# **VEGA TECHNOLOGIES**

# INC.

# INSTRUCTION MANUAL

# Non-contacted Infrared forehead

# thermometer

Model No.: IR-05MT

V3.0

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# Read this instruction manual carefully before use

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# 1. Introduction

Thank you very much for purchasing our Non-contacted Infrared forehead thermometer IR-05MT. To ensure safe and correct use of this device, please read this instruction manual carefully before using. We also recommend you to keep this manual at hand for future reference.

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages. It allows you quickly and easily to measure temperature, and values are saved automatically. The thermometer has been clinically tested and proven to be safe and accurate and no any side effects when used in accordance with the operating instruction manual.

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages

The device has direct mode(object temperature mode) and adjust mode(forehead temperature mode). The direct mode is designed for measuring object temperature, while the adjust mode is designed for measuring human body temperature. Since the direct mode is used to measure surface temperatures of objects, the direct mode does not fall under any medical function with defined target populations or indications.

# 2. Information about the device:

# 2-1. Intended use:

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages. It allows you quickly and easily to measure temperature, and values are saved automatically.

# 2-2. Intended User:

The Non-contacted Infrared Forehead Thermometer is intended for use by qualified medical professional and lay persons.

# 2-3. Intended patients: People of all ages.

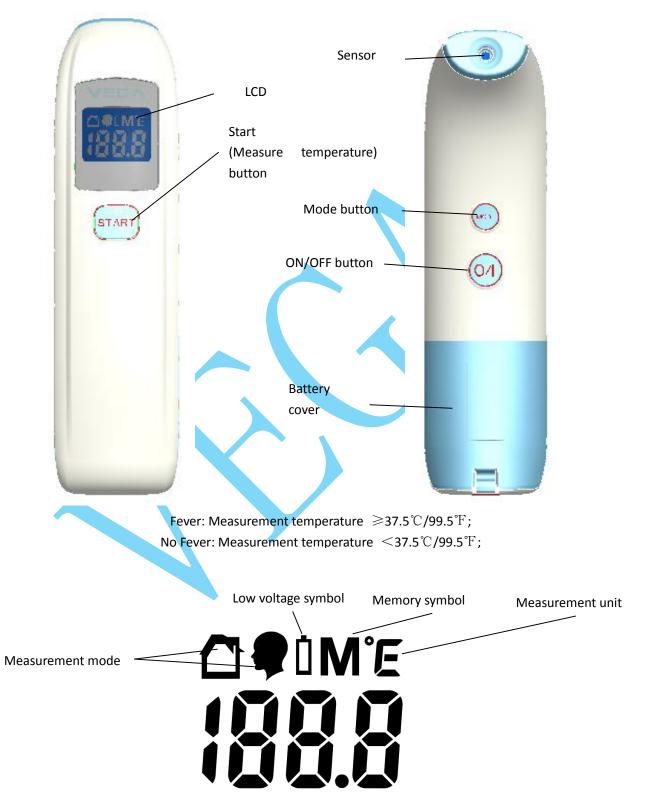
# 2-4. Intended Environment:

This product is intended for use in a medical facility, such as Hospital, clinic and doctors office, and in a room of general household.

# 2-5. Precautions for use:

Warnings and cautions described in the instruction manual should be observed.

# 3. Product description:



# 3-1. Visual appearance and structure

# 3-2. Accessory:

AAA Size (LR03) alkaline battery: 2PCS

# 4. Product features:

- ♦ Ideal design for easy use;
- ♦ Ultra jumbo display, with backlight, easy to read;
- ♦ Non-contact, clean, safety and accurate;
- ♦ Automatic shut off;
- ♦ Beeper alarm;
- ♦ Fast measurement within 1 second;
- ♦ 24 sets memories recall ;
- ♦ °C & °F switchable;
- Two modes: Direct Mode(object temperature mode) and Adjust Mode(forehead temperature mode);
- ♦ Wide range of measurement;
- ♦ Low voltage indication;
- ♦ With AAA size (LR03) alkaline battery (2pcs);
- ♦ Optional storage case and carrying bag for easy storage.

# 5. Device specifications

| NO | Item                | Specification                                    |  |  |
|----|---------------------|--|--|--|
| 1  | Operation mode      | Continuous mode                                  |  |  |
| 2  | Measure mode        | Non-contacted infrared forehead thermometer      |  |  |
| 3  | Product Type        | Internally powered ME equipment                  |  |  |
| 4  | Power supply        | 2 x AAA size (LR03) alkaline battery             |  |  |
| 5  | Classification      | Class II equipment, Type BF applied part         |  |  |
| 6  | Unit                | ℃ / ℉ switchable                                 |  |  |
|    |                     | Direct Mode(object temperature mode):            |  |  |
|    |                     | 0℃- <mark>100</mark> .0℃ (32.0°F-199.9°F)        |  |  |
| 7  | Measuring range     | Adjust Mode(forehead temperature mode):          |  |  |
|    |                     | 34.0℃-43℃ (93.2°F-109.4°F)                       |  |  |
|    | Laboratory accuracy | °C: 34.0≤T<35.5°C & 42.0≤T<43.0°C, ±0.3°C        |  |  |
|    |                     | 35.5≤T<42.0℃, ±0.2℃                              |  |  |
|    |                     | 0≤T<34.0℃ &43.0≤T<70.1℃, ±0.5℃                   |  |  |
| 8  |                     | <b>70.1≤T≤100.0℃</b> , ±1℃                       |  |  |
| ð  |                     | °F: 93.2°F≤T<95.9°F&107.6≤T<109.4°F,±0.6°F       |  |  |
|    |                     | 95.9°F≤T<107.6°F,±0.4°F                          |  |  |
|    |                     | 32.0°F≤T<93.2°F&109.4°F≤T<158.2°F, ±0.8°F        |  |  |
|    |                     | 158.2≤T≤199.0°F,±1.6°F                           |  |  |
| 9  | Resolution          | 0.1°C /0.1°F                                     |  |  |
| 10 | Measure position    | Human forehead or the surface of object          |  |  |
| 11 | Measure speed       | about 2 s  |  |  |
| 12 | Measure distance    | ≤3 cm (the distance between the sensor and being |  |  |
| 12 | ivieasure distance  | measure person forehead or surface of object.)   |  |  |
| 13 | High and low        | Direct Mode(object temperature mode):            |  |  |
| 13 | temperature warning | <0°C: display "Lo";                              |  |  |

|    |   | >100℃: display "Hi "  |  |  |
|----|---|---|--|--|
|    |   | Adjust Mode(forehead temperature mode):                                   |  |  |
|    |   | <34.0°C: display "Lo";  |  |  |
|    |   | >43.0℃: display "Hi";   |  |  |
|    |   | The symbol" Lo" represents low temperature; "Hi"                          |  |  |
|    |   | represents high temperature.  |  |  |
| 14 | Fever temperature (adjust                 | ≥37.5℃(99.5°F)  |  |  |
| 14 | mode)                                     |   |  |  |
|    |   | Open the device: One "Bi" emits;  |  |  |
|    |   | Already for the test: One "Bi" emits;                                     |  |  |
|    |   | Direct Mode(object temperature mode): One "Bi" emits                      |  |  |
| 15 | Sound notice                              | when finish the test  |  |  |
|    |   | Adjust Mode(forehead temperature mode): One "Bi" emits                    |  |  |
|    |   | when body temperature $<$ 37.5 $^\circ\!\mathrm{C}$ ; Six "Bi" emits when |  |  |
|    |   | body temperature≥37.5℃  |  |  |
| 10 | Automatic shut off                        | Stop operating the device, it wills automatic shut off after              |  |  |
| 16 |   | 60 ± 20 seconds.  |  |  |
|    | Low power display                         | Π   |  |  |
| 17 |   | The device will display 🛄 when the battery power is in                    |  |  |
|    |   | the range 2.6V± 0.2V.   |  |  |
| 18 | Memory function                           | 24 sets   |  |  |
| 19 | Working voltage                           | 3V (2pcs AAA size (LR03) alkaline battery)                                |  |  |
| 20 | Work current                              | <1 <mark>0m</mark> A  |  |  |
| 21 | standby current                           | <2uA  |  |  |
| 22 | Battery life                              | At least 3000 measurement   |  |  |
| 23 | Dimension (L x W x H)                     | 150 x 40 x 51mm   |  |  |
|    | Operating Temperature &<br>Humidity Range | 10°C to 40°C (50°F to 104°F);   |  |  |
|    |   | 30% to 85% RH   |  |  |
| 24 |   | Atmospheric pressure:700 hpa~1060 hpa                                     |  |  |
|    |   | Note: if the operation temperature is not in the range from               |  |  |
|    |   | 10°C to 40°C (50°F to 104°F), the device will display "Err".              |  |  |
|    | Storage Temperature &<br>Humidity Range   | -10°C to 60°C (14°F to 140°F)   |  |  |
| 25 |   | 25% to 90 % RH  |  |  |
| 25 |   |   |  |  |
| 25 | Humany Kange                              | Atmospheric pressure:700 hpa~1060 hpa                                     |  |  |
| 25 | lifetime                                  | Atmospheric pressure:700 hpa~1060 hpa<br>2years(300h)                     |  |  |

# 6. Operating Instructions:

# 6-1. Function instructions:

# Please read the following information carefully before measure the temperature.

# 6-1-1. Switch ON/OFF the unit

# A. Power on and self-check function

 $\diamond$  Press the ON/OFF button to switch on the thermometer, it will go directly into

self-check mode in 1 second and then the LCD display all symbol, then shows the last memory temperature and after this, "---  $^{\circ}$ C" or "---  $^{\circ}$ F" will be showed, at the same time, a "Bi" sounds from the buzzer.

♦ At this time, the measurement can start. Press the start button to start the measurement.

#### B. Switch off:

- ♦ After startup, press ON/OFF button and then the unit turn off in the Direct Mode.
- ♦ After startup the unit will be shutdown automatically after 60 seconds if no any operation.

#### **6-1-2.℃/** <sup>°</sup>F switchable:

- Firstly, Press the mode button for about 2 seconds while the device is in ON state.
- ♦ Secondly, the device will come into the switchable state, and display the original setting unit ( $^{\circ}$ C or  $^{\circ}$ F) for 0.5s.
- Then, the automatic switch the other unit as not same as the original setting unit.
- $\diamond$  In the end, waiting for 5 seconds, the switchable unit ( $^{\circ}$  or  $^{\circ}$ F) operation is done.

#### 6-1-3. Direct mode / adjust mode switchable:



Adjust Mode(forehead temperature mode)

Direct Mode(object temperature mode)

——Press the ON/OFF button to switch on the thermometer, it will go directly into self-check mode in 1 second and then the LCD display all symbol, then shows the last memory temperature and after this, "--- C" or "--- F" will be showed directly.

--Then press the mode button, it switches between the direct mode / adjust mode

#### 6-1-4. Memories recall:

- When the device is startup and all symbol display on the screen, the device defaults to display the final measurement result.
- At this time, press start button to enter the memories mode, click start button in order for 1~24 set temperature memories.
- After the 24th set temperature memory, press the start button will loop back in the first set temperature memory.
- During in the "memory recall" mode, if more than 5 seconds no operation, the device will automatically exit the "memory recall" mode.

- When the memory of temperature displays on the screen, at the same time, the screen will display " (adjust mode)" or " (direct mode)" corresponding to indicate that the current memory temperature is the human body temperature (adjust mode) or the object's surface temperature (direct mode).
- During in the "memory recall" mode, press the start button for 3 seconds, it will delete all memory records.

#### 6-1-5. Low power alarm:

When the battery power voltage is in the range 2.6V (±0.2V), the symbol **W** will be light and display in the LCD screen. It means that the user needs to replace new battery.

#### Note: Handle of the new battery need by the adult or the children under adult supervision.

#### 6-2. Measure temperature.

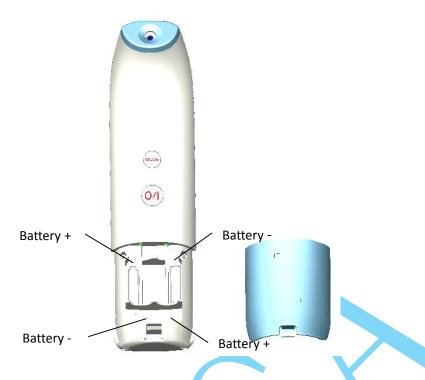
- When the device is in the measure temperature mode, place the sensor head right in front of the measurement position (patient forehead or object) and the distance is not exceed 3cm.
- Secondly, press the start button to measure the temperature. After 1 second, the buzzer makes a "Bi" sound, and the result will display in the LCD screen.
- If you need to measure the person temperature, please choice the adjust mode, and the LCD screen will display the symbol. (Please see the chapter" 6-1-3. Direct mode / adjust mode switchable)
- If you need to measure the object temperature, please choice the direct mode, and the LCD screen will display the symbol. (Please see the chapter" 6-1-3. Direct mode / adjust mode switchable)

#### 6-3. Replacement parts:

There is no part that needs to be replaced by the user except for the AAA size (LR03) alkaline battery.

#### Note: If the device has a long time not to be used, please remove batteries from the device. Batteries replacement process:

- Step1.\_ Push down the battery cover;
- Step2.\_ Take batteries out from the battery slot;
- Step3.\_ Insert the new batteries into the battery slot correctly;
- Step4.\_ Insert and pull up the battery cover.



# 7. Cleaning & Disinfecting

Please keep the device is clean after every use.

- Please use a clean soft cloth or cotton bud that can be moistened with 70% alcohol to clean the sensor.
- The measuring sensor is the most sensitive part of the thermometer, take great care of the measuring sensor when cleaning the device.
- Please use a soft cloth slightly moistened with a mild soapy solution to clean the entire device. Under no circumstances may liquid enter the device. Do not use the device again until it is completely dry.
- ♦ Never use abrasive cleaning agents, thinners or benzene for cleaning.
- ♦ Do not scratch the surface of the lens and the LCD.
- Do not put the device into the water cleaning, in order to avoid damage to the device, use cotton swabs dipped in alcohol or using alcohol content of 70% cotton cloth or cotton to cleaning the enclosure and probe. Please note that don't let the liquid infiltration inside the thermometer, or use any corrosive cleaner, do not soak with water or other solvents or gasoline detergent.

#### 8. Storage/Maintenance/Repair

#### 8-1. Storage

To keep your device in the best condition and protect the device from damage follow these directions:

- Do not leave the device unattended with infants or persons who cannot express their consent.
- Do not subject the device or the parts to any strong shocks such as dropping the device

on the floor.

- Do not use or store the device in extreme hot or cold temperatures, high humidity or under direct sunlight or dust.
- Dispose of the device and any used accessories or optional parts according to applicable local regulations.

# 8-2. Maintenance

- The manufacturer accepts no liability for unauthorized and incorrect reprocessing of this device by external companies!
- The replacement of the battery must only be performed by adult.
- The replacement of the parts must only be performed by the manufacturer or by the distributor.

This device is used only for the purposes described in the instruction. The manufacture shall not be liable for damage caused by incorrect use.

#### Note:

- Those parts of the device that shall not be serviced or maintained while in use with a PATIENT.
- The patient or the user can replace of batteries, and the children use or replace the battery need under the adult supervision.

# 8-3.Repair

- Never open or attempt to repair the device by yourself, as otherwise proper function is no longer guaranteed. Failure to observe this regulation shall void the warranty.
- The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT
- If you need to repair the device, contact your equipment provider or that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

# 9. TROUBLESHOOTING

| Problem/Question | Possible Cause/Remedy |
|------------------|-----------------------|
|                  |                       |

| The device does not work when the switch is pressed | The device does not assemble the batteries or<br>the internal battery may run out of power and<br>need to assemble or replace with new<br>batteries.  |
|---|---|
| The device measure result is not accurate.          | <ul> <li>The measure sensor is dirty, and need to use a clean soft cloth or cotton bud that can be moistened with 70% alcohol.</li> <li>The patient uses the device immediately after exercising or walking a long time. And need to rest for 5 mins to 10mins to measure the temperature.</li> </ul> |
| The device displays the symbol "Err".               | The operation environment temperature<br>changes suddenly, and the temperature<br>difference is greater than $8^{\circ}$ , the device will<br>display "Err". And it just needs to put the<br>device in the operation environment for<br>20mins and more, after that to use the device.                |

# **10. Safety precaution:**

——Indicates a potentially hazardous situation which, if not avoided, could result in serious

injury.

Read all instructions carefully before use.

Warning:

- No modification of this equipment is allowed.
- Skin condition may affect measurement accuracy.
- Check the thermometer for signs of damage or wear before each use. Damaged or worn thermometer should not be used.
- Under any circumstances, the temperature taking result is ONLY for reference. Before taking any medical action, please consult your physician.
- MR UNSAFE: The device cannot be used in an MR environment.

• The user should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

# **10-1.** Product cautions:

- The direct mode shall not be used to measure human body temperature.
- If the sensor is degraded or loosened, and the measure value is incorrectly, please stop using the device immediately and contact your equipment provider.

- To avoid electrical shock: Keep the unit away from water. Do not immerse the unit in liquid. Do not use while bathing. Do not reach for a unit that has fallen into water.
- Never operate the unit if it has any damaged parts, if it has been dropped or submersed in water. Promptly send it to a service center for examination and repair.
- If any abnormality occurs, discontinue use until the unit has been examined and repaired.
- Do not use other attachments unless recommended by manufacturer.
- This device is not a mirrored one.
- Children are not allowed to use the device unwatched, supervision is needed.
- This device is not waterproof and should not be immersed in water or other liquids. If cleaning is required, please follow the instructions in the "clean and disinfect" section. If you think this device is damaged or abnormal, please stop using this device and do not open it without permission.
- Failure to read and observe all precautions could result in personal injury or equipment damage.
- Do not use the device to treat the animals, and keep the device away from the pets to avoid damaging the device.
- If the device does not function correctly, stop using the device immediately.
- Switch the device off immediately if it is defective or malfunctioning.
- Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- Keep children away from packaging materials risk of suffocation.
- Store the parts in a clean location for avoiding infection.
- Do not use the device after exercising, and need to rest for 5 mins to 10mins to measure the temperature.
- Make sure that the sensor is clean before use.
- The unit housing temperature is not exceeding 43°C.
- Protect the device from strong impacts.
- ——Do not use the device if it has fallen or been dropped on the floor, been exposed to extreme humidity or is otherwise damaged in case of doubt, contact our customer service department or your local dealer

#### **10-2.** Operating Cautions:

- Close adult supervision is highly recommended when this unit is used by children or invalids.
- Never operate if this unit has a damaged part, and if it has been dropped into water.

- The operation environment temperature changes suddenly, and the temperature difference is greater than 8°C, the device will display "Err". Please put the device in the operation environment for 20mins and more, after that to use the device.
- Incorrectly selected the measuring temperature mode incorrectly should result in wrong data. Please operated the device according the chapter 6" operating instructions".

# 10-3. Storage Cautions:

- Do not store the unit under direct sunlight, high temperature or humidity.
- Keep the unit out of reach of small children.
- When you are not using the thermometer, please retain it in the storage box.
- Keep the unit stay away from fire and water. Do not test the high temperature or fire so as not to damage the body of the unit.

# **10-4.** Cleaning Cautions:

- Use the cotton buds to clean the probe inside when it has dirt.
- Do not use water or fingers to contact with the probe directly.
- Do not immerse the unit in water. It may damage the unit.

| Refer to instruction<br>manual/booklet |                         |        | Manufacturer           |
|--|-------------------------|--------|------------------------|
| LOT Batch code                         |                         | $\sim$ | Date of manufacture    |
| SN                                     | SN Serial number        |        | Caution                |
| Ŕ                                      | Type BF applied part    | -10°C  | Temperature limitation |
| ×.                                     | Keep away from sunlight |        | Protection class II    |
| Humidity limitation                    |                         | IP22   | Ingress protection     |

# 11. SYMBOL GLOSSARY

|                           | Direct current  |           | Keep away from rain                |
|---------------------------|---|-----------|------------------------------------|
|                           | "ON"/"OFF" (push-push)  | $\langle$ | Alternating current                |
| <b>CE</b> <sub>0123</sub> | This device complies with<br>the requirements of<br>Regulation (EU) 745/2017  | QTY       | Quantity                           |
| <u><u>†</u>†</u>          | This way up   | EC REP    | Authorized representative          |
| Ţ                         | Fragile; handle with care   |           | Atmospheric pressure<br>limitation |
|                           | In according with European<br>directive 2002/96/EC on<br>waste electrical and<br>electronic equipment, this<br>symbol indicates that the<br>product must not be<br>disposed of unsorted<br>municipal waste, but should<br>be collected separately | MD        | Medical Device                     |
|                           | Use by date   |           | 1                                  |

# **12. WARRANTY & DISPOLSAL**

#### Warranty

Vega Non-contacted Infrared forehead thermometer's warranty period is 2 years from date of purchase from VEGA Technologies Inc. The warranty is limited to repair or replacement, at VEGA Technologies Inc. sole option, of any such component or equipment claimed to be defective when claim is shown to be bona fide by evaluation by VEGA Technologies Inc. This warranty does not extend to any components or equipment subjected to misuse, improper operation, accidental damage, or unauthorized repairs, and is not extended to charges of, or for, labor repairs. All items returned must be properly packaged and shipped, prepaid, by the distributor servicing the unit. VEGA Technologies Inc. shall not be liable to purchaser or others for loss of use of equipment or for indirect, or incidental or consequential damages that might arise.

#### Disposal

# Danger of infection!

The device and accessories may come into contact with infectious material and be contaminated during their lifetime. For this reason the device and its accessories should be decontaminated before disposal or transportation.



Dispose of the device properly at the end of its service life. According to the European Directives 2002/96/EC (WEEE) and 2002/95/EC (RoHS) the device may not be disposed of with unsorted domestic waste. Look for a careful separation of materials. Consider the country-specific laws and regulations that apply to the disposal of the device. The proper disposal of the device prevents environmental and human damage.

Outside the EU the appropriate national regulations for disposal must be observed.

The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.

# **13.** Information about Electromagnetic Compatibility

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC). The device needs to be installed and put into service according to the EMC information provided in this chapter.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the device as recommended below.

# Warning:

The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Please avoid using the device immediately after taking a shower or in other scenarios that may impact skin condition and temperature, such as taking temperature readings immediately upon entering the room from outside in the summer or after exercise, as this can impact measurement accuracy. Additionally, please ensure that the sensor head does not exceed a distance of 3 cm from the patient's forehead during temperature measurement.

| Guidance and manufacturer's declaration –electromagnetic emissions |                     |   |  |  |  |
|--|---------------------|---|--|--|--|
| The device is intended f   | or use in the elect | romagnetic environment specified below. The customer  |  |  |  |
| or the user of the device  | e should assure the | at it is used in such an environment.   |  |  |  |
| Emissions test   | Compliance          | Electromagnetic environment - guidance  |  |  |  |
| RF emissions<br>CISPR 11   | Group 1             | 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. |  |  |  |
| RF emissions<br>CISPR 11   | Class B             | The device is suitable for use in all establishments other than domestic and those directly connected to  |  |  |  |
| Harmonic emissions<br>IEC 61000-3-2                                | Not applicable      | the public low-voltage power supply network that supplies buildings used for domestic purposes.   |  |  |  |
| Voltage fluctuations /<br>flicker emissions<br>IEC 61000-3-3       | Not applicable      |   |  |  |  |

Table 1

| discharge (ESD)P±8 kV air± 8 kV airceramic tile. If floors are covered<br>with synthetic material, the relative<br>humidity should be at least 30 %.Electrical fast<br>transient/burst<br>IEC 61000-4-4±2 kV for power<br>supply lines<br>±1 kV for<br>input/output<br>linesNot applicableMains power quality should be that<br>of a typical commercial or hospital<br>environment.Surge<br>LEC 61000-4-5±1 kV for<br>input/output<br>line(s)Not applicableMains power quality should be that<br>of a typical commercial or hospital<br>environment.Voltage<br>voltage variations<br>on power supply<br>input lines×5 % UT<br>(59 % dip in<br>UT)<br>for 0.5 cycles<br>< % dip in UT)<br>for 5 cycles<br>< % dip in UT)<br>for 5 cycles<br>< % % dip in<br>UT)Not applicableMains power quality should be that<br>of a typical commercial or hospital<br>environment.IEC 61000-4-11(60 % dip in UT)<br>for 5 cycles<br>< % W dip in<br>UT)<br>for 5 cycles<br>< 5% W dip in<br>UT)<br>for 5 sNot applicablePower frequency<br>(50/60 Hz)3 A/m3 A/mPower frequency magnetic fields<br>should be at levels characteristic of a<br>typical location in a typical<br>commercial or hospital environment.   |  | Table 2   |                       |   |  |  |  |  |
|--|--|---|-----------------------|---|--|--|--|--|
| The customer or the user of the device should assure that it is used in such an environment.       Immunity test       IEC 60001 test level       Compliance level       Electromagnetic environment – guidance         Electrostatic discharge (ESD)       IB±6 kV contact       ± 6 kV contact       ± 6 kV contact       # 6 kV contact       Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.         Electrical fast transient/burst IEC 61000-4-4       ± 2 kV for power supply lines       Not applicable       Mains power quality should be that of a typical commercial or hospital environment.         Surge       ± 1 kV line(s) to line(s)       Not applicable       Mains power quality should be that of a typical commercial or hospital environment.         Voltage       dips, <5% UT   | Guid   | ance and manufact   | turer's declaration – | electromagnetic immunity  |  |  |  |  |
| Immunity test     level     Compliance level     guidance       Electrostatic<br>discharge (ESD)     I∄±6 kV contact     ± 6 kV contact     Floors should be wood, concrete or<br>ceramic tile. If floors are covered<br>with synthetic material, the relative<br>humidity should be at least 30 %.       Electrical fast<br>transient/burst<br>IEC 61000-4-4     ± 2 kV for power<br>supply lines     Not applicable     Mains power quality should be that<br>of a typical commercial or hospital<br>environment.       Surge     ± 1 kV for<br>input/output<br>lines     Not applicable     Mains power quality should be that<br>of a typical commercial or hospital<br>environment.       Voltage dips,<br>short     <5 % UT<br>(>95 % dip in<br>UT)     Not applicable     Mains power quality should be that<br>of a typical commercial or hospital<br>environment.       IEC 61000-4-11     for 0.5 cycle<br>40 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in<br>UT)     Not applicable     Mains power quality should be that<br>of a typical commercial or hospital<br>environment. If the user of the<br>device requires continued operation<br>during power mains interruptions, it<br>is recommended that the device be<br>powered from a continuous power<br>supply or a battery.       IEC 61000-4-11     3 A/m     3 A/m     Power frequency magnetic fields<br>should be at levels characteristic of a<br>typical location in a typical<br>commercial or hospital environment.  |  |   |                       |   |  |  |  |  |
| discharge (ESD)P±8 kV air± 8 kV airceramic tile. If floors are covered<br>with synthetic material, the relative<br>humidity should be at least 30 %.Electrical fast<br>transient/burst<br>IEC 61000-4-4±2 kV for power<br>supply lines<br>±1 kV for<br>input/output<br>linesNot applicableMains power quality should be that<br>of a typical commercial or hospital<br>environment.Surge<br>LEC 61000-4-5±1 kV for<br>input/output<br>linesNot applicableMains power quality should be that<br>of a typical commercial or hospital<br>environment.Voltage<br>voltage variations<br>on power supply<br>input linesSorgeNot applicableIEC 61000-4-11(59 % dip in<br>UT)<br>for 5 cycles<br>< 5% UT<br>(50 % dip in UT)<br>for 5 cyclesNot applicableIEC 61000-4-11Mains power quality should be that<br>of a typical commercial or hospital<br>environment.IEC 61000-4-11(60 % dip in UT)<br>for 5 cycles<br>< 5% UT<br>(s95 % dip in<br>UT)<br>for 5 cycles<br>< 5% UT<br>(s95 % dip in<br>UT)<br>for 5 sPower frequency<br>(50/60 Hz)3 A/m3 A/mPower frequency<br>(50/60 Hz)3 A/mIEC 61000-4-83 A/m  | Immunity test  | Immunity test   |                       |   |  |  |  |  |
| Electrical fast<br>transient/burst<br>IEC 61000-4-4       ±2 kV for power<br>supply lines<br>±1 kV for<br>input/output<br>lines       Not applicable       Mains power quality should be that<br>of a typical commercial or hospital<br>environment.         Surge       ±1 kV line(s) to<br>line(s)       Not applicable       Mains power quality should be that<br>of a typical commercial or hospital<br>environment.         EEC 61000-4-5       ± 2 kV line(s) to<br>line(s)       Not applicable       Mains power quality should be that<br>of a typical commercial or hospital<br>environment.         Voltage       dips,<br>short       <5 % UT<br>(>95 % dip in<br>UT)<br>for 0.5 cycle       Not applicable       Mains power quality should be that<br>of a typical commercial or hospital<br>environment.         IEC 61000-4-11       60 % dip in UT)<br>for 5 cycles       Not applicable       Mains power quality should be that<br>of a typical commercial or hospital<br>environment. If the user of the<br>device requires continued operation<br>during power mains interruptions, it<br>is recommended that the device be<br>powered from a continuous power<br>supply or a battery.         IEC 61000-4-11       70 % UT<br>(30 % dip in UT)<br>for 5 cycles<br>< 5 % UT<br>(>95 % dip in<br>UT)<br>for 5 s<br>(>95 % dip in<br>UT)<br>for 5 s       3 A/m         Power frequency<br>(50/60 Hz)       3 A/m       Power frequency magnetic fields<br>should be at levels characteristic of a<br>typical location in a typical<br>commercial or hospital environment. | Electrostatic<br>discharge (ESD)<br>IEC 61000-4-2  |   |                       | Floors should be wood, concrete or<br>ceramic tile. If floors are covered<br>with synthetic material, the relative<br>humidity should be at least 30 %. |  |  |  |  |
| IEC 61000-4-5line(s)<br>± 2 kV line(s) to<br>earthof a typical commercial or hospital<br>environment.Voltage dips,<br>short<br>interruptions and<br>voltage variations<br>on power supply<br>input lines<5 % UT<br>(>95 % dip in<br>UT)<br>for 0.5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(30 % dip in UT)<br>for 25 cycles<br>  | Electrical fast<br>transient/burst<br>IEC 61000-4-4  | supply lines<br>±1 kV for<br>input/output   | Not applicable        | Mains power quality should be that<br>of a typical commercial or hospital   |  |  |  |  |
| short<br>interruptions and<br>voltage variations<br>on power supply<br>input lines<br>IEC 61000-4-11<br>Power frequency<br>(50/60 Hz)<br>magnetic field<br>IEC 61000-4-8   | Surge<br>IEC 61000-4-5   | line(s)<br>± 2 kV line(s) to  | Not applicable        | Mains power quality should be that<br>of a typical commercial or hospital<br>environment.   |  |  |  |  |
| (50/60 Hz)<br>magnetic field<br>IEC 61000-4-8  | short<br>interruptions and<br>voltage variations<br>on power supply<br>input lines<br>IEC 61000-4-11 | (>95 % dip in<br>UT)<br>for 0.5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in<br>UT) | Not applicable        |   |  |  |  |  |
| NOTE UT is the a.c. mains voltage prior to application of the test level.  | Power frequency<br>(50/60 Hz)<br>magnetic field<br>IEC 61000-4-8                                     | 3 A/m   | 3 A/m                 | typical location in a typical   |  |  |  |  |
|  | NOTE UT is th  | NOTE UT is the a.c. mains voltage prior to application of the test level.   |                       |   |  |  |  |  |

Table 2

Table 3

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

| Conducted<br>RF<br>IEC<br>61000-4-6<br>Radiated RF<br>IEC<br>61000-4-3  | 80MHz<br>3V/m | o Not<br>applicable<br>3V/m | Portable and mobile RF communications<br>equipment should be used no closer to any part<br>of the device, including cables, than the<br>recommended separation distance calculated<br>from the equation applicable to the frequency of<br>the transmitter.<br>Recommended separation distance<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80MHz to 800MHz<br>$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz<br>where P is the maximum output power rating of<br>the transmitter in watts (W) according to the<br>transmitter manufacturer and d is the<br>recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as<br>determined by an electromagnetic site survey,<br>should be less than the compliance level in each<br>frequency range. Interference may occur in the<br>vicinity of equipment marked with the following<br>symbol:<br>((•)) |  |  |
|---|---------------|-----------------------------|--|--|--|
|   |               |                             | equency range applies.   |  |  |
|   | -             |                             | objects and people.  |  |  |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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 reorienting or relocating the device. |               |                             |  |  |  |
| b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.   |               |                             |  |  |  |
| Table 4   |               |                             |  |  |  |
| Recommended separation distances between<br>portable and mobile RF communications equipment and the device  |               |                             |  |  |  |
| The device is   |               |                             |  |  |  |
|   |               |                             | ctromagnetic environment in which radiated RF<br>or the user of the device can help prevent  |  |  |

disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| Rated                        | Separation distance according to frequency of transmitter m |                    |                   |  |  |
|------------------------------|---|--------------------|-------------------|--|--|
| maximum<br>output            | 150kHz to 80MHz   | 80MHz to 800MHz    | 800MHz to 2.5GHz  |  |  |
| power of<br>transmitter<br>W | d = 1.2 $\sqrt{P}$  | d = 1.2 $\sqrt{P}$ | d =2.3 $\sqrt{P}$ |  |  |
| 0.01                         | 0.12  | 0.12               | 0.23              |  |  |
| 0.1                          | 0.38  | 0.38               | 0.73              |  |  |

| 1   | 1.2 | 1.2 | 2.3 |
|-----|-----|-----|-----|
| 10  | 3.8 | 3.8 | 7.3 |
| 100 | 12  | 12  | 23  |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

| reference body site: axilla ; measuring site: forenead |                 |              |              |          |            |  |  |  |
|--|-----------------|--------------|--------------|----------|------------|--|--|--|
| Clinical bias(△cb)                                     |                 |              | -0.9 ~ -0.13 |          |            |  |  |  |
| Limits of agreement(LA)                                |                 |              | 0.51 ~ 0.84  |          |            |  |  |  |
| Clinical repeatability(or)                             |                 |              | 0.20 ~ 0.26  |          |            |  |  |  |
| Table6 Accessory battery description                   |                 |              |              |          |            |  |  |  |
| Accessory<br>name                                      | Model           | Specificatio | ons          | Supplier | Photograph |  |  |  |
| battery  | AAA size (LR03) | 1.5V         |              | Excell   |            |  |  |  |
| battery  | AAA size (LRO3) | 1.5V         |              | Maxell   |            |  |  |  |

# **14. Contact information**



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reference body site: axilla ; measuring site: forehead

**CE** 0123

