

Forehead Thermometer

Model Name : TF4.0

Brand Name : NantLife

FCC ID: OXJTF40

Version # 2

05-17-2012, VJ

Smart Forehead Thermometer - User Guide

1.1. Introduction

Thank you for choosing the NantLife Smart Forehead Thermometer. This innovative medical device relies on advanced infrared (IR) technology to measure temperature instantly.

Your new digital thermometer uses the infrared heat generated by patient's skin. The thermometer then converts it into a temperature value displayed on the OLED screen.

Note: The thermometer does not emit any infrared signal.

With its unique wireless integrated technology, the NantLife Smart Forehead Thermometer enables you to perform first-class, comfortable and extremely gentle body temperature measurements. You have chosen the most up-to-date form of healthcare management. Measured values are transmitted automatically to a secured database via a Bluetooth-enabled mobile phone and/or the HBox® hub.

Choose between 2 basic configurations:

- a) Smart Medical Home with the HBox®
- b) Mobile Health with your Bluetooth-enabled smartphone

The NantLife Smart Forehead Thermometer comes with the following components:

- Monitor with OLED display
- ON/OFF button
- Instruction Manual printed in English, *French and Spanish*
- Warranty card

Thank you for your trust; we are available at any time for service and product questions.

More Information at: www.NantLife.com

SAVE THESE INSTRUCTIONS

1.2. Intended Use

- NantLife Smart Forehead Thermometer is intended for home monitoring of body temperature.
- The NantLife Smart Forehead Thermometer is not intended to be a diagnostic device.
- Never change your medication on the basis of results you have obtained. The evaluation of the measurements and the treatment based on them may only be carried out by the treating physician.
- This device is intended for use in measuring body temperature b

1.3. Safety Information

To assure the correct use of the thermometer, basic safety measures should always be followed including the warnings and cautions lifted in this instruction manual.

1.3.1 Operating the device -

1.3.1.1 Warnings!

Read all of the information in the instruction manual and any other instruction in the box before operating the thermometer. If you experience discomfort during a measurement- Remove the probe and stop using the device. Please contact NantLife Customer Service.

In addition, please note:

- Proper technique is crucial to getting accurate temperature readings. **Please read this manual carefully before using the device.**
- Basic safety precautions should always be observed, especially when the thermometer is used on or near children and disabled persons.
- Do not under any circumstances use the device in the bath or the shower. If, however, liquid get into the device, you must remove the batteries immediately and refrain from further use. Contact our service department (see front cover).
- The device may not be used near a nuclear magnetic tomographic resonance.
- Using components that are not part of the scope of delivery can produce faulty measurements (Exception: battery replacement).
- DO NOT subject the monitor to strong shocks such as dropping the unit on the floor.
- DO NOT damage the batteries. If battery fluid gets in your eyes, immediately rinse with plenty of clean water and contact a physician immediately.
- Keep away from source of fire and/or heat.
- Store the device in a clean, safe location.
- DO NOT disassemble the Forehead Thermometer.
- DO NOT use the Forehead Thermometer in a MRI or CT environment.
- DO NOT use the Forehead Thermometer in the presence of flammable anesthetics.
- Explosion hazard: DO NOT use the Forehead Thermometer in an explosive atmosphere.
- Chemicals from OLED panel are toxic if ingested. Use caution if the Forehead Thermometer display screen is broken.
- The Forehead Thermometer is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the Forehead Thermometer application site frequently to determine skin sensitivity of the patient.
- Use only 1.5V alkaline batteries with this device. Other type of battery may damage the unit.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device components, including batteries.
- Only the authorized service personnel can repair this device.

1.3.1.2 Cautions

- Autoclaving, ethylene oxide sterilizing, or immersing the Forehead Thermometer in liquid may cause inaccurate measurements.
- Excessive user movement may cause inaccurate readings.
- All NantLife devices are designed to be compliant with rules and regulations in locations they are sold and are labeled as required.

- Any changes or modifications to NantLife equipment, not expressly approved by NantLife void the user's authority to operate the device.

1.4 Before taking a Measurement

General information about normal body temperature and fever.

Body temperature can vary from one individual to the next. It also varies by location on the body and time of the day. See below the statistical normal ranges for different sites:

Body Site	Normal Temperature Range	
Oral	35.5°C – 37.5°C	95.9°F – 99.5°F
Axillary (underarm)	34.7°C – 37.3°C	94.5°F – 99.1°F
Rectal	36.6°C – 38.0°C	97.9°F – 100.4°F
Ear	35.8°C – 38.0°C	96.4°F – 100.4°F
<i>Chamberlain, J.M. Terndrup, T.E., New Light on Thermometer Readings, Contemporary Pediatrics, March 1994</i>		

Temperatures measured from different sites, even at the same time, should not be compared.

Fever indicates that the body temperature is higher than normal. This symptom may be caused by infection, overdressing or immunization. Some people may not experience fever even if they are ill. These include, but are not limited to, infants under 3 months old, persons with compromised immune systems, person with chronic diseases, person taking antibiotics, steroids or antipyretic such as aspirin, ibuprofen and/or acetaminophen.

Please consult your physician when you feel ill even if you do not have fever.

Your healthcare providers want to get an accurate picture of your body temperature and chart what happens over time. Body temperature is a vital indicator of one's health. A number of diseases are accompanied by characteristic changes in body temperature. Likewise, the course of certain diseases can be monitored by measuring body temperature. The efficiency of many treatments can be evaluated by monitoring body temperature and changes therein. Fever is a reaction to disease-specific stimuli, where the set point of the temperature control center is varied to promote the body's defenses against the disease process. Fever is the most common form of pathological (disease-related) elevation of body temperature.

To ensure a reliable reading follow these recommendations:

- Do not take a reading while eating, talking, drinking alcohol, smoking, exercising, and bathing for more than 30 minutes before taking your measurement. Rest for 15 minutes before taking the measurement.
- Do not take measurement when you have been exposed to extreme temperature.
- Remain still and do not talk during measurement..

2. Operating Instructions

2.1. Know your NantLife Smart Forehead Thermometer

(goes with a drawing of the device numbered- circled numbers –VJ to do)

1. Top Cover
2. “Start/Stop” button
3. Bluetooth application
4. Batteries compartment on the underside
5. OLED Screen Display

2.2. Unit Display

Illustration picture of the display- VJ to do

Showing:



Temperature Display

Low battery indicator

Temperature Unit

Wireless Communication signal symbol

2.3. Display Symbols

Symbols	Operation	Measure/Solution
°F	Temperature unit	Fahrenheit
°C	Temperature unit	Celsius
	Batteries indicator, empty	Replace batteries
	Mobile Data transmission	Icon flash to indicate Data transmitting.

2.4. Battery Installation

(Drawing of the batteries compartment open with batteries insertion)

1. Use a coin to twist the bottom following the indicating open direction, the cover will popup once twist to the right position.
2. Install 2 “AAA” size batteries so the + (positive) and the – (negative) match the polarities of the battery compartment.
3. Replace the battery cover

2.5. Battery Replacement

(image of low battery indicator)

When the low battery indicator appears on the display screen, turn off the monitor and remove all the batteries. Replace with new “AAA” 1.5V alkaline batteries. Reattach the battery cover.

WARNING: *If battery fluid gets in your eyes, rinse with plenty of clean water and contact a physician immediately.*

CAUTION: *Dispose of the device and empty batteries according to applicable local regulations.*

Unlawful disposal may cause environmental pollution.

2.6. Using the device

CAUTION: Read all the information in the instruction manual and any other documents in the box before operating the unit.

1. Remove the probe cover
2. Check the probe for cleanliness and obstruction
3. Wipe gently the probe if necessary with a 70% alcohol swab or soft cloth moistened with 70% alcohol.
4. Dry thoroughly before using
5. Unit setting:
Long press START/STOP button to enter into setting menu, short press to shift the light-spot to the "Unit" item, you can chose the unit of °F or °C by long pressing START/STOP button for 3 seconds.

2.7 Taking a measurement



1. Press and release the START/STOP button to turn on the thermometer, when ready the thermometer displays the LOGO "Nant Life" for 2 seconds.
2. Let the probe face the forehead with the instance at about 8cm to 15cm. c
3. Press and release the START/STOP button.
4. After one second you will hear a beep indicating the reading is complete.

Notes: The thermometer will automatically turn off in 20 seconds without any operation after the LOGO Nant Life displayed.

The thermometer will automatically turn off in 20 seconds after sending the measure value to pairing devices or when Bluetooth is switched off.

The thermometer will automatically turn off in 60 seconds when it can't find a Bluetooth connection.

2.8 Bluetooth Activation & PairingBluetooth setting:

Long press the START/STOP button for 3 seconds to enter into the setting menu as below figure,(we need the photo to explain the setting menu), you can see  " behind Bluetooth and hear, it indicates the Bluetooth function is ON. Otherwise you will see  ", then press START/STOP button for 3 seconds to switch on Bluetooth function. After switched on, short press START/STOP button shift to "Exit" and Long press START/STOP button to exit the setting menu.

Before readings can be transmitted via your mobile phone or the HBox® to your Health Diary, the NantLife Smart Forehead Thermometer needs to be paired to your smartphone and/or to the HBox® hub.

(If NantLife has already prepared the pairing of the device, go directly to 2.9 for "Data transmitting" instructions.

Pairing with SmartPhones:

Step 1: First, set up your mobile phone to receive data by Bluetooth (see your mobile phone user guide). If your phone is already activated, go to step 2.

Step 2: Press the Start/Stop to activate the thermometer. The display screen turns on. The device is activated.

Step 3: On your smartphone NantLife Application, hit the “Scan” button

Step 4: When the thermometer icon is highlighted, select it to pair.


Caution: Your mobile phone must have a wireless Bluetooth LE Interface. While performing the measurements you must be close to the phone or HBox hub (max.10 meters away put equivalence in feet). You can find more information at www.nantlife.com

Pairing with HBox®: 3 easy steps

Step 1: Press the Start/Stop to activate the thermometer. The display screen turns on. The device is activated.

Step 2: Plug the HBox® in a wall electrical outlet. Wait for the LED green light turns on.

Step 3: Gently tap to pair the activated thermometer with the HBox®. The LED yellow light on the hub will flash or music will play to confirm pairing.

The wireless icon “” display stably on the OLED indicating pairing successfully.

2.9 Data transmission

The measurement results saved in the thermometer are transmitted automatically to the Bluetooth® enabled smartphone and/or The HBox®.

The models of transmission include Realtime Bluetooth® transmission and Non-Realtime Bluetooth® transmission. After each temperature measurement, the reading is transmitted automatically. The wireless blinks every 200ms. The Thermometer stores the latest 50 records if it cannot transmit the data to the paired device.

2.10 Using the software and/or NantLife Applications

NantLife Health Management Software and Application allow you to connect, control and share your temperature readings with the persons of our choice on a secured Healthcare dedicated platform. You can access NantLife portal at www.NantLife.com and download for free NantLife application from the Apple store and Android Apps stores.

2.11 Evaluation by your care provider

Your temperature measurements are stored in your virtual NantLife virtual Health Diary. You can share them with care providers, family members, etc. For more information on sharing, please go www.NantLife.com

3 Care and Maintenance

3.7 Cleaning

If required, wipe the plastic casing with a damp cotton cloth only.

Do not use abrasive or volatile cleaners.

To clean the probe between measurements, wipe it gently with a 70% alcohol swab or soft cloth moistened with 70% alcohol. The probe is not waterproof, do not immerse in any liquid and dry thoroughly.

The body of the thermometer is not water resistant. Never put the thermometer under a running tap or submerge it. Do not use abrasive cleaners.

3.8 Maintenance

Place back the top cover of the thermometer to protect the probe when not in use.

Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries at the same time with new ones.

Use the unit in a manner that is consistent with the user guide manual provided.

4 Troubleshooting

4.1 Error Indicators

Error Code	Cause	Solution
Er	Ambient temperature is out of the range of + 10°C to + 40°C	Use the thermometer at the operating ambient condition.

4.2 Troubleshooting tips

Description of Problem	Solution
The START button is pressed but the measurement does not take place. The thermometer does not beep	Check the batteries and replace them if necessary
No symbols appear on the screen	Check the batteries and replace them if necessary
Battery symbol appears empty on the screen	Replace the batteries

5 FCC statement

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)

This equipment has been tested and complies 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 when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the user guide manual, might cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful

interference to radio or television reception, which can be determine by turning the product on and off, the user is encourage to try to correct the interference by one of the following actions:

- Reorient or relocate the receiving antenna
- Increase the separation between the product and the receiver
- Consult the dealer or an experience radio/TV technician for help
- Plug the product (if relevant) in an outlet on a circuit different from that to which the receiver is connected

NantLife is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users 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 might not cause harmful interference, and (2) this device must accept any interference received, including interference that might cause undesired operation.

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled "Digital Apparatus", ICES-003 of the Canadian Department of Communications. Cet appareil numérique respecte les limites de bruits radioélectriques applicables aux appareils numériques de Classe B prescrites dans la norme sur le matériel brouilleur: "Appareils Numériques", ICES-003 édictée par le ministre des communications.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to use the equipment.

6 CE mark

NantLife Smart Forehead Thermometer complies with the provisions of Council Directive 93/42/EEC of 14 June 1993 as well as national laws concerning medical devices.

NantLife Smart Forehead Thermometer complies with the provisions of Council Directive 99/5/EC(R&TTE). It carries the CE mark as proof of this.

This model complies with the provisions of the European Standard EN 12470-5:2003 Clinical thermometers—Part 5: Performance of infra-red Forehead Thermometer (with maximum device); EN 60601-1:2006 Medical electrical equipment, Part 1: General requirements for safety; EN60601-1-2:2007 Medical electrical equipment- Part 1: General requirements for safety -2: Collateral standard- Electromagnetic compatibility- Requirement and tests.

7 Warranty

1. The Smart Forehead Thermometer is warranted to be free from defects in material and workmanship appearing within one year from the date of purchase when the monitor is used in accordance with the instructions provided with the thermometer. Proof of purchase must be supplied in the form of a correctly completed warrantee card or a receipt. Include a \$5.00 for return shipping and handling. Include a letter with your name, address, phone number, and description of the problem. Pack the product carefully to prevent damages during transportation.
2. Defects due to faulty material or workmanship will be repaired free of charge during the warranty period.
3. The warranty period is not extended as a result of warranty services being provided, either for the devices as a whole or for any components.

4. The warranty excludes:

- Any damage caused by improper use, e.g. through failure to observe the operating instructions,
- Damage caused by maintenance or interventions carried out by the purchaser or unauthorized third parties
- Damage resulting from transport, either from the manufacturer to the consumer, or on the way to the customer services.
- Component parts subject to normal wear and tear (cuff, batteries etc.)

5. Liability is excluded for direct or indirect damage caused by the device, even if the damage to the device falls within the terms of the warranty

6. The above warranty extends only to the original retail purchaser.

6. Unauthorized modification of the warranty card invalidates it.

7. NantLife shall not be liable for loss of use or any other incidental, consequential or indirect costs, expenses or damages.

8. To obtain warranty service contact NantLife for the address of the repair location. Call 1-855-NANTCARE or visit our website at www.NantLife.com

For Customer Service

Visit our website at www.NantLife.com

Call toll free at 1-855-NANTCARE

7 Specifications

Model	STF 4.0
Measuring range	32°C to 43°C (89.6°F to 109.4°F)
Operating temperature range	+ 10°C to + 40°C (+ 50°F to + 104°F)
Operating humidity	15 to 95% RH
Storage temperature	-20°C to 60°C (-4°F to 140°F)
Storage Humidity	15 to 95% RH
Temperature Units	°C for Celsius and °F for Fahrenheit
Accuracy Meet the accuracy requirement specified in ASTM E 1965-98	±0.2°C (±0.4°F) for the range of 36.0°C to 39.0°C (96.8°F to 102.2°F) ±0.3°C (±0.5°F) for the range less than 36°C or greater than 39.1°C
Memory Capacity	50 measurements
Display Resolution	0.1°C (0.1°F)

Display OLED	organic light-emitting diode
Operating elements	One button: start/stop
Data transmission	Bluetooth Class II – Bluetooth Class 4
Power supply	2 alkaline 1.5V AAA batteries
Battery life	Approximately 300 uses starting with new alkaline batteries
Unit dimensions with top cover	40mm x 40mm x 113mm (1.57" x 1.57" x 4.45")
Weight	90g (3.2oz) not including batteries
UPC Code	0 00000 00000 0

Note: These specifications are subject to change without notice.

8 Manufacturer

Manufactured by NantCare LLC

Made in China

Distributed by NantCare LLC dba NantLife

2929 N 44th Street

Phoenix, Arizona 85018

Toll free phone 1-855-NANTCARE

www.NantLife.com

The manufacturer has calibrated the device for a period of two years. Metrological inspection and adjustment must take place of two years. Metrological inspection and adjustment is subject to a fee and can be carried out by NantLife, a responsible authority, or an authorized maintenance service.

NantLife certifies that:

The **NantLife Smart Forehead Thermometer** meets the standard:

ASTM E1965-98:2003, Standard specification for infrared thermometers for intermittent determination of patient temperature.

The **NantLife Smart Forehead Thermometer** meets the relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

9 Manufacturer's electromagnetic guidelines

IMPORTANT REGULATORY 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 that is received, including any interference that may cause undesired operation.

WARNING:

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.