Guidance and manufacturer's declaration - electromagnetic immunity

The IET2 Device is intended for use in the electromagnetic environment specified below.

The customer or the user of the IET2 Device should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 Ghz	3 A/m	Portable and mobile RF communications equipment should be used no closer to any part of the IET2 Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance : $\frac{d}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{80}{2} \cdot \frac{80}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{80}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{800}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{800}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{800}{2} \cdot \frac{1.2\sqrt{P}}{2} \cdot \frac{1.2\sqrt{P}}$

NOTE 1: At 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. 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 the oretically 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 IET2 Device is used exceeds the applicable RF compliance level above, the IET2 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 IET2 Device.

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

Recommended separation distances between portable and mobile RF communications equipment and the IET2 Device

The IET2 Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IET2 Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IET2 Device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter					
power of transmitter	150 kHz to 80 Mhz $d = 1.2\sqrt{P}$	80 MHz to 800 Mhz d 1.2 \sqrt{P}	800 MHz to 2,5 Ghz $d=2.3\sqrt{P}$			
0.04						
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			



REP Kinetik Medical Devices Ltd,

IET2 IB UK 20180525



Inner Ear Thermometer

REF IET2

Scan buttor

User Instructions

Please read the instructions carefully before using.

The ear thermometer is a device capable of achieving infra-red temperature measurement when placed in the auditory canal of a subject. It is a safe means of measuring human body temperature through the ear.

Specification

The standard we adopted is EN12470-5:2003 Clinical thermometers -- Part 5: Performance of infrared ear thermometers (with maximum device).

Probe membrane

Batterry cover

Disposable probe cove

Probe cap

This device complies with the requirements of IEC 60601-1,IEC 60601-1-11 and IEC 60601-1-2.

Range of displayed temperature : $34\degree -44\degree (93.2\degree -111.2\degree)$ Display L°(L°F) when the temperature is under $34\degree (93.2\degree)$ Display H°(H°F) when the temperature is over $44\degree (111.2\degree)$

Operating ambient:

Temperature: 16°C~35°C(60.8°F~95.0°F) Humidity: ≤80%rh

Storage and transport condition:

Temperature: -10°C to 55°C(14°F to 131°F) Humidity: 30%rh to 90%rh

Display resolution temperature range: $0.1^{\circ}C(0.1^{\circ}F)$

Accuracy: $\pm 0.2^{\circ}$ C (from 35.5°C to 42.0°C) $\pm 0.4^{\circ}$ F (from 96.0°F to 107.6°F)

Display: liquid crystal display, 4 digits

temperature value: display the maximum temperature in measuring process

temperature unit: centigrade or fahrenheit display of memory: last ten memories

low battery warning: the LCD display = 1 and then a beep sound is heard

Power consumption: ≤ 30 mW

Battery: two 1.5V alkalescence batteries (AAA)

Battery life: 4000 takes or 6 months with 3-min.usege per day

Dimension: 134mm by 37mm by 67mm

Net weight: 74g

Beeper sign: on/off, measuring finish and low voltage warning, etc.

 $\textbf{Self-testing sequence:} \ Press\ the\ \textbf{'on/recall'}\ button\ to\ turn\ on\ the\ thermometer\ and\ all\ of\ symbol$

(See Fig A) should be displayed on the LCD in one second.

Calibration: This thermometer is calibrated at the time of manufacture. If the thermometer is used

according to the instructions, periodic re-calibration is not required.

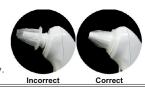
Manufacturing Batch code: see the label within the battery compartment.

⚠ Cautions

- 1. Condition the thermometer at room temperature for 30 minutes before taking a reading.
- 2. Use a new probe cover with each and every measurement to prevent inaccurate readings.
- 3. Please keep your ear canal clear, if not, the measuring result shall be inaccurate.
- 4. The '?' symbol on the display indicates the device is ready for use.
- 5. Do not scratch the probe membrane as this will affect the accuracy of measurements.
- 6. If the LCD does not change or respond when you press any of the buttons, remove the batteries and then replace to reset.
- 7. Please don't use the thermometer if your ear canal has become inflamed. Do not force the thermometer into the ear canal. If pain occurs, stop using immediately.
- 8. Do not expose this thermometer to electric shock.
- 9. Do not expose the thermometer to sunlight or to water.
- 10. Do not use near strong electromagnetic fields, i.e. Keep it away from any radio systems and mobile phones.
- 11. Do not modify this device without authorization of the manufacturer.
- 12. This device must always be kept in a clean, dry area.
- 13. 🖈 : Degree of protection against electric shock is Type BF applied part.
- 14. 🕮: Battery disposal should be completed in accordance with local regulations.

Note:

- In order to avoid the spreading of germs, use a new probe cover for each measurement
- Check to ensure probe cover is fitted on firmly before use (please see the diagrams right).
 - If the probe cover is broken, discard and apply a new one immediately.



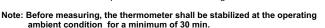
How to use (°C displays for example) Measuring human body temperature in the Ear Canal

- 1. Press the 'on/recall' button to turn on the thermometer. After the beep the thermometer will be ready to read when the LCD display matches Fig B.
- 2. Straighten the ear canal by pulling the outer ear up and back to give a clear view of the eardrum.
- For children under 1 year, Pull the ear straight back.
- · For children ages 1 year to adult, Pull the ear up and back. (Caution: Many pediatricians suggest use of ear thermometers for children older than 6 months.)



- 3. While pulling the outer ear, insert the probe snugly into the ear canal (insert as deep as is comfortable, do not force, the probe into the ear canal). Press and immediately release the 'SCAN' button. Do not remove the thermometer from the ear until you hear the beep sound - this beep means that the measurement is complete. Remove the thermometer from the ear. The display shows the measured temperature.
- 4. Repeat measurements: wait at least 1 minute between measurements. Ensure the Ear symbol is visible in the LCD.
- 5. Memory seach: Press the 'on/recall' button, the last ten memories (NO.9-NO.0) will take turns to display on the LCD as Fig C and Fig D.







7. Shut off: The thermometer shall automatically shut off without manipulating in one minute.

Changing from Celsius to Fahrenheit

To switch the display between °C and °F, turn the unit on. Press and hold the on/recall button for 3 seconds, the display will show as Fig. F, the unit will prepare for a measurement.



Explanation of symbols

battery is empty Product disposal instructions

The battery in this product complies with the LC or LF subject temperature is under 34°C.

REF Model Reference M Memory Type BF equipment Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"

or A Read IFU carefully HC or HF subject temperature is above 44℃

RE Authorised representative in the european community Symbol for "MANUFACTURER" Classification according to the degree of protection against ingress of water as detailed in IEC 529 LOT Lot Number

Product disposal

Please ensure environmental protection. Batteries do not belong in the domestic waste. Please hand them in at collection point or the municipal recycle material centre as special waste. This symbol on products and/or accompanying documents means that consumed electronic products must not be mixed with conventional domestic waste. Take these products to the corresponding collection points for correct treatment and reycling, where they will be accepted free of charge. For more information on the closeset collection point. Please enquire with your local authorities.

Cleaning and Storage

1. Store thermometer and the Disposable probe covers in a dry location free from dust and contamination and away from direct sunlight. The ambient temperature at the storage location should remain fairly constant and within the range of -10°C to 55°C.



- 2. Use an alcohol swab or cotton swab moistened with alcohol (70% Isopropy) to dean the thermometer casing and the measuring probe before each use. Ensure that no liquid enters the interior of the thermometer
- 3. Never use abrasive cleaning agents, thinners or gasoline for cleaning and never immerse the instrument in water or other cleaning liquids. Take care not to scratch the surface of the probe membrance or display.

Replacing the batteries

- 1. When voltage of the batteries are low, the LCD will display ' symbol, please replace two new batteries in unit. Thethermometer cannot work accurately under the condition of low voltage.
- 2. The thermometer is supplied with two 1.5VALKALESCENCE BATTERIES (AAA). Insert new batteries when the low battery symbol appears on the LCD.
- 3. Remove the battery cover and take out the old batteries.
- 4. Place two new batteries according to the '+' or '-'
- 5. Please take out the batteries to avoid battery leaking if unit not used for over six months.
- 6. The disposal of the probe cover, battery and device shall comply with the local environment requirements. The lithium battery or fuel cell may lead to excessive temperatures, fire or explosion.

Guarantee

This product is guaranteed for a period of one year from the date of purchase against mechanical and electrical manufacturing defects. There are no serviceable parts inside this device. Any attempted repair by unauthorised persons invalidates the warranty. In the unlikely event that you experience a problem, please return it to the retailer where you made the purchase, along with your receipt. This does not affect your statutory

Guidance and manufacturer's declaration - electromagnetic emissions

The IET2 Device is intended for use in the electromagnetic environment specified below. The customer or the user of the IET2 Device should assure that it is used in such an environment.					
Emissions test	Compliance	Electromagnetic environment - guidance			
RF emissions CISPR 11	Group 1	The IET2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.			
RF emissions CISPR 11	Class B				
Harmonic emissions IEC 61000-3-2	Not applicable	including domestic establishments and those directly connected to			
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	the public low-voltage power supply network that supplies building used for domestic purposes.			

Guidance and manufacturer's declaration - electromagnetic immunity

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IMMUNITY test	IEC 60601 test level	Compliance	Electromagnetic environment - guidance					
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 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 %.					
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.					