Zimmer
MedizinSysteme

User Manual

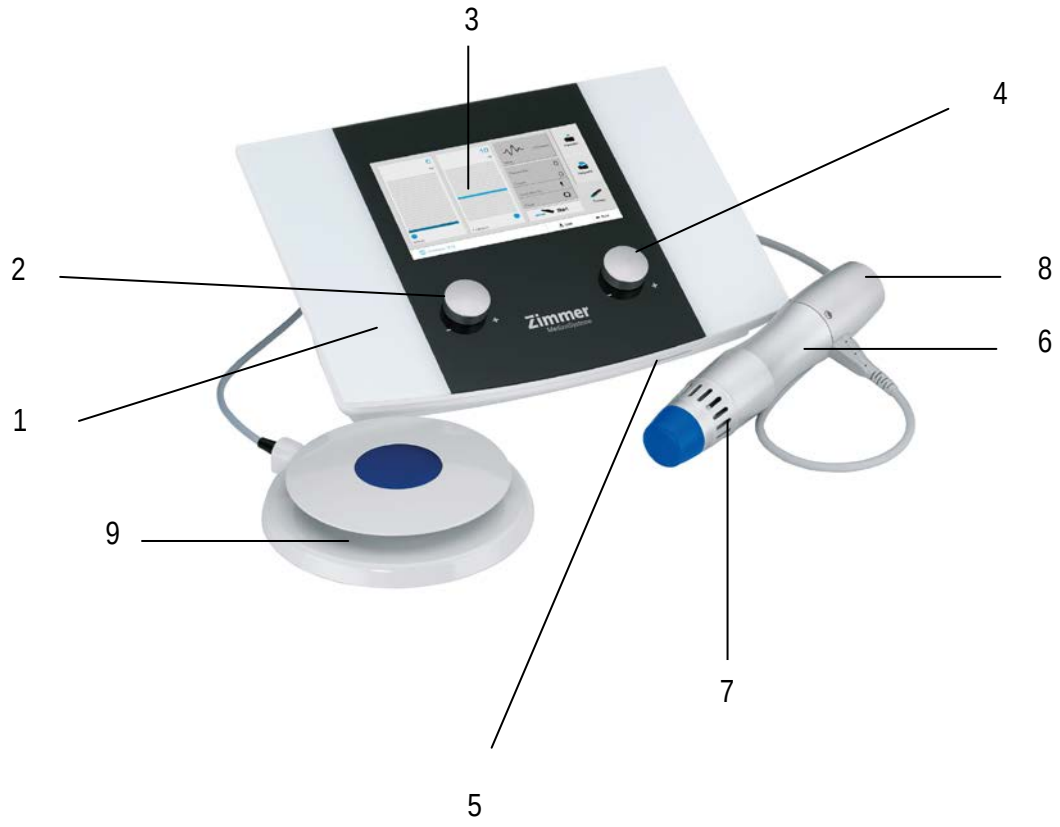
enPuls
Version 2.0

USA

Illustrations

Front of the device

Fig. 1

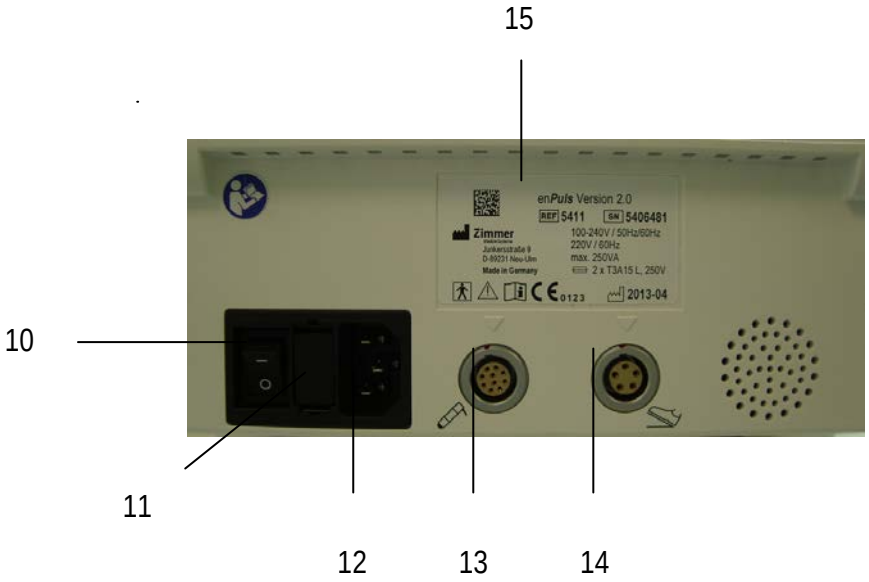


Selection and operating elements	1	Control unit
	2	Pulse energy controller
	3	Display
	4	Frequency controller
	5	Slot for SD card
Handpiece	6	Handpiece
	7	Vent, front
	8	Vent with fan, rear
Footswitch	9	Footswitch

Illustrations

Rear of the device

Fig. 2

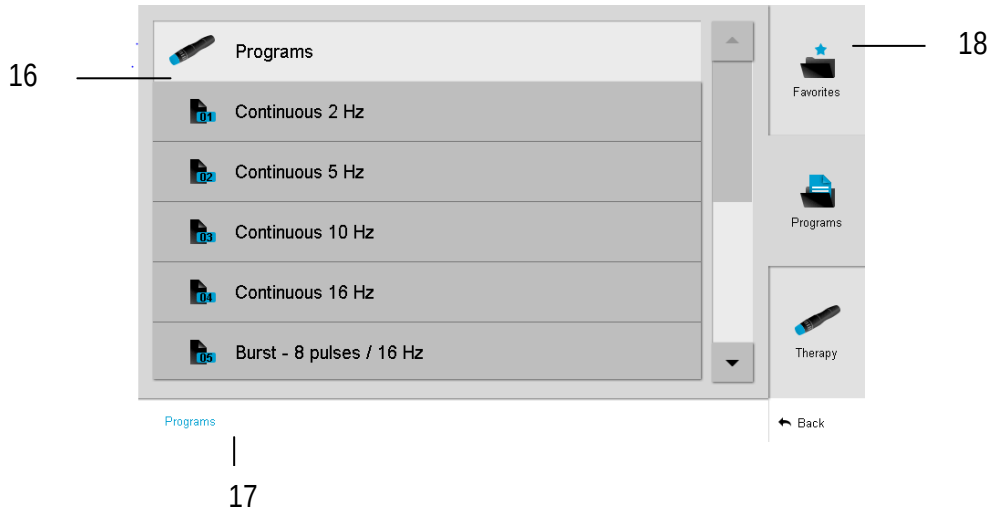


Switches / Connector sockets	10	Power switch
	11	Mains fuse
	12	Socket for mains cable
	13	Socket for handpiece
	14	Socket for footswitch
	15	Identification plate

Illustrations

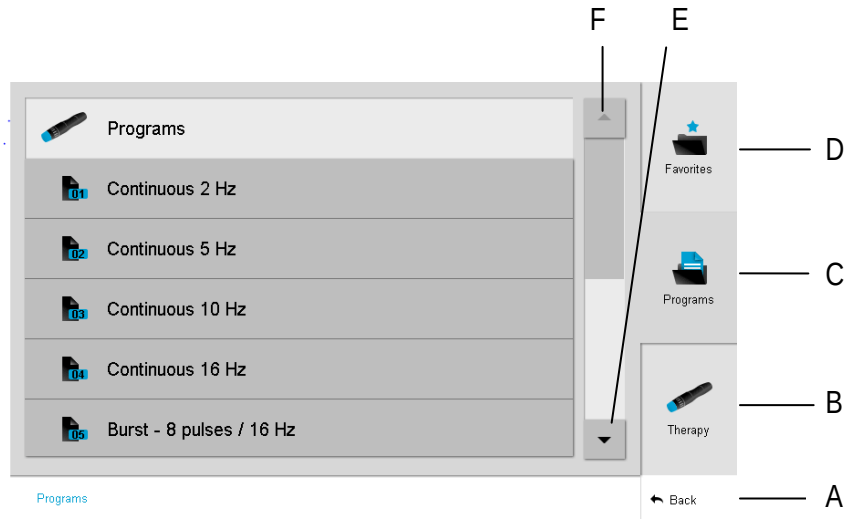
Screens / Displays

Fig. 3



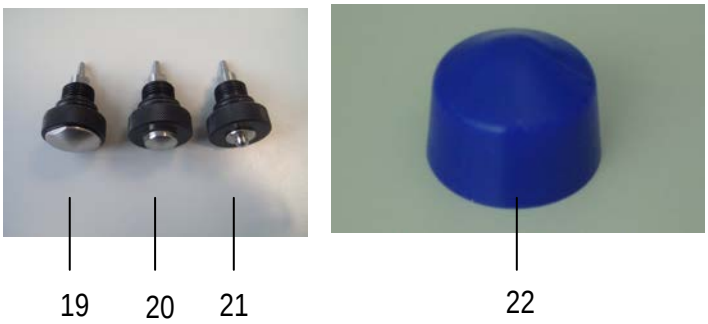
Displays / Therapy screen	16	On-screen buttons
	17	Status bar
	18	Navigation bar

Fig. 4



Navigation bar Description of the functions	(A) Back	Takes you back one step
	(B) Therapy	Switches to the therapy screen
	(C) Programs	Switches to the program list
	(D) Favorites	Switches to the favorites area
	(E) Scroll forward	Moves ahead one page
	(F) Scroll backwards	Moves back one page

Fig. 5



Applicator heads	19	Applicator head, 25 mm
	20	Applicator head, 15 mm
	21	Applicator head, 6 mm
Accessories	22	Silicone protection cap

Explanation of Symbols

In the instructions for use, this symbol indicates **danger**.

Caution!

In the instructions for use, this symbol indicates a **"Caution" with regard to possible damage of the device.**

Socket for handpiece

Socket for footswitch

User Manual

Follow user manual

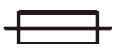
Serial number

Article number

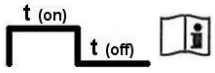
Manufacturer

Date of manufacture

Applied part type BF



Value of accessible fuses



Interval operation - Follow user manual

Contents

Contents

Valid for the device en*Puls* Version 2.0 (NG).

This user manual is an integral part of the device.
It must be stored with the device and kept accessible at all times for anyone authorized to operate this device. Full observation of these instructions is a requirement for the correct application and operation of the equipment and for consequent safety for patient and operator.

The user manual is valid as of February 2016.

U.S.A. Federal Law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Indications / Contraindications

Indications

- For relief of minor muscle aches and pains and for temporary increase in local blood circulation.

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.

Side Effects

Treatments with enPuls Version 2.0 may occasionally cause irritation, petechial, bruising, swelling or pain.

Before using the device on a patient, the user should become acquainted with the operating instructions and individual treatment methods as well as the indications / contraindications, warnings and application information. Additional sources of information about types of therapy should be consulted.

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

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

en*Puls* Version 2.0 is not suitable for use in areas with an explosive, flammable or combustive environment.

When in operation, the device must be positioned in such a way that direct access to the device's central power supply is possible, so that it can be disconnected from the mains at any time.

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

Inspect the device prior to use. If damaged, it must not be used.

Caution! Only accessories provided by Zimmer MedizinSysteme GmbH are to be used.

Caution! The device may cause malfunctions or may interfere with the operation of equipment in the vicinity by electromagnetic effects. It may be necessary to take appropriate remedial action, such as realignment, re-arrangement of the device or the electromagnetic shielding.

Caution! The handpiece of the device is not designed for continuous operation. After max. 6,000 shocks, a break of 15 min. must be observed.

Caution! If en*Puls* Version 2.0 is not mounted on the designated system cart, make sure that en*Puls* Version 2.0 is placed on a stable surface.

Caution! To avoid heat accumulation in the handpiece, it is essential to ensure that your hand or any other object does not block the ventilation openings on the top and especially on the bottom of the handpiece.

Caution!

In exceptional cases, the maximum treatment time is limited to 4 min followed by a break of at least 15 min.
If the treatment time is exceeded, the handpiece may overheat.

Caution!

Users of the en*Puls* Version 2.0 radial pulse therapy device must be instructed in the proper use of the system and must possess the appropriate skills.

Caution!

The device is intended to be used exclusively by medical professionals.

Caution!

Any treatment instructions regarding treatment location, duration and intensity require medical knowledge and should be given by authorised physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.

The patient must not be left unattended during therapy.

Persons undergoing simultaneous treatment involving the reduction and / or alteration of blood clotting or the prolongation of the blood clotting time (e.g. acetylsalicylic acid) should consult their therapist regarding a possible suspension of this therapy, as the use of radial pulse in such patients may cause bleeding and bruising in varying degrees.

Radial pulse become significantly scattered in air-filled areas and generate reflections that can have negative effects.
Therefore, do not perform treatments directly above the lungs (intercostal space) or the gastrointestinal area.

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

Dispose of the packaging material properly. Make sure that it is not accessible to children.

On patients with implants or implanted electronic device do not conduct treatment before the risk has been assessed and found negligible.

Patients may not be connected to a high-frequency surgical device at the same time. This can lead to burns.

This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in presence of unexplained calf pain.
Consult a physician.

In worst case condition maximum therapy time is limited to 4 minutes treatment time and a break time of 5 min. If you will exceed this duty cycle the handpiece can be in overtemperature.

en*Puls* Version 2.0 - in brief

What is en*Puls* Version 2.0?	A state of the art therapeutic massager.
Radial pulse therapy	Radial Pulse Therapy is a procedure for relief of minor muscle aches and pains and for temporary increase in local blood circulation.
What does en*Puls* Version 2.0 do?	The handpiece contains a projectile that is accelerated through the electromagnetic transfer of kinetic energy. This kinetic energy is transferred into impact energy in the applicator head. The impact energy delivered from the applicator head results in radial pulses developed in the target tissue. With en*Puls* Version 2.0, a maximum penetration depth of about 35 mm into human tissue can be achieved.
How does en*Puls* Version 2.0 generate radial pulses?	An electromagnetic field is generated at the rear end of the handpiece by means of a coil. A projectile is accelerated through the field crashing into the applicator head at the front of the handpiece generating radial pulses that spread radially into the tissue.
Why en*Puls* Version 2.0*?*	The innovative technology allows for a compact design without a compressor. The modern multi-color display, showing all therapy-relevant parameters, the modern touch operation and the ability to simultaneously connect 2 handpieces. Customizable program startup settings and a clear, simple menu offer maximum convenience for the user. Adjustable frequencies and various applicators enable the therapy to be tailored to the respective status of the patient.
Intended use	en*Puls* Version 2.0 is an electromagnetic therapy system for the generation and application of radial pulses in orthopedics and physiotherapy.
Note:	*The application of the device is reserved to medical professionals (such as physicians, therapists and health paraprofessionals).* *enPuls Version 2.0 has been constructed and designed solely for the application on superficial skin problems in humans.* *The device is intended for use mechanical massage devices.*

Note:	*If enPuls Version 2.0 is not mounted on the designated system trolley, please make sure that it is standing on a stable surface. We recommend using the optional swivel base.*
Note:	*Make sure that the power switch on the device is set to "0".*
Connecting the power cable	Connect the power cable to the designated socket (12) on the device and connect the cable to the mains.
Note:	The device must only be connected to power outlets with an earthing contact.
Connecting the handpiece	Connect the handpiece to one of the designated socket (13) and set it down.
Note:	Make sure that an applicator head is placed inserted to handpiece and that it is correctly and completely screwed in.
Connecting the footswitch	Connect the footswitch to the designated socket (14) and place it on the floor.
Switching the device on	Switch the device on using the power switch (10).
Switching the device off	The device is switched off using the power switch (10). In order to completely disconnect the device (all-phase) from the mains, remove the power cord.
Caution**!**	All cables must be protected against jamming or other mechanical damage.

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

Start –up screen

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

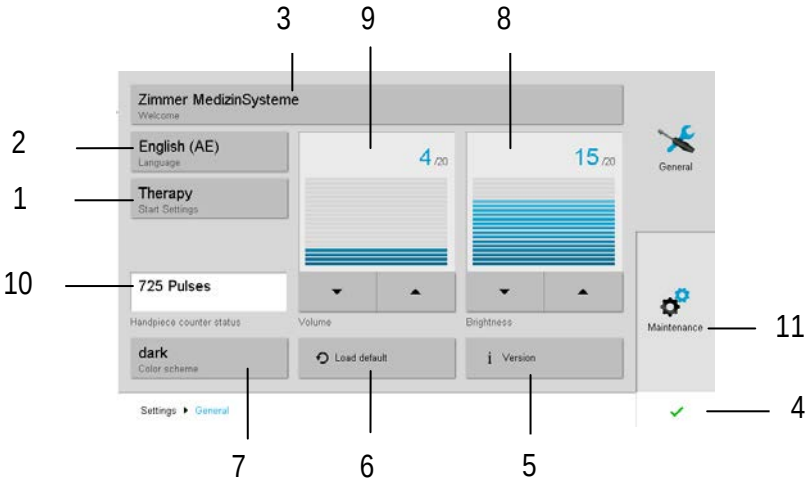
Note: *Pressing the "Therapy" button (1) immediately switches to the therapy screen*

Configuration menu

The factory settings can be changed and adjusted individually using the configuration menu.

Selecting Configuration

Pressing the "Settings" button (2) opens the "Settings" screen.



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

(1) Startup settings

1. Start menu:
Individual startup settings options.
The selection is made directly in the corresponding row.

(2) Language

Selecting the language.
The selection is made directly in the corresponding row.

(3) Welcome

Pressing the "Welcome" field opens a window with an alphabetic keyboard to enter a welcome message for the start-up screen.
Pressing the “OK” key saves the text that has been entered.
Pressing the “X” key returns you to the configuration menu.

(4) OK

Pressing the button switches to the home screen.

(5) Version

Pressing the "Version" button opens a window with information regarding the current software version.

(6) Load default

Pressing the "Load default" button restores the default factory settings.

(7) Colour scheme

Pressing the key switches between the two display settings. You can choose from either a light or dark background.

(8) Brightness

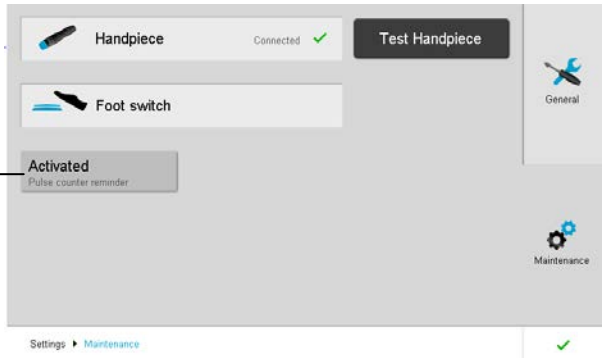
The Adjustment of the brightness is made using the two arrow keys.

(9) Volume

The Adjustment of the volume is made using the two arrow keys.

(10) Counter status of handpiece

In this display panel, the counter status of the handpiece is shown.



(11) Maintenance

After pressing the (1) key in the maintenance menu, the maintenance message, which appears after 1.8 and 2 million collisions, can be turned off. Deactivation results in a one-time maintenance message after 1.8 and 2 million shocks.
The maintenance message can only be deactivated by customer service.
The following points are not relevant for the user. They are used only by customer service.

Handpiece

The handpiece (6) contains the radial pulse generator, a cooling fan for heat dissipation and the socket for the various applicator heads. It is connected to the control device (1).

Note:

The generator in the handpiece is a wear part and must be replaced after a certain period of operation, as its ability to function decreases with time.

Zimmer MedizinSysteme GmbH guarantees unrestricted use of at least 2 million shocks per radial pulse generator.
Depending on power and frequency, the generator can produce far in excess of 2 million radial pulses.

Further information regarding the need to replace the radial pulse generator can be found in Chapter 16.

In order to use the handpiece on the patient, an applicator head must be completely and securely screwed onto the handpiece.

Interval operation

The handpiece is not suitable for continuous operation. As a result of the frictional heat, the temperature of the applicator increases with increasing duration of treatment to the extent that thermal damage to the patient cannot be excluded.
Please refer to the chart in Chapter 9.1 for the maximum values for treatment. After reaching the specified values, the treatment must be interrupted; it can be resumed only after the applicator has cooled to room temperature.

Note:

Please note that the temperature control of the handpiece (described on page 11) is only a technical shutdown to protect the mechanical parts inside the handpiece. It does not provide information about the temperature of the applicator head.

Recommendation:

To avoid interruption to ongoing therapy in the case of treatments with more than 6,000 shocks, the connection of a second hand piece is recommended. During the cooling phase for one handpiece, you can switch to the second hand piece and immediately continue the treatment.

Note:

When switching from one handpiece to another during ongoing therapy, the pulse frequency and the number of shocks remain unchanged. The pulse energy returns to 0 and must be reset.

Handpiece temperature monitoring / regulation

The generation of mechanical shock energy causes substantial heat generation within the handpiece. A thermal safety switch is integrated so that the life of the handpiece is not affected. In the event of overheating, an internal shut-off switch ensures the cooling down of the handpiece.

In addition to temperature monitoring, en*Puls* Version 2.0 features temperature regulation by means of a temperature sensor in the handpiece. The fan in the handpiece starts upon activation using the footswitch and automatically stops when a certain temperature is reached.

When the temperature reaches a critical level, a cooling phase is initiated. This is indicated in the display by the following message:
"Overtemperature in the applicator. Please allow the applicator to cool."
The emission of pulses is no longer possible.

After confirming the message with "OK", the treatment screen comes to the foreground. The footswitch symbol changes to a disabled handpiece and appears instead of the start key until the handpiece is once again ready for operation.

Once the handpiece has reached operating temperature, the footswitch symbol appears with the text "start", and the treatment can be resumed.

Applicator heads

There are 3 different applicator heads available for therapy.

Changing the applicator heads

To change the different applicator heads, hold the handpiece with one hand and unscrew the applicator head from the handpiece with the other hand, turning in an anti-clockwise direction. Then screw in the desired head, turning clockwise until it stops.

Note: *The applicator heads are subject to wear and must be replaced after a certain period of operation (see Chapter 13.2 Maintenance).*

Footswitch

Position the corresponding foot switch in such a way that is can be easily reached during therapy. The control element of the switch is not direction-dependent, meaning that the precise alignment of the footswitch is not necessary.

To avoid damage, ensure that only light pressure is applied to the switch. The switch should be operated with the front of the foot, not the heel.

The switch has no locking mechanism, i.e. it only remains activated for as long as pressure is applied to the switch.

Therapy

Please hold the handpiece as shown in the picture below.

en*Puls* Version 2.0 works using 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 the radial pulse is enabled, it is possible to work either with the handpiece stationary on one point, or dynamically, across a whole area.
In order to reduce friction on the skin, the use of the en*Puls* lotion provided is recommended.

Due to the weight of the handpiece, it is usually not normally 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!

When using en*Puls* lotion or other lubricants, the applicator head must be covered using the silicone protection cap.

Note:

Despite the high level of self-damping provided by the weight and the design of the handpiece, vibrations may cause strain to the hand of the user.

Recommended precautions:
- Restriction of the stress duration
- Passive support

Note:

The patient should be carefully monitored during the treatment.

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

Program startup Pressing the "Therapy" button on the home screen opens the therapy screen.

Selecting an applicator Choose the applicator to suit your desired therapy and screw it correctly into the handpiece.

Applying the handpiece / applicator Place the handpiece on the selected treatment point / area. In order to avoid friction on the skin, en*Puls* lotion can be applied to the treatment area prior to treatment when necessary.

Caution! When using lubricants, the applicator head must be covered using the silicone protection cap.

Setting the pulse energy Set the pulse energy using the left controller.

Note: *enPuls Version 2.0 offers two options for the pulse output.*

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

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

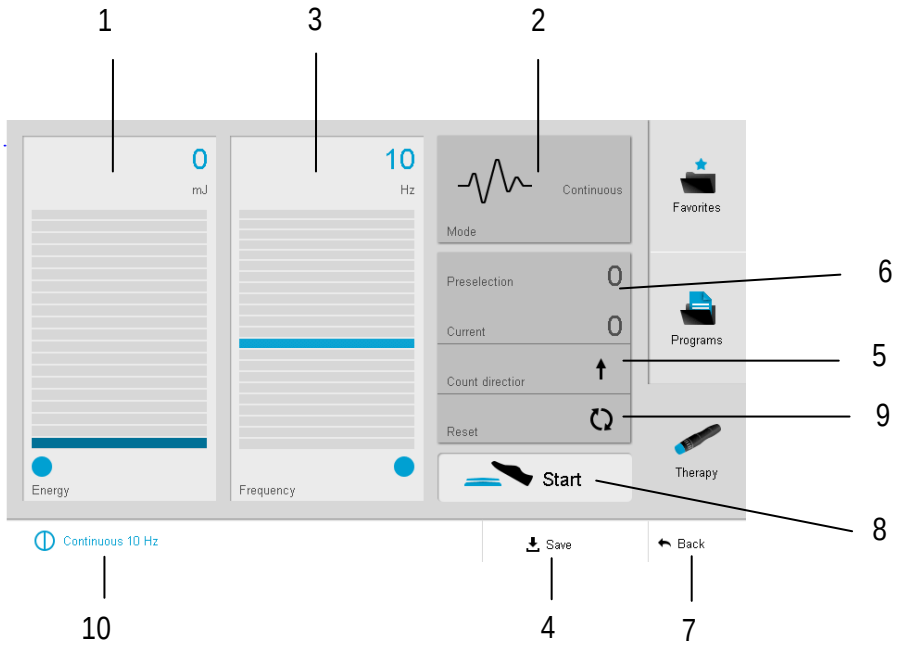
Start of treatment The treatment starts once the footswitch has been activated.

Note: *The radial pulse should only be activated via the footswitch once the handpiece has been placed on the patient.*

End of treatment By de-activating the footswitch, the treatment is interrupted or terminated.

Note: *During the treatment, the patient must be monitored carefully. If any issues arise, the treatment should be adjusted or terminated.*

Description of the display elements and buttons



(1) Pulse energy

Displays the pulse energy setting. During active therapy, the bar graph is filled. The pulse energy can be set both before and during the delivery of pulses. The pulse energy is adjustable between 60 and 185 mJ, in 10mJ increments.

(2) Mode

Displays the selected mode. Upon activation of the window, the selection menu with the operating modes is displayed:
Series Pulse, Burst 4 Pulse, Burst 8 Pulse, Burst 12 Pulse.
The desired mode of operation is selected directly on the corresponding line.

(3) Frequency

Displays the set frequency.
Frequency range: 1 Hz - 22 Hz, adjustable using the right controller. Here the maximum selectable frequency depends on the selected power level.

(4) Saving

Pressing the key opens the field to enter the individual name of a program. The program is automatically stored in the favourites list.

(5) Counting direction

Pressing the button sets the counting direction (ascending or descending) for the number of pulses emitted.

(6) 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.
Ascending or descending display the counting direction.
Pressing the pulse number field opens the entry menu to enter a pre-set number of pulses. The pre-set is done in increments of 100.

(7) Back

For ascending counting direction, this resets to 0; for descending counting direction, this resets to the pre-set number of pulses.

(8) Start	Starts the program
(9) Reset	For ascending counting direction, this resets to 0; for descending counting direction, this resets to the pre-set number of pulses.
(10) Status line	Displays the name of the currently selected program.

SD card

Custom settings are stored on the SD card.

If the SD card is not inserted, the following message appears when the "Favorites" is pressed:

"No SD card found".

The use of "Favorites" requires an SD card.

Insert the card and confirm with "OK".

Note: *Disable the message as described in Chapter 16.*

The parameters of the pre-defined programs can be individually modified and saved.

Saving and naming the program

Pressing the "Save" button opens the field for entering the program name.

The program name is entered via the keyboard.

Note: *There are 120 memory locations available for each.*

Saving to the Favorites list

Pressing button (1) opens the list of favorites and automatically stores the program in the Favorites list.

Pressing button (2) interrupts the save procedure.

Note: *If the button(1) is activated without a program name having been entered, the following message appears:*

"Please input a name!"

Confirm the message, enter the program name and repeat the save process.

The individually stored programs are listed in the Favorites list.

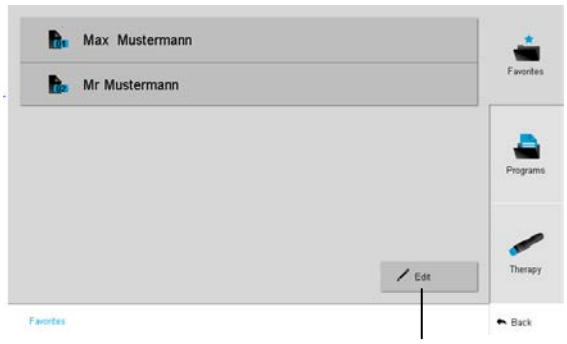
Here these can be

1. retrieved for treatment
2. edited (the sequence altered or entries deleted).

Select favorites list Pressing the "Favorites" button opens the favorites list.

Retrieve program The selection of the desired program is carried out directly on the corresponding line.

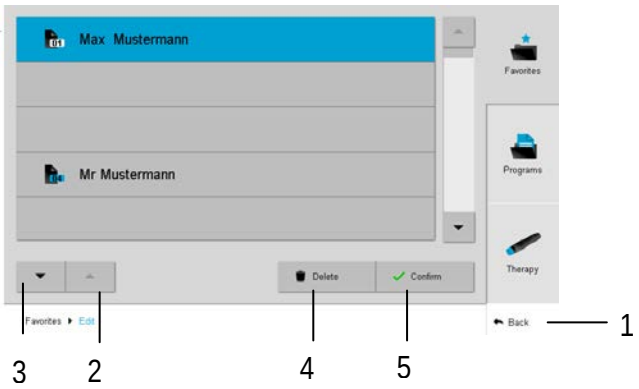
Edit favorites list



1

Pressing the (1) key opens the “Edit favourites” screen.

Edit favorites



Pressing button (1) returns you to the program.
Pressing button (2) moves the program up.
Pressing button (3) moves the program down.
Pressing button (4) deletes the program.
Pressing button (5) confirmed the processing.

Note:

Pressing button (4) triggers a confirmation prompt:

"Do you really want to delete this program?"

Pressing the "yes" button deletes the program.
Pressing the "No" button cancels the delete routine.

Basic unit

Power supply	100 – 240 V/ 50/60 Hz; 220 V/60 Hz
Fuse	2 × T3A15L, 250 V
Power consumption	250 VA
Protection class	I
Application class	BF
Application part	Applicator head Silicone protection cap
Frequency range	1 – 22 Hz, adjustable in 1 Hz increments Three burst modes with four, eight or twelve 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
Precision	± 20%
Dimensions	H 322 mm × W 235 mm × L 130 mm
Weight	2.7 kg
IP class	IPX0 Device IPX5 Footswitch IPX0 Handpiece

enPuls 2.2 handpiece

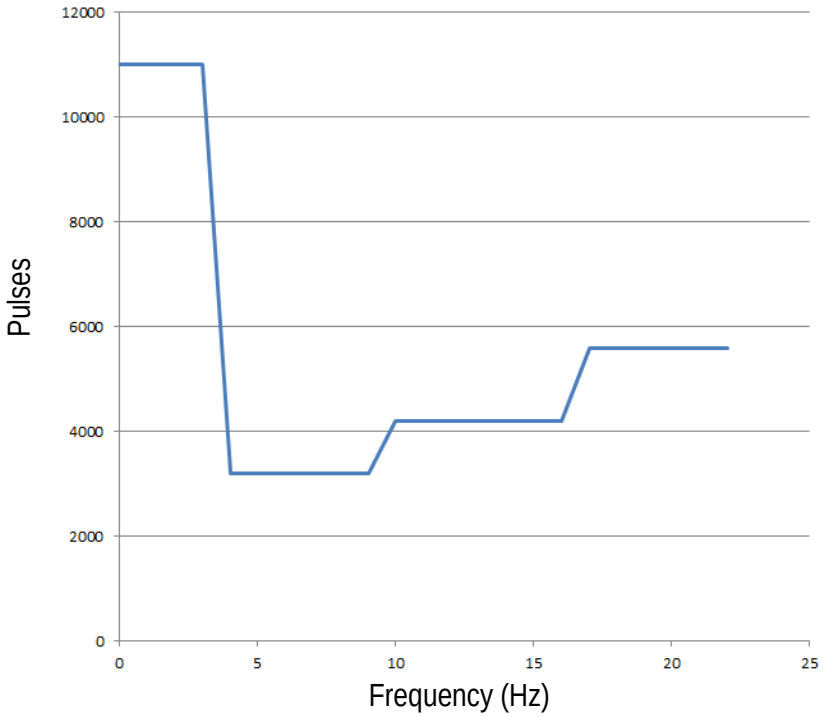
Dimensions	230 mm long, 50 mm diameter
Weight	850 g
Lifetime	2,000,000 pulses (at least)
Applicator heads	6/15/25 mm diameter, can be changed without tools 150,000 pulses guaranteed

Total unit

Dimensions	H 580 mm × W 250 mm × L 470 mm (complete with case)
Total weight	13 kg (complete with case)
Operation	50 to 77°F (10 to 25°C), 20% to 80% relative humidity, non-condensing at 700 hPa – 1060 hPa
Storage and Transport	14 to 122 °F (-10 to 50°C), 10% to 90% relative humidity, non-condensing at 700 hPa – 1060 hPa
Note:	*Storage and transport only in original packaging.*

Subject to technical changes.

Maximum pulses per treatment



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

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

- Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.

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

- In order to minimize the risk of infections do always wear protective gloves for cleaning and disinfection.

- The device and its applied part are not considered critical in relation to hygiene when used on non-injured and healthy skin (see for example RKI-Guideline).

Housing / Foot switch

Cleaning (only manually)

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

In case of visible contaminations the housing, foot switch and the tubing can be cleaned with commercially available alcohol-free plastic cleaners.
Wipe the surface until the contamination 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 application instructions of the manufacturer.

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.

Housing and foot switch can be disinfected by wiping. Use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloth pre-impregnated with disinfectant (wipes).
If applicable, also observe requirements for drying or post-cleaning.

Applicator head / handpiece

Cleaning (only manually)

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

Remove the silicon protective cap from the applicator head before cleaning. Then proceed as indicated 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 silicon protective cap from the applicator head before cleaning. Then proceed as indicated under “housing / foot switch”.

Silicon protective cap

Cleaning (only manually)

Tools:
- Drinking water, lukewarm
- Vessel, e.g. kidney dish
- Brush, e.g. tooth brush medium hard
- Alcohol-free plastic cleaner (e.g. cleaner for medical devices)

Remove the silicon protective cap from the applicator head before cleaning. Prepare a solution of the cleaning agent following the instructions of the manufacturer. Put the silicon protective cap into the solution. Clean the inner and outer surfaces of the protective cap by using the brush. Rinse off the protection cap under running water.

Disinfection, manually:

Tools:
- Vessel, e.g. kidney dish
- 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.

Prepare a solution of the disinfection agent following the instructions of the manufacturer. Put the silicon protective cap into the solution. Make sure that

the inner and outer surfaces of the protective are wetted. Leave the protective cape in the solution as long as defined by the manufacturer of the disinfection agent. Rinse off the protection cap under running water.

Cleaning / Disinfection, by machine:

Preparation:
Visible contaminations must be removed by manually before performing cleaning / disinfection. Proceed as described above.

Performance:
Perform a cleaning and disinfection by machine using the following parameters:

- Cleaning agent: neodisher® MediClean forte (manufacturer: Dr. Weigert)
- Cleaning: 10 minutes at 55°C
- Disinfection: 5 minutes at 93°C

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

Suitable Disinfection agents

For manual disinfection, the following agents are suitable:

- mikrozid® sensitiv wipes
- Antifect FF
- Gigasept FF
- Quartamon Med

Observe the application information of the corresponding manufacturer.

Note: *Only use the device in a completely hygienic environment.*

Caution!

When using lubricants, the silicone protection cap must be placed over the applicator head in order to avoid contamination.
If the device is used without the cap, lubricant may enter the interior of the applicator head and the handpiece, which can lead to permanent contamination and malfunction.

Note: *In this case, the warranty is null and void.*

Scope of delivery

Art. No.		
5418-01	1	en*Pulse* Version 2.0 controller unit
5413	1	Handpiece (version 2.2)
93133521	1	Applicator head, 6 mm
93133511	1	Applicator head, 15 mm
93133502	1	Applicator head, 25 mm
50500017	10	Silicone protection caps
50500018	1	en*Pulse* lotion
94130411	1	Footswitch
93130312	1	Holder for handpiece
118	1	Mains cable
10102381	1	User Manual
63061010	1	Template

Accessories

Art. No.	
5413	Handpiece (version 2.2)
93130312	Holder for handpiece
93133521	Applicator head, 6 mm
93133511	Applicator head, 15 mm
93133501	Applicator head, 25 mm
50500017	Silicone protection caps
50500018	en*Puls* Lotion
94130411	Footswitch
118	Mains cable
87053009	Transport case with foam insert
10102381	User Manual

Device Combinations

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For en*Puls* Version 2.0 no combinations devices are provided by the manufacturer.

Anyone who, acting contrary to this specification, combines devices and thus operates a medical system does so at their own risk.

14.1 Safety

The en*Puls* Version 2.0 is manufactured in accordance with the DIN EN 60601-1 safety regulations.

Zimmer MedizinSysteme GmbH shall only be held responsible for the safety and reliability of the device 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 device is operated in accordance with the operating instructions,
- extensions, readjustments, or modifications are only performed by persons authorized by Zimmer MedizinSysteme GmbH,
- the user has been instructed in the functional safety, proper operating condition, and the mechanical integrity of the device and handpiece prior to use,
- the device is only operated by properly trained personnel,
- the device is not operated in hazardous areas and/or a combustive atmosphere,
- the device is immediately disconnected from the power supply upon the penetration of liquid.

The device contains no parts that can be maintained or 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.

Before commencing cleaning and maintenance, the machine must always be switched off at the main switch and the mains socket.

Checking the impact dome

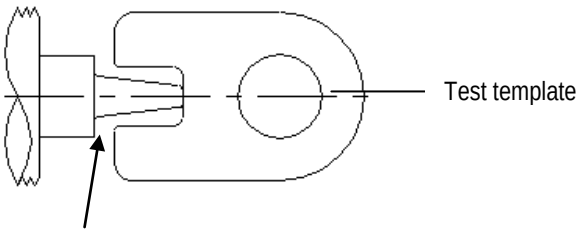
During the course of normal use, a deformation / shortening of the rear impact dome on the applicator heads may occur. As long as the changes are small, functionality is not affected.

In cases of more extensive deformation of the impact dome or considerable shortening, the applicator head must be replaced.

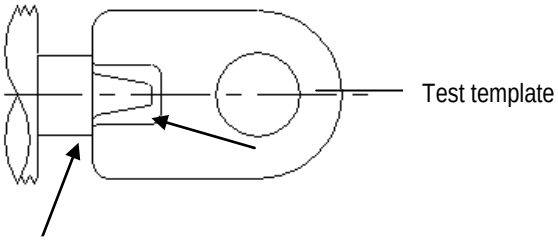
To check the proper condition of the applicator head, a test template is supplied with the device in order to test whether the wear limit has been reached.

The test should be performed at least once a month, regardless of the frequency of use.

To do so, the applicator head is removed and measured using the test template supplied.



Air gap ➔ Applicator OK



Template sits flush or there is an air gap at the top ➔ Wear limit reached

en*Puls* Version 2.0 performs a self-test when switched on checking all the internal components.

In the event of a fault, an error message appears.

In addition, a further function test can be performed as described below.

This test should be performed monthly or in case of doubt about the proper function of the device.

Note: *Before performing the function test, check that the handpiece and footswitch are properly connected to the device.*
Check that the mains cable is properly connected to the device and that it is connected to the mains.

Function test

Switch the device on.

Briefly activate the footswitch - the fans and generator should start immediately, whereby the radial pulse generator must operate at the frequency shown on the display (5 Hz is the default value).

Note: *After completing the function tests, switch off the enPuls Version 2.0.*
If a therapy is to be carried out directly afterwards, set the desired treatment parameters and proceed as described in Chapter 8.

Safety Check
Metrological Control

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Neither a safety check (STK) nor a metrological control (MTK) is required for the en*Puls* Version 2.0 in Germany.

In Germany, the Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung, MPBetriebV) and the DGUV (Vorschrift 3 Elektrische Anlagen und Betriebsmittel) apply in their current version, amongst other regulations.

Note: *These requirements apply to the operation of the device in Germany. Please observe the national regulations in your country.*

Loss of function handpiece

In the status bar the message "Ready" appears and no pulse is emitted even though the footswitch has been activated.

Possible cause 1
Handpiece / footswitch not properly connected or defective.
Remedy for cause 1
Make sure that the footswitch and handpiece are correctly connected. The plug must be fully inserted.
Check the cable of the footswitch for damage or kinks. Replace the footswitch in the event of visible damage.
Check whether the switch dome of the footswitch can be moved or is blocked. If possible, remove the blockage.

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 delivery of pulses / excessive heating of the handpiece.

Possible cause 1
Wear to the applicator head / restricted movement due to wear
Remedy for cause 1
The applicator heads are wear parts and must be replaced after a certain number of radial pulse emissions.

Removal of wear debris:
Remove the applicator head from the handpiece and thoroughly clean the rear dome. Then hold the handpiece, without the applicator head, with the opening facing downwards. With the frequency set to 2 or 5 Hz and at the lowest energy level, trigger a small number of pulses (maximum 10). Then attach the applicator head again.
If the malfunction still remains, the applicator head must be replaced.

Possible cause 2
Wear to the pulse generator
Remedy for cause 2
The pulse generator is a part subject to wear and must be replaced after 2 million shocks.
Check the total shock count of the device in the configuration menu.
If the total number of shocks has reached or exceeded 2 million, the pulse generator must be replaced.
To replace the pulse generator, please contact your authorized sales representative or contact the head office in Irvine, CA.

Applicator not found

In the status bar, the message "No applicator found" appears.

Possible cause
Handpiece not or improperly connected.
Remedy for cause
Make sure that the handpiece is properly connected. The connector must be fully inserted.

Device malfunction

No response to the main switch / display remains dark

Possible cause 1
Mains power connection
Remedy for cause 1
Check whether the mains cable is properly plugged into the electrical outlet and that the plug is firmly inserted into the socket of the device.
Check the power cord for damage. Replace it in the event of visible damage.
Check the power supply and mains socket.

Possible cause 2
Fuse
Remedy for cause 2
In the power input socket of the device there are micro-fuses that disconnect the power supply in the event of an electrical problem. Open the cover and check the fuses. If necessary, replace the faulty fuse.

Only replace the fuse with a replacement that has the same name / is an exact equivalent. Perform a complete check of the power supply for possible faults beforehand.

If the fault persists, contact the service representative / customer service immediately.

Error message SD card

If the SD card is not inserted, the following message appears when the "Favorites" button is pressed:

"No SD card found.
The use of "Favorites" requires an SD card.

Insert the card and confirm with "OK".

Over temperature warning

When the temperature reaches a critical level, a cooling phase is initiated. This is indicated in the display by the following message:

"Over temperature in the applicator. Please allow the applicator to cool down."

When this message appears, pulse input is no longer possible.

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 still occurs, please contact the customer service via the office in Irvine, CA.

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Disposal

Please observe the national regulations regarding disposal. Contact your distributor if necessary.

The device may only be returned to the factory in the original packaging. It must be disposed of by Zimmer MedizinSystems.

Medical electrical equipment such as the en*Puls* Version 2.0 are subject to special precautions with regard to EMC (electromagnetic compatibility) and must be installed and commissioned in accordance with the EMC information contained in the user instructions or the accompanying documents.

Portable and mobile RF communications equipment (e.g. mobile phones) can affect electrical medical equipment.

en*Puls* Version 2.0 may only be operated with the original power cord indicated in the scope of delivery.
The operation of the device with a different power cable may result in increased emissions or to a reduction in the device's interference immunity..

Guidelines and Manufacturer's Declaration - Electromagnetic Emissions		
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 must ensure that it is operated in such an environment.		
Emissions measurements	Compliance	Electromagnetic environment - guidelines
RF emissions in accordance with CISPR 11	Group 1	The en*Puls* Version 2.0 device uses exclusively RF energy for its internal function. As a result, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF emissions in accordance with CISPR 11	Class B	The en*Puls* Version 2.0 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purposes.
Emissions of harmonics in accordance with IEC 61000-3-2	Category A	
Emissions of voltage fluctuations / flickers in accordance with IEC 61000-3-3	Compliant	

The device must not be used in direct proximity to or stacked directly on top of another device. If operation near to or stacked on top of another device is unavoidable, the device should be monitored to verify its proper operation within this setup.

Guidelines 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 ensure that it is used in such an environment.			
Interferance immunity tests	IEC 60601 - Test Level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made from wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient / burst in accordance with IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	± 2 kV for power supply lines Not applicable for input and output lines	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage variations in accordance with IEC 61000-4-11	<5% U_T (>95% dip in U_T for ½ a period) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) <5% U_T (> 95% dip in U_T for 5 seconds)	<5% U_T (> 95% dip in U_T for ½ a period) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) 5% U_T (> 95% dip in U_T for 5 seconds)	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of en*Puls* Version 2.0 requires continued operation, even in the event of interruptions to the power supply, it is recommended that the en*Puls* Version 2.0 be be powered from an uninterruptible power supply or a battery.
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Key features of the en*Puls* Version 2.0 are: interference-free delivery of radial pulses, trouble-free operation of all functions. Continuous operation is not required for the intended use.

Guidelines 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 ensure that it is used in such an environment.			
Immunity tests	IEC 60601 - Test Level	Compliance level	Electromagnetic environment - Guidelines
Conducted RF disturbance variables in accordance with IEC 61000-4-6 Radiated RF disturbance variables in accordance with IEC 61000-4-3	3 V_{RMS} 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{RMS} 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should not be used any closer to the en*Puls* Version 2.0, including cables, than the recommended separation distance calculated using the equation relevant for 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 power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). At all frequencies, the field strengths of fixed RF transmitters should, according to an on-site[a] investigation, be less than the compliance level[b]. Faults may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all cases. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The field strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasters cannot be theoretically predicted with accuracy. In order to assess the electromagnetic environment with regard to fixed RF transmitters, a study of the electromagnetic phenomena at the location should be considered. If the measured field strength in the location in which the en*PulS* Version 2.0 device is used exceeds the above compliance level, the en*PulS* Version 2.0 device must be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as the realignment or relocation of the en*PulS* Version 2.0.

[b] Within the frequency range from 150 kHz to 80 MHz, field strengths should be lower than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the en*PulS* Version 2.0 device

The en*PulS* Version 2.0 device is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the en*PulS* Version 2.0 device can thus help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the en*PulS* Version 2.0 device – depending on the output power of the communications equipment as indicated below.

Rated power of the transmitter W	Separation distance depending on the frequency of transmitter M		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
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 power is not specified in the above table, the recommended separation distance d in metres (m) can be calculated using the equation that belongs in the respective column, where P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all cases. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

enPuls
Version 2.0

User Manual

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