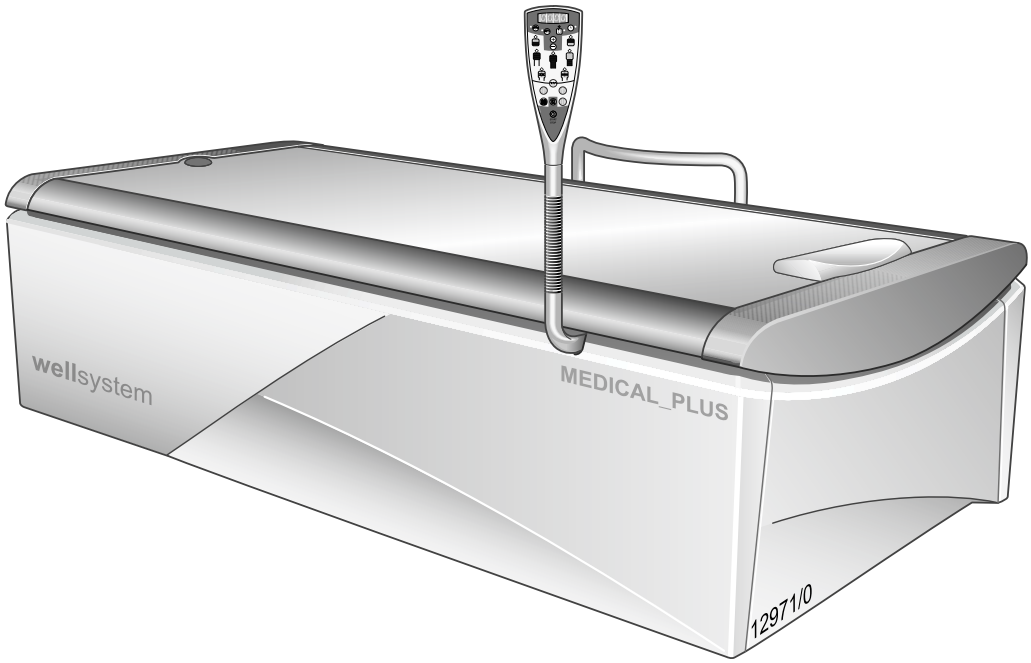
Dry water massage device



CE 0197

Operating instructions

Translation of the original operating instructions

WELLSYSTEM MEDICAL_PLUS

1009909-03B / en / 04.2016

Date of issue 28-04-2016

wellsystem™

Legal notice

Manufacturer: **JK-Products GmbH**
Rottbitzer Straße 69
53604 Bad Honnef (Rottbitze)
GERMANY
Tel.: +49 (0) 22 24 / 818-140
Fax: +49 (0) 22 24 / 818-166

Customer service / Technical service (Spare part orders for components): **JK-International GmbH, Division JK-Global Service**
Köhlershohner Straße
53578 Windhagen
GERMANY
Tel.: +49 (0) 22 24 / 818-863
Fax: +49 (0) 22 24 / 818-205
E-mail: service@jk-globalservice.de

Spare part orders for consumables: **Wellsystem GmbH**
Köhlershohner Straße
53578 Windhagen
GERMANY
Tel.: +49 (0) 22 24 / 818-250
Fax: +49 (0) 22 24 / 818-254
E-mail: info@wellsystem.de

DANGER!

Failure to observe these instructions:

- can result in serious injury and death,
- can result in damage to the device and the environment.

– Read these instructions carefully before putting this device into operation.

– Please observe the instructions and the code of conduct required to operate the device safely.

– Please make the instructions and additional information from the manufacturer available to the personnel at their workplace.

Table of contents

1 Safety instructions and warnings

To ensure safe operation of the device, it is necessary to read the following safety instructions and warnings carefully and comply with them.

The safety instructions summarized here are repeated in the corresponding chapters, where necessary.

1.1 General

1.1.1 Definitions

Operator

Person who provides dry water massage devices on a commercial basis. The operator is responsible for the orderly operation of the device as well as compliance with the maintenance intervals.

User/Patient

Person who uses the dry water massage device at a commercial location.

Personnel

People who are responsible for the operation, cleaning and general maintenance work and who instruct the users in the operation of the devices.

Electrician

A person with suitable professional training, knowledge and experience and knowledge of the applicable regulations which enable them to identify and avoid the dangers which can arise from working with electricity.

Authorized, trained and qualified personnel

Qualified staff from an external company who have been trained and authorized by the manufacturer to undertake assembly and maintenance work on specific equipment.

Dry water massage device

In these operating instructions the dry water massage device is referred to in the short form 'device'.

1.1.2 Symbol explanation

The following types of safety notices are employed in these operating instructions:

DANGER!

Type and source of hazard

This safety notice indicates the existence of a direct danger to body and life.

DANGER!

Type and source of hazard

This safety notice warns of dangers to body and life which are caused by electricity.

WARNING!

Type and source of hazard

This safety notice warns of machine, material or environmental damage.

NOTE:

This symbol does not identify any safety notices, but provides additional information to better understand the processes.

1.1.3 Symbols on the device

The following symbols are displayed on the device:


Manufacturer, production year and month


Type BF application part


Read and comply with the manufacturer's documentation


Electric device label (do not dispose of via household refuse)

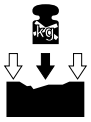

ESD-sensitive components


Follow Operating Instructions.

Maximum 2 devices stack.

Maximum transport weight


This side up.


Only on the edge load.


Keep dry.


Temperature limitations.


Recyclable material.

1.2 Intended use

This device is used to apply a dry water massage to one adult patient using the programmes described in these operating instructions. More detailed information can be found on pages 25 and 28.

Infants and small children up to age 7 may not utilize this device.

Children and adolescents from 8 up to and including 17 years of age are only allowed to use this device in agreement with a parent or guardian or after consulting a doctor.

The device is only intended for commercial use (e.g. for use in doctors surgeries, by physical therapists or in hospitals and clinics) and not for domestic use.

The device is only to be operated by trained personnel. Patients must not operate the device.

The duration and type of application must be determined by your doctor.

A water cooling system must be connected to the device if it is to be used for more than 1 hour per day at maximum pressure. The high pressure hoses must not be removed. Please contact the customer service department without fail before putting the device into operation – see page 2.

The device may only be operated with the high-pressure hoses included in the scope of delivery.

Any other use shall be considered improper. The manufacturer cannot be held liable for damage or injuries resulting from this. The operator bears the sole risk for this.

Proper use also includes compliance with the manufacturer's instructions and its operating and maintenance conditions. The device may only be operated, maintained and repaired by trained professionals familiar with this device and who have been informed of the dangers involved.

1.3 Foreseeable misuse

The following uses of the device are explicitly prohibited:

Multiple patients may not use the device at the same time.

People with a body weight of more than 210 kg may not use the device.

The device must never be used in combination with other medical devices.

The device must never be used if it is empty.

Devices without a cooling system connected may only be used for a maximum of 1 hour per day at maximum pressure.

1.4 Safety information for the dry water massage system

1.4.1 Contraindications

Fresh wounds

Acute inflammations

Infections

Suspected phlebitis and thrombosis (danger of embolism)

Severely painful muscle stiffness with additional myogelosis (only targeted, regulated and local procedures with local techniques)

The state after operations have been carried out on the vertebrae at the point in time when sufficient posture and mobility stability still cannot be expected, i.e. in general the initial application is only possible after 8 weeks at the earliest

The state after vertebral fractures, again initial application is only possible after 8 weeks at the earliest

Acute disease patterns, especially with radicular symptoms, in which high tensioning of the posture muscles is actually desirable

Painful vertebrae blockages with reactive muscle stiffness

Vertebral disorders with increased inflammation parameters (spondylitis, rheumatic spondylarthritis)

Acute exacerbation of chronic symptoms

Bechterew's disease (inflammatory condition of the bone joints)

High-grade scoliosis

The state after hip joint and knee-joint endoprosthetic surgery 6 weeks post-op

Neurological disorders with motor and sensory defects

Haematoma in areas to be treated

Chronic polyarthritis (chronic joint inflammation)

Functional vertebrae defects in patients with (medication-based) coagulation disorders

1.4.2 Indications

Increase or reduction in muscle tone

Improvement of local blood circulation and metabolism

Relaxation of the subcutaneous tissue

Venous and lymphatic decongestion

Reflexive easing of chronic pain conditions

Loosening of scar tissue

Activation or attenuation of the vegetative nervous system with beneficial effects on the internal organs

Increase in the efficiency of subsequent therapeutic measures (extensions, manual therapy, physiotherapy, etc.)

Potential reversal of functional disorders of the spinal column

Sub-acute lumbago (less advisable for acute lumbago)

Fibromyalgia (mild form)

Psychovegetative dystonia (functional disorders of different organs as a primary condition)

Excessive muscular fatigue

Cervical and thoracic spinal conditions, sciatica

Cervical migraine

Periarthritis humeroscapularis with accompanying muscular stiffness

Scoliosis, curvature of the spine

Trapezius insufficiency and stiffness

Cervical brachial syndrome

1.5 Safety instructions and warnings

1.5.1 Operator's obligations

As the operator you are responsible for providing clear operating, cleaning and maintenance instructions and ensuring the intended use and the proper operation of the device by means of training and instruction for the personnel.

Your operating instructions must enable the safe use and safe operation of the device and take into account the characteristics and expertise of your company and also the national work safety and environmental protection regulations (within the European Union, the EU directive 89/391/EEC).

Any accidents or other incidents that occur when using the dry water massage device must be reported to the responsible authority in compliance with Directive 93/42/EEC – see page 63.

Commissioning of the device is prohibited in the event of

defective cables,

defective plugs,

defective housing parts,

malfunctions.

1.5.2 Personnel training

The device is only to be used by personnel who are able to accept responsibility for correct operation due to their training, knowledge or practical experience.

As the operator you are obliged to train your personnel and instruct them in the established legal and accident prevention regulations. Ensure that your staff have understood and observe these operation instructions. This applies, in particular to the

Information in 'Intended use' and 'Foreseeable misuse'

Safety notes in Chapter 1.4 and Chapter 'Operation'

Operating instructions

Cleaning, disinfection and maintenance instructions

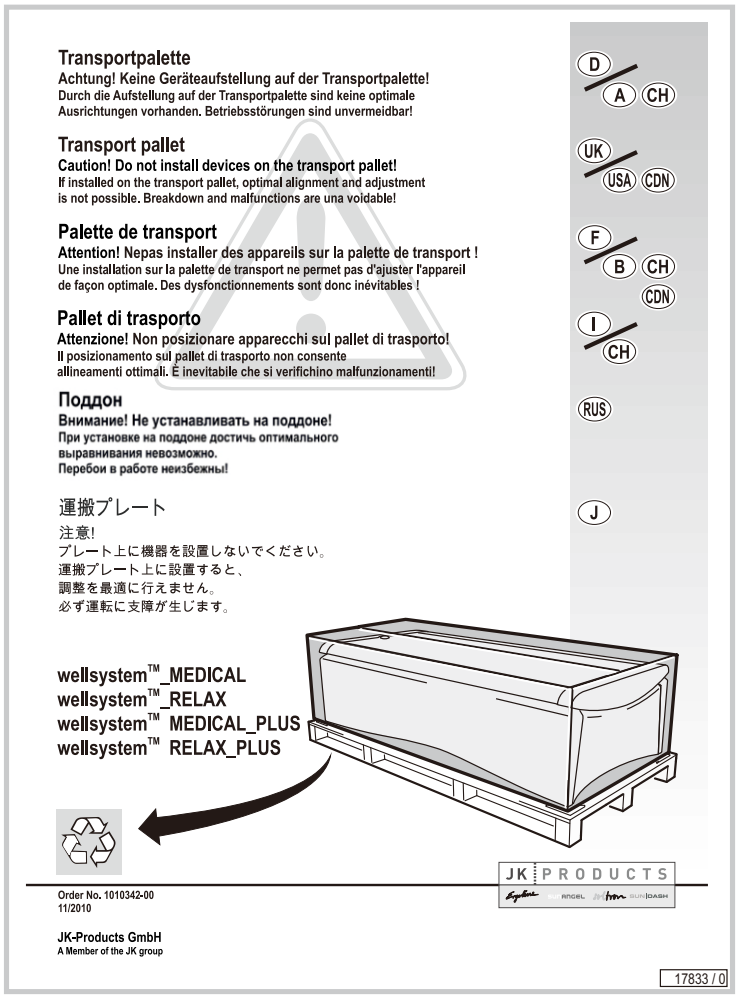
– Please make the instructions and additional information from the manufacturer available to the personnel at their workplace.
– Regularly check your personnel's safety consciousness and awareness of the risks, taking into account your operating instructions.
– You must ensure that the cleaning and disinfection intervals are complied with, in particular cleaning and disinfection after every session.
– You must ensure that your staff provide your user/patients with appropriate advice, in particular regarding the types of application, possible risks and the operation of the device.

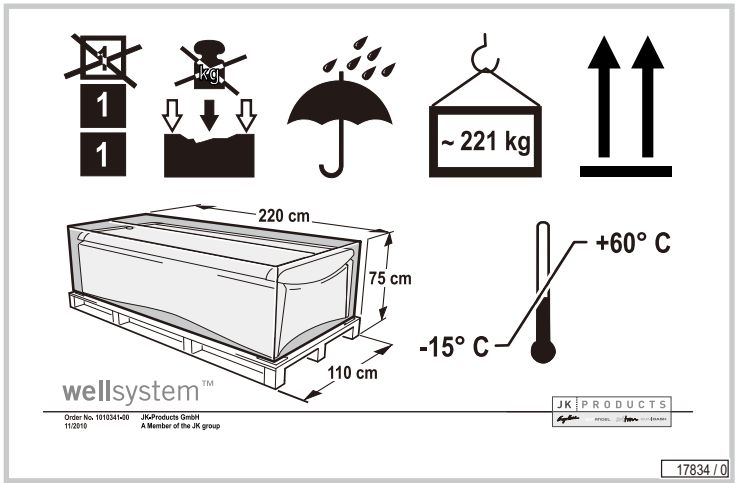
1.5.3 Scope of delivery

Information regarding the scope of delivery is contained in the 'Description' chapter on page 22.

1.5.4 Transport, assembly and setup

The device may not be mounted on the palette!





The device is delivered by a specialist company and assembled and set up by the manufacturer's own service personnel or by an authorized service company.

As the operator you are responsible for abiding by the electrical regulations applicable at the installation site as well as adhering to the stipulated water pressure and the permitted coolant temperature, see 'Setup location'.

Assembly

DANGER!

Personal danger due to electric shock or burns!

- The assembly and electrical connection must comply with the national regulations.
- Wellsystem Medical_Plus incorporates special preventive measures with regard to the electromagnetic compatibility and must be installed and commissioned according to the EMC instructions obtained from the assembly instructions.
- Assembly, installation, upgrading or servicing of the device may only be carried out by personnel specially trained and authorized by JK-Global Service.

Information regarding the disassembly and assembly of the device is available in the separate assembly instructions. These assembly instructions are intended solely for use by the manufacturer's service personnel or by qualified specialists authorized by the manufacturer.

Setup location

WARNING!

Overheating from inadequate cooling!

The device might be damaged!

- Maintain the minimum distances from the walls! Dimensions are given on page 53.
- Do not change, obstruct or block the air inflow and outflow to the device or make any unauthorized changes to the device.

Salty air! Contaminated air!

Device damage due to corrosion of the housing and electrical components.

- Do not install the device at swimming pools.
- Do not operate the device in locations with aggressive environmental conditions (e.g. air containing chlorine)

Damage to device possible!

Where there are great differences in temperature between the transport route and the installation site the device may not be put into operation immediately after being set up.

- Wait at least 2 hours before connecting the device to the power supply.

Environmental conditions

Optimum ambient temperature: Between 15 °C and 32 °C

Storage temperature: Between -15 °C and +60 °C (the well, pump and the hoses must not contain any water)

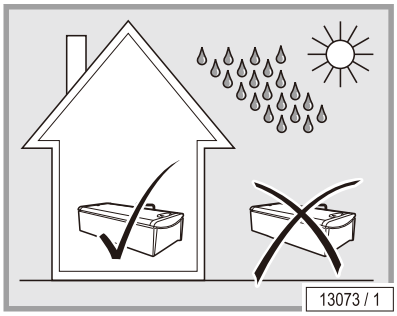
Relative humidity: Between 30 % and 75 %

Air pressure: Between 700 hPa and 1060 hPa

Water and cooling conditions

Permissible water pressure (water inlet): 8 bar

Maximum coolant temperature: 16°C



The device is not to be used outdoors.

The device is not suitable for operation in mobile facilities (ships, buses, trains or oil platform). The unit has to be adapted in order to guarantee trouble-free operation when used in mobile facilities.

Adaptation of the unit is required for operating altitudes greater than 2000 m above sea level in order to guarantee trouble-free operation.

Please contact the customer service department without fail before putting the device into operation - see page 2.

1.5.5 Commissioning

Initial commissioning will be undertaken by the manufacturer's own service personnel or by an authorized service company. The device will be handed over ready for use.

If the device has not been used for a longer period of time then it must first be inspected by our customer service staff or by another authorized company before being put back into operation again.

The device is only to be used if it is working correctly!

None of the safety devices (e.g. switch) or safety warnings are to be removed or deactivated as this would impair the safe operation of the device!

The device must never be used if it is empty.

A water cooling system must be connected to the device if it is to be used for more than 1 hour per day at maximum pressure. The high pressure hoses must not be removed. Please contact the customer service department without fail before putting the device into operation – see page 2.

The device may only be operated with the high-pressure hoses included in the scope of delivery.

A water shut-off valve must be used.

High frequency mobile communication systems can interfere with the way the device functions.

Heat therapy devices (microwave therapy devices, etc.) installed in the vicinity may lead to electromagnetic interference. Contact our customer service department if this happens – see page 2.

The device must be connected to the mains via an all pole master switch. One power supply circuit (power supply lead) may only power one device.

Venting

The tank must be vented 3 days after commissioning or after it has been initially filled – see page 51. After this, venting is unnecessary unless leakages occur and the tank has to be topped up.

The device may no longer be used in the event of water loss (puddles on the floor). Please inform our customer service department – see page 2.

1.5.6 Operation and maintenance

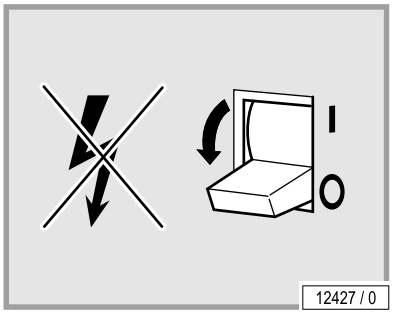
Error-free operation, maintenance and service are required in order to ensure that the health and safety of the patients is not endangered during operation and to ensure that the device is in a fault-free operating condition.

Always abide by the information and recommendations given in this operating manual. Ensure that the intervals for the inspection, maintenance and service are complied with. The maintenance work must be carried out by the customer services of the manufacturer or by qualified specialist personnel authorized by the manufacturer following a check list. Inspection work that has been carried out correctly can be entered and confirmed on 'Sheet D Maintenance measures / Service' in the Book of Medical Devices, see page 62.

Unauthorized modifications and changes to the device and its control unit are prohibited. Failure to comply with this voids the operating licence!

To avoid hazards, the device must not be used if the mains power cable is damaged. A damaged mains power cable must be replaced by the manufacturer or their customer services, or by trained and qualified specialist personnel.

1.5.7 Decommissioning



The device must be disconnected from the power supply in order to temporarily or permanently decommission it.

You must abide by the legal disposal requirements when permanently decommissioning the device.

1.5.8 Storage

Store the devices in a dry, frost-free location with a stable temperature. The well, pump and the hoses must not contain any water. Once the device has cooled off, pack it in plastic wrapping to protect it against scratches.

Storage temperature: Between -15 °C and +60 °C

1.5.9 Disposal

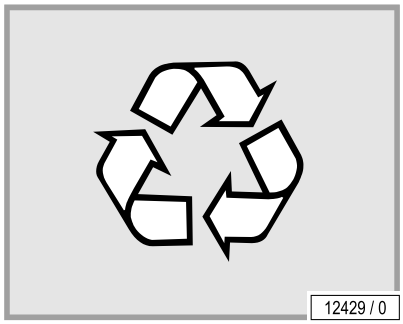
Environmental regulations – disposal of batteries

Batteries contain heavy metal compounds.

Within the European Union the national implementation of the Waste Framework Directive 2008/98/EC applies. According to the national waste disposal laws and in accordance with the community waste regulations, proof must be provided of the proper disposal of batteries.

Operating water disposal

The device is filled with normal tap water without additives. The water can be drained off into the public sewage system after it has been used.


12429 / 0

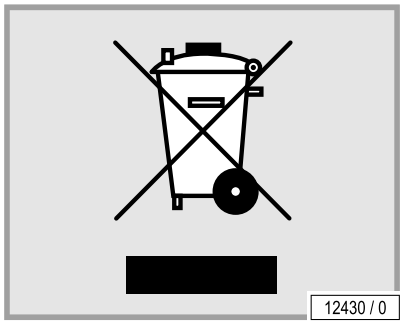
Packaging

All packaging consists of 100 % recyclable materials. Packaging brought into circulation by the JK Corporate Group that is no longer required can be returned to the JK Corporate Group. Your partner agency or dealer will be happy to advise.

Disposal of old devices

The device has been manufactured using recyclable materials. The JK Corporate Group will provide you with information on the content or potential hazards of the materials used.

The manufacturer is obliged to take back and dispose of certain electrical and electronic components in accordance with the 2002/96/EC Directive.


12430 / 0

The components and devices are labelled with the following symbol:

The device will, if requested, be properly disposed of by the JK Corporate Group. This service is available free of charge. Your partner agency or dealer will be happy to advise.

1.5.10 Directives

This device was built according to the following guidelines:

EU directive for medical products 93/42/EEC (according to the version valid at the time).

1.5.11 Export

We emphasize that these devices are only intended for the European market and must not be exported to or operated in other countries e.g. the USA or Canada! The manufacturer does not accept any liability in the event of non-observance! We explicitly emphasize that non-compliance may result in high liability risks for the exporter and/or the operator.

1.5.12 Technical modifications

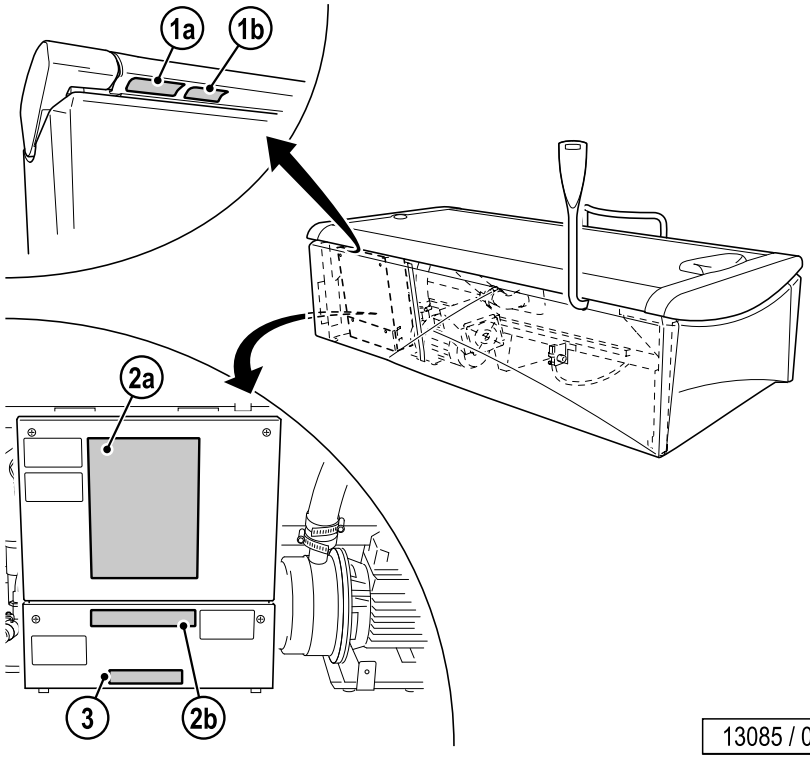
The device has been constructed in accordance with the current state-of-the-art and the applicable safety regulations. The illustrations and specifications on these instructions are subject to technical modifications which are required in order to improve the device.

Unauthorized modifications and changes to the device and its control unit are prohibited. Failure to comply with this voids the operating licence!

Please use only original spare parts. Any liability for damage or injury proven to be the result of the use of non-genuine spare parts is excluded.

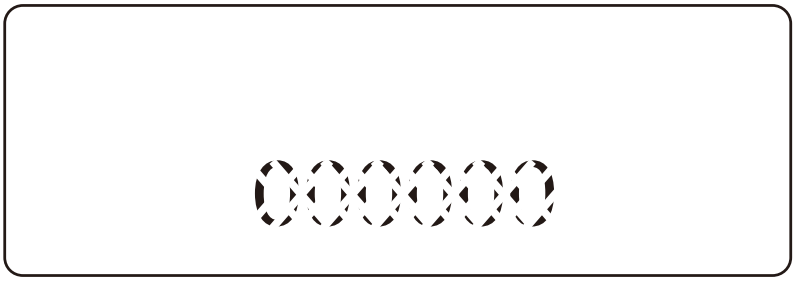
1.6 Signs and stickers on the device

Danger area warning signs and important information about components are attached to the device. The signs shown below are examples. Ensure that the warning signs are always clearly recognisable and legible. Any missing warning signs or stickers must be replaced.



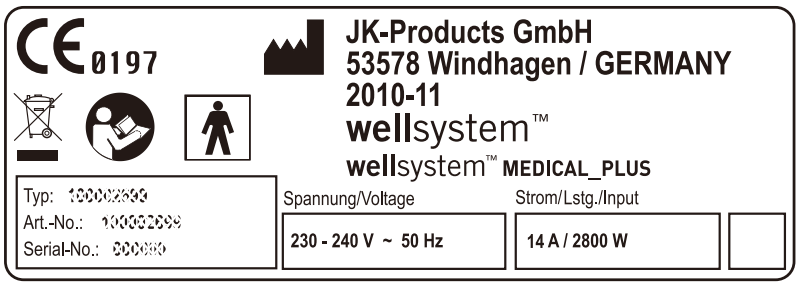
13085 / 0

1a: Serial-No. plate



13094 / 0

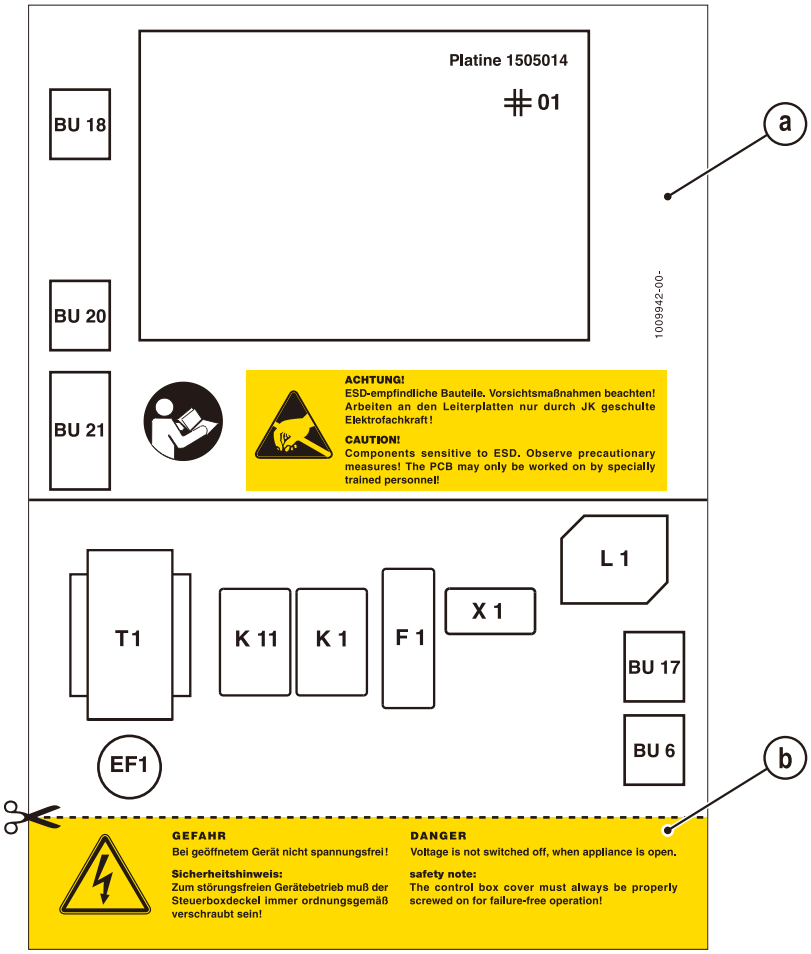
1b: Type plate



13082 / 3

The name plate and the Serial-No. plate are fitted underneath the handle at the feet end. They contain important information for identifying the device (e.g. the serial number = Serial-No.).

2: ESD-sensitive component sticker (a) and 'Voltage present' warning sticker (b) (1009942-..)



13051 / 1

The sticker is located behind the front panel on the control box.

3:"No export USA/Canada" sticker (84829-..)

HINWEIS
Wir weisen darauf hin, daß die Geräte nicht in die USA oder nach Kanada exportiert und dort betrieben werden dürfen. Bei Nichtbeachtung dieses Hinweises wird keine Haftung übernommen.

NOTE
We emphasize that these devices must not be exported to or operated in the USA or Canada! The manufacturer does not accept any liability in case of non-observance of this notice!

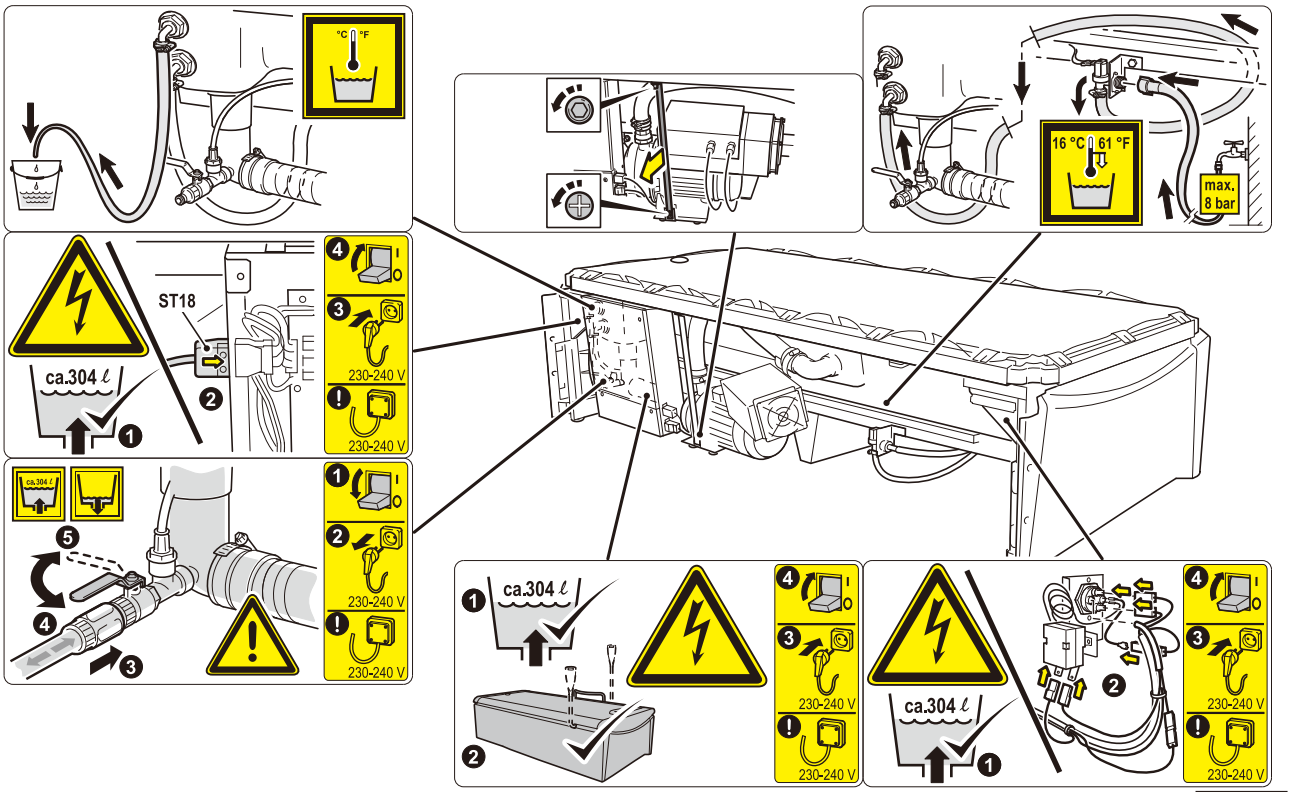
REMARQUE
Nous attirons votre attention sur le fait que les appareils ne doivent pas être exportés ni utilisés aux Etats-Unis ou au Canada! Nous ne pourrons nullement être tenus responsables de dommages si cette remarque n'est pas respectée!

84829-03-

11977 / 1

The sticker is located behind the front panel on the control box.

Warning label (1009943-..)



13065 / 2

1.7 Warranty

Wellsystem guarantees to the customer for 24 months starting from hand-over that the goods do not present any faults which remove or decrease the value or the capability of the device in normal use. The rubber blanket, toothed belt and drive motors are components of the device that are subject to wear and tear in everyday use. If the defect in the goods is attributable to wear and tear of these components, claims under warranty by the customer will not be entertained.

1.8 Warranty and liability exclusions

Warranty and liability claims for personal injury and property damage are excluded if they are the result of one or more of the following causes:

- improper use of the device;
- improper assembly, commissioning, operation and maintenance of the device;
- operating the device with faulty safety equipment or improperly attached or non-functional safety and protective equipment including warning signs;
- operating the device at maximum pressure for longer than 1 hour a day without a cooling system;
- not complying with the information in the operating instructions regarding transport, storage, assembly, commissioning, operation and maintenance;
- the use of untrained personnel;
- unauthorized changes to the device or the control unit;
- inadequate monitoring of parts subject to wear;
- repairs carried out improperly;
- the use of non-original spare parts;
- emergencies and disasters resulting from the influence of foreign materials or force majeure.

2 Description

2.1 Scope of delivery

Dry water massage device

Technical documentation (folder with instructions, brochures for error codes and default settings and additional documentation)

Service card 12668-..

Headrest 801091-..

High-pressure hose 90906-.. (10 m, 3/8"); Inlet: 90 bar

High-pressure hose 50909-.. (10 m, 1/2"); Outlet: 12 bar

2.1.1 Accessories (optional)

Chip card set 500001071 (programs 8, 9, 10)

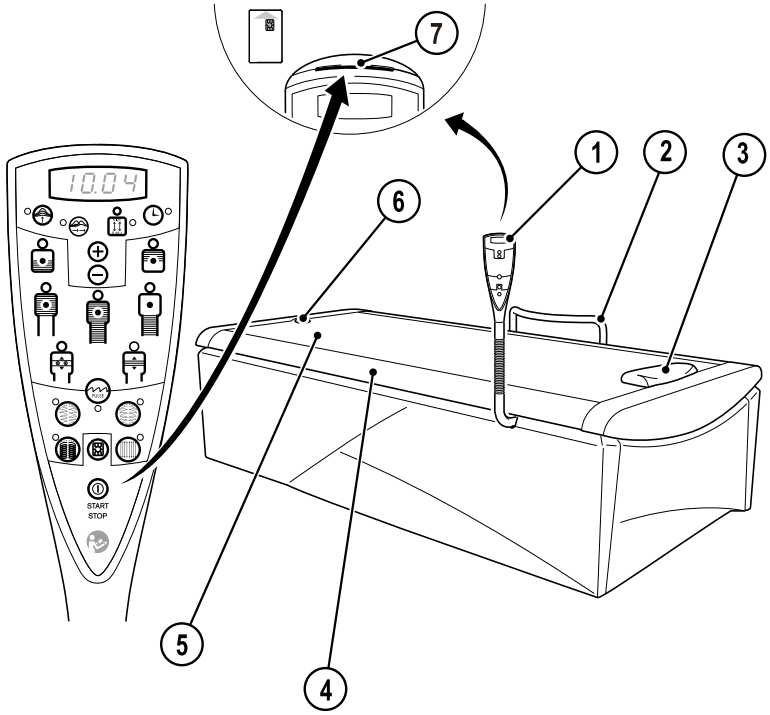
Chip card set 500001072 (blank chip cards = PROGRAMMABLE)

Extension cushion 34528100

2.1.2 Non-medical accessories

Wellsystem SPA (Wellness accessory)

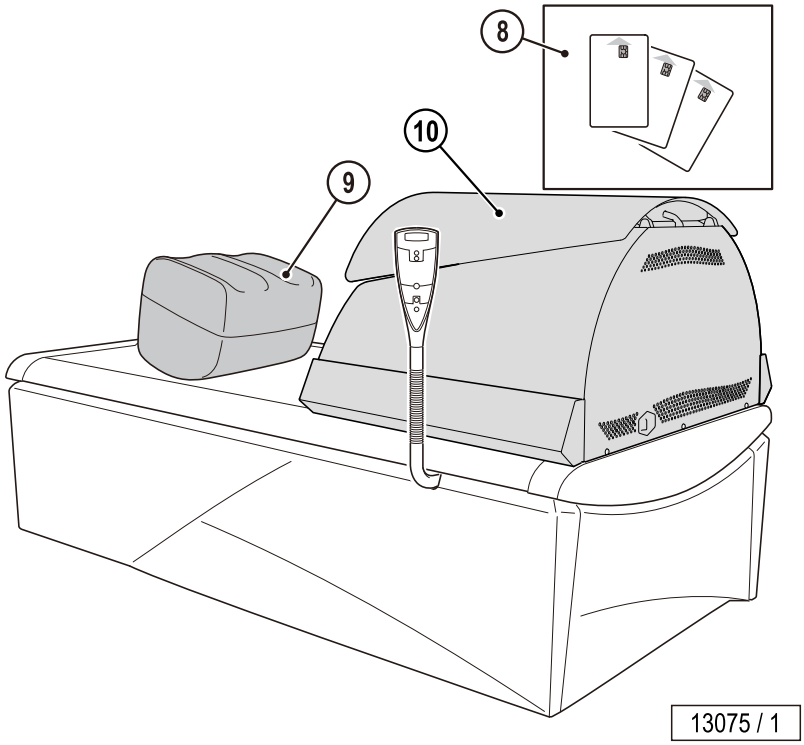
2.2 Device description



13074 / 1

1. Operating panel
2. Grab handle
3. Headrest
4. Tank
5. Bed surface (rubber blanket)
6. Valve (venting)
7. Chip card slot

2.3 Accessories (optional)



8. Chip card sets
9. Extension cushion
10. Wellsystem SPA (Wellness accessory)

2.4 Functional description

Dry water massage involves the treatment of the body or individual parts of the body by kneading, pummelling, rubbing, stroking and pressing the muscles.

In principle mechanical massage with the WELLSYSTEM MEDICAL _PLUS can be used for all symptomatic and non-symptomatic stiffening of the back muscles, gluteal muscles and the leg muscles.

Hydrostatic pressure, which can put a lot of strain on the circulation during treatment in water, is completely avoided with this device. The person does not make direct bodily contact with the water jets. The risk of a water-borne infection is therefore also eliminated.

Mechanical massage using this device must not be undertaken if this will result in excessive demands being made on the tensed muscles or even damaging them or other spinal column or pelvis tissue structures, i.e. the vertebrae, the ligaments in a vertebral motor segment, the sacroiliac joints or the hip joints.

The massage must not result in negative or somatic reactions such as pain or signs of inflammation and it must never be used in areas where the structure is loose, e.g. from endoprosthesis, as mechanical vibrations can be expected in these areas.

The vertebrae must be stabilized and mobilized sufficiently so that they can be moved during treatment.

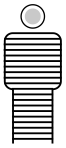
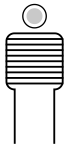
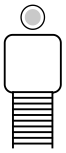
The benefits of this device as compared to other forms of physical therapy:

- No circulation strain
- No sweating afterwards
- Individual and reliable dosing
- Quicker for the user

2.4.1 Massage areas and massage types

If you use a chip card, the program stored on it will run automatically. If you are not using a chip card then the full-body massage combined with the parallel stroke continuous massage will be activated after start-up. You can change the areas to be massaged and the type of massage at any time just by pressing the relevant button.

Massage areas

Button	Function	Button	Function
Whole body massage		Upper body massage	
	For the whole body massage, the massage nozzles move along the entire bed.		For the upper body massage, the massage nozzles only move over the top half of the bed.
Lower body massage		Neck / shoulder massage	
	For the lower body massage, the massage nozzles only move over the lower half of the bed.		The massage nozzles only move in the neck and shoulder area.
Lumbar area massage		Zone massage	
	The massage nozzles only move in the lumbar area.		During zone massage the massage nozzles move in an area of approx. 20 cm. Select the whole body massage, wait until the nozzles have reached the desired body area when moving from the head end to the foot end and then press zone massage.
Point massage			
	For the point massage, the massage nozzles move back and forth over a short distance. Select the whole body massage, wait until the nozzles have reached the desired body area when moving from the head end to the foot end and then press Point massage.		

Massage types

Button	Function	Button	Function
Parallel stroke massage		Parallel massage	
	For the parallel stroke massage, the massage nozzles move back and forth along the length of the body. The nozzles are offset from the outside to the inside.		For the parallel massage, both massage nozzles move back and forth in the same direction to the left and to the right on the bed in the massage area defined in the pre-selection.
Mirror image massage		Circular massage	
	For the mirror massage, both massage nozzles move from the inside to the outside on the bed in the massage area defined in the pre-selection.		For the circular massage, the massage nozzles move in a circle on the bed in the massage area defined in the pre-selection.
Pulse massage			
	Pulse massaging can be switched on for all types of massage. The water jets from the massage nozzles are briefly and regularly interrupted during a pulse massage; the selected massage area does not change.		

3 Operation

3.1 Application tips

3.1.1 Safety instructions

WARNING!

Damage to the nozzle carriage may occur.

– The patient is only to lie down on the device or leave it when it is stopped.

Procedures before and during a massage:

Clothing dyes or hair dye may lead to a discolouring of the rubber blanket. A large towel should be placed on the bed in this case.

Sharp edged objects, such as jewellery, belt buckles, etc., may damage the rubber blanket and should therefore be removed beforehand.

Light-weight and strong clothing should always be worn during use.

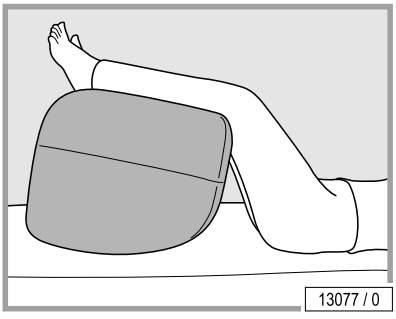
Lie down with your back on the device.

3.1.2 Preparing the patients

The default program must be set up to match the patients' different body sizes. The length of the patient's back must be measured to be able to realize this.

– Measure the length of the back from vertebrae C7 (cervical vertebrae) down to vertebrae S1 (sacrum).
– Enter the value, see page 44.

3.1.3 Using the extension cushion



An extension cushion can be placed underneath for greater comfort during the massage.

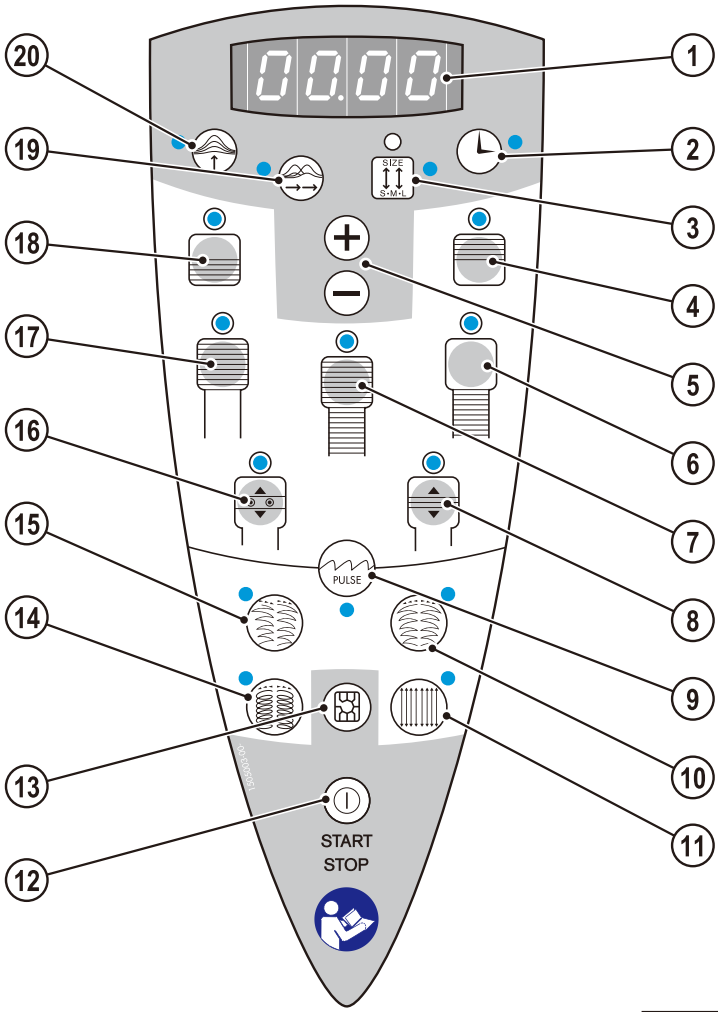
This does **not** apply to the following massage areas:

Full body massage area

Lower body massage area

Zone massage area, if the set area includes the leg area.

3.2 Operating overview

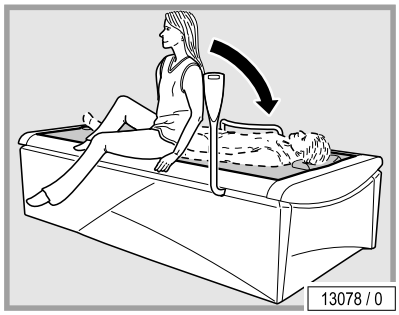


12976 / 1

	Function	Information
1	Display	4-digit
2	Massage time button	—
3	Back length button	min. 45, max. 65
4	Neck / shoulder button	Massage area
5	Plus button, minus button	—
6	Lower body button	Massage area
7	Whole body button	Massage area
8	Zone button	Massage area
9	Pulse button	Massage type
10	Mirror button	Massage type
11	Parallel stroke button	Massage type
12	START / STOP button	—
13	Save program button	—

	Function	Information
14	Circle button	Massage type
15	Parallel button	Massage type
16	Point button	Massage area
17	Upper body button	Massage area
18	Lumbar area button	Massage area
19	Speed button (nozzle carriage)	Speed levels
20	Massage pressure button	min. 0.5, max. 4.00

3.3 Starting a massage



NOTE:

If and how the massage time can be selected depends on the presettings – see page 54.

– Setting the massage time – see page 44.
– Lie down on the unit. In doing so place your head on the positioned headrest.
– Select the type of massage that you want and then press the START / STOP button.

NOTE:

The zone or point massage selection only functions when the nozzles are moving from the head end to the foot end.

If you have missed the right moment:

First select whole body massage again.

Wait until the nozzles reach the desired position while moving from the head end.

Press zone or point massage.

NOTE:

The cooler in the base of the device is switched on and off automatically whilst the device is being used.

3.3.1 Using a chip card to start

A set of chip cards loaded with 3 additional massage programs is available as an accessory – see page 33.

NOTE:

If and how the massage time can be selected depends on the presettings – see page 54.

NOTE:

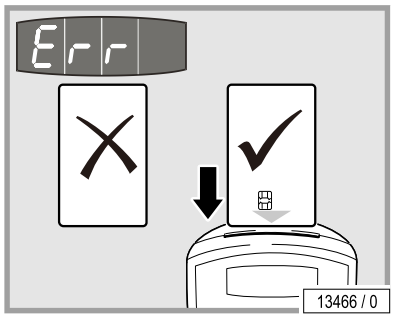
Any massage time setting can be entered prior to starting when using a chip card (up to the maximum default time permitted). The massaging pressure can be decreased or increased at any time whilst the unit is working.

The type of massage cannot be changed!

– Setting the massage time – see page 44.
– Insert the chip card.
– Lie down on the unit. In doing so place your head on the positioned headrest.
– Press the START / STOP button.

The program stored on the chip card will run automatically.

Chip card inserted incorrectly



If the chip card is inserted incorrectly, the error message **Err** is shown on the display.

3.3.2 Using a coin unit to start

– Set the massage time on the coin device.
– Lie down on the unit. In doing so place your head on the positioned headrest.
– Select the type of massage that you want or insert the chip card.
– Press the START / STOP button.

3.4 Ending a massage

The massage will be terminated automatically after the set massage time has expired. A flashing StOP sign will be shown in the display.

When the set massage time has expired, the nozzles move at high speed to the head end and then change to a smoothing, final massage. The pressure is reduced for the final massage. This pressure can only be changed by customer service. The nozzles move once completely from the head end to the feet end as for a full body massage.

The massage does not end until the nozzles stop at the end of the foot and the display blinks at 0.00.

The final massage is omitted if a chip card is not being used. At the end of the massage time, the nozzle carriage moves to the head end and comes to a stop there.

3.4.1 Interrupting the massage

– Press the START / STOP button.
  The massage pressure is considerably reduced. The nozzle carriage will cover the shortest route to either the head or feet end of the massage device and will continue to run there, but at reduced pressure.
  Do not get off the massage device until the nozzle carriage has reached one of the end positions. The massage time will keep running.

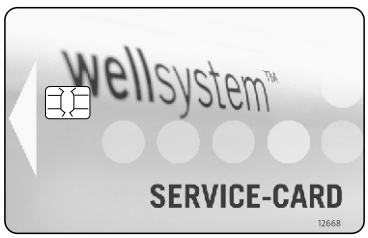
– Press the START / STOP button once again to restart the massage.

3.4.2 Terminating the massage before the time has expired

– Press the START / STOP button and keep it pressed down for 3 seconds:
  The nozzle carriage will move up to the head end of the device and it will then be switched off.

3.5 Service card

The service card (12668-..) is used to call up device information and for modifying some default settings such as the water temperature – see Page 54.

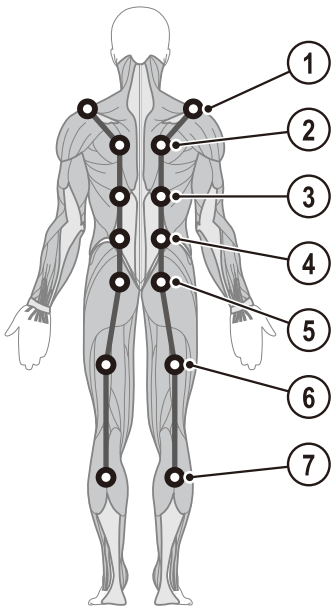


13123 / 0

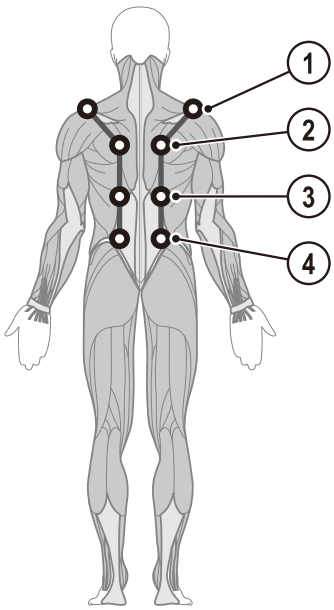
3.6 Default massage program

There are 6 therapeutic massage programs saved on the device. The following summary shows which muscle groups are affected by the specific programs.

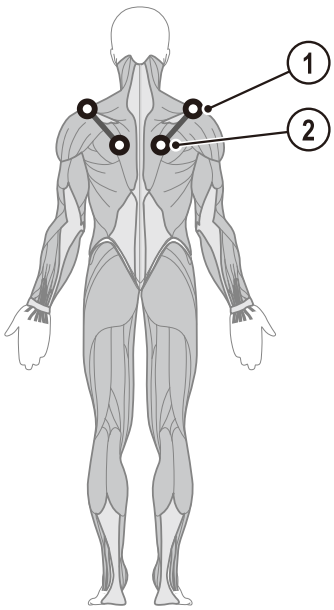
Program 1



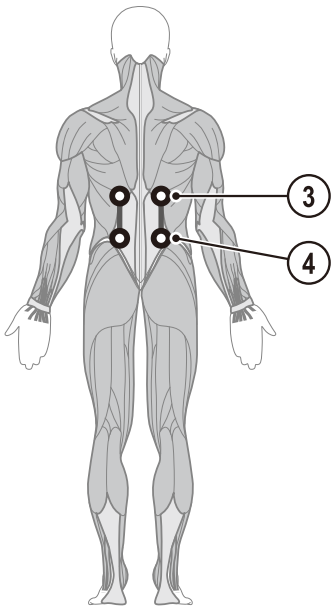
Program 2



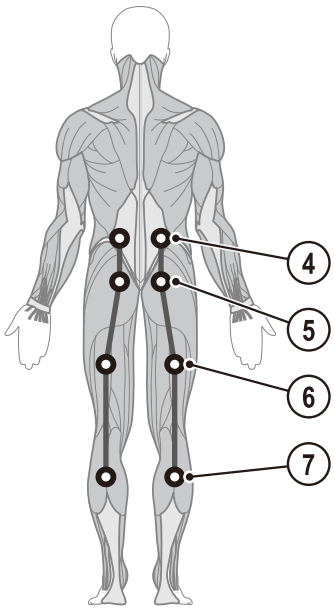
Program 3



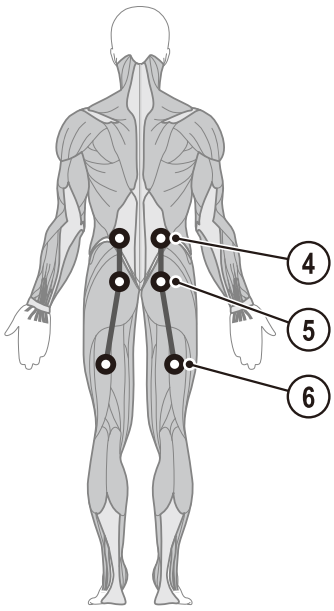
Program 4



Program 5



Program 6



13148 / 0

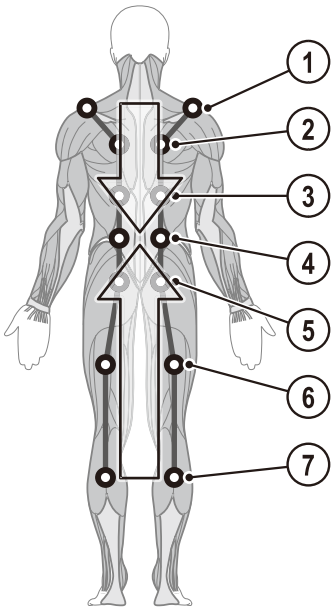
Muscle groups targeted

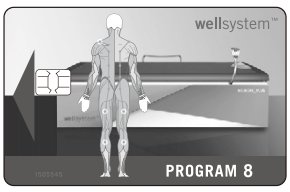
1. Shoulder / neck area: M. trapezius, M. levator scapulae
2. Thoracic spine parietal vertex: Mm. rhomboidei, M. serratus post. sup.
3. Upper lumbar spine to L3: M. iliocostalis lumborum
4. Ileo sacral area
5. Buttocks: M. piriformis, gluteal muscles
6. Thigh dorsal area: M. biceps femoris, M. rectus femoris
7. Calf muscles: M. gastrocnemius, M. soleus

3.6.1 Additional massage programs

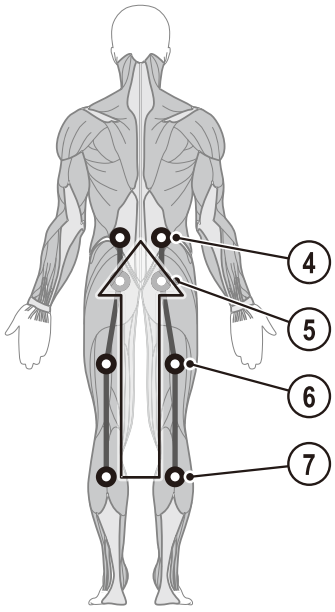
A set of chip cards loaded with 3 additional massage programs is available as an accessory.

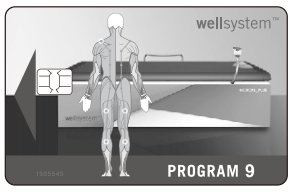
Program 8



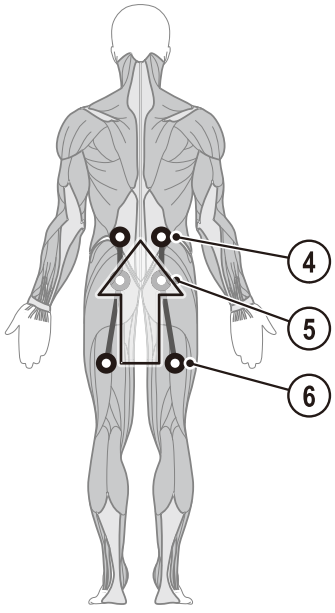


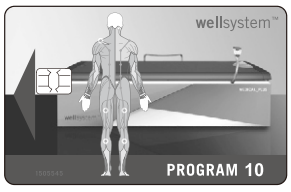
Program 9



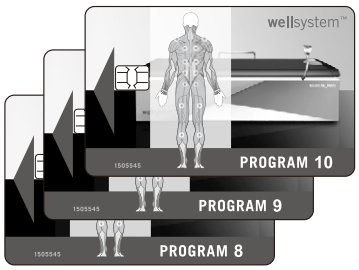


Program 10





13509 / 0



13124 / 1

3.6.2 Selecting a massage program

The following options are available:

Without a chip card: Select program on the device. Programs 1-6 are included with the device, program 7 allows a customized program to be saved on device, see 3.7 Programming on page 35.

Chip card set accessories (500001071): Select the chip card with the desired program.

Blank chip card set (500001072): Select an individual compiled massage program, see 3.7 Programming on page 35.

With chip card:

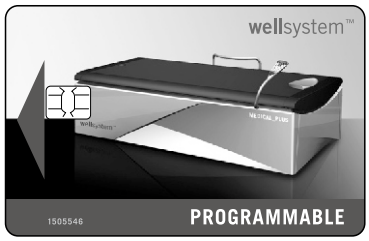
– Insert the chip card.
– Press the START / STOP button.

Without a chip card:

– Press the save program button.
– Use the plus or minus keys to select the program that you want to use (e.g. Pr.02).
– Press the START / STOP button.

Variable settings such as the massage pressure can be entered during the massage, see page 44.

3.7 Programming

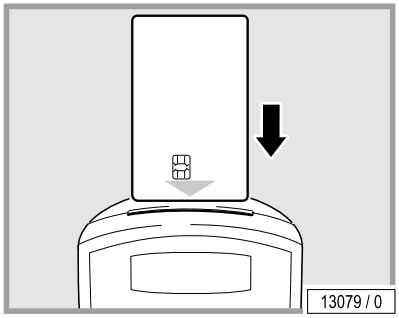


13125 / 0

A memory slot (PR07) is reserved on the device for an individually compiled massage program. Additional customized programs can be saved to blank chip cards.

There are two methods of compiling a customized massage program: Phased programming or free, customized programming in which every step is defined individually. The presettings determine which procedure is be used as the default procedure, see page 54.

During programming the unit switches on automatically and follows the button input. Nevertheless, the programming can be continued without interruption.



13079 / 0

With chip card:

– Insert the chip card.
– Press and hold down the save program button for 3 seconds.

The display will change over to programming mode. The PH.01 display will alternate with the phase duration (in minutes) during phase mode programming. The St.01 display will alternate with the time entry (in seconds) during free, specific programming mode.

Without a chip card:

NOTE!

Data loss!

A customized massage program stored on the device is overwritten.

– Check to see if the memory slot is already in use.

– Press and hold down the save program button for 3 seconds.

The display will change over to programming mode. The PH.01 display will alternate with the phase duration (in minutes) during phase mode programming. The St.01 display will alternate with the time entry (in seconds) during free, specific programming mode.

The program is automatically saved on the device and can be selected as PR.07 upon completion.

3.7.1 For programming specific phases

Up to 45 different phases can be defined for a massage program using this programming mode. All of the basic settings (massage pressure, body area, type of massage, etc.) can be set up separately for each phase.

A single phase must last for at least 1 minute and up to a maximum of 45 minutes. The times must be entered using minute cycles. The defined phases will run in sequence. The sequence will be repeated until the entered massage time has expired.

NOTE:

Pay special attention to the full massage time when creating a program. Not all of the phases can be run if, for example, a program has 40 phases and each one last for one minute but the overall time entry was only 30 minutes! The massage will stop after the 30th phase.

An example program with 3 phases is shown below.

The PH.01 display will alternate with the phase duration (in minutes). Use the plus or minus buttons to select the phases.

Phase	Configuring the settings	Button sequence	Example setting / Display
	Optional: Insert chip card		
	Start	Press and hold the save program button for 3 s.	
PH.01	Massage time	−/+	5.00
	Massage pressure	−/+	3.75
	Speed	−/+	SP.15
	Pulse massage		
	Body area		
	Massage type		
	Store the phase		done
	Select a new phase		PH.02
PH.02	Massage time	−/+	3.00
	Massage pressure	−/+	2.75
	Speed	−/+	SP.05
	Body area		
	Massage type		
	Store the phase		done
	Select a new phase		PH.03

Phase	Configuring the settings	Button sequence	Example setting / Display
PH.03	Massage time	⊖/⊕	2.00
	Massage pressure	⊖/⊕	1.75
	Speed	⊖/⊕	SP.15
	Pulse massage	PULSE	
	Body area		
	Massage type		
	Store the phase		dONE
	Select a new phase	⊕	PH.04

End programming:

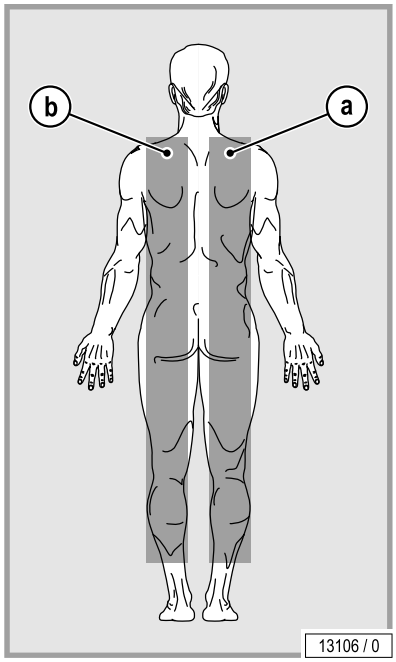
– Use the plus button to change over to a new phase after all of the phases have been entered. In the example shown above PH.04 is the next phase and it cannot be re-programmed.

– Press the START / STOP button.

NOTE:

The START / STOP button must be pressed to activate the card. The card will be erased if the button is not pressed and it will have to be re-loaded.

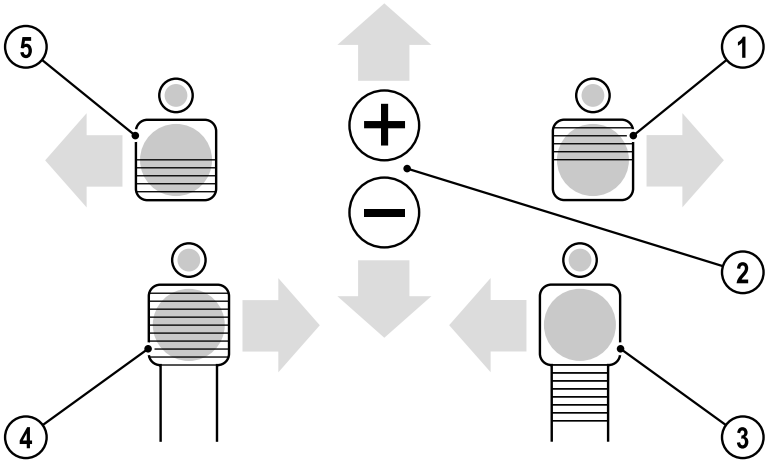
– Remove the card.



3.7.2 Free, specific programming

Up to 50 different steps can be defined for a massage program using this programming mode. The specific step sequence can be defined in the path displayed on the left. The right nozzle carriage is marked as (a) and the left nozzle carriage is marked as (b).

The sequence can be programmed using the following buttons:



1. Right nozzle carriage moves outwards
2. Plus button: Nozzle carriage moves up to the head end;
   Minus button: Nozzle carriage moves down to the foot end
3. Right nozzle carriage moves inwards
4. Left nozzle carriage moves inwards
5. Left nozzle carriage moves outwards

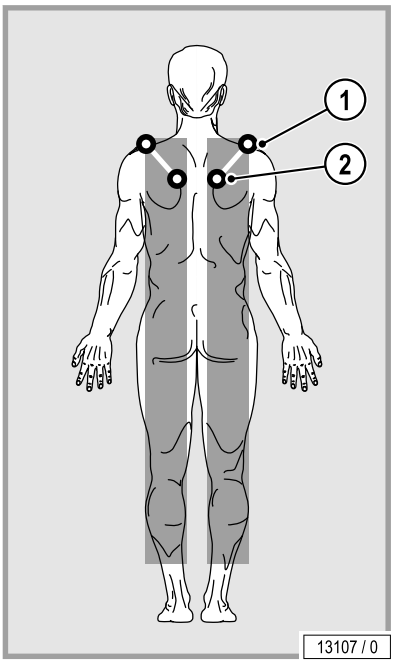
The right (a) and left (b) sides can be moved synchronously or differently. The left and right nozzle carriage buttons must be pressed down together to move the carriages synchronously. The position is displayed for checking purposes.

The massage pressure, speed and the time in seconds for the specific steps can also be defined in addition to the sequence. When a time is set up it means that the nozzles will stay in the same position for the defined period. If the time is set to 000 then the nozzles will move straight on to the next step. The maximum time setting for each step is 120 seconds.

The defined steps will run in sequence. The sequence will be repeated until the entered massage time has expired.

An example program with 2 steps is shown below.

The St.01 display will alternate with the step duration (in seconds). The display will move onto the next step after a step has been saved.



Step	Configuring the settings	Button sequence	Example setting / Display
	Optional: Insert chip card		
	Start	Press and hold the save program button for 3 s.	
St.01	Massage time	−/+	045
	Massage pressure	−/+	2.75
	Speed	−/+	SP.15
	Position (1) defined as the start point: Both nozzle carriages will move synchronously outwards; keep both buttons pressed down simultaneously		
	Step completed The display will now change over from done to St.02		done St.02
St.02	Massage time	−/+	0.00
	Massage pressure	−/+	1.75
	Speed	−/+	SP.25
	Moving into Position (2): The nozzle carriages will move downwards	−	
	Both nozzle carriages will move synchronously inwards; keep both buttons pressed down simultaneously		
	Step completed The display will now change over from done to St.03		done St.03

End programming:

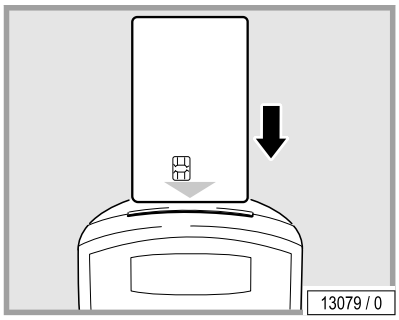
– Press the START / STOP button after all of the steps have been entered.

NOTE:

The START / STOP button must be pressed to activate the card. The card will be erased if the button is not pressed and it will have to be re-loaded.

– Remove the card.

3.8 Loading a chip card



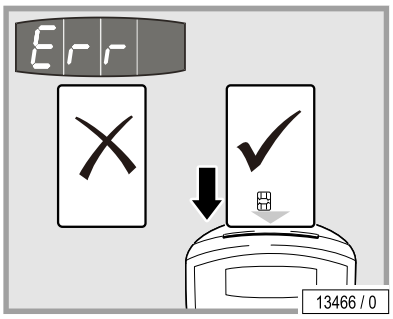
The pre-programmed and user programmable chip cards can be topped up for further massage sessions as often as necessary (see 'Presettings', page 55).

When topping up, the chip cards are upgraded to a new software version and can no longer be used in devices in which older software is used.

Remaining credit

Upgraded chip cards briefly display the number of massages left after they have been inserted. The operating screen is displayed afterwards.

Chip card inserted incorrectly



If the chip card is inserted incorrectly, the error message **Err** is shown on the display.

3.9 Configuring the settings

3.9.1 Basic settings

Increasing / decreasing the intensity of the display and the lights inside the buttons

Operating button	Basic settings / Display	Remarks
⊕ ⊖	Display 	**Standby mode:** Press the plus or minus buttons to alter the display's light intensity and the intensity of the lights inside the buttons by up to 10 increments. Plus button: Increases the intensity. Minus button: Reduces the intensity.
	Massage time button 	
	Back length button 	
	Massage pressure button 	
	Speed button 	
	Whole body button 	
	Circle massage button 	
	Pulse massage button 	

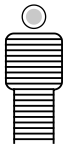
Activating and interrupting the massage times

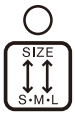
Operating button	Basic settings / Display	Remarks
	START / STOP button 	**Massage start:** Press the START / STOP button. The device switches on.
	Massage time display 	**Massage time sequence:** The display counts down in seconds, e.g. from 30.00 down to 0.00.
		**Massage time finish:** The nozzle carriage moves down to the feet end and then up to the head end. The display will change from 0.00 to StOP.
		
		A new massage session can now be called up.
		**Massage start:** Press the START / STOP button. The device switches on again.
		**Massage stop:** Press the START / STOP button and keep it held down for approx. 3 s. The device switches off. The display will start to flash.
		A new massage session can now be called up.
		**Massage start:** Press the START / STOP button. The device switches on again.
	Massage time display 	**Program interruption**[1] Press the START / STOP button and hold down for approx. 1 s.
	Program interruption 	**Note:** The massage time will keep running. The nozzle carriage moves in the direction of the foot end or head end. It remains in this waiting position until the START / STOP button is pressed again.
	Massage time display 	**Continue program:** Press the START / STOP button. The nozzle carriage moves back into the position for the preset program.

[1] Only possible if the pause function (13) has been activated while in pre-setting mode

3.9.2 Variable settings

Massage time, massage pressure, speed and body size settings

Operating button	Settings / Display	Remarks
	START / STOP button Massage time display 	The device switches on. **After starting:** The variable settings can be defined separately for the specific massage areas and the the massage types, e.g.: 1. Step (massage area): Whole body button  2. Step (massage type): Parallel massage 
	Altering the massage time, e.g. from  to 	Press the massage time button and hold down for approx. 1 s. The display will flash. Press the plus or minus buttons to set up the value that you want. **Basic setting:** Changes can only be made using the service card in the default settings mode. Factory setting: 30 minutes Minimum and maximum massage times in minutes: 5.00 to 45.00 in minutes
	Altering the massage pressure, e.g. from  to 	Press the massage pressure button and hold down for approx. 1 s. The display will flash. Press the plus or minus buttons to set up the value that you want. **Basic setting:** Changes can only be made using the service card in the default settings mode. Factory setting: 1.50 Minimum and maximum massage pressure: 0.5 to 4 in 0.25 intervals

Operating button	Settings / Display	Remarks
	Altering the nozzle carriage speed, e.g. from  to 	Press the speed button and hold down for approx. 1 s. The display will flash. Press the plus or minus buttons to set up the value that you want. Factory setting: SP.15 Minimum and maximum speeds: 05 to 30 in increments of 1
	Altering the back length, e.g. from  to 	Press the back length button and hold down for approx. 1 s. Display flashes. Press the plus or minus buttons to set up the value that you want, see page 28. Factory setting: 55 Minimum and maximum back lengths in cm: 45 to 65 increments of 1
	Altering the water jet 	Factory setting: Pulse massage inactive Pressing the pulse button to activate pulse massage: The water jet will be continually interrupted. The diode is illuminated. Deactivating the pulse massage option: Press the pulse button again

Altering the massage area and the type of massage

NOTE:

The zone or point massage selection only functions when the nozzles are moving from the head end to the foot end.

If you have missed the right moment:

First select whole body massage again.

Wait until the nozzles reach the desired position while moving from the head end.

Press zone or point massage.

– Press the new massage area button.
– Press the new massage type button.

Massage area default factory setting: Whole body

Massage type default factory setting: Parallel stroke

4 Cleaning and maintenance

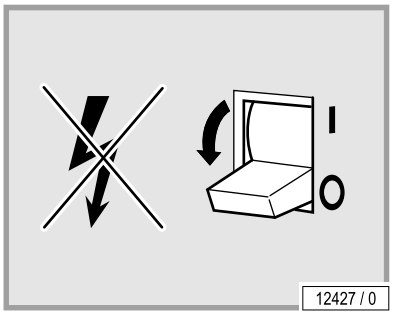
4.1 Safety instructions for maintenance

DANGER!

Electricity throughout entire device!

Personnel danger due to electric shock or electric burns.

– Before beginning work, disconnect all of the power connections from mains voltage.
– Secure all of the disconnected connections against accidental reactivation.
– Check that the device is disconnected from mains voltage.
– All of the work and electrical connections must comply with the national regulations of the country in which the device is being operated (e.g. the VDE regulations in Germany) and must be undertaken by appropriately trained specialists.

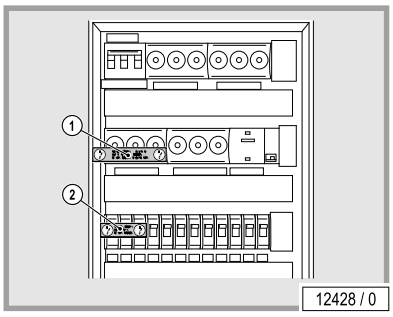


If work is to be performed on the devices, they must be deenergized. That means that all live cables must be switched off.

Switching off the device alone is insufficient, as certain points may remain energized. Therefore, switch off fuses before performing any work and – if possible – remove them.

Accidental reactivation can result in serious accidents. Immediately after deenergizing, secure all switches or fuses used for deenergizing against being switched on again.

– Lock the fuse box with a padlock.



In case of circuit breakers which cannot be unscrewed, a strip of adhesive tape may be applied over the actuation lever with the wording 'Do not switch, danger!' (1 + 2).

A prohibition sign with the text:

'Work in progress!'

'Place: .....'

'Sign may only be removed by: .....'

must always be securely mounted immediately.

DANGER!

Electricity is present throughout the entire device!

Personnel danger due to electric shock or electric burns.

– Prohibition signs must not be fixed to live parts nor touch these.

4.2 Faults

Error codes are output to the display to simplify troubleshooting:

If an error occurs, the error code flashes on the display.

If several errors occur, the error messages are displayed alternately.

NOTE:

Certain error messages can be switched off by pressing the **START / STOP** button.
In other cases the error can be eliminated by switching the device off for 1 minute (switch off using the main switch / the fuse).

Inform our customer service department if the same error code is displayed again after pressing the **START / STOP** button or switching the device back on – see page 2.

More detailed information regarding the error description and solutions can be found in 'Error Codes', (order no. 801290-..).

4.3 Cleaning and disinfection

DANGER!

Infections can be spread by skin contact!

All objects / device parts touched by the user during use must be disinfected after every use:

- Handle
- Control panel
- Rubber blanket
- Frame
- Headrest

4.3.1 Disinfection

13104 / 0

We recommend the following cleaning agents for rapid and thorough disinfection:

mikrozid® sensitive fast disinfectant cleaner

1	mikrozid® sensitive liquid, 1 litre	Order no.:	1010283-..
2	Spray nozzle	Order no.:	1010284-..
3	mikrozid® sensitive wipes (container), 200 wipes	Order no.:	1010285-..
4	mikrozid® sensitive wipes (refill pack), 200 wipes	Order no.:	1010286-..

NOTE:

Adhere to the stipulated times to ensure thorough disinfection. Follow the manufacturer's instructions for use.

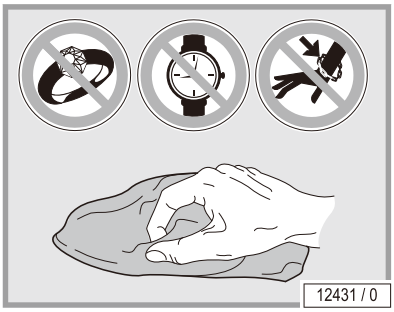
4.3.2 Cleaning the surfaces

WARNING!

Do not rub with a dry cloth – danger of scratching!

Failure to comply voids any warranty claims.

– Only the specially-developed fast disinfectant mikrozid® sensitive cleaner should be used for fast, hygienic and correct cleaning of surfaces.
– Do not use other cleaning agents, especially concentrated disinfectants or solvents (e.g. Lysoform, ethyl alcohol or other fluids containing alcohol) for cleaning.



Plastic surfaces

For cleaning the painted and unpainted plastic surfaces, it is best to simply use warm water and a leather cloth. Never use aggressive cleaning agents containing alcohol or essential oils. These may lead, in the long run, to damages not covered by the guarantee.

During cleaning a slight discolouration of the leather cloth by the rubber seals must be expected for production-related reasons.

Prevent the plastic surfaces from being damaged.

– Remove rings, watches, bracelets etc. before starting cleaning work.

4.4 Maintenance performed by the customer service

NOTE:

The maintenance work must be carried out by WELLSYSTEM MEDICAL _PLUS the customer services of the manufacturer or by qualified specialist personnel authorised by the manufacturer following a check list.
Inspection work that has been carried out correctly can be entered and confirmed on 'Sheet D Maintenance measures / Service' in the Book of Medical Devices, see page 62.

NOTE:

If the device is operated for longer than 10 years, it must be completely overhauled by the customer services of the manufacturer or by qualified specialist personnel authorised by the manufacturer.

We would like to point out that the device must be subjected to regular inspections by our customer service or an approved specialized company every 12 months (from commissioning) to maintain its proper condition!

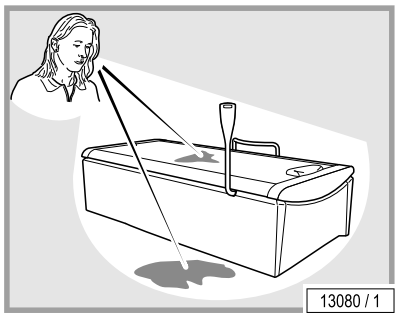
WARNING!

Only use **genuine spare parts** of the same type! Material damage or personal injuries may result when using other parts.

Any liability for damage or injury proven to be the result of the use of non-genuine spare parts is excluded.

4.5 Maintenance performed by the operator

4.5.1 Daily visual inspection

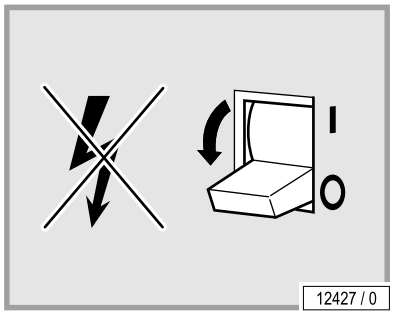


– Inspect the device for leaks.

WARNING!

The device might be damaged by moisture!

– The device may no longer be used in the event of water loss (puddles on the floor). Please inform our customer service department – see page 2.
– Do not switch the device on if there are leaks or if it is damaged. Inform our customer service department – see page 2.



4.5.2 Venting

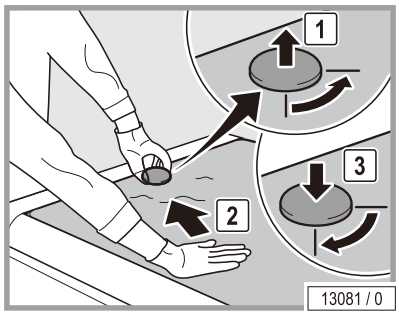
The tank must be vented 3 days after commissioning or after it has been initially filled. After this, venting is unnecessary unless leakages occur and the tank has to be topped up.

DANGER!

Illnesses can be caused by contaminated water!

The water in the tank is untreated and can be contaminated with bacteria.

– Wear protective gloves if you are likely to come into contact with the water.



– Open the valve.
– Press the rubber blanket down gently, so that the air escapes.
– Shut the valve again afterwards.

5 Technical data

5.1 Power, connection rating and weight

WELLSYSTEM MEDICAL _PLUS	
Power consumption rating:	2800 W
Rated frequency:	50 Hz
Rated voltage:	230-240 V ~
Type of connection:	Landline connection (3.00 m)
Noise level 1m away from device:	56.3 dB(A)
Noise level at the head end:	<56 dB(A)
Classification by the type of protection against electric shock: by the degree of protection against electric shock:	 Protection class I Type BF application part
Protection class:	I
Protection type:	IP20
Empty weight (unfilled):	approx. 168 kg
Total weight (filled):	approx. 472 kg

5.2 Water and cooling conditions

The device is filled with normal tap water without additives. The water can be drained off into the public sewage system after it has been used.

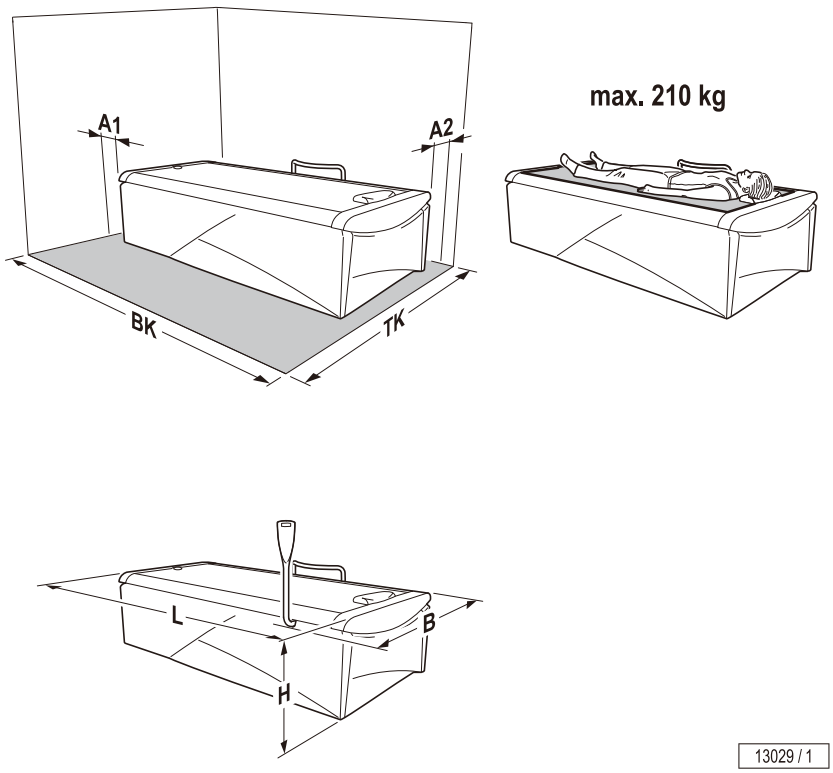
Water and cooling conditions

Permissible water pressure (water inlet): 8 bar

Maximum coolant temperature: 16 °C > setpoint temperature and set time.

The device may only be operated with the high-pressure hoses included in the scope of delivery.

5.3 Dimensions



A1 = 70 mm

A2 = 70 mm

BK = 2,450 mm

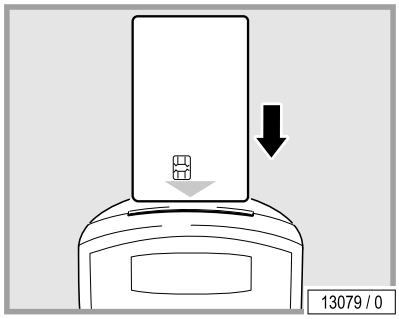
TK = 1,900 mm

L = 2,150 mm

B = 1,100 mm

H = 570 mm

6 Presettings



Operating states can be called up and presettings entered in service / preset mode.

See page 29.

– Insert service card.
– The code for the last function setting is displayed on the screen e.g. 06 and SER alternating.
– Press the massage pressure button to display the current setting for this function, e.g. 10.00.
– Press the plus or minus button (5) to modify the setting.
– Press the massage pressure button (20) to confirm the setting. 06 will be displayed on the screen again.
– Press the plus button (5) to scroll up to the next function.
– Press the minus button (5) to scroll down to the next function.
–

No.	Description	On delivery	Values from - to
01	Total operating hours (Reset: Press the plus and minus keys simultaneously)	0	0 - 9999
02	Operating hours since the last service (Reset: Press the plus and minus keys simultaneously)	0	0 - 9999
03	Water temperature unit The change from °C to °F and back is done by conversion; the actual temperature may vary slightly.	°C	°F, °C
04	Time controller (FREE = freely selectable massage time, SEAL = default time setting, COIN = coin operation)	FREE	FREE, SEAL, COIN
05	Maximum massage time in minutes (when Setting 04 = FREE)	30	5 - 45
06	Default massage time / chip card program time in minutes (when Setting 04 = SEAL)	30	5 - 45
07	Water default temperature setting in °C Water default temperature setting in °F	35 95	20 - 40 68 - 104
08	Actual water temperature in °C or °F	–	–
09	Normal operation = FREE – see 'Expanding the chip card functions'; chip card-dependent operation = PAY	FREE	FREE, PAY
10	Chip card upgrading – see 'Expanding the chip card functions' (number of massages)	20	1 - 50
11	Reset the device default status (i.e. delivery status) by pressing the plus and minus buttons simultaneously and holding them down.	–	RSET
12	Programming mode (OFF = programming mode switched off, PHAS = phase mode programming, FREE = free, specific programming)	OFF	OFF, PHAS, FREE

No.	Description	On delivery	Values from - to
13	Pause function – if the START / STOP button is pressed during a massage (ON = massage will be interrupted, OFF = the massage will continue without being interrupted) then STOP will be displayed briefly)	OFF	ON, OFF
14	Pressure at massage start	1.50	0.5 - 2.75
15	Cooling time after massage Starts to cool once the selected setpoint temperature (07) has been exceeded. Selection: 0- 60 minutes, when ON continuous until the setpoint temperature has been reached.	60	00 - 60

6.1 Expanding the chip card functions

The chip card (massage card) can now also be used as a means of payment. Two further pre-setting possibilities are added for this purpose: 09 and 10.

09 controls the device operation:

Button sequence	Description
	Service card
⊕ 09	Select 09
↑ FrEE	If FREE is selected then the device will operate as before.
⊕ PAY	If 'PAY' is selected then the device can only be used with an upgraded chip card (massage card).
↑ 09	
	

10: Number of massages / Chip card upgrade

WARNING!

Any credit remaining on the chip card will be overwritten when topped up!

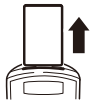
– Check the remaining credit on the chip card.

– Any new massages that are entered will be added to the remaining massages.

NOTE:

After inserting, chip cards upgraded to the new software version briefly display the number of massage sessions still available and then the operating mode display reappears.

Loading procedure:

Button sequence	Description
	Service card
 	Select 10
 	Press the plus or minus button to enter the number of massages (1 - 50). Add on the remaining credit!
 	

WARNING!

The card can be destroyed.

– Never pull the chip card out during upgrading.

Button sequence	Description
	Chip card (massage card)
	The LED in the time display will flash. Wait until the upgrade has been completed (flashing stops).
	The card can be removed when 'Cout' is displayed on the screen.
	
	Service card
	
 	Exiting sub-menu.
	

This procedure can be repeated with as many chip cards as required. When the loading procedure has been completed and no chip card has been inserted within approx. 4 minutes the system exits the loading procedure automatically.

The service card must be reinserted to be able to swap to another menu.

7 Appendix

7.1 MEDICAL _PLUS: EMC information

7.1.1 Table 201: Guidelines and manufacturer's declaration – Electromagnetic emissions

The WELLSYSTEM MEDICAL _PLUS massage device has been designed for use in the electromagnetic environment specified below. The device operator must ensure that it is used such an environment.

Emission measurements	Conformity	Electromagnetic environment – Guidelines
HF emissions as per CISPR 11	Group 1	WELLSYSTEM MEDICAL _PLUS uses HF power solely for internal functions. Therefore the HF emissions are very low and it is highly unlikely that it will cause any interference to adjacent electronic equipment.
HF emissions as per CISPR 11 Harmonics IEC 61000-3-2	Class B Class A	WELLSYSTEM MEDICAL _PLUS has been designed for use in all devices, including those in residential areas, and it has been determined that it can be used for residential purposes as soon as it is connected up to a public mains supply that also supplies buildings.
Voltage fluctuations / Flicker IEC 61000-3-11	Fulfilled	The obligations listed in Sub-section 6.2.2 of EN 61000-3-11:2000 must be taken into consideration. In particular, the 0.14 ohm line impedance must be guaranteed for pulse massaging.

7.1.2 Table 202: Guidelines and manufacturer's declaration – Electromagnetic interference

The WELLSYSTEM MEDICAL _PLUS massage device has been designed for use in the electromagnetic environment specified below. The device operator must ensure that it is used such an environment.

Interference immunity tests	IEC 60601 - Test level	Defined level	Electromagnetic environment – Guidelines
Discharging static electricity (ESD) IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	–
Fast transient electrical noise / bursts IEC 61000-4-4	±2 kV for mains supplies	±2 kV for mains supplies	–
Surges 61000-4-5	±1 kV series mode voltage ±2 kV common mode voltage	±1 kV series mode voltage ±2 kV common mode voltage	–
Magnetic field radiated by supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	–
Voltage drops, Short interruptions and supply voltage fluctuations IEC 61000-4-11	<5% U_T (>95% drop in U_T) for 0.5 periods 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods <5% U_T (>95% drop in U_T) for 5 s	<5% U_T (>95% drop in U_T) for 0.5 periods 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods <5% U_T (>95% drop in U_T) for 5 s	–

Note: U_T is the mains alternating voltage used for the test levels.

7.1.3 Table 204: Guidelines and manufacturer's declaration – Electromagnetic interference

The WELLSYSTEM MEDICAL _PLUS massage device has been designed for use in the electromagnetic environment specified below. The device operator must ensure that it is used such an environment.

Interference immunity tests	IEC 60601 - Test level	Defined level	Electromagnetic environment – Guidelines
Conducted HF noise IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile radios are not to be used at shorter distances to the Wellsystem Medical_Plus and its cables other than the recommended safe distance, which has been calculated according to the transmitting frequency are made. **Recommended safe distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz P is the transmitter's maximum output power (nominal rating) in Watts (W) according to the details provided by the manufacturer of the transmitter and the recommend safe distance is given in metres (m). The field strength of the stationary radio transmitter is for all frequencies[b] in accordance with tests that were carried out onsite[a] less than the determined level. Interference is possible in the immediate surrounding of equipment that carry the following symbols. 
Radiated HF noise IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Comment 1: The higher value applies to 80 MHz und 800 MHz.

Comment 2: These guidelines might not apply to all situations. The propagation of electromagnetic waves is affected by absorption and reflexes caused by buildings, objects and people.

a The field strength of a stationary transmitter e.g. standard cell phone stations (mobile / cordless phones) and public mobile radio services, amateur stations, MW and UHF radio and TV transmitters) cannot be precisely determined for theoretical reasons. It is recommended that an onsite test should be carried out in order to determine the electromagnetic environment caused by stationary HF transmitters. If the field strength of the massage device determined at the installation site exceeds the defined HF level listed above then the device must be monitored with regard to its normal operation. If any abnormal characteristics are recorded then it will be necessary to introduce additional measures, such as reorientation or converting the device.

b The field strength must be less than 3 V/m over the frequency ranges from 150 kHz to 80 MHz.

7.1.4 Table 206: Recommended safe distances between portable and mobile HF communications equipment and WELLSYSTEM MEDICAL _PLUS

WELLSYSTEM MEDICAL _PLUS has been designed for use in an electromagnetic environment in which the radiated HF interference is controlled. The operator of the massage device can help to reduce electromagnetic interference by maintaining a safe distance between the portable and mobile HF communication devices (transmitters) and the device itself as recommended below with regard to the communication device's maximum output power.

Nominal transmitter power (W)	Safe distance with regard to the transmitting frequency (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The recommended safe distance (d) in metres (m) can be determined by using the equation that applies to the transmitters frequency in the case of transmitters where their nominal power is not listed above, whereby 'P' is the nominal transmitter power in Watts (W) according to the details supplied by the manufacturer of the transmitter.

Comment 1: The higher value applies to 80 MHz und 800 MHz.

Comment 2: The propagation of electromagnetic waves is affected by absorption and reflexes caused by buildings, objects and people.

7.2 Routine checks

The checks and tests forms can be found in the Book of Medical Devices (order no. 1010298-..).

Book of Medical Devices

Device master data and record sheet for the inventory listings in accordance with the medical devices operator ordinance*

* in Germany 'MP BetreibV': Ordinance covering the installation, operation and use of medical devices

Operators address:

.....

.....

.....

.....

.....

Device: **wellsystem™ MEDICAL_PLUS massage device**

Agent / contact partner for massage device:

.....

.....

.....

Sheet A	**Master data sheet (general details)**
Sheet B	**Initial instruction / commissioning**
Sheet C	**Technical safety checks (TSC)**
Sheet D	**Maintenance measures / service**
Sheet E	**Functional defects and similar repeated operating errors**
Sheet F	**Incident reports sent to the authorities and the manufacturer**

Sticker:

11/2010 1010298-00 Wellsystem GmbH 1

7.3 Form for reporting incidents

The supplementary report form can be found in the Book of Medical Devices (order no. 1010298-..).

MHRA ADVERSE INCIDENT REPORT FORM

Please tick (4) the appropriate boxes

Origin of report:

Reporting Body……
Address……..……...
Reporter ……..…….
Position……...……
Telephone number……..
Consultant-in-charge (if known) ……

This report confirms a telephone report o a fax report o neither o

Type of device: (tick one only)

q Active implantable devices	q External defibrillators & pacemakers	q Physiotherapy equipment
q Administration & giving sets	q Feeding tubes	q Radiotherapy equipment
q Anaesthetic machines & monitors	q Gloves	q Radionuclide equipment
q Anaesthetic & breathing masks	q Guidewires	q Resuscitators
q Autoclaves	q Hearing aids	q Staples & staple guns
q Bath aids	q Hypodermic syringes & needles	q Stretchers
q Beds & mattresses	q Implant materials	q Surgical instruments
q Blood pressure measurement	q Infant incubators	q Surgical power tools
q Breast implants	q Infusion pumps, syringe drivers	q Sutures
q Cardiovascular implants & devices	q Insulin syringes	q Thermometers
q Commodes	q Intravenous catheters & cannulae	q Ultrasound equipment
q Contact lenses & care products	q Joint prostheses	q Urinary catheters
q CT systems	q Lasers & accessories	q Ventilators
q Dental materials & appliances	q Magnetic resonance equipment & accessories	q Walking sticks / frames
q Dialysis equipment	q Mobile x-ray systems	q Wound drains
q Diathermy equipment & accessories	q Monitors & electrodes	q X-ray equipment, systems & accessories
q Dressings	q Non-active implants	q Other (please specify)
q Endoscopes & accessories	q Ophthalmic equipment	.....
q Endotracheal tubes & airways	q Patient hoists	
q Enteral feeding systems	q Patient monitoring equipment	

Further details can be given on additional sheets if necessary

8 Index

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R

S

T

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W

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Wellsystem GmbH
Koehlershohner Strasse
53578 Windhagen/ Germany
Tel. 02224/818-257
Fax 02224/818-254
info@wellsystem.de
www.wellsystem.com

UK A CH

Wellsystem GmbH
Koehlershohner Strasse
53578 Windhagen/ Germany
Phone +49 2224/818-250
Fax +49 2224/818-254
contact@wellsystem.com
www.wellsystem.com

wellsystem™