

## Directions For Use

Read these instructions fully before using the TempShield™.

### INDICATIONS FOR USE

TempShield™ 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. TempShield™ is intended for single use and for persons older than 5 years in healthcare facilities and home environments.

### CONTRAINDICATIONS

The TempShield™ is contraindicated for patients who exhibit allergic reactions to Silicon adhesives (tape), Silicone rubber, or Polyester.

### DESCRIPTION

The TempShield™ is a wearable device that senses body skin temperature and communicates with an app on your smartphone to calculate your internal body temperature as referenced to oral temperature. When the TempShield™ is connected to your device, it sends all temperature (°F or °C) measurements automatically.

The smart phone application requires that the user allow for notifications, has access to location services, and enables both NFC and Bluetooth services to fully activate the TempShield™. The only reason for location services is to allow Bluetooth to operate when the Android phone goes into Sleep mode. AION Biosystems does nothing with location data. Each TempShield™ has a unique serial number (*UUID*) and a random pin assigned. The random pin is in the NFC memory chip on the TempShield™.

You can wear an TempShield™ 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 AION Biosystems account.

### WARNINGS, CAUTIONS, AND NOTES

- The TempShield™ should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with your physician.
- The TempShield™ should be free of any visible defects, discoloration, or damage. Do not use the TempShield™ and ask your physician for another TempShield™ if any visible defects, discoloration, or damage is present.
- No heavy exercise or contact sports when using the TempShield™. 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 TempShield™ and do not rub aggressively. If adhesive lifts up replace it.
- After showering the temperature reading may be lower for several minutes as the chest area is cooler.
- You may also remove the TempShield™ before taking a shower, dry off and re-apply.
- The TempShield™ may take up to 15 minutes to reach a stable body temperature.
- If you feel discomfort or pain from the patch or TempShield™, contact your doctor.
- If you see the following, replace the 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 TempShield™. Wear loose-fitting clothes when possible.
- Do not use the TempShield™ during MRIs, X-Rays, or CT Scans as it may result in physical harm.
- Avoid contact with TempShield™ during defibrillation.
- Do not use the TempShield™ 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 TempShield™ during electrocautery.
- Avoid placing the TempShield™ 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 TempShield™ should not be used near electrical equipment that may affect the shield's performance.
- Check the TempShield™ site to ensure skin integrity and to avoid damage or irritation to the skin.
- Incorrect readings may be caused by an TempShield™ that is not placed on an appropriate application site.
- The TempShield™ placement site should be hair-free, cleaned of debris, and dry before placement.
- The TempShield™ 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 TempShield™. Localized temperature exposure of the shield may result in no or incorrect readings.
- An TempShield™ 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 TempShield™ site for proper adhesion to minimize the risk of incorrect or no readings.
- Changes 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 TempShield™ in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave, or ethylene oxide as it will damage the TempShield™.
- Do not attempt to reprocess, recondition, or recycle the TempShield™.
- 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 TempShield™.
- Keep the TempShield™ away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.
- The TempShield™ does not include an adhesive on the device. Do not attempt to peel away any part of the TempShield™ and use the specified adhesive patches for application to the body.
- Keep the TempShield™ protected from excessive dust.
- If in an environment with a temperature below the operational temperature range specified in the environmental section, ensure the TempShield™ is covered by warm clothing.
- Do not use the adhesive other than the one provided with the TempShield™ unless prescribed by the physician.
- Do not swallow the TempShield™.
- Children should be supervised while using the TempShield.
- Keep the TempShield™ 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 AION Biosystems could void the user's authority to operate the equipment.

This is a reference table that shows where the TempShield is most accurate.

The device readings may be accurate or inaccurate based on the activities described below:

	<b>Accurate</b>	<b>Inaccurate</b>
<b>Activity</b>	<p>Non-exertional activity such as:</p> <ul style="list-style-type: none"> <li>• sitting</li> <li>• walking</li> <li>• self-care</li> <li>• household chores</li> </ul>	<p>Exertional activity such as:</p> <ul style="list-style-type: none"> <li>• swimming</li> <li>• fast walking</li> <li>• exercise</li> <li>• other strenuous activities</li> </ul>
<b>Ambient Environment</b>	<p>Temperatures*</p> <ul style="list-style-type: none"> <li>• above 66°F</li> <li>• below 82°F</li> </ul> <p>*wearing uninsulated clothing</p>	<p>When exposed to direct sunlight or airflow; in temperatures</p> <ul style="list-style-type: none"> <li>• below 66°F</li> <li>• above 82°F</li> </ul>
<b>Water Emersion Environment</b>		<p>All water emersion activities*</p> <ul style="list-style-type: none"> <li>• swimming</li> <li>• showering</li> </ul> <p>*note: the device is waterproof</p>
<b>Apparel/Body Covering</b>	<p>Uninsulated indoor coverings such as:</p> <ul style="list-style-type: none"> <li>• shirts</li> <li>• blouses</li> </ul>	<p>Insulated clothing such as:</p> <ul style="list-style-type: none"> <li>• jackets</li> <li>• sweaters</li> <li>• fleeces</li> </ul>
<b>Sleeping/Recumbent</b>	<p>Sleeping on your back or side with no blanket(s) in direct contact with the device</p>	<ul style="list-style-type: none"> <li>• Laying or sleeping on the stomach</li> <li>• Laying or sleeping on your back or side with a blanket(s) directly covering the device</li> </ul>

### INSTRUCTIONS

#### Using the AION Shield mobile app

Install the AION 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 TempShield™ overview on the phone application, select “Enable” and then select “OK” to allow the device to connect with your phone.
- The AION app will ask the user to enable notifications. This is to allow Bluetooth to operate while an android application is in sleep mode. AION Biosystems does nothing with the location data.
- 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 AION Shield mobile app, make sure your mobile device:

- Is an iPhone with iOS 11 or greater or Android phone with Android 11 or greater.
- 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 °F or 101.2 °F)
- In Celsius,
  - With two digits and one decimal place (for example 37.0 °C or 38.4 °C)
- 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 TempShield™ 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.

## **Alerts and Alarms on the TempShield.**

There are two classes of alarms and alerts on the TempShield. One is physical device and connection related; the other are physiology (or prescription) related. At the time of the prescription by the physician, the physician will enable temperature thresholds that he/she deems normal, elevated, or febrile. This will set your TempShield to and the mobile application to provide you both text messages, and in-application alerts and will provide red icon indicators and banner notifications that you are above the temperature that you physician is concerned about.

- Physical Device
  - When your TempShield is out of range of your mobile device there will be a notification on the display that the TempShield is out of range.
  - If the Battery charge level is less than 10% you there is a banner alert notifying you to get a replacement.
- Prescription alerts

- When your temperature goes above the physician’s safe threshold there will be a text message sent to the patient, and the physician if prescribed.
- When your temperature goes above the physician’s safe threshold the TempShield mobile app will provide a notification to the user, provide a red icon, and display your temperature is high.

Alarm Condition	Patient	Clinician
Temperature exceeds Prescribed Temperature Threshold	Display on Mobile Application will say in red temperature High	
Temperature Exceed Prescribed temperature threshold	Will get a text message if prescribed	Will get a text message if prescribed. Monitoring Dashboard indicates Red Alert
Battery Level < 10%	Battery warning replace the Shield.	Will get a text message if prescribed.
Battery Level <10%	Will get a text message if prescribed	
TempShield Out of Range of Mobile Device	Will get a notice TempShield out of Range	
TempShield not detected for >24 hours	Will get a text message if prescribed	Will get a text message if prescribed

## Applying the TempShield™ to the body

### Prepare chest

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

### Adhere sensor to patch or tape

- a) Tear a three-inch strip from the tape roll or select a patch.
- b) Peel off the inside liner from the adhesive patch or if required the tape.
- c) 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

- a) If you use a patch, peel off the outside liners from the adhesive patch.

- b) Adhere the patch to the chest, pressing the patch firmly to secure it to the skin.
- c) Avoid pressing against the sensor. The AION logo is facing away from the body.
- d) Avoid stretching adhesive patch or tape when applying it to skin.

Avoid touching the adhesive surface.

**How to Remove the Adhesive**

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

**TROUBLESHOOTING GUIDE**

App Message	Solution
Shield association was unsuccessful and there are characters aabbccdd11 displayed.	The TempShield™ 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"> <li>• Restart your mobile device.</li> <li>• Make sure the internet connection and Bluetooth are on and function and try to connect your Shield again.</li> <li>• If it still fails, contact the support number, and replace the shield.</li> </ul>
App does not connect via NFC and NFC pop-up disappears	<ul style="list-style-type: none"> <li>• Remove your phone from the case and try again to connect your Shield.</li> </ul>
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

For additional help, contact AION Biosystems at 1-203-208-8570

**Environmental**

Storage/Transport Temperature	32 degrees F( 0 °C) to 86 degrees F(30 °C)
Operating Temperature	50 degrees F (10 ° C) to 109.4 degrees F (43 °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 TempShield outside of the environmental ranges listed above might lead to inaccurate results or a damaged device.

### Specifications

Temperature Measurement Accuracy	+/- 0.18 F (0.1°C) in the range of 77.0 F ( 25°C) to 109.4 F (43°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 TempShield 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 TempShield™ is within specified distance and line of sight of the host device and avoid stacking units or keeping them 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 TempShield™ 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 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	+/- 8 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	+/- 15 kV air	+/- 15 kV air	
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.

**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 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.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT						
TEST FREQUENCY	BAND (A) (MHZ)	SERVICE (A)	MODULATION (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 deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation (b) 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (b) 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation (b)	2	0,3	28

		DECT; LTE Band 1, 3.4 35: UMTS	217 Hz			
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						
<p><b>Note:</b> 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.</p> <p>(a) For some services, only the uplink frequencies are included.          (b) The carrier shall be modulated using 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 worse case.</p>						

### WARRANTY

AION Biosystems warrants each new TempShield™ 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 AION Biosystems Customer Support at 1 (203) 208-8570




### NO IMPLIED LICENSE


















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 using Sensors designated for single patient use only, there is no further license granted by AION Biosystems to use the Sensors and they must be returned to AION Biosystems.

**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 the 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	FCCID:	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: TempShield

Model #: DWF-1824

Version #: 1

FCC ID: 2A8QA-ITEMPS

Manufacturer: AION Biosystems

Manufacturer Location:

175 Cabot Street

Suite 100

Lowell, MA 01854