Vpatch System

ECG Remote Event Monitor

Instructions for Use
(User Manual)

WRH-N-06232-02

Table of Contents

1.0 Equipment Supplied

1 Vpod device
1 Vcell device
1 Mascot Type 2240 Li-Ion battery charger (4.2 V)
The Vpatch Biosensor Array is essential and supplied separately.

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 hand-held device) and the REM Biosensor Array (Biosensor). The Vpod is connected to the REM Biosensor, which is worn by the patient.

The Vpod is pre-programmed to monitor ECG signals on a continuous basis using the Biosensor Array. 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. GPRS 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) when 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 Biosensor Array (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.
- Persons 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 biosensor array. The presence of thee magnetic studs may affect the performance of the implanted device.

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 6.5, 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 Biosensor Array **should not** be submerged in water, for example during a bath or while swimming.
- A biosensor array has a shelf-life of 28 days once it is removed from the sealed plastic pouch.
- 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 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.

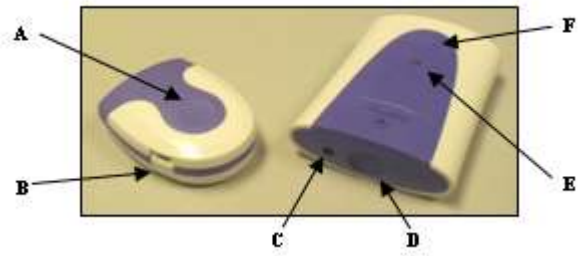
4.0 Vpatch System Equipment

4.1 REM Biosensor Array

The REM Biosensor Array (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 Biosensor Array 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.
- Excessive exercise and perspiration may decrease the length of time that the Biosensor Array can be worn.
- Avoid touching or rubbing the Biosensor Array once it has been applied.
- Apply a new Biosensor Array if reduced adhesion is observed.
- A slight reddening of the skin or minor irritation underneath and/or immediately adjacent to the Biosensor Array 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 Array can be worn in the shower (excluding power showers) with the Vpod device disconnected. The Biosensor Array 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.

6.0 System Operation

6.1 Device Preparation

- 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 6.5, Page 11 and Table 5 in Section 8.0 on Page 15.
- The patient must recharge the Vcell overnight and thereafter 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' i.e. have no physical obstruction between the two devices.
- **The system is to be cleaned before and after use on each patient. The device may be cleaned using an alcoholic or non-alcoholic wipe and dried with a lint-free cloth.**

6.2 Cleaning

- **The system MUST be cleaned before and after each patient use. The device may be cleaned using an alcoholic or non-alcoholic 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 Whiteley Matrix wipe. Discard wipe after use. Do not use any other chemical product.

6.3 Skin Preparation

- The Biosensor Array 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. To prevent irritation due to hair re-growth, it may be acceptable to carefully trim chest hair if there is not heavy coverage. It is important to ensure that any chest hair present does not prevent the Biosensor Array 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-alcoholic skin wipe ensuring that the skin surface is thoroughly dried BEFORE applying the Biosensor Array.
- The Biosensor Array must be applied within two hours of skin preparation.

6.4 Biosensor Array Application

- It is essential for the collection of clear event and episode recordings that a suitably trained healthcare professional apply the Biosensor Array 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 Biosensor Array during the monitoring period.
- The Vpod device should be placed onto the Biosensor Array **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 Biosensor Array 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 Biosensor Array is to be applied to the patient's chest.

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

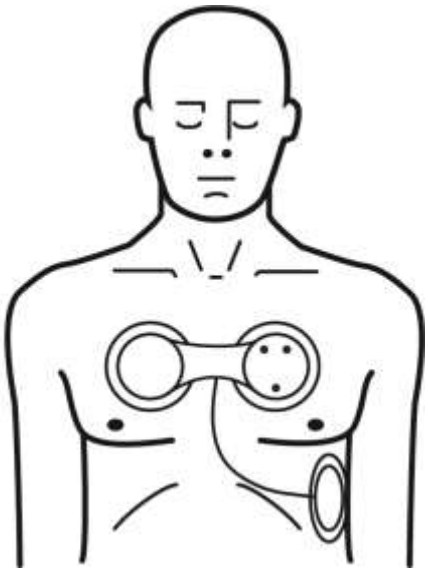


Figure 2: Biosensor Array Placement

- 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 Biosensor Array in place. This is done to maximize patient comfort during wear.
- The health care professional must ensure that the Biosensor Array 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 Biosensor Array 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 firmly on the Biosensor Array beside each stud.

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

6.5 Vpatch Website

The default setting of a Vpatch System records up to 20 seconds of pre-and 30 seconds of post arrhythmia detection events (as listed in Section 2.0) or as a result of the person pressing the Event Button on the Vpod.

Once a recording is complete, the data is sent to a central server for display on the Vpatch website. To modify this default setting the Vpatch Website must be accessed to create a custom setup.

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

- Add new patients to the server database
- Assign a Vpatch monitor to the patient
- 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.

6.6 Device Operation

6.6.1 Switching the Vpod on and off

The Vpod device is switched on when the 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 14 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 18.

* 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 the Troubleshooting section on Pages 23-24.

During monitoring, the Vpod should only be switched off during the following; when batteries are being replaced, once monitoring has concluded or if the person intends not to wear the Vpod for several hours.

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

6.6.2 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.

Pairing clears any stored events from the device memory and restores the Vpatch System's to 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).

Figure 14 indicates V Patch device labelling.

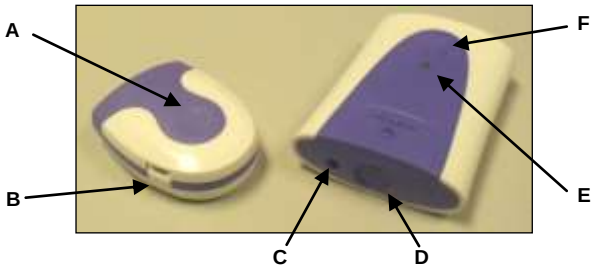


Figure 14: Device Labelling

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

The healthcare professional responsible for issuing, assigning or fitting a V Patch System must read and understand the contents in Table 1 "System Setup", be familiar with the device operation and expert in the listed contents of section 14.0 "Troubleshooting" PRIOR to using the device.

Function	Indication
To configure the device, please refer to Section 6.4.2, before use. The length of the monitoring period is chosen during the previous system configuration.	
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. 'E' 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 6.5.1, Page 12)
Press and hold 'A' on Vpod:	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
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.**	
Sending configuration settings	'E' will be orange for a short time while data is transferred 3 beeps will be heard from the Vpod
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 green approximately every 10 seconds 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

Table 1: System Setup

6.7 To Begin Monitoring

- Once the devices have been set up and connected to the patient via the Biosensor Array, 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 GPRS 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.

6.8 During the Monitoring Period

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

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".

This recorded data is sent to the central receiving station for analysis by the patient's clinician.

6.8.2 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 again.

6.8.3 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 6.5.1). 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 6.5.1, Page 12).

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.

6.8.4 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 6.5.1). 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”

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.

6.9 Viewing the Patient’s ECG Data

To view the patient’s ECG file:

1. Log on to the Vpatch website using a user name and password.**)**
2. Refer to Section 6.4.2 for more information on selecting the correct patient.
3. Click on the patient’s first or last name in order to see the Patient Dashboard.
4. From the files listed in the “Recent Measurements” the clinician can view any of the most recent ECG measurements sent to the Vpatch website.
5. Clicking on the “Overview” link will bring the clinician to the full list of events sent to the website, with each monitoring period in a separate section.

7.0 Transmission of Data

If any events are recorded in an area of limited GPRS 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 GPRS 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

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 6.5.1)

NOTE: The batteries MUST be removed when the Vpod is 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.

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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

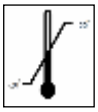
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

9.0 Storage Conditions

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



Temperature Limitation

Handle with care

10.0 Disposal

The information below was taken from a recommended battery manufacturer's guidelines:

Lithium-Batteries Technical Handbook 2002. Available from http://www.panasonic-industrial.com/public/eu/en/product-range/1/16/20/CR3032.html)

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.

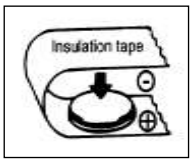


Figure 15

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		
	Batch code		Non-ionizing electromagnetic radio		Defibrillator Proof Type BF: This device is a type BF device and has a high level of protection against defibrillation energy as per EN60601-1		

Table 6

11.1 Vpatch System Serial Numbers

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

Vpod devices will have a serial number as “101-XXXXXX”.
Vcell devices will have a serial number as “201-YYYYYY”.

The first three digits of the serial number indicate the device type (Vpod or Vcell).

The last six digits indicate device ID.

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 GPRS 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 21). 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 6.5) 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 6.5) 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 GPRS. 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 6.4 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 Biosensor Array are clean and free of all debris. Ensure the Vpod is securely connected to the Biosensor Array via each of the magnetic studs. Ensure the Biosensor Array has been applied correctly, as outlined in Section 6.3, 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 6.4). If the Vpatch System is an area of limited or zero GPRS 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 GPRS 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 GPRS coverage. Move to an area of GPRS 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), obtaining the European CE Mark.

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

IEC 60601-1 : (Third edition 2005)	ISO 14971:2012	BS EN 980:2008
IEC 60601-1-2 : (Fourth edition 2014-02)	EN 1041 : 2008	BS PD IEC TR 60878:2003
IEC 60601-1-6 : 2010	ANSI/AAMI EC57:2012	EC38 : 1998
IEC 60601-2-27 : 2011	BS EN 60529: 1992	
IEC 60601-2-47 : 2012	ISO 15223-1:2012	
EN60950-1 : 2001 plus amendments A11:2004	ISO 13485 : 2016	

Table 8

16.0 Warranty

Medical Manufacturers Pty Ltd products are warranted to be free from manufacturing and material defects for a period of 1 year from the date of shipment by the manufacturer to the distributor or directly to the health care professional workplace.

Excluded from this warranty are the CR3032 Lithium Coin Cell Batteries and the Mascot Battery Charger.

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 Distributor Details

Vpatch Cardio Pty Ltd.

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3124

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

18.0 Manufacturer Details

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19.0 Authorized Representative in the European Community

EC REP

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