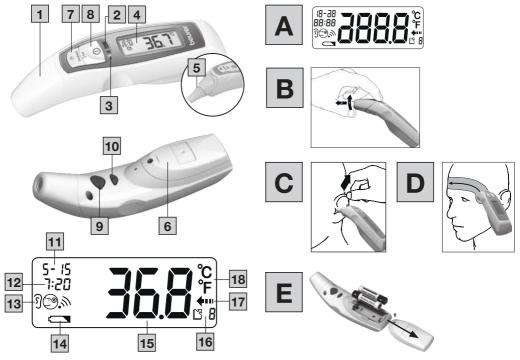
# beurer



Multi-functional thermometer Instructions for use





#### **ENGLISH**

#### **Contents**

| 1. Included in delivery                     | 3  |
|---------------------------------------------|----|
| 2. Signs and symbols                        | 3  |
| 3. Intended use                             | 5  |
| 4. Warnings and safety notes                |    |
| 5. Information about this thermometer       |    |
| 6. Device description                       |    |
| 7. Initial use                              |    |
| 8. Switching on and setting the thermometer | 9  |
| 9. Measurement                              | 9  |
| 9.1 Ear temperature mode                    | 9  |
| 9.2 Forehead temperature mode               | 10 |
| 9.3 Object temperature mode                 | 10 |
| 9.4 Displaying stored measurements          | 11 |
| 10. Cleaning and maintenance                | 11 |
| 11. What if there are problems?             | 11 |
| 12. Disposal                                |    |
| 13. Technical specifications                |    |
| 14. Directives                              |    |
| 15. Warranty/service                        |    |
| •                                           |    |



Read these instructions for use carefully. Follow the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the instructions for use to the next user as well.

#### 1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

- Thermometer
- 2x 1.5 V AAA batteries (LR03)
- Instructions for use
- Forehead/cover cap

#### 2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

#### **A** WARNING

Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.

#### **A** CAUTION

Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may result.

#### NOTICE

Indicates a potentially harmful situation. If it is not avoided, the device or something in its vicinity may be damaged.



#### Product information

Note on important information



#### Observe the instructions

Read the instructions before starting work and/or operating devices or machines



The electronic device must not be disposed of with household waste



Manufacturer



Date of manufacture



#### CE labelling

This product meets the requirements of the applicable European and national directives.



## Separate the packaging elements and dispose of them in accordance with local regulations.



Marking to identify the packaging material.

A = material abbreviation, B = material number:

1-7 = plastics, 20-22 = paper and cardboard



Separate the product and packaging elements and dispose of them in accordance with local regulations.



Device protected against foreign objects ≥12.5 mm and against water dripping at an angle

\_\_\_ Di

Direct current

UDI

Unique device identifier (UDI)
Identifier for unique product identification



Article number



Serial number



Medical device



Type number



Type BF applied part



Temperature limit



Humidity limitation



Importer



Protect from sunlight



Keep away from rain

#### 3. INTENDED USE

#### **Purpose**

The thermometer is intended exclusively for measuring human body temperature in the ear canal (ear temperature mode) or on the forehead (forehead temperature mode). The thermometer is only intended for private use at home, not for commercial use.

#### **Target group**

The thermometer is intended for use in the home healthcare environment, not in professional healthcare facilities. The clinical thermometer can be used on newborns weighing 2.5 kg and above, as well as on infants, toddlers and children under supervision; it can be used for self-testing by anyone over 12 years of age.

#### Clinical benefits

The thermometer can be used in a home environment to measure the body temperature in the ear canal or on the forehead.

The temperature is monitored in °C (or °F) to one decimal place.

#### Indications

The thermometer allows the user to quickly and easily measure the human body temperature in the ear canal or on the forehead. This enables the body temperature to be monitored.

#### Contraindications

The measurement must not be taken

- in an ear affected by inflammatory diseases (e.g. discharging pus or secretion)
- after possible ear injuries (e.g. eardrum damage)
- · in the healing period after surgery

#### 4. WARNINGS AND SAFETY NOTES

#### **GENERAL NOTES**

### Product information

- The device needs to be in the room in which the measurement is taken for at least 30 minutes before use.
- After physical activity, a bath or spending time outdoors, wait approx. 30 minutes before you take a measurement on your forehead.
- Measure your temperature regularly to obtain your normal average temperature. If you suspect you have a fever, simply compare your normal average temperature with the temperature measured currently.
- The thermometer is only designed for the measuring area on the human body stated in the instructions for use.
- The thermometer is calibrated during production. If the thermometer is used according to the instructions for use, further calibration is not necessary.
- Each time before using the device, check that the sensor tip is intact. If it is damaged, please contact your retailer or the service address.
- Should you have any questions about using the device, please contact either your retailer or Customer Services.

#### **AWARNING**

Do not self-diagnose or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.

- The measurements taken by you are for your information only

   they are no substitute for a medical examination. Consult a
   doctor before you undertake any medical treatment.
- Keep the device away from children, animals and vermin.
- Children must not be allowed to use the device. Medical devices are not toys.
- The manufacturer is not liable for damage resulting from improper or incorrect use.

#### **RISKS TO THE DEVICE**

#### NOTICE

- Repairs must only be carried out by authorised service centres, otherwise the warranty is invalidated.
- This thermometer is a sensitive electronic device. Do not drop the device or subject it to any mechanical impacts.
- Do not expose the device to direct sunlight, extreme temperatures or high humidity.
- Do not expose the device to liquids. The device is not waterproof. Avoid all direct contact with water or other liquids.
- Portable and mobile HF communication systems may interfere with this device
- Do not touch the sensor tip with your fingers.
- Clean the thermometer after each use.

#### **NOTES ON HANDLING BATTERIES**

#### **A** WARNING

- Always insert the batteries correctly, taking into account the polarity (+ / -). Keep batteries clean and dry and away from water.
   Always select the correct battery type.
- Never short-circuit batteries and battery compartment contacts.
- Never charge, forcibly discharge, heat, disassemble, deform, encapsulate or modify batteries.
- · Never weld or solder on batteries.
- Never mix batteries of different manufacturers, capacities (new and used), size and type within a device.
- Risk of explosion! Failure to comply with the points mentioned above can result in personal injury, overheating, leakage, venting, breakage, explosion or fire.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance.
- Choking hazard! Keep batteries out of the reach of children.
   Seek medical attention immediately if swallowed. Swallowing them may cause severe internal burns and death.
- Never allow children to replace batteries without adult supervision.

#### **A** CAUTION

- Store batteries away from metal objects in a well-ventilated, dry and cool place.
- Never expose batteries to direct sunlight, excessive heat or rain.

- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.
- Remove batteries from the device if it is not going to be used for a long period of time. Do not use the product if the battery compartment lid no longer closes properly.
- Dispose of discharged batteries immediately and properly. Never dispose of batteries in fire or hot ovens.

#### NOTICE

When disposing of batteries, keep batteries with different electrochemical systems separate.

#### 5. INFORMATION ABOUT THIS THERMO-METER

The temperature measurement varies depending on the part of the body where the measurement is taken. In a healthy person, the variance can be between 0.2°C and 1°C (0.4°F and 1.8°F) in different parts of the body.

Normal temperature range with various thermometers:

|                         | Measurements                            | Thermometer used              |
|-------------------------|-----------------------------------------|-------------------------------|
| Forehead temperature    | 35.8°C to 37.6°C<br>(96.4°F to 99.7°F)  | Forehead thermom-<br>eter     |
| Ear temperature         | 36.0°C to 37.8°C<br>(96.8°F to 100.0°F) | Ear thermometer               |
| Oral temperature        | 36.0°C to 37.4°C<br>(96.8°F to 99.3°F)  | Conventional ther-<br>mometer |
| Rectal temper-<br>ature | 36.3°C to 37.8°C<br>(97.3°F to 100.0°F) | Conventional ther-<br>mometer |



- Temperatures measured with different thermometers should never be compared with one another.
- Tell your doctor what type of thermometer you used to take your body temperature and on what part of the body. Also bear this in mind if you are diagnosing yourself.

Holding the thermometer in your hand for too long before taking a measurement can cause the device to warm up. This means the measurement could be incorrect.

#### Influences on body temperature

- · A person's individual metabolism
- Age:

Body temperature is higher in infants and toddlers than in adults. Greater temperature fluctuations occur faster and more often in children. Normal body temperature decreases with age.

- · Clothing
- Outside temperature
- Time of day:

Body temperature is lower in the morning and increases throughout the day towards evening.

 Activity: Physical

Physical and, to a lesser extent, mental activities increase body temperature.



Taking the body temperature provides a current measurement of a person's temperature. If you are uncertain about interpreting the results or if the values are abnormal (e.g. fever), please consult your doctor. This also applies in the case of slight temperature changes if there are other symptoms of illness such as agitation, heavy sweating, flushed skin, fast pulse rate, tendency to collapse, etc.

#### 6. DEVICE DESCRIPTION

The associated drawings are shown on page 3.

1 Forehead/cover cap

2 LED (red) (fever indicator)

3 LED (green)

4 LCD

Sensor tip with lens (cover cap removed)

6 Battery compartment lid

|    | Tasten   | Funktionen                                                      |
|----|----------|-----------------------------------------------------------------|
| 7  | 0        | Forehead thermometer mode button                                |
| 8  | 9/Ɗ      | Ear thermometer mode/on button                                  |
| 9  | M        | Memory button: Calling up saved values and saving menu settings |
| 10 | <b>©</b> | Set button: Setting the basic functions                         |

#### **Display description**

11 Date

12 Time

Measurement mode ("Ear", "Forehead", "Object")

Battery warning symbol

15 Measurement display

"Memory" symbol and storage space number

"Measurement in progress" symbol

Unit of measurement (°C or °F)

#### 7. INITIAL USE

#### Inserting the batteries

- Loosen the screw on the battery compartment lid and pull the lid off downwards.
- Insert both batteries into the battery compartment according to the specified polarity.
- Only use brand-name batteries of type: 2 x 1.5 V AAA batteries (LR03). Do not use rechargeable batteries.
- Then close the battery compartment by positioning the lid and clicking it into place.
- Secure the battery compartment cover using the screw that was previously unscrewed.

The thermometer automatically switches on and the settings menu appears in the display ("8. Switching on and setting the thermometer").

#### Replacing the batteries

When the batteries get weak, the battery warning symbol appears It is still possible to measure temperature. The batteries must be replaced. When the battery symbol flashes appears in the display, the batteries must be replaced. If the batteries are too flat, then the thermometer will switch off automatically.

To replace the batteries, follow the previous steps from "Inserting the batteries" and also observe the following steps:

- Take the used batteries out of the battery compartment.
- Insert new batteries. Make sure that the batteries are inserted the correct way round.

## 8. SWITCHING ON AND SETTING THE THERMOMETER

Press the ① button for 1 second to switch the thermometer on. The device performs a brief self test: all elements of the display are shown for approx. 1 second A. Following a successful self test, the device emits two short beeps. In Standby mode, the date and time are shown and "--" is displayed.

## Set the unit for the temperature display as well as the date and the time.

When the thermometer is used for the first time and each time the batteries are changed, the date and time are displayed (after the self test) in the basic setting (I- I  $\square \square \square \square$ ). Now set the unit in which the temperature will be displayed, the date and the time. To set the device, proceed in stages: Unit – year – month – day – hours – minutes.

 Press the button for approx. three seconds in order to reach Set mode.

The setting to be changed will flash each time.

- Press the button 🕥 to change the selected setting.
- Press the button (M) to save the setting.
- After this process, the thermometer shows the word UFF in the display and switches off automatically.

#### 9. MEASUREMENT

#### 9.1 Ear temperature mode



 Some people produce different readings in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear.

- The ear thermometer may be used by children only under adult supervision. Measurement is usually possible over the age of 6 months. In infants under 6 months, the ear canal is still very narrow so the temperature of the eardrum often cannot be recorded and the result displayed is often too low.
- The measurement must not be taken in an ear affected by inflammatory diseases (e.g. discharging pus or secretion), after possible ear injuries (e.g. eardrum damage) or in the healing period after operative procedures. In all of these cases, please consult your doctor.
- This thermometer may only be used without a disposable protective cover.
- If you have been lying on one ear for some time, the temperature is slightly raised. Wait a little while or measure in the other ear.
- As ear wax can affect the measurement, you should clean the ear before measuring if necessary.

#### Measuring body temperature in the ear

- Press the button for 1 second to switch the thermometer on. Following a successful self test, the device emits two short beeps.
- Remove the cap by gently pushing it up (1) and then pulling it off forwards (2).

Make sure that the sensor tip and also the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip. This is important so that the sensor tip can be pointed directly at the eardrum.

- Insert the sensor tip carefully and press the button for 1 second.
- Release the ① button. The end of the measuring time is signalled with a short beep and the measured value appears on the display.

If the measured value is within the normal range (< 38°C/100.4°F), the green LED lights up for 3 seconds. If the measured value is higher (≥ 38°C/100.4°F, high temperature), the red LED is illuminated.

#### 9.2 Forehead temperature mode

Before starting the measurement, please check the following points:
- Correct measurement range

#### Remember:

- Physical activity, increased perspiration on the forehead, taking vasoconstrictive medication and skin irritations can distort the measurement.
- The forehead must be free of sweat, hair, cosmetics and dirt. If the forehead area is covered, clean the area and then wait for 10 minutes to improve the accuracy of the measurement.

#### **NOTICE**

We recommend that you take three measurements on the forehead. If the three measurement results differ, take the highest reading.

#### Measuring the body temperature on the forehead

- Place the measuring head with the forehead/cover cap fitted on the temples, hold down the <sup>(3)</sup> button and move the thermometer smoothly over the forehead to the other temple.
- Then release the ⊕ button. The end of the measuring time is signalled with a short beep and the measured value appears on the display.

If the measurement is < 38°C (100.4°F), the LED lights up green 3. This indicates that the body temperature is in a normal range.

If the measurement is  $\geq 38^{\circ}\text{C}$  (100.4°F) the LED lights up red 2. This indicates that the body temperature is above the normal range. The measurement is automatically saved with the date/time, memory space number and measurement mode.

The device automatically switches off after approx. 60 seconds.

#### 9.3 Object temperature mode

If you want to use the thermometer to measure the surface temperature, switch to object temperature mode.

The device switches to the object temperature mode.

- Press and hold the ① button or ② Forehead and point the sensor tip towards the object or liquid to be measured (never immerse in liquids), maintaining a distance of 3 cm.
- Release the button or Forehead. The end of the measuring time is signalled with a short beep and the measured value appears on the display.

Please note that the displayed temperature is the measured and not the adapted surface temperature. It is not the same as the forehead/ ear temperature. To switch back to the Ear/Forehead thermometer mode, press the  $\stackrel{\frown}{M}$  and  $\stackrel{\frown}{M}$  buttons simultaneously for 3 seconds until the  $\stackrel{\frown}{M}$  symbol disappears and there is a short beep. When switched on again, the object temperature mode is exited automatically.

#### 9.4 Displaying stored measurements

The device automatically stores the values from the last 10 measurements.

If the 10 memory spaces are full, the oldest value is deleted.

The memory can be called up as follows:

- Press the button. The most recent measurement is displayed.
   The date, time, memory space number, the measurement mode symbol and the temperature are each displayed.
- Pressing the button again will display the next measured value.

Removing the batteries completely erases the measurement memory.

## 10. CLEANING AND MAINTENANCE Cleaning the device

#### NOTICE

- The sensor tip is the most sensitive part of the thermometer. Be very careful with the sensor tip when cleaning the device.
- Do not use any harsh cleaning products.
- Always observe all safety notes for users and the device. ("4. Warnings and safety notes")

Clean the sensor tip after each use. Use a soft cloth or cotton bud that can be moistened with 75% medical alcohol (e.g. isopropyl). Under no circumstances may liquid enter the device.

Do not use the device again until it is completely dry.

#### Storing the device

#### NOTICE

The device must not be stored or used at an excessively high or low temperature or humidity ("13. Technical specifications"), in sunlight, in association with an electrical current or in dusty locations. Measurement inaccuracies can otherwise occur.

If prolonged storage is planned, you should remove the batteries.

#### 11. WHAT IF THERE ARE PROBLEMS?

| Display | Cause                                                                                                                                  | Solution                                                                                                                                                                                         |
|---------|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "Hi"    | The recorded temperature is higher than 1. Ear/Forehead thermometer mode: 109.4 °F (43 °C) 2. Object temperature mode: 212 °F (100 °C) | Operate the thermometer only between the specified temperature ranges. If necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or customer services. |
| "Lo"    | The recorded temperature is lower than  1. Ear/Forehead thermometer mode: 93.2°F (34°C)  1. Object temperature mode: 32°F (0°C)        | Operate the thermometer only between the specified temperature ranges. If necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or customer services. |
|         | The batteries are weak.                                                                                                                | Replace the batteries.                                                                                                                                                                           |

| Display | Cause                                                                          | Solution                                                               |
|---------|--------------------------------------------------------------------------------|------------------------------------------------------------------------|
| "Err"   | The operating temperature is not in the range from 50 to 104°F (10°C to 40°C). | Operate the thermometer only between the specified temperature ranges. |

#### 12. DISPOSAL

For environmental reasons, do not dispose of the device in household waste at the end of its service life.

Dispose of the device at a suitable local collection or recycling point in your country.

Dispose of the device in accordance with EC Directive Waste Electrical and Electronic Equipment (WEEE). If you have any questions, please contact the local authorities responsible for waste disposal.



- Empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
- The codes below are printed on batteries containing harmful substances:

Pb = Battery contains lead,

Cd = Battery contains cadmium,

Hg = Battery contains mercury.

# Pb Cd Hg

If the device is used for commercial medical purposes, the applicable national regulations determine whether it must be tested for accuracy by appropriate means.

We reserve the right to make technical changes to improve and develop the product.

| Name and model                     | FT 65                                                                                              |
|------------------------------------|----------------------------------------------------------------------------------------------------|
| Туре                               | FT 65                                                                                              |
| Measurement method                 | Infrared measurement                                                                               |
| Basic functions                    | Ear temperature measurement<br>Forehead temperature measurement<br>Object temperature measurement  |
| Measurement units                  | Celsius (°C) or Fahrenheit (°F)                                                                    |
| Operating mode                     | Comparison mode                                                                                    |
| Operating conditions               | 15 °C to 35 °C (59 °F to 95 °F)<br>at a relative humidity ≤ 85 %,<br>700-1060 hPa ambient pressure |
| Storage and transport conditions   | -25 °C to 55 °C (-13 °F to 131 °F) at a relative humidity ≤ 85 %                                   |
| Minimum<br>measurement<br>duration | ≤ 1 second                                                                                         |

#### 13. TECHNICAL SPECIFICATIONS

If the device is not used according to the specifications, perfect functionality cannot be guaranteed!

The accuracy of this thermometer has been carefully checked and it has been developed with a long service life in mind.

| Clinical accuracy                               | Ear thermometer mode (at the eardrum):<br>Clinical bias: -0.03 °C<br>Limit of Agreement: 0.36 °C<br>Clinical repeatability: ± 0.07 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 | Forehead thermometer mode (on the forehead skin): Clinical bias: -0.04 °C Limit of Agreement: 0.38 °C Clinical repeatability: ± 0.08 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Measurement ranges                              | Ear and forehead temperature mode:<br>34 °C - 43 °C (93.2 °F - 109.4 °F)<br>Object temperature mode:<br>0 °C - 100 °C (32 °F - 212 °F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Laboratory measurement precision                | Ear temperature mode: $\pm 0.20  ^{\circ}\text{C}  (\pm 0.40  ^{\circ}\text{F})  \text{at } 35\text{-}42  ^{\circ}\text{C}  (95\text{-}107.6  ^{\circ}\text{F}),$ outside this range $\pm 0.30  ^{\circ}\text{C}  (\pm 0.5  ^{\circ}\text{F})$ Forehead temperature mode: $\pm 0.20  ^{\circ}\text{C}  (\pm 0.40  ^{\circ}\text{F})  \text{at } 35\text{-}42  ^{\circ}\text{C}  (95\text{-}107.6  ^{\circ}\text{F}),$ outside this range $\pm 0.30  ^{\circ}\text{C}  (\pm 0.5  ^{\circ}\text{F})$ Object temperature mode: $\pm 1.5  ^{\circ}\text{C}  (\pm 2.7  ^{\circ}\text{F})  (30  ^{\circ}\text{C}  (86  ^{\circ}\text{F});$ $\pm 5\%  > 30  ^{\circ}\text{C}  (86  ^{\circ}\text{F})$ |
| Memory function of body temperature measurement | Automatically stores the last 10 measurements.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

| Acoustic signal                         | When the device is switched on, during measurement, at the end of the measurement and if the body temperature is above the usual range (= fever). |  |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Display                                 | LCD                                                                                                                                               |  |
| Energy-saving functions                 | The device switches off automatically after 60 seconds.                                                                                           |  |
| Dimensions<br>Width x depth x<br>height | 38.2 x 138.0 x 48.0 mm                                                                                                                            |  |
| Weight                                  | approx. 63 g (without batteries)                                                                                                                  |  |
| Battery 2 x1.5V AAA<br>(LR03)           | Batteries last for approx. 2000 measurements                                                                                                      |  |
| IP protection                           | IP22: protected against solid foreign bodies larger than 12.5 mm in diameter and water dripping at an angle of 15°                                |  |
| Expected useful life                    | Information on the service life of the product can be found on the homepage.                                                                      |  |
| Classification                          | Internally powered ME device. Continuous operation. BF applied part                                                                               |  |
| Display resolution                      | 0.1°C/°F                                                                                                                                          |  |
|                                         |                                                                                                                                                   |  |

The serial number is located on the device or in the battery compartment.

#### 14. DIRECTIVES

The device complies the European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR11, IEC61000-4-2, IEC61000-4-3, IEC61000-4-8) and is subject to particular precautions with

Subject to errors and changes

regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device. For more details, please contact our Customer Services at the address indicated.

#### 15. WARRANTY/SERVICE

Further information on the warranty and warranty conditions can be found in the warranty leaflet supplied. Before submitting a claim, please check the batteries and replace them if necessary.

#### Notes on electromagnetic compatibility

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's resistance to electromagnetic interference; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above could impair the performance of the device

#### Notification of incidents

For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.



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