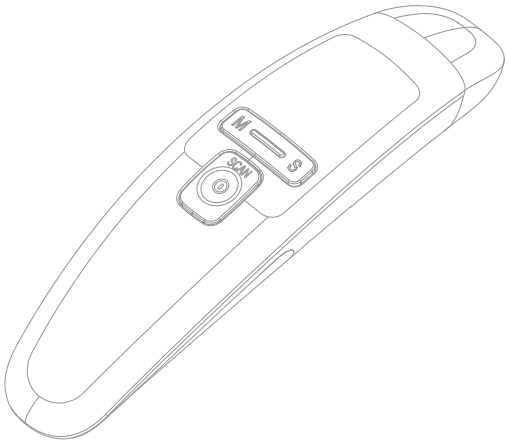
Owner's Manual

Infrared Ear/Forehead Thermometer

Model DS 22



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

EC REP European Authorized Representative:
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Contents

Introduction 02
Product Description 03
Lcd Display Introduction 04
Basic Functions 05
Real Time Clock Setting 06
Body Temperature 08
Illustration For Use 09
Temperature Taking Hints 15
Memory Mode 17
Turn On/Off Beep Sound 18
Care And Cleaning 19
Battery Replacement 21
Specifications 22
Troubleshooting 23
Calibration 25
Service 26
Warranty 27
Electromagnetic Compatibility Information 28

Introduction

The ear/forehead thermometer is intended solely 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.

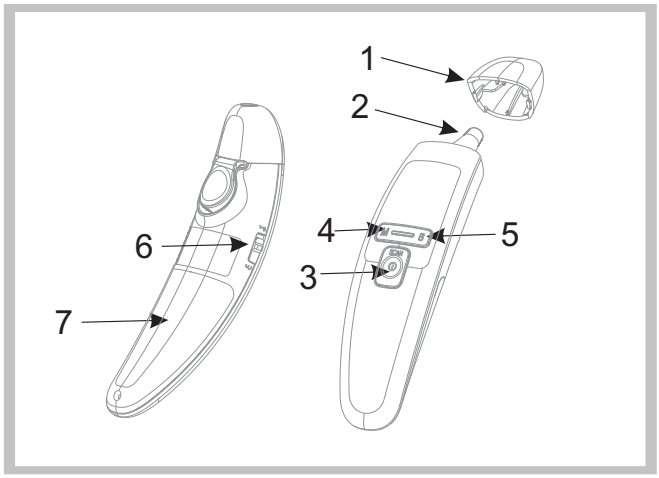
Please read all instructions carefully and thoroughly before using this product.

Warning:

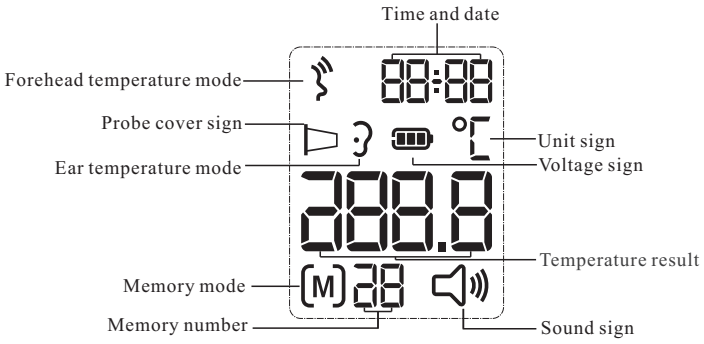
1. It's not meant to replace a visit to the doctor. Please consult with doctor if you have health concerns.
2. There is no gender or age limitation for using infrared ear/forehead thermometer.
3. Do not allow children to take their temperatures unsupervised,some parts are small enough to be swallowed.
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℃/-13℉ or over 55℃/131℉) 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.

Product Description

1. Forehead Cover
2. Probe
3. Scan Button
4. M Button
5. S Button
6. Mode Switch
7. 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.
Beep Alarm	If thermometer detects a body temperature ≥ 37.6℃ under ear mode, there will be a long beep sound followed by three short beep sound to warn the user for potential fever.
Memory Mode	There are 10 sets of memory for ear and forehead measurements. Each memory also records the measurement/date/time/mode icon.
Beep Sound	The thermometer allows to turn on/off beep sound by touching S BUTTON.
Probe cover eject function	The thermometer has been designed for use with or without probe cover. Users can press the eject button to remove the probe cover.
Probe Cover Automatic Detection	Automatic detection function, convenient for test with or without probe cover.

Real Time Clock Setting

When using thermometer for the first time, please set the parameters of the thermometer. With the thermometer power on, press and hold *S BUTTON* to enter into setting mode for 3 seconds.



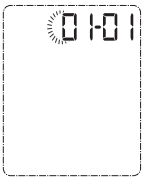
①Set the year

Press and release the *S BUTTON* to advance one year until the correct year appears. After the year is set, press *M BUTTON*, the Month figure will appear.



② Set the month

Press and release the *S BUTTON* to advance one month until the correct month appears. After the month is set, press *M BUTTON*, the Date figure is flashing automatically.



③ Set the date

Press and release the *S BUTTON* to advance one day until the correct day appears. After the day is set, press *M BUTTON*, the Hour figure is flashing automatically.

Real Time Clock Setting



④ Set the hour
Press and release the *S BUTTON* to advance one hour until the correct hour appears.
After the hour is set, press *M BUTTON*, the Minute figure is flashing automatically.



⑤ Set the minute
Press and release the *S BUTTON* to advance one minute until the correct minute appears.
After the minute is set, press *M BUTTON*, the thermometer turns off .

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.

The temperature varies depending on the part of the body where the measurement is taken. The difference can be between 0.2℃(0.4℉) and 1℃(1.8℉) for a healthy person.

The normal temperature ranges are as follows:

- On the forehead: 35.8℃(96.4℉) to 37.6℃(99.7℉) , measured with a forehead thermometer
- In the ear: 36.0℃(96.8℉) to 37.8℃(100.0℉) , measured with an ear thermometer
- In the mouth: 36.0℃(96.8℉) to 37.4℃(99.3℉) , measured with a conventional thermometer

In order to track temperature change, always take the measurements in the same part of the body.

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.

▶ 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.

Illustration For Use

1. Install the forehead cap.
2. Press the *Scan BUTTON* to switch on the thermometer and the display is activated to show all segments.
3. After self-checking, place the switching button on "Forehead", Figure 1 appears on the display screen with beeps, so you can start a new measurement.
4. Press and hold the *Scan BUTTON* to start measurement.
6. Move the thermometer smoothly over the forehead to the other temple and back, the highest value appears on the display.
7. After releasing *the Scan BUTTON*, the result is shown and the end of the measuring is signalled by a short beep.
8. The thermometer will shut off automatically after 60 seconds of inactivity. To prolong battery life, press and hold the *Scan BUTTON* for 10 Seconds to turn the thermometer off.

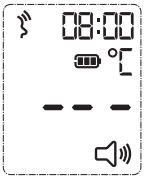


Figure 1

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.
- To achieve accurate readings, 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.

1. Remove the forehead cap.
2. Press the *Scan BUTTON* to switch on the thermometer and the display is activated to show all segments.
3. After self-checking,place the switching button on "Ear", Figure 2 appears on the display screen with beeps, so you can start a new measurement.

   Remarks:

   a. Probe cover sign stand for taking the ear temperature with probe cover now and vice versa.

Illustration For Use

   b. To avoid the risk of cross contamination, it is recommended that you always measure the ear temperature with probe cover.

4. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip. (See Figure 3)
   - When using the thermometer on infants under age 1, pull the ear up making sure the sensor faces the eardrum.(See Figure 4)
   - When using the thermometer on individuals over the age of 1, pull the ear back making sure the sensor faces the eardrum. (See Figure 5).
5. Press the *Scan BUTTON* to start the measurement.
6. The measured value appears on the display and the end of the measuring is signalled by a short beep.

   Note: A waiting period of 20 seconds between testing is recommended to avoid excessive cooling of the skin.
7. The thermometer will shut off automatically after 60 seconds of inactivity. To prolong battery life, press and hold the *Scan BUTTON* for 10 Seconds to turn the thermometer off.

Illustration For Use

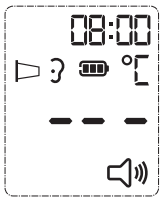


Figure 2

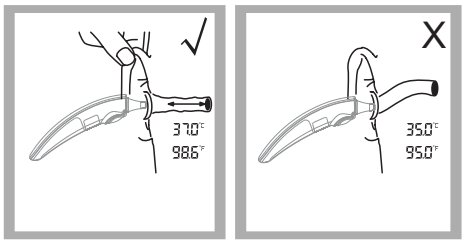


Figure 3

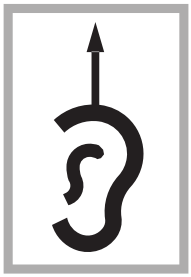


Figure 4



Figure 5

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.)

▶ Temperature indicator:

In Ear/Forehead mode:

1. If the temperature reading is below 37.6℃ (99.7℉) , the light bar above the button will be green.
2. If the temperature reading is 37.6℃ (99.7℉) or above, the light bar above the button will be red.

▶ BackLight:

The display will be lighted blue for 5 seconds when the thermometer is ready for measurement and a measurement is completed.The backlight design is to the benefit of reading in the night .

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.

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.

Memory Mode

1. The Memory Mode can be accessed ether in ear mode or forehead mode:
   When the thermometer has been turned on and followed by the last measured temperature or finished testing, press and release the *M BUTTON*, then the recent memory appears on the display.
2. The thermometer will automatically memorize the last 10 temperature readings. Each memory also records the measurement date/time/mode icon. Each time the *M BUTTON* is pressed, the memory number adds one and the screen shows another memory. The number 1 reflects the most recent reading, while the number 10 reveals the oldest reading stored in memory. (See Figure 6)
3. In the memory mode, The user can press the *Scan BUTTON* to take a new measurement.

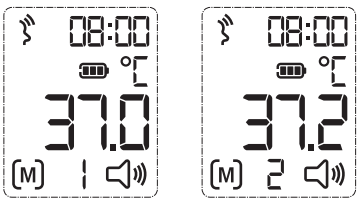


Figure 6

Turn On/Off Beep Sound

1. Turn the thermometer on and wait until the device is ready for use.
2. Press the *S BUTTON* to turn on/off the beep sound. The loudspeaker symbol will be shown when beep sound is turned on.(See Figure 7)

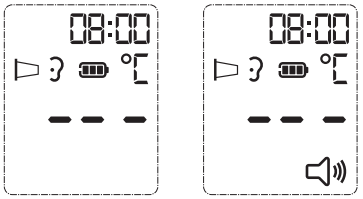


Figure 7

Care And Cleaning

1. Probe covers are intended for single use only!
   Absent, damaged, perforated, or soiled probe covers can lead to inaccurate temperature readings.
2. 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.
3. Fingerprints, earwax, dust and other soiling compounds reduce transparency of the window and result in lower temperature readings. If the thermometer is accidentally placed in the ear without a probe cover installed, the window must be cleaned immediately.
4. 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.
5. Use a soft, dry cloth to clean the thermometer display and exterior.
6. The thermometer is not waterproof. Do not submerge the unit in water when cleaning.

Care And Cleaning

7. Store the thermometer and probe cover in a dry location, free from dust and contamination and away from direct sunlight.
8. 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.
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.

Battery Replacement

1. When " " appears in the middle of LCD (See Figure 8), the battery is low and the thermometer still works. Please replace battery as soon as possible.
2. Slide battery cover down as shown in Figure 9.
3. Remove battery and install 2 new AAA alkaline batteries as shown in Figure 10.
4. Slide battery cover back on.

Figure 8

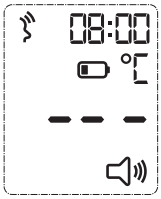


Figure 9

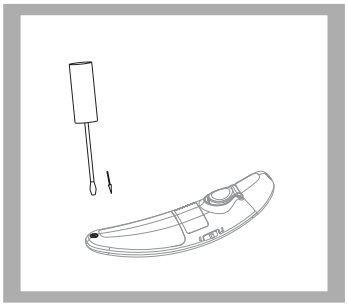
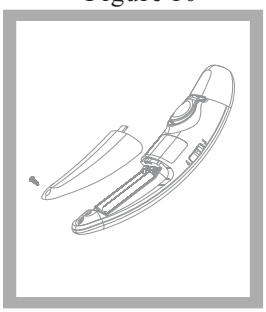


Figure 10



Specifications

Measuring range	34.0℃~43.0℃
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	±0.2℃ during 35.5℃~42.0℃ at 15℃~35℃operating temperature range ±0.3℃ for other measuring and operating temperature range
Display resolution	0.1℃
Measure time	Ear mode mode: Approx. one second Forehead: After releasing *Scan Button* in 10 seconds
Operating temperature range:	10℃~40℃, 15%~85%RH, non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa
Storage and transport temperature range	-25℃~ 55℃ , 15%~95%RH, non-condensing Atmospheric Pressure : 700hPa ~ 1060hPa
Clinical accuracy	0-1 year: Ear temperature: Clinical bias: 0.05℃ ;Clinical repeatability: 0.21℃ ; Limits of agreement: 0.76℃ Forehead temperature: Clinical bias: 0.08℃ ;Clinical repeatability: 0.33℃ ; Limits of agreement: 0.73℃ 1~5 years: Ear temperature: Clinical bias: 0.11℃ ;Clinical repeatability: 0.34℃ ; Limits of agreement: 1.36℃ Forehead temperature: Clinical bias: 0.24℃ ;Clinical repeatability: 0.40℃ ; Limits of agreement: 1.49℃ over 5 years: Ear temperature: Clinical bias: 0.21℃ ;Clinical repeatability: 0.21℃ ; Limits of agreement: 0.99℃ Forehead temperature: Clinical bias: 0.22℃ ;Clinical repeatability: 0.26℃ ; Limits of agreement: 1.10℃
Shock	withstands drop of 3 feet
Dimension	155 × 42× 35mm
Weight	Approx.81grams(with batteries)
Battery	DC3V(2×AAA battery)
Battery life	Approx. 5000 readings
Expected service life/ Shelf life	Three years
Ingress protecting rating	IP22
Accessories	Battery,probe cover
Contraindications	None
Applied part	Probe

Troubleshooting

Error message	Problem	Solution
Er 1	The ambient temperature is not within the range between 10℃ and 40℃.	Place the thermometer in a room for at least 30 minutes at room temperature between 10℃ and 40℃.
Er 2	The thermometer is placedincorrectly or unsteady.	Read Illustration For Use thoroughly and take a new temperature measurement.
Er 3	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.
CAP	The earmuff is detected in forehead mode.	Take off the earmuff or switch to ear mode.
	The thermometer works properly.	Use the thermometer normally
	The batery is getting weak.	Replace the battery as soon as possible.

Troubleshooting

Error message	Problem	Solution
Hi	In Ear/Forehead mode: Temperature taken is higher than 43.0 ℃.	Read Temperature Taking Hints Thoroughly, then take a new temperature measurement.
Lo	In Ear/Forehead mode: Temperature taken is lower than 34.0 ℃.	Read Temperature Taking Hints thoroughly , then make sure the lens filter are clean, then take a new temperature measurement.
Lo	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 two years 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 power button long time until entering into calibrate mode, software version will be displayed.)

TYPE BF APPLIED PART

UDI 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

LOT Batch Code

-25℃ 55℃ Storage and Transportation Temperature Limit: -13℉～131℉(-25℃~55℃)

70kPa 106kPa Atmospheric pressure limitation

MD Medical Device

Date of manufacture

15% 95% 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

CE 0123 The product conforms to the requirements of the EC Directive MDR (EU) 2017/745 on medical devices

EC REP Authorized representative in the European Community

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°

Caution

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. Additionally this warranty becomes void, if the thermometer is operated with anything other than this brand thermometer probe covers.

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**	**Electromagnetic environment – guidance**
Conducted emission CISPR 11	Not applicable	The device 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.
Radiated emission CISPR 11	Group 1 Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	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	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See Table 3	See Table 3
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

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

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.

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.				

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.