User's Manual

LiDCO Rapid

Fluid management just got easier

LiDCO™

LiDCO Cardiac Sensor Systems

www.lidco.com

Version 1.04

Manufactured by:
LiDCO Ltd
16 Orsman Road
London N1 5QJ UK

LiDCO*rapid* User's Manual
Software V1.04

This device is covered by one or more of the following patents:
US Pat 006071244; WO9724982; other patents applied for.

This device bears the CE mark in accordance with the provisions of the Directive 93/42/EEC of June 14, 1993, concerning medical devices.

CE 0120

Caution: (USA) Federal Law restricts this device to sale by or on the order of a physician.

All LiDCO devices are intended for use by qualified medical personnel only.

Carefully read all manuals that are provided with your device before use.

Printed in the Untied Kingdom.

This device is subject to the EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment. LiDCO Ltd has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact your local LiDCO Ltd organization.

Safety and Maintenance

1. Read these safety instructions carefully.
2. Keep this User's Manual for later reference.
3. All cautions and warnings on the equipment should be noted.
4. Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
5. Use only the power supply unit supplied with the equipment.
6. Use only the correct adapter for the power supply unit to suit the power source.
7. The power outlet socket must be located near the monitor and must be easily accessible. Position the power cord so that people cannot step on it. Do not place anything over the power cord.
8. Disconnect this equipment from any AC outlet before cleaning. Use a damp cloth. Do not use liquid or spray detergents for cleaning.
9. Keep this equipment away from humidity.
10. Never pour any liquid into an opening. This may cause fire or electrical shock.
11. The openings on the enclosure are for air convection. Protect the equipment from overheating. DO NOT COVER THE OPENINGS.
12. Put this monitor on a reliable surface during installation. Dropping it or letting it fall may cause damage. The monitor should be mounted on the LiDCO desktop stand, or a dedicated roll stand, or an engineered support to provide stability during use. Follow the instructions supplied with the mounting arrangement to ensure correct fitting.
13. If the equipment is not used for a long time, disconnect the monitor and the power supply unit from the power source to avoid damage by transient over-voltage.
14. Never open the equipment. For safety reasons, the equipment should be opened only by qualified service personnel.
15. If one of the following situations arises, get the equipment checked by service personnel:
    a. The power cord, or power supply unit, or other cable is damaged.
    b. Liquid has penetrated into the equipment.
    c. The equipment has been exposed to moisture.
    d. The system does not work well, or you cannot get it to work according to the User's Manual.
    e. The equipment has been dropped and damaged.
    f. The equipment has obvious signs of breakage.

16. DO NOT LEAVE THIS EQUIPMENT IN AN UNCONTROLLED ENVIRONMENT WHERE THE STORAGE TEMPERATURE IS BELOW -20° C (-4° F) OR ABOVE 60° C (140° F). THIS MAY DAMAGE THE EQUIPMENT.

The sound pressure level at the operator's position according to IEC 704-1:1982 is no more than 70dB(A).

Although compliant with the applicable EMC requirements this equipment may still be affected by, and may still affect other equipment. If interference is occurring, the user is encouraged to try to correct the interference by one of the following measures:

- Repositioning either equipment to reorient and/or increase the separation between the equipments
- Connect the equipment to a power outlet on a circuit different from that to which the other equipment is connected
- Consult an experienced technician for help.

Table Of Contents

1.0 Introduction

The LiDCO*rapid* is a minimally invasive hemodyamic monitor that derives nominal stroke volume and heart rate from the patient's existing arterial pressure waveform using the PulseCO algorithm. The display is designed into a single screen for ease of viewing and decision making.

The LiDCO*rapid* helps to optimally deliver goal directed management (GDM) strategies using its patented and clinically validated PulseCO algorithm. It was developed for the acute care physician to get immediate feedback on a patient's fluid and hemodynamic status.

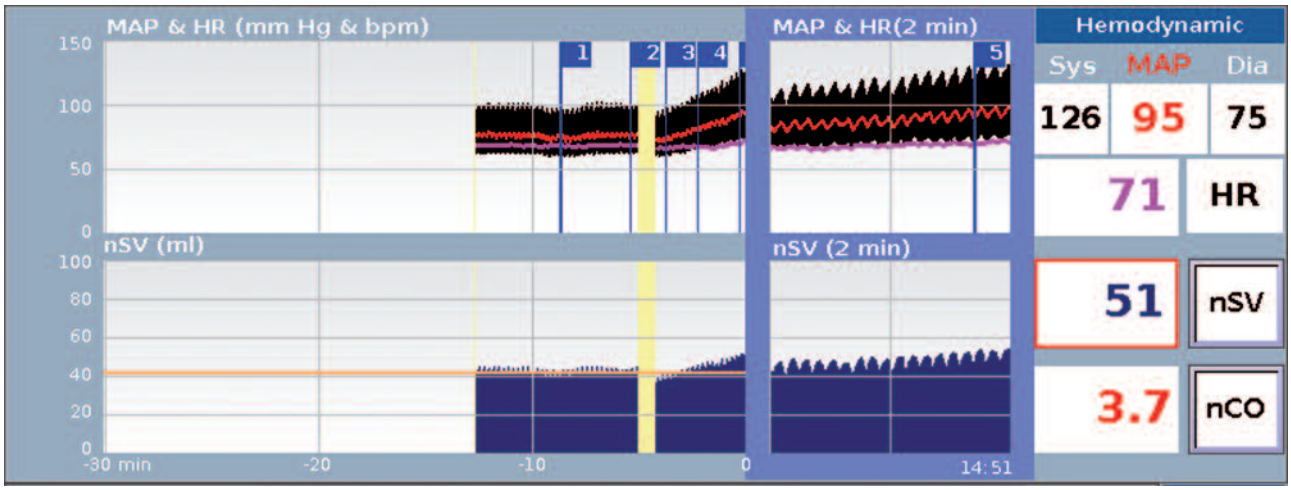
- The LiDCO*rapid* monitor is designed to be simple to interpret, quick to set-up and an effective way of managing the hemodynamics of surgical or any hemodynamically unstable patient requiring fluid and drug support.
- The LiDCO*rapid* is designed to be used by a physician or nurse to detect potentially deleterious changes in the hemodynamic status of the patient and then helps the user choose, use, and monitor the response of the patient to the therapeutic intervention.
- The LiDCO*rapid* is the first hemodynamic monitor specifically designed for use in the highly demanding conditions encountered in the operative room. The product's continuously available, beat-to-beat hemodynamic data will facilitate the use of enhanced fluid and drug based surgical optimization programs in a substantial number of the patients undergoing moderate and high-risk surgical procedures. This form of advanced care has been previously demonstrated to reduce complications and hospital length of stay.[1]

1.1 Standard Hemodynamic Monitoring

The LiDCO*rapid* is a combination of both standard and functional hemodynamic monitoring.

The standard monitoring portion is comprised of two trend display periods and associated numeric values of hemodynamic parameters. The parameters are combined in a natural grouping to facilitate ease of interpretation. The upper trend shows the Blood Pressure (Systolic, Mean and Diastolic) with the Heart Rate. The lower trend is normally set to display Stroke Volume. This can be configured to display Cardiac Output or Systemic Vascular Resistance instead. The values displayed in the lower trend are nominal unless the monitor is calibrated with a known value for Cardiac Output.

The two display periods are designed to show both an acute change and the full procedure. The acute change portion is shown to the left of the numeric display and is set to a fixed scale of 2 minutes. This provides an early warning of significant changes in the displayed parameters so that appropriate action can be taken. The full procedure trend is shown to the left of the acute change. This window will display all data and automatically rescale the time axis as more data is collected (maximum window size is 8hrs). The full procedure trend provides a complete picture of changes and is useful in examining long term increases or decreases as well as change from start for the hemodynamic parameters.

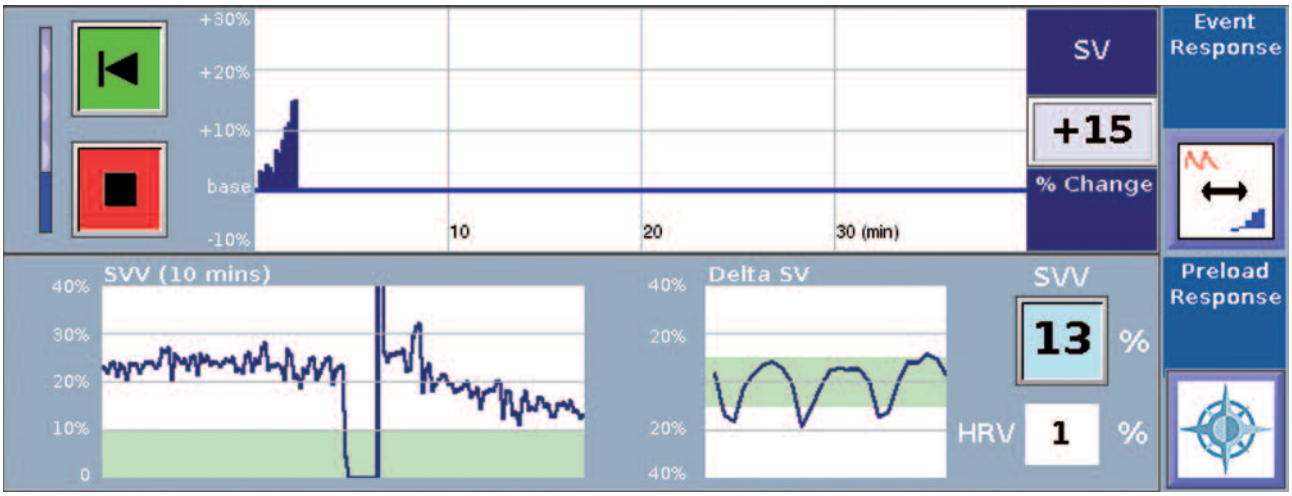


1.2 Functional Hemodynamic monitoring

The LiDCO*rapid* is a combination of both standard and functional hemodynamic monitoring.

The functional monitoring portion is comprised of two different sets of display (See Figure) that provide both a predictive indication of fluid responsiveness and the ability to assess changes in hemodynamic parameters as a result of interventions such as fluid boluses, vasoactive drugs or inotropes. All the data are derived via continuous beat-to-beat Pulse Pressure and Stroke Volume analysis.

The event response display is used to monitor the change in a hemodynamic parameter after an intervention (e.g. fluid challenge or change in drug therapy). The display is designed to calculate a % change from baseline and display a graphical trend. This allows for a clear understanding of the actual hemodynamic response to the intervention.



The preload responsiveness variables display provides either Stroke Volume Variation or Pulse Pressure Variation information as a long term trend and a short term trend of Delta SV (or PP). Both trends have a defined zone that indicates the currently accepted cut-off for potential fluid responsiveness. SVV tends to predict fluid responsiveness when the values are consistently above 10%[2]. PPV tends to predict fluid responsiveness when the values are consistently above 13%[3]. The long term trend is adjustable between 10 and 60 minutes and provides an easy to interpret picture of the value and general trend in these parameters. As the values and trend go above the 'green zone' it becomes more likely that the patient will respond to fluids. The short term trend covers a 30s period and can be used in a similar manner. As the amplitude of the wave increases beyond the 'green zone' it becomes more likely that the patient will respond to fluids. It is also possible to interpret the stability of the input data as well as confirm the respiratory rate using this display.

A numeric display is also provided for ease of data recording

The combination of preload responsiveness variables and event response displays, in combination with other clinical signs, provides the opportunity to anticipate the necessary intervention and to observe the patients actual hemodynamic response.

1.3 Quick Start

Step 1: Connect Cables and Switch ON (Figure 1)

1. Connect the power cable to the monitor and an appropriate power socket
2. Switch on the monitor via the power switch on the bottom
3. Connect the appropriate blood pressure cable to the LiDCO*rapid* monitor and to the primary monitor *

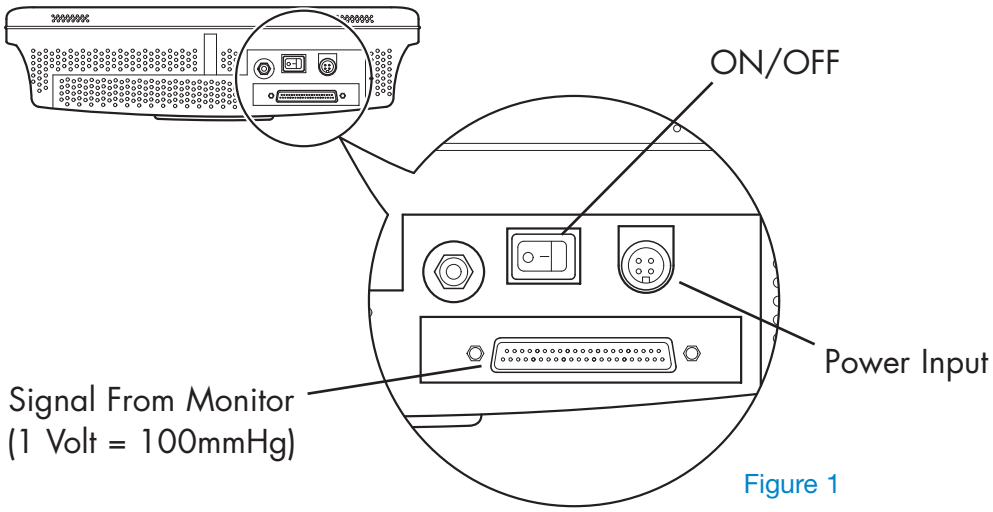


Figure 1

Step 2: Insert the LiDCOsmart Card (Figure 2)

1. These instructions are on the monitor and the LiDCOsmart as well
2. Obtain a new LiDCOsmart when starting a new patient
3. Orient the LiDCOsmart so that LiDCO*rapid* can be read and the arrow points to the monitor
4. Insert the card into the reader – the gold chip should be facing you
5. When complete the Startup Screen will indicate 'Start'
6. Press 'Start ' to begin. The Setup Screen will be displayed next

Figure 2

* See Section 3.1.1 for alternate signal sources via the BP Module.

Step 3: Setup Screen data entry

1. Enter the Patient's identification, age, height and weight
2. Observe the blood pressure waveform matches the primary monitor
3. Check the values for Systolic, Mean, Diastolic Blood Pressure and Heart Rate are within 5% of the primary monitor's displayed values

Step 4: Start LiDCO*rapid*

1. Press the Navigate button to display a submenu

2. Select the Main Screen button

2.0 Indications, Contraindications and Warnings

Indications for Use of the LiDCO*rapid* Hemodynamic Monitor System

Intended Use

The LiDCO*rapid* Hemodynamic Monitor System is intended for use as a diagnostic aid for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients.

Suitable Patients

Patients who have had arterial catheters inserted and require monitoring.

Locations of use

- Medical & Surgical ICU's - Operating Suites - Step Down / High Dependency Units
- Trauma / A&E (ER) Departments - Coronary Intensive Care Units - Cardiac Catheter Laboratories

Contraindications

The following patients are contraindicated for use with the LiDCO*rapid* Hemodynamic Monitor:

- Patients with aortic valve regurgitation
- Patients being treated with an intra-aortic balloon pump (IABP)
- Patients with highly under or over damped peripheral arterial lines due to blood clots, kinks or air bubbles in the line
- Patients with severe peripheral arterial vasoconstriction/vasospasm*

* Severe peripheral arterial vasoconstriction/vasospasm may negatively affect peripheral arterial blood flow and therefore the accuracy of the arterial blood pressure measurements themselves and hence any arterial waveform derived cardiac output reading will also be affected. This is a rare event and may be associated with severe peripheral vascular disease, extremes of vasopressor drug administration or patients treated with deep hypothermia. In such circumstances if accurate arterial blood pressure is required for patient management, then a femoral or more central aortic catheter maybe required.

Warnings

⚠ WARNING: Do not use the LiDCO*rapid* Hemodynamic Monitor with the patients types listed above - the performance of the device may be significantly compromised in such patients. Before use of the LiDCO*rapid* Hemodynamic Monitor familiarize yourself with the full list of indications, contraindications and warnings.

⚠ WARNING: Product Instructions and Training - Before use of the LiDCO*rapid* Monitor System please ensure that you have been trained in the use of the system and familiarize yourself with the:

- Contraindications & Warnings - Operating Instructions - Section 3

⚠ Warnings - LiDCO*rapid* Hemodynamic Monitor Initial Checks of Patient Pathology and Peripheral Artery Condition

- Before use, check the patient notes for the presence of aortic valve regurgitation. The LiDCO*rapid* Hemodynamic Monitor may be inaccurate in such patients.
- Severe peripheral arterial vasoconstriction/vasospasm may negatively affect the arterial pressure waveform and therefore the accuracy of the LiDCO*rapid* Hemodynamic Monitor - such events may occur in severe peripheral vascular disease, extremes of vasopressor drug administration and hypothermic patients.

Other Warnings

- On set-up and during use of the LiDCO*rapid* Hemodynamic Monitor always cross-check to the pressure parameters and heart rate displayed by host monitor. The following parameters: heart rate, systolic, diastolic and mean pressures should all be within 5% of the values displayed by the host/primary monitor. Pay attention to the heart rate and, if necessary, adjust the threshold for detecting the beat in order to adjust the rate - see section 3.1.5.
- Dynamic Preload response variables (e.g. SVV or PPV) are only valid in patients with closed chests on full mode control ventilation.
- Dynamic Preload response variables (e.g. SVV or PPV) are unreliable in patients with significant arrhythmia. The LiDCO*rapid* will alert when heart rate variation exceeds 10%.
- Always use the correct LiDCO*rapid* Hemodynamic Monitor cable assembly for connection to the primary monitor or the LiDCO BP Module. LiDCO Ltd has a list of compatible monitor cable assemblies.
- The BP Module allows the arterial blood pressure waveform to be accessed directly via a standard invasive blood pressure transducer when connected to a patient monitor.
- The BP Module is used when it is difficult or not possible to access the arterial blood pressure waveform via a standard analog output from the patient monitor.
- The BP Module will accept a standard analog output from the patient monitor.
- The scaling factor estimate cannot be as precise as an independent calibration of the PulseCO algorithm with a well performed indicator dilution measurement.
- The estimate used has boundary conditions similar to any device using a nomogram-based approach to estimate physical characteristics. Individual patient history may include a variety of potentially confounding conditions such as chronic hypertension, arteriosclerosis and/or diabetes, which may alter aortic capacitance.
- Care should be taken when using the LiDCO*rapid* in patients with severe peripheral vasoconstriction due to pre-existing disease or as a result of vasoactive drug treatment. In these cases the radial artery pressure may be substantially different to the central aortic pressure.
- The scaling factor estimate is derived from in vivo radial artery data and may be less accurate in patients with femoral arterial catheters[11].
- Always shut down the monitor before using it on a different patient. This is in order to avoid the possibility that incorrect set-up parameters and/or calibration factors are used in the calculation of the new patient's hemodynamics.
- The central venous/right atrial pressure is manually entered on the Configuration Screen - always check that the correct venous filling pressure is being used for the calculation of the systemic vascular resistance/index.
- LiDCO*rapid* Hemodynamic Monitor is not required to be directly connected to the patient applied part (pressure transducer). The data processed is the isolated pressure analog output from an approved patient monitor.
- The LiDCO*rapid* Hemodynamic Monitor should not be connected to any electrical equipment that is not compliant with EN 60601-1-1 and EN 60601-1-2 (or equivalent) electrical safety and EMC standards.

Make sure the LiDCO*rapid* monitor is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment.

Do not expose the LiDCO*rapid* monitor to extreme temperatures.

Do not obstruct the LiDCO*rapid* monitor ventilation openings.

3.0 Operation of LiDCO*rapid*

3.1 Setup

3.1.1 Equipment Setup

Mounting Recommendations

Securely mount the LiDCO*rapid* Hemodynamic Monitor according to your institution's practices. Optional mounting accessories can be purchased from approved medical equipment suppliers. Contact your local LiDCO representative for recommendations on alternative mounting options.

Set-Up Procedure:

Connecting the Power supply

After the monitor is securely mounted, attach the DC power cord supplied with the monitor at the back and connect it to a hospital-grade power outlet. The LiDCO*rapid* power supply automatically adjusts for power voltages from 100 to 240 VAC and converts the input voltage to 24VDC for supply to the monitor POC model only.

⚠ WARNING:

Do not use extension cords or multiple socket devices to connect power to the monitor. Do not use any other detachable power cords other than the power cord provided.

Connecting the LiDCO*rapid* to Primary Patient Monitor

Option 1: Direct Analog Input

The LiDCO*rapid* Hemodynamic Monitor is designed to interface with standard patient monitors that provide an analog arterial pressure waveform output. LiDCO Ltd or your local distributor can provide a list of compatible patient monitors / modules together with the appropriate cable assembly to connect to the patient monitor analog pressure out.

Option 2/3: LiDCO BP Module

- The BP Module allows the arterial blood pressure waveform to be accessed directly via a standard invasive blood pressure transducer when connected to a patient monitor.
- The BP Module is used when it is difficult or not possible to access the arterial blood pressure waveform via a standard analog output from the patient monitor.
- The BP Module will accept a standard analog output from the patient monitor.

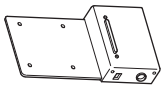
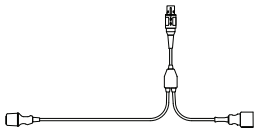
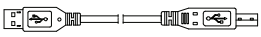
⚠ WARNING:

It is important that the primary blood pressure monitor is correctly calibrated. Check that the pressure display on the monitor is the same as the pressure displayed on the LiDCO*rapid* screen.

Note: The LiDCO*rapid* Hemodynamic Monitor does not have a mouse or keyboard. All user interactions are mediated through the touch sensitive screen.

Contraindications: None
Precautions:
Check the BPM cable and module before use.
Do not use in the event of damage.
When connecting cables do not try to force, instead align them and gently connect.
Insert and remove cables using the connector. Use the mark to align connectors.

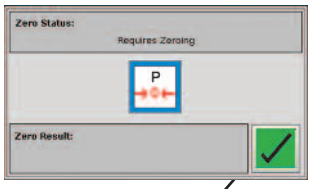
LiDCO BPM **Components**

Blood Pressure Module		Weight: 300g HxWxD: 10x207x4mm
BPM Interface Cable (specific to transducer type)		Cable Length: 3m
USB Cable		Cable Length: 20cm A to B USB cable

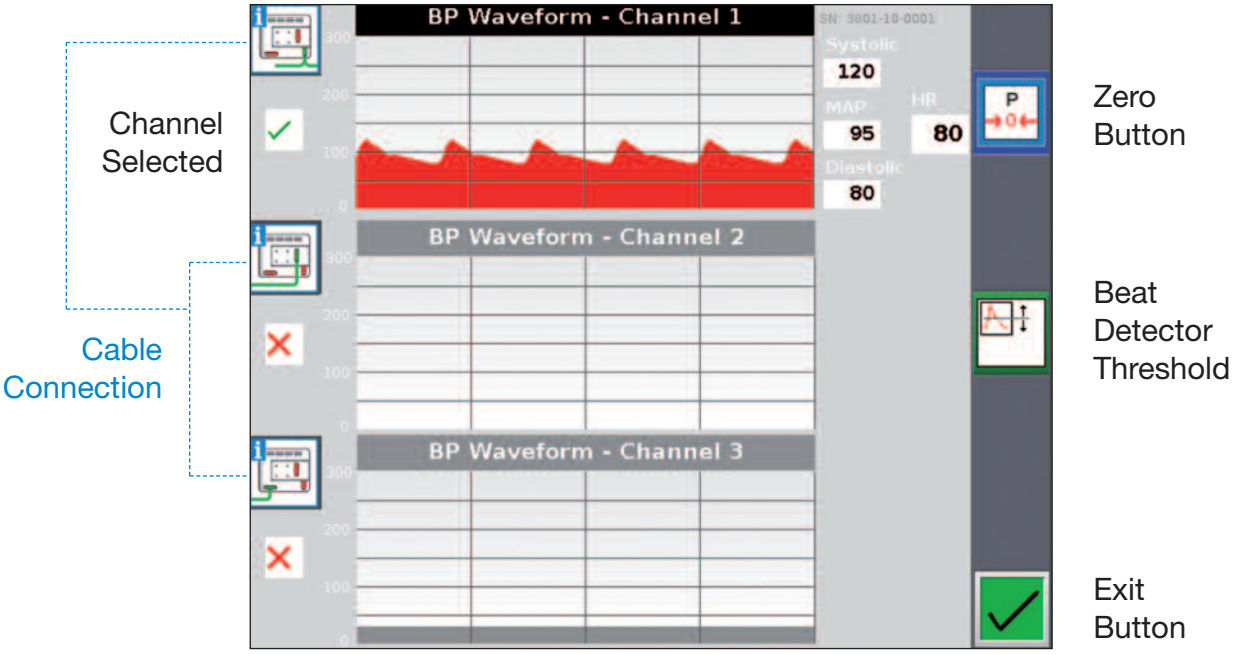
LiDCO BPM Channel Selection

Channel Selection is required on first use of the BP Module. The selected channel becomes the default for future use. Channel selection is required again only if the cable input channel is changed.

- Press  to display the channel selection window. (see below)
- Choose the channel that matches the cable connection.
  A waveform will display in the associated window that is connect to the IBP.
  - Channel 1: IBP Transducer - BP Module
  - Channel 2: Analog BP Waveform - BP Module
  - Channel 3: Analog BP Waveform - LiDCO Monitor



- Confirm the Pressure and Heart Rate match the Patient Monitor
  - Note: Channel 1 must be zero'ed before pressure and heart rate values will display
  - Press  to zero the pressure on Channel 1 when the Patient Monitor is zero'ed
  - Press  when finished to return to the previous screen



Channel 1 Connection:

IBP Transducer Input

1. Connect BPM cable to BPM
2. Connect BPM cable to Patient Monitor cable
3. Connect BPM cable to IBP Transducer cable
4. Connect the USB cable to LiDCO Monitor and BPM

Channel 2 Connection:

Alternate Analog Input

4. Connect the USB cable to LiDCO Monitor and BPM
5. Connect analog output cable from patient monitor to BPM

LiDCO BPM Troubleshooting

No BP Waveform is observed on any channel For Channel 2 zero the Patient Monitor IBP waveform	Check all cable connections
No values are displayed for Channel 1	Channel 1 must be zero'ed before values will display
Zero Fail: Signal Varying Zero Fail: Offset too large	Confirm Patient Monitor and Transducer are in Zero position
No BP waveform or values are displayed for Channel 2	Zero Fail: Signal VaryingCheck cable connections
No cable for Channel 2	Contact your LiDCO representative to obtain a cable. Specify the Make/Model of your Patient Monitor.
The BPM is compliant with the applicable EMC requirements. It may still be affected by and/or affect other equipment. If interference occurs:	Reposition to reorient and/or increase the separation between the equipment. Connect the equipment to a power outlet on a different circuit.

LiDCO BPM Specifications & Symbols

- Compatible transducers sensitivity 5uV/Ve/mmHg.
- Analog waveform 1V=100mmHg, 0-2.5VDC, 0V offset.
- Accuracy: +/-3% of full scale.
- Power (USB): 5VDC, 500mA max.
- Not protected against water ingress.
- type CF applied part. F-type isolated (floating) patient part providing a high degree of protection against shock and is suitable for use during defibrillation. Defibrillation recovery <5 seconds.
- **Rx ONLY** Federal law (USA) restricts the sale of this device by or on the order of a physician.
- CE Complies with the requirements of the Directive 93/42/EEC (as amended) concerning medical devices.
- The BPM is not Category AP or Category APG and should not be used in the vicinity of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

LiDCO BPM Installation & Cleaning

Cleaning:

1. Clean the cable & module with a soft cloth moistened with water.
2. Wipe off excess water and allow to air dry.

Cautions: Never immerse or soak the cable or module.

Disinfection:

1. Disinfect the cable & module with a soft cloth moistened with 75% ethanol or 70% isopropanol or 2% glutarldehyde.
2. Wipe off excess liquid and allow to air dry.

The BP Module is mounted to the VESA plate on the back of the LiDCO Monitor

- LiDCO*rapid* can be mounted on a Stand and/or a Pole Clamp
- LiDCO*plus* can be mounted on a Rollstand

Disconnect the Monitor from the voltage supply before cleaning/disinfecting.

M4 Screw Lengths, mm	LiDCO*rapid* (POC-125)	LiDCO*rapid* (DTP-1201)
Figure A Pole Clamp	25mm	12mm
Figure C Stand & Pole Clamp	25mm	16mm
Figure D Stand	25mm	16mm

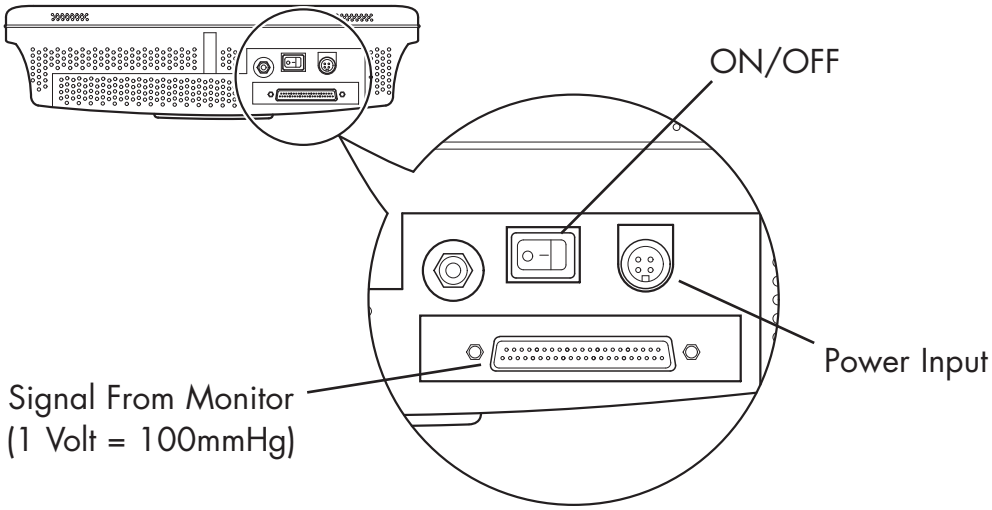
Refer to page 52 for illustrations of BP Module installation.

Starting the Monitor

Switch on the power using the ON/OFF switch located near to the power cable. The power switch is not latching and will return to the original position. The monitor will complete it's startup routine and display the Startup Screen.

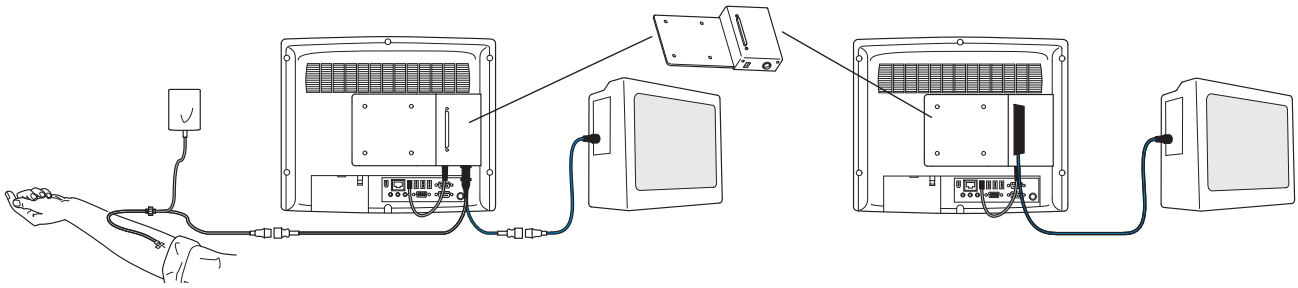
Switch off the power by pressing the ON/OFF switch.

Option 1: Direct analogue signal input into LiDCO*rapid* via Channel 3



Option 2: Analogue input via BP Module into Channel 2

Option 3: Direct BP input via the BP module into Channel 1.

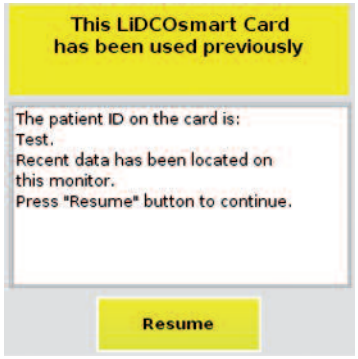


3.1.2 Startup Screen

The Startup Screen is the entry point to initiate patient monitoring with the LiDCO*rapid*.

A LiDCOsmart is inserted into the card reader to begin.

Press 'Start' to begin monitoring. This will display the Setup Screen.

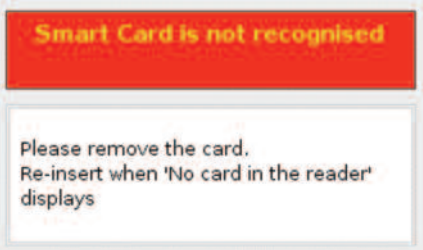


If the LiDCOsmart has been used previously on this patient and hasn't expired, then the Startup Screen will indicate that the LiDCOsmart has been previously used. If the same patient is being monitored then press the "Resume" button. This will display the Setup Screen. All the patient details will be automatically entered.

If the LiDCOsmart has expired then the Startup Screen will indicate this and a new LiDCOsmart will be required.

⚠ WARNING:

The LiDCOsmart must be fully inserted into the card reader. If the card is not recognised, remove and reinsert.

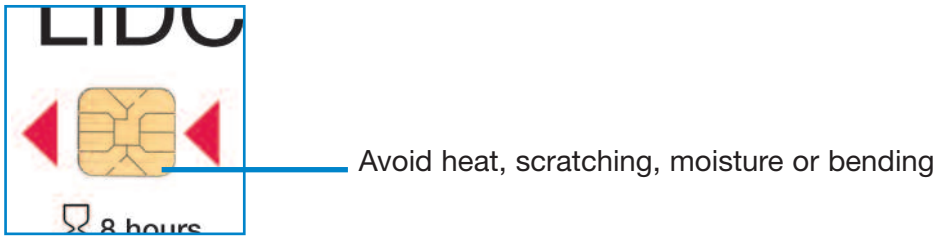


3.1.3 LiDCOsmart

The LiDCOsmart card is used to access the LiDCO*rapid* Hemodynamic Monitor. The LiDCOsmart is a single patient use card. When a valid LiDCOsmart is inserted, the Startup Screen will indicate "Press Start New Patient" to begin. If the LiDCOsmart was used previously the Startup Screen will indicated "Press Resume Previous Patient".

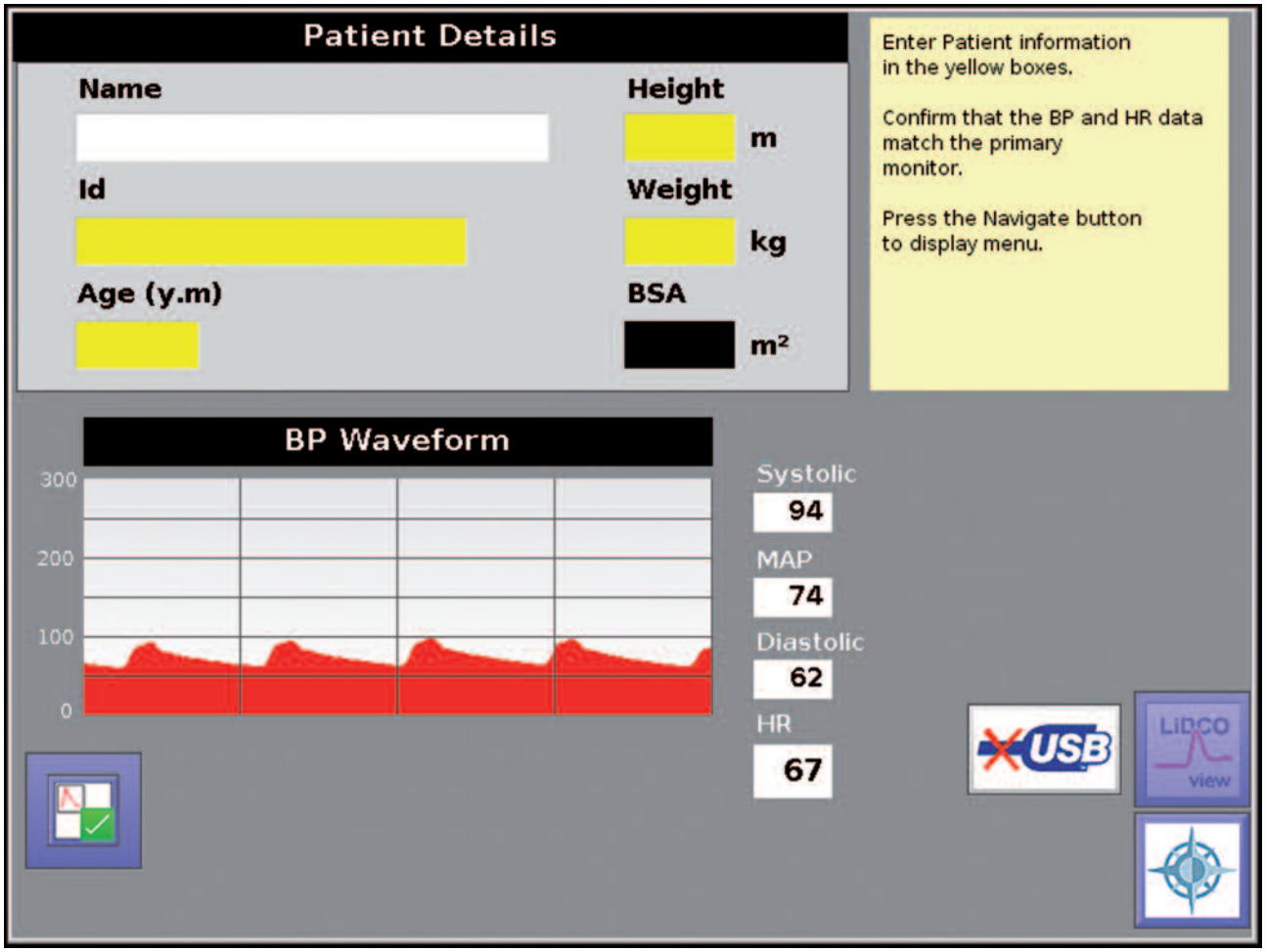
The LiDCOsmart has a predefined period of use that is printed on the card. The start is recorded when monitoring begins. Once the period has elapsed, the card becomes expired. If this happens while in use, monitoring will continue. Once the card is removed from the monitor or the monitor is shutdown that LiDCOsmart can no longer be used.

How to insert the Card:



3.1.4 Setup Screen

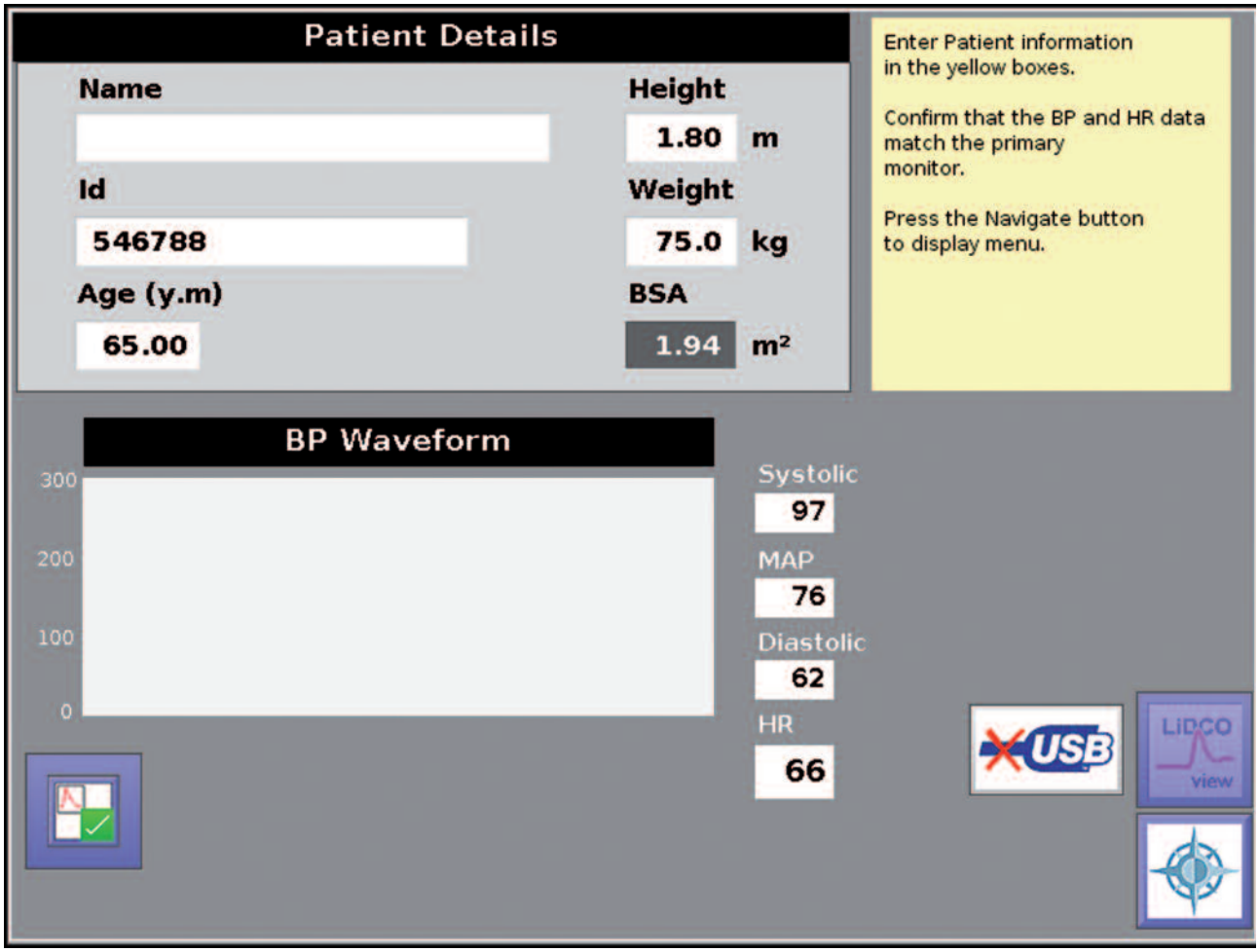
Enter Patient Information in the yellow highlighted boxes for a new patient. If resuming a previous patient these boxes will be automatically filled in and cannot be altered.



The blood pressure waveform will appear when the signal cable or BP module is connected.

The values for pressure and heart rate will appear within a few seconds.

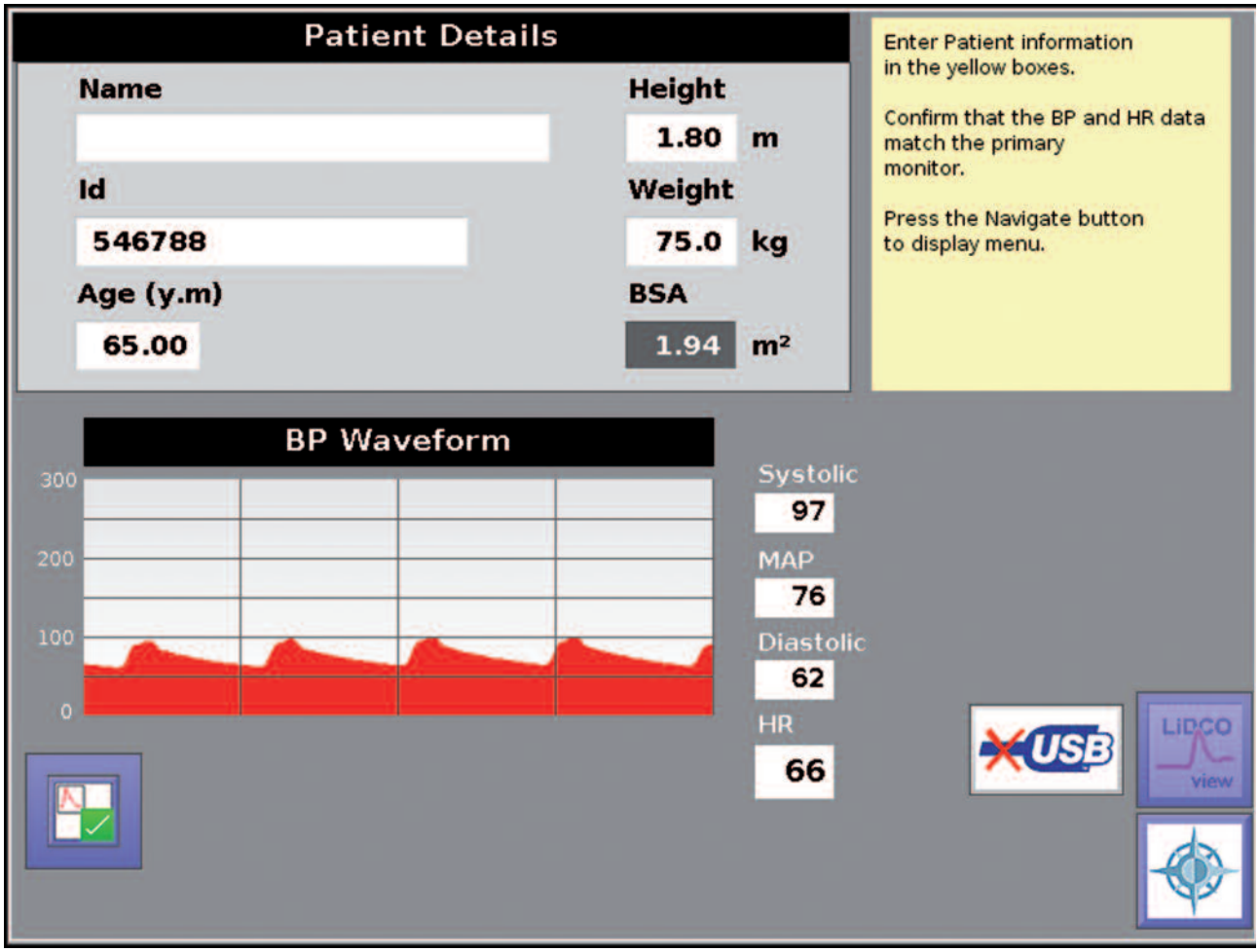
The LiDCO*rapid* reports values for stoke volume (SV) and cardiac output (CO) that are based on the PulseCO algorithm scaled to the patient's specific characteristics. The PulseCO scaling factor reflects the patient-specific maximum aortic capacitance and will generally remain constant over short periods of time. The PulseCO algorithm has been demonstrated to trend without the need for recalibration in numerous studies for up to to 24 hours[5-10,12].



The LiDCO*rapid* uses a nomogram-based estimate of the patient specific scaling factor. This was developed using in vivo calibration data from post surgical patients with radial arterial blood pressure waveform data. The nomogram estimate was then validated in an independent cohort of medical ICU patients giving a good correlation (r^2=0.77), no bias and acceptable limits of agreement (+/-26%) when compared with indicator dilution based calibration.

Warnings

- The scaling factor estimate cannot be as precise as an independent calibration of the PulseCO algorithm with a well performed indicator dilution measurement.
- The estimate used has boundary conditions similar to any device using a nomogram-based approach to estimate physical characteristics. Individual patient history may include a variety of potentially confounding conditions such as chronic hypertension, arteriosclerosis and/or diabetes, which may alter aortic capacitance.
- Care should be taken when using the LiDCO*rapid* in patients with severe peripheral vasoconstriction due to pre-existing disease or as a result of vasoactive drug treatment. In these cases the radial artery pressure may be substantially different to the central aortic pressure.
- The scaling factor estimate is derived from in vivo radial artery data and may be less accurate in patients with femoral arterial catheters[11].

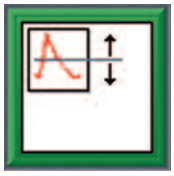


Press the Navigate button

to display a sub-menu:

Press this button to go to the main monitoring Screen
(See Section 3.2.1)

Press the CO button to enter a CO Value directly and calibrate the monitor
(see section 3.1.6)



Press the Beat Detector Threshold to adjust for incorrect HR display
(See Section 3.1.5)

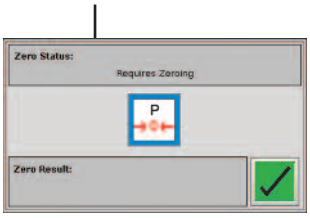
Press the Configuration button to change the LiDCO*rapid* screen
(See Section 3.2.6)

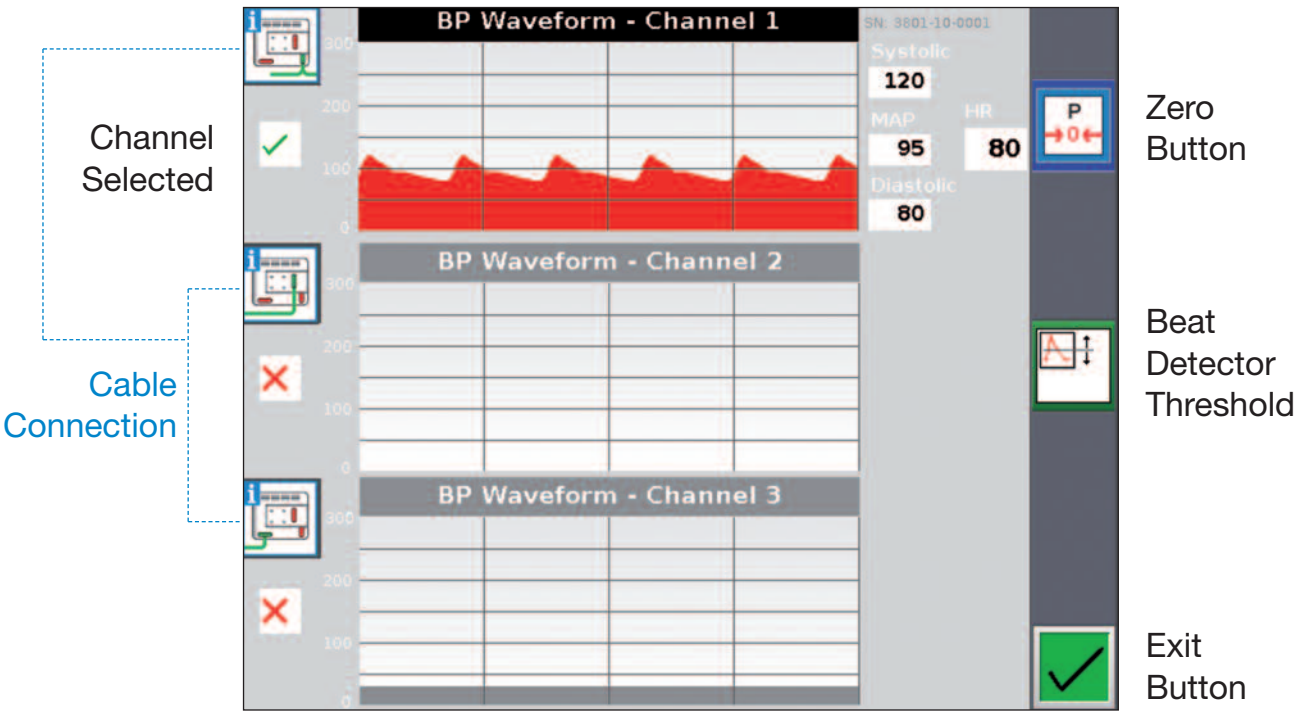
Press the Exit button to shutdown the LiDCO*rapid*

LiDCO BPM Channel Selection

Channel Selection is required on first use of the BP Module. The selected channel becomes the default for future use. Channel selection is required again only if the cable input channel is changed.

- Press  to display the channel selection window.
- Choose the channel that matches the cable connection.
  A waveform will display in the associated window that is connect to the IBP.
  - Channel 1: IBP Transducer - BP Module
  - Channel 2: Analog BP Waveform - BP Module
  - Channel 3: Analog BP Waveform - LiDCO Monitor
- Confirm the Pressure and Heart Rate match the Patient Monitor
  - Note: Channel 1 must be zero'ed before pressure and heart rate values will display
  - Press  to zero the pressure on Channel 1 when the Patient Monitor is zero'ed
  - Press  when finished to return to the previous screen

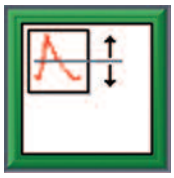


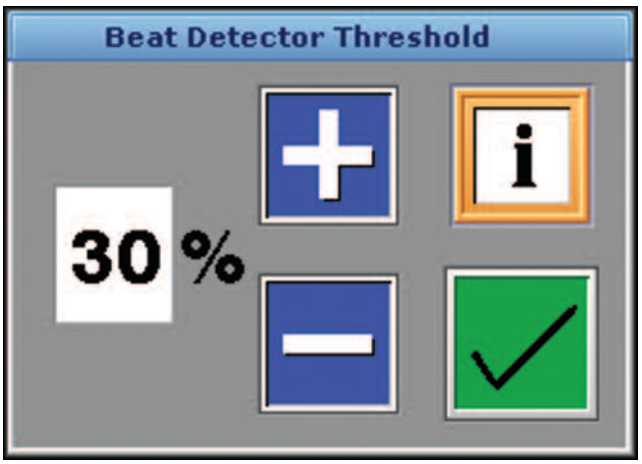


3.1.5 Beat Detector Threshold

Heart rate display adjustment procedures

Press to display the beat detector Threshold adjustment window.





If heart rate displayed on primary monitor is lower than that displayed on the LiDCO*rapid*

Press  to raise threshold until displayed heart rate matches.

If heart rate displayed on primary monitor is higher than that displayed on the LiDCO*rapid*

Press  to lower threshold until displayed heart rate matches.

Note:

- Patients with a pronounced diastolic pressure 'bounce' can cause the LiDCO*rapid* Hemodynamic Monitor to double trigger the heart rate. The Beat Detector Threshold should be increased as above.
- Patients experiencing bigemini instability will, on occasion, cause the LiDCO*rapid* Hemodynamic Monitor to under-estimate the heart rate. Decrease the threshold to obtain the correct heart rate

Press to reveal this information on the LiDCO*rapid* Hemodynamic Monitor.

3.1.6 Calibration via CO or CF Entry

The LiDCO*rapid* can be calibrated by entering a known value for Cardiac Output (CO) or Calibration Factor (CF). It is important that calibration is carried out in a hemodynamically stable period with minimal variation in blood pressure or heart rate. The entry of the cardiac output should be done in a timely manner to avoid introducing a bias due to a change in the patient's condition.

Pre-calibration Check List

The performance of the LiDCO*rapid* Hemodynamic Monitor may be compromised in the following patients:

- Patients with aortic valve regurgitation
- Patients being treated with an intra-aortic balloon pump (IABP)
- Patients with highly damped peripheral arterial lines
- Patients with peripheral arterial vasoconstriction

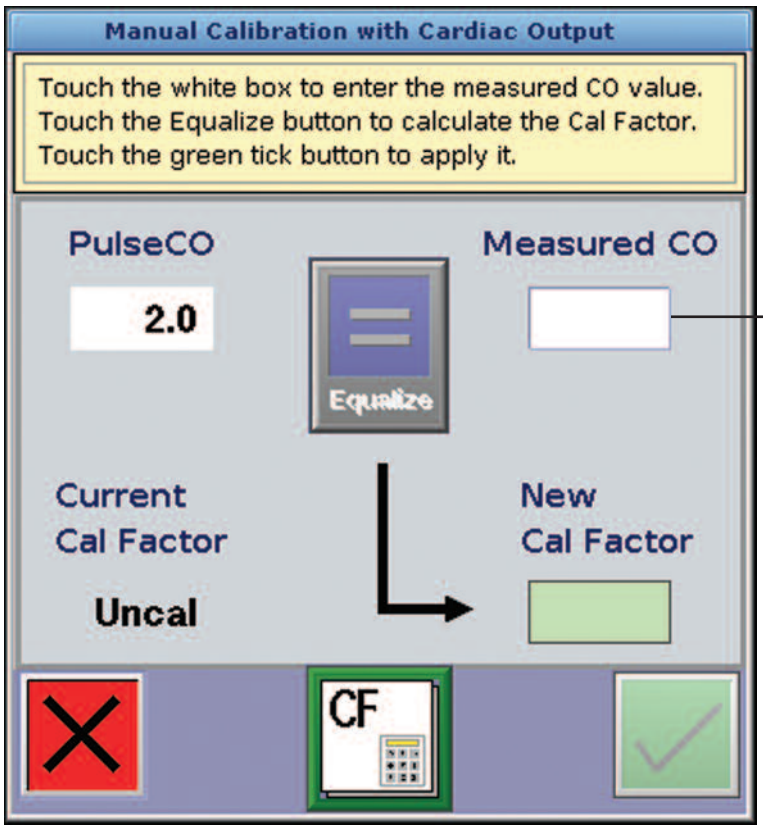
⚠ WARNING: Do not use the LiDCO*rapid* Hemodynamic Monitor with the patient types listed above - the performance of the device may be significantly compromised in such patients. Before use of the LiDCO*rapid* Hemodynamic Monitor familiarize yourself with the full list of indications, contraindications and warnings.

The calibration is performed on the Setup or main Screens.

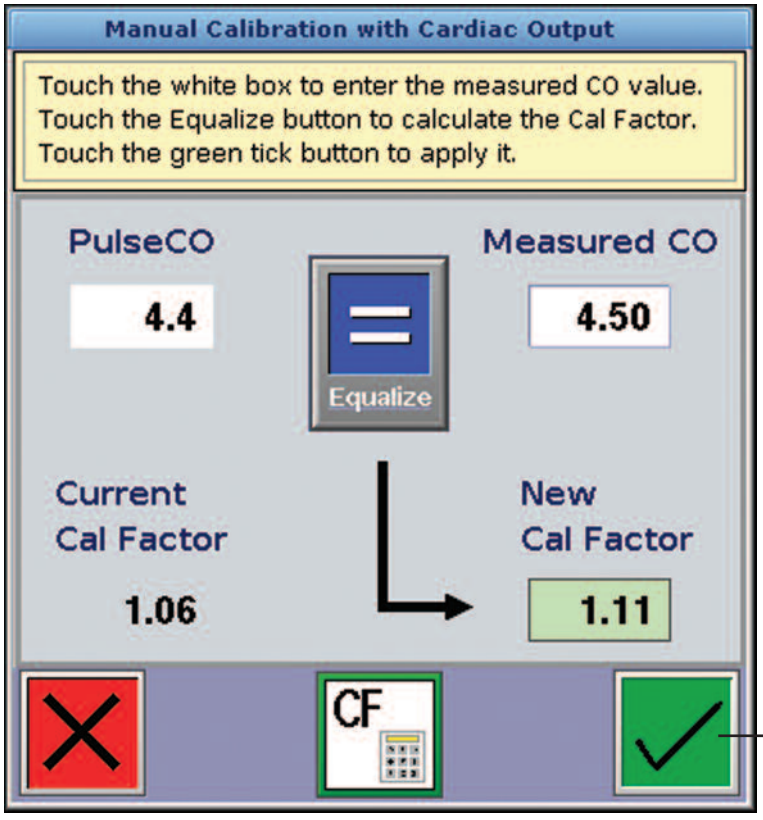
Press the Navigate button to display the submenu

Press the CO Entry button to display the window for cardiac output calibration.

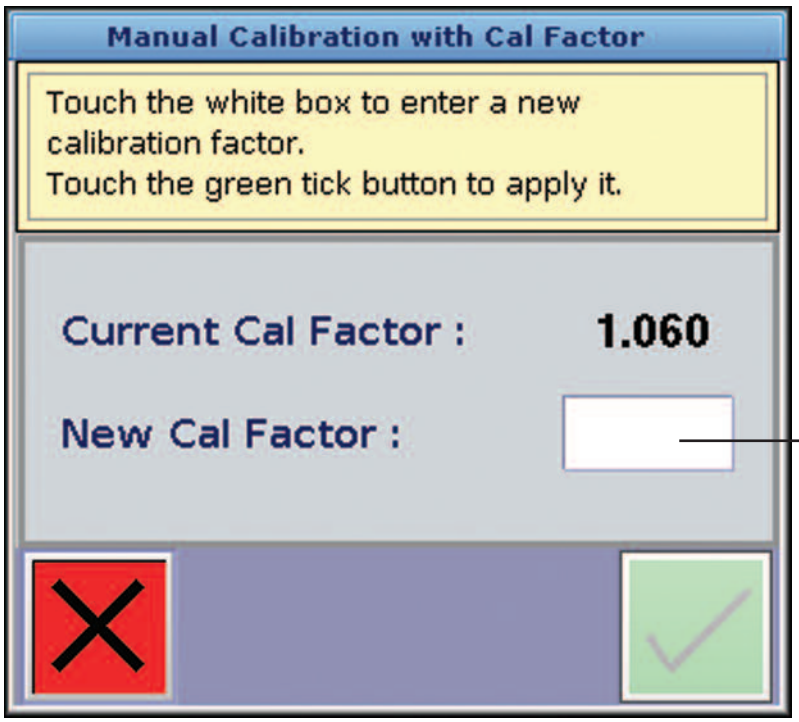
When the LiDCO*rapid* is calibrated by either method the 'n' is removed from the variables SV, CO and SVR. A yellow flag is placed on the SV and CO trends.



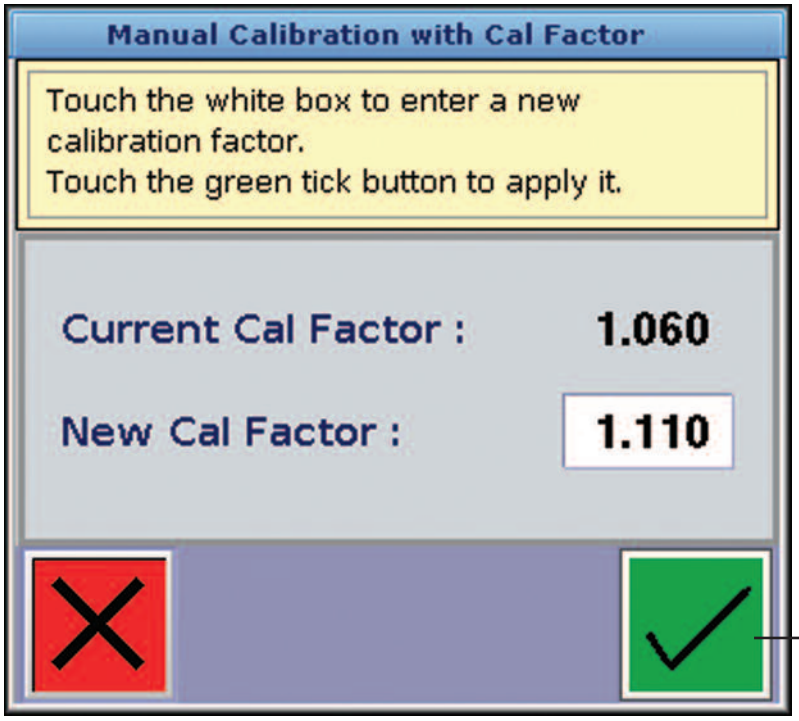
Enter the value for CO in the Measured CO box and press the Equalize Button to generate a calibration factor.



Press the Green tick to accept the calibration or press the Red X to cancel.



Enter the value for CF in the Measured CF box

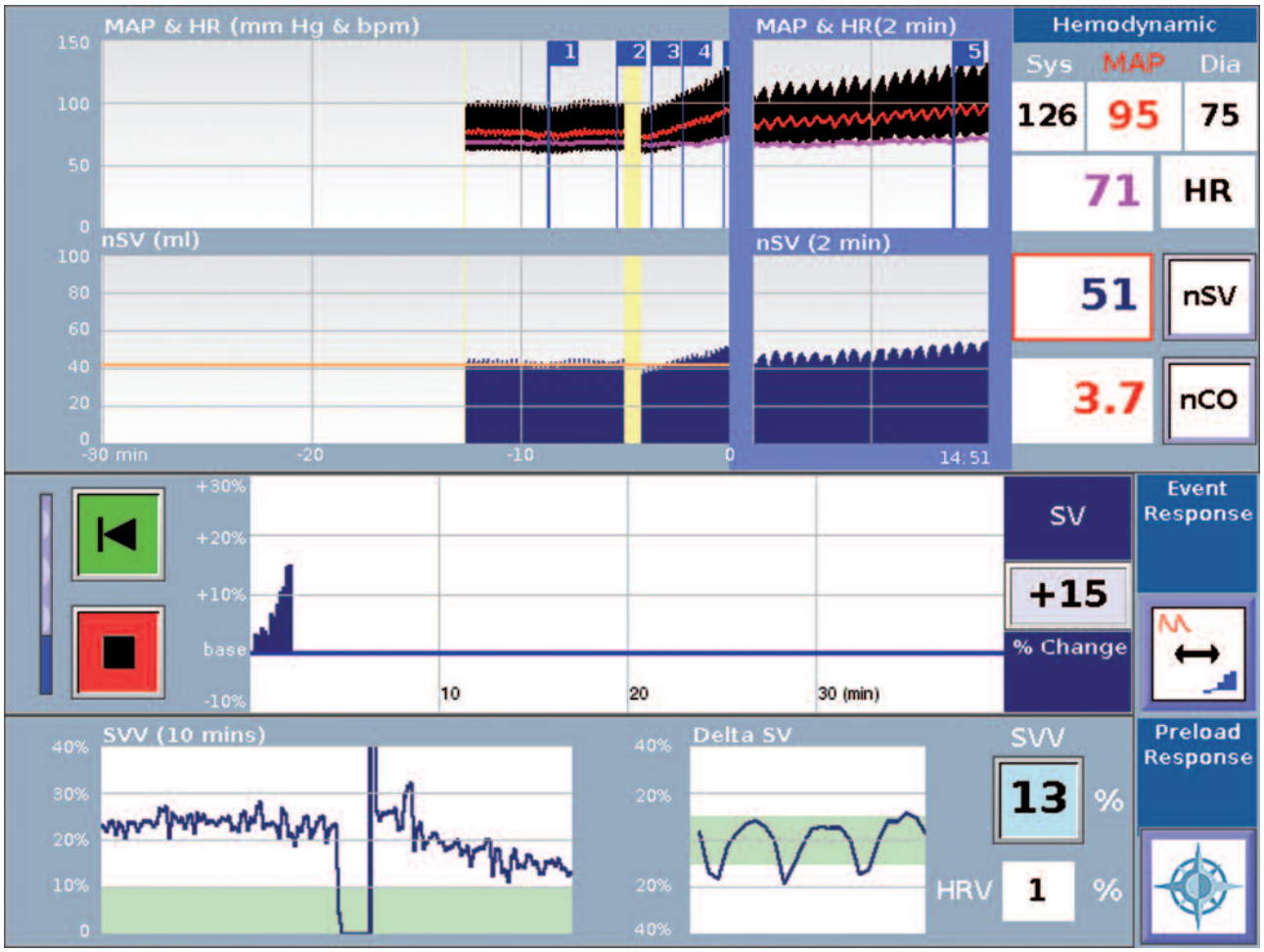


Press the Green tick to accept the calibration or press the Red X to cancel

3.2 Operation

3.2.1 Overview of LiDCO*rapid* Screen

The main monitoring screen is a single 'heads up' display that combines both standard and functional hemodynamic monitoring. In this way the user can see both long term and short term trends in key parameters such as BP, HR and SV. Dynamic preload responsiveness parameters SVV or PPV, give predicted fluid responsiveness assessment. Functional hemodynamic change in parameters such as SV or CO via Event Response provides immediate feedback on interventions.



Navigating the Screen

Press the CO button 

to change to a trend of CO. Press the SV button to change to a trend of SV.

Press the CO (SV, SVR) numeric display 

to display CI (SVI, SVRI) for 10 seconds.

Press to switch between the Event Response display and the BP waveform

Press to Change the parameter displayed in the Event Response window

Press to reveal a submenu

Press to return to the Setup Screen (3.1.4)

Press to return to the Configuration Screen (3.2.6)

Press to enter an event (3.2.5)

Press to capture the screen as a JPG file

Press to shutdown the monitor

Press the CO button to enter a CO Value directly and calibrate the monitor (see section 3.1.6)

Press to display the Chart screen (3.2.8)

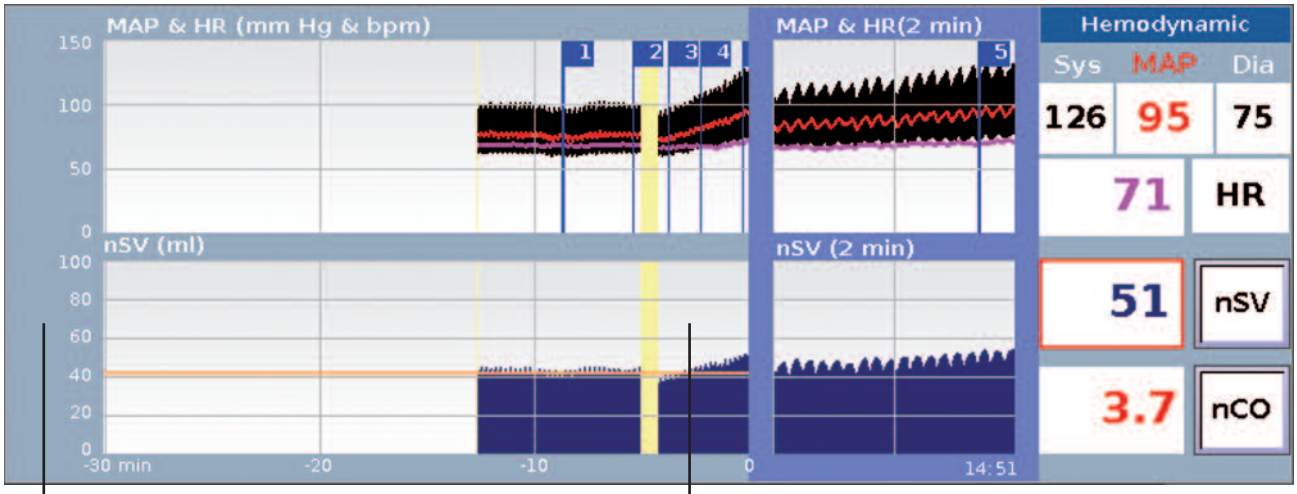
Press to display the History screen (3.2.8)

3.2.2 Hemodynamic Monitoring Display

The LiDCO*rapid* provides standard hemodynamic parameters of blood pressure and heart rate in a unique trend display that allows both long term and short term views. In addition, using the PulseCO blood pressure waveform analysis algorithm, the monitor also displays nominal stroke volume.

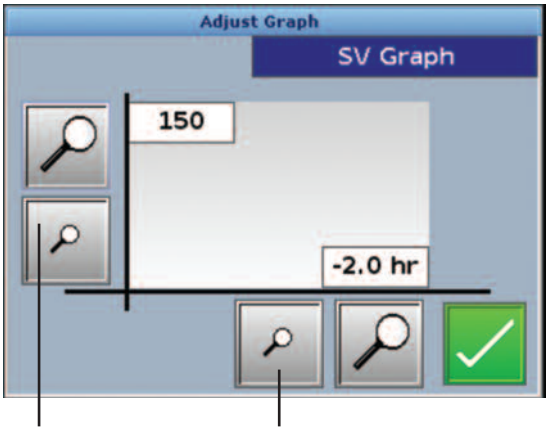
The long term display contains the entire case up to a maximum of 8 hours. The time axis automatically adjusts scale to provide the highest resolution possible for the duration displayed. This display provides a complete overview of the case with the ability to identify trends and also where targets were met. A marker line can be placed on the lower trend screen to mark a baseline or set a target.

The short term or acute display shows data over a fixed 2 minute period. This provides an easy way to observe immediate changes and give an early warning for more immediate response.

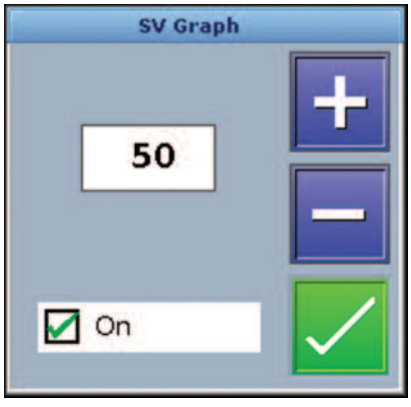


Touch the vertical axis to display the control window.

Touch inside the graph to display the target window for CO, SV or SVR



The scale of both axes can be adjusted by de-selecting "Auto-scale" and using the increase/decrease buttons.



The target line can be added by selecting the "on" box; it can be adjusted by using the increase/decrease buttons.

When events are marked, they are displayed on both the short and long term trend displays of MAP and HR.

The display of numeric data to the right can be averaged over periods of 10, 20 or 30 seconds. This is can be adjusted in the configuration screen (3.2.6).

To change the trend display press the button parameters.

Press the CO button 

to change to a trend of CO. Press the SV button to change to a trend of SV.

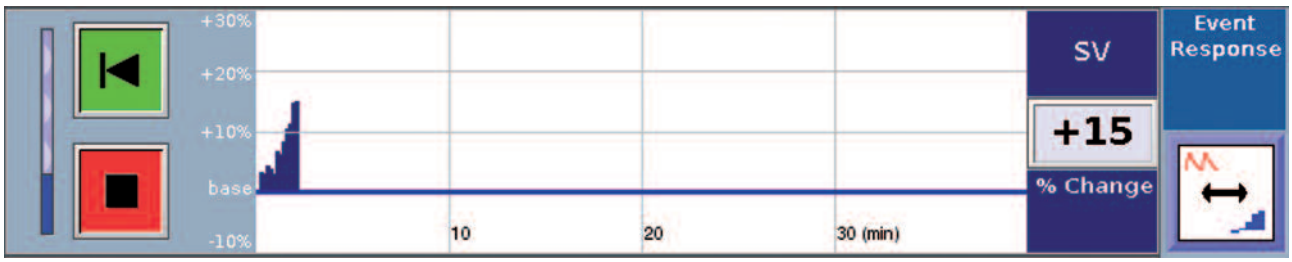
Indexed or absolute numeric values can be quickly displayed by pressing inside the number display.

Press the CO (SV, SVR) numeric display to display CI (SVI, SVRI) 

The alternate value is shown in reversed colours for 10 seconds.

3.2.3 Event Response Display

The Event Response Display is used to track changes in a hemodynamic parameter as a result of a therapeutic intervention. Simply press the green 'play' button to start and the display will show the relative change in the parameter both graphically and numerically, at regular intervals over a period of up to 40 minutes. Press the red 'stop' button when complete. To reset the start, simply press the green 'restart' button and the display will clear and start over again.



The default parameter for display is Stroke Volume and the display/averaging interval is 10 seconds (adjustable to 20, 30 secs or off). These can be changed by using the configuration screen (see section 3.2.6). Alternately press the parameter name to switch between Cardiac Output, Mean Arterial Pressure, Heart Rate or Systemic Vascular Resistance.

When an event is started, restarted or stopped, an event flag is automatically set. If not required, this flag can be cancelled by selecting the red X. The event information is entered as normal to keep a record of the intervention. Other events can still be entered when the event response is running. (see 3.2.5)

The Event Response will become a trend when the Event Response display reaches 40 minutes of data. Each new data point will appear on the right and the earliest point will disappear on the left.

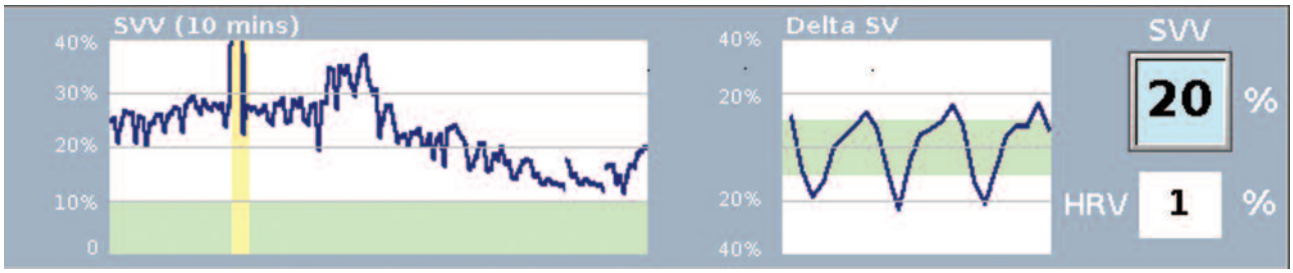
Press to switch between the Blood Pressure waveform display and the Event Response display.

3.2.4 Dynamic Preload Responsiveness Display

The Dynamic Preload Responsiveness Display is used to assess the likely response of a patient to a fluid challenge. Data is displayed both graphically and numerically on this screen for ease of use.

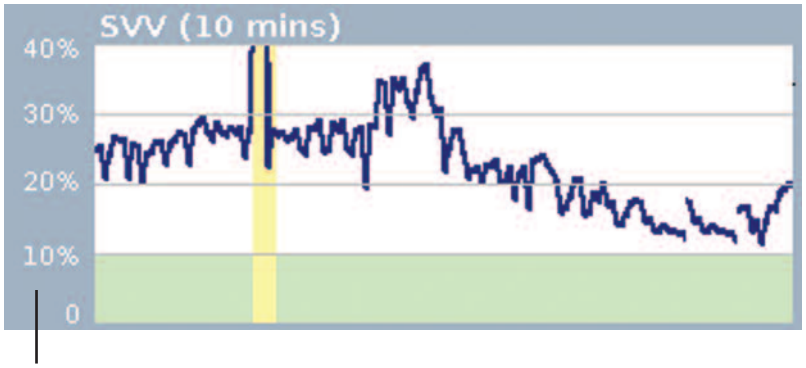
⚠ WARNING: Dynamic Preload response variables (e.g. SVV or PPV) are only valid in patients with closed chests on full mode control ventilation.

⚠ WARNING: Dynamic Preload response variables (e.g. SVV or PPV) are unreliable in patients with significant arrhythmia. The LiDCO*rapid* will alert when heart rate variation exceeds 10%.

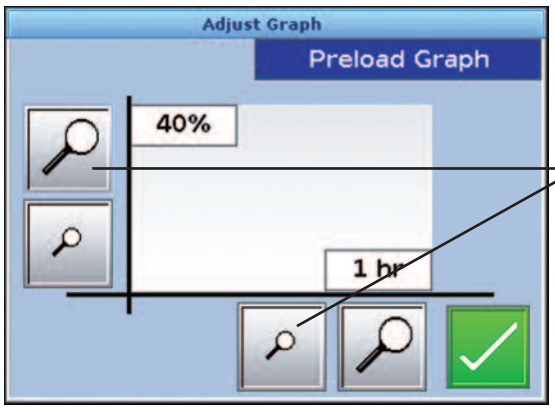


The display is made up of two independent graphical trends.

The first is a trend of either the Stroke Volume Variation (SVV) or the Pulse Pressure Variation (PPV) over an adjustable 10 - 60 minute period.

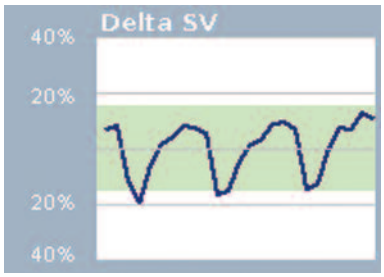


Touch the vertical axis area to adjust the Preload display.

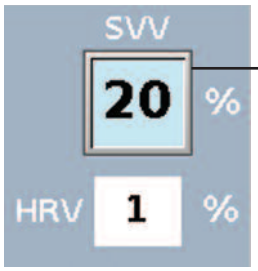


Adjust time period or scale by pressing the increase/decrease buttons in the control window.

The second, Delta SV (or PP), is a fixed 30 second trend of the change in stroke volume (or pulse pressure) normalised to the current mean stroke volume (or pulse pressure). This results in a percentage value that oscillates around a baseline of 0. This display gives a clear graphical indication of the respiratory cycle and signal quality. The more sinusoidal the signal, the better the quality. Each wave reflects a respiratory cycle as reflected by change in SV (or PP).



The numeric value of SVV (or PPV) is displayed along with the heart rate variation. When the HRV exceeds 10% the SVV (or PPV) is considered unreliable. The background of the HRV display will change to yellow and the Trend of the dynamic preload responsiveness display will indicate unreliable data by using a yellow line for each affected data point.



Press this button to switch the display to PPV.

3.2.5 Event marking

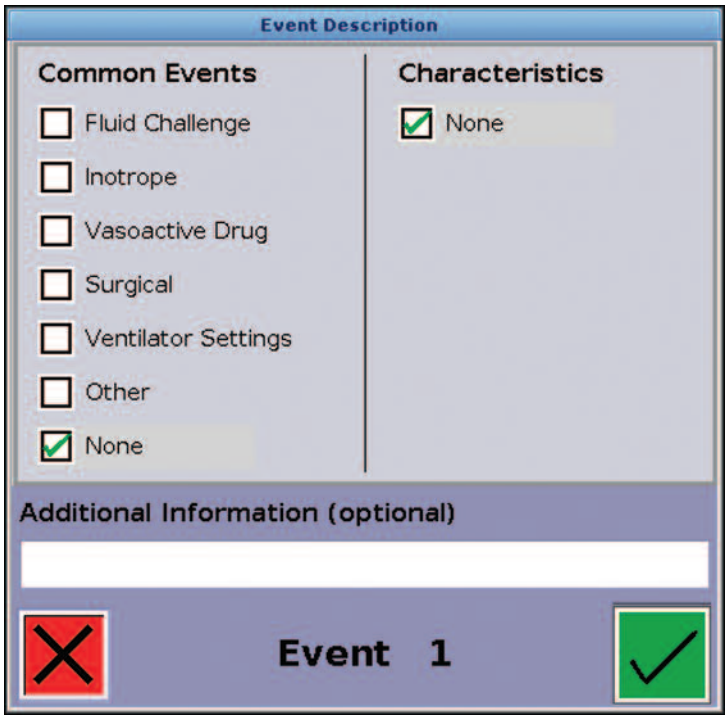
Events can be marked at any time during the use of the LiDCO*rapid*. A flag is placed on the hemodynamic monitoring display with the event number. Each event can be individually annotated. Standard event types are listed and additional information can be entered as well.

A full list of events is available for review at any time, and past event information can be edited (see section 3.2.7).

Press to display the submenu and choose

to mark an event

Use the following window to annotate the event:



Choose an Event Type and Characteristic.

Press the white box to add additional information

Press the 'green' tick when complete, which will add the flag, or the red 'X' to cancel.

Note: The event flag is located to the nearest beat at the time the button is pressed.

3.2.6 Configuration of LiDCO*rapid* Screen

The LiDCO*rapid* Screen can be configured to display different parameters, at different averaging intervals or with different targets than the defaults.

Press the configuration button  to make changes to the display.

Hemodynamic Trend:

Parameters can be displayed as either absolute or indexed to body surface area

The averaging period for numeric display can be chosen from: No Average, 10, 20(default) or 30 seconds

CO/SV (default) or CO/SVR or SV/SVR can be displayed

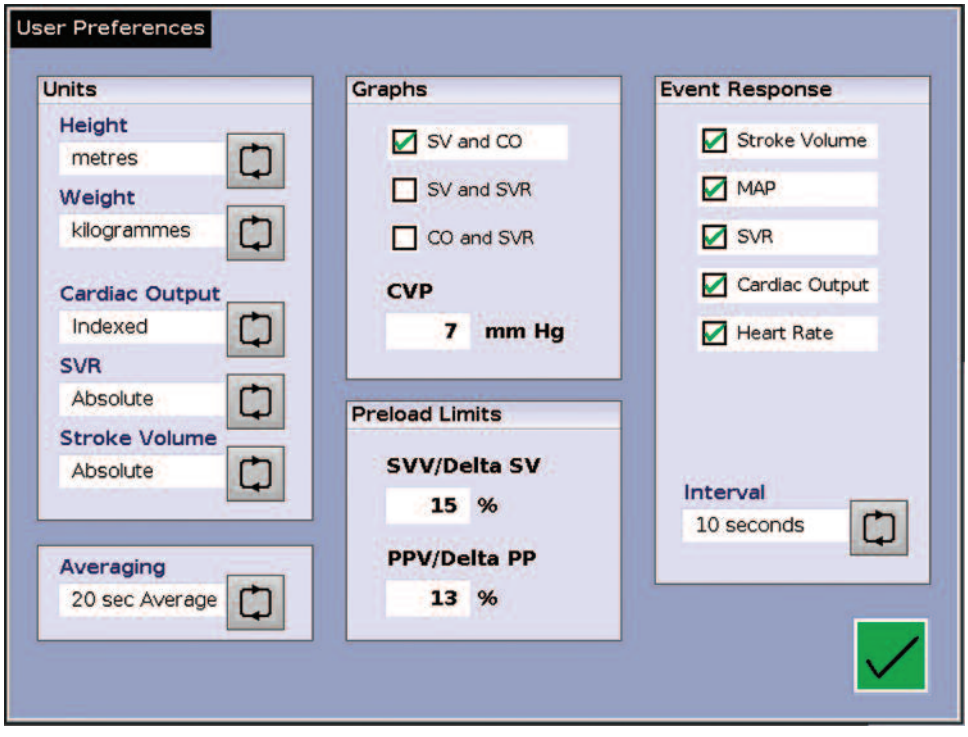
Event Response:

Stroke Volume (default) can be replaced with CO, MAP, HR or SVR
The frequency of data update can be chosen from 10(default), 20 or 30 seconds

Dynamic Preload Responsiveness Parameters:

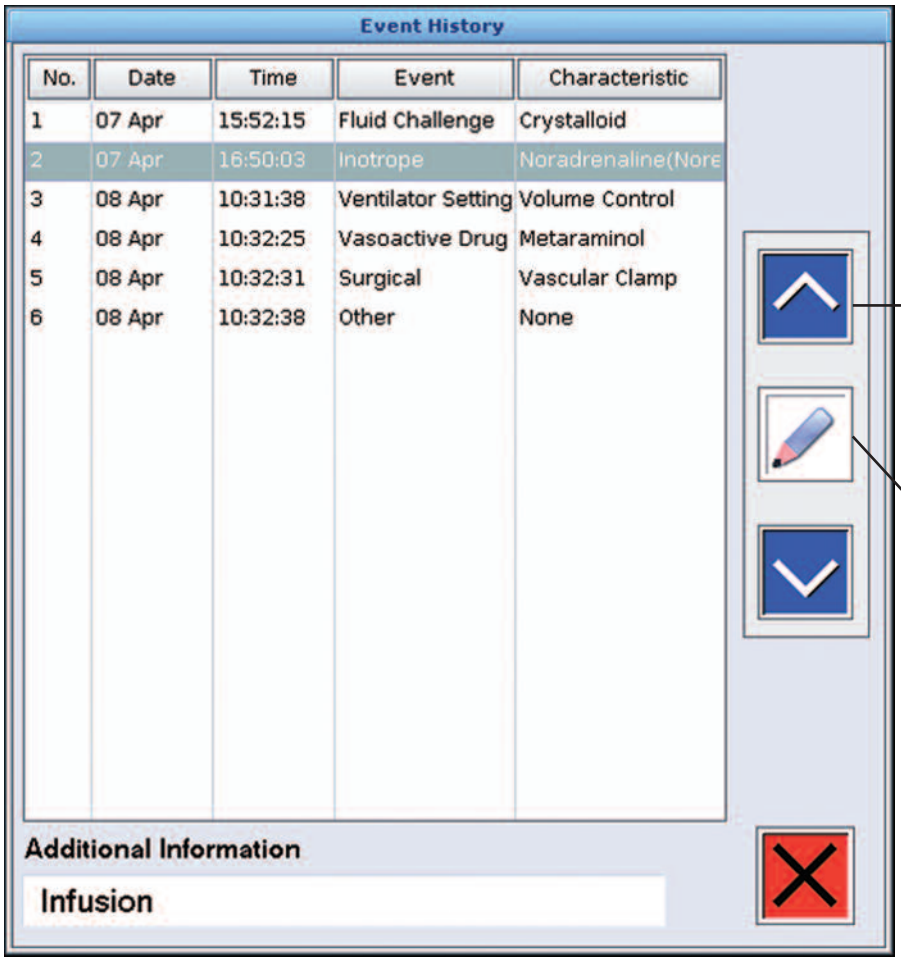
SVV (default) or PPV

SVV target zone limit: 10% (default)
PPV target zone limit: 13% (default)



3.2.7 Event List

Press this button to display a list of events as shown below



To select an event press these buttons to scroll through the events, or simply touch the event information line.

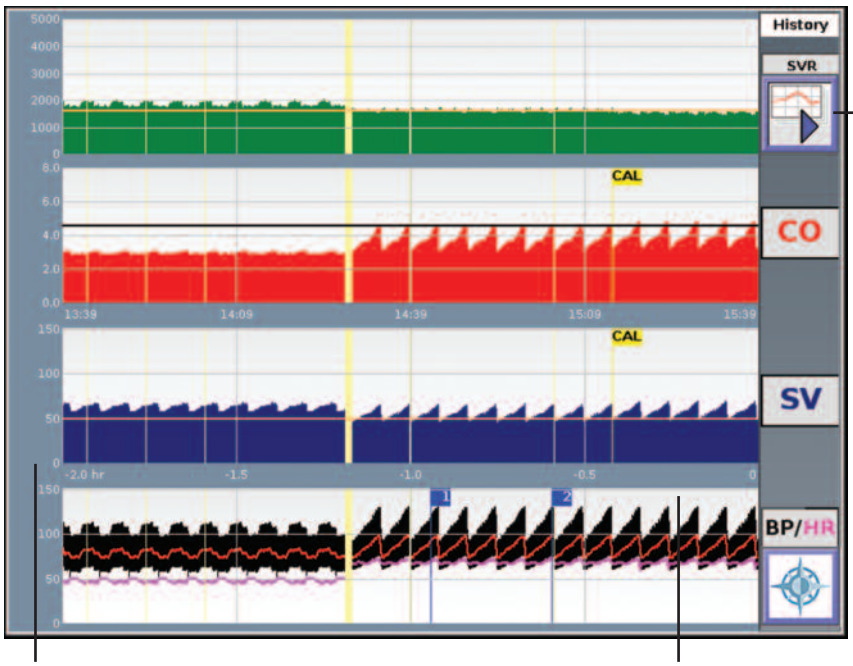
Press this button to edit event information such as Event, Characteristic or Additional Information.

Note: The timing of the event cannot be changed.

3.2.8 History and Chart Screens

Press this button to access the History Screen.

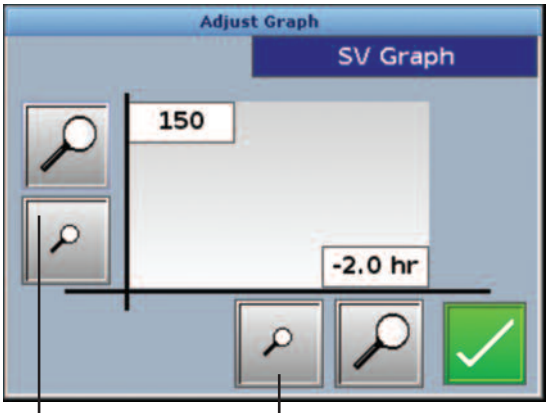
The History screen can be used to look back over up to 24hrs of hemodynamic data, including preload response parameters SVV, PPV and HRV. Absolute or index values are displayed based on the configuration screen settings (3.2.6).



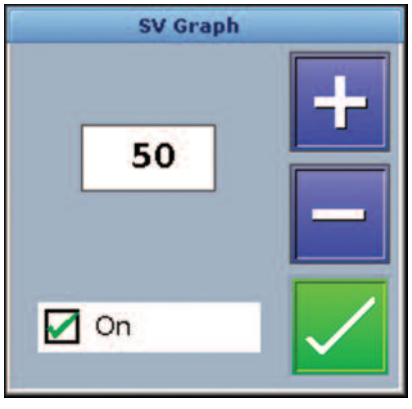
Press here to alternate this graph between SVV, PPV and SVR

Touch the vertical axis to display the control window.

Touch inside the graph to display the target window for CO, SV or SVR



The scale of both axes can be adjusted by de-selecting "Auto-scale" and using the increase/decrease buttons.



The target line can be added by selecting the "on" box; it can be adjusted by using the increase/decrease buttons.

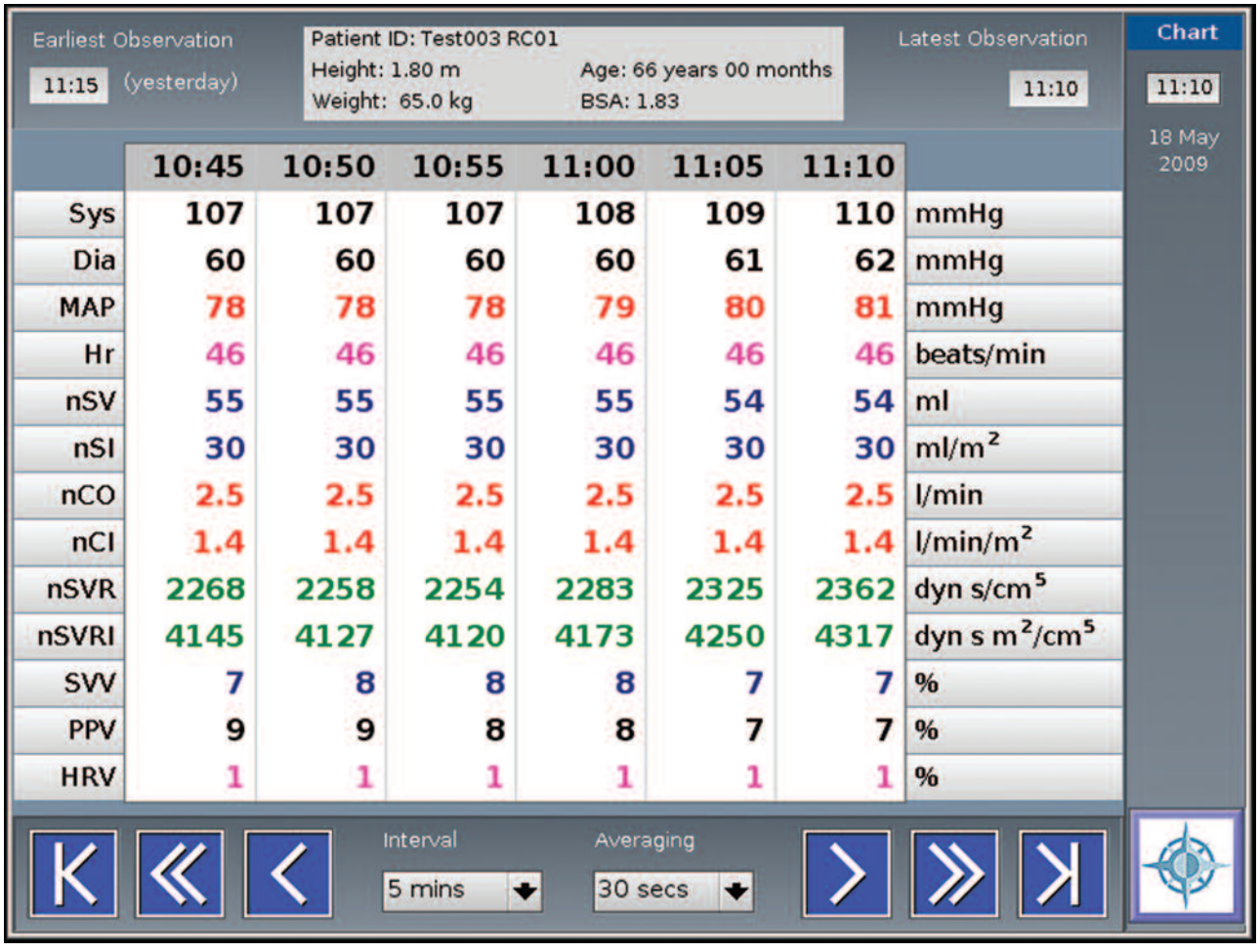
Press this button to enter the chart screen

The Chart Screen allows for numeric data display to assist in recording values for routine clinical charts as well as general review. The Chart screen displays all the LiDCO*rapid* hemodynamic parameters, including absolute and index values, in six (6) columns. Data are available for up to the past 24hours.

The Earliest data is the oldest data available

Patient Information

The Latest data is the most recent data available.



	10:45	10:50	10:55	11:00	11:05	11:10	
Sys	107	107	107	108	109	110	mmHg
Dia	60	60	60	60	61	62	mmHg
MAP	78	78	78	79	80	81	mmHg
Hr	46	46	46	46	46	46	beats/min
nSV	55	55	55	55	54	54	ml
nSI	30	30	30	30	30	30	ml/m^2
nCO	2.5	2.5	2.5	2.5	2.5	2.5	l/min
nCI	1.4	1.4	1.4	1.4	1.4	1.4	$l/min/m^2$
nSVR	2268	2258	2254	2283	2325	2362	$dyn\ s/cm^5$
nSVRI	4145	4127	4120	4173	4250	4317	$dyn\ s\ m^2/cm^5$
SVV	7	8	8	8	7	7	%
PPV	9	9	8	8	7	7	%
HRV	1	1	1	1	1	1	%

Data Navigation:
Press to move

- by one column
- by one page
- to start of data

Interval the period between each displayed time point. The interval choices are 5 (default), 15 and 30 minutes or 1, 2 and 4 hours. For example, hourly data intervals will display data at the start of each clock hour, starting when the first full hour has passed.

Averaging the time period for data averaging at each time point. The data can be averaged for periods of 10 (default), 30 or 60 seconds.

3.3 Safety Instructions, Maintenance and Cleaning

Safety Instructions (see also inside front cover)

- Always refer to the LiDCO*rapid* Hemodynamic Monitor User's Manual.
- Check the power supply voltage is suitable for use with the LiDCO*rapid* Hemodynamic Monitor before connecting the equipment to the power outlet.
- Disconnect the LiDCO*rapid* Hemodynamic Monitor and the power supply unit from the voltage supply when not being used.
- Disconnect this equipment from any AC outlet before cleaning. Use a damp cloth and do not use liquids or spray detergents for cleaning.
- The BPM is not Category AP or Category APG and should not be used in the vicinity of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.
- When disconnecting a cable, pull on the connector not the cable itself.
- Do not attempt to remove the back cover of the LiDCO*rapid* Hemodynamic Monitor or open the power supply unit as you will be exposed to an electric shock hazard. This operation should only be performed by LiDCO Ltd certified service personnel.
- To avoid the risk of electric shock, or permanent damage to the product, do not expose any of the LiDCO*rapid* Hemodynamic Monitor or power supply unit components to rain, liquids or excessive moisture.
- Consult qualified service personnel if the LiDCO*rapid* Hemodynamic Monitor does not operate normally, the power supply unit or power cord is damaged or moisture/liquid has penetrated the product.

Maintenance

The following maintenance is required for the LiDCO*rapid* Hemodynamic Monitor
1. Annual electrical safety check in accordance with hospital protocol

Cleaning

⚠ WARNING: To avoid potentially life-threatening patient cross infection always follow your hospital's recommended microbiological decontamination procedure for cleaning the LiDCO*rapid* System.

Recommended cleaning materials and methods are shown below:

To clean: Wipe with a cloth moistened with a soap solution.

To disinfect: Wipe with a gauze moistened with a dilute alcohol or glutaraldehyde-based disinfectant.

Dry thoroughly with a lint-free cloth.

3.4 Troubleshooting the LiDCO*rapid*

Description	Possible Causes and Corrective Measures
1. Setup Screen	
Cannot access the LiDCO*rapid* Screen	• Data must be filled into the fields: Patient's ID, Height, Weight and Age before accessing the LiDCO*rapid* Screen Enter data in yellow boxes Press Start button
2. Set-Up Procedure	
Difference of greater than 5% between parameters displayed on primary monitor and those shown on the BP Window of the LiDCO*rapid*	• BP Cable not connected to primary monitor and/or at the LiDCO*rapid* ADC connection Check connections • Primary Monitor analogue output is not to the LiDCO*rapid* Hemodynamic Monitor ADC Specification of 100 mmHg = 1 volt Check analogue pressure output specification of Monitor or Module used • LiDCO*rapid* ADC faulty Confirm with PulseCO simulator or another Primary Monitor
No BP Waveform is observed on any channel	• Check all cable connections • For Channel 2 zero the Patient Monitor IBP waveform
No values are displayed for Channel 1	Check all cable connections
Zero Fail: Signal Varying Zero Fail: Offset too large	Channel 1 must be zero'ed before values will display
No BP waveform or values are displayed for Channel 2	Check cable connections
No cable for Channel 2	Contact your LiDCO representative to obtain a cable. Specify the Make/Model of your Patient Monitor.
The BPM is compliant with the applicable EMC requirements. It may still be affected by and/or affect other equipment. If interference occurs:	Reposition to reorient and/or increase the separation between the equipment. Connect the equipment to a power outlet on a different circuit.

Description	Possible Causes and Corrective Measures
3. LiDCOSmart Card	
Smartcard is not recognised or Invalid Smartcard	• Wrong card or inserted incorrectly Check card is a LiDCOsmart and is oriented facing the user with the chip-end entering the monitor first (see section 3.1.3)
Smartcard is expired	• Card has expired and can no longer be used Replace card with a new LiDCOsmart
4. Data Download	
Buttons Not Active Download does not complete	• USB device is not attached • USB device is full • USB device is not compatible Check USB device is attached Try a different USB device
5. Serial Data Interface	
Data does not appear on Philips Monitor Data does not appear on Interfacing Monitor	• Vuelink Enabled not selected for Serial Link Select Vuelink in Engineering Screen, Data Communications, then restart monitor • LiDCOserial Enabled not selected Serial Link Select LiDCOserial in Engineering Screen, Data Communications, then restart monitor

4.0 Appendices

A. Engineering Screen

The LiDCO*rapid* has an Engineering Screen which allows for configuration of the monitor, downloading of data files and a demonstration mode.

The Engineering Screen is accessed from the Startup Screen by pressing the Engineering Screen button.

The Engineering Screen has three main purposes

Demonstration
Data Download
Engineering Functions

Engineering Functions

The following is a brief description of the Engineering functions. Where noted, these functions should be performed by LiDCO personnel, authorised representatives or suitably trained staff.

Set Date/Time: adjust date or time

Serial Interface: turn RS232 interface on/off and configure frequency of data transfer

Configure TCP/IP: set ethernet communications details

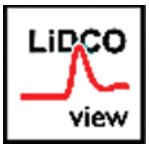
Update Software: used to upgrade software (LiDCO or authorised representative)

Engineering Logs: monitor functional details and error capture (LiDCO or authorised representative)

Demonstration

Calibrate Touchscreen: LiDCO or authorised representative only

LiDCOsmart card: LiDCO or authorised representative only



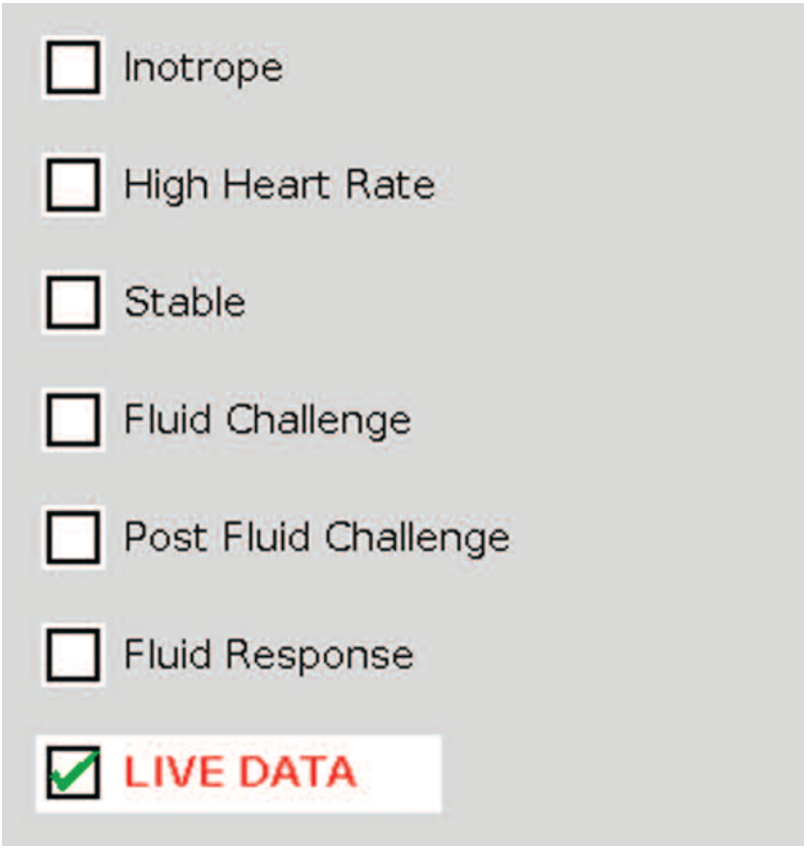
Data Download

Demonstration

Demonstration mode allows the user to playback one of several waveforms into the LiDCO*rapid*.

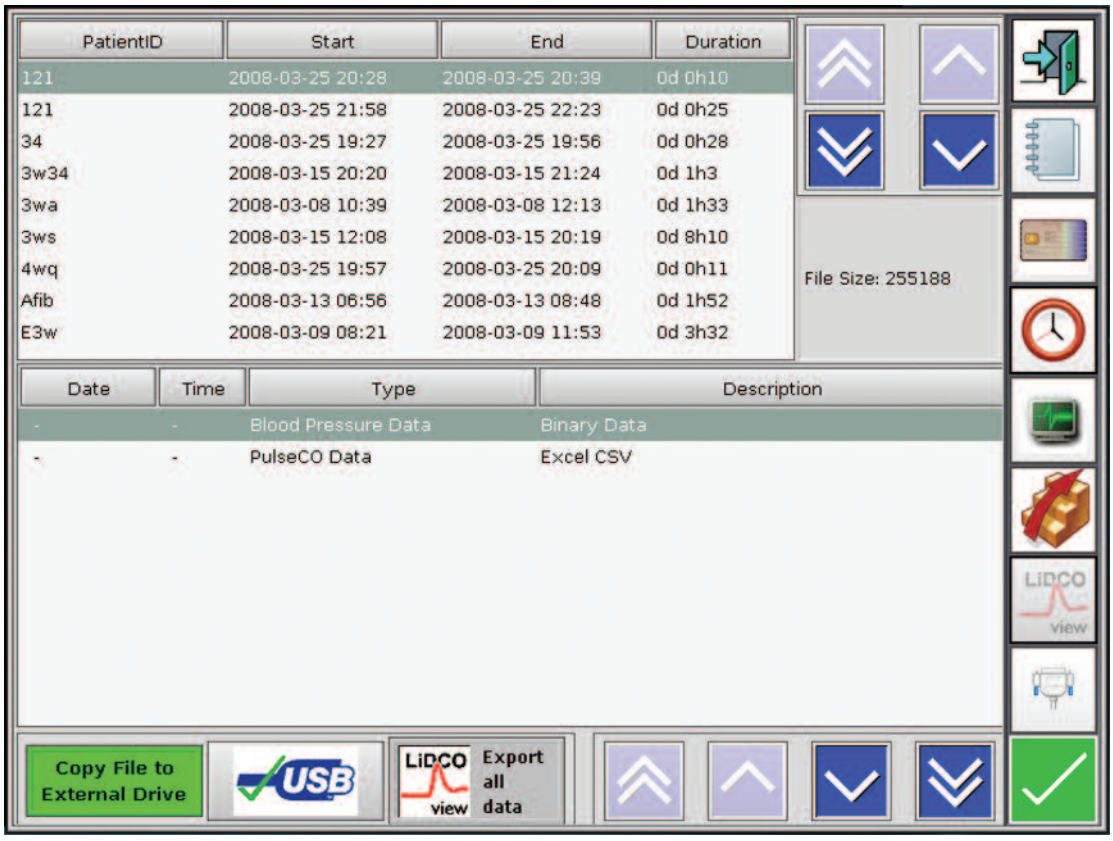
Note that the monitor will display a periodic message when a demonstration waveform is being displayed. In this mode, the normal blood pressure signal input is ignored.

The following waveforms are available in demonstration mode:



Inotrope
High Heart Rate
Stable
Fluid Challenge
Post Fluid Challenge
Fluid Responsive

Data Download



The LiDCO*rapid* stores patient data for 6 months. The data download feature allows patient files to be downloaded either as LiDCO*view* files (*.LVU) or for the specific files to be downloaded separately. All data is downloaded to USB drives which must be inserted before a download can occur. The files are organised according to the patient ID field. The patient's name is not included in any of the data files.

The download screen allows easy navigation of the available data by collecting all files with the associated patient ID 'folder'. These 'folders' can be sorted by Patient ID, Start, Stop or Duration. In the lower window all the associated files are displayed.

To download data

1. Attach a USB device and ensure it is acceptable 
2. Select the Patient ID
3. Press the LiDCO*view* button to download the entire data set (*.LVU) or
4. Select the specific file in the lower window and press the Green 'File Download' button.

Note: Some USB devices may not work with LiDCO*rapid*.

Data Communications

Press this button to enter Data Communications

Connect 9-pin D-type cable to COM1 port

Data Output: CO/CI, SV/SVI, SVR/SVRI, PPV, SVV, HRV

Philips VueLink

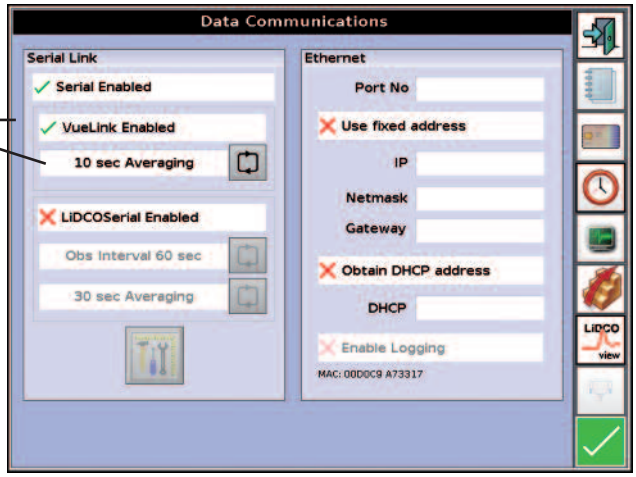
Press Serial Enabled and Vuelink Enabled

Requires Vuelink Module 'Aux Plus' (M1032A, A05)

And Interface Cable: M1032-61699, K6C

Interval is set by Philips

Averaging can be set to: No, 10, 20 or 30 seconds

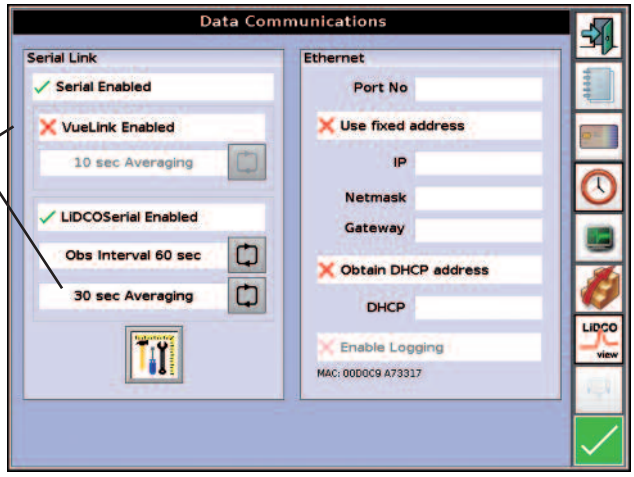


Other RS-232 Connections

Press Serial Enabled and LiDCOSerial Enabled

Interval can be selected from beat data to 4 hourly

Averaging can be set to: 10, 20, 30 or 60 seconds



Contact LiDCO for a detailed interface specification.

B. Specifications

General Specifications:

Monitor - HM 81-01		
Platform:	POC-125	DTP1201
Weight:	4.8kg	4.75kg
Dimensions:	420 x 323 x 106mm	370 x 230 x 75
Input:	24VDC	100-250 VAC 50-60 Hz
Power Consumption:	50W	60W
Display:	12" Colour LCD	12" Colour LCD
User Interface:	Touchscreen	Touchscreen
External Connections:	Power	Power
	Analog Blood Pressure Input	Analog Blood Pressure Input
	File Download	File Download
Operating Conditions:	10-40°C	10-40°C
	30-75% RH non-condensing	30-75% RH non-condensing
	700-1060 hPa	700-1060 hPa
Input Signal Specification:		
Output Scaling:	1V/100mmHg	
Range:	0-2.5VDC (0-250mmHg)	
Accuracy:	± 3% of full scale	
Signal to noise:	better than -55dB	
Internal ADC card Specification:		
Resolution:	12bit	
Accuracy:	0.01% ± bit	
	Stability: better than 0.5% Full Scale (over 4 hours)	
Equipment Classification:	SELV (IEC 601)	Class 1
	For Continuous Use	For Continuous Use
	Not Protected Against Water Ingress	
	Not for Use in the Presence of Flammable Gases	
Fitted with a 3V, 195mA lithium battery. Only to be replaced by qualified service personnel. Dispose of the old battery in a safe manner that complies with applicable laws.		

Desktop Stand: Li10533 Spacer for Desktop Stand Li10532 Li10532 Desktop Stand for POC-125 Monitor Platform	
Weight:	1.0kg
Dimensions:	383 x 214 x 93mm
Rotation:	Fixed at 20°

Power Supply Unit: POC - 125 PSU PCM80P524	
Input:	100-250 VAC 50-60Hz
Output:	24VDC
Equipment Classification:	Class 1 (IEC 601)

LiDCOsmart Card Li10506	
Type	Microprocessor-integrated chip
Size (WxLxT)	Nominal: 86x54x0.76mm(7816-1)
Memory	1Kb minimum

C. Electrical Safety

Appendix 4 - IEC 60601-1-2:2001 (BS EN 60601-1-2:2002) Guidance and Manufacturer's Declaration

The LiDCO*rapid* Hemodynamic Monitor System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below. Portable and mobile RF communications equipment can affect the LiDCO*rapid* Hemodynamic Monitor System.

To assure compliance the LiDCO*rapid* Hemodynamic Monitor System should only be used with the following cables, supplied by LiDCO:

Description	Maximum length
AC Power Cord	<3.0m
DC Power Cord	<3.0m
PulseCO (LiDCO*rapid*) to Patient Blood Pressure Monitor	<3.0m
BPM Interface Cable	<4.0m

Use of accessories and cables with the LiDCO*rapid* Hemodynamic Monitor System, other than those supplied by LiDCO, may result in increased emissions or reduced immunity of the LiDCO*rapid* Hemodynamic Monitor System.

Guidance and manufacturer's declaration – electromagnetic emissions		
The LiDCO*rapid* Hemodynamic Monitor System is intended for use in the electromagnetic environment specified below. The customer or the user of the LiDCO*rapid* Hemodynamic Monitor System should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The LiDCO*rapid* Hemodynamic Monitor System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LiDCO*rapid* Hemodynamic Monitor System is suitable for use in all establishments, including domestic establishments and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic emissions	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The LiDCO*rapid* Hemodynamic Monitor System should not be used adjacent to or stacked with any other equipment and that if adjacent or stacked use is necessary the LiDCO*rapid* Hemodynamic Monitor System should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic immunity			
The LiDCO*rapid* Hemodynamic Monitor System is intended for use in the electromagnetic environment specified below. The customer or the user of the LiDCO*rapid* Hemodynamic Monitor System should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be less than 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ±1kV for input/output lines	± 2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 secs	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 secs	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LiDCO*rapid* Hemodynamic Monitor System requires continued operation during power mains interruptions it is recommended that the LiDCO*rapid* Hemodynamic Monitor System be powered from an uninterruptable power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 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.			

Electrical Safety Testing

The LiDCO*rapid* POC-125 monitor is a (SELV) Safety Extra Low Voltage device, powered using a Class 1 power supply. There are no patient applied parts or protective earth connection. Electrical safety is achieved through the monitor being a SELV device and through the construction of the Class 1 power supply. The system has been tested and complies with all relevant clauses of IEC 60601-1 standard.

Electrical Safety Testing:

1. Test the system as a Class 1 Type B IEC 60601-1 device. (Refer to your Electrical Safety Analyser user manual)
2. The protective earth resistance test is *not* a requirement for the POC-125 LiDCO*rapid* monitor. Either omit the test manually or ignore the test result if it is part of an automatic test sequence.
3. All tests must pass the IEC 60601-1 test limits with the exception of the protective earth resistance test.

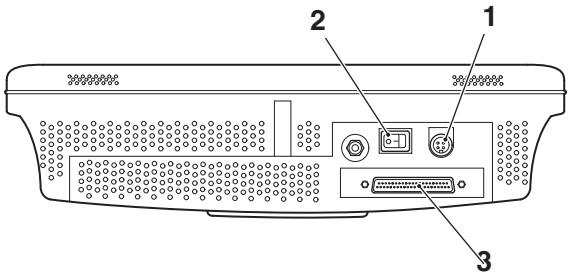
Note: The stud on the rear of the monitor is an equipotentiality connection only. This should *not* be confused with a protective earth connection ⏚.

The LiDCO*rapid* DTP1201 is a Class 1 device. The system has been tested and complies with all relevant clauses of IEC 60601-1 standard.

D. Monitor Connectors Layout

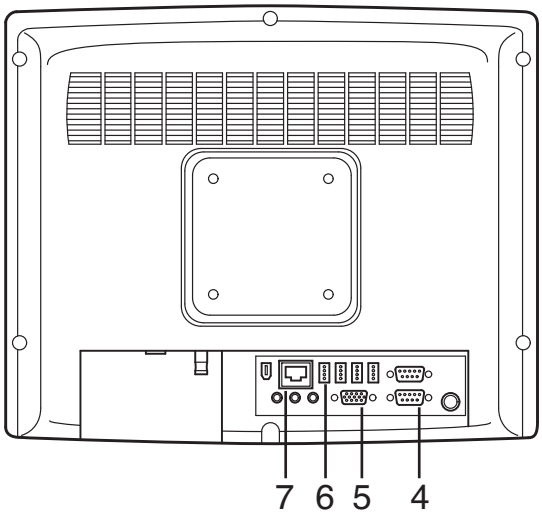
POC-125/127

Bottom view of monitor



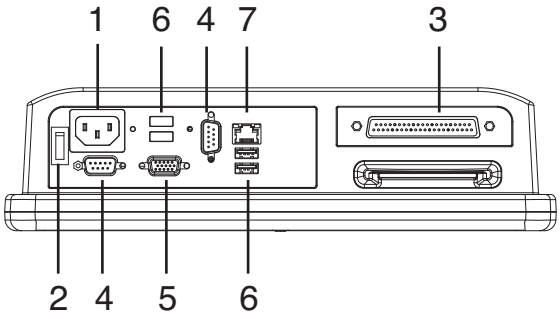
1. Power cable input
2. On/off switch
3. BP signal input to ADC card

Rear View of monitor



4. RS232
5. VGA
6. USB ports
7. Ethernet

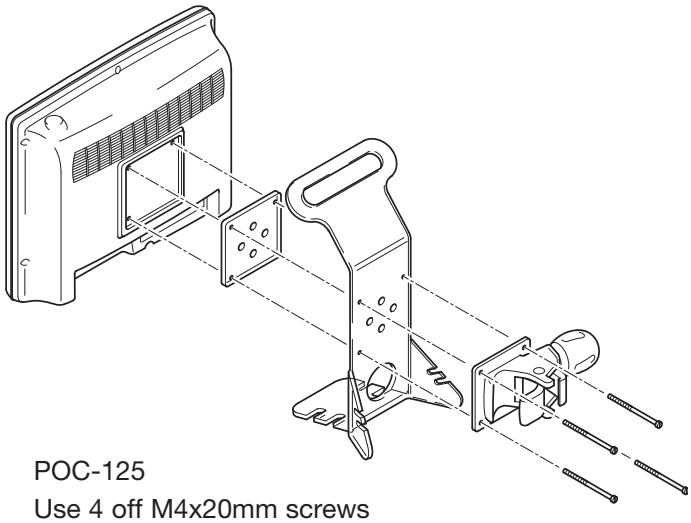
DTP-1201



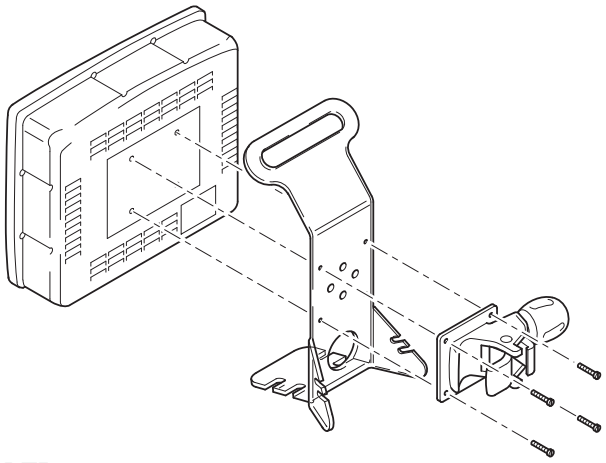
1. Power cable input
2. On/off switch
3. BP signal input to ADC card
4. RS232
5. VGA
6. USB ports
7. Ethernet

E. LiDCO*rapid* mounting options

• Desk top stand and pole mount clamp

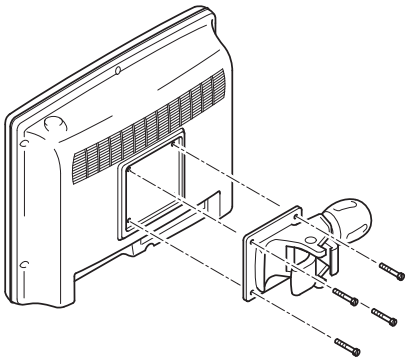


POC-125
Use 4 off M4x20mm screws

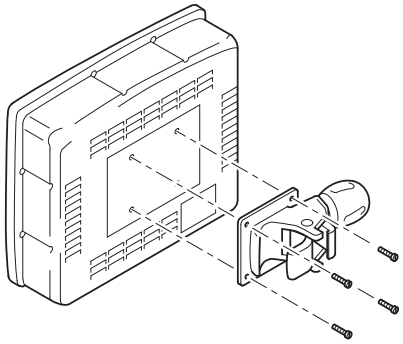


DTP 1201
Use 4 off M4x16mm screws

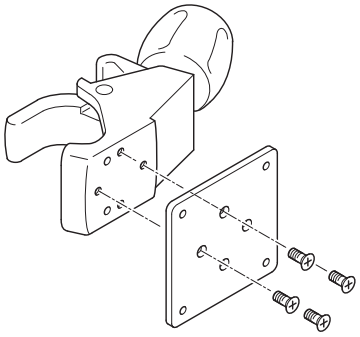
• Pole mount clamp



POC-125
Use 4 off M4x12mm Screws



DTP 1201
Use 4 off M4x10mm screws



Use 4 off 10-32 x 5/16" FHMS

LiDCO Blood Pressure Module Installation

M4 Screw Lengths, mm	LiDCO*rapid* (POC-125)	LiDCO*rapid* (DTP-1201)
Figure A Pole Clamp	25mm	12mm
Figure C Stand & Pole Clamp	25mm	16mm
Figure D Stand	25mm	16mm

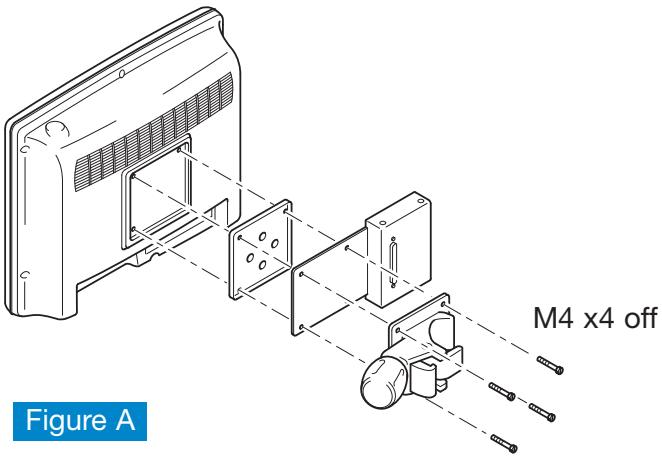
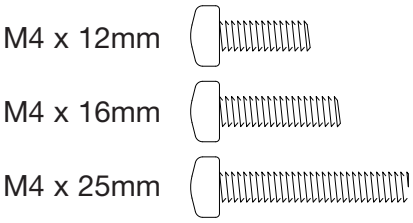


Figure A



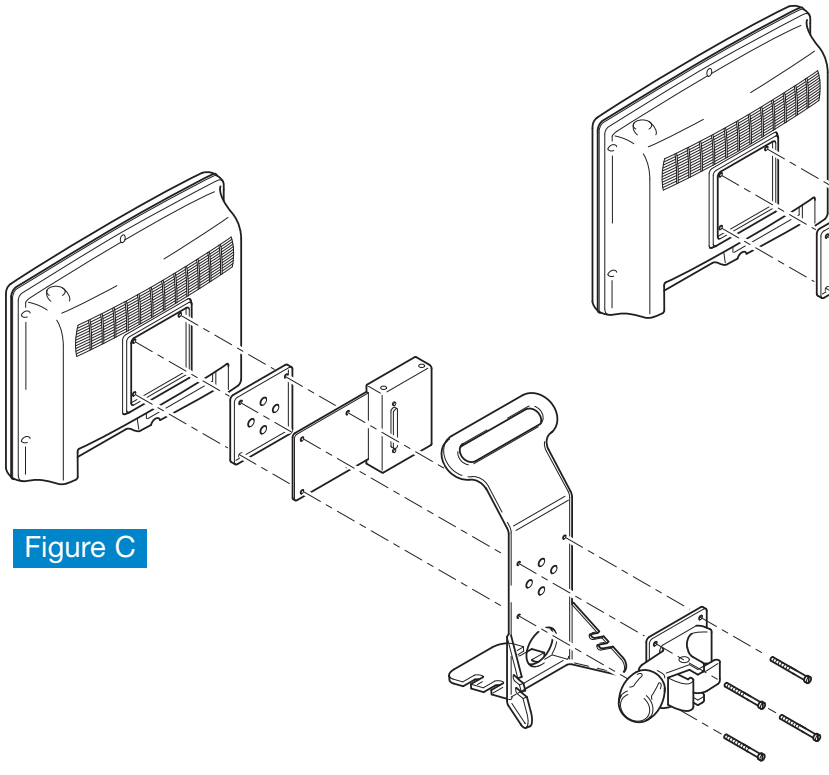


Figure C

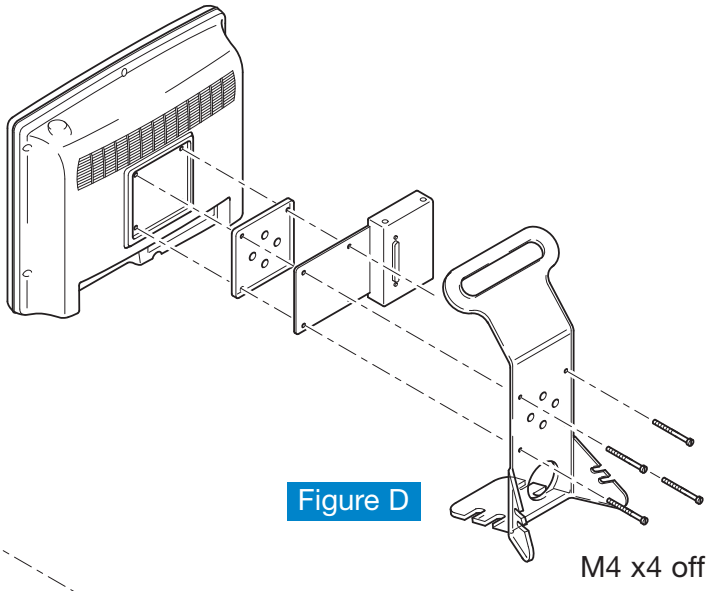


Figure D

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