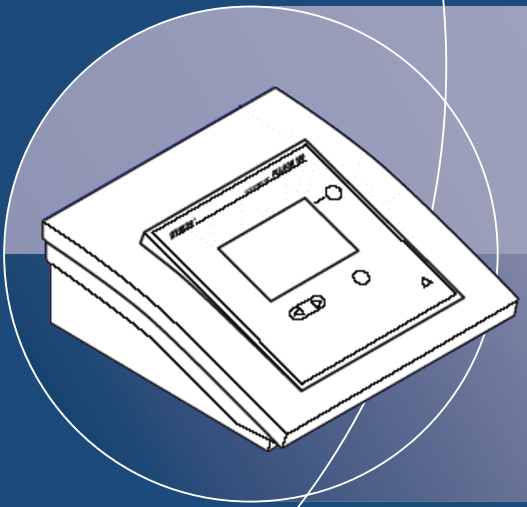
User Manual



Pulson 100

User Manual Pulson 100

Device for ultrasound therapy

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CE 0344

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Abbreviations

EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
HAC	Hospital Antiseptic Concentrate
US	Ultrasound

Symbols on the equipment

 Read the manual

 Manufacturer

Symbols in the manual

 Warning or important information.

TABLE OF CONTENTS

1 SAFETY

1.1 Purpose

The Pulson 100 is intended solely for medical applications. You can use the Pulson 100 for ultrasound therapy. The device is suited for continuous use.

1.2 Safety instructions

1.2.1 General

- Only qualified people who are trained in the application of the therapies may use the appliance.
- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories.
- Follow the instructions and directions in these user instructions.
- Place the equipment on a horizontal and stable base.
- Keep the ventilation openings at the bottom and rear of the equipment free.
- Do not place any objects on the equipment.
- Do not place the equipment in the sun or above a heat source.
- Do not use the equipment in a damp area.
- Do not let any liquid flow into the equipment.
- Do not disinfect or sterilise the equipment. Clean the equipment with a dry or moistened cloth. *See §5*.
- Only treat patients with electrical implants (pacemaker) after obtaining medical advice.
- The 'Directive on Medical Devices' from the European Commission (93/42/EEG) requires that safe devices are used. It is recommended to perform a yearly technical safety inspection. *See §5.1.2*.
- For optimum treatment, a patient investigation must first be performed. On the basis of the findings of the investigation, a treatment plan with objectives will be formulated. Follow the treatment plan during the therapy. This will limit possible risks, related to the treatment, to a minimum.
- Always keep these user instructions with the equipment.

1.2.2 Electrical safety

- Only use the equipment in an area with facilities that meet the applicable legal regulations.
- Connect the equipment to an outlet with a protective earth terminal. The outlet must meet the locally applicable requirements for medical areas.

1.2.3 Prevention of explosion

- Do not use the equipment in an area where combustible gases or vapours are present.
- Switch off the equipment when it is not used.

1.2.4 Electro Magnetic Compatibility

- Medical electrical equipment requires special precautions for Electro Magnetic Compatibility (EMC). Follow the instructions for the installation of the equipment. *See §2*
- Do not use mobile telephones or other radio, shortwave, or microwave equipment in the vicinity of the equipment. This kind of equipment can cause disturbances.
- Only use the accompanying accessories that are supplied by GymnaUniphy. *See §7.5 and §7.6*.
  Other accessories can lead to an increased emission or a reduced immunity.

1.2.5 Ultrasound therapy

- Move the US head evenly over the skin during the treatment. This prevents internal burns.
- The US treatment heads are exchangeable. The device detects the characteristics and supplies the right power at the right frequency.
- Handle the US heads carefully. With rough handling, the characteristics can change. Test the US head if it falls on the ground or knocks against something. *See §5.1.1*.
- Check the US head at least once a month. During the check, look for dents, cracks and other damage that could allow liquids to ingress. Check whether the insulation of the cable is still intact. Check whether all pins are present and straight in the connectors. Replace the US head if the head, the cable or the connector is damaged. *See §5.1*.

1.3 Medical Devices Directive

The device complies with the essential requirements of the Medical Device Directive of the European Committee (93/42/EEC) as most recently changed.

1.4 Liability

The manufacturer cannot be held liable for injury to the therapist, the patient or third parties, or for damage to or by the equipment used, if for example:

- an incorrect diagnosis is made;
- the equipment or the accessories are used incorrectly;
- the user instructions are wrongly interpreted or ignored;
- the equipment is badly maintained;
- maintenance or repairs are performed by people or organisations that are not authorised to do so by GymnaUniphy.

Neither the manufacturer nor the local GymnaUniphy dealer can be held liable, in any way whatsoever, for the transfer of infections by accessories.

2 INSTALLATION

2.1 Receipt

1. Check whether the equipment has been damaged during transport.
2. Check whether the accessories are intact and complete. *See §7.5 and §7.6*.
   - Inform your supplier of any damage or defects by no later than within 3 working days after receipt. Report the damage by telephone, fax, e-mail or letter.
   - Do not use the equipment if it is damaged or defective.

2.2 Placing and connection

1. Place the equipment on a horizontal and stable base.
   - Keep the ventilation openings at the bottom and rear of the equipment free.
   - Do not place the equipment in the sun or above a heat source.
   - Do not use the equipment in a wet area.
2. Check whether the mains voltage that is stated on the rear of the equipment corresponds with the voltage of your mains supply. The equipment is suited for a nominal mains voltage from 100 V to 240 VAC, 50/60 Hz.
3. Connect the device to an outlet with protective earth terminal.

2.3 Performing the functional test

1. Switch the equipment on with the switch at the rear of the equipment.
2. When the equipment is switched on, it automatically performs a test.

2.4 Transport and storage

Take account of the following matters if the equipment has to be transported or stored:

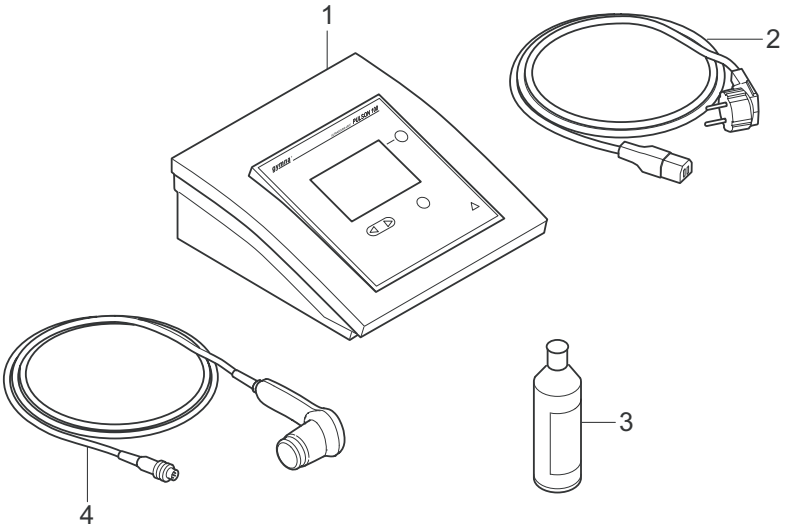
- Transport or store the equipment in the original packaging.
- The maximum period for transport or storage is: 15 weeks.
- Temperature: -20 °C to +60 °C.
- Relative humidity: 10% to 100%.
- Atmospheric pressure: 200 hPa to 1060 hPa.

2.5 Reselling

This medical equipment must be traceable. The equipment, the US head and some other accessories have a unique serial number. Provide the dealer with the name and address of the new owner.

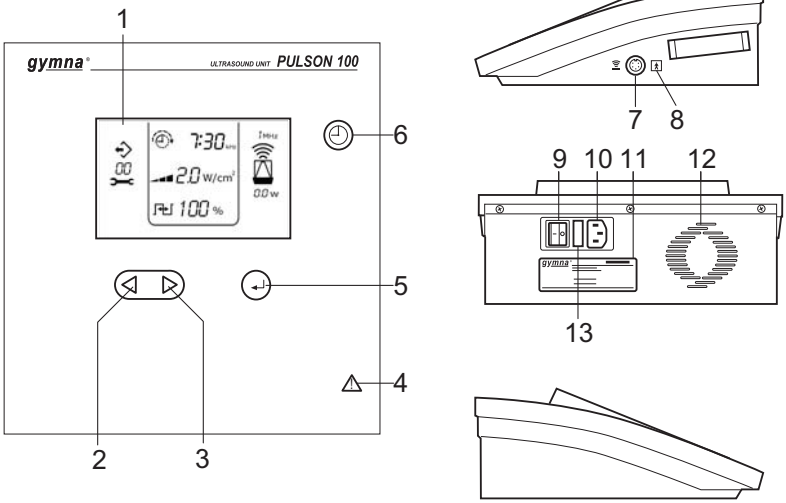
3 DESCRIPTION OF THE EQUIPMENT

3.1 Pulson 100 and standard accessories



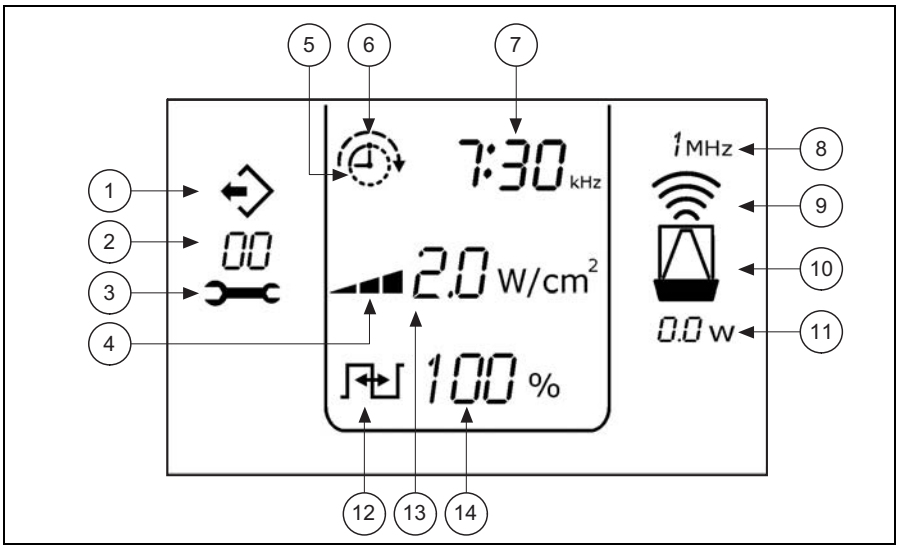
1. Pulson 100. *See §3.2*.
2. Power cord
3. Contact gel
4. US head

3.2 Components of the Pulson 100



1. Display. *See §3.3.*
2. Decrease the selected parameter
3. Increase the selected parameter
4. Indication: Read manual
5. Enter
6. Timer
7. Connector for US head
8. Indication: Floating patient circuit
9. On/off switch
10. Connection to mains supply
11. Type plate
12. Ventilation opening
13. Fuse holder

3.3 Display



1. Treatment mode
2. Program number/System settings number
3. System settings mode
4. Intensity symbol
5. Treatment time symbol
6. Timer on/off during bad US contact
7. Timer value
8. Ultrasound frequency
9. Ultrasound output indication
10. Type of US head
11. Ultrasound output power
12. Duty cycle symbol
13. Ultrasound intensity value
14. Duty cycle value

3.4 Display symbols


Program number


Treatment time


System settings


Ultrasound output


Timer Off during bad contact


US head 1 cm²


US head 4 cm²

3.5 Parameter symbols

 Intensity

W Output power

 Duty cycle

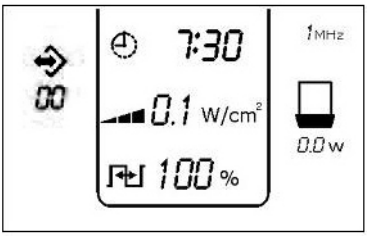
MHz Ultrasound frequency

4 OPERATION

4.1 Power up

The Pulson 100 starts up in program number 00 with the following parameters:

- Treatment Time: 7:30
- Intensity 0.1 W/cm2
- Duty cycle: 100%



The type of US head will be detected automatically by the Pulson 100. If no US head is connected, the symbols △ and □ are displayed alternating.
The Ultrasound frequency is fixed at 1 MHz.

4.2 Parameter setting

The parameter symbol blinks to indicate which parameter can be changed (program number, time, intensity, duty cycle).

- Press ◁ or ▷ to decrease or increase the parameter value.
- Press ↵ to confirm the value and select the next parameter.

4.2.1 Parameters

Program number (0 - 11)
The selected program number. See §9.1.2.
Every program number is related to an indication (See §9.1.2.) and contains advised parameter values. The parameter values of each program can still be changed.

Treatment time (mm:ss)
The duration of the treatment.
The value can be set in steps of 15 seconds.

Intensity (W/cm^2)
The power (W) of the US head per cm^2.
The value can be set in steps of 1.0 W/cm^2.

Duty cycle (10, 20, 30, 40, 50, 100%)
Ratio of the pulse duration to the period duration.

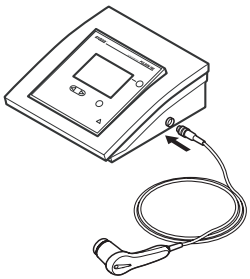
- 100%: Continuous ultrasound.
- 10, 20, 30, 40, 50%: Pulsating ultrasound.

4.3 Performing ultrasound therapy

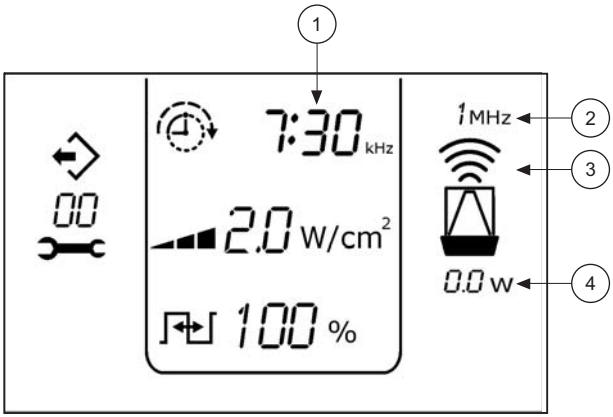
Move the US head evenly over the skin during the treatment. This prevents internal burns.

If no USTH is connected, the symbols and are displayed alternating. The treatment can not be started.

1. Plug the connector of the US head into the connector of the Pulson 100.
2. Select the desired program number. For the US head placement see §9.1.2. for the number in the placing diagrams.
3. Apply contact gel to the skin to be treated and to the US head.
4. Place the head on the skin.
5. Press . The Ultrasound treatment starts.
6. Move the US head evenly over the skin during the treatment. This prevents internal burns.
7. Check the patients reaction and the effect of the treatment. Repeat this check regularly during the treatment.
8. The equipment stops the treatment and indicates that the treatment is completed.



4.4 Read out values



1. Remaining treatment time.
2. Ultrasound frequency.
3. Ultrasound output symbol.
4. Output power.

Remaining treatment time (mm:ss)
Counts down during treatment

Ultrasound frequency
Fixed value: 1 MHz.

Ultrasound output symbol
- wave animation: good US contact.
- blinks: bad US contact.

Test the US head if the conduction is bad. Refer to §5.1.1.

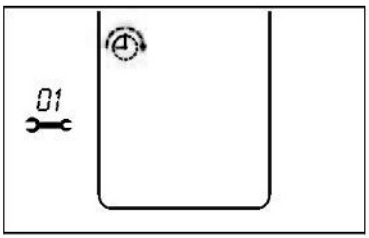
Output power (W)
The output power is the calculated value of Iset x ERA x duty cycle. The power therefore depends on the size of the US head and the contact with the skin.
This value is 0.0 W if the contact with the skin is bad. In this case, the ultrasound treatment of the equipment is stopped to prevent overheating of the transducer.

4.5 System settings

- Press and hold ↵ for 3 seconds to enter or leave the system settings menu.
- Press ↵ to confirm the value and to select the next system setting.

4.5.1 01: Stop time if bad US

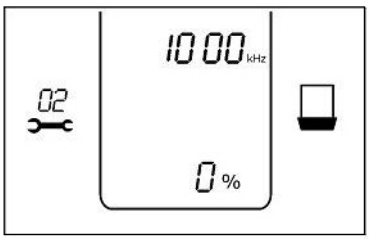
1. Press ◁ or ▷ to switch the parameter ON or OFF.
   - ON: the dashed arrow is visible. During bad US contact the timer will stop countdown (the arrow is only visible in system setting mode).
   - OFF: the dashed arrow is invisible. During bad US contact the timer will continue countdown.



4.5.2 02: Automatic Frequency tuning

The stored default frequency (kHz) is displayed.

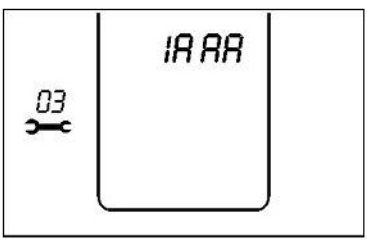
- US headsize △ or □ is displayed if a head is connected.
- If no US head is connected, the symbols △ and □ are displayed alternating.



1. Press ⏱ to start frequency tuning if a US head is connected. The %-value of the duty cycle counts up to 100%.
2. The tuned frequency value (kHz) is displayed.

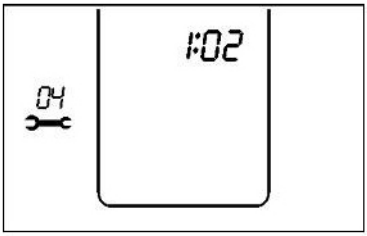
4.5.3 03: HW code

The hardware code of the main PCB is displayed.



4.5.4 04: SW code

The software-version is displayed.



5 INSPECTIONS AND MAINTENANCE

5.1 Inspections

Component	Check	Frequency
US head	Dents, cracks or other damage	At least 1x per month
	Test US head. See *§5.1.1*.	With bad operation or at least 1x per year
Cable of US head	Damage Pins in connector straight	At least 1x per month
Equipment	Technical safety inspection. See *§5.1.2*.	At least 1x per year

5.1.1 US head test

Test the US head if its conduction is bad. The conduction is bad if the Ultrasound indication blinks during treatment and the Pulson 100 generates a 'bad contact' sound.

1. Switch on the Pulson100.
2. Place the US head in a bowl with water.
3. Press 'timer' to start the treatment.
4. Check if the output power is increasing and the US symbol is in animation mode.
5. Press 'Intensity UP' to increase the output intensity to maximum.
6. Contact your local GymnaUniphy dealer in case of bad US contact.

5.1.2 Technical safety inspection

The 'Directive on Medical Devices' from the European Commission (93/42/EEG) requires that safe devices are used. It is recommended to perform a yearly technical safety inspection. If the legislation in your country or your insurer prescribes a shorter period, you must adhere to this shorter period.

- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories.
- The inspection may only be performed by a suitably qualified person. In some countries this means that the person must be accredited.

Inspection points
The technical safety inspection contains the following tests:
1. Test 1: General: Visual inspection and check on the operating functions
2. Test 2: Ultrasound therapy
3. Test 3: Electrical safety inspection: measurement of the earth leakage current and patient leakage current according to DIN/VDE 0751-1 ed. 2.0.

Inspection result
1. A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. See *§8.3*.
2. Copy this appendix.
3. Complete the copied appendix.
4. Keep the inspection reports for at least 10 years.

The inspection is successful if all inspection items are passed.
Repair all faults on the equipment before the equipment is put back into operation.
By comparing the registered measurement values with previous measurements, a possible slowly-deteriorating deviation can be ascertained.

5.2 Maintenance

Component	Check	Frequency
US head	Cleaning. See *§5.2.1*.	After each use

Accessories that come in contact with the body of the patient must be washed with pure water after the disinfection to prevent allergic reactions.

5.2.1 Cleaning the US head
1. Clean the US head with a lightly moistened soft cloth.
2. Disinfect the treatment surface with a cotton bud that is soaked in a 10% HAC solution.
3. Rinse the US head thoroughly with clean water.

6 MALFUNCTIONS, SERVICE AND GUARANTEE

6.1 Malfunctions

Component	Problem	Solution
Pulson 100	Equipment cannot be switched on	See *§6.1.1*.
	Equipment does not react to commands or a fault report appears	See *§6.1.3*.

6.1.1 Equipment cannot be switched on

1. Check if the mains voltage has failed.
2. Check if the main switch is switched on ("I").
3. Check if the power cord and the fuses are in order. If necessary, replace the fuse. See *§6.1.2*.
4. Contact your dealer if the equipment still cannot be switched on.

6.1.2 Replacing a fuse

1. Switch the main switch off ("O").
2. Unplug the power cord from the equipment.
3. Pull the fuse holder carefully out of the equipment. If necessary, use a screwdriver.
4. Replace the fuse. If necessary, order new fuses from your dealer.
5. Install the fuse holder and plug in the power cord.
6. Switch the main switch on again ("I").

6.1.3 Equipment does not react to commands

The safety system of the equipment has ascertained a fault. You cannot continue to work. An instruction usually appears on the screen.

1. Disconnect the connection to the patient.
2. Switch the main switch off ("O").
3. Wait 5 seconds and switch the main switch on again ("I").
4. Contact your dealer if the equipment still does not react to commands.

6.2 Service

- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories to perform repairs. The equipment does not contain any components that may be replaced by the user.
- If possible, open the screen with the system settings before you contact the technical service department. See *§4.5*.

Service and guarantee are provided by your local GymnaUniphy dealer. The conditions of delivery of your local GymnaUniphy dealer apply.
If you have qualified technical personnel that are authorised by GymnaUniphy to perform repairs, your dealer can provide diagrams, spare parts lists, calibration instructions, spare parts and other information on request, for a fee.

6.3 Guarantee

GymnaUniphy and the local GymnaUniphy dealer declares itself to be solely responsible for the correct operation when:

- all repairs, modifications, extensions or adjustments are performed by authorised people;
- the electrical installation of the relevant area meets the applicable legal regulations;
- the equipment is only used by suitably qualified people, according to these user instructions;
- the equipment is used for the purpose for which it is designed;
- maintenance of the device is regularly performed in the way prescribed. See *§5.*;
- the technical life time of the equipment and the accessories is not exceeded;
- the legal regulations with regard to the use of the equipment have been observed.

The guarantee period for the equipment is 2 (two) years, beginning on the date of purchase. The date on the purchase invoice acts as proof. This guarantee covers all material and production faults. Consumables do not fall under this guarantee period.

This guarantee does not apply to the repair of defects that are caused:

- by incorrect use of the equipment,
- by an incorrect interpretation or not accurately following these user instructions,
- by carelessness or misuse,
- as a consequence of maintenance or repairs performed by people or organisations that are not authorised to do so by the manufacturer.

6.4 Technical life time

The expected life time of the equipment is 10 years, calculated from the date of manufacture. See the type plate for this information.
In so far as possible, GymnaUniphy will supply service, spare parts and accessories for a period of 10 years from the date of manufacture.

7 TECHNICAL INFORMATION

7.1 General

Dimensions Pulson 100 (w x h x d)	266 x 275 x 100 mm
Weight Pulson 100	3,1 kg
Weight including accessories	4,15 kg
Mains voltage	100 - 240 VAC, 50/60 Hz
Maximum power, in operation	35 VA
Safety class	Class I (earthed socket required)
Insulation	Type BF (floating patient circuit)
Fuses	2 x T1AL250V

7.2 Ultrasound therapy

7.2.1 General

Insulation classification	Type BF
Peak power	0 - 2 W/cm^2, duty cycle = 100% 0 - 3 W/cm^2, duty cycle < 100%
Accuracy of intensity	± 10% of maximum at set values above 10% of this maximum
Treatment time	0 - 30 min.
Deviation of time clock	< 0,5%
Modulation frequency	100 Hz
Modulation type	CW (rectangular on/off)
Repetition period of pulses	10 ms

7.2.2 Modulation and pulse duration

Modulation duty cycle	**100**	**50**	**40**	**30**	**20**	**10**	**%**
Pulse time	∞	5	4	3	2	1	ms
Ratio of p_{tm} - p	1	2	2,50	3,33	5	10	

7.2.3 US heads

US head, model 104		
Acoustic operating frequency	**1,0**	**MHz**
Output power	8,0	W
Effective intensity of output voltage	2,0	W/cm^2
Effective Radiating Area (ERA)	4,0	cm^2
Beam Non-uniform Ratio (BNR)	5,1	
Maximum intensity of beam	10,2	W/cm^2
Beam type	Collimated	

US head, model 101		
Acoustic operating frequency	**1,0**	**MHz**
Output power	2,6	W
Effective intensity of output voltage	2,0	W/cm^2
Effective Radiating Area (ERA)	1,3	cm^2
Beam Non-uniform Ratio (BNR)	6,2	
Maximum intensity of beam	12,4	W/cm^2
Beam type	Divergent	

7.3 Environmental conditions

Temperature	+10 °C to +40 °C
Relative humidity	30% to 75%
Atmospheric pressure	700 hPa to 1060 hPa

7.4 Transport and storage

Transport weight	5,0 kg
Storage temperature	-20 °C to +60 °C
Relative humidity	10% to 100%, including condensation
Atmospheric pressure	200 hPa to 1060 hPa
Transport classification	Single piece, by post

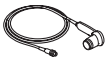
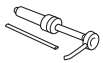
The transport and storage specifications apply to equipment in the original packaging.

7.5 Standard accessories

	Quantity	Description	Art. no.
	1	US head, 1 MHz - ERA 4 cm^2 incl. holder	332.310
	1	Contact gel, 500 ml	100.016
	1	Power cord[1]	100.689
	1	User manual	NL: 331.991 FR: 331.969 EN: 331.958 DE: 331.947 ES: 332.013 PT: 332.002 IT: 331.980
	1	US placing diagrams	117.277

1 This power cord has a CEE 7/7 type plug. For countries with other outlets, a different power cord with the appropriate plug is supplied.

7.6 Optional accessories

	Quantity	Description	Art. no.
	1	US head, 1 MHz - ERA 1 cm^2, incl. holder	332.321
	1	Contact gel, can 5 l	100.019
	1	Pump for can, 5 l	100.020

Article numbers can change in the course of time. Check the article numbers in the most recent catalogue or ask your dealer.
The drawings are merely indicative, no rights can be derived from them.

8 APPENDICES

8.1 EMC directive

Use only US heads that are specified in this manual. See *§7*. The use of other accessories can have a negative effect on the electromagnetic compatibility of the equipment.
If you use the Pulson 100 in the vicinity of other equipment, you must check that the Pulson 100 is functioning normally.
The following paragraphs contain information about the EMC properties of the equipment. Because this information is intended for technicians, the information is given in English.

8.1.1 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The 100-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 100-series device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The 100-series devices use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The 100-series devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The 100-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 100-series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact / ±8 kV air No loss of performance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV power / ±1 kV I/O No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV diff. / ±2 kV comm. No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	U_T - 100% (0,5 period) No loss of performance U_T - 60% (5 periods) No loss of performance U_T - 30% (25 periods) No loss of performance U_T - 100% (5 seconds) Device resets to a safe state. (60601-1 § 49.2)	Mains power quality should be that of a typical commercial or hospital environment. If the user of a 100-series device requires continued operation during power mains interruptions, it is recommended that the 100-series device be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration - electromagnetic immunity			
The 100-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 100-series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of a 100-series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V_{rms} AM 1 kHz 80% 150 kHz to 80 MHz	10 V.....0,15-80 Mhz 51 V.....6,78 Mhz 54 V.....13,56 Mhz 50 V.....27,12 Mhz 45 V.....40,68 Mhz	$d = 0,35\sqrt{p}$ $d = 0,07\sqrt{p}$ $d = 0,06\sqrt{p}$ $d = 0,07\sqrt{p}$ $d = 0,08\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m AM 1 kHz 80% 80 MHz to 2,5 GHz	10 V/m..0,08-1,0 Ghz 26 V/m....1,4-2,0 Ghz 30 V/m...433,92 Mhz 30 V/m.....915 Mhz	$d = 0,35\sqrt{p}$ 80 MHz to 800 MHz $d = 0,70\sqrt{p}$ 800 MHz to 2,5 GHz $d = 0,12\sqrt{p}$ $d = 0,23\sqrt{p}$
Radiated RF ENV 50204	3 V/m CW 200 Hz d.c. 50% 895 MHz to 905 MHz	30 V/m.895-905 Mhz	$d = 0,23\sqrt{p}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey can be considered. If the measured field strength in the location in which a 100-series device is used exceeds the applicable RF compliance level above, the 100-series devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 100-series device.
b Over the frequency range 150 kHz to 80 MHz, field strengths must be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the 100-series device

The 100-series device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of a 100-series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 100-series devices as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0,35\sqrt{p}$	80 MHz to 800 MHz $d = 0,35\sqrt{p}$	800 MHz to 2,5 GHz $d = 0,70\sqrt{p}$
0,01	0,04	0,04	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8.2 Technical safety inspection

Pulson 100 with serial number..... is / is not[1] in good working order		
	Inspection performed by:	Owner:
Location:	Name:	Name:
Date:	Initials:	Initials:

1 Cross out what does not apply.

If a specific test does not apply to this equipment, place a mark in the NA (not applicable) column.

8.2.1 Test 1: General

		Yes	No	NA
1.	The results of earlier safety inspections are available.	☐	☐	☐
2.	The logbook is present.	☐	☐	☐
3.	The type plate and the supplier's label are legible.	☐	☐	☐
4.	The housing, keys and display are undamaged.	☐	☐	☐
5.	The power connection and power cord are undamaged.	☐	☐	☐
6.	The output connectors are undamaged.	☐	☐	☐
7.	The cables and connectors of the US head(s) are undamaged.	☐	☐	☐
8.	The US head(s) do not display any cracks or other damage that can endanger the insulation.	☐	☐	☐
9.	The automatic self-test at switch-on does not give an error message.	☐	☐	☐
10.	The display does not show any defective points or lines.	☐	☐	☐

8.2.2 Test 2: Ultrasound

		Yes	No
1.	Connect the treatment head and place it in an ultrasound measurement device.		
2.	Select continuous (duty cycle 100%), 2 W/cm^2 The measured value is within ±20% of the output power value in the display.	☐	☐
3.	Select duty cycle 50%, 3 W/cm^2 The measured value is within ±20% of half the output power value in the display.	☐	☐
4.	Select duty cycle 50%, 0.5 W/cm^2 With a dry treatment surface, the output value becomes 0.0 W.	☐	☐

The maximum power transfer takes place at the operating frequencies. If the equipment does not function at the correct frequency, this results in a too low output power. It is therefore not necessary to check the operating frequencies.

8.2.3 Test 3: Electrical safety test (VDE 0751-01)

		Yes	No
1.	The resistance of the safety earth is less than 0.2 Ω	☐	☐
2.	The housing leakage current is less than 1000 µA	☐	☐
3.	The patient leakage current is less than 5000 µA	☐	☐

Notes:

8.3 Disposal

Take account of the following environmental aspects when disposing of the equipment and the accessories:

- The basic device and the cables fall under small chemical waste (electrical and electronic equipment waste). These components contain lead, tin, copper, iron, various other metals and various plastics, etc. Dispose according to national regulations.
- Gels contain only organic material and do not require any special processing.
- Packaging materials and manuals can be recycled. Deliver them to the appropriate collection points or include them with the normal household waste. This depends on the local organisation of the waste processing.

Notify your dealer about the disposal.

9 REFERENCE

9.1 Function overview

9.1.1 System settings

Press ↵ for 3 seconds
Timer On/Off during bad contact
Frequency tuning
HW code
SW code

9.1.2 Indication list

The head placement numbers refer to the numbers in the placing diagrams.

Indication	Program number	US head placement
Arthrosis, Chronic	1	US03, US16, US20, US25, US27
Arthrosis, Subacute	2	US03, US16, US20, US25, US27
Fractures	3	US40
Frozen shoulder	4	US01, US06, US12
Myalgia	5	US11, US13, US17, US18, US23
Neuropathy	6	US26, US32
Posttraum. diseases, Acute	7	US27, US37, US38, US39
Posttraum. diseases, Subacute	8	US27, US37, US38, US39
Scar tissue, Acute	9	None
Sprain, Acute	10	US03, US06, US09, US15, US16, US25, US27, US31
Sprain, Subacute	11	US03, US06, US09, US15, US16, US25, US27, US31

9.1.3 Contra indication

Ultrasound therapy

General

High fever
Severe cardiovascular problems
Psychological problems
Cancer with tumor metastasis
Generalised tuberculosis

Specific relative for pulsing ultrasound

Pacemaker
Pregnancy

Specific relative for continuous ultrasound

Infections
Acute inflammations
Thrombosis, thrombophlebitis
Varices
Increased risk to haemorrhage
Pacemaker
Epiphyseal disc (children)
Decreased sensibility
Menses
Cement of endoprosthesis
Diabetes mellitus

9.2 Literature

A literature list can be sent on request. Please contact GymnaUniphy.

10 INDEX

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