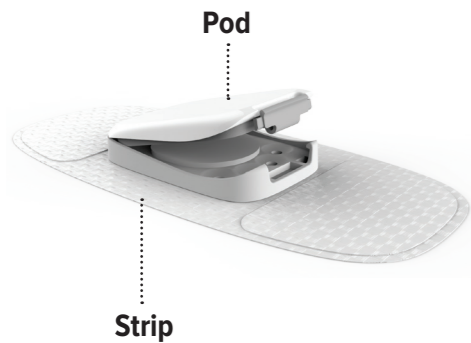




Follow the instructions in your app to put your patch together, connect it with your mobile device, and place it on your body.

Patch



Your patch is made up of a pod and disposable strip. The pod can be used for weeks or months at a time. It captures and sends information to your mobile application (app). The disposable strip is changed weekly. It sticks to the skin on your torso and contains a small battery that powers the pod.

Your patch measures heart rate, activity, body position, and when an ingestible sensor is detected. When taken with an ingestible sensor, you can see the pattern and regularity of how you take your medications. You can also see your sleep patterns by analyzing activity and body position over time. You can use your app to view your data and keep track of how you are doing.

Your patch can also measure ambient temperature. It is not intended to be used to measure human body temperature, and should not be used to diagnose medical conditions.

The data collected are securely transferred and then stored in Proteus' databases.

Your patch can be worn during most activities, including showering, exercising and on airplanes. However, after putting on a new strip avoid showering or exercising vigorously for a few hours to allow the strip to stick properly. How long it takes for a strip to stick varies from person to person. If your strip doesn't stick well the first time wait a few hours longer when applying your next one. Before placing a strip on your body, ensure the area of the skin is free of hair, dry, and healthy. Do not apply lotion before applying a new strip. Clean your pod using household soap and water. You can rinse your pod under running water.

Strip disposal

Your strip contains the batteries that power the patch. Dispose of your used strip in a sanitary fashion, and in the same way as you would household batteries or electronics (please check local electronic waste disposal standards). Do not throw out the pod. Keep the pod for reuse.

Patch specifications

Battery	Coin Cell
Strip Wear Duration:	Approximately 7 days
Storage Conditions:	Original package under normal room temperature and humidity.
Degree of Ingress Protection:	IP27 (Water resistant to 3.3 feet or 1 meter)
Protection against Electrical Shock:	Internally powered medical equipment
Degree of Protection:	Type BF Applied Part
Mode of Operation:	Continuous

- This product complies with ISO 10993-1-2009, ISO 10993-5-2009, and ISO 01993-10-2010
- This product complies with IEC 60601-1-2005, IEC 60601-1-2-2014, IEC 60601-1-11-2010
- This device has no essential performance
- This product complies with RoHS
- The pod and strip do not contain natural latex rubber

Ingestible sensor pill

The ingestible sensor pill contains a tiny ingestible sensor made out of ingredients found in dietary supplements. The ingestible sensor sends a signal to the patch after it reaches your stomach.

Indications for use

The Proteus® Digital Health Feedback Device consists of a miniaturized, wearable sensor (Proteus Patch) for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), and time-stamped patient logged events, including events signaled by the co-incidence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Proteus Digital Health Feedback Device is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The Proteus Digital Health Feedback Device may be used in any instance where quantifiable analysis of event associated physiological and behavioral metrics is desirable, and enables unattended data collection for clinical and research applications.

Safety and performance

The ingestible sensor was extensively tested in clinical studies. Overall, 492 volunteers (Age range 21–85, Mean: 44.6) participated in the wearable sensor studies representing 6,407 wearable sensor-use days. During these studies, 412 of these volunteers also took ingestible sensors representing 5,656 ingestion days (total of 20,993 ingestible sensor ingestions). No serious adverse events were observed in these clinical studies. Adverse events that occurred in ≥ 1% of study subjects are detailed as follows. Sixty-one (12.4%) of the study subjects experienced self-limited skin rashes localized at the site of wearable sensor placement. In the ingestion studies, four subjects (1.0%) reported nausea/vomiting which were possibly related to the ingestible sensor. In comparison with direct observation, the ingestible sensor was detected in 97.3% of ingestions, with 100% correct identification. In other words, one out of every 37 sensors may not be detected due to reasons other than non-adherence.

Cautions

General

- Check the component expiration dates before use.
- Keep components out of reach of children.
- DO NOT** store components in extremely hot, cold, humid or bright conditions.
- DO NOT** use as sole basis for medication treatment decisions. Detection accuracy is less than 100%. Patients instructed by a physician to take an Ingestible Sensor with medication may selectively adhere to one or the other. Therefore, Ingestible Sensor data should be interpreted with caution. Physicians should discuss medication-taking history with patients prior to making medication changes.
- Proteus Digital Health makes no warranty for any data or information that is collected erroneously by the ingestible sensor and/or patch, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Users of the ingestible sensor and/or patch who experience clinical worsening or new clinical symptoms should seek medical attention. Healthcare providers should exercise their clinical judgment in interpreting and using any data from ingestible sensor and/or patch for clinical decision-making.
- Heart rate data may not be accurate for patients with pacemakers

Ingestible sensor pill

- Take the ingestible sensor pill with a sufficient amount of water.
- DO NOT** chew.
- DO NOT** tamper with or place in water before ingestion.
- DO NOT** exceed 30 ingestions per day.

Patch

- DO NOT** continue use until further instructed by a physician if your skin is irritated, inflamed, or red around the disposable adhesive strip.
- DO NOT** place in locations where your skin is scraped, cracked, inflamed or irritated.
- DO NOT** place in a location that overlaps the area of the most recently removed strip.
- DO NOT** use if you are allergic to adhesive tape.
- DO NOT** drop or bump with excessive force.
- DO NOT** use to diagnose heart-related conditions.
- DO NOT** wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.
- DO NOT** dispose of strips with household waste
- DO NOT** throw out the pod: keep it for use with your next strip
- Pod may pose a choking hazard to children under 3 years of age.
- Patch does not contain medication.
- The device contains no serviceable parts or components
- Replace the strip about once per week or as prompted by mobile app.
- Warning: No modification of this equipment is allowed. Modifying the Proteus Patch may cause a safety hazard for the user.

Additional information

For more detailed technical information, please visit: www.proteus.com/instructions

Troubleshooting

If you experience difficulties in operating your patches or sample ingestible sensors, refer to the troubleshooting tables below or contact customer support.

Strip

Problem	Solution
You have visible skin changes, e.g. rash or blistering, around the strip.	Remove your patch from your torso, remove the pod from the strip, and set pod aside. Seek medical attention. Do not use another patch until told to do so by your healthcare provider.

Problem	Solution
Your patch is itchy or uncomfortable (no visible skin changes).	Remove your patch from your torso, remove the pod from the strip, place the pod into a new strip, and attach the new patch to your torso in a new location.

Problem	Solution
Your patch no longer sticks to your skin.	Remove the pod from the strip, place the pod into a new strip, and place the new patch on your body. The "Patch" section on the left-hand side of this document contains further information.

Pod

Problem	Solution
The green light does not appear when the pod is placed in the strip.	Confirm that the pod and strip are put together correctly. If the green light still does not appear, replace the strip. If the green light still does not appear, contact Customer Support.

Problem	Solution
You have misplaced your pod.	If you cannot find your pod, contact Customer Support.

Ingestible sensor pill

Problem	Solution
The pill gets wet or damaged.	Do not take. Swallow a replacement pill if provided

The patch needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

WARNING: Portable and mobile RF communications equipment can affect the Patch. Portable and mobile F 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 Patch. Otherwise, degradation of the performance of the Patch could result.

Equipment symbols

	Batch code
	Serial number
	Catalog number
	European Authorized Representative Manufacturer
	Read instructions before use
	Type BF applied part
	Emits radio waves
	Single use only
	Temperature range
	Humidity range
	Atmospheric Pressure range
	Use by YYYY-MM-DD
	Do not dispose with household waste
	Ingress Protection rating of IP27
	General warning

Customer support

Phone: +1 855.255.5858
Email: helpdesk@proteus-support.com

Proteus Digital Health, Inc.
2600 Bridge Parkway
Redwood City, CA 94065, USA
T +1-650-632-4031

MedPass International Ltd.
Windsor House
Bretforton, Evesham
Worcestershire, WR11 7JJ, UK



LBL-OXXX, Rev X, DDDMMYYYY

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.



Instructions for Use Patch and Ingestible Sensor Pills