



# SURROSENSE RX™ SYSTEM

Instructions for Use





The SurroSense Rx™ system is a tool to help actively prevent peripheral neuropathy complications and track progress.

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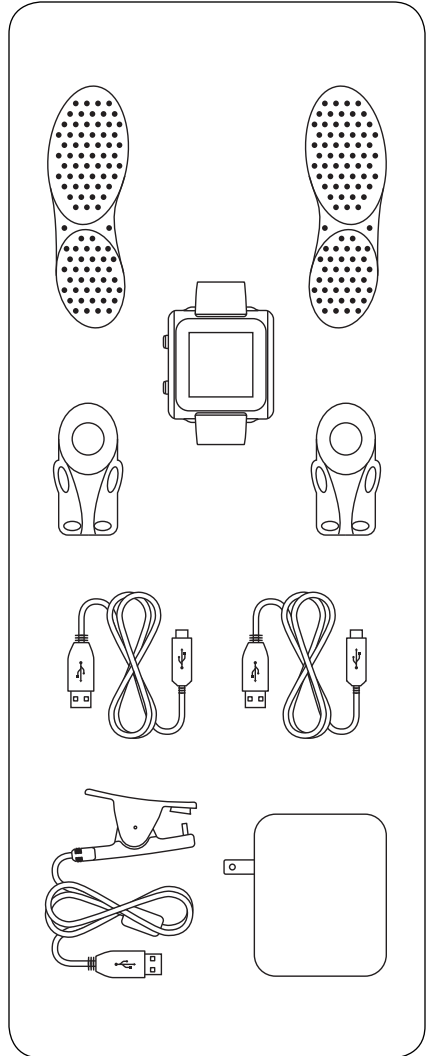
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## 1.0 The SurroSense Rx™

Peripheral neuropathy is a condition that results in loss of feeling in the feet. This inability to sense and respond to tissue damage can lead to the development of blisters and ulcers, which can lead to surgical amputation. The SurroSense Rx™ notifies the user when dangerous pressure levels are detected, so that behavior can be changed and damage avoided. The SurroSense Rx™ system is a tool to help actively prevent peripheral neuropathy complications and track progress.


### INCLUDED WITH PURCHASE

- A.** SurroSense Rx™ Insert (Left and Right)
- B.** SurroSense Rx™ Smartwatch
- C.** SurroSense Rx™ Shoe Pod (Left and Right)
- D.** SurroSense Rx™ Mobile App Download (not shown)



## I. INTENDED USE

The SurroSense Rx™ 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 inserts are wirelessly transmitted to the SurroSense Rx™ smartwatch. The device can be worn both indoors and outdoors as often as desired by the patient; or as recommended by Podiatrist/ Physician. If the feedback is properly adhered to, the medical benefits of using the system may include the prevention of peripheral neuropathy-related complications including the development of blisters and ulcers, which can lead to surgical amputation.

 Use of the SurroSense Rx™ device does not negate the need for regular diabetic foot care with a health care professional.

## II. CONTRAINDICATIONS

There are no known contraindications for the SurroSense Rx™ system 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.









## FIELD OF APPLICATION

The SurroSense Rx™ was developed for everyday activities. For the necessary environmental conditions, please see Section 10.0. The SurroSense Rx™ is designed exclusively for use on one patient. 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™ 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 insert replacement schedule.
- ✓ 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.


## 2.0 Symbols and Definitions

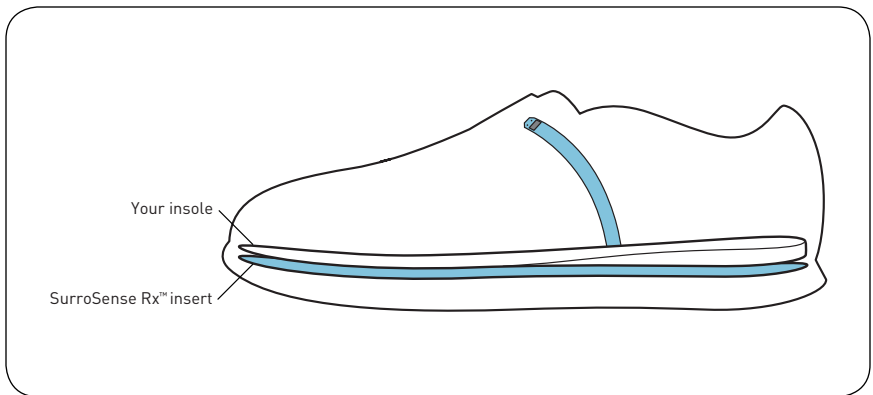
Symbol	Definition
	Caution
	Operating Instructions
	Manufactured By
	Authorized Representative (EU Only)
	Keep Dry
	Waste Electrical & Electronic Equipment
	CE Alert Mark
	Year of Manufacture

## 3.0 Setting up your system

### A. HOW TO PROPERLY FIT YOUR SURROSENSE Rx™ INSERTS

The SurroSense Rx™ inserts are made to fit under your existing shoe insole. Whether it's a custom orthotic, over-the-counter or manufacturers insole, the SurroSense Rx™ insert will fit underneath. Simply remove the existing insole, and place the appropriate left or right SurroSense Rx™ insert into the shoe. The lead, (which is on the inside edge of the insert) should run along the inside of the shoe, up towards the tongue. When in place, your existing insole can be put back into the shoe on top of the SurroSense Rx™ insert.

 \*Note: The SurroSense Rx™ should not be used with insoles that have a hard plastic heel cup as it damages the

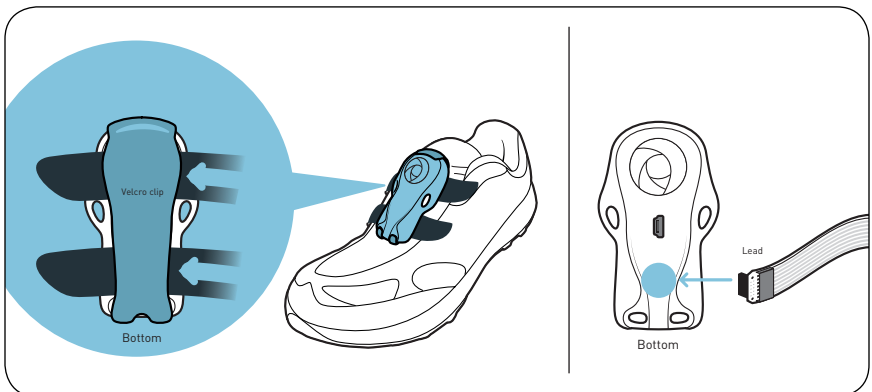




## B. HOW TO PROPERLY FIT YOUR SURROSENSE RX™ SHOE PODS

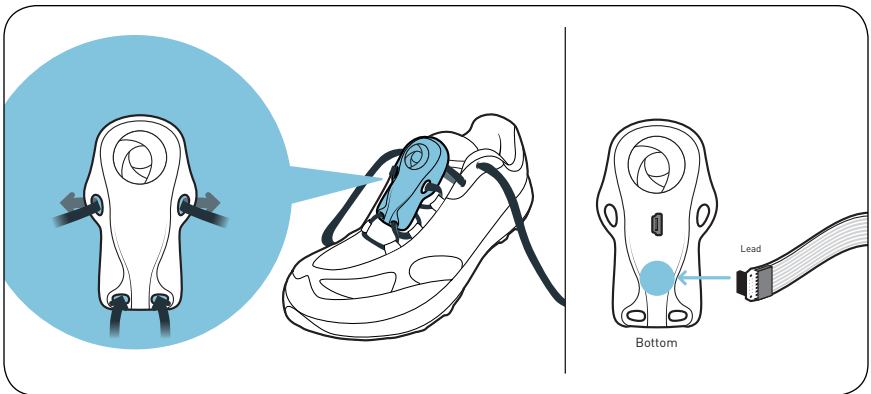
The shoe pods are to be fastened on top of either a Velcro or laced shoe. For a Velcro shoe, use the clip provided. Place the clip where you would like it underneath the Velcro straps. Attach the connector (located at the end of the lead) into the back of the shoe pod. Once connected, slide the rounded top of the shoe pod into the clip, then push the bottom of the shoe pod into the clip so that the clip posts snap into the eyelets on the top and bottom of the shoe pod. This will ensure the shoe pods are secure.

\*Note: The clip for the shoe pod can also be used with laced shoes. Simply place the clip underneath the existing lacing and fasten the shoe pod on top.




For laced shoes, undo the laces to the bottom of the shoe. Place the shoe pod where comfortable and lace pod to shoe using lace holes. When in place, attach the connector (located at the end of the lead) into the shoe pod.

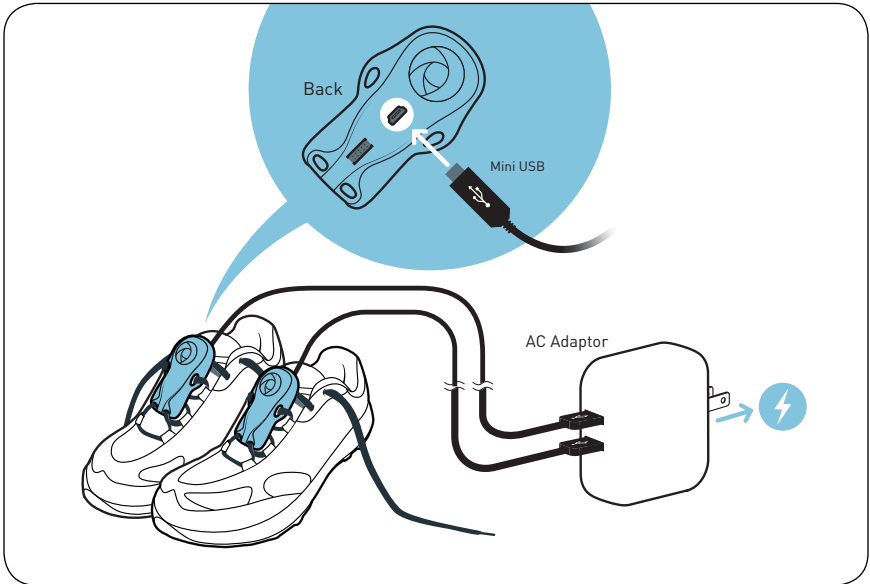
\*Note: We recommend fully charging shoe pods before use to ensure optimal battery performance.



### C. HOW TO CHARGE THE SHOE PODS

With regular use, the shoe pods will require a charge approximately once per week. Battery life for the shoe pods can be monitored from the foot map screen on the smartwatch. To charge the shoe pods, remove the connector from the back of the shoe pod and insert the mini USB cable into the mini USB port. The other end of the cable is to be inserted into the AC adaptor, which plugs directly into an electrical outlet. When the shoe pods are charging they flash a green light, when they are fully charged there is a solid green light.

 \*Note: The device should only be charged with the AC adaptor included with purchase.



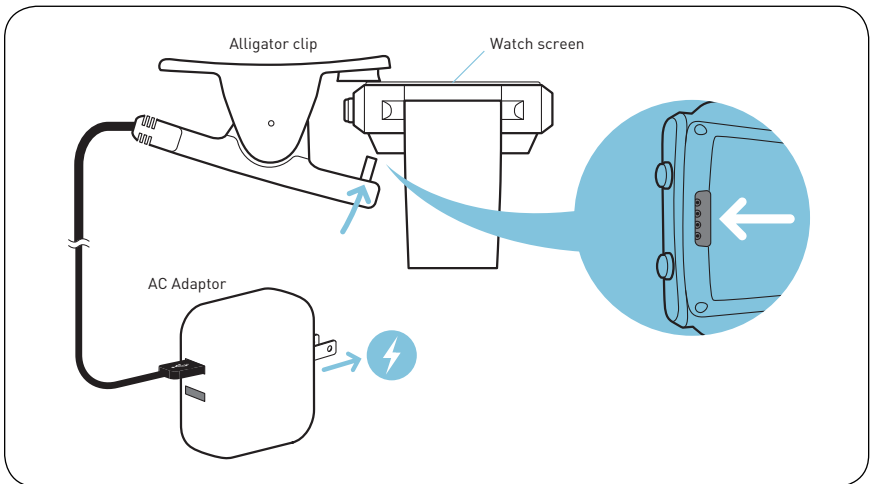
## D. HOW TO GET STARTED WITH YOUR SMARTWATCH

Your smartwatch will come wirelessly connected to your shoe pods. To turn the watch on, press the top left button. The screen will light up and you will see the general date and time display. To set the date and time please see section 4.0.

\*Note: We recommend fully charging the smartwatch before use to ensure optimal battery performance.

## E. HOW TO CHARGE THE SMARTWATCH

Your smartwatch should be charged every night. Battery life is displayed on the upper right hand side of the watch. To charge the smartwatch, attach the alligator clip to the watch so that the side with the rubber pads is on the watch screen. The USB end of the cable fits into the AC adaptor, and can be plugged into an electrical outlet. If the alligator cable is connected correctly, the smartwatch screen will light up.



## F. DOWNLOADING THE MOBILE APP

The SurroSense Rx™ comes with a free mobile app download. This is an optional tool for patients to use as an educational resource. To download the app, go to the iTunes store and search Orpyx. Click "Install App" and enter your Apple ID information. Please note that the SurroSense Rx™ device DOES NOT include a smartphone with purchase.

## 4.0 Using the SurroSense Rx™ Smartwatch

The SurroSense Rx™ smartwatch effectively tracks the pressure exerted over the bottom of the feet while your inserts are in use. If the smartwatch has not detected activity on any of the sensors for one minute, the device will go into sleep mode to preserve battery life. As soon as pressure is detected on the insert again, the smartwatch will continue to monitor pressure.

In addition to providing the 1:1 feedback, the smartwatch also tracks and stores data over time. In order to access your data to track progress sign up for an Orpyx Connect account.

**Menu** – takes you to the main navigation screen

**Shoes** – shortcut to the foot map

**Top left** – takes you to the time screen from any other screen. This button will wake up the watch after the display goes to sleep.

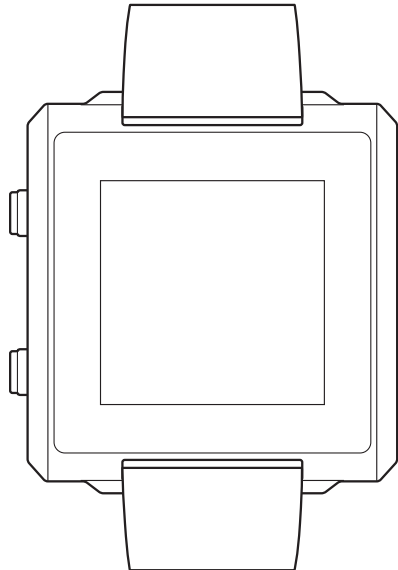
**Bottom left** – takes you to the foot map from any other screen.

**Foot Map** – display of pressure exerted over the bottom of the feet

**Help** – steps to offload high-pressure alerts

**Watch Setup** – set the date and time for the watch

**Connect** – here you will enter the connection codes for the device



## FOOT MAP

The foot map screen is where you can actively monitor your feet throughout the day to check for undue stress or damage. When the inserts are connected to the smartwatch the foot display will be glowing and the 4 regions of the foot are visible. Direct feedback is provided from the feet notifying the user of three possible pressure levels: low, medium and alert. If one of the four regions on either foot has exceeded recommended pressure, the user will receive an alert (vibrate and beep on the smartwatch) notifying them to offload pressure to avoid complications. For guidance on how to offload pressure, click the 'Help' button located on the lower right hand side of the foot map.

## HELP

To read the offloading steps vertically slide your finger down the watch screen. To move to the next step, slide your finger horizontally across the watch screen.

## WATCH SETUP

You will be prompted to set the time followed by the date. You must press

the 'Next' button (located on the lower right hand side) for both the time and date to confirm the settings.

## CONNECT

Your smartwatch will come connected to your shoe pods. In the event that your device loses the stored connection codes, follow this procedure to re-establish connection:

You will be prompted to enter the values for the right connection code, followed by the left. When the information has been entered, click 'connect'. The 'connecting' screen will last up to 90 seconds.

If you receive the re-enter codes screen, go through the steps again to ensure the codes entered are correct.

When both the right and left inserts have been connected a screen will appear that says 'successfully connected'. Pressing 'Next' will take you directly to the foot map.

\*Note: Your connection codes are the unique serial codes for your shoe pods and can be found: on the back of the

box, the IFU and within your Orpyx Connect account.

## ALERTS

### DOWNLOAD YOUR DATA

We recommend you download your data every week. The smartwatch display will notify you when data storage is getting full.

Download your data 75% = you have approximately 2.5 days left until data storage in the device is full

Download your data 90% = you have under a day before your device is full

When the data storage reaches capacity (100%) there will be no new data recorded. Once you download the data onto your Orpyx Connect account you are able to start recording new data again.

### HIGH PRESSURE DETECTED

This alert is to let you know that dangerous pressure levels have been detected on your foot. When this screen is displayed you can either press 'dismiss', which will take you to the foot map screen, or 'help' which provides instructions on how to offload

pressure. Irreversible pressure damage can occur in as little as 15 minutes; therefore, it is important to offload the pressure alert as soon as possible to avoid damage to the foot. When the insert has detected the user offloading pressure the 'offloading' screen will appear.

### LOST SIGNAL

If the smartwatch loses connection with the shoe pods, a lost signal alert will appear. Press 'connect' to automatically re-establish connection. If unsuccessful, the user will be prompted to manually re-enter connection codes by pressing 'ok'. Pressing 'menu' will take you to the foot map screen.

### LOW BATTERY

With regular use, your smartwatch battery should last for 12 hours a day, on average. If you press 'dismiss' the low battery warning will not be issued again.

### REPLACE SENSOR INSERTS

Your inserts start to reach the end of their life cycle at approximately 12 months. Replacing them at this time will ensure the most accurate pressure

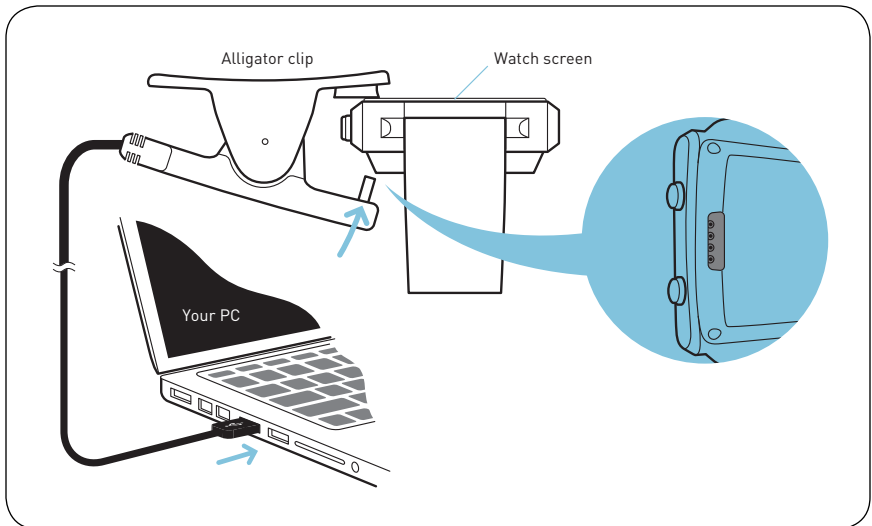
readings from the sensors.

Replacement inserts can be purchased online at [Orpyx.com](http://Orpyx.com) or through your authorized re-seller.



## 5.0 Orpyx Connect

Creating an Orpyx Connect account ([connect.orpyx.com](http://connect.orpyx.com)) is quick and easy. Through this account you will be able to: register your device warranty, upload your data to track progress over time, recover your connection codes, and stay up-to-date with the latest Orpyx product updates.



## 6.0 Maintenance and Cleaning

### SURROSENSE RX™ MAINTENANCE

This system does not require any user maintenance. There are no user repairable components in the SurroSense Rx™. If problems occur, contact Orpyx Customer Care.

### CLEANING THE SURROSENSE RX™

A damp cloth with mild detergent may be used to wipe the outside of the SurroSense Rx™ shoe pods. DO NOT use a strong cleaning solution that contains bleach, or immerse the SurroSense Rx™ 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.

## 7.0 Storage and Handling

### SURROSENSE RX™ HANDLING

 AVOID dropping the SurroSense Rx™ shoe pods. Although robustly designed, damage may occur that could cause the system to malfunction.

 DO NOT open the SurroSense Rx™ shoe pods for any reason.

 DO NOT submerge the SurroSense Rx™ shoe pods in water for any reason. They have been designed to be water resistant, not waterproof.



Keep Dry.

### SURROSENSE RX™ STORAGE



Keep Dry.

## 8.0 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 (available on the smartwatch 'Help' screen), you can effectively offload an alert within 3 minutes.

**Q:** Do I need to turn the system off when not in use?

**A:** No, if pressure has not been detected on the inserts for over a minute, they will intuitively go into sleep mode. While in sleep mode, the device is not transmitting information. When pressure is applied to the inserts, it will take one minute for the device to fully turn on and start collecting data again.

**Q:** What should I do if the screen on my smartwatch has gone black?

**A:** This could mean that the smartwatch has run out of battery power, and requires being charged. If you are having difficulty, contact Orpyx Customer Care Representatives.

**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. This is done to ensure the lowest possible battery consumption with the shoe pods.

**Q:** What happens when I get replacement inserts?

**A:** When you receive replacement inserts, you will have to disconnect and remove your old insert from your shoes. Place the new inserts into the shoe and connect to the shoe pod.

**Q:** What error message will show up when the shoe pods are not working?

**A:** If there is no data being transmitted from one or both of the shoe pods, a 'lost signal message' indicating this will pop up. Additionally, the foot map screen will show a "NOT CONNECTED" icon beside the insert of concern. Ensure that the inserts are connected to the shoe pod and that the connection codes are entered correctly. If problems persist, contact Orpyx Customer Care Representatives.

**Q:** Can my SurroSense Rx™ inserts be transferred to an alternate pair of shoes?

**A:** Once the SurroSense Rx™ inserts and shoe pods have been fitted to your shoes, it is possible to transfer them to another pair of shoes. Carefully unlace your shoelaces and release both of the shoe pods. If using the shoe pod clip, simply feed the Velcro strap through the clip to release the shoe pods. The shoe pods and inserts should stay connected throughout the transfer process. If they disconnect, plug the connector back into the shoe pod. Then, place the inserts 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.

## 9.0 Regulatory Compliance Information

### FCC COMPLIANCE STATEMENT

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 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.

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.

## CANADIAN COMPLIANCE STATEMENT

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.

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.

## INDUSTRY CANADA STATEMENT

Complies with the Canada ICES-003 Class B specifications. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada. This device complies with RSS 210 of Industry Canada.

## EUROPEAN COMMUNITY

This device complies with the R&TTE Directive. A copy of the EU Declaration of Conformity is available online at:



## SOFTWARE LICENSE AGREEMENT

A copy of the Orpyx Software License Agreement is available online at:

## 10.0 Technical Information and Specifications

### RADIO FREQUENCY STANDARDS

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, EU 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™ device, please note that the product uses wireless communication, and is not to be used during flight. We recommend that you disconnect your inserts from the shoe pods when traveling. This will ensure your device is in not in transmitting mode. 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 RF 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 RF emissions. Disconnect your inserts from shoe pods to ensure they are not transmitting 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 RF emissions of this device. Please consult the manufacturers of these devices to ensure compatibility with the SurroSense Rx™.

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

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