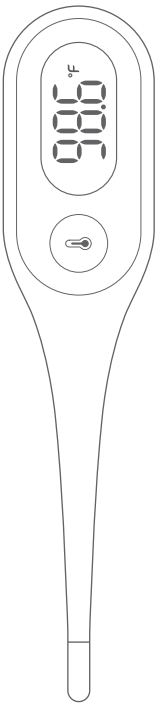
iHealth

Clinical Digital Thermometer

Model: PT1



User's Manual

Version 1.1

Contents

Indication for Use

The Clinical Digital Thermometer is intended to measure the body temperature oral, rectal, or axillaries (under the arm) and to be used by medical professionals in clinic and by consumers in household environments. It is intended for use on adults and children ages 4 and up.

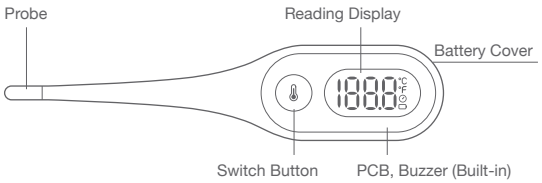
Product Introduction

Thank you for choosing iHealth Clinical Digital Thermometer, a reliable instrument providing a safe, accurate, and fast temperature measurement. You can easily and quickly develop full awareness of your family's health condition, without the concerns of traditional mercury-in-glass thermometers.
Product Name: Clinical Digital Thermometer
Model: PT1

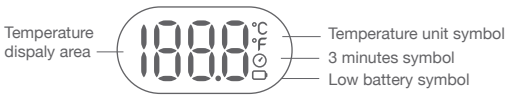
Structure and Components

The thermometer is mainly comprised of a shell, probe, thermopile sensor, PCB, LCD display, and buzzer.

(1)Thermometer structure shown as below:



(2)LCD screen instructions



Specifications

1. Measurement position: oral, rectal, or axillary (under the arm)
2. Power source: CR1632, DC ⎓ 3.0V, button battery
3. Resolution: 0.1 ℉/0.1 ℃
4. Device dimensions: 128mm×28mm×13mm
5. Screen dimensions: 29mm×15mm
6. Net weight: 18g (battery included)
7. Measurement range: 89.6 ℉–109.4 ℉ (32 ℃-43 ℃) ("--- ℉" appears when below 89.6 ℉ (32 ℃) or above 109.4 ℉ (43 ℃))
8. Measurement precision (in constant temperature flume):
   89.6 ℉-96.7 ℉ (32 ℃-35.9 ℃) ±0.2 ℉/0.1 ℃
   96.8 ℉-102.2 ℉ (36 ℃-39 ℃)±0.2 ℉/0.1 ℃
   102.3 ℉-109.4 ℉ (39.1 ℃-43 ℃)±0.4 ℉/0.2 ℃
   (Measured at room temperature of 77 ℉ (25 ℃))

9. Waterproofness: probe portion only.
10. Operating conditions:
    Temperature: 41°F - 104°F (5℃-40℃)
    Humidity: 15% ~ 95% RH, non-condensing
    Atmospheric Pressure: 70kPa ~ 106kPa
11. Transportation and storage conditions:
    Temperature: -4°F ~ +131°F (-20℃-55℃)
    Humidity: 15% ~ 95% RH, non-condensing
    Atmospheric Pressure: 50kPa ~ 106kPa

Contraindications

DO NOT use on the injured area.
DO NOT use if allergic to stainless steel or ABS plastic.

Safety Warnings

(1) About measurement

1. For human body temperature measurement only.
2. Predict Mode for oral use only. If you want to use in other positions, such as axillary or rectal, please refer to the section of the Monitor Mode or consult your physician. Incorrect operation may cause inaccurate measurement results and injuries.
3. Thermometer readings should be regarded as a reference. DO NOT attempt self-diagnostics or self-treatment using the temperature readings. Please seek professional medical advice when necessary.
4. 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.
5. Patients should not bathe, drink hot or cool water, eat, or be physically active for 30 minutes before taking a reading. Temperature readings taken when a body is in a state of stable equilibrium is more accurate and useful as a reference.
6. DO NOT measure body temperature immediately after consuming a drug that raises body temperature. Temperature readings taken at this time will not be accurate.
7. DO NOT measure body temperature in an environment with strong EM interference (examples include places close to a working microwave, induction cooker, or cellphone in-use) as EM interference may cause errors in the reading or even device failure.
8. This product should be considered a personal device. Clean and sanitize the product properly before use to prevent cross-contamination.
9. Make sure babies and children do not operate the thermometer on their own, incorrect usage may result in injury without proper adults' supervision.
10. Do not take temperature measurement over scar tissue, open sores or abrasions.
11. This thermometer conforms to all of the requirements established in ASTM standard E1112.Full responsibility for conformance of this product to the specification is assumed by (manufacturer: ANDON HEALTH CO., LTD. Add: No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China).

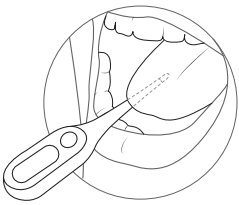
(2) About product

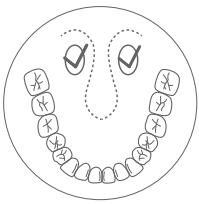
1. The thermometer is a precise instrument. Please properly store in the protective case after use to prevent unnecessary damage.
2. DO NOT tread, or bend the thermometer, which may cause product damage.
3. Make sure the thermometer is not damaged from shock. If broken, DO NOT attempt to re-assemble.
4. Keep the thermometer out of reach of children. Small parts and packaging materials may cause a choking hazard.
5. DO NOT throw the thermometer and batteries into an open fire.
6. Remove the battery if the device will not be used for more than one month.
7. If you are allergic to plastic/ABS, please DO NOT use this device.
8. Expected service life: 5 years (battery excluded)
9. 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.

Instruction for Use

(1) Measurement Procedures

1. Place the probe tip well under the tongue. Place the sensor tip in areas marked with marked with " ✓ ". The mouth should remain closed during the measurement to ensure an accurate reading. Be careful not to bite the thermometer.
2. Hold the thermometer during the measurement to prevent moving.

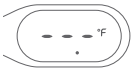




(2) Predict Mode

1. The thermometer provides Predict Mode for oral use. Simply press the button once to activate the thermometer, beep will sound when activated.

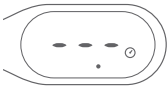
2. When "°F" sign is flashing on the screen, place the probe tip well under the tongue and hold well.



3. A gentle beep will sound in 30 seconds when measurement is completed and the results will display on the screen.

(3) Monitor Mode

The thermometer could be used orally, rectally or axillary.
To enter Monitor Mode, make sure the thermometer is in the OFF mode, press and hold the button for 5 seconds, beep will sound when activated.
Then follow the measurement procedures as usual, the results will display in 3 minutes.

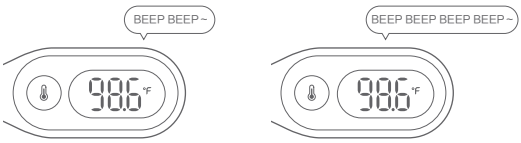


(4) Recall Function

Make sure the thermometer is in the OFF mode. Hold the button until the last measurement result displays on the screen (approximately 10 seconds).

(5) When measurement is completed

1. When the measurement is completed, 2 beeps will sound for 3 times when the results is less than 99.5°F(37.5℃) , otherwise 4 beeps will sound for 3 times.



2. When the measurement is completed, "°F" sign will stop flashing with backlighting.
3. The thermometer will power off automatically 30 seconds after the last measurement is completed.
4. If no more measurement is required, press and hold the on-off button to power off manually to save batteries power.

⚠ Possible Reasons For Measurement Failure
- The thermometer falls during the measurement.
- The environmental temperature doesn't meet the requirements.
- The subject temperature is beyond measurement range.
- Please power off the thermometer and wait for 1 mins for remeasurement.

Unit Switching

1. Make sure the thermometer is in the OFF mode.
2. Hold the button until ONLY ℃ and °F symbols flash on the right corner of the screen (approximately 8 seconds). Then release the button immediately.
3. Briefly press the button to select the measurement unit you prefer.
4. Once the selected unit symbol flashes on the screen, hold the button until the unit symbol stops flashing (approximately 8 seconds), then release the button, the thermometer will power off automatically.

Reminder: If you do not press and hold the On/Off button for 8 seconds to confirm the unit selected before the screen switches off, the system will consider the switch as a failure and retain the original unit for temperature measurements.

Replacing Battery

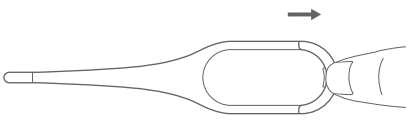
(1) Installing and replacing battery

1. Battery CR1632 already installed in the thermometer.
2. When switched ON for use, the thermometer will automatically detect remaining battery capacity. If battery capacity is low but adequate for measurements, the low power symbol [▭] will be displayed with the measurement results to remind replacing new battery. However, if the battery capacity is too low for measurements, the screen will display a single, flashing [▭] icon for 10 times and automatically switches OFF. To continue using the device, old battery must be replaced.

Note: the original battery installed in the thermometer may not last as long as new battery.

(2) Replacing battery

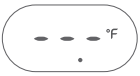
1. Press down and hold the battery cover with the finger and apply some force to slide the cover backwards to open the battery compartment.



2. Remove the old battery.
3. Refer to the battery polarity symbols to orient the new battery properly during installation. Make sure that the new battery is tightly inserted into the battery compartment and make sure that the polarity is not reversed during installation.
4. Return the battery cover to close the battery compartment.

- Comply with relevant national laws and regulations when disposing of the used batteries.
- Do not dispose of batteries directly into the trash bag.
- Remove the battery if the device will not be used for more than one month.
- Do not throw batteries into fire.

Troubleshooting

Problem	Item to detect	Solution
	Battery depleted.	Replace the battery.
	Battery have been installed with the wrong polarity. Battery are not installed properly.	Take out the battery and re-install them correctly.
	Unable to carry out measurement as current battery capacity is too low.	Replace the battery.
	Current battery capacity is too low.	Replace the battery ASAP.
 3 Beeps sould	89.6℉—109.4℉(32℃-43℃) Subject tempreture is beyond the measurement range. The thermometer falls or is removed from the mouth during measurement.	Power off and wait for 1 min to re-measure.
 Current state: All symbols are ashing on the screen.	The product is not usable.	Please contact customer services.

Care & Maintenance

1. The probe is the most intricate part of the thermometer, and should be kept clean and intact to acquire accurate readings. Use the following method to clean the probe:
   ① Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl alcohol) to clean the thermometer casing thoroughly, the wiping process preferably lasts 15 seconds.
   ② Allow at least 5 minutes drying time before taking a temperature.
   ③ After cleaning, if the device is not visually clean when observed with magnification and adequate lighting, please repeat the clean steps above.
2. Use a piece of soft, dry cloth to clean the display screen and external surface of the thermometer. If the thermometer is very dirty, the cloth can be moistened with some Isopropyl alcohol to clean the device.
3. Do not use sonicleaning or strong waterspout to clean the thermometer.
4. Do not soak the thermometer in water or other liquids.
5. Make sure the thermometer is stored in the protective case. Do not put the thermometer under direct sunlight, high temperature, or moist environments.
6. This company has not authorized any agency or individual to carry out product repairs or maintenance. Do not attempt to disassemble or modify the thermometer if you suspect functional issues with the device.
7. The thermometer is an extremely precise instrument. Any improper maintenance, disassembly, or modification may lead to inaccuracies of the product measurements.

8. If you suspect any product issues during the warranty period, please contact customer services for subsequent handling.

Box Contents

1 Clinical Digital Thermometer	1 CR1632 battery (installed)
1 thermometer protective case	1 User's Manual

* Use only accessories provided by the original manufacturer, and check for any missing accessories.

Signs & Symbols

Attention: Follow instructions for use!
(The sign background color: blue. The sign graphical symbol: white.)

The batteries and electronic instruments must be disposed of in accordance
with the locally applicable regulation, not with domestic waste.

Manufacturer information

Symbol for "WARNING"

Symbol for "Type BF Applied Parts"

SN

Serial number

EC REP

Authorized representative in the European Community

IP22

IP code of the device: this device's grade of against ingress of solid foreign objects -- ≥12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted).

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

Electronic 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 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 ±2kV, ±4kV, ±8kV, ±15kV 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, ±5kHz 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		

Safety Precautions

⚠ Warning

● Use of this thermometer is not intended as a substitute for consultation with your physician. Please consult your doctor if you have any doubt about the temperature reading.

● Keep the thermometer out of reach of children. For accidental swallowing of the battery or other components, please contact emergency services immediately.

● Batteries must not be thrown into an open fire or short circuited.

Warranty

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt with clear statement of defect description. The warranty terms as below:

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 under the warranty
   - ● All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
   - ● All damage which is due to repairs or tampering by the customer or unauthorized third parities.
   - ● Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
   - ● Accessories which are subject to normal wear and tear.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

The device is not FDA approved or cleared.
Manufactured for iHealth Labs, Inc.

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EC REP

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CE 0197