The Proteus Patch, also called the Patch, is a body-worn sensor that collects physiological and behavioral metrics such as heart rate, activity, body angle and time-stamped user-logged events generated by swallowing the Proteus ingestible sensor. The ingestible sensor is embedded inside an inactive tablet (the Pill) for ease of handling and swallowing. Once the ingestible sensor reaches your stomach, it activates and communicates its presence to the Patch. The Patch stores, and wirelessly communicates this information along with your physiological and behavioral data to a mobile computing device for display.

**The Pill**

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

**The Patch**

The Patch is a body-worn sensor that detects signals from the ingestible sensor and records when the ingestible sensor has been taken. The Patch also records physiological and behavioral metrics such as heart rate, activity, body angle and time-stamped user-logged events generated by swallowing the Proteus ingestible sensor. All data are periodically transferred to the computing device. The Patch may be worn during most activities including exercising and bathing. The Patch should be changed weekly or sooner as needed.

**Patch button**

Press and hold the patch button for 3 seconds to initiate communication to Mobile Computing Device.

**Indicator light**

A blinking green light indicates that the communication to the Mobile Computing Device has begun.

**Safety and Performance**

The ingestible sensor was extensively tested in clinical studies. Overall, 492 (Age range 21–85, Mean: 44.6) volunteers 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 20,953 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.

**Replacing a Patch**

To Start, launch the app, then...

1) Tap on the arrow to open the Wearable Sensor screen.

2) Tap the “Connect” button and follow the instructions provided on the screen.

**1. Remove**

Pull the used Patch away from your skin. Do not discard until your new Patch is connected.

**2. Connect**

Follow instructions in the application to connect a new Patch.

**3. Place**

When you are connected:

1. Select a location on the left side of your body just above the lower edge of your rib cage (see indicated areas in figures).

   - Avoid locations:
     - Where undergarments may press against the Patch.
     - Where your previous Patch was just removed.

2. Prepare your skin by using clippers to trim any hair from the selected location. Gently pat the location you have selected with an alcohol wipe. Wait for your skin to dry.

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

4. Dispose

Finally, check status of the previously removed used Patch on your Mobile Computing Device. When the data transfer is complete, dispose of the used Patch as you would any household battery or electronics (please check your local electronic waste disposal standards).
TROUBLESHOOTING
If you experience difficulties in operating your Proteus products, refer to the troubleshooting tables below or contact technical support.

THE PATCH

**PROBLEM**
The Patch feels hot.

**SOLUTION**
Remove immediately and replace with a new Patch.

**PROBLEM**
You have skin irritation around the Patch.

**SOLUTION**
Remove the Patch. Seek medical attention. Do not use another Patch until told to do so by your healthcare provider.

**PROBLEM**
The Patch is intolerably itchy or uncomfortable.

**SOLUTION**
Remove the Patch and put a replacement in a new location.

**PROBLEM**
The Patch no longer sticks to your skin. The Patch is falling apart.

**SOLUTION**
Replace with a new Patch.

**PROBLEM**
The indicator light does not flash upon push and hold.

**SOLUTION**
Replace with a new Patch.

**PROBLEM**
You do not see any new data.

**SOLUTION**
Open your Proteus application. Visit the Patch view in the Feedback System to check your Patch battery and skin contact.

**THE PILL**

**PROBLEM**
The Pill gets wet or damaged.

**SOLUTION**
Do not take. Swallow a replacement Pill if provided.

**PROBLEM**
The Pill is chewed before swallowing.

**SOLUTION**
Swallow a replacement Pill if provided.

**THE MOBILE COMPUTING DEVICE**

**PROBLEM**
The Mobile Computing Device screen is dark.

**SOLUTION**
OPTION 1: Press the power button once.

OPTION 2: Press and hold the power button for six seconds.

OPTION 3: Connect the Mobile Computing Device to your power charger and plug it in.

**PROBLEM**
The Mobile Computing Device is on, but it does not respond to touch.

**SOLUTION**

OPTION 2: Restart your Mobile Computing Device: press and hold the power button to turn the Mobile Computing Device off and press and hold the button to turn it back on.

**PROBLEM**
You do not see any new data.

**SOLUTION**
OPTION 1: Open your Proteus application. Visit the Patch view in the Feedback System to check your Patch battery and skin contact.

OPTION 2: Restart your Mobile Computing Device: press and hold the power button to turn the device off and press and hold the button to turn it back on.

CAUTIONS

**GENERAL**
DO NOT store components in extremely hot, cold, humid or bright conditions.

DO NOT use for medication treatment decisions. Accuracy is less than 100%. Contact your physician with any questions or concerns regarding medication use.

DO check the component expiration dates before use.

DO keep components out of reach of children.

Proteus Digital Health makes no warranty for any data or information that is intentionally 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. The ingestible sensor and/or Patch are not to be used to screen or to diagnose disease. 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.

**THE 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.

**THE 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 airplane travel.

DO NOT wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.

**THE MOBILE COMPUTING DEVICE**

DO NOT start patch change.

Remember: Use mobile device to start patch change.

ADDITIONAL INFORMATION

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

PATCH SPECIFICATIONS

<table>
<thead>
<tr>
<th>Battery</th>
<th>Coin cell</th>
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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 under normal room temperature and humidity</td>
</tr>
<tr>
<td>Water Resistant</td>
<td>Yes</td>
</tr>
</tbody>
</table>

ELECTROMAGNETIC & OTHER INTERFERENCES

The 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

Instructions For Use

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