

Quanta Computer

QOCA Disposable BLE Thermometer
User Manual

CIH418-01 Ver.: 2A



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SAFETY NOTES

- Please read through this user guide carefully before using QOCA DISPOSABLE BLE THERMOMETER.
- The QOCA DISPOSABLE BLE THERMOMETER is to be used for clinical assessment and personal reference only.
- The QOCA DISPOSABLE BLE THERMOMETER consists entirely of sophisticated medical electrical parts. Maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.
- The QOCA DISPOSABLE BLE THERMOMETER must be used with its specified accessories. The use of accessories from other brands can damage the device or cause inaccurate readings.
- Do not allow the connectors or contacts on the devices to come into contact with any kind of power source during use.
- Damaged or faulty accessories should not be used.
- When the QOCA DISPOSABLE BLE THERMOMETER is low on battery power, it will automatically stop taking measurements and the corresponding indicator lights will blink.

- Avoid using devices that can affect the accuracy of the readings when the QOCA DISPOSABLE BLE THERMOMETER is taking measurements.
- Avoid using other electronic devices when the QOCA DISPOSABLE BLE THERMOMETER is taking measurements. If using another other electronic device is necessary, please check to ensure the thermometer is continuing to take measurements normally.
- Do not use the QOCA DISPOSABLE BLE THERMOMETER near open flames or in excessive heat.
- Pay attention to ensure that the QOCA DISPOSABLE BLE THERMOMETER is not swallowed by pets or children.
- If QOCA DISPOSABLE BLE THERMOMETER must be used to take measurements over an extended period of time, please inspect the contact point of the thermometer at least once every 24 hours to make sure that the thermometer is in the right position and that there is no allergic reaction on the user's skin.
- Do not use high-frequency instruments or electrical medical equipment when using the QOCA DISPOSABLE BLE THERMOMETER.

- The QOCA DISPOSABLE BLE THERMOMETER can only take measurements while the subject is at rest (e.g., while sitting or lying down) or engaging in ordinary activity. Any activities not permitted by the attending physician may affect the accuracy of the measurements.
- Do not expose QOCA DISPOSABLE BLE THERMOMETER to extreme temperatures, extremely moist environments, dust, or direct sunlight.
- Do not clean the QOCA DISPOSABLE BLE THERMOMETER with corrosive or abrasive cleaning agents.
- The QOCA DISPOSABLE BLE THERMOMETER and its accessories should be disposed of properly. Disposal of the device and its accessories should comply with the relevant local regulations.
- The QOCA DISPOSABLE BLE THERMOMETER has been tested and certified to international electro-magnetic compatibility (EMC) standards for medical equipment (EN 60601-1 and EN 60601-1-2). If abnormal behavior is observed due to EMC disturbances, please relocate the device accordingly.
- **The expected service life of the QOCA DISPOSABLE BLE THERMOMETER is 1 years.**

- People with sensitive skin or with known skin conditions should use the QOCA DISPOSABLE BLE THERMOMETER with caution. If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, instruct patients to remove the QOCA DISPOSABLE BLE THERMOMETER immediately and have them contact their physician.
- Do not use QOCA DISPOSABLE BLE THERMOMETER on patients with known skin allergies or family history of skin allergies.
- Do not use QOCA DISPOSABLE BLE THERMOMETER in MRI or X-ray room.
- This device should not be used adjacent to or stacked with other equipment.
- Due to electrostatic discharge (ESD) sparks may cause sparks. QOCA DISPOSABLE BLE THERMOMETER is not suitable for use in an explosive environment.
- Avoid using heavy electronic equipment or other sources of electromagnetic interference (such as electric blankets) when using the QOCA DISPOSABLE BLE THERMOMETER.

PRODUCT OVERVIEW




Indication for Use

QOCA DISPOSABLE BLE THERMOMETER detects body temperature continuously. Attached to a unique tape and sensor user can easily monitor their body temperature in daily life at home or at hospital. QOCA DISPOSABLE BLE THERMOMETER can be measured and transferred body temperature via BLE up to 14 days. And those body temperature data can be forwarded to the cloud server by mobile phone or gateway for further data analysis.

Package Contents

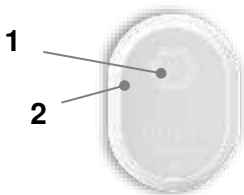
After purchasing the QOCA DISPOSABLE BLE THERMOMETER , please check the product package to ensure that the following items are included:

Q-temp-w1 product package

		
Q-temp-w1 Sensor x 1	User Manual x 1	Adhesive x 1

Components

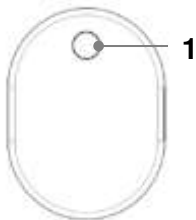
Sensor Front



1	Power Button
2	LED (see <i>LED Indicators</i> for more information)

NOTE: Electrode button connector will support plug in/off test under 1000 times.

Back



1	Temperature Sensor Contact Point
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Product Requirements

In order to properly use the QOCA DISPOSABLE BLE THERMOMETER the following items are required:

For Body Patch:

- The Sensor with adhesive
- A Bluetooth-enabled Android Smartphone* (with Android version 8.x or above and a display resolution of 1920x1080 or 2560x1440)

- The Q-temp APP *

** Items not included in the product package.*

BEFORE YOU START

Before you start using the QOCA DISPOSABLE BLE THERMOMETER you must:

1. Install the Q-temp APP on your Android smartphone
2. Enable Bluetooth on your smartphone

Installing the App

To install the app, search for and download “Q-temp APP” on Google Play Store.

NOTE: In order to install the Q-temp APP your smartphone will need at least 5MB of storage capacity available.

Enabling Bluetooth

To enable Bluetooth, enter the Settings menu on your smartphone and enable Bluetooth.

GETTING STARTED

Once you have completed the steps described in *Before You Start*, you can begin using the QOCA DISPOSABLE BLE THERMOMETER by following these steps:

1. Pair your smartphone to the sensor via Bluetooth
2. Wear the QOCA DISPOSABLE BLE THERMOMETER

Pairing

1. When enter the APP, it would show the nearby BLE devices. Please select the name “MH8XXXXXXXXX” .
2. It takes a few seconds to do the pairing. Please wait for a while.
3. Wait until a entering the main page of Q-temp APP on your smartphone indicating that the pairing is complete.

NOTE: *If pairing within the Q-temp APP fails, please check the Bluetooth status on the smartphone.*

Wearing the QOCA Disposable BLE Thermometer

The following steps describe the body patch wearing process:

A. Preparing the Skin

Step 1: Remove all hair over armpit area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the sensor will be placed.

Step 2: Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

B. Wearing the QOCA disposable BLE thermometer

Step 3: Place the QOCA disposable BLE thermometer in 90 degrees dump position. (As below figure) And Tear off the release paper.



Step 4: Adhere the QOCA disposable BLE thermometer under armpit as shown below figure.



Step 5: Hand pressure on the body patch (especially on the connect point) for at least 30 seconds.

Step 6: Do not exercise or take shower after adhesive sensor on the body for at least 2 hours.

IMPORTANT: Able to engage in daily activities, do not do strenuous exercise, or swimming.

IMPORTANT: The Patch needs 24 hours to fully stick to your skin, we recommend showering briefly with your back to the water, and avoid any activities that cause sweating during this period. Skin exfoliation will help the contact of patch.

IMPORTANT: *If the skin at the contact point develops a rash, blisters, reddening, or other irritation, please contact a medical professional or physician.*

THE Q-TEMP APP

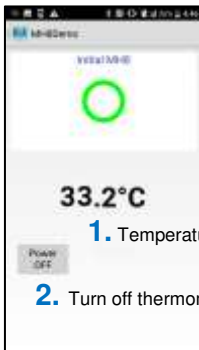
Main Screen

Once you have successfully launched and worn the QOCA Disposable BLE Thermometer, the Q-temp APP's BLE device list will display on your mobile phone. Select the device's name "MH8Demo" for BLE connection.



Take a Measurement

When the BLE is connected, it would take measurement automatically. And the temperature value will show on the middle of screen.



ADDITIONAL INFORMATION

LED Indicators

The following tables describe the indicators on both the sensor and charger:

Event	Action	Behavior
Power on	Press power button	The LED flashing green until it's connected or auto power off.
Low battery	N/A	Battery LED flashing orange light.

Cleaning

The appropriate cleaning methods:

Item	Cleaning Method
Sensor	Wipe with a dry cloth when it's dirty. And clean it every day if it is frequently used.

Specifications

Model	Q-temp-w1
Temperature range	77 – 113°F (25 – 45°C)
Reading resolution	(1) 0.1°C (0.1°F)
Accuracy	35.5 – 42°C +/-0.1°C (+/-0.18°F)
Battery	25 – 35.5°C & 42 – 45°C +/-0.2°C (+/-0.36°F)
Measured location	Armpit
Connectivity	BLE 5.0 (measured range: open space 5 m)
Transmission Frequency	Temperature sensing default at every 30 seconds. (The body temperature will be stable after attached on body for five minutes)
Battery Type	Coin Battery CR2016
Battery Life	Up to 14 days (every 10 minutes takes one measurement)

IP Rating	IP34
Button	One power button
Indicator	<p>One LED</p> <ol style="list-style-type: none"> 1. Flash green light while power on 2. Flash red light while low battery 3. LED turn off while BLE connected 4. Automatic turn off while temperature lower 30°C for 5 mins
Weight	5.8g
Dimension (mm) L x W x H	39.3 x 29.2 x 4.6 (mm)
Anti-Allergy Contact	3M 4075 adhesive
	SUS 304 stainless steel medical grade
Working Temperature	5 – 45°C
Storage Temperature	-20 – 60°C

Troubleshooting

- 1) **Cannot pair the QOCA DISPOSABLE BLE THERMOMETER with the Q-temp APP.**

Refer to the notes listed in *Pairing*.

Gateway mode information

When using QOCA DISPOSABLE BLE THERMOMETER, the data needs to be transmitted to many different servers at the same time. The Gateway part is not included in the package. You must use compatible gateway device for the QOCA disposable BLE thermometer to work properly. or any gateway device that match the following specifications:

Customer Support

For additional technical information, contact Quanta Customer Support Department.



Quanta Computer Inc.(QCI)

Address:

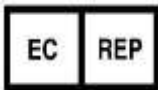
No. 188, Wenhua 2nd Rd.,
Guishan Dist., Taoyuan City 333, Taiwan

TEL: +886-3-327-2345

FAX: +886-3-318-4207

Email: MedicalService@quantatw.com

EU Representative



EU Representative: MedNet **EC-REP** GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

Label Information:



SN: MH8XW2026001

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMH8

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.

This device complies with part 15 of the FCC Rules. 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.

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.

FCC RF Radiation Exposure Statement:

1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines

Regulatory Marks

The QOCA DISPOSABLE BLE THERMOMETER conforms to the following regulatory requirements.

Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)






Article 12





Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to an approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere with legal communications. If found, the user shall cease operation immediately until no interference is achieved.

The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

	<p>CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.</p>
	<p>Type applied part</p>
	<p>Indicates that the body sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)</p>
	<p>Indicates the manufacturer's catalogue number</p> <p>Attention: Catalogue number may also be referred to as the reference number or reorder number.</p>
	<p>Indicates the manufacture's serial number.</p>

	<p>Indicates the manufacturer's name and address</p>
	<p>To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.</p>
	<p>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself</p>
	<p>Indicates the need for the user to consult the instructions for use.</p>
<p>IP34</p>	<p>Protected against solid objects down to 12mm. Protection against low pressure jets of water, limited ingress permitted.</p>

Supplier's Declaration

The QOCA DISPOSABLE BLE THERMOMETER conforms to the international EN 60601-1 and EN 60601-1-2 standards for electromagnetic compatibility with medical electrical devices and systems.

Manufacturer's declaration-electromagnetic emissions		
<p>The <u>Q-temp-w1</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.</p> <p>The customer or the user of the <u>Q-temp-w1</u> should assure that it is used in such an environment.</p>		
Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The <u>Q-temp-w1</u> 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 <u>Q-temp-w1</u> 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Bluetooth Technical Specification:

Technical Specification	Value
Operating Frequencies	2402~2480MHz
Channel Spacing	2MHz
Channel number	40
Operating Voltage	1.8V
Modulation	GFSK
Antenna Gain	Chip Antenna, Peak Gain: -1.48 dBi
Antenna Efficiency (%)	9% with body

Manufacturer's declaration-electromagnetic immunity

The Q-temp-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the Q-temp-w1 should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical

IEC 61000-4-4	$\pm 1\text{kV}$ for input/output lines	Not applicable	home healthcare environment.
Surge IEC 61000-4-5	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line(s) to line(s) $\pm 0.5\text{kV}$, $\pm 1\text{kV}$, $\pm 2\text{kV}$ line(s) to earth	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line(s) to line(s)_Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT ; 0,5 cycle 0 % UT ; 1 cycle 70 % UT ; 25/30 cycles Voltage interruptions: 0 % UT ; 250/300 cycle	Voltage dips: 0 % UT ; 0,5 cycle 0 % UT ; 1 cycle 70 % UT ; 25 cycles Voltage interruptions: 0 % UT ; 250 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the <u>Q-temp-w1</u> requires continued operation during power mains interruptions, it is recommended that the <u>Q-temp-w1</u> be powered from an uninterruptible power supply or a battery.

Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The <u>Q-temp-w1</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
<p>The <u>Q-temp-w1</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.</p> <p>The customer or the user of the <u>Q-temp-w1</u> should assure that it is used in such and environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
<p>Conducted RF</p> <p>IEC 61000-4-6</p>	<p>3 Vrms:</p> <p>0,15 MHz – 80 MHz</p> <p>6 Vrms:</p> <p>in ISM and amateur</p>	<p>3 Vrms:</p> <p>0,15 MHz – 80 MHz</p> <p>6 Vrms:</p> <p>in ISM and amateur radio bands between 0,15 MHz and 80 MHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>Q-temp-w1</u> including cables, than the recommended separation distance calculated from the equation</p>

<p>Radiated RF</p> <p>IEC 61000-4-3</p>	<p>radio bands between 0,15 MHz and 80 MHz</p> <p>80 % AM at 1 kHz</p> <p>10 V/m</p> <p>80 MHz – 2,7 GHz</p> <p>80 % AM at 1 kHz</p>	<p>80 % AM at 1 kHz</p> <p>10 V/m</p> <p>80 MHz – 2,7 GHz</p> <p>80 % AM at 1 kHz</p>	<p>applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the</p>
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			<p>recommended separation distance in metres (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations.</p> <p>Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Recommended separation distance between portable and mobile RF communications equipment and the Q-temp-w1

The Q-temp-w1 is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Q-temp-w1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Q-temp-w1 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 $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output

power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic emissions

The Q-temp-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the Q-temp-w1 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The <u>Q-temp-w1</u> 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 <u>Q-temp-w1</u> 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	