

G Medical Innovations

VSMS ECG Patch



Professional User Guide

SML-0008; Rev. EUA, May 2020














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1 INTRODUCTION

1.1 Symbol Glossary

Symbol	Title, Ref. #	Meaning	Standard title, Desig. #
	Prescription only	In the USA. Caution: Federal law restricts this device to sale by or on the order of a physician.	Device Labeling Guidance #G91-1 (blue book memo)
	Do not use if package is damaged	Do not use if, when out of package, you notice package is damaged.	ISO 15223-1 2016 Symbols to be used with medical device labels; symbol 5.2.8
	Humidity limitation	The range of humidity to which the medical device can be safely exposed.	ISO 15223-1, symbol 5.3.8
	Temperature limits	Temperature limits to which the medical device can be safely exposed.	ISO 15223-1, symbol 5.3.7
	Atmospheric pressure limitation	The range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1, symbols 5.3.9
	Consult instructions for use	Mandatory: Follow instructions for Use.	IEC 60601-1:2005 + A1:2012, Part 1 Medical electrical equipment: General requirements for basic safety and essential performance. Table D.2, symbol 10
	Direct Current 5031	Direct Current	IEC 60417 - Graphical Symbols for Use on Equipment.
	Type BF applied part 5333	Type BF applied part.	IEC 60417 - Graphical Symbols for Use on Equipment.
	Keep away from sunlight	Medical device that needs protection from light sources.	ISO 15223-1, symbol 5.3.2
	Fragile, handle with care	Medical device can be broken or damaged if not handled carefully.	ISO 15223-1, symbol 5.3.1
	Dustbin	Separate collection for electrical and electronic equipment.	WEEE Directive 2012/19/EU
	Serial Number	Serial Number	ISO 15223-1, symbol 5.1.7
	Catalogue Number	Marketing Catalogue Number.	ISO 15223-1, symbol 5.1.6

Symbol	Title, Ref. #	Meaning	Standard title, Desig. #
	Manufacturer	The person placing the device on market.	ISO 15223-1, symbol 5.1.1
	Date of Manufacture	This symbol is accompanied by the date the device was manufactured.	ISO 15223-1, symbol 5.1.3
	CE mark	Indication of conformity with health, safety, and environmental protection standards for products sold within the European economic area.	MDD, 93/42/EEC (consolidated 2007)
	FCC mark	The electromagnetic interference from the device is under limits approved by the United States Federal Communications Commission.	CFR-2004, Title 47
	IP code	Degree of protection provided against intrusion, dust and water by mechanical casings and electrical enclosures.	-
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	<u>ISO 15223-1, symbol 5.1.2</u>
	The VSMS patch is MRI unsafe	Remove device before MRI procedures	ISO 7010-P001 General prohibition sign and template for constructing a prohibition sign
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1, symbol 5.4.2

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.

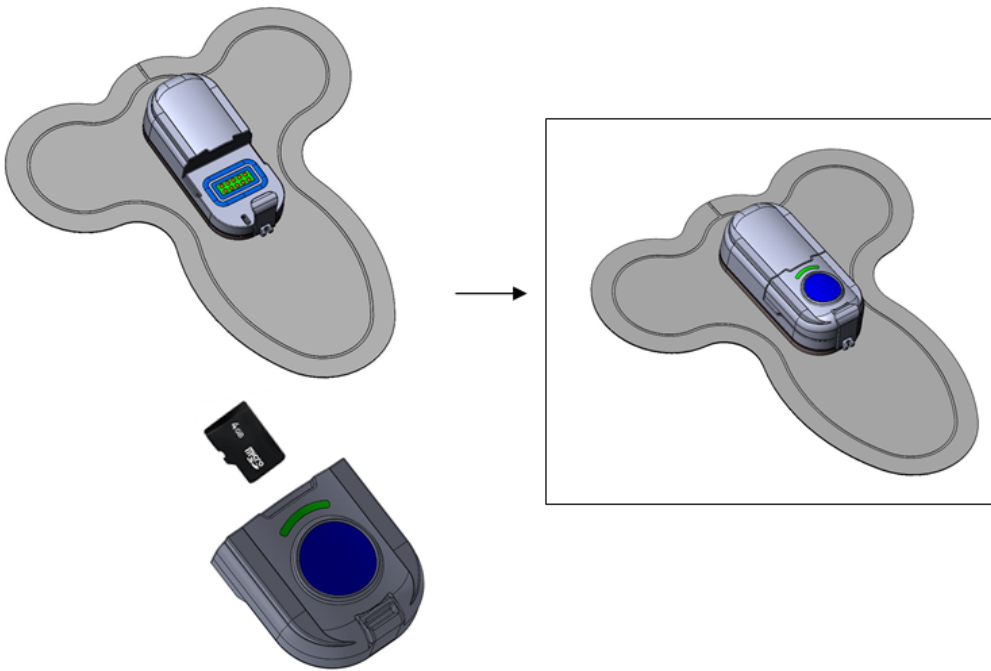


Figure 1: Units of the VSMS patch

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

	WARNINGS
	<ul style="list-style-type: none">• The VSMS patch is NOT intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.• 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.• 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.• ECG electrodes may damage the skin if removed carelessly.• If a skin reaction is developed, remove the unit and assess the situation before continuing. Reddening or slight irritation of the skin is normal.

- 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.
- DO NOT expose to strong electromagnetic fields.
- 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.

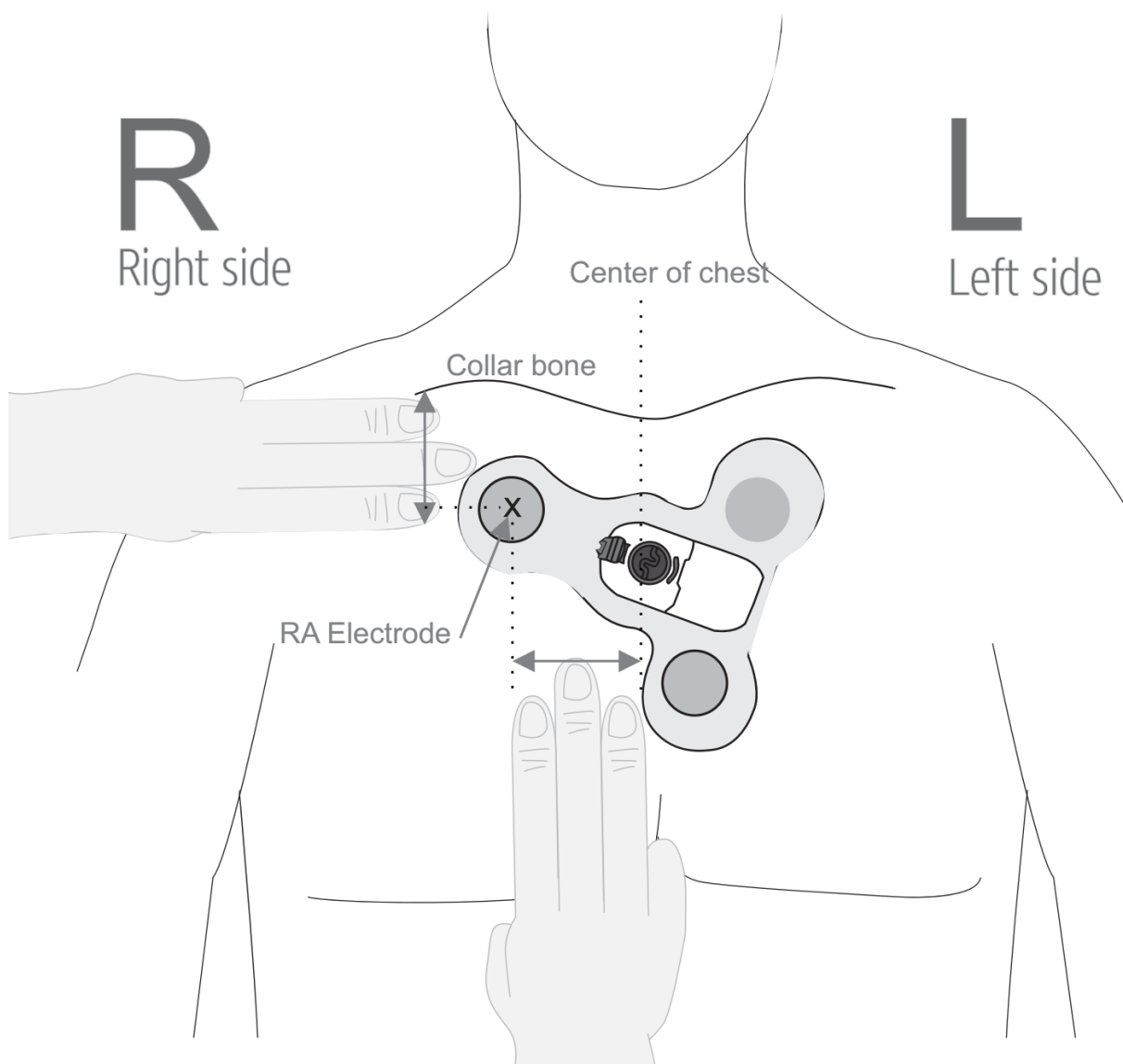
RUNNING MONITORING SESSIONS

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.

	NOTE
	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

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.

	CAUTION
	Do not apply the VSMS patch to skin that is cracked or irritated, or over an open wound.

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)

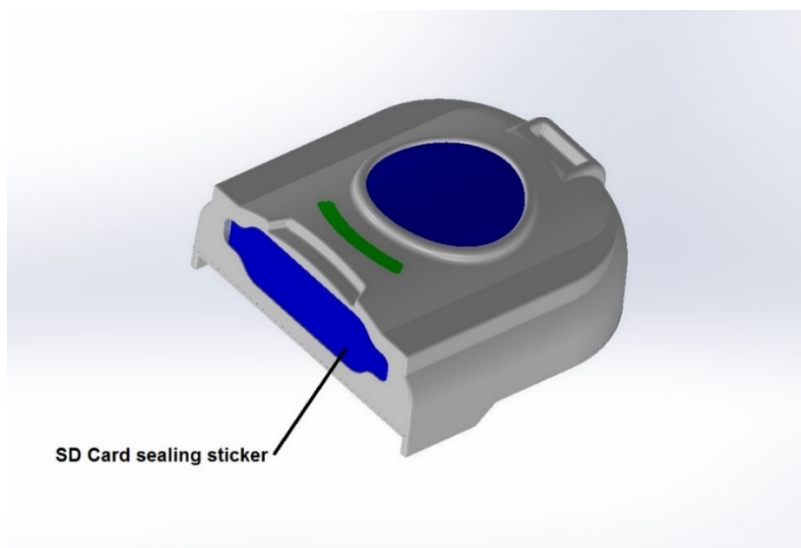



Figure 3: Slot for insertion of SD card into the VSMS patch recorder

	CAUTION
	Do not attempt to open the SD card cover at any time.

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

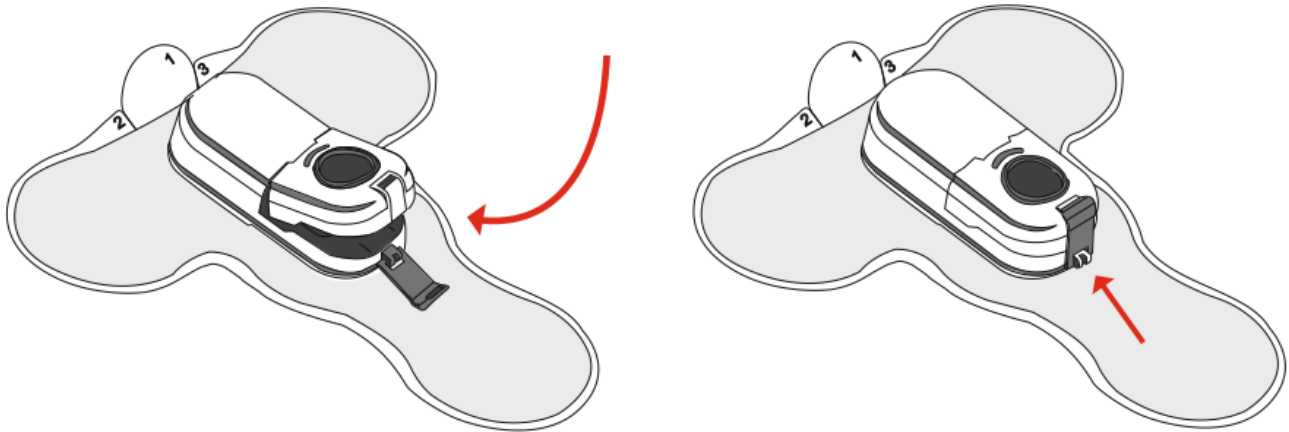




Figure 4: Insertion of the recorder into the cradle

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.

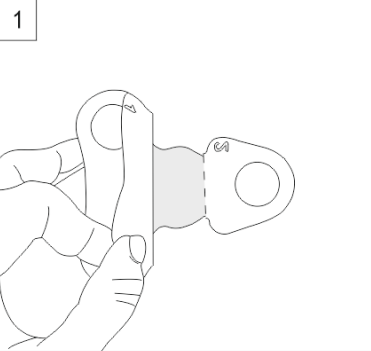
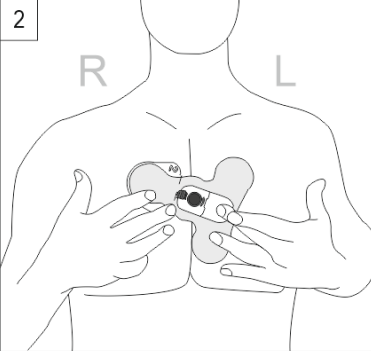
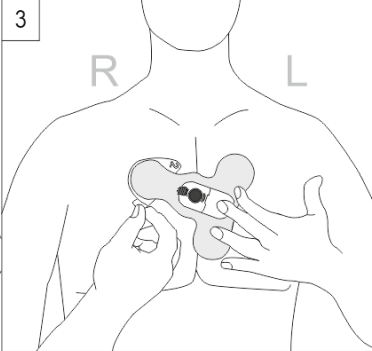
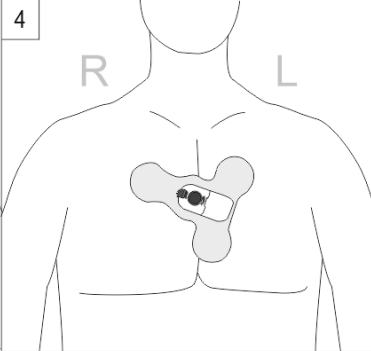
	CAUTION
	If the VSMS patch recorder's red LED is blinking, a reset process should be executed by pressing the blue button on the reusable unit for 10 seconds until the blue and red are blinking. If the red LED is still blinking, the unit should be replaced.

2.10 Placing the VSMS Patch on Chest

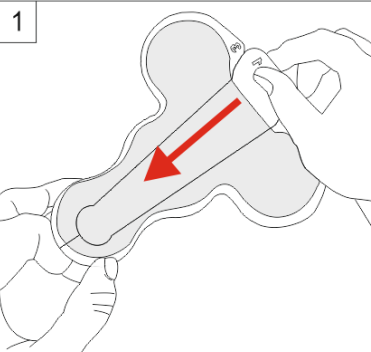
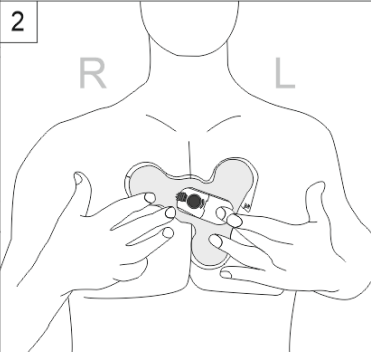
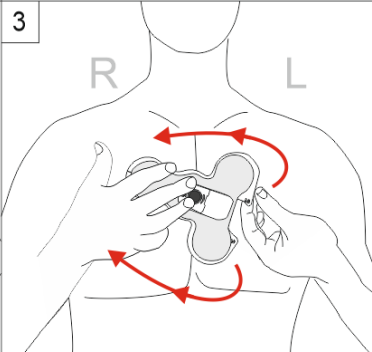
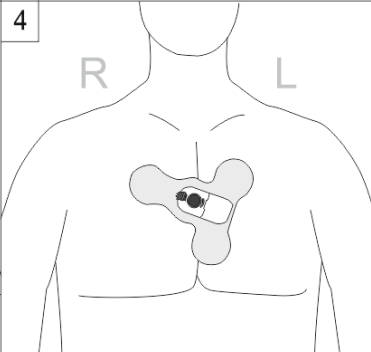
After preparing the chest as set out in section 3.2 and inserting recorder as set out in section 3.3, perform the steps illustrated below to attach the physical patch to the chest.


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

VSMS patch with 2 protective liners

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

VSMS patch with 3 protective liners

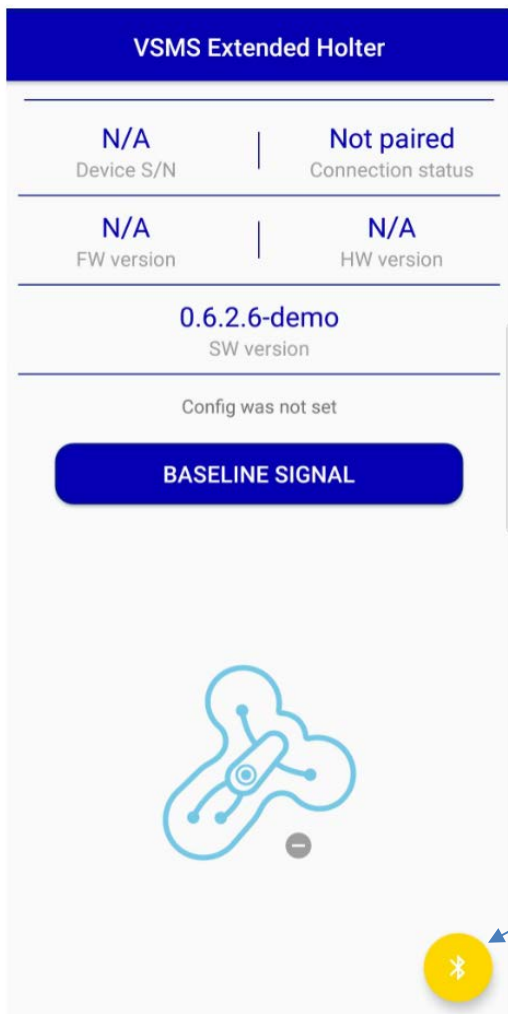
1	2	3	4
			
Flip patch so the bottom is facing up, and peel off protective liner #1.	Place on chest as shown in the picture and press firmly.	Peel off protective liners #2 and #3, then press all edges of the patch firmly to the skin for two minutes.	Patch shown in correct position.

	NOTE
	<p>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.</p>

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.



Bluetooth icon will turn blue when connected

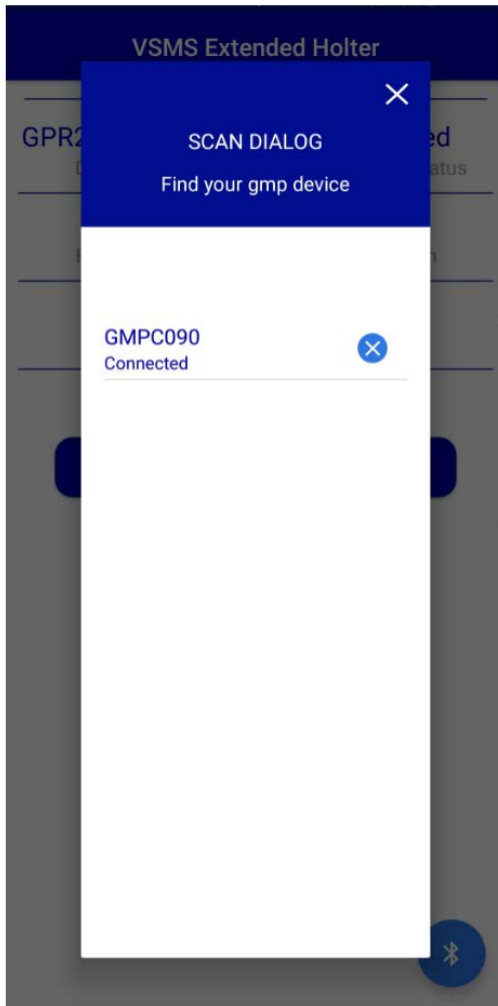
3. In case of several devices in the area the relevant device should be chosen from a list of recognized devices



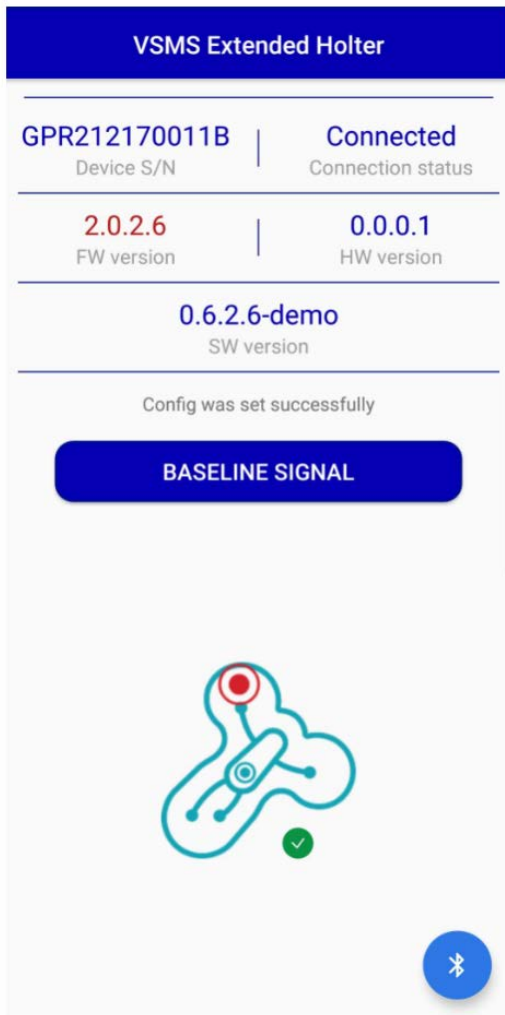
4. The phone will indicate while pairing with the chosen device



5. Once pairing process completed, the phone will indicate on the connected device

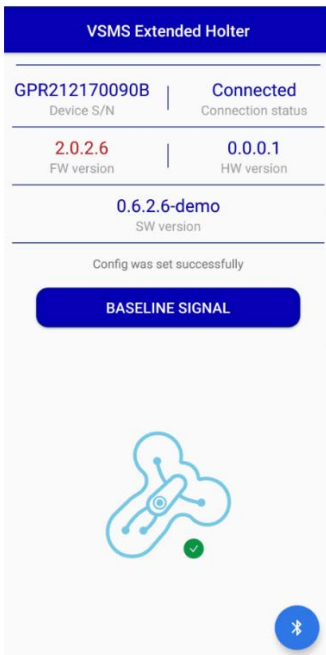


6. The following screen will appear in case one of the electrodes are not connected properly to the skin

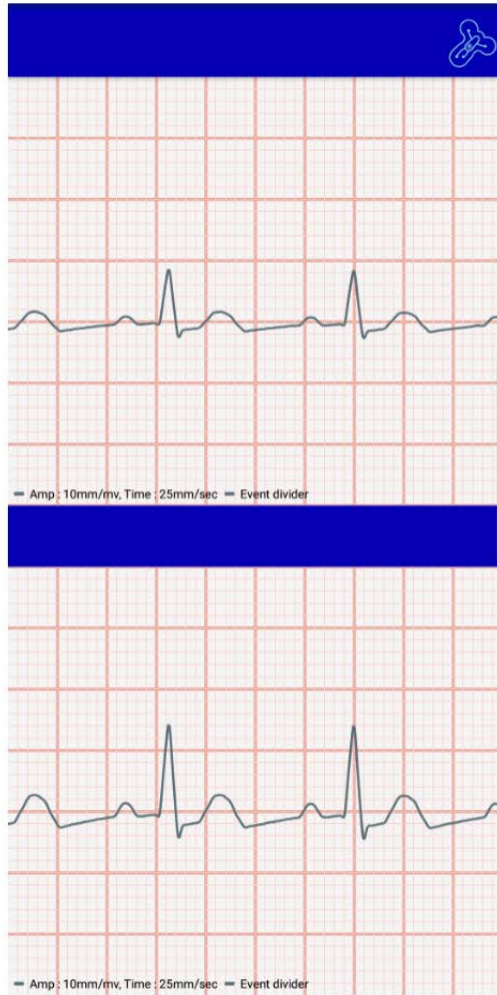


7. Performing a Baseline:

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

	CAUTION
	Pressing the button for more than 10 seconds will result in a reboot of the VSMS patch recorder (no loss of data will occur).

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”.

The screenshot shows the G Medical Portal dashboard. At the top left is the logo for G-MEDICAL with the tagline 'Mobility in Healthcare'. To the right, there is contact information: 'Customer Support (800)-747-4455', an email address 'support.us@gmedinnovations.com', and a 'Help' link. Below this is a user profile for 'Tal, Benny'. The main navigation area includes 'Select Doctor:' (All), 'Filter:' (All), and 'Location:' (--Select--). There are buttons for 'Go', 'Advanced Search', and 'Manage Devices'. At the bottom, there are buttons for 'Patient Enrollment', 'Upload Data', and 'Request Supplies', along with a search bar for 'Name or MRN'.

- Select “Add Device”

The screenshot shows the 'Device Manager' interface. It features a 'Serial Number Search' field with a magnifying glass icon and an 'Add Device' button. Below is a table with the following data:

Make & Model	Serial No	Added On	Status	#Action
G-Medical Innovations-GMP	1234567890	8/30/2018 10:07:20 AM	Assigned	
G-Medical Innovations-GMP	0987654321	8/30/2018 3:02:00 PM	Assigned	
G-Medical Innovations-GMP	47505232313231373031303842	9/6/2018 2:18:58 AM	Assigned	
G-Medical Innovations-GMP	47505232313231373031303333	9/6/2018 5:47:29 AM	Assigned	

There is a 'Back' button at the bottom left of the table area.

- Click on “Brand”
- Select “G-Medical Innovations”.

The screenshot shows the 'Add Device' form. It has the following fields:

- Brand ***: A dropdown menu with 'G-Medical Innovations' selected.
- Model ***: A dropdown menu with 'GMP' selected.
- Serial No ***: An empty text input field.
- Confirm Serial No ***: An empty text input field.
- Select Leads ***: A dropdown menu with '--Select--' selected.

At the bottom, there are 'Add' and 'Cancel' buttons.

- 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

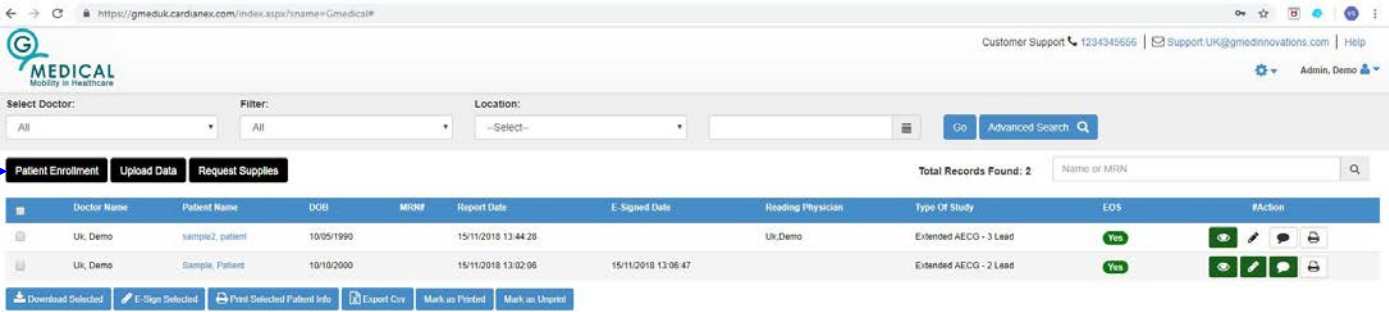
- Click “OK” to approve.
The device will appear in the Device Manager list.

- Click Back to return to the main screen.

Make & Model	Serial No	Added On	Status	#Action
G-Medical Innovations-GMP	1234567890	8/30/2018 10:07:20 AM	Assigned	
G-Medical Innovations-GMP	0987654321	8/30/2018 3:02:00 PM	Assigned	
G-Medical Innovations-GMP	47505232313231373031303842	9/6/2018 2:18:58 AM	Assigned	
G-Medical Innovations-GMP	47505232313231373031303333	9/6/2018 5:47:29 AM	Assigned	
G-Medical Innovations-GMP	12345678900	9/6/2018 11:27:02 AM	Active	Edit

2.13.2 Adding a new patient

Select “Patient Enrollment”



The screenshot shows the Gmedical web application interface. At the top, there is a navigation bar with the Gmedical logo and the text "MEDICAL Mobility in Healthcare". Below the navigation bar, there are search filters for "Select Doctor:", "Filter:", and "Location:". A blue arrow points to the "Patient Enrollment" tab, which is highlighted in black. Below the tabs, there is a table with columns: Doctor Name, Patient Name, DOB, MRN#, Report Date, E-Signed Date, Reading Physician, Type Of Study, EOS, and #Action. The table contains two rows of data. Below the table, there are several action buttons: Download Selected, E-Sign Selected, Print Selected Patient Info, Export Corr, Mark as Printed, and Mark as Unprint.

Doctor Name	Patient Name	DOB	MRN#	Report Date	E-Signed Date	Reading Physician	Type Of Study	EOS	#Action
UK, Demo	sample2_patient	10/05/1990		15/11/2018 13:44:28		UK, Demo	Extended AECG - 3 Lead	Yes	[Icons]
UK, Demo	Sample, Patient	10/10/2000		15/11/2018 13:02:06	15/11/2018 13:06:47		Extended AECG - 2 Lead	Yes	[Icons]

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:

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

Click “Next” to confirm and to move to the next tab.

The screenshot shows a web application interface for patient data entry. On the left, a sidebar contains a table with columns for Doctor Name, Patient Name, and DOB. Two rows are visible: one for 'Uk, Demo' with patient 'sample2, patient' (DOB 10/05/1990) and another for 'Uk, Demo' with patient 'Sample, Patient' (DOB 10/10/2000). Below the table are buttons for 'Download Selected', 'E-Sign Selected', and 'Print Selected Patient Info'. The main content area has three tabs: 'Device Service Information' (selected), 'Patient Information', and 'Insurance Information'. The 'Device Service Information' tab contains several sections:

- Physician Information:** Three dropdown menus for 'Ordering Physician', 'Location', and 'Reading Physician', each currently set to '--Select--'.
- Device Information:** A dropdown for 'Select Device' (set to '--Select--') and a text input for 'Enter Serial Number'.
- Service Information:** Three dropdown menus for 'Type Of Study' (set to '--Select--'), 'Duration' (set to '2 Days -48 Hours'), and 'Diagnosis (ICD-10)' (set to '--Select--').
- Hookup Information:** A date input for 'Date Of Service' (format DD/MM/YYYY) and a time input for 'Hookup time' (set to '12:25').

 At the bottom of the form is a blue link 'Edit Patients Setup' and a green 'Next' button.

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.

The screenshot displays the Gmeduc Cardianex web application interface. On the left sidebar, there is a 'Select Doctor:' dropdown set to 'All' and a 'Filter:' dropdown also set to 'All'. Below these are buttons for 'Patient Enrollment', 'Upload Data', and 'Request Supplies'. A table lists patient records with columns for 'Doctor Name', 'Patient Name', and 'DOB'. The table contains two entries: 'Uk, Demo' with patient 'sample2, patient' (DOB 10/05/1990) and 'Uk, Demo' with patient 'Sample, Patient' (DOB 10/10/2000). Below the table are buttons for 'Download Selected', 'E-Sign Selected', and 'Print Selected Patient Info'. The main content area has three tabs: 'Device Service Information', 'Patient Information' (which is active), and 'Insurance Information'. The 'Patient Information' form includes the following fields:

- Patient Name :** Three input fields for 'First Name', 'Middle (opt)', and 'Last Name'.
- Address :** Two input fields for 'Address line1' and 'Address line2'.
- City :** Input field, followed by a '--State--' dropdown menu, and a 'Zip' input field.
- Date Of Birth :** Input field with a placeholder 'DD/MM/YYYY'.
- Telephone :** Input field.
- Email :** Input field.
- Patient ID (MRN/SSN) :** Input field.
- Sex :** Dropdown menu with '--Select--'.
- Implanted Device :** Radio button options for 'Unknown', 'None', 'Pacemaker', and 'ICD'.
- Additional Comments :** A large text area for notes.

 At the bottom of the form are 'Previous' and 'Next' buttons.

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.

← → ↻ https://gmeduk.cardianex.com/index.aspx?sname=Gmedical#

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Select Doctor: All Filter: All

Patient Enrollment Upload Data Request Supplies

Doctor Name	Patient Name	DOB
Uk, Demo	sample2, patient	10/05/1990
Uk, Demo	Sample, Patient	10/10/2000

Download Selected E-Sign Selected Print Selected Patient Info Export Csv Mail

Device Service Information Patient Information **Insurance Information**

Type of Insurance : * --Select--

Insurance Company : * Company Name

Relation to Patient : * --Select--

Subscriber Name : * Name

Subscriber DOB --Sex-- Same as Patient

Address : * Street Address

City --State-- Zip

Policy/ID Number : * ID

Group : * Group

Claims Telephone : *

Address : * Street Address

City --State-- Zip

Prior Authorization # (if needed) : Authorization

Additional Comments:

Add Secondary

E-Sign Print Form

- 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.

Patient Enrollment Successfully Saved.

CLOSE

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).

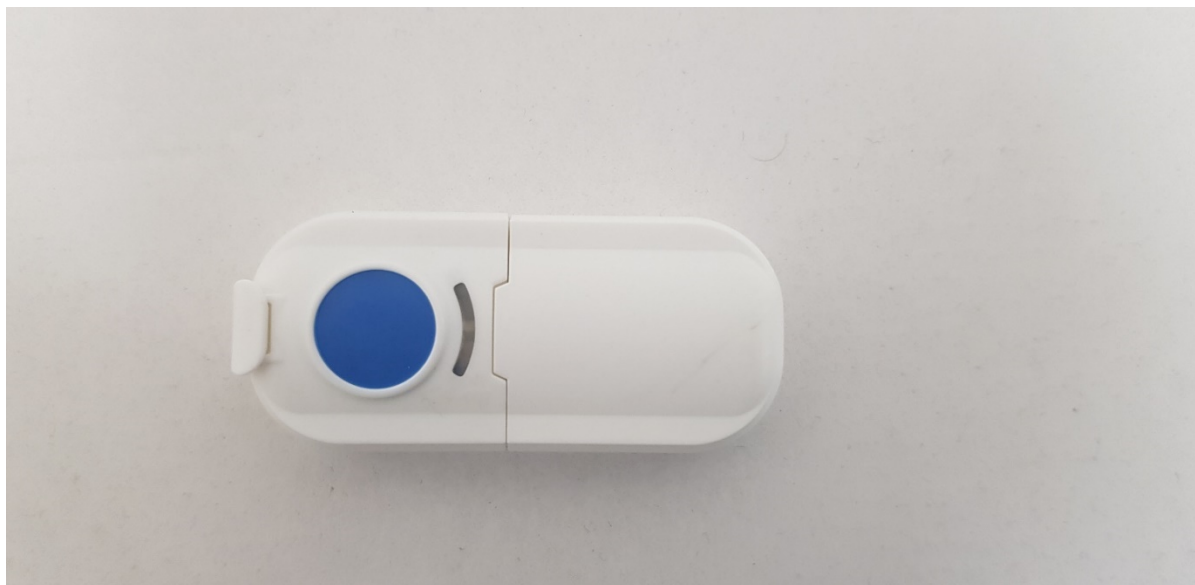


Figure 6: Led light indicator on recorder

LED indication	Meaning	Action
Red LED blinks	Initialization failure (BIT), VSMS patch critical low battery, SD card full, high Impedance, device temperature or HW failure.	Replace patch. If indication persists, return VSMS patch kit to Service for replacement.

Blue/Red LEDs blink alternately.	VSMS patch recorder is initializing.	No action required.
Blue LED blinks	Normal mode. VSMS patch is acquiring and recording ECG data.	No action required.

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

ECG Channel	2 X ECG channels, 4 X electrodes
Dynamic range	±5 mV
CMRR	65dB
Frequency Response	0.05 Hz to 65 Hz
Input Impedance	>10 MΩ
DC Offset	±300 mV
Sampling Rate	250 samples/second
Resolution	23-bit

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

Operational Temperature	Normal body temperature
Operational Humidity	Normal body humidity
Storage Temperature	+5 to +27 °C Storage
Storage Humidity	35% to 50% (non-condensing)
Operational/Transport/Storage Atmospheric Pressure	700 to 1060 hPa (525 to 795 mmHg)
IP Degree of Protection	IP 54

5.6 Environmental Specifications – VSMS patch reusable

Operational Temperature	+10 to +40°C
Operational Humidity	10% to 95% (non-condensing)
Storage Temperature	-20 to +60°C Storage
Storage Humidity	10% to 95% (non-condensing)
Operational/Transport/Storage Atmospheric Pressure	700 to 1060 hPa (525 to 795 mmHg)
IP Degree of Protection	IP54

	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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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:

Radio	
Frequency	2.360GHz to 2.500GHz
Modulations	GFSK at 1 Mbps, 2 Mbps data rates
Transmit power	+4 dBm
Receiver sensitivity	BMD-350: -94 dBm (BLE mode)
Antenna	BMD-350: Ceramic Chip



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

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

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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