Introduction

Your Proteus Digital Health Feedback Device consists of a mobile application, a wearable sensor patch and ingestible sensors. Your patch is worn on your torso and collects physiological and behavioral metrics such as heart rate, activity, body position, and skin temperature. Your circadian rhythms and patterns can also be analyzed by examining activity and body position as a function of time. It also measures the pattern and regularity of your medication taking — medication adherence — when your medication is taken along with the Proteus ingestible sensor. All collected data are securely transferred and stored in Proteus’ databases.

Connecting a Wearable Sensor Patch

Before placing your patch on your body, turn on your mobile device and start the app. The app will guide you through the process of connecting your patch. To connect a new patch, tap ‘Start’ and follow the instructions on the screen.

The patch status screen shows you if your patch is working or if you need to replace it.

Remember

Patch Placement

Your wearable sensor stores your data and regularly sends it to the mobile application for display to help you keep track of how you are doing, your activity and your rest patterns.

1. Select a location on the left side of your body just above the lower edge of your rib cage (see shaded area in figure).
   - Avoid locations below your rib cage.
   - Avoid locations where undergarments may press against the patch.
   - Avoid locations where you have recently worn a patch.
   - To facilitate patch removal, use clippers to trim any hair from your selected location.

2. Prepare your skin by gently wiping the location you have selected with the provided alcohol wipe. Wait for your skin to dry.

3. Apply the sensor
   - Remove a patch from its pouch and peel off the first backing. Take care not to wrinkle the adhesive.
   - Stand in a comfortable, upright position. With the patch button facing upwards, apply the sensor to your selected area.
   - Make sure to peel off the smaller second backing along the edge of the patch. Then smooth the edges around your patch with your fingers.

To Remove a Used Wearable Sensor...

Gently pull the wearable sensor away from your skin. Dispose of the wearable sensor as you would any household batteries or electronics (please check your local electronic waste disposal standards).

The Sensor-Enabled Pill

Your wearable sensor patch records the time the ingestible sensor is detected. Information from your patch will transfer to your mobile device regularly and automatically. Your patch may be worn during most activities including exercise and bathing, and should be changed weekly or sooner as needed.

Note: Your wearable sensor can also measure ambient temperature at the skin, but this measurement is not displayed, not intended to be used as a thermometer to measure human body temperature, and should not be used for diagnosis of medical conditions.

Patch Button & Light

When prompted by the app, press and hold the patch button until you see a green light next to it. This means that your patch has started communicating with your mobile device.

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The Sensor-Enabled Pill

The sensor-enabled pill contains an ingestible sensor made out of ingredients that do not easily react with other chemicals and are found in the food chain.

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 below.

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 ingestion studies, with 100% correct identification. In other words, one out of every 37 sensors may not be detected due to reasons other than non-adherence.

Ingestible Sensor

Pill with Ingestible Sensor inside

Mobile Device & App

Your wearable sensor stores your data and regularly sends it to the mobile application for display to help you keep track of how you are doing, your activity and your rest patterns.

Sensor-Enabled Pill

The ingestible sensor is embedded inside a placebo pill and communicates with your mobile device. The ingestible sensor after it reaches your stomach.

Wearable Sensor Patch

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Troubleshooting

If you experience difficulties in operating your Proteus products, refer to the troubleshooting tables below or contact technical support.

Mobile Device

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
</table>
| Your Mobile Device screen is dark. | Option 1: Press the power button once.  
Option 2: Connect your Mobile Device to your power charger and plug it in. |
| Your Mobile Device is on, but it does not respond to touch. | Option 1: Unlock the Mobile Device screen. Refer to the Mobile Device manual for specific instructions.  
Option 2: Restart your Mobile Device: press and hold the power button to turn your Mobile Device off and press and hold the button to turn it back on. |
| You do not see any new data. | Option 1: Open App and check your patch status.  
Option 2: Restart your Mobile Device: press and hold the power button to turn your device off and press and hold the button to turn it back on. |

Wearable Sensor Patch

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>You have visible skin changes, e.g. rash or blistering, around the patch.</td>
<td>Remove your patch. Seek medical attention. Do not use another patch until told to do so by your healthcare provider.</td>
</tr>
<tr>
<td>Your patch is intolerably itchy or uncomfortable (no visible skin changes).</td>
<td>Remove your patch and put a replacement in a new location.</td>
</tr>
<tr>
<td>Your patch no longer sticks to your skin. Your patch is falling apart.</td>
<td>Replace with a new patch.</td>
</tr>
</tbody>
</table>

Sensor-Enabled Pill

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Pill gets wet or damaged.</td>
<td>Do not take. Swallow a replacement Pill if provided.</td>
</tr>
<tr>
<td>The Pill is chewed before swallowing.</td>
<td>Swallow a replacement Pill if provided.</td>
</tr>
</tbody>
</table>

Cautions

General

DO check the component expiration dates before use.  
DO 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 device, 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 wearable sensor 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 wearable sensor patch for clinical decision-making.

Sensor-Enabled Pill

DO NOT chew.  
DO NOT tamper with or place in water before ingestion.  
DO NOT exceed 30 ingestions per day.  
DO take with a sufficient amount of water.

Wearable Sensor Patch

DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor.  
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 wearable sensor patch.  
DO NOT use if you are allergic to adhesive tape.  
DO NOT wear the same wearable sensor patch for longer than one week.

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.

Body Position Definition

<table>
<thead>
<tr>
<th>Position</th>
<th>Angle</th>
<th>Depiction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upright</td>
<td>+90.0° through +67.6°</td>
<td><img src="image" alt="Upright" /></td>
</tr>
<tr>
<td>Leaning</td>
<td>+67.5° through +30.1°</td>
<td><img src="image" alt="Leaning" /></td>
</tr>
<tr>
<td>Flat</td>
<td>+30.0° through -29.9°</td>
<td><img src="image" alt="Flat" /></td>
</tr>
<tr>
<td>Upside Down</td>
<td>-30.0° through -90.0°</td>
<td><img src="image" alt="Upside Down" /></td>
</tr>
</tbody>
</table>

Wearable Sensor Specifications

- Battery: Coin Cell  
- Charge Time: 5 – 7 days  
- Storage Conditions: 5 – 7 days  
- Ingress Protection rating of IP27  
- Humidity range: 5 – 7 days  
- Temperature range: 5 – 7 days  

Electromagnetic & Other Interferences

The wearable sensor patch has been tested and deemed in conformance with the relevant requirements in EN60601-1-2-2007 Class B for Electromagnetic Compatibility (EMC).

Equipment Symbols

- Batch code  
- Serial number  
- Catalogue number  
- European Authorized Representative  
- Manufacturer  
- Read instructions before use  
- Type BF applied part  
- Emissions (radio waves)  
- Single use only  
- Temperature range  
- Humidity range  
- Atmospheric Pressure range  
- Use by yyyy-mm  
- Do not dispose with household waste  
- Ingress Protection rating of IP27

Additional Information

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