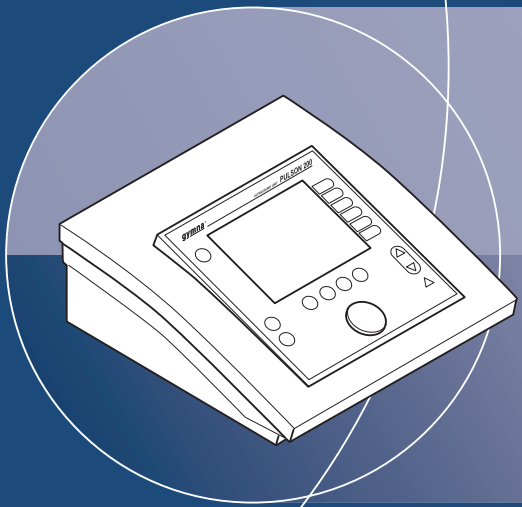
User Manual



PULSON 200

USER MANUAL PULSON 200

Device for ultrasound therapy

Manufacturer	GymnaUniphy N.V.
Main office	Pasweg 6A
	B-3740 BILZEN
Telephone	+(32) (0)89-510.510
Fax	+(32) (0)89-510.511
E-mail	info@gymna-uniphy.com
Website	www.gymna-uniphy.com

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gymna®

ABBREVIATIONS

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

SYMBOLS ON THE EQUIPMENT

Read the manual.

SYMBOLS IN THE MANUAL

Warning or important information.

TABLE OF CONTENTS

1 SAFETY

1.1 Purpose

The Pulson 200 is intended solely for medical applications. You can use the Pulson 200 for ultrasoundtherapy. 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 'Medical Devices Directive' 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 §7.6.**
  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 §7.6.
   - 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 Setting contrast and selecting language

1. Press ⮌ for 5 seconds The **System setting** menu appears. See §4.5.
2. Press ▭ next to **Contrast**, 1st key from the top.
3. If necessary, change the contrast with △ and ▽.
4. Press ▭ next to **Language**.
5. If necessary, change the language with △ and ▽.
6. Press ⮊ to return to the start menu.

2.5 Transport and storage

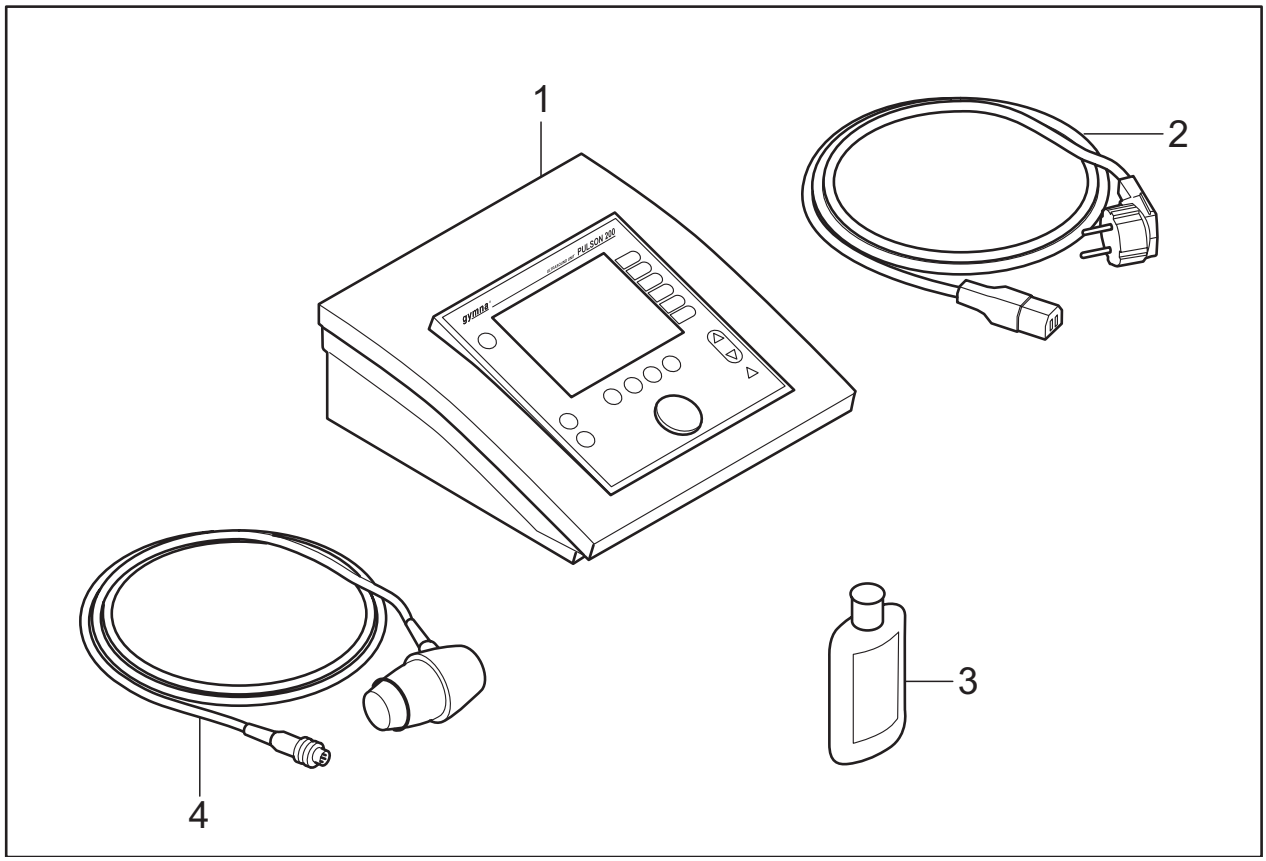
Take account of the following matters if the equipment has to be transported or stored:

- 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.

2.6 Reselling

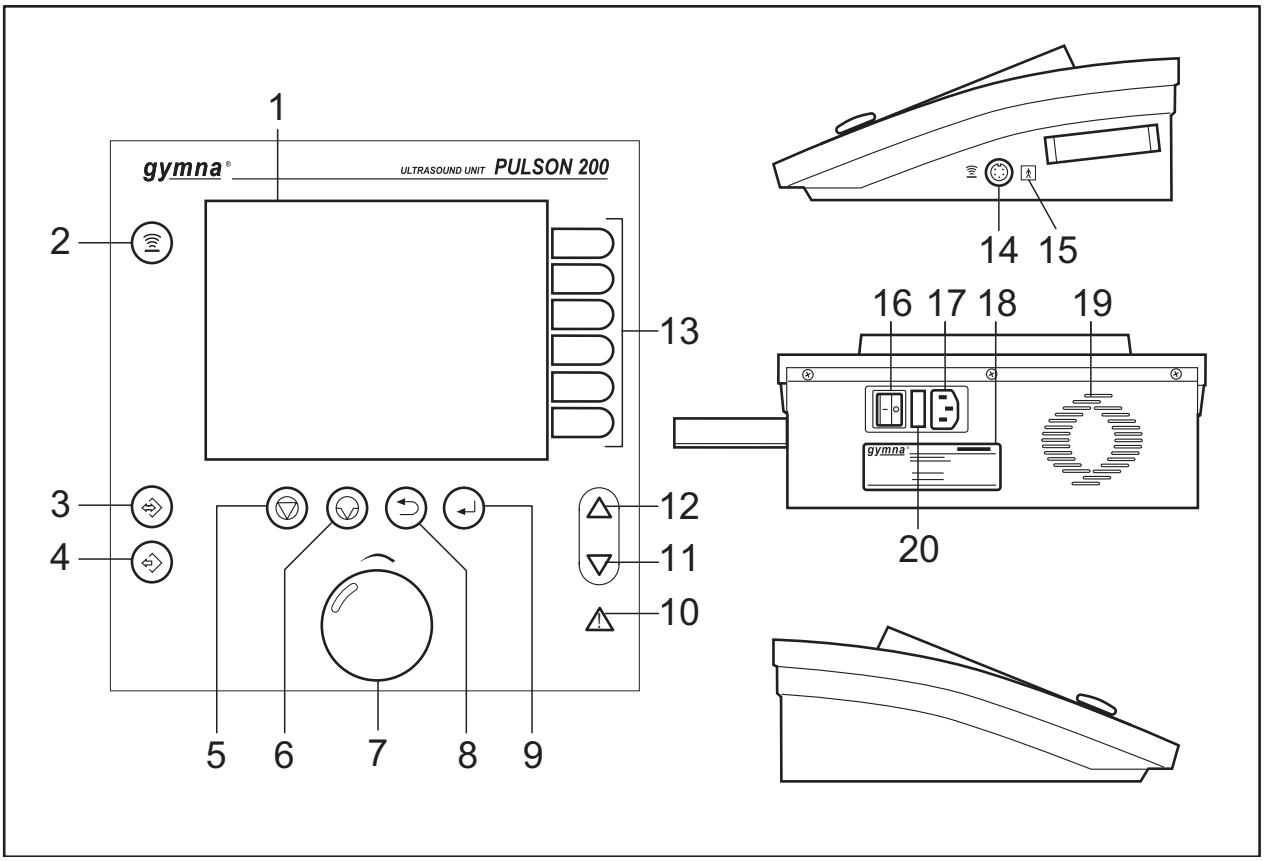
This medical equipment must be traceable. The equipment, the US head and some other accessories have a unique serial number. Provide the dealer with the name and address of the new owner.

3 DESCRIPTION OF THE EQUIPMENT



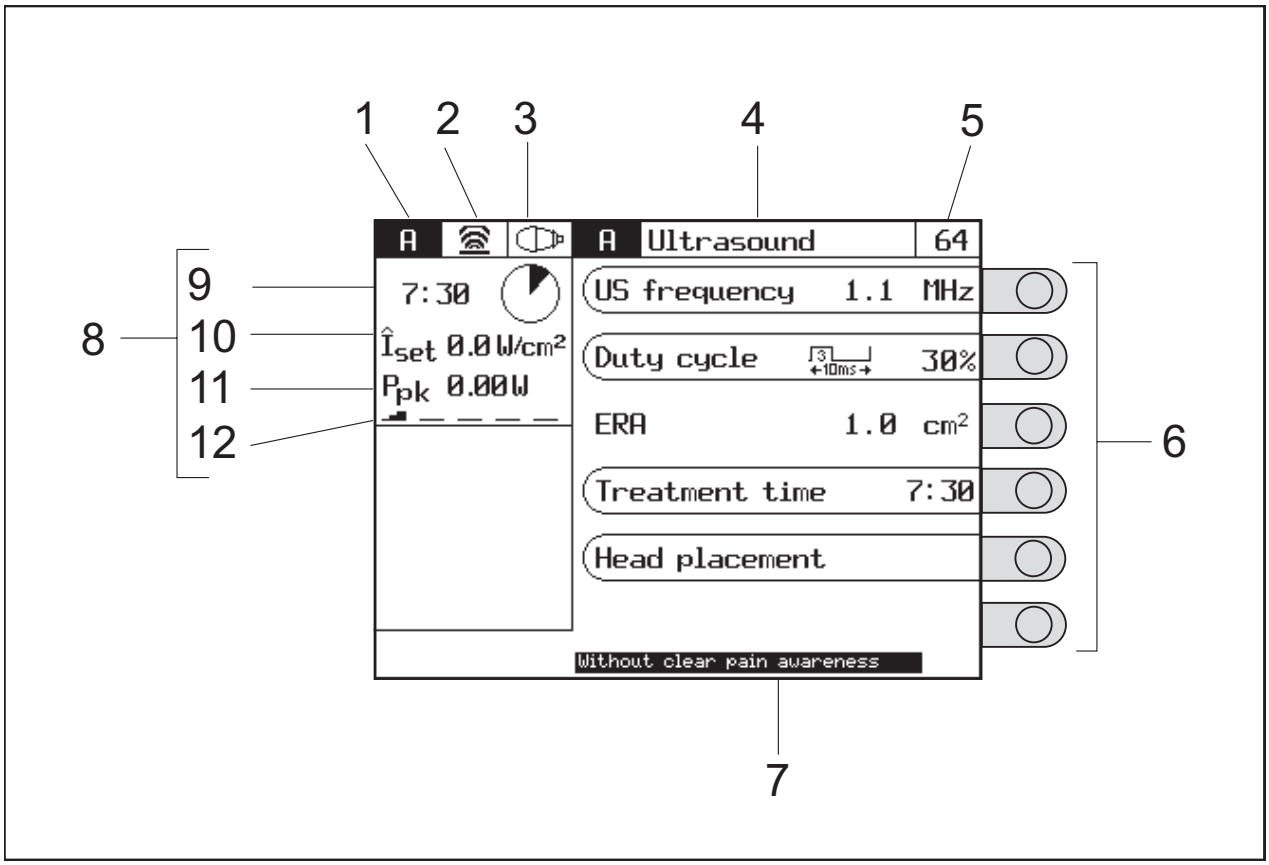
1. Pulson 200. See §3.1.
2. Power cord
3. Contact gel
4. US head

3.1 Components of Pulson 200



1. Display. See §3.2.
2. Ultrasound therapy
3. Memory
4. Start menu
5. Stop
6. Pause
7. Intensity
8. Return to previous menu
9. Enter
10. Indication: Read manual
11. Down
12. Up
13. Select parameter or menu
14. Connector for US head
15. Indication: Floating patient circuit
16. On/off switch
17. Connection to mains supply
18. Type plate
19. Ventilation opening
20. Fuse holder

3.2 Display



1. Channel
2. Ultrasound therapy
3. Type of US head
4. Title of the screen
5. Program number
6. Parameters with selection knobs
7. Explanation or recommendation
8. Screen for channel A. See §4.3.2.
9. Remaining treatment time
10. Îset
11. Ppk
12. Contact of the US head

3.3 Display symbols

Ultrasound therapy	Treatment time
A Channel A	**0:00** Treatment completed

3.4 Parameter symbols

10ms **10%** US duty cycle 10%	$\hat{I}_{set}$ Set US intensity
10ms **20%** US duty cycle 20%	P_{pk} Peak US output power
10ms **30%** US duty cycle 30%	W/cm^2 Unit of the set US intensity
10ms **40%** US duty cycle 40%	
10ms **50%** US duty cycle 50%	
100% US duty cycle 100%	

4 OPERATION

4.1 Therapy selection

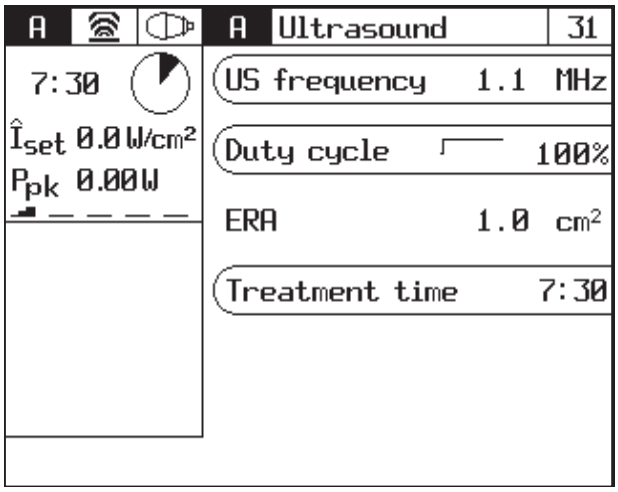
You can select a therapy in different ways, with the therapy key or with the parameters in the Start menu:

- **Therapy key**: Quickly select a therapy with the therapy key. See §4.1.1.
- **Objectives**: Select a therapy on the basis of an objective. See §4.1.2.
- **Indication list**: Select a therapy on the basis of a medical indication. See §4.1.3.
- **Program number**: Select a certain program number or a program number that you previously saved. See §4.1.4.
- **Diagnostic programs**: Perform a diagnosis. See §4.1.5.
- **Contra-indications**: Display an overview with contra-indications for the ultrasound therapy. See §4.1.6.

Besides this, you can change the system settings. See §4.5.

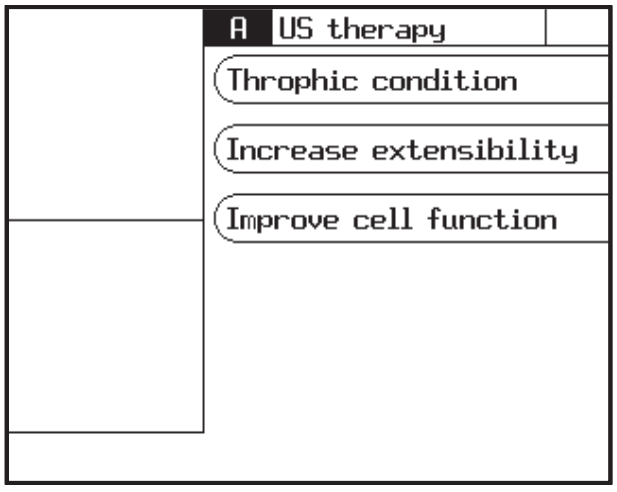
4.1.1 Therapy key

Press : Ultrasound therapy. The Ultrasound screen appears.



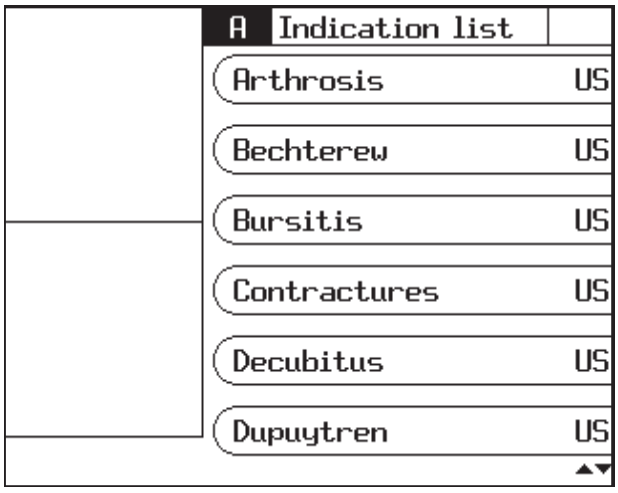
4.1.2 Therapy selection via objectives

1. Press to go to the start menu.
2. Select Objectives.
3. Select the desired treatment with .



4.1.3 Therapy selection via indication list

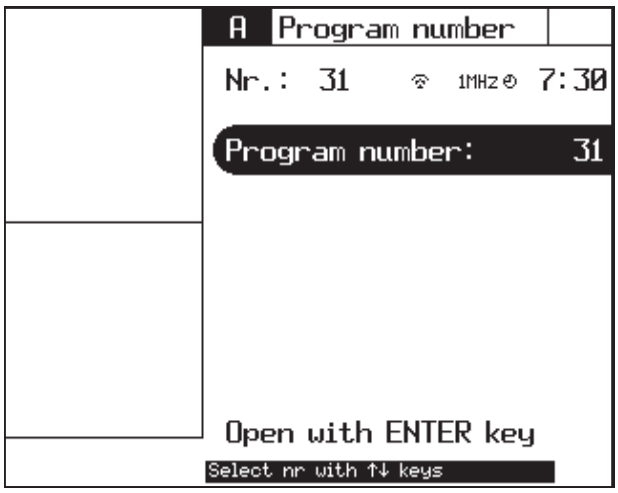
1. Press ⏎ to go to the start menu.
2. Select Indication list.
3. Go to the following indications with △ or ▽. See §9.3.4.
4. Select the desired indication with ◯.
   - US: Ultrasound therapy



4.1.4 Program number selection

1. Press ⏎ to go to the start menu.
2. Select Program number.
3. Select the desired program with △ or ▽. See §9.3.
4. Press ↵.

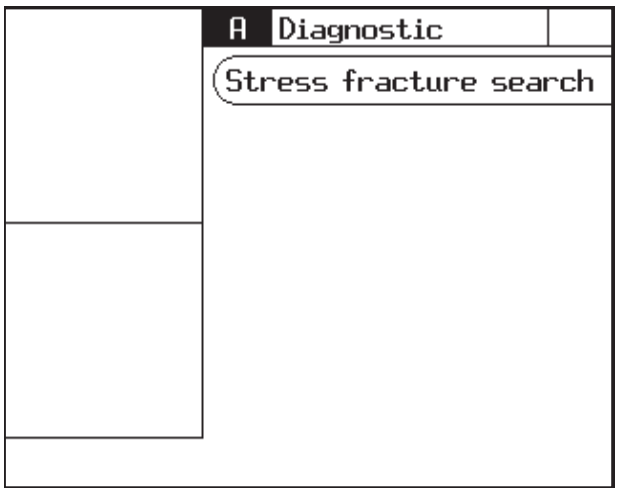
See §4.4.



4.1.5 Diagnostic program selection

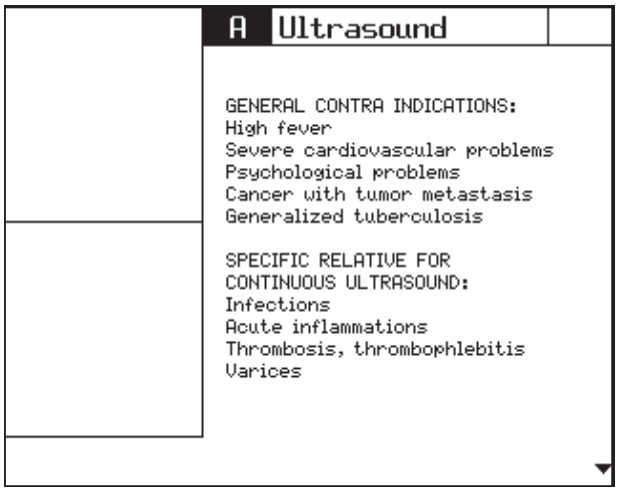
With the diagnostic programs, you can search for stress fractures.

1. Press ⏎ to go to the start menu.
2. Select Diagnostic programs.
3. Select Stress fracture search with ◯.

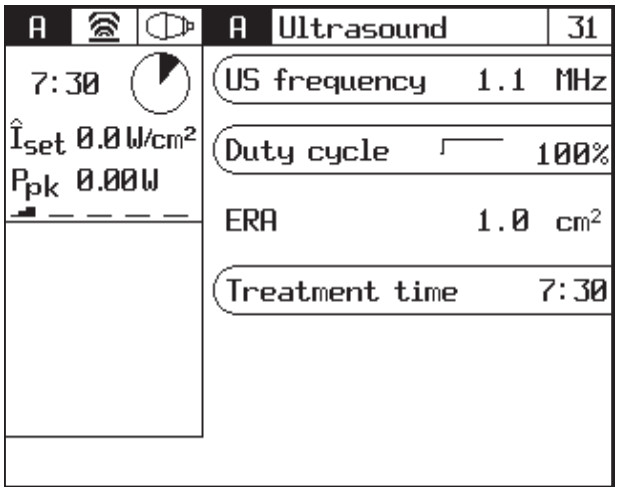


4.1.6 Contra indication selection

1. Press ⏎ to go to the start menu.
2. Select Contra indications.

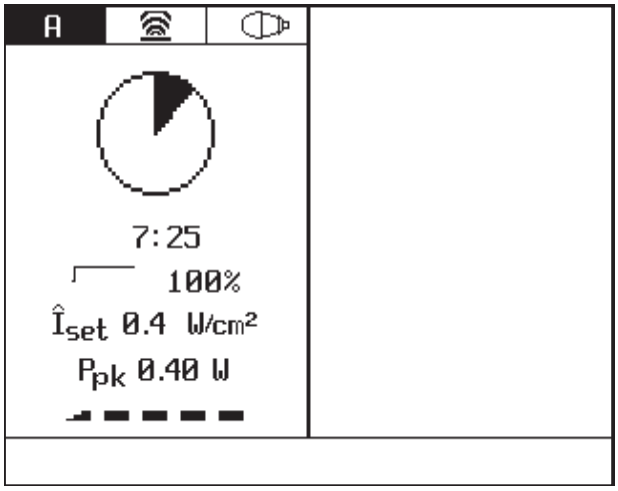


4.2 Set and start therapy



1. Press ⏎ to go to the start menu.
2. Select the desired menu with ○ until the treatment appears.
3. Select the desired parameters with ○. You can only change the outlined parameters.
   Set the **Treatment time as follows:**
   Press once on ○ to set the minutes, press twice on ○ to set the seconds.
4. Change the value of the parameter with △ and ▽. The setting range of the parameter is shown at the bottom of the screen. You can change the parameter as long as the parameter has a black background.
5. Rotate intensity knob to start the treatment and to set the desired intensity. The set intensity is displayed in the screen.

4.2.1 Opening the intensity screen



1. Set the treatment. See §4.2.
2. Rotate intensity knob to start the treatment.
3. Press ↵. The intensity screen appears.
4. Press ⮌ to return to the setting menu.

4.2.2 Temporary interruption of treatment

1. Press ⏲ during the treatment. The treatment time of the selected channel is stopped. **Pause** appears on the screen. The parameter settings are retained.
2. Press on ⏲ again to restart the treatment. The intensity now increases gradually to the set level and the treatment time continues again.

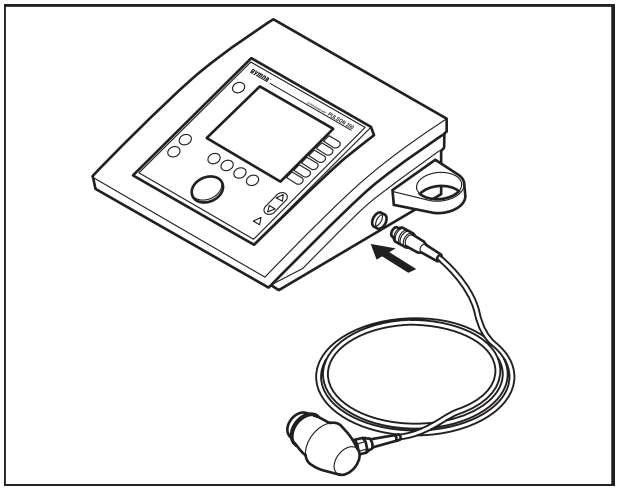
4.2.3 Immediately stop treatment

1. Press ▽. All active treatments are stopped immediately. **Stop** appears on the screen. The parameter settings are retained.
2. Set the intensity of the channel again to continue the treatment.

4.3 Ultrasound therapy

4.3.1 Performing ultrasound therapy

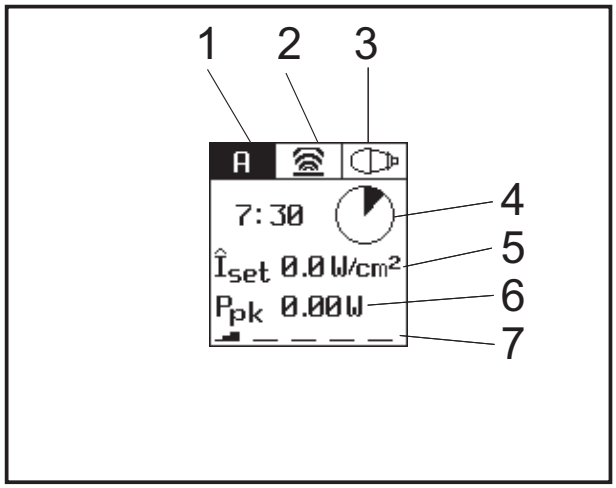
Move the US head evenly over the skin during the treatment. This prevents internal burns.



1. Plug the connector of the US head into the connector of the Pulson 200.
2. Select the desired ultrasound therapy. With some treatments, the parameter Head placement refers to 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. Rotate intensity knob to start the ultrasound therapy.
6. Move the US head evenly over the skin during the treatment. This prevents internal burns.
7. Check the patient's 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.

4.3.2 Read-out values

1. Channel
2. Ultrasound therapy
3. Type of US head
4. Remaining treatment time
5. Îset
6. Ppk
7. Contact of the US head



Contact of US head

The contact of the US head with the skin:

- ▟ ▁ ▁ ▁ ▁: Bad contact, US head switched off (0 W).
- ▟ ■ ▁ ▁ ▁: Bad contact.
- ▟ ■ ■ ▁ ▁: Sufficient contact.
- ▟ ■ ■ ■ ▁: Good contact.
- ▟ ■ ■ ■ ■: Very good contact

Test the US head if its conduction is bad. See §5.1.1.

Îset (W/cm^2)

The power (W) of the US head per cm².

Ppk (W)

The peak power of the US head (Îset * ERA). The peak power delivered 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.

4.3.3 Parameters

Treatment time (mm:ss)

The duration of the treatment.

Duty cycle (10, 20, 30, 50%, continuous)

Ratio of the pulse duration to the period duration.

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

Select a high duty cycle for an intensive treatment. Select a low duty cycle for a mild treatment.

ERA (cm^2)

The effective radiating area expressed in cm² of the treatment head connected. This area equals the cross-sectional area of the beam at the treatment surface. The ERA depends on the frequency. This parameter remains empty if no US head is connected.

Head placement

Instructions for placing the US head. Consult the placement diagrams.

US frequency (MHz)

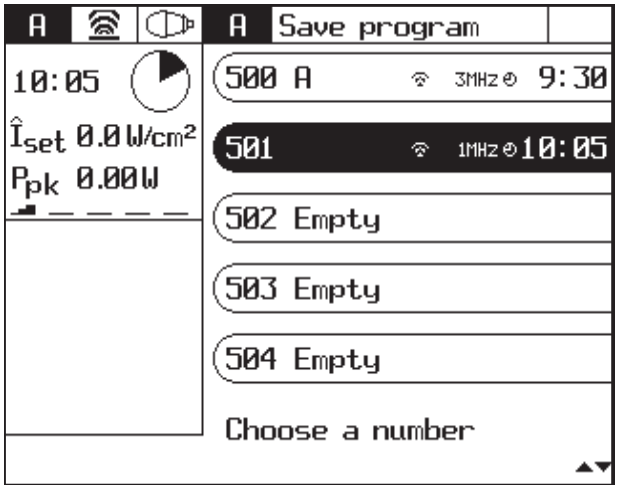
The frequency of the US head. The absorption at a US frequency of 3 MHz is three times higher and the penetration depth is three times less than at a US frequency of 1 MHz. Use 3 MHz for superficial tissue and 1 MHz for deeper tissue.

4.4 Programs

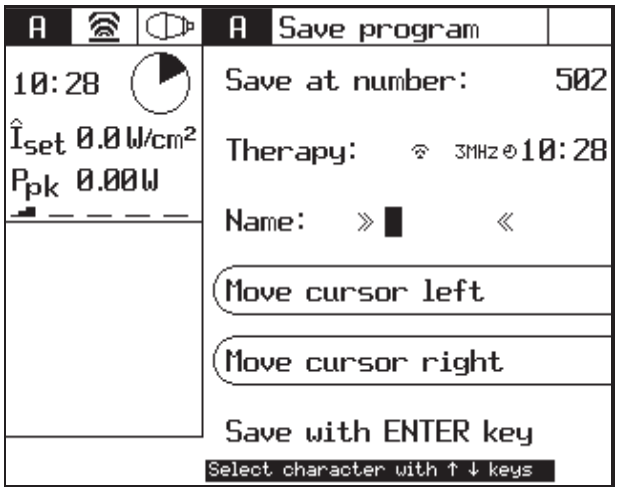
You can save 20 of your own programs for later use: programs 500 up to and including 519. You can modify these programs for much-used settings for a certain patient.

4.4.1 Saving a program

1. Select a therapy. See §4.1.
2. Change the settings for the patient. See §4.2.
3. Press ⏎.
4. Select **Save**,
5. Select a free program number with ◯.
   If desired, go to the following programs with △ or ▽.



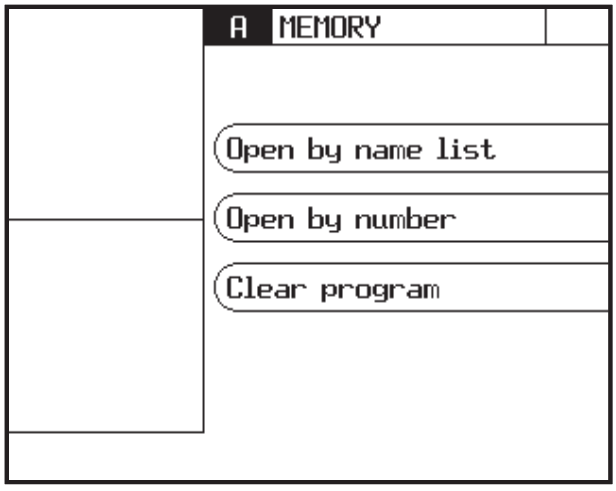
6. Enter the name of the program. Use the name or the number of the patient, for example.
   - Select a character with △ and ▽.
   - Select **Cursor to left/right** to move the cursor.
7. Press ↵ to save the program.



4.4.2 Selecting a saved program

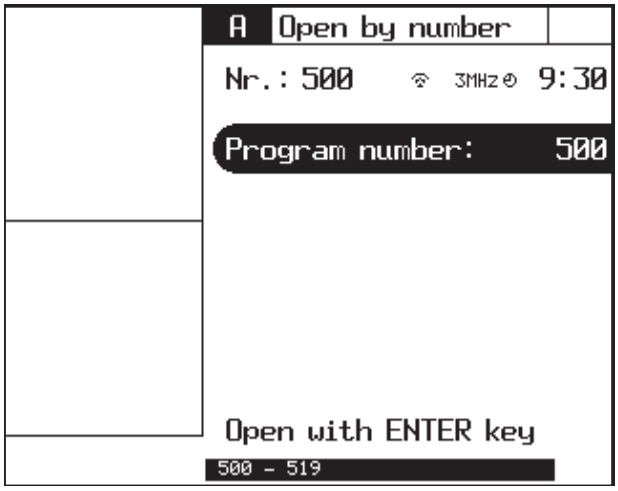
4.4.2.1 Selecting a program by the name list

1. Press ⏎.
2. Select **Open by name list**.
3. Go to the desired program with △ or ▽.
4. Select this program with ◯.



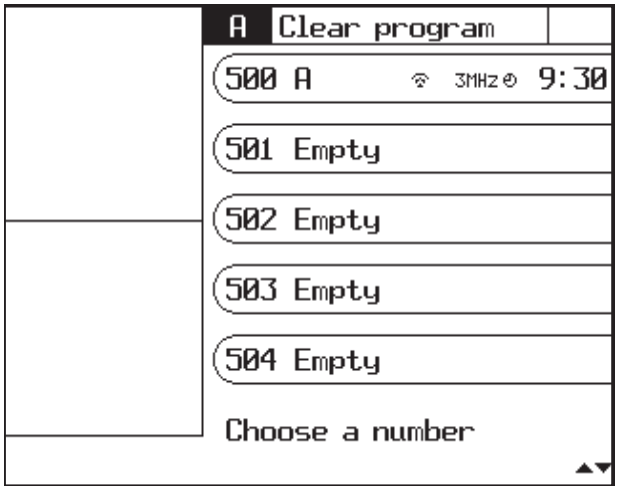
4.4.2.2 Selecting a program by the number

1. Press ⏎.
2. Select Open by number.
3. Select the desired program with △ or ▽.
4. Press ↵.



4.4.3 Clear a program

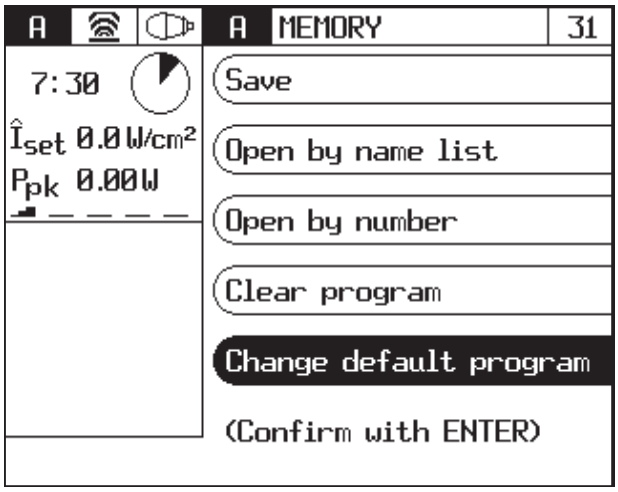
1. Press ⏎.
2. Select Clear program.
3. Select the program that must be deleted with ◯.
   If desired, go to the following programs with △ or ▽.
4. Press ↵ to clear the program.



4.4.4 Editing a standard program

Standard programs have a program number that is lower than 50. You can only edit standard programs with the therapy key.

1. Select a program with the therapy key ⦿.
2. Press ⏎.
3. Select Change default program.
4. Press ↵ to edit the standardprogram.



You can also save an edited standard program under a free program number. See §4.4.1.

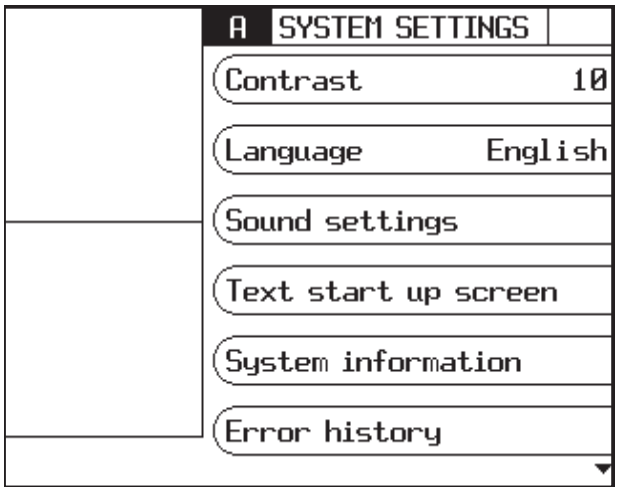
You can reset the standard settings of the standard programs with Reset Menu. See §4.5.2.

4.5 System settings

With the system settings, you can adapt the Standard settings of the equipment. You cannot change the system settings during a therapy.

4.5.1 Changing the system settings

1. Press ⮌ for 5 seconds. The screen appears with the system settings.
2. Change the desired systemsetting. See §4.2.



4.5.2 Parameters

Contrast (1 - 20)

The contrast of the display.

Language

The language selection: select the language with which the read-out must work.

Sound settings

Sound settings. See §4.5.3.

Text start up screen

The text that appears in the top of the start up screen, after the equipment is switched on. See §4.5.4.

System information

System information of the equipment

Always have this information available when you contact the technical service department.

Error history

The total number of error reports that the equipment has had and details about the last 10 error reports.

Always have this information available when you contact the technical service department.

Reset menu

- Reset working hours: Set the number of working hours of an US head to zero.
- Reset programs 1-50: This restores the standard settings of the standard programs. See §4.4.4.
- Erase total memory: Restores the standard settings of the standard programs and of the edited programs.

Press ◯ again to confirm.

Stopping time with bad US contact

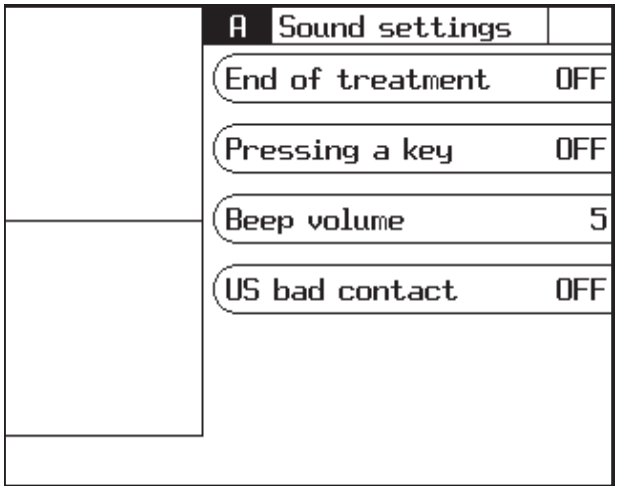
On: The treatment stops during a bad contact of the US head.

Counter working hours (hours, minutes, sec.)

The time that the accessories for ultrasound therapy have been in use. For this, the output of the channel must have been higher than zero.

4.5.3 Setting the sound

1. Press ⮌ for 5 seconds.
2. Select Sound settings,
3. Change the desired sound setting. See §4.2.



End of treatment

On: A sound signal will be heard at the end of the treatment.

Pressing a key

On: A sound signal will be heard every time a key is pressed.

Beep volume (min.1, standard 5, max.10)

The volume of the sound signals.

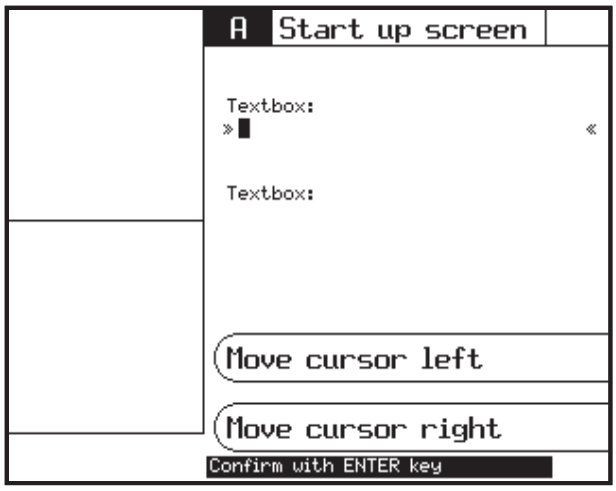
US bad contact

On: A sound signal will be heard if the US head does not make good contact with the skin.

4.5.4 Set text for start up screen

You can set your own text for the start up screen. For example, you can put your name or address information here.

1. Press ⮌ for 5 seconds, select **Text start up screen**.
2. Enter the name for the start up screen.
   - Select a character with △ and ▽.
   - Select **Cursor to left/right** to move the cursor.
3. Press ↵ to confirm the name.



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. This is the case when the indication bar for the Ppk value displays ▟ ▁ ▁ ▁ ▁ or ▟ ■ ▁ ▁ ▁.

1. Select an ultrasound therapy.
2. Place the US head in a bowl with water.
3. Rotate intensity knob to start the treatment.
4. Check in the screen of the channel to see if the Ppk value is increasing.
5. Contact your local GymnaUniphy dealer if the indication bar still displays ▟ ▁ ▁ ▁ ▁ or ▟ ■ ▁ ▁ ▁.

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.**

5.1.2.1 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.

5.1.2.2 Inspection result

A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. See §8.2. Copy this appendix. Complete the copied appendix. 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 registred measurement values with previous measurements, a possible slowly-deteriorating deviation can be ascertained.

5.2 Maintenance

Component	Maintenance	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 200	Equipment cannot be switched on	See §6.1.1.
	Equipment does not react to commands or a fault report appears	See §6.1.3.
	Foreign language on the screen	Change the language. See §4.5.2.

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. Only use the fuses supplied. 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 or an error message appears

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 error message reappears.

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 1 (one) year, 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 200 (w x h x d)	266 x 275 x 100 mm
Weight Pulson 200	3,650 kg
Weight including accessories	4,6 kg
Mains voltage	100 - 240 VAC, 50-60 Hz
Maximum power, in operation	85 VA
Safety class	Class I (earthed socket required)
Insulation	Type BF (floating patient circuit)
Fuses	2 x T2AL250V

7.2 Ultrasound therapy

7.2.1 General

Insulation classification	Type BF
Peak power	0 - 2 W/cm², duty cycle = 100%
	0 - 3 W/cm², 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 204

Acoustic operating frequency	**1,1**	**3,2**	**MHz**
Output power	8,1	9,5	W
Effective intensity of output voltage	2,0	2,0	W/cm²
Effective Radiating Area (ERA)	4,1	4,7	cm²
Beam Non-uniform Ratio (BNR)	4,5	5,8	
Maximum intensity of beam	9,0	11,7	W/cm²
Beam type	Collimating	Collimating	

US head, model 201

Acoustic operating frequency	**1,1**	**3,2**	**MHz**
Output power	3,8	2,8	W
Effective intensity of output voltage	2,0	2,0	W/cm²
Effective Radiating Area (ERA)	1,9	1,4	cm²
Beam Non-uniform Ratio (BNR)	5,2	3,3	
Maximum intensity of beam	10,5	6,6	W/cm²
Beam type	Collimating	Collimating	

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	5.5 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 pieces, by post

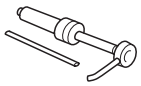
The transport and storage specifications apply to equipment in the original packaging.

7.5 Standard accessories

	Quantity	Description	Art. no.
	1	US head, 1/3 MHz - ERA 4 cm² incl. holder	117.122
	1	Contact gel, 150 ml	100.018
	1	Power cord*	100.689
	1	User instructions	NL: 117.124 FR: 117.125 EN: 117.126 DE: 117.127
	1	US placing diagrams	117.128

*) 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

	Description	Art. no.
	US head, multi-frequency,1/3 MHz - ERA 1 cm² incl. holder	117.123
	Contact gel, bottle 500 ml	100.016
	Contact gel, can 5 l	100.019
	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 200 in the vicinity of other equipment, you must check that the Pulson 200 is functioning normally.

The following paragraphs contain information about the EMC properties of the equipment.

8.1.1 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The 200-series devices are intended for use in the electromagnetic environment specified below. The custumer or the user of a 200-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 200-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	The200-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 200-series devices are intended for use in the electromagnetic environment specified below.The custumer or the user of a 200-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 200-series device requires continued operation during power mains interruptions, it is recommended that the 200-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 200-series devices are intended for use in the electromagnetic environment specified below.The custumer or the user of a 200-series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	[V_1] V	Portable and mobile RF communications equipment should be used no closer to any part of a 200-series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 80 MHz to 800 MHz: $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz: $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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:  .
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2,5 GHz	[E_1] V/m	
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 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 200-series device is used exceeds the applicable RF compliance level above, the 200-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 200-series device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths must be less than [V_1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the 200-series device

The 200-series device is intended for use in the electromagnetic environment in which radiated RF disturbances are contolled. The custumer or the user of a 200-series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 200-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 $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01			
0.1			
1			
10			
100			

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 200 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, adjusting knobs, 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. Press to select the ultrasoundtherapy.		
2. Select 1 MHz, continuous (duty cycle 100%), 2 W/cm² The measured value is within ±20% of the Ppk value in the channel window.	☐	☐
3. Select 1 MHz, duty cycle 50%, 3 W/cm² The measured value is within ±20% of half the Ppk value in the channel window.	☐	☐
4. Select 3 MHz, continuous (duty cycle 100%), 2 W/cm² The measured value is within ±20% of the Ppk value in the channel window.	☐	☐
5. Select 3 MHz, duty cycle 50%, 3 W/cm² The measured value is ±20% of half the Ppk value in the channel window.	☐	☐
6. Select 3 MHz, duty cycle 50%, 0.5 W/cm² With a dry treatment surface, the Ppk value becomes 0.	☐	☐
7. Select 1 MHz, duty cycle 50%, 0.5 W/cm² With a dry treatment surface, the Ppk value becomes 0.	☐	☐

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 necesary to check the operating frequencies.

8.2.3 Test 3: Electrical safety test (VDE 0751)

	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 en the cables fall under small chemical waste (or electronic waste). These components contain lead, tin, copper, iron, various other metals and various plastics, etc. Consult the applicable 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.

9 REFERENCE

9.1 Terminology

trophic: The state of nourishment.

9.2 Literature

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

9.3 Function overview

9.3.1 Therapy key

The numbers refer to the program numbers.

Ultrasound therapy

9.3.2 System settings

Press ⮌ for 5 seconds

Contrast
Language
Sound settings
Text start up screen
System information
Error history
Counter working hours
Reset menu
Stopping time if bad US

9.3.3 Objectives

The numbers refer to the program numbers.

Ultrasound therapy

Trophic condition

Increase extensibilty

Improve cell function

9.3.4 Indications

US: Ultrasound therapy
The numbers refer to the program numbers.

Arthrosis, US

Contractures, US

9.3.5 Diagnostics

9.3.6 Contra indications

Ultrasound therapy

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

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

Specific relative for pulsing ultrasound
Pacemaker
Pregnancy

9.4 Index

Pasweg 6A
B-3740 Bilzen

Tel.: (+32) (0) 89/510.510
Fax: (+32) (0) 89/510.511

www.gymna-uniphy.com
E-mail: info@gymna-uniphy.com

Your dealer: