

## Symbols

### Documentation symbols

	Follow instruction for use		<b>Caution</b> The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
--	----------------------------	--	--

### Product symbols

	To take an accurate measurement the thermometer should be positioned 1 to 5 cm from the forehead		Press the button to take measurement
--	--	--	--------------------------------------

### Shipping, storing, and environment symbols

	Temperature limits		Keep dry
	This device shall be disposed of in accordance with national laws after its useful life.		Humidity limitation

### Miscellaneous symbols

	Manufacturer		Serial number
	Date of Manufacturer		Type BF applied part
	European authorized representative		

### Indicator symbols

	Two-second beep sound indicating an error		Two beep sound indicating the completion of a process
--	---	--	---

### Battery level indicator

	10 to 0 percent of useable battery capacity remaining When the battery flashes, no measurements can be taken
--	--

## Introduction Intended use

The Ario™ Touch Free thermometer is a clinical-grade device intended for the intermittent measurement of human body temperature in patients of all ages in professional-use and home healthcare environment.

## General warnings and cautions

Warning and caution statements can appear on the thermometer, the packaging, the shipping container, or in this document. The thermometer is safe for patients and clinicians when used in accordance with the instructions and with the warning and caution statements presented in this manual. Before using the thermometer, familiarize all operating personnel with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual.

- Failure to understand and observe any warning statement in this manual could lead to patient illness, injury, or death.
- Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of patient data.

**WARNING** Patient safety. The thermometer is designed for the intermittent measurement of the human body's temperature, and can be used upon people of all ages. The following recommendations must be carefully observed during the product's use. Any activities that are inconsistent with or do not take into account these recommendations could result in personal injury or could affect the accuracy of the thermometer itself.

**WARNING** Patient safety. If the accuracy of any measurement is in question, check the patient's temperature with an alternate method and then check to verify the device is functioning properly.

**WARNING** Safety risk. The thermometer battery must be kept strictly out of the reach of children, as ingestion of the battery could result in poisoning or other serious health risks.

**WARNING** Safety risk. Always dispose of batteries in accordance with applicable legal regulations.

**CAUTION** Always use new batteries of the type and specification indicated in this manual. Mixing old and new batteries will shorten the battery life.

**CAUTION** Do not use rechargeable batteries, as these may be of inferior quality and duration. The use of rechargeable batteries could compromise the performance of this device.

**CAUTION** Leaking batteries can damage the device. Remove the batteries whenever the device is not expected to be used for an extended period of time (e.g. multiple months).

**CAUTION** If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.

**CAUTION** Proper measurement distance between 1 and 5 cm from the patient's forehead is essential to the accuracy of the temperature measurement determination.

**CAUTION** Unauthorized modifications to the device are not permitted. Do not modify the product in any way without the manufacturer's prior authorization.

**CAUTION** Avoid touching the infrared sensor lens directly with your fingers.

**CAUTION** Do not expose the thermometer to extreme temperatures or humidity levels. Make sure that you follow the instructions provided in this manual. Do not expose to direct sunlight.

**CAUTION** The thermometer is NOT waterproof.

**CAUTION** Avoid dropping the device.

**CAUTION** Do not autoclave. Follow only the cleaning procedures described in this manual.

**Note** Both the patient and the thermometer should be kept within the same environmental conditions for at least 30 minutes prior to each measurement.

**Note** Avoid taking temperature measurements for at least 30 minutes after physical activity, bathing, swimming, consuming food or beverages, or spending time outdoors.

**Note** Avoid pointing the infrared sensor at any heat source other than a patient. This might affect patient measurements.

**Note** Avoid exposing the device to external heat sources. This might affect patient measurements.

**Note** If possible, measurements should always be taken by pointing the infrared sensor at the same area of the forehead. Temperatures measured at different locations on the temples or on opposite sides of the head can vary considerably.

**Note** Holding the thermometer in your hands for too long or exposing the device to external heat sources could result in distorted temperature readings. For this reason, the body temperature reading could result as being higher or lower than the actual value.

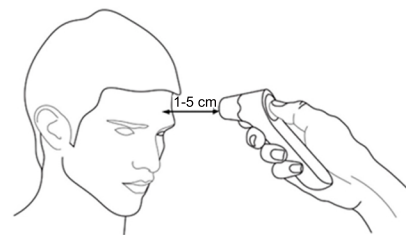
**Note** The thermometer measures skin temperature directly and then adjusts it using mathematic formulas (which is obtained by human body thermal simulations and experimental tests) to reach sublingual temperature.

## Take a measurement

1. Press Measure to power on the thermometer.

A full display flashing appears after power on, when the device is ready, a triple dash appears on the screen, and beep sound.

2. In case of measuring in forehead mode, a forehead icon appears on display. Position the thermometer between 1 and 5 cm from the center of the patient's forehead, and aim above of between the eyebrows. Press and release the Measure button in 1 second and read the result.



3. In case of measuring surfaces or objects, press and hold measure button for 7 seconds then the object related LED (which is a Baby bottle) appears on display. Now you can take objects temperature. To switch back to body mode repeat above procedure till forehead's icon appears again.

**Note** If the eyebrow area is covered with hair, sweat, or dirt, clean the area and wait 10 minutes to before taking a measurement.

**Note** Hold the thermometer and the forehead steady during measurement. Movement can impact the measurement.

**Note** Note that taking forehead (body) temperature in object mode and vice-versa leads to inaccurate readings and errors.

**Note** The complete measurement or Err message displays for 10 seconds. After 10 seconds, the thermometer returns to sleep in case of inactivity.

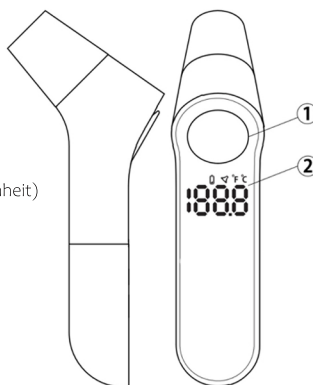
## Troubleshooting and error messages

Error message displayed	Possible cause	Suggested action
	The ambient temperature of the room is outside the operating range of 15.0 °C to 40.0 °C ( 59 °F to 104 °F)	Move to a room with the proper ambient temperature and wait 30 minutes for the thermometer to stabilize
	The measurement is lower than 34 °C (93.2 °F) in forehead mode.	Take the measurement again. Follow the steps in the "Take a measurement" section.
	The measurement is higher than 42.9 °C (109.22 °F) in forehead modes.	Take the measurement again. Follow the steps in the "Take a measurement" section.
	The battery is low on power	Replace the battery with two AAA (LR03) alkaline batteries.

## Using the thermometer

### Button functions

1. Measure, C/F (Celsius/Fahrenheit)
2. Display



## Maintenance

### Replace the batteries

The thermometer comes with two AAA batteries. Replace with two new AAA batteries when the flashing battery symbol appears on the display

1. Open the batteries cover.
  2. Slide open the battery cover and remove the batteries.
  3. Replace the batteries. Make sure to align the batteries as indicated inside the battery compartment.
  4. Replace the battery cover.
- Remove the batteries before storing the thermometer for an extended period of time.

# Clean and disinfect the thermometer

The thermometer can be cleaned and an intermediate-level of disinfection can be achieved using the following method.

**CAUTION** Never submerge the thermometer in water or any other liquid

**CAUTION** Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids.

**CAUTION** Never insert a sharp object into the probe or any other open surface on the thermometer.

**CAUTION** Do not use unapproved cleaning or disinfection agents. Use of these agents may cause damage to components.

**CAUTION** Do not use chemicals other than isopropyl or ethyl alcohol on the lens.

## Cleaning the sensor window

Slightly moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wipe the surface of the lens using a side-to-side (not circular) motion.

## Cleaning the thermometer

Use a pre-moistened wipe or soft cloth slightly moistened with an approved cleaner to gently clean the thermometer.

## Disinfecting the thermometer

Use a pre-moistened wipe or soft cloth slightly moistened with an approved disinfectant to disinfect the thermometer. Follow the manufacturer's recommendations.

Note After cleaning or disinfecting, wait at least 10 minutes before taking another measurement.

## Approved cleaning agents

Examples of disinfectants that can be used for the case of monitor are listed below:

- Alcohol 70%
- Isopropanol

Warning: Do not use EtO gas to disinfect the thermometer.

Warning: Manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

# Calibration testing

The thermometer is calibrated at the time of manufacture. If the thermometer is operating according to these instructions, periodic readjustment is not required.

These recommendations do not supersede any legal requirements. You must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device. These controls are required by the scope of relevant laws, directives or ordinances where the device is used.

# Disposal

## Thermometer

The thermometer contains no hazardous materials. Discard without environmental risk.

Remove the batteries before disposal.

## Battery

Dispose of empty batteries in accordance with national or local regulations.

Specifications	
Device Type	Digital Thermometer
Technology	Infrared
Measurement Site	Forehead, surface
Users	Adults, Children, Neonate
Display Resolution	0.1 °C (0.1 °F)
Body temperature range	34.0 °C to 43.0 °C (93.2 °F to 109.4 °F)
Laboratory Accuracy	±0.2 °C (33.0 °C to 42.0 °C)
Measurement Distance	1-5 cm
Measurement Time	Less than 2 Seconds
Warm up Time	Up to 2 Seconds
Sleep Mode	Approximately 10 seconds after last measurement
Operating Temperature	15.0 °C to 40.0 °C (59 °F to 104 °F)
Operating Humidity	15% Up to 95%
Storage Temperature	-25 °C to 55 °C (13 °F to 131 °F)
Storage Humidity	15% Up to 95%
Environment Pressure	0.7 to 1.06 atm
Other Features	C/F conversion
Battery	2 x 1.5 V type AAA
Average Battery Life	3000 measurements

# Clinical Results

Term	Value	Unit
Clinical Bias ( $\bar{d}$ or $\Delta_{cb}$ )	-0.018	°C
Limits of Agreement ( $L_A$ )	0.398	°C
Clinical Repeatability ( $\sigma_r$ )	0.07	°C
Reference Body Site:	Sublingual	
Measuring Site:	Forehead	

## Guidance and manufacturer's declaration EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with EN 60601-1-2:2015.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment. The device complies with all applicable and required standards for electromagnetic interference.
- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the central station in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

## EMC Declaration for ario

Guidance and manufacturer's declaration – ario emissions		
The ario is intended for use in the electromagnetic environment specified below. The customer or the user of the ario, should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The ario must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The ario is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N.A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N.A	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27
450	430-470	GMSR 460, FRS 460	FM <sup>c)</sup> ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
5240	5100-5900	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.  
 b) The carrier shall be modulated using a 50% duty cycle square wave signal.  
 c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.


Release Date                      version  
 September, 2020      D01024/V3

Guidance and manufacturer's declaration – electromagnetic immunity			
The ario is intended for use in the electromagnetic environment specified below. The customer or the user of the ario should assure that it is used in such an environment.			
Immunity test	Port	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 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%.
	Patient coupling	± 8 kV air	
	Signal input/output parts	N.A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Surge IEC 61000-4-5	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U<sub>T</sub> is the a.c. mains voltage prior to application of test level.

**Standards**  
 EN ISO 80601-2-56: 2017  
 EN 60601-1-2: 2015  
 EN 60601-1: 2006 / A1: 2013  
 EN 13485: 2016

For information about any Saadatco product, call Saadatco Technical Support (<http://www.saadatco.com>)

 Pooyandegan Rah Saadat No. 4, East. 1st St, Ettehad Blvd. Damavand Ave., 1658916599  
 Tehran, Iran, Islamic Republic  
 Telephone +98-21-73098000  
 Fax +98-21-77964239  
 info@saadatco.com  
 www.saadatco.com

**EC REP** Trionara Technologies AB Polygonvagen  
 21.18766. Taby, sweden



Guidance and manufacturer's declaration – electromagnetic immunity			
The ario is intended for use in the electromagnetic environment specified below. The customer or the user of the ario should assure that it is used in such an environment.			
Immunity test	Port	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	Input a.c. power	N.A	
	PATIENT coupling Signal input/output parts		
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

# SENSE IT.