Vpatch System

ECG Remote Event Monitor

Instructions for Use
(User Manual)

WRH-N-06232-05

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1.0 Equipment Supplied

1 Vpod device
1 Vcell device
1 Mascot Type 2240 Li-Ion battery charger (4.2V)
1 Quick Reference Guide

Note: The Vpatch REM Biosensor Array (BSA) is supplied separately.

This User Manual is available electronically, for viewing or download, at www.vpatchcardio.com/ifu

2.0 General Description of Vpatch System

The Vpatch System is a Remote Event Monitoring (REM) system that records a patient's ECG signals and detects whether one of the following arrhythmias is present:

- Bradyarrhythmia
- Ventricular Tachycardia
- Supraventricular Tachycardia
- Ventricular Fibrillation
- Atrial Flutter
- Atrial Fibrillation
- First Degree Heart Block
- Second Degree Heart Block
- Third Degree Heart Block

This small battery operated portable system consists of the Vpod (a body-worn device), the Vcell (a portable device) and the REM Biosensor Array (BSA). The Vpod is connected to the BSA, which is worn by the patient.

The Vpod is pre-programmed to monitor ECG signals on a continuous basis using the BSA. If an event is detected by the Vpod or triggered by the user (by pressing the Event Button), the relevant ECG data is sent via a wireless link to the Vcell. Cellular communication technology is used to send the data to a remote device/receiving station for analysis by the patient's clinician.

Note: This device is NOT a life saving device nor can it be used in any way to summon first responders to administer first aid or emergency care. If there is a concern regarding the health of the individual (i.e. chest pain or any other health concerns) while wearing the device; the individual or nearest bystander should contact a medical professional or emergency services IMMEDIATELY.

3.0 Indications for Use

The Vpatch System is intended for patients requiring ambulatory monitoring and is controlled via a central point by a clinician. The system is suitable for patients experiencing symptomatic or asymptomatic cardiac arrhythmias.

3.1 Contraindications

- The BSA (and therefore the Vpatch System) should not be applied to patients with a skin disorder or patients with known sensitivities to hydrogels or adhesives.
- The Vpatch System including the BSA has not been tested or approved for use to during an MRI scan and **therefore MUST** be REMOVED from the patient prior to the MRI procedure being performed.
- Patients fitted with an "active" implantable medical device such as a pacemaker or ICD should not use the Vpatch System due to the presence of magnetic studs on the

BSA. The presence of these magnetic studs may affect the performance of the implanted device.

- The BSA must be removed from the patient prior to using a cardiac defibrillator

3.2 Warnings

- The device must be issued by health care professional. The issuing health care professional must ensure that the person wearing the device, or their carer is capable of and instructed in how to change the Vpod batteries and recharge the Vcell as per the instructions outlined in Section 6.2, and Table 5 in Section 8.0
- Care should be taken to ensure that the Vpod and Vcell devices do not come into contact with water or any other liquids. The BSA **should not** be submerged in water, for example during a bath or while swimming.
- The Vpod should only be opened to replace discharged batteries or at the completion of the monitoring period or if the batteries have discharged. **DO NOT** remove the coin cell batteries from the Vpod ***during monitoring.***
- The Vcell should be used in accordance with restrictions that apply to the use of cellular mobile telephones.
- Care should be taken when changing the CR3032 coin cell batteries in the Vpod as they may present a choking hazard.
- The CR3032 coin cell should be disposed of correctly as described in Section 10.0 on page 18
- The Vpatch electronics should only be operated at temperatures between 0 °C and 40 °C (32 °F and 104 °F). Exceeding the recommended storage conditions and conditions for use can result in impaired system performance.
- A separation distance of at least 20 cm **MUST** be maintained between the Vcell and all persons whilst the device is transmitting on the 2G/3G network. For details on recommended separation distance see section 8.0 with reference to section 8.3.

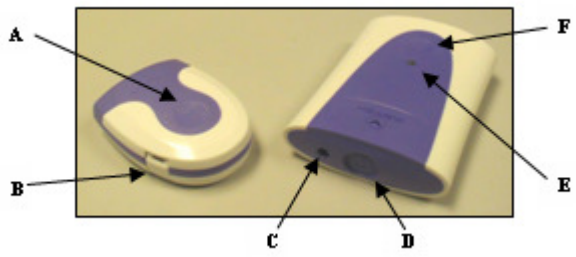
4.0 Vpatch System Equipment

4.1 REM Biosensor Array (BSA)

The BSA provides quality ECG measurements to facilitate event analysis, as well as being flexible and comfortable to wear.

4.2 Vpod and Vcell Devices

The Vpod and Vcell are shown below in Figure 1. The Vpod monitors ECG signals when connected to the BSA on the patient's body.



A	Event Button/Pairing Button
B	Release Clips
C	Charging Port
D	On/Off Button
E	LED
F	Pairing Button

Figure 1: Vpod and Vcell Devices

5.0 Conditions of Use

The patient should adhere to the following conditions while using the Vpatch System:

- The Vpatch System is to be operated under the restrictions which apply to the use of cellular/mobile telephones.
- Only use a genuine BSA that is supplied with the device or sourced from an approved agent.
- The Biosensor should be within its shelf life.
- Biosensors are single-use only and should not be used if they are damaged.
- The use of damaged or unsuitable Biosensors may lead to poor results or unnecessary skin irritation.
- Excessive exercise and perspiration may decrease the length of time that the BSA can be worn.
- Avoid touching or rubbing the BSA once it has been applied.
- Apply a new BSA if reduced adhesion is observed.
- A slight reddening of the skin or minor irritation underneath and/or immediately adjacent to the BSA border is normal. If this is uncomfortable for the person wearing the device, it is recommended they contact the issuing Healthcare professional for consideration of discontinuation, replacement or re-positioning of the BSA.
- The Vpatch System including the BSA has not been tested or approved for use to during an MRI scan and **therefore MUST** be REMOVED from the patient prior to the MRI procedure being performed.
- The Biosensor (BSA) is not defibrillation-proof and **therefore MUST** be REMOVED prior to the use of a cardiac defibrillator on the patient.
- The BSA can be worn in the shower (excluding power showers) with the Vpod device disconnected. The BSA should be gently dabbed dry with a lint free cloth and the Vpod device cleaned and reconnected as soon as possible thereafter.
- The Vpod device can be worn during sleep.
- The Vpatch devices and accessories should be kept out of the reach of children and pets.
- The Vpatch Devices are designed to be resistant to normal environmental conditions such as lint, dust and light including sunlight. All care should be taken to minimise exposure. If required cleaning instructions are included in section 6.3 Cleaning
- There are no user serviceable parts.

6.0 System Operation

6.1 Device Preparation and Charging

- The device should be prepared by a trained health care professional.
- The issuing health care professional must ensure that on each occasion a device is fitted that the patient or their carer is issued with a fully charged Vcell and that new batteries are inserted into the Vpod.
- The issuing health care professional must ensure that the person wearing the device or their carer is capable of and instructed in how to change the Vpod batteries and recharge the Vcell as per the instructions outlined in Section 6.2, Page 5 and Table 5 in Section 8.0 on Page 15.
- The patient must recharge the Vcell whenever the low battery alarm sounds (i.e. when there is one beep heard from the Vcell every 5 seconds).
- When in use, the Vpod and Vcell can be up to 10 metres apart however they must be in 'line of sight'. The distance may be reduced if there are physical obstructions between the two devices.

6.2 Charging

- The Vcell must only be charged using the supplied charger.
- The Vcell can be used while charging.
- For charger and battery specifications see Section 8.0

To Charge:

First plug the charger into the charging port of the Vcell, then plug the charger into the mains socket and turn it on. The indicator on the charger will turn red, indicating that it is in charging mode. The indicator light will turn green when the unit is charged.

Charging can take up to 3 hours.

When charging is complete, turn off the mains power and remove the plug from the Vcell charging port.

A fully charged battery should provide up to 7 days operation in normal monitoring conditions. This can vary between patients depending on the amount of activity.

Note: It is important that the charger be connected to the Vcell before turning on the mains power to ensure the charging function is activated correctly.

6.3 Cleaning

- **The system MUST be cleaned before and after each patient use. It is recommended that the device be cleaned using an alcohol wipe (without applying undue pressure) and dried with a lint-free cloth.**
- General Cleaning - Surfaces which do not have contact with a patient have no special cleaning requirements, however it is recommended that the instrument is wiped with a dry cloth once a week to reduce the build-up of dust in the device.
- Patient Contact Surfaces - Clean patient contact surfaces between patients. Cleaning should be performed using any biofilm removing wipe. Discard wipe after use. Do not use any other chemical product.

6.4 Skin Preparation

- The BSA must be applied to clean, dry skin that is free from body hair.
- Body hair can be removed using hair removal cream, shaving or waxing. It is important to ensure that any chest hair present does not prevent the BSA from adhering well to the skin.

- To ensure the collection of diagnostic quality ECG recordings and to reduce the collection of “noise events” the skin MUST be cleaned using a non-alcohol skin wipe ensuring that the skin surface is thoroughly dried BEFORE applying the BSA.
- The BSA must be applied within two hours of skin preparation.

6.5 Biosensor Array Application

- It is essential for the collection of clear event and episode recordings that a suitably trained healthcare professional apply the BSA to the patient for the first time.
- It is the responsibility of this healthcare professional to provide education and instruction to the patient for replacing the BSA during the monitoring period.
- The Vpod device should be placed onto the BSA **after** the array is applied to the patient’s chest.
- It is advisable to determine the optimum electrode placement on the patient before removing the paper liners from the electrodes.

NOTE: The BSA is a single-use product, which is recommended for use on the patient for a duration of up to 7 days, after which a new BSA is to be applied to the patient’s chest.

- The BSA must be applied to the patient in the configuration as illustrated in Figure 2.

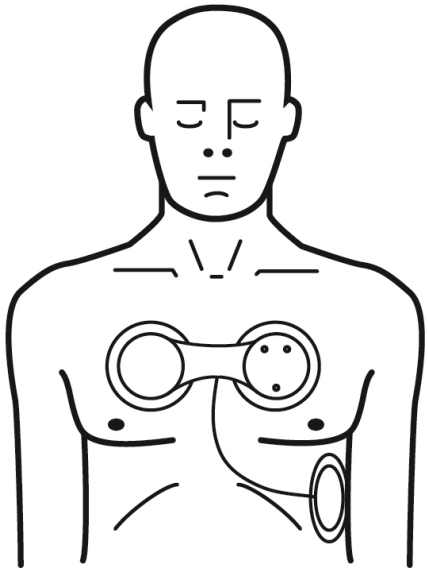


Figure 2: BSA Placement

- After removing the release liners to expose the adhesive foam, it is recommended the Health care professional instruct the patient to inhale and hold a deep breath while they position the BSA in place. This is done to maximize patient comfort during wear.
- The health care professional must ensure that the BSA is securely fixed to the patient’s body by smoothing each adhesive area firmly to the skin ensuring that there are no creases.
- Loose fitting outer clothing and minimal contact between the BSA and undergarments is highly recommended.
- When removing the Vpod to replace batteries or prior to bathing or showering, remove one stud at a time while pressing down securely on the BSA beside each stud.

NOTE: Incorrect BSA application may impair the quality of ECG recording.

6.6 Vcentral

Once an event has been recorded, the data is sent to a central server for display on Vcentral. To modify this default setting the Vpatch Website must be accessed to create a custom setup.

The default setting of the Vpatch System records an event with up to 20 seconds pre-and 30 seconds post detection (as listed in Section 2.0) whether the detection was automatically triggered, or as a result of manually pressing the Event Button on the Vpod.

The Vpatch website (V Central) allows the healthcare professional to:

- Add new patients to the server database
- Assign a Vpatch device to the patient
- Initiate a monitor session
- Specify the period of time that the patient will be monitored
- Change the monitoring settings
- View ECG data recorded by the Vpatch System

The Vpatch System devices MUST be re-assigned and re-configured every time they are used by a new patient, or each time there is a new monitoring period.

Failure to reconfigure a monitor may result in ECG data not reaching the Vpatch website.

NOTE: Please contact your distributor to obtain login details for the Vpatch website. Your distributor will also ensure that the correct devices are added to your facility. This is necessary for assigning a device to a patient in support of successful monitoring.

NOTE TO DISTRIBUTORS: When adding new devices to a customer's inventory, you must enter the Vpod serial number correctly, to enable the clinician or HCP to assign the device to a patient.

6.7 Device Operation

6.7.1 Switching the Vpod on and off

The Vpod device is switched on when the CR 3032 batteries are inserted and the case is closed using the release clips. Once the case is opened using the release clips, the Vpod is switched off.

To insert the Vpod batteries:

1. Open the Vpod device using the release clips (labelled 'B' in Figure 3 below).
   Note:
   The Left Release Clip can be opened by using the fingers only while the **Right Release Clip needs a tool to be unlocked** (See Figure 3 and 4 below).
2. Place both coin cell batteries into the case, positive side upwards (i.e. the smooth side with writing, '+' symbol will be etched on this side).
3. Close the Vpod case by securing the release clips.
4. The Vpod will beep once* to indicate '*Power On'.*

Ensure older batteries are not used with new batteries in the device. Only new batteries should be inserted into the device when replacing used batteries. For information on battery disposal please refer to Section 10.0, Page 17.

If the Vpod memory is full, two beeps will be heard approximately 30 seconds after the 'Power On' beep during Vpod start-up, otherwise only the 'Power On' beep will be heard. If three beeps are repeatedly heard immediately after switching on, please see Section 14.0 Troubleshooting Guide.

The Vpod should only be switched off to replace the batteries or when the monitoring session has concluded.

NOTE: Healthcare professionals and patient must be familiar with the correct procedure for inserting and replacing Vpod batteries.

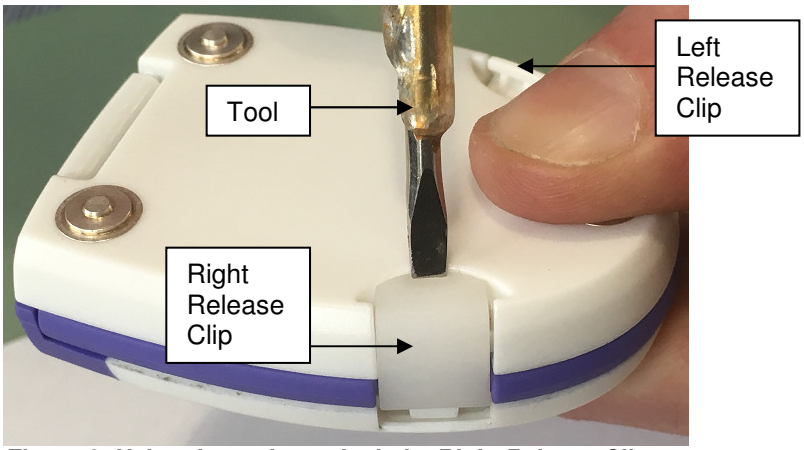


Figure 3: Using the tool to unlock the Right Release Clip.

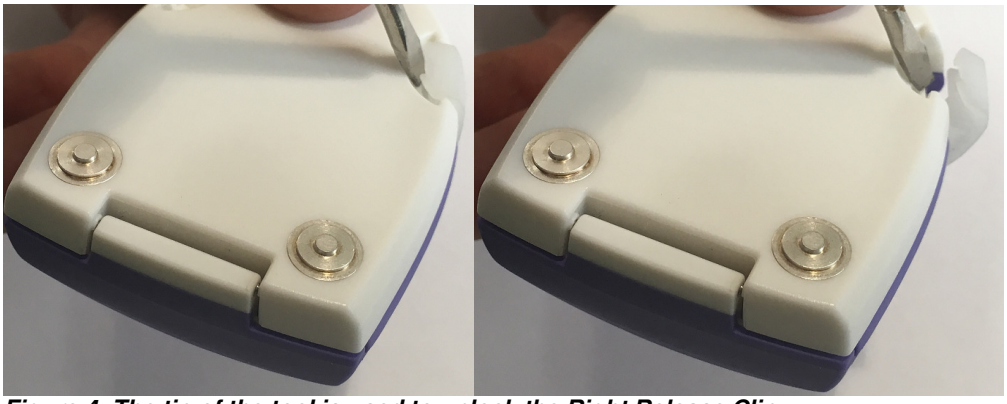


Figure 4: The tip of the tool is used to unlock the Right Release Clip.

6.7.2 Device Start-up

After the configuration settings have been selected the devices are now ready to be set up. A Vpod must be paired with a Vcell before the system is used to allow the patient's ECG data to be sent to the Vpatch website.

Before commencing a new monitoring period or using the devices on a new patient, it is important to pair the Vpod and Vcell, even if the devices have been paired previously.

The pairing process clears any stored events from the device memory and restores the default settings, i.e. the system records up to 20 seconds pre-event and 30 seconds post-event ECG data when the Event Button is pressed or when one of nine arrhythmias are detected (See Section 2.0 for a list of arrhythmias).

The healthcare professional responsible for issuing, assigning or fitting a V Patch System must be familiar with the device operation and the listed contents of Section 14.0 "Troubleshooting Guide" PRIOR to using the device.

Function	Indication
To configure the device for monitoring, please refer to Section 6.6 before use..	
Switch on the Vcell by pressing 'D':	'E' will turn orange and then green while 1 beep is heard.
To pair the devices, press and hold 'F' on the Vcell until the pairing mode indication is seen:	
Enter Pairing Mode on the Vcell by pressing and holding 'F':	1 beep and 'E' is green when 'F' is *pressed initially* 'E' flashes green to indicate that it is in pairing mode and is *searching* for Vpod. 'F' can now be released.
Once 'E' begins to flash green, the user has 60 seconds to complete the pairing process by switching on the Vpod and placing it in pairing mode. **If pairing is not completed within 60 seconds the devices will timeout and return to normal operation. If pairing is still required, the healthcare professional must switch the devices off and then on again and repeat the sequence.**	
Insert the coin cell batteries into the Vpod and close the case using 'B':	1 beep or 3 beeps (See Section 6.7.1, Page 7)
Press and hold 'A' on Vpod until repeated beeping is heard:	1 beep (depending on previous configuration) when 'A' is *pressed initially* Repeated fast beeping while *searching* for Vcell Long beep when *successfully paired* with Vcell 'E' on Vcell is stops flashing when *successfully paired* with Vpod
1 long beep is heard from the Vpod and 'E' stops flashing on the Vcell to indicate that it has successfully paired and that the system has been reset to the default settings (30 seconds of ECG data recorded when an arrhythmia is detected or when Event Button is pressed). **The Vcell will connect to the network to retrieve configuration settings.** ***Please note the solid orange LED described below to confirm that the device has connected successfully.***	
While the device is searching for a Network connection	'E' is flashing orange
When a successful connection has been established	'E' is solid orange
If the Vcell is unable to connect to the network	'E' will stop flashing orange and return to green
The Vcell will then ensure it is in range with the Vpod (whether there is a successful connection to the network or not). **The Vcell will then send any new configuration settings available to the Vpod. The LED sequence may vary at this stage; however the system has successfully received the new settings when 3 beeps are heard from the Vpod.**	
Retrieving configuration settings	'E' will remain orange for while data is transferred 3 beeps will be heard from the Vpod to confirm configuration settings are set.
Devices in range	'E' will remain solid green
'E' will become solid green again when the system is ready for use. **This indicates that the paired Vpod and Vcell are within range of each other.** **The Vpod can now be connected to the Biosensor Array that is applied to the patient.**	
When the devices are out of range, 'E' will not be lit, but will flash in 10 second cycles as it searches for the Vpod it was previously paired with.	
To switch off the Vcell, press and hold 'D'.	
Vcell switching off	'E' is solid orange while 1 beep is heard

6.8 To Begin Monitoring

- Once the devices have been set up and connected to the patient via the BSA, the Event Button 'A' should be pressed to send an initial ECG trace to the server. This will allow a predefined amount of data to be recorded and sent to the Vcell. One beep will be heard from the Vpod when the event button is pressed.

- The ECG file will be present on the website within a few minutes providing there is a constant and uninterrupted cellular network signal. It is highly recommended that the ECG file is viewed before the patient leaves the healthcare professionals workplace. This verifies that the system is configured correctly.

6.9 Frequently Used Functions During the Monitoring Period

NOTE: If the Vpod becomes disconnected from the BSA during the monitoring period, it should be reconnected as soon as possible.

NOTE: All of the functions available to the patient during a monitoring period are safe.

6.8.1 Pressing the Event Button

If the patient feels unwell during monitoring they must press the Event Button, 'A'. One beep will be heard from the Vpod. The Vpod will queue up to ten events if it is already recording data. Two beeps will be heard from the Vpod every 5 minutes or when 'A' is pressed on the 5th occasion, and thereafter.

If events are queued on the Vpod, ensure that the Vcell is in range and in line of sight. If events remain queued, please refer to Section 14.0 "Troubleshooting Guide".

This recorded data is sent to Vcentral for analysis by the patient's clinician.

6.9.2 Out of Range Indicators

During use, the LED on the Vcell will be green to indicate that the Vpod and Vcell are within range of each other. Should the Vpod and Vcell be out of range, the green LED will flash approximately every 10 seconds until the devices are back in range.

6.9.3 Low Battery Alarms

Low battery alarms may sound during the monitoring period:

Vpod: Single beep sounding every 5 seconds. The patient should replace the batteries if the battery alarm sounds. (See Section 6.7.1). This alarm may be silenced by pressing and holding 'A' until a long beep is heard. The low battery alarm can only be silenced 5 times before the batteries must be changed.

Vcell: Single beep sounding every 5 seconds. This alarm can be silenced by pressing and holding 'F' or connecting the device to the charger provided. The Vcell should be connected to the charger as soon as possible.

If the battery level of the Vpod is no longer sufficient to record and transmit events, a critical low battery alarm will sound. Batteries **MUST** be replaced at this point. The critical low battery alarm on the Vpod is described below:

Vpod: Single beep sounding every 2 seconds. The wireless link between Vpod and Vcell is now shut down and the Vcell will appear to be out of range ('E' will flash green once every 10 seconds). The patient should replace the batteries as soon as possible. (See Section 6.7.1,).

The battery level of the Vcell can be checked by pressing 'F' once at any time during use.

- One beep and a **green LED** will indicate that there is sufficient battery level power in the Vcell.
- One beep and an **orange LED** will indicate that the battery level is low and the Vcell requires charging.

6.9.4 Restarting the Vpod and Vcell

Should the Vpod or Vcell be switched off (intentionally or unintentionally), the user is not required to re-pair the devices as outlined in Table 1. The Vpod and Vcell retains the most recent device pairing information. It is important that the user avoids switching devices off unnecessarily during any monitoring period.

To restart the devices:

Vpod: Ensure fresh batteries are inserted and that the Vpod case is closed correctly (See Section 6.7). The sounding of one beep indicates correct operation. If two beeps are sounded within 30 seconds, the Vpod memory is full. ECG data will send to the Vcell when both devices are in range again. If three beeps are repeated after switching on, please see Section 14.0 “Troubleshooting Guide”

Vcell: If the Vcell has sufficient charge, it should be switched on again by pressing ‘D’. Otherwise connect the device to the charger provided and press ‘D’ if required.

6.10 Viewing the Patient’s ECG Data

To view the patient’s ECG file the user must be familiar with the operation of the web-based platform, Vcentral. Refer to Section 6.6:

7.0 Transmission of Data

If any events are recorded in an area of limited cellular network signal, the system is equipped to ensure that no data is lost **if** communications are restored before the devices are re-paired. Up to 10 events may be stored on the Vcell device at any one time.

The cellular communications also support global roaming functionality, permitting the user to move between countries without losing any of the benefits of the Vpatch System.

8.0 Specifications

Size and Weight:

- Vpod: External dimensions: 59mm x 48mm x 18mm
  Weight: 34grams
- Vcell / 3G Vcell: External dimensions: 86mm x 61mm x 20mm
  Weight: 78grams

IP Rating:

- Vpod: IP22
- Vcell / 3G Vcell: IP21

FCC ID:

- Vpod: 2ARNZ-1001
- 3G Vcell: 2ARNZ-1002.

The Vpod requires 2 x CR3032 Lithium coin cell batteries. Care must be taken to insert the batteries correctly, with the positive side facing upwards. (See Section 6.7)

NOTE: The batteries MUST be removed from the Vpod when not in use.

Power Sources:

Device	Battery Voltage (V)	Battery Type
Vpod	3.0	Coin Cell: Non-Rechargeable
Vcell	3.7	Li-Ion: Rechargeable

Table 2

CR3032 Coin Cell Battery:
(Specifications)

Nominal Voltage (V)	3
Nominal Capacity (mAh)	500
Continuous Standard Load (mA)	0.2
Operating Temperature (C)	-30 to +60

Table 3

Mascot Type 2240 Li-Ion Battery Charger
(Containing 1.3 mm x 3.8 mm power connector):

Input Voltage (VAC)	Output Voltage (V)	Current (Max) (A)	Operating Temperature (°C)
90-264	4.2	1.3	-25 ~ +40

Table 4

LED Indicators on Mascot Type 2240 Li-Ion Battery Charger	
Red LED	Green LED
Vcell is not fully charged	Vcell is fully charged

Table 5

NOTE: Do not use any other mains adapter with the charger as it may result in damage to the Vcell unit or affect system operation.

Expected Service Life
The Li-Ion battery in the Vcell is rated to last for at least 300 charging cycles. At maximum use, assuming a charging cycle of every 5 days, this should provide an expected service life of 5 years.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Wireless ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless ECG Monitor should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The Wireless ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless ECG Monitor should assure that it is used in such an environment			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$V/m	d = [1.17]√P…80MHz to 800 MHz d = [2.33]√P…800 MHz to 2.5GHz 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 Wireless ECG Monitor is used exceeds the applicable RF compliance level above, the Vpatch System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Wireless ECG Monitor.		
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$V/m		

Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life-supporting

Recommended separation distances between portable and mobile RF communication equipment and the Wireless ECG Monitor		
The Wireless ECG Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless ECG Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wireless ECG Monitor 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 m**	
	80 MHz to 800 MHz $d = [1.17]\sqrt{P}$	**800 MHz to 2.5GHz** $d = [2.33]\sqrt{P}$
0.01	**0.12**	**0.23**
0.1	**0.37**	**0.75**
1	**1.17**	**2.33**
10	**3.70**	**7.36**
100	**11.70**	**23.30**
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.		

Recommended separation distances between portable and mobile RF communications equipment and the equipment and system – for equipment and systems that are not life supporting

8.1 EMC Compliance

This product is compliant with the electromagnetic compatibility requirements of IEC60601-1-2.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Vpatch System (Vpod and 3G Vcell) is intended for use in the electromagnetic environment specified below. The customer or the user of the Vpatch System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	GROUP 1	The Vpatch System 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 Vpatch System is suitable for use in all establishments other than domestic 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

8.2 FCC Compliance

The Vpod device and 3G Vcell device comply 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.

NOTE:

This equipment (Vpod device and 3G Vcell device) 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.

Caution:
Changes or modifications (not expressly approved by the party responsible for compliance) could void the user's authority to operate the equipment.

8.3 Radio Wave Emissions

The Vpod device and 3G Vcell device both operate in various radio wave frequency bands and at different output powers, each of which are listed below.

Maximum radio-frequency power transmitted in the frequency band(s) in which the 3G Vcell operates.

Frequency Bands	Power Level
2400 MHz to 2438.5 MHz	0.11 mW e.i.r.p.
824.2 MHz to 848.8 MHz	2.1 W e.r.p.
1850.2 MHz to 1909.8 MHz	2.2 W e.i.r.p.
1852.4 MHz to 1907.6 MHz	0.5 W e.i.r.p.
826.4 MHz to 846.6 MHz	0.24 W e.r.p.

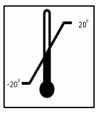
Maximum radio-frequency power transmitted in the frequency band(s) in which the Vpod operates.

Frequency Bands	Power Level
2400 MHz to 2438.5 MHz	0.14 mW e.i.r.p.

Note:
The compliance to EMC, FCC, RED and RCM is granted to the Vpod (Serial/Model Number: 101-XXXXXX and 0010XXXXX) and 3G Vcell (Serial/Model Number: 301-XXXXXX). See Section 11.1 Vpatch System Model/Serial Numbers.

9.0 Storage and Transport Conditions

The Vpatch System electronics must be stored between the temperatures of -20 °C and 40 °C (-4 °F and 104 °F) and at 30% relative humidity. The electronics must be protected from water and other liquids at all times.



Temperature Limitation

Handle with care

	Temperature	Relative Humidity	Air Pressure
Transport	-10 to +60°C	10 to 90%**	700 to 1013 hPa
Storage	-20 to +40°C	10 to 85%**	700 to 1013 hPa
Operation	0 to +40°C	20 to 80%**	800 to 1013 hPa

**Wet bulb limit of 7°C

9.1 Maintenance

Vpatch System Should be kept clean and periodically checked to ensure the integrity of the case, hinges, contact points and battery contact points. Power leads and battery charger should also be visually inspected for signs of wear and damage.

The system is to be cleaned before and after use on each patient, as per the instructions in Section 6.3..
It is recommended that that the device is kept in the supplied case while not in use and the rechargeable battery charged periodically.

The following guidelines should be adhered to.

- Care should be taken to ensure that the Vpod and Vcell devices do not come into contact with water or any other liquids.
- There are no user serviceable parts.

10.0 Disposal

The information below is sourced from a recommended battery manufacturer's guideline material:

When disposing batteries, insulate the (+) and (-) terminals of batteries with insulating tape, etc. (see Figure 15). When disposed of improperly, lithium batteries may short, causing them to become hot, burst or ignite.

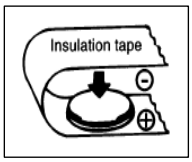


Figure 15

The Vpod and Vcell are electronic devices and must be returned to the distributor for disposal.

Do not heat or dispose of any part of the Vpatch System in fire. The devices may burst or release toxic materials.

Do not disassemble, apply excessive pressure or deform any part of the Vpatch System.

NOTE: Electronics and battery disposal must be in accordance with local and state regulations

11.0 Explanation of Symbols Used on Vpatch System Documentation

The symbols used in the documentation for the Vpatch System are summarised in the following table:

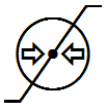
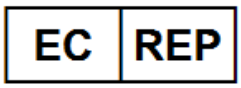
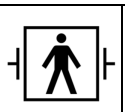
Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		Temperature limitation		CE Mark		Serial Number
	Use-by date		Handle with care		Consult Instructions for Use		Equipment should not be disposed of with normal waste stream
	Do not get wet		Date of manufacture		Catalogue Number		Humidity limitation
	Pressure limitation		Do not use if package is damaged			European Representative	
	Batch code		Non-ionizing electromagnetic radio		Defibrillator Proof Type BF: The Vpod device is a type BF device and has a high level of protection against defibrillation energy as per EN 60601-1.		

Table 6

11.1 Vpatch System Model/Serial Numbers

The Vpatch System model/serial numbers are in the format shown below.

Vkit model number FG06120 contains:
1 x Vpod
1 x Vcell
1 x Mascot battery charger type 2240
1 x Carry case

3G Vkit model number FG06127 contains:
1 x Vpod
1 x 3G Vcell
1 x Mascot battery charger type 2240
1 x Carry case

The first three digits of the model/serial number are the model number and indicate the device type (Vpod or Vcell or 3G Vcell). The last five or six digits are the serial number.

Vpod devices will have the model/serial numbers:
101-XXXXXX
001-XXXXX

Vcell devices will have the model/serial numbers:
201-XXXXXX Vcell representing models for 2G cellular communication.
301-XXXXXX 3G Vcell representing models for both 2G and 3G cellular communication.

Note: Refer to Section 15 'Standards' for compliance information. The Vpod and 3G Vcell are compliant to:

- 47 CFR FCC Part 15.249.
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU.
- Radio Equipment Directive (RED) 2014/53/EU.
- Regulatory Compliance Mark (RCM) at Compliance Level 1.

The device labels include a Global Trade Item Number (GTIN) that provides an additional form of model identification.

12.0 Start-Up Guide

The following indicators and actions are required to start and configure the Vpatch System.

Press 'D' to switch on Vcell and wait for green LED and 1 beep.

⇩

START UP	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Setup		1 flash				
Setup complete		1 sec		Single beep		

⇩

If PAIRING is not required, switch on the Vpod immediately and skip to NETWORK.
To PAIR devices, press and hold 'F' on the Vcell until 'E' begins to flash.
Then switch on the Vpod and press and hold 'A' until 1 long beep is heard.
This indicates successful pairing.

⇩

PAIRING	VCELL LED		VCELL BUZZER		VPOD BUZZER	
While searching		Fast flashing				Fast beeping
Successful pairing		Successful pairing				Long beep
Default Settings reset	Vcell moves on to next stage (see next table)					Single beep

⇩

The Vcell will then immediately connect to the Network. This LED sequence may vary slightly.

⇩

NETWORK	VCELL LED		VCELL BUZZER		VPOD BUZZER	
While searching		Slow flashing				
Successful connection		For duration of action				

⇩

The Vcell will then check that it is in range with the Vpod.

⇩

RANGE	VCELL LED		VCELL BUZZER		VPOD BUZZER	
In Range						

⇩

The Vcell will check for configuration settings and transfer them to the Vpod.

⇩

CONFIGURATION	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Sending configuration data						Three beeps

⇩

The green LED on the Vcell will light up, indicating that the devices are in range.
The system is now ready for use.

13.0 Indicator Guide

The following indicators can occur at any time during normal use.

Vpod/Vcell Range

RANGE	VCELL LED		VCELL BUZZER		VPOD BUZZER	
In Range						
Out of Range		1 flash every 10 seconds				

ECG Data Transfer (from Vpod to Vcell)

If Vpod is in range of Vcell

⇩

ECG Data Transfer	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Vpod to Vcell ECG Transfer		Flashing for duration				

ECG Data Transfer (from Vcell to Internet)

If ECG Data is on Vcell

⇩

ECG Data Transfer	VCELL LED		VCELL BUZZER		VPOD BUZZER	
While searching		Slow flashing			N/A	N/A
Successful connection and data transfer		Fast flashing for duration of transfer			N/A	N/A

Vcell Network Checks

Every 4 hours the Vcell will connect to the Internet to check for new configuration settings. The clinician/patient is not required to take any action.

⇩

NETWORK	VCELL LED		VCELL BUZZER		VPOD BUZZER	
While searching		Slow flashing			N/A	N/A
Successful connection		For duration of action			N/A	N/A

Warning Indicators

The following indicators can occur at any time during normal use. These indicators require a corrective action to rectify the issue.

Low Battery

LOW BATTERY	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Vpod Low Battery	N/A	N/A	N/A	N/A		Beep every 5 sec
Vcell Low Battery	N/A	N/A		Beep every 5 sec	N/A	N/A
Vpod Critically Low Battery		Flash every 10 sec	N/A	N/A		Beep every 2 sec

⇩

Connect Vcell to charger or Replace Vpod batteries

Vpod Memory Full

MEMORY FULL	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Ten events stored on Vpod	N/A	N/A	N/A	N/A		Double beep every 5 min or when Event Button pressed

⇩

Ensure Vpod is in range of Vcell

Vcell Memory Full

MEMORY FULL	VCELL LED		VCELL BUZZER		VPOD BUZZER	
Ten events stored on Vcell		Double flash every 5 min		Double beep every 5 min		

⇩

Move to an area of cellular network coverage.

Vpod System Error

SYSTEM ERROR	VCELL LED		VCELL BUZZER		VPOD BUZZER	
System error	N/A	N/A	N/A	N/A		Repeated triple beep on Start Up

⇩

Switch Vpod off and on again. If error persists contact you distributor.

Vcell System Error

SYSTEM ERROR	VCELL LED		VCELL BUZZER		VPOD BUZZER	
System error	 	Alternating green and orange LEDs		One beep every sec	N/A	N/A

⇩

Switch Vcell off and on again. If error persists contact you distributor.

For further information on warning indications, please see the Troubleshooting Guide (Table 7).

14.0 Troubleshooting Guide

Problem	Possible Solution
One beep heard every 5 seconds from the Vpod	This is the low battery alarm. To silence the alarm, press and hold 'A' until a long beep is heard. Insert new batteries into the Vpod as soon as possible.
One beep heard every 2 seconds from the Vpod	This is the critical low battery alarm. The Vpod has shut down communications with the Vcell, which will therefore show the "Out of Range" indication (See Section 13, Page 23). Insert new batteries into the Vpod as soon as possible.
One beep heard every 5 seconds from the Vcell	This is the low battery alarm. To silence the alarm, press and hold 'F' or connect the device to the charger provided. The Vcell must be connected to the charger as soon as possible.
Vcell will not switch on	Connect the Vcell to the charger provided. If the LED on the charger is red the Vcell requires charging. If the LED on the charger is green you may need to disconnect the charger from the mains while it is still connected to the Vcell, reconnect and try again. The Vcell should be charged for 3hrs (minimum). If the device does not switch on after charging, 'D' should be pressed and held for approximately 15 seconds. Release 'D' and switch the Vcell on as normal. The Vcell will then switch on. This results in a full reset of the Vcell.
Vcell will not switch off	Press and hold 'D' for approximately 15 seconds. Release 'D' and switch the Vcell on as normal. The Vcell will then switch on. This is a full reset of the Vcell. Any ECG data stored on the device can still be transmitted to the Vpatch website.
No beep heard from Vpod when switched on	Switch the Vpod off and on again. If there is still no beep heard on start up, place new batteries in the Vpod (See Section 6.7) and retry. If there is no audible tone after new batteries have been inserted, please contact your distributor.
No pairing beeps heard from Vpod / No flashing green LED from Vcell / Devices will not pair	Pairing beeps may be heard from the Vpod up to 10 seconds after initially pressing and holding the pairing button. If no pairing beeps or LED indications are heard or seen after this time, ensure that enough digital pressure is consistently placed on the device buttons. Switch both devices off and on again and re-try. Insert new batteries into the Vpod and re-try.
No beep heard from the Vpod when Event Button is pressed	Switch the Vpod off and on again. If there is still no beep heard when the Event Button is pressed, place new batteries in the Vpod (See Section 6.7) and retry. If there is no tone after new batteries have been inserted, please contact your distributor.
Two beeps heard from the Vpod every 5 minutes and when the Event Button is pressed	The Vpod has ten events stored in its memory and is now full. Ensure the Vpod and Vcell are within range and are in direct line of sight of each other.
Two beeps and two orange LED flashes from Vcell every 5 minutes	The Vcell has ten events stored in its memory and is now full. Ensure the user is in an area of good cellular network. Press 'F' on the Vcell twice, ensuring a beep is heard with each press to allow the Vcell to attempt a network connection. Additionally, the Vcell will do this every 4 hours itself.

Table 7 (continued on following page)

Problem	Possible Solution
Three beeps heard from the Vpod when the Event Button is pressed	The Vpod has not been configured to record ECG data when 'A' is pressed. See Section 6.6 for information on configuration.
Three beeps repeatedly heard from the Vpod when it is switched on	This is a system error. The Vpod must be switched off and on. If the error persists, please contact your distributor.
Alternating green and orange LEDs and one beep every second on the Vcell	This is a system error. The Vcell must be switched off and on. If the error persists, please contact your distributor.
Poor quality ECG signal from one or more leads	Ensure that the recommended skin prep and removal of excessive body hair were followed and attended to if not. Ensure the magnetic studs on the Vpod and BSA are clean and free of all debris. Ensure the Vpod is securely connected to the BSA via each of the magnetic studs. Ensure the BSA has been applied correctly, as outlined in Section 6.5, Page 4.
Events cannot be viewed on Vpatch System website	Ensure the correct Vpod Serial Number is assigned to the correct patient and that the monitoring period has not ended (See Section 6.6). If the Vpatch System is an area of limited or zero cellular network coverage, ECG data sent from the Vpod to the Vcell cannot be transmitted to the Vpatch website. The Vcell can store up to ten events in its memory. Once the system returns to an area of cellular network coverage any stored events will be transmitted to the Vpatch website.
The Vcell does not connect to network during set-up	If the Vpatch System is being set up in an area of limited or zero cellular network coverage. Move to an area of cellular network coverage and re-try. You can initiate the Vcell to attempt to connect to the network by pressing 'F' twice, ensuring that a beep is heard with each button press. If the Vcell consistently fails to connect to the network, please contact your distributor.

Table 7 (Continued)

15.0 Standards

The Vpatch System has been designed and tested to conform to the essential requirements and provisions of European Council Medical Devices Directive 93/42/EEC Annex II (excluding Section 4) for a Class IIa device, (under Annex IX Rule 10 – non-invasive active device) and the Radio Equipment Directive 2014/53/EU, obtaining the European CE Mark.

The device has been designed to conform to the following International Standards:

IEC 60601-1 : 2005/AMD1:2012/COR1:2014	ISO 13485: 2016	AS/NZS 4268:2017
IEC 60601-1-2 :2014	ISO 14971:2012	ETSI EN 301 489-1 V2.2.0 (2017-03)
IEC 60601-1-6 : 2010+AMD1: 2013	ISO 15223-1:2016	EN 61000-3-2:2014
IEC 60601-1-11:2015	Final Draft ETSI EN 300 440 V2.1.1 (2017-01)	EN 61000-3-3:2013
AAMI EC 12:2000 (R2015)	IEC 61000-3-2: 2018	CISPR 11:2015
ANSI/AAMI EC57:2012	IEC 61000-3-3:2013/AMD1: 2017	

Table 8

Note: The Vpod and 3G Vcell are also compliant to:

1) 47 CFR FCC Part 15.249.
2) Electromagnetic Compatibility (EMC) Directive 2014/30/EU.
3) Radio Equipment Directive (RED) 2014/53/EU.
4) Regulatory Compliance Mark (RCM) at Compliance Level 1.

16.0 Warranty

One Year Limited Warranty

The Vpod and Vcell are warranted by Vpatch Cardio Pty Ltd (Vpatch Cardio) to be free from defects in materials or workmanship for one year from the date of purchase by the original purchaser. Within this period, Vpatch Cardio Pty Ltd will, at its sole option, repair or replace any components that fail in normal use. Such repairs or replacement will be made at no charge to the customer for parts or labour, provided that the customer shall be responsible for any transportation cost. This Limited Warranty does not apply to: (i) cosmetic damage, such as scratches, nicks and dents; (ii) consumable parts, such as batteries, unless product damage has occurred due to a defect in materials or workmanship; (iii) damage caused by accident, abuse, misuse, water, flood, fire, or other acts of nature or external causes; (iv) damage caused by service performed by anyone who is not an authorised service provider of Vpatch Cardio; (v) damage to a product that has been modified or altered without the written permission of Vpatch Cardio, (vi) damage to a product that has been caused by connection to power and/or data cables that are not supplied by Vpatch Cardio. In addition, Vpatch Cardio reserves the right to refuse warranty claims against products or services that are obtained and/or used in contravention of the laws of any country. This product must not be used for any purpose other than its intended use.

This Limited Warranty also does not apply to the supplied battery charger or the CR3032 Lithium Coin Cell Batteries.

If during the warranty period you submit a claim for warranty service in accordance with this Limited Warranty, then Vpatch Cardio will: (i) repair the device using new parts or previously used parts that satisfy Vpatch Cardio's quality standards, (ii) replace the device with a new device or a refurbished device that meets Vpatch Cardio's quality standards, or (iii) exchange the device for a full refund of your purchase price. SUCH REMEDY SHALL BE YOUR SOLE

AND EXCLUSIVE REMEDY UNDER AND FOR ANY BREACH OF THIS LIMITED WARRANTY. Repaired or replaced device have a 90-day warranty. If the unit sent in is still under its original warranty, then the new warranty is 90 days or to the end of the original 1-year warranty, whichever is longer.

Before seeking warranty service, please access and review the online help resources available at www.vpatchcardio.com . If your device is still not functioning properly after making use of these resources, contact your distributor or a Vpatch Cardio Authorised representative in the original country of purchase or follow the instructions on www.vpatchcardio.com to obtain warranty service.

If you seek warranty service outside of the original country of sale or purchase, Vpatch Cardio cannot guarantee that the parts and products needed to repair or replace your product will be available due to differences in applicable standards, laws and regulations. In that case, Vpatch Cardio may require you to ship your product to a Vpatch Cardio Authorised Service facility in the country of original purchase or to a Vpatch Cardio Authorised service facility in another country that can service your product, in which case you will be responsible for complying with all applicable import and export laws and regulations and for paying all custom duties, V.A.T., shipping fees and other associated taxes and charges. In some cases, Vpatch Cardio and its dealers may be unable to service your product in a country outside of the original country of purchase or return a repaired or replaced product to you in that country due to applicable standards, laws or regulations in that country.

Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

For service or technical support contact your distributor.

17.0 Declaration of Conformity

Hereby, Medical Manufacturers declares that the radio equipment type 101 (Vpod), 201 (2G Vcell) and 301 (3G Vcell) are in compliance with Directive 93/42/EEC Annex II (excluding Section 4) for a Class IIa device and Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:

https://www.vpatchcardio.com/ifu

18.0 Distributor Details

Vpatch Cardio Pty Ltd.

Suite 3, 1221 Toorak Road,
Camberwell, Victoria,
Australia
3124

w: www.vpatchcardio.com
e: info@vpatchcardio.com

19.0 Manufacturer Details

Manufactured by:

Medical Manufacturers
Unit 131, 45 Gilby Road,
Mt. Waverley, Victoria,
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CE
0805

20.0 Authorized Representative in the European Community

EC REP

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