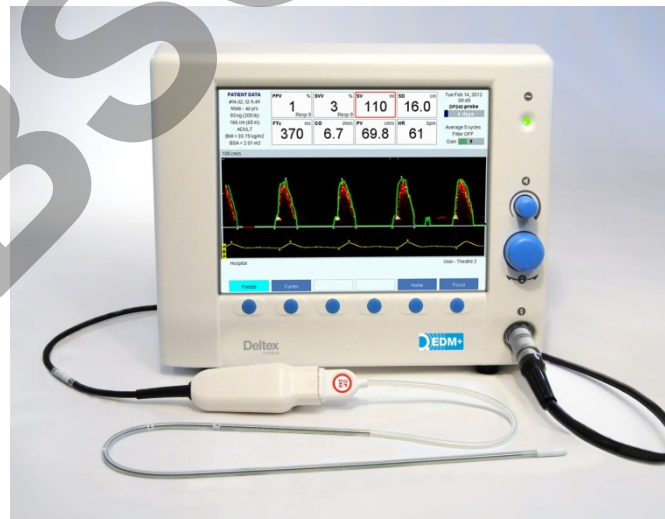


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Deltex Medical Inc.



Fluid Management and Cardiac Output Monitoring System



OPERATING HANDBOOK

This operating handbook reflects the specification of the CardioQ-EDM+™ fluid management and cardiac output monitoring system and its operation at the time of publication. Deltex Medical™ Limited reserves the right to change the specification at any time, without notice.

This operating handbook describes the operation of the CardioQ-EDM+ using 4.0x series application software (x refers to software revisions that do not affect instructions in this operating handbook).
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Software upgrades will be carried out by your Deltex Medical representative as necessary.

The CardioQ-EDM+ software may have a time-limited license applied.

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Contents

1.	Conventions Used in the Handbook	1
2.	Indications, Precautions, Warnings and Contraindications	2
2.1	Indications	2
2.2	Precautions.....	2
2.3	Warnings	2
2.4	Contraindications.....	4
3.	Monitor Description	5
3.1	Front and Rear Panels	5
3.2	Position of Monitor, Patient and User in Normal Use.....	5
3.3	Patient Data storage.....	5
3.4	Control Philosophy	6
3.5	Use of Pressure-Based Data.....	7
4.	Deltex Medical Doppler Probes for the CardioQ-EDM+	8
4.1	General Information.....	8
4.2	Probe Storage	8
4.3	Probe Disposal	8
4.4	Probe Expiry	8
4.5	Adult Oral/Nasal Probes	8
4.6	Nomogram Limits	9
5.	Setting Up the Monitor for Use.....	10
5.1	Initial Assembly.....	10
5.2	Mounting the CardioQ-EDM+	10
5.3	Set Up.....	10
5.4	Changing the Selected Language	10
5.5	Changing the Date, Time or Daylight Saving Time (DST)	10
5.6	Connecting the Probe.....	11
5.7	Turning Off the Monitor.....	11
6.	Initial Screens.....	12
6.1	Remaining Probe Use Indicator	12
6.2	Patient Identification	12
6.3	Patient Data Screen	13
6.4	Monitoring a New Patient	13
6.5	Monitoring an Existing Patient With a New Probe.....	13
6.6	Deleting a Patient	13
7.	Obtaining the Correct Flow Signal (Doppler)	14
7.1	Positioning the Probe	14
7.2	Setting the Range.....	15
7.3	Setting the Signal Filter	16
7.4	Setting the Signal Gain.....	16
7.5	Finding the Maximum Flow	17
7.6	Full width Run Screen	17
7.7	Changing the Number of Cycles Averaged for Calculations	18
7.8	Ventilator related variables.....	18
7.9	Freezing the Display.....	18
7.10	Probe Disconnection	19
7.11	Probe Reconnection	19
8.	Additional Calculations.....	20
8.1	Systemic Vascular Resistance (SVR) and Systemic Vascular Resistance Index (SVRI).....	20
8.2	Displaying SVR Calculations	21
8.3	Delivered Oxygen (DO ₂) Delivered Oxygen Index (DO ₂ I)	21
8.4	Displaying DO ₂ Calculations.....	22
9.	Pressure Monitoring.....	23
9.1	Calibration	23
9.2	Probe Disconnection and Reconnection	23
10.	Snapshots	24
10.1	Taking a Snapshot.....	24

10.2	Viewing Snapshots	24
10.3	Comparing Snapshots	24
10.4	Deleting Snapshots	25
11.	Events	26
11.1	Recording Events	26
11.2	Recalling Events	26
12.	Trend Display	27
12.1	Historical Data-Continuous Trends	27
12.2	Displaying Trend Information	27
12.3	Graphical Trends	28
13.	Customizing the Monitor	29
13.1	Restoring the Factory Settings	29
13.2	Adding a Hospital Name	29
13.3	Linking to a Patient Monitor	29
13.4	Selecting a User	30
13.5	Multiple User Setups	30
13.6	Setting User Profiles	30
13.7	Setting Default Results	31
13.8	Setting Machine Default Settings	31
13.9	Change Adult or Linear Settings	31
14.	USB and Offloading Patient Data	32
14.1	Saving Screens	32
14.2	Recording Continuous Data	32
14.3	Signal Recording	32
14.4	Offloading Patient Data	33
14.5	Offloading Information for Deltex Medical	33
15.	Demonstration Mode	34
15.1	Running the CardioQ-EDM+ in Demonstration Mode	34
16.	Fault Diagnosis Guide	35
16.1	Fault Diagnosis	35
16.2	Checking the Software Version	35
17.	System Specifications	36
17.1	Classification	36
17.2	Performance Characteristics	36
17.3	Physical Characteristics	36
17.4	Environmental Characteristics	36
17.5	Monitor and Lead Disposal	36
17.6	System Characteristics	36
17.7	Acoustic Output	37
17.8	Acoustic Output Safety	38
17.9	Ranges	38
17.10	Accuracy	39
17.11	Results	41
17.12	RS232 Protocols	41
17.13	Power Supply	41
17.14	Auxiliary Connections	42
17.15	Symbolic Markings	42
17.16	Accessories and Spares	43
17.17	Probes and Probe Accessories	43
17.18	Electromagnetic Compatibility (EMC)	43
17.19	Manufacturer's Declaration	44
18.	Cleaning, Maintenance and Warranty	47
18.1	Monitor Cleaning	47
18.2	Routine Maintenance	47
18.3	Repairs, Servicing and Calibration	47
18.4	Warranty	47

1. Conventions Used in the Handbook

The following symbols or text appear in the operating handbook:

	Any similar symbol instructs the user to press the button below the button label.
	'And then' or 'then press'.
	Please note.
	Warning.
	Rotate the Control Knob to make a selection. In the operating handbook, this excludes button selection.
	Press the Control Knob to confirm a selection.
<i>Probe Focus Screen</i>	Any such text indicates a specific screen.
	Snapshot icon in <i>Trend Screens</i> .
	Signal recording icon.
	Signal recording terminated icon.
	Continuous data recording icon.
	Scroll icon in <i>Graphical Trend Screen</i> .
	Patient monitor not connected.
	Patient monitor connecting.
	Patient monitor connected.
	Saving data.

2. Indications, Precautions, Warnings and Contraindications

2.1 Indications

The CardioQ-EDM+ fluid management and cardiac output monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM+'s beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

2.2 Precautions

The probes are only approved for oral or nasal placement into the esophagus, depending on the type of probe. Depending on the method of placement and probe type, the patient may be fully sedated, or under general or local anesthesia. Refer to the individual probe packaging for instructions for use.

The data may change as a result of cross clamping of the aorta. However, during the cross clamping period, the data are reliable and can be used to guide clinical practice. This data in the cross-clamping period should not be compared with data obtained in the periods when the aorta is not clamped.

The Doppler probes have a designated time limit and when that limit is exceeded, the probes will cease to function. Refer to the individual probe packaging for instructions for use.

No major esophageal complications have been reported with probe use. As with any naso-gastric or naso-esophageal tube/probe, some local inflammation can be seen on endoscopy after a number of days.

Interpretation of cardiac function should always be considered in conjunction with other clinical signs and symptoms. Users should review the manufacturer's clinical materials, as there is a learning curve that may affect the interpretation of results.

When using stroke volume variation (SVV), stroke distance variation (SDV) or pulse pressure variation (PPV) to guide fluid management please note that the parameters sensitivity is optimal when tidal volume is $\geq 7-8$ ml/kg and that higher tidal volumes elicit higher variations.

The CardioQ-EDM+ excludes arrhythmic events based on heart rate variability ($\geq 20\%$) and excessive variation in stroke volume. However the user should be aware that in periods of arrhythmia SVV, SDV or PPV should not be used to guide fluid management.

SVV, SDV-or PPV parameters are only of clinical use in patients which are fully mechanically ventilated with closed chest Varying PEEP settings may affect hemodynamic measurements.

When using SVV, SDV or PPV parameters may be compromised during laparoscopic procedures or where the patient is in such a position that additional pressure is applied to the thorax e.g. prone or head down procedures.

2.3 Warnings

Do not use undue force upon insertion. Remove if difficulty arises and seek advice.

Coagulation status should be verified against the possibility of nasal bleeding when nasal placement is considered.

The CardioQ-EDM+ is not a vital signs monitor, nor should it be used as a substitute for one.

This equipment is not suitable for use in the presence of flammable anesthetics with air or oxygen or with nitrous oxide.

To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

No modification of this equipment is allowed.

Any unauthorized connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with IEC 60601-1) to the CardioQ-EDM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

DPn and I₂n probes are approved for use on a single patient only and must be disposed of as soon as use on that patient is no longer required. Under no circumstances should the probe be used in a different patient.

Warnings and mandatory limitations are available on the probe packaging.

DO NOT pull on the cables to remove the connectors from their sockets.

If space is needed for a patient when a probe is connected, the patient with the oldest last use time is automatically deleted without user intervention.

When the probe usage expires, "Probe expired" is displayed on an orange bar and flow monitoring will cease immediately. If valid pressure data are displayed, pressure monitoring will continue for up to four hours. If it is necessary to continue flow monitoring the patient, the probe should be changed as soon as possible.

The CardioQ-EDM+ can store details for 16 patients. If space is needed for a patient when a probe is connected, the patient with the oldest last use time is automatically deleted without user intervention.

Patients' data will be automatically deleted to create space.

Inappropriate range/scale settings will affect the data displayed.

Wherever possible, the patient treatment should be carried out with the same filter settings. Changing the filter settings while monitoring is in progress or if the filter is used when not required, this may cause inappropriate placement of the base arrows and may affect the reported results. This must be taken into account when interpreting trend or graphical data.

The data will not be displayed if the heart rate: respiratory rate ratio is <4 i.e. there must be at least 4 heart beats in each respiratory period. It will also not be displayed if the heart rate variability is >20%. The respiratory rate must be in the range of 7-40bpm.

If the CardioQ-EDM+ is reset to factory settings, the selected language will change to the global default; English (UK), and any historical data held in the monitor will be deleted and the User profiles will be deleted.

Disconnect power for at least 30 seconds first.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

2.4 Contraindications

Doppler probes (DP240 and I₂n) should not be placed in patients under 16 years of age.
Do not use where nasal injuries are apparent or may have occurred.
Do not use where nasal polyps exist.
Do not use where there are circumstances of facial trauma.
Do not use where there is a risk of brain injury.
Do not use in patients undergoing intra-aortic balloon pumping.
Do not use with carcinoma of the pharynx, larynx or esophagus.
Do not use with aneurysms of the thoracic aorta.
Do not use with tissue necrosis of the esophagus or nasal passage.
Do use in close proximity to laser surgery.
Do not use in patients with pharyngo-oesophago-gastric pathology and/or severe bleeding diatheses.



For detailed precautions and warnings on probe usage, refer to the individual probe packaging for instructions for use.

For further information including a Technical Report on how esophageal Doppler monitoring works, summaries of randomized clinical trials and case histories, visit www.deltexmedical.com.

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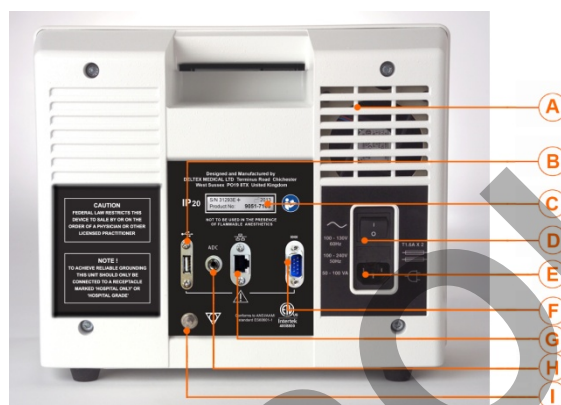
3. Monitor Description

3.1 Front and Rear Panels



- A. Green power indicator. When illuminated, this shows that AC power is present and that the unit is switched on.
- B. Color LCD display.
- C. **Volume Control Knob.**
- D. **Control Knob** used to make selections.
- E. The six push buttons which control the monitor functions.
- F. The patient interface cable socket.

Figure 3.1.1. Front of Monitor.



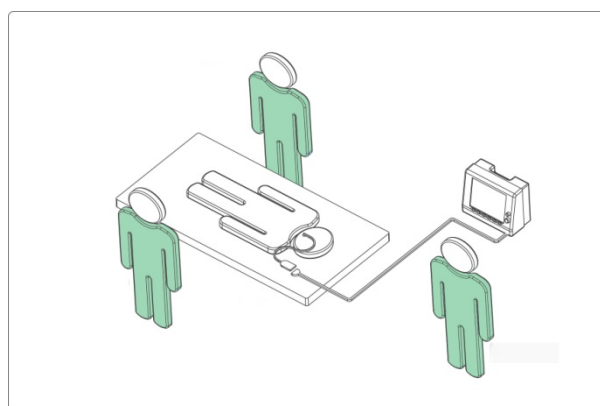
- A. The vents on the rear and base of the unit are required for cooling and must **NOT** be obstructed.
- B. USB port for offloading data.
- C. Model and serial numbers.
- D. On/Off switch.
- E. Mains input.
- F. Serial (RS232) port
- G. Network Port (UTP) for future use.
- H. Analogue to Digital Converter connector (ADC).
- I. Equipotential earth terminal if required. See section 17.14.

Figure 3.1.2. Rear of Monitor.



Any unauthorized connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with IEC 60601-1) to the CardioQ-EDM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

3.2 Position of Monitor, Patient and User in Normal Use



3.3 Patient Data storage

The monitor can store data for 16 patients for an indefinite time or until that patient is deleted from the monitor. This data can be offloaded. See section 14.4.

3.4 Control Philosophy



There may be two rows of button labels at the bottom of the screen. Use this button to switch rows. If a button has no function on a screen, no label is displayed for it.



Many screens contain this button. Pressing this button displays the top-level menu. This menu allows a selection of various views. Navigation sometimes starts with this button.



Pressing this also confirms a selection and exits an existing screen. Press this to move up a level in the menu to locate the **Home** button.



Pressing this also confirms a selection and exits an existing screen.



This button cancels a selection and exits an existing screen. Press to move up a level in the menu to locate the **Home** button.

Rotate the **Control Knob** to make a selection. A cyan-colored area on the screen, if present, indicates where the **Control Knob** is operating.



This icon is present when the **Control Knob** is controlling a selected area in the *Graphical Trend Screen*.

If the **Control Knob** is not being used to scroll or make a list selection etc, it may be used to select a button and pressing the **Control Knob** will action the button when this is available. The available button will be displayed in cyan. Rotating the **Control Knob** will select other buttons in either row.

Push the **Control Knob** to confirm the selection, or press **Finished** or **Continue**.



Accept data or **Confirm** buttons cannot be selected or actioned with the **Control Knob**. These buttons must be pressed.

A confirmation screen will be displayed in yellow in certain circumstances, in case of accidental selection.

A message will be displayed on a yellow background if there are certain events or suggested changes.

Text may be entered in various screens. Follow the on-screen instructions to enter text when prompted to do so. Use the **Control Knob** as described above and use upper or lower case letters or numbers with the controls illustrated in **Table 3.4.1**.

Control	Function	Description
	Start	Go to beginning
	Delete	Delete character
	End	Go to end
	Insert	Insert a character
	Left	Move left one character
	Right	Move right one character
	Shift	Alternate between upper and lower case letters



If an irrecoverable error or failure occurs in the monitor, a fault message or code will be displayed on a red background in the central part of the screen and the unit will stop. Make a note of the fault code, as it may be required by Deltex Medical if the monitor continues to malfunction. In order to recover from this situation, the power must be turned off and on again. If the fault persists, please contact your Deltex Medical representative.

3.5 Use of Pressure-Based Data



In order to use the pressure-based data, input is required from an arterial blood pressure (ABP).

These inputs must be scaled as $1v=100\text{mmHg}$.

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4. Deltex Medical Doppler Probes for the CardioQ-EDM+

4.1 General Information

Deltex Medical manufacture a range of Doppler probes designed for use with the CardioQ-EDM+. These probes are supplied in various multi-packs, with each probe in its own container. These multi-packs are sold separately.



Refer to the label on the probe packaging to ensure that a probe is suitable for the patient and placement type intended. Warnings will appear on the screen if the patient data entered indicates that the connected probe is unsuitable, or a specific placement method must be used. All probe variants may not be available in certain countries. For more details on probe availability, contact your Deltex Medical representative.



Take care when removing the probe from the packaging, as the internal spring will cause the probe to uncoil and straighten on release from the packaging.



DPn and I₂n probes are approved for use on a single patient only and must be disposed of as soon as use on that patient is no longer required. Under no circumstances should the probe be used in a different patient.



Warnings and mandatory limitations are available on the probe packaging.

4.2 Probe Storage

All probes should be stored in dry conditions and should not be exposed to direct U.V. light or strong odors. The ideal storage temperature is between **-20°C and 60°C**. Probes may be stored at lower temperatures down to **-20°C**, but must be then allowed to recover for at least **30 minutes** at room temperature before use. The probe shaft may become inflexible if the temperature is too low.

4.3 Probe Disposal

Used probes should be disposed of in accordance with the appropriate guidelines for clinical waste.



The Doppler probes manufactured by Deltex Medical contain materials which are not completely destroyed by incineration.

4.4 Probe Expiry

When the usage time expires, the probe will cease to function immediately. Audible and visual alert are given 20 minutes and 5 minutes before this occurs in the *Probe Data Area*, allowing a new probe to be prepared if it is necessary to continue monitoring the patient. **See section 6.5.** All historical data on the CardioQ-EDM+ on which the new probe is started will be transferred to the new probe. Data held on other CardioQ-EDM+ monitors will not be transferred.

4.5 Adult Oral/Nasal Probes

The esophageal Doppler probe (DPn) and the I₂n are for oral and nasal insertion and have a maximum usage time, which is defined on the probe packaging. The probe usage time remaining is displayed on the screen. The DPn and I₂n probes are supplied sterile.

These probes are approximately 90cm long and only approved for oral or nasal placement into the esophagus of a single patient 16 years or over in age.

The probe shaft has three depth markers visible through the transparent cover at 35 (marker 1), 40 (marker 2) and 45 cm (marker 3) These markers facilitate correct probe placement. Although patient characteristics will vary between individuals, in an adult patient, signal acquisition is normally achieved at a depth of between 35 (1) and 40 cm (2) using an orally placed probe, or at a depth of between 40 (2) and 45 cm (3) for a nasally placed probe. For taller patients the insertion depth will

be greater, and for shorter patients the insertion depth will be less.



If using the **DPn** series, the patient **should** be under full sedation or general anesthesia.



If using the **I₂n** series, the patient **may** be awake or under full sedation or general anesthesia. If the patient is not under full sedation or general anesthesia, a local anesthetic may be applied to the nasal passage and back of the throat. The probe **must** be placed nasally in 'awake' patients.

4.6 Nomogram Limits

The adult nomogram:	
Age:	16 to 99 yrs.
Weight:	30 to 150 kg (66 to 330lb).
Height:	149 to 212 cm (59 to 83 in).



If the patient's age, weight and height are such that the nomogram cannot be used to calculate volumetric output, then the message "Linear" is displayed, with the entered value(s) which are outside of the limits displayed in red. If use of the nomogram is precluded then a reduced set of variables (linear) is available for display.

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5. Setting Up the Monitor for Use

5.1 Initial Assembly

Before setting up the monitor for use check the following items are present:

- CardioQ-EDM+
- Power cord
- Operating handbook
- Patient interface cable
- Appropriate pressure connection cable



On first power up, confirmation of date and time may be requested.

A suitable Deltex Medical esophageal Doppler probe will also be required.



If there are any shortages, please notify Deltex Medical or its representative.

5.2 Mounting the CardioQ-EDM+

The CardioQ-EDM+ can be placed on a shelf or roll stand. Roll stands and interface kits are available as accessories. **See section 17.16.**



For further details, contact your Deltex Medical representative.

5.3 Set Up

Insert the patient interface cable and power cord into the appropriate sockets. **See figures 3.1.1 and 3.1.2..**



DO NOT pull on the cables to remove the connectors from their sockets.

Connect the arterial blood pressure interface lead to the ADC input socket at the rear of the CardioQ-EDM+. **See Figure 3.1.2..**



Contact Deltex Medical for further installation assistance.

Turn on the CardioQ-EDM+ using the ON/OFF switch on the rear of the monitor. **See figure 3.1.2..** A screen will appear within about 15 seconds in the currently selected language. If the language, date or time is incorrect, the selection must be changed. **See sections 5.4 and 5.5.**

5.4 Changing the Selected Language



This can only be done when no probe is connected.



Monitors are supplied with the available languages installed. If the language required is not shown, contact your Deltex Medical representative for information.

5.5 Changing the Date, Time or Daylight Saving Time (DST)



This can only be done when no probe is connected.



Once probes are being used with the CardioQ-EDM+, changes in time or date other than to accommodate DST or to correct small deviations from the correct time, may cause probes to expire prematurely. While a probe is connected, only DST can be altered.

To go to **Time/Date Setup Screen:**



To change the hours,



To change the minutes,



To change the year,



To change the day and date,



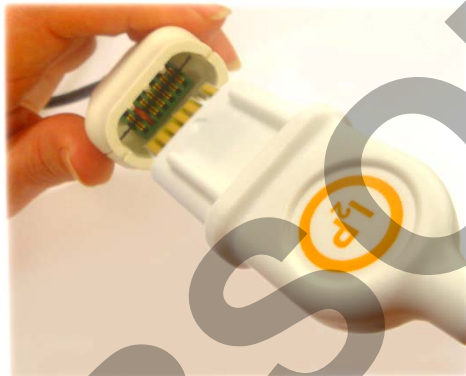
If the hour goes through either end of the day, the date will change.
If the date goes through either end of the year, the year will change.

To change DST,



If DST is on, one hour is added to all times before being displayed by the monitor.

5.6 Connecting the Probe



In order to monitor and collect data from a patient, a suitable probe must be connected to the monitor. The probe connector can only be inserted one way round into the end of the patient interface cable and must be firmly seated. The correct orientation is achieved as shown on the left.

Figure 5.6.1. Connecting the probe to the Patient Interface Cable.

5.7 Turning Off the Monitor

Turn off the CardioQ-EDM+ using the ON/OFF switch on the rear of the monitor. There is no special power-down procedure. The CardioQ-EDM+ may be turned off at any time without damage to the monitor or its software, though it may be prudent to wait a few seconds after modifying the monitor settings.

In the off position, the switch isolates the monitor from the mains supply.

6. Initial Screens

When the CardioQ-EDM+ is switched on, the first screen displayed varies depending on whether a probe is connected and the validity of the probe connected:

- If no probe is connected, the user may access the Demonstration Mode (**see section 15**) view a selected patient's data, offload a selected patient's data or delete existing patients.

    to view data stored on the monitor for that patient, OR 

to offload patient data to a connected USB stick. **See section 14.4** OR  to permanently delete a patient off the monitor.

- If an incompatible probe is connected a message will appear to that effect. Correct this situation by connecting a suitable Deltex Medical probe to the patient interface cable.
- If an invalid probe is connected, contact your Deltex Medical representative, or use a probe of a type for which the CardioQ-EDM+ is enabled.
- If a time expired probe is connected a message will appear to that effect. If recorded data relating to the time-expired probe is available from the monitor, the user can view or offload the data. **See sections 11.2 and 13.4.**
- If an unused probe is connected, data can be copied from the list of patients to continue monitoring a specific patient, or a new patient's details can be entered. **See sections 6.4 and 6.5.**
- If a used probe is connected, commence or continue monitoring or offload data. **See Sections 6.2 and 14.4.**



If space is needed for a patient when a probe is connected, the patient with the oldest last use time is automatically deleted without user intervention.

6.1 Remaining Probe Use Indicator

When a probe is connected to the CardioQ-EDM+ the remaining probe usage is displayed, both as a bar graph and as text, in the top right part of the screen.

As the remaining probe usage reduces, the bar changes color and the fiducial marks change from days to hours and then minutes.

When the remaining probe usage reaches 20 and then 5 minutes, the bar changes to red, and an audible alert is sounded. All buttons change to "Mute", and the audible alert will be muted if any button or the **Control Knob** is pressed. If a probe is connected with less than 20 or 5 minutes usage respectively remaining, this alert will also be sounded when *Probe Focus Screen* is entered.



When the probe usage expires, "Probe expired" is displayed on an orange bar and flow monitoring (Doppler) will cease immediately. If valid pressure data are displayed, pressure monitoring will continue for up to 12 hours. If it is necessary to continue flow monitoring the patient, the probe should be changed as soon as possible.

6.2 Patient Identification

Patients will need an identification code added to their details. On the *New Probe Screen* an auto identification number can be used and will be allocated by the CardioQ-EDM+ or the user can input a more suitable ID. The auto number is created from the date and time when the probe was connected.

In the New Probe Screen,  OR    OR 

to enter text. **See section 3.4.**

If an auto identification number has been used, this can be changed to a preferred identification number at a later time when the used probe has been reconnected. **See section 3.4.**

In the *Used Probe Screen*,  ►  ►  ►  ►





If a probe is started on a CardioQ/CardioQP and then used on a CardioQ-EDM+, an auto ID is generated. The gender must be set before proceeding to the *Probe Focus Screen*.

6.3 Patient Data Screen

The *Patient Data Screen* is used to enter and display the patient's gender, age, weight and height. Some of this information is used to calculate the body surface area (BSA) and other constants required to derive stroke volume and cardiac output. The CardioQ-EDM+ serial number, probe serial number and probe usage remaining are also displayed on the screen.

Follow the on-screen instructions to input patient data.

6.4 Monitoring a New Patient

In the *New Probe Screen*:  ►  OR  ► 


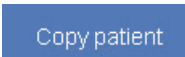
to enter alternative patient ID. **See sections 3.4 and 6.2.**



The CardioQ-EDM+ can store details for 16 patients. If space is needed for a patient when a probe is connected, the patient with the oldest last use time is automatically deleted without user intervention.

6.5 Monitoring an Existing Patient With a New Probe

Patient's details already recorded in the monitor will be displayed on the screen.

In the *New Probe Screen*:  to select a patient, ► 

The patient ID can be changed if an automatic ID number has not yet been altered before **Accept data** is pressed. **See sections 3.4 and 6.2.**



This will associate all existing data for that patient with the new probe.

6.6 Deleting a Patient

All patients' data will remain in the CardioQ-EDM+ until deleted. A patient can be deleted manually if the data are no longer required **See sections 6 and 14.4.**



Patients' data will be automatically deleted to create space. See section 6.

In the *New Probe Screen*:  ►  ►  OR 

7. Obtaining the Correct Flow Signal (Doppler)

7.1 Positioning the Probe

In the *Probe Focus Screen*, the Doppler signal and accompanying audio are activated.

Probe positioning to achieve an optimal signal is essential. Incorrect probe placement will adversely affect the accuracy of data displayed on the screen. **See Figures 7.1.1 and 7.1.2.**

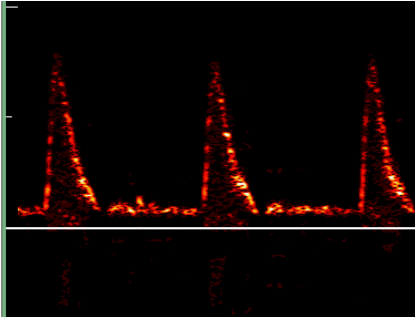


Figure 7.1.1. Good signal quality.

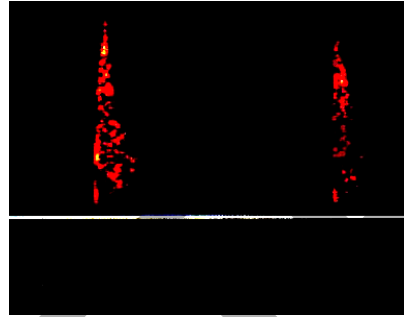


Figure 7.1.2. Poorly defined waveform.

Probe movement can occur so it is essential to achieve the optimal signal during monitoring. It may be necessary to return to the *Probe Focus Screen* and re-optimize the signal.



Identify the correct depth markers on the probe and insert to the appropriate proximal marker, and then rotate to locate the characteristic signal. If this is not obtained, withdraw slightly and rotate again. Repeat until the correct signal is obtained. The correct signal is also accompanied by the characteristic audible signal.



Adjust the position of the probe until the clearest and sharpest aortic waveform possible is obtained, in terms of both visual display and audible pitch. Typically, the aortic waveform with the highest peak velocity denotes the optimal signal. **See Figure 7.1.1.**

An 'ideal' aortic waveform should have a sharp, well-defined outline, with a predominantly black centre, and a small amount of white in the trailing edge of the waveform. **See Figures 7.1.1 and 7.1.2.**

The green line, seen in the *Run Screen*, is the maximum velocity follower and should outline the waveform closely. There should be no 'spikes' in the maximum follower.

The three white arrows should be visible at the beginning and end of systolic flow as well as at peak velocity. **See Figure 7.3.1.** Incorrect placement of the arrows will affect the data displayed. **See Figure 7.1.3.** Refocus the probe.

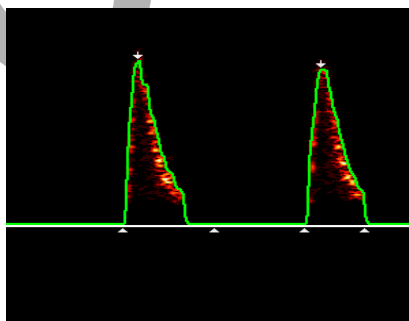


Figure 7.1.3. Misplacement of white arrows.

Signals from vessels other than the descending aorta will result in incorrect results. See Figures 7.1.4 to 7.1.7.

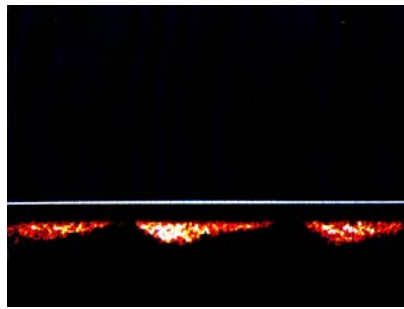


Figure 7.1.4. Venous signal.

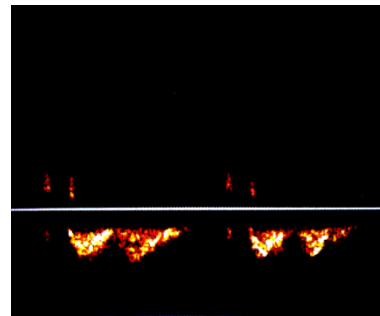


Figure 7.1.5. Cardiac signal.

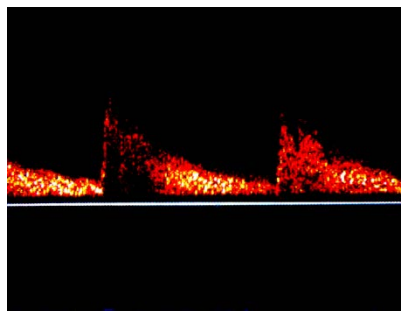


Figure 7.1.6. Celiac axis.



Figure 7.1.7. Pulmonary artery.

7.2 Setting the Range

For optimal use, the displayed waveform should peak in the upper half of the displayed area, but below the top range/scale marker.



Inappropriate range/scale settings will affect the data displayed. See Figures 7.2.1 and 7.2.2.

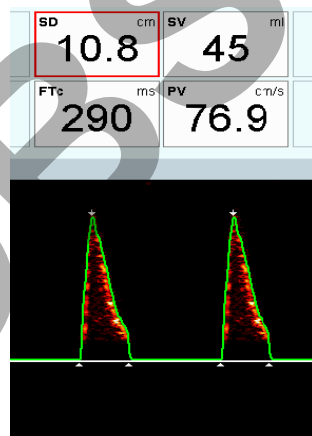


Figure 7.2.1. Appropriate range for this patient of 100cm/s.

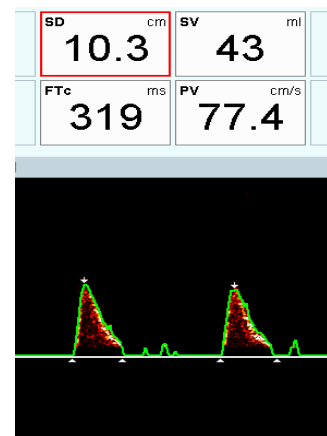


Figure 7.2.2. Inappropriate range for the same patient of 200cm/s.

To change the range temporarily,

Focus

from a Full Run Screen only,

▶ Range

The settings will change from 100cm/s to 200cm/s to 250cm/s to 50cm/s to 100cm/s. This setting may change automatically during gain optimization. This will not alter the default setting.

7.3 Setting the Signal Filter

The CardioQ-EDM+ has a filter, which can be used to remove artifacts caused by low frequency signals due to excess heart valve or wall motion noise. This filter is off by default.



Wherever possible, the patient treatment should be carried out with the same filter settings. Changing the filter settings while monitoring is in progress or if the filter is used when not required, this may cause inappropriate placement of the base arrows and may affect the reported results. This must be taken into account when interpreting trend or graphical data. See Figures 7.3.1. and 7.3.2.

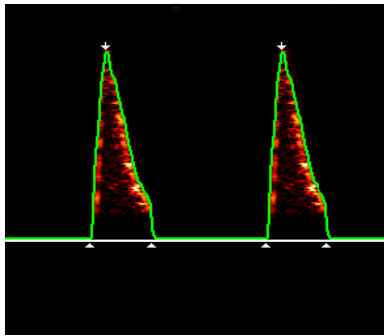


Figure 7.3.1. Filter not required.

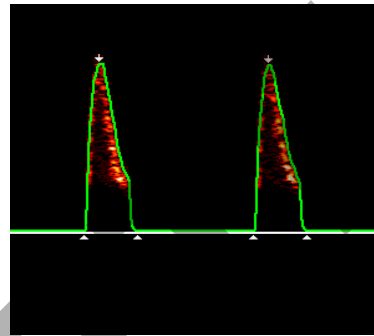


Figure 7.3.2. Inappropriate use of the filter.

To turn on the filter temporarily,



7.4 Setting the Signal Gain

The amount of amplification applied to the signal in the CardioQ-EDM+ is called the Gain. Insufficient or excessive gain will result in a poor quality signal. See figures 7.1.1, 7.4.1 and 7.4.2.

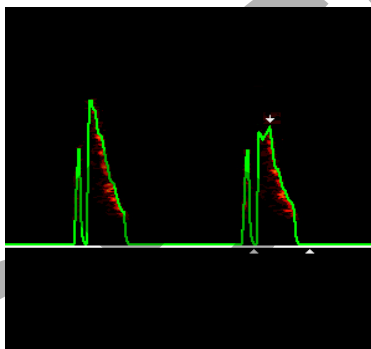


Figure 7.4.1 Insufficient gain

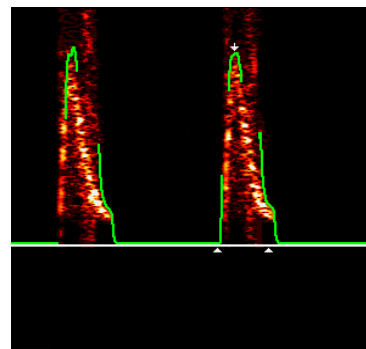


Figure 7.4.2. Excessive gain.

To increase or decrease the signal strength,



The gain will increase or decrease on the numerical scale and will be seen by a corresponding increase or decrease of white within the trailing edge of the waveform.



The audio volume is not affected by the gain setting.

The CardioQ-EDM+ contains a system for automatically optimizing the gain setting once a correct signal has been obtained.



Once the auto gain sets the gain satisfactorily the display will automatically change to the *Run Screen*.

7.5 Finding the Maximum Flow

Rotate the probe as needed to obtain blood flow in the midstream of the descending thoracic aorta. This is denoted by a sharp, well defined outline indicating maximal velocity. This is accompanied by the sharpest audible pitch.



Blood flow at the aortic wall travels at a greater range of flow velocities producing more spectral dispersion and a less distinct sound indicating an inadequate signal.

To help identify the best waveform, use the Peak Velocity Display (PVD). A horizontal blue line will appear indicating the highest peak velocity seen by the monitor.

To turn on PVD,



To turn off PVD,



7.6 Full width Run Screen

The waveform is displayed on a *Full-Width Screen* which scrolls from right to left. The waveform follower is shown on this display as a green line, with white arrows showing the position of the peak velocity and systole points on each heartbeat complex. The display window covers a period of 4.3 seconds.

Any pressure waveforms will be automatically displayed at the base of the screen.

There are no scales displayed with pressure waveforms.



Significant points on the pressure waveforms are indicated by arrows.

The monitor will reject any heartbeat complexes which contain excess noise when performing systole-based calculations. It will also reject complete complexes for heart rate calculations if excess noise is detected between peaks. If the monitor is unable to calculate the heart rate, a triple dash ("---") will be displayed for the values of the appropriate results.

The CardioQ-EDM+ suppresses narrow-band noise of a constant frequency or interference from external sources every 5 seconds. If noise is detected, it will be ignored. If the frequency is varying, the CardioQ-EDM+ will not be able to resolve the waveform.



If electrical noise is present, for example from an electro-surgery unit, then the CardioQ-EDM+ will suppress the waveform follower when it encounters excess noise.

If continuous noise is detected, the waveform is removed and the white centre line changes to blue. A message will be displayed to indicate continuous noise and the results will remain visible for up to 1 minute or before if new results can be calculated.

Small white and blue marker lines can also be observed scrolling across the top of the waveform display. The blue markers occur every 30 seconds and indicate a trend storage point.

Averaging of the cycles will depend on the chosen average cycle time. A white mark appears at the top of the waveform above the diastolic area to indicate when the last average was taken. For example, if using beat to beat, the waveforms will be marked between each beat.

7.7 Changing the Number of Cycles Averaged for Calculations

It may be helpful to adjust the cycles in some situations, for example 1-2 cycles during diathermy or 10-20 for irregular heart rhythms or a marked respiratory swing.

To change the cycles temporarily,



OR



7.8 Ventilator related variables

See section 2.2.

In order to display these results, the respiratory rate must be entered on a *Run Screen*.



To view these results, they must be selected as default results. See section 13.7.



The respiratory rate is displayed with the result in the result boxes, but not on trends and snapshot displays.



The data will not be displayed if the heart rate: respiratory rate ratio is <4 i.e. there must be at least 4 heart beats in each respiratory period. It will also not be displayed if the heart rate variability is $\geq 20\%$. The respiratory rate must be in the range of 7-40bpm.

7.9 Freezing the Display



When the screen is frozen, as well as examining the waveform, the following can be done:

Snapshots. See section 10.

Save screen See section 14.1.

Add point to graphical trend See section 12.3.

To stop the display,  in a *Run Screen*.

A scroll indicator bar will appear above the screen and the colored section shows that part of the available waveform data currently displayed on the screen.



to scroll through the waveform. Up to 30 seconds of stored spectral data are available to be viewed.

A red marker box may also appear around part of the display area. This is part of the snapshot function. See section 10.

Although the data displayed on the screen will not change in Freeze mode, the CardioQ-EDM+ will continue to record trend information.

If the **Control Knob** is used to scroll through the frozen waveforms, the data in the results boxes will change according to waveforms selected and the average cycle time at the time of data collection.



to return to the normal real-time display.

7.10 Probe Disconnection

If the probe is disconnected from the monitor then:

- *Flow Monitoring Mode* will cease if there is no valid pressure wave for *Pressure Monitoring Mode* and then the *No Probe Screen* will appear.
- If there is a valid pressure wave, then monitoring will continue in *Pressure Monitoring Mode*, and:
 - If the calibration is within the valid period, cardiac output based on pressure and the derived results will be available until the calibration period expires.



If running with only the pressure line connected and no pressure wave signal is detected for five minutes, *Pressure Monitoring Mode* will cease immediately and the *No Probe Screen* will appear.

Calibration is transferred on the probe to another ODM+ if required, by reconnecting the probe to the ODM+. The probe may not need to be reinserted into the patient unless clinically indicated.

7.11 Probe Reconnection

If a probe is connected to any ODM+ which has a valid pressure calibration for the patient i.e. within the last 12-hours then it is possible to continue pressure-based monitoring without inserting the probe into the patient.



Once pressure parameters are displayed, the probe may be disconnected or removed.

Termination of pressure-based monitoring then applies. **See Section 7.10.**

8. Additional Calculations

8.1 Systemic Vascular Resistance (SVR) and Systemic Vascular Resistance Index (SVRI)



These calculations are not available if the patient data are outside the nomogram limits since volumetric results will be required.

Spot calculations:



The cardiac output (CO) recorded when the screen was frozen is displayed at the top of screen.

Enter mean arterial pressure (MAP):



If MAP is not available,



to enter systolic and diastolic BP.

Then enter central venous pressure (CVP):



The most recent CVP entered will be used as the default.

SVR and SVRI will be displayed in the *Patient Data* area temporarily.



Continuous calculations:

If the pressure line is connected and valid data are being read, continuous SVR and SVRI can be displayed on both *Flow (Doppler)* and *Pressure Monitoring Modes* by entering CVP and selecting SVR or SVRI as a displayed result in the eight boxes. **See section 13.7.**

CO is calculated from either flow (Doppler) or pressure according to the screen selected.

To enter CVP,



The most recent CVP entered will be used as the default.

To cancel CVP,

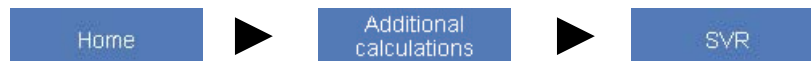


8.2 Displaying SVR Calculations

Spot calculations:

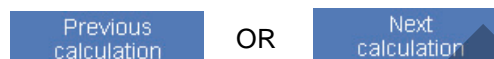
SVR and SVRI will be displayed temporarily in the *Patient Data area* when the calculation is made.

To recall the calculations, go to *Additional Calculations Screen*:



The most recent calculation will be displayed in the top left box.

To recall other available SVR calculations,



These also appear as an event in the trend history, and the calculated values can be accessed through the *Continuous Trend Screen*. **See section 12.**



SVR or SVRI can be displayed in the 8 results boxes providing these are chosen as default settings and will be displayed on a green background. **See section 13.7.**

Continuous calculations:

SVR or SVRI can be displayed in the 8 results boxes providing these are chosen as default settings and will be displayed on a white background in both flow monitoring mode and pressure monitoring mode. **See section 13.7.**

In flow monitoring mode, this will automatically change to a green background for spot readings only, if the arterial line is disconnected. In pressure monitoring mode, if the arterial line is disconnected, the flow monitoring mode is automatically displayed instead.

If the result is more than **4 hours** old, the text color changes in the results box.

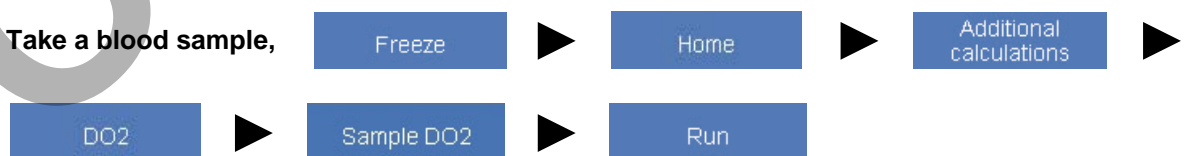
If the CardioQ-EDM+ is turned off, or the probe is disconnected, then the data are retained. When monitoring recommences, the results of the last accepted SVR/SVRI are displayed within the 8 boxes, if already chosen as a default.

8.3 Delivered Oxygen (DO₂) Delivered Oxygen Index (DO₂I)



These calculations are not available if the patient data are outside the nomogram limits since volumetric results will be required.

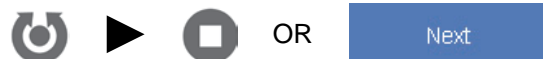
Take a blood sample,



When blood sample results are available,



The time when the blood sample was taken is displayed at the top of screen. To alter,






The CO recorded when the sample was taken is displayed at the top of screen. To alter,



If no sample was recorded, the current CO will be displayed. To alter, see above.

Then enter saturated arterial oxygen (SaO₂):    OR 

Then enter hemoglobin (Hb):    OR 



To change Hb units if required, 

DO₂ and DO₂I will be displayed temporarily in the *Patient Data* area.



  

8.4 Displaying DO₂ Calculations

DO₂/DO₂I will be displayed temporarily in the Patient Data area when the calculation is made.

To recall the calculations, go to *Additional Calculations Screen*:

     The most recent calculation will be displayed.

To recall other DO₂ calculations,  OR 

These calculations appear as an event in the trend history, and the calculated values can be accessed through the *Continuous Trend Screen*. See section 12



DO₂ or DO₂I can be displayed in the 8 results boxes providing these are chosen as default settings. See section 13.7.



If the CO changes by more than **20%** or the result is more than **4 hours** old, the text color changes in the results box, but only the message “Check value” appears if displayed in the left-hand box.

If the CardioQ-EDM+ is turned off, or the probe is disconnected, then the data are retained. When monitoring recommences, the results of the last accepted DO₂/DO₂I are displayed within the 8 boxes if already chosen as a default.

9. Pressure Monitoring

In order to enable *Pressure Monitoring Mode*, there must be an arterial blood pressure signal line connected and pressure data must be available.



The pressure waveform is not valid unless the pulse pressure is >15mmHg and systolic and diastolic points are being identified and indicated by arrows on the waveform.

Before the pressure data are declared valid, five seconds of valid pressure waveform must be detected

If *Pressure Monitoring Mode* is interrupted and no valid pressure wave is detected for five minutes, *Pressure Monitoring Mode* will cease if the Doppler probe is disconnected.

9.1 Calibration

Before cardiac output-based results can be displayed in *Pressure Monitoring Mode*, the pressure data must be calibrated using the flow waveform (Doppler).

Flow mode



ensure optimal flow signal (Doppler). is achieved, results are displayed and pressure data are valid,



Calibrate Pressure



A minimum of 10 heart beats or 10 seconds are required to calibrate.

The screen will change to *Pressure Monitoring Mode* with the calibration status displayed as “in progress”. A bar graph with the calibration period remaining will be displayed on completion.

When the calibration time expires, all cardiac output-based parameters in *Pressure Monitoring Mode* will cease to function immediately. Audible and visual alert are given 20 minutes and 5 minutes before this occurs in the *Probe Data Area*, allowing a new calibration to be performed.

A calibration can be performed at any time providing a suitable flow signal can be obtained.



If the pressure-based SV changes by $\geq 20\%$ from that recorded at the time of calibration, a “Recalibration advised” message will flash and the SV and SVI will be displayed in red.

9.2 Probe Disconnection and Reconnection

See Sections 7.10 and 7.11.



10. Snapshots

10.1 Taking a Snapshot



Snapshots are not available in *Pressure Monitoring Mode*.

The monitor can store up to eight snapshots of the waveform per patient.


 A red outline will appear around the real-time area, indicating the area which will be “snapped”,
 



The red outline will move across individual waveforms, but the results in the 8 boxes will change in accordance with the selected average cycles at the time of freezing the screen.


The screen then changes to display the snapshot and associated results in the right-hand panel.



A point may be added to the Graphical Trend.



If there are already 8 snaps stored for the patient, the **Take snapshot** button changes to red to indicate that a snapshot must be deleted first to create space. **See section 10.4.** Pressing the red **Take snapshot** button takes the user to the *Select Snap Screen* to allow a snapshot to be deleted.


 To delete the snapshot from the *Select Snapshot Screen* and to save the newly created snapshot.

To return the left hand side to a real time display,



To return to a whole screen real time display,




10.2 Viewing Snapshots



 If only one snapshot has been stored, it will automatically be displayed as above.

If there is more than one available, the *Select Snap Screen* is displayed,


 OR 



If the range setting at the time of recording is different from the current setting, the numeric range for the large snapshot is displayed on a red background, or a small red rectangle is displayed in the top left-hand corner of a small snapshot.


While in the *Continuous Trend Screen* a recorded snapshot can be displayed. **See section 12.**

To return to a whole screen real time display,



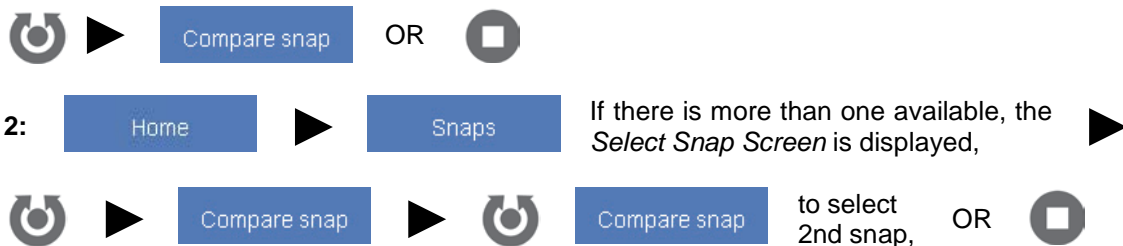

10.3 Comparing Snapshots

There are two methods to compare snapshots:

- 1:  The initial waveform to be compared with will be outlined in red within the *Select Snap Screen*.



If only two snapshots have been stored, they will automatically be displayed for comparison.



Up to 8 results are displayed on each large snapshot corresponding to the 8 results at the top of the screen. The highlighted result only will be displayed on the small snapshot.

To display results of the initial left-hand waveform: Show results



If the range setting at the time of recording is different from the current setting, the numeric range for the snapshot is displayed on a red background.

To return to a whole screen real time display, Home Full screen

10.4 Deleting Snapshots

To delete the snapshot from the *View Snapshot Screen*, Delete snap

To delete the snapshot from the *Select Snapshot Screen*, 

The green outline will move over the selected snapshots, Delete snap



If there are no snapshots left, the screen returns to the *Full-Width Run Screen*.

11. Events




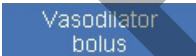
11.1 Recording Events

The CardioQ-EDM+ records events within the historical data for later recall and display. SVR or DO₂ calculations and snapshots are recorded automatically as events, but the user may record an array of other events on a manual basis:

Go to Events Screen:  ►  and then select from the menu which event is to be added.

There may be further selections that allow the event to be modified using the appropriate sub-type menu.

Fluid events:  OR  OR  OR  ►  OR  to select volume, ► 

Vasodilator events:  ►  OR  OR  OR  OR 

Vasoconstrictor events: As vasodilator events.

Inotrope events: as vasodilator events.

Miscellaneous events:  ►  OR 
OR  OR 

When electrocautery occurs, 

For all events: A yellow confirmation message appears, ►  OR 

The screen will then return to the *Run* or *Split Screen* as before.



Once an event has been added, it cannot be deleted. If **Cancel** is pressed, the event will not be recorded.

11.2 Recalling Events

Events can be seen in the *Continuous Trend Screen*. **See section 12.**



Any events recorded are shown as vertical bars on the event marker line. If a snapshot is available, a green bar will be seen as well as this icon. If there is more than one event, the number of events at that time will be displayed in brackets.

12. Trend Display

12.1 Historical Data-Continuous Trends

The CardioQ-EDM+ records historical data for certain results, and can display the changes in these results graphically. This stored information can be used to monitor trends in the patient and also to establish the effects of various interventions.

While the average values for each of the results are stored every 30 seconds, trend data on up to three results can be graphically displayed.

Snapshots appear as “events” in the historical data and can be used to provide a visual record of the waveform data at various times during the patient’s treatment. Results of SVR, SVRI, DO₂ and DO₂I calculations and any added events are also stored for later recall.

Once the Doppler signal is activated and the probe has been positioned, trend data will be recorded by the monitor even if the screen is frozen. If the user returns to the *Probe Focus Screen*, the collection of trend data will be interrupted until the user returns to the *Full-Width Run Screen*.



All trend and snapshot data are stored in the CardioQ-EDM+ and not in the probe.

12.2 Displaying Trend Information

The Continuous Trend can either be displayed as either a block or line graph. **See section 13.8.**

The display consists of a graphical scrolling area and a text area, and shows three hours of data and builds from the right.

At the top of the graphical area is a horizontal event marker line which indicates the signal strength at the time of recording. If this line is black there were no data recorded; red – the signal was weak; green – the signal was acceptable; white – the signal was too strong.



Any events recorded are shown as vertical bars across this event marker line. If a snapshot is available, a green bar will be seen as well as the icon seen on the left. If there is more than one event, the number of events at that time will be displayed in brackets.

Up to three results are displayed, shown as red, yellow, and green line or block graphs with a zero-line shown faintly in the same color. These can be selected as defaults for individual users. **See section 13.7.** The time line at the bottom has vertical white bars to indicate the hour points.



To view historical data at any recorded time,



The graphs are scaled automatically based on the maximum values seen in the data.

To view list of events if more than one was recorded at the same time,

Show events



If DO₂ or SVR is one of the events, the results of these additional calculations will also be displayed.

To locate certain events,

Previous event

OR

Next event

OR

Current trend

OR



To revert to the general results display on the right-hand side,

Show results

To view snapshots that are marked as an event,



To return to the *Continuous Trend Screen*,



12.3 Graphical Trends

A graph can be created for one or two results when the screen is frozen.



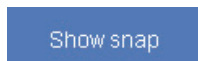
The monitor has one default result which can be changed, or a second may be added, through the *Default Screen*. See section 13.7.

In a *Run Screen* with results visible,

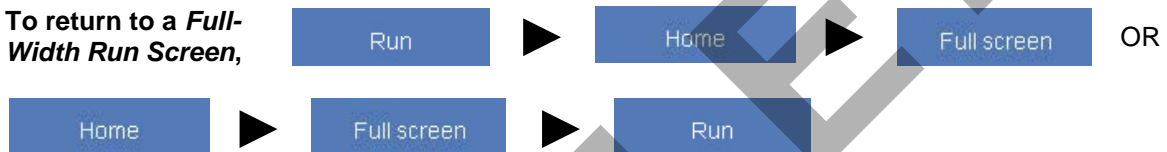


A point may be added when a snapshot is taken.

To view snapshots that are marked as an event,



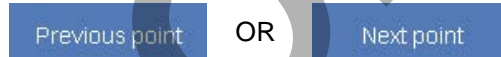
To return to a *Full-Width Run Screen*,



To view graph,



To locate data points,



A percentage change from the previous point will be displayed for each result used.

To alter the visible graphical period,



The setting will change from 1 to 3 hours to 12 hours to 24 hours to 1 hour.

An arrow is displayed if there are more points available before the first displayed point. The graph period may need to be altered to view these points.



Graphical trend is only available to view if a point has been stored to start the graph.

13. Customizing the Monitor



This can only be done when no probe is connected.

13.1 Restoring the Factory Settings



If the CardioQ-EDM+ is reset to factory settings, the selected language will change to the global default; English (UK), and any historical data held in the monitor will be deleted and the User profiles will be deleted.



13.2 Adding a Hospital Name

The hospital name can be displayed on the screen:



13.3 Linking to a Patient Monitor

This may not be available for all patient monitors. Please contact a Deltex Medical representative for further details.



If there are additional settings for the monitor selected, they will be displayed.

If the selected protocol needs the baud rate set, then **Select baud rate** button will appear.



If the selected protocol can support optional hardware flow control, the **Flow control** button will appear.



If a patient monitor has been selected, an icon will appear to indicate the status of the connection:



- Patient monitor not connected.
- Patient monitor connecting.
- Patient monitor connected.

13.4 Selecting a User

There are two default User settings which cannot be renamed or deleted, but can be temporarily altered; Default 1 which uses CSV format and Default 2 which uses SCSV format. Any changes to these default settings cannot be saved. Up to 4 additional new User profiles can be created. When a User is selected all the default setting for that User will be displayed unless altered.

There are two methods of selecting a User:

1:  ► select a User from the menu.

2: **Go To User Profile Screen:**



To select a User,




13.5 Multiple User Setups

Go to User Profile Screen:



To create a new profile,



 to enter text,



To delete a User,



13.6 Setting User Profiles

Each User can set individual defaults which will be displayed when that User is selected.



Default 1 and Default 2 Users changes cannot be saved.

Go to User Profile Screen:



Or go to **Defaults Screen** if the monitor or a specific User is already in use:



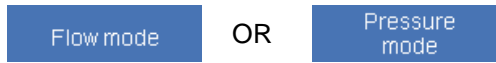
The User will automatically be able to change selected results. **See section 13.7.**

13.7 Setting Default Results

Select user as above.

Results may be chosen for the selected monitoring mode.

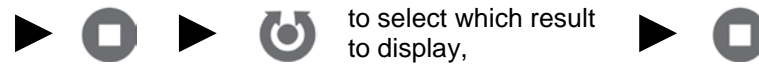
To switch between *Flow* and *Pressure Monitoring Modes*



To change any of the 8 results, the Continuous Trend results or the Graphical Trend results,



to select which result to display,



Graphical trend is not available in *Pressure Monitoring Mode*.

13.8 Setting Machine Default Settings

Select User as above.

To set the Cycles default for both *Flow* and *Pressure Monitoring Modes* simultaneously,



To set the Range default in *Flow Monitoring Mode* only,



The settings will change from 100cm/s to 200cm/s to 250cm/s to 50cm/s to 100cm/s.

To set the Continuous Trend Display for *Flow* or *Pressure Monitoring Mode* as appropriate,



To change the highlighted result in *Flow Monitoring Mode* only,



A red box around the highlighted result will change from SV to SVI to none to SD to SV.

To enable recording, for both *Flow* and *Pressure Monitoring Modes* simultaneously,

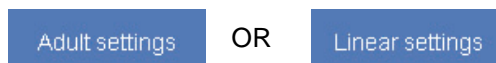


These settings will change from “manual” to “disabled” to “automatic” to “manual”. See Section 14.2.

13.9 Change Adult or Linear Settings

If no probe is connected, then the settings for Adult or linear use can be changed. If a probe is connected, only the settings for the nomogram used by that probe can be altered.

In the *Default Screen*,



14. USB and Offloading Patient Data



The monitor will only recognize 4GB memory sticks or smaller.

14.1 Saving Screens

Up to 20 saved screens can be stored per patient and can be made up of either split screens or full screens.



The saved screen is confirmed by a yellow message.

If there are already 20 screens stored for the patient, the **Save screen** button changes to red to indicate that all available saved screens have been used.

14.2 Recording Continuous Data



Recording must be enabled to save continuous data and signal data. **See section 13.8.**

This allows the user to record all the results of every real-time calculation together with the time stamp and save in a file for offloading. If recording is set to automatic, continuous data will be recorded whenever a real-time calculation is performed.

If recording is set to manual:



Recording is in progress whenever this icon is present.



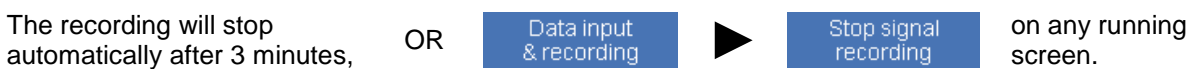
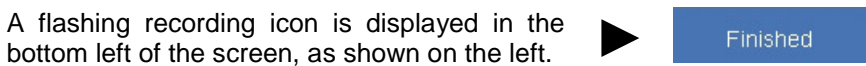
The icon will not be seen when the recording is stopped.

14.3 Signal Recording

If an interesting or difficult waveform is encountered, Deltex Medical may request that a copy is sent to the Research and Development team for analysis.



Recording must be enabled to save continuous data and signal data. **See section 13.8.**



Signal recording has stopped whenever this icon is present.



The user must still press **Stop signal recording** in order to save or discard the recording.



Data is being saved, but monitoring can continue. A new signal recording cannot be started until the previous one has been saved.

A new file is created for each recording session, with a maximum of 50 minutes (50 files) per patient. This may be subject to remaining disc space.



If the probe is disconnected while unsaved data is present, the user will be asked if the file is to be saved.

14.4 Offloading Patient Data

Patient data, including trends, events, graphs, additional calculations saved screens, signal waveforms and continuous data can be offloaded using any suitable USB memory stick and then transferred onto a computer.

Patient data will not be deleted from the monitor until the patient is deleted and therefore data can be offloaded several times if required.

Patient data can be offloaded in the *No Probe Screen* or the *Used Probe Screen*.

Offloading from the *No Probe Screen*:

Insert a memory stick into the USB port on the rear of the monitor. **See Figure 3.1.2.,**



Offloading from the *Used Probe* or *Expired Probe Screens*:



To offload the specific patient's data, the probe may have to be disconnected and reconnected to get to this screen.

Insert a memory stick into the USB port on the rear of the monitor. **See Figure 3.1.2.,**



This will create a folder on the USB stick with the patient ID as the title. If requested to do so, the file can then be transferred to a computer and emailed to Deltex Medical. For further information, please refer to the Deltex Medical website.



14.5 Offloading Information for Deltex Medical

If a fault occurs, Deltex Medical may require information from the *Version Data Screen*. This can only be done when there is no probe connected.



Insert a memory stick into the USB port on the rear of the monitor. **See Figure 3.1.2.,**



If requested to do so, the file can then be transferred to a computer and emailed to Deltex Medical.


15. Demonstration Mode

The monitor can also be operated using a set of pre-recorded waveform signals. This allows the CardioQ-EDM+ to be demonstrated without the need for external signal sources. It also allows users to familiarize themselves with the operation of the CardioQ-EDM+ and the various facilities available, without having a patient connected to the monitor.

This can only be accessed from the *No Probe Screen*.

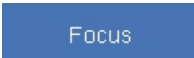







If a probe is connected to the CardioQ-EDM+ while it is running in demonstration mode, the CardioQ-EDM+ will exit the demonstration mode and return to normal running, as appropriate.

15.1 Running the CardioQ-EDM+ in Demonstration Mode

To select demo mode,  from the *No Probe Screen*.

To select a waveform,    OR 

Follow the on-screen instructions to enter or alter the patient's gender, age, weight and height.

To select an alternative waveform,  from a full *Run Screen* only,    
  OR 




It is not possible to alter the patient ID in the demo mode.

The Filter button will have no audible effect on the signal during the demonstration mode, but the effect on the displayed signal will be seen.

During a demonstration session, trend data will only be displayed for the current session, though other data stored in the CardioQ-EDM+ will not be deleted.

To end the demonstration,  from a full *Run Screen* only,   

 OR connect a probe to the patient interface cable.

Demo data cannot be offloaded.

16. Fault Diagnosis Guide

16.1 Fault Diagnosis

This section provides details of simple fault diagnosis and corrective action. For further information, or should the monitor still fail to respond, contact Deltex Medical or its representative.

Power on but LED off:

- Check the On/Off switch on rear panel is ON.
- Check supply is live.
- Check the power lead is correctly seated.



Disconnect power for at least 30 seconds first.

Power LED on but no screen display:

The monitor is faulty and should be returned for repair to a Deltex Medical approved service facility.

No probe connected message:

- Check that the probe is firmly connected to the patient interface cable.
- Check that the patient interface cable is firmly connected to its front panel connector.

'SETTINGS FILE corrupt-reboot' appears in red box in centre of the screen:

The machine settings file has been found to be corrupt or contains an illegal value. The old file has been deleted and a new one has been created with default settings. This may occur following a software upgrade. If this occurs at any other time, inform Deltex Medical.

A red box appears in the centre of the screen during operation, or a colored rectangle appears on a blank screen while the monitor is starting up, and the unit then stops and displays the following fatal error codes:

User Interface Errors	US001 to US068
Data Collection Process Errors	DC001 to DC012
Digital Signal Processor Errors	DSP001 to DSP006
Calculation Thread Error	CALC001
VueLink Thread Errors	VL001 to VL007
Doppler Control Process	TX001 to TX005
USB Handler Errors	USB001 to USB002

Note the contents of the box or color and position of the rectangle, and contact Deltex Medical.

16.2 Checking the Software Version



This can only be done when no probe is connected.



The Application version is shown in field reference (2). The software release and revision are the last part of this number, which is in the form "M.nn", where 'M' is the release, and 'nn' is the revision.



Deltex Medical may request this information. It can also be offloaded using a USB memory stick and sent electronically. **See section 14.5.**

17. System Specifications

17.1 Classification

Protection Type	Class 1 equipment
Degree of Protection	Type BF applied part
Ingress Protection	IP20
Mode of Operation	Continuously available (may need refocusing)
Medical Device Classification	I Ib

The equipment is constructed and tested as defined in IEC 60601-1 (Safety of Medical Equipment) Class 1 Type BF.

This equipment may be affected by the use of high-energy electro-surgical equipment (e.g. electrocautery) in close proximity. This may be recognized by major visual interference displayed in the scrolling area. Results obtained during periods of such interference may not be reliable and should be discarded.

17.2 Performance Characteristics

This specification is valid after the monitor has warmed up for 30 minutes in an ambient temperature of 0°C to 40°C.

17.3 Physical Characteristics

Width	315mm (12.4in)
Depth	176mm (7in) (including knobs) 186mm (7.4in)
Height	249mm (9.8in) (including feet) 259mm (10.2in)
Weight	4.9kg (10.8lb)
Operating Position	Horizontal on bottom feet

17.4 Environmental Characteristics

Ambient temperature:	
Operating	0 to 40°C (32°F to 104°F)
Transport and Storage	-20 to 60°C (-4°F to 140°F)
Relative humidity:	
Operating, transport and storage	5%-90% (non-condensing)
Atmospheric pressure:	
Transport and storage:	700hPa to 1060hPa (525mmHg to 795mmHg)

17.5 Monitor and Lead Disposal

For the safe disposal of the CardioQ-EDM+ monitor and patient interface cable, please refer to the WEEE mark for additional details. **See section 17.15.**

The Deltex Medical supplied power cords and leads contain no hazardous substances and apart from used probes no special disposal is required.

Used probes should be disposed of in accordance with the appropriate guidelines for clinical waste.

17.6 System Characteristics

- Ultrasound
 - 4.02MHz continuous wave Doppler ultrasound ($I_{spta} < 250\text{mW}/\text{cm}^2$ at 5 mm in situ)
 - 450Hz and 900Hz high pass filters
- Real-time spectral display
 - Full-color LCD display – commercial quality – specification available on request
 - 512-point fast Fourier transform (FFT) spectral analysis

- Maximum velocity follower with automatic detection of systolic complexes
 4.3 seconds (*Full Screen*) or 1.4 seconds (*Split Screen*) display length
- Continuous operation

17.7 Acoustic Output

The following table provides maximum acoustic output measurements from the 4 MHz esophageal Doppler probe transmitting Continuous Wave ultrasound (in *Probe Focus* and *Run* modes) when connected to the CardioQ-EDM+ monitor.

These measurements were determined in accordance with the AIUM/NEMA (American Institute of Ultrasound in Medicine and National Electrical Manufacturers Association) document, entitled "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (1998)".

The CardioQ-EDM+ only has one fixed acoustic output level which is fixed by the circuitry and cannot be adjusted by the user.

Acoustic Output Reporting Table for Track 1				
Transducer model:		DP240 probe 9070-7006 I₂S probe 9090-7015 I₂P probe 9090-7016 I₂C probe 9090-7017		
Application: Cardiac - Transesophageal		Operating mode: Continuous Wave Doppler		
Acoustic Output		MI Mechanical Index	I _{SPTA-3} (mW/cm ²)	
Global Maximum Value		0.02 (± 18%)	62 (± 23%)	
Associated Acoustic Parameter	P _{r,3} (MPa)	derated peak rarefactional pressure	0.04 (± 18%)	
	W ₀ (mW)	ultrasonic power	5.7 (± 28%)	
	f _c (MHz)	center frequency	4.02 (± 3%)	
	Z _{sp} (cm)	axial distance for measurements	0.46	
	beam dimensions	X ₋₆ (cm)		0.23
		Y ₋₆ (cm)		0.34
	EBD	Azimuthal (cm)		0.30
Elevational (cm)			0.12	

The reported uncertainties are based on standard uncertainties multiplied by a coverage factor, k=2, providing a level of confidence of approximately 95%.

Symbols represent the following parameters:

I_{SPTA,3} derated spatial-peak temporal-average intensity

X₋₆, Y₋₆ in-plane (azimuthal) and out-of-plane (elevational) –6 dB beam dimensions, where Z_{sp} is found.

EBD the entrance beam dimensions for the azimuthal and elevational planes, taken from the dimensions of the transducer crystal.

The derated intensities were derived from those measured in water by using the following attenuation factor of 0.3 dB/cm/MHz:

$$I_{SPTA,3} = I_{SPTA}(\text{water}) * 10^{[Z_{sp} * f_c * (-0.3)/10]}$$



The values for the output beam dimensions, and the output beam intensity, are derived from the geometrical crystal dimensions provided by the manufacturer.

17.8 Acoustic Output Safety

The esophageal Doppler probe transducer has a static continuous wave (CW) output. This output is fixed therefore; TI and MI values cannot be changed by any system controls available to the user.

Testing to the requirements of IEC 62359 has determined the Thermal Indexes (TI) as follows:

Parameter	Value
Soft-tissue thermal index, TIS, for non-scanning modes	0.11 ± 28%
Bone thermal index, TIB, for non-scanning modes	1.2 ± 28%



The reported uncertainties are based on standard uncertainties multiplied by a coverage factor, k=2, providing a level of confidence of approximately 95%.

17.9 Ranges

The CardioQ-EDM+ has four velocity measurement ranges; 50, 100, 200 and 250 cm/s. These are nominal ranges and relate to the on-screen spectral data display.

The ranges over which each standard Doppler flow parameter can be measured is specified in the table below:

Parameter	Measurement Range		Units
	Minimum value	Maximum value	
PV	10	250	cm/s
FTp	6	750	ms
FTc	24	999	ms
SD	0.2	165	cm
MA	0.1	366	cm/s ²
HR	20	360	bpm
MD	4	59400	cm
SV	0	999	ml
CO	0	99.9	l/min
CI	0	99.9	l/min/m ²
SVI	0	99.9	l/m ²
SVR	0	9999	dyne.s.cm ⁻⁵
SVRI	0	999	dyne.s.cm ⁻⁵ .m ²
SVV	0	100	%
DO2	0	8040	ml/min
DO2I	0	3965	ml/min/m ²

The ranges over which each combined pressure-flow based parameter when using direct flow measurement results is specified in the table below:

Parameter	Measurement Range		Units
	Minimum value	Maximum value	
CPO	0	110	Watts
CPI	0	2778	Watts/m ²

The ranges over which each pressure-based parameter can be measured is specified in the table below:

Parameter	Measurement Range		Units
	Minimum value	Maximum value	
HR	0	360	bpm
SV	0	999	ml
SVV	0	100	%
CO	0	99.9	l/min
CI	0	99.9	l/min/m ²
SVI	0	99.9	ml/m ²
SVR	0	9999	dyne.s/cm ⁵
SVRI	0	999	dyne.s.m ² /cm ⁵
DO2	0	8040	ml/min
DO2I	0	3965	ml/min/m ²
Psys	15	500	mm of Hg
Pdia	0	485	mm of Hg
Pmap	7.5	492.5	mm of Hg
PPV	0	100	%
BP	15/0	500/485	mm of Hg

The ranges over which each combined pressure-flow based parameter when using a flow result derived from the pressure signal is specified in the table below:

Parameter	Measurement Range		Units
	Minimum value	Maximum value	
CPO	0	110	Watts
CPI	0	110	Watts/m ²

17.10 Accuracy

Data acquisition is dependent upon probe positioning and patient anatomy and physiology, therefore, interpretation depends less on absolute values than on comparative measurements.

Accuracy from a known spectrum is dependent on the measurements SD, PV, HR, FT and FTp, upon which all other calculations are based.

For a correctly aligned probe the resolution of velocity measurement is 1% of the nominal full-scale value of the selected range. The timing resolution is 6ms, which is the interval at which FFTs are performed and the screen is updated. However, by averaging the calculation over several heartbeats, the perceived resolution may be improved.

The accuracy to which each of the basic five parameters (above), plus the two directly derived parameters MA and MD can be measured, is shown in the table below:

Parameter	Accuracy
PV	± 1%
FTp	Typically ± 6%
FTc	Typically ± 2%
SD	Typically ± 3%
MA	Typically ± 8%
HR	Heart beat per minute ± 1
MD	± 3%
SV	+/- 15%*
SVV	+/- 6%*
CO	+/- 15%*
CI	+/- 15%*
SVI	+/- 15%*
SVR	†
SVRI	†
DO ₂	†
DO ₂ l	†

The accuracy of arterial Blood Pressure based parameters are detailed below:

Parameters	Accuracy
HR	+/- 1 heart beat per minute
SV	+/- 15%*
SVV	+/- 6%*
CO	+/- 15%*
CI	+/- 15%*
SVI	+/- 15%*
SVR	†
SVRI	†
DO ₂	†
DO ₂ l	†
Psys	§
Pdia	§
Pmap	§
PPV	+/- 2%
BP	§

The accuracy of combined arterial Blood Pressure and flow based parameters are detailed below:

Parameters	Accuracy
CPO	§
CPI	§

Key to symbols:

* At time of calibration

[The post-calibration accuracy of any device that mathematically derives cardiac output from arterial blood pressure will be affected by changes in arterial compliance. For this reason, to obtain the most accurate information it is recommended that the device be re-calibrated prior to and following any hemodynamic change.]

† Requires manual input of data by operator, the accuracy of which cannot be assessed.

§ Input signal may be from various monitors the accuracy cannot be determined.

17.11 Results

Results based on flow (Doppler):

CO	- cardiac output (not available in linear only mode)
SV	- stroke volume (not available in linear only mode)
HR	- heart rate
MD	- minute distance
SD	- stroke distance
FTc	- corrected flow time
FTp	- flow time to peak
MA	- mean acceleration
PV	- peak velocity
CI	- cardiac index (not available in linear only mode)
SVI	- stroke volume index (not available in linear only mode)
SVV	- stroke volume variation (not available in linear only mode)
SDV	- stroke distance variation (only available in linear mode)
SVR	- systemic vascular resistance (not available in linear only mode)
SVRI	- systemic vascular resistance index (not available in linear only mode)
DO₂	- delivered oxygen (not available in linear only mode)
DO₂I	- delivered oxygen index (not available in linear only mode)

Results based on pressure:

CO	- cardiac output (not available in linear only mode)
SV	- stroke volume (not available in linear only mode)
HR	- heart rate
CI	- cardiac index (not available in linear only mode)
SVI	- stroke volume index (not available in linear only mode)
SVV	- stroke volume variation (not available in linear only mode)
SVR	- systemic vascular resistance (not available in linear only mode)
SVRI	- systemic vascular resistance index (not available in linear only mode)
PPV	- pulse pressure variation
Psys	- systolic blood pressure
Pdia	- diastolic blood pressure
Pmap	- mean arterial pressure
BP	- blood pressure
DO₂	- delivered oxygen (not available in linear only mode)
DO₂I	- delivered oxygen index (not available in linear only mode)

Results based on flow (Doppler) and pressure:

CPO	- cardiac power output (not available in linear only mode)
CPI	- cardiac power index (not available in linear only mode)

17.12 RS232 Protocols

Please contact your Deltex Medical representative for details.

17.13 Power Supply

Power requirements:	100 – 240v AC (~) 50 – 60 Hz 60 – 80 VA
Fuses:	2 x 1.6A(T) 250v

17.14 Auxiliary Connections



Any unauthorized connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with IEC 60601-1) to the CardioQ-EDM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

- RS232 port - For serial data offload by linking to a patient monitor or bedside terminal server for electronic medical records (EMR).
- USB port - For offloading data using a USB memory stick.
- Network port - For future use.
- ADC port - For connection to arterial blood pressure (ABP) signal, input scale must be 1volt per 100mmHg at an input impedance of 1 mega Ohm. For display of pressure parameters.

See Figure 3.1.2.

17.15 Symbolic Markings

	Consult accompanying documents		Refer to instruction manual booklet
	Type BF		Latex-free product
	Sterilized with ethylene oxide		Certified for use in US and Canadian markets
	Use by YYYY-MM		Date of manufacture
	Catalogue number		Batch code
	Serial number		Storage temperature
	Degree of protection against harmful ingress of water		Degree of protection against solid foreign objects.
	USB Port		Network Port
	RS232 Port		Analogue to digital converter port
	Equipotential earth terminal		Alternating current
	Probe connector orientation mark		Fuses
	AC power applied		AC power input
	AC power switch ON position		AC Power switch OFF position
	Volume Control Knob		Control Knob
	Fragile. Do not get wet. This side up.		Do not reuse. Single patient use only.

17.16 Accessories and Spares

Part number	Description
9051-7166	CardioQ-EDM+ Monitor
9051-7002	Patient Interface Cable (9' 6" long cable connects between monitor and probe)
9051-5601	Operating Handbook (English US)
9051-7051	Roll Stand (5 start roller base, hydraulic assisted adjustable height feature, pull handle, and equipment basket)
9051-2036	Roll Stand Interface Kit (for fixing monitor to roll stand)
9051-7008	Power Cord (USA) (10' 3-Pin Hospital Grade Clear Nema 5-15P Plug to 10A Female Connector)
	Pressure interface cable

Please contact your Deltex Medical representative for details.

17.17 Probes and Probe Accessories

Part number	Description
9070-7006	Deltex Medical 240 hour Esophageal Doppler Probe (DP240)
9090-7015	Deltex Medical 6 hour Esophageal Doppler Probe (I ₂ S)
9090-7016	Deltex Medical 24 hour Esophageal Doppler Probe (I ₂ P)
9090-7017	Deltex Medical 72 hour Esophageal Doppler Probe (I ₂ C)

The DP240 is for use under full sedation or general anesthesia.

These items are available in various multi-packs – please contact your Deltex Medical representative for details.

17.18 Electromagnetic Compatibility (EMC)

The CardioQ-EDM+ system has been tested to, and complies with, the current Electromagnetic Compatibility (EMC) standard for medical electrical equipment IEC 60601-1-2 which stipulates limits for emissions of, and immunity to, electromagnetic radiation. Although these limits are designed to ensure reasonable protection from electromagnetic interference, there may well be high levels of such interference present in a hospital environment, either from equipment which does not comply with the above standard or which is exempt from the requirements because the device must emit electromagnetic energy to be able to perform its intended function, e.g. electrocautery (diathermy) equipment. Furthermore, portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment, such as the CardioQ-EDM+.

If noise is observed on the spectral display then the following steps can be used to eliminate or at least identify the source of the interference:

- Switch off and on equipment in the immediate vicinity in order to isolate the source of the noise.
 - Relocate and/or re-orientate the offending equipment if possible.
 - Increase the distance between the CardioQ-EDM+ and the offending equipment as much as possible.
- Interference may be borne by the mains supply, so re-connect the CardioQ-EDM+ to a different power outlet to see if this makes a difference.

If possible, the CardioQ-EDM+ should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the CardioQ-EDM+ should be observed to verify normal operation in the configuration in which it will be used.

To avoid increased emissions or decreased immunity of the CardioQ-EDM+ system, use only accessories and peripherals recommended by Deltex Medical.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

17.19 Manufacturer’s Declaration

The CardioQ-EDM+ system is intended for use in the electromagnetic environment described in Tables 1, 2 & 3.

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

OBSOLETE

Table 2. Guidance and manufacturer's declaration – electromagnetic immunity.			
The CardioQ-EDM+ is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioQ-EDM+ should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance.
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV 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 seconds)	<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 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CardioQ-EDM+ requires continued operation during power mains interruptions, it is recommended that the CardioQ-EDM+ be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level.			

Table 3. Guidance and manufacturer’s declaration – electromagnetic immunity.			
The CardioQ-EDM+ is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioQ-EDM+ should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the CardioQ-EDM+ system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. $d = 1.2 \sqrt{P}$.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz. $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CardioQ-EDM+ is used exceeds the applicable RF compliance level above, the CardioQ-EDM+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as orientating or relocating the CardioQ-EDM+. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

18. Cleaning, Maintenance and Warranty

18.1 Monitor Cleaning

Deltex Medical recommends that the CardioQ-EDM+ is cleaned with Cavicide® surface disinfectant spray following the instructions for use on the bottle. The monitor must be switched off, and the power cord disconnected, before cleaning.



Do not use solvents or cleaners containing solvents. Care must be taken that no fluid runs down behind the screen or switch panel. Care must be taken when cleaning the air vents to prevent water entering the unit. Care must also be taken that no cleaning fluid enters the connectors. As with any electronic equipment the monitor must not be immersed in liquid nor should any liquid be allowed to enter the unit.

The use of Cavicide spray is also recommended for cleaning the Patient Interface Cable. Under no circumstances should the cable and cable ends be immersed in liquid.

18.2 Routine Maintenance

CardioQ-EDM+ routine maintenance is limited to cleaning as detailed above and inspection of cables and connectors for wear or damage. Deltex Medical recommends that the cables be inspected at least once a month. These cables and connectors should be replaced if any cracks are found that would allow ingress of conductive fluids.

18.3 Repairs, Servicing and Calibration

The monitor does not require regular servicing or calibration; however. If the unit is damaged or fails to perform correctly it should be switched off. The monitor contains no user-serviceable parts. Only an accredited service agent appointed by Deltex Medical should undertake repairs. In case of difficulty obtaining service, please contact your Deltex Medical representative.



Deltex Medical will be responsible for the safety, reliability and performance of this equipment only if:

- Adjustments, modifications or repairs are made only by persons authorized by Deltex Medical.
- Any work performed is in accordance with the service manual.
- The electrical supply at the point of use complies with appropriate local requirements and is within the specification of the monitor.
- The monitor is used in accordance with the instructions for use identified in this operating handbook.

18.4 Warranty

The warranty gives a comprehensive level of repair and service and applies for one year from date of purchase. It will ensure that if the CardioQ-EDM+ does develop a problem it will be rectified in the quickest possible time with the minimum inconvenience.

The agreement includes all parts and labor, packing and carriage. It excludes repairs due to loss or willful damage.

Please call Deltex Medical Ltd and a loan CardioQ-EDM+ will be dispatched for earliest possible delivery. Should the equipment develop the same fault on three different occasions within the first year it will be replaced with a new CardioQ-EDM+. The Maintenance Agreement can be extended after the one year warranty period. Contact your Deltex Medical representative for more details.