



**TFA**

CE 0197

**Digital Clinical thermometer DT-01B**

GB

Thank you for choosing this instrument from TFA.

**1. Before you use this product**

- Please make sure you read the instruction manual carefully.
- Following and respecting the instructions in your manual will prevent damage to your instrument and loss of your statutory rights arising from defects due to incorrect use.
- We shall not be liable for any damage occurring as a result of non-following of these instructions.
- Likewise, we take no responsibility for any incorrect readings and for any consequences which may result from them.
- Please take particular note of the safety advice!
- Please keep this instruction manual safe for future reference.

**2. For your safety**

- The unit is suitable exclusively for measuring human body temperature. The product should only be used as described within this instruction.
- Before each measurement check intactness of tip and display. Use the unit only when intact.
- Unauthorised repairs, modifications or changes to the product are prohibited.
- Operation in strong electromagnetic fields, such as next to a mobile phone, can lead to malfunction. Keep a minimum distance of 3.3 m from such devices when using this device.
- The minimum measurement time until the beep must be maintained without exception.
- Discuss the measured values with your doctor.

**Caution!**  
Risk of injury:

- The instrument contains small parts that could be swallowed by children. Keep this instrument and the battery out of reach of children. Use under parental supervision.
- Batteries contain harmful acids and may be hazardous if swallowed. If a battery is swallowed, this can lead to serious internal burns and death within two hours. If you suspect a battery could have been swallowed or otherwise caught in the body, seek medical help immediately.
- Batteries must not be thrown into a fire, short-circuited, taken apart or recharged. Risk of explosion!
- Low batteries should be changed as soon as possible to prevent damage caused by leaking.
- Wear chemical-resistant protective gloves and safety glasses when handling leaking batteries.

**Important information on product safety!**

- Do not place the unit near extreme temperatures, vibration or shock. Do not bend the instrument.
- The instrument is not waterproof. Protect from moisture.

**3. Elements and buttons**

**A:** Battery compartment                      **B:** ON/OFF button  
**C:** Display for the temperature            **D:** Temperature probe

**4. Use**

- Disinfect the tip before each use!
- Press the ON/OFF button for switching on and off.
- When switching on a brief beep tone will sound and all LCD segments will light up for a short moment. The instrument starts a self-test.
- The display shows for about 2 seconds the last measured temperature.
- Lo stays in the display and °C flashes. If the room temperature is higher than 32 °C, the room temperature would be displayed instead of Lo °C. The unit is ready for use.
- The actually measured temperature is permanently shown on the display and the symbol °C flashes. The measurement is completed when the temperature rises less than 0.1 °C within 16 seconds.
- If the maximum temperature remains stable, an alarm will sound 10 times and °C is no longer flashing.
  - a) Normal alarm (beep ... beep ... beep ...), body temperature below 37.8 °C
  - b) Fever alarm (beep beep beep ... beep beep beep ...), body temperature 37.8 °C or above
- For axillary measurements, the recommended measuring time has to be observed despite the beep tone.
- Remove the thermometer carefully. Press the ON/OFF button to switch off the instrument. The instrument will turn off automatically after approx. 10 minutes.

**4.1 Measurement methods****Rectal measurement:**

- This is the safest method of measurement. It is especially good for babies and infants. Gently insert the thermometer tip 1-2 cm into the anus. Minimum measuring time: 1 minute.

**Oral measurement:**

- Place the temperature tip in one of the two pockets under the tongue, left or right at the root of the tongue. Close your mouth during the measurement and breathe calmly. This will prevent the measurement results from being falsified by breathing air. The measured temperature is on average 0.3 to 0.8 degrees C lower than the rectally measured temperature. Minimum measuring time: 1 min.

**Axillary measurement (under the armpit):**

- From the medical point of view this method always provides inaccurate values. A deviation from the rectal measurement of 0.5 to 1.5 degrees C must be expected. Minimum measuring time: 5 min.

**5. Care and maintenance**

- Clean the instrument after each use with a soft damp cloth. For disinfection please use water-diluted isopropyl alcohol according to the manufacturer's instructions. Any other cleansing substances or cleansing method can cause dysfunction or damage to the instrument. Do not immerse in water or sterilize by boiling method, gas or steam autoclaves.
- Remove the battery if you do not use the product for a long period of time.
- Keep the instrument in its case in a dry place.

**Instruction manual****TFA**

Art.-No. 15.2015

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**5.1 Battery replacement**

- Change the battery when the battery symbol appears on the display.
- Remove the blue cover and slide out the battery compartment.
- Carefully remove the battery with a pointed object and insert a new LR 41 battery. Make sure the polarity is correct (+ pole above).
- Slide back the battery compartment and replace the blue cover.

**6. Troubleshooting**

Problem	Solution
No display	→ Switch on the instrument → Ensure battery polarity is correct (+ pole above) → Change the battery
Incorrect display	→ Change the battery → Check the correct position of the thermometer (see: Measurement methods)

If your device fails to work despite these measures contact the supplier from whom you purchased it.

**7. Legal basis for placing of the product in the EU market**

- The Digital Thermometer DT-01B, Art.-No.15.2015 is a medical device class 2a according the EU Medical Device Directive 93/42/EWG. The Digital Thermometer meets the requirements of the standards EN 12470-3:2000+A1:2009, EN 60601-1:2006+A1:2013, EN 60601-1-11:2015, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN ISO 15223-1:2016, EN ISO 10993-1,-5:2009, EN ISO 10993-10:2010, EN ISO 14971:2012

**8. Waste disposal**

This product has been manufactured using high-grade materials and components which can be recycled and reused.



Never dispose of empty batteries and rechargeable batteries in household waste. As a consumer, you are legally required to take them to your retail store or to appropriate collection sites depending on national or local regulations in order to protect the environment.

The symbols for the heavy metals contained are: Cd=cadmium, Pb=lead, Hg=mercury



This instrument is labelled in accordance with the EU Waste Electrical and Electronic Equipment Directive (WEEE).

Please do not dispose of this instrument in household waste. The user is obligated to take end-of-life devices to a designated collection point for the disposal of electrical and electronic equipment, in order to ensure environmentally-compatible disposal.

**9. Specifications**

Type:	Maximum thermometer
Measuring range:	32 °C...42.9 °C
Lo °C	Surrounding temperature lower than 32 °C
Hi °C	Surrounding temperature higher than 42.9 °C
Accuracy:	±0,1 °C at 35.5 °C...42.0 °C ±0,2 °C at 32.0 °C...35.5 °C, 42.0 °C...42.9 °C
Resolution:	0.1 °C
Storage and transport conditions:	Temperature -25 °C...+55 °C / humidity: ≤ 95 % rH
Ambient conditions during use:	Temperature 5 °C...35 °C / humidity: ≤ 80 % rH
Battery:	LR 41 included
IP protection class:	IP22
Housing dimension:	18 x 10 x 130 mm
Weight:	9 g (instrument only)

**10. Explanation of symbols**

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Declaration of European conformity, number of the notified body (TÜV Rheinland)



Device complies with protection class BF



Consult instructions for use

Storage and transport conditions:  
Temperature: -25 °C...+55 °C  
Humidity: ≤ 95 % rHAmbient conditions by use:  
Temperature: +5 °C...+35 °C  
Humidity: ≤ 80 % rH

LOT

Lot number



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EC REP

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Made in P.R.C.

04/2020/IGB