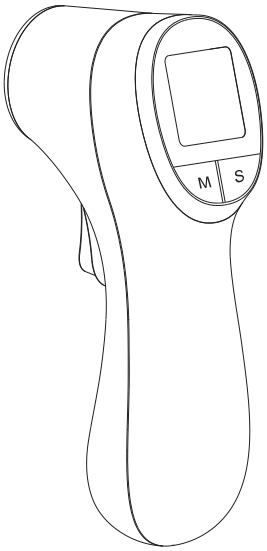
Owner's Manual

Infrared Forehead Thermometer

Model DET-3012b



Importer:

JOYTECH Healthcare Co., Ltd.
No.365, Wuzhou Road,311100 Hangzhou, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

Telephone: +86-571-81957767
Fax: +86-571-81957750

CE 0123 The product is in compliance with the requirements of MDR(EU) 2017/745, "0123" is the identification number of notify body

EU REP European Authorized Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

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Contents

Introduction

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

The DET-3012b infrared forehead thermometer is specifically designed for safe use on the forehead. The Infrared Forehead Thermometer is a device capable of measuring people's body temperature by detecting the intensity of infrared light emitted from the forehead. It converts the measured heat into a temperature reading displayed on the LCD. When properly used, it will quickly assess your temperature in an accurate manner.
Intended use:The infrared forehead thermometer is intended for the intermittent measurement of human body temperature from the skin surface of forehead. The device can be reused by people of all ages for home use and clinical use.
Indications for Use:The infrared forehead thermometer is used to measure body temperature by measuring forehead.
Intended user:People of all ages.

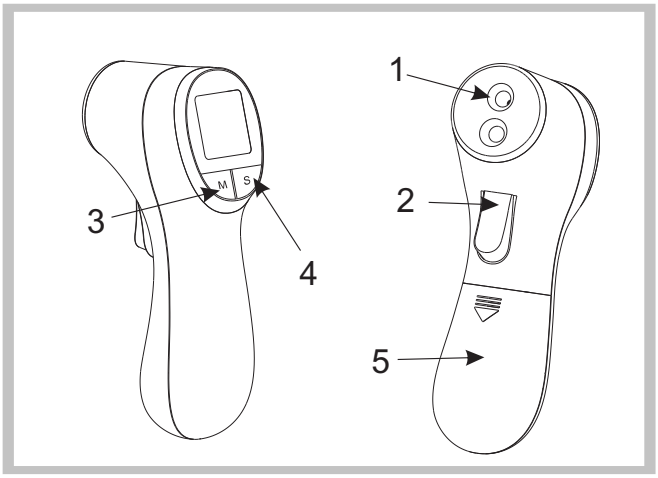
This appliance conforms to the following standards:
ISO 80601-2-56 Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,
IEC 60601-1-11 Medical electrical equipment —Part 1-11: General requirements 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.

Warning

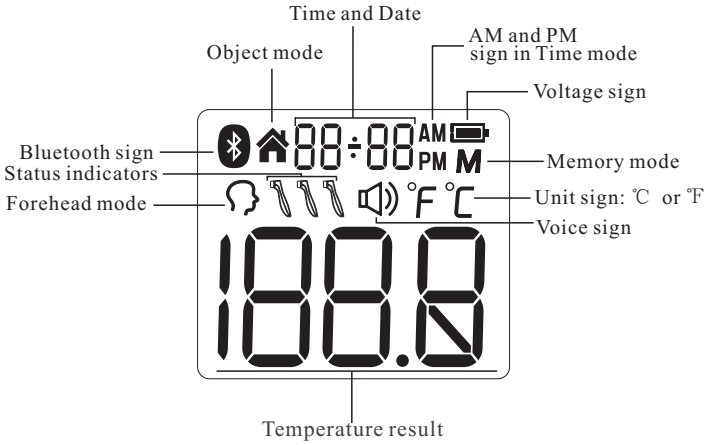
1. There is no gender or age limitation for using infrared forehead thermometer.
2. Do not touch the temperature probe with hands .
3. Use of this Forehead thermometer is not intended as a substitute for consultation with your physician.
4. Do not allow children to take their temperatures unsupervised, some parts are small enough to be swallowed.
5. Never immerse this device in water or other liquids.
6. Do not modify this equipment without authorization of manufacturer.
7. Do not expose the thermometer to temperature extremes (below -25℃/-13℉ or over 55℃/131℉) nor excessive humidity (>95%RH).
8. Keep the battery away from children.
9. Remove battery from the device when not in operation for a long time.
10. Do not put the thermometer in direct sunlight or with cotton wool, otherwise the accuracy will be affected.
11. Portable and mobile RF communications can affect the devise. The device needs special precaution regarding EMC according to the EMC information provided in the accompany documents
12. ME equipment should not be cleaned and wiped while in use.
13. 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.
14. The probe of the ME equipment shall not be serviced or maintained while in use with a patient.

Product Description

1. Probe
2. Test Button
3. Memory Button
4. Setting Button
5. Battery Cover



LCD Display Introduction

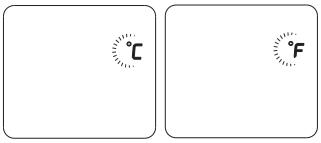


Basic Functions

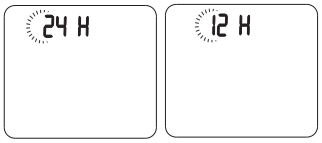
Real Time Clock	The real time clock will be recorded with the memory function and help you to recognize each measurement result. → Please see the Real time clock setting section to learn how to setup the time in the first use.
Forehead Mode	The thermometer has been designed for practical use. It's not 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 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. Measuring range of object mode: 0℃~100℃(32℉~212℉) Laboratory accuracy of object mode: ±4% or ±2℃(4℉) whichever is greater. → Please see the Illustration For Use section to learn how to measure the object temperature.
Memory Mode	There are each 30 sets memories for forehead and object measurements. Each memory also records the measurement date/time/mode icon.
Distance Detection	If the object is too far away from the probe, the temperature will not be measured until the probe is moved within the measured range.
Bluetooth sign	If the APP is successfully connected to the machine,the Bluetooth sign will always be on, otherwise it will keep flashing.
℃/ ℉ Switch	Please see the Real Time Clock Setting to learn how to change between Celsius and Fahrenheit.
Voice	The thermometer will broadcast the result after finishing measurement.
Voice on/off	You can use the button to choose whether to turn on or off the sound.

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 *Setting Button* to enter into setting mode.



①Set the unit
Press *Memory Button* to select the unit you want.
After the unit is set,press *Setting Button* ,the time format figure will appear .



② 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 *Memory button* to select the format. With the preferred time format on the display, press *Setting Button*, the Hour figure is flashing automatically.

③ Set the hour
Press and release the *Memory Button* to advance one hour until the correct hour appears.
After the hour is set, press *Setting Button*, the Minute figure is flashing automatically.

Real Time Clock Setting

④ Set the minute
Press and release the *Memory Button* to advance one minute until the correct minute appears.
After the minute is set, press *Setting Button*, the Year figure is flashing automatically.

⑤ Set the year
Press and release the *Memory Button* to advance one year until the correct year appears.
After the year is set, press *Setting Button*, the Month figure will appear.

⑥ Set the month
Press and release the *Memory Button* to advance one month until the correct month appears.
After the month is set, press *Setting Button*, the Date figure will appear.

⑦ Set the date
Press and release the *Memory Button* to advance one day until the correct month appears.
After the day is set, press *Setting Button* to exit the setting mode.

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. Users must be inside for 30 minutes before taking a measurement. Note: Users and the thermometer should be in the same ambient temperature for at least 10 minutes before taking a reading.
3. Users should not drink, eat, or be physically active such as bathing, showering, shampooing and hair drying before/while taking the measurement. Remove hat and hair and wait 10 minutes before taking a reading.
4. 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.

Temperature Taking Hints

5. Holding a hand on the forehead for any length of time will affect the temperature reading.
6. Do not take temperature over scar tissue, open sores or abrasions.
7. Do not use the thermometer on a perspiring or sweating forehead, as this may affect the reading.
8. Don't take a measurement while or immediately after nursing a baby.
9. Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
10. 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.
11. 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.
12. It is not intended for use in the oxygen rich environment and presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

Illustration For Use

▶ To measure forehead temperature:

1. Press the *Test Button*, The display is activated to show all segments. After self-checking Figure 1 appears on the display screen with voice, so you can start a new measurement.
2. Aim the thermometer at the center of the forehead with a distance less than 5cm (See figure 2) and then press the *Test Button*.
   Note: Do not remove the thermometer from the forehead before hearing voice.
   Note2:If the object to be tested is too far from the probe, a prompt will appear(See figure 3).
3. Read the temperature on the display.
4. Press and hold *Test Button* to turn off.

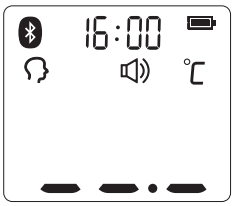


Figure 1

Figure 2

Figure 3

Illustration For Use

▶ How to turn on or off sound:

You can press *Setting Button* to turn on or off sound.

▶ How to change the forehead mode and object mode:

You can press and hold *Setting Button* to switch the mode between Forehead mode and Object mode.

▶ To measure object temperature:

1. Press the *Test Button* to turn on the thermometer, you can take the object temperature after hearing voice.(see figure 4)
2. Aim the thermometer at the center of the object you want to measure with a distance less than 5cm.
3. Press the *Test Button* and then read the temperature on the display.
4. Press and hold *Test Button* to turn off.

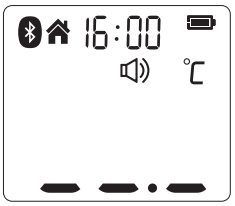


Figure 4

Illustration For Use

▶ After measurement:

1. Power off: Device will automatically shut off if left idle for more than 1 minute 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 Forehead mode:

1. The display will be lighted GREEN for 3 secondswhen the unit is ready for measurement and a measurement is completed with a reading less than 37.3℃(99.1℉).
2. The display will be lighted YELLOW for 3 secondswhen a measurement is completed with a reading less than 37.8℃(100.0℉).
3. The display will be lighted RED for 3 seconds when a measurement is completed with a reading equal to or higher than 37.8℃(100.0℉).

In Object mode:

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

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".

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.

Memory Mode

1. The Memory Mode can be accessed either in forehead mode or object mode:
   When the thermometer has been turned on and followed by Figure 1/4 or finished testing, press the *Memory Button* . The letter M will appear in the center right corner of the display. (See Figure 5)
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 6)
3. In the memory mode, mark or mark will not change. The user can press the *Test Button* to take new measurements.

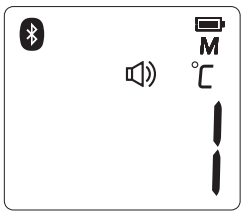


Figure 5

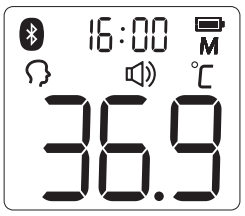


Figure 6

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, fingerprints, dust and other soiling compounds on the probe window. Degraded sensors can degrade performance or cause other problems.
2. The probe window is the most delicate part of the thermometer. Use a soft cloth slightly moistened with a 75% isopropyl alcohol solution to disinfect probe window and the thermometer. Do not use abrasive cleaners. After cleaning, allow at least 10 minutes drying time before taking temperatures.
   Note: Do not use any chemical other than isopropyl alcohol to clean the probe window.
3. Use a soft, dry cloth to clean the thermometer display and exterior.
4. Do not put the thermometer into water directly.
5. Store the thermometer in a dry location, free from dust and contamination and away from direct sunlight.
6. Put the thermometer back to the original packaging after using.

Battery Replacement

1. Replace battery when " " appears in the upper right corner of LCD display. (See Figure 7)
2. Slide battery cover down as shown in Figure 8.
3. Remove battery and install 2 new AAA alkaline batteries as shown in Figure 9.
4. Slide battery cover back on.

Figure 7

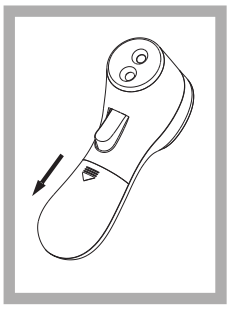


Figure 8

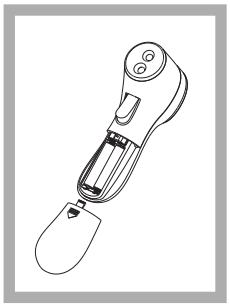
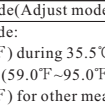
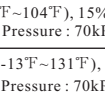


Figure 9

Specifications

Measuring range	Forehead mode: 34.0℃~43.0℃(93.2℉~109.4℉)
Measuring site	Forehead(Forehead Mode)
Reference body site	Oral (This thermometer converts the forehead temperature to display its “oral equivalent.”)
Operation mode	Forehead mode(Adjust mode)
Laboratory accuracy	Forehead mode: ±0.2℃ (0.4℉) during 35.5℃~42.0℃ (95.9℉~107.6℉) at 15℃~35℃ (59.0℉~95.0℉) operating temperature range ±0.3℃ (0.5℉) for other measuring and operating temperature range
Display resolution	0.1℃ or 0.1℉
Measure time	Approximately 1 second
Operating temperature range:	5℃~40℃(41℉~104℉), 15%~85%RH, non-condensing Atmospheric Pressure : 70kPa~ 106kPa
Storage and transport temperature range	-25℃~ 55℃ (-13℉~131℉), 15%~95%RH, non-condensing Atmospheric Pressure : 70kPa~ 106kPa
Clinical accuracy	0-1 year: Clinical bias: -0.19℃（-0.34℉）; Clinical repeatability: 0.06℃(0.11℉) ; Limits of agreement: 0.68℃(1.22℉) 1-5 years: Clinical bias: -0.25℃（-0.45℉）; Clinical repeatability: 0.07℃(0.13℉) ; Limits of agreement: 0.73℃(1.31℉) over 5 years: Clinical bias: -0.25℃（-0.45℉）; Clinical repeatability: 0.17℃(0.31℉) ; Limits of agreement: 0.60℃(1.08℉)
Shock	withstands drop of 3 feet
Dimension	148*46.7*68.8mm
Weight	Approx.117 grams(with batteries)
Battery	DC3V(2×AAA battery)
Battery life	Approx. 3000 readings
Applied part	Probe
Expected service life/ Shelf life	Three years
Ingress protecting rating	IP22
Accessories	Battery
Contraindications	None
Bluetooth technical parameters	Modulation mode: GFSK Frequency range: 2400-2483.5MHz Bandwidth occupied: ≤2MHz Transmit power: ≤20db

Troubleshooting

Error message	Problem	Solution
	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.
	The ambient temperature is not within the range between 5℃ and 40℃ (41℉~104℉).	Place the thermometer in a room for at least 30 minutes at room temperature between 5℃ and 40℃ (41℉~104℉)

Troubleshooting

Error message	Problem	Solution
	In Forehead mode: Temperature taken is higher than 43.0 ℃ (109.4℉). In Object mode: Temperature taken is higher than 100 ℃ (212℉).	Read Temperature Taking Hints Thoroughly, then take a new temperature measurement.
	In Forehead mode: Temperature taken is lower than 34.0 ℃ (93.2℉). In Object mode: Temperature taken is lower than 0℃ (32℉).	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.

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.)

Symbol Explanation

	Manufacturer
	General symbol for recovery/recyclable
EU REP	European Union Authorized representative
	Date of manufacture
LOT	Batch Code
UDI	Unique device identifier
-25℃ 55℃	Storage and Transportation Temperature Limit: -25℃~55℃(-13℉~131℉)
	TYPE BF APPLIED PART
	Refer to instruction manual/booklet
70kPa 106kPa	Atmospheric pressure limitation
15% 95%	Storage and Transportation Humidity limitation: 15%~95%RH
	Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products.
IP22	The first num.2:Protected against solid foreign objects of 12,5 mm ∅ and greater. The second num.2:Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
CE 0123	The product conforms to the requirements of the EC Directive MDR(EU) 2017/745 on medical devices
MD	Medical Device
	Caution

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.

Warranty

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.

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.

Electromagnetic Compatibility Information

Table 1

Guidance and manufacturer´s declaration – electromagnetic emission	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emissions test	**Compliance**
Conducted emission CISPR 11	Not applicable
Radiated emission CISPR 11	Group 1 Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable

Electromagnetic Compatibility Information

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
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
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz
Proximity magnetic fields	IEC 61000-4-39	See Table 3
NOTE: UT is the a. c. mains voltage prior to application of the test level.		

Electromagnetic Compatibility Information

Table 3

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.

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

Electromagnetic Compatibility Information

Table 4 continued

NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies.NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM(industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHzto6,795 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,21,0MHz to 21,4MHz,24,89 MHz to 24,99 MHz,28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHZ.

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

c Field strengths from fixed transmitters, such as base stations for radio(cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Electromagnetic Compatibility Information

Table 5

Recommended separation distances between RF wireless communications equipment				
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.				
Frequency MHz	**Maximum Power W**	**Distance**	**IEC 60601 Test Level**	**Compliance Level**
385	1.8	0.3	27	27
450	2	0.3	28	28
710	0.2	0.3	9	9
745				
780				
810	2	0.3	28	28
870				
930				
1720	2	0.3	28	28
1845				
1970				
2450	2	0.3	28	28
5240	0.2	0.3	9	9
5500				
5785				
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

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.