

SurroSense[®] PROTECT[™] Custom Smart Insole System

Instructions for Use
Important Information enclosed. Do not discard.



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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: 1-855-990RPYX (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

SurroSense[®] PROTECT[™]

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Symbols and Definitions

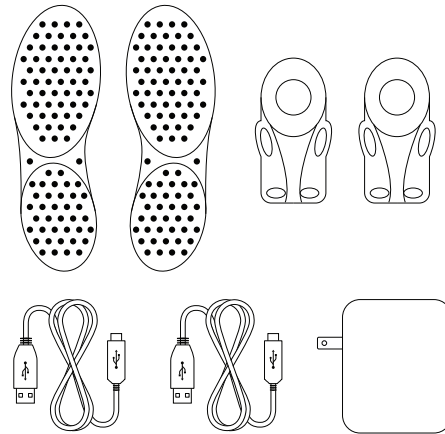
Symbol	Definition
	Caution
	System Lot Number
	Keep Dry
	Manufactured By
	Serial Number
	Waste Electrical & Electronic Equipment
	Year of Manufacture

1. The SurroSense[®] PROTECT[™] System

The SurroSense[®] PROTECT device is a custom smart insole system designed to help patients manage their diabetic feet. The system warns individuals of pressure overload on the bottom of the foot via a mobile app. The system consists of pressure sensors integrated into custom fabricated foot insoles, connected to pods which wirelessly communicate with a mobile app on a smartphone.

INCLUDED IN PURCHASE:

- SurroSense[®] PROTECT Insoles (Left and Right)
- SurroSense[®] PROTECT Shoe Pods (Left and Right)
- Charging Cables:
 - 6ft USB-A to USB-mini cable
 - USB-mini splitter cable
- AC Adaptor



A. INDICATIONS FOR USE

The SurroSense[®] PROTECT custom smart insole system is a powered limb overload warning device intended for monitoring the condition of peripheral neuropathy in diabetic patients to warn a patient of an overload in the amount of pressure placed on a foot.



Use of the SurroSense[®] PROTECT system does not eliminate the need for regular diabetic foot care as advised by a healthcare professional.

B. CONTRAINDICATIONS







There are no known contraindications for the SurroSense[®] PROTECT system at this time.

C. FIELD OF APPLICATION

The SurroSense[®] PROTECT system was developed for use throughout everyday activities. The SurroSense[®] PROTECT system is designed exclusively for use by one user.

Users with active skin ulceration or partial amputation must have these wounds appropriately monitored and dressed by a healthcare professional. Users with partial amputations or active foot ulcers should seek the advice of a healthcare professional prior to wearing a SurroSense[®] PROTECT.

D. WARNINGS AND PRECAUTIONS

-  Disregarding WARNING information may cause improper operation, inaccurate results and may void the warranty.
-  Disregarding error information may reduce the life expectancy of the product and/or damage the product; and may void the warranty.
-  This product uses and receives radio frequency signals. For proper operation, this product must be configured and operated as per the instructions provided in this manual.
-  This product uses low power radio communications and can affect other medical electrical equipment. Refer to Section 11 for more information.
-  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.
-  Do not use SurroSense[®] PROTECT if you have an open wound without consulting a healthcare professional

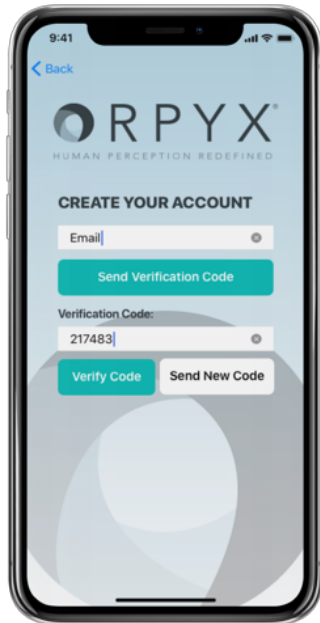
2. SurroSense[®] PROTECT[™] Application



STEP 1

DOWNLOADING THE MOBILE APPLICATION

The SurroSense[®] PROTECT is free and compatible with devices operating iOS 10.1 or newer. You can find the SurroSense[®] PROTECT application by typing “SurroSense[®] PROTECT” in the search bar on the App Store for iOS. Download and install the application and enable Bluetooth on your smartphone, this can be done in the device settings.



STEP 2

CREATE A SURROSENSE[®] PROTECT ACCOUNT

Launch the SurroSense[®] PROTECT application and click the “Sign Up” button on the Login page.

Enter your email address and click the “Send Verification Code” button.

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.

STEP 4

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



STEP 5

SIGN IN SUCCESSFUL

The application will now walk you through the Setup and Tutorial.



STEP 6

INSTALLING YOUR SURROSENSE® PROTECT SENSOR INSOLES

The SurroSense® PROTECT insoles fit inside your diabetic or walking shoe.

To install, remove the existing insole or sock liner from your shoes. Place the appropriate left and right SurroSense® PROTECT insole into each shoe. The lead should run along the inside instep of the shoe, up and over the shoe tongue.



STEP 7

HOW TO PROPERLY FASTEN YOUR SURROSENSE[®] PROTECT SHOE PODS

Attach the shoe pods to the lead on the insoles. Each lead and shoe pod are labeled with a L or R to indicate that it is the left or right.



STEP 8

Fasten shoe pods using the removeable clip provided. Ensure the shoe pods sits on the side of the shoe and secure using the clip.



STEP 9

PAIRING YOUR SYSTEM TO THE APPLICATION

To start using your device, you will need to pair your system with the mobile application.

Pressure must be detected on the insoles to connect. With you shoes on and standing, click the settings button in the upper right hand corner and then click the "Select Devices" button. Select the left and right devices by clicking the footprint icons (once selected they will turn blue). Click the "Done" button on the bottom.*

*Connecting your system may take up to 30 seconds. If the application still does not connect to your system, please contact Orpyx Customer Care.

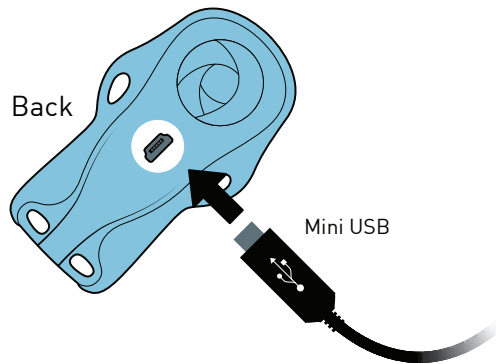


STEP 10

You have successfully paired your system.

3. Charging Your SurroSense® PROTECT™ Custom Smart Insole System

A. HOW TO CHARGE THE SHOE PODS



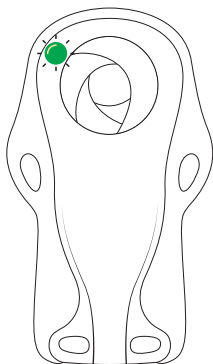
With regular use, the shoe pods will require daily charging. It is recommended that the pods are charged overnight.

To charge the shoe pods, lift the black cover and insert the mini USB cable into the mini USB port on the back of the shoe pod. You should hear a click when in place. The other end of the cable should be inserted into the AC adaptor, which plugs directly into an electrical outlet.

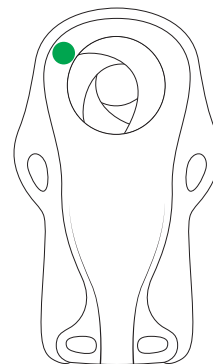
The system should only be charged with the AC adaptor included with the system.

B. CHARGING INDICATIONS

Charging – Green light flashes

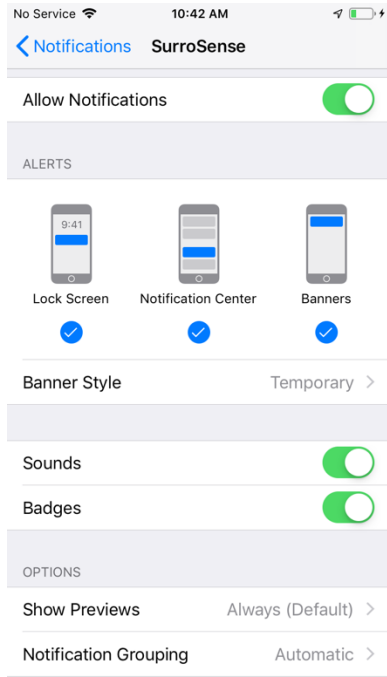


Fully Charged – Green light is ON



4. Using Your SurroSense® PROTECT™ Custom Smart Insole System

A. RECEIVING AN ALERT



Ensure that the default system settings is selected to allow notifications. You can check this by going into your iOS system Settings, Notifications, and selecting SurroSense.

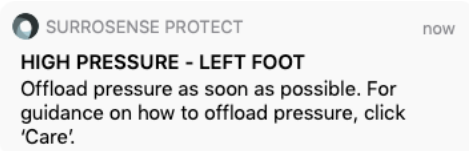
Turn on Allow Notifications, Sounds and Badges.



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 feedback.

TYPES OF ALERTS:

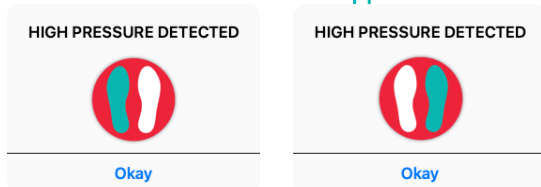
High Pressure Detected Notification



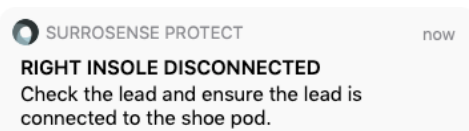
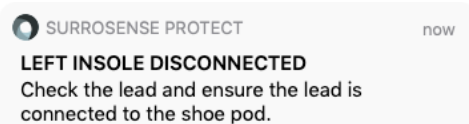
This alert indicates that dangerous pressure and time levels have been detected underfoot. When this screen is displayed, you can click on the notification which will take you to the foot map screen. For guidance on how to offload pressure, click "Care" in the lower right-hand corner.

If the user does not offload pressure effectively, the alert will be re-issued every 3 minutes until the alert is offloaded successfully.

High Pressure Detected Alert in App



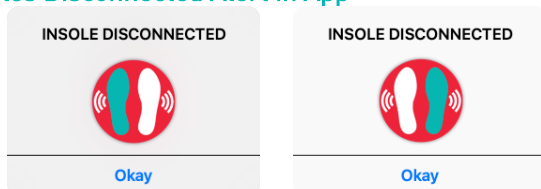
Insoles Disconnected Notification



If your insole becomes disconnected from a shoe pod, the application will notify you that your insole disconnected. Make sure the insole is connected to the shoe pod.

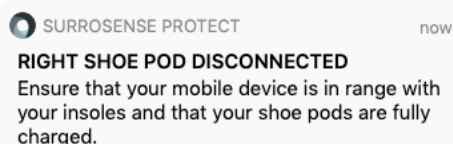
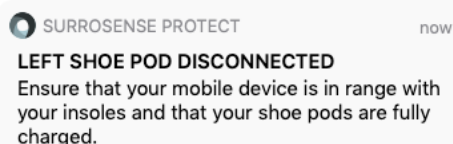
Ensure that pressure is applied when wearing your insoles. The application will automatically try to re-establish wireless connection.

Insoles Disconnected Alert in App



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

Shoe Pods Disconnected



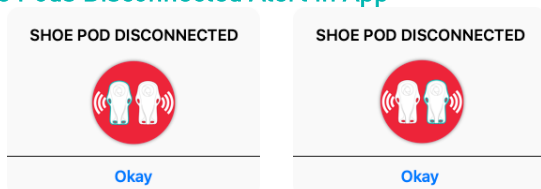
An alert will notify you when the paired shoe pods are disconnected. Ensure that your mobile device is in range with your insoles and that your shoe pods are fully charged.

If your shoes are off, your system will disconnect automatically. Therefore, ignore the “Shoe Pod Disconnected” alert.

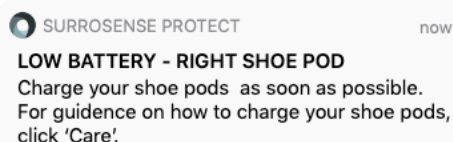
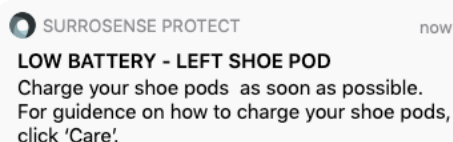
Ensure that pressure is applied when wearing your insoles. The application will automatically try to re-establish wireless connection.

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

Shoe Pods Disconnected Alert in App

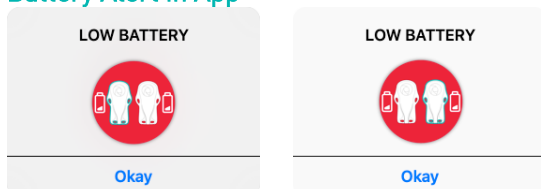


Low Battery



With regular use your custom smart insole, your battery should last on average, twelve hours per day. When the custom smart insole battery runs low, a low battery alert will appear. For guidance on how to charge your system, click “Care” in the lower right-hand corner.

Low Battery Alert in App



B. PRESSURE OFFLOADING STEPS



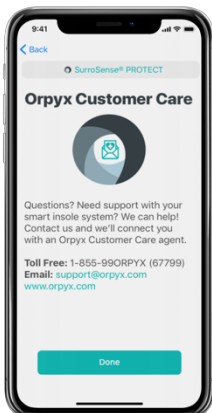
The areas of high pressure are displayed on the My feet screen. In order to relieve pressure, follow the steps below until the high pressure region fades back to grey.

STEP ACTION



1. Walk around (or on the spot) until the red region has turned grey. If this is ineffective after three minutes, then:
2. Sit down and take pressure off red region of the foot. If this is ineffective after three minutes, then:
3. Ensure that footwear laces are not too tight and that there are no foreign objects (ie. rocks) in the shoe
4. Check your feet for cuts, blisters, redness and swelling. If none of these steps prove effective, please contact your healthcare practitioner

C. CONTACTING ORPYX CUSTOMER CARE



If you have any additional questions or concerns, please contact Orpyx Customer Care by clicking the Care button on your application, or:

Toll Free: 1-855-99ORPYX (67799)

Email: support@orpyx.com

www.orpyx.com

5. Maintenance

A. SURROSENSE® PROTECT SYSTEM MAINTENANCE

This system will require daily charging. It is recommended that the pods are charged overnight. For guidance on how to charge your system, please refer to page 12.

B. SURROSENSE® PROTECT CUSTOM SMART INSOLE REPLACEMENT

Your insole will need to be replaced after approximately one year.



DO NOT use a strong cleaning solution that contains bleach or immerse the SurroSense® PROTECT system in water.

D. DISPOSAL OF THE DEVICE



There are no user repairable components in the SurroSense® PROTECT system. When the device has reached the end of its useful life, please dispose of properly in accordance with all local and national regulations.

6. Storage and Handling

SURROSENSE® PROTECT SYSTEM HANDLING



DO NOT open the SurroSense® PROTECT shoe pods for any reason.



DO NOT submerge the SurroSense® PROTECT shoe pods in water for any reason.



DO NOT cut, trim or alter the SurroSense® PROTECT insoles, this could damage sensors and prevent the device from working properly.

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 3 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.

Q: How do I turn the system on?

A: When pressure is detected, 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 custom smart insole system?

A: To ensure accurate readings, the custom smart insoles will need to be replaced approximately every twelve months.

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. Check to see if your shoes are tied too tight.

Q: Can my insoles get wet? What happens when it gets wet?

A: The insoles are water resistant but not water proof. If submerged, the insole may stop functioning properly.

Q: Can I take my smart insole system through airport security?

A: Yes, we recommend packing your system in your luggage and be prepared to show the device working if asked by security, but not wear it.

Q: How often should I wear my insoles?

A: It is recommended that you wear your insoles daily, 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 SurroSense[®] PROTECT 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 SurroSense[®] PROTECT may cause interference in other electronic equipment. Therefore, please take the following precautions:

Travel or International Use

If you plan to travel with the SurroSense[®] PROTECT device, 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 SurroSense[®] PROTECT system at least 6 inches (15 cm) from the pacemaker when the device is active.

Hearing Aid Compatibility

The SurroSense[®] PROTECT system may interfere with some hearing aids. If you experience interference, consult your hearing aid manufacturer or your physician for solutions or alternatives.

Other Medical Devices

If you use any other personal medical devices, consult the medical device manufacturer to ensure that these devices are adequately shielded from RF emissions produced by devices such as the SurroSense[®] PROTECT system.

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.

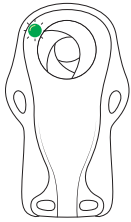
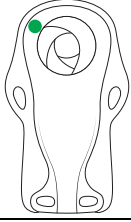
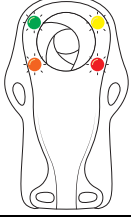
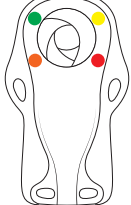
Other Wireless Technologies

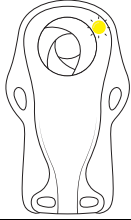
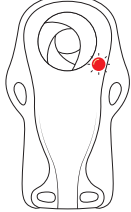
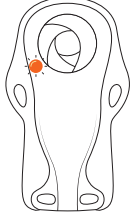
The SurroSense[®] PROTECT system is FCC compliant. However, there may be some newer wireless technologies that interfere with the RF emissions of this device. Please consult the manufacturers of these devices to ensure compatibility with the SurroSense[®] PROTECT system.

TECHNICAL SPECIFICATION FOR SURROSENSE® PROTECT	
Size	2.75in x 1.18in x 0.47in (L x W x H)
Weight	0.7oz. (20g)
Power Source	160mAh Rechargeable LiPo battery
Frequency Band	ISM 2.4 Ghz, 2400 to 2483.5 MHz
Wireless Technology	Frequency Hopping Spread Spectrum
Number of Operation Modes	2 – ON / Sleep
Storage Temperature	Temperature -4 to 131 Fahrenheit / -20 to +55 Celsius / 95%humidity
Operation	Temperature -4 to 131 Fahrenheit / -20 to +55 Celsius / 95%humidity
Water Resistance	No. Do not submerge

SHOE POD INDICATOR LIGHTS

There are red, yellow, green and orange lights inside each shoe pod to indicate system status. The meaning of the lights is as follows:

INDICATOR LIGHT	STATUS
 <p>Flashing green while plugged in</p>	Charging.
 <p>Solid green while plugged in</p>	Charging is complete.
 <p>All colors (Red, Yellow, Green, Orange) flashing simultaneously</p>	The system has been reset and is initializing.
 <p>Constant light of all colors (Red, Green, Orange)</p>	<p>Sensor error.</p> <p>Plug the shoe pod into charger, wait 30 seconds then remove. If the error re-appears after a reset, contact Orpyx Customer Care.</p>

 <p>Flashing yellow once every 10 seconds</p>	<p>When not connected to iOS device, indication that pod is alive and ready to connect.</p>
 <p>Flashing red while wearing system</p>	<p>When not connected to iOS device, an alert has been triggered. See application display.</p>
 <p>Flashing orange while wearing system</p>	<p>When not connected to iOS device, battery level is low.</p>

WARRANTY

Orpyx Medical Technologies Inc. guarantees that the SurroSense® PROTECT system 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.

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

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

OTHER STANDARDS AND COMPLIANCE

The SurroSense[®] PROTECT smart insole 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

Orpyx Medical Technologies Inc.

The SurroSense[®] PROTECT[™] system is a tool to help actively prevent peripheral neuropathy complications and track progress.

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