Domotherm Free

Non-contact thermometer for forehead temperature measurement



Instructions for use

ÜEBE
Germany est.1890

Table of contents

Intended use 3

How it works 3

Safety instructions 4

Operating the device

Device description 6
Display 7
Inserting/replacing batteries, battery icon 8
Changing the temperature unit °C/°F. 8
Selecting the measuring mode 9
Measuring body temperature (forehead mode) 10
Measuring surface temperatures (object mode) 11
Retrieving saved readings 12
Deleting the measured value memory 13

Technical information

Error messages 14
Technical data 14
Standards applied 16
Customer service 17
Metrological inspection 17
Explanation of symbols 18
Disposal 18
Electromagnetic compatibility (EMC) 18

Cleaning and disinfecting the thermometer 21

Warranty 22

Read these instructions for use carefully to ensure that you have understood all of the functions and the safety information.

Intended use

Domotherm Free is an electronic infrared thermometer for regular non-contact measurement of human body temperature. It is suitable for adults and children of all ages.

How it works

The device measures thermal radiation emitted from the surface of the skin on the forehead. An infrared sensor takes this thermal radiation and converts it into temperature values. The measured temperature is shown on the display.

The innovative infrared technology enables the body temperature to be measured in just one second. This makes it particularly suitable for use with children. A measurement can even be taken as a child sleeps without disturbing them.

An internal memory stores the 30 most recently measured temperature values. This allows you to track the change in temperature over time.

Illuminated display: The display's backlight makes it easy to use in the dark.

Fever alarm: If the temperature is above 38.0°C, the thermometer indicates the increased temperature through beeps and a red light.

Night mode: The thermometer's beep function can be switched off. You may wish to do this if, for example, you do not wish to disturb a sleeping child when performing the measurement.

Object mode: The thermometer has an extended measuring range of 0°C to 100°C. The thermometer can therefore also be used to measure surface temperatures, e.g. the surface temperature of milk in baby bottles, the surface temperature of bathing water for infants or the ambient temperature.

The following basic safety instructions must be observed when using this device. Failure to observe these safety instructions can cause personal injury or damage the device.

- The device must be used solely for the purpose described in these instructions for use. The manufacturer shall not be held liable for any damage caused by improper handling.
- Measuring body temperature in a location other than the forehead can lead to inaccurate measurements.
- Measurements taken on a sleeping patient cannot be compared to measurements taken while awake. Body temperature is usually lower during sleep.
- Do not take a temperature measurement for at least 30 minutes after physical exertion, a bath or time outdoors.
- Remain calm during the measurement.
- We recommend that you take three measurements in a row. If the readings are different, use the highest reading.
- Wait one minute between successive measurements.
- Infrared forehead temperature measurements are comparable to oral temperature measurements.
- Do not touch the lens of the temperature sensor with your fingers.
- Clean the measuring sensor after each use.
- Normal body temperature can vary from person to person. Perform temperature measurements on yourself to determine your

personal normal temperature and to have comparative values for assessing fever.

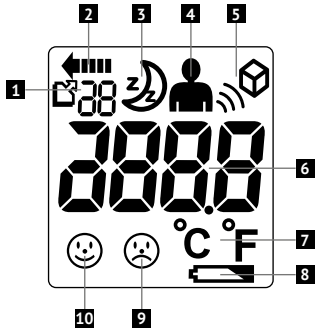
- The values measured using this device do not provide a diagnosis. They are no substitute for visiting a doctor. Do not rely solely on the result obtained; always take the patient's other symptoms into account too. In case of doubt, please call a doctor or paramedics to help.
- The thermometer contains small parts (e. g. battery) that could be swallowed by children. Do not leave the device unattended with children.
- Ensure that you do not drop the device or subject it to shocks. Protect the device against extreme temperatures, dirt, dust, powerful sunlight, heat and cold.
- Never open the device (except to replace the battery). If the unit has been opened, it must be subjected to a metrological inspection by an authorised institution.
- If the device is not being used for an extended period of time, remove the batteries.
- If the device has been stored at temperatures below 16 °C or above 40 °C, leave it to stand at room temperature for at least 30 minutes before using it.

Device description



1. Infrared sensor
2. LED light
3. MODE button
4. START button, measurement button
5. Battery compartment lid
6. MEMO button (memory button)
7. Display

Display



1. Memory icon with memory number
2. Measurement in progress
3. Night mode
4. Forehead mode
5. Object mode
6. Measurement
7. Temperature unit °C (Celsius)/°F (Fahrenheit)
8. Battery display
9. Measured body temperature of 38°C or higher
10. Measured body temperature below 38°C.

Inserting/replacing batteries, battery icon

- Open the cover of the battery compartment on the back of the device by sliding it in the direction indicated by the arrow (Figure 1).
- Remove the old batteries from the device and insert the new ones. Please ensure correct polarity (marking in battery compartment).

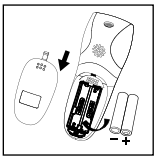


Figure 1

- Only use long-life alkaline batteries (2 x 1.5 V, size AAA/LR03).
- Close the battery compartment again by sliding the cover in the opposite direction to that indicated by the arrow until it clicks into place.



Figure 2

When the "Empty battery" symbol first appears on the display (figure 2), you will still be able to take further measurements, but you will need to have replacement batteries ready.

When the batteries are completely flat, "Lo" is shown on the display together with the battery symbol (Fig. 3). This means you will not be able to take any measurements until you have replaced the batteries.

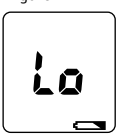


Figure 3

Changing the temperature unit °C/°F.

The thermometer can display the measured temperature values in degrees Celsius °C or degrees Fahrenheit °F.

- To change the temperature unit, switch on the device by pressing the start button.
- Press the MEMO and MODE buttons simultaneously to change the temperature unit. The selected temperature unit is shown on the display.

Selecting the measuring mode

The device has four different mode settings:

Forehead mode

Object mode

Forehead mode + night node

Object mode + night mode

Forehead mode is used to measure body temperature in the medical measurement range of between 34°C and 43°C.

Object mode allows you to measure the surface temperature of objects within a temperature range of between 0°C and 100°C.

In night mode, the device beeps are switched off.

To change the measuring mode, press the MODE button repeatedly while the device is switched on until the desired measuring mode is shown on the display.

Measuring body temperature (forehead mode)

- Switch on the device by pressing the start button.



Figure 1

- The device now performs an internal self-test. All display segments will be displayed (Figure 1)
- The device then switches to measuring mode. Two dashes will be shown on the display (Figure 2).

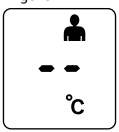


Figure 2

- Use the MODE button to select the desired measuring mode (see page 9). Ensure that forehead or forehead/night mode is selected to measure body temperature.
- Hold the thermometer in front of the forehead, no more than 3 cm from the centre of the forehead. The measuring sensor is directed between the eyebrows.
- The forehead must not be covered with hair, sweat or dirt. If necessary, clean the measuring point and then wait ten minutes before carrying out the measurement.
- Hold the device firmly in your hand during the measurement. Do not move. Movements during the measurement may result in an inaccurate measurement.
- Press the start button to start the measurement.
- The measurement takes only about one second. The measured value is shown on the display (Figure 3).



Figure 3

- At temperatures above 38.0°C (Figure 4), an acoustic fever alarm sounds (three beeps in quick succession, not in night mode) and the red LED below the display lights up.
- The device switches off automatically approx. 30 seconds after the last measurement.



Figure 4

Measuring surface temperatures (object mode)

- Switch on the device by pressing the start button.



Figure 1

- The device now performs an internal self-test. All display segments will be displayed (Figure 1)
- The device then switches to measuring mode. Two dashes will be shown on the display (Figure 2).

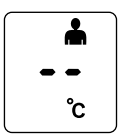


Figure 2

- Use the MODE button to select the desired measuring mode (see page 9). To measure surface temperatures, select object or object/night mode.
- Position the thermometer 0.5 to 3 cm from the surface to be measured.
- Press the start button to start the measurement.

- The measurement takes only about one second. The measured value is shown on the display (Figure 3).
- The device switches off automatically approx. 30 seconds after the last measurement.



Figure 3

Retrieving saved readings

The thermometer has a measured value memory that can store 30 measured values. The last measured value is stored in memory location 1, the value measured prior to that is stored in memory location 2, and so on. If more than 30 measurements are taken, the oldest value (no. 30) is deleted so that the latest value (no. 1) can be saved.

To retrieve the stored measured values, proceed as follows:

- Switch on the device by pressing the start button.
- Then press the MEMO button. The most recent measurement no. 1 is now shown (Figure 1). Press the MEMO button repeatedly to open older measurements (no. 2, no. 3, and so on).
- The display also indicates whether the measurement was performed in forehead mode or in object mode. This allows you to determine whether it is a body temperature measurement or a surface measurement.
- The device switches off automatically after approx. 30 seconds.

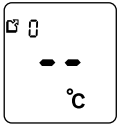


Figure 1

Deleting the measured value memory

Only the entire memory can be deleted. It is not possible to delete individual measurements or to distinguish between body temperature measurements and surface measurements.

- Switch on the device by pressing the start button.
- Press and hold the MEMO button for at least 3 seconds
- A beep confirms the memory deletion. The following display appears:
- The device switches off automatically after approx. 30 seconds.



Error messages

Error	Cause	Remedy
	The measured temperature is above 43°C (forehead mode) or 100°C (object mode) and is therefore outside the measuring range.	Only use the thermometer within the measuring range. If necessary, clean the lens of the measuring sensor. If the error occurs repeatedly, please contact the customer service centre.
	The measured temperature is below 34°C (forehead mode) or 0°C (object mode) and is therefore outside the measuring range.	
	The ambient temperature is below 16°C or above 40°C and is therefore outside the operating conditions.	Use the thermometer only within the permissible operating conditions.
	Low battery.	Have a spare battery ready.
	Battery flat.	Please replace the battery.

Technical data

Model:	Domotherm Free
Mode:	Calibration mode

Measuring point:	Forehead, 0.5–3 cm distance from the centre of the forehead between the eyebrows
Reference point (body):	Ear canal
Measuring distance:	0.5 to 3 cm
Measuring range:	Forehead mode: 34°C to 43°C (93.2°F to 109.4°F, Object mode 0°C to 100°C (32°F to 212°F)
Laboratory measurement accuracy:	Forehead mode: ± 0.2°C between 34°C and 43°C (± 0.4°F between 93.2°F and 109.4°F), Object mode: ± 1°C at temperatures up to 20°C, ± 5% at temperatures above 20°C
Validation of clinical measurement accuracy*:	Group A1 (0 to 3 months): Δcb = -0.01°C, LA = 0.18, σr = ± 0.08°C Group A2 (3 months to 1 year): Δcb = -0.06°C, LA = 0.22, σr = ± 0.08°C Group B (1 to 5 years): Δcb = -0.01°C, LA = 0.20, σr = ± 0.07°C Group C (over 5 years): Δcb = -0.01°C, LA = 0.18, σr = ± 0.07°C
Measurement resolution:	0.1 °C/°F
Memory:	30 measured values
Operating conditions:	Ambient temperature 16 °C to 40 °C (60.8 °F to 104 °F), maximum relative humidity 95 %, not condensing
Conditions for storage and transport:	-25 °C to +55 °C (-13 °F to +131 °F), maximum relative humidity 95 %, not condensing
Time to adjust from minimum/maximum storage temperature to operating temperature:	30 minutes

Automatic switch-off:	Approx. 30 seconds after last activity
Power supply:	2 x 1.5 V AAA LR03 alkaline manganese batteries
IP classification:	IP 22: protected against solid foreign bodies with a diameter of 12.5 mm and above, protected against dripping water.
Size:	approx. 128.5 mm (L) x 48.83 mm (W) x 38.85 mm (H)
Weight:	approx. 80 g with batteries

* Δcb = clinical systematic error (bias)
LA = compliance limits
σr = clinical repeatability

Standards applied

This product complies with the Medical Devices Directive 93/42/EEC concerning medical devices. The following standards apply to the design and/or manufacture of the product:

ISO 80601-2-56 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

IEC/EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC/EN 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances – Requirements and tests

RoHS 2011/65/EU: Restriction of the use of certain hazardous substances in electrical and electronic equipment

Reach Regulation (EC) 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

Customer service

Device repairs may only be performed by the manufacturer or an expressly authorised body. Please contact:

UEBE Medical GmbH
Bürgermeister-Kuhn-Straße 22
97900 Külsheim, Germany
info@uebe.com
www.uebe.com

Metrological inspection

In accordance with the Medizinprodukte-Betreiberverordnung (German Medical Device Operator Ordinance), professional users in Germany are required to arrange for a metrological inspection to be performed at yearly intervals. Private users are advised to arrange for a technical inspection of the device every two years.

The inspection can be performed either by UEBE Medical GmbH, an authority responsible for metrology or an authorised maintenance service. Please refer to your national regulations.

Upon request, responsible authorities or authorised maintenance services will receive a "test instruction for metrological inspection" from the manufacturer.

Explanation of symbols

CE 0598 This product complies with Council Directive 93/42/EEC of 5 September 2007 concerning medical devices and bears the mark CE 00598 (SGS FIMCO OY, Helsinki, Finland).


Degree of protection against electric shock: TYPE BF


Consult the instructions for use


Manufacturer


Authorised representative in the European community

IP22 Protected against solid foreign bodies with a diameter of 12.5 mm and above, protection against dripping water.

SN Device serial number

REF Reference number = item number

Disposal


Technical equipment and batteries do not belong in household waste. They must be disposed of at appropriate collection and disposal points.

Electromagnetic compatibility (EMC)

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.

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.

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.

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.		
Guidance and manufacturer's declaration - electromagnetic emissions		
Phenomenon	**Professional healthcare facility environment [a]**	**Home Healthcare Environment [a]**
Conducted and radiated RF Emissions	a)	CISPR 11 Group 1 Class B
Harmonic distortion	Not applicable	
Voltage fluctuations and flickering	Not applicable	
a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network. b) The test is not applicable in this environment unless the ME equipment and ME system used will be connected to the public mains network and the power input is otherwise within the scope of the Basic EMC standard.		

Guidance and manufacturer's declaration - electromagnetic immunity - enclosure port			
Phenomenon	**Basic EMC standard or test method**	**Immunity test level**	
		Professional healthcare facility environment [a]	**Home Healthcare Environment [a]**
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a]	IEC 61000-4-3	a)	10 V/m b, 80 MHz - 2.7 GHz, 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the device can be requested from the manufacturer using the contact information provided in this manual. However, it is advisable to keep the electromechanical aerosol equipment at an adequate distance of, at least, 0.5 m from mobile phones or other RF communications transmitters to minimise possible interference.	
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz	
a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive immunity acceptance limits have been considered and applied. b) Before modulation is applied c) This test level assumes a minimum distance of at least 15 cm between the ME equipment or ME system and sources of power frequency magnetic fields.			

Cleaning and disinfecting the thermometer

The measuring sensor must be cleaned after each use. Use a clean cloth or cotton swab moistened with 75% alcohol.

Clean the housing with a soft cloth slightly moistened with mild soap solution.

To disinfect, use 75% ethanol or isopropyl alcohol (available from your pharmacy).

Make sure that no liquid enters into the thermometer itself.

Allow the device to dry completely before you use it again.

The device has been manufactured and tested with all due care. Nevertheless, in the event of defects upon delivery, we provide a warranty under the following conditions:

During the warranty period of 2 years from the date of purchase, we remedy such defects at our discretion and at our expense in our plant through repair work or replacement delivery of a defect-free device.

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. unsuitable power sources, breakage, leaking batteries) and/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 asserted during the warranty period and upon presentation of the proof of purchase. In the case of a warranty claim, the device along with the proof of purchase and a description of the complaint must be sent to:

UEBE Medical GmbH
Service-Center
Zum Schlag 18
97877 Wertheim, Germany

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 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 case of a warranty claim, please make sure to enclose the proof of purchase.

Domotherm Free

REF 0885

PZN-16787516

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UEBE Medical GmbH
Bürgermeister-Kuhn-Straße 22
97900 Külsheim, Germany
info@uebe.com
www.uebe.com

Standard specification for infrared thermometer:
ISO 80601-2-56:2017

Manufacturer:
AVITA (Wujiang) Co. LTD.
No. 858, Jiao Tong Road, Wujiang Economic Development Zone
Suzhou City, Jiangsu Province, P.R.C
Made in China

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