Deltex medical

ODM+

Fluid Management and Cardiac Output Monitoring System

OPERATING HANDBOOK

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

This operating handbook describes the operation of the CardioQ-ODM+ using 5.0x 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-ODM+ software may have a time-limited license applied.

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1. Conventions Used in the Handbook

The following symbols or text appear in the operating handbook:

Home	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.
Probe Focus Screen	Any such text indicates a specific screen.
	Snapshot icon in *Trend Screens*.
	Signal recording icon.
	Signal recording terminated icon.
	Continuous data recording icon.
	Scroll icon in *Graphical Trend Screen.*
	Patient monitor not connected.
	Patient monitor connecting.
	Patient monitor connected.
	Saving data.

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2. Indications, Precautions, Warnings and Contraindications

2.1 Indications

The Deltex Medical CardioQ-ODM+ is indicated for use as a fluid management and cardiac output monitoring system.

Deltex Medical produces a range of esophageal Doppler probes which should only be used by clinically trained and qualified clinical personnel, or under the direct supervision of such personnel. All of these probes are approved for oral placement into the esophagus. Certain probes are also approved for nasal placement.

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 peak velocity variation (PVV), or pulse pressure variation (PPV) to guide fluid management please note that the parameters sensitivity is optimal when tidal volume is ≥7-8 ml/kg and that higher tidal volumes elicit higher variations.

The CardioQ-ODM+ excludes arrhythmic events based on heart rate variability (≥20%) and excessive variation in Stroke Volume. However the user should be aware that in periods of arrhythmia SVV, SDV, PVV or PPV should not be used to guide fluid management.

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

When using SVV, SDV, PVV 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.

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2.3 Warnings

There is a risk of esophageal perforation during the subsequent insertion of devices when an esophageal Doppler probe or other device is already in place in the esophagus.

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

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 Kinder Doppler probe (KDP) is for use in pediatrics and is only approved for oral placement in patients over 2.5 kg in weight.

The CardioQ-ODM+ 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-ODM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

DPn, I_2n and KDP 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.

Nasal placement of any probes in pediatric patients is not approved, nor is usage of the CardioQ-ODM+ for patients below 2.5 kg in weight.

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 (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..

The CardioQ-ODM+ 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.

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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-ODM+ 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.

Connecting any mains-powered devices to the USB port is strictly prohibited

Disconnect power for at least 30 seconds first.

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

2.4 Contraindications

Doppler probes (DPn and I_2n) 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 not use in close proximity to laser surgery.
Do not use in patients with pharyngo-esophagi-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.

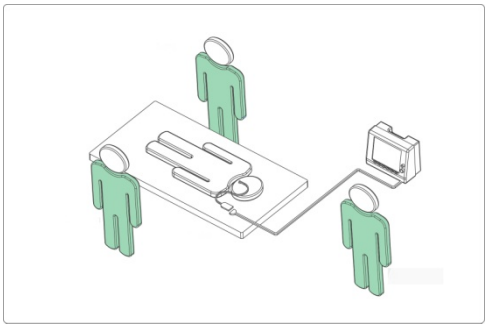
Figure 3.1.1. Front of Monitor.

A. The vents on the rear and base of the unit are required for cooling and must **NOT** be obstructed.
B. USB port.
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-ODM+ 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.**

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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-coloured 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.**

Table 3.4.1. Additional Text Entry Controls.

	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

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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=100mmHg.

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

4.1 General Information

Deltex Medical manufacture a range of Doppler probes designed for use with the CardioQ-ODM+. 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, I_2n and KDP 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 odours. 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-ODM+ on which the new probe is started will be transferred to the new probe. Data held on other CardioQ-ODM+ monitors will not be transferred.

4.5 Adult Oral/Nasal Probes

The esophageal Doppler probe (DPn) and the I_2n 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 I_2n 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.

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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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 anaesthesia.

If using the **I_2n** series, the patient **may** be awake or under full sedation or general anaesthesia. If the patient is not under full sedation or general anaesthesia, a local anaesthetic may be applied to the nasal passage and back of the throat. The probe **must** be placed nasally in 'awake' patients.

4.6 Pediatric Probes

The Deltex Medical Doppler probe for use in pediatrics is the Kinder Doppler Probe (KDP).

The KDP probe is 72 centimetres long and has maximum usage time which is defined on the probe packaging. The KDP probe is supplied sterile.

It is only approved for **ORAL** placement into the esophagus of a single patient over 2.5 kg in weight. The patient **should** be under full sedation or general anaesthesia.

The probe shaft has six depth markers visible through the transparent cover starting at 15 (cm) through to 40 (cm) incrementing in steps of 5 (cm). These markers act as a guide to facilitate correct probe placement. Signals are normally acquired as shown in the following table.

Patient Height (cm)	50-60	61-80	81-100	101-120	121-140	Over 140
Acquisition depth (cm)	15-20	15-25	15-30	20-30	25-35	25-40

4.7 Usage Limits

Age	0-127yrs
Weight	2.5-450kg (5.5 to 992lb)
Height	45-300cm (17.7 to 118in)

Some probes may only be compatible with certain monitors. **See section 4.1.**

4.8 Nomogram Limits

The adult nomogram:		**The pediatric nomogram:**	
Age:	16 to 99 yrs.	Age:	0 to 15 yrs.
Weight:	30 to 150 kg (66 to 330lb).	Weight:	3 kg to 60 kg (6.6 lb to 132lb).
Height:	149 to 212 cm (59 to 83in).	Height:	50 cm to 170 cm (20 to 67in).

The pediatric nomogram is only available with the KDP.

Nasal placement of any probes in pediatric patients is not approved, nor is usage of the CardioQ-ODM+ for patients below 2.5 kg in weight.

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-ODM+
- 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 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.

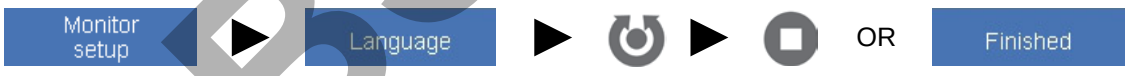
Connect the arterial blood pressure interface lead to the ADC input socket at the rear of the CardioQ-ODM+. **See Figure 3.1.2**.

Contact Deltex Medical for further installation assistance.

Turn on the CardioQ-ODM+ 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 5.3 and 5.4.**

5.3 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.

5.4 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-ODM+, 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,

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To change the year, Change date ▶ ↻ ▶ ■ OR Next

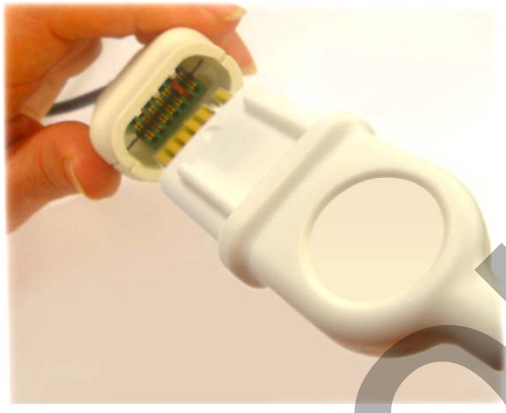
To change the day and date, Change date ▶ ↻ ▶ ■ OR Next

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, Change DST ▶ Finished

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

5.5 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.

5.6 Turning Off the Monitor

Turn off the CardioQ-ODM+ using the ON/OFF switch on the rear of the monitor. There is no special power-down procedure. The CardioQ-ODM+ 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.

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6. Initial Screens

When the CardioQ-ODM+ 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.

Patients ▶ View patient data to view data stored on the monitor for that patient, OR Offload patient data to offload patient data to a connected USB stick. **See section 14.4,** OR Delete patient 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-ODM+ 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 12.2 and 14.4.**
- 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-ODM+ 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-ODM+ 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*, Copy patient OR New patient ▶ Auto-number OR

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

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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*, Change ID ▶ ↻ ▶ ■ ▶ Continue ▶

Accept data

If a probe is started on a CardioQ/CardioQP and then used on a CardioQ-ODM+, an auto ID is generated.

6.3 Patient Data Screen

The *Patient Data Screen* is used to enter and display the patient's 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-ODM+ 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*: New patient ▶ Auto-number OR ↻ ▶ ■

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

The CardioQ-ODM+ 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, ▶ Copy 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-ODM+ 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*: ↻ ▶ Delete patient ▶ Confirm OR Cancel

OBSOLETE

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.**

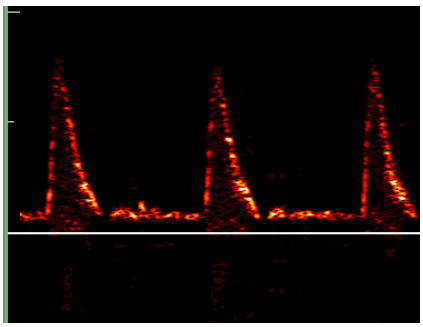

Figure 7.1.1. Good signal quality.

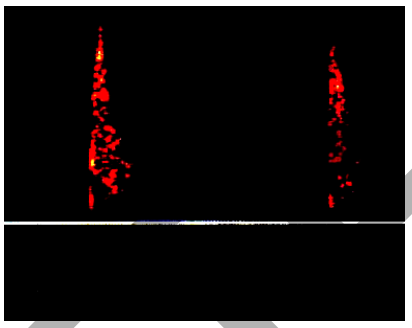

Figure 7.1.2. Poorly defined waveform.

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.

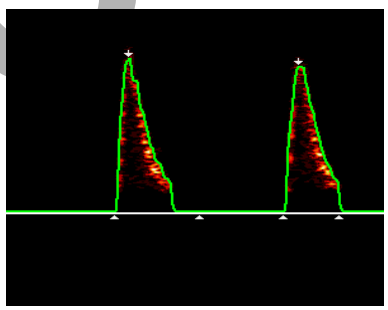

Figure 7.1.3. Misplacement of white arrows.

OBSOLETE

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

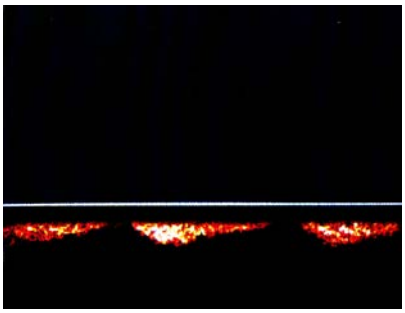

Figure 7.1.4. Venous signal.

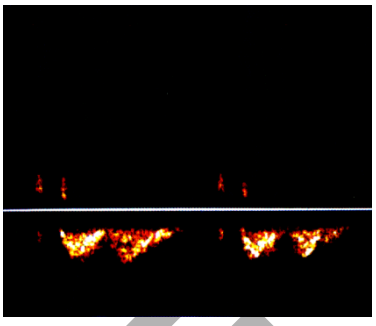

Figure 7.1.5. Cardiac signal.

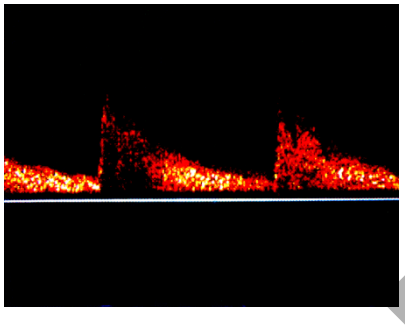

Figure 7.1.6. Celiac axis.

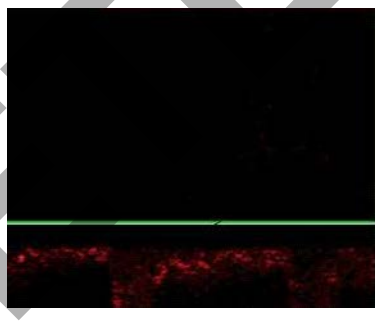

Figure 7.1.7. Pulmonary artery.

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.

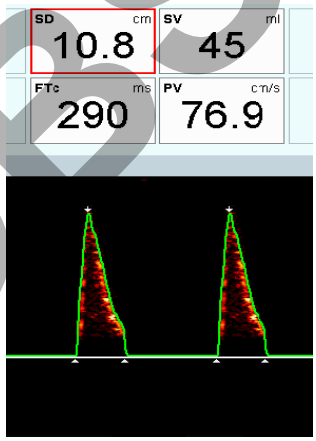

Figure 7.2.1. Appropriate range for this patient of 100cm/s.

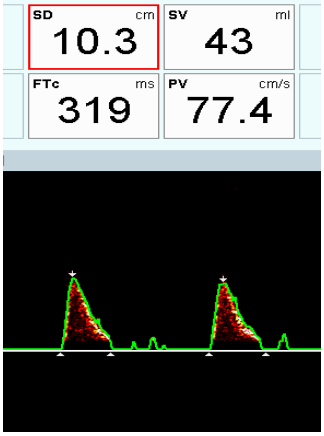

Figure 7.2.2. Inappropriate range for the same patient of 200cm/s.

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.

OBSOLETE

7.3 Setting the Signal Filter

The CardioQ-ODM+ 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.

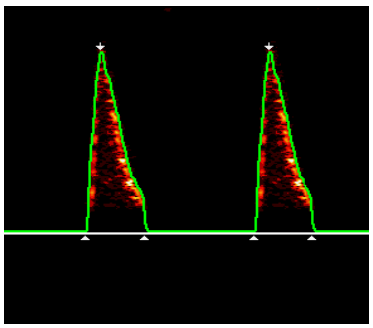

Figure 7.3.1. Filter not required.

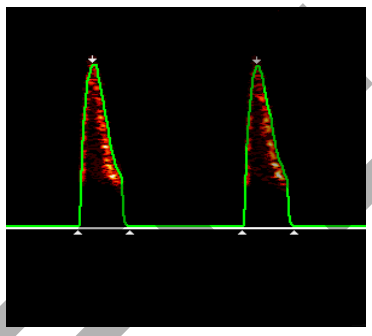

Figure 7.3.2. Inappropriate use of the filter.

To turn on the filter temporarily, Focus from a *Full Run Screen* only, ▶ Filter

7.4 Setting the Signal Gain

The amount of amplification applied to the signal in the CardioQ-ODM+ 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.**

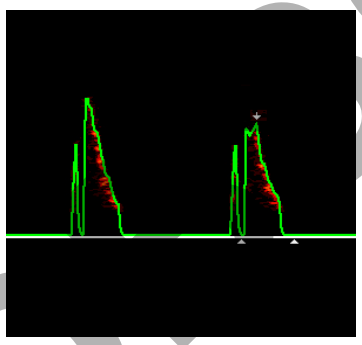

Figure 7.4.1. Insufficient gain.

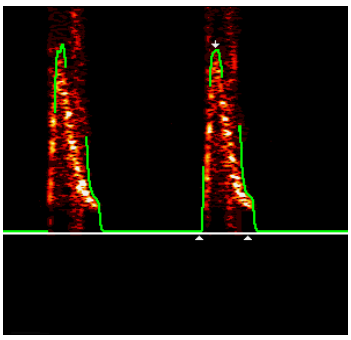

Figure 7.4.2. Excessive gain.

To increase or decrease the signal strength, Focus ▶ ↻ ▶ Run

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.

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The CardioQ-ODM+ 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-ODM+ 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-ODM+ will not be able to resolve the waveform.

If electrical noise is present, for example from an electro-surgery unit, then the CardioQ-ODM+ 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

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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, Data input & recording ▶ Cycles for calculation ▶ ▶

OR Finished

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*.

Data input & recording ▶ Respiratory rate ▶ OR Finished

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 >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, Freeze 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-ODM+ 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.

Run to return to the normal real-time display.

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7.10 Probe Disconnection

If the probe is disconnected from the monitor then:

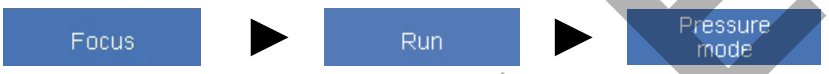
- *Flow Monitoring Mode* will cease if there is no valid pressure wave for *Pressure Monitoring Mode* and then the *No Probe Screen* will appear.
- If there is a valid pressure wave, then monitoring will continue in *Pressure Monitoring Mode*, and:
    - o If the calibration is within the valid period, 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**.

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8. Additional Calculations

SVR, SVRI, DO2, DO2I, CPO, CPI, Ea and dynEa calculations will only be displayed while the CO is within calibration. If CO drifts by >20% the calculations will be replaced with "---" and will not be displayed again until a new calibration is performed.

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.

Only Spot calculations are available in flow monitoring mode where there is no arterial line connected.

Freeze ▶ Home ▶ Additional calculations ▶ SVR ▶ Calculate SVR

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

Enter mean arterial pressure (MAP): ▶ OR Next

If MAP is not available, Enter SysBP ▶ Next to enter systolic and diastolic BP.

Then enter central venous pressure (CVP): ▶ OR Next

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

SVR and SVRI will be displayed in the PATIENT DATA area temporarily.

Accept data ▶ Finished ▶ Run

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, Data input & recording ▶ Enter CVP ▶ ▶ ▶ OR

Finished ▶ Finished

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

To cancel CVP, Data input & recording ▶ Enter CVP ▶ No value available ▶

Accept data ▶ Finished

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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*:

Home ▶ Additional calculations ▶ SVR

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

To recall other available SVR calculations, Previous calculation OR Next calculation

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.**

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

If the CardioQ-ODM+ 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.

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-ODM+ 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 (DO_2) Delivered Oxygen Index (DO_2I)

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

Take a blood sample, Freeze ▶ Home ▶ Additional calculations ▶

DO2 ▶ Sample DO2 ▶ Run

When blood sample results are available,

Home ▶ Additional calculations ▶ DO2 ▶ Calculate DO2

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

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

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

Then enter saturated arterial oxygen (SaO_2): OR Next

Then enter hemoglobin (Hb): OR Next

To change Hb units if required, Change Hb units

DO_2 and DO_2I will be displayed temporarily in the *Patient Data* area.

Accept data ▶ Finished

8.4 Displaying DO_2 Calculations

DO_2/DO_2I will be displayed temporarily in the *Patient Data* area when the calculation is made.

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

Home ▶ Additional calculations ▶ DO2 The most recent calculation will be displayed.

To recall other DO_2 calculations, Previous calculation OR Next calculation

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.**

DO_2 or DO_2I 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-ODM+ is turned off, or the probe is disconnected, then the data are retained. When monitoring recommences, the results of the last accepted DO_2/DO_2I are displayed within the 8 boxes if already chosen as a default.

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9. Pressure Monitoring

Any unauthorised 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-ODM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

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

Connect Deltex ABP cable **see section 17.18** into the ADC connection **see figure 3.1.2.** *Please contact your Deltex Medical representative for details.*

With the monitors connected using a Deltex ABP cable **see figure 7.4.3**, check for systolic/diastolic and MAP pressure values on both the ODM+ and Patient Monitor displays to ensure equivalence.

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

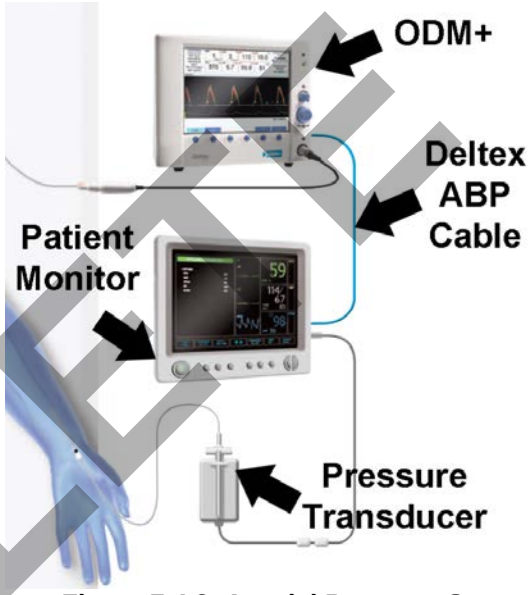

Figure 7.4.3. Arterial Pressure Setup.

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 ≥20% from that recorded at the time of calibration, a “Recalibration advised” message will flash and the SV and SVI will be displayed in yellow.

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9.2 Probe Disconnect and Reconnection

See Sections 7.10 and 7.11.

OBSOLETE

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.

Freeze — A red outline will appear around the real-time area, indicating the area which will be "snapped", ▶ Take snapshot

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.

▶ Delete snap — 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, Run

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

10.2 Viewing Snapshots

Home ▶ Snaps — 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,

▶ Show snap 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, Home ▶ Full screen

10.3 Comparing Snapshots

There are two methods to compare snapshots:

1: Compare snap — 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.

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2:

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

to select 2nd snap, OR

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:

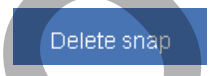
If the range setting at the time of recording is different from the current setting, the numeric range for the snapshot is displayed on a red background.

To return to a whole screen real time display,

10.4 Deleting Snapshots

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

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

The green outline will move over the selected snapshots, ▶ 

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

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11. Events

11.1 Recording Events

The CardioQ-ODM+ records events within the historical data for later recall and display. SVR or DO_2 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*: Home ▶ Events 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: Fluid OR Crystalloid OR Colloid OR

Blood product ▶ Quantity not specified OR to select volume, ▶ Confirm

Vasodilator events: Vasodilator ▶ Decrease vasodilator OR Increase vasodilator OR

Start vasodilator OR Stop vasodilator OR Vasodilator bolus

Vasoconstrictor events: As vasodilator events.

Inotrope events: as vasodilator events.

Miscellaneous events: Miscellaneous ▶ Clamp on OR Clamp off

OR Position changed OR Other event

When diathermy occurs, Diathermy

For all events: A yellow confirmation message appears, ▶ Confirm OR Cancel

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.

OBSOLETE

12. Trend Display

12.1 Historical Data-Continuous Trends

The CardioQ-ODM+ 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, DO_2 and DO_2I 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-ODM+ 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,

If **DO_2 or SVR** is one of the events, the results of these additional calculations will also be displayed.

To locate certain events,

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

OBSOLETE

To view snapshots that are marked as an event, Show snap

To return to the *Continuous Trend Screen*, Home ▶ Continuous trend

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, Freeze ▶ Add point to graph

A point may be added when a snapshot is taken.

To view snapshots that are marked as an event, Show snap

To return to a *Full-Width Run Screen*, Run ▶ Home ▶ Full screen OR

Home ▶ Full screen ▶ Run

To view graph, Home ▶ Graphical trend

To locate data points, Previous point OR Next point

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

To alter the visible graphical period, Graph 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 is only available to view if a point has been stored to start the graph.

OBSOLETE

13. Customizing the Monitor

This can be done in No Probe Connected Screen.

13.1 Restoring the Factory Settings

If the CardioQ-ODM+ 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.

Monitor setup ▶ Reset all ▶ A confirmation will appear, ▶ Confirm OR

Cancel

13.2 Adding a Hospital Name

The hospital name can be displayed on the screen:

Monitor setup ▶ General ▶ Hospital name ▶ ▶

to enter text, ▶ Finished

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.

Monitor setup ▶ General ▶ Patient monitors ▶ ▶

to select available patient monitor, ▶ Finished

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

Baud rate ▶ ▶ ▶ Finished

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

Flow control ▶ Finished

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.

OBSOLETE

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 user ▶ select a User from the menu.

2: *Go To User Profile Screen*: Monitor setup ▶ Users

To select a User, ↻ ▶ ■ ▶ Select user ▶ Finished

13.5 Multiple User Setups

Go to *User Profile Screen*: Monitor setup ▶ Users

To create a new profile, ↻ ▶ New profile ▶ Change name ▶ ↻ ▶

■ to enter text, ▶ Finished

To delete a User, ↻ ▶ Delete user ▶ Confirm OR Cancel

▶ Finished

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*: Monitor setup ▶ Users ▶ ↻ ▶

Select user ▶ User settings

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

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* Flow mode OR Pressure mode

OBSOLETE

To change any of the 8 results, the Continuous Trend results or the Graphical Trend results, Select results ▶ to select a result, ▶ ▶ 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, Machine settings ▶ Cycles ▶

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

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, Machine settings ▶ Trend display

To change the highlighted result in *Flow Monitoring Mode* only, Machine settings ▶ Highlighted result

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, Machine settings ▶ Recording

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

OBSOLETE

14. USB and Offloading Patient Data

Any unauthorised 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-ODM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

Connecting any mains-powered devices to the USB port is strictly prohibited

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.

In a *Run Screen*, Freeze ▶ Save screen ▶ Run

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:

To start recording on any running screen, Data input & recording ▶ Start data recording ▶ Finished

A flashing recording icon is displayed in the bottom left of the screen.

Recording is in progress whenever this icon is present.

To stop recording on any running screen, Data input & recording ▶ Stop data recording ▶ Finished

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.**

To start recording on any running screen, Data input & recording ▶ Start signal recording

A flashing recording icon is displayed in the bottom left of the screen, as shown on the left. ▶ Finished

OBSOLETE

The recording will stop automatically after 3 minutes OR Data input & recording ▶ Stop signal recording on any running screen.

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,** ▶ Offload patient data ▶ to select a patient,

▶ Continue

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,** ▶ Offload patient data

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.

Delete patient if the data are no longer required.

14.5 Offload Summary

This function allows the offload summary of patient-relevant details
Patient ID
Date of initial use
Time of initial use
Probe type
Duration of use

Offloading from the *No Probe Screen*:

OBSOLETE

Insert a memory stick into the USB port on the rear of the monitor. **See Figure 3.1.2,** ▶ Offload Summary ▶ to select a patient,

▶ Continue

14.6 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.

Monitor setup ▶ Version data

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

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

OBSOLETE

15. Demonstration Mode

The monitor can also be operated using a set of pre-recorded waveform signals. This allows the CardioQ-ODM+ to be demonstrated without the need for external signal sources. It also allows users to familiarize themselves with the operation of the CardioQ-ODM+ 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-ODM+ while it is running in demonstration mode, the CardioQ-ODM+ will exit the demonstration mode and return to normal running, as appropriate.

15.1 Running the CardioQ-ODM+ in Demonstration Mode

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

To select a waveform, ▶ OR Continue

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

To select an alternative waveform, Focus from a full *Run Screen* only, ▶ Select waveform ▶ ▶ OR Continue

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-ODM+ will not be deleted.

To end the demonstration, Focus from a full *Run Screen* only, ▶ Select waveform ▶

End demo OR connect a probe to the patient interface cable.

Demo data cannot be offloaded.

OBSOLETE

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 14.6.**

OBSOLETE

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	IIb

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. diathermy) in close proximity. The equipment uses a software trap to recognise when diathermy is in use and screens out the interference, a blue line along with a “noise detected” message will be displayed for the duration of the interference. When in the “Noise Detected” mode the last good calculations will be frozen and displayed on screen for up to one minute, if after one minute if the interference is still present the numbers will be replaced by “---”.

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-ODM+ 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.

OBSOLETE

17.6 System Characteristics

•Ultrasound
- 4.02MHz continuous wave Doppler ultrasound (I_{spta} < 250mW/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-ODM+ 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-ODM+ only has one fixed acoustic output level which is fixed by the circuitry and cannot be adjusted by the user.

Mode / Parameter		***Run*** and ***Probe Focus*** modes
Peak-negative acoustic pressure	p_-	140 kPa
Spatial-peak temporal average intensity	I_{spta}	680 mW.cm^{-2}
System settings		*not applicable*
Distance from transducer output face to point of maximum pulse-pressure-squared integral	l_p	0.5 mm
-6 dB beam width at l_p	w_{b6} (||) (⊥)	0.46 mm 2.33 mm
Output beam dimensions*	(||) (⊥)	1.16 mm 3.01 mm
Arithmetic mean acoustic working frequency	f_{awf}	4.02 MHz
Initialization and power-up modes		*not applicable*
Maximum power output		5.7 mW
Output beam intensity*	I_{ob}	110 mW.cm^{-2}
Acoustic output freeze		No
Transducer stand-off distance	l_{ts}	contact

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

OBSOLETE

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.

The Mechanical Index (MI) are below 1.0 for all device settings.

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 Parameter Measurement Ranges

The CardioQ-ODM+ 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	$ml/min/m^2$
SOI	0	4163	$ml/s/m^2$

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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
Ea	0.27	10	mmHg/ml
Eadyn	0	10	mmHg/ml/ 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%*

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SVI	+/- 15%*
SVR	†
SVRI	†
DO_2	†
DO_2I	†
SOI	†

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_2I	†
Psys	§
Pdia	§
Pmap	§
PPV	+/- 2%
BP	§

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

Parameters	**Accuracy**
CPO	§
CPI	§
Ea	§
Eadyn	§

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 haemodynamic 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 only mode)

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PVV - peak velocity variation
SVR - systemic vascular resistance (not available in linear only mode)
SVRI - systemic vascular resistance index (not available in linear only mode)
DO_2 - delivered oxygen (not available in linear only mode)
DO_2I - delivered oxygen index (not available in linear only mode)
SOI - stroke output 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 (adult only) (not available in linear only mode)
SVRI - systemic vascular resistance index (adult only) (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

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)
Ea - arterial elastance (not available in linear only mode)
Eadyn - dynamic arterial elastance (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

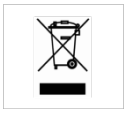
Any unauthorized connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with IEC 60601-1) to the CardioQ-ODM+ while the monitor is connected to a patient, unless a medical grade isolator meeting IEC 60601-1 is used.

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 and providing a connection to Deltex Medical approved devices.
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.

OBSOLETE

17.15 Symbolic Markings

	Consult accompanying documents		Refer to instruction manual booklet
	Type BF		Latex-free product
	WEEE Mark (European Directive 2002/96/EC)*. Indicates separate treatment from general waste at end of life.	CE	Conformité Européenne (CE) Marking of conformity to European Medical Device Directive
STERILE EO	Sterilized with ethylene oxide		Certified for use in US and Canadian markets
	Use by YYYY-MM		Date of manufacture
REF	Catalogue number	LOT	Batch code
SN	Serial number		Storage temperature
IPx7	Degree of protection against harmful ingress of water	IP20	Degree of protection against solid foreign objects.
	USB port		Network port
10101	RS232 port	ADC	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	O	AC Power switch OFF position
	Volume Control Knob		***Control Knob***
	Fragile. Do not get wet. This side up.		Do not reuse. Single patient use

OBSOLETE

* **Within the European Union** – EU-wide legislation, as implemented in each Member State requires that the waste electrical and electronic products carrying this mark must be disposed of separately from normal household waste. This includes the monitor and electrical accessories, such as the PIC Lead and power cord. For UK customers contact Deltex Medical customer Services to arrange return. **Outside the European Union** – If you wish to dispose of used electrical and electronic products outside the European Union, please contact your local authority to ensure the equipment does not end up in the 'normal' household waste.

17.16 Accessories and Spares

Part number	Description
9051-7165	CardioQ-ODM+ monitor
9051-7002A	Patient interface cable
	Power cord. Please contact your Deltex Medical representative for details.
9051-5606	Operating handbook (English US-Canada)
	RS232 null modem cable (Screened, 3m or less in length) – not provided by Deltex

GCX Anaesthesia station arms/mounts (Available for GE & Dreager stations) – not provided by Deltex
Pressure interface lead

Please contact your Deltex Medical representative for details.

17.17 Probes and Probe Accessories

Part number	Description
9070-7005	Deltex Medical 240 Hour Esophageal Doppler Probe (DP240)
9081-7001	Deltex Medical 72 Hour Kinder Doppler Probe (KDP72)
9090-7012	6 Hour Deltex Medical I_2S Probe
9090-7013	24 Hour Deltex Medical I_2P Probe
9090-7014	72 Hour Deltex Medical I_2C Probe

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

17.18 ABP Cables

Part number	Description
9051-3947	Fukuda Denshi
9051-3949	GE Datex
9051-3950	Philips
9051-3951	Draeger
9051-3952	GE PDM
9051-3953	GE Marquette
9051-3957	GE Datex & Marquette
9051-3958	Spacelabs
9051-3959	Fukuda Denshi
9051-3960	Datascope (Now Mindray)
9051-3962	Mindray
9051-3964	Mindray
9051-3965	GE Datex
9051-3966	Nihon Kohden

17.19 Electromagnetic Compatibility (EMC)

The ODM system is designed for use in the professional health care environment except near the RF shielded room of an ME system for magnetic resonance imaging where the intensity of EM disturbances is high. Where the waveform is displayed correctly the calculated parameters will be within their stated accuracy. The system is sensitive to airbourne interference especially in its band of operation. Where the interference is influencing the placement of markers the accuracy of the system may be compromised this is clearly visible on the waveform display in both flow & HD-ICG modes. In flow mode the accuracy of the ODM system depends on the green line follower and the placement of markers at the start, end and peak flow as described in section 7.1. In HD-ICG mode the accuracy is dependent the derived waveform and the placement of coloured squares as described in 10.8.

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-ODM+ and the offending equipment as much as possible.
- Interference may be borne by the mains supply, so re-connect the CardioQ-ODM+ to a different power outlet to see if this makes a difference.
- Connect the equipotential earth point to a local earth

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If possible, the CardioQ-ODM+ should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the CardioQ-ODM+ 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-ODM+ 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.

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17.20 Manufacturer's Declaration

The CardioQ-ODM+ system is intended for use in the electromagnetic environment described in Tables 1, 2, 3 & 4.

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions		
The CardioQ-ODM+ is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioQ-ODM+ should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CardioQ-ODM+(1 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.
	Group 2	The CardioQ-ODM+(2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this Equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

1. CardioQ ODM+ without hub
2. CardioQ ODM+ with hub

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Table 2: Guidance and manufacturer's declaration – electromagnetic immunity			
The CardioQ-ODM+ is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioQ-ODM+ should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance.
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 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-ODM+ requires continued operation during power mains interruptions, it is recommended that the CardioQ-ODM+ be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

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Table 3: Guidance and manufacturer's declaration – electromagnetic immunity

The CardioQ-ODM+ is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioQ-ODM+ should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CardioQ-ODM+ system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	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-ODM+ is used exceeds the applicable RF compliance level above, the CardioQ-ODM+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as orientating or relocating the CardioQ-ODM+.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 4: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment			
Test frequency (MHz)	Band (MHz)	Service	Immunity Test Level
385	380 - 390	TETRA 400	27
450	430 - 470	GMRS 460, FRS 460	28
710	704 - 787	LTE Band 13, 17	9
745			
780			
810	800 - 960	GSM 800/900, TETRA 8OO, iDEN 820, CDMA 850, LTE Band 5	28
870			
930			
1720	1700 - 1990	GSM 18OO; CDMA 19OO; GSM 19OO; DECT; LTE Band 1,3, 4, 25; UMTS	28
1845			
1970			
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28
5240	5100 - 5800	WLAN 802.11 a/n	9
5500			
5785			
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ODM system, Including cables specified by Deltex Medical. Otherwise, degradation of the performance of this equipment could result.			

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18. Cleaning, Maintenance and Warranty

18.1 Monitor Cleaning

Deltex Medical recommends that the CardioQ-ODM+ is cleaned at least once a month. It may be appropriate to clean the monitor more frequently depending on the environment in which it is used. The monitor must be switched off, and the power cord disconnected, before cleaning.

Deltex Medical recommends that the CardioQ-ODM+ system is cleaned with 1% Sodium Hypochlorite (Milton - 10,000ppm) solution. A damp soft cloth should be used.

The display window should be cleaned with a soft cloth dampened with the solution to avoid scratching the screen. Do not use solvents, or cleaners containing solvents. Care must be taken to avoid liquid cleaning solution entering the monitor.

The monitor case, including the rear panel, knobs and buttons, may be cleaned with a soft cloth dampened with the solution. Solvents must not be used. Care must be taken when cleaning the air vents to prevent fluid entering the unit. Care must be taken to avoid liquid entering the connector sockets. As with any electronic equipment the monitor must not be immersed in liquid nor should any liquid be allowed to enter the unit.

The Patient Interface Cable may be cleaned using a soft cloth dampened with the cleaning solution. Under no circumstances should the ends of the cable be immersed in the solution. Deltex Medical does not recommend sterilisation of the monitor or cable.

18.2 Routine Maintenance

CardioQ-ODM+ 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, Deltex Medical does recommend that the monitor has one planned preventative maintenance (PPM) check per year. This can either be arranged through Deltex Medical or one of its representatives. Deltex Medical has a return to manufacturer policy for repair and servicing however, service and repair training is also available. *Please contact your Deltex Medical representative for details*

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.

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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-ODM+ 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-ODM+ 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-ODM+. The Maintenance Agreement can be extended after the one year warranty period. Contact your Deltex Medical representative for more details.

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