Zimmer
MedizinSysteme

Instructions for Use

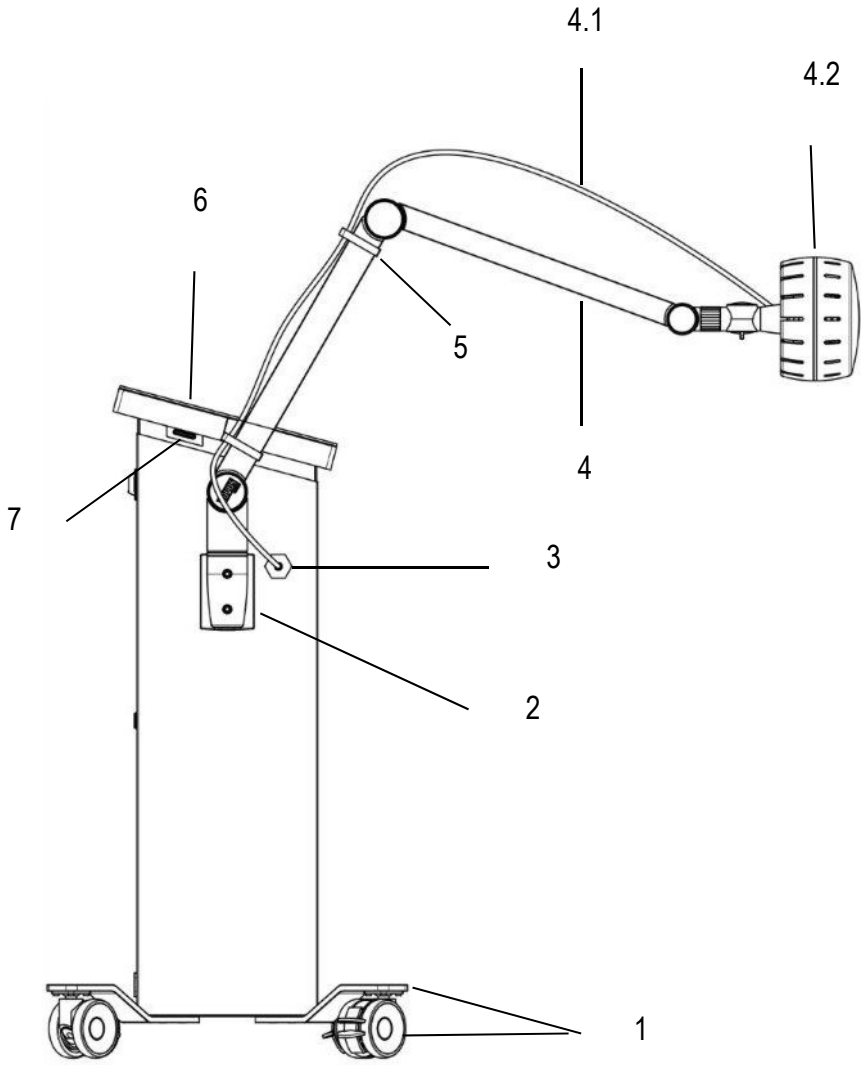
Thermo*Pro*

GB

Illustrations

Side view of the Device

Fig. 1



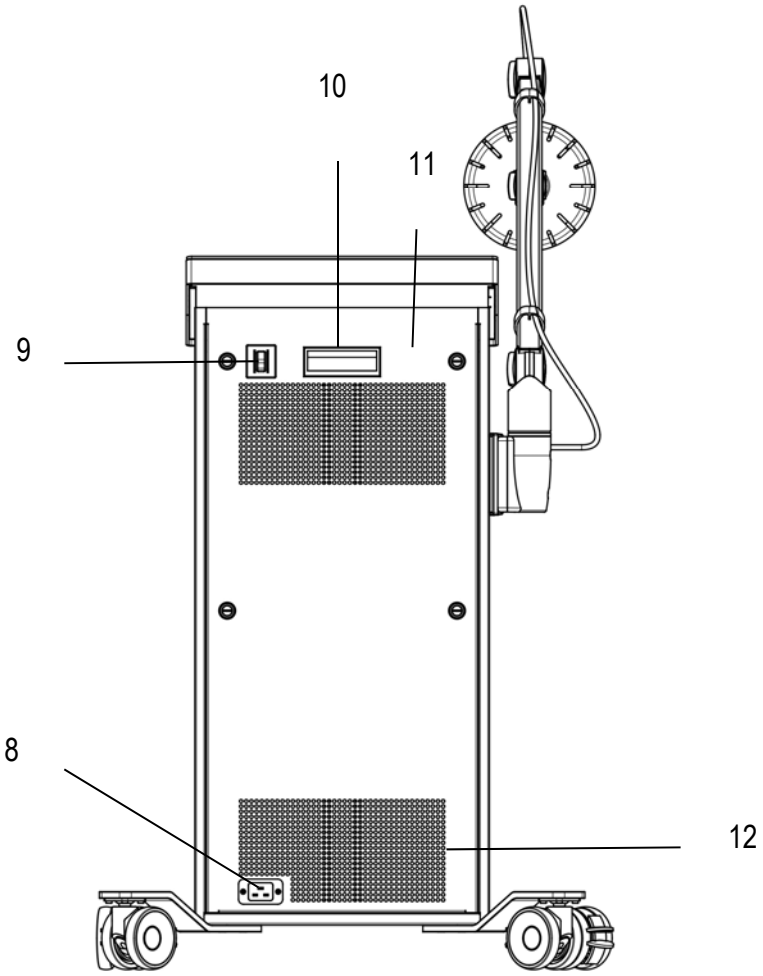
Device and Operating Elements

1 Mounting bracket with castor including locking device
2 Connection for supporting arm
3 Applicator cable connection
4 Supporting arm including applicator cable (4.1) and applicator (4.2)
5 Cable clip
6 Display
7 Slot for SD card

Illustrations

Rear view of the Device

Fig. 2

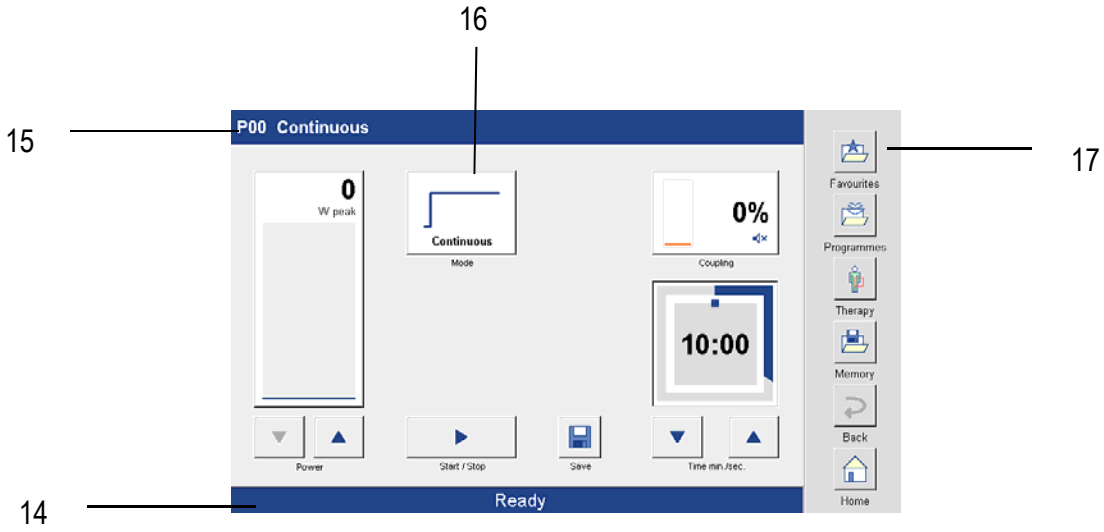


Device and Operating Elements	8	Mains cable socket
	9	Power switch
	10	Recessed grip
	11	Identification plate
	12	Ventilation openings

Illustrations

Screens / Displays

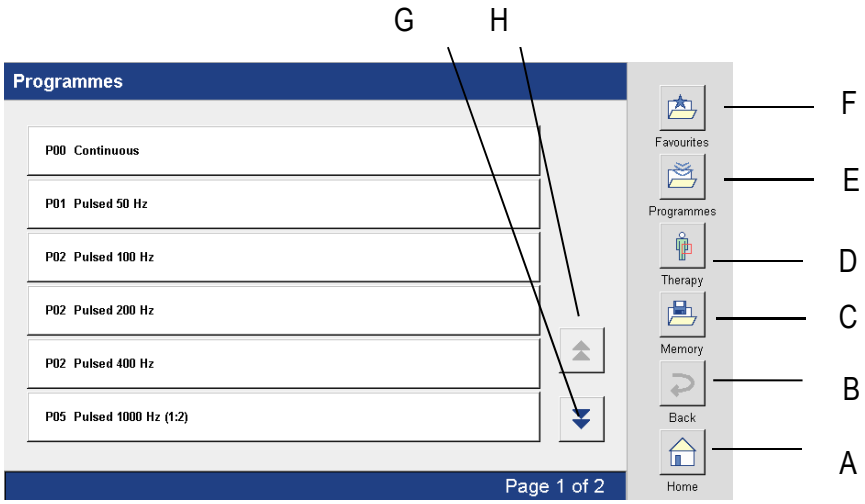
Fig. 3



Displays/
Therapy screen

14 Status bar
15 Title bar
16 Buttons on screen
17 Navigation bar

Fig. 4



Navigation Bar Description of functions	(A) Start	Returns to the Start page
	(B) Back	Takes you one step back
	(C) Memory	Switches to the Memory area
	(D) Therapy	Switches to the Indications menu
	(E) Programme	Switches to the Program list
	(F) Favourites	Switches to the Favourites area
	(G) Scroll Forward	Moves down a page
	(H) Scroll Backwards	Moves up a page

Explanation of symbols

In the instructions for use this symbol indicates “Danger”.

Caution!

In the instructions for use this symbol indicates
"Caution" with regard to possible damage of the device.

Operating instruction

Follow the instructions for use.

Serial number

Article number

Manufacturer

Date of manufacture

Applied part type BF

The unit emits non-ionizing electromagnetic radiation.

Contents

Contents

Valid for the Thermo*Pro* device.

This manual is an integral part of the device. It should be kept with the device so that the persons assigned to operate the device can access it at any time.

The instruction manual is valid from software version 1.0.

Indications / Contraindications

1

Indications

Thermo*Pro* is intended to support healing processes in tissues. Here several effects are used, which support the treatment of various indications.

Pain relief

Typical applications: Arthrosis, Achyllodynia, Sinusitis, Distortion, Contusion, Tendopathy, Tendovaginitis, Dysfunction of the temporomandibular joint, Spondylosis, Discopathy, Lumbago, Lumboischialgia, Pelvic pathology, Impingement syndrome, Whiplash, Periathropathia humeroscapularis, Peritrochanteric pain syndrome, Bursitis, Plica syndrome, Retropatellar chondrosis, Epicondylopathy, Myalgia, Muscle tension, Sympathische Reflexdystrophie, z.B. M. Sudeck (Stadium III, IV)

Reduction of muscle spasm

Typical applications: Dysfunction of the temporomandibular joint, Shoulder stiffness, Spondylosis, Discopathy, Lumbago, Lumboischialgia, Impingement syndrome, Periathropathia humeroscapularis, Peritrochanteric pain syndrome, Myalgia, Muscle tension

Improvement of range of motion

Typical applications: Shoulder stiffness, Tendopathy, Tendovaginitis, Distortion, Discopathy, Impingement syndrome, Whiplash, Plica syndrome, Epicondylopathy

Contractures

Typical applications: Arthrosis, Spondylosis, Spondylarthritis, Uncovertebral arthrosis, Bursitis, Pelvic pathology, Periathropathia humeroscapularis, Retropatellar chondrosis

Increase blood flow

Typical applications: Arthrosis, Spondylosis, Retropatellar chondrosis, Reflex sympathetic dystrophy, e. g. M. Sudeck`s (stage III, IV)

Contraindications

- Acute/sub-acute thrombophlebitis
- Peripheral arterial circulatory disorders
- Lack of temperature sensation (e.g. polyneuropathies)
- Pregnancy and menses
- Acute pelvic inflammatory disease, parametritis, endometritis
- Acute periarthropathia humeroscapularis
- Acute traumatic lesions, haematoma
- Metal foreign body in the tissue (implants, pacemaker)
- Sudeck syndrome stage I
- Significant fluid retention in the body (for example, pleural effusion, ascites)
- Febrile infectious diseases, tuberculosis, acute neuritis
- Acute prostatitis
- Tumours and metastases
- Unconscious or not fully responsive patients, babies and infants
- Damp clothes or wet dressings

Side effects

Treatment with the Thermo*Pro* can occasionally cause temporary local reddening of the skin.

Prior to applying the device to the patient, the operator should be familiar with the instructions for use and individual treatment methods, indications/ contra-indications, warnings and application information. Additional sources of information about the therapy should also be consulted.

Caution! Before use, ensure that the device is operated via a properly earthed power point with safety contacts (electrical installation according to DIN VDE 0100 Part 710). The device must be operated with the power cord supplied. The power cord must be protected against mechanical stress.

Caution! Operating the device in the vicinity of strong electromagnetic fields (e.g. MRI, X-ray or other diathermy equipment) can interfere with the operation of the device. Please maintain a safe distance of several metres.

Caution! ThermoPro is not suitable for use in areas having an explosive, flammable or combustive environment.

Caution! During use, the device should be positioned to allow more direct access to the central power supply of the device, so that it can be disconnected from the mains at any time.

Caution! To avoid the risk of electric shock, before performing any maintenance or cleaning activities, the device must be disconnected by removing the mains plug from the mains supply.

Caution! Inspect the unit before use. If damage is found it must not be used. A device that is not safe to operate must be taken out of operation and secured against further use.

Caution! Only accessories from Zimmer MedizinSysteme GmbH should be used. Replace defective parts, in particular the applicator and applicator cable, only with original parts from Zimmer MedizinSysteme.

Therapy Recommendation

Dosage level for diathermy (acc. to Schliephake):
Level I: no thermal sensation
Level II: noticeable thermal sensation
Level III: moderate, comfortable thermal sensation
Level IV: explicit thermal sensation (no heat)

State of Disorder	Dosage Level	Therapy Time	Therapy Interval	Therapy Series
Acute	I	3 to 6 min	Daily	About 5 treatments
Sub-acute / Sub chronic	I - III	5 to 10 min	3 x weekly	About 10 treatments
Chronic	III - IV	8 to 15 (20) min	2 x weekly	10 to 15 treatments

Treatment instructions about the location of the treatment and the duration and intensity of the treatment require medical knowledge and may only be given by approved doctors, therapists and members of the paramedical professions. These instructions must be followed.

The patient must not be left unattended during therapy.

Performing intracranial, cardiac trans occipital and occipital cervical treatments is prohibited. Failure to observe this can endanger the patient.

Simultaneous connection of a patient to ThermoPro and a high-frequency surgical device is prohibited. Failure to observe this can endanger the patient.

The function of certain implanted electrical devices, such as pacemakers or hearing aids, can be affected by therapy with shortwave therapy devices. In case of doubt, please seek advice from the physician responsible for the patient.
Persons with implanted devices should not enter rooms in which diathermy devices (such as ThermoPro) are operated.

Parts of the patient's body containing metal implants (for example, a bone pin) should generally be excluded from the treatment, unless special techniques are used.

Patients should not normally undergo shortwave therapy if they have reduced heat sensitivity in the body region to be treated, unless the attending physician is notified.

Shortwave treatment should not be performed on patients through items of clothing. Conductive materials should be removed from the treatment area. Shortwave treatment should also not be performed on patients wearing metallic objects such as jewellery or clothing with metallic materials (e.g., metal buttons, snap fasteners, buckles, zips or metal threads).

Ensure that the applicator is never directed towards the eyes and testicles during operation. During irradiation of other parts of the body, the applicator must be positioned so that the eyes and testicles are not within the irradiated area.

The radiation issuing from the applicator should not be directed onto electronic devices in the immediate vicinity or onto the ThermoPro itself. The devices can be impaired or permanently damaged.

The function of other appliances connected to the patient may be affected by the operation of shortwave therapy equipment.

Use in wet areas is not permitted: non-compliance may lead to considerable damage and endanger both the patient and the operator.

Patients should not come into contact with conductive parts that are earthed or have a high capacitance to earth and may represent unwanted pathways for high-frequency current. In particular, no bearings or chairs with metal frames should be used.

Cabling to the applicator should be performed in such a way as to avoid contact with the patient or with conductive or energy-absorbing articles.

Ensure that the applicator is not directed onto metallic surfaces (e.g., bed, sink, equipment housing, etc.).

Ensure that hearing aids as well as other electronic equipment the patient wears on the body are removed before treatment.

Ensure that the applicator and the applicator cable are handled with the necessary care. Severe shocks and impacts can change the radiation pattern.

Ensure that the device is not opened. Opening the device can generate life-threatening voltage.

Make sure that the device is not operated with a damaged applicator or applicator cable.

Make sure that the device is operated only when the applicator cable and supporting arm are fully and correctly mounted on the device housing.

Ensure that the ventilation openings at the back of the device are kept clear.

Make sure that if liquid or foreign matter gets inside the casing, the power cord is immediately unplugged from the mains socket and the appliance checked by an authorized service centre before you return it to operation.

Be sure to observe a safe distance of 5 metres from simultaneously operated medical equipment.
If case of faults, stop the treatment.

To completely disconnect the device from the mains, unplug the power cord from the outlet.

Non-ionizing radiation is generated in the device!

The device generates lethal high voltage!

Ensure that there is no power output during the positioning of the applicator and thus no accidential irradiation of patient and user.

Ensure that the user doesn't stay in the applicator's field during therapy.
All persones not treated should stay furhter than 1.5 m from the applicator.

What is Thermo*Pro*?	A modern shortwave therapy system.
How does Thermo*Pro* work?	In contrast to the heat treatment method in which heat (e.g. heat packs) is supplied from the outside, at shortwave therapy conversion of electric power into heat energy takes place directly inside the tissue.
How is electrical energy converted into heat energy?	The high-frequency field generates eddy currents in the treated tissues that lead to molecular excitations and convert the electrical energy into heat.
Why Thermo*Pro*?	The modern and clear colour display which displays all the parameters relating to the therapy and the modern touch controls, which ensure enthusiasm and motivation during treatment. Individual program start setting and a clear, simple menu provide maximum user comfort. User information on indications will support you during therapy.
What else does Thermo*Pro* offer?	The option of either pulsed or non-pulsed application opens up a wide range of indications to the operator.
Intended Use	Thermo*Pro* is a shortwave diathermy device for the treatment of certain conditions by applying electromagnetic energy in the 27.12 MHz RF band. It is intended to generate deep heat in body tissues and can be applied, for example, for pain relief, muscle relaxation or joint contractures. The device is not intended for the treatment of malignant diseases.
Note:	*The application of the device is reserved to medical professionals (e.g. doctors, therapists, members of the paramedical professions).*

Note: *Make sure that the power switch on the device is set to "0".*

Assembling mounting bracket

Install the 4 mounting brackets including castors (1) on the bottom of the unit.

Assembling supporting arm

Slide the supporting arm (4) into the connection for the supporting arm (2).

Assembling applicator cable

Bolt the applicator cable (4.1) to the cable connection of the applicator cable (3).

Connecting the power cable

Connect the power cable to the provided socket (8) on the unit, connect the cable to the mains.

Note: *The device may only be connected to power outlets with a protective contact.*

Note: *After completion of the assembly, check again to see whether the supporting arm connection is properly inserted into the connector.*
Check that the applicator cable is properly connected to the connector.

The device may only be operated when the applicator cable has been properly connected. Otherwise a risk to people and environment or damage the device may occur.

Switching on the device

Turn on the unit with the mains switch (9).

Switching off the device

The device is switched off using the power switch (9).
To completely disconnect the device (all-pole) from the mains, the power cord must be disconnected.

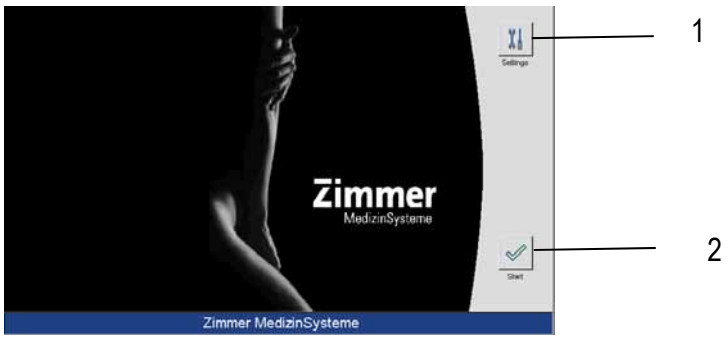
Caution!

All cables must be protected against jamming or other mechanical damage.

Note: *Changes to the basic settings can only be made in the start-up screen.*

Start-up screen

After switching on the device and performing the self-test, the start-up screen opens.



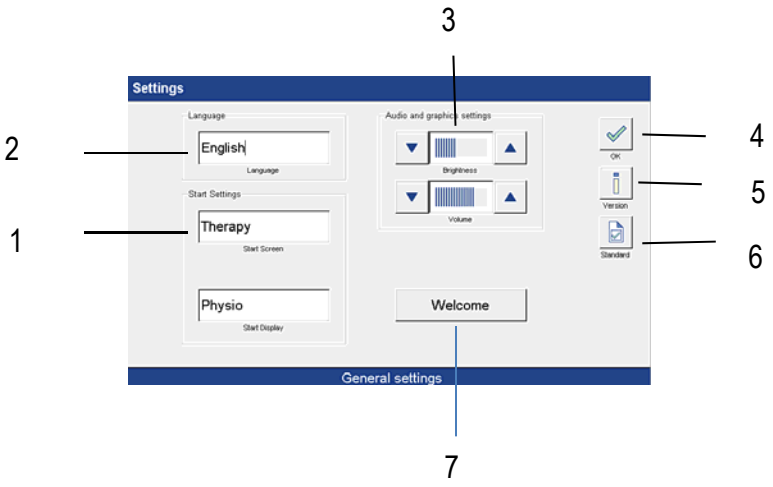
Note: *Activating the "Start" (2) button will immediately switch to the application screen.*

Settings menu

In the settings menu, the factory settings can be individually changed and adjusted.

Selecting settings

Pressing the "Settings" (1) button opens the "Settings" screen.



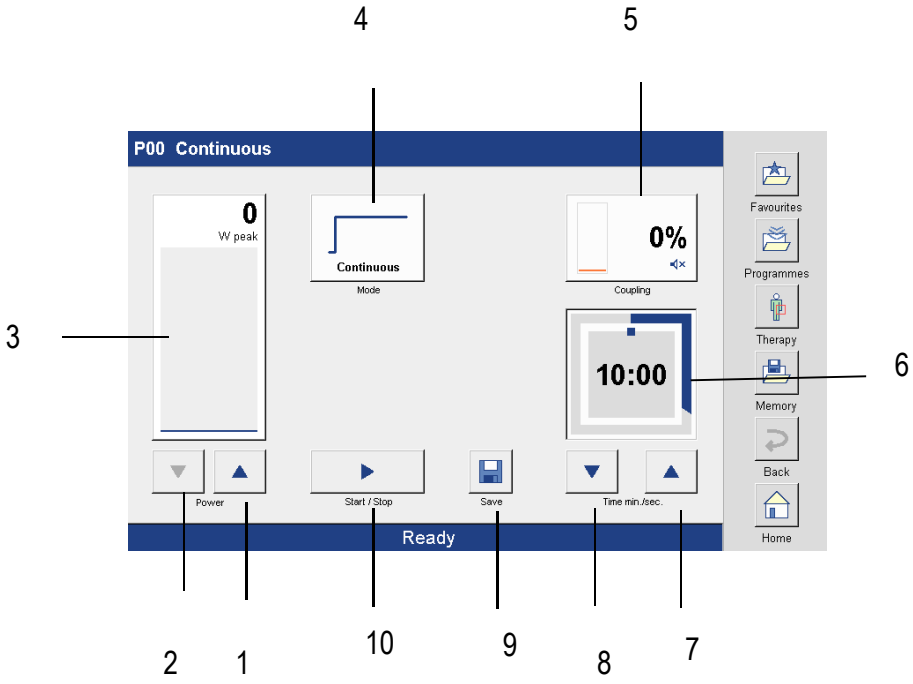
The settings are described below.
The default settings are pre-programmed as shown on the screen.

(1) Start Settings	1. Start menu: Individual selection options for start settings. 2. Start screen: Choice of two start screens. The selection is made in the corresponding row.
(2) Language	Select the language. The selection is made in the corresponding row.
(3) Audio/graphics settings	1. Brightness: Adjust the screen brightness. 2. Volume: Set the volume of the confirmation beeps that sound when the control panels are activated. Adjustment is done by using the two arrow keys.
(4) OK	Touch the "OK" button to switch to the start screen.
(5) Version	Touching the "Version" button opens a window with information about the current software version.
(6) Default settings	Touching the "default" button restores the default factory settings.
(7) Welcome	Clicking in the "Welcome" field opens a window with an alphabetic keyboard for entering a customised welcome message on the start screen. Touching the "OK" button saves the entered text. Touching the "Cancel" button returns to the configuration menu.

8.1 Performing Treatment

Note:	*All buttons, menus and sub-menus can be activated directly on the screen by touching with your finger.*
Start program	Touching the “Start” button in the start-up screen opens the application screen.
Positioning of the patient	Position the patient on a therapy table or a chair. Make sure that the area to be treated is easily accessible for the applicator and other body parts are not penetrated by radiation. Observe the warning notices.
Positioning applicator	Place the applicator on the area to be treated. Observe the coupling indication. A maximum coupling should always be achieved. The better the coupling, the more energy is transferred. A distance of max. 1 cm is recommended.
Output settings	Set the output by using the arrow keys or bar graph.
Starting therapy	Pressing the “Start” button begins the therapy. The function of the “Start” button changes to “Stop”. The display in the status bar changes from "Ready" to "Active".
Ending therapy	After expiration of therapy time, the power will be reset to "zero" and the therapy is finished. The function of the “Stop” button changes to “Start”. The display in the status bar changes from "Active" to "Ready".
	For immediate cancellation of the therapy press the button “Stop”.
Note:	*During therapy, the patient must be carefully monitored. Therapy should be adjusted or cancelled if problems occur.*

Description of the display elements and buttons

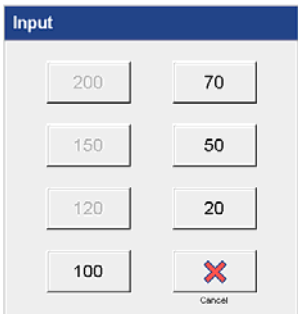


(1) / (2) Arrow keys Power

Pressing the arrow key (1) increases the power.
Pressing the arrow key (2) reduces the power.
0 – 10 W in increments of 5.
10 – 200 W in increments of 10.

(3) Bar graph

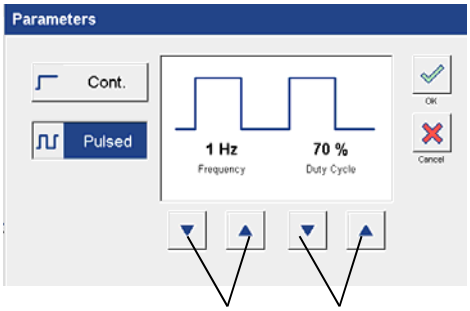
Function 1:
Displays the set power. During active therapy, the bar graph is filled in.
Function 2:
Activating the bar graph (3) opens the window to select the power. Selection options: 20, 50, 70, 100, 120, 150 and 200 W.
Selecting the desired output is performed in the corresponding field.



Pressing the “Cancel” button cancels the operation.

(4) Mode

Displays the selected operating mode.
When the window is activated, the parameter window for selecting unpulsed and pulsed operating modes opens.



Selecting the desired mode of operation is performed in the corresponding field.

Select the desired parameter using the arrow buttons (1).
Activating the arrow key (2) increases or decreases the value.

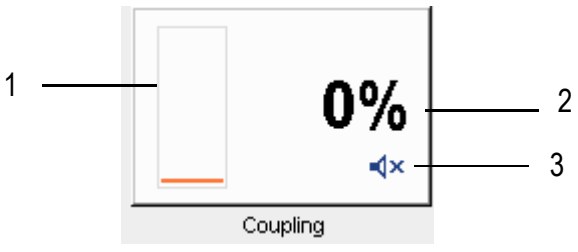
Setting options in pulsed operating mode:
Frequency: 0.5, 1, 2, 5, 10, 20, 50, 100, 200, 500, 1000 Hz
Duty cycle: 10, 20, 30, 40, 50, 60, 70, 80, 90%

(5) Coupling

Graphic display of the coupling (1).
Percentage display of the coupling (2).
Symbol of acoustic coupling signal (3).
The acoustic coupling signal can be switched on and off by pressing the symbol. The symbol changes accordingly.

Coupling signal activated

coupling signal disabled



Note:

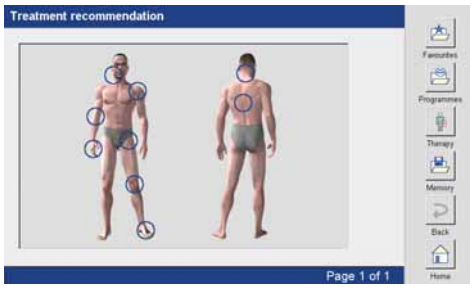
Sufficient coupling is necessary to ensure optimum energy transfer. Please note that the effectiveness also depends on the distance between the applicator and the skin, therefore place the applicator in such way, that proper coupling is ensured.
A maximum distance of 1 cm is recommended.

(6) Time	Displays the therapy time. Can be adjusted from 0 - 30 minutes. The treatment time is reduced by one-second intervals.
(7)/(8) Time arrow keys	Touching the arrow key (7) increases the time in 1-minute increments. Touching the arrow key (8) reduces the time in 1-minute increments.
(9) Save	Touching the button opens the box to input the name of a particular program to be stored in the memory or favourites list.
(10) Start/Stop	Touching the “Start” button after entering the output starts the therapy. The function of the “Start” button changes to “Stop”. Touching the “Stop” button during therapy sets the output to zero and the therapy time is suspended. The function of the “Stop” button switches to “Start”. Touching the “Start” button after the therapy has ended sets the therapy time back to the default value.

The "Therapy Recommendations" menu is used to assist in choice of therapy.

Therapy

Pressing the Therapy button opens the "Therapy recommendations" menu.

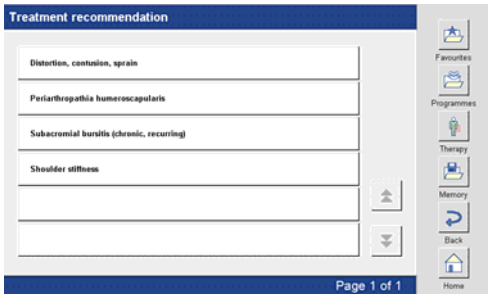


Selecting region of the body

You can select the region of body by clicking the blue circle.

Selecting symptoms

After selecting the desired region of body, the window with symptoms for the desired body region opens.



Selecting the symptoms is done in the corresponding row.

Therapy information

Selecting the symptoms opens a window with detailed therapy and treatment information.

Selecting therapy program

Touching the “Therapy” button opens the screen with the selected therapy program.

The parameters of the pre-defined programs can be individually modified and saved.

Saving and naming programs

Activating the "Save" button opens the field for entering the program name.

Enter the program name via the keyboard.

Note: *The programs can be saved in the favourites list or memory list. 120 memory locations are available.*

Save in Favourites list/Memory list

Touching the button (1) opens the list of favourites and automatically stores the program in the Favourites list.
Touching the button (2) opens the memory list and stores the program in the Memory list.

Touching "OK" closes the "Save" screen and transfers the program to the corresponding list.

The program is always stored in the first available space on the list.

Touching the button (3) interrupts the save operation.

Note: *If the “Favourites” or "Memory" button is activated without entering a program name, the following message appears:*

"Please enter a name!"

Confirm the message with "OK", enter the program name and repeat the save process.

Individually stored programs are listed in the favourites list.

These can be

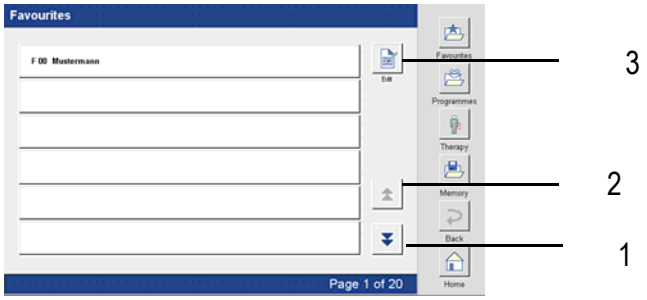
1. *retrieved for therapy,*
2. *edited (moved position and deleted).*

Note: *The steps to retrieve and edit the favourites/memory list are identical; so only the steps for retrieving and editing the favourites list are described.*

Select Favourites List Pressing the "Favourites" button opens the favourites list.

Retrieving Program The desired program is directly selected in the corresponding row

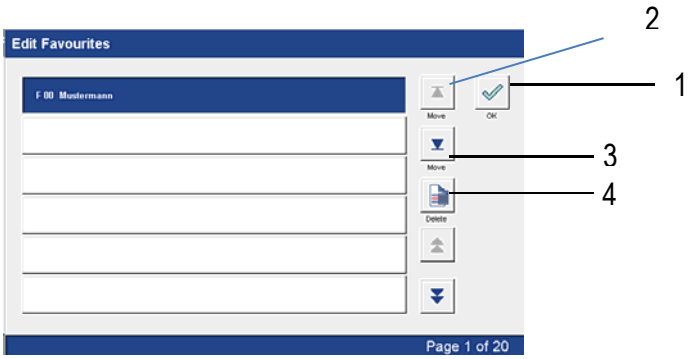
Editing Favourites List



Activating the buttons (1) and (2) allows individual favourite pages to be viewed. Button (1) scrolls forward, button (2) backwards.

Activating the button (3) opens the "Edit Favourites" screen.
Select the favourites to be edited directly in the line.

Editing favourites



Activating the button (1) returns you to the program.
Activating the button (2) moves the program to the top.
Activating the button (3) moves the program down.
Activating the button (4) deletes the program.

Note:

Activating the button (4) triggers a safety query:

"Do you really want delete the program?"

Activating the "Yes" button deletes the program.
Activating the "No" button will cancel the deletion.

Power supply	100 – 240 V, 50/60 Hz 220 V, 60 Hz
Power input	Max. 700 W
Mains fuse	Circuit breaker in the mains switch
Protection class	I
Applied part	Type BF The front side of the applicator is regarded as applied part.
Applicator	Coil field method
Output frequency	27.12 MHz ± 0.5%
Output power	
Unpulsed	Max. 100 W ± 20%
Pulsed	Max. 200 W peak ± 20% *The output power values were obtained at a load (impedance) of 50 Ω, and a distance between the applicator and the patient of a maximum of 1 cm.*
Pulsed mode	
Duty cycle	10, 20, 30, 40, 50, 60, 70, 80, 90% (equivalent to 1 : 10 to 9 : 10)
Pulse rate	Adjustable: 0.5, 1, 2, 5, 10, 20, 50, 100, 200, 500, 1000 Hz
Dimensions	Width 581 mm x depth 459 mm x height 854 mm
Weight	37 kg
Operation	10 to 30 °C, 20% to 80% relative humidity, no condensation at 700 hPa – 1060 hPa
Storage / Transport	-10 to 50 °C, 10% to 90% relative humidity, no condensation at 700 hPa - 1060 hPa
Note:	*Storage and transport in original packaging.*

Subject to technical modifications!

Cleaning
Disinfection

10

- Before starting any maintenance and cleaning measures the device must always be turn off at the main switch and unplugged.

- Make sure that when cleaning and disinfecting the labels of the device (such as warnings, labels of control devices, identification plate) are not damaged.

- Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.

- If during cleaning or disinfecting liquid penetrates the device, please put the unit out of service, protect it from getting used again and contact your service representative.

- The device and its applied part are considered “non-critical” in terms of hygiene guidelines when used on uninjured and healthy skin.

Housing/Applicator

Cleaning: In the event of visible contamination, the housing, the applicator and all cables can be cleaned using commercially available soft alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping.

Disinfection: We recommend that disinfection to be carried out at least once a week, as well as in the event of evidence of possible contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

Housing, applicator and cables can be disinfected using disinfectant wipes. To do so, use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or use pre-impregnated disinfectant wipes (so-called wipes). If applicable, also observe requirements for drying or post-cleaning.

Caution: If flammable solutions are used for cleaning and disinfection, sufficient time must be allowed for the solutions to evaporate before using the device. Otherwise, it may lead to inflammation!

Note: *Only use the device in a hygienic environment.*

CE-mark

11

The product bears the CE-mark

CE 0123

According to the EC directive 93/42/EEC on medical devices.

Scope of Delivery

1	Thermo*Pro* base uniti
1	Applicator including applicator cable
1	Supporting arm
4	Mounting bracket with castors incl. locking device
2	Cable clip
1	Power cable
1	User manual
1	Assembly instruction

Accessories

Art.Nr.	
95523110	Applicator including applicator cable
91525010	Supporting arm
93521010	Mounting bracket with castors incl. locking device
80000410	Cable clip (2 count)
67300124	Power cable
10102153	User manual
10102148	Assembly instruction

Device Combinations

13

For Thermo*Pro* no combination devices are provided by the manufacturer.

Anyone who, contrary to these guidelines, combines devices and operates a medical system in this way does so at their own risk.

Thermo*Pro* is manufactured according to the safety regulations of DIN EN 60601-1.

As manufacturer Zimmer MedizinSysteme can only be considered responsible for the safety and reliability, if

- the device is operated at a proper power outlet with an grounding contact and the electrical installation complies with DIN VDE 0100 part 710 or similar,
- the device is operated in accordance with the instructions for use,
- extensions, readjustments or modifications are only carried out by persons authorized by Zimmer MedizinSysteme,
- the operator is satisfied regarding functional safety, proper condition and mechanical integrity of the device and applicator prior to use of the device,
- the device is operated only by properly qualified personnel,
- the device is not operated in hazardous areas and/or a combustible atmosphere,
- the device is immediately disconnected from the mains in the event of penetration of liquids.

The device does not contain any parts that can be serviced or repaired by the operator.

Warning**!**

No modification of this equipment allowed!

Regularly check the ventilation openings to ensure they are free of dirt. Clean if necessary.

Note:

ThermoPro or its components do not require any periodic preventive maintenance.

Thermo*Pro* performs a self-test after it is switched on, which checks all the internal components.

An error message will appear when a fault occurs.

An extended function test as described below can also be performed.

This test should be performed monthly or if there are any doubts about the functionality of the device.

Function test

Select unpulsed operating mode and set an output power of 5 W.
Move your forearm into the treatment field and make sure that the coupling indicator displays at least 50%.

Safety Check
Metrological Control

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For the device Thermo*Pro* neither a safety check (STK) nor a metrological control (MTK) is required in Germany.

In Germany, among others, the Medical Devices Operator Ordinance (MPBetreibV) and BG regulation – Electrical systems and equipment (BGV A3) apply in their current version.

Note: *These requirements apply to operation of the device in Germany. Please consider divergent national regulations of your country.*

Device malfunction

No response to network switch/display remains dark

Possible cause
Network connection
Troubleshooting
Check that the power cord is properly plugged into the power outlet and the plug is firmly inserted into the socket of the device.
Check the power cord for damage. In case of visible damage, replace it.
Check the power supply and power outlet.

The power switch jumps into position "0" self-acting

Possible cause
Overload
Troubleshooting
After waiting 5 minutes, turn the switch back to position "I". If it jumps to position "0" again, please contact customer service.

Applicator malfunction

Possible cause
Faulty connection or damaged applicator or applicator cable.

Troubleshooting
Check the correct position of the supporting arm and that the applicator cable is correctly joined to the applicator cable connection. Check the applicator for visible damage.

Error message SD card

If the SD card is not inserted, the following message appears when you press the "Favourites" "Memory" and "Therapy" buttons:

"No SD card found."

Using "Favourites", "Memory" and "Therapy" requires an SD card.

Insert the card and confirm with "OK".

Overtemperature

If the message “Overtemperature. Please let device cool down.” Appears, switch off the device and wait for 30 minutes before switching on the device again.

General

For all other malfunctions, switch the machine off and wait 5 seconds before switching it on again. If the fault persists, please contact customer service at head office in Neu-Ulm.

Head office

Zimmer MedizinSysteme GmbH
Junkersstrasse 9
89231 Neu-Ulm, Germany
Tel. +49 731. 9761-0
Fax +49 731. 9761-118
www.zimmer.de

Disposal

The device must be returned to the factory in its original packaging. It must be disposed of only by Zimmer MedizinSysteme.

In foreign (European) countries, please refer to the national regulations for disposal. Contact your distributor, if necessary.

Medical electrical devices like Thermo*Pro* are subject to specific precautions relating to EMC (electromagnetic compatibility) and must be installed and set up in accordance with the EMC information contained in the operating instructions or accompanying documents.

Portable and mobile high-frequency communications equipment (e.g. mobile phones, cell phones) can affect medical electrical equipment.

ThermoPro may only be operated with the original power cable indicated in the list delivered with the appliance. Operating the device with a different power cable can result in increased emissions or decreased interference resistance of the device!

Guidance and manufacturer's declaration – Electromagnetic emissions		
The ThermoPro device is suitable for use in the specified electromagnetic environment. The purchaser or user of the ThermoPro device should assure that it is used in an electromagnetic environment as described below:		
Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 2	The ThermoPro device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	This ThermoPro device is suitable for use in all establishments, including 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 fluctuations/flicker emissions IEC 61000-3-3	Complies	

The device should not be used adjacent to or stacked with other equipment. When it is necessary to operate close to or stacked with other equipment, the device should be checked to verify its correct operation in this arrangement.

Guidance and manufacturer's declaration – Electromagnetic immunity			
The ThermoPro device is suitable for use in the specified electromagnetic environment. The purchaser or user of the ThermoPro device should assure that it is used in an electromagnetic environment as described below:			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	IEC 60601-1-2 Test level	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_n for 0.5 cycles 40 % U_n for 5 cycles 70 % U_n for 25 cycles 0 % U_n for 5 s	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ThermoPro device requires continued operation during power mains interruptions, it is recommended that the ThermoPro device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magentic field IEC 61000-4-8	3 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Key features of the ThermoPro are: emission of RF energy and trouble-free operation of all functions. Continuous operation is not required for the intended application.

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – Electromagnetic immunity</td></tr>
<tr><td colspan="4">The Thermo device is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermo device should assure that it is used in such an environment</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601-1-2
Test level</td><td>Compliance level</td><td>Electromagnetic environment</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the ThermoPro device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Recommended separation distance</td></tr>
<tr><td>Radiated RF

EN 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>d = 1.2 √P 80 MHz to 800MHz
d = 2.3 √P 800 MHz to 2.5GHz</td></tr>
<tr><td>Conducted RF

EN 61000-4-6</td><td>3 V
150 kHz to 80 MHz</td><td>3 V rms</td><td>d = 1.2 √P</td></tr>
<tr><td></td><td></td><td></td><td>Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the Thermo device

The ThermoPro device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ThermoPro device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the ThermoPro device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter (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

For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Thermo*Pro*

Instructions for Use

Zimmer MedizinSysteme GmbH
Junkersstraße 9
D-89231 Neu-Ulm
Tel. +49 7 31. 97 61-291
Fax +49 7 31. 97 61-299
export@zimmer.de
www.zimmer.de

Zimmer
MedizinSysteme

GB 10 102 154 UR 0814 I Version 1 I