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## 1 INTRODUCTION

### 1.1 Symbol Glossary

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title, Ref. #</th>
<th>Meaning</th>
<th>Standard title, Desig. #</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Rx]</td>
<td>Prescription only</td>
<td>In the USA. Caution: Federal law restricts this device to sale by or on the order of a physician.</td>
<td>Device Labeling Guidance #G91-1 (blue book memo)</td>
</tr>
<tr>
<td>![Not allowed]</td>
<td>Do not use if package is damaged</td>
<td>Do not use if, when out of package, you notice package is damaged.</td>
<td>ISO 15223-1:2016 Symbols to be used with medical device labels; symbol 5.2.8</td>
</tr>
<tr>
<td>![Humidity limit]</td>
<td>Humidity limitation</td>
<td>The range of humidity to which the medical device can be safely exposed.</td>
<td>ISO 15223-1, symbol 5.3.8</td>
</tr>
<tr>
<td>![Temperature limit]</td>
<td>Temperature limits</td>
<td>Temperature limits to which the medical device can be safely exposed.</td>
<td>ISO 15223-1, symbol 5.3.7</td>
</tr>
<tr>
<td>![Atmospheric pressure limit]</td>
<td>Atmospheric pressure limitation</td>
<td>The range of atmospheric pressure to which the medical device can be safely exposed.</td>
<td>ISO 15223-1, symbols 5.3.9</td>
</tr>
<tr>
<td>![Type BF applied part]</td>
<td>Type BF applied part 5333</td>
<td>Type BF applied part.</td>
<td>IEC 60417 - Graphical Symbols for Use on Equipment.</td>
</tr>
<tr>
<td>![Keep away from sunlight]</td>
<td>Keep away from sunlight</td>
<td>Medical device that needs protection from light sources.</td>
<td>ISO 15223-1, symbol 5.3.2</td>
</tr>
<tr>
<td>![Fragile, handle with care]</td>
<td>Fragile, handle with care</td>
<td>Medical device can be broken or damaged if not handled carefully.</td>
<td>ISO 15223-1, symbol 5.3.1</td>
</tr>
<tr>
<td>![Dustbin]</td>
<td>Dustbin</td>
<td>Separate collection for electrical and electronic equipment.</td>
<td>WEEE Directive 2012/19/EU</td>
</tr>
<tr>
<td>![SN]</td>
<td>Catalogue Number</td>
<td>Marketing Catalogue Number.</td>
<td>ISO 15223-1, symbol 5.1.7</td>
</tr>
<tr>
<td>![REF]</td>
<td>Serial Number</td>
<td>Serial Number</td>
<td>ISO 15223-1, symbol 5.1.6</td>
</tr>
<tr>
<td>Symbol</td>
<td>Title, Ref. #</td>
<td>Meaning</td>
<td>Standard title, Desig. #</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
<td>---------</td>
<td>-------------------------</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
<td>The person placing the device on market.</td>
<td>ISO 15223-1, symbol 5.1.1</td>
</tr>
<tr>
<td><img src="image" alt="Date of Manufacture" /></td>
<td>Date of Manufacture</td>
<td>This symbol is accompanied by the date the device was manufactured.</td>
<td>ISO 15223-1, symbol 5.1.3</td>
</tr>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>CE mark</td>
<td>Indication of conformity with health, safety, and environmental protection standards for products sold within the European economic area.</td>
<td>MDD, 93/42/EEC (consolidated 2007)</td>
</tr>
<tr>
<td><img src="image" alt="FCC mark" /></td>
<td>FCC mark</td>
<td>The electromagnetic interference from the device is under limits approved by the United States Federal Communications Commission.</td>
<td>CFR-2004, Title 47</td>
</tr>
<tr>
<td><img src="image" alt="IP code" /></td>
<td>IP code</td>
<td>Degree of protection provided against intrusion, dust and water by mechanical casings and electrical enclosures.</td>
<td>–</td>
</tr>
<tr>
<td><img src="image" alt="Authorized representative in the European Community" /></td>
<td>Authorized representative in the European Community</td>
<td>Indicates the authorized representative in the European Community.</td>
<td>ISO 15223-1, symbol 5.1.2</td>
</tr>
<tr>
<td><img src="image" alt="The VSMS patch is MRI unsafe" /></td>
<td>The VSMS patch is MRI unsafe</td>
<td>Remove device before MRI procedures</td>
<td>ISO 7010-P001 General prohibition sign and template for constructing a prohibition sign</td>
</tr>
<tr>
<td><img src="image" alt="Do not re-use" /></td>
<td>Do not re-use</td>
<td>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure</td>
<td>ISO 15223-1, symbol 5.4.2</td>
</tr>
</tbody>
</table>
1.2 VSMS ECG PATCH Description

The VSMS ECG patch device (VSMS patch in short) of G Medical Innovations Ltd. (G Medical in short) is a two lead, cardiac event monitor with an additional calculated lead.

The VSMS patch comprises the following sub-units:

- The disposable unit, a physical patch attached to the patient’s chest
- The reusable unit
- An Android OS based smartphone

The recorded ECG data is saved into a SD card located in the VSMS patch reusable unit.

See Figure 1 below for a depiction of the two units of the VSMS patch.

![Figure 1: Units of the VSMS patch](image)

The device operates as an ECG event recorder on hospitalized patients whom the medical staff decides to monitor. The device records the ECG event data acquired from the body (length of event will be defined by the physicians), saves and then transmits them to a smartphone which acts as a gateway. The data received on the phone will be sent wirelessly to the G Medical Call Center for analysis. In case there is a communication problem, the data will be saved until the communication is restored and then resent. Once the data was analyzed by the call center technicians, an event report will be sent to the hospital (to the relevant physician).
1.3 **Indications for Use**

The G Medical VSMS patch is indicated for in-hospital use to remotely monitor drug-induced QT prolongation on the surface ECG in non-critical care patients 18 years of age or older under treatment for COVID-19.

1.4 **Shelf Life**

The shelf life of the physical VSMS patch is 12 months.

1.5 **Contraindications**

- The device is NOT intended for use during external defibrillation procedures; such use may cause the defibrillator’s discharge pulse to be ineffective for the patient.
- The device is NOT to be used in a magnetic resonance imaging (MRI) environment. The device must be removed from the patient’s skin before any MRI procedure.
- The device is NOT intended for use on patients with unhealed surgical incisions/dressings on the thoracic regions.
- The VSMS patch is NOT intended for use on patients with skin or soft tissue damage in the area where the VSMS patch is placed (such as burns, irritation, infections, wounds, etc.).

1.6 **Warnings and Cautions**

<table>
<thead>
<tr>
<th>WARNINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The VSMS patch is NOT intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.</td>
</tr>
<tr>
<td>• The VSMS patch is NOT intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable gases and substances.</td>
</tr>
<tr>
<td>• DO NOT use if there is a known sensitivity to the medical adhesives or applications to the skin used in this product. Ask the patient if he has any skin sensitivities.</td>
</tr>
<tr>
<td>• ECG electrodes may damage the skin if removed carelessly.</td>
</tr>
<tr>
<td>• If a skin reaction is developed, remove the unit and assess the situation before continuing. Reddening or slight irritation of the skin is normal.</td>
</tr>
</tbody>
</table>
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the VSMS patch, otherwise, interference may occur.

- DO NOT expose the device to environmental conditions outside the range specified in this manual (see device specifications), for both storage and operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the VSMS patch. Otherwise, interference could occur.

- DO NOT use the device if there are visible cracks or signs of damage, particularly in the protective liner. Check the device for any signs of wear before each use. Do not use the device if the protective liner is not covering the adhesive surface properly.

- After the patch has been removed from its packaging, it can be used within the duration of the prescribed service time, so long as the protective liner has not been damaged or removed. Return an open, unused patch that is beyond the service time, to the G Medical Service center.

- DO NOT use the device if you suspect any type of fault, such as: LED not functional, VSMS patch recorder not inserted properly, etc. Contact the G medical service center for assistance and for a replacement.

- DO NOT use over an open wound or infected skin.

- DO NOT drop or bump with excessive force.

- DO NOT replace the battery of the physical patch.

- DO NOT reuse the patch and DO NOT transfer it from one patient to another. The patch is intended to be used only for a single patient and for a single use. Failure to comply may result in cross contamination.

- ECG electrodes should be properly disposed of if they are disposable by design or they are reusable but cannot be fully cleaned between uses.

- DO NOT use device If the expiry date has passed or is about to expire during the recording time, or when liner edges are pulled off, or if the liner is not covering the entire adhesive surface.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories other than those specified or provided by G-Medical with this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

---

**CAUTIONS**

- The device does not perform diagnostic or therapeutic functions
• The device has not been tested for, and is not intended for, use in patients younger than 18 years of age.
• Keep the VSMS patch device out of reach of children.
• DO NOT open or attempt to repair the VSMS patch device. Only authorized service personnel may repair the system units.
• To avoid damage to the system, the system units should be kept away from extreme heat sources.
• DO NOT store the device where it will be continuously exposed to moisture or steam. Such extended exposure may cause malfunction.
• The VSMS patch device is designed to withstand splash conditions (IP 54) but is NOT completely waterproof. When taking a shower with the VSMS patch device attached to your chest, splashing water over the device is allowed. DO NOT swim with the device or submerge it in water.
• Avoid direct mechanical impacts towards the VSMS patch units. Strong mechanical impacts may crack or break the plastic case. In the event of a mechanical impact which causes a crack in the plastic case immediately remove the VSMS patch unit from the chest, return it to the medical facility and request a replacement.
2 CLEANING, DISPOSAL AND MAINTENANCE

2.1 Cleaning Instructions

The reusable unit (recorder) of the VSMS patch needs to be cleaned between use by patients. Clean according to the following instructions:

Use a soft, lint-free cloth lightly moistened with 70% alcohol solution. Wipe and air dry.

i. DO NOT use solvents, abrasive or highly alkaline cleaners.

ii. NEVER scrape with squeegees, razor blades or other sharp instruments.

iii. NEVER USE Benzene, gasoline, acetone, or carbon tetrachloride.

iv. DO NOT clean products in hot sun or at elevated temperatures.

v. DO NOT use common household solvents or any strong chemical-based cleaning solutions.

2.2 Patch Disposal

The VSMS patches are for a single use only and must be disposed of in a designated medical waste bin or area in the hospital or other clinical environment.

2.3 Preventive Maintenance

Preventive maintenance consists of all actions needed to keep the equipment in proper working order. Check the Recorder and its accessories periodically to assure equipment is in proper working condition, not broken, with no external damage and that the recorder performs according to specifications.

NOTE: If you detect or experience any problems that cannot be solved, please contact manufacturer.

During transportation, storage, and between use, it is recommended to store the Recorder and accessories in the package provided to protect all items and be free of debris. The packaging provides sufficient protection against light, accidental impact.

The manufacturer is not responsible for malfunction or damage to the Recorder caused by patient abuse or resulting from poor maintenance performed by personnel other than manufacturer, which could result in reparation for repairs or replacement.

2.4 Corrective Maintenance

Corrective maintenance is the process to correct Recorder errors and keep the Recorder functioning properly after a malfunction or misuse. If you detect a fault in the Recorder that prevents normal operation, please contact your provider for assistance.

2.5 Maintenance

Maintenance and service of the VSMS patch device is performed only in a laboratory or service center authorized by G Medical for this purpose.
Except for the removal of the disposable unit from the chest and the attachment of a new disposable unit, do not tamper with or repair the VSMS patch device in any way.

2.6 Service

The VSMS patch Recorder and the USB Card Reader have no user-serviceable parts. The Recorder requires no calibration. The Recorder is a sealed device and is not serviceable.
RUNNING MONITORING SESSIONS

2.7 Initialization of Event monitoring with the VSMS patch

In case there is a decision to monitor a patient, the medical staff will connect the patient to the patch, activate the phone and App will start automatically. Once the App and VSMS patch connected (via Bluetooth) the nurse double presses the blue button to initiate a baseline. This manual event will be sent to G Medical call center and mark the beginning of the monitoring session.

2.8 Preparing the Chest

The VSMS patch is placed on the center of the chest over the sternum bone, three closed fingers width below the clavicle and three closed fingers over the sternum bone; see Figure 2 below:
Position patch on center of chest
1. Three fingers below collar bone to center of RA electrode
2. Three fingers from center of chest to center of RA electrode

*Figure 2: Exact location of the patch on the chest of the patient*
Before placing the patch on the body, prepare the chest of the patch user as follows:

1. Shave the hair from the chest area using the shaving kit supplied in the package.

<table>
<thead>
<tr>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Although a shaver is supplied with the Event recorder kit, we recommend using an electric trimmer or clipper to avoid any cuts or damage to the epidermis; such cuts can increase the chances for irritation or rash after the VSMS patch is placed on the skin</td>
</tr>
</tbody>
</table>

2. Clean the skin on the upper part of the chest using a gauze pad lightly moistened with isopropanol alcohol (60-70% propanol). For your convenience, alcohol pads are supplied in the kit.

3. Rub the adhesion site dry with a gauze pad and wait until fully dry (at least 2 minutes) before proceeding.

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not apply the VSMS patch to skin that is cracked or irritated, or over an open wound.</td>
</tr>
</tbody>
</table>

2.9 Inserting the VSMS patch recorder into the base of the cradle

To insert the VSMS patch recorder into the cradle of the disposable patch:

1. Verify that the SD card of the VSMS patch recorder slot is sealed (see Figure 4)
2. Place the VSMS patch on a flat sturdy area and:
   a) Put the VSMS patch recorder into the base of the cradle  
   b) push recorder down and snap latch in place

3. Upon insertion of the reusable unit into the cradle base of the physical patch, power is provided to the VSMS patch recorder. The blue and red LEDs will alternately blink to indicate that the system is initializing. Eventually, only the blue LED will blink if the system behaves normally.

4. Check visually that the LED indicators turn on when the reusable unit is inserted.

   CAUTION
   If the VSMS patch recorder’s red LED is blinking, a reset process should be executed by pressing the blue button on the reusable unit for 10 seconds until the blue and red are blinking. If the red LED is still blinking, the unit should be replaced.
2.10 Placing the VSMS Patch on Chest

After preparing the chest as set out in section 3.2 and inserting recorder as set out in section 3.3, perform the steps illustrated below to attach the physical patch to the chest.

| NOTE |
| The VSMS patch is available with 2 protective liners or 3 protective liners. Follow the directions for placement according to your VSMS patch version. |

**VSMS patch with 2 protective liners**

1. Peel off protective liner #1
2. Place on chest as shown in the picture
3. Peel off protective liner #2 and press all edges of the patch firmly to the skin for two minutes
4. Patch shown in correct position

**VSMS patch with 3 protective liners**

1. Flip patch so the bottom is facing up, and peel off protective liner #1
2. Place on chest as shown in the picture and press firmly.
3. Peel off protective liners #2 and #3, then press all edges of the patch firmly to the skin for two minutes.
4. Patch shown in correct position.

| NOTE |
| The liner should be removed just before applying the patch to the chest. If the liner is damaged or not placed properly, replace with a new patch. |
2.11 Creating a Baseline

To start the monitoring:

1. Once the patch is positioned properly on the chest and the recorder is plugged-in and working, turn on the smartphone. The App will start automatically after phone turned on.

2. Wait for Bluetooth connectivity between the recorder and the phone.

3. In case of several devices in the area the relevant device should be chosen from a list of recognized devices.
4. The phone will indicate while pairing with the chosen device
5. Once pairing process completed, the phone will indicate on the connected device
6. The following screen will appear in case one of the electrodes are not connected properly to the skin:
7. Performing a Baseline:

If there is no red sign of disconnected electrodes and the LED on the recorder is alighted as shown in the figures it is time to perform a Baseline.
a. Press the Baseline button on the screen. The screen will change to an ECG viewer with Lead I and II presented.

b. Verify the signal quality.

c. If approved, double click the patch icon on the right top of the screen and the baseline will be recorded and transmit to the call center to indicate the monitoring has started.

2.12 Creating manual event

1. If you feel a symptom, mark the event manually by pressing double quick clicks on the blue button on the reusable unit; see Figure 6

   Make sure the smartphone received with the kit is turned on and in range of up to 30ft.
### Figure 5: Blue button on the reusable unit

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressing the button for more than 10 seconds will result in a reboot of the VSMS patch recorder (no loss of data will occur).</td>
</tr>
</tbody>
</table>
2.13 Adding a new patient and a new device

2.13.1 Register the device on the G Medical Portal.

- Login to the G Medical Portal
- If you forget your password, then send as Email to Support@gmedinnovations.com
- Select the “Setting” icon
- From the dropdown menu, select “Manage Devices”.

- Select “Add Device”

- Click on “Brand”
- Select “G-Medical Innovations”.
• Open “Model” and Select “GMP”
  a. Enter the Serial number
  b. Enter the Serial number again to confirm it
  c. Select “Extended AECG - 2 Lead”
  d. Click “Add” to confirm your choice

• Click “OK” to approve.
The device will appear in the Device Manager list.

• Click Back to return to the main screen.
2.13.2 Adding a new patient

Select “Patient Enrollment”

The “pop-up” screen includes three tabs for entering patient enrolment information:

i. **Device Service Information**

ii. **Patient Information**

iii. **Insurance Information**

2.13.2.1 Description of the tabs

2.13.2.1.1 **Device Service Information Tab**

Complete this tab by entering the following information:

- Enter Physician information.
- Select the device type from the dropdown list.
- Select Study Type and Duration time (24hr or custom).
- Confirm that the inserted date & time are correct.

Click “Next” to confirm and to move to the next tab.
2.13.2.1.2 Patient Information Tab

Complete this tab by entering the following information:

- Enter Patient information.
- Select if the patient wears Implanted Device.
- Add additional comments if needed.

Click "Next" to confirm and to move to the next tab.
2.13.2.1.3 Insurance Information Tab

If the patient has insurance, then complete this tab by entering the details of the insurance; if not, then click on the “self-pay” field.
• Enter the relevant information in the patient’s “Insurance Information” tab. An asterisk indicates a required field.
• Press “Next” to confirm.
• Click “Save for Later” to confirm and continue.
• When “Patient Enrollment Successfully Saved” appears, click “Close”.
• The patient is enrolled on the system and is ready to begin the monitoring study.
3 REPLACING OR REMOVING THE PATCH

3.1 To replace the patch, follow the steps below.

1. Hold skin down and slowly peel off the patch. You may place a warm wet cloth on top of the patch to loosen the adhesive.
2. Open the snap locker of the VSMS patch recorder and pull out the unit from the physical patch.
3. Insert the VSMS patch recorder into the new patch.
4. Remove any patch adhesive on your skin by using the adhesive tape remover.
5. Clean the skin on the upper part of the chest using a gauze pad lightly moistened with isopropanol alcohol (60-70% propanol). Allow the skin to dry for at least 1 minute.
6. Place the new patch on the chest by following the instructions in sections 2.8 to 2.10.

3.2 To remove the patch, follow the steps below.

1. Hold skin down and slowly peel off the patch. You may place a warm wet cloth on top of the patch to loosen the adhesive.
2. Open the snap locker of the VSMS patch recorder and pull out the unit from the physical patch.
3. Remove any patch adhesive on your skin by using the adhesive tape remover.
4 TROUBLESHOOTING

4.1 LED Indications in VSMS patch recorder

The VSMS patch recorder includes blue and red LEDs which indicate the status of the device (see Figure 5 for the location of the LED indicator, beneath the blue button).

![LED light indicator on recorder](image)

*Figure 6: Led light indicator on recorder*

<table>
<thead>
<tr>
<th>LED indication</th>
<th>Meaning</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red LED blinks</td>
<td>Initialization failure (BIT), VSMS patch critical low battery, SD card full, high Impedance, device temperature or HW failure.</td>
<td>Replace patch. If indication persists, return VSMS patch kit to Service for replacement.</td>
</tr>
<tr>
<td>Blue/Red LEDs blink alternately.</td>
<td>VSMS patch recorder is initializing.</td>
<td>No action required.</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>----------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Blue LED blinks</td>
<td>Normal mode. VSMS patch is acquiring and recording ECG data.</td>
<td>No action required.</td>
</tr>
</tbody>
</table>
4.2 Low storage in VSMS patch recorder

The Critically Low Storage Space indicator appears via red led blinking when the VSMS patch recorder can no longer store medical data on the internal SD card.

**Actions:**

Stop monitoring and contact G Medical service center for further assistance.

4.3 Patch High Temperature

The VSMS patch high temperature indicator appears by means of a red led blinking on the reusable unit when the temperature of this unit rises above normal.

**Actions:**

1. Remove the patch from the chest.
2. Return the patch and VSMS patch recorder to the G Medical Service center

4.4 Patch ECG Lead Disconnected

The VSMS patch lead disconnection indicator appears by means of a red led blinking on the reusable unit when lead one or two of the ECG leads on the patch are not detected.

**Actions:**

1. Check that the patch is properly affixed to the chest by firmly pressing around the patch edges.
2. If the indication persists, replace the patch (see section 3).
5 SPECIFICATIONS

5.1 ECG

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG Channel</td>
<td>2 X ECG channels, 4 X electrodes</td>
</tr>
<tr>
<td>Dynamic range</td>
<td>±5 mV</td>
</tr>
<tr>
<td>CMRR</td>
<td>65dB</td>
</tr>
<tr>
<td>Frequency Response</td>
<td>0.05 Hz to 65 Hz</td>
</tr>
<tr>
<td>Input Impedance</td>
<td>&gt;10 MΩ</td>
</tr>
<tr>
<td>DC Offset</td>
<td>±300 mV</td>
</tr>
<tr>
<td>Sampling Rate</td>
<td>250 samples/second</td>
</tr>
<tr>
<td>Resolution</td>
<td>23-bit</td>
</tr>
</tbody>
</table>

5.2 Power

- Power supply: 1/2AA 3.6V lithium thionyl chloride battery

5.3 Physical Characteristics – Disposable patch

- Length/Width/Thickness: 140x130x18 mm
- ECG electrodes materials: Hydrogel AG640
- ECG electrodes barrier: PE
- Patch adhesive: Nonwoven PE with Acrylic adhesive

5.4 Physical Characteristics – VSMS patch reusable unit (recorder)

- Length/Width/Thickness: 31x30x13.5 mm
- External envelope material: Polycarbonate
### 5.5 Environmental Specifications – VSMS patch disposable

<table>
<thead>
<tr>
<th>Specification</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational Temperature</td>
<td>Normal body temperature</td>
</tr>
<tr>
<td>Operational Humidity</td>
<td>Normal body humidity</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>+5 to +27 ºC Storage</td>
</tr>
<tr>
<td>Storage Humidity</td>
<td>35% to 50% (non-condensing)</td>
</tr>
<tr>
<td>Operational/Transport/Storage Atmospheric Pressure</td>
<td>700 to 1060 hPa (525 to 795 mmHg)</td>
</tr>
<tr>
<td>IP Degree of Protection</td>
<td>IP 54</td>
</tr>
</tbody>
</table>

### 5.6 Environmental Specifications – VSMS patch reusable

<table>
<thead>
<tr>
<th>Specification</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational Temperature</td>
<td>+10 to +40ºC</td>
</tr>
<tr>
<td>Operational Humidity</td>
<td>10% to 95% (non-condensing)</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>-20 to +60ºC Storage</td>
</tr>
<tr>
<td>Storage Humidity</td>
<td>10% to 95% (non-condensing)</td>
</tr>
<tr>
<td>Operational/Transport/Storage Atmospheric Pressure</td>
<td>700 to 1060 hPa (525 to 795 mmHg)</td>
</tr>
<tr>
<td>IP Degree of Protection</td>
<td>IP54</td>
</tr>
</tbody>
</table>

**NOTE**

Operational conditions under normal body conditions are anticipated to allow a continuous use for up to 14 days; however, abnormal temperature and humidity conditions may shorten the duration.

**NOTE**

The IP degree of protection is guaranteed only when the G Medical patch is connected to the VSMS patch recorder.
6 MANUFACTURER

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Email: info@gmedinnovations.com
7 US AUTHORIZED REPRESENTATIVE

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Fax: 1-888-965-7697
24/7 Lab: 1-800-747-4455
Website: https://us.gmedinnovations.com/contact/
Email: support.us@gmedinnovations.com
8 ELECTRICAL SAFETY, EMISSION, AND IMMUNITY

The VSMS patch complies with the following safety and/or EMC standards:

- IEC-60601-1, Ed. 3.1
- IEC-60601-1-11, Ed. 2
- IEC-60601-1-2 2007, Ed. 3 and 2014 Ed. 4, Emission class – Group 1 class B.

8.1 BLE transmitter

The VSMS patch contains a BLE transmitter and receiver which complies with BT SIG. The BLE receiver and transmitter radio specifications:

<table>
<thead>
<tr>
<th>Radio</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>2.360GHz to 2.500GHz</td>
<td></td>
</tr>
<tr>
<td>Modulations</td>
<td>GFSK at 1 Mbps, 2 Mbps data rates</td>
<td></td>
</tr>
<tr>
<td>Transmit power</td>
<td>+4 dBm</td>
<td></td>
</tr>
<tr>
<td>Receiver sensitivity</td>
<td>-</td>
<td>BMD-350: -94 dBm (BLE mode)</td>
</tr>
<tr>
<td>Antenna</td>
<td></td>
<td>BMD-350: Ceramic Chip</td>
</tr>
</tbody>
</table>

NOTES

The BLE transceiver module has FCC approval, with FCC ID: 2AA9B05. This module complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference; (2) This device must accept any interference received, including interference that may cause undesired operation.

8.2 EMC testing

The VSMS patch was tested for EMC (Electromagnetic Compatibility) according to both the 3rd and 4th editions of the IEC 60601-1-2 standards. The device was found to be in compliance with the requirements of the standards IEC 60601-1-2 (2014). Environment of intended uses: Professional Healthcare and Home Healthcare Facility Environment.
## 8.2.1 Summary of EMC test results

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard</th>
<th>Class/ Severity level</th>
<th>Test result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emission (IEC 60601-1-2 section 7.2)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated emission</td>
<td>CISPR 11</td>
<td>Group 1 Class B</td>
<td>Complies</td>
</tr>
<tr>
<td>Freq. range: 30 - 6000 MHz</td>
<td>EN 301 489-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immunity (IEC 60601-1-2 section 8.9 &amp; 8.10)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunity from Electrostatic discharge (ESD)</td>
<td>IEC 61000-4-2</td>
<td>8 kV contact discharges &amp;</td>
<td>Complies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 kV air discharges</td>
<td></td>
</tr>
<tr>
<td>Immunity from radiated electromagnetic fields</td>
<td>IEC 61000-4-3</td>
<td>10.0 V/m</td>
<td>Complies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 MHz ÷ 2.7 GHz, 80% AM, 1kHz</td>
<td></td>
</tr>
<tr>
<td>Immunity from Proximity field from wireless communications equipment</td>
<td>IEC 61000-4-3</td>
<td>List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz</td>
<td>Complies</td>
</tr>
<tr>
<td>Immunity from power frequency magnetic field</td>
<td>IEC 61000-4-8</td>
<td>30 A/m, 50/60Hz</td>
<td>Complies</td>
</tr>
</tbody>
</table>
9 LEGAL NOTICES

9.1 Liability

G Medical shall in no event be liable for any direct, indirect, special or consequential damages including without limitation damages for loss of business profits, loss of income, business interruption, loss of business information, loss of use or other related exposures, however caused, arising from the faulty or incorrect use of the product.

9.2 Statement

G Medical guarantees that the product delivered has been thoroughly tested to ensure that it meets its published specifications.

9.3 Warranty

G Medical warrants the products manufactured or distributed by them to be free from faulty materials and workmanship for a period of 12 months from date of original shipment to first end user except for disposable products or products which have a stated guarantee longer or shorter than 12 months. G Medical will perform warranty service at its factory.

The obligations under this guarantee shall be limited to repair, or at G Medical's option, replacement of necessary parts or assemblies and shall not include costs of shipping.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the products must specify both the name of the product and its serial number as written on the label on the product.

Use of the equipment for other than its intended use, or if it has been repaired by anyone except G Medical or a G Medical authorized service center or altered or modified or used without following the instructions in the user manual, will void this warranty.

9.4 Copyright

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10 CONTACT INFORMATION

For help with this device, please contact:

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Note: The information in this document is subject to change without notice.

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0344 (pending approval)