



Instructions for Use

Otsuka Digital Feedback Device

Customer support

Otsuka America Pharmaceutical, Inc.
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Rx Only

LBL-0555, Rev 1, 15Dec2022

Introduction

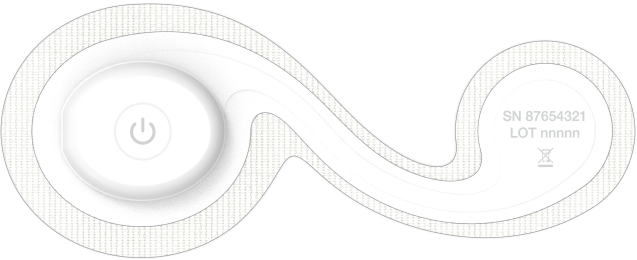
Your Otsuka Digital Feedback Device consists of a mobile application (App), a patch and ingestible sensors.

Your patch is worn on your torso and collects physiological and behavioral metrics such as heart rate, activity, and body position. 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, when your medication is taken along with the ingestible sensor.

All collected data are securely transferred and stored in controlled databases.

The tiny ingestible sensor is made out of ingredients found in the human diet. The ingestible sensor is contained inside a placebo pill. The ingestible sensor sends a signal to the patch after it reaches your stomach.

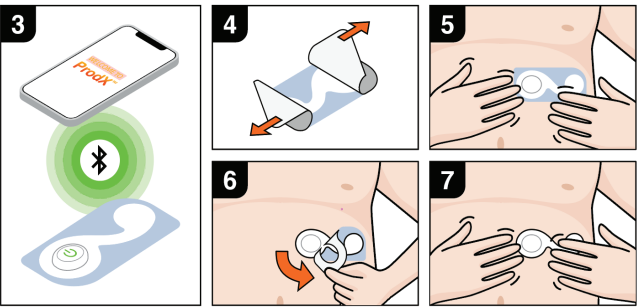
Patch



The patch is changed weekly. It sticks to the skin on your torso and contains a small battery that powers the patch. Your patch records the time the ingestible sensor is detected. 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. Your patch can be worn during most activities, including showering and exercising. Before placing a patch, ensure the skin on your torso is free of hair, clean, dry, and healthy. Do not apply lotion on your torso before applying a new patch.

Patch application

1. Clean and dry an area above your belly button on either side of your ribcage.
2. Take a patch out of its packaging. Place it in front of you.
3. Ensure Bluetooth is enabled from your phones' "Settings" and have the Digital Feedback Viewer (app) ready to be launched.
 - Hold down on the power button of your patch until you see a blinking light. Once the light on the patch starts blinking, launch the Digital Feedback Viewer.
 - Click on "Start Scan" button and wait for the "Patch-DT-XXXXXXX", representing the patch serial number, to appear.
 - Once the patch serial number appears, click "Stop Scan" followed by "Connect".
 - Click on "Pair" button when the pairing pop-up appears.
4. Carefully remove just the white liners from the center of the patch while holding the blue backing. Helpful tip: Avoid the sticky adhesive by holding the patch by the blue backing.
5. Stand up straight and hold the patch by the blue backing. Place the sticky side of the patch on the left or right side you cleaned earlier. Gently smooth the patch in place.
6. Remove the blue backing from your patch.
7. Gently smooth down your patch to secure it to your skin.



Patch disposal

Replace your patch about once a week or as prompted by your app. Your patch contains a battery. It should be disposed of in the same way as household batteries or electronics. Please check local electronic waste disposal standards.

Patch specifications

Battery: Coin Cell

Patch Wear Duration: Approximately 7 days

Storage Conditions:

Patch	Temperature	Humidity
>30 days	+5°C(+41°F) - +27°C(+80.5°F)	15% - 93%
<30 days	+0°C(+32°F) - +40°C(+104°F)	15% - 93%

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 patch complies with ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010 (Biological evaluation of medical devices).
- This patch complies with IEC 60601-1-2:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+A1:2020, IEC 60601-1-11:2015+A1:2020, and IEC 60601-1-6:2010+A1:2013+A2:2020 (Safety of medical electrical equipment).
- This patch has no essential performance (if the device is compromised there is no unacceptable risk to the user).
- This patch complies with RoHS.
- **The patch does not contain natural latex rubber.**
- The patch contains no serviceable parts or components.

Indications for use

The Otsuka Digital 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 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 Otsuka Digital 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 Otsuka Digital 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 pill

- 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 told by a physician to take an Ingestible Sensor with medication may choose to only take one or the other. Therefore, Ingestible Sensor data should be interpreted with caution. Physicians should discuss with patients how they take their medications before making medication changes.
- Otsuka America Pharmaceutical, Inc. makes no warranty for any data or information that is collected erroneously by the device. Otsuka America Pharmaceutical, Inc. makes no warranty for any misuse or malfunction due to abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Seek medical attention if your clinical condition gets worse or you have new symptoms when using the ingestible sensor or patch. Healthcare providers should use their clinical judgment in interpreting and using any data from the ingestible sensor and/or patch to make clinical decisions.
- Heart rate data may not be accurate for patients with pacemakers.

Ingestible sensor pill

- Take the ingestible sensor pill with plenty 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** use if you are allergic to adhesive tape.
- **DO NOT** place in locations where your skin is scraped, cracked, inflamed or irritated.
- **DO NOT** place on the same area of skin as the most recently removed patch.
- **DO NOT** wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.
- **DO NOT** continue to use if your skin is irritated or inflamed around the patch. Contact your physician.
- **DO NOT** drop or bump with excessive force.
- **DO NOT** use to diagnose heart-related conditions.
- **DO NOT** dispose of patches with household waste.
- Patch does not contain medication.

Please be aware...

- **WARNING:** No modification of this equipment is allowed. Modifying the patch may cause a safety hazard for the user.
- The patch needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the "LBL-0556 Otsuka Digital Feedback Device Technical Description, Patch" document.
- Portable and mobile RF communications equipment can affect the Patch. Portable and mobile RF 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.

Additional information

For more detailed technical information, please see document "LBL-0556 Otsuka Digital Feedback Device Technical Description, Patch".

Troubleshooting

For support using your patches or ingestible sensor pills, see the solutions below. Otherwise contact customer support.

Patch

Problem

You have visible skin changes, e.g. rash or blistering, around the patch.

Solution

Remove your patch from your torso. Seek medical attention. Do not use another patch until told to do so by your healthcare provider.

Problem

Your patch is itchy or uncomfortable or no longer sticks to your skin (no visible skin changes).

Solution

Remove your patch from your torso. Place the new patch on your torso in a new location.

Problem

The green light does not appear on patch when button is pressed.
Solution
Press and hold the button longer (>3 seconds) until green light appears. If the green light still does not appear, try a new patch. If green light still does not appear, contact Customer Support.

Ingestible sensor pill

Problem

The ingestible sensor pill gets wet or damaged.

Solution

Do not take ingestible sensor pill

Equipment symbols

LOT	Batch code
SN	Serial number
REF	Catalog number
QTY	Quantity
MODEL	Model number
	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
IP27	Ingress Protection rating of IP27
	General warning
FCC	Federal Communications Commission ID