

Instructions for use



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

- Measuring your temperature for self-diagnosis is dangerous! Please consult a doctor for an interpretation of the measurement readings. Self-diagnosis can aggravate an existing medical condition.
- Please read through these instructions carefully before using the thermometer.
- This device is not suitable for temperature measurement in the ear.
- 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 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 (battery etc.) which children could swallow. Do not let children use the device unsupervised.
- Protect the device from high temperatures and direct sunlight.
- 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.
- Use outside the intended operating conditions or storage outside the intended storage and transport conditions can result in inaccurate measurements.
- Store the thermometer in the transparent box when not in use.
- Remove the battery when the device is not being used for a long period.

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

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.

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 the temperature from the display. The thermometer will switch itself off automatically after approx. 10 minutes. You can also turn it off earlier by pressing the on/off button.

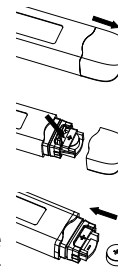
CLASSIFICATION OF THE TEMPERATURES MEASURED

Body temperature measured orally is on average between 35.7 and 37.3 °C. For temperature classification, please refer to the following approximate values:
 37.3 °C to 37.7 °C: elevated temperature
 37.8 °C to 38.9 °C: moderate fever
 39.0 °C and above: 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.

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.
- Please use a non-metallic pointed object to remove the battery from its holder.
- Insert a new battery (LR41 or SR41, 1.5V) with the + sign towards the top.
- Push the battery holder back into the casing and replace the battery compartment cover. Take care not to damage or misalign the seal when doing this.



CLEANING

Clean the thermometer before and after every use, using a soft cloth and isopropyl alcohol diluted with water, or cold soapy water. For cleaning, do not use petrol, thinner or any other strong solvent. Do not immerse the device in alcohol for a prolonged period. Do not expose the thermometer to temperatures over 50 °C. Do not use ultrasonic cleaning.

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.

METROLOGICAL INSPECTION

Basically, a metrological inspection is recommended at intervals of 2 years. 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.

EXPLANATION OF SYMBOLS

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
- Storage and transportation conditions
Ambient temperature -20 to 55 °C, rel. air humidity 15 to 95 %
- Lot number
- Manufacturer
- DC direct current

ERROR MESSAGES

- Measured temperature is below 32.0 °C and thus outside the measurement range.
- Measured temperature is above 42.9 °C and thus outside the measurement range.
- Electronic error. If error persists, please contact UEBE customer service.

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 |
| Operating conditions: | Ambient temperature 15 to 35 °C, relative humidity 15 to 95 % |
| Storage and transport conditions: | Ambient temperature -20 to 55 °C, relative humidity 15 to 95 % |
| Battery: | LR41 or SR41, 1,5 V |
| Battery life: | Approx. 200 hours |
| IP rating: | IP 27: protection from solid foreign bodies with diameters of 12.5 mm and above, protection against temporary submersion |

WARRANTY

The device has been manufactured and tested with great care. However, in the unlikely event of a defect being detected after delivery, we provide warranty in accordance with the following terms and conditions:
 During the warranty period of 2 years from the date of purchase we reserve the right either to repair any such defect at our expense or to supply a perfect replacement unit. The cost of returning the unit to our factory shall be borne by the sender. UEBE shall refuse to accept return deliveries that have not been paid for by the sender.
 Excluded from the warranty are parts subject to normal wear and tear as well as damage caused by non-compliance with the instructions for use, improper handling (e.g. unsuitable power sources, breakages, leaking batteries) and/or disassembly of the unit by the purchaser. Furthermore, no claims for damages against us are substantiated by the warranty.
 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 Ottersberg 9, 97877 Wertheim, Germany
 The statutory claims and rights of the buyer against the seller (claims for defect, manufacturer's liability, for example) 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 _r (>95 % dip in UT) for 0.5 cycle 40 % U _r (60 % dip in UT) for 5 cycles 70 % U _r (30 % dip in UT) for 25 cycles <5 % U _r (>95 % dip in UT) 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. Recommended separation distance: $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz bis 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 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:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |

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 $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ |
| 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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