ARC InstaTemp MD ™

Non-Touch Thermometer

User Manual

98.6°F

ARC Devices Ltd.

INTRODUCTION

The ARC InstaTemp MD™ is a sophisticated, technologically advanced electronic medical device that has been carefully engineered to quickly and accurately measure human body temperature without requiring any contact with the human body. To ensure the best results with your ARC InstaTemp MD™ thermometer, please be sure to read the following operational and procedural manual carefully. If you give this device to another adult, it is vital that you include this user manual.

Intended Use
The ARC InstaTemp MD™ is intended for use by a Health Care Professional, in a clinical environment, for the measurement and display of human body temperature for patients of all ages. This device is not intended for home use.

$C\,C$ 0123	The CE Mark of this device refers to the EC Directive MDD 93/42/EEC.

KEY INFORMATION

Only use ARC InstaTemp MD™ in ambient temperatures ranging from 59–95˚F (15–35˚C). The thermometer and patient must remain in a stable temperature environment and away from ventilation sources and heat sources for at least 20 minutes before measuring temperature. Always protect the sensor, which is in the recess at the top of the device (see illustration on page 4) from shocks or contamination. See Precautions (page 22) and Cleaning (page 25) for more details.
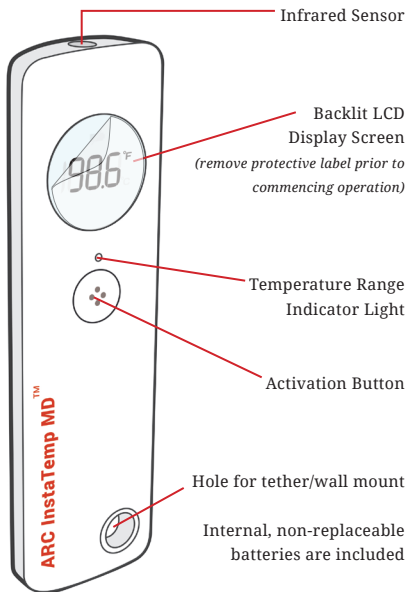
Package Contents

The package contains:

- The ARC InstaTemp MD™
- This instruction booklet
- Wall mount
- Retractable tether

ARC InstaTemp MD™

Infrared Sensor

Backlit LCD
Display Screen
*(remove protective label prior to
commencing operation)*

Temperature Range
Indicator Light

Activation Button

Hole for tether/wall mount

Internal, non-replaceable
batteries are included

GETTING TO KNOW
The ARC InstaTemp MD™

Features

1. Accurate body temperature measured from the forehead in 2.5 seconds

2. LCD screen with backlight for ease of use in low-light conditions

3. Temperature shown in either degrees Fahrenheit (˚F) or degrees Celsius (˚C)

4. The temperature reading, when ready, is displayed on backlit LCD screen for 4 seconds

5. Turns off automatically when not in use

6. Fast temperature readings that meet the ASTM 1965-98 and IEC80601-2-56 standards

7. LED display temperature range indicator system: Green, Orange, Red.

8. Low battery indicator

9. Test mode for LCD screen check

DEVICE SETUP
The ARC InstaTemp MD™

Before using the device for the first time:

1. REMOVE FROM PACKAGING

2. READ ALL SECTIONS OF THE IFU.

3. REMOVE THE PROTECTIVE LABEL FROM THE LCD SCREEN

4. SET THE UNITS

The ARC InstaTemp MD™ can display temperatures in degrees Fahrenheit or degrees Celsius. Follow the steps page on 7 to toggle between °F or °C and select the preferred measurement units for display.

5. AFFIX THE WALL MOUNT

While not in use, the ARC InstaTemp MD™ should be stored using the wall mount. In an operational environment make sure to secure the wall mount away from any direct heating, cooling or ventilation systems. Otherwise the ARC InstaTemp MD™ should be stored in a manner which protects the sensor from contamination or damage. [See Carrying and Storage, page 21]

6. ATTACH THE RETRACTING TETHER

The retracting tether can be used to safely carry the ARC InstaTemp MD™ between uses. While not in regular use, the ARC InstaTemp MD™ should be returned to the wall mount.

OPERATIONS

Changing Between Fahrenheit and Celsius:

The ARC InstaTemp MD™ is set to Fahrenheit by default. To change to Celcius, follow these simple steps:

(1) Press and hold the activation button to get a reading, which can be a temperature reading, Lo, Hi or "---".

(2) Once the reading appears on screen in Fahrenheit, press and release the activation button again —the reading will automatically change to Celsius.

Repeat steps 1 and 2 to change back.

Note: Once the display units are set (°F or °C), they remain as the default display units until changed again

Prepare the patient.

Move hair if present and all obstructions away from the path of the sensor

Wipe perspiration from the forehead, if apparent

Ensure that the person has been in a stable temperature environment for 20 minutes

Do not touch the lens of the sensor or the area surrounding the front of the device. It is the most delicate part of the ARC InstaTemp MD™

Do not measure the person's temperature immediately after he/she has been exposed to really cold or hot climates, including any heating or cooling systems in the operational environment, if the person has been wearing a hat, or has consumed hot or cold food or liquids as it may temporarily change the surface temperature of the skin.

In these instances, wait 20 minutes before taking a temperature reading.
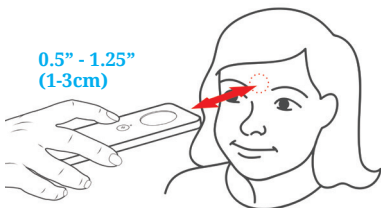
**0.5" - 1.25"
(1-3cm)**

**Hold for
2.5 seconds**

A Point the thermometer at the patient, without touching them, as shown above.

Ensure the device is approximately 0.5-1.25" (between 1 and 3cm) from the forehead, above the eyebrows and between the eyes.

⚠ *Thermometer must be held steady, perpendicular to and pointing directly at the center of the forehead at the area above the eyebrows and between the eyes when taking a temperature.*
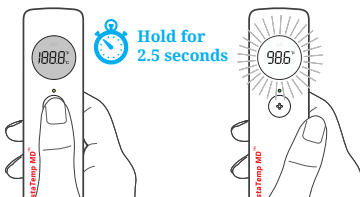
B   Hold the thermometer in position. Press and hold the activation button until the display is illuminated and a temperature reading is displayed on the screen. This will take approximately 2.5 seconds.

The activation button should be released when the display back light turns on and the result is displayed on the screen.
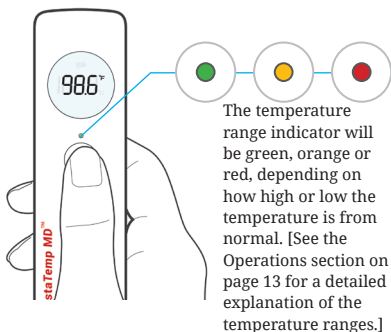
⚠️ *Keep the device as steady as possible during the measurement process. The LCD backlight is off and displays "188.8" during the measurement process. The backlight of the LCD comes on when the measurement process is complete.*

The temperature will be displayed for 4 seconds on the display screen. The LCD display will show a temperature in ˚F or ˚C.

The temperature range indicator will be green, orange or red, depending on how high or low the temperature is from normal. [See the Operations section on page 13 for a detailed explanation of the temperature ranges.]

⚠ *Should you wish to take a second reading, wait for the LCD display to turn off first. Wait 15 seconds between measurements.*

⚠ *Holding the device in your hand for prolonged periods of time may affect the readings. It is not recommended to hold the device in your hand between measurements.*

The temperature range indicator will display one of three colors: green, orange, or red.

⚠️ *The temperature range indicator colors indicate the degree to which the patient's temperature is outside the "normal" range.*

Green: Temperatures within normal range. *(see tables on pages 14 & 15)*

Orange: Temperature is mildly outside of normal range (whether hot or cold) (see tables on pages 14 & 15)

Red: Temperature is excessively outside of normal range (whether hot or cold) *(see tables on pages 14 & 15)*

FAHRENHEIT (˚F)

Temperature Range	Indicator Light	Display Readout
>109.1°F	🔴	HI
≥100.5⁰F - ≤109.1⁰F	🔴	Temp in ˚F
≥99.0⁰F - <100.5⁰F	🟡	Temp in ˚F
≥96.7⁰F - <99.0⁰F	🟢	Temp in ˚F
≥94.9⁰F - <96.7⁰F	🟡	Temp in ˚F
≥89.5⁰F - <94.9⁰F	🔴	Temp in ˚F
<89.5⁰F	🔴	LO

⚠️ *Note: a red indicator light may mean "very hot" or "very cold".*

⚠️ *Outside the measurable range, 89.5˚ - 109.1°F, the screen shows "HI" or "LO" as applicable.*

CELSIUS (°C)

Temperature Range

Temperature Range	Indicator Light	Display Readout
>42.8°C	🔴	HI
≥38.0ºC - ≤42.8ºC	🔴	Temp in ˚C
≥37.2ºC - <38.0ºC	🟡	Temp in ˚C
≥36.0ºC - <37.2ºC	🟢	Temp in ˚C
≥35.0ºC - <36.0ºC	🟡	Temp in ˚C
≥32.0ºC - <35.0ºC	🔴	Temp in ˚C
<32°C	🔴	LO

⚠️ *Note: a red indicator light may mean "very hot" or "very cold".*

⚠️ *Outside the measurable range, 32˚ - 42.8˚°C, the screen shows "HI" or "LO" as applicable.*

A "HI" Reading

The LCD will display 'HI'. This indicates that the temperature which the thermometer has measured is outside the device's measurement range (i.e. >109.1°F/ >42.8°C).

⚠ Above 109.1° F / 42.8° C

A "LO" Reading

The LCD will display 'LO'. This indicates that the temperature which the thermometer has measured is outside the device's measurement range (i.e. <89.5° F/ <32° C).

⚠ Below 89.5° F / 32° C

Indication	*Meaning*
1888.	After 4 seconds the backlight, LCD display and temperature range indicator turn off and the thermometer powers down. ⚠ *If the display remains in this state after the button is pressed then the battery is no longer working.*
Er 1	An Error message indicates an internal problem with the thermometer (see pg. 26 for error codes). ⚠ *If an Error message is displayed, please contact ARC Devices or your distributor.* *Contact info on page 36 of this document.*

Indication	Meaning
	This indicates an invalid reading. This is due to incorrect usage, such as: • trying to measure a temperature when the ambient temperature is outside the operating temperature range. • an indeterminate reading because the activation button was not held until the display was illuminated. • temperature measurement failed due to too much movement by the operator or patient. Wait 15 seconds and repeat the temperature. Repeat the temperature measurement as described in the section titled "Taking the Temperature." (page 10)

Indication	*Meaning*
	Flashing battery symbol will start being displayed when there is battery power for approx. 500 measurements left. ⚠ *Contact ARC Devices or your distributor for a replacement unit.*
	Steady battery symbol & red indicator light: insufficient battery power for a measurement. Replace your ARC InstaTemp MD™ ⚠ *Contact ARC Devices or your distributor for a replacement unit.*

CARRYING & STORAGE

The wall mount is provided to help protect the sensor in its recess position by mounting the ARC InstaTemp MD™ on the wall mount with the sensor facing toward the floor. The retractable tether is provided as means of carrying the ARC InstaTemp MD™ and keeping the device at ambient temperature.

⚠️ *Note: You should choose to use either the wall mount or the retractable tether, as they do not work together. Do not place the wall mount in any location with direct cooling or ventilation.*

Wall Mount
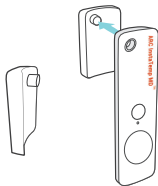
The wall mount can be attached to any smooth vertical surface using its adhesive pad on the rear of the wall mount. Because it is magnetic, the wall mount can also be attached to any metal surface. The internal magnet also keeps the ARC InstaTemp MD™ gently attached to the wall mount.

CARRYING & STORAGE

ARC InstaTemp MD™ should be attached
with its sensor facing downwards, as shown
in the illustration on page 20.

Retractable Tether

The extending tether is attached by threading
the lanyard through the hole in the body of the
ARC InstaTemp MD™, as shown in the
illustration below. The retractable tether can
then be attached to a suitable exterior pocket,
waistband or belt.
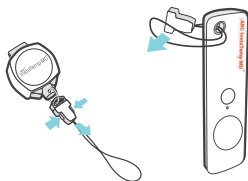
⚠️ *Body heat can raise the ambient
temperature of the thermometer or
contaminants may lodge in the sensor,
either of which can affect the ability to
make accurate measurements.
Therefore, do not carry the ARC Insta-
Temp MD™ under your clothing or in
your pocket.*

PRECAUTIONS

The thermometer and the patient must remain in a stable temperature environment for at least 20 minutes before a reading can be taken. Do not measure the patient's temperature immediately after he/she has been exposed to really cold or hot climates, or has consumed hot or cold food or liquids. In these instances, wait 20 minutes before taking a temperature reading. Do not apply any hot or cold compress, cloth or gel, on the patient's forehead prior to the measurement for at least 20 minutes.

Only use the ARC InstaTemp MD™ in climate conditions ranging from 59-95°F (15-35°C). Outside of this range, a "---" will be displayed when a measurement is taken. Move the device and patient to an area inside the recommended temperature range, wait 20 minutes for temperatures to stabilize, then take a patient temperature measurement.

If the ARC InstaTemp MD™ touches or comes into contact with the patient follow your local procedure for cleaning devices before using with another patient.

PRECAUTIONS

Do not use or store outside or close to a heat or cooling source. Using the thermometer in these conditions may affect the accuracy of the temperature reading.

Do not drop, tap or shake the ARC InstaTemp MD™ thermometer. It is a precision device and any damage may result in an inaccurate reading.

Do not allow the ARC InstaTemp MD™ thermometer to become damp or immersed in water or other liquids.

Do not touch the lens of the infrared sensor, any damage or scratches may affect the accuracy or function of the ARC InstaTemp MD™.

Do not attempt to take a patient temperature measurement if there is any evidence of damage to the device or if it has been exposed to extreme conditions.

Storage temperature range 45 to 90°F (7-32°C)

PRECAUTIONS

Do not use in oxygen rich environments.

Do not use in or close to strong magnetic fields or X-Ray sources.

Failure to understand these precautions and warning statements provided in this section of the document could lead to device damage and or inaccurate temperature measurements.

If the informational content of the LCD display is in question then the LCD display test mode (see troubleshooting section, page 26), should be used to check the display.

Do not touch the lens of the sensor. It is the most delicate part of the ARC InstaTemp MD™ thermometer and must be protected from dirt and damage.

Do not immerse the ARC InstaTemp MD™ in water or other liquids. It is not water resistant.

Take care not to scratch the lens of the sensor, the display or the housing.

Never use aggressive cleaning agents.

When cleaning is required, the external surfaces of the thermometer, Wall Mount and Retractable tether can becan be safely wiped with a cloth moistened with a 70% IPA (isopropyl alcohol) solution.

WARNING: DO NOT immerse or soak the thermometer in any type of fluid, or use any heat or steam sterilization process.

TROUBLESHOOTING

Error Codes

The table below lists the error codes which the ARC InstaTemp MD™ can display. If the device continues to display one of these errors, the device should be returned to the manufacturer.

Error Code	*Explanation*
Er1	Sensor Voltage Error
Er2	Sensor Configuration Error
Er3	Sensor Self-Test Error
Er4	Sensor Read Error
Er5	Core Processor Frequency
Er6	System Configuration Memory

LCD/LED Display Testing

The LCD can be tested for consistency at regular intervals, or if any LCD figures seem incomplete, by activating the display test mode in the following manner:

Press the activation button and hold until after the display period is complete. The ARC InstaTemp MD™ then enters test mode and runs the display test once.

During Test Mode, the device behaves as follows:

(1) The display turns off for 1 second, then turns on with all segments active.

(2) The LCD then cycles through the following sequence to exercise all the segment combinations:

> 1. The tens and units values of the display will increment from 0 to 9.

> 2. The hundreds unit will toggle between the upper and lower segment.

3. The ˚F and ˚C symbols will be display alternately.

4. The battery symbol and decimal point will both turn on and off alternately.

5. The green and red LEDs will be display alternately.

If any of the above steps fail, the device may be faulty and should not be used. Should this occur, please contact ARC Devices customer service (see page 35).

WARNINGS

Do not attempt to fix or repair the thermometer yourself; there are no user-serviceable parts in the ARC InstaTemp MD™.

Do not cover the sensor aperture wholly or partially, or insert any objects or material into the aperture.

Do not attempt to replace the internal batteries. The internal batteries are non-removable, non-replaceable and non-serviceable.

Do not open the thermometer casing. If the case is not correctly closed, do not use the device.

Avoid Strong magnetic fields.
Avoid X-ray.
Avoid oxygen rich environment.

DISPOSAL

The ARC InstaTemp MD™ contains batteries: do not dispose in fire, or domestic waste. Dispose in accordance with local regulations at local authority collection points

For more information about disposal please contact ARC Devices customer service (see page 35).

ICON IDENTIFICATION

This instruction manual belongs to this device. It contains important information about operating the ARC InstaTemp MD™ non-touch thermometer. Read the instruction manual carefully as non-observance of these instructions can result in inaccurate temperature readings or damage to the device

Manufacturer

Caution; consult section titled 'Understanding the Temperature Range Indicator System' and 'Taking a Temperature'.

Degree of protection against electrical shock; there is no conductive connection to the person; Type BF Protection

ICON IDENTIFICATION

Device to be disposed of in segregated waste (WEEE Directive 2012/19/EU)

Protect from liquids

Device conforms with RoHS directive (2002/95/EC)

The CE Mark of this device refers to the EC Directive MDD 93/42/EEC

TECHNICAL SPECIFICATIONS

Item	*Value*
Model	ARC InstaTemp MD™
Display System	Digital segmented display (LCD) with backlight
Reported measurement range	89.6 - 109.1°F (32 - 42.8°C)
Operating temperature / humidity range	59 - 95 °F (15 - 35°C) *Operational up to 95% humidity non-condensing*
Storage/ Transport Temperature range	45°F - 90°F (7°C - 30°C)
Temperature measurement accuracy	+/-0.4°F and +/-0.2°C in the measurement range 89.6 - 109.1°F (32 - 42.8°C) whilst in an ambient temperature range of 59-95°F (15-35°C) (In accordance with ASTM E1965-98 and ISO80601-2-56 pt 2-56)
Temperature display	Units °F or °C, user selectable

TECHNICAL SPECIFICATIONS

Item	*Value*
Power supply	Contains two AAAA alkaline batteries, non-replaceable
Battery life	Approximately 13,000 measurements. Low battery warning displays when approximately 500 measurements left.
Thermometer Dimensions	1.37" x 0.55" x 5.08" (3.5cm x 1.4cm x 12.9cm)
Weight	1.94 oz (55 gm)
Wall Mount & Retractable Tether	Wall Mount: • 1.24" x 2.125" x 0.42" *(31.5mm x 54mm x 10.7mm)* Tether: • 1.4" x 2.12" x 0.56" (35.3mm x 53.8mm x14.2mm) • Retractable cord length: 27" (69cm)
Compliance with standards	Electromagnetic compatibility: IEC60601-1-2 Clinical thermometer: ASTME1965-98(Reapproved 2009), ISO 80601-2-56

LIMITED TWO YEAR WARRANTY

ARC Devices warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of two years from the date of purchase from ARC Devices, its authorized distributors or agents. The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from ARC Devices, 2) the date specified during product registration, 3) the date of purchase of the product from an ARC Devices authorized distributor as documented from a receipt from said distributor. This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by ARC Devices, and 4) accidents.

Shipping cost to return a device to ARC Devices or an ARC Devices Service center is not included.

A service notification number must be obtained from ARC Devices prior to returning any products or accessories to ARC Devices' designated service centers for repair. To obtain a service notification number, contact ARC Devices Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ARC DEVICES'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. ARC DEVICES IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY

LIMITED TWO YEAR WARRANTY

How to return your thermometer

Should service be required during or after the warranty period, you must call ARC InstaTemp MD™ Customer Service Department to obtain a return authorization number and shipping address. 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, your return authorization number, and your return address.

Send the ARC InstaTemp MD™ thermometer prepaid and insured.

For Customer Service Department contact:

USA and Canada: +1 561 287 5487
Monday - Friday 8:00 AM to 5:00 PM ET

EMEA and RoW: +353 91 886 002
Monday - Friday 8:00 AM to 5:00 PM GMT

CONTACT ARC DEVICES

Designed, manufactured and distributed in all territories except USA by:

ARC Devices Ltd
2 Deerpark Industrial Estate
Oranmore
Co Galway
Ireland

Phone: +353 (91) 398 191
EMail: clinical@arcdevices.com
Web: www.arcdevices.com

Distributed in USA by:

ARC Devices USA, Inc.
1200 N. Federal Hwy, Ste 207,
Boca Raton, FL 33432
USA

Phone: 561.282.6074

CE

0123

PT-100153-IMD Rev 00