Zimmer
MedizinSysteme

Instructions for Use

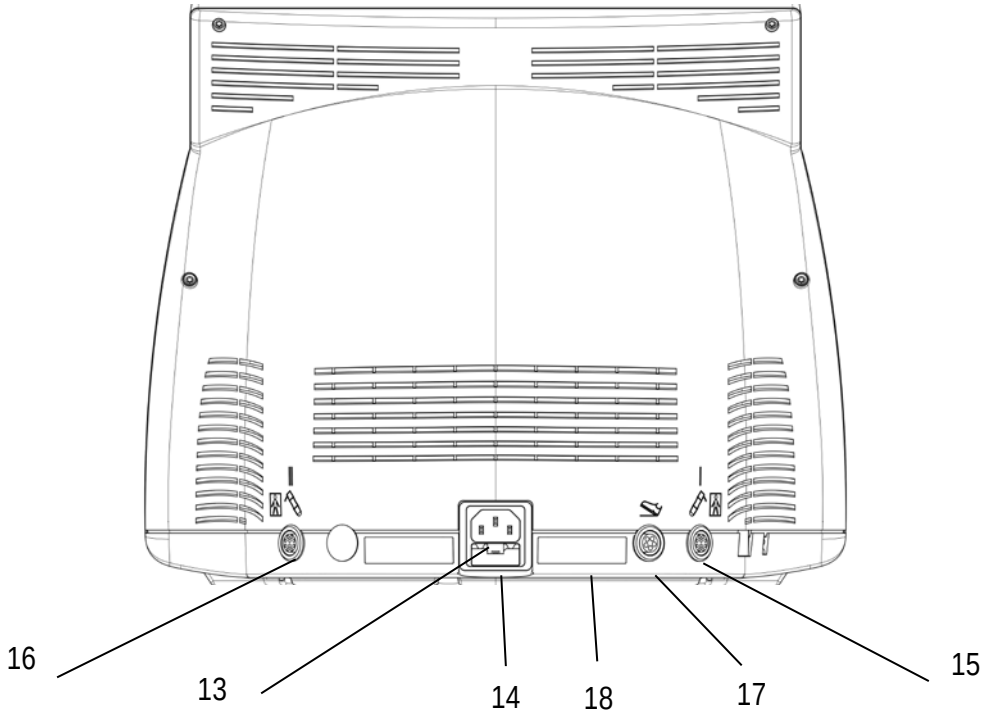
enPuls*Pro*

EN

Fig. 1

Selection and operating elements	1	Control unit
	2	Pulse energy controller
	3	Display
	4	Frequency controller
	5	Slot for SD card
	6	Mains switch
Handpiece	7	Handpiece
	8	Vents, front
	9	Vents with fan, rear
	10	Holder for handpiece
Foot switch	11	Foot switch
Optional accessories	12	Rotatable swivel foot

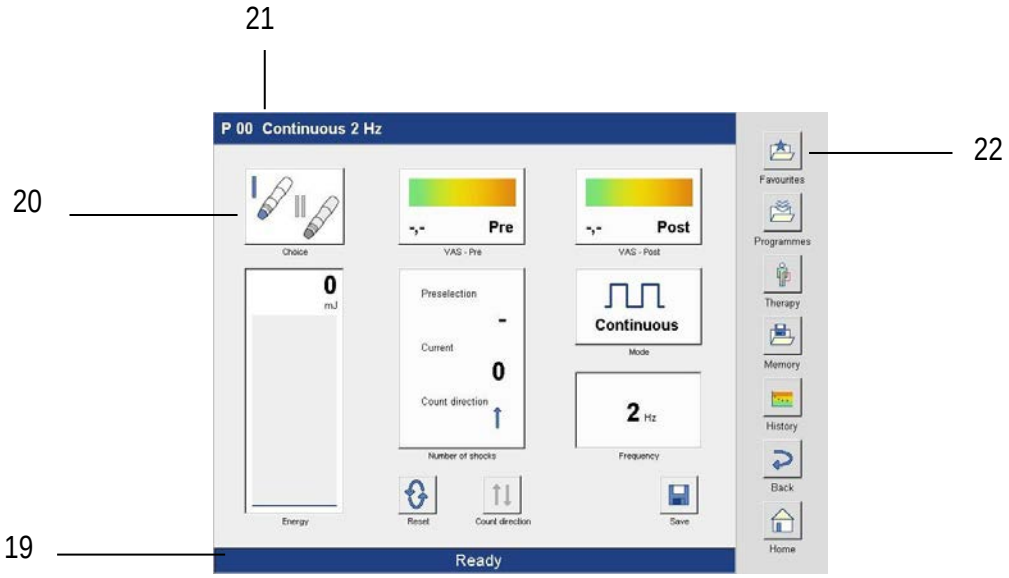
Fig. 2



Switches / ports

13 Port for power cable
14 Mains fuse
15 Port for handpiece channel I
16 Port for handpiece channel II
17 Port for foot switch
18 Serial no./identification plate

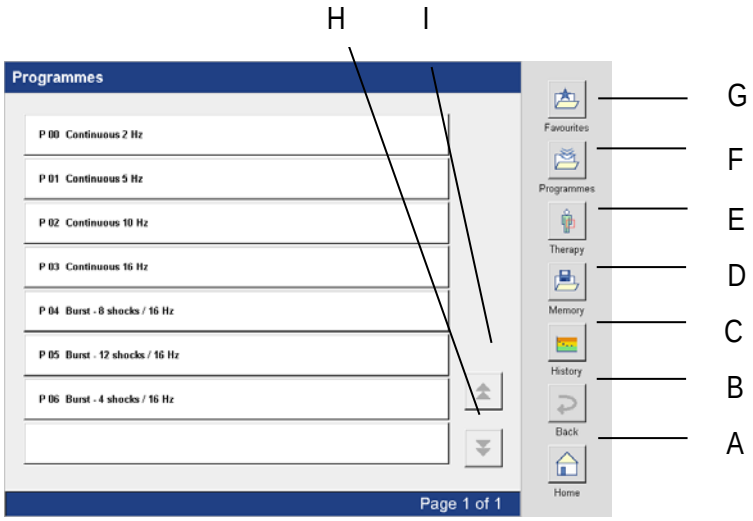
Fig. 3



Display/ therapy screen

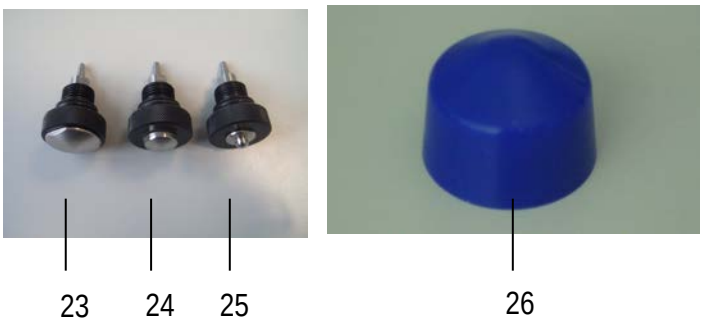
19 Status line
20 Buttons on the screen
21 Heading
22 Navigation menu

Fig. 4



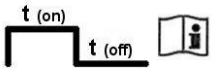
Navigation menu Description of the functions	(A) Home	Switches back to start page
	(B) Back	Moves one step back
	(C) Evaluation	Switches to the VAS evaluation
	(D) Memory	Switches to the memory area
	(E) Therapy	Switches to the therapy recommendation
	(F) Programs	Switches to the program list
	(G) Favourites	Switches to Favourites
	(H) Scroll forwards	Goes forward one page
	(I) Scroll backwards	Goes back one page

Fig. 5



Applicator heads	23	Applicator head, 25 mm
	24	Applicator head, 15 mm
	25	Applicator head, 6 mm
Accessories	26	Silicone protection cap

Explanation of symbols

	In the instructions for use this symbol indicates “Danger”.
Caution!	In the instructions for use this symbol indicates "Caution" with regard to possible damage of the device.
	Connection port for handpiece
	Connection port for foot switch
	Instructions for use
	Follow instructions for use.
SN	Serial number
REF	Item number
	Manufacturer
	Date of manufacture
	Applied part type BF
	Rating of the accessible fuses
	Interval operation - Follow instructions for use

Content

Content

Valid for the device enPuls*Pro*.

These instructions for use 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.

Last updated: November 2017

Indications / Contraindications

1

Indications

- Radial and ulnar epicondylitis
- Calcifying tendonitis / shoulder problems
- Condition post blunt muscle injuries
- Chronic patellar tendon syndrome
- Patellar tendonitis
- Chronic tendinopathy of the Achilles tendon
- Plantar fasciitis
- Heel spurs
- Myofascial trigger point treatment, e.g. in the neck
- Myofascial trigger point treatment, e.g. in the back in the case of muscular back pain
- Trochanteric bursitis
- Periostitis / Tartan syndrome (condition post overloading)

Contraindications

- Vascular diseases in or in the vicinity of the treatment area
- Open wounds in or in the vicinity of the treatment area
- Local infections in the treatment area
- Use in the region of malignant/benign tumours
- Application directly to cartilage surfaces or in the area of the small facet joints in the spine
- Application directly via implanted electronic devices, e.g. pacemakers, pain pumps, etc.
- In areas where mechanical energy in the form of vibrations leads to damage of the tissue, e.g. metal implants
- After fracture, in the case of torn muscle fibres or muscle tears

In general, treatments are not recommended

- For bleeding disorders or treatments that result in a change in blood coagulation
- During pregnancy
- In diseases involving a disorder of the vasomotor system in the treatment area
- Via air-filled spaces (e.g. treatment of the thoracic spine etc.)
- Generalised pain syndrome, e.g. fibromyalgia
- In children, especially in the area of the epiphyseal plates

Caution is indicated in the case of persons

- who have sensitivity disorders
- who have significant vegetative disorders
- who are under the influence of drugs and/or alcohol

since significant circulatory stress and inadequate treatment reactions cannot be ruled out.

Side Effects

Treatments with enPuls*Pro* may occasionally cause irritation, petechiae, haematoma, swelling, or pain.

Prior to using the device on a patient, the user should become familiar with the instructions for use and individual treatment methods to be used as well as the indications / contraindications, warnings and application information. Additional sources of information about the treatment should also be followed.

Caution!

Before use, ensure that the device is powered via a properly grounded mains socket (electrical installation according to DIN VDE 0100 Part 710). The device must only be operated with the supplied power cable. The power cable must be protected against mechanical stress.

Caution!

Operation of this device in the vicinity of strong electromagnetic fields (e.g. tomographs, X-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several meters.

enPuls*Pro* is not suitable for use in areas with an explosive, flammable or combustive environment.

During use, the device is to be located in a position allowing direct access to the device´s central mains supply so that it can be disconnected from the mains at any time.

To avoid the risk of electric shock, the plug must be disconnected from the power supply before performing any cleaning or maintenance activities.

Inspect the device before use. If there is any damage, it must not be used.

Caution!

Only accessories provided by Zimmer MedizinSysteme GmbH must be used.

Caution!

The device handpiece is not designed for continuous operation. After a max. 6,000 strokes, a treatment pause of 15 min is required.

Caution!

If the enPuls*Pro* is not mounted on the intended system wagon, ensure that the device is placed on a stable surface.

Caution!

To avoid heat accumulation in the handpiece, ensure that the vents on the top and especially the bottom of the handpiece are not blocked (i.e. by the hand holding it or otherwise).

Treatment instructions regarding treatment location, duration and intensity require medical knowledge and may only be given by authorised physicians, therapists and medical paraprofessionals. These instructions must be followed.

The patient must not be left unattended during treatment.

Persons undergoing simultaneous treatment with reduction and/or alteration of blood clotting or a prolongation of clotting time (e.g. acetylsalicylic acid) should consult their therapist about a possible discontinuation of this treatment as the use of radial shock waves can readily lead to increased bleeding and bruising in these patients.

Shock waves are strongly scattered in air-filled areas and produce reflections that can have negative effects.
Direct treatments should therefore not be performed above the lungs (intercostal space) and gastrointestinal area.

Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user.

In exceptional circumstances the treatment time is limited to 4 minutes followed by a break of at least 15 minutes.
The handpiece can overheat if the treatment time is exceeded.

What is enPuls*Pro*?	An ultra-modern, innovative shock wave treatment device.
Shock wave treatment	Radial, ballistic shock wave treatment is a versatile method. From superficial orthopaedic problems to myofascial trigger point treatment.
What does enPuls*Pro* do?	It generates shock waves by means of an ergonomic handpiece and emits shock waves through special applicators. The enPuls*Pro* can penetrate human tissue for up to approximately 35 mm.
How are shock waves generated with enPuls*Pro* do?	A coil generates an electromagnetic field in the rear of the handpiece. A projectile is accelerated through the field. This crashes against the applicator head at the front of the handpiece and generates shock waves that spread radially in the tissues.
What are the advantages of enPuls*Pro?*	The innovative technology allows for a compact design without a compressor. The modern, clear colour display showing all therapy-related parameters, the modern touch operation and the ability to connect 2 handpieces at the same time ensure enjoyment and motivation during treatment. Individual program start adjustment and clear, simple menus offer the user maximum convenience. Different, continuously adjustable frequencies and a choice of applicators allow a treatment that is individually suited to the particular condition of the patient.
Are there any other advantages to using enPuls*Pro*?	An integrated VAS scale gives an overview of the time course and success of the treatment.
Intended use	enPuls*Pro* is a treatment system for the electromagnetic generation and application of radial shock waves in orthopaedics and physiotherapy.
Note:	*The application of the device is reserved for medical professionals (such as physicians, therapists and health paraprofessionals).* *enPulsPro is designed and intended solely for the treatment of superficial orthopaedic problems in humans.*

Note: *If the enPulsPro is not mounted on the intended system wagon, ensure that the enPulsPro is placed on a stable surface.*

Note: *Make sure that the power switch of the device is set to “0”.*

Connect power cable — Connect the power cable to the provided port (13) on the device and connect the cable to the mains.

Note: *The device may only be connected to power outlets with a protective contact.*

Connect handpiece — Connect the handpiece to one of the ports provided channel I (15) or channel II (16) and set it down.

Note: *Ensure that an applicator head is inserted in the handpiece and that it is screwed in correctly and completely.*

Connect foot switch — Connect the foot switch to the port provided (17) and put it on the floor.

Switch device on — Switch on the device using the power switch (6).

Switch device off — The device is switched off using the power switch (6).
To fully (all poles) disconnect the device from the mains, the power cable must be disconnected.

Caution! — All cables must be protected from pinching or other mechanical damage.

Note: *Changes to the default settings can only be made from the start-up screen.*

Start-up screen

After the device has been switched on and the self-test performed, the start-up screen opens.

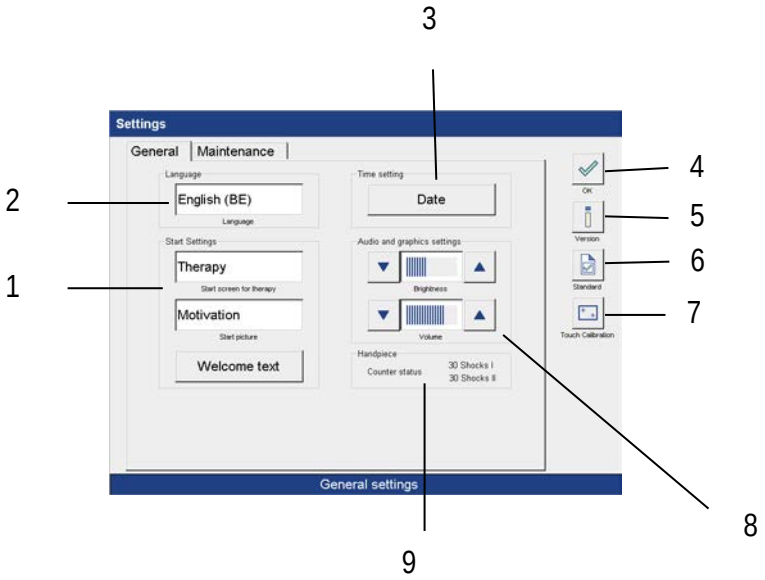
Note: *Activating the "instant start" button (2) switches immediately to the therapy screen.*

Configuration menu

Factory settings can be changed and individually adjusted in the configuration menu.

Select configuration

Activating the “Configuration” button opens the “Configuration” screen.



The setting options are described below.
The default settings are pre-programmed in the factory as shown on the screen.

(1) Start settings	1. Start menu: Options to individually select the start-up settings. 2.Start-up image: Option to select from two start-up images The selection is made directly in the corresponding line. 3. Welcome text: Activating the “Welcome text” field opens a window with an alphabetical keyboard to enter an individual welcome text in the start-up screen. Activating the “OK” button saves the text entered. Activating the “Cancel” button leads back to the configuration menu.
(2) Language	Language selection. The selection is made directly in the corresponding line.
(3) Setting the time	Activating the “Date” field opens the time settings input menu. The current time and date are displayed here. The time and date are changed by the two arrow keys. Activating the “OK” button saves the changed setting. Activating the “Cancel” button leads back to the configuration menu.
(4) OK	Activating the “OK” button switches to the start screen.
(5) Version	Activating the “Version” button opens a window with information on the current software version.
(6) Standard settings	Activating the “Standard” button restores the factory default settings.
(7) Touch calibration	Activating the “Touch calibration” button opens the screen to perform a touch calibration. This can lead to an improvement in the event of insufficient accuracy during touch input. Follow the instructions on screen for touch calibration.
(8) Audio / video settings	1. Brightness: Option to adjust the brightness of the screen illumination. 2. Volume: The volume of the signal sounds can be adjusted by activating the control panels. The adjustment can be made using the two arrow buttons.

(9) Handpiece	In this display panel, the meter reading of any connected handpiece(s) is shown.
Maintenance	The “Service” menu is not relevant for the user. The points listed here are only used in the event of service by customer service.

Handpiece

The handpiece (7) contains the shock wave generator, a fan for heat dissipation, and the ports for the different applicator heads. It is connected to the control unit (1).

Note: *The shock wave generator in the handpiece is subject to wear and must be replaced after a certain length of use because its functionality decreases with time.*

Zimmer MedizinSysteme GmbH guarantees unrestricted use at a rate of at least two million shocks per shock wave generator.
In some cases, depending on power and frequency, well over
2 million shocks can be emitted.

More information on the need to replace the shock wave generator is given in chapter 17.

To work with the handpiece on the patient, one of the applicator heads **must** be screwed firmly and completely into the handpiece.

Interval operation

The handpiece is not suitable for continuous operation. Frictional heat causes the temperature of the applicator head to rise with increasing duration of treatment, so much so that thermal damage to the patient cannot be excluded. Please comply with the warning in chapter 4. Treatment must be interrupted once the time stated has been reached and can only be continued after the applicator head has cooled down to room temperature.

Note: *Please note that the temperature monitoring of the handpiece described on page 11 below is only a technical shutdown to protect the mechanical parts inside the handpiece. It does not give any information about the temperature of the applicator head.*

Recommendation: *To avoid interruption in treatments with more than 6,000 shocks, the connection of a second handpiece is recommended.*
While one handpiece is cooling the unit can be switched to the second handpiece and treatment can be continued without delay.

Note: *When switching from one handpiece to another during a single session of treatment, pulse frequency and the number of shocks remain unchanged.*
Pulse energy returns to 0
and must be reset.

Handpiece temperature monitoring / regulation

The production of mechanical impact energy generates considerable heat within the handpiece. A temperature switch has been integrated to prevent damage to the life of the handpiece. In the case of overheating, this forces cooling of the handpiece through an internal shutdown.

In addition to temperature monitoring, the enPuls*Pro* regulates the temperature using a temperature sensor in the handpiece. The fan in the handpiece is started when activated by the foot switch and automatically stops when it reaches a certain temperature.

If the temperature reaches a critical limit, a cooling phase is initiated. This is indicated by the following message in the display:
“Overheating of the applicator. Please allow the applicator to cool down.”
Pulses can no longer be emitted.

After confirming the message with "OK", the therapy screen moves to the foreground with the “Overtemperature” message in the status bar and a notification when the handpiece returns to operating temperature.

Once the handpiece has reached operating temperature, the message "Overtemperature" in the status bar is replaced by the message "Ready" and therapy can be resumed.

Applicator heads

Three different applicator heads are available for treatment.

Changing the applicator heads

To change the applicator heads, hold the handpiece with one hand and turn the applicator head anti-clockwise with the other hand to remove it from the handpiece. Then insert the head you wish to use by turning it clockwise until it clicks into place.

Note:

The applicator heads are subject to wear and must be replaced after a certain length of use (see chapter 14.2 Maintenance).

Foot switch

Place the foot switch so that it can be easily reached during treatment. The operating element of the switch is independent of direction, and so precise alignment of the foot switch is unnecessary.

To avoid damage, ensure that only slight pressure is exerted on the switch. Use the forefoot rather than the heel to operate the switch.

The switch has no locking mechanism, and so operates only while pressure is applied to the switch.

Therapy

Please hold the handpiece as shown in the picture below.

The enPuls*Pro* uses mechanical energy, which is transferred to the patient via a handpiece.

In order to achieve this, the handpiece with the applicator head is placed perpendicular to the treatment area or the point of treatment.

While shock wave application is activated, you can work either with the handpiece stationary on one point, or dynamically across an area.
We recommend using the en*Puls* lotion supplied to reduce friction on the skin.

The weight of the handpiece means that it is usually not necessary to press down firmly on the treatment area / point.
The handpiece is applied and held in position with the hand in a relaxed posture.
If required, pressure can also be applied in the direction of the tissue and the angle of use can be varied.

Caution!

The silicone protection cap must be pulled over the applicator head when using lubricants in order to avoid soiling.
If the protective cap is not used, the lubricant can penetrate the applicator head and the handpiece, which can lead to lasting soiling and malfunction.

Note:

This invalidates the warranty.

Note:

Despite high internal attenuation through the weight and construction of the handpiece, the user's hand can suffer stress through vibrations.

Recommended protective measures:
- Limit exposure time
- Passive support

Note:

The patient should be carefully monitored during treatment.

Note: *All buttons, menus and sub-menus can be activated directly on the screen with finger pressure.*

Program start Activating the "instant start" button in the start screen switches to the programs screen.

Select applicator Select the applicator suitable for your desired therapy and screw it correctly into the handpiece.

Place handpiece/applicator Place the handpiece on the selected treatment point/area. To prevent friction on the skin, lotion can be applied to the treatment area before treatment.

Set pulse energy Use the left-hand controller to set pulse energy.

Note: *enPulsPro offers two pulse emission options.*

Pulse emission with pre-set number of pulses
For pulse emission with a pre-set number of pulses, treatment is terminated by the device after the pre-set number of pulses has been emitted.
The foot switch is deactivated and pulses can no longer be emitted.
Treatment can be continued by resetting the current number of pulses or adjusting the preselection.

Pulse emission without pre-set number of pulses
For pulse output without a pre-set number of pulses, treatment is not terminated by the device. Pulses are emitted as long as the foot switch is activated.
For pulse emission without pre-set, only the ascending counting direction is active.

Start of therapy Activating the foot switch starts the therapy.

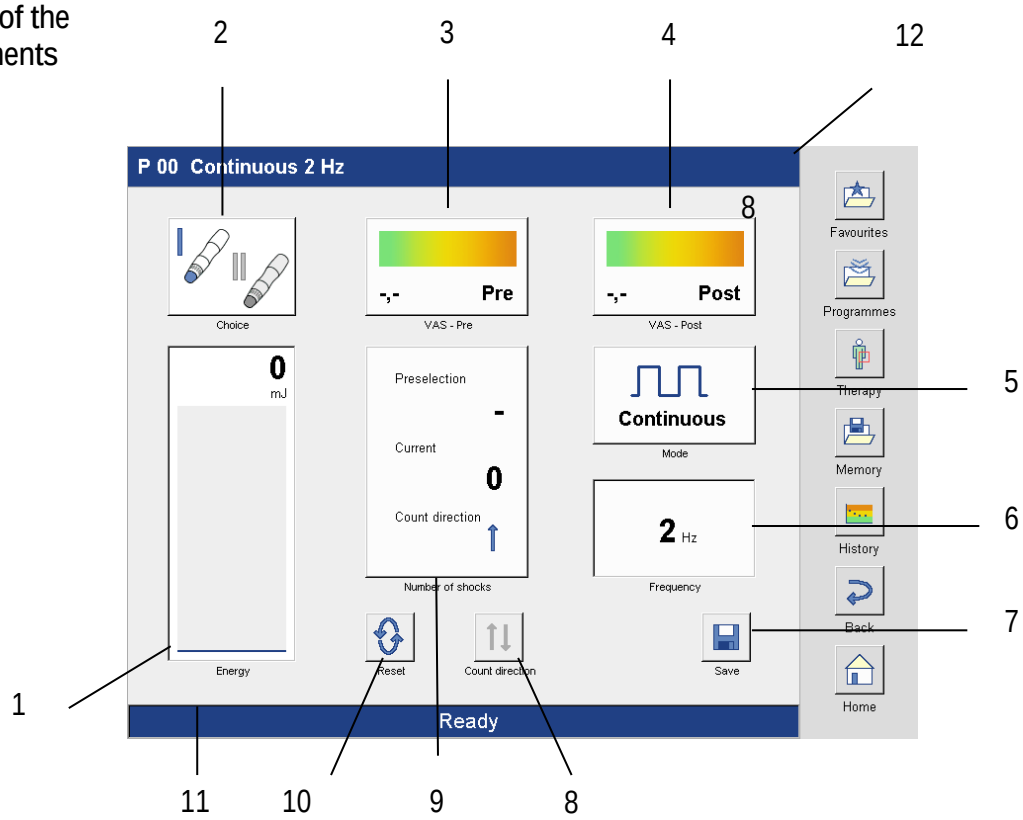
The display in the lower status bar changes from “Ready” to “Active”.

Note: *The shock wave should be activated via the foot switch only after placing the handpiece on the patient.*

End of therapy Deactivating the foot switch interrupts or terminates the therapy. The display in the lower status bar changes from “Active” to “Ready”.

Note: *The patient should be monitored carefully during therapy and if necessary, the therapy should be adapted or discontinued if problems occur.*

Description of the display elements and buttons



(1) Pulse energy

Displays the set pulse energy. During active therapy, the bar graph is filled in. Pulse energy can be set before and during pulse emission. Pulse energy can be set in 10 mJ increments to between 60 and 185 mJ.

(2) Selection of handpiece

Connecting one handpiece:
If only one handpiece is connected, the channel of the connected handpiece is shown in the selection window. The handpiece is activated automatically regardless of the connected channel.

Connecting two handpieces:
When connecting two handpieces, the handpiece on channel I is activated first. The desired handpiece is activated by directly selecting the handpiece in the selection window.
The activated handpiece is shown by the blue applicator head.

(3) VAS Pre

Activating the VAS Pre window opens the screen to measure the subjective sensation of pain prior to treatment.

(4) VAS Post

Activating the VAS Post window opens the screen to measure the subjective sensation of pain after treatment.

The precise procedure for this measurement is described in detail in chapter 8.8.

(5) Mode	Displays the set operating mode. Activating the “Mode” window pulls up the selection menu with the operating modes: Series Pulse, Burst 4 Pulse, Burst 8 Pulse, Burst 12 Pulse. The desired operating mode is selected directly in the corresponding line.
(6) Frequency	Displays the set frequency. Frequency range: 1 Hz – 22 Hz, adjustable via the right-hand controller. The maximum selectable frequency depends on the energy level set.
(7) Saving	Activating the button opens the field to enter the individual name of a program to be saved in the memory list or favourites list.
(8) Counting direction	Activating the button sets the counting direction (ascending or descending) of the number of pulses emitted.
(9) Pulse count	Display of the preselected number of pulses and the currently emitted pulses as well as the total number of pulses emitted in the case of non pre-set pulse number. The counting direction can be displayed ascending or descending. Activating the pulse count window opens the entry menu for entering a pre-set number of pulses. The preset value can be set at intervals of 100 or 1000.
(10) Reset	For ascending counting direction, this resets to 0; for descending counting direction, this resets to the pre-set number of pulses.
(11) Status display	Displays information regarding the current status of therapy. If therapy is not active, the text "Ready" appears, while during ongoing therapy the text "Active" appears.
(12) Title bar	Displays the name of the currently selected program.

SD card

The user-defined settings as well as the list of indications are saved on the SD card.

If the SD card is not inserted, the following message appears when the "Favourites", “Memory” and "VAS" buttons are activated:

"No SD card found."

The use of "Favourites", “Memory” and "VAS" requires an SD card.

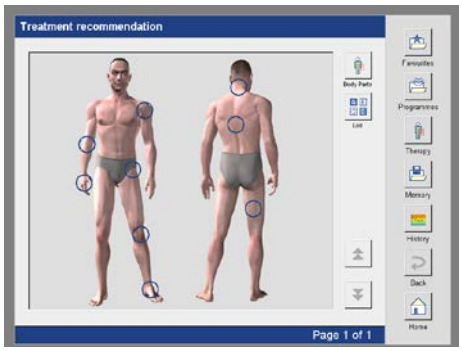
Insert the card and confirm with "OK".

Note: *Deactivate the message as described in section 7.*

The “Therapy recommendations” menu assists in therapy selection.

Therapy

Activating the therapy button opens the “Therapy recommendations” menu.

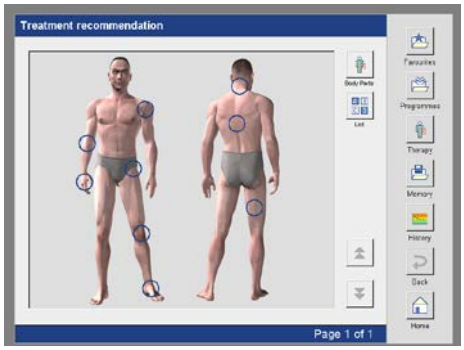


Note:

The “Therapy” menu offers two ways of selecting the desired therapy:
- via the body regions
- via the list

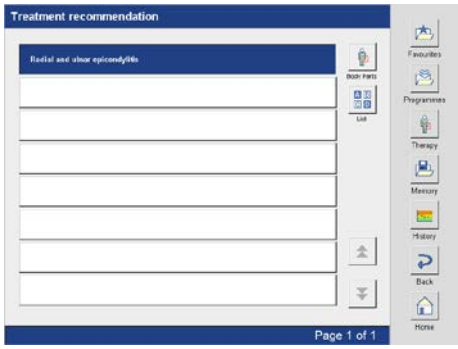
Therapy selection via body region

The body region is selected by clicking on the blue circle.



Select body region

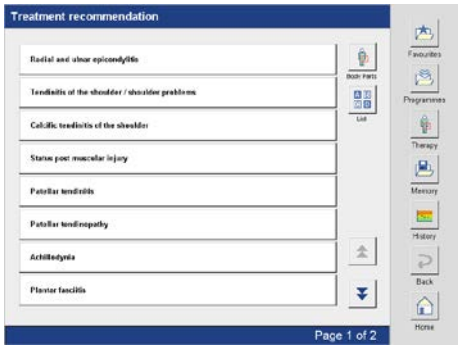
After selecting the desired body region (in this case the elbow),
the window for therapy recommendations in the elbow region opens.



The clinical picture is selected directly in the corresponding line.

Therapy selection via list

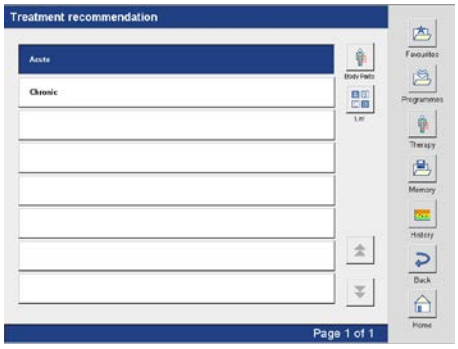
Activating the List button opens the list with indications.



Note: *Regardless of whether the indication is selected via the body regions or the list, the program steps leading to the therapy screen are similar, and are therefore described only once below.*

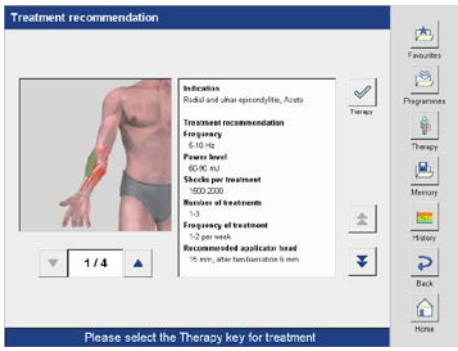
Select differentiated condition of the clinical picture

The differentiated condition of the clinical picture is selected directly in the corresponding line (here: acute).



Therapy information

After selecting the differentiated condition of the clinical picture, another window with detailed therapy and treatment information opens.



Select therapy program

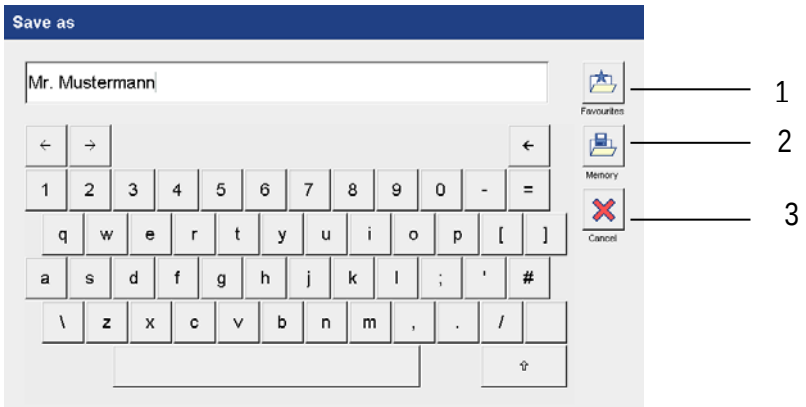
Activating the button opens the therapy screen with the corresponding program.

Note: *If the therapy screen is activated from the "Therapy recommendations" menu, an additional “Info” button appears. Activating the "Info" button opens a window with therapy information regarding the selected clinical picture.*

The parameters of the predefined programs can be individually modified and saved.

Save and name program

Activating the “Save” button opens the field to enter the program name.



The program name is entered via the keyboard.

Note:

The programs can be saved in the Favourites list or Memory list. There are 120 storage locations available in each case.

Saving in the Favourites list / Memory list

Activating the button (1) opens the Favourites list and automatically saves the program in the Favourites list.
Activating the button (2) opens the Memory list and saves the program in the Memory list.

Activating the “OK” button closes the “Save” screen and adds the program to the corresponding list.

The program is always saved in the first open space in the list.

Activating button (3) interrupts the save procedure.

Note:

If the “Save” button is activated without a program name being entered, the following message appears:

"Please enter a name!"

Confirm the message by pressing “OK”, enter program name and repeat save procedure.

The individually saved programs are listed in the Favourites list.

These can be

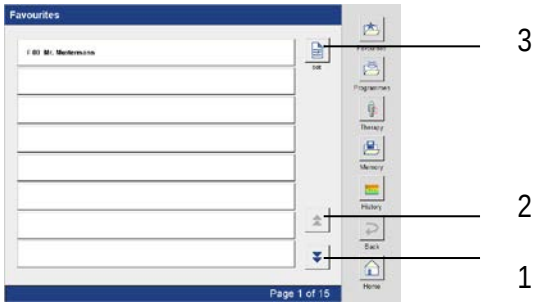
1. retrieved here for therapy,
2 . edited (moved in the sequence and deleted).

Note: *The steps to retrieve and edit the Favourites/Memory list are identical, so only retrieving and editing the favourite list is described.*

Select Favourites list Activating the “Favourites” button opens the favourites list.

Retrieve program The desired program is selected directly in the corresponding line

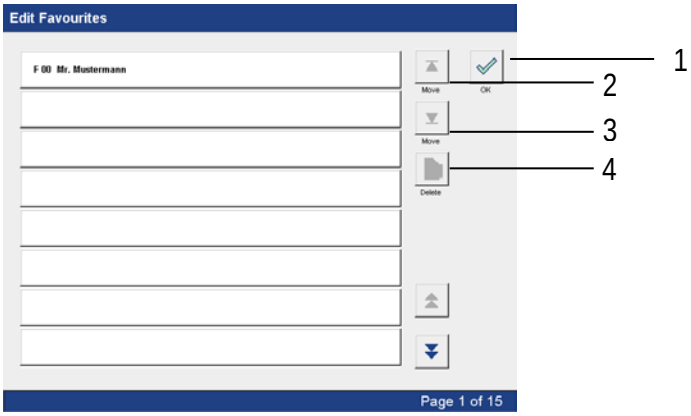
Edit Favourites list



By activating the buttons (1) and (2), the individual pages in Favourites can be viewed. Button (1) scrolls forward, button (2) scrolls backward.

Activating the button (3) opens the “Edit Favourites” screen.
Select the favourites to be edited directly in the line.

Edit Favourites



Activating button (1) leads back to the program.
Activating the button (2) moves the program up.
Activating the button (3) moves the program down.
Activating the button (4) deletes the program.

Note: *Activating button (4) triggers a confirmation prompt:*

“Do you really want to delete the program?“

Activating the “Yes” button deletes the program.
Activating the “No” button interrupts the deletion process.

Information on VAS

enPuls*Pro* has a visual analogue scale, also called a pain scale. The pain scale is often used in pain therapy.
It measures the patient's subjective pain intensity.

The patient rates the current pain on a scale of 0–10, whereby 0 = "no pain" and 10 = "worst pain imaginable".

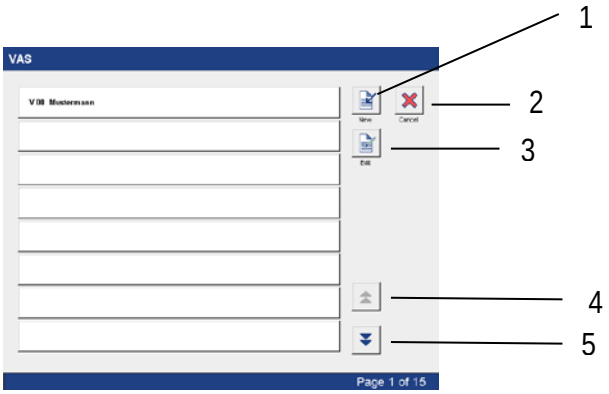
The measurement is carried out before and after each treatment.

When documented repeatedly, this method gives an overview of the time course and success of a therapy.

VAS list

Activating the "VAS Pre" / "VAS Post" field in the therapy screen opens the "VAS" screen.

In the VAS list,
1. New patients are entered for measurements
2. Patients that have already been entered are called up for further measurement
3. Data are processed (moved in the sequence or deleted)



Activating button (1) opens the field to enter the patient name. Activating button (2) interrupts the process and returns to the therapy screen.

Editing the VAS list

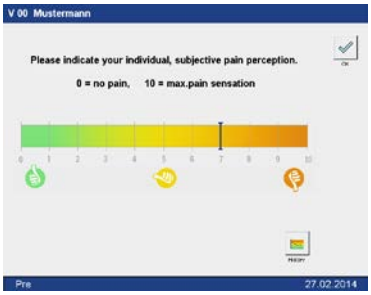
Activating button (3) and selecting the program to be edited directly in the line opens the screen for editing the data.
Activating the “Delete” button deletes the program.
Activating the "Scroll" arrows moves the program one place up or down.
Activating buttons (4) and (5) scrolls forwards and backwards through the pages of the VAS list.

Enter new patient

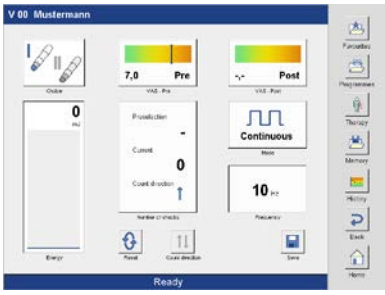
Activating the "VAS Pre" field in the therapy screen opens the VAS screen. Activating the “New” button opens the field to enter the patient’s name.

Enter the patient's name. Activating the “Save” button transfers the data and the pain scale screen
opens automatically.

Performing VAS Pre



The patient marks his/her current perception of pain before therapy on the scale from 0 to 10. This is transferred to the scale, shown by a blue line and automatically saved. Activating the “OK” button switches to the therapy screen.



Performing VAS Post

The perception of pain after therapy is determined by activating the “VAS Post” field.

Note:

“VAS Post” is performed in exactly the same way as “VAS Pre”, and so is not described again.

Repeating measurement

Patients that have already been entered are activated in the VAS list directly on the corresponding line.
Once the line has been activated, the screen opens automatically with the pain scale so that a new measurement can be performed.

Note:

Up to 40 measurements per patient can be stored.
Once this figure has been reached, the following information appears:
"The maximum number of measurements that can be saved per patient has been reached. A maximum of 40 measurements can be stored."

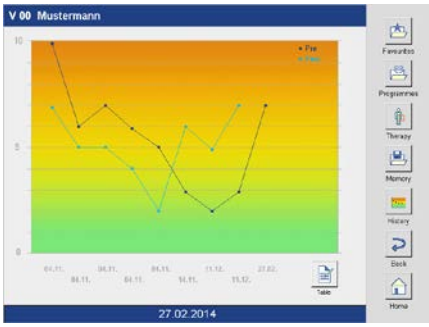
To perform more measurements on this patient,
the patient must be entered again.

Activating the "OK" button closes the information window with the message.

Evaluating VAS

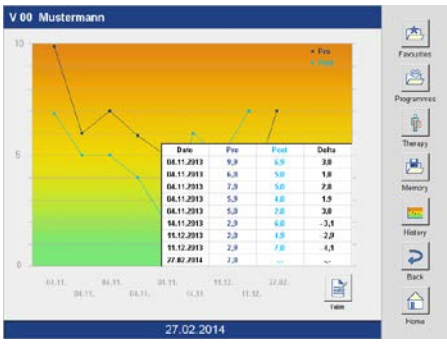
Activating the "Evaluation" button in the navigation bar allows the progression of therapy of individual patients to be accessed in the VAS list.

The patient to be assessed is selected directly in the line. Once the line has been activated, the screen opens automatically with the progression curve of the therapy.



Table

Activating the "table" button also displays the progression of therapy in tabular form.



Basic device	
Power supply	100 – 240 V / 50/60 Hz; 220 V / 60 Hz
Fuse	2 x T3A15L, 250V
Power consumption	250 VA
Protection class	I
Use class	BF
Applied part	Applicator head Silicone protection cap
Frequency range	1 Hz – 22 Hz, adjustable in 1 Hz increments 3 burst modes with 4, 8 or 12 pulses
Pulse energy levels	60 – 185 mJ (at the applicator) freely adjustable in 10 mJ increments at 22 Hz max. 90 mJ at 16 Hz max. 120 mJ at 10 Hz max. 185 mJ
Operating mode	Interval operation
Accuracy	± 20%
Dimensions	
enPuls*Pro* with SysCart	H 138 cm x W 53 cm x L 52 cm
enPuls*Pro*	H 30 cm x W 35 cm x D 20 cm
SysCart	H 109 cm x W 53 cm x L 52 cm
Weight	
enPuls*Pro* with SysCart	19.3 kg
enPuls*Pro*	3.8 kg
SysCart	15.5 kg
IP class	Device IPX0 Foot switch IPX5 Handpiece IPX0
Handpiece	
Dimensions	Length 230 mm, diameter 50 mm
Weight	850 g
Guarantee	2,000,000 shocks (at least)
Applicator heads	6 / 15 / 25 mm diameter / no tools needed for switching 150,000 shocks guaranteed
Operation	10 to 25°C, 20% to 80% relative humidity, without condensation at 700 hPa – 1060 hPa
Storage / Transport	-10 to 50 °C, 10% to 90% relative humidity, without condensation at 700 hPa – 1060 hPa

Note: *Storage and transport only in original packaging.*

Subject to technical changes!

– Before starting any maintenance and cleaning measures the device must always be switched off at the main switch and the mains cable must be disconnected.

– Make sure that when cleaning and disinfecting the labelling of the device (such as warnings, labels of control devices, identification plate) is not damaged.

– Make sure that during cleaning or disinfection no liquid penetrates the device, foot switch or handpiece. Do not use sprays.

– If during cleaning or disinfecting liquid penetrates the device or handpiece, please put the device out of service, protect it from being used again and contact your service representative.

– Always wear protective gloves for cleaning and disinfection to minimise the risk of infection.

– The device and its applied part are considered as uncritical in relation to hygiene due to the use on non-injured and healthy skin.
(see RKI guideline for example).

Housing / Foot switch

Cleaning (only manually)

Tools:
- Disposable wipes (cellulose, paper)
- Alcohol-free plastic cleaner (e.g. cleaner for medical devices)

In the event of visible contamination, the housing, foot switch and all cables can be cleaned using commercially available alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Disinfection (only manually):

Tools:
- Disposable wipes (cellulose, paper)
- Commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties or wipes. Observe the instructions for use of the respective manufacturer.

We recommend that disinfection is carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.

The housing and foot switch can be disinfected using disinfectant wipes. Wipe all surfaces using a soft cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloths pre-impregnated with disinfectant (wipes). Also observe requirements for drying or post-cleaning, where applicable.

Applicator head / Handpiece

Cleaning (only manually)

Tools:
- Disposable wipes (cellulose, paper)
- Alcohol-free plastic cleaner (e.g. cleaner for medical devices)

Remove the silicone protection cap from the applicator head prior to cleaning. Then follow the procedure described under "Housing / foot switch".

Disinfection (only manually):

Tools:
- Disposable wipes (cellulose, paper)
- Commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties or wipes.

We recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection. Remove the silicone protection cap from the applicator head prior to disinfection. Then follow the procedure described under "Housing / foot switch".

Silicone protection cap

Cleaning, manually:

Tools:
- Drinking water, lukewarm
- Vessel, e.g. kidney dish
- Brush, e.g. medium hard toothbrush

- Alcohol-free plastic cleaner (e.g. cleaner for medical devices)

Remove the silicone protection cap from the applicator head prior to cleaning. Prepare a solution of the cleaning agent following the instructions of the manufacturer. Put the silicone protection cap in the solution. Use the brush to clean all the inner and outer surfaces of the protection cap. Finally rinse the protection cap under running water.

Disinfection, manual:

Tools:
- Vessel, e.g. kidney dish
- Commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties.

We recommend that disinfection is carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.
Prepare a solution of the disinfection agent following the instructions of the manufacturer. Put the silicone protection cap in the solution. Make sure that all the inner and outer surfaces of the protection cap are coated. Leave the protection cap in the solution for the time specified by the manufacturer of the disinfection agent. Finally rinse the protection cap under running water.

Cleaning/disinfection, mechanical:

Preparation:
Visible contamination must be removed manually prior to cleaning/disinfection. Proceed as indicated above.

Procedure:
Carry out mechanical cleaning and disinfection using the following parameters:
- Cleaning agent: neodisher® MediClean forte (manufacturer: Dr. Weigert)
- Cleaning: 10 minutes at 55°C
- Disinfection: 5 minutes at 93°C

Note: The material is suitable for steam sterilisation at 134°C.

⚠ *Caution: If flammable solutions are used for cleaning and disinfecting, sufficient time must be allowed for the solutions to evaporate before using the device. Otherwise, it may lead to inflammation.*

Suitable disinfection agents

The following agents are suitable for manual disinfection:
- mikrozid® sensitive wipes
- Antifect FF
- Gigasept FF
- Quartamon Med

Observe the instructions for use of the respective manufacturer.

Note: *Use the device only in a hygienic environment.*

CE mark / manufacturer

11

The device has a CE mark

CE 0123

in accordance with the EC directive on medical devices 93/42/EEC.

Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 731. 9761-291
Fax +49 731. 9761-299
www.zimmer.de

Scope of delivery
in combination with SysCart

Item no.		
5430	1	enPuls*Pro* control unit
9160	1	SysCart with tray mount
5413	1	Handpiece complete
93133521	1	Applicator head, 6 mm
93133511	1	Applicator head, 15 mm
93133502	1	Applicator head, 25 mm
65135110	10	Silicone protection caps
50500038	1	en*Puls* / ZWave lotion
94130410	1	Foot switch
65410410	1	Storage tray for accessories
117	1	power cable
10102109	1	instructions for use

Scope of delivery
Table device

Item no.		
5430	1	enPuls*Pro* control unit
5413	1	Handpiece complete
93133521	1	Applicator head, 6 mm
93133511	1	Applicator head, 15 mm
93133502	1	Applicator head, 25 mm
65135110	10	Silicone protection caps
50500038	1	en*Puls* / ZWave lotion
94130410	1	Foot switch
65410410	1	Storage tray for accessories
117	1	power cable
65410110	1	Holder for handpiece
10102109	1	instructions for use

Accessories

Item no.	
5413xxx	Handpiece complete
65410110	Holder for handpiece
93133521	Applicator head, 6 mm
93133511	Applicator head, 15 mm
93133502	Applicator head, 25 mm
65135110	Silicone protection cap
50500038	en*Puls* / ZWave lotion
94130410	Foot switch
93410210	Holder for foot switch
65410410	Storage tray for accessories
117	Power cable

Device combinations

13

For enPuls*Pro* no combination devices are provided by the manufacturer.

Anyone who combines devices against these guidelines and thus creates a medical system does so under his/her own responsibility.

enPuls*Pro* is manufactured according to the DIN EN 60601-1 safety regulations.

As the manufacturer, Zimmer MedizinSysteme can only consider itself to be responsible for safety and reliability if

- the device is operated using a proper power outlet with earth contact and the electrical installation complies with DIN VDE 0100 part 710,
- the equipment is operated in accordance with the instructions for use,
- extensions, readjustments or modifications are carried out only by persons authorised by Zimmer MedizinSysteme,
- the user has ascertained the functional safety, the proper operating condition and mechanical integrity before using the device and handpiece
- the device is operated only by properly trained personnel,
- the device is not operated in hazardous areas and / or a combustive atmosphere,
- the device is immediately disconnected from the mains when penetrated by liquid.

The device does not contain any parts that can be repaired by the operator.

⚠

Modification of this device is not permitted.
Service and replacement of components may only be performed by certified service technicians from Zimmer MedizinSysteme GmbH.

14.2 Maintenance

Before starting any cleaning and maintenance measures the device must always be switched off at the main switch and the mains cable must be disconnected.

Zimmer guarantees 150,000 shocks per applicator head.
It is recommended that the applicator head be replaced after this number of shocks has been reached.
The applicator head should also be replaced if therapy starts to become less successful or the applicator is observed to be deformed. Visual checks should be carried out regularly for this reason.

enPuls*Pro* performs a self-test when switched on, checking all internal components.

If an error occurs, an error message will appear.

In addition, an enhanced functional test as described below can be performed.

This test should be performed monthly or if the proper functioning of the device is in doubt.

Note: *Check whether the handpiece and foot switch are correctly connected to the device before carrying out the functional test.*
Check whether the power cable is correctly connected to the device and live.

Functional test

Switch device on.

Briefly activate the foot switch - the fans and generator should start immediately, and the shock wave generator must operate at the frequency shown on the display (5 Hz is the default value).

Note: *Switch off enPulsPro after the functional tests ends.*

If therapy is to be performed immediately afterwards, adjust the desired treatment parameters and proceed as described in section 8.

The enPuls*Pro* device is not listed in annex 1 of the MPBetreibV (German Medical Devices Operation Ordinance).

The device is not listed in annex 2 of the MPBetreibV (German Medical Devices Operation Ordinance).

In Germany, the German Social Accident Insurance (DGUV) (Regulation 3 – Electrical systems and equipment), as amended, must also be observed.

Note: *This information applies to the operation of the unit in Germany. Please consider divergent national regulations in your country.*

Handpiece loss of function

The message "Ready" appears in the status bar but no pulse is triggered although the foot switch has been activated

Possible cause 1
Handpiece / foot switch not properly connected or defective.
Remedy for cause 1
Check whether the foot switch and handpiece are correctly connected. The plugs must be fully engaged.
Check the cable of the foot switch for damage or kinks. Replace the foot switch if it is visibly damaged.
Check whether the dome of the foot switch can move or is blocked. Remove the blockage if possible.

Possible cause 2
Program settings incorrect.
Remedy for cause 2
Check whether the pulse energy is set, and if not set it.

Handpiece malfunction

Irregular shock wave emission / overheating of handpiece

Possible cause 1
Applicator head worn / hard to manipulate due to wear
Remedy for cause 1
The applicator heads are subject to wear and need to be replaced after a certain number of shock waves.

Removal of worn parts:
Remove the applicator head from the handpiece and clean the rear dome thoroughly. Then hold the handpiece without applicator head with the opening facing downwards. With the frequency set to 2 or 5 Hz at the lowest energy level, trigger a small number of shocks (maximum 10). Then reattach the applicator head.
If the error recurs, the applicator head must be replaced.

Possible cause 2
Shock wave generator wear
Remedy for cause 2
The shock wave generator is subject to wear and should be replaced after 2 million shocks.
Check the total number of shocks emitted by the device on the configuration menu.
If the total number of shocks is 2 million or above, the shock wave generator must be replaced.
To replace the shock wave generator, please contact your sales representative or the main office in Neu-Ulm.

Applicator not found

The message “No applicator found” appears in the status bar.

Possible cause
Handpiece not (or not correctly) connected.
Remedy for cause
Check whether the handpiece is correctly connected. The connector must be fully engaged.

Device malfunction

No response to the main switch / display remains dark

Possible cause 1
Mains connection
Remedy for cause 1
Check whether the mains plug is correctly plugged into the socket and the device plug is firmly inserted in the port of the device.
Check the power cable for damage. Replace it if it is visibly damaged.
Check the mains and socket.

Possible cause 2
Fuse
Remedy for cause 2
The mains input socket of the device contains microfuses which disconnect the device from the mains in the event of an electrical problem. Open the flap and check the fuses. If necessary, replace the defective fuse.

⚠ Replace the fuse only with one with the exact same name/equal rating. Before doing so, check the power supply thoroughly for possible faults.

If the error recurs, immediately inform the service department/customer service.

Error message SD card

If the SD card is not inserted, the following message appears when the "Favourites", “Memory” and "VAS" buttons are activated:

"No SD card found."
The use of "Favourites", “Memory” and "VAS" requires an SD card.

Insert the card and confirm with "OK".

Overheating warning

If the temperature of the handpiece reaches a critical limit, a cooling phase is initiated. This is indicated by the following message in the display:

“Overheating of the applicator. Please allow the applicator to cool down”.

Pulse emission is no longer possible when this message appears.

After confirming the message with "OK", the therapy screen moves to the foreground with the message in the status bar when the handpiece returns to operating temperature.

In the case of other malfunctions, switch the device off and then on again after a 5-second delay. If the error is still present, please inform customer service via the main office in Neu-Ulm.

Main office

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 731. 9761-291
Fax +49 731. 9761-299
www.zimmer.de

Disposal

The device may only be returned to the factory in its original packaging. It must be disposed of by the factory in Neu-Ulm.

In foreign (European) countries, disposal is handled by dealers authorised by Zimmer MedizinSysteme.

Medical electrical devices, such as enPuls*Pro*, are subject to special precautionary measures with regard to EMC (electromagnetic compatibility) and must be installed and put into operation according to the EMC information in the instructions for use or accompanying documentation.

Portable and mobile HF communication devices (such as mobile phones, cell phones) can affect medical electrical devices.

enPuls*Pro* may only be operated with the original power cable indicated in the list of the scope of delivery and accessories. Operation of the device with a different power cable can lead to increased emissions or reduced interference immunity of the device!

Guidelines and manufacturer's declaration – Electromagnetic emissions		
The enPuls*Pro* device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the enPuls*Pro* should ensure that it is operated in such an environment.		
Interference emission measurements	Compliance	Electromagnetic environment - Guideline
HF emissions according to CISPR 11	Group 1	The enPuls*Pro* device uses HF energy only for its internal functioning. This means that its HF emissions are very low, and it is very unlikely that adjacent electronic devices would suffer interference.
HF emissions according to CISPR 11	Class B	The enPuls*Pro* device is suitable for use in all facilities, including those in a residential area, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/flickers according to IEC 61000-3-3	Complies	

The device should not be used in the direct vicinity of or stacked with other devices. If operation near or stacked with other devices is necessary, the device should be observed to check its proper operation in the arrangement used.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The enPuls*Pro* device is intended to be operated in the electromagnetic environment indicated below. The customer or user of the enPuls*Pro* device should ensure that it is used in such an environment..			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Rapid transient electrical disturbances/bursts according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	± 2 kV for power cables Not applicable for input and output cables	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11.	<5% U_T (>95% dip in the U_T for ½ cycle) 40% U_T (60% dip in the U_T for 5 cycles) 70% U_T (30% dip in the U_T for 25 cycles) <5% U_T (>95% dip in the U_T for 5 seconds)	<5% U_T (>95% dip in the U_T for ½ cycle) 40% U_T (60% dip in the U_T for 5 cycles) 70% U_T (30% dip in the U_T for 25 cycles) <5% U_T (>95% dip in the U_T for 5 seconds)	The quality of the supply should correspond to that of a typical business or hospital environment. If the user of the enPuls*Pro* requires continued function even if interruptions in the power supply occur, it is recommended to power enPuls*Pro* from an uninterruptible power supply or a battery.
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment.
Note: U_T is the a.c. supply voltage prior to application of the test level.			

Key performance features of the enPuls*Pro* are: smooth output of shock waves, smooth operation of all functions. Uninterruptible operation is not necessary to the intended use.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The enPuls*Pro* device is intended to be operated in the electromagnetic environment indicated below. The customer or user of the enPuls*Pro* device should ensure that it is used in such an environment..			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radio equipment should not be used at a distance away from the enPuls*Pro*, including the cables, that is less than the recommended safety distance which is calculated according to the equation applicable to the transmission frequency. Recommended safety 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 with P as the rated output of the transmitter in watts (w) according to the information of the manufacturer of the transmitter and d as the recommended safety distance in meters (m). At all frequencies, the field strength of stationary radio transmitter should be less than the compliance level[b] according to on-site testing[a]. In the environment of devices which bear the following symbols, interferences are possible: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.			

[a] The field strength of stationary transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to the stationary transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the enPuls*Pro* device is used exceeds the above compliance level, the enPuls*Pro* device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the enPuls*Pro* device.

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

Recommended safety distances between portable and mobile HF telecommunication devices and the enPuls*Pro* device

The enPuls*Pro* device is intended to be operated in an electromagnetic environment in which the HF disturbances are controlled. The customer or user of the enPuls*Pro* device can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the enPuls*Pro* device – depending on the output power of the communication device as indicated below.

Rated output of the transmitter W	Safety distance depending on the transmission frequency 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 whose maximum rated output is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, where 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 applies.
NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.

enPuls*Pro*

Instructions for Use

EN 10 102 109 TW 1117 I Version 4 I subject to change

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