



Directions For Use

Read these instructions fully before using the iTempShield™.

INDICATIONS

iTempShield is a battery-powered wearable thermometer intended for continuous measurement of human body temperature on the upper chest via wireless communication to a smart device application. iTempShield is intended for single-use and for persons older than 5 years in healthcare facilities and home environments. The patient is the intended user of the iTempShield.

Note: iTempShield™ is not FDA approved or cleared.

CONTRAINDICATIONS

iTempShields are contraindicated for patients who exhibit allergic reactions to Silicon adhesives (tape), Silicone rubber, or Polyester.

DESCRIPTION

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

You can wear an iTempShield™ for up to 60 days and check your current temperature and temperature measurements history at any time. You have the ability to share the data with your clinician if your clinician has established an IDION account.

WARNINGS, CAUTIONS, AND NOTES

- The iTempShield™ should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with your physician.
- The iTempShield™ should be free of any visible defects, discoloration, or damage. Do not use and ask your physician for another iTempShield™ if any visible defects, discoloration, or damage is present.
- No heavy exercise or contact sports when using the iTempShield™. Exercise may interfere with temperature measurement accuracy.
- Avoid extreme heat or cold for more than a few minutes. This could affect performance or accuracy.
- When taking a shower, Pat dry the iTempShield™ do not rub aggressively. If adhesive lifts up replace it.
- After shower the temperature reading may be lower for several minutes as the chest area is cooler.
- You may also remove the iTempShield™ before taking a shower dry off and re-apply.
- The iTempShield™ may take up to 20 minutes to reach stable body temperature.



- If you feel discomfort or pain from the patch or iTempShield™, contact your doctor.
- If you see the following, replace adhesive patch right away:
 - Adhesive patch's edges lift easily or curl up more than 3 mm
 - Sensor or adhesive patch have shifted from their original location
- When changing clothes, avoid snagging the iTempShield™. Wear loose-fitting clothes when possible.
- Do not use the iTempShield™ during MRIs, X-Rays, or CT Scans as it may result in physical harm.
- Avoid contact with iTempShield™ during defibrillation.
- Do not use the iTempShield™ in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of exposure.
- Avoid using the iTempShield™ during electrocautery.
- Avoid placing the iTempShield over compromised skin, excessive hair, implants, ports, subcutaneous or dermal fillers or scar tissue, as it may result in incorrect readings.
- Do not apply over or near pacemakers to avoid any potential interference from the Bluetooth communication.
- The iTempShield™ should not be used near electrical equipment that may affect the shield's performance.
- Check the iTempShield™ site to ensure skin integrity and to avoid damage or irritation to the skin.
- Incorrect readings may be caused an iTempShield™ that is not placed on an appropriate application site.
- The iTempShield™ placement site should be hair-free, cleaned of debris, and dry before placement.
- The iTempShield™ may not reflect the actual body temperature when used on patients undergoing treatments that may alter their normal temperature regulation (e.g., therapeutic hypothermia, antipyretics).
- Avoid direct heating or cooling of the iTempShield™. Localized temperature exposure of the shield may result in no or incorrect readings.
- An iTempShield™ that becomes partially dislodged may cause no or incorrect readings.
- Rapid or large changes in ambient temperature may cause no or incorrect readings.
- Periodically check the iTempShield™ site for proper adhesion to minimize the risk of incorrect or no readings.
- Change or modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- To prevent damage, do not soak or immerse the iTempShield™ in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave, or ethylene oxide as it will damage the iTempShield™.
- Do not attempt to reprocess, recondition, or recycle the iTempShield™.



- 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 iTempShield™.
- Keep the iTempShield™ away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.
- The iTempShield™ does not include an adhesive on the device. Do not attempt to peel away any part of the iTempShield™ and use the specified adhesive patches for application to the body.
- Keep the iTempShield™ protected from excessive dust.
- If in an environment with a temperature below the operational temperature range specified in the environmental section, ensure the iTempShield™ is covered by warm clothing.
- Do not use adhesive other than the one provided with the iTempShield™ unless prescribed by the physician.
- Do not swallow the iTempShield™.
- Children should be supervised while using the iTempshield.
- Keep the iTempShield™ away from pets.

Note: Loss of essential performance caused by the conditions highlighted above can result in loss of or inaccurate readings.

Note: Changes or modifications not expressly approved by Idion could void the user's authority to operate the equipment.

INSTRUCTIONS

Using the IDION Shield mobile app

Install the IDION Shield app on your mobile device by scanning this QR code with the device's camera app.



- Enable "Allow notifications," and select the box to agree to the Terms and Conditions.
- 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.
- If you are an iPhone user, tap the top of your phone (camera area) 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.

Before using the IDION Shield mobile app, make sure your mobile device:

- Has a near-field communication (NFC) feature
- Has the NFC and Bluetooth features enabled

The Shield sends temperature readings using Bluetooth. For more accurate temperature history:



- Keep Bluetooth enabled on your device at all times
- Keep your Shield and mobile device close to each other, with a maximum range of 32 feet (10 meters) and no physical obstacles (such as a wall) between them.

History Screen

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.

Temperature threshold

When your body temperature exceeds the high temperature threshold value, the reading is marked with a red dot in the temperature history, and you have enabled communication with your clinician the data is sent to your clinician immediately.

Temperatures below the high temperature threshold will be marked with blue dots.

Temperature Screen (Main Screen)

The Temperature screen shows the latest temperature measurement and Shield battery level. When the Shield first connects to the app, it sends temperature readings every 30 seconds. The Shield takes approximately 20min to warm up to body temperature and sends temperature readings approximately every 5 minutes.

Adding an oral temperature

To add an oral temperature reading, tap the Add button at the bottom of the Temperature screen. Enter your oral temperature:

- In Fahrenheit,
- With two or three digits and one decimal place (for example 98.6 or 101.2)
- You can also add an activity, such as taking a shower, etc.

To save the temperature, tap the Save button . The Oral temperature will be added to the Temperature History and can be available to your Clinician.

Battery level

The Shield sensor's battery level is shown on the Temperature screen. Each sensor has enough battery power to last 60 days. When the sensor battery level drops below 10%, the app will notify you.

When the low battery notification occurs, follow clinician's instructions.

Disposal of Product: Comply with local laws in the disposal of the sensor, battery, and its accessories.

First time Users

It is recommended that prior to applying the iTempShield™ sensor to the adhesive patch, the user download the app and go through the screens to connect to the shield. With Android phones the sensor is in the back of the phone near the middle. With the iPhone it is along the top edge.

Applying the iTempShield™ to the body



Prepare chest

- Select an area on the left or right side of your chest where you will place Shield.
- If needed, trim hair on the area to make sure the adhesive tape or patch will contact the skin.
- Clean and dry the area.

Adhere sensor to patch or tape

- Tear a three-inch strip from the tape roll or select a patch.
- Peel off the inside liner from the adhesive patch or if required the tape.
- Place the sensor on the adhesive patch or tape, with the sensor's logo facing the patch's sticky side.

Adhere patch or tape to chest

- If using a patch, peel off the outside liners from the adhesive patch.
- Adhere the patch to the chest, pressing the patch firmly to secure it to the skin.
- Avoid pressing against the sensor. The IDION logo is facing away from the body.
- Avoid stretching adhesive patch or tape when applying it to skin.

Avoid touching the adhesive surface.

How to Remove the Adhesive

- Begin slowly peeling off the adhesive at a low angle.
- With your other hand, press down skin under adhesive tape to stabilize skin.
- Continue slowly pulling tape away from skin and pressing skin down until you fully remove adhesive tape.
- After removing adhesive tape from skin, lift iTempShield™ off of adhesive tape.
- If adhesive residue remains on device, use alcohol wipe to remove residue.
- Throw away used adhesive tape but keep the iTempShield™.

TROUBLESHOOTING GUIDE

App Message	Solution
Shield association was unsuccessful and there are characters aabbccdd11 displayed.	The iTempShield™ was improperly registered by your clinician. You must call with that number available so the problem can be rectified.
Shield association was unsuccessful and there is just a phone number	Call the number your shield is not working properly.
Shield association was unsuccessful due to technical error	<ul style="list-style-type: none">Restart your mobile device.Make sure internet connection and Bluetooth are on and functioning and try to connect your Shield again.If it still fails, contact the support number, and replace the shield.
App does not connect via NFC and NFC pop-up disappears	<ul style="list-style-type: none">Remove your phone from the case and try again to connect your Shield.



Check your connection	Make sure the mobile device and Shield are within 32 feet (10 meters) of each other and without significant obstacles between them
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For additional help, contact IDION at 1-203-208-8570

Environmental

Storage/Transport Temperature	0 degrees C to 30 degrees C
Operating Temperature	10 degrees C to 43 degrees C
Storage/Transport Humidity	40% - 75% RH (non-condensing)
Operating Humidity	10% - 95% RH (non-condensing)
Atmospheric Pressure	700 hPa to 1060 hPa

Caution: Using/storing iTempshield outside of the environmental ranges listed above might lead to inaccurate results or a damaged device.

Specifications

Temperature Measurement Accuracy	+/- 0.1 C in the range of 34 C to 42 C
Application Site	Upper Chest, below the left or right collarbone
Product Use/Battery Life	Minimum of 60 days of continuous use
Maximum Storage Life	1 year

Note: The iTempShield complies with IEC 60601-1 and IEC 80601-2-56.

WIRELESS TECHNOLOGY INFORMATION

Type	Bluetooth Low Energy	NFC
Data Transmission Rate	1 MB/sec	424 KB/sec
Max. Output Power	2.3 dBm	N/A
Modulation	Spread spectrum	Single frequency
Frequency Range	2.4 to 2.483 Ghz	13.56 MHz
Antenna Peak Gain	5.3 dB	N/A

FCC ID: 2A8QA-ITEMPS, FCC Code: 2A8QA

CAUTION: In order to maintain Bluetooth connectivity with the host device ensure that iTempShield™ is within specified distance and line of sight of the host device and avoid stacking units or keeping the close together when operating. Failure to do so might lead to connection issues and loss of data.

RF Radiation Exposure Statement: This equipment has been exempted from FCC RF radiation exposure testing and IC RSS 102 RF radiation exposure limits set forth for an uncontrolled environment.

Note: This device complies with part 15 of FCC Rules and Industry Canada’s license-exempt RSS. 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.

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 receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) the device may not cause harmful interference, and (2) the device must accept any interference received, including interference that may cause undesired operation.

Note: When using iTempShield™ consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

RECOMMENDED SEPARATION DISTANCES

Recommended separation distance between portable and mobile RF communication equipment and the ME equipment		
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.		
Rated Maximum Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)	
	80 MHz to 800 MHz $d = 1.17 \cdot \sqrt{P}$	800 MHz a 2.5 GHz $d = 2.33 \cdot \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	0.17	2.33
10	3.7	7.37
100	11.7	23.3

GUIDANCE AND MANUFACTURER'S DECLARATION -ELECTROMAGNETIC EMISSIONS		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF Emissions CISPR 11	Group 1	The ME Equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency



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communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment 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	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Guidance - Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	RECOMMENDED SEPERATION DISTANCE
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = [3,5/(E1)]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/(E1)]\sqrt{P}$ 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.
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, 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 ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT						
TEST FREQUENCY	BAND (A) (MHZ)	SERVICE (A)	MOCLATION (B)	MAXIMUM POWER (W)	DISTANCE (M)	IMMUNITY LEVEL (V/M)
385	380-395	TETRA 400	Pulse modulation (b) 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM (c) +/-5 kHz	2	0,3	28



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			deviation 1 kHz sine			
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						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3.4 35: UMTS	Pulse modulation (b) 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation (b) 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0,2	0,3	9
5500						
5785						

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

(a) For some services, only the uplink frequencies are included.

(b) The carrier shall be modulated use a 50% duty cycle square wave signal.

(c) 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.

WARRANTY

IDION warrants each new iTempShield™ patch against defects in materials or workmanship until the expiration date of the product and agrees to replace any defective product without charge. The life of the product is 60 days after activation if activated prior to expiration date.

WARRANTY EXCLUSIONS

The 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. To obtain warranty replacement, call IDION Customer Support at 1 (203) 208-8570

NO IMPLIED LICENSE



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Possession of the Equipment does not convey any express or implied license. Sensors designated for single patient use only are licensed to Customer to be used on a single patient only, and Customer. After use of Sensors designated for single patient use only, there is no further license granted by IDION to use the Sensors and they must be returned to IDION.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Follow instructions for use		Federal Communications Commission (FCC) Licensing		Bluetooth
	Consult instructions for use		Lot code	FCQD:	Identifies unit has been registered as a radio device
	Manufacturer		Catalogue number (model number)		Medical device
	Date of Manufacture YYYY-MM-DD		Storage temperature range	IP57	IP57 Protected from limited dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.
	Use By YYYY- MM-DD		Storage humidity Limitation		Unique device identifier
	Caution		Do not use if package is damaged and consult instructions for use		Non-sterile
	Type BF medical device		Device is single use.		Comply with local laws in the disposal of the sensor, battery and its accessories
	U.S. Food and Drug Association				

Product Information:

Model: iTempshield

Model #: DWF-1824

Version #: 1

FCC ID: 2A8QA-ITEMPS

Manufacturer: Idion

Manufacturer Location: 67 North Road Chelmsford, MA 01824