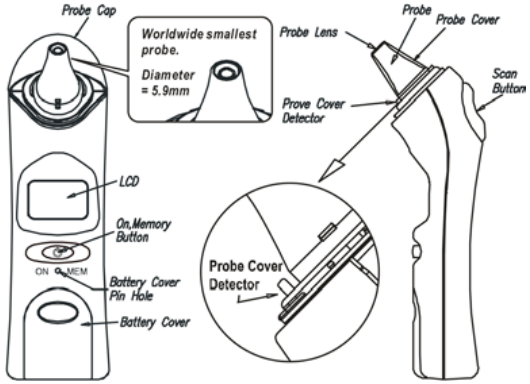
medicare

MD1882

INFRARED EAR THERMOMETER



Intended use: This infrared ear thermometer is an electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from the ear canal in people of all ages.

Intended operator: Any person with over eight years of education.

Thank you for purchasing the Infrared Ear Thermometer. This thermometer is designed with an advanced infrared and ambient temperature compensation technology for instantaneous self-diagnosis and accurate temperature measurements. Do not use this device for alive/dead decisions or safety related applications. Please consult with doctor if you have health concerns.

Operating Instructions:

NOTE: **The device must stay in a stable ambient (room) temperature for 15 minutes before operating.**

1. Gently squeeze the opposite ends of thermometer to pull off the probe cap. Do not use force to remove the cap.
2. Always use a new and undamaged prove cover. Make sure ear canal is clean.
   Warning: Choking from swallowing small parts and batteries by children or pets is possible. Please keep small parts and batteries out of reach of children and pets.
3. Install Probe Cover:
   a. Place a new probe cover on the connection ring (see Figure 1).
      NOTE: Make sure to place the 'adhesive side' of the probe cover 'upward'.
   b. Align the probe with the centre of the probe cover. Insert the probe into the cover connection ring (see Figure 2).
   c. Push the connection ring until the 'click' sound. This means the probe cover has been installed successfully.
      NOTE: If the probe cover did not install correctly, ⊳ will flash on the LCD screen and the thermometer will not take the ear temperature (you will hear 4 beep sounds without a reading showing on the LCD screen when measuring). Please check the setting of the probe cover again.

Figure 1


Figure 2


Figure 4-1


Figure 4-2

⚠ **Warning: Proper installation of probe cover and using specific probe cover will ensure accurate measurements.**

4. Press 'ON/MEM' button to power on. The thermometer is ready to use after the ear icon stops flashing and two short beep sounds are heard.
5. Gently pull the ear back to straighten the ear canal and snugly position the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading (see Figure 4-1).
6. Measuring the ear temperature:
   a. Using your index finger to trigger, press the 'Scan' button until you hear a long beep (see Figure 4-2).
   b. After each ear measurement, wait until the ear icon stops flashing to be ready for the next measurement.
7. Powering Off:
   a. Device will automatically shut down after 1 minute pending extended battery life.

NOTE: Make sure to place the 'adhesive side' of the probe cover 'upward'.

a. **Before the measurement, please stay in a stable environment for 5 minutes and avoid exercise or a bath for 30 minutes.**
b. **It is recommended that you measure 3 times with the same ear. If the 3 measurements are different, select the highest temperature.**
c. **To avoid the risk of cross contamination, please clean the probe according to the 'Cleaning and Storage' section after each use.**
d. **The 'Clinical Bias' is -0.2 ~ -0.4°C.**
e. **The 'Limits of Agreement' are 0.58.**
f. **The 'Repeatability' is 0.17°C.**

Fever Indication :
If the thermometer detects a body temperature ≧37.5°C (or 99.5°F), three short beep sound will follow one long beep sound to warn the user for potential fever.

Switching between Fahrenheit(°F) and Celsius(°C) :
In "***Power Off***" mode, press and hold the "SCAN" button, then press the "ON/MEM" button for 3 seconds, icon "**°C**" will be switched to icon "**°F**". You can also use the same process to change the LCD display from **°F** to **°C**.

Memory Function:
When in power on, press the "ON/MEM" button to see the temperature stored. The thermometer provides 9 sets memory for the body temperature.

Replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.

Cleaning and Storage:

The probe is the most delicate part of the thermometer.

Use with care when cleaning the lens to avoid damage.
Storage temperature Range: It should be stored at room temperature between -20~+50°C, RH≦85%

Keep the unit dry and away from any liquids and direct sunlight. The Probe should not be submerged into liquid.
**** If device is accidentally used without probe cover, clean the probe as follows:**

a) Please use the cotton swab with Alcohol (70% concentration) to clean the lens (on the inside of the probe).
b) Allow the probe to fully dry for at least 1 minute.

NOTE: Please check the device if damaged once it falls. If you can't make sure of it, please send the complete device to the nearest retailer for recalibration.

⚠ Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

Changing the Battery:

This device is supplied with one lithium cell (CR2032 x 1).
①Open the battery cover: Insert a pointed object into the battery cover pick hole. At the same time, use thumb to remove battery cover. (See Figure 1) ②Flip the battery out with a small screw driver (See Figure 2) ③ Insert the new battery under the metal hook on the left side and press the right side of the battery down until you hear a "click". (See Figure 3) ④Replace the battery cover

⚠ The positive (+) side **Up** and the negative (-) side pointed **Down**.


Figure 1


Figure 2


Figure 3

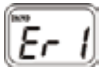
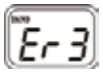
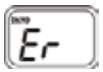
Specifications:
- ☑ Temperature measurement range: 34~42.2°C (93.2~108°F)
- ☑ Operating temperature range: 10~40°C (50~104°F) , 15%~85% RH
- ☑ Storage temperature Range: It should be stored at room temperature between -20~+50°C, RH≦85%
  Transportation temperature shall be less than 70°C, RH≦95%
- ☑ Atmospheric pressure: 800~1013 hPa
- ☑ Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993 RoHS.
- ☑ Accuracy: ±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for other range.
- ☑ This thermometer is an adjusted mode thermometer that converts the ear canal temperature to its "oral equivalent" (according to the result of the clinical evaluation to get the offset value).
- ☑ Enclosure Rating: IP22
- ☑ Dimensions: 141.4 x 40.4 x 43.5 mm

☑ Weight: 67.3 grams including battery
☑ Battery life: around 3,000 continuous readings.
☑ Expected Service Life: 4 years

⚠ The device should not submerge into any liquids and expose it to direct moisture.

⚠ There is no gender and age limitation for using infrared thermometer. ⚠ This is not an AP or APG product.

Troubleshooting:

Error Message	Problem	Solution
	Device stabilisation in process.	Wait until stops flashing.
	Battery is low and no more measurements are possible.	Replace the battery.
	Measurement before device stabilisation.	Wait until stops flashing.
	The ambient temperature is not within the range between 10 °C and 40 °C (50 °F ~104 °F).	Allow the thermometer to rest in a room at least 15 minutes at room temperature: 10˚C ~ 40˚C (50˚F ~ 104˚F).
	Error 5~9, the system is not functioning properly.	Unload the battery, wait for 1 minute and re-power it. If the message reappears, contact the retailer for service.
	Temperature taken is higher than 42.2˚C (108.0˚F).	Check the integrity of the probe cover and take a new temperature measurement.
	Temperature taken is lower than 34˚C (93.2˚F).	Make sure the probe cover is clean and take a new temperature measurement.
	Device can not be powered on to the ready stage.	Change with a new battery.

Warranty: 12 months
Manufacture Date: as the serial number (please open the battery cover, it is shown on the inside of the device).
Ex.SN:E512A000001, the first "E" is External, the second number "5" is the last number of manufacture year, the third and the fourth number "12" is the manufacture month, the others are the serial number.

Note: The thermometer is calibrated at the time of manufacture. If at any time you question the accuracy of temperature measurements, or meet any unexpected event, please contact the dealers or nearest service address.

⚠ **WARNING: No modification of this equipment is allowed.**
Please report to the manufacturer and the competent authority of the member state in which you are established any serious incident that has occurred in relation to this device.

Please read the instructions for use. **BF type applied part.**

CE 1639

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EC REP **Medical Technology**
Promedt Consulting GmbH
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Corcanree Business Park
Dock Rd, Limerick, Ireland
WWW.FLEMINGMEDICAL.IE

Date of issue: 2020-04-04

Rev.:17092020

Symbol Descriptions					
CE 1639	The CE mark and Notified Body Registration Numbers, the requirement of Annex II from Medical Device Directive 93/42/EEC, are met.		This device is subject to the Waste Electrical and Electronic Equipment Directive in the European Union. To protect the environment, please do not dispose of this product in the household waste at the end of its useful life. Disposal can take place at appropriate collection points provided in your country.		To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.
	Caution.		Refer to instruction manual / booklet.		Paper Recycling.
	Manufacturer.		BF type applied part.		Do not reuse.
EC REP	Authorized representative in the European community.	IP22	Classification for water ingress and particulate matter.	MD	Medical Device.

Guidance and manufacturer's declaration – electromagnetic emissions		
MD1882 is intended for use in the electromagnetic environment specified below. The customer or the user of MD1882 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	MD1882 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	MD1882 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
MD1882 is intended for use in the electromagnetic environment specified below. The customer or the user of MD1882 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% A/m at 1 kHz	10V/m 80 MHz - 2,7 GHz 80% A/m at 1 kHz	**Recommended separation distance** $d = 1,2\ \sqrt{P}$ $d = 1,2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\ \sqrt{P}$ 800 MHz to 2,7 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 meters (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. 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) 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 MD1882 is used exceeds the applicable RF compliance level above. MD1882 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating MD1882.			

Guidance and manufacturer's declaration – electromagnetic immunity

MD1882 is intended for use in the electromagnetic environment specified below. The customer or the user of MD1882 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%.**
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 and 60 Hz	The MD1882 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distances between portable and mobile RF communications equipment and the MD1882

MD1882 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MD1882 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MD1882 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 $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

Manufacturer's declaration – electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

MD1882 is intended for use in the electromagnetic environment specified below. The customer or the user of MD1882 should assure that it is used in such an environment.

Test Frequency (Mhz)	Band [a] (Mhz)	Service [a]	Modulation [a]	Maximum Power (W)	Distance (m)	Immunity Test Level (m)	Compliance Level (V/m) (for home healthcare)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1,8	0,3	27	27
450	430-470	GMRS 460, FRS 460	FM c) 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	2	0,3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217Hz	2	0,3	28	28
1845							
1970							
2450	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217Hz	2	0,3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	0,2	0,3	9	9
5500							
5785							

NOTE If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m text distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be worst case.