

Instructions for use



PiezoWave2 Control Unit with PiezoWave2 Device Cart

100506/100905

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Subject to technical changes!

Due to ongoing development, the product descriptions, figures, and technical data may deviate slightly from the current state.

For further information about our products, please contact Richard Wolf GmbH or a local representative.

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1 General information

1.1 Safety instructions and levels of danger



WARNING

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in death or extremely serious injuries.



CAUTION

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in minor or moderate injury.

ATTENTION









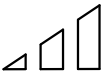

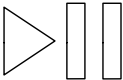
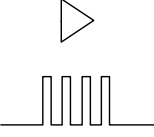
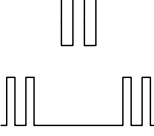
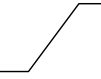
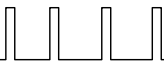

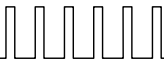


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
















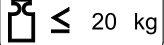
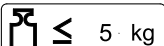









NOTE

This signal word indicates additional useful information for the reader, such as hints for easier operation as well as cross references.

1.2 Symbols

Symbols	Designation
	Follow the instruction manual
	Medical device
	Off/On (supply, disconnection from/connection to the power supply)
	Equipotentiality
	TYPE B APPLIED PART
	Fuse
	Alternating current (AC)
	Number of shockwaves
	Shockwave intensity
	Pulse rate
	T-burst frequency mode
	Pulse duration
	Pause duration
	T-ramp frequency mode
	Initial frequency
	Time frame
	Target frequency
	Increase value
	Decrease value

Symbols	Designation
	Stop at
	Delete last input
	"Reset" button
	Substages activated/deactivated
	Volume loud/quiet
	Menu
	Confirm input
	Cancel input
	Therapy source
P_+	Positive peak pressure
ED	Energy flux density
	Treatment duration
	Remaining treatment duration
	Check box not selected/selected
	Option field not selected/selected
	Secure area
	Footswitch
	Footswitch shockwave triggering
	Permissible total weight
	Permissible shelf weight
	Permissible weight of center shelf
	Manufacturer

Symbols	Designation
	Manufacturing date
	Recycle the product separately. Do not discard together with other waste.
	A Registered Trademark of a Recognized Testing Laboratory, confirms the compliance to the standard of Medical Electrical Equipment CAN/CSA C22.2 No.60601-1 (c) and ANSI/AAMI ES60601-1 (US)
	USB interface
	Network, LAN (Ethernet) interface
	<p>CE identification with code number of the competent authority in conformity with Directive 93/42/EEC on medical products or EU regulation 2017/745 on medical products.</p> <p>Only valid if the product and/or the packaging is marked with this identification.</p> <p>Products where a notified body is not involved in the conformity assessment procedure are marked with the CE-identification without the code number of the notified body.</p> <p>The CE identification on the title page of these instructions for use relates exclusively to the Richard Wolf main product or, if several identical products are described, to the Richard Wolf product with the highest classification. The CE identification of the other Richard Wolf products and, if applicable, of products made by other manufacturers, described in these instructions for use results exclusively from the identification on the product and/or packaging.</p>

2 General safety notes and instructions for use



⚠ WARNING

- The product must only be used as intended following the instruction manual by adequately trained and qualified medical personnel.
- Maintenance and repair must be carried out by authorized experts.



⚠ CAUTION

- Reprocess the products in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.



⚠ CAUTION

- Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual.
- The product must not be altered in any way.



NOTE

The instruction manual is an integral part of the product and must be stored in such a way that it is accessible at all times during the entire life cycle. It must be passed on to any subsequent owner or user.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Any severe incident occurring in conjunction with this product must be reported to the manufacturer and the competent authority of the country where the user and/or patient resides.

3 Product description

The PiezoWave2 is a compact extracorporeal shockwave therapy device that enables treatment with piezoelectric shockwaves. The PiezoWave2 features a simple and intuitive user interface which allows the key treatment parameters to be set quickly and easily. The control unit can be used as a desktop device or as a mobile device in conjunction with the device cart. The optional footswitch extends the operating functions to assist with manually performed shockwave therapy. Different therapy sources can be connected to and combined with the control unit. A therapy source holder supports the handling and storage of multiple therapy sources. The device cart enables the storage of the gel pad ranges used in the various therapy sources.

4 Intended purpose

Control units for extracorporeal shockwave therapy (ESWT) sources

100506	PiezoWave2 Control Unit
--------	-------------------------

Active and reusable control units for extracorporeal shockwave therapy (ESWT) sources are used for short (under 60 minutes), non-invasive interventions. The products are used for controlling compatible piezoelectric therapy sources.

Footswitch for shockwave devices

100038	FOOTSWITCH 3 PEDALS
--------	---------------------

Non-active and reusable footswitches for shockwave devices are used for short, non-invasive interventions (under 60 minutes). The products are used to control control units and therapy sources for emitting sound waves into the human body.

Therapy source holder

100915	THERAPY SOURCE HOLDER
--------	-----------------------

Non-active and reusable therapy source holders are used for non-invasive interventions. The products are used for holding therapy sources.

Device cart for shockwave devices

100905	PIEZOWAVE2 DEVICE CART
--------	------------------------

Non-active and reusable device carts for shockwave devices are used for non-invasive interventions. The products are used for transporting and storing shockwave devices in practice environments.

User

The product is intended exclusively for use by medical experts and may only be used by adequately qualified and trained medical personnel.

5 Indications

The product is used in the disciplines of orthopedics, dermatology, and urology for extracorporeal shockwave therapy (ESWT) and trigger point shockwave therapy (TPST).

Patient group

For urology applications, use is restricted to male patients aged 14 or older.

There is no restriction regarding ethnicity, height, weight, or other general conditions.

For orthopedic applications, use is restricted to patients aged 14 or older. There is no restriction regarding ethnicity, sex, height, weight, or other general conditions.

Regarding dermatological applications, the intended patient group is not limited with regard to ethnicity, age, sex, height, or weight.

Before treatment, the responsible user must make sure that the product can be used safely on the patient with respect to its dimensions or settings.

6 Contraindications and side effects

6.1 Contraindications

When using the products, the following general contraindications must be taken into account:

- Infections in focus
- Lungs in focus
- Environment of a pacemaker
- Arterial hypertension
- Clotting disorders (the patient's coagulation status is required) or treatment with blood-thinning drugs
- Brain or nerves in focus (central nervous system)

The following contraindications must be taken into account for use in urology:

- Bacterial prostatitis
- Penile prosthesis
- Hypogonadism
- Neurological diseases (e.g., multiple sclerosis, brain diseases)
- Mental illnesses (e.g., manic/chronic depression)
- Alcohol/drug abuse

The following contraindications must be taken into account for use in dermatology:

- Pregnancy
- Infectious wounds (grades B and D according to Wagner-Armstrong)
- Necrotic wounds (grade 4–5 according to Wagner-Armstrong)
- Thrombosis in the treated area
- Large blood vessels in the treated area
- Cartilage tissue during the growth phase

The following contraindications must be taken into account for use in orthopedics:

- Pregnancy
- Open growth plates in focus
- Cartilage tissue during the growth phase

The responsible user must decide on the basis of the patient's general condition whether the intended treatment is possible or not.

6.2 Side effects

The following side effects must be taken into account for use in urology:

Slight pain and petechiae.

There is a possibility of short-term hematospermia (bloody semen), hematuria (reddish tinted urine), acute bacterial prostatitis, urinary tract infection, interim urinary retention (due to possible swelling of the prostate), or a temporary increase in PSA (prostate-specific antigen).

The following side effects must be taken into account for use in dermatology and orthopedics:

Petechial hemorrhage, local hematoma, edema, or irritation of the skin at the treatment area may occur.

7 Combinations



⚠ CAUTION

Tissue/vascular damage.

- Observe the instruction manuals of the products used in combination with this product.

ATTENTION

Persons combining products to form a system are responsible for not impairing the system's compliance with performance and safety requirements, and for ensuring that the technical data and the intended use are adequately fulfilled.

Possible electromagnetic or other interference that may occur between the product and other products can cause faults or malfunctions.

When selecting system components, check that they meet the requirements for the medical environment in which they are to be used (IEC/EN 60601-1 in particular). In case of doubt, contact the manufacturer(s) of the system components.

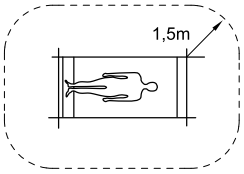
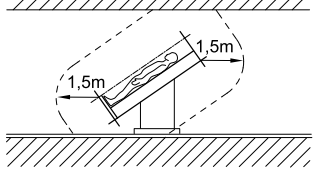
Do not touch connectors for electrical connections between various components (such as signal input connectors and signal output connectors for video signals, data exchange, controls) and the patient at the same time.

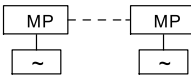
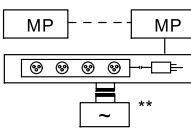
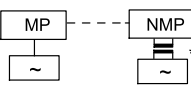
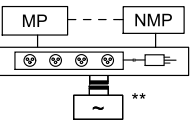
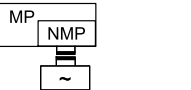
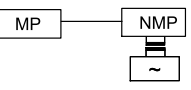
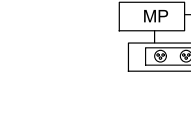
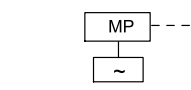
The PiezoWave2 must only be used in conjunction with the therapy sources approved by Richard Wolf and in accordance with the instruction manual of the therapy source used.

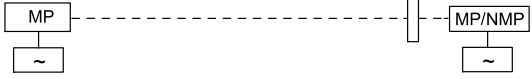


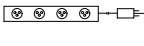

7.1 Overview of permissible combinations and requirements

Product no.	Designation
100671	THERAPY SOURCE F7 G3
100681	THERAPY SOURCE F10 G4
100691	THERAPY SOURCE F10 G10
100731	THERAPY SOURCE FBL10X5 G2
100751	THERAPY SOURCE FB10 G6

7.2 Requirements for the products / components of a combination

		<p>The general requirements depend on whether the products/components are inside or outside the patient environment.</p>
---	---	--

Medically used room		Non-medically used room	Requirements / measures
within the patient environment	outside the patient environment		Leakage currents to IEC/EN 60601-1
	-----	-----	<p>Measurement of leakage currents a) additional protective earth connection (to be clarified with the corresponding manufacturer), or b) additional isolating transformer **</p>
			
			
			
			
			
			
		-----	<p>Measurement of leakage currents a) no plugs with metal housing, or b) additional separating device (to avoid voltage differentials)</p>

Medically used room		Non-medically used room	Requirements / measures		
within the patient environment	outside the patient environment		Leakage currents to IEC/EN 60601-1		
		Verification of leakage currents a) joint protective earth connection, or b) additional protective earth connection at MP (verify with the corresponding manufacturer), or c) additional separating device (to avoid voltage differentials), or d) no plugs with metal housing in the patient environment			
	additional "isolating transformer with galvanic separation to IEC/EN 60601-1 **		additional isolating device to IEC/ EN 60601-1		Multi-socket strip*
- - - -	Functional connection		Power supply grid		
MP	= medical electrical device to IEC/ EN 60601-1, ANSI/AAMI es60601-1, CSA C22.2 No. 60601-1				
NMP	= non-medical electrical device in accordance with product-specific IEC/EN/UL standards				
*	When connected via the same multiple socket strip under standard conditions, the earth leakage current of the socket strip must not exceed 5 mA.				
**	e.g. Richard Wolf video cart with "isolating transformer"				
Only connect devices with a safety extra-low voltage of no more than 60 V DC / 42.4 V AC peak to the connectors for electrical connections, i.e. the signal inputs and outputs.					

7.3 Electromagnetic compatibility (EMC) - IEC 60601-1-2 : 2014



NOTE

The device/system in the following called product always refers to the product mentioned in the chapter on "intended purpose".


Guidelines and manufacturer's declaration - Electromagnetic emissions

The product is intended for use in the environment specified below. The user must assure that the product is used in such an environment.		
Emissions measurement / test	Compliance with	Electromagnetic environment - Guidelines
HF emissions to CISPR 11	Group 1	The product uses HF energy for its internal function. The HF emission level is extremely low and is not likely to cause any interference in nearby electronic equipment.
HF emissions to CISPR 11	Class A	The product is suitable for use in buildings other than residential buildings and buildings that are immediately connected to the public power supply network that also supplies buildings used for residential purposes provided the following warning is observed: Warning: The product is only intended for use by specialized medical staff. In residential areas this product can cause radio interference which may require taking adequate remedial measures such as new alignment, new location or screening the product or filtering the connection to the installation site.
Harmonic emissions to IEC 61000-3-2	Class A	
In conformity with IEC 61000-3-3 "Emission of voltage fluctuations / flicker"		

Guidelines and manufacturer's declaration - Electromagnetic immunity

The product is intended for use in the environment specified below. The user must assure that the product is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) to IEC 61000-4-2	± 8 KV contact discharge ± 15 KV air discharge	Yes	Floors should be wood, concrete or ceramic tile. With floors made of synthetic material, the relative humidity of the ambient air must be at least 30%.
Electrical fast transients / bursts to IEC 61000-4-4	± 2 KV for mains power lines ± 1 KV for input and output lines	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Surge voltage (surges) to IEC 61000-4-5	± 1 KV voltage Phase to phase ± 2 KV voltage phase to earth	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and supply voltage variations to IEC 61000-4-11	0% U_T * ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T * ; 1 period and 70% U_T * ; 25/30 periods Single-phase: at 0 degrees 0% U_T * ; 250/300 periods	Yes	Mains/line power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains/line interruptions it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field, to IEC 61000-4-8	30A/m	Yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
* REMARK: U_T is the line / mains voltage prior to application of the test levels.			

Guidelines and manufacturer's declaration - Electromagnetic immunity for products that are not life-supporting

The device is intended for use in the electromagnetic environment defined below. The user must assure that the product is used in such an environment.			
Immunity tests	Test level to IEC 60601	Compliance level	Electromagnetic environment - Guidelines
HF conducted disturbances to IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms} 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to the device, including cables, than the recommended separation distance of 30 cm. The field strength of stationary radio transmitters determined within the scope of on-site investigations should be below the compliance level for all frequencies. ^b In the vicinity of devices with the following symbol interference is possible: 
	6 V _{rms} ^a in ISM frequency bands 150 kHz to 80 MHz	6 V _{rms} ^a in ISM frequency bands 150 kHz to 80 MHz	
Radiated HF interference to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
<p>REMARKS: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflexion from buildings, objects and people.</p> <p>a) The ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.</p> <p>b) The field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. In the case of unusual behaviour during operation, additional measures may be necessary, such as a changed alignment or a different location of the device.</p>			

Recommended safety distances between portable and mobile HF telecommunication devices and the product

Definition relative to high-frequency wireless communication devices			
Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)
380–390	385	Pulse ^a – 18 Hz	27
430–470	450	FM ± 5 kHz deviation or pulse ^a – 18 Hz	28
704–787	710, 745, 780	Pulse ^a – 217 Hz	9
800–960	810, 870, 930	Pulse ^a – 18 Hz	28
1700–1990	1720, 1845, 1970	Pulse ^a – 217 Hz	28
2400–2570	2450	Pulse ^a – 217 Hz	28
5100–5800	5240, 5500, 5785	Pulse ^a – 217 Hz	9
<p>REMARKS:</p> <p>Between portable HF communication devices transmitting in the specified frequency band and the product, a minimum safety distance of 30 cm should be maintained. This comprises mobile phones, LAN, RFID and Bluetooth devices. Non-compliance can cause the power characteristics of the device to be impaired.</p> <p>a) Pulse modulation is defined as a square signal with a 50% duty cycle.</p>			

7.4 Equipotentiality

The potential equalization cable represents a direct connection between a medical electrical device and a potential equalization rail.

It serves to equalize differences in potential between enclosures of electrical equipment and firmly installed conductive parts in the patient environment.

8 Illustration

8.1 Figure: Front view of PiezoWave2 control unit

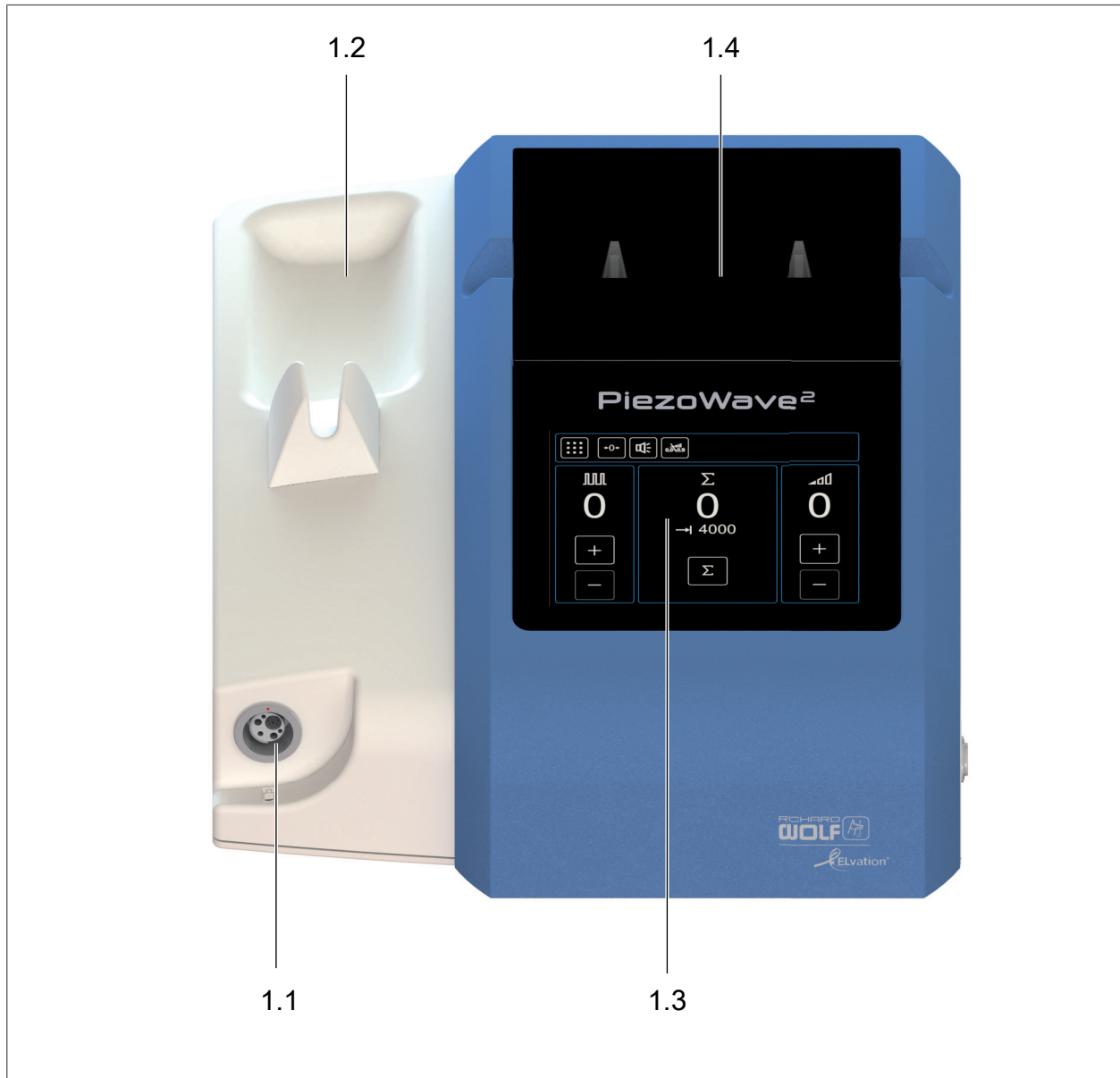


Fig. 1

1.1	Connection socket for therapy source (type B applied part)	1.3	Operating and display unit
1.2	Holder for therapy source	1.4	Tablet holder

8.2 Figure: Rear view of PiezoWave2 control unit

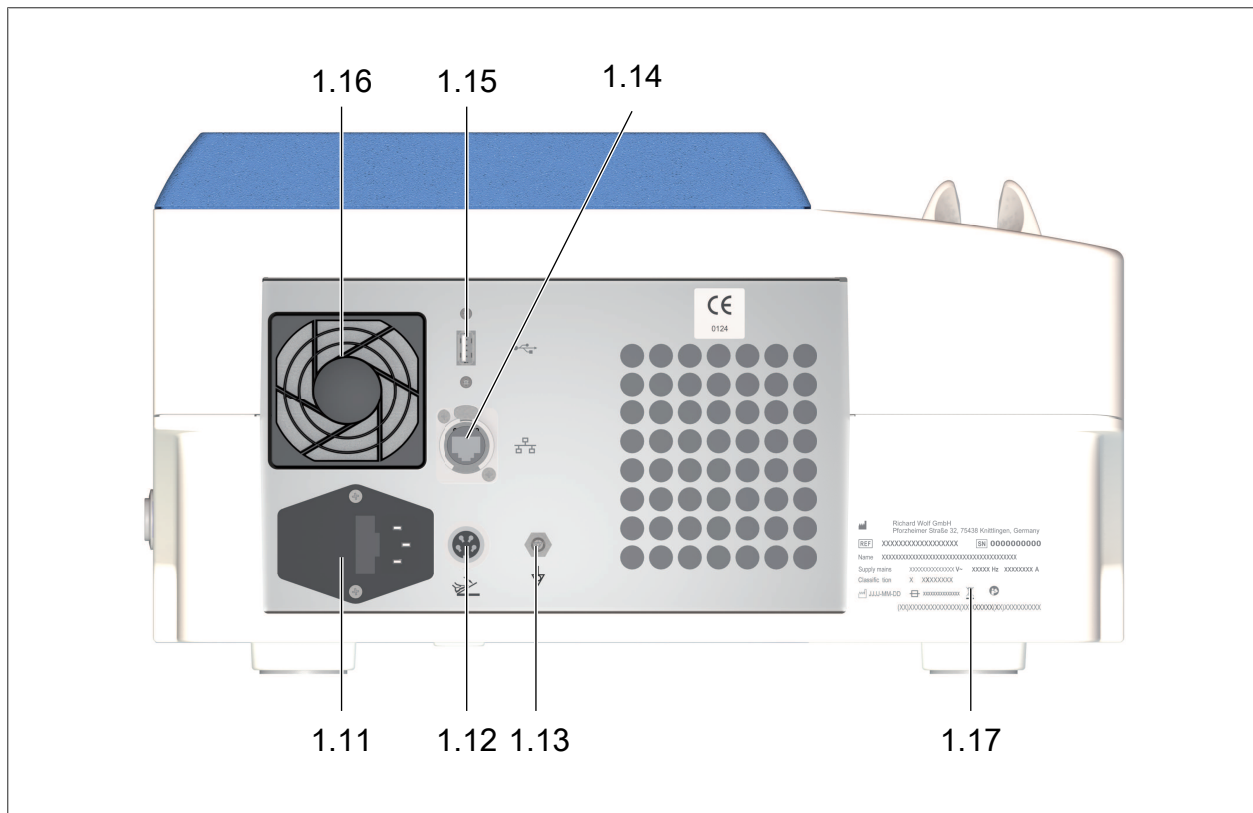


Fig. 2

1.11	Power input connector with fuse holder	1.15	USB data interface (for service only)
1.12	Socket for footswitch	1.16	Fan grid with filter unit
1.13	Potential equalization connector	1.17	Control unit identification plate
1.14	Ethernet data interface (for service only)		

8.3 Other figures

8.3.1 Side view of the PiezoWave2 control unit

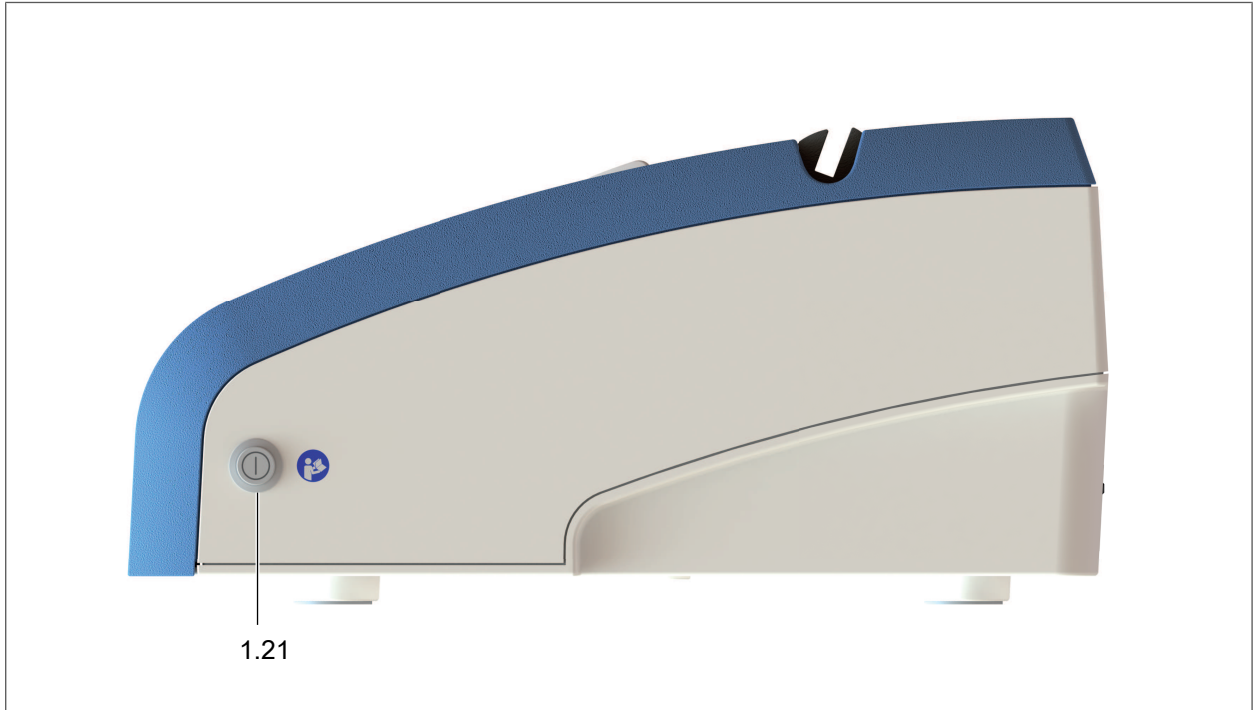


Fig. 3

1.21	Power switch		
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8.3.2 View of PiezoWave2 device cart

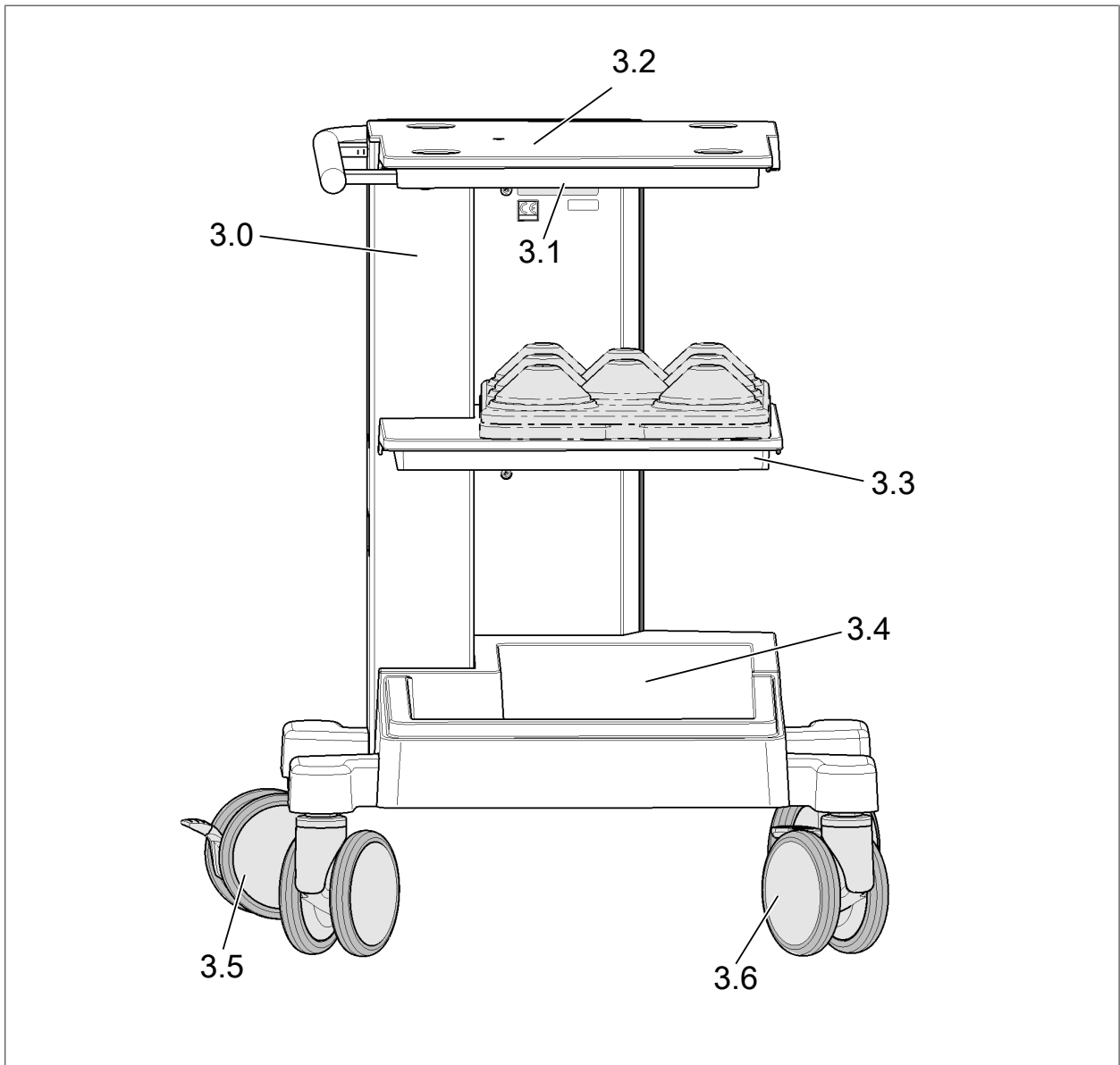


Fig. 4

3.0	Device cart	3.4	Lower tray
3.1	Device cart identification plate	3.5	Double casters, front, with parking brake
3.2	Stowage area for control unit	3.6	Double casters, rear, with parking brake
3.3	Shelf with fixation for gel pad trays		

8.3.3 View of footswitch with 3 pedals

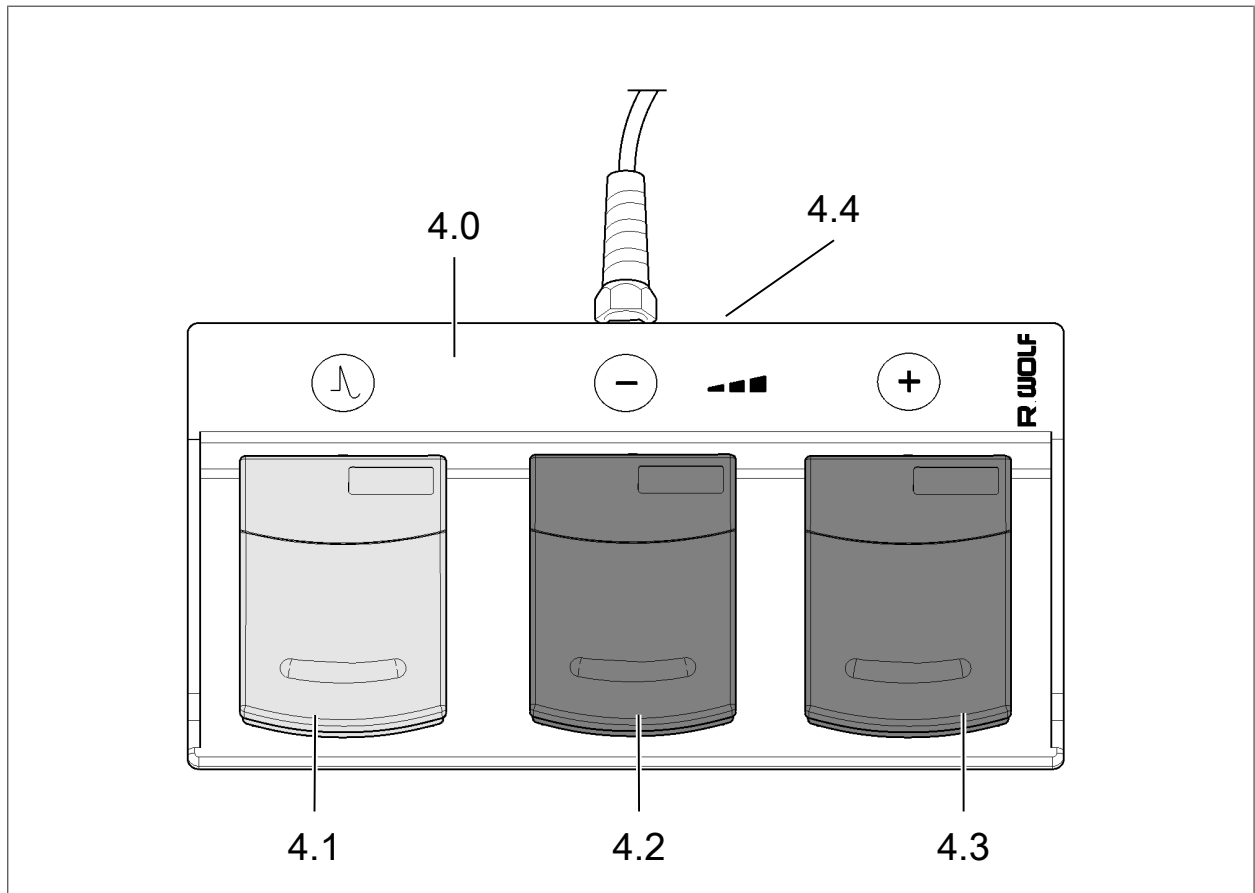


Fig. 5

Item	Designation	Item	Designation
4.0	Footswitch with 3 pedals	4.3	Increase shockwave intensity “+”
4.1	Shockwave triggering	4.4	Identification plate
4.2	Decrease shockwave intensity “-”		

9 Checks



⚠ CAUTION

Injury due to damaged or incomplete products!

Injuries of the patient, user and others are possible.

- Run through the checks before and after each use.
- Do not use the products if they are damaged or incomplete or have loose parts.
- Return damaged products together with any loose parts for repair.
- Do not attempt do to any repairs yourself.

9.1 Visual check

1. Check the device and accessories for damage, loose or missing parts, hygiene, and completeness.
2. Check all connection cables for damage.
3. Any inscription, lettering, or labeling necessary for the safe intended use must be legible.
 - ⇒ Any inscription, lettering or labeling leading to handling or reprocessing errors must be reinstated.
4. Check the therapy source in accordance with the corresponding instruction manual.

9.2 Function check

ATTENTION

Before you perform the function checks, make sure that the devices are in perfect working order and are set up correctly. This must also be guaranteed within the scope of the visual check.

1. Connect the therapy source to the device and switch on the power switch of the device.
 - ⇒ The device carries out a self-test.
 - ⇒ No errors must be displayed.
2. Set the intensity to **10** using the graphical user interface and/or the optional footswitch.
3. Trigger shockwaves via the optional therapy source button or the optional footswitch.
 - ⇒ When shockwaves are triggered, it is clearly audible.

10 Preparation / Commissioning



⚠ WARNING

Danger of explosion

The device is not protected against explosions.

- Do not operate this device in areas where there is a danger of explosion.



⚠ WARNING

Risk of electric shock.

- Only connect the device to supply voltages that match the details on the identification plate.
- The device must only be connected to a power supply with protective earth.
- Connect the device only via the supplied power cable or a power cable with the same specifications.
- Do not open the device.



⚠ CAUTION

Fire hazard or product damage.

After unpacking and before setting up the device, allow the device to acclimate to room temperature for at least 2 hours to prevent condensed water from forming on components.



⚠ CAUTION

Danger of injury or product damage due to falling.

- When not in use, always secure the therapy source in the therapy source holder.



⚠ CAUTION

Danger of injury due to weight overload.

- Observe the maximum permissible load on the shelves.



⚠ CAUTION

Danger of injury from moving device cart.

- Lock the parking brake before treatment.
- The parking brake must remain locked during treatment.
- Lock the parking brakes before and keep them locked when installing/removing the control unit.



⚠ CAUTION

Danger of tipping over.

- Do not lean on device carts.
- Place the device cart on a level surface for use.
- Pay close attention when moving the device cart on inclined surfaces.



⚠ CAUTION

Fire hazard or product damage.

- Do not cover or block ventilation slots required for cooling.

ATTENTION

Incorrect operation.

Do not operate the devices side by side or stack them with other devices.

- If it is necessary to stack the devices or place them next to each other and HF interference is observed, make sure that the devices are operated as intended.

ATTENTION

Safety distance from portable HF communication devices.

Medical electrical devices can be influenced by mobile HF communication devices.

- Do not operate HF communication devices in the immediate vicinity of medical electrical devices. Non-compliance may impair the device's performance.

ATTENTION

Influence on interference emissions and interference immunity.

Use only accessories or cables specified or supplied by the manufacturer.

- Other accessories and cables can cause increased electromagnetic interference or a reduced electromagnetic immunity of the device and lead to malfunctions.

ATTENTION

Initial instructions are given to the person responsible for the device by either the manufacturer or a person authorized by them.

10.1 Connection

10.1.1 Connecting the footswitch with 3 pedals



- Connect the footswitch plug to the socket on the rear panel of the control unit and screw home.

10.1.2 Connecting the therapy source



NOTE

To prepare the therapy source, observe the instruction manual of the therapy source used.

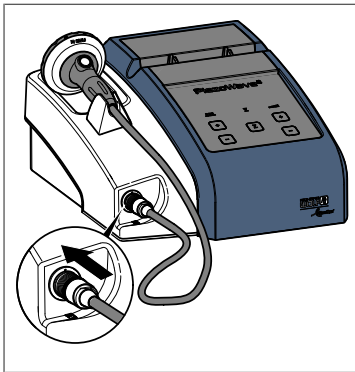


Fig. 6

- Connect the plug of the therapy source to the control unit.
 - ⇒ Make sure that the markings on the plug and on the socket are aligned.
 - ⇒ The plug must engage tangibly and audibly.
 - ⇒ Always place the therapy source into the therapy source holder on the control unit.

10.2 Preparation



⚠ CAUTION

Danger of injury from moving device cart.

- Lock the parking brake before treatment.
- The parking brake must remain locked during treatment.
- Lock the parking brakes before and keep them locked when installing/removing the control unit.

10.2.1 Device cart parking brakes

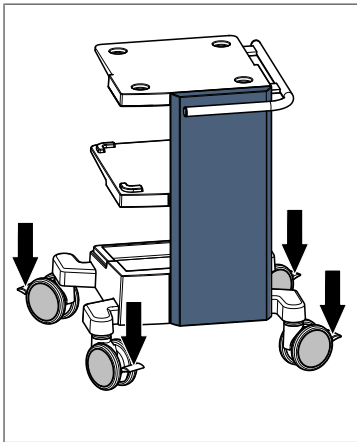


Fig. 7

- The parking brakes on the double casters secure the device cart against rolling.
- The four casters allow the device cart to move freely even in confined spaces.

10.2.2 Device cart shelves

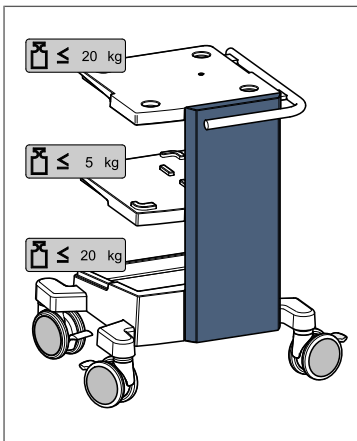


Fig. 8

Maximum loading of shelves:

- The upper and lower shelf can be loaded with a maximum of **20.0 kg** each.
- The center shelf can be loaded with a maximum of **5.0 kg**.
 - ▷ Contains fixation options for the gel pad trays.

10.2.3 Installing the control unit on the device cart

1. Carefully lower the control unit onto the top shelf of the device cart.
⇒ Make sure that the feet of the control unit fully engage in the recesses of the top shelf.
2. Fasten the control unit to the top shelf from below using the mounting screw (M6x50) and the washer.

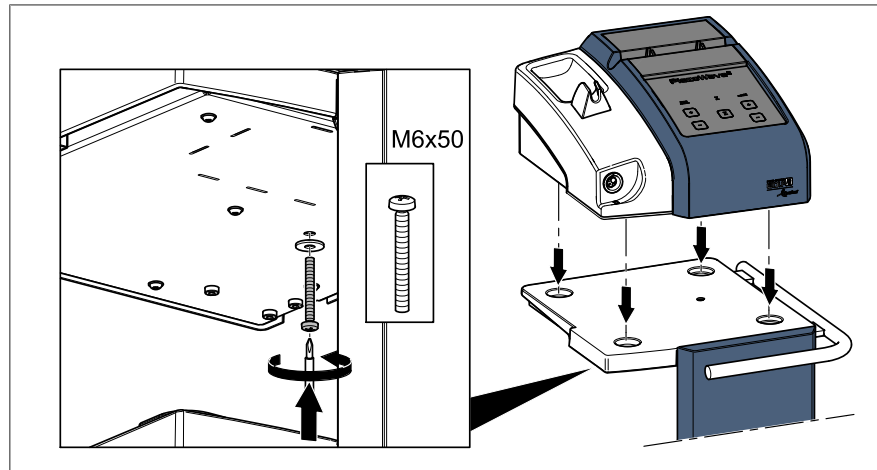


Fig. 9

10.2.4 Removing the control unit from the device cart

1. Unscrew the mounting screw (M6x50) and remove together with the washer.
2. Carefully lift off the control unit from the device cart in vertical direction.

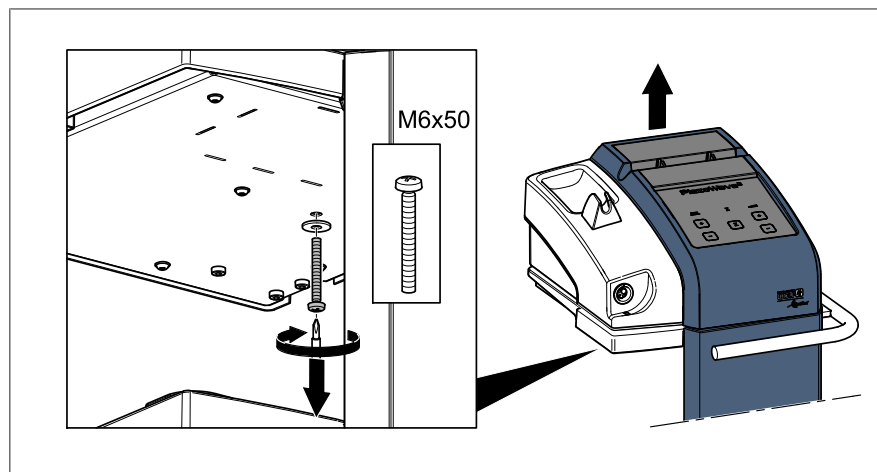


Fig. 10

10.2.5 Setting the language

1. Switch on the power switch on the control unit.
2. Access the main menu by pressing the Menu button.
3. Navigate to Language in the menu.
4. Select the required language.
5. Confirm the language selection.

11 Use

11.1 General notes and instructions for use



⚠ CAUTION

Tissue/vascular damage.

- Only use the products if you have a clear view of the treatment area.



⚠ CAUTION

Danger of tipping over when moving the cart on inclined surfaces

Observe the following:

- Do not exceed the maximum permissible load rating of the shelves.
- The therapy source must be secured in the therapy source holder.
- Always place the device cart on a level surface for use.



⚠ CAUTION

Danger of infection.

- Before treatment, cover open wounds in such a way that no bodily fluids can leak out.
- Disinfect the device after treatment.
- Follow the disinfectant manufacturer's instructions.



⚠ CAUTION

Tissue damage.

- Limit the number of shockwaves per treatment to the number stated in the instruction manual of the therapy source used.



⚠ CAUTION

Pressure-induced arrhythmia or tissue damage.

- Prevent treatment of organs with air pockets (e.g., lungs, intestines).
- Pay attention to the entry direction of the shockwaves.
- Observe the penetration depth.
- Position the therapy source accordingly.



⚠ CAUTION

Danger of infection.

- Reprocess the products before and after each use.
- Reprocess the products before returning them.
- Follow the instruction manuals of the combined products.



⚠ CAUTION

Allergic reactions.

- Only use ultrasound gels that are approved for use on patients.
- Please observe the gel manufacturer's instructions.



NOTE

The pressure pulse is attenuated when passing through tissue and additional energy is absorbed in bones.



NOTE

The use of local anesthesia can reduce the patient's bio-feedback which may impair the treatment success.

11.1.1 Operating principle

11.1.1.1 Piezoelectric principle

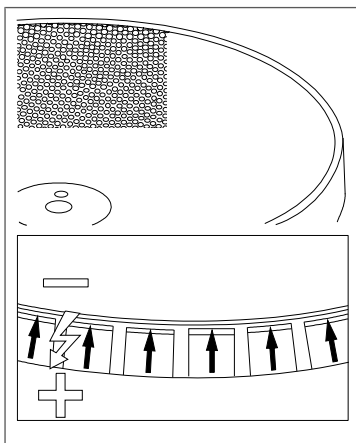


Fig. 11

The physical basis for generating piezoelectric shockwaves is based on the rapid expansion of ceramic material, excited by a brief high-voltage pulse. This expansion of the ceramic parts generates a pressure wave which is coupled into the patient's body.

The piezo elements are arranged like a mosaic on a carrier dish and are all simultaneously triggered by a pulse generator. The geometry of the carrier dish determines the shape and pressure of the shockwave or pressure wave.

The section entitled "Operating principle" describes how the pressure waves different therapy sources are propagated.

The system allows single pulse or continuous pulse mode. The intensity of the shockwave can be adjusted according to the patient in question.

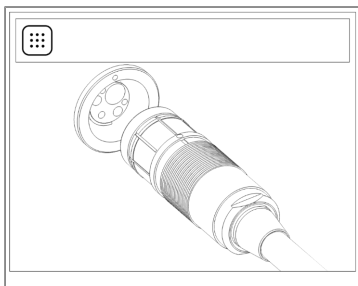
11.2 Control elements and operating modes

11.2.1 Power switch



The PiezoWave2 control unit is de-energized by switching off the power switch (disconnecting the power supply).

11.2.2 Connecting the therapy source



— The therapy source is not connected.
 ⇨ Please connect a therapy source.

Fig. 12

11.2.3 Menu structure

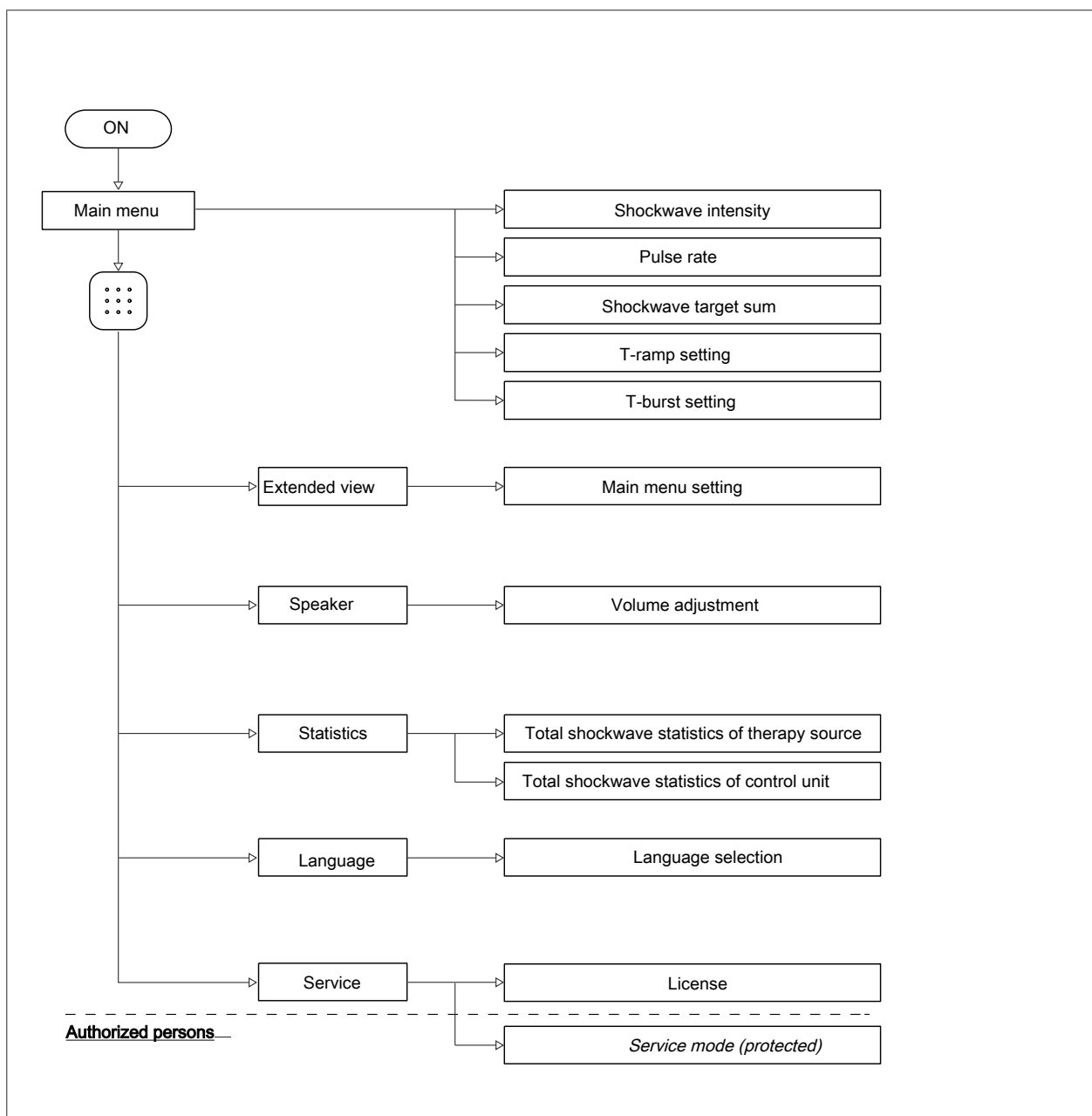
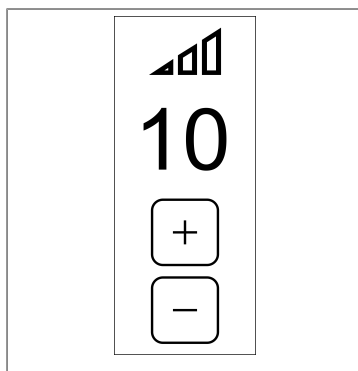


Fig. 13

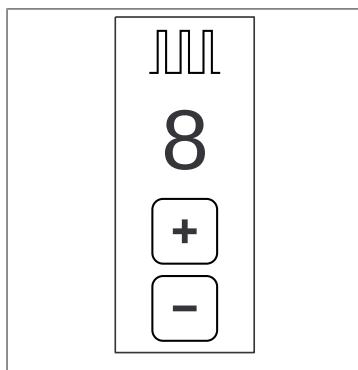
11.2.4 Setting the shockwave intensity



Use “+” and “-” to set the required shockwave intensity.

Fig. 14

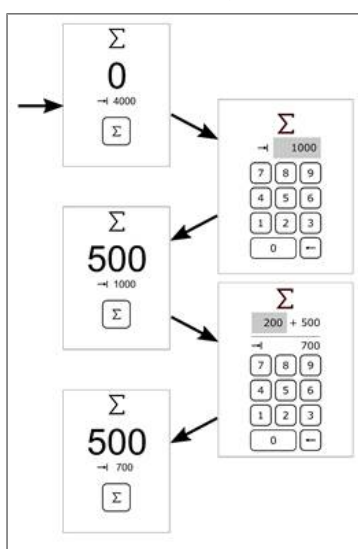
11.2.5 Setting the pulse rate



Use “+” and “-” to set the required pulse rate.

Fig. 15

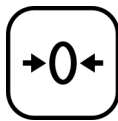
11.2.6 Setting the shockwave target sum



1. Press the Sum button to access the menu for entering the shockwave target sum.
2. Enter and confirm the shockwave target sum.
 - ⇒ The shockwave target sum can be corrected by pressing the “<--” button.
 - ⇒ During the treatment, the shockwave target sum can be corrected by pressing the Sum button again.
3. Enter the number of shockwaves still to be applied.
 - ⇒ The new shockwave target sum is displayed.

Fig. 16

11.2.7 Resetting the treatment settings



— This control button resets the current treatment settings.

Fig. 17

11.3 Operating the product

11.3.1 Treatment sequence



⚠ CAUTION

Tissue/vascular damage.

- Observe the instruction manuals of the products used in combination with this product.

11.3.1.1 Shockwave therapy



⚠ CAUTION

Tissue and vascular damage.

- Clearly identify the target area.
 - Select the therapy source according to the target area.
 - Select a gel pad according to the required penetration depth.
 - Check that the focus and target area match.
 - Assess and weigh up the severity of any impairments to the treatment area.
 - Only trigger the shockwave if it is deemed appropriate to do so.
-
- Start at a low shockwave intensity and then slowly increase the intensity according to the indication.
 - A shockwave target sum can be set for a fixed-dose treatment protocol.
 - When treating larger therapy areas, it helps to position the focus on different areas one after the other.



NOTE

Automatic shockwave stop.

After the shockwave target sum is reached, shockwave triggering stops automatically.

To continue treatment, enter a new shockwave target sum.

Triggering shockwaves using the footswitch with 3 pedals

1. Trigger the shockwave by pressing the pedal for shockwave triggering (4.1).
2. When releasing the footswitch, shockwave triggering stops.
3. The other two pedals are used to reduce (4.2) or increase (4.3) the shockwave intensity.

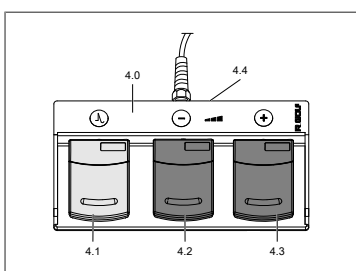


Fig. 18

11.3.2 Extended functions

11.3.2.1 Setting the substages – intensity levels 0.0 to 0.9

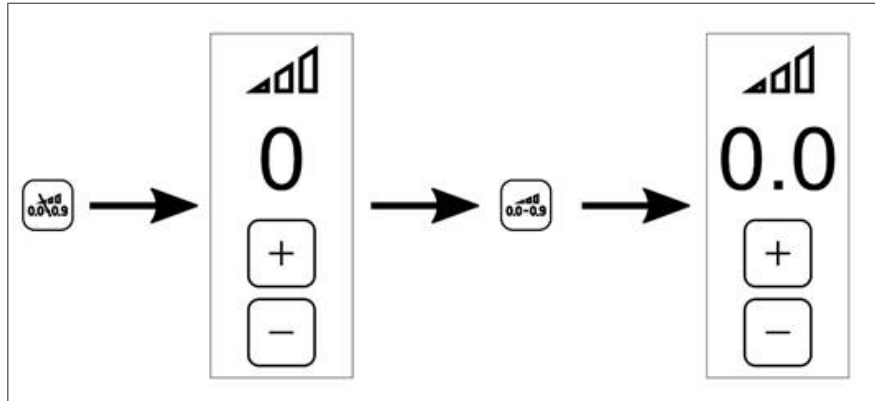


Fig. 19

- The substage control button is used to activate and deactivate the selection range of the lower intensity levels 0.0 to 0.9

11.3.3 Setting the extended parameter view



NOTE

Acoustic KPIs shown on the device display are measured under laboratory conditions according to IEC 61846 and may deviate from the displayed values under real conditions.

Always pay attention to the patient's feedback during treatment.

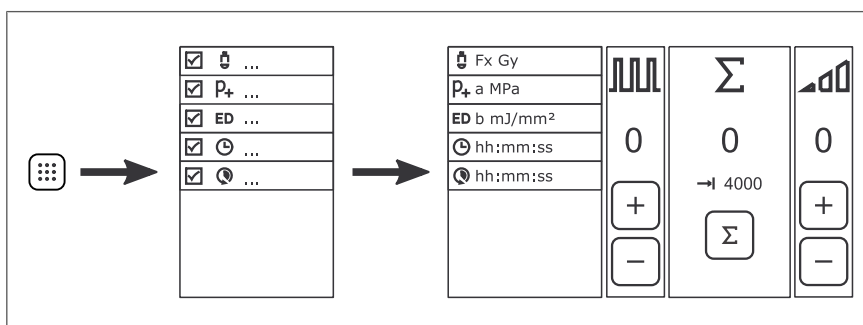
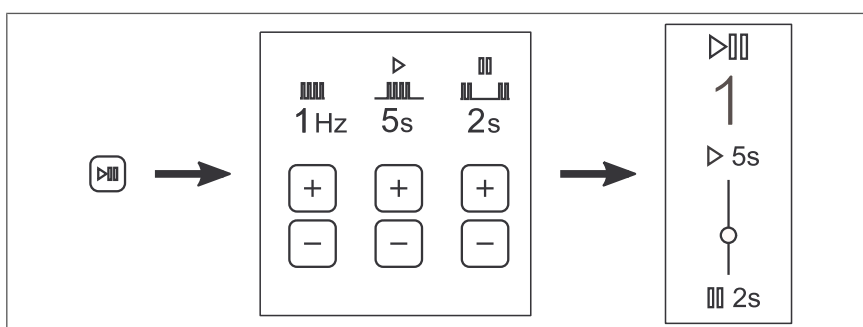


Fig. 20

1. Pressing the Menu button opens the dialog for setting the extended parameter view.
 - ⇒ If one or more parameters are selected, they will be displayed on the main window.
2. Activate and deactivate the parameters via touch.
3. Confirm your input.

11.3.4 Setting T-burst frequency mode

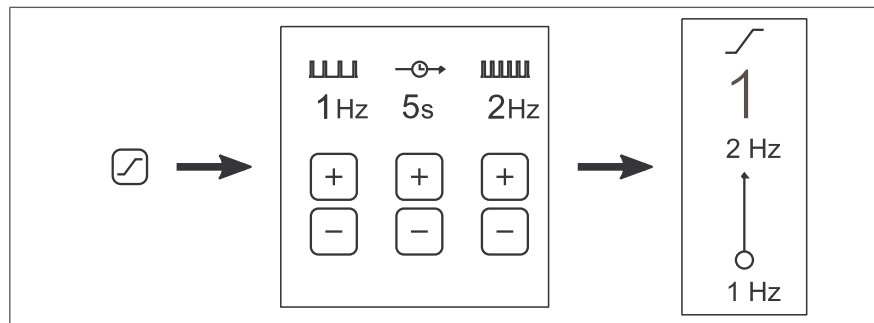
In T-burst frequency mode, shockwaves are emitted in the form of pulse packets.



1. Open the settings menu by pressing the T-burst button.
2. Use the "+" and "-" buttons to set the required pulse rate, pulse duration, and pause duration.
3. Confirm your input.
4. The main menu switches to T-burst frequency mode.
 - ⇒ When the shockwaves are activated, the view alternates between pulse and pause.

11.3.5 Setting T-ramp frequency mode

In T-ramp frequency mode, shockwaves are emitted with an increase in frequency. When the shockwaves are activated, pulses are triggered at the initial frequency. The ramp function is activated by pressing the button for shockwave triggering again. The ramp function increases the frequency up to the target frequency within the set time frame.



1. Open the settings menu by pressing the T-ramp button.
2. Use the “+” and “-” buttons to set the required initial frequency, time frame, and target frequency.
3. Confirm your input.
4. The main menu switches to T-ramp frequency mode.
 - ⇒ When the ramp function is activated, the view alternates between the initial frequency and the target frequency.

11.3.6 Setting the control unit volume

1. Access the main menu by pressing the Menu button.
2. Navigate to Speaker in the menu.
3. The slider can be used to adjust the speaker volume.

11.3.7 Displaying the statistics

1. Access the main menu by pressing the Menu button.
2. Navigate to Statistics in the menu.
3. The total shockwave statistics of the therapy source and the control unit are displayed.

11.3.8 Displaying the software version

1. Access the main menu by pressing the Menu button.
2. Navigate to Service in the menu.
3. The software version is displayed next to “Version”.

11.3.9 Licenses

1. Access the main menu by pressing the Menu button.
2. Navigate to Service in the menu.
3. Enter the service area without entering the key.
4. The license is listed under “License”.

11.3.10 Taking out of service

- To take the device out of service, switch off the power switch and disconnect the device from the power supply / mains.
 - ⇒ To fully disconnect the device from the power supply / mains, it is necessary to disconnect the power cable.



⚠ CAUTION

When taking the products out of service for long-time storage or disposal, the products must be reprocessed in accordance with the instructions for use (manual) to protect patients, users and others.

12 Reprocessing and maintenance

12.1 Reprocessing



⚠ WARNING

Risk of electric shock

Moisture may enter the device.

- Before reprocessing, switch off and disconnect the device from the power supply.
- Do not immerse in liquids.
- Do not clean under running water.

ATTENTION

The use of surface disinfectants, which are not designated for medical devices by the manufacturer, can lead to damage to the device surface.



NOTE

For chemicals whose material compatibility has been approved by Richard Wolf for the reprocessing of Richard Wolf products, please refer to the listing in document GA-J055. This document can be requested from Richard Wolf or downloaded from our website.

RICHARD WOLF in the Internet

- www.richard-wolf.com/en/solutions/reprocessing/

Clean/disinfect the surface of the device and accessories with surface disinfectant after use. Observe the information provided by the chemical manufacturer.

Only surface disinfectants that are approved for medical devices may be used.

Examples of suitable ingredients:

- Propanol
- Ethanol
- Didecyldimethylammonium chloride
- Dimethylbenzylammonium chloride

Examples of suitable and approved surface disinfectants:

Manufacturer	Trade name	Ingredient
BODE Chemie, Hamburg	Bacillo [®] AF	Propanol/ethanol
B. Braun Melsungen	Melliseptol [®] sensitive	Didecyldimethylammonium chloride, non-ionic surfactants
Ecolab, Düsseldorf	Incidin [™] Alcohol Wipes	2-propanol & 1-propanol
Schülke, Germany	antifect [®] N liquid	Propanol/ethanol
	pursept [®] A Xpress	Ethanol
	mikrozid [®] sensitive liquid	Didecyldimethylammonium chloride, dimethylbenzylammonium chloride

Reprocessing of touch panels and monitors

Follow the notes and instructions of the touch panel and monitor manufacturers as well as the disinfectant manufacturer's instructions.

12.2 Maintenance



NOTE

In your inquiries or correspondence please always specify the model number and series number indicated on the identification plate. Further documentation is available from the manufacturer on request.

Sales and service partner:

ELvation Medical GmbH
 +49 7231/ 56 36 28
 service@elvation.de

12.2.1 Maintenance intervals



CAUTION

Tissue/vascular damage.

- Maintenance must be carried out by authorized experts.
- Have maintenance performed at appropriate intervals.
- Have the integrity, functional and operational safety checked at least every 12 months.
- Depending on the frequency of use, have checks/tests repeated at shorter intervals.

13 License conditions

- This product contains open source software of third party providers that are subject to the license agreements for the corresponding software packages.
- A storage medium with the software license agreements valid at the time of delivery and other contents, if applicable, is packed with the product.
- Please read these texts in detail for comprehensive information about your rights with regard to the aforementioned licenses.
- For further information and contents please contact the manufacturer (www.richard-wolf.com/service).

14 Technical description

14.1 Troubleshooting

ATTENTION

If you cannot eliminate the faults with the help of this table, please call the service department or send in the device for repair.

- Do not attempt to do any repairs yourself.

14.1.1 Status and error messages on the display

Message text	Possible cause	Corrective action
Internal device error. Please contact Customer Service.	An internal software or hardware error of the control unit has occurred.	Switch off the device and restart after one minute. Have an authorized service technician repair the device.
Therapy source malfunction. Please replace the therapy source. If this error message appears again, please contact Customer Service.	An error has occurred in the therapy source or the control unit.	Replace the therapy source. Have an authorized service technician repair the device.
Therapy source button defective or pressed when connecting the therapy source. Release the button or remove the therapy source. If this error message appears again, please contact Customer Service.	The therapy source button is pressed or defective when the therapy source is plugged in.	Release the therapy source button. Replace the therapy source. Have an authorized service technician repair the device.
Footswitch defective or pressed when switching on the device. Release the button or remove the footswitch and then restart the device. Do not use a defective footswitch. If this error message appears again, please contact Customer Service.	The footswitch is pressed or defective when the control unit is switched on.	Release the footswitch and restart the device. Replace the footswitch and restart the device. Have an authorized service technician repair the device.

1. If a message text appears on the display, the treatment must be interrupted.
2. The device can be switched off for one minute and then restarted.
3. If the message is displayed again, follow the instructions on the screen.
4. To narrow down the cause of the error, please specify the message number.

14.1.2 Device errors

Error	Possible cause	Corrective action
Device without function	Power switch is not on	Press the power switch
	Power cable is not connected	Connect the power cable
	Line fuse defective	Replace the line fuse
	No line voltage	Check the in-house power supply

Error	Possible cause	Corrective action
No shockwave	Footswitch is not connected or defective	Connect or replace the footswitch

14.2 Technical data

14.2.1 Technical data – control unit

ESWT control unit	Voltage V ~	Fre- quency Hz	Power consumption VA	Current rating A	Fuse A
100506	100–240	50/60	100	0.8–0.4	T 1.6 AH 250 V

Electromagnetic compatibility EMC to	EN/IEC 60601-1-2
Medical Devices Directive 93/42/EEC	Class IIb
Protection against electric shock	Type B applied part
Protection class to EN/IEC 60601-1; ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 601.1 (for USA)	I
Degree of protection against the ingress of liquids	IP 20 (not protected)
Operating mode	Continuous operation
Noise level	43 dB (A)
Degree of protection in the presence of flammable mix- tures	This device is not protected against explosions (do not operate this device in explosive atmospheres)
Weight	approx. 12 kg
Dimensions L x W x H	450 mm x 405 mm x 226 mm
Pulse rate	See therapy source
Intensity stages	See therapy source

Control unit interfaces

Footswitch connector	4-pin socket
Service interfaces	Ethernet and USB

14.2.2 Technical data – device cart

Model	100905
Medical Devices Directive 93/42/EEC; Regulation (EU) 2017/745 on medical devices	Class I
Device cart weight	approx. 33 kg (approx. 72.7 lbs)
Device cart dimensions (L x W x H)	570 mm x 601 mm x 795 mm
Weight of device cart with control unit	approx. 45 kg
Dimensions of device cart with control unit (L x W x H)	570 mm x 601 mm x 1,021 mm
Permissible total weight (device cart + control unit)	104 kg (approx. 226.1 lbs)
Required floor space with therapy source	approx. 1 m ²

The products can be combined as required provided the relevant technical data and intended uses are observed. For the general overview please refer to the latest catalog sheets and brochures, or contact Richard Wolf GmbH or your Richard Wolf representative.

14.2.3 Technical data – footswitch with 3 pedals

Model	100038
Medical Devices Directive 93/42/EEC; Regulation (EU) 2017/745 on medical devices	Class I
Degree of protection against the ingress of liquids	IP X5 (protected against water jets)
Degree of protection in the presence of flammable mixtures	Device is not protected against explosions (do not operate this device in explosive atmospheres)
Weight	approx. 1.85 kg (approx. 4.1 lbs)
Dimensions (W x H x D)	311 mm x 36 mm x 160 mm

14.3 Performance characteristics

- Correct indication of shockwave intensity
- No unintended shockwave triggering

14.4 Operating, storage, transport and shipping conditions



⚠ CAUTION

Danger of injury due to product falling.

- Before transporting the device, secure all components against falling.

ATTENTION

Product damage.

- Use original packaging to transport the products.

ATTENTION

Product damage.

- Before transporting the device outside a building, disconnect the therapy source from the control unit and transport all components individually.



NOTE

The device cannot be transported for the purpose of home visits with subsequent treatment.

Operating conditions	+10°C to +35°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1,060 hPa
Storage, transport, and shipping conditions	-20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1,060 hPa

15 Spare parts

15.1 Spare parts

Product no.	Description
72315073	FUSE T 1.6 AH 250 V
2440.03	POWER CABLE
73205.031	SCREW DIN 7985 M6 X 50 For fastening the control unit to the device cart
73208.023	WASHER DIN 9021 A 6.4 For fastening the control unit to the device cart
72325.093	CONNECTION CABLE 4 SQMM/POAG-K4
9500.059	ULTRASOUND GEL 850 ML

15.2 Replacing parts

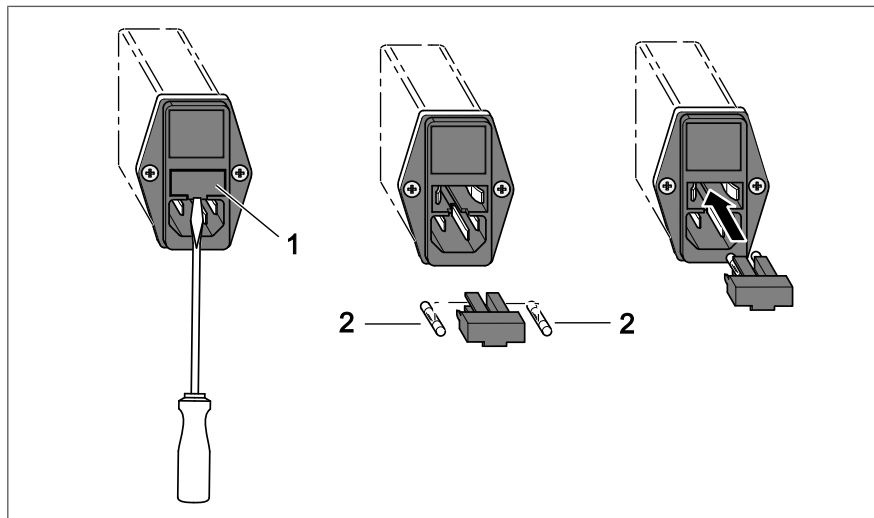


⚠ CAUTION

Fire hazard or device malfunction.

- Only use the fuses specified in the spare parts list.
- Only use fuse ratings that correspond to those specified on the identification plate.

Power input connector with fuse holder



1. Switch off the device and disconnect the power cable from the wall socket and from the power input connector of the device.
2. Unscrew the fuse holder [1] using a screwdriver.
3. Take the fuses [2] out of the fuse holder [1] and replace them with new ones.
4. Reinsert the fuse holder [1] and push in until it clicks into place.

16 Disposal



⚠ CAUTION

Infections, injuries, environmental damage

- Before disposal: Reprocess product.
- Take safety precautions for disposal.
- Observe the relevant regulations and laws valid in the country of use.
⇒ For further information please contact the manufacturer.