Zimmer
MedizinSysteme

Microwave Therapy Device

MicroPro

Instructions For Use

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1 Introduction

1.1 Preface

Safe operation of the microwave therapy unit requires knowledge of both medicine and electricity.

For this reason, the microwave therapy unit may be used only by persons with the appropriate training, knowledge and practical experience necessary to ensure proper handling of the unit and who have been properly trained in the use of the unit based on these instructions for use.

- Therefore, please read this manual thoroughly and be sure to comply with the safety instructions!

We will be glad to answer any questions you may have concerning this unit or other Zimmer MedizinSysteme GmbH products.

Our address can be found at the beginning of this manual.

1.2 Scope

The information provided in these instructions for use refer to the

MicroPro microwave therapy unit

from Zimmer MedizinSysteme GmbH.

1.3 Intended use

The **MicroPro** is used for microwave therapy (diathermy).

By means of a high-frequency electro-magnetic field, a tissue warming effect in continuous mode, and an athermal effect in pulsed mode is generated.

The patient group includes adults and youths persons. Operators are trained professionals such as doctors, doctor's assistants or physiotherapists in professional facilities such as doctor's or physiotherapist's practices or clinics.

The microwave therapy unit MicroPro may be used only according the intended purpose for this type – **microwave therapy in the medical treatment of human beings for gently tissue warming or athermal treatment** – in compliance with Chapter 11 Contraindications!

Microwave therapy is always an auxiliary therapy in the set of standard therapies like manual therapy, Ultrasound therapy and Current Stimulation therapy.

No side effects are known if the device is operated in compliance with the intended use.

Any other use is deemed not authorized and can cause personal injury or damage to property!

Indication

The device can be used to treat pain in the musculoskeletal system.

1.4 Warranty

For the **microwave therapy unit MicroPro** the legal warranty regulations apply.

!!

Note!
Repair of the unit be performed only by the manufacturer or a person or company authorized by the manufacturer!

1.5 Exclusion of liability

All obligations of the manufacturer are regulated by the appropriate sales contract or in case of claims for liability, by the product liability law.

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

- Unauthorized use of the unit
- Improper operation and maintenance of the unit
- Operation of the unit with protective covers removed, apparent damage to insulators (cables, radiator) or faults in the building's power supply (protective conductor, residual-current circuit-breaker)
- Failure to comply with the information in these instructions for use concerning the operation, maintenance and repair of the unit
- Use of accessories and replacement parts of other manufacturers
- Unauthorized modification, repairs or structural modifications to the unit
- Unauthorized modification of the unit controls
- Failure to inspect parts that are subject to wear
- Treatment of patients without a medical indication
- Catastrophes due to foreign objects or superior force

1.6 Symbols used in the documentation

Warning!
Warnings which have to be observed by all means!

Caution!
Observe the instructions for use!

Note!
Information that will facilitate your work.

- This dot identifies direct instructions for action.

- This dash identifies enumerated items.

1.7 Explanation of key symbols

0123 CE – conformity sign

Follow the instructions for use!

Danger for persons with pacemakers or similar implanted devices!

Do not push, rest on it and lean against it.

General warning sign. Here:
Adjustment or replacement of internal components can cause failure to comply with EN 60601-1-2 and Clause 202 of EN 60601-2-6.

Non ionizing radiation

Application part, protection degree Type B.

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment. The waste removal at the end of the service life will be done by the manufacturer.

Indicates the medical device manufacturer, as defined in EU Directive 90/385

Indicates the manufacturer’s catalogue number so that the medical device can be identified. The catalogue number is placed adjacent to the symbol.

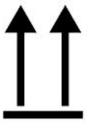
Indicates the manufacturer’s serial number so that a specific medical device can be identified. The serial number is placed adjacent to the symbol.

Indicates the manufacturer’s batch code so that the batch or lot can be identified. The batch code is placed adjacent to the symbol.

Indicates the maximum and minimum temperature at which the item shall be stored, transported or used.

Indicates that the transport package shall be kept away from rain and in dry conditions.

To indicate that the contents of the transport package are fragile and the package shall be handled with care.



To indicate correct upright position of the transport package.

2 Safety instructions

The **microwave therapy device MicroPro** and the accompanying components and individual elements fulfill singly and as a unit the currently valid safety standards and comply with the requirements of EN 60601 and the medical device directive.

The device and its external components (accessory elements) are safe when used as intended and in compliance with the explanations and instructions provided in this documentation.

Warning!
Nevertheless, the unit or its external components can pose dangers!

We therefore advise all persons working with the microwave therapy device to inform themselves about the potential dangers of the device and its external modules before carrying out any work!

Please read and observe all safety instructions in this instruction for use.

2.1 Responsibilities

- The microwave therapy unit may be used only by doctors, physiotherapists or trained assistants under the direction of a doctor or physiotherapist!
- Before treating a patient, an anamnesis must be performed by the attending physician, during which the patient must be consulted concerning possible contraindications!

An accurate diagnosis is always required for each treatment!

- All service work (safety inspections and repairs) must be performed only by service technicians who have been authorized by the manufacturer!
- For your own safety, please read the following safety instructions carefully and observe the information contained therein!
- Perform all work
  - **according to the explanations in this instruction manual,**
  - **correctly and as precisely as possible and**
  - **in compliance with the relevant safety and accident prevention regulations!**

2.2 Personal safety

Warning!

In case of improper or unauthorized use of the unit, the operator, the patient or other persons may be subjected to the danger of electric shock, the danger of influence on active implantations by electromagnetic fields produced by the device and the danger of being burned due to metal parts in and on the body or incorrectly positioned radiators or false parameters such as the duration of treatment, power output or operating mode!

- Before operating the unit, please read these instructions for use carefully and observe the information given!
- Pay special attention to the list of contraindications!

(See chapter 11 Contraindications)

- Before operating the unit each time, check whether
  - the unit has been correctly connected to the building's power supply,
  - the unit has been set up so that it is free-standing and the patient is not in direct contact with metal objects such as heating radiators, metal beds or other equipment,
  - the insulation of the power supply and radiator cable is not damaged,
  - the radiator cable is properly connected and screwed, is not in contact with the patient or with conductive or energy-absorbing objects,
  - only accessories (cables, radiator) approved by the manufacturer are connected,
  - the patient to be treated (and the personnel) have removed all electric devices (e. g. hearing aids, electrotherapy electrodes, mobile telephones) and all conductive objects (e. g. rings, chains, watches, earrings or other jewelry, glasses) and that they are not in the immediate vicinity of the unit,
  - the patient is in a composed state and the bodily areas to be treated are dry on the exterior,
  - the radiator is positioned according to the doctor's instructions (to be checked by the doctor or physiotherapist if applied by assisting personnel),
  - there is no danger of unwanted local warming due to electrode constrictions and
  - no other persons are located within 1.5 m of the radiator!
- Before using the unit, speak with the patient to make sure that
  - he is in a comfortable position during the entire treatment,
  - he is not in contact with the unit, the radiator cable, the radiator or other devices or metal objects and
  - he should (and can) let you know if he feels unwell!
- Do not treat patients on metal chairs or metal beds.

- Do not touch simultaneous the patient and touchable contacts of connectors.
- Do not treat parts of the patient's body containing metallic implants, unless special techniques are used.
- At regular intervals during the treatment, check
  - that the unit is functioning properly,
  - for moisture development[1] (perspiration) in the area of the radiator and
  - whether the patient feels well[2]!
- After the treatment, ask the patient about his tolerance of the treatment and visit the treatment environment (doctor or physiotherapist).

During service and maintenance work it is not allowed to treat a patient!

2.3 Device protection

Caution!

Improper installation, operation or maintenance of the microwave therapy unit may result in malfunctions of this device, other devices or other devices connected to the patient!

Therefore, observe the following instructions in order to prevent mal-functions:

- In order to prevent electromagnetic disturbances, place the unit at least 3 meters from any other devices! Also make sure that there is sufficient distance between the unit and power supply or data cables in walls, ceilings and floors, since the electromagnetic radiation from the unit can pass these essentially without hindrance!

In selecting the location for the unit, make sure that the patient has contact during the treatment to metal elements (especially if they are earthed), such as heating radiators, metal beds or other earthed devices!

- Before connecting the unit, make sure that
  - the voltage rating on the rating plate corresponds to the mains voltage.
  - the frequency rating on the rating plate corresponds to the system frequency,
  - an earthed socket outlet with earthing contact is available for connecting the unit,
  - the routing of the power cable from the unit to the socket outlet with earthing contact does not pose a danger for personnel or the patient and that

[1] The affected parts of the body should be unclothed during treatment, since accumulation of moisture on the skin or in folds can cause local overheating of the skin. This is especially important in case of clothing made of moisture-resistant fabric such as silk or synthetic fibers!
[2] The output power must always be set according to the subjective sense of the patient! Particular care is to be taken with patients who have a reduced capacity for heat perception!

- the power supply of the building is designed for the comparatively high (possibly additional) power input of the unit (see technical data) and the line is sufficiently protected in accordance with regulations!

Do not connect the unit to the power supply until these requirements have been fulfilled!

- Before putting the unit into operation, check to make sure that the radiator cable and the radiator are undamaged and have been connected correctly to the unit!

The device must not be placed in front of a radiator or radiant heater.
The device must not be covered by pillows or blankets while in operation.
The device is not made for outdoor operation.

- Do not treat Patients on metal chairs or metal beds.
- Keep credit cards, camera, mobile phone, car key, USB sticks, memory cards and other interference sensitive storage media away from the unit!
- Clean and disinfect the unit only when the power supply is deactivated (mains switch off, power plug disconnected)!
- Clean and disinfect the unit only by means of disinfection by wiping! Disinfecting by spraying can damage the unit due to penetrating moisture!
- Never clean the unit with abrasives, disinfectants or solvents that could scratch the housing or damage the unit!
- Never perform service work on your own!
- The device must not be used as a step or a seat!

All service work (safety inspections and repairs) must be performed only by service technicians who have been authorized by the manufacturer!

During service and maintenance work it is not allowed to treat a patient!

3 Installation

3.1 Requirements for installation

Before the unit can be installed and put into operation, certain requirements must be fulfilled in the building where the unit is to be operated!

Caution!

If the unit cannot be installed immediately after delivery, the unit and its external components or accessory elements must be stored in their original packaging in a dry place!

Do not store or operate the unit in a dusty environment!

3.2 Characteristics of the installation location

Warning!

The unit must be installed so that there is no danger to the patient, the operator or other persons!

To place the unit, each plane surface is appropriate. Please take notice of having enough space around the device to reach the power switch comfortably and to be able to pull off the mains plug. Keep a wall distance of at least 20 cm.

Warning!

The mains plug is used for all pin disconnection from the mains power supply. Make sure that the mains plug is easily reachable to the operator.

Therefore, you must read the safety instruction in Chapter 2 and the following information!

- By selecting a suitable location for setting up the unit or by means of structural measures, contact during the treatment by the personnel or the patient with conductive materials that are earthed or have a high capacity to earth must be prevented and which may provide unwanted pathways for the radio-frequency current (e.g. heating pipes, water faucets, metal chairs, metal beds or other earthed devices).
- The unit must be set up so that the (normal) release of electromagnetic radiation during operation does not hinder the function of other devices or data media. The minimum distance to other devices or their power supplies or data transfer lines is 3 meters! Please note that the radiation can easily pass walls, ceilings and floors.
- The room and the installation location must be large enough so that the unit can be operated from the front even if the radiator is positioned inconveniently.
- The unit is not intended for use in potentially explosive areas.
- The unit is not intended for use in areas with inflammable anaesthetics.

3.3 Transport of the unit

Measures concerning the transport of the unit from the manufacturer to the operator are based on the individual circumstances and are defined in the general terms of business.

In the transport position, the support arm points vertically upwards. Radiator and radiator cable may be mounted in the transport position.

In the event of subsequent transport of the unit, the dealer or the operator is responsible for the unit and for compliance with the safety and accident prevention regulations.

3.4 Unpacking the unit

The unit is generally delivered with the packaging material supplied by the manufacturer. Since the unit weighs approximately 44 kg without support arm, radiator and radiator cable, it must be unpacked by at least two persons.

Proceed as follows:

- Position the transport packaging so that the arrow mark is pointing upward.
- Remove the safety bands from the transport packaging.
- Remove the transport packaging upward.
- Remove the remaining foam material.
- At least two people should lift the device out of the lower part of the packaging using the two handles.

3.5 Receiving inspection

Perform the following steps directly after unpacking the device:

- Verify the delivery documents to make sure that the delivery is complete.
- Check all components (device, external components and accessories) for possible damage due to transport and defects.

In case of damage from the transport, report to the forwarding company and the distributor. Do not put the device into operation if it is damaged.

Warning!
In case of damage from transport that could endanger personal safety, the unit must not be connected to the power supply!

3.6 Complaints

Claims for damages resulting from transport damage can only by asserted if the transport company and the manufacturer are informed immediately. Notification of the manufacturer and the remedy of the damage are generally carried out by the dealer.

- Immediately create a damage report and send it to the transport company and to the dealer.
- When returning the unit, include the following information:
  - Name and address of the sender and receiver
  - Type and serial number of the unit
  - Description of the defect (damage report)
  - Date and signature

4 Description of the unit

4.1 Operator side

Fig. 4-1 Front view – MicroPro

4.2 Patient side

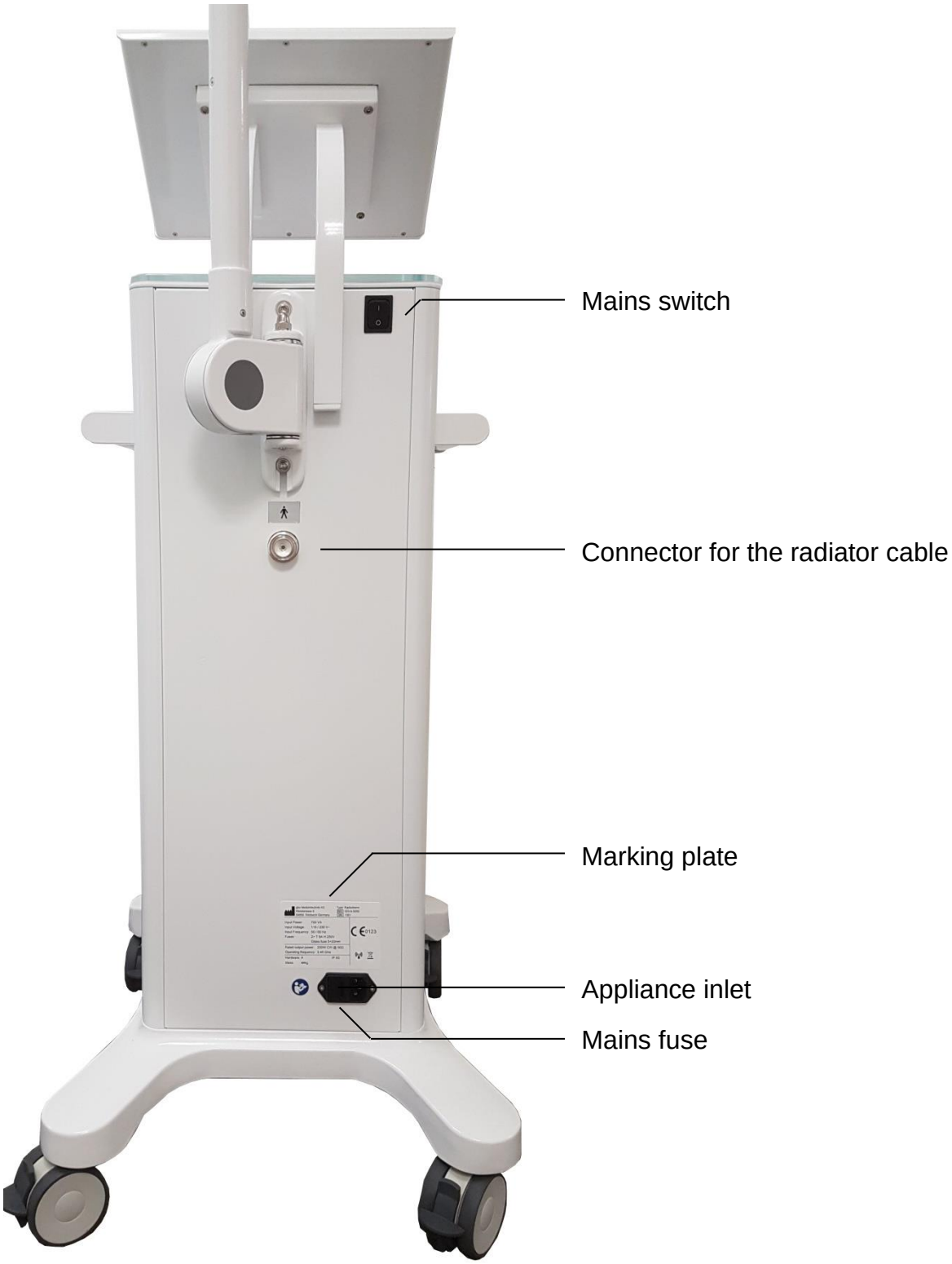


Fig. 4-2 Back view – MicroPro

4.3 Accessories

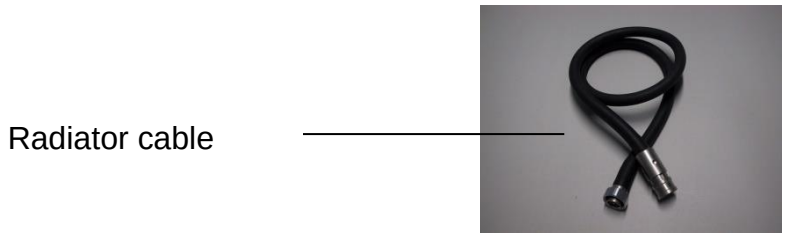


Fig. 4-3 Radiator cable

Fig. 4-4 Focus radiator

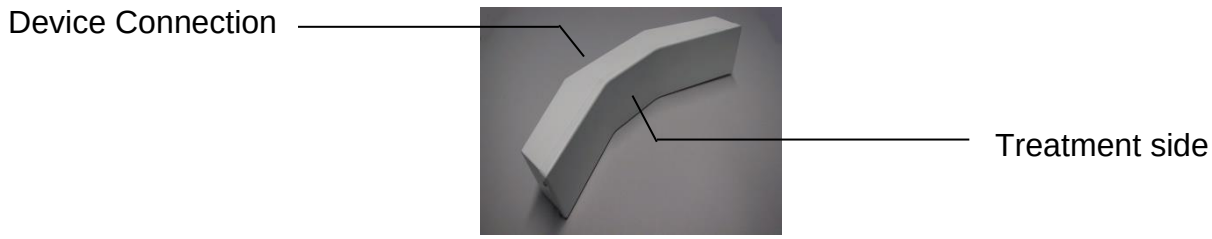


Fig. 4-4 Cradle radiator

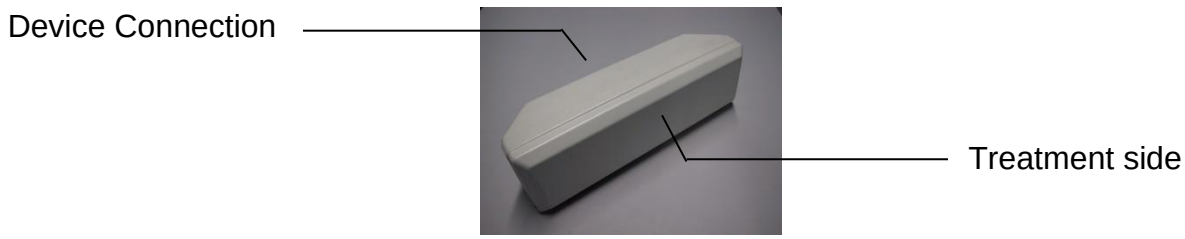


Fig. 4-6 Long-field radiator

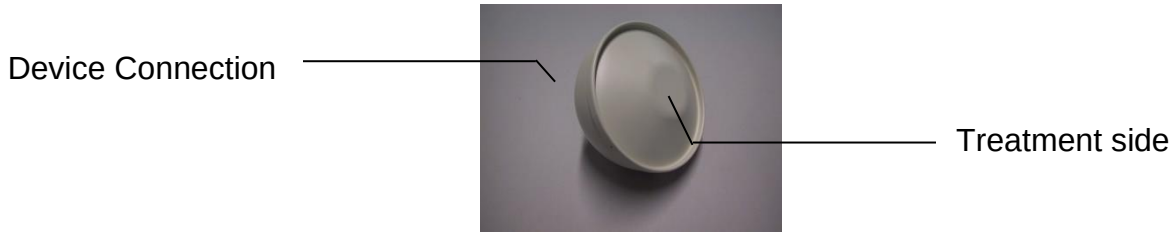


Fig. 4-5 Circular-field radiator

5 Description of functions

The microwave therapy unit MicroPro can produce dielectric warming by means of electromagnetic fields of varying intensity in essentially any region of the body and can therefore be used for a wide variety of applications.

Treatments can be carried out using a variety of different radiators. Depending on the treatment the circular-field, the focus, the cradle or the long-field radiator may be used.

5.1 Applications

The microwave therapy unit is suitable for nearly all heat therapy processes for use in clinics and private practices.

Classical therapy applications can be conducted with different radiators in continuous or pulsed mode.

The application of high-frequency energy in heat therapy has the advantage of greater depth penetration as opposed to simpler methods, such as packs, baths, infrared light and heat cushions.

Zimmer MedizinSysteme GmbH microwave therapy units are therefore used for a wide range of applications in hospitals, by doctors and physiotherapists.

5.2 Information for use of the radiator

- Patients with diminished capacity for perception of heat in the area intended for microwave therapy should not be treated.
- Patients who are not able to give quick response according to the microwave treatment should not be treated.
- Radiators should not be oriented to eyes or testicles.
- If necessary patients should wear radiation protection goggles.
- Persons who are not treated should at least stay away 1.5 m to the radiator.

5.3 Microwave therapy with circular-field radiator

The circular-field radiator, the so called distance radiator, is used for irradiation of body parts with locally defined disease processes. Typical application areas are e.g. shoulder or knee joint, jaw joint, lower arm carpal region, tenovaginitis, etc.

The proper treatment distance between radiator and body part should be about **10 cm**. If the distance is increased the set power output is distributed upon a larger area and thus upon a larger body volume. This means that the power output meeting the affected body per surface unit is decreased. By that also the yielded warmth is reduced.

5.4 Microwave therapy with focus radiator

The focus radiator is determined for treating very tightly limited body parts. This kind of radiator is preferably used for the head area (**ENT** etc.). During the treatment the radiator is to lay upon the skin.
The focus radiator can only be used with a maximum output power of **25 W**. The power limit is granted by radiator identification.

Caution!
During treatment respect that the radiator must not be directed at eyes.

Patients should wear radiation protection goggles.

5.5 Microwave therapy with cradle radiator

The cradle radiator enables a comprehensive exposure to radiation of body parts of medium and large diameter. This radiator has to be put generally direct on the application area. A sufficient distance between radiator and the patient's body is already provided by its design.

By concentric penetration of the energy a higher depth effect can be reached imposing the same strain to the skin.

5.6 Microwave therapy with long-field radiator

This radiator is used for irradiation of elongated parts of the body. The proper treatment distance between radiator and body part should be about 5 cm.

6 Start of operation

The unit has been completely assembled in the factory and is ready for use except the installation of the radiator and the radiator cable.

Warning!
For preventing a change of the radiators directionality it should be handled gently.

Proceed as follows in order to prepare the unit for operation:

- Set the mains switch to the off position.
- Make sure that the voltage indicated on the type plate matches the mains voltage of the building.
- Plug the radiator cable into the socket on the back of the unit and screw it.
- Insert the radiator cable into the recess at the upper end of the support arm. Subsequently fasten the radiator cable with the locking screws.
- Connect the free end of the radiator cable to the desired radiator. Therefore the locking ring of the coupler must be pulled back towards the support arm. Subsequently insert the radiator connector fully into the coupler and release the locking ring. The locking ring must spring back to its original position. Push and pull the radiator in the axial direction of the coupler to ensure that the locking ring has also properly engaged. The radiator is now firmly connected.
- Plug the cold appliance plug into the corresponding socket on the rear of the unit.

6.1 Check for operational safety

Warning!
The unit and the radiator must be positioned so that there is no danger of personal injury! Therefore, you must read and observe the safety instructions and the list of contraindications before putting the unit into operation!

(See 2 Safety instructions and 11 Contraindications)

- Check the condition of the housing and the insulation of the radiator, radiator cable and the power supply cable. Also make sure that the cables have been routed correctly.
- To avoid risk of electric shock, the MicroPro must only be connected to supply mains with protective earth.
- The mains plug is used as separation measure to the mains. The device must not be positioned in such a way that the mains plug cannot be reached.

6.2 Moving the device

To move the device, establish the transport position by aligning the support arm vertically upwards. Remove the mains plug and loosen the lockable castors. Now the device can be moved in all directions.

Caution!
Due to the possibility of overbalancing, the device must always be moved in transport position with the holding arm pointing vertically upwards.

To overcome a threshold, move the device slowly over it and, if necessary, lift the device slightly.

6.3 Positioning the radiator

- Position the required radiator on the part of the body to be treated according to the medical indication. Please note the following information:

Caution!
Please note that positioning of the radiator may only be made when the power is switched off!

Local overheating can occur with the presence of metal foreign bodies (e.g. earrings, metallic implants) in the electromagnetic field.

6.4 Switching on the unit

- Connect the MicroPro with the mains cable to an earthed socket with a functioning protective ground conductor.
- Switch on the device with the mains switch.

After switching on the unit by means of the mains switch, a short self-test is conducted. After that the main menu appears.

6.5 Beginning treatment

The treatment is always started from the main menu by turning up the output power to the desired value with the intensity regulator starting from zero.

Caution!
In order to prevent unbearable warming of tissue, the individual diminished capacity for perception of heat must be respected while setting the output power.

According to Schliephake the patient's subjective sensitivity to heat can be divided into four stages according:

Dose I: Heat not perceptible. First set dose so that there is a slight sensation of heat, and then turn control back slightly.

Dose II: Heat just perceptible.

Dose III: Heat noticeable, pleasant.

Dose IV: Heat still tolerable.

Before beginning treatment you must read and observe the safety instructions and the list of contraindications.

Begin the treatment as follows:

- Make sure that the radiator is in correct position.
- Check the parameter setting.
- By turning the intensity regulator slowly increase the output power. Observe the well-being of the patient (verbal response).
- If necessary, adjust the parameter setting during the treatment.

Note!
During active treatment it is not possible to switch directly from continuous mode (CW mode) to pulsed mode and vice versa.

6.6 Interrupting / ending treatment

- To interrupt the treatment, turn the output power back to 0 W or wait until the treatment time has elapsed.
- Remove the radiator from the patient and enquire the patient's condition.

6.7 Placing out of operation

In order to place the device out of operation, no further measures are required apart from disconnection from the mains power supply. The treatment can be stopped at any time by turning the output power back to 0 W.

7 Operating

The MicroPro is equipped with a touch screen display, an on/off switch and a connection plugs for the radiator cable.

The MicroPro is operated via the control panel of the touch screen. The user will obtain explanations regarding the device's operation und functionality of individual elements via a help system during operation.

7.1 Display and control elements

Every button is clearly labeled. Visually, the user can differentiate operating from non-operating, grayed-out buttons. In case of doubt, the user can obtain further information via the direct help system.

The sliders or control wheels are operated as on a PC: touch the slider and drag it to the desired position. Control wheels have to be touched and turned in the desired direction. If a control wheel is released while turning it will stop after short time.

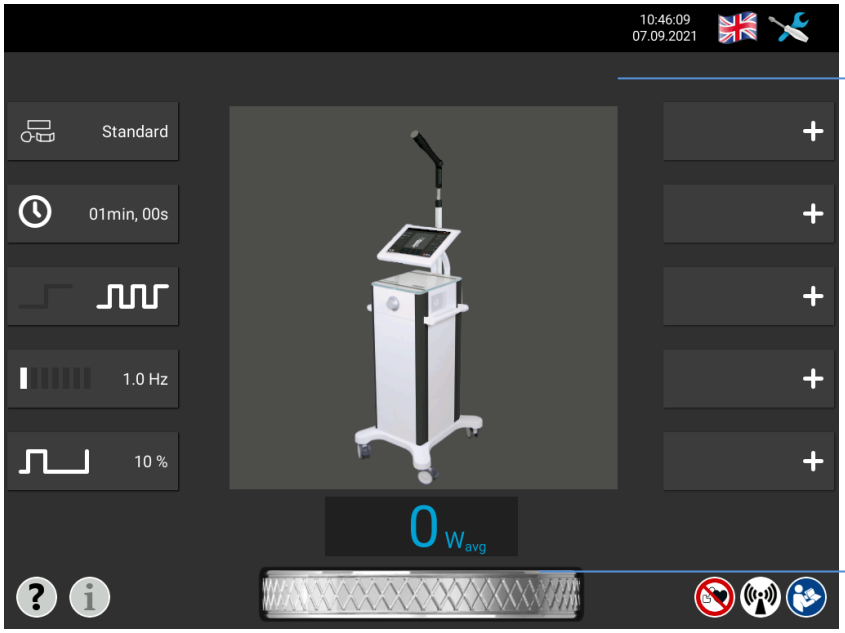


Fig. 7-1 Display and control elements

The intensity regulator is used to adjust the output power during therapy. The power is increased by turning to the right and decreased by turning to the left. The intensity is shown in Watt on the display. To set the desired intensity, it may be necessary to turn the regulator several times.

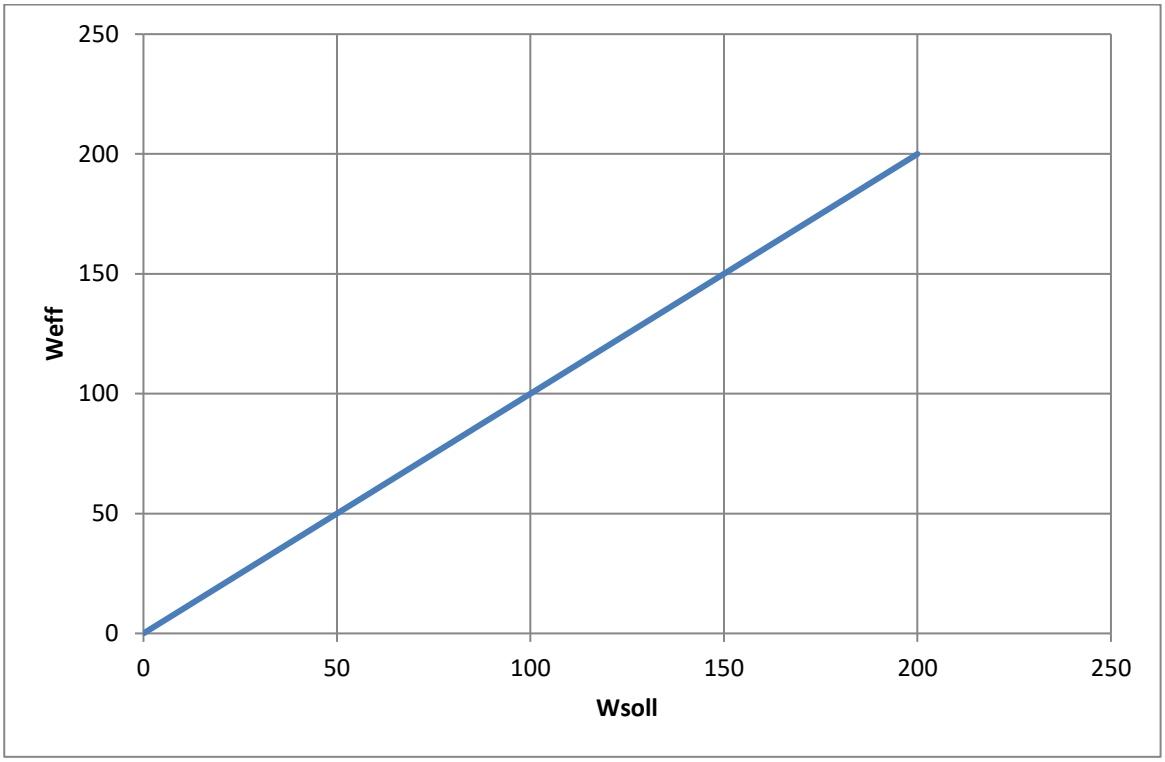


Fig. 7-2 Effective output power depending on the set power

Note!

Increasing the intensity appears as long as the finger touches the intensity regulator and is moved to the right.
Decreasing the intensity starts by moving the finger at the intensity regulator to the left. Here, an acceleration function and trailing is present, allowing the intensity to be reduced in short time.

The USB port and the SD card reader on the back of the touch screen display are only for connecting USB sticks and SD cards. Printers, scanners, cameras, keyboards and other devices with USB Interface are not suitable for the USB port.

7.2 Main menu

The main menu is displayed when the device is switched on. The therapy parameters are displayed on the left side of the screen. Below these are the buttons for direct help and for service information.

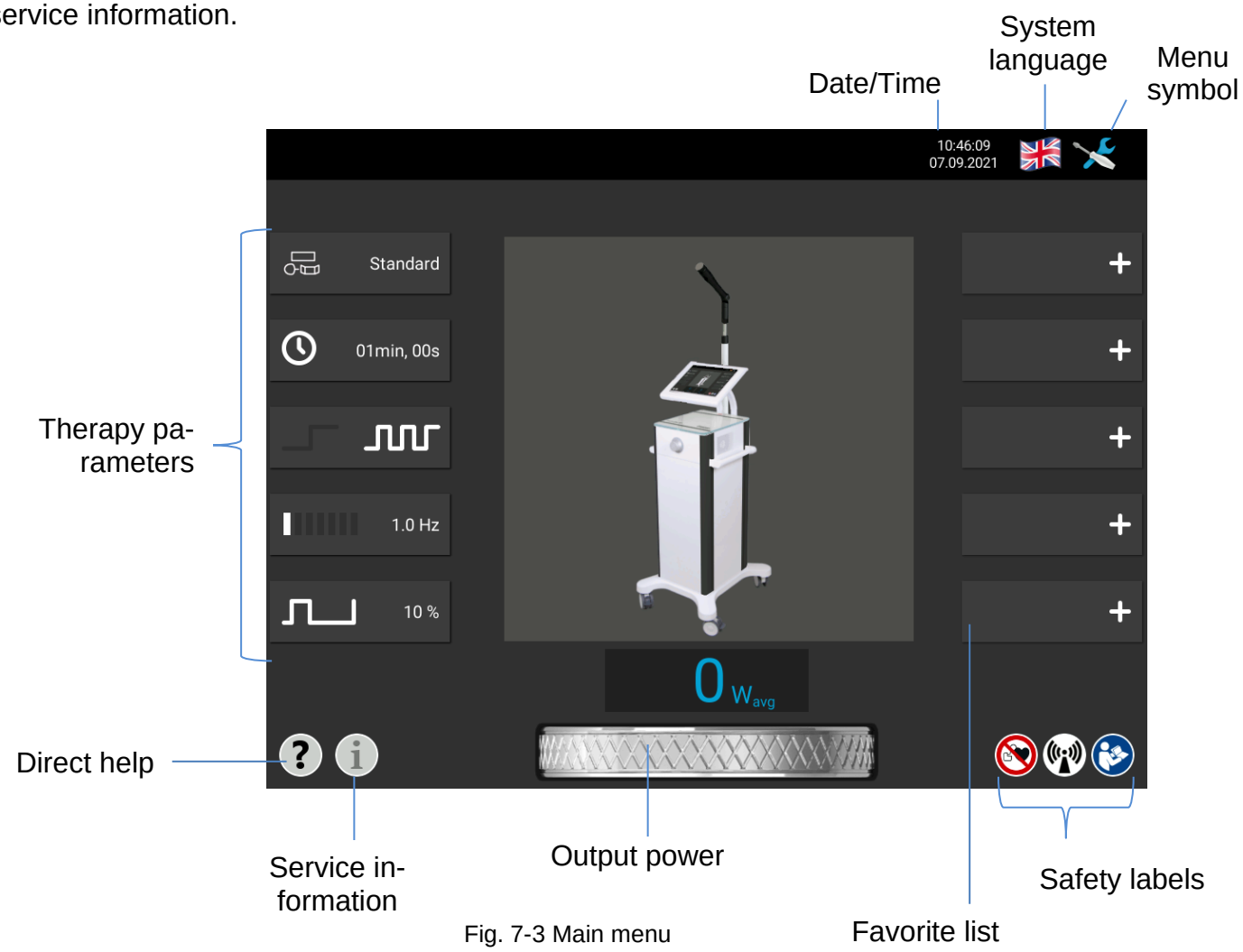


Fig. 7-3 Main menu

On the right-hand side, the current time and date can be seen at the top of the screen. To the right is a flag indicating the currently set system language, which can be changed by pressing it. Next to it is the menu symbol. Pressing the menu symbol opens a menu with options for saving therapies, settings, applications or service. Below the menu symbol is the Favorites list and at the bottom of the screen there are warning labels to be observed.

7.3 Direct help

The user of the MicroPro is guided by the operating software. The direct help explains the selected buttons directly on the screen.

Fig. 7-4 Direct help

To call up the direct help press the “?” button. The button lights up green after selection. Then press the button for which you desire information. An information window opens, which gives information about the selected button. Pressing another button opens a new information window. The direct help can be closed again by pressing an open information window or by pressing the “?” button.

7.4 Settings

The settings menu can be accessed by pressing the menu symbol in the upper right corner of the screen and then pressing the “Settings” button.

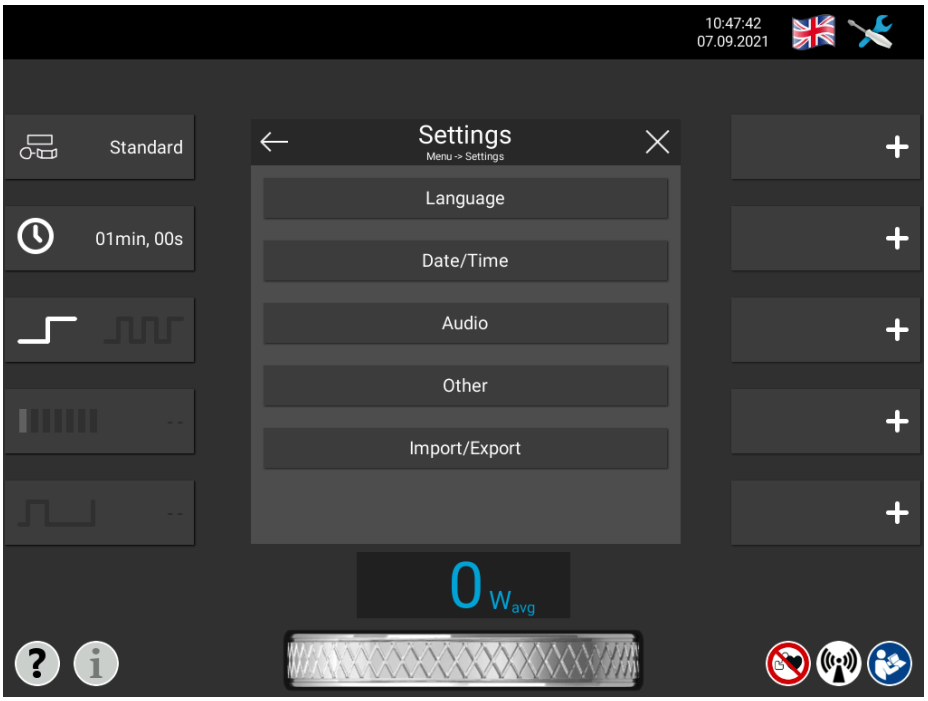


Fig. 7-5 Settings menu

You find the following items in the settings menu:

Language By pressing a country flag, the language corresponding to the country can be selected as the system language.

Date/Time Both the date and time as well as the date format and time format can be changed here. Also it is possible to change the time zone.

Audio System tones, such as the end of therapy tone, can be changed here. The tones can be listened to and assigned to the corresponding functions. The volume of the tones can be adjusted. There is an option for repeating tones.

Other Under this point the name of the practice and the brightness of the display can be changed.

Import/Export Under this point the own therapy settings can be exported to USB stick or SD card.

8 Therapy

The parameters for the therapy are selected via the selection keys on the left side of the screen. The connected radiator is shown.

Directly underneath there is a selection button for the treatment duration. The third selection key can be used to set the impulse or continuous operation mode. In pulse mode, two further selection keys can be used to set the pulse frequency and pulse width. In continuous operation, the selection keys for pulse frequency and pulse width are inactive and grayed out. The lower part of the screen displays the effective output power (patient effective power).

Fig. 8-1 Main menu

The therapy is started by adjusting the output power with the intensity regulator. The setting must always be set according to the subjective sense of the patient! The treatment duration starts to count down. Once the time is elapsed, the therapy is terminated, the output power is reset to 0 W.

The therapy can be terminated at any time by turning the output power back to 0 W.

8.1 Saving a therapy

A therapy can be given a name and saved. By opening the menu and then pressing the "Save therapy as" button, a keyboard opens. Enter the desired name for the therapy and save the therapy by pressing the Return key “↵”.

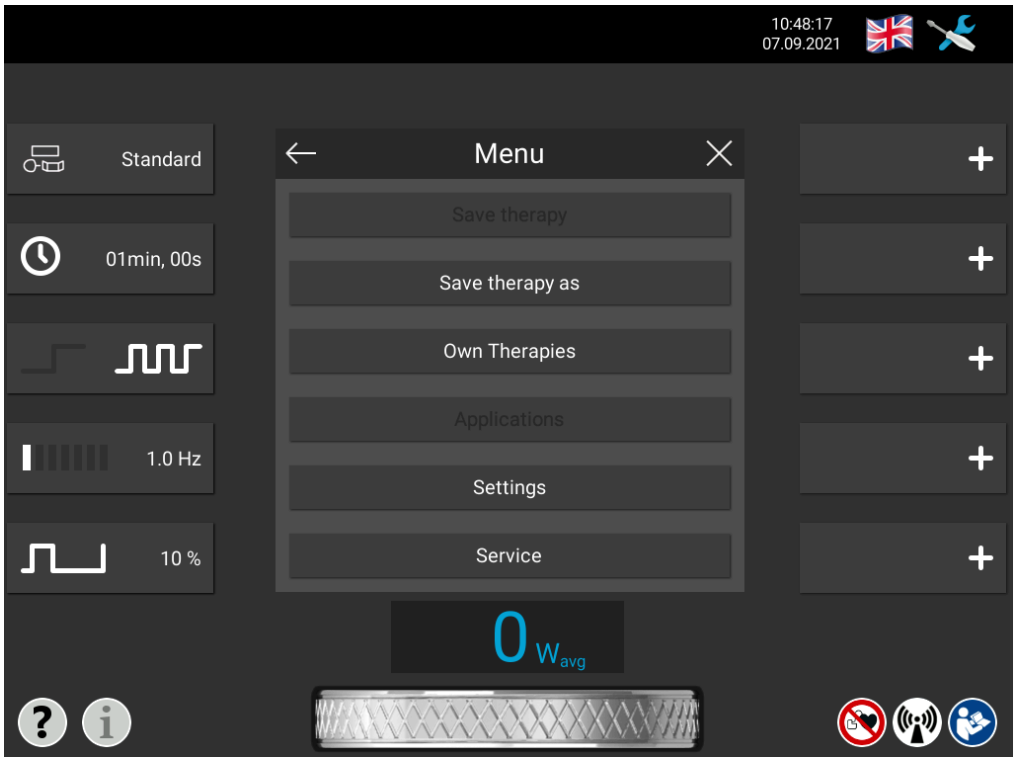


Fig. 8-2 Menu bar

All saved therapies can be found under "Own therapies" in the menu. Individual therapies can be accepted, changed and deleted here.

The parameters of an already saved therapy can be changed. To save this change, open the menu and press the "Save therapy" button. Changes to a therapy that have not been saved are indicated in the main menu by square brackets around the therapy name.

8.2 Frequently used therapy settings (favorites)

The user interface makes it easy for the user to quickly start frequently used therapies. Therefore it is possible to save the current settings of the therapy by pressing on a free favorite field on the right side of the screen.

Al already saved therapy under “Own Therapies” can be accepted and additionally added to the list as a favorite by pressing on a free field.

Pressing and sliding a Favorite to the right will delete it.

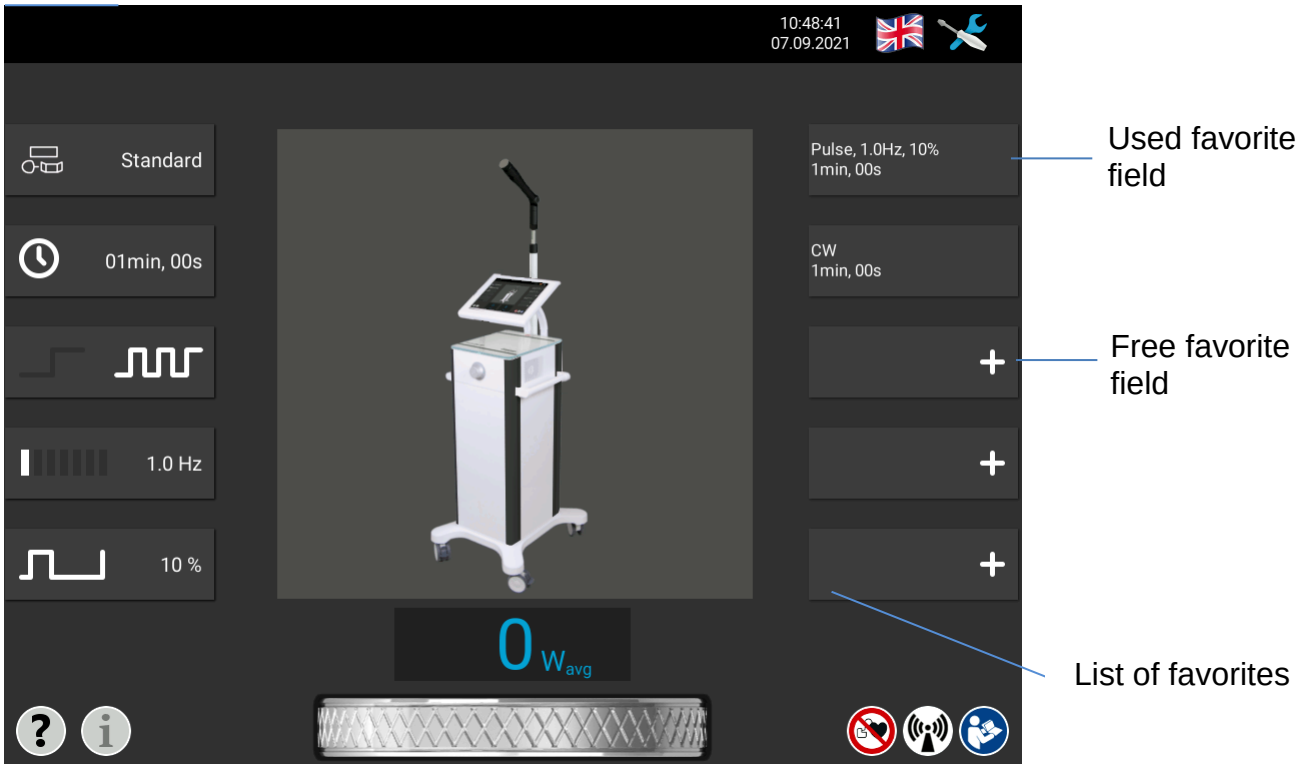


Fig. 8-3 Frequently used therapy settings

9 Maintenance

Performance, reliability and safety characteristics of the device are guaranteed only if the device is handled in accordance with the instructions for use. Safety checks, maintenance, repair and modifications must only be carried out by the manufacturer or by service agents authorized by the manufacturer. In the event of failure, parts which affect the safety of the device must only be replaced by original spare parts from the manufacturer. The electrical room installation must comply with the requirements of VDE/IEC.

The device does not contain any parts that have to be maintained by the user.

Warning!
No parts of the device are allowed to be serviced while a patient is under treatment.

However, the operator has the option of selecting the Submenu “System information” under the point “Service” in the menu bar. This includes information about the “Software version”, “operating hours” and “serial number” of the device.

With the point “Reset” the therapy settings already made can be reset to default values. A further point is the export of an error log file. In order to export the error log, a USB stick must be connected to the USB socket behind the display. The button “Service menu” respectively the menu behind is reserved for service partners and helps to search for errors in the hardware.

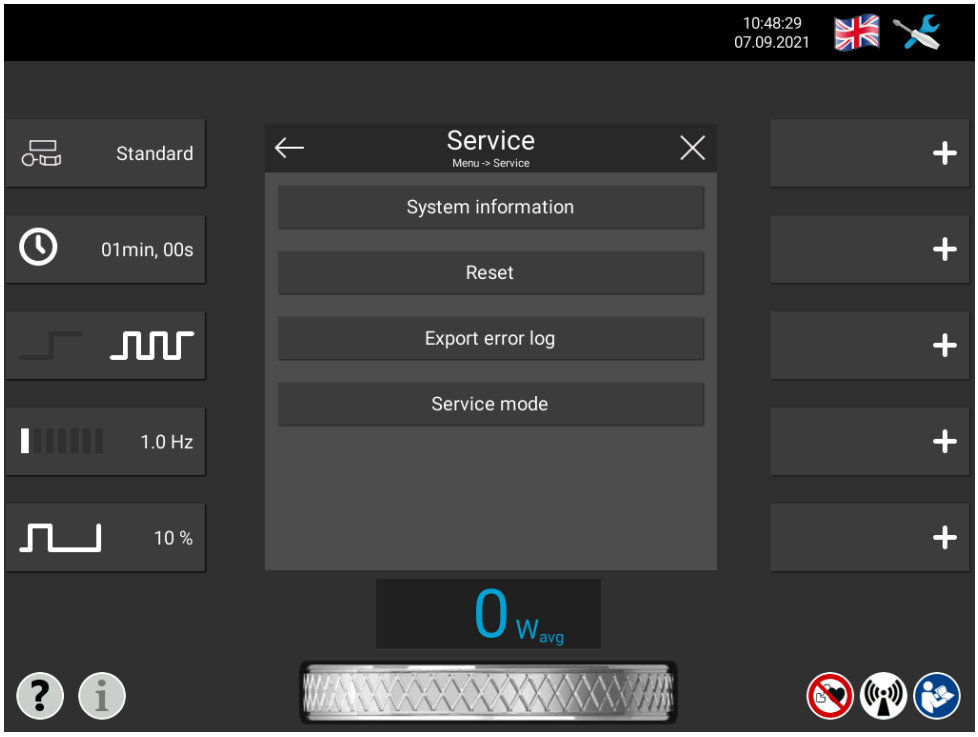


Fig. 9-1 Service options

9.1 Legal requirements and regulations

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be observed in particular.

9.2 Technical safety checks

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked by the manufacturer or by a maintenance service authorized by the manufacturer every 12 months.

Refer to separate periodic safety check list for details.

The check includes inter alia the following criteria:

Visual inspection

- Housing undamaged?
- Power cable undamaged?
- Radiator connection sockets undamaged?
- Mains switch OK?
- Radiator cable undamaged?
- Radiator undamaged (no cracks or brittle material)?

Functional test

- Correct function of the indicators
- Operation via touch screen possible
- All fans working

Electrical test (acc. to IEC 62353)

- Device leakage current
- Protective conductor resistance
- Isolation resistance

Note!
The safety inspections have to be documented in a medical device book in order to document the results of the inspection.

Warning!
If the unit is not safe for operation, then it must be repaired by the authorized service personnel.

9.3 Cleaning and disinfection

For cleaning and disinfection of the device and accessories, do not use any agents containing larger amounts of phenol derivatives, chlorine compounds or peracetic acid. Never use an abrasive. Fingerprints on the touchscreen can be cleaned with a dry cloth or some isopropanol.

- Switch off the device at mains switch.
- Unplug the mains plug from the socket before cleaning or disinfecting the unit.
- Clean and disinfect the unit and its accessories on all external surfaces by wiping with a slightly damp cleaning cloth. Use a commercially available cleaning or disinfection agent that is intended for use in medical facilities.
- Wait until the unit is completely dry before operating it again.

Note!
The device is suitable for wipe disinfection. We recommend Bacillol-AF for the disinfection. (Please follow the recommendations of the manufacturer.)

Caution!
Under no circumstances may liquid penetrate the openings on the unit, e.g. the connecting sockets of the radiator cable! Therefore, do not use cleaning or disinfectant sprays! The unit, radiator and cables may not be sterilized using steam or gas.

Never clean the unit with abrasives, disinfectants or solvents that could scratch the housing or damage the unit.

9.4 Repair

Warning!
Do no perform service work under any circumstances!

All service work (safety inspections, repairs) may only be performed by service personnel authorized by the manufacturer!

9.5 Disposal of the device and accessories

According to the WEEE Directive 2012/19/EU (waste electrical and electronic equipment) this device must not be disposed of with the domestic waste. The device must be returned to the manufacturer for disposal. The manufacturer is committed to guarantee the disposal of all devices marketed. This is also indicated by the WEEE sign (crossed out waste container).

The device and also the accessories must be cleaned before the disposal.

10 Troubleshooting

Problems are indicated by the device acoustically and optically on the display. Most of the problems can be solved by following the instructions on the display.

In general:

- The malfunction is shown on the display.
- An acoustic error signal is heard.
- Follow the instructions on the display.

Additional suggestions:

- Turn off the unit and turn it on again.
- If the error occurs again, the device is not functioning. Please contact a service authorized by the manufacturer.

Further errors:

Symptom	Probable cause	Possible remedy
The device cannot be switched on. No display shown.	Power supply interrupted. Mains cable, mains plugs or sockets defect or not properly connected.	1. Check that the mains cable, mains plugs and sockets carry voltage. 2. Check the mains cable, mains plugs and sockets for integrity and whether the plugs are properly connected to the sockets.
No acoustic signal is heard (e.g. end of therapy).	Volume of the acoustic signal to low.	Check the audio settings in the “Settings” submenu of the menu bar. The volume must be greater than 0.
Texts in the display are not readable. Unknown font.	Wrong language selected.	Check the language settings. Press the flag in the top right corner and select your preferred language.

Please contact your service agent or the manufacturer if the problems cannot be solved by the measures mentioned above.

11 Contraindications

The following list of contraindications, which is based on the current knowledge, has always to be observed when applying microwave treatment for therapeutic purposes!

Always be sure to ask the patient about these contraindications, as not all contraindications are immediately recognizable by the therapist (e.g. pregnancy)!

In addition, any external signs that might point to the existence of contraindications (e.g. scars, etc.) should always be reason enough to ask the patient about contraindications!

As a rule, any microwave therapy must be strictly based on an accurate diagnosis!

11.1 Absolute contraindications

- Anesthetized patients
- Limitations in reactivity, cognitively impaired patients
- Febrile infections, acute infections, acute injuries
- Tuberculosis
- Haemorrhages or risk of haemorrhage
- Septic conditions and empyemas
- Malignant tumors and tumors that are not yet identified, active cancer treatment
- Patients with cancer in prior two years
- Severe heart diseases (heart valve diseases, myocardial insufficiency, myocardiac infarct, severe coronary sclerosis)
- Impaired or defective arterial circulation, ischemia, thrombosis
- Epiphyseal cartilages in children until completion of growth
- Lymphedema
- Severe osteoporosis
- Patients with pathologic conditions known to be sensitive to increased cell proliferation rates

11.2 Local contraindications

- Metal and/or active implants including pumps, pacemakers and electrodes, metal inclusions, stents, stent grafts
- Swellings
- Thermal hyperesthesia
- Thermal hypoesthesia
- Acute inflammations, local infections
- Severe arterial obstructions (stage III and IV)

- Gynecological disorders involving acute inflammation
- Wetness, perspiration or damp bandages
- Pregnancy, because irradiation of the abdomen could cause teratogenous damage
- Menstrual bleeding
- Sudeck's syndrome, stage I and II
- Basedow's disease (irradiation could cause serious states of agitation)
- Varicose veins (irradiation could cause inflammation and thrombosis)
- Coloured and white tattoos
- Wet clothing
- Endoprostheses of hip, knee, shoulder…
- Screw connections and stabilization of the spine
- Treatment of the skin with radiotherapy in the last 6 month, recent radiotherapy

11.3 Of particular importance

- It is recommended not to use clothing for microwave therapy on patients. Conductive material should be excluded from the treatment area. The therapy must not be used on patients who wear metallic objects such as jewelry or clothing containing metallic material (e.g. metallic buttons, clips or threads).Particular care must be taken if the patient's clothing is wet or damp, since the garments may heat up faster and more intensely than the patient's body.
- Synthetic fibers (perlon, nylon, etc.) are characterized by low absorbency, which can cause the skin beneath such fabrics to quickly become moist.

  Therefore, it is recommended that the body areas to be treated be completely unclothed and the patient's skin dried, particularly where perspiration accumulates in folds of the skin. This applies especially when a higher dosage is being applied.
- Since the effects of high-frequency fields on unborn life have not yet been sufficiently researched, we recommend that operators who are pregnant do not remain in the immediate vicinity of the applicator when the unit is activated.
- The output power must always be set according to the subjective sense of the patient! Therefore, special care must be taken in case of patients with a diminished capacity for perception of heat!

Caution:

At this point it has to be pointed out that it is advisable to place warning notices for pacemaker wearers in rooms in which high-frequency therapy (e.g. microwave therapy) takes place.

Moreover, a distance of at least 3 m must be maintained between the unit and any low-frequency therapy that is being carried out at the same time!

11.4 Known side effects

Possible side-effects have been rarely reported in total during the application of this type of therapy and were not of a serious nature. It is important to note that they are related to the type of therapy, not to the device itself:

- Transient aggravation of symptoms
- Dizziness
- Erythema
- Itching
- Flaking skin

11.5 Information for the therapist

Pregnant therapists should not operate the device.

Operating personnel should maintain a distance of at least 1.5m during emission of HF energy.

12 List of standard and optional accessories

Accessories included:

MicroPro			**58090010**
	1	Instructions for use	10105289
	1	Adjustable electrode arm (self-locking, extractable)	58090022
	1	Radiator cable	58090019
	1	Radiation protection goggles	58090020
	1	Mains cable	58090024
	1	Suction cup (for service technician)	58090023
	1	Test lamp	58090021

For the **MicroPro** we offer a large variety of accessories:

Specification	**Part number**
Circular field radiator	58090018
Long-field radiator	58090016
Cradle radiator	58090017
Focus radiator	58090015
Radiator cable	58090019
Radiation protection goggles	58090020
Mains cable	58090024
Test lamp	58090021
Fully adjustable electrode arm (self-locking, extractable)	58090022

!!

Note!

Only use Zimmer Medizinsysteme original accessories to ensure safe operation of the device.

13 Technical data

Supply voltage:	230 V~ (Modifiable to 115 V~)	
Supply frequency:	50/60 Hz	
Power consumption:	900 VA	
Mains fuses:	2× T4A H 250V, Glass fuse 5 × 20 mm	
Output frequency:	2.45 GHz ± 1.5%	
Output power:	200 W ± 20 %, continuous mode, in 10 W increments 200 W AVG in pulsed mode	
Accuracy of timer:	± 2 %	
Type of radiation:	Non-ionizing	
Applied part:	Complete applicator	
Type of applied parts:	B	
Load Impedance:	50 Ω	
Mode of operation:	Continuous	
MDD device class:	IIa	
Protection class:	I	
IP class:	IP X0	
Dimensions*:	1110 x 450 x 530 mm (h × w × d)	
Weight:	44 kg	
Display:	12.1“ TFT with capacitive touchscreen	
Battery:	CR 2032	
Measurement of the rated output power:	HF power meter	
Environmental conditions:	Operation of the device:	Temperature range +10 ... +35°C Relative humidity 30 ... 75 % Air pressure: 780 … 1060 hPa
	Transport and storage:	Temperature range -10 °C ... +50°C Relative humidity < 90 %, not condensing Air pressure: 730 … 1060 hPa

* Without radiator, support arm and radiator cable

By request, spare parts list and circuit diagrams can be offered to technical personnel for repair purposes.

The mains inlet is used for all-pin disconnection from the mains power supply. Make sure, that the mains inlet is easily reachable to the operator.

The exchange of the battery is described in the service manual.

To check the output power the included test lamp can be used. During therapy hold the test lamp close to the radiator.

Warning!
The test lamp can be only used to check if the device is emitting microwave power. This test doesn't show the level of the emitted microwave power. To get an exact inspection of the output power please contact a service technician

Zimmer MedizinSysteme GmbH reserves the right to modify design and specifications without prior notice.

14 Appendix

Comments according to the Medical Device Directive

The **MicroPro** is a mains operated microwave therapy device of protection class **I**.

The device is in accordance with the EC directive for medical devices (93/42/EWG) and therefore carries the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type plate.

The **MicroPro** is class **IIa** device according to the MDD.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

- the device is used in accordance with the instructions for use;
- the electrical installation of the location where the device will be used meets the respective current requirements of electrical safety;
- the device is not used in potentially explosive environments and humid locations;
- mountings, amplifications, re-adjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
- the operator regulation of this EC directive is observed within the scope of MDD.

Technical support may be obtained by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 7 years.

MicroPro is an electronic device. For its disposal the according regulations for electronic devices have to be observed.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare parts lists, and adjustment instructions as far as these are necessary for the qualified technical staff of the operator.

Comments on electromagnetic compatibility (EMC)

Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the ac-companying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are **obliged by law** to provide the following information.

Guidance and manufacturer's declaration – electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions, CISPR 11	Group 2	The equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions, CISPR 11	Class B	The equipment is suitable in all establishments including than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD), IEC61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV outer conductor – outer conductor ±2 kV outer conductor - ground	±1 kV outer conductor – outer conductor ±2 kV outer conductor - ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	0 % U_τ for ½ cycle in 45° steps (100 % dip) 0 % U_τ for 1 cycle (100 % dip) 70 % U_τ for 25 or 30 cycle at 50 or 60 Hz (30 % dip) 0 % U_τ for 250 or 300 cycle at 50 or 60 Hz (100 % dip)	0 % U_τ for ½ cycle in 45° steps (100% dip) 0 % U_τ for 1 cycle (100 % dip) 70 % U_τ for 25 or 30 cycle at 50 or 60 Hz (30 % dip) 0 % U_τ for 250 or 300 cycle at 50 or 60 Hz (100 % dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted HF disturbances, IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff} in ISM and amateur radio bands	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff} in ISM and amateur radio bands	Recommended separation distance $d=1,2\sqrt{P}$
Radiated HF disturbances, IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distance $d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Comments on software

This device uses free/open software and software from third parties, which meet the conditions of the GNU General Public License v2 and v3 (GPLv2/GPLv3), the GNU Lesser General Public License v3 (LPGLv3) and/or other copyright licenses, disclaimers and notes.

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Notes

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