Ltd.

Shenzhen

Rev. A0

Model: MDI111



Catalog

1. Product Brief	2
2. Product use and scope of application	2
3. Environmental conditions for product use	2
4. Product features	2
6. Product specifications	3
7. Installation and adjustment	3
8. Operation and use	5
9. Troubleshooting	6
10. Precautions	7
11. Symbolic explanation	7
12. Product maintenance	8
13. Transportation and storage	8
14. Product unpacking and inspection	8
15. EMC Declaration	9

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Rev. A0				

1. Product Brief

Infrared thermometer is a kind of thermometer that uses infrared technology to measure human body temperature. It can measure human body temperature through human ear cavity or through human forehead. When it is used, it only needs to align the product temperature measuring head with the measuring target, press the measuring button, and complete and display the measured value within one second. The whole measuring process is simple and fast.

2. Intended Use

The Infrared thermometer is a multi-function infrared thermometer intended for the intermittent measurement of human body temperature by Ear mode or Forehead mode for people of all ages.

3. Environmental conditions for product use

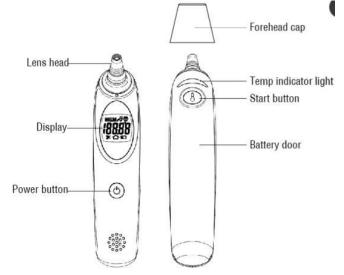
- Ambient temperature: 10 °C ~ 40 °C
- Relative humidity: $\leq 85\%$
- Atmospheric pressure: 70kpa-106 kPa

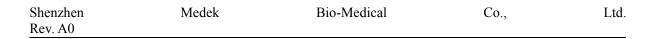
4. Product features

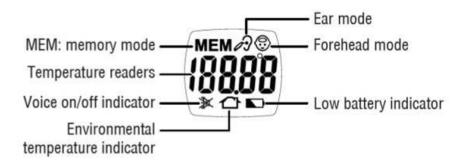
The infrared thermometer can quickly measure the body temperature through the forehead and ear cavity of the human body.

5. Product structure

Infrared thermometer consists of shell, circuit board, temperature measuring component, display screen, power supply, etc.







6. Product specifications

Product name	Infrared thermometer
Product model	MDI111
Measuring location	Ear cavity or forehead (by removing or installing the upper cap)
Temperature unit	°C/°F
Measuring range	32.0°C~43.0°C
Resolving power	0.1 °C
Accuracy	$35.0^{\circ}C \sim 42.0^{\circ}C \pm 0.2^{\circ}C$, Outside $\pm 0.3^{\circ}C$
Clinical repeatability	±0.3 °C
Using the operating environment	Temperature: 10 °C ~ 40 °C relative humidity: $\leq 85\%$
Packaging storage environment	Temperature: - 20 °C ~ 55 °C relative humidity: $\leq 85\%$
Number of memory groups	32 group
Automatic shutdown time	(60 ± 5) seconds without any operation
size	160.0* 35* 45.5mm
weight	78g±10g(Battery free)
Battery	1.5V AA model (No.5) 2
Term of validity	5 years
Safety classification	Type BF equipment
Waterproof grade	IP22

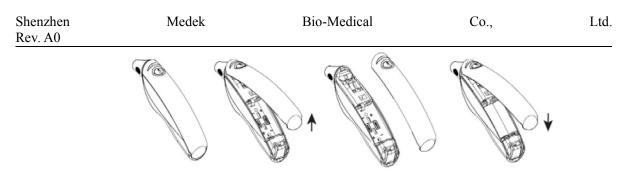
7. Installation and adjustment

• Battery installation and replacement:

When the product display indicates low voltage or the product needs to be replaced or installed before use



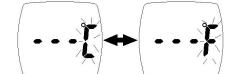
Replace battery indicator



As shown in the figure above, open the battery cover, take two 1.5V AA batteries, install them according to the direction indicated by the symbol in the battery cavity, and then cover the battery cover to complete the battery replacement.

• Function setting:

Conversion of temperature units from ° C to °F

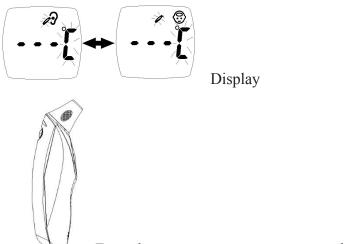


In the off state, press and hold the measurement key for about 4 seconds, and "beep" will be prompted. The display will display the current temperature unit. Press the measurement key for a short time to complete the temperature unit conversion, and then press the on key to confirm and enter the measurement state.

• Transformation between ear temperature measurement mode and frontal temperature measurement mode:



Ear temperature measurement mode status



Frontal temperature measurement mode status

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Rev A0				

When the product is removed or installed with the forehead temperature measurement cap, the transformation between ear temperature measurement and forehead temperature measurement mode can be completed.

• Measurement memory value query:



In the off state, press the measurement key briefly to prompt the audio to display the measured and recorded values in turn as shown in the figure above.

• Calibration mode (object mode):

In the off state, press and hold the measurement key for about 6S before entering the calibration mode. The corresponding position offset and the corresponding statistical method used to calculate the estimation mode are completed by using the empirical data table and subsection approximate curve.

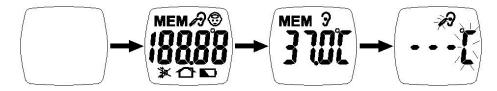
8. Operation and use

• Ear temperature measurement

Remove the forehead temperature measuring cap and enter the ear temperature measuring mode.



Press the on key to turn on, the LCD will display for about 2 seconds, then the LCD will display the last measurement record value for about 2 seconds, the buzzer "beeps" for a short time, the product will enter the ear temperature measurement mode, put the temperature measuring head into the ear channel, press the measurement key once accompanied by the "beep" tone to complete the measurement and display the measurement results, when the temperature is $< 37.5^{\circ}$ C, the green backlight will be on, when the temperature is 38.0° C > T \geq 37.5 °C, it will show the orange backlight, when the temperature is \geq 38.0 °C, the backlight is bright red. The following picture:



Note: Newborn under one year old: when using for newborn, it is better to pull and fix the auricle back and down, and the temperature measuring head is easier to align with the tympanic membrane for measurement.

Children and adults over one year old: hold the auricle back and up, so that the ear canal can be in a straight line, and the temperature head can be easily aligned with the tympanic membrane for

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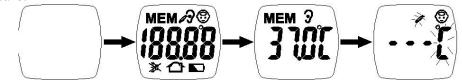
measurement.

• Frontal temperature measurement

Put the product on the forehead temperature measurement cap and enter the forehead temperature measurement mode.



Press the on key to turn on, the LCD will display for about 2 seconds, then the LCD will display the last measurement record value for about 2 seconds, the buzzer will beep briefly, the product will enter the forehead temperature measurement mode, align the temperature measurement head with the forehead of the measurement person, press the measurement key once, accompanied by the beep tone to complete the measurement and display the measurement results (if the measurement key is held for a long time, accompanied by multiple beeps, then Enter the scanning measurement, release the measurement key to complete the measurement), when the temperature is lower than 37.5 °C, the green backlight will be on, when the temperature is lower than 37.5 °C, the orange backlight will be on. The following picture:



Note: during the measurement, the body temperature should be aligned and close to the forehead and brow center.

• Shutdown

After the measurement, press the on key to shut down directly. If there is no operation, the product will shut down automatically for about 60 seconds.

9. Troubleshooting

Undesirable phenomena	Bad reason	Treatment countermeasures
٤ <u>r</u>	Ambienttemperatureabove40 $^{\circ}$ Cor10 $^{\circ}$ C0	Move to the product environment for use
X, C	Human body temperature is higher than 43.0 °C	 Operate strictly according to the instructions Contact the manufacturer
Lol	Human body temperature is lower than 32.0 $^{\circ}$ C	 Operate strictly according to the instructions Contact the manufacturer
	Low power	Battery replacement

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	ErrE ErrX	Sensor or hardwa damage	are Contact manufacturer	

10. Precautions

- 1) Please read the operation manual carefully before use. Improper use may lead to product performance degradation and incorrect measurement value.
- 2) Do not use the product to measure the body temperature when the ear canal is wet or suffering from ear diseases.
- 3) Earwax and other obstacles or inflammation, trauma, postoperative and other local lesions at the measurement site will affect the accuracy of the product.
- 4) The infrared thermometer has been calibrated. If it is used in accordance with the instructions, it does not need to be recalibrated.
- 5) Do not use excessive force channel to insert the temperature probe into the ear channel.
- 6) Infrared thermometer cannot replace the diagnosis and treatment of doctors, and the medicine must be diagnosed and treated by doctors.
- 7) Please do not shower or exercise before measurement. Please keep the measured person and infrared thermometer in the measurement environment for more than 30 minutes.
- 8) Please use the infrared thermometer under the operating environment when measuring.
- 9) Please do not fall on the ground to avoid strong impact and shock.
- 10) When it is not used for a long time (more than 1 month), please take out the battery and put the product into the package.
- 11) Please do not store the product in direct sunlight, high temperature and humidity, dusty and corrosive gas environment.
- 12) Do not use the battery if it leaks or becomes moldy. Do not put the battery close to the fire source or into the fire to avoid explosion. Do not install the positive and negative poles in reverse during use.
- 13) Discard batteries or infrared thermometers and packages in accordance with local regulations.
- 14) Please do not use toxic liquid or volatile oil, diluent or gasoline to wipe the infrared thermometer.
- 15) Statement: the company can provide circuit diagram, list of components, drawing notes and correction details as required, and designate the data necessary for the repaired equipment parts to the user's qualified technical personnel for repair, but it is better to return the repair to the manufacturer for completion.
- 16) Notice to the user and/or patient: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- 17) The device cannot be used in an MRI environment.

11. Symbolic explanation

No.	Graphical symbols	Description	
1	1 EC REP Authorized representative in the European Union		
2	SN	Serial number	
3	8	The operation guide must be read.	

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4	AAA	Manufacturer		
5	C € 0123	CE mark: indicates that the dev	vice complies with	n the EU 2017/745
6	X	ENVIRONMENT PROTECT not be disposed of with hou facilities exist. Check with recycling advice.	isehold waste. Pl	ease recycle where
7	\triangle	Caution: indicates the need for for use for important cautional precautions that cannot, for a v medical device itself.	ary information su	ich as warnings and
8	IP22	IP code of the device: this dev foreign objects \geq 12.5mr hazardous parts with finger); (150 tilted).	n diameter (and t	he against access to
9	*	Type BF applied parts		

12. Product maintenance

Keep the surface of the product clean and tidy, which is helpful to prolong the service life of the infrared thermometer.

When it is not used for a long time, take out the battery, put the product into the package, and place it in a dry environment of about 25 degrees, which will help to extend the service life of the infrared thermometer.

If the infrared thermometer is dirty, please wipe it with dry soft cotton cloth. If the cleaning is not clean, the soft cotton cloth can be wiped with little water or neutral detergent, and then dry it with dry cloth.

The temperature measuring head shall be kept clean, and the mirror surface shall not be dirty or scratched. If there is any foreign matter, it can be cleaned with cotton swab.

13. Transportation and storage

Product transportation and storage environment:

Temperature: - 20 °C ~ 55 °C

Relative humidity: $\leq 85\%$

Precautions for product transportation and storage:

Handle with care, do not squeeze by gravity, insect and rat proof.

14. Product unpacking and inspection

Product unpacking: please open the color box along the buckle position of the packing box to avoid

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disordering the packing box.

Inspection after unpacking: Please note that in addition to this machine, there are two AA type trial batteries + a manual (including warranty card) + a certificate of conformity in the packing box. Please check when you buy.

Note: please do not discard the package at will. Please handle according to the local regulations.

15. EMC Declaration

or the user of the "X	XXX" should ensure that	at it is used in such an env	pecified below. The customer vironment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 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 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	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	<pre><5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec</pre>	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "XXX" requires continued operation during power mains interruptions, it is recommended that the "XXX" be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typica commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity					
The "XXX" is inter the user of the "XX	The "XXX" is intended for use in the electromagnetic environment specified below. The customer or the user of the "XXX" should ensure that it is used in such an environment.				
Immunity test IEC 60601 test Compliance level Electromagnetic environment – guidance					

nzhen . A0	Medek	Bio-Medica	al Co.,	Ltd.
	level			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	power rating of the	any part of the nan the distance calculate he frequency of the distance MHz GHz maximum outpute ts (W) according to the recommende RF transmitters, a urvey, ^a should be ce level in eac in the vicinity of
NOTE 2 These gu absorption	z and 800 MHz, the h idelines may not app structures, objects an	oly in all situation	ons. Electromagnetic propag	gation is affected b
telephones mobile radi theoreticall with accura electromag survey shou used exceed verify normal ope	and land os, amateur radio, AN y acy. To assess the e netic site ald be considered. If the ds the applicable RF of	M and FM radio electromagnetic he measured field compliance level erformance is ol	as base stations for radii broadcast and TV broadcast environment due to fixed d strength in the location in above, the Medical XXX sl bserved, additional measure	RF transmitters, a which the "XXX" involute the observed to

Guidance and manufacturer's declaration – electromagnetic emissions				
The "XXX" is intended for use in the electromagnetic environment specified below. The customer or the user of the "XXX" should ensure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment – guidance		

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RF emise CISPR 1		Group 1	The "XXX" uses RF energy only for its internal function. Therefore, its RF emissions very low and are not likely to cause any interference i nearby electronic equipment.		F emissions are
RF emiss CISPR 1		Class B		suitable for use in all , including domestic	establishments
Harmoni IEC 610	c emissions 00-3-2	Class A	and those directly connected to the pub power supply network that suppli		c low-voltage
Voltage flicker er IEC 610		Complies	for domestic purposes.	oses.	

Recommended separation distances between portable and mobile RF communications equipment and the Medical XXX

The "XXX" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical XXX can help prevent electromagnetic interference

by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "XXX" as recommended below, according to the maximum output power of the communications

"XXX" as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m			
output power of transmitter W	$d = \begin{bmatrix} \frac{3.5}{V_1} \end{bmatrix} \sqrt{P} \\ kHz to \\ 80 \text{ MHz} \end{bmatrix}$	80 N $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ /IHz	800 $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ GHz	
0,01	0.12	0.12	0.23	
0,1	0.38	0.38	0.73	
1	1 1.2 1.2		2.3	
10	3.8	3.8	7.3	
100	12	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: Shenzhen Medek Bio-Medical Co., Ltd.,

Address of manufacturer: No.101 Wenhao Industrial Park, No.13 Yuanxin Road, Tongle Community, Baolong Street, Longgang District, 518100 Shenzhen, P. R. China Tel: 0755-29677529



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