ORPYX®

Instructions for Use
Orpyx® Custom Sensory Insoles

Hub   Sensory Insoles   App

Important information enclosed.
Do not discard.

Indications and Intended Use

The Orpyx Custom Sensory Insole system consists of a powered limb overload warning technology to provide real time notifications for pressure offloading. For wellness purposes, the system also includes temperature sensors to monitor physiological parameters such as plantar foot skin temperature and motion sensors to measure activity. The Orpyx Custom Sensory Insole is fabricated from a foot impression.

The Orpyx Custom Sensory Insole system is intended to act as an adjunct to standard foot care, not a replacement. It is designed for use throughout everyday activities.

Contraindications

There are no known contraindications for the Orpyx Custom Sensory Insole system.

Warnings

Orpyx Custom Sensory Insoles

- If there is any evidence of tissue breakdown on your feet, consult your healthcare professional immediately.

- Do not use the Orpyx Custom Sensory Insole system if the insoles or accessories show visible damage, wear, or contamination (e.g., exposure to bodily fluids, dirt, or harsh chemicals). Continued use may cause injury.

- Wear the Orpyx Custom Sensory Insoles with socks to reduce the risk of contact injuries due to friction or allergic reactions/sensitivities.

Warnings (cont.)

Orpyx Custom Sensory Insoles (cont.)

- If you experience unexpected behavior or observe any damage due to shipping or use, immediately discontinue use as a precaution and contact Orpyx for guidance. Continued use may cause injury. Do not attempt to open or modify any components to resolve the issue.

- The Orpyx Custom Sensory Insole system is not rated for use in areas with a high concentration of flammable gases, vapors, or dust, as there is a risk of ignition.

- The Orpyx Custom Sensory Insole system does not replace routine foot care. Regular self-examination, proper footwear, and periodic check-ups by a healthcare provider are essential to maintaining foot health.

- The Orpyx Custom Sensory Insole system does not diagnose any specific disease state. It should be used under the direction of a healthcare professional and prompts communication between a patient and healthcare professional between scheduled and/or routine foot examinations.

Orpyx Hub

- Before plugging in your Orpyx Hub, verify that the input voltage on the back of the Orpyx Hub matches the voltage of your power outlet. Using an incorrect voltage may result in equipment damage or electrical hazards.

- Do not open or modify the Orpyx Hub. Doing so may expose you to risks of electrical shock, malfunction, or fire.

Cautions

Orpyx Custom Sensory Insoles

- Orpyx Custom Sensory Insoles are prescription use only. They are not intended for use by another user.

- Improper use of the Orpyx Custom Sensory Insoles (e.g., incorrect sizing or wearing without socks) may lead to foot complications, including blisters or skin breakdown. Always follow the fitting instructions provided by a healthcare professional.

- Failure to remove an existing insole or sock liner from your shoe before inserting the Orpyx Custom Sensory Insoles may impact system performance or cause potential foot complications resulting from improper shoe/insole fit.

- If the Orpyx Custom Sensory Insoles have been transported or stored in a hot or cool location, allow the components to acclimate to room temperature for at least one hour prior to use.

- To clean the Orpyx Custom Sensory Insoles, follow the cleaning instructions provided by Orpyx in this manual. Do not submerge in water or use harsh chemicals.

- No modifications to any component of the Orpyx Custom Sensory Insole system are permitted, except by a qualified healthcare professional to ensure proper fit and functionality.

- Safety is a priority. Do not interact with the Orpyx App or insoles while performing activities that could distract you, such as driving, or when it is unsafe to do so.

Cautions (cont.)

Orpyx Custom Sensory Insoles (cont.)

- Do not submerge your Orpyx Custom Sensory Insoles in water. Do not place your insoles in a location where they are likely to get wet (e.g., by a sink, shower, or nebulizer).

- Do not expose the Orpyx Custom Sensory Insoles to direct sunlight, high temperatures, or heat sources (e.g., dryers, vents, space heaters, fireplaces), as this could damage the components.

- Keep your Orpyx Custom Sensory Insoles away from pets, as they contain a coin cell battery that may pose a chemical, burn, or choking hazard if chewed or swallowed.

Orpyx Hub

- The Orpyx Hub should only be used indoors in dry, climate-controlled environments. Exposure to extreme environmental conditions may affect its performance or lead to device damage.

- If the Orpyx Hub has been transported or stored in a hot or cold location, allow the components to acclimate to room temperature for at least one hour prior to use.

- Keep your Orpyx Hub dry at all times. Do not submerge the Hub in water or expose it to moisture (e.g., near sinks, showers, or nebulizers), as moisture exposure may damage the device or cause electrical malfunction.

Cautions (cont.)

Orpyx Hub (cont.)

- Only plug in your Orpyx Hub with dry hands.

- Do not place the Orpyx Hub near heat sources such as vents, space heaters, or fireplaces, as excessive heat may damage internal components.

- Avoid using the Orpyx Hub in extreme temperatures or high humidity environments, as these conditions may cause malfunction or reduce the lifespan of the device.

- Do not place objects on top of or cover the Orpyx Hub, as this may obstruct airflow, leading to overheating or device damage.

- Keep your Orpyx Hub away from children and pets. The Hub contains small parts, such as the button, which may present a choking hazard if dislodged and swallowed.

- Regularly inspect your Orpyx Hub for signs of dust or debris buildup. Before cleaning, ensure the device is unplugged. Follow the cleaning instructions provided by Orpyx in this manual to maintain optimal functionality.

Symbols and Definitions

🏭	**Manufacturer** Indicates the device manufacturer *ISO 15223-1 5.1.1*
〰️	**Date of manufacture** Indicates the date when the device was manufactured *ISO 15223-1 5.1.3*
REF	**Catalogue number** Indicates the manufacturer's catalogue number so that the device can be identified *ISO 15223-1 5.1.6*
SN	**Serial number** Indicates the manufacturer's serial number so that a specific device can be identified *ISO 15223-1 5.1.7*
📦	**Distributor** Indicates the entity distributing the device into the locale *ISO 15223-1 5.1.9*
#	**Model number** Indicates the model number or type number of a product *ISO 15223-1 5.1.10*

Symbols and Definitions (cont.)

☔	**Keep dry** Indicates a device that needs to be protected from moisture *ISO 15223-1 5.3.4*
🌡	**Temperature limit** Indicates the temperature limits to which the device can be safely exposed *ISO 15223-1 5.3.7*
🌢	**Humidity limitation** Indicates the range of humidity to which the device can be safely exposed *ISO 15223-1 5.3.8*
⊙	**Atmospheric pressure limitation** Indicates the range of atmospheric pressure to which the device can be safely exposed *ISO 15223-1 5.3.9*
🗍	**Type BF applied part** Identifies an electrically isolated part that touches the patient (but does not have a direct electrical connection to the heart) and provides a higher degree of protection against electric shock than Type B parts as per IEC 60601-1. Type BF Applied Parts are not suitable for direct cardiac application. *IEC 60417-5333*
∿	**Alternating current** Identifies equipment that is suitable for alternating current only. *IEC 60417-5032*

Symbols and Definitions (cont.)

▢	**CLASS II equipment** Identifies equipment meeting the safety requirements specified for Class II equipment *IEC 60417-5172*
IPX0	**Ingress Protection Rating IPX0** Identifies a device with no protection against vertically falling water drops. Keep dry. *IEC 60529:2013*
⌂	**For indoor use only** Identifies electrical equipment designed for indoor use *IEC 60417-5957*
IP22	**Ingress Protection Rating IP22** Identifies a device that is protected against the entry of objects greater than 12 mm in diameter (about the size of an adult finger) and protected from water spray at an angle of 15 degrees from vertical. *IEC 60529:2013*
📖	**Consult instructions for use** Indicates the need for the user to consult the instructions for use *ISO 15223-1 5.4.3*
⚠	**Caution** Indicates that caution is necessary when operating the device or that the current situation needs operator awareness or operator action to avoid undesirable consequences *ISO 15223-1 5.4.4*

Symbols and Definitions (cont.)

UDI	**Unique device identifier** Indicates a carrier that contains unique device identifier information. (01) Device Identifier (21) Device Serial Number *ISO 15223-1 5.7.10*
	No natural rubber latex Indicates there is no presence of dry natural rubber or natural rubber latex as a material of construction within the device or the packaging of a device *ISO 15223-1 5.4.5*
℞ only	**Prescription use only** Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed medical practitioner. *21 CFR 801.109 Labeling, Prescription Devices*
	Do not dispose of device in trash Dispose of the product and packaging in accordance with your local regulations. *IEC 60417-6414*

The *Symbols and Definitions* table references the following standards:

- ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

- IEC 60417:2025 Graphical Symbols for Use on Equipment

- IEC 60529:2013 Degrees of protection provided by enclosures (IP Code)

Product Info

The Orpyx Custom Sensory Insole system is designed to help patients at risk of foot complications. The system includes Orpyx Custom Sensory Insoles, the Orpyx App (downloadable for your smartphone), and the Orpyx Hub for uploading data to the cloud to enable remote patient monitoring (RPM) by your healthcare professional team.

Your Orpyx Custom Sensory Insoles are embedded with powered limb overload warning technology that monitors plantar pressure, plantar temperature, step count, and usage. Your Orpyx Custom Sensory Insoles replace your regular insoles in your shoes.

Using the Orpyx App on your personal smartphone (iOS and Android), you can view real-time pressure, real-time notifications for pressure offloading, and report summaries about your daily, weekly, and monthly activity.

Your Orpyx Hub is an information gateway that plugs into a power outlet in your home. When you walk by or store your insoles near your Orpyx Hub, it automatically connects to your insoles and sends your insole data to the cloud for remote monitoring by your healthcare professional team.

Product Info (cont.)

As a patient, you are the intended operator of the Orpyx Custom Sensory Insole system. No special skills, training, or knowledge are required to use this product. You can use all functions of the sensory insoles, Orpyx App, and Orpyx Hub. You are not expected to carry out any service or maintenance except periodic inspection and cleaning as described in these instructions for use.

The Orpyx Starter Kit Includes:

• Orpyx Custom Sensory Insoles

• Orpyx Hub

• Orpyx App

• Getting Started Guide

• Instructions for Use

• Terms of Use and Privacy Policy

• Medical Documentation Card

The Orpyx Refill Kit Includes:

• Orpyx Custom Sensory Insoles

• Pairing your Insoles Guide

• Instructions for Use

1. Plug in the Orpyx Hub

Orpyx Hub automatically transfers the data generated by your insoles to your Orpyx Nurse.

2. Put Your Orpyx Insoles Into Your Shoes

Replace the insoles already in your shoes with your new Orpyx Custom Sensory Insoles. For more information, please refer to Section 3 - Set Up.

3. Download the Orpyx App

The Orpyx App allows you to receive real-time pressure notifications and view your activity reports.

Scan either the iOS or Android QR code to download the app or visit orpyx.com/orpyxapp.

App Store for iPhone

Google Play for Android

4. Call Orpyx Customer Care

To complete the onboarding process, call Orpyx Customer Care at **+1 (855) 996-7799**

Insole Placement and Recommendations

It is recommended that the Orpyx insoles are worn in diabetic shoes that are properly sized and fitted by your healthcare provider.

Remove the existing insole or sock liner from your shoes. Place the left and right Orpyx insoles into the appropriate shoe and run your hand over the entire insole to ensure that the insole is lying flat.
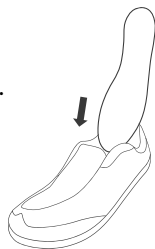
⚠ Wear the Orpyx insoles with socks to reduce the risk of contact injuries due to friction or allergic reactions/sensitivities.

If the Orpyx insoles have been transported or stored in a hot or cool location, allow the components of the insoles to acclimate to room temperature for at least one hour prior to use.

Failure to remove an existing insole or sock liner from your shoe before inserting the Orpyx insoles may impact system performance or cause potential foot complications resulting from improper shoe/insole fit.

No modifications to any component of the Orpyx Custom Sensory Insole system are permitted, except by a qualified healthcare professional to ensure proper fit and functionality.

Orpyx Hub

Plug the Orpyx Hub into a power outlet in an open area close to where you store your shoes with the Orpyx insoles. The Orpyx Hub will automatically connect to your insoles, allowing your healthcare team to monitor your data and contact you about your foot health.

The Orpyx Hub should remain plugged in for the system to operate successfully.

If you consistently see an amber light when you check the status of the Orpyx Hub, please reach out to Orpyx Customer Care or mention it to your Orpyx Nurse so they can confirm your Orpyx Hub is working correctly.

When traveling in North America, take your Orpyx Hub with you to continue transmitting data to the Orpyx Nursing team (unless otherwise noted by your healthcare team).

Orpyx Hub Interface

Nightlight

Orpyx logo button

Left insole connection

Right insole connection

Cellular connection

Bluetooth® connection
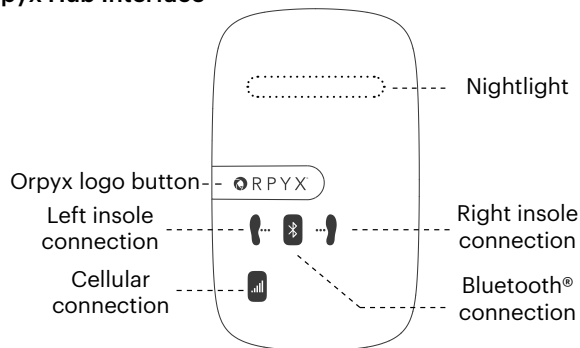
Orpyx Hub interface: Start-up

Light	Status	Meaning
Nightlight	On - Medium brightness (default)	Orpyx Hub has power
Bluetooth connection	Solid blue	Bluetooth is working
	Solid amber	Bluetooth is not working
Left insole connection	Blinking blue	Searching for left insole
	Solid blue	Connected to left insole
	Solid amber	No left insole connection
Right insole connection	Blinking blue	Searching for right insole
	Solid blue	Connected to right insole
	Solid amber	No right insole connection
Cellular connection	Blinking blue	Searching for cellular
	Solid blue	Connected to cellular
	Solid amber	No cellular network detected

All icons turn off within 10 minutes of plugging the Orpyx Hub into a power outlet.

If you consistently see an amber light when you check the status of the Orpyx Hub, please reach out to Orpyx Customer Care or mention it to your Orpyx Nurse so they can confirm Orpyx Hub is working correctly.

Orpyx Hub Interface

Press the Orpyx logo button to adjust the brightness level of the nightlight, show the status of Orpyx Hub, and send diagnostic information to Orpyx.

When pressing the Orpyx logo button, you can do a *short press* (less than two seconds) or a *long press* (more than two seconds):

Short Press (Less Than Two Seconds):

• Change the brightness of the nightlight

  Medium (default) ⟳ High ⟳ Off ⟳ Low ⟳ Medium

• Show the last connection status of the Orpyx Hub within the last 24 hours

Long Press (More Than Two Seconds):

• Enter diagnostic mode by holding the button until the nightlight pulses

• Diagnostic mode shows the current connection status of the Orpyx Hub and sends a diagnostic report to Orpyx.

Contact Customer Care

Please contact the Orpyx Customer Care Team at **+1 (855) 996-7799.** They will help you set up your system and answer your questions. This 5-10 minute call provides important information to ensure you experience the full benefits of this program.

Please save the toll free numbers below in your cell phone contacts so you know when Orpyx is calling. We will only call you from one of these numbers.

Orpyx Customer Care
+1 (855) 996-7799

Orpyx Remote Nurse
+1 (833) 502-2171

If you are experiencing a medical emergency, immediately call your healthcare provider or call 911.

Orpyx® App

The Orpyx App allows you to track your foot health and receive pressure notifications in real-time. This is an important component of the Orpyx Custom Sensory Insole system to aid in decreasing the risk of diabetic foot ulcer formation and complications.

The app works with most Android and iPhone smartphones made since 2021. It requires operating systems Android 12 or newer and iOS 16 or newer.

If you have already downloaded the Orpyx App, please continue to the next page.

Scan the appropriate QR code with your smartphone camera to download the app.

App Store for iPhone

Google Play for Android

Terms and Conditions

Once downloaded, you are asked to agree to the terms and conditions of using the Orpyx Custom Sensory Insoles. Press *Accept* to continue.

Bluetooth® Wireless Technology

The Orpyx App collects and transmits health data from the insoles. The Orpyx App must ask permission to use Bluetooth technology on your phone.

Select *Allow* to enable the Orpyx App to find and connect to Bluetooth enabled devices nearby.

Enable Notifications

Select *Allow* to enable Orpyx to send you real-time pressure notifications.

Note: You can modify the notifications for the app from your phone's settings. If notifications are disabled or you do not allow the Orpyx App to send you notifications, you will not receive pressure notifications.
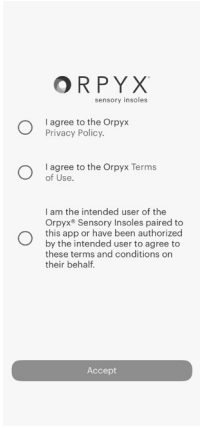
Pairing Your Sensory Insoles

To pair your insoles, enter the 8-digit serial number into the respective right and left insole serial number boxes.

The serial numbers are found on the inside lid of the box or the label on the bottom of each insole. Carefully enter both right and left serial numbers into the appropriate boxes. Press *Connect My Insoles* to continue.

Note: When you receive insole refills, you also need to pair them with the Orpyx App using the same method. Please dispose of your old insoles in accordance with your local guidelines.
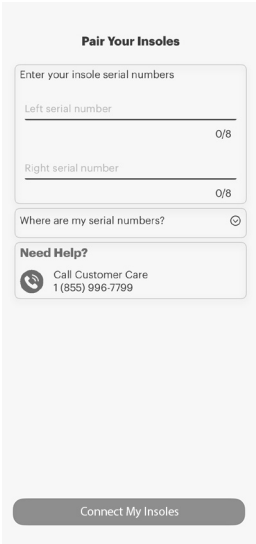
Wearing Your Insoles

Now that you have everything set up, the next step is to take your first steps in your new Orpyx insoles.

Real-Time Pressure Notifications

Too much pressure can lead to foot complications like calluses and wounds. The Orpyx App sends you a notification when sustained pressure is detected by the sensory insoles so you can take action and offload the pressure.
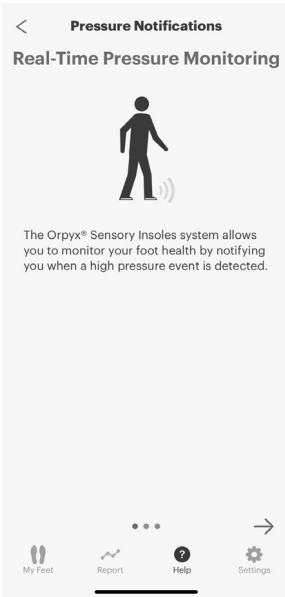
My Feet

There are four tabs at the bottom of the Orpyx App: *My Feet, Report, Help, and Settings*

The first is *My Feet*. This screen allows you to see the pressure your insoles are detecting. Blue areas indicate normal pressure, but red areas indicate high pressure that must be offloaded.

Report

The Report tab shows your activity, including insole activity collected while you were away from your phone. The report updates when your insoles connect to the Orpyx App and shows:

• The number of steps you've taken

• The hours you've used the insoles

• The percentage of time you've spent in an acceptable pressure state.

At the top of the screen, tap the tab to view your activity for the day, week, or month.
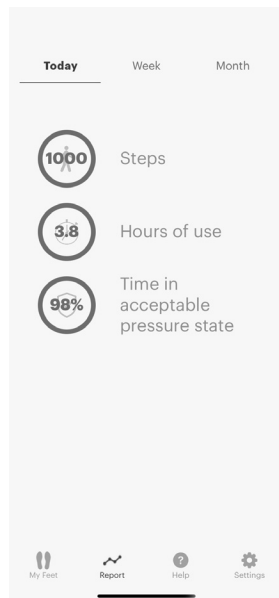
Help

The *Help* tab has links to call Orpyx Customer Care, which is available Monday-Friday from 9:00 am – 5:30 pm ET, except statutory holidays.
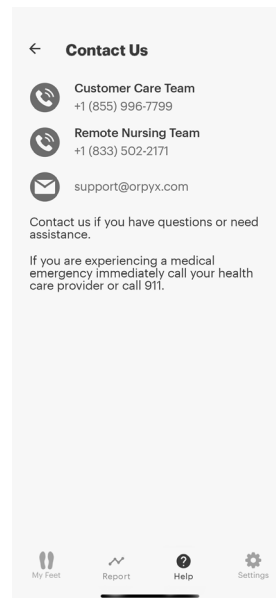
Settings

The *Settings* tab allows you to add or delete insoles. For instructions on how to pair your insoles, please see page 25 or consult the *Pairing Your Insoles* guide in your refill kit.

Note: Notifications for the Orpyx App are managed from your phone's settings.
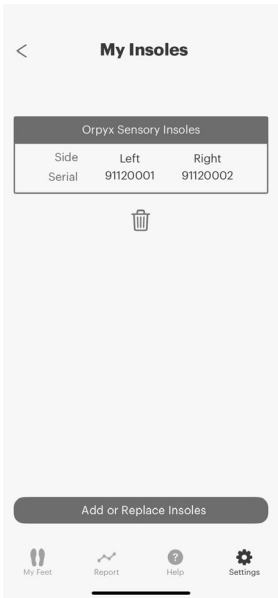
Pressure Notifications

High pressure notifications are generated when there is an area of sustained pressure detected under your foot.

The notification appears as a banner on your smartphone. Tap the notification to go to the *My Feet* screen. The area of high pressure is indicated in red.

When the area of pressure is successfully offloaded, the pressure notification clears within 30 seconds.

If the pressure notification is not cleared, an additional notification is sent every hour until it is cleared.

For additional guidance and detailed steps to offload pressure, tap *Help* at the bottom of the app.

⚠️ You may not receive notifications if your smartphone is set to silent, vibrate, or do not disturb.

Offloading Pressure Notifications ————————

Step 1: Walk Around

First, try walking around to see if the red area goes away on the *My Feet* screen.

Step 2: Sit Down

If the red area remains after two minutes, try sitting down to take the pressure off your feet.

Step 3: Inspect Your Shoes

If the red area is still there after another two minutes, make sure your laces are not too tight and that there are no foreign objects (ex: rocks) in your footwear.

Step 4: Inspect Your Feet

If a red area is still there after another two minutes, check your feet for cuts, blisters, redness or swelling.

Note: Pressure notifications may take up to 30 seconds to disappear.

If none of the above steps prove effective after several attempts, please contact Orpyx Customer Care.

Discontinuing Use ————————

Your Orpyx insoles are battery powered. Once you remove the insoles from their packaging, the Orpyx insoles are powered continuously until the battery is depleted. Remove the Orpyx insoles from your shoes to discontinue use.

Your Orpyx Hub is powered continuously by your power outlet. Unplug the Orpyx Hub to discontinue use.

Maintenance

The Orpyx insoles and Orpyx Hub contain no user repairable or replaceable parts. Do not open or attempt to modify your Orpyx insoles or Orpyx Hub.

Do not cut, trim or alter the Orpyx insoles. If you feel modifications are needed, please contact your healthcare provider.

Routine Inspection

Inspect your insoles monthly for signs of damage, such as holes in the foam, sharp edges protruding from the foam, and battery leakage. Discontinue use in the event of damage and contact Orpyx Customer Care.

Inspect your Orpyx Hub monthly for damage or defects. Do not use your Orpyx Hub if it appears damaged or defective and contact Orpyx Customer Care.

Cleaning

Prior to cleaning, unplug the Orpyx Hub from the power outlet to prevent the risk of injury from electric shock.

To clean the Orpyx insoles or Orpyx Hub, gently wipe with a clean cloth lightly dampened with cool, clean water once a month or as needed. Do not submerge the Orpyx insoles or Orpyx Hub in water. Never use thinner or other harsh chemicals. Allow to dry completely prior to use.

Only plug in your Orpyx Hub with dry hands.

After cleaning, plug Orpyx Hub into the power outlet.

Storage and Handling

Keep dry. The Orpyx Hub should only be used indoors in dry, climate-controlled environments. Do not submerge the Hub in water or expose it to moisture (e.g., near sinks, showers, or nebulizers), as moisture exposure may damage the device or cause electrical malfunction.

Do not expose the Orpyx insoles or Orpyx Hub to direct sunlight or place them near heat sources such as vents, space heaters, or fireplaces, as excessive heat or UV exposure may damage internal components.

Do not place objects on top of or cover the Orpyx Hub, as this may obstruct airflow, leading to overheating or device damage.

Keep your Orpyx insoles away from pets, as they contain a coin cell battery that may pose a chemical, burn, or choking hazard if chewed or swallowed.

Keep your Orpyx Hub away from children and pets. The Hub contains small parts, such as the button, which may present a choking hazard if dislodged and swallowed.

If the Orpyx insoles or Orpyx Hub have been transported or stored in a hot or cold location, allow the components to acclimate to room temperature for at least one hour prior to use.

For environmental storage conditions, please refer to the Technical Specifications tables on pages 52-63.

Safe Disposal

The Orpyx Custom Sensory Insole system is designed to last for the expected product lifespan under normal usage conditions. The Orpyx insoles include electronics and a non-rechargeable and non-replaceable battery, and the Orpyx Hub contains electronics.

At the end of their useful life, dispose of the Orpyx insoles and the Orpyx Hub in accordance with all local and national regulations for electronic and hazardous waste.

Insoles Aren't Connecting

Gray Insoles on *My Feet* Screen

On the *My Feet* screen, if one or both feet are light gray, your insole(s) is/are not paired to your Orpyx App.

Action: If you've received replacement insoles, follow the instructions on the *Pairing Your Insoles* guide in your refill kit or contact Orpyx Customer Care for support.

Spinning Icon on *My Feet* Screen

On the *My Feet* screen, if one or both feet have a loading icon, your insole(s) is/are trying to connect to your Orpyx App.

Action: Wear your shoes to wake your insoles. In your phone settings, turn off and then turn back on Bluetooth. If the problem continues, contact Customer Care.
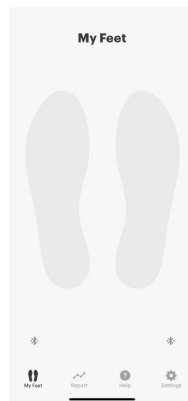
High Pressure Notification

On the *My Feet* screen one or both feet have a red pressure notification. These pressure notifications indicate that there are areas of sustained pressure under your foot.

Action: Offload the pressure on your feet until the red areas are gone.

Try the following to clear the pressure notification:

1. Walk for 2 minutes
2. Sit for 2 minutes
3. Check lace tightness
4. Check shoes for foreign objects

For more details on offloading pressure, go to the *Help* tab, or contact Customer Care.

Bluetooth® Connection Issues

If your insoles cannot connect to the Orpyx App, it may be because you need to turn on Bluetooth on your phone.

Action: In your phone's settings, turn on Bluetooth.

Tap OPEN SETTINGS if you see the message *Bluetooth is Off*.
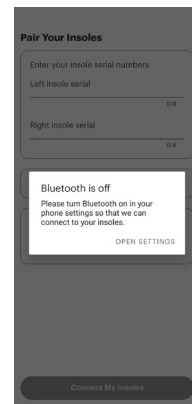
No Internet Connection

You cannot view the Orpyx legal policies because your phone doesn't have an internet connection. Please connect to the internet and retry.

Action: Connect your phone to a Wi-Fi or cellular network to view the page.
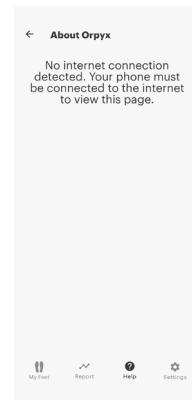
No Saved Insoles Found

The Orpyx insoles have either not been added or have been removed from the Orpyx App. Add or replace insoles to continue.

Action: Please select the *Add or Replace Insoles* button and follow the instructions for pairing insoles on page 25 or follow the instructions on the *Pairing Your Insoles* guide if you have received a set of refill insoles.

← **Your Insoles**

No saved insoles found.
Please add a new insole to have its information
displayed here.

Add or Replace Insoles
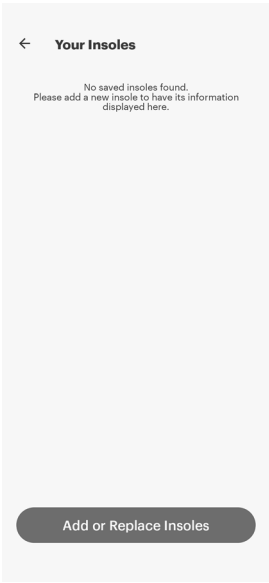
Unable to Pair Insoles

If you encounter a red circle with an exclamation point on the *Pair Your Insoles* screen it may be one of the following:

Issue(s)	Action(s)
The serial number(s) is/are entered incorrectly.	In the *Left serial number* box, enter the serial number of the left insole. In the *Right serial number* box, enter the number of the right insole.
Your insole(s) are not awake.	Wake your insoles by walking on them.
Your insole is not in range of your phone.	Move your insole(s) in range of your phone.
Your insoles are not working or are unable to connect.	Contact Orpyx Customer Care.

Orpyx Hub Interface

Start-Up and Diagnostic Mode

Orpyx Hub shows diagnostic lights on the front of the device when you first plug it in or when you long press the Orpyx logo button (hold the button for more than 2 seconds). The lights show the current status of the connections.

All lights on the front of Orpyx Hub will turn off within 10 minutes at start up or after 1 minute in diagnostic mode.

Orpyx Hub
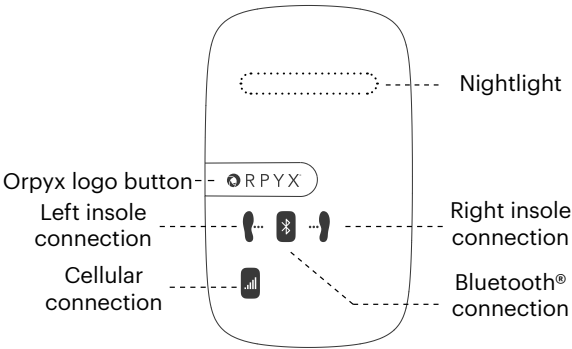
Nightlight

Orpyx logo button

Left insole connection

Cellular connection

Right insole connection

Bluetooth® connection

Orpyx Hub Interface (cont.)

Start-Up and Diagnostic Modes (cont.)

Light	Status	Meaning	User Action
Nightlight (start-up)	On - Medium brightness (default)	Orpyx Hub has power	No action required
Nightlight (diagnostic mode)	Light pulses	Indicates you are in diagnostic mode	No action required
Bluetooth connection	Solid blue	Bluetooth is working	No action required
	Solid amber	Bluetooth is not working	Unplug and re-plug the Orpyx Hub. If the issue continues, contact Orpyx Customer Care.

Orpyx Hub Interface (cont.)

Start-Up and Diagnostic Modes (cont.)

Light	Status	Meaning	User Action
Left insole connection / Right insole connection	Blinking blue	Searching for left and/or right insole	Wait to see if the light goes solid blue
	Solid blue	Connected to left and/or right insole	No action required
	Solid amber	No left and/or right insole detected after 1 minute of searching	Move your insole(s) to wake them from sleep. Move your insole(s) in range of your Orpyx Hub. Wait 15 minutes to see if your insoles connect to the Orpyx Hub. If the insole connection is still amber, contact Orpyx Customer Care.

Orpyx Hub Interface (cont.)

Start-Up and Diagnostic Modes (cont.)

Light	Status	Meaning	User Action
Cellular connection	Blinking blue	Searching for cellular network	Wait to see if the light goes solid blue
	Solid blue	Connected to cellular network	No action required
	Solid amber (start-up)	No cellular network detected	Wait to see if the problem resolves within 24 hours. Long press the Orpyx button until the nightlight pulses. If the Cellular connection is still amber, contact Orpyx Customer Care.
	Solid amber (diagnostic mode)	No cellular network detected	Unplug and re-plug the Orpyx Hub. If the issue continues, contact Orpyx Customer Care.

Orpyx Hub Interface (cont.) ———

Last Status in the Past 24 Hours

When you short press the Orpyx logo button (less than 2 seconds), the lights on the front of Orpyx Hub show the status of the Orpyx Hub within the last 24 hours. The lights turn off within 1 minute.

Additionally, the nightlight changes to the next level by doing a short press.

  Medium (default) ⊙ High ⊙ Off ⊙ Low ⊙ Medium

Light	Status	Meaning	User Action
Bluetooth connection	Solid blue	Bluetooth is working	No action required
	Solid amber	Bluetooth is not working	Unplug and re-plug the Orpyx Hub. If the issue continues, contact Orpyx Customer Care.

Orpyx Hub Interface (cont.) ———

Last Status in the Past 24 Hours (cont.)

Light	Status	Meaning	User Action
Left insole connection / Right insole connection	Solid blue	A left and/or right insole has connected to the Orpyx Hub in the last 24 hours.	No action required
	Solid amber	No left and/or right insole has connected to the Orpyx Hub in the last 24 hours.	Contact Orpyx Customer Care.
Cellular connection	Solid blue	Orpyx Hub has connected to a cellular network in the last 24 hours.	No action required
	Solid amber	Orpyx Hub has not connected to a cellular network in the last 24 hours.	Unplug and re-plug the Orpyx Hub. If the issue continues, contact Orpyx Customer Care.

The Orpyx Custom Sensory Insole system(s) that is/are the subject of the Purchase Order(s) to which these terms and conditions are attached is/are subject to the following limited warranty (the "Limited Warranty"):

1. In the absence of a written agreement to the contrary, the Limited Warranty for the Orpyx Custom Sensory Insole system(s) is as follows:

   Orpyx Medical Technologies Inc. ("Orpyx") warrants that the insoles and hub that form the Orpyx Custom Sensory Insole system(s) shall be free from defects in material and workmanship for up to 180,000 steps per insole or a period of 120 days from the date of shipping, whichever comes first.

2. Notwithstanding anything else contained herein, if the insoles that form part of the Orpyx Custom Sensory Insole system(s) do not fit properly, cannot be trimmed to fit, and Orpyx is not able to provide a replacement pair that resolves the issue (collectively, a "Fit Issue"), Orpyx will provide a full refund to the User/Customer. All warranty claims for a Fit Issue must be made within 60 days from the date of shipping. This warranty for a Fit Issue is invalid if the User/Customer information was incomplete or inaccurate at the time of the Purchase Order (e.g. shoe size, shoe make and model, inadequate foot scan/mold/cast). In such circumstances, a new Purchase Order would be required.

3. The Limited Warranty provided for herein covers manufacturing defects only and is not transferable.

4. Accompanying this Limited Warranty is a copy of the Orpyx Custom Sensory Insole system(s) instructions for use manual (the "Manual"). No warranty is provided for defects arising as the result of fluid ingress or faulty or negligent treatment and any operation of the Orpyx Custom Sensory Insole system(s) contrary to the recommended uses, operations or procedures set forth in or contemplated by the Manual shall void this Limited Warranty in full. Any adjustment, alteration or correction made to the Orpyx Custom Sensory Insole system(s) by a person other than an Orpyx authorized agent shall also void this Limited Warranty in full.

5. Disregarding warning information may cause improper operation, inaccurate results and may void this Limited Warranty in full. Disregarding information for proper use may reduce the life expectancy of the Orpyx Custom Sensory Insole system(s) and/or damage the Orpyx Custom Sensory Insole system(s) and may void this Limited Warranty in full.

6. Orpyx will bear no responsibility or liability for parts which are subject to normal wear and tear or are designed to be replaced or renewed as part of the purchase and use of the Orpyx Custom Sensory Insole system(s).

7. All warranty claims must be made during the applicable warranty period, and such claims must be made within 30 days after discovery of any claimed defect covered by this Limited Warranty. All warranty claims must be submitted to Orpyx via electronic mail. All warranty claims are processed

and approved in the Calgary head office of Orpyx by authorized personnel, who shall have final discretion in the resolution of a warranty issue. In the case of a justified and timely complaint about a defect, Orpyx will at its discretion provide new parts as well as reasonable and customary labor needed to correct the defect. Parts replaced under this warranty shall become the property of Orpyx.

1. The warranty for a replaced part expires at the same time as the original warranty of the supplied Orpyx Custom Sensory Insole system(s). Any parts of the Orpyx Custom Sensory Insole system(s) that are replaced outside the terms of this Limited Warranty shall require a new Purchase Order.

2. THIS LIMITED WARRANTY AND THE LIABILITIES SET FORTH HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OF THEIR LIABILITIES AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE AND CONSTITUTES THE ONLY WARRANTY OF ORPYX WITH RESPECT TO THE ORPYX CUSTOM SENSORY INSOLE SYSTEM(S).

3. ORPYX EXCLUDES ALL LIABILITY FOR OR ARISING FROM ANY NEGLIGENCE ON ITS PART OR ON THE PART OF ANY OF ITS EMPLOYEES, AGENTS OR REPRESENTATIVES IN RESPECT OF THE MANUFACTURE OR SUPPLY OF THE ORPYX CUSTOM SENSORY INSOLE SYSTEM(S) OR THE PROVISION OF SERVICES RELATING TO THE ORPYX CUSTOM SENSORY INSOLE SYSTEM(S). ORPYX SHALL ALSO NOT BE LIABLE FOR ANY FAILURE TO PERFORM DUE TO CAUSES BEYOND ITS CONTROL.

4. NOTWITHSTANDING ANYTHING ELSE CONTAINED HEREIN OR IN A PURCHASE ORDER, THE AGGREGATE LIABILITY OF ORPYX IN ANY WAY RELATING OUT OF OR RELATED TO A PURCHASE ORDER SHALL BE LIMITED TO THE REPLACEMENT OF DEFECTIVE PARTS OF THE ORPYX CUSTOM SENSORY INSOLE SYSTEM(S) OR A REFUND OF THE PURCHASE PRICE FOR THE ORPYX CUSTOM SENSORY INSOLE SYSTEM(S). IN NO EVENT SHALL ORPYX BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INDIRECT DAMAGES, EVEN IF IT IS GIVEN NOTICE OF SAME, INCLUDING LOST PROFITS, LOSS OF REVENUE OR FAILURE TO REALIZE EXPECTED SAVINGS. THESE LIMITATIONS APPLY IN RESPECT OF ALL CAUSES OF ACTION, WHETHER FOR BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE.

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 Custom Sensory Insole system 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 system may cause interference in other electronic equipment. Therefore, please take the following precautions:

Travel or International Use

When traveling by air, please note that the Orpyx Custom Sensory Insoles use wireless communication. If you are traveling outside of the United States or Canada with your insoles, check with your travel agent prior to travel to ensure that the use of wireless products is permitted in your country of destination.

This product should not be used during flight, instead, pack the Orpyx Custom Sensory Insoles and Orpyx Hub in your carry-on luggage and bring your Orpyx Medical documentation card for presentation to airport security personnel if requested.

Before plugging in your Orpyx Hub, ensure the input voltage stated on the back of the Orpyx Hub is compatible with the power outlet.

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 to avoid potential interference between these devices. People with pacemakers should always keep the Orpyx Custom Sensory Insole system at least 6 inches (15 cm) from the pacemaker when the device is active. Notify your prescribing provider if you have a pacemaker.

Hearing Aid Compatibility

The Orpyx Custom Sensory Insole system may interfere with some Bluetooth-enabled 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 Custom Sensory Insole system.

Healthcare Facilities

Hospitals and healthcare facilities may use equipment that is particularly sensitive to external RF emissions. Do not wear the Orpyx Custom Sensory Insoles in areas of hospitals or healthcare facilities with restrictions on radio frequency emitting devices. Wear alternate footwear or remove the insoles from your shoes and leave them outside of restricted areas when instructed by hospital staff or signage.

Other Wireless Technologies

The Orpyx Custom Sensory Insole 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 Custom Sensory Insole system.

Environment

The Orpyx Custom Sensory Insole system is designed to be used in a patient's footwear during their daily activities.

The Orpyx Custom Sensory Insole system is not rated for use in areas with a high concentration of flammable gases, vapors, or dust, as there is a risk of ignition.

Essential performance

The Orpyx Custom Sensory Insole system is designed to provide the user with real-time, individualized notifications for pressure offloading. The Orpyx Custom Sensory Insoles are intended to act as an adjunct to standard foot care, not a replacement. The Orpyx Custom Sensory Insole system has no essential performance. In the event the operation of the Orpyx Custom Sensory Insoles is degraded due to external interference, the custom insoles continue to provide the wearer with the current standard of care.

⚠️ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Orpyx Custom Sensory Insoles, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Orpyx Custom Sensory Insoles

Model	SI000010
Applied part	Type BF
Operator	Patient
Temperature accuracy	± 0.6 °C (± 1 °F) 95% confidence between 15°C to 40°C / 59°F 104°F
Power source	500 mAh Non Rechargeable CR3032 3V Coin Type Lithium Battery Non Replaceable
Operating voltage	1.8 Vdc
Wireless technology	Bluetooth Low Energy (BLE)
Frequency band	ISM 2.4 GHz, 2402 to 2480 MHz
Modulation	Gaussian Frequency-Shift Keying (GFSK)
Maximum Effective Radiated Power (EIRP)	8.1 dBm
Mode of operation	Continuous operation
Number of operation modes	4 – Searching / Connected/ Hibernate / Off

Orpyx Custom Sensory Insoles (cont.)

Transport and storage conditions	-25°C to +70°C / -13°F to 158°F, Relative humidity up to 90% (non-condensing Water vapour pressure up to 50 hPa / 37.5 mmHg
Operational conditions	Temperature +5°C to +40°C / 41°F to 104°F. Humidity 15%-90% (non-condensing). Atmospheric pressure 700-1060hPa / 525 - 795 mmHg
IP rating	IP22: Orpyx Custom Sensory Insoles are protected against the entry of objects greater than 12 mm in diameter (about the size of an adult finger) and protected from water spray at an angle of 15 degrees from vertical.
Service life	120 days, 8 hours of daily active use
Battery Life	6 Months, 8 hours of daily active use

Orpyx Hub

Model	OH000010
Operator	Patient
Rated input voltage and frequency	120 Vac~ 50-60 Hz
Rated input current	0.2 A
Classification	Class II
Frequency bands	2.402-2.480 GHz BLE v5; 13.56 MHz NFC; 699-1915 MHz LTE Bands B2, B4, B5, B12, B13, B25, B26, and B66
Wireless technologies	Bluetooth® Low Energy (BLE); Near Field Communication (NFC); LTE CAT-M1 (Uplink - Orthogonal Frequency Division Multiple Access, Downlink - Single-Carrier Frequency Division Multiple Access)
Mode of operation	Continuous operation
Number of operation modes	1 - Normal operation

Orpyx Hub (cont.)

Transport and storage conditions	Temperature -40°C to 80°C / -40°F to 176°F. Relative Humidity up to 95%
Operating conditions	Temperature -25°C to 60°C / -13°F to 140°F. Rel. Humidity up to 95%. Atmospheric pressure 700-1060 hPa / 525 - 795 mmHg
IP rating	IPX0: Orpyx Hub has no water resistance. Keep dry and use in an indoor environment. Exposure to water could lead to malfunction or complete failure.
Dimensions L x W x H	Approx. 160 x 100 x 60 mm / 6.3 x 4 x 2.4 in
Weight	Approx. 105 g / 4 oz
Mean useful service life	3 years

Orpyx Custom Sensory Insoles

The Orpyx Custom Sensory Insoles are intended for use in the electromagnetic environment specified in the tables below. The user of the Orpyx Custom Sensory Insoles should assure that it is used in such an environment.

Electromagnetic Emissions

Standard	Compliance	Electromagnetic Environment - Guidance
Conducted Emission CISPR 11	Not Applicable	Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.
Radiated Emissions CISPR 11	Class B	The Orpyx Custom Sensory Insoles use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic Current IEC 61000-3-2	Not Applicable	Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 test levels		Compliance levels	Electromagnetic Environment Guidance
	Healthcare environment	Home healthcare environment		
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact + 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV air		± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. See **Recommended Separation Distances** table. Interference may occur in the vicinity of equipment marked with the following symbol:

Note: See the Manufacturer's Declaration- Test Specifications for Immunity to Proximity Fields from RF wireless communications equipment (IEC 61000-4-3) table.

Electric Fast Transients Immunity IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines		N/A - Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.	
Surges Immunity IEC 61000-4-5	± 0.5 kV, ± 1 kV Line-to-line ± 0.5 kV, ± 1 kV ± 2 kV Line-to-earth		N/A - Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.	

Electromagnetic Immunity (cont.)

Immunity Test	IEC 60601-1-2 test levels		Compliance levels	Electromagnetic Environment Guidance
	Healthcare environment	Home healthcare environment		
Conducted Immunity IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	N/A - Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.	
Power Frequency (50/60Hz) Magnetic Field Immunity IEC 61000-4-8	30 A/m 50 Hz or 60 Hz		30 A/m 50 Hz or 60 Hz	The Orpyx Custom Sensory Insole power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips & Interruption IEC 61000-4-11	Voltage dips: 0% UT; 0.5 cycle 0% UT; 1 cycle 70% UT; 25/30 cycles Voltage interruptions: 0% UT; 250/300 cycles		N/A - Orpyx Custom Sensory Insoles are battery powered. The insoles do not connect to the AC Mains or any other wired port.	
Proximity Magnetic Fields Immunity IEC 61000-4-39	134.2 kHz 2.1 kHz pulse modulation 13.56 MHz 7.5 A/m 50 kHz pulse modulation	30 kHz no modulation (CW) 134.2 kHz 2.1 kHz pulse modulation 13.56 MHz 7.5 A/m 50 kHz pulse modulation	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	-

Recommended Separation Distances

The Orpyx Custom Sensory Insoles are for use in a home healthcare environment in which radiated radio frequency disturbances are controlled. The user of the Orpyx Custom Sensory Insoles can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (transmitters) and the Orpyx Custom Sensory Insoles as recommended in the following table, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to the frequency of the transmitter [m]		
	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.7 GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's Declaration

Test Specifications for Immunity to Proximity Fields from RF Wireless Communications Equipment (IEC 61000-4-3)

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	Immunity test level (m)	Compliance level (V/m) for home healthcare
385	380-390	Tetra 400	Pulse modulation [b] 18 Hz	27	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 KHz sine	28	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9	9
810 870 930	800-960	GSM 800/900, Tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GMS 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9	9

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be the worst case.

FCC Supplier's Declaration of Conformity

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:

FCC Suppliers Declaration of Conformity (cont.)

- 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 ISED.

RF Exposure Statement

The Orpyx Hub is intended to be installed and operated in an area where the distance between the Orpyx Hub and operators or bystanders is greater than 20 centimeters / 8 inches.

Déclaration d'exposition aux RF

L'Orpyx Hub est destiné à être installé et utilisé dans un endroit où la distance entre l'Orpyx Hub et les opérateurs ou passants est supérieure à 20 centimètres / 8 pouces.

Other Standards and Compliance

The insoles are certified to the following EMC standard: IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

Thank you for choosing the Orpyx Custom Sensory Insole system

To view the IFU in a larger format please visit:
www.orpyx.com/instructions

If you have any questions or need to report unexpected operation or events, please call Orpyx Customer Care.

Orpyx Customer Care
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Orpyx Remote Nurse
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