

# User Manual

Find Injury Early



## **User Assistance Information**

Should you have any questions, please contact a customer service representative at Siren Inc. They may be contacted either by:

Phone: (+1) 415-855-1744

Email: [info@siren.care](mailto:info@siren.care)

## **General Warning and Cautions**

The Siren Diabetic Sock is designed for a person that has been diagnosed with neuropathy of the feet. People that have neuropathy (reduced feeling in their feet) are at a high-risk to develop foot ulcers that can potentially lead to amputation. Clinical studies have shown that before an ulcer breaks the surface of the skin, inflammation or heat may develop. The Siren Diabetic Sock is designed to detect and measure this heat/inflammation earlier. The Siren Diabetic Sock should be used every day by the patient to detect the inflammation earlier. Once the inflammation is detected, actions can be taken by the patient, in consultation with their doctor, to potentially avoid the ulcer and further complications such as infection, gangrene, and amputation. The Siren Diabetic Sock integrated micro thermometer in the fabric that is non-invasive and is not painful to use. It is using non-replaceable

battery operated and the battery life is approximately six months (7 pairs), assuming daily use.

IT IS RECOMMENDED THAT A PERSON WITH DIABETES AND NEUROPATHY USE THE SIREN DIABETIC SOCK TO TAKE TEMPERATURE MEASUREMENTS ON THEIR FEET EVERY DAY.

## USER'S MANUAL

### Glossary

**Diabetic Neuropathy** – Diabetic neuropathy is a peripheral nerve disorder caused by diabetes. The symptoms of diabetic neuropathy are often slight at first; numbness, pain or tingling in the feet or legs may lead to weakness in the muscles of the feet. The loss of sensation in the feet may increase the possibility for foot injuries to go unnoticed and develop into ulcers or

lesions that become infected. **Inflammation** – A local response to cellular injury that is marked by capillary dilatation, leukocytic infiltration, redness, heat, pain and that serves as a mechanism initiating the elimination of noxious agents and of damaged tissue.

### Included in the box

- 5 pairs of sock
- 1 Smart hub
- 1 wash bag
- 1 user manual
- 1 QR CODE printed on the inner top

### How it Works

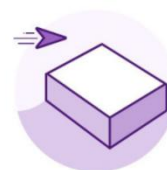
Wear the Siren Diabetic Socks every day, just like normal socks.  
Check your feet with Siren App. All socks will be connected to your phone by Bluetooth low energy technology.  
Wash it in the end of the week.  
Enjoy your life



1. Wear your Siren socks daily



2. Get notifications



3. New socks ship every 6 mos.

## Instructions for Setup

The Siren sock is used to track foot temperature on the bottom of your feet  
Let's get start

Step1: prepare what we need to start:

- 1 Siren box with at least a pair of sock
- 2 Smart phone / tablet and your phone number (which can receive txt msg during the process)
- 3 Find an outlet which near where you spend most time in your house
- 4 Prepare your foot medical records in 6 months if you have (optional)

Step2: Download siren app and install it.

- 1 Make sure your phone or tablet has already connected to internet
- 2 Open google store / App store and search "siren sock"



- 3 Download "siren sock" app to your smart phone / tablet and install it
- 4 You can also download from Siren's website  
[www.siren.care/app](http://www.siren.care/app)
- 5 Install the App



You can find the app at following address:

Or you can directly download from Ios App store or google App store  
Siren App is available for Android v4.4 upper and IOS v9.0 upper

Step3: Open app and register your account

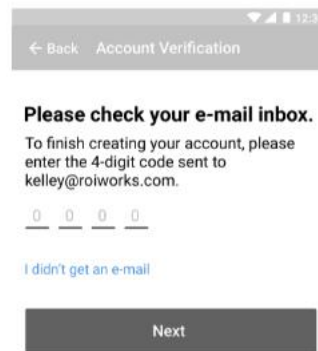
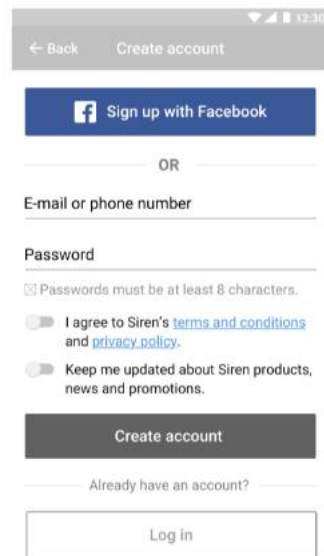
Please follow instructions on the APP to finish registration

1 Make sure your phone can receive Text msg

2 Enter your phone number when the app required

3 You will receive a 4-dig code on your phone, enter the code to the App and Siren will active your account

4 If you don't have phone with you, you can use your email to receive the code and enter the code to Siren App (optional)



#### Step4: Report your foot health situation

please note this part takes 3~5 mins, it is very important for us to provide the best service to you. Please follow the instruction on the App.

- 1 Prepare and review your medical record in 6 months
- 2 Enter information we required on the APP



#### Step5: Setup your sock and device

Thank you so much for your patient, let's start to setup your device. Please follow instructions on the APP and let's do it step by step.

Note: During the setup process you will be asked to allow several permissions for Siren APP to work properly, please allow it.

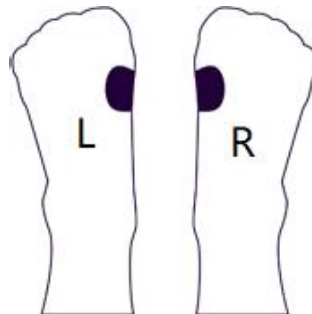
- 1 Make sure your smart phone / tablet already connected to your home wifi or data service
- 2 Open your siren box, find the QR CODE and scan it



The QR code is on the inside of your Siren box at the top.

3 Find the Hub in your box. Plug in your hub, please select the place where you spend most of your time in your house and make sure on blocks in front of the hub

4 pick up a pair of siren sock, remove the label and put it  
Please wear the sock correctly like the picture showing:



5 Check your first temperature reading!

Siren will help you track your feet's temperature once the sock has been worn, so please wear siren sock as much as you can

Enjoy

#### **CARE AND MAINTENANCE**

Wash: Siren Diabetic Sock is machine washable

Dryer: Please dry Siren Diabetic Sock under 63C / 145F degree (Medium / Low heat

mode)

Battery: Siren Diabetic is water proof, user don't need to take out batteries when washing

or drying.

Store/Carry: Please put your Siren Diabetic socks together in the Siren package box, so you can manage them better. If you take them with you on flight, you should take them with you based on FFC principles.



### **Product Specification/Technical Information**

Clinical Accuracy  $\pm 1.0^{\circ}$  F or  $\pm 0.5^{\circ}$  C

Temperature Range 69 to 114 $^{\circ}$  F (20 to 45 $^{\circ}$  C)

Operating Environment 50 to 130 $^{\circ}$  F (10 to 54 $^{\circ}$  C)

Resolution 0.1 $^{\circ}$  F or 0.1  $^{\circ}$  C

Response Time Approximately 1 second

Battery life a pair of sock have 1 month for daily use, 6 months in standby mode. So 7

pairs of sock can use for at least 7 month

Sizing M: Men shoe size 8.5-10.5 Women shoe size 10-12

Type: Crew

Environmental Conditions for Storage and Transportation: Temperature: 10 - 40  $^{\circ}$  C,

60-105  $^{\circ}$ F Humidity: 30 – 75% Altitude: 700 – 1060 hPa 0843





EC REP: MDSS GmbH, Schiffgraben 41, 30175 Hannover German

## **Limited Warranty and Disclaimer Information**

### **Limited warranty**

Siren Inc. warrants each Siren Diabetic Sock against defects in materials or workmanship for a period of 1 year from the date of purchase, and agrees to repair or replace any defective product without charge. IMPORTANT: This warranty does not cover damage resulting from accident, misuse or abuse, lack of reasonable care, the affixing of any attachment not provided with the product. Use of unauthorized replacement parts will void this warranty. Siren Inc. will not pay for warranty service performed by a non-authorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages. In order to obtain warranty service, simply call Diabetica Solutions Inc. Customer Service, 415-855-1744, for a Return Material Authorization Number (RMA). Then send the product, postage or shipping prepaid, to Siren Inc. in accordance with the instructions given with the RMA number. It is suggested that for your protection, you ship the product, insurance prepaid. Damage occurring during shipment is not covered by this warranty.

**NOTE: Siren Inc. authorizes no other warranty, written or verbal. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.**

## **Disclaimer and venue**

The Siren Diabetic Sock is intended to act as an aid in caring your feet, and are not intended to replace, be used without, or in lieu of, monitoring by a responsible adult.

Warning: Siren Diabetic Sock is not a medical device

Do not use Siren Diabetic Sock as a diagnostic tool.

It does not diagnose, cure, lessen, monitor, treat, nor prevent disease or injury;

Our products and services are only intended to be a health and wellness product and are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease.

Siren Diabetic Socks help you to keep track of your foot health data, but should not be used as a diagnostic.

[REFERENCE TO STANDARD DIABETIC FOOT CARE GUIDELINES]

[REFERENCE TO CLINICAL TRIALS BY LAVERY + ARMSTRONG]

## **FCC Warning**

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.
- 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.

## **ISED Statement**

- English: This device complies with Industry Canada license - exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device. The digital apparatus complies with Canadian CAN ICES - 3 (B)/NMB - 3(B).

- French: Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter has been approved by Industry Canada to operate with the antenna types listed with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le présent émetteur radio a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal. Les types d'antenne non inclus dans cette liste, et dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

## **Radiation Exposure Statement**

- English: This equipment complies with FCC and ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

- French:Le dispositif répond aux limites d'exposition aux rayonnements spécifiées par FCC et ISED pour les environnements incontrôlés. Cet appareil doit être installé et exploité à une distance minimale de 20 cm entre le radiateur et votre corps.