ECHO BLASTER 128 INT-1Z KIT

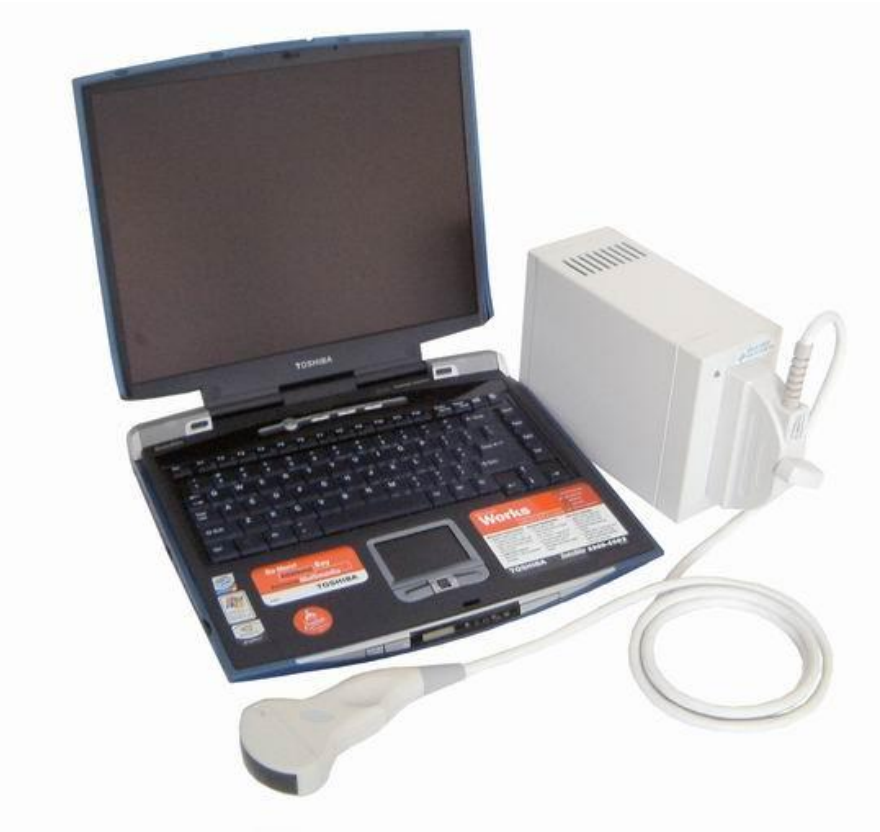
ECHO BLASTER 128 INT-2Z KIT

ECHO BLASTER 128 EXT-1Z KIT

ECHO BLASTER 128 CEXT-1Z KIT

ECHO BLASTER 64 INT-1T KIT

ECHO BLASTER 64 EXT-1T KIT



USER GUIDE

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ATTENTION:

This USER GUIDE is related to ECHO BLASTER 128 and ECHO BLASTER 64 family scanners.
The description is done by the example of ECHO BLASTER 128.
Some modes and features are not available for models of ECHO BLASTER 64 scanners!

See Echo Wave II Software User Manual and Echo Wave II Software Reference Manual on CD.

1. INTRODUCTION

Dear customer,
our **Echo Blaster 128 / Echo Blaster 64** family systems are intended for the multipurpose ultrasound examinations, based on electronic linear and convex scanning.

It is ideal budget solution for hospitals, specialized diagnostic centers, public and private clinics.

Our new class of PC-based compact ultrasound scanners now is featuring:

- 128-element beamformer with multi-frequency probes support for **Echo Blaster 128**;
- Scan-converter free architecture, 128(64) element probes connection for **Echo Blaster 128(64)**;
- Industry standard ZIF (Zero Insertion Force) probe connector for **Echo Blaster 128**;
- Connectivity via fast USB 2.0 interface to any PC (Desktop /Notebook /Tablet);
- +12 V powered from external power supply / battery / standard PC power line;
- External / internal power lines digital monitoring (displaying reports) for **Echo Blaster 128**;
- Digitally controlled acoustic power;
- Light weight, true mobility, flexible architecture.

Here in **User Guide** you can find a common information about **Echo Blaster 128 / 64** families, how to assemble the system components and install the software, safety and maintenance information.

Operation Manual contains controls description.

1.1. About the system / Intended use

Echo Blaster 128 / Echo Blaster 64 system is intended to be used for applications in fetal, abdominal, pediatric, small organ, cardiac (adult and pediatric), transvaginal, peripheral vessel and musculo-skeletal. It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

Echo Blaster 128 / Echo Blaster 64 family scanners offers to get a real-time and “frozen” echo images in B-mode, B+B-mode (two echo images on the screen simultaneously, one real time and one “frozen”), M-mode , B+M-mode (two real time images in B- and M- modes). These echo images can be either full size or zoomed.

Unlike ordinary ultrasound devices this scanner is based on modern digital technologies. PC and USB 2.0 application enables many powerful innovative features such as:

- user friendly, easy-to-use intuitive graphic user interface;
- echo images storage on hard disk or any other devices;
- storage a sequence of full size echo images (cineloop) with possibility to save it in video file format;
- image and cineloop file formats enables using other applications for viewing stored data;
- using a variety of peripheral devices;
- direct echo image and even video e-mail sending at one click.

A variety of available ultrasound probes makes possible application for examinations in therapy, obstetrics, gynecology, urology, pediatrics, oncology and others.

Common view of **Echo Blaster 128 EXT-1Z Kit** is shown on the **Figure 1**.

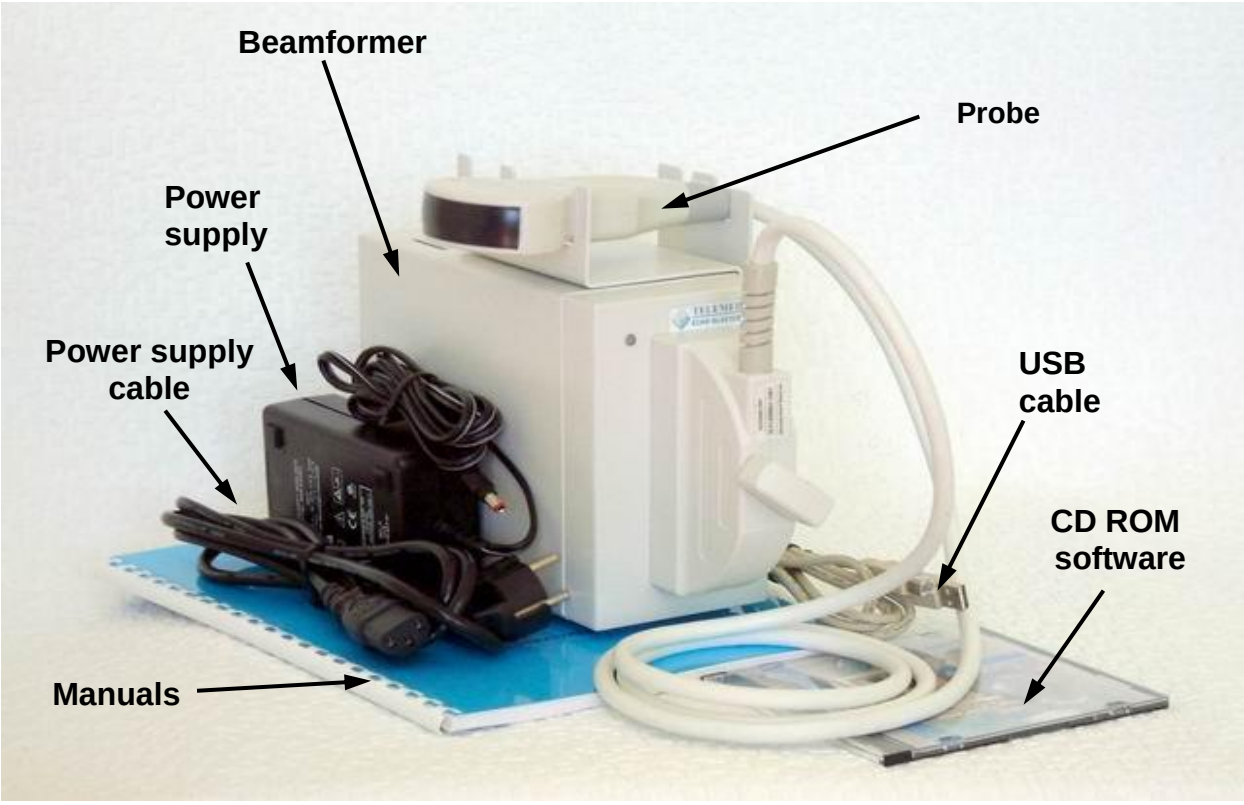


Figure 1

Common view of Echo Blaster 128 INT-1Z Kit is shown on the Figure 2.

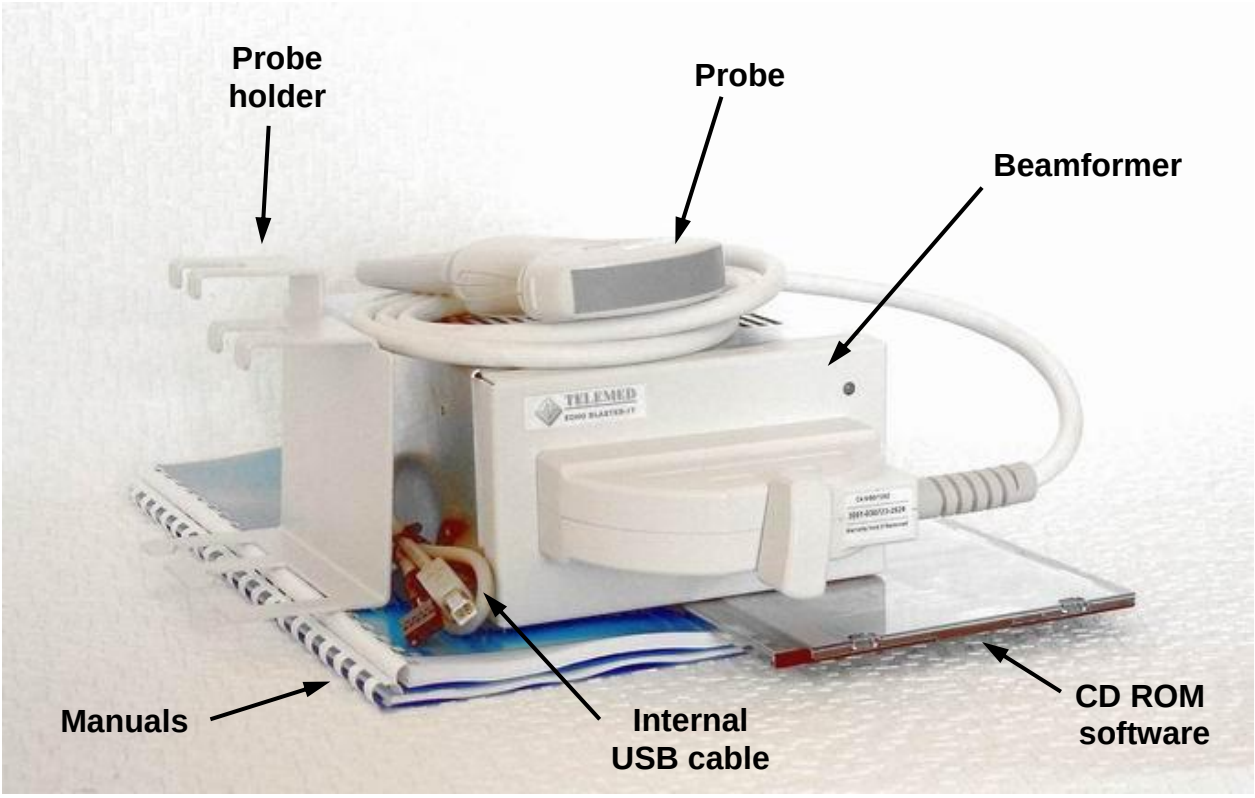


Figure 2

Common view of Echo Blaster 128 EXT-2Z Kit is shown on the Figure 3.

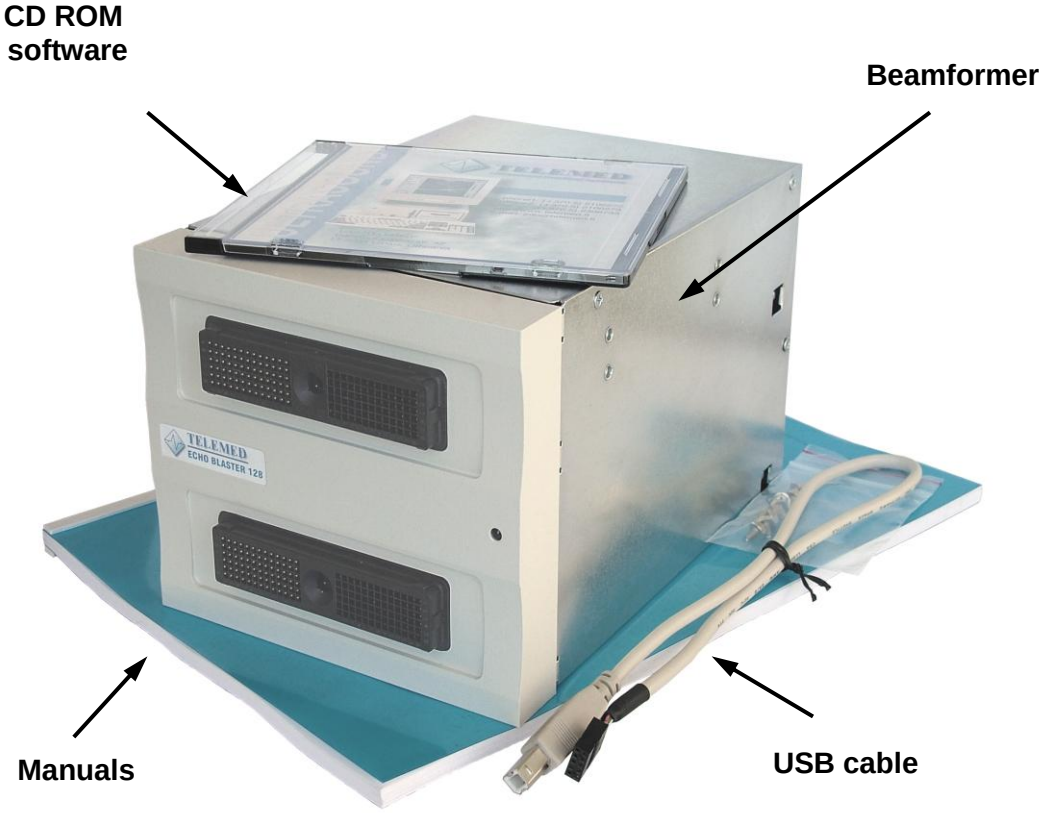


Figure 3

Common view of Echo Blaster 64 INT-1T Kit is shown on the Figure 4.

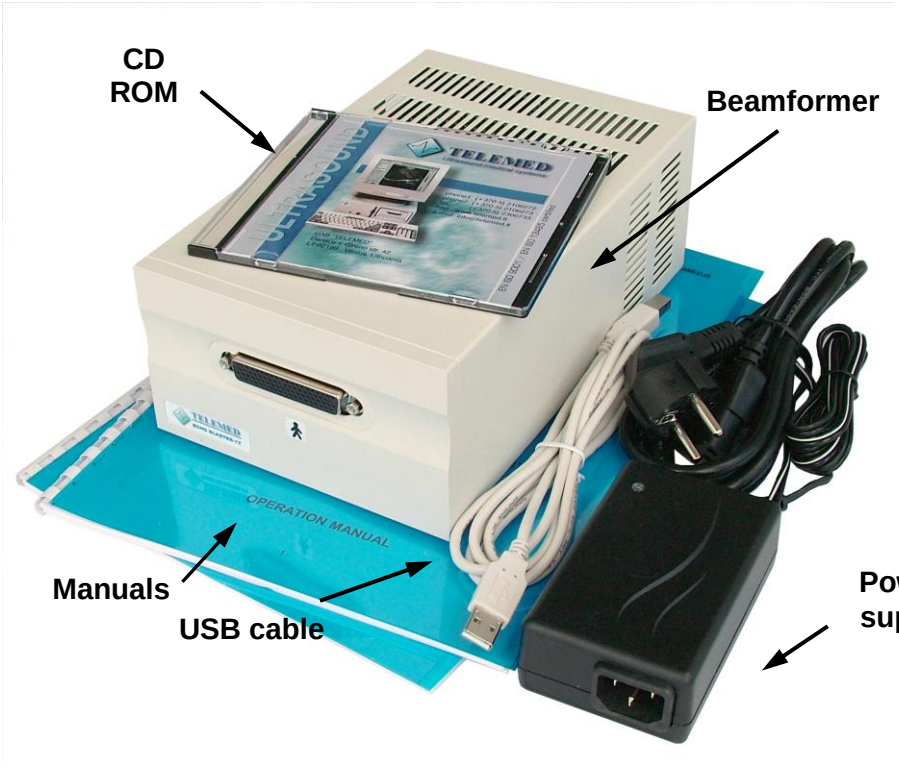


Figure 4

1.2. Delivery set

ECHO BLASTER	64 EXT-1T	128 (C)EXT-1Z	128 INT-1Z	128 INT-2Z
Beamformer	●	●	●	●
User guide	●	●	●	●
Operation manual	●	●	●	●
Software (CD-ROM)	●	●	●	●
Probe holder	●	●	●	●
Standard USB cable	●	●		
Internal USB cable			●	●
Power supply (medical grade)	●	●		
Ultrasound probe	Types and quantity is defined by customer			

1.3. About the system software

Your diagnostic system contains **Echo Wave II** software to control its operation. TELEMED provides latest **Echo Wave II** software version and **TELEMED Drivers Package** with your system. In the software the unique technologies making the intellectual property of TELEMED are used. Latest software version can be downloaded from http://www.telemed.lt internet site. See **Echo Wave II Software User Manual** and **Echo Wave II Software Reference Manual** on CD.

1.4. Technical Specification

Table 1 contains technical specifications of **Echo Blaster 128 / Echo Blaster 64**:

Table 1

IMAGING MODES	
• B • B+B • 4B	• B+M • M
SCANNING METHOD	
• Electronic linear • Electronic convex • Electronic microconvex	
ULTRASOUND IMAGING	
• ultrasound image size: automatically adjustable to screen resolution • gray scale: 256 • full motion and full size real-time ultrasound imaging, up to 120 fps (depends on selected scan depth, scan angle, focus mode, High Line Density setting, computer speed)	• zoom mode: from 60% to 600% in all modes (Scan, Freeze, B, B+B, 4B, M-zoom, cineloop and etc) • viewing area variable for frame rate maximizing: 6 steps • "FREEZE" mode • cineloop recording/play: several thousands frames (depends on computer memory size and scan mode)

Depth Selection	
• 2 – 30 cm (depth range depends on probe type and scanner model)	
PROBES	

Echo Blaster 64	• 64 elements probes (up to 7 different types available):
	  ○ from 2 MHz to 7.5 MHz
	  ○ multifrequency
	• Automatic probe recognition

Echo Blaster 128	• 128 elements probes (up to 31 different types available):
	  ○ from 2 MHz to 10 MHz
	  ○ multifrequency
	• Automatic probe recognition
	• 2 probe ports (**Echo Blaster 128 INT-2Z**)

FOCUSING	
Hybrid Beamformer	• 16 channels (**Echo Blaster 64**) • 32 channels (**Echo Blaster 128**)
Digital transmit focusing	• Yes
Multi focus mode	• Transmit/receive focusing, max 4 points • Programmable focus area presets
Dynamic focus mode (**Echo Blaster 128**)	• Transmit variable focus, 8 points • Dynamic receive focus, 8 zones
SIGNAL PROCESSING	
• High Line Density scan mode for better resolution (**Echo Blaster 128**) • TGC Control, 5 sliders 40 dB • dynamic range: 120 dB, 8 values • overall gain control • M - mode sweep speed control • acoustic power control • variable frame averaging • brightness, contrast • advanced gamma control: 8 fixed curves, 8 user defined (custom) • scan direction, rotation, up-down controls • negative / positive control • bi-linear interpolation • echo enhancement control • noise rejection function • speckle reduction function (optional)	
FUNCTIONS	
General Measurements and Calculations	• Mouse / trackball / keyboard operation of multiple calipers • B-mode: Distance / Length / Area / Circumference / Volume / Angle / Stenosis % / A/B Ratio

	• M-mode: Distance / Time / Velocity / Heart Rate / Stenosis % / A/B Ratio
Human Measurements and Calculations Packages	• General calculations package • Obstetrics / Gynecology (OB / GYN) calculations package • Gynecology (GYN) • Abdominal exam measurements and calculations • Urology • Endocrinology • Vascular exam measurements and calculations • Cardiology
Veterinary Calculations Packages	• Obstetrics: Canine / Feline / Ovine / Bovine / Equine / Llama / Goat • Animal Cardiology
User Interface	• The set of predefined skin schemes for user interface • User-friendly pop-up menus and dialogue boxes • Unlimited programmable presets for clinically specific imaging • Image comment / save / recall browsing • Anatomical Icons with probe position indicator
Indication	• Power LED indicator of system status (**Echo Blaster 128**)
Image and video save / load	• JPG BMP PNG TIF AVI
Cineloop	• Recording up to 2048 frames to memory • Play / Pause / Stop / Frame selection • Saving ultrasound video file to disk • Loading ultrasound video file from disk
Printing	• System printer
Internet	• Direct e-mail sending function with image or video attachment
TV output	• Standard TV output using computer's display adapter (option)
RECOMMENDED COMPUTER REQUIREMENTS	
Computer type	• IBM PC compatible Desktop/Notebook/Tablet PC
Interface	• USB 2.0 Interface
CPU	• Core Duo / Core 2 Duo 1.6 GHz or better
Operating system	• Windows® XP SP2 / Windows® Vista SP1
RAM	• 512 Mb of or better
ULTRASOUND SOFTWARE	
Drivers	• TELEMED Drivers Package
Software	• Echo Wave II software (B/W modes)
Plug-Ins	• ClearView plug-in (optional) • 3DView plug-in (optional) • PanoView plug-in (optional)

Library for programmers	• SDK documentation / sample code (available by agreement)
DIMENSIONS AND WEIGHT OF BEAMFORMER	
Dimensions W x D x H mm	• 146 x 185 x 85 **Echo Blaster 64 EXT-1T Kit** • 146 x 185 x 85 **Echo Blaster 64 INT-1T Kit** • 86 x 197 x 149 **Echo Blaster 128 EXT-1Z Kit** • 62 x 210 x 165 **Echo Blaster 128 CEXT-1Z Kit** • 149 x 200 x 86 **Echo Blaster 128 INT-1Z Kit** • 149 x 200 x 126 **Echo Blaster 128 INT-2Z Kit**
Weight, kg	• 2 **Echo Blaster 64 EXT-1T Kit** • 2 **Echo Blaster 64 INT-1T Kit** • 1.6 **Echo Blaster 128 CEXT -1Z Kit** • 2 **Echo Blaster 128 INT-1Z Kit** • 2,2 **Echo Blaster 128 INT-2Z Kit**
POWER +12 V	
External medical grade power supply	• **Echo Blaster 64 EXT-1T Kit** • **Echo Blaster 128 (C)EXT-1Z Kit**
Standard computer internal power line	• **Echo Blaster 64 INT-1T Kit** • **Echo Blaster 128 INT-1Z Kit** • **Echo Blaster 128 INT-2Z Kit**
SAFETY	

Electromechanical safety	IEC601-1-2 Medical electrical equipment part 1: General requirements for safety.
	• Externally powered by Class I medical approved power supply/adapter
	  ○ **Echo Blaster 64 EXT-1T Kit**
	  ○ **Echo Blaster 128 (C)EXT -1Z Kit**
	• Class I
	  ○ **Echo Blaster 64 INT-1T Kit**
	  ○ **Echo Blaster 128 INT-1Z Kit**
	  ○ **Echo Blaster 128 INT-2Z Kit**
	• Type B (BF for **Echo Blaster 128 CEXT -1Z Kit**)

EMC/EMI standards	• European Norm EN 55011:1998 (CISPR 11:1999) Industrial, scientific and medical (ISM) radio-frequency equipment. Radio disturbance characteristics. Limits and methods of measurement.
Ultrasound exposure	• CEI/IEC 61157:1992, International Electro technical Commission, Requirements for The Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment. • AIUM/NEMA: Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.1992.
OPERATIONAL ENVIRONMENT	
Nominal operational environment	• Temperature of the environment: 10 - 45 ° C • Relative humidity not exceeding: 85 % • Atmospheric pressure: 70 - 106 kPa

2. SAFETY

Please read this information before using the diagnostic system. It applies to the ultrasound system, transducers, accessories and peripherals.

2.1. Electrical safety

This system complies with the applicable medical equipment requirements and meets IEC601-1, Class I internally-powered equipment requirements (or powered by Class I approved external medical power supply for **Echo Blaster 64 EXT-1T Kit / Echo Blaster 128 (C)EXT-1Z Kit**) / Type B (BF for **Echo Blaster 128 CEXT -1Z Kit**) safety requirements.

NOTE :

Everybody who connects computer equipment as medical appliance configures a medical system and is therefore responsible for ensuring that the system complies with IEC 601-1-1. The achievement the PC compliance with the requirements of IEC 601-1 is based on electrical safety. A standard PC power supply almost certainly does not comply with the electrical IEC 601-1 requirements from several standpoints, e.g. leakage current requirements, dielectric strength requirements.

Possible solution is powering the PC (and computer monitor) via a 1:1 medical insulation transformer, which has been designed to IEC 60601-1. The best solution is completely IEC 601-1 certified PC or a battery operated portable PC and wireless peripheral devices.

All system (including monitor and other connected parts) must be configured to comply with IEC 601-1-1. If in any doubt contact the technical service department of your local representative.

Note that in any case PC used should be approved to the safety standard for IT (Information Technology) equipment, i.e. IEC 60950, or its national variants.

Electrical specification is shown below and placed on the rear panel of scanner.

To avoid electrical shock use only the supplied power cables and connect it to properly grounded power socket. Do not use a three pin to two pin adapter. This defeats the purpose of safety grounding. System should be operated within the voltage limits.

If ultrasound scanner will be moved or leaved for a long time without switching on it must be disconnected from power supply. If scanner will be switched on, do not make any interrupts while operating system and ultrasound software is loading. Time for this operation is approx. 1-2 min.

To avoid the risk of electrical shock and fire hazard:

- before using the probe, inspect the probe face, housing, and cable, do not use the probe if the probe or its cable is damaged;
- always disconnect the AC power supply from the system before cleaning the system;
- do not use any probe that has been immersed beyond the specified cleaning or disinfection level;
- inspect the power supply, AC power supply cable and plug on a regular basis, ensure they are not damaged;
- use only accessories and peripherals recommended by TELEMED.

WARNING:

To avoid risk of electrical shock don't open cover of device/blocks. There are no parts that can be repaired by yourself. In case of troubles contact TELEMED service department or nearest local authorized distributor.

2.2. Equipment protection

To protect your ultrasound system, transducer and accessories, follow these precautions:

- excessive cables bending or twisting can cause a failure or intermittent operation;

- improper cleaning or disinfecting of any system part can cause permanent damage, for cleaning and disinfecting instructions see chapter below;
- do not use solvents such as thinner/benzene, or abrasive cleaners on any part of the system;
- do not spill liquid on the system;
- incorrect assembly or configuration and using an improper power source may damage the system.

WARNING:
Ultrasound probes can easily be damaged by improper handling! Failure to follow these precautions can result in serious injury and equipment damage!

2.3. Biological safety

Observe the following precautions related to biological safety:

- do not use the system if it exhibits erratic or inconsistent behavior;
- discontinuities in the scanning sequence are hardware failure indication that must be corrected before use;
- do not use the system if it exhibits artifacts on the LCD screen, either within the clinical image or on the area outside it;
- artifacts are indication of hardware and/or software errors that must be corrected before use;
- perform ultrasound procedures prudently, use the ALARA (As low As Reasonably Achievable) principle (see **APPENDIX 12.1: Guidelines for the safe use of diagnostic ultrasound**).

WARNING:
At detection of discrepancy to patient's safety requirements (occurrence or probability of risk) you need to inform immediately the local dealer and the manufacturer (for single European customers – to inform the EC representative labeled on the rear panel).

2.4. Ultrasound waves/exposure

Ultrasound waves used in diagnostic system have frequencies from 3,5 MHz to 7,5 MHz. Sound waves with such frequency are weaken in air, so can be measured for example in water. Ultrasound waves, sent by converter have so small power (medium intensity less than 100mW/cm²), that according to International Electro technical Commission (IEC 1157) standards (is within AIUM/NEMA standards), and have not any impact for patient health (unnecessary exposure should be avoided).

Detailed information is expounded in **APPENDIX 12.1: Guidelines for the safe use of diagnostic ultrasound**.

2.5. Cybersecurity

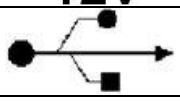
Vulnerabilities in cybersecurity may represent a risk to the safe and effective operation of networked medical devices.

Network administrators in health care organizations and information technology vendors should assure an adequate degree of protection from threats such as viruses and worms, to avoid the opportunity for unauthorized access to the network or the medical device/database.

3. LABELING

Table 2 describes the purpose and location of safety labels and other important information provided on the equipment.

Table 2

LABEL/SYMBOL	DESCRIPTION	LOCATION
Identification and Rating Plate	• Manufacturer name and address; • Model; • Serial number; • Electrical ratings; • EC representative;	Rear panel
Type/Class Label	Used to indicate the degree of safety or protection	Rear panel (along with rating plate label)
	ATTENTION - This symbol is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the appliance.	Rear panel (complete system), beamformer cover (kit)
	Type B Equipment (man symbol) IEC 878-02-03 indicates B type equipment which is providing a particular degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and reliability of the PROTECTIVE EARTH CONNECTION if present.	External (probe outlet)
	Type BF Equipment (man symbol) IEC 878-02-03 indicates BF type equipment which is providing a particular degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and reliability of the PROTECTIVE EARTH CONNECTION if present.	External (probe outlet)
	The symbol indicating separate collection for electrical and electronic equipment (Annex IV of Directive 2002/96/EC)	Rear/bottom panel
	MAINS ON / OFF indicates the power on position of the mains power switch	On the power switch, complete system
	CE marking	Rear panel (rating plate label)
	DC power input	Rear panel **Echo Blaster 128 (C)EXT-1Z Kit / Echo Blaster 64 EXT-1T Kit** beamformer
	USB connector	Rear panel

4. SYSTEM OVERVIEW

Here is main information about **Echo Blaster 128 / Echo Blaster 64 Kits** based scanners.
The system consists of (see **Figure 5**)

- Beamformer
- Ultrasound Probe
- Personal Computer (Desktop / Notebook / Tablet PC)
- Battery / External Power Supply (option).

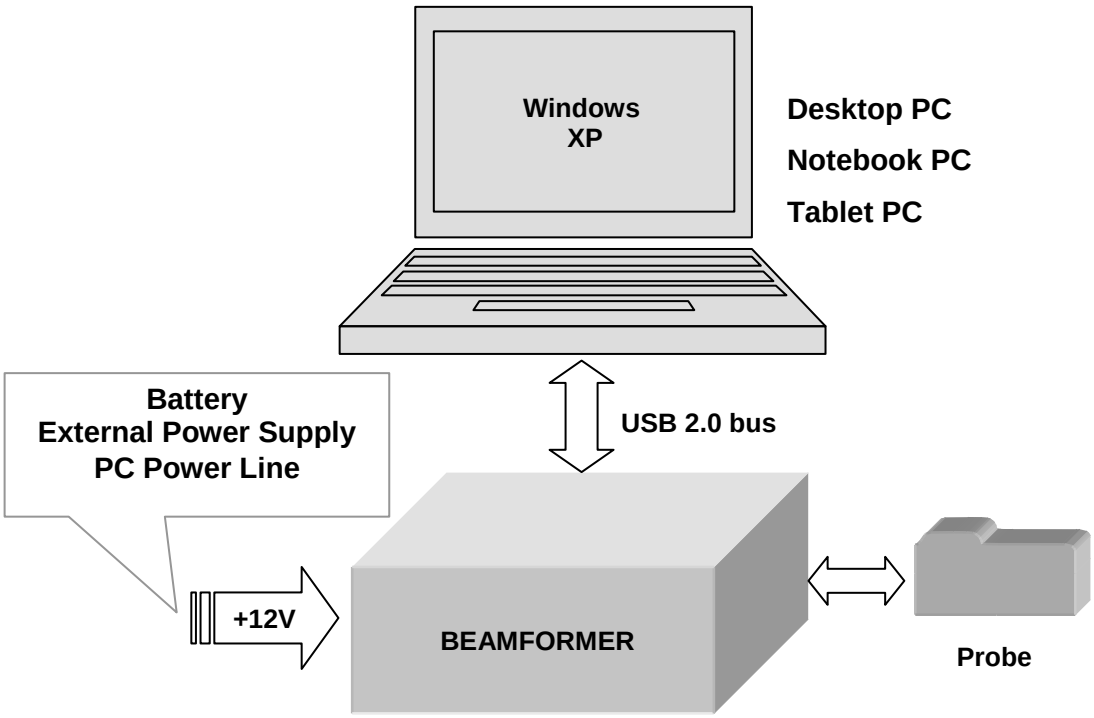


Figure 5

The **Echo Blaster 64** family systems handles a 16 channel multielement probe. Total numbers of independent elements in probe – up to 64.

The **Echo Blaster 128** family systems handles a 32 channel multielement probe. Total numbers of independent elements in probe – up to 128.

The number of channels indicates the maximum number of elements to create one echo line.

4.1. Principle of operation

Ultrasound diagnostic system is based on the effect of ultrasound wave reflection from the tissue edges with different acoustic impedance levels. Ultrasound waves sent out by the probe head are emitted into the patient's body. Reflections from the specific types of tissue and their external surface/edges cause partial reflections of the propagating sound wave. Return echo comes back to the probe head and after being detected and amplified is displayed on the monitor screen as a pixel combination with various shades of brightness, creating an ultrasound image.

4.2. Components & Modifications

All **Echo Blaster 128** family scanners based on **Echo Blaster 128 INT-1Z / EXT-1Z/ INT-2Z Kits**. It is a main component of ultrasound scanner based on IBM PC compatible computer.

Existing modifications of the scanners and kits are:

- **Echo Blaster 128 INT-1Z/ INT-2Z** (internal, to be installed into regular computer case);

- **Echo Blaster 128 EXT-1Z Kit** (external, made as external device to be placed nearby the PC computer);
- **Echo Blaster 128 CEXT-1Z Kit** (compact external, made as external device to be placed nearby the PC computer);
- **Echo Blaster 128 PC-1Z** scanner (**Echo Blaster 128 INT-1Z Kit** integrated into PC computer);
- **Echo Blaster 128 PC-2Z** scanner (**Echo Blaster 128 INT-2Z Kit** integrated into PC computer);
- **Echo Blaster 128 PC-1Z Portable** (**Echo Blaster 128 INT-1Z Kit** integrated into portable case with LCD panel);
- **Echo Blaster 128 PC-2Z Portable** (**Echo Blaster 128 INT-2Z Kit** integrated into portable case with LCD panel)

All other characteristics of these scanners and kits are same. Detailed specifications of all modifications possible are available here: http://www.telemed.lt

4.2.1. Beamformer

Beamformer functions are:

- excite electric pulses to fire the probe;
- ultrasound echo signals pre-amplification;
- compensation of the ultrasound attenuation due to travel depth;
- reordering the receiving signal sequence and focusing by applying the appropriate time delays;
- shifting the center frequency of BPF (band pass filter) to follow the frequency shift that occurs according to the travel depth;
- the ultrasound signal compression by means of Log Amplifier, detection the echo signal envelope

4.2.2. Probe Unit

Probe unit is piezoelectric transformer which provides the acoustical pulse used to exanimate the medium and used for both transmission and reception, i.e., the transducer is used in pulse-echo mode. A voltage waveform is applied to the transducer and the converted into an acoustic waveform (inverse piezoelectric effect). Acoustic pulse is then partially transmitted and partially reflected by intervening soft tissues structures in the body. The reflected acoustic waveform is received by the same transducer and is converted into a voltage waveform (direct piezoelectric effect).

The probe unit consists up to 128(64) piezoelectric elements. Probe enclosure has a relief to affix the scanning direction.

Probes for Echo Blaster 64															
Type / Order Code	**Probe Central Frequency, MHz**	**System Frequencies, MHz**	**Radius of Curvature, mm**	**Field of View / Degree, mm**	Abdominal	Cardiac	Obstetrics	Pediatrics	Small Parts	Transrectal	Transvaginal	Vascular	Veterinary	Food Industry	**Biopsy Adapter**
PV6.5/10/64D	6.5	5.0 6.25 7.5	10	147					●			●	●		
EC6.5/10/64D	6.5	5.0 6.25	10	147						●	●				●

		7.5													
C3.5/20/64D	3.5	2.0 3.0 4.0	20	104	●	●									
C3.5/60/64D	3.5	3.0 4.0 5.0	60	63	●		●	●							
HL7.5/40/64D	7.5	5.0 6.25 7.5	-	38				●	●			●	●		●
LV7.5/65/64D	6.5	4.5 6.0 7.5	-	63									●		

Probes for Echo Blaster 128

Type / Order Code	Probe Central Frequency, MHz	System Frequencies, MHz	Radius of Curvature, mm	Field of View / Degree, mm	Abdominal	Cardiac	Obstetrics	Pediatrics	Small Parts	Transrectal	Transvaginal	Vascular	Veterinary	Food Industry	Biopsy Adapter
PV6.5/10/128Z	6.5	5.0 6.0 7.0 8.0	10	156					●			●	●		
EC6.5/10/128Z	6.5	5.0 6.0 7.0 8.0	10	156						●	●				●
EC8.0/10/128Z	8.0	6.0 7.0 8.0 9.0 10.0	10	156						●	●				●
C5.0/15/128Z	5.0	4.0 5.0 6.0 7.0 8.0	15	101	●								●		
C3.5/20/128Z	3.5	2.0 3.0 4.0	20	104	●	●									
C3.5/40/128Z	3.5	2.0 3.0 4.0 5.0	40	75	●		●	●							●
C3.5/60/128Z	3.5	2.0 3.0 4.0 5.0	65	59	●		●	●							

C4.5/50/128Z	4.8	3.0 4.0 5.0 6.0 7.0	50	70	●		●	●	●						●
HL9.0/40/128Z	9.0	5.0 6.0 7.0 8.0 9.0 10.0	-	39				●	●			●	●		●
HL9.0/60/128Z	9.0	5.0 6.0 7.0 8.0 9.0 10.0	-	59				●	●			●	●		
LV7.5/60/96Z	7.5	5.0 6.0 7.0 8.0	-	59									●		
L3.5/170/96Z	3.5	2.0 3.0 4.0 5.0	-	170										●	

4.2.3. Personal Computer

All controls apply by computer keyboard and mouse / trackball / touchpad.

Refer **Echo Wave II Software User Manual** and **Echo Wave II Software Reference Manual** on CD.

As a result, all ultrasound data and software interface can be observed on SVGA monitor (LCD panel).

4.3. Connection and Indication

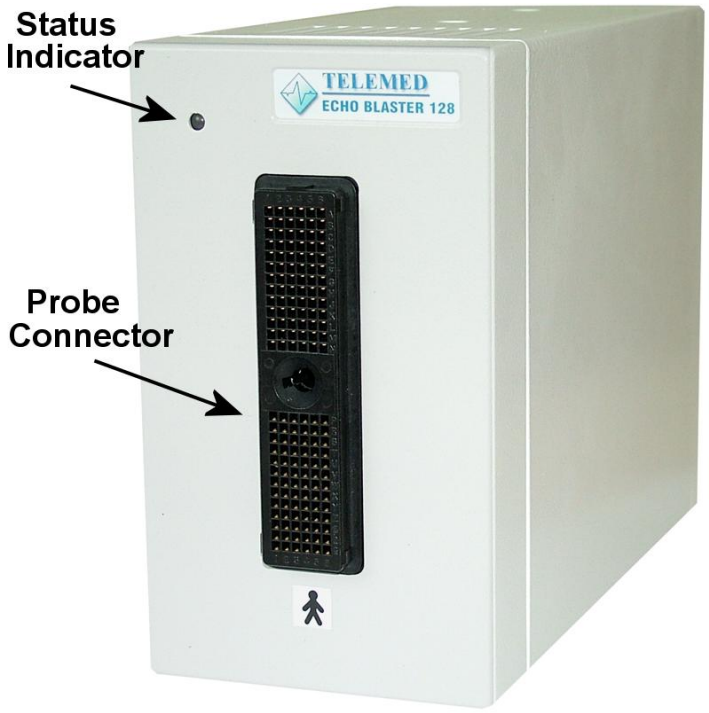


Figure 6: front view of **Echo Blaster 128 EXT-1Z** beamformer.

Figure 6

Figure 7: rear view of **Echo Blaster 128 EXT-1Z** beamformer.

Figure 7

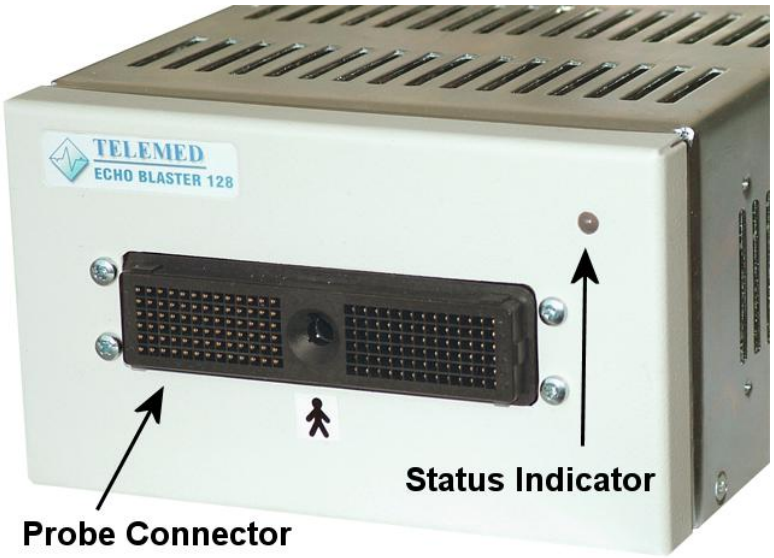
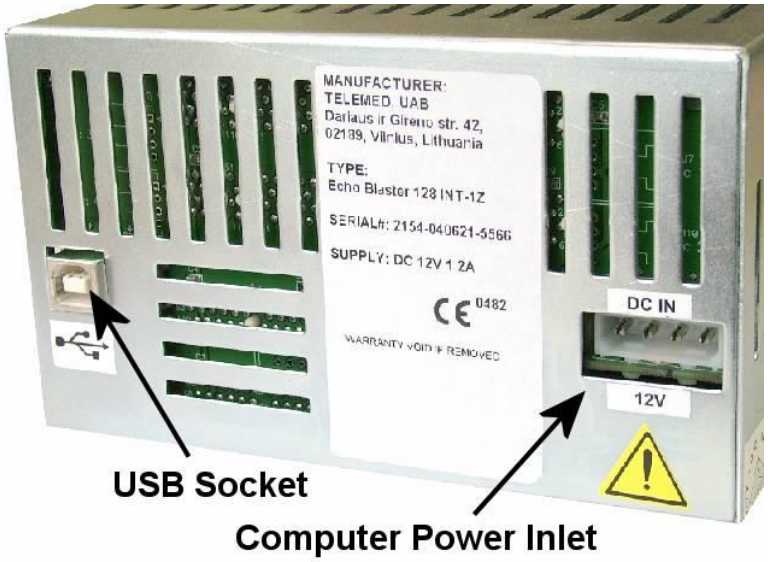


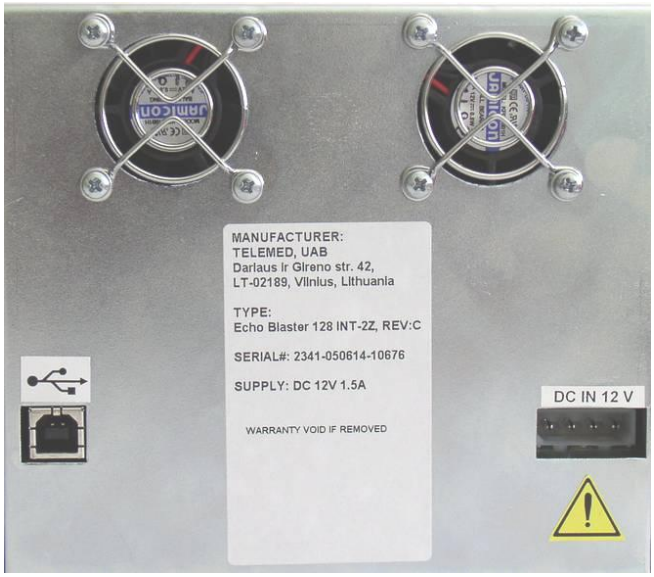
Figure 8: front view of **Echo Blaster 128 INT-1Z** beamformer.

Figure 8



Rear view of **Echo Blaster 128 INT-1Z** beamformer**.**

Front view of **Echo Blaster 128 INT-2Z** beamformer.



Rear view of
Echo Blaster 128 INT-2Z
beamformer**.**

Front view of
Echo Blaster 64 EXT-1T
beamformer.

Rear view of
Echo Blaster 64 EXT-1T
beamformer**.**

<u>IMPORTANT NOTE</u>:
The Echo Blaster 128(64) Kit is partially powered through USB from the computer to which it is connected.
For compliance with IEC601.1 any computer equipment connected to the USB interface of the Echo Blaster 128(64) Kit must be certified to IEC standards (e.g. IEC 950) and configured to comply with IEC 601-1-1. Everybody who connects computer equipment to this interface configures a medical system and is

therefore responsible for ensuring that the system complies with IEC 601-1-1. If in any doubt contact the technical service department of your local representative.

4.4. Peripherals/Compatibility

Echo Blaster 128(64) family scanners can work / operates with standard PC features:

- PS/2 mouse
- PS/2 keyboard
- SVGA monitor
- Laser printer 600 dpi, (preferred HP printers), optional

Optional accessories:

- Image Processing Packages
  - 3DView
  - PanoView
  - ClearView
- Additional Probes
- Probes Carrying Cases
- Biopsy Clip Bracket C- type (for convex probes)
- Biopsy Clip Bracket HL- type (for linear probes)
- PV-Biopsy Clip Bracket PV- type (for endovaginal probes)

4.5. Status Indicator (for ECHO BLASTER 128)

The multicolor LED on the front panel indicates system status:

- RED – probe not connected or probe drivers not installed;
- YELLOW – FREEZE mode;
- GREEN – scanning mode (acquisition).

5. INSTALLATION WARNINGS

- Ultrasound scanner should be installed in the premises specifically intended such as an ultrasound scanner lab, which area no less than 10 m2, with window coverings to provide some diffused illumination.
- Power supply wires and other accessories used with the device should be delivered by producer or be the same type as in specification.
- For proper work and excellent effects use set completed and recommended by producer.
- Do not connect too many electrical devices to the same power net. It may cause problems with proper work or even make failure of the device.
- Device connected to power net is still supplied even if switched off.
- Any changes made in ultrasound scanner made by user are prohibited and cause loss of guarantee.
- Always disconnect the scanner from power supply if notice:
    - Failure of power supply cable
    - Device was dropped
    - Work is not correct
    - Strange noises or smoke from the cover.
- Damage of the scanner made by wrong use cause loss of guarantee.
- Keep device from temperature shock.
- When you will move the scanner from cold to warm place, please wait 0,5 to 1 hour before switch on. It is necessary because of water condensation at electronic parts.
- Do not use the scanner close to moisture source or in place with high moisture.
- Do not use compressed air or vacuum to clean the device.
- Do not drop, hit or shake.
- Take care when work with ultrasound probe. Probes should be clean after work from gel and other deposits. Do not use any aggressive chemicals. To increase life time of probes, always leave them after work with freeze acquisition.
- Probes changing can be done only at FREEZE mode or POWER OFF.
- Ultrasonic waves have a low transmittivity in air and gas within the living body. If air is present between the probe and the skin, examination may be impossible.
    - Therefore, it is necessary to apply an acoustic coupler (special gel, olive oil, liquid paraffin, etc.) so that the probe adheres closely to the skin.
    - It is also impossible to examine regions of the body which contain gas or air, such as the lungs.
- The quality of an ultrasound diagnosis depends on where the scan cut is set.
    - Before starting an examination, carefully consider where to set the cut to be scanned by the probe so that the region to be examined could be precisely localized by ultrasound.
- If you have any questions or suggestions about diagnostic system using please contact TELEMED Company.

NOTES:
The term „Acquisition" is understood here as the image forming process whereby a picture is displayed on monitor screen as a result of emitting the ultrasound wave and receiving echoes by the transducer in the ultrasound probe. Both the transducer and the probe are activated during the acquisition process.
The term FREEZE is understood as the stoppage of the acquisition. The button FREEZE turns the ultrasound probe and the transducer circuit.

6. SYSTEM SETUP

6.1. System Requirements and Windows configuring

IMPORTANT NOTE:
This description and screenshots based on Windows XP Service Pack 2. Dialog windows of Windows Vista can differ, but generally software installation is same.

6.1.1. Hardware

We recommend such PC configuration:

- IBM PC compatible Desktop/Notebook/Tablet PC
- CPU Core Duo / Core 2 Duo 1.6 GHz or better
- 512 Mb DDR RAM or better
- Intel chipset based motherboard with integrated USB 2.0 controller: i845, i855, i865, i875 and newest.
- The TCO'92 '95 '99 certificated SVGA monitor with 1024x768 resolution or better
- Certificated for medical use computer's power supply
- 50 MB free hard disk space
- display adapter with 8 MB video memory or more

6.1.2. Software

- Windows XP installed with latest Service Pack 2 or Windows Vista with Service Pack 1
- Installed Microsoft .NET Framework 2.0 Redistributable Package or .NET Framework 3.0 Redistributable Package (for Windows XP only)

6.1.3. Windows XP / Windows Vista configuring

Configure e-mail program (Outlook Express for example). It is necessary for normal operation of direct e-mail sending feature of ultrasound software.

Note: No need to configure e-mail software if you are not planning to use it or your computer is not connected to Internet.

6.2. Ultrasound Hardware installation / connection

Read the User Guide manual information before start:

- SAFETY
- OPERATIONAL ENVIRONMENT
- INSTALLATION WARNINGS

Configure the computer according to the requirements. Always connect power cable's female part to the power connector and the male part to the hospital grade power socket of a proper voltage.

6.2.1. Assembling and connecting **ECHO BLASTER 128 INT-1Z KIT**

NOTE:
Assembling and connection for Echo Blaster 128 INT-2Z Kit is the same except 3 free drive bays needed.

Described below hardware installation steps are based on typical computer desktop case. Cases, available on the market, can differ. Before installing the hardware learn the manual of concrete case intended for use.

- Turn off the computer and unplug its power cable;
- Disconnect all the external cables/devices;

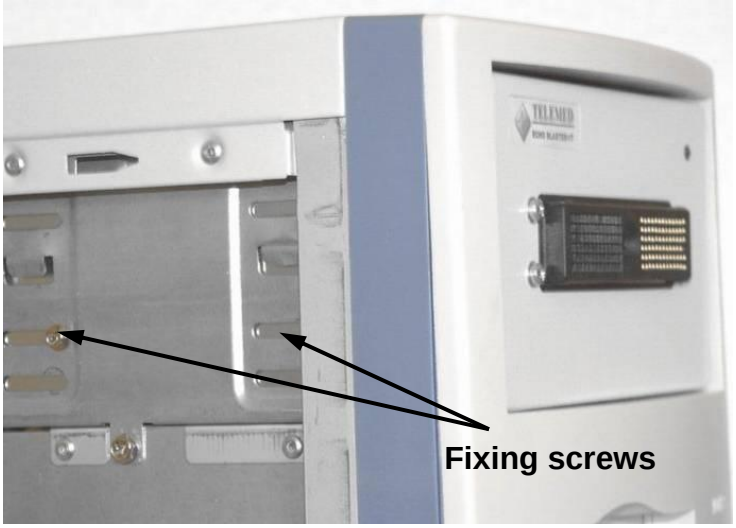
- Remove the computer's cover according to the computer manual directions;

- Remove stubs from the computer case front panel;
- Insert the beamformer module to the drive bays (do not insert it completely before connecting all the cables to it).

- If supporting holders are between the bays, unbend it to insert the beamformer.

- Connect the computer power supply connector to beamformer power connector;
- Connect USB cable between PC and beamformer using one of these:
  - internal USB cable if motherboard is featuring High-Speed USB 2.0 and has internal USB on-board connector (refer the motherboard manual);
  - standard USB cable if motherboard is featuring USB 2.0 and has only external port (through any matching opening);
  - standard USB cable if PCI to USB 2.0 Adapter is inserted (using internal port).

- Insert the beamformer completely and fix it (both sides);



- Temporary disconnect USB cable from beamformer to USB port (necessary for proper drivers installation);
- Connect the power cable, monitor and other external devices / accessories;

- DO NOT turn on the power. Follow software installation instructions according to chapter 6.3. Software installation for Windows XP / Windows Vista.

6.2.2. Assembling and connecting **ECHO BLASTER 128(64) EXT-1Z(T) KIT**

- Connect external power supply to the power socket (rear panel).
- DO NOT insert USB cable to the beamformer and PC ports.
- DO NOT connect the ultrasound probe to the beamformer connector.
- Start the software installation according to chapter 6.3. Software installation for Windows XP/Vista.

NOTE :
Beamformer is powered partially from PC via the USB and draws approx. 250 mA. If you need to use a USB Hub to share the USB connection with other devices it is important to ensure that you use a self-powered Hub that can supply power to its connected devices. The device may not function if connected to a passive or bus powered USB Hub.

6.3. Software installation for Windows XP/Vista

Ultrasound scanners software consists of 2 packages:

- TELEMED Drivers Package
- Echo Wave

First at all it is necessary to install TELEMED Drivers Package package. This package contains USB drivers for beamformer and ultrasound probes.

At second it is necessary to install Echo Wave II software package. It is graphical user interface.

The installation process of TELEMED Drivers Package and Echo Wave II described below.

IMPORTANT:

DO NOT insert USB cable to beamformer (for all systems).

To install ultrasound software package You must be logged on as an Administrator or a member of the Administrators group.

Uninstall previous version of ultrasound software if it is present. Close all application programs running on PC.

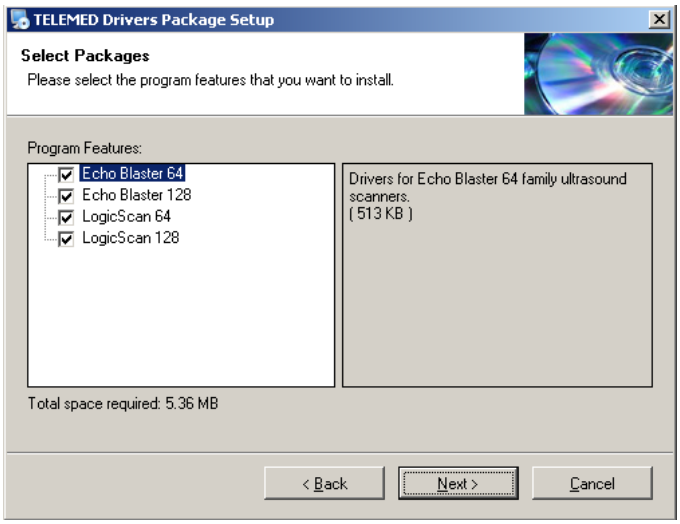
6.3.1. TELEMED Drivers Package installation

- Turn computer on;
- Be sure that USB cable disconnected from beamformer
- Insert in to CD-ROM drive supplied with system compact disc;
- You will see autorun window as shown at the right side;
- Click on INSTALL SOFTWARE button;

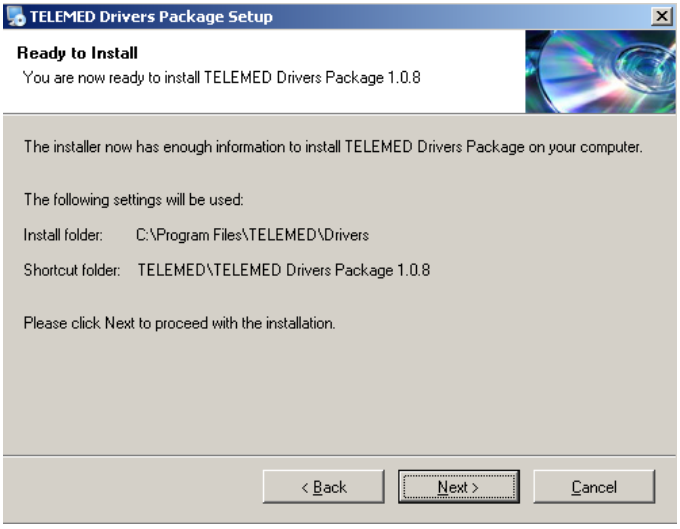
- Click on the TELEMED Drivers Package menu item;

- Welcome screen will appears;
- Click Next.

- Choose necessary system (Echo Blaster 64, Echo Blaster 128, LogicScan 64 or LogicScan 128);
- Click Next



- Install drivers window;
- Click Next



- Finalize drivers installation
- Click Finish

- Connect USB cable to beamformer.
- Windows operating system will find new device, let Windows to find drivers automatically.

Note:

If pop-up message will appear (stating the driver is not digitally signed by Microsoft). You will need to acknowledge this message (by clicking Continue Anyway / Allow, not Cancel) to proceed with driver installation.

Information for advanced users. After installation drivers are stored in the

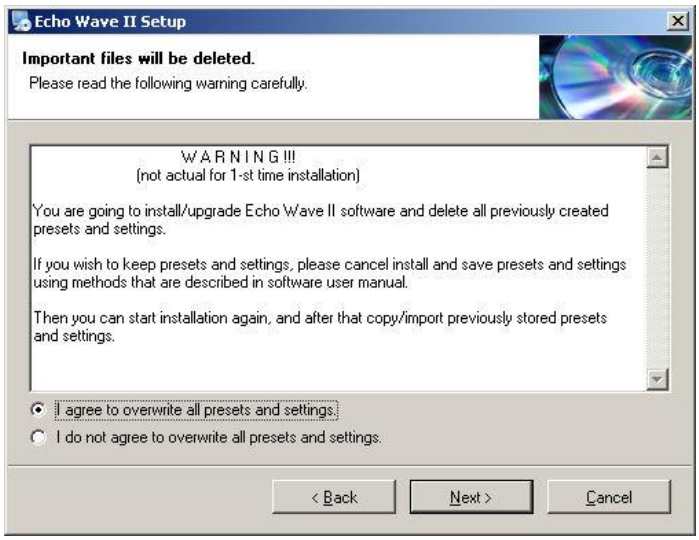
C:\Program Files\TELEMED\Drivers folder.

6.3.2. ECHO WAVE II software installation

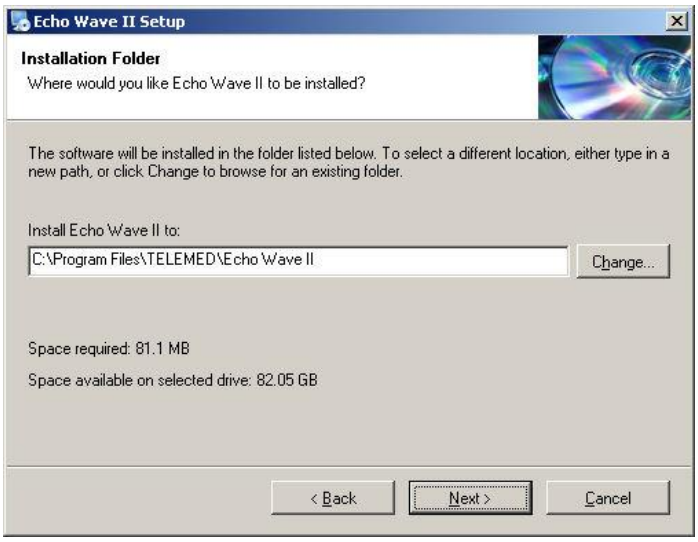
- Click on Echo Wave II software menu item;

- Welcome screen will appears;
- Click Next to continue;

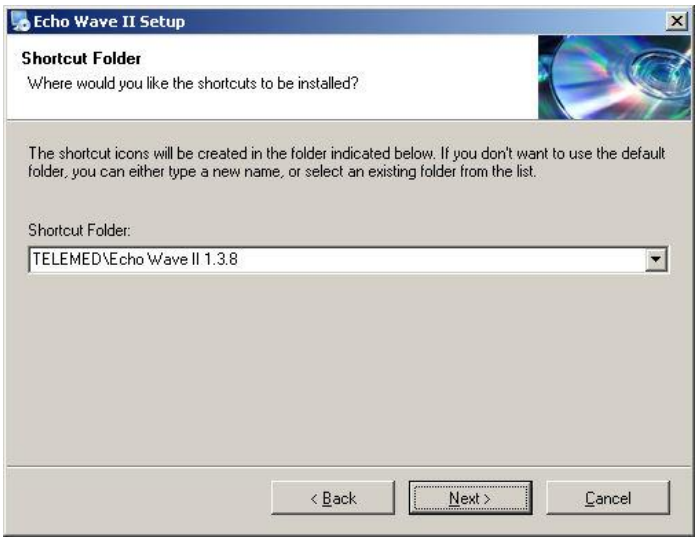
- Warning screen will appears. This screen remind you that all settings and presets will be overwritten;
- If you want to save settings and presets before installation, click Cancel and using internal tools of Echo Wave II export them to file;
- For 1-st (clean) installation do not pay attention to this screen, choose I agree… and click Next;



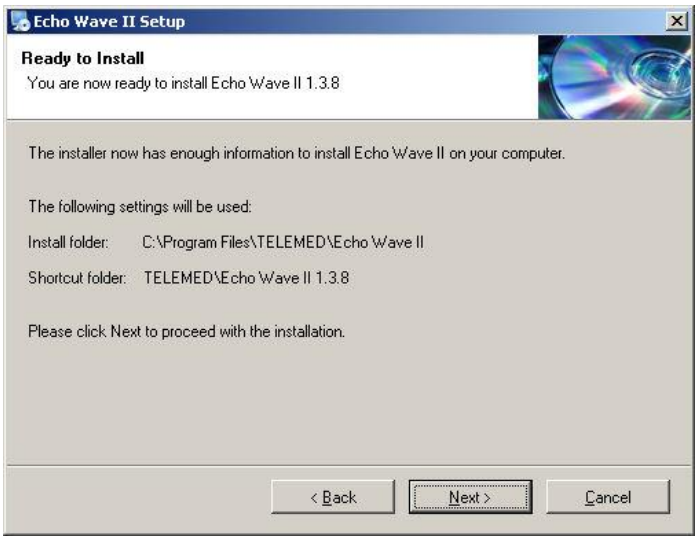
- Window with default installation folder will appears;
- Click Next;

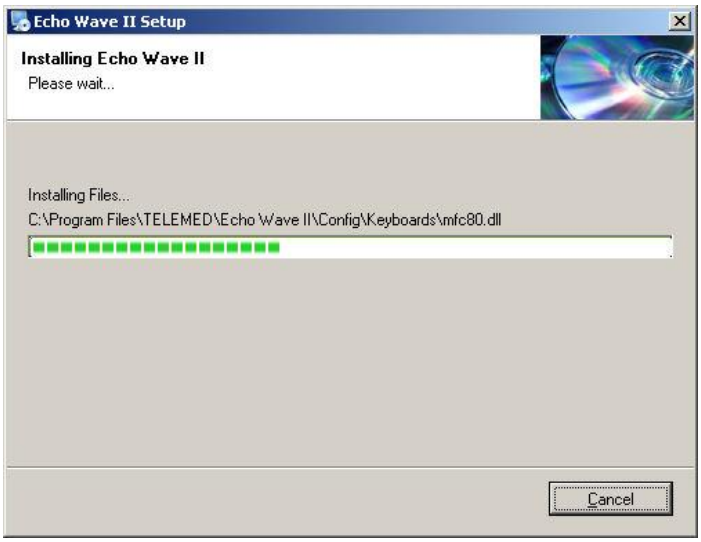


- Window with default shortcut folder will appears;
- Click Next;



- Software is ready to be installed;
- Click Next;





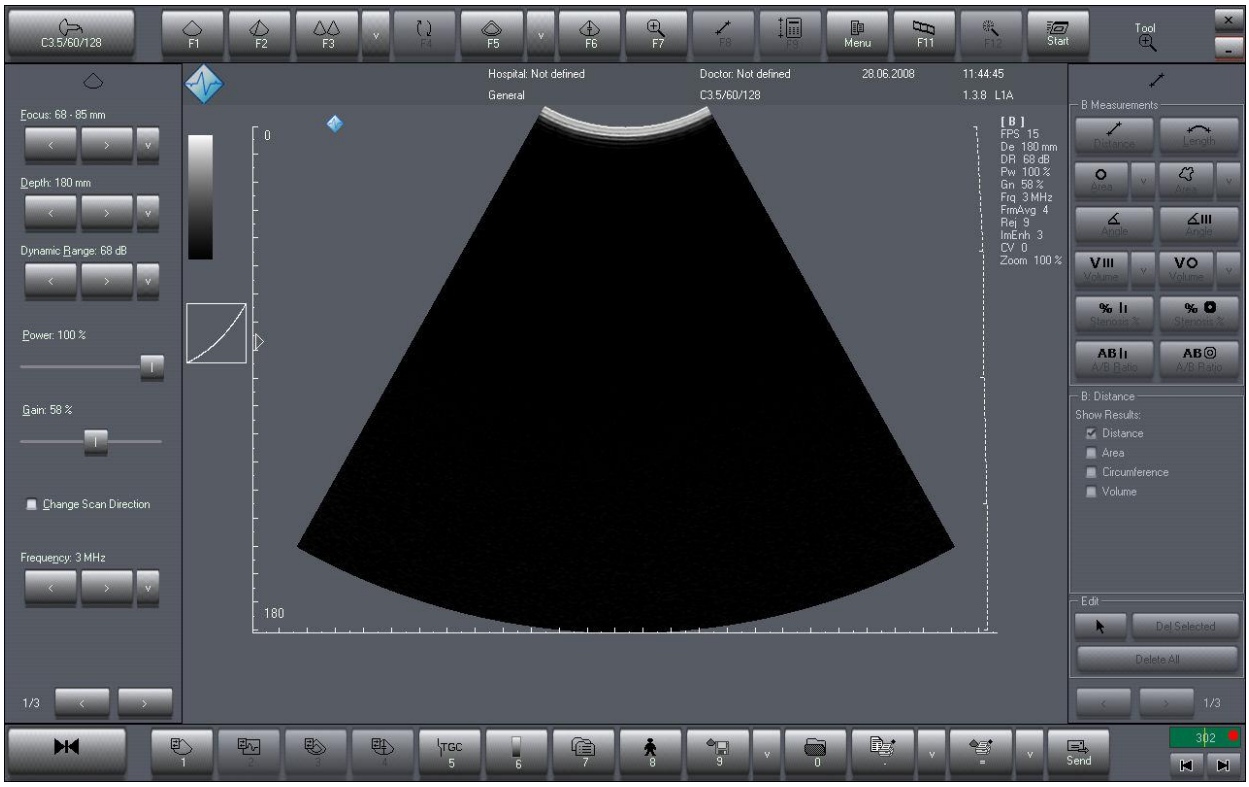
- Installation in progress;
- Please wait;

- Installation is finished;
- Click Finish;

NOTE:

Echo Wave II require to be installed Microsoft .NET Framework 2.0 (for Windows XP only).
If your operating system Windows Vista, no need to install it.

- The Echo Wave II icon will appear at the desktop after installation;
- Connect the power cable and the probe;
- Double click on Echo Wave II icon, please wait a while, you will see images like shown below…



NOTE:

Do not unplug power cable during scan mode. You can damage scanner. Exit from software and only after that unplug power cable.

Do not unplug USB cable during scan mode. You can damage scanner. Exit from software and only after that unplug USB cable.

6.3.3. Ultrasound Scanner Monitor utillity

Ultrasound Scanner Monitor utility is used for system status monitoring. Also this utility helps to see when and how Echo Blaster 128(64) beamformer is connected to computer.

- Utility icon  is located in Tray Bar

- When the icon is lightened RED - drivers for Echo Blaster 128(64) beamformer are not installed properly or beamformer is not connected to USB port or power is not connected to beamformer.

- When the icon is lightened GREEN - drivers for Echo Blaster 128(64) beamformer are installed properly, beamformer is connected to USB port, power is connected to beamformer and system is ready for start

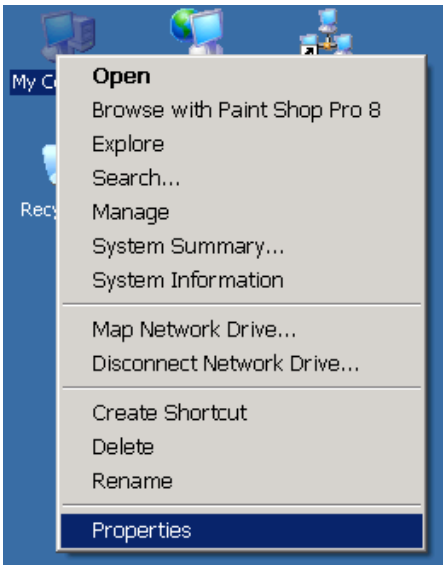
7. TROUBLESHOOTING

Read this chapter carefully before you will call Tech Support service.

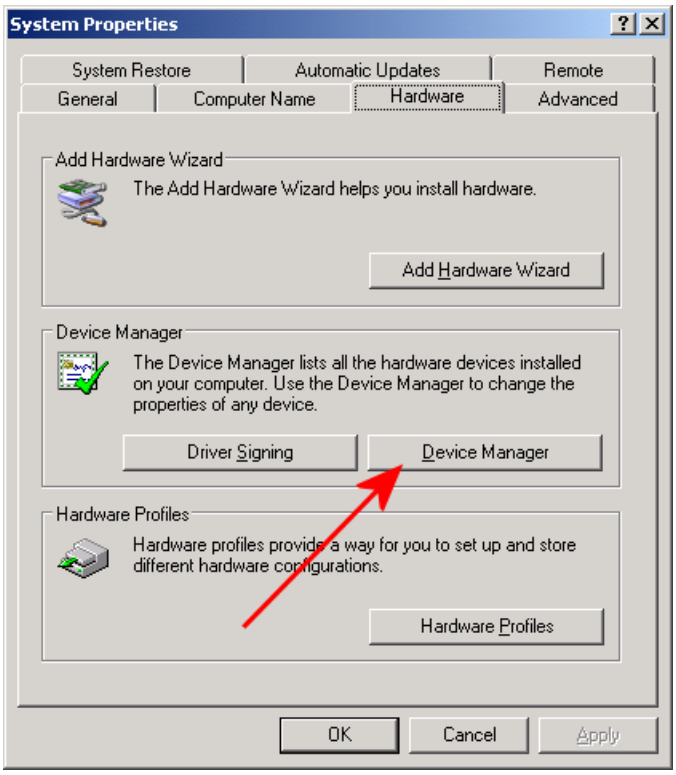
7.1. TELEMED Drivers installation checking

Sometimes during Windows or **Echo Blaster 64/128** canners/probes installation needs to check driver's installation using Device Manager utility. Process of Device Manager utility checking described below:

- Find on the desktop My Computer icon

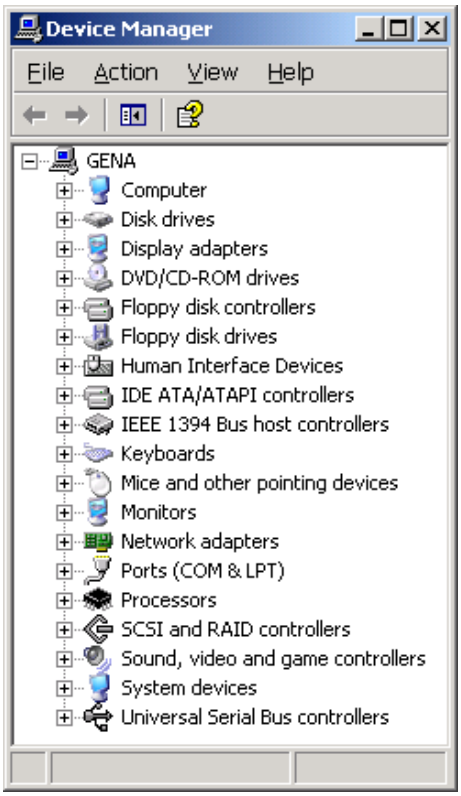


- Click on My Computer icon by right mouse button
- Drop-down menu appears
- Select Properties menu item



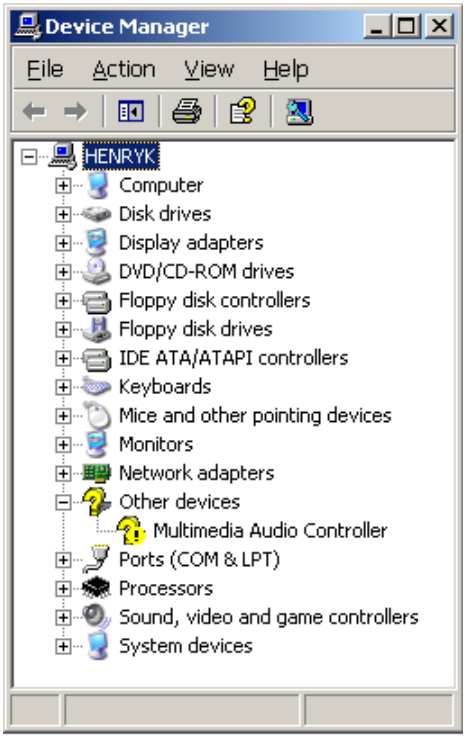
- System Properties window appears
- Select Hardware tab
- Press Device Manager button

- Device Manager window will appear

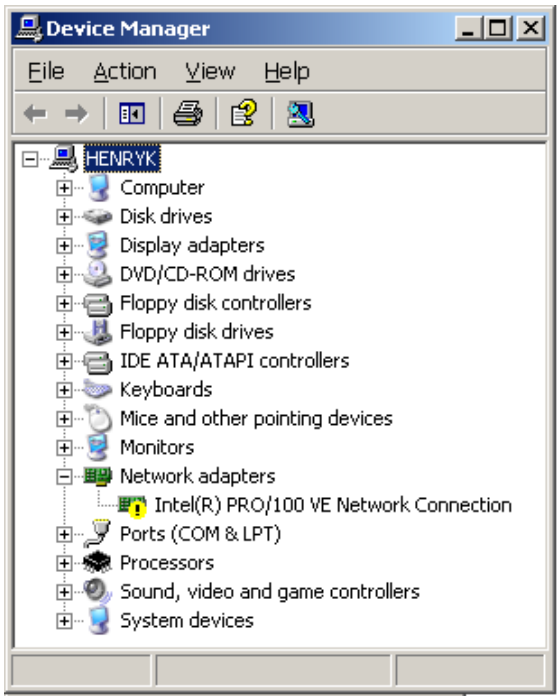


Note. It is only example. In your computer the set of hardware can differ

- If in the Device Manager window under ? symbol (unknown device) you see not installed device, it must be installed completely

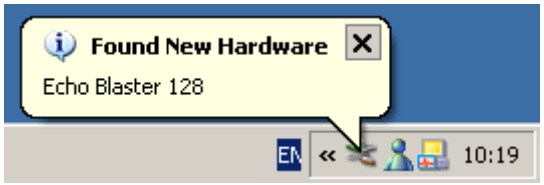


- If in the Device Manager you see device with attached ! symbol, it means resource conflicts in your computer

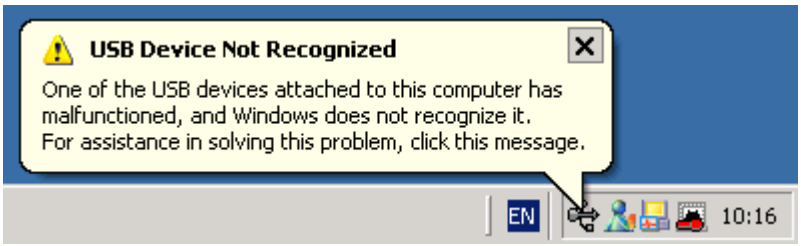


7.2. FAQ

Q. Connecting beamformer to USB port, instead typical success message Found New Hardware

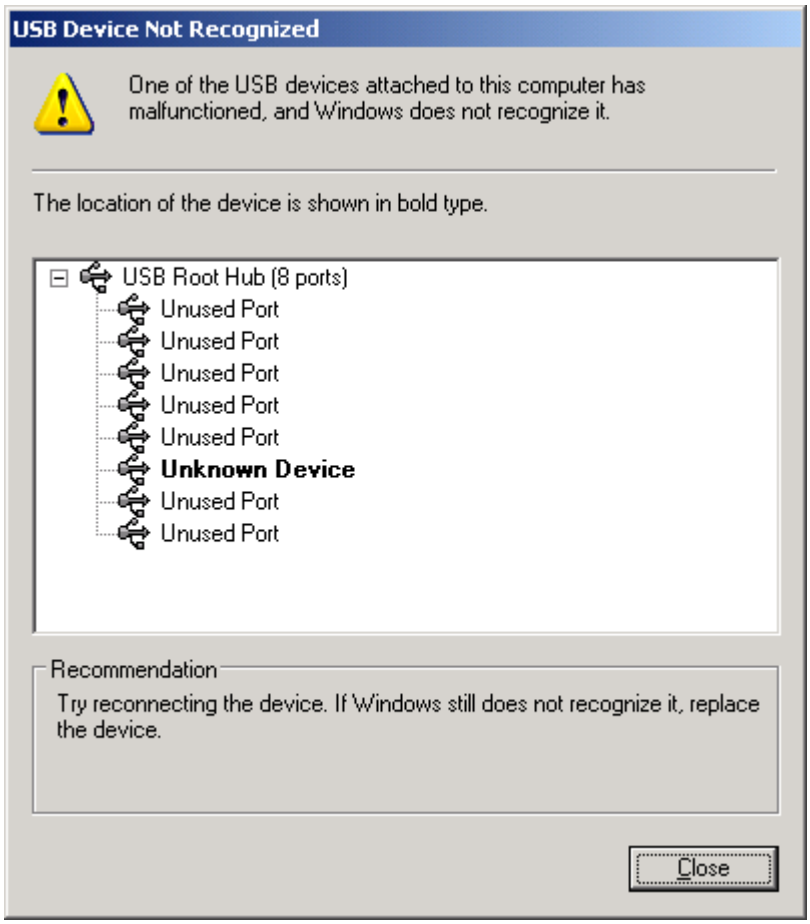


I see warning message USB Device Not Recognized



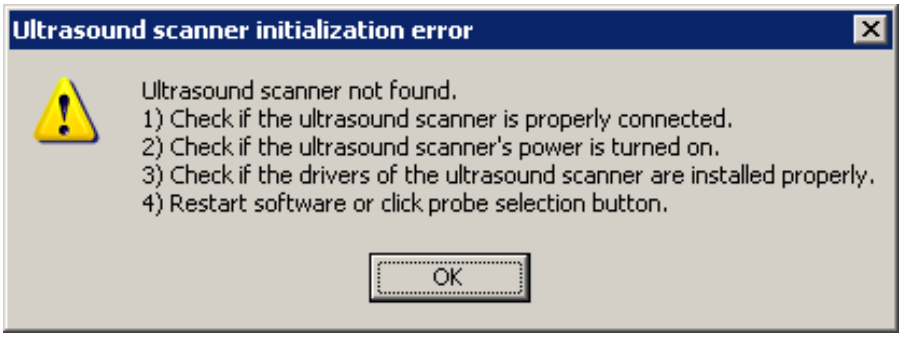
I see window named USB Device Not Recognized

How to solve this problem?



A. At the rear/front panel of computer several USB port connectors are located. Connect beamformer to another USB port.

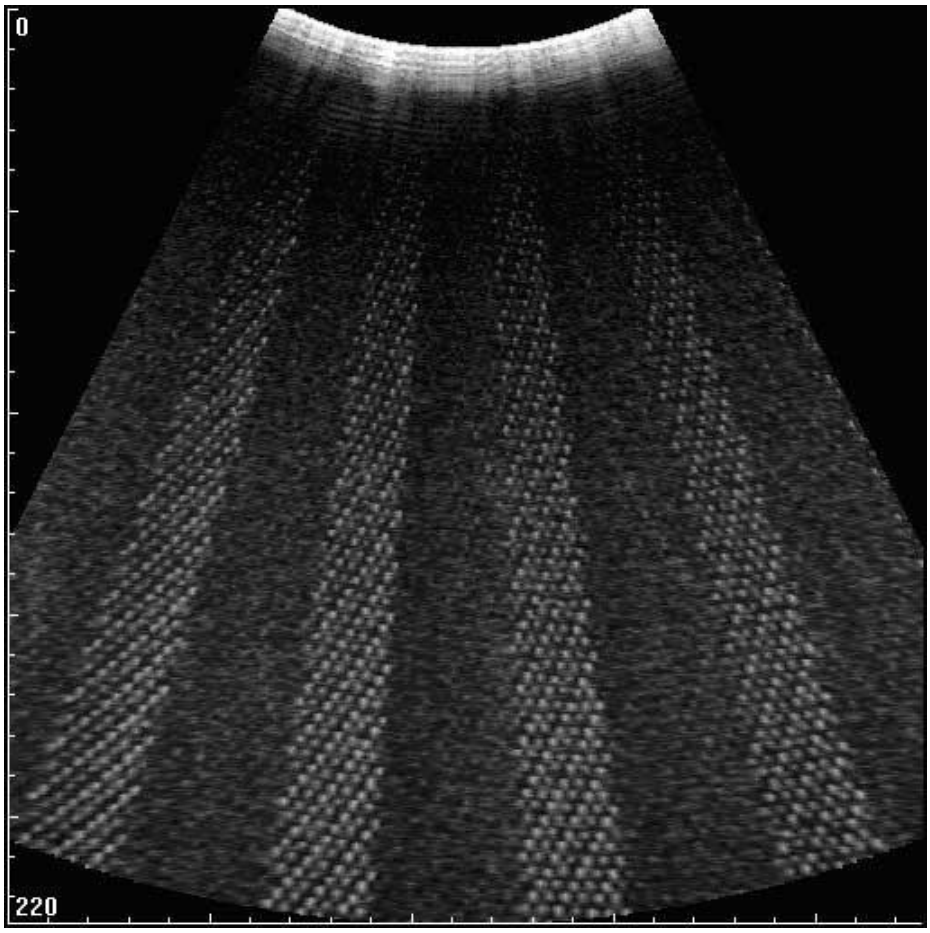
Q. Trying to run Echo Wave II software the error message (see picture below) appears. What does it mean?



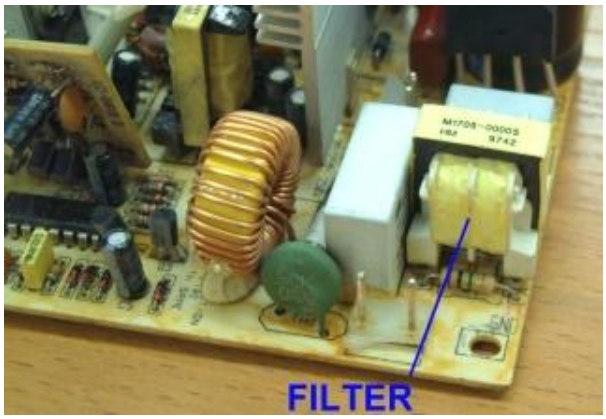
A. The reasons of this message can be:

- The USB cable is not connected between beamformer and computer's USB port. Check proper connection of this cable.
- The beamformer drivers are not installed properly, for example see chapter 7.1.TELEMED Drivers installation checking. Install/update beamformer drivers.

Q. An increased level of noises and interferences is observed on ultrasound image, as shown at picture below. What I need to do for noise decreasing?



A. The reason of this appearance can be a non-conforming computer power supply unit. The main problem of such cheap power supplies is not mounted power filter components to reduce the electromagnetic noises level.



Mounted filter components

Not mounted filter components. Power supply manufacturer save on several dollars.

Ask your computer manufacturer/retailer to change non-conforming power supply to another one certificated and labeled by **CE, TUV, UL, CSA, CB, VDE, FCC, FTZ** etc.

Also be sure that your computer monitor is conforming to TCO'92, TCO'95 or TCO'99 electromagnetic radiation standards (see the label on the monitor).

Q. Trying to run software computer hangs or starts to reboot during startup. What is wrong?

A. The main reason of this problem is that computer power supply is weak and not able to hold peak currents during system start-up. It is main problem of cheap power supplies: instead

declared 200 or 300 Wt real power is 100 or 150 Wt. Ask your computer manufacturer/retailer to change non-conforming power supply to another one.

This situation is actual only for **LogicScan 128 INT-1Z/2Z (**internal variants powered from PC).

Q. Instead of declared high frame rate up to 30-120 fps, in the frame rate indicator I see low value 4-5 fps. What is wrong?

A. The main reasons of such low frame rate are:

- Computer hardware doesn't meet the requirements. Instead of High-Speed USB 2.0 interface the ultrasound system was connected to Low-Speed USB 1.1. You need to update computer hardware;
- Not installed Service Pack 2 for Windows XP;
- Your USB 2.0 controller isn't configured properly, for example USB 2.0 drivers are not installed and controller works in USB 1.1 mode.

Q. Instead of declared high frame rate up to 30-120 fps in the frame rate indicator I see low value 7-10 fps. What is wrong?

A. The main reasons of such low frame rate are:

- CPU speed of your computer is too slow, see chapter 6.1. System Requirements and Windows configuring;
- Power Saving feature of your computer is not disabled, for example Power Saving on your Notebook computer is turned on and as result CPU works 2 times slower;
- Service Pack 2 for Windows XP is not installed, Service Pack 1 for Windows Vista not installed

Q. Program Echo Wave II doesn't start, error messages not appear.

A. Computer operating system doesn't meet the requirements. For example installed Windows 2000.

Q. Instead of declared high frame rate up to 30-120 fps in the frame rate indicator I see 0 fps value. Sometimes computer hangs. What is wrong?

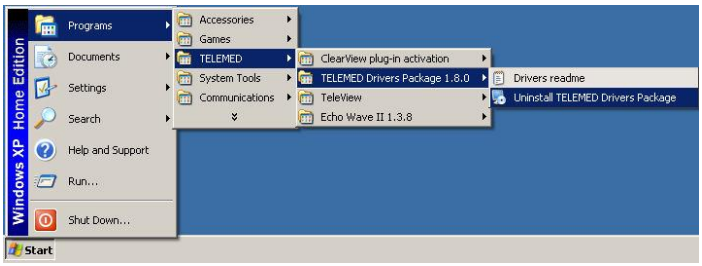
A. The main reasons of such low frame rate are:

- Service Pack 2 for Windows XP is not installed, Service Pack 1 for Windows Vista not installed;
- Instead Windows XP/Vista installed Windows 2000.

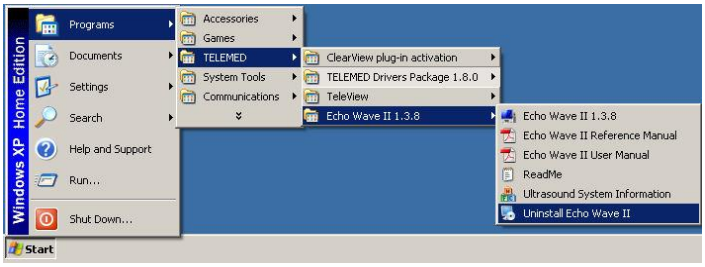
Q. How to reinstall or update software?

A. You must uninstall previous installed software: TELEMED Drivers Package and Echo Wave II software. Do the next:

- Disconnect USB cable from beamformer;
- Go to the TELEMED Drivers Package icon group;
- Click on Uninstall TELEMED Drivers Package icon;
- Follow the uninstall instructions;



- Go to the Echo Wave II icon group and click on Uninstall Echo Wave II icon;
- Follow the uninstall instructions;



- Download (if need) latest TELEMED Drivers Package or Echo Wave II software from http://www.telemed.lt Internet site;
- Install TELEMED Drivers Package and Echo Wave II software as described above;
- Connect USB cable and follow the Windows installation instructions as described above.

Q. I see dark echo-image and low penetration (weak visualization at the depth more than 3 cm). What is wrong?

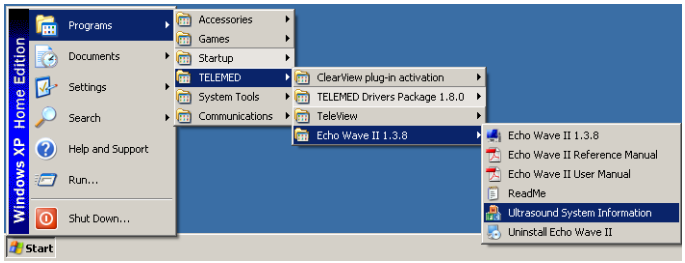
A. The main reasons of such low penetration are:

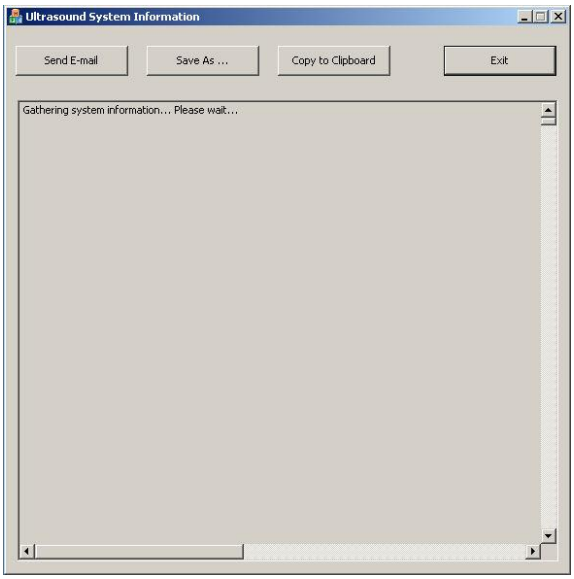
- Working surface of transducer is dirty. Necessary to clean transducer surface. See corresponding chapter in this manual;
- No ultrasound gel on the transducer. Apply an adequate amount of gel or water to the scan surface;
- Very low gain. Incorrect Echo Wave II software controls settings. Set image controls to Default settings.

7.3. Contact with technical support service

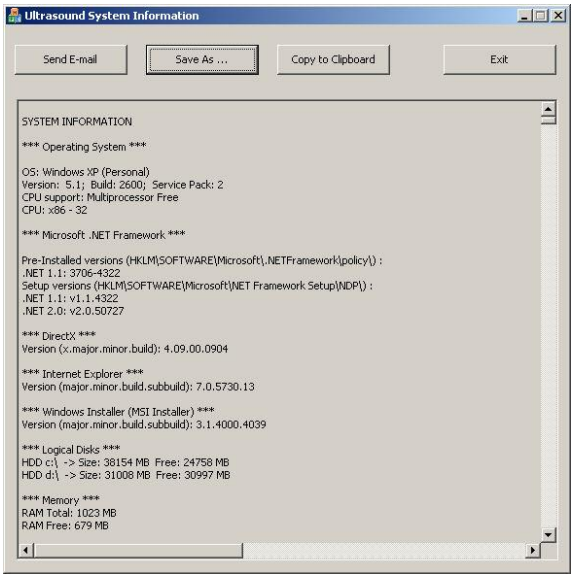
If problems during installation or operation remains and you can't solve it by yourself, use support@telemed.lt e-mail address. First at all send to technical support service such information:

- Scanner type (for example: **Echo Blaster 128 INT-1Z Kit**);
- Serial number of the scanner (for example: 2351-050428-9686);
- Probe type (for example: HL9.0/40/128Z);
- Serial number of the probe (for example: 3241-050504-9701);
- TELEMED Drivers Package version (for example: TELEMED Drivers Package 1.8.0);
- Echo Wave II software version (for example: Echo Wave II 1.3.8);
- Detailed description of the problem (for example: drivers and software installed correctly, system works but I see very weak echo-signal);
- Attached example of the bad image if need (scanner settings must be in default settings, see Operation Manual for details).
- Attached Log file generated by Ultrasound System Information utility:
  - Run Ultrasound System Information software as shown;





- Wait a while, utility will collect all necessary information about ultrasound device and installed ultrasound software;



- After technical details will appear in this window, please send this information to support@telemed.lt e-mail address;
- You can send this information using Send E-mail, Save As…, or Copy to Clipboard buttons;
- This Log contains a lot of important information about your computer and its configuration. This file can help to TELEMED qualified specialists offer the optimal configuration and best solution for problem fixing.

After technical support service will receive this information, during short time you must receive recommendations about steps to solve problem.

8. WARRANTY AND SERVICE INFORMATION

8.1. Warranty

TELEMED warrants the diagnostic system to be free from defects in material and workmanship at the original purchaser's location for 24 months (exception: the probe is warranted for 12 months). This warranty covers parts for the full 24 months (or 12 months, respectively) and labor for 90 days. In order to comply with this warranty, all service must be performed by a TELEMED qualified field engineer or with the express permission of TELEMED. Items excluded from this warranty are misuse, negligence or accidental damage. TELEMED points out that data loss is not warranted.

The foregoing warranty is exclusive and in lieu of all other warranties and representations, expressed or implied including but not limited to any warranty of merchantability or fitness for any particular trade usage. This warranty is also in lieu of any other obligation, liability, right or claim, whether in contract or in tort, including any right arising from negligence on the part of TELEMED for any direct, incidental, consequential or other damage.

8.2. Warranty Shipments, Returns and Adjustments

- A warranty claim must be made promptly and must be received during the applicable warranty period by TELEMED.
- If it becomes necessary to return a product for repair and/or adjustment, prior authorization from TELEMED must be obtained. Instructions as to how and where these products should be shipped will be provided by TELEMED.
- Any product or component returned for examination and/or warranty repair shall be sent insured prepaid via the means of transportation specified by TELEMED. Shipping charges for all products or components replaced or repaired under warranty should be defined separately.
- In all cases, TELEMED has sole responsibility for determining the cause and nature of failure, and TELEMED's determination with regard thereto shall be final.

8.3. Service Contract

A service contract may be obtained for the TELEMED may be after the warranty period has expired. The contract provides for any service calls that may be necessary to keep the system operational and will include at least one regularly scheduled service visit per year. As part of the scheduled maintenance the service representative will do a complete inspection and test / calibration of the system.

To providing our customers with the best possible support send your comments and suggestions to support@telemed.lt

9. MAINTENANCE

Performance and Safety Checks see in the table below:

Recommended Maintenance	Frequency
General cleaning	As Need
Inspect the system, cables and probes	Before Use/Daily
System accuracy and performance verification	Annually

9.1. General cleaning

The LCD/CRT screen and all external surfaces may be cleaned with a soft cloth dampened with a neutral detergent. Do not use solutions with chlorine, ammonia, fluoro-carbons or hydro-carbons. Do not use abrasive cleaners or high fiber wipes that may scratch the surface.

NOTE:
Before cleaning the unit, ensure the unit is off and the mains power cable is disconnected.

9.2. Inspecting the System

Examine the exterior for cleanliness and general physical condition. Ensure the housing is intact, hardware is present and secure, and labeling is legible.

Check the cables (especially power cable). If there is any peeling or cracking of the outside insulation, carefully disconnect the cable and replace it with a new one.

9.3. Probe maintenance and disinfection

All transducers are supplied non-sterile.
Transducers in Endocavity Procedures should normally be used with a sterile sheath.
Transvaginal probes may be used with a surgically clean sheath.

The following disinfectants have been tested with your transducers.

Use of any other disinfectants can void system warranty and service contract.

The following disinfectants for soaking or wiping are recommended:

High level Disinfectants	Low level Disinfectants
• Cidex plus™ • Wavicide® -01 • Omnicide™– FG2	• Sani-Cloth • T-spray

NOTE:
Among above disinfectants, High level disinfectants can be applied to Endocavity probe, however Low level disinfectants are not appropriate for disinfects of Endocavity probe.
CAUTION : Customer must follow the disinfectant manufacturer's instructions carefully.

9.3.1 Chemicals that Damage Transducers:

Some of these chemicals, such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide, are commonly found in clinic or hospital settings; others are found in

antibacterial skin cleaners or lotions. Use of these chemicals will cause damage to a transducer.

This damage is not covered by the warranty or service contract.

9.3.2 Recommended Procedures for Probe Processing

Inspect probe cable, connector and lens surface. Contacts on the probe connector must be without bends. The surface of probe lens must be clean without scraps and bladders. Check for any crack which will allow liquid to enter the probe (especially joints such as cable/connector and cable/probe). If any such damage is found do not use the probe till replaced.

Use care to avoid getting solution in the probe connector. Wrap the connector in the plastic bag to avoid liquid contact with the connector.

Use an EPA registered germicide intended for use on plastic medical instruments (2% Glutaraldehyde type solutions without surfactants are recommended). Follow the germicide manufacturer's instructions regarding concentration, time of contact, storage and disposal.

Do not use alcohol or alcohol based solutions. Thoroughly rinse all residues from the probe with sterile distilled water after removal from the germicide. Do not wipe the strain relief/housing joint, the strain relief, or the cable with isopropyl alcohol. Isopropyl alcohol can cause damage to these parts of the transducer. This and any mechanical damage is not covered by the warranty or your service contract.

9.3.3 General Cleansing for Transducers Used in Non-Invasive Procedures

These general cleaning instructions are indicated for non-critical category transducers.

All transducers which do not contact mucus membranes, blood, compromised tissue, and are not used in sterile fields can be cleaned by using these instructions. It is important that customer cleans the transducer and cable according to the following procedures :

1. After every patient exam, wiping the ultrasound transmission gel off the transducer.
2. Wiping the transducer and cable with a dry or water-moistened soft cloth.
3. Wiping the transducer with either :

• A recommended disinfectant
• Enzol (Cidezyme)
• Metrizyme
• Klenzyme

4. Also is possible to wipe the cable with T-spray, a low-level disinfectant for the cleaning of external transducers only. Not allowed to use isopropyl alcohol on the cable and strain relief/housing joint.

9.3.4 Cleansing and Disinfection of Transducers Used in Endocavity Procedures

It is highly recommended to use Transducer's Sheath for Endocavity and Invasive uses.

The transducer disinfection should be done prior to the first exam, and after every exam thereafter.

The disinfectant procedure includes the following steps:

1. Unplugging the transducer from the system.
2 .Washing the transducer head and cable with soap and water to remove any protein buildup; however the transducer must not be rinsed or immersed near the strain relief.
3. Disinfection the transducer and the cable with one of the disinfectants listed as Legally Marketed. During the disinfection it is necessary:

• To avoid transducer contact with strong solvents such as acetone, freon, and other industrial cleansers.
• To do not soak the transducer for extended periods of time, such as overnight.
• To do not rinse or immerse near the strain relief.

4. Removing the transducer from the disinfectant and thoroughly rinsing with sterile water.
5. Checking the transducer for any residual organic material. If any is present, disinfection of the transducer should be done again.

9.4. System accuracy and performance verification

System accuracy and performance verification should be conduced annually or if doubt exists about image quality or distance estimation.

Use tissue mimicking phantoms for evaluation of accuracy and performance of the system. Refer to Manual supplied with the phantom for detailed description of accuracy and performance verification.

During the performance assessment or tests (using phantoms etc) the probe lens may be short-time immersed in water or other special liquid.

NOTE:
The System was designed for sound velocity in tissue 1540 м/sec. For accuracy verification need to use phantoms which was calibrated for this sound velocity.

10. TRANSPORTATION, STORAGE AND UTILIZATION

10.1. Transportation and storage

Ultrasound scanner should be stored and moved according to the package technical documentation and the standard procedures.

10.2. Utilization

Utilization/recycling of this equipment should be made by specialized company and be according to the local law.

11. DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

CE 0482

We, **TELEMED UAB**

Dariaus ir Gireno str. 42, Vilnius, LT-02189 Lithuania

Declare under our sole responsibility that:

Equipment ***Ultrasound scanners***

Model names ***Echo Blaster 64 EXT-1T***
Echo Blaster 128 INT-1Z
Echo Blaster 128 INT-2Z
Echo Blaster 128 EXT-1Z
Echo Blaster 128 PC-1Z Portable
Echo Blaster 128 PC-2Z Portable

Classification **Class IIa** (in compliance with Annex II, Art.11 Medical Device Directive)

are in conformity with:

Essential Requirements of Council directive **93/42/EEC**

(Medical Device Directive)

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60601-2-37

The compliance with the Council Directive 93/42/EEC is under the monitoring of the Notified Body:

MEDCERT GmbH Karpfanger Straße 14 D- 20459 Hamburg, code: 0482

Date July 19, 2006

Dmitry Novikov, president

12. APPENDICES

12.1. Guidelines for the safe use of diagnostic ultrasound

A. Recommendations

General

- The use of diagnostic ultrasound to obtain information about function or structure in human beings should be restricted to situations in which the medical benefit that may accrue from the diagnostic data outweighs any foreseeable risk. Most such situations are limited to clinical examinations of the ill or potentially ill patient, or pregnant women.
- Situations of training, demonstration or research may also provide a medical benefit from diagnostic data that outweighs any foreseeable risk. Here, information is obtained for people, who are not necessarily in the categories of Recommendation (1), above. In all situations of training, demonstration or research, if either of the Thermal Index or Mechanical Index will be greater than 1, then a subject should be informed of the anticipated exposure condition and how it compares in safety with conditions for normal diagnostic practice.
- Ultrasound should not be used for any of the following:
    - to have a picture of the fetus, solely for *non-medical* reasons;
    - to learn the sex of the fetus solely for *non-medical* reasons;
    - for commercial purposes, such as trade shows, or producing pictures or videos of the fetus.

Thermal Effects

- M-mode is valuable clinical tool and, despite potential risks, is not contraindicated. However operators should be careful to limit exposure to critical structures and utilize the exposure information provided by the manufacturer.
- In particular, users should employ exposures which are **As Low As Reasonably Achievable (ALARA)**[1] because of the potential for **ultrasonic heating** of tissue during M-mode imaging and, normally to a significantly greater extent, Doppler ultrasound blood flow examinations. Exposure can be reduced by either reducing the **Thermal Index** using output controls or by reducing the **dwell time**, the amount of time that the transducer remains in one place.

Mechanical Effects

- Users should employ exposures, in any relevant mode, which are **As Low As Reasonably Achievable (ALARA)** because of the potential for:
    - ultrasonically induced capillary hemorrhaging in lung if it is exposed during pediatric diagnostic ultrasound examinations, particularly for infants and neonates, especially if they are pre-term;
    - ultrasonically induced capillary hemorrhaging of the intestine where intestinal peristalsis is inhibited or conditions promote intraluminal or submucosal gas collections;
    - ultrasonically induced capillary hemorrhaging in other soft tissues when Gas Contrast Agents are used.

- Use of Gas Contrast Agents in a diagnostic ultrasound examination is not recommended within 24 hours before extracorporeal shock wave lithotripsy.

- Exposure can be reduced by lowering the **Mechanical Index** using output controls. Reducing the **dwell time** is of use if threshold pressures are exceeded.

Quality Assurance

It is recommended that equipment operators implement quality assurance measures to maintain the capability of obtaining reliable diagnostic information at acoustic exposures which are **As Low As Reasonably Achievable**.

As the quality of diagnostic information depends, in part, on operator training, it is also recommended that sonographers (ultrasound technologists) be appropriately qualified and registered in regional organizations of ultrasound professionals.

B. Conclusions

General

- Although there are many exposure conditions for which the risk of injury during a diagnostic ultrasound examination is negligible, this is not the case for every possible exposure condition using currently available equipment. Therefore, the persons responsible for the ultrasonic exposure must ensure that the exposure is justified, i.e., that reliable diagnostic information can be achieved and that the benefits outweigh the risk
- The conclusions listed below provide guidance as to the risks due to thermal and mechanical effects arising from ultrasound exposure. To be useful, all the conclusions need to be taken into consideration.

Thermal Effects

- At the time of writing, the information published on output levels during B-mode imaging indicates that the risk of injury from **ultrasonic heating** is negligible during this type of examination. At this time, there appears to be no reason on thermal grounds to limit such scanning for any clinical indication, including ultrasound examination of normal pregnant women.
- In all other operating modes, especially those used for Doppler blood flow examinations, risk of injury from **ultrasonic heating** depends on the temperature elevation and the **dwell time**, as indicated by the conclusions given below.
- If the **Thermal Index (TI)** does not exceed 1, currently available evidence indicates that the risk of an injury due to **ultrasonic heating** is negligible for the vast majority of conditions of the diagnostic ultrasound examination.
- For first trimester transabdominal fetal examinations through a bladder path greater than 5 cm in length, evidence indicates that it is possible that the maximum temperature elevation which could be obtained is as much as 2-3 times that of the displayed **Soft Tissue Thermal Index (TIS)**. More caution may be warranted in these situations, particularly if the **TIS** exceed 1.
- The **Soft Tissue Thermal Index (TIS)** is the appropriate indicator of the potential for **ultrasonic heating** for examinations in which the ultrasound beam travels a path which is made up principally of homogeneous soft tissue or a soft tissue/fluid path, as in a first trimester fetal examination or an abdominal examination.
- If bone, including 2nd or 3rd trimester fetal bone is within the ultrasound beam, then the **Bone Thermal Index (TIB)** is often the appropriate indicator, except as noted in the next conclusion.
- If bone is in contact with the transducer then the **Cranial Thermal Index (TIC)** is the appropriate indicator. If bone is within about 1 cm of the transducer and this is closer than the nearest focal zone, the **Cranial Thermal Index (TIC)** is the appropriate indicator. More caution may be warranted in these cases because of the potential for transducer self-heating; heating of the transducer may add significantly to any **ultrasonic heating** which may occur.

- Generally, more caution may be warranted for transvaginal, transesophegeal and transrectal examinations because heating of the transducer has the potential to produce additional heat to adjacent tissue.
- This conclusion and the following one provide guidance to the user if the temperature elevation in the fetus could exceed 1 °C as a result of a diagnostic ultrasound exposure. If the exposure produces a maximum *in situ* temperature of no more than 38.5 °C (1.5 °C above normal physiological levels) then it may be used clinically without reservation on thermal grounds.
- To be considered potentially hazardous on thermal grounds, it appears that a diagnostic ultrasound exposure must elevate embryonic and fetal *in situ* temperatures to the following temperatures for approximately the corresponding durations:

  39 °C, (2 degrees above normal), 60 minutes;
  40 °C, (3 degrees above normal), 15 minutes;
  41 °C, (4 degrees above normal), 4 minutes;
  42 °C, (5 degrees above normal), 1 minute;
  43 °C, (6 degrees above normal), 0.25 minutes.

Mechanical Effects

- At exposures that do not exceed the output limits recommended in Section **Thermal effects**, there is no demonstrated risk of clinically significant damage in humans from mechanical effects of ultrasound exposure during a diagnostic examination. However, capillary hemorrhaging has been observed in lung and the intestine of mammals at diagnostically relevant exposures. This effect has also been observed in other soft tissues if gas contrast agents are used. For the most part, thresholds are just as likely to be exceeded for B-mode as for pulsed Doppler or color flow Doppler modes. However, thresholds are lower for pulsed Doppler modes with relatively long pulses.
- If the **Mechanical Index (MI)** exceeds 1, there is a small risk of capillary hemorrhaging in the lung during ultrasound examinations involving exposure of the neonatal and infant chest. The risk may increase in more unusual exposures where the surface of the lung is near the focus. Although clinically significant hemorrhaging is unlikely, in part because of the small volume of tissue that is affected, the potential for achieving clinical significance may increase in the premature infant.
- At the current maximum values for the **MI** of 1.9, it is unlikely that diagnostic ultrasound exposure would lead to clinically significant intestinal hemorrhage in humans. However, the likelihood may increase for pathologic conditions inhibiting intestinal peristalsis and promoting intraluminal and submucosal gas collections.
- A limited number of experimental studies suggests that use of ultrasound gas contrast agents (GCAs) (micro bubbles) during a diagnostic examination has the potential to increase the likelihood of capillary hemorrhaging in tissues other than lung. In experiments on animals, the risk of significant hemorrhaging from lithotripter fields is increased for several hours after injection.
- As long as the recommended output limits are not exceeded, mechanical effects are far less likely to be important in obstetrical ultrasound because of the absence of gas bodies.

Biological Effects

The clinical effect of an exposure depends on the nature and degree of tissue injury. This can be assessed from biological effects studies. Several extensive reviews have been published regarding the adverse biological effects of **ultrasonic heating** based on animal studies, particularly in mammalian species (Lele 1985, NCRP 1992, WFUMB 1992, AIUM 1993, WFUMB 1998). With regard to adult tissues, the available literature suggests that tissue temperature elevations in the range of 8-10 °C, sustained for 1 to 2 minutes will cause tissue injury (Bly, *et al*., 1992, Lele 1985). The reviews have also considered studies of teratogenic effects, usually on the developing brain,

due to whole body heating of the embryo or fetus. The recommendations resulting from these reviews can be succinctly expressed as follows (WFUMB 1998):

- a diagnostic ultrasound exposure that produces a maximum *in situ* temperature rise of no more than 1.5 °C above normal physiological levels (37 °C) may be used clinically without reservation on thermal grounds,
- a diagnostic ultrasound exposure that elevates embryonic and fetal *in situ* temperature above 41 °C (4 °C above normal temperature) for 5 minutes or more should be considered potentially hazardous,
- the risk of adverse effects is increased with the duration of exposure.

In addition, it has been reported that water immersion body heating of rats yielded the development of encephalocoeles in the rat fetuses in as little as 1 minute at a temperature elevation of 5 °C above normal physiological temperature. (WFUMB 1998).

For temperature elevations greater than 1.5 °C above normal physiological levels (37 °C), this information can be approximately matched to a functional form recommended by the NCRP (NCRP 1992). This yields an equation for combinations of temperature elevation and time which should be considered potentially hazardous:

$$t = 4^{5-\Delta T}$$

where t is the time in minutes at the specified temperature and $^{\Delta T}$is the temperature elevation above normal (37 °C).

Barnett, et al., (1997) have recently published an updated review of thermal effects, focusing on the potential for effects on the fetus. They note that there is little information on the teratogenic effects from localized heat damage by ultrasound.

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D. Glossary of Terms

ALARA (As Low As Reasonably Achievable): a principle which is used to reduce unnecessary, potentially hazardous exposure to individuals, by keeping doses As Low As Reasonably Achievable.

As shown throughout this guideline, application of the ALARA principle to diagnostic ultrasound differs from its common usage in diagnostic X-ray imaging where it is assumed that there is no threshold exposure.

In the use of diagnostic ultrasound, there are three ranges of exposure, i.e., combinations of Thermal or Mechanical Indices and dwell time that need to be considered. At exposures that are clearly below the thresholds for health effects, further reduction of exposure is not justified, whether

it is via reductions in dwell time or acoustic output. There can also be exposures that are or may be above thresholds for health effects. In these cases, ALARA refers to using the lowest value of potentially hazardous exposure, i.e. combination of acoustic output and dwell time, needed to achieve the required diagnostic information.

Bone Thermal Index (TIB): the Thermal Index for an exposure model in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

Cranial Bone Thermal Index (TIC): the Thermal Index for an exposure condition in which the ultrasound beam passes through bone near the beam entrance into the body.

derated: a derated quantity is one which has been measured in water using standard methods and then multiplied by a derating factor. This accounts for attenuation of the ultrasound field by the tissue between the transducer and a particular location in the body along the beam axis. The derating factor is 0.3 dB/cm-MHz in these guidelines.

derated spatial peak time average intensity: the largest value in an ultrasound beam of any derated time averaged intensity.

dwell time: the amount of time that the transducer is actively transmitting ultrasound while staying in one place during part of an examination.

rarefactional pressure: the amplitude of a negative instantaneous ultrasonic pressure in an ultrasound beam

Soft Tissue Thermal Index (TIS): the Thermal Index for an exposure model in which the ultrasound beam heats primarily soft tissue.

spatial average, pulse average intensity at the face of the transducer: the spatial average, temporal average intensity at the face of the transducer divided by the duty factor, where the duty factor is the product of the pulse duration and the pulse repetition frequency.

spatial average, temporal average intensity at the face of the transducer: the time averaged intensity, averaged over the face of the transducer.

Thermal Index (TI): a quantity related to the potential for **ultrasonic heating**. It is proportional to a calculated or estimated temperature rise for model exposure conditions. The **Thermal Index** is given by the ratio of the ultrasonic power emitted by the transducer to the ultrasonic power required to raise tissue temperature by 1 °C for the model exposure conditions. In the calculation of all Thermal Indices, the average ultrasonic attenuation in the body is assumed to be 0.3 dB/cm-MHz along the beam axis (e.g., the ultrasonic intensity is reduced by 3 dB, a factor of 2, for a 5 MHz beam, 2 cm into the body along the beam axis.)

Mechanical Index (MI): a quantity related to the potential for mechanical effects during a diagnostic ultrasound examination. It is given by the ratio of the largest value in the ultrasound beam of any derated rarefactional pressure to the square root of the transducer frequency. The pressure is in Megapascals and the frequency is in MHz.

ultrasonic heating: the heating of tissue (including bone) due to the absorption of ultrasound.

ultrasonic power: the total amount of ultrasound energy emitted by the transducer per unit time.

12.2. Acoustic output

The terms used in the acoustic output table follow:

MI the Mechanical Index

ISPTA.3 the derated spatial-peak temporal-average intensity in milliWatts per square centimeter

ISPPA.3 the derated spatial-peak pulse-average intensity in Watts per square centimeter

Acoustic Output Tables for Track 1(Global Maximum Values)

The following values represent global maximum values of acoustic output for all system and transducer combination (3 samples of each type of probe)

PROBE MODEL	IMAGING MODE	MI	ISPTA.3 (MW/CM2)	ISPPA.3 (W/CM2)
C3.5/60/64	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.794 0.746 0.794	5.28 11.0 5.28	43.8 37.7 43.8
	B-Mode/M-Mode combined	0.794 0.746 0.741	24.2 20.3 21.4	43.8 37.7 37.5
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.794 0.746 0.741	10.9 9.29 9.53	43.8 37.7 37.5
HL7.5/40/64	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.457 0.448 0.533	14.0 11.0 16.1	112 101 156
	B-Mode/M-Mode combined	0.457 0.448 0.533	26.5 20.8 30.2	112 101 156
	M-Mode	0.457 0.448 0.533	12.5 9.84 14.1	112 101 156
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.457 0.448 0.533	12.5 9.84 14.1	112 101 156
PV6.5/10/64	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.508 0.508 0.528	6.84 6.25 7.14	50.3 43.1 45.0

	B-Mode/M-Mode combined	0.508 0.508 0.528	12.6 11.1 12.2	50.3 43.1 45.0
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.508 0.508 0.528	5.74 4.83 5.10	50.3 43.1 45.0
C3.5/60/128Z	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.591 0.570 0.596	7.71 7.03 8.07	25.9 23.9 25.1
	B-Mode/M-Mode combined	0.591 0.570 0.596	13.11 12.0 13.25	25.9 23.9 25.1
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.591 0.570 0.596	5.40 4.97 5.18	25.9 23.9 25.1
HL9.0/40/128Z	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	1.53 1.38 1.52	49.8 43.4 48.5	410 367 401
	B-Mode/M-Mode combined	1.53 1.38 1.52	62.0 55.0 61.01	410 367 401
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	1.53 1.38 1.52	42.0 37.6 41.6	410 367 401
L5.0/80/128Z	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.920 0.888 0.903	20.2 21.3 21.1	122 133 134
	B-Mode/M-Mode combined	0.920 0.888 0.903	39.5 42.5 42.2	122 133 134
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.920 0.888 0.903	19.3 21.2 21.2	122 133 134
PV6.5/10/128Z	Autoscanning Mode Fetal Imaging & Others			
	B-Mode	0.965 0.784 0.901	13.9 10.9 12.9	142 114 128
	B-Mode/M-Mode combined	0.965 0.784 0.901	28.2 22.8 25.9	142 114 128
	Non-Autoscanning Mode Fetal Imaging & Others			
	M-Mode	0.965 0.784 0.901	14.3 11.9 13.0	142 114 128

12.3. Vigilance system

This equipment is a subject to TELEMED vigilance system (post-marketing vigilance) in case of potential or real hazards for the patient or for the operator which might occur during the normal system functioning, in order to be able to remove them with the best efficiency and timing.

Therefore if the user records any malfunction or deterioration in the characteristics and/or performances of the device, as well as any inadequacy in the labeling or the instructions for use which might lead to potential or real hazards for a patient or for an operator, we kindly request to inform **immediately** TELEMED office or local Competent Authority or our official dealer/distributor sending the following form (or reporting in other way the same data containing in this form) and **do not use** this device. All data relating to the system can be found on its identification label. In this way we'll be able to take all adequate, opportune and effective actions.

Post-Marketing Vigilance Form

To: Quality Assurance Department
UAB "TELEMED"
Dariaus ir Gireno str. 42
Vilnius LT-02189
Lithuania
Phone1: (+370-5) 2106272
Phone2: (+370-5) 2106273
Fax: (+370-5) 2306733

System/device name _____

Serial number _____

Description of potencial hazard _____

_____

Notes and suggestions _____

_____

Contact person/ Department _____

Address _____

Phone _____ Fax _____

Email _____

Date _____ Signature _____

12.4. Returned product form

RETURNED PRODUCT №_____ **200 _._____._____**
(filled in TELEMED) (filled in TELEMED)

COMPANY (filled by sender)		
ADDRESS (filled by sender)		
SERIAL NUMBER (filled by sender)		
REASON OF RETURN (filled by sender)		
INSTRUCTIONS (filled in TELEMED)		
REGISTERED BY (filled in TELEMED)		
NC REPORT № (filled in TELEMED)		
PROPERTY OF (filled in TELEMED)	☐ **TELEMED**	☐ **CUSTOMER**
WARRANTY (filled in TELEMED)	☐ **YES**	☐ **NO**

REVISION HISTORY

REVISION	REVISION COMMENTS	ISSUE DATE
2.12	Added CEXT-1Z modification	2010.06.04
2.11	Changed descriptions, added Acoustic Output tables Changed installation description	2008.05.30
2.10	Changed chapters Safety and Disinfection, added Optional Accessories	2007.05.19
2.9	Changed chapter of installation description.	2007.03.19
2.8	Vigilance system / Returned product forms are added Declaration of Conformity is changed due to test result	2006.06.30
2.7	Misc. changes	2005.12.12
2.5	Edited and renamed to common Echo Blaster 128 / 64 KIT User Guide due to release of ECHO BLASTER 64 series scanners	2005.07.28
2.4	Updated Troubleshooting chapter	2005.05.06
2.3	Updated Technical Specification chapter	2005.03.10
2.2	Updated Windows XP configuring chapter	2004.08.20
2.1	Updated Technical Specification chapter	2004.07.10
2.0	Updated FAQ section	2004.04.06
1.91	Too many changes, many chapters revised	2004.03.17
1.8	Updated FAQ section	2004.03.08
1.7	Updated FAQ section	2004.02.25
1.6	Too many changes, all chapters revised	2004.02.18
1.5	Power supply condition added	2003.12.05
1.4	Edited Technical Specification chapter	2003.11.27
1.3	Added description of Echo Blaster 128 Monitor utility; Added chapter Declaration Of Conformity	2003.11.14
1.2	Added PCMCI to USB 2.0 adapter picture and description	2003.10.06
1.1	Updated description of Echo Blaster 128 beamformer drivers installation	2003.10.04
1.0	Initial release of the Echo Blaster 128 INT-1Z / EXT-1Z KIT User Guide	2003.09.30