

MYCITE® Patch (wearable sensor) Technical Description

This *Technical Description* refers only to the MYCITE® Patch (wearable sensor).

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Table of Contents

| | | |
|------|---|---|
| 1. | Intended Use | 2 |
| 2. | Description..... | 2 |
| 3. | Important Safety Warnings and Precautions | 2 |
| 5. | Patch Specifications..... | 3 |
| 5.1. | Product Identification | 3 |
| 5.2. | Environmental Specifications..... | 4 |
| 5.3. | Compliance to IEC 60601-1 | 4 |
| 5.4. | Compliance to ANSI/AAMI EC13:2002..... | 4 |
| 5.5. | Compliance to other Standards | 5 |
| 5.6. | Functional Specifications..... | 5 |
| 5.7. | Bluetooth® Wireless Technology Specifications | 5 |
| 5.8. | EMC Information..... | 5 |
| 6. | Conformance with EU Requirements | 8 |
| 7. | FCC Declarations..... | 8 |
| 7.1. | FCC Interference Statement..... | 8 |
| 7.2. | FCC Wireless Notice..... | 9 |
| 7.3. | FCC Identifier | 9 |
| 8. | Manufacturer | 9 |

1. Intended Use

The MYCITE® Patch (wearable sensor), when used with a tablet embedded with an Ingestible Event Marker (IEM) sensor, is intended to track drug ingestion in adults.

2. Description

The MYCITE® Patch (wearable sensor) works through three connected parts: a two-part patch consisting of a data pod and adhesive strip, a tablet with an embedded Ingestible Event Marker (IEM) sensor and a mobile application.

The patch is a miniaturized, wearable sensor for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, and body angle relative to gravity (body position).

Upon ingestion of the tablet embedded with the IEM sensor, the sensor communicates with the MYCITE® Patch to record and transmit ingestion data to a mobile patient application (app). The patch stores the data and regularly sends it to the mobile application for display.

The compatible mobile app display allows the patient to review their medication ingestion. The data can also be shared with healthcare providers and caregivers.

The patch sticks to the skin on the torso and contains a small battery that powers the data pod. The pod and adhesive strips do not contain medication. The data pod can be used for weeks, or months, at a time. The adhesive strip is changed weekly.

The patch can be worn during most activities, including showering and exercising. Before placing the adhesive strip, ensure the skin on the torso is free of hair, clean, dry, and healthy. Do not apply lotion before applying a new adhesive strip.

Clean the data pod using household soap and water.

The patch contains no serviceable parts or components.


















The MYCITE® Patch (wearable Sensor) does not contain natural latex rubber.

3. Important Safety Warnings and Precautions

- Check the expiration date printed on the MYCITE® Patch (wearable sensor) packaging before use.
- DO NOT use if any part of device system is damaged, torn or expired.
- DO NOT use patch if allergic to adhesive tape.
- Stop use if skin is irritated or inflamed around the adhesive strip and consult physician.
- DO NOT apply to areas where skin is scraped, cracked, inflamed or irritated.
- DO NOT apply on the same area of skin as the most recently removed adhesive strip.
- DO NOT wear during magnetic resonance imaging (MRI), cautery or external defibrillation procedures.
- Keep MYCITE® Patch (wearable sensor) components out of the reach of children.
- Do not store components in extremely hot, cold, humid or bright conditions.
- Avoid dropping or bumping. Excessive impact can damage the device.
- Do not throw out the data pod: keep it for use with the next adhesive strip.
- Do not dispose of adhesive strips with household waste. Dispose in accordance with applicable local regulations.

- There may be a delay in the detection of the tablet and sometimes the detection of the tablet might not happen at all. The use of the MYCITE® Patch (wearable sensor) to track drug ingestion in “real-time” or during an emergency is not recommended because detection may be delayed or not occur. Users of the tablet embedded with 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 the ingestible sensor and/or patch for clinical decision-making.

4. Equipment Symbol Glossary

| | |
|---|--------------------------------------|
|  | Batch code |
|  | Serial number |
|  | Catalog 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-DD |
|  | Do not dispose with household waste |
| IP27 | Ingress protection rating of IP27 |
|  | General warning |
| FCC | Federal Communications Commission ID |

5. Patch Specifications

5.1. Product Identification

The MYCITE® Patch (wearable sensor) is approved for use in the ABILIFY MYCITE® System by the Food and Drug Administration (FDA) under a supplemental New Drug Application (sNDA).

For information regarding ABILIFY MYCITE® (aripiprazole tablets with sensor), refer to the [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

Patch Model#  SPC-1913, SPC-2540

5.2. Environmental Specifications

Temperature:

| | |
|--------------------------------|------------------------------|
| Operating: | 5°C – 40°C (41°F – 104°F) |
| Storage/Transportation, Pod: | -25°C – 70°C (-13°F – 158°F) |
| Storage/Transportation, Strip: | 5°C – 27°C (41°F – 80.5°F) |
| Short term (< 30 days) | |
| Storage/Transportation, Strip: | 0°C – 40°C (+32°F – 104°F) |

Humidity:

| | |
|--------------------------------|----------------------------|
| Operating: | 15% - 93% (non-condensing) |
| Storage/Transportation, Pod: | 15% - 93% (non-condensing) |
| Storage/Transportation, Strip: | 15% - 93% (non-condensing) |


Altitude:

| | |
|------------|--------------------|
| Operating: | 700 hPa – 1060 hPa |
|------------|--------------------|

5.3. Compliance to IEC 60601-1

The MYCITE® Patch (wearable sensor) has been evaluated and deemed compliant with all the applicable requirements of:

- IEC 60601-1: 2005 + A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1-11: 2015
- IEC 60601-1-6: 2010+A1:2013

| | | |
|---|--|---|
| Degree of Protection: | Type BF applied Part |  |
| Protection against Electrical Shock: | Internally powered medical equipment | |
| Mode of Operation: | Continuous | |
| Enclosure degree of Ingress Protection: | IP27 (waterproof to 1m – 3.3 feet) | IP27 |
| Essential Performance: | This device has no essential performance (if the device is compromised, there is no unacceptable risk to the user) | |
| Use Environment: | The MYCITE® Patch is intended to be used in a home healthcare environment | |

5.4. Compliance to ANSI/AAMI EC13:2002

The MYCITE® Patch (wearable Sensor) has been evaluated and deemed compliant with all the applicable requirements for heart rate meters of ANSI/AAMI EC13:2002 cardiac monitors, heart rate meters, and alarms.

| | |
|--------------------------------|---|
| Heart rate range: | 30 to 250 bpm |
| Heart rate averaging: | Averaged over 14 seconds |
| Heart rate response time: | Up to 5 mins, depending on patch operating mode |
| Response to Irregular Rhythms: | |
| Ventricular Bigeminy (VB) | 80 bpm |
| Slow Alternating VB | 60 bpm |

| | |
|----------------------------|--|
| Rapid Alternating VB | 120 bpm |
| Bidirectional Systole | 90 bpm |
| Pacemaker pulse rejection: | Heart rate data may not be accurate for patients with pacemakers |

5.5. **Compliance to other Standards**

- The MYCITE® Patch (wearable sensor) has been evaluated and deemed compliant with all the applicable requirements of ISO 10993-1-2009, ISO 10993-5-2009, ISO-10993-10-2010 (biological evaluation of medical devices).
- The MYCITE® Patch (wearable sensor) has been evaluated and deemed compliant with all the applicable requirements of JIS S7200 Pedometers.
- MYCITE® Patch (wearable s) packaging materials meet the transit requirements per ASTM D4169, distribution cycle 16, Assurance Level II.
- This product complies with all applicable provisions of the EU Restriction of Hazardous Substances directive (RoHS).
- This product complies with all applicable provisions of the EU Medical Device Directive (MDD).

5.6. **Functional Specifications**

| | |
|------------------------|---|
| Battery (in strip): | CR2016 Lithium Manganese Dioxide coin cell (3V) |
| Battery capacity: | Sufficient for at least 7 days of use |
| Patch memory capacity: | Sufficient for at least 14 days of continuous recording w/o uploads |

5.7. **Bluetooth® Wireless* Technology Specifications**

| | |
|----------------------|--|
| Compliance: | Version 4.0 single mode low energy |
| Operating Frequency: | 2.4 to 2.4835 GHz |
| Output Power: | TX: -15dBm (P=0.03125mW) |
| Effective Bandwidth: | 1.25 MHz |
| Modulation: | Frequency hopping using GFSK (Gaussian Frequency Shift Keying) |

5.8. **EMC Information**

| | |
|---------------------------|-----------------------|
| RF Emissions: | CISPR 11 Group 1 |
| RF Environment: | CISPR 11 Class B |
| RF Interference Immunity: | IEC 61000-4-3 Level 3 |
| ESD Discharge Immunity: | IEC 61000-4-2 Level 4 |

The MYCITE® Patch (wearable sensor) uses Radio Frequency (RF) energy for its internal function. Its RF emissions are, however, very low and are not likely to cause any interference in nearby electronic equipment. This device is suitable for use in all establishments, including domestic.

The device should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories, sensors, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Table 1.

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|-------------------|--|
| The MYCITE® Patch (wearable sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of patch should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The patch uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The patch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | |

Table 2.

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---------------------------------|---|
| The MYCITE® Patch (wearable sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the patch should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 8kV contact +/- 15kV air | +/- 8kV contact +/- 15kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient / burst IEC 61000-4-4 | +/- 2 kV for power supply lines +/- 1 kV for input/output lines | Not applicable | N/A |
| Surge IEC 61000-4-5 | +/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth | Not applicable | N/A |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s | Not applicable | N/A |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE : UT is the a.c. mains voltage prior to application of the test level. | | | |

Table 3.


| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|--|-------------------------------------|---|
| The MYCITE® Patch (wearable sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the patch should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>10V/m 80 MHz to 2,5 GHz</p> | <p>Not Applicable</p> <p>10 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the patch, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>Not Applicable</p> <p>$d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the patch is used exceeds the applicable RF compliance level above, the patch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the patch.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

Table 4.

| Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MYCITE® Patch (Wearable Sensor) | | | |
|---|---|---|--|
| The MYCITE® Patch (wearable sensor) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the patch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the patch as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter | | |
| | 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2,3 \sqrt{P}$ |
| 0.01 | Not applicable | 0.1 | 0.23 |
| 0.1 | Not applicable | 0.4 | 0.74 |
| 1 | Not applicable | 1.2 | 2.3 |
| 10 | Not applicable | 3.7 | 7.4 |
| 100 | Not applicable | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. | | | |
| NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

6. Conformance with EU Requirements

Hereby, Otsuka America Pharmaceutical, Inc., declares that the MYCITE® Patch (wearable sensor) complies with the essential requirements and other relevant provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices and the Radio Equipment Directive 2014/53/EU. The product is compliant with the following standards and/or other normative documents:

| | |
|-----------------------------|--|
| Safety (art. 3.1a): | EN 60601-1: 2006 + A1: 2013, IEC/ EN 60601-1-11: 2015 |
| EMC (art. 3.1b): | EN 301 489-1/-17, V2.1.1/ V3.1.1 |
| Spectrum (art. 3.2): | EN 300 328 v2.1.1 |
| Other: | EN 60601-1-2 (2015) EN 60601-1-6: 2010/A1:2015 |

7. FCC Declarations

7.1. FCC Interference Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Otsuka America Pharmaceutical, Inc. could void your authority to operate the equipment.

7.2. **FCC Wireless Notice**

This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

7.3. **FCC Identifier**

FCC ID: X7901913

8. **Manufacturer**



Otsuka America Pharmaceutical, Inc.

3956 Point Eden Way
Hayward, CA 94545
USA

ABILIFY MYCITE® and MYCITE® are registered trademarks of Otsuka Pharmaceutical Co., Ltd.

*Bluetooth® Wireless is a registered trademark of Bluetooth SIG, Inc.

©2020 Otsuka America Pharmaceutical, Inc. All rights reserved.

March 2021

12US21EBC0034