Geratherm®
Medical Warming Systems

Instruction manual | PatientWarmingSystem

www.geratherm.com

Warmth that saves lives

UniqueResc+

UniqueResc+

Thank you for choosing a Geratherm Patient Warming System.

The benefits of Geratherm UniqueResc+ are:

- Active warming from above
- Due to semiconductor-coated textiles respectively carbon fibres as heating material a consistent and plane heating is ensured
- Microprocessor-controlled
- Thin, cosy warming blankets by application of modern insulating material
- Noiseless, no distribution of germs through air disturbance
- Simple to use:
  Plug in – forthwith warming
- Highly durable and easy to clean as the outer material is made up of welded PU fabrics
- Due to special Geratherm line adapter, as an optional feature, it is adaptable to all alternating current networks from 90 V until 230 V (50Hz/60Hz)

Geratherm UniqueResc+ has been developed for the prevention of hypothermia at the rescue scene, for instance is the system by application of a lithium-ion battery over a longer period of time independent of supply systems.

Before using the Patient Warming System, please read through the operating instructions carefully!

Contents

1 Identification

The Geratherm UniqueResc+ can be identified as follows:

Manufacturer's designation:

Geratherm®
Medical Warming Systems

Model:
Geratherm UniqueResc+ Rescue Warming System

Type: R130
R150

Device/ software version:
Version: 1. and 2. digit of the serial number

Serial number:
The serial number is to be found under the transparent window of the control cover plate, on the commercial invoice and in the attached documentation.

MPG classification:
Geratherm UniqueResc+ has been categorised as a Class IIb device.

Geratherm UniqueResc+ meets the requirements of Council Directive 93/42 EEC of 14.06.93 on Medical Devices and of the standard DIN EN 60601-1 (Medical electrical equipment, Part 1: General requirements for safety), DIN EN 60601-1-2 (Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests), and DIN EN 60601-2-35 (Medical electrical equipment, Part 2: Particular requirements for the safety of blankets, pads and mattresses intended for the warming of patients in medical use).

A DIN EN ISO 13485 certified quality management system ensures that these requirements are met and entitles the manufacturer to use the CE 0118 label.

2 Purpose

Geratherm UniqueResc+ has been developed for the prevention of hypothermia. The warming blankets are light-weight, cosy and warm the patient from above.

The use of several blankets per patient is possible. The flexibility of the blankets makes it possible to warm the patient even during complicated rescue operating terms.

Geratherm UniqueResc+ is suitable for use with adult patients of all sizes.

Geratherm UniqueResc+ shall only be operated under the supervision of the user.

3 Safety precautions

- To ensure safe use, it is necessary to read all the way through the operating instructions.
- Like all medical devices, Geratherm Patient Warming Systems require special care with regard to EMC. The safety precautions described in these operating instructions (e.g. avoiding placing the device on EEG equipment) must be strictly adhered to.
- ***Note: In order to avoid hazards, the unit should be only used at direct current low voltage power sources (12V up to 28V), as e.g. by on-board power supply systems of rescue vehicles or by the optional Geratherm power adapter. As well the use of suitable batteries is possible.***
- It should be noted that portable and mobile HF communication equipment could affect medical devices.
- The use of extension cables can cause dysfunctions. In areas around thermally conductive materials as water, snow and similar substances the patient's body temperature could cool down as long as the device is disconnected.
- All of the Geratherm UniqueResc+ must not be operated on DC or AC power out of the indicated range (12 – 28V). Connections to other power supplies respectively the operation on not approved adapters can result in serious personal injury and material damage. Only special Geratherm adapters are allowed to be used.
- If the Geratherm power adapter is applied it should be only connected to one warming blanket!
- ***Geratherm UniqueResc+ warming blankets must not be cleaned in a washing machine or autoclave!***
- To ensure safe use, it is necessary to read all the way through the operating instructions.
- Like all medical devices, Geratherm Patient Warming Systems require special care with regard to EMC. The safety precautions described in these operating instructions (e.g. avoiding placing the device on EEG equipment) must be strictly adhered to.

- Do not operate the control unit in areas subject to explosion hazard!
- Do not use Geratherm UniqueResc+ warming blankets together with other heat sources (e.g. radiation lamps, incubators or hot water bottles)! This could be detrimental to the patient's health.
- Do not place the control unit directly on top of ECG or EEG equipment. Otherwise, faults may arise, e.g. the devices may produce false readings!
- ***Before each use, check the surface of the warming blankets for any visible damage! Discontinue use of any damaged blankets immediately!***
- Put the Geratherm UniqueResc+ warming blankets completely on the patient. To prevent overheating, do not under any circumstances fold the equipment!
- Do not place any objects on top of the warming blankets to avoid any localised overheating or heat accumulation.
- It must be checked whether any fixture is required to keep the patient in place. If so, the same must be positioned underneath the warming blankets.
- The temperature setting (only by model type R130) is the responsibility of the physician.
- ***Do not use Geratherm UniqueResc+ on patients with impaired circulation! The manufacturer is not aware of any other contra-indications.***
- Whenever heat treatment is applied, the core body temperature of the patient must be monitored at regular intervals. The length of the intervals shall be determined by the medical staff.
- Geratherm UniqueResc+ shall only be used under the supervision of the medical staff.
- ***Do not apply adhesive tape to the warming blankets. This will lead to permanent soiling of the surface.***

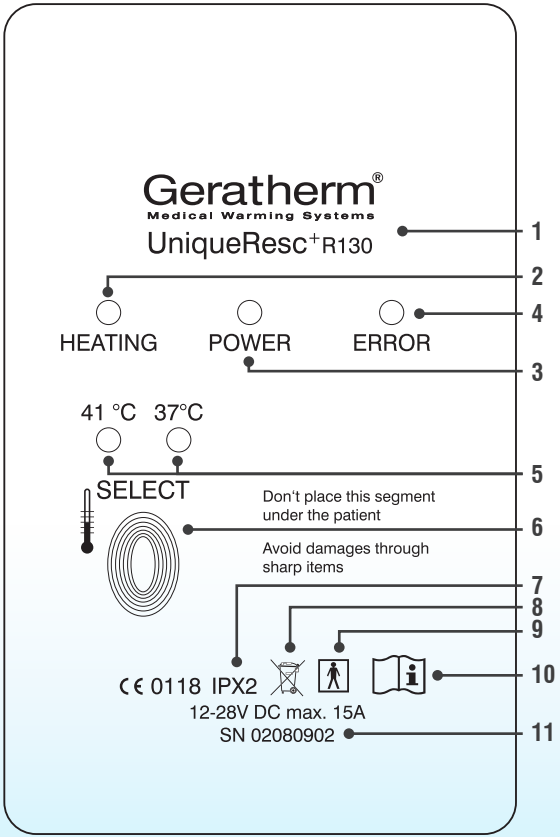
4 Description

4.1 Overview of the components and manual control elements

4.1.1 Type R130

Complete warming blanket

example of application



control unit

1 Device description and type

2 LED display HEATING (display flashes during heating-up)

3 LED display POWER (display lights up during operating)

4 LED display ERROR (lights up if a fault occurs)

5 Display of the selected set temperature

6 SELECT button for switching-over the set temperature

7 Safety class

8 Do not dispose of in household waste

9 BF type applied part

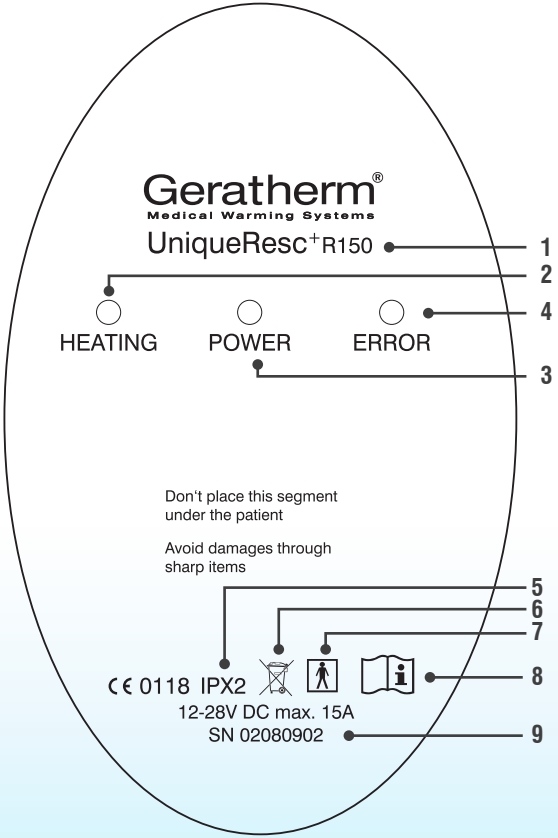
10 Read operating instructions

11 Serial number of the device

4.1.2 Type R150

Complete warming blanket

example of application



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9 Serial number of the device

4.2 Safety features

Geratherm UniqueResc+ has an optical and acoustic alarm system, which indicates all faults.

The system possesses monitoring installation of hardware as well as software.

A short tone after the unit is switched on indicates that the alarm system and the independent safety device have been automatically checked and are operational. The control unit will not switch on if the safety device is faulty.

5 Starting up and operation

5.1 Assembly and installation

Geratherm UniqueResc+ warming blankets must be laid on the patient in such a way that they cover as large a proportion of the patient's body surface as possible.

The range of different warming blankets enables an optimum covering of the most frequently case of operations possible.

5.2 Positioning the blankets

- ***Do not lay the patient on top*** of the Geratherm UniqueResc+ warming blankets!

- Put the warming blankets on the patient ***in such a way that the control unit´s window side is facing away the patient.***
  The warming blankets can be put directly on the patient; strongly insulating layers placed in between will inhibit the transfer of heat to the patient.

  - **Note:**
    If the warming blankets are placed on the patient with the side on which the control unit is positioned facing the patient, the patient will not be warmed, i.e. Geratherm UniqueResc+ will not have any effect!

5.3 Starting up

After connecting the warming blanket to the supply voltage the heating process in the warming blanket is immediately after short self test activated.

In case of using the Geratherm power adapter it will be ready for use approx. two seconds after connecting to the AC voltage (showed by a green LED).

- ***Warning:*** If the Geratherm power adapter is applied it should be only connected to one warming blanket!

Procedure after switching on the control unit:

- All of the 3 LED's light up briefly. All required heating system equipment checks are performed automatically in this period of time.
- At the same time, a short tone signal announces the test of the acoustic alarm function.
- Then, the red ERROR LED has gone out now that the green HEATING LED flashes consistently until the pre-selected blanket temperature is reached.
- If needed, type R130 now allows changing the final temperature from 41 °C to 37 °C by pressing three times the temperature selection button (SELECT button).
- Due to high sensitivity of the sensors, the ERROR LED could probably flash briefly (ca. 2 – 3 seconds) during the heating process. This is no system error and it is reset autonomously.

5.4 Switching off the warming blankets

The switching off of the warming blanket is achieved by disconnecting it from the voltage source.

- **Note:**
  The heating phase of the warming blanket from 20 °C to 37 °C is approx. 5 minutes.

When executing R130 and the power supply is interrupted, the temperature is re-set independently from the eventually preselected temperature to 41 °C. If another temperature is required, the pre-selection of temperature has to be activated anew as shown in chapter 5.3.

- **Note:**
  To get the blanket unplugged, only pull the plug, never pull the cable!

6 Shutting down

6.1 Shutting down between the operations

See chapter:
5.4 Switching off the warming blankets

6.2 Long-termed shutting down of the Geratherm UniqueResc+

Prior to storing UniqueResc+ no maintenance is required.

The system may only be deposited dryly.

If ring connectors are often used, it is recommended to lightly grease (Vaseline) the contacts of the ring connectors to avoid oxidation.

7 Messages and faults

The control unit is equipped with a program which recognizes errors autonomically and displays them by the red ERROR LED.

The type of disorder of devices with infrared module can be read-out additionally with an infrared adapter by the service technician.

Due to high sensitivity of the sensors, the ERROR LED could probably flash briefly (ca. 2 – 3 seconds) during the heating process. This is no system error and it is reset autonomously.

If another error occurs, the warming blanket must be put out of operation immediately. Our customer service department is glad to can be at your disposal.

If you return the system for repairs, please send only disinfected warming blankets.

8 Preparation and hygiene measures

8.1 Cleaning and disinfecting

The Geratherm UniqueResc+ warming blankets can be wished off and wiped with disinfectant. For this purpose, please use only commercially available alcohol-based colourless disinfectants in accordance with the instructions of the manufacturers of the disinfectant.

Users should not employ any cleaning or decontaminating procedures other than those recommended by the manufacturer without first checking with the manufacturer whether the proposed procedures could damage the device.

When disinfectant is used, its compatibility with the materials must first be tested on a test area. Upon request, Geratherm will be pleased to provide samples of the materials for such tests. A suitable product is, for example, Incidur-Spray manufactured by Ecolab GmbH, P.O. Box 130406, D-40554 Düsseldorf.

If you wish to use other cleaning agents or procedures, you must consult the manufacturer first. Otherwise there is a risk that the warming system will be damaged.

- **Warning!**
  Insufficiently disinfected blankets constitute an infection hazard.

Do not clean or sterilise the warming blankets in a washing machine or autoclave.

- **Warning!**
  Care must be taken to ensure that the blankets are completely dry after cleaning and prior to storing respectively before stowing into the transportation containers.

8.2 Checks after processing

Check the warming blankets and connecting cables regularly for any damage.

Any damage to the surface coating due to long-term intensive use or strong mechanical forces necessitates replacement by the manufacturer.

Damaged blankets shall not be used again.

8.3 Replacement of consumables

There are no consumables!

9 Maintenance

Servicing and safety checks must be carried out in compliance with EN60601-1 and MPBetreibV (in Germany only) using the Geratherm Service Manual of Rescue Warming Systems UniqueResc+ and the checks for medical electrical equipments are instructed **every 24 months**. The warming systems must be subjected to technical inspections, including safety-related checks, by the manufacturer or an authorised person every 24 months. Checking the calibration of the systems is only required after the replacement of assembly modules and as part of the safety-related checks.
The Service Manual can be obtained free of charge from the manufacturer upon request.

- **Warning!**
  Alterations to the UniqueResc+ are not permitted without the consent of the manufacturer.

10 Disposal

The device must be disposed of in accordance with the WEEE Recycling Directive, not as household waste.

Disposal does not entail any particular hazards.

11 Warranty

Geratherm Medical AG provides a 24-month warranty on the warming blankets. The warranty does not include the remedying of damage arising as a result of

- accidents, disasters, improper use or other external influences,
- use of parts that do not belong to the product,
- maintenance work that is not carried out by Geratherm Medical itself or by an authorised person.

12 Technical data

12.1 Type R130

Art.No.: 8001110615
Nominal voltage: 12V to 28 V DC
Power: max. 100 VA
Fuse: 16A M delayed action (6x25)mm in the car plug
Default temperatures: 37,0 °C / 41,0 °C
Dimensions (W x D): 50 cm x 86 cm
Weight: 0,9 kg
Classification under Directive 93/42 EEC: II b
Operating environment:
Temperature: -30 °C to +40 °C
Humidity: to 95 %
Transport and storage:
Temperature: -30 °C to +70 °C
Humidity: to 95 %

12.2 Type R150

Art.No.: 8001110616
Nominal voltage: 12V to 28 V DC
Power: max. 100 VA
Fuse: 16A M delayed action (6x25)mm in the car plug
Default temperature: 41,0 °C
Dimensions (W x D): 48 cm x 49 cm
Weight: 0,6 kg
Classification under Directive 93/42 EEC: II b
Operating environment:
Temperature: -30 °C to +40 °C
Humidity: to 95 %
Transport and storage:
Temperature: -30 °C to +70 °C
Humidity: to 95 %

 All blankets are BF type applied parts, i.e. suitable for direct application to the body.

12.3 Geratherm power adapter

Art.No.: 8001110940
Nominal voltage: 100V to 240V AC
Frequency: 50/60 Hz
Power: 150W
Fuse: 1,6A
Dimensions: 7 cm x 11 cm x 19 cm
Weight: 0,85kg
Safety class: I
Degree of protection: IPX2 Protection against splashing water
Output voltage: 12V DC
Operating environment:
Temperature: -10 °C to +40 °C
Humidity: to 95 %
Transport and storage:
Temperature: -30 °C to +70 °C
Humidity: to 95 %

12.4 Scope of delivery

- UniqueResc+ R130
  Art.-Nr.: 8001110615
  Warming blanket (50cm x 86cm) with instruction manual

- UniqueResc+ R150
  Art.-Nr.: 8001110616
  Warming blanket (48cm x 49cm) with instruction manual

- Power adapter UniqueResc+
  Art.-Nr.: 8001110940
  Power adapter UniqueResc+ (optional available)

The parts listed under Point 12.4 can be reordered from your dealer or from the manufacturer, citing the Art. No.

12.5 Symbols used

SN Serial number of the warming blanket

CE 0118 CE mark (confirms the conformity of the medical product with Directive 93/42 EEC).

The identification number 0118 stands for the Thuringian State Office for Measurement and Calibration.

 Pay attention to operating instructions

 BF type device

IPX2 Device is splash-proof in a 15° incident angle

 Device must not be disposed of as household waste

Annex

Annex from EN 60601-1-2:2001 and A1:2006

Information on the essential performance characteristics:
Essential performance characteristics:
Characteristics those were necessary in order to keep the residual risk level within acceptable limits.
During the insensitivity test, each function of the device and/or system shall be tested in the mode that, in respect of the result, is most critical for the patient on the basis of a risk analysis, using device options, cable arrangement and accessories in a typical configuration as in normal use. This risk analysis is not necessary if all modes of the device and/or system are tested. If the device and/or system are not intended for continuous operation, the operating mode can be selected in such a way that reliable operation is achieved for the respective duration of the test.

6.8.2.201 Operating instructions

a) Requirements for all devices and/or systems

The operating instructions must contain the following:

1.) A declaration that medical electrical devices require special precautions as regards elec romagnetic compatibility (EMC) and must be installed and operated in compliance with the EMC information included in the accompanying documentation.

2.) A statement that portable and mobile HF communication equipment may affect the function of medical electrical devices.

6.8.3.201 Technical description

a1) Cables, maximum lengths of cables and accessories:
A list of all cables and the maximum length of cables (if applicable), transducers and other accessories with which the manufacturer of the device or system claims compliance with the requirements of sub-clauses 36.201, Emissions, and 36.202, Insensitivity. Accessories which do not affect compliance with the requirements of these sub-clauses do not need to be listed.

a2) Warning concerning the use of accessories A warning that the use of other accessories, other transducers and other cables than the specified ones – except transducers and cables sold via the manufacturer of the device or system – as replacement parts for internal components can lead to higher emissions and/or reduced insensitivity of the device or system.

a3) Advice on electromagnetic compatibility - Emission
In the following the Geratherm UniqueResc^{+} is designated as a device or system.

Notes and statement of manufacturer – Electromagnetic emissions		
The device or system is suitable for use in the electromagnetic environment described below. The purchaser and/or user of the device or system must ensure that it is used in an electromagnetic environment that conforms to the following description.		
Emission test	Compatibility	Notes on the electromagnetic environment
HF emissions CISPR 11	Group 1	The device or system uses HF energy only for its internal functioning. Therefore its HF emissions are very low, and it is unlikely that they will affect electronic instruments located nearby.
HF emissions CISPR 11	Class B	The device or system is suitable for use in all facilities, including households and facilities that are directly connected to the public low-voltage electricity supply network that supplies buildings used for residential purposes.
Overtone emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Compatible	

a4) Warning regarding installation
The device or system should not be used next to other devices or be stacked with other devices and a warning shall be given that if use next to or stacking with other devices is unavoidable, the device or system shall not be used for the purpose of verifying normal operation in the configuration in which it is being used.

a5) Compatibility level
The device meets the insensitivity test level required under IEC 60601.

a6) Advice on electromagnetic compatibility – insensitivity

Notes and statement of manufacturer – Electromagnetic insensitivity			
The device or system is suitable for use in the electromagnetic environment described below. The purchaser and/or user of the device or system must ensure that it is used in an electromagnetic environment that conforms to the following description.			
Insensitivity test	IEC 60601 – test level	Compatibility level	Notes on the electromagnetic environment
Electrostatic discharge (ESE) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The floors should be of wood, concrete or ceramic tiles. If floors are covered with a synthetic material, the relative humidity should be at least 30 %.
Short duration electrical surge / discharge bursts IEC 61000-4-4	± 2 kV for electricity supply lines	± 2 kV for electricity supply lines	The quality of the line current should correspond to that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential mode ± 2 kV Common mode	± 1 kV Differential mode ± 2 kV Common mode	The quality of the line current should correspond to that of a typical commercial and/or hospital environment.
Voltage reductions, short interruptions and voltage fluctuations in electricity supply lines IEC 61000-4-11	< 5 % UT for 0.5 of a cycle (> 95 % reduction of UT) 40 % UT for 5 cycles (60 % reduction of UT) 70 % UT for 25 cycles (30 % reduction of UT) < 5 % UT for 5 seconds (> 95 % reduction of UT)	< 5 % UT for 0.5 of a cycle (> 95 % reduction of UT) 40 % UT for 5 cycles (60 % reduction of UT) 70 % UT for 25 cycles (30 % reduction of UT) < 5 % UT for 5 seconds (> 95 % reduction of UT)	The quality of the line current should correspond to that of a typical commercial and/or hospital environment.If the user of a device or system requires continued operation during power supply interruptions, it is recommended that the device or system be supplied via an uninterruptible power supply or by battery.
Electrical frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should be measured at the intended installation location to ensure that it is sufficiently low.
NOTE: Geratherm UniqueResc+ is the network AC voltage prior to application of the test level.			

Notes and statement of manufacturer – Electromagnetic insensitivity			
The device or system is suitable for use in the electromagnetic environment described below. The purchaser and/or user of the device or system must ensure that it is used in an electromagnetic environment that conforms to the following description.			
Insensitivity test	IEC 60601 – Test level	Compatibility level	Notes on the electromagnetic environment
			Portable and mobile HF communication equipment should not be used closer to any part of the device system, including cables, than the recommended distance calculated using the correct equation for the frequency of the transmitter.
			Recommended distance:
Conducted HFIEC 61000-4-6	3 V effective value 150 kHz to 80 MHz	3 V effective value	$d = [3.5/3]\sqrt{P} = 1.17\sqrt{P}$
Radiated HF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	10 V/m	$d = [3.5/10]\sqrt{P} = 0.35\sqrt{P}$ 80 MHz to 800 MHz
			$d = [7.0/10]\sqrt{P} = 0.70\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum rated output of the transmitter in (W) according to the manufacturer of the transmitter and d is the recommended distance in metres (m) . The field strengths of fixed HF transmitters measured in an electromagnetic location check should be lower than the compatibility level in each frequency range. Interference may occur close to devices bearing the following symbol:
NOTE 1:	At 80 MHz and 800 MHz the higher frequency range is to be used.		
NOTE 2:	These guidelines may not apply to all situations. Electromagnetic radiation is influenced by absorption and reflection from buildings, objects and persons.		

Notes and statement of manufacturer – Electromagnetic insensitivity
a) The field strengths of transmitters such as base stations for mobile phones (mobile or cordless phones) and mobile non-public radio equipment, amateur radio transmitters, SW and VHF radio transmissions and television broadcasts cannot be precisely predicted in theory. In order to evaluate the electromagnetic environment around fixed HF transmitters, an electromagnetic location check should be considered. If the field strength measured at the location where the device or system is used exceeds the aforesaid HF compatibility level, the device or system should be observed in order to verify normal operation. If abnormal operation is observed, further measures may be necessary, such as realigning the device or system or transferring it to a different location. b) Above the frequency range from 150 kHz to 80 MHz the field strengths should be lower than 3 V/m.

Recommended distances between portable and mobile HF communication equipment and the device or system			
The device or system is suitable for use in the electromagnetic environment described. The purchaser and/or user of the device or system can avoid electromagnetic interference by adhering to the minimum distance between portable and mobile HF communication equipment (transmitters) depending on the output of the communication equipment, as follows:			
Maximum rated output of the transmitter in Watt	Distance / m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1{,}17\sqrt{P}$	$d = 0{,}35\sqrt{P}$	$d = 0{,}70\sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,70
10	3,70	1,11	2,21
100	11,70	3,50	7,00
For transmitters the rated output of which is not listed above, the distance can be estimated using the equation in the corresponding column, with P representing the maximum rated output of the transmitter in Watt (W) according to the information provided by the manufacturer of the transmitter.			
NOTE 1:	At 80 MHz and 800 MHz the higher frequency range is to be used.		
NOTE 2:	These guidelines may not apply to all situations. Electromagnetic radiation is influenced by absorption and reflection from buildings, objects and persons.		

Manufacturer:

Geratherm®
Medical Diagnostic Systems

The manufacturer reserves the right to make technical modifications in keeping with technical advances.

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