

microlife[®]



PT₂₀₀

Bluetooth[®]
Patch Thermometer

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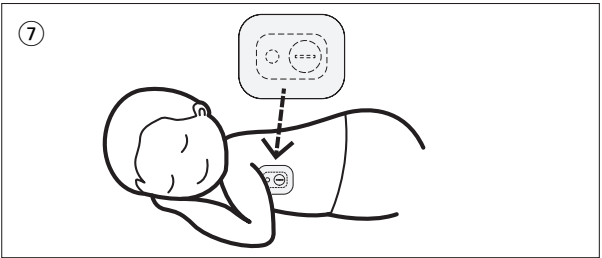
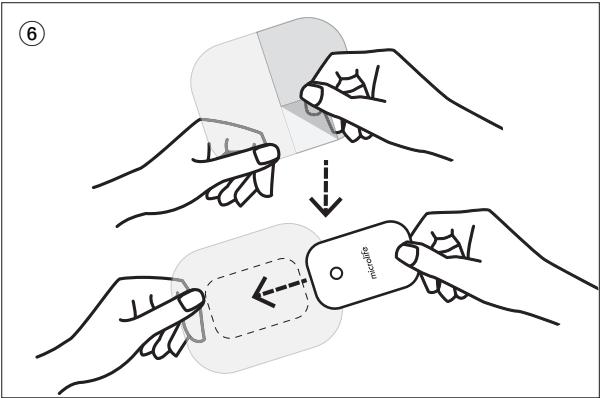
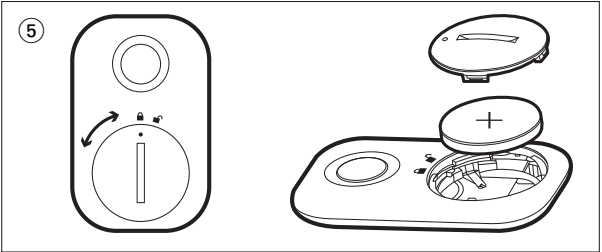
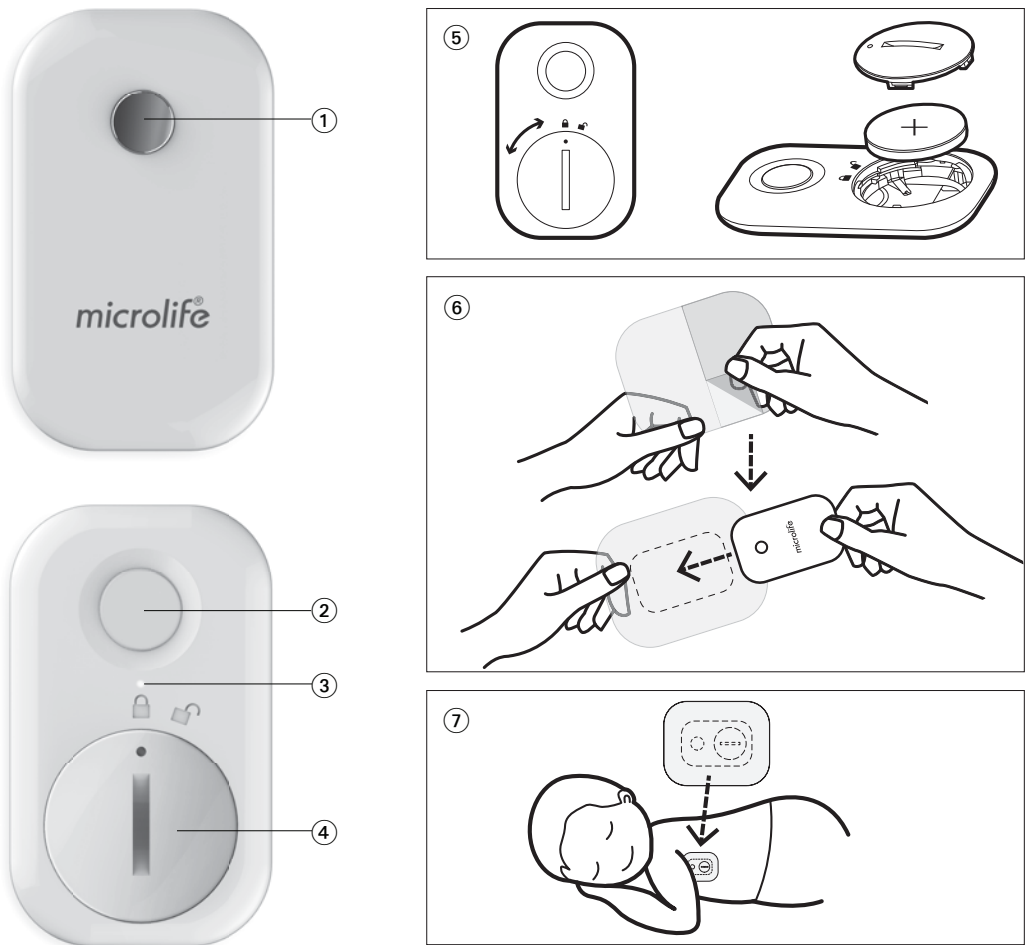
Made in China

IB PT 200 EN 4818



Microlife PT 200





- ① Measuring sensor
- ② ON/OFF button
- ③ Power indicator
- ④ Battery Compartment
- ⑤ How to insert the battery
- ⑥ Preparing the device for use
- ⑦ Correct positioning of the device

 Read the instructions carefully before using this device.

 Type BF applied part

This Microlife thermometer is a high quality product incorporating the latest technology and tested in accordance with international standards. With its unique technology, this device can provide a stable, heat-interference-free reading with each measurement. The device performs a self-test every time it is switched on to always guarantee the specified accuracy of any measurement. This Microlife thermometer is intended for the periodic measurement and monitoring of human body temperature.

This thermometer has been clinically tested and proven to be safe and accurate when used in accordance to the operating instruction manual. Please read through these instructions carefully in order for you to understand all functions and safety information.

Indications for Use
The device is used for the periodic measurement and monitoring of human body temperature in the axilla for the adults, children and neonates, the device to be used by average consumers and healthcare professionals in both home and clinical environments, the test data can be transferred and stored in the APP by BT transmission.

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1. The Advantages of this Thermometer

Accurate and reliable

The unique assembly construction incorporates an advanced sensor, ensuring an accurate and reliable measurement. A measurement is taken every 5 seconds and transferred to the App.

Safe, hygienic and biocompatible

- No risk of broken glass or mercury ingestion.
- Completely safe for use on children.
- The adhesive patches included are 100% biocompatible and do not harm the skin cells.
- Cleaning of the device can be done with an alcohol-moistened cotton tissue, making this thermometer completely hygienic for use by the whole family.

High temperature alarm

Continuous beeps (until the user acknowledges the alert) on the «Microlife Thermo 24» App, alert that the body temperature is equal to or higher than 37.5 °C. The default High temperature alarm setting is 37.5 °C. Users can also set alarm points for high and low temperatures individually. So when the temperature exceeds these limits, the colour of

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Date of Purchase / Date d'achat / Data d'acquisto / Kaufdatum / Satın alma tarihi / Fecha de compra / Data da compra / Datum van aankoop / Ημερομηνία αγοράς / تاريخ الشراء / شماره سریال

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تاريخ خرید / التاجر المختص

the displayed circle will turn red (high temperature) or blue (low temperature) and an alarm beep will be triggered. Please consult with your doctor if you do not know the appropriate body temperature.

Bluetooth® Function

This device connects to the «Microlife Thermo 24» App by using Bluetooth® 4.0 and enables easy monitoring of temperature.

2. Important Safety Instructions

- Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- This device only works in conjunction with a smartphone or tablet as described in these instructions.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.
- Do not scratch or press the measuring sensor.
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- **Never immerse this device in water or other liquids. For cleaning please follow the instructions in the «Cleaning and Disinfecting» section.**
- The adhesive patches are for single use only – do not use them repeatedly. Only use them in smooth and undamaged condition.
- If the measurement result is not consistent with the patient's finding or unusually low, double check the result by another core body temperature measurement.
- Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.
- Do not use this device close to strong electromagnetic fields. Keep a minimum distance of 3.3 m when using this device.
- Protect it from:
 - extreme temperatures
 - impact and dropping
 - contamination and dust
 - direct sunlight
 - heat and cold

- If the device is not going to be used for a prolonged period the battery should be removed.
- Read the additional safety information provided within the individual sections of this instruction manual.



WARNING: The measurement results given by this device is not a diagnosis. It is not replacing the need for the consultation of a physician, especially if not matching the patient's symptoms. Do not rely on the measurement result only, always consider other potentially occurring symptoms and the patient's feedback. Calling a doctor or an ambulance is advised if needed.

3. Using the Device for the First Time

Insert the battery as described in chapter «Battery Replacement».

Downloading the «Microlife Thermo 24» App

Download «Microlife Thermo 24» App for free from Google Play™ (Android) or App Store (iOS) and install it on your smartphone.

Connecting the «Microlife Thermo 24» App

1. Activate Bluetooth® on your smartphone.
 2. Press and hold the ON/OFF button ② for at least 3 seconds until the power indicator ③ flashes green 3 times to activate the Bluetooth® on the device.
 3. Start the «Microlife Thermo 24» App on the smartphone and create a profile, to establish a connection between the device and the smartphone. A temperature display will appear on the smartphone, when a successful connection has been established.
-  Create different profiles for various patients, so they can be tracked separately.
-  We recommend to activate the flight mode on the smartphone, while Bluetooth® is activated, to avoid disturbances of the connection by phone calls.

App Tutorial

To access the tutorial, select «Help & About» in the menu of the «Microlife Thermo 24» App (located in the upper left corner on the screen) and press «Tutorial».

4. Measuring the body temperature

1. The device and the patient must remain in a stable environment for at least 5 minutes before measuring the temperature.
2. Clean the armpit and the surrounding area.

3. Take one adhesive patch, remove the protective film and place the device right in the middle of the patch (⑥). The battery compartment (④) side should be stuck on the patch. The measuring sensor (①) needs to be in contact with the skin and as close as possible to the armpit.
4. Place the device with the adhesive patch directly on the skin below the armpit (⑦).
5. Lower the arm and wait around 15 minutes until the temperature rises to the body temperature level.
6. The temperature display will appear on the smartphone.
7. Press and hold the ON/OFF button (②) for 3 seconds to turn off the device; otherwise the device will automatically switch off after approx. 30 minutes, when removed from the body.

 To keep a good connection, avoid distances above 5 m between the device and the smartphone.

 Obstacles (e.g. walls) may weaken the connection.

 NOTE:

- Regularly check for sufficient skin contact of the device, in order to avoid measurement errors.
- Sudden movements or low battery power may lead to inaccurate measurement results.
- The adhesive patches are for single use only – do not use them repeatedly. Only use them in smooth and undamaged condition.
- Don't use the thermometer in high humidity environments.
- Doctors recommend rectal measurement for newborn infants within the first 6 months, as all other measuring methods might lead to ambiguous results.
- **Readings from different measuring sites should not be compared as the normal body temperature varies by measuring site and time of day**, being highest in the evening and lowest about one hour before waking up.

Normal body temperature ranges:

- Axillar: 34.7 - 37.3 °C / 94.5 - 99.1 °F
- Oral: 35.5 - 37.5 °C / 95.9 - 99.5 °F
- Rectal: 36.6 - 38.0 °C / 97.9 - 100.4 °F
- Microlife PT 200: 34.7 - 37.3 °C / 94.5 - 99.1 °F

5. Monitoring the body temperature

Monitor the body temperature for up to 72 hours, once the device is connected to the App. A measurement is taken every 5 seconds and transferred to the App. You can also track the temperature trend of the past hours and the data of previous measurements.



If the device is disconnected from the App, the device will save one measurement every minute and send the stored results to the App, once Bluetooth® is connected again.

6. Cleaning and Disinfecting

Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the thermometer casing and the measuring sensor. Ensure that no liquid enters the interior of the device. Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids. Take care not to scratch the measuring sensor.

7. Battery Replacement

This device is supplied with one lithium battery type CR2032. The battery needs replacing, when the power indicator (③) is blinking red and a notification on the smartphone App is shown.

Remove the battery cover (④) by using a coin and rotate clockwise to open. Insert the new battery with the + at the top (⑤). Then position the battery cover and rotate it counterclockwise to close.

Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

8. Guarantee

This device is covered by a **5 year guarantee** from the date of purchase. The guarantee is valid only on presentation of the guarantee card completed by the dealer (see back) confirming date of purchase or the receipt.

- The guarantee covers the device. The battery and packaging are not included.
- Opening or altering the device invalidates the guarantee.
- The guarantee does not cover damage caused by improper handling, a discharged battery, accidents or non-compliance with the operating instructions.

Please contact Microlife-service.

9. Technical Specifications

Type:	Patch Thermometer PT 200
Measurement Operation:	Direct Mode
Measurement range:	32.0 - 43.0 °C / 89.6 - 109.4 °F
Resolution:	0.1 °C / °F
Measurement accuracy:	Laboratory: ± 0.1 °C / ± 0.2 °F
Memory:	4320 readings if not linked to the smartphone
Operating conditions:	10 - 40 °C / 50 - 104 °F 15-95 % relative maximum humidity
Storage conditions:	-25 - +60 °C / -13 - +140 °F 15-95 % relative maximum humidity
Automatic Switch-off:	Automatic switch off after 30 minutes, when removed from the body.
Communication:	Bluetooth® 4.0 10 m valid transmission distance in free space
Compatibility:	iOS: iOS 8.0 or newer Android: Android 5.0 or newer
Battery:	1 x CR2032 battery 3V
Battery lifetime:	approx. 9 days when used 8 hours per day (using a new battery)
Dimensions:	53 x 31.5 x 8 mm
Weight:	11 g (with battery), 8 g (w/o battery)
IP Class:	IP22
Reference to standards:	ISO80601-2-56, ASTM E1112; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11
Expected service life:	5 years

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications to the product are not approved by Microlife USA and could void the user's authority to operate the equipment under FCC jurisdiction.

Note: This equipment has been verified to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by increasing the distance between the product and the affected device, can by one or more of the following measures

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Electromagnetic compatibility: This device fulfills the stipulations of the standard IEC 60601-1-2 (EMC).

Technical alterations reserved.

According to the Medical Product User Act a biennial technical inspection is recommended for professional users. Please observe the applicable disposal regulations.

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Portable and mobile RF communications equipment can affect the device

NOTE: Do not use this device in the presence of electromagnetic or other interference outside the normal range specified in IEC60601-1-2.

10. www.microlife.com

Detailed user information about our thermometers and blood pressure monitors as well as services can be found at www.microlife.com.

Appendix

Guidance and manufacturer's declaration – electromagnetic emissions		
The model PT 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT 200 should assure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The model PT 200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model PT 200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

1.

Guidance and manufacturer's declaration – electromagnetic immunity			
The model PT 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT 200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment --guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines and patient coupled lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) and neutral	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\%$ U_T ($>95\%$ dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles $<5\%$ U_T ($>95\%$ dip in U_T) for 5s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the model PT 200 may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

2.

Guidance and manufacturer's declaration – electromagnetic immunity			
The model PT 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the model PT 200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the model PT 200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model PT 200 is used exceeds the applicable RF compliance level above, the model PT 200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model PT 200. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

3.

Recommended separation distances between portable and mobile RF communications equipment and the model PT 200			
The model PT 200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model PT 200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model PT 200 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			