

NC° THERMOMETER (GEN3)

Instructions For Use

Model number NCTG3

This thermometer is being imported under FDA Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 Public Health Emergency. This device meets performance requirements but is not yet FDA-cleared.

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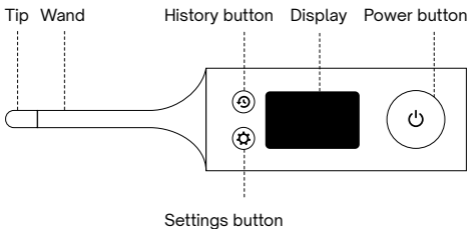
Introduction

Please read and save these instructions

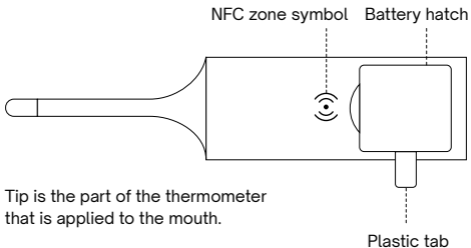
Thank you for purchasing the NC° Thermometer (Gen3), Please read these instructions carefully to ensure proper use and safe operation of your thermometer. If you have any questions or comments about the thermometer, contact Customer Support at help@naturalcycles.com.

Thermometer key parts

Front



Back



Package Contents

- NC° Thermometer (Gen3)
- Instructions for Use
- Founder welcome card

The Thermometer is intended to be used on its own or with iOS/Android smartphones using a dedicated App.

Indications for Use

The NC° Thermometer (Gen3) is used orally for the intermittent measurement and monitoring of human body temperature. The device can be used by adults and children over the age of 5 years old.

Warnings And Cautions

The thermometer may be used by itself or alongside the Natural Cycles app. See Natural Cycles application IFU for information regarding use of the app.

- This product is not intended to diagnose or treat any health problem or disease and should not be used as a substitute for the consultation and advice of a physician or other medical professional.
- The thermometer should not be used by children under the age of 5. The thermometer should only be used by children over the age of 5 if under the supervision of an adult.
- This thermometer should be held during use; the user should be seated or lying down during measurements.
- Keep the device away from sources of high levels of power line magnetic fields to reduce the likelihood of interference.
 - The device is suitable for use in all environments

listed in these instructions for use, including domestic environments.

- The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- If the thermometer is not likely to be used for some time, please remove the battery.
- Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Precautions

- This thermometer uses Bluetooth Low Energy 5.0 and

Near Field Communication (NFC) to interact with a dedicated iOS/Android smartphone App.

- Clean the thermometer probe before and after use. The Thermometer is water resistant, not waterproof. Never dip the thermometer into water or other liquids. Do not boil the probe. For cleaning and disinfecting, please see the Care and Cleaning section.
- Keep out of reach of young children and pets. Do not bend or bite the probe as this may damage the probe.
- Do not use the thermometer if there are signs of damage or after a drop/shock that might have caused damage. If damaged, do not attempt to repair. Please contact Customer Support at help.naturalcycles.com.
- Parts of the NC° Thermometer (Gen3) are not to be serviced or maintained while in use with the patient.
- The patient is the intended operator.
- The NC° Thermometer (Gen3) is a continuous operating device per IEC 60601-1.
- Do not store in direct sunlight or at high temperatures –see Product Specifications section.
- Avoid exercise and drinking hot or cold beverages before taking a temperature as these activities may affect the accuracy of the measurement. If the thermometer has been stored in cold conditions, it should be left for 30 minutes to stabilize to room temperature before attempting a measurement.
- The use of heat and cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the device and increase the risk of injury to the patient.

- The manufacturer recommends using a password on your smartphone.

About Temperature Measurements

Normal oral temperature measurements vary throughout the day. Level of activity, time of day, beverages, smoking and other factors may also affect body temperature.

This device is calibrated at the time of manufacturing. No recalibration is required. Contact Customer Support at help.naturalcycles.com for any accuracy issues.

Operating Your Thermometer

The Thermometer can either be used by itself or the user can sync the temperature data to the Natural Cycles app on their smartphone. Before using the thermometer for the first time, pull the plastic tab sticking out of the battery hatch to activate the battery.

To Set Up Your Thermometer With A New Mobile Device

1. Open iOS/Android Natural Cycles smartphone app for additional pairing instructions if using thermometer with smartphone. When the thermometer finds the smartphone app, a connection is established.
2. Press the settings button on the thermometer. Pressing the settings button will make the thermometer look for the app to establish connection for 60 seconds, if the app is not found, the thermometer shuts itself off.
3. Once the thermometer connects with the phone/device, you should see the setup complete screen.

Fahrenheit Celsius Switchable Feature

The thermometer takes measurements in both Fahrenheit and Celsius. When the thermometer is off, press and hold the settings button for 5 or more seconds to switch the measurements from Fahrenheit to Celsius or Celsius to Fahrenheit. The thermometer screen will confirm the switch to Fahrenheit or Celsius. You can change thermometer settings in the app as well.

History Mode

The thermometer includes a recall of the past ten temperatures taken. Press the history button to see the last temperature. Continue pressing the history button to see previous temperatures one at a time up to ten temperatures.

Oral Use

1. Press the power button and then place the thermometer in your mouth to begin measuring.
2. Place the probe under the tongue as near as possible to



a heat pocket at the back of the mouth, as noted in the diagram below.

3. Hold the thermometer in place during the measurement; do not bite down on the thermometer. The mouth must remain closed to ensure accurate results. The measurement should take approximately 40 seconds.
4. When the measurement is complete the thermometer will provide feedback. The feedback can be light and/or sound based on user settings. The final temperature value will be displayed on the thermometer screen.
5. After a measurement is completed, simply press the power button to turn the thermometer off or the thermometer will shut off automatically.

Troubleshooting / Error Codes

Performance may be affected should one or more of the following occur:

- Operation outside stated temperature and humidity range
- Storage outside stated temperature and humidity range
- Mechanical shock
- User temperature is below ambient temperature

Syncing temperatures with NC App

You can sync the temperature to your phone right after you measure or later by following the instructions in the app.

There are two ways to sync temperatures with the NC app.

1. After a successful measurement is completed, the thermometer will advertise the value via NFC or Bluetooth.*

*NFC/Bluetooth depends on user settings which can be changed in the NC app.

Error**Problem/Cause****Solution**

Temperature too low,
try again

Starting temperature value is below 60.8°F (16°C) or final temperature value is too low, below 89.6°F (32.0°C)

Try measuring the temperature again. Make sure that your environment is in the operating range and that the thermometer is placed as described in the diagram in the 'Oral Use' section.

Temperature too high,
try again

Starting temperature value is above 104°F (40°C) or final temperature value is too high, above 107.6°F (42.0°C)

Try measuring the temperature again. Make sure that your environment is in the operating range and that the thermometer is placed as described in the diagram in the 'Oral Use' section.

No measurement detected

No placement of
thermometer in mouth
detected

Try measuring the temperature again. Make sure that the thermometer is placed as described in the diagram in the 'Oral Use' section.

Error	Problem/Cause	Solution
Battery low	Battery is depleted	Change the battery as described in the section 'Replacing The Battery'.
Critically low battery life	Battery is depleted	Change the battery as described in the section 'Replacing The Battery'.
Measuring error	User does not take a stable measurement (moving thermometer around mouth, taking thermometer in and out of mouth).	Wait 10 seconds before trying again. The thermometer screen will display a count-down from 10. When the thermometer reaches 0 the thermometer will return to screen "Start measuring".

2. When the thermometer is in History mode it also advertises unsynced values via NFC or Bluetooth.

Syncing temperatures troubleshooting

If you have issues syncing your temperature from the thermometer into the app, please visit help.naturalcycles.com or scan the QR code below and find the instructions for different types of devices.



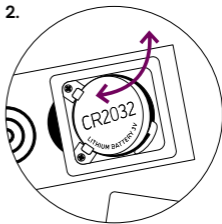
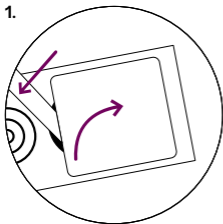
Maintaining Your Thermometer

Care And Cleaning Instructions

Store the thermometer in the provided protective case when not in use. Do not store the thermometer where it will be exposed to direct sunlight, dust or humidity. Avoid extreme temperatures. Do not attempt to disassemble the thermometer. Clean the thermometer by wiping with 75% medical alcohol solution or mild soap and water. Do not submerge in any liquid or autoclave. Wipe the thermometer with a dry cloth and allow it to air dry.

Replacing The Battery

If the thermometer is low in battery, 'battery low' or 'critically low battery life' messages will appear on the thermometer screen. Open the hatch in the back of the thermometer to remove the existing battery, and replace it with a new battery.



Product specifications

Battery	CR2032
Battery voltage	3V
Battery Life	6 months
Automatic Shut-Off	1 minute
Measurement Range	32-42°C (89.6-107.6°F)
Suggested Time Between Measurements	10 minutes if device left at rest, 3 minutes if shaking the device in the air
Measurement Time	40 seconds nominally
Accuracy	± 0.1°C / 0.2°F within measurement range
Operating Temperature	15-40°C (59-104°F)
Storage Temperature	-25-50°C (-13-122°F)
Humidity	≤ 95% R.H.
Atmospheric Pressure	70 kPa to 106 kPa
Display	OLED Screen
Display Resolution	0.01°C or 0.02°F
Dimensions	136.8mm x 11.0mm x 29.0mm
Weight	25g

Memory Function	10 logs
Service Life	5 Years
RF interface	Bluetooth LE(2400–2483.5 MHz): 2402–2480 MHz; 0 dBm NFC (13.56MHz): 13.553~13.567MHz
Operating Mode	Adjusted
Intended Operator	Thermometer can be used by adults and children (patient) in non-medical settings.

The operator can contact Customer Support at help@naturalcycles.com to obtain special test mode(DIRECT MODE) data.

FCC Statement

IMPORTANT INFORMATION REQUIRED BY THE FCC

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

The equipment is suitable for use in domestic establishments and is tested to CISPR emissions Class B Group 1 as well as home healthcare immunity criteria found in IEC 60601-1-2 Table 4, 6, and Table 9. During the IEC 60601-1-2 immunity tests performed the thermometer will accurately measure temperature or display an error. NC° Thermometer (Gen3) utilizes Bluetooth Low Energy (BLE), which uses the 2.4 GHz ISM band. BLE operates between 2.402 and 2.480 GHz. And Near Field Communication (NFC), Which use the 13.56MHz ISM band. NFC operates between 13.553 and 13.567MHz. NC° Thermometer (Gen3) transmits less than-2 dBm effective radiated power.To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations. Keep out of reach of young children, elderly and pets.

FCC WARNING: Changes or modifications not expressly approved by Intretech could void the user's authority to operate the equipment.

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 to 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 Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

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

Statement

NC° Thermometer (Gen3) conforms to all the requirements established in ASTM standard E1112.

Warranty Information

- The manufacturer provides the warranty of 1 year, starting from the date on which the appliance is sold to the end user
- The warranty only covers defects in material or workmanship
- The repairs under warranty may only be carried out by an authorized service centre. When making a claim under the warranty, the original bill of purchase (with purchase date) must be submitted.

The warranty will not apply in cases of:

- Normal wear and tear
- Incorrect use, e.g. overloading of the appliance, use of non-approved accessories
- Use of force, damage caused by external influences
- Damage caused by non-observance of the user manual, e.g. connection to an unsuitable mains supply or non-compliance with the installation instructions
- Partially or completely dismantled appliances

Proposition 65 Warning

- **WARNING:** This product may contain chemicals known to the State of California to cause birth defects or other reproductive harm.

Guidance and Manufacturers Declaration -electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8kV, ±15kV air	±8 kV contact ±2 kV, ±4kV, ±8kV, ±15kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	Not applicable	Not applicable
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz - 2,7 GHz, 80 % AM at 1 kHz 80 MHz - 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz

**Guidance and Manufacturer's Declaration
-IMMUNITY to proximity fields from RF wireless communications equipment**

Immunity Test IEC60601 test level Compliance level

Test frequency	Modulation	Maximum power	Immunity level
Radiated RF IEC 61000-4-3 385 MHz	**Pulse Modulation: 18Hz	1.8 W	27 V/m
450 MHz	*FM +5Hz deviation: 1kHz sine	2 W	28 V/m
710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m
810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m
1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m
2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m
5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

- For more information on Proposition 65 chemicals, please visit: <https://www.p65warnings.ca.gov/>

Explanation of Symbols



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



Consult the instructions for use



Dust tight, Protected against splashing water



Degree of protection against electric shock TYPE BF



Manufacturer



Reference Number



Lot Number



(01)06970094056006
(11)211221
(10)099923
(21)0001

(01)06970094056006
(11)211221
(10)099923
(21)0001

Manufacturer identification
Date of manufacture
Batch number
Serial number

Name of the Manufacturer

Xiamen Intretech Inc.

Address of the Manufacturer

No. 100, Dongfu West Road,
Haicang District, Xiamen, Fujian, China

Contact Information

<http://www.intretech.com/>
86-(0)592-5797666

Device Name

NC° Thermometer (Gen 3)

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Natural Cycles^o