

CE 2764
Model: Breeze

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Suzhou Melodicare Medical Technology Co., Ltd

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1. Introduction

Breeze measures the body temperature through receiving the infrared energy radiation from the human body. There are two modes available for the device, forehead temperature mode and ear temperature mode. The measurement result will be directly shown on the LED screen. The main components of the product include infrared temperature sensors, signal receiving processor, buttons, buzzer, LED display, battery, etc.

1.1 Product intended use/Indications for Use

The infrared thermometer is intended for the measurement and monitoring of human body temperature by physician in healthcare environment or person at home. The ear mode of the device is not intended for infants less than three months.

Contradictions: There are no known contraindications.
Side-effects: Not applicable.

1.2 Safety Information

Warnings:

- The device is not intended for Professional Use.
- The measurement results cannot replace the physician diagnosis.
- Read the instruction manual before using this device.
- The thermometer should be placed where children can't get access.
- Do not measure against the eyes.
- Do not try to change the product default settings.
- Use the thermometer in a stable temperature environment. If the environment temperature changes too often, for example from outdoor to indoor, please put the thermometer indoor for about half an hour before measuring.
- Do not measure body temperature immediately when the current two measured temperatures differ significantly, but 10 minutes later to perform the measurement.
- Keep the thermometer away from any liquid to avoid any damage to the device.
- Do not use in high or low temperature environment for a long time.
- Do not collide, and avoid any falling and disassembly by the user.
- Do not use in strong electromagnetic interference environment.
- Do not operate the thermometer when the ear is not clean, or the skin of the forehead is sweating.

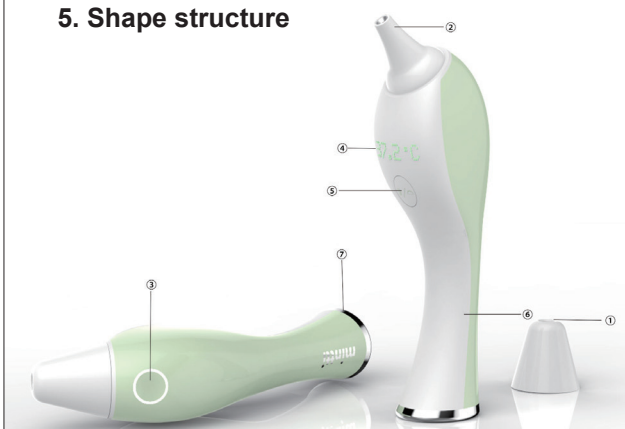
4. Technical parameters

Measurement Mode	Ear Mode	34.0°C~42.4°C (93.2°F~108.3°F)
	Forehead Mode	34.0°C~42.4°C (93.2°F~108.3°F)
Measurement accuracy	Ear Mode	±0.2°C/0.4°F
	Forehead Mode	±0.2°C/0.4°F
Display resolution	0.1°C/°F	
Operating environment	16°C - 35°C (60.8°F to 95°F) ≤ 85% moisture noncondensing	
Storage condition	-20°C - 55°C (-4°F to 131°F) ≤ 90% moisture noncondensing	

Power supply	DC1.5V×2 AAA
Power consumption	When off ≤ 10 uw
	When measuring ≤ 200 mw
Auto power-off	30 seconds
Weight	About 62 g (without battery)
Dimensions	161.5mm *35.8mm *55.9mm(length×width×height)
Product accessories	2x AAA Batteries, 1x User Manual, 1x Maintenance & Service card and 1x QC Certificate

- * 1. Clinical accuracy characteristics and procedures are available from the manufacturer on request.
2. *51M laboratory accuracy requirements in the display range of 37 to 39 °C (80 to 102 °F) for IR thermometers is ±0.2 °C (±0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ±0.1 °C (±0.2 °F)."

5. Shape structure



1. Forehead cover;
2. Measuring key and Memory key;
3. Conversion key and ON/OFF;
4. LED display;
5. Infrared probe;
6. Handle;
7. Battery cover

Function Key	Functional Description
Measuring key	Press to measure the temperature
Memory key	Press to get the current 32 sets of measuring data
Conversion key	Long press to adjust °C / °F
ON/OFF key	Long press the key, device will be power off

Note: Forehead cover is a reusable component of the thermometer.

6. Definition of display icon

Icon definition	Icon	Definition
Measuring mode1		Forehead temperature measurement mode
Measuring mode2		Ear temperature measurement mode
Memory symbol		Record the current 32 sets of measurement data
Temperature unit		Celsius degree; Fahrenheit degree °F and °C is convertible
Battery capacity		Indicates low battery status
Memory symbol		Record the current 32 sets of measurement data
		Caution
		The electronic waste should be disposed by professionals after use
		Manufacturer
		RF type application device
		Keep dry
		Upward
		Fragile, handle with care
IP22		2 Protected against solid foreign objects of Ø12.5 mm and greater; 2 If keeping the thermometer in 15 degree angle, the water drops can still be prevented
CE REP		EC Representative
CE 2764		CE mark
		Date of manufacture
		Please refer to the manual
SN		Product serial number

7. Settings

A. Memory mode:
Take off the bottom cover and install the battery, then all symbols will be displayed on the screen. Then press the Memory key to check the current 32 sets of measurement data.
Note:
a. The record order is 1,2,3...20, 21,...,32.
b. The record will be deleted when uninstalling the battery.

B. Temperature unit switch setting:
When the device is off, press the Conversion key for 5s until the LED display “°C” or “°F” appears, then press the Conversion key one more time to switch to the right unit. Then the device will be power off automatically after 3s, which means the unit setting is done.
Note: The default temperature unit is “°C”. The setting will come back to the default when uninstalling the battery.

C. Voice switch setting:
When the device is on, long press the Memory key for 2s, then the device will be on, and the voice can be set ON or OFF.
Note: The sound key can be set on/off depending on the situation, e.g. it can be off when the application is appreciated.

D. Shutdown key:
When the device is on, long press the NO/OFF key for about 2s, it will be powered off automatically.

- Hold the thermometer and near the temporal artery of forehead, then press the measurement key. When buzzer beeps, the temperature will be displayed on the LED screen. The thermometer must be kept near the forehead before the end of the measurement.



8.2 Ear temperature measurement

- Install the batteries and press the ON/OFF key.
- Take off the forehead cover, and make sure the icon shows up before the measurement. Be sure that the forehead cover is removed and converted to the ear measuring mode.

- Press the measuring key after inserting the probe into the ear. When the buzzer beeps, the temperature will be displayed on the LED screen.



Warning

- Do remember to put on the disposable probe cover before the measurement.
- Do remember to change the disposable probe cover after each measurement or for different person.
- Do not push hard into the ear to avoid hurting the eardrum.
- Only use probe covers that are Melodicare-approved for use with this device; otherwise, the results will be inaccurate.

● When the measured temperature value is 38°C or above, the thermometer will send out an indication and the backlight will turn red.
Note:
1. If no indication can be observed when using, please check whether the sound function is turned off or contact the service in time.
2. If thermometer produces a false indication, especially when used for infants or children, please contact the service in time.
● Keep the battery beyond the child's reach and prevent it from being swallowed. If the battery is swallowed, please contact the doctor immediately.
● The measurement results of the thermometer is only for reference and cannot replace the clinical diagnosis result. If feeling unwell, please consult the doctor in time.

Caution

1. All memory records will be lost when uninstalling the battery.
2. All settings will come to default when uninstalling the battery. If the settings need to be adjusted, please install the battery and renew the settings.
3. The thermometer will be power off automatically after 30s without any operation.
4. When the measurement value is between 37.5-37.9°C, it is defined as low fever, please consult the doctor for further diagnostic.
5. When there is any wound in the ear measurement area, please do not use the thermometer to avoid aggravating the severity of the wound.

9. Replacement of batteries

- The battery life is approx. 3000 readings per year and 200 minutes when in constant use.
- Take off the bottom cover, and remove the old battery.
- Pay attention to the positive and negative when installing a new battery.

Caution

1. If it is not to be used for one month, please remove the battery to prevent any leakage.
2. Do not put waste battery in the fire to avoid any exploding.
3. The dispose of the waste battery should be accorded to local regulations.

10. Cleaning and maintenance

Use only the Melodicare-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods. Melodicare has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional or lay person to ensure that the instructions are followed so as to ensure adequate cleaning.

10.1 General Guidelines

Keep your thermometer free of dust and dirt. To prevent the device from damage, please follow the procedures:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Unless otherwise specified, do not immerse any part of the device in liquid.
- Do not pour liquid into the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver pol. sh).
- Inspect the device after they are cleaned and disinfected.

Warning

1. If you spill liquid on the probe sensor or LED, or they are accidentally immersed in liquid, contact your service personnel or service engineer.
2. Before cleaning, make sure that the device is switched off and disconnected from the power line.
3. After cleaning with Isopropanol, allow the thermometer to air dry. Use a soft, dry cloth to clean the thermometer body and LED display.
4. Do not use abrasive cleaners. Never submerge this thermometer in water or any other liquid.
5. Please keep the inner cavity of the sensors and probes clean, otherwise it will affect the measuring accuracy.

10.2 Point-of-Use Processing

If the point(s) has been in contact with the patient without the replaceable ear cover co-packaged, e.g. surface of infrared probe and protective cover, then cleaning is required after each use to avoid contamination. If there has been no patient contact and there is no visible contamination, including the handle, battery cover and compartment, LED, keys and inside and outside surface of the protective cover, or when the probe is used with the replaceable ear cover, daily cleaning may be not necessary, and the suggestion is to do it weekly. But cleaning after each patient is recommended, and only the legally market protective cover suggested by the manufacturer can be used with the device to make sure the measurement accuracy of the device. Water should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

To do surface-cleaning to the thermometer, please follow these steps:

1. Switch off the thermometer and uninstall the battery.
2. Wipe the entire exterior surface of the thermometer for two minutes by using a soft cloth which has been dampened with the cleaning solution thoroughly for 30s until no visible contaminants remain under room temperature.

10.3 Thorough Cleaning

The device should be thoroughly cleaned after the point-of-use processing after each use. The validated cleaning agents for cleaning the monitor and reusable accessories are: Isopropanol (70%)
Cleaning substances should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

To do surface-cleaning to the thermometer, please follow these steps:

1. Switch off the thermometer and uninstall the battery.
2. Wipe the entire exterior surface, including the handle, battery cover and compartment, LED, keys and inside surface of the protective cover, of the equipment for five minutes using a soft cloth which has been dampened with the cleaning solution thoroughly for 30s until no visible contaminants remain under room temperature.
3. Wipe off the cleaning substances for three minutes with a fresh cloth or towel, dampened with tap water for 30s after cleaning until no visible cleaning substances remain under room temperature.
4. Dry the thermometer in a ventilated and cool place for 10 minutes under room temperature.

Voltage dips, short interruptions and voltage variations in power supply input lines IEC 61000-4-11	<5% UT I_P=95 dip in UT for 0.5 cycle 40% UT I_P=60% dip in UT for 5 cycles 70% UT I_P=50% dip in UT for 25 cycles <5% UT_I=95% dip in UT for 5s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of BREEZE requires continued operation during power mains interruptions, it is recommended that BREEZE be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment

Guidance and manufacturer's declaration-electromagnetic immunity			
BREEZE is intended for use in the electromagnetic environment specified below.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of BREEZE including cables, than the recommended separation distance calculated from the equation applicable to the transmitter. Recommended separation distance

Radiated RF IEC 61000-4-3	3V/m 80kHz to 2.5GHz	3V/m	d=1.2 P 80MHz to 800MHz d=2.3 P 800MHz to 2.5MHz Here 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 form fixed RF transmitters, 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:
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NOTE 1 At 90MHz and 800MHz, 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 BREEZE is used exceeds the applicable RF compliance level above, BREEZE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating BREEZE.

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

Recommended separation distances between portable and mobile RF communications equipment and BREEZE

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

11. Troubleshooting

Diagnosis	Solution
The screen shows "Lo" or "Hi"	1. Check the measurement site. It is unable to measure accurately when the forehead is with water, sweating, hair-covered or applying cosmetics. 2. Check the operation environment. Environment changes will greatly influence the measurement result. Temperature change is significant. It's better to use after 10 minutes to achieve a new heat balance. 4. The measured body temperature is higher than 42.4°C or lower than 34.0°C 5. The measured object is not correct.
Screen flashes after measurement	The environment temperature is not among the normal working arrange which is 16°C - 35°C (60.8°F to 95°F)
Buttons have no response	1. Install and uninstall the battery 2. Check if the setting is in the progress.
No display or display abnormal	Uninstall the battery and re-install
Power off when opens	Check the battery, uninstall and re-install the battery

12. EMC Information

Guidance and manufacturer's declaration-electromagnetic emissions			
BREEZE is intended to be used in the electromagnetic environment specified below. The customer or the user of BREEZE should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	BREEZE 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 Harmonic emissions IEC 61000-3-2 Voltage fluctuations flicker emissions IEC 61000-3-3	Class B N/A	BREEZE is suitable for use in all establishments other than domestic 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			
BREEZE is intended to be used in the electromagnetic environment specified below. The customer or the user of BREEZE should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6kV for Contact discharge ±2, ±4, ±8kV for air discharge	±2, ±4, ±6kV	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 a.c. power lines ±1 kV for d.c. power lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration-electromagnetic immunity			
BREEZE is intended for use in the electromagnetic environment specified below.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of BREEZE including cables, than the recommended separation distance calculated from the equation applicable to the transmitter. Recommended separation distance

NOTE 1 At 90MHz and 800MHz, 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 BREEZE is used exceeds the applicable RF compliance level above, BREEZE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating BREEZE.

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

Recommended separation distances between portable and mobile RF communications equipment and BREEZE

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter			
	150kHz to 80MHz d=1.2 P	80MHz to 800MHz d=1.2 P	800MHz to 2.5GHz d=2.3 P	
0.01	0.01	0.12	0.23	
0.1	0.1	0.38	0.73	
1	1	1.2	2.3	
10	10	3.8	7.3	
100	100	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 80MHz and 800MHz, 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.

13. Commitment to quality and after-sales service

The warranty period of the product is one year.
Note: The free service during warranty period does not include the failure and damage due to user's personal reasons or unauthorized disassembly.

Prompt
Please keep the purchase vouchers to facilitate future maintenance.

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成品尺寸: 85*140mm
材质: 128g铜版纸
封面封底过哑胶
四色印刷
骑马钉
20P