DIGI-LITE™
Transcranial Doppler
User Manual

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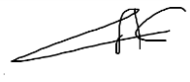
Gal Shani		29.04.2018	Alon Mizrachi		29.04.2018

DIGI-LITE™ Transcranial Doppler Operation Manual
Revision 26, April 2018. Software Version 2.3.1.05

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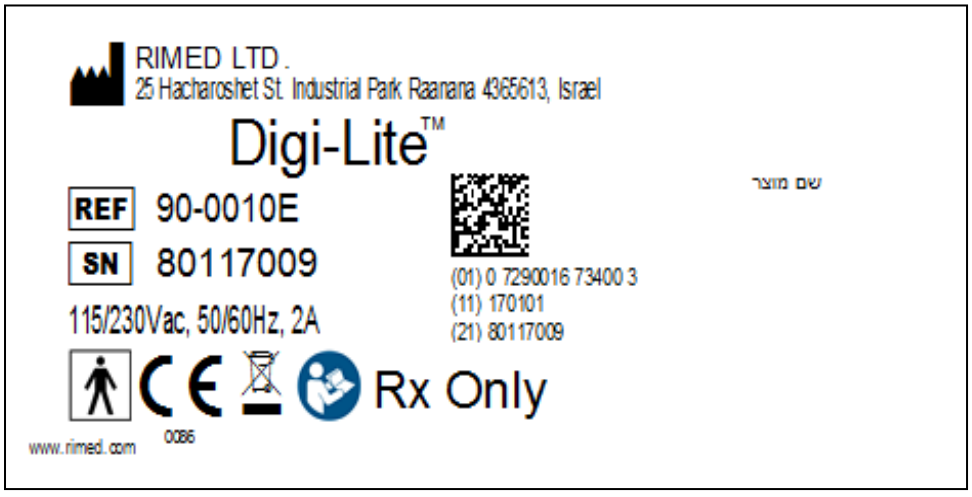

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1. Introduction

The DIGI-LITE is a non-invasive, Transcranial Doppler (TCD) system. The system employs ultrasound energy to perform a variety of studies for the complete assessment of Extracranial and intracranial circulation. The system utilizes a number of Doppler probes (2 MHz PW, 4 MHz CW/PW, 8 MHz CW/PW, 16 MHz PW) to allow insonation of most major intracranial and Extracranial blood vessels.

DIGI-LITE is a computer driven system operating under the Microsoft® Windows 7® operating system. For ease-of-use, the DIGI-LITE offers a standard Windows 7 environment. The user interface looks and operates similar to other programs in Windows 7. You don't need to learn any special skills or complex computer terminology to use the program. When you turn on the computer, the intuitive DIGI-LITE main screen appears, and you can begin working without typing any prior commands.

DIGI-LITE offers a variety of studies types supporting up to 64 Doppler gates per probe, starting with unilateral (intracranial, Extracranial and peripheral) study types for basic diagnosis and examination, bilateral study types for simultaneous intracranial examination and monitoring of blood flow velocities on both sides of the head with two 2 MHz PW probes, multi-frequency study types for simultaneous examination with any combination of two Doppler probes (CW or PW), and monitoring study types with special trend display of all clinical parameters as well as up to 8 external analog inputs.

DIGI-LITE allows emboli detection based on multi-layer algorithm, improving performance and reliability.

1.1. About this manual

This manual is designed for medical professionals using the Rimed DIGI-LITE Transcranial Doppler system. This manual covers all aspects of user interface and system operation. It is designed to give operating information for all levels of users, from beginning to advanced users of the DIGI-LITE system.

Note: The DIGI-LITE Operation Manual assumes that the basic user is a medical professional familiar with the use of probes for taking blood flow measurements. Instructions on insonation of blood vessels are beyond the scope of this manual. See the relevant RIMED publications.

This manual is divided into the following chapters:

Quick Tour (Chapter 5) familiarizes you with the main screen views and the tools you can use to manipulate the screen. This includes explanations of how to use the keyboard, remote control and touch screen tools.

Perform Routine Examination (Chapter 6) contains an explanation of the routine TCD examination.

Using the DIGI-LITE (Chapter 7) contains an explanation of the steps you go through each time you work with the system. This chapter is the core of the book, providing step-by-step instructions for all the basic procedures you use when operating DIGI-LITE.

Monitoring (Chapter 8) contains information on Monitoring examinations.

Vasomotor Reactivity Test (Chapter 9) contains information on VMR examinations.

Probe Holder (Chapter 10) contains information on using the probe holder.

Setup (Chapter 11) contains information on customizing the system. Configuration allows you to control the display and printing features of the DIGI-LITE system. You may choose to skip this section completely and use the defaults provided by Rimed.

Functions (Chapter 12) explains the functions menu, supplying an alternative way to perform screen operations.

Calculations (Chapter 13) explains the calculations of clinical parameters.

External Channels (Chapter 14) explains about external signals that can be input or output to and from the DIGI-LITE system.

Packing the system and system components for shipping (Chapter 15) contains details on packing procedure.

FAQ (chapter 16) contains different questions about operating the system.

Service Log File (chapter 17) explains how to send a log file for debugging problems.

1.2. Explanation of Symbols Used

	**Manufacturer**	115/230Vac, 50/60Hz, 2A	**Power note**
	**Recorder number**		**Equipotentiality**
	**Serial number**	**Rx Only**	**Available for sale upon order of a physician or licensed health care provider**
	**Applied part: type BF**		
	**Communite Europeene certified**		
	**Recycle the product separate from other disposables**		
	**Read manual**		

1.3. Related documentation

Service technicians and individuals who need to perform hardware service or software installation can refer to Rimed for complete specifications, service, installation and packaging information.

1.4. Typographical conventions

This manual uses the following typographical conventions:

- Arrow brackets <> are used to signify a key on the keyboard used for a function. This may be a single key, such as <N>, or a special key, such as <Esc>.
- **Bold** is used to emphasize text, particularly text in a list which signifies a function, key or menu choice that appears on the screen.
- SMALL CAPITALS are used to denote menu choices or commands.

1.5. Abbreviations

The terminology used in this manual and on the DIGI-LITE screens is standard terminology used for Transcranial Doppler analysis. This manual avoids technical jargon other than that used in the medical profession.

PW: Pulsed Wave

CW: Continuous Wave

BV: Blood Vessel

HITS: High Intensity Transient Signals

FFT: Fast Fourier Transform

MHz: Mega-Hertz

2. Indications and contraindications

2.1. Indications for use

The instrument is intended for use in the non-invasive evaluation of intracranial and Extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.

2.2. Contraindications

- Avoid using the probe on skin surfaces with recent wounds/ operative cuts. Use all sterility procedures applicable to your institution.
- Consider the application of long term monitoring in febrile patients with caution. Use of Transcranial Doppler can raise the temperature of the skull or the surrounding tissue. While this is not believed to present a health risk for patients with normal body temperatures, use of the device on febrile patients could elevate brain temperature above the level of the fever.

 CAUTION

This system and its options should be used no longer than is necessary for the appropriate diagnostic procedure. In order to minimize exposure to acoustic energy, switching on only at critical phases of surgery or at special events is recommended.

 CAUTION

ALARA caution: The operator is cautioned to use Doppler power levels as low as reasonably achievable, and to avoid the use of any power level greater than that necessary to insure the gathering of adequate Doppler information.

 CAUTION

Not intended for fetal use.

 CAUTION

Not intended for neonatal use.

3. Precautions and warnings

3.1. Warranty and factory service

Rimed Ltd. warrants the DIGI-LITE™ equipment, including its electronic boards, against defective materials or workmanship for a period of one year from the date of delivery of the system.

Equipment under this warranty is limited to the repair of the DIGI-LITE™ AND the electronic cards. In case of any defect or malfunction, the equipment or components must be returned directly to the Rimed Service Department.

This warranty covers all malfunctions encountered in normal use of the equipment and does not apply in cases of failure to follow instructions, of loss or damage of the equipment due to abuse, accident, or mishandling such as liquid immersion, autoclaving and ETO sterilization.

This warranty is valid on the condition that repairs and service are performed only by technicians trained by Rimed Ltd.

Rimed Ltd. warrants the ultrasonic probes for a period of 90 days from time of shipment. The warranty does not apply if damage was caused by abuse, mishandling, or failure to follow instructions, including, liquid immersion, autoclaving and ETO sterilization.

In the event of any service or maintenance problem, please contact the Rimed Service Department directly at:

Tel: 972-9-7484425 or Fax: 972-9-7484417 or E-mail: admin@rimed.com.

If the instrument is being returned for service please send it, protected in its original package, to:

Rimed Ltd.

25 Hacharoshet st., P.O. Box 2402, Industrial Park

Raanana 4365613

Israel

3.2. Environmental Requirements

Operating Temperature	+16°C to +40°C (60.8°F to + 104.0°F)
Storage Temperature	-20°C to +70°C (-4°F to + 158°F)
Transport Temperature	-20°C to +70°C (-4°F to + 158°F)

3.3. System dimensions and specifications

Dimensions of main console without monitor: (basic)

Height: 32 cm

Width: 40 cm

Depth: 33 cm

Weight: 7 kg

Power: 100-125 Vac, 50/60 Hz, 3.0 A max. or

200-240 Vac, 50/60 Hz, 1.5 A

Main fuses: 4x20 mm slow blow.

For main console: 2A, (2 fuses) 250V

Classification: Class 1 Type BF

MDD Class IIa

3.4. Standards

The DIGI-LITE™ equipment fully complies with the following standards:

- EN60601-1. Safety for medical diagnostic equipment
- EN60601-1-2. Electromagnetic emissions and immunity compatibility

3.5. Customer responsibility

The DIGI-LITE™ system equipment performs properly only when operated and maintained as specified in this manual. It is the responsibility of the customer to use the equipment in accordance with the instruction manuals and equipment warnings and labels.

Paragraphs no. 4 and 15 in this manual: ("Installation and upgrade instructions" and "Packing the system and system components for shipping") contain instructions for unpacking and packing the equipment. Paragraph no. 4 "Installation and upgrade instructions", contains instructions for carrying the system.

 **Caution:**

It is essential to ship the equipment to Rimed using the original packing materials, including the wooden pallet**.**

 ***Caution:***

If the system is moved from one place to another it is essential to insert it into its original dedicated carrying case.

If the product is found to be defective it should not be used. The system should not be operated if any parts are missing or damaged. Parts which are visibly broken, worn out, warped, or contaminated must be replaced immediately with new parts supplied by Rimed Ltd. No components should be replaced with parts from any other manufacturer. If the customer suspects a part may be defective, it is the customer's responsibility to contact Rimed Ltd.

Rimed Ltd. is responsible for parts supplied in accordance with the warranty. If the customer requires repair or replacement of parts beyond the warranty period, the customer should consult Rimed regarding service and replacement of parts.

Rimed is responsible for the software originally installed on the system. When the user wishes to install additional software, it is recommended to consult with Rimed's technical department.

This can prevent software conflicts and assure optional performance. Rimed will not be responsible for software installations that were not confirmed.

The systems are scanned for software viruses. As new software viruses appear constantly, Rimed cannot be responsible for virus damage when additional software or files are used. The user should be responsible for using updated Antivirus software in such cases.

The owner of the product has sole responsibility for any malfunction resulting from improper use or maintenance, including service by someone other than an authorized Rimed service representative. The owner of the product is also solely responsible for any malfunction caused by use of parts not manufactured by or authorized by Rimed Ltd., including parts that are altered without authorization of a Rimed service representative.

3.6. Using this manual

This manual contains safety precautions and interfacing procedures.

 **WARNING**

The WARNING label identifies conditions or practices that may present danger to the patient or user.

 **CAUTION**

The CAUTION label identifies conditions or practices that could result in damage to the equipment

3.7. Electrostatic discharge (ESD)

Objects become charged as a result of being separated. Atoms near any surface will transfer electrons and upon separation, end up with either a surplus of electrons, known as a negative charge, or a deficiency in electrons, known as a positive charge. Objects can be charged easily to potentials as high as 30,000 volts, by such simple acts as walking or sliding. Materials that easily transfer electrons between atoms are known as conductors and are said to have “free” electrons. Materials which do not easily transfer electrons are known as insulators. Both conductors and insulators may be “charged” with static electricity.

When a conductor is charged, the free electrons give it the ability to discharge rapidly when it comes near another conductor with a different potential. The potential required for a spark, noticeable by most people, is about 3,000 volts. ESD has become a problem in electronics, as electronic circuits have become smaller.

 **CAUTION**

When using CMOS chips, some devices may be damaged by ESD events caused by potentials as low as 30 volts and up to 30,000 volts. At the lower voltages, people do not notice this level of electricity.

3.8. Static protection

 **CAUTION**

In order to avoid damage to the CMOS ICs in the electronic board, care needs to be taken to guard against electrostatic discharge. Anyone handling internal hardware, specifically circuit boards, must use electrostatic protection to prevent damage to the hardware. The technician should not handle any circuit boards without using an electrostatic protective wrist strap and using a work surface mat. Static shielding bags are used to cover electronic boards during shipping. Every card sent for repair or replacement to Rimed Ltd. must be enclosed in a static-shielded bag.

3.9. Warnings and cautions

 **WARNING**

The DIGI-LITE™ system will operate correctly when used in accordance with the instructions in this manual. The operator should have a thorough understanding of these instructions before attempting to operate the system. The DIGI-LITE™ system may be operated only by a PHYSICIAN or a TRAINED MEDICAL TECHNICIAN, with the operator present at all times while the patient is connected to the system.

 **WARNING**

Electrical shock hazard. Do not remove cover. For service, contact a qualified service representative.

WARNING

Switch off all power to the system before attempting any service or maintenance activity related to cabling or connections.

CAUTION

Switch off all power to the system before connecting or disconnecting any system components. Failure to turn off the power may result in damage to the system components.

WARNING

Replacement parts and hardware maintenance should be obtained only from authorized service representatives of Rimed Ltd. Rimed is not responsible for malfunctions caused by misuse or improper operation of the system, by improper or inadequate maintenance, or by repair work or replacement parts obtained from unauthorized sources

WARNING

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

CAUTION

This device must be used in accordance with all instructions and labels.

WARNING

Line Power Connection: The DIGI-LITE™ SHOULD only be plugged into a grounded (three-prong) hospital-grade outlet. Do not use the system or any accessory if the power plug or cord appears damaged. The system must be matched to the power line voltage in use. Line voltage tolerance is +/-10%.

The monitor power cord should be plugged only to the appropriate socket on the back of the instrument.

CAUTION

Have a service engineer check every year the integrity of the system ground and leakage current.

WARNING

If you disconnect the cables, make sure to reconnect them in the proper locations. For a diagram showing the proper locations for the cable connections, refer to Rimed Service Department.

CAUTION

Inspect the power cord frequently for signs of fraying or other damage. Do not operate the system if the power plug or cord is damaged.

CAUTION

Do not substitute unauthorized transducers for the transducers provided with the system. Transducers (probes) supplied by other manufacturers may not transmit the correct sound level or quality and may degrade the quality of test.

WARNING

None of the transducers supplied with the DIGI-LITE™ system are intended for fetal use.

WARNING

Do not switch on any power systems unless all cables have been properly connected and verified. If there is any doubt contact a Rimed service representative.

WARNING

Do not use ultrasound intensities greater than 14% for trans-orbital examinations.

CAUTION

If you use additional external monitor, use a color monitor which complies with EN60950 standards.

CAUTION

Do not attempt to reinstall the system software without consulting a qualified Rimed service representative first. Reinstalling software may destroy data.

CAUTION

This equipment uses a three-wire power cord which should be connected to a hospital grade plug (for international applications, EN60601-1 approved plug). The chassis is earth grounded. For grounding reliability, connect the device to a hospital grade or hospital only receptacle (for international applications, EN60601-1 approved plug).

CAUTION

For best results, use only high quality ultrasonic transducer gel.

WARNING

Do not allow water or other liquids to enter the system. If the system does come in contact with water, shut the system down, disconnect the system from the power cable and contact your Rimed service representative.

CAUTION

Always handle transducers with care.

CAUTION

Do not drop or bang the transducers.

CAUTION

Clean the probes with a clean cloth or tissue paper at the end of each day to remove remains of gel.

WARNING

Do not immerse transducers in water or any other fluids.

CAUTION

Problems caused by interference from outside systems are indicated by vertical lines of different frequencies on the screen. In these cases, move the system away from the source of the disturbance. If problems continue, contact the Rimed service representative.

3.10. Ultrasound safety

Ultrasound works by sending a pulse of ultrasound energy to the human tissue, waiting for parts of the pulse to be reflected back. The transducer is able to send the pulses and receive the ultrasound echo. Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. This effect is extremely low when using the Transcranial Doppler. However, it is important to control and limit patient exposure to ultrasound pulses. Authorities and governing bodies in the field of ultrasound have issued statements saying that there are no known adverse effects from the use of diagnostic ultrasound; however, exposure levels should always be limited to As Low as Reasonably Achievable (the ALARA principle).

In practice: after obtaining a good quality signal, reduce power to the minimal setting while still keeping sufficient quality. Remember to reduce power whenever examining a certain blood vessel for a longer period.

3.10.1.Factors affecting ultrasound power output

Ultrasound exposure can be limited by adjusting the system. The following factors can be controlled to affect ultrasound power output:

Ultrasonic power: The power control adjusts the power of the ultrasonic signal. Increasing the power setting increases the duty cycle of the transmitted wave, resulting in a higher ultrasonic output at the transducer. The power is expressed in terms of percentage of maximum system output which is restricted so as not to exceed the recommended FDA guidelines.

Pulse Duration: The sample volume is the axial length of the area from which the Doppler signals are obtained. For a larger sample volume, the transducer produces a longer pulse burst, and the ultrasound output power increases accordingly.

Pulse Rate: The pulse rate, or range, represents the pulse repetition frequency, that is, the number of pulses bursts per second. At a higher range setting, there will be a higher ultrasound output.

This manual contains specific instructions on adjusting these factors when performing diagnostics.

4. Installation and upgrade instructions

4.1. Unpacking the system

When unpacking the system, remove all parts carefully. The system arrives in a box, on a wooden pallet used for shipping. The box, packing material and wooden pallet are necessary when shipping the system back to Rimed in case of malfunction. Thus, the packing material should be kept in case it becomes necessary to send the equipment back for service.

To unpack the system, proceed as follows.

1. Cut the plastic bands holding the box to the pallet. Cut open or remove the packing tape on the top of the box.
2. Lift off the upper foam guard. Underneath are the accessory attachments to the instrument, including the keyboard, probes, remote control and AC power cable (may be omitted in some countries). These components are fitted into a middle foam guard which is custom-designed specifically for these parts.
3. Carefully lift the instrument out of the box and place it on a table or working surface where it is to be installed.
4. Underneath the instrument are the remaining CDs, including the licensed copy of Microsoft Windows package. Make sure to remove all CDs, literature, and any other components that are packaged under the instrument.
5. Keep the foam guards and box in case the equipment needs to be shipped back to Rimed for service.

Once you have removed the equipment from the packaging, proceed to inspect it to make sure no damage was incurred during shipping. Assemble the system according to the directions and diagram shown in the following sections.

4.2. Installation of a new system

4.2.1. System components

Once you have unpacked the system, make sure that you have all of the components and that they have not been damaged during shipping. If parts are missing or damaged, contact the service department of Rimed Ltd.

The Digi-Lite have two configurations, Unilateral and Bilateral.

The basic system for Digi-Lite Unilateral configuration includes the following components:

- Main Console
- Mini Keyboard
- Mouse
- Remote control
- 2 MHz Probe
- CDs and documentation for Windows 7®
- CD containing the Rimed DIGI-LITE™ software
- CD containing Rimed DIGI-LITE™ User Manual
- CD containing Computer and Touch Screen drivers
- Dedicated Carrying Box

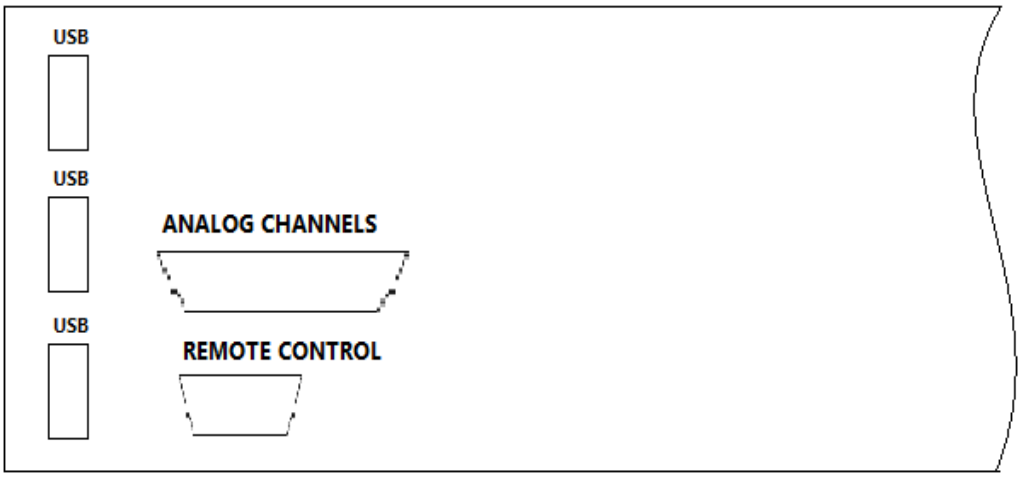
The basic system for Digi-Lite Bilateral configuration includes the following components:

- Main Console
- Mini Keyboard
- Mouse
- Remote control
- 2 MHz Probe – 2 pcs.
- Probe Holder – LMY-3
- CDs and documentation for Windows 7®
- CD containing the Rimed DIGI-LITE™ software
- CD containing Rimed DIGI-LITE™ User Manual
- CD containing Computer and Touch Screen drivers
- Dedicated Carrying Box

In addition to the basic standard components listed above, several optional components are also available. Check the items that should be included along with the basic system according to the customer order. Following are the possible options that may be ordered with the DIGI-LITE™ system.

- 4 MHz Probe
- 8 MHz Probe
- 16 MHz Probe
- Probe Holder – LMY-3
- Foot-Switch.
- Dedicated cart
- Dedicated Carrying Case

4.2.2. Setting up the system



The DIGI-LITE™ system comes complete with all software loaded. If no damage was incurred during shipping, it is necessary to attach all the components to the main console. Figure 4-1 shows the back panel with all connectors.

Figure 4-1 Back Panel

Remote Control is connected to the back panel as shown in Figure 4-1.

;USB to connect printer, or mouse, or CD-RW, or disk on key or other

Analog channels to connect analog input and output channels

Figure 4-2 shows the bottom panel with all connectors.

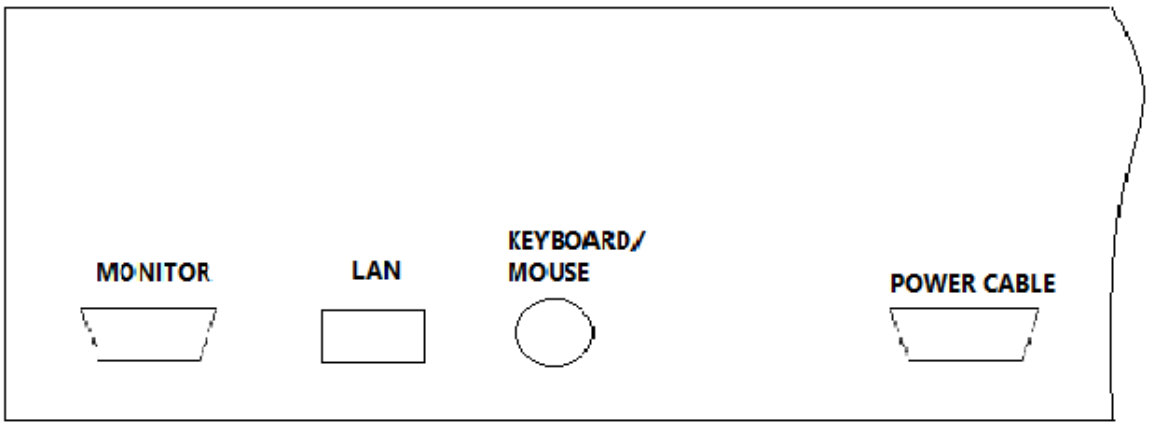


Figure 4-2 Bottom Panel

Keyboard is connected to the PS2 Keyboard/Mouse port.

Mouse: The mouse can be connected to the PS2 Keyboard/Mouse port or to USB or to COM1.

Monitor is connected to the bottom panel, as shown in Figure 4-2. Used to connect external monitor.

LAN: to connect to Local Network

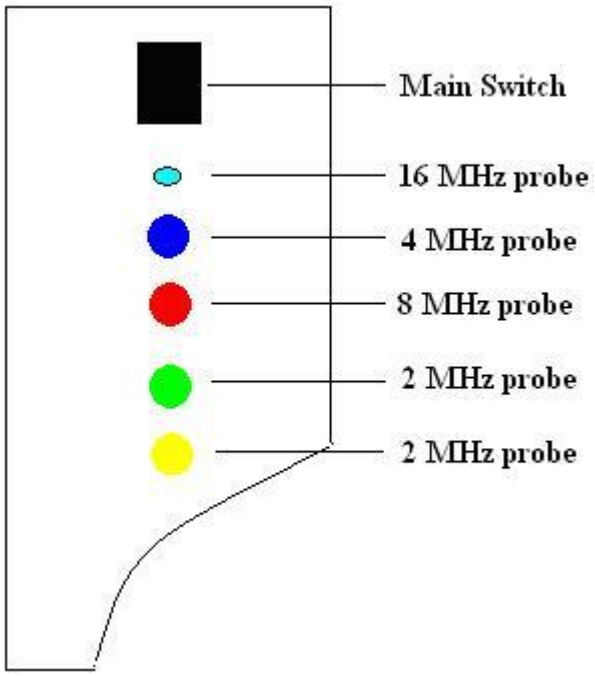


Figure 4-3 Probes connection

Probes are connected on the left side of the console (when facing the front of the console). The probes are color coded for simple assembly. Figure 4-3 shows the probe connections for the system. Pay attention to the differences between the probes: The 2MHz, 4 and 8 MHz probes have Lemo connectors. To connect, align the red dots on the probe's connector and on the panel. Then push the connector. To disconnect, pull the sliding sleeve on the connector towards you.

4.2.3. Checking functionality of the system

If you are unable to boot the system, and it appears that the hard disk drive or the information on the hard drive may be damaged, contact Rimed Ltd.

Once the system is set up, perform the following system checks to make sure it is functioning properly. This check should be done by a Rimed representative or a user who is already familiar with the system.

The following acceptance tests should be performed on all systems. Turn on the power of the system.

1. Go to the Unilateral Default study screen, 2 MHz. With a 2 MHz probe in the default state, check the signal at the depth of 55 mm, 60 mm, or 70 mm. Check that you receive good M-Mode and spectrum signals on the vessels and that the sound is clean.

2. In Unilateral Default study press on *Add Spectrum* icon and check the signal. Change the depth according to the signal and make sure that you receive a good signal for each one of the different depths on screen.

3. Repeat step 2 for up to 8 spectrums.

4. Go to the Extracranial Default study screen Extracranial probe of 4 MHz PW. Perform a blood vessel check. Check that you receive good spectrum and M-Mode signals on the vessels and that the sound is clean.

5. In Extracranial Default study press on *Add Spectrum* icon and check the signal. Change the depth according to the signal and make sure that you receive a good signal for each one of the different depths on screen.

6. Repeat step 5 for up to 8 spectrums

7. Go to the Extracranial Default study screen Extracranial probe of 4 MHz CW. Perform a blood vessel checks. Check that you receive good spectrum signals on the vessels and that the sound is clean.

8. Go to the Extracranial Default study screen Extracranial probe of 8 MHz PW. Perform a blood vessel check. Check that you receive good spectrum and M-Mode signals on the vessels and that the sound is clean.

9. Go to the Extracranial Default study screen Extracranial probe of 8 MHz CW. Perform a blood vessel checks. Check that you receive good spectrum signals on the vessels and that the sound is clean.

If the system is bilateral, perform the following additional acceptance tests.

1. Go to the Monitoring Unilateral or Bilateral Default study. Check the blood flow of two different vessels simultaneously in the bilateral mode using two 2 MHz probes.

2. Change the depth for one probe. Make sure that this does not influence the spectrum frequency of the other probe. Change the depth of the second probe. Make sure this does not influence the spectrum of the first probe. Repeat for the other Doppler parameters.

3. In Monitoring Unilateral or Bilateral Default study press on *Add Spectrum* icon and check the signal. Change the depth according to the signal and make sure that you receive a good signal for each one of the different depths on screen.

   Note: achieving 4 or more spectrums in different depths are not easy, depending on vessel anatomy. If not successful, change depths so that you see spectrums in part of the windows.

4.3. Carrying the system from one place to other

When carrying the system from one place to other it's essential to insert it into the original carrying case and to take special care of the screen.

Pay attention to place the system into the carrying case as follows:

Place the system with its back panel turning to the case back side and the screen turning to the thicker side of the case cover.

5. Quick tour

The Quick Tour chapter gives an overview of how the system works and how to manipulate the various operational mode study types and screens. It gives an overview on how to control the results displayed by DIGI-LITE.

5.1. System operation

The DIGI-LITE system allows you to record and display the blood flow spectrum for various Extracranial and intracranial blood vessels. The system works in two basic states: Freeze and Unfreeze. When the screen is in the Unfreeze state, you see the display of the blood flow being insonated. In the Freeze state, no input is received and the probes are not active.

When you switch from Freeze to Unfreeze, you immediately get the display of whatever the probe detects, whether the probe is directed at a blood vessel or not. When you switch from Unfreeze to Freeze, the resulting spectrum and M-Mode are the registered for that particular examination.

5.2. The Main screen

When you turn on the DIGI-LITE system, you enter the main screen. The main screen contains areas which show the blood flow being examined and calculated parameters of the blood flow. Additionally, the main screen contains selections and buttons which allow control of the program's function. See figure 5-1.

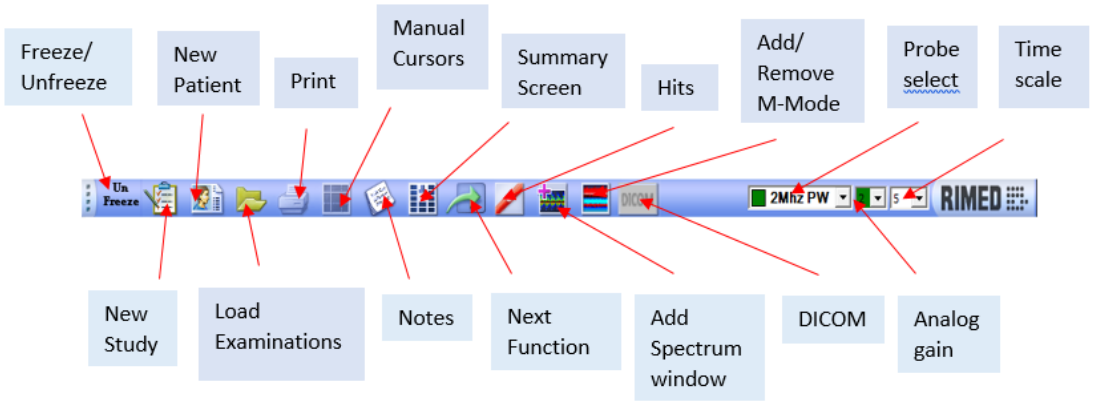


Figure 5-1 Unilateral study main screen buttons

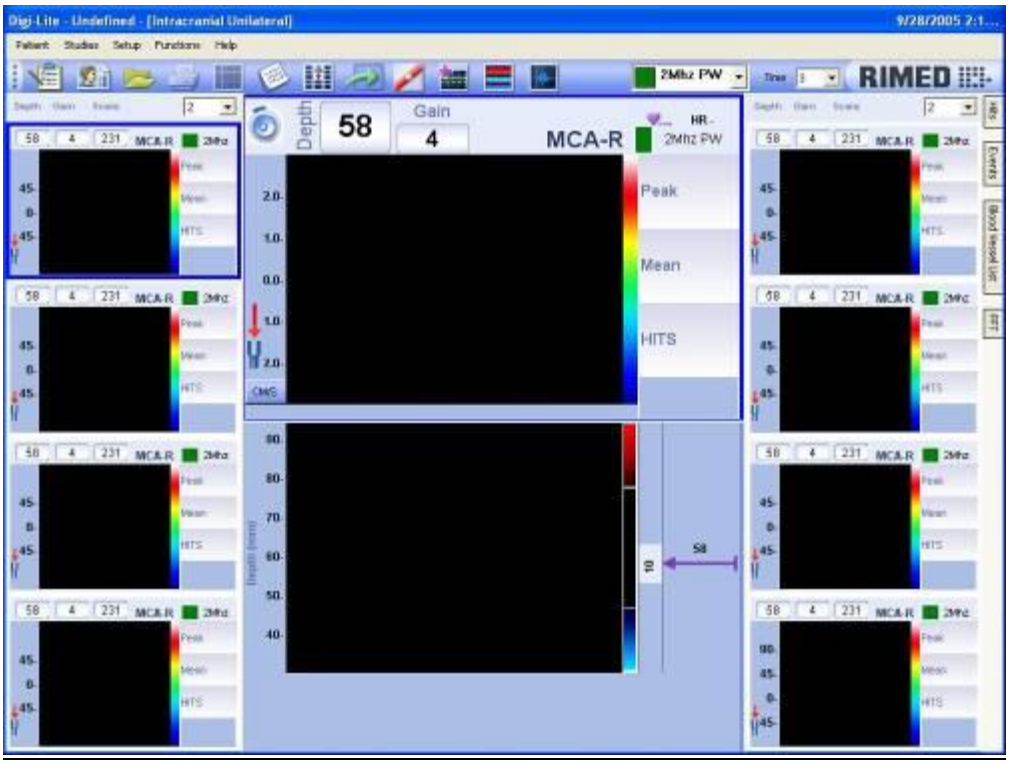


Figure 5-2 Unilateral study with 8 spectrums

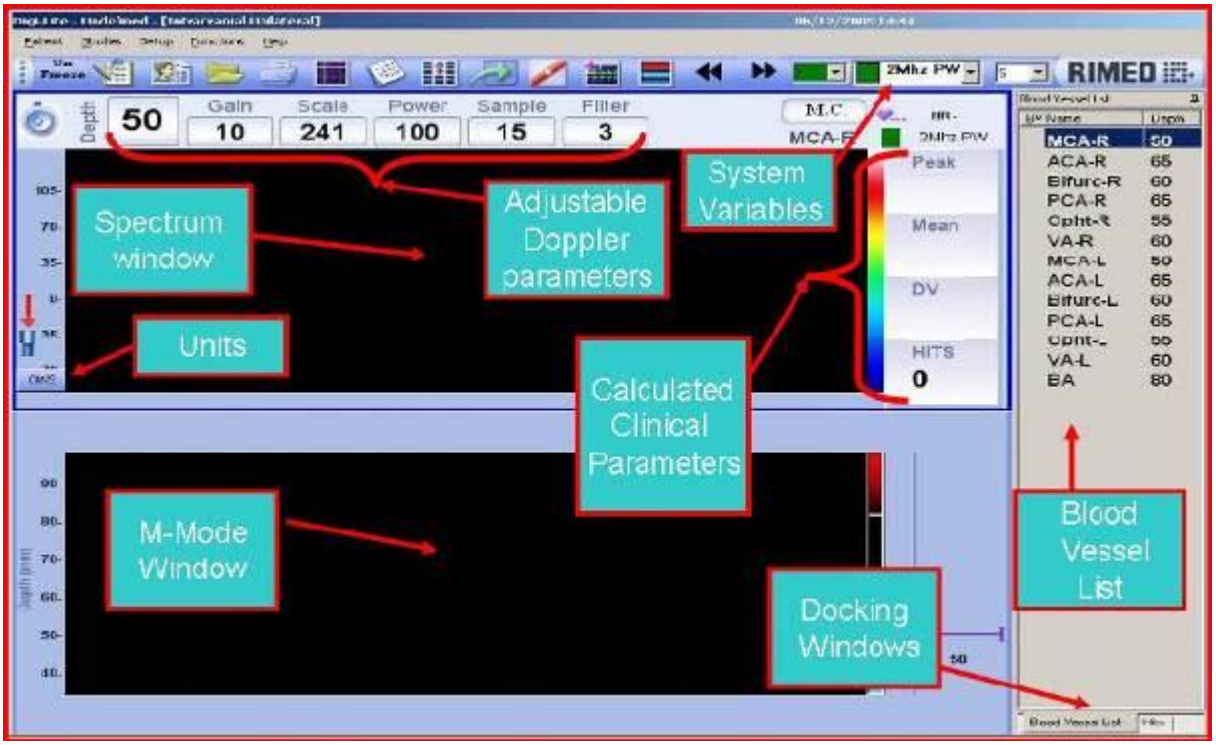


Figure 5-3 Unilateral study main screen

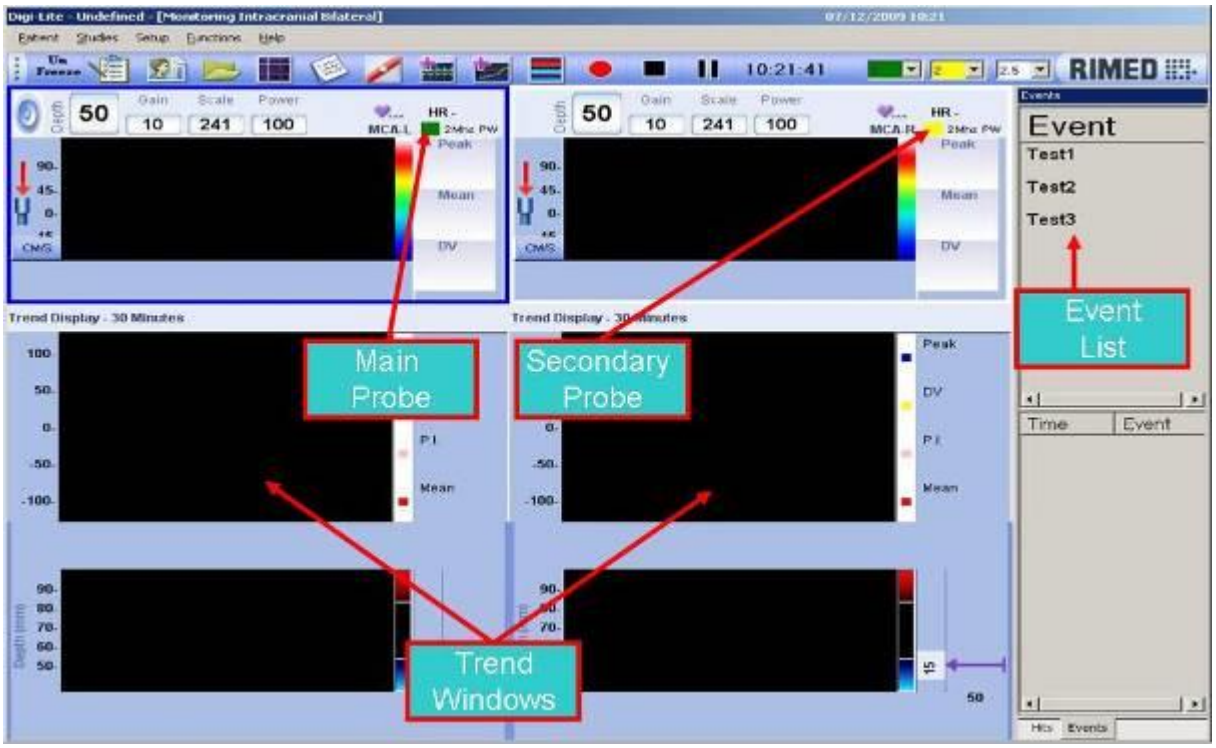


Figure 5-4 Monitoring Bilateral study

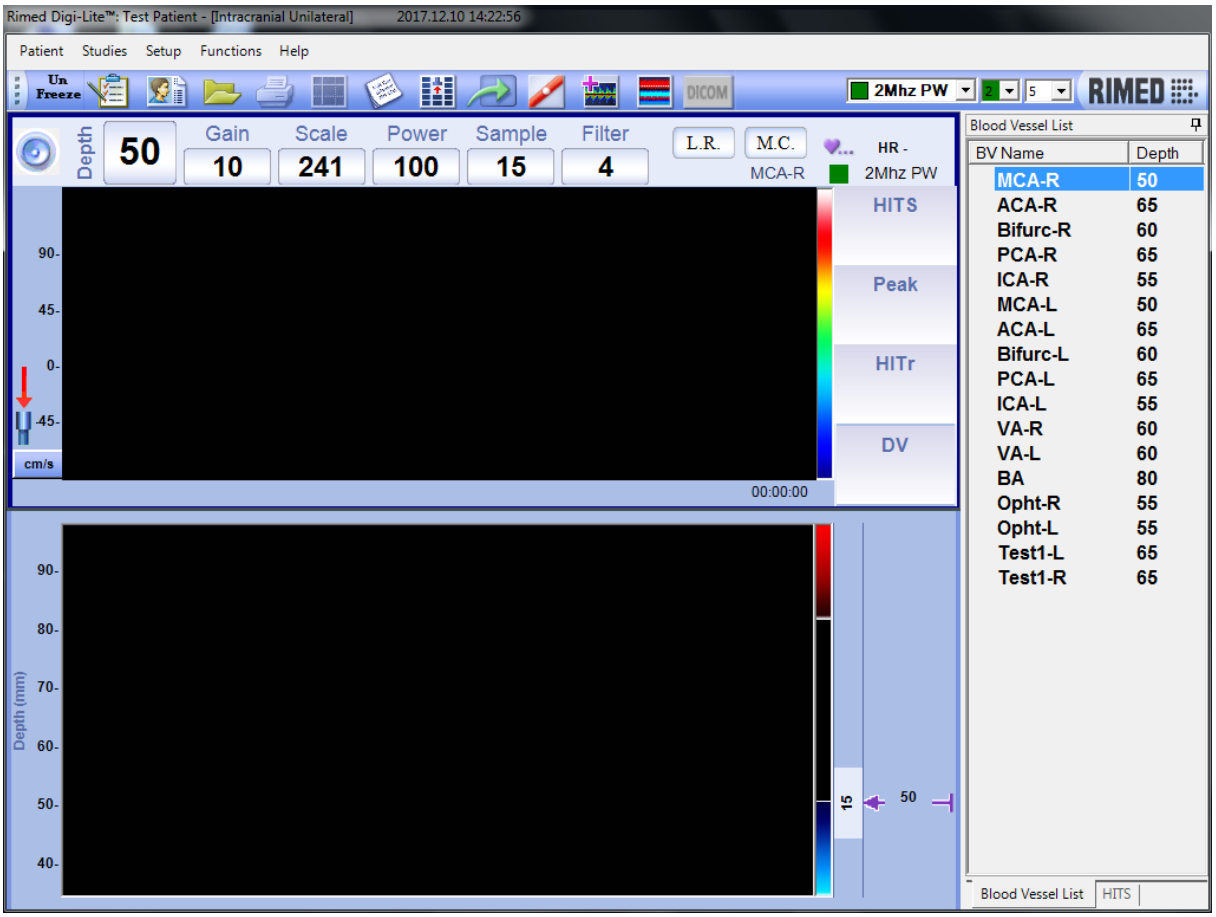


Figure 5-5 Main screen with Blood Vessels List

The Functional Region: The functional region relates to on screen items which can be accessed or controlled by the user.

Patient Name, Study Name, Date and time: The patient bar is the blue bar at the top of the screen which includes the following items: System name, Patient Name and Study Name at the left side; and the date and hour at the right side. The patient name is displayed as defined in the patient details window. If no patient name is entered, "Undefined" appears as the default name.

Menu Bar: The menu bar is the white bar at the top of the screen which includes the following items**:** Patient, Studies, Setup, Functions and Help. Upon clicking on any of these items on touch screen or with the mouse, or pressing MENU and then RTN (RETURN) on the remote control, the respective menu of each item is displayed for user selection. The menu bar contains all the system's items and is used for system configuration and operations which are not typically part of a routine examination.

Tool Bar (Icons): The icon bar is located below the white menu bar. The icons represent frequently-used functions, and can be activated by clicking on them on the touch screen or with the mouse. The function of each icon is displayed in a "balloon" form when the cursor points at the icon. See chapter 5.9 for details. At the right side the following are displayed: Probe changer button, Spectrum Time and Rimed logo. Probe changer button is used to change the probe. Time button is used to display spectrum window time and to change it, if necessary.

Spectrum Windows: The spectrum window, the black window in the center of the screen, is the most important part of the screen. The spectrum window is used for display of the blood flow velocity spectrum, the corresponding spectrum envelopes, the zero line, and the 64 spectrum color codes. To the left of the spectrum window there is a white display region of the Y axis and a picture of the direction of the blood flow relative to the probe. If more than two spectrum windows are open, only one spectrum is displayed big and the others are displayed as small spectrums in right and left side of the big spectrum and M-Mode windows – see *Figure 5-2*

Units: The Units button is located right below the direction indicator and displays the current unit selected. Units can be either in KHz or Cm/s. To toggle between these two options simply click on the "Units" button. In addition to changing the Y axis scale, toggling of the units also displays the clinical parameters in the new unit selected. See Figure 5-3

M-Mode Windows: The M-Mode window is used to display the blood flow energy level along the ultrasound beam at straight line. It is used for quicker find the insonation window, for blood vessel localization and identification and for more accurate emboli detection. The M-Mode window displays Doppler signal energy as function of time and depth. It is a 3D graph: horizontal - X AXIS is time, vertical -Y AXIS is depth and color encoded -Z AXIS is Doppler power and direction. Red colors family represent blood flow direction to the probe and blue colors family, direction away from the probe. Black color represents no flow. The white dotted line in the M-Mode and the arrow located in the right side of the M-Mode represent the depth of the selected spectrum (the big spectrum whose signal is heard on speakers). See Figure 5-3

System Variables: The system variables are located in boxes just above the spectrum window. These variables can be controlled through the remote control or keyboard, and are used to improve insonation. If continuous wave (CW) probes are used the pulse wave (PW) variables are not displayed. See chapter 5.6 and 6.5 for details. In the right side are displayed the name of the current blood vessel, to the left, and the current probe on its right. The probe type is accompanied with a colored square which identifies the activated probe. Above this is displayed the Heart Rate value. See Figure 5-3

Clinical Parameters The clinical parameters are located in boxes to the right of the spectrum screen. These parameters are the outcome of calculations automatically performed on the blood flow spectrum. If no blood flow is detected by the system the boxes remain empty. If only reverse flow is detected, the parameter values appear with a minus sign (–). If both forward and reverse flows are detected, both parameters appear in each box, with the top number relating to the forward flow and bottom number corresponding to the reverse flow. See Figure 5-3

Docking windows: At the right side of the working screen there are 2 docking windows. The docking windows can be fixed to remain open by sticking in the small stab in its right top corner. The docking windows are as follows: Selected Blood Vessels List, HITS Histogram and Events list (in monitoring studies).The blood vessel list displays the selected blood vessels for the present study. If a PW probe is defined for a particular vessel, then the insonated depth is displayed. Blood vessels which have already been insonated appear in blue in the list. The user may select any blood vessel by clicking on its name in the list. See Figure 5-3

Scrolling after "freezing" diagnostic examination: When the user reach a point (by navigating with the arrows) in the examination that he wants to save (Rather then the default point - the "end" point after freeze), he can right click (the mouse should be over the spectrum image) and choose "Update Summary Image". The new data will be auto populating to the clinical parameters, Summary screen images, and the patient reports images and table.

5.3. Touch Screen Options

The Transcranial Doppler System has a Touch Screen option in order to change the parameters by touching the screen directly. Each parameter has two options: in order to increase the user should press the label, and in order to decrease the user should press the number. These Touch Screen options are functional during unfreeze or in freeze before the examination was done and are not functional in load state.

DEPTH: Increase or decrease insonation depth of selected gate.

GAIN: Increase or decrease spectrum gain.

SCALE: Increase or decrease spectrum scale size.

PWR (Power): Increase or decrease power of insonation.

SMPL VOL (Sample Volume): Increase or decrease the sample volume width of insonation.

FILTER: Increase or decrease spectrum filters value.

5.4. Replay

In Replay state the system will display the spectrum and M-Mode windows with the examination that was done on the selected BV:

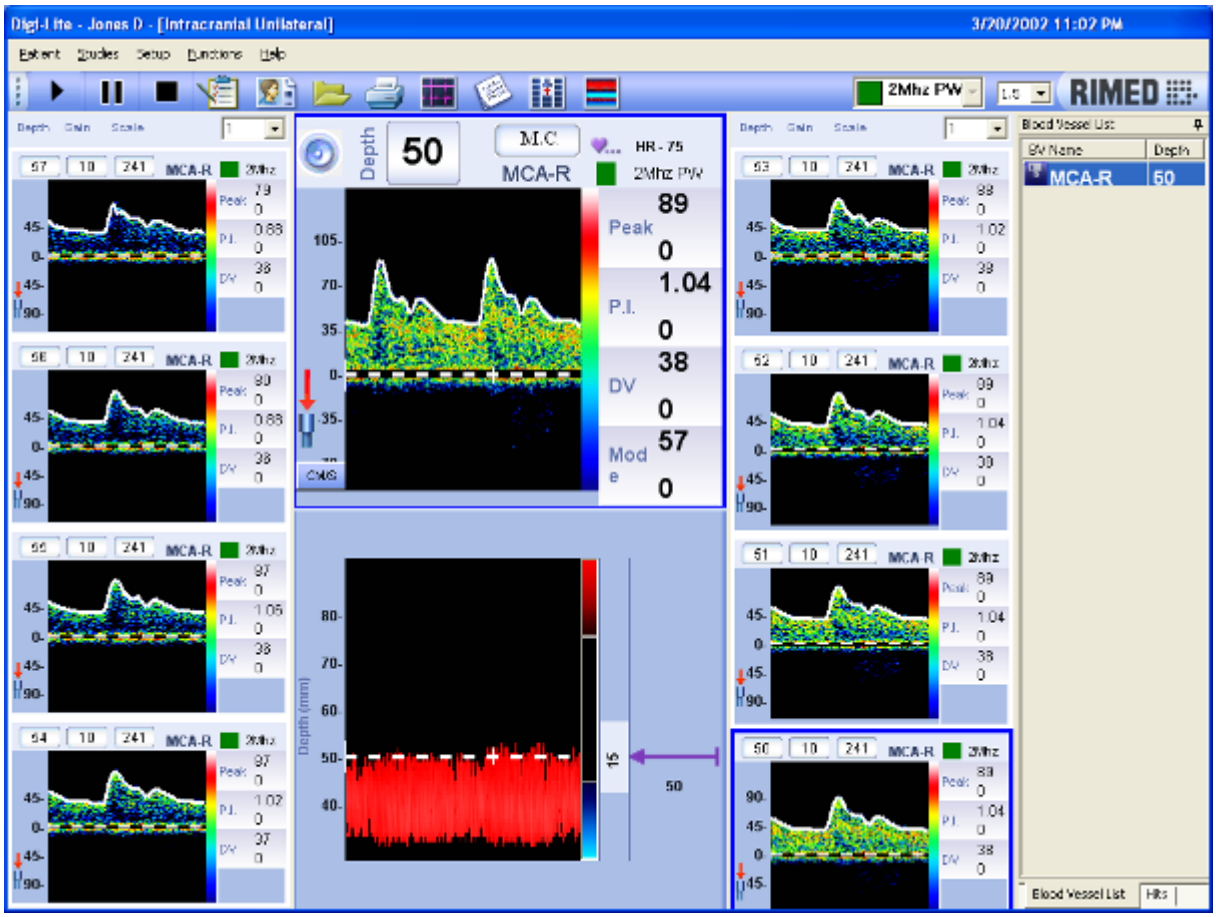


Figure 5-6 Replay

 Start Replay: begin to replay the current displayed examination (spectrum, sound and M-Mode as during examination real time).

 Stop Replay: stop to replay the examination. The spectrum and M-Mode will freeze.

 Stop Replay: stop to replay the examination. The spectrum and M-Mode will freeze.

To replay the examination done on other blood vessel, open the Blood Vessels List docking window and press on other blood vessel name.

 Start Recording: After starting a replay (on the  icon) the recording icon appears. Clicking on it starts the recording of an WMV file (Windows Media Video) and it will blink with red and black while the recording is active. Additional click on it will stop the recording and an option to save the file will appear.

5.5. The summary screen

For each study type (except monitoring) there is a dedicated summary screen. The summary screen includes all the insonated spectrums, and an anatomical picture in the center of the screen. All right sided vessels are displayed on the right hand side of the screen, and all left sided vessels on the left. Vessels which have no particular side, such as the basilar artery, are displayed in the middle below the anatomic picture.

There is no limit to the number of spectrums from a particular vessel that can be stored in the summary screen. If more than 5 spectrums are stored on one side, the user needs to scroll the screen using the scroll bar on the right in order to view the rest of the spectrums.

The order of display is according to the predefined blood vessel list shown in the spectrum screen. The spectrum display order is such that always right sided vessels are displayed at the same level of their corresponding left sided vessels. You can move a spectrum to other location in the same side, by drugging it.

To return to the spectrum screen press the “Return” icon (the picture of back arrow). To replay or view any particular spectrum in more detail, simply double click on the selected spectrum and it opens in the spectrum screen.

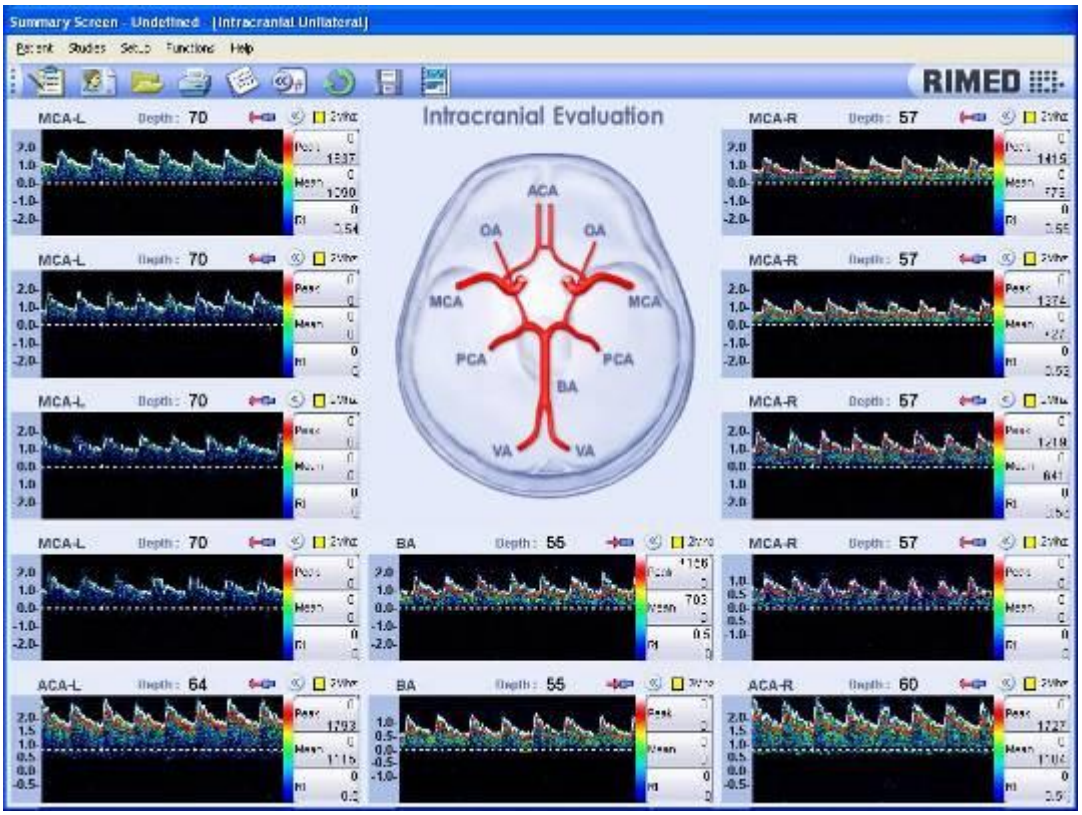


Figure 5-7 Summary Screen

 Expand clinical parameters: gives the option to display 3 or 6 clinical parameters in summary screen

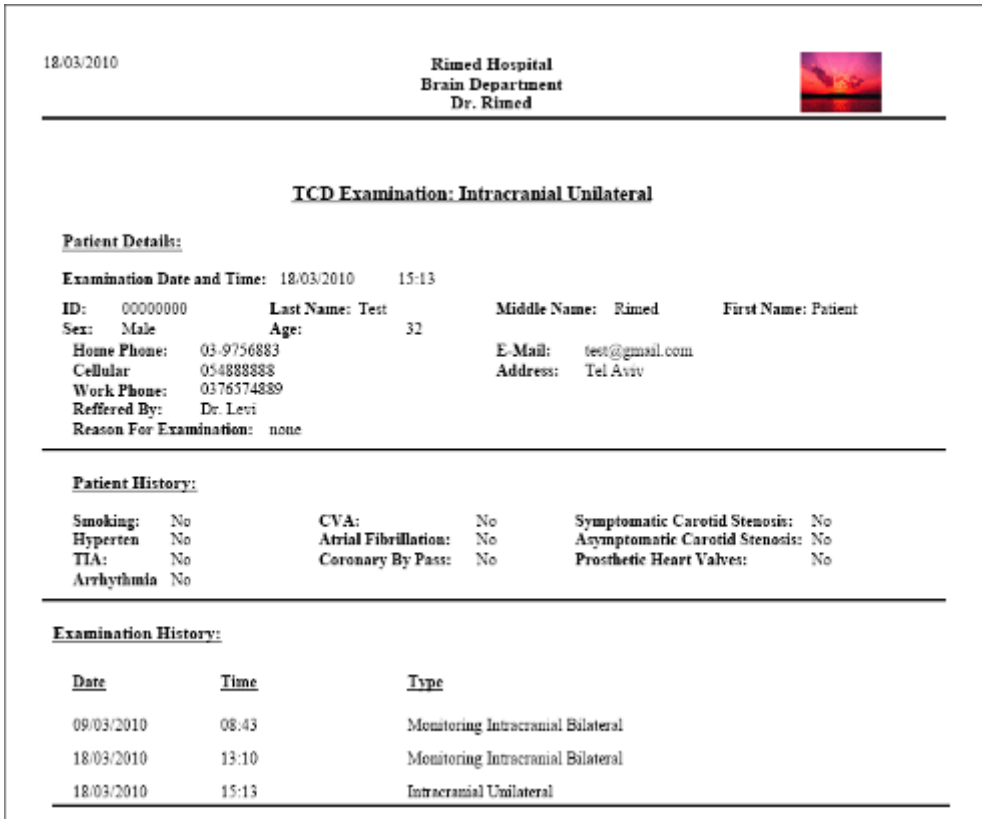
 Return: to return to spectrums screen.

 Examination Notes: To add notes to the current examination.

 Patient Report: To display the patient report of the current examination.

5.6. Patient report

The patient report contains general information about hospital, operator and patient together with examination details, pictures and clinical parameters. All this information can be displayed or only part of it, according to user configuration. For more details on user configuration options, see “Setup Configuration”.



18/03/2010

Rimed Hospital
Brain Department
Dr. Rimed

TCD Examination: Intracranial Unilateral

Patient Details:

Examination Date and Time: 18/03/2010 15:13

ID: 00000000 **Last Name:** Test **Middle Name:** Rimed **First Name:** Patient
Sex: Male **Age:** 32
Home Phone: 03-9756883 **E-Mail:** test@gmail.com
Cellular 054888888 **Address:** Tel Aviv
Work Phone: 0376574889
Reffered By: Dr. Levi
Reason For Examination: none

Patient History:

Smoking:	No	**CVA:**	No	**Symptomatic Carotid Stenosis:**	No
Hyperten	No	**Atrial Fibrillation:**	No	**Asymptomatic Carotid Stenosis:**	No
TIA:	No	**Coronary By Pass:**	No	**Prosthetic Heart Valves:**	No
Arrhythmia	No				

Examination History:

Date	Time	Type
09/03/2010	08:43	Monitoring Intracranial Bilateral
18/03/2010	13:10	Monitoring Intracranial Bilateral
18/03/2010	15:13	Intracranial Unilateral

Figure 5-8 Patient Report

5.6.1. United Patient Report (Digi-Lite™+IP)

Another unique option in our TCD system is the possibility to merge between the DL final patient report and the IP images.

In order to do the merge you will need first of all to enter to the TCD software and choose setup→report generator wizard→press next→press next→choose in the next window the option 2 images per page and then press next → and then press finish. When asked to press OK.(See figure 5-9)

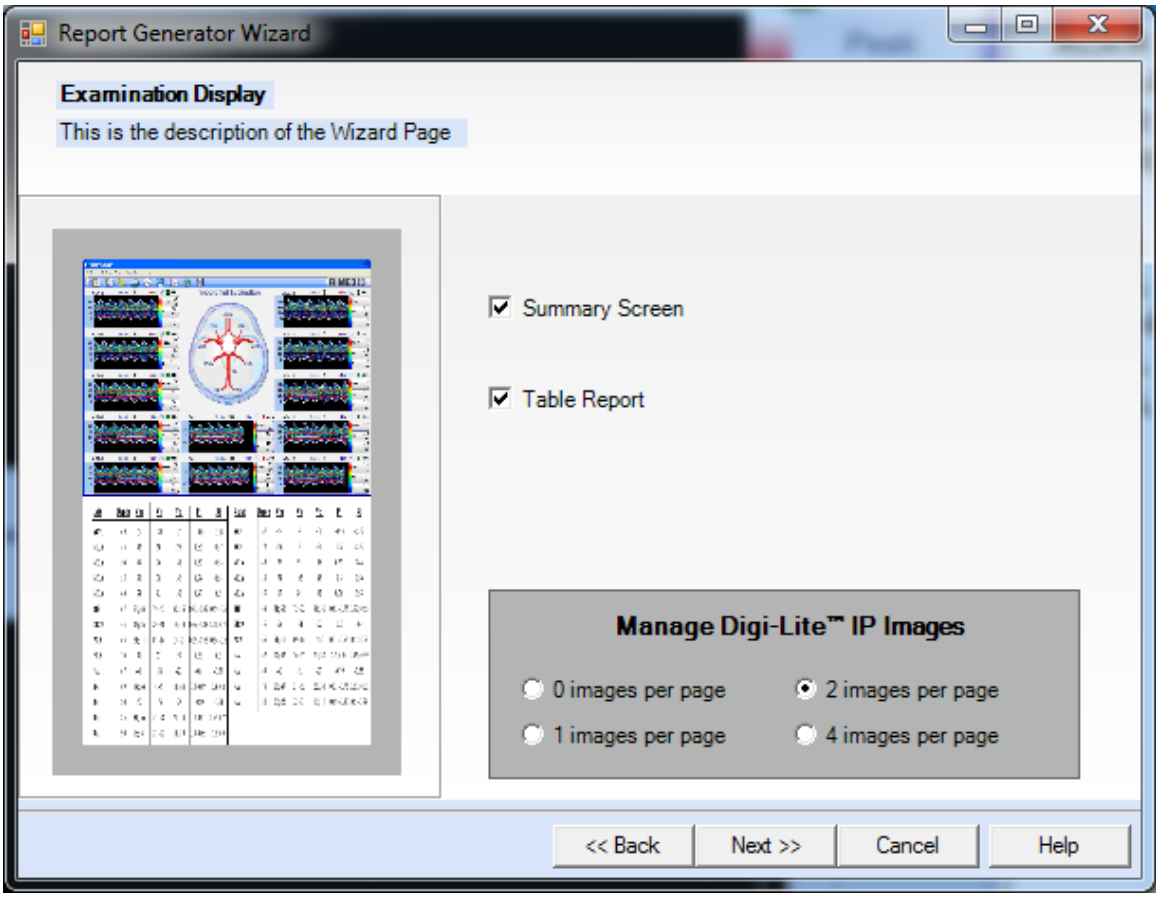


Figure 5-9 United Report

Steps:

1. Go to the TCD software create New Patient and do a test in order to create Summary Screen for the patient then save the test.

2. Go to the IP software and create New Patient (the same name you created in the TCD test) then do a test and save it with quick save option in the button toolbar (number 9 

).

3. Go back to the TCD software and load the test that you made in stage 1.

4. Go to the final patient report (from the summary screen press on the  button) and go to the page where you see the headline is Manage DIGI-LITE™ IP images (See figure 5-10)

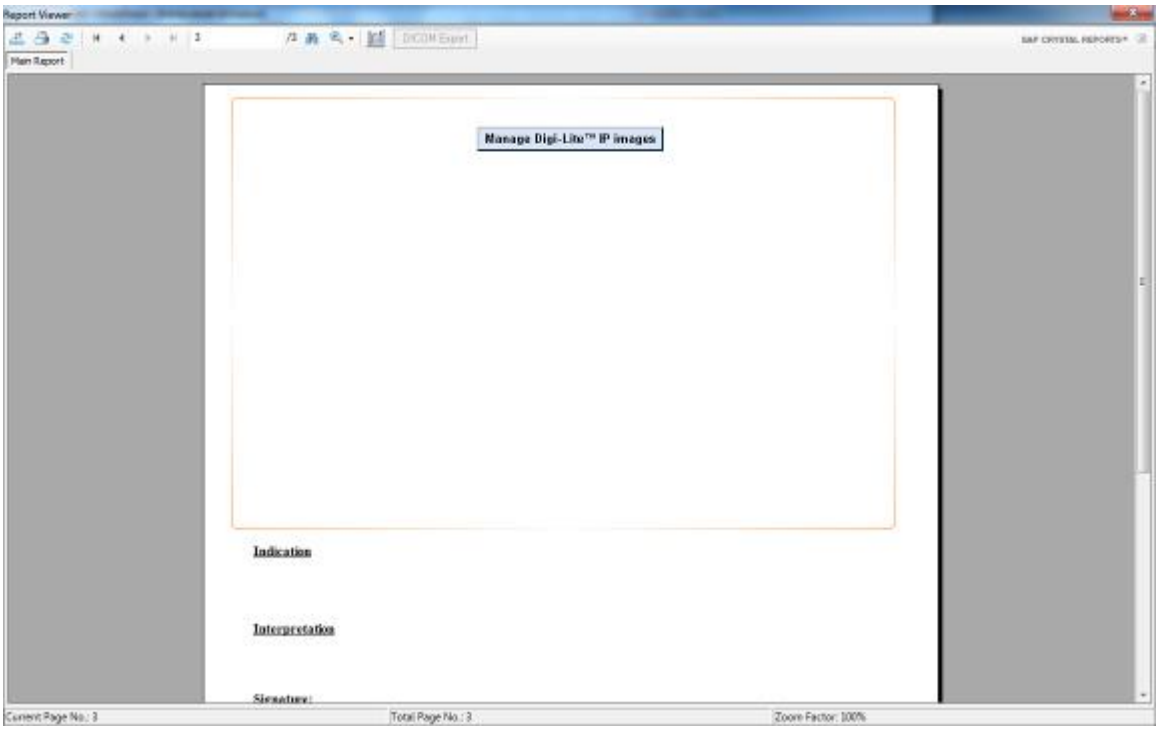


Figure 5-10 Manage IP Images Page

press the button and then press on the + icon and add the images from the test that you have done in stage 2.

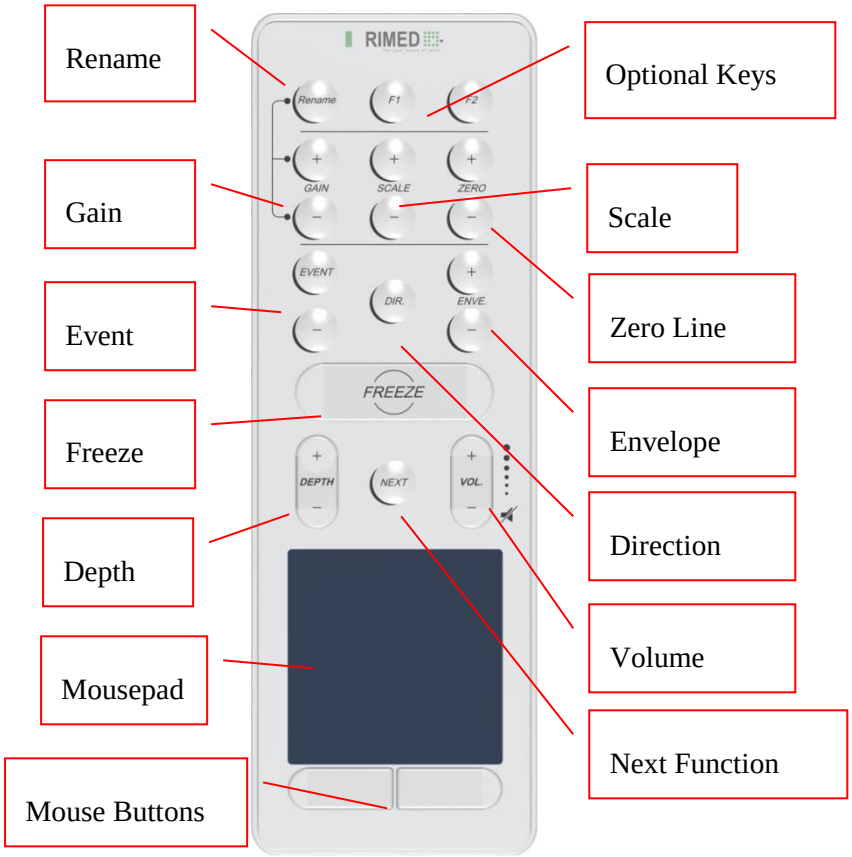
5. After you arrange the images press on the save button in the dialog box.

6. After you finish to do all changes please press on the SAVE ICON  near to the DICOM EXPORT in the upper toolbar.

7. you will get a message that says the report was saved.

5.7. The remote control

The remote control allows you to perform important on-line system functions, especially those needed to obtain and manipulate insonated blood velocity spectrums. Although all of the remote control functions can be also performed using the on-screen features or the keyboard, the remote control is designed to allow you to operate the system without having to be next to the computer. This is particularly useful when examining the patient. There are two types of remote controls, both presented below, first the new remote control and then the previous version:



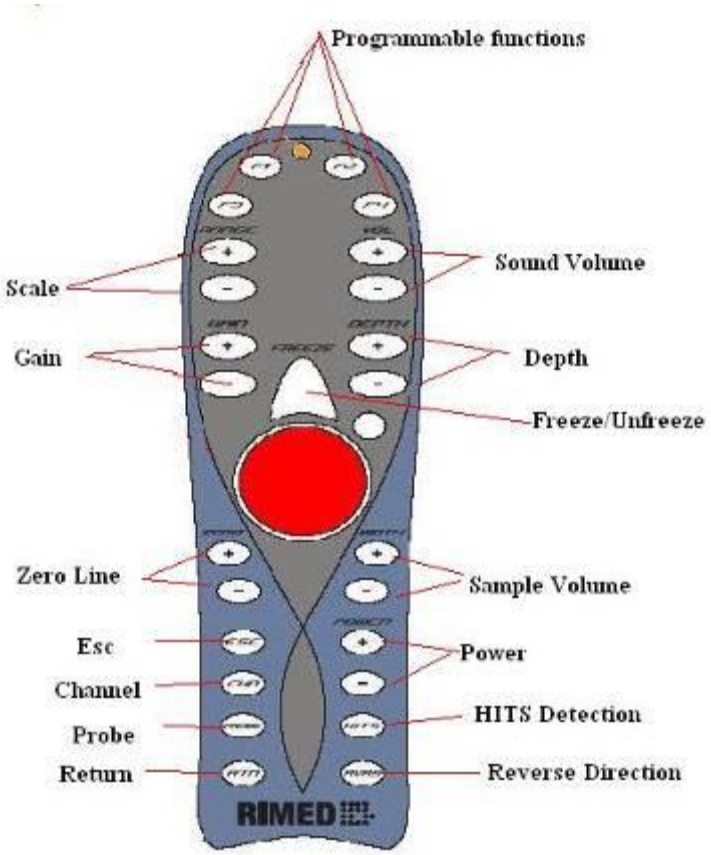


Figure 5-*11 Remote Control*

The new version of the remote control provides five groups of remote control functions.

- User Programmable keys
- Doppler parameters
- Frequently used functions
- Main system functions
- Mouse functions

User Programmable keys

New version:

The new remote control has two buttons – F1, F2 – that can be assigned with any function from the list below throughout the setup. The options are: **Print, Record WMV, Next BV, Previous BV, HITS Detection, Add Spectrum, Send to DICOM, Export Image, PU and Return BV.**

Previous Version

F1- **NEXT FUNCTION**: Perform next function as defined by the user

F4- **Mute sound volume**

Doppler parameter keys

The Doppler parameter keys control the Doppler parameters operation. Each parameter has two keys: + to increase, and – to decrease. Excluding the zero line option, these keys are functional during unfreeze or in freeze before the examination was done and are not functional in load state.

SCALE (Y axis scale**):** Increase or decrease the frequency scale (range or PRF).

VOL (Volume): Increase or decrease speaker sound volume.

GAIN: Increase or decrease spectrum gain.

DEPTH: Increase or decrease insonation depth of selected gate (PW**:** probes only).

FREEZE: Toggle between FREEZE and UNFREEZE states

ZERO: Increase or decrease the zero line position of the selected gate.

SMPL VOL (Sample Volume): Increase or decrease the sample volume width of insonation (PW**:** probes only)

PWR (Power): Increase or decrease power of insonation (PW**:** probes only).

Frequently used function keys

CHN (Channel): This key is used to toggle between the open windows displayed in study types with more than one window (both during freeze and unfreeze).

RVRS: This key is used to reverse the direction of the flow on the spectrum during unfreeze.

PROB: This key is used to change probe (1 MHz, 2 MHz, 4 MHz, 8 MHz).

HITS: Activates/ deactivates automatic emboli detection function.

Main function keys

This group of keys is used to perform main system functions.

ESC: This is equivalent to the keyboard <Esc> key, and is used to exit the summary screen display or the cursor mode.

RTN: This is the equivalent of the keyboard <Return> key, and is used to confirm selections from the screen menus.

FREEZE: This key is equivalent to the <Space> bar on the keyboard, and is used to toggle between the freeze and unfreeze states.

5.8. Keyboard shortcuts

Selected important system functions can be performed, in addition to operation of the remote control or on-screen functions, also using dedicated keyboard keys. The selection of keyboard keys functions was done to facilitate system operation. The user is not required to memorize the function of each key. However, it is recommended that the user remembers the functions of frequently used functions. Most key functions are logical, i.e. <M> for Mute, etc. There are two main groups of keyboard functions**:** those that are active during the freeze state and those that are active only during unfreeze state. Several keys are functional during both periods.

Key	Function in Freeze state	Function in Unfreeze state
SPACE	Toggle to Unfreeze state	Toggle to Freeze state
ALT SHIFT I	Change Current Probe	Change Current Probe
CTRL C,	Toggle display spectrum	Toggle display spectrum
M	Mute (Silence the speakers)	Mute (Silence the speakers)
ALT SHIFT O	Toggle between open windows	Toggle between open windows
CTRL H	Emboli (toggle activation of emboli)	Emboli (toggle activation of emboli)
Alt	Select Menu	
X		Toggle display of peak mode envelope
Ctrl X		Toggle display of reverse mode envelope
Z		Toggle display of peak envelope
Ctrl Z		Toggle display of reverse envelope
Esc	Remove cursor and distribution, return to spectrum screen (or load screen) from summary screen.	
F1	Depth down	Depth down
F2	Depth up	Depth up
F3	Gain down	Gain down
F4	Gain Width up	Gain Width up
F5	Scale down	Scale down
F6	Scale up	Scale up
F7	Power down	Power down

F8	Power up	Power up
F9	Sample volume down	Sample volume down
F10	Sample volume up	Sample volume up
F11	Filter down	Filter down
F12	Filter up	Filter up
1	Zero line down	Zero line down
2	Zero line up	Zero line up
+	Volume up	Volume up
–	Volume down	Volume down

5.9. Menu bar

DIGI-LITE provides commands encompassing all system functions in the five menus displayed in the menu bar at the top of the screen. Each menu provides a related set of functions.

5.9.1. Patient menu

Patient menu provides operations for patient file creation, modification, search and delete. It also provides backup, export and some printer functions. In some windows programs these functions are referred to as “file” functions. (See figure 5-12)00

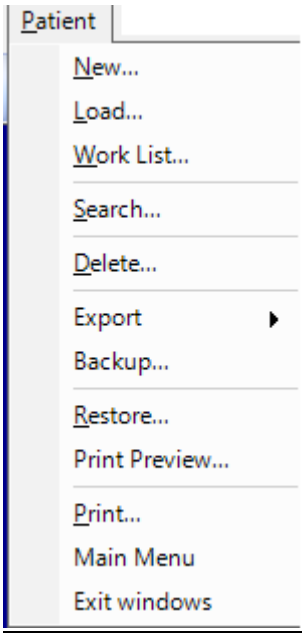


Figure 5-12 Patient Menu

New: Creates a new patient file, opening the Patient Details dialog box. Make sure you have saved any previously recorded data before choosing this option. (chapter 6.3.1)

Load: Allows you to load (open) the information for any patient stored in the database. When you select this option, the Load Patient dialog box opens. (Chapter 6.3.2)

Work List: Allows you to load examinations to preform over scheduled patients. The Worklist window is displayed.

Search: Allows you to search patients according to different entries. When you select this option, the Load Patient dialog box opens. (Chapter 6.3.2)

Delete: Allows you to delete a patient from the database. When you select this option, the Delete Patient dialog box opens.

Export: Provides options for you to export the patient information for use with other software packages. You can export picture files or text files. You can export trends to excel software.

Backup: Allows you to backup patient data to an external device. You must insert a diskette into the floppy drive to use this option.

Restore: Recovers or loads patient information from an external device. You may use this option when looking for old patient files that were deleted.

Print Preview: This is used to preview the examination as it will be printed in Print Screen mode

Print: Prints in Print Screen mode.

Printer Setup: Allows configuration of the printed paper (orientation, size, etc.)

Exit DIGI-LITE(MAIN MENU): Exits the DIGI-LITE program and enters the program manager of the Windows operating system.

CAUTION

If you exit the DIGI-LITE program, do not reopen the program before shutting down Windows and restarting the TCD machine.

Exit Windows: You should select this option before shutting down the computer.

CAUTION

Use software shut down and avoid turning the unit off without exiting windows. Explain this to all users of the instrument. Otherwise, the windows environment can be damaged.

5.9.2. Study type menu

Study type allows you to select the preferred operation mode. The study types are discussed in detail in "Selecting study types". See Figure 5-13

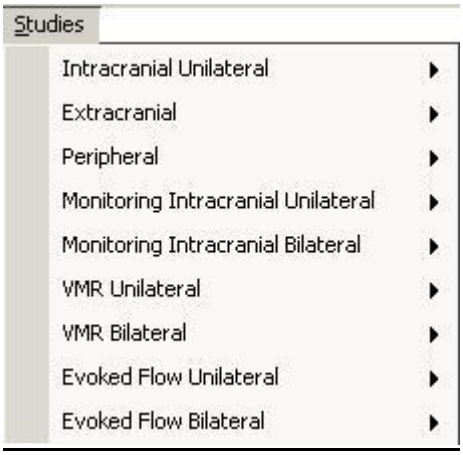


Figure 5-13 Studies Menu

Intracranial Unilateral: This study type is used for intracranial unilateral examination with one probe.

Extracranial: This study type is used for Extracranial examination with one probe.

Peripheral: This study type is used for peripheral examination with one probe

Monitoring Intracranial Unilateral: This study type is used for continuous monitoring in unilateral study and recording of TCD parameters. (Chapter 8)

Monitoring Intracranial Bilateral: This study type is used for continuous monitoring in bilateral study and recording of TCD parameters. (Chapter 8)

VMR Unilateral: This study type is used to perform vasomotor reactivity tests in unilateral study and calculates VMR parameter. Chapter 9 gives full information about this study type.

VMR Bilateral: This study type is used to perform vasomotor reactivity tests in bilateral study and calculates VMR parameter. Chapter 9 gives full information about this study type.

Evoked Flow Unilateral: This study type is used to perform Evoked Flow tests in unilateral study and calculates flow change parameter. Chapter 10 gives full information about this study type.

Evoked Flow Bilateral: This study type is used to perform Evoked Flow tests in Bilateral study and calculates flow change parameter. Chapter 10 gives full information about this study type.

CAUTION

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

5.9.3. Setup menu

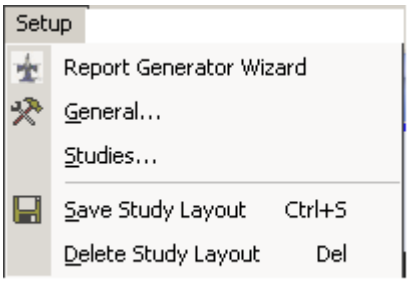


Figure 5-14 Setup Menu

Setup allows you to set custom configurations for the DIGI-LITE system. You normally do not use these functions during diagnostics, but rather when you want to change how the system is setup. Using the setup menu is discussed in Setup Configuration. (Chapter 11)

Report Generator Wizard: This wizard is used to configure the patient report.

General: This menu is used to configure general system parameters.

Studies: This menu is used to configure each one of the studies separately.

Save Study Layout: This option enables to save a favorite layout by the user.

Delete Study Layout: This option enables to delete a layout by the user.

5.9.4. Functions menu

Functions are used to perform operations on the spectrum being displayed.

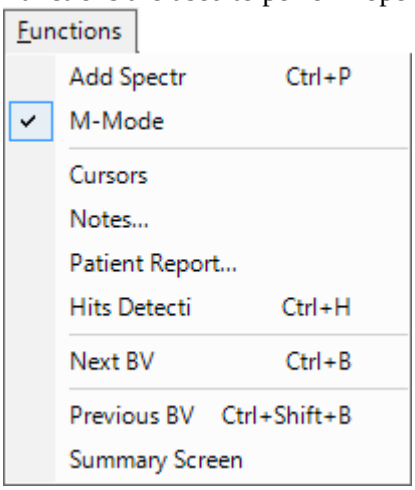


Figure 5-15 Functions Menu

Actually, the functions menu can replace icon operation, if the user prefers menus. As usual with Windows software, you can use the keyboard, clicking Alt + the underlined letter, to open a specific menu. Continue pressing the “ALT” key, while clicking on other letters as needed to open submenus. (See figure 5-15)

Using the functions menu is discussed in chapter 12.

5.9.5. Help menu

Help provides version information on DIGI-LITE and an on-line help system. The on-line help provides most of the material contained in this user manual. (See figure 5-16)

Figure 5-16 Help Menu

Content: Opens the on-line help menu content.

Index: Opens the index of all the items in the software.

Search: Gives the possibility to search specific items.

What is this? : This menu is used to display help of an item by pointing at it with the mouse.

About: Gives the copyright information and version number of your DIGI-LITE system, displayed at the bottom left corner.

5.10. Right click menu

In addition to the menu bar, the DIGI-LITE provides also right click commands for the important software items. The right click menu is specific per item, and it contains the most used actions in the specific situation. The options in the menus are enabled or not, according to system state.

5.10.1.Right click on Spectrum window

By clicking the right mouse button on a specific spectrum window the following menu will appear.

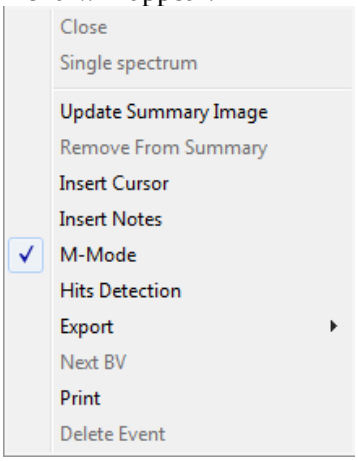


Figure 5-17 Right Click on Spectrum

Update Summary Image: Adds the spectrum to the Summary Screen. Active in Freeze state, after the examination was done, or in LOAD state.

Single Spectrum: Closes multiple spectrums to one in a single click.

Insert Cursors: Insert cursors to the spectrum. Active in Freeze state, after the examination was done, or in LOAD state.

Insert Notes: Insert notes related to the spectrum. Active in Freeze state, after the examination was done, or in LOAD state.

M-Mode: Open/ Close (toggle) M-Mode window related to the spectrum. Always active.

HITS Detection: Enable/ Disable (toggle) HITS detection function for the spectrum. Always active.

Export : Send spectrum to: Active in Freeze state, after the examination was done, or in LOAD state.

Next BV: Examine the next blood vessel from the blood vessels list, or display the examination done on next blood vessel. Active in Freeze state.

Print: Send the spectrum to print in order to print it according to print configuration. Active in Freeze state, after an examination was done, or in LOAD state.

Close: Close the spectrum window. Active always.

5.10.2.Right click on M-Mode window

By clicking the right mouse button on a specific spectrum window the following menu will appear.

Figure 5-18 Right Click on M-Mode

Close: Close the M-Mode window. Active always.

5.10.3.Right click on Summary screen window

By clicking the right mouse button on the summary screen – on the picture in the middle of the screen, the following menu will appear. Summary Screen is active in Freeze state, after an examination was done, or in LOAD state.

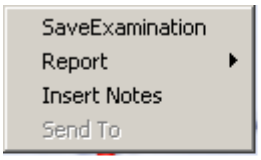


Figure 5-19 Right Click on Summary Screen

Save Examination: Save the current summary screen

Report: Opens patient report for the current summary screen. The following options are available:

Patient Report: Opens patient report for the current summary screen. The following options are available:

Examination Summary: Print summary screen:

Insert Notes: Insert notes related to the spectrum. Active in Freeze state, after the examination was done, or in LOAD state.

By clicking the right mouse button on the summary screen – on a specific spectrum, the following menu will appear

Figure 5-20 Right Click on Spectrum in Summary Screen

Replay: Enlarge the selected spectrum and go to replay state.

Delete Spectrum: Remove the selected spectrum from the actual summary screen. This feature is applicable for the main screen while a recorded BV is selected.

5.11. Toolbar

The most commonly used items in the menu are shown in the toolbar. (See figure 5-21) Instead of selecting items from the menus, you can simply click on the icon in the toolbar to perform the same function. When you hold the cursor above any of the icons, DIGI-LITE displays a bubble giving a quick description of the icon.

This section describes the icons in order of appearance on the toolbar. The toolbar appears to the right of the patient name. In this illustration, the patient's name is Smith John.

Figure 5-21 Toolbar

Freeze/Unfreeze Button: Instead of click on the spectrum image you can now use this new button

Study type: The Study type icon is pictured as a register. Clicking on this icon opens the Study type dialog box. (See chapter 7.3)

New Patient: Pictured as a man face. Clicking on this icon is the same as selecting NEW from the PATIENT menu. (See chapter 7.2.1)

Load: The Load icon is pictured as an open folder. Clicking on this icon is equivalent to selecting LOAD from the PATIENT menu. (See chapter 7.2.2)

Print: The Print icon is pictured as a printer. Clicking this icon is equivalent to selecting PRINT from the FUNCTIONS menu. (See chapter 7.10)

Cursors: The Cursors icon is pictured as a black screen with two pairs of cursors. Clicking this icon is equivalent to selecting CURSORS on the FUNCTIONS menu. (See chapter 13)

Notes: The Notes icon is pictured as a notepad. This is the equivalent to selecting NOTES from the FUNCTIONS menu. (See chapter 12)

Summary screen: The summary screen icon is pictured as a minimized summary screen with a big probe and red arrow in the middle. Upon clicking on this icon the spectrum display changes into the summary screen display. To return from the summary screen display back to the spectrum display press the ESC key.

Next: pictured as a curved arrow. Clicking this icon will perform NEXT FUNCTION as selecting NEXT FUNCTION from the FUNCTIIONS.

HITS: The HITS icon is pictured as a red blood vessel with a small white embolus in the blood stream. Clicking this icon is equivalent to selecting HITS from the FUNCTIONS menu. (See section 11.3.3)

Add Spectrum: The Add Spectrum icon is pictured as a minimized spectrum with a big red plus sign at its left top corner. Clicking this icon is equivalent to selecting Add Spectrum from the FUNCTIONS menu. (See chapter 12)

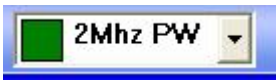
M-Mode: The M-Mode icon is pictured as a minimized M-Mode display. It is a toggle function that display or close M-Mode display. Clicking this icon is equivalent to selecting M-Mode from the FUNCTIONS menu. (See chapter 12)

Scroll Option: This buttons enables to scroll through the spectrum window.

Dicom: This button sends the image spectrums to PACS server in Dicom format.

5.12. Probe, Time display and Analog gain

At the right side of the toolbar there are 2 dialog boxes: Probe and Display speed.



Probe: Displays the actual active probe and enables changing probes. Each probe is represented by a color displayed here in a small rectangle. The same appears on the probe connector. The probe is characterized by its frequency (2MHz in this case) and type (PW or CW).

Display Speed (seconds): Determines how many seconds of the ultrasound spectrum are shown on the screen. This box enables changing display speed. from 2.5 seconds in unilateral and 1 second in bilateral.

Analog gain: Determines the analog gain for the probe. There are 4 analog gain levels (from 1 to 4). 1 is for minimal gain and 4 for maximal gain. This box enables changing analog gain to receive the best spectrum signal: if the signal is too weak choose 4, and if it's too strong, choose 1. The default is 2 and is recommended for regular signals.

6. Performing Diagnostic Studies

This paragraph contains a brief description of a general diagnostic examination, according to system existent setup. The setup can be factory setup or changed by each user according to his needs. After defining the setup, the users can perform different diagnostic examinations.

6.1. Turn ON system

6.2. Define patient

Define patient by using one of the following three ways:

6.2.1. Define New Patient.

Define New patient as detailed in para.*7.2.1 Adding a new patient*

6.2.2. Load existent patient

Load existent patient as detailed in Para. *7.2.2 Loading or searching for an existent patient*

6.2.3. Search for a patient

Search for a patient according to specific characteristics, as detailed in Para. *7.2.2 Loading or searching for an existent patient*

6.3. Define the Study

6.3.1. Define new study type

Define new study type as detailed in Para. *7.3 Save Study*

6.3.2. Open existent study

Open existent study as detailed in Para. *7.3 Selecting study type*

6.4. Examine the blood vessels

Examine the blood vessels according to the blood vessel list defined for the selected study, as follows:

6.4.1. Press UNFREEZE

Press UNFREEZE and find the first blood vessel in the blood vessels list (for blood vessel list see para.*11.3.1 Select blood vessels*), as follows:

6.4.1.1. For faster finding and identification of the blood vessel, use M-Mode window

Search the depth with maximum energy in the vicinity of the predefined depth of the first blood vessel. Press on screen to automatically change the depth of the active spectrum.

6.4.1.2.Find the Doppler variables for the best insonation

If necessary change GAIN, DEPTH, ANALOG GAIN, SCALE, POWER, SAMPLE VOLUME, FILTER to receive the best signal and the lower noise possible.

6.4.1.3.Keep the probe in the best location for few seconds

Keep the probe in the best location, as found in the precedent step, for few seconds. The time is according to active spectrum time defined in setup (see Para. *5.2 Main screen*). When at least a full spectrum window of good and stable signal, with clinical parameters is displayed, you can press FREEZE.

6.4.2. Press FREEZE

Press FREEZE and then press Next Blood Vessel (see Para. *12 Functions*).

6.4.3. Repeat step 6.4.1 and 6.4.2

Repeat step 6.4.1 and 6.4.2 for all the blood vessels in the blood vessels list

In order to save time it is possible to press only once for two actions: Next bv and UNFREEZE .in order To do this the user must define the function Next Function to perform these two functions automatically (see Para. *11.2.4 Next Function*)

6.5. Open Summary Screen

If you want to edit the examination, open the Summary Screen after performing the examination on all the blood vessels in the list. In the Summary Screen you can delete or move examinations.

6.6. Replay the examination

Right click on the spectrum to replay. Press PLAY

6.7. Replace the spectrum in the Summary Screen, if needed

If during examination replay you want to replace the spectrum that was initially in the Summary Screen, perform as follows:

- Replay the examination
- Press PAUSE when you see the best spectrum. The replay will stop
- Right click on spectrum and press Update Summary Image

This option is available also after loading a study.

6.8. Rename BV, if needed

If after performing insonation or loading a recorded study you decide to rename the BV to a different one, it is possible with right clicking the BV and "Rename"/ using the "Rename" function in the remote control.

6.9. Recalculate Clinical Parameters if needed

If during examination replay you want to replace the automatic clinical parameters calculations by clinical parameters manually calculated, perform as follows:

- Replay the examination
- Press PAUSE when you see the best spectrum. The replay will stop
- Press on MC (Manual Calculations) button. The software will prompt you to insert CURSORS
- Insert CURSORS
- Put one horizontal CURSOR on Peak Systole level and the other on End Diastole level
- Press MC Button again. The software will replace the old automatic clinical parameters with the new manually calculated clinical parameters
- Right click on spectrum and press Update Summary Image

This option is available also after loading a study.

6.10. Edit Summary Screen

Repeat the steps 6.5, 6.6 or 6.7 for all the blood vessels in the examination, if necessary

6.11. Open Patient Report

Add Indications and Interpretations, if needed.

Print or export the patient report.

6.12. Save the examination

6.13. To perform other study for the same patient

To perform other study for the same patient, repeat steps 6.3 to 6.11 for next study.

6.14. To perform examination on other patient

To perform examination on other patient, repeat steps 6.2 to 6.11 for next patient.

7. Using the DIGI-LITE system

To use DIGI-LITE, the normal sequence of events is as follows (for a diagnostic examination):

1. Turn on the computer.
2. Choose a study type.
3. Select or define a patient.
4. Insonate the blood vessels, following the order in selected BV's list.
5. View the blood vessel summary screen and add your diagnostics, remarks or comments.
6. Save and Print the results.

These steps and other optional procedures are described in detail in this chapter.

CAUTION

Always handle transducers with care.

CAUTION

Do not drop or bang the transducers.

CAUTION

Clean the probes with a clean cloth or tissue paper at the end of each day to remove remains of gel. Gel that dries on the plastic might damage it.

WARNING

Do not immerse transducers in water or any other fluids.

7.1. Entering DIGI-LITE

To start the DIGI-LITE application, simply turn on your computer. The monitor automatically displays the test working screen of the DIGI-LITE.

The DIGI-LITE operates under Microsoft Windows 7 operating system
Configuring the system

The DIGI-LITE system contains a number of dialog boxes which allow you to configure the system display and printout.

For a full description of all the configuration dialog boxes and parameters, see SETUP CONFIGURATION (Chapter 11).

7.2. Creating and selecting a patient

The Patient menu is used to handle all functions that deal with patient management, such as saving, loading and deleting of files or patients, and handling of the patients' database.

7.2.1. Adding a new patient

1. To add a new patient, Select New from the Patient Menu. The Patient Details form, shown below, appears. (see figure 7-1)
2. Fill in the relevant patient information by typing on the keyboard. You **must** fill in an identification number. All other fields are optional.
3. You move from one field to the next by pointing the mouse or pressing the tab button.
4. At the bottom side of the form there is an area with clinical details that you may want to fill in for the patient.
5. When you complete the form click on the OK button.
6. You can now proceed to record spectrum information for the patient. (ID# is mandatory field and must be filled. All other fields are optional).

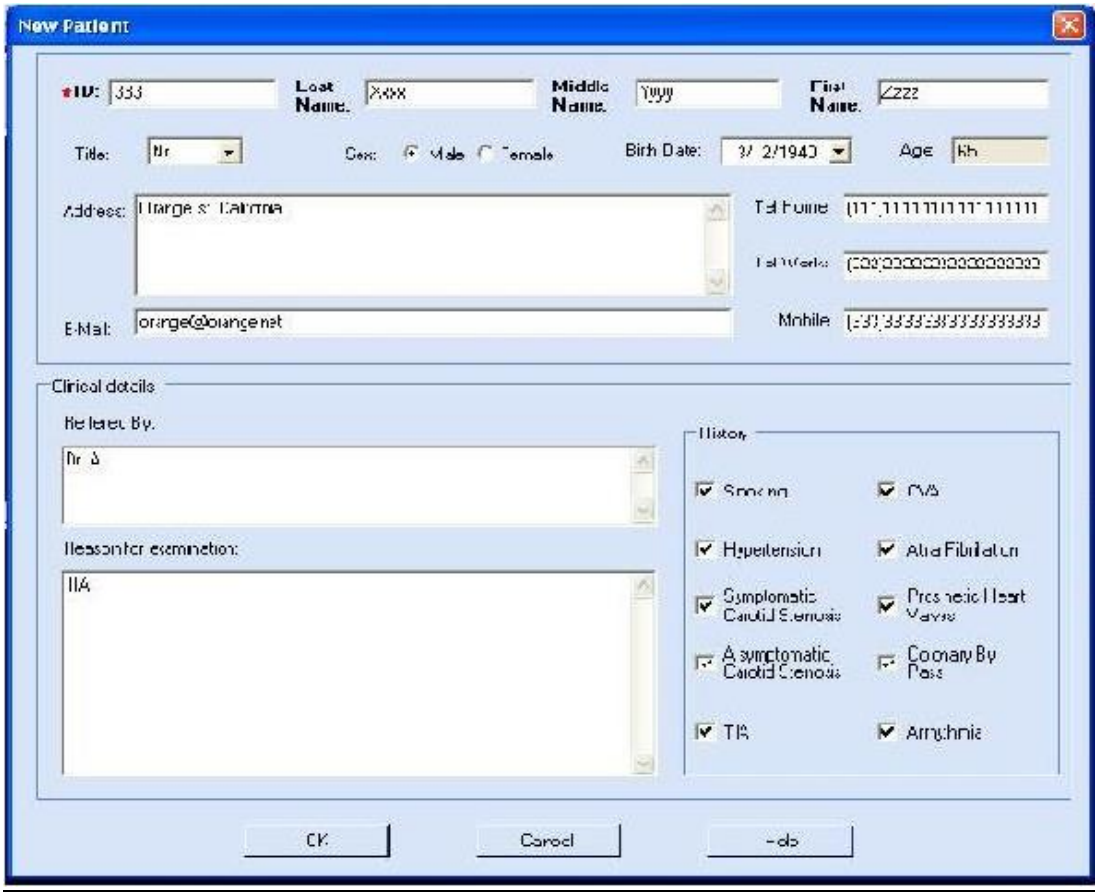


Figure 7-1 New Patient dialog box

The following fields appear in the Patient Details form.

ID #: The patient's identification number. This can consist numbers or letters. No hyphens, spaces. You must enter an ID number for all patients. The system will not accept an ID which already exists and will give an alert.

Last Name: The patient's family name. If you don't enter a name, a star will appear instead of the name.

Middle Name: The patient's middle name.

First Name: The patient's first name. This can be made up of any letter characters.

Title: One of the following titles can be entered: Mr., Miss., Mrs., Ms., Dr., Prof or no title.

Sex: Male or female click box.

Birth Date: The patient's birth date in the format: day - month - year or day/month/year. It is necessary to enter the year in a 4-digit format. The patient's age is automatically calculated and placed in the age box.

Age: Patient's age will be calculated automatically from the birth date. If you don't type a birth date, you can type the age directly in this box.

Tel #: The patient's telephone number. Any character is accepted as part of the telephone number. The following telephone numbers can be written: telephone at home, telephone at work and mobile telephone.

Address: The patient's address. Any characters can be typed in this box.

E-Mail address: The e-mail address. Any characters can be typed in this box.

Clinical details:

Referred by: The name of the doctor who referred the patients. Any characters can be typed in this box.

Reason for Examination: The symptoms leading to the present examination. Any characters can be typed in this box. You can use this field to record changes in the patient's status. If on entering a new patient you write a short summary of clinical history and status, and you add information anytime you re-examine the patient, a very useful record is formed.

Clinical History: You can mark characteristics relevant to the patient's clinical history and risk factors. To mark events, simply select the event with the mouse and click on it. A check mark appears in the small box next to the event.

7.2.2. Loading or searching for an existing patient

You may wish to add or modify information for an existing patient, perform another Doppler examination for an existing patient, display examination, display patient report or search patients according to specific characteristics. To do so, you use the Search/Load Patient function. (See figure 7-2)

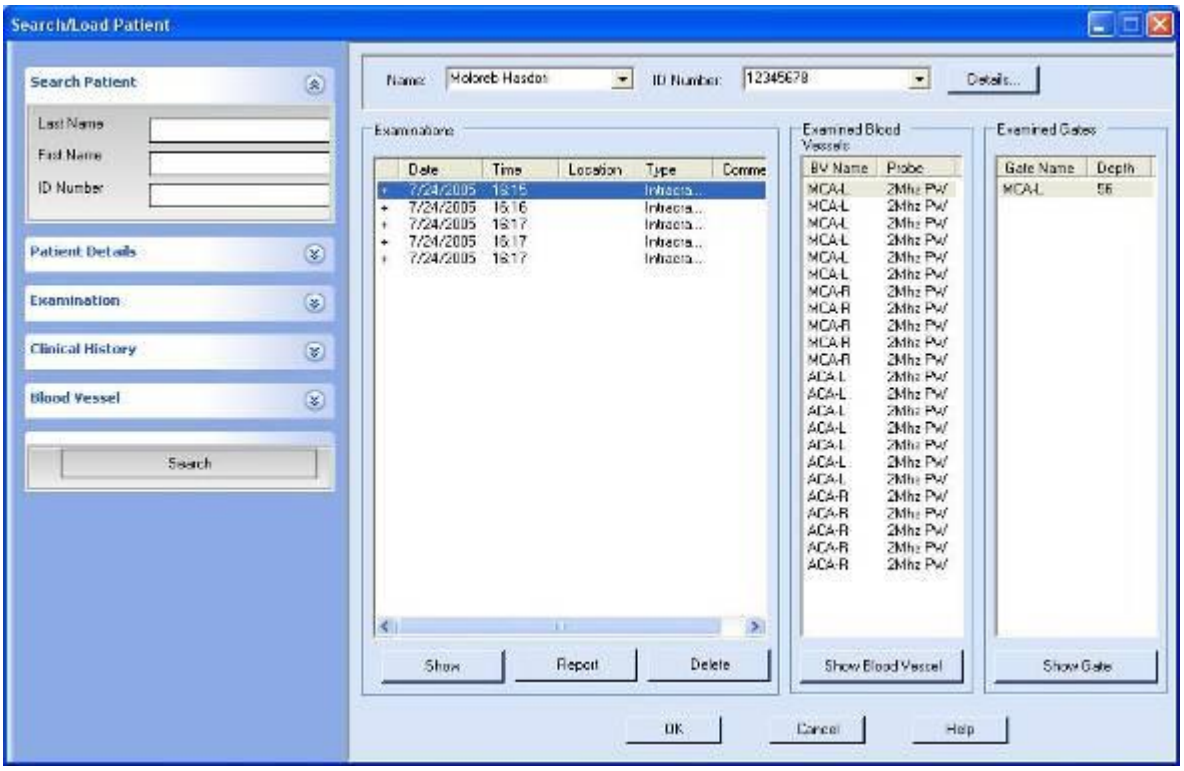


Figure 7-2 Load dialog box

The Search/Load Patient dialog box contains two areas: Search functions at the left side and Load functions at the right side. It contains the following fields and buttons:

Load area:

Name: Name selection field. Contains a list of patients in the database, listed by name in alphabetical order with the family name first followed by first name.

ID #: ID selection field. Contains a list of patients in the database, in numerical order.

Patient Details: Pressing this button allows you to view the patient details.

Examinations: Displays list of all the examinations saved for the selected patient with the following examinations information: date, time, location, study type and comments entered by physician for the examination.

Examined Blood Vessels: Displays the blood vessels names and Doppler probe type of the blood vessels examined and saved (for the examination highlighted in the Examination List).

Examined Gates: Displays the Doppler probe type and depth of the blood vessels examined and saved (for the examination highlighted in the Examination List).

The column headings in this field are:

HD: Shows if the examination is saved on the hard disk. A '+' (Plus) sign means that it is on the hard disk. A '-' (minus) means that the examination was erased from the hard disk.

Date: Date of examination (Day-Month-Year format).

Time: Time of examination.

Location: The location to which a backup copy was saved. The options are:

- blank - no backup was done.
- (fixed) - to the hard disk of the instrument.
- (Removable) - to an external memory device (such as a read-write CD-Rom).

Search patient area:

In this area you can search patients according to the following characteristics:

- **Search patient:** To search patient by:

  Last Name

  First Name

  Id. Number

- **Patient Details:** To search patient by:

  Sex

  Age: find patients in specific age range

  Referred by: search by name of the doctor who referred the patient

  Reason: search by reason of examination

- **Examination:** To search patient by:

  Date: find examinations done between two dates

  Type: search by type of examination done on this patient (e.g. Intracranial Unilateral, Extracranial etc...)

  Location: search according to the location of the examination (in the hard disk, on CD-RW, etc...)

  Other: search by words appearing in the patient's details

- **Clinical History:** Search patient by clinical history as inserted in New Patient – clinical details
- **Blood Vessels:** Search patient according to what blood vessels were examined.

Viewing Records from the Database

1. To load details on an existing patient, select LOAD from the PATIENT menu or click on the icon that looks like an open folder.

   The Load Patient form, shown above, appears. (See figure 7-2)

2. Click on the arrow next to the NAME field. A list of all patient names is displayed. Use the up and down arrows on the scroll bar to scroll the patient name list and click on the name of the patient whose records you want to recall. When you select a patient, a list of all previous examinations is displayed in the dedicated fields below the name. To search for a specific patient, you can type the first few characters of the last name of the patient to highlight the first matching name.

   If you prefer, you can search by ID#, using the same procedure.

3. You move from one field to the next by pointing the mouse or pressing the tab button.

4. If you want to view or modify the patient details, click on the Patient Details button. The form described above (Figure 7-1).

5. You can view previous spectrum examinations of the patient by double-clicking on the relevant line.

6. When you have selected the patient and examination you want, click on the Show Examination, Show Blood Vessel, Show Gate or OK button, depending on what you wish to display.

   - Click “Show Examination” if you want to view the complete summary screen.
   - Click “Show Examined Blood Vessels” if you want to view the examinations (spectrums and M-Modes) recorded for a specific blood vessel.
   - Click “Show Examined Gates” if you want to view the spectrum recorded for a specific gate (depth).
   - Click “OK” if you want to start a new examination for that specific patient. The new examination will be added to that patient’s database. (See also below)

You can now proceed to record or review spectrum information for the patient.

Displaying examination summary screen

You can view the summary information directly from the Load Patient dialog box, as follows.

1. On the Load Patient dialog box, select the patient using the Name or ID field.
2. From the “examination list” windows, double-click on the examination you wish to view. The summary screen for that examination appears. Alternately, you can click the “Show examination” button.
3. You can perform any of the regular summary screen options from this screen.
4. To return to the Select Patient dialog box press on LOAD icon.

Displaying a single blood vessel examination

After highlighting an examination, double click on a specific blood vessel name from the “Examined blood vessels” list on the middle. Alternately, highlight and click the “Show Blood Vessel” button.

Displaying a single gate examination

After highlighting an examination and a blood vessel name, double click on a specific depth from the “Examined gates” list on the right. Alternately, highlight and click the “Show gate” button.

Opening a new examination file for an existing patient:

When a patient comes back for examination, the correct procedure should be:

1. On the Load Patient dialog box, find the patient’s name (or his/her ID).
2. Click the <OK> button.
3. You can start a new examination; it will be saved and filed together with other examinations already done for this patient.

Modifying Examinations in the Database

Deleting an examination

You can delete the results of one or more of the examinations for a particular patient. Note that once you have removed this data from the database, you cannot restore it unless you have made a back up.

1. On the Load Patient dialog box, select the patient using the Name or ID field.
2. From the "examination list" window, click on the examination you wish to delete.
3. Click on the Delete Examination button.
4. Confirm that you want to delete this examination information.

7.2.3. Deleting a patient

You can delete a patient from the database. Deleting a patient also erases all examination data relevant to that patient. You cannot recover deleted data unless you have made a backup. See Backing up and restoring data in chapter 7.9.

To delete a patient:

1. Select DELETE from the PATIENT menu. The delete patient data form appears (See figure 7-3)
2. Select the NAME or ID# of the patient to be deleted. You select from the list by clicking the arrow next to the NAME or ID# field, and clicking on the patient.
3. Once you select a patient, all the other fields in the dialog box show the details of the patient.
4. The system prompts for you to confirm your action.

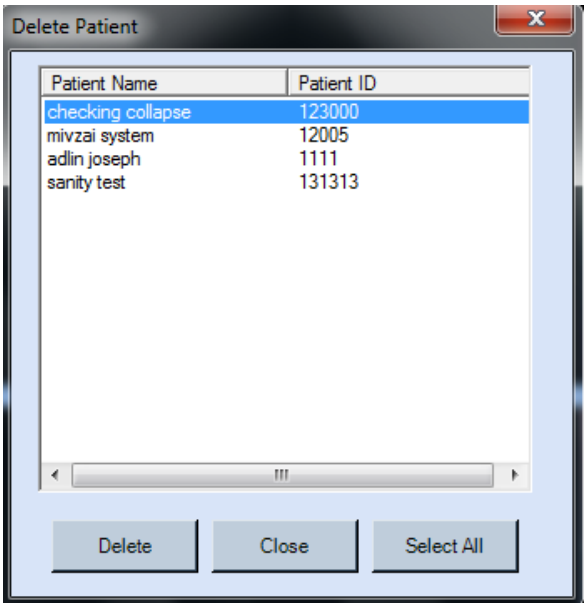


Figure 7-3 Delete Patient dialog box

The Delete Patient dialog box contains the following fields.

Name: Name selection field. Contains a list of patients in the database, listed by name in alphabetical order with the family name first, followed by first name.

ID #: ID selection field. Contains a list of patients in the database, in numerical order.

Delete Patient: This button is used to delete a patient from the patient database. All patient details and previous examinations are deleted with the patient.

Close: This button confirms the delete process and exits the dialog box.

Selecting study type, basic operation

The STUDY TYPE menu helps the user to select the current working operation mode or study type of the system. The study types are for unilateral or bilateral diagnosis or monitoring. Each study type has a default configuration defined at factory and can have also customized studies defined by the users.

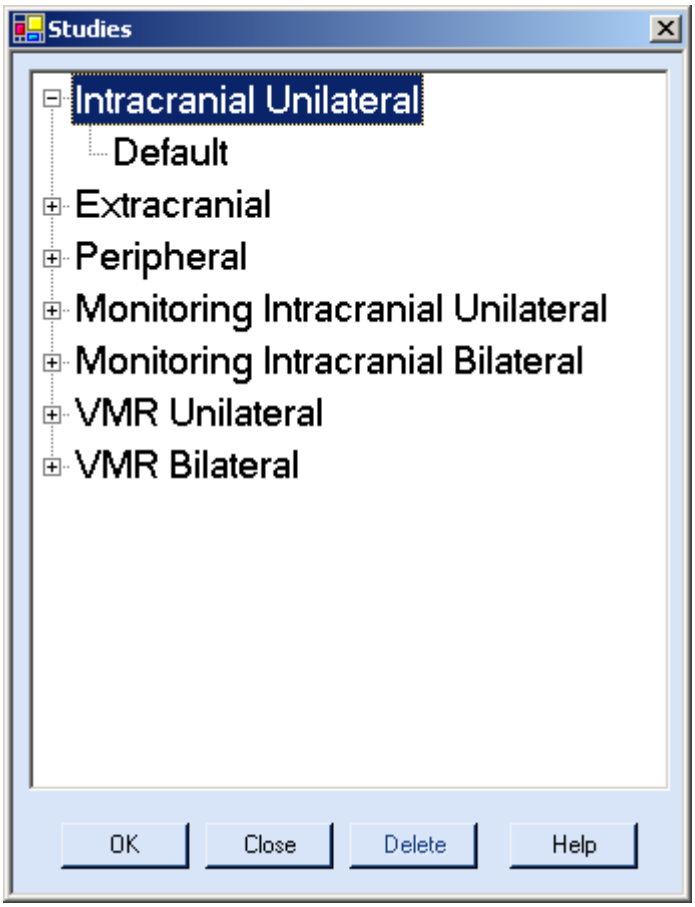


Figure 7-4 Studies dialog box

When recording the examinations using the various study types, you should perform the following steps.

1. From the STUDY TYPE menu (See figure 7-4), select one of the study types described below.
2. The display screen for that study type appears. For unilateral study types the display screen shows only spectrums and M-Mode belonging to one spectrum screen. For bilateral study types, the screen is divided in half, and each half contains the spectrums and M-Mode belonging to other probe. The CHN button on the remote control or the <T> key on the keyboard or mouse, allow you to toggle between the open windows on screen (spectrums and M-Modes). The selected window is distinguished by its blue frame
3. Press the <Space> bar (on the keyboard) or the Freeze button (on the remote control) to begin spectrum examination with the selected probe.

4. When the signal shown on the spectrum is stable and appears on the display in a satisfactory manner, press the <Space> bar or the Freeze button to freeze the spectrum.
5. If you wish you can unfreeze and re-record (according to system setup).
6. The active spectrum window has blue frame, and the inactive spectrum windows have gray frames. The sound relates to the active spectrum window.
7. Return to step 1 to record spectrums for other blood vessels.
8. When you have finished recording all the spectrums needed the examination is complete. You can display a summary screen, modify screens, save the spectrum, or print the patient report, as described in the appropriate sections of this manual.

Note: Whenever you record the spectrum of any blood vessel, it is automatically added or not to the appropriate summary screen, according to Summary Screen setup. See **Summary screen** setup on (11.2.5).

CAUTION

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

7.2.4. Intracranial unilateral study type

Intracranial Unilateral study type is used for single probe examinations of the intracranial circulation. This option is useful for a careful examination of arteries comprising the Circle of Willis, the Vertebral and Basilar arteries, and the Ophthalmic arteries. Although a 2 MHz PW probe is the default choice for all arteries (except the Ophthalmic, which may be insonated with an 8 MHz CW probe as well), you can select other probes for this exam. You can display up to seven clinical parameters to the right of the selected spectrum. Up to 8 spectrums can be displayed for simultaneous examination at up to 8 different depths with a single 2 MHz PW probe. This option is used to allow comparison of blood flow velocities at up to 8 different depths (such as at a stenosis and proximal or distal to it), or to capture the movement of a cerebral emboli. Control of the spectrum in each window is performed independently of the spectrum in the other window. Pressing the CHN button on the remote control or <T> on the keyboard toggles between the two spectrum windows. The spectrum of the active window is shown in blue, and the inactive windows are shown in gray. The sounds are from the active spectrum window.

An M-Mode window can be displayed for fast screening of intracranial blood vessels, finding and identifying of blood vessels, visualization of the emboli movement and improvement of emboli detection.

A dedicated summary screen of the intracranial circulation is included with this study type.

7.2.5. Extracranial study type

Extracranial study type is used for single probe examinations of the arteries of the neck (primarily CCA, ICA, ECA). The preferred probes to examine these arteries are 4 MHz or 8 MHz – PW or CW probes. You can also use 2 MHz PW probe. You can display up to seven clinical parameters to the right of the spectrum. If the probes are used in PW mode, than an M-Mode window can be displayed and up to 8 different depths, in the same manner as in Intracranial study type.

A dedicated summary screen of the Extracranial circulation is included with this study type.

7.2.6. Peripheral study type

Peripheral study type is used for examinations of blood vessels in the upper and lower limbs. The controls and display of this study type are similar to those in Unilateral study type. All probes may be used for Peripheral study type. The preferred probes to examine these arteries are 4 MHz or 8 MHz – PW or CW probes. You can also use 2 MHz PW probe. You can display up to seven clinical parameters to the right of the spectrum. If the probes are used in PW mode, than an M-Mode window can be displayed and up to 8 different depths, in the same manner as in Intracranial study type.

A dedicated summary screen of the peripheral circulation is included with this study type.

7.2.7. Monitoring unilateral and bilateral studies type

Monitoring is used for continuous monitoring and recording of TCD parameters. Chapter 8 gives full information about working with this mode.

CAUTION

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

7.2.8. Vasomotor Reactivity (VMR) study type

The vasomotor reactivity test mode performs vasomotor reactivity tests and calculates VMR parameter. The VMR parameter is calculated in real time during the test, and can be recalculated also off line, after the test was finished. Chapter 9 gives full information about working with this mode.

7.3. Spectrum examination and modification

Once you have created a new patient or loaded an existing patient, and selected the study type, you can proceed with the examination of the patient.

1. Select the probes for insonating the blood vessel.
2. Begin recording by toggling the Freeze button to start the spectrum.
3. Insonate the vessel by viewing the display on the M-Mode screen and choosing the best spectrum depth according to M-Mode display. Adjust the control variables to get the best insonation.
4. When the best signal was get and it's stable, select the HITS option if you wish to record HITS.
5. When the display shows a satisfactory spectrum, toggle Freeze to freeze the spectrum on the screen.
6. You may save the spectrum if you wish.
7. If you want to record another blood vessel, select new vessel from the BV list or use the Next function, repeat this procedure until all required blood vessels were examined.
8. Click the "Summary Screen" icon.

   The summary screen, described in the next section, shows a comprehensive display of all the results of a set of examinations.
9. Save results.
10. Print a patient report, if needed.

7.4. MC (manual calculation) cursors saved on Summary Screen and in Patient Report.

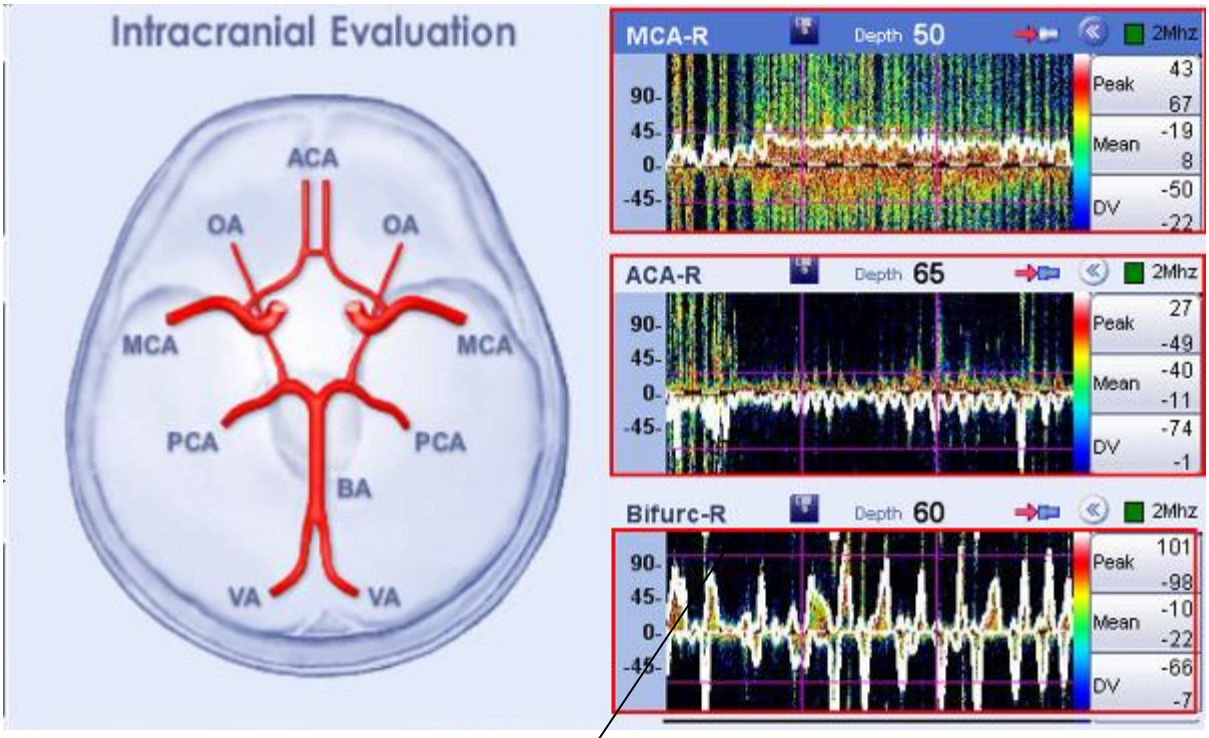
Go to Intracranial Unilateral Study, makes Unfreeze/Freeze, adds cursors to the screen, clicks MC and gets new numbers for Peak, Mean etc. Then go to Summary Screen. The summary screen images updates according to this screen.

Now Cursor Lines is added on the image in Summary Screen and in Final Patient Report) (see figure 7-5).

The same happens with M.C marks.

This enables the doctor to notice what calculation was done automatically & what manually.

This option is available also after loading a study.



Manual
Calculation
Lines

Figure 7-5 Manual Cursors

7.5. LR (Lindegaard Ratio)

This clinical parameter – after calculated is presented in the main screen – Under the L.R. button and in the Lindegaard Ratio window, the Summary Screen and the Patient Report. It can be calculated only after having measurements of both the MCA and ICA on the same side. It takes the maximum mean value of each vessel and divides them. (mean velocity of MCA / mean velocity of ICA). After receiving values from those BVs, manual L.R. calculation can be performed inside the L.R. function.

7.6. Controlling the summary display

There are three default summary displays: Extracranial vessels, intracranial vessels, and peripheral vessels. The blood vessel spectrums shown for each summary are automatically configured with the system. However, if you want to customize which spectrums to send to summary screen or which blood vessels are shown in the displays, you can do so using the Setup options: General- Summary Screen configuration and Studies- Select blood vessels.

Once you have recorded the blood vessels you want for the patient, you can view all of the displays as one summary display.

To display the summary screen (after performing the examination):

1. Click on the summary icon or select SUMMARY from the FUNCTIONS menu.
2. You can add comments to the summary screen, using the write icon or function.
3. If you wish, you can print the summary screen (use the patient icon)
4. If you wish, you can display the patient report (use the patient report icon)
5. If you wish, you can change the order of the BV's to be displayed by dragging them in the summary screen. This is also available after loading a study.
6. To return to the spectrum display, press return icon.

7.7. Saving patient information and results

It is possible to save patient and spectrum information. To save the information recorded during the examination, simply press on the Save icon in the summary screen window.. DIGI-LITE saves only the information currently displayed on the screen.

7.8. Display Patient report

The patient report contains general information about hospital, operator and patient together with examination details, pictures and clinical parameters (figure 7-6). All this information can be displayed or only part of it, according to user configuration. For more details on user configuration options, see “Setup Configuration”. (Chapter 11)

29/05/2016

Rimed Hospital
Brain Department
Dr. Rimed

TCD Examination: Intracranial Bilateral

Patient Details:

Examination Date and Time: 29/05/2016 09:31

ID: 00000000 **Last Name:** Test **Middle Name:** Rimed **First Name:** Patient
Sex: Male **Date of Birth:** 10/01/1974

Home Phone: 03-9756883 **E-Mail:** test@gmail.com
Cellular Phone: 054888888 **Address:** Tel Aviv
Work Phone: 0376574889
Referred By: Dr. Levi
Reason For Examination: none

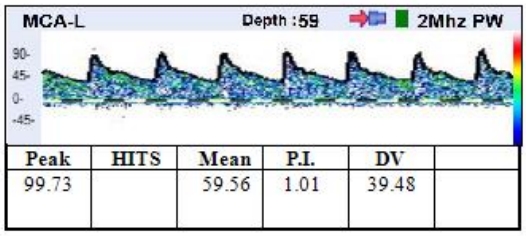
Patient History:

Smoking:	No	**CVA:**	No	**Symptomatic Carotid Stenosis:**	No
Hypertens	No	**Atrial Fibrillation:**	No	**Asymptomatic Carotid Stenosis:**	No
TIA:	No	**Coronary By Pass:**	No	**Prosthetic Heart Valves:**	No
Arrhythmia:	No				

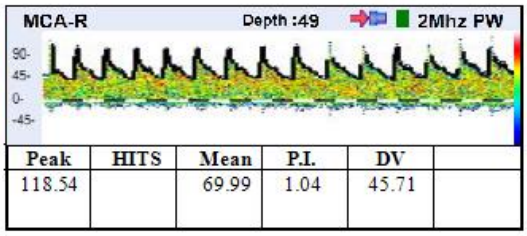
Examination History:

Date	Time	Type
17/05/2016	11:36	Intracranial Bilateral
17/05/2016	11:38	Monitoring Intracranial Unilateral
17/05/2016	11:50	Intracranial Bilateral
24/05/2016	10:40	Monitoring Intracranial Bilateral
24/05/2016	10:41	Monitoring Intracranial Bilateral
24/05/2016	16:01	VMR Bilateral
24/05/2016	16:04	Monitoring Intracranial Bilateral
24/05/2016	16:04	Monitoring Intracranial Bilateral
24/05/2016	16:05	Monitoring Intracranial Bilateral
29/05/2016	09:31	Intracranial Bilateral

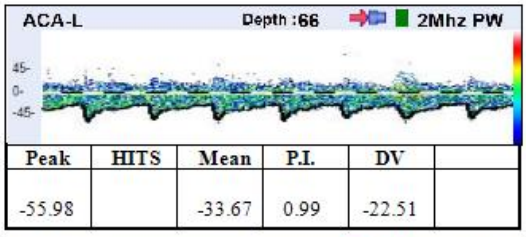
Summary Screen



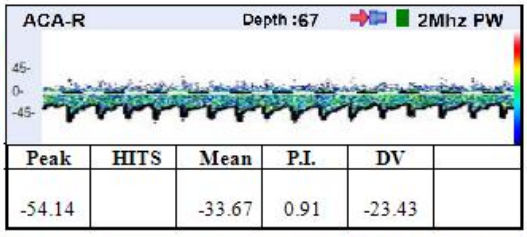
Peak	HITS	Mean	P.I.	DV	
99.73		59.56	1.01	39.48	



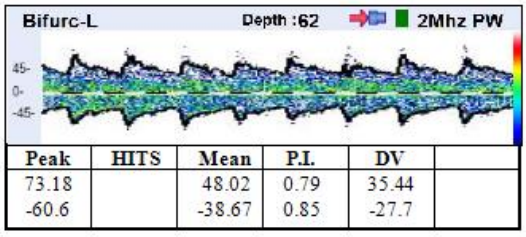
Peak	HITS	Mean	P.I.	DV	
118.54		69.99	1.04	45.71	



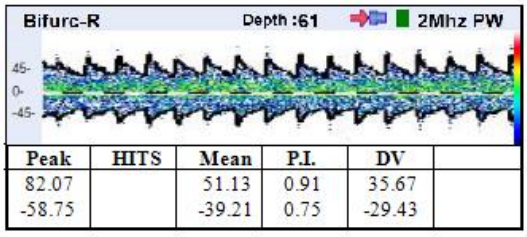
Peak	HITS	Mean	P.I.	DV	
-55.98		-33.67	0.99	-22.51	



Peak	HITS	Mean	P.I.	DV	
-54.14		-33.67	0.91	-23.43	



Peak	HITS	Mean	P.I.	DV	
73.18		48.02	0.79	35.44	
-60.6		-38.67	0.85	-27.7	



Peak	HITS	Mean	P.I.	DV	
82.07		51.13	0.91	35.67	
-58.75		-39.21	0.75	-29.43	

	Left Side							Right Side							
	Depth (mm)	Peak cm/sec	Mean cm/sec	HITS cm/sec	P.I. ratio	DV cm/sec	S/D ratio	Depth (mm)	Peak cm/sec	Mean cm/sec	HITS cm/sec	P.I. ratio	DV cm/sec	S/D ratio	
MCA	50	69.6 -36.28	39.75 -21.93		1.13 0.98	24.82 -14.76	2.8 2.46	54	77.57	67.72		0.22	62.79	1.24	MCA
MCA	53	63.37 -30.93	46.29 -18.7		0.55 0.98	37.74 -12.59	1.68 2.46	57	79.64	43.17		1.27	24.93	3.19	MCA
MCA	55	60.25 -26.37	35.17 -15.95		1.07 0.98	22.62 -10.74	2.66 2.46	60	76.64	44.02		1.11	27.7	2.77	MCA
ACA	67	-59.21	-30.28		1.43	-15.81	3.74	65	-55.98	-34.28		0.95	-23.43	2.39	ACA
Bifurc	64	44.21 -59.33	22.97 -30.47		1.39 1.42	12.35 -16.04	3.58 3.7	63	61.87 -58.52	33.78 -35.36		1.25 0.98	19.74 -23.78	3.13 2.46	Bifurc
PCA	65	20.55	11.39		1.21	6.81	3.02	59	32.2	17.51		1.26	10.16	3.17	PCA
VA	59	-29.78	-15.54		1.37	-8.43	3.53	58	-31.97	-18.51		1.09	-11.77	2.72	VA

Middle

	Depth (mm)	Peak cm/sec	Mean cm/sec	HITS cm/sec	P.I. ratio	DV cm/sec	S/D ratio
BA	83	-25.16	-12.31		1.57	-5.89	4.27
BA	86	-27.7	-15.54		1.17	-9.47	2.93

Lindegaard-Ratio Left: Lindegaard-Ratio Right:

Manage Digi-Lite™ IP Images

Indication

Interpretation

NORMAL TCD EXAMINATION OF THE ACA\ MCA\ PCA \ VA BILATERALLY AS WELL AS OF THE BASILAR ARTERY
NO EVIDENCE OF INTRACRANIAL STENOSIS BY TCD

Signature:

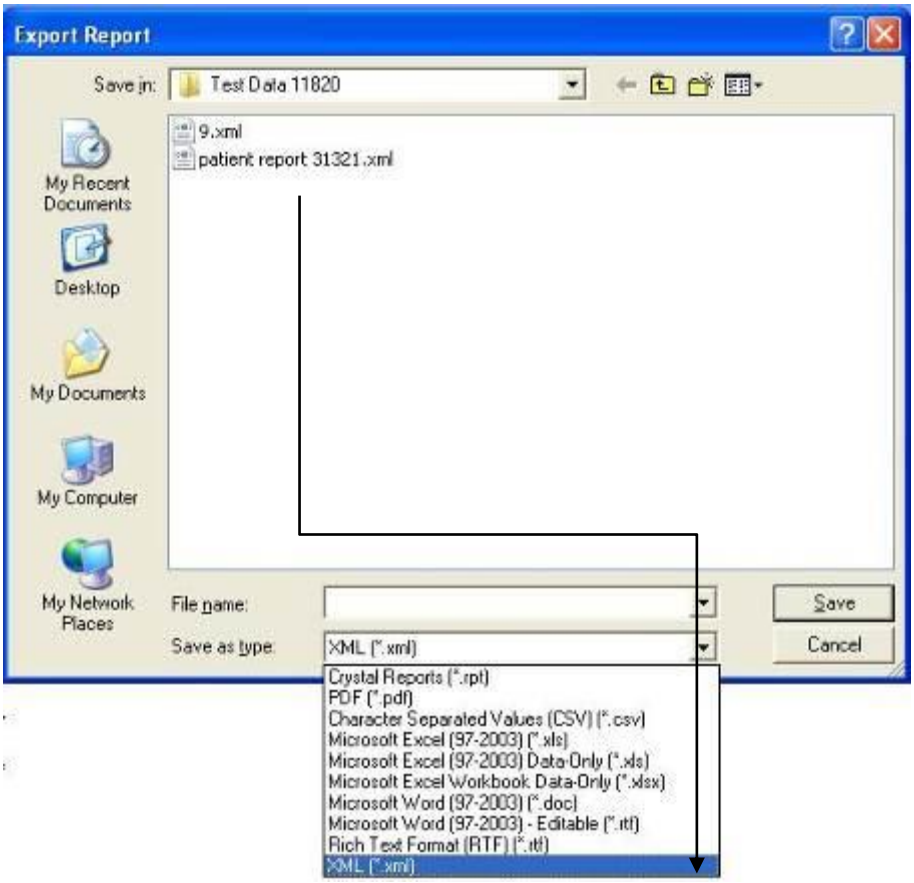
Figure 7-6 Patient Report example

The patient report for a specific examination can be open from two different places:

- In summary screen display press on Patient report icon. After performing an examination, open summary screen, configure it by deleting or moving spectrums, save it, and then press on patient report icon. The patient report of the examination will be displayed according to the setup. It can be printed, saved, exported to other applications or sent by email. It can be saved on different formats, as: Acrobat -*.PDF, Microsoft Excel - *.xls, Microsoft Word- *.doc or Rich Text Format - *.rtf.

After you have performed full examination you can enter to the summery screen and then to the Final patient report and as you can see there is a button to export the report

Then in the export report window you can see you can chose in which format you want to save the report and save it in your Disk On Key



- In addition, there is an easy option to export the report to PDF by the next icon

- If you want to display the patient report of a saved examination, press LOAD icon, choose the patient and select the examination, then press on Report icon. The selected patient and examination patient report will be displayed according to patient report configuration.

7.9. Backing up and restoring data

Examination files take up a lot of disk memory. When many patients were examined or long monitoring sessions done, you need to remove them. **Backup** is used to make copies that can be archived in a safe place for future needs. When you need to review a patient's examination that no longer exists on the HD, you will use the **restore** function.

7.9.1. Making Backup Copies

Backup is most often used to move large amounts of examinations. It can also be used to copy single examinations for any purpose. For backing up efficiently, it is recommended to use an instrument such as a read-write CD-ROM, network disks or any other storage devices. They can be commercial instruments that connect externally to a PC. As this line of products is changing quite fast, contact Rimed's customer support for the latest recommendations. (Consult with Rimed technical support regarding electrical safety standards when using commercial accessories).

To backup data, perform the following procedure:

1. If you are using an external device, verify that it is properly installed and connected.
2. Select Backup from patient menu. The "Backup patient" dialog box appears. (See figure 7-7).

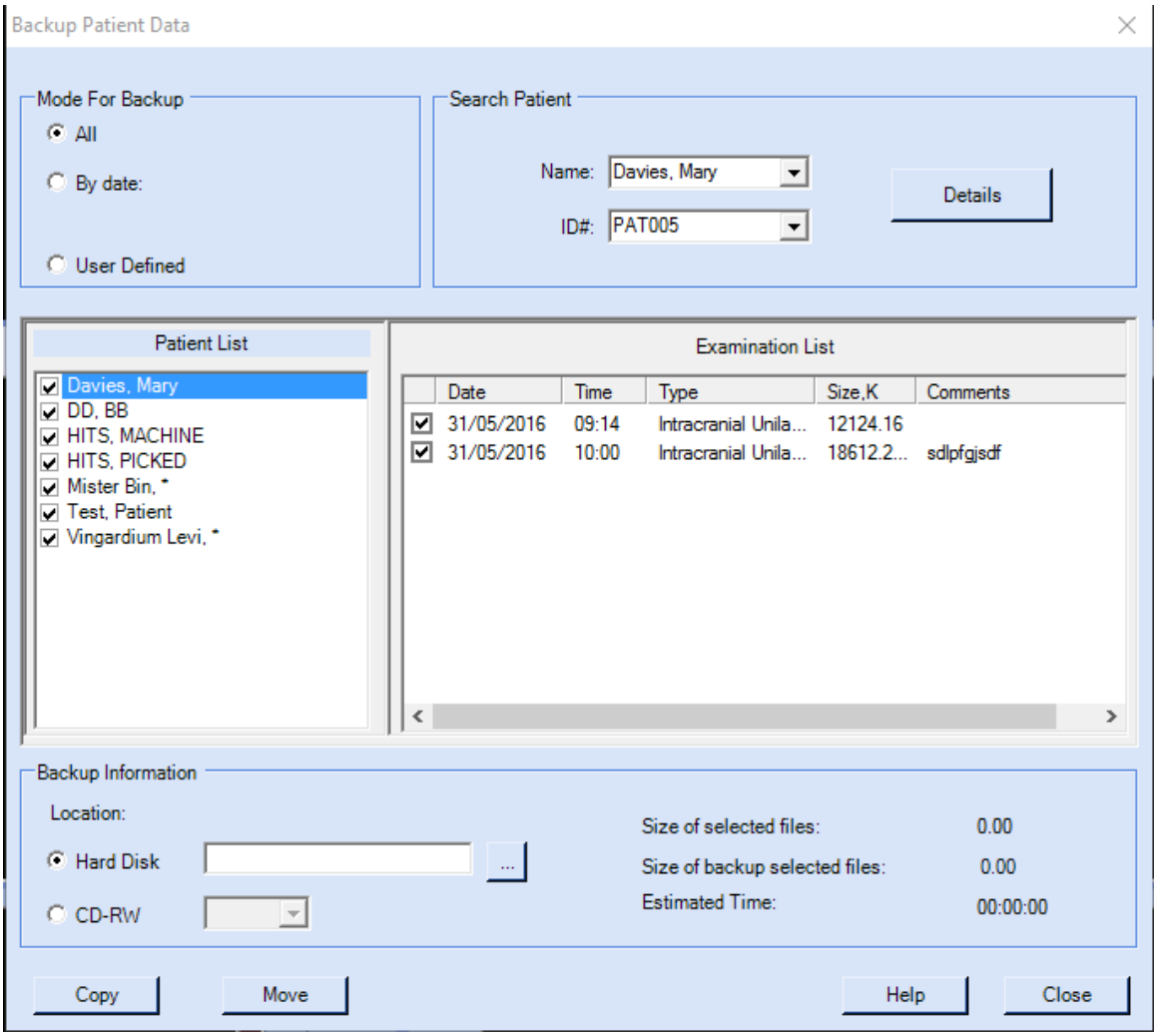


Figure 7-7 Backup dialog box

The backup function can work in the default mode for routine backups. This is very simple and straight forward. If you want to modify it, some options are available.

Periodical, routine backup:

The Backup patient data opens with the following setting:

Mode for Backup: By date (the system automatically sets the default date for 'today', thus selecting all the examinations made during this day).

Location: system defaults (files will be put under TCD/Backup directories on the media that you choose).

- Choose a drive for backup (lower left corner of the dialog box. [-c-] if you want to backup on the hard disk, [-d-] for an external drive ([-d-] is available only if an external device is connected) or other drives if the system is connected to a network.

- Choose “copy” or “move”. click “Copy” If you want to leave the examinations on the hard disk. If you want to delete them after backup, click “Move”. If you clicked “Move”, the system warns you that all the examinations will be deleted. Confirm by clicking OK, or cancel.

- The system shows a warning: “Ready to start backup ”. Estimated time ____h ____m ____s. Confirm by clicking OK. The time estimate may not be very accurate, depending on the media you use. Anyhow, it will give you a good idea. If you want to use the instrument soon and backup would take a long time, you can cancel and start again later, at a more convenient time. You can also see the size of selected files (written under the patient’s list). Once you click OK, an advancing blue bar will show the percentage of files that have been backed up.

3. A message appears: “compression successfully finished”. Confirm by clicking OK.

4. Click “CLOSE” to exit the backup dialog box.

WARNING

If the hard disk is almost full. The back-up procedure might fail. Make a habit of routine periodical backups (depending on number of examinations saved) to keep enough free space on the hard disk.

Backup options:

Mode for backup:

- If you want to make backup copies of all examinations present on the HD (even those that were backed-up) choose “ALL” in “Mode for Backup”.
- If you want to make backup copies for examinations made during specific dates (range or a specific day) choose "By date" in "Mode For Backup". This will automatically select all the examinations made during those dates.
- If you want to select specific files for backup, choose “User Defined”. Then choose by the Patient’s names (or #Ids). Click twice on each patient name for which you need backup. The list of examinations for that patient will appear on the right side. Highlight the examinations you want to backup. Repeat for other patients.

  Proceed as before - “Copy” or “Move”. Confirm when needed, “Close” to exit.

CAUTION

It is important to label the CD (use the number given by the system), or list the patients by Name or ID number on the diskette itself, when you are storing information which you plan to erase from the DIGI-LITE computer. Make sure that you keep careful track of where all data is stored and that the date is written on the diskette.

7.9.2. Restoring backup information

You use this function to retrieve old files that were backed-up and erased from the system. Choose “Restore” from the patient menu.

Once you select Patient - Restore, the restore patient data dialog box appears. In the system default mode:

1. Select drive to restore
2. Under patient’s list, choose the name you are looking for. Click twice on it, high-light the examinations you want to restore (under examinations list).
3. Click OK. A warning shows you the estimated time. Confirm by clicking OK if time limits permit.
4. A Blue bar shows the advancement of the restoring process.
5. Confirm “Decompression successful” by clicking OK.

Restore Options:

- Locate: Choosing locate enables you to restore from directories different than the default one (if backup was done to another directory). Browse through the desired drive and directory from the “Select directory to restore” dialog box.

7.10. Printing

There are three different ways to print examinations:

1. Print screen: You can print the results by selecting PRINT from the PATIENT menu or clicking on the PRINT icon.

2. Print selected spectrum windows in predefined layout: right click on spectrum window that you want to print. The selected windows will be printed in the predefined layout. Refer to section (11.2.8) "Print Settings" to learn how to configure printing.

3. Print Patient report: select print from Patient Report in order to print the patient report as predefined by the user in setup.

7.11. Exporting results to other software

The export function helps you exchange data with other programs that you use. Theoretically you can even install them on the same platform. However, since sometimes there can be a conflict between different programs, you must contact Rimed and confirm that the specific software can be installed. If the combination was already checked, an authorized permit will be sent to you. Otherwise, Rimed can not be held responsible for any damages that might occur.

The export options are:

Pictures: Exports the spectrum or summary screens as picture files. Pictures can be sent in standard format like .jpg, bmp.

Select the export function needed. Under the field "File Name", enter the patient's name (or according to your choice) with an appropriate extension (*.jpg for picture, *.txt for text files). After clicking OK, the file will be saved (as default) under c:\export. Later you can open it using suitable software, for analysis or any other use. You can also choose another directory for saving the exported files. See figure 7-8 for an example of an Export screen.

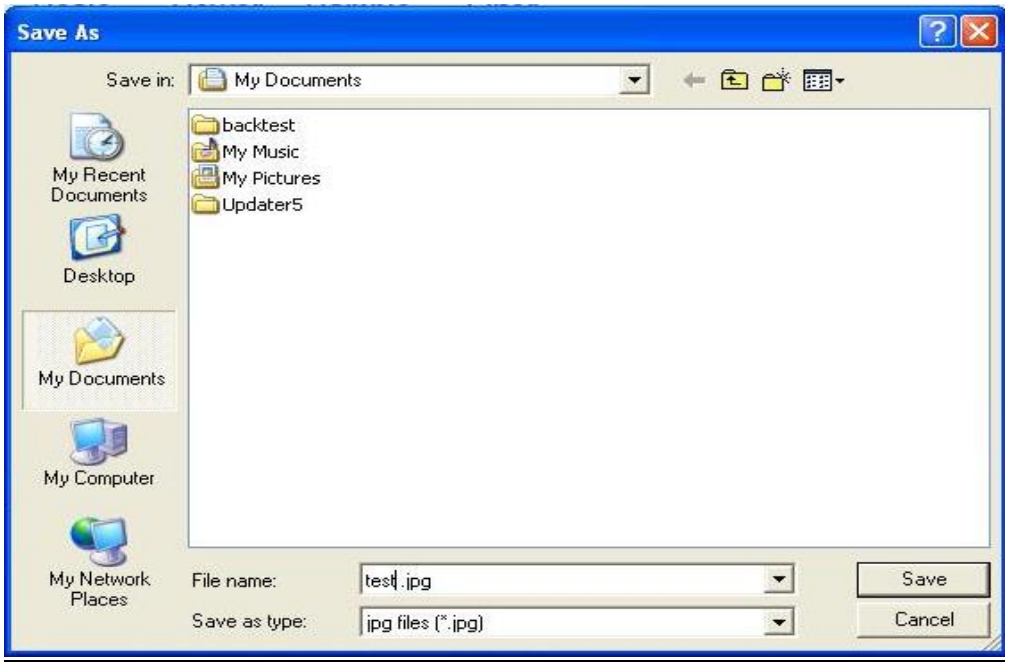


Figure 7-8 Export dialog box

Export Trends to excel: Exports all the trends in monitoring studies to excel file for research purposes. See “Exporting clinical parameters in monitoring and VMR studies to excel” (section 11.2.9)

Export Log Fie: Exports a log file for services issues. See Chapter 17.

8. Monitoring Unilateral or Bilateral Studies

The monitoring studies of the DIGI-LITE system allow you to monitor blood flow velocity over an extended period of time. Using a dedicated probe holder which can be attached to the patient's head, you can monitor blood flow over a period of hours, recording information about events occurring during the monitoring period.

You perform monitoring just as you do any other kind of insonation. The difference is that you are in monitoring study type rather than on one of the other study types shown on the STUDY TYPE menu. See figure 8-1 for a typical monitoring screen.

You can perform Post-processing on the study you just recorded – in order to add or delete Events or HITS in offline and also have the tools using the cursors and additional spectrum window to analyze the results.

 **WARNING**

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

 **WARNING**

While monitoring patients for long periods, switching on (Unfreeze) only at critical phases of surgery (or follow-up period) is preferred to continuous monitoring.

8.1. Selecting Monitoring Unilateral or Bilateral study

Enter Monitoring test using menu bar Studies, or Change study icon in toolbar.

Monitoring examination is done in Unfreeze Real time and can be further inspected in LOAD off line state.

8.2. Monitoring Intracranial Unilateral Layout during Recording

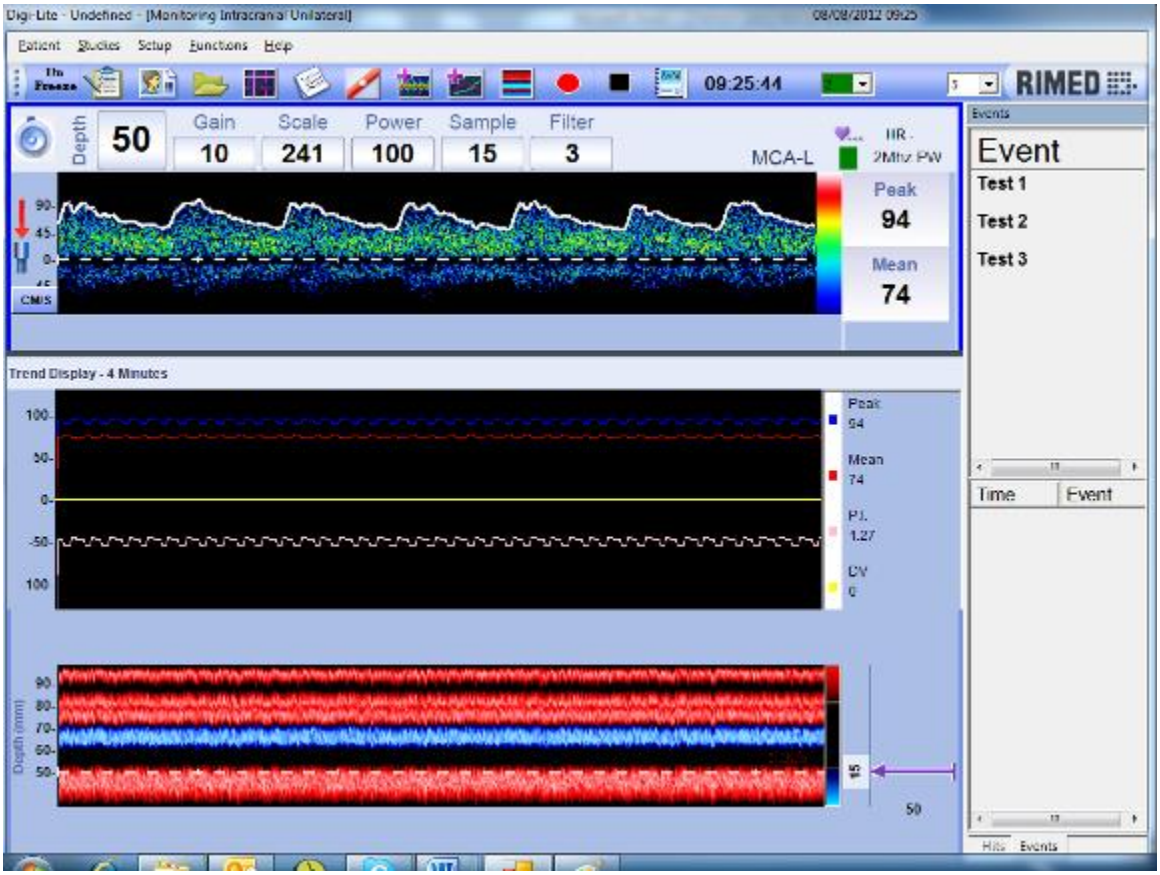


Figure 8-1 Monitoring Layout during Recording

The upper half of the monitoring screen is almost identical to the spectrum screens you already know. Notice the two “Tape Buttons” added to the icon row. After you unfreeze, you use them to control recording: (A record examination is saved automatically to the hard disk). See figure 8-2

The lower part of the monitoring screen displays the trend windows. In the trend window, you see how different parameters (derived from spectrum calculations or from external instruments) change during the examination period.

8.3. Monitoring Intracranial Bilateral Layout during Recording

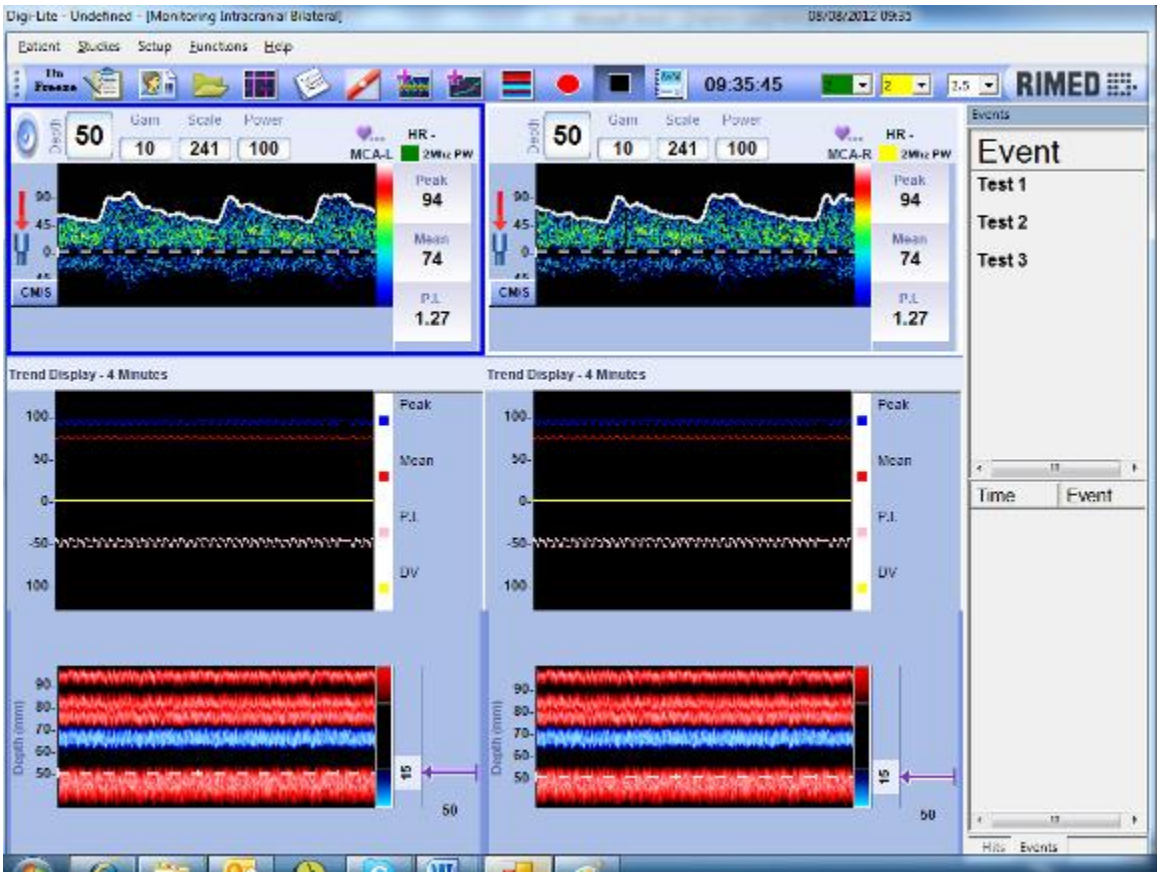


Figure 8-2 Monitoring Intracranial Bilateral Layout during Recording

In this study type the user can insonate in both channels simultaneously by using the probe holder (Chapter 10) and see the result in one screen. See figure 8-2

The upper half of the monitoring screen is almost identical to the spectrum screens you already know. Notice the three “Tape Buttons” added to the icon row. After you unfreeze, you use them to control recording: (A record examination is saved automatically to the hard disk).

The lower part of the monitoring screen displays the trend windows. In the trend window, you see how different parameters (derived from spectrum calculations or from external instruments) change during the examination period.

Figure 8-3 Monitoring Taskbar during Recording

HITS: The HITS icon is pictured as a red blood vessel with a small white embolus in the blood stream

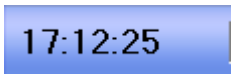
Spectrum Window: Add spectrum window **(you can add only 1 additional spectrum window)**

Trend Window: Add / Remove trend window

Red Circle: Start Recording.

Black Square: Stop Recording (you will have 3 options: Save, Don't Save, Continue Recording).

Final Patient Report: To display the patient report of the current examination (Events/Hits Pictures Only)



Examination Clock: The actual time of the examination: hour, minutes and seconds

Right click menu on Trends: Size of Trend Window: Determines the display size of the trend window in minutes.

CAUTION

This system and its options should be used no longer than is necessary for the appropriate diagnostic procedure. In order to minimize exposure to acoustic energy, switching on only at critical phases of surgery or at special events is recommended.

CAUTION

ALARA caution: The operator is cautioned to use Doppler power levels As Low As Reasonably Achievable, and to avoid the use of any power level greater than that necessary to insure the gathering of adequate Doppler information.

To optimize the monitoring software for your needs, use the setup monitoring options, described below.

8.4. Monitoring Layout during Replay

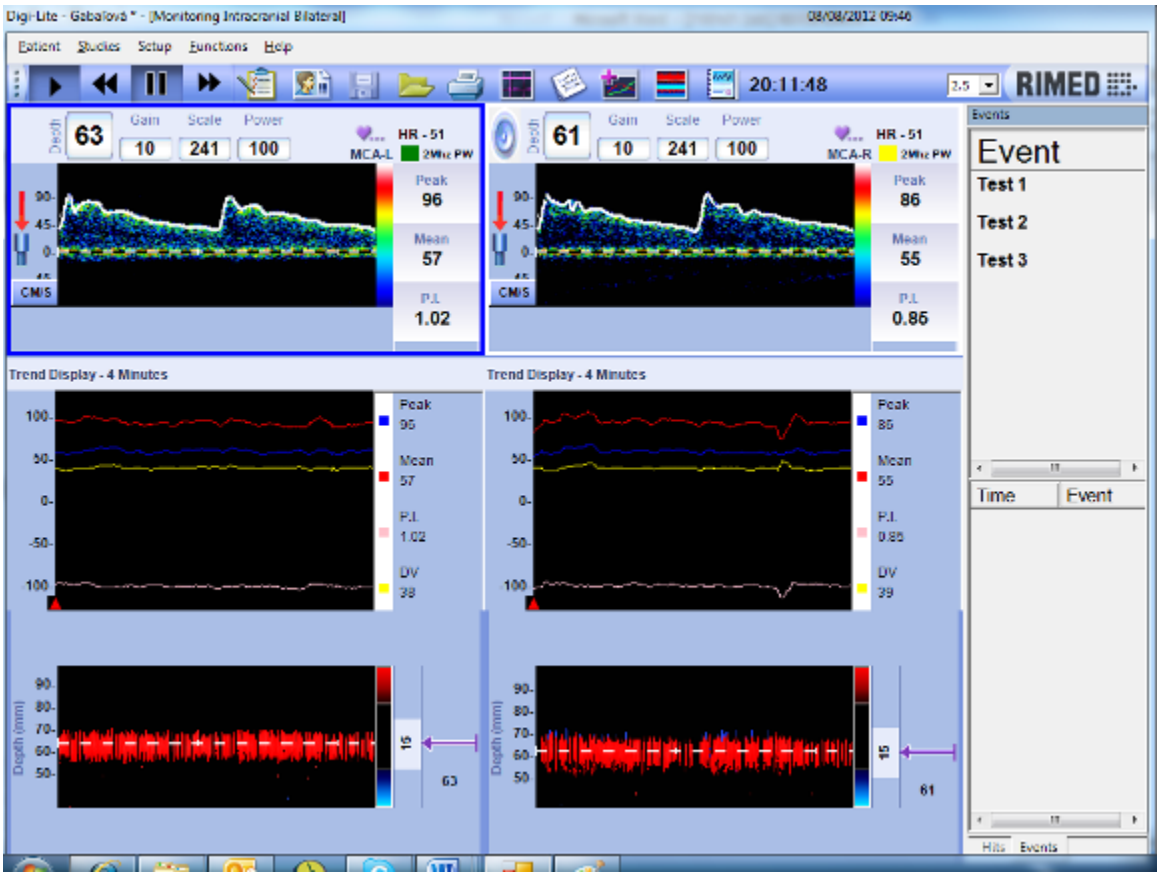


Figure 8-4 Monitoring Layout during Replay

Figure 8-5 Monitoring Taskbar during Replay

Replay Examination: Replay the examination beginning with the time displayed (spectrum, m-mode, trends and sound)

Scroll back the Examination: Scroll back the spectrum, m-mode and trends from the time displayed. The time gradients are equal to the spectrum window size.

Scroll forward the Examination: Scroll forward the spectrum, m-mode and trends from the time displayed. The time gradients are equal to the spectrum window size.

Black Vertical Lines: Pause / Resume replay.

Scroll Bar: Scroll to any point during the examination at replay mode

8.5. Monitoring examination setup

The following characteristics of the Monitoring examinations can be changed:

Size of Trend Window: To change the size of trends right click on TRENDS window and choose the option TIME DISPLAY. The TRENDS window time will change according to the selection

Figure 8-6 Size of Trend Window

Setting Monitoring events: You can configure the predefined events which you may want to place as markers during the monitoring period. The events list allows you to define new events for monitoring. Choose Setup➔Studies➔*Study name* ➔ clicking the "Event" tab (See figure 8-7).

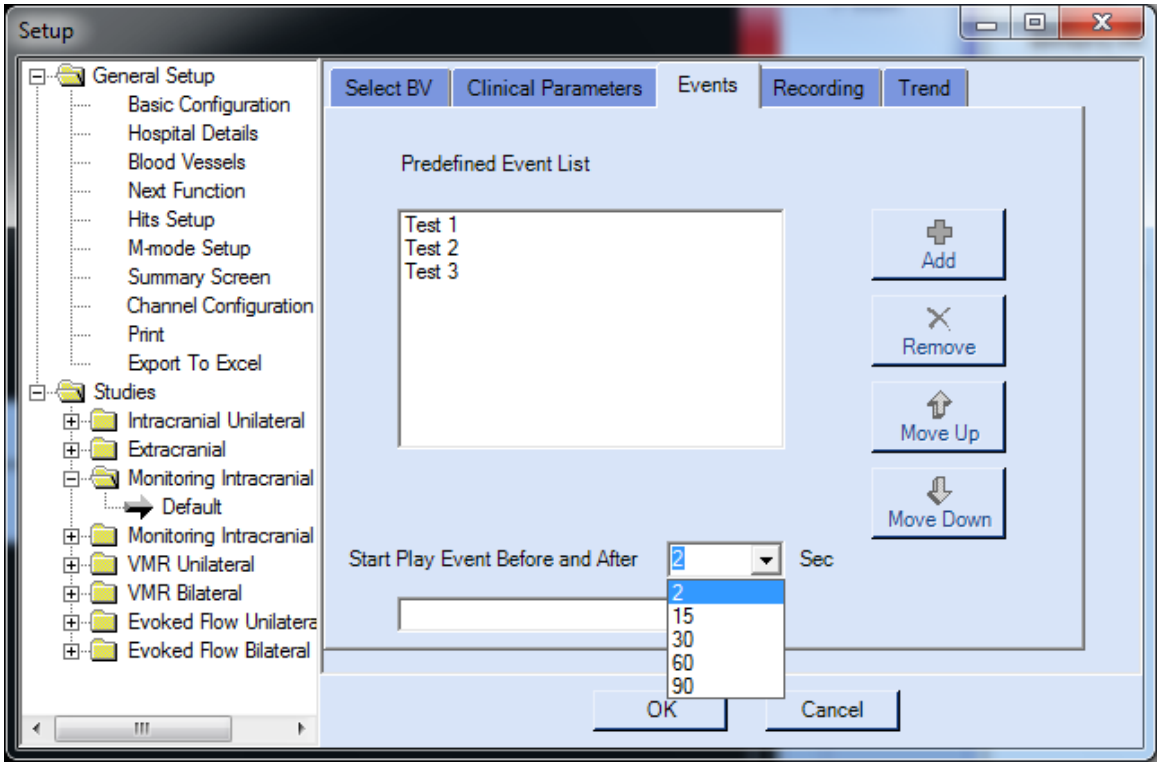


Figure 8-7 Events Form

To add an event, type in the new name and click the “Add” button. Repeat as needed, and then click OK. To delete an event, highlight the event and click on the Remove button. Then click OK.

Start Play Event before and after- this option is controlling on the time period of the selected event. (By default we use 2 seconds).

Setup the study trends - As a helper to create flexibility in the trend component, we have implemented the ability to select the trends that you will like to see in a given study. This window is very strait forward and will be very friendly and familiar to the expert user. It's using the same logic of adding clinical parameters/ blood vessels for study. You will see the next screen after going from the main menu to Setup➔Studies➔*Study name* ➔ clicking the "Trend" tab. (See figure 8-8)

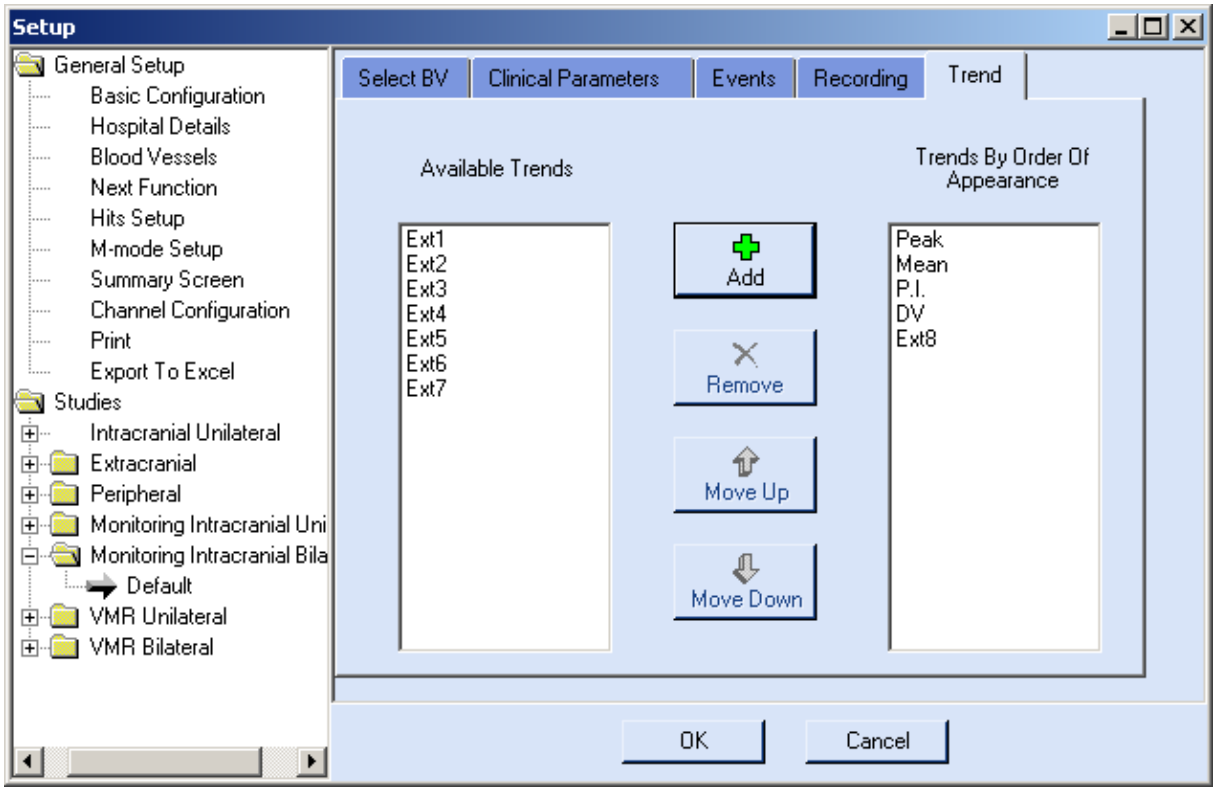


Figure 8-8 Trends Form

In the image we can see that the user chose to see 5 trends in the trend window at the "Monitoring intracranial Bilateral" study. 4 are a familiar clinical parameter and on external channel (The 8th one).

8.6. Performing a Monitoring examination in Unilateral or Bilateral

8.6.1. Beginning a new examination

To begin a new examination, press the UNFREEZE button (the recording will start automatically) and Perform a good insonation.

To monitor with two Doppler spectrum windows, you have to add the additional window before starting the examination.

8.6.2. Performing the examination

During the examination the following actions can be done:

- Add predefined events. To do this press on the specific event (one click) - in the EVENTS LIST. The name of the event will appear in the EVENTS HISTORY with the time of appearance. A yellow vertical line will appear on TRENDS window at the same time
- Enable/disable HITS. After enabling HITS an automatic HITS event will appear in HITS HISTORY window and a correspondent yellow line in TRENDS
- Add/ remove M-MODE
- Pause/continue the recording

8.6.3. Finishing the test

After the test was finished, press “STOP RECORDING” and save the examination.

8.7. Further inspection of the Monitoring examination off line

You can inspect the recorded Monitoring examination off line. To do this, load a saved Monitoring Unilateral or Bilateral examination and then you can perform any of the following actions (See figure 8-9):

- Choose an event from the EVENTS HISTORY. To do this double click on the event in the EVENTS HISTORY window
- Pay attention that when you choose an event it’s in PAUSE state, so if you want to REPLAY, you have to press on PAUSE/CONTINUE icon.
- Choose to replay the whole examination or from a specific event
- Choose to scroll the spectrum back or forward
- Choose to change the size of Trend Window

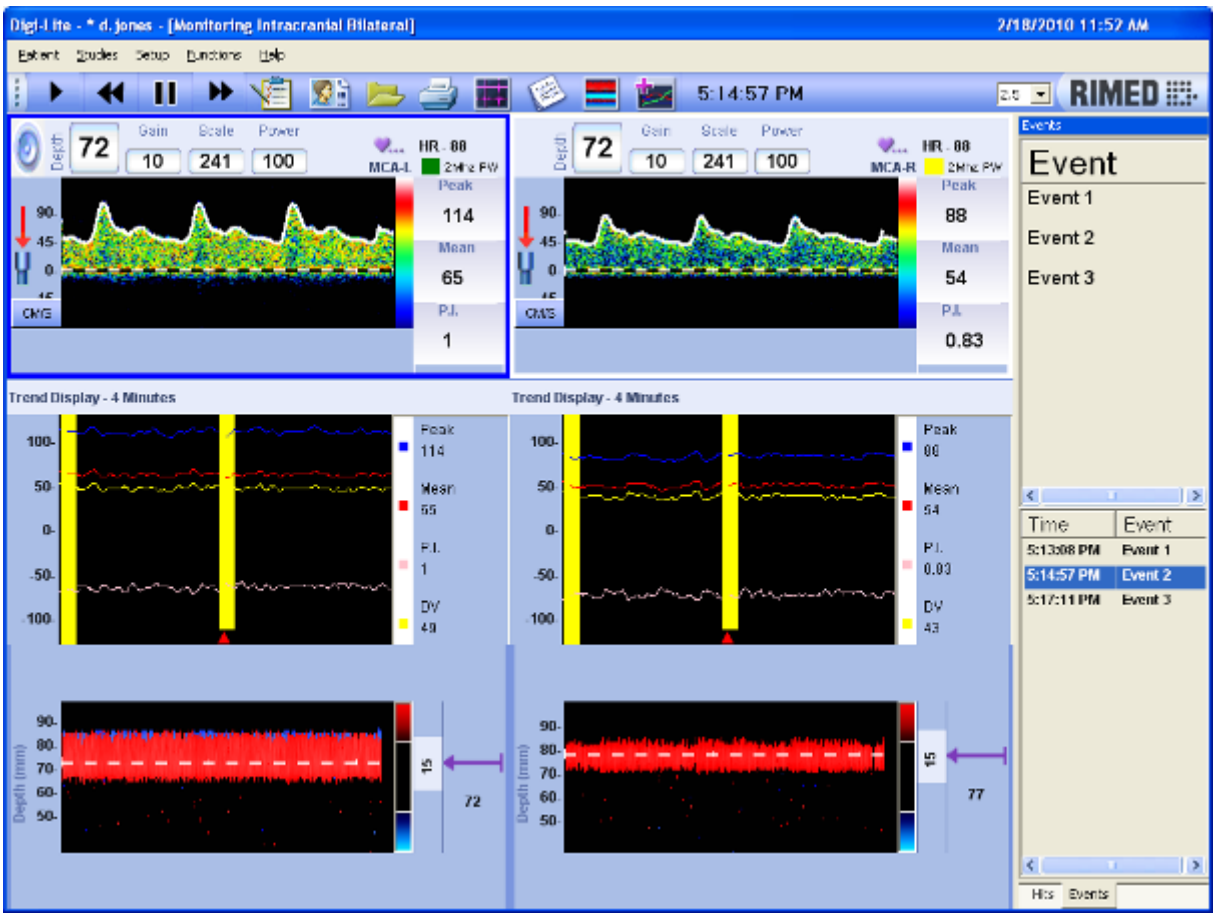


Figure 8-9 Monitoring Intracranial Unilateral

8.8. Monitoring Post-Processing

8.8.1. Additional Spectrum Window.

In order to detect if an Emboli is real or not you can use this tool to see different Depths of the same insonation that you have made.

You must use this option **before starting recording**. (You will have the option to close the M-Mode window or the Trend Window)

This option is used in Monitoring Unilateral and Bilateral studies.

Figure 8-10 Monitoring Intracranial Bilateral

Spectrum Window: Add spectrum window **(For each channel you can have up to 2 spectrum windows simultaneously)**

Cursors: The Cursors icon is pictured as a black screen with two pairs of cursors

8.8.2. Cursors and time delay display.

Another tool to help determining a real emboli or artifact is the cursors option and time delay display.

After finishing recording the study and loading the study, you can add the cursors using the button mentioned above.

Two cursors are added, each cursor contains the time stamp from the beginning of the test . One of the cursors contains the time delay between the cursors.

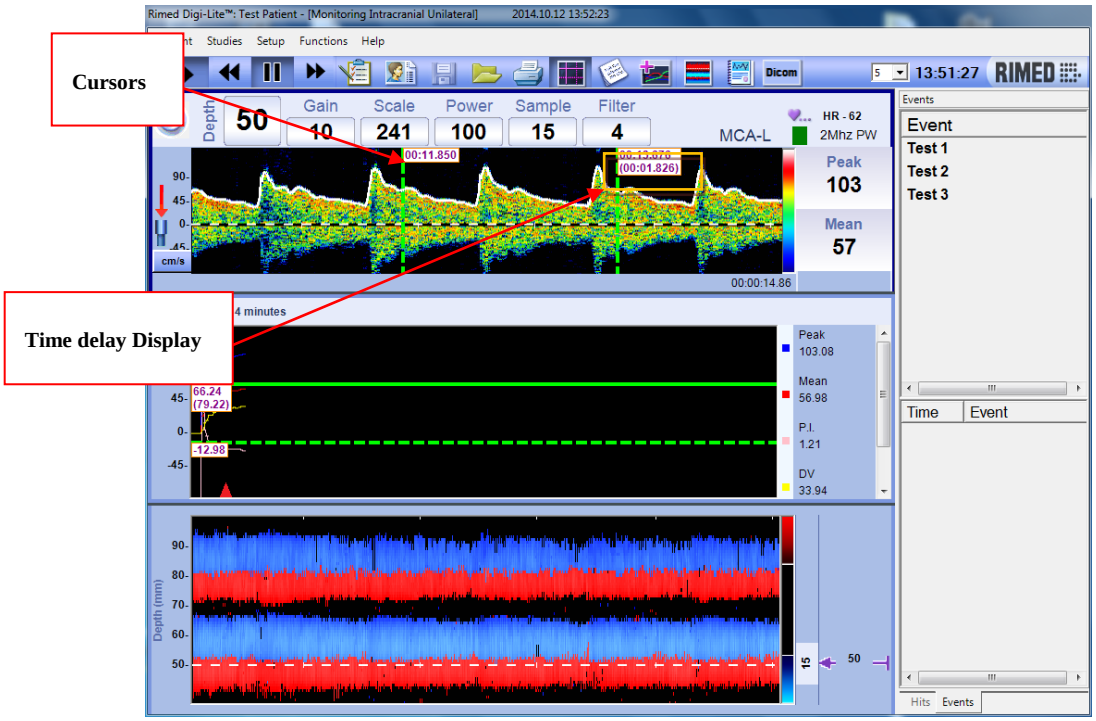


Figure 8-11 Cursors and Time delay display

8.8.3. Add/Delete Emboli

After determining artifact emboli or new emboli that wasn't automatically detected by the system you can add or/and delete Emboli using the cursors in replayed monitoring study. (See figure 8-12).

To add emboli put the main cursor (not the doted one) on the emboli that was not automatically detected by the system in the upper main window and right click on the cursors and press Add Hit. - The HIT event will automatically be shown in the event list, the HIT counter will be increased by 1, yellow bar will be added to the trend window and a green mark will be shown in the added spot. After you finish editing press on the SAVE button. (See figure 8-13)

To delete emboli put the main cursor (not the doted one) on the automatically detected emboli that was detected by the system (marked by orange marker) in the upper main window and right click on the cursors and press Delete Hit. - The HIT event will automatically remove from the event list, the HIT counter will be decrease by 1 , yellow bar will be added to the trend window and the orange mark will be removed after you confirmed. After you finish editing press on the SAVE button. (See figure 8-14)

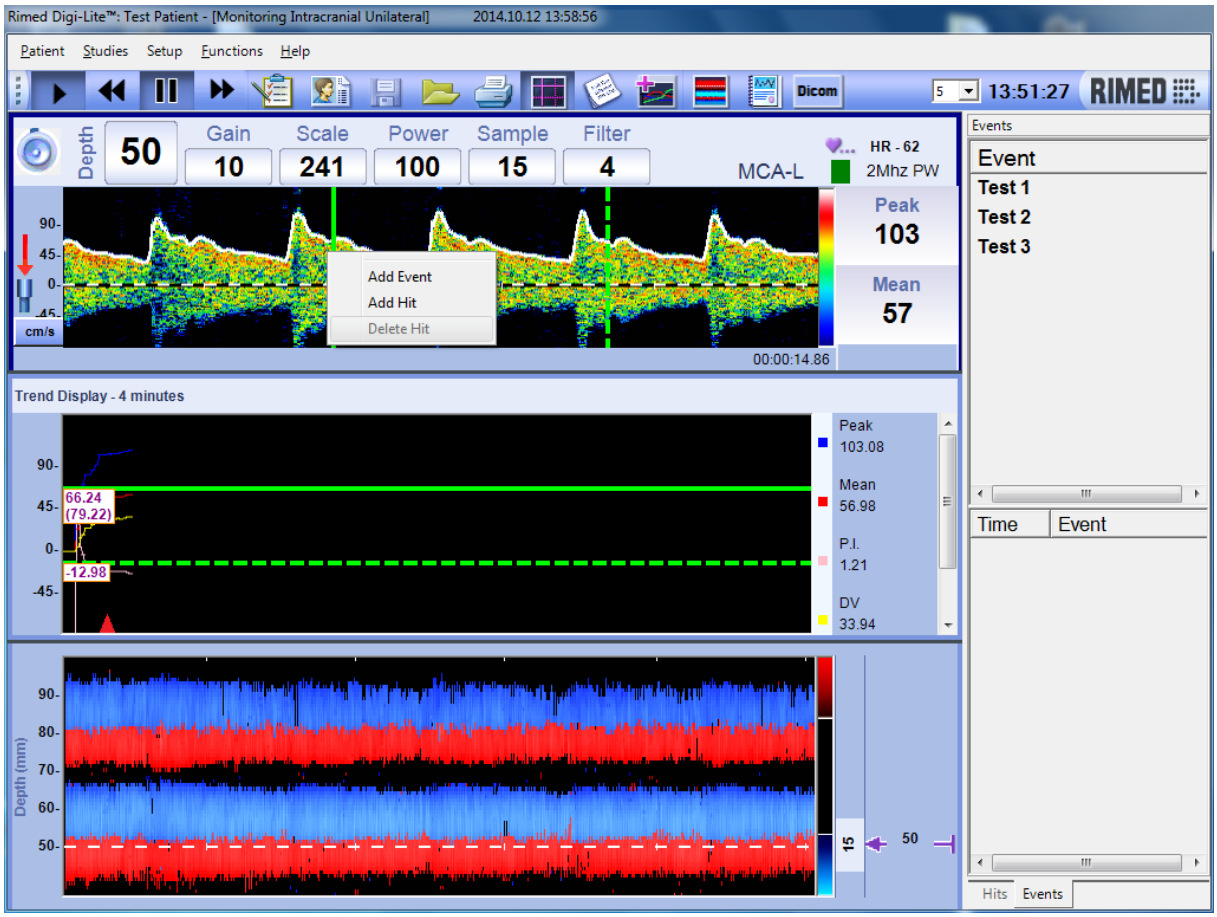


Figure 8-12 Add/Delete Emboli.

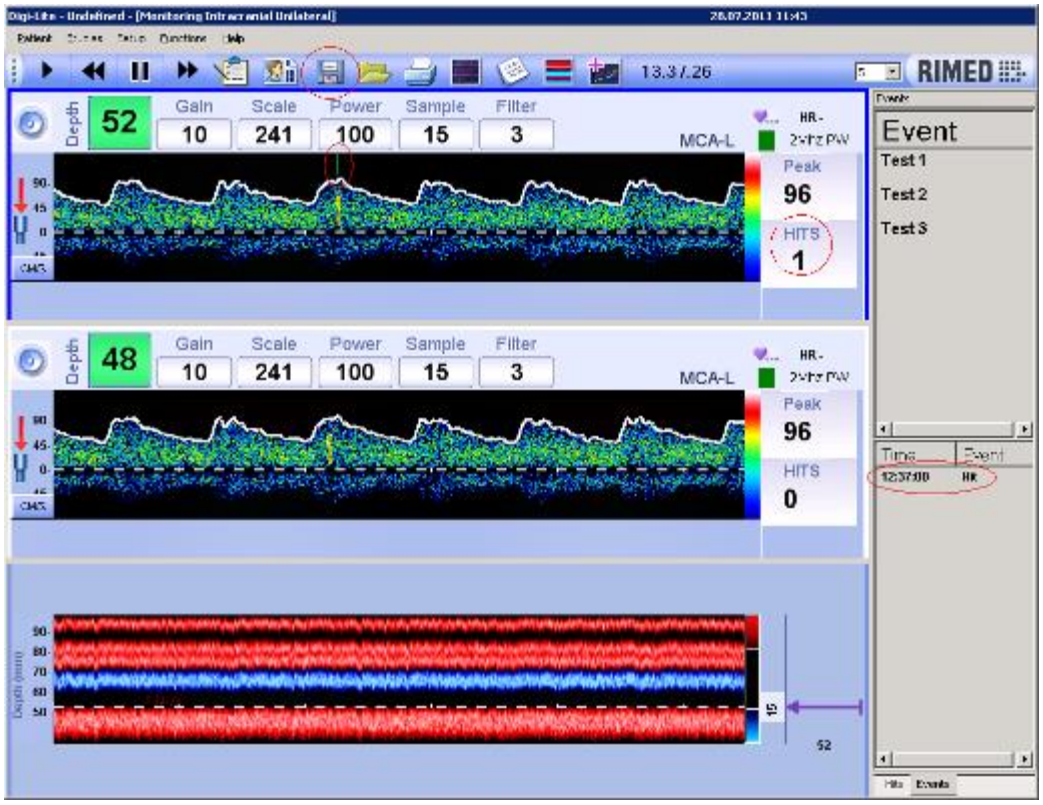


Figure 8-13 Add Emboli.

Figure 8-14 Delete Emboli.

8.8.4. Add/Delete Event

After loading monitoring study from the Data Base. You have the ability to Add or /and Delete an event in offline mode.
To add Event play the monitoring study till you get to the preferred spectrum picture and press pause button. Right click on the upper main window and then choose from the popup menu Add Event, in the next popup window you will need to choose Event from the predefined Event list or Enter new event name and press Ok.
New event is now added to the event list and yellow bar is added to the trend window
After you finish editing press on the SAVE button (See figure 8-15)

To delete Event double click on the event you want to delete from the event list. Right click on the upper main window and then choose from the popup menu Delete Event you wll need to confirm and then press Ok.

Your event will be deleted from the event list and yellow bar will be removed from the trend window.
After you finish editing press on the SAVE button (See figure 8-16)

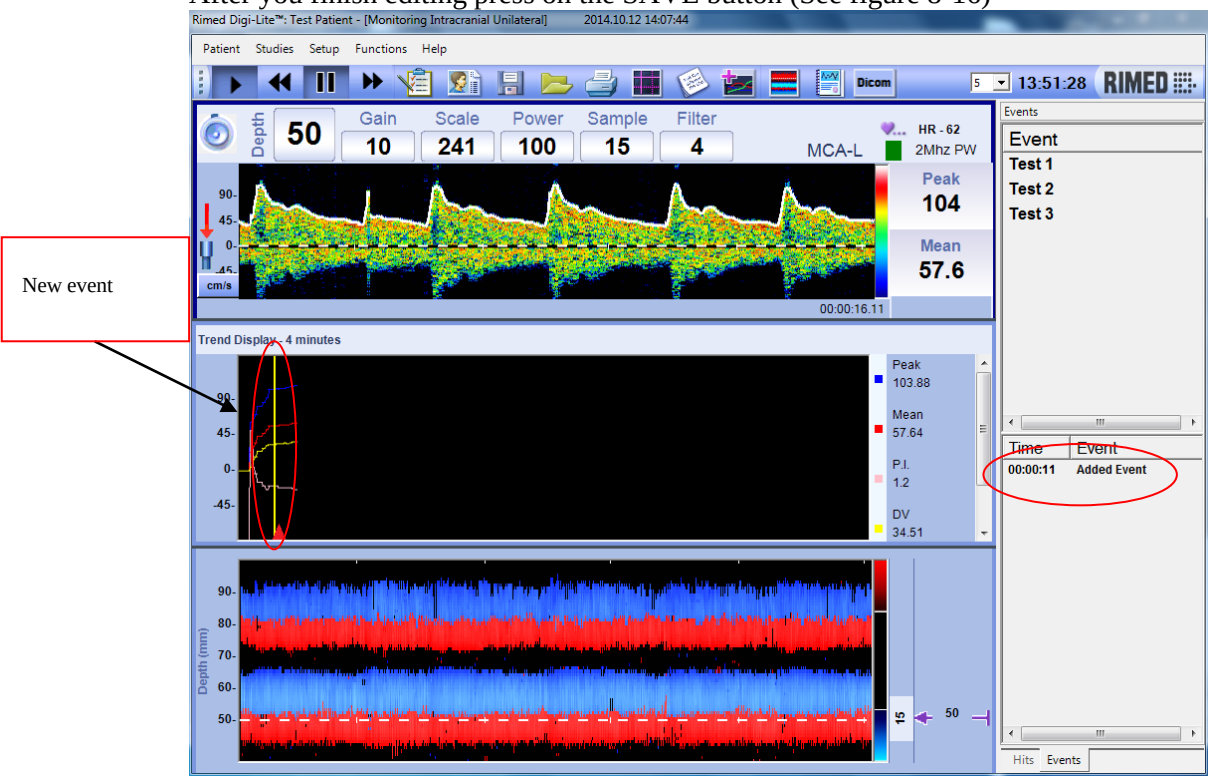


Figure 8-15 Add Event.

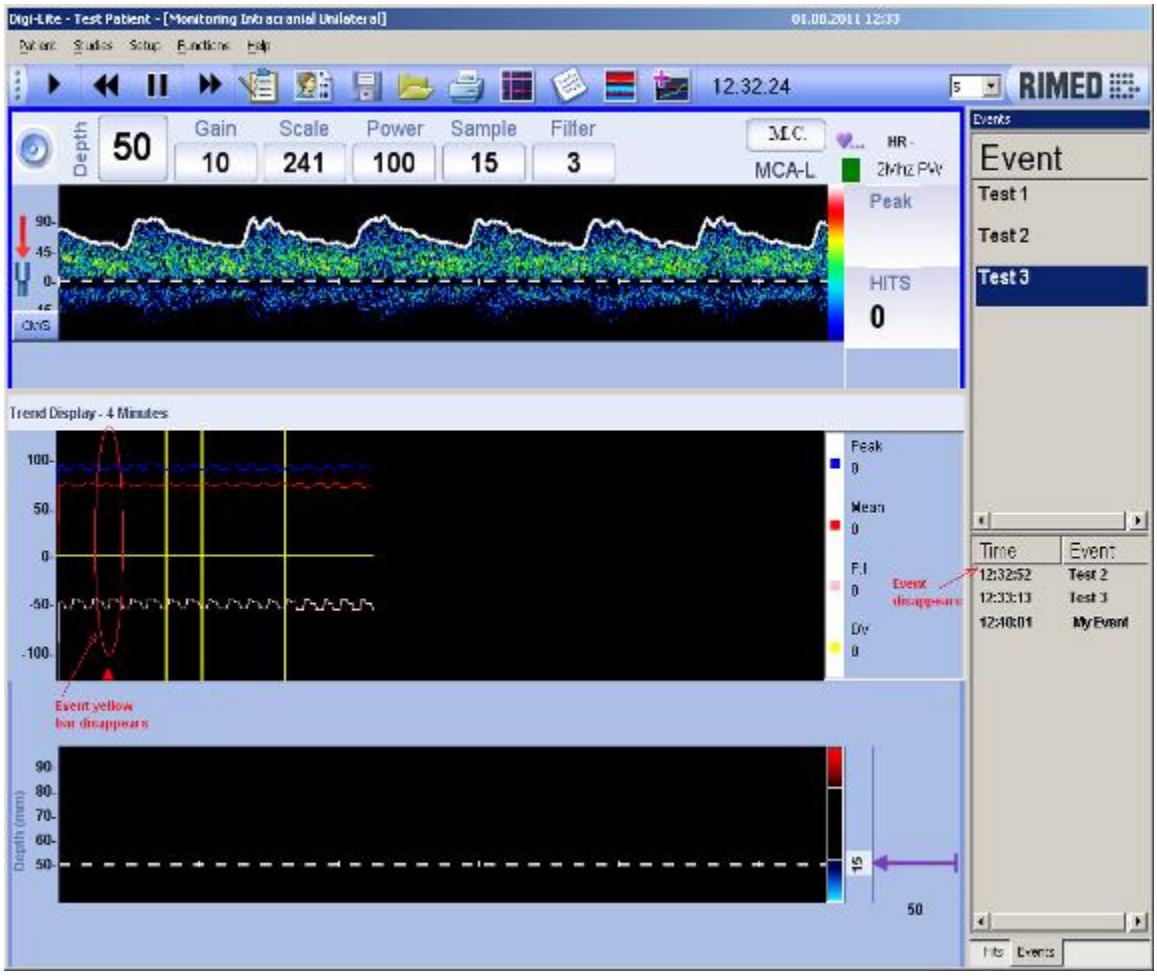


Figure 8-16 Delete Event.

8.8.5. Hits Histogram

In order to see the energy and the amount of hits from each channel you can use the Hits Histogram table that is located at the docking window in Hits tab.

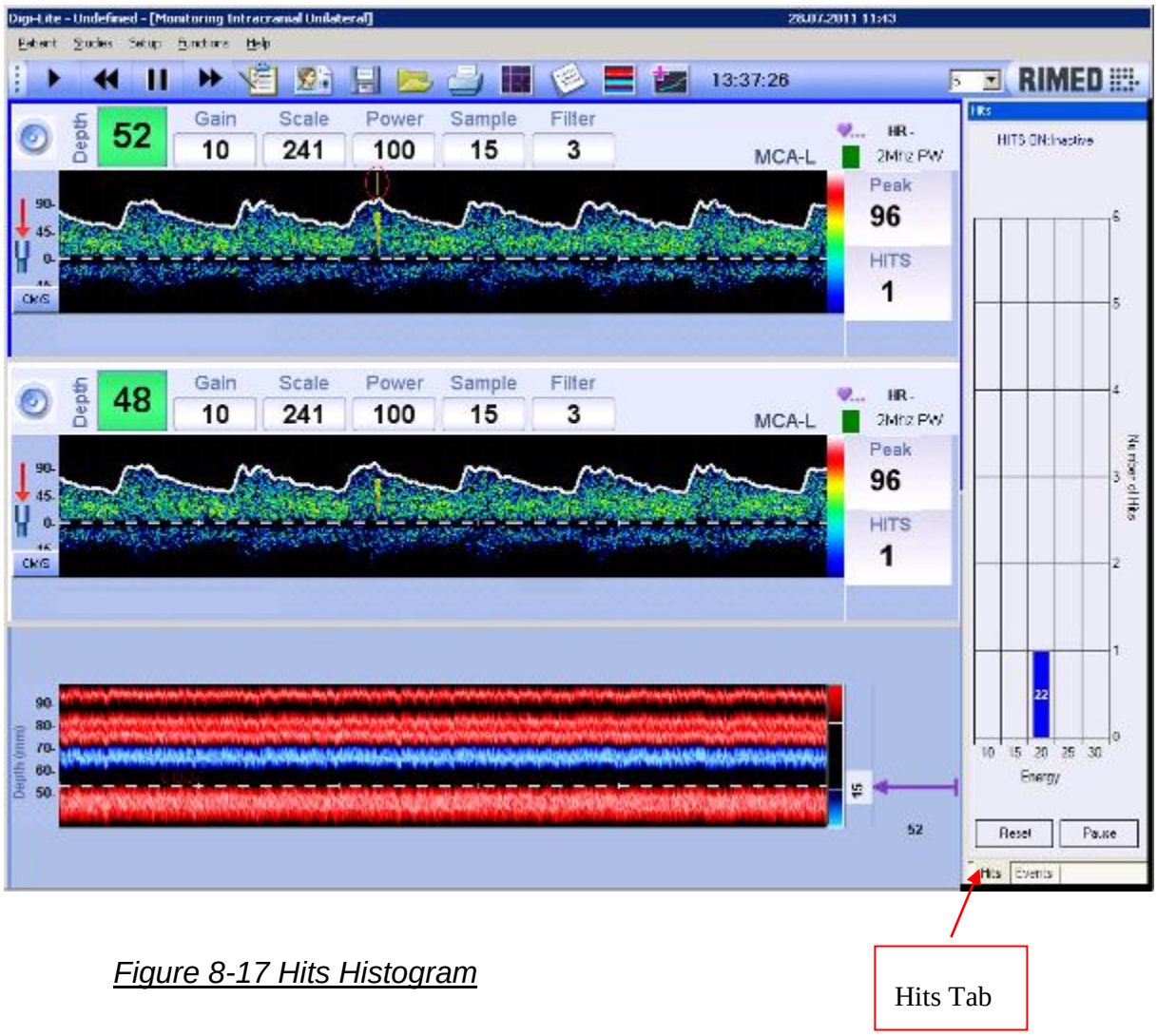


Figure 8-17 Hits Histogram

8.8.6. New Time Stamp From the Beginning of the Test

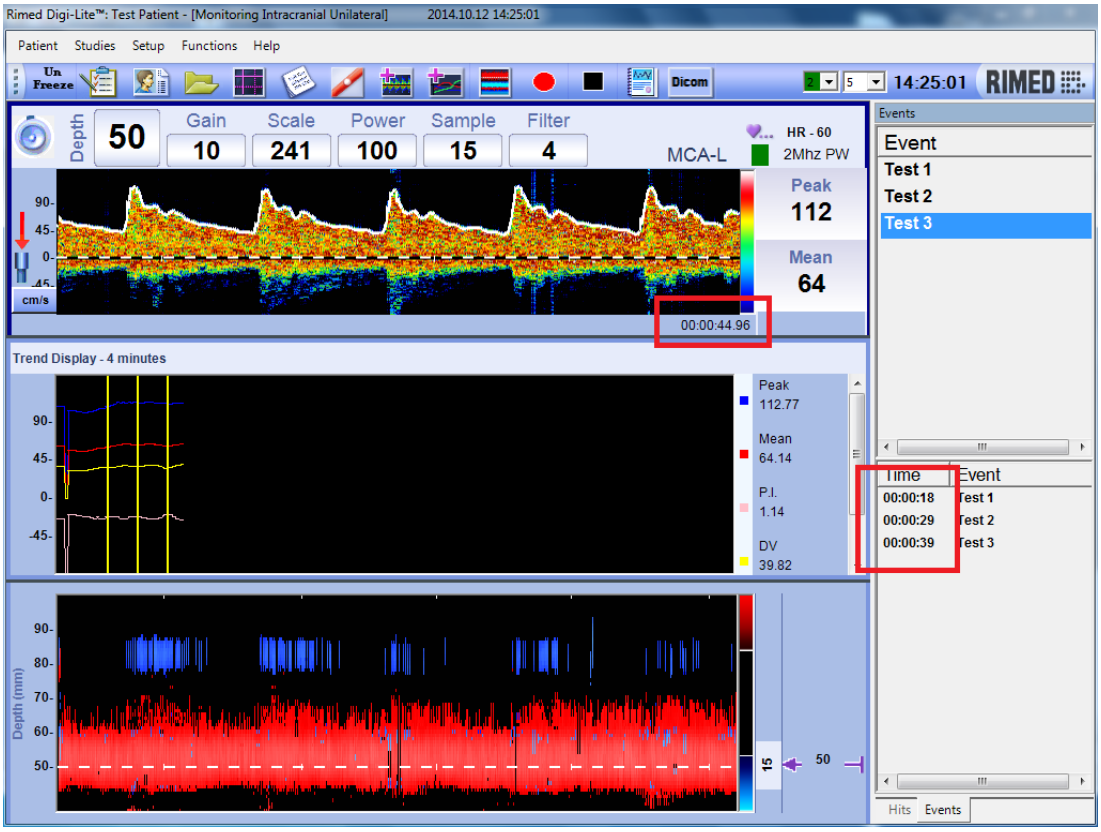


Figure 8-18 Time Stamp

9. Vasomotor Reactivity Test in Unilateral or Bilateral Studies

9.1. Selecting Vasomotor Reactivity study

Enter Vasomotor Reactivity (VMR) test using menu bar Studies, or Change study icon in toolbar.

VMR test is performed in a similar way as Monitoring: the examination is done in Unfreeze Real time.

The examination can be further inspected in LOAD OFF LINE state.

9.2. Vasomotor Reactivity test setup

Vasomotor Reactivity Test setup is based on Monitoring Unilateral or Bilateral.

Size of Trend Window: The size of trends can be changed in the same way as in Monitoring mode.

Figure 9-1 Size of Trend Window in VMR

Setting VMR events: The predefined events can be configured in the same way as in Monitoring studies. The difference is that in VMR there are two new predefined events: Baseline velocity and Test velocity. As in Monitoring, you can define and add new events. Choose SETUP- STUDIES-VMR and press the Events tab. The “EVENTS setup” form appears.

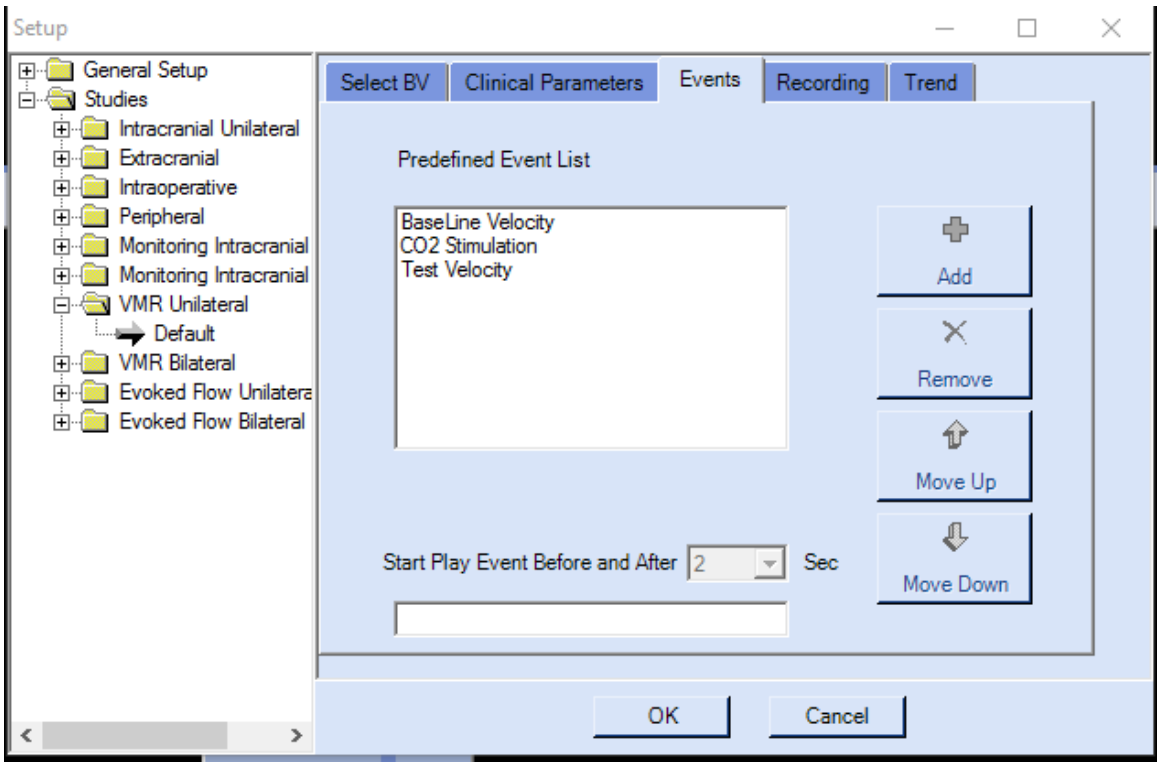


Figure 9-2 Events Form in VMR study

9.3. Performing a VMR test examination

9.3.1. Beginning a new examination

To begin a new examination, press the UNFREEZE button. Perform a good insonation, and press “RECORDING”.

9.3.2. Control state

At this stage the patient is in the control state and breaths normally. When a steady state velocity is achieved, press on the event named “BASELINE VELOCITY” in the PREDEFINED EVENTS area.

9.3.3. Test state

Perform the test, either by injecting drugs, breathing CO2 or breathe holding. The velocity will increase. Wait until the velocity achieves a new steady state value. At this moment press on the predefined event “TEST VELOCITY”. The VMR parameter is automatically calculated using the velocity values selected by you in steps 9.3.2 “Control state” and 9.3.3 ”Test state”. You can end the test, or continue it by performing different additional maneuvers and see the behavior of the velocity.

9.3.4. Finishing the test

After the test was finished, press “STOP RECORDING” and “FREEZE”.

9.4. Further inspection of VMR test examination OFF LINE

You can inspect the recorded VMR unilateral or bilateral examination off line. To do this, load a saved VMR test examination and then you can perform any of the following actions (See figure 9-3):

- Choose an event from the EVENTS HISTORY: BASELINE VELOCITY or TEST VELOCITY or other. To do this double click on the event in the EVENTS HISTORY window
- Pay attention that when you choose an event it’s in PAUSE state, so if you want to REPLAY, you have to press on PAUSE/CONTINUE icon.
- Open the Patient Report to view the events created, patient details/history and enter the Indication and Interpretation.
- Choose to replay the whole examination or from a specific event
- Choose to scroll the spectrum back or forward
- Choose to change the size of Trend Window

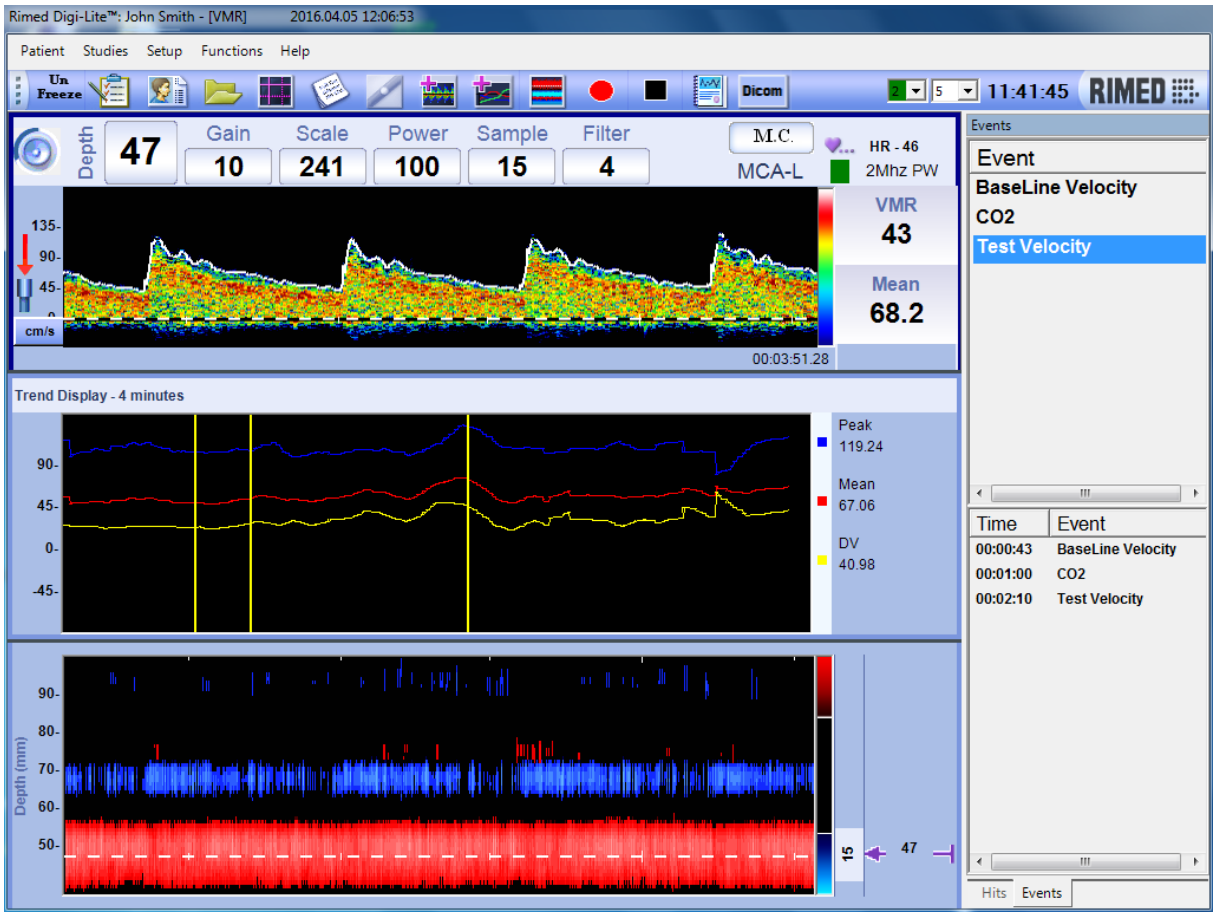


Figure 9-3 VMR Study

10. Evoked Flow Test in Unilateral or Bilateral Studies

10.1. Selecting Evoked Flow study

Enter Evoked Flow test using menu bar Studies, or Change study icon in toolbar.

Evoked flow test is performed in a similar way as Monitoring: the examination is done in Unfreeze Real time.

The examination can be further inspected in LOAD OFF LINE state.

10.2. Evoked Flow test setup

Evoked Flow Test setup is based on Monitoring Unilateral or Bilateral.

Size of Trend Window: The size of trends can be changed in the same way as in Monitoring mode.

Figure 10-1 Size of Trend Window in Evoked Flow

Setting Evoked Flow events: The predefined events can be configured in the same way as in Monitoring studies. The difference is that in Evoked Flow there are two new predefined events: Start Stimulation and Stop Stimulation. As in Monitoring, you can define and add new events. Choose SETUP- STUDIES-Evoked Flow and press the Events tab. The “EVENTS setup” form appears.

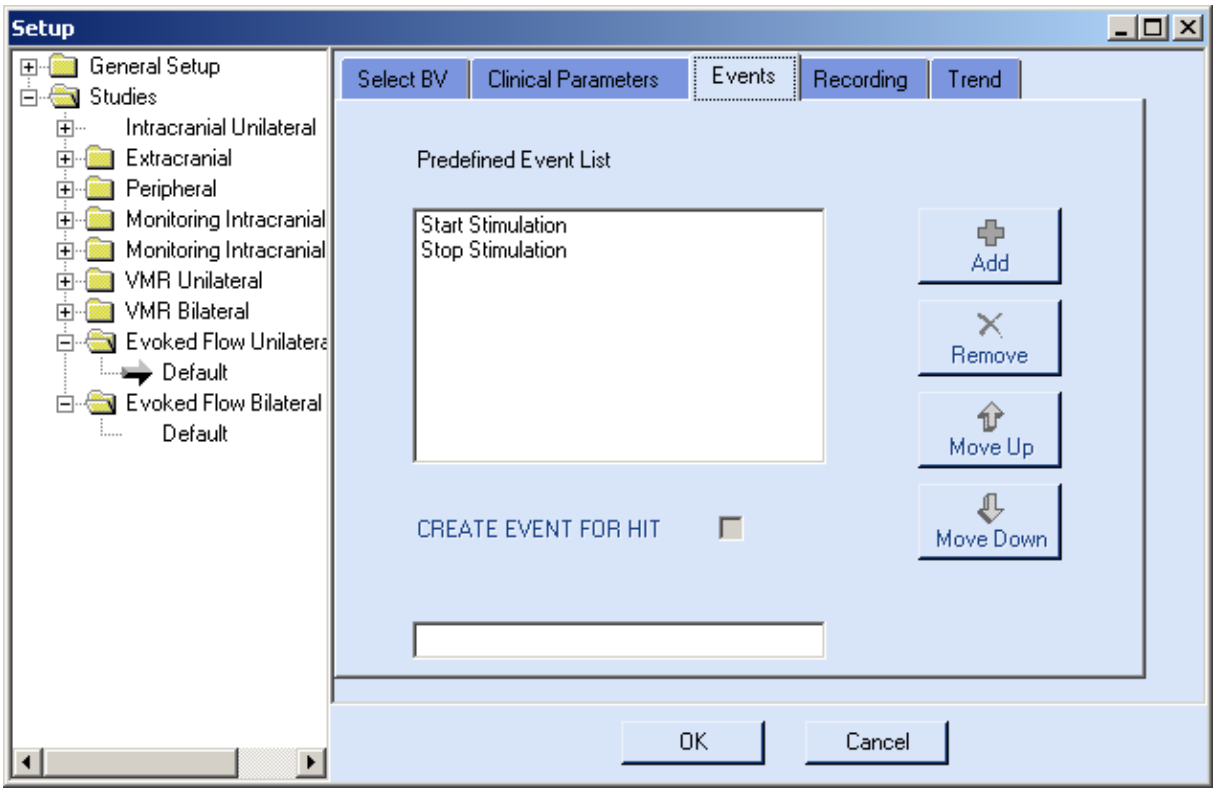


Figure 10-2 Events Form in Evoked Flow study

10.3. Performing an Evoked Flow test examination

10.3.1.Beginning a new examination

To begin a new examination, press the UNFREEZE button. Perform a good insonation, and press "RECORDING".

10.3.2.Control state

At this stage the patient is in the control state and breaths normally. When a start stimulating the brain the user need to press on "Start Stimulation" in the PREDEFINED EVENTS area.

10.3.3.Test state

Perform the test by stimulating the brain. There will be a change in the flow. Wait until you will see a change in the flow, at this moment press on the predefined event "Stop Stimulation". The Flow Change is automatically calculated in the upper right of the trend window using the peak values selected by you in steps 10.3.2 "Control state" and 10.3.3 "Test state". You can end the test, or continue it by performing different additional maneuvers and see the behavior of the peak values.

10.3.4.Finishing the test

After the test was finished, press “STOP RECORDING” and “FREEZE”.

10.4. Further inspection of Evoked Flow test examination OFF LINE

You can inspect the recorded Evoked Flow unilateral or bilateral examination off line. To do this, load a saved Evoked Flow test examination and then you can perform any of the following actions (See figure 10-3):

- Choose an event from the EVENTS HISTORY: Start Stimulation Or Stop Stimulation or other. To do this double click on the event in the EVENTS HISTORY window
- Pay attention that when you choose an event it’s in PAUSE state, so if you want to REPLAY, you have to press on PAUSE/CONTINUE icon.
- Choose to replay the whole examination or from a specific event
- Choose to scroll the spectrum back or forward
- Choose to change the size of Trend Window

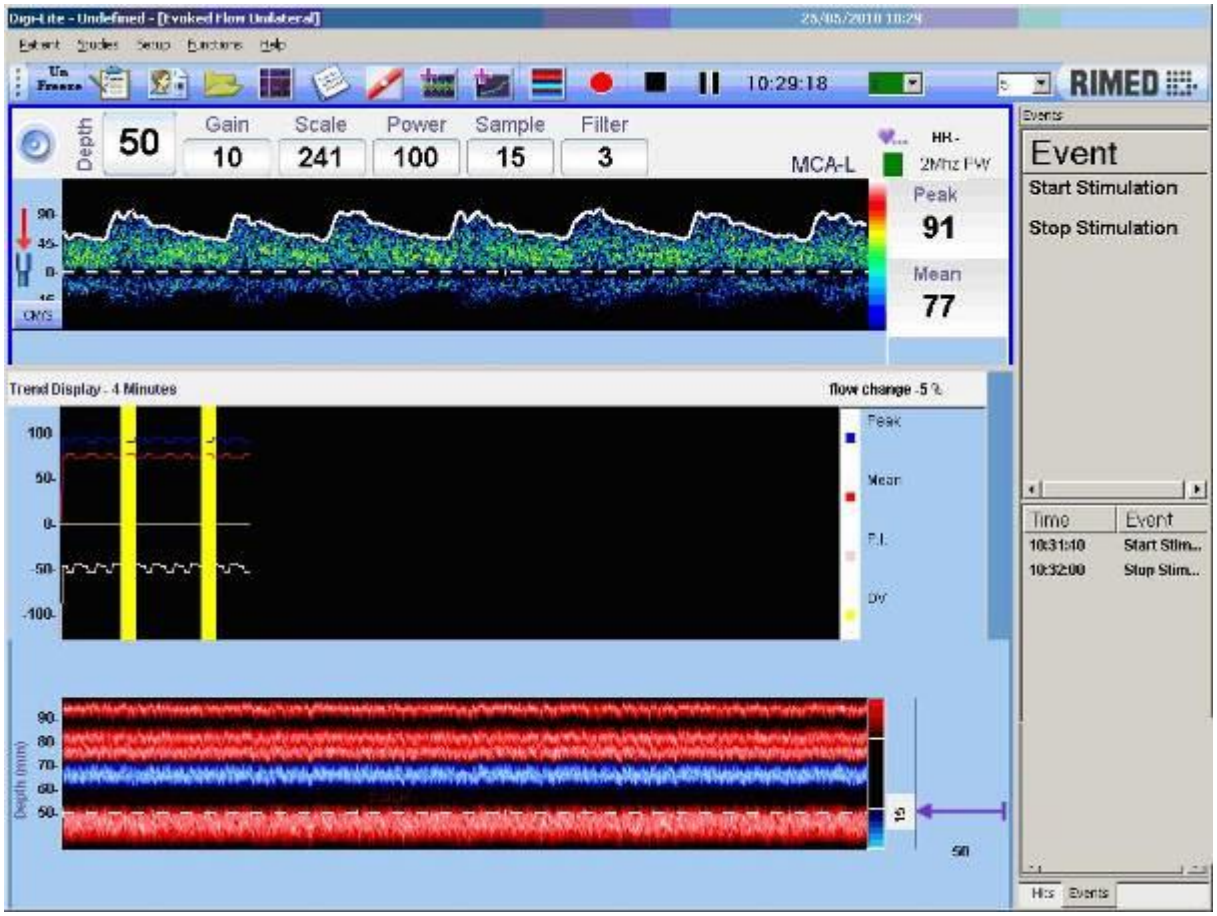


Figure 10-3 Evoked Flow Study

11. Probe Holder use in Monitoring: Technical description

The probe holder is used to attach the ultrasonic probes to the skull for continuous monitoring. Proper use will enable stable signal acquisition for long periods. The device is built of two separate parts. One is the frame; the second is the connecting set for the probes.

WARNING

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

WARNING

While monitoring patients for long periods, switching on (Unfreeze) only at critical phases of surgery (or follow-up period) is preferred to continuous monitoring.

Using the probe holder is easy if you keep in mind the following steps:

1. Attach the probe (or probes)

2. Put the frame on the patient's head

3. Locate the temporal window

4. Lock the probe in place

5. Repeat for the other side

The frame is placed on the patient's head. The connecting set enables positioning of the probe on the patient's skin, in the area where the ultrasonic window is usually found. It is made of two arms: The first connects to the frame, the second to the first arm. Both can rotate freely relative to the frame and to each other. Once the probe is in the correct position and a signal is obtained, eccentric locks will keep the arms in that position.

The probe is connected to the end of the second arm with a ball and socket mechanism. This allows for changing the probe's angle - to optimize the Doppler signal. A third eccentric lock keeps that angle constant

Tips for use: It is very helpful to locate the temporal window before attempting to put on the probe holder. Marking the area can help if the examination is done a few hours prior to surgery.

Cleaning and disinfection: All parts can be cleaned and disinfected. Recommended cleaning instructions are using water and mild soap for general cleaning, followed by sterilization with FDA approved disinfecting solutions.

Figure 11-1 Probe Holder

11.1.1.Operation guide

1. Connecting the probe:

   Take off the handle from the probe.

   Connect the probe to the screw protruding out of the device's handle (Tip: screw it out enough to be manipulated easily).

   Make sure to tighten this screw against the probe's surface.

2. Frame adjustment:

   Open the frame to its full extent (both horizontally and vertically).

   Rimed suggests to take off the large rubber padding. A thin adhesive padding can be ordered and put on the frame. This increases stability as it reduces empty spaces between the frame and the skull.

   Put the probe holder on the patient's head, knob facing forward.

   The back of the frame should rest low relative to the skull, to increase stability.

   The front of the frame should be adjusted on the forehead, with the temporal ultrasonic window in mind (too low would hide the window; too high decreases stability).

   Remove hair that is caught between the frame and the skin.

   Tighten the front knob, communicating with the patient. You need his/ her cooperation, so check in advance that it is not painful. When the patient is unconscious, use the minimal tension that gives good stability.

   Tighten the upper knob, just enough to make good contact with the skull. Don't over-tighten, as this tends to "pull" the frame off the head and decreases stability.

3. Locating the TCD signal

   Using sufficient quantities of ultrasonic gel apply the probe to the temporal window and search for a signal.

   Best results are achieved when the signal was located and marked before.

   When starting to look for the signal, adjust the probe's pressure against the skin to a minimum. This would allow easy movement and "natural" searching.

   After the best signal has been found, increase the probe's pressure. Don't overdo it – the probe should feel stable, but avoid causing pain. Remember that this pressure will be held for a long period of time.

4. Locking

   Locking on the signal is simple – just move the small lever fully from unlocked position to lock.

   However, before attempting to lock, you should feel that the probe "holds itself". Avoid exerting pressure on the probe before locking – the elasticity of the frame will move it from the optimal position. This is best learned by experimenting on you and colleagues before rushing with the device to the operating room.

   If after locking the signal changed and is not optimal, release the lever (with experience, you can release it only halfway) while holding the probe in position. Adjust the signal again and lock in place.

   Additional operating tips:

   Removing the mechanism on one side:

When only unilateral monitoring is needed (during carotid endarterectomy, for example), you can take off the mechanism from the other side. To do this, make sure that the locking lever is in the unlocked position. Then unscrew the large, notched cap that is connected to the frame. Put the mechanism in a secure place until needed again.

Before re-connecting, check that the lever is in the unlocked position. Screw the cap in place, until friction is felt. Do not over-tighten, as this can damage the unit and will not add to stability.

12. Setup configuration

The Setup Configuration menu allows the user to configure all system settings for routine system operation.

The DIGI-LITE has a very powerful and user friendly setup menu, that gives the possibility to change almost all the system's characteristics, providing the flexibility of using the system in multiple and various applications by different users.

DIGI-LITE comes from the factory with a default configuration. However, if you want to, you can customize the configuration to meet your needs. The setup contains three main setup categories:

1. Patient Report Wizard: to configure the patient report
2. General Setup: to configure general system parameters
3. Studies Setup: to configure specific parameters for each study separately
4. Save Study: to save a customized study as it was defined by the user

12.1. Patient report wizard

To reach the Patient report wizard dialog box select SETUP-PATIENT REPORT WIZARD from the SETUP menu. (See figure 12-1)

The patient report can contain details on hospital, patient and examinations. Each user can configure the patient report according to his needs and choose what information to display and what not.

There is a very friendly wizard that will help you to configure the patient report according to your needs.

The wizard contains three dialog windows with configuration details. At the right side of each window there are check boxes for each detail that can be inserted or not to the patient report. To choose what information will appear in the report, mark the appropriate box. At the left side there is a preview of the report, as it looks, according to the actual chosen configuration. To configure the patient report, fill each one of the three dialogs and then press NEXT. After filling the last dialog press FINISH.

The three dialog windows are:

12.1.1.First window: Report header and general information

The first window contains the report header and the following general details:

- Date display: mark this if you want to display examination date
- Hospital details: mark this if you want to display hospital details
- Hospital logo: mark this if you want to display hospital logo
- Title display: mark this if you want to display the title: “TCD Examination…”
- Patient details: Full or Minimal: If you choose Full: all the details will appear in the report. If you choose Minimal: only partial information will appear.
- Patient History: mark this if you want to display the patient clinical history (as it was written in New patient form)
- Examination history: mark this if you want to display a list of all the examinations that were done for the selected patients in the past
- One Page Report: 1 page patient report. It includes only patient details & clinical parameters table & signature that all & it occupies one page only. For choosing 1 page Patient report you should go to Setup -> Report Generator Wizard. Choose One-page report checkbox. Patient History and Examinations History deactivated. In Patient Details Minimal radio-button is checked automatically.

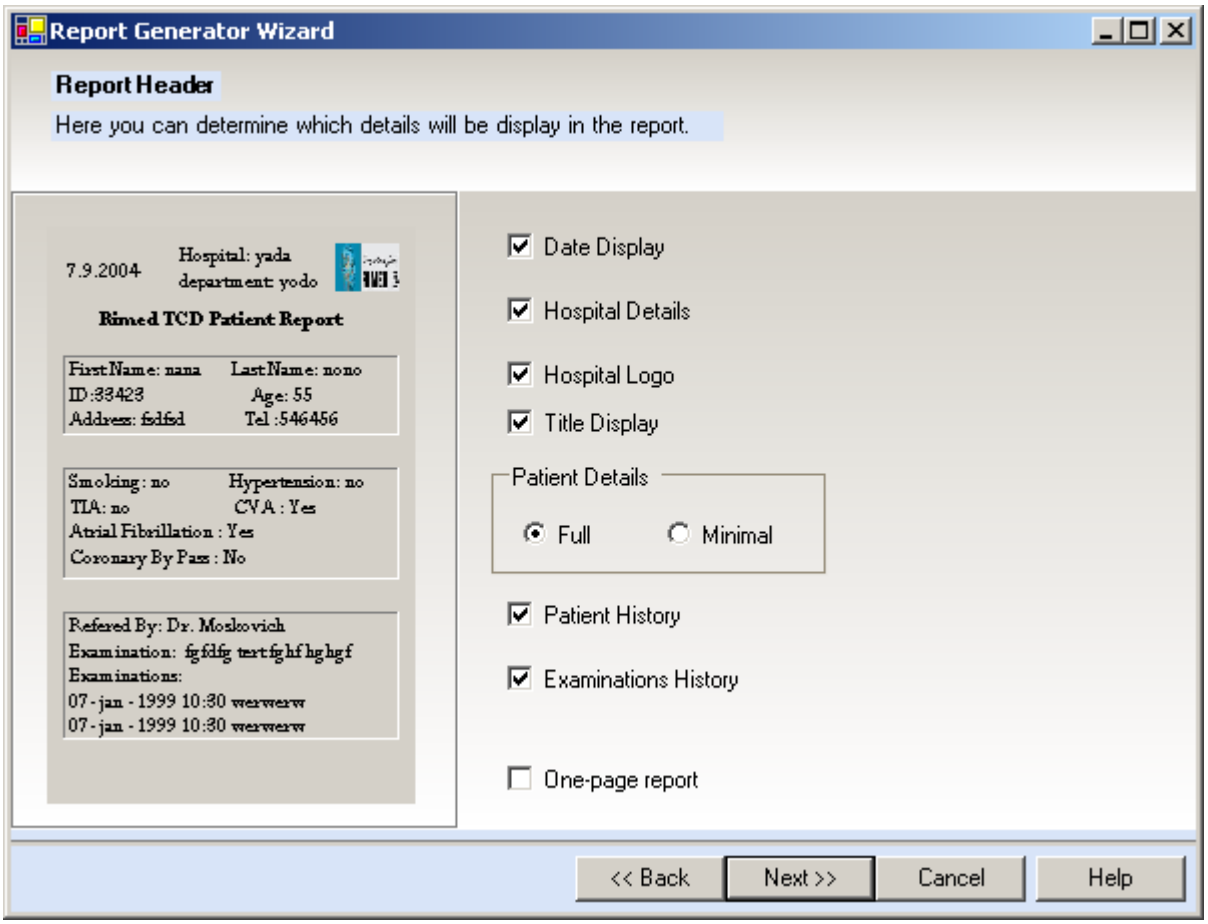


Figure 12-1 Patient Report first Dialog box

12.1.2.Second window: Examination display

The second window contains two check boxes that define examination display configuration, as follows:

- Summary Screen: mark this if you want to display the summary screen of the actual examination with all the spectrums appearing in the summary screen
- Table Report: mark this if you want to display a table containing information on the actual examination with the clinical parameters for each blood vessel, as appears in the summary screen, but without the spectrums' pictures
- Mark both Summary Screen and Table Report: if you want to display both in the patient report
- If you don't mark any of the two options, no pictures and no clinical parameters will appear for the actual examination

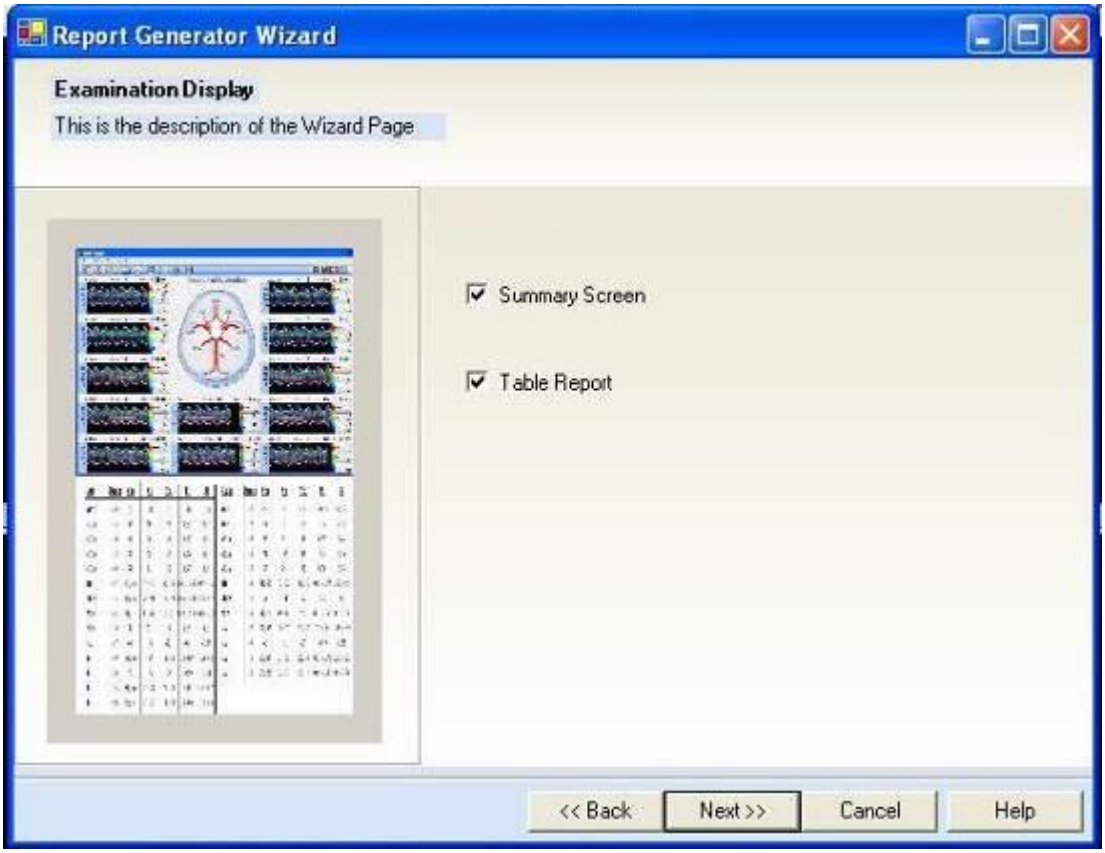


Figure 12-2 Patient Report second Dialog box

12.1.3.Third window: Report footer

The third window is the report footer and it contains operator and doctor's comments and signature for the actual examination. All these comments will be written after the specific examination was done, and you want to build the patient report. It contains the following three check boxes:

- Indication: mark this if you want to display indications for the actual examination
- Interpretation: mark this if you want display interpretations for the actual examination
- Signature: mark this if you want to add doctor's manual signature to the patient report for validation. The signature can be added only manually, after printing the report.

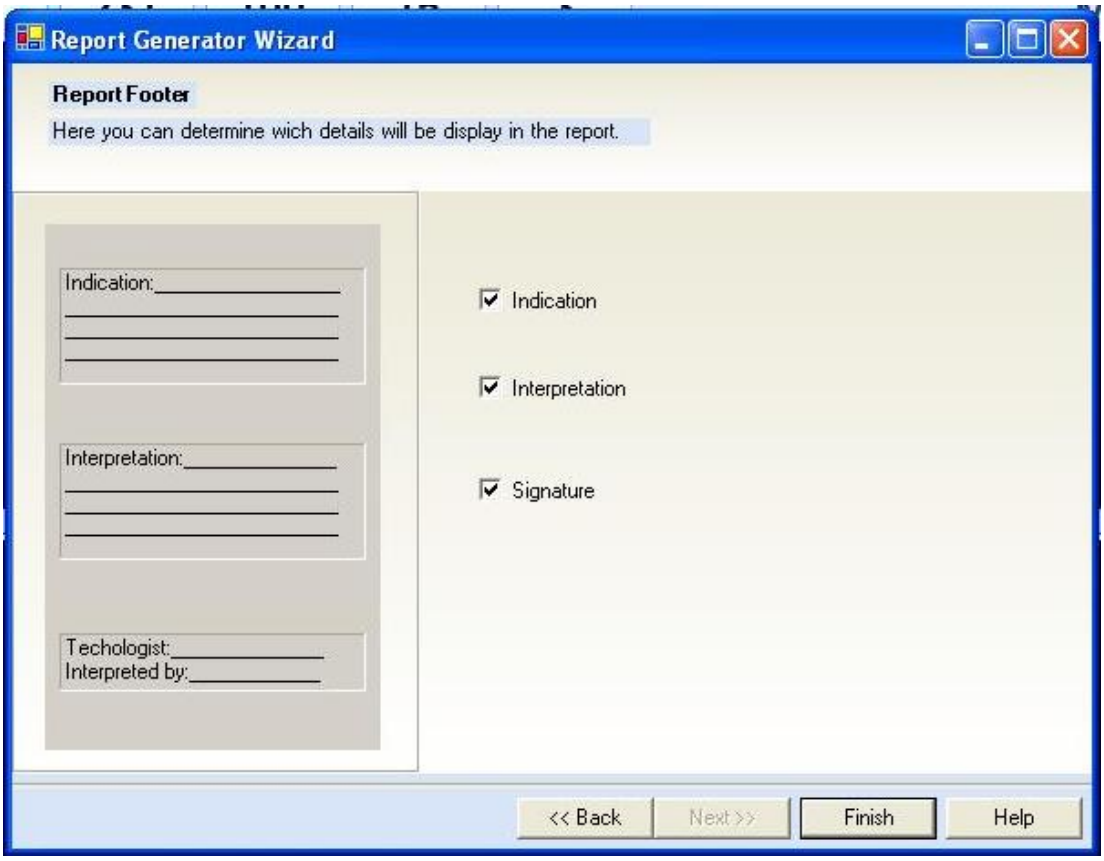


Figure 12-3 Patient Report third dialog box

12.1.4. One Page Report Option

The one-page Report option includes only patient details & clinical parameters table & signature that all & it occupies one page only. For choosing 1 page Patient report you should go to Setup -> Report Generator Wizard. Choose One-page report checkbox. Patient History and Examinations History deactivated. In Patient Details Minimal radio-button is checked automatically. (See figure 12-4)

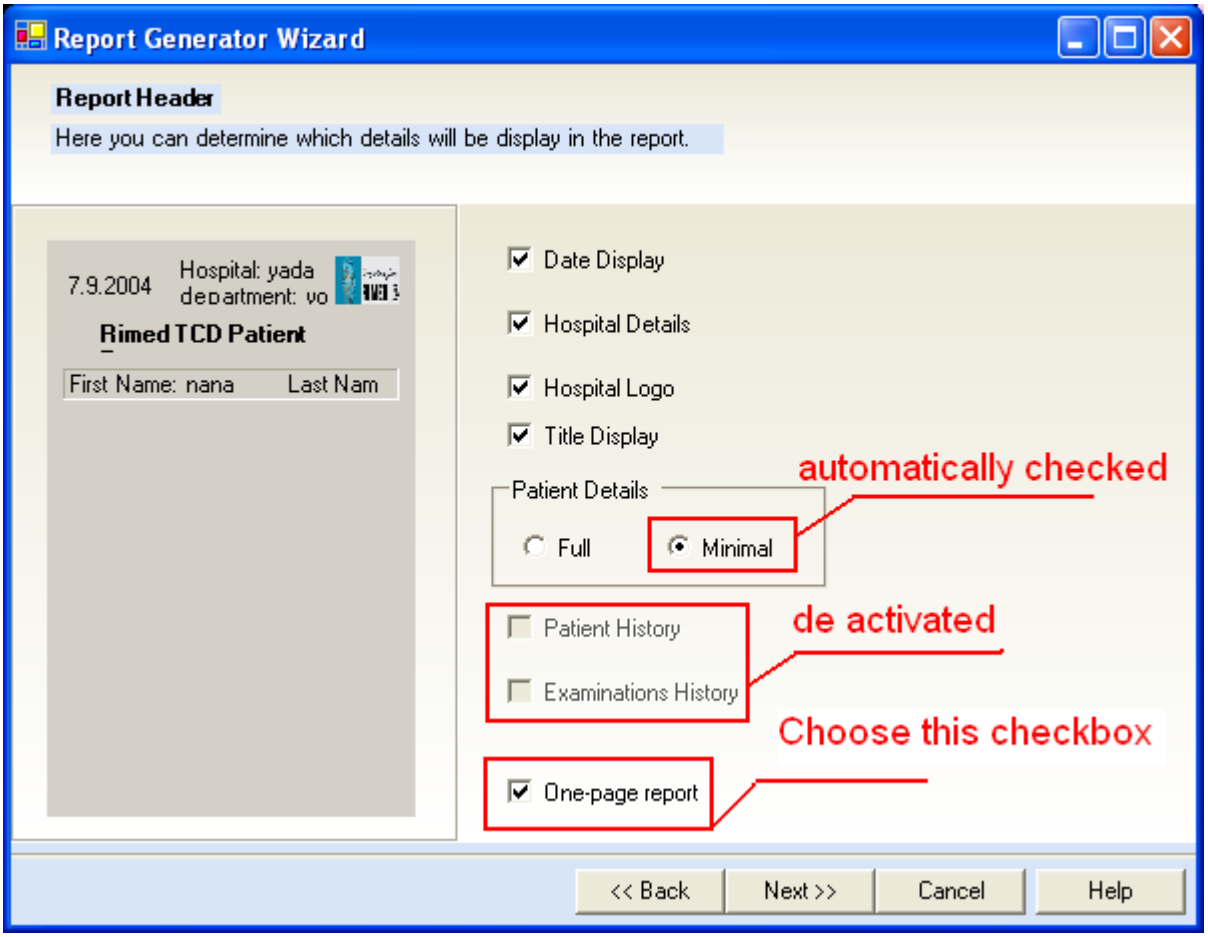


Figure 12-4 Patient Report first Dialog box (one page report option)

Click on “Next” button. Summary Screen checkbox deactivated. Table report checkbox deactivated also but always checked. (See figure 12-5)

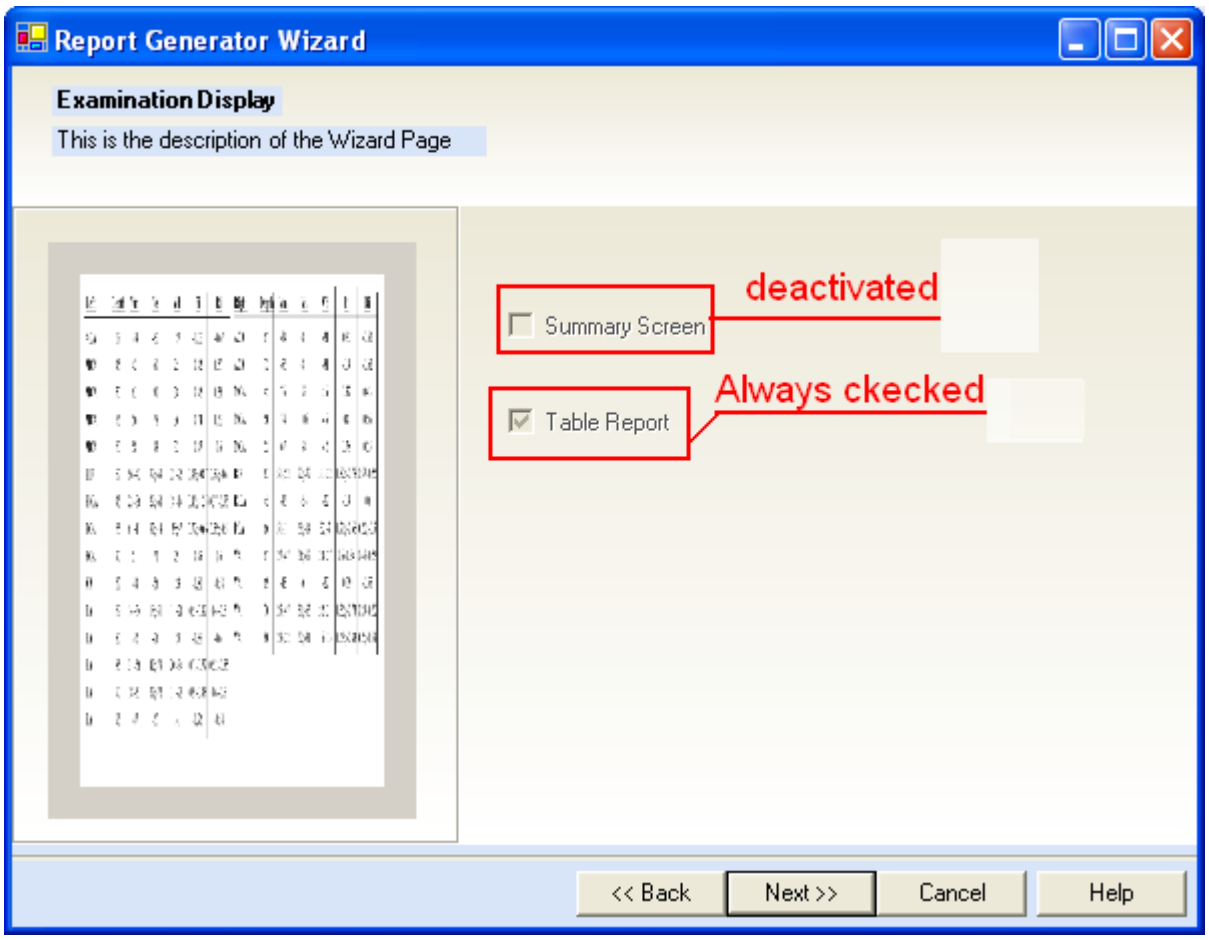


Figure 12-5 Patient Report second Dialog box (one page report option)

Click on “Next” button. Indication, Interpretation and Signature checkboxes deactivated. But Signature checkbox always checked.

After creation of “one page report” has finished in Full Patient Report will appear all changes.

12.2. General Setup

To reach the General Setup dialog box select SETUP-GENERAL SETUP from the SETUP menu. (See figure 12-6). The SETUP dialog box contains two areas: setup explorer area with general setup items in the left side and configuration details for the specific item in the right side. The setup item can be accessed either by choosing the item from the SETUP menu, or by opening the SETUP menu and selecting the item in the explorer left side.

12.2.1.Basic Configuration

The Basic Configuration dialog box contains parameters which determine how the spectrums are displayed on your screen. It also contains sound parameters. To reach the Basic Configuration dialog box select BASIC CONFIGURATION from the SETUP- GENERAL SETUP menu. (See figure 12-6)

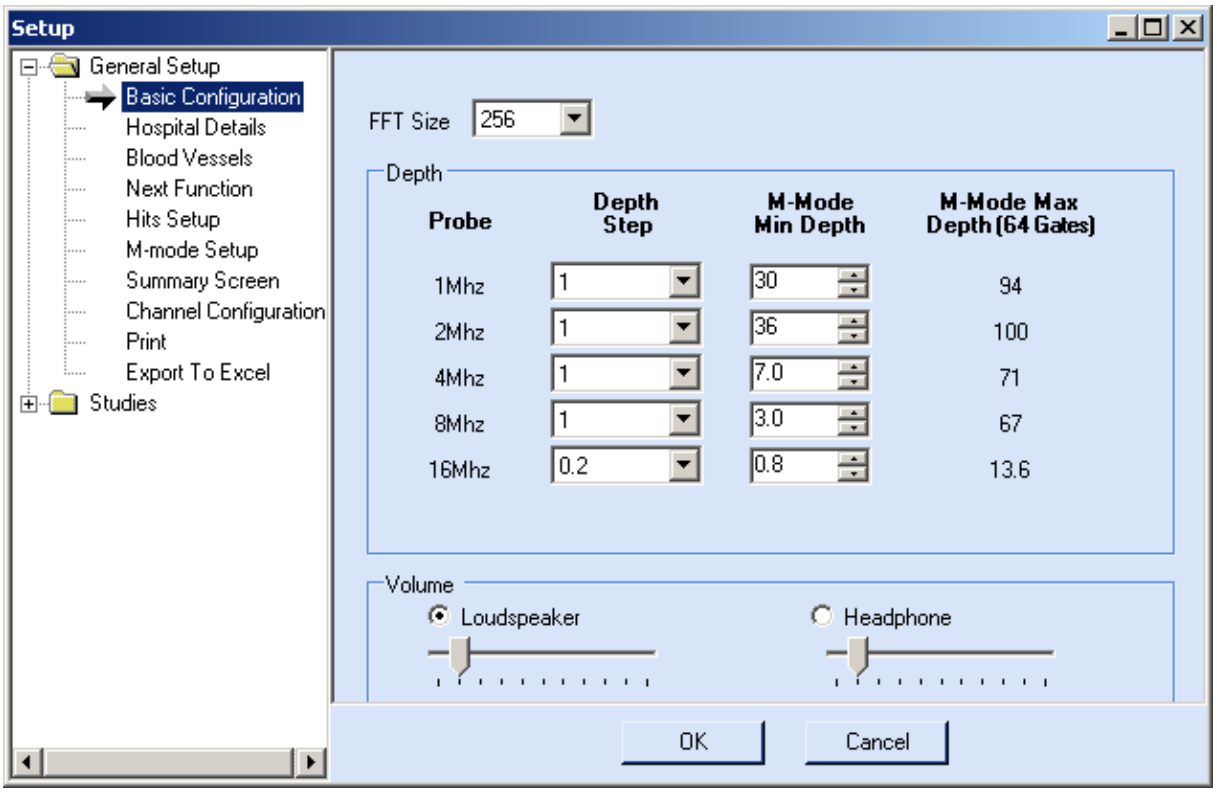


Figure 12-6 Basic Configuration

FFT Size: Sets the resolution of FFT spectrum analysis. A higher number gives a higher level of detail. The recommended default is 256 points.

Enable Blood Vessels Default Depth: This check box gives the option either to enable predefined depth for each blood vessel, or to keep the same depth when performing insonation on next blood vessel. If you check this box, the depth will change according to predefined values when changing blood vessel. If you don't check this box the depth will remain the same giving the possibility to scan the blood vessels without skipping any part of it. In this last case the depth will be manually changed only by the user.

Depth table: This table gives the possibility to define depth step and M-Mode depth range for each one of the PW probes. You can set Minimum Depth and Depth step, and the software will calculate Maximum Depth according the following formula: ***Min Depth + Step * 64 = Max Depth (all in millimeters).*** If you want wider depth range increase the step. The default steps are 1 mm for 2, 4 and 8 MHz and 0.2 mm for 16 MHz probes.

Sound Volume: Choose to hear sound either thru Loudspeaker or Headphones. When headphone is selected the loudspeakers are silenced (mute condition) and the opposite. Also sets the default sound volume, on a scale of 0 (mute) to 20 (maximal volume), in the loudspeakers and headphone.

12.2.2.Hospital details

The Hospital Details dialog box is used to input hospital information to be printed as a header with each patient report printout. These details are optional, and used only when this option is activated in the Patient Report wizard first screen. To reach the hospital details dialog box select "Hospital details" from SETUP-GENERAL SETUP menu. (See figure 12-7)

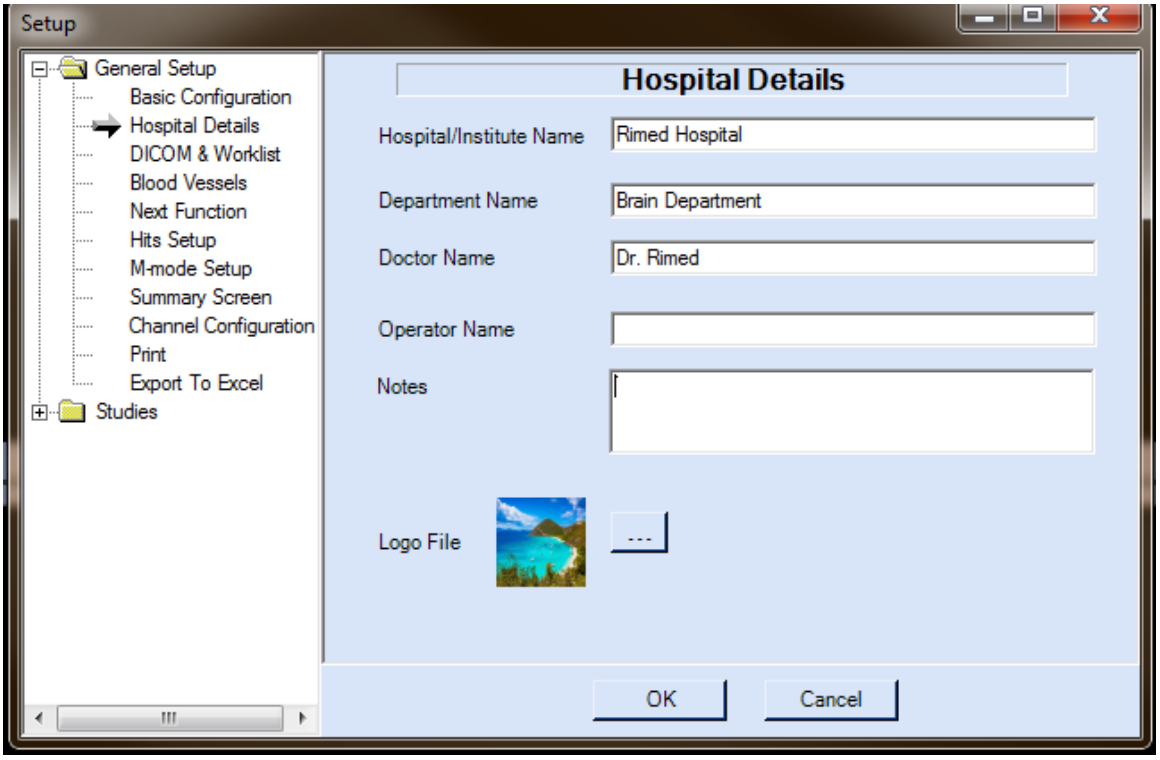


Figure 12-7 Hospital Details Configuration

Hospital / Institute Name: Hospital name.

Department Name: Department name.

Doctor Name: Name of responsible doctor.

Operator Name: DIGI-LITE operator name.

Notes: Other notes or information written by the user

Hospital Logo: Hospital or any other logo may be entered here. Click on the Browse button and select the Hospital logo picture in any standard picture format.

12.2.3.DICOM & Worklist

The DICOM & Worklist tab is used to input server information to retrieve or send data from/to the hospital server. The DICOM is used to push screenshots or the Patient Report with DICOM protocol. The Worklist is used to retrieve a list of patients. (See figure 12-8)

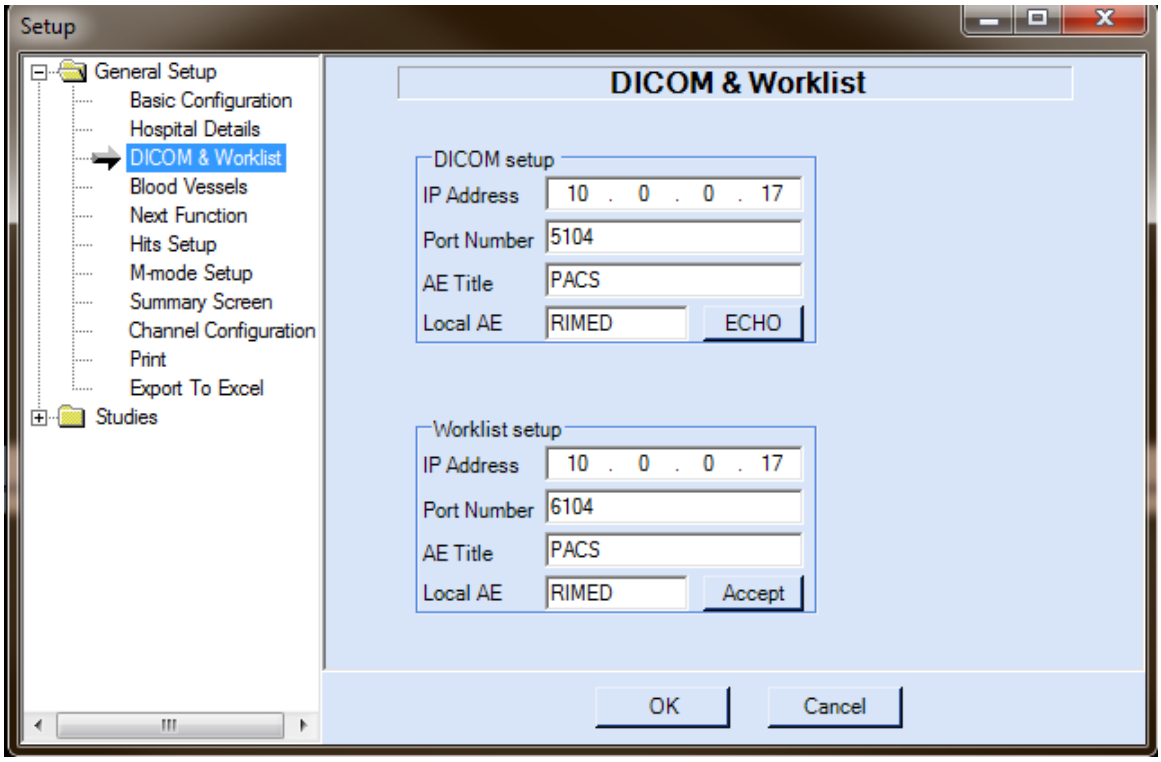


Figure 12-8 DICOM & Worklist Configuration

DICOM Setup: Please note that in order to be able to send data to DICOM server and see appropriate menu items, you must set IP address and port of your DICOM server inside the DICOM Setup. In order to confirm that all the parameters are correct press on the ECHO Button.

Worklist Setup: Please note that in order to be able to retrieve data of patients from the server and see appropriate menu items, you must set the IP address and the port of your modality worklist server inside the Worklist Setup. After that press Accept.

12.2.4.Blood vessel configuration

Blood vessel configuration allows the user to configure default settings for each selected blood vessel. To reach the blood vessel defaults dialog box select “Blood vessel defaults” from SETUP- GENERAL SETUP menu. (See figure 12-9)

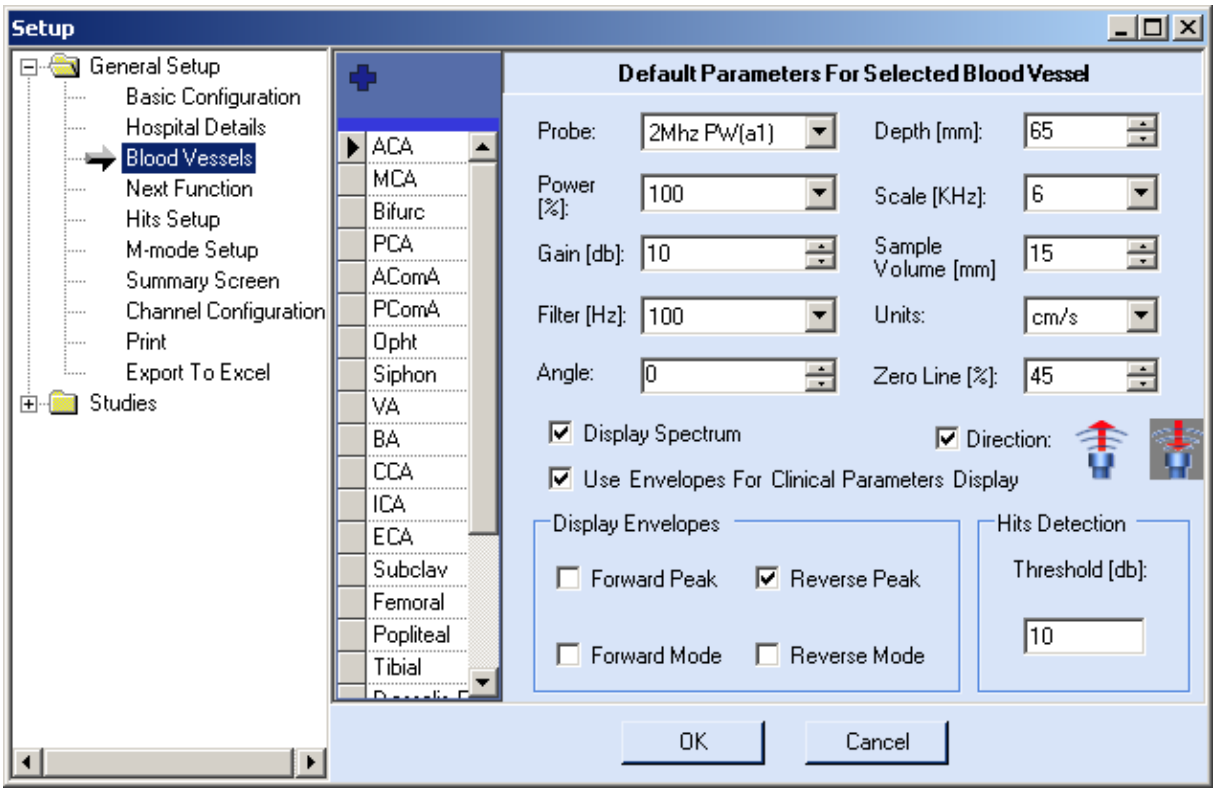


Figure 12-9 Blood Vessels Configuration

At the left side there is a list that displays all the blood vessels selected in the study configuration for all the studies. It is possible to add new blood vessel or to delete existent blood vessel.

 Add new blood vessel. To add a vessel that is not shown in one of the available vessels lists, click on the Add button (+ in the top of the blood vessel list). A dialog box opens for you to type in the name of the vessel you want to add (see Figure 12-10). You can also use this function if you use different names for the cerebral blood vessels. Take care to use the exact spelling (including spaces etc.) for arteries on both sides (to keep the summary screen well organized).

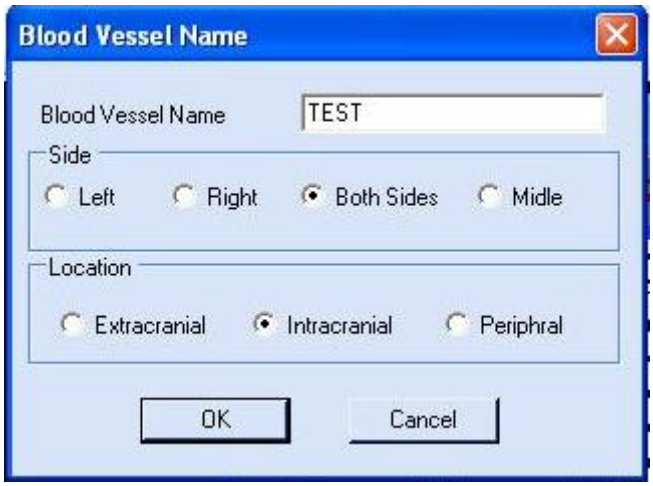


Figure 12-10 Add New Blood Vessel

Blood Vessel Name: Fill in the name of the new blood vessel that you want to define.

Side: Choose one of the following 4 options for blood vessel side: Left (only), Right (only), Both Sides or Middle.

Location: Choose the location of the blood vessel from the options: Extracranial, Intracranial or Peripheral.

Default Parameters for Selected Blood Vessels: Sets the default probe type, depth, power, frequency scale, gain, sample volume width, filter, units, angle, zero line position and direction of flow for each blood vessel selected from the list. To set up the next vessel simply click on it, and the settings for the previous vessel are saved. When a probe type of either 4 MHz CW or 8 MHz CW is selected, the depth, width and power are not activated. The angle is an estimation of the angle (in degrees) between the ultrasound beam and the blood vessel, for calculations of blood velocity from the Doppler equation for pulse wave mode. For intracranial applications the default is 0 degrees. For Extracranial applications the default is 45 degrees.

Display Spectrum: Determines whether the screen displays the blood flow spectrum. If a V mark is not clicked, only the envelope will appear, but no spectral display.

Display Envelopes: The type of envelope shown as default for each vessel. More than one envelope may be selected.

Use Envelops For Clinical Parameters Display: Determines whether the screen displays the clinical parameters only when the envelops are displayed, as selected by the user in **Display Envelopes** check boxes (see details above). If a V mark is not clicked, both forward and reverse flow clinical parameters are displayed if the software detects both flows.

HITS Detection threshold: Sets the threshold intensity (in db) above the background flow for emboli detection algorithm.

WARNING

Do not use ultrasound intensities greater than 36% for trans-orbital examinations.

12.2.5.Next function configuration

Next function configuration allows the user to configure the next function as a preprogrammed function that enables fast and automatic performance of several actions using one click. To reach the next function dialog box select “Next function” from SETUP- GENERAL SETUP menu. (See figure 12-11).

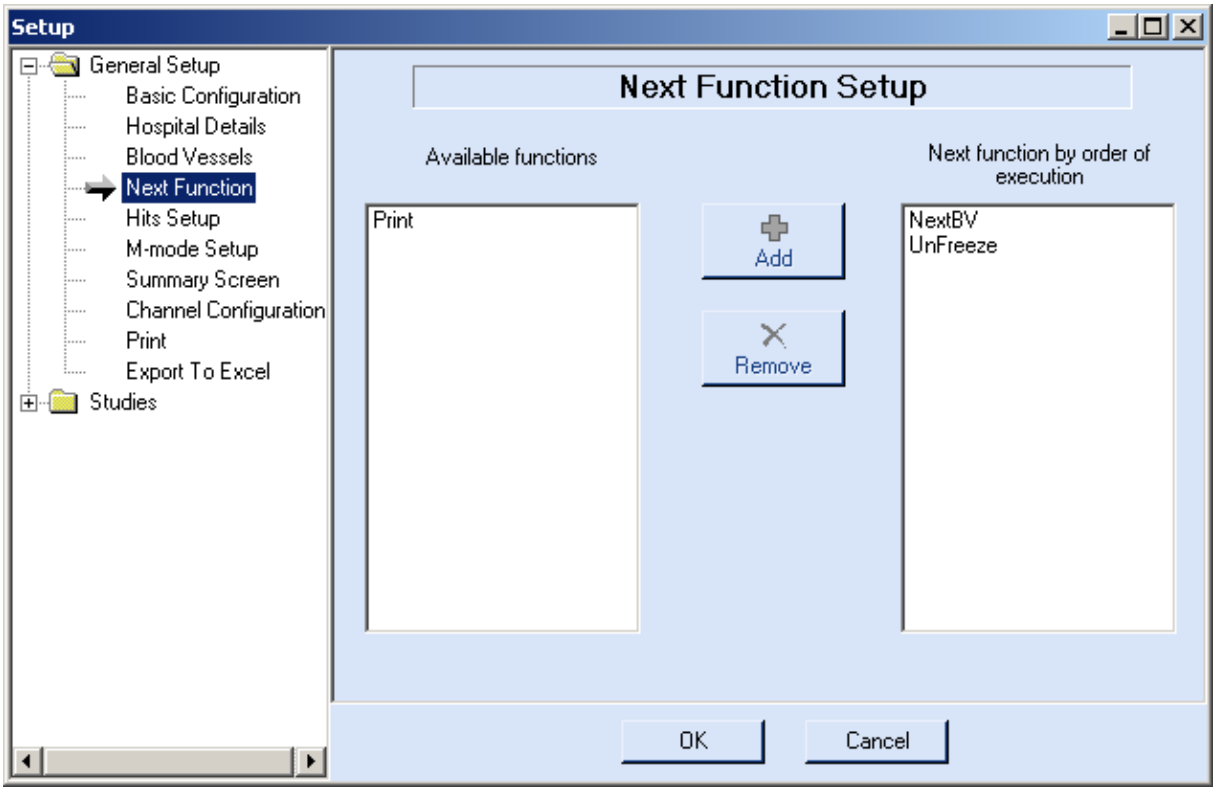


Figure 12-11 Next Function Configuration

Available functions: This list contains the available functions that can be performed after pressing on Next function.

Next function by order of execution: This list contains the functions that were selected to be can be performed after pressing on Next function. To add new function in this list select the function in the Available functions list and press ADD. To remove a function in this list select the function and press REMOVE.

12.2.6.Remote Control

Next function configuration allows the user to configure the next function as a preprogrammed function that enables fast and automatic performance of several actions using one click. To reach the next function dialog box select “Next function” from SETUP- GENERAL SETUP menu. (See figure 12-11).

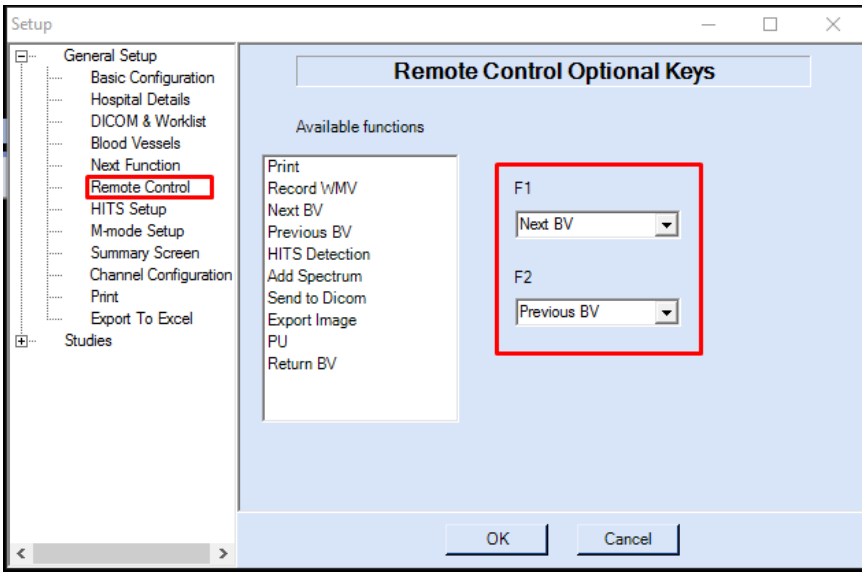


Figure 12-12 Remote Control Configuration

Available functions: This list contains the available functions that can be performed with F1, F2.

12.2.7.Summary screen configuration

Summary screen configuration allows the user to configure what spectrums will be sent to the summary screen. To reach the summary screen dialog box select "Summary Screen" from SETUP- GENERAL SETUP menu. (See figure 12-12).

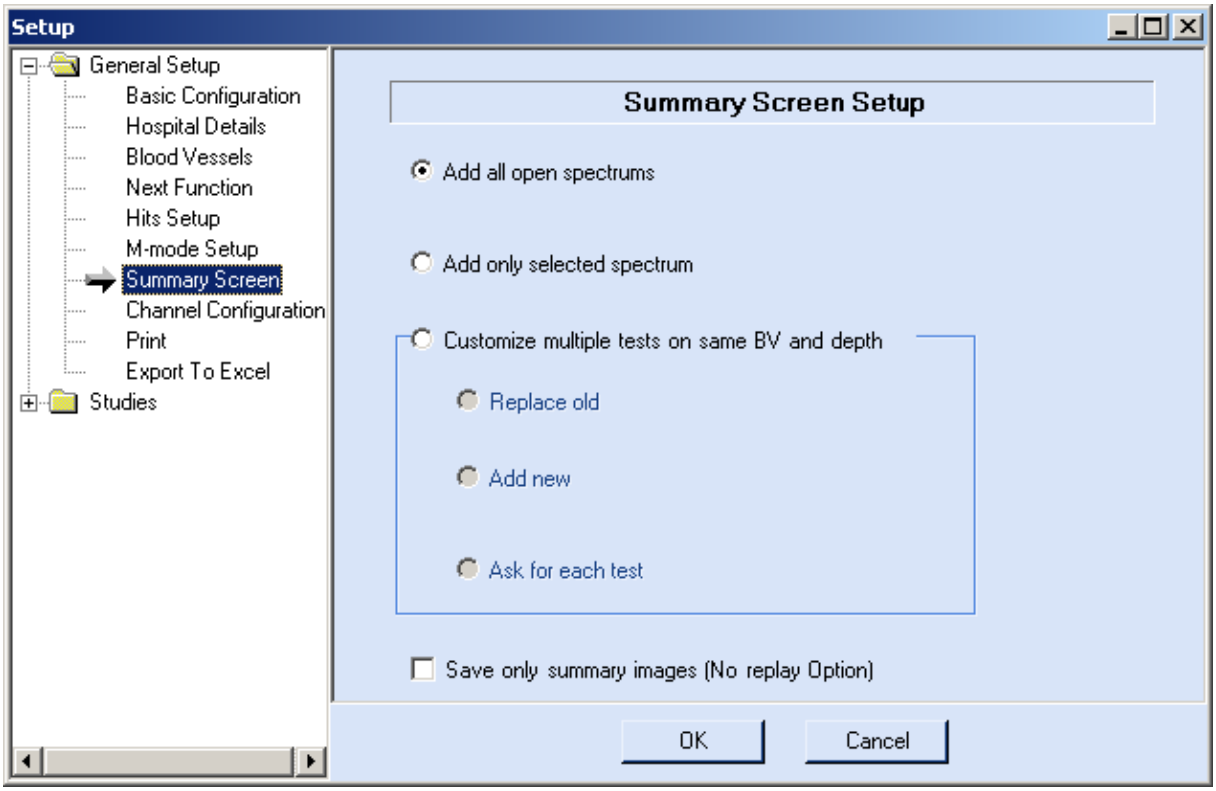


Figure 12-13 Summary Screen Configuration

Add all open spectrums: Choose this option if you want to send to the summary screen all the examined spectrums. This is useful if you make several measurements for the same blood vessel.

Add only selected spectrum: Choose this option if you want to add only the selected spectrum for each examination. This can be for the same blood vessel or not. This option is useful if you don't want to add all the examined gates to the summary screen.

Customize multiple tests on same blood vessel and depth: Choose this option if you want more customization for the case that several measurements are done for the same blood vessel (in different depths, for example). One of the following three options can be chosen:

Replace old: Choose this if you want to have only one recording for each blood vessel. In this case the previous examination will be replaced by the new one.

Add new:

Ask for each test: A dialog box will appear after going to freeze state (from the second measurement to the same blood vessel). You can choose to replace the previous examination, add the new one, or discard the new one.

Save only summary images: choose this option if you want to save space disk. This option only saves the images without any replay. (see section 12.2.6)

12.2.8.Economic data saving:

As you can see in the next image, in the "General setup" ➔ "Summery screen", there is a new check box with the caption of "Save only summary images (No replay option)". As it title suggest, checking this option will cause that by default, only the last image of an examination, the images that will be shown at the summary screen and the patient report will by saved. After you save the examination you will not be able to "replay" this blood vessel but only to watch the static images.

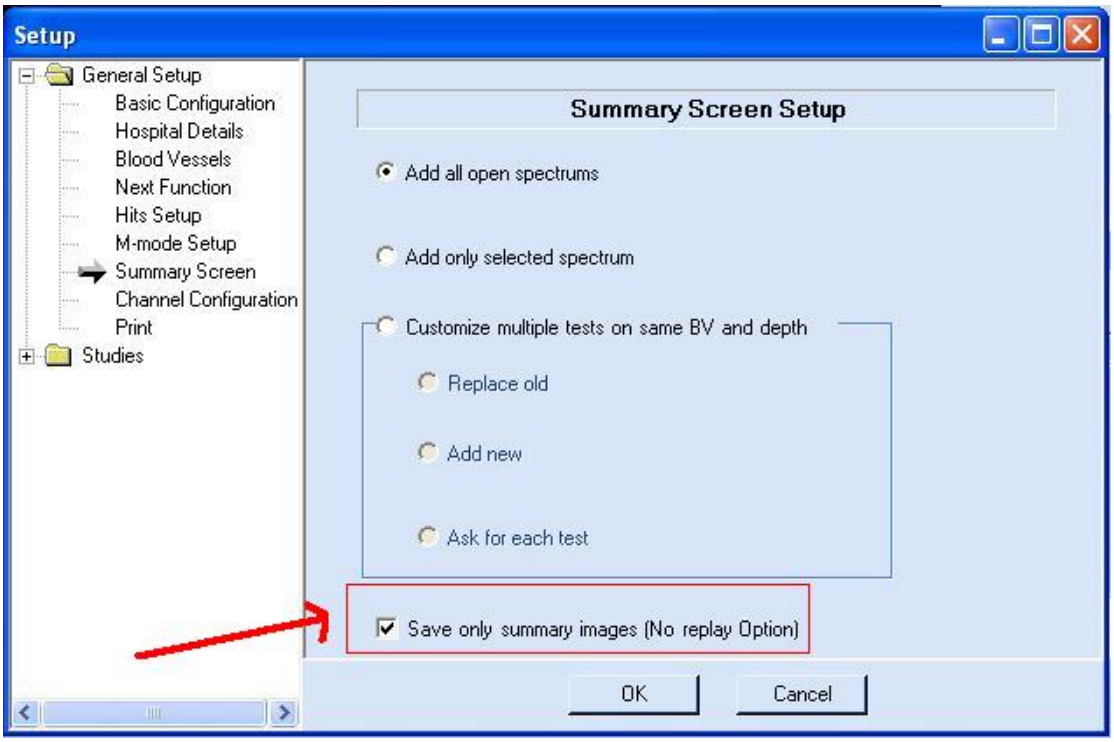


Figure 12-14 Summary Screen Configurations (Economic Saving)

- Overwrite the default behavior

No matter what was your choice in the previous window, you can always overwrite it. After you perform "Unfreeze" on a specific blood vessel you will see that a new icon will pop up to the left of the BV name (see figure 12-14). An icon with a floppy disk means that the "Replay Data" will be saved for this BV. If you see a "Stop" warning sing on the floppy disk that means no replay data will be saved.

Clicking the icon will change its "Value".

There is also an option to do the same, by performing the same operation but from the summary screen window (see figure 12-15). This is very useful when the user ending the procedure and go to the summary screen. Now he can select the most interesting part of the examination (The ones that there a good chance he would like to replay).

Important note: Notice that at any case, if you don't delete the BV from the summary screen you will always be able to see it statically by reload the examination from the HD.

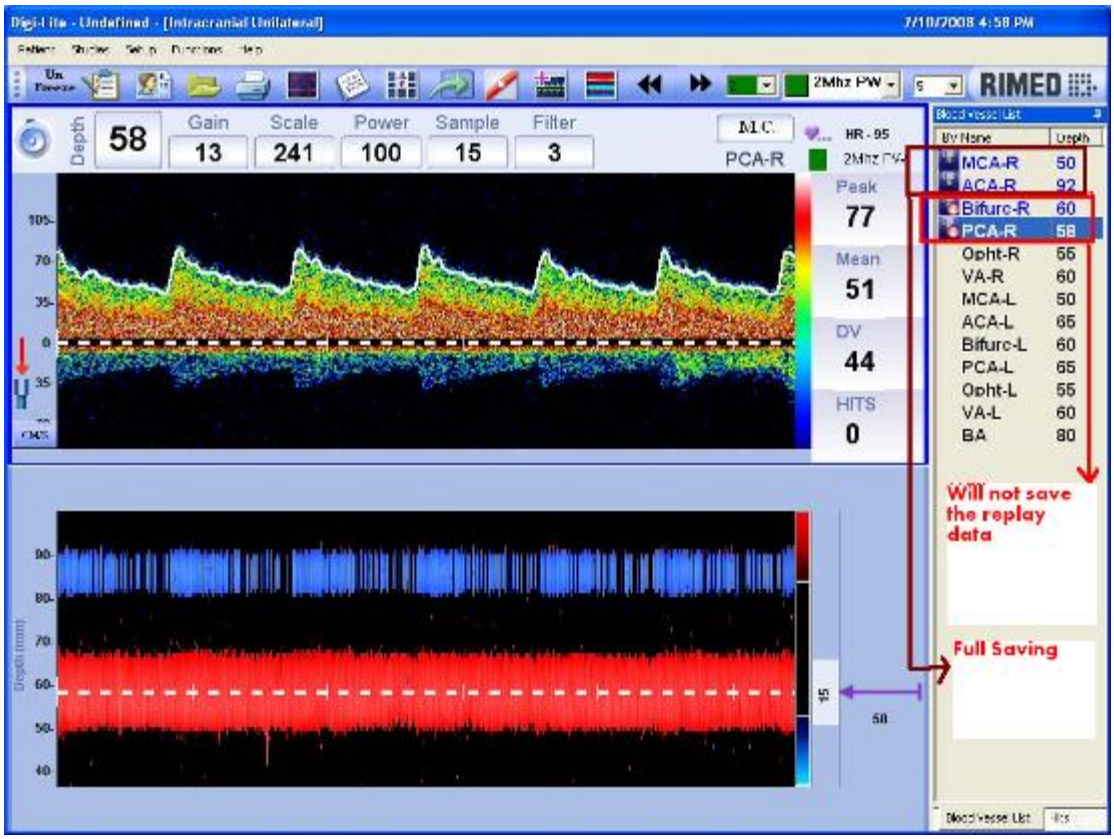


Figure 12-15 selecting the saving mode per BV on the main screen

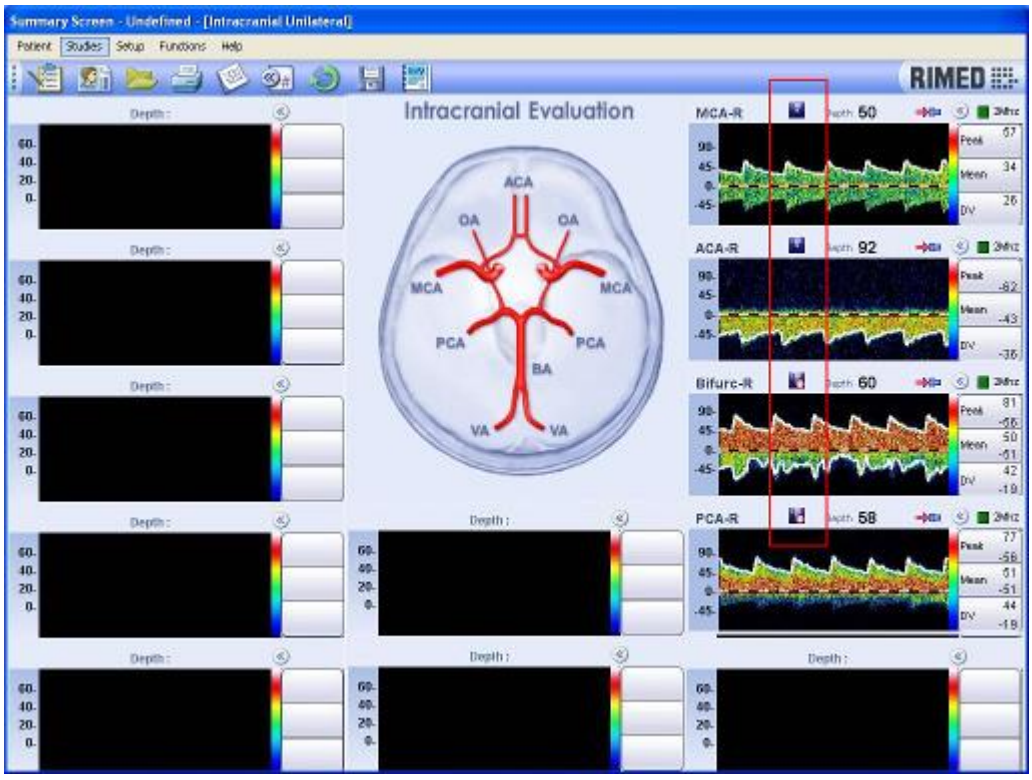


Figure 12-16 selecting the saving mode per BV on the summary screen (for the same examination)

At "Replay" mode you will see an indication (Again, by using the same "Floppy disk" icons at the same location) that will point out if you can replay this BV. Notice that if the replay data was not saved, the ability to replay the BV includes the buttons, the space bar and the remote control button will be blocked.

12.2.9.Clinical parameters trends / external channel configuration:

The user can configure the trends/channels by using the "General setup" ➔ "Channel configuration" screen. This allows the user to configure some parameters. In case of a channel that represent a clinical parameter channel (see figure 12-16) the first 4 channels it will like this:

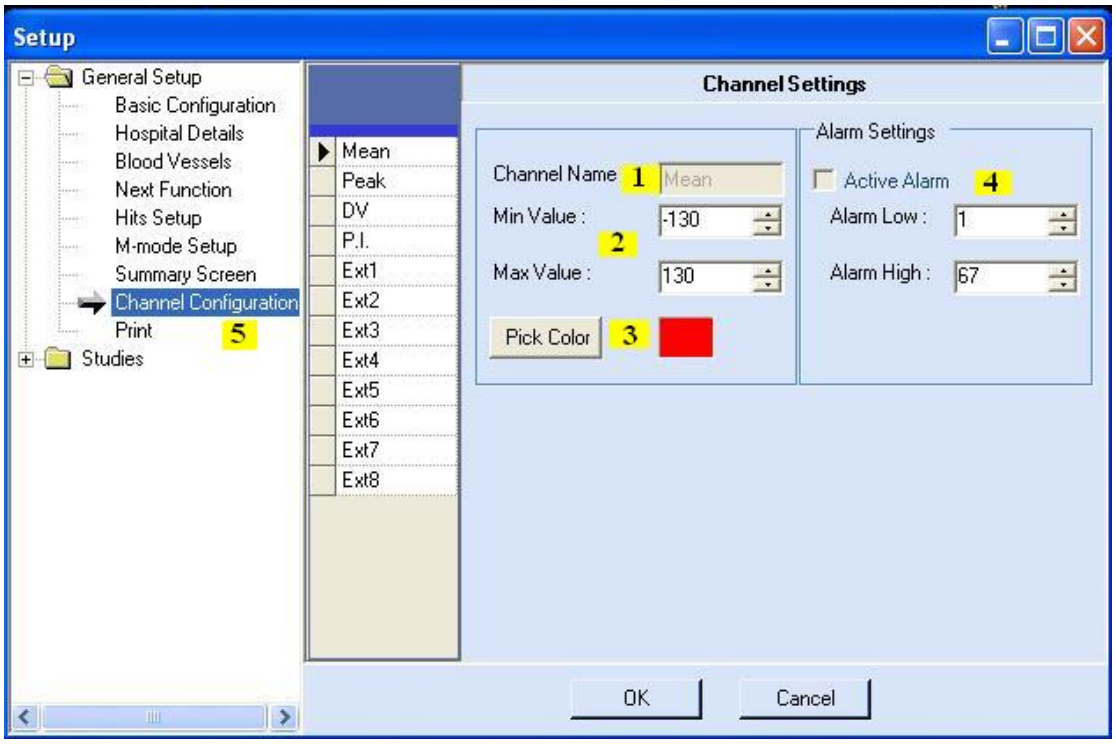


Figure 12-17 Channel Configuration first steps

According to the number (1,2,3,4,5) :

1) The name of the channel/trend. In case of clinical parameters this name is hard coded and can not be replaced.
2) Minimum and maximum values – That will be the values that you expect to see in the examination. The values that you enter are will influence directly on the scale of the trends. Values outside of the ranges will not be showed at all.
3) Color – simply enable you to choose the color of the trend in the window
4) Alarm – this option will allow (in the future) invoking an alarm when the values of the parameter are out of predetermined values that you enter in this window. In this version the option is disabled and there no use to enter any values.
5) The entry point for the channels setup.

In case of selecting External channel you will able to set additional parameters

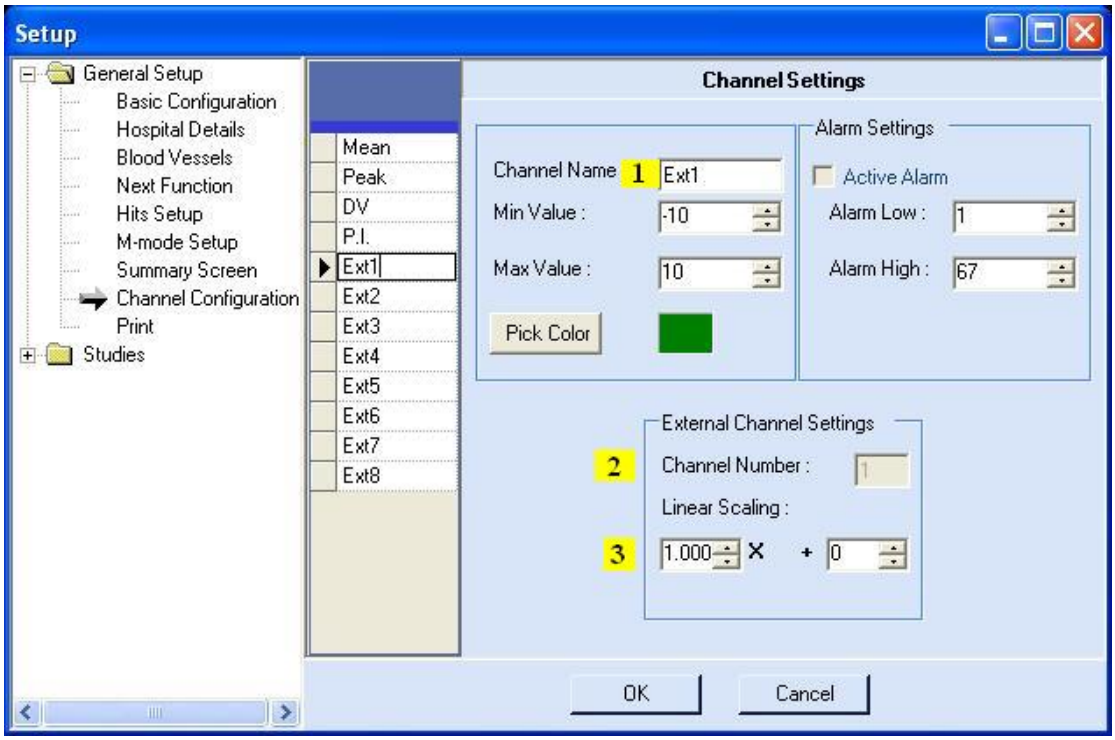


Figure 12-18 Channel Configuration second steps

1) Channel name – in case of external channel you can modify the name of the channel. As mentioned before you will see it in the trend window. You will also see this name in the study-trends setup (see later in this document).
2) Channel number – actually this one is hard wired, but will help you to remember the physical channel that wired to the logical name you gave it
3) Linear scaling – this important setting allows you to determine how the analog signal from your device will be normalized to the expect values in the trend window.

- Calibration: This step transforms the graph to one with the correct numbers. It is done separately for each external instrument. Calibration ends when the numbers on the Digi-Lite trends are the same as the numbers on the external instruments. The following instructions relate to calibrating trends from blood pressure measurements, as an example.

To calibrate an external channel, follow the step described below (an example of values derived from a blood pressure monitor are given)

1) Check (setup – general setup- channel Configuration: ExternalChannelName) that the linear scaling shows 1 * X + 0. If it shows 0 * X + 0, nothing will be showed except a straight line.
2) Start recording in monitoring mode. In the trend window, a signal from the external instrument should appear. If you see only a straight line at zero, stop and enter setup again. Change the linear scaling to -1 instead of 1. This will change the wave phase in 180°.
3) Write down the minimum and maximum values shown on the external instrument. Calculate the difference d1= Extmax- Extmin.
4) Stop recording. Load the examination from memory. Measure minimum and maximum values for the trend graph. Calculate the difference d2 = Trendmax - Trendmin.
5) Calculate: $a = \frac{d_1}{d_2}$.
6) Insert the value of "a" instead of "1" in linear scaling.

7) Start the recording again. Write down a single reproducible value (maximum blood pressure, for example).
8) Stop recording. Load. Measure the same value. Calculate b = Ext - Trend.
9) Insert “b” in linear scaling (in the right-side box, instead of the previous o).
10) Check again. Now the numbers should fit.

Numerical Example:

1) Suppose that a blood pressure measuring instrument shows BP of 120/80 mmHg. In step 3, you calculate d1 = 120 - 80 = 40.
2) On the trend window, you measure 50/30. In step 4, you calculate d2 = 50 - 30 = 20.
3) Step 5 gives a = $\frac{d_1}{d_2} = \frac{40}{20} = 2$.
4) After changing the setup so that the linear scaling is 2 * x + 0, you get on the trend window a graph showing 100/60. If systolic BP remains at 120(g), you get in step 8: b = 120 - 100 = 20.
5) After changing the setup so that the linear scaling is 2 * x + 20, both instruments should show a BP of 120/80.

12.2.10.Print settings

Print settings are used to configure printing operations. To reach the Print Configuration dialog box select "Print Configuration" from SETUP- GENERAL SETUP menu. (See figure 12-18).

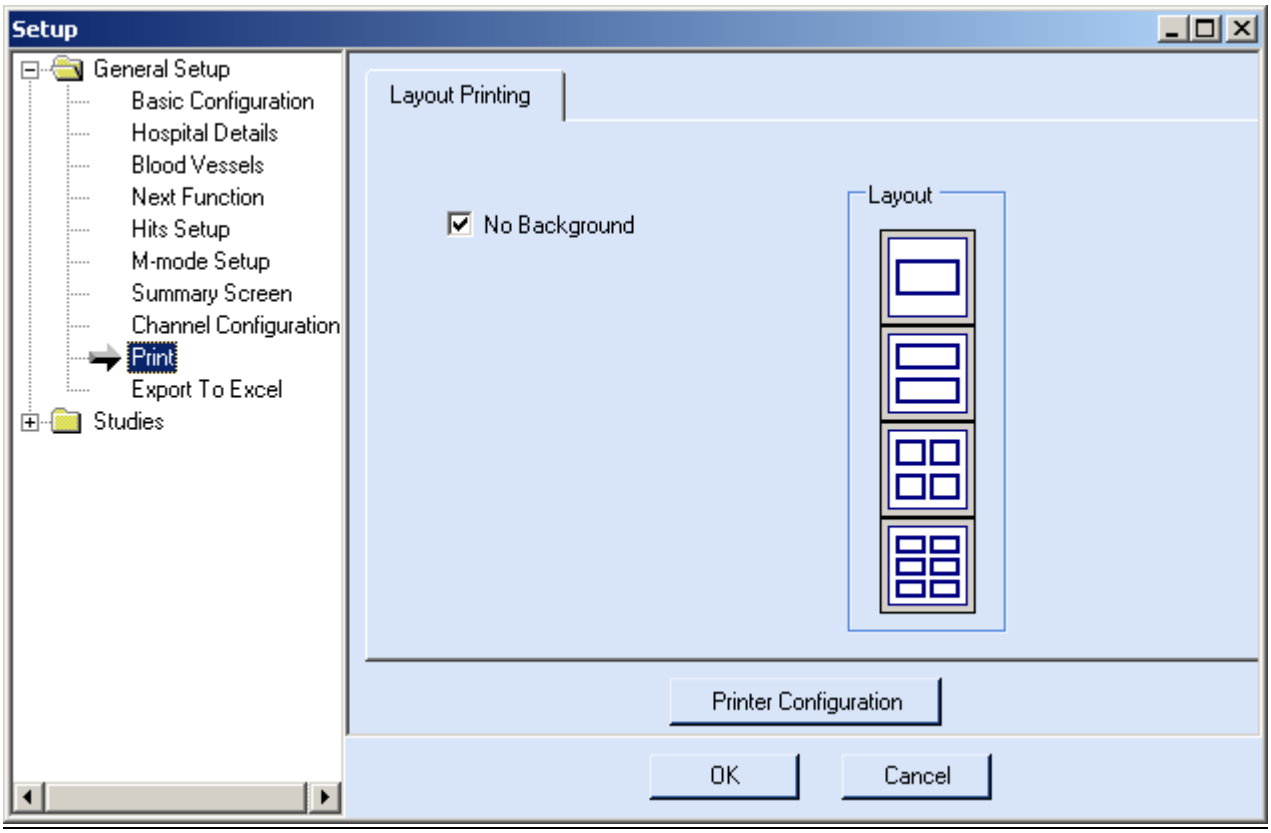


Figure 12-19 Print Configuration

Printing Layout: Allows selection of preferred printing layout. Spectrum screens may be printed either 1, 2, 4, or 6 per page.
After sending a spectrum screen for printing, a message appears: "Spectrum sent to print buffer". Only when the last spectrum is sent, the printer will start printing.

12.2.11.Exporting clinical parameters in monitoring and VMR studies to excel

This option working In monitoring Unilateral, Bilateral and VMR Unilateral, Bilateral studies this feature is implemented

Please follow the screens bellow

From main-menu enter the tcd system

go to setup→general→export to excel

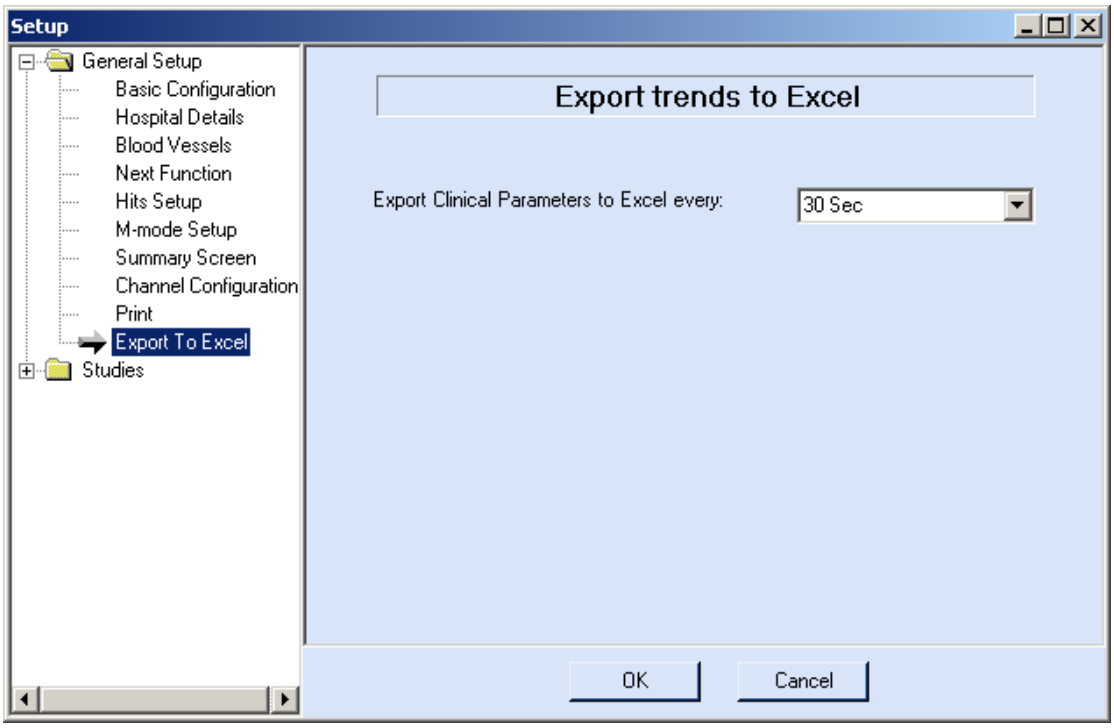


Figure 12-20 Export To Excel

Choose your preferred interval of sampling 2 sec, 30sec or 1 min and after that press the OK button

12.2.11.1. Perform a test in one of your preferred studies (mentioned above)

12.2.11.2.After recording the examination is finished perform the following steps to receive the excel file

12.2.11.3.Go to Patient→Export→Export trends to excel

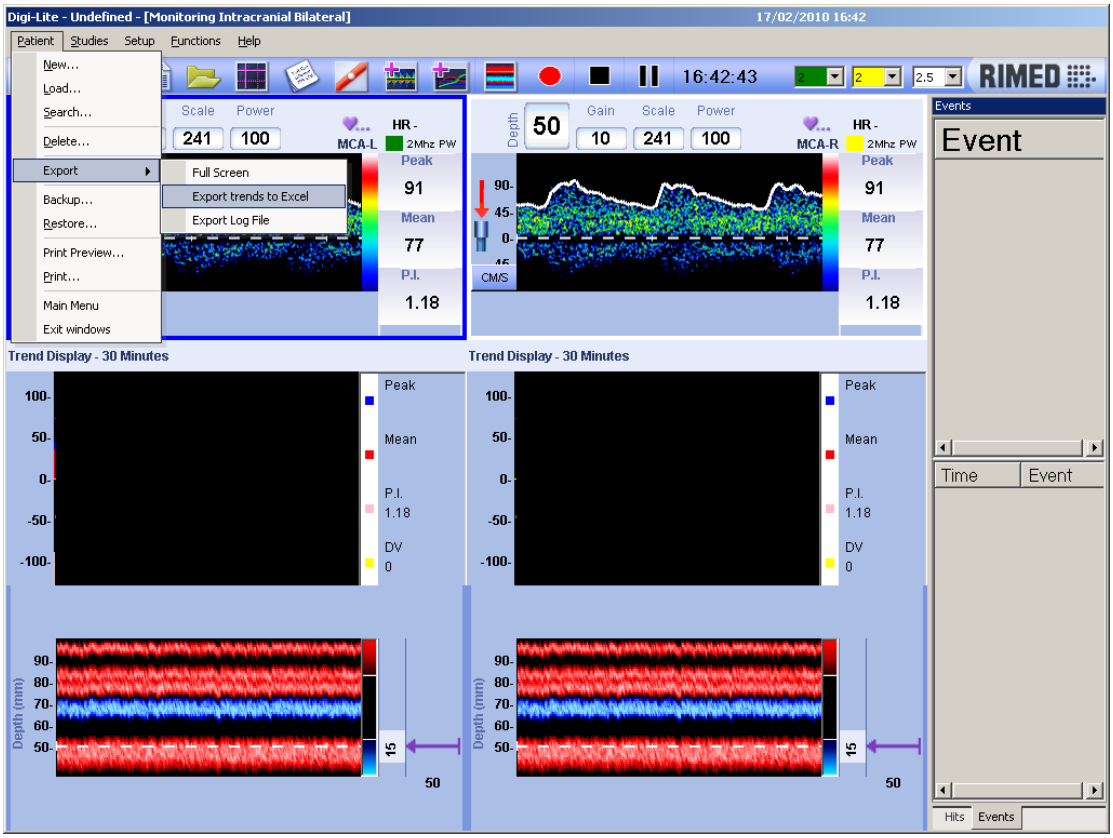


Figure 12-21 Export to Excel Menu Bar

12.2.11.4. Save the excel file (identify the file by patient name and date) in an external device (such as disk on key)

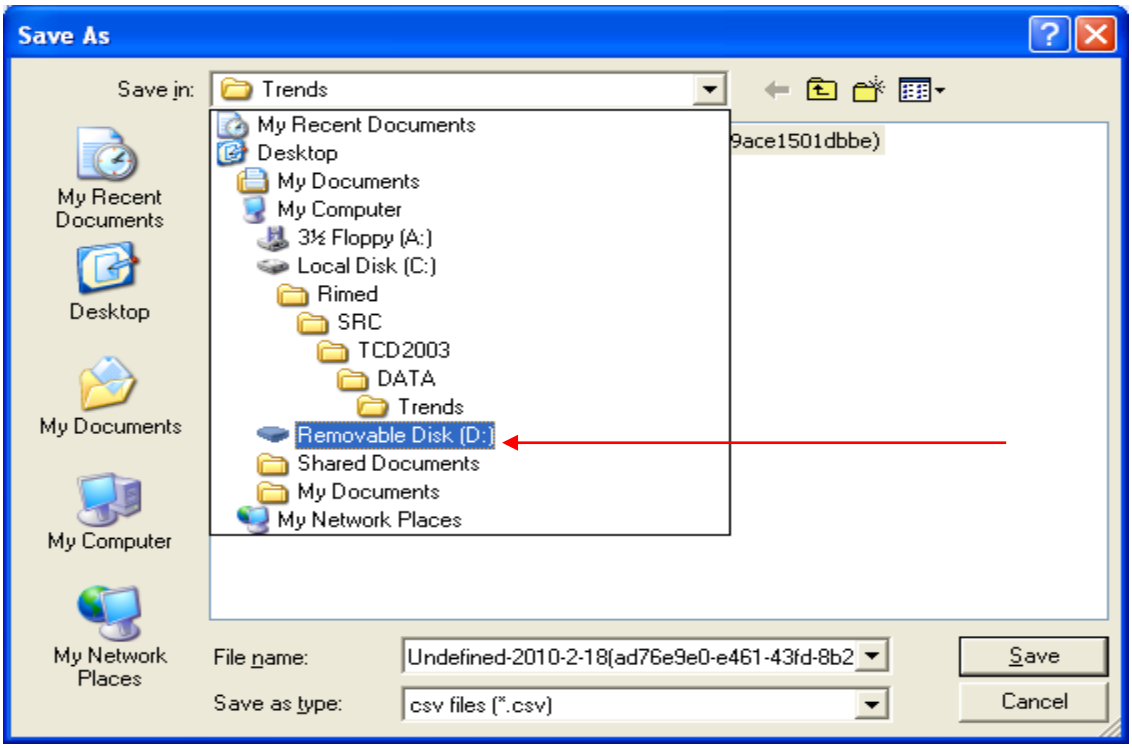


Figure 12-22 Export To Excel Saving Bar

12.2.11.5. After saving the test in the disk on key you will be able to open the file using Microsoft-excel in any personal computer

12.3. Studies configuration

1. To reach the Study Configuration dialog box select SETUP- STUDIES from the SETUP menu. (See figure 12-22).
2. In the left side of the SETUP dialog click on the study you want to customize: default or customized: Intracranial, Extracranial or Peripheral.
3. Then click on a tab at the top of the right side of the SETP dialog box to choose the item to be configured, as detailed above:

12.3.1.Select blood vessels

Select blood vessels configuration allows the user to define blood vessels for each type of study by order of examination. The blood vessels selected appear in blood vessels list and on the summary screen for that type of study.

You can customize the blood vessel list as follows:

1. First select the study to be configured in the SETUP explorer side (left panel)
2. To reach the Select Blood Vessels dialog box press on first tab (the leftmost) in the right panel of the selected study dialog box
3. The right panel will display the Select blood Vessels dialog box (figure 12-22)
4. The right panel contains the following information: in the left side: Available BVs: a list with the names of all the defined blood vessels. The list in the right side: BVs Order: shows the blood vessels which are displayed in the selected study by order of appearance.
5. To add a blood vessel to the study display, select the name of the blood vessel in the list Available BVs, then click Add.
6. To remove a blood vessel from the study display, select the name of the blood vessel in the list BVs Order, then click Remove.
7. To change the order of the blood vessels displayed, use the “Move Up” and “Move Down” buttons.
8. When you have finished configuring the study, click OK to activate the changes, or “Cancel” to cancel the changes.

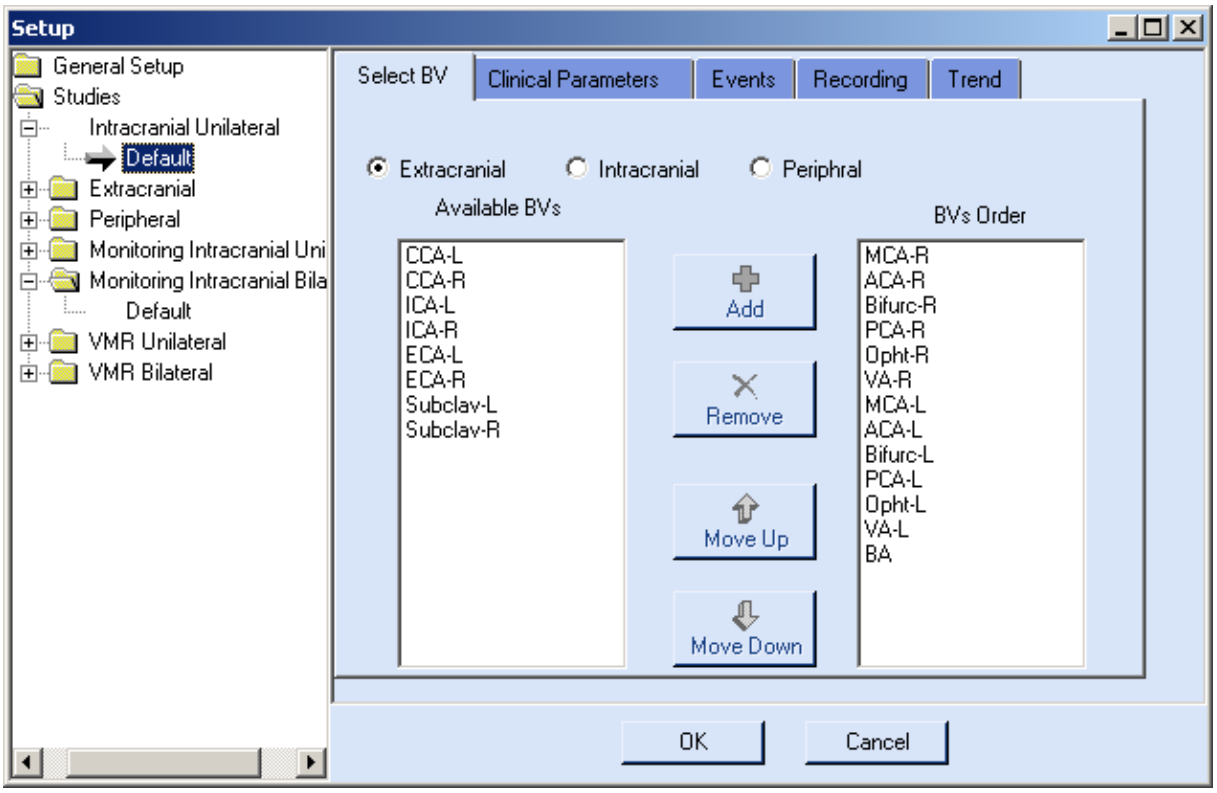


Figure 12-23 Select Blood Vessels

Intracranial/Extracranial/Peripheral: Choosing one of these options shows different lists of available blood vessels in Available BVs list, from which specific arteries can be chosen and moved to the right column.

BVs Order: A list of the blood vessels by order of appearance for routine examination in the spectrum screen or display in the summary screen. This list determines the preset order of examination – when you go back to the examination screen the blood vessel list will be arranged according to this order.

12.3.2.Clinical parameters

Clinical Parameters dialog box allows you to select the clinical parameters to be displayed and the order of appearance on the screen.

You can customize the clinical parameters as follows:

1. First select the study to be configured in the SETUP explorer side (left panel)
2. To reach the Clinical Parameters dialog box press on second tab (from the left) in the right panel of the selected study dialog box
3. The right panel will display the Clinical Parameters configuration dialog box (See figure 12-23).

4. The right panel contains the following information: in the left side: Available Clinical Parameters: a list with the names of all the available blood vessels. The list in the right side: Clinical Parameters By Order of Appearance: shows the clinical parameters that are displayed in the selected study by order of appearance.

5. To add a clinical parameter to the study display, select the name of the parameter in the list Available Clinical Parameters, then click Add.

6. To remove a clinical parameter from the study display, select the name of the parameter in the list Clinical Parameters By Order of Appearance, then click Remove.

7. To change the order of the clinical parameters displayed, use the "Move Up" and "Move Down" buttons.

8. When you have finished configuring the study, click OK to activate the changes, or "Cancel" to cancel the changes.

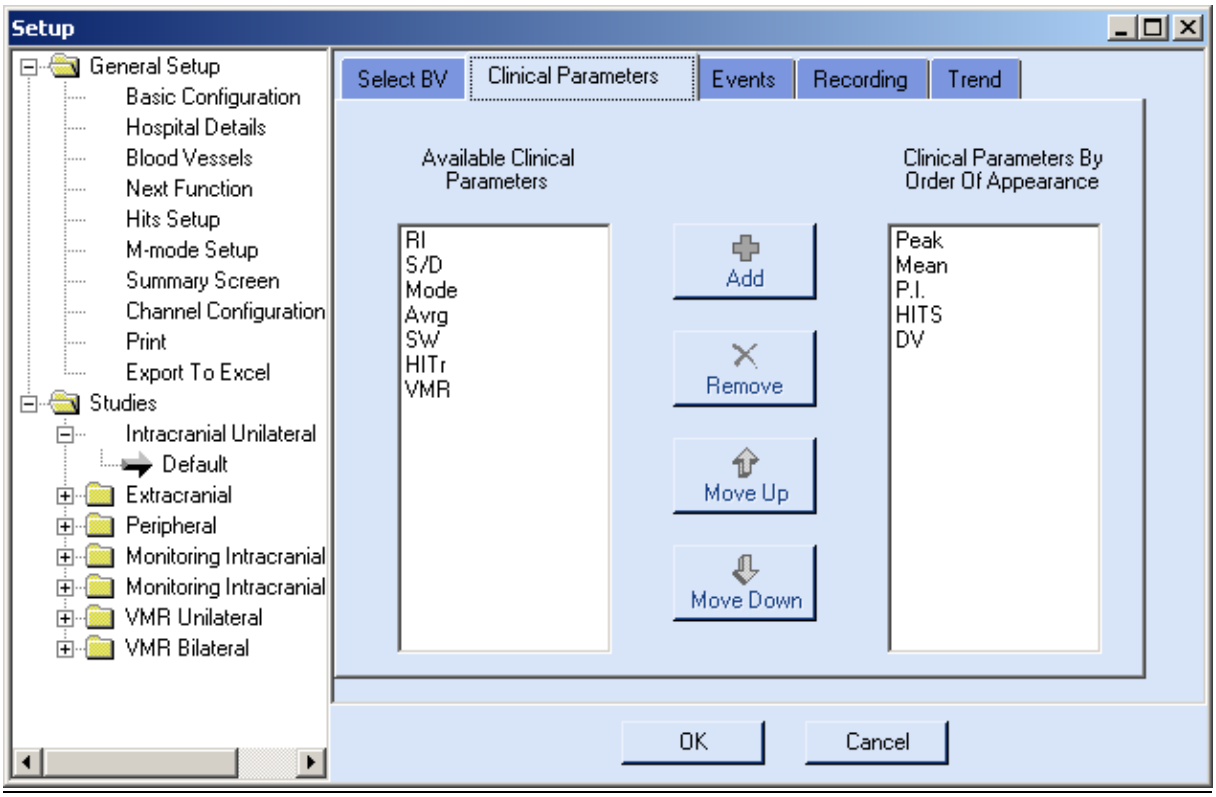


Figure 12-24 Clinical Parameters Configuration

Available Parameters: Displays all clinical parameters available.

Clinical Parameters by order of appearance: Displays all clinical parameters displayed on screen for the selected study.

<< Add: To add a parameter for display, select one or more parameters from the available parameters list and click on the << Add button.

Remove>>: To remove a parameter from one of the display lists, select one or more parameters and click on the Remove >> button. If the display lists are already full, parameters must be removed first in order to allow selection of a new parameter to be added.

Move Up/Move Down: These 2 buttons are used to move a selected parameter in the display lists up or down the list. This will change the order of appearance on the screen.

12.3.3.HITS setup

The HITS setup dialog box is used to define parameters that are related to detection and counting of High Intensity Transient signals (HITS). To see it, choose SETUP- GENERAL-HITS SETUP.

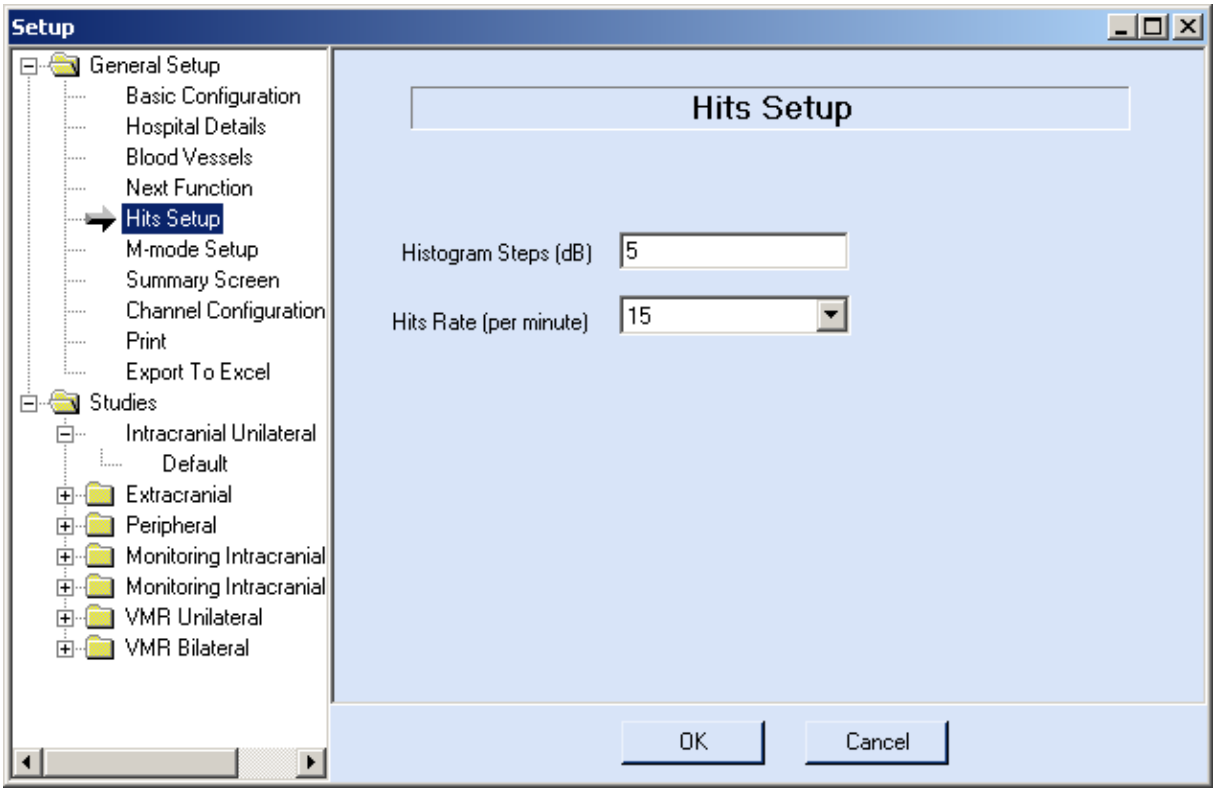


Figure 12-25 Hits Setup

HITS Threshold: This variable sets the threshold level for HITS detection. The threshold, in dB, relates to the difference in the Doppler intensity between the intensity of the suspected HITS event and the intensity of the average blood flow spectrum prior to the suspected HITS event. A low threshold may result in artifacts recognized as HITS, while a high threshold may miss low energy embolic signals. For normal operation a threshold in the range of 10dB is recommended.

Histogram Steps: The number of HITS (suspected embolic events) can be displayed on a histogram as a function of HITS intensity levels above the blood intensity, in dB. This option allows the user to set the step sizes (in dB) in the histogram display.

While performing HITS detection, the following is recommended:

1. Achieve a reasonable signal: Adjust the gain so that the peak envelopes follow the signal well. Intensity colors should be in mid-range (not too faint, not too bright).
2. Adjust the range so that the signal captures about tow thirds of the window height, leaving enough dynamic range for high velocity signals.
3. Reduce Thump to minimum (3 cm/sec or 100 Hz). This is best done through Setup-Blood Vessel defaults, so that you do not have to remember changing thump each time you enable HITS detection. To change thump on real time, use the “1” or “2” keyboard buttons (“1” to decrease, “2” to increase).

12.4. Save Study

To reach the Save Study dialog box select SETUP-SAVE STUDY LAYOUT from the SETUP menu. (See figure 12-25)

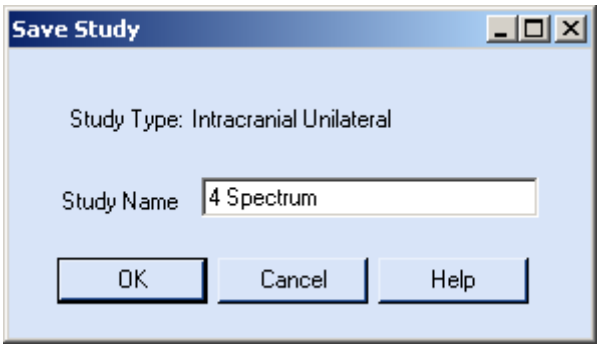


Figure 12-26 Save Study Layout

To define a new study, perform as follows:

1. First select an existent study (default or custom) in the STUDIES menu.
2. Then add or remove spectrums or M-Mode windows until you reach the desired layout.
3. Then press on SETUP- SAVE STUDY Layout. The SAVE STUDY dialog box will open (see figure 12-24).
4. The study type that you are in will be written.
5. Write the name of the new study in STUDY NAME.
6. Click OK to save the new defined study or “cancel” to cancel the changes.

12.5. Delete Study Layout

For delete some layout you should go to Setup -> Delete Study Layout. Once "Delete Study Layout" window is opened, choose required Study from which you want to Delete Layout, choose necessary Layout and click on Delete button. If you are currently using layout that you want to delete, then you can not do it. First, you need to go to any other layout and then begin the process of removal. Default layout can't be deleted.

13. Functions menu

Functions are used to perform operations on the actual displayed screen. See figure 13-1.

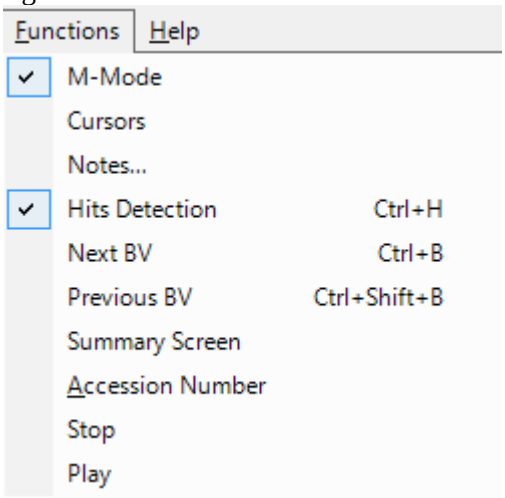


Figure 13-1 Functions Menu

Actually, the functions menu can replace icon operation, if the user prefers menus. As usual with Windows software, you can use the keyboard, clicking Alt + the underlined letter, to open a specific menu. Continue pressing the “ALT” key, while clicking on other letters as needed to open submenus.

Add Spectrum: Add new spectrum to the current display. The new spectrum will be at the same depth as the current selected spectrum. The screen layout change according to the number of windows, as follows:

1. One spectrum without M-Mode: one big spectrum will appear on the entire screen (see Figure 13-2)

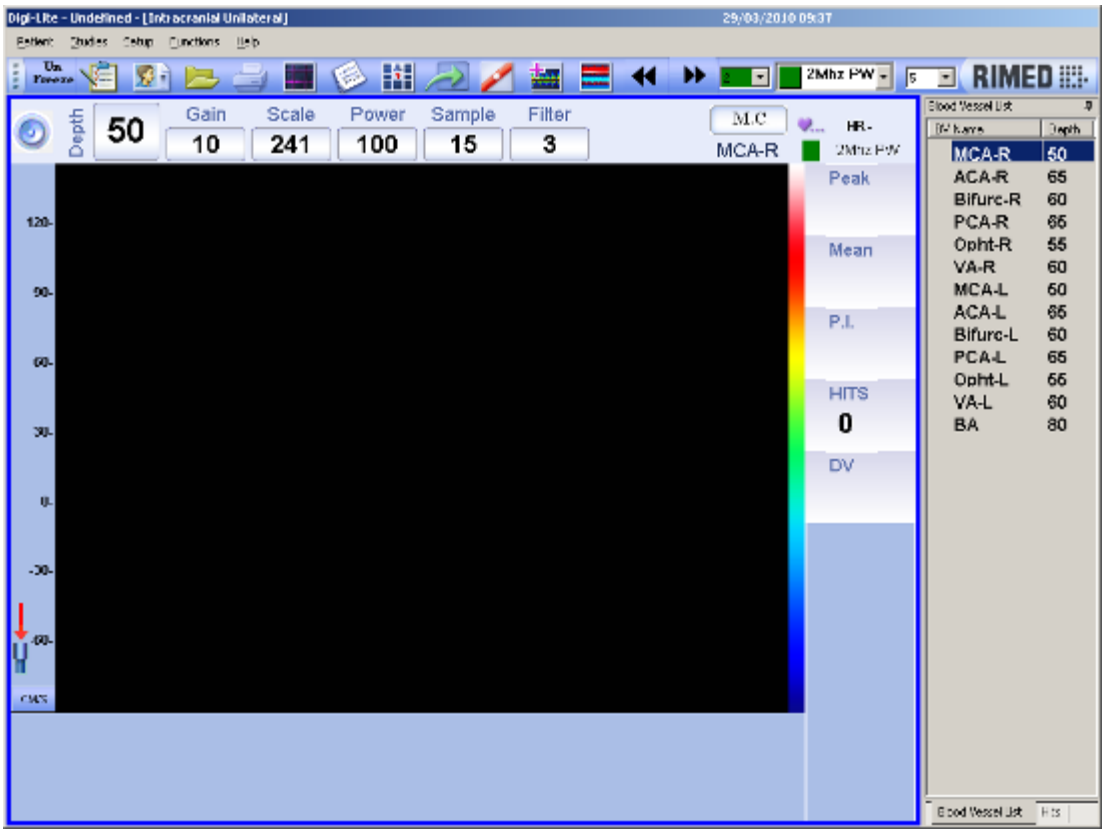


Figure 13-2 One spectrum without M-Mode

2. One or two spectrums with M-Mode: a spectrum in the upper side and an M-Mode in the lower side of the screen (see Figure 13-3)

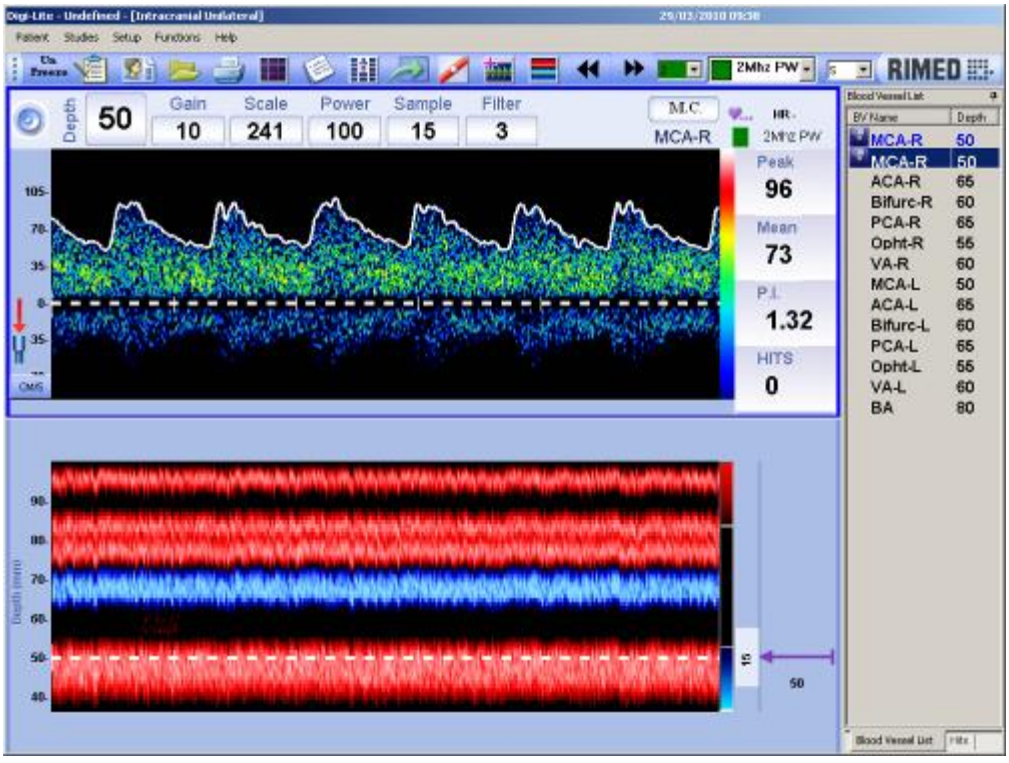


Figure 13-3 One spectrum and an M-Mode

3. Three or four spectrums with M-Mode: a big spectrum in the upper left side, an M-Mode in the lower left side and small spectrums in the right side of the screen (see Figure 13-4)

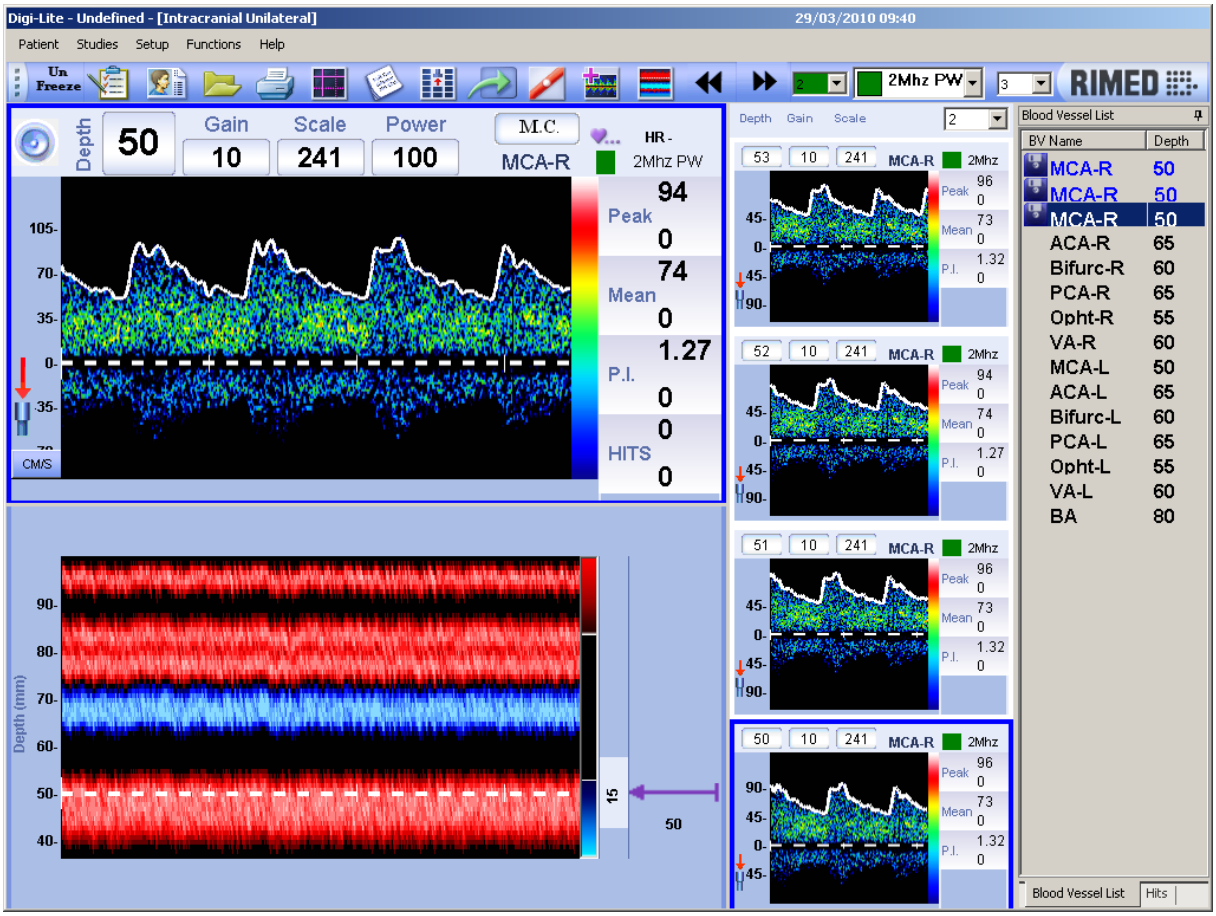


Figure 13-4 Four spectrums and an M-Mode

4. From five to eight spectrums with M-Mode: a big spectrum in the center upper side, an M-Mode in the center lower side and small spectrums in the left and right sides of the screen (see Figure 13-5)

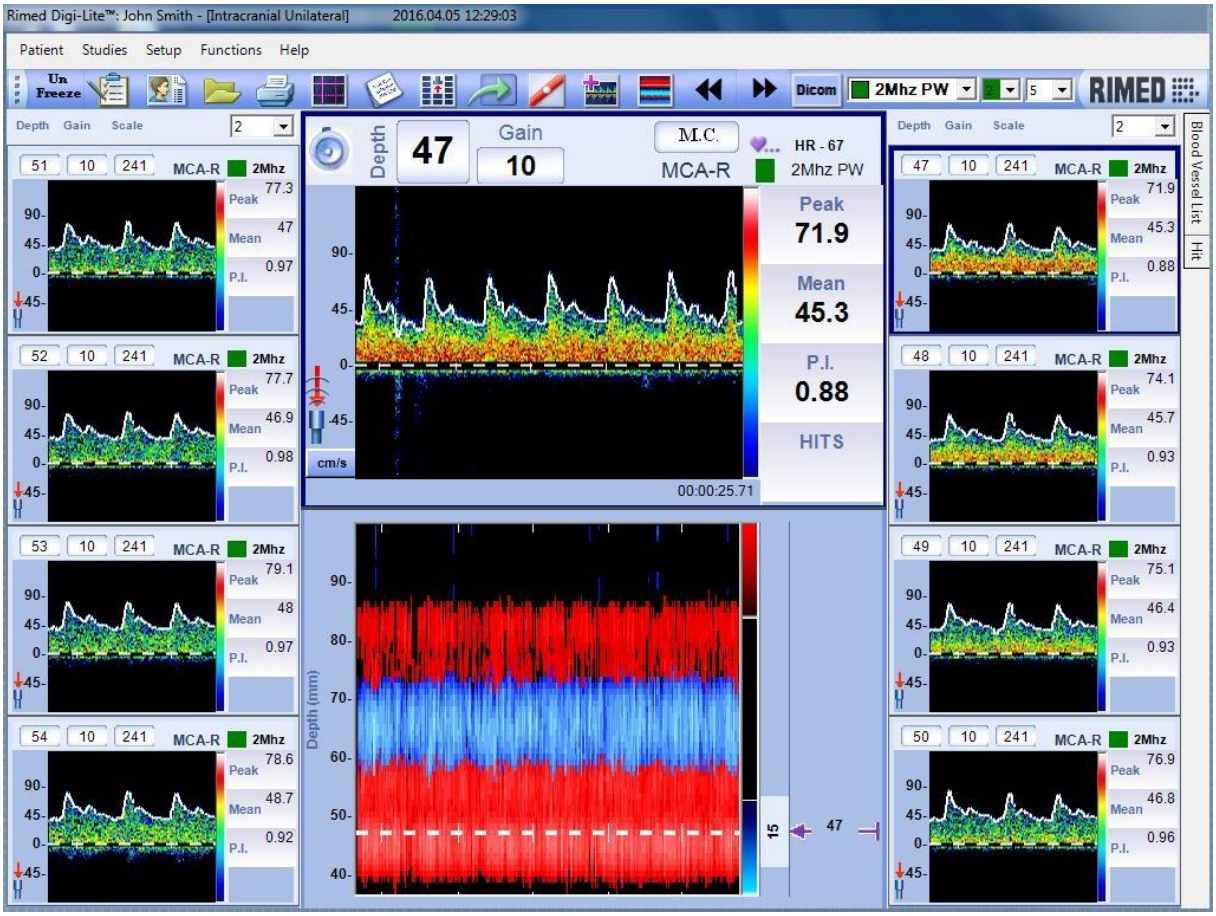


Figure 13-5 Eight spectrums and an M-Mode

M-Mode: Toggle (add or remove) M-Mode display. The M-Mode will always be associated to the selected spectrum, his depth indication line will indicate the depth of this spectrum and the width indicator is according to selected spectrum width. The M-Mode will appear below the selected spectrum.

Cursors: Inserts a grid on the spectrum screen. This is useful when you want to perform calculations related to the spectrum. The cursors option can be activated while in the freeze state in the spectrum screen. When you select this option, two sets of cursors appear on the screen, horizontal and vertical. In each pair, one cursor is solid (master cursor) and the second is dotted.

Pressing the up/down or right/left arrows moves the solid lined cursor. To move the second cursor click on one of the two new icons those appear next to the patient's name**:** horizontal or vertical. This toggles between the two cursors. The cursors can also be moved simply by clicking on the cursor you want to move and dragging it with the mouse to another position.

The cursor's position is shown in a window next to the end of the cursor line. The difference between each pair of cursors is also displayed.

The spectrum energy distribution is shown in a separate window on the right hand side of the screen. The energy distribution relates to the master vertical cursor, and the display changes with each cursor movement.

The values of E1 and E2 (in dB) shown above the distribution window relate to the position of the two horizontal cursors. In bilateral and multigate mode study types two pairs of cursors appear in each spectrum window, and cursor movement is done simultaneously in both windows. Similarly, two distribution windows, one per spectrum window, are shown

Notes: Allows you to write text in the form of a short report or diagnosis which is saved and/or printed with the spectrum screen or summary screen. This option opens a window where you can enter text. You can return to this window at any time in order to add, modify or delete previously inserted text.

HITS detection: Enables the HITS detection algorithm, which records, marks and counts the HITS events detected in the spectrum. HITS (High Intensity Transient Signals) are usually considered as micro-emboli flowing in the blood stream. HITS detection is available only for 2 MHz PW probes. When active, the HITS counter is updated every time the system recognizes HITS. In addition, when HITS is enabled, a histogram is displayed at the right hand side of the screen. The histogram displays the number of HITS as a function of HITS energy above the mean blood flow energy. The toolbar also displays the Reset and Pause buttons which pause and reset the HITS counter.

Next BV: Displays the next blood vessel in the series.

Previous BV: Shows the previous Blood Vessel

Summary: The summary button brings you to the summary screen of the current mode study type. To return from the summary screen display back to the spectrum display press the Return button.

CAUTION

Remember that exposure levels should always be limited to as low as reasonably achievable (the ALARA Principle).

14. Calculations

14.1. Calculation of clinical parameters

There are two sets of calculated clinical parameters, one for PW mode and one for CW mode. All parameters are averaged over the number of cardiac cycles that are displayed on the screen. The accuracy of the calculations is +/- 5%.

14.1.1.Intracranial examinations parameters

Peak: Maximal systolic frequency/velocity in KHz or cm/s.

Mean: Mean frequency/velocity calculated for ten cardiac cycles over the envelope of the spectrum. The envelope designates maximal frequency/velocity at any given time; therefore, *Mean* represents the average maximal frequency/velocity over the cardiac cycle. If a horizontal line was to be drawn at the calculated mean frequency/velocity level, then the area of the envelope above the mean should equal the area below the mean. Mean is measured in KHz or cm/s.

DV: DV stands for the diastolic velocity, which is calculated as the minimal end-diastolic velocity of the spectrum envelope in KHz or cm/s.

PI PI represents Gosling's pulsatility index, and is calculated based on the envelope parameters to define the pulsatility nature of the blood flow velocity.
PI = (Peak - DV) / Mean.

RI RI represents Pourcelot's resistance index, and is also calculated based on the envelope parameters to define the pulsatility nature of the blood flow velocity and changes in distal resistance.
RI = (Peak - DV) / Peak

S/D S/D, or the systolic to diastolic flow ratio, is another way to describe the pulsatility nature of the blood flow velocity and changes in distal resistance.
S/D = Peak / DV

HR HR, or heart rate, indicates the number of cardiac beats per minute.

HITS HITS, or high intensity transient signals, is the total count of such signals within the blood velocity spectrum. To differentiate HITS, which are considered as micro-emboli, from artifacts, HITS are identified as high energy signals with energy above the background blood energy, short in duration, unidirectional, and appearing anywhere in the spectrum.

LR L.R. or Lindegaard Ratio, indicates the ratio of blood flow velocity in two different arteries - The MCA and the ICA.
L.R. =Mean_velocity(MCA) / Mean_velocity(ICA)

14.1.2.Extracarnial examinations parameters

Peak: Maximal systolic frequency/velocity in KHz or cm/s.

Mode: Frequency/velocity of the FFT cell with maximal energy during peak systole in KHz or cm/s.

Average: Frequency/velocity of the FFT cell with the average energy, calculated during peak systole in KHz or cm/s.

DV: DV stands for the diastolic velocity, which is calculated as the minimal end-diastolic velocity of the spectrum envelope in KHz or cm/s.

PI: PI represents Goslings' pulsatility index, and is calculated based on the envelope parameters to define the pulsatility nature of the blood flow velocity.
PI = (Peak - DV) / Mean

RI: RI represents Pourcelot's' resistance index, and is also calculated based on the envelope parameters to define the pulsatility nature of the blood flow velocity and changes in distal resistance.
RI = (Peak - DV) / Peak

S/D: S/D, or the systolic to diastolic flow ratio, is another way to describe the pulsatility nature of the blood flow velocity and changes in distal resistance.
S/D = Peak / DV

HR: HR, or heart rate, indicates the number of cardiac beats per minute.

15. External Signals

15.1. Digi Lite Analog Output

- Analog output range – (0 - 4.096) V.
- Number of separated analog outputs – 8 channel
- Permissible load impedance per each channel – not less than 2kOhm
- Output voltage value is calculated according to equation $V_{OUT} = 4.096 * VEL / SCALE$,
    - Velocity is calculated from signal voltage according to equation:
      $VEL = SCALE * V_{OUT} / 4.096$
    - Where SCALE – chosen scale in cm/s, VEL – current positive velocity value cm/s.
- Analog channels connector – DB25F (same to PC connector for parallel printer)
- The DB25F connector pin out image is shown below in Fig. 14-1.

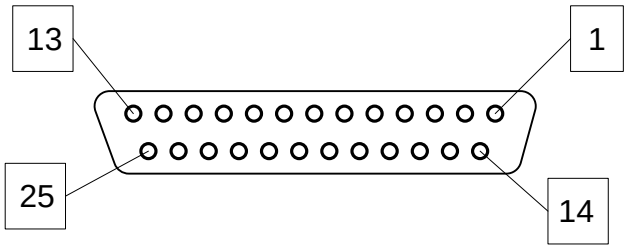


Figure 15-1 Analog channels connector pin out

- Analog channels connector pin-out:
    - GND pins – 14, 15, 19…25.
    - Analog output pins – 9...13, 16, 17, 18.
- Default function of analog output channels is positive envelope per each spectrum window. The connector pin number and default function per each channel is shown in the table below Figure 15-2.

Analog output channel #	Connector pin #	Unilateral mode	Bilateral mode
0	13	Spectrum window 1	Probe A (Green) spectrum window 1
1	12	Spectrum window 2	Probe A (Green) spectrum window 2
2	11	Spectrum window 3	
3	10	Spectrum window 4	
4	9	Spectrum window 5	Probe B (Yellow) spectrum window 1
5	16	Spectrum window 6	Probe B (Yellow) spectrum window 2
6	17	Spectrum window 7	
7	18	Spectrum window 8	

Figure 15-2. Connector pin number and default function per each channel

- The spectrum windows layouts are shown in Fig.15-3 and Fig.15-4

<table>
<tr><td>Spectrum 8</td><td rowspan="2">Spectrum i</td><td>Spectrum 4</td></tr>
<tr><td>Spectrum 7</td><td>Spectrum 3</td></tr>
<tr><td>Spectrum 6</td><td rowspan="2">M-Mode</td><td>Spectrum 2</td></tr>
<tr><td>Spectrum 5</td><td>Spectrum 1</td></tr>
</table>

Figure 15-3 Spectrum windows layout in Unilateral study

Spectrum 2	Spectrum 2
Spectrum 1	Spectrum 1
M-Mode	M-Mode

Figure 15-4 Spectrum windows layout in Bilateral study

15.2. Digi Lite Analog Input

- Analog signal input range from minus –5V till +5V relative GND (pins 14, 15, 19…25).
- Number of separated analog inputs – 8 channels. Inputs via connector Fig. 15-1 Channel #1 – pin 1, Channel #2 – pin 2, Channel #8 – pin 8.
- Positive full scale number + 32767, negative full scale number minus –32768
- Displayed range should be scaled via general setup.

15.3. Cleaning and decontamination of 4mhz and 8mhz probes

The sterilization that recommended by the manufacturer is:

1. The preferred sterilization method is ethylene oxide gas at low temperature up to max 55° Celsius at low pressure up to max. 5. 5 bar.

2. Also certain aqueous disinfectants and alcohol impregnated wipes are most preferred for disinfecting.

3. Further the probes tested with 10 cycles of high pressure ETO sterilization at 55° Celsius and 5,5 bar for 30minutes. After measuring the probes before and after sterilization there was no damage at the probes.

The measurements showed: all acoustic and electric data were unchanged and identical to the data before the sterilization tests.

The concluding to sterilize on these two ways come after checking the probes in different procedures that not recommended.

1. In general, due to the combination of plastics, rubber or rubber like items, together with various internal metals and electronic parts the preferred decontamination by the DHSS method (not steam) cannot be used.

2. The probes were totally immersed in fungicidal, virucidal aqueous solutions as:

Gigasept	5%	for 1 hour and for 16 hours
Gigasept	10%	for 1 hour and for 2 hours
Buraton	1%	for 1 hour and for 4 hours
Buraton	2%	for 1 hour and for 16 hours

In each case the plastic housing and acoustic windows of the probes had slightly softened at their surfaces. After rinsing with water and drying them carefully, and after about 1 hour, they had returned to their former hardness.

Some liquid had entered via cables, connectors and buckling pieces.

Putting the probes into the heater at 60° Celsius for abt.1 to 2 hours will get the liquid out.

Thereafter the measurements showed all acoustic and electric data unchanged and identical to the data of before the immersion tests.

However, the requirements to meet the safety standards concerning patient applied parts do not allow total immersion in aqueous solutions e.g. as described herein.

15.4. Probes Visual Inspection After Cleaning

Visual inspection of the probes including the cable and the connector after the cleaning and decontamination procedure: carry out checking by sight for damage and wear or tear. The coating of the probe must not be damaged (if needed check by sight under a microscope).

In case of no damage is seen, test the probe with Digi-Lite Doppler device for a signal.

16. Sending Data to DICOM Server

Enter in the SETUP-GENERAL-DICOM & Worklist the following parameters of the DICOM setup (IP address of the PACS, Port Number of the PACS, AE Title of the PACS, and the local AE of the system.). See Figure 12-8

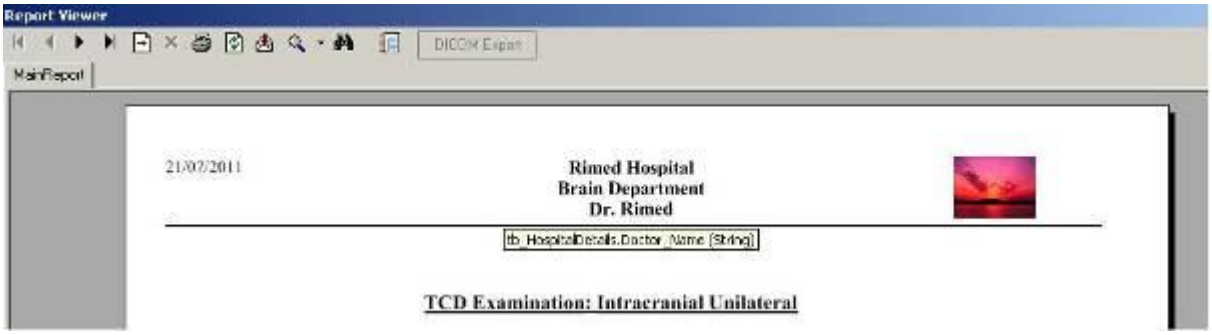


Figure 16-1 Final Patient Report - DICOM Export

After you have filled the DICOM setup and checked if the connection is good (press on ECHO button and verify you get the message "Echo test PASS"),

Then you are able to use the button DICOM Export in the final patient Report in order to send the report to the PACS. See Figure 16-1

17. Retrieving Data from the Server with Modality Worklist

Enter in the SETUP-GENERAL-DICOM & Worklist the following parameters of the Worklist Setup (IP address of the PACS, Port Number of the PACS, AE Title of the PACS, and the local AE of the system.). See Figure 12-8

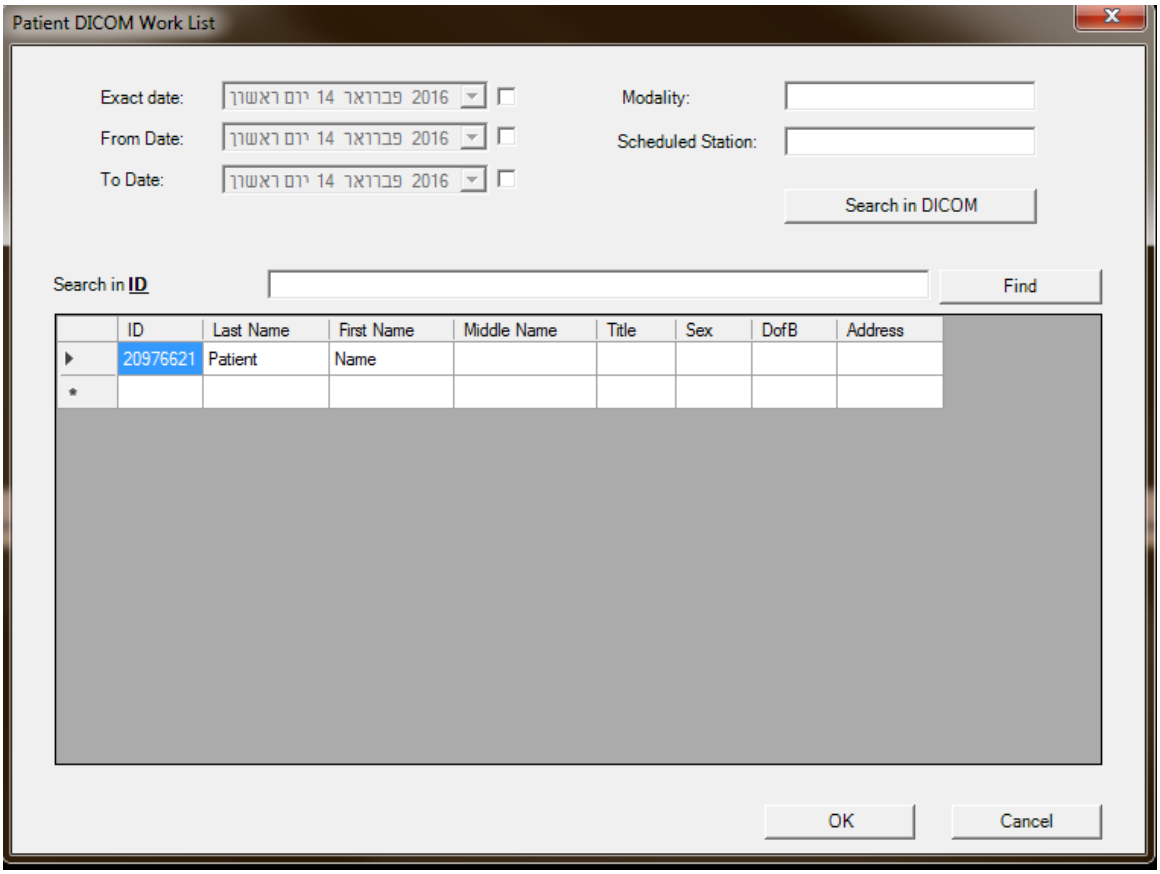


Figure 16-2 Modality Worklist

After you have filled the Worklist Setup and pressed "Accept", Then you are able to use the Worklist. On the top menu bar press "Patient" ⇨ "Work List".

(See Figure 16-2)

18. Packing the system and system components for shipping

Rimed ships the DIGI-LITE™ system in a box measuring 45 cm X 40 cm X 30 cm, on a wooden pallet used for shipping. This box includes three foam guards for protecting the components, plus a separate foam guard for the probes. It is essential to ship the equipment to Rimed using the original packing materials, including the wooden pallet**.**

Caution:

If you do not have all of the original packing materials, contact Rimed Ltd.

To pack the system in its original box, proceed as follows.

1. Carefully place the console in the foam guard.
2. Place the middle foam guard on top of the system console. It should fit snugly, with the compartments on the upper side.
3. Place the system console in the box guard, if there is any extra material you want to send to Rimed, put it in the extra space on the foam guard above the console.
4. Place the probes in the special foam guard provided for that purpose.
5. In the middle foam guard, place the remote control, power cable, keyboard, probes and foot switch
6. Close the box and seal it with packing tape.
7. Place the box on a wooden shipping pallet and secure the box to the pallet with plastic bands.

The system is now ready to be shipped.

19. FAQ

19.1. The LCD showing white\gray\only light on the screen.

1) connect external monitor
2) press DEL key and turn on the system to get in the BIOS
3) go to "ADVANCED CHIPSET FEATURES" line and press ENTER
4) go to "BOOT DISPLAY" line and press ENTER
5) go with the arrows to CRT+LVDS and press ENTER
6) go to "PANEL TYPE" line and press ENTER
7) go to 1024X768 LVDS and press ENTER
8) PRESS F10 and y
9) press ENTER
10) press ENTER
11) the system will get in to the win xp then to the rimed software- -IF NOT YOU WILL NEED TO REPLACE HD-CONTACT RIMED FOR SPARE PARTS
12) get out from the win software by clicking PATIENT- EXIT
13) on the WIN XP desktop click the icon of the LCD that you have on the win bar that is on the right side of the win clock
14) go to GRAPHICS OPTIONS line and press ENTER
15) go to OUTPUT TO line and press it
16) click on INTEL (R) DUAL DISPLAY CLONE
17) and click MONITOR+NOTEBOOK
18) you will see the external monitor working and the lcd as well IF YOU DON'T SEE THE LCD SCREEN (PLEASE SEE IF STAGE 19 IS OK IF NOT YOU WILL NEED TO REPLACE THE LCD CABLE PLEASE CONTACT RIMED FOR SPARE PARTS
19) if after restarting the system you get in the bios and see that the data that your changes has been saved it's ok .if not you will need to replace the bios battery in the motherboard
20) if all this stages doesn't help you will need to replace Motherboard- - CONTACT RIMED FOR SPARE PARTS

19.2. The LCD is showing black and there is no sound of windows rising.

1) When turning the system on dose the light in the main switch is on, does the fans working?

   - If not check the fuses or the power cable.

2) Connect an external screen and turn on the system while you are pressing the Del button down. Do you see the bios screen?

   - If you see the Bios screen continue with the first question in the beginning of this document.

3) Open the system by unscrewing the four screws from two sides of the system.
4) Check the voltages in the power supply, but first disconnect the DC power cable.
5) You will find the schematic chart and power table in the end of this document. If one of the outputs is not in the boundaries of limitation you will need to replace the power supply.
6) If the power supply is in the limits reconnect the DC power cable and check the power in the connectors of the hard drive, motherboard and the DHW card.
7) If one of the outputs is not in the boundaries of limitation replace the DC power cable.
8) If the power is in its limits unscrew rimed card and the motherboard and disconnect the motherboard from Rimed DHW card.
9) Use an insulation plate to place the motherboard on and turn the power on.
10) If the screen is showing windows you will need to replace the DHW card.
11) If the screen is still black disconnect the hard drive and see if the screen showing the dos screen.
12) If yes replace the hard drive
13) If not replace the motherboard.

19.3. When I turn on the system I can hear windows rising but the LCD screen is showing black.

* see figure 17-3

19.4. When entering the software I receive Error to load DSP\FPGA massage.

1) Reboot the system
2) If the massage is still showing close the system and check the connection between the DHW, passive back plane and computer board.
3) If the massage is still showing check if you see any question mark in the device manger.
4) If you see an exclamation mark on the device inside the JUNGO directory try replacing the passive back plane.
5) If it dose not help try to replace the DHW card.
6) If that dose not help replace the motherboard.

19.5. The background of the printed windows are consuming to much black ink. How can we remove the background color?

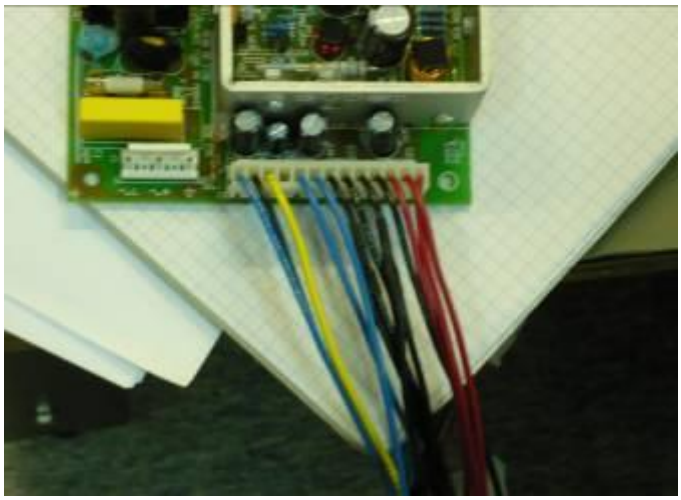
1) Go to setup → general → print.
2) Mark the option no background.
3) In order to print without the background select the spectrum window you want to print by pressing on it with right button and choose print.
4) Make sure that in setup → general → print. The option layout is on one if not you will need to choose more windows to print as chosen in the layout option.

19.6. There is no sound in one direction of the probe (blue or red).

1) Open the system by removing the 4 screws from the two sides of the system.
2) Check that there is a shortcut between the two pins of each speaker cable when the cable is still connected to rimed card.
3) If there is no shortcut between the pins of one of the speakers replace the faulty cable

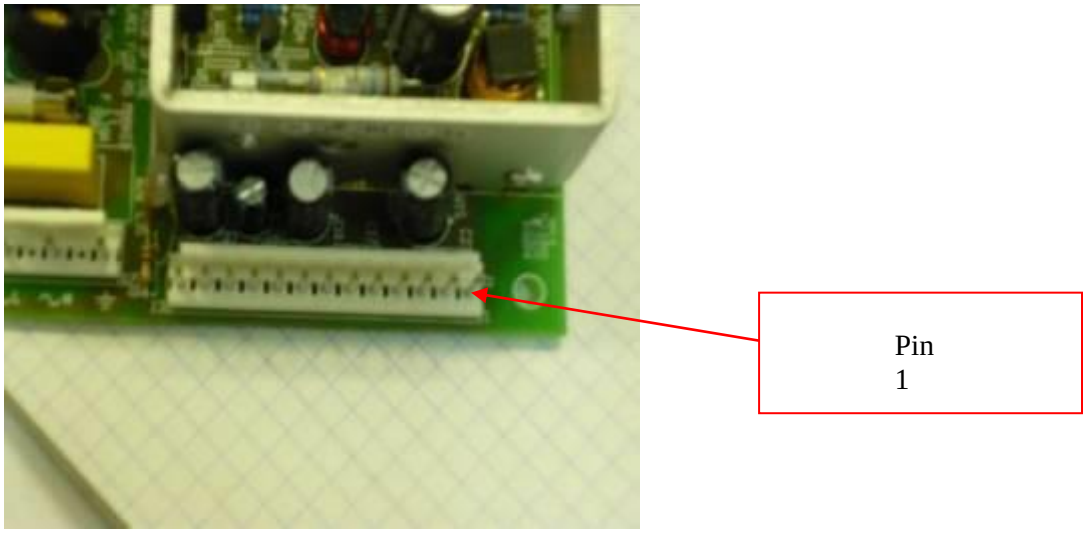
17.7. The TCD software fails or is stuck

1) Restart WINDOWS
2) Restart computer.
3) Close all the other applications when running TCD software.
4) Check if there is enough free space in your HARD DISK.
5) If there is less than 40MB free it is recommended to free up disk space. In order to know the amount of free HARD DISK:
6) Double click “MY COMPUTER, click the disk “C”
7) On the “FILE” menu, click “PROPERTIES”.
8) If there isn’t enough free space, perform the following steps:
9) Empty the “RECYCLE BIN” – on the “DESKTOP”, double click the “RECYCLE BIN”. If you don’t need the files listed, click the “FILE” menu, and then click “EMPTY RECYCLE BIN”
10) Use “SCANDISK” to check for errors on HARD DISK. Perform steps 2.5.1 and 2.5.2 from above. In the window “C – PROPERTIES – click TOOLS – choose – THOROUGH – AUTOMATICALLY FIX ERRORS – after the procedure finished, delete “LOST FILES “ if you are asked by the computer.
11) Back up and remove or uninstall from the disk unneeded files or software.
12) Look in directory “C:\WINDOWS\TEMP” (use “MY COMPUTER” or “WINDOWS EXPLORER”). You can delete all the files beginning with “~”. Also you can delete all the other unneeded files.
13) In DL software back up examinations to storage media, like CD-WR, or other. Use in “DL” software – the menu “PATIENT – BACKUP – MOVE EXAMINATION”.
14) For more details on freeing HARD DISK space, see WINDOWS HELP – click “START – HELP”
15) Reinstall TCD software:
16) Reinstall DL software. Download latest DL software version from RIMED INTERNET site: www.rimed.com – menu “distributor entrance”. To download the software you need username: login, and password: user. In the Web site press on download and download the latest software/
17) Check if there is a HARDWARE problem in your system:
18) Click “START – SETTINGS – CONTROL PANEL” – double click on “SYSTEM”- open “DEVICE MANAGER”
19) There is a list with all the hardware devices of the system. See if there is a yellow circled exclamation point through an icon. If yes, this means the hardware has a problem.
20) In order to know what the problem is, select the device and press “PROPERTIES”.
21) If there is a faulty HARDWARE device, try to reinstall the device.
22) See WINDOWS “HELP” and “TROUBLESHOOT” for more details.
23) If there are problems to save, backup or restore examinations:
24) Check if there is enough free space in HARD DISK. If not, free space. For more details see par. 6.5 above.
25) Reinstall TCD software (first the same version, then, if the problem was fixed, you can upgrade the software version).



No	Color	Max V	Min V
1	Red	5.2V	4.8V
2	Black	GND	GND
3	Blue	12.2V	11.8V
4	Yellow	N.C	N.C

Figure 17-1 Voltage in Power Cable



No'	Pin no'	Voltage
1	1	5V
2	2	5V
3	3	5V
4	4	GND
5	5	GND
6	6	GND
7	7	GND
8	8	12V
9	9	12V
10	10	-12V
11	11	12V

Figure 17-2 Voltage in Power Connector

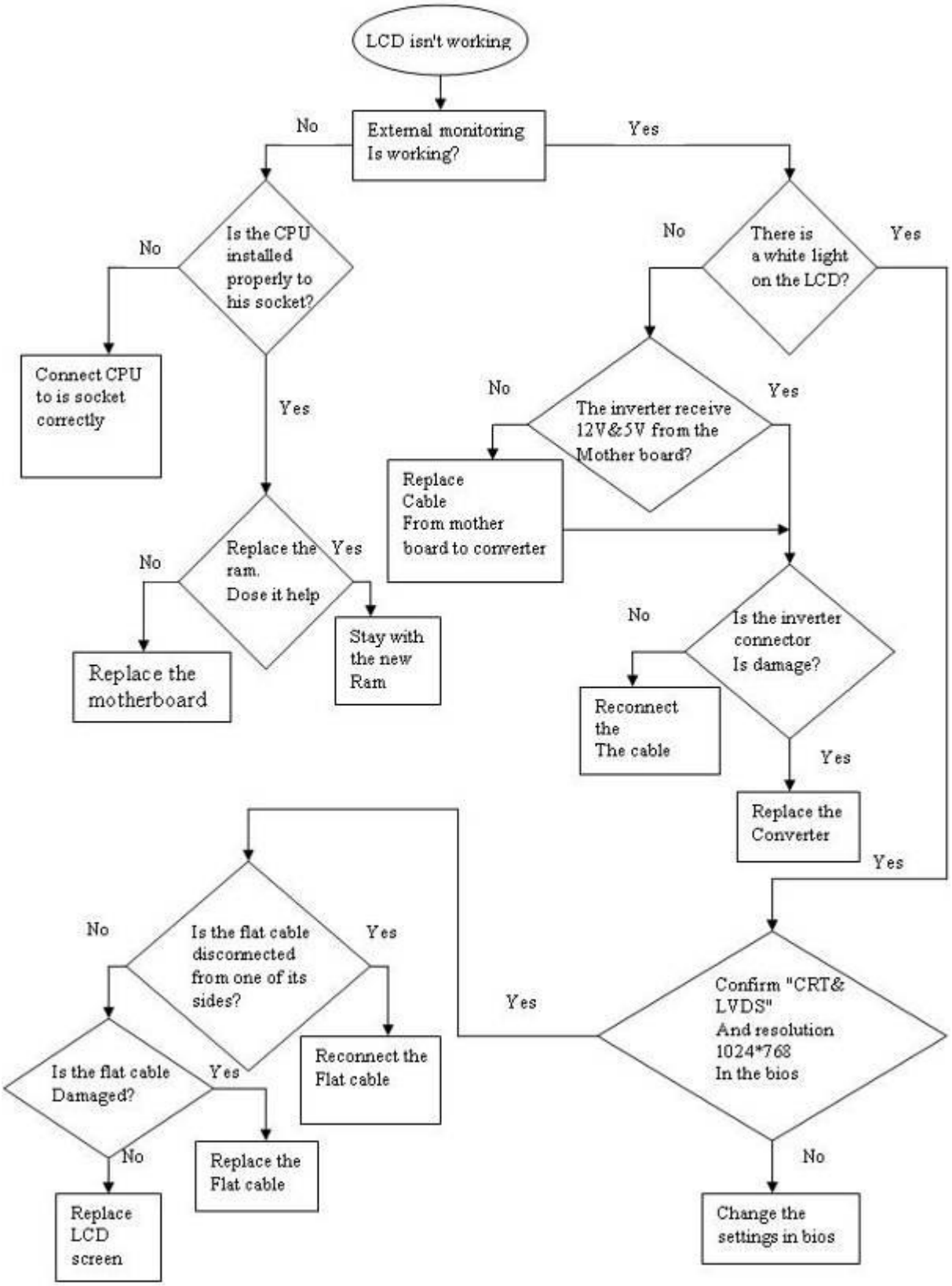


Figure 17-3 Block Diagram LCD

20. Service Log-File

In order to improve our service and to find out where the software is stuck we added a detailed log file that collects the user clicks the sequence of operation and it will show the log file using the following procedure:

From main-menu enter the tcd system

Patient→export→export log file

Save the file name "log file" in disk on key and send it by mail to alon@rimed.com

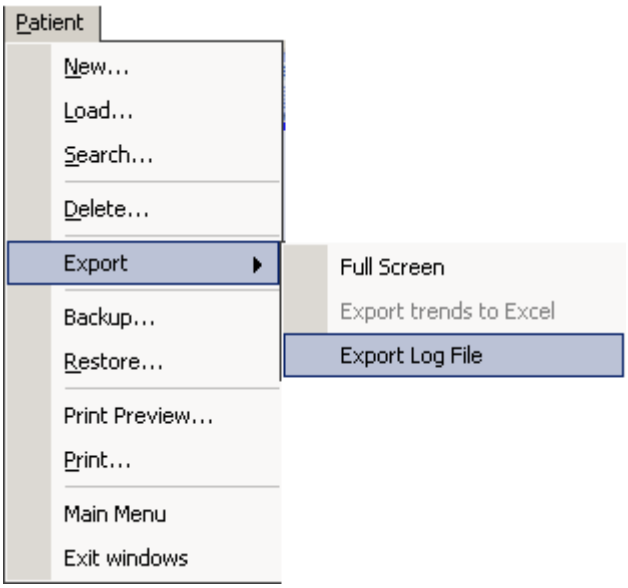


Figure 18-1 Export Log File Menu

21. Guidance and Manufacturer's Declaration For Electromagnetic Compability (EMC)

for the **DIGI-LITE** according to EN 60601-1-2:2007

(Tables 1, 2, 4 and 6)

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions – DIGI-LITE

The **DIGI-LITE** is intended for use in the electromagnetic environment specified below; The customer or the user of the **DIGI-LITE** should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **DIGI-LITE** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	Digi-Lite is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may be necessary to take mitigation measures, such as re-orienting or relocating Digi-Lite or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2			
Guidance and manufacturer's declaration – electromagnetic immunity – DIGI-LITE			
The **DIGI-LITE** is intended for use in the electromagnetic environment specified below; The customer or the user of the **DIGI-LITE** should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or Ceramic tile. If floors are covered with synthetic material, the relative humidity Should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital Environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital Environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 .	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital Environment. If the user of the **DIGI-LITE** requires continued operation during power mains interruptions; it is recommended that **DIGI-LITE** be powered from an uninterruptible power Supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital Environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity – DIGI-LITE

The **DIGI-LITE** is intended for use in the electromagnetic environment specified below; The customer or the user of the **DIGI-LITE** should assure that it is used in such an environment.

Immunity test	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the **DIGI-LITE**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter . **Recommended separation distance** $d = 1.17\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 k Hz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2.34\sqrt{P}$ 800 MHz t o 2,5 GHz where P i s the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer and d i s the recommended separation Distance in meters (m). Field strengths from fixed R F transmitters, as determined by an electromagnetic site survey ,[a] should be less than t he compliance level in each frequency range .[b] Interference may occur in t he vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations .Electromagnetic propagation is affected by absorption

And reflection from structures objects and people.

a

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **DIGI-LITE** is used exceeds the applicable RF compliance level above, the **DIGI-LITE** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **DIGI-LITE**.

b

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the DIGI-LITE

The **DIGI-LITE** is intended f or us e in an electromagnetic environment in which radiated RF disturbances are Controlled. The customer or the user of t **DIGI-LITE** can help prevent electromagnetic interference by maintaining

a minimum distance between port able and m obi le RF communications equipment (transmitters)and the **DIGI-LITE** as recommended below, according t o t he maximum out put power of t he communications equipment .

Rated maximum output power of transmitter **Watts [W]**	**Separation distance according to frequency of transmitter** **Meters [m]**		
	150kHz to 80MHz $d = 1.17\sqrt{P}$	**80MHz to 800MHz** $d = 1.17\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.34\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.7	3.7	7.4
100	11.7	11.7	23.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

22. Acoustic output report

The following tables indicate the acoustic output for the system and transducer combinations. These tables are organized by transducer model and imaging mode.

The acoustic output for this ultrasound system has been measured and calculated in accordance with “Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment” (AIUM - NEMA 1993).

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 420 mW/cm2 for all imaging modes. (For either the Ophthalmic examination, the acoustic output is limited to the following values: ISPTA does not exceed 17 mW/cm2; TI does not exceed 1.0, and MI does not exceed 0.057.)

Additionally, one means for meeting the ALARA principle (“as low as reasonably achievable.”) is to set the MI or TI values to a low index value and then modifying this level until a satisfactory image or Doppler mode is obtained. For more information on MI and TI, see BS EN 60601-2-37:2007: Annex CC.

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount, type of tissue, and the frequency of the ultrasound passing through the tissue. The intensity value in the tissue, In Situ, has been estimated.

Acoustic output reporting table

Transducer Model 2MHz
Operation Mode: PW Doppler
Applications Transcranial

Acoustic Output			MI	ISPTA (mW/cm^2)	ISPPA (W/cm^2)
Global Maximum Value			0.067	181.3	2.28
Associated Acoustic Parameter	Pr (Mpa)		0.095		
	Wo (mW)			212.8	212.8
	Fc (MHZ)		1.953	1.953	1.953
	Zsp (cm)		6	6	6
	Beam Dimensions	X-0.6(cm)		0.366	0.366
		Y-0.6(cm)		0.368	0.368
	PD (uS)		6.5		6.5
	PRF (Hz)		12207		12207
	EBD	Az. (cm)		1.6	
		Ele. (cm)		1.6	
Operating Control Condition	Cont.1 Sample Width (cm)		1	1	1
	Control 2 Power (%)		100	100	100
	Control 3 PRF(kHz)		12	12	12
	Control 4				

Transducer Model 2MHz

Operation Mode: PW Doppler
Applications Ophthalmic Power 7%

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.0284	15.99	0.101
Associated Acoustic Parameter	Pr.3 (Mpa)		0.0397		
	Wo (mW)			4.61	4.61
	Fc (MHZ)		1.953	1.953	1.953
	Zsp (cm)		5.9	5.9	5.9
	Beam Dimensions	X-0.6(cm)		0.362	0.362
		Y-0.6(cm)		0.364	0.364
	PD (uS)		12.9		12.9
	PRF (Hz)		12207		12207
	EBD	Az. (cm)		1.6	
		Ele. (cm)		1.6	
Operating Control Condition	Cont.1 Sample Width (cm)		2	2	2
	Control 2 Power (%)		7	7	7
	Control 3 PRF(kHz)		12	12	12
	Control 4				

Transducer Model 2MHz

Operation Mode: PW Doppler
Applications Ophthalmic Power 14%

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.057	16.527	0.407
Associated Acoustic Parameter	Pr.3 (Mpa)		0.08		
	Wo (mW)			9.28	9.28
	Fc (MHZ)		1.953	1.953	1.953
	Zsp (cm)		5.9	5.9	5.9
	Beam Dimensions	X-0.6(cm)		0.362	0.362
		Y-0.6(cm)		0.364	0.364
	PD (uS)		6.65		6.65
	PRF (Hz)		6104		6104
	EBD	Az. (cm)		1.6	
		Ele. (cm)		1.6	
Operating Control Condition	Cont.1 Sample Width (cm)		1	1	1
	Control 2 Power (%)		14	14	14
	Control 3 PRF(kHz)		6	6	6
	Control 4				

Transducer Model 4MHz

Operation Mode: PW Doppler
Applications Peripheral Vessel

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.0616	232.2	0.726
Associated Acoustic Parameter	Pr.3 (Mpa)		0.122		
	Wo (mW)			21.7	21.7
	Fc (MHZ)		3.906	3.906	3.906
	Zsp (cm)		1.62	1.62	1.62
	Beam Dimensions	X-0.6(cm)		0.29	0.29
		Y-0.6(cm)		0.297	0.297
	PD (uS)		13.2		13.2
	PRF (Hz)		24414		24414
	EBD	Az. (cm)		0.8	
		Ele. (cm)		0.8	
Operating Control Condition	Cont.1 Sample Width (cm)		2	2	2
	Control 2 Power (%)		100	100	100
	Control 3 PRF(kHz)		24	24	24
	Control 4				

Transducer Model 4MHz

Operation Mode: CW Doppler
Applications Peripheral Vessel

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.0323	183	0.183
Associated Acoustic Parameter	Pr.3 (Mpa)		0.064		
	Wo (mW)			14.25	14.25
	Fc (MHZ)		3.906	3.906	3.906
	Zsp (cm)		1.71	1.71	1.71
	Beam Dimensions	X-0.6(cm)		0.263	0.263
		Y-0.6(cm)		0.233	0.233
	PD (uS)		--		--
	PRF (Hz)		--		--
	EBD	Az. (cm)		0.8	
		Ele. (cm)		0.8	
Operating Control Condition	Control 1		--		
	Control 2		--		
	Control 3		--		
	Control 4		--		

Transducer Model 8MHz

Operation Mode: PW Doppler
Applications Peripheral Vessel

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.0322	149.8	0.469
Associated Acoustic Parameter	Pr.3 (Mpa)		0.0902		
	Wo (mW)			1.24	1.24
	Fc (MHZ)		7.8125	7.8125	7.8125
	Zsp (cm)		1.09	1.09	1.09
	Beam Dimensions	X-0.6(cm)		0.143	0.143
		Y-0.6(cm)		0.164	0.164
	PD (uS)		13.1		13.1
	PRF (Hz)		24416		24416
	EBD	Az. (cm)		0.5	
		Ele. (cm)		0.5	
Operating Control Condition	Cont.1 Sample Width (cm)		2	2	2
	Control 2 Power (%)		100	100	100
	Control 3 PRF(kHz)		24	24	24
	Control 4				

Transducer Model 8MHz

Operation Mode: CW Doppler
Applications Peripheral Vessel

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.0324	414	0.414
Associated Acoustic Parameter	Pr.3 (Mpa)		0.0906		
	Wo (mW)			2.512	2.512
	Fc (MHZ)		7.8125	7.8125	7.8125
	Zsp (cm)		0.167	0.167	0.167
	Beam Dimensions	X-0.6(cm)		0.194	0.194
		Y-0.6(cm)		0.162	0.162
	PD (uS)		--		
	PRF (Hz)		--		
	EBD	Az. (cm)		0.5	
		Ele. (cm)		0.5	
Operating Control Condition	Control 1		--		
	Control 2		--		
	Control 3		--		
	Control 4		--		

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