Instructions for Use:

Device Model #: MT16W2

Product REF #: NCTG2

Introduction

Document Scope

Thank you for purchasing the NC° Thermometer (Gen2)! This instruction of Use contains important information about the device safety, performance, and operation. If you have any questions or comments about the thermometer, contact Customer Support at help@naturalcycles.com

Please read these Instructions for Use, the device label, and all other information provided with this product, before using the device.

Disclaimers

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks on this device is under license.

Apple, the Apple logo, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Android and Google Play are both trademarks of Google Inc.

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Important Information

Device Description

The NC° Thermometer (Gen2) is used orally for the intermittent measurement and monitoring of human body temperature.

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Intended Use

The NC° Thermometer (Gen 2) is a medical digital thermometer (direct mode) for the self-measurement of human basal body temperature.

The device transmits the measured values to the Natural Cycles app via a Bluetooth 4.0 interface.

The device is intended for use with the Natural Cycles app. The device cannot be operated with other apps.

Intended User

The device is intended to be operated by adults capable of understanding the content of these instructions for use and operating general household electrical appliances, for use of self-monitoring or monitoring of other subjects.

Intended Patient

The device is intended for measurements of adults and children over the age of 5 years old.

Intended Use Environment & Conditions

The device is intended for use in a home healthcare environment (for example general household) by patients (for self-measurement) or by a care giver.

Indication for Use

The NC° Thermometer (Gen2) is used orally for the intermittent measurement and monitoring of human body temperature.

Contra-Indications & Limitations

The device is not suitable for subjects who are unable to conduct the measurement correctly, for example:

Patients unconscious or in disabling conditions that does not allow correct self-measurement operating conditions.

Warning

WARNING: Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

This device may only be used for the purposes described in this instruction. The manufacturer cannot be held liable for damage caused by incorrect application.

KEEP new and used batteries **OUT OF REACH of Children**. DO NOT leave the device unattended with children or allow children to use the device unsupervised. **INGESTION HAZARD**: The device contains smalls parts that could be swallowed by children. **DEATH** or series injury can occur if ingested. A swallowed button cell or coin cell battery can

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cause **Internal Chemical Burns** in as little as **2 hours**. **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Inspect the device for integrity or damage before use. DO NOT use the device or parts if they appear damaged or operating abnormally.

DO NOT bite or chew or bend the device probe more than 45°. This can cause damage and lead to malfunctions.

DO NOT use this device in oxygen rich environment or near flammable gas.

Caution ⚠️

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the device or other property.

Protect the device & accessories from the following to avoid damaging the device:
Water, other liquids, and moisture
Extreme temperatures
Impacts and vibrations
Direct sunlight
Contamination and dust

Stop using this device and consult with your doctor if you experience skin irritation or discomfort.

Using the thermometer in a way that does not comply with the intended operating conditions can result in inaccurate measurement values.

DO NOT operate the device under conditions beyond specified in section "Technical Specifications". If the device has been stored at temperatures below 50°F or above 104°F, allow it to stand at room temperature for at least 2 hours before using it.

Use this device only with compatible accessories from the manufacturer. Using non-compatible accessories may compromise the safety and performance of the device.

DO NOT use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or measurement inaccuracies.

DO NOT dissemble or attempt to service the device, accessory and parts, during use or in storage. Access to the device's internal hardware and software is prohibited. Unauthorized access and servicing of the device, during use or in storage, may compromise the safety and performance of the device.

DO NOT use this device or parts after the expiration of its stated service life.

Electromagnetic Compatibility Information

This device is compliant with IEC 60601-1-2 Electromagnetic Disturbances standard.

DO NOT use this device close to strong electromagnetic fields and portable radio frequency communication devices (for example microwave oven and mobile devices). Keep a minimum distance of 0.3 m from such devices when using this device.

This device features Bluetooth that emits radio frequency (RF) in the 2.4GHz band. Do not use this device in locations where RF is restricted (for example, on an aircraft). Turn off the device and remove the power source if necessary when in RF restricted locations.

This device is not certified to be used in vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instruments.

FCC Compliance Information

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. Changes or modifications to the product are not approved by Microlife USA and could void the user's authority to operate the equipment under FCC jurisdiction.

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: 1) Reorient or relocate the receiving antenna. 2) Increase the separation between the equipment and receiver. 3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. 4) Consult the dealer or an experienced radio/TV technician for help.

This device 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.

Device Information

Package Contents

- NC° Thermometer (Gen2)
- Instructions for Use

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- Founder welcome card
- Battery: CR2032

Device Description

- Gold-plated measuring tip
- Bluetooth button
- Illuminated display
- On/off button
- Battery compartment

Device User Interface

Display

A. Temperature unit
B. Bluetooth data connection
C. Battery display
D. Date
E. Time
F. Memory mode
G. Synchronizing

Device Optional Parts

Batteries: 3V, CR2032.

Device Installation & Setup

Mobile Software Installation

You must install the Natural Cycles app on your smartphone before setting up the device for the first time. The NC° Thermometer (Gen 2) cannot be set up without the Natural Cycles app.

Download the Natural Cycles app from the App Store or Google Play.

Open the Natural Cycles app. Follow the instructions in the app.

Device Date & Time Setup

Now initiate the initial setup of the thermometer. To do this, hold the Bluetooth button for at least 1 second.

The device switches on and automatically goes into SET mode, where you can set the date and time (Figure 1).

The date and time are synchronized automatically from the Natural Cycles app. To do this, the device connects to the app via Bluetooth (Figure 2).

If the connection is successful, the "APP" indicator appears (Figure 3).

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If the device cannot connect to the app, it switches off after 60 seconds. If this occurs, check whether Bluetooth is enabled on your smartphone and that the Natural Cycles app is running. Now try to establish a connection again.

Battery Installation

The battery is pre-installed in NC° Thermometer (Gen 2). In case the battery needs to be replaced, follow these steps to install or replace the battery:

NOTE: If the device is left unused for longer periods, remove the battery.

Battery Replacement

When the battery low symbol appears in the display, the device is inoperable until the batteries have been replaced with a new battery (3V CR2032).

1. Open the battery compartment.
2. Remove the old battery and insert a new CR2032 battery following polarity symbols in the compartment.
3. Reinstall the battery compartment cover.

Refer to "Disposal" for information about handling of used batteries.

NOTE: Battery Replacement

After battery replacement, the device date / time setting needs to be re-set.

Measurement Preparation

Before measuring temperature

Caution: If the device has been stored at temperatures below 50°F or above 104°F, allow it to stand at room temperature for at least 2 hours before using it.

Remove the transparent protective cover from the thermometer before taking a measurement.

Switch on the device by pressing and holding the on/off button for at least 1 second. The word "On" will appear on the display (Figure 1).

The device now performs an internal self-test; all display elements are displayed (Figure 2).

Checking the data transfer status

The device now checks whether all previous measurement values have already been transferred to the Natural Cycles app. The device can temporarily store up to 30 measurements.

The number of measurement values not yet transferred is shown on the display (Figure 3).

If more than 25 saved measurements have not been transferred to the Natural Cycles app, the message "APP/FULL" (Figures 4 and 5) appears on the display to remind you to transfer the measurement values to the app as soon as possible.

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If you perform more than 30 measurements without transferring the values to the app, the oldest value is deleted to make room for a new measurement.

Once the transfer status has been checked, the display flashes and/or a beep is sounded. The device is now ready to perform a new measurement.

Never begin a measurement before the display flashes and/or the beep sounds (if the sound is activated). The thermometer must already be in measurement mode when you start measuring to be able to correctly record the progress of the measurement.

Measurement Operation & Measurement Interpretation

Place the probe tip underneath your tongue on either the left-hand or right-hand side. The temperature sensor must make good contact with the tissue.

Close your mouth and breathe calmly through your nose so that the measurement result is not affected by the air that you breathe.

If the measured temperature remains below the measuring range (89.6℉ to 111.2℉), the display shows L (low) (Figure 6). Have a little patience during the measurement. The sensor must first warm up from room temperature to body temperature.

During the measurement, the current temperature is shown on the display. You must wait until the measurement is complete to ensure the accuracy of the temperature value.

A long beep indicates that the measurement is complete. If the sound is deactivated, the display flashes to indicate that the measurement is complete. The measurement value is shown on the display (Figure 7).

If the thermometer measures an elevated temperature of 99.5℉ or above, the display will illuminate yellow and/or 10 beeps will sound in rapid succession. The display switches between showing the temperature and "HI" (fever alert, Figure 8).

The device now tries to establish a Bluetooth connection to transfer the measured value to the Natural Cycles app. Make sure that the smartphone is within range, Bluetooth is enabled and the Natural Cycles app is running.

If the connection is successful, the "APP" indicator appears (Figure 9). Once the data has been transferred, the thermometer switches off automatically (Figure 10).

If the device cannot establish a connection, the measurement value is stored on the device to be transferred later. The device can temporarily store up to 30 measurement values. The thermometer then switches itself off (Figure 10).

Memory Function Operation

The thermometer has a measurement value memory with 30 save slots. The measurement values are saved automatically together with the date and time of the measurement. The most recently measured value is stored in save slot 1; the value measured prior to that is stored in save slot 2, and so on.

The measurement values and lots of additional information are saved in the Natural Cycles app, where they can be analyzed with ease.

You can also recall the last 30 readings directly from the NC° Thermometer (Gen2). To do so, proceed as follows:

Review Measurement Readings in Memory

With the device switched off, press and hold the Bluetooth button for at least 5 seconds until the   icon appears on the display. The device switches to memory mode (Figure 1).

The most recently measured value, no. 1, is now displayed (Figure 2, Figure 3). The display switches between the measurement value and the year, month/day and time. For measurement values that have been transferred to the Natural Cycles app, the symbol ⌗ is displayed.

By repeatedly pressing the Bluetooth button, you can call up the previous measurements (no. 2, no. 3 ...).

If no measurement values are saved, the following appears on the display (Figure 4):

Memory Full

If more than 30 measurements are taken, the oldest value (no. 30) is deleted so that the most recent value (no. 1) can be saved.

Bluetooth Datalink Function Operation

Automatic Data Transfer (after measurement)

The device now tries to establish a Bluetooth connection to transfer the measured value to the Natural Cycles app. Make sure that the smartphone is within range, Bluetooth is enabled and the Natural Cycles app is running.

If the connection is successful, the "APP" indicator appears (Figure 9). Once the data has been transferred, the thermometer switches off automatically (Figure 10).

If the device cannot establish a connection, the measurement value is stored on the device to be transferred later. The device can temporarily store up to 30 measurement values. The thermometer then switches itself off (Figure 10).

Manual Data Transfer

If the measurements cannot be transferred to the Natural Cycles app immediately after the measurement (e.g., if your smartphone is not within Bluetooth range or the Natural Cycles app is not open), you can transfer the measurements to the Natural Cycles app later. To do so, proceed as follows:

Open the Natural Cycles app on your smartphone.

With the device switched off, press and hold the Bluetooth button for at least 1 second, but no more than 5 seconds, until the Bluetooth symbol ⌷ appears in the display. If you hold down the button for more than 5 seconds, you will enter memory recall mode.

The device now connects to the app via Bluetooth (Figure 1).

If the connection is successful, the "APP" indicator appears (Figure 2).

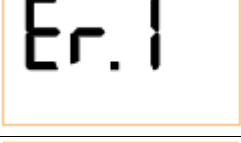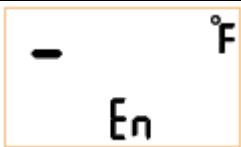If the device cannot connect to the Natural Cycles app, it switches itself off after 60 seconds. If this occurs, check whether Bluetooth is enabled on your smartphone and that the Natural Cycles app is running, then try again.

Errors/Issues & Troubleshooting

Device Errors & Troubleshooting

Issue or Error Message	Cause of Issue or Error	Troubleshooting
H °F ⏰PM06:00	The measured temperature is above 111.18°F and is therefore outside the measuring range.	Temperature measured is outside of the range of normal body temperature. Re-try measurement following the instructions.
L °F ⏰PM06:00	The measured temperature is below 89.60°F and is therefore outside the measuring range.	Temperature measured is outside of the range of normal body temperature. Re-try measurement following the instructions.
Er.H °F ⏰PM06:00	The ambient temperature is above 104°F and is therefore outside the permissible operating conditions.	Ambient temperature is outside of the device's operating condition specifications. Move the device to a location with appropriate ambient temperature and allow it to stabilize for at least 2 hours before using it.
Er.L °F ⏰PM06:00	The ambient temperature is below 50 °F and is therefore outside the permissible operating conditions.	Ambient temperature is outside of the device's operating condition specifications. Move the device to a location with appropriate ambient

		temperature and allow it to stabilize for at least 2 hours before using it.
HI °F ⏰PM06:00	Fever warning. Temperature higher than 99.5℉ measured.	Not applicable for device trouble shooting. User is recommended to re-take measurement and/or consult with healthcare professional if fever or other conditions suspected.
FULL ↻Ⓜ 30	Device memory is full.	Connect the thermometer to the Natural Cycles app to transfer the measured values to the app.
On ✻ ▯	Battery low.	Have a spare battery ready.
▯	Battery flat.	Please change the battery.
	No display after switching on.	Check whether the battery is positioned correctly and if the polarity (+/-) is correct. If the error persists, change the battery.
FL ✻	Bluetooth connection error	
Er.1	Sensor error.	If this occurs repeatedly, please contact Natural Cycles customer support.
Er.2	Measurement was cancelled prematurely.	Repeat the measurement and wait until the measurement is compete before removing the thermometer from the measurement point.
Er.CA	Calibration error.	If this occurs repeatedly, please contact Natural Cycles customer support.

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— °F En	The device is in technical test mode.	Switch it off and on again after a few seconds to return to normal mode.

Device Maintenance & Disposal

Cleaning & Disinfecting

Clean the thermometer with a soft cloth and isopropyl alcohol diluted with water or cold, soapy water.

Caution: Do not use aggressive cleaning agents, solvents or petroleum spirit to clean the device.

Caution: Make sure that the surface of the measuring sensor and the display do not get scratched.

The thermometer can be immersed in water or a disinfectant solution when cleaning.

Caution: Do not sterilize the device by boiling it, using gas or placing it in a steam autoclave.

After cleaning the measuring sensor with alcohol, wait 5 minutes before taking the next temperature measurement so that the thermometer can return to the required operating temperature.

Storage

Always store the thermometer in the protective cover. Store the device in spaces away from direct exposure of sunlight, heat, humidity, and vibrations, under storage conditions specified in the section "Technical Specifications".

NOTE: For long term storage without use, remove the batteries before storage.

Calibration & Support

The device is pre-calibrated based on the measuring tube accompanying the device. The device does not require calibration by the user before use.

Device calibration and repairs may only be performed by the manufacturer or an expressly authorized body.

Caution: DO NOT open the device for service or repair.

Each NC° Thermometer (Gen 2) has a unique signature assigned to a specific user. Signatures are assigned during initial setup when the device is synchronized with the Natural Cycles app for the first time. If your device is lost or faulty, you can assign a new NC° Thermometer (Gen 2) to your user account. To do this, go to the Top Menu in the Natural Cycles app and follow the instructions. Please note: If you change device during a cycle, the current cycle becomes inactive in the Natural Cycles app. For your safety, the app only accepts measurement data from a single device during a cycle.

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Please contact:

NaturalCycles Nordic AB

St Eriksgatan 63b

112 34 Stockholm, Sweden

help.naturalcycles.com

www.naturalcycles.com

Disposal

Technical equipment and batteries do not belong to household waste. They must be disposed of at appropriate collection and disposal points.

WARNING: Removed and immediately recycle or dispose of used batteries according to local regulations and keep away from children. Do NOT dispose of batteries in household trash or incinerate. Even used batteries may cause severe injury or death.

Specifications & Compliances

Technical Specifications

NOTE: Technical specifications are subject to change without notice.

Type: Digital thermometer

Operating Mode: Direct mode

Measuring Site & Reference Body Site: rectal, oral, vaginal

Temperature unit: ℉

Resolution: 0.01℉

Measuring range (Rated Output Range): 89.60℉ to 111.18℉

Measurement accuracy: ± 0.10℉ between 95.00℉ and 100.40℉, ± 0.20℉ in other temperature ranges

Memory: 30 measurement values with date and time can be recalled in memory mode

Operating conditions: Ambient temperature 50℉ to s104℉, maximum relative humidity 15% to 95%

Conditions for storage and transport: -13℉ to +131℉, maximum relative humidity 15% to 95%

Time to adjust from minimum/maximum storage temperature to operating temperature: 30 minutes

Battery: 1 x CR2032, 3.0 V, mercury-free

Battery life: approx. 400 measurements

Applied part: Type BF

Electrical Protection Type: Internally powered ME equipment.

Operation mode: Continuous operation

Data transfer: Bluetooth 4.0 LE (low energy)

Ingress Protection (IP) Rating: IP67: dust tight, protection against temporary submersion

Expected service life: 5 years or 10,000 uses.

Dimensions: 137 mm (L) x 32 mm (W) x 15 mm (H)

Weight: 27 g with battery

Compliance Information

Applicable standards:

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-11

ISO 80601-2-56

Supplement Information for Users & Patients

Information about body temperature measurement

Limited Warranty

The device has been manufactured and tested with all due care. Nevertheless, in the event of defects upon delivery, we provide a warranty under the following conditions:

During the warranty period of 2 years from the date of purchase, we remedy such defects at our discretion and at our expense in our plant through repair work or replacement delivery of a defect-free device.

The warranty does not cover normal wear and tear of wearing parts or damage caused by failure to observe the instructions for use, improper handling (e.g., unsuitable power sources, breakage, leaking batteries) and/or disassembly of the device by the buyer. Furthermore, the warranty does not constitute grounds for asserting claims for damages against us.

Warranty claims can only be asserted during the warranty period and upon presentation of the proof of purchase. In the case of a warranty claim, the device along with the proof of purchase and a description of the complaint must be sent to:

NaturalCycles Nordic AB, St Eriksgatan 63b, 112 34 Stockholm, Sweden.

The cost of returning the device to our factory shall be borne by the sender. Complaints that are sent back without prepayment will not be accepted.

The statutory claims and rights of the buyer against the seller (for example, defect claims, producer liability) are not restricted by this warranty.

Please note: In the case of a warranty claim, please make sure to enclose the proof of purchase.

The Instructions for Use can be found online at help.naturalcycles.com. If you would like a paper copy of the Instructions for Use in additional languages, we will send you one at no cost. Contact customer support with your request.

Symbols & Definitions

Read instructions for use before operating the device.

Catalogue Number

Lot Number

FCC symbol

Keep out of reach of children

Country of Manufacture (China)

Microlife Corporation

Applied Part: Type BF

Manufacturer

Warning

Caution

Temperature limitation

Humidity limitation

UDI

Unique Device Identifier

Manufacturer & Certification

Manufacturer:

Microlife Corporation.

9F, 431, Ruiguang Road, Nei-Hu, Taipei, Taiwan, China

Distributed by:

Natural Cycles Nordic AB

St Eriksgatan 63b, 112 34 Stockholm, Sweden

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