

# SurroSense Rx System

## User Guide

Orpyx Medical Technologies Inc.

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## Warranty

Orpyx Medical Technologies Inc. guarantees that the SurroSense Rx shoe node(s) and the technology contained therein will be free of defects in material and workmanship for two (2) years, valid from the date of purchase, with proof of purchase. Orpyx Medical Technologies Inc. guarantees that the sensor-embedded SurroSense Rx Insoles will accurately measure and transmit pressure data for a period of 6 months (based on an average daily use of 10 hours per day, 7 days per week), if used as directed. If SurroSense Rx Insoles are not replaced when recommended, Orpyx Medical Technologies Inc. no longer guarantees accuracy of sensor readings. The guarantee extends only to the original purchaser and is not transferable. Battery replacement, SurroSense Rx Insole trimming and initial fitting must be performed by an Orpyx-certified technician, and recorded using a service maintenance record. Failure to do so will render the warranty null and void.

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#### 1.0 The SurroSense Rx Lite

The SurroSense Rx Lite is a system designed to restore feedback to those with decreased, or absent plantar pressure to help avoid associated complications such as infection, ulceration and amputation. The system collects pressure data over time from the bottom of the feet through specialized sensor-embedded insoles, wirelessly sending that information to the user via their smartphone. The SurroSense Rx mobile app alerts the user when excessive pressure is detected so that behavior can be changed to help avoid associated complications.



#### Included with purchase:

- A SurroSense Rx Insole (Left and Right)
- B SurroSense Rx Node (Left and Right)
- C SurroSense Rx Node Clip x2 (not shown)
- D SurroSense Rx Mobile App Download

Figure 1: SurroSense Rx Lite (\*Smartphone not included with purchase)

#### i. Intended Use

The SurroSense Rx Lite is a wearable plantar pressure monitoring system that is indicated for patients who have decreased or absent sensation in the feet resulting from a condition known as peripheral neuropathy. As the patient goes about their

daily routine, data from the sensor-embedded insoles are wirelessly transmitted to the SurroSense Rx mobile app via their smartphone. If the feedback is properly adhered to, the medical benefits of using the system may include the prevention of peripheral neuropathy-related complications including infection, ulceration and amputation. The device will also enable the patient to more actively manage their condition in concert with their healthcare provider, preemptively inform them of potential problem areas, and empower them to live more healthfully.

## **ii. Contraindications**

There are no known contraindications for the SurroSense Rx Lite at this time.

## **iii. Warnings and Precautions**

WARNING: Disregarding WARNING information may cause improper operation and inaccurate results.

CAUTION: Disregarding CAUTION information may reduce the life expectancy of the product and/or damage to the product.

CAUTION: This product uses and receives radio frequency signals. For proper operation, this product must be configured and operated as per the instructions provided in the manual.

WARNING: This product uses low power radio communications and can affect other medical electrical; equipment.

### ***Qualification of the Healthcare Professional***

The SurroSense Rx Lite may only be fit for use by Prosthetists, Pedorthists, Orthotists and other allied healthcare professionals who have been authorized with the corresponding Orpyx training.

### ***Field of Application***

The SurroSense Rx was developed for everyday activities and athletic uses\*. For the necessary environmental conditions, please see Section 10. The SurroSense Rx Lite is designed exclusively for use on one patient. Use of this product by persons other than the prescribed patient is not approved by the manufacturer. In order to effectively use this device, the patient must meet the following requirements:

- ✓ The patient must meet the physical and mental requirements with regard to the perception of alert-based feedback (acoustic signals and/or mechanical vibrations).
- ✓ The SurroSense Rx Lite is not recommended for people who are unwilling or unable to actively respond to the real-time feedback the system provides, and to adhere to the recommended maintenance and insole replacement schedule through their certified healthcare professional.
- ✓ The skin on the residual limb must be fully healed. If the patient does have active skin ulceration or partial amputation, it is necessary that the patient have these wounds appropriately monitored and dressed by a healthcare professional.

\*Approved for patients weighing up to 136 kg/300 lbs.

### ***Radio Frequency Interference***

This device produces radio-frequency emissions. Radio-frequency (RF) emissions from electronic equipment can impact the operation of other electronic equipment, causing them to malfunction. Although the SurroSense Rx is designed, tested, and manufactured to comply with regulations governing radio frequency emission in countries such as the US and Canada, the wireless transmitters and electrical circuits in the SurroSense Rx may cause interference in other electronic equipment. Therefore, please take the following precautions:

#### **TRAVEL OR INTERNATIONAL USE**

If you plan to travel with the SurroSense Rx Lite, please note that the product uses wireless communication and is not permitted to be used during flight. Please ensure that your receiving device (smartphone, iPad, or iPod Touch) has been set to airplane mode prior to travel to ensure that the SurroSense Rx Lite is not transmitting during flight. If you are traveling outside of the United States or Canada, check with your travel agent prior to travel to ensure that the use of wireless products is permitted in your country of destination.

#### PACEMAKERS

The Health Industry Manufacturers Association recommends that a minimum separation of 15 cm (6 inches) be maintained between certain RF emitting devices and pacemakers in order to avoid potential interference between these devices. Persons with pacemakers should always keep SurroSense Rx system at least 15 cm (6 inches) from the pacemaker when the device is active.

#### HEARING AID COMPATIBILITY

The SurroSense Rx may interfere with some hearing aids. If you experience interference, consult your hearing aid manufacturer or your physician for solutions or alternatives.

#### OTHER MEDICAL DEVICES

If you use any other personal medical devices, consult the medical device manufacturer to ensure that these devices are adequately shielded from radio frequency emissions produced by devices such as the SurroSense Rx.

#### HEALTH CARE FACILITIES

Hospitals and healthcare facilities may use equipment that is particularly sensitive to external radio frequency emissions. Turn off your receiving device (e.g. a smartphone) when hospital staff or signage instructs you to do so.

#### OTHER WIRELESS TECHNOLOGIES




The SurroSense Rx is FCC compliant. However, there may be some newer wireless technologies that interfere with the radio frequency emissions of this device. Please consult the manufacturers of these devices to ensure compatibility with the SurroSense Rx.

#### **iv. Cautions**

Use of the SurroSense Rx Lite near to other treatment, or diagnostic equipment, or other may result in interference to or from the adjacent equipment potentially causing improper operation or inaccurate results. Please check to ensure use of wireless products are permitted before using the SurroSense Rx Lite in a clinical environment.

- ✓ The SurroSense Rx Lite should ONLY be used with approved accessories.
- ✓ AVOID dropping the SurroSense Rx Nodes. Although robustly designed, damage may occur that could cause the system to malfunction.
- ✓ NEVER cut past the trim guidelines provided on the SurroSense Rx Insoles. Doing so would break the circuit and render the device inoperable. SurroSense Rx Insoles should only be trimmed by an Orpyx-certified technician.
- ✓ DO NOT open the SurroSense Rx Nodes for any reason. An Orpyx-certified technician must perform battery replacement, insole replacement, insole fitting, and/or any device maintenance as required.
- ✓ DO NOT submerge the SurroSense Rx Nodes in water for any reason. They have been designed to be water resistant, not waterproof.

#### **2.0 Symbols and Definitions**

<i>Number</i>	<i>Symbol</i>	<i>Reference</i>	<i>Title</i>
1		ISO 7000.0434A	Caution
2		IEC 60417.5840	Type B Applied Part
3		ISO 7000.1641	Operating Instructions

#### **3.0 SurroSense Rx Lite Controls and Indicators**

Illustrations and descriptions required in this section:

SurroSense Rx Node (top and side view) – Node release mechanism including warning  
SurroSense Rx Node (inside view) – Showing the battery compartment including warning  
SurroSense Rx Node (attached to shoe) – Showing the node laced through shoelaces  
SurroSense Rx Node Clip (attached to node) – Showing how the clip engages to node  
SurroSense Rx Node Clip (engaged to shoe with Velcro or Mary Jane style)  
SurroSense Rx Insole (top view with sleeve and node) – Explaining the sleeve connection point  
SurroSense Rx Insole (bottom view) – Show trim lines and includes warning (only HCP)

#### **4.0 General Operating Instructions**

a. How to properly fit the SurroSense Rx Lite

The SurroSense Rx Lite must initially be fitted by an Orpyx-certified technician. Once the device is ready for fitting, you'll be asked to visit your healthcare provider in order to have the Insoles and Nodes properly fit to your shoes. First, the Orpyx-certified technician will trim the Insoles to fit your shoes. ***This must ONLY be executed by the technician.*** If the Insoles are improperly trimmed, the sensors embedded within could potentially be damaged. Once the insoles are fit properly, the technician will open the right and left Nodes to insert a coin cell battery. The SurroSense Rx mobile app has a battery indicator built in for monitoring. It's recommended that your Insoles be replaced every 6-9 months depending on usage (the mobile app will provide you with warnings as the Insoles near expiration), and the battery life should be sufficient for the duration. If the coin cell batteries require replacement before you need to purchase new Insoles, please have the technician perform this task for you.

b. Transferring the SurroSense Rx Lite to an alternate pair of shoes

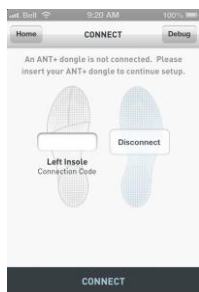
Once the SurroSense Rx Insoles and Nodes have been fit to your shoes, it is possible to transfer them to another pair of shoes. Carefully unlace your shoelaces and release both of the Nodes. If using the Node Clip, simply feed the Velcro strap through the Clip, releasing the Nodes. The Nodes and Insoles must stay connected throughout the transfer process. Never attempt to disengage the connection lead. Then simply insert the Insoles into an alternate pair of shoes, and re-secure the Nodes to the top of the shoe using either the lace holes, or the Velcro straps (the Node Clip attachment is required if the shoe has Velcro straps).

c. Compatible smartphones and personal electronic devices

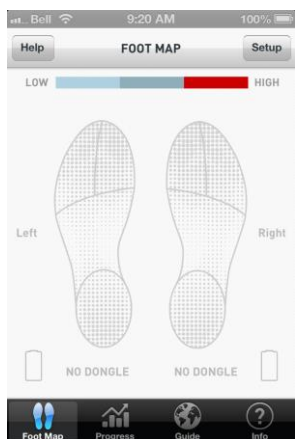
The SurroSense Rx Lite is compatible with the following smartphones and personal electronic devices. Apple operating system iOS 5 or newer on: iPod 4<sup>th</sup> generation or newer, iPhone 3GS or newer. The SurroSense Rx mobile app is available for download through the Apple iTunes Store. The system is also compatible with Android 2.3 or newer on any Sony Xperia smartphone, or HTC Rhyme. For all compatible Android devices, the app can be downloaded from the Google Play store. Please note: All Apple devices require a Dongle key to allow the system to effectively communicate with the device using the ANT+ wireless protocol. If required, Dongle keys may be purchased from any Orpyx re-seller.

d. Connecting the SurroSense Rx Lite to your smartphone or personal electronic device

The SurroSense Rx Lite communicates with the users smartphone or personal electronic device through the SurroSense Rx mobile app. Once an Orpyx certified technician has fit the device, including the SurroSense Rx Insoles and Nodes, and the user has downloaded the mobile app to their smartphone, it must be paired with the Nodes in order to start receiving data. Please use the following guide to pair your SurroSense Rx Insoles:



1. Start up the SurroSense Rx mobile app and work your way through the set-up screens until you reach the device connection step (shown on the left)
2. Both your left and right SurroSense Rx Nodes come with a unique connection code. You'll find these codes on stickers directly on the Nodes, and also on the last page of this User's Guide for easy reference.
3. Carefully enter your left insole connection code first, and then move on to the right
4. Hit 'Connect' and wait for the system to pair with the mobile app; this can take up to 90 seconds
- e. Understanding the SurroSense Rx mobile app



The SurroSense Rx mobile app effectively tracks the pressure exerted over the bottom of the feet while your insoles are in use. If the app hasn't detected any activity within a five-minute time frame, the device will go into sleep mode in order to preserve battery life. As soon as pressure is detected again, the app will continue to monitor pressure. The Foot Map screen is the app's default screen (illustrated on the left). When the app has successfully connected to the device, the battery cells will light up and each footprint should have the word 'Connected' below. There are three possible pressure levels including low, medium and alert. If one of the four regions on either your left or right foot have exceeded recommend pressure in a 15 minute time frame, you will receive an auditory and vibration alert to tell you to offload pressure to avoid complications. The app provides detailed instructions as to how to effectively offload pressure in the event you should receive an alert. The app also tracks data including: % of alerts effectively offloaded, # of hours device is in use per day on average, and

# of alerts in each of the regions on each foot. The data is stored locally in the mobile device, and can be viewed within the app, or can be emailed to yourself, or your healthcare provider to help track progress and improve collaborative care. In addition to providing these preventative alerts, the app also has a robust FAQ tab, access to Orpyx's social media community, and a guide to best diabetic foot care practices.

Please note: Mobile device should be stored somewhere close to your person in order to ensure that you effectively receive the auditory and/or vibration alerts. Please reference the app tour and FAQ screen for more information.

## 5.0 Maintenance and Cleaning

### SurroSense Rx Lite Maintenance

Other than replacing the battery periodically, this system does not require any user maintenance. There are no user repairable components in the SurroSense Rx Lite. If problems occur, contact an authorized service representative for repair. CAUTION: Only Orpyx-certified technicians are licensed to replace Node coin cell batteries. Failure to comply may result in failure of the unit to function properly, reduced battery life, or inaccurate readings.

### Cleaning the SurroSense Rx Lite

Rubbing alcohol or a damp cloth with MILD detergent may be used to wipe the outside of the SurroSense Rx Lite Nodes. DO NOT use a strong cleaning solution that contains bleach, or immerse the SurroSense Rx Lite in water.

### Disposal of the Device

When the device has reached the end of its useful life, please dispose of properly, in accordance with all local and national regulations.

## 6.0 Troubleshooting – Frequently Asked Questions

Q: How long does it take to "offload" an alert?

A: The length of time it takes to offload an alert depends on how long that alert has been present for. When proper offloading steps have been taken, the offloading time could range from a minimum of seconds to a maximum of 3.5 minutes.

Q: If I am not wearing my insoles, how long does it take for them to go into Sleep mode?

A: Once you have taken off your insoles, and no pressure has been applied to them for five minutes, your insoles will go into sleep mode. Once you have put your insoles back on, and reapplied pressure to them, it will take up to a maximum of one minute for the device to fully turn on and start collecting data again.

Q: What impact does this device have on draining my cellphone battery?

A: Having the SurroSense Rx device run in the background on your cellphone has a minimal effect on your cellphone's battery life.

Q: How often is the Foot Map screen updated?

A: The image of the Foot Map is updated every minute. It is important not to expect to see a real-time, live foot map displayed on the screen. Although the device is capturing information in real-time, the image that is displayed on the App will be intermittently transmitted. This is done to ensure the lowest possible battery consumption with the foot nodes.

Q: What should I do when the battery indicator reads empty?

A: You will receive alerts when the battery is close to expiry. At that point, you should schedule an appointment with your Orpyx-certified technician to have the coin cell battery in your shoe nodes replaced. Battery replacement should only be done by an Orpyx approved service technician.

Q: How can I use the progress reports to improve outcomes?

A: The progress reports are designed to provide you with useful information to track compliance over time. The most important metrics to track month-to-month include: average hours used per day, percentage of alerts successfully offloaded, and number of alerts per regions. This information may be shared with your healthcare practitioner to help them preemptively identify problem areas and help you develop a more comprehensive care plan.

Q: Do I need an Internet connection to use this app?

A: No outside network is required to run the app.

Q: What happens when I get new Insoles?

A: When your Insoles start to reach the end of their life cycle (6-9 months on average), you will get a series of notifications through the app that remind you that it's time to purchase new insoles. When the insoles have completed their life cycle, the app will no longer provide live pressure feedback, and the foot map will disengage. At that time, order a replacement pair through your healthcare practitioner, who will procure the order on your behalf and properly fit your new insoles and reengage the device.

Q: Why does the App only store six months of data?

A: The application receives a great deal of data with consistent use. Storing more than six months of data would be prohibitive. For this reason, we've enabled the progress reports to be emailed in PDF format, so that you can personally keep track of improvements over time.

Q: What error message will show up when the nodes are not working?

A: If there is no data being transmitted from one or both of the insole nodes, an error message indicating this will pop up. Additionally, the Foot Map screen will show a "NOT CONNECTED" icon below the insole of concern, and no Pressure Level data will be shown on the corresponding foot map. If this is the case, ensure that the nodes have fresh batteries and that they are properly connected to your insoles. If problems persist, contact your service provider.

(New page)

## **7.0 SurroSense Rx Lite Statement of Understanding**

I, \_\_\_\_\_, have reviewed the contents of the SurroSense Rx Lite User Manual with my practitioner. I understand the general operating instructions and general maintenance of the SurroSense Rx Lite system. I have been advised to follow the instructions for use and have been advised to contact my practitioner immediately with any questions I may have with the SurroSense Rx Lite.

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Print Patient Name:

Date:

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Patient Signature:

Date:

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Practitioner Signature:

Date:

### **8.0 Technical Specifications**

**FCC ID: 2AAH8-SSV1**

**IC ID: 10789A-SSV1**

**Model #: SSV1**

Size	70mm x 30mm x 12mm (L x W x H)
Weight	20 grams
Power Source	80mAhCR2032 coin cell battery
Frequency of Operation	2406-2475 MHz
Max. 20 dB Bandwidth	1 Mhz
Max Output Power	+0 dBm
Number of operation modes	1 – ON
Storage	Temperature -20 to +55 Celsius / 95% humidity
Operation	Temperature -20 to +55 Celsius / 95% humidity
Environmental Protection	IPx4

**This device complies with part 15 of the FCC rules and with Industry Canada license-exempt RSS standard(s) 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: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

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.