surepulse

Every second counts

VS Newborn Heart Rate Monitor

Operating Manual

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MEDICAL – PATIENT-MONITORING EQUIPMENT

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI 60601-1, ISO 80601-2-61, CAN/CSA-C22.2 No. 60601-1 2014

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CONTENTS

CHAPTER 1

Welcome

This chapter contains the following sections

Purpose

This Operating Manual for the SurePulse VS Newborn Heart Rate Monitor instructs the user in safe use. It should be read thoroughly before first use of the Heart Rate Monitor, with particular regard to the warnings and cautions. This Operating Manual is relevant to routine clinical use.

Intended Use

The SurePulse VS Newborn Heart Rate Monitor (VS) is a device which utilises reflectance photoplethysmography (PPG) to determine heart rate (HR) in newborn babies. The sensor is placed on the head of the newborn baby such that the sensor contacts the forehead of the baby. The sensor may be integrated into a soft cap or affixed separately. The HR and PPG signals are transmitted to a Display via a wireless connection. The device is intended for application only by medically qualified personnel.

The Caps are designed for head circumferences from 20 cm to 40 cm in five sizes. The Cap and Sensor are single-use items. The device is non-invasive. The Cap and Sensor can be worn for up to four hours. However, the Sensor can be removed from the Cap, and the Cap on its own can be worn as long as is required up to 30 days. The Cap serves to keep the baby's head warm and to provide a fixation point for an endotracheal tube holder or CPAP apparatus.

The user should take precaution to read all information in the Operating Manual, where all relevant cautions and warnings are provided.

Contraindications

The SurePulse VS has been designed to measure heart rate of newborn babies. The contraindications are listed as follows:

- Its use is contraindicated if any part of the device is broken, damaged or dirty.
- The device should be used in conjunction with this Operating Manual by trained staff only and is not suitable for domestic use.
- The contraindications for using the device include any skin condition where the integrity of the skin could be breached.
- For the sensor being used continuously for more than 4 hours
- For the cap being used (without the sensor) for more than 30 days
- Outside the operating temperature range of 0 to 40 degrees Celcius.

Benefits

The benefits of the device to the patient are accurate and wireless heart rate monitoring and highly customized design for the newborn population.

The sensor placement is over the forehead microcapillary bed. This bed is supplied from arteries which also feed the brain. Unlike the periphery of the body the perfusion around the brain is maintained even during physiological compromise and hence the heart rate can be detected. The trade-off is that sensitivity is reduced due to the usage of reflection mode

which makes signal detection marginally more challenging. However, the provision of such a device allows the pulsatile signal to be measured closest to the important brain organ.

Conventions

The following conventions are used within this document.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use. Failure to observe a caution may result in minor or moderate injury or damage to the equipment or other property and possibly a remote risk of more serious injury.

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in serious injury to the user or patient.

System Overview

The VS Newborn Heart Rate Monitor has the following parts, which are sold separately:

1. VS System: VS Display including two removable VS Modules
2. VS Sensor: Optical sensor (single-use only) for measuring the PPG
3. VS Cap: VS Sensor integrated into soft Cap (single use only, available in 5 sizes)

Principles of Operation

The device uses a technique called photoplethysmography. It is an optical technique which measures changes in blood volume under the skin surface. The sensor shines light into the skin, some light is absorbed by tissue and blood, some is scattered and some returns to the optical sensor. The amount of light absorbed is proportional to the amount of blood present in the tissue. As the heart beats, the volume of blood changes and therefore so does the amount of light absorbed. This means that the sensor captures a signal which represents the changes in blood volume, and thus the pulses of the heart. The heart rate can then be extracted from this signal. The Display outputs both the photoplethysmogram (PPG) signal and the calculated heart rate.

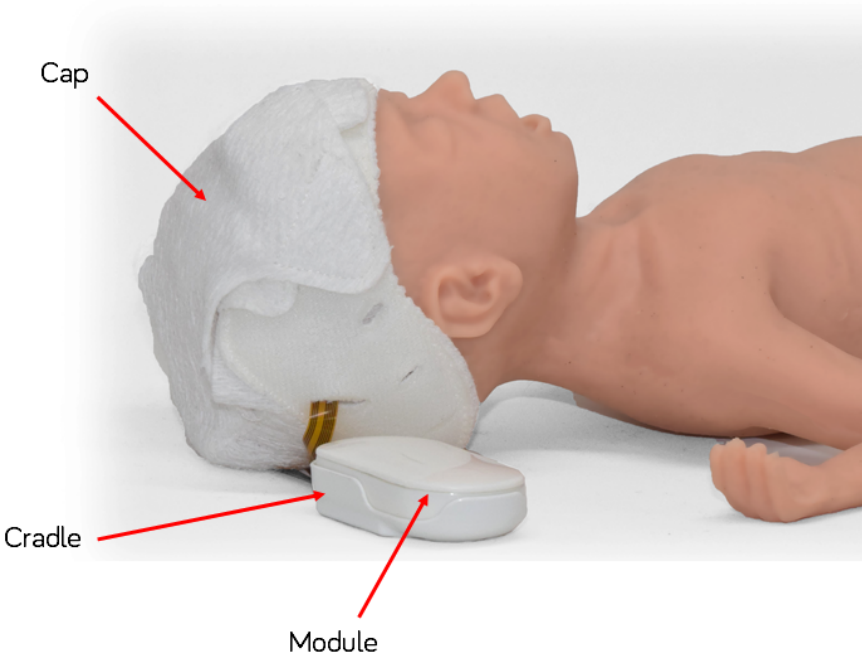

Figure 1-1 *The VS Sensor is integrated into a single use cap (VS Cap). The sensor may also be affixed separately from the cap. The Module is mounted into the Cradle.*

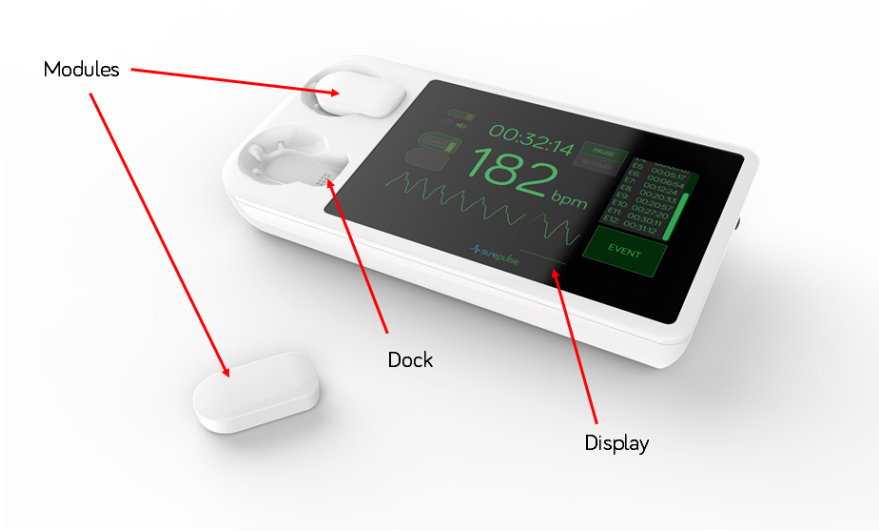

Figure 1-2 *VS Display with VS Modules. There are two Docks for charging and storing the Modules.*

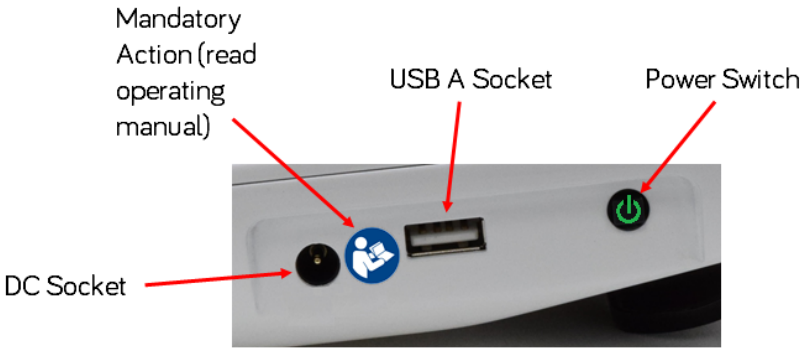

Figure 1-3 *Side of the Display. There is a socket for the supplied 5V AC/DC power supply unit, a USB A socket, and a power switch with indicator LED.*

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CHAPTER 2

Installation

This chapter contains the following sections

Box Contents

VS System Box

The system box contains the following items:

1. Display
2. Two Modules
3. Operating Manual
4. 5V AC/DC Power Adaptor

VS Cap Box

A Cap box contains individually packaged single-use Caps with integrated sensors. The outside of the box shows the number of Caps and sizes packaged inside.

Each Cap is packaged with a separate CPAP exhaust strap. Remove the strap before use of the Cap and only reintroduce the strap if affixing CPAP equipment.

VS Sensor Box

A Sensor box contains individually packaged single-use sensors. The outside of the box shows the number of sensors packaged inside.

Warning: Only use genuine parts supplied by SurePulse Medical Ltd or an authorised distributor. Check that all parts are compatible before use, otherwise patient injury may result.

Setting Up

System Inspection

It is recommended to perform the inspections listed in the checklists in " Display Inspection" on page 85 and " Module Inspection" on page 87 before first use of the system.

Charging the Batteries

Ensure all packaging is removed. Retain packaging to use if any return is required. Place both Modules onto the Display docks. Plug the 5V AC/DC plug into the side of the Display and plug the mains adaptor into a mains socket. The battery in the Display and the batteries in the Modules will now charge. Full charging of the Display and two Modules should take no longer than five hours. The LEDs on the Modules will turn green when fully charged, as will the LED on the side of the Display.

It is recommended to leave the device on charge before use, otherwise batteries may deplete and the device may be unavailable for use. This will not degrade the lifetime of the batteries.

The 5V AC/DC plug is the device which provides isolation from the supply mains if disconnection from the mains is required.

Caution: Do not position the device so that it is difficult to disconnect the 5V AC/DC adaptor cable.

Placement

The hook on the back of Display is designed to operate both as a carrying handle and as a mount for the Display. The Display can either be placed flat with the hook used to prop up the screen at an angle, or it can be mounted on a vertical plastic edge.

Caution: Ensure the Display is mounted in a stable location.

The Display should not be placed within reach of the baby in case the baby inadvertently touches the Display screen or electrical contacts.

Caution: Do not place the Display within reach of the baby.

The active battery life of the Display is up to four hours. The active battery life of a Module is up to three hours. Therefore the Display does not need to be plugged into the mains whilst in use. However it is recommended to leave the Display with Modules in the Display docks on charge to ensure they are available for use when required.

Operational Check

Switch the Display on by holding the power button at the side. The LED on the power button will turn green (unless any alarms are activated) and the LCD will display the main screen (see section "Touchscreen Interface" on page 45).

Test the wireless system in the intended use environment to check for interference. This can be achieved by unplugging a Module from the Display and placing it into a sensor cradle. The signal trace should activate. Move the Module and sensor cradle further from the Display. The system should still function with a range of up to 3 metres.

Caution: Check that the wireless system functions correctly in the intended use environment.

CHAPTER 3

System Usage

This chapter contains the following sections

Device Application

Equipment Placement

The Display can be mounted on a vertical plastic edge using the hook or laid flat in a convenient location, using the hook to tilt the Display at an upwards angle. The Display can be powered using its internal battery or via the supplied 5V AC/DC adaptor. The adaptor part number is VEP15US05.

Warning: Only use the 5V AC/DC adaptor supplied with the system or a manufacturer approved replacement unit.

Patient Considerations

If the caps are used, they are intended to be applied on newborn babies with head circumference 20 to 40 cm.

The device is intended to be used in hospitals, delivery suites, midwife-led units and other birthing centres by healthcare professionals only. It is not intended for domestic use. The device can be moved but is not designed to be mobile whilst actively used for heart rate monitoring.

Warning: Only use the device in intended environments.

The device is intended for continuous supervised use whilst actively displaying heart rate data from the newborn baby.

Warning: The device should always be used in the presence of a qualified healthcare professional.

Each Cap or sensor is intended to be used for single patient use only. If a Cap or sensor is re-used, this may lead to infection. The Display and Modules can be used as often as required, assuming adequate battery power, and that periodic cleaning and maintenance procedures are followed.

Warning: Do not re-use a Cap or sensor. The Cap and sensor are for single patient use only.

The Sensor should be applied for a maximum of four hours to prevent tissue damage. Undesirable side-effects of prolonged usage could include marking of the skin. If the cap is being used to hold CPAP equipment or an endotrachael tube holder, the sensor should be removed from the cap after fours hours to minimise this risk. See the section on Removal of the Sensor below.

Caution: Do not use the Sensor for more than four hours or skin irritation may result.

Warning: Do not overtighten the Cap and therefore apply too much pressure to the baby's head. Patient injury may result.

If using the Cap and following removal of the sensor, the Cap can be left on the baby's head for up to a maximum of 30 days, as required.

Device Inspection

Before using the VS, inspect the Display and Modules for any signs of damage. Damage includes cracks to the plastic or touch panel glass, or any damage caused by excess liquid. Ensure that the device is clean and dry.

Warning: If any part of the Modules or Display is damaged, discontinue use of the system.

More detailed device inspection should be carried out routinely (in line with local equipment maintenance guidelines). Checklists can be found in " Display Inspection" on page 85 and " Module Inspection" on page 87.

Selecting a Cap Size

The sensor may be integrated into a Cap or affixed separately. If using a Cap with integrated sensor, the correct Cap size can be selected by the head circumference (more accurate) or gestational age (less accurate). The following table shows approximate sizing.

Cap Size	Head Circumference	Gestational Age
Extra Small	20 cm to 27 cm	23 to 32 weeks
Small	25 cm to 31 cm	30 to 36 weeks
Medium	29 cm to 35 cm	32 to 38 weeks
Large	32 cm to 38 cm	34 to 40 weeks
Extra Large	34 cm to 40 cm	36 to 42 weeks

Preparing a Cap for Use

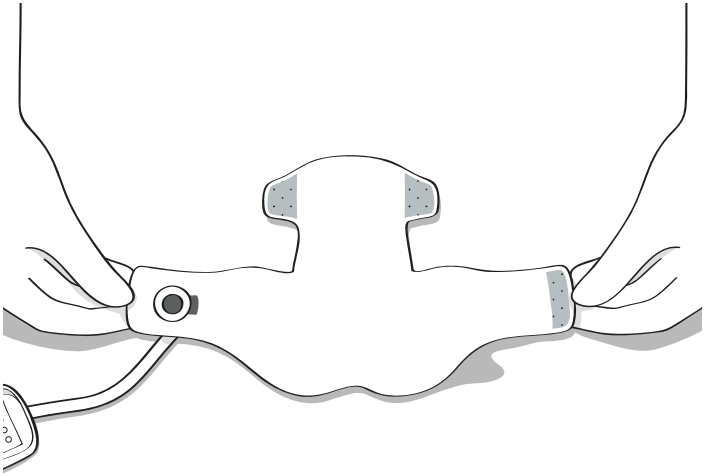

Figure 3-1 *Unpack the Cap from the packaging and lay it out flat. Remove the separate CPAP strap.*

Warning: If any part of the Cap or Sensor surface is dirty or damaged, discontinue use of the Cap.

The Module can be placed into the cradle at this point or can be left in the Display to be applied later (see the section below on Cap Application).

Cap Application

If using the Cap with integrated sensor, this section illustrates how to apply the Cap to the head of a newborn baby.

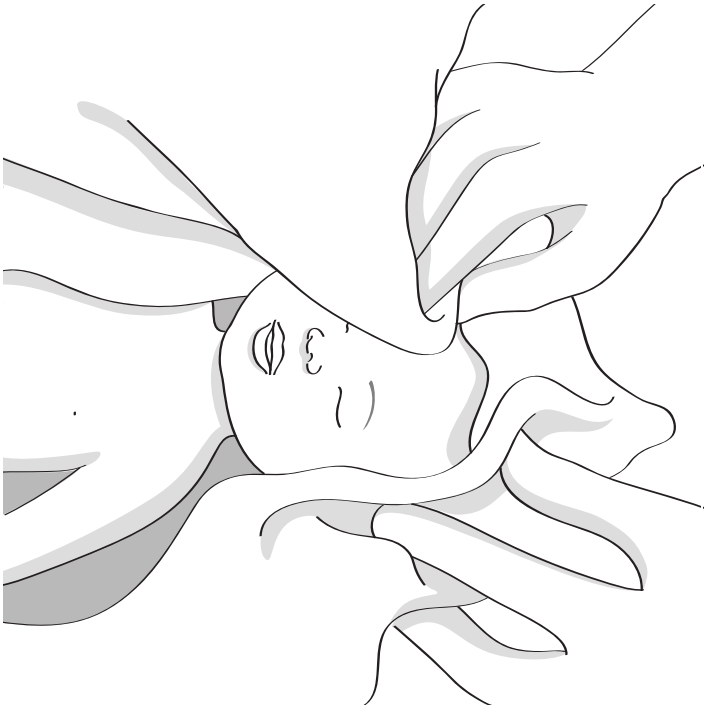

Figure 3-2 *When the baby is born, dry and wipe the head.*

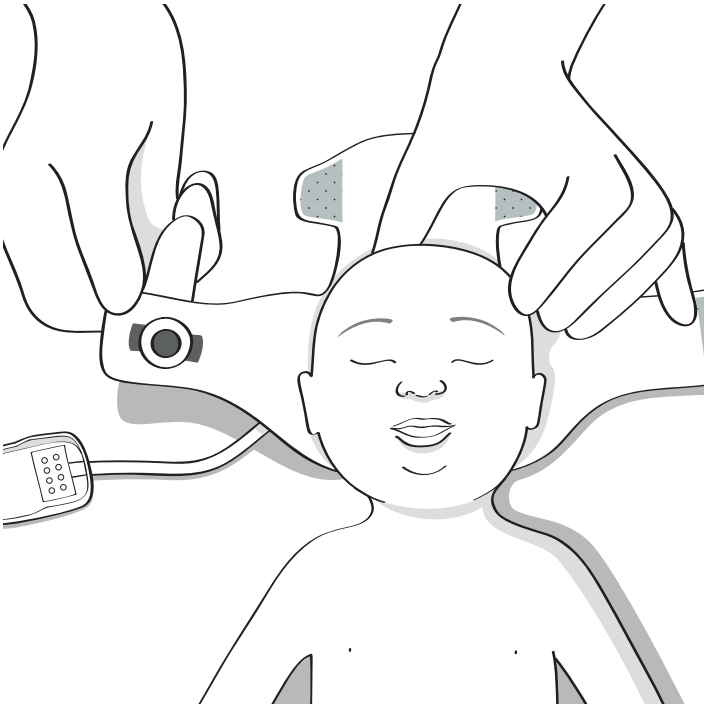

Figure 3-3 *Place the baby on the folded out Cap so that the back of the head is placed on the central portion.*

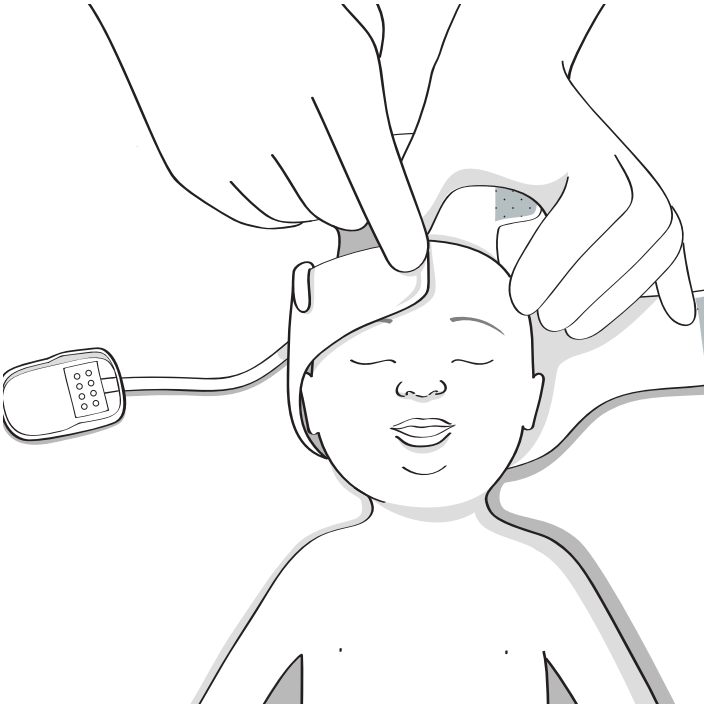

Figure 3-4 *Fold the flap containing the Sensor (the right hand side if standing at the head end of the baby) over the baby's forehead so that the Sensor contacts the area just above the right eyebrow of the baby. The Caps are marked with the sensor location to facilitate correct location. Hold the flap in position.*

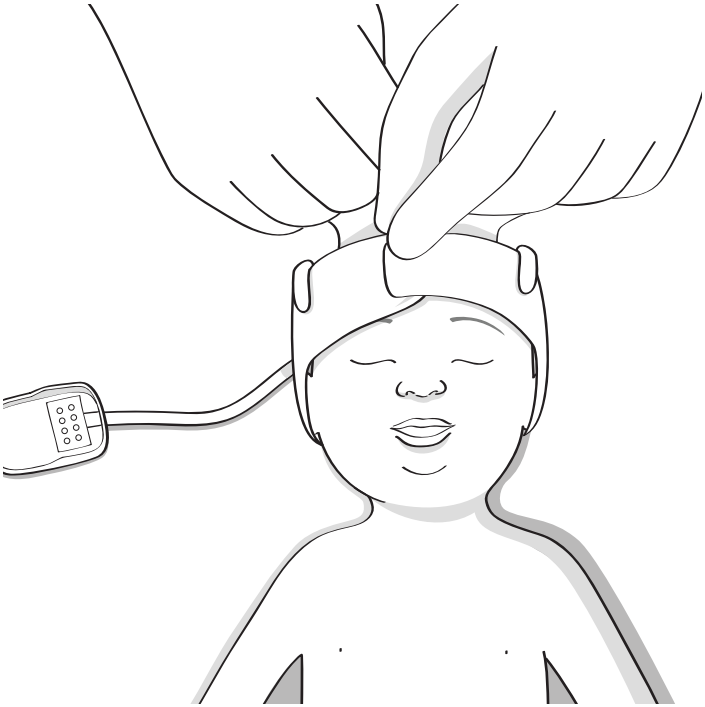

Figure 3-5 *Fold the opposite flap over the forehead and attach to the first flap using the Velcro attachment. The Cap should be secure but comfortable for the baby. If the Cap is too tight then the blood supply to the forehead can be impaired.*

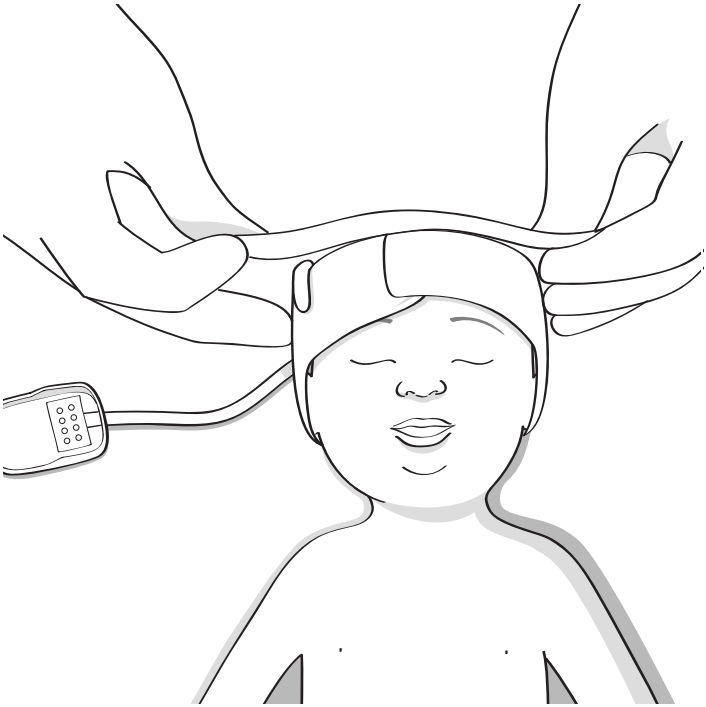

Figure 3-6 *Hold the two tabs of the top flap and fold it over the top of the baby's head.*

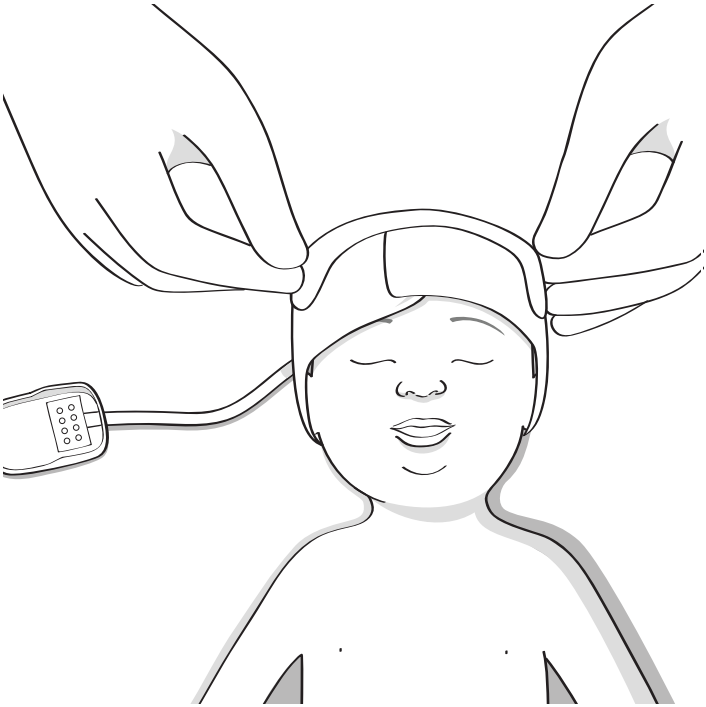

Figure 3-7 *Use the two Velcro tabs of the top flap to secure it to the side flaps on the forehead of the baby. The Cap is now attached to the baby.*

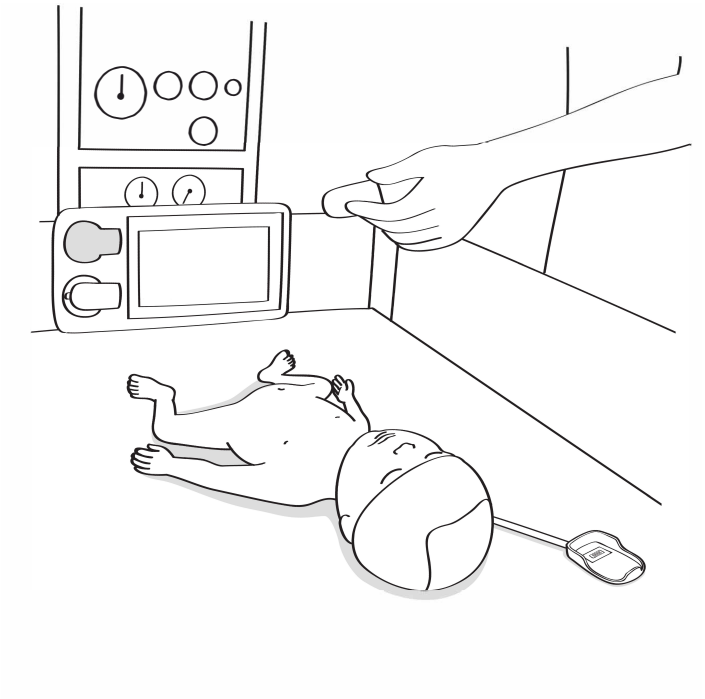

Figure 3-8 *If not already completed, remove one Module from the Display Dock.*

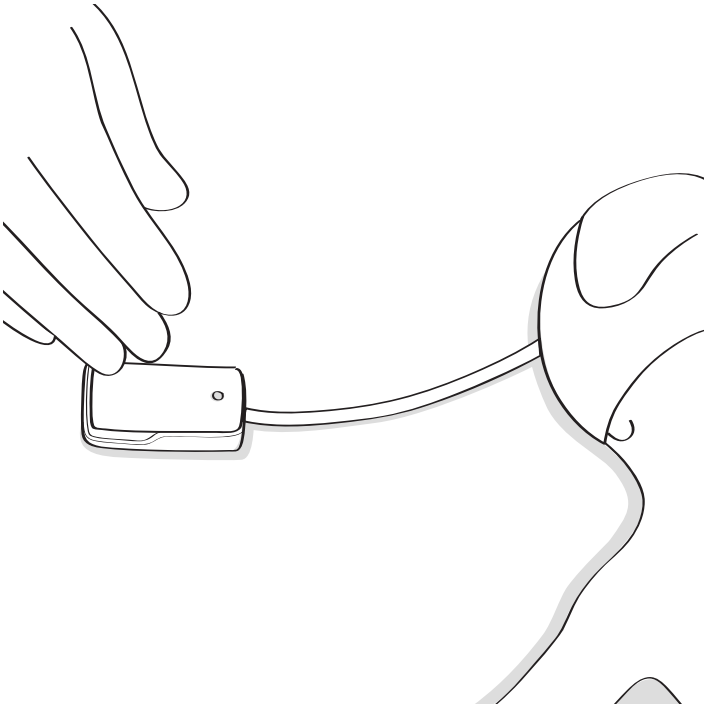

Figure 3-9 *Place the Module into the Cap Cradle. The screen on the Display should indicate a connection and a signal trace should appear. The Display will indicate if there is any fault.*

Caution: Ensure that the sensor is placed below the hairline and above the eyebrow to achieve adequate signal quality.

Breathing Apparatus

Either an endotracheal tube holder or CPAP apparatus may be attached to the Cap whilst it is in use. Multiple positioned eyelets on the sides of the Cap can be used to secure either an endotracheal tube holder or CPAP apparatus. The two small velcro flaps on either side of the Cap can be used to secure the airway tubing for the CPAP system. The separate strap packaged with the Cap can be used to secure the exhaust tube.

Removal of the Sensor

The Sensor can be removed from the Cap whilst the Cap is left on the baby's head. This could be important, for example, if thermal protection needs to be maintained or if breathing apparatus is attached that should not be disturbed. Remove the Module from the Cradle before following the steps below.

Warning: Be careful not to disturb breathing apparatus if still attached to the Cap whilst the sensor is removed.

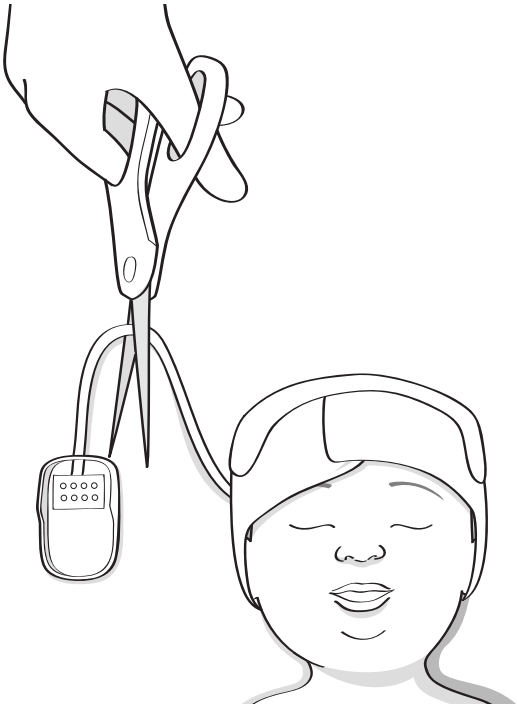

Figure 3-10 *Using a pair of scissors, cut the flat cable connecting the Cradle to the Sensor in the Cap.*

Caution: Remove the Module from the Cradle before cutting the Sensor cable.

Figure 3-11 *Lift the brim of the Cap, and expose the sensor.*

Figure 3-12 *Gently pull the Sensor out, pulling the flat cable with it. Replace the brim of the Cap.*

The Sensor head, flat cable and Cradle may be biologically contaminated and should be disposed of according to local disposal practices for infectious waste. Re-use of the sensor may lead to infection.

Warning: Do not re-use the Sensor.

Sensor Only

The sensor may be affixed separately from the Cap. Unpack the sensor from its packaging.

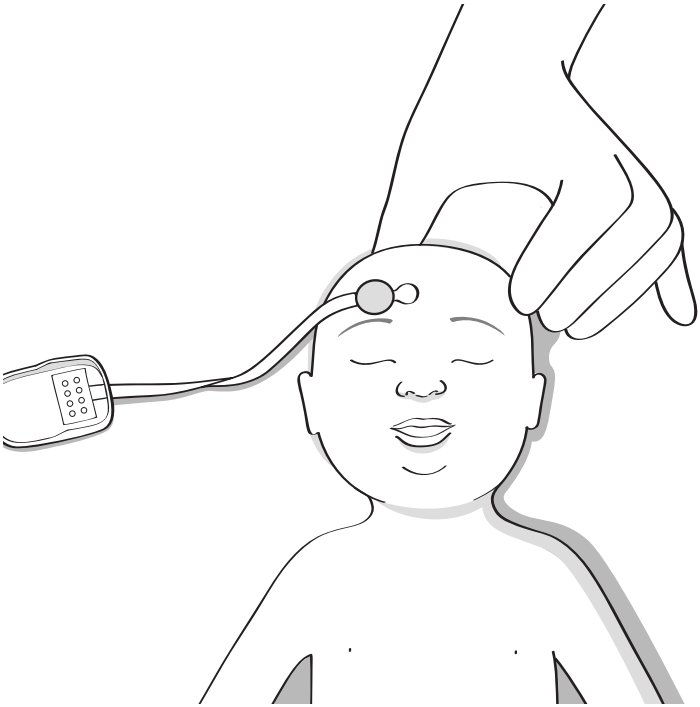

Figure 3-13 *Position the sensor above the right eyebrow.*

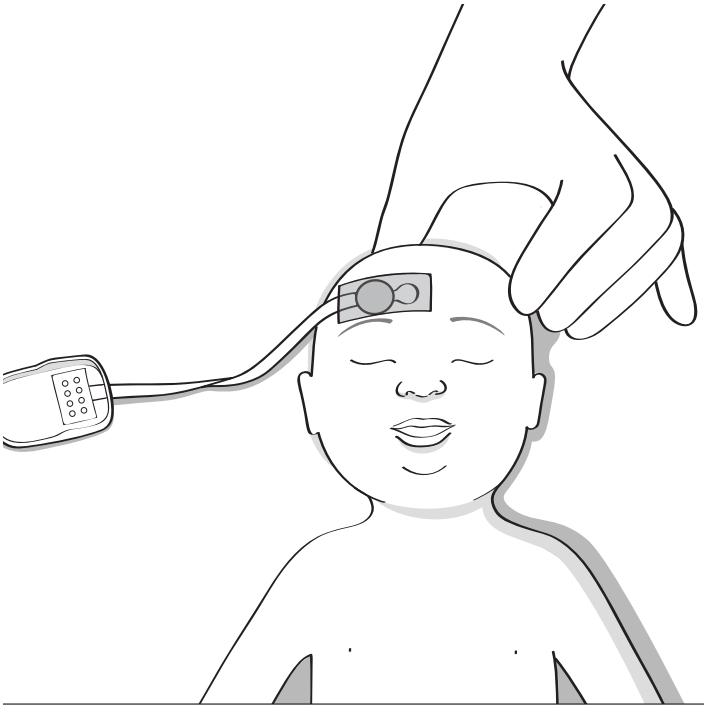

Figure 3-14 *Secure in place using surgical tape.*

Use surgical tape appropriate for the skin condition of the neonate.

Connect a charged Module to the cradle (this step can be done before affixing the sensor). The screen on the Display should indicate a

connection and a signal trace should appear. The Display will indicate if there is any fault.

Touchscreen Interface

This section describes how the user can interact with the touchscreen interface. The interface is designed to be able to be used whilst the user is wearing clinical gloves, although use should be tested before heart rate monitoring functions are initiated.

Upon switching the unit on, the user will be presented with the main screen.

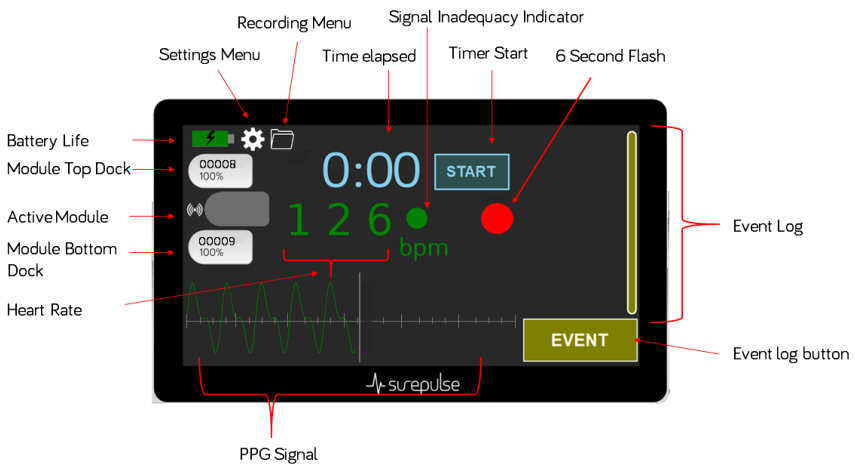

Figure 3-15 *The main screen of the device.*

The main screen has an Event Log, a PPG signal trace, a heart rate value in Beats-Per-Minute (BPM), a signal inadequacy indicator, an elapsed time and timer controls, a six-second timer, menu options for settings and recordings management, battery status and Module's statuses. The PPG signal trace is six seconds long and each main segment (the taller lines) are at one second increments. The smaller lines are at quarter second increments.

Initiating Monitoring

To prepare a Module, remove a Module from the Display dock and place it into the sensor cradle. The serial number of the connected Module will appear in the Active Module section of the interface.

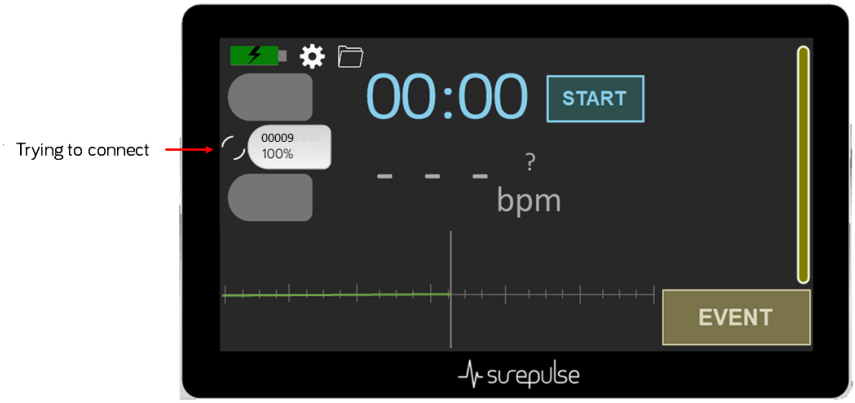

Figure 3-16 *When the Module is removed from the Display, it will become the Active Module and will try and connect wirelessly to the Display.*

Once the Module tries to connect to the Display, it will enter one of two states. Either it will be connected successfully, or it will enter a countdown timer mode.

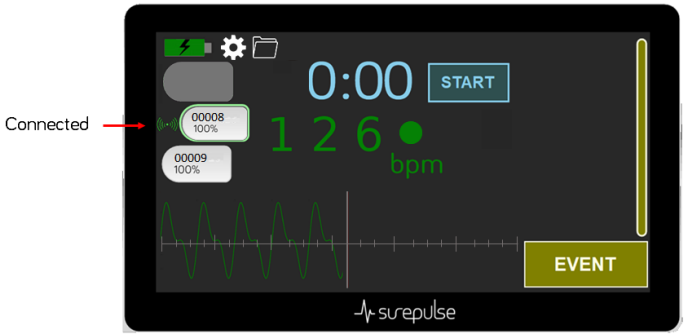

Figure 3-17 *The Active Module is connected successfully.*

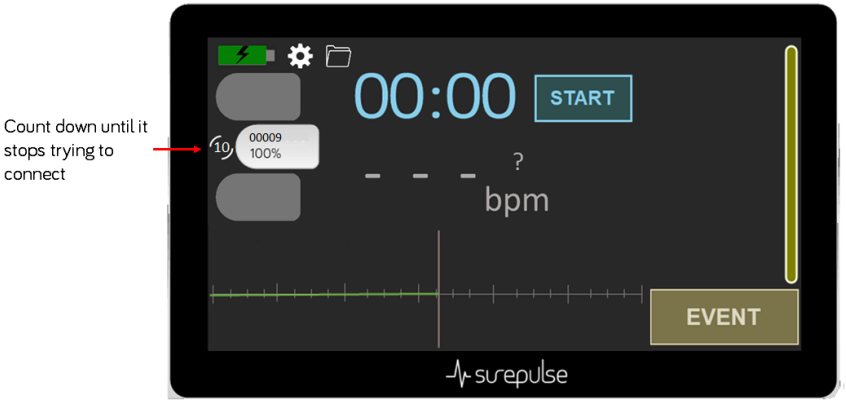

Figure 3-18 *The Active Module is trying to connect. There is a count-down timer for the connection attempt. If the connection attempt fails, replace the Module in the Display and try another Module.*

Once the Module is successfully connected, the signal trace will scroll.

Start the timer at birth or another desired reference point. If necessary, reset the timer from a previous recording by pressing the RESET button. Place the Cap or sensor on the baby (as per "Device Application " on page 23) if not already positioned.

If the sensor is correctly positioned then it should detect a PPG trace. The Display automatically adjusts the scale of the PPG trace depending on the

size of the signal, therefore a Signal Inadequacy Indicator is also included on the screen.

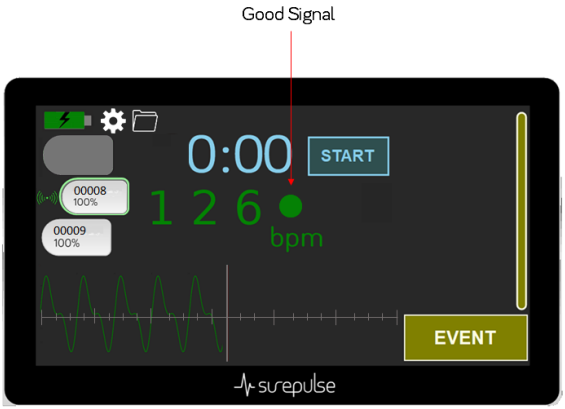

Figure 3-19 *If the trace is of adequate signal quality, then the heart rate (represented by the green BPM figure) will be updated every 5 seconds and the Signal Inadequacy Indicator will show a green filled circle.*

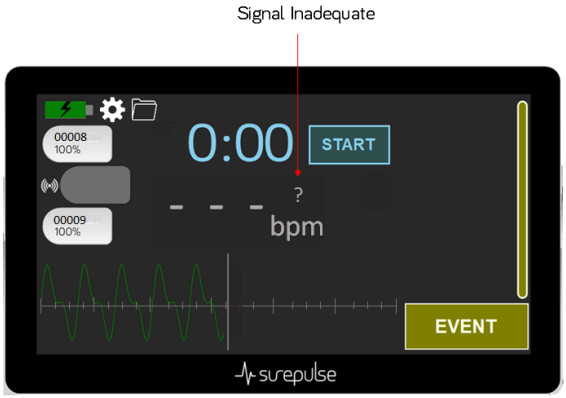

Figure 3-20 *If the signal is inadequate to calculate a heart rate, then a "?" (question mark) symbol will appear on the screen.*

At times where the signal was adequate for the last 5 seconds but, in the current 5 seconds, it is not adequate, the last known good heart rate will appear in grey with a question mark beside the number. If the signal is still inadequate during the next 5 second window, the heart rate will disappear as in the above figure. This is illustrated in the following table.

Time Period	5 second period 1	5 second period 2	5 second period 3
Signal Status	Adequate signal	Inadequate signal	Inadequate signal
BPM colour	Green	Grey	Grey
BPM reading	Heart rate current period	Heart rate last period	---
Signal Adequacy Indicator	Green filled circle	?	?

If the signal is persistently inadequate, then it is suggested to adjust the positioning of the Cap and/or sensor until a PPG signal can be found.

The Display does not average the heart rate beyond the previous 5 second window.

The range of the heart rate displayed is 25 bpm to 240 bpm.

Recording Events

Events can be recorded to enable an accurate log of the timings of clinical interventions. The timer must have been started to facilitate recording of events. Once an event has been recorded, it is listed at the side of the screen and also available for download after the monitoring has concluded for accurate documentation.

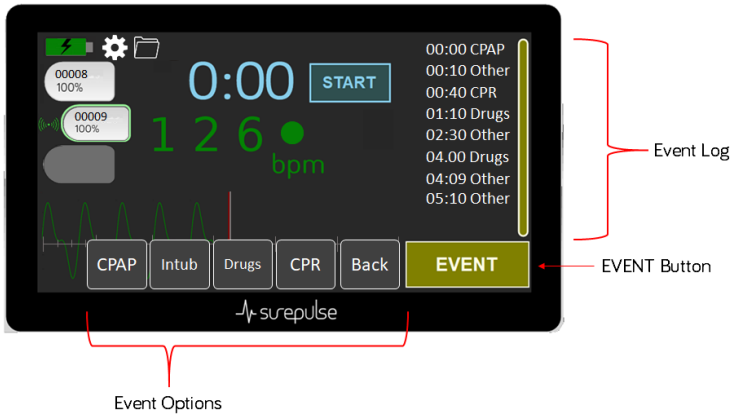

Figure 3-21 *Pressing the EVENT button brings up a list of possible events to record. Press the desired event button and it will be added to the "Event Logged" list along with the elapsed time. Pressing "Back" closes the Event options list. If the EVENT button is pressed twice in succession, it is automatically coded as "Other" (to be used, for example, if there is no time to select an option).*

Alarms

There are no physiological alarms on the device, as the device is intended to be used in constant supervision with medically qualified personnel. The operators position for detection of alarm conditions should be within view of the screen of the Display.

There are technical alarms which are activated and notified as per the following table. Touchscreen Output for alarms relating to the Modules will only occur if the Module is physically connected to or paired with the Display.

Alarm Title	Alarm Condition	Screen Display	Display LED	Module LED	Audible	Recommended User Action
Display Battery Low	Display battery is less than 10%	YES	YELLOW	No change	YES	Plug Display into 5V adaptor
Display Battery Very Low	Display battery is less than 5%	YES	RED	No change	YES	Plug Display into 5V adaptor
Module Battery Low (In-Use)	Module battery is less than 12%	YES	No change	No change	YES	Swap Module with spare charged Module.
Module Battery Low (Not In-Use)	Module battery is less than 10%	NO	No change	RED	NO	Plug Module into Display dock

Alarm Title	Alarm Condition	Screen Display	Display LED	Module LED	Audible	Recommended User Action
Low Memory	Available space less than 2 hours of recording	YES	No change	NO	YES	Delete some recordings to clear space
Wireless Connection Failed	Active Module wireless connection drops for greater than 30 seconds	YES	No change	FLASH (1 s)	YES	Swap Module with spare Module
General Technical Error (Display)	Internal fault with hardware	YES	RED	No change	YES	Discontinue use of the system
General Technical Error (Module)	Internal fault with hardware	NO	No change	RED FLASH	NO	Swap Module with spare Module. Discontinue use of faulty Module
Over temperature (Display)	Display internal temperature greater than 49°C	YES	No change	No change	YES	Move Display to cooler area, disconnect from 5V AC/DC Adaptor

Alarm Title	Alarm Condition	Screen Display	Display LED	Module LED	Audible	Recommended User Action
Over temperature (Module)	Module internal temperature greater than 49°C	YES	No change	ORANGE	YES	Move Module to cooler area, remove Module from Display dock
Sensor Detection Fail	Module plugs into sensor cradle and sensor hardware test fails	NO	No change	RED rapid flash	NO	Try reseating Module in Cradle, or replace sensor or Cap

All alarm priorities are low. The audible alarms will not sound if the audio is muted.

The alarm system can be verified by allowing Module and/or Display batteries to deplete whilst the Module is connected to a sensor Cradle and the Display is receiving data.

Figure 3-22 *If the Display is over temperature, then a prompt will appear. Move the Display to a cooler location.*

Warning: Do not leave the Display unit under a radiant warmer for extended periods of time.

Figure 3-23 *The Mute Icon will indicate if the audible alarms are silenced.*

Module Swapping

If a Module needs swapping during a recording (for example, if the battery on the active Module is low), then the following procedure should be followed.

1. For the Module swap to be successful, the spare Module must have been paired with the Display by inserting it into the Display dock, and ensuring the serial number is registered on the Display screen.

2. Remove the spare Module from the Display dock. A box with a swap button appears on the screen (see figure below).
3. Press YES to swap the active Module.
4. Remove the old Module from the sensor cradle and place the spare Module into the sensor cradle. The monitoring will continue.
5. Put the old Module into the Display dock.

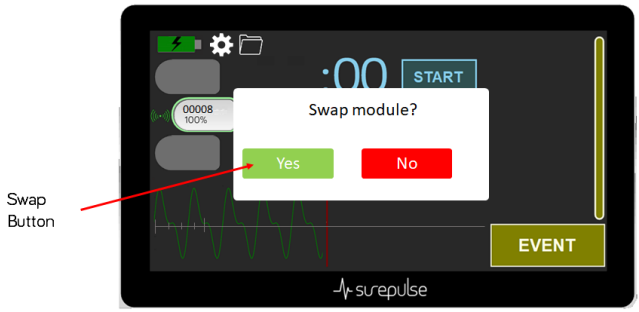

Figure 3-24 *Removing a spare Module during active monitoring brings up the swap box.*

Ending Monitoring

The timer can be stopped by pressing the STOP button, which will replace the START button when the timer is activated. The timer is then reset by pressing the RESET button. Replace the Module back into the Display. The Display can be switched off by holding down the power button on the side of the Display for 2 seconds.

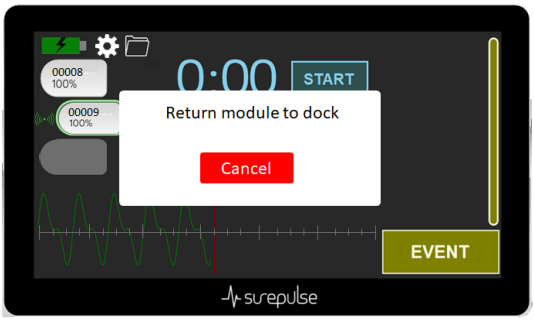

Figure 3-25 *The Display prompts to return the Module after pressing the STOP button.*

Six second timer

This is a useful extra feature designed to support more accurate stethoscope assessments. The red circle on the screen will pulse every six seconds. Having a six second timer allows a user to count the number of heart beats in one full six second period, and multiply the number by 10. This feature is always running and will allow clinical staff to make stethoscope assessments if the VS is not providing heart rate outputs at that time.

Charging and Storage

The VS can be charged by ensuring both Modules are placed into the Display docks, and the 5V AC/DC adaptor is plugged into the side of the Display and turned on at the mains socket.

Display

The Display will indicate using the battery icon when it is being charged by being plugged into the mains (see figure below). The LED at the side of the Display will slowly flash yellow every two seconds. This means that the Display should be left to charge if possible. The LED will turn solid green when fully charged.

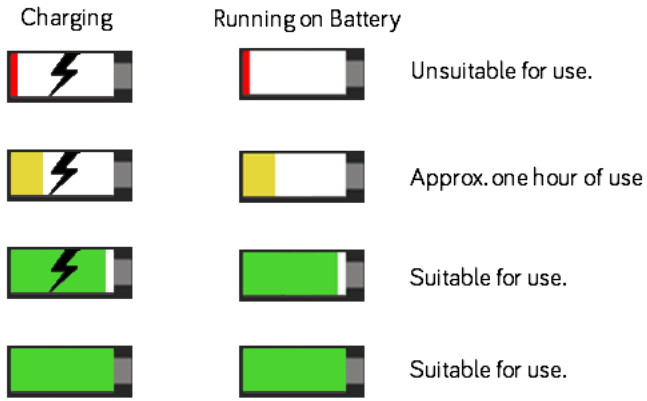

Figure 3-26 *Summary of Display battery states.*

If the mains DC plug is removed, the icon will change to remove the lightning bolt. The battery icon is green when battery percentage is over 40%. At 10% to 40% the battery icon will turn yellow. 40% indicates approximately one hour of use. At 10% or below the battery will turn red and the unit must be charged!

Module

The LED on the Module will slowly flash orange every two seconds when it is charging on the Display dock. This means that the Modules should be left to charge if possible. The LED will turn solid green when fully charged.

The battery indicators for the Modules on the Display screen will also indicate when the Modules are being charged.

The Display will charge the Modules from its own internal battery when the Display is not plugged into the 5V AC/DC adaptor.

Storage

The VS can be stored whilst remaining on charge. This ensures that the system always has full battery. For information, the system knows when the battery is full and disconnects the battery from the charging circuit, so that leaving the system on charge does not decrease the lifetime of the battery adversely.

To store the VS for a longer period of time, disconnect the Modules from the Display, turn the Display off, and place the system in a dry location where the temperature is maintained between 0°C and 40°C. Fully charge the Display and both Modules before use.

CHAPTER 4

System Management

This chapter contains the following sections

Data Management

The VS records heart rate data alongside the events and times. The data file is identified through the start time and date of the recording in the following format:.

Language	Format
English	DD/MM/YYYY HH:MM:SS
Swedish	YYYY-MM-DD HH:MM:SS
French	DD/MM/YYYY HH:MM:SS
German	YYYY-MM-DD HH:MM:SS
Spanish	DD/MM/YYYY HH:MM:SS
Italian	DD/MM/YYYY HH:MM:SS
Danish	DD.MM.YYYY HH:MM:SS
Dutch	DD-MM-YYYY HH:MM:SS
Norwegian	DD.MM.YYYY HH:MM:SS

Insert a USB memory stick into the USB slot on the side of the Display to be able to download data.

When the device is not being used for monitoring, press the Recording Menu icon. The following screen appears.

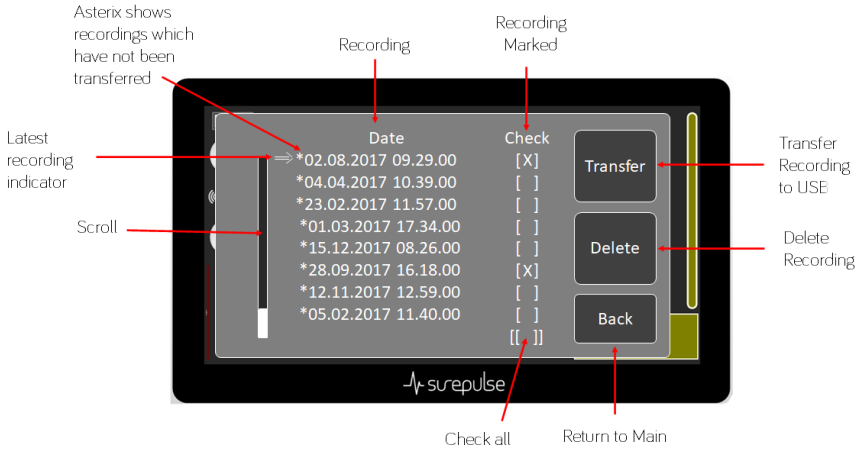

Figure 4-1 *The Recording Menu button brings up a list of recordings of monitoring sessions by date and time. The scroll buttons can be used to scroll through the recordings.*

A recording which has not previously been downloaded has an asterix (*) next to it. Check the relevant boxes and either delete the recording or transfer to USB. It is possible to transfer multiple files at once.

Settings Menu

Press the Settings Menu button to bring up the following screen.

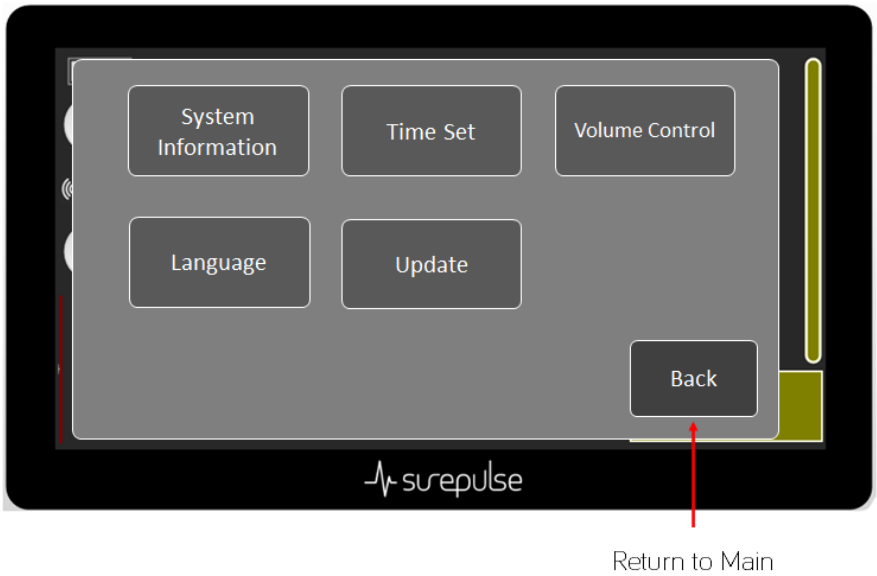

Figure 4-2 *The Settings Menu screen*

Setting the Date/Time

Press the Time Set button. The time set screen appears.

Use the Increase and Decrease buttons to change the time and date, and then press Set to save the changes.

The date format for the chosen language can be found in the Data Management section.

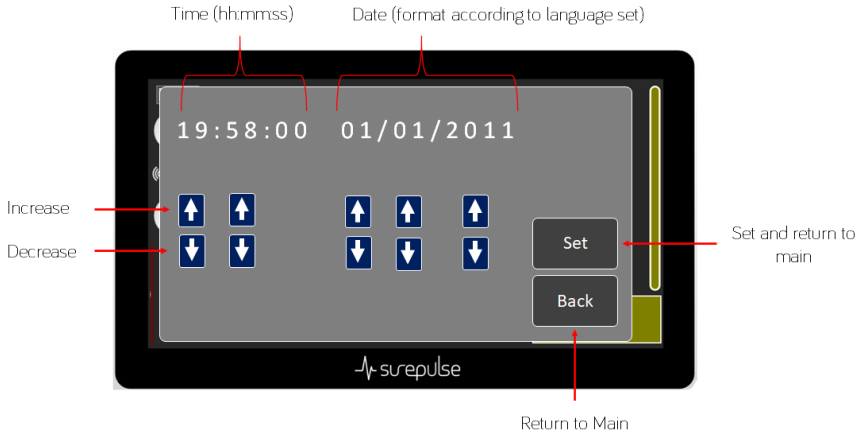

Figure 4-3 *The time and date can be set using this screen.*

Setting the Volume

Press the Volume Control button. The volume control screen appears.

Select the required volume.

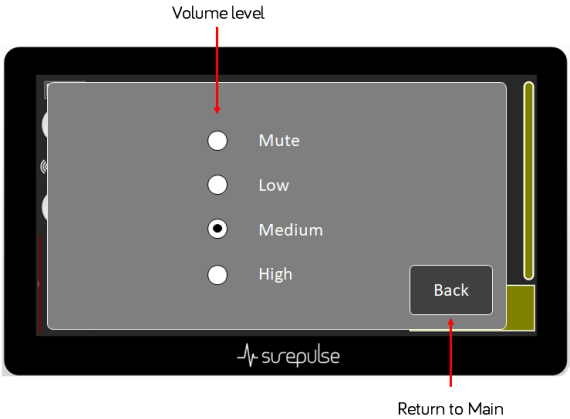

Figure 4-4 *The volume can be set using this screen.*

System Information

Press the System Information button. The system information screen appears.

The version of the Firmware and Hardware in the system can be checked here. The status of the health of the battery can also be verified. The lifetime of the battery is two years. This screen will indicate if the battery life is exceeded and the device is due for service.

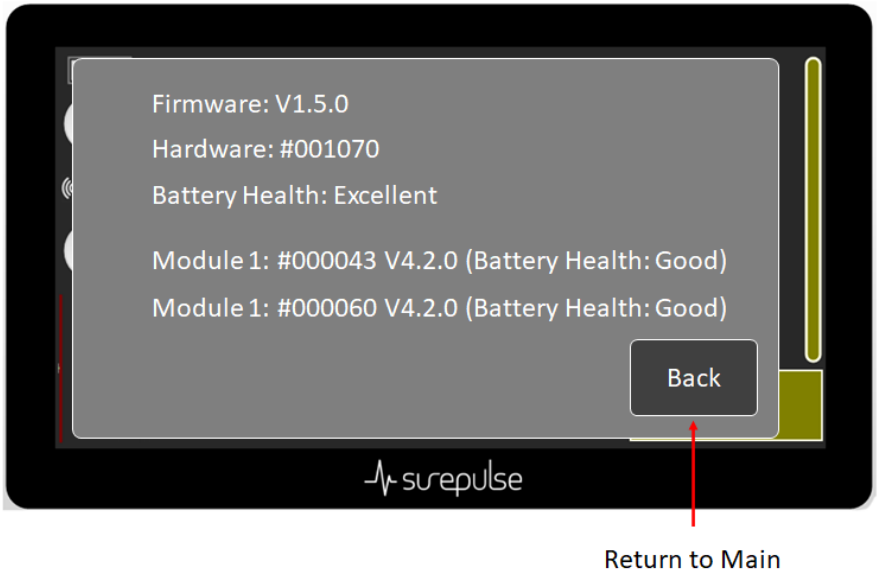

Figure 4-5 *The System Information screen.*

Language

Press the Language button. The language selection screen appears. The language can be set from here.

Update

Please refer to the service manual for instructions on how to update the device firmware.

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CHAPTER 5

Safety

This chapter contains the following sections

Electrical Safety

Warning: The IP rating of the Display is IPX1. Do not immerse the Display in liquid.

Warning: The IP rating of the Module is IP54. Do not immerse the Module in liquid.

Warning: Only connect the 5V AC/DC adaptor into a Mains outlet providing 100-240 V AC.

Warning: Only the Sensor and Module are suitable for use in oxygen rich environments. Do not place the Display in an oxygen rich environment.

Warning: Not suitable for use in the presence of flammable anaesthetics.

Warning: Only use the 5V AC/DC adaptor supplied with the system, or a SurePulse Medical approved alternative.

Warning: Do not cover the 5V AC/DC adaptor whilst plugged into a Mains outlet, or the adaptor may overheat.

Caution: Do not touch the Module pins or the contacts on the Display dock and the patient at the same time.

Caution: Minimise wireless interference by removing other wireless devices from 30 cm vicinity of the Module.

Mains Isolation

Isolation from the electrical Mains is provided by unplugging the 5V AC/DC adaptor from a Mains socket.

USB Port

The USB A port is designed to be connected to a USB memory stick or other portable storage media. It is not intended to be used to connect to other IT equipment.

Caution: Only connect portable storage media to the USB port. Do not connect mains powered equipment to the USB port.

Symbols and Labels

The following symbols can be found on the packaging and device labels.

MD	Medical device signifier
UDI	Unique device identifier
EC REP	EU Authorised Representative
	De-fibrillation proof type-BF applied part
REF	Device part number
	Manufacture date (YYYY-MM-DD)
	Manufacturer

LOT	Batch number
CE	CE mark
	Do not reuse
	Expiry date (YYYY-MM-DD)
	Operational temperature range
	Read operating manual (mandatory action)
SN	Serial number

	Intentional RF radiation
	Class II device
	Dispose of waste electrical and electronic equipment according to WEEE Directive
Rx	Prescription only
IP	Ingress Protection rating

The Data Matrix contains information on the manufacturer, the device part number, manufacturing and expiry date, the lot number and the serial number if applied to the device.

Notices

European Union

Should any serious incident occur in relation to the device, this should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The address of SurePulse Medical Limited's EU Authorised Representative is: Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

United States of America

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

• Increase the separation between the equipment and receiver.

• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

• Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved Surepulse Medical could void the user's authority to operate the equipment

Canada

This device complies with Industry Canada license-exempt RSS standard (s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

CHAPTER 6

Maintenance

This chapter contains the following sections

Cleaning

The Modules and Display should be cleaned after each use to prevent cross-contamination and infection.

Warning: Clean the Module after each use.

Warning: Clean the Display after each use.

The cleaning procedure is as follows: Wipe the Module, Display enclosure and Display touchscreen with a Commercial '70% V/V IPA disinfectant wipe' that has been tested to demonstrate their effectiveness as a surface disinfectant. Use only IPA wipes that have been tested against EN 13697 or EN 16615 which confirms its effectiveness as a surface disinfectant for the safe reduction of bactericidal and fungicidal activity. One such example is the pre-packed IPA wipe provided by SteriClean® called "SteriClean® Individual Wipes – Large (XXTB6725)". Do not use aerosol preparations. Do not pour fluids directly on the unit. If absolutely necessary, scrub with a 70% V/V IPA solution using a soft bristled brush. Do not allow liquid to enter internal parts of the Display or it may damage the unit.

Caution: Ensure any cleaning solutions have evaporated or been wiped off the Modules and Display before use.

The Cap or sensor are not to be cleaned and re-used and should be disposed of as infectious waste according to local procedures.

Display Inspection

The Display should be inspected and tested for continued suitability using the following checklist, in line with local guidelines for electrical equipment maintenance. The checklist may be copied for ease of completing the inspection.

	Check
Usage Date	
Check that the Display is in use within 2 years of issue or last service	
Mechanical	
Check the plastic case works for any sign of damage or cracking	
Check the metal connectors in the docks for any signs of corrosion	
Check the display touchscreen for any signs of cracking or chipping	
Electrical Safety	
With the Power Supply Unit (PSU) disconnected, verify that the central pin of the DC power supply socket is not shorted to the ground connector	
With the Modules disconnected and PSU disconnected, verify that a short circuit does not exist between any two sets of Module pads on the same connector	
Check that the PSU delivers 5 V	
With the Modules disconnected from the docks and 5V AC/DC PSU plugged in to the DC socket, verify that no current >10 uA flows between any two sets of metal pogo pins	
With the Modules disconnected from the docks and 5V AC/DC PSU plugged in to the DC socket, verify that no current >10 uA flows between any part of the enclosure and earth	
With the Modules disconnected from the docks and 5V AC/DC PSU plugged in to the DC socket, verify that no voltage >3 V is present on any metal pads	
If a suitable 5 V power supply with ammeter can be used, the current consumption of the Display with one Module attached should not exceed 1 A, or 1.5 A with two Modules	
Performance	
When plugging in the PSU, the Display screen should indicate that the Display is charging.	

	Check
When plugging a Module into the dock, the Module's LED flashes orange to indicate charging (top dock)	
When plugging a Module into the dock, the Module's LED flashes orange to indicate charging (bottom dock)	
Hygiene	
Clean the Display according to cleaning instructions	
Labelling	
Ensure that all labels are legible and firmly affixed to the caseworks	

PASS YES / NO:

Inspection date:

Inspected by (Name/Institution):

Serial number:

Module Inspection

The Module should be inspected and tested for continued suitability using the following checklist, in line with local guidelines for electrical equipment maintenance. The checklist may be copied for ease of completing the inspection.

	Check
Usage Date	
Check that the Module is still in use within its stated lifetime (two years)	
Mechanical	
Check the plastic case works for any sign of damage or cracking	
Check the metal pogo pin connectors for any signs of corrosion	
Check that the metal pogo pin connectors can move freely up and down in their casing	
Check that the plastic lid is still firmly fitted to the bottom of the Module case	
Electrical Safety	
With the Module disconnected, verify that no current >10 uA flows between any two sets of pogo pins	
With the Module disconnected, verify that no voltage >3 V is present on any pogo pin	
With the Module disconnected, verify that a short circuit does not exist between the ground pogo pin and any other pogo pin	
When the Module is charging, verify that the Module does not get appreciably hot to touch (>40 °C in 25 °C environment)	
Performance	
When placing a partially or fully discharged Module onto charge, the orange LED flashes	
After three or fewer hours on charge, the green LED should be always on to indicate full charge	
After the Module is fully charged and the device removed from the Display and placed into a sensor cradle, the Display should be able to recognise the Module	
Connect the Module into a sensor cradle. Green and Red LEDs should be visibly lit on the sensor head	
The Module, from full charge, should be able to run and continuously transmit data for greater than two hours	
Hygiene	

	Check
Clean the Module according to cleaning instructions	
Labelling	
Ensure that all labels are legible and firmly affixed to the caseworks	

PASS YES / NO:

Inspection date:

Inspected by (Name/Institution):

Serial number:

Returns

There are no user serviceable parts in the VS. In the event of device failure or damage, or failure of the battery to charge, please contact SurePulse Medical Ltd.

If there are suspected changes in the performance of the device, a PPG functional tester may be used to test for correct operation. For details, please contact SurePulse Medical Ltd.

Warning: Do not modify the equipment or patient or user injury may result.

The Cap and Sensor comes into contact with each patient and is designed to be single use only. It does not require servicing.

Regular inspection of the Module and Display is recommended. If these units are found to be damaged (for example, if there are cracks in the plastic caseworks) then it should be returned to SurePulse Medical Ltd.

Returning the Device for Servicing

All parts must be cleaned and stored in original packaging where possible, before being returned. See "Cleaning" on page 83.

Caution: DO NOT return parts that have not been cleaned

To initiate a return, please contact SurePulse Medical by email or phone first (details below) to obtain a Returns Authorisation. Do not send parts back to SurePulse Medical without an authorisation or loss may result. Parts can be returned to SurePulse Medical Ltd at the following address:

SurePulse Medical Ltd

Medicity,

D6 Thane Road,

Nottingham, NG90 6BH, U.K.

Telephone: +44 333 577 1133

Email: **info@SurePulseMedical.com**.

Website: www.SurePulseMedical.com

For shipping via ground services, parts should placed in original packaging where possible. They can be posted via standard mail services.

For shipping via air, parts must be placed in original packaging (conforming to Packaging Instruction 967 Section II and 980 Section II). The air waybill must contain the statement "Lithium ion and metal batteries in compliance with Section II of PI 970 and Section II of PI 967 respectively".

Service Life

The Cap and/or sensor are intended for single use only.

The Module has a service life of two years, based on an average charge and discharge cycle of once per day. After two years of use, contact SurePulse Medical Ltd to arrange a service. Alternatively, if the usage time of a Module is less than two hours after a full charge, please contact SurePulse Medical Ltd for service.

The Display has a service life of at least five years. This is predicated on a service with interval of not less than two years.

Disposal

The single-use Cap and sensor should be disposed of according to local practices for disposal of infectious waste.

The Modules and Display should be disposed of according to the WEEE directive. They can alternatively be sent back to SurePulse Medical Limited by following instructions in the Returns section and marking them for disposal.

CHAPTER 7

Specifications

This chapter contains the following sections

Device Specifications

Measurements	
Pulse Rate Accuracy*	+/- 5 bpm
Display Pulse Rate Refresh Rate	Every 5 s
Pulse Rate Range	25 bpm to 240 bpm
Pulse Rate Averaging	Single 5 s window
Wavelengths	530 nm, 660 nm, 940 nm
Maximum Average Output Power	0.42 mW, 0.32 mW, 0.26 mW
Data Storage	128 MB
Battery Life	
Module (each)	2 hours
Display	4 hours
Mains Adaptor	UK mains adaptor VEP15US05 Input: 100-240 V, 50-60 Hz Output: DC 5 V 2 A
Dimensions	
Module	5 cm x 2.5 cm x 1.2 cm
Display	26.5 cm x 13.8 cm x 4.5 cm
Weight	
Module	20 g
Display	754 g

Cap Sizes	Extra Small Small Medium Large Extra Large
Operating Temperature	0°C to +40°C
Storage Temperature	0°C to +40°C
Operating Humidity	5% to 95% non-condensing
Operating Pressure	500 mbar to 1060 mbar
Ingress Protection Module Display Sensor	 IP54 IPX1 IPX1
Standards	BS EN 60601-1: 2006 BS EN ISO 10993:2009 BS EN 62471:2008
Directives	Medical Device Directive 93/42/EEC Radio Equipment Directive 2014/53/EU RoHS Directive 2011/65/EU WEEE Directive 2012/19/EU
EMC Compliance	BS EN 60601-1-2:2015 Class A Non-life supporting immunity test levels applied

Service Life VS System VS Cap VS Sensor	 5 years (service not more than every 2 years) Single-use only Single use only
Wireless Interface USA FCC ID Industry Canada Certification Number	2.4 GHz Class II ISM T9J - RN42 6514A - RN42
Data Interface	USB A
Language	English
Manufacturer	Surepulse Medical Ltd Medicity, D6 Thane Road Nottingham, NG90 6BH, U.K.
EU Notified Body	Polish Centre for Testing and Certification; Number 1434
EU Authorised Representative	Advena Limited, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

*Pulse Rate Accuracy has been determined both on newborn babies in comparison with an ECG machine and by using an electronic pulse simulator.

Electromagnetic Compliance

This section contains information required by EN 60601-1-2:2015.

The only power supply adaptor and cable suitable for use with the SurePulse VS is the mains adaptor by XP POWER (part number VEP15US05) fitted with a Wurth Elektronik Split Core Ferrite (part number 74271112). The ferrite should be fitted 10 cm from the DC plug. These are both supplied by SurePulse as part of the SurePulse VS system.

Warning: The use of accessories, transducers, cables and parts other than those specified or supplied directly by SurePulse, may result in increased emissions or decreased immunity.

Warning: The SurePulse VS should be observed to verify normal operation when placed in the configuration in which it will be used.

The essential performance of the device is operation within specified pulse rate limits (+/- 5 bpm) or indication of abnormal operation.

Guidance and Manufacturers Declaration - Electromagnetic Emissions		
The SurePulse VS is intended for use in the electromagnetic environment specified below. The customer or the user of the SurePulse VS should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The SurePulse VS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SurePulse VS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturers Declaration - Electromagnetic Immunity			
The SurePulse VS is intended for use in the electromagnetic environment specified below. The customer or the user of the SurePulse VS 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	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 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%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, shorts interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SurePulse VS requires continued operation during power mains interruptions, it is recommended that the SurePulse VS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturers Declaration - Electromagnetic Immunity			
The SurePulse VS is intended for use in the electromagnetic environment specified below. The customer or the user of the SurePulse VS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 V	Portable and mobile RF communications equipment should be used no closer to any part of the SurePulse VS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	**Recommended separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ **80 MHz to 800 MHz** $d = 2.3\sqrt{p}$ **800 MHz to 2.5 GHz** 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 SurePulse VS is used exceeds the applicable RF compliance level above, the SurePulse VS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SurePulse VS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SurePulse VS			
The SurePulse VS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SurePulse VS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SurePulse VS 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		
	150 KHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

Test specifications for enclosure port immunity to RF wireless communications equipment (Table 9 in BS EN 60601-1-2:2015 IEC:2014). The SurePulse VS has been tested to the levels specified below.						
Test frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Maximum power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	28

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