

MICRUS EXT-1H



USER GUIDE

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ATTENTION:



See Echo Wave II Software User Manual and Echo Wave II Software Reference Manual on USB key.

1. INTRODUCTION

Dear customer,

our Ultrasound scanner is intended for the multipurpose ultrasound examinations, based on electronic linear and convex scanning.

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

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

- Scan-converter free architecture beamformer;
- Connectivity via fast USB 2.0 / 3.0 interface to any PC (Desktop /Notebook /Tablet PC);
- powered from medical grade external power supply or USB;
- Digitally controlled acoustic power;
- Light weight, true mobility, flexible architecture.

Here in **User Guide** you can find a common information about Ultrasound scanners, how to assemble the system components and install the software, safety and maintenance information.

Operation Manual contains **Echo Wave II** software description.

1.1. About the system / Intended use

MicrUs scanners are intended to be used for applications in cardiac (adult and pediatric), fetal, abdominal, pediatric, small organ, transvaginal, peripheral vessel and musculo-skeletal. The **MicrUs** is a highly portable PC controlled ultrasound systems used to acquire and display real time high resolution ultrasound data in B-mode, M-mode, B+B-mode, 4B-mode, B+M-mode, Compound, Trapezoid or in a combinations of these modes.

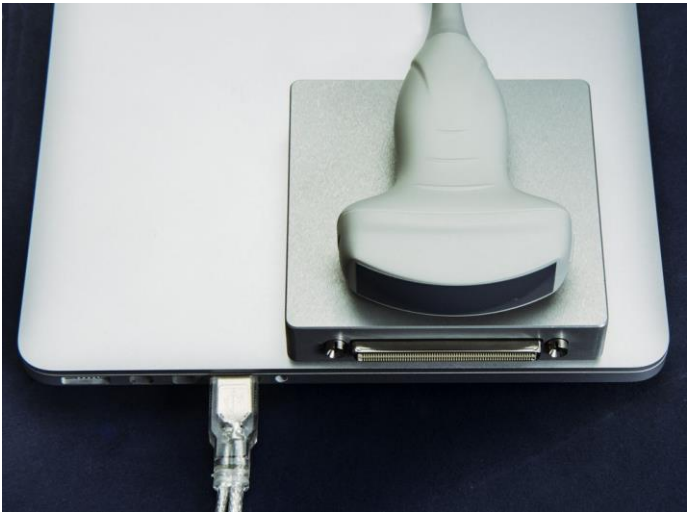
The systems have measurement capabilities for anatomical structures and fetal biometry that provide clinical diagnostic information. It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

System offers to get a real-time and “frozen” echo images in all scanning modes. Unlike ordinary ultrasound devices this scanner is based on modern digital technologies. PC and USB 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 storage devices;
- storage a sequence of full size echo images (cineloop) with possibility to save it in video file format;
- telecommunication possibilities;
- using a variety of peripheral devices.

Common view of

MicrUs



1.2. Delivery set



Beamformer	•
Operation manual	•
User guide	•
Software and manuals (eIFU)	•
USB mini cable	•
Power supply (medical grade) XP Power VEP 15US05	•
Ultrasound transducer	Types and quantity are 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 <https://pcultrasound.com> internet site. See **Echo Wave II Software User Manual** and **Echo Wave II Software Reference Manual** on USB key.

1.4. Technical Specification

Technical specifications of ultrasound scanner:

IMAGING MODES	
• B • B+B • 4B • B+M • M • Compound • Trapezoid	
ULTRASOUND IMAGING	
• ultrasound image size: automatically adjustable to screen resolution • gray scale: 256 • color 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)	• cineloop recording/play: several thousand frames (depends on computer memory size and scan mode) • 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" and "AUTO FREEZE" modes
SCANNING METHOD	
• Electronic linear • Electronic convex • Electronic microconvex	
DEPTH SELECTION	

2 – 31 cm (depth range depends on transducer type and scanner model)	
FOCUSING	
Transmitting	variable, 8 zones
Receiving	point to point, dynamic
SIGNAL PROCESSING	
- High Line Density scan mode for better resolution - TGC Control, 5 - 10 sliders (customizable) 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 - and structure improvement PureView, NeatView, QuickView: 8 algorithms each	
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
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 transducer position indicator
Image and video save / load	• AVI • JPG • BMP • PNG • TIFF • XLSX • DCM (DICOM uncompressed) • DCM (DICOM-JPEG RGB/YBR) • DCM (DICOM-JPEG RGB/YBR Video) • TPD (Telemed Picture Data) • TVD (Telemed Video Data)
Cineloop	• Recording / playback up to several thousands frames (depends on computer memory size and scan mode) • Play / Pause / Stop / Frame selection • Saving ultrasound video file to disk • Loading ultrasound video file from disk
Printing	• System printer
Telemedicine	• LiveView • TeleView
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 2.0/3.0 Interface
CPU	• Core Duo / Core 2 Duo 1.6 GHz or better
Monitor / Graphics	• screen resolution 1024x768 or more • Nvidia graphic card, 256 Mb, Cuda 2.3 support

Operating system	Windows® XP SP3, Windows® Vista SP2, Windows® 7 (all versions 32/64-bit)
RAM	1 Gb or more
ULTRASOUND SOFTWARE	
Drivers	TELEMED Drivers Package
Software	Echo Wave II software
Plug-Ins	3DView (optional, 32-bit Windows® only) - PanoView (optional, 32-bit Windows® only)
Library for programmers	SDK documentation / sample code (available by agreement)
DIMENSIONS AND WEIGHT OF BEAMFORMER	
Dimensions W x D x H mm	106 x 105 x 21
Weight, kg	0.26
POWER	
External AC medical grade power supply (if connected to USB 2.0)	90-264 VAC, 47-63 Hz (if connected to USB 2.0)
from USB port (if connected to USB 3.0)	5V 1.0A
SAFETY	
Electromechanical safety	- IEC 60601-1: 2005, Part 1: General requirements for basic safety and essential performance - Externally powered by Class II medical approved power supply/charger or USB 3.0 powered - Type BF applied part
EMC/EMI standards	IEC 60601-1-2: 2007, Part 1: General requirements for basic safety and essential performance, 2.Collateral

	standard: Electromagnetic compatibility - Requirements and tests
Ultrasound exposure	• IEC 60601-2-37: 2007-08 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment • NEMA UD 2-2004: 2003, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment • NEMA UD 3-2004: 2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment • AIUM MUS: 2002, Medical Ultrasound Safety
Degree of protection (watertight)	• IPX0 enclosure MICRUS • IPX1 – ultrasound transducer/transducer assembly (only the area of the transducer acoustic window is watertight – IPX7).
OPERATIONAL ENVIRONMENT	
Nominal operational environment	• Temperature of the environment: 10 - 40 ° C • Relative humidity not exceeding: 85 % • Atmospheric pressure: 70 - 106 kPa
Storage conditions	• Storage temperature: 10°C - 40°C • Storage humidity: 5-95% Relative (non-condensing)

2. SAFETY



CAUTION

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



WARNING

In the event of detecting a discrepancy regarding patient safety requirements (occurrence or probability of risk) you must to inform the local dealer and the manufacturer immediately

2.1. Electrical safety

This system complies with the applicable medical equipment requirements and meets IEC 60601-1, Class II powered by Class II approved external medical power supply Type BF safety requirements.

NOTE

All persons connecting computer equipment as medical appliance are configuring a medical system and are therefore responsible for ensuring that the system complies with IEC 60601-1. The achievement of PC compliance with the IEC 60601-1 requirements is based on electrical safety. A standard PC power supply is almost certain to not comply with IEC 60601-1 electrical requirements in several ways, e.g. leakage current requirements, dielectric strength requirements.



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

All systems (including monitors and other connected parts) must be configured to comply with IEC 60601-1. If in any doubt please contact the technical service department of your local representative.

Note that regardless of the above stipulations all personal computers used should be approved regarding the IT (information technology) safety standards for electrical) equipment (such as IEC 60950 or equivalent) .

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 left 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 transducer, inspect the transducer face, housing, and cable, do not use the transducer if the transducer or its cable is damaged;
- always disconnect the AC power supply from the system before cleaning the system;
- do not use any transducer 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;
- do not connect non-original AC power supply, not supplied by TELEMED;
- only use 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 difficulties 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 transducers can easily be damaged by improper handling! Failure to follow these precautions can result in serious injury and equipment damage!

2.3. Biological safety

WARNING

Some transducer covers may contain talc and natural rubber latex. Examine the package labeling to confirm latex content. We strongly recommend that health-care professionals identify their latex-sensitive patients, and refer to the FDA's March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions promptly.

NOTE

TELEMED diagnostic ultrasound systems and transducers do not contain natural rubber latex that contacts humans.

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**);
- devices are contraindicated for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

**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.

2.4. Ultrasound waves/exposure

Ultrasound waves used in diagnostic system have frequencies from 2 MHz to 10 MHz. Sound waves with such frequency are weakened in air, so can be measured for example in water.

Detailed information is expounded in

APPENDIX 12.1: Guidelines for the safe use of diagnostic ultrasound.

APPENDIX 12.2: Acoustic output

Perform ultrasound procedures prudently, use the ALARA (As low As Reasonably Achievable) principle (see **APPENDIX 12.1**).

The interactive system features (user controls) that may affect the acoustic output are:

- acoustic output control,
- transmit frequency;
- scanning depth;
- transmit focal length;
- scanning angle
- range in 2D-Mode,

Also acoustic output depends on the imaging mode selected. The choice of mode (B-Mode, M-Mode, B+M-Mode) determines whether the ultrasound beam is stationary or in motion. B+M-Mode has highest acoustic output.

The default output level is set at the factory and is based on device settings that yield an optimum image for the type of patient examination and do not exceed the recommended limits.

This default level is set:

- when the system is first turned on;
- when the transducer is first turned on.

It is highly recommended to set default level:

- when changing from one exam category to another;
- when changing from one application to another;
- when changing from one transducer to another;
- when a new patient is entered.

Once an optimal image is achieved, the need for increasing acoustic output or prolonging the exposure cannot be justified. Watch the POWER level (on-screen display) permanently. Where possible, controls and system features should be used to optimize the image before increasing the acoustic output level. Follow the principle of ALARA in all patient exams. **MicrUs** employs the principle of ALARA in configuring factory defaults.

The system and transducer combination do not exceed an MI or TI of 1.0 in any operating mode. Therefore, the MI or TI output display is not required and is not displayed on the system for these modes.

CAUTION :

Gas ultrasound contrast agents are used during echocardiography to enhance a cardiac image but may cause side effects (cardiac rhythm disturbances during perfusion studies).



Because of this, see the package labelling / insert about the risks of both cardiopulmonary and hypersensitivity reactions (unstable status). It is recommended the monitoring of vital signs, cardiac rhythm and oxygen saturation, and having equipment for resuscitation and trained personnel readily available.

Additional Information:

FDA MedWatch Safety Alert. Micro-bubble Contrast Agents (marketed as Definity (Perflutren Lipid Microsphere) Injectable Suspension and Optison (Perflutren Protein-Type A Microspheres for Injection). October 12, 2007.

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#bubble>



CONTRAINDICATION :

This device is contraindicated for ophthalmic use or any application that causes the acoustic beam to pass through the eye

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.

2.6. Accuracy Measures



WARNING:

Clinical diagnostic errors may result from the inappropriate use of calculations. Review the referenced source of the stated formula or method to become familiar with the

intended uses and possible limitations of the calculation. Calculation formulas and databases are provided as a tool to assist the user, but should not be considered an undisputed database, in making a clinical diagnosis.

The accuracy of measurements is determined not only by the TELEMED Echo Wave II software, but also by proper use of medical protocols.

Distance and area/circumference measurements are displayed to 0.1 mm.

The following general assumptions can be made about the accuracy of any ultrasound system:

- Velocity of sound is constant - 1540 m/s
- Velocity of sound uncertainty = 5%
- Caliper placement accuracy is one pixel (operator dependent)
- Measurement accuracy is based on the root-mean-square combination of all independent sources of error
- RMS errors are due to velocity of sound uncertainty, pixel error, and typical transducer geometry

Note: The below measurement accuracies apply to all transducers and to all modes.

The linear distance measurement components have the accuracy and range shown in the following tables:

2D Measurement Accuracy

2D Measure Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Axial Distance	< $\pm 5\%$ or 1mm	Acquisition	Phantom**	0.1-20 cm
Lateral Distance	< $\pm 5\%$ or 1mm	Acquisition	Phantom**	0.1-20 cm
Diagonal Distance	< $\pm 5\%$ or 1mm	Acquisition	Phantom**	0.1-20 cm
Area *** Trace & Ellipse	< $\pm 4\%$ plus 1% of full scale*	Acquisition	Phantom**	0.1-1000 cm ²
Circumference ****	< $\pm 3\%$ plus 1% of full scale*	Acquisition	Phantom**	0.1-70 cm
Angle	< $\pm 5\%$	Acquisition	Phantom**	0 -180°

* Full scale for distance implies the maximum depth of the image.

** An ATS model 539 phantom with 0.7 dB/cm-MHz attenuation was used.

***The area accuracy is defined using the following equation: % tolerance = $((1 + \text{lateral error}) * (1 + \text{axial error}) - 1) * 100 + 0.5\%$.

****The circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation: % tolerance = $((\text{maximum of 2 errors}) * 100) + 0.5\%$.

M-mode Measurement and Calculation Accuracy

M-mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Distance	< $\pm 5\%$ or 1mm	Acquisition	Phantom **	0.1-20 cm
Time	< $\pm 2\%$ plus 1% of full scale *	Acquisition	Phantom****	0.1-10 sec
Heart Rate	< +/- 2% + (Full Scale *** x Heart Rate/100) %	Acquisition	Phantom****	20-300 bpm

* Full scale for distance implies the maximum depth of the image.

** An ATS model 539 phantom with 0.7 dB/cm-MHz attenuation was used.

*** Full scale for time implies the total time displayed on the scrolling graphic image.

**** TELEMED special test equipment was used.

Other Measurement and Calculation Accuracy

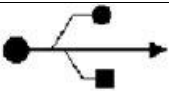
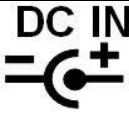
Parameter		System Tolerance	Reference / Formula
Volume		< $\pm 9\%$	4.2.3 Perimeter, square and volume measurements by Ellipse method
Fetus Weight	1 method	< $\pm 16\%$	4.5.1 Hadlock85 (USA)
	2 method	< $\pm 12\%$	4.5.2 Shepard82 (EU)
	3 method	< $\pm 17\%$	4.5.3 Tokyo
	4 method	< $\pm 16\%$	4.5.4 Osaka
Left Ventricle Volume	1 method	< $\pm 15\%$	4.6.2 Cubed

	2 method	< $\pm 11\%$	4.6.2 Pumbo
	3 method	< $\pm 13\%$	4.6.2 Teihholz
Stroke Volume		< $\pm 15\%$	4.6.3 Stroke Volume
Ejection Fraction		< $\pm 12\%$	4.6.4 Ejection Fraction
Cardiac Output		< $\pm 15\%$	4.6.5 Cardiac Output
Left Ventricle Internal Dimension Fractional Shortening		< $\pm 10\%$	4.6.6 Left Ventricle Internal Dimension Fractional Shortening
Aortic Valve Measurements and Calculations		< $\pm 8\%$	4.6.7 Aortic Valve Measurements and Calculations

3. LABELING

Table 1 describes the purpose and location of safety labels and other important information provided on the equipment.

Table 1

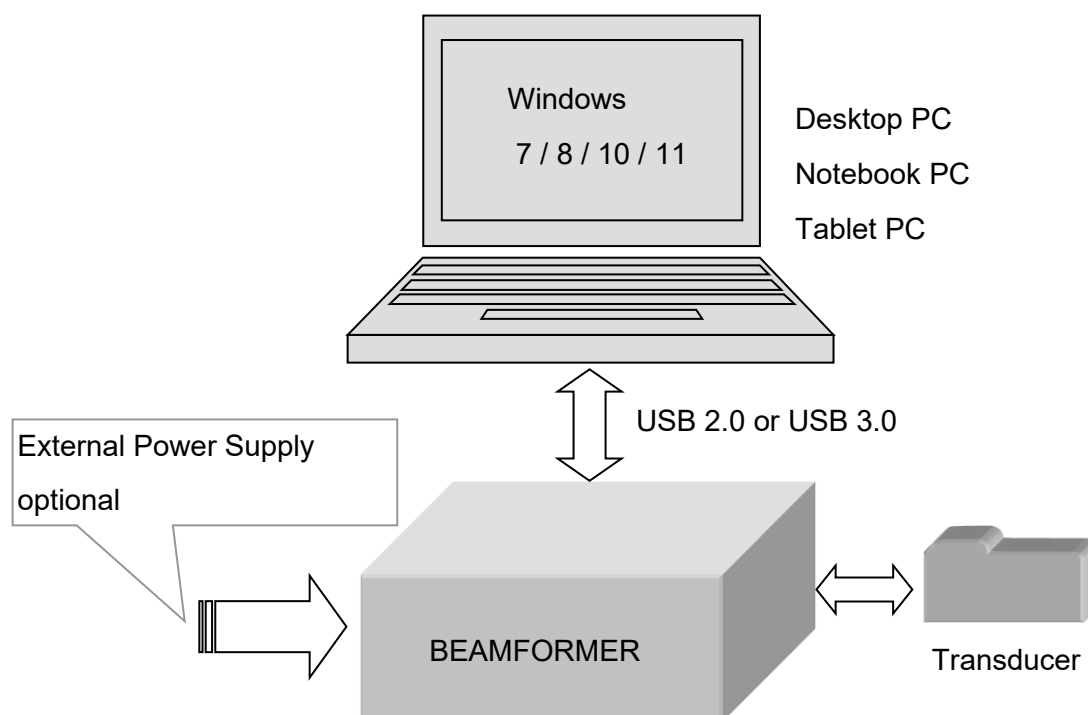
LABEL / SYMBOL	DESCRIPTION	LOCATION
	Caution, consult accompanying documents This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself	ID Label
	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 (transducer outlet)
	Consult instructions for use NOTE This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device	ID Label
	The symbol indicating separate collection for electrical and electronic equipment (Annex IV of Directive 2002/96/EC)	ID Label
	CE mark This mark is a declaration by the manufacturer that the respective component complies with the relevant directives and standards as issued by the European Union.	ID Label
	USB connector. This label indicates USB connector.	Rear panel
	+5VDC power input	Rear panel
	Manufacturer name and address	ID Label

	Model / Catalogue number	ID Label
	Date of manufacture YEAR -MONTH- DAY	ID Label
	Serial number	ID Label

4. SYSTEM OVERVIEW

Here is main information about Ultrasound Scanners. The system consists of, see figure below:

- Beamformer
- Ultrasound Transducer
- Personal Computer (Desktop / Notebook / Tablet PC)
- powered from Power Supply +5V



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 transducer 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 transducer 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

4.2.1. Beamformer

Beamformer functions are:

- excite electric pulses to fire the transducer;
- 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;
- preparing digital data for transferring via USB interface

4.2.2. Transducer Unit

Transducer unit is piezoelectric transformer which provides the acoustical pulse used to examine 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). Transducer enclosure has a relief to affix the scanning direction.

Transducers												
Type / Order Code	Transducer Central Frequency, MHz	System Frequencies, MHz	Radius of Curvature, mm	Field of View / Degree, mm	Abdominal	Cardiac	Obstetrics	Pediatrics	Small Parts	Transrectal	Transvaginal	Vascular
C5-2R60S-3	3.5	2.0 3.0 4.0 5.0	60	64°	•		•	•	•			
L12-5L40S-3	7.5	5.0 7.5 10.0 12.0	-	38mm	•		•	•				
L15-6L25S-3	10	6 10 15	-	24mm			•	•	•			
MC8-4R20S-3	6.5	4 6 8	20	91.7mm	•			•				

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 USB key.

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

4.3. Connection and Indication

Front view of **MicrUs**
beamformer



Rear view of **MicrUs**
beamformer



IMPORTANT NOTE

The Ultrasound Scanner is partially powered through USB from the computer to which it is connected.



For compliance with IEC 60601-1 any computer equipment connected to the USB interface of the Ultrasound Scanner must be certified to IEC standards (e.g. IEC 950) and configured to comply with IEC 60601-1 . Everybody who connects computer equipment to this interface configures a medical system and is therefore responsible for ensuring that the system complies with IEC 60601-1. If in any doubt contact the technical service department of your local representative.

4.4. Peripherals/Compatibility

Ultrasound Scanners can work / operates with standard PC features:

- mouse
- keyboard
- SVGA or better monitor
- Laser printer 600 dpi, (preferred HP printers), optional

Optional accessories:

- Additional Transducers
- Transducers Carrying Cases
- PV-Biopsy Clip Bracket PV- type (for microconvex Transducers)
- Biopsy Clip Bracket C- type (for convex Transducers)
- Biopsy Clip Bracket HL- type (for linear Transducers)

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 Transducer. Transducers should be clean after work from gel and other deposits. Do not use any aggressive chemicals. To increase life time of Transducers, always leave them after work with freeze acquisition.

Transducers changing can be done only at FREEZE mode or POWER OFF.

Ultrasonic waves have a low permeability in air and gas within the living body. If air is present between the Transducer 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 Transducer 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 Transducer 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 Transducer. Both the transducer and the Transducer are activated during the acquisition process.

The term “FREEZE” is understood as the stoppage of the acquisition. button FREEZE turns the ultrasound Transducer 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 process is same.

6.1.1. Hardware

Recommended Windows PC configuration:

- Windows® based computer
- HD/Full HD screen resolution, IPS technology
- CPU i5/i7/i9 2.0 GHz or faster
- 8 Gb RAM or more
- 256 Gb internal Solid State Drive (SSD)
- Type A USB 2.0 port
- certified for medical use computer power supply

6.1.2. Software

- Windows® 8, 8.1, 10, 11 (all versions 32/64-bit)

6.1.3. Windows 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 chapters 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.

- Connect external power supply to the power socket on side panel.
- DO NOT insert USB cable to the beamformer and PC ports.

Start the software installation according to chapter **6.3. Software installation for Windows**

NOTE

Beamformer can be powered from PC via the USB 2.0/3.0 and draws approx. 1000 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. If the power is not sufficient, use external 5V power supply from delivery set

6.3. Software installation for Windows

Ultrasound scanners software consists of 2 packages:

- **TELEMED Drivers Package**
- **Echo Wave II**

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

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

Please refer to Echo Wave II Quick Start Guide for drivers installation instructions. Echo Wave II Quick Start Guide is located on installation USB stick or can be found on a Telemed website by the following link: <https://www.pcultrasound.com/support/manuals/>

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

Please refer to Echo Wave II Quick Start Guide for software installation instructions. Echo Wave II Quick Start Guide is located on installation USB stick or can be found on a Telemed website by the following link: <https://www.pcultrasound.com/support/manuals/>

6.3.3. Ultrasound Scanner Monitor utility

Ultrasound Scanner Monitor utility is used for system status monitoring. Also, this utility helps to see when and how **MicrUs** beamformer is connected to the computer.

- The utility icon  is located in Tray Bar
- When the icon is lightened RED - drivers for **MicrUs** beamformer are not installed properly or beamformer is not connected to the USB port or power is not connected to the beamformer.
- When the icon is lightened GREEN - drivers for **MicrUs** beamformer are installed properly, the beamformer is connected to the USB port, power is connected to the beamformer and the system is ready for start



7. TROUBLESHOOTING

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

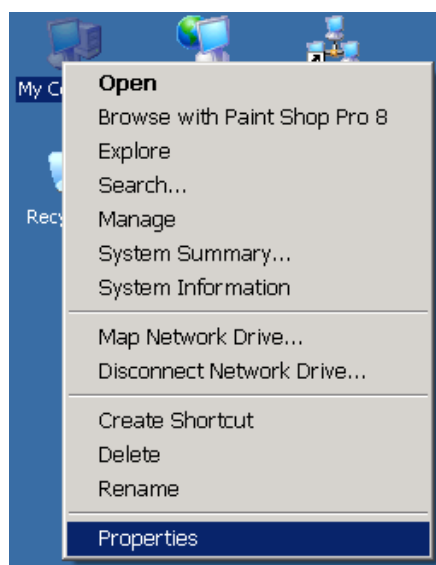
7.1. **TELEMED Drivers Package installation checking**

Sometimes during Windows or **MicrUs** scanners/transducers, installation needs to check the driver's installation using the **Device Manager** utility. Process of **Device Manager** utility checking is described below:

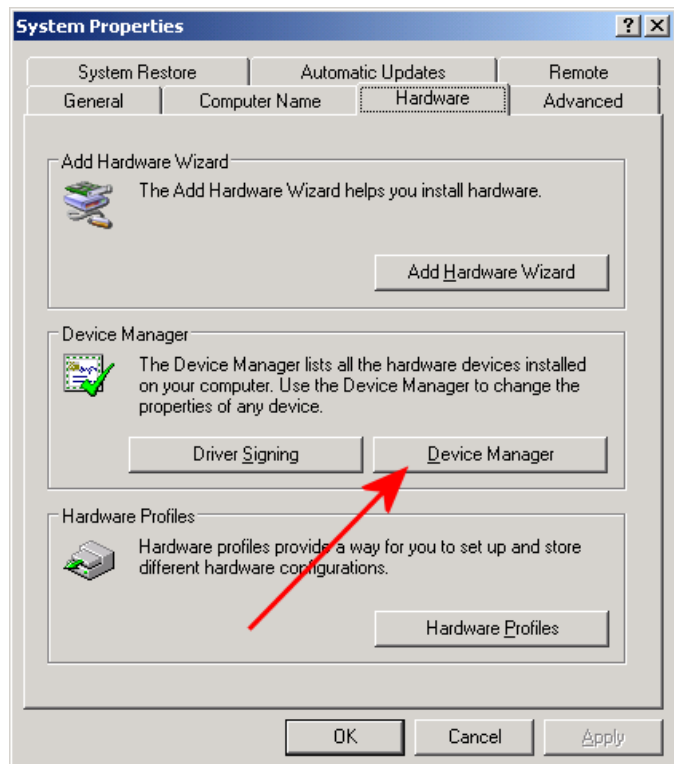
- Find on the desktop **My Computer** icon



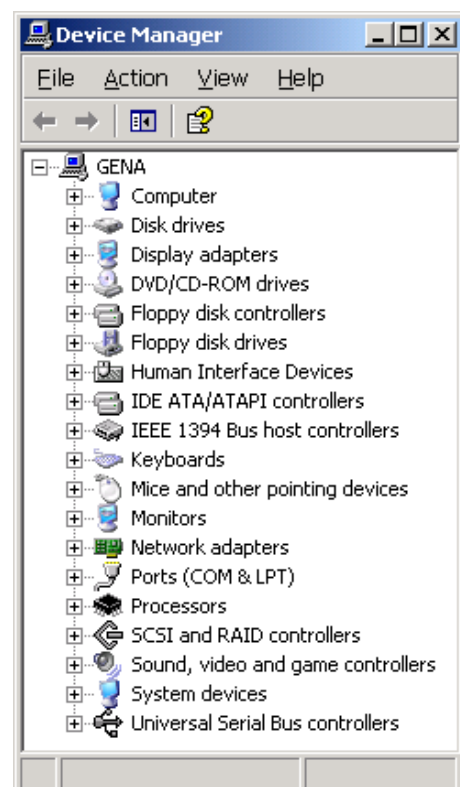
- Click on **My Computer** icon by right mouse button
- Drop-down menu appears
- Select **Properties** menu item



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



- Device Manager window will appear

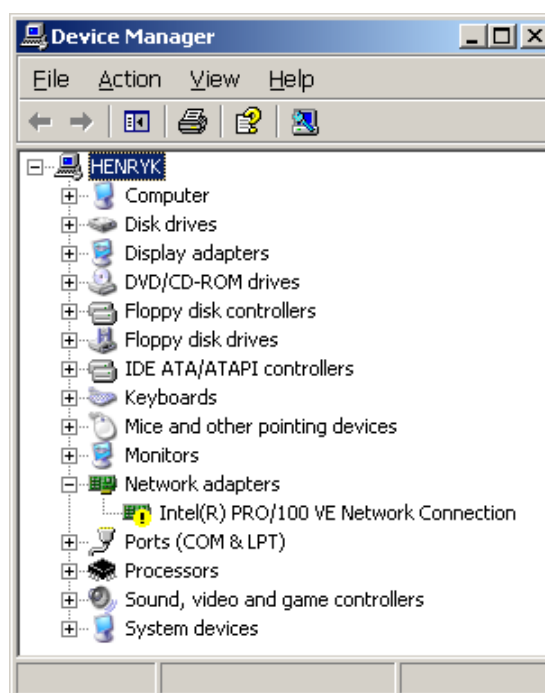


Note. It is only an example. In your computer, the set of hardware can differ.

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

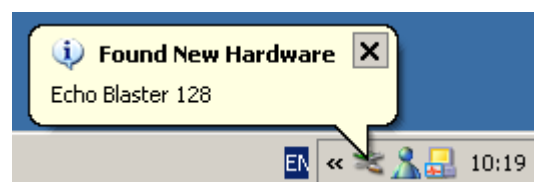


- If in the **Device Manager** you see device with attached! symbol, it means resource conflicts in your computer

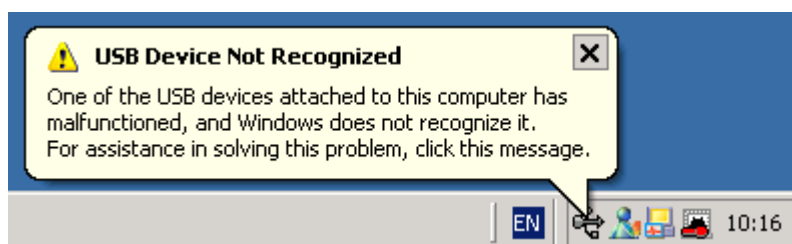


7.2. FAQ

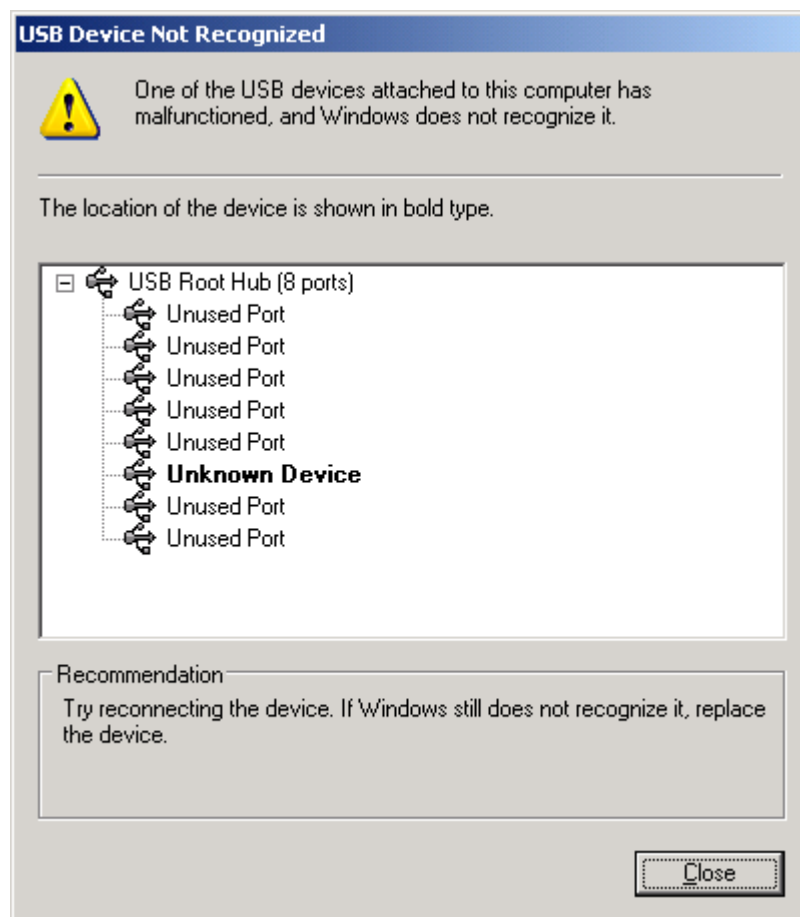
Q. Connecting beamformer to USB port, instead of typical success message **Found New Hardware**



I see a warning message **USB Device Not Recognized**



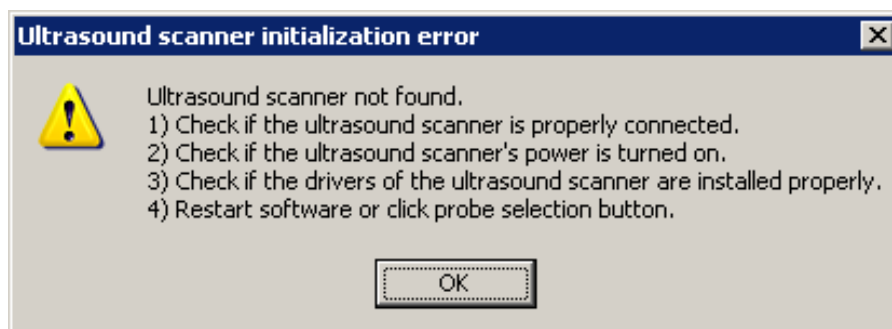
I see a window named **USB Device Not Recognized**



How to solve this problem?

A. At the rear/front panel of the computer several USB port connectors are located. Try switching the 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 for this message can be:

- The USB cable is not connected between the beamformer and the computer's USB port. Check the 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. Instead of declaring a high frame rate of up to 30-120 fps, in the frame rate indicator I see a low value of 4-5 fps. What is wrong?

A. The main reasons for such a 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 the computer hardware;
- Your USB 2.0 controller isn't configured properly, for example, USB 2.0 drivers are not installed and the controller works in USB 1.1 mode.
- 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 a result CPU works 2 times slower;

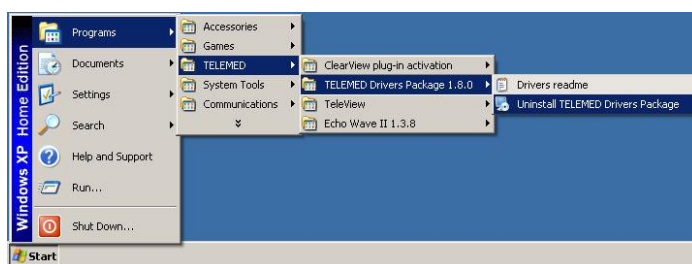
Q. Program **Echo Wave II** doesn't start, error messages do not appear.

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

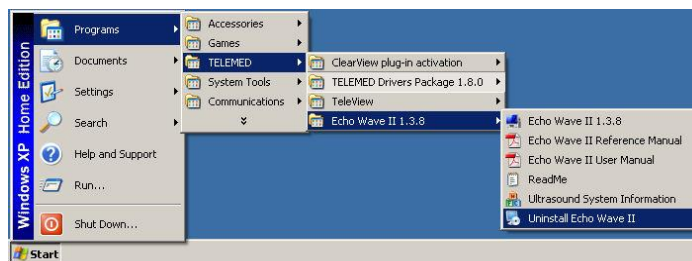
Q. How to reinstall or update software?

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

- Disconnect the USB cable from the 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) the latest **TELEMED Drivers Package** or **Echo Wave II** software from <https://pcultrasound.com/support/software/>;
- 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:

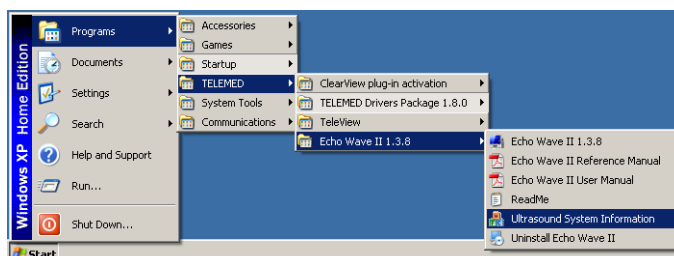
- Working surface of transducer is dirty. Necessary to clean transducer surface. See corresponding chapter in this manual;
- No ultrasound gel on the transducer. Apply an adequate amount of gel or water to the scan surface;
- Very low gain. Incorrect **Echo Wave II** software controls settings. Set image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

7.3. Contact technical support service

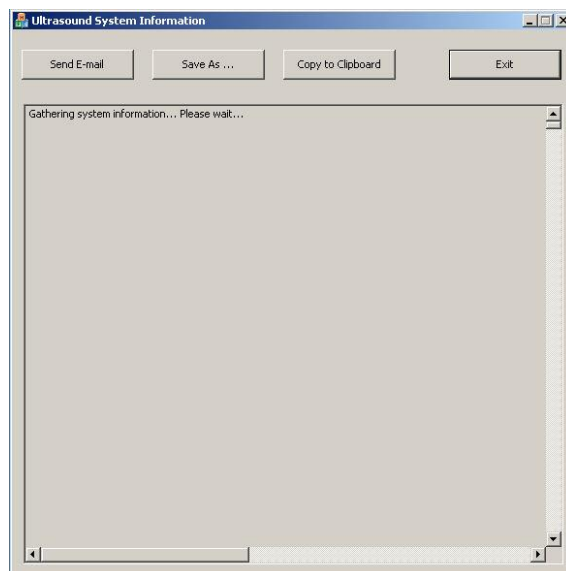
If problems during installation or operation remain and you can't solve them by yourself, use support@pcultrasound.com e-mail address. First of all, send to the technical support service such information:

- Scanner type (for example: **MicrUs**);
- Serial number of the scanner (for example: **2578-140428-9686**);
- Transducer type (for example: **MCV9-5R10S-3**);
- Serial number of the transducer (for example: **3951-090504-9701**);
- **TELEMED Drivers Package** version (for example: **TELEMED Drivers Package 1.15.2**);
- **Echo Wave II** software version (for example: **Echo Wave II 3.3.2**);
- 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:

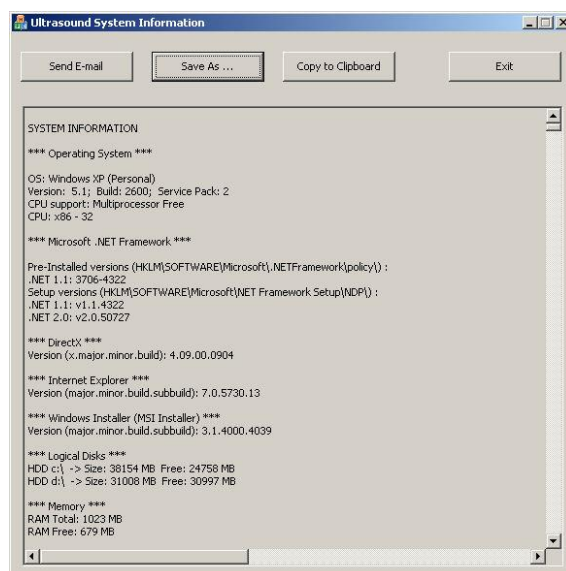
- Run **Ultrasound System Information** software as shown;



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



- After technical detail MicrUs will appear in this window, please send this information to support@pcultrasound.com 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 the technical support service will receive this information, during a short time you must receive recommendations about steps to solve the 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 transducer is warranted for 18 months). This warranty covers parts for the full 24 months (or 18 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 provide our customers with the best possible support send your comments and suggestions to support@pcultrasound.com

9. MAINTENANCE

Performance and Safety Checks see in the table below:

Recommended Maintenance	Frequency
General cleaning	As Need
Inspect the system, cables and transducers	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. Transducer maintenance and disinfection

All transducers are supplied non-sterile.

Transducers in Endocavity Procedures should normally be used with a sterile sheath.

The following disinfectants have been tested with your transducers.

Using 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 transducer, however Low level disinfectants are not appropriate for disinfects of Endocavity transducer.

CAUTION: Customer must follow the disinfectant manufacturer's instructions carefully.

Do not submerge transducers above strain relief.

9.3.1. Chemicals that Damage Transducers:

Some of these chemicals, such as phenol, benzothionium 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 Transducer Processing

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

Use care to avoid getting solution in the transducer 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 transducer 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 conducted 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 transducer lens may be short-time immersed in water or other special liquid.



NOTE:

The System was designed for sound velocity in tissue 1540 m/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



EU DECLARATION OF CONFORMITY

TELEMED UAB

SRN: LT-MF-000002268

Located: Savanoriu ave. 178A, Vilnius LT-03154, Lithuania

We, as the manufacturer,
in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the
transitional provisions for certain medical devices, in particular with respect to:

- the validity of certificate issued under Council Directive 93/42/EEC on Medical Devices (MDD)
by **NB Medcert 0482**, No. **2785GB410191203**
- the compliance of the devices and us as their manufacturer with the conditions for the continued
placing on the market and putting into service

declare under our sole responsibility:

MicrUs Ultrasound System

Product	Model	Basic UDI-DI
Ultrasound scanner	MicrUs EXT-1H	4772057_MicrUs_K9
Ultrasound Transducers	C5-2R60S-3 L12-5L40S-3 L12-5N40-M3 L12-5N40-MV3 L15-6L25S-3	MC4-2R20S-3 MC8-4R20S-3 MC10-5R10S-3 MCV9-5R10S-3

Medical Device Class: Class IIa (in compliance with Annex II, Art.11 Medical Device Directive)
and **Class IIa** (according to Annex VIII p.6.2. Rule 10 of Regulation (EU) 2017/745) conform with:

Essential Requirements of Council Directive 93/42/EEC (Medical Device Directive)

EN ISO 13485:2016

EN 60601-1:2006 + AC:2010 + A1:2013 + A1:2013/AC:2014 + A12:2014

(IEC 60601-1: 2005 + A1:2012)

EN 60601-1-2:2015 (IEC 60601-1-2:2014)

EN 60601-2-37:2008 + A11:2011 + A1:2015 (IEC 60601-2-37:2007 + AMD1:2015)

EN ISO 10993-1:2020 (ISO 10993-1:2018)

EN ISO 10993-5:2009 (ISO 10993-5:2009)

EN ISO 10993-10:2010 (ISO 10993-10:2010)

EN 62304:2006 + A1:2015 (IEC 62304:2006 + AMD1:2015)

EN ISO 14971:2019 (ISO 14971:2019)

ISO 15223-1:2021

And for the above listed device(s):

- the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met
and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of
the MDR for continued placing on the market and putting into service.
- The transition of appropriate surveillance in respect of a legacy device from **NB Medcert 0482**
to **NB Kiwa Dare 1912** under transfer date effective on 2024-09-24
- NB number changed from **NB 0482** to **NB 1912** on 2025-02-07
- Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU2023/607) is
2028-12-31

Vilnius, 2025-03-26, Dmitry Novikov, President

Vilnius, 2025-03-26, Yury Sokolov, PRRC

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 **dwel 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 **dwelt 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 **dwelt 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, transesophageal 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:

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

where t is the time in minutes at the specified temperature and ΔT 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.

C. References

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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.

dwel 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. 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
TELEMED UAB
Savanoriu pr. 178A
Vilnius LT-02301
Lithuania
Phone1: (+370-5) 2106272
Phone2: (+370-5) 2106273
Fax: (+370-5) 2306733

System/device name _____

Serial number _____

Description of potential hazard _____

Notes and suggestions _____

Contact person/ Department _____

Address _____

Phone _____ Fax _____

E-mail _____

Date _____ Signature _____

12.3. Returned product form**RETURNED PRODUCT №** _____

(filled in TELEMED)

202 __-__-__

(filled in TELEMED)

COMPANY (filled by Customer)	
ADDRESS (filled by Customer)	
SERIAL NUMBER (filled by Customer)	
REASON OF RETURN (filled by Customer)	
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

12.4. Acoustic Output Tables

The MicrUs system with any transducer combination is not exceeding neither TI (Thermal Index) of 1.0 nor MI (Mechanical Index) of 1.0 in any operating mode, thus the following mean of the global maximum value for each transducer of ISPTA.3, TI (TIS, TIB, or TIC), MI, and IPA.3 @ Mimax are provided in a table below.

System: MicrUs

Transducer Model	ISPTA.3	TI Type	TI Value	MI	IPA.3@Mimax
C5-2R60S-3	204.007	TIS	0.379	0.58	71.06
		TIB	0.784		
		TIC	0.89		
L12-5L40S-3	398.623	TIS	0.259	0.801	180.44
		TIB	0.899		
		TIC	0.492		
L12-5N40-M3	427.43	TIS	0.295	0.617	146.38
		TIB	0.877		
		TIC	0.518		
L15-6L25S-3	486.857	TIS	0.219	0.716	160.62
		TIB	0.824		
		TIC	0.445		
MC4-2R20S-3	106.211	TIS	0.46	0.559	37.140
		TIB	0.799		
		TIC	(a)		
MC8-4R20S-3	386.479	TIS	0.363	0.563	125.95
		TIB	0.852		
		TIC	0.506		
MC10-5R10S-3	253.865	TIS	0.252	0.490	83.36
		TIB	0.682		
		TIC	(a)		
MCV9-5R10S-3	229.18	TIS	0.197	0.501	73.39
		TIB	0.578		
		TIC	(a)		

(a) Intended use does not include cephalic so TIC is not computed.

REVISION HISTORY

Revision History

Revision	Revision COMMENTS	ISSUE Date
1.0	Initial release of the MICRUS User Guide	2014.07.24
3.0	Labeling corrections	2014.12.18
4.0	Edited 2.4.Ultrasound waves/exposure	2014.12.29
5.0	Corrections	2015.03.21
5.1	Corrections for FDA	2016.05.02
5.2	Correction by FDA approval	2017.08.30
5.3	Address change	2018.10.13
5.4	Chapter 2.1 changes, warning added	2019.05.15
5.5	File Info: Title changed to display correct document name. Ch.11 Updated Declaration of Conformity. Ch.12.4. Acoustic tables replaced with a more compact index maximums summary table.	2023-05-18
5.6	Updated computer requirements	2024-11-18
5.6a	Changed company's address postal code	2025-08-19
5.7	Updated Ch11 Declaration of Comformity	2026-05-18