THE PROTEUS Extended-Use PATCH
SPC-0655
USER SUPPLEMENTAL INFORMATION

Table of Contents

1. TECHNICAL INFORMATION

1.1 – Classification

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

The Proteus Patch is categorized as Class II (in US) and IIa (in EU).
The User (patient) is the intended Operator of the Proteus Patch.

1.2 – Environmental Conditions

The Proteus® Patch is intended for storage and operation in a room-temperature environment. Do not subject the Proteus Patch to transport conditions for more than 7 days.

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

1.3 – Minimizing Skin Irritation

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

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

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 wear the same Patch for more than one week.

DO NOT drop or bump with excessive force.

1.4 – Protection against Ingress of Solids and Liquids

The Proteus Patch 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 Patch immediately and replace it with a new one.

1.5 – Avoiding Unsafe Use Conditions

The Proteus Patch is not a diagnostic device. DO NOT attempt to use it to diagnose heart-related conditions, an incorrect diagnosis may result.

The Proteus Patch has not been tested or approved as safe for operation during air travel. DO NOT use the Patch during air travel; it may interfere with the aircraft navigational instruments.

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

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

1.6 – Information on Electromagnetic and Other Interferences

The Proteus Patch 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 Patch 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 Patch operation is normal in the configuration(s) in which it will be used.

1.7 – Information on the Radio Subsystem

The Proteus Patch incorporates a Bluetooth^{Tm} 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 40 frequency bands which are equally spaced at 2MHz 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 = 0.032mW)

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 ensure 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 ensure 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	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 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 ▫+/- 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	
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	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 Patch is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus Patch should ensure 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	3 V/m 80 MHz to 2,5 GHz	3 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 $d = 1{,}2\ \sqrt{P}$	**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 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.

1.8 – European R&TTE Declaration of Conformity

Hereby, Proteus® Digital Health, Inc., declares that the Proteus 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 (2007)*

The Proteus Patch 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 Patch 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: X7906550

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

Proteus Digital Health, Inc
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065

Phone Number: 650-632-4031
Fax Number: 650-632-4071

United Kingdom

Proteus Digital Health UK Ltd
6th Floor, 41-44 Great Queen St.
London WC2B 5AD


proteus
DIGITAL HEALTH