



User Guide



CAUTION -- Investigational device.
Limited by Federal law to investigational use.

Assistance Information

For technical help, please call Podimetrics, Inc.

Phone: 1-888-498-6489
Email: info@podimetrics.com
Mail: Podimetrics, Inc.
231 R Holland St.
Somerville, MA 02144

Complaints related to device functionality, performance, or service can be submitted by phone or email.

Indications for use

The Sole Defender is part of the Podimetrics Remote Temperature Monitoring System which is intended to be used by a patient for periodic evaluation of the temperature over the soles of the feet for signs of inflammation in conjunction with a healthcare professional or caretaker. It will assist in determining when the patient and healthcare provider should communicate for further diagnosis and treatment regarding any persistent localized inflammation observed on their feet via the electronic sensing system and remote visualization of its data. The Podimetrics RTM System is for prescription use only and is intended to be used under the direction of a healthcare professional as an adjunct to, and not in replacement of, self-examination and periodic foot care and examination conducted by a healthcare professional and does not diagnose any specific disease state.

The Podimetrics RTM System is for daily use in the home or clinic by people at risk for inflammatory foot diseases.

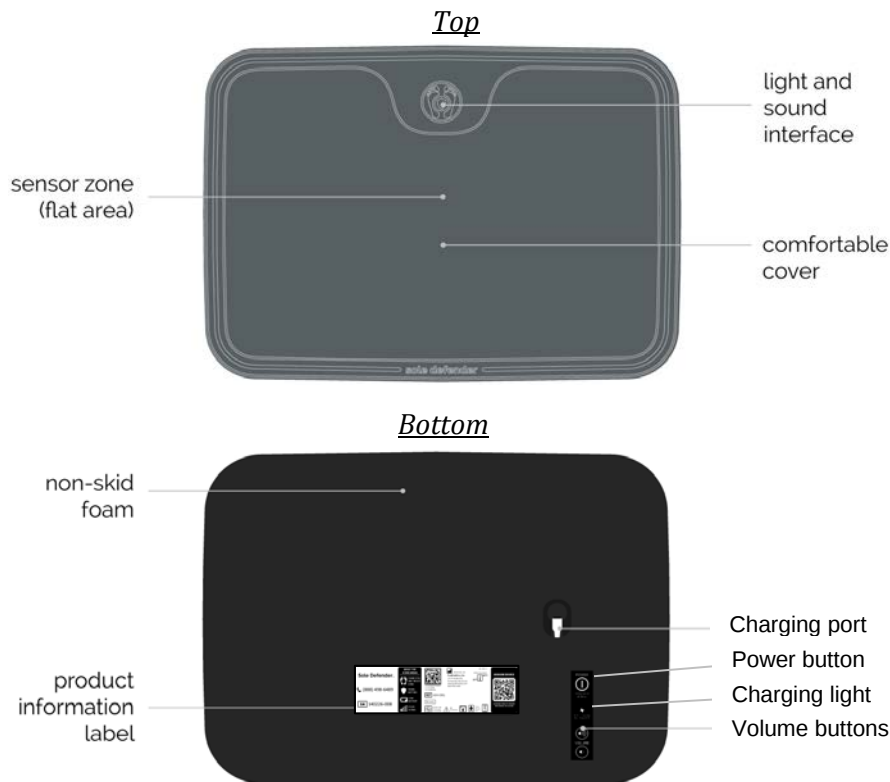
Contraindications

The Sole Defender mat should not be used by patients with active ulcers or other lesions that have broken the skin on the plantar surface of the foot.

About the Sole Defender

The Sole Defender includes sensitive electronics to measure the temperature over the soles of the feet and transmit that data wirelessly to a remote server for evaluation. The flexible temperature sensors are directly under the cover and on top of a layer of foam that compresses when you stand on it. The bottom surface is covered with an anti-skid foam and includes the power button, volume buttons, and charge port.

Each thermal scan that is taken with the mat is transmitted wirelessly to a server where it can be reviewed by your healthcare provider for signs of inflammation on your feet.



The Sole Defender box includes: 1 Sole Defender mat, 1 Battery charger, a Quick Start Guide, and a User Guide (this document).

Risks and Benefits

Risks. The Sole Defender does not cause any pain or discomfort to use. The top layer has been tested for skin biocompatibility and has been treated with antibacterial silver to limit bacterial growth. If damaged or used improperly, inaccurate temperature readings may be taken which could affect the clinician's evaluation of inflammation.

Benefits. It can be difficult for patients at risk for inflammatory foot diseases to evaluate the soles of their feet for signs of inflammation associated with an injury. The temperature data transmitted wirelessly by the Sole Defender may be used by your doctor to identify signs of inflammation on your feet. With this information, your doctor may contact you to initiate actions to avoid complications like foot ulcers, infection, gangrene, and amputation.

General Warnings and Precautions

Do not use the mat without training from a podiatrist or other qualified clinician.

Do not use the mat if it appears damaged or contaminated.

Do not use the mat for more than one person because it may lead to cross-contamination or patient data mix-up.

If any irritation, redness, or rash develops on the bottom of your feet, discontinue use and contact your healthcare provider immediately.

If you observe any changes in mat behavior or performance or any damage due to shipping or use, do not continue use and contact Podimetrics for instruction. **WARNING:** Do not open or modify this equipment in an attempt to correct a problem. There are no user serviceable parts inside.

The mat uses a cellular data communication modem that generates, uses, and can radiate radio frequency energy comparable with a cellular phone. It is recommended to keep wireless communication devices at least 4 feet away from the mat.

Do not place other objects or coverings on the mat when it is being used. The mat's measurements will not be accurate if used with an external covering.

Setup Instructions

- 1. Assign the mat to a patient.** Visit the secure web portal (by navigating to <https://www.podimetrics.com/assign-device> or scanning the mat's QR code) to assign the mat to the patient.

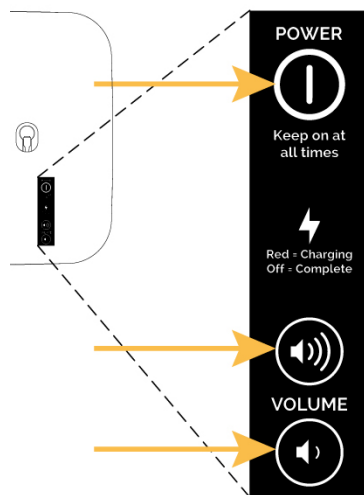


Scan the QR code to assign the mat

- 2. Remove the mat from the box.** With both hands, take the mat out of the box, remove the protective plastic covering, and place it upside down on a table for setup. **Keep the box** for storing the charger and instructions, and for shipping the mat back to Podimetrics after use. Don't use the mat if it appears damaged or contaminated.

- 3. Turn on the mat.** Click on the power button. The mat will chime to let you know it's ready to use.

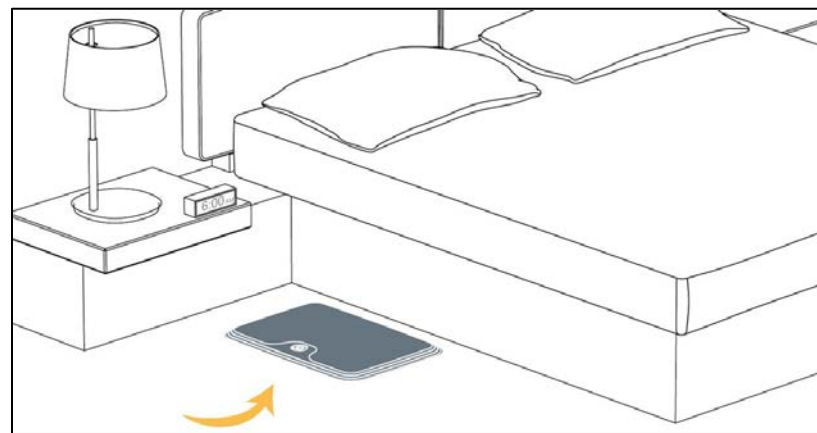
- 4. Set the volume.** There are four volume settings, Off, Low, Medium, and High. Press the volume UP or volume DOWN button until the audible tone is your preferred level.



- 5. Position the mat for use.** Set the mat on a flat floor where it is unobstructed by other objects and where you can comfortably stand for at least 20 seconds. The gray side should be facing up. It is recommended to place the mat beside your bed so you can use it first thing in the morning.

CAUTION:

- Do not place the mat in a high-traffic area like a hallway or doorway.
- Do not place the mat in a location where it is likely to get wet, such as by a sink or shower.
- Do not place the mat in direct sunlight or next to heat sources like vents or space heaters.
- Place the mat in a location that minimizes the risk of tampering by children or pets.



Correct mat placement

Usage Instructions

For best results, follow this process every morning.

1. **Perform daily foot exam.** Continue to perform your daily foot inspection, as instructed by your healthcare provider, examining your feet for signs of developing ulcers or open wounds.

WARNING: If you notice broken skin or a developing ulcer, discontinue use of the mat and contact your healthcare provider immediately.

2. **Check the mat.** Before use, inspect the mat for wetness, damage, or discoloration. Make sure the mat is dry before using it. If it is damaged, do not use the mat and contact Podimetrics for a replacement. If it is discolored, try to clean off any residue. If the discoloration cannot be removed, contact Podimetrics to see if a replacement is necessary.

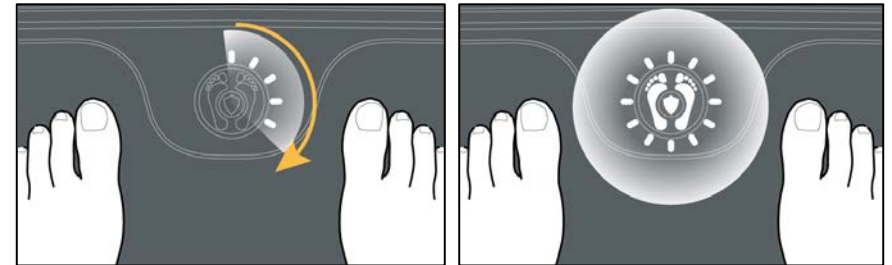
3. **Stand on the mat, barefoot.** To start a scan, stand with both bare feet completely inside the outlined sensing region of the mat. Once you are standing still, the scan will automatically start. It will make a chime and the lights will turn on.

CAUTION: Do not use the mat with water or lotion on your feet



Correct foot position, scan started

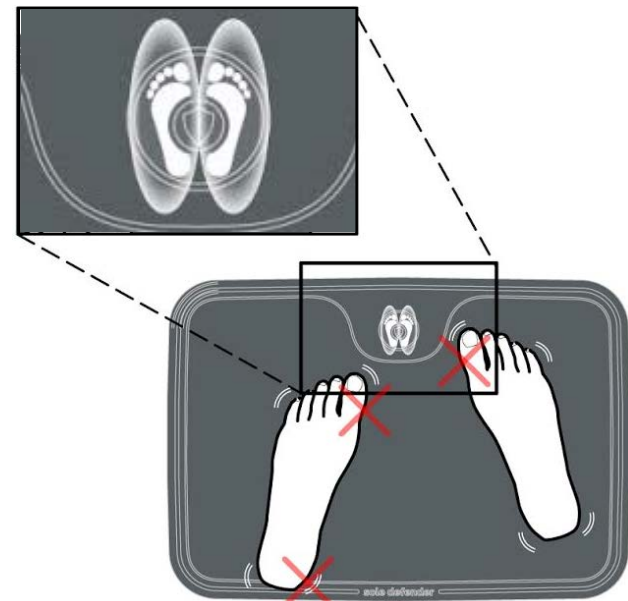
4. **Complete the scan.** Keep your feet still for 20 seconds while the scan completes. The lights will progress around a circle and when the scan is finished, the full circle will light up and the mat will chime again.



Scan in progress

Scan complete

If either foot is on the edge of the sensor zone or moves during the scan, the feet will light up and an error chime will sound, indicating a scan failure. Restart the scan by placing both feet within the scanning zone and keeping them still until the new scan starts.



Incorrect foot position, error indication

5. Automatic data transmission.

When the scan is complete, the mat will automatically transmit the data to Podimetrics through the cellular network. The shield light will blink until the data transfer is complete.

If the mat is unable to communicate with the cellular network the “no cell signal” light  will turn on.

Move the mat to a location with stronger cellular reception, such as closer to a window, or to an upper level floor.

Cellular coverage may not be available in all regions. Contact Podimetrics if you have difficulty completing a transmission. The data may not be transmitted outside of the United States.



Transmitting (blinking)

6. Podimetrics Monitoring. If Podimetrics hasn’t received a scan from your mat in a while, you may receive a call to make sure everything is ok with you and your mat.

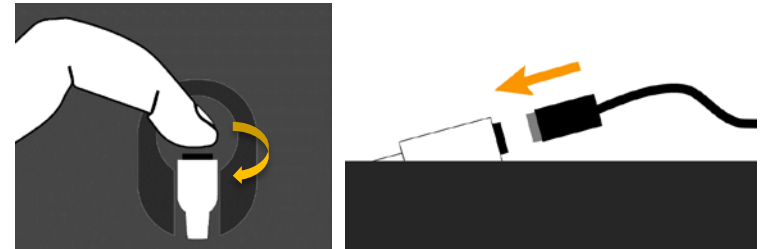
7. Thermogram Review. Your healthcare provider will review the data from your mat periodically for signs of inflammation through an online web application called the Thermogram Explorer™. This application displays a thermal image of your feet and allows the healthcare provider to analyze areas of elevated temperature for each scan that is transmitted. He or she may contact you for further evaluation based on their observations.

Care and Maintenance

Monthly cleaning. Once per month or as needed, wipe the top surface of the mat with an evaporating disinfecting cleaner (like Lysol®) and a clean cloth or cleaning wipes to remove any dirt or residue that may build up and affect the sensor reading or make it slippery. Let the mat completely air dry before use. If it is difficult for you to clean while the mat is on the floor, you can place it on a table.

CAUTION: Do not clean the mat with soap as it may leave a slippery residue.

Battery charging. The low battery light  will turn on when the battery has about 10% capacity remaining. To charge, place the mat upside down on a table or counter nearby an electrical outlet. Plug in the charger to a standard wall outlet. Tilt the white charging port out of its cavity on the bottom of the mat and plug in the charger. Charging an empty battery takes about 8 hours and the yellow “charging” light  will turn off when complete. While the mat is plugged in, a scan cannot be taken.



1. Tilt the port out

2. Plug in the charger

CAUTION:

- Use only the supplied charging cable for charging. Using other cables may damage the internal electronics.
- Keep the charging cable off the floor and away from walkways to prevent creating a trip hazard.
- Keep the charging cable out of the reach of children. The charging cable may be a strangulation risk.
- Your charger may not work in other countries.

Mat Storage. Store the mat in its shipping box in a cool, dry place out of direct sunlight. The materials may degrade over time if exposed to sunlight or high temperatures.

Travelling with your mat. Feel free to take your mat with you in its box and use it at your destination. Especially if flying, turn the mat off while in transit. If you don’t plan to bring the mat with you, call Podimetrics to let them know that you won’t be using it.

Mat Return. Contact Podimetrics for instructions for returning the used mat. Do not dispose of the mat in a municipal trash facility as the electronics may be damaging to the environment.

Technical Information

Operating Range:	15 to 40 °C (59 to 104 °F)
Storage and Transport:	-25 to 45 °C (-4 to 113 °F)
Temperature Accuracy:	± 0.5 °C (± 1°F)
Resolution:	0.1 °C (0.2 °F)
Normal Scan Time:	20 seconds
Device Dimensions:	25 x 17 x 0.85 inches
Device Weight:	6 lbs (2.7 kg)
Maximum User Weight:	375 lbs (170 kg)
Service life:	2 years of normal, daily use
Cellular Modem:	1xRTT CDMA radio, 800/1900 MHz, 24 dB maximum transmit power
Battery:	Rechargeable lithium ion battery, 3.4 to 4.2 V, 1800 mAh, 2 to 4 months of daily use.
Battery Charger:	Medical Power Supply; 100-240 V A/C, 50-60 Hz input; 5 V D/C max 1.2 A output, Mfg. P/N: GlobTek GTM41076-0605.
Product Certifications:	IEC 60601-1 3 rd ed., IEC 60601-1-2 EMC for residential environment, IEC 60601-1-6, IEC 60601-1-11
Patents:	US and Foreign patents Pending

Safety Symbols



Do not use the product if the packaging is damaged.



See the operating instructions.



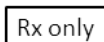
This product is rated IP21. It is protected against inserted fingers and dripping water.



The mat is a Type B applied part.



This product contains electronics. Do not dispose of in municipal waste facilities.



This product is for prescription use only.

If the instructions in this table do not resolve the issue or if you experience any malfunction or injury, please call Podimetrics technical support at 1-888-498-6489.

Problem	Meaning	Action
“Low battery” light turns on. 	The battery is low.	Plug in the charging cable to charge the mat battery overnight.
“No cell signal” light turns on 	The mat does not have enough cellular signal in its location.	Move the mat to an area with better cellular coverage such as closer to a window or upstairs.
“Scan error” light turns on 	Your feet may have moved or were on the edge of the sensors during the scan.	Make sure both feet are fully inside the sensing zone and stand still until the full scan is completed.
The mat doesn't start scanning when you stand on it.	The mat may be busy - or - The mat may be off - or - The battery may be empty	If the transmitting light is on, wait until it turns off before trying to take a scan. If there are no lights on, try pressing the volume UP button. If the mat doesn't make a sound, press the power button to turn the mat on. If the mat still doesn't turn on, you may need to charge the battery.
The mat does not make any sounds.	The volume may not be turned on.	Turn on the volume by pressing the volume UP button on the bottom of the mat.