NIRA TEMP

Quick Start & Instructions For Use

820.009 Rev 01

1. Get TestFlight

Open this link from your phone or tablet:
https://testflight.apple.com/join/htMatc38
Click "View in App Store"
Download TestFlight & ensure the download has completed

2. Join the Beta

Return to the page from Step 1, or click this link again: https://testflight.apple.com/join/htMatc38
Click "Start Testing" to complete Step 2.
This should open the TestFlight app. You will be guided through the installation process.

3. Stick To Activate

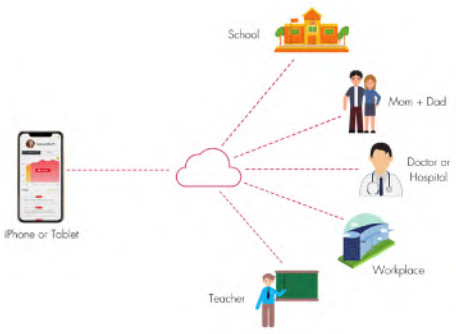
Peel the patch and place the device on clean, dry skin under the armpit. The sensor should touch the skin.

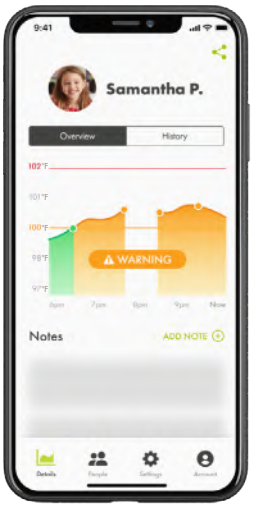
4. Connect & Assign User

Once connected to the NIRA Temp App, assign the device to yourself or a loved one.

5. Monitor In Real Time

Get a real-time look at your temperature and get notified at the first sign of an abnormal temperature.





Important: Read instructions carefully before use. High, prolonged fever requires medical attention. If symptoms persist, contact your healthcare provider.

Important: Read the instructions for use before using NIRA Temp

Introduction to NIRA Temp

Welcome to NIRA Temp, a wearable smart thermometer.
NIRA Temp is a Bluetooth® wearable smart thermometer with disposable patches. The device senses, records and transmits body temperature via Bluetooth®. Temperature information from the sensor is monitored using a smart device (Apple® or Android™ with Bluetooth® Version 4.1 or higher capability running the NIRA Temp app). This product is suitable for ages 3 and up.

Intended Use

The wireless thermometer, Model 2, is a battery-operated electronic device with an intended use of measuring human body temperature. This device is reusable and intended for armpit temperature readings for people of ages 3 and up.

Temperature Measurement

NIRA Temp measures under-the-arm “axillary” temperature and display it in the NIRA Temp app.

Battery Life

The battery is non-rechargeable and is intended to operate at least 12 months of normal use. During his time the battery voltage will be gradually reduced, which is normal and expected. The current battery level is displayed in the mobile app screen in remaining percentage units and the device will stop operation soon after the battery level will reach 0%. As battery discharges, the LED brightness will go down, but the strength of the BLE signal and thermometer accuracy will not be affected. The NIRA Temp accuracy is verified for the entire range of possible battery voltages and meets the specification as long as device is capable to measure and transmit the information to the mobile device.

Alert Levels

The device uses color coding to aid the user:

Normal - (temperature is less than user defined warning limit, the default value is 95.36°F - 97.8°F (35.2°C-36.56°C)).

Warning – Prompt response by user is required. (Temperature exceeds user defined warning limit, the default value range is 97.8°F - 98.78°F (36.5°C - 37.1°C)).

Alarm – Immediate response by user is required. (Temperature exceeds user defined limit, the default value is 98.78°F (37.1°C)).

What's included (Normal Package)

Name	Number
NIRA Temp thermometer	1
Adhesive patches	30
Quick start guide for the device	1
Getting Started Instruction	1

What's included (Refill Package)

Name	Number
Adhesive patches	90

For Best Results

- Wear NIRA Temp all day for the full benefits of 24/7 temperature tracking.
- Peel the adhesive patch and center the device onto the patch with the sensor (metal piece) side up.
- Apply the patch with the device onto clean, dry skin in the center of the armpit. For best results, use NIRA Temp on a shaven armpit.
- Ensure that the device is fully covered by the patch. The sensor should touch the skin.
- The device should be fully enclosed in the armpit when your arm is relaxed along your side.
- Temperature measurements can be affected by cold ambient temperatures.
- Dampen the patch with lukewarm water prior to slowly removing the patch from the skin.

Things To Note

- It may take up to 10 - 20 minutes after application for the device to warm up to display your real-time temperature in the NIRA Temp app.
- During warm up, your graph displayed in the app may be blue.
- If your phone has been off or in sleep mode, it may take a couple minutes for the app to sync and display your real-time temperature and history temperature in table and graphic forms.
- If you experience skin irritation from the adhesive patch, alternate armpits or contact a medical professional.

Troubleshooting

Regular Operation		
State	BLE advertisement	Visual indication
Standby	None	Green and Yellow LED, reduced brightness, once in 6 second
Standby (low battery at or below 25%)	None	Yellow and Red LED, reduced brightness, once in 6 seconds
User Connection	Once in 3 seconds, 0 dBm	All 3 LED, once in 3 seconds
Monitoring, normal temperature	Once in 9 seconds, +4 dBm	Green LED, once in 3 seconds
Monitoring, low grade fever	Once in 9 seconds, +4 dBm	Yellow LED (full brightness), once in 3 seconds
Monitoring, high grade fever	Once in 9 seconds, +4 dBm	Red LED, once in 3 seconds

Warnings and Precautions

When using this product always follow these basic safety precautions to ensure that the patch accurately reads temperature and to avoid skin irritation. Failure to follow these precautions could result in inaccurate temperature readings, or could result in skin irritation and mild discomfort.

- ⚠ DO NOT use the device for any other purpose besides measuring human body temperature.
- ⚠ DO NOT place the device on wounds, sores or abrasions.
- ⚠ DO NOT drop or throw the device.
- ⚠ DO NOT use the device if it has been damaged.
- ⚠ DO NOT attempt to take apart the device; there are no user serviceable parts.
- ⚠ Patch Adhesive may irritate skin. Contact doctors if irritations persists.
- ⚠ No modification of this equipment is allowed.
- ⚠ The device or its components are not intended to be serviced, or repaired.
- ⚠ The patches are intended ONLY for single use.
- ⚠ The device disposal at the end of it's life should be compliance with local laws and regulations.
- ⚠ CHOKING HAZARD -Small parts. Not for children under 3 years.
- ⚠ Alcohol is a flammable liquid. Do not use alcohol for disinfection or any other purposes near an open flame!
- ⚠ Device is powered by a 3V non-rechargeable battery. Not intended to be recharged, serviced, replaced, or repaired.
- ⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NIRA Temp, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Cleaning and Disinfection

The NIRA Temp device is intended for use by a single individual. As such, it does not require disinfection after detachment from the body and attachment with a new adhesive patch. It can be cleaned for hygienic purposes such as removal of sweat and odor.

To clean, use liquid soap, cool or warm tap water (temperature from 20°C - 30°C). For best results, dampen a cotton ball, pad, or paper towel in soapy water, clean the front and back of the device for 15-30 seconds, rinse the device in running water for another 15-30 seconds, and dry using a clean paper towel or air dry for 10 minutes.

In the case that the same device is shared with multiple individuals, disinfect it by using rubbing alcohol (60 - 90% solution) or alcohol wipes at room temperature (20°C - 30°C) after cleaning. To disinfect, dip the cotton ball or pad or in alcohol or use an alcohol wipe, wipe down the device with a clean paper towel to ensure that no excess alcohol is present, and let it air dry for 5 minutes or until no alcohol is left on the surface.

Instruction for NIRA Temp App

Start the App

Start the App

Once the app is downloaded and installed. Tap to open the app.

NIRA Temp

①

Pair the Device

Pair the Device with QR code

QR code found on the sensor side of the device.

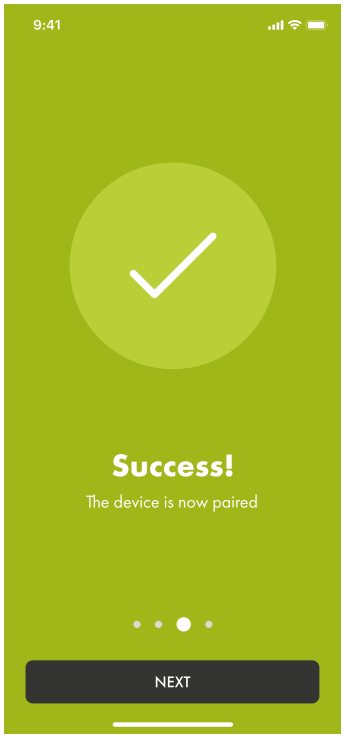
②

Scan the Device

Once located, tap scan Place camera over the QR code.

③

Pair Successfully



Message will appear that the device have been paired successfully.

④

Pair the Device

Pair the Device with Bluetooth

Tap "No QR Code? Pair with Bluetooth" located on the Pair Screen.

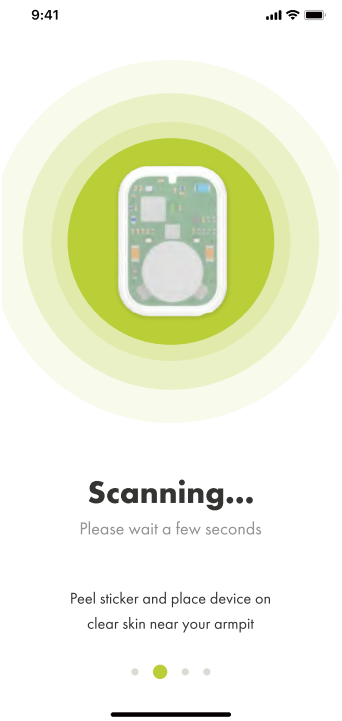
①

Stick to Activate

Apply device to skin to activate.

②

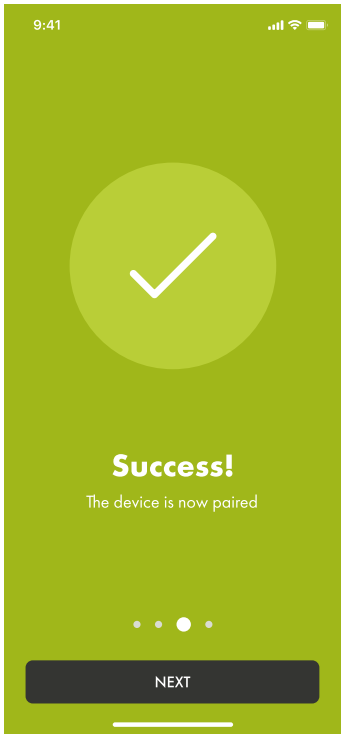
Scan the Device



Wait 3 to 5 min for the device to reach nominal temperature in order for the device to be scanned by the app.

③

Pair Successfully

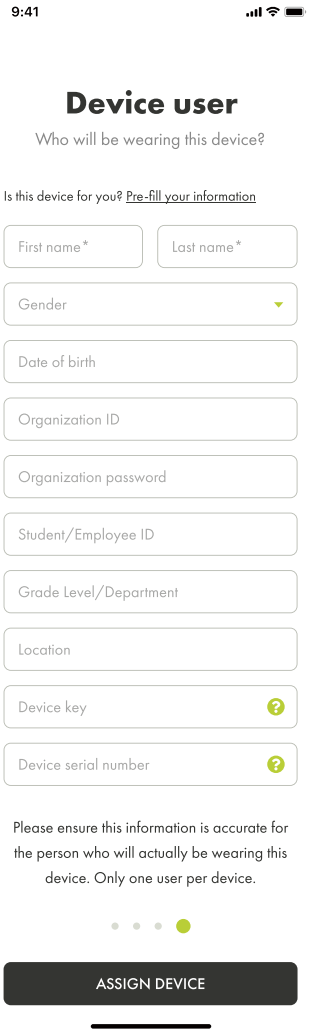


Message will appear that the device have been paired successfully.

④

Pair the Device

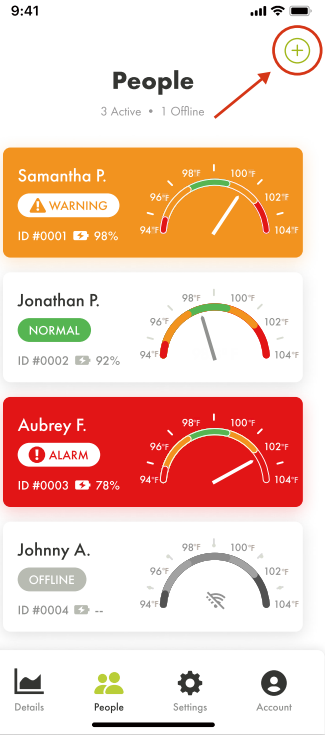
Register the Device



Fill in the information about device user after device is paired.

①

Add Device Afterwards



Add additional devices afterwards. Go to People and tap the "Add/plus sign" in the corner of the app.

②

Graph

View Graph

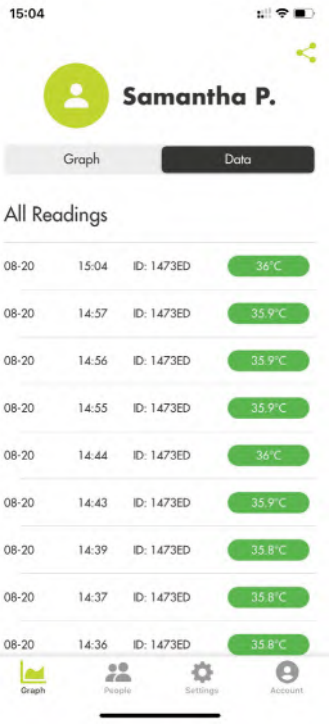
The graph detail screen shows user current temperature and previous temperature in a graph and data form.

To view graph tap "Graph".

Data can be viewed in 6H(6 hours) 12H(12 hours) 1D(1 day) 7D(7 days) or 14D(14 days).

①

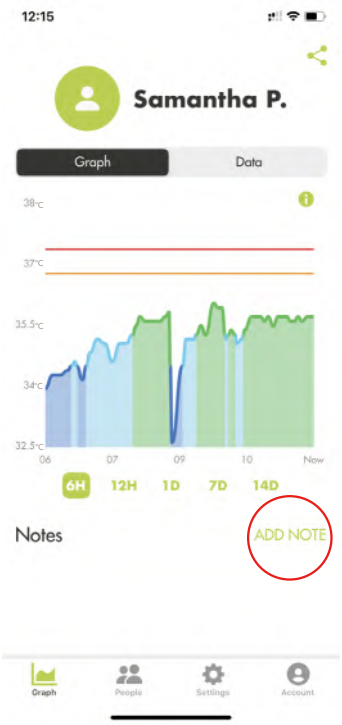
View Data



To view data tap "Data".

②

Add Note



Notes are available at any data point.

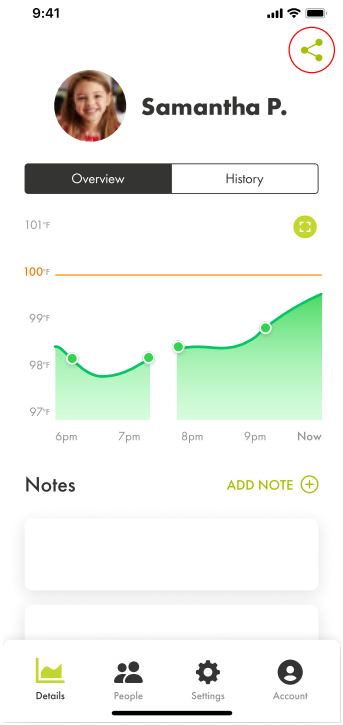
To add note go to > add note > select note detail > type in your notes > tap add note.

For more information tap (i)

③

Graph

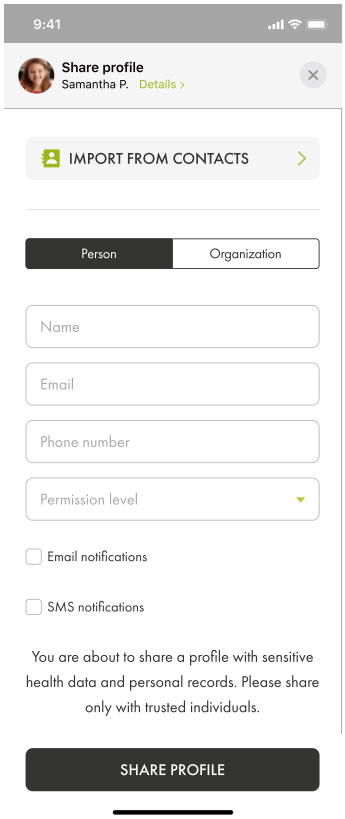
Share Data



To share you data with a person tap > 3 dot on top right

1

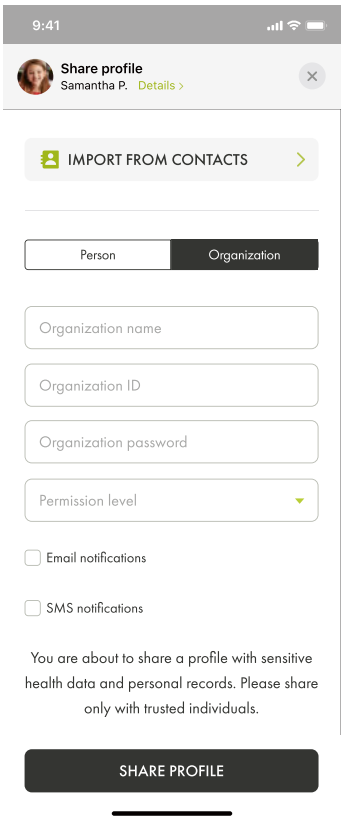
Share Data with a Person



To share you data with a person tap > 3 dot on top right > select person > input email address > check data you want to share (temperature, share warnings, share alarms, or share location) > tap share profile

2

Share Data with an Organization



To share you data with an organization tap > 3 dot on top right > select organization > input organization ID > organization password > student or employee id > grade level > department > address > check data you want to share (temperature, share warnings, share alarms, or share location) > tap share profile

3

People

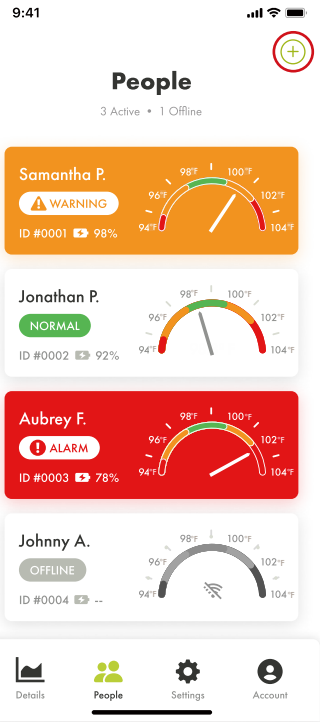
People Tab

The people screen allows you to see your device as well as devices that are shared with you.

To see device data tap on the device you want and it will take you to the data tab of that device.

1

Add a Device Afterwards

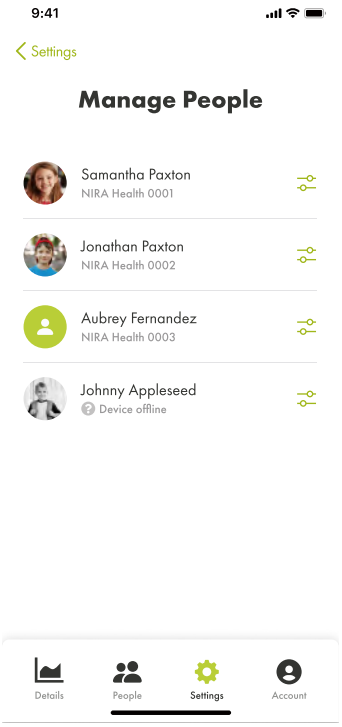


To add a device go to > + > pair using qr code > tap scan > device is paired

2

Settings

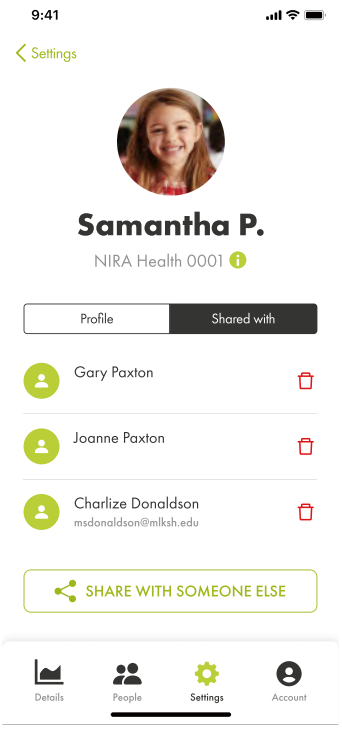
Manage People



Allow you to see your profile as well as share and receive people temperature data. To see your profile tap settings > manage people > pick your profile > profile > update profile > save changes

1

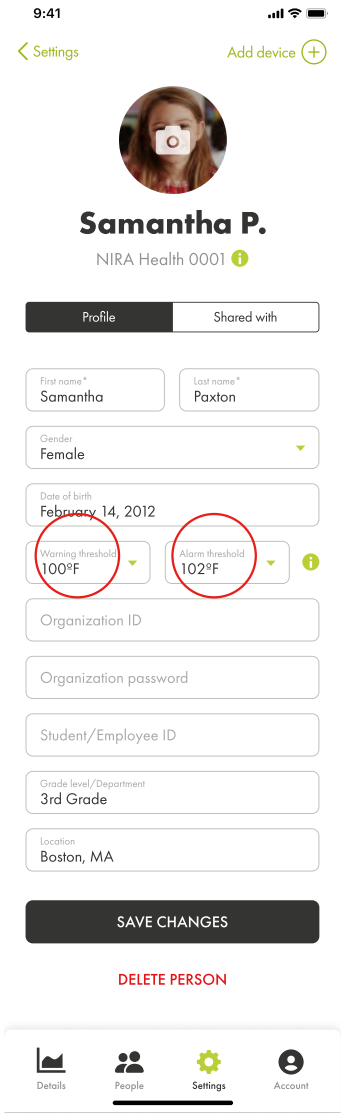
Who You Shared with



To see who you shared a profile with tap > pick your profile > tap shared with > profile of shared with email will be available.

3

Alert and Warning

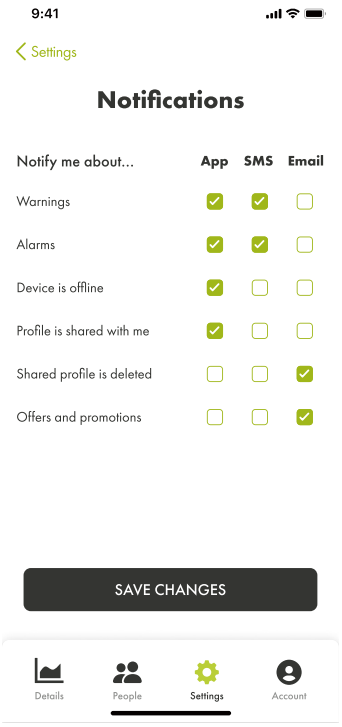


Alerts and warnings are have a default setting but can be changed by the user. To change user setting go to > settings > manage people > tap on the user and device > select warning threshold > select alarm threshold > tap save.

2

Settings

Notifications



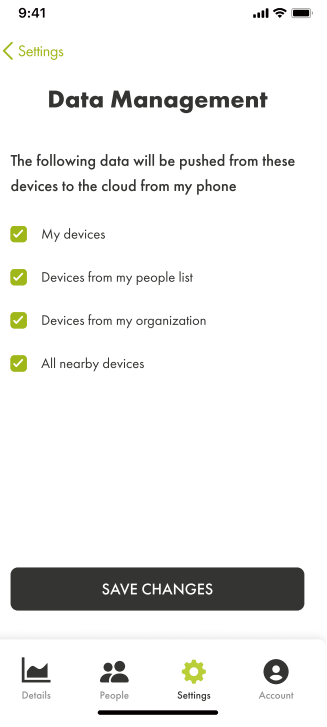
Notification allows you to receive alerts and warnings via app, SMS or email.

Notification for warnings, alarms, device is offline, profile is shared with me, shared profile is deleted and offers and promotions can be selected by user.

To select notification tap > notification > check applicable boxes > save changes

①

Data Management



Data management allows user to select what type of data can be pushed to the cloud from the phone.

To select data type tap > data management > select applicable choices > tap save

②

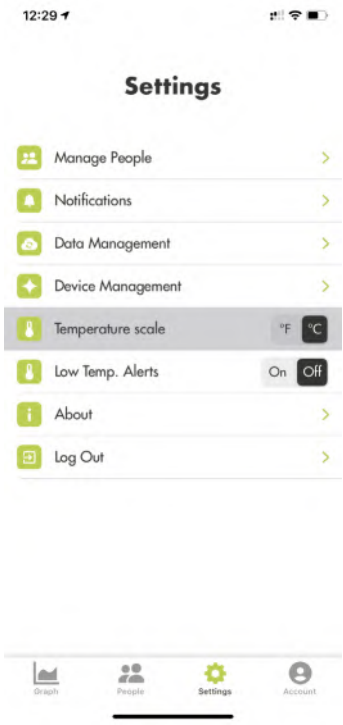
Device Management

Allows user to enable or disable readings from that device.

To turn a device on or off go to > device management > go to device > select on or off > device setting will be save

③

Device Management

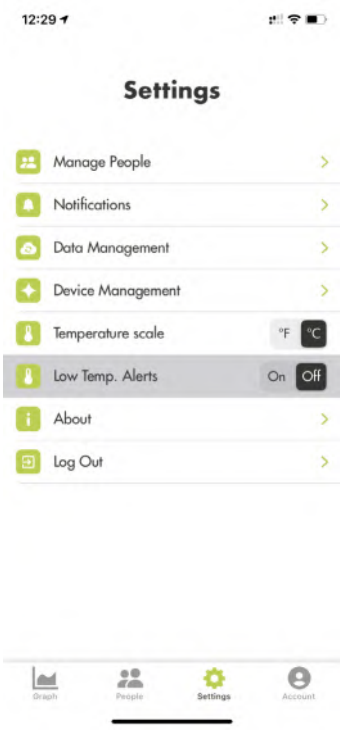


Allows user to switch temperature indication between Celsius and Fahrenheit.

④

Settings

Low Temperature Alert



Allow user to turn low temp alerts on or off.

①

About

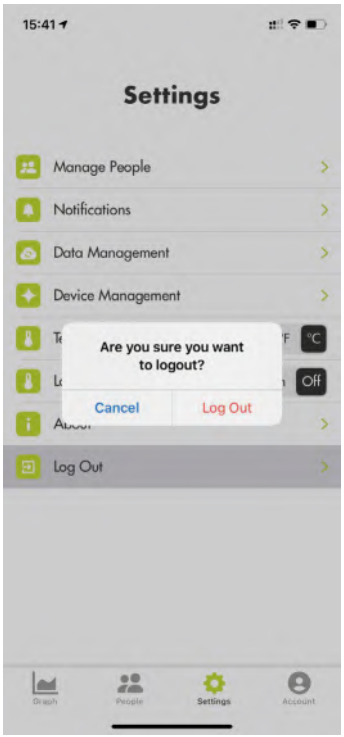
Display NIRA Temp Version

NIRA Temp FCC ID

Term of Use
How it works
Privacy Policy

②

Device Management

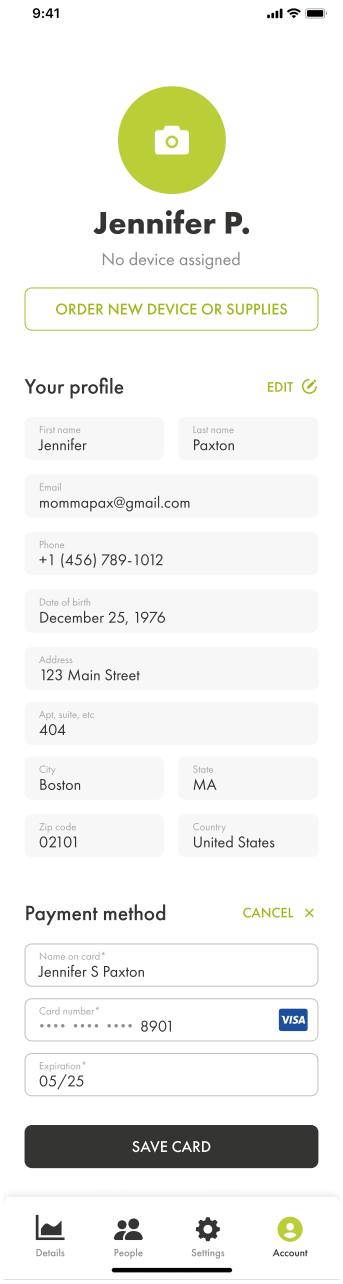


To log out > select log out > tap log out > user will be log out.

③

Settings

Accounts



Allows user to create account and order new device and supplies .

To create new account > select account > fill in your profile > tap saves

To edit account > select account > tap edit > tap save

To order new device or supplies > select order new device or supplies > follow the order instructions > email confirmation will be sent via email.

1

Specifications

Model Number	Model 2
Device Dimensions	30 mm x 22 mm x 6 mm
Device Weight	4 grams
Device Operating Life	12 Months
Mode of Operation	Direct Mode
Environmental Conditions •Storage •Shipping •Use	Storage Conditions: Temperature -4°F to 95°F (-20°C to 3°C), Relative Humidity 10 – 100%, Atmospheric Pressure 50-106 kPa Transport Conditions: Temperature -40°F to 122°F (-40°C to 50°C), Relative Humidity 10 –100%, Atmospheric Pressure 50-106 kPa Use Conditions: Temperature 77°F to 104°F (25°C to 40°C), Relative Humidity (non-condensing) 30-100%, Atmospheric Pressure: 70-106 kPa
Temperature Measurement Location	Axillary (under the arm)
Temperature Range	77°F to 113°F (25°C to 45°C)
Temperature Indications	Green: Temperature is in normal range. Yellow : Caution – prompt response by user is needed. Indicates a possible low fever as defined by the user. Red : Warning – Immediate response by user is required. Indicates a high fever as defined by the user.
Accuracy or Essential Performance	Ability to measure and communicate accurate results are considered as essential performance for the purposes of risk and electrical safety analysis. Also ability to communicate battery voltage.
Battery	Non-rechargeable Nominal voltage Range: voltage range 2.2-3.2 V
Accuracy	±0.3°C (±0.5°F) in the range of less than 35.8°C (96.4°F) ±0.2°C (±0.3°F) in the range of 35.8°C (96.4°F) to less than 37°C (98.0°F) ±0.1°C (±0.2°F) in the range of 37.0°C (98.0°F) to 39.0°C (102.0°F) ±0.2°C (±0.3°F) in the range of greater than 39.0°C (102.0°F) to 41.0°C (106.0°F) ±0.3°C (±0.5°F) in the range of greater than 41.0°C (106.0°F)
Transmission Distance	Up to 30 feet
Compatible Smart Devices	IOS, Android.
Standards	Compliant with the following standards: **ISO 10993-10:2010** Biological evaluation of medical devices **ASTM E112:2018** Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature **AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)** Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance. **IEC 60601-1-2:2014** Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. **ISO 80601-2-56:2017** Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement. **IEC 60601-1-11:2015** Medical electrical equipment- Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical system used in the home healthcare environment. **IEC 60601-1-2:2014,** Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. **FCC Part 15 Rule 247** for intentional radiation of radio frequency **ASTM D4169-14** Standard Practice for Performance Testing of Shipping Containers and Systems
Regulatory Requirements	The NIRA Temp shall comply with the medical device and radiofrequency emitting device regulations for the territories it will be marketed to. In particular, it shall comply with Class II medical device regulations of US Food and Drug Administration (FDA) and Federal Communication Commission (FCC) regulations for intentional emitters of RF radiation in the United States of America.
Water Ingress Protection	IP67
IMPORTANT:	Read instructions carefully before use.
Type BF Applied Part	

Warranty

NIRA is committed to quality. NIRA Temp device is rigorously designed for quality and performance. This limited warranty covers defects in materials and workmanship of your NIRA Temp device if you purchased it from an authorized partner or directly from the manufacturer (NIRA). Your limited warranty is valid for you alone, the original purchaser and cannot be transferred. The limited warranty begins on the date of purchase and is in effect for 30 days.
This limited warranty does not cover damage resulting from accident, misuse or abuse, or lack of reasonable care. No responsibility is assumed for any special, incidental or consequential damages. In order to obtain warranty replacement, simply contact our Customer Care Department at info@niraskin.com.

FCC Statement and Legal

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.

FCC WARNING: any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment under FCC regulations.

NOTE: 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 the 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 ID: 2ADZENIRE

EMC Information

The NIRA Temp needs special precautions regarding EMC and needs to be used according to EMC information. The device contains hardware capable of Bluetooth Low Energy (BLE) communication. This hardware can receive and transmit RF energy in 2400—2483.5 MHz frequency range with GFSK modulation. It is compliant with CFR Title 47, FCC part 15.247, and equivalent isotropically radiated power is less than 10 dBm (10mW).
Caution: Mobile RF communications equipment can affect the NIRA Temp device.

Electromagnetic Immunity Declaration			
The NIRA Temp is intended for use in the electromagnetic environment specified below. The customer or the user of the NIRA Temp should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Complies	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the NIRA Temp, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.17 150 kHz to 80 MHz d = 1.17 80 MHz to 800 MHz d = 2.33 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NIRA Temp is used exceeds the applicable RF compliance level above, the NIRA Temp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NIRA Temp. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Electromagnetic Emissions Declaration		
The NIRA Temp is intended for use in the electromagnetic environment specified below. The customer or the user of the NIRA Temp should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The NIRA Temp 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 NIRA Temp is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the NIRA Temp			
The NIRA Temp is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIRA Temp can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIRA Temp 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 the transmitter (m)		
	150 kHz to 80 MHz d = 1.17	80 MHz to 800 MHz d = 1.17	800 MHz to 2.5 GHz d = 2.33
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using 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. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Test specifications for NIRA Temp immunity to RF wireless communications equipment						
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 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 [b] 18 Hz	2	0.3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5,500						
5,785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the NIRA Temp may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						

Symbols

The following symbols are used within this document or on the NIRA Temp device, mobile application and its packaging:

Read Instruction For Use

Radiofrequency Radiation

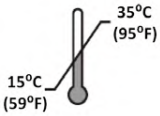
IP67

Dust tight. Protection against the effects of immersion in water up to 1 m for 30 minutes.

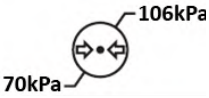
Batch code

Type BF Applied Part

Relative Humidity Range



Temperature Range



Atmospheric Pressure Range

Non-sterile

NIRA TEMP

Customer Care
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