



Omega Critical Care truCCOM Monitor



continuous cardiac output monitoring system

Operator Manual

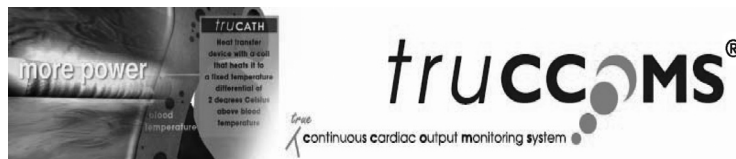
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English version

1-14



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Operator Manual

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PREFACE

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

The Omega Critical Care Continuous Cardiac Output Monitor (truCCOM) is only for use with the Omega Critical Care Pulmonary Artery Catheter (truCATH.ip).

WARNING: Carefully read the truCCOM Monitor operator manual and truCATH.ip Catheter directions for use before attempting to use the Omega Critical Care (OCC) truCCOM monitoring system. Indications, contra-indications, cautions, warnings & complications relevant to the catheter are included in the truCATH.ip catheter DFU.

NOTE: Current revisions of both the truCCOM Monitor operator manual and truCATH.ip catheter directions for use are available on the Omega Critical Care web site www.omegacriticalcare.com

WARNING: Continuous Cardiac Output Monitoring should always be discontinued when blood flow around the heat transfer device (HTD) is stopped or reduced. Clinical situations where Continuous Cardiac Output Monitoring should be discontinued include but are not limited to: time periods when a patient is on cardiopulmonary bypass, partial withdrawal of the catheter so that the thermistor is not in the pulmonary artery, or removal of the catheter from the patient.

PURPOSE AND SCOPE

The purpose of this manual is to provide the operator of the OCC truCCOM Monitor with setup and operating instructions, device application, limitation and routine performance verification procedures. To achieve satisfactory result, the operator must read this manual thoroughly before attempting to use the Monitor.

AUDIENCE

This manual has been prepared for use by trained critical care clinicians, nurses, and physicians in any hospital environment where critical care is administered (for example, emergency rooms, operating rooms, intensive care units, etc.).

TRAINING

Training on the truCCOM system is provided by Omega Critical Care via the Customer Service Department.

Initial training is provided to all new customers/ distributors and any new customer/ distributor staff members employed and appointed to use truCCOMS.

Customer/ distributor training is routinely reviewed on an annual basis by Omega Critical Care's Customer Service Department, unless requested at an earlier date by the customer/ distributor. If during the review, refresh training is deemed necessary, training will be scheduled and provided by Omega Critical Care at an agreed time and location.

PRODUCT LABELING AND CONVENTIONS USED

The labels and conventions used in this manual and on the product are compliant with EN60601-1 and EN980. A complete copy of the labels found on the system can be found in Appendix F.

DOCUMENT ORGANISATION

This manual is organised into the following sections:

- Chapter 1: Introduction**
Provides a brief introduction to the *OCC truCCOM* Monitor.
- Chapter 2: Operating the *OCC truCCOM* Monitor**
Describes the information needed by the user to operate the *OCC truCCOM* Monitor.
- Chapter 3: Principles of Operation**
Describes the theory of operation of the *OCC truCCOM* Monitor.
- Appendix A: Specifications**
Provides technical and environmental specifications of the *OCC truCCOM* Monitor.
- Appendix B: Equations for Calculated Patient Parameters**
Provides equations used to calculate patient parameters.
- Appendix C: Monitor Default Settings**
Describes the default settings of the *OCC truCCOM* Monitor.
- Appendix D: Service and Support**
Provides service and support information for contacting the OCC Customer Service Department.
- Appendix E: Warranty**
Describes the warranty terms and conditions of the *OCC truCCOM* Monitor.
- Appendix F: Labels**
Copy of labels and symbols used on the *OCC truCCOM* Monitor.
- Appendix G: Troubleshooting Guide**

DEFINITIONS

Abbreviation	Definition
BSA	Body Surface Area
CCO	Continuous Cardiac Output
CI	Cardiac Index
CO	Cardiac Output
CVP	Central Venous Pressure
Delta T	Temperature Difference
DFU	Directions For Use
EEPROM	Electrically Erasable Programmable Read-Only Memory
EL	Electro-luminescent
ESU	Electrosurgical Unit
HTD	Heat Transfer Device (Coil)
IV	Intravenous
LCD	Liquid Crystal Display
MAP	Mean Arterial Pressure
OCC	Omega Critical Care
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
T1	Thermistor 1 (Distal Thermistor)
T2	Thermistor 2 (Proximal Thermistor)
TD	Thermodilution
TDCO	Thermodilution Cardiac Output
TDCF	Thermodilution Correction Factor
truCATH.ip	Omega Critical Care Continuous Pulmonary Artery Catheter
truCCOM	Omega Critical Care Continuous Cardiac Output Monitor

CHAPTER 1

Introduction

INTRODUCING THE OCC truCCOM

The OCC *truCCOM* Monitor (*truCCOM*) is an advanced patient monitor designed to continuously measure a patient's cardiac output in conjunction with an OCC continuous cardiac output pulmonary artery catheter (*truCATH.ip*).

Continuous cardiac output (CCO) measurements are based on the thermodynamic principles of heat transfer. The principles of operation of *truCCOMS* are described in Chapter 3 of this operator manual.

Following initialisation of the *truCCOM* monitor and system test of the attached OCC *truCATH.ip* catheter, cardiac output measurements are graphically displayed on the monitor LCD screen by selecting CCO mode of operation. The monitor continuously displays the patient's cardiac output without the need for user calibration or intervention.

The OCC *truCCOM* monitor is designed to be used by trained clinicians in a variety of critical care settings. Principal areas of use include operating rooms, intensive care units and recovery rooms, as well as hospital emergency rooms, cardiac care and burns units.

CHAPTER 2

Operating the OCC truCCOM Monitor

OVERVIEW

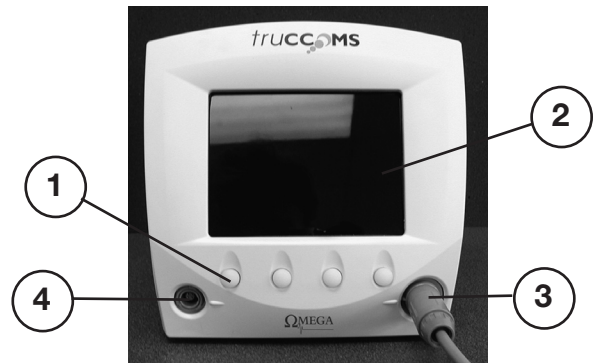
The OCC *truCCOM* Monitoring System consists of four major components: a medical grade monitor, detachable catheter interface cable, injectate temperature measurement probe and a power cord. The System is principally intended for use with OCC *truCATH.ip* catheters to measure cardiac output continuously. Alternatively, the monitor can be used to measure cardiac output intermittently, through its thermodilution mode, using the OCC *truCATH.ip* catheters.

INTENDED USE:

The *truCCOMS* intended use is for the assessment of a patient's haemodynamic condition through direct intracardiac (right heart) and pulmonary artery pressure monitoring, cardiac output determination and for continuous infusion of solutions. The distal port on the catheter also allows for sampling of venous blood.

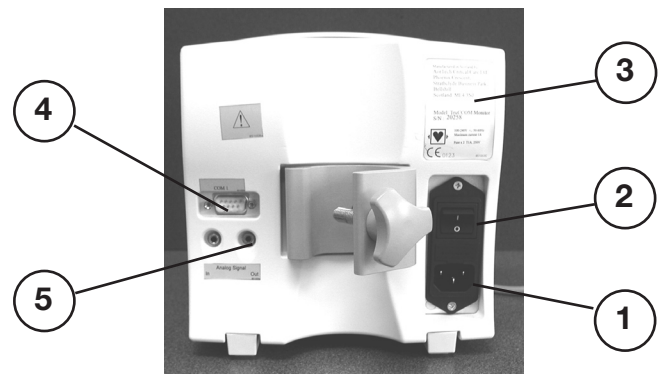
The *truCCOM* monitor determines and displays the patient's cardiac output.

CONTROLS – FRONT VIEW



- 1. Keypad**
- 2. Display**
LCD unit with integral EL backlight.
- 3. Catheter Interface**
This connector provides the interface for the *truCATH.ip* catheter via the *truCCOM* monitor patient cable. The interface connections have alignment guides and lock/ release mechanisms.
Caution: Before connecting the patient cable to the *truCATH.ip* catheter, refer also to “Basic Operation” instructions. Connections are electrically isolated from earth ground.
- 4. TD port**
The TD port provides connection for the TD probe cable and is used to measure injectate temperature in thermodilution mode. The connectors have an alignment guide and lock/ release mechanism.

CONTROLS – REAR VIEW



- 1. AC Power Input**
Use only the power cord supplied with the monitor. This connector accepts AC power ranging from 100 to 240 VAC 50/60 Hz.
Caution: DO NOT remove rear panel. Refer servicing to qualified personnel.
- 2. Power switch**
Turns the system power On or Off.
- 3. Instrument Serial Number**
This numerical identification is required when contacting OCC Customer Service.
- 4. Serial Interface**
Allows connection to instrument to download data files via a 9-way D-type connector.
- 5. Analogue Output**
Analogue signal output.

BASIC OPERATION

The truCCOM monitor is a menu driven system. There are four hard keys that correspond to the menu items immediately above them on the LCD screen, these items will change depending on the mode of operation.

Each of the operating modes and the system set up is described in detail in subsequent sections.

The truCCOM monitor provides the option of working in eight languages: English (En), German (De), Dutch (Nl), Italian (It), Danish (Da), Spanish (Es), Swedish (Sv) and French (Fr). The language can be changed from SYSTEM MODE.

Note: English is the default language. For English use there is no need to change the language setting.

GETTING STARTED

Remove all packaging and store in a safe place. Ensure that all the items on the packing list are present. Care should be taken when unpacking to ensure there is no damage to accessory items.

The unit can be attached to a drip stand/IV pole or placed on a table top. The rear legs of the unit can be raised to adjust the viewing angle if required when it is table mounted.

CAUTION: If table mounted ensure the monitor is positioned on a flat surface and is stable before use. When attaching the unit to an IV pole, care should be taken to ensure that the unit clamp is securely fastened and the Monitor is stable before use.

For additional support refer to truCCOMS Quick Reference Guides. Quick reference guides are provided during training and are available on request via OCC Customer Service Department (See Appendix D).

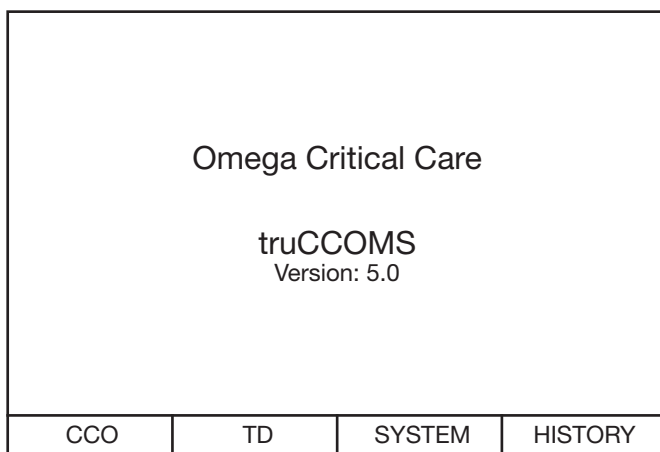
Attach the power cord to the AC power inlet and connect to the mains supply.

Connect the patient cable to the socket on the front of the unit.

Power up the system by putting the switch on the AC inlet to the on position.

INITIALISATION SEQUENCE

When power is applied the keys on the front of the system will light up green and the LCD screen will come on. The system will run through its start up sequence, which will last approximately 30 seconds. When it has completed the start up sequence the following Main Menu screen will be displayed.



The following table shows the key options available from the Main Menu Screen. Any one of the four modes of operation can be selected by pressing the corresponding key.

MAIN MENU OPTIONS

CCO	Continuous (CCO) Mode
TD	Thermodilution (TD) Mode
SYSTEM	System Mode
HISTORY	History Mode

truCATH.ip Testing

Refer to truCATH.ip Catheter DFU section “Catheter Preparation”.

To detect damage of the catheter thermistors, heat transfer device (Coil) or EEPROM connections that could potentially occur due to handling before use, the catheters electrical continuity must be tested prior to insertion into the patient. When testing, the Heat Transfer Device (HTD) and the T2 thermistor must be fully immersed in sterile saline greater than 25°C.

Connect the truCATH.ip to the patient cable by aligning the red dot markers and gently pushing the patient cable connector into the truCATH.ip catheter connector until secured in place.

The catheter test is carried out from the ‘SYSTEM’ menu. Press the ‘SYSTEM’ key then using the ‘SELECT’ key move the cursor to the ‘System Test’ item. ‘ENTER’ will start the test.

Testing will last approximately 5 seconds and once it is complete one of two messages will be displayed.

‘truCATH.ip connected’ indicates that the test has been successful and the catheter is okay.

‘Catheter fault! Code *n*’ indicates that a fault has been detected with the catheter where *n* refers to the type of fault discovered.

Code	Fault source
0	EEPROM
1	T1 thermistor
2	T2 thermistor
3	Coil

In the event of a fault occurring the catheter must not be used.

The catheter can be removed from the patient cable by sliding back the patient cable connector release collar whilst gently pulling the truCATH.ip catheter connector in the opposite direction. The faulty catheter should be retained for return to OCC as detailed in Appendix D.

CONTINUOUS MODE (CCO)

Attach the catheter end of the patient cable to the catheter connector taking care to ensure the alignment of the key is correct.

Verify that the OCC truCATH.ip Catheter is properly inserted into the patient.

CAUTION: Prior to catheter insertion, refer to the directions for use provided with each catheter for complete description, instructions, warning, cautions, and specifications.

CAUTION: The use of Electrosurgical units (ESU) may cause interference with the truCCOMs instrument. When an ESU is in use the readings for cardiac output should be discarded. Wait for at least 10 seconds after the ESU has been switched off before accepting any readings for cardiac output. An alert is displayed on the monitoring screen during presence of interference and is removed when the signal recovers.

CAUTION: During the period when the error message "Interference Detected" is displayed, the CCO and Tools screens will show the last recorded CO and CI values calculated prior to interference being detected in both analogue and/or digital format. Once the signal has been re-established, the tracing and digital readings will revert to the current CO and CI values calculated by the system. The Clinician should be aware that during the period when the signal is attempting to re-establish, the milli-wattage will increase and decrease, as the system attempts to re-establish the delta temperature. This may cause a tracing to appear in the history file that may be downloaded following the procedure. The data during this period should be ignored, as it may be erroneous.

Press the key corresponding to CCO from the Main menu screen and an initialisation message will be displayed.

After around 10 seconds the monitoring screen will be displayed with a graph for cardiac output and numbers for Cardiac Output and Body temperature.

The message "Wait: Delta T not established" is displayed on the monitoring screen for a period of approximately 30 seconds until a temperature difference has been established between Thermistor 1 and Thermistor 2. During this period key presses to edit MAP, CVP, Weight and Height are ignored.

Cardiac Index will be displayed once the body surface area (BSA) has been calculated. The BSA can be set using the SVR/BSA edit options, accessed using the Tools Key.

SCALE ADJUSTMENT

The Scale + key provides the option of displaying the CCO trace on a high-definition scale. The outer limits of the high-definition scale are the CCO value at selection +/- 1 L/min and the CCO value is displayed to two decimal places. The system will revert back to the normal scale if CCO goes beyond the limits of Scale + or if the Scale - key is selected. If Scale + is desired it can be obtained by selecting Scale + again.

EVENT

The event marker can be added to the CCO trace by pressing the Event button. Up to 99 individual event markers can be placed before the event marker number resets back to 1. These markers will be visible in History mode and will be logged in the History data file.

The following CCO menu options are available:

CCO MENU OPTIONS

Exit	Return to main menu
Scale + / Scale -	Scale + Selects high-definition scale, Scale - returns to full scale
Tools	Displays SVR and BSA edit screen and shows data in text format. Provides path to Utilities (History/Alarm).
Event	Places an Event Marker on the Screen.

TOOLS SCREEN

NOTE: The TOOLS screen provides access for patient data parameter entry Weight/ Height, MAP & CVP values.

The screen allows the user to enter values for the patient's mean arterial pressure (MAP) and the central venous pressure (CVP) and will calculate the systemic vascular resistance (SVR). It also allows the user to enter values for patient height and weight and so calculate the BSA. Once the BSA is calculated the Cardiac Index and if appropriate the SVR index (SVRI) will be displayed. In addition the blood temperature, coil temperature, power and temperature difference can be viewed. Data is displayed in text format. This screen also provides the path via the Utilities Key to view CCO history and to edit the Alarm Status.

CALCULATING SVR

Select SVR from the menu and the MAP value will be displayed in green. If no previous value has been entered then a default value will be displayed. Using the up and down arrows adjust the MAP to the required value. Press 'SAVE' and the CVP value will be displayed in green. Adjust the CVP to the required value and save. The SVR will be shown and the elapsed time display will revert to 00:00:00. The elapsed time is the period since the last SVR calculation was carried out. If the BSA has been calculated then the SVRI will also be displayed.

CALCULATING BSA

Select BSA from the menu and the patient Height will be displayed in green. A default height will be shown if no previous value has been entered. Adjust the height using the up and down arrows and press 'SAVE'. The weight will now be displayed in green and this can be adjusted using the arrows. Once the weight has been saved the BSA will be displayed. To change the default height and weight units from metric to imperial use the system menu prior to entering CCO mode.

CCO

To return to the continuous graphic display press 'CCO'.

UTILITIES

To Access History details in CCO mode or to edit the status of the system Alarms press the 'Utilities' button.

TOOLS MENU OPTIONS

SVR	Edits MAP and CVP to calculate SVR
BSA	Edits height and weight to calculate BSA
CCO	Returns to the graphical CCO screen.
Utilities	Gives Access to Utilities Menu (History/Alarms)

SVR AND BSA EDIT MENU OPTIONS

Exit	Return to Tools screen
↑	Increments value
↓	Decrements value
Save	Saves value

UTILITIES MENU

The utilities menu allows the user to toggle the alarms ON or OFF and to view history for the current session while still monitoring CCO.

UTILITY MENU OPTIONS

Back	Return to Tools Screen
History	View History
Alarms	Toggle alarm status On/Off

HISTORY

From the Utilities Menu select History. The latest history data will be displayed in graphical format in green. By selecting the < Key the system will page back through the history if more data is available. All TD, CO, SVR and events will be displayed. Selecting the > Key allows the user to page forward through the history.

Select the Exit Key to Exit History mode and return to the Utilities Menu.

HISTORY MENU OPTIONS

Exit	Return to Utilities Screen
<	Page Back
>	Page Forward

ALARMS

The truCCOM monitor provides an audible alarm that provides indication of system errors or that system parameters have gone outside defined limits that are set by the user. Select the Alarms Key to toggle ON or OFF the alarms. The alarm is automatically set to the ON condition whenever the system is switched on, CCO mode enabled and the delta temperature is established. Refer to Appendix C for alarm limit default settings.

THERMODILUTION MODE (TD)

When operating the truCCOM monitor in thermodilution (TD) mode, thermodilution cardiac output (TDCO) should only be performed by personnel appropriately qualified and experienced in the method of setting up TD apparatus and performing thermodilution injections. Refer to truCATH.ip catheter DFU prior to performing TDCO.

1. Enter SYSTEM mode from Main Menu and input the injectate temperature, thermodilution correction factor (TDCF) by selecting the appropriate computation constant from the specifications at the back of the truCATH.ip DFU in relation to temperature and injection volume.
2. Return to the Main Menu and press the button for TD.
3. After a short initialisation the TD screen will be displayed with a graph for the injectate trace and digital values for Body Temperature and Injectate Temperature.
4. The message 'Please wait...' will be displayed for 10 seconds and during this period the keypad will be locked out.
5. The Display will change to show 'Press Start' on screen.
6. Attach the TD probe cable connector to the monitor TD port and fit the TD probe tip to the injectate apparatus ensuring the adaptor is secured in place.
7. Press **Start** to start the data collection.
8. The prompt 'Inject Now!' will appear on the display. Inject the saline. Wait for the trace to stop and the CO to be displayed.
9. Repeat step 7 as required.
10. The TD data can be reviewed by pressing the **Review** key.
11. To leave this mode, press the key for **Exit** at any time.

TD MENU OPTIONS

Exit	Return to main menu
Review	Review TD data
Start	Start injection run.

REVIEW TD DATA

A maximum of six TD curves can be saved per session. The user will be able to review the data for the TD curves recorded, by pressing the **Review** key. In the review mode the user can scroll through each of the TD curves within the session and accept or reject the curve on display. If a curve is rejected it is removed permanently and the average value for CO obtained from that curve removed from the average value of the session.

REVIEW TD DATA OPTIONS

Exit Rev	Return to TD Menu
>	Scroll through the TD Curves
Accept	Accept the TD curve in view
Reject	Reject and permanently remove the TD Curve in view

SYSTEM MODE (SYSTEM)

Choose the system mode by pressing the key corresponding to **SYSTEM** from the start up menu. A list of system parameters will be displayed.

SYSTEM SETTING SCREEN : PAGE 1

System Settings		En
Catheter Number		
Units	Kg/cm	
Time	14:15:00	
Date	Mon May 15	
TDCF	0.595	
Window Time (min)	15	
High Resolution Mode	Off	
System Test	Start	
	Next	
Exit	File	Select
		Edit

SYSTEM SETTINGS MENU OPTIONS

Exit	Return to the start up screen.
File	File operation
Select	Select the required field.
Edit	Edit the highlighted field.

To move to the next page, press **Select** until **Next** is highlighted and press the **Enter** key. The System Setting screen will change to show the next page of the System Setting screen.

SYSTEM SETTING SCREEN : PAGE 2

System Settings	
Temp Upper Limit °C	45.0
Temp Lower Limit °C	25.0
CCO Upper Limit l/m	12.0
CCO Lower Limit l/m	2.0
TD Scale	0.25
CCO Scale	12.0
	Back
Exit	File
	Select
	Edit

To move back to the previous page, press **Select** until **Back** is highlighted and press the **Edit** key. The System Setting screen will change to show the previous page of the System Setting screen.

CHANGING SYSTEM SETTINGS

Using the **Select** key move to highlight the field which requires editing. Pressing the **Edit** key will allow the user to change the settings.

EDIT MENU OPTIONS

Exit	Return to the System Setting screen.
↑	Increment
↓	Decrement
Save	Save new setting

CHANGING THE LANGUAGE

Press the **Select** key until the language reference on the top right corner of the 'System Setting' screen is highlighted. Press the **Edit** key to enter the Language Screen. The language screen provides a list of eight languages to choose from. The user can select the language reference, which applies to them using the ↑ or ↓ arrows until their language is highlighted.

LANGUAGE SCREEN

truCCOMS			
		En	
		De	
		NI	
		It	
		Da	
		Es	
		Sv	
		Fr	
	↑	↓	OK

Pressing **OK** sets the System to the new language and returns to the System Setting Screen. The language selection is only required to be set once. Once selected the new language setting will remain set even after the monitor has been switched off.

Note: English is the default language. For English use there is no need to change the language setting.

LANGUAGE SCREEN MENU OPTIONS

↑	Move up language table
↓	Move down language table
OK	Set new language & return to System Setting screen

HIGH RESOLUTION STATUS

High resolution status defaults to off at startup. To change the status press **Select** until High Resolution is highlighted then press the **Edit** key to toggle On/Off. In high resolution mode data is written to the history data file in 1 second intervals for approximately 5 minutes after an event is recorded.

FILE OPERATIONS

Inclusive of the current catheter history file the truCCOM monitor can store a maximum of four catheter history files.

The **File** menu allows the user to download the history files to a computer and to erase any redundant history files.

The available **File** operations promote good working practices to maintain sufficient memory capacity to support instances of catheter longer term monitoring up to the recommended maximum period of 72 hours, (refer to truCATH.ip DFU).

If files are not erased manually, attaching a new catheter will automatically and permanently delete the oldest, fourth history file from monitor memory.

To erase a history file, use the **↑** or **↓** arrows to highlight the history file to be erased then select **OK**. Select **Erase** from the menu options.

To proceed select **Yes** or to halt select **No**.

To download the history file to another device attach a cable to the COM1 port on the rear of the system. Connect to a computer with a serial port. The settings are as follows.

Baud rate	57600
Parity	None
Stop bits	1
Data bits	8

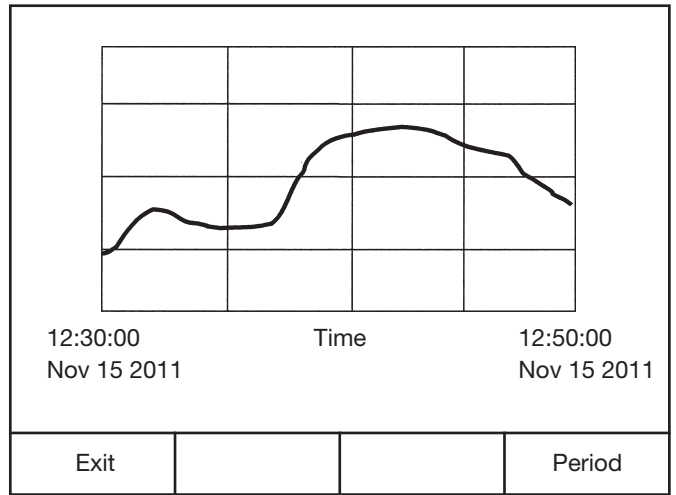
To download a history file, use the **↑** or **↓** arrows to highlight the history file to be downloaded then select **OK**. Select **Download** from the menu options. The system will send the data to the serial port as a series of characters. No handshaking or hardware control is recognised by the system. It is the responsibility of the receiving system to save the data in an appropriate format.

FILE MENU OPTIONS

Exit	Return to the System Setting screen.
Download	Download history file
Erase	Erase History File

HISTORY MODE (HISTORY)

This mode allows the user to review the history of the patient. When the **HISTORY** key is pressed the history screen displays all the CCO and TD data measured on this patient in a graphical format as well as the start and finish times.



HISTORY MENU OPTIONS

Exit	Return to main menu
Period	Period adjustment

Press **Exit** to return to the Main Menu screen or **Period** to adjust the window on view.

PERIOD ADJUSTMENT

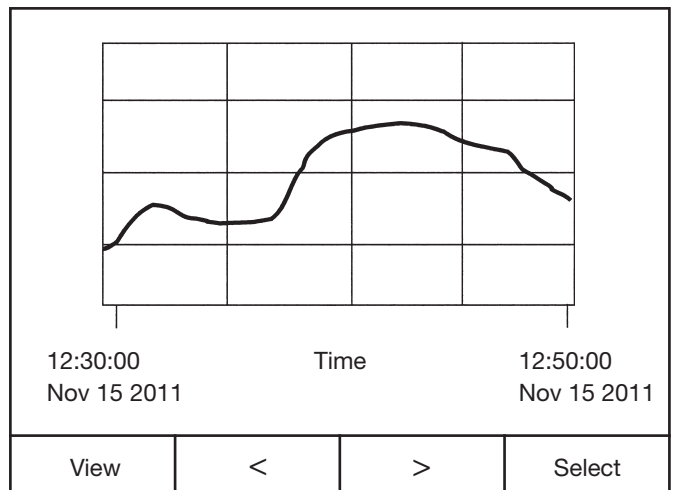
A cursor will appear opposite the Start time. Start time will appear green. In addition a Start Time and End time marker will appear below the graph screen.

The **Select** key can be used to select either the Start or End time marker and the arrow keys **<** **>** can be used to move the marker to the desired position below the graph.

Pressing **View** will expand the graph to show the section within the Start/End markers.

PERIOD MENU OPTIONS

View	Show the period between the time markers.
<	Move the current time marker to the left
>	Move the current time marker to the right
Select	Change the current time marker



CHAPTER 3

Principles of Operation CONTINUOUS CARDIAC OUTPUT

Continuous cardiac output (CCO) measurements are based on the thermodynamic principles of heat transfer.

truCCOMS measures cardiac output by supplying power to maintain the temperature of a Heat Transfer Device (HTD) at 2°C above blood temperature. As blood flows across the HTD it is cooled thus triggering the monitor to supply more power to the HTD to maintain the 2°C differential. If cardiac output, i.e. flow increases, more power is required. If cardiac output decreases, less power is required. The power needed is directly proportional to flow and is converted to flow using a predetermined algorithm.

The general thermodynamic formula for heat transfer via a turbulent system is:

$$q \propto m \times c_p \times (T_s - T_b)$$

where

q = rate of heat transfer

m = Mass flow

c_p = Specific Heat Capacity of blood

T_s-T_b = Temperature differential between HTD surface and ambient blood °C.

α = Proportional to

INJECTATE CARDIAC OUTPUT

For intermittent bolus cardiac output measurement, the Monitor uses a Stewart-Hamilton thermodilution equation:

$$CO = \frac{\text{Correction factor} \times (T_b - T_i)}{\text{Area}}$$

where:

CO = cardiac output in litres/min.

Area = area under temperature washout curve.

T_b = Blood temperature

T_i = Temperature of Thermal Indicator solution

Correction factor = Computation constant for the catheter (refer to truCATH.ip DFU Computation Constants)

Constants)

The calibration constant incorporates compensation for the following:

- specific heat of injectate
- density of injectate
- volume of injectate
- correction factor for injectate temperature rise as it passes through the catheter.

APPENDIX A SPECIFICATIONS

GENERAL

Product Description: The OCC truCCOM Monitor measures cardiac output continuously when used with OCC Continuous Cardiac Output Catheters.

Standard EN60601-1	Medical Electrical Equipment Classification	Class 1 Type CF applied part defibrillation-proof IPX0 Not AP or APG Continuous
Standard EN60601-1-2 [Electromagnetic Compatibility]	Classification	Class B [Conducted and Radiated Emissions]
Weight		2.0 Kg
Dimensions	Height Width Depth	200mm 200mm 240mm
Patient Cable	Length	2m
Display System	Display size	5.7" (145mm) diagonal
Trend Display	Length Parameters (2 max.)	30 minutes to 24 hours CO, CI

CARDIAC OUTPUT MEASUREMENT

Continuous Mode	Range Accuracy* Response	1 to 15.0 l/min 3% or 0.3 l/min, whichever is greater less than ≤ 1 sec.
Injectate Mode	Range Accuracy*	1.0 to 15.0 l/min 3% or 0.3 l/min, whichever is greater
Blood Temperature Range		25 to 45 °C, 1%
Injectate Temperature Range		0 to 25 °C, 1%

* Coefficient of variation - measured using flow bench collected data.

TECHNICAL INFORMATION

System Interface	Analogue Output Serial Interface	Span 0 - 4 volts RS-232 COM1
Electrical	Voltage Current Fuses	100 to 240 volts AC, 50/60 Hz. 1Amp maximum. T1A, 250V Cartridge (5 x 20mm)

SIGNAL OUTPUT

The truCCOMs instrument provides one analogue output and a COM1 RS232 compatible serial communications port.

ANALOGUE OUTPUT

An analogue output signal between 0 and 4V can be supplied by the system to a chart recorder or other medical device, via a 3.5 mm phono-socket on the rear of the system.

COM1

Serial communication is possible with the instrument via a 9 way 'D' type plug on the rear of the system. A standard cable can be used to connect to this port. The pin out of the connector is shown below.

Pin No.	Signal
1	N/C
2	Rx
3	Tx
4	N/C
5	0V
6	N/C
7	N/C
8	N/C
9	N/C

COM1 supports the following communications protocol.

Baud Rate: 57600
 Parity: None
 Data bits: 8
 Stop bits: 1
 Flow control: None

When selected the serial communications port can be used to transfer data to other medical devices. (Refer to "FILE OPERATIONS")

ENVIRONMENTAL REQUIREMENTS

Operating Temperature	10 to 35 °C
Storage Temperature	-20 to 65 °C
Operating and Storage Relative Humidity	10% to 95% non-condensing

ACCESSORIES

Pulmonary Artery Catheter (truCATH.ip)	TCH-5100
Patient Cable	251022
TD Probe Cable	252026
Mains cable USA	152034
Mains cable UK	152033
Mains cable Europe	152032
Data Download Cable (Optional)	252040

APPENDIX B

EQUATIONS FOR CALCULATED PATIENT PARAMETERS

This section describes the equations used to calculate patient parameters displayed on the Cardiac Profile screen.

Note: Calculated patient parameters contain more decimal places of accuracy than are displayed on the screen. Consequently, attempts to verify the accuracy of the Monitor's display using the following equations may produce results that are slightly different from the data displayed by the Monitor.

1. CI = CO/BSA (L/min/m²)

where: CI - Cardiac Index
 CO - Cardiac Output, L/min
 BSA - Body Surface Area, (m²)

2. SVR = ((MAP-CVP)/CO)*80 (dyne *sec*cm⁻⁵)

where: SVR - Systemic Vascular Resistance
 MAP - Mean Arterial Pressure (mmHg)
 CVP - Central Venous Pressure (mmHg)
 CO - Cardiac Output (L/min)

3. SVRI = SVR*BSA (dyne *sec*cm⁻⁵*m²)

where: SVRI - Systemic Vascular Resistance Index
 SVR - Systemic Vascular Resistance
 BSA - Body Surface Area (m²)

APPENDIX C

MONITOR DEFAULT SETTINGS

The information in this section defines the default settings for the OCC truCCOM Monitor that includes: Alarm Limits, Display Settings, and Communication Port Settings.

ALARM LIMITS

Parameter	High Limit	Low Limit	Status	Units
CO	12	2	On	L/min
Blood Temperature	45	25	On	°C

DISPLAY SETTINGS

Trend Time Scale	15 Minutes
Graph 1	CO L/min.
Temperature Units	°C
Time Format	12-hour

COMMUNICATION PORT SETTING

Port	Setting
Analogue Output	None
Analogue Input	Not Applicable (Not Enabled)
Digital Port RS-232	None

APPENDIX D

SERVICE AND SUPPORT

Service and Support

The OCC truCCOM Monitor does not require regular user maintenance other than normal cleaning nor does it need routine servicing to maintain its optimum performance level.

OCC provides a Customer Service Department for user support and for arranging user training. To respond to customer enquiries or complaints relating to product, this department will need the serial number of the unit which can be found on the back panel of the monitor. In the unfortunate event of a product fault it is important that the failure is reported to OCC quickly, all relevant information is provided on the failure being reported and where possible associated catheter and accessory cables are retained for return to OCC for investigation.

Only OCC truCATH.ip catheters should be used with the OCC truCCOM Monitor. Replacement OCC truCATH.ip catheters for use on the OCC truCCOM Monitor can be purchased from Omega Critical Care Ltd.

Telephone inquiries for service, reporting faults, technical support, supplies, or miscellaneous questions are made by calling the number below:

Customer Service Department: +44 (0) 1355 265733

Address orders and miscellaneous correspondence to:

Omega Critical Care Limited

Omega House

2 Cairn Court, Nerston West

East Kilbride, Scotland G74 4NB

Telephone: +44 (0) 1355 265733

Facsimile: +44 (0) 1355 239094

Email: info@omegacriticalcare.com

WARNING: The OCC truCCOM Monitor contains no user-serviceable parts. Removal of the cover or disassembly will expose hazardous voltages. To avoid injury or instrument damage, do not disassemble or service the instrument unless you are qualified to do so.

CLEANING THE MONITOR

The surface of the OCC truCCOM Monitor may be cleaned with a cloth dampened with 70% isopropyl alcohol or with mild detergent. The top, bottom and front surfaces may be lightly wiped with the cloth, but DO NOT spray or pour any liquid directly onto the Monitor or its accessories.

DO NOT allow any liquid to come in contact with the power connector, or switches, nor to penetrate connectors or openings in the chassis. If any of the foregoing does occur, DO NOT attempt to operate the Monitor. Disconnect power immediately and call OCC Customer Service Department.

DO NOT attempt to clean the rear panel of the Monitor.

FUSELINKS

WARNING: Do not attempt to replace the fuses.

In the event that the truCCOM monitor fails to power up or loses power during use, switch OFF and disconnect from the Mains supply. Refer to the troubleshooting guide (Appendix G) for instruction.

APPENDIX E

WARRANTY

The monitor has a warranty of 36 months. Patient cables and TD accessories are not included in this warranty. In the event of a failure during the warranty period the product should be returned to the manufacturer and it will be repaired or replaced with an equivalent unit.

Omega Critical Care Ltd. reserves the right to supply an alternative unit to the same or higher specification.

WARNING

The truCCOM monitor contains no user serviceable parts. Any unauthorised modifications or disassembly may invalidate the warranty.

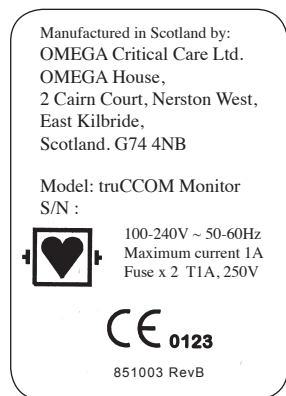
EXPECTED SERVICE LIFE

Provision for repair, refurbishment and/ or product upgrade, to maintain maximum product performance over the expected service life of the truCCOM monitor, is available through OCC customer service department as detailed in Appendix D and may be carried out at either the customer or OCC's request throughout the expected service life. It is anticipated that the truCCOM monitor will continue to operate beyond the expected service life at which time OCC will request the opportunity to review the truCCOM monitor condition in order to determine its continued suitability.

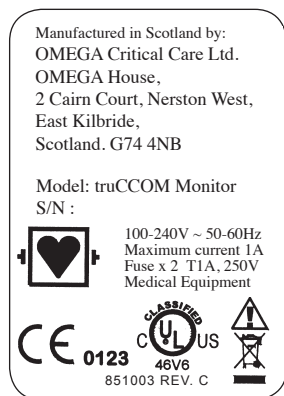
DECOMMISSIONING/ DISPOSAL

Decommissioning/ disposal of the truCCOM monitor is carried out in accordance with WEEE regulations and is arranged via the Customer Services Department.

APPENDIX F LABELS



1A. MAIN LABEL



1B. MAIN LABEL
includes USA and
CANADA



2. ANALOGUE SIGNAL INPUT AND OUTPUT



3. ATTENTION, CONSULT ACCOMPANYING DOCUMENTS



4. SERIAL COMMUNICATIONS PORT



5. RECYCLING LABEL (Fitted to non-UL compliant product only)

SYMBOLS

Symbol	Symbol Reference	Meaning	Description
	Directive 2002/96/EC Annex IV	Product falls within WEEE regulations and should not be disposed of in general domestic waste	This symbol indicates that separate collection for WEEE product is required for recycling via a designated collection facility.
T	—	T - type fuse	Time lag (slow blow) Fuse
	EN 60601-1 Table D1 No. 27 (IEC 60417-5336)	Defibrillation- Proof Type CF Applied Part.	This symbol on medical equipment identifies the equipment as a defibrillation-proof type CF applied part complying with IEC 60601-1 where C= Cardial and F= Floating Applied Part.
~	EN 60601-1 Table D1 No. 1 (IEC 60417-5032)	Alternating Current	This symbol indicates that the equipment is suitable for alternating current only.
	EN 60601-1 Table D1 No. 10 EN 980 (5.11)	Attention, see instructions for use	Consult accompanying documents



WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1.
WITH RESPECT TO ELECTRICAL SHOCK, FIRE, MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1 (CAN/CSA 601.2XX, IF APPLICABLE) MEDICAL EQUIPMENT CERTIFIED FOR CANADA E221155.

Standards (Referenced standards are current versions unless otherwise stated)

Standard:	Title:
EN60601-1	Medical electrical equipment - Part 1: General requirements for safety and essential performance
EN60601-1-2	Medical electrical equipment - General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests
EN980	Symbols for use in the labelling of medical devices

APPENDIX G
TROUBLESHOOTING GUIDE

Fault Condition:	Action:
<p>Monitor fails to power up at start up or Monitor loses power during use.</p>	<p>Switch both the monitor and Mains switches to the OFF position. Check that the Mains cable connections are secure. Switch Mains and monitor switches to the ON position to reset.</p> <p>If problem persists. Switch OFF the monitor & Mains switches and replace the monitor.</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>WARNING: This condition may indicate that a fault has damaged the monitor fuses. Do not attempt to replace the fuses. The faulty monitor should be returned to OCC for repair. Refer to Appendix D - Service & Support.</p> </div>
Monitor On Screen Message / Fault Condition:	Action:
<p>code 0 Catheter Fault</p>	<p>Check cable connections. Switch off/on to reset. <i>If problem persists, replace catheter.*</i></p>
<p>code 1 Catheter Fault</p>	<p>Check cable connections. Switch off/on to reset. <i>If problem persists, replace catheter.*</i></p>
<p>code 2 Catheter Fault</p>	<p>Check cable connections. Switch off/on to reset. <i>If problem persists, replace catheter.*</i></p>
<p>code 3 Catheter Fault.</p>	<p>Check cable connections. Switch off/on to reset. <i>If problem persists, replace catheter.*</i></p>
<p>Message "truCATH.ip not connected"</p>	<p>Check catheter is inserted and connections correct. Switch system off/on to reset. <i>If problem persists, replace catheter.*</i></p>
<p>Message "Please wait..."</p>	<p>Ensure that temp is > 25 degrees Celsius if the catheter is outside patient. Switch system off/on to reset. <i>If problem persists, replace monitor.</i></p>
<p>Message No answer to request (No answer acknowledgement received¹)</p>	<p>Switch off/on system to reset. <i>If the problem persists, replace monitor.</i></p>
<p>Message No response from FE board</p>	<p>Restart CCO or TD. Switch off/on to reset. <i>If the problem persists, replace the monitor.</i></p>
<p>Message Command time out</p>	<p>Restart CCO or TD. Switch off/on to reset. <i>If the problem persists, replace monitor.</i></p>
<p>Message T1 or T2 is <25degrees or >45 degrees</p>	<p>Check catheter is inserted and connections correct. <i>If the problem persists, replace catheter.*</i></p>
<p>Message T1 - T2 > 2degrees C.</p>	<p>Check catheter is inserted and connections correct. <i>If the problem persists, replace catheter.*</i></p>
<p>Interference Detected</p>	<p>If ESU/ Diathermy in use, wait until the interference detected alert is removed from the display and CCO will restart. If no ESU/ Diathermy in use, switch system off and on to reset. Check catheter is inserted and connections correct. <i>If the problem persists, replace the catheter.*</i></p>
<p>Message: Invalid EEPROM Data</p>	<p>Switch off/on system to reset. <i>If the problems persist, replace the monitor.</i> <i>If the problems still persist, replace the catheter.*</i></p>
<p>Message: No EEPROM comms</p>	<p>Switch off/on system to reset. <i>If the problems persist, replace the monitor.</i> <i>If the problems still persist, replace the catheter.*</i></p>
<p>Message: FE Packet not received</p>	<p>Switch off/on system to reset. <i>If the problems persist, replace the monitor.</i></p>
<p>Message: Failed to read CLB file</p>	<p>Switch off/on system to reset. <i>If the problems persist, replace the monitor.</i></p>

* To confirm that the fault lies within the catheter it is advisable to firstly connect the inserted catheter to an alternative truCCOM and patient cable, if available.

¹ English version only.

MANUFACTURER:

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