



This equipment needs to be installed and put into service in accordance with the information provided in this manual

# INTRODUCTION

This Thermometer is intended to be used as the intermittent measurement of human body temperature for people of all ages in the home environment.

Utilizing infrared technology, this thermometer takes temperatures in seconds by measuring heat generated by the ear. This product conforms to the provisions of the EC directive MDD(93/42/EEC). Its advantages include:

- 1 Far measurement
- 2. Probe cover not required
- 3. Waterproof probe design
- 4. One-second reading
- 5. Auto power off for power saving
- 6. Low-battery Indicator
- 7. Warning indication indications for battery condition and measuring range.
- 8. Jumbo LCD Display
- 9. Memory function

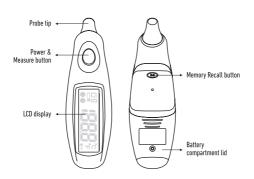
# IMPORTANT INFORMATION BEFORE USE

When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

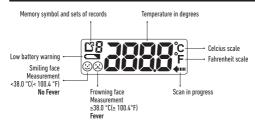
- Do not disassemble, repair, or remodel the thermometer.
- 2. Be sure to clean the thermometer lens each time after usage.
- 3. Avoid direct finger contact with the lens.
- 4. No modification of this equipment is allowed.
- It is recommended that user may take 3 temperatures. If they are different, use the highest reading.
- Do not expose the thermometer to extreme temperature, very high humidity, or direct sunlight.
- 7. Avoid extreme shock or dropping the device.
- Before the measurement, users and thermometer should stay in steady state room condition for at least 30 minutes.
- Avoid measuring temperature for 30 minutes after exercise, bathing, or returning from outdoors.

- To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.
- 11. It is ill-advised to disassemble the thermometer.
- 12. Please use the thermometer solely for its intended purpose.
- 13. Carefully hold the device when in use to avoid dropping the device.
- Allow one minute between successive measurements as slight variations may occur if measurements are taken over a short period of time. Use average temperatures instead.
- 15. There are no absolute body temperature standards. Keep reliable records of your personal temperature to serve as a reference for judging a fever.
- Under any circumstances, the temperature taking result is ONLY for reference.
   Before taking any medical action, please consult your doctor.
- 17. It is recommended calibrate the device every 1 year.

# PRODUCT IDENTIFICATION



# DESCRIPTION OF LCD DISPLAY



# TIPS FOR MEASURING HUMAN TEMPERATURE

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.

NOTE:

- 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.
- The ear thermometer may be used by children only under adult supervision.
   Measurement is usually possible over the age of 6 months. In infants under 6 months, the ear canal is still very narrow so the temperature of the eardrum often cannot be recorded and the result disolaved is often too low.
- The measurement must not be taken in an ear affected by inflammatory diseases (e.g. discharging pus or secretion), after possible ear injuries (e.g. eardrum damage) or in the healing period after operative procedures. In all of these cases, please consult your doctor.
- Use of the thermometer on different persons can be inappropriate in the event of certain acute infectious diseases because of the possible spread of germs despite cleaning and disinfection. If you have any doubts, please consult your doctor.
- This thermometer may only be used without a disposable protective cover.
- If you have been lying on one ear for some time, the temperature is slightly raised.
   Wait 60 seconds or measure in the other ear.
- As ear wax can affect the measurement, you should clean the ear before measuring
  if necessary.

# MEASURING BODY TEMPERATURE IN THE EAR

 Press the Power & Measure Button for 1 second to switch the thermometer on. All screen data will display on screen. Then wait for beep sound to let you know the appliance is ready and followed by last temperature reading.



Make sure that the sensor tip and also the ear canal are clean. As the ear canal is slightly curved, you have to pull the ear slightly up and backwards before inserting the sensor tip. This is important so that the sensor tip can be pointed directly at the eardrum.





# Under 1 year

Have child lay flat with the head sideways, so that the ear is facing upwards. Gently pull the ear straight back.



#### 1 vear +

Stand behind and slightly to the side of the child/adult. Gently pull the ear up and back to straighten the ear canal.

- Insert the probe into the ear canal (the probe must insert well to ensure an accurate temperature measurement), then press the Power & Measure Button for about 1 second, release the button and you will hear 1 short beep sound means complete the measurement.
- 4. You may take out the device to read the measurement result.
- The backlight display will remain light for approximately 5 seconds each time the Power & Measure Button is pressed, after each reading is completed, and each time the Memory button is pressed to recall a previous reading.
- 6. The thermometer will automatically shut off after one minute without use.

#### NOTE:

- 7. To ensure accuracy, please wait at least 1 minute between successive readings.
- Clean the thermometer lens again after use. After cleaning, wait at least 10 minutes between readings, to ensure accuracy.

#### The readings

If the temperature measurement is below 38 °C (100.4°C), a smiling face © will be appear next to the reading.

If the reading is 38 °C (100.4 °C) or above, a frowning face 2 will be displayed.





# CHANGING THE MEASUREMENT UNIT (°C/°F)

Changing °C/ °F, please make sure the device is in power on condition. Press the Power & Measure and Memory Recall buttons together to togqle between °C and °F.



# MEMORY FUNCTION

You can recall up to 10 stored measurements in memory to share with your doctor or trained healthcare professional.

- Press the Memory Recall button. The first reading displayed is the latest measurement stored in memory.
- Continue to press the Memory Recall button button to view the next previously stored measurement.
- Any new measurement will be recorded and the oldest memory deleted without you having to do anything.





# CLEANING AND DISINFECTING

For home use device disinfection, 70% Ethanol or Isopropyl alcohol (available in the pharmacy) can be used.

Clean the measuring sensor after each use.

Use a clean cloth or cotton bud that can be moistened with 70 % alcohol.



Gently clean with an alcohol swab.

Do not use water to wash the thermometer lens directly.



Clean with a soft, dry cloth.

Do not use water to rinse the device.







# APPLIED STANDARDS

This product conforms to the provisions of the EC directive MDD(93/ 42/ EEC). The following standards apply to design and/or manufacture of the products:

#### 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/EN 60601-1

Medical electrical equipment- Part 1: General requirement for safety

### IEC/EN 60601-1-2

Medical electrical equipment- Part 2: Collateral standard: Electromagnetic compatibility - Requirements and tests

#### IEC/EN 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

# BATTERY INSTALLATION

#### Low battery warning

When the batteries get weak, the battery warning symbol appears — It is still possible to measure temperature. The batteries must be replaced. When the battery symbol



flashes and Lo appears in the display, the batteries must be replaced. If the batteries are too flat, then the thermometer will switch off automatically.

#### NUTE:

- It is recommended to remove the batteries if the unit will not be used for an extended period of time.
- · Please store batteries away from small children and heat.
- · Do not use rechargeable batteries.
- Dispose of used batteries in accordance with the applicable legal regulations.
   Never dispose of batteries in the normal household waste.

#### Replacing the Battery

- Use a Phillips head screwdriver to loosen battery cover screw. Remove the battery cover.
- 2. Remove used battery.
- Replace with a lithium 3V CR2032 battery in designated area. The + sign on the battery should be facing upwards.
- Place the battery cover on the thermometer and tighten the screw to secure it in place.



# BATTERY SAFETY WARNING

#### WARNING

A BUTTON/COIN BATTERY ring can cause severe or fatal injuries

Keep batteries out of reach of children (whether new or used).

If you think batteries may have been swallowed or placed inside any part of the body, seek



Swallowing can cause severe or fatal injuries within 2 hours.

Keep batteries out of reach of children (whether new or used).

If you think batteries may have been swallowed or placed inside any part of the body. seek immediate medical attention

CAUTION: Vigilance must be maintained with "flat" or spare button or coin batteries in the home and the products that contain them.

There are no obvious specific symptoms when a button or coin battery is stuck in a child's oesophagus (food pipe). However, the child might exhibit the following symptoms:

- Excessive coughing, gagging or drooling
- Appear to have a stomach upset nr virus
- Vomiting
- Pointing to their throat or stomach
- Pain in their ahdomen, chest or throat
- · Tiredness and lethargy
- · Be quieter or more clingy than usual
- · Loss or reduction of appetite
- · Refusal or inability to eat solid foods

A specific symptom of button or coin battery ingestion is vomiting fresh (bright red) blood. Seek immediate medical attention if this occurs.

If a button/coin battery is ingested, please contact the Poisons Information Centre on 131126 immediately for further advice on what actions to take.

# CLINICAL ACCURACY VALIDATION METHOD

This device is an adjusted mode clinical thermometer

the validated information for clinical accuracy in each adjusted mode are:

 GroupA1:
 ∆cb=-0.01 °C, L₁=0.18, δr = ±0.08 °C

 GroupA2:
 ∆cb= 0.06 °C, L₄=0.22, δr = ±0.08 °C

 GroupB :
 ∆cb=-0.01 °C, L₄=0.20, δr = ±0.07 °C

 GroupC :
 ∆cb=-0.01 °C, L₄=0.18, δr = ±0.07 °C

Δcb: CLINICAL BIAS

La: LIMITS OF AGREEMENT

δr: CLINICAL REPEATABILITY

# ERROR CODES

When a malfunction or incorrect temperature measurement occurs, an error message will appear as described below.

LCD Display	Cause	Solution
Lo	The temperature measured is lower than 34 °C (93.2 °F)	Operate the thermometer only between the specified temperature
Ж.	The temperature measured is higher than 43 °C (109.4 °F)	ranges. If necessary, clean the sensor tip. In the event of a repeated error message, contact your retailer or Customer Services.
Err	The operating temperature is not in the range 15 °C~35 °C (59 °F~95 °F)	Operate the thermometer only between the specified temperature ranges.

# TECHNICAL SPECIFICATION

- Measuring range: Human Body: 34 °C ~43 °C (93.2 °F ~ 109.4 °F)
- Laboratory Accuracy: 34 °C ~43 °C±0.2 °C (93.2 °F ~ 109.4 °F ±0.4 °F)
- Measuring site: Ear

- · Reference body site: Oral
- · Calibration Accuracy:
  - ±0.2 °C(±0.4 °F): from 35 °C ~42 °C (95 °F ~ 107.6 °F)
  - ±0.3 °C(±0.5 °F): out of range
- Display resolution: 0.1 °C/°F
- Operating environment:
- 15 °C~35 °C (59 °F ~ 95 °F) with relative humidity up to 95 % (non condensing)
- Storage/transportation environment:
  25 to 55 °C/ 12 to 121 °E) with relative h
  - -25 to 55 °C(-13 to 131 °F) with relative humidity up to 95 % (non condensing)
- Power supply: A lithium 3V CR2032 battery
- Memory: 10 sets
- Weight: approx. 49 g (with battery)
- Dimensions: approx. 112.8 mm × 34.4mm × 44.5 mm (L×W×H)
- Shelf life: 3 years

# EMC TABLES

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information.

- Electromagnetic/Radio Frequency Interference (EMC/RFI): Readings may be
  affected if the unit is operated within a radio frequency electromagnetic
  field strength of approximately 3 volts per metre, but the performance of the
  instrument will not be permanently affected. Care should be taken to keep the
  thermometer at least 15cm/6 inches away from R/C transmitters to avoid radio
  frequency interference.
- Avoid keeping the thermometer too close to objects that continuously generate high heat (like a hot plate) for long periods of time, which can cause overheating of the thermometer.

### Table 1 For all ME EQUIPMENT and ME SYSTEMS

# Guidance and manufacturer's declaration-electromagnetic emissions

The Ear Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Ear Thermometer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance	
RF emissions CISPR 11	CISPR 11	The Ear Thermometer 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		The Ear Thermometer is suitable for	
Harmonic emissions IEC 61000-3-2	Not applicable	use in all establishments other that domestic and those directly connected	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Not applicable	to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

### Table 2 For all ME EQUIPMENT and ME SYSTEMS

# Guidance and manufacturer's declaration-electromagnetic immunity

The Ear Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Ear Thermometer 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	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with shythetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ± 1 kV air for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (-95 % dip in UT for 0.5 cycle 40 % UT (60 % dip in UT for 5 cycles 70 % UT (30 % dip in UT for 25 cycles 5 % UT (>95 % dip in UT for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the use of the Ear Thermometer requires continued operation during power mains interruptions, it is recommended that the Ear Thermometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

#### Table 3 For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

#### Guidance and manufacturer's declaration-electromagnetic immunity

The Ear Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Ear Thermometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Ear Thermometer, including cables, than the recommended separation distance
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d=1.2.\( \pi \) 80 MHz to 800 MHZ d=2.3.\( \pi \) 800 MHz to 2.5 Ghz where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: \( \frac{\pi}{\pi} \)

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.

Field strengths from fixed transmitters, such as base stations from radio (cellular/cordiess) telephones and land mobile radios, amateur radio. AM and FM radio broadcast and TV broadcast can not be predicted theoretic call 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 Ear Thermometer is used exceeds the applicable RF compliance level adove, the Ear Thermometer should be observed to verify mornal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ear Thermometer. Over the requency range of 150Ms to 90MHz, field strengths should be less than I/I) I Wm.

#### Table 4 For FOUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Far Thermometer

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

Rated maximum output power of transmitter / W	Separation distance according to frequency of transmitter / m			
	150 kHz to 80 MHZ d=1.2 √P	80 MHz to 800 MHZ d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √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	

If this product does not reach you in an acceptable condition please contact our Customer Services Department by www.salterhousewares.com.au.

Please have your delivery note to hand as details from it will be required.

If you wish to return this product please return it to the retailer from where it was purchased with your receipt (subject to their terms and conditions).

# EXPLANATION OF SYMBOL $\epsilon$ The CE marking with the Registration Number of the Notified Body. This denotes the compliance of European Medical Device Directive 93/42/EEC Consult the instruction for use Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority Type of protection of applied part against electric shock, body floating This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of IP22 12.5 mm Ø and greater and against vertically falling water drops when enclosure tilted up to 15°) Temperature limits EC REP European Authorized Representative Manufacturer's name and address SN YYMWWWYYYYY SN SN: Product Serial Number YY: year, MM: month, WWW: working sheet, XXXXX: serial no. 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. RnHS This product fulfilling the requirements of the RoHS Directive 2011/65/EU.



REACH

Manufactured by
AVITA Corporation 9F., No. 78, Sec. 1,
Guangfu Road, Sanchong District,
New Taipei City, Taiwan, R.O.C.

the concentration of 0.1 % weight by weight.

Imported into AUS by Brand Merchant
Brand Merchant Pty Ltd
Suite 8, 8A St Andrews Street,
Brighton Victoria 3186, Australia

TC20DDMEN

This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above

the limit of 0.1 %. No substance(s) is/are present in the parts of the product above