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iHealth® PT5

Infrared Ear Thermometer



User's Manual

Version 1.1

iHealth Infrared Ear Thermometer (PT5) User's Manual

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Introduction

Thank you for choosing our product.

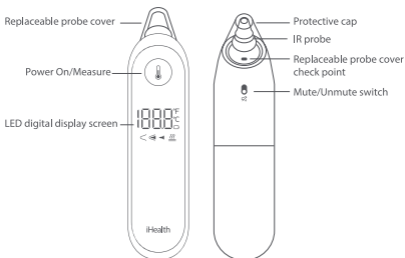
This product is iHealth's next-generation infrared (IR) ear thermometer designed to take human body temperature by measuring the energy of IR emitted from inside the ear. In addition, the probe preheating function of the ear thermometer makes the measuring experience more gentle and comfortable and the measurements more accurate. It is a body temperature measurement tool suitable for use at both home and healthcare facilities.

Product Name: iHealth Infrared Ear Thermometer

Product Model: PT5

Get to know your thermometer

The iHealth Infrared Ear Thermometer consists of a plastic housing, printed circuit board (inside), IR temperature sensor, digital display screen, Power On/Measure button, Mute/Unmute switch, protective cap, and replaceable probe cover (see the illustration below).



LED screen instructions




Specifications

1. Product Name: iHealth Infrared Ear Thermometer
2. Product Model: PT5
3. Dimensions: 138 mm x 34 mm x 57 mm
4. Weight: 100 g
5. Power Source: DC 3V; 2 x 1.5V \equiv AAA batteries
6. Battery Life: Approximately 200x measurements
7. Expected Service Life: 5 years
8. Display Screen Type: LED digital
9. Measurement Site: Ear
10. Operating Mode: Adjusted mode
11. Reference Body Site: Oral
12. Clinical Reproducibility: Within $\pm 0.5^{\circ}\text{F}$ ($\pm 0.3^{\circ}\text{C}$)
13. Measure Time: ≤ 3 seconds
14. Resolution: 0.1°F (0.1°C)
15. Measurement Range: 93.2°F - 109.2°F (34.0°C - 42.9°C)
16. Measurement Precision: $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$)
within 93.2°F - 107.6°F (34.0°C - 42.0°C),
outside this measurement range: $\pm 0.5^{\circ}\text{F}$ ($\pm 0.3^{\circ}\text{C}$).
17. Measurement Units: Fahrenheit ($^{\circ}\text{F}$) or Celsius ($^{\circ}\text{C}$)
18. Operating Conditions:
Temperature: 50°F - 104°F (10°C - 40°C)
Humidity: $\leq 95\%$ RH, non-condensing
Atmospheric Pressure: 70 KPa~106 KPa
19. Transportation/Storage Conditions:
Temperature: -4°F ~ 131°F (-20°C ~ 55°C)
Humidity: $\leq 95\%$ RH, non-condensing
Atmospheric Pressure: 70 KPa~106 KPa
20. Software Version: V1.1

Intended use

The iHealth Infrared Ear Thermometer is intended for the intermittent measurement of body temperature from the ear canal on people of all ages except for babies under 3 months. It is suitable for home use and healthcare facility use.

Contraindications

 The iHealth Infrared Ear Thermometer is not recommended for people whose measurement sites have local lesions such as inflammation, trauma, postoperative, etc.

⚠ CAUTION

(1) Measurements


1. Thermometer readings should be regarded as for reference only. Do not attempt self-diagnostics or self-treatment using the temperature readings. Please seek professional medical advice when necessary.
2. It is advised that an adult should take the measurement for infants and children who cannot use the ear thermometer themselves.
3. If there is a temperature difference between the thermometer just taken out of its storage and the ambient environment around the patient, please allow 30 minutes for the thermometer to adjust to the ambient environment's temperature before use.
4. The probe cover is for one-time use and should be replaced after each use to ensure measurement accuracy and avoid cross infection.
5. Before taking a measurement, make sure that the probe is not covered with small foreign objects (such as earwax, dander, droplets, dust, etc.). After taking the measurement, please put the protective cap back on the probe to protect it from dirt or damage.
6. Some people (especially younger children) may have more earwax in their ear canals than others. To get good accuracy, please consider cleaning out any excess earwax before taking measurements.
7. Right after swimming, taking a bath, or entering a warm room from the cold outside, the people will have ear canals exhibiting lower than normal temperatures to allow for accurate measurements. Please wait for 30 minutes before taking a measurement.
8. Side sleepers, headphone users, hearing aid users, and people with long hair covering their ears may have warmer than normal ear canals. Please wait for 30 minutes before taking a measurement.
9. Do not measure body temperature immediately after taking medicine that raises the body temperature. Temperature readings will be elevated until the effect of the medicine wears out.
10. Do not eat, drink, or exercise before or during measurement. A temperature reading taken with the body in a state of equilibrium tends to be more accurate and thus more useful as a reference. Please wait for 30 minutes before take measurement.
11. Keep quiet and remain still during measurement. Follow the instructions in the user's manual to ensure accuracy.

12. The physiological curvatures of ear canals may vary from person to person. When taking measurement, please aim the probe at the eardrum as much as possible to achieve better results.
13. The left and right ears of a patient may give different temperature readings. When monitoring the change in body temperature, please continue measuring from the same ear.
14. The body temperature fluctuates over time, and the body temperature collected in each part of the body will also be different. When observing changes in body temperature. It is recommended that you measure and observe at the same part multiple times.
15. Different types and brands of temperature measurement products may not make good comparison. When observing body temperature, it is recommended that you use the same temperature measurement product for multiple observations in order to better gauge the temperature changes.
16. Please use the probe cover (Models: ET20 and ET40) that is compatible with this product. Unspecified probe covers will result in inaccurate measurements.
17. Keep parts such as protective cap and disposable probe cover away from children to safeguard against potential choking hazards.
18. Do not use this device if experiencing ear diseases such as external otitis and otitis media. Using the device may worsen such conditions.
19. Do not perform measurements while in direct sunlight or under an outlet/vent of an HVAC as this may affect temperature readings.

(2) About the product

1. The probe lens is a very delicate part of this product. Care should be taken to protect the probe lens. Please do not touch the probe directly with your fingers or blow on it. Probe should be covered by the protective cap after measurement.
2. Before use, check the probe lens to make sure that it is clean. If necessary, please clean the probe lens by following the steps below:
 - a. Use 70% isopropyl alcohol wipes to gently clean the probe lens.
 - b. Wait for one minute to allow the probe lens to dry, then place a new probe cover onto the probe.
3. Do not use the thermometer in an environment with strong electromagnetic interference (EMI). Some common examples of EMI sources include an operating microwave oven,

- induction cooker, and in-use cell phone. EMI could cause less accurate results or even device damage.
4. Keep the thermometer out of reach of children. If children try to measure by themselves, they may damage their ears.
 5. Keep the product at a place inaccessible to children to prevent children from swallowing the batteries or small parts.
 6. Please keep the product in accordance with the storage conditions so as not to cause usage problems and measurement errors.
 7. Avoid dropping or subjecting the product to external forces. It may cause measurement errors or product failures.
 8. Do not disassemble, repair, or modify the product.
 9. Remove the batteries if you are not going to use the device for an extended period of time.
 10. Do not keep the thermometer under direct sunlight, in high temperature, or moist environments. Do not submerge the thermometer in water or other liquids.
 11. Do not place the product where an electric shock may result.
 12. Please contact customer service if there are any issues with your thermometer. You should not repair it by yourself.
Note: Non-OEM parts will cause measurement inaccuracy.
 13. This product is a measurement device. It is recommended that the accuracy of the product be verified annually by the manufacturer or a qualified third-party organization.
 14. This product is in human body temperature measurement mode during normal use.
 15. Use of this thermometer is not intended as a substitute for consultation with your physician. Please consult your doctor if you have any doubts about the temperature reading.
 16. Do not throw batteries into an open fire or short-circuit the batteries.
 17. There is no absolute standard for human body temperature. Knowing your own normal body temperature range is important to accurately determine if you have a fever.
 18. It is normal for readings taken from continuous measurement to fluctuate within a small range. During continuous measurement, the subject's body temperature may be transmitted to the thermometer, affecting measurement accuracy. We recommend taking only up to 3 consecutive readings within a short period.
 19. If thermometer temperature readings are inaccurate, one or more of the following may have occurred:
 - a. Operation outside of the manufacturer-specified subject temperature range.
 - b. Operation outside of the manufacturer-specified

- operating temperature and humidity ranges.
 - c. Storage outside of the manufacturer-specified ambient temperature and humidity ranges.
 - d. Mechanical shock.
 - e. Manufacturer-defined soiled or damaged infrared optical components.
20. ASTM laboratory accuracy requirements in the display range of 98°F to 102 °F (37 to 39 °C) for IR thermometers is ± 0.4 °F (± 0.2 °C), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ± 0.2 °F (± 0.1 °C).
 21. Earwax can affect the measurement, you should clean the ear before measuring if necessary.
 22. Do not use the iHealth Infrared Ear Thermometer if you are allergic to plastics or rubber.
 23. The patient contact materials have been evaluated according to the standards of ISO 10993-5 and ISO 10993-10. No toxicity, allergy, or irritation reactions were reported. Based on the current science and technology, other potential allergic reactions are unknown.
 24. The patient is the intended operator.
 25. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - a. This device may not cause harmful interference, and
 - b. This device must accept any interference received, including interference that may cause undesired operation.
 26. The thermometer may be used by children only under adult supervision. In infants under 6 months, the ear canal is still very narrow so the temperature is for reference only. Please consult your doctor.
 27. Do not CARE OR PERFORM MAINTENANCE while the iHealth Infrared Ear Thermometer is in use.
 28.  This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it with other household waste, but take it to appropriate local collection points.
 29. Following mechanical shock, the thermometer should not be used before recalibration.
 30. **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the the thermometer. Otherwise, degradation of the performance of this equipment could result.

Instructions for use

1. Install 2x AAA batteries

Press down and hold the battery cover with your finger and apply some force to slide the cover backwards to open the battery compartment. Refer to the battery polarity symbols to orient the batteries properly during installation. Make sure that the new batteries are correctly installed in the battery compartment and that the batteries' polarities are correct. Put the battery cover back on to close the battery compartment. After powering on and performing the initial self-test, the thermometer will automatically detect and display the battery level. (Please ignore the battery level indicator during power-on and self-test.)

Note: The thermometer is supplied with two 1.5 V type AAA (FR 03) batteries. For best performance, we recommend FR03 batteries.

2. Attach a probe cover

To achieve accurate measurements, make sure a new, clean probe cover is put in place before each measurement.

When attaching a new probe cover, please make sure that the probe cover presses against the probe cover detection point at the bottom of the thermometer probe.



3. Power on and self-check


Press the Power On/Measure button, and the ear thermometer will power on with an accompanying beep. The device will first run a self-check, and all on-screen icon will be displayed during the check. If the device completes the self-check successfully, it will be ready for use. The device will not be usable if any of the following conditions occurs:

(1) No replaceable probe cover attached

If the probe cover did not get installed correctly, a fault will be detected, and the corresponding icon will be displayed on the screen. The device will not be able to measure temperature. The screen will automatically turn off after a set period of time. If the Power On/Measure button is pressed, the device will beep four times (no beeping if in silent mode).

✘ The device will return to normal operating mode after it detects that a probe cover is properly installed.

(2) Probe warming is in progress

While the probe is warming up, the screen will display an "  " icon and "--°F" icon; no measurement can be taken during this period. The screen will automatically turn off after a set

period of time. If the Power On/Measure button is pressed, the device will beep four times (no beeping if in silent mode).

✘ The device will enter normal operating mode after it is warmed up.

(3) Hardware malfunction

When this malfunction is detected, the device will not be usable, and the screen will automatically turn off within 30 seconds.

(4) Batteries depleted

When the low battery icon is shown on the screen, the device will cease to function, and the screen will turn off within 30 seconds.

4. Ear temperature measurement

- 1 Press the Power On/Measure button, and the thermometer will power on with a beep. When self-check starts, the screen will turn on, and the device will beep to signal the completion of self-check.



- 2 When the "---°F" icon appears on the screen, keep the patient's head steady and gently tug the ear to straighten the ear canal. Then place the probe into the ear canal and align towards the eardrum. Make sure the probe completely fills the ear canal.



✘ When inserting the probe, the ear thermometer sensor should be aligned towards the eardrum. If the probe is not properly aligned, the measured temperature will be lower than the actual body temperature.



Methods of straightening the ear canal

Children under one year: Pull the ear straight back.



Children of one year or older and adults: Pull the ear up and back.



- 3 Press the Power On/Measure button to start the measurement. After the measurement is done, there will be a beep, and the result will be displayed on the screen.



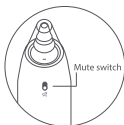
- (1) If the measurement is successful, the temperature value will be displayed on the screen, and the ear thermometer will beep once.
- (2) If the measurement fails, the screen will display "--- °F" and beep 4 times. Common causes of measurement failures are:
 - a) The measurement position is wrong.
 - b) The ambient temperature is outside of the allowed operating temperature range.
 - c) The target temperature exceeds the range 93.2°F-109.2°F (34°C-42.9°C).
- 4 Repeat Step 3 above before shutting down the thermometer and trying to restart and measure again. Please follow the correct measurement method shown in Step 2 when measuring.
- 5 After the temperature measurement is completed, the ear thermometer will automatically shut down in 15 seconds. You can also press and hold the Power On/Measure button for 2 seconds to manually turn off the thermometer.



✘ If the thermometer is in silent mode, the buzzer will be off.

5. Silent mode

While the device is on, toggle the Mute/Unmute switch to turn the sound off/on.



6. Replacing batteries

- 1) Find the battery cover on the back of the device. Press down on the battery cover and slide the cover down to open the battery compartment.
- 2) Remove the old batteries.
- 3) Refer to the battery polarity symbols to orient the batteries properly. Make sure that the new batteries are tightly inserted into the battery compartment and that the polarity is not reversed during installation.
- 4) Replace the battery cover to close the battery compartment.
 - Comply with relevant regional laws and regulations when disposing of the used batteries.
 - Do not dispose of batteries directly into the trash .
 - Remove the batteries if the device will not be used for more than one month.
 - Do not touch the batteries and the patient at the same time while the device is in use.
 - Do not throw batteries into fire.

7. Changing Temperature Unit

- 1) When the device is powered off, press and hold the measurement button for 8 seconds to enter unit switching mode. Your device is in unit switching mode when both the "C" and "F" symbols are flashing at the same time.







- 2) While in unit switching mode, press the measurement button to toggle between Fahrenheit and Celsius. The symbol corresponding to the selected unit will flash.
- 3) After selecting the unit, press and hold the measurement button for 8 seconds to exit the unit switching mode.



Note: If you do not press and hold the measurement button for 8 seconds to confirm the unit selected before the screen switches off, the system will consider the unit switching aborted and retain the original unit for temperature measurements.

Special instructions for safe use

1. A new probe cover is required for each use.
2. When measuring ear temperature, press the measurement key only after the ear thermometer is in place in the ear canal.

Product errors and troubleshooting

Problem	Detected Error	Solution
	No probe cover.	Replace the probe cover.
	Current battery level is too low.	Replace the batteries.
	Unable to carry out measurement as current battery level is too low.	Replace the batteries.
	The probe is not warmed up; the ear thermometer is adjusting.	Wait for at least 30 seconds or place the thermometer under normal temperature: 50°F-104°F (10°C-40°C).
	Current state: All symbols are flashing on the screen. The device is not yet operational.	Remove the batteries and wait for one minute before reinstalling the batteries. If the fault persists, please contact customer service.
	Environment temperature does not meet the requirements of the device's operating temperature range.	Place the device in the supported temperature range of 50°F-104°F (10°C-40°C) and wait for 30 minutes.

	<p>Target temperature is beyond range of measurements 93.2°F-109.2°F (34°C-42.9°C).</p>	<ol style="list-style-type: none"> 1. Replace the probe cover. 2. Try taking the temperature again by following the proper instructions.
	<ol style="list-style-type: none"> 1. Battery depleted. 2. Batteries have been installed with the wrong polarity. 3. Batteries are not installed properly. 	<ol style="list-style-type: none"> 1. Replace old batteries with new ones. 2. Remove the batteries and reinstall them correctly.
<p>Note: 1. If your problem cannot be solved by the above methods, please contact customer service. 2. If you have switched from Fahrenheit to Celsius, it will be shown in °C.</p>		

Box contents

- Ear Thermometer
- Box of Disposable Probe Covers (20 Count)
- 2 x AAA Batteries
- User's Manual
- Quick User Guide
- Carrying Case

Body temperature


- Normal body temperature is around 95.9°F to 100°F (35.5°C-37.8°C). To determine if one has a fever, compare the temperature measured with the person's normal temperature.
- Different measurement sites (rectal, axillary, oral, frontal and auricular) will give different readings. Therefore it is inappropriate to compare the measurement taken from different sites.

Care, cleaning, and maintenance

1. Use a soft and dry cloth to clean the thermometer display and exterior. The thermometer is mainly for home use, if use for multiple patients, please clean the device in between uses per the following steps:
 - a. Use an alcohol swab or cotton tissue moistened with alcohol (70% isopropyl) to clean the ear thermometer housing thoroughly. The wiping process preferably lasts 15 seconds.
 - b. Allow at least 5 minutes drying time before taking a temperature.
 - c. After cleaning, if the device is not visually clean when observed with magnification and adequate lighting, please repeat the cleaning steps above.

Note 1: The above cleaning steps have been validated according to the FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Note 2: The product is not waterproof. Make sure that no liquid enters the interior of the device. Do not use abrasive cleaners, thinners, or benzene for cleaning, and never submerge the device in water or other liquids.

2. The probe is the most delicate part of the thermometer. It must be kept clean and intact to ensure accurate readings. If the infrared sensor is dirty, please wipe the surface of the probe gently with 70% isopropyl alcohol wipes. If you have questions on how to clean the device, please contact our customer service.
Do not wipe with toilet paper or paper towels.
3. The device must not be stored or used at an excessively high or low temperature or humidity (see technical data), in sunlight, in association with an electrical current, or in dusty locations. Avoid dropping or subjecting the product to external forces. Otherwise inaccuracies can occur.
4. Do not put the thermometer under direct sunlight, high temperature, or moist environments. Do not allow it to come into contact with re-vibration or harsh vibrations.
5. If the ear thermometer is not going to be used for a long time, the batteries should be removed.
6. If the symbol "  " appears on the screen, it means that the batteries are low and need to be replaced as soon as possible.
7. The device is made of custom chips and sensors with reliable performance and quality. When running into product issues that you cannot resolve by yourself, please contact our customer service.
8. No individuals or agencies have been authorized to carry out maintenance and repair. Do not attempt to disassemble or modify the thermometer even if you suspect malfunction of the device.
9. The thermometer is a high-precision device. Any improper maintenance, disassembly, or modification may lead to reduced measurement accuracy.
10. If the device is accidentally dropped, please check it to make sure it is not damaged. When in doubt, please contact customer service for help.
11. The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the instructions for use, periodic re-adjustment is not required. If any time you doubt the accuracy of measurement during the warranty period, please contact customer service.

12. The device is not self-serviceability. PCB diagrams, component part list, and repair instructions can be provided to qualified technicians to repair those parts of the device that are designated as repairable.
13. The method for verifying the clinical accuracy of the thermometer can be provided at request; please contact our customer service.
14. Do not directly touch the probe with your fingers or blow on it. Measurements taken using a damaged or dirty IR probe may be inaccurate.

Signs and symbols

The following symbols appear in the instructions for use and on the device:



Symbol for "THE OPERATION GUIDE MUST BE READ"
(The sign's background color: blue. The sign's graphical symbol color: white.)



Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household trash. Please recycle at local recycling facilities. Check with your local authority or retailer for recycling advice".

IP22 The first characteristic numerical symbol refers to "Degrees of protection against access to hazardous parts and against solid foreign objects". The second characteristic numerical symbol refers to "Degrees of protection against ingress of water".



Symbol for "MANUFACTURER"



Symbol for "CAUTION"



Symbol for "SERIAL NUMBER"











Symbol for "EUROPEAN REPRESENTATIVE"



Symbol for "Application part, type BF"

CE 0197 Symbol for "COMPLIANCE WITH MDD93/42/EEC REQUIREMENTS"

	Symbol for "KEEP DRY"
	Symbol for "Fragile, handle with care"
	Symbol for "KEEP AWAY FROM SUNLIGHT"
	Symbol for "Do not re-use"
	Symbol for "THIS WAY UP"
	Symbol for "STACKING LIMIT BY NUMBER"
	Symbol for "Not made with natural rubber latex".
	Symbol for "MAGNETIC RESONANCE (MR) UNSAFE"

iHealth is a trademark of iHealth Labs, Inc.

STANDARDS AND COMPLIANCES

This device complies with the EU Directive 93/42/EEC concerning medical products, IEC 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2 (Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests), the ASTM (American Society for Testing and Materials) E 1965 - 98, the European Standard EN 12470-5: Clinical thermometers – Part 5: Requirements for infrared ear thermometers (with maximum device), ISO 80601-2-56 (Medical Electrical Equipment – Part 2-56: Particular Requirements For The Basic Safety And Essential Performance Of clinical thermometers for body temperature measurement). Please note that portable and mobile HF communication systems may interfere with this unit.

This infrared ear thermometer meets the requirements established in ASTM Standard (E1965-98). Full responsibility for the conformance of this product to the standard is assumed by the manufacturer.

The SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device has also been tested against this SAR limit.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 - Emission limits per environment

Phenomenon	Compliance	Electromagnetic environment
Conducted and radiated RF emissions	CISPR 11 Group 1, Class B	The device is intended to be used in a home healthcare environment
Harmonic distortion	IEC 61000-3-2 NA	The device is powered by battery
Voltage fluctuations and flicker	IEC 61000-3-3 NA	The device is powered by battery

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 - Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ± 5 kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

WARRANTY

Please contact your dealer or iHealth customer support for warranty claims. If the device needs to be returned, please enclose a copy of your receipt and a description of the product defect or malfunction.

The warranty terms are as follows:

1. The warranty period for device is one year from date of delivery. In case of a warranty claim, the date of delivery has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty do not extend the warranty period.
3. The following cases are excluded from the warranty:
 - All damages resulting from improper use of the device (for example, use the device without following the instructions for use).
 - All damages resulting from repairs or tampering by the customer or an unauthorized third-party.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
 - Normal wear and tear of the device's accessories.
4. Liability for direct or indirect consequential losses caused by the device is excluded even if the damage to the device is accepted as a warranty claim.

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Date of Issue: July 22, 2022