ArtUs EXT-1H

Ultrasound Diagnostic System

USER GUIDE

Manufactured by

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1. INTRODUCTION

CAUTION:
United States federal law restricts this device to be used by, or on the order of, a licensed physician.

Dear customer,

Our **ArtUs EXT-1H** system is intended for multipurpose ultrasound examinations, based on electronic linear and convex scanning.

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

Here in the **User Guide** you can find information about **ArtUs EXT-1H** and safety and maintenance information.

Echo Wave II Software Operation Manual contains a description of the controls.

1.1. About the system / Intended use

ArtUs EXT-1H system is intended to be used for applications in fetal, abdominal, pediatric, small organ (breast, thyroid, testicles), adult cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial) cardiac adult, cardiac pediatric, peripheral vessel (B and M-mode, combined modes imaging, including imaging for needle guidance) It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical applications and in operating rooms/critical care units.

ArtUs EXT-1H ultrasound systems provide many different scanning technologies: B, B+B, 4B, B+M, M, CFM, Tissue Harmonic Imaging (THI). Echo images can be either full size or zoomed.

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

1. user friendly, easy-to-use intuitive graphic user interface;
2. echo image storage on hard disk or other devices;
3. storage of a sequence of full size echo images (cine) with the possibility to save it in video file format;
4. image and cine file formats enable using other applications for viewing stored data;
5. using a variety of peripheral devices;
6. image and video sending by E-mail.

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A variety of available ultrasound probes provides many different applications for examinations in therapy, obstetrics, gynecology, urology, pediatrics, oncology and other areas.

Common view of **ArtUs EXT-1H** is shown below (without probe).

1.2. Delivery set

Beamformer	●
Operation manual	●
User guide	●
Software and manuals (eIFU)	●
Standard USB cable	●
Power supply (medical)	●
Ultrasound probe	Types and quantity defined by customer

1.3. About the system software

Your diagnostic system contains **Echo Wave II** software to control its operation. TELEMED provides the latest **Echo Wave II** software version and drivers package together with your system. In the software the unique technologies making the intellectual property of TELEMED company are used. Latest software versions can be downloaded directly on the Internet from http://www.telemed.lt.

1.4. Technical Specification

Table 1 contains technical specifications of **ArtUs EXT-1H**.

Table 1

IMAGING MODES
1. B 2. B+B 3. 4B 4. B+M 5. M 6. Color Doppler (CFM) 7. Tissue Harmonic Imaging (THI)
ULTRASOUND IMAGING
1. ultrasound image size: automatically adjustable to screen resolution 2. gray scale: 256 3. color scale: 256 4. full motion and full size real-time ultrasound imaging, up to 120 fps (depends on selected scanning depth, angle, focusing mode, Lines Density setting, computer speed) 5. cine recording/play: several thousand frames (depends on computer memory size and scanning mode) 6. zoom mode: from 60% to 600% in all modes (Scan, Freeze, B, B+B, 4B, Doppler modes, M-zoom, cine, etc.) 7. variable view area for maximizing frame rate: 6 steps 8. "FREEZE" mode
SCANNING METHOD
1. Electronic linear 2. Electronic convex 3. Electronic micro-convex
COLOR DOPPLER
1. PRF variable: 0.5-10 kHz 2. wall filter settings: 3 steps (5%, %10%, 15% PRF) 3. gain control: 40 dB 4. angle steering for linear probes: ±25° 5. real-time spatial filter: 4 values 6. CFM palette: 10 maps 7. B/Color priority control 8. color threshold control 9. CFM baseline control 10. Doppler frequency selection: 2-3 frequencies for each probe 11. color frame averaging: 8 values
DEPTH SELECTION
1. 2 – 30 cm (depth range depends on probe type)
PROBES
1. from 1.5 MHz to 18 MHz 2. Multi-frequency 3. Automatic probe recognition

FOCUSING

1. transmit: variable, 8 zones
2. receive: point to point, dynamic

SIGNAL PROCESSING

1. lines density control for better resolution
2. TGC control
3. dynamic range
4. overall gain control
5. M - mode sweep speed control
6. acoustic power control
7. variable frame averaging
8. brightness, contrast
9. advanced gamma control: 8 fixed curves, 8 user defined (custom)
10. scan direction, rotation, up-down controls
11. negative / positive control
12. bi-linear interpolation
13. echo enhancement control
14. noise rejection function
15. speckle reduction function

FUNCTIONS

General Measurements and Calculations	7. Mouse / trackball / keyboard operation of multiple calipers 8. B-mode: Distance / Length / Area / Circumference / Volume / Angle / Stenosis % / A/B Ratio 9. M-mode: Distance / Time / Velocity / Heart Rate / Stenosis % / A/B Ratio
Human Measurements and Calculations Packages	10. General calculations package 11. Obstetrics / Gynecology (OB / GYN) calculations package 12. Gynecology (GYN) 13. Abdominal exam measurements and calculations 14. Urology 15. Endocrinology 16. Vascular exam measurements and calculations 17. Cardiology
User Interface	18. The set of predefined skin schemes for user interface 19. User-friendly pop-up menus and dialog boxes 20. Unlimited programmable presets for clinically specific imaging 21. Image comment / save / recall browsing 22. Anatomical icons with probe position indicator
Image and video save / load	23. JPG BMP PNG TIF AVI DCM DCM-JPG TVD TPD
Cine	24. Recording up to 2048 frames to memory 25. Play / Pause / Stop / Frame selection 26. Saving ultrasound video file to disk 27. Loading ultrasound video file from disk

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Printing	28. System printer
Internet	29. Direct E-mail sending function with image or video attachment
TV output	30. Standard TV output using computer's display adapter (option)
ULTRASOUND SOFTWARE	
Drivers	31. TELEMED Drivers Package
Software	32. Echo Wave II software (B/W + Doppler modes)
DIMENSIONS AND WEIGHT	
Dimensions W x D x H, mm	136 x 189 x 28
Weight, kg	0.77
POWER	
12 VDC 2.5 A	33. External AC medical grade power supply (100-240 VAC, 50-60 Hz)
SAFETY	
Electromechanical safety	34. IEC 60601-1 Medical electrical equipment part 1: General requirements for safety. Class I Type BF applied part
EMC/EMI standards	35. 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	36. CEI/IEC 61157:1992, International Electrotechnical Commission, Requirements for The Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment. 37. AIUM/NEMA: Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.1992.
Degree of protection (watertight)	38. Main unit IPX1 39. Transducers IPX7 (only the area of the transducer array acoustic window)
OPERATIONAL ENVIRONMENT	
Nominal operational environment	40. Environment temperature : 10 - 40 ° C 41. Relative humidity not to exceed: 85 % 42. Atmospheric pressure: 70 - 106 kPa

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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 I 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).

The electrical specification is shown below and is labeled on the rear panel of scanner.

To avoid electrical shock only use the supplied cables and connect it to properly earthed power socket. Do not use a three pin - two pin adapter. This defeats the whole purpose of earthing for safety reasons. Systems should be operated within the voltage limits.

If the ultrasound scanner will be moved or left unused for a long period of time without being switched on it is recommended that it be disconnected from power supply. If a scanner is to be switched on, do not interrupt this while operating the

system and while the ultrasound software is being loaded. The time for this operation is approximately 1 minute.

To avoid the risk of electrical shock and fire hazard:

43. before using the probe, inspect the probe face, housing, and cable and do not use the probe if the probe or the cable is damaged;
44. always disconnect the AC power supply from the system before cleaning the system;
45. do not use any probe that has been immersed beyond the specified cleaning or disinfection level;
46. inspect the power supply, AC power supply cable and electrical plug on a regular basis to ensure they are not damaged;
47. do not connect non-original AC power supply, not supplied by TELEMED;
48. only use accessories and peripherals recommended by TELEMED.

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WARNING:
To avoid the risk of electrical shock do not open the cover of device/blocks. There are no parts that you can repair yourself. In case of difficulties please contact the TELEMED service department or your nearest local authorized distributor.

2.2. Equipment protection

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

49. excessive bending or twisting of electrical cables can cause a failure or intermittent operation;
50. incorrect cleaning or disinfecting of any system part can cause permanent damage, for cleaning and disinfecting instructions see the relevant chapter below;
51. do not use solvents such as thinners/benzene or abrasive cleaners on any parts of the system;
52. do not spill liquids on the system;
53. incorrect assembly or configuration and using an incorrect power source may damage the system.

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

2.3. Biological safety

WARNING: Some probe 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 probes do not contain natural rubber latex that contacts humans.

Observe the following precautions related to biological safety:

54. do not use the system if it displays erratic or inconsistent behavior;
55. interruptions to the scanning sequence are signs of hardware failure that must be corrected before use;
56. do not use the system if it displays artifacts on the LCD screen, either within the clinical image or on the area outside it;
57. artifacts are indications of hardware and/or software errors that must be corrected before use;
58. perform ultrasound procedures prudently, use the ALARA (As low As Reasonably Achievable) principle (see **APPENDIX: Guidelines for the safe use of diagnostic ultrasound**);
59. 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.

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2.4. Ultrasound exposure and ALARA principle

Perform ultrasound procedures prudently, use the ALARA (As low As Reasonably Achievable) principle (see ***APPENDIX: Guidelines for the safe use of diagnostic ultrasound***).

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

60. acoustic output control,
61. transmit frequency;
62. scanning depth;
63. transmit focal length;
64. scanning angle.

Acoustic output also 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 the highest acoustic output.

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

This default level is set:

65. when the system is first turned on;
66. when the probe is first turned on.

It is highly recommended to set the default level:

67. when changing from one exam category to another;
68. when changing from one application to another;
69. when changing from one probe to another;
70. 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. Whenever possible, controls and system features should be

used to optimize the image before increasing the acoustic output level. Follow the ALARA principle during all patient examinations.

The **ArtUs** devices employ the ALARA principle in configuring factory defaults.

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

Ultrasound waves used in diagnostic system have frequencies ranging from 2 MHz to 18 MHz. Sound waves with such frequencies are weakened in the air, so can be measured, for example, in water. Ultrasound waves sent by a converter are so weak (medium intensity less than 100 mW/cm²), that, according to International Electrotechnical Commission (IEC 1157) standards (well within AIUM/NEMA standards), they do not have any impact on patient health (however any unnecessary exposure should be avoided).

Detailed information is found in
APPENDIX*: *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. Store only relevant and necessary software on working computers.

Network administrators in healthcare organizations and information technology providers should assure an adequate degree of protection from threats such as viruses and worms to avoid the risk of any unauthorized access to the network or the medical device/database. Please share with your local administrator detailed settings information from this document section **"Windows configuring"**.

2.5.1 Information Security

When entering and saving data it is your responsibility to protect your security credentials and the personal information of patients.

2.5.2 Network Security

Use a network supporting Wi-Fi 802.11n and WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as your security protocol.

Refer to your network equipment documentation for setting wireless network security.

Do not use an untrusted wireless access points, it may allow third party to perform harmful actions. When no secure access point is available, operate in Wi-Fi Direct mode – it will automatically set up encryption.

For security purposes:

71. Use secure passwords
72. Use secure protocols, secure wireless equipment with the latest firmware/software
73. Lock your PC

The following actions could introduce new risks to patients, operators and third parties:

74. Changing network configuration
75. Connecting to additional networks or disconnecting from existing networks
76. Upgrading to new equipment or updating existing equipment

2.5.3 Confidentiality

If you want the data encrypted, connect to a:

77. Wi-Fi network where only trusted parties are permitted. The Wi-Fi network encrypts all image data sent from other Wi-Fi networks.
78. Wi-Fi Direct network. The Wi-Fi Direct network encrypts all image data, and because no other users are on the Wi-Fi Direct network, the image data is confidential. Because Wi-Fi Direct network is a peer-to-peer connection using the Wi-Fi protocol, it disallows other users from connecting, thereby reducing DDOS (Distributed Denial of Service) attacks.

2.5.4 Integrity

Integrity of the data transmitted between the device and network is assured as follows:

79. Authenticated encryption prevents malicious users from intercepting and modifying data.
80. TCP channels used over Wi-Fi ensures that data is delivered correctly.

2.5.5 Accountability

Ownership (i.e. the active user) of a PC is assigned to one user at a time. Once you begin using the PC, no other user can connect to the same device. All data transmitted between the device and network is owned by the active user.

2.6. Accuracy Measures

WARNING:

Clinical diagnostic errors may result from the incorrect 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 calculations. Calculation formulas and databases are provided as a tool to assist the user and should not be considered as an undisputed database when making a clinical diagnosis.

The accuracy of measurements is determined not only by the TELEMED Echo Wave II software but also by the 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:

81. Velocity of sound is constant - 1540 m/s
82. Velocity of sound uncertainty is 5%

83. Caliper placement accuracy is one pixel (operator dependent)
84. Measurement accuracy is based on the root-mean-square combination of all independent sources of error
85. 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	< ±5% or 1mm	Acquisition	Phantom**	0.1-20 cm
Lateral Distance	< ±5% or 1mm	Acquisition	Phantom**	0.1-20 cm
Diagonal Distance	< ±5% or 1mm	Acquisition	Phantom**	0.1-20 cm
Area *** Trace & Ellipse	< ±4% plus 1% of full scale*	Acquisition	Phantom**	0.1-1000 cm^2
Circumference ****	< ±3% plus 1% of full scale*	Acquisition	Phantom**	0.1-70 cm
Angle	< ±5%	Acquisition	Phantom**	0 -180º

* 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 + lateral error) * (1 + 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 = ((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	< ±5% or 1mm	Acquisition	Phantom **	0.1-20 cm
Time	< ±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.

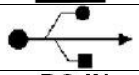
Other Measurement and Calculation Accuracy

Parameter		**System Tolerance**	**Reference / Formula**
Volume		< ±9%	4.2.3 Perimeter, square and volume measurements by Ellipse method
Fetus Weight	1 method	< ±16%	4.5.1 Hadlock85 (USA)
	2 method	< ±12%	4.5.2 Shepard82 (EU)
	3 method	< ±17%	4.5.3 Tokyo
	4 method	< ±16%	4.5.4 Osaka
Left Ventricle Volume	1 method	< ±15%	4.6.2 Cubed
	2 method	< ±11%	4.6.2 Pombo
	3 method	< ±13%	4.6.2 Teichholz
Stroke Volume		< ±15%	4.6.3 Stroke Volume
Ejection Fraction		< ±12%	4.6.4 Ejection Fraction
Cardiac Output		< ±15%	4.6.5 Cardiac Output
Left Ventricle Internal Dimension Fractional Shortening		< ±10%	4.6.6 Left Ventricle Internal Dimension Fractional Shortening
Aortic Valve Measurements and Calculations		< ±8%	4.6.7 Aortic Valve Measurements and Calculations

3. LABELING

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

Table 2

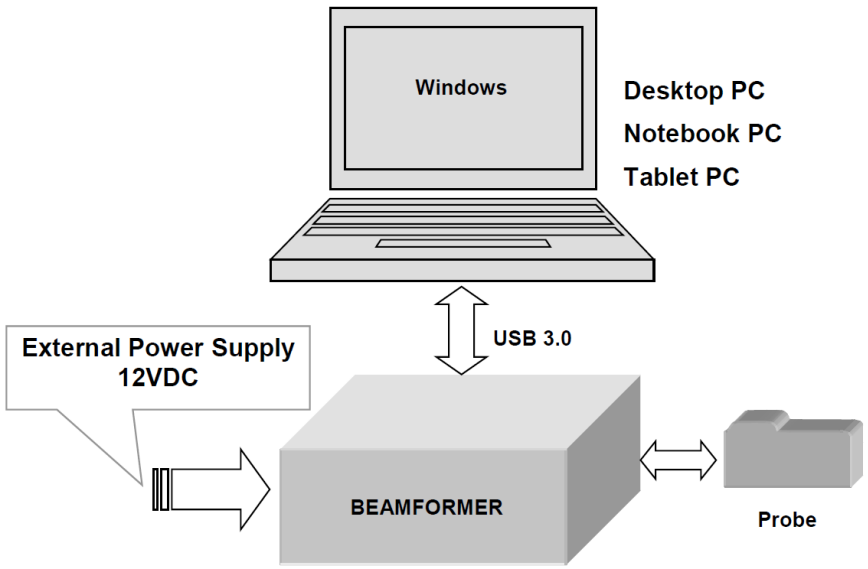
LABEL/SYMBOL	DESCRIPTION	LOCATION
CE	**CE mark** This mark is a declaration by the manufacturer that the respective component complies with the relevant directives and standards as issued by the European Union.	Rear panel (rating plate label)
	**Type BF Equipment** (man symbol) IEC 878-02-03 indicates BF type equipment which provides a particular degree of protection against electric shocks, particularly regarding allowable LEAKAGE CURRENT and reliability of the PROTECTIVE EARTH CONNECTION if present.	External (probe outlet)
	**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	Rear panel (along with rating plate label)
	**Consult instructions for use** This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device	Rear panel (along with rating plate label)
	The symbol indicating separate collection for electrical and electronic equipment (Annex IV of Directive 2002/96/EC)	Rear/bottom panel
	USB connector	Rear panel
DC IN 12V	DC power input	Rear panel
	Manufacturer name and address	ID Label
REF	Model / Catalogue number	ID Label
	Date of manufacture **YEAR -MONTH- DAY**	ID Label
IPX7	Protection (watertight, only the area of the probe acoustic window)	Probe
 (01)04772057000116 (21)3971-170615-0143	UDI GS1 Data Matrix 2D barcode	ID Label Probe

4. SYSTEM OVERVIEW

The **ArtUs EXT-1H** system handles the multi-element probes.

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

86. Beamformer
87. Ultrasound Probe
88. Personal Computer (Desktop / Notebook / Tablet PC)
89. powered from
90. Power Supply +12VDC



4.1. Principle of operation

The 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. The 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

4.2.1. Basic unit / Beamformer

Basic unit functions are:

91. excite electric pulses to fire the probe;
92. ultrasound echo signals pre-amplification;

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93. compensation of the ultrasound attenuation due to travel depth;
94. re-ordering the receiving signal sequence and focusing by applying the appropriate time delays;
95. shifting the center frequency of BPF (band pass filter) to follow the frequency shift that occurs according to the travel depth;
96. the ultrasound signal compression by means of Log Amplifier, detection of the echo signal envelope

4.2.2. Probe Unit

The probe unit is a piezoelectric transformer which provides the acoustical pulse used to examine the medium and is used for both transmission and reception (the transducer is used in pulse-echo mode). A voltage waveform is applied to the transducer and then converted into an acoustic waveform (inverse piezoelectric effect). An acoustic pulse is then partially transmitted and partially reflected by the 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 of many piezoelectric elements. The probe enclosure has a relief to affix the scanning direction.

Probe Type **Order Code**	**System Frequencies, MHz**	**Radius / Length, mm**	**Abdominal**	**Cardiac**	**Obstetric**	**Paediatric**	**Small Parts**	**Transrectal**	**Transvaginal**	**Vascular**	**Veterinary**
C5-2H60-A5	2-5	60	●		●	●					
L12-5N40-A4	5-12	40				●	●			●	●
L15-7H40-A5	7-15	40				●	●			●	●
L18-10H30H-A4	10-18	30				●	●			●	
P5-1S15-A6	1-5	-	●	●							
LV8-5N60-A2	5-8	60									●

4.3. Peripherals/Compatibility

ArtUs EXT-1H scanner can work / operate with standard PC features:

97. mouse
98. keyboard
99. SVGA monitor
100. Laser printer 600 dpi, (preferred HP printers), optional

Optional accessories:

101. Image Processing Packages
    a. 3DView
    b. PanoView
102. Additional Probes
103. Probes Carrying Cases
104. Biopsy Clip Bracket C- type (for convex probes)
105. Biopsy Clip Bracket HL- type (for linear probes)
106. PV-Biopsy Clip Bracket PV-type (for microconvex probes)

5. INSTALLATION WARNINGS

107. The ultrasound scanner should be installed in the premises specifically intended for such use such as an ultrasound scanner lab with an area not less than 10 m^2 and with window coverings to provide some diffused lighting.
108. Power supply cables and other accessories used with the device should be delivered by the manufacturer or be the same type as according to the specification.
109. To work correctly and to ensure excellent effects please use the complete set completed as recommended by the manufacturer.
110. Do not connect too many electrical devices to the same power source. It may cause problems working with the device or even lead to failure of the device.
111. The device is still powered up when connected to a power source even if switched off.
112. Any changes made to the ultrasound scanner by users are prohibited and may result in the guarantee no longer being valid.
113. Always disconnect the scanner from the power supply in the event of:
    - 114. Failure of the power supply cable;
    - 115. Device being dropped;
    - 116. Fails to work correctly;
    - 117. Strange noises or smoke coming from the cover.
118. Damage of the scanner due to incorrect use may mean that the guarantee no longer applies.
119. Do not subject the device to excessive temperatures.
120. When moving the scanner from a cold to a warm place please wait for 0,5 to 1 hour before switching on the device. This is necessary because of water condensation which may form on electronic parts.
121. Do not use the scanner close to any moisture source or in place with high humidity.
122. Do not use compressed air or vacuum cleaners when cleaning the device.
123. Do not drop, hit or shake the device.
124. Take care when working with ultrasound probes. Probes should be cleaned after work removing any gel and other deposits. Do not use any aggressive chemicals. To increase the lifespan of probes always leave them after work with freeze acquisition.
125. Probe changing should only be done during FREEZE mode or POWER OFF mode.
126. Ultrasonic waves have a low level of transmission in air and gases inside the living body. If air is present between the probe and the skin the examination may be impossible to perform.
    - a. It is therefore necessary to apply an acoustic coupler (special gel, olive oil, liquid paraffin, etc.) so that the probe sticks to the skin.
    - b. It is also impossible to examine regions of the body which contain gases or air such as the lungs.
127. The quality of an ultrasound diagnosis depends on where the scan cut is set.
    - a. Before starting an examination, carefully consider where to set the cut to be scanned by the probe so that the region to be examined can be precisely localized by the ultrasound.

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128. If you have any questions or suggestions about this diagnostic system please contact TELEMED Company.

NOTES:

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

5.1. Getting started with

We recommend such PC configuration:

129. IBM PC compatible Desktop/Notebook/Tablet PC
130. Intel chipset based motherboard with integrated USB 2.0 controller
131. CPU Intel Core i5/i7 1.8 GHz or faster
132. 2 GB of RAM or more
133. NVIDIA graphic card, 256 Mb, CUDA 2.3 support
134. USB 3.0/3.1 interface
135. Bluetooth LE v4.0+
136. Wi-Fi 802.11n and Wi-Fi Direct
137. TCO certified monitor with screen resolution 1024x768 or more, IPS or PLS technology
138. Certified for medical use computer power supply
139. Microsoft Windows® 7, Windows® 8, Windows® 10 (all versions 32/64-bit) operating system

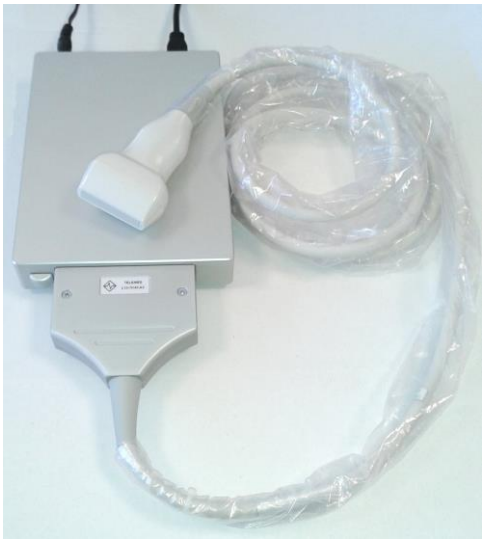
Before installation please read information from web:

ftp://213.197.173.186/Public/Software/TELEMED%20Drivers%20Package/readme.txt
ftp://213.197.173.186/Public/Software/Echo%20Wave%20II%20LB2/readme.txt

Refer:

140. ECHO WAVE II Operation Manual
141. this User Guide
142. chapter 2.5 Cybersecurity
143. chapter 5.3 Windows configuring

Connect the power supply and USB cable. Insert the probe connector into the socket and turn the lock on (move towards probe connector) – please refer the picture below (according configuration for **ArtUs EXT-1H**).



Switch on the computer power and wait until Windows is ready.

Double click on the **Echo Wave II** icon displayed on the desktop. The ultrasound software now starts.

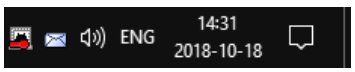
Note. Please observe the battery status (charging, battery volume etc) in the Windows system tray. If the system is battery powered, a warning will be displayed on the screen when only 15% is remaining. In such case you should charge the system before future use.

5.2. Ultrasound Scanner Monitor utility

Ultrasound Scanner Monitor utility is used for system status monitoring. In addition, this utility helps to see when and how the **ArtUs** is connected to the computer and to view the generated Log file.

144. Utility icon is located in the Windows system tray bar; here shown system tray image corresponds to Windows 10, in other Windows versions it may slightly differ;

145. When the icon is highlighted in RED – the drivers for the **ArtUs** beamformer have not been installed properly or the beamformer is not connected to the USB port;



146. When the icon is highlighted in GREEN – the drivers for the **ArtUs** beamformer are properly installed and the beamformer is connected to the USB port and the system is ready to start;

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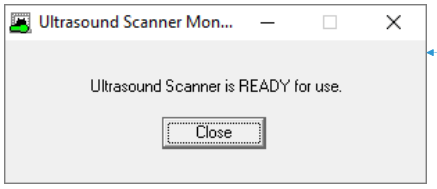
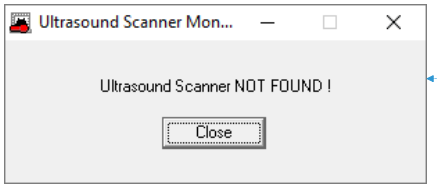
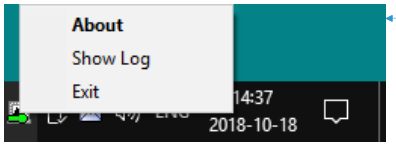
147. Using the left mouse button double click on the GREEN highlighted Ultrasound Scanner Monitor icon and this message will appear;

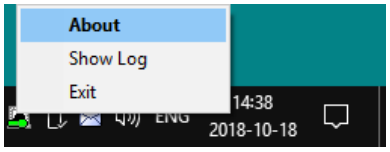


148. Using the left mouse button double click on the RED highlighted Ultrasound Scanner Monitor icon and this message will appear;

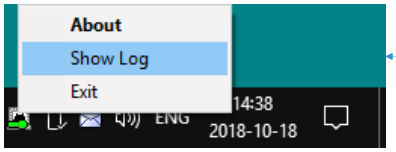


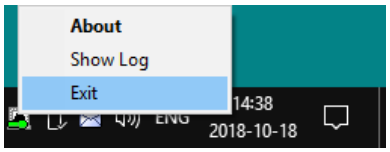
149. By clicking with the right mouse button on the Ultrasound Scanner Monitor icon an additional menu will appear;





150. By clicking on the left mouse button you can select About, Show Log and Exit menu items;





NOTE:
Do not unplug the power cable during the scan mode. Doing this may cause damage to the scanner. Exit the software and only unplug the power cable once this has been done.

5.3. Windows configuring

5.3.1 E-mail

Configure the E-mail program (for example, Microsoft Outlook Express, Mozilla Thunderbird). It is necessary for normal operation of the direct E-mail sending feature of the ultrasound software.

Note. There is no need to configure the E-mail software if you are not planning to use it or if your computer is not currently connected to the Internet.

5.3.2 Windows account

For each system user must be created Windows account with separate login and password.

151. Create a local user account
https://technet.microsoft.com/en-us/library/cc770642(v=ws.11).aspx
152. Create a user account in Windows
https://support.microsoft.com/en-us/help/13951/windows-create-user-account
153. User Accounts
https://technet.microsoft.com/en-us/library/dd277409.aspx

5.3.3 Windows security

It is strongly recommended that in Windows security will be strengthened using Security Policy Settings and monitored using Windows Security Audit.

154. How to Configure Security Policy Settings
https://technet.microsoft.com/en-us/library/dn135243(v=ws.10).aspx
155. Security Auditing Overview
https://technet.microsoft.com/en-us/library/dn319078(v=ws.11).aspx

5.3.4 Antivirus

It is strongly recommended that on computers will be installed antivirus software, for example, Microsoft Security Essentials, Windows Defender, and will be turned on its updates.

156. Microsoft Security Essentials Download
https://support.microsoft.com/en-us/help/14210/security-essentials-download
157. Windows Defender
https://support.microsoft.com/en-us/help/17464/windows-defender-help-protect-computer
158. Updating your Microsoft antimalware and antispyware software
https://www.microsoft.com/security/portal/definitions/adl.aspx

5.3.5 Firewall

It is strongly recommended that on computer will be turned on Windows Firewall.

159. How to Configure Windows Firewall on a Single Computer
https://msdn.microsoft.com/en-us/library/cc875811.aspx

5.3.6 Windows updates

It is strongly recommended that computers will have turned on Windows Updates.

160. Windows Update: FAQ
https://support.microsoft.com/en-us/help/12373/windows-update-faq

5.3.7 Network communication

It is strongly recommended that for network communication will be used secure Virtual Private Networks (VPN).

161. Virtual Private Networks
https://technet.microsoft.com/en-us/library/cc977889.aspx

5.3.8 Digital Signature

Ultrasound software distribution packages (setup(s)) and essential ultrasound software parts (drivers) are digitally signed.

This means that the user can check file properties and see if file signature (digital certificate) is valid and what company signed that file. 64-bit Windows operating systems does not load drivers that do not have signature or signature is invalid. This means that ultrasound scanning will not be started (driver will not be loaded) if it is modified by any malware.

162. Digital Signatures for Kernel Modules on Systems Running Windows Vista
https://msdn.microsoft.com/en-us/library/bb530195.aspx

163. Digital signatures and certificates
https://support.office.com/en-us/article/Digital-signatures-and-certificates-8186cd15-e7ac-4a16-8597-22bd163e8e96

5.3.9 Windows AppsLocker

It is strongly recommended that in Windows will be configured what applications can be run by what user(s) by using Windows AppLocker.

164. Windows AppLocker
https://technet.microsoft.com/en-us/library/dd759117(v=ws.11).aspx

5.3.10 Encrypted file system.

It is strongly recommended that computer data will be protected by using encrypted file system.

165. The Encrypting File System
https://technet.microsoft.com/en-us/library/cc700811.aspx

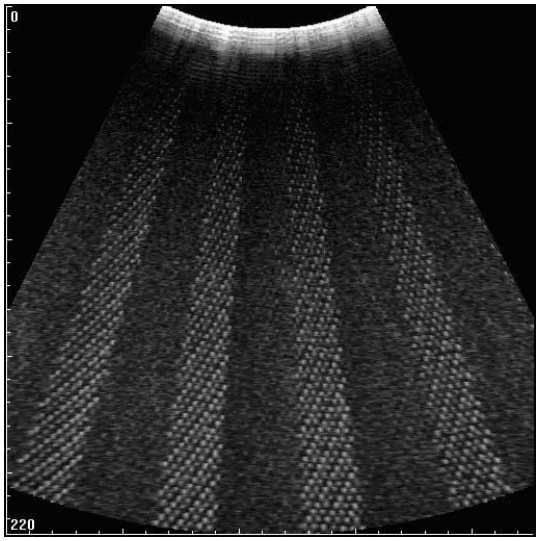
166. BitLocker
https://technet.microsoft.com/library/cc732774.aspx

6. TROUBLESHOOTING

Read this chapter carefully before calling the Technical Support service.

6.1. FAQ

Question. An increased level of noise and interference is observed on ultrasound images as shown at image below. What do I need to do in order to reduce the noise levels?



Answer. The reason for this appearance may be electronic equipment and devices which emit this type of electromagnetic noises. Please position ultrasound scanner, ultrasound probe and its cable at some distance from such equipment.

6.2. Contact with technical support service

If you encounter problems during the installation or during operation and you are still unable to solve them contact us via the support@telemed.lt E-mail address. First please send to technical support service the following information:

167. Scanner type (for example: **ArtUs EXT-1H**);
168. Serial number of the *scanner* (for example: 2351-120428-9686);
169. Probe type (for example: C5-2H60-A5);
170. Serial number of the *probe* (for example: 3241-120504-9701);
171. TELEMED Drivers Package version (for example: TELEMED Drivers Package 1.17.3);
172. Echo Wave II software version (for example: Echo Wave II 3.7.1);
173. Attached Log file generated by scanner (see section “Ultrasound Scanner Monitor utility”)

174. Also please start sysinfo.exe utility from Echo Wave II installation folder, wait while it will generate log and send this log to us. Usually the path to sysinfo.exe utility is as follows:

"C:\Program Files (x86)\TELEMED\Echo Wave II\sysinfo.exe" (on 64-bit Windows)

"C:\Program Files\TELEMED\Echo Wave II\sysinfo.exe" (on 32-bit Windows)

7. WARRANTY AND SERVICE INFORMATION

7.1. Warranty

TELEMED guarantees that the diagnostic system is free from defects regarding materials and workmanship at the original purchaser's location for a period of 24 months (the one exception being the probe which is guaranteed for 18 months). This guarantee or warranty covers parts for the full 24 months (or 18 months for probes) and labor for 90 days. In order to comply with this warranty, all service must be performed by a TELEMED qualified field engineer or only with the express permission of TELEMED. Items not included in this warranty are misuse, negligence or accidental damage. TELEMED wishes to point out that the loss of data loss is not included in this guarantee.

The foregoing warranty is exclusive of 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 obligations, liabilities, rights or claims, whether included in the contract or not, including any rights arising from negligence on the part of TELEMED for any direct, incidental, consequential or any other damages.

7.2. Warranty Shipments and Returns

175. A warranty claim must be made without delay and must be received during the applicable warranty (guarantee) period by TELEMED.
176. If it is necessary to return a product for repair and/or adjustment, prior authorization from TELEMED must be obtained first. Instructions as to how and where these products should be shipped will be provided by TELEMED.
177. Any product or component returned for examination and/or warranty repair shall be sent insured and 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.
178. In all cases, TELEMED has sole responsibility for determining the cause and nature of failure, and TELEMED decisions with regard to this shall be final.

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7.3. Service Contract

A service contract may be obtained for the TELEMED after the original warranty or guarantee 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 help us provide our customers with the best possible support please send your comments and suggestions to support@telemed.lt

8. 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

8.1. General cleaning

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

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

8.2. Inspecting the System

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

8.3. Probe maintenance and disinfection

All transducers are supplied as 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 may void the system warranty (guarantee) and service contract.

The following disinfectants are recommended for soaking or wiping:

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

NOTE:
Among the above-listed disinfectants, High level disinfectants can be applied to Endocavity probe, however Low level disinfectants are not appropriate for disinfects of Endocavity probe.
CAUTION: Customers must follow the disinfectant manufacturer instructions carefully.
Do not submerge transducers above strain relief.

8.3.1 Chemicals that Damage Transducers:

Some of these chemicals, such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide, are commonly found in clinics or hospital settings while others are often 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.

8.3.2 Recommended Procedures for Probe Processing

Inspect the probe cable, connector and the lens surface. Contacts on the probe connector must not be bent. The surface of probe lens must be clean without any remnants left. Check for any cracks which might allow liquids to enter the probe (especially joints such as cable/connector and cable/probe). If any such damage is found, do not use the probe until it is replaced.

Use care to avoid getting solution in the probe connector. Wrap the connector in the plastic bag to avoid contact between liquids and the connector.

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

Do not use alcohol or alcohol-based solutions. Thoroughly rinse all residues from the probe using sterile distilled water after removal from the germ killer. 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.

8.3.3 General Cleansing for Transducers Used in Non-Invasive Procedures

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

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

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

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

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

8.3.4 Cleansing and Disinfection of Transducers Used in Endocavity Procedures

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

The transducer disinfection should be done prior to the first exam, and following 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 buildups but the transducer however must not be rinsed or immersed near the strain relief.
3. Disinfection of the transducer and the cable with one of the disinfectants listed as Legally Marketed. During the disinfection it is necessary:
   179. avoid transducer contact with strong solvents such as acetone, freon, and other industrial cleansers.
   180. avoid soaking the transducer for extended periods of time, such as overnight.
   181. avoid rinsing or immersing 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 materials are present the disinfection of the transducer should be done again.

8.4. System accuracy / performance verification

System accuracy and performance verification should be conducted annually or if any doubts exist about image quality or distance estimation.

Use tissue mimicking phantoms for evaluation of accuracy and performance of the system. Refer to the 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 immersed in water or other special liquid for a short period of time (but not above strain relief).

NOTE:

The System was designed for sound velocity in tissues at 1540 m/sec. For accuracy verification phantoms which have been calibrated for this sound velocity should be used.

9. TRANSPORTATION, STORAGE AND UTILIZATION

9.1. Transportation and storage

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

9.2. Utilization

Utilization/recycling of this equipment should be carried out by a specialized company and be performed in accordance with local laws and legislation.

10. DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

CE 0482

We, **TELEMED UAB**

Highway Business Centre
Savanoriu pr. 178A
Vilnius, LT-03154
Lithuania

Declare under our sole responsibility that:

Equipment	**Ultrasound scanners**	**Probe**
	ArtUs EXT-1H	***C5-2H60-A5***
		L12-5N40-A4
		L15-7H40-A5
		L18-10H30H-A4
		P5-1S15-A6
		LV8-5N60-A2
Software	***Echo Wave II***	
Drivers	***TELEMED Drivers Package***	

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: 2005, Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2007, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-37:2007 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO-10993-1:2009, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process.
ISO-10993-5, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity , 1999
ISO-10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for irritation and skin sensitization
IEC 62304: 2006 Medical device software -- Software life cycle processes
ISO 14971:2012 Medical devices -- Application of risk management to medical devices
NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment - Revision 3.

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

MEDCERT GmbH Pilatuspool 2 20355 Hamburg, code: 0482

Date of issue: 13.10.2018

Dmitry Novikov, president

11. APPENDICES

11.1. Guidelines for the safe use of diagnostic ultrasound

~~A.~~182. Recommendations

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General

183. The use of diagnostic ultrasound to obtain information about functions or structures 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.

184. Situations such as training, demonstrations or research may also provide a medical benefit from diagnostic data and one that outweighs any foreseeable risk. Here, information is obtained for people who are not necessarily in the categories of Recommendation (1), above. During all training, demonstration or research situations, if either the Thermal Index or the Mechanical Index exceeds 1, then a subject should be informed of the anticipated exposure condition and how it compares regarding safety with conditions for normal diagnostic practice.

185. Ultrasound should not be used for any of the following:

- 186. obtaining pictures of the fetus solely for *non-medical* reasons;
- 187. learning the sex of the fetus solely for *non-medical* reasons;
- 188. for commercial purposes, such as trade shows, or producing pictures or videos of the fetus.

Thermal Effects

189. The M-mode is a valuable clinical tool and, despite any potential risks, is not contraindicated. Operators however should be careful to limit exposure to only vital structures and utilize the exposure information provided by the manufacturer.

190. In particular, users should employ exposures which are **As Low As Reasonably Achievable (ALARA)**[1] because of the potential for **ultrasonic heating** of tissues 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 the output controls or by reducing the **dwell time** which is the amount of time that the transducer remains in any one place.

Mechanical Effects

191. Users should employ exposures, regardless of the mode used, which are
As Low As Reasonably Achievable (ALARA) because of the potential for:

- 192. ultrasonically induced capillary hemorrhaging in lung tissues if it is exposed during pediatric diagnostic ultrasound examinations, particularly in the case of infants and neonates and especially if they are pre-term;

193. ultrasonically induced capillary hemorrhaging of the intestine where intestinal peristalsis is inhibited or conditions promote intraluminal or sub-mucosal gas collections;
194. ultrasonically induced capillary hemorrhaging in other soft tissues when Gas Contrast Agents are used.
195. Use of Gas Contrast Agents during a diagnostic ultrasound examination is not recommended within 24 hours before extracorporeal shock wave lithotripsy.
196. Exposure can be reduced by lowering the **Mechanical Index** using the 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**.

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

B.197. Conclusions

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General

198. 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 significantly outweigh the risk involved

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199. The conclusions listed below provide guidance as to the risks due to thermal and mechanical effects resulting from ultrasound exposure. To be useful, all the conclusions need to be taken into consideration.

Thermal Effects

200. 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 based on thermal grounds to limit such scanning for any clinical indication, including ultrasound examination of normally pregnant women.

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201. In all other operating modes, especially those used for Doppler blood flow examinations, the risk of injury from **ultrasonic heating** depends on the temperature elevation and the **dwell time** as indicated by the conclusions given below.
202. 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.

203. During the first trimester, and in the case of trans-abdominal fetal examinations through a bladder path greater than 5 cm in length, current 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** exceeds 1.

204. 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 principally made up of homogeneous soft tissue or a soft tissue/fluid path, as during a first trimester fetal examination or an abdominal examination.

205. If bone, including 2nd or 3rd trimester fetal bone, is within the ultrasound beam the **Bone Thermal Index (TIB)** is often the appropriate indicator, except as noted in the next conclusion.

206. If bone is in contact with the transducer the **Cranial Thermal Index (TIC)** is the appropriate indicator. If bone is within approximately 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 and heating of the transducer may add significantly to any **ultrasonic heating** which may occur.

207. Generally, more caution may be warranted for transvaginal, transesophegeal and transrectal examinations because heating of the transducer may potentially produce additional heat to adjacent tissue.

208. This conclusion and the following one provide guidance to the user if the temperature elevation in the fetus can possibly 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.

209. 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

210. At exposures that do not exceed the output limits recommended in the section entitled **Thermal effects**, there is no demonstrated risk of clinically significant damage in humans from the mechanical effects of ultrasound exposure during a diagnostic examination. However, capillary hemorrhaging has been observed in lungs and in 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.

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211. 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 affected, the potential for achieving clinical significance may increase in premature infants.

212. At the current maximum values for the **MI** of 1.9, it is unlikely that diagnostic ultrasound exposure could lead to clinically significant intestinal hemorrhaging in human beings. However, this likelihood may increase for pathologic conditions inhibiting intestinal peristalsis and promoting intraluminal and sub-mucosal gas collections.

213. A limited number of experimental studies suggest that the use of ultrasound gas contrast agents (GCAs or micro bubbles) during a diagnostic examination may potentially increase the likelihood of capillary hemorrhaging in tissues other than lung tissue. In animal experiments, the risk of significant hemorrhaging from lithotripter fields is increased for several hours after injection.

214. 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 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 regards 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):

215. 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,
216. 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,
217. 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 resulted in the development of encephalocoeles in the rat fetuses following 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 caused by ultrasound.

~~C.~~218. References

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Abbott, JG. Rationale and derivation of MI and TI - a review. Ultrasound in Med. and Biol. 25:431-441; 1999.

American Institute of Ultrasound in Medicine (AIUM). Bioeffects and safety of diagnostic ultrasound. Laurel, MD: AIUM Publications; 1993.

American Institute of Ultrasound in Medicine/National Electrical Manufacturers Association (AIUM/NEMA). Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 1. Laurel, MD: AIUM Publications; 1998a.

American Institute of Ultrasound in Medicine/National Electrical Manufacturers Association (AIUM/NEMA). Acoustic output measurement standard for diagnostic ultrasound equipment. Laurel, MD: AIUM Publications; 1998.

American Institute of Ultrasound in Medicine (AIUM). Medical ultrasound safety. Rockville, MD: AIUM Publications; 1994.

American Institute of Ultrasound in Medicine (AIUM). Standard Methods for Measuring Performance of Pulse Echo Ultrasound Imaging Equipment. Rockville, MD: AIUM Publications; 1991.

American Institute of Ultrasound in Medicine (AIUM). Methods for Measuring Performance of Pulse-Echo Ultrasound Equipment, Part II: Digital Methods. Rockville, MD: AIUM Publications; 1995a.

American Institute of Ultrasound in Medicine (AIUM). AIUM Quality Assurance Manual for Gray-Scale Ultrasound Scanners. Rockville, MD: AIUM Publications; 1995b.

American Institute of Ultrasound in Medicine (AIUM). Mechanical Bioeffects from Diagnostic Ultrasound: AIUM Consensus Statements. J. Ultrasound in Medicine 19: number 2; (February 2000). (Also available from AIUM Publications.)

Apfel, R.E. and Holland, C.K. Gauging the likelihood of cavitations from short-pulse, low duty cycle diagnostic ultrasound. Ultrasound in Med. and Biol. 17:179-185; 1991.

Barnett, S.B., ter Haar, G.R., Ziskin, M.C., Rott, H.D., Duck, F.A. and Maeda, K. International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine. Ultrasound in Med. and Biol. 26:355-366; 2000.

Bly, S.H.P., Vlahovich, S., Mabee, P.R. and Hussey, R.G. Computed estimates of maximum temperature elevations in fetal tissues during transabdominal pulsed Doppler examinations. Ultrasound in Med. and Biol. 18:389-397; 1992.

Carstensen, E.L., Duck, F.A., Meltzer, R.S., Schwarz, K.Q., Keller, B. Bioeffects in echocardiography. Echocardiography 6:605-623; 1992.

Child, S.Z., Hartman, C.L., McHale, L.A and E.L. Carstensen. Lung damage from exposure to pulsed ultrasound. Ultrasound in Med. and Biol. 16:817-825; 1990.

Dalecki, D., Raeman CH, Child SZ, *et al*, . The influence of contrast agents on hemorrhage produced by lithotripter fields. Ultrasound in Med. and Biol. 23:1435-1439; 1997.

Doody, C. Porter, H., Duck, F.A. and Humphrey, V.F. *In vitro* heating of human fetal vertebra by pulsed diagnostic ultrasound. Ultrasound in Med. and Biol. 25:1289-1294; 1999.

Duck, F.A., Starritt, H.C., ter Haar, G.R. and Lunt, M.J. Surface heating of diagnostic ultrasound transducers. Br. J. Radiology 67:1005-1013; 1989.

Duggan, P.M. and McCowan, L.M.E. Reference Ranges and Ultrasonographic Exposure Conditions for Pulsed Doppler Sonographic Studies of the Fetal Internal Carotid Artery. J Ultrasound in Medicine 12:719 - 722; 1993.

Henderson, J., Willson, K., Jago, J.R. and Whittingham, T. A survey of the acoustic outputs of diagnostic ultrasound equipment in current clinical use. Ultrasound in Med. and Biol. 21:699-705; 1995.

Holland, C.K., Deng, C.X., Apfel, R.E., Alderman, J.L., Fernandez, L.A., and Taylor, K.J.W. Direct evidence of cavitation *in vivo* from diagnostic ultrasound. Ultrasound in Med. and Biol. 22:917-925; 1996.

Lele, P.P. Local hyperthermia by ultrasound for cancer therapy. In: Nyborg, W.L.; Ziskin, M.C., eds. Biological effects of ultrasound. Clinics in diagnostic ultrasound, Vol.16. New York: Churchill Livingstone: 135-155; 1985.

Lopez, H. How to Interpret the Ultrasound Output Display Standard for Higher Acoustic Output Diagnostic Ultrasound Devices. J. Ultrasound in Medicine, Vol 17, pg 535 (1998).

Miller, D.L. and Gies, R.A. Gas-body-based contrast agent enhances vascular bioeffects of 1.09 MHz ultrasound on mouse intestine. Ultrasound in Med. and Biol. 24:1201-1208; 1998.

National Council on Radiation Protection and Measurements (NCRP). Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms. Bethesda, MD: NCRP; June 1, 1992.

National Council on Radiation Protection and Measurements (NCRP). Exposure criteria for medical diagnostic ultrasound: II. Criteria based on mechanical mechanisms. Bethesda, MD: NCRP; in preparation

O'Neill, T.P., Winkler, A.J. and Wu, J. Ultrasound heating in a tissue-bone phantom. Ultrasound in Med. and Biol. 20:579-588; 1994.

Patton, C.A., Harris, G.R. and Phillips, R.A. Output Levels and Bioeffects Indices from Diagnostic Ultrasound Exposure Data Reported to the FDA. IEEE Trans Ultras Ferro, Freq Cont 41:353-359; 1994.

Ramnarine, K.V., Nassiri, D.K., Pearce, J.M., Joseph, A.E.A., Patel, R.H. and Varma, T.R. Estimation of *in situ* ultrasound exposure during obstetric examinations. Ultrasound in Med. and Biol. 19:319-329; 1993.

Shaw, A., Preston, R.C. and Bond, A.D. Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data. NPL Report CIRA (EXT) 018; 1997.

Shaw, A., Pay, N.M. and Preston, R.C. Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stages II and III: experimental assessment of scanner/transducer combinations. NPL Report CMAM 12; 1998.

Siddiqi, T.A., O'Brien, W.D., Meyer, R.A., Sullivan, J.M. and Miodovnik, M. *In situ* human obstetrical ultrasound exposimetry: estimates of derating factors for each of three different tissue models. Ultrasound in Med. and Biol. 21:379-391; 1995.

U.S. Food and Drug Administration (FDA). Information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. Rockville, MD: FDA; Sept 30, 1997.

World Federation for Ultrasound in Medicine and Biology (WFUMB) WFUMB Symposium on Safety and Standardization in Medical Ultrasound, Chapter 1, ed., Barnett, S.B. and Kossoff, G. Ultrasound in Med. and Biol. 18:739-750; 1992.

World Federation for Ultrasound in Medicine and Biology (WFUMB) WFUMB Symposium on Safety of Ultrasound in Medicine. Conclusions and recommendations on thermal and non-thermal mechanisms for biological effects of ultrasound. ed., Barnett, S.B. Ultrasound in Med. and Biol. 24: Supplement 1, 1998.

~~D.~~219. Glossary of Terms

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ALARA (As Low As Reasonably Achievable): a principle which is used to reduce any unnecessary and 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 exposure that is or may be above thresholds for health effects. In these cases, ALARA refers to using the lowest value of potentially hazardous exposure, i.e. a 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 any 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 (MPa) 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.

11.2. Acoustic Output

11.2.1 L15-7H40-A5

Table 201.103 – Acoustic output reporting table

MODE: B-Mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.724	0.927		1.474		1.474
Index component value				0.927	0.927	1.474	0.927	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.098					
	P	(mW)		44.530		44.530		44.530
	P_{1x1}	(mW)		23.200		23.200		
	z_s	(cm)			0.110			
	z_b	(cm)					0.110	
	z_{MI}	(cm)	1.100					
	$z_{pii,\alpha}$	(cm)	1.100					
	f_{awf}	(MHz)	8.389	8.389		8.389		8.389
Other Information	prr	(Hz)	13536.000					
	srr	(Hz)	282.000					
	n_{pps}		1.000					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	145.150					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	305.855					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	578.188					
	p_r at z_{pii}	(MPa)	2.885					
Operating control conditions	282 Hz scan rate 1.91 cm scan length 48 lines per scan Focal depth 45 mm Frequency 10 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: M-Mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.338	0.051		0.159		0.066
Index component value				0.051	0.028	0.066	0.159	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.571					
	P	(mW)		1.504		1.504		1.504
	P_{1x1}	(mW)		1.504		1.504		
	z_s	(cm)			0.120			
	z_b	(cm)					0.120	
	z_{MI}	(cm)	1.2					
	$z_{pii,\alpha}$	(cm)	1.2					
	f_{awf}	(MHz)	7.119	7.119		7.119		7.119
Other Information	prr	(Hz)	512					
	srr	(Hz)	512					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	555.33					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	75.852					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	136.765					
	p_r at z_{pii}	(MPa)	4.795					
Operating control conditions	Focal depth 15 mm Frequency 7.5 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: B(B+M) sub-mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.724	0.927		1.474		1.474
Index component value				0.927	0.927	1.474	0.927	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.098					
	P	(mW)		44.530		44.530		44.530
	P_{1x1}	(mW)		23.200		23.200		
	z_s	(cm)			0.110			
	z_b	(cm)					0.110	
	z_{MI}	(cm)	1.100					
	$z_{pii,\alpha}$	(cm)	1.100					
	f_{awf}	(MHz)	8.389	8.389		8.389		8.389
Other Information	prr	(Hz)	13536.000					
	srr	(Hz)	282.000					
	n_{pps}		1.000					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	145.150					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	305.855					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	578.188					
	p_r at z_{pii}	(MPa)	2.885					
Operating control conditions	282 Hz scan rate 1.91 cm scan length 48 lines per scan Focal depth 45 mm Frequency 10 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,}$ apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: M(B+M) sub-mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.338	0.051		0.159		0.066
Index component value				0.051	0.028	0.066	0.159	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.571					
	P	(mW)		1.504		1.504		1.504
	P_{1x1}	(mW)		1.504		1.504		
	z_s	(cm)			0.120			
	z_b	(cm)					0.120	
	z_{MI}	(cm)	1.2					
	$z_{pii,\alpha}$	(cm)	1.2					
	f_{awf}	(MHz)	7.119	7.119		7.119		7.119
Other Information	prr	(Hz)	512					
	srr	(Hz)	512					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	555.33					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	75.852					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	136.765					
	p_r at z_{pii}	(MPa)	4.795					
Operating control conditions	Focal depth 15 mm Frequency 7.5 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: B+M

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.338	0.978		1.086		1.54
Index component value				0.978	0.955	1.54	1.086	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	3.571					
	P	(mW)		46.034		46.034		46.034
	P_{1x1}	(mW)		1.504		1.504		
	z_s	(cm)			0.120			
	z_b	(cm)					0.120	
	z_{MI}	(cm)	1.2					
	$z_{pii,\alpha}$	(cm)	1.2					
	f_{awf}	(MHz)	7.119	7.119		7.119		7.119
Other Information	prr	(Hz)	14048					
	srr	(Hz)	282					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	555.33					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	75.852					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	136.765					
	p_r at z_{pii}	(MPa)	4.795					
Operating control conditions	See contribution sub-mode tables							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: B(B+CFM) sub-mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.724	0.093		0.148		0.148
Index component value				0.093	0.093	0.148	0.093	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.098					
	P	(mW)		4.485		4.485		4.485
	P_{1x1}	(mW)		2.336		2.336		
	z_s	(cm)			0.11			
	z_b	(cm)					0.11	
	z_{MI}	(cm)	1.1					
	$z_{pii,\alpha}$	(cm)	1.1					
	f_{awf}	(MHz)	8.389	8.389		8.389		8.389
Other Information	*prr*	(Hz)	1363					
	srr	(Hz)	28.4					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	145.15					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	30.802					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	58.229					
	p_r at z_{pii}	(MPa)	2.885					
Operating control conditions	28.4 Hz scan rate 1.91 cm scan length 48 lines per scan Focal depth 45 mm Frequency 7.5 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: CFM(B+CFM) sub-mode

Index label			*MI*	*TIS*		*TIB*		*TIC*
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.805	1.985		2.487		2.487
Index component value				1.985	1.985	2.487	1.985	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.081					
	P	(mW)		62.297		62.297		62.297
	P_{1x1}	(mW)		62.297		62.297		
	z_s	(cm)			0.17			
	z_b	(cm)					0.17	
	z_{MI}	(cm)	1.7					
	$z_{pii,\alpha}$	(cm)	1.7					
	f_{awf}	(MHz)	6.69	6.69		6.69		6.69
Other Information	*prr*	(Hz)	11636					
	srr	(Hz)	283.8					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	270.47					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	3552.83					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	7787.16					
	p_r at z_{pii}	(MPa)	3.081					
Operating control conditions	11 packets 283.8 Hz scan rate 0.82 cm scan length 41 lines per scan Focal depth 19 mm Frequency 6.7 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Table 201.103 – Acoustic output reporting table

MODE: B+CFM

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.805	2.078		2.078		2.635
Index component value				2.078	2.078	2.635	2.078	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.081					
	P	(mW)		66.782		66.782		66.782
	P_{1x1}	(mW)		62.297		62.297		
	z_s	(cm)			0.17			
	z_b	(cm)					0.17	
	z_{MI}	(cm)	1.7					
	$z_{pii,\alpha}$	(cm)	1.7					
	f_{awf}	(MHz)	6.69	6.69		6.69		6.69
Other Information	prr	(Hz)	12999					
	srr	(Hz)	312.2					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	270.47					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	3552.83					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	7787.16					
	p_r at z_{pii}	(MPa)	3.081					
Operating control conditions	11 packets 283.8 Hz scan rate 0.82 cm scan length 41 lines per scan Focal depth 19 mm Frequency 6.7 MHz							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

11.3. Vigilance system

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

Therefore, if a 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 that you **immediately** inform the TELEMED office or local Competent Authority or our official dealer/distributor including sending us the following form (or reporting the same data contained in this form in some other manner) and **do not use** this device. All data relating to the system can be found on its identification label. In this way we will be able to take all adequate, opportune and effective actions.

Post-Marketing Vigilance Form

To: Quality Assurance Department
UAB "TELEMED"
Highway Business Centre
Savanoriu pr. 178A
Vilnius, LT-03154
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 _____

Email _____

Date _____ Signature _____

11.4. Returned product form

RETURNED PRODUCT №_____ 20__.____.____

COMPANY	
ADDRESS	
PRODUCT **□ TELEMED** **□ OTHER**	
SERIAL NUMBER	
REASON FOR RETURN	
INSTRUCTIONS	
REGISTERED BY	
NC REPORT №	
PROPERTY OF	**□ TELEMED □ CUSTOMER □ WARRANTY**
WARRANTY	**□ YES □ NO**

Rows to be filled by sender: ***COMPANY•ADDRESS•PRODUCT•SERIAL NUMBER•REASON OF RETURN***

REVISION HISTORY

REVISION	REVISION COMMENTS	ISSUE DATE
1.0	Initial release of the ArtUs EXT-1H User Guide	2018.10.18