

VS200 User Manual

Version: 0.6
SVN version: \$Rev:: 947 \$

Date: February 2011



Table of Contents

1. Equipment Supplied	4
2. Intended Use	4
3. Warnings	5
4. VS200 General Monitoring System: Overview	6
4.1 The VS200 GMS Network and Internet Interface	6
4.2 Summary of Features and Capabilities	7
4.3 Important Terminology	7
4.4 Documentation Conventions	7
4.5 The VS200 Monitor	8
5. Using the VS200 Monitor	9
5.1 VS200 Electrode Array	9
5.2 VS200 Device	9
6. Conditions of Use	10
7. System Operation	11
7.1 Device preparation	11
7.2 Skin Preparation	11
7.3 Electrode Array Application	11
8. Patient Alert and Monitoring Server (PAMS)	12
8.1 Setting Up the VS200 Monitor	13
8.2 Charging the VS200 Battery	13
8.3 Logging into PAMS software	15
8.4 Applying VS200 System to the Patient	16
8.5 Instructions for Patient Use of VS200	18
8.6 Instructions for Healthcare Professional Use of the VS200 System	19
9. Monitoring Patients with PAMS	20
9.1 The PAMS Clinical View Screen Layout	21
9.2 PAMS Clinical View Task – View Patient Status Messages	22
9.3 PAMS Clinical View Task – View the Patient’s ECG Events	24
9.4 PAMS Clinical View Task – Patient’s Respiration Review Settings	25
9.5 PAMS Clinical View Task – Manage the Patient’s Alarm Settings	26
9.6 PAMS Clinical View Task – Send “See Nurse” Request to the Patient	28
9.7 PAMS Clinical View Task – ‘Get new vitals’ sends Data on Demand	29
9.8 PAMS Clinical View Task – Get last device status Data on Demand	30
9.9 PAMS Clinical View Task – Get New device status Data on Demand	31
9.10 PAMS Clinical View Task – Get New device status Data on Demand	32
9.11 The PAMS Admin View Screen Layout	33
9.12 PAMS Admin View Task – Change Currently Logged in Staff	34
9.13 PAMS Admin View Task – Assign device to new staff	35

9.14	PAMS Admin View Task – Change staff.....	36
9.15	PAMS Admin View Task – Change staff.....	37
9.16	PAMS Admin View Task – Assign device to patient.....	39
9.17	PAMS Admin View Task – Transfer patient care	40
9.18	PAMS Admin View Task – End Patient Monitoring	41
9.19	Logging Out of PAMS.....	42
10.	Device Operation	43
10.1	Switching the VS200 device on and off	43
10.2	Device Start-up	43
11.	System Set up	45
11.1	To Begin Monitoring	45
12.	During the Monitoring Period	45
12.1	Pressing the Event Button.....	45
12.2	Out of Range Indicators	45
13.	Changing System Settings	45
13.1	Low Battery Alarms.....	46
14.	Restarting the VS200 System	46
Appendices	47
	Appendix 1 – Alarm Limit Defaults	47
	Appendix 2 – Accessories and Recommended Supplies	47
	Appendix 3 – Troubleshooting	48
	Appendix 4 – VS200 GMS Specifications	49
	Appendix 5 - Indicator Guide	50
15.	Specifications	51
16.	Storage conditions	55
17.	Explanation of Symbols Used on the VS200 Device.....	56
18.	Disposal.....	56
19.	Warranty	57
20.	Manufacturer Details	57

1. Equipment Supplied

- 1 VS200 Device
- 1 VS200 Charging Dock
- 1 Battery Charger for VS200 Device
- 1 Fig 8 mains lead
- 1 Intelesens Electrode Array
- PAMS Compatible Third Party Software
- PC System Requirements:
 - Wi-Fi network connection

2. Intended Use

The VS200 is intended to collect and accumulate basic patient physiological parameters and wirelessly transmit the parameters and related alarms and alerts to healthcare practitioners. The system is intended to be used with adult and patients who may be in bed or ambulatory, including low to moderate activity.

3. Warnings



<i>Page Number</i>	<i>Message</i>
5	Rx only
7	The VS200 system must never be used on patients with a pacemaker or an ICD. It must be removed prior to undergoing an MRI scan or x-ray
11	Never apply the VS200 system to a patient with a skin disorder. Incorrect electrode array application may impair the quality of ECG and respiration recordings.
12	Never charge the VS200 monitor when it is connected to an electrode. The patient should be careful to avoid pressing the power button ('A') on the VS200 monitor while wearing device.
14	Only use the charger dock and adapter cord supplied with the system. Use of any other charger dock with this VS200 monitor may result in damage to the battery or affect system operation.
15	The patient should be careful to avoid pressing the power button (bottom button) on the VS200 monitor while wearing device.
54	<p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:</p> <p>(1) This device may not cause harmful interference, and</p> <p>(2) This device must accept any interference received, including interference that may cause undesired operation.</p> <p>No changes shall be made to the equipment without the permission of Intelesens Ltd. as this may void the user's authority to operate the equipment.</p>
54	<p>This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.</p> <p>The Aingeal has been tested and meets the FCC RF exposure guidelines when used against the body under normal usage conditions.</p> <p>The maximum SAR value reported is 0.878 W/kg.</p> <p>This transmitter must be installed in accordance with the operating instructions and must not be co-located or operating in conjunction with any other antenna or transmitter.</p>

4. VS200 General Monitoring System: Overview

4.1 The VS200 GMS Network and Internet Interface

VS200 wirelessly communicates over the GMS network using Wi-Fi network. The VS200 device is intended for patients requiring ambulatory and non-ambulatory monitoring and is controlled via a central point using 'PAMS' by a healthcare professional. The VS200 system monitors an area that is presently unmonitored.

The Server collects all the patient data. The healthcare professional can view and manage patient data with the Internet-based Patient Alarms and Management System (PAMS). The Server also sends alarms directly to the healthcare professionals for their assigned patients shown in *Figure 1 below*.

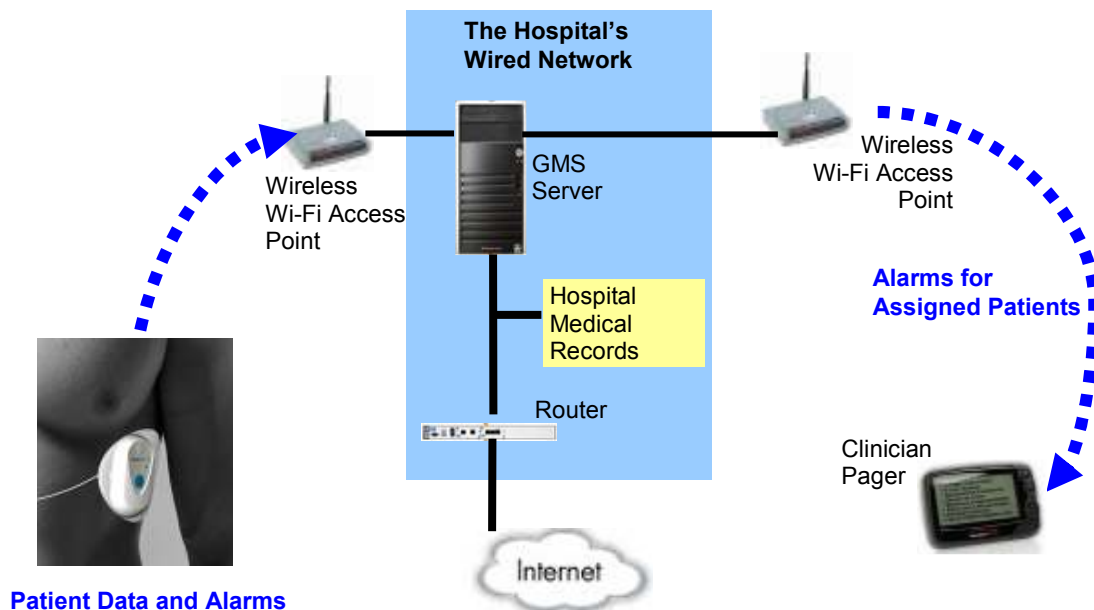


Figure 1.

The VS200 GMS Network



Rx only

4.2 *Summary of Features and Capabilities*

The wireless, wearable VS200 General Monitoring System (GMS) collects and accumulates the following physiological parameters:

- ECG
- Heart Rate
- Respiration Rate
- Skin temperature
- Body orientation
- Lethal and high acuity arrhythmias (Asystole, Ventricular Tachycardia, Ventricular Fibrillation, Bradycardia, Tachycardia, and Supra-Ventricular Fibrillation)

VS200 GMS provides the following on-monitor capabilities for the patient:

- “Emergency Event” button
- “See Nurse” indicator
- “Out-of-Communication-Range” indicator

VS200 GMS provides the following on-monitor capabilities for the healthcare professional:

- Acknowledge events in daily use and emergencies
- Device status i.e. battery level, device patient is assigned to
- Ability to send “See Nurse” indicator to patient
- Patient alert notifications on pager or other mobile communication device
- Software management of assigned patients and patient monitoring settings
- Software review of patient data, including a variety of parameters, trends, and assigned location
- Easy-to-use software features for assigning patients to healthcare professionals
- Easy integration with hospital health records

4.3 *Important Terminology*

GMS – General Monitoring System

PAMS – VS200 ‘Patient Alarms and Management System’ component of GMS

VS200 – GMS patient monitor component of GMS

4.4 *Documentation Conventions*

Bold text – A word or term that is defined in the Important Terminology section above.

Bold italic text – Key information for VS200 GMS users

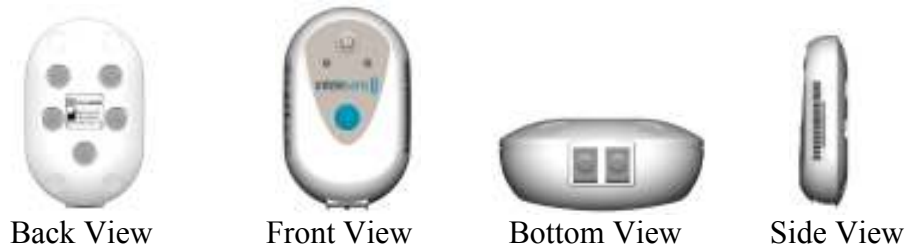
Box with white background

– A button label on the VS200 monitor or on the PAMS screen

4.5 The VS200 Monitor

The VS200 system monitors physiological parameters and is a wireless, wearable vital signs and respiratory monitor. It is a small, battery operated system comprising the VS200 monitoring unit (a body worn device), and the VS200 Electrode Array. VS200 is connected to the electrode array via magnetic studs, and the array is positioned as appropriate on the patient's body (between the 5th and 7th rib on the intercostal muscle on the side of the rib cage). The VS200 device connects to the network server using Wi-Fi, recognized and configured by 'PAMS' software.

VS200 Monitoring Unit



VS200 Electrode Array



Figure 2. The Wireless, Wearable VS200 System



The VS200 system must never be used on patients with a pacemaker or an ICD. It must be removed prior to undergoing an MRI scan or x-ray

5. Using the VS200 Monitor

5.1 VS200 Electrode Array

The VS200 electrode array comes in a sealed package. To open, tear the package seal across the top, starting from the incision on the side shown in Figure 3 below.



Figure 3. VS200 Electrode Array

Inside the package is the VS200 electrode array. The VS200 electrodes have the ability to obtain an ECG signal. The wire between the two electrodes is 55 centimeters therefore any patient wider than this (one side of rib cage to the other) may not be suitable for monitoring by the VS200 system as the measurement site will not give accurate results.

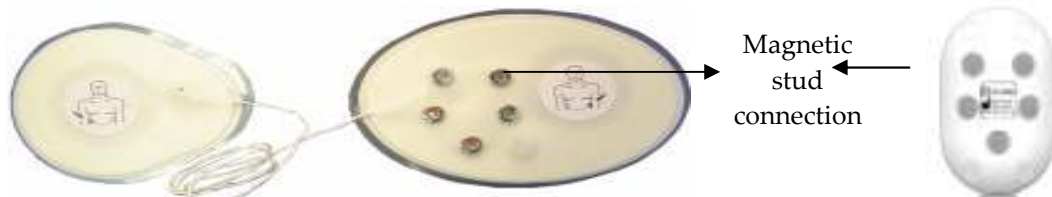
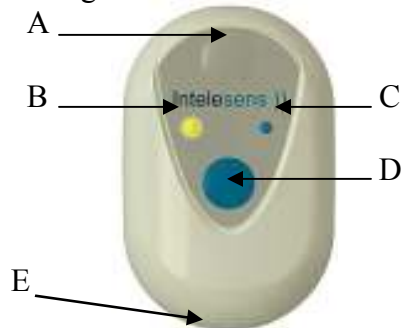


Figure 4. VS200 Electrode Array

5.2 VS200 Device

The VS200 Device is shown in Figure 5. The VS200 device monitors ECG and respiration signals when connected to the electrode array on the patient's body.



A	On / Off button
B	Configuring LED
C	Out-of-range or nurse call LED
D	Emergency Event Button
E	Charger connectors

Figure 5. Monitoring VS200 Device

6. Conditions of Use

The user should adhere to the following conditions while using the VS200 System:

- The VS200 System is to be operated under the restrictions outlined in this VS200 User Manual.
- Care should be taken to ensure that the VS200 device does not come into contact with water or any other liquids.
- The Electrode Array should not be applied to patients with a skin disorder.
- Excessive exercise will decrease the length of time that the Electrode Array can be worn due to perspiration.
- Avoid touching or rubbing the Electrode Array once it has been applied.
- Apply a new Electrode Array if there is a lack of adhesion.
- Reddening or slight irritation of the skin from Electrode Array is normal.
- The Electrode Array should not be submerged in water, for example during a bath or while swimming.
- The Electrode Array can be worn in the shower (excluding power showers) with the VS200 device removed. The electrode should be gently dabbed dry with a lint free cloth and the VS200 device cleaned and reconnected as soon as possible thereafter.
- The VS200 device can be worn when the patient is asleep.
- The VS200 electronics should only be operated at temperatures between 0 °C and 45 °C (32 °F and 113 °F).
- Exceeding the recommended storage conditions and conditions for use can result in impaired system performance.



Temperature Limitation



Do not get wet

7. System Operation

7.1 *Device preparation*

- The patient must charge the VS200 device for at least an hour following 'Charging VS200 Battery' (Section 8.2, Page 12).
- The clinician must be aware of the low battery alert on the PAMS software and know to recharge the device (Section 8.2, page 12).
- The VS200 device must be cleaned with an alcoholic wipe before and after use.
- When in use, the VS200 device must be in range of the Wi-Fi network in order to connect to PAMS within the healthcare facility. If the system is out of range, an alert on PAMS is seen in the message tab and a continuous blue LED will illuminate with a continuous buzzing.

7.2 *Skin Preparation*

- The VS200 Electrode Array must be applied to clean, dry and hair-free skin.
- Skin preparation is essential for electrode adhesion to be accurate.
- The skin should be cleaned using an alcoholic wipe.

7.3 *Electrode Array Application*

- It is recommended that a trained healthcare professional applies the electrode array to the patient.
- The VS200 device should be placed onto the electrode array after the array is applied to the correct measurement site.
- It is advisable to determine the optimum electrode arrangement on the patient before removing the paper liners from the electrodes.
- The Electrode Array must be applied to the patient in as shown in Figure 6 below.

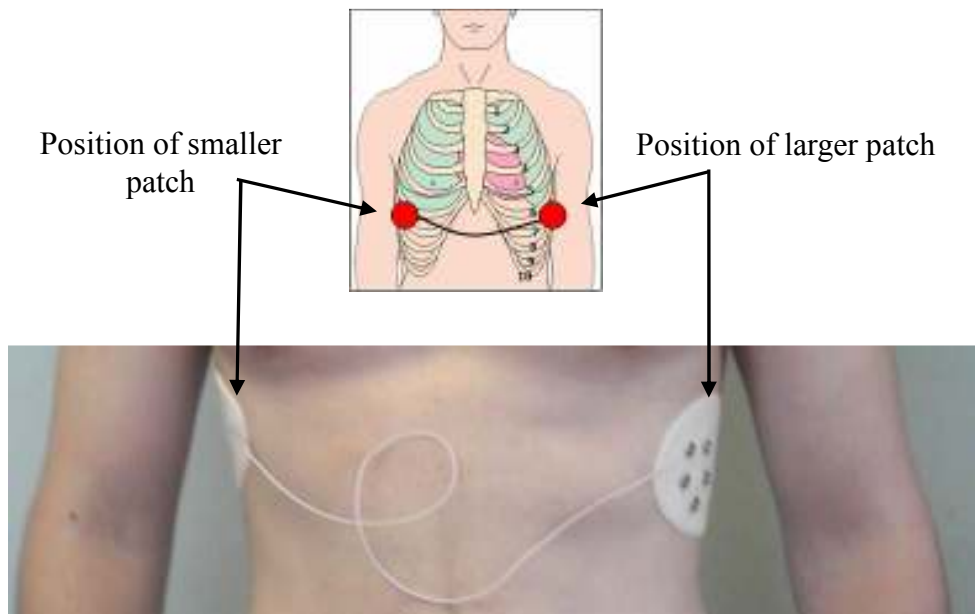


Figure 6. *Electrode Measurement Site*

- After removing the release liners to expose the adhesive foam, the patient should hold a deep breath before and during the electrode array application in order to maximize comfort during wear.
- The electrode array must be placed between the 5th and 7th rib parallel to the Xiphoid (bottom of the sternum) to the patient's body around the side of the rib cage for optimum recording quality.
- Smooth each adhesive area firmly to the skin ensuring that there are no creases.
- Minimize the contact of undergarments with the electrode array.
- When removing the VS200 device to recharge the battery or for showering, remove one stud at a time while pressing down firmly on the electrode array beside each stud.



Never apply the VS200 system to a patient with a skin disorder. Incorrect electrode array application may impair the quality of ECG and respiration recordings.

8. Patient Alert and Monitoring Server (PAMS)

The VS200 System is initially configured when switching on the VS200 device, after being attached to the electrode array within the Wi-Fi network. Build version for PAMS is 10-18-2010. The system can be reconfigured, refer to Section 9.5 Page 25.

The VS200 device is paired with PAMS allowing the clinician to:

- Add device to patient
- Add patient to clinician care
- Assign device to staff (for example pager, mobile)
- View patients ECG, respiration rate, temperature and location
- Send 'See Nurse' request to patient
- Send 'Emergency Call' message to clinician
- Specify the period of time that the patient will be monitored for
- Change monitoring settings
- Get last device status including battery life

The VS200 devices should be re-charged and re-configured each time they are used by a new patient, or each time there is a new monitoring period.

Failure to reconfigure a monitor that is no longer assigned to a patient, or if the monitoring period has ended, will result in ECG or / and respiration data not reaching PAMS.

8.1 Setting up the VS200 Monitor

How to prepare the VS200 device for use:

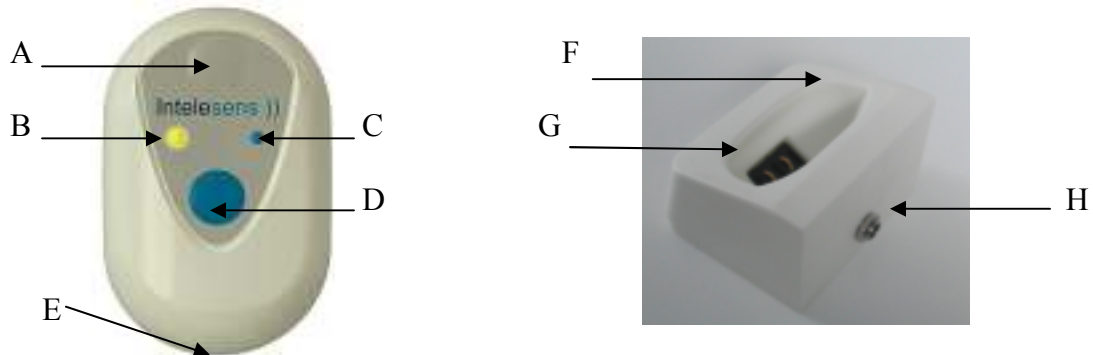
- Step 1:** Charge the VS200 monitor for at least one hour before using, ensuring the monitor is fully charged. See “Charging the VS200 Battery” below for detailed charging instructions.
- Step 2:** Clean the VS200 monitor thoroughly with an alcoholic wipe (See Page 46 Appendix 2, “Accessories and Recommended Supplies”).

8.2 Charging the VS200 Battery

- Step 1:** If the VS200 device is on, switch off the device by holding down the ‘On / Off button’ shown in Figure 7 below, for 15 seconds.



Never charge the VS200 monitor when it is connected to an electrode.



A	On / Off button
B	Device status LED: Orange / Green LED indicates monitor status
C	Blue LED: Out-of-range or nurse call LED
D	Emergency Event Button
E	Charger Connectors on the VS200 device
F	VS200 Charging Dock
G	Charging Connectors on the Charging dock
H	VS200 Charger Port Connector

Figure 7. VS200 Monitor Buttons and LED Indicators

- Step 2:** Place the VS200 device into the VS200 charging dock provided. The dock must have access to a plug socket. The connectors must meet the custom fit cradle holder of the charging dock shown in Figure 8 and Figure 9 below.

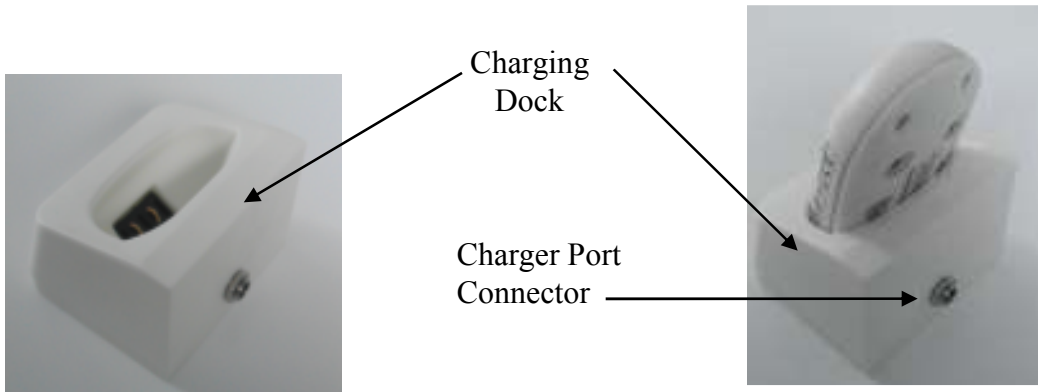


Figure 8.

VS200 Charging Dock Back View



Figure 9.

VS200 Charging Dock Front View

Step 3:

Connect the charger, shown below to a mains cable and plug, into an electrical socket. The device status LED on the charger will illuminate in red to indicate that the device is charging. Continue charging until the device status LED illuminates in green to indicate that charging is complete as shown in Figure 10 below.

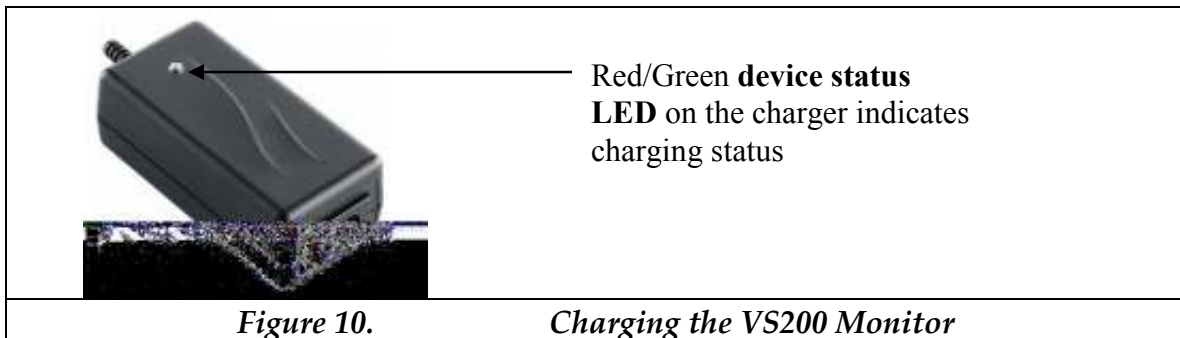


Figure 10.

Charging the VS200 Monitor



Only use the charger dock and adapter cord supplied with the system. Use of any other charger dock with this VS200 monitor may result in damage to the battery or affect system operation.

8.3 Logging into PAMS software

Your assigned care area might operate the VS200 web interface in a continuous central station mode. If not, you will need to login to PAMS. The PAMS login screen is shown in Figure 11 below.



Figure 11. PAMS Login Screen

Type in your 'Staff name' and 'Password' or scan your login barcode into PAMS as shown above.

How to Log In as a staff member:

Type in your login information as follows:

- Step 1:** Type in your 'Staff name' and 'Password'. Your system will have a list of existing user name to select from. If not, click the 'Not registered? Click here' tab and follow the steps for registering.
- Step 2:** Select Log In. As shown in the figure above, the PAMS screens will display the 'Clinical View' screen selected shown in Figure 11.

8.4 Applying VS200 System to the Patient

You can apply the VS200 monitor to your patient before or after you have assigned the device to your patient.

This is a step by step guide for using the VS200 system in the most logical and efficient way possible. Following these 'How to' steps allows the user to see each individuals' configured information and highlights the outcomes when the steps have been undertaken.

How to apply the VS200 monitor to the patient:

Step 1: Ensure the 'Patient Alert and Monitoring Server' is functional, the VS200 system is running and the wireless access point is functioning correctly (see the "PAMS Administration Instructions" document for more information on 'PAMS' operation and use). Switch on the VS200 device and see if PAMS picks up the configured information before placing on patient.

Step 2: Switch on the VS200 device by holding down the power button for two seconds. The device status LED will illuminate orange. The unit attempts to retrieve its configured settings from the PAMS system. Once the PAMS server has been contacted, the VS200 device will beep (softly) and the LED will turn green. When starting the VS200 device for the first time there is a single beep with subsequent activations marked by a double beep.

Step 3: Make sure the application area on the patient's skin is clean, dry, and free of hair.



***The skin should be cleaned using an alcoholic wipe.
The electrode array should be applied within two hours
of skin preparation.***

Step 4: After removing the release liners to expose the adhesive foam, the patient should hold a deep breath before and during the electrode array application in order to maximize comfort during wear. The electrode array must be placed between the 5th and 7th rib around the side of the rib cage, parallel to the xiphoid at the bottom of the sternum, for optimum recording quality.

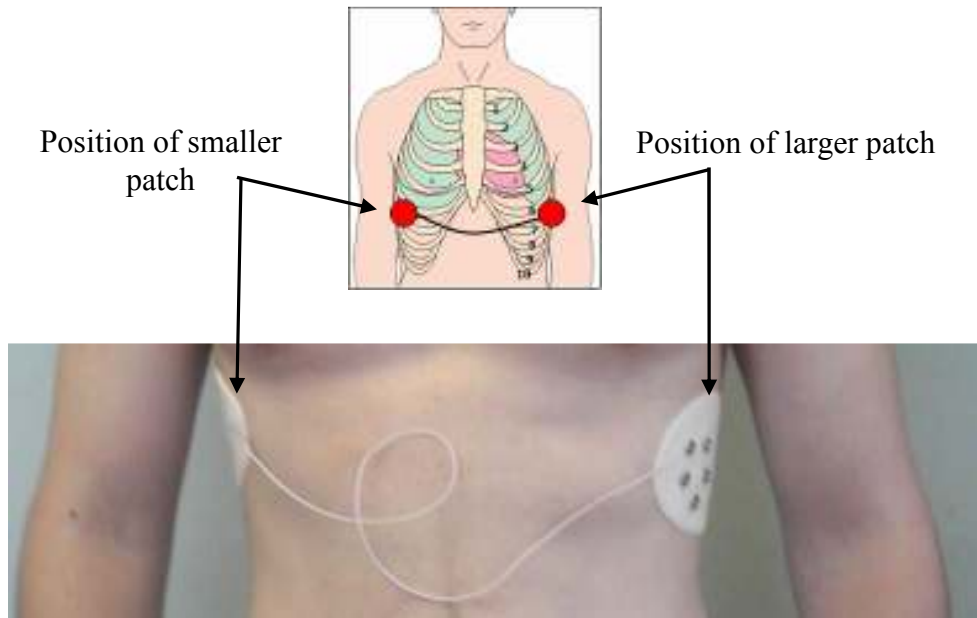


Figure 12.

Positioning the VS200 Electrode Array



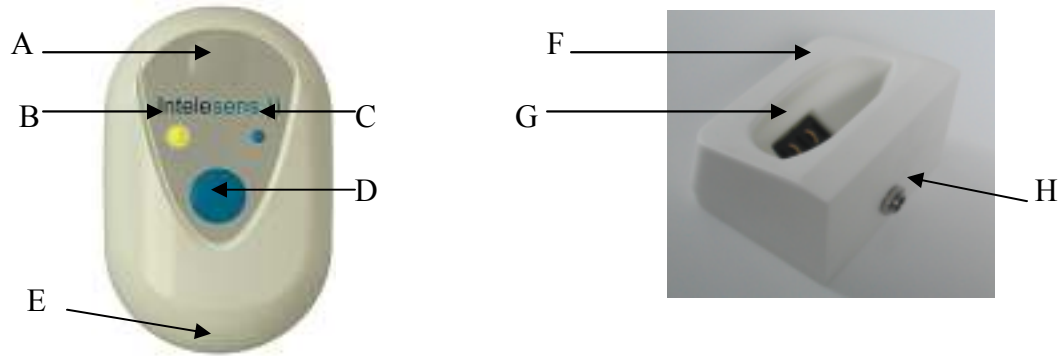
Incorrect application of the electrode array may impair the quality of ECG and respiration data.

Step 5:

Using the magnetic studs arranged in a unique pattern to those on the device, attach the VS200 monitor to the larger electrode patch on the left hand side, as shown above in Figure 12 above.

8.5 Instructions for Patient Use of VS200

This section describes interactions of the patient with the VS200 monitor. Figure 13 shows the buttons and LED's on your VS200 monitor.



A	On / Off button
B	Device status LED: Orange / Green LED indicates monitor status
C	Blue LED: Out-of-range or nurse call LED
D	Emergency event button
E	Charger Connectors on the VS200 device
F	VS200 charging dock
G	Charging connectors on the charging dock
H	VS200 charger port connector

Figure 13. VS200 Monitor Buttons and LED Indicators

If a patient moves out of range of the Wi-Fi network, an alarm occurs on the device in form of visual blue (LED C) and audible (beeping alarm).

How to end 'Out-of-Range' warning tone:

Your VS200 monitor will sound a warning tone with the blue LED ('C') illuminating when you move too far away from your assigned care location with the Wi-Fi network available. To end the "Out-of-Range" warning tone, you must do the following:

Step 1:

The patient should move back into range of the assigned care location. If the patient is in difficulty or in pain and needs immediate attention, an alarm can be raised by patient to notify the healthcare professionals via PAMS.

How to send an 'Emergency Call' warning tone:

In an emergency, you can send an 'Emergency Call' to your care provider.

Step 1:

Make sure that you are not "Out-of-Range" of your care location (that is, there is no warning tone sounding on your VS200 monitor).

Step 2:

Press the blue button ('D') on the VS200 device to send an 'Emergency Call' and a beep will sound.



The patient should be careful to avoid pressing the power button ('A') on the VS200 monitor while wearing device.

If the healthcare professional sees a change in the patient's vital signs and the patient is not in the immediate vicinity, a message can be sent to the device via PAMS telling the patient to come and see them.

How to end 'See Nurse' request:

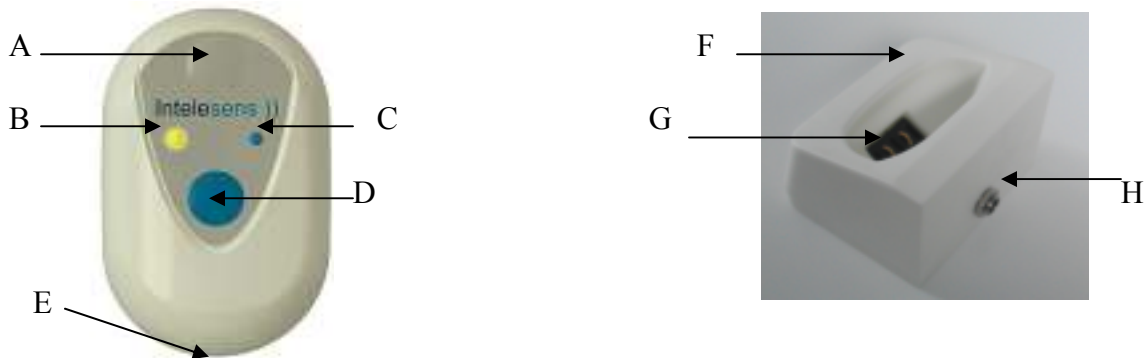
Refer to Section 9.6 and Page 26. You can also receive a "See Nurse" request from your care provider. The blue LED light on your monitor will flash and the device will produce an audible "beep" sound when a 'See Nurse' request has been sent to you. When you arrive at the nurses' station, the nurse will use the blue button on the device to silence the alert tone.

Step 1: Press the blue button ('D') for 5 seconds to acknowledge the 'See Nurse' request.

Step 2: The constant pulsating beep will become a continuous buzz when finger is removed after 5 seconds. The blue LED ('C') will go off and the alert tone will stop sounding.

8.6 Instructions for Healthcare Professional Use of the VS200 System

This section describes interactions that the healthcare professional can have with the VS200 monitor.



A	On / Off button
B	Device status LED: Orange / Green LED indicates monitor status
C	Blue LED: Out-of-range or nurse call LED
D	Emergency event button
E	Charger connectors on the VS200 device
F	VS200 charging dock
G	Charging connectors on the charging dock
H	VS200 charger port connector

Figure 14. VS200 Monitor Buttons and LED Indicators

The healthcare professional can use the patient's VS200 monitor to acknowledge alarms at the patient's location as follows:

How to acknowledge the 'See Nurse' request as a clinician:

Step 1: Press the 'message button' ('D') for at least 2 seconds to acknowledge the 'See Nurse' request. A short audible beep will sound to indicate that the acknowledgement has been sent to PAMS.

9. Monitoring Patients with PAMS

The VS200 interface is also known as the VS200 Patient Alarm and Monitoring System (PAMS).

PAMS provides two screen views for patient monitoring and alarm management. The figure below illustrates the view "tabs" that are available in the upper left corner of the PAMS screen.



Figure 15. PAMS Screen Opens in Clinical View at Login

Clinical View – shows the current patient's information sending constant messages in relation to the highlighted patient, a constant trend of ECG and respiration rates, timed individual ECG graphs, timed individual respiration rate graphs, a tab to define alarm settings and device features tab to allow interactions between patients and clinical staff.

Admin View – Allows the clinical staff to change monitoring of a patient, assign device to staff, assign device to patient, transfer patient care and end patient monitoring.

Screen view tabs in upper left corner of all PAMS screens;
Clinical View screen is selected by default at Login

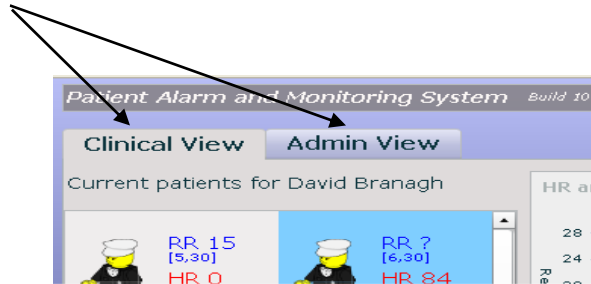


Figure 16. PAMS View Tabs

Change the PAMS screen to a different view if required when wanting to acknowledge another patient or transfer care between clinicians or know where the patient is located.

How to change the PAMS screen View:

Step 1: Select the tab for the view that you want to display. The new view will now display. The tab for the new view will now be highlighted. The tab for the previous view will no longer be highlighted.

9.1 The PAMS Clinical View Screen Layout

As shown in the Figure 17, the PAMS Clinical View screen consists of three main display areas:

Patients Display – shows an annotated icon for each patient assigned to the logged in care provider

Trend Review Display – this scrollable display shows a plot of trended heart rate and respiration rate values

Clinical Tasks Display – displays related information the currently selected clinical task

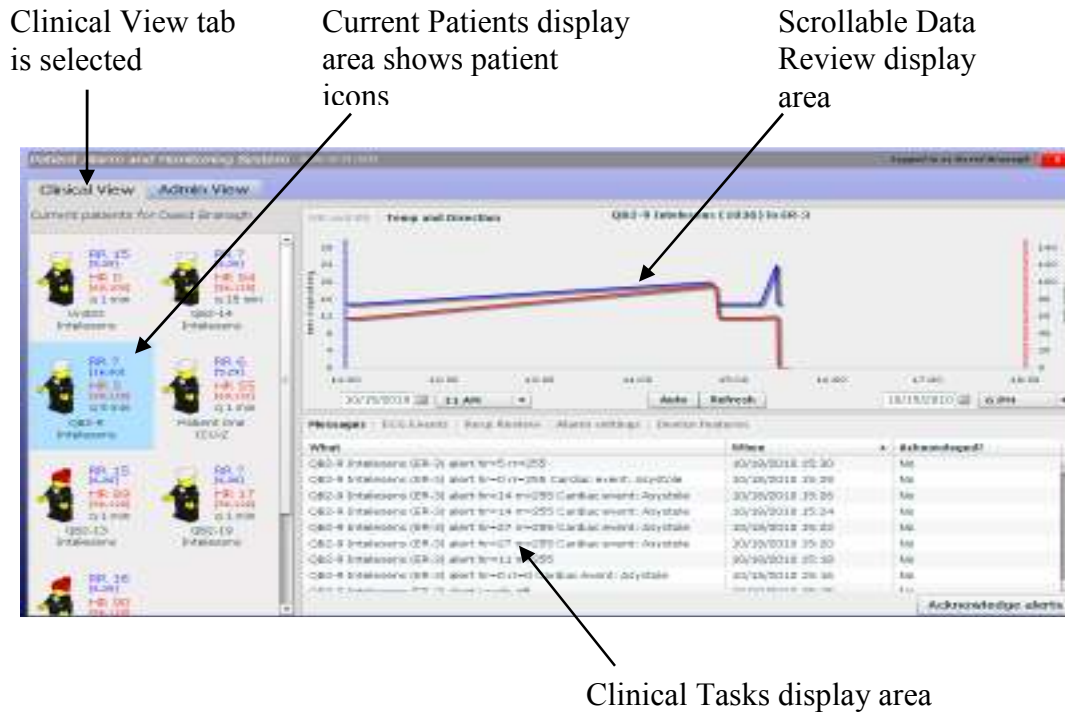


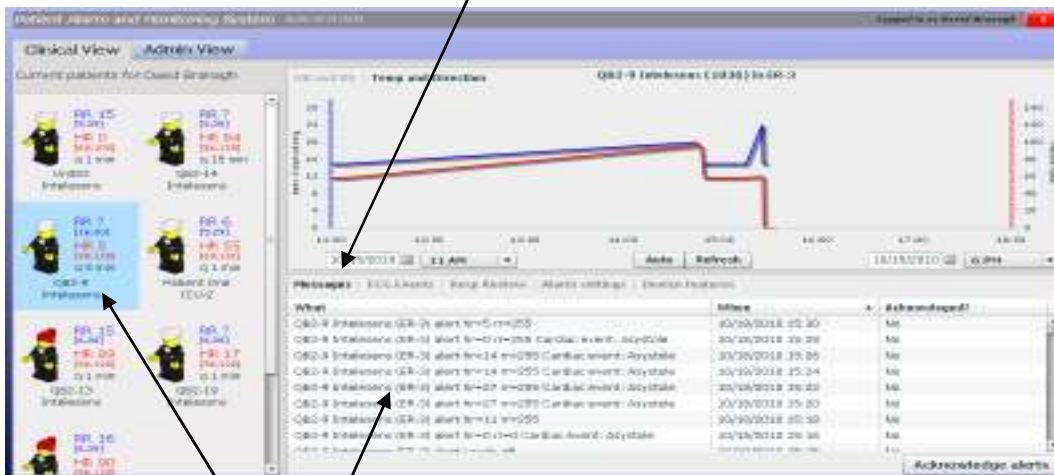
Figure 17. The PAMS Clinical View Screen

9.2 PAMS Clinical View Task – View Patient Status Messages

If the clinician wants to know if there are any problems with their patient or if the patient is not in close range view and are in trouble, the message alerts and constant updates show if the patient is in danger or their vital signs are dangerously high or low.

Intelesens Limited

Click to select the Message Tab in the clinical tasks display area



Scrollable list of all alarm/alert messages for the selected patient including low battery alert

Figure 18. *The PAMS Patient status messages*

How to see alert messages and recorded events for individual patients:

Healthcare professional can view the list of status messages for an individual patient as follows:

- Step 1:** Select the patient's icon in the 'Current Patients' screen area in the 'Clinical View' tab. The icon will be highlighted to show that it is selected.
- Step 2:** Select the 'Messages' tab in the clinical tasks area of the screen. The scrolling list of message will show all messages for your patient, along with the time of the message including heart rate or respiration abnormalities or battery low alerts. A button is present on the right hand side of the screen to acknowledge event or message by a healthcare professional.

9.3 PAMS Clinical View Task – View the Patient’s ECG Events

Message alerts and continuous updates sent by the device to PAMS allow the healthcare professional to become aware of any pre-defined changes in patient vital signs.

Click to select the ECG Tab
in the clinical tasks display area



Scrollable list of all ECG readings for the selected patient

Figure 19. *The PAMS ECG Event*

How to select patient and select ECG information tab:

View ECG Event data for an individual patient as follows:

- Step 1:** Select the patient’s icon in the ‘Current Patients’ screen area. The icon will be highlighted to show that it is selected. Make sure the top trend tab is selected on HR and RR. Each point on trend graph can be looked at if the mouse is held over the trend line.
- Step 2:** Select the ECG Events tab in the ‘Clinical Tasks’ area of the screen. The scrolling list of ECG traces will show 30 seconds of data before and after each ‘ECG Event’ that has occurred for the patient. Each event trace is labeled with the time and date of the event on the left hand side of the individual ECG data.

9.4 PAMS Clinical View Task – Patient’s Respiration Review Settings

The individual respiration rate graphs, shown below, belong to the patient that is highlighted on the left hand side. These can be studied by the healthcare professional if a change in vital signs results in an alert message is being sent to PAMS.

With the ‘Resp Review’ tab selected,
Graphical event strips recorded



Figure 20.

The PAMS Patient Respiration Review events

How to select patient and select Resp Review information tab:

- Step 1:** Select the patient’s icon in the ‘Current Patients’ screen area. The icon will be highlighted to show that it is selected.
- Step 2:** Select the Resp Review tab in the ‘Clinical Tasks’ area of the screen. The scrolling list of respiration rate traces will show every 30 seconds of data before and after each event that has occurred for the patient. Each event trace is labeled with the time and date of the event and can also get any point on trend by holding mouse control over the trend line.

9.5 PAMS Clinical View Task – Manage the Patient’s Alarm Settings

There are two options when setting the Alarm setting.

- Firstly, as shown below, a Routine setting can be chosen where the information highlighted is automatically saved to settings visible.

With the Alarms settings tab selected, click to select “Routine” alarm settings

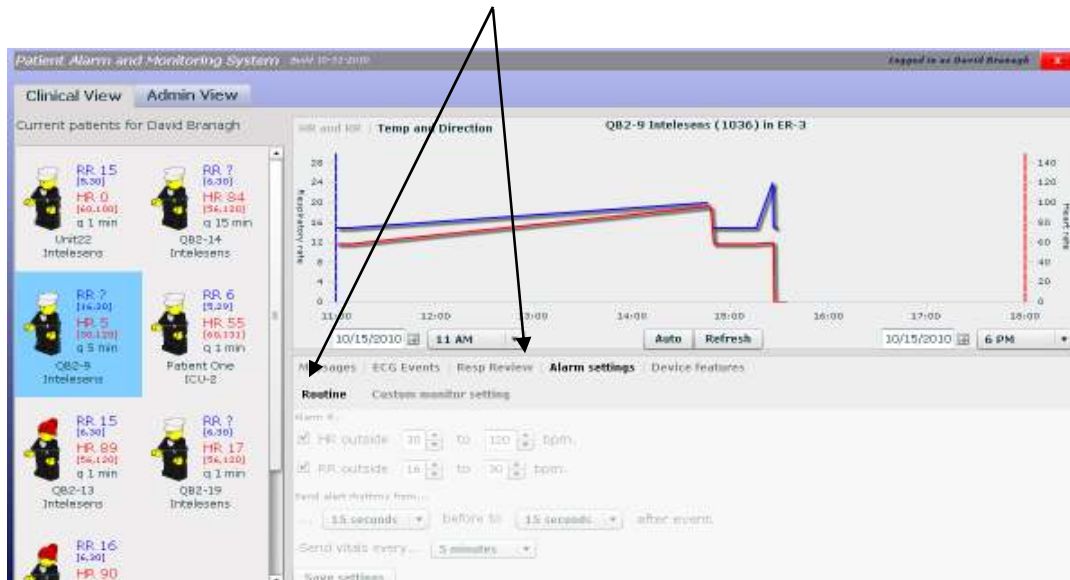


Figure 21. The PAMS Patient Alarm settings

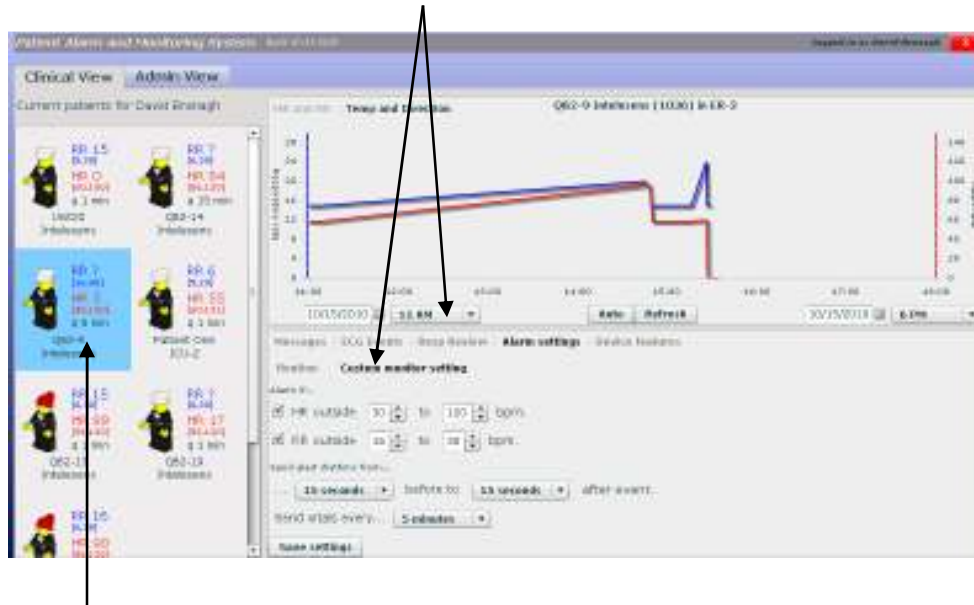
How to manage the Routine alarm settings for individual patients:

- Step 1:** Select the patient’s icon in the ‘Current Patients’ screen area. The icon will be highlighted to show that it is selected.
- Step 2:** Select the ‘Alarm settings’ tab in the ‘Clinical Tasks’ area of the screen. Select the ‘routine’ tab. The information will not allow any setting to be changed and will automatically save the settings shown.

Intelesens Limited

- Secondly, as shown below, a Custom monitoring setting can be chosen where the limits for 'Alarm settings' can be changed to suit patients' requirements.

With the Alarms settings tab selected, click to select "Custom monitor settings"



This function applies custom alarm/alert settings and data collection settings to the selected patient

Figure 22. The PAMS Patient custom alarm settings

How to manage the Custom monitoring setting for individual patients:

- Step 1:** Select the patient's icon in the 'Current Patients' screen area. The icon will be highlighted to show that it is selected.
- Step 2:** Select the Alarm settings tab in the Clinical Tasks area of the screen will automatically save the settings shown. In the Custom monitoring setting the alarms and limits can be set individually for each patient. Save settings upon change completion

9.6 PAMS Clinical View Task – Send “See Nurse” Request to the Patient

When a patient has a change in heart rate or respiration rate and the nurse/clinician is not in view of the patient, an alert can be sent to the patient for them to come to the clinician in an allocated area.

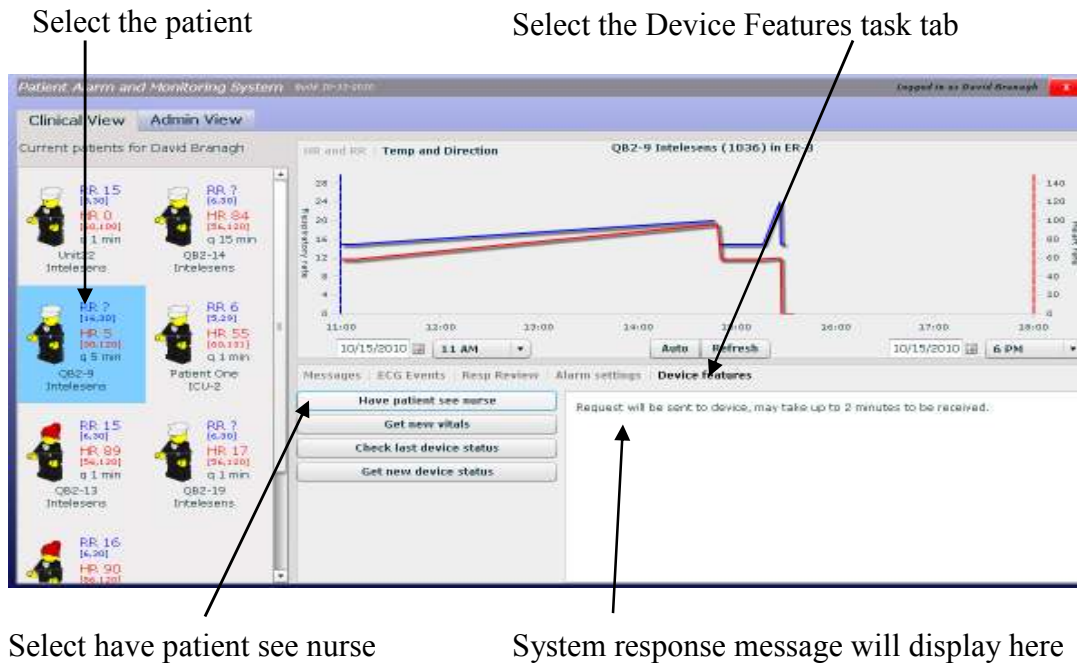


Figure 23. The PAMS Patient “See nurse” request

How to send a message to ‘have patient see nurse’ for individual patients:

- Step 1:** Select the Have patient see nurse button in the ‘Device feature’ tab. A message will appear saying the ‘Request will be sent to device it may take up to 2 minutes’
- Step 2:** The alarm cannot be turned off until the patient sees the clinician. The clinician must hold down the emergency event button ‘D’ for five seconds. The alarm stops upon release of the emergency event button.

9.7 PAMS Clinical View Task – ‘Get new vitals’ sends Data on Demand

When the clinician wants to see the most up to date vital signs of an individual patient, the highlighted tabs below are necessary for result.

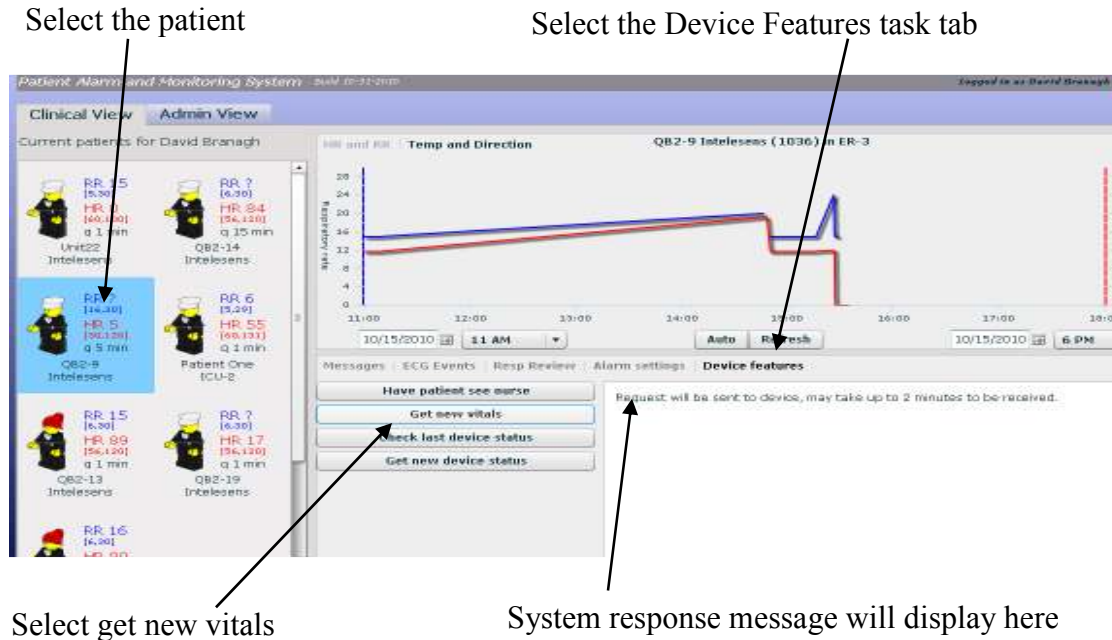


Figure 24. The PAMS Patient Vital signs data on demand

How to manage Get new vitals for individual patients:

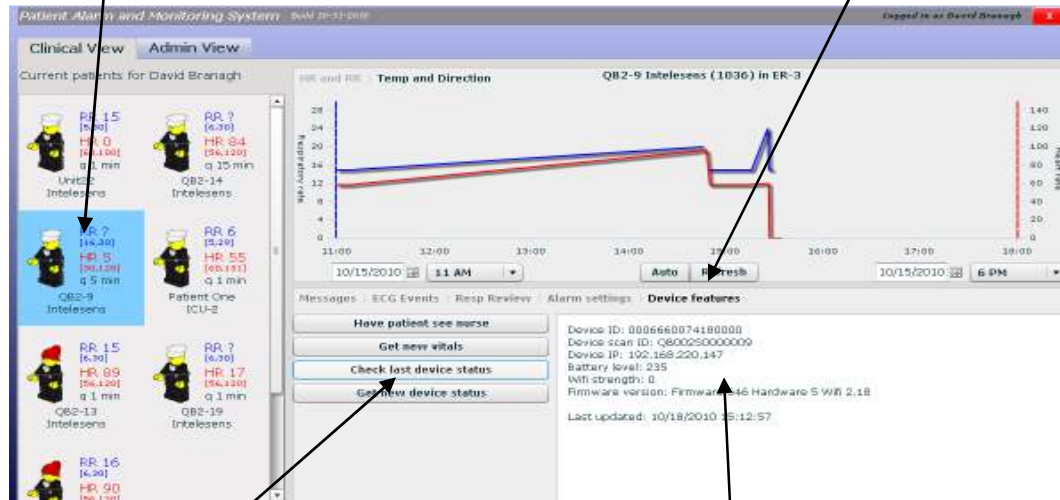
Step 1: Select the Get new vitals button in the device feature tab. A message will appear saying the ‘Request will be sent to device it may take up to 2 minutes’.

9.8 PAMS Clinical View Task – Get last device status Data on Demand

If there is any doubt on the clinician's behalf of what device is being used or which device they want to be using, the Check last device status option within the device features tab can be used.

Select the patient icon patient

Select the Device Features task tab



Select Check Last Device Status

System response message will display here

Figure 25.

The PAMS last device status on demand

How to manage Check last device status for individual patients:

Step 1: Select the Check last device status button in the device feature tab. The system response will show the information of the VS200 device

Step 2: The information includes device ID, device scan ID, device IP, the battery level, Wi-Fi strength, the firmware version and details of when it was last updated.

9.9 PAMS Clinical View Task – Get New device status Data on Demand

If there is any doubt on the clinician's behalf of what device they are using or which one they want to be using, the Get new device status option within the device features tab will give all required details.

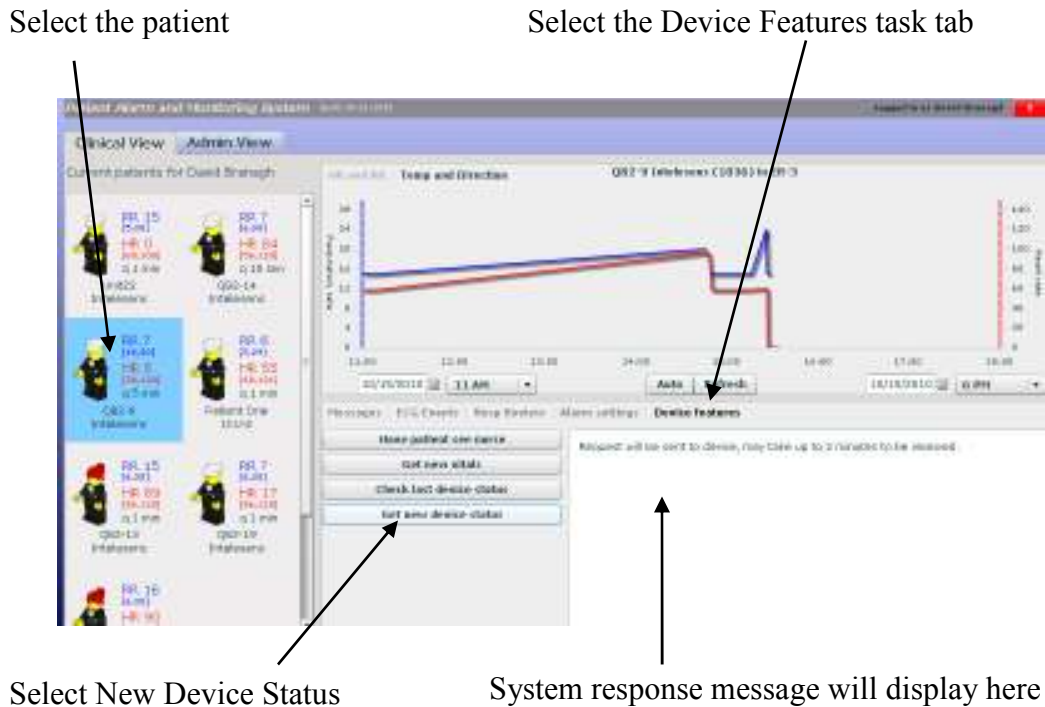


Figure 26. The PAMS new device data on demand

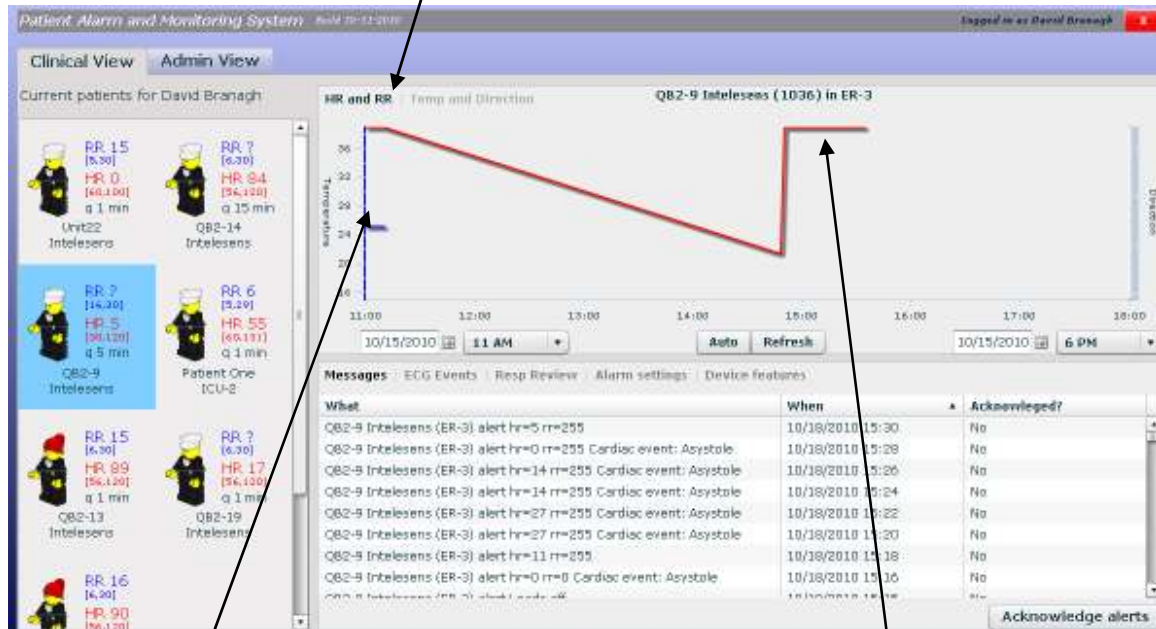
How to manage 'Get new device status' for individual patients:

- Step 1:** Select the 'Get new device status' button in the 'Device feature' tab. A message will appear saying the 'Request will be sent to device it may take up to 2 minutes'
- Step 2:** The information for the device status will appear in the message tab

9.10 PAMS Clinical View Task – Get New device status Data on Demand

If the clinician wants to choose between 'Heart rate and Respiration Rate' view or 'Temperature and Direction' view.

To get the skin temperature and direction of the device click the 'temp and direction' tab as shown below



The blue line trend represents the skin temperature of the patient

Red line trend symbolizes direction showing location of the patient in the 'Orientation'

Figure 27.

The PAMS patient temperature and direction trend

9.11 The PAMS Admin View Screen Layout

As shown in the figure below, the PAMS Admin View screen consists of three main display areas:

Patients Display – shows an annotated icon for each patient assigned to the logged in care provider

Current Staff Information Display – shows name and contact information for the currently logged in care provider

Administrative Tasks Display – shows the available administrative tasks or the individual steps for a selected task, show as ‘change staff’, ‘assign device to staff’, ‘assign device to patient’, ‘transfer patient care’ and ‘end patient monitoring’.

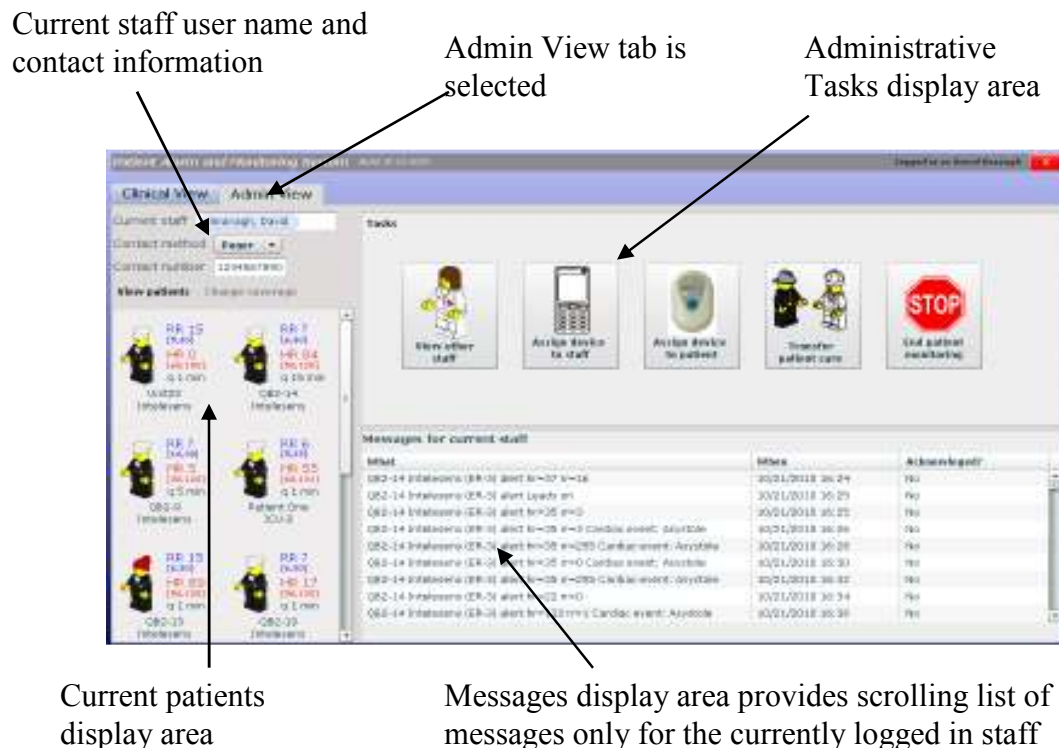


Figure 28.

The PAMS Admin View Screen

9.12 PAMS Admin View Task – Change Currently Logged in Staff

When clinician wants to change the patients' monitoring onto another healthcare professional the 'Change Staff' button is chosen.

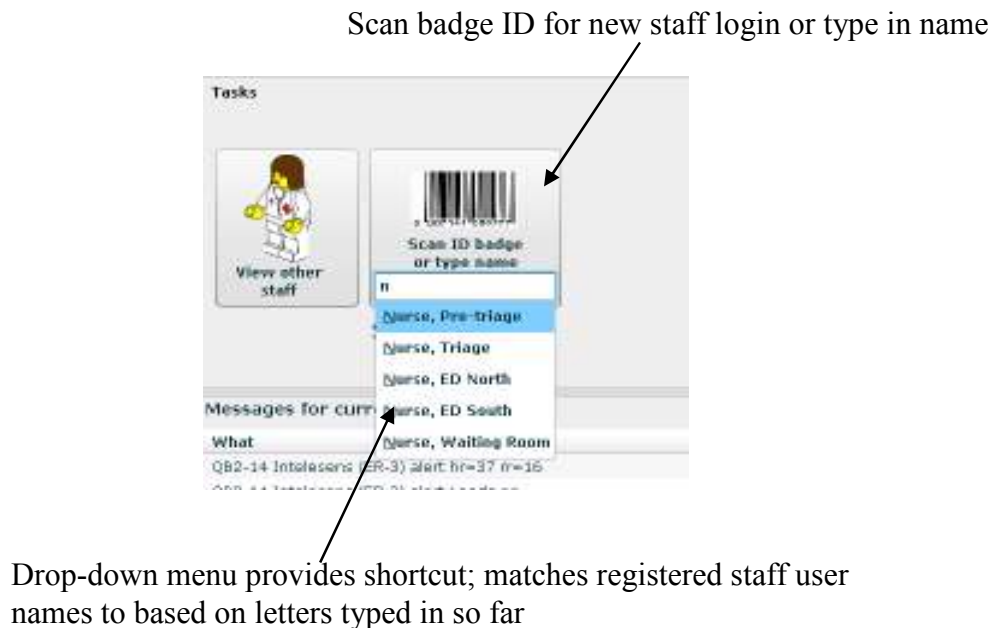


Figure 29. *Change currently logged in staff*

How to Change Staff:

In the Tasks display area of the Admin View screen, change the currently logged in staff as follows:

- Step 1:** Select Change Staff (task button). The next step button will replace all other task buttons, as shown below. The staff names will already be saved on the system; therefore selection of the name is all that's required.
- Step 2:** As indicated by the instruction button, scan the badge ID for the new staff or type in the login name. If the name is typed in, a follow-up instruction button will request a password.
- Step 3:** To revert back to the Admin View, click on the 'Change Staff' icon and it will bring back the main option tab

9.13 PAMS Admin View Task – Assign device to new staff

The healthcare professional wants to add a device in which to receive emergency calls and alerts from a patient they are monitoring.

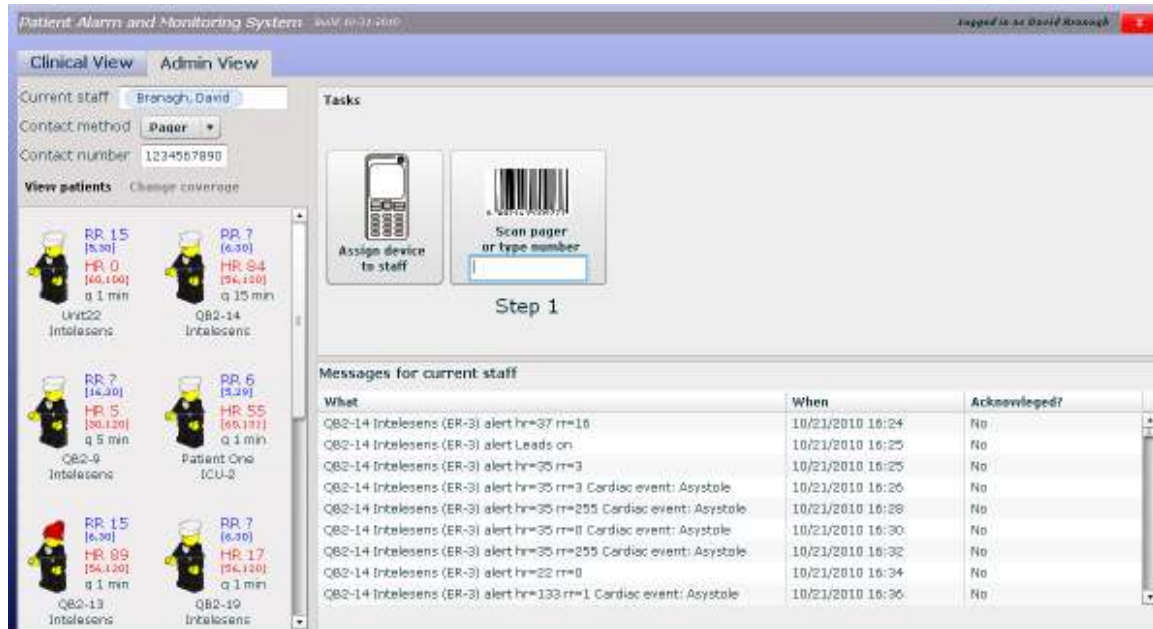


Figure 30. Assign device to staff tab

How to ‘Assign device to staff’:

In the Tasks display area of the Admin View screen, you can change the currently assign device to new staff as follows:

- Step 1:** Select Assign device to staff (task button). The next step button will replace all other task buttons, as shown below. The staff names will already be saved on the system therefore selection of the name is all that’s required (if not they must be registered to login).
- Step 2:** As indicated by the instruction button, scan the badge ID for the new staff or type in the login name. If the name is typed in, a follow-up instruction button will request a password. The pager or mobile contact information can be added as stated in the registration page for clinicians.
- Step 3:** To revert back to the Admin View, click on the ‘Assign device to staff’ icon and it will bring back the main option tab

9.14 PAMS Admin View Task – Change staff

In the Tasks display area of the Admin View screen, you can change the currently assign device to Change staff for change of monitoring control.

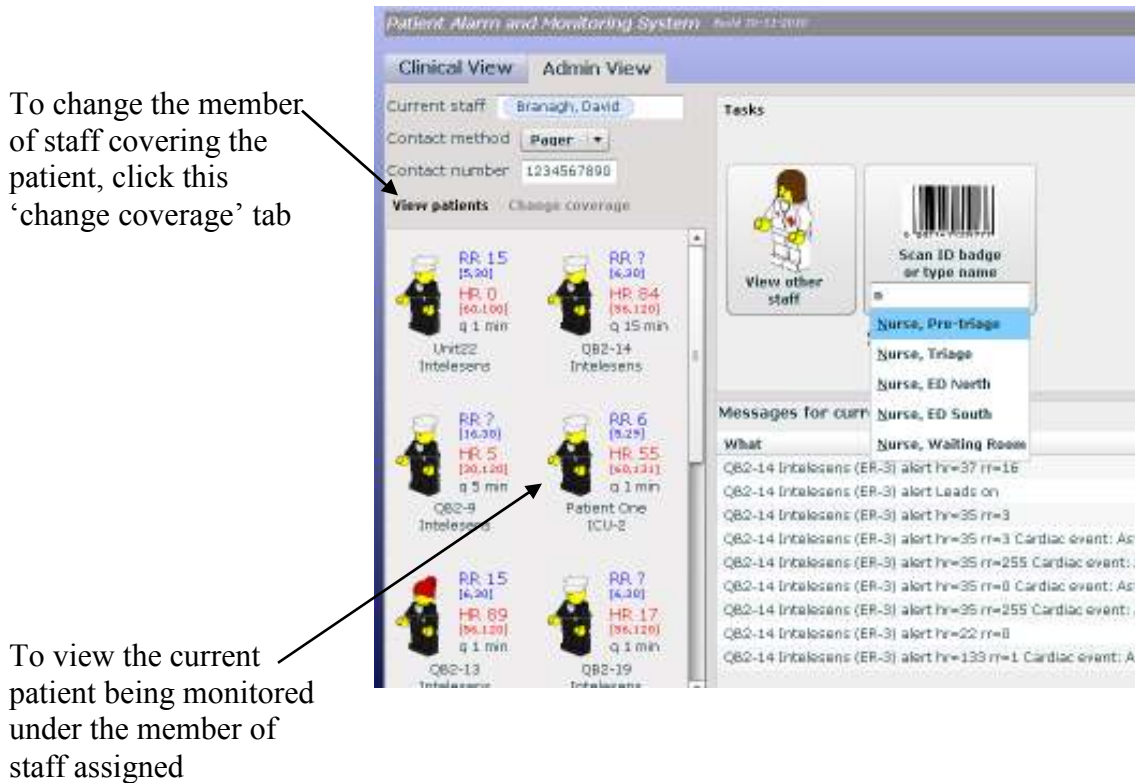


Figure 31. Change staff monitoring a patient

How to ‘Change staff’ with respect to ‘view patients’:

In the Tasks display area of the Admin View screen, you can change the currently assign device to new staff as follows:

- Step 1:** Select Change staff (task button). The next step button will replace all other task buttons, as shown above in Figure 31. Staff names are already saved on the system therefore selection of the name is required (if not there must be registered to login) refer to PAMS administration instructions
- Step 2:** As indicated by the instruction button, scan the badge ID for the new staff or type in the login name. If the name is typed in, a follow-up instruction button will request a password. This will automatically bring up the ‘View patients’ tab as shown above in Figure 31.
- Step 3:** To revert back to the Admin View, click on the icon displayed and it will bring back the main option tab

9.15 PAMS Admin View Task – Change staff

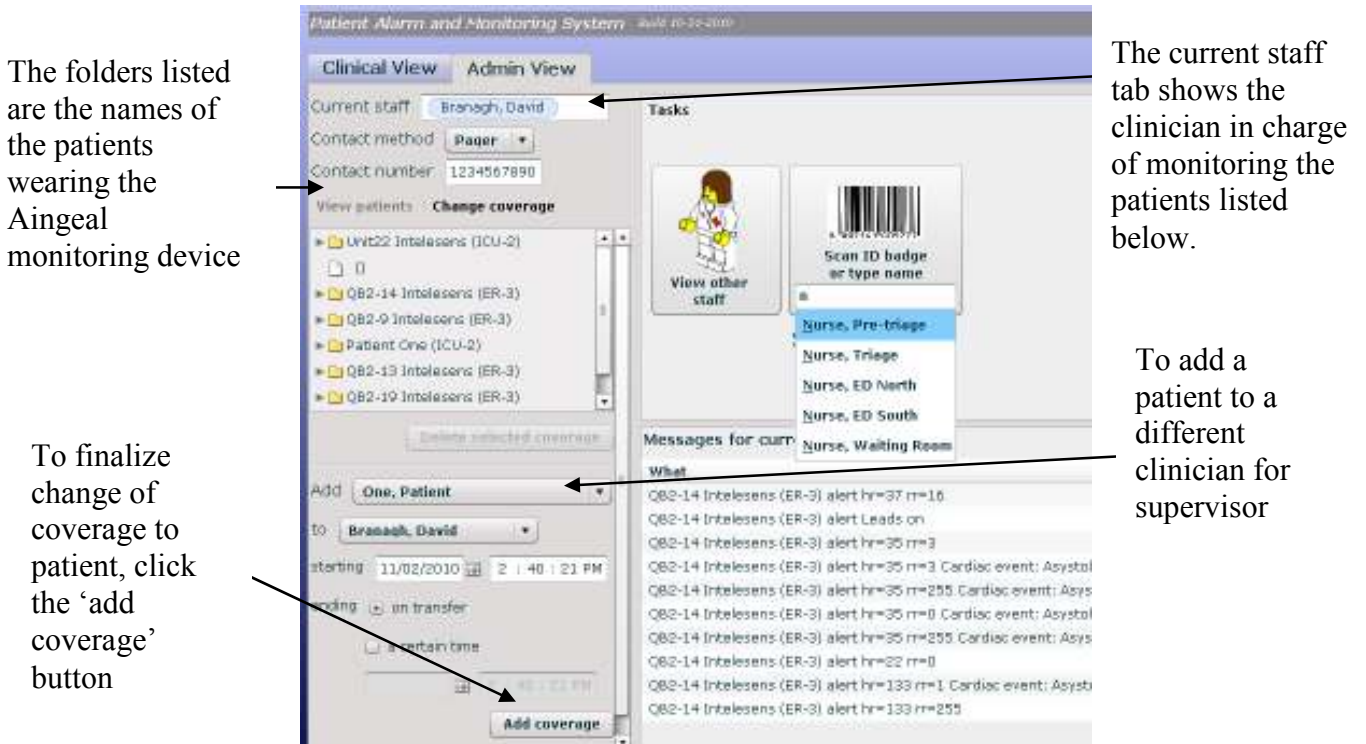


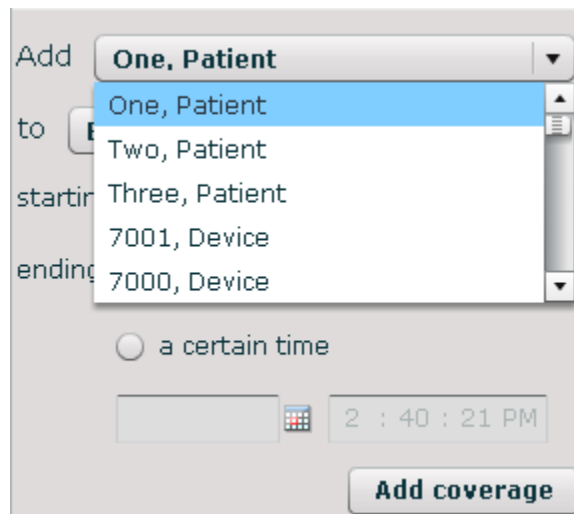
Figure 32. 'Change coverage' tab for staff monitoring a patient

When a clinician has finished their shift or has to leave in an emergency, a patient can easily be transferred to be monitored under another healthcare professional.

How to 'Change staff' with respect to 'change coverage':

- Step 1:** Select Change Staff (task button). The staff names will already be saved on the system therefore selection of the name is all that's required (if not there must be registered to login). Refer to Section 8.3 Page 14
- Step 2:** A scroll list of the patients under the clinicians monitoring, as shown below in Figure 33 will allow fast selection of patient

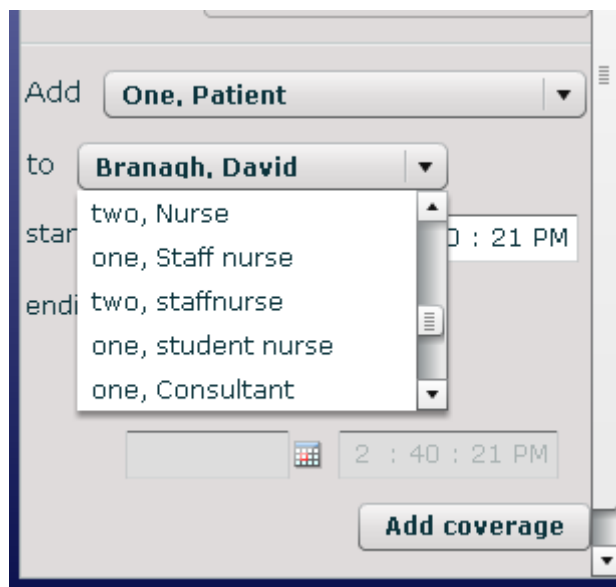
Intelesens Limited



The screenshot shows a software interface for adding coverage. It features a dropdown menu labeled 'Add' with the selected option 'One, Patient'. Below this, a scrollable list displays the following items: 'One, Patient' (highlighted in blue), 'Two, Patient', 'Three, Patient', '7001, Device', and '7000, Device'. To the left of the list, the text 'to', 'startin', and 'ending' is partially visible. Below the list, there is a radio button labeled 'a certain time' and a time field showing '2 : 40 : 21 PM'. At the bottom right, there is an 'Add coverage' button.

Figure 33. *List of patients being monitored under each clinician.*

Step 3: A scroll list, as shown in Figure 34 in below will allow fast selection of clinician taking over supervision.



The screenshot shows the same software interface as Figure 33, but with a different dropdown menu. The 'Add' dropdown now shows 'Branagh, David'. Below it, a scrollable list displays the following items: 'two, Nurse', 'one, Staff nurse', 'two, staffnurse', 'one, student nurse', and 'one, Consultant'. The text 'to', 'star', and 'endi' is visible to the left of the list. The time field still shows '2 : 40 : 21 PM', and the 'Add coverage' button is at the bottom right.

Figure 34. *List of clinicians available in the hospital to transfer care*

Step 4: When all fields are selected and the clinician is happy with the choices, the Add coverage button, shown above, is pressed.

9.16 PAMS Admin View Task – Assign device to patient

When a patient is ready for discharge the VS200 device should be disconnected from the electrode, cleaned, charged and assigned to the next patient to be monitored using PAMS.



Figure 35. The PAMS assigning device to patient

In the Tasks display area of the Admin View you can change the currently assign device to new patient as follows:

How to Assign device to patient with respect to ‘change coverage’:

Step 1: Select Assign device to patient (task button). The next step button will replace all other task buttons, as shown below. The patient names will already be saved on the system therefore selection of the name is all that’s required or can drag the patient icon from the left hand side and place on top of bar code task button.

Step 2: As indicated by the instruction button, scan the badge ID for the new patient

Step 3: To revert back to the ‘Admin View’, click on the icon ‘Assign device to patient’ and it will bring back the main option tab

9.17 PAMS Admin View Task – Transfer patient care

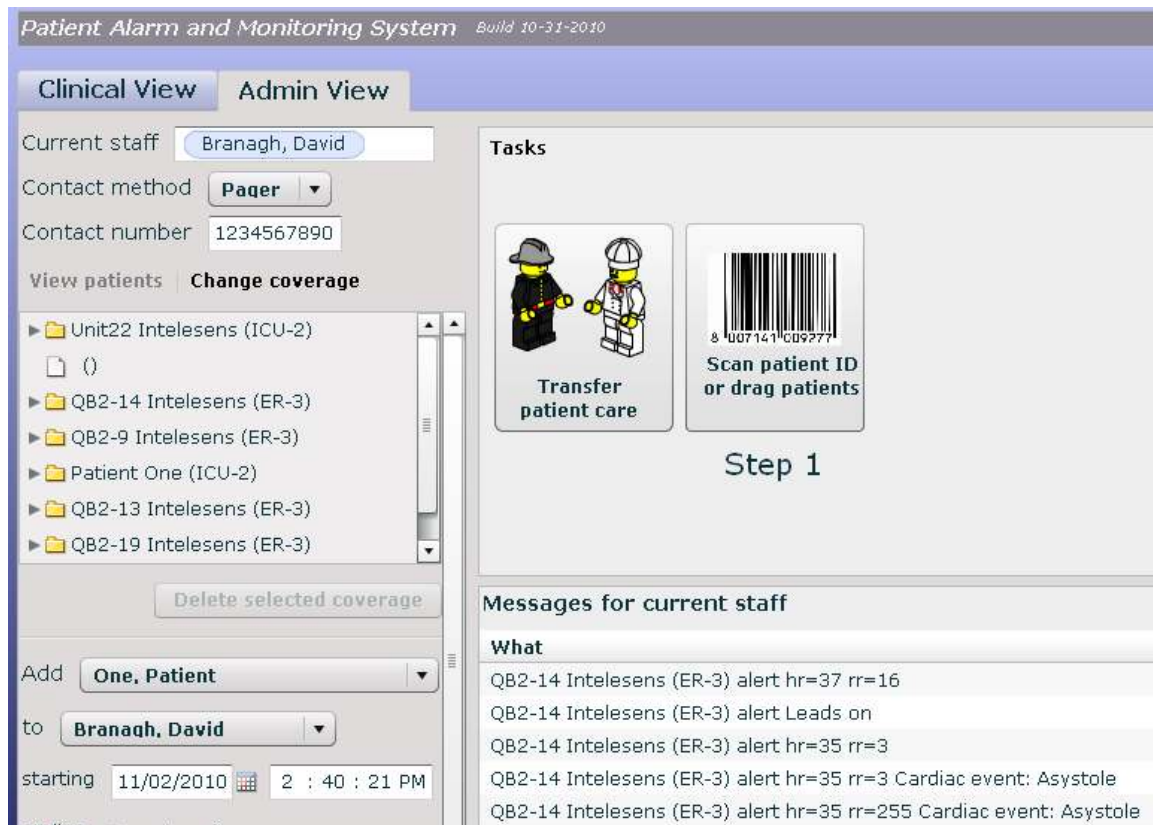


Figure 36. The PAMS transferring patient care

In the Tasks display area of the Admin View screen, you can change the currently transfer patient care as follows:

How to Transfer patient care through Admin View tab:

- Step 1:** Select Transfer patient care (task button). The next step button will replace all other task buttons, as shown below. The patient names will already be saved on the system therefore selection of the name is all that's required or can drag the patient icon from the left hand side and place on top of bar code task button.
- Step 2:** As indicated by the instruction button, scan the badge ID for the new patient or type in the login name.
- Step 3:** To revert back to the Admin View, click on the "Transfer Patient Care" icon

9.18 PAMS Admin View Task – End Patient Monitoring



Figure 37. The PAMS end of patient monitoring

When the patient is ready to leave the hospital and all treatment is complete, the clinician will want to end monitoring from the VS200 system.

How to End patient monitoring through Admin View:

- Step 1:** Select End patient monitoring (task button).
- Step 2:** 'Scan patient ID' and the information will already be saved on the system 'or drag patient' icon from the left hand side and place on top of bar code task button.
- Step 3:** It will ask again if the clinician wants to 'End patient monitoring'. Click 'yes' if this is the case

9.19 Logging Out of PAMS

As shown in the Figure 38 below, each view of PAMS displays the Logout button in the upper right corner of the screen

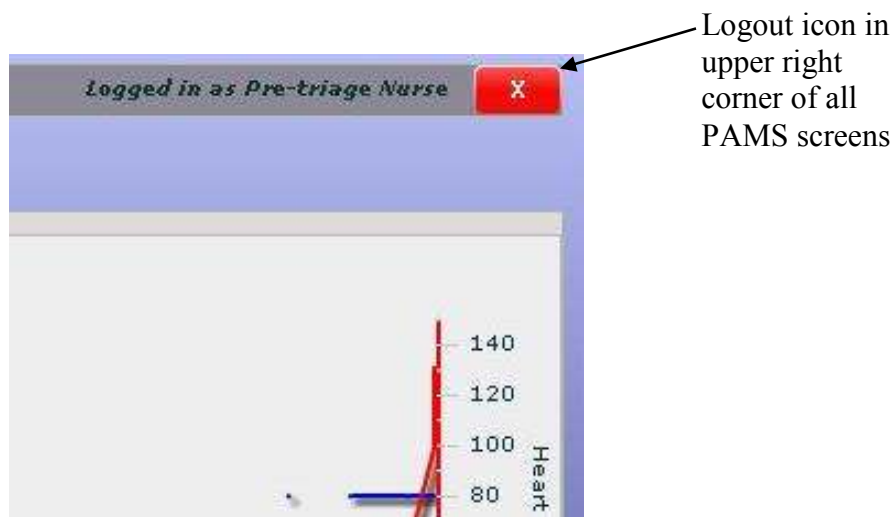


Figure 38.

The PAMS Logout Button

How to Log out of PAMS:

- Step 1:** Select the logout button (). The Log In screen will display.
- Selecting Screen Views in PAMS

10. Device Operation

10.1 Switching the VS200 device on and off

The VS200 device is switched on once the battery is fully charged (Section 8.2. Page 12). Hold down the On / Off button (Section 5.2 Page 8) for two seconds. If device removed from the Electrode Array before battery runs out, hold down the On / Off button (Section 2.2 Figure 5 (A)) for 15 seconds to switch off.

* If the VS200 device has configured with PAMS, two beeps will be heard approximately 15 seconds after the On / Off button is pressed when starting up .

NOTE: Clinician should be familiar with recharging the battery and replacing the VS200 device with another one for constant monitoring.

10.2 Device Start-up

After the configuration settings have been selected in PAMS (Section 9.5, Page 25) the device is now ready to monitor respiration and vital signs and report data on PAMS.

Before beginning a new monitoring period or using the devices on a new patient, it is important to remove monitoring from that patient and clinician (Section 9.18 on Page 40).

Note: The configuration and plotting of the first trend point may take up to two minutes but in the message box, a 'leads on' message will show the device is configuring (if this message is not seen, see troubleshooting Appendix 3 Page 47)

For reference, Figure 39 below indicates the device labeling.

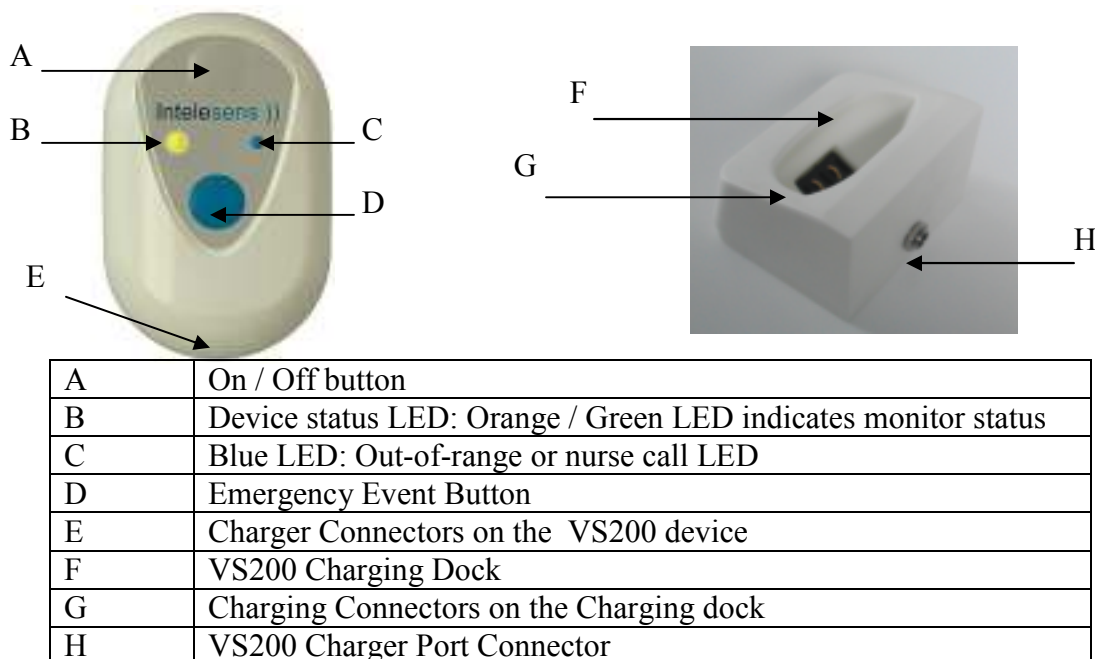


Figure 39. VS200 Monitor Buttons and LED Indicators

Please read through the table below and the Troubleshooting section on Page 47 in order to become familiar with the operation process and indicators BEFORE using the device.

Function	Indication
Ensure device is registered with administration on PAMS	
Switch on the VS200 device by pressing 'A':	'B' will turn orange initially when configuring and then solid green when configured, while 1 beep is heard on first use then 2 beeps thereafter.
Insert the VS200 device into 'F'	LED will illuminate red when charging and green when charged (Section 5.2, page 13)
The VS200 device will connect to the network to retrieve configuration settings. Please note the solid green LED described below to confirm that the device has connected successfully.	
While the device is searching for PAMS	'B' is a solid orange
When a successful connection has been established	'B' is solid green and 2 beeps will be heard
If the VS200 device is unable to connect to PAMS	'B' will remain orange
The VS200 device will remain connected unless the patient is out of range.	
Devices in range	'B' will remain solid green
Nurse call send to device	'C' will Flash blue until patient sees nurse with a constant pulsed beep approximately every 5

	seconds
The VS200 device must be connected to the Electrode Array that is applied to the patient when configuring the data to PAMS.	
When the VS200 device is out of range, 'C' will be illuminated a solid blue and a prolonged beep occurring approximately every 10 seconds as it searches PAMS connection.	
To switch off the VS200 device, press and hold 'A'.	
VS200 device switching off	Hold down 'A' for 15 seconds and 'B' will stop illuminating

11. System Set up

11.1 To Begin Monitoring

The Respiration rate and ECG files will be present on PAMS providing there is a good Wi-Fi signal. The trace should be viewed before the clinician leaves the patient for monitoring allowing the clinician to verify that the system is configured correctly and that the electrode arrangement is correct. To view the patient's ECG and respiration data see Section 9.3 Page 23 and 9.4 on Page 24 respectively.

NOTE: If the VS200 device becomes disconnected from the Electrode Array during the monitoring period, PAMS will display a 'leads off' message and the device should be reconnected as soon as possible.

12. During the Monitoring Period

12.1 Pressing the Event Button

If the patient feels unwell during monitoring they must press the Emergency Event Button, 'D'. A message will display on PAMS and must be acknowledged by the clinician before it goes away. Recorded data is saved on the PAMS network for analysis by the patient's clinician.

12.2 Out of Range Indicators

During use, the LED on the VS200 device will be green to indicate that the Wi-Fi and PAMS connection are within range of each other. Should the VS200 device be out of range, the LED 'C' illuminates solid blue and a continuous tone is heard until the devices are back in range again and 'C' will stop illuminating and the tone will cease.

13. Changing System Settings

The clinician may adjust the configuration settings while the patient is being remotely monitored by the VS200 System:

The clinician should select the correct patient by clicking on their icon on PAMS (Section 9.1, Page 21).

The VS200 device that the patient is currently using should be re-assigned if the clinicians shift is finished as previously described (Section 9.15, Page 36). This will also allow the length of the monitoring period to be changed.

13.1 Low Battery Alarms

The battery level of the VS200 can be checked by using PAMS under ‘get last device status data on demand’ (Section 9.8, Page 29). A low battery message will be sent to PAMS showing on the message display screen.

14.Restarting the VS200 System

Should the VS200 device be switched off (intentionally or unintentionally), the user needs to reconnect the VS200 system to PAMS.

Appendices

Appendix 1 – Alarm Limit Defaults

VS200 Alarm/Alert Defaults – Adults					
Alarm Type	Priority	Default Receiver	High Limit	Low Limit	Alarm ON/OFF in Clinician UI?
V Tach	1	Nurse	N/A	N/A	No
V Fib	1	Nurse	N/A	N/A	No
Asystole	1	Nurse	N/A	N/A	No
HR	2	Nurse	150	50	Yes
RESP	3	Nurse	30	8	Yes
SpO2 (Optional)	6	Nurse	None	90	Yes
Temp (Optional)	7	Nurse	37.8°C	35°C	Yes
BP Systolic (Optional)	8	Nurse	220mmHg	75 mmHg	Yes
BP Diastolic (Optional)	8	Nurse	110mmHg	40mmHg	Yes
Emergency Call	4	Nurse	N/A	N/A	Yes
Out-of-Range	9	Technician	N/A	N/A	No
Equipment Alert	5	Technician	N/A	N/A	No
See Nurse	10	Patient	N/A	N/A	No

Appendix 2 – Accessories and Recommended Supplies

Accessories	Recommended Use
Alcoholic wipes	Cleaning VS200 device before and after every use minimizing bio-contamination
Plug socket	Make sure there a plug socket for the VS200 battery charger as the VS200 device needs charged before every use.
Wi-Fi network	Make sure there's a Wi-Fi network available for patient's needs and movement
PAMS	Require PAMS to configure data using Wi-Fi network
User Manual	Keep this user manual with the VS200 system at all times for reference if needed

Appendix 3 – Troubleshooting

If This Happens:	Try This
“This” alarm is sounding	Low Battery Alarm – place on charger
“This” alarm is sounding	Out of Range Alarm – Go back into range. If device is in range, ensure there is adequate signal quality to facilitate a reliable connection.
Device will not switch on	Place the VS200 device on the charger and observe the LED colour. If the LED changes from green to red the VS200 device requires charging. The charger may need to be disconnected and reconnected to allow the LED to change.
Device will not switch off	Ensure that the top button / describe button is pressed for 15 seconds to facilitate device switch off.
Switching on VS200 Device	If the device fails to configure, where the ‘B’ LED stays illuminated orange, the device needs to move into Wi-Fi range to connect to PAMS. The device is only connected to PAMS when the ‘leads on; message appears under the message tab.
None or poor quality ECG signal or respiration waveform	<p>Ensure skin is cleaned thoroughly with an alcoholic wipe before electrode placement.</p> <p>Ensure Electrode Array is applied to the patient as outlined in Section 4.3 on Page 15, Figure 6. It is important that the electrodes are applied to the correct location to ensure correct respiration measurement.</p> <p>Ensure there is good adhesion between the Electrode Array and skin, particularly at the gold contacts on the electrodes.</p> <p>Ensure the magnetic studs are clean and free from any debris.</p> <p>Ensure the VS200 device is securely connected to the Electrode Array via the sets of magnetic studs.</p>
Out of range or nurse call LED (C in 2.2, Figure 5)	Go to clinician and check there is definitely data being configuration through the PAMS system. Switch off and on again and re-configuration after trying to move back into range.

Appendix 4 – VS200 GMS Specifications

VS200 Monitor













Feature	Specification
Weight	60 grams
Battery	Rechargeable Expected Battery Life (24 hours, 500 uses, shelf life 2 years, 1 hour recharge time to full charge)
Battery Charger	Input Voltage 90 – 264 VAC Output Voltage 4.2 V Max Current 0.75 A
Operating Temperature Range	0 °C to 40 °C (32 °F to 104 °F)
Storage Conditions	1 year @ -20 °C to 20 °C (-4 °F to 68 °F) 3 months @ - 20°C to 45°C (-4 °F to 113 °F) 1 month @ -20°C to 60°C (-4 °F to 140 °F) Protect from liquids at all times
PAMS (‘Patient Alert and Monitoring Server’) 8-18-2010	Software. Must be available on network
Wi-Fi network	Available to transfer information from VS200 system.
VS200 Device	Drop resistant, water resistant, LED colour change and easily visible.

GMS Patient Alarms Management System

Feature	Specification
Clinical View	View patients, HR, RR, skin temperature and location
	Define alerts, patient calls, messages from device and recording settings
	Individual ECG, Respiration rate graphs recording at defined intervals (usually 5 minutes)
Admin View	Change of patient coverage, change of device on patient, monitoring staff for individual patients and end patient monitoring when complete.
	Change the contact method associated with clinician (e.g. mobile or pager messages) therefore alerts when patient needs treatment

Appendix 5 - Indicator Guide

The following indicators and actions are required to start and configure the VS200 System.

Press 'A' to switch on VS200 device. When green LED on charger and green LED on VS200 device and 2 beeps are heard attach to electrode.				
START UP	VS200 LED (B)		VS200 BUZZER	
Set up		10 second constant		
Set up complete		Constant		Double beep (after first time single beep)
↓				
While VS200 device connects to network to talk to PAMS				
↓				
NETWORK	VS200 LED (B)		VS200 BUZZER	
While searching		Constant		Fast beeping Long beep
Successful connection		Constant, successful connection		
↓				
The VS200 system will then immediately connect to the Network.				
↓				
RANGE	VS200 LED (C)		VS200 BUZZER	
In Range		Constant		
Out of Range		For duration of action		5 second beep every 15 seconds
↓				
The blue LED (C) on the VS200 device will go back to not illuminating, indicating that the devices are in range. The system is now ready for use.				

15.Specifications

Mascot 2240 LI 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	0.75	-25 ~ +40

Table 1 VS200 Battery Charger Specification


LED Indicators on Mascot 2240 Li-Ion Battery Charger	
Red LED	Green LED
VS200 is not fully charged	VS200 is fully charged

Table 2 LED indications on the VS200 Charger

NOTE: Do not use any other mains adapter with this charger as it may result in damage to the VS200 unit or affect system operation.

Guidance and manufacturer's declaration – electromagnetic immunity			
The VS200 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the VS200 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)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2	±8 kV air	±8 kV air	

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The VS200 Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the VS200 Monitor should assure that it is used in such an environment			
<p>Radiated RF</p> <p>IEC 61000-4-3</p>	<p>3 V/m</p> <p>80 MHz to 2.5 GHz</p>	<p>$[E_1]$V/m</p>	<p>$d = [1.17]\sqrt{P} \dots 80\text{MHz to } 800 \text{ MHz}$</p> <p>$d = [2.33]\sqrt{P} \dots 800 \text{ MHz to } 2.5\text{GHz}$</p> <p>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)</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 
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 VS200 Monitor is used exceeds the applicable RF compliance level above, the VS200 Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the VS200 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 is not life-supporting

Recommended separation distances between portable and mobile RF communication equipment and the VS200 Monitor		
The VS200 Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VS200 Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VS200 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
<p>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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>		

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

FCC Declaration

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

No changes shall be made to the equipment without the permission of Intelesens Ltd. as this may void the user's authority to operate the equipment.

SAR Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

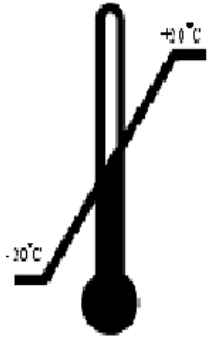
The Aingeal has been tested and meets the FCC RF exposure guidelines when used against the body under normal usage conditions.

The maximum SAR value reported is 0.878 W/kg.

This transmitter must be installed in accordance with the operating instructions and must not be co-located or operating in conjunction with any other antenna or transmitter.

16.Storage conditions

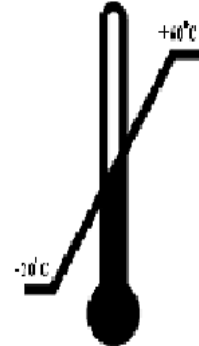
The VS200 electronics must be stored between the temperatures of -20 °C and 20 °C (-4 °F and 68 °F). The electronics must be protected from water and other liquids at all times.



1 year @
-20 °C to 20 °C
(-4 °F to 68 °F)



3 months @
- 20°C to 45°C
(-4 °F to 113 °F)



1 month @
-20°C to 60°C
(-4 °F to 140°F)
















Temperature Limitation



Handle with care

17.Explanation of Symbols Used on the VS200 Device

The symbols used in the documentation for the VS200 device are summarized in the following table:

Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
	Date of Manufacture		Temperature limitation as in storage conditions		Batch code		Serial Number including Date of Manufacture
	Not for general disposal		Handle with care		Attention		CE Mark
	Do not get wet		Manufacturer		Consult Instructions for Use		Federal Communication Commission
	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			Rx only	US Federal law restricts this device to sale by or on the order of a licensed physician. No modifications to the equipment is allowed		

18.Disposal

The VS200 electronic device and must be returned to the distributor for disposal.

Do not heat or dispose of any part of the VS200 system in fire. The devices may burst or release toxic materials.

Do not disassemble, apply excessive pressure or deform any part of the VS200 system.

19.Warranty

Intelesens 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.

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.

20.Manufacturer Details

Manufactured by:

Intelesens Ltd.
4 Heron Road,
Belfast,
BT3 9LE
UK

w: www.intelesens.com

e: info@intelezens.com

CE
0120

