# Domotherm's

**Infrared Ear Thermometer with disposable protective probe covers** 



Instructions for use



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Domotherm S is an electronic infrared thermometer for regular measurement and monitoring of the human body temperature in the ear canal. It is suitable for adults and children from the age of 6 months.

# How it works

The device measures the infrared energy that is emitted by the middle ear and the surrounding tissue. A sensor takes this thermal radiation and converts it into temperature values. The measured temperature appears on the display.

Measurements taken on the surrounding tissue of the ear canal will result in lower measured values and can lead to an incorrect diagnosis of a fever. You should therefore follow the instructions on avoiding inaccurate measurements on page 12.

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.

The disposable probe covers make the thermometer particularly hygienic and safe, especially when used by multiple persons.

Its ergonomic design makes the thermometer easy and convenient to use.

It features a measured value memory that stores the last 12 measured temperature values along with the date and time of the measurement. This allows you to track the change in temperature over time.

Fever alarm: If temperature values above 37.5  $^{\circ}$ C are measured, then three short beeps and a red background light on the display indicate that this is a raised temperature.

How it works Safety instructions

Silent 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.

The thermometer has an extended measuring range of 0  $^{\circ}$ C to 100  $^{\circ}$ C. As well as measuring body temperature in the ear, the thermometer can therefore also be used to measure surface temperatures, e.g. the surface temperature of the milk in baby bottles, the surface temperature of the bathing water for infants or the ambient temperature.

This thermometer has been clinically tested and verified as reliable and accurate when used in accordance with the instructions for use.

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

Take the time to familiarise yourself with the thermometer. Perform test measurements and practice using the thermometer in the correct way until you achieve consistent measured values. Follow the instructions for avoiding inaccurate measurements on page 12.

Caution: Check that the measuring tip is clean before each use. Despite the use of probe covers, the measuring tip may still become contaminated. Any contamination of the measuring tip will cause malfunctions and inaccurate measurements. Please follow the cleaning instructions on page 24.

#### Important patient information

- 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.
- The thermometer must only be used with disposable probe covers. For each measurement, use a new and undamaged probe cover.
- Do not drink, eat or play sport before or during the measurement.
- Do not use the thermometer on inflamed ears.
- Do not use the thermometer in environments with a high level of humidity.
- Earwax in the ear canal can result in lower measured temperature values. Before taking the measurement, make sure that the ear canal is clean.
- If the measured value is not consistent with the patient's state of health, or if the measured value is unusually low, repeat the measurement after waiting 15 minutes. Check the result with a different method of measuring body temperature.
- 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 (battery, probe covers etc.) that could be swallowed by children. Do not leave the device unattended with children.

# **Important technical information**

- The device is not waterproof. Never immerse it in water or any other liquids. For information on cleaning and disinfection, please see the instructions on page 24.
- Ensure that you do not drop the device or the disposable probe covers or subject them to shocks. Protect the device and the probe covers against extreme temperatures, dirt, dust, powerful sunlight, heat and cold.
- Do not use the device if you find signs of damage or any other abnormality.
- 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.
- The use of this device in the vicinity of mobile phones, microwaves or other devices with strong electromagnetic fields can cause malfunctions.
   Maintain a distance of at least one metre from such devices when using the thermometer. If you cannot maintain the minimum distance, check that the thermometer is working correctly before you use it.
- If the device is not being used for an extended period of time, remove the battery.
- The device contains sensitive parts and must therefore be handled with care. See the storage and transport conditions as well as the operating conditions on page 21.
- If the device has been stored at temperatures below 10°C or above 40°C, leave it to stand at room temperature for at least 2 hours before using it.

# **Device description**

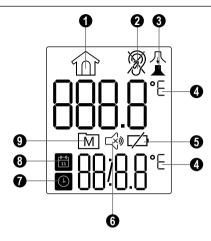


- Measuring sensor
- 2 Display
- 3 START button (start measurement)
- 4 MEMO button (memory button)
- **5** O/I button (on/off button)

- 6 Battery compartment
- **7** MODE button
- **3** Container for storing and attaching the probe covers
- Probe cover for the measuring probe

# Operating the device

# Display



1 Ambient temperature

- 6 Battery display
- Ready for measurement
- **6** Beep

3 Attach probe cover

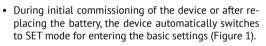
- **7** Time
- Temperature unit °C (Celsius)/°F (Fahrenheit)
- 8 Date
- Memory mode

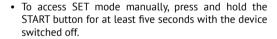
# Initial commissioning of the device

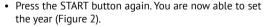
- Open the battery compartment (see page 19). Pull the transparent battery contact separation strip that protrudes out of the battery compartment and remove it from the housing in the direction indicated by the arrow. Close the battery compartment again.
- The device turns on and switches to SET mode for entering the basic settings (date, time, temperature unit).

# Setting the date, time and temperature unit (°C/°F)

Before using the device for the first time, set the date and time so that the measurements can be saved together with the date and time.







- Press the MODE button to increase the year or the MEMO button to reduce the year. Once the correct value is set, confirm the entry by pressing the START button.
- You are now able to set the month. (Figure 3). Press the MODE button to increase the value displayed, and press the MEMO button to reduce the value displayed.



Figure 1



Figure 2

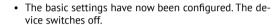


Figure 3

# Operating the device

Set the correct month and confirm the entry by pressing the START button.

- Repeat these steps to enter the day (Figure 3) and the hours and the minutes (Figure 4).
- You are now able to set the temperature unit (Figure 5).
   Press the MODE button to switch between °C (Celsius) and °F (Fahrenheit). Set the required temperature unit and confirm the entry by pressing the START button.



If no button is pressed for approximately 30 seconds while configuring the basic settings, the device switches off automatically. However, any entries that have already been confirmed will still be saved.



Figure 4



Figure 5

After changing the battery, you must enter the date and time again.

# Switching the beep on/off

With the device switched off, press the MODE button. The current status of the beep function is shown on the display:



Beep switched on



Beep switched off

You can now use the MODE button to switch the beep function on or off.

Switch off the device by pressing the on/off button or wait until the device switches off automatically after approximately ten seconds.

### Attaching the disposable probe cover

For each measurement, use a new and undamaged probe cover.

Only use the Domotherm probe covers intended for this thermometer (see Accessories, page 22).

- Remove a probe cover from the probe cover dispenser and tear it off.
- Place the probe cover into the probe cover holder of the dispenser with the paper side facing up (Figure 1).
- Hold the measuring probe perpendicular to the centre of the probe cover (Figure 2).
- Press the measuring probe fully into the opening in the probe cover holder (Figure 3).
- Carefully pull the measuring probe with the attached disposable probe cover out of the probe cover holder.
- Check that the probe cover is positioned correctly. If the probe cover is damaged or not positioned correctly, remove it and use a new one.



Probe cover attached correctly



Probe cover attached incorrectly



Figure 1



Figure 2



Figure 3

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### Avoiding inaccurate measurements

Taking measured values directly from the middle ear (eardrum) ensures the most accurate temperature measurement. Measurements taken on the surrounding tissue of the ear canal will result in lower measured values and can lead to an incorrect diagnosis of a fever.

For this reason, it is very important to position the thermometer in the ear correctly. It is essential to follow the instructions on positioning the thermometer in the ear in the chapter "Measuring the temperature" on page 13.

Rest for at least 5 minutes before taking the measurement.

Always measure the temperature in the same ear, as the temperature values may vary from ear to ear.

In the following situations, you should take three consecutive temperature measurements in the same ear and take the highest result as the measured value:

- In children under three years of age with a vulnerable immune system where the presence or absence of fever may be critical.
- If you are familiarising yourself with the device and are practising how to use the infrared ear thermometer correctly until you achieve consistent measured values.
- If you feel the measured values are unusually low.

Make sure that the measuring sensor is clean at all times, particularly if the probe cover has been damaged. A dirty or clogged measuring sensor can lead to incorrect measurements.

## Measuring the temperature

- Switch on the device by pressing the on/off button.
- The display shows "On" and the display is illuminated in green (Figure 1).

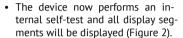
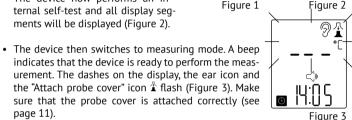




Figure 1





Retrieving the last measured value

page 11).

• Before performing the measurement, you can retrieve the last measured temperature value by pressing the MEMO button. The last measured temperature value is shown together with the flashing Micon at the bottom of the display (Figure 4). The thermometer then switches back to measuring mode.

# Figure 4

Retrieving the ambient temperature

· You also have the option to check the ambient temperature by pressing the MODE button. The ambient temperature is shown on the display together with the  $\widehat{\mathbf{w}}$ icon (Figure 5). The thermometer then switches back to measuring mode.



Figure 5

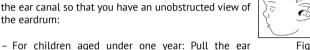
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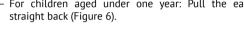
# Operating the device

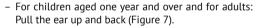
#### Performing measurement

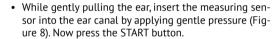
• The best way to perform the measurement on small children is to lie them flat on their stomach with their head facing to the side so that the ear is pointing upwards. For older children or adults, it is better to stand slightly behind and to the side of the patient.

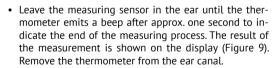
• Pull the ear slightly up/down from the middle to stretch the ear canal so that you have an unobstructed view of the eardrum:

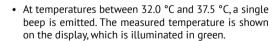












• At temperatures of 37.5 °C to 42.2 °C, three beeps are emitted in quick succession. The measured temperature is shown on the display, which is illuminated in red (fever alarm).



Figure 6



Figure 7



Figure 8



Figure 9

- After approx, ten seconds, the thermometer is ready for the next measurement. The °C icon on the display starts to flash again.
- You can now compare the current measured temperature value with the previous measured value by pressing the MEMO button. The most recently measured temperature value is now shown in the lower area of the display along with the flashing M symbol (Figure 10). The thermometer then switches back to measuring mode and again shows the current temperature value.



- The device switches off automatically approx. 30 seconds after the last measurement. You can also switch off the device before this by pressing the on/off button.
- Remove the used disposable probe cover from the measuring probe.

# Classifying the measured values

When classifying a measured value as a fever, you can use the following reference values as a guide:

37.5 °C to 38.0 °C: high temperature 38.0 °C to 39.0 °C: moderate fever 39.0 °C and above: high fever

#### Caution: It is essential to consult a doctor in cases of high fever!

Measurement results of different measurement types cannot be compared with each other as the normal body temperature varies depending on where the measurement is taken.

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# Operating the device

Normal body temperature ranges:

Axillary (under the arm): 34.7 °C to 37.3 °C Oral (in the mouth): 35.5 °C to 37.5 °C Rectal (in the anus): 36.6 °C to 38.0 °C

Measured with Domotherm S (in the ear): 35.4 °C to 37.4 °C

Even the time of day has an effect on body temperature. It is highest in the evening and lowest approx. one hour before waking up.

# Larger measuring range/surface temperature measurements

The thermometer has an extended measuring range of 0  $^{\circ}$ C to 100  $^{\circ}$ C. This range goes both below and above the medical measuring range of 32.0  $^{\circ}$ C to 42.2  $^{\circ}$ C.

As well as measuring body temperature, the thermometer can therefore also be used to measure surface temperatures, e.g. the surface temperature of the milk in baby bottles, the surface temperature of the bathing water for infants or the ambient temperature.

When taking the measurement, hold the thermometer 3–5 cm away from the surface being measured.

The temperature on the surface of an object can differ markedly from the temperature inside the object.

Never immerse the thermometer in water or any other liquids. Please use a suitable watertight thermometer to measure the internal temperature of liquids.

Taking measurements over boiling or steaming liquids may cause condensation to form on the measuring sensor, which will have an adverse effect on the measurement accuracy.

Caution: Always use a disposable probe cover, including for measuring surface temperatures.

The results of body temperature measurements and surface temperature measurements are shown on the display in different ways:



The ear icon is shown for measurement results within the medical measuring range of 32.0 °C to 42.2 °C.



The crossed-out ear icon is shown for measurement results outside the medical measuring range.

The relevant icon is saved together with the measured value.

### Retrieving saved readings

The thermometer has a measured value memory that can store 12 measured values. The measured values are automatically saved together with the date and time of the measurement. 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 12 measurements are taken, the oldest value (no. 12) is deleted so that the latest value (no. 1) can be saved.

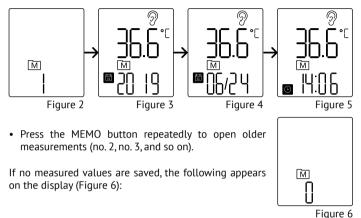
To retrieve the stored measured values, proceed as follows:

• With the device switched off, press the MEMO button. The device switches to memory mode (Figure 1).

M O O O Figure 1

Figure 1

• The most recent measured value no. 1 is now shown (Figure 2). The measured value is alternately shown on the display with the year (Figure 3), month/day (Figure 4) and time (Figure 5).



# Deleting the measured value memory

- · Open any stored measured value.
- Press and hold the START button for at least five seconds.
- The display first shows CL (Clear), then the memory number 0 (Figure 6).

The device switches off automatically after 30 seconds. You can also switch off the device before this by pressing the on/off button.

# Replacing the battery

The device is equipped with a CR2032 lithium battery.

If the battery icon I flashes on the display while the thermometer is in use. the battery is low. Although you are still able to take temperature measurements, you should have a spare battery ready.

Change the battery if:

- After switching on the device, the "flat battery" indicator (Figure 1) appears on the display. You must insert a new battery before you can take any temperature measurements.
- If nothing is shown on the display despite pressing the on/off button.



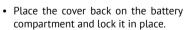
Operating the device

Figure 1

Figure 2

To open and close the battery compartment cover, use the rounded side of the protective cap (see Figure 2).

- Unlock the cover on the battery compartment and lift it off.
- Remove the old battery and insert a new battery (CR2032) with the + sign facing up.



After replacing the battery, you will need to reset the date and time (see page 9). The saved measured values and the set unit of measurement (°C/°F) are retained when the battery is changed.



Cover of battery Cover of battery compartment unlocked



compartment locked

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# **Technical information**

# **Technical information**

# **Error messages**



Measured temperature is above 100.0 °C and is therefore outside the measuring range.



Measured temperature is below 0 °C and is therefore outside the measuring range.



Ambient temperature is above 40.0 °C and is therefore outside the operating conditions.



Ambient temperature is below 10.0  $\,^{\circ}\text{C}$  and is therefore outside the operating conditions.



Electronic fault. If the fault occurs again, contact the UEBE customer service centre.



Low battery. Have a spare battery ready.



Battery flat. Please replace the battery.



No display after switching on. Check that the battery is positioned correctly and the polarity (+/-) is correct. If the error persists, replace the battery.

#### Technical data

| Type:   | Domotherm S ear thermometer  |  |  |
|---|--|--|--|
| Measuring range:  | 0.1 °C to 99.9 °C (32.2 °F to 211.8 °F)  |  |  |
| Measurement resolution:   | 0.1 °C/°F  |  |  |
| Measurement accuracy in the laboratory:   | ± 0.2 °C between 32.0 °C and 42.2 °C<br>(± 0.4 °F between 89.6 °F and 108.0 °F)<br>± 1 °C (± 2 °F) in other temperature ranges (with<br>probe cover attached)  |  |  |
| Display:  | Liquid crystal display (LCD), four digits plus special icons   |  |  |
| Fever alarm:  | If temperature values above 37.5 °C are measured, then three short beeps and a red background light on the display indicate that this is a raised temperature. |  |  |
| Memory:   | 12 measured values with date and time can be opened in memory mode   |  |  |
| Operating conditions:   | Ambient temperature 10 °C to 40 °C (50 °F to 104 °F), maximum relative humidity 15 % to 95 %   |  |  |
| Conditions for storage and transport:   | -25 °C to +55 °C (-13 °F to +131 °F), maximum relative humidity 15 % to 95 %   |  |  |
| Time to adjust from minimum/maximum storage temperature to operating temperature: | 2 hours  |  |  |
| Automatic switch-off:   | Approx. 30 seconds after last activity   |  |  |

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Technical information

| Battery:              | 1 x CR 2032, 3.0 V  |
|-----------------------|---|
| Battery life:         | Approx. 1000 measurements (with a new battery)  |
| IP classification:    | IP 22: protected against solid foreign bodies with a diameter of 12.5 mm and above, protected against dripping water. |
| Average service life: | Five years or 12,000 measurements   |
| Dimensions:           | 145 mm (L) x 38 mm (W) x 36 mm (H)  |
| Weight:               | 54 g with battery, 52 g without battery   |

#### **Accessories**

Domotherm hygienic probe covers Art. no. 8601, PZN-04084666 One pack contains 40 probe covers

#### **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.

# Technical information

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**



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



Degree of protection against electric shock: TYPE BF



Consult the instructions for use



Only use once!



Manufacturer



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



Device serial number



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.

Cleaning and care Warranty

Check the measuring tip for contamination after every use. If the measuring sensor is dirty or clogged, the measurements obtained may not be accurate

- Use a cotton sponge, cotton cloth or cotton bud moistened with alcohol (70 % isopropyl alcohol), to clean the housing and the measuring probe.
- Make sure that no liquid enters into the thermometer itself.
- Do not use aggressive cleaning agents, solvents or benzene for cleaning purposes. Never immerse the device in water or other cleaning fluids.
- Make sure that the surface of the measuring sensor and the display do not become scratched.
- After cleaning the measuring sensor with alcohol, wait five minutes before taking the next temperature measurement. This will ensure that the thermometer can return to the required operating temperature.

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.

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# Domotherm's

**REF** 0865

#### PZN-11613757



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7 0865 201 EA 2021-11