plusmed
health management

Model: **pM-101**
Digital Thermometer

Warning:

- ⚠ Read instructions thoroughly before using digital thermometer.
- ⚠ Choking Hazard: Thermometer cap and battery may be fatal if swallowed. Do not allow children to use this device without parental supervision.
- ⚠ Do not use thermometer in ear. Designed use is for oral, rectal, and armpit (axilla) readings only.
- ⚠ Do not place thermometer battery near extreme heat as it may explode.
- ⚠ Note: Use of the probe cover may result in a 0.1℃(0.2℉) discrepancy from actual temperature.
- ⚠ It is recommended the performance should be checked every two years.
- ⚠ Remove battery from the device when not in operation for a long time.
- ⚠ The use of temperature readings for self-diagnosis is dangerous. Consult your doctor for the interpretation of results. Self-diagnosis may lead to the worsening of existing disease conditions.
- ⚠ Do not attempt measurements when the thermometer is wet as inaccurate readings may result.
- ⚠ Do not bite the thermometer. Doing so may lead to breakage and/or injury.
- ⚠ Do not attempt to disassemble or repair the thermometer. Doing so may result in inaccurate readings.
- ⚠ After each use, disinfect the thermometer especially in case the device is used by more than one person.
- ⚠ Do not force the thermometer into the rectum. Stop insertion and abort the measurement when pain is present. Failure to do so may lead to injury.
- ⚠ Do not use thermometer orally after being used rectally.
- ⚠ For children who are two years old or younger, please do not use the devices orally.
- ⚠ Life time of this product is 3 years.

PLEASE READ CAREFULLY BEFORE USING

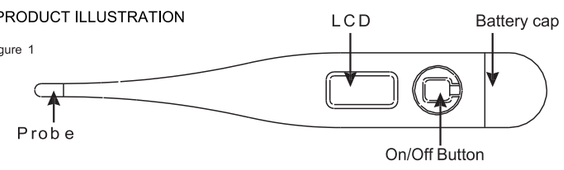
This digital thermometer provides a quick and highly accurate reading of an individual's body temperature. To better understand its functions and to provide years of dependable results, please read all instructions first.

CONTENTS

1 Thermometer, 1 Owner's Manual, 1 Storage Case

PRODUCT ILLUSTRATION

Figure 1



PRECAUTION

* The performance of the device may be degraded should one or more of the following occur:
- Operation outside the manufacturer s s tated te mperature a nd h umidity r ange.
- Storage outside the manufacturer s s tated te mperature a nd h umidity r ange.
- Mechanical shock (for example, drop test).
- Patient temperature is below ambient temperature.

* Portable and mobile RF communications can affect the device. The device needs special pre-cautions regarding EMC according to the EMC information provided in the accompany documents.

SYMBOL EXPLANATION

CE 0197	The product is in compliance with the requirements of MDD 93/42/EEC, "0197"is the identification number of notify body's.		Disposal of this product and used batteries should be carried out in accordance with the national regulations forthe disposal of electronic product).
⎓	Direct Current	LOT	Batch code
	Type BF Applied Part		Manufacturer
	Caution, consult accompanying documents		Consult instruction for use
	Temperature Conditions		Humidity Conditions
	Keep it uprightt		Keep Dry
	Fragile		

SPECIFICATIONS

Type:	Digital Thermometer (Not Predictive)
Range:	32.0℃~42.9℃(90.0℉-109.9℉) (℃/℉ chosen by manufacturer)
Accuracy:	± 0.1℃,35.5℃~42.0℃(± 0.2 ℉,95.9℉-107.6℉)
	±0.2℃ under 35.5℃ or over 42.0℃ (±0.4 ℉ under 95.9℉ or over107.6℉)
	at ambient temperature of 18℃ to 28℃ (64.4℉ to 82.4℉)
Display:	Liquid crystal display, 3 1/2 digits
memory:	For storing the last measured value
Battery:	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)
Battery life:	Approx 200 hours
Dimentions:	12.4cm x 1.8cm x 0.9cm (L x W x H)
Weight:	Approx. 10 grams including battery
Using environment:	Temperature: 5℃~40℃ (41℉~104℉) Atmospheric Pressure: 700hPa ~ 1060hPa Relative humidity: 15%~95%RH
Storage and transportation condition:	Temperature: -20℃~55℃ (-4℉~131℉) Atmospheric Pressure: 700hPa ~ 1060hPa Relative humidity: 15%~95%RH
Ingress Protection Rating:	IPX0
Classification:	Tip BF

INTENDED USE

Digital Thermometer is intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages. Not allow children to use the device without the parents supervision.

Indications:

• Infectious diseases • Certain inflammatory conditions such as rheumatoid arthritis • A malignant tumor • Some medications, such as antibiotics • Other causes such as dehydration, vaccine reactions

Target users are the patients who indicated with above mentioned situations.

Contraindications:

- Contraindication of oral temperature: • Unconscious patients • Inflammation or surgery of mouth • Persistent frequent coughing • Mouth breathing patients.
- Contraindication of axillary temperature: • Skin disease • Axillary operation.
- Contraindication of rectal temperature: • Patients with surgical operation in the rectum or perineal region • Disease or inflammation of the rectum • Diarrhea.

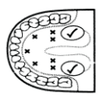
Side effects:

There is no side effect related with digital thermometer. These devices are for measuring and monitoring purposes.

DIRECTIONS

1. Press the *On/Off* Button next to LCD display. A tone will sound as the 188.8.E as the screen shows followed by last recorded temperature. After showing the self-test temperature, the thermometer is now in the testing mode.

* Note: If the measured temperature is less than 32℃ or 90℉, the LCD will display Lo, if the measured temperature is higher than 42.9℃ or 109.9℉ , the LCD will display Hi.



2. Position thermometer in desired location (mouth, rectum, or armpit.)
a) **Oral Use:** Place thermometer under tongue as indicated by "√" position shown in Figure 2. Close your mouth and breathe evenly through the nose to prevent the measurement from being influenced by inhaled/exhaled air. Normal temperature between 35.7℃ and 37.3℃ (96.3℉ and 99.1℉)
b) **Rectal Use:** Lubricate silver probe tip with petroleum jelly for easy insertion. Gently insert sensor approximately 1cm (less than 1/2" into rectum. Normal temperature between 36.2℃ and 37.7 ℃ (97.2℉ and 99.9℉).
c) **Armpit Use:** Wipe armpit dry. Place probe in armpit and keep arm pressed firmly at side. From a medical viewpoint, this method will always provide inaccurate readings, and should not be used if precise measurements are required. Normal temperature between 35.2℃ and 36.7℃ (95.4℉ and 98.1℉).

3. The degree sign flashes throughout the testing process. When flashing stops the device will beep for approximately 10 seconds. The measured reading will appear on the LCD simultaneously. The minimum measurement time until the signaling tone (beep) must be maintained without exception. The measurement continues even after the buzzer notification. The displayed temperature will not change when thermometer is removed from its testing position.
measurement result, recommend to keep the probe in mouth and rectum about 2 minutes, or in armpit about 5 minutes regardless of the beep sound and at least 30 seconds measurement interval should be maintained.

* Note: Normally the buzzes are " Bi-Bi-Bi-Bi-" ;The device beeps more rapidly when temperature reaches 37.8 ℃ (100 ℉) or higher ,and the buzzes are" Bi-Bi-Bi----- Bi-Bi-Bi------- Bi-Bi-Bi"

4. To prolong battery life, press the *On/Off* Button to turn unit off after testing is complete. If no action is taken, the unit will automatically shut off after around10 minutes.
5. Store the thermometer in its protective case.

BATTERY REPLACEMENT

1. Replace battery when " appears in " " the lower right corner of LCD display.
2. Pull battery cover off as shown in Figure 3.
3. Gently pull out plastic circuit board with battery chamber approximately 1 cm (slightly less than1/2" (See Figure 4)
4. Use pointed object such as a pen to remove old battery. Discard battery lawfully. Replace with new 1.5V DC button type LR41 or SR41,UCC392, or equivalent. Be sure battery is installed with "+" polarity facing up. (See Figure 5)
5. Slide battery chamber back into place and attach cover.

Figure 3

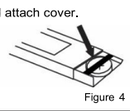


Figure 4

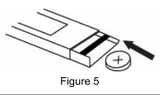


Figure 5

CLEANING AND DISINFECTION

Wipe the thermometer with a soft clean cloth.
For stubborn stains, wipe the thermometer with a cloth that has been dampened with water or a neutral detergent solution and then wring thoroughly. Finish by wiping with a soft dry cloth.
Observe the following to prevent damage to the thermometer.
-Do not use benzene, thinner, gasoline or other strong solvents to clean the thermometer.
-Do not soak the sensing section in alcohol for long periods of time or attempt to sterilize it using hot water (water at a temperature of 50 ℃(122 ℉) or higher).
-Do not use ultrasonic washing to clean the thermometer.

CALIBRATON

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, we recommend checking calibration every two years or whenever clinical accuracy of the thermometer is in question at the authorised laboratories.

LIMITED WARRANTY

The thermometer is guaranteed for 2 years from the date of purchase. If the thermometer does not function properly due to defective components or poor workmanship, we will repair or replace it free of charge. All components are covered by this warranty excluding the battery. The warranty does not cover damages to your thermometer due to improper handling. To obtain warranty service, an original or copy of the sales receipt from the original retailer is required.

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

Guidance and manufacturer´s declaration – electromagnetic emission

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device 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 device 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	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a. c. mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz 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). 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:

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 The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output 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 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

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.

Table 5

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E=\frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS!

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

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