Zimmer
MedizinSysteme

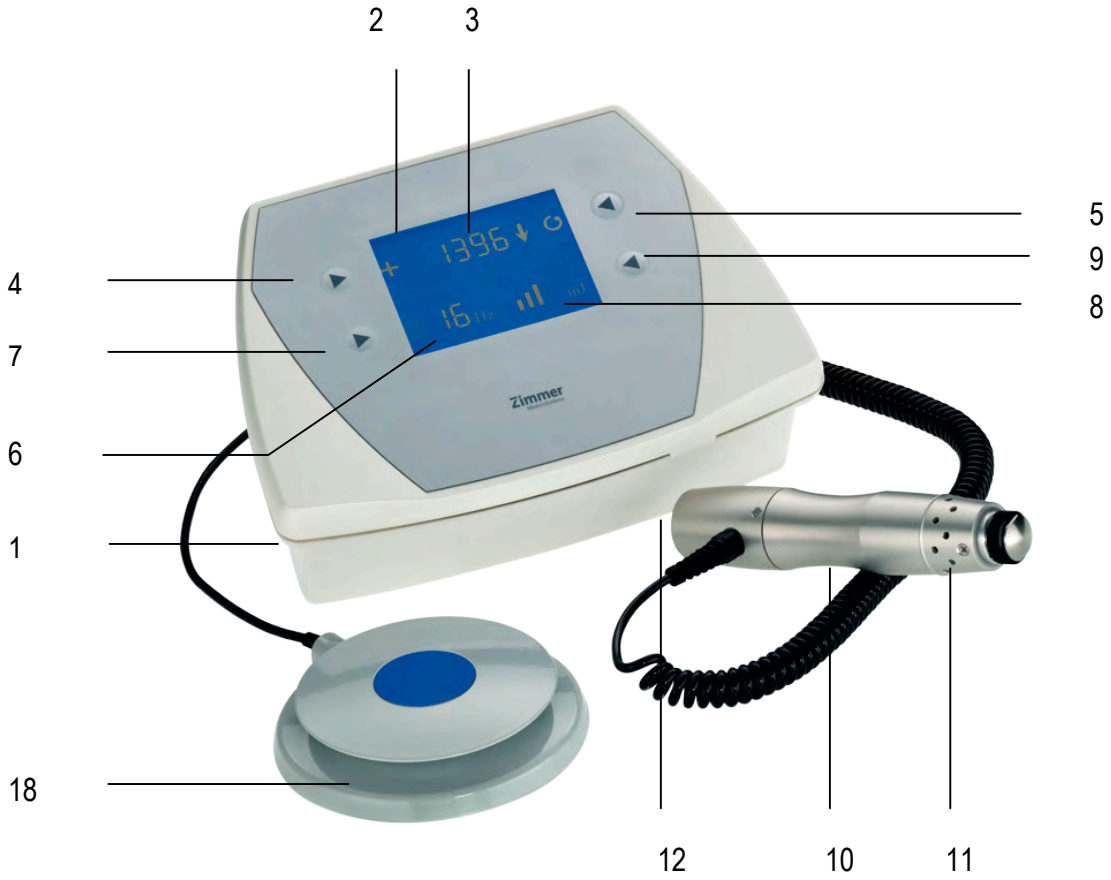
Instructions for Use

en*Puls*

GB

Diagrams

Front View / Handpiece / Footswitch



Front View	1	Control unit
	2	Display
	3	Shockwave meter / counting direction
	4	Control for presetting number of shocks
	5	Control for resetting number of shocks
	6	Frequency display
	7	Control for adjusting frequency
	8	Energy level display
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	11	Air vents, front
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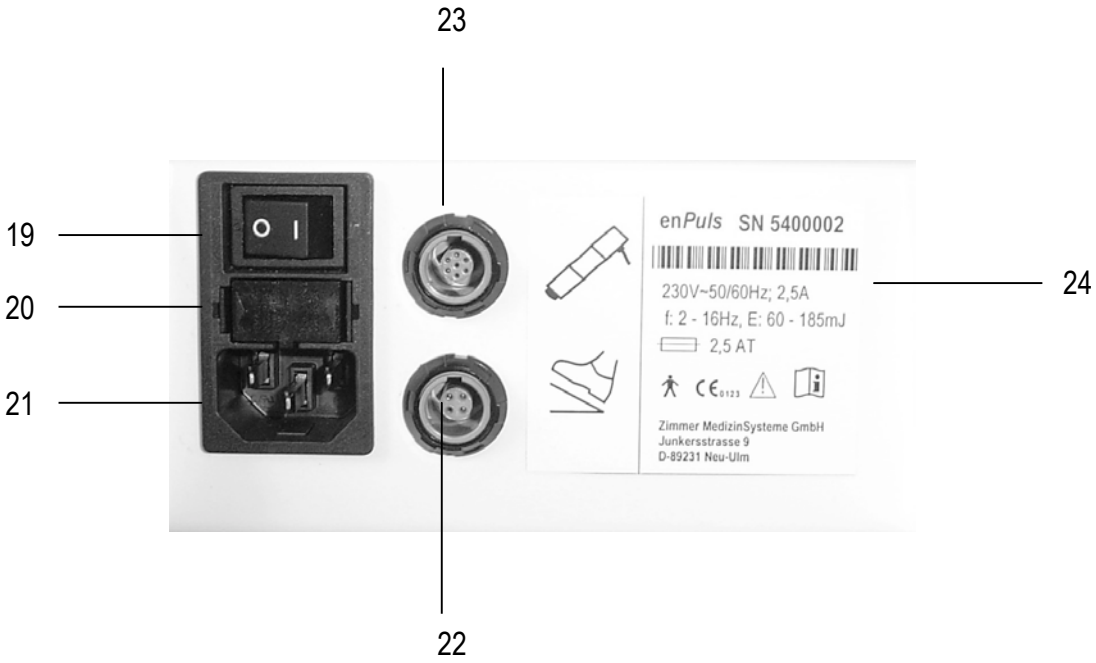
Rear View of Device / Accessories



Rear View

19	Main switch
20	Mains fuse
21	Port for mains cable
22	Port for footswitch
23	Port for handpiece
24	Standard rating plate

Accessories

16

16 Silicone cap standard

13 14 15

13	25 mm applicator head
14	15 mm applicator head
15	6 mm applicator head

Contents

These instructions are an integral part of the device. Strict adherence to these instructions is a prerequisite for the prescribed use and correct handling of the device as well as to ensure the safety of the patient and the user.

They must be stored with the device in order to be accessible at all times to anyone appointed to operate this device.

These instructions contain general information on safety, operation, maintenance and care for owners and users of the en*Puls* shockwave therapy device.

These instructions are valid at the date of printing. Requirements in terms of product and therapy technique are subject to constant change; therefore we reserve the right to make any technical and structural changes.

In order to ensure reliable and successful operation, please observe all the advice and information in these instructions.

If you are operating the device, you must follow all the up-to-date instructions and precautions for electrically operated radial (ballistic) shockwave therapy equipment.

en*Puls* 1. Summary

What is en*Puls*?

A state of the art, innovative shockwave therapy device.

Shockwave therapy

Radial ballistic shockwave therapy is a versatile procedure for treating conditions ranging from superficial orthopedic problems to myofascial trigger points.

What does the en*Puls* do?

The en*Puls* generates shockwaves by means of an ergonomic handpiece and delivers shockwaves via special applicators.
It allows a maximum penetration depth of approximately 35 mm to be reached in human tissue.

How are shockwaves generated with en*Puls*?

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

What are the advantages of en*Puls*?

A large display showing all the parameters relevant to the treatment as well as clear, simple menu navigation ensure optimal user comfort.

Different frequencies and applicators allow individual treatment adapted to the particular condition of the patient.

Its lightweight and compact structure allows it to be used in the tightest of spaces.

Note:

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

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

Explanation of Symbols 2.

Danger / Warning In the User Manual, this symbol stands for **Danger / Warning**.

Caution In the User Manual, this symbol stands for 'Caution' with regard to possible material damage.

!

Handpiece port

Footswitch port

Follow instructions for use.

Device type B: Protection level against electric shock

Value of accessible fuses

Quick start guide for the system 3.

Note:	*Make sure that the main switch on the device is set to'0'.*
Fitting the mains cable	Connect the mains cable to the designated port on the device and then plug into the mains.
Fitting the handpiece	Connect the handpiece to the designated port on the device.
Fitting the footswitch	Connect the footswitch to the designated port on the device.
Switching on the device	Switch on the device using the rocker switch (I).
Setting treatment parameters	Set the required frequency, energy level and meter mode according to therapeutic criteria.
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 to the treatment area if necessary.
Note:	*When using enPuls Lotion, the applicator head must be covered with a silicone cap to protect it.*
Start of treatment	Treatment is started by activating the footswitch.
Note	*Only activate the shockwave via the footswitch once the handpiece has been positioned on the patient.*
End of treatment	Treatment is interrupted or ended by releasing the footswitch.
Note:	*During treatment, the patient must be observed closely and the treatment must be adjusted if necessary or discontinued should any problems develop.*

Start-up
Function Test

4.

Start-up

Note *To start up the device, remove it from its transport case and place it on a suitable stable surface. This device is not designed for use in the case.*

Make sure that the main switch on the device is set to '0'.

Note *Before connecting the mains cable, make sure there is a suitable power outlet according to regulations, with the correct mains voltage. Once any mains plug or adapter required by the country in question has been professionally fitted, connect the mains cable to the device and the socket.*

Fitting the mains cable Connect the mains cable to the designated port (21) on the device and then plug into the mains.

Fitting the handpiece Connect the handpiece to the designated port (23) on the device.
Put down the handpiece.

Fitting the footswitch Connect the footswitch to the designated port (22) on the device.
Place the footswitch on the floor.

Note *The footswitch and handpiece connectors are both marked with arrows. These arrows must be pointing exactly upwards during insertion. If the arrow is aligned correctly, the connector can easily be pushed into the port. If necessary, turn the connector until it can be inserted easily. Never force the connector into the port if it is in any other position.*

Start-up Function Test 4.

Note: *Make sure that an applicator head is inserted into the handpiece and that this is properly screwed in as far as it will go.*

Switching on the device

Switch on en*Puls* using the rocker switch (I).

System test

After power-up, en*Puls* runs a system test and if this is completed successfully it is then ready for use.

Function test

Performance

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

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

If a treatment is to be performed immediately afterwards, set the required treatment parameters and proceed as described in Section 3.

Description of Functions 5.

Shockwave meter

In the basic setting and after a reset (5), the central meter (3) on the display counts the shocks delivered up to a maximum of 9999 and then starts again from zero. Counting is summative, that is, the meter counts upwards as long as the shockwave is activated by the footswitch (18) and stops if you remove your foot from the switch. If you activate it again, the meter continues counting from the current meter reading.

Button (5) allows you to zero the meter reading, if required.

Button (4) can be used to reverse the counting direction and preset the system, in each case in increments of 100. Every time the button is pressed, the presetting increases by 100 shocks. On activation using the footswitch (18), the meter now counts down until the meter is at zero. The system then stops and has to be reactivated.

Frequency setting

Button (7) is used to set the shockwave frequency. This function is only available if the shockwave is not activated. It is possible to select a burst program of 9 pulses as well as additional 4 programs with frequencies of 2 Hz, 5 Hz, 10 Hz and 16 Hz. Every time the button is pressed, the system advances a stage further. Continuously variable adjustment is not possible.

The possible frequency setting depends on the selected energy level. The frequency 16 Hz is only possible at the first three energy levels. At the highest energy level, the maximum frequency setting that is possible is 10 Hz.

Description of Functions 5.

Energy level

Button (9) allows the energy level (that is, the impact hardness of the shockwave generator in the handpiece) to be set at 4 fixed levels. The function is only available when the shockwave is not activated. The amount of energy which is delivered and transferred to the applicator head at every impact is as follows:

Level 1:	60 mJ
Level 2 :	90 mJ
Level 3 :	120 mJ
Level 4 :	185 mJ

Note: *The set level always defines the impact of the shock through the shockwave generator that is in turn transmitted to the applicator heads.*

As the size of the contact surface varies between patients, the amount of energy distributed is correspondingly more or less. This has an impact on the effect of the treatment and therefore must be taken into consideration.

General Operating Instructions 6.

For the user

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 vertical.

When the shockwave is activated it is possible to work both stationarily 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 work angle can be varied.

Note: ***!*** *When using enPuls Lotion, 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 measures:
- Limit the duration of exposure
- Passive support

General Operating Instructions 6.

Handpiece

The handpiece (10) contains the shockwave generator, a fan to dissipate heat and the slot for the different applicator heads. It is connected to the control unit (1) by means of an extensible helix cable.

Note !

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

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

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

For more information on the need to replace the shockwave generator, see Section 7.

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

The helix 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 air vents at the top and particularly on the base of the handpiece are not blocked by the hand holding it or anything else.

Standby mode on device and handpiece

The fan in the handpiece is actuated by depressing the footswitch and stops automatically 3 minutes after pressure on the footswitch is removed.

The control unit automatically switches to standby mode 10 minutes after the last actuation, whereby the display is also deactivated. It can be reactivated by pressing any one of the four buttons at the top of the device.

General Operating Instructions 6.

Applicator heads

There are 3 different applicator heads available for treatment.

Changing the 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 into 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 !

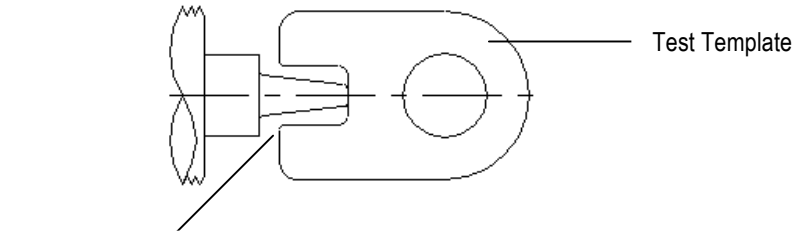
Applicator heads are expendable parts and must be replaced after a certain period of use.

Wear of the applicator head

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

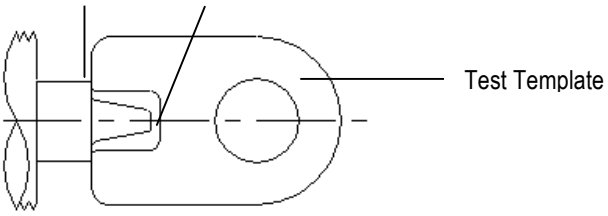
In cases of greater deformation of the rear impact dome or shortening the applicator head must be replaced.

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 okay

Template touching, no air gap, limit of wear reached



General Operating Instructions 6.

Footswitch

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

To avoid damage please note that only slight pressure is needed or should/must be exerted on the switch using the front part of your foot, not the heel.

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

Errors Troubleshooting 7.

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 helix cable of the handpiece for any mechanical damage.

Irregular delivery of shockwaves / overheating of handpiece

Possible cause 1: Wear of shockwave generator

The shockwave generator is an expendable part and should be replaced after 2 million shocks.

Check the total number of shocks of the device.

To check the total number of shocks, first press button 5 and keep it depressed while pressing button 7. At the top of the shock meter (3), the display indicates the total number of shocks delivered by the device.

Remedying Cause 1

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

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

Possible cause 2: Wear of the applicator head / stiffness due to abrasion

Applicator heads are expendable parts and must be replaced after a specific number of shocks.

Remedying Cause 2

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 downwards and, at 2 or 5 Hz frequency, release a few shocks (maximum 10) at the lowest energy level. Then reinsert the applicator head.

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

Errors Troubleshooting 7.

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.

Check mains cable for any damage.
Check the power supply system and the power outlet.

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 defective fuse if necessary.

Important:

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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 Customer Service department.

Handpiece stops operating, device functioning normally

The shockwave generator in the handpiece is fitted with a thermal switch which automatically interrupts operation if there is a risk of overheating.

This can occur, for example, with applications of over 8,000 shocks at high frequency and maximum energy level.

The integrated fan cools the handpiece down to regular temperature and then normal operation can be resumed.

Display is working, no reaction to footswitch

Make sure that the footswitch is properly connected to the device – the connector must engage fully in the port.
Check the footswitch cable for any damage or kinks.
Check whether the footswitch dome can be moved or whether it is blocked.

Appliance starts with an error message in the display

The device can usually be operated normally after pressing any button at the top of the device.
This is most frequently caused by disconnecting accessories and the mains cable while the device is still operating. This can happen especially in standby mode, as the deactivated display is often interpreted as a sign of the device being switched off.

Maintenance 8.
Cleaning / Disinfection
Disposal

Maintenance

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

A separate service is not necessary with this product. You should, however, check the en*Puls* (device / handpiece / footswitch and all cables) at regular intervals (at least once every six months) to ensure that it is in mechanically sound condition.

You should also check the applicator domes for any wear, as described in Section 6.

Note **!**

When using en*Puls* Lotion, it is essential to pull a silicone cap over the applicator head.
If you do not use any protective cap, lotion can get inside the applicator head and handpiece which can lead to permanent soiling and malfunctioning.

Cleaning / disinfection

Clean the device and handpiece with just a damp cloth. We particularly recommend using a commercially available microfiber cloth for this.
More stubborn soiling is easily removed by adding a mild cleaning agent.

Please note:

Only use washing lotions or alcohol-free or solvent-free cleaning agents/disinfectants.

Do not use solvent, chloride, polish, synthetic cleaning agent, wax polish or aerosol spray.

Note

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

Disposal

Never dispose of the device or packaging in household waste. Zimmer Medizinsysteme GmbH undertakes to dispose of any parts that cannot be repaired.

Warnings 9.

- Users of the en*Puls* shockwave therapy 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 physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.

- Treatment must always be carried out under medical supervision.

- **Important:**
  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 hemorrhaging and bruising when radial shockwaves are applied.

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

- Use in wet areas is inadmissible and, if ignored, can cause serious harm and endanger both the patient as well as the user.

The equipment should only be operated with the mains cable provided. Protect the mains cable from any mechanical stress.

10. Indications Contraindications

Indications

en*Puls* is designed to treat superficial orthopedic and neurological problems such as the following:

Tendinitis
Bursitis
Insertion tendopathy
Calcaneal spurs
Myofascial trigger points, etc.

Contraindications

- vascular diseases present in or near the treatment area
- local infections in the treatment area
- around malignant or benign tumors
- 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 treatment

- in patients with blood clotting disorders or the patient is receiving treatment that results in a change in the blood clotting behavior
- during pregnancy
- in 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 plate

Care is required for patients

- that present with impaired sensibility
- that present with severe autonomous disorders
- that are under the influence of drugs and/or alcohol

as circulatory stresses and inadequate treatment responses cannot be excluded.

Technical Data 11.

en*Puls*:	
Treatment system for electromagnetic generation/application of radial shockwaves in orthopedics/physiotherapy	
Length	330 mm
Width	250 mm
Height	185 mm
Weight	5.4 kg
Power supply	230 VAC / 50/60 Hz, 2.5 A
Fuse	2.5 AT
Conformity	Protection class I / application class B
Modes:	
4 selectable frequencies	2/ 5 / 10 / 16 Hz
1 burst mode	9 pulses with16 Hz (0.5 s)
Energy levels:	
4 selectable fixed settings	60 / 90 / 120 / 185 mJ (on applicator) at 16 Hz max. 120 mJ
Precision	± 20%
Shockwave handpiece:	
Ergonomic model with anodized aluminum case and fan cooling	
Dimensions:	230 mm in length, 50 mm diameter
Weight:	0.94 kg (with cable)
Service life:	2,000,000 shocks (minimum)
Applicator heads exchangeable without any tools (6 / 15 / 25 mm diameter)	
Contents on delivery:	Case with device, handpiece, applicator heads (6 / 15 / 25 mm), protective caps, footswitch, mains cable
Dimensions: (W / D / H)	600 mm / 400 mm / 230 mm
Weight:	11.5 kg (total)
Ambient conditions:	
Operation:	10 to 35°C (50 to 95°F)
	Up to 2400 m NMH / 20 to 80% rel. humidity, not condensed
Storage/Transport:	
Short-term:	-10 to 55°C (14 to 131°F)
Long-term:	0 to 40°C (32 to 104°F)

Contents on delivery / Accessories 12.

Contents on delivery

1	Control unit for en*Puls*
1	Handpiece, complete
1	6 mm applicator head
2	15 mm applicator head
1	25 mm applicator head
20	Silicone cap, standard
1	en*Puls* Lotion
1	Footswitch
1	Mains cable
1	Instructions for use
1	Template
1	Transport case

Accessories

5402	Handpiece, complete, without applicator heads
50 500 016	Holder for handpiece
50 500 003	6 mm applicator head
50 500 004	15 mm applicator head
50 500 005	25 mm applicator head
50 500 017	Silicone cap standard
50 500 018	enPuls Lotion
50 500 008	Footswitch
118	Mains cable
50 500 009	Transport case with foam insert

13. Manufacturer's Declaration of Electromagnetic Compatibility

Medical electrical devices such as en***Puls*** 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*** 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.

Guidelines and manufacturer's declaration – electromagnetic interference		
The device en***Puls*** is intended for operation in an electromagnetic environment as indicated below. The customer or user of the en*Puls* should ensure that it is operated in such an environment.		
Interference tests	**Conformity**	**Electromagnetic environment guideline**
RF emissions according to CISPR 11	Group 1	The device en***Puls*** 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.
RF emissions according to CISPR 11	Class A	The device en***Puls*** 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.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuation emissions and flicker according to IEC 61000-3-3	Conforms	

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.

13. Manufacturer's Declaration of Electromagnetic Compatibility

Guidance and manufacturer's declaration – Electromagnetic immunity			
The en*Puls* device is intended for use in the electromagnetic environment specified below. The customer or the user of the en*Puls* 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* requires continued operation during power mains interruptions. It is recommended that the en*Puls* 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 13.

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

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The device en***Puls*** is intended for operation in the electromagnetic environment specified below. The customer or user of the en*Puls* 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*, including cables, than the recommended separation distance calculated from the equation applicable to the transmission frequency. **Recommended separation distance:** d= 1.2 √P d= 0.35 √P for 80 MHz to 800 MHz d= 0,7 √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 13.

[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* device is to be used exceeds the above compliance levels, the en*Puls* 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* 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* device

The en***Puls*** device is intended for operation in an electromagnetic environment where RF disturbances are monitored. The customer or user of the en***Puls*** device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the en***Puls*** 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.

Declaration of Conformity
Legal Information

14.

Declaration of Conformity

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

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

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

Legal Information

National laws and regulations must be observed when installing and operating this treatment device. In Germany, the current version of the Medical Devices Operator Ordinance (MPBetreibV) and the German Regulation for the Prevention of Industrial Accidents BGV A3 apply.

en*Puls*

Instructions for Use

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