Zimmer
MedizinSysteme

Operating Instructions

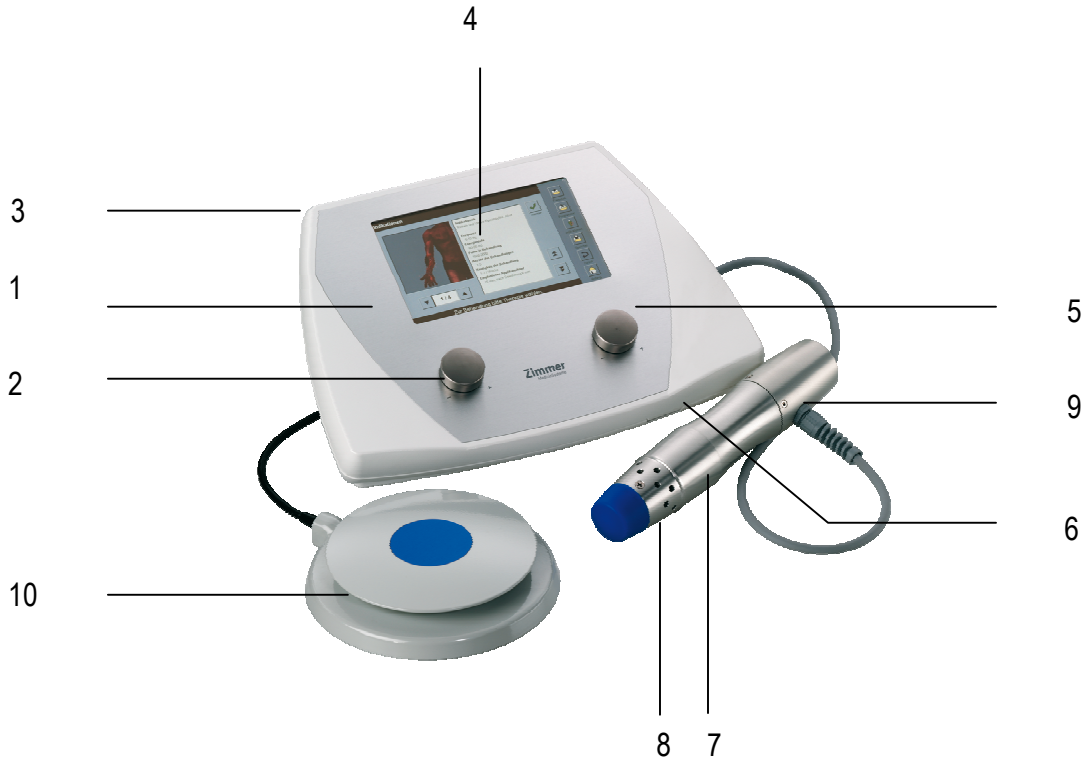
enPuls
Version 2.0

GB

Figures

Front view of device

Control unit / Handpiece / Footswitch



Selection and control elements	1	Control unit
	2	Shock energy controller
	3	Touch pen in holder
	4	Display
	5	Frequency controller
	6	SD card slot
Handpiece	7	Handpiece with applicator head 25 mm
	8	Air vents, front
	9	Air vents with fan, rear
Footswitch	10	Footswitch

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Front view of device

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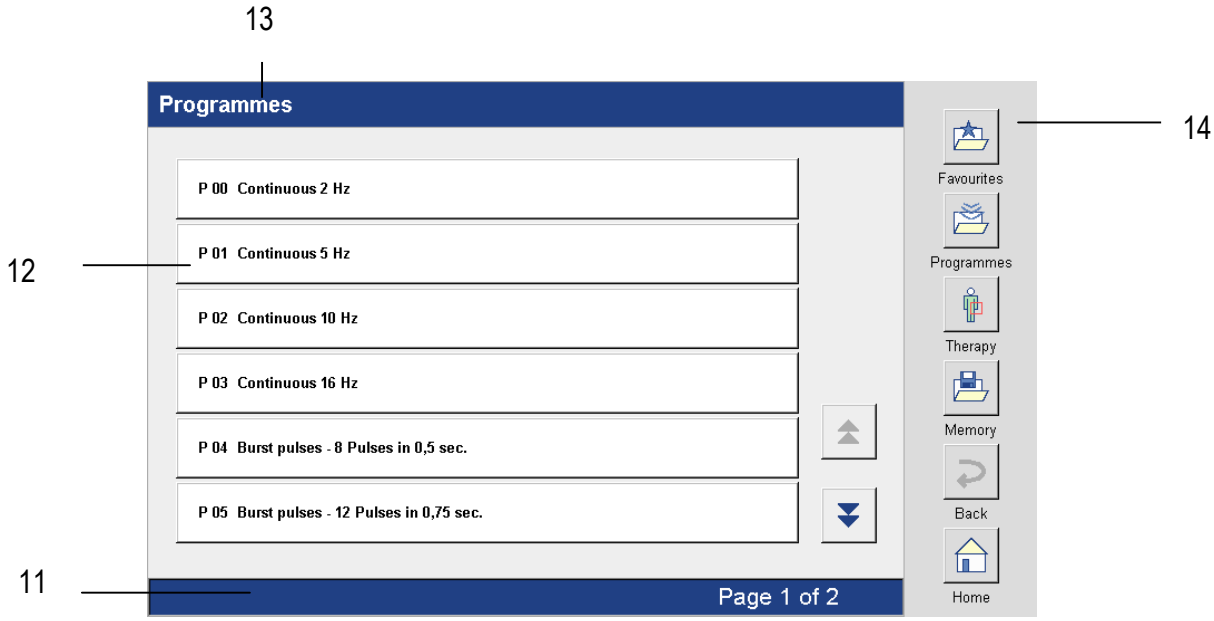

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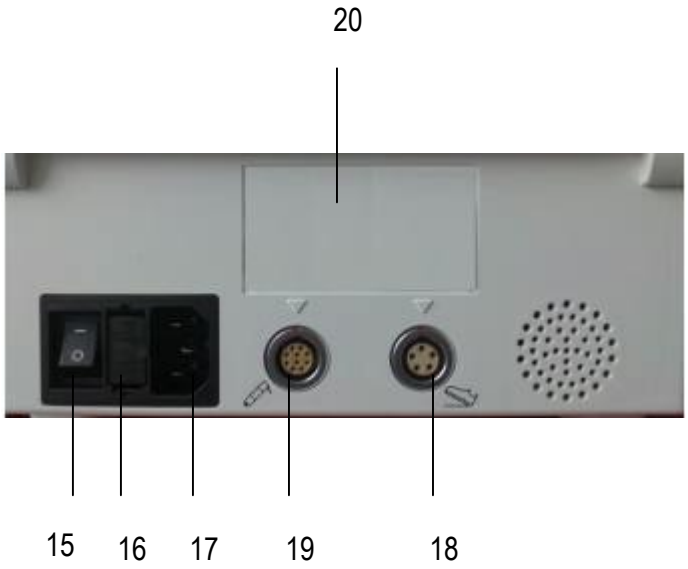

Switch / Connector sockets	15	Main switch
	16	Mains fuse
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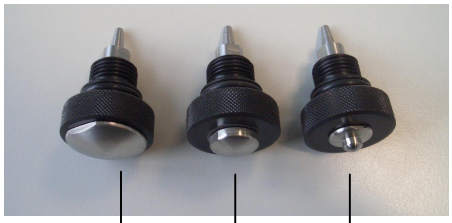


22 23 24

21 Silicone cap
22 25 mm applicator head
23 15 mm applicator head
24 6 mm applicator head

Contents

Contents

Valid for the en*Puls* V.2.0 devices
These operating instructions are an integral part of the device.
They must be stored with the device and kept accessible at all times for anyone authorised to operate this device.
These operating instructions are valid from 01 March 2010.

en*Puls* briefly

1

1.1. Summary

What is en*Puls*?

A state of the art innovative shockwave treatment device.

Shockwave treatment

Radial, ballistic shockwave treatment is a procedure with a wide range of applications ranging from superficial orthopaedic problems to myofascial trigger point treatment.

What does en*Puls* do?

Creation of shockwaves using an ergonomic handpiece and the transmittal of the shockwaves via special applicators.
en*Puls* has a maximum penetration depth of about 35 mm in human tissue.

How are shock waves generated with en*Puls*?

An electromagnetic field is generated via a coil in the back of the handpiece.
A projectile is accelerated as a result of the field; this strikes against the applicator head at the front of the handpiece and generates shockwaves, which spread out radially in the tissue.

What are the advantages of en*Puls*?

The innovative technology allows a compact design with no need for a compressor.
The clear and modern colour display shows all relevant parameters for treatment and the modern touch operation ensures pleasure and motivation when providing treatment.
Individual programme start configuration and clear, simple menu navigation make operation of the device easy and comfortable for users.

Infinitely variable frequencies and various applicators allow treatment to be adapted to the particular condition of the patient.

The compact design saves room in the practice and is highly suited for use in home visits.

Note:

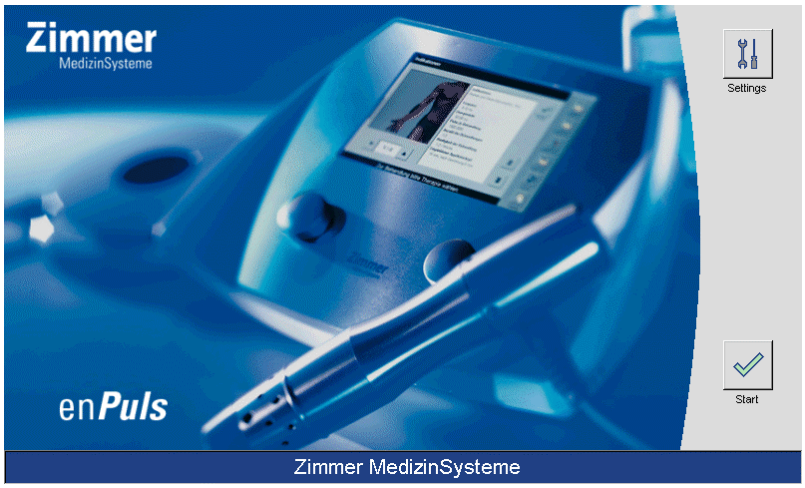
The device should only be used by medical specialists (e.g., doctors, therapists and health paraprofessionals).

en*Puls* has been constructed and designed solely for the treatment of superficial orthopaedic problems in humans and animals.

Note: *The following descriptions are all based on the factory settings.*

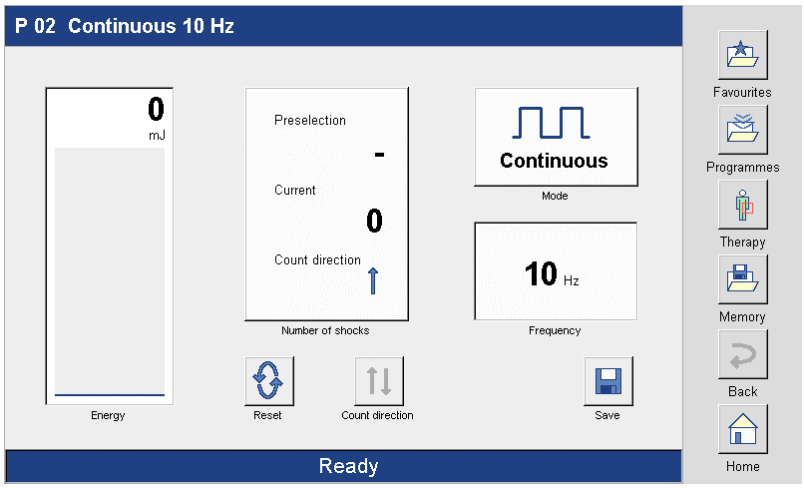
Note: *All buttons, menus and submenus are activated directly on the screen by touching it or using the touch pen.*

Starting the programme



Press the “Start” button to open the treatment screen for programme P 02.

Treatment screen



Applicator

Select the appropriate applicator head for the treatment you wish to carry out and screw this correctly onto the handpiece.

Positioning handpiece / applicator

Position the handpiece on the selected treatment point / field. To avoid any friction on the skin, en*Puls* lotion may first be applied onto the treatment area.

1.2. Quick operation instruction

Caution!	When using lubricants, the applicator head must be covered with a silicone cap to protect it.
Setting the shock energy	Adjust the shock energy using the left controller.
Starting treatment	Depress the footswitch to start the treatment. The display in the bottom status bar changes from ‘Ready’ to ‘Active’.
Note:	*Only activate the shockwave via the footswitch once the handpiece has been positioned on the patient.*
Ending treatment	Deactivating the footswitch interrupts or ends the treatment. The display in the bottom status bar changes from ‘Active’ to ‘Ready’.
Note:	*During treatment, the patient must be observed closely and the treatment must be adjusted, if necessary, or discontinued, should any problems arise.*

1.3. How to use en*Puls*

Start treatment

en*Puls* operates with mechanical energy.

The energy is transmitted to the patient via a handpiece, which is usually held in one hand.

To do this, the handpiece is placed on the area or point of treatment with the applicator head held vertically.

When the shockwave is activated, it is possible to work either steadily on a single site or dynamically over an area.
It is advisable to use en*Puls* lotion (included in the accessories) in order to reduce friction on the skin.

The weight of the handpiece means that it is normally not necessary to apply pressure to the treatment area / point.
The handpiece is placed on the treatment area / point and held loosely in position with one hand.
If required, additional pressure may be applied in the direction of the tissue, and the working angle can be varied.

Caution!

When using en*Puls* lotion or other lubricants, the applicator head must be covered with a silicone cap to protect it.

Note:

Despite high internal damping as a result of the weight and design of the handpiece, vibrations may cause strain to the user's hand.

Recommended protective measure:
- Limit the duration of exposure

Note:

The patient should be carefully monitored throughout the treatment.

1.4. Handpiece

The handpiece (7) contains the shockwave generator, a fan to dissipate heat and the slot for the different applicator heads. It is connected to the control
unit (1).

Note:

The shockwave generator in the handpiece is an expendable part and has to be replaced after a specific period of use, as its functionality decreases over time.

Zimmer MedizinSysteme GmbH guarantees unrestricted use of at least 2 million shocks per shockwave generator.

Wear on the shockwave generator varies. Depending on performance and frequency, sometimes far more than 2 million shocks can be delivered.

For more information on the need to replace the shockwave generator, see chapter 11.

To work with the handpiece on a patient, it is essential that one of the applicator heads is screwed tightly onto the handpiece as far as it will go.

The cable should not be stretched beyond its maximum length and must be protected against pinching or any other mechanical damage.

To avoid heat accumulating in the handpiece, it is essential to ensure that the hand holding it or anything else does not block the air vents at the top, and particularly, on the base of the handpiece.

Standby mode on device and handpiece

The fan in the handpiece is started by depressing the footswitch and stops automatically after reaching a certain temperature.

1.5. Applicator heads

There are 3 different applicator heads available for treatment.

Changing applicator heads

To change the various applicator heads, hold the handpiece in one hand and unscrew the applicator head from the handpiece with the other hand (anticlockwise). Screw the required head tightly onto the handpiece (clockwise), until the black outside ring of the applicator head rests on the handpiece (there should no longer be any thread visible).

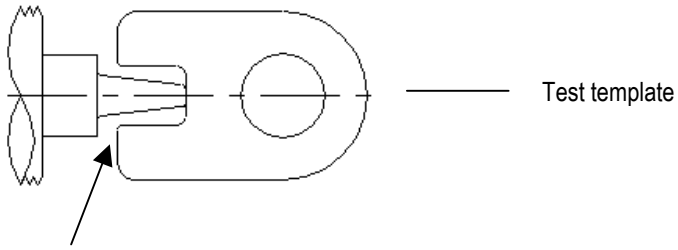
Note:

Applicator heads are expendable parts and must be replaced after a certain period of use.

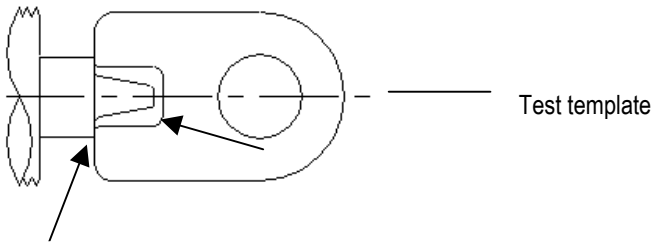
Minor / slight deformation or shortening of the rear impact dome does not affect functionality.

In cases of greater deformation or stronger shortening of the rear impact dome the applicator head must be replaced.

A test template is supplied with the device that enables the user to test if the wear limit has been reached
(see diagram).



Air gap ➔ applicator OK



Template makes contact or air gap at the tip ➔ Wear limit has been reached

1.6. Footswitch

Place the footswitch so that it can be reached easily during treatment. The footswitch control unit is multi-directional so it is not necessary to align the footswitch exactly.

To avoid damage, please note that only slight pressure needs to be exerted on the switch. Use the front part of your foot, not the heel to operate the footswitch.

The switch does not have a locking device, which means that it only remains actuated as long as pressure is applied to it.

Installation

2.1. Fitting the cables, starting the system

2

Note:	*Before starting up the system, remove enPuls from its transport case. Do not operate the device while it is in the case.* *Ensure that enPuls is placed on a stable surface.*
Note:	Make sure that the main switch on the device is set to '0'.
Connecting the mains cable	Connect the mains cable to the designated port (17) of the device and then plug into the mains.
Connecting the handpiece	Plug the handpiece into the appropriate socket (19) of the device and place it on the table.
Note:	Ensure that an applicator head is inserted into the handpiece and that it is properly screwed in as far as it will go.
Connecting the footswitch	Plug the footswitch into the appropriate socket (18) of the device and then place it on the floor.
Switching on the device	Switch on the device using the main switch (15).

Note: *Changes to the default settings can only be made from the start screen. Press button "Settings" to open the Settings screen*

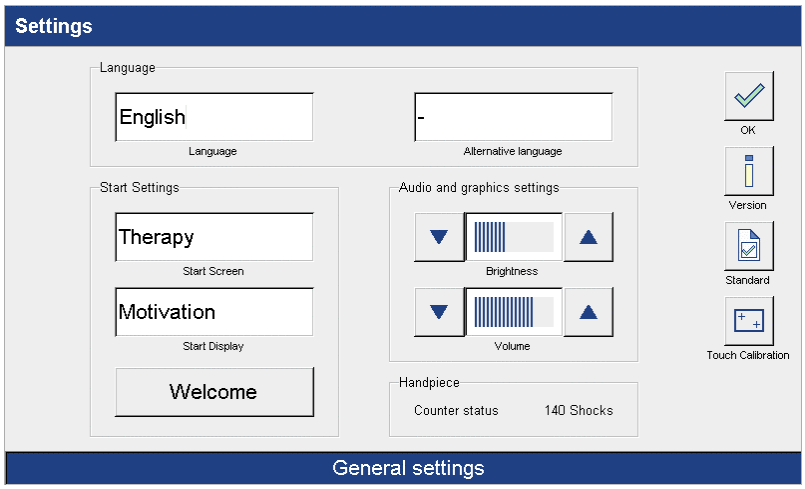


Figure 1

Language Press this button to open the menu to select the language. The language is selected by pressing on the appropriate row in the pull down menu.

Start settings

Start screen Option to choose between 5 start screens.
Press the button to open the pull down menu to select the start screen.
The start screen is selected by pressing on the appropriate row.

Start display Option to choose between 2 start displays:
Press the button to open the menu to select the start display.
The start display is selected by pressing on the appropriate row.

Welcome message Option to configure an individual welcome message.
Activate the welcome message field to open the keyboard in order to enter a welcome message.

Audio / graphic settings

Brightness	Option to adjust the brightness of the screen lighting.
Volume	Option to adjust the volume of the signals when activating the control fields. Adjust the volume using the two arrow keys.
Handpiece counter status	The counter status for the handpiece that is currently connected, is shown in this display field.
Version	Press the version button to open the window with information about the current software version of the device.
Default settings	Press the default button to reset the factory default settings.
Touch calibration	Press the “Touch Calibration” button to open the screen to carry out the touch calibration. This can be done to improve the touch input if it is not sufficiently accurate. + + First press the + symbol in the top left corner. A + symbol appears then in the lower right corner. Then precisely press the + symbol in the lower right corner. Repeat the procedure to complete the touch calibration.
Alternative language	The option “Alternative language” is inactive.

SD-Card

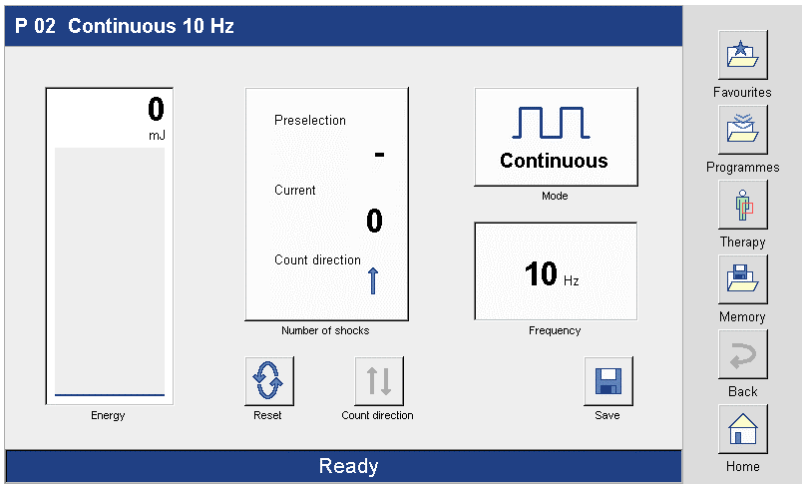
3

User-defined settings and the treatment recommendation list are saved on the SD card.

Note:

*If the SD card is not inserted, the message 'SD card not found' appears when the '*Favourites*' and '*Memory*' buttons are pressed.*
The 'Therapy' button is not shown.

Deactivate the message by pressing the button "OK" and continue.



Title bar

The title bar shows the name of the current programme.

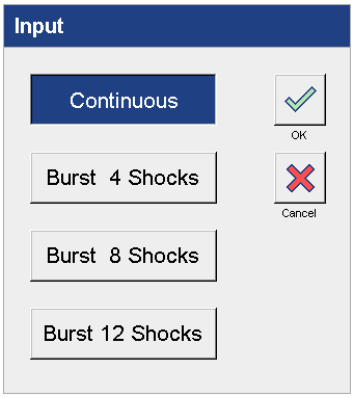
Status bar

The status bar shows the information about the current status of the treatment. If the treatment is not active, it shows the word 'Ready' and if treatment is running the text 'Active' appears.

Mode

Shows the selected operational mode (continuous in this case).

Press the 'Mode' button to open the 'Input' window and select the operational mode (continuous, Burst 4 Shock, Burst 8 Shock, Burst 12 Shock)



Frequency

Shows the selected frequency.
Change the frequency using the right controller.
Frequency range: 1 Hz – 16 Hz, adjustable using the right controller in 1 Hz steps.

Energy/ Bar graph

Shows the selected shock energy. When treatment is active the bar graph is filled in.
Setting the shock energy can be done either before or during shock delivery.
The shock energy can be set at the levels 60, 90, 120 or 185 mJ.

Save

After changing the parameters, based on individual needs, press the button “Save” for saving the settings either in the Favourites list or the Memory list

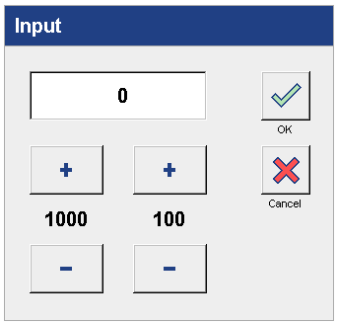
Count direction

Press to set the count direction (increasing or decreasing) of the number of shocks set.

Number of shocks

Shows the pre-selected shock numbers as well as the current number of shocks delivered to the patient.
Also the count direction (increasing in this case) is shown.

Pressing the “Number of shocks” field opens the Input window, defining pre-selection.



Note:

enPuls offers two options for shock delivery:

Shock delivery without pre-selecting the shock number

For shock delivery with no pre-selected number of shocks, the device does not end the treatment. As long as the footswitch is activated, shocks will be delivered.

For shock delivery with no pre-selected number of shocks, only the upward count direction is active.

Shock delivery with pre-selection of the number of shocks

For shock delivery with a pre-selected shock number, the device ends the treatment once the pre-selected number of shocks has been reached.

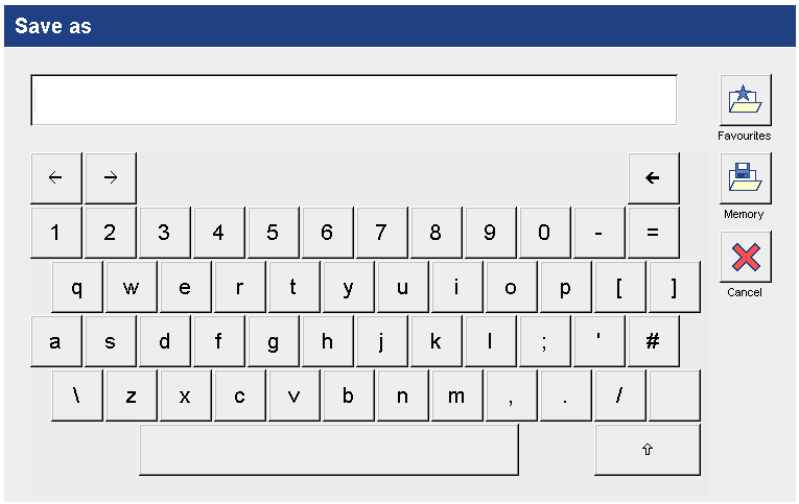
The footswitch is deactivated and shock delivery is no longer possible.

The treatment can be continued by resetting the current number of shocks or by adjusting the pre-selection.

When the number of shocks is pre-selected the count direction is automatically set to decreasing. By pressing the 'Count direction' button on the treatment screen the increasing count direction button can be selected

5.1. Saving modified programmes

Programmes can be stored either in the Favourite list or the Memory list.



Programme name

For saving the programme enter the programme name using the keyboard

Favourites

Press the “Favourites” button to open the Favourites list and automatically save the programme.
The programme is automatically saved in the first free space in the list.

Memory

Press the “Memory” button to open the Memory list and automatically save the programme.
The programme is automatically saved in the first free space in the list.

Note:

If the 'Memory' or ‘Favourites’ button is pressed without entering a programme name, an error message appears.
Acknowledge these message with ‘OK’, enter a programme name and repeat the save procedure as described above.

5.2. Retrieving and editing Favourites list and the Memory list

Note

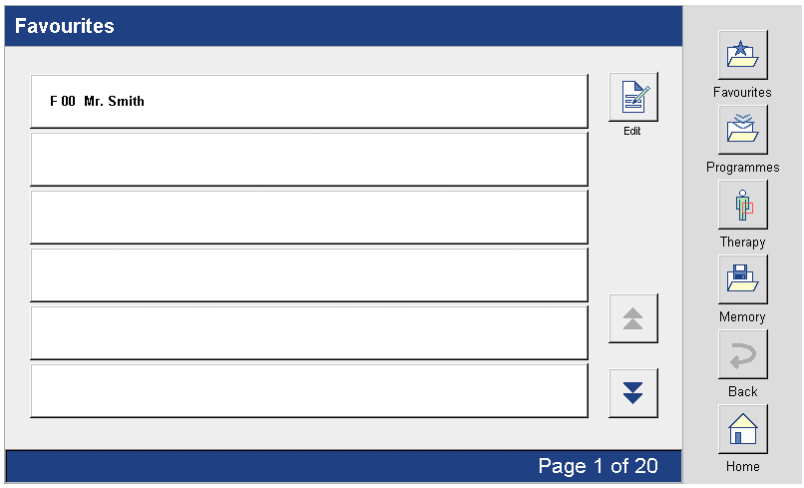
The following steps to edit the Favourites list correspond exactly to those used to edit the Memory list.

Individual saved programmes are listed in Favourites or Memory list. From here they can be:

1. retrieved for treatment or
2. edited (sequence changed or deleted).

Selecting the Memory or Favourites list

In the navigation bar press the ‘Favourites’ or ‘Memory’ button to open the corresponding list.

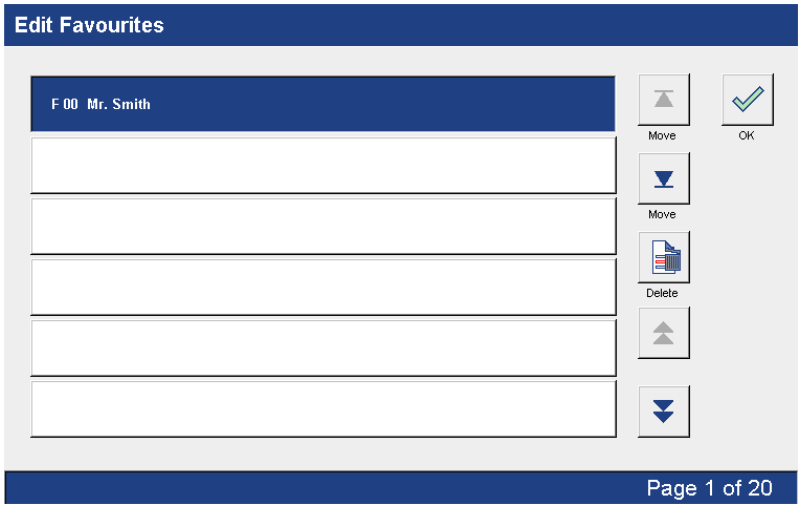


Retrieving a programme

In the list select the desired programme by pressing the appropriate row.

Editing

Press the ‘Edit’ button to open the 'Edit Favourites' screen



Activate the desired programme by pressing the appropriate row.

You are now able to

- Move or
- Delete

the selected programme.

Press the button to open the screen to save a programme

The “Save” button can only be pressed from the treatment screen.

Can be used to reverse the counting direction.

Pressing the key reset the current number of shocks

- to 0 by increasing counting direction
- to the preset value by decreasing counting direction.

Press the button to move an item of the list upwards by one position.

Press the button to move an item of the list downwards by one position.

Press the button to delete the selected programme from the list.

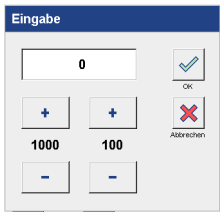
Scrolling forwards
Press the button to scroll one page down the list.

Scrolling backwards
Press the button to scroll one page up the list.

The changes are applied by pressing the button.

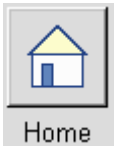
Press the button to reject the changes made.

Activation of the „+“ button increase the pulse rate in 1000 increments, activation of the „-“ button reduces the number of the pulses in 1000 steps.



Activation of the „+“ button increase the pulse rate in 100 increments, activation of the „-“ button reduces the number of the pulses in 100 steps.

Press the button to open the Programmes window

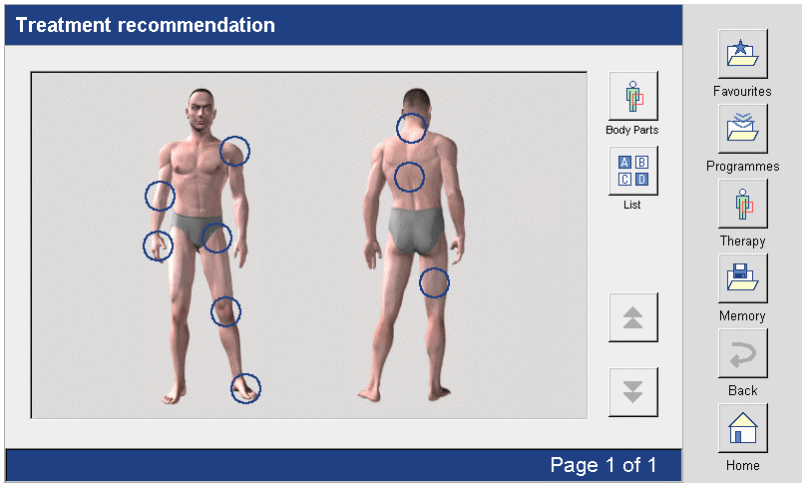


Press the button to return to the Start screen.

The Treatment recommendation menu helps you to select the treatment. The treatment can be selected using the body region menu or the treatment recommendation list.

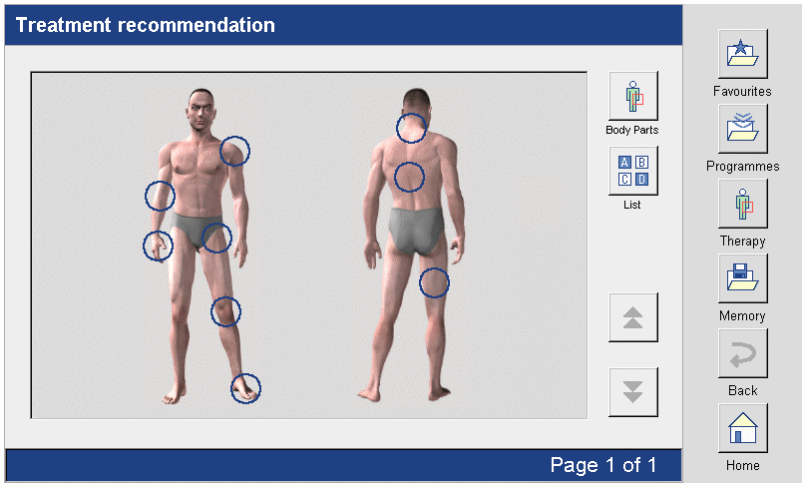
Therapy

Press the “Therapy” button to open the “Selecting by body region” window.



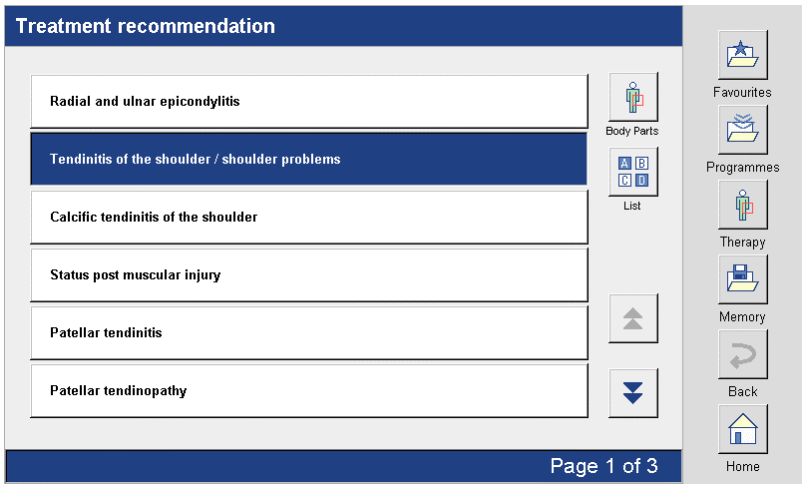
Selecting by body region

Select a body region by touching a circle.



Selecting by treatment recommendation list

Press the “List” button to open the list.



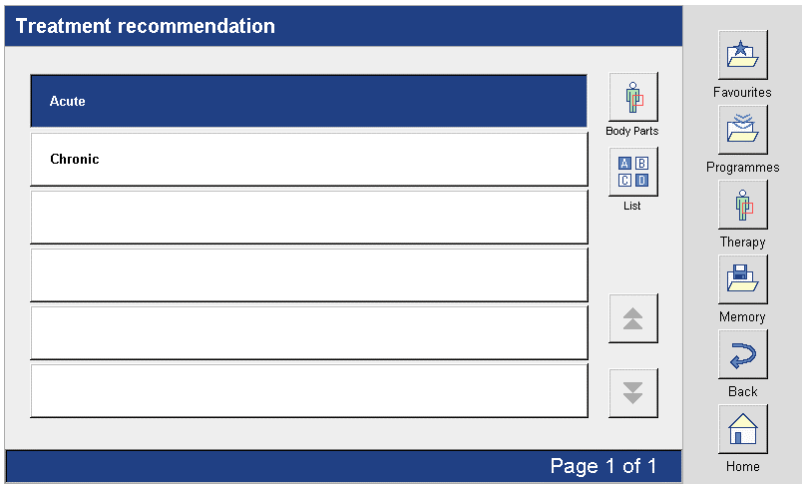
Note:

Further steps will only be described once, as the selection though Body Parts or List opens a similar list.

Selecting detailed symptoms

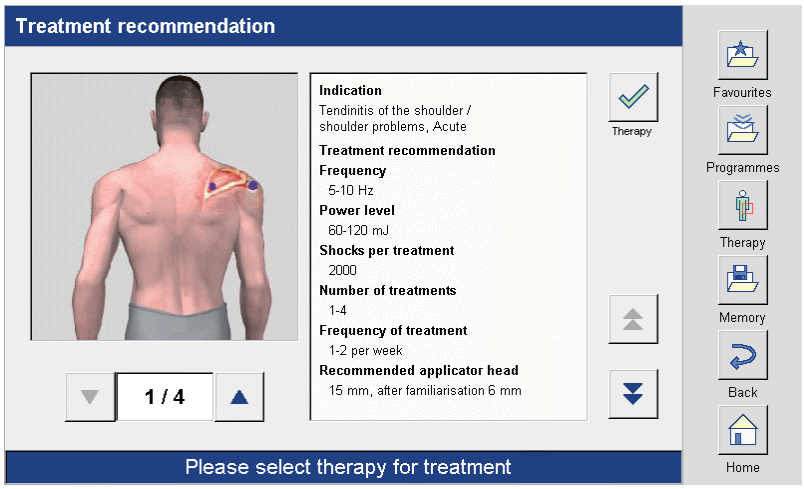
The selection of a treatment recommendation opens another window showing the detailed symptoms.

The detailed symptoms are selected by clicking directly on the row ('Acute' in this example).



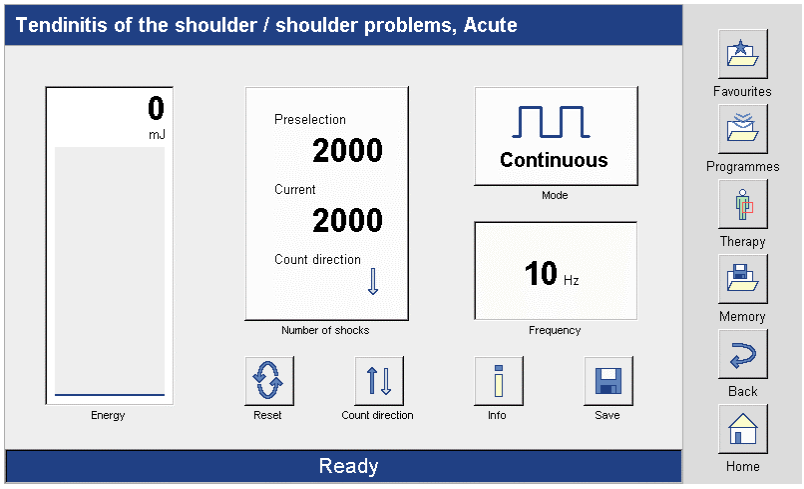
Treatment information

After selecting the detailed symptoms, another window opens showing detailed treatment and treatment information.



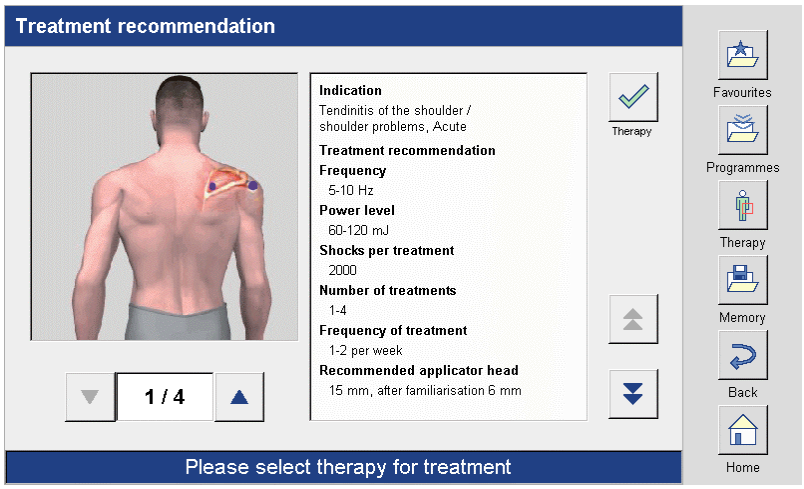
Selecting the treatment programme

Press the “Therapy” button to open the treatment screen with the programme.



Retrieving treatment information

Press the “Info” button to open the window with the treatment information.



Medical information

8

8.1. Indications

- Radial and ulnar epicondylitis
- Calcific tendonitis of the shoulder / shoulder problems
- Status post muscular injuries
- Chronic patellar tendonitis
- Jumper's knee
- Achillodynia
- Plantar fasciitis
- Heel spurs
- Myofascial trigger point treatment e.g. neck
- Myofascial trigger point treatment e.g. back, muscular back pain
- Bursitis Trochanterica
- Periostitis / shin splints (status post strain)

8.2. Contraindications

- vascular diseases present in or near the treatment area
- local infections in the treatment area
- around malignant or benign tumours
- directly on cartilage surfaces or near the small facet joints of the spinal column
- directly over implanted electronic devices such as pacemakers, analgesic pumps, etc.
- in areas, in which mechanical energy in the form of vibrations may lead to tissue damage such as metal implants after a fracture

In general we advise against treatments

- if blood clotting disorders are present or the patient is receiving treatment that results in a change in the blood clotting behaviour
- during pregnancy
- on patients with neurological diseases resulting in impairment of the vasomotor function in the treatment area
- over air-filled cavities such as treatment on the thoracic spine, etc.
- on children, particularly around the epiphyseal plates

Care is required for patients

- with impaired sensibility
- with severe autonomic disorders
- under the influence of drugs and/or alcohol

as circulatory stresses and inadequate treatment responses cannot be excluded.

General information

9.1. Explanation of symbols

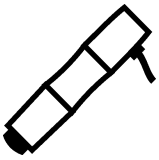
Danger / Warning

In the Operating Instructions, this symbol stands for **Danger / Warning**.

Caution

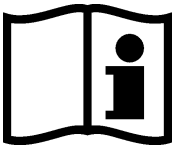
!

In the Operating Instructions this symbol stands for '**Caution**' with regard to possible damage to property.



Port for handpiece

Port for footswitch



Follow Operating Instructions

Instrument type BF (according EN60601-1):
Degree of protection against electric shock
Device must not be used at heart

Value of the accessible fuses

9.2. Warnings

- Users of the en*Puls* shockwave treatment device must be trained in how to use the system properly and have the appropriate skills.
- Any treatment instructions regarding treatment location, duration and strength require medical knowledge and should only be given by authorised doctors, therapists and health paraprofessionals. It is imperative that these instructions are followed.
- Treatment must always be carried out under medical supervision.
- The en*Puls* handpiece is not designed for permanent use. After a treatment with max. 6000 shocks, a break of 15min. becomes necessary.

- **Caution:**
  Patients who are concurrently receiving treatment involving a reduction and/or modification of blood clotting or prolongation of the blood clotting time (e.g. with acetylsalicylic acid) should consult their therapist about possibly stopping this treatment as these patients may be more prone to greater haemorrhaging and bruising when radial shockwaves are applied.
- Shockwaves are strongly scattered in air pockets and create reflections that may have negative effects.
  You must therefore never perform any direct treatments over the lungs (intercostal spaces) or the gastrointestinal area.
- It must not be used in wet areas. If it is used in wet areas, significant damage may result, and patients and users may be endangered.

The instruments must only be operated with the mains cable provided. Protect the mains cable from any mechanical stress.

en*Puls* Version 2.0:	Treatment system for electromagnetic generation / application of radial shockwaves in orthopaedics and physiotherapy.
Dimensions	L 322 mm / W 235 mm / H 130 mm
Weight	2.7 kg
Power supply	100–240 VAC / 50/60 Hz, 220 VAC / 60 Hz
Fuse	3,15 AT
Conformity	Protection class I / Application class BF
Frequency range	1 Hz – 16 Hz, can be adjusted in 1 Hz steps
3 burst modes	4, 8, 12 shocks with 16 Hz (0.5 s)
Shock energy levels	
4 selectable fixed settings	60 / 90 / 120 / 185 mJ (at the applicator) at 16 Hz max. 120 mJ
Mode of operation	Intermittent use max. 6000shocks / 15min. break
Accuracy	± 20%
Shockwave handpiece:	Ergonomic model with anodized aluminium case and fan cooling
Dimensions	230 mm in length, 50 mm diameter
Weight	850 g (with cable)
Service life	2,000,000 shocks (minimum)
	Applicator heads exchangeable without any tools (6 / 15 / 25 mm diameter)
Dimensions (complete with case)	L 580 mm / W 470 mm / H 250 mm
Total weight	13 kg (total with case)
Environmental conditions	
Operational environment	10 to 35 °C (50 to 75 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed
Storage / Transport	
Short-term	-10 to 55 °C (14 to 131 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed
Long-term	0 to 40 °C (32 to 104 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed

9.4. Technical information

As the manufacturer Zimmer MedizinSysteme can only be responsible for the safety and reliability under the following circumstances:

- if the device is operated from an approved, grounded wall socket and the electrical installation conforms to DIN VDE 0100 Part 710
- if the device is operated in accordance with the Operating Instructions
- if extensions, reconfigurations or modifications are implemented only by persons authorised by Zimmer MedizinSysteme
- users must ensure that the device and the handpiece are operating correctly; are mechanically intact and are in good condition before using them
- the device must be operated by appropriately trained personnel only
- disconnect the device from the power supply immediately if it is exposed to liquids.

The device does not contain any parts that must be maintained or repaired by the operator.

9.5. CE Marking / Legal information

CE Marking

This product bears the marking CE 0123 in accordance with EU Medical Products Directive 93/42/EEC and meets the essential requirements of Annex I to this Directive.

The product was developed, manufactured and tested using the quality management system according to DIN EN ISO 13485.

The product is rated in Class IIa according to Annex IX of the Directive.

Legal Information

National laws and regulations must be observed when installing and operating this treatment device.

Maintenance

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Separate servicing is not required for this product.

Before starting any maintenance or cleaning, the device must always be switched off at the main switch and the plug pulled out.

You should also check the applicators domes for any wear, as described in chapter 1.5.

Attention !

When using lubricants, it is essential to pull the silicone cap over the applicator head.
If you do not use the protective cap, the lubricant can get inside the applicator head and handpiece, which can lead to permanent soiling and malfunctioning.

Note: *In this case the warranty becomes void.*

Cleaning / disinfection

Clean the device and handpiece with soap lotions or cleaning agents that do not content alcohol or solvents.

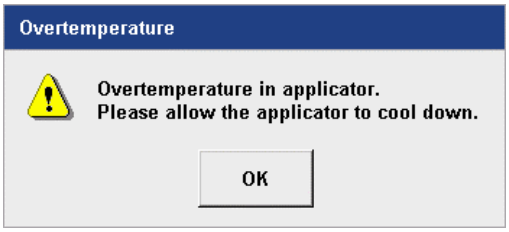
Conventional disinfecting products used for medical equipment are suitable.

Note: *It is essential to ensure that no moisture gets into the system when cleaning.*

Monitoring the handpiece temperature

Generating mechanical shockwave energy causes a considerable build up of heat in the handpiece. To avoid shortening the lifetime of the handpiece, a temperature switch has been integrated. This triggers an internal switch-off, if the temperature becomes too high, forcing the handpiece to cool.

If the temperature switch is activated, this is indicated by a message on the display and shocks can no longer be emitted.



After acknowledging the message with ‘OK’, the treatment screen comes to the foreground with the message 'Over temperature' in the status bar.

As soon as the handpiece has reached the operating temperature, the message 'Over temperature' is replaced by the message 'Ready' in the status bar and the treatment can be continued.

Failure or malfunction of the handpiece

Check to ensure that the handpiece plug is properly connected to the device.
It must be fully engaged.

Check the cable of the handpiece for any mechanical damage.

Irregular delivery of shockwaves / overheating of handpiece

Possible cause 1: Wear of applicator head
Difficult to move due to wear

Applicator heads are wear parts and should be replaced after a specific number of shocks.

Remedying cause 1

Removal of parts subject to abrasion:
Remove the applicator head from the handpiece and clean the rear dome thoroughly. Then hold the handpiece, without the applicator head, with the opening downward and, at 2 or 5 Hz frequency, release a few shocks (maximum 10) at the lowest energy level. Then reinsert the applicator head.

If the error still occurs, the applicator head has to be changed.

Possible cause 2: Wear of shockwave generator

The shockwave generator is an expendable part and should be replaced after 2 million shocks.
Check the total number of shocks of the device in the configuration menu.

Remedying cause 2

If the total number of 2 million shocks has been reached or exceeded, the shockwave generator must be replaced.

To replace the shockwave generator, contact a qualified customer engineer or the head office in Neu-Ulm, Germany.

Troubleshooting

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No response at main switch / display remains dark

Make sure that the mains plug is properly inserted in the power outlet and the device connector is firmly plugged into the device port.

Inspect the mains cable for damage.
Check the power supply and the power plug.

Above the mains input socket of the device, there are fine-wire fuses, which isolate the mains voltage in the event of any electrical problem.
Open the flap and check the fuses.
Replace any faulty fuses.

Only replace a fuse with one of exactly the same name or one that is equivalent. Before doing this, check the entire power supply for any possible faults.

If the error occurs again, it is essential to inform the service/after-sales service department.

Function test

en*Puls* runs a self-test that checks all internal components after it is switched on.

An error message is shown in case of faults.

In addition, a function test shall be made as follows.

This test shall be made monthly or in case of doubt about the proper function of the device.

Note: *Before performing the function test, check whether the handpiece and the footswitch are connected correctly to the device.*
Check for proper mains connection.

Function test

Testing Switch on the device.

Depress the footswitch briefly – the fan and shockwave generator will start immediately, whereby the shockwave generator has to operate at the frequency indicated on the display (5 Hz as default value).

Note: *On conclusion of the test, switch off the device at the main switch.*

If a treatment is to be performed immediately afterwards, set the required treatment parameters and proceed as mentioned in Chapter 4.

Error Messages

In the status bar the message 'Handpiece not found' appears.	Check that the handpiece is correctly connected
Monitoring the handpiece temperature	Generating mechanical shockwave energy causes a considerable build up of heat in the handpiece. To avoid shortening the lifetime of the handpiece, a temperature switch has been integrated. This triggers an internal switch-off, if the temperature becomes too high, forcing the handpiece to cool. If the temperature switch is activated, this is indicated by a message on the display and shocks can no longer be emitted. After acknowledging the message with ‘OK’, the treatment screen comes to the foreground with the message 'Over temperature' in the status bar. As soon as the handpiece has reached the operating temperature, the message 'Over temperature' is replaced by the message 'Ready' in the status bar and the treatment can be continued.
In the status bar the message 'Ready' appears and despite depressing the footswitch no shock is triggered.	Check that the shock energy is set. Check that the footswitch is correctly connected. Inspect the footswitch cable for any damage or kinks. Check whether the footswitch dome can be moved or whether it is blocked. Please contact after-sales service if this fails. After-sales service is reached through your authorised sales representative or by contacting the head office in Neu-Ulm.
No SD-Card found	If the SD card is not inserted, the message ‘SD card not found’ appears when the 'Favourites' and 'Memory' buttons are pressed. Insert card and confirm with ‘OK’.
Disposal	The device must be disposed of by an approved disposal company and must not be discarded with household or special waste.

Scope of delivery, Accessories

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Scope of delivery

1	Control unit en*Puls* Version 2.0
1	Handpiece, complete with a 15 mm applicator head
1	6 mm applicator head
1	15 mm applicator head
1	25 mm applicator head
10	Silicone caps
1	en*Puls* lotion
1	Footswitch
1	Mains cable
1	Operating instructions
1	Test template
1	Transport case
2	Touch pen
1	Holder for handpiece

Accessories
Item No.

50500016	Holder for handpiece
93133520	6 mm applicator head
93133510	15 mm applicator head
93133500	25 mm applicator head
50500017	Silicone cap
50500018	en*Puls* lotion
94130410	Footswitch
118	Mains cable
87053010	Transport case with foam insert
10101524	Operating Instructions
63061010	Test template
65800410	Touch pen

Manufacturer's declaration of Electromagnetic Compatibility

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Medical electrical devices such as en*Puls* Version 2.0 are subject to special precautions with regard to electromagnetic compatibility (EMC) and must be installed and commissioned in accordance with the EMC advice given in the instructions for use and accompanying documents.

Portable and mobile RF communication systems (e.g. mobile phones) may interfere with medical electrical equipment.

en*Puls* Version 2.0 should only be operated with the original mains cable specified in the list of contents delivered. Operating the device with any other mains cable can lead to increased emissions or reduced interference immunity of the device.

<table>
<tr><th colspan="3">Guidelines and manufacturer's declaration – electromagnetic interference</th></tr>
<tr><td colspan="3">The device enPuls Version 2.0 is intended for operation in an electromagnetic environment as indicated below. The customer or user of the enPuls Version 2.0 should ensure that it is operated in such an environment.</td></tr>
<tr><th>Interference tests</th><th>Conformity</th><th>Electromagnetic environment guideline</th></tr>
<tr><td>RF emissions according to CISPR 11</td><td>Group 1</td><td>The device enPuls Version 2.0 uses RF energy solely for its internal functioning. Its RF emission is therefore very low and it is unlikely that this will cause interference to neighbouring electronic equipment.</td></tr>
<tr><td>RF emissions according to CISPR 11</td><td>Class A</td><td rowspan="3">The device enPuls Version 2.0 is suitable for use in all installations including those in a residential environment and those which are directly connected to the public mains network which also supplies buildings which are used for residential purposes.</td></tr>
<tr><td>Harmonic emissions according to IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation emissions and flicker according to IEC 61000-3-3</td><td>Conforms</td></tr>
</table>

The device should not be used when placed immediately next to or stacked on top of other devices. If operation is necessary when immediately next to or stacked on top of other devices, the device should be monitored to ensure it is operating as intended in this arrangement.

Manufacturer's declaration of Electromagnetic Compatibility

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Guidance and manufacturer's declaration – Electromagnetic immunity			
The en*Puls* Version 2.0 device is intended for use in the electromagnetic environment specified below. The customer or the user of the en*Puls* Version 2.0 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) to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 seconds)	<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 seconds)	Mains power quality should be that of a typical commercial or hospital environment. The user of the en*Puls* Version 2.0 requires continued operation during power mains interruptions. It is recommended that the en*Puls* Version 2.0 be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commerical or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Manufacturer's declaration of Electromagnetic Compatibility

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The main features of the en*Puls* Version 2.0 are as follows: interference-free delivery of shockwaves, interference-free control of all functions. Uninterrupted operation is not required with the use intended.

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The device en*Puls* Version 2.0 is intended for operation in the electromagnetic environment specified below. The customer or user of the en*Puls* Version 2.0 should ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Conducted RF disturbance variables according to IEC 61000-4-6 Radiated RF disturbance variables according to IEC 61000-4-3	3 $V_{effektive\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 $V_{effektive\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radio equipment should not be used any closer to the en*Puls* Version 2.0, including cables, than the recommended separation distance calculated from the equation applicable to the transmission frequency. **Recommended separation distance:** $d = 1.2 \sqrt{P}$ $d = 0.35 \sqrt{P}$ for 80 MHz to 800 MHz $d = 0,7 \sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the rated power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). According to an investigation in situ[a], the field strength of stationary radio transmitters should be less than the compliance level at all frequencies. Interference may occur in the vicinity of equipment which is marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz the higher frequency range is applicable. NOTE 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer's declaration of Electromagnetic Compatibility

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[a] Theoretically, it is not possible to exactly predict the field strengths of fixed transmitters such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting. To determine the electromagnetic environment in relation to the fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the en*Puls* Version 2.0 device is to be used exceeds the above compliance levels, the en*Puls* Version 2.0 device should be monitored in order to ensure that it is functioning as intended. If unusual features are noticed, additional measures may be necessary such as re-orienting or relocating the en*Puls* Version 2.0 device.

[b] Above the frequency range from 150 kHz to 80 MHz the field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF telecommunications equipment and the en*Puls* Version 2.0 device

The en*Puls* Version 2.0 device is intended for operation in an electromagnetic environment where RF disturbances are monitored. The customer or user of the en*Puls* Version 2.0 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the en*Puls* Version 2.0 device – according to the output power of the communications device, as indicated below.

Rated output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d= 1.2 √P	**80 MHz to 800 MHz** d= 0.35 √P	**800 MHz to 2.5 GHz** d= 0.7 √P
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.1	2.2
100	12	3.5	7

For transmitters rated at a maximum output which is not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the respective column, whereby P is the maximum rated output of the transmitter in Watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz the higher frequency range is applicable.
NOTE 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

en*Puls*
Version 2.0

Operating Instructions

GB 10 101 524 VS 0812 I Version 4 I Right of modifications reserved

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