Proteus Patch

Technical Description

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1. Product Identification

Two-Part Patch REF SPC-2005, SPC-2008

The Proteus Two-Part Patch is categorized as a Class II device under The Food and Drug Administration's regulations (in US), and as a Class IIa device, under the Medical Device Directive (in EU).

2. Manufacturer

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3. Indications for Use

The Proteus® Digital Health Feedback Device consists of a miniaturized, wearable sensor (Proteus 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 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.

4. Description

The two-part patch is made up of a reusable pod and a replaceable adhesive strip. The pod captures information and sends this to an app. It can be used for weeks or months at a time. The pod is worn on the torso using the adhesive strip. The strip contains a small coin cell battery to provide power to the pod, and is changed weekly for comfort and a fresh battery.

The pod measures heart rate, activity, body angle relative to gravity (body position) and the time of ingestible sensor detection. The pod is connected with a mobile device via Bluetooth®, using a mobile application (app), such as Proteus Discover.

Your app will prompt you when it is time to change your patch strip. Always refer to your app when changing your strip to ensure your patch is put together correctly and connected with your mobile device.
The patch can be worn at anytime and during all your regular activities, including showering, exercising and on airplanes. However, after putting on a new patch avoid showering or exercising vigorously for a few hours to allow the patch to stick properly. How long it takes for a patch to stick varies from person to person. If your patch doesn't stick well wait a few hours longer when applying a new patch. Before placing, ensure the area of the skin is free of hair, dry, and healthy. Do not apply lotion before applying a new patch.

The patch can also measure ambient temperature. It is not intended to be used as a thermometer to measure human body temperature, and should not be used to diagnose medical conditions.

5. Cautions And Warnings

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

General

- Take the ingestible sensor pill with a sufficient amount of water.
- 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 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. 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.
- Heart rate data may not be accurate for patients with pacemakers

Ingestible sensor pill

- Do not chew.
- Do not tamper with or place in water before ingestion.
- Do not exceed 30 ingestions per day.

Two-part patch

- Do not continue use until further instructed by a physician if your skin is irritated, inflamed, or red around the replaceable adhesive strip.
- 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 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.
- Do not dispose of strips with household waste
- Do not throw out the pod: keep if for use with your next strip
- Pod may pose a choking hazard to children under 3 years of age.
- Patch does not contain medication.
- The device contains no serviceable parts or components
- Replace the strip about once per week or as prompted by mobile app.

Warning: No modification of this equipment is allowed. Modifying the Proteus Patch may cause a safety hazard for the user.

6. Equipment Symbols

LOT	Batch code
SN	Serial number
REF	Catalog number
EC REP	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

7. Specifications

7.1. Environmental Specifications

Temperature:

Operating, Patch:	+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 tern (< 30 days)		
Storage/Transportation, Strip	+0°C – +40°C -	+32°F – 104°F
Humidity		
Operating, Patch:	15% - 93% (non condensing)	
Storage/Transportation, Pod	15% - 93% (non condensing)	
Storage/Transportation, Strip	15% - 93% (non condensing)	
Altitude		
Operating, Patch	700 hPa – 1060 hPa	

7.2. Compliance to IEC 60601-1

The Proteus Two-part Patch has been evaluated and deemed compliant with all the applicable requirements of:

IEC 60601-1 2005
IEC 60601-1-2 2014
IEC 60601-1-11 2010

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 (water proof to 1m – 3.3 feet) **IP27**
Essential Performance:	The essential performance of this device is defined as biocompatibility of the patch materials, as established by compliance to the ISO 10993 series of standards
Use Environment	The Proteus Two-part Patch is intended to be used in the Home Healthcare environment

7.3. Compliance to ANSI/AAMI EC13:2002

The Proteus Two-part Patch has been evaluated and deemed compliant with all the applicable requirements for heart rate meters of ANSI/AAMI EC13:2002 Cardiac monitors, hear 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 Rythms:	
Ventricular Bygeminy (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

7.4. Compliance to other Standards

- The Proteus Two-part Patch 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 Proteus Two-part Patch has been evaluated and deemed compliant with all the applicable requirements of JIS S7200 Pedometers

- 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)
- The pod and strip do not contain natural latex rubber
- Strip and Pod packaging materials meet the meet transit requirements per ASTM D4169, distribution cycle 13, Assurance Level II.

7.5. Patch 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

7.6. Blutooth® 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)

7.7. 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 two-part Patch uses 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.

The patch needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

WARNING: Portable and mobile RF communications equipment can affect the Patch. Portable and mobile F 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.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Proteus Patch is intended for use in the electromagnetic environment specified below. The customer or the user of Proteus 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Proteus Patch 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	
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
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	
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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Proteus Patch is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus Patch should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Proteus Patch, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2,5 GHz 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 metres (m). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, 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.

[a] Field strengths 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 Proteus Patch is used exceeds the applicable RF compliance level above, the Proteus 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 Proteus Patch.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Proteus Patch

The Proteus Patch 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 Proteus 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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1{,}2\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
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 d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P 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.

8. European R&TTE Declaration of Conformity

Hereby, Proteus® Digital Health, Inc., declares that the Proteus two-part Patch is in compliance with the essential requirements and other relevant provisions of R&TTE (Radio and Telecommunications Terminal Equipment) Directive 1999/5/EC. The product is compliant with the following standards and/or other normative documents:

Safety (art. 3.1a):	***EN 60601-1, 3rd Ed, IEC 60601-1-11***
EMC (art. 3.1b):	***EN 301 489-17 v2.2.1***
Spectrum (art. 3.2):	***EN 300 328 v1.8.1***
Other:	***EN 60601-1-2 (2014)***

The Proteus two-part Patch can be used in all countries in the European Union.

9. FCC Declarations

9.1. 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 Proteus Digital Health could void your authority to operate the equipment.

9.2. 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.

9.3. FCC Identifier

FCC ID: X7901913