

THE FITWELL WEARABLE SENSOR  
SPC-0532  
SPC-0801  
SPC-1006  
USER SUPPLEMENTAL INFORMATION

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## 1. TECHNICAL INFORMATION

### 1.1 General

The Proteus® FitWell Wearable Sensor (Also known as FitWell Patch) is a not-for-medical-use device intended for Fitness and Wellness applications. The FitWell Wearable Sensor (WS) collects a variety of health and behavioral information.

Note:

Proteus Digital Health, Inc. is the manufacturer of both medical and non-medical devices. Although the FitWell Wearable Sensor device is not intended to be used for any medical purposes or therapy, the FitWell Wearable Sensor is built under more stringent quality standards used for Proteus Patch, the medical product. Hereby this equipment has been tested and found to comply with the limits for a Class B Medical Electrical Equipment.

### 1.2 Environmental Conditions

The Proteus FitWell Wearable Sensor is intended for storage and operation in a room-temperature environment.

| Condition | Temperature  | Humidity  | Pressure (Altitude)  |
|-----------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Operating | 20C – 28C                                                                                     | 15% - 93%                                                                                  | 700 hPa – 1060 hPa                                                                                      |
| Storage   | 15C – 30C                                                                                     | 15% - 93%                                                                                  | 700 hPa – 1060 hPa                                                                                      |
| Transport | 2C – 38C                                                                                      | 15% - 85%                                                                                  | 700 hPa – 1060 hPa                                                                                      |

### 1.3 Minimizing Skin Irritation

The Proteus FitWell Wearable Sensor has been designed to minimize the possibility of skin irritation. Observing these cautions will reduce the likelihood of skin irritation or bruising under the FitWell Wearable Sensor:

DO NOT continue use until further instruction by a physician if your skin is irritated or inflamed around the FitWell Wearable Sensor.

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 FitWell Wearable Sensor.

DO NOT use if you are allergic to adhesive tape.

DO NOT wear the same FitWell Wearable Sensor for more than one week.

DO NOT drop or bump with excessive force.

### 1.4 Protection against Ingress of Solids and Liquids

The Proteus FitWell Wearable Sensor has an Ingress Protection rating of IP27. This means that the enclosure has no penetrations and it has been rated for immersion in liquid up to 1m depth. For

continued safety, should the enclosure become penetrated or torn, remove the FitWell Wearable Sensor immediately and replace it with a new one.

IP27

### **1.5 Avoiding Unsafe Use Conditions**

The FitWell Wearable Sensor is a Fitness and Wellness device. The Proteus FitWell Wearable Sensor has not been tested or approved as safe for operation during air travel. DO NOT use the FitWell Wearable Sensor during air travel; it may interfere with the aircraft navigational instruments.

The Proteus FitWell Wearable Sensor has not been tested or approved for use in the presence of strong magnetic or electric fields. DO NOT wear the FitWell Wearable Sensor during magnetic resonance imaging (MRI), cautery, and external defibrillation procedures. Damage to the FitWell Wearable Sensor, your skin, or an unexpected magnetic attraction may result. Please inform your healthcare professional that the FitWell Wearable Sensor must be removed prior to engaging in one of these procedures.

**WARNING:** No modification of this equipment is allowed. Modifying the Proteus FitWell Wearable Sensor may cause a safety hazard for the user.

### **1.6 Information on Electromagnetic and Other Interferences**

The Proteus FitWell Wearable Sensor has been evaluated and deemed compliant with the requirements in EN60601-1-2 Class B for Electromagnetic Compatibility (EMC). Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The Proteus FitWell Wearable Sensor should not be used adjacent to or stacked with other electromagnetic equipment. If adjacent or stacked use with other electromagnetic equipment is necessary, verify that the Proteus FitWell Wearable Sensor operation is normal in the configuration(s) in which it will be used.

### **1.7 Information on the Radio Subsystem**

The Proteus FitWell Wearable Sensor incorporates a Bluetooth™ radio subsystem which is compliant with the Bluetooth standard. The following information is provided to satisfy the requirements of EN/IEC 60601-1-2:

The Bluetooth radio transmits and receives on 79 frequency bands which are equally-spaced at 1MHz intervals between 2402MHz and 2480MHz.

The effective receive bandwidth is 1.25MHz.

The transmit modulation is frequency-hopping using GFSK (Gaussian Frequency Shift Keying) with a bandwidth-bit period product  $BT=0.5$ . The Modulation index is between 0.28 and 0.35.

The effective radiated power is -15dBm ( $P = 0.032\text{mW}$ )

| <b>Guidance and manufacturer's declaration – electromagnetic emissions</b>                                                                                                                                                    |                   |                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Proteus FitWell Wearable Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of Proteus FitWell Wearable Sensor should ensure that it is used in such an environment. |                   |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Emissions test</b>                                                                                                                                                                                                         | <b>Compliance</b> | <b>Electromagnetic environment – guidance</b>                                                                                                                                                                                                                                                                                                                                                                          |
| RF emissions<br>CISPR 11                                                                                                                                                                                                      | Group 1           | The FitWell WS 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.<br><br>The FitWell WS 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. |
| RF emissions<br>CISPR 11                                                                                                                                                                                                      | Class B           |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                                           | Not applicable    |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3                                                                                                                                                                   | Not applicable    |                                                                                                                                                                                                                                                                                                                                                                                                                        |

| <b>Guidance and manufacturer's declaration – electromagnetic immunity</b>                                                                                                                                                 |                                                                                                                                                                 |                                |                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| The Proteus FitWell Wearable Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the FitWell Wearable Sensor should ensure that it is used in such an environment. |                                                                                                                                                                 |                                |                                                                                                                                               |
| <b>Immunity test</b>                                                                                                                                                                                                      | <b>IEC 60601 test level</b>                                                                                                                                     | <b>Compliance level</b>        | <b>Electromagnetic environment – guidance</b>                                                                                                 |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                                                                                                                            | +/- 6kV contact<br>+/- 8kV air                                                                                                                                  | +/- 6kV contact<br>+/- 8kV 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<br>+/- 1 kV for input/output lines                                                                                              | Not applicable                 |                                                                                                                                               |
| Surge IEC 61000-4-5                                                                                                                                                                                                       | +/- 1 kV line(s) to line(s)<br>+/- 2 kV line(s) to earth                                                                                                        | Not applicable                 |                                                                                                                                               |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11                                                                                                                    | <5 % UT (>95 % dip in UT) for 0,5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br><5 % UT (>95 % dip in UT) for 5 s | Not applicable                 |                                                                                                                                               |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8                                                                                                                                                                | 3A/m                                                                                                                                                            | 3A/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 FitWell Wearable Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus FitWell Wearable Sensor should ensure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Immunity test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | IEC 60601 test level        | Compliance level | Electromagnetic environment – guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 3 Vrms<br>150 kHz to 80 MHz | Not Applicable   | Portable and mobile RF communications equipment should be used no closer to any part of the Proteus FitWell Wearable Sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br><b>Recommended separation distance</b><br><br>Not Applicable                                                                                                                                                                                                                                                                                                                |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 3 V/m<br>80 MHz to 2,5 GHz  | 3 V/m            | $d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz<br><br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <sup>a</sup> 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 FitWell Wearable Sensor is used exceeds the applicable RF compliance level above, the Proteus FitWell Wearable Sensor 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 FitWell Wearable Sensor. |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <sup>b</sup> 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 FitWell Wearable Sensor                                                                                                                                                                                                                                                                                                                                                                |                                                           |                                         |                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------|------------------------------------------|
| The Proteus FitWell Wearable Sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FitWell Wearable Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Proteus FitWell Wearable Sensor as recommended below, according to the maximum output power of the communications equipment. |                                                           |                                         |                                          |
| Rated maximum output power of transmitter<br><b>W</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           | Separation distance according to frequency of transmitter |                                         |                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 150 kHz to 80 MHz<br>$d = 1,2 \sqrt{P}$                   | 80 MHz to 800 MHz<br>$d = 1,2 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2,3 \sqrt{P}$ |
| 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 metres (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.                                                                                                                                                                                                                                                                                                                              |                                                           |                                         |                                          |

## 1.8 European R&TTE Declaration of Conformity

Hereby, Proteus Digital Health, Inc. declares that the Proteus® FitWell Wearable Sensor 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, 3<sup>rd</sup> 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 (2007)*

The Proteus FitWell Wearable Sensor can be used in countries in the European Union.

## 1.9 CISPR Interference Statement

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section of the manual.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. The Proteus FitWell Wearable Sensor may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

#### **1.10 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.

#### **1.11 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.

#### **1.12 FCC Identifier**

FCC ID: X7901750 - For SPC-0532

FCC ID: X7906120 - For SPC-0801

FCC ID: X7906550 - For SPC-1006

## 2 DISPOSAL OF WASTE PRODUCTS

Production of this equipment required the extraction and use of natural resources. The equipment may contain substances that could be harmful to the environment or human health if improperly handled at the product's end of life. In order to avoid release of such substances into the environment and to reduce the use of natural resources, all devices, both used and unused, should not be disposed with household waste. Return to a recycling point for electric and electronic devices.



### 3 MANUFACTURER CONTACT INFORMATION

To request technical information or to report unexpected events, please contact the manufacturer at one of these locations.

#### United States



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