Introduction
Your Proteus Digital Health Feedback Device consists of a mobile application, a wearable sensor patch (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 ingestible sensor. All collected data are securely transferred and stored in Proteus’ databases. Your patch 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.

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

Connecting a Patch

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

**Patch Placement**
Once your patch is connected to your mobile device, you may place it on your body.

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

Ingestible Sensor Pill
The ingestible sensor 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 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-reported events, including events signaled by the co-occurrence 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 patch studies representing 6,407 patch-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 patch 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.

**The Patch**
Your 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 patch 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.

Ingestible Sensor Pill
Troubleshooting

If you experience difficulties in operating your Proteus products, refer to the troubleshooting tables below or contact customer support at 855-255-5858.

Mobile Device

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Mobile Device screen is dark.</td>
<td>Option 1: Press the power button once.</td>
</tr>
<tr>
<td></td>
<td>Option 2: Connect your Mobile Device to your power charger and plug in.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Your Mobile Device is on, but it does not respond to touch.</td>
<td>Option 1: Unlock the Mobile Device screen. Refer to the Mobile Device manual for specific instructions.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>You do not see any new data.</td>
<td>Option 1: Open App and check your patch status.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
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<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
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<tbody>
<tr>
<td>Your patch is intolerably itchy or uncomfortable (no visible skin changes).</td>
<td>Replace with a new patch.</td>
</tr>
<tr>
<td>Your patch no longer sticks to your skin.</td>
<td>Replace with a new patch.</td>
</tr>
<tr>
<td>Your patch is falling apart.</td>
<td>Replace with a new patch.</td>
</tr>
</tbody>
</table>

Ingestible Sensor 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>
</tbody>
</table>

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>+90.0°</td>
</tr>
<tr>
<td>Leaning</td>
<td>+67.5° through +30.1°</td>
<td>+67.5°</td>
</tr>
<tr>
<td>Flat</td>
<td>+30.0° through -28.9°</td>
<td>+30.0°</td>
</tr>
<tr>
<td>Upside Down</td>
<td>-30.0° through -90.0°</td>
<td>-30.0°</td>
</tr>
</tbody>
</table>

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 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 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.

Ingestible Sensor Pill

DO NOT chew.

DO NOT tamper with or place in water before ingestion.

DO NOT exceed 30 ingestions per day.

Take with a sufficient amount of water.

Patch

DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the patch.

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 patch.

DO NOT use if you are allergic to adhesive tape.

DO NOT wear the same 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.

Patch Specifications

<table>
<thead>
<tr>
<th>Battery</th>
<th>Coin Cell</th>
</tr>
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<tbody>
<tr>
<td>Data Recording Time</td>
<td>5 – 7 days</td>
</tr>
<tr>
<td>Storage Conditions</td>
<td>Original package at temperatures between 15 °C to 30 °C</td>
</tr>
<tr>
<td>Water Resistant</td>
<td>3.3 Foot (1 meter)</td>
</tr>
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</table>

Electromagnetic & Other Interferences

The patch has been tested and deemed in conformance with the relevant requirements in EN50601-1-2:2007 Class B for Electromagnetic Compatibility (EMC).

Equipment Symbols

- Batch code
- Serial number
- Catalogue number
- Quantity
- Model 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 or YYYY-MM-DD

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