



Orpyx® Hub Instructions for Use

Important information enclosed.
Do not discard.



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DOC, ORPYX HUB IFU ENGLISH, Rev 1

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Orpyx® Hub

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Symbols and definitions

Symbol	Definition
	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 <i>ISO 15223-1 5.4.4</i>
	Consult instructions for use Indicates the need for the user to consult the instructions for use <i>ISO 15223-1 5.4.3</i>
	Catalog number Indicates the manufacturer's catalogue number so that the device can be identified <i>ISO 15223-1 5.1.6</i>
	Model number Indicates the model number or type number of a product <i>ISO 15223-1 5.1.10</i>
	Serial number Indicates the manufacturer's serial number so that a specific device can be identified <i>ISO 15223-1 5.1.7</i>
	Manufacturer Indicates the device manufacturer <i>ISO 15223-1 5.1.1</i>
	Distributor Indicates the entity distributing the device into the locale <i>ISO 15223-1 5.1.9</i>



Date of manufacture

Indicates the date when the device was manufactured

ISO 15223-1 5.1.3



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



For indoor use only

Identifies electrical equipment designed for indoor use

IEC 60417-5957



Keep dry

Indicates a device that needs to be protected from moisture

ISO 15223-1 5.3.4

IPX0

Ingress Protection Rating IPX0

Identifies a device with no protection against vertically falling water drops. Keep dry.

IEC 60529:2013



Class II equipment

Identifies equipment meeting the safety requirements specified for Class II equipment

IEC 60417-5172



Alternating current

Identifies equipment that is suitable for alternating current only.

IEC 60417-5032



Do not dispose of device in trash

Dispose the product and packaging in accordance with your local regulations.

IEC 60417-6414

Safety information

Warnings

- 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

- 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.
- 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.

About your Orpyx Hub

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

No special skills, training, or knowledge are required to use this product. You can use all the functions of the 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.

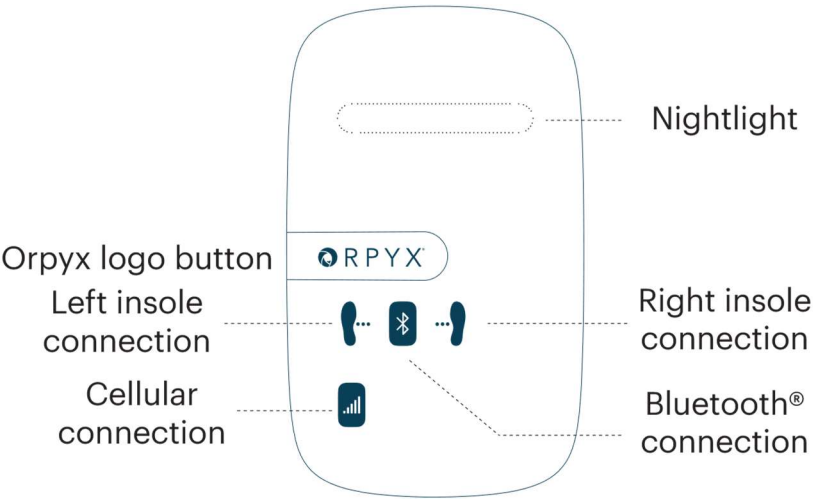
Package contents

- Orpyx Hub
- Instructions for Use

Approved accessories

- Orpyx Sensory Insoles

Orpyx Hub parts identification



Label and Contact Information

REF

ORPYXHUB

#

OH000010

2025-06

Input: 120Vac~, 50-60Hz, 0.2A
Class II

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SGS

801108

CAUTION: Risk of electric Shock. Dry location use only.

ATTENTION: Risque de choc électrique. Utilisation dans un endroit sec uniquement.

FCC ID: 2AAH8-OH000010
IC: 10789A-OH000010

Contains FCC ID: 2ANPO00NRF9151
Contains IC: 24529-NRF9151

UDI

(01)10185571000523
(21)00000001

UID:
00017000
RegKey:
13U5S-UNIM93

v1.0

Setting up your Orpyx Hub

Plug your Orpyx Hub into a power outlet in an open area close to where you store your shoes with the Orpyx Sensory 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.

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



Allow your Orpyx Hub to adapt to the surrounding environment for about one hour before use if stored or transported outside of the recommended temperature and humidity range.

1. Unbox your Orpyx Hub.
Save the product packaging should you need to return your Orpyx Hub.
2. Plug your Orpyx Hub into a household power outlet.
Orpyx recommends your Orpyx Hub is plugged into a power outlet in a room with a strong cellular network signal near where you store your shoes with your Orpyx Sensory Insoles.
3. The Orpyx Hub lights illuminate to show the status of your Orpyx Hub. See Orpyx Hub interface: Start-up on page 10.
4. Within 10 minutes, your Orpyx Hub shows the following lights as solid blue and fades off:



Bluetooth connection



Cellular network connection

NOTE: If the Bluetooth connection or cellular network connection indicator on the front of your Orpyx Hub changes from blue to amber or remains amber, follow the steps described in the Troubleshooting section on page 14 of this manual.

Orpyx Hub interface: Start-up

Light	Status	Meaning
Nightlight (White)	On - Medium Brightness (default)	Orpyx Hub is powered on.
 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 the left insole
	Solid amber	No left insole connection
 Right insole connection	Blinking blue	Searching for right insole
	Solid blue	Connected to the right insole
	Solid amber	No right insole connection
 Cellular connection	Blinking blue	Searching for cellular network
	Solid blue	Connected to cellular network
	Solid amber	No cellular network detected

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

Using your Orpyx Hub

Transferring your insole data

Data transfers occur automatically as needed when your Orpyx Sensory Insoles are in range of your Orpyx Hub.

Wear or place your insoles within range (less than 3 meters / 10 feet) of your Orpyx Hub.

Best Practice Tip:

After a full day of wearing your Orpyx Sensory Insoles, leave your insoles within 3 meters / 10 feet of your Orpyx Hub for at least 30 minutes. This ensures that all the data for the day is transferred. Do this daily to ensure consistent data transfer.

Adjust the nightlight and show last connection status

When you first plug in your Orpyx Hub, the nightlight always illuminates at medium brightness.

With a short press of the Orpyx logo button, you can adjust the brightness of the nightlight and show the last connection status of the Orpyx Hub within the last 24 hours.

- **Short press (less than two seconds)** the Orpyx logo button:
 - Changes the brightness of the nightlight to the next level (**Medium** (default) ➡ **High** ➡ **Off** ➡ **Low** ➡ **Medium**), and
 - Shows the last connection status of the Orpyx Hub within the last 24 hours.

Send a diagnostic report and show current connection status

With a long press of the Orpyx logo button, you can view the current connection status of your Orpyx Hub and send a diagnostic report to Orpyx. This is useful if you have a technical issue with your Orpyx Hub.

- **Long press (more than two seconds)** the Orpyx logo button until the nightlight pulses:
 - Shows the current connection status of the Orpyx Hub, and
 - Sends a diagnostic report to Orpyx.

Turn off Orpyx Hub

Unplug your Orpyx Hub from the power outlet.

Product care and maintenance

Maintenance

Orpyx Hub contains no user repairable or replaceable parts.
Do not open or attempt to modify your Orpyx Hub.

Routine Inspection

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 Hub, gently wipe with a clean cloth lightly dampened with cool, clean water once a month or as needed. Do not submerge the 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 your Orpyx Hub into the power outlet.

Storage and handling



Keep dry. 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 Hub to direct sunlight or place it 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 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 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.

For environmental storage conditions, please refer to the Technical Specifications table on page 19.

Safe disposal



There are no user repairable or replaceable parts in the Orpyx Hub. Orpyx Hub contains electronics. At the end of its useful life, dispose of the device properly in accordance with all local and national regulations.

Troubleshooting

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.

Light	Status	Meaning	Recommended action
Nightlight (Start-up)	On - Medium Brightness	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.
 Left 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.
 Right insole connection	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.

Light	Status	Meaning	Recommended 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.

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 last status of the Orpyx Hub within the past 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	Recommended 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.

Light	Status	Meaning	Recommended action
 Left insole connection	Solid blue	A left and/or right insole has connected to the Orpyx Hub in the last 24 hours.	No action required.
 Right insole connection	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.

Warranty terms and conditions

Orpyx Medical Technologies Inc. warrants Orpyx® Hub as per the Orpyx Sensory Insole system warranty.

Contacting Orpyx® Customer Care

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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Technical information and regulatory statements

Technical specifications for Orpyx® Hub	
Name	Orpyx® Hub
Model	OH000010
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 - SingleCarrier Frequency Division Multiple Access)
Mode of operation	Continuous
Number of operation modes	1 - Normal operation
Storage and transport conditions	Temperature -40°C to 80°C / -40°F to 176°F Rel. Humidity up to 95%
Operating conditions	Temperature -25°C to 60°C / -13°F to 140°F Rel. Humidity up to 95% Air 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

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 Orpyx Hub 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 Orpyx Hub may cause interference in other electronic equipment. Therefore, please take the following precautions:

Travel or international use

Orpyx Hub is not certified or registered for use outside of the United States or Canada.

Pacemakers

The Health Industry Manufacturers Association recommends that a minimum separation of 15 centimeters / 6 inches be maintained between certain RF emitting devices and pacemakers to avoid potential interference between these devices. Persons with pacemakers should always keep the Orpyx Hub at least 15 centimeters / 6 inches from the pacemaker when the device is active. Notify your prescribing provider if you have a pacemaker.

Hearing aid compatibility

Orpyx Hub 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 Hub.

Other wireless technologies

Orpyx Hub 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 Orpyx Hub.

Environment

Orpyx Hub is designed for use in patient home healthcare environments.



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 centimeters / 12 inches to any part of the Orpyx Hub, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING: No modification of this equipment is allowed.

FCC suppliers' 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:

- 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 numérique de la classe B est conforme à la norme NMB-003 du Canada. This device complies with RSS 210 ofISED.

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.



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