ORPYX®

HUMAN PERCEPTION REDEFINED

Orpyx® SI
Sensory Insoles

Instructions for Use
Important information enclosed. Do not discard.
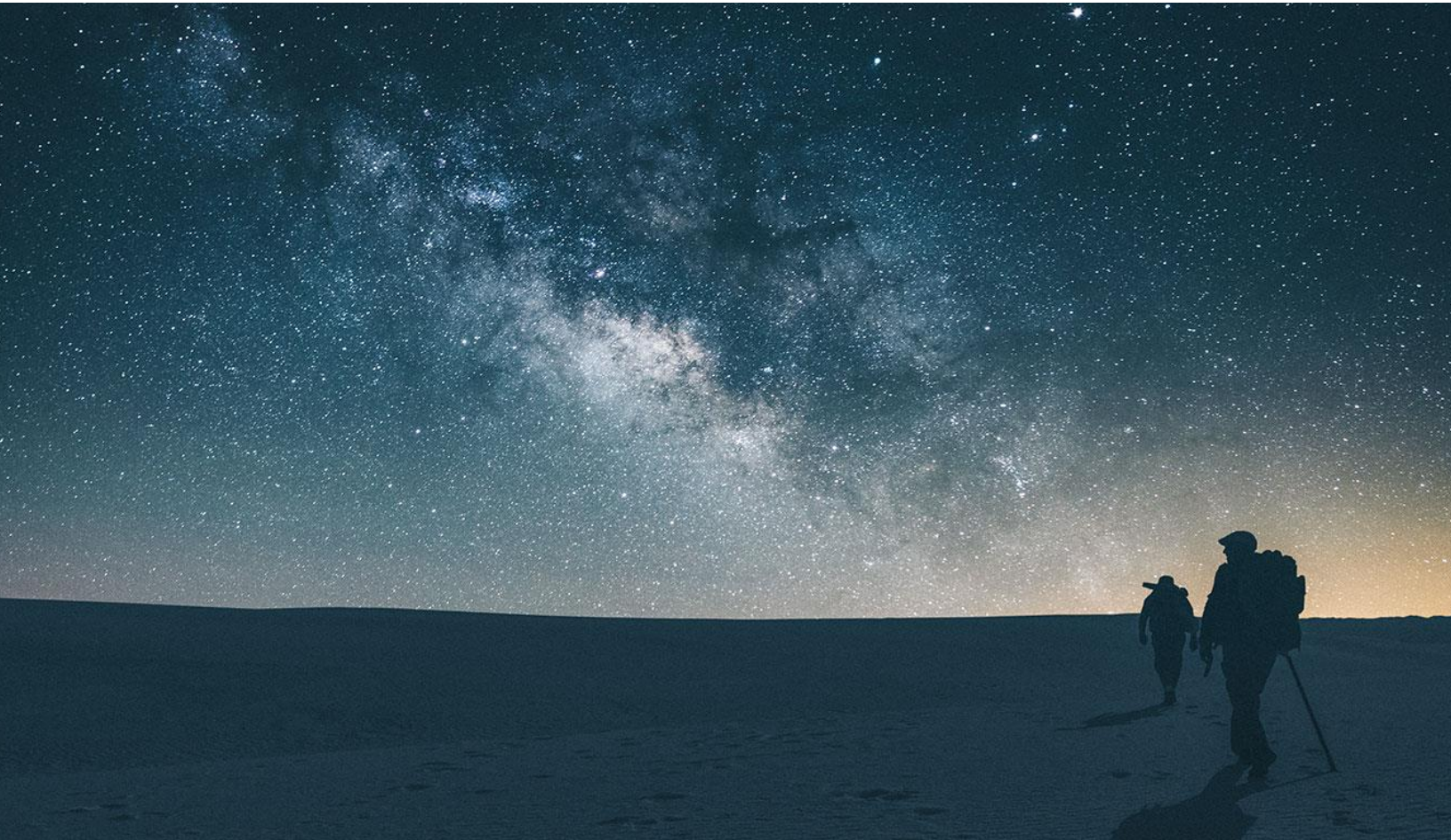
Manufactured by:
Orpyx® Medical Technologies Inc.
Bay 2, 1440 – 28 Street N.E.
Calgary, AB T2A 7W6 Canada
www.orpyx.com

Orpyx Customer Care
Toll Free: 1-855-99ORPYX (67799)
Email: support@orpyx.com

A manual in French can be provided on request at support@orpyx.com.
Un mode d'emploi en Français peut être fourni sur demande à support@orpyx.com.

A manual in Spanish can be provided on request at support@orpyx.com.
Contáctenos por support@orpyx.com si requiere un manual en español.

Orpyx® SI
Table of Contents

Symbols and Definitions

Symbol	Definition
⚠	Caution
SN	Serial Number
LOT	System Lot Number
⚙	Year of Manufacture
⬛	Manufactured By
☂	Keep Dry
⬚	Waste Electrical & Electronic Equipment
立	TYPE BF Applied Part
📖	Manual Must Be Read
IP22	IP Rating

1. Orpyx® SI Sensory Insoles

The Orpyx® SI sensory insole system is designed to help patients at risk of foot ulceration. The system consists of pressure sensors integrated into custom fabricated shoe insoles which wirelessly communicate with a display application running on a smartphone or companion device. In addition to pressure, the device monitors plantar foot temperature and movement. Sensor data is collected by the device and sent to the cloud for remote monitoring purposes.

INCLUDED IN PURCHASE:
- Orpyx® SI Sensory Insoles (Left and Right)
- USB Cable
- Instructions for Use Manual
- Power Adapter
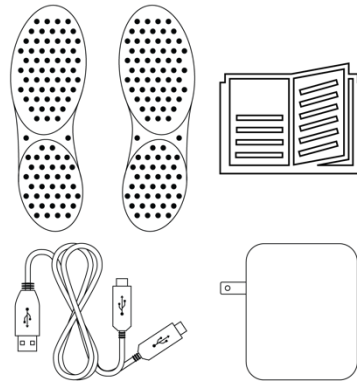
A. INDICATIONS & INTENDED USE
Orpyx SI Sensory Insoles are custom insoles embedded with powered limb overload warning technology intended for monitoring physiologic parameters, including plantar pressure, tracking movements and temperature. It provides the user with real-time, individualized cues for pressure offloading. It is intended to act as an adjunct to standard foot care, not a replacement.

Orpyx SI sensory insoles are designed for use throughout everyday activities.

When using Orpyx SI sensory insoles with an active foot ulcer, please notify your healthcare professional.

⚠ **The custom insoles are made specific to an individual's foot and are not transferable to another user.**

⚠ **Use of Orpyx SI sensory insoles does not eliminate the need for regular diabetic foot care as advised by a healthcare professional.**

⚠ **Users should continue to consult their healthcare provider in addition to checking feet daily and wearing proper footwear. In the event there is any evidence of tissue breakdown, consult your healthcare provider immediately.**

B. CONTRAINDICATIONS
There are no known contraindications for the Orpyx SI sensory insoles at this time.

2. Orpyx® SI Mobile Application

STEP 1

DOWNLOADING THE MOBILE APPLICATION

The Orpyx SI mobile application is free and compatible with an iPhone 6 or newer and with devices operating iOS 10.1 or newer. You can find the Orpyx SI mobile application by typing "Orpyx SI" in the search bar on the App Store for iOS.

Download and install the mobile application and enable Bluetooth on your smartphone (this can be done in the device settings).
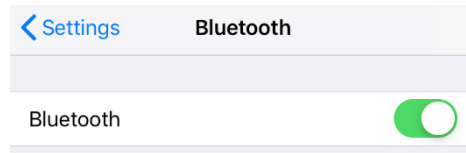
STEP 2

CREATE AN ORPYX SI ACCOUNT

Click on the Orpyx SI icon to launch the Orpyx SI mobile application.

Click the "Sign Up" button on the Login page.

Enter your email address and click the "Send Verification Code" button. If you do not already have an email address, you will need to setup one.

A verification code will be sent to your email. Enter in the verification code to verify your account. This step helps us confirm your identity and secure your account.
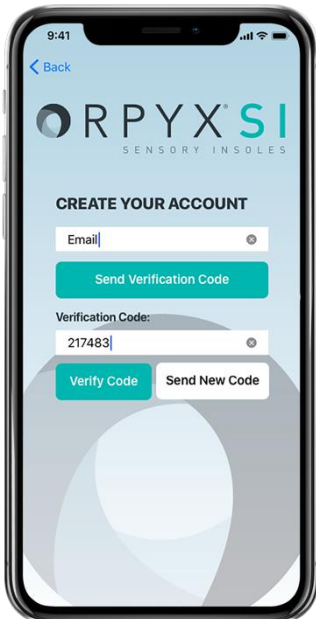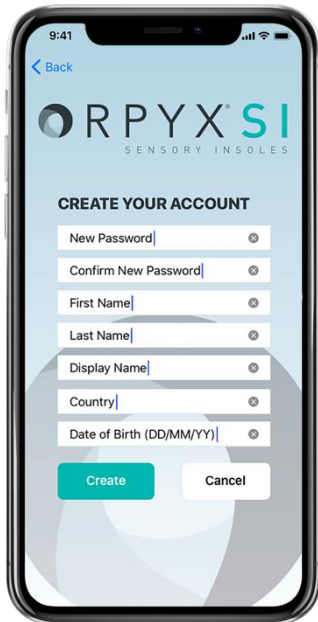
STEP 3

Complete the creation of your account by entering your New Password, Confirm New Password, First Name, Last Name, Display Name. For security purposes, your password requires:

- minimum 8 characters
- maximum 16 characters in length
- include 3 of 4 character classes:
  - o uppercase letter
  - o lowercase letter
  - o number
  - o symbol
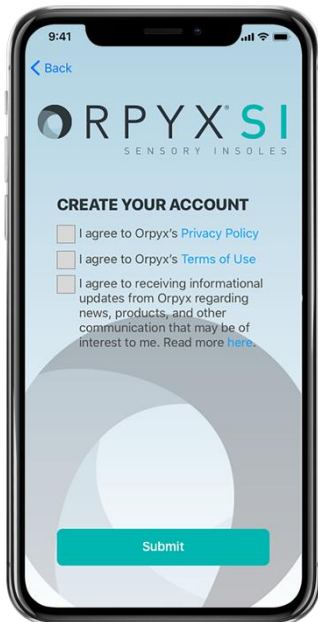
STEP 4

Review and agree to Orpyx's Privacy Policy and Terms of Use. Click submit.

You have now signed in successfully. The mobile application will walk you through the Setup and Tutorial.

STEP 5

Fully charge your insoles prior to wearing. For detailed information on how to charge your insoles, please refer to section 3 in the Instructions for Use Manual or press "Care" on your mobile application for "How to Charge your Sensory Insoles".

STEP 6

PAIRING YOUR INSOLES TO THE MOBILE APPLICATION

To start using your system, you will need to pair your Orpyx SI sensory insoles with the mobile application.

Plug in your insoles and connect to a power source. Please refer to section 3 in the Instructions for Use Manual or press "Care" on your mobile application for "How to Charge your Sensory Insoles". If they are already connected to power, unplug and re-plug your insoles.

STEP 7
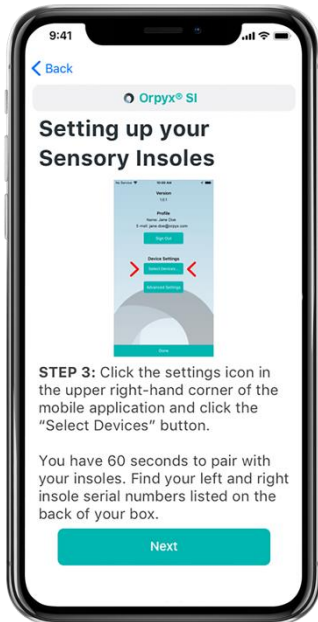
Click the settings icon in the upper right-hand corner of the mobile application and click the "Select Devices" button.

You have 60 seconds to pair with your insoles. Find your left and right insole serial numbers listed on the back of your box (see image below).
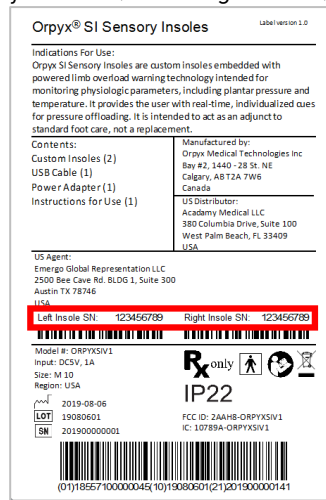
STEP 8

When you plug in your insoles, two grey footprints will appear and their corresponding serial numbers. Select the left and right insoles by tapping on the footprint icons (once selected they will turn blue). Click the "Done" button on the bottom.

Your device will timeout after 60 seconds if not selected.*

If pairing is unsuccessful, please repeat steps 6 to 8.

STEP 9

You have successfully paired your system and will be automatically directed to the My Feet screen.

⚠️ **To receive alerts, ensure that your mobile device is within 1m of your person, and placed in a location where you can hear, feel or see the alert indications on the device.**

3. Charging Your Orpyx® SI Sensory Insoles

With regular use, the insoles will require daily charging, therefore it is recommended they are charged overnight. For detailed information on how to charge your insoles, press "Care" for How to Charge your Sensory Insoles.
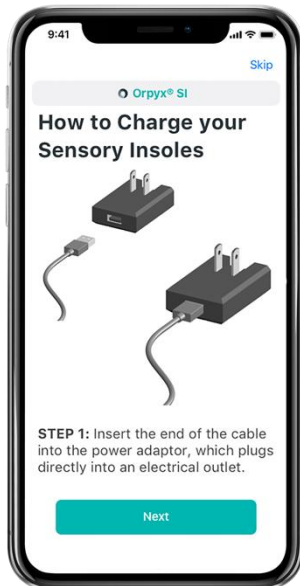
STEP 1

Insert the other end of the cable into the power adaptor, which plugs directly into an electrical outlet.

STEP 2

Align the magnetic USB cable with the USB port on the back of the insoles. Your mobile application displays the battery levels when your insoles are charging.

When plugged in to the wall adapter, a blue light will appear on the USB indicating a powered connection.
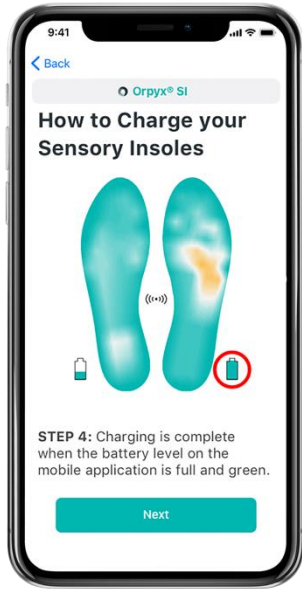
STEP 3

Charging is complete when the battery level on the mobile application is full and green.

⚠ **Do not wear your device when it is charging.**
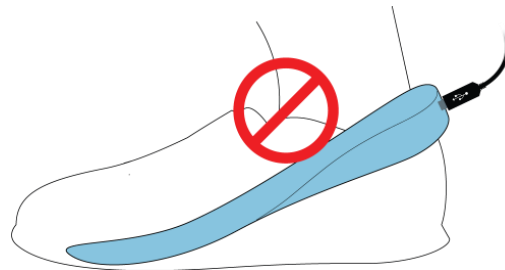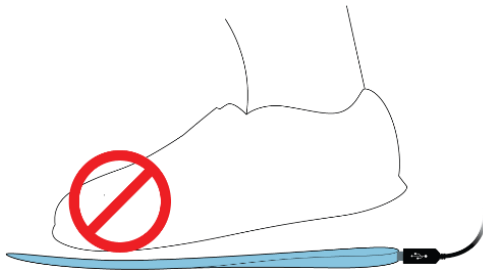
4. Using Your Orpyx® SI Sensory Insoles System

A. STARTING YOUR ORPYX SI SENSORY INSOLE SYSTEM

STEP 1
Start the Mobile Application on your smartphone by clicking the Orpyx SI icon.

STEP 2
Your Orpyx SI sensory insoles are made to fit inside your diabetic or walking shoes. First, remove the existing insole or sock liner from your shoes. With standard shoes, the sock liners may need to be removed.

Orpyx SI Sensor Insoles may come in contact with a patient during normal use. It is recommended the user wears sock with their Orpyx SI Sensor Insoles
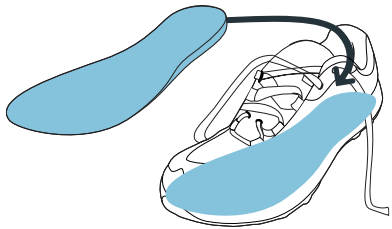
⚠ **Failure to remove an existing insole or sock liner from your shoe before inserting the Orpyx SI sensory insole may result in a persistent high pressure state.**

Place the appropriate left and right Orpyx SI sensory insoles into each shoe and run your hand over the entire insole to ensure that the insole is lying flat. It is recommended that you wear your insole system with the shoes that have been fitted by a professional.

⚠ **Do not modify the Orpyx SI Sensory Insole, if required a professional orthotist or podiatrist can modify insole outside the indicated margin to ensure proper fit.**

When the insoles have been stored at a temperature below 5C, or above 40C, please allow 30 minutes for the insoles to acclimate before using the system.

STEP 3
To start using your system, put on your shoes and apply pressure by standing and walking. This will "wake up" the system and re-establish a wireless connection to your mobile application.

If your device is not connected, ensure that your device is fully charged and pair your device. Please refer to section 2 in the Instructions for Use Manual or press "Care" on your mobile application for "Setting up your Sensory Insoles".

B. SETTINGS
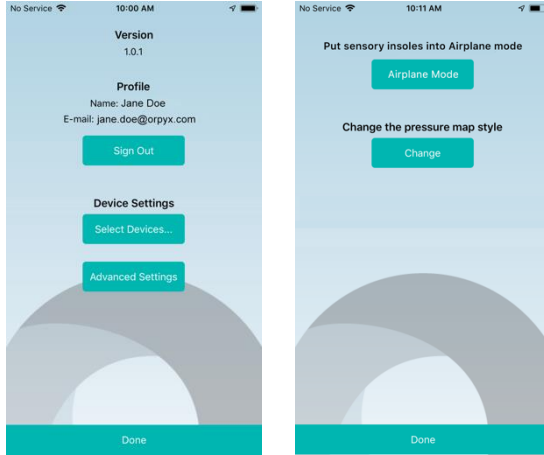
Within your Advanced Settings, you have the ability to put your connected insoles in Airplane Mode..*

*You will not receive alerts when the system is put into airplane mode.

To disable airplane mode, insert the magnetic USB cable with the USB port on the back of the insoles. Insert the other end of the cable into the power adaptor, which plugs directly into an electrical outlet. Your mobile application will alert you when your insoles are charging meaning you are now ready to use your system.

In Settings, you have the ability to Change the "My Feet" Pressure Map style to Pins or Topographic Map (see images below).

PINS
Without Pressure   With Pressure

TOPOGRAPHIC MAP
Without Pressure   With Pressure

C. RECEIVING AN ALERT
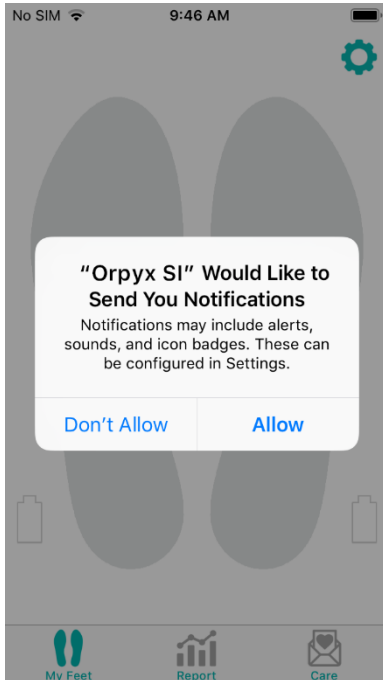
Ensure that your mobile device's settings allow notifications to be sent by the Orpyx SI mobile application. You can check this by going into your mobile device. On iOS go to Settings, Notifications, and select Orpyx SI. Turn on Allow Notifications, Sounds and Badges.

⚠️ If notifications are turned off, you may not receive high pressure alerts from your system. It is recommended to turn notifications on in order to receive system alerts.

⚠️ To receive alerts, ensure that your mobile device is within 1m of your person, and placed in a location where you can hear, feel or see the alert indications on the device.

ORPYX SI
SENSORY INSOLES

TYPES OF ALERTS:

High Pressure Detected Notification

⬤ ORPYX® SI

HIGH PRESSURE - LEFT FOOT
Offload pressure as soon as possible. For guidance on how to offload pressure, click 'Care'.

⬤ ORPYX® SI

HIGH PRESSURE - RIGHT FOOT
Offload pressure as soon as possible. For guidance on how to offload pressure, click 'Care'.

This alert indicates that high pressure and time levels have been detected underfoot. When this screen is displayed, you can click on the notification which will take you to the foot map screen. For guidance on how to offload pressure, click "Care" in the lower right-hand corner of the mobile application.

If the user does not offload pressure effectively, the alert will be re-issued every three minutes until the alert is offloaded successfully.

Insoles Disconnected Notification

⬤ ORPYX® SI

LEFT INSOLE DISCONNECTED
Check mobile device settings, device proximity, and battery levels.

⬤ ORPYX® SI

RIGHT INSOLE DISCONNECTED
Check mobile device settings, device proximity, and battery levels.

If an insole becomes disconnected from the mobile application, the application will notify you.

When putting on your insoles, apply pressure by standing and walking. This will "wake up" the system and re-establish a wireless connection.

Double check that you are within range of your phone and that the insoles are fully charged. You will also receive an alert if Bluetooth is turned off.

If the mobile application still does not connect to your phone, please contact Orpyx Customer Care.

D. PRESSURE OFFLOADING STEPS

When areas of high pressure are detected, they will be displayed on the My Feet screen. To relieve pressure, follow the steps below until the high-pressure area goes away.

STEP ACTION

1. Walk around (or on the spot) until the red region has gone away.

2. If that is ineffective after two minutes, sit down and take pressure off red region of the foot.

3. If that is ineffective after two minutes, ensure that footwear laces are not too tight and that there are no foreign objects (i.e. rocks) in the shoe.

4. If that is ineffective after two minutes, check your feet for cuts, blisters, redness and swelling.

5. If none of these steps above prove effective after several attempts or approximately 15 minutes, please contact Orpyx Customer Care for resolving the alerts.

E. CONTACTING ORPYX CUSTOMER CARE
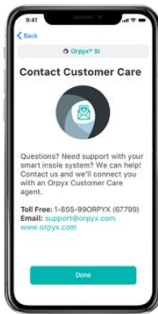
If you have any additional questions, concerns , require assistance setting up and maintaining your device, or have encountered an unexpected operation or event, please contact Orpyx Customer Care by clicking the Care button on your application or via the following:
Toll Free: 1-855-99ORPYX (67799)
Address: 1440 – 28 Street N.E., Calgary, Alberta Canada T2A 7W6
Email: support@orpyx.com
www.orpyx.com

5. Maintenance & Cleaning

A. ORPYX® SI MAINTENANCE
This system requires daily charging; therefore, it is recommended that the insoles are charged overnight. For additional guidance on how to charge your system, please refer to section 2 in the Instructions for Use Manual or press "Care" on your mobile application for "How to Charge your Sensory Insoles".

⚠ **To clean Orpyx SI sensory insoles, gently wipe with a damp cloth, or disinfectant wipe as needed or on a monthly basis.**

B. ORPYX® SI SENSORY INSOLES REPLACEMENT
Your insoles will need to be replaced after every 12 months or at your healthcare practitioner's discretion (which could be up to 3 times per year).

C. ORPYX® SI SENSORY INSOLES ACCESSORIES
The accessories provided along with the insoles such as the charging cable and the power adapter are expected to last 100K hours of use.

D. DISPOSAL OF THE DEVICE
There are no user repairable components in Orpyx SI sensory insoles. The system contains batteries and electronics, please dispose of properly in accordance with all local and national regulations.

6. Storage and Handling

ORPYX® SI SENSORY INSOLES SYSTEM HANDLING

☂ Keep dry.

⚠ **DO NOT cut, trim or alter Orpyx SI sensory insoles, this could damage sensors and prevent the device from working properly.**

For environmental storage conditions, please refer to the Technical Specifications table on page 21.

7. Frequently Asked Questions

Q: How long does it take to offload an alert?
A: The time to offload an alert depends on the length of time that alert has been present. With proper offloading, alerts can be offloaded within three minutes.

Q: How do I turn the system off when not in use?
A: If pressure is not detected on the insoles for a period of time, they will go into sleep mode automatically. Your insoles can also be put in airplane mode within your settings.

Q: How do I turn the system on?
A: When pressure is detected and a step is taken, the system will automatically turn on and connect to the mobile application provided the app is running and within range of the system.

Q: When should I replace my sensory insoles?
A: To ensure accurate readings, the sensory insoles will need to be replaced after every 12 months or at your healthcare practitioner's discretion (which could be up to 3 times per year).

Q: Why is my system alerting when my feet are up?
A: Ensure that both feet are up without resting on your heels or toes and check to see if your shoes are tied too tight.

Q: Can my insoles get wet? What happens when it gets wet?
A: Do not submerge. To clean Orpyx SI sensory insoles, gently wipe with a damp cloth, or disinfectant wipe. If they do get slightly wet, remove them from the shoes and allow to dry thoroughly before use. If submerged, the insoles may stop functioning properly.

Q: Can I take my sensory insoles system through airport security?
A: Yes. While wearing your device in flight, ensure that it is set to Airplane Mode within your settings.

Q: How often should I wear my insoles?
A: It is recommended that you wear your insoles throughout daily activities, unless told otherwise by your healthcare professional.

8. Technical Information, Specifications and Warranty

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 Orpyx® SI sensory insoles 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 Orpyx® SI sensory insoles may cause interference in other electronic equipment. Therefore, please take the following precautions:

Travel or International Use

If you plan to travel with the Orpyx® SI sensory insoles, please note that the product uses wireless communication, and is not to be used 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 6 inches (15 cm) be maintained between certain RF emitting devices and pacemakers in order to avoid potential interference between these devices. Persons with pacemakers should always keep the Orpyx® SI sensory insoles at least 6 inches (15 cm) from the pacemaker when the device is active.

Hearing Aid Compatibility

The Orpyx® SI sensory insoles 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 Orpyx® SI sensory insoles.

Health Care Facilities

Hospitals and healthcare facilities may use equipment that is particularly sensitive to external RF emissions. Disconnect your system to ensure it is not transmitting when hospital staff or signage instructs you to do so.

Other Wireless Technologies

The Orpyx® SI sensory insoles system 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 Orpyx® SI sensory insoles.

TECHNICAL SPECIFICATIONS FOR ORPYX® SI ELECTRONIC COMPONENTS	
Model	ORPYXSIV1
Power Source	2x80 mAh Rechargeable LiPo battery Non Replaceable
Operating Voltage	3.7-4.2Vdc
Rated Input Voltage	5Vdc
Rated Input Current	2.4A
Frequency Band	ISM 2.4 Ghz, 2400 to 2483.5 MHz
Wireless Technology	Frequency Hopping Spread Spectrum
Number of Operation Modes	4 – On / Sleep / Charging / Airplane
Storage Conditions	Temperate 0-40C / Humidity 15%-90% (non-condensing) / 700-1060 hPA
Operational Conditions	Temperature 5-40C / Humidity 15%-90% (non-condensing) / 700-1060 hPA
IP Rating	IP22

REQUIRED TECHNICAL SPECIFICATIONS WALL ADAPTER	
Model	HDP-MD Series
Rated Input	100-240Vac, ~50/60Hz, 0.3A
Rated Output	5Vdc 1A/2.4A
Certifications	60601-1/60601-1-2

WARRANTY

Orpyx Medical Technologies Inc. guarantees that Orpyx SI sensory insoles will be free of defects in material and workmanship for one year, valid from the date of purchase. Warranty is void if the system has been damaged due to water, improper treatment or use. Normal wear will occur overtime.

The warranty extends only to the original purchaser and is not transferable.

⚠ **Disregarding WARNING information may cause improper operation, inaccurate results and may void the warranty.**

⚠ **Disregarding information for proper use may reduce the life expectancy of the product and/or damage the product; and may void the warranty.**

9. Regulatory Compliance Information

FCC COMPLIANCE STATEMENT

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.

CAUTION: 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.

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.

CANADIAN COMPLIANCE STATEMENT

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique 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;
2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

INNOVATION, SCIENCE AND ECONOMIC DEVELOPMENT CANADA STATEMENT

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

OTHER STANDARDS AND COMPLIANCE

The Orpyx® SI sensory insoles system is in compliance with the following standards:
IEC 60601-1-2:2013: Medical Electrical Equipment – Part 1: General Requirements for Safety IEC 60601-1

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Version 1.0 – August 2019