Instructions for use

Domotherm® Easy

Digital Medical Thermometer

CE 0123

REF 0816

PZN-10407062



INTENDED USE

This digital thermometer is intended to measure the human body temperature in regular mode orally (in the mouth), rectally (in the anus) or axillary (under the arm). It is reusable for clinical or home use on people of all ages.

SAFETY INSTRUCTIONS

- Please read through these instructions carefully before using the thermometer.
- The device is not suitable for aural use (see types of measurement).
- For rectal measurement, do not insert the measuring tip with force. Discontinue the measurement if you feel any pain. Risk of injury!
- Do not use the thermometer for oral measurements if it has previously been used for rectal measurements.
- Do not conduct oral measurements on children under the age of 2.
- Do not use the thermometer when wet as this can lead to inaccurate measurements.
- Do not bite the thermometer. This can cause damage or injury!
- Do not drop the thermometer. It is not resistant to shock or impact.
- Where protective coverings are used, the temperature measurement can deviate by around 0.1°C.
- The thermometer contains small parts (batteries etc.) that could be swallowed by children. Risk of suffocation! Do not leave the device unattended with children.
- Do not expose the battery to extreme heat. Risk of explosion!
- Do not open the casing (except to change the battery).
- Using the unit in the immediate vicinity of mobile phones, microwave appliances or other devices with strong electromagnetic fields may result in impaired functioning. Maintain a minimum distance of 3 m from such devices when using this unit.
- Discuss the measured values with your doctor. Do not assess the measurement results yourself. Self-diagnosis can aggravate an existing medical condition. Always consult a doctor if the reading shows a high fever.
- Use outside the intended operating conditions or storage outside the intended storage and transport conditions can result in inaccurate measurements.
- If the body temperature of the patient is lower than the ambient temperature, this will lead to inaccurate measurement results.
- If the device has been stored at temperatures below 5°C or above 40°C, allow it to stand at room temperature for at least 15 minutes before using it.
- Clean and disinfect the thermometer after every use, especially if the thermometer is to be used by more than one person.
- Remove the battery when the device is not being used for a long period.

MEASUREMENT TYPES

In the rectum (rectal measurement)

Apply some Vaseline to the measuring tip to aid insertion. The measuring tip is carefully inserted 1 cm into the anus.

In the mouth (oral measurement)

Insert the tip into one of the two heat pockets under the tongue, on the left- or right-hand side of the root of the tongue. Close the mouth and breathe calmly through the nose.

Under the arm (axillary measurement)

The skin must be completely dry. Position the measuring tip under your arm in such a way that the measuring tip is in good contact with your skin. Press your arm closely to your body. From a medical perspective, the axillary measurement method produces inaccurate measurement readings and should not be used if you wish to take precise measurements.

MEASURING THE TEMPERATURE

To turn on the thermometer, press the on/off button. A short beep indicates that the thermometer is on. At the same time, an optical full segment check of the display will be carried out. Then the last temperature measured will be displayed for approx. 2 seconds, along with a small M (for memory). Then an internal test value appears and the thermometer switches to measuring mode.



Place the thermometer at the desired measurement point. During measurement the current temperature is shown on the display with a flashing "°C" symbol. A beep sound signals the end of the measurement. It is imperative you adhere to the minimum measurement time denoted by this signal tone. Please note that the thermometer will continue to measure after the signal tone. To obtain the most accurate results, we recommend a measuring time of 2 minutes for rectal and oral use and 5 minutes for axillary use.

For temperatures up to 37.8 °C, the normal sound will be made (10 long, equal beeps). For temperatures over 37.8 °C, the fever alarm will sound (30 short beeps in groups of 3).

Read out the measurement. The thermometer switches off automatically after approximately 10 minutes. To conserve battery power, the device can also be switched off before this by pressing the on/off button.

CLASSIFICATION OF THE TEMPERATURES MEASURED

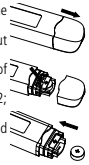
35.7°C to 37.2°C: normal temperature
37.3°C to 37.7°C: elevated temperature
37.8°C to 38.9°C: moderate fever
Over 39.0°C: high fever

Temperatures measured rectally are generally 0.5 °C higher than those measured orally, while temperatures measured under the arm are 0.5 °C lower.

Warning: Always consult a doctor if the reading shows a high fever.

CHANGING THE BATTERY

When the display shows the symbol, the battery needs to be changed.



- Remove the battery compartment cover from the thermometer.
- Carefully pull the battery holder about 1 cm out of the casing.
- Use a pointed object to slide the battery out of the holder.
- Insert a new battery (type LR41, SR41 or V392; 1.5 V) with the + symbol facing upwards.
- Push the battery holder back into the casing and replace the battery compartment cover.

CLEANING AND DISINFECTING THE THERMOMETER

Immerse the tip of the thermometer in distilled water for at least 1 minute. Wipe the thermometer with a clean, soft cloth to remove any residue. Repeat 3 times until no dirt is visible after cleaning.

To disinfect the thermometer, wipe the tip with a clean, soft cloth dipped in 70% medical alcohol. Repeat 3 times for at least 1 minute each time.

Disinfection instructions for professionals

Immerse the thermometer tip in a 0.55% OPA solution (o-Phthaladehyde) such as CIDEX OPA for at least 12 minutes at a temperature of 20°C. Refer to the instructions for use for the OPA disinfectant.

To remove OPA residues, immerse the tip of the thermometer in distilled water for at least 1 minute. Wipe the thermometer with a clean, soft cloth. Repeat 3 times.

We strongly recommend following the instructions for professional disinfection after a rectal measurement. OPA is not readily available outside of medical establishments; we therefore do not recommend using the thermometer for rectal measurements at home.

Do not use benzene, paint thinner or other strong solvents to clean the thermometer.

Do not immerse the appliance in alcohol or OPA for an extended period of time. Do not expose the thermometer to temperatures above 50°C. Do not clean the device in an ultrasonic bath.

EXPLANATION OF SYMBOLS

CE 0123 — This product complies with the Council Directive 93/42/EC from 5 September 2007 regarding medical devices and bears the mark CE 0123 (TÜV SÜD Product Service GmbH).

Degree of protection against electric shock: TYP BF

Please observe operating instructions

LOT — Lot number

Manufacturer

DC direct current

DISPOSAL

Batteries and technical appliances must not be disposed of with domestic waste, but should be handed in at the appropriate collection and disposal points.

Error messages

Lo °C	Measured temperature is below 32.0 °C and thus outside the measurement range.
Hi °C	Measured temperature is above 42.9 °C and thus outside the measurement range.
Err	Electronic error. If error persists, please contact UEBE customer service.
	Battery flat. Replace the battery.

TECHNICAL DETAILS

Type:	Maximum thermometer, direct mode
Range:	32.0 °C to 42.9 °C
Accuracy:	± 0.1 °C between 35.5 °C and 42.0 °C ± 0.2 °C in other temperature ranges
Size:	12.4 x 1.8 x 1.1 cm
Weight:	approx. 11 g, including the battery
Operating conditions:	Ambient temperature 5 to 40 °C, relative humidity 15 to 95 %, air pressure 700 to 1060 hPa
Storage and transport conditions:	Ambient temperature -20 to 55 °C, relative humidity 15 to 95 %, air pressure 700 to 1060 hPa
Battery:	1 x LR41, SR41 or V392, 1.5 V
Battery life:	approx. 200 hours or approx. 1 year if used 3 times per day
Expected service life:	3 years
IP rating:	IP 27: protection from solid foreign bodies with diameters of 12.5 mm and above, protection against temporary submersion

METROLOGICAL INSPECTION

We recommend sending the device for metrological inspection every two years or if the accuracy of the measurements is in doubt. However, professional users in Germany have to comply with the aforementioned according to „Regulation for Operators of Medical Devices". This can be implemented either by UEBE Medical GmbH, an authority responsible for metrology, or authorised maintenance services. For this, please observe your national provisions.

WARRANTY

During the warranty period of 2 years from the date of purchase, we remedy defects at our discretion and at our expense in our plant through repair work or replacement delivery of a defect-free device. The cost of returning the device to our factory shall be borne by the sender. Complaints that are sent back without prepayment will not be accepted by UEBE.

The warranty does not cover normal wear and tear of wearing parts or damage caused by failure to observe the instructions for use, improper handling (e.g. breakage, leaking batteries) or disassembly of the device by the buyer. Furthermore, the warranty does not constitute grounds for asserting claims for damages against us.

Warranty claims can only be advanced in the warranty period and by presenting proof of purchase. In the event of a warranty claim, the unit must be sent to the following address together with the proof of purchase and a description of the complaint: UEBE Medical GmbH, Zum Schlag 18, 97877 Wertheim, Germany.

The statutory claims and rights of the buyer against the seller (for example, defect claims, producer liability) are not restricted by this warranty.

Please note: In the event of a warranty claim it is essential to attach the proof of purchase.

Electromagnetic compatibility (EMC) - Technical description

The unit is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use.

The unit satisfies the EMC requirements of the international standard IEC60601-1-2. The requirements are satisfied under the conditions described in the tables below.

Portable and mobile HF communications equipment can affect the unit. Use of the unit in conjunction with non-approved accessories can affect the unit negatively and alter the electromagnetic compatibility. The unit should not be used directly adjacent to or between other electrical equipment.

Table 1 Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 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	N/A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	N/A	

Table 2 Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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	N/A	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec.	N/A	
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.

Table 3 Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF radio equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: $d=[\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz bis 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz bis 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, 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:

Table 4 Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using 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.

NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Scope of delivery: thermometer, storage case, instruction manual

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