphones
	Doppler not producing audio	Check for audio output at headphone jack or rear connectors
	No Doppler signal on display	Gently tap face of probe, verify signal is visible
No Doppler audio on remote headphones	Defective headphones	Try replacing headphones
	Headphone connection	Try front panel headphone jack. Verify that headphone is not inserted in microphone jack
No voice output during playback	Voice volume too low	Increase VOICE volume
	Voice not recorded	Check microphone connection
Rear panel outputs do not produce audio	Bad cable connection or internal circuit problem	Check for audio output at rear connectors

CATEGORY – DATA STORAGE AND ACCESSORIES

Observation	*Possible reason*	*Action*
Cannot store new data	Internal disk full	Export older data, then delete the old data from internal disk.
Cannot export data to CD / DVD	Missing CD/DVD disk	Insert disk
	Destination disk type or format is not supported.	Use compatible CD or DVD format.
	Insufficient free space on destination disk.	Insert new, blank disk.
	Destination disk is damaged or defective.	Insert new, blank disk.
CD/DVD is not accepted when inserted	Power not on.	Check power is on.
	Disk already present.	Eject disk and retry.
External video monitor doesn't work	Defective video cable or monitor.	Test with another cable and monitor.
	Internal malfunction.	Repeat test with a second video monitor.

Observation	*Possible reason*	*Action*
Printer doesn't work	Printer power is off.	Check power input cable. Plug in and turn on power
	USB cable not properly connected.	Check printer USB cable connection
	First time printer connected.	Turn unit off, connect printer, turn power on
	Printer is out of paper.	Add printer paper, reset printer and retry.
	Selected printer does not match connected printer.	In SETUP menu, select connected printer from list of installed printers.
	Printer drivers are not installed.	Use standard printer model specified in Operator's manual Contact service to install drivers for nonstandard printers
	Printer compatibility	Verify printer is listed as supported. Use compatible printer.
Poor print quality	Printer driver does not match connected printer model	Verify correct printer selected
	Printer ink cartridge empty	Check printer ink cartridge. See printer manual.

CATEGORY – MISCELLANEOUS

- **Remote control is not detected (Serial Number < 15210).** On rare occasion the system may indicate that the remote control is not detected even though the remote was connected before power-on and is actually fully functional. This issue is identified by the appearance of the following message on the Start Menu: *"Remote Control Not Detected. Connect remote control before power-on."*

  If this scenario is encountered, press the START button on the remote control and verify that the patient information screen is shown. This indicates that the remote is operating properly. It is safe to continue to use the remote despite the notification that it was not detected.

- A "**License key missing or invalid**" message may be cleared by disconnecting the unit from AC for 5 minutes followed by restarting normally. In software version 1.5.7 and above, this error may be reported as **Hardware Error Ch0** along with a loss of audio. If the error does not clear then contact technical support for service.

- **Slow Boot or Startup Time**. The number of exams present on the device may certainly impact the time it takes to boot. It is important to note that it is the number of exam folders, not the amount of disk space being used, that contributes to a slower boot because the system needs to traverse and process these folders. A system with hundreds of exam folders that only uses 10% of the disk will boot much slower than a system with a few exam folders that uses 90% of the disk. Recommendations for this issue are as follows:
  1) Please archive some of the data (patient folders + exam folders) from the device.
  2) Perform disk defragmentation through System Options in the SETUP menu.
  3) If the boot time is still excessive, shut down the system, disconnect everything except the power cord, and then turn on the unit. If boot time improves, repeat the process as peripherals are added until a peripheral is identified as the accessory causing the slow boot.

Appendix D – Maintenance and Care

ST3 / PMD150 MONITOR

Preventative maintenance consists of periodically cleaning the exterior of the monitor. It is recommended that cleaning and patient leakage current safety testing be performed at least annually. This system does not require calibration.

The monitor and remote surfaces may be cleaned using a soft cloth with mild detergent and water. The monitor screen may be cleaned with a soft, dry cloth, without any chemicals.

Warning: Disconnect the System from the power source prior to cleaning. Failure to do so may result in electrical shock.

Caution: Do not immerse the monitor or remote in water. Doing so can damage the monitor or remote

Caution: Do not spray cleaning or other solutions directly on system monitor or remote. Spraying liquids onto the monitor or remote can damage the monitor or remote.

Caution: Clean the monitor screen only with a soft, dry cloth without chemicals. Use of chemicals or abrasives on the monitor screen can damage the screen.

TRANSDUCERS

Transducers used with the System are intended only to contact intact skin, and are not intended for use within the sterile field. After each use, remove acoustic coupling gel and any other foreign material with running water, then clean with soap and water. Do not immerse the transducer in water since damage will result. Additional disinfection is recommended following the procedures below.

Warning: Do not drop or knock the transducer against a hard surface. Rough handling can damage the transducer electrical insulation which may result in electrical shock.

Caution: Do not immerse the transducer in water. Doing so can damage the transducer

Caution: Disconnect the transducer from the monitor prior to cleaning or disinfecting. Failure to do so can damage the monitor.

Caution: Do not drop or knock the transducer against a hard surface. Rough handling can damage the transducer crystal.

DISINFECTION

Follow local hospital or clinic guidelines for additional low-level disinfection. After cleaning and disinfection, dry completely with a soft cloth or paper towel. Allow transducers to dry completely before reusing. Additional guidance for the user:

- Use care when performing disinfection and monitor over time to minimize any damage to the ST3 / PMD150 or probe. The user is responsible for equipment damage resulting from disinfection.
- Remove any bioburden with water and/or a mild detergent before applying disinfectants.
- The probe face may be affected by heat at temperatures below those typically used for sterilization. Avoid all sources of heat.
- The probe face may deteriorate from repeated exposure to alcohol. Do not clean the probe with rubbing alcohol.
- The probe face material exhibits good to excellent chemical resistance to quaternary ammonium compounds (Quat[1], Neutracide 64[2]), butyl ether of ethylene glycol (Cavicide[3], Caviwipe[3], Envirocide[3]), and phenols (Prospray Wipes[4]). Realize, however, that disinfectants may contain multiple chemical components with some being damaging to the probe[6, 9].
- Avoid the use of disinfectants featuring high (>50%) concentrations of alcohol (Transeptic[5], Citrex[6]), halogens (Germicidal Wipes[6], Betadine[7]), strong reducing agents (hydroxides, Phenolic 256 DC[8]), oxidizers (peroxide), aldehydes (Cidex[9], Metricide[3]), or strong acids.
- Observe all warnings and cautions related to probe damage, inspection, and cleaning found in this manual.

Warning: Do not subject the transducer to sterilization processes. Exposure to heat or EtO gas can damage the transducer electrical insulation which may lead to electrical shock.

Caution: Do not subject the transducer to sterilization processes. Exposure to heat or EtO gas can damage the transducer.

Caution: Do not use transducers in sterile field, or on abraded skin. Transducers are not sterile and may transmit infectious agents.

Representative products may be registered trademarks of:
[1] 3M - St. Paul, MN 55144
[2] Carroll Co. - Garland, TX 75041
[3] Metrex - Orange, CA 92867
[4] Certol - Commerce City, CO 80022
[5] Parker Labs - Fairfield, NJ 07004
[6] Clorox Healthcare Solutions - Oakland, CA 94612. Citrex Spray Disinfectant is phenol based but also contains up to 70% ethanol.
[7] Purdue Products - Stamford, CT 06901
[8] Central Solutions - Kansas City, KS 66115. Phenolic 256 DC is phenol based but also contains up to 5% Sodium hydroxide.
[9] Advanced Sterilization Products - Irvine, CA 92618

Appendix E – Product Specifications

- Dimensions: 13” (33cm) wide x 9.8” (24.9cm) high x 7” (17.7cm) deep
- Weight: 12 lbs (5.5 kg)
- AC Power: 100V-240V~, 50-60 Hz, 1.5A. For Korea: 220V~, 60 Hz, 1.5A
- Peripheral Interface: USB 2.0 high speed, Windows XP compatible
- Audio Connections:
  - Microphone: 3.5mm monaural connection
  - Headphone: 3.5mm stereo connection
- Rear Panel Mounting: 100mm hole spacing
  - Use mounting hardware compliant with VESA MIS-D, 100, C (reference VESA FDMI-2006-1) or equivalent.
  - Use mounting hardware with a rated working load > 5.5 kg (12 lbs) and safety factor ≥ 4.
  - Use 4 standard mounting screws 4mm ø x 0.7mm x 10mm.
- Windows XP Embedded operating system
- (Minimum) 40 GB internal HDD (30 GB data storage)
- Removable Optical Media: CD-R, CD-RW, DVD+R, and DVD+RW
- CPU: Celeron M 600MHz
- 256MB RAM
- Classification:
  - Class I Equipment
  - Type BF isolated patient-applied parts (transducers)
  - IPX0 ordinary protection against ingress of water, equipment
  - IPX1 protected against vertically falling drops, transducers
  - Continuous operation
  - CISPR 11 Group 1 Class A

Appendix F – List of System Components

Warning: **To avoid the risk of electric shock, do not connect non-medical (commercial) grade OEM accessories to AC mains power when monitoring/examining the patient.**

Caution: **The use of accessories other than those listed may damage the System.**

Caution: **Do not mount or transport the System on accessories that do not meet the requirements of EN/IEC 60601-1 (Section Four, Clause 24 - Stability in Normal Use; equipment shall not overbalance in normal use when tilted through an angle of 10°), or equivalent. Use of equipment stands or carts that are not stable may cause injury to the patient or user, or may damage the equipment.**

ST3 / PMD150 DIGITAL TRANSCRANIAL DOPPLER SYSTEM COMPONENTS

Description	*Catalog # (REF)*
SYSTEM	
Basic System, ST3, NVD, Bilateral	info@spencertechnologies.com
Basic System, ST3, NVD, Unilateral	
Basic System, ST3, PFO, Bilateral	
Basic System, ST3, PFO, Unilateral	
DISPOSABLE	
Mouthpiece (Package of 10)	info@spencertechnologies.com
Gel, Ultrasonic	
Pad Set Pack, Headframe (5 Sets)	
ACCESSORIES	
Software Option, ST3, Vasospasm	info@spencertechnologies.com
Software Option, ST3, Embolus Detection	
Software Option, ST3, PFO	
Option, ST3, DICOM Store	
Option, ST3, DICOM MWL	
Warranty, Additional 1 year	
Warranty, Additional 2 years	
Warranty, Additional 3 years	
Marc Series Headframe, Bilateral	info@spencertechnologies.com

Description	*Catalog # (REF)*
Marc Series Headframe, Unilateral	
Manometer with articulated arm	
Printer, Color Inkjet, USB[1, 2, 3]	
Cable, USB, 2.0, A/B, 6'	

[1] Contact Spencer Technologies for a list of supported printers.
[2] Do not use non-medical (commercial) grade items in the patient environment.
[3]USB 2.0 high speed, Windows XP compatible

Appendix G – List of Replacement Parts

Replacement Parts

The following replacement parts are available for the System:

Description	***Catalog # (REF)***
FOR USE WITH THE SYSTEM	
Manual, Operator's (ST3)	info@spencertechnologies.com
Transducer, Handheld	
Holder, Handheld Transducer	
Remote Control	
Remote Control Cable	
Carrying Case	
Power Cord[2]	
Mouse, Corded USB[3]	
Keyboard, USB[3]	
Stereo Headset with Microphone	

[2]Do not use non-medical (commercial) grade items in the patient environment.
[3]USB 2.0 high speed, Windows XP compatible

Appendix H - Warranty and Service Policy

Warranty Policy

Spencer Technologies warrants that this product shall perform in accordance with its specifications and shall be free from defects in material and workmanship under normal use and service for a period of one (1) year from the date it is shipped. This warranty covers parts, labor, and standard product software exclusively. Any damage caused as a result of misuse will not be covered. Spencer Technologies will be the sole determiner of misuse.

Software upgrades shall be provided at no cost for the life of the product.

Accessory products provided by but not manufactured by Spencer Technologies shall carry the original manufacturer's warranty.

Spencer Technologies makes no warranty of merchantability or fitness for a particular purpose. Notwithstanding any other provisions in this policy, Spencer Technologies shall not be liable for any incidental or consequential loss, personal injury, damage or expense, including loss of profits, arising directly or indirectly from the sale or use of the product whether such claim is based on warranty, contract, tort or otherwise, and in no event shall Spencer Technologies be liable for any damages in excess of the amount paid for the product.

Limitations and Remedies

Spencer Technologies at its option will repair, replace, or refund the purchase price of any monitor, disposables, and accessories which are defective in materials or manufacturing during the appropriate warranty periods.

The customer must notify Spencer Technologies or their customer sales representative of the defect within 30 days of discovering any defect, and no later than 30 days after the end of the appropriate warranty period. The customer must then return the monitor, disposable, or accessory, freight prepaid, to Spencer Technologies. The returned material authorization (RMA) policy must be followed.

THIS REMEDY IS YOUR EXCLUSIVE REMEDY. Spencer Technologies will not be liable for any consequential or incidental damages, including lost profits.

Service Policy

Except for software maintenance, product servicing will be accomplished at Spencer Technologies in Seattle, WA, USA, or by a Spencer Technologies authorized service organization. The customer shall be responsible for inbound product shipment, and Spencer Technologies shall pay return shipping costs. Service loaner units shall be available.

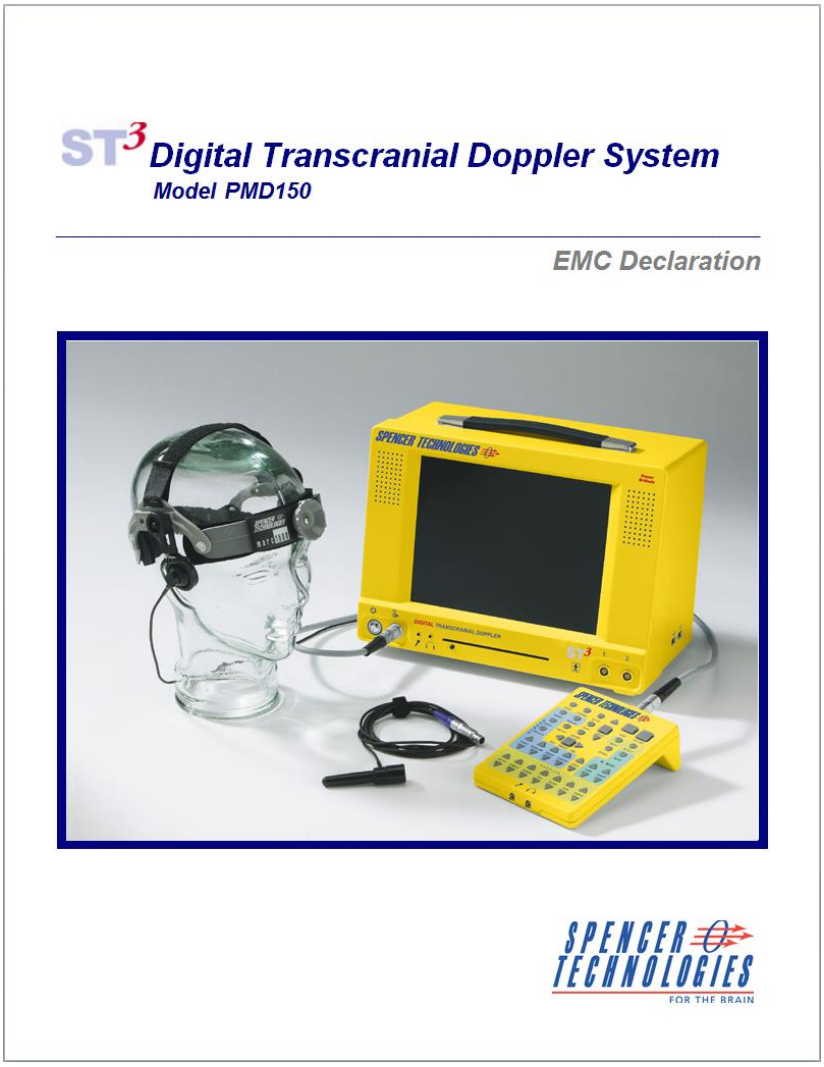
Caution: Do not ship the system in packaging that is not approved by Spencer Technologies. Shipping the system in an unapproved container may damage the equipment.

Appendix I – Electromagnetic Compatibility (EMC)

This device has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical device to IEC 60601-1-2:2001 (Second Edition).

MANUFACTURER'S DECLARATION

Contact Spencer Technologies to obtain the EMC Declaration for this device.



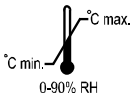
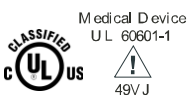
Appendix J - Glossary of Terms

ALARA principle:	ALARA is an acronym from the phrase "As Low As Reasonably Achievable." In Doppler ultrasound, the ALARA principle is used in order to minimize the exposure of the patient to ultrasound energy.
Baseline:	The line in the spectrogram used to separate flow towards and away from the probe.
Channel:	Channel (1 or 2) indicates which signal is being monitored when there are two transducers connected to the machine.
Cursor:	The cursor buttons allow the user to position horizontal bars over a frozen Doppler spectrogram image to obtain velocity and derived measurements.
Delete:	The delete button removes selected files.
DELTA %:	Delta percent, the percent change from an initial reference velocity established by pressing the "DELTA%" button with the envelope on.
Depth:	The depth is the distance from the probe at which the center of the Doppler sample volume is being obtained.
DIAS:	Average end-diastolic velocity in cm/sec calculated from the spectrogram envelope over a 4-second interval. Each detected systole in this interval will contribute the preceding end-diastolic velocity to the average. (see Envelope)
Display:	The display button is used to cycle from displaying Channel 1 Doppler output to displaying Channel 2 Doppler output to displaying Channel 1 and Channel 2 Doppler outputs concurrently.
Embolus:	A moving particle in the bloodstream that is not normally present in blood. Emboli may be formed elements (solid) or bubbles (gaseous).
Embolus detection:	The embolus detection function analyzes the Doppler signal to detect emboli flowing past the ultrasound beam. It counts the emboli detected.
ENVLP Envelope:	The envelope function is a trace on the spectrogram display that continuously tracks the maximum blood flow velocity in the spectrogram.
Export:	The export button is used to copy selected information to an external storage device or printer. The export button is also used to import selected information from an external storage device.
Files:	The files button is used to activate the list of previously recorded exams and provide access to recorded data for playback, export, or deletion.
Filter:	The filter adjusts the level of low frequency noise removal for the selected channel.
Freeze:	The freeze button is used to pause and resume the display sweep.
FWD:	Forward. The FWD button controls the direction of file navigation and playback.
Gain (Doppler):	A display adjustment for the spectrogram color scale. Where spectrogram data falls below this setting, the spectrogram is colored black.

Gain (M-Mode):	A display adjustment for the M-Mode color scale Where the Power M-Mode data falls below this setting, the M-Mode display is colored black.
Import:	The import function copies files from an external storage device onto the internal drive. See Export.
Invert:	The invert function is used to vertically flip the spectrogram display. This function is normally utilized to provide better viewing of blood flow moving away from the probe.
Lindegaard ratio:	The Lindegaard ratio is the flow velocity of the middle cerebral artery divided by the flow velocity of the extracranial internal carotid artery; i.e.: MCA / ICA-EC.
M-Mode:	The Power M-Mode display is a presentation of Doppler data used to assist in the location of the cerebral arteries.
MEAN:	Average velocity in cm/sec calculated in one of two ways: If the cursors are placed manually on the spectrogram, then MEAN = (DIAS + 0.4*(PEAK – DIAS)), where the cursor with the higher value is PEAK and the cursor with lower value is DIAS If the envelope is automatically detected, then MEAN is the average value of the envelope trace over valid heart cycles in the past four second interval.
Mute:	The mute function is used to deactivate audio output to the speakers and the headphones. Note that plugging in the headphones will also turn off audio output to the speakers.
NVD:	Neurovascular Diagnostic
PEAK:	Average peak systolic velocity in cm/sec calculated over a 4-second interval. Each systole in this interval will contribute one peak systolic velocity to the average.
PFO:	Patent Foramen Ovale
P.I.:	Pulsatility Index or Gosling Index, a dimensionless number calculated as (PEAK – DIAS) / MEAN.
Power:	The power control is used to adjust the transducer output power level for the selected channel.
R.I.:	Resistance Index or Pourcelot Index, a dimensionless number calculated as (PEAK-DIAS) / PEAK.
Range (Doppler):	The Doppler range control is used to adjust the range of signal strengths spanned by the spectrogram color scale. For a given signal, a larger range will decrease color contrast and a smaller range will increase color contrast. See Gain (Doppler) definition above.
Range (M-Mode):	The M-Mode range control is used to adjust the range of signal strengths spanned by the M-Mode color scale. See Gain (M-Mode) definition above.
Record:	The record button is used to turn on and turn off the continuous recording of new data.
REV:	Reverse. The REV button controls the direction of file navigation and playback.
RLS:	Right to left shunt.

Sample length, Sample volume:	The sample control is used to adjust the size of the Doppler sample volume. Larger sample lengths include more depth range over which spectrogram and M-Mode observations are made. For example, a setting of depth = 45mm and sample = 6mm includes flow at 45 ± 3mm. A setting of sample = 9mm includes flow at 45 ± 4.5mm. For a setting of sample = 6mm, the M-mode color and intensity at any display depth position is constructed from flow signals within ±3mm of that depth.
Save:	The SAVE function is used to store a segment of Doppler data to the internal disk. The resulting file segment is referred to as a "Save File" or simply as a "SAVE".
Scale:	The scale function selects the spectrogram vertical scale (velocity range).
Setup:	Press the setup button to access main system setup menu for custom configuration, system operation, and maintenance.
Start:	The Start button is used to start a new exam and to initiate entry of patient information.
Sweep:	The sweep buttons are used to adjust the sweep speed of the data in the M-Mode and spectrogram screens.
USB:	Universal Serial Bus, a standard for connection of peripheral devices to computers.
Vessel:	The vessel button provides access to a vessel label selection list. A label can be selected for each Doppler channel.
Voice volume:	The voice volume control is used to adjust the volume level of the voice annotation on playback. This button is active only during playback of previously recorded data.
Volume:	The volume control is used to adjust the volume level of the Doppler signal output from the speakers or headphones.

SYMBOLS

REF	Symbol for “Catalog number”	~	Alternating current
	Case		Direct current
	Warning – Do Not connect to telephone line		Warning – electrical shock hazard
	Caution – Consult accompanying documentation		Earth Ground
	Best if stored between given temperatures		USB Port
			Ethernet Port
RH	Relative humidity		Standby
	This way is up		Output
	Fragile, handle with care		Microphone
	Keep dry		Headphone
EC REP	Authorized representative in the European community		DO NOT OPEN
PN	Part number	RC	Remote Control
Rx ONLY	Prescription Device (USA)	1	Channel 1
SN	Serial Number	2	Channel 2
	Date of manufacture	VGA	Video
	Manufacturer		Separate collection for electrical and electronic equipment
	Type BF Equipment		UL classification mark for Canada and the United States
LOANER	Spencer Technologies owned goods lent for temporary use	Model	Model

Appendix K - Patents

Patents:
Spencer Technologies products are covered by the following U.S. patents:
6616611, 6524249, 6547736, and 6196972.

Other patents pending.

Spencer Technologies Redmond, WA USA
PN 12021-1EN R10 09/2014

For more information, contact:

SPENCER TECHNOLOGIES
14907 NE 95th Street
Redmond, Washington 98052-2559
USA
206-329-7220 phone
206-329-7230 fax
800-684-0586 toll free (US, CA)
info@spencertechnologies.com