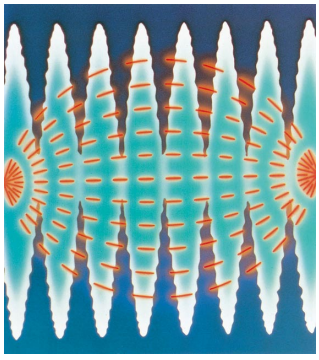
Short-wave-Therapy-Unit



ULTRATHERM 908i

User Manual

Version 1.6

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The gbo Medizintechnik AG has taken care in preparation of this operating instruction, but makes no expressed or implied warranty of any kind and assume no responsibility for errors or omissions.

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Comments according to the Medical Device Directive

ULTRATHERM 908i is a mains operated short-wave therapy unit.

The device fulfils the EC directive for medical devices and bears the CE-mark. You will find the appropriate symbol on type label. The applicated regulations and standards are given in the EC-declaration of conformity.

ULTRATHERM 908i is, according to the medical devices directive, an equipment of class IIb.

As manufacturers, we can assume responsibility for the safety of the unit and for its reliability and performance only if:

- the unit is used in accordance with the operating instructions;
- the electrical room installation complies with common standards, such as IEC or VDE;
- the unit is not operated in wetrooms or areas where there is a risk of explosion;
- maintenance, repairs and modifications have been carried out by us or by agencies expressly authorized by us;
- all user directives are met within the scope of the medical devices directive, especially concerning safety controls.

Unaffected from the medical devices directive or national regulations a safety inspection every 12 month is recommended. This inspection should be carried out by the manufacturer or an authorized service agency.

Technical support is available from the manufacturer or from agencies, authorized by the manufacturer. The product is intended for a lifetime of 10 years.

ULTRATHERM 908i is an electronic device. Disposing has to be done according to regulations for electronic devices.

On request, the manufacturer supplies for all serviceable parts additional information, such as wiring diagrams, spare part lists and service informations as far as they are of use for the qualified and authorized service personnel of the user.

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 accompanying 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.		
Emissions 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 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 fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	
(*) Note: For devices with a power consumption between 75 W and 1000 W only.		

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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, 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 differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% 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.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d=1,2\sqrt{P}$ 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: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the tranmission frequency (m)**		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	**80 MHz to 800 MHz $d=1,2\sqrt{P}$**	**800 MHz to 2,5 GHz $d=2,3\sqrt{P}$**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

EC - DECLARATION OF CONFORMITY

Name of manufacturer	:	gbo Medizintechnik AG
Address	:	Kleiststrasse 6 D - 64668 Rimbach Germany

We hereby declare under our sole responsibility that the product described below conforms in design and make as well as in the versions delivered to the corresponding safety and protection requirements defined in the applicable EC regulations.

Harmonized standards have been used for all conformity checks, national standards have not been applied.

Any change to the product design that is not validated by us will render this declaration invalid.

Type of product	:	Short-WaveTherapy Unit
Label	:	ULTRATHERM 908i
Options	:	Diplode, Monode, Minode, Capacitor-Field-Radiator, Soft-Rubber-Radiator
Corresponding EC regulations:		EC medical devices directive (93/42/EEC)
Conformity assessment procedure	:	Annex VI of the directive 93/42/EEC
Classification	:	IIb (according to MDD, appendix IX)
Name und registration no. of the notified body	:	TÜV Product Service in Munich/Germany with the registration no. 0123
Additional information	:	none
Date	:	January-1, 2006
Name of persons responsible	:	Dr. Eberhard Keck
Title/Function	:	CEO
Signature	:	

Contents

1 Intended Use

The **ULTRATHERM 908i** is a high performance short wave therapy unit for high frequency heat therapy that operates at the well proved frequency of 27.12 MHz (wave length 11 m). It enables the classical therapy in capacitor-field and electromagnetic coil fields in both the continuous and the modern pulsed modes of operation and, therefore, it is suited for all heat therapy treatments in clinic as well as practice.

The use of high frequency energy for heat therapy has the advantage of larger penetration depth in contrast to the conventional methods, such as hotpacks, baths, infrared light and heat pillows, and even to the microwave.

The heat endogenically generated by this therapy unit induces a whole range of physiological processes which, for example, spasmodically influence the muscular system, tendons and other connective tissue structures, increase the cell metabolism and rate of enzyme reaction and improve the blood circulation in the area under treatment.

As the high frequency energy can be applied in short but high energy shocks (pulsed mode) the penetration depth can be increased further, particularly the positive effect on the blood circulation, while the thermosensitive skin hardly feels the heat.

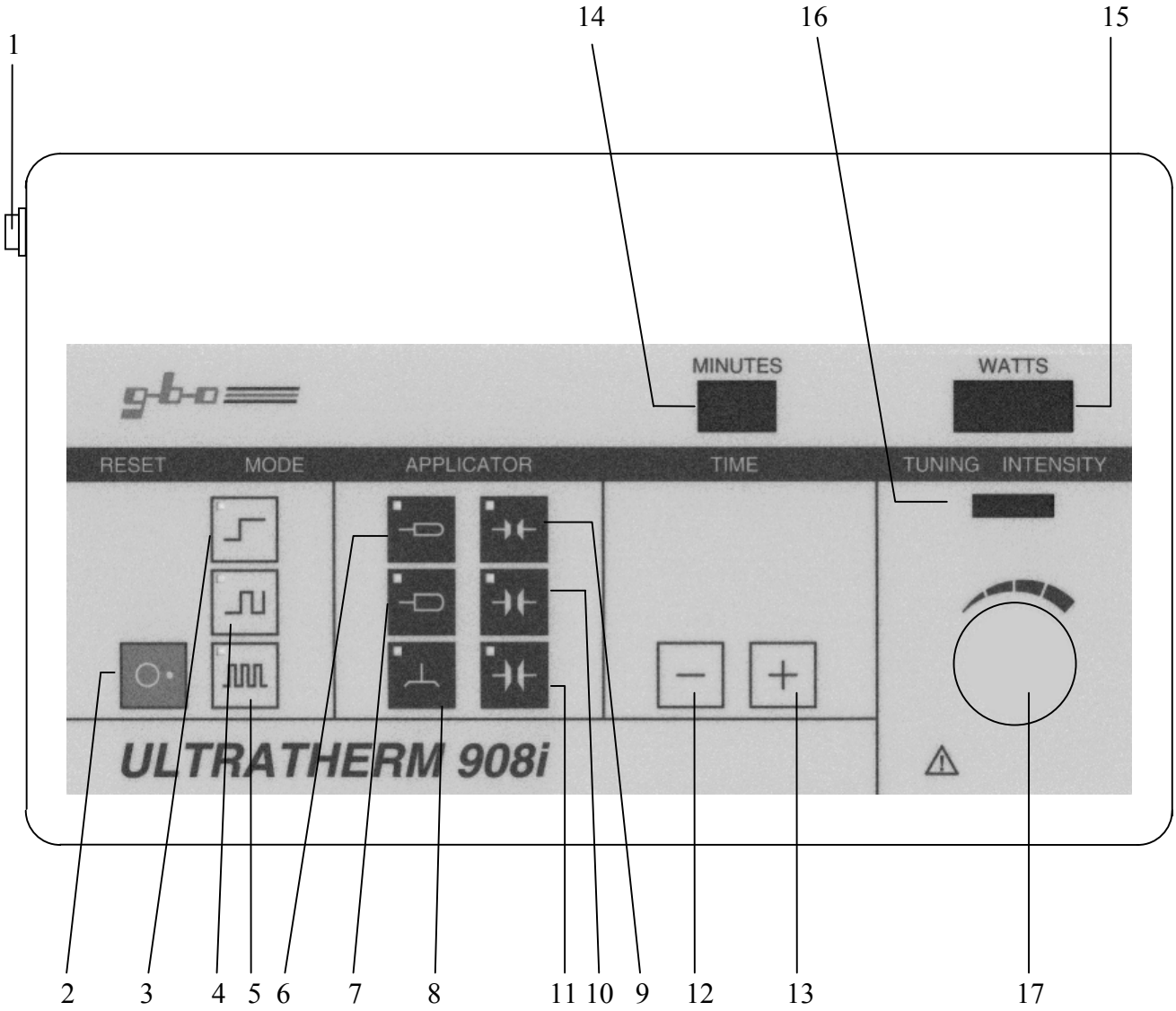
High frequency heat therapy can be applied in a wide field. It is particularly suited for all rheumatic ailments of the joints and muscular system, inflammatory ailments of respiratory organs, kidneys and urinary tracts and all ailments caused by poor blood circulation.

Please, observe the table of application.

For acute conditions the pulsed mode of operation offers advantages.

2 Functional description

2.1 Control panel



1 Power switch with light indicator

2 RESET key

3 Key „Continuous mode of operation“

4 Key „Pulsed mode of operation“ 70 Hz/2 ms

5 Key „Pulsed mode of operation“ 350 Hz / 0.4 ms

6 Key „Coil applicator“ MINODE ∅ 8 cm

7 Key „Coil applicator“ MONODE ∅ 14 cm

8 Key „ Coil applicator“ DIPLODE 18 x 39 cm

9 Key „Capacitor-field applicator“ ∅ 4.2 cm and
„Capacitor-field applicator, elastic 8x12 cm

10 Key „Capacitor-field applicator“ ∅ 8.5 cm and
„Capacitor-field application“, elastic 12x18 cm

11 Key „Capacitor-field application“ ∅ 13 cm
„Capacitor-field application“, elastic 15x25 cm

12 Key „Decrease treatment time“

13 Key „Increase treatment time“

14 Display „Treatment time“ in minutes

15 Display „Dosage“

16 Display „Coupling with patient“

17 Dosage knob

2.2 Structure of the unit

The therapy unit is trolley-mounted with casters, two of which are fitted with brakes that can be actuated for the required stability.

The top part of the therapy unit is designed as control panel. On the panel, covered by an easily cleaned and, thus, user-friendly protective foil, there are arranged all the necessary control and display elements.

By means of dosage knob **(17)** the output power is adjusted via an angular impulse generator. Power switch **(1)** (ON/OFF) is provided on the left side of the panel. At the rear of the therapy unit there are the screws for attaching the arms **(46)**,the sockets for connecting the cables of the capacitor-field **(43)** and coil **(30)** applicators and the connection part of the detachable mains supply cable **(44)** including fuses. The ripcord **(45)** for the patient emergency-OFF switch passes through a bushing mounted in the arm fastening area so that it can be pulled from all directions.

2.3 Support Arms

If DIPLODE coil-field electrodes are to be used, a support is required; 2 support arms are required when using capacitor field electrodes according to Schliephake .

In general, support arms which have only one joint close to the electrode are used - apart from the double joint where the support arm is fixed.

For applications on high treatment couches or for other special treatment situations, flexible arms (Fig. 4) with an additional lockable joint **(18)** in the middle of the arm can be used. These arms are available for right and left operation.

Both types of support arm can be adjusted by means of a fixing knob **(19)** axial displacement **(20)** and rotatory displacement **(21)**.
The connecting cables and most electrodes are secured to the support arm head by means of plug and socket connections. The large electrodes hole **(22)** accepts the electrodes which are locked in position by a spring pin locking fixture.

To do this, move the sliders **(23)** on each side perpendicular to the hole so that the locking pin **(24)** does not prevent insertion of the electrodes.

Insert the adjuster pin of the Schliephake electrode into the hole **(25)** and plug socket end of the electrode cable into the pin socket **(26)** underneath.

2.4 Applicators and applicator cables

Coil as well as capacitor-field applicators can be used with the **ULTRATHERM 908i** (see also paragraph 7, Accessories).

2.4.1 Capacitor-field applicators (distance applicators according to „Schliephake")

Three pairs of different diameters are available. The capacitor-field electrode consists of 2 caps **(27/28)**, screwed together with enclose an axially movable metal plate with shaft (the actual electrode c). An adjuster pin **(30)** on the shaft enables the plate electrode spacing to be adjusted in a defined manner.
The smaller cap **(28)** is fitted with a slotted bush **(31)** with an external thread with which the metal plate shaft can be guided and by means of which the locking nut **(32)** can be secured. The locking nut has 4 holes **(33)** around its periphery and a guide groove (**34**). The locking pin of the support arm must engage in one of the 4 holes. The locking nut is slotted on one side **(35)**, so that the entire electrode can be held by spring force in the support-arm head.

When the locking pin of the support arm is engaged, the electrode is disengaged by twisting the two caps anticlockwise **(36)**. The desired electrode spacing can be axially adjusted **(38)**.

The electrode setting can then be secured by twisting the two caps clockwise **(37).** For further information see paragraphs 2.4, 2.5 and 2.6.

2.4.2 Capacitor-field applicators, elastic

These applicators are available in three different-sized pairs. The permanently attached, highly flexible cable ensures maximum flexibility at the point of applicator connection and high adaptability to bent or curved parts of the patient's body. The optimum distance between applicator and skin is achieved with thick felt spacers that have to be placed in a cloth bag together with the applicator. Velcro fastener or rubber bands can be used for fastening this applicator arrangement.

2.4.3 Coil applicators

Three different sizes of different effective surfaces can be used for adjusting to size and volume of the different treatment areas (for further information see subparagraphs 2.4, 2.5 and 2.6).

The electrode is held above the connection at the support arm (as for the capacitor-field electrode).

The DIPLODE is designed as special electrode. Because of its swivelling side sections, it is suitable for large-surface treatment and for treatment enclosing the area.

The twin-core electrode cable is permanently screwed to the diplode. A ball joint **(39)** in the centre section facilitates optimum electrode application. The attachment to the support arm is by means of the connection **(40)** into the fixing hole **(41)** of which the locking pin of the support arm must snap. The claw **(42)** is to stabilize the electrode attachment and must enclose the narrow side of the support-arm head.

2.4.4 Applicator connection cables

Highly flexible, low-loss special cables are used to connect the capacitor-field applicators.

To avoid any unwanted and inadmissible heat application to the patient he/she should not touch a cable. Therefore, abundant cable length should be fed through the lower arm part **(24)** to secure it.

2.5 Cleaning and disinfecting

Before cleaning or disinfecting the therapy unit must be switched off and the mains plug disconnected.
For cleaning and disinfecting the therapy unit and accessories (except for the felt spacers, of course) we recommend commercially available surface disinfectants to be used according to their instructions for use.

For reasons of material acceptance, only surface disinfectants basing on agents like aldehydes, alcohols or ammonium compounds are suitable for wipe and spray disinfection. They are to be used according to their instructions for use and duration of action.

Examples:	Hexaquart	Nucosept o. F.
	Ultrasol	Bazillotox
	Hansa-Sept	Buratron 10F
	Lysoform	Dismozon
	Incidur	Frekanol
	Melsitt	

For users in the Federal Republic of Germany we basically recommend the use of disinfectants published in the DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie) list. The DGHM list contains also the basic agent of the corresponding disinfectant.

For reasons of possible material damage, also products basing on halogen-splitting compounds, strong organic acids and oxygen-splitting compounds, solvents, benzene and similar agents are not suitable.

ATTENTION! While cleaning and disinfecting it is to be observed that no fluid penetrates into the therapy unit or accessories. Sockets that have become wet are to be thoroughly dried before any further use!

2.6 Tests, safety and regulations

The **ULTRATHERM 908i** conforms to MDD class IIb. Due to the strict application of legal standards and rules and maintaining the definitions of the design documentation it complies with the general requirements of labour safety.

According to the MDD this electromedical device shall only be applied by people which ensure the correct handling due to their special training or knowledge and practical experience and which have been trained for the correct operation on the basis of the present operating instructions. The training shall be only performed by people which are suited for instructing the handling of the device due to their knowledge and practical experience.

As the manufacturer of this therapy unit we only consider ourselves responsible for the technical safety qualities if the **ULTRATHERM 908i** is used according to the present operating instructions.

Any repair - including opening the unit - shall only be performed by our staff or after-sales service shops especially authorized by us. In the interest of functional safety of the therapy unit we recommend at least one annual safety check by the after-sales service.

The experience showed that most of the supposed troubles base only on inadvertent operation errors. Therefore, please, check the operation prior to any contacting the after-sales service.

Prior to the application, the therapy unit has to be checked by the user for convincing that its function and condition are correct. This includes regular inspections of all cables and lines for possible insulation defects.

The **ULTRATHERM 908i** complies to the Medical Devices Directive (MDD) 93/42/EEC and therefore carries the CE sign with the number of the notified body for medical devices.

ATTENTION: According to its designation the therapy unit generates high frequency electric and magnetic fields that penetrate even walls, ceilings and floors. It cannot be excluded that components of these fields exists in the vicinity of the therapy unit. Sensitive electronic instruments which are arranged in the immediate vicinity of the **ULTRATHERM 908i** can be disturbed. This danger largely depends on the distance between the devices. Therefore, during the installation of the therapy unit, it should be taken into consideration that the distance to other sensitive devices should exceed 5 m, if possible, and the applicators are not directed to sensitive devices, as for instance current stimulators.

This problem can be completely eliminated when the therapy unit is accommodated in a shielded room, that means in a Faraday cage. (A Faraday cage enclosed by a metal housing or grid prevents the penetration of electric fields.) Often, a sufficient interference suppression is obtained by only connecting the devices to isolated mains circuits or using screening curtains (special curtains between the treatment cabins). Supplier is:

nsp- Sicherheitsprodukte GmbH
Hauptstr. 17
86695 Nordendorf
Germany
Phone: 049-8273-1031.

To stay within the limits given by DIN 0848, Part 2, we recommend that the operators and other persons keep a distance of at least 2 meters to the applicators and cables. In case of doubt, it is recommended to measure the field strength. Pregnant women should not operate the therapy unit.

ATTENTION: The therapy unit is not designed to be operated in environments in which there is danger of explosion. If used in anaesthesia rooms where inflammable narcotics are simultaneously used an explosion can not be ruled out!

3 Installation

3.1 Mains connection

The standard therapy unit is to be connected to a mains voltage of 230 V +/- 15 %, 50/60 Hz. However, a special version is also available for the connection to 115V +/- 15 %, 50/60 Hz. (The actual value is shown on the rating plate at the rear of the unit).

Before connecting to the supply mains check the conformity of the voltage values of the available mains and therapy unit. The therapy unit is to be only connected to a properly installed earthend socket outlet by means of the shielded mains connecting cable included in the basic accessories.

For the 230-V mains we recommend a slow-acting 10-A fuse.

3.2 Switching on

Switch on the power with switch **(1)** on the left of the operating panel. Now, the therapy unit is in the stand-by mode of operation. The indicators „Dosage" **(15)** and „Treatment time" **(14)** are lit. Further settings are to be made on the keyboard (cf. figure).

3.3 Mode of operation

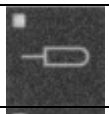
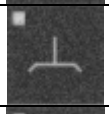
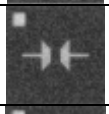
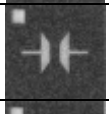
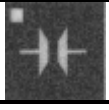
Select the mode of operation with the buttons **(3)**, **(4)** and **(5)** in the **„MODE"** field. Pressing button **(3)** turns the therapy unit to the continuous mode of operation. Different pulsed modes of operation can be selected by pressing button **(4)** or **(5)**. They differ in pulse width and pulse repetition frequency (cf. paragraph 6). The chosen mode is shown by the indicator light in the corresponding button marked by the symbol. The mode of operation can only be selected when the dosage display **(15)** shows **„0"**.

3.4 Choice of the applicator

The choice of the appropriate applicator is made according to area and volume of the body parts to be treated and according to preferring the coil or capacitor-field field application.

By pressing button **(6), (7), (8)** or **(9), (10), (11)** in the **"APPLICATOR"** button pad the dosage (output power) is limited according to the selected applicator so that an unintended overheating of the tissues is avoided.

The following buttons are assigned to the corresponding applicators:

Button	Applicator	Symbol
6	Coil applicator Minode,∅ 8 cm	
7	Coil applicator Monode, ∅ 14 cm	
8	Coil applicator Diplode,18 x 39 cm	
9	Capacitor-field applicator; ∅ 4.2 cm capacitor-field applicator, elastic, 8x12 cm	
10	Capacitor-field applicator; ∅ 8.5 cm capacitor-field applicator, elastic, 12x18 cm and larger	
11	Capacitor-field applicator; ∅ 13 cm	

As mentioned above, any programming is only possible with the dosage display **(15)** showing **„0".**

WARNING: The coil applicator **MONODE** must not be used in the pulsed mode of operation!

3.5 Connection of the applicators

Applicators are electrically connected to the sockets **(43).**

Insert the plug pins into the socket up to the stop!

Please, observe that in any case only the connectors of the capacitor-field applicator cables or the connectors of the coil applicator cable are plugged into sockets **(43)**.

3.6 Treatment time

Set the treatment time with buttons **(12)**, increasing, or **(13)**, decreasing. The actual value is shown on display **(14)**. Pressing the buttons for a short time will set the time in 1 -minute intervals, pressing them continuously will set the time in 5-minute intervals. When both buttons are simultaneously pressed the time is reset to „O". The maximum time that can be set is 30 minutes. Changing the time during the treatment is also possible.

After the clock is set it starts automatically when dosage knob **(17)** is shortly turned to the right, display **„Ab"** fades and the selected treatment time appears again on display **(14).** During the treatment the remaining time is shown on display **(14).** The end of the programmed time is acoustically signalled. This signal is constantly repeated every minute until dosage knob **(17)** is reset to 0 (turn to the left).

3.7 Setting the dosage

After the settings described in subparagraphs 2.3, 2.4 and 2.6 have been completed the dosage can be selected with dosage knob **(17).** Before the automatic tuning process can start the „MODE" and the „APPLICATOR" have to be selected. An incomplete setting results in the error message **„FEO"** appearing on „Dosage" display **(15).** Cancel the error message by turning the dosage knob to the left and complete the setting. Keep in mind that the dosage is to be only selected with the applicator(s) correctly adjusted to the patient's body and connected to the therapy unit according to subparagraphs 2.5. Dosage knob **(17)** has no right and left stops. Turning to the right increases the dosage in dependence on the dosage range in the following steps per lock point:

Up to		30 W in	3-W steps
From	30 W to	90 W in	5-W steps
From	90 W to	200W in	10-W steps

This applies for both the continuous and pulsed modes of operation.

In order for the therapy unit to deliver the high frequency dosage level selected with dosage knob **(17)** it is automatically tuned to the patient data after a short right turn of dosage knob **(17).**

During this process the tuning symbol **„Ab"** appears on the „Treatment time" display **(14)** instead of the treatment time. No further operator settings are accepted by the unit in this time period. Termination is only possible by pressing **„RESET"** button **(2).** The effect of the tuning process is shown on the display „Coupling to the patient" **(16).** The best RF power transfer to the patient is achieved when display **(16)** is totally lit. As the tuning takes place with minimum dosage the position of the applicator(s) to the patient can be changed during this process to enhance the dosage transfer. After the tuning process is terminated the treatment time is shown on display **(14)** again and, starting at this moment, the actual output power (dosage) is shown on display **(15).** The tuning process can be repeated by turning dosage knob **(17)** to the left down to „0" and subsequently turning it to the right again. The dosage can then be increased to the desired level by turning dosage knob **(16)** further to the right.

The display shows first the selected dosage. After the tuning it changes to the actual value. Then, this dosage level is stored and automatically readjusted by the therapy unit in case the patient moves or the mains voltage fluctuates. Thus, any accidental increase of the dosage due to patient movements is safely avoided, too.

3.8 Switching off (emergency disconnection by the patient)

The high frequency power or the entire therapy unit can be switched off by either of the following ways:

a) Turn off the power switch **(1).** (Entire therapy unit).
b) Press the **RESET** button **(2).** (The therapy unit is set to the stand-by mode as after switching on the power switch.)
c) Simultaneously press the time buttons **(12)** and **(13)**. (The mode of operation and applicator type remain stored.)
d) Turn dosage knob **(17)** to the left until „0“ appears on display **(15).** (The mode of operation, applicator type and remaining treatment time are kept stored.)
e) End of the adjusted treatment time. (The mode of operation and applicator type remain stored. Cancel the acoustic signal by turning the dosage knob to the left.)
f) Emergency off by the patient by using the ripcord **(45)**. Any use of the ripcord is indicated by an intermittent „beep“ sound and „FEC“ appearing on display **(15).** Switching back to the stand-by mode is done by pressing the RESET button **(2).**

3.9 Switching off by the safety circuit

After switching on the therapy unit and during the operation the microcontroller, in charge of the entire control functions of the unit, automatically performs many control sequences to ensure the safety of patient and therapy unit. If any error is being detected it is shown on the “Dosage“ display **(15)** and the output power is immediately switched off. This error condition is additionally indicated by an intermittent acoustic signal.

The error messages are indicated by the symbols:
FE 1, FE 2, FE 4, FE 5, FE 6, FE 7, FE 9, FE a, FE b, FEC.

If anyone of these error messages is displayed the therapy unit must be switched off and the after-sales service informed.

The FE 0 message means the parameter settings are incomplete. This condition is to be eliminated as described in subparagraph 2.7. No acoustic signal follows this error message.

4 Treatment

4.1 Preparation of the patient

To ensure an optimum therapy the patients and especially the parts of their bodies that are to be treated should be completely relaxed. A comfortable lying or sitting position is the best condition for this.

Patients shall never be treated on metal chairs or beds.

Hearing aids, watches, rings, chains, bracelets and other metal objects are to be removed for safety reasons before the treatment is started. This also applies to persons close to the therapy unit or applicators and cables, e. g. the operating staff.

The parts of the body involved should be treated in unclothed condition. Especially clothes made of synthetic materials are to be removed because they absorb moisture insufficiently, so that local areas with excessive moisture (e.g. skin folds) can absorb too much energy and can cause local overheating.

Before starting the treatment the ripcord is to be handed to the patient so that he/she can switch off the therapy unit when he/she feels nausea or unbearable heat sensation.

4.2 Implants

High frequency heat therapy is contra-indicated for patients with pacemakers.

Body parts with metal insertions (e. g. bone-fixation nails, grenade splinters, etc.) shall not be treated.

4.3 Pregnant women, endangered organs

Treatment of pregnant women is contra-indicated in the abdominal area.

Other contra-indications are growing-grooves, tumours, tuberculosis, disturbed arterial blood circulation of stages III and IV, varicose veins, general tendency to bleeding.

The doses must be carefully selected for organs with low vascularization and low blood circulation (e. g. eyes, testicles)!

4.4 Heat effect of the applicators

The evaluation of the heat effect of applicators on the basis of the subjective heat sensation by the patient is strongly influenced by a number of factors, e. g. the thickness of fat layers, treatment through clothes or bandages, blood circulation, temperature of the skin, etc.

Therefore, the following subparagraphs generally explain the operation of the applicators used with the
ULTRATHERM 908i. The heat effect of the electrodes differs fundamentally between the inductive and capacitive method of application.

4.4.1 Capacitive method of application

With the capacitive method of application the transformation of energy into heat mainly takes place in tissues with low blood circulation (e. g. fat, connective tissue). Thus, the greater part of heat is generated in areas near the surface (upper-skin fat tissue) so that not only the transformed energy but also the distance between applicator and skin is important for the subjective sensation of heat.

4.4.2 Inductive method of application

The high frequency magnetic field of a coil applicator generates eddy currents in the tissue. These currents increase with the electric conductivity of the corresponding tissue region (tissues with good blood circulation, e. g. muscle tissue and inner organs).

To reach these deeper tissues the coil applicators of the **ULTRATHERM 908i** are provided with an electrostatic shielding that prevents the technically unavoidable electric field of the coil applicator from effecting the upper-skin fat tissue and its heating. Therefore, the feeling of heat is basically delayed and it is recommended to start the treatment with a dosage level below the desired one and increase then guided by the patients heat sensation in the treated area. The dosage and treatment time values given in the application table should be observed.

During all the treatment time, the patient must be in contact with the Diplode!

If the patient is excessively heated up, do not change the body-Diplode contact position but decrease the output power or the patient turns off the **ULTRATHERM 908i** by pulling the ripcord.

Intermediate checks are recommended. In doing, observe the actual dosage shown on display **(15)** to obtain reproducible results within a treatment series.
An excessive output power (dosage) and missing intermediate inspections by the therapist often result in mismatching in the practice because the patient often does not switch off the **ULTRATHERM 908i** by means of ripcord and emergency-off switch but changes his/her

position so that the necessary body-Diplode contact does not exist. This is indicated by the luminous band indicator in the way that not 8 to 10 LEDs as desired but only a few are lit. This might even result in the fact that the coupling to the patient becomes completely interrupted, i.e. no more LEDs are on and the output power is greatly reduced.

The good matching between patient and Diplode by body contact is indicated by the fact that 8 to 10 LEDs of the luminous band indicator are lit, i. e. the optimum of about 80 to 100 per cent of the adjusted output power is converted into heat in deeper tissues of the patient.

In special applications with the DIPLODE, e. g. both knees at the same time, the maximum matching that can be obtained is only a few LEDs. The same is possible while using the MINODE or the MONODE. This constitutes nevertheless a regular operating condition for the **ULTRATHERM 908i** . Relevant for the emitted HF power and thus for the success of the therapy is the value giver in the dosage display.

4.5 Power rating of the applicators

The power rating of the individual applicators depends on their surface. Overheating of the applicators, in particular the coil applicators, on the one hand and an unbearable heating of the tissue on the other hand is avoided as the therapy unit automatically limits the output power (dosage) of the applicator, selected according to subparagraph 2.4, to its admissible level.

The following table shows the limited dosage values of the individual applicator types:

Button	Type of applicator	Limited power in Watts
6	Coil applicator Minode, ∅ 8 cm	30
7	Coil applicator Monode, ∅ 14 cm	90
8	Coil applicator Diplode, 18 x 39 cm	200
9	Capacitor-field applicator, ∅ 4,2 cm Capacitor-field applicator, elastic 8x12 cm	21 21
10	Capacitor-field applicator, ∅8,5 cm Capacitor-field applicator, elastic 12x18 cm	80 80
11	Capacitor-field applicator, ∅13 cm Capacitor-field applicator, elastic 15x25 cm	200

When different capacitor-field applicators are combined the smallest type of applicator determines the maximum dosage.
Deviations are possible in dependence on the heat sensation of the patient.

5 Warnings and Safety Precautions

Attention !

- Patients must not be treated on metal chairs or beds.
- Pieces of jewellery, glasses and other metal parts have to be taken off during the treatment.
- In case of patients with implanted electronic device carry out electrical stimulation treatment only after having checked whether there is any risk.
- Turn off cellular phones and radiophone or place them in a distance of 3 m from the device.
- Cardiac pacemakers can extremely be disturbed. In these cases the therapy should be only carried out under continuous pulse and ECG control.
- If the patient and/or the patient cable is in direct range of a high-frequency, short-wave or micro-wave therapeutic device, a damage to the device or an injury of the patient cannot be excluded. Please keep a distance of 3 m.
- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.
- In case of all visible failures contact immediately gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG.

6 Troubleshooting

Experience has shown that the most problems by far occur because of inadvertent operating errors. Therefore, before suspecting a fault in the therapy unit, please, check whether the present operating instructions have been correctly followed (cf. paragraphs 2 and 3).

When after switching on the therapy unit the displays **(14)** and **(15)** and the indicator lamp in power switch **(1)** do not light, check whether the therapy unit is correctly connected to the mains socket outlet and the last one is alive. If so, check the fuses at the mains voltage connection of the therapy unit **(44).** To do this, lift the latch and take the „drawer“ with the fuses out of the mains voltage connector **(44).** After checking and, if required, replacing a fuse re-insert until the latch catches.

ATTENTION: Fuses shall only be replaced by ones of the same rating and type. If fuses blow more frequently, please, contact our after-sales service.

If the error message **„FE 0“** appears on the „Dosage“ display **(15)** when turning the dosage knob **(17)** to the right check whether all parameters (mode of operation, applicator, time) were chosen or not. If display **(16)** shows only little or no coupling during the automatic tuning process indicated by **“Ab“** on display **(14)** check whether the applicator(s) used correspond(s) to that chosen by the actuated **„APPLICATOR“** button(s).

Furthermore, check whether the applicator cable connection and the applicator positions are correct. The area to be treated should be larger than or at least as large as the applicator surface.

Incorrect adjustment at the therapy unit during the treatment is acoustically signalled. For safe operation of the therapy unit and, thus the safety of the patient, a number of control measures were programmed which in case of error result in switching off the output power and displaying the type of error (cf. subparagraph 2.9).

7 Summary of operations

	See subparagraph
• Connect the therapy unit to the mains socket outlet	3.1
• Connect the applicator(s) to the therapy unit	3.5
• Attach the applicator(s) to the patient	4
• Turn on the therapy unit with switch **(1)**	3.2
• Select the mode of operation, buttons **(3), (4), (5)**	3.3
• Select the applicator(s), buttons **(6)** to **(11)**	3.4
• Set the treatment time, buttons **(12), (13)**	3.6
• Set the dosage knob **(17)**	3.7

- Electric power is applied to the output, the treatment timer starts operation.
- After the chosen treatment time has elapsed the therapy unit automatically turns off, on the display an **E**(ND) is shown and the unit emits an intermittent acoustic signal for about 10 s. This signal is repeated every minute until the dosage knob **(17)** is reset by turning to the left (counterclockwise).
- When an error is displayed (except for **FE 0**) press **RESET** button **(2)** and readjust, if required.
- The entire therapy unit is switched off by actuating switch **(1)** again.

8 Technical data

Mains voltage On request	230 Vac. +/- 15 %, 50/60 Hz 115 Vac. +/- 15 %, 50/60 Hz
Electric fuses (external)	10 A, slow acting for 230 Vac. 16 A, slow acting for 115 Vac.
Safety class	I
Protection degree	B
Protection against ingress of liquids:	IP X1
Power consumption, maximum Stand-by operation	about 700 W about 100 W
Frequency	27.12 MHz +/- 0.6 %
Power equivalent	400 W
RF output power at 50 Ω Continuous mode, Pulsed mode	 200 W 30 W
Pulse parameters Peak pulse power Pulse repetition frequency Pulse width	 400 W 70 Hz/350 Hz 2 ms / 0.4 ms
Dimensions	85 cm x 38 cm x 39 cm
Weight	approx. 40 kg
Safety test	DIN EN 60601-1 DIN EN 60601-2-3
Environmental conditions	operation of the device: temperature range +10 °C ... +40 °C relative humidity of air 30 ... 75 % transport and storage: temperature range +5 °C ... +50 °C realtive humidity of air < 90 %, non condensing

9 Accessories

Coil applicator (needs one (1) support arm)	
Minode with cable	23-50-114 Q 4558
Monode with cable	23-47-573 Q 4544
Diplode with cable	42-26-809 Q 4562
Capacitor-field set, consisting of:	
2 Schliephake spacer electrodes complete with calibration pin	
a) Plate-diameter 42 mm, Outer-diameter 85 mm	23-58-984 Q 4547
b) Plate-diameter 85 mm, Outer-diameter 130 mm	23-58-976 Q 4547
c) Plate-diameter 130 mm, Outer-diameter 172 mm	23-58-968 Q 4547
d) Plate-diameter 172 mm, Outer-diameter 220 mm	23-58-950 Q 4547
2 support arms per choice (2 x regular arms or flexible arm, left and right	see other accessory
2 Applicator-connection cable 120 cm without lead protection	19-05-215 Q 4824
2 Cable holder (for cable without lead protection)	23-38-499 Q 5028
1 Cable clamp, small (for cable without lead protection)	23-51-245 Q 4562
or	
2 Applicator-connection cable 120 cm with lead protection	19-89-870 Q 4824
1 Cable clamp, big (for cable with lead protection)	19-53-363 Q 4514
Plate-Applicator set 1, consisting of:	
2 Soft-rubber plate applicators, 8 cm x 14 cm with cable and plug	19-53-413 Q 3236
4 Felt spacer 9 x 16 cm	19-53-272 Q 3236
2 Cloth coating	23-95-606 Q 3236
2 Rubber bands 42 cm	45-38-971 EH 725
4 Fastening buttons	22-74-801 Q 1320
Plate-Applicator set 2, consisting of:	
2 Soft-rubber plate applicators, 12 cm x 18 cm with cable and plug	19-53-421 Q 3236
4 Felt spacer 13 x 20 cm	19-53-280 Q 3236
2 Cloth coating	23-95-614 Q 3236
2 Rubber bands 42 cm	45-38-971 EH 725
4 Fastening buttons	22-74-801 Q 1320
Plate-Applicator set 3, consisting of:	
2 Soft-rubber plate applicators, 18 cm x 27 cm with cable and plug	19-53-439 Q 3236
4 Felt spacer 19 cm x 29 cm	19-53-298 Q 3236
2 Cloth coating	23-95-622 Q 3236
2 Rubber bands 135 cm	45-38-963 EH 725
4 Fastening buttons	22-74-801 Q 1320
Other accessory:	
Applicator-connection cable, Length 120 cm	19-05-215 Q 4824
Applicator-connection cable with lead protection, Length 120 cm	19-89-870 Q 4824
Arm, regular	011-1-0156
Flex arm, on the left	011-1-0169
Flex arm, on the right	011-1-0170
Cable holder (for cable without lead protection)	23-38-499 Q 5028
Clamp, small (for cable without lead protection)	23-51-245 Q 4562
Clamp, big (for cable with lead protection)	19-53-363 Q 4514
Indicator discharge tube	22-53-722 Q 3215

10 Key to symbols

CE-mark

Warning !
Pay careful attention to the operating instructions!

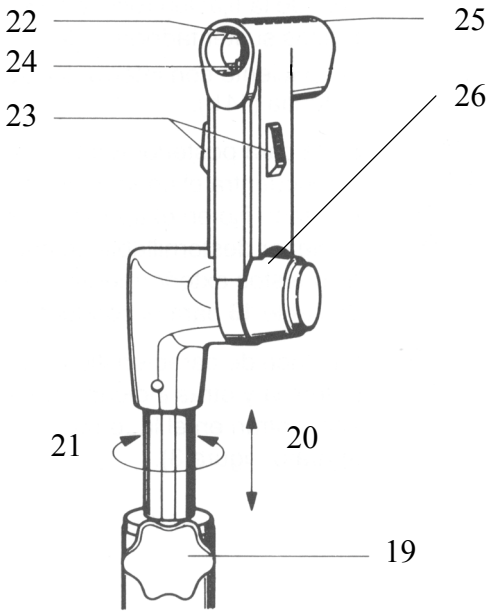
Connector for patient cable;
Type B, unit suitable for external and internal application to the patient, except to the heart.

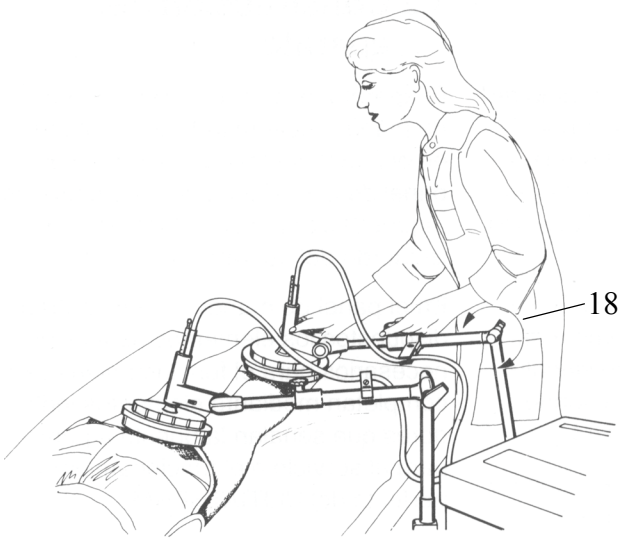
Non ionizing radiation

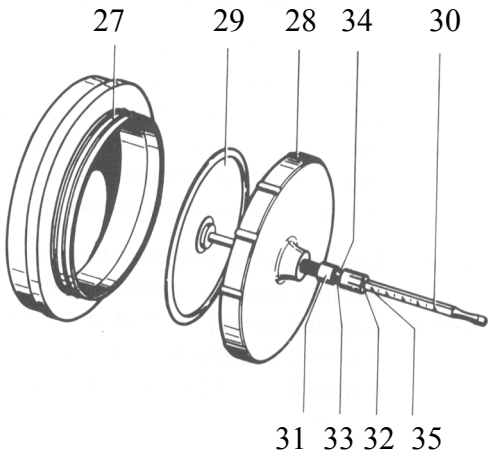
This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

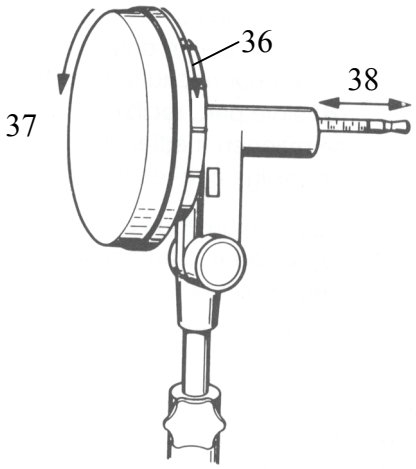
Appendix A: Drawings

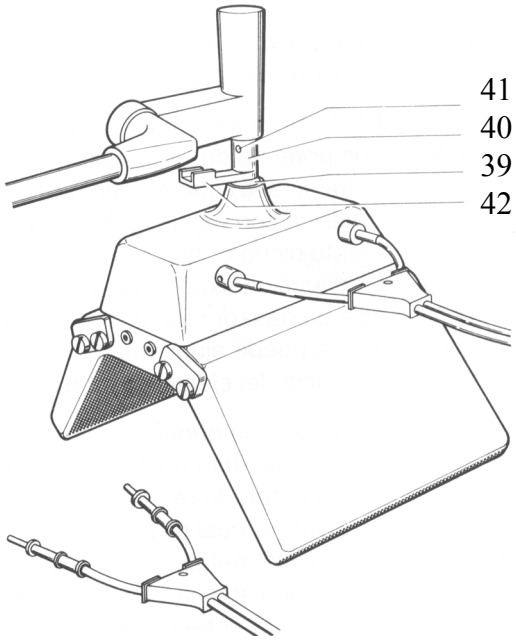
(18) Lockable joint
(19) Fixing knob
(20) Axial displacement
(21) Rotatory displacement
(22) For electrodes hole
(23) Sliders
(24) Locking pin
(25) Hole for Schliephake adjuster pin
(26) Pin socket
(27) Front cap
(28) Back cap
(29) Electrode
(30) Adjuster pin
(31) Slotted bush
(32) Locking nut
(33) 4 fixing holes
(34) Guide groove
(35) Slotted locking nut
(36) Lock electrodes
(37) Unlock electrodes
(38) Axial adjustment
(39) Ball joint
(40) Connection
(41) Fixing hole
(42) Claw
(43) Sockets for capacitor-field applicators
(44) Mains voltage connection
(45) Emergency-OFF switch (ripcord)
(46) Screw holes for arm attachment

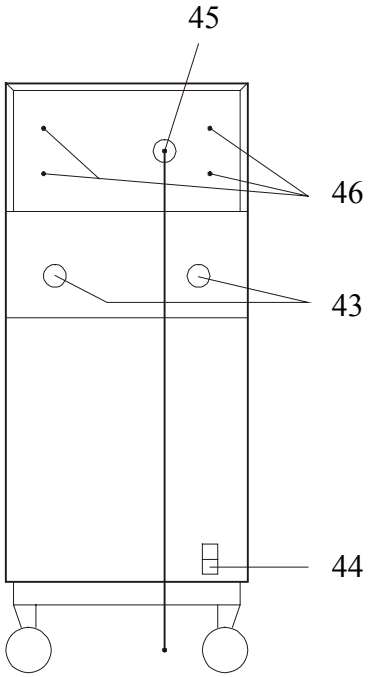












Rückseite

Appendix B: Treatment table

In the table, the doses are stated according to Schliephake, who distinguishes between four stages:

Dose I No perceptible heat. First set output to low perception of heat and then turn slightly down.
Dose IIBarely perceptible heat.
Dose III Perceptible agreeable heat.
Dose IV Still bearable heating.

In the event of exacerbation, pauses should be made and treatment continued with reduced intensity. Chronic processes of the skeletal system call for stronger applications of heat.

Disease:	Electrodes preferred: *	Dose acc. to Schliephake:	Treatment time (min):
Frostbite, local, acute	WE; SE; WE+SE; M	I	3 - 8
Frostbite, local, chronic	WE; SE; WE+SE; M	I - II	10
Erythema	M, DI	I - II	5 - 10
Furuncle, carbuncle	M	I - II	3 - 5
Hydradenitis	SE, M	II	10
Panaritia	WE, M, DI	I - II	5 - 10
Arthritis	SE, DI	II - III	10 - 15
Bursitis	M	II - III	10
Sprains, contusions	SE, DI	II - III	5 - 10
Epicondylitis	M	II - III	10 - 20
Lumbago	DI	II - III	10 - 20
Bechterew's disease	SE, DI	II - III	10 - 20
Myalgia	WE, SE, DI	I - III	10 - 20
Periarthritis	SE, M, DI	II - III	10 - 20
Periostitis	WE, SE, WE + SE, DI	II - III	5 - 10
Polyarthritis	SE, DI	II - III	5 - 10
Spondylosis	WE, SE, DI	II - III	15 - 20
Tendovaginitis	SE, M	II - III	10 - 15
Sciatica, acute	WE, SE	I - II	5 - 8
Sciatica, chronic	WE, SE	II - III	10 - 20
Neuralgias	WE, SE, DI	I - III	5 - 15
Neuritis	WE, SE, DI	I - III	3 - 15
Angina pectoris (dose carefully)	WE, SE, DI	II	3 - 5
Impaired peripheral circulation	WE, SE	II -III	10 - 15
Thrombophlebitis	WE, SE	II	5 - 10

Cholecystitis	WE, SE, DI	II - III	10 - 15
Hepatitis	SE, DI	II - III	10 - 15
Cardiospasmus	WE, DI	II	10 - 15
Colitis	WE, WE + SE	II - III	10 - 20
Obstipation spast.	WE, WE + SE	II	5 - 10
Anuria in acute nephritis	WE , SE, DI	II - III	30 - 60
Cystitis	WE, SE, WE + SE	II - III	10 - 20
Nephritis, acute and chronic	WE, SE, WE + SE	II - III	15 - 30
Pyelitis	WE, SE, WE + SE	II - III	15 - 30
Prostatitis	SE, M	II - III	10
Adnexitis, acute	WE, WE + SE	I - II	3 - 5
Adnexitis, chronic	WE, WE + SE	II - III	5 - 10
Amenorrhea	WE, WE + SE	II - III	5 - 10
Abscess of Douglas	WE, WE + SE	II - III	5 - 20
Dysmenorrhea	WE, WE + SE	II - III	10
Mastitis	SE, DI	I - III	5 - 10
Parametritis, perimetritis	WE, WE + SE	II	5 - 10
Ovarian insufficiency (hypophysis-treatment)	SE	II	10
Bronchial asthma	SE, DI	II - III	5 - 10
Bronchiectasis	SE, DI	II - III	10 - 30
Bronchitis	SE, DI	II - III	10 - 15
Abscess of the lung	WE, SE, WE + SE	II - III	10 - 30
Thoracic empyema	WE, SE, WE + SE	II - III	5 - 20
Pleuritis	SE, DI	III	5 - 15
Interstitial pneumonia	SE, DI	II - III	5 - 10
Gingivitis, stomatitis	M	I - II	5 - 10
Inflammation of the maxillary joint	SE, M	II - III	10
Laryngitis	M	I - II	5 - 10
Otitis media	M	II	5
Post-operative otitis	M	II - III	5 - 10
Parotitis	M	I - II	5
Sinusitis	M	I - II	5 - 10
Iritis (dose carefully)	SE	I - II	5 - 10
Herpetic keratitis (dose carefully)	SE	I - II	5 - 10
Ulcus corneae (dose carefully)	SE	I - II	5 - 10

* WE = rubber-pad electrodes
SE = air space electrodes of Schliephake type
M = MINODE or MONODE
DI = DIPLODE

Correction sheet

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- Dokumentation -
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D-64668 Rimbach
Germany

Please revise the following errors and stimulation to the document:

page	**line**	**wrong text**	**right text**

Sender:

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