Zimmer MedizinSystems

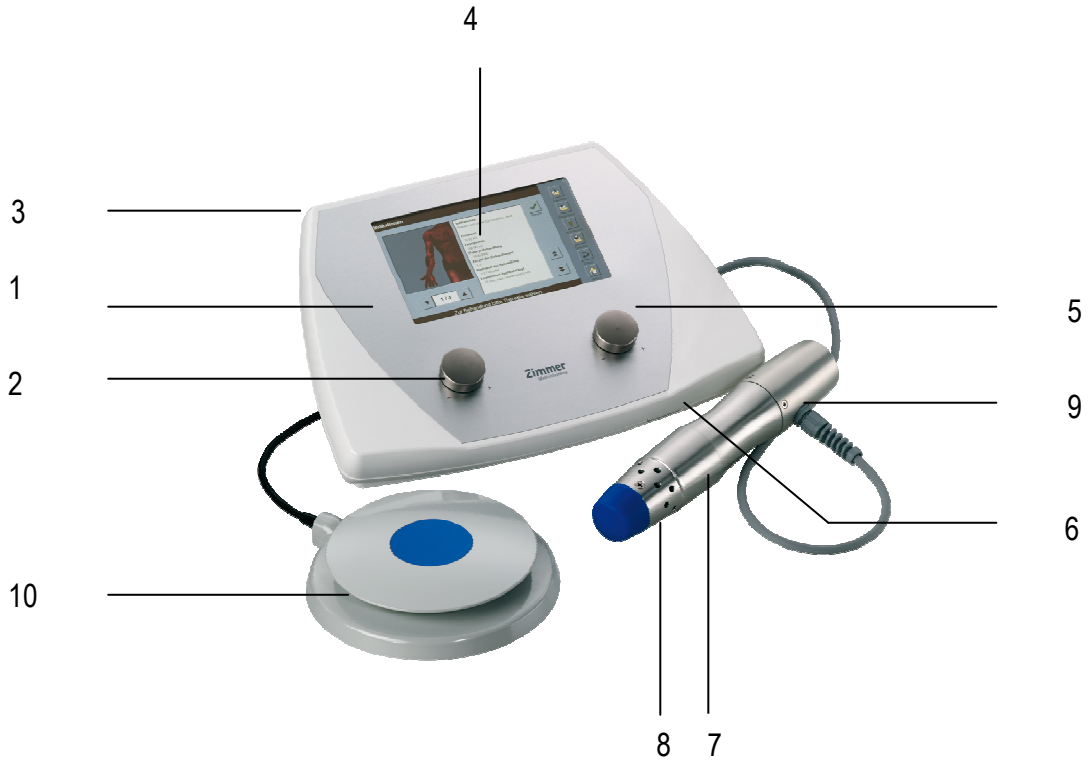
User Manual

enPuls
Version 2.0

Figures

Front view of device

Control unit / Handpiece / Footswitch



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Front view of device

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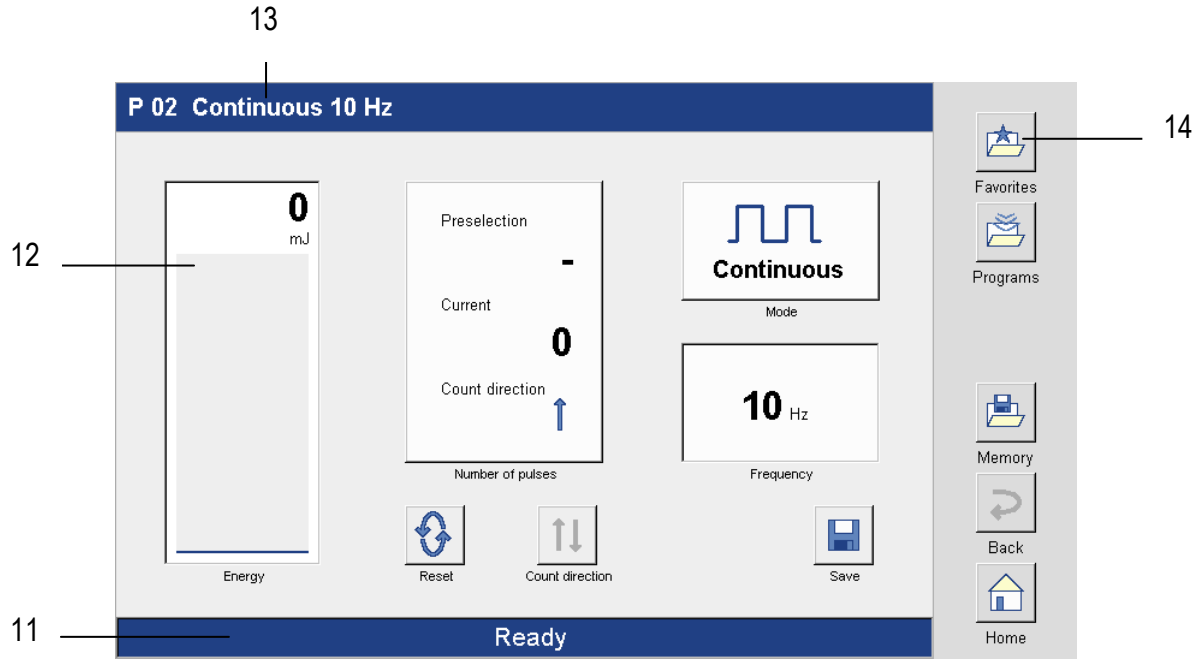

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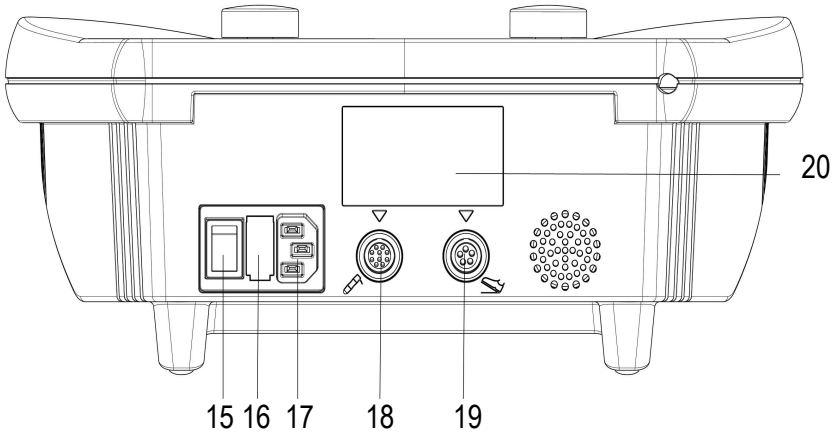

Switch / Connector sockets	15	Main switch
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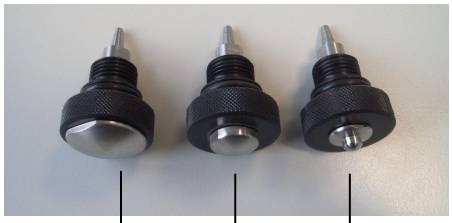


22 23 24

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

Contents

Contents

Valid for the en*Puls* V.2.0 devices
These operating instructions are an integral part of the device.
They must be stored with the device and kept accessible at all times for anyone authorized to operate this device. These Instructions form is a part of the appartures and must be kept with it at all times. Full observation of these instructions is a requirement for the correct application and operation of the equipment and for consequent saftey for patient and operator.

These operating instructions are valid from 01 June 2011.

en*Puls* briefly

1

1.1. Summary

What is en*Puls*?

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* do?

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

How are radial pulses generated with en*Puls*?

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

What are the advantages of en*Puls*?

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

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

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

The unit must only be operated by medical practitionars.

Note:

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

! Caution

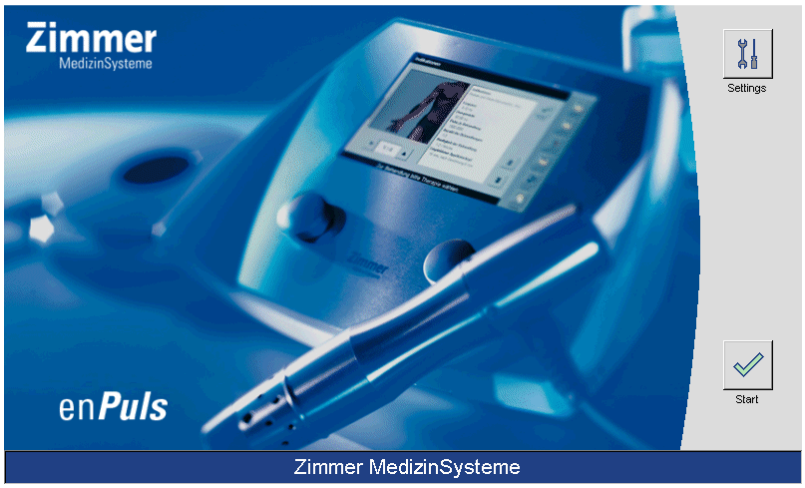
Federal law restricts this device to sale by or on the order of a physician.

1.2. Quick operation instruction

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

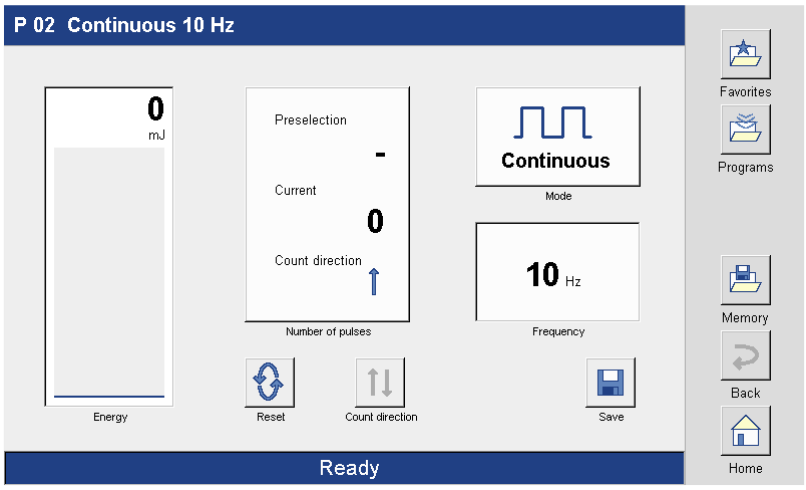
Note: *All buttons, menus and submenus are activated directly on the screen by touching or using the touch pen.*

Starting the program



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

Treatment screen



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

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

1.2. Quick operation instruction

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

1.3. How to use en*Puls*

Start treatment

en*Puls* operates with mechanical energy.

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

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

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

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

! Caution

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

Note:

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

Recommended protective measure:
- Limit the duration of exposure

Note:

The patient should be carefully monitored throughout the treatment.

1.4. Handpiece

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

Note:

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

Zimmer MedizinSystems guarantees unrestricted use of at least 2 million pulses per pulse generator.

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

For more information on the need to replace the pulse generator, see chapter 10.

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

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

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

Standby mode on device and handpiece

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

1.5. Applicator heads

There are 3 different applicator heads available for treatment.

Changing applicator heads

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

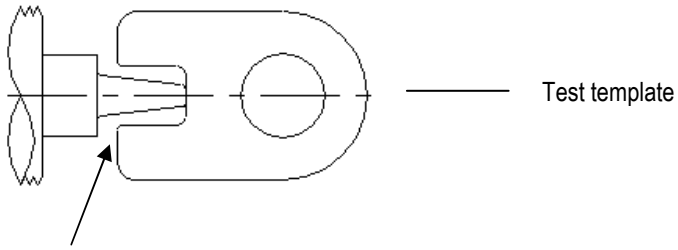
Note:

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

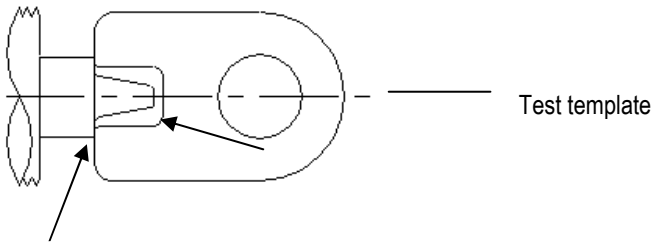
Minor / slight deformation or shortening of the rear impact dome does not affect functionality.

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

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



Air gap ➔ applicator OK



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

1.6. Footswitch

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

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

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

Installation

2.1. Fitting the cables, starting the system

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

2.2. Settings

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

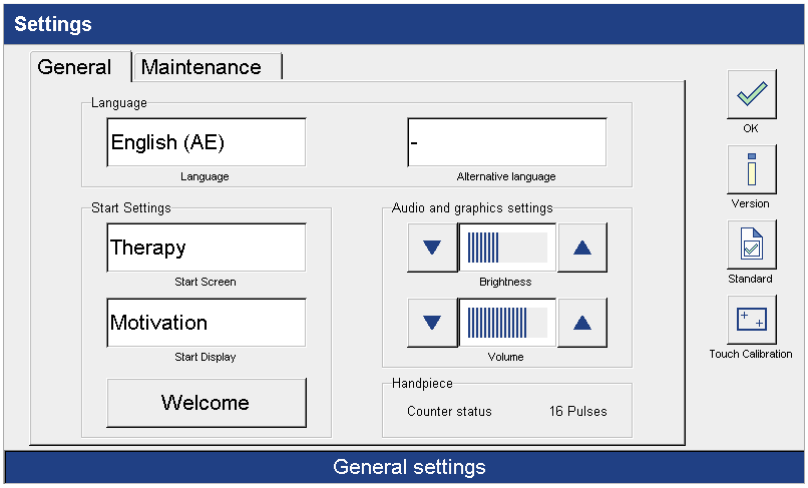


Figure 1

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

Start settings

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

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

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

Audio / graphic settings

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

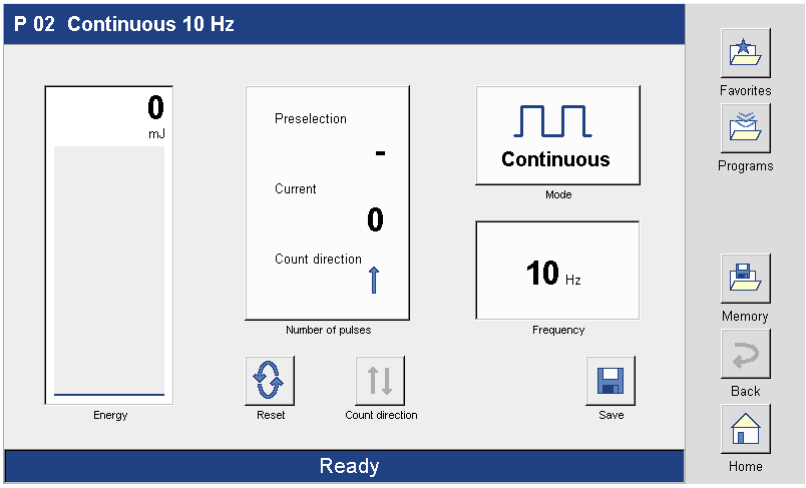
SD-Card

3

User-defined settings are saved on the SD card.

Note: *If the SD card is not inserted, the message 'SD card not found' appears when the 'Favorites' and 'Memory' buttons are pressed.*

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



Title bar

The title bar shows the name of the current program.

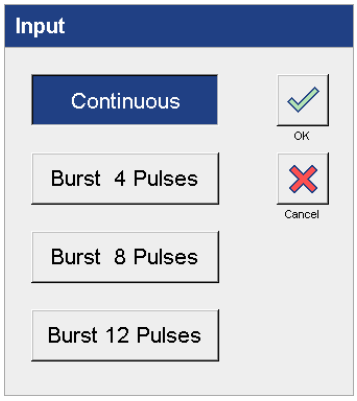
Status bar

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

Mode

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

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



Frequency

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

Energy/ Bar graph

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

Save

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

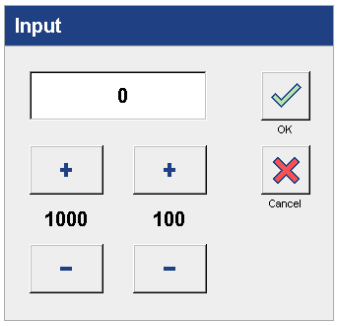
Count direction

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

Number of pulses

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

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



Note:

enPuls offers two options for pulse delivery:

Pulse delivery without pre-selecting the pulse number

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

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

Pulse delivery with pre-selection of the number of pulses

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

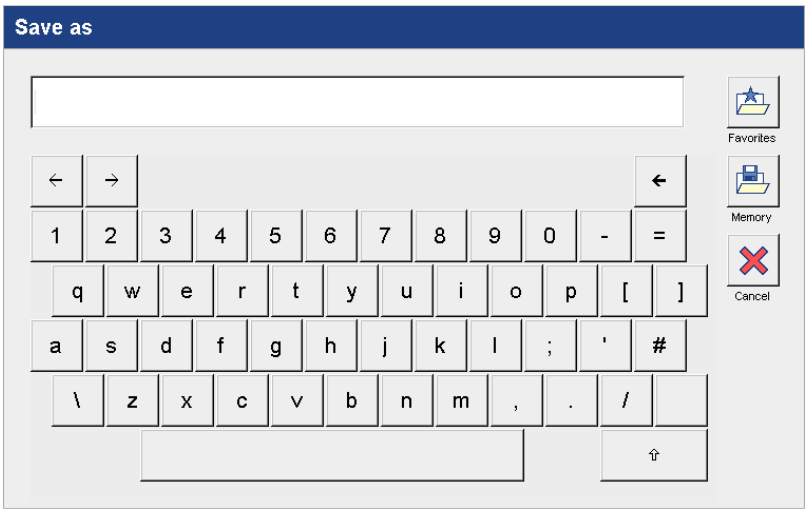
The footswitch is deactivated and pulse delivery is no longer possible.

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

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

5.1. Saving modified program

Programs can be stored either in the Favorites list or the Memory list.



Program name For saving the program enter the program name using the keyboard

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

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

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

5.2. Retrieving and editing Favorites list and the Memory list

Note

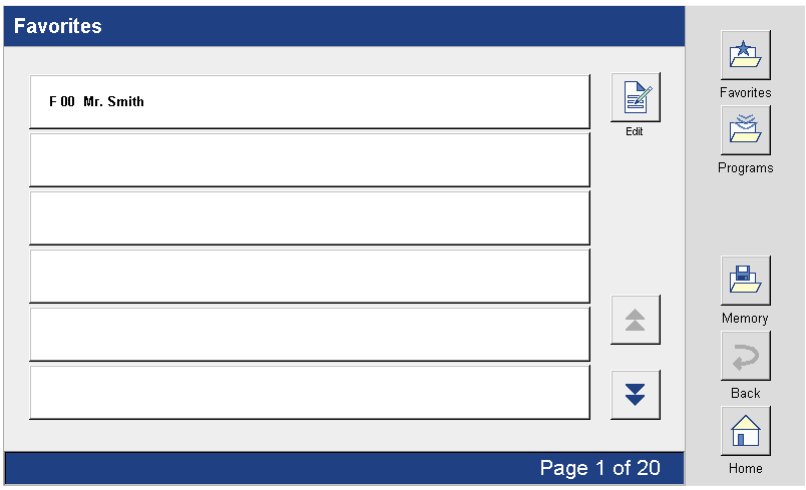
The following steps to edit the Favourites list correspond exactly to those used to edit the Memory list.

Individual saved programs are listed in Favorites or Memory list.
From here they can be:

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

Selecting the Memory or Favorites list

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

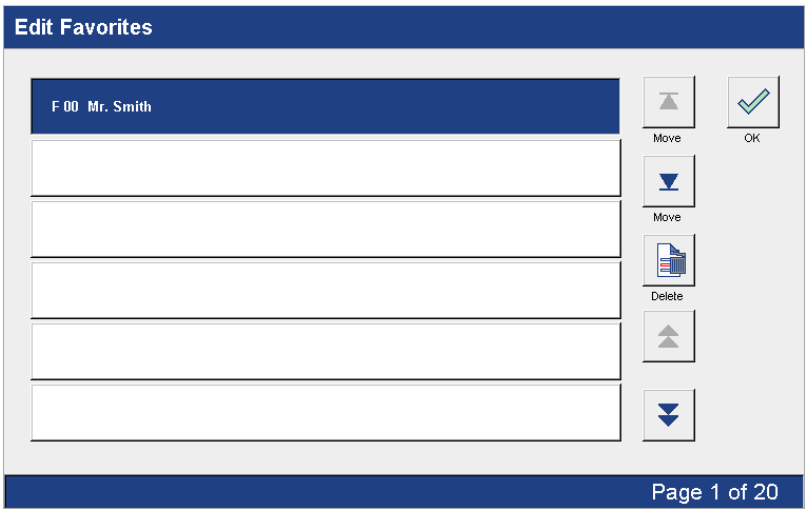


Retrieving a program

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

Editing

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



Activate the desired program by pressing the appropriate row.

You are now able to

- Move or
- Delete

the selected program.

Description of the selection keys

Press the button to open the screen to save a program.

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

Can be used to reverse the counting direction.

Pressing the key reset the current number of pulses

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

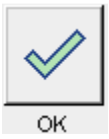
Press the button to move an item of the list upwards by one position.

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

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

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

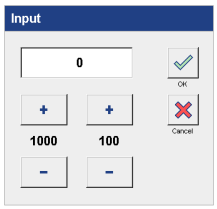
Scrolling backwards
Press the button to scroll one page up the list.



The changes are applied by pressing the button.

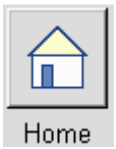
Press the button to reject the changes made.

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



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

Press the button to open the Program window.



Press the button to return to the Start screen.

Medical information

7

7.1. Indications

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

7.2. Contraindications

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

In general we advise against treatments

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

Care is required for patients

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

as circulatory stresses and inadequate treatment responses cannot be excluded.

General information

8.1. Explanation of symbols

8

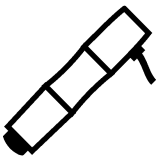
Danger / Warning

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

Caution

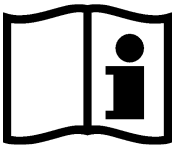
In the Operating Instructions this symbol stands for '**Caution**' with regard to possible damage to property.

!



Port for handpiece

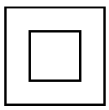
Port for footswitch



Follow Operating Instructions

Instrument type BF (according IEC60601-1):
Degree of protection against electric shock
Device must not be used at heart

Value of the accessible fuses



Class II

ETL Testmark

8.2. Warnings

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

- **Warning:**
  Patients who are concurrently receiving treatment involving a reduction and/or modification of blood clotting or prolongation of the blood clotting time (e.g. with acetylsalicylic acid) should consult their therapist about possibly stopping this treatment as these patients may be more prone to greater haemorrhaging and bruising when radial pulses are applied.

- Radial Pulses are strongly scattered in air pockets and create reflections that may have negative effects.
  You must therefore never perform any direct treatments over the lungs (intercostal spaces) or the gastrointestinal area.

- It must not be used in wet areas. If it is used in wet areas, significant damage may result, and patients and users may be endangered.

- **Warning:**
  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.

8.3. Technical data

Intended use:	Therapeutic massager
Dimensions	L 322 mm / W 235 mm / H 130 mm
Weight	2.7 kg
Power supply	100–240 VAC / 50/60 Hz
Fuse	3,15 AT
Protection class	II
Application class	BF
Frequency range	1 Hz – 16 Hz, can be adjusted in 1 Hz steps
3 burst modes	4, 8, 12 pulses with 16 Hz (0.5 s)
Pulse energy levels	
4 selectable fixed settings	60 / 90 / 120 / 185 mJ (at the applicator) at 16 Hz max. 120 mJ
Mode of operation	Intermittent use max. 6000 pulses / 15min. break
Accuracy	± 20%
Handpiece:	Ergonomic model with anodized aluminium case and fan cooling
Dimensions	230 mm in length, 50 mm diameter
Weight	850 g (with cable)
Service life	2,000,000 Pulses (minimum)
	Applicator heads exchangeable without any tools (6 / 15 / 25 mm diameter)
Dimensions (complete with case)	L 580 mm / W 470 mm / H 250 mm
Total weight	13 kg (total with case)
Environmental conditions	
Operational environment	10 to 35 °C (50 to 75 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed
Storage / Transport	
Short-term	-10 to 55 °C (14 to 131 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed
Long-term	0 to 40 °C (32 to 104 °F); 700 hPa – 1060 hPa 20% to 80% rel. humidity, not condensed
Regulatory Compliance	IEC/EN 60601-1 IEC/EN 60601-1-2

8.4. Technical information

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

- if the device is operated from an approved, grounded wall socket
- if the device is operated in accordance with the Operating Instructions
- if extensions, reconfigurations or modifications are implemented only by persons authorized by Zimmer MedizinSystems
- users must ensure that the device and the handpiece are operating correctly; are mechanically intact and are in good condition before using them
- disconnect the device from the power supply immediately if it is exposed to liquids.

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

8.5. Legal information

Legal Information

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

Maintenance

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Separate servicing is not required for this product.

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

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

! Attention !

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

Note:

In this case the warranty becomes void.

Cleaning / disinfection

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

Conventional disinfecting products used for medical equipment are suitable.

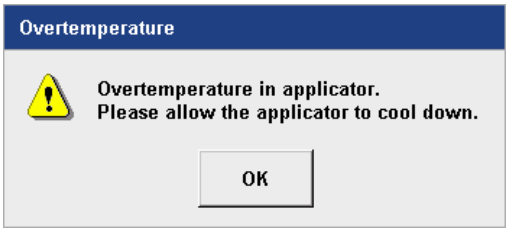
Note:

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

Monitoring the handpiece temperature

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

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



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

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

Failure or malfunction of the handpiece

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

Check the cable of the handpiece for any mechanical damage.

Irregular delivery of radial pulses / overheating of handpiece

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

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

Remedying cause 1

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

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

Possible cause 2: Wear of pulse generator

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

Remedying cause 2

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

To replace the pulse generator, contact a qualified customer engineer or the head office in Irvine, USA.

Troubleshooting

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No response at main switch / display remains dark

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

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

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

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

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

Function test

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

An error message is shown in case of faults.

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

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

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

Function test

Testing Switch on the device.

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

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

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

Error Messages

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

Scope of delivery, Accessories

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Scope of delivery

5416	1	Control unit en*Puls* Version 2.0
5410	1	Handpiece, complete with a 15 mm applicator head
93133521	1	6 mm applicator head
93133511	1	15 mm applicator head
93133501	1	25 mm applicator head
50500017	10	Silicone caps
50500018	1	en*Puls* lotion
94130410	1	Footswitch
67300128	1	Mains cable
10101888	1	Operating instructions
63061010	1	Test template
87053010	1	Transport case
65800410	2	Touch pens
63230311	1	Holder for handpiece

Accessories
Item No.

63230311	Holder for handpiece
93133521	6 mm applicator head
93133511	15 mm applicator head
93133501	25 mm applicator head
50500017	Silicone cap
50500018	en*Puls* lotion
94130410	Footswitch
67300128	Mains cable
87053010	Transport case with foam insert
10101888	Operating Instructions
63061010	Test template
65800410	Touch pen

Manufacturer's declaration of Electromagnetic Compatibility

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

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

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

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

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

Manufacturer's declaration of Electromagnetic Compatibility

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Guidance and manufacturer's declaration – Electromagnetic immunity			
The en*Puls* Version 2.0 device is intended for use in the electromagnetic environment specified below. The customer or the user of the en*Puls* Version 2.0 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T for 5 seconds)	<5% U_T (>95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T for 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. The user of the en*Puls* Version 2.0 requires continued operation during power mains interruptions. It is recommended that the en*Puls* Version 2.0 be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commerical or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Manufacturer's declaration of Electromagnetic Compatibility

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

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

Manufacturer's declaration of Electromagnetic Compatibility

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

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

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

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

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

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

en*Puls*
Version 2.0

User Manual

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