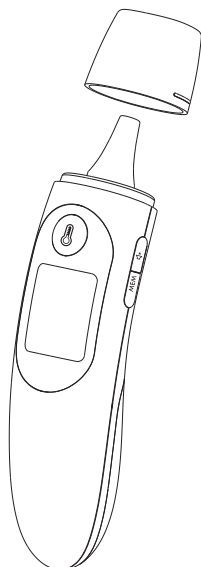


Owner's Manual

Infrared Ear/Forehead Thermometer

Model DET-2129b



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Introduction

The ear/forehead thermometer is intended for measuring forehead temperature and ear temperature. It allows you to quickly and easily measure body temperature. It converts the measured heat into a temperature reading displayed on the LCD.

Intended use: The infrared ear/forehead thermometer is intended for the intermittent measurement of human body temperature. The device can be reused by people of all ages for home use and clinical use.

Indications for Use: The infrared ear/forehead thermometer is used to measure body temperature.

Intended user: People of all ages. There is no gender or age limitation for using infrared ear/forehead thermometers.

Claims: No specific claim except the achievement of the intended use.

Complications: None.



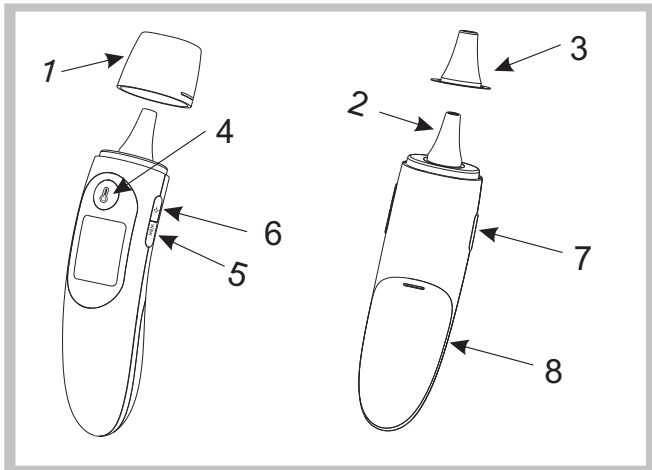
Please read all instructions carefully and thoroughly before using this product.

Warning:

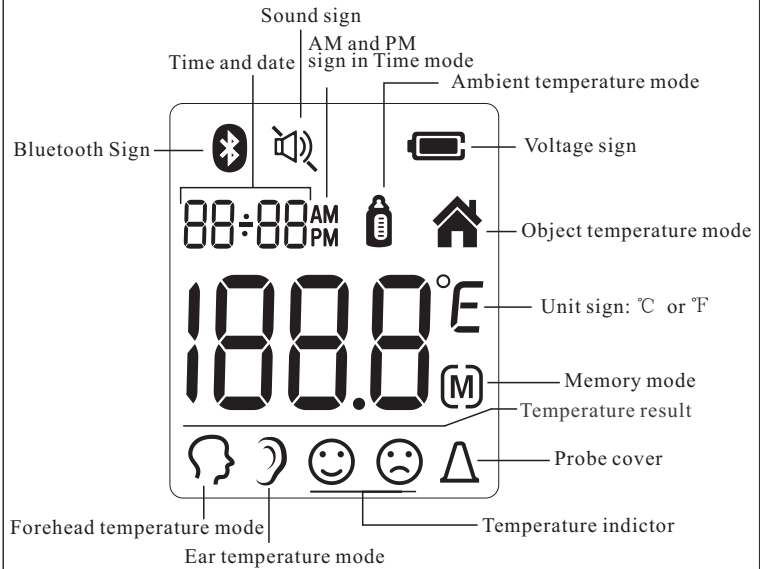
1. It's not meant to replace a visit to the doctor. Please consult with doctor if you have health concerns.
2. There is no gender or age limitation for using infrared ear/forehead thermometer.
3. Do not allow children to take their temperatures unsupervised, some parts are small enough to be swallowed.
4. Never immerse this device in water or other liquids (not waterproof).
5. Do not modify this equipment without authorization of manufacturer.
6. Do not expose the thermometer to temperature extremes (below -25°C/-13°F or over 55°C/131°F) nor excessive humidity (>95%RH).
7. Keep the battery away from children.
8. Remove battery from the device when not in operation for a long time.
9. 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.
10. ME equipment should not be cleaned while in use.
11. The probe of the ME equipment shall not be serviced or maintained while in use with a patient.
12. To avoid inaccurate readings, always attach a new, clean probe cover for each temperature reading.
13. This thermometer must only be used with this brand thermometer probe covers.

Product Description

1. Forehead Cover
2. Probe
3. Probe cover
4. Test Button
5. Memory Button
6. Sound Button
7. Mode Button
8. Battery Cover



LCD Display Introduction



Basic Functions

Real Time Clock	The real time clock will be recorded with the memory function and help you to recognize each measurement result. → Please see the Real time clock setting section to learn how to setup the time in the first use.
Ear/Forehead Temperature Mode	The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. → Please see the Illustration For Use section to learn how to measure the body temperature.
Object Temperature Mode	The object mode shows the actual, unadjusted surface temperatures, which is different from the body temperature. It can help you to monitor if the object temperature is suitable for the baby or patient, for example the baby's milk. Measure time of object mode: Approx. one second. Measuring range of object mode: 0°C~100°C(32°F~212°F). Laboratory accuracy of object mode: ±4% or ±2°C(4°F) whichever is greater. → Please see the Illustration For Use section to learn how to measure the object temperature.
Memory Mode	There are 30 sets memories for ear, forehead and object measurements. Each memory also records the measurement date/time/mode icon.
°C/°F Switch	Please see the Illustration For Use section to learn how to change between Celsius and Fahrenheit.
Voice	The thermometer will broadcast the result after finishing measurement.
Vibration	After the voice is turned off, the vibration will be automatically turned on. The thermometer will vibrate at the end of the measurement.
Bluetooth sign	If the APP is successfully connected to the machine, the Bluetooth sign will always be on, otherwise it will keep flashing.

Real Time Clock Setting

When using thermometer for the first time, please set the parameters of the thermometer. With the thermometer off, press and hold **Test Button** to enter into setting mode.

24 h

12 h

① Set the time format
The device can display the time in either an AM/PM (12-hour) or a 24:00 (24-hour) format. Press and release **Test Button** to select the format. With the preferred time format on the display, press **Mode Button**, the Hour figure is flashing automatically.

16:00

② Set the hour
Press and release the **Test Button** to advance one hour until the correct hour appears. After the hour is set, press **Mode Button**, the Minute figure is flashing automatically.

16:00

③ Set the minute
Press and release the **Test Button** to advance one minute until the correct minute appears. After the minute is set, press **Mode Button**, the Year figure is flashing automatically.

20 20

④ Set the year
Press and release the **Test Button** to advance one year until the correct year appears. After the year is set, press **Mode Button**, the Month figure will appear.

Real Time Clock Setting

12-22

⑥ Set the month

Press and release the *Test Button* to advance one month until the correct month appears. After the month is set, press *Mode Button*, the Date figure is flashing automatically.

12-22

⑦ Set the date

Press and release the *Test Button* to advance one day until the correct month appears. After the day is set, press *Mode Button* to exit the setting mode.

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Body Temperature

The temperature of a healthy person is affected by various factors: the person's individual metabolism, their age (body temperature is higher in babies and toddlers and decreases with age. Greater temperature fluctuations occur faster and more often in children, e.g. due to growth spurts), their clothing, the ambient temperature, the time of day (body temperature is lower in the morning and increases throughout the day towards evening), the preceding physical and, to a lesser extent, mental activity.

It is suggested that users develop the habit of daily measurement, and use this product to establish a private normal temperature range for themselves and their families as a reference for measurement.

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Illustration For Use

► Before measurement:

- Check before each use that the lens is intact. If it is damaged, contact your retailer or the service address.
- Bear in mind that the thermometer needs to have been in the room in which the measurement is taken for at least 30 minutes before use.
- Users and the thermometer should be in the same ambient temperature.
- Before each measurement, make sure that the device is in the appropriate mode for the measurement that you wish to take.

► How to switch between ear/forehead mode, object mode and ambient temperature mode:

- When the forehead cap is installed, the thermometer will automatically switch to forehead mode and when not installed, the thermometer will automatically switch to ear mode.
- When in forehead/ear mode, press *Mode Button* to switch to object mode or ambient temperature mode.

► How to set sound on/off:

- When in test mode or memory mode, press *Sound Button* to set sound on/off.

► How to set measurement unit:

- When in test mode, press and hold *Sound Button* for 3 seconds to switch to measurement unit setting mode, and press *Test Button* to change the unit between °C and °F, press *Sound Button* to exit the mode.

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Illustration For Use

► To measure forehead temperature:

- **Note:** Oils or cosmetics on the forehead may give a lower temperature reading than the actual one. Remove dirt from the forehead before taking a measurement. Wait at least 10 minutes after washing the forehead area before taking a reading.
 - Do not use the thermometer on a perspiring or sweating forehead, as this may affect the reading.
 - Remove hat and hair and wait 10 minutes before taking a reading.
1. Install the forehead cap.
 2. Press the *Test Button* to switch on the thermometer and the display is activated to show all segments (See Figure 1).
 3. After self-checking, Figure 2 appears on the display screen with voice, so you can start a new measurement.
 4. Place the probe with the forehead cover fitted on the forehead (See Figure 3).
 5. Press the *Test Button* to start measurement.
 6. The measured value appears on the display and the end of the measuring is signaled by voice. If the voice is turned off, the end of the measurement is signaled by vibration.
 7. The thermometer will shut off automatically after 30 seconds of inactivity.

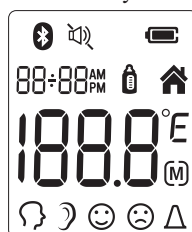


Figure 1



Figure 2

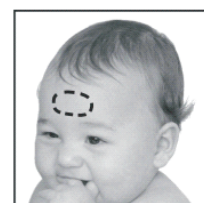


Figure 3

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Illustration For Use	Illustration For Use
► To measure ear temperature: - Some people produce different readings in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear. - As ear wax can affect the measurement, you should clean the ear before measuring if necessary. - Remove the forehead cover. To achieve accurate readings, if a probe cover is needed, make sure a new, clean probe cover is in place before each measurement. Place a new probe cover on the probe firmly; making sure the probe and the inner portion of the probe cover fit snugly. - Press the <i>Test Button</i> to switch on the thermometer and the display is activated to show all segments. - After self-checking Figure 4 appears on the display screen with voice, so you can start a new measurement. - Make sure that the sensor tip and the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip. (See Figure 5) - When using the thermometer on infants under age 1, pull the ear up making sure the sensor faces the eardrum (See Figure 6). - When using the thermometer on individuals over the age of 1, pull the ear back making sure the sensor faces the eardrum. (See Figure 7). - Press the <i>Test Button</i> to start the measurement.	- The measured value appears on the display. Note: A waiting period of 20 seconds between testing is recommended to avoid excessive cooling of the skin. - The thermometer will shut off automatically after 30 seconds of inactivity. Note: Probe cover sign Δ stand for taking the ear temperature with probe cover. Figure 4 Figure 6 Figure 7 Figure 5
Illustration For Use	Illustration For Use
► To measure ambient temperature: - Press the <i>Test Button</i> to switch on the thermometer. - When in forehead mode or ear mode, press <i>Mode Button</i> to switch to ambient temperature mode. The thermometer measures temperature automatically, and ambient temperature appears on the display screen (See Figure 8). Figure 8	► To measure object temperature: - Press the <i>Test Button</i> to switch on the thermometer. - When in forehead mode or ear mode, press <i>Mode Button</i> to switch to ambient temperature mode. And press <i>Mode Button</i> again to switch to object mode (See Figure 9). - Aim the thermometer at the center of the object you want to measure with a distance of 1 to 2 cm. - Press the <i>Test Button</i> to start measurement. - The measured value appears on the display and the end of the measuring is signaled by voice. If the voice is turned off, the end of the measurement is signaled by vibration. - To exit object temperature mode, press <i>Mode Button</i> to switch back to forehead/ear mode. - The thermometer will shut off automatically after 30 seconds of inactivity. Remarks: This mode shows the actual, unadjusted surface temperatures, which is different from the body temperature. Figure 9

Illustration For Use

► After measurement:

1. Power off: Device will automatically shut off if left idle for more than 30 seconds to extend battery life.
2. Clean the probe after each use to ensure an accurate reading and avoid cross contamination.
(See the section of Care and Cleaning for details.)

► BackLight:

In Ear/Forehead temperature mode:

1. The display will be lighted GREEN for 3 seconds with a happy face 😊 when the unit is ready for measurement and a measurement is completed with a reading less than 37.3°C(99.1°F).
2. The display will be lighted YELLOW for 3 seconds with a happy face 😊 when a measurement is completed with a reading less than 37.8°C(100.0°F).
3. The display will be lighted RED for 3 seconds with a bad face ☹ when a measurement is completed with a reading equal to or higher than 37.8°C(100.0°F).

In Object/Ambient temperature mode:

The display will only be lighted WHITE for 3 seconds when the unit is ready for measurement and a measurement is completed.

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Illustration For Use

► Bluetooth requirements

The thermometer requires a bluetooth device with:

- . Bluetooth 5.0 or later
- . Android 6.0 or later
- . IOS 10.0 or later

And works with:

- . iphone , iPod, iPad
- . Android Phones and Tablets

► Using for the first time

1. Download the "JoyHealth" App from Website or APP Store (Such as Apple Store).
2. Open the App on your phone or tablet. If requested, you should enable Bluetooth on your device. You can enable Bluetooth under the Settings menu on your smart phone or tablet.
3. Create a new user login, or login with your existing user name and password.
4. Selection device "Thermometer".

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Illustration For Use

► Match your thermometer with a Smart Device

1. If this is your first time using it, bind first. Open "SETTING" menu, choose "Bind and unbind device" and select the appropriate model.
The date and time on your thermometer will automatically be updated when it's connected with your phone.
2. Confirm that your thermometer is connected successfully.
When your thermometer is connected successfully to your smart phone, the "📶" symbol stop flashing and keep showing.

► Transfer your readings

1. As soon as your measurement is finished, open the app on your smart phone to transfer the readings.
Note: On the matched smart phone, Bluetooth must be enabled.
2. You can view your temperature readings in the app.

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Temperature Taking Hints

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading.

1. It is important to know each individual's normal temperature when they are well. This is the only way to accurately diagnose a fever. To determine normal temperature, take multiple readings when healthy. Re-measure with a standard digital thermometer for confirmation.
2. The probe window of the thermometer is the most delicate part of the device. Do not touch the probe window. The accuracy of the reading may be affected if the probe window is damaged or dirty.
3. Users should not drink, eat, or be physically active such as bathing, showering, shampooing and hair drying before/while taking the measurement. In these cases, wait 20 minutes prior to taking a temperature.
4. Holding a hand on the forehead for any length of time will affect the temperature reading.

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Temperature Taking Hints

5. Do not take temperature over scar tissue, open sores or abrasions.
6. Don't take a measurement while or immediately after nursing a baby.
7. Do not use this thermometer outdoors.
8. Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
9. If the thermometer is stored in a significantly different environment than testing location, place it in the testing location for approximately 30 minutes prior to use.
10. The patient is an intended operator.

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Memory Mode

1. The Memory Mode can be accessed either in ear mode, forehead mode or object mode:
When the thermometer has been turned on and followed by Figure 2/4/9 or finished testing, press the *Memory Button*. The letter M will appear in the lower right corner of the display. (See Figure 10)
2. The thermometer will automatically memorize the last 30 temperature readings. Each memory also records the measurement date/time/mode icon. Each time the *Memory Button* is pressed, the screen displays past readings that correspond with a number 1-30. The number 1 reflects the most recent reading, while the number 30 reveals the oldest reading stored in memory. (See Figure 11)
3. In the memory mode, the mode icon always exists. The user can press the *Test Button* to take new measurements.

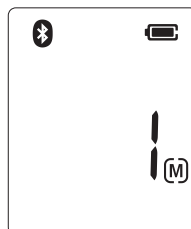


Figure 10



Figure 11

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Care And Cleaning

1. The probe window must be kept clean, dry, and undamaged at all times to ensure accurate readings. The accuracy of temperature readings can be affected by damage to the probe window, or the presence of dirt and ear wax on the probe window.
2. Fingerprints, earwax, dust and other soiling compounds reduce transparency of the window and result in lower temperature readings.
3. The probe window is the most delicate part of the thermometer. To safely clean the window, gently wipe its surface with a cotton swab slightly moistened with isopropyl alcohol and immediately wipe dry with a clean cotton swab. After cleaning, allow at least 5 minutes drying time before taking temperatures.
Note: Do not use any chemical other than isopropyl alcohol to clean the probe window.
4. Use a soft, dry cloth to clean the thermometer display and exterior.
5. The thermometer is not waterproof. Do not submerge the unit in water when cleaning.
6. Store the thermometer in a dry location, free from dust and contamination and away from direct sunlight.

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Care And Cleaning

7. Periodic cleaning of the device following use to prevent patient cross infection.
-Use a soft cloth slightly moistened with a 75% isopropyl alcohol solution to wipe the thermometer and probe. Do not use abrasive cleaners.
8. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
9. Do not remove or modify the equipment without permission.
10. Strong electromagnetic fields may interfere with the proper operation of the thermometer. The device needs special pre-cautions regarding EMC according to the EMC information.
11. It is not intended for use in the oxygen rich environment and presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
12. Put the thermometer back to the original packaging after using.

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Battery Replacement

1. Replace battery when "  " appears in the upper right corner of LCD display. (See Figure 12)
2. Slide battery cover down as shown in Figure 13.
3. Remove battery and install 2 new AAA alkaline batteries as shown in Figure 14.
4. Slide battery cover back on.



Figure 12

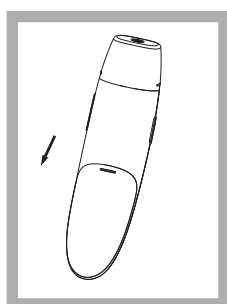


Figure 13

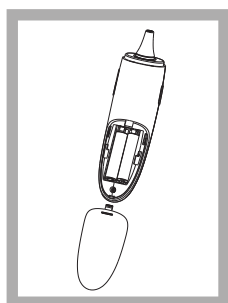


Figure 14

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Specifications

Measuring range	Ear/Forehead mode: 34.0°C~43.0°C(93.2°F~109.4°F)
Measuring site	Ear canal(Ear Mode), Forehead(Forehead Mode)
Reference body site	Oral (This thermometer converts the ear temperature to display its "oral equivalent.")
Operation mode	Ear/Forehead mode(Adjust mode)
Laboratory accuracy	Ear/Forehead mode: ±0.2°C (0.4°F) during 35.5°C~42.0°C (95.9°F~107.6°F) at 15°C~35°C (59.0°F~95.0°F) operating temperature range ±0.3°C (0.5°F) for other measuring and operating temperature range
Display resolution	0.1°C or 0.1°F
Measure time	Ear/Forehead mode: Approx. one second
Operating temperature range:	10°C~40°C(50°F~104°F), 15%~85%RH, non-condensing Atmospheric Pressure : 70kPa ~ 106kPa
Storage and transport temperature range	-25°C ~ 55°C (-13°F~131°F), 15%~95%RH, non-condensing Atmospheric Pressure : 70kPa ~ 106kPa
Clinical accuracy	0-1 year: Ear temperature: Clinical bias: 0.05°C (0.09°F); Clinical repeatability: 0.21°C (0.38°F); Limits of agreement: 0.76°C (1.37°F) Forehead temperature: Clinical bias: 0.08°C (0.14°F); Clinical repeatability: 0.33°C (0.59°F); Limits of agreement: 0.73°C (1.31°F) 1-5 years: Ear temperature: Clinical bias: 0.11°C (0.20°F); Clinical repeatability: 0.34°C (0.61°F); Limits of agreement: 1.36°C (2.45°F) Forehead temperature: Clinical bias: 0.24°C (0.43°F); Clinical repeatability: 0.40°C (0.72°F); Limits of agreement: 1.49°C (2.68°F) over 5 years: Ear temperature: Clinical bias: 0.21°C (0.38°F); Clinical repeatability: 0.21°C (0.38°F); Limits of agreement: 0.99°C (1.78°F) Forehead temperature: Clinical bias: 0.22°C (0.40°F); Clinical repeatability: 0.26°C (0.47°F); Limits of agreement: 1.10°C (1.98°F)
Shock	withstands drop of 3 feet
Dimension	155.7*42*44.2mm
Weight	Approx. 102 grams(with batteries)
Battery	DC3V(2×AAA battery)
Battery life	Approx. 3000 readings
Expected service life/ /Shelf life	Three years
Ingress protecting rating	IP22
Accessories	Battery
Contraindications	None
Applied part	Probe
Bluetooth technical parameters	Modulation mode: GFSK Frequency range: 2400-2483.5MHz Bandwidth occupied: ≤2MHz Transmit power: ≤20db

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Troubleshooting

Error message	Problem	Solution
---	Measurement before thermometer is ready	Take a measurement until thermometer is ready(ear mode).
E-2	The ambient temperature is not within the range between 10°C and 40°C (50°F~104°F).	Place the thermometer in a room for at least 30 minutes at room temperature between 10°C and 40°C (50°F~104°F)
E-3	The thermometer is placed incorrectly or unsteady.	Read Illustration For Use thoroughly and take a new temperature measurement.
E-4	The thermometer showing a rapid ambient temperature change.	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: between 10°C and 40°C (50°F~104°F)
E-5	The thermometer is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.

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Troubleshooting

Error message	Problem	Solution
H _i	In Ear/Forehead mode: Temperature taken is higher than 43.0 °C (109.4°F). In Object mode: Temperature taken is higher than 100 °C (212°F).	Read Temperature Taking Hints Thoroughly, then take a new temperature measurement.
L _o	In Ear/Forehead mode: Temperature taken is lower than 34.0 °C (93.2°F). In Object mode: Temperature taken is lower than 0°C(32°F).	Read Temperature Taking Hints thoroughly, then make sure the lens filter are clean, then take a new temperature measurement.
	The thermometer works properly.	Use the thermometer normally
	When battery outline flashes, it indicates that the power is low, but you can continue to measure.	The thermometer will take a proper measurement but batteries must be replaced soon.
	The thermometer could not work due to low battery.	Replace two new alkaline batteries size AAA.

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Calibration

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 recommends checking calibration every year or whenever clinical accuracy of the thermometer is in question. Please send the complete device to the dealers or manufacturer.

The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

A clinical summary and procedures for checking calibration are available upon request. (Turn on the thermometer and press the test button long time until entering into calibrate mode, software version will be displayed.)



TYPE BF APPLIED PART



Unique device identifier



Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products



Refer to instruction manual/booklet



Batch Code



Storage and Transportation Temperature Limit:
-13°F ~ 131°F (-25°C ~ 55°C)



Atmospheric pressure limitation



Medical Device



Date of manufacture

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Storage and Transportation Humidity limitation: 15%~95%RH

Service

The thermometer has a limited one year warranty. Do not attempt to disassemble or repair the thermometer by yourself. Should service be required during or after the warranty period you must contact the manufacturer. Repackage the thermometer carefully in its original packaging or securely pack to avoid damage during shipping. Include the original sales slip indicating the date of purchase, a note describing the problem, and your return address. Send the thermometer prepaid and insured.

The lay operator or lay responsible organization should contact the manufacturer or the manufacturer's representative:

- for assistance, if needed, in setting up, using or maintaining the thermometer; or
- to report unexpected operation or events.



Manufacturer



General symbol for recovery/recyclable



0123

The product conforms to the requirements of the EC Directive MDR (EU) 2017/745 on medical devices



Authorized representative in the European Community



The first num.2: Protected against solid foreign objects of 12,5 mm Ø and greater.

The second num.2: Protection against vertically falling water drops when ENCLOSURE tilted up to 15°



Caution

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Warranty

This appliance conforms to the following standards:

ISO 80601-2-56 Medical electrical equipment —Part 2-56:

Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,

IEC 60601-1-11 Medical electrical equipment —Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment and complies with the requirements of IEC 60601-1-2(EMC) , IEC 60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

Thermometer is warranted by manufacture to be free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery to the first user who purchases the instrument. This warranty does not cover batteries, damage to the probe window, or damage to the instrument caused by misuse, negligence or accident, and extends to only to the first purchaser of the product.

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FCC Information

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment.

*Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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FCC Information
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. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.
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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.
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Electromagnetic Compatibility Information

EMISSION limits per environment			
Phenomenon	Professional healthcare facility environment ^{a)}	HOME HEALTHCARE ENVIRONMENT ^{a)}	Compliance
Conducted EMISSIONS	CISPR 11	CISPR 11 ^{c)}	Not applicable
Radiated RF EMISSIONS	CISPR 11	CISPR 11 ^{c)}	Group 1 Class B
Harmonic distortion	See IEC 61000-3-2 ^{b)}	See IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker	See IEC 61000-3-3 ^{b)}	See IEC 61000-3-3	Not applicable
a) See 8.9 for information about the environments of INTENDED USE. b) This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard. c)Standards applicable to modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.			

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Electromagnetic Compatibility Information

Table 2			
Power input voltages and frequencies during the tests			
Test	Power input voltage	Power frequency	Compliance
Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	Minimum and maximum ^{c) d)} RATED voltage	Any one frequency ^{b)}	N/A
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	10 V/m	80 MHz to 2.7 GHz	P
Harmonic current EMISSIONS IEC 61000-3-2	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 240 V or 380 V to 415 V; If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz or 60 Hz	N/A
Voltage changes, voltage fluctuations and flicker EMISSIONS IEC 61000-3-3	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 250 V line to neutral: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz	N/A
ELECTROSTATIC DISCHARGE IMMUNITY IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		P
Radiated RF electromagnetic field IMMUNITY IEC 61000-4-3	10 V/m	80 MHz – 2,7 GHz 80 % AM at 1 kHz	P

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Electromagnetic Compatibility Information

Table 2 continued

Test	Power input voltage	Power frequency	Compliance
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	See Table 7: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment		P
Electrical fast transient/burst IMMUNITY – a.c. mains IEC 61000-4-4	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
Electrical fast transient/burst IMMUNITY – I/O SIP/SOP PORTS IEC 61000-4-4	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
Surge IMMUNITY IEC 61000-4-5	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) – a.c. mains IEC 61000-4-6	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted DISTURBANCE IMMUNITY) – SIP/SOP PORTS IEC 61000-4-6	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
Power frequency magnetic field IMMUNITY IEC 61000-4-8	30 A/m	50 Hz or 60 Hz	P

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Electromagnetic Compatibility Information

Table 2 continued

Test	Power input voltage	Power frequency	Compliance
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage ^{c) d)}	Any one frequency ^{b)}	N/A
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage ^{a)}	Any one frequency ^{b)}	N/A
Proximity magnetic fields IEC 61000-4-39	See Table 5: Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		P

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.
c) If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.
d) ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

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Electromagnetic Compatibility Information

Table 3

ENCLOSURE PORT			
Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM ^{a)} fields	IEC 61000-4-3	3 V/m ^{f)} 80 MHz – 2,7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}	10 V/m ^{f)} 80 MHz – 2,7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10.	
RATED power frequency magnetic fields ^{d)}	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Proximity magnetic fields	IEC 61000-4-39	See 8.11.	

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.
c) If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.
d) ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.
f) Before modulation is applied.

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Electromagnetic Compatibility Information

Table 4

Input d.c. power PORT			
Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts ^{a) g)}	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges Line-to-line ^{a) b) g)}	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges Line-to-ground ^{a) b) g)}	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields ^{a) c) d) i)}	IEC 61000-4-6	3 V ^{b)} 0,15 MHz – 80 MHz 6 V ^{b)} in ISM bands between 0,15 MHz and 80 MHz ^{j)} 80 % AM at 1 kHz ^{c)}	3 V ^{b)} 0,15 MHz – 80 MHz 6 V ^{b)} in ISM and amateur radio bands between 0,15 MHz and 80 MHz ^{j)} 80 % AM at 1 kHz ^{c)}
Electrical transient conduction along supply lines ^{f)}	ISO 7637-2	Not applicable	As specified in ISO 7637-2

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.
b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test
c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.
d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems
g) Direct coupling shall be used.
h) r.m.s., before modulation is applied.

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Electromagnetic Compatibility Information

Table 4 continued

I) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
j) 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.

Table 5

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz ^{a)}	CW	8
134,2 kHz	Pulse modulation ^{b)} 2,1 kHz	65 ^{c)}
13,56 MHz	Pulse modulation ^{b)} 50 kHz	7,5 ^{c)}
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.		
b) The carrier shall be modulated using a 50% duty cycle square wave signal.		
c) r.m.s., before modulation is applied.		

Electromagnetic Compatibility Information

Table 6

PATIENT coupling PORT			
Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts ^{a) g)}	IEC 61000-4-4	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields ^{a) c) d) i)}	IEC 61000-4-6	3 V ^{b)} 0,15 MHz – 80 MHz 6 V ^{b)} in ISM bands between 0,15 MHz and 80 MHz ^{j)} 80 % AM at 1 kHz ^{c)}	3 V ^{b)} 0,15 MHz – 80 MHz 6 V ^{b)} in ISM and amateur radio bands between 0,15 MHz and 80 MHz ^{j)} 80 % AM at 1 kHz ^{c)}
a) The following apply: – All PATIENT-COUPLED cables shall be tested, either individually or bundled – PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used. – No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case. – Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. – Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables. – If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range. – 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) r.m.s., before modulation is applied c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.			

Electromagnetic Compatibility Information

Table 7

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment				
Frequency (MHZ)	Band ^{a)} (MHZ)	Service ^{a)}	Modulation	IMMUNITY TEST LEVEL(V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460,FRS 460	FM ^{c)} ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13,17	Pulse modulation ^{b)} 217Hz	9
745				
780				
810	800 to 960	GSM 800/900,TETRA 800, iDEN 820,CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800;CDMA 1900; GSM 1900;DECT;LTE Band 1,3,4,25;UMTS	Pulse modulation ^{b)} 217Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth,WLAN, 802.11b/g/n,RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217Hz	9
5500				
5785				
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 1 m.The 1 m test 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,the carrier may be pulse modulated using a 50%duty cycle square wave signal at 18 Hz.While it does not represent actual modulation,it would be worst case				

Electromagnetic Compatibility Information

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.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.
- Do not use the devices in the MR environment.
- The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES.
- PRECAUTION: The performance of the device may be degraded should one or more of the following occur:
 - Operation outside the manufacturer's stated temperature and humidity range.
 - Storage outside the manufacturer's stated temperature and humidity range.
 - Mechanical shock (for example, drop test) or degraded sensor.
 - Patient temperature is below ambient temperature.