Withings

Inspire health

WIFI TEMPORAL THERMOMETER

Read this manual before use. Keep it for further reference.

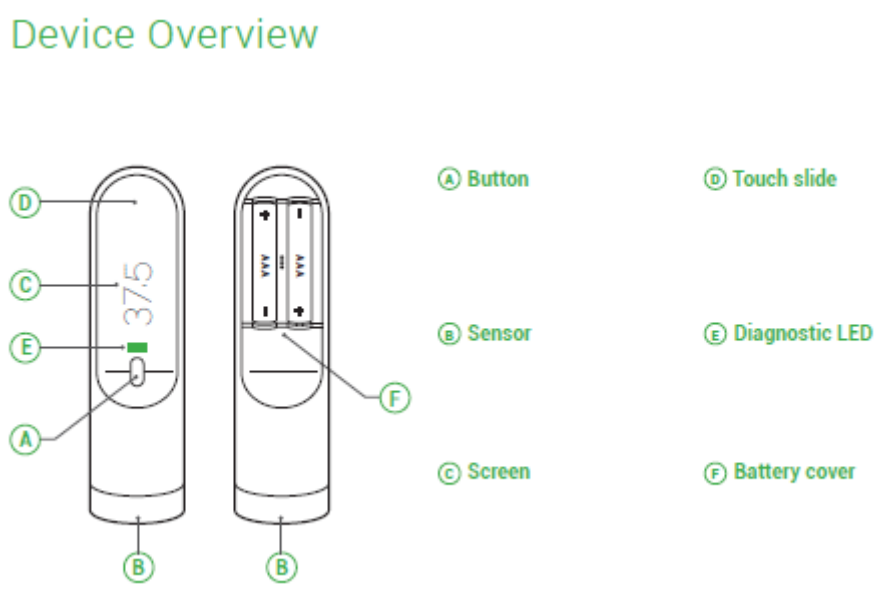
Disclaimer: Information in this guide may change without notice.
The manufacturer assumes no responsibilities for errors that may appear in this guide.

Changer smart temporal thermometer

INTRODUCTION

Package content
Withings Thermo
Protective cap
Two AAA Alkaline (LR3) batteries (already inserted)
Notice of use

Product description



WARNING AND PRECAUTIONS
Please read this section carefully before using Withings Thermo thermometer.

Intended use – Important safety information
The device is intended for use in measuring temperature in adult population, children and babies population. This device is not suitable for children born before term.

Withings Thermo (SCT01) is intended for the intermittent monitoring of human body temperature at home. Always consult your doctor. Self-diagnosis of measurement results and self-treatment are dangerous. Pregnant women should consult a doctor before using the thermometer. Please consult your doctor when there is a temperature rise on:

- Neonates and babies under 3 months
- Patients over 60 year old
- Immunocompromised patients
- Bedridden patients
- Transplanted patients

Please consult your doctor if other symptoms (vomiting, diarrhea, pain, shivering, stiff neck….) occur even if there is no fever.
This device is a precision thermometer measuring equipment liable to be understood by lay user but it still should be handled with care.

General safety

- Do not use the device on premature babies (babies born before term)
- Do not use this device for purpose other than the one described in this manual
- Keep the device out the reach of children. Children must not play, swallow or eat the device.
- This device is for personal use at home only.
- The sensor lens is fragile: do not touch it with your fingers.
- Do not expose the device to humidity or water. In case the unit is wet, wait until it is dry.
- To clean the lens, use a soft dry cloth to wipe it or a cotton bud. For cleaning and disinfection, please report to the cleaning section of this manual
- Never try to disassemble or repair the product.
- A long exposure of the device to lint, dust or sunlight might reduce its life time or damage it. Damaged sensor might lead to incorrect measurements.
- Do not leave the thermometer unattended with infants or persons who cannot express their consent.
- Do not use the thermometer for any purpose other than measuring temperature.
- Do not disassemble the thermometer.
- Do not use a cellular phone near the device. It may result in an operational failure.
- Do not store the device at extreme temperatures (see operating range temperatures below)

Precautions before use

- Remove the protective cap prior to taking a measurement
- The device and the patient should be in the same ambient temperature for 10 minutes.
- Infants' body temperature might vary more than adults'. Avoid making measurements on babies after nursing or while they are crying. It is recommended to make measurements children when they are calm.
- Do not take measurement over irritated skin or scars.
- Please perform 3 measurements in a row in case of children under 3 months… If the 3 measurements are different, always take the highest one.
- If the patient has taken a bath or made exercise, please wait for 15 minutes before proceeding to a measurement.
- If the thermometer was stored in a cool or a warm room, wait for 15 minutes before proceeding to a measurement.
- Do not move the thermometer while taking the temperature measurement.
- Please wait for one minute between two measurements.
- Remove hair or sweat prior to taking a measurement.

AAA alkaline cells usage

– If AAA alkaline cells fluid should get on your skin or clothing, immediately rinse with plenty of clean water.

– Use only two AAA alkaline cells with this blood pressure monitor. Do not use any other types of AAA alkaline cells.

– Do not insert AAA alkaline cells with their polarities incorrectly aligned. – Replace old AAA alkaline cells with new ones immediately. Replace all two AAA alkaline cells at the same time.

– Do not use new and used AAA alkaline cells together.

AFTER USE

Cleaning

– Do not use an alcoholic-base or solvent agent to clean the device
– Clean the device with a soft and dry cloth
– Do not submerge the device or any of the components in water. Ensure that no liquid enters the interior of the thermometer.
– Do not dismantle the device or try to repair it by yourself. If any problem happens, refer to the distributor
– Do not operate the device under severe environment of extreme temperature or humidity, or direct sunshine
– Do not shake the unit violently
– Do not let the device under strong shocks, such as dropping the unit on the floor
Wait for 10 minutes after cleaning before taking a temperature measurement.

Storage

– If you are not using the device for an extended period, remove the alkaline cells from the alumimum tube for storage.
– Store the device and the components in a clean and safe location
– Do not store the device in a wet, humid or dusty location. Do not store the device if it is directly exposed to the sunlight.
– Ensure that you place the protective cap on the sensor after each use to prevent damages to the sensor.

Maintenance

If you can't fix the problems using the troubleshooting instructions, request service from our dealer. Manufacturer will make available on requested circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist manufacturer's staff or authorized representative for repair. It is generally recommended to have the device inspected every 2 years, to ensure proper functioning and accuracy.

TROUBLESHOOTING

If you one of the following problems while you are using Withings Thermo, refer to this section to help solve the problem. If the problem persists, please contact our customer service. For any enquiry, the serial number must be provided. It can be found inside the battery cover. It is made of 12 characters grouped by 2, each group separated by a column, for instance XX:YY:XX:YY:XX:YY

Problem	Cause	Solution
Blank display. The device does not turn on.	Multiple possible causes	1. Check and correct the AAA alkaline cells polarities 2. Remove the AAA alkaline cells and wait for one minute. Then install the AAA alkaline cells back.

		3. Replace the AAA alkaline cells
“Low battery icon”	Battery is low	Replace batteries.
“Error”	The temperature is outside ranges. Body mode : lower than 35°C (95°F) or higher than 43.2°C (109.76°F) Surface mode : lower than 22°C (71.6°F) or higher than 40°C (104°F)	1. Make a new temperature measurement, referring to the user manual.
“Error”	System error	Contact customer service
The temperature seems rather high	The unit has been stored in a cold room	Leave the unit in the room where is the patient for 30 minutes prior to the next measurement
The temperature seems rather low	The skin has sweat on it or there is hair on the skin	Ensure that there is no haire in front of the sensor. Clean the skin with a dry piece of cloth and wait for 5 minutes prior to taking a measurement
	Measurement was taken in surface mode	Switch in body mode (see manual)
	The patient has been staying in a cold room	Wait until the patient is warmer before proceeding to measurement
	Measurement was not taken on the temple	Please refer to the user manual to place the sensor on the correct location
Bluetooth does not seem to work	Smartphone is out of range	Please get your smartphone closer to your device.
	Smartphone’s Bluetooth is OFF	Please switch your smartphone Bluetooth ON
Wi-Fi does not seem to work	Device is out of range from the Wi-Fi source	Please get your smartphone and device closer to your device.
	Wi-Fi is OFF	Please switch your smartphone Wi-Fi ON as well as your router Wi-Fi on

Replacing the AAA alkaline cells

If the low battery symbol appears in the Withings application, replace all two AAA alkaline cells at the same time.

1. Remove the AAA alkaline cells cover at the back of the thermometer.
2. Install or replace two AAA alkaline cells so that the + (positive) and – (negative) polarities match the polarities indicated on the AAA alkaline cells compartment.
3. Put the AAA alkaline cells cover back in place.

If the device will not be used for a long period of time, it is advised to remove the alkaline cells.

TECHNICAL DATA

Product Description	Infrared temporal thermometer
Brand	Withings
Model	Withings Thermo
Model number	SCT01
Sensor	Thermopile
Temperature display	3 digits (°C) and 4 digits (°F)
Resolution	0.1 °C / 0.1 °F
Measuring range	Body mode : 35°C – 43.2°C (95°F – 109.8°F) Surface mode : 22°C – 40°C (71.6°F – 104°F)
Accuracy (Body mode)	± 0.2°C on 35.5°C – 42.0°C range (± 0.4°F on 95.9°F-107.6°F range) ± 0.3°C (± 0.5°F) outside this range
Accuracy (Surface mode)	± 0.3°C on 22°C – 40°C range (± 0.5°F on 71.6°F – 104°F range)
Operating conditions of use (Ambient temperature / Humidity)	10°C - 40°C (50 °F - 104 °F) 15% ≤ RH ≤ 95%
Storage conditions (Temperature / Humidity / Air Pressure)	-25°C (-13°F) - 55°C (131°F) 15% ≤ RH ≤ 95% 200 hPa ≤ RH ≤ 1060 hPa
Power Supply	2 x 1.5V (LR03 AAA Battery)
Battery Life	2 to 3 years
Automatic switch-off	30 seconds
Protection against electric shock	Internally Powered ME equipment
Size	L = 116 mm (4.57 in.) x Diam= 33.2 mm (1.31 in.)
Weight	Approx. 75g (battery included) – 0.165 lbs.
Package content	Main unit, 2 AAA (LR03) batteries (already installed), Protective lens cap, Quick start guide, Instruction manual

Notes

Specifications are subject to change without prior notice or any obligation on the parts of the manufacturer

Type BF

FC CE 0434

Read this manual before use

WEEE

EC REP **EU REPRESENTATIVE**

-25°C (-13°F) 55°C (131°F) Storage temperature

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14th Floor - Withings Inc
CAMBRIDGE, MA 02142

FCC ID : XNASCT01

Keep it dry

FCC STATEMENT

Federal Communications Commission (FCC) Statement 15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
– Reorient or relocate the receiving antenna.
– Increase the separation between the equipment and receiver.
– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
– Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:
1) this device may not cause harmful interference and
2) this device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.
This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This device complies with
Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

RF STATEMENT

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following.
– Interference may occur in the vicinity of equipment marked with
– Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.
– The use of accessories and cables other than those specified may result in increased emissions or decreased immunity
– 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
– The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
– Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
– The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Any other accessories, transducers and cables may result in increased emissions or decreased immunity and EMC performance.
– The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, which should be observed to verify normal operation in the configuration in which it will be used.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following. Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The Withings Thermois intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Thermo should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic
environment - guidance</th></tr>
<tr><td>CE emissions
CISPR11</td><td>Group 1</td><td rowspan="2">The SCT01 Withings Thermo 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.</td></tr>
<tr><td>RE emissions
CISPR11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td><td rowspan="2">The SCT01 Withings Thermo is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

EMC DATA

Declaration – electromagnetic emissions and immunity for equipment and systems that are not life-supporting and are specified for use only in a shielded location

Non-Life Support Equipment Separation Distance Calculation (3Vrms / 3V/m compliance)			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz in ISM bands *d = [3,5] P V***1**	80 MHz to 800 MHz *d = [3,5] P E***1**	800 MHz to 2.5 GHz *d = [7] P E***1**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

The Withings Thermo declaration electromagnetic immunity
The Withings Thermo system is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Thermo system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.

Declaration – electromagnetic immunity
The Withings Thermo is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Thermo system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge	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 %.

(ESD)IEC 61000-4-2			
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	N/A	A 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	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or of hospital environment.

DISPOSAL

Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of devices useful life, the user must deliver it to the able collecting centers for electric and electronic garbage, or give back to the retailer when purchasing a new device. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of which it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the environment and health. In case of abusive disposal of device by the user, will be applied administrative endorsements in compliance with current standard. The device and its parts is marred with regard to disposal, as appropriate, in accordance with national or regional regulations.

Reference to standards

This device complies with the following normative documents : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC
– EN ISO 80601-2-56 : Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
– EN ISO 12470-5: 2003 : "Clinical thermometers" – Part 5: Performance of infrared thermometers (with maximum device)
– ASTM 1965E : ASTM Standard for Infrared Clinical Thermometer
– EN ISO 13485: 2003/AC: 2009: Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2003) Reference to standards contd.
– EN ISO14971: 2012: Medical devices – Application of risk management to medical devices (ISO 14971: 2007, Corrected version 2007-10-01)
– IEC60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007); EN 60601-1: 2006 + AC (2010): Medical electrical equipment – Part 1: General requirements for basic safety and essential Performance
– EN60601-1-2: 2007 CISPR: 2011: Medical electrical equipment: Part 1-2: General requirements for basic safety and essential performance-collateral standard electromagnetic compatibility
– IEC/EN 60601-1-11: 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
– IEC 80601-2-30: 2009 (First Edition) for use in conjunction with IEC 60601-1:2005
– EN300328 V1.8.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
– EN301489-1-3 V1.9.2 (2011) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
– EN301489-1-17 V2.2.1(2012) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
– EN 55011: 2009/A1: 2010: Industrial, scientific and medical equipment –Radiofrequency disturbance characteristics – Limits and methods of measurement
– FCC part B 15B: 2013 Electromagnetic Compatibility
– FCC Rule Part: 15.247 Cat: DSS (Bluetooth) FCC Rule Part: 15.247 Cat: DTS (BT4.0)
– EN ISO 10993-1: 2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
– EN 980 : 2008 Symbols for use in labeling of medical devices