Electrical Thermometer

Model UT-201BLE-A

— Oral type —

Instruction manual

Original

ENGLISH

— Type oral —

Manuel d'instructions

Traduction

FRANÇAIS

— Tipo oral —

Manual de instrucciones

Traducción

ESPAÑOL

— Tipo orale —

Manuale di istruzioni

Traduzione

ITALIANO

— Oraler typ —

Bedienungsanleitung

Übersetzung

DEUTSCH

— 口溫計 —

使用手冊

翻譯

中文

Bluetooth®

Continua™ CERTIFIED

1WMPD4003378C

Contents

Dear Customers

Congratulations on purchasing a state-of-the-art A&D thermometer, one of the most advanced thermometers available today. Designed for ease of use and accuracy, this thermometer will facilitate your thermometer regimen.

We recommend that you read through this manual carefully before using the device for the first time.

Preliminary Remarks

- ❑ This device conforms to the European Directive 93/42 EEC for Medical Products. This is made evident by the CE0123 mark of conformity.
  (0123 : The reference number to the involved notified body.)
- ❑ This device fulfills the provisions of BS EN 12470 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device.
- ❑ Hereby, A&D Company, Limited declares that the radio equipment type UT-201BLE-A is in compliance with Directive 2014/53/EU. The full text of the EU declaration is available at the following internet address:
  `http://www.aandd.jp/products/manual/manual_medical.html`
- ❑ The device is a Continua certified, *Bluetooth*® wireless technology enabled medical device.
- ❑ The device is designed to be used in the medical facilities.
- ❑ This device is designed to measure body temperature.
- ❑ This device is designed to be operated by an adult (18 years old or older).
- ❑ This device intends to measure the body temperature of the patient (5 years old or older).

Precautions

- ❑ Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided. It may be cause of losing performances of sensor, battery, electrical terminals and this device.
- ❑ This device is the thermometer to measure an oral temperature of bottom side of tongue. Do not measure a temperature of other position so it is incorrect.
- ❑ Clean the device with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device.
- ❑ Clean the device before and after use. Keep cleanly to be able to insert into mouth. It may be the cause of occurring a cross-infection if not clean.
- ❑ Avoid excessive shock. It may be the cause of a malfunction.
- ❑ Do not put the device in the neighborhood of heater. Prevent the device from splashing of a hot water. It may be the cause of a malfunction.
- ❑ The device is not water resistant. Prevent rain, sweat and water from soiling the device.
- ❑ Measurements may be distorted if the device is used close to televisions, microwave ovens, X-ray or other devices with strong electrical fields.
- ❑ Wireless communication devices, such as networking devices, mobile phones, cordless phones and their base stations, walkie-talkies can affect this thermometer. Therefore, a minimum distance of 30 cm should be kept from such devices.
- ❑ When reusing the device, confirm that the device is clean.
- ❑ Used equipment, parts and battery are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.
- ❑ Do not modify the device. It may cause accidents or damage to the device.
- ❑ Do not let children use the device by themselves and do not use the device in a place within the reach of infants.
- ❑ There are small parts that may cause a choking hazard if swallowed by mistake by infants.
- ❑ When the liquid inside of the battery invades into an eye, wash eye with large quantities of water as quickly as possible, consult the doctor for diagnose and treatment. It may be the cause of blindness and injury, if not perform.

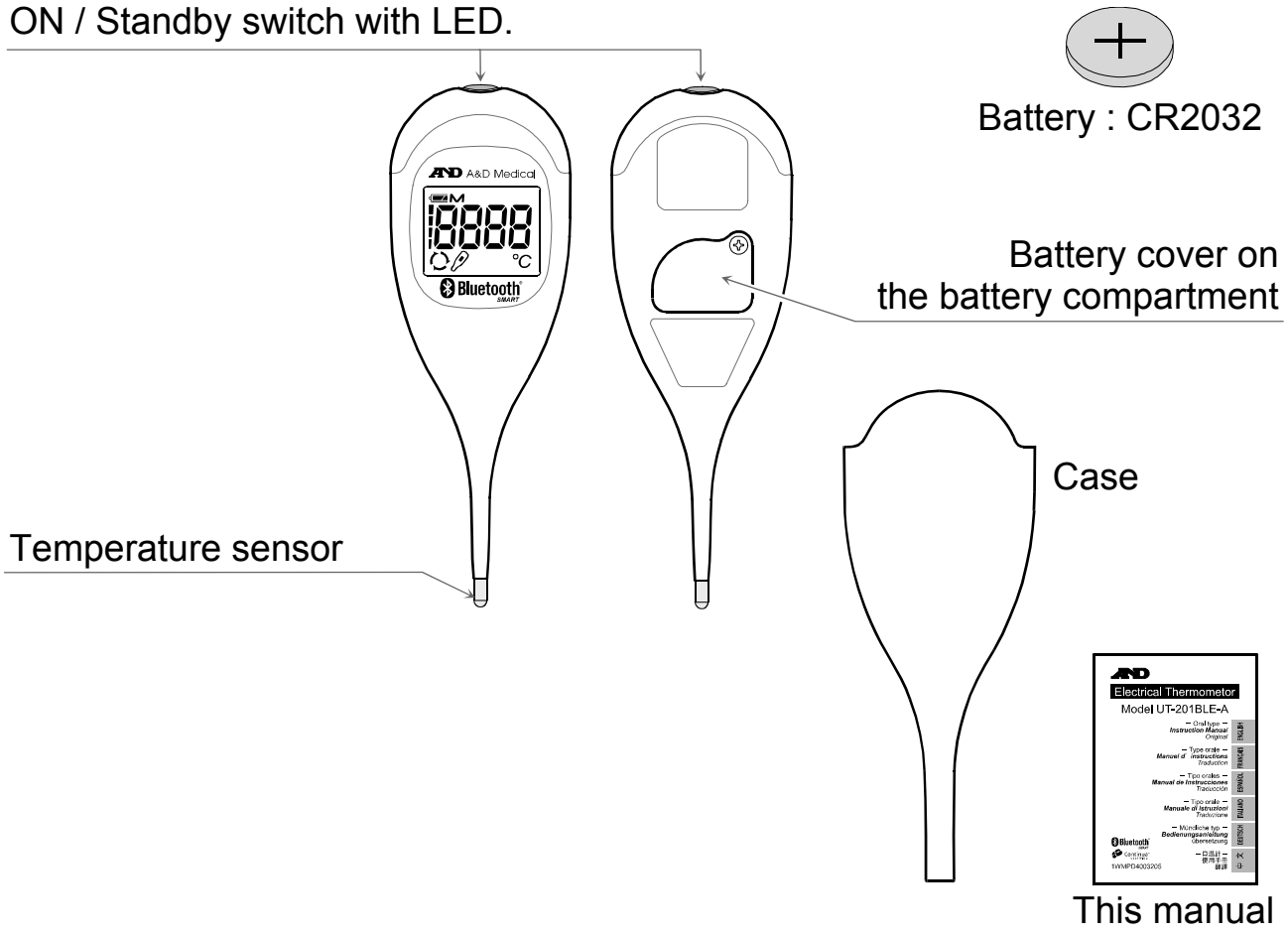
- ❑ When your skin and cloth are touched to the liquid inside of the battery, wash them with large quantities of water.
- ❑ Replacement of battery by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion).
- ❑ Use the battery, removable parts and materials that are described in this manual. It may be the cause of malfunction and injury, if not use.
- ❑ Insert the battery with proper polarities (+) and (−) into the compartment. It may be the cause of malfunction and injury, if not insert correctly.
- ❑ Do not short-circuit the battery. Failure to do so may lead to fluid leakage, heat generation or bursting, and resulting in injury.
- ❑ Do not heat the battery. Failure to do so may lead to fluid leakage, bursting, and resulting in injury.
- ❑ Prevent the device from chewing and bending. It may be the cause of malfunction and injury, if it is chewed and bended.
- ❑ We recommend that you read through this manual carefully before using the device for the first time.
- ❑ Do not use this device with equipment such as a sensor cover. This may affect the accuracy of measurements.

Contraindications

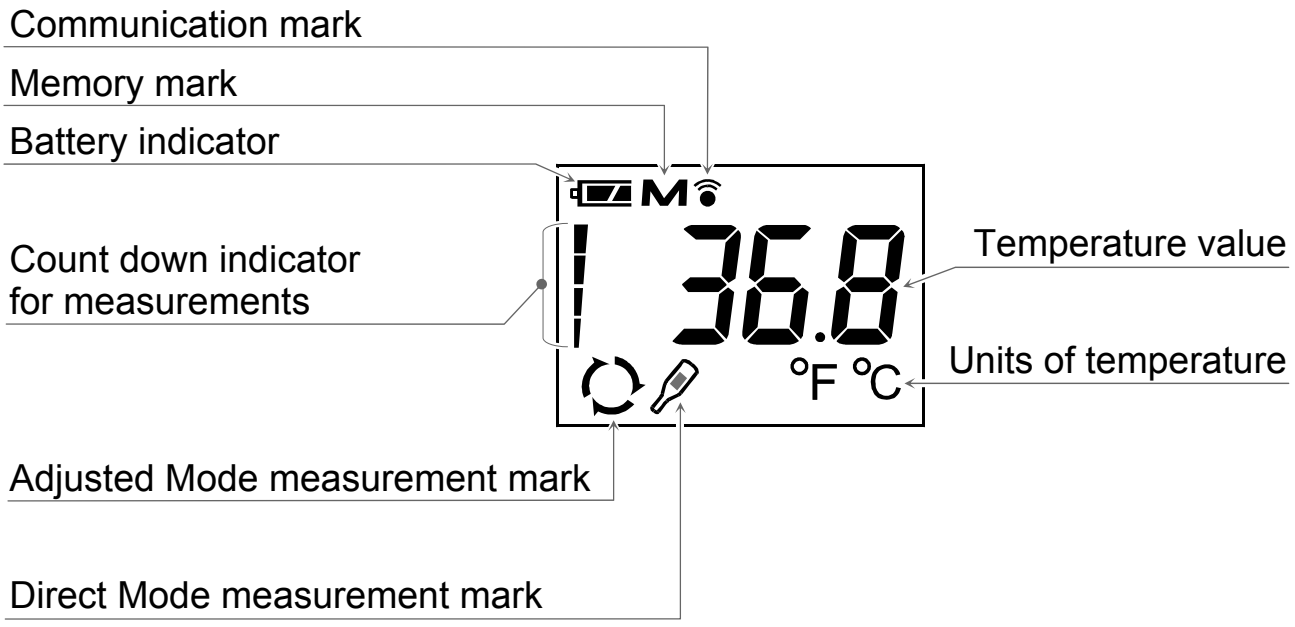
The following are precautions for proper use of the device.

- ❑ Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
- ❑ Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion.

Parts Identification



Display



Symbols

Symbols that are displayed on the device

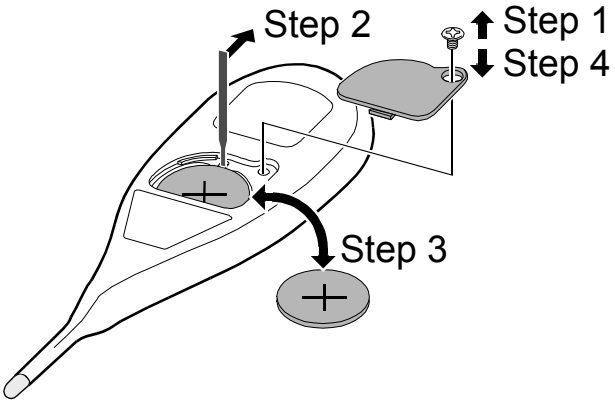
Symbols	Function / Meaning
⏻	Standby and turn on the thermometer.
M	Last reading is stored in memory when the mark is displayed.
	Full battery mark.
	Low battery mark: A half of the battery capacity was consumed.
	Battery is low when it blinks. Replace a battery with new one.
H	Temperature is above 42 °C during measurement.
L	Temperature is below 32 °C during measurement.
HH	Thermometer or room temperature is above 40 °C.
LL	Thermometer or room temperature is below 10 °C
Err 1	Measurement is not correct. Check the way of use.
Err 2	Malfunction of thermometer. Contact your dealer.
E-10	Time out of Bluetooth communication.
E-11	Bluetooth communication error.
	Bluetooth communication mark.
Pr	Pair mark to construct Bluetooth communication pair.
	Adjusted Mode measurement mark.
	Direct Mode measurement mark.
°C °F	Temperature units of Celsius and Fahrenheit.
	Count down indicator for measurements means a waiting time until displaying temperature. This indicator may include few timing error in process.
⎓	Direct current.
	Type BF: Device is designed to provide special protection against electrical shocks.
CE 0123	EC directive medical device label
EC REP	EU-representative
	Manufacturer
2016	Date of manufacture
	Not waterproof
	Class II device
	WEEE label
SN	Serial number
BT	Bluetooth address
	Refer to instruction manual/booklet
	Negative electrode

Symbols	Function / Meaning
(((•)))	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

Using the Thermometer

Installing / Changing the Battery

1. Remove the battery cover.
2. Remove the used battery with a stick.
3. Insert a new battery into the battery compartment as shown, taking care that the polarities (+) and (−) are correct.
4. Replace the battery cover.
   Use only CR2032 battery.



Caution

- ❑ Insert the battery as shown in the battery compartment. If installed incorrectly, the device will not work.
- ❑ When  (Low battery mark) blinks in the display, replace the battery with a new one. Replace the battery after the device turns off and wait for two seconds or more.
- ❑  (Low battery mark) does not appear when the battery is drained.
- ❑ Use the specified battery only. The battery provided with the device is for testing thermometer performance and may have a limited life.
- ❑ Remove the battery if the device is not to be used for a long time.

  The battery may leak and cause a malfunction.

- ❑ ⚠ Keep the thermometer out of the reach of children. A child may swallow the battery while playing with it. If a child should swallow the battery, seek medical treatment immediately.

Using the Thermometer

Wireless Function

Caution

- ❑ In the unlikely event that this thermometer causes radio wave interference to a different wireless station, change the location where this thermometer is used or stop use immediately.
- ❑ Be sure to use in a location where visibility between the two devices that you want to connect is good. The connection distance is reduced by the structure of buildings or other obstructions. In particular, connection may be impossible when devices are used on either side of reinforced concrete.
- ❑ Do not use *Bluetooth*® connection in the range of a wireless LAN or other wireless devices, near devices that emit radio waves such as microwaves, in locations where there are many obstructions, or in other locations where signal strength is weak. Doing so may result in frequent loss of connection, very slow communication speeds and errors.
- ❑ Using close to an IEEE802.11g/b/n wireless LAN device may cause mutual interference to occur, which may result in reduced communication speeds or which may prevent connection. In this case, switch off the power supply to the device that is not being used, or use the thermometer in a different location.
- ❑ If the thermometer does not connect normally when used near a wireless station or broadcast station, use the thermometer in a different location.
- ❑ A&D Company, Limited cannot accept liability for any damages incurred due to impaired operation or data loss, etc. that occur through the use of this device.
- ❑ This device is not guaranteed to connect to all *Bluetooth*® compatible devices.

Using the Thermometer

Bluetooth® Transmission

This device is equipped with a *Bluetooth*® wireless function and can connect to the following *Bluetooth*® devices.

- ❑ Continua certified devices
- ❑ iPhone, iPad, iPod (iPhone 4S or later)
- ❑ Applications and devices that are compatible with Bluetooth 4.0.

Each device needs an application to receive data.
For connection methods, refer to the manual for each device.

Bluetooth® devices carry the *Bluetooth*® logo mark.

Continua certified devices carry the Continua logo mark.

Using the Thermometer

Pairing

A *Bluetooth*® device needs to be paired with a different specific device in order to communicate with that device. If this thermometer is paired with a receiver device from the start, measurement data is transmitted automatically to the receiver device each time a measurement is made.

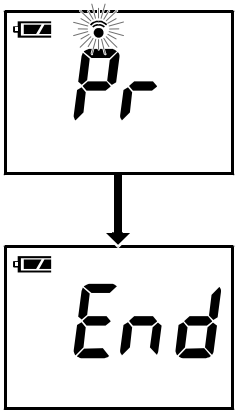
Cautions for Pairing

- ❑ Only one device can be paired with this thermometer at one time. If the receiver device cannot receive measurement data, try pairing again
- ❑ If another receiver device is paired, the first device will be unpaired to enable the new device to be paired.

Follow the steps below to pair the thermometer with a *Bluetooth*® compatible receiver device. Also refer to the manual of the receiver device. Please use a pairing wizard if one is provided.

Pairing Procedure

1. Follow the instructions in the manual of the receiver device to switch it to the pairable status. When pairing this thermometer, place it as close as possible to the receiver device to be paired with.
2. Install the battery as described on page 7.
   Press the ⏻ switch to turn the thermometer on.
   Press the ⏻ switch while "L" is displayed.
   The thermometer can be found by the receiver device while "Pr" is displayed for approx. one minute.
3. Find, select and build a pair with the receiver device in accordance with its manual. When the pairing of the receiver device is built, "End" of the decision of the pairing is displayed.
4. If "E- 10" is displayed or pairing is failed, remove the battery and try steps 1 to 3 again.
5. Follow the manual of the pairing receiver device to search for, select and pair with this thermometer.



Communication Distance

The communication distance between this thermometer and the receiver device is approximately 5 m.
This distance is reduced by the conditions in the surrounding environment, so be sure to check that the distance is short enough for a connection to be made after measurement is complete.

Using the Thermometer

Measurement and Transmitting Data

The communication performs the following steps after building the paring. Keep the condition of the receiver device so as to communicate.

1. Turn on the thermometer. Data is measured automatically.
2. Data is transmitted after finishing the measurement.

Transmitting Temporarily Stored Data

In cases when the receiver device cannot receive measurement data, the measurement data is temporarily stored in the thermometer memory. The data stored in the memory is transmitted the next time a connection is successfully made to the receiver device

A total of 90 sets of measurement data can be stored. When the amount of data exceeds 90 sets, the oldest data is deleted and the new data is stored. The amount of data that can be stored temporarily may vary with the application.

Time

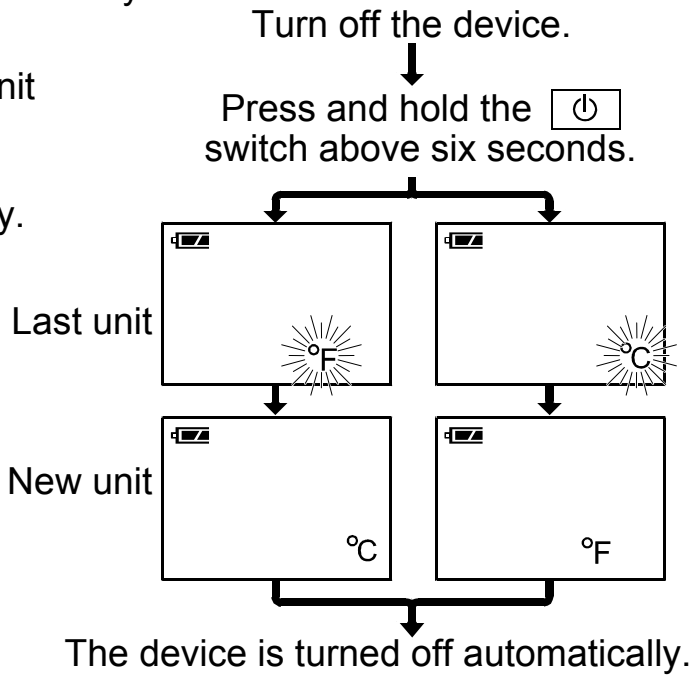
This thermometer has a built-in clock. The date and time that a measurement was taken is included in the measurement data.

The built-in clock is designed to be automatically adjusted by syncing with the clock of a receiver device. Refer to the specifications of the receiver device. This thermometer has no clock adjustment function.

Changing Units

1. Press and hold the ⏻ switch above 6 seconds when turning off the thermometer. The new unit is displayed after blinking the last unit. The thermometer turns off automatically.
2. When the same operation is performed again, an effective unit is exchanged.

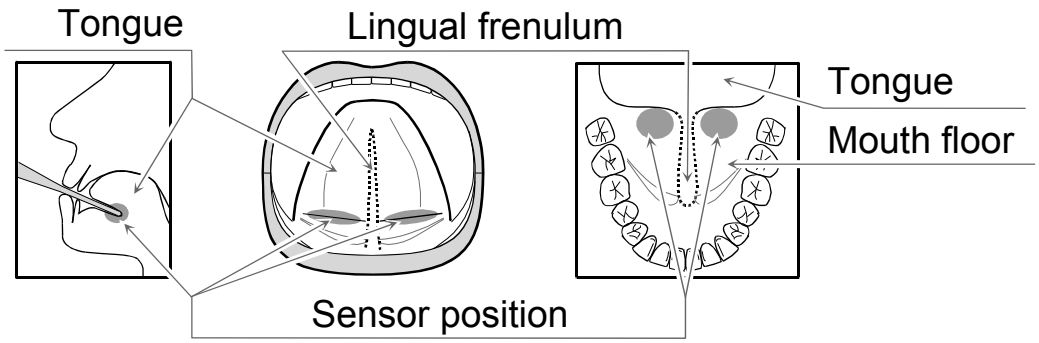
   The unit is stored in the memory. The unit of the factory setting is °C (centigrade).



Using the Thermometer

Applying the Thermometer

- ❑ Put the thermometer sensor on the mouth floor under the tongue, at the root of the tongue and at the side of the lingual frenulum.
- ❑ Keep the position of the sensor during measurement



Measurement Time

- ❑ When the adjusted mode measurement is used, keep the sensor position for approximately 30 seconds with placing the sensor at a correct position in the mouth.
- ❑ When the direct mode measurement is used, keep the sensor position for approximately 5 minutes with placing the sensor at a correct position in the mouth.

  We recommend to use the direct mode measurement for a precision thermometry.

After Measurement

After measurement, press and hold the ⏻ switch for one or more seconds to turn the device off.

Note: The device has an automatic power shut-off function, which turns the power off approximately one minute after measurement.

Measurements

Adjusted Mode Measurement

1. Press the ⏻ switch.
   When the last measurement is stored, it is displayed for approximately two seconds.

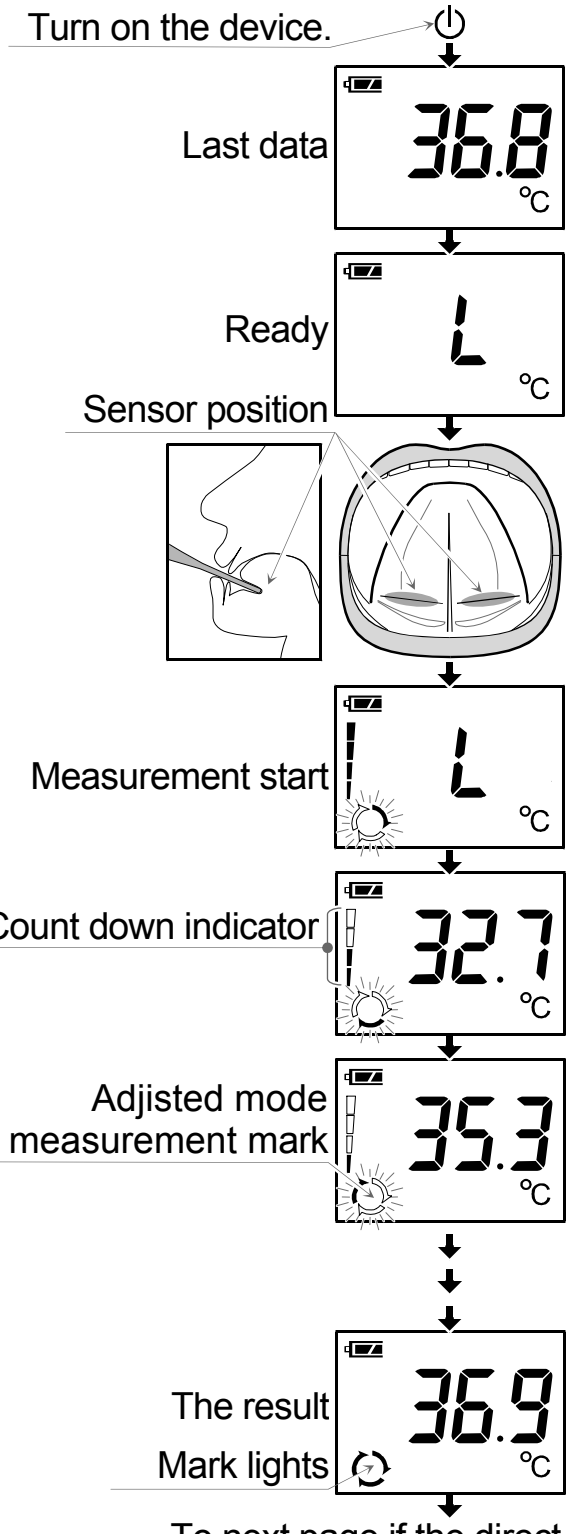
2. Wait until "L" is displayed.

3. Put the temperature sensor on the mouth floor (under the tongue, at the root of the tongue and at the side of the lingual frenulum).
   Close the mouth gently.

4. keep the sensor position during measurement for approximately 30 seconds.

5. The count down indicator is displayed.
   The adjusted mode measurement mark blinks and rotates.

6. The result is displayed for approximately 15 seconds, the adjusted mode measurement mark lights, the LED of the ⏻ switch blinks and buzzer sounds when the adjusted mode measurement finishes.



7. Select an operation.
   - ❑ Press the ⏻ switch to turn the thermometer off.
   - ❑ Keep the sensor position to use the direct mode measurement. Proceed to next page.

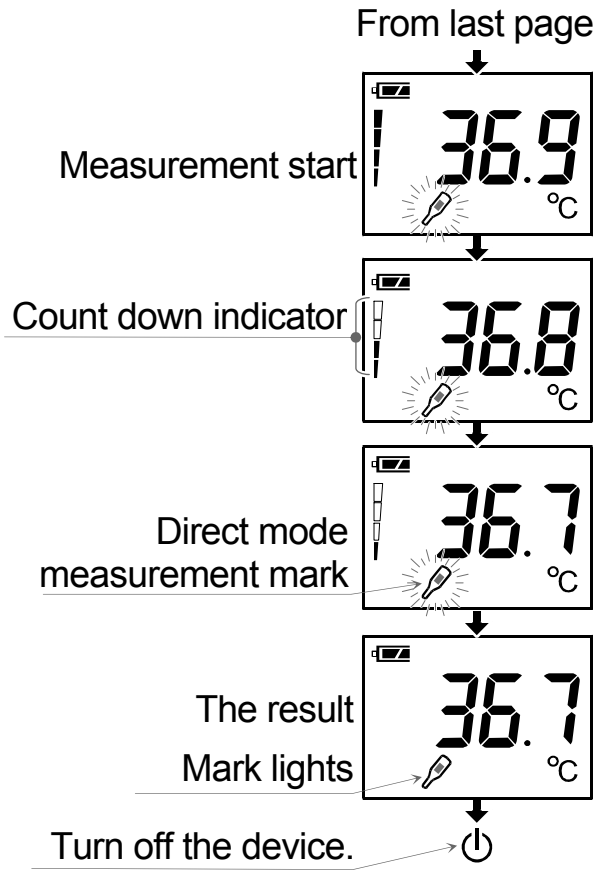
Measurements

Direct Mode Measurement

8. When the direct mode measurement starts, the mark blinks. Keep the sensor position for approximately five minutes.

9. The result is displayed for approximately one minute, the direct mode measurement mark lights, the LED of the ⏻ switch blinks and buzzer sounds when the direct mode measurement finishes.

10. Press and hold the ⏻ switch to turn the device off.

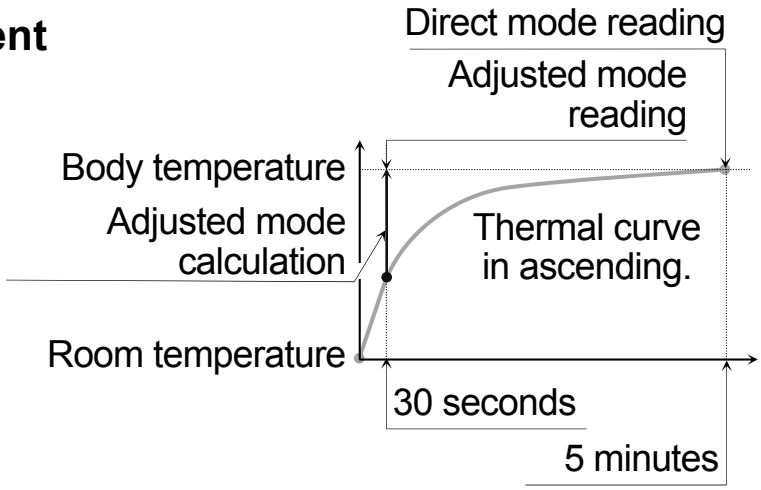


Notes for Accurate Measurement

- ❑ The M mark lights when the data is stored in memory.
- ❑ The direct mode measurement is performed after the adjusted mode measurement is finished.
- ❑ The device is provided with an automatic power shut-off function with the buzzer that the device is turned off at approximately one minute later from removing it or displaying data.
  The device can be turned off when pressing and holding the ⏻ switch.
- ❑ In measurement, breathe with using nose and closing mouth.
- ❑ Should the device detect a condition that is abnormal, it will stop the measurement and display an error symbol. See page 6 for the description of the symbols.
- ❑ This thermometer is intended for use by adults only. Consult with your physician before using this device on a child. A child should not use this device unattended.
- ❑ To ensure accurate measurement, wait at least 30 seconds between each use to allow the thermometer to return to room temperature.

Features

Adjusted Mode Measurement



- ❑ The adjusted mode measurement calculates the direct mode temperature after five minutes when the body temperature is measured for 30 seconds. It is based on an ascending thermal curve.
  If you need a precision data, we recommend to use the direct mode measurement for a precision thermometry.

- ❑

Results of Clinical Evaluation	
Clinical Bias	-0.06 °C
Clinical Repeatability	0.12 °C
Limit of Agreement	0.22 °C
Standard Deviation	0.08 °C

Direct Mode Measurement

- ❑ The body temperature can be measured using for five minutes.

Switch with Flash Action

- ❑ When pressing the ⏻ switch , this switch flashes.
  When finishing the measurement, this switch flashes.

Last Reading Display and Memory

- ❑ The previous reading stored in memory is automatically displayed when turning on the thermometer. The new reading is stored in memory when measuring the temperature.

Temperature Unit

- ❑ Temperature unit of Celsius or Fahrenheit can be selected .

Bluetooth®

- ❑ Temperature data can be transmitted to the receiver that is paired with the thermometer.

Troubleshooting

Problem	Possible Reason	Recommended Action
Nothing appears in the display, even when the power is turned on.	Battery is drained.	Replace the battery with a new one.
	Battery terminals are not in the correct position.	Reinstall the battery with negative and positive terminals matching those indicated on the battery compartment.
No measurement	Battery power is low. If the battery is drained completely, the mark does not appear.	Replace the battery with a new one.
Normal body temperature includes error.	Temperature will change at awaking, in activity, after eating.	Measure the temperature under the same condition.
Body temperature is displayed low.	Incorrect sensor position	Check the sensor position.
Body temperature is displayed high.	The device calculates an direct mode temperature after five minutes. Therefore, it includes error.	Measure after several minutes again or use the direct mode measurement.
Data transmission error	The paring is not established.	Place the device in proximity of the receiver. Make a paring.
	Battery is not enough.	Replace the battery with a new one.

Note: If the actions described above do not solve the problem, contact the dealer. Do not attempt to open or repair this device, as any attempt to do so will make your warranty invalid.

Maintenance

Maintenance

- ❑ Do not open the device. It uses delicate electrical components and an intricate air unit that could be damaged. If you cannot fix the problem using the troubleshooting instructions, request service from your dealer or from the A&D service group. The A&D service group will provide technical information, spare parts and units to authorized dealers.
- ❑ The device was designed and manufactured for a long service life. However it is generally recommended to have the device inspected every two years, to ensure proper functioning and accuracy. Please contact the authorized dealer in your area or A&D for maintenance.

Cleaning

- ❑ Clean the device with a dry, soft cloth or a cloth dampened with water and a neutral detergent and wrung tightly.
- ❑ Wipe the temperature sensor of the device with a cloth to soak disinfectant ethanol (76.9 to 81.4 v/v%).

Storage

- ❑ Store the device with avoiding extremes in temperature, humidity, direct sunlight, vibration, shock, dust or fire. Keep it put into the case with dry air and room temperature.

Cautions

- ❑ The device is not a waterproof device. Do not splash water on it and avoid exposure to moisture.
- ❑ Do not use an organic solvent such as thinner or benzene.
- ❑ The device cannot be sterilized by autoclave, EOG or formaldehyde etc.

Regular Inspection

- ❑ The thermometer is a precision device. Therefore, inspect it regularly. Request an inspection to the dealer where you have purchased the device when the device is in needs of an inspection.

Disposal

- ❑ This equipment and battery are not treated as ordinary household waste and must be disposed of according to the applicable local regulations.

Item	Parts	Material
Package	Box Cushioning material	Cardboard PVC
Main unit and accessories	Enclosure	ABS
	Internal parts Storage case	General electronic components PP
Temperature sensor Battery	SUS CAP	SUS304 Lithium battery

Technical Data

Model	UT-201BLE-A
Measurement method	Adjusted mode measurement using thermistor, Direct mode measurement using thermistor
Measuring site/Reference body site	Oral, under tongue
Temperature sensor	Thermistor
Measurement range	32.0 to 42.0 °C (89.6 to 107.6 °F)
Measurement accuracy	±0.1 °C
Measurement time	Adjusted mode measurement : Approx. 30 seconds Direct mode measurement : Approx. 5 minutes
Display	3 digits, resolution 0.1 °C 4 digits, resolution 0.1 °F
Power supply	CR2032 x1 (3V Lithium battery) Use only battery that conforms to the IEC 60086-4.
Battery life	Adjusted mode measurement : Approx. 350 times Direct mode measurement : Approx. 120 times
Useful life	5 years
Wireless communication	VZ (MURATA Manufacturing Co. Ltd.) Bluetooth® Ver.4.0, low energy, HTP Frequency band: 2402 MHz to 2480 MHz Maximum RF output power: 1.6 dBm Modulation:GFSK
EMD	IEC 60601-1-2 : 2014
Memory	Last measurement
Classification	Internally powered ME equipment Continuous operation mode
Applied part	Type BF
Operating conditions	+10 °C to +40 °C / 15%RH to 85%RH 800 kPa to 1060 kPa
Transport/Storage conditions	−20 °C to +60 °C / 15%RH to 95%RH 700 kPa to 1060 kPa
Dimensions	Approx. 40 [W] x 117 [H] x 15 [D] mm
Weight	Approx. 25 g including battery
Accessory	Case, a temporary battery, this instruction manual

Note: Specifications are subject to change for improvement without prior notice.

EMD Technical Data Battery-operated Blood Pressure Monitor

Medical Electrical Equipment needs special precautions regarding EMD and needs to be installed and put into service according to the EMD 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 1 －EMISSION Limits－

Phenomenon	Compliance
Conducted and radiated RF EMISSION CISPR 11	Group 1、Class B

Table 2 －IMMUNITY TEST LEVELS：Enclosure Port－

Phenomenon	IMMUNITY TEST LEVELS
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table 3
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3 －Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment－

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13、17	Pulse modulation 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 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 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Blutooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

MEMO

A&D Company, Limited
1-243 Asahi , Kitamoto-shi, Saitama 364-8585, JAPAN
Telephone: [81] (48) 593-1111 Fax: [81] (48) 593-1119

EC REP **Emergo Europe B.V.**
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel: [31] (70) 345-8570 Fax: [31] (70) 346-7299

A&D INSTRUMENTS LIMITED
Unit 24/26 Blacklands Way, Abingdon Business Park, Abingdon, Oxfordshire OX14 1DY United Kingdom
Telephone: [44] (1235) 550420 Fax: [44] (1235) 550485

A&D ENGINEERING, INC.
1756 Automation Parkway, San Jose, California 95131, U.S.A.
Telephone: [1] (408) 263-5333 Fax: [1] (408)263-0119

A&D AUSTRALASIA PTY LTD
32 Dew Street, Thebarton, South Australia 5031, AUSTRALIA
Telephone: [61] (8) 8301-8100 Fax: [61] (8) 8352-7409

OOO A&D RUS ООО "ЭЙ энд ДИ РУС"
121357, Российская Федерация, г.Москва, ул. Верейская, дом 17
(Business-Center "Vereyskaya Plaza-2" 121357, Russian Federation, Moscow, Vereyskaya Street 17)
тел.: [7] (495) 937-33-44 факс: [7] (495) 937-55-66

A&D Technology Trading(Shanghai) Co. Ltd 爱安德技研贸易（上海）有限公司
中国 上海市浦东新区浦东大道138号永华大厦21楼A室 邮编200120
(21F Room A, Majesty Building, No.138 Pudong Avenue, Pudong New Area, Shanghai, 200120, China)
电话: [86] (21) 3393-2340 传真: [86] (21) 3393-2347

A&D INSTRUMENTS INDIA PRIVATE LIMITED ऐ&डी इन्स्ट्रूमेन्ट्स इण्डिया प्रा० लिमिटेड
509, उद्योग विहार , फेस –5, गुड़गांव – 122016, हरियाणा , भारत
(509, Udyog Vihar, Phase–Ⅴ, Gurgaon – 122 016, Haryana, India)
फोन : 91–124–4715555 फैक्स : 91–124–4715599

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