PILLSENSE™
GI BLEED DETECTION SYSTEM

Quick Reference Guide

The PillSense system consists of an ingestible blood-diagnostic capsule for the detection of blood in the upper GI tract and a wireless receiver to display real-time results. The capsule and the receiver are packaged separately.

PillSense is contraindicated in patients with the following conditions: hemodynamic shock; cardiac pacemaker or other implanted electronic device; known or suspected gastrointestinal obstructions, strictures, or fistulas; Crohn's disease (CD) and/or other inflammatory bowel disorders; gastroparesis; swallowing disorder or difficulties in swallowing the capsule.

Step 1

Power on the receiver by depressing the power button on the side of the receiver.

The button will light up when the receiver is powered on.

Note: Ensure the receiver is charged. Do not use the receiver while it is plugged into a wall outlet.
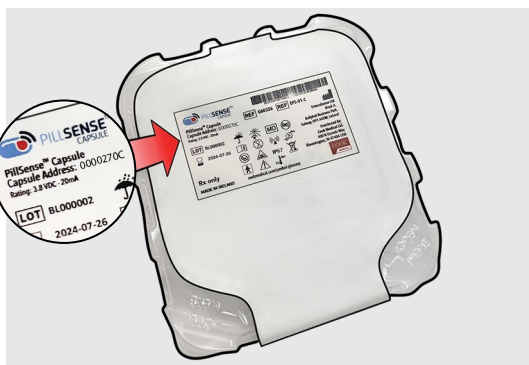
Step 2

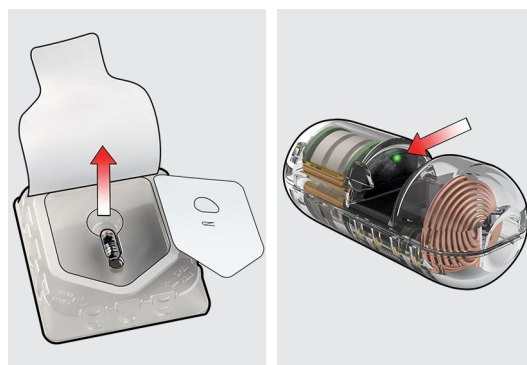To begin a new session, select **START NEW MONITORING**.

Step 3

Use the provided stylus to enter the patient ID and select **OK**. To proceed, select **CONTINUE**.

Step 4

Add the PillSense capsule address, taken from the capsule packaging label, to the patient record and the patient card.
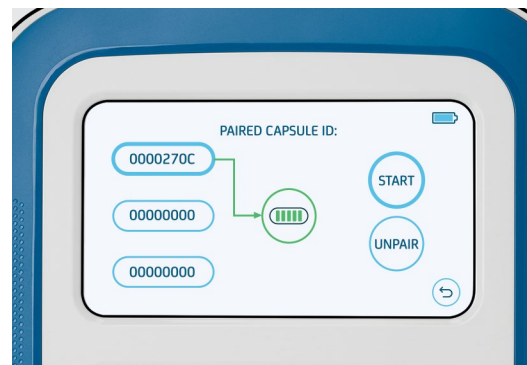
Step 5

Activate the capsule by removing it from the tray.

Note: When removed from the tray, the capsule will have a blinking LED. This indicates the capsule has been activated and is ready to pair.

Warning:
- Do not open the capsule tray until just before use.
- Ensure the magnet remains in the tray.
- Inspect the capsule for any visible crack or damage.
- Let's make this its own bullet point.
- Do not use a damaged capsule.
- Do not drop the capsule.
- Dispose of dropped capsules.

Step 6

On the pairing screen, select the capsule address that is shown on the capsule's packaging label. This will allow the receiver to perform a quick system check and confirm the capsule is communicating with the receiver. If the system check fails, select **UNPAIR** and restart the procedure with a different capsule.
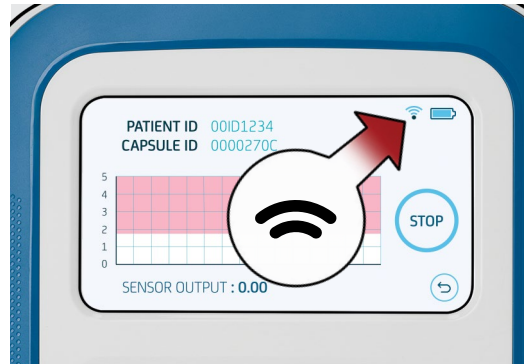
Step 7

Instruct the patient to swallow the capsule with a full glass of water (minimum of 150 mL or 5 ounces).

After they have swallowed the capsule, instruct the patient to lie on their **left side** for the duration of the monitoring session.

Patient warning:

- Ensure the patient does not swallow a capsule that has not been paired successfully.
- The patient should avoid biting the capsule.
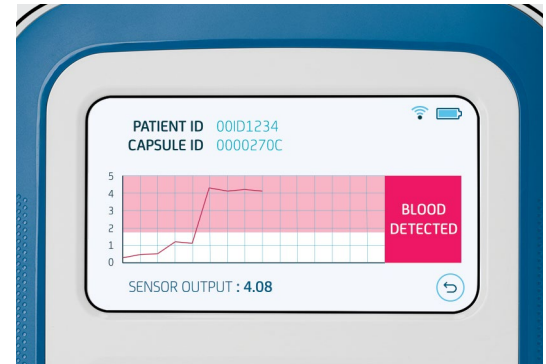- Ensure the patient drinks the recommended volume of water, at a normal pace.

Step 8

Once the patient is lying down, tap **START** to initiate the monitoring session. A screen will now show you the monitor display and time. During use, ensure the receiver stays close to the patient and that there are no obstructions (such as another person or object) between the patient and the receiver.
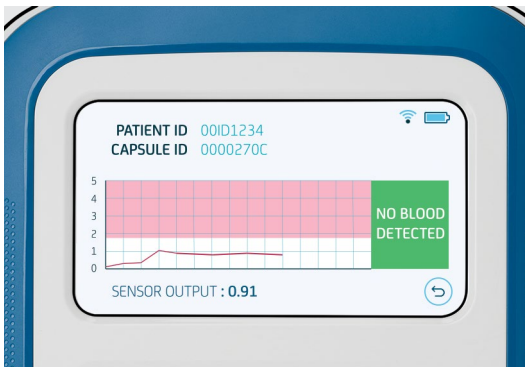
Note: If communication is lost during monitoring, a crossed-out gray signal will appear. Move the receiver closer to the patient until a blue signal appears on the screen.

Step 9

If blood is detected in the upper GI tract, a message will immediately appear on the screen stating **BLOOD DETECTED**. At this point, you may choose to stop the monitoring session.

Step 10

If blood is not detected in the upper GI tract, a message will appear on the screen stating **NO BLOOD DETECTED**.

The monitoring session will automatically stop after 10 minutes.

To stop the monitoring session early, press and hold **STOP** and select **TERMINATE**. Turn off the receiver by pressing the **POWER** button.

Note: A minimum of 5 minutes of monitoring is required to get a **NO BLOOD DETECTED** result. If the session ends before 5 minutes, a message will appear on the screen in an **orange** box stating **INCONCLUSIVE RESULTS**.

Note: Wipe the receiver clean after every use.

Please refer to the product's Instructions for Use (IFU) for full prescribing information, warnings, precautions, contraindications, and potential adverse events.

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