



VS Newborn Heart Rate Monitor
Operating Manual

Copyright 2017 Surepulse Medical Ltd. All rights reserved.

Information in this document is subject to change without notice. Any software described in this document is furnished under a license agreement or nondisclosure agreement. The software may be used or copied only in accordance with the terms of those agreements. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or any means electronic or mechanical, including photocopying and recording for any purpose other than the purchaser's personal use without the written permission of SurePulse Medical Ltd.



Surepulse Medical Ltd
St Thomas House, Mansfield Road
Derby, DE1 3TN, U.K.
Phone +44 1332 547 100

Document number: QMS-NB-TF-0007

Document version: 3.0

Date of issue: 11th December 2017



0843



CONTENTS

CHAPTER 1

Welcome	5
Purpose	6
Intended Use	7
Conventions	9
System Overview	10

CHAPTER 2

Installation	15
Box Contents	16
Setting Up	17

CHAPTER 3

System Usage	21
Device Application	22
Touchscreen Interface	42
Charging and Storage	59

CHAPTER 4

System Management	63
Data Management	64
Settings Menu	66

CHAPTER 5

Safety	71
Electrical Safety	72
Symbols and Labels	74

CHAPTER 6

Maintenance	79
Cleaning	80
Display Inspection	81
Module Inspection	83
Returns	85
Service Life	87

CHAPTER 7

Specifications	89
Device Specifications	90

INDEX	93
-------------	----

CHAPTER 1

Welcome

This chapter contains the following sections

Purpose	6
Intended Use	7
Conventions	9
System Overview	10

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.

Scope

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 integrated into a soft Cap placed on the head of the newborn baby such that the sensor contacts the forehead of the baby. 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 with integrated sensor is a single-use accessory. 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 attachments for intubation 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 cap mounted PPG device has been designed to measure heart rate of new born 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.

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 is comprised of three main components:

1. Cap incorporating optical sensor (single-use only)
2. Modules (x2)
3. Display with 5V AC/DC power supply unit

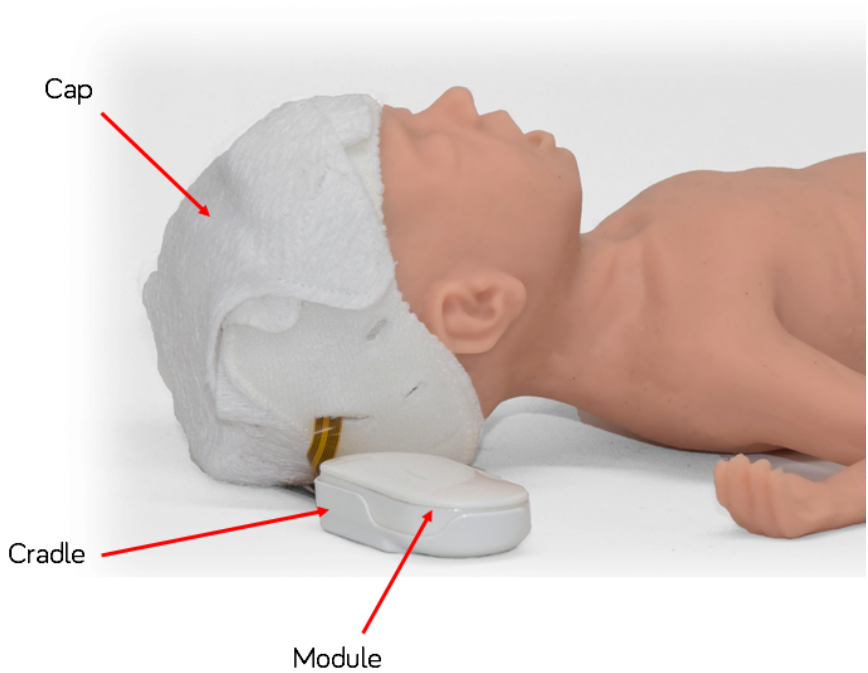


Figure 1-1 Cap incorporating optical sensor. The Module is mounted into the Cradle at the side of the Cap.



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

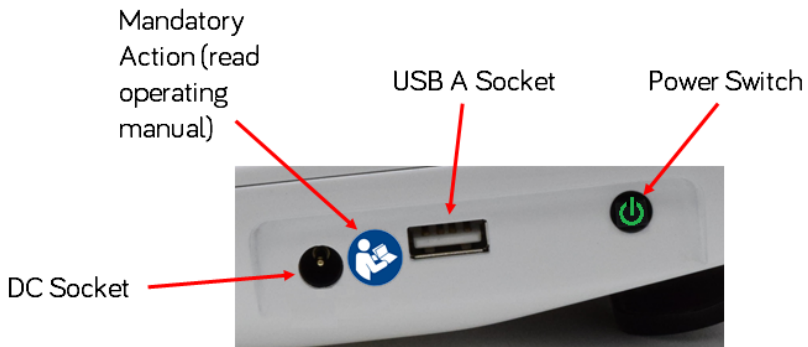


Figure 1-3 Side of the Display. There is a socket for the supplied 5V AC/DC power supply unit, a USB A socket, and a power switch with indicator LED.

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.

CHAPTER 2

Installation

This chapter contains the following sections

Box Contents	16
Setting Up	17

Box Contents

System Box

The system box contains the following items:

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

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.

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 81 and "Module Inspection" on page 83 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.

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 using 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 42).

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 Cap cradle. The signal trace should activate. Move the Module and Cap 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.

This page intentionally left blank.

CHAPTER 3

System Usage

This chapter contains the following sections

Device Application	22
Touchscreen Interface	42
Charging and Storage	59

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

The device is intended to be used on newborn babies with head circumference 20 to 40 cm. It is designed to be applied to the head of the baby only using the supplied Caps.

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 is intended to be used for single patient use only. If a Cap 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. The Caps are for single patient use only.

The Sensor integrated in the Cap should be applied for a maximum of four hours to prevent tissue damage.

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.

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 81 and "Module Inspection" on page 83.

Selecting a Cap Size

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

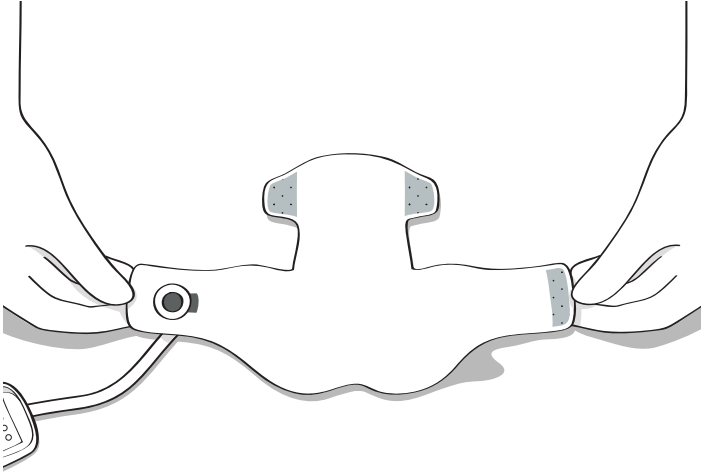


Figure 3-1 *Unpack the Cap from the packaging and lay it out flat. Remove the separate CPAP strap.*

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

This section illustrates how to apply the Cap to the head of a newborn baby.

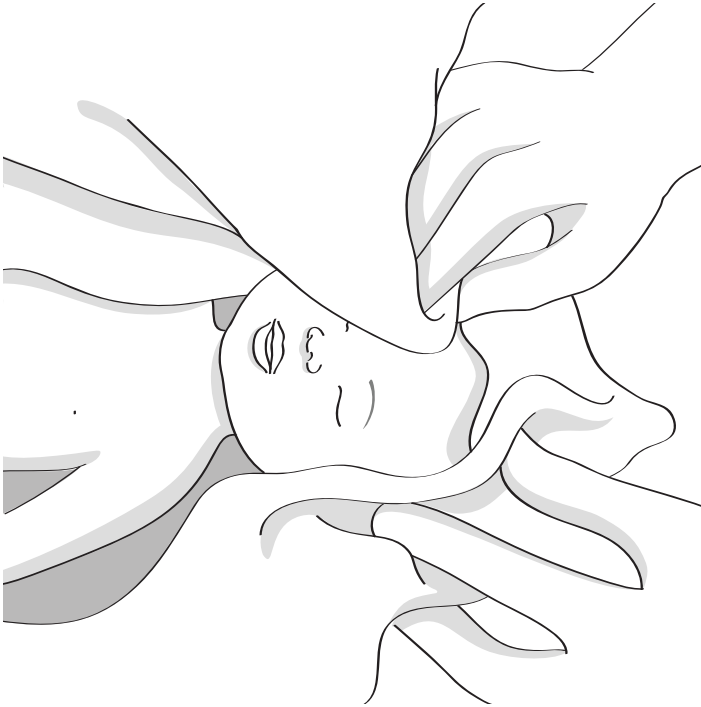


Figure 3-2 When the baby is born, dry and wipe the head.

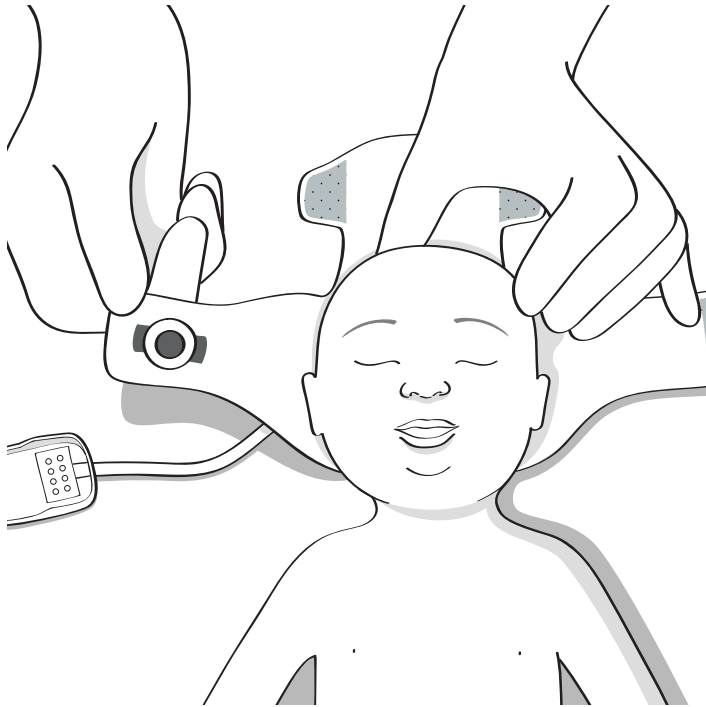


Figure 3-3 Place the baby on the folded out Cap so that the back of the head is placed on the central portion.

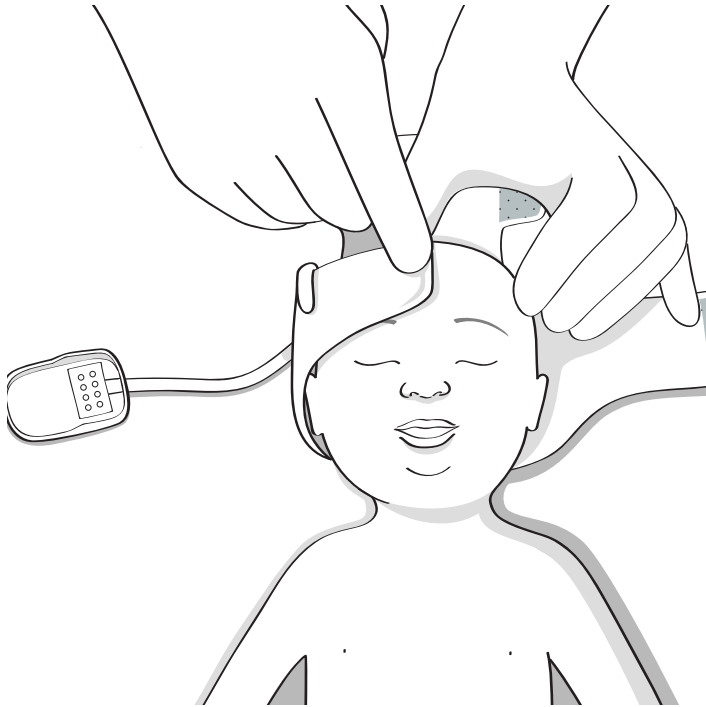


Figure 3-4 *Fold the flap containing the Sensor (the right hand side if standing at the head end of the baby) over the baby's forehead so that the Sensor contacts the area just above the right eyebrow of the baby. The Caps are marked with the sensor location to facilitate correct location. Hold the flap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

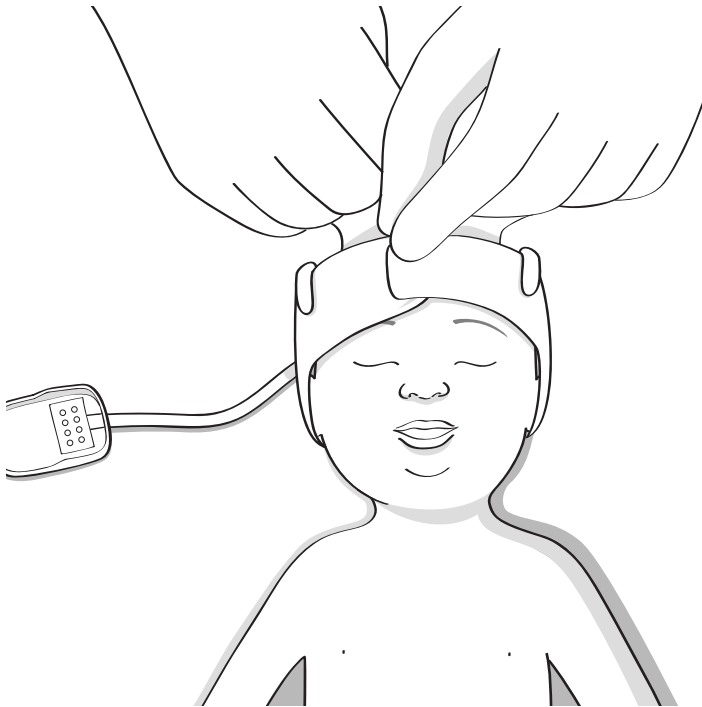


Figure 3-5 *Fold the opposite flap over the forehead and attach to the first flap using the Velcro attachment. The Cap should be secure but comfortable for the baby. If the Cap is too tight then the blood supply to the forehead can be impaired.*



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

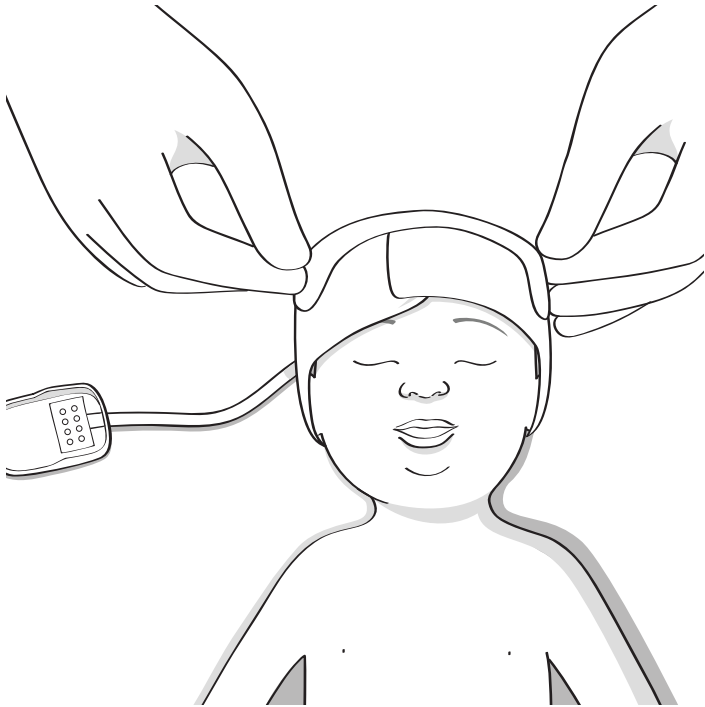


Figure 3-7 Use the two Velcro tabs of the top flap to secure it to the side flaps on the forehead of the baby. The Cap is now attached to the baby.

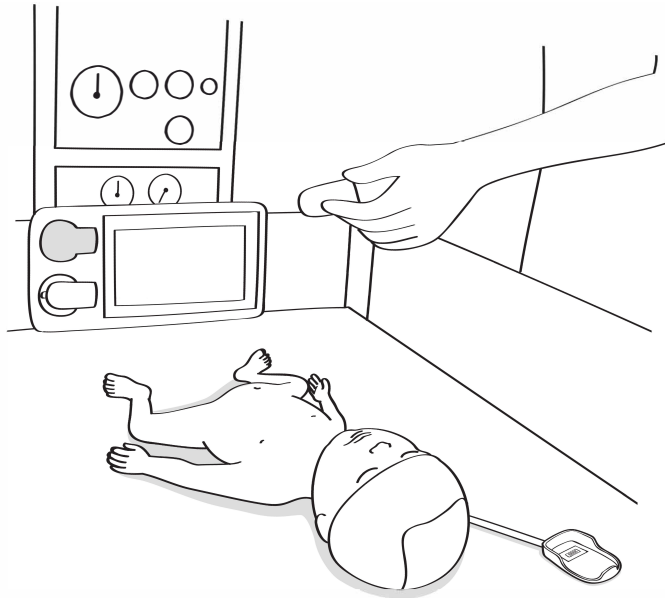


Figure 3-8 *If not already completed, remove one Module from the Display Dock.*

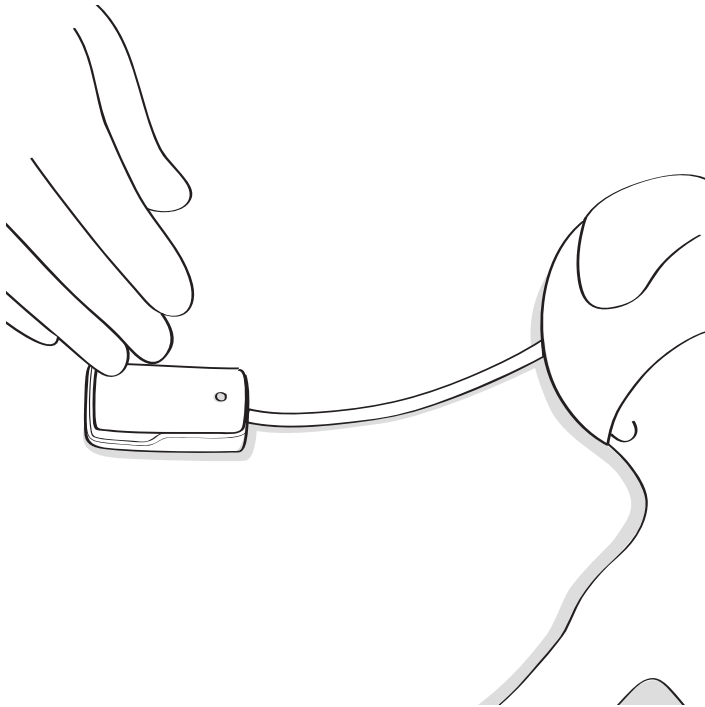


Figure 3-9 Place the Module into the Cap Cradle. The screen on the Display should indicate a connection and a signal trace should appear. The Display will indicate if there is any fault.

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

Breathing Apparatus

Either intubation 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 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.

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

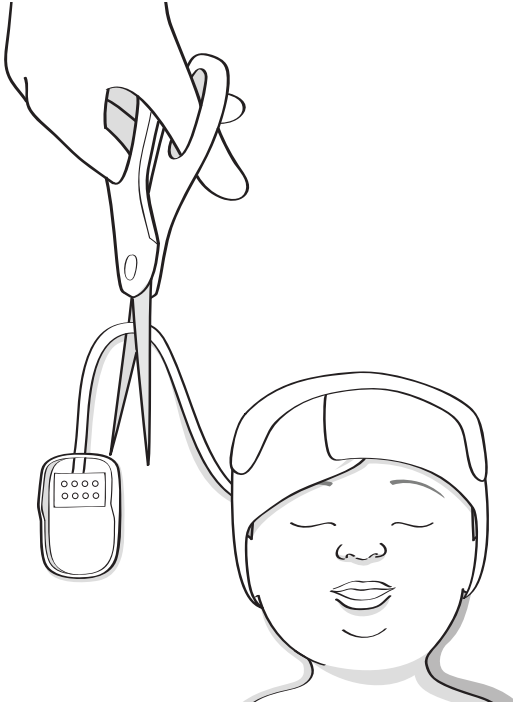


Figure 3-10 Using a pair of scissors, cut the flat cable connecting the Cradle to the Sensor in the Cap.



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.

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.

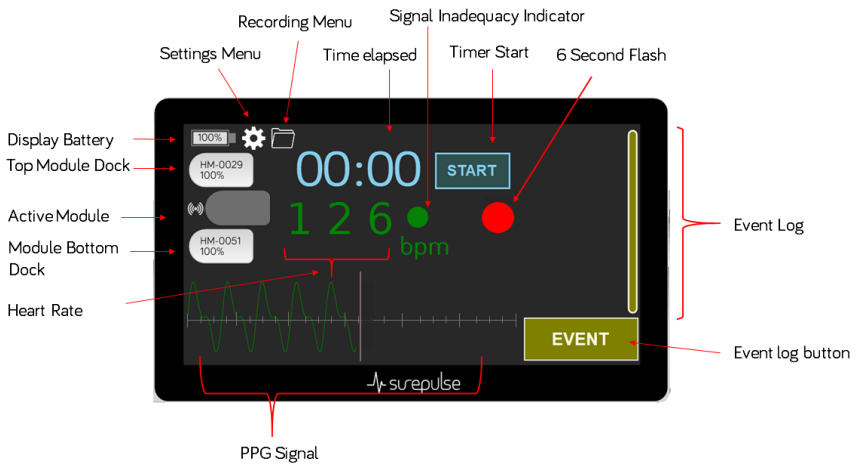


Figure 3-13 The main screen of the device.

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 Modules statuses.

Initiating Monitoring

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

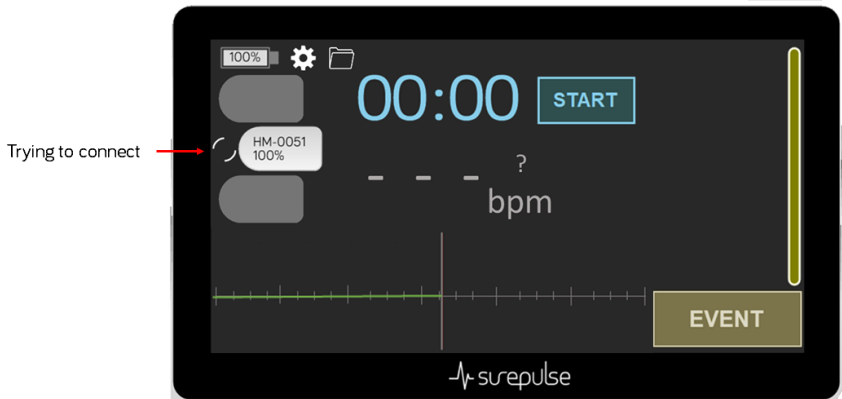


Figure 3-14 *When the Module is removed from the Display, it will become the Active Module and will try and connect wirelessly to the Display.*

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.

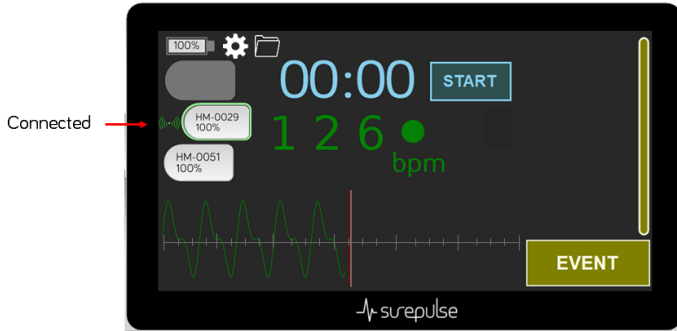


Figure 3-15 The Active Module is connected successfully.



Figure 3-16 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. Place the Cap on the baby (as per "Device Application " on page 22) if not already positioned.

If the Cap is correctly positioned then the sensor 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.

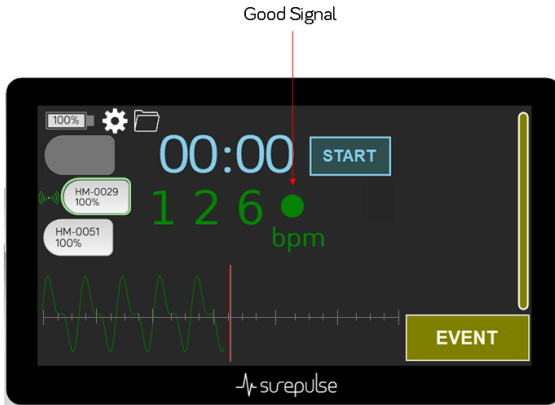


Figure 3-17 *If the trace is of adequate signal quality, then the heart rate (represented by the green BPM figure) will be updated every 5 seconds and the Signal Inadequacy Indicator will show a green filled circle.*

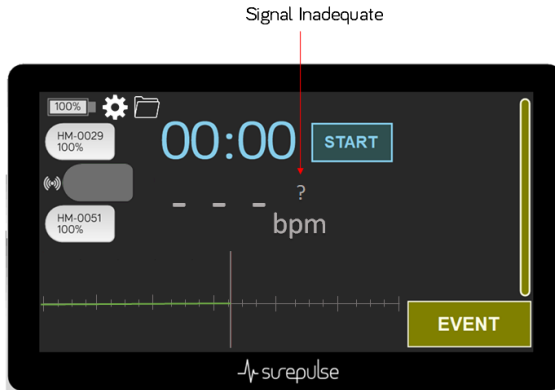


Figure 3-18 *If the signal is inadequate to calculate a heart rate, then a "?" (question mark) symbol will appear on the screen.*

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 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.

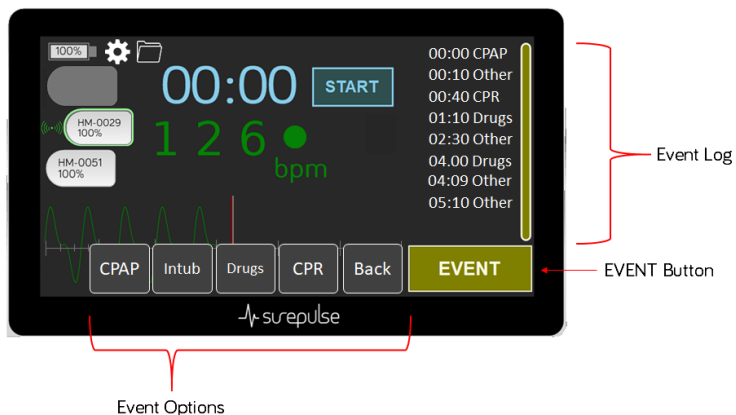


Figure 3-19 Pressing the **EVENT** button brings up a list of possible events to record. Press the desired event button and it will be added to the "Event Logged" list along with the elapsed time. Pressing "Back" closes the Event options list. If the **EVENT** button is pressed twice in succession, it 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	NO	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 10%	YES	No change	RED	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
Low Memory	Available space less than 2 hours of recording	YES	No change	NO	NO	Delete some recordings to clear space

Alarm Title	Alarm Condition	Screen Display	Display LED	Module LED	Audible	Recommended User Action
Wireless Dis-connection	Active Module wireless connection temporarily drops	YES	No change	GREEN FLASH (1 s)	YES	Wait for automatic reconnection attempt
Wireless Con-nection Failed	Active Module wireless connection drops for greater than 30 seconds	YES	No change	YELLOW FLASH (1 s)	YES	Swap Module with spare Module
General Tech-nical Error (Display)	Internal fault with hard-ware	YES	RED	No change	YES	Discontinue use of the system
General Tech-nical Error (Module)	Internal fault with hard-ware	NO	No change	RED	NO	Swap Module with spare Module. Dis-continue use of faulty Module
Over tem-perature (Dis-play)	Display internal tem-perature greater than 49°C	YES	No change	No change	NO	Move Display to cooler area, disconnect from 5V AC/DC Adaptor
Over tem-perature (Mod-ule)	Module internal tem-perature greater than 49°C	YES	No change	YELLOW	NO	Move Module to cooler area, remove Module from Display dock

Alarm Title	Alarm Condition	Screen Display	Display LED	Module LED	Audible	Recommended User Action
Sensor Detection Fail	Module plugs into Cap cradle and sensor hardware test fails	YES	No change	RED rapid flash	NO	Try reseating Module in Cradle, or Replace Cap with different Cap

All alarm priorities are low as defined in standard IEC 60601-1-8 2007. 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 Cap Cradle and the Display is receiving data.

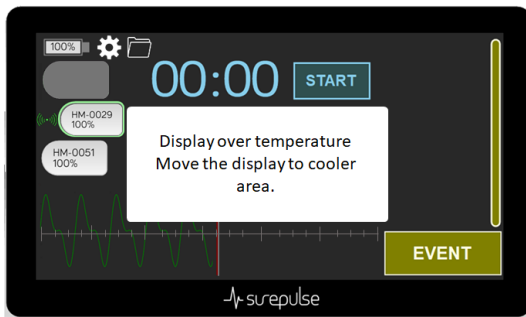


Figure 3-20 If the Display is over temperature, then a prompt will appear. Move the Display to a cooler location.

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



Figure 3-21 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 Cap cradle and place the spare Module into the Cap cradle. The monitoring will continue.
5. Put the old Module into the Display dock.

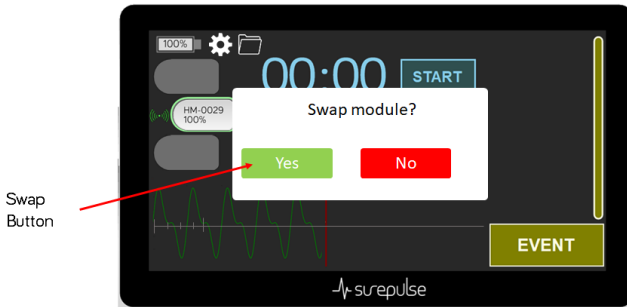


Figure 3-22 *Removing a spare Module during active monitoring brings up the swap box.*

Ending Monitoring

The timer can be stopped by pressing the STOP button, which will replace the START button when the timer is activated. 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.

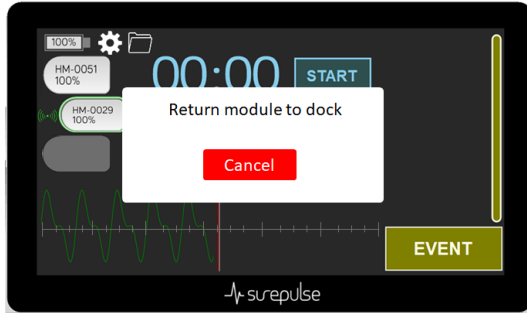


Figure 3-23 *The Display prompts to return the Module after pressing the STOP button.*

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.

The Display will indicate using the battery icon when it is being charged by being plugged into the mains (see Figures 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 3-24 *This icon will show when the Display is plugged into the mains via the DC plug.*

If the mains DC plug is removed, the icon will change to show the percentage charge.

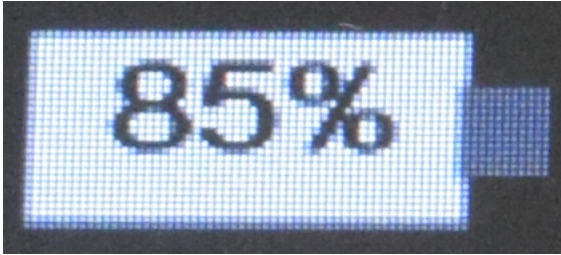


Figure 3-25 The percentage charge will show when the Display is running on its internal battery.

The LED on the Module will slowly flash yellow 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.

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.

This page intentionally left blank.

CHAPTER 4

System Management

This chapter contains the following sections

Data Management	64
Settings Menu	66

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 format 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.

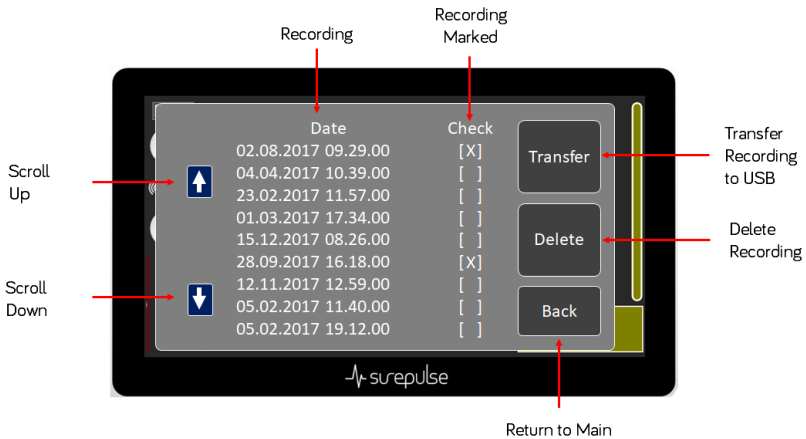


Figure 4-1 *The Recording Menu button brings up a list of recordings of monitoring sessions by date and time. The scroll buttons can be used to scroll through the recordings.*

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.

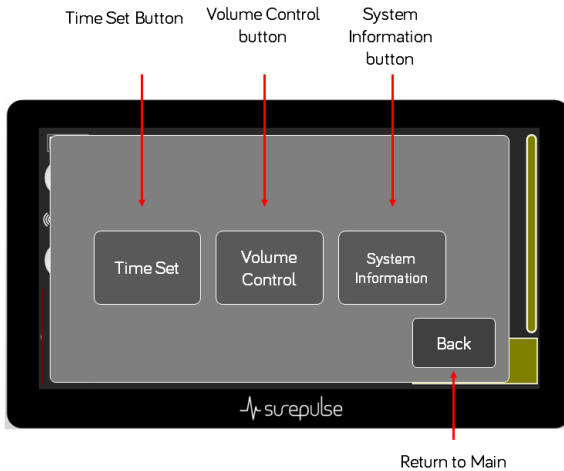


Figure 4-2 The Settings Menu screen

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.

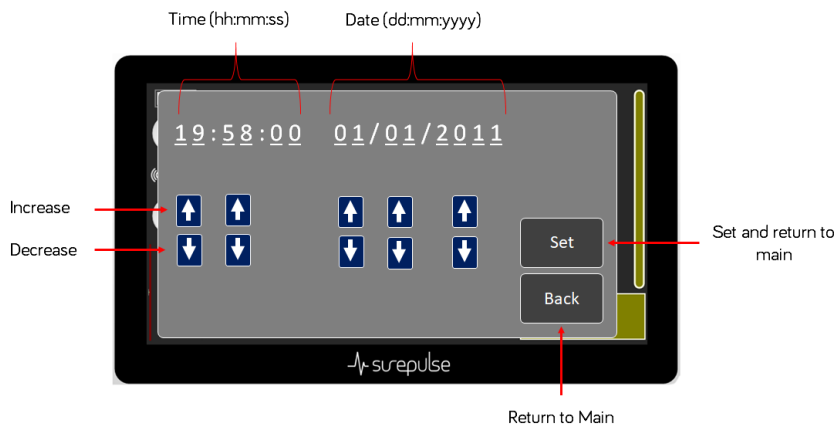


Figure 4-3 The time and date can be set using this screen.

Setting the Volume

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

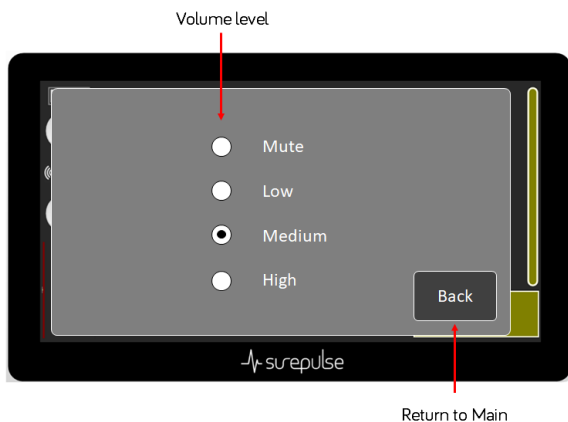


Figure 4-4 The volume can be set using this screen.

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 life-time of the battery is two years. This screen will indicate if the battery life is exceeded and the device is due for service.

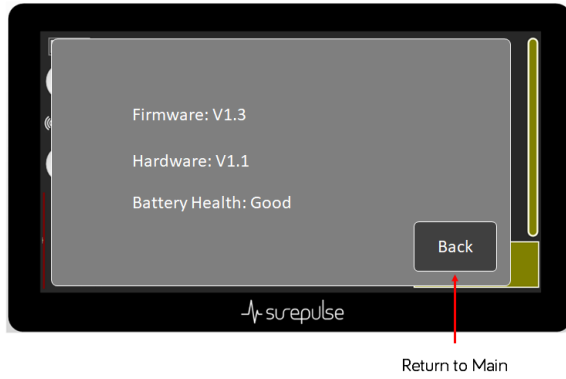


Figure 4-5 *The System Information screen.*

This page intentionally left blank.

CHAPTER 5

Safety

This chapter contains the following sections

Electrical Safety	72
Symbols and Labels	74

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 Cap 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.

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

Cap Packaging

The label for the Cap will be placed on the outside of the packaging of the individually packaged Caps.

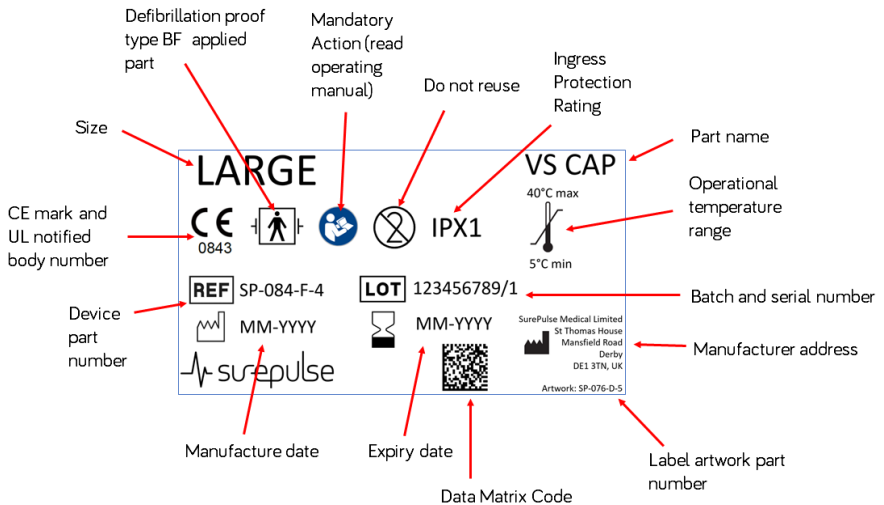


Figure 5-1 The label for the Caps.

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

Module label

The label for the Module will be placed on the underside of the Module unit.

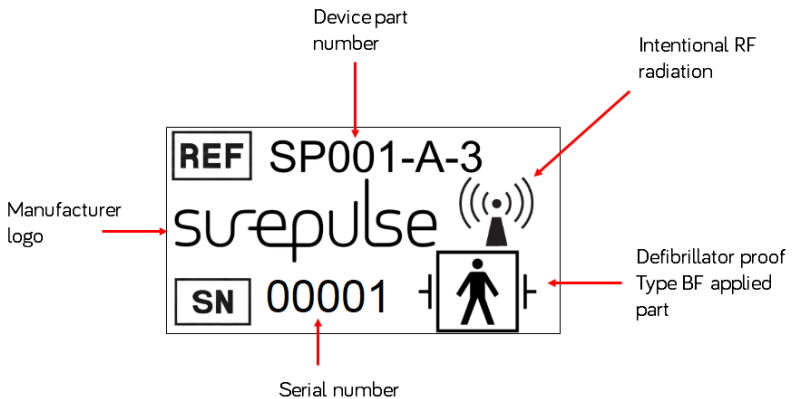


Figure 5-2 The label for the Module.

The IP rating of the Module is IP54 (not shown on the label) according to IEC 60529. This means it offers protection against dust ingress and water splashes from all directions.

Display labels

The labels for the Display will be placed on the back of the Display.

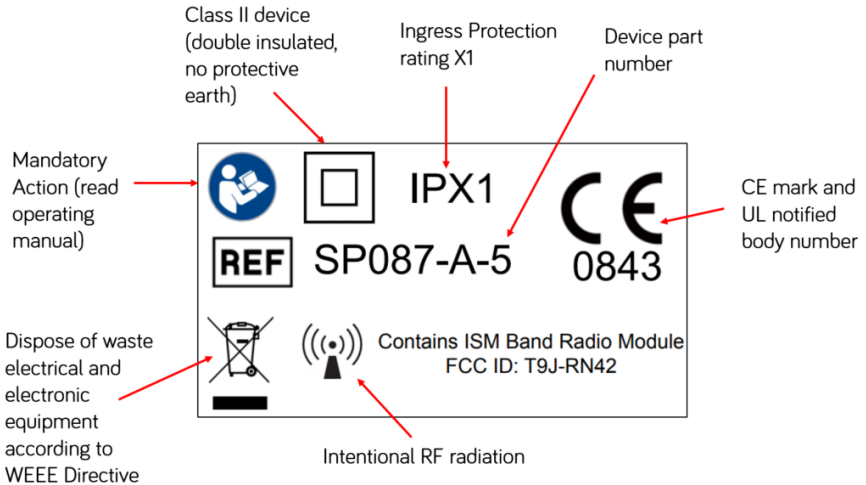


Figure 5-3 *The label for the Display referring to safety and other aspects.*

The IP classification of the Display (IPX1) means that it offers protection against vertically falling drops when the equipment is placed in its normal position.

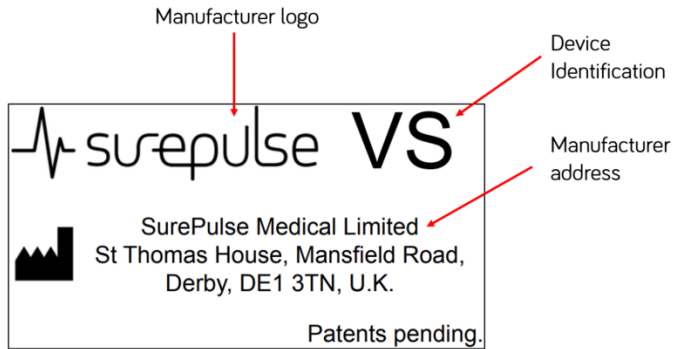


Figure 5-4 *The label for the Display referring to manufacturer contact information.*

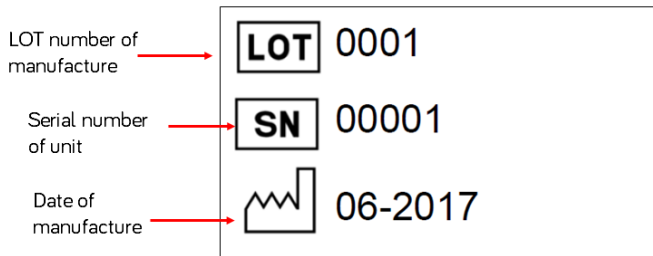


Figure 5-5 *The label for the Display referring to manufacturing information.*

Side label on Display

The mandatory action symbol for requiring the user to read the operating manual is placed on the side of the Display next to the USB A port and DC socket.

CHAPTER 6

Maintenance

This chapter contains the following sections

Cleaning	80
Display Inspection	81
Module Inspection	83
Returns	85
Service Life	87

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 equipment with a soft, non-abrasive cloth, or disposable wipe, that is soaked in aqueous detergent/disinfectant, or other solution such as 70% isopropyl alcohol (99.999% kill rate, or kill log 5 equivalent). Prepare any detergent according to the manufacturer's recommendations. If necessary, scrub with the solution using a soft bristled brush. Do not use aerosol preparations. Do not pour fluids directly on the unit and its accessories. 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 is 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.	
When plugging a Module into the dock, the Module's LED flashes yellow to indicate charging (top dock)	

	Check
When plugging a Module into the dock, the Module's LED flashes yellow 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 yellow 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 Cap cradle, the Display should be able to recognise the Module	
Connect the Module into a Cap with sensor attached. 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	

		Check
Hygiene		
	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 or its accessories. In the event of device/accessory 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 80.

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

St Thomas House,

Mansfield Road,

Derby, DE1 3TN, U.K.

Telephone: 01332547100

Email: info@SurePulseMedical.com.

Website: www.SurePulseMedical.com

For shipping via ground services, parts should be 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 is 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, please return to the manufacturer (SurePulse Medical Ltd) for service. Alternatively, if the usage time of a Module is less than two hours after a full charge, please return to the manufacturer 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.

This page intentionally left blank.

CHAPTER 7

Specifications

This chapter contains the following sections

Device Specifications	90
-----------------------------	----

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	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	+5°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	IP54
Display	IPX1
Cap (Sensor)	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
Service Life	
Module	2 years
Display	5 years (battery replacement every 2 years)
Cap	Single-use only
Wireless Interface	2.4 GHz Class II ISM

Data Interface	USB A
Language	English
Manufacturer	Surepulse Medical Ltd St Thomas House, Mansfield Road Derby, DE1 3TN, U.K.
Notified Body	UL International (UK) Ltd; Number 0843

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

INDEX

A

Application [22](#)

C

Cap [22](#)

Charging [59](#)

Cleaning [80](#)

Contents [16](#)

Contraindications
[8](#)

Conventions [9](#)

D

Data [64](#)

Date [66](#)

Display [22, 42, 81](#)

Disposal [87](#)

Download [64](#)

E

Electrical [72](#)

I

Inspection [81, 83](#)

Installation [16](#)

Intended Use [7](#)

Interface [42](#)

Isolation [73](#)

L

Labels [74](#)

M

Maintenance [80](#)

Menu [66](#)

Module [22](#), [42](#), [83](#)

O

Overview [10](#)

Oxygen [72](#)

P

Purpose [6](#)

R

Returns [85](#)

S

Safety [72](#)

Service Life [87](#)

Setting Up [17](#)

Size [24](#)

Specifications [90](#)

Status [66](#)

Storage [59](#)

Symbols [74](#)

System [10](#)

T

Time [66](#)

Touchscreen [42](#), [64](#), [66](#)

U

USB [64](#), [73](#)

V

Volume [66](#)

