iTempShield™

Patient Guide

CCR No:CR2022114 , DocFolder Id:Design-IFU-00006 , Revision:4 , Ve
Effective Date:10-Nov-2022 Report generated by: JoshSape
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Scan this QR Code to watch the instructional video to set up your iTempShield™ device:

Read these instructions fully before using the IDION iTempShield.™

This Patient Guide provides important safety information about the IDION iTempShield™ and its mobile application. For complete instructions go to www.idion.us/userguide. Please do not self-diagnose based solely on the device readings. Always consult your physician.

System Overview

The IDION iTempShield™ is a wearable device that senses body temperature and communicates with a mobile app on your smartphone or tablet. When the iTempShield™ is connected to your device, it sends all temperature measurements automatically.

The iTempShield™ can be worn for 60 days before needing to be replaced. The IDION Shield phone application allows you to view current and historical temperature measurements.

If this device is being provided by a clinician they may have real-time access to your temperature data and may be able to review all of your readings.

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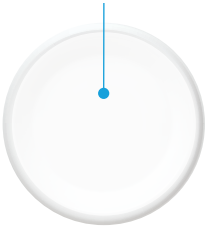
System Contents

IDION
iTempShield™

DO NOT REMOVE THE BACK OF THE DEVICE



There is no adhesive on the back of the iTempShield.™ Adhesive tape is provided to be applied over the top of the device.

Patient guide
(this document)

Adhesive Tape

Smart Phone Required

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Activating & Using Your iTempShield™

Getting started

Install the IDION Shield app on your phone by scanning this QR code with the camera on your phone.

You can also install the IDION Shield app by downloading it directly from the app store in your phone.

If you are an iPhone user, go to

If you are an Android user go to Google Play

Type in IDION Shield and click on this image

IDION Shield
Health & Fitness
OPEN

Download
IDION SHIELD APP

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1. Enable "Allow notifications," and select the box to agree to the Terms and Conditions.
2. After viewing the brief iTempShield™ overview on the phone application, select "Enable" and then select "OK" to allow the device to connect with your phone.
3. If you are an iPhone user, tap the top area of the back of your phone to the device. If you are an Android user, tap the middle of your phone to the device. If the connection is not made, move the device across the back of the phone and try again.
4. Keep Bluetooth enabled on your phone at all times.
5. Keep your iTempShield™ device and your phone close together, with a maximum range of 32 feet (10 meters) and no physical obstacles (such as a wall) between them.

20 mins

It will take up to 20 minutes for the device to adjust to your temperature.

You can use each device for up to 60 days.

Apple and app store and google play are registered trademarks of Apple Inc and Google LLC.
Bluetooth word mark is registered trademark owned by Bluetooth SIG, Inc.

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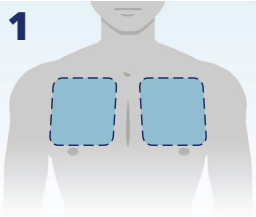
Applying the iTempShield™



Prepare chest

a. Select area on left or right upper chest.

b. If needed, trim hair to ensure good contact with skin.

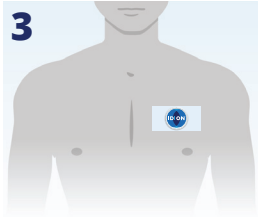
c. Clean and dry skin.

d. DO NOT apply iTempShield™ to an open wound or wet/ moist skin.

Adhere sensor to tape

a. Tear a three inch strip from the tape roll.

b. With the device logo visible and upright, place the adhesive tape over the top.



Adhere tape to chest

a. Avoid stretching adhesive tape when applying it to skin.

b. Place tape's adhesive side on chest, then firmly press tape against skin to secure it.

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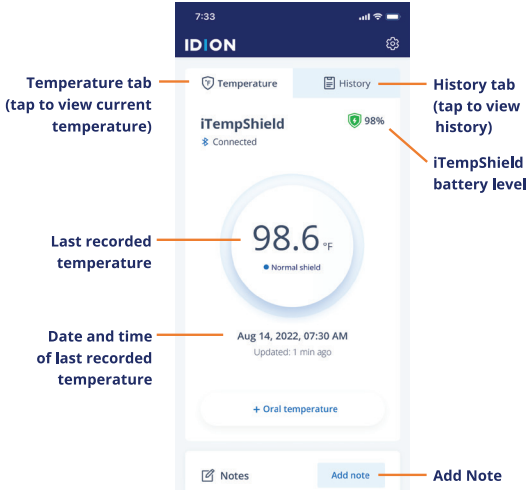
Temperature screen (main screen)

The Temperature screen shows the latest temperature measurement and device battery level. When the iTempShield™ first connects to the app, it sends temperature readings every 5 seconds. After the first 10 minutes, the device sends temperature readings approximately every 5 minutes.



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How to track your temperature

To view your temperature history, tap the History tab. On the history screen you can review the temperature measurements as a List (☰) or as a Chart (📈).

List view

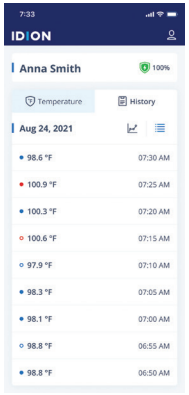
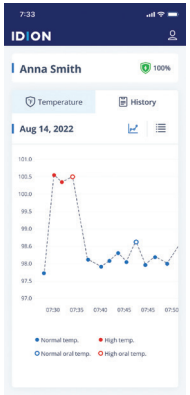


Chart view



Temperature threshold

Your clinician may set up a threshold for your temperature measurements. When your core temperature exceeds the threshold value, the reading is marked with a red dot (🔴) in the temperature history and your clinician is informed immediately.

Temperatures below the threshold will be marked with blue dots (🔵).

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How to care for your iTempShield™

Avoid...

- Swimming.
- Heavy exercise or contact sports.
- Extreme heat or cold for more than a few minutes.
- Do not bend or flex iTempShield.™ Bending the device can damage it and prevent it from communicating with mobile devices.

When you shower...

- Pat dry when you dry off.
- Do not aggressively scrub the tape and device.

When you change clothes...

- Take your time to avoid snagging the device.
- Wear loose-fitting clothes when possible.

CAUTION

Do not wear the iTempShield™ during an MRI, X-Ray, or CAT Scan procedure as it may result in physical harm.

If you feel discomfort or pain from the tape or device, contact your doctor.

Do not apply the iTempShield™ to an open wound or wet/moist skin.

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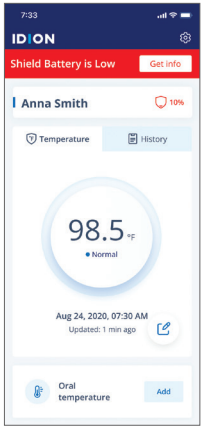
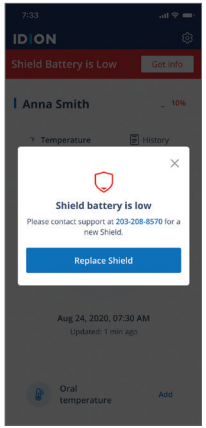
Battery level

- The iTempShield™ must be replaced before the battery is depleted (after approximately 60 days of use).
- When you see the Battery is Low notification in the phone app, contact your healthcare provider for instructions.





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When to replace the iTempShield™ Adhesive

Remove and replace adhesive every 2 days or every day as necessary. Move the device to the other side of the chest when replacing the adhesive tape.

Always replace adhesive if:

- Adhesive tape edges lift or loosen.
- Device or adhesive tape has shifted.

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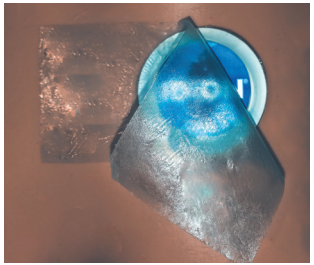
How to Remove or Replace the Adhesive Tape



Slowly remove tape

a. Slowly peel adhesive tape until fully removed from skin.

b. For fragile skin: Use other hand to press down on and stabilize skin while removing tape.

c. After removing adhesive tape from skin, lift iTempShield™ off of adhesive tape.

d. Clean any remaining adhesive residue from iTempShield™.

e. Use a new piece of adhesive tape to re-apply the iTempShield™ (see instructions on Page 5).

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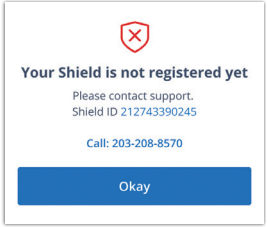
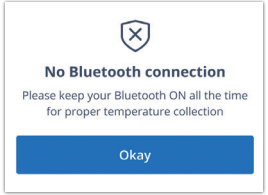
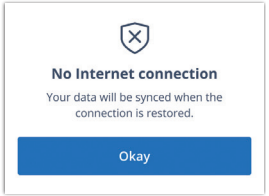
Troubleshooting

If you see this screen...	Do this...
	• If you do not connect to the shield and you a phone protective case, please remove the case on your phone and try again.
	• Restart your phone. • Make sure internet connection and Bluetooth are on and functioning. • Try to connect your iTempShield™ again. If it fails a second time, contact support at 203-208-8570 and replace the device.

If you see this screen...	Do this...
	• Make sure the phone and iTempShield™ are within 32 feet (10 meters) of each other and without significant obstacles between them.
	• Make sure your phone is not in airplane mode and you have a cellular connection.

Need help?

If you have any questions about the iTempShield™ system, call our customer support line at: **203-208-8570**

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