

Overview

Siren Diabetic Socks are wireless sensor-embedded socks, made of neurofabric textile with microsensors embedded directly into the fabric—for continuous temperature monitoring of the feet of people with diabetes—and wireless reporting. They are designed to be easy to use and are washable as well as reusable. One pair of Siren Diabetic Socks has over a month of daily use.

Components of the Siren Diabetic Socks and Foot Monitoring System

The Siren Diabetic Socks and Foot Monitoring System is composed of a pair of sensor-embedded socks, a Hub, smartphone App, and the backend system.

Sensor-embedded Socks: The socks are made of “smart textile”: textile with microsensors woven directly into the fabric (Siren Diabetic Socks, Neurofabric™, Siren Care, San Francisco, CA). These virtually invisible sensors are seamlessly integrated into the socks to monitor temperature changes on the bottom of the feet. Multiple sensors or thermistor (1 mm x 0.5 mm x 0.5 mm) are embedded in the socks at six different points to monitor temperature. The 6 sensors take temperature measurements at 5-second intervals to track temperature increases at the bottom of the user's feet, at the hallux, metatarsals 1, 3, 5, midfoot and heel (Figure 1B).

The seamless design is compliant with ADA requirements. The sensor-embedded socks are designed to be reusable and are machine washable and dryable.

Socks are provided in pairs, with the left and right sock identified with lettering L and R. At the outer ankle position of the left sock is a **tag (include figure with all components marked)**, whose water-proof plastic case encloses several essential components.

1. Temperature sensing wires from the six different points on the foot.
2. An accelerometer for detecting steps taken.
3. A gyroscope for detecting changes in the position of the feet.
4. A microcontroller unit with flash memory that can hold temperature data collected for up to six days. A Bluetooth chip for connecting with the hub plugged into an electrical outlet. (System on chip solution which combines MCU with BLE)
5. Crystal for the watch function for keeping time.
6. A battery, a lithium magnesium dioxide button cell.
7. A Hall effect sensor for detecting magnetic fields. Prior to use, a magnetic band around the keeps the socks in deep sleep mode.

Figure 1 A. image of socks with tag (circled) containing battery, microcontroller unit and Bluetooth labeled and B. bottom of socks where sensors are located at hallux (sensor 1), metatarsal heads 1,3 and 5 (sensors 2-4), midfoot (sensor 5), and heel (sensor 6).



Figure 1. Smart sock overall picture

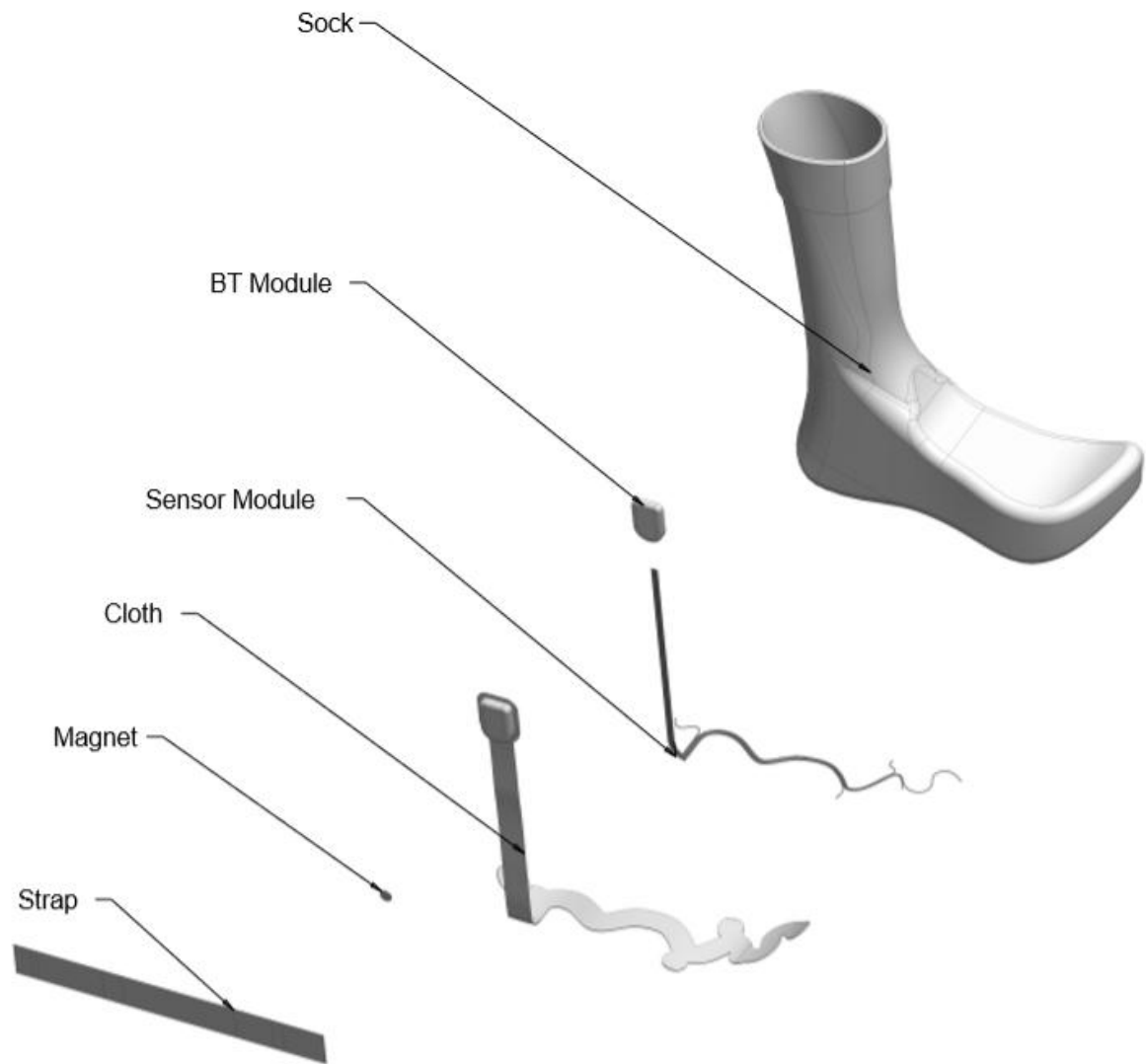


Figure 2. Smart sock explode drawing

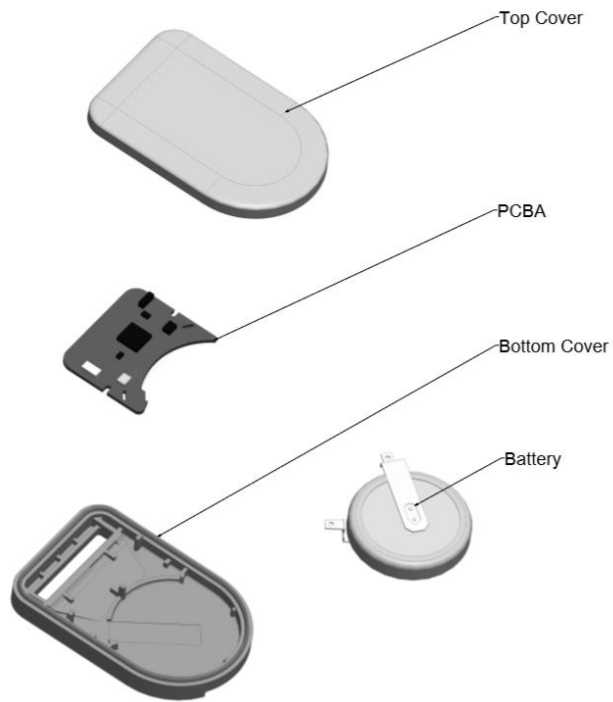


Figure 3. BT module explode drawing

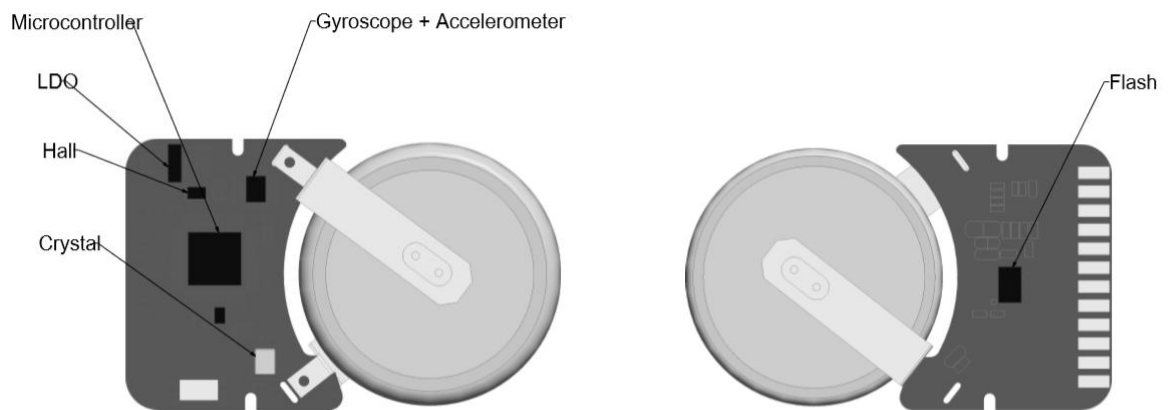


Figure 4. BT PCBA drawing

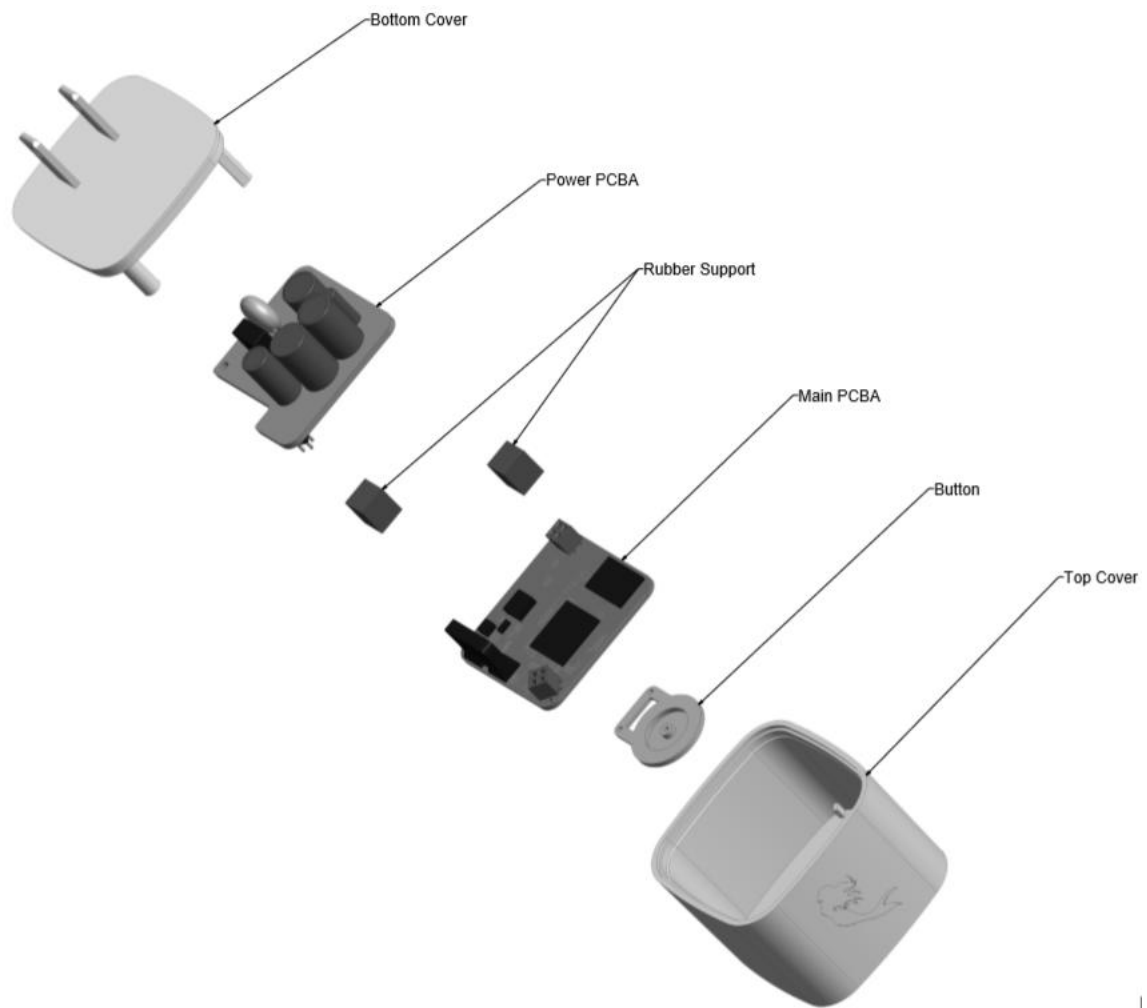


Figure 5. Hub explode drawing

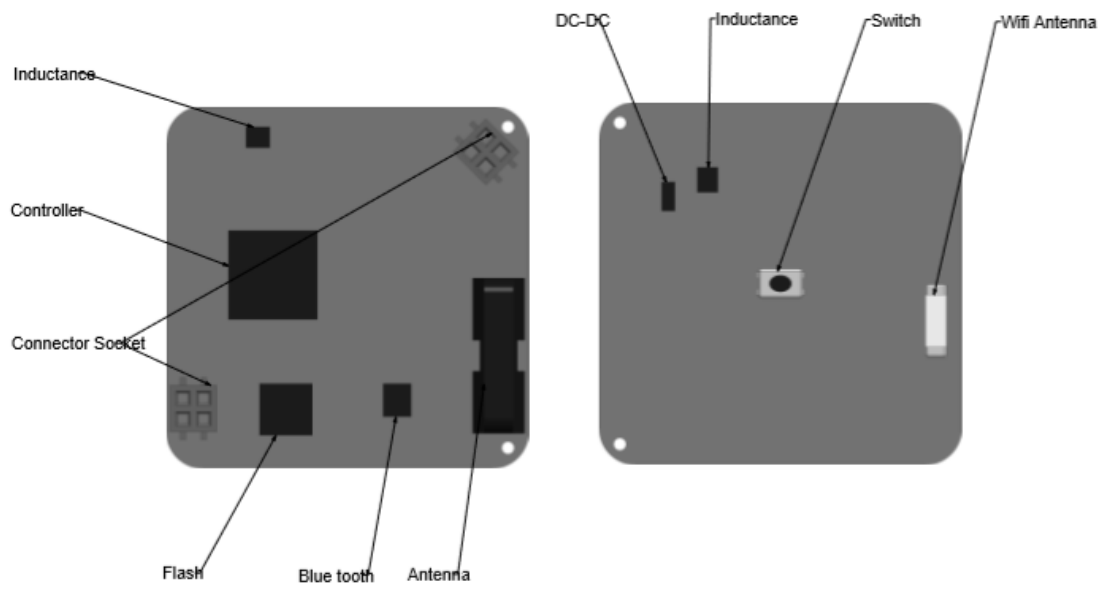


Figure 6. Hub PCBA drawing

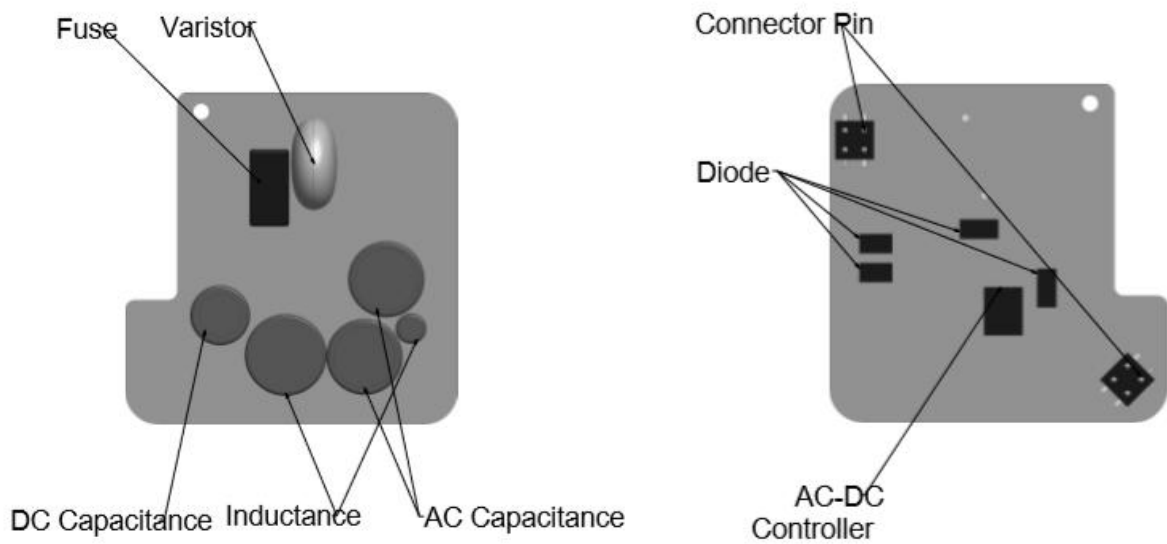


Figure 7. Hub power PCBA drawing

The data are stored in the tag and sent via Bluetooth to the smartphone paired with each pair of socks.

Siren App: The smartphone app can be programmed to generate alerts when backend found the user's feet showing temperature increases at one or more points in comparison to the contralateral position on the other foot. When it is running, it will send all measurement data in Siren Diabetic Socks to backend.

Siren Hub: Siren Hub will work with Siren Socks and Siren Backend (AWS). Its main purpose is to ensure all measurement data in Siren Diabetic Socks are uploaded to backend as early as possible. When smartphone is not running.

Backend system: The backend system is used to save all the measurement data which collect from all users. More important is that Siren's Algorithm will running on that and act base on the algorithm required, such as send out an alert.

FCC Warning:

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

This equipment complies with FCC 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.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.