TERUMO

CDI® Blood Parameter
Monitoring System 500
Operator's Manual

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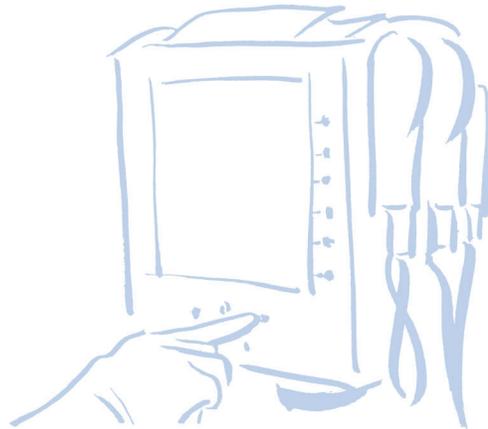# table of contents

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What is the CDI™ System 500?

The Terumo Cardiovascular Systems (TCVS) CDI™ Blood Parameter Monitoring (CDI System 500) is a blood monitoring system to be used on a single patient during cardiopulmonary bypass procedures. It continuously monitors the blood in the extra-corporeal circuit and provides ongoing information about the blood parameters. This information is displayed on the CDI System 500's easy-to-read screen.

The CDI System 500 monitors and displays the values of the following blood parameters:

- Partial pressure of oxygen (PO_2)
- Partial pressure of carbon dioxide (PCO_2)
- pH
- Potassium (K^+)
- Oxygen saturation (SO_2)
- Hematocrit (HCT)
- Hemoglobin (Hgb)
- Temperature

In addition, the CDI System 500 can calculate and display the following values:

- Base excess (BE)
- Bicarbonate (HCO_3^-)
- Oxygen saturation (SO_2) [calculated when measured is not available]
- Oxygen consumption ($\dot{V}O_2$)

The CDI System 500 can display the blood parameters either at actual temperature or adjusted to 37°C.

The CDI System 500 includes a built-in printer that can provide a printed copy of the displayed blood parameter values.

Indications

The CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

Contraindications

None

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Operator Profile

Rx Only This device is typically operated by a certified clinical perfusionist qualified by professional credentialing and in some cases licensure that has undergone academic and clinical education to provide extracorporeal patient care services. Perfusion training programs are university based and are offered at the undergraduate level and at the postgraduate level to individuals who have obtained a bachelor's degree in a related field. The perfusionist functions independently while under the direction of a physician.

Training Requirements

Before you set up or operate the CDI System 500, it is vital that you read and understand all the material in this manual. To arrange additional training, please contact your local Terumo Cardiovascular Systems representative or call 1-800-521-2818 and ask about CDI 500 system training.

How to use this manual

⚠ Before you set up or operate the CDI System 500, it's vital that you read and understand all the material in this manual.

Once you're familiar with the contents of the manual, you can use it as needed for reference. To help you find things quickly, here's a description of the manual's organization.

■ **Getting Started**

Chapter 1 introduces the CDI System 500 and its parts.
Chapter 2, "Quick Start," gives an overview of the tasks required to set up and use the system.

■ **Using the CDI System 500**

Chapter 3 explains how to set up the monitor, calibrator, and printer.
Chapter 4 shows how to specify the appropriate software settings.
Chapter 5 tells how to calibrate the sensors.
Chapter 6 gives instructions for installing the sensors in the extracorporeal circuit.
Chapters 7 and 8 describe how to use the system during a procedure.

■ **Reference**

Chapter 9 gives information to help you troubleshoot problems.
Chapter 10 contains instructions for system maintenance.
Appendices A and B list the system components and specifications (respectively).
Appendix C gives instructions for communicating with an external device.
Appendices D, E, F and G contain information about the product symbols, warranty, service policy, patents, and software license (respectively).
Appendix H is a glossary of terms.

If, upon reading this manual, you find that you need clarification or additional information, you can direct questions to your local Terumo Cardiovascular Systems representative, or to:

Terumo Cardiovascular Systems
6200 Jackson Road
Ann Arbor, MI 48103
Phone: (800) 521-2818

Conventions

This manual contains important warnings, cautions, and notes:

▲ Warning

- **Warnings like this alert you to safety issues with the CDI System 500. You must read these warnings before using the CDI System 500.** ▲

➤ Caution

- Cautions contain important information about the operation and maintenance of the CDI System 500. Read these carefully in order to avoid any problems. ➤

Note: Notes contain information that help with the operation of the CDI System 500.

How the CDI System 500 works

The CDI System 500 is an AC-powered, microprocessor-based monitor. It uses an optical fluorescence technology to measure blood gases, pH, and potassium. In addition, it uses an optical reflectance technology to measure oxygen saturation, hematocrit, and hemoglobin.

Optical fluorescent measurement. Two cable assemblies (one venous and one arterial) connect the monitor to disposable CDI Shunt Sensors which are inserted into the extracorporeal circuit. The CDI Shunt Sensors contain fluorescent microsensors, which are the heart of the CDI System 500 measurement system. Light emitting diodes (LEDs) in the cable-heads direct light pulses towards the microsensors. The microsensors are composed of fluorescent chemicals that emit light in response to the stimulating pulses. The intensity of the emitted light depends upon the concentrations of potassium, oxygen, carbon dioxide and hydrogen ions coming into contact with the microsensors. The light emitted by the fluorescent microsensors is returned to the cable-heads and measured by a light detector. The output signal of the detector is converted by the microprocessor to numerical data, which is displayed on the monitor's screen.

Optical reflectance measurement. The monitor's optical probe sensing surface contains light emitting diodes (LEDs) and a photodetector. The LEDs direct light pulses at the blood through an optical window in the TCVS CDI™ H/S Cuvette, which is inserted into the extracorporeal circuit. The intensity of the resulting reflections are analyzed (on the basis of the characteristic spectra of the oxy- and deoxy- forms of hemoglobin) to determine the oxygen saturation, hematocrit, and hemoglobin. These values are displayed on the monitor's screen.

Before you begin

You must read and understand all the information in this manual − the CDI™ Blood Parameter Monitoring System 500 Operator's Manual − and the instructions for use that came with associated disposables before using the system. Pay special attention to the following important safety information:

▲ Warning

- **Possible explosion hazard. Do not use the CDI System 500 Monitor in the presence of flammable anesthetics or other explosive gases.**

- **Do not use an apparently malfunctioning device in an operation.**

- **Computer equipment in the operating room environment may interfere with the operation of existing monitoring or therapeutic devices, and may be susceptible to interference from such devices. To insure that such interference will not occur, care must be taken in the selection of computer equipment or printers to be interfaced with the CDI 500 Monitor and in the manner in which this interface is accomplished.**

- **Maintain adequate levels of anticoagulation during extracorporeal circulation by monitoring activated clotting time (ACT) or another appropriate measurement. Use of a heparin treated device does not substitute for adequate anticoagulation levels.**

- **Do not use products treated with the heparin treatment on patients with heparin sensitivity. Devices with heparin treated surfaces may cause an adverse reaction in patients with heparin sensitivity.**

- **Equipment connected to the monitor's serial port shall meet IEC 60601-1 current leakage specifications. The combination of the two pieces of equipment shall be checked for safe system/leakage current.**

- **Do not immerse the CDI Blood Parameter Module (BPM) or CDI H/S Probe in liquid at any time. Immersion can cause damage to electronic components within the fiberoptic head.**

- **Avoid prolonged exposure to high humidity environments.**

- **Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management.**

- **If the lab-measured value is outside the operating range for a parameter, the user may not be able to adjust the CDI System 500 measured value to the lab-measured value. Accuracy has not been established for displayed values outside the operating range; therefore, displayed values outside the operating range should not be used for patient management. While this condition exists, continue patient management with another source (e.g., laboratory or point-of-care blood gas analyzer).**

- **Use of certain intravascular dyes during cardiovascular surgery such as Indocyanine green (Cardiogreen) and Methylene Blue may cause inaccuracies in displayed values. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**

- Elevated levels of blood substances including irregular cell morphologies, protein levels, plasma free hemoglobin and bilirubin may interfere with blood measurements. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.

- Blood conditions such as hemoglobinopathies, thalassemia and a variety of anemic conditions (sickle cell, iron deficiency, macrocytic), may affect the accuracy of hemoglobin and hematocrit measurements. Independent external analysis is required for accurate determination of these measurements as needed to guide therapeutic decisions.

- The CDI System 500 should only be used when there is blood flow through the extracorporeal circuit. To perform accurately, the H/S Cuvette requires blood flow rates shown in the following table:

H/S Cuvette Size	Min Flow	Max Flow
1/2"	1.0 LPM	7.0 LPM
3/8"	0.5 LPM	4.0 LPM
1/4"	0.2 LPM	1.5 LPM

  The TCVS CDI™ Shunt Sensor requires a minimum of 35 cc/min. Restoration of blood flow above the minimum through the CDI Shunt Sensor or the TCVS CDI™ H/S Cuvette will restore performance of the system.

- Do not make simultaneous contact with the patient and certain parts of non-medical electrical equipment. Certain parts that can be accessed without the use of a tool (e.g. connectors or communication ports) may contain live voltages.

- Use caution when administering novel pharmacological agents when the user is unfamiliar with the potential effect of such agents on the CDI sensors.

- Do not attempt in-vivo recalibration expecting to re-align values affected by interference due to intravascular dyes or pharmacological agents; the interference may be prolonged resulting in continuing inaccuracies.

- Exposure of the shunt sensor to prime solutions and/or blood during cardiopulmonary bypass with pH greater than 7.8 or less than 7.0 pH units or a sodium measurement greater than 160 or less than 120 mEq/L can interfere in the accurate measurement of potassium.

- Do not expose the monitor to condensing (water vapor) conditions. Condensation may occur when the instrument is equilibrated to a warm and humid environment and then is rapidly subjected to a much colder room temperature. Condensation may affect the measurement performance of the monitor.

- Do not expose the monitor to large changes in environmental temperature (>10°C) or humidity (>20%) during use. Such changes may affect the measurement performance of the monitor. If exposed to severe environmental changes (>10°C), allow the monitor to equilibrate to the new environment for 24 hours before using.

- Failure to perform a proper set-up including a full two point tonometered gas calibration, and a complete calibration of the potassium sensor and all other parameters may result in compromised system performance that does not meet the system accuracy limits found in appendix B.

- **Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management. At the beginning of a case, the user must complete calibration of all measurable blood parameters by comparing them to a laboratory measurement done on a blood sample. The values are dimmed on the CDI System 500 screen to indicate that the values are not accurate until an initial in-vivo calibration is performed.**

- **The temperature measured by the shunt sensor is local to the sensor and does not reflect the actual patient arterial blood temperature. Do not use this measurement for patient management. ▲**

➤ **Caution**

- Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

- Do not connect a shunt sensor to an unprimed circuit. Prolonged "dry" exposure can damage the sensors.

- To achieve grounding reliability, you must connect this equipment to an equivalent receptacle (marked "Hospital Use" or "Hospital Grade") that has been inspected for proper grounding.

- Do not use chemical solvents such as alcohol, ether, and acetone − or anesthetics such as Forane (isofluorane) − as cleaning agents on any part of the system. These chemicals can be destructive to the device. Follow the cleaning procedure in Chapter 10, "Routine Maintenance," using only the recommended cleaning agents. ➤

Note: The hemoglobin measurement technique used in this instrument measures total hemoglobin, and therefore includes other hemoglobin species such as carboxy-, met-, sulf-, and fetal hemoglobin.

Terumo CDI™ blood parameter monitoring systems are intended to monitor blood gas values including pH, PCO_2, PO_2, K^+, Oxygen Saturation (SO_2), Hematocrit (HCT), and Hemoglobin (Hgb). When used in accordance with their instructions for use, the systems have been demonstrated to provide reliable reports of these values with an accuracy characterized in Appendix B of the Operator's Manual.

➤ **Caution**

- Failure to follow the instructions can cause the monitoring system to display inaccurate values.

   The accuracy of the results is dependent upon the following:

   - Reading and understanding the instructions for use

   - Proper set-up, full two point tonometered gas calibration, and complete calibration of the potassium sensor and all other parameters

   - Use of all available system features

   - Periodic comparison to a laboratory reference sample

   Verify the accuracy of displayed values with another source (i.e. laboratory or point of care blood gas analyzer) before initiating treatment. ➤

CDI System 500 components

Monitor

The next figure shows the front panel of the monitor.

Note: The screens in this manual reflect a particular configuration of modules ("Arterial/Venous Blood Gases & Hematocrit/Saturation"). If you have a different set of modules, your screens will look different from the ones in this manual.
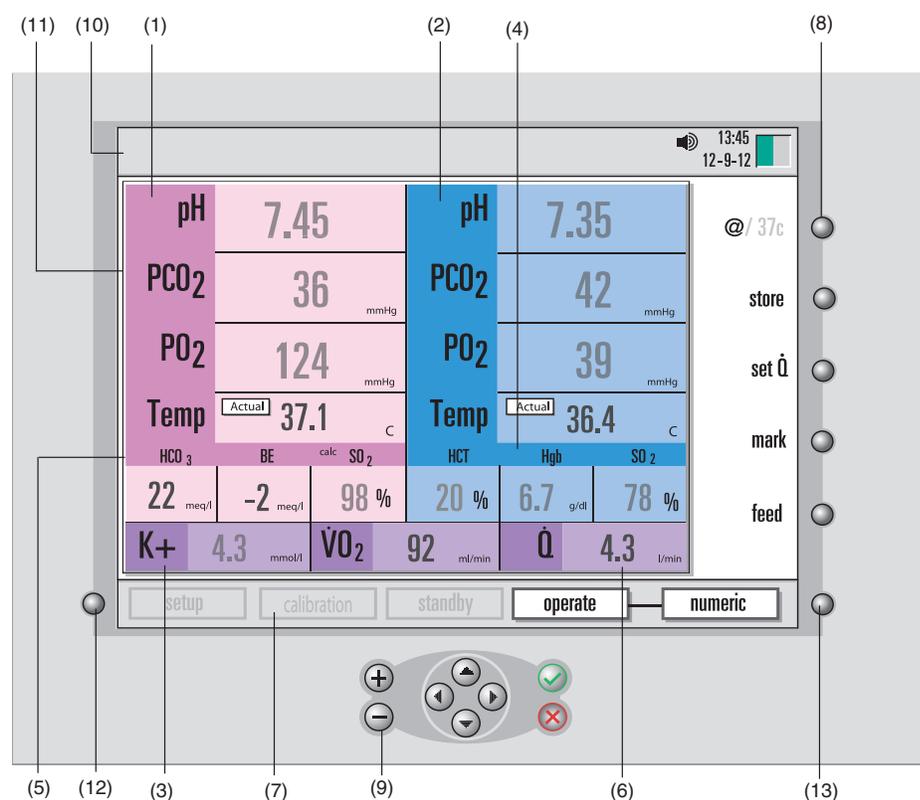
(1) **Arterial parameter values** (highlighted in red). pH values are displayed in pH units, while PO_2, and PCO_2, can be displayed in either mmHg or kPa. Calculated base excess and bicarbonate are displayed in meq/1.

(2) **Venous parameter values** (highlighted in blue). pH values are displayed in pH units, while PO_2, and PCO_2, can be displayed in either mmHg or kPa.

(3) **Potassium value.** Potassium (K^+) values are displayed in mmol/1. If both venous and arterial sensors are being used, the K^+ is taken from the arterial sensor.

(4) **Hematocrit/Oxygen Saturation values.** Oxygen saturation and hematocrit are displayed as percentages (%), while hemoglobin is displayed in g/dl.

(5) **Calculated values.** Base Excess (meq/1), Bicarbonate (meq/1), arterial Oxygen Saturation (%), and Oxygen Consumption (ml/min or ml/min/m^2) are calculated values. If the CDI H/S Probe is not used and the venous blood gas module is used, calculated venous oxygen saturation is displayed.

Note: Calculated SO_2 values are distinguished by a "calc" label.

(6) **Flow values.** The pump flow rate, used for calculating oxygen consumption, is entered either manually or through a pump connected to the CDI System 500's pump interface port.

(7) **System map.** Includes the labels for the different modes (setup, calibrate, standby, and operate) and the label for the operate mode display choice (numeric, tabular, or graphic).

(8) **Soft keys.** Software-driven function keys. Their purpose can vary from screen to screen.

(9) **Navigation/input keys.** Include the + (Plus), - (Minus), √ (OK), X (Cancel), and ◄► ▲ ▼ (left-, right-, up- and down-arrow) keys.

(10) **Message bar.** The area that displays current system status and alerts (above the parameter display window).

(11) **Parameter display window.** Contains mode-specific data or information displays.

(12) **System mode select key.** Pressing this key activates the system map.

(13) **Operate mode toggle key.** You press this key during operate mode to switch among the three types of displays:— numeric, tabular, and graphic.

The next figure shows the side panel of the monitor.
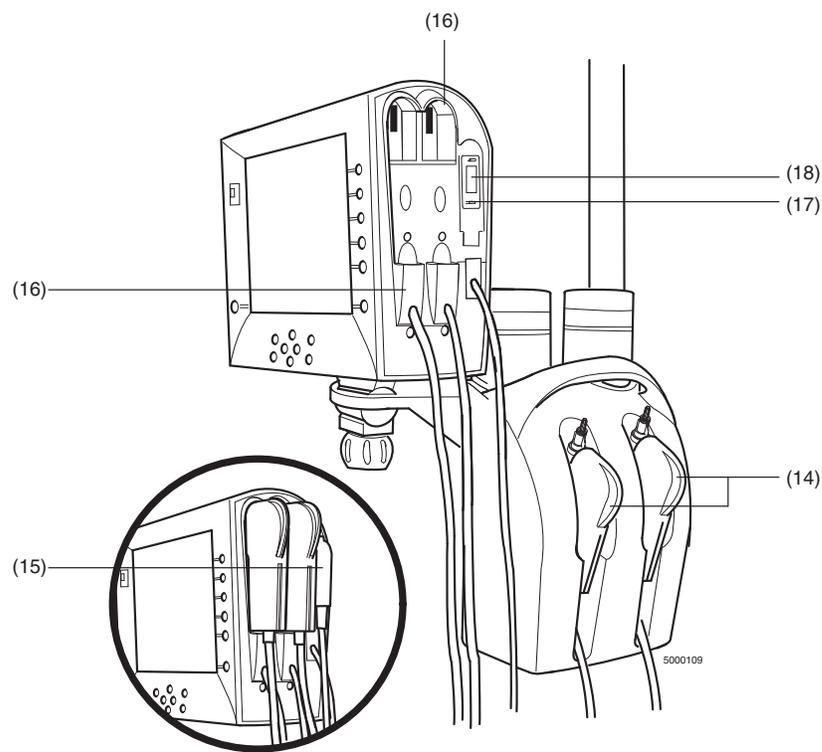
(14) **Arterial and/or venous blood parameter module (BPM) cable-heads.**
Modules for monitoring pH, PCO_2, PO_2, potassium and temperature.

(15) **H/S (Hematocrit/Saturation) Probe.** Module for measuring continuous oxygen saturation, hematocrit, and hemoglobin.

(16) **Cable-head ports.** Secures the cable-heads to the monitor when the monitor is not in use, protecting the cable-head optics.

(17) **H/S probe holder.** Secures the CDI H/S Probe to the monitor when the monitor is not in use, protecting the CDI H/S Probe optics.

(18) **Hematocrit/saturation optical reference color chip.** Allows connection of the CDI H/S Probe to the optical reference color chip. When the monitor is powered on, the system automatically performs a self-check.

This figure shows the back panel of the monitor.
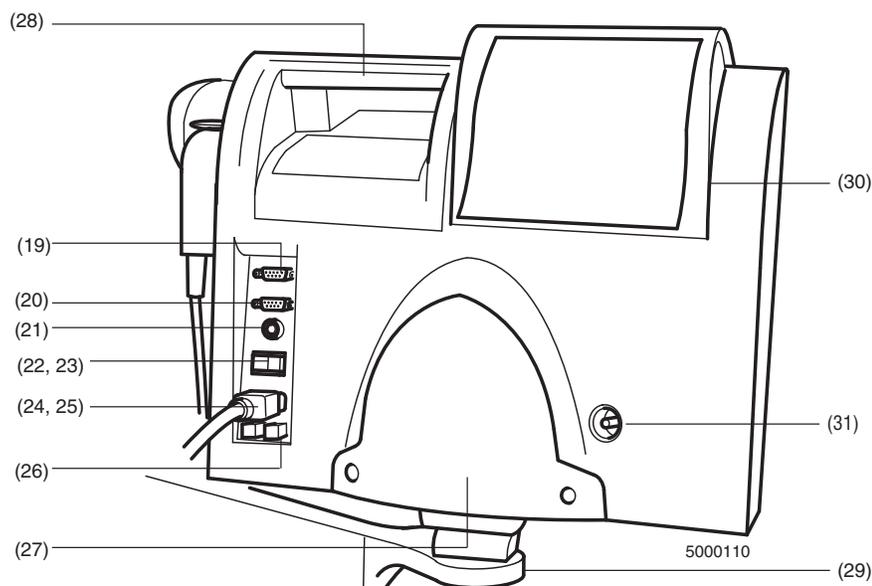
(19) **Data output port.** Allows serial transmission of blood parameter values to an external computer or data acquisition device.

(20) **Pump interface port.** Allows the input of blood flow data from a Terumo® Advanced Perfusion System 1, a TCVS Sarns™ Perfusion System 9000, a TCVS Sarns™ Modular Perfusion System 8000, a TCVS Sarns™ Centrifugal System, Stöckert[1] SIII/SC, Jostra[2] HL20, or a Medtronic Bio-Console®[3] 550, for use in the calculation of oxygen consumption.

(21) **Calibrator cable port.** The receptacle for attaching the TCVS CDI™ Model 540 Calibrator.

(22) **System power switch.** Turns the power to the monitor on or off. When the monitor is turned off, the most recent calibration values and setup parameters are saved in memory. After you turn the monitor back on, these values are automatically recalled.

Note: To turn off the system completely, you must turn off the power switch. If the power switch is left on and the cord unplugged, the battery will power the system (and will be discharging).

Note: If you turn the monitor off, wait at least 5 seconds before powering monitor back on.

(23) **Battery charge indicator.** When illuminated, indicates that the battery is being charged by AC power. While the monitor is connected to AC power, this green light shall be on steadily.

(24) **Power cord connector.** The receptacle for the power cord (when connected to an AC power supply).

[1] Stöckert is a member of Sorin Biomedica.
[2] Jostra is a registered trademark of Maquet GmbH and Company.
[3] Bio-Console is a registered trademark of Medtronic, Inc.

(25) **Power cord.** The CDI System 500 is supplied with a hospital grade AC power cord.

(26) **Fuse holder.** Contains two fuses.

(27) **Cable guide.** Excess cable can be wrapped here for convenient storage when not in use or during transport of the monitor.

(28) **Handle.** Allows the monitor to be carried or steadied during placement.

(29) **Monitor bracket.** Allows easy mounting (and dismounting) of the monitor to the monitor pole clamp tray.

(30) **Printer cover.** Protects the printer and paper from spills.

(31) **Ground equalization stud.** This stud is used to reduce differences of electrical potential between bodies of medical electrical devices and conductive parts of other objects.
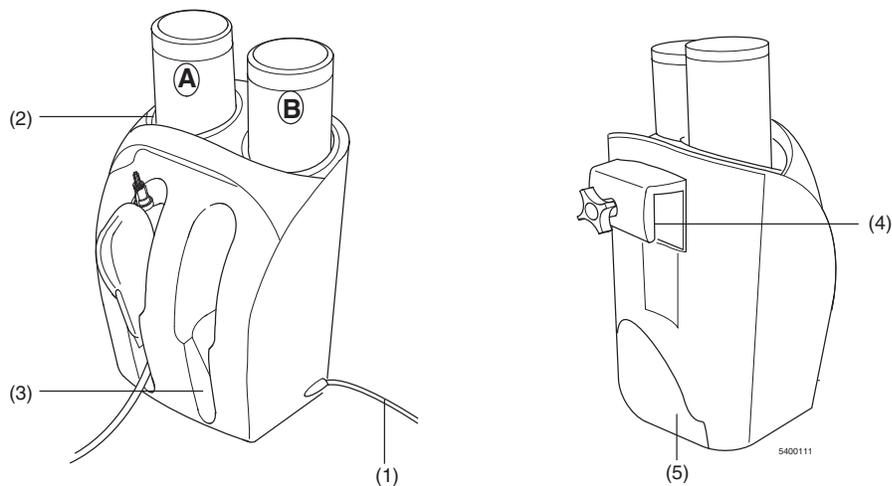
Calibrator

The CDI Model 540 Calibrator is designed for automatic calibration of the CDI System 500 Monitor and CDI Shunt Sensors, utilizing tonometered gases. The device is designed so that two sensors can be calibrated at the same time.

Note: If only one CDI Shunt Sensor is to be calibrated, either calibrator pocket can be used. Gas flow will be automatically shut off to the unused cable-head pocket.

(1) **Calibrator cable.** Connects the calibrator to the monitor. Once connected, the calibrator receives its power from the monitor.

(2) **Calibrator gas bottle receptacles.** These hold the Gas A and Gas B bottles properly, to ensure correct calibration.

(3) **Calibrator pockets.** Supports and aligns the sensor/cable-head assembly during calibration.

(4) **Calibrator mounting hook.** Fits onto the monitor pole clamp for optional mounting on the CDI Model CDI517 Pole Clamp.

(5) **Calibrator cable guide.** Allows wrapping of the calibrator cable when not in use.

Calibration gases

The two-point tonometered calibration of the CDI Shunt Sensors requires the use of precision mixtures of CO_2 and O_2 gas in order to expose the sensors to well-defined pH, PCO_2, and PO_2 values. The set of gas bottles shall provide enough gas for approximately 80 individual sensor calibration procedures.

Gas A (TCVS CDI™ Model CDI506):
CO_2: 7.5 +/- 0.1%
O_2: 27.5 +/- 0.1%
N_2: Balance

Gas B (TCVS CDI™ Model CDI507):
CO_2: 2.8 +/- 0.1%
O_2: 4.0 +/- 0.1%
N_2: Balance

▲ Warning

- **The contents of the gas bottles are under pressure. Protect them from sunlight, and do not expose them to temperatures exceeding 50°C (122°F). Do not pierce or burn them, even after use. Do not spray the contents of the gas bottles on a naked flame or any incandescent material. ▲**

➤ Caution

- Check the expiration date on the gas bottles before use. Use of the calibration gas bottles after expiration may result in inaccurate calibration. ➤

TCVS CDI™ Shunt Sensor

The CDI Shunt Sensors contain the K+, PO_2, PCO_2, and pH fluorescent microsensors, as well as the thermistor contact site for temperature measurement. The sensors are single use, non-toxic, and non-pyrogenic.

The heparin-coated, sterile CDI Shunt Sensors, Model CDI510H, are intended for placement into shunt lines, purge lines, sampling lines, shunt bypass lines, or any similar line that has blood flow. A minimum flow requirement of 35 ml/min is necessary for proper measurement.

The filter/sparger found on one end of the sensor ensures a sterile barrier when the sensor is placed into the calibrator. The sparger on the filter is located inside the sensor. Don't remove this filter/sparger until you are ready to place the sensor into the circuit.

Filter/sparger

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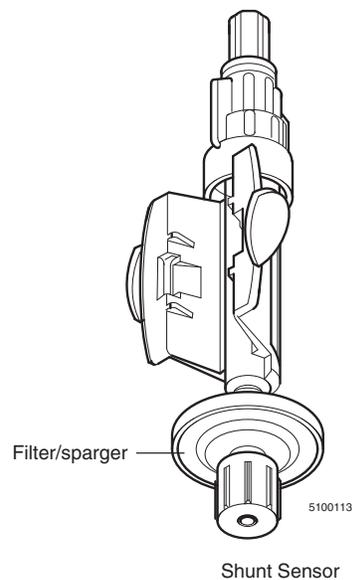
Shunt Sensor

A transparent optical interface material found on the back side of the CDI Model CDI510H Shunt Sensors provides a means of consistent optical connection between the sensor and the fiberoptic cable connector. This material reduces the risk of measurement errors caused by moisture trapped between the micro-sensors and the cable-heads. A thermal well on each sensor allows the thermal transfer from the circuit to the thermistor cap located on each cable-head.

Optical
Interface

Thermal
well

Optical
Interface

5100113a
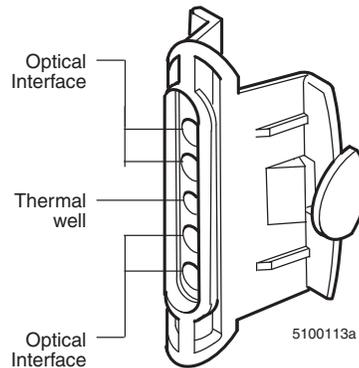
Each sensor contains a buffered calibration solution. This solution stabilizes the microsensors during storage. It also reacts with the tonometered gases during calibration to establish predictable pH, PCO_2, and PO_2 values. This buffer solution works in conjunction with the calibration gases during post-calibration checks (which are described in the section "Verifying calibration" in Chapter 5).

Each CDI Shunt Sensor is intended for a single use. Aseptic technique must be used when adding the CDI Shunt Sensor to the circuit. Luer caps and a sterile filter/sparger assembly are provided on the sterile assemblies at each end of the shunt sensor to protect the blood pathway from contamination prior to insertion into the circuit.

The CDI Shunt Sensor remains sterile as long as the package is unopened and undamaged. Each shunt sensor is individually packaged in a foil pouch and has a recommended shelf life indicated by the lot number expiration date printed on each package. For additional information, refer to shunt sensor instructions for use.

▲ Warning

- **Products treated with the heparin treatment should not be used on patients with heparin sensitivity.**

- **Maintain adequate levels of anticoagulation during extracorporeal circulation by monitoring activated clotting time (ACT) or another appropriate measurement. Use of a heparin treated device does not substitute for adequate anticoagulation levels.**

- **Store CDI Shunt Sensors between 0°C (32°F) and 35°C (94°F). Freezing of the CDI Shunt Sensor, or storage at temperatures outside the stated range, can result in inaccurate performance.**

- **Do not reuse CDI Shunt Sensors. Used CDI Shunt Sensors are contaminated and cannot be resterilized. Resterilization damages the microsensors.**

- **Shunt Sensors are sterile, heparin-coated, non-toxic, non-pyrogenic, single use devices and for use in cardiopulmonary bypass procedures for up to 6 hours.**

- **Use of certain intravascular dyes during cardiovascular surgery such as Indocyanine green (Cardiogreen) and Methylene Blue may cause inaccuracies in displayed values. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**

- **Elevated levels of blood substances including irregular cell morphologies, protein levels, plasma free hemoglobin and bilirubin may interfere with blood measurements. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**

- **Blood conditions such as hemoglobinopathies, thalassemia and a variety of anemic conditions (sickle cell, iron deficiency, macrocytic), may affect the accuracy of hemoglobin and hematocrit measurements. Independent external analysis is required for accurate determination of these measurements as needed to guide therapeutic decisions.**

- **Use caution when administering novel pharmacological agents when the user is unfamiliar with the potential effect of such agents on the CDI sensors.**

- **Do not attempt in-vivo recalibration expecting to re-align values affected by interference due to intravascular dyes or pharmacological agents; the interference may be prolonged resulting in continuing inaccuracies. ▲**

➤ **Caution**

- Do not use a CDI Shunt Sensor after the lot number expiration date printed on the package label. Using a CDI Shunt Sensor after its lot number expiration date can result in inaccurate performance.

- Do not use a CDI Shunt Sensor if the foil pouch it is packaged in has been damaged. A damaged foil pouch can result in inaccurate performance.

- This product contains Germall II in the calibration fluid. A potential byproduct of Germall II may be formaldehyde. Exposure may cause adverse reactions in patients with formaldehyde sensitivity. ➤

The Shunt Bypass Line

The shunt bypass line is a tubing pack modification designed to allow connection of the CDI Shunt Sensor when an "in-line" application is desired. Two opposing Y-connectors allow a small fraction of the total blood flow to pass through the sensor while minimizing any additional flow resistance. The shunt bypass line is recommended when continuous venous side monitoring is desired and/or when a continuous shunt/purge line is not available on the arterial side. The lines can be supplied as sterile individual assemblies for incorporation into the circuit at the time of use, or by a tubing pack supplier as a modification to an existing tube pack. Three tubing sizes are supported: 1/2", 3/8" and 1/4".
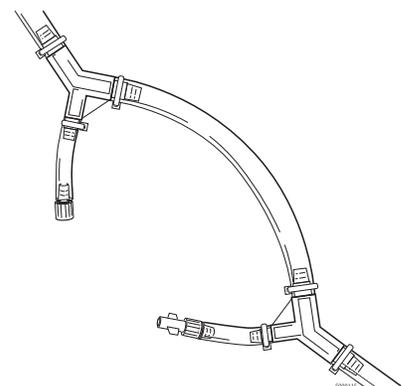
▲ Warning

- **The CDI System 500 is not intended for use in situations in which there is no flow of blood through the CDI Shunt Sensor. A minimum blood flow of 35 cc/min is recommended to maintain measurement performance of the shunt sensor. Flows below the minimum may result in a slower time response. To maintain the minimum blood flow through the sensor, keep total blood flow in the shunt bypass line above 1.5 L/min for 1/2 inch tubing, 0.6 L/min for 3/8 inch tubing, and 0.2 L/min for 1/4 inch tubing. Restoration of minimum blood flow through the shunt line after an interruption will restore optimal performance of the system.**

- **Use aseptic technique when inserting the shunt bypass line into the extracorporeal circuit to ensure that the blood contact surfaces remain sterile.**

- **For all shunt bypass line applications: Use an arterial filter distal to the shunt bypass line when utilizing the shunt bypass line on the arterial side of the circuit. This protects against the introduction of air into the blood circulation. ▲**

➤ Caution

- For single sterile shunt bypass line assemblies. Do not use the shunt bypass line after the date printed on the package label. Use beyond the date may result in inaccurate performance.

- The shunt bypass lines, which are supplied sterile, will remain so as long as the package is unopened and undamaged.

- Secure all connections on the shunt bypass line with stay straps. ➤

TCVS CDI™ Hematocrit/Saturation Cuvette

The CDI Hematocrit/Saturation (H/S) Cuvette is a flow-through device inserted directly into the extracorporeal circuit. The CDI H/S Cuvette is for a single use only. It is supplied sterile and individually packaged, for incorporation into the circuit at the time of use, or can be supplied non-sterile to tubing pack manufacturers for pre-connection.

The CDI H/S Cuvette contains an optical window that provides a means of consistent optical connection between the CDI H/S Probe and the CDI H/S Cuvette. A magnet placed in the CDI H/S Cuvette provides verification of the correct connection between the CDI H/S Probe and the CDI H/S Cuvette.

Note: When the CDI H/S Cuvette is inserted into the circuit, the optical window should be pointing down. This minimizes interference from intermittent air bubbles in the line.

Optical Window

Magnets

5170116
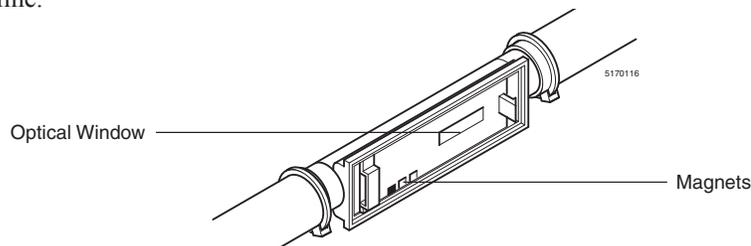
Aseptic technique must be used when adding the CDI H/S Cuvette to the circuit. End caps are provided on the sterile assemblies at each end of the cuvette to protect the blood pathway from contamination prior to insertion into the circuit. The CDI H/S Cuvette remains sterile as long as the package is unopened and undamaged. Each CDI H/S Cuvette has a recommended shelf life indicated by the lot number expiration date printed on each package. For additional information, refer to the CDI H/S Cuvette instructions for use.

▲ **Warnings**

- **Maintain adequate levels of anticoagulation during extracorporeal circulation by monitoring activated clotting time (ACT) or another appropriate measurement.**

- **Do not attempt to re-sterilize the CDI H/S Cuvette. Improper sterilization can reduce system accuracy or cause the CDI H/S Cuvette to leak under pressure.**

- **Do not reuse CDI H/S Cuvettes. CDI H/S Cuvettes are intended for a single use only.**

- **The H/S cuvettes are sterile, non-toxic, non-pyrogenic, single use devices and for use in cardiopulmonary bypass procedures for up to 6 hours.**

- **Use of certain intravascular dyes during cardiovascular surgery such as Indocyanine green (Cardiogreen) and Methylene Blue may cause inaccuracies in displayed values. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**

- **Elevated levels of blood substances including irregular cell morphologies, protein levels, plasma free hemoglobin and bilirubin may interfere with blood measurements. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**

- **Blood conditions such as hemoglobinopathies, thalassemia and a variety of anemic conditions (sickle cell, iron deficiency, macrocytic), may affect the accuracy of hemoglobin and hematocrit measurements. Independent external analysis is required for accurate determination of these measurements as needed to guide therapeutic decisions.**

- **Use caution when administering novel pharmacological agents when the user is unfamiliar with the potential effect of such agents on the CDI sensors.**

- **Do not attempt in-vivo recalibration expecting to re-align values affected by interference due to intravascular dyes or pharmacological agents; the interference may be prolonged resulting in continuing inaccuracies. ▲**

➤ **Caution**

- Do not use a CDI H/S Cuvette after the lot number expiration date printed on the package label.

- The CDI H/S Cuvette tubing connections should be secured with tie bands. ➤

TCVS CDI™ Monitor Pole Clamp

The CDI Monitor Pole Clamp attaches to standard heart-lung machine poles, and consists of an arm and a tray with an alignment cone. The monitor attaches to the tray for easy mounting and dismounting. The pole clamp is available in two arm lengths: 7 inches (CDI Model CDI517) and 4 1/2 inches (CDI Model CDI518). The shorter arm cannot accommodate the calibrator hook.

Once the monitor is placed on the tray, push the locking screw up towards the monitor and tighten in a clock-wise direction to secure monitor to the monitor pole clamp.

▲ Warning

- **Never leave the monitor on the pole clamp tray without securing the locking screw. ▲**

TCVS CDI™ Cable-head Bracket

The CDI Model CDI519 Cable-Head Bracket attaches to standard heart lung machine poles, and can accommodate one or two cable-head assemblies. The cable-head assembly slides into the bracket for easy mounting and dismounting. The bracket can be positioned vertically or horizontally, and at varying lengths from the pole.

S170117a
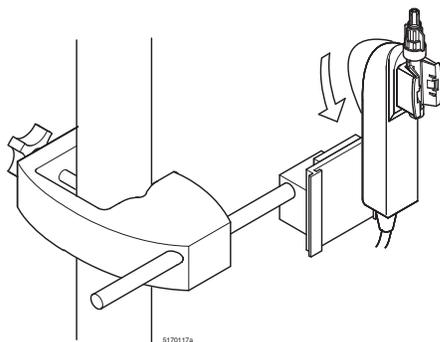
This chapter gives a brief overview of the steps involved in setting up and using the Terumo Cardiovascular Systems CDI™ Blood Parameter Monitoring System 500. You can use this chapter to get a preview of the system's operation, or refer to it when you need a reminder of one or more steps in the process.

Note: If your CDI System 500 has been set up and configured, some of the steps listed in this chapter may have been done already.

Setup

See Chapters 3 and 4 for all warnings and more details on setup.

1   Attach the pole clamp to the pole.

2   Attach the monitor to the pole clamp.

3   Install the cable-head bracket.

4   Optional: Connect the serial cables for the external data acquisition system, computer, and or pump.

5   Plug in the monitor.

6   Turn on the monitor. The system diagnostics and module self-tests will automatically run.

7   Set up the software by choosing options on the monitor configuration and monitor setup screens.

Calibration

See Chapter 5 for all warnings and more details on calibration.

1   Install the calibrator on the pole clamp or on a flat surface near the monitor.

2   Connect the calibrator cable to the monitor.

3   Set the monitor to calibrate mode.

4   Verify the K^+ calibration value from the sensor package on the calibration screen. Edit if necessary. Press the √ key.

5   Install the calibration gas bottles in the calibrator by placing the corresponding bottle into the calibrator and turning clockwise until the gas bottle level indicator on the "Calibrate" screen shows that the bottle has been engaged. After engagement, give an additional one-half turn to the bottle.

6   Open the sensor package and remove the sensor. Make sure the buffer solution completely covers the microsensors.

7   Remove the cable-head from the monitor.

8   Attach the sensor assembly to the cable-head.

9   Remove the small, blue bottom luer cap. (Do not remove the sensor filter/sparger assembly).

10   Loosen the large, blue top luer cap using aseptic technique. (Do not remove the small white luer cap).

11   Place the cable-head assembly into the calibrator pocket.

12   If you are calibrating another sensor, repeat steps 6-10 for the second sensor.

13   Press √ on the monitor twice to initiate calibration. Calibration will take about 10 minutes.

14   When calibration successfully ends, disconnect the calibrator from the monitor.

15   Tighten the large blue top caps(s) (using sterile technique). If you're not putting the sensor into the circuit immediately, replace the bottom small blue luer cap.

Loosen large blue luer

Small white luer cap

5000204

Remove small blue luer

Filter/sparger assembly

5000204a
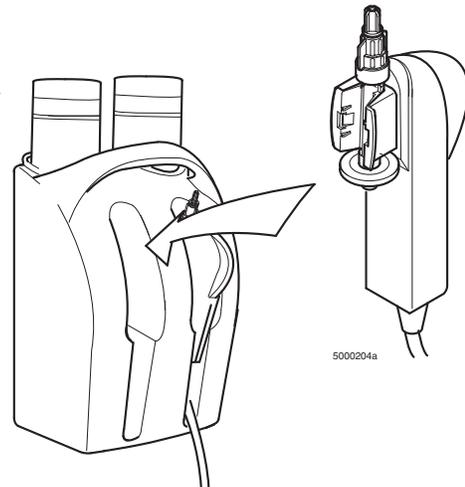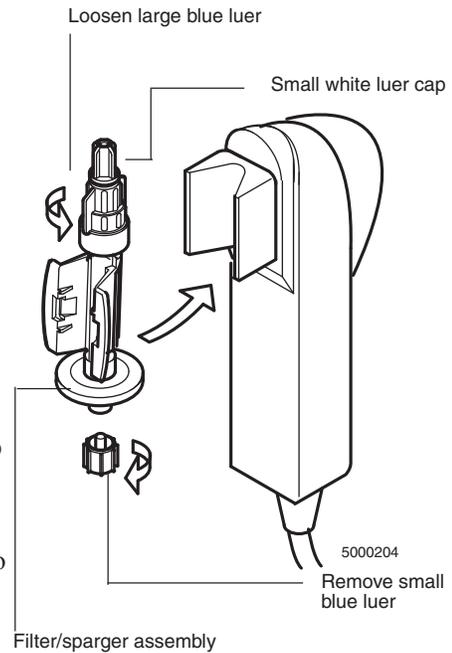
■ Installation

See Chapter 6 for all warnings and more details on installation.

1   If the TCVS CDI™ H/S Cuvette is in a single
    sterile package, remove it and insert it into the
    extracorporeal circuit using aseptic technique.

2   Prime the circuit.

3   Install the CDI Shunt Sensor into the circuit
    using aseptic technique:

    ■ Place the cable-head on the cable-head
      bracket.

    ■ Remove the top white luer cap and attach
      the top of the sensor to the purge/shunt line
      in the circuit.

    ■ Remove the sensor filter/sparger assembly
      using aseptic technique and attach the end
      of the purge/shunt line to the bottom of the
      sensor.

5000605

4   If you are using a shunt bypass line, install the
    CDI Shunt Sensor into the shunt bypass line
    using aseptic technique:

    ■ Stop the pump and/or clamp off the 1/4 inch legs of the shunt bypass line.

    ■ Remove the blue cap from the female end of the shunt bypass line and the
      small top luer cap (white) from the top of the CDI Shunt Sensor. Attach the
      CDI Shunt Sensor to the female end of the shunt bypass line.

    ■ Remove the white cap from the male rotating luer connector on the shunt
      bypass line. Remove the filter/sparger assembly (clear) from the CDI Shunt
      Sensor. Attach the male rotating luer end of the bypass line to the CDI Shunt
      Sensor, and securely tighten the rotating luer onto the CDI Shunt Sensor.

    ■ Unclamp the shunt bypass lines.

5   Prime and debubble the CDI Shunt Sensor(s), by inspecting the purge/shunt
    line, the shunt bypass line, and the CDI Shunt Sensor for bubbles.

6   Attach the CDI H/S Probe to the CDI H/S Cuvette:

    ■ Remove the CDI H/S Probe
      from the probe holder.

    ■ Connect the bottom of the CDI
      H/S Probe to the bottom of the
      H/S Cuvette.

    ■ Press the CDI H/S Probe and
      CDI H/S Cuvette together until
      the release lever latches.

5000206
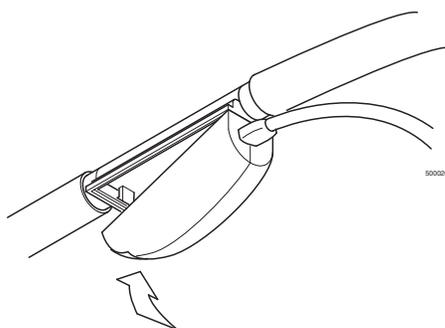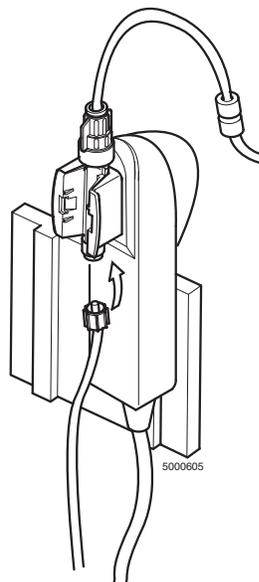
Operation

See Chapter 7 for all warnings and more details about operating functions.

1   Set the monitor to "Operate" mode.

▲ Warning
Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management. ▲

2   When the case has begun and the values have stabilized, complete a calibration of all measurable blood parameters, including; pH, PCO_2, PO_2, SO_2, K+, HCT, Hgb, by performing an in-vivo recalibration.

3   Options:
   - Change display modes for viewing data (choices are numeric, graphic, or tabular).
   - Mark or print data.
   - Perform in-vivo recalibration of the monitor.
   - Change patient temperature mode.
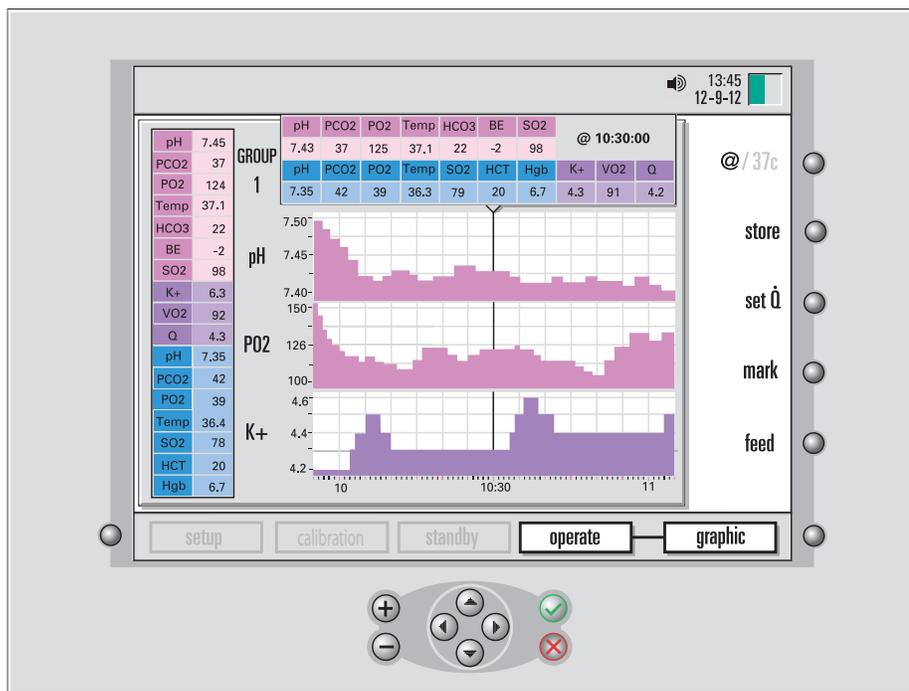
5000206a

■ Conclusion of case

See Chapter 8 for all warnings and more details on concluding a case.

1   Tear off printout. If necessary, press the "feed" button in the operate mode to
    clear printout from printer cover.
    Option: Print a post-case report (from the printer options setup screen).

2   Set the monitor to "standby" mode or turn it off.

3   Remove the sensor(s) from the cable-head(s).

4   Return the cable-head(s) to their docking mechanisms on the monitor.

5   Detach the H/S Probe from the CDI H/S Cuvette and return the probe to its
    docking mechanism on the monitor.

6   Wipe down the monitor and cables with cleaning agent, taking care to avoid
    optical surfaces.

7   Option: Disconnect the serial and power cables from the monitor, remove the
    monitor from the pole clamp tray, stow the cables, and store the monitor.

This chapter explains how to set up the Terumo Cardiovascular Systems CDI™ Blood Parameter Monitoring System 500 Monitor, printer, and TCVS CDI™ Model 540 Calibrator, and describes the process of powering up the monitor.

Setting up the monitor

To set up the monitor, follow these steps:

1   **Attach the monitor pole clamp securely to a heart-lung machine pole.**
    Tighten the pole clamp until it's secure.

2   **Attach the CDI System 500 Monitor to the tray of the monitor pole clamp.**
    Place the monitor on the tray, positioning it correctly on the alignment cone,
    then push up while turning the locking screw on the bottom of the tray until it's
    tight. Loosen the adjustment knob and adjust the monitor to the desired
    position. Tighten the adjustment knob to secure.

Alignment cone

Locking screw
Adjustment knob

5000303
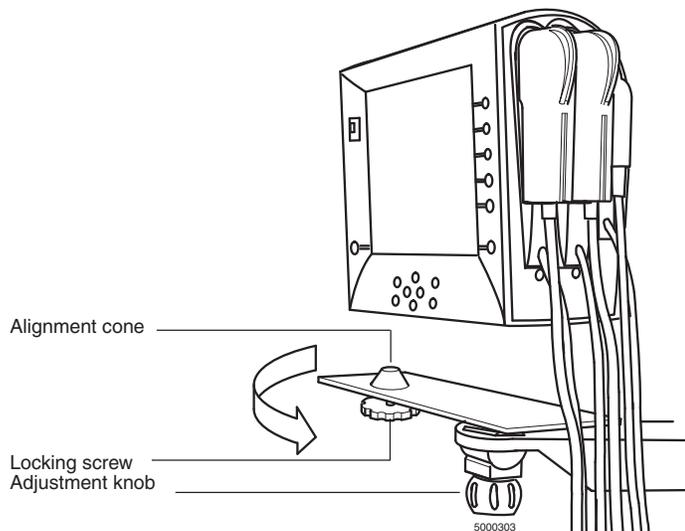
When you want to remove the monitor from the tray, you can loosen the locking
screw until the monitor is no longer locked to the tray.

▲ **Warning**
  • **Never leave the monitor on the pole clamp tray without securing the
    locking screw.**

  • **Do not roll equipment over the cables of the CDI System 500.
    Mishandling can cause damage and deterioration of system
    performance.** ▲

Note: When the monitor is not in use, always leave the cable-heads docked in their designated ports on the monitor side panel (their ports are color-coded for easy identification). Connecting the modules in this way provides protection for the optical surfaces.

Turning on the monitor

Before turning on the monitor, make sure the CDI H/S Probe is docked in its designated port on the monitor. This allows the system diagnostics and module self-test to run automatically. These tests verify the function of the monitor electronics, and check for electronic or optical drift in the modules, which could result in calibration failure or reduced accuracy. These checks should be done completely and routinely, prior to each use of the CDI System 500.

Once the cable-heads are docked properly, follow these steps to power up the monitor:

1   **Make sure that all the cable connectors are correctly in place on the monitor and that the monitor is off.**
Secure the connections of the monitor's power cord, the cable-heads, any serial cable(s), and the calibrator cable, if applicable.

2   **Turn on the monitor's power switch.**
The startup sequence begins, and the following display appears:

| startup | ver 1.69 |

⊤ TERUMO®

CDI™ System 500

Startup diagnostics in progress . . .
Checking memory . . .

Time remaining: 8 seconds

5000304

The system diagnostic testing takes about 40 seconds. During these diagnostics, the BPM self-test(s) and/or a CDI H/S Probe self-test are completed.

A time bar under the startup message indicates the progression of tests. The software version number is displayed in the upper right hand corner.

Note: When the monitor is turned on, do not press any of the keys on the front panel for at least the first 5 seconds. The keys are being tested during this time. Inadvertent key presses, or a key that is stuck down during system initialization, will result in error message code "F00D" being displayed.

3   If an error is detected during the system diagnostics, an error message will appear in the center of the screen.

5000305
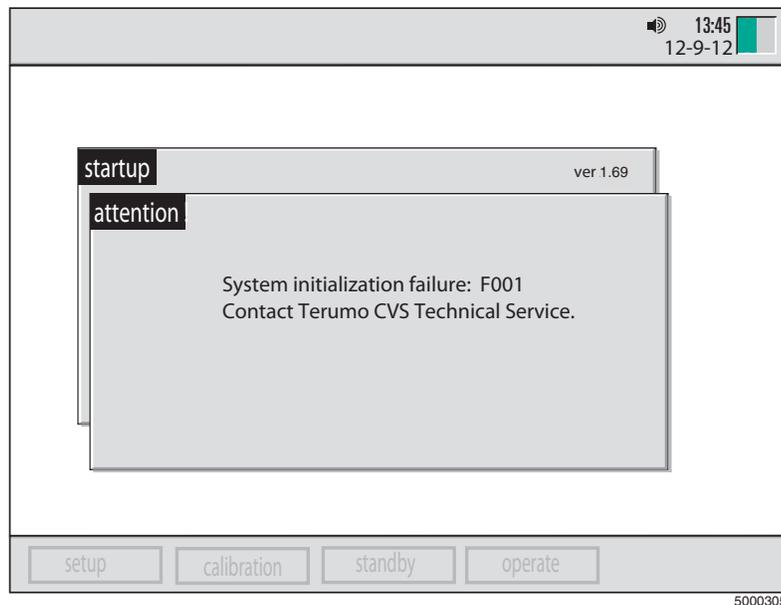
Errors that are recoverable will offer an option to continue − usually by pressing the √ (OK) key. Any consequences of continuing despite the error are noted in the error message. The message may recommend contacting TCVS Technical Service to resolve the error at a later time.

Errors that are not recoverable will not offer an option to continue. A brief description of the error, perhaps with a specific error code, will be displayed. This information should be provided to TCVS Technical Service for assistance.

Consult Chapter 9, "Troubleshooting," for more specific information on error messages.

Note: If upon power-up, an extended audible alert sound and/or the display remains blank, contact TCVS Technical Service for assistance.

After the completion of the system diagnostics and the module self-tests, the printer prints a heading like the following:

Terumo CVS™ CDITM 500
Blood Parameter Monitoring System

Date: 01/01/1999
Time: 13:00:49
Serial Number: 1001

Patient ID:
Monitor diagnostics: PASS
Arterial SRS check: PASS
Venous SRS check: PASS
H/S check   PASS

Last calibration values in use

Note: The printout will note any monitor diagnostics failures.

Choosing a monitor configuration

After the system diagnostics and module self-tests have been completed, the **monitor configuration** screen appears. On this screen, you specify the configuration of your system − that is, which modules you want to use.

Note: If any of the modules failed their SRS or color chip checks, an error message "REFERENCE SENSOR TEST FAILURE" appears in the message bar. The "A", "V", and/or "H/S" module indicators will flash indicating the failed modules.

1   **Press the ▲ and ▼ keys to move the highlight to the configuration you want.**

Note: The dimmed configurations are not available on your system and cannot be selected.

Note: The starting choice will be the last one used.

2   **Press the √ key when the desired configuration is highlighted.**
If a blood parameter module (BPM) or a CDI H/S Probe has failed its self-test, you will see a message that gives you two options:

■ **Cancel.** If you choose this option, you're prompted to re-select your monitor configuration.
■ **Retry.** If you choose this option, the module self-test repeats.

These colored tabs indicate which modules are included in the highlighted configuration. (A gray tab indicates an excluded module. A=arterial, V=venous, H/S=hematocrit/saturation)

A yellow highlight indicates the current selection.

startup – monitor configuration

A   V   H/S

Select a monitor configuration, then press the OK (✔) key ...

1 Arterial / Venous Blood Gases & Hematocrit / Saturation
2 Arterial / Venous Blood Gases
3 Arterial Blood Gases & Hematocrit / Saturation
4 Venous Blood Gases & Hematocrit / Saturation
5 Arterial Blood Gases
6 Venous Blood Gases
7 Hematocrit / Saturation

setup   calibration   standby   operate

13:45
12-9-12

5000307

System mode select key

Use the + and - keys or the ▲ and ▼ keys to move the highlight up and down.

Note: If any module self-test fails, clean the affected module with water and a soft cloth, re-seat the module onto the monitor and retry the self-test. If the module still fails, refer to the Troubleshooting section in Chapter 9.

After you've successfully selected the appropriate configuration, the monitor automatically goes into standby mode, with other system modes enabled.

To move on to the setup screens, simply press the ◀ or ▶ keys until the setup mode is highlighted. Press the √ key to enter the setup mode.

■ Preparing the printer

There are 2 styles of printer for the CDI 500 Monitor. See graphics below to help identify whether Printer Style 1 or Printer Style 2 is installed. Certain CDI 500 monitors have been equipped with Printer Style 2, these include the following:

- Monitors with serial numbers 5500 and higher.
- Monitors that have undergone a service repair requiring a replacement printer.
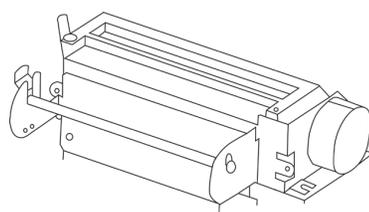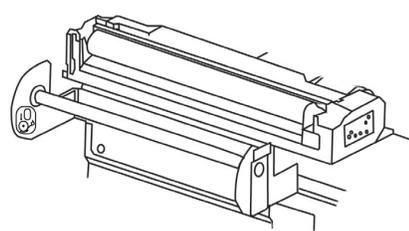
Printer Style 1   Printer Style 2

Printer Style 1

To load the printer paper into Printer Style 1, follow these steps:

1   **Make sure that the monitor is powered on.**

2   **Raise the printer cover.**

3   **Orient the paper roll so that when it's on the paper roll axle the free end of the paper feeds from the bottom, toward the front of the monitor. Follow the paper path label located on the printer bracket.**

4   **Disengage the free end of the printer paper axle and slide the paper roll into position. Secure the open end of the axle in the printer bracket clip.**

Printer bracket clip   Paper release lever

Printer cover   Paper

Paper axle
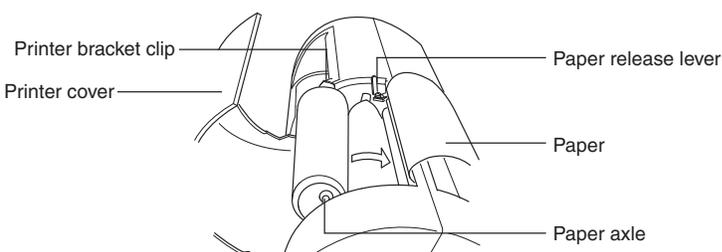
5   **Guide the free end of the paper into the slot below the black roller. The paper advances automatically until it's in the proper position. If it doesn't advance, push down on the paper release lever to remove and re-insert the paper end until the paper advances through to the top of the roller. Bring the paper release level back into the upright position. Pressing the "feed" soft key may be necessary to feed the paper.**

6   **Hold down the release lever and pull the paper through until you're sure that it's long enough to go through the slot in the top of the printer cover.**

7   **Return the paper release lever to its full upright position.**

8   **Place the free end of the paper through the printer cover slot, and lower the cover.**
If necessary, you can tear off excess paper using the upper edge of the printer cover slot.

Note: Thermal printer paper TCVS CDI™ Model 7310 is sensitive to the heat, light, chemical, and mechanical damage. The paper remains sensitive even after an image has been printed on it. Used paper should be stored in the dark at an ambient temperature below 25°C and 65% relative humidity.

Printer Style 2

To load the printer paper into Printer Style 2, follow these steps:

1   **Make sure that the monitor is powered on.**

2   **Raise the printer cover.**

3   **Orient the paper roll so that when it's on the paper roll axle, the free end of the paper feeds from the bottom toward the front of the monitor.**
Follow the paper path label located on the printer bracket.

4   **Disengage the free end of the printer paper axle and slide the paper roll into position. Secure the open end of the axle in the paper axle clip.**
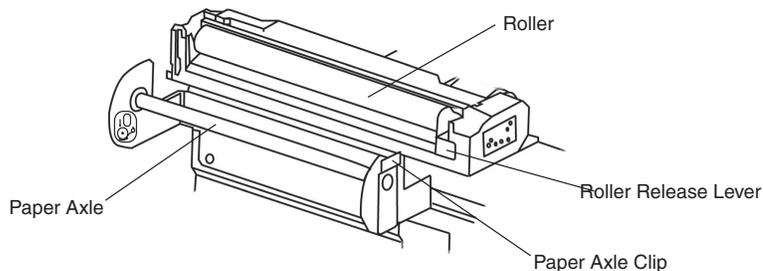
5   **Guide the free end of the paper into the slot below the roller and push it forward.**

The roller will sense the paper and advance it automatically a few inches. If the paper does not advance, push down on the roller release lever to release the roller and remove it. Align the paper so that it will be positioned under the roller and place the roller on top of the paper. Press the roller down evenly to snap it into place.

Note: The printer may sense the paper and try to automatically advance the paper even when the roller is removed. If this happens, wait a few seconds for the motor to stop before pressing the roller into place.

6   **If necessary, you may enter operate mode and press the feed soft key several times to advance the printer paper until it is long enough to pass through the printer cover slot.**

7   Place the free end of the paper through the printer cover slot and lower the cover.

Note: The printer cover must be securely closed for normal operation and for cleaning.

Note: Thermal printer paper TCVS CDI™ Model 7310 is sensitive to heat, light, chemical, and mechanical damage. The paper remains sensitive even after an image has been printed on it. Used paper should be stored in the dark at an ambient temperature below 25°C and 65% relative humidity.

Preparing the calibrator

To prepare the TCVS CDI™ Model 540 Calibrator to perform a tonometered calibration of the sensors, you need the CDI Model 540 Calibrator, one TCVS CDI™ Gas A bottle (Model CDI506), and one TCVS CDI™ Gas B bottle (Model CDI507). Ensure the calibrator cable is connected to the back of the monitor.

To install the gas bottles in preparation for calibration:

1   Press the system mode and press the ◀ or ▶ keys until the calibrate mode is highlighted. Press the √ key to enter the calibrate mode. Advance to the screen where the gas bottle level indicators are shown.

2   Check the expiration date on the gas bottles. Each gas bottle has a shelf life indicated by an expiration date printed on the bottle label.

3   Remove the caps from the calibration gas bottles.

4   Place the bottle of Gas A into the corresponding Gas A slot (orange sleeve) on the calibrator, and turn the bottle clockwise until the gas bottle level indicator on the "Calibrate" screen shows that the bottle has been engaged. After engagement, give an additional one-half turn to the bottle.

5   Repeat step 4 with the bottle of Gas B into the corresponding Gas B slot (blue sleeve) on the calibrator.

For the calibration procedure, you can hang the calibrator securely on the monitor pole clamp arm (CDI Model CDI517 only), or rest it on a flat surface.
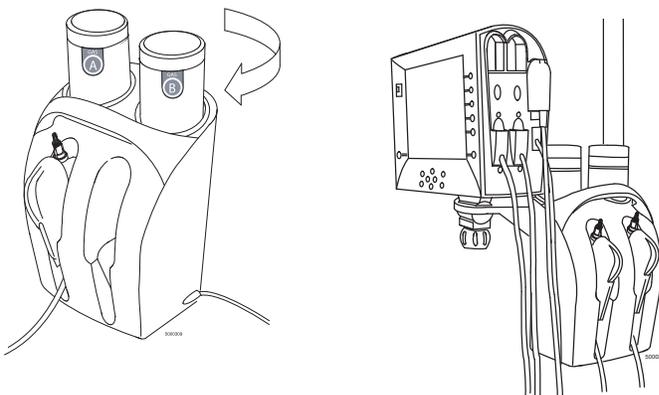
▲ Warning

- **Protect gas bottles from sunlight and do not expose to temperatures exceeding 50°C (122°F). Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. ▲**

➤ Caution

- Use only CDI Gas A and CDI Gas B calibration gas bottles intended specifically for use with the CDI Model 540 Calibrator. Use of any other gases will result in calibration failure or yield inaccurate calibration results, causing inaccurate system performance.

- Do not use the gas bottles after the recommended expiration date. Use of the gas bottles after that date may result in inaccurate calibration values.

- Contact with combustible material may cause fire. ➤

Note: TCVS recommends that the gas bottles remain in the calibrator at all times to avoid introducing debris into the calibrator. If the calibrator is to be stored for a long period of time, the gas bottles should be removed but the openings should be covered to avoid introducing debris into the calibrator.

Note: The calibrator must be placed in an upright position to ensure correct calibration.

Note: CDI gases are contained in disposable cylinders. These non-returnable cylinders contain non-toxic, non-flammable gases and gas mixtures. To dispose of the cylinders:

1   Make sure all residual gas is out of the bottle. For gases or mixtures containing less than 21% oxygen, this should be done in a well ventilated area to avoid asphyxiation by displacement of oxygen.

2   Remove or obliterate markings which indicated the cylinder contains hazardous material. Do not remove markings prohibiting refill of the cylinder.

3   Discard the cylinder as you would other metallic or hard goods waste as permitted by local authorities, rules or regulations.

Preparing the Cable-head Bracket

Place the cable-head bracket on the pole nearest to the shunt/purge line used for shunt sensing. Adjust the rod arm as desired so that the cable-head, when attached to the bracket plate, will be in a convenient position to route the shunt line tubing through the shunt sensor.
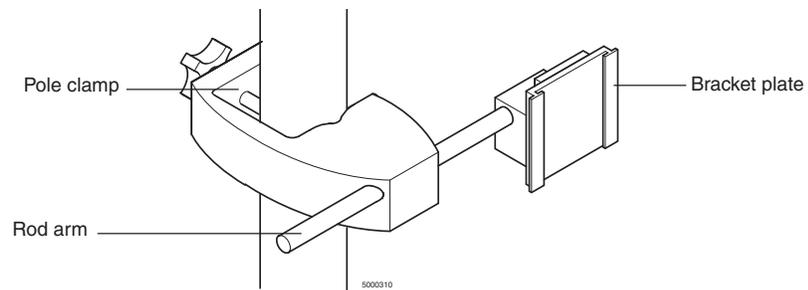
The cable-head bracket can be adjusted four ways:

1   The location of the cable-head bracket on the pole can be changed using the pole clamp tightening knob.

2   The rod arm length can be changed using the arm adjustment knob.

3   The bracket plate location can be changed on the rod arm by using the bracket adjustment knob.

4   The rotation of the bracket plate can be changed by pulling the bracket plate away from the rod arm and rotating the bracket plate 90° or 180° right or left.

     The bracket plate will lock into place in either the vertical or horizontal orientation.

This chapter explains how to choose system settings − settings that customize your Terumo Cardiovascular Systems CDI™ System 500 for the way you plan to use it. You choose these settings on a series of setup screens that appear on the TCVS CDI™ System 500 Monitor. Here's a list of the setup screens and a brief description of what you do with each one (the details are in the sections that follow):

■ **Printer options screen.** Choose options for how and when you want to print patient blood parameter values.

■ **Alerts screen.** Set high and low parameter thresholds to alert you when patient blood parameter values fall outside the limits you specify.

■ **Graphic display screen.** Choose which values you want to see displayed in graphical format during operations.

■ **General screen.** Choose general screen parameters: which language you want your monitor to display, the current date, time, date format, and more.

■ **Calculations screen.** Specify values to be used in calculations performed by the system as well as setting up a pump interface for blood flow acquisition.

■ **Serial port configuration screen.** Set parameters for sending data to a computer or data acquisition system.

For most of the options, once you've made your selections, you don't need to do it again unless there are changes in your system, your preferences, or the way you use the system.

Selecting options on the setup screens

To choose options on the setup screens, use the navigation/input keys and the edit key as shown in the next figure. In general, here's how these keys work on the setup screens:

■ To move the yellow highlight up or down, use the ▲ and ▼ keys. (The highlighted value is the selected one.)

■ To change the selected (yellow-highlighted) value, first press the edit key (this changes the highlight to black), then press the ▲ and ▼ keys to scroll through the possible settings for that value. The + and − keys scroll through the selections quickly if you continue to press the key, while the ▲ and ▼ keys move one selection with each press of the key.

■ To confirm the setting for the selected option, press √. (To cancel, or revert to the original value, press X.) When you press √ or X, the highlight changes back to yellow.

■ If there is more than one box, or field, on a line, the first selection in the line will become black when you press the edit key. You will be able to move the black highlight back and forth between the fields using the ◀ and ▶ keys.

■ When you've selected and confirmed all your choices on a screen, you can move on to the next screen by pressing the ▶ key.

Note: You can return to the monitor configuration screen from any of the setup screens by pressing the **configure key** (near the upper-right corner of the screen).

Note: For software versions prior to 1.4, the editing highlight color may be white.

Configure key
Edit key
Navigation/input keys

5000404

Setting printer options

The first screen in setup mode − the **printer options** screen − allows you to specify your printing preferences. When this screen appears, the first option (Printing On/Off) is highlighted in yellow.

1. To edit the value for the yellow-highlighted option, first press the edit key. This changes the highlight to black.

2. Use the ▲ and ▼ keys to scroll through available settings.

3. Press √ to save the current setting in the black-highlighted option.

5000404B
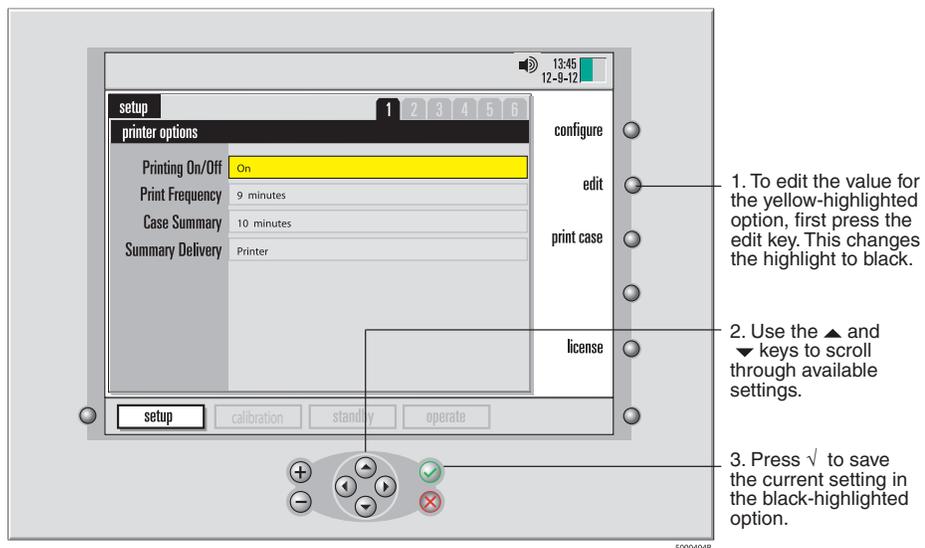
The following table describes the printer options and their settings.

Printing On/Off	Determines whether the printer is used during a procedure.
Print Frequency	Determines how often to print values during a procedure. Possible values are 0 − 15 minutes (in increments of 1 minute) or 15 − 60 minutes (in increments of 5 minutes).
Case Summary	Determines the time intervals for the inclusion of data in the case report, which you can print at the end of the case. Possible values are 1 − 15 minutes, (in increments of 1 minute). *Note:* The case data is erased when you return to operate mode after the next power up. Be sure to print the case report before that point.
Summary Delivery	Determines where the case summary is sent. Options are to the printer, to the serial port, or to both simultaneously. *Note:* A case summary will only be sent when the "print case" soft key is pressed.

When you have made all your selections and confirmed them, press the ▶ key to move on to the next screen.

There are two special soft key functions that only appear in the printer options screen. These are described as follows:

Print case	Executes the printing of the post-case summary report.
License	Executes the display of the software license agreement between you and TCVS. Use the ▲ and ▼ keys to view the entire license agreement.

Setting alerts

This icon indicates that an audible alert is set. When the audible alert is off, this icon is crossed out.

Set the audible alert volume by pressing the + and – keys (a tone plays to demonstrate your choice).

setup

alerts

configure

edit

defaults

Alert volume

Alert Thresholds

13:45
12-9-12

	Min. Value	Max. Value	Units
pH	7.38	7.59	
PCO2	35	45	mmHg
PO2	100	245	mmHg
Temp	15	40	C
SO2	90	100	%
K+	3.0	7.45	mmol / l
VO2	80	120	ml / min
pH	7.35	7.55	
PCO2	40	70	mmHg
Temp	15	40	C
PO2	35	70	mmHg
SO2	60	100	%
Hgb	5	12	g / dl
HCT	15	36	%

setup   calibration   standby   operate

5000406
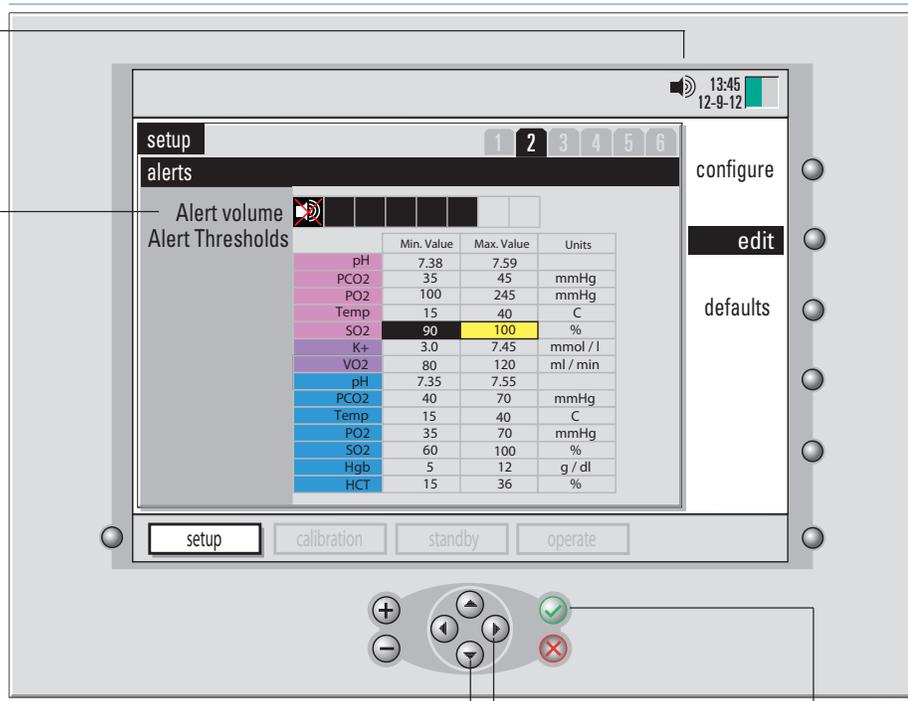
Use the ▲ and ▼ keys to highlight the line you want to change. Then press edit, and use the + and – keys or ▲ and ▼ to change the selected value.

Press the ◀ and ▶ arrow keys to highlight a different value on the same line.

Press √ to accept the selected value.

The second screen in setup mode − the **alerts** screen − allows you to set alerts that notify you about possible problems during a procedure. On this screen, you can set the acceptable ranges for a patient's blood parameters and the volume of the alert that sounds when a patient's values fall outside the acceptable range.

Note: Although values outside these ranges may be displayed, the alerts limits can be set only within these ranges.

Note: The lowest setting for the alert volume is the mute setting indicated by a crossed-out speaker.

Note: The minimum value cannot be higher than the maximum value, and the maximum value cannot be lower than the minimum value.

Note: The minimum and maximum values set become the range of values on the y-axis in the "graphic" display screen. (See Chapter 7 for more information on the "graphic" mode).

Note: When an alert is activated, an audible and visual alert occur (if the alert volume is not set to mute). If the audible alert for a given parameter is dismissed (the audible tone can be dismissed by pressing the X button) and a second alert occurs, or the parameter that caused the alert falls back within acceptable range then falls out of the acceptable range, the audible alert will respond. The default setting for an alert is both audible and visual alerts active.

Note: The audible portion of the alert may be inhibited upon startup prior to entering into Operate mode by setting the alert volume to mute (crossed-out speaker).

When an alert is activated, an audible and visual alert will occur (if the alert volume is not set to mute). If the audible alert for a given parameter is dismissed and a second alert occurs, or the parameter that caused the alert falls out of the acceptable range, the audible alert will respond. The default setting for an alert is both audible and visual alerts are active.

The audible portion of the alert cannot be inhibited after entering into the Operate mode without first turning off the CDI System 500 Monitor and making this selection during setup. If the monitor is turned off, all calibration information will be lost, and all calibration steps will need to be repeated.

The following table shows the lowest numbers you can use for the minimum values and the highest numbers for the maximum values. These are the default settings for alert limits

The minimum and maximum values are provided in the table below are the same as the operating range of the monitor (see Appendix B for table of system operating ranges).

Parameter		Minimum Value	Maximum Value	Units
pH	Arterial	6.80	7.80	
PCO$_2$	Arterial	10	80	mmHg (1.3-10.7 kPa)
PO$_2$	Arterial	20	500	mmHg (2.7-66.7 kPa)
Temp	Arterial	15	40	°C
SO$_2$	Arterial	60	100	%
K+		3.0	8.0	mmol/l
VO$_2$		10	400	ml/min
pH	Venous	6.80	7.80	
PCO$_2$	Venous	10	80	mmHg (1.3-10.7 kPa)
PO$_2$	Venous	20	500	mmHg (2.7-66.7 kPa)
Temp	Venous	15	40	°C
SO$_2$	Venous	60	100	%
Hgb	Venous	5.6	12.6	g/dl
HCT	Venous	17	38	%

When you've made all your selections and confirmed them, press the right-arrow key to move on to the next screen.

Choosing graphic displays

During blood parameter measurement in the "operate" mode, the CDI System 500 can display the patient's blood gas parameter values in a graphical format. The graph will show blood parameter values over two selectable time periods, so you can see changes in a patient's blood parameters at a glance.

The third screen in setup mode − the **graphic display** screen − allows you to choose which parameter values to display in the graphical format. You can specify up to six groups of three parameters for graphic display; Three graphs, each displaying values for one parameter, can be displayed at one time.

On the graphic display setup screen, here's how you use the selection and edit keys:

1   **Press the ▲ and ▼ keys to select a group.**
2   **Press edit.**
3   **Use the ◂ and ▸ keys to highlight a particular item within the selected group.**
4   **Use the + and − or ▲ and ▼ keys to change the entry for the selected item.**
    The possible entries are listed in the next table.

5   **After you've selected all three items for a group, press √.**

Note: Any group can have one or more parameter(s) disabled. Only if all three are disabled will the group be skipped over in graphics display. If a group has one or two disabled parameters, that one or two will show up as a blank graph in the graphics display.

6   **Repeat steps 1 − 5 for all the groups you want to set.**
    Depending on your chosen module configuration, you can select parameters available from the following group:

To highlight the group you want to change, use the ▲ and ▼ arrow keys.

To change the highlighted group, press edit, select an item in the group with the ◂ and ▸ aarrow keys, then press + and − to change the entry for that item.

Press √ when you're finished selecting all the items in a group.

Group 1	Arterial PCO2	Arterial pH	Venous pH
Group 2	Arterial PCO2	Arterial PO2	Venous pH
Group 3	Arterial PCO2	Arterial Temp	Venous PO2
Group 4	Arterial PCO2	Arterial pH	Arterial PO2
Group 5	Arterial PCO2	Arterial HCO3	Arterial BE
Group 6	Disabled	Disabled	Disabled

setup   1 2 **3** 4 5 6

graphic display   configure   edit

13:45 12-9-12

setup   calibration   standby   operate

5000408

Arterial pH	Arterial PCO$_2$	Arterial PO$_2$
Arterial Temp	Arterial HCO$_3$	Arterial BE
Arterial SO$_2$	K+	$\dot{V}O_2$
$\dot{Q}$	Venous pH	Venous PCO$_2$
Venous PO$_2$	Venous Temp	Venous HCT
Venous Hgb	Venous SO$_2$	Disabled

Note: If you are using a venous BPM only (with or without CDI H/S Probe), HCO$_3{}^-$ and BE will refer to venous values.

When you've made all your selections and confirmed them, press the ▶ key to move on to the next screen.

The following figure shows an example of bar graphs that display blood parameter values during an operation. The graphs make it easy to see the changes in the values over time. The graphed parameters are the ones you specify on the **graphic display** screen described above. During an operation you can choose to view patient data in this form.
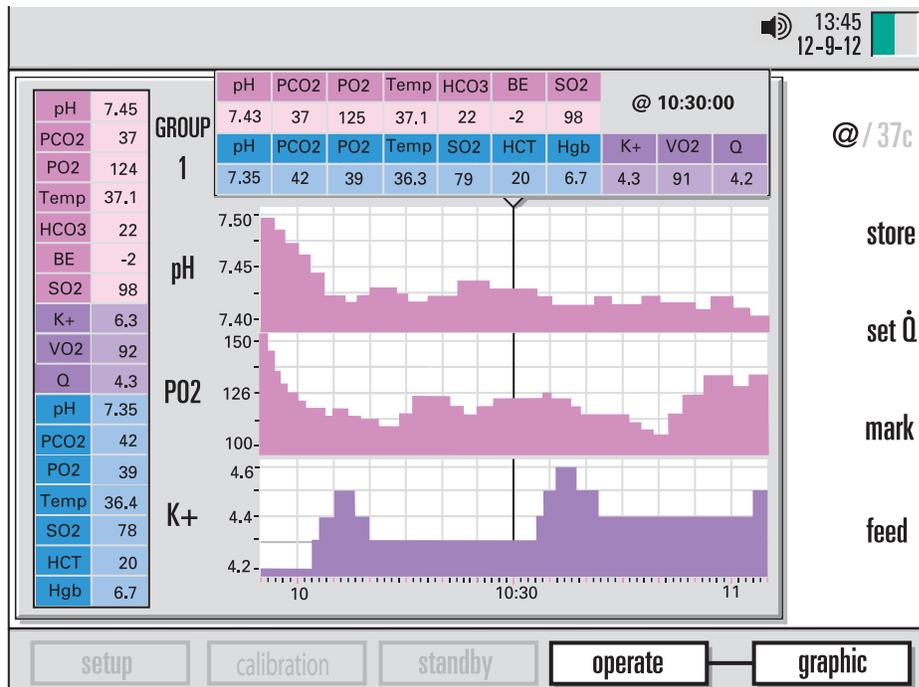
Note: Groups can be rotated in the "operate-graphic" screen by using the ▲ or ▼ keys. The group number is displayed in the upper left section of the screen. (See the section "Choosing display modes" in Chapter 7 for more information.)

■ Choosing general settings

The fourth screen in setup mode − the **general** screen − allows you to choose general settings (as shown in the next figure).

To move the yellow high-light up or down, use the ▲ and ▼ keys.

To set the highlighted option, first press the edit key, then use the + and − keys as described in the next table.

5000410

Press √ to confirm the settings for each option.

The general options are:

Language	Press the + and − or ▲ and ▼ keys to select a language. The choices are English, French, German, Italian, Japanese, Spanish, Swedish, Danish, and Dutch. *Note:* Once changed, the language setting will not take effect until the monitor is turned off and then on again.
Date	Use the ◀ and ▶ keys to highlight an item you want to change (the month, day, or year). Press the + and − or ▲ and ▼ keys to change the value of the highlighted item. When the month, day, and year are all correct, press √.
Date Format	Use the + and − or ▲ and ▼ keys to choose either the "Month Day Year" format or the "Day Month Year" format.
Time	Use the ◀ and ▶ keys to highlight an item you want to change (the hour or minute). Press the + and − or ▲ and ▼ keys to change the value of the highlighted item. When the hour and minute are both correct, press √. *Note:* Changing the time during a case will result in restating the pre-existing data as displayed in the "graphic" and "tabular" operate screens. The printed case summary will show times as they were.

PCO₂ PO₂ Units	Use the ▲ and ▼ keys to choose either "mmHg" or "kPa."
H/S Application	"Venous" is the only option currently available.
Default Calibration	Use the + and − or ▲ and ▼ keys to choose either the "factory default values" or "last calibration values."
	Note: This section determines what calibration values are used as a default if a two-point tonometered gas calibration is not done. "Last calibration values" are simply the values obtained from your last gas calibration. "Factory default values" are average calibration values determined from factory experience. An in-vivo recalibration from the operate mode should be done to improve the applicability of these default values.
	▲ Warning
	• Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management. Failure to perform a proper set-up, full two-point tonometered gas calibration, and initial in-vivo calibration may result in compromised system performance that does not meet the system accuracy limits found in Appendix B. ▲
	Note: Once changed, the default calibration status will not take effect until the monitor is turned off and on again.
Verify Calibration	Use the + and − or ▲ and ▼ keys to choose either "Enabled" or "Disabled." If you choose Enabled, a verify key will appear on the screen after each calibration procedure. You can press it immediately to verify that the system is calibrated properly. The verify function will remain available to checkthe gas calibration values until the monitor is turned off.

When you've made all your selections and confirmed them, press the ▶ key to move on to the next screen.

Specifying values used in calculations

On the fifth screen in setup mode − the **calculations** screen − you can specify certain values to be used in system calculations (as shown in the next figure).

To move the highlight up and down through the options, use the ▲ and ▼ keys.

To set the selected (highlighted) option, first press the edit key, then press +, −, ▲ or ▼ keys to change the value.

Press √ to confirm your choice for the selected option.
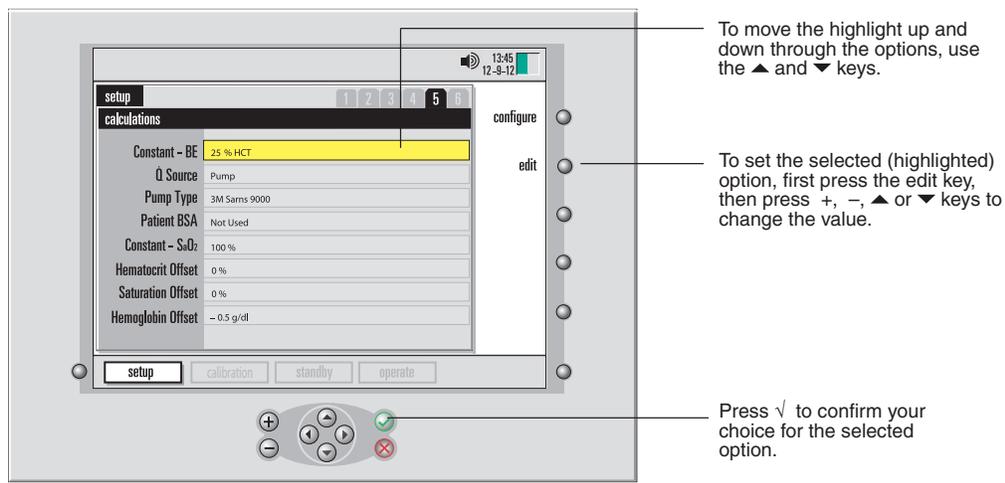
The following table explains the purpose and possible values for the settings on the calculations screen.

Constant - BE	Use the + and − or ▲ and ▼ keys to select a value between 10 and 47% Hematocrit. This value is used only for the calculation of Base Excess. The default value is 25%.
Q̇ Source	Flow rate input source. Choices are None, Manual, or Pump (the default is None). Used in the oxygen consumption calculation (which can be done only if you're using at least two modules).
Pump Type	Defines the pump type connected to the pump interface port. Choices are "Not Used," TCVS Sarns™ 9000, TCVS Sarns™ 8000 Comm. Module, TCVS Sarns™ Centrifugal, Medtronic Bio-Console® 550, Jostra (Maquet) HL20, Stökert (Sorin) SIII/SC and CDI Pump Interface. The default is "Not Used." *Note:* Use TCVS CDI Pump Interface when connecting to the Terumo® Advanced Perfusion System 1. *Note:* If you select the Stöckert SIII/SC, the arterial pump position number (1 − 6) is required. Enter this number in the adjacent numerical field by using the ▶ key to highlight, then using the ▲ and ▼ keys to adjust.
Patient BSA	Patient Body Surface Area. Possible values are 0.1 to 20.0m² (in 0.05 increments), or "Not Used." Used to index the oxygen consumption calculation. This value automatically resets to "Not Used" when you turn on the monitor.
Constant − SaO₂	Possible values are 50 − 100% in increments of 1%. The default is 100%. This is the arterial oxygen saturation value for use in the oxygen consumption calculation if no arterial BPM is used.
Hematocrit Offset	Possible values are -5 to +5% in increments of 1% (0 is default).
Saturation Offset	Possible values are -10 to +10% in increments of 1% (0 is default).
Hemoglobin Offset	Possible values are -2 to +2 g/dL in increments of 0.1 g/dL (0 is default).

Note: The oxygen saturation, hematocrit, and hemoglobin offset should be used only if a consistent difference appears between hospital laboratory results and the CDI System 500. When values are entered for these offsets, the offset remains in use unless you change it in the setup mode. A message stating the current offset value prints at the start of calibration.

When you've made all your selections and confirmed them, press the ▸ key to move on to the next screen.

Setting parameters for communicating with an external device

On the sixth screen in setup mode − the **serial port configuration** screen − you can set parameters for communicating with an external serial printer, computer, or data acquisition system. When attached to an external device, the CDI System 500 can send operational information and blood parameter values at a prescribed frequency or on demand.

The following table lists the possible settings for the parameters on the serial port configuration screen.

Output Type	Possible settings are "ASCII Output," "TCVS Sarns™ 9000," or "Packet Mode." If Sarns 9000 is selected, all other values on the screen become fixed and are dimmed.
Data Bits	Possible settings are "8 data/1 stop" or "7 data/2 stop."
Parity	Possible settings are None, Even, or Odd.
Baud Rate	Possible settings are 1200, 2400, 4800, 9600, 19200, or 38400.
Output Interval	Possible values are 0, 0.1, 0.5, or 1 − 10 minutes (in 1 minute increments). Determines how often data will be sent to an external device via the serial port. If this option is set to 0, the CDI System 500 sends data on demand only.

Note: The data bit, parity, and baud rate selections will depend on the specific receiving device.

Note: The serial port settings are applicable to the data output port only (top 9-pin connector on rear panel). The pump interface port, directly beneath the data output port, is setup through the "Pump Type" and "Q̇ Source" selection in screen 5.

Note: See Appendix C for more information on the use and configuration of the serial port.

When you've finished adjusting all the system settings, you can switch from setup mode to a different mode. Here's how:

1 **Press the system mode select key to activate the system map.**
2 **Use the ◀ and ▶ keys to select the mode you want.**
3 **Confirm your choice of modes by pressing the √ key.**

This chapter explains how to calibrate sensors prior to clinical use.

Setting up and starting calibration

For the calibration procedure, you need the following: the Terumo Cardiovascular Systems (TCVS) CDI™ System 500 Monitor, the TCVS CDI™ Model 540 Calibrator with the Gas A and Gas B bottles installed, and the sensor(s) you're calibrating (arterial and/or venous sensors).

Before calibration, make sure the calibrator is set up as described in the section "Preparing the calibrator" in Chapter 3. (First insert the gas bottles into the calibrator, then either hang the calibrator on the monitor pole clamp or place it on a flat surface near the monitor.)

Note: The calibration procedure is not available if running on backup battery power.

> ▲ **Warning**
> - **Failure to perform the gas calibration on the shunt sensor before use may result in compromised system performance that does not meet the System Accuracy Limits found in Appendix B. ▲**

> ▲ **Warning**
> - **Failure to complete calibration as described in Chapter 7, Completing Calibration of the CDI System 500 Measurements, may result in compromised system performance that does not meet the System Accuracy Limits found in Appendix B. ▲**

After the calibrator has been set up properly, follow these steps to calibrate the sensors:

1   Put the monitor into calibrate mode.
To do this, first press the system mode select key, use the ◀ and ▶ keys to highlight the "calibrate" label (at the bottom of the screen), then press √.

The following screen appears when you enter calibrate mode:
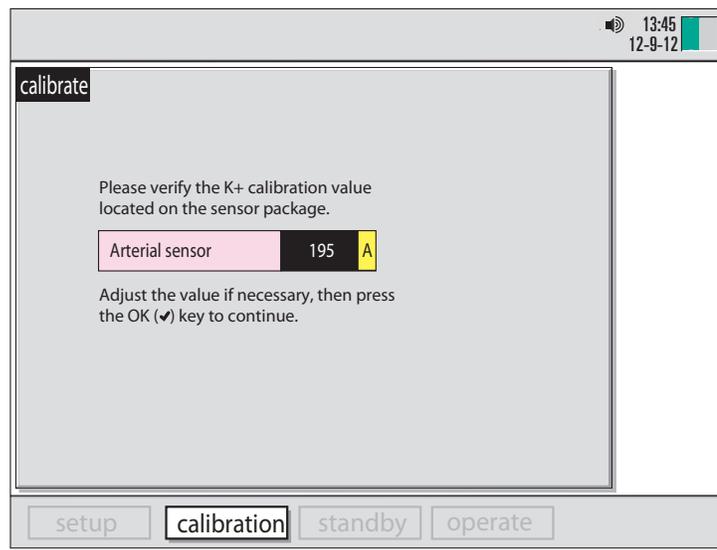
2 **K+ calibration value consists of a number and a letter. The number is from one to three digits. Verify that the K+ calibration value, from the sensor's foil pouch label, K+ code matches what is shown on the screen.** If the calibration value on the foil pouch does not match the value on the screen, adjust the screen value by using a +, −, ▲ , or ▼ key.

To change the letter code following the numeric value, enter that value by using the ▶ key to highlight the entry field and use the ▲ and ▼ keys to enter the corresponding letter.

Press the √ when the calibration values match.

The following screen appears after you verify the K+ calibration value:
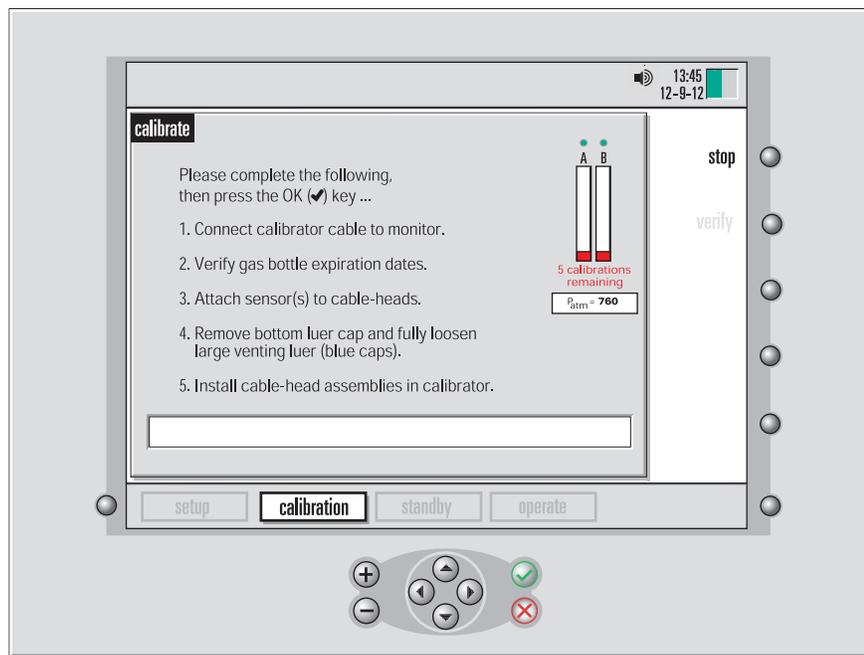
Note: If you don't have time to do a full gas calibration, the K+ calibration value from the pouch should still be entered.

3   Connect the calibrator cable to the monitor. (Align the red dot on the cable to the red dot on the monitor.)

Connect the calibrator cable to the monitor.

5000504a
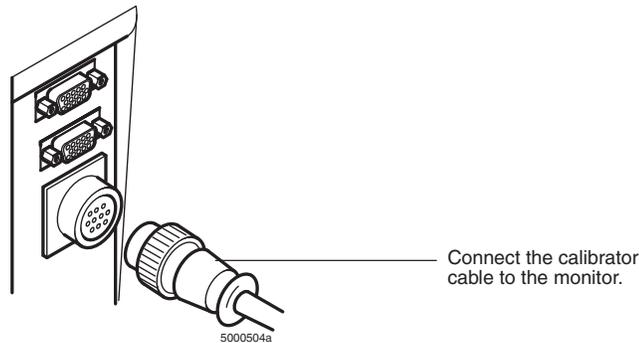
Verify that the gas bottle level indicators appear on the screen and that sufficient gas exists for the calibration.

Note: A bottle low on gas will cause its level indicator bar to show red. If the level of gas is too low to perform a calibration, an error message will appear after starting calibration prompting you to replace the appropriate gas bottle.

4   When you're ready to calibrate, open the sensor package, remove the sensor, and do a visual check for damage to the optical surface of the sensor body.

➤ **Caution**

•   Do not open the pouch until the sensor is to be used. Once the pouch is opened, the sensor must be used within 24 hours or inaccurate calibration may result.

•   Do not use the sensor if the foil pouch has been damaged. Damage to the foil pouch can result in inaccurate calibration. ➤

5   Check that the sensor contains adequate buffer solution before calibration.
To do this, hold the sensor assembly vertically and check to make sure the buffer solution completely covers all four microsensors.

▲ **Warning**

•   **Avoid touching the optical surfaces of the CDI Shunt Sensor and cablehead. Fingerprints on these surfaces can reduce the accuracy of the system.**

•   **Do not add or remove solution in the sensor assemblies. The composition and volume of the buffer solution has been preset during manufacturing for optimum calibration time and accuracy. ▲**

- Do not use sensor assemblies that are not filled adequately with buffer solution. Sensor assemblies not filled with adequate buffer solution may not calibrate properly.

- Do not try to wipe moisture or particulates from the surface of the sensor assembly that connects to the cable-head. Damage to this surface can result in inaccurate performance. ➤

6   Remove the appropriate cable-head from the monitor.

Remove the cable-head that corresponds to the sensor you're calibrating.
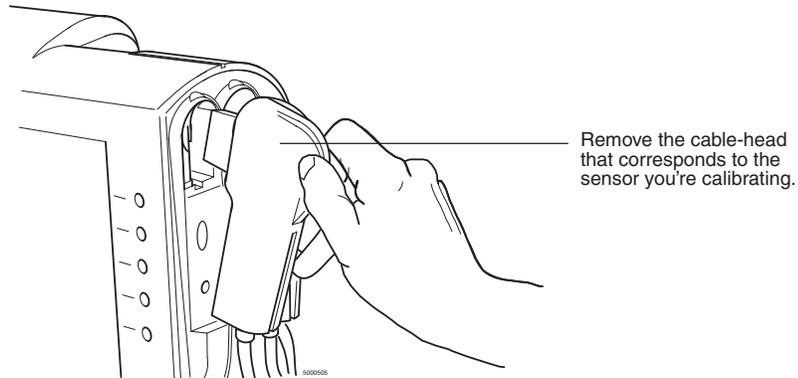
7   Attach the sensor assembly to the cable-head.
See the figure after step 8.

The sensor will snap securely onto the cable-head and will fit only one way on the cable-head.

8   How to attach the shunt sensor to the cable-head.
Align the shunt sensor with the cable-head and then press firmly in the center of the shunt sensor (between the wings) until the shunt sensor snaps into place.

9   Remove the small, blue bottom luer cap from the sensor assembly (as shown in the next figure).

▲ **Warning**

- **Do not remove the sensor filter/sparger assembly from the CDI Shunt Sensors until you're ready to connect them to the circuit. The microsensors inside the CDI Shunt Sensors must be kept sterile and moist. Exposure to air for more than a few minutes can damage the microsensors. ▲**

Loosen large blue luer cap

Filter/sparger assembly

Remove the small, blue bottom luer

Attach the sensor to the cable-head
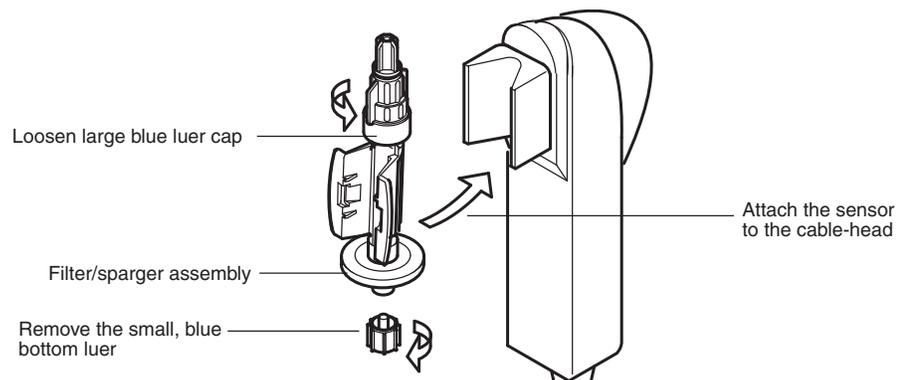
10 **Using sterile technique, fully loosen the large, blue top venting luer cap on the sensor(s).**
The cap will stay attached to the top of the sensor, allowing venting of the buffer solution without compromising the sterility.

The filter/sparger assembly will prevent the buffer solution from leaking out of the sensor.

11 **Place the cable-head assembly in the calibrator pocket, pushing it down until it stops and locks into place.**
The cable-head is connected properly if it can resist a gentle tug. This ensures a good connection between the sensor and calibrator.

Note: The small dots over the gas bottle indicators will turn green when a sensor/cable-head has been engaged in that sensor/cable-head pocket.

Put the cable-head assembly into the calibrator, pushing down until it locks into place.

5400507
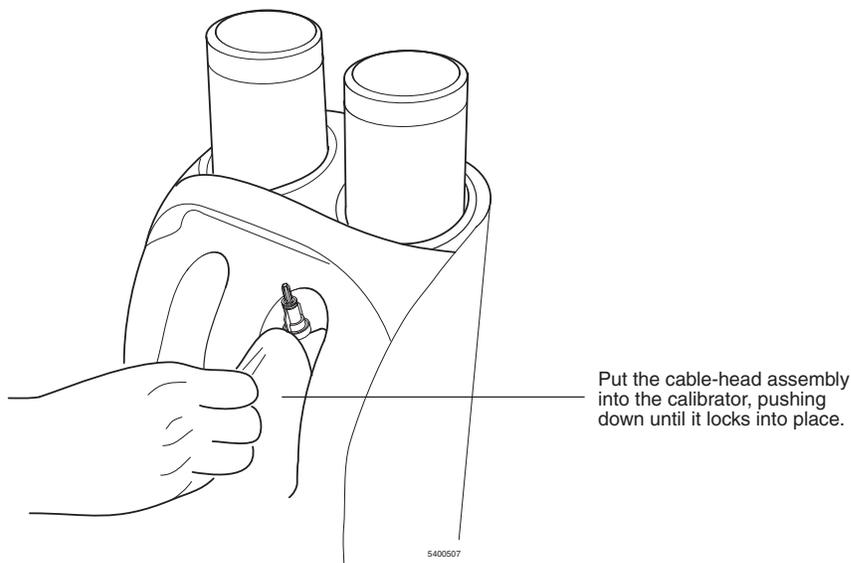
12 **To calibrate a second sensor, repeat steps 4 − 11 for that sensor.**
Note: If only one sensor is being calibrated, the calibrator will automatically detect the port being used and shut off flow to the unused port.

13 **Press the √ key on the monitor to initiate calibration.**
If no errors occur, the calibration proceeds and you see a screen like the one shown in the next figure.

If any error messages appear, follow the instructions on the screen, or consult Chapter 9, "Troubleshooting," to resolve the problem.

Note: A small amount of calibration fluid may be initially displaced from the sensor through the top fitting. This loss of fluid is normal and does not affect calibration accuracy.

Note: In normal calibration, you hear gas bubbling through each sensor.

Note: The barometric pressure as measured by the TCVS CDI™ Blood Parameter Monitoring System 500 is not a user-adjustable parameter. You can compare this value with a measured barometric pressure in the room if you suspect there is a problem.

These indicate how much gas is left in the bottles.

This shows the atmospheric pressure (in mmHg) as measured by the CDI System 500.

This shows how much time is left in the calibration process.
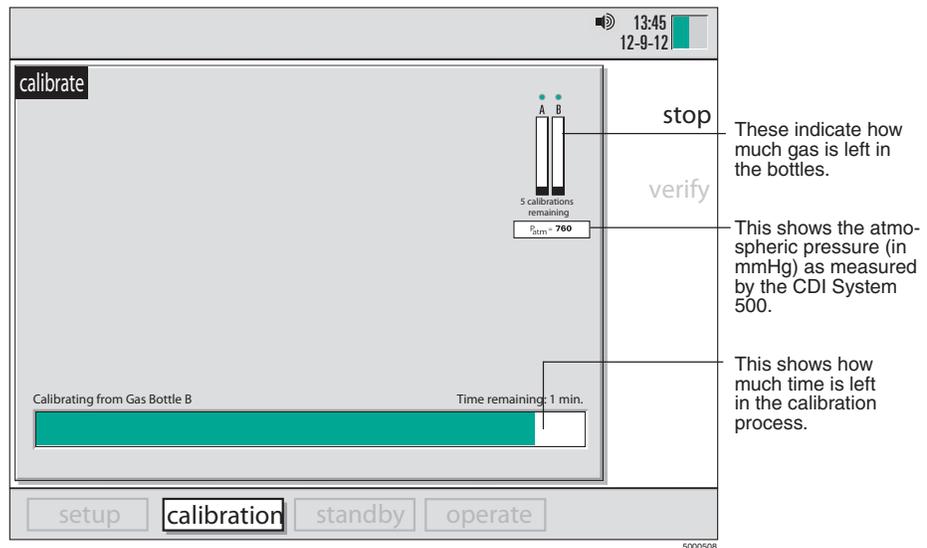
Note: The number of calibrations remaining, as displayed under the gas level indicators, reflects the approximate number of individual sensor calibrations left. If you are calibrating sensors for both arterial and venous monitoring, the count will decrease by two for each calibration procedure. A set of full gas bottles should provide enough gas for approximately 80 individual sensor calibrations.

At any time during calibration, you can press the stop key (in the upper-right corner of the monitor's front panel) to halt the calibration process. You can then resume calibration by pressing the √ (OK) key.

If you run out of time and you need to abort the calibration, press the stop key. You can then press the cancel (X) key to exit and return to Standby.

If you switch to operate mode and begin measurement without having completed the two-point calibration, the CDI System 500 automatically uses the calibration values specified for the Default Calibration option on the general setup screen (as follows):

■ If "Last calibration values" is selected for the Default Calibration option on the general setup screen, the monitor will use the values from the previous complete two-point calibration.

■ If "Factory default values" is specified, average calibration values preset at the factory are used.

■ When using either source of default calibration values, an in-line calibration using reference values (from your laboratory) can be used to improve the applicability of these default values.

Note: A full 2-point tonometered gas calibration procedure is highly recommended to get the best measurement performance. Use of default values should be limited to unusual circumstances which preclude the ability to do the normal calibration procedure. In any case, it is highly recommended that you enter the K+ calibration value from the sensor pouch to ensure optimal K+ measurement performance.

■ If the last calibration values are suspect for any reason, it is recommended that you change the default setting to "Factory default values" before entering Operate mode.

Note: You must turn the monitor off and back on for a change in calibration status to take effect.

Note: If you intend to turn off the monitor after calibration and then power it back up before operation, you should use the "Last calibration values" setting. This will ensure that the calibration values will be retained upon power up.

Note: An aborted calibration will not affect stored "Last calibration values" as defaults.

When the calibration is finished, the calibration results are printed (if the printer is active), the values are stored, and the following screen appears (if the calibration was successful).

Calibration successful.

Please complete the following, then press the OK (✔) key...

1. Close large venting luer.
2. Remove cable-head assemblies from calibrator.
3. Unplug calibrator cable from monitor.

5 calibrations remaining

$P_{atm} = 760$

stop

verify

You can press this key to perform a calibration verification, if enabled in setup.

You can compare this value with the actual barometric pressure in the operating room, if you suspect there's a problem.

setup   calibration   standby   operate

5000509

Note: If there are any error messages, consult Chapter 9 "Troubleshooting," to help resolve the problem.

Concluding calibration

After the calibration is finished, follow these steps to conclude the process:

1 **Verify that the sensors have been successfully calibrated by checking to make sure that no error messages or failures appeared on the monitor or were printed by the printer.**

2 **Disconnect the calibrator cable from the monitor.**

3 **Using sterile technique, tighten the large, blue top luer cap(s) on the shunt sensor(s).**

▲ Warning

• **Make sure the large blue luer cap of each shunt sensor is tightened securely to avoid leakage and maintain sterility. ▲**

4 **Remove the cable-head assemblies from the calibrator. If you are not placing the sensor in-line within one hour of calibration, re-attach the bottom blue luer cap to the filter/sparger assembly.**

➤ Caution

• Do not use the cable connected to the cable-head to pull the cable-head out of the calibrator. Pulling on the cable may result in wire damage. ➤

5 **Place the cable-head(s) on the mounting bracket. The filter/sparger should remain attached to the sensor until you to connect it to the circuit.**

▲ Warning

• **Do not empty calibration fluid from sensor assembly as microsensors must be kept wet. If the shunt sensor is left uncapped for more than a few minutes, dry-out may occur affecting sensor performance. Drain contents just prior to priming the shunt line only. ▲**

6 **Press the √ key.**
The monitor switches to standby mode when the √ key is pressed.

Note: After calibration, as long as buffer solution level is above the top microsensor and all caps are tightly fastened, the sensors can be used for up to 24 hours.

Sensors that have been calibrated successfully are ready for placement into the extracorporeal circuit. (See Chapter 6, "Installing Disposables," for instructions).

Note: The CDI System 500 remembers the most recent calibration data, even when turned off or placed into standby mode. The calibration data is replaced only when a new calibration is performed or when the Default Calibration option on the general setup screen is set to "Factory default values."

➤ Caution

• Once calibrated, do not remove and replace the sensor from the cable-head prior to use. Removal and replacement could affect the measurement accuracy of the system. ➤

■ Verifying calibration

If the "Verify Calibration" option is set to "Enabled" on the "general" setup screen, the verify key appears on the screen shown in the previous figure.

Note: The calibration verification procedure isn't available while the monitor is running on battery power.

Note: Calibration verification can only be utilized after a current successful calibration is completed, before the monitor is turned off. Turning off the monitor will require another calibration to enable verification.

If you want to verify the calibration, follow these steps:

1   Make sure the sensors are still on the cable-heads and the cable-heads are in the calibrator.

Note: The original calibration buffer solution must be retained.

2   Press the "verify" key.

The following screen appears:

5000510

Pressing √ begins calibration verification.
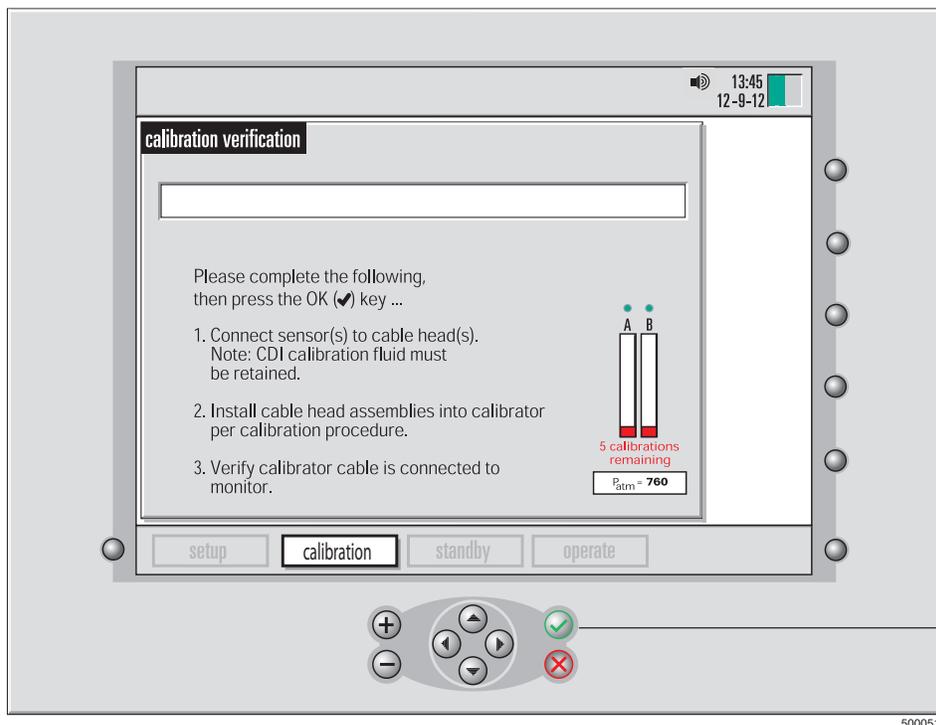
3   Press the √ key to begin the calibration verification.
The calibration verification takes about 5 minutes. The following screen appears during the process.
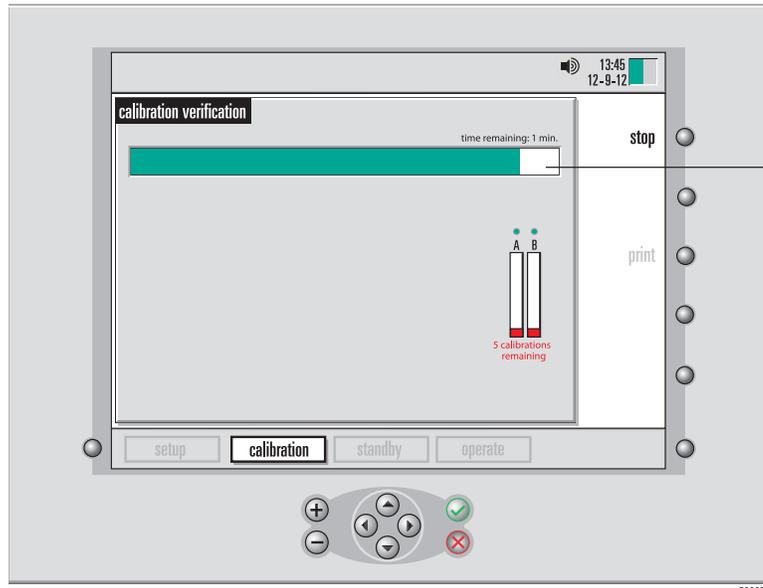
This shows how much time is left in the verification process.

When the calibration verification is finished, the results are reported:
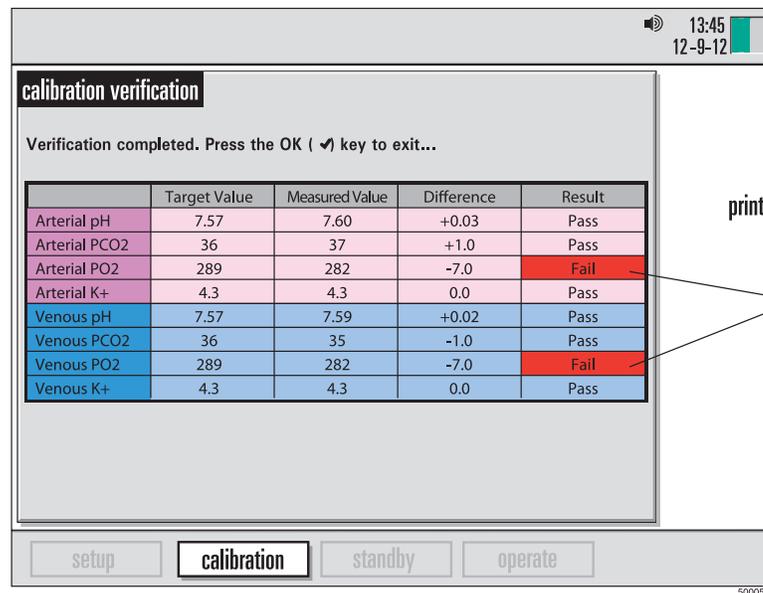
These values fall outside the acceptable ranges for these parameters.

calibration verification

Verification completed. Press the OK (✔) key to exit...

	Target Value	Measured Value	Difference	Result
Arterial pH	7.57	7.60	+0.03	Pass
Arterial PCO2	36	37	+1.0	Pass
Arterial PO2	289	282	-7.0	Fail
Arterial K+	4.3	4.3	0.0	Pass
Venous pH	7.57	7.59	+0.02	Pass
Venous PCO2	36	35	-1.0	Pass
Venous PO2	289	282	-7.0	Fail
Venous K+	4.3	4.3	0.0	Pass

4 **Press the "print" key to print the results table.**

Note: If there are any failures, set aside the failed sensor and calibrate another sensor.

5 **Press the √ (OK) key to exit verification. The monitor will go immediately to Standby.**

This chapter explains how to place the sensors and hematocrit/saturation cuvette into the extracorporeal circuit.

Preparing to install sensors

You need the following items: the Terumo Cardiovascular Systems (TCVS) CDI™ Shunt Sensor(s) you're installing, TCVS CDI™ H/S Cuvette, and access to the by-pass circuit. For additional information, refer to disposable instructions for use.

Note: CDI Shunt Sensor can be used for either arterial or venous application.

▲ Warning

- **Once calibrated, do not remove and replace the sensor from the cable-head prior to use. Removal and replacement could affect the measurement accuracy of the system. ▲**

➤ Caution

- Care should be taken to prevent BPM cable-heads from dropping onto any hard surface or otherwise receiving severe shock. If a drop occurs, the cable-head should be carefully inspected for any damage to the silver-domed thermistor contact, the optical pathways, or the cable-head housing surfaces. If the cable-head had a sensor installed and calibrated, you should replace the sensor and repeat the calibration. ➤

Installing the Shunt Bypass Line and CDI H/S Cuvette

If the Shunt Bypass Line and CDI H/S Cuvette are supplied in a single sterile package, remove them from the package and aseptically insert them into the extracorporeal circuit. If they are supplied as part of a tubing pack, this installation isn't necessary.

▲ Warning

- **Aseptic technique must be used when inserting the CDI H/S Cuvette and Shunt Bypass Line into the extracorporeal circuit to ensure that the blood-contacting surfaces remain sterile.**

- **Use an arterial filter distal to the Shunt Bypass Line on the arterial side of the circuit. This protects against introduction of air into the blood circulation.**

- **The presence of air bubbles on the optical window of the CDI H/S Cuvette can result in reduced measurement accuracy. Intermittent bubbles, once moved from the optical window, will not affect the long-term accuracy of the system.**

- **Avoid touching the optical surfaces of the CDI H/S Cuvette and the optical CDI H/S Probe. Fingerprints on these surfaces can reduce the accuracy of the system. Instructions for cleaning can be found in Chapter 10 of this manual. ▲**

- Secure the Shunt Bypass Line tubing connection with stay straps.

- The CDI Shunt Sensor can only be connected to the Shunt Bypass Line in one direction. The Shunt Bypass Line should be oriented in the bypass circuit to the desired placement of the cable-head and cable direction.

- The Shunt Bypass Line should have the CDI Shunt Sensor side down in the circuit to prevent air trapping in the CDI Shunt Sensor.

- The CDI H/S Cuvette contains an optical window that provides a means of consistent optical connection between the optical TCVS CDI™ H/S Probe and the CDI H/S Cuvette. When the CDI H/S Cuvette is inserted into the circuit, the optical window should be facing down, so that the CDI H/S Probe, when attached, will be on the lower side of the CDI H/S Cuvette. This minimizes interference from intermittent air bubbles in the line.

- End caps are provided (on the single sterile assemblies) at each end of the Shunt Bypass Line and the CDI H/S Cuvette to protect the blood pathways from contamination prior to insertion into the tubing. The Shunt Bypass Line and CDI H/S Cuvette remain sterile as long as the package is unopened and undamaged. ➤

Installing a CDI Shunt Sensor

The heparin-coated, sterile TCVS CDI™ Shunt Sensors, Model CDI510H, are intended for placement into shunt lines, purge lines, sampling lines, Shunt Bypass Lines, or any similar line that has constant blood flow.

▲ **Warning**

- **The CDI Shunt Sensor is supplied sterile. Aseptic technique must be used when inserting it into the extracorporeal circuit to ensure that the blood-contacting surfaces remain sterile.**

- **Avoid touching the optical surfaces of the cable-head and shunt sensor(s). Fingerprints on these surfaces can reduce the accuracy of the system. ▲**

➤ **Caution**

- The CDI Shunt Sensor should be placed distal to a purge line one-way valve to avoid possible back flow of air.

- TCVS recommends that you not connect the CDI Shunt Sensor directly onto another rigid plastic piece, such as a manifold, without extra support for the shunt sensor. Connecting the unsupported CDI Shunt Sensor directly to another rigid plastic piece may make the unsupported piece or the CDI Shunt Sensor susceptible to breakage. TCVS recommends having a length of pliable tubing between a supported CDI Shunt Sensor and any other rigid plastic part. ➤

Note: The CDI Shunt Sensor can be placed in the shunt/purge line at any time during priming or bypass, as long as there is fluid in the circuit. You must stop the fluid flow upstream of the sensor before insertion to avoid loss of fluid.

Note: The sensor is bidirectional. Blood can flow through it in either direction.

Note: If you're placing the CDI Shunt Sensor in a sampling line, place it on the inlet side of the sample port to avoid intermittent interruption of blood parameter data during medication administration.

Note: The end of the CDI Shunt Sensor that has the large blue luer cap is a male luer connector. The end of the CDI Shunt Sensor attached to the filter/sparger assembly is a female luer connector.

Follow these steps to install the CDI Shunt Sensor into a shunt/purge line:

1   **Slide the cable-head assembly onto the cable-head bracket plate. Make sure the positioning of the cable-head and CDI Shunt Sensor is convenient for connection into the shunt/purge line.**
2   **Using sterile technique, remove the top luer cap (white) from the CDI Shunt Sensor and attach one end of the "shunt/purge" line to the top of the CDI Shunt Sensor. Make sure the large blue top venting luer is completely tightened.**

Note: The sensor remains attached to the cable-head while being installed in the circuit.

3   **Remove the sensor filter/sparger assembly from the bottom of the sensor and attach the other end of the shunt/purge tubing circuit to the sensor.**
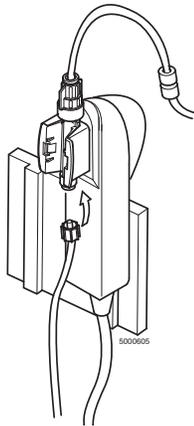
▲ **Warning**
   •   **Do not remove the sensor filter/sparger assembly from the CDI Shunt Sensor until you're ready to connect it to the circuit. The microsensors on the CDI Shunt Sensor must be kept moist. Exposure to room air for more than a few minutes can damage the sensor. ▲**

4   **Prime and debubble the shunt/purge line, inspecting the line and CDI Shunt Sensor for bubbles.**
     Air bubbles may clear more easily from the CDI Shunt Sensor if it's in an upright postion. Intermittent bubbles, once removed from the CDI Shunt Sensor, will not affect its long-term accuracy.

▲ **Warning**

- **Prime solutions containing acetate ions such as Isolyte-S, Normosol-R, or Plasmalyte-A can cause damage to the PCO_2 sensor. If the pH channel reads less than 7.00 after the sensor is placed in the circuit, you should either recirculate the prime solution using a CO_2-free sweep gas or add sufficient buffer to raise the pH of the prime above 7.00. Exposure to acetate-containing prime solutions below pH 7.00 for longer than a few minutes can cause significant PCO_2 inaccuracy.**

- **Exposure of the shunt sensor to prime solutions with pH greater than 7.8 or less than 7.0 pH units or a sodium measurement greater than 160 or less than 120 mEq/L can interfere in the accurate measurement of potassium.**

- **Make sure all luer lock connections are securely tightened before priming the shunt/purge line. Connections that aren't secure can result in a leak.**

- **The presence of air bubbles in CDI Shunt Sensors can affect the results. Intermittent bubbles, once removed from the CDI Shunt Sensor, will not affect its long-term accuracy.** ▲

5   Adjust the monitor cabling to clear excess cable from the work area.

Installing a CDI Shunt Sensor into the Shunt Bypass Line

▲ **Warning**

- **Do not allow the CDI Shunt Sensor to dry out. Make sure the circuit has prime fluid in it before attaching the Shunt Sensor. Exposure to air for more than a few minutes can damage the sensor and cause inaccurate results.** ▲

➤ **Caution**

- Do not remove the CDI Shunt Sensor from the cable-head to make sensor connections. ➤

1   Stop the pump and/or clamp off the Shunt Bypass Line.
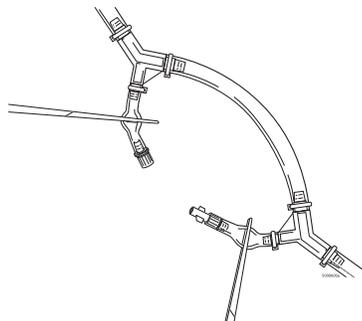
2   Using sterile technique, remove the blue cap from the female luer end of the Shunt Bypass Line and the small top luer cap (white) from the top of the CDI Shunt Sensor. Attach the CDI Shunt Sensor to the female luer end of the Bypass Shunt Line.

3   Using sterile technique, remove the white cap from the male rotating luer connector on the Shunt Bypass Line. Remove the filter/sparger assembly (clear) from the CDI Shunt Sensor. Discard calibration soultion just prior to use, then attach the male rotating luer end of the Shunt Bypass Line onto the CDI Shunt Sensor.

Note: Blood flow can go either direction through the shunt sensor, but the sensor will fit onto the Shunt Bypass Line only one way.
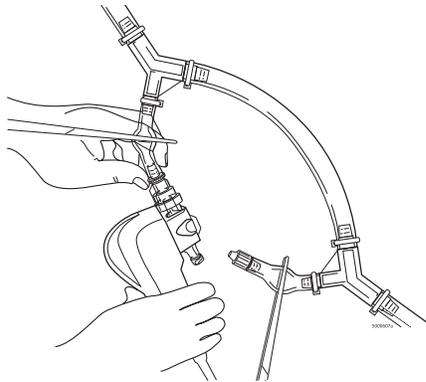
4   Unclamp the Shunt Bypass Lines and start the pump to circulate prime solution through the shunt sensor. Prime and debubble CDI Shunt Sensor and the Shunt Bypass Line, inspecting the line and CDI Shunt Sensor for bubbles. Verify that the cable-head is sufficiently supported and that the tubing is not kinked.
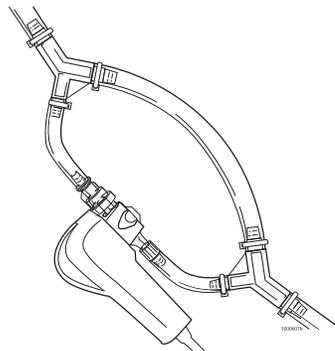
Note: If the Shunt Bypass Line has been placed in the bypass circuit and the CDI Shunt Sensor is not going to be used, one of the following steps should be taken:

■   Remove the Shunt Bypass Line from the circuit, or

■   Connect the short legs of the Shunt Bypass Line together (female luer connector to male rotating luer connector).

Attaching the CDI H/S Probe for Hematocrit/ Saturation measurement

Follow these steps to attach the CDI H/S probe to the CDI H/S Cuvette for hematocrit and oxygen saturation measurement.

1 Remove the CDI H/S Probe from the probe holder by pressing down on the release lever on top of the probe.

2 Clip the probe to the CDI H/S Cuvette by inserting the tab on the cable end of the probe into the receptacle on the CDI H/S Cuvette.

3 Press the CDI H/S Probe and CDI H/S Cuvette together until the release lever latches.
A magnet in the CDI H/S Cuvette ensures the correct connection between the CDI H/S Probe and the CDI H/S Cuvette.

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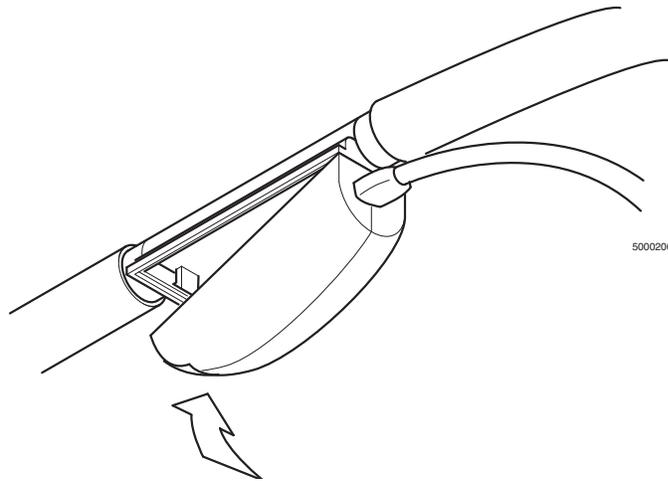
▲ Warning

- **Avoid touching the optical surfaces of the CDI H/S Cuvette and the CDI H/S Probe. Fingerprints on these surfaces can reduce the accuracy of the system. Instructions for cleaning can be found in Chapter 10 of this manual. ▲**

➤ Caution

- Although the CDI H/S Probe can be connected to the CDI H/S Cuvette any time after passing the self-check, the numbers reported will be invalid until blood enters the CDI H/S Cuvette. ➤

Note: The CDI H/S Probe is designed for use on the venous side only. If a venous BPM is used without a CDI H/S Probe, a calculated oxygen saturation value will be provided.

This chapter explains the procedures for observing and recording patient data during the "operate" mode of the Terumo Cardiovascular Systems CDI™ Blood Parameter Monitoring System 500.

◼ Initiating "operate" mode

When you're ready to begin in-line measurement of blood parameters, set the TCVS CDI™ Model 500 Monitor to "operate" mode by following these steps:

1   **Press the system mode select key to highlight the system map.**
2   **Use the ▶ key to highlight the "operate" label.**
3   **Press √.**

   ▲ Warning

   • **Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management. ▲**

Dashes appear for values that are out of the display range, which is located in Appendix B. If a value is outside the alert limits specified on the alerts setup screen the value appears with a red HIGH or LOW in the parameter window and an audible alert sounds at the volume specified in the alerts setup screen.

Note: When an alert is activated, an audible and visual alert occurs. If the audible alert is dismissed and a second alert occurs, both an audible and visual alert will be activated.

   ▲ Warning

   • **Use of Halothane anesthetic will result in significant PO₂ inaccuracy.**

   • **Prime solutions containing acetate ions such as Isolyte-S, Normosol-R, or Plasmalyte-A can cause damage to the PCO₂ sensor. If the pH channel reads less than 7.00 after the sensor is placed in the circuit, you should either recirculate the prime solution using a CO₂-free sweep gas or add sufficient buffer to raise the pH of the prime above 7.00. Exposure to acetate-containing prime solutions below pH 7.00 for longer than a few minutes can cause significant PCO₂ inaccuracy.**

   • **Exposure of the shunt sensor to prime solutions with pH greater than 7.8 or less than 7.0 pH units or a sodium measurement greater than 160 or less than 120 mEq/L can interfere in the accurate measurement of potassium. ▲**

Note: If you turn off the monitor during a case, you lose some of the settings including the Patient BSA (Body Surface Area), the ability to verify the current calibration, and any adjustments you've made to values during in-vivo recalibration. In this case, you need to re-enter the Patient BSA (if used) after turning the power back on. If you performed an in-vivo recalibration and adjusted some values before powering off (including initial K+ adjustment), you also need to draw another blood sample and recalibrate. Calibration values will have been replaced if the default is set to "Factory default values." If you don't turn off the monitor but the power is interrupted, the backup battery takes over (if it's charged) and you won't lose these settings.

Note: When you turn the monitor off and on again and return to "operate" mode, the previous case data is lost and cannot be printed. If you intend to print the case summary after power down, you must do so before entering the "operate" mode.
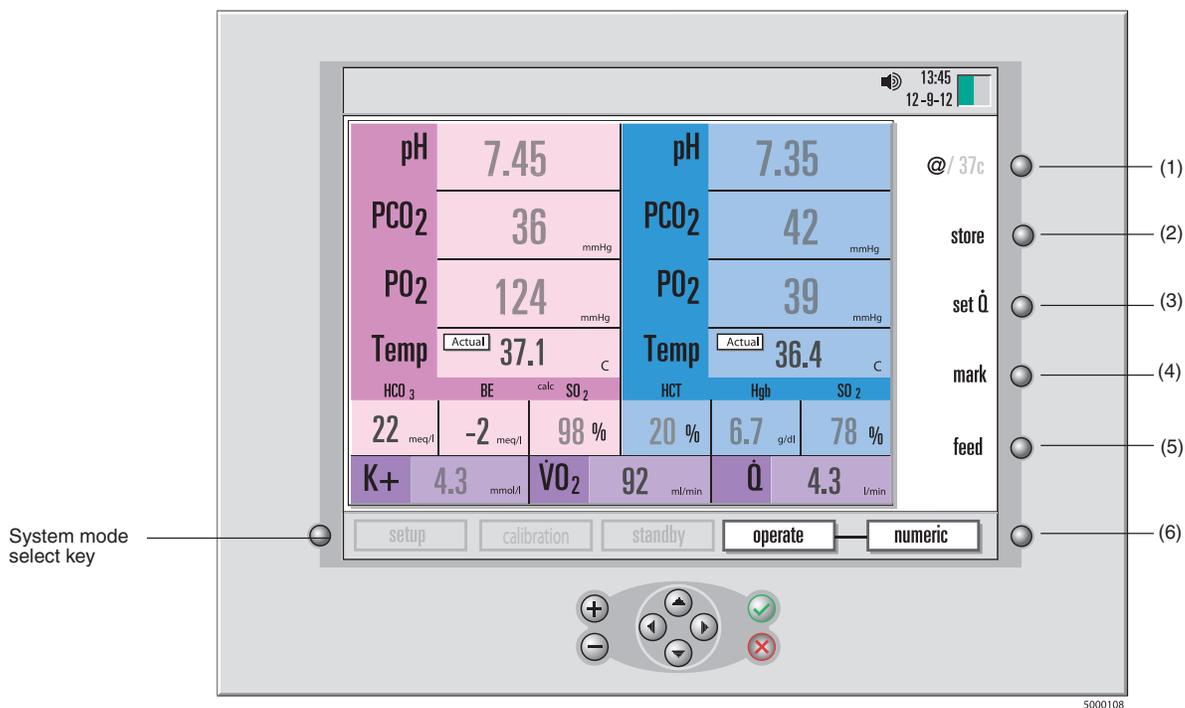
System mode select key

5000108

Note: The screens in this manual reflect a particular configuration of modules ("Arterial/Venous Blood Gases & Hematocrit/Saturation") per statement on page 1-7. Only parameters that can be in-vivo recalibrated will have numeric values that can be 'dimmed'.

The soft keys (along the right side of the monitor) shown in the figure above perform the following functions:

(1)   **@/37°C.** This key allows you to switch between alpha stat (37°C) and pH stat (actual) temperature mode for the display of blood parameter values.

(2)   **store.** You press this to store the current blood parameter values for a lab comparison. After you press "store," its function changes to "recall" until you press it again for a review of the stored values.

(3)   **set Q̇.** You press this to enter the flow rate manually for the calculation of oxygen consumption. This key is available only if the "Q̇ Source" option on the "calculations" setup screen (in "setup" mode) is set to Manual.

(4)   **mark.** Pressing this key marks the current values with an asterisk (*) for the historical record, and prints the current values. Marked values remain marked and will print with asterisks whenever you print. Marked values are also stored in the "operate-tabular" display.

(5)   **feed.** This function advances the printer paper.

(6)   **Operate mode toggle key.** You can press this key to switch among the three display modes —: numeric, graphic, and tabular. (See the section "Choosing display modes," later in this chapter).

■ Completing Calibration of the CDI System 500 Measurements

At the beginning of a case, you must complete calibration of all measurable blood parameters by comparing them to a laboratory measurement done on a blood sample. The numeric values are dimmed on the CDI System 500 screen to indicate that the values are not considered to be accurate until an initial in-vivo calibration is performed.

▲ Warning

- **Measured values prior to initial in-vivo calibration may not be accurate. Do not use values prior to initial in-vivo calibration for patient management. ▲**

Note: To differentiate between 'dimmed' and 'normal' values on the screen, compare the font shades of grey between the numeric values for parameters such as pH or PCO_2 and the numeric values for temperature. If the font shade of grey for the numeric values of parameters is lighter than the font shade of grey of numeric temperature, then the values are 'dimmed' which means that an initial in-vivo recalibration has not yet been performed. If the font shades of grey of the values are the same, then an initial in-vivo recalibration has been performed. The figure on page 7-2 shows that the CDI Monitor has not gone through an initial in-vivo recalibration.

Note: The terms "recalibrating the monitor" and "in-vivo recalibration" both refer to the same process and are used interchangeably throughout this manual.

Note: If you don't have time to do a full gas calibration, the K+ (Potassium) calibration value from the pouch should still be entered.

Note: To ensure accuracy of the potassium value, the pH of the blood should be between 7.0 and 7.8 on the CDI System 500.

To complete calibration of all measurable blood parameters, follow these steps:

1 When the values on the monitor have stabilized, press the "store" key.
➤ **Caution**

- For the best comparison with your laboratory, press the "store" key only after the circuit has been stabilized for approximately five minutes (when there have been no changes in temperature, Fraction of Inspired Oxygen in a gas mixture (FiO_2), gas or blood flows, or other parameters that would cause changes in displayed values). If the "store" key is pressed and/or the recalibration blood sample is drawn during periods of significant temperature or gas change, the system may not meet the system accuracy limits found in Appendix B. ➤

2 Immediately draw a blood sample from a sampling port close to the shunt sensor.
➤ **Caution**

- Draw the blood sample as close as possible to when the "store" key is pressed to ensure the blood parameter values are calibrated as accurately as possible. ➤

3 Send the sample for a laboratory measurement of all blood parameters.

Note: If the laboratory blood gas values are 37°C, the monitor must be in 37°C mode. If the laboratory gas values are at patient temperature, the monitor must be in actual (@) mode. The stored temperature mode can be switched in the recalibration screen; however, the temperature value used in the actual temperature mode cannot be adjusted.

➤ **Caution**

• Ensure that the stored and recalled temperature mode are the same as the laboratory sample to ensure proper calibration. Calibrating to different temperature modes compromises the system accuracy limits, as described in Appendix B. ➤

4   When the lab value is received, press the "recall" key.
The recalibration window opens (as shown in the next figure). The potassium value highlights (black background) automatically when you press "recall" for the first time.

When the recalibration screen first opens, the potassium value is highlighted.
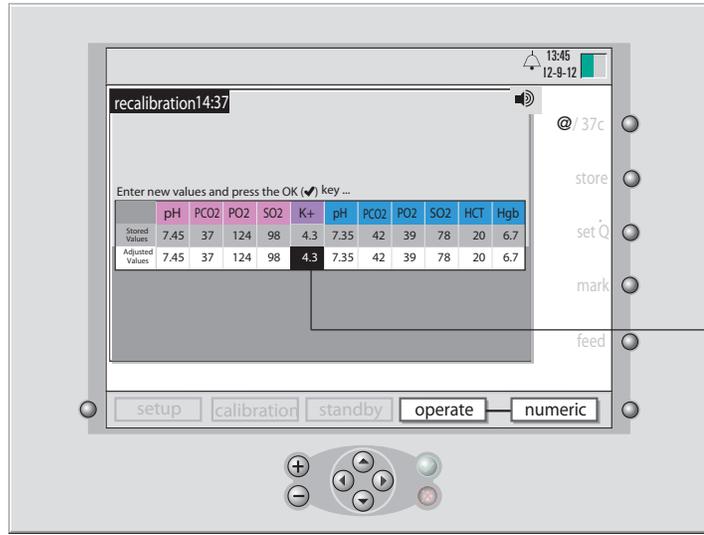
Use the + and – keys to change the highlighted value.

**5   Change the potassium value to match the lab value by using the + and −
 or ▲ and ▼ keys.**
**6   Change the other blood parameter values to match the lab value, by using
 the + and – or ▲ and ▼ keys and ◀ and ▶ keys.**
**7   Press √ only when you've finished adjusting all of the blood parameter
 recall values.**
Or, press X to cancel the adjustment and leave the "recall" key active.

▲ Warning

• **Measured values prior to initial in-vivo calibration may not be
 accurate. Do not use values prior to initial in-vivo calibration for
 patient management. Failure to perform a proper set-up, full two-
 point tonometered gas calibration, and initial in-vivo calibration may
 result in compromised system performance that does not meet system
 accuracy limits found in Appendix B. To perform additional in-vivo
 recalibrations see Chapter 7 –9 , "Monitoring a Patient: Recalibrating
 During a Procedure. ▲**

Note: If you press √ without changing any values, the stored potassium value be-comes the adjusted value and is used to set the potassium slope. Upon returning to operate, the "CAL" indicator will disappear and the K+ value will appear normal. The other stored blood parameter values become the adjusted values. Upon returning to operate, the values will no longer appear dimmed as shown on page 7-5.

Choosing display modes

During a case, you can press the operate mode toggle key to switch among three display modes − numeric, graphic, and tabular. Continuous blood parameter values are shown in each display mode. The soft keys − @/37°C, store, set Q, and feed − work the same way in the graphic and tabular display modes as they do in numeric display mode. However, the "mark" key is different − it becomes the "print" key in the tabular display. It prints all the blood parameter values displayed in the current tabular format. The "mark" function is retained in the "graphic" display as it is in the "numeric" display.

In the **numeric** display mode (shown in the next figure), the current blood parameter values are shown in full-size.

Press the operate mode toggle key to switch to a different display mode.
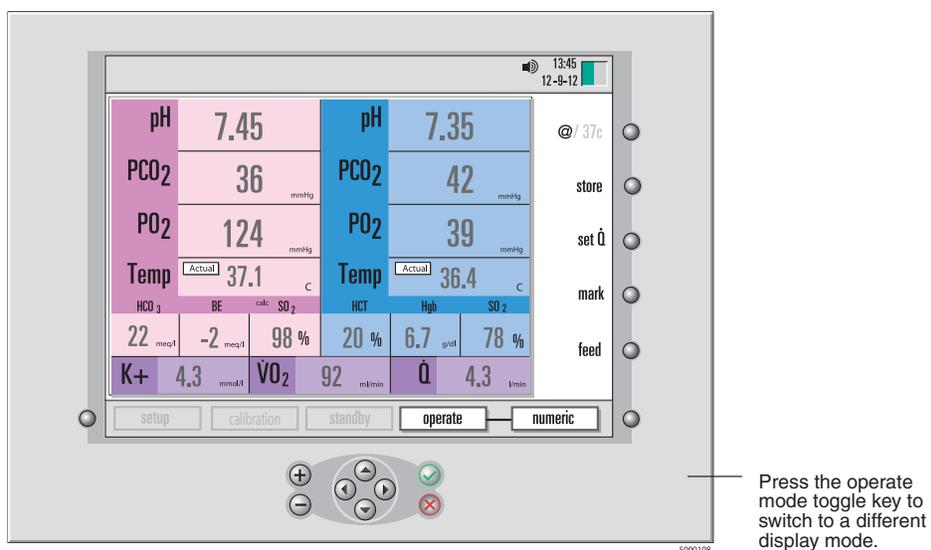
In **graphic** display mode (shown in the next figure), the current blood parameter values are shown (in a reduced size) on the left side of the screen.

The current blood parameter values.

The values from the selected time (indicated on the X-axis).

This symbol indicates that the blood parameters were displayed at the actual temperature.

The time cursor selects a point in time for the display of historical values.

Use the + and – keys to switch between 30-second and 5-minute intervals for the graphing of data.

Use the ◀ and ▶ keys to move the time cursor along the X-axis.

Use the ▲ and ▼ keys to scroll through the graph groups. The group number appears in the upper left

The graphs are updated as new data becomes available unless the most recent point is not shown (due to the cursor position). Progression of time is charted from left to right.

The range of the X-axis (time scale) is either 36 minutes (30 second intervals) or 6 hours (5 minute intervals).

The range of values along each graph's Y-axis is determined automatically by the alert thresholds set on the alerts setup screen (in setup mode).

Note: Historical values are displayed in the original temperature mode (either actual or 37°C), regardless of the current temperature mode.

Note: If you change the PCO_2/PO_2 units (mmHg or kPa) during a case, the historical graphic data will be restated to match the current units.

In **tabular** display mode (shown in the next figure), the current blood parameter values are shown (in a reduced size) on the left side of the screen. The newest data will continue to be added to the bottom (at 1 minute intervals) as long as the scroll bar is at the bottom. If the scroll bar is put elsewhere in history, the rows of data displayed will be held constant until the scroll bar is put to the bottom.

The current blood parameter values.

The values from the selected time.

This symbol indicates when you pressed the store key.

The print key prints all the blood parameter values for the displayed historical range.

This symbol indicates when you did a recalibration adjustment.

Use the ▲ and ▼ arrow keys to scroll up and down through the table.

Use the ◀ and ▶ keys to view values to the right or left of the current display.

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Time	pH	PCO2	PO2	Temp	HCO3	BE	SO2	K+	VO2
Begin									
@ 12:29	7.49	37	124	37.1	22	-2	98	4.3	92
@ 12:30	7.43	38	125	37.1	24	-2	97	4.3	92
@ 12:31	7.43	34	123	37.1	20	-2	99	4.3	93
@ 12:32	7.46	34	122	37.1	23	-2	98	4.3	91
@ 12:33	7.43	40	126	37.1	21	-2	97	4.2	92
@ 12:34	7.49	34	127	37.1	22	-2	99	4.2	92
@ 12:35	7.43	34	125	37.1	24	-2	95	4.3	92
@ 12:36	7.45	38	122	37.1	20	-2	95	4.3	91
@ 12:37	7.43	34	123	37.1	23	-2	97	4.3	93
@ 12:38	7.45	34	123	37.1	21	-2	99	4.3	94
@ 12:39	7.46	36	122	37.1	23	-2	98	4.3	94
@ 12:40	7.45	35	125	37.1	21	-2	97	4.3	92
@ 12:41	7.44	39	123	37.1	23	-2	99	4.3	92
@ 12:42	7.49	34	122	37.1	21	-2	95	4.3	92
@ 12:43	7.49	36	123	37.1	21	-2	95	4.3	93

Left-side current values: pH 7.45, PCO2 37, PO2 124, Temp 37.1, HCO3 22, BE -2, SO2 98, K+ 4.3, VO2 92, Q 4.3, pH 7.35, PCO2 42, PO2 39, Temp 36.4, HCT 20, Hgb 6.7, SO2 78

@/ 37c

store

set Q̇

print

feed

setup   calibration   standby   operate   tabular

12:45 12-9-12

Note: Historical values are displayed in the original temperature mode (either actual or 37°C), regardless of the current temperature mode. The "@" symbol indicates the actual temperature mode. No symbol indicates 37° data.

Note: If you change the PCO_2/PO_2 units (mmHg or kPa) during a case, the historical tabular data will be restated to match the current units.

Note: If a parameter alert event occurs while in the graphic or tabular display modes, the background color of the current parameter value will flash red. An indication of HIGH or LOW will not be shown.

Setting the patient temperature mode

You can display arterial and venous blood gas values either at actual temperature (measured) or corrected to 37°C. Use the "@/37" soft key (in the upper-right corner of the screen) to change the patient temperature mode. When the monitor is in numeric display mode, either "Actual" or "37°C" is displayed next to the temperature readings. The temperatures displayed are those measured in the circuit at the sensor site.

Note: The temperature measured by a CDI Shunt Sensor will be that of the shunt/purge line, which may differ slightly from the temperature in the rest of the circuit because of the exposure of the shunt line to room air temperatures.

Entering the blood flow rate ($\dot{Q}$)

Blood flow rate data is used in the calculation of oxygen consumption ($\dot{V}O_2$). You specify the source of blood flow data on the "calculations" setup screen in setup mode (see Chapter 4 for details). The choices are "None," "Manual," and "Pump." If you specify "Pump" as the source of flow data (and the CDI System 500 is connected to a pump, as explained in Appendix C), you will also need to specify the particular pump type in the same "calculations" setup screen.

If you specify "Manual" as the source of flow data, you can enter the flow rate manually during a case. To do this (in operate mode), follow these steps:

1   **Press the "set $\dot{Q}$" key.**
     The background color of the flow value will reverse to black.

2   **Use the +, −, ▲ , or ▼ keys to enter a value.**
3   **Press √ when you're finished entering the flow rate.**
The oxygen consumption value will be recalculated at the next screen update.

The calculated oxygen consumption value continues to recalculate using the same flow rate until you enter a new flow rate.

Note: If you chose "None" for the "$\dot{Q}$ Source" option on the calculations setup screen, there will be no display of $\dot{Q}$ or $\dot{V}O_2$.

Note: You need either one CDI Blood Parameter Module (BPM) and one CDI H/S Probe, or 2 CDI BPMs to get enough data to calculate oxygen consumption. This assumes the CDI H/S Probe is always placed on the venous side. If in addition to the CDI H/S Probe, only a venous BPM is used, an arterial oxygen saturation value will be assumed. This value is selectable in the "calculations" page of the setup mode ("Constant-SaO_2").

Note: You can enter flow data manually only if "manual" is specified for the "$\dot{Q}$ Source" option on the "calculations" setup screen (in setup mode).

Note: If oxygen consumption is desired when using 2 CDI BPMs (only), you must supply a hematocrit value. A set value for hematocrit will be displayed, and is adjustable in the operate mode, by pressing the "adjust VO_2" soft key. In this monitor/module configuration, both arterial and venous oxygen saturations are calculated, and the hematocrit is entered by you. Blood flow data is obtained in the same ways described above.

Recalibrating during a procedure

It is necessary to recalibrate the monitor periodically during in-line operation if you want the monitor's measured values to correlate more closely with those from the institution's blood parameter laboratory. More frequent in-vivo calibrations may be required by local hospital protocols. More reference blood gas samples should be taken weaning patients from the cardiopulmonary bypass procedure.

Note: The terms "recalibrating the monitor" and "in-vivo recalibration" both refer to the same process and are used interchangeably throughout this manual.

Follow these steps to recalibrate the monitor:

1   When the blood parameter values have stabilized, press the "store" key before drawing the sample(s).
This saves the currently displayed values in the monitor's memory. The "store" key changes to "recall" when the values are stored.

➤ **Caution**

- For the best comparison with your laboratory, press the "store" key only after the circuit has been stabilized for approximately five minutes (when there have been no changes in temperature, Fraction of Inspired Oxygen in a gas mixture (FiO_2), gas or blood flows, or other parameters that would cause changes in displayed values). If the "store" key is pressed and/or the recalibration blood sample is drawn during periods of significant temperature or gas change, the system may not meet the system accuracy limits found in Appendix B.

- Draw the blood sample as close as possible to when the "store" key is pressed to ensure the blood parameter values are calibrated as accurately as possible. ➤

▲ **Warning**

- **If the lab-measured value is outside the operating range for a parameter, the user may not be able to adjust the CDI System 500 measured value to the lab-measured value. Accuracy has not been established for displayed values outside the operating range; therefore, displayed values outside the operating range should not be used for patient management. While this condition exists, continue patient management with another source (e.g., laboratory or point-of-care blood gas analyzer).** ▲

Note: If the stored values are outside of a parameter's operating range, you will not be allowed to adjust that parameter.

Note: If the laboratory blood gas values are 37°C, the monitor must be in 37°C mode. If the laboratory gas values are at patient temperature, the monitor must be in actual (@) mode. The stored temperature mode can be switched in the recalibration screen, however the temperature value used in the actual temperature mode cannot be adjusted.

➤ **Caution**

- Ensure that the stored and recalled temperature mode are the same as the laboratory sample to ensure proper calibration. Calibrating to different temperature modes will compromise the system accuracy limits, as described in Appendix B. ➤

2 **Draw a blood sample from each port that corresponds to values being recalibrated.**

3 **When you obtain the laboratory results, press the "recall" key.**
The recalibration screen opens, as shown in the next figure.

13:45
12-9-12

recalibration   14:37

@/ 37c

store

Enter new values and press the OK (✔) key ...

set Ô

	pH	PCO2	PO2	SO2	K+	pH	PCO2	PO2	SO2	HCT	Hgb
Stored Values	7.45	37	124	98	4.3	7.35	42	39	78	20	6.7
Adjusted Values	7.45	37	124	98	4.3	7.35	42	39	78	20	6.7

mark

feed

setup   calibration   standby   **operate**   **numeric**

The top line displays the stored values.

The bottom line will reflect any changes you make in the values.

Use the ◀ and ▶ keys to move the highlight.

5000705

Use the + and – keys to change the value of the selected parameter.

4 **Adjust the potassium stored value to match the lab value.**
To adjust the highlighted value, use the + and − or ▲ and ▼ keys. To move the highlight, use the ◀ and ▶ keys.

5 **Adjust the other stored values, if necessary, to match the lab values.**

6 **Press the √ key when you're finished to enter the adjusted values and return to display mode.**
Or press X to cancel the adjustments.

If you press √, the recall key becomes "store" again (and the stored values are no longer available). Pressing X leaves the "recall" key active and keeps the stored values.

Note: When the monitor is turned off, all recalibration adjustments (including the initial completion of the calibration of all parameters) are lost.

Operating on emergency battery power

The CDI System 500 is supplied with a 12 volt rechargeable sealed lead/acid battery for backup power. If power to the monitor is interrupted, the backup battery can power the monitor continuously for up to 25 minutes (if it's fully charged).

Note: The TCVS CDI™ Model 540 Calibrator and the TCVS CDI™ Model 500 Monitor printer will not work while the monitor is on battery power.

When the monitor is working on battery power, a battery symbol appears in the message bar, indicating that the battery is in use and showing approximately how much battery time is left. (See next figure). After the monitor battery runs down, you must plug the monitor into an electrical outlet for at least 8 hours to fully recharge the battery.

Battery Symbols

Full charge (approximately 25 minutes)

3/4 charge

1/2 charge

1/4 charge

< 5 minutes remaining (symbol flashes)
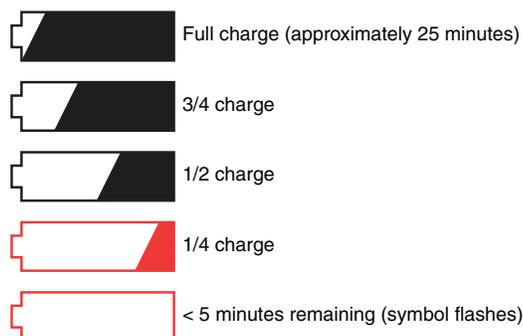
The battery can be serviced only by trained, certified TCVS service technicians. Contact your TCVS representative or Customer Administration if the battery needs to be replaced.

➤ **Caution**
   • Monitors left unused (and not plugged in) for 2 months or more may exhibit lower battery life, even after a full 8 hour charge. In this case, the battery will need to be replaced to regain full 25 minute capability. It is recommended that you plug the monitor in overnight at least once a month if it might be left unused for periods exceeding 2 months. ➤

Note: For optimal battery performance over its lifetime, you should allow the battery to fully discharge on an occasional basis.

This chapter explains the procedures to be followed at the conclusion of a patient case.

Printing or sending a report

Immediately after an extracorporeal case, you can print a case summary that contains the data recorded during the case. You can also send the case summary data to a computer via the serial port. The post-case report will include data at the time interval specified in the "Case Summary" option in the setup mode. Special events, which include "store," "recalibration" and "mark" functions are part of the summary.

➤ **Caution**

• The case data is lost if you return to the "operate" mode after the next power up. Be sure to print the case report before that point. ➤

To print or send a case report:

1   Go to the setup mode.
To do this, press the system mode select key, press the ◀ or ▶ key until "setup" mode label highlights, then press √.

2   Make sure the "Summary Delivery" selection is set to the action you want: print and/or send serial data.

3   Make sure the "Case Summary" data interval is set the way you want.

4   Press the "print case" key.

Press the "print case" key to print the case report for the current case.

This setting determines the time interval for the inclusion of data in the case report.
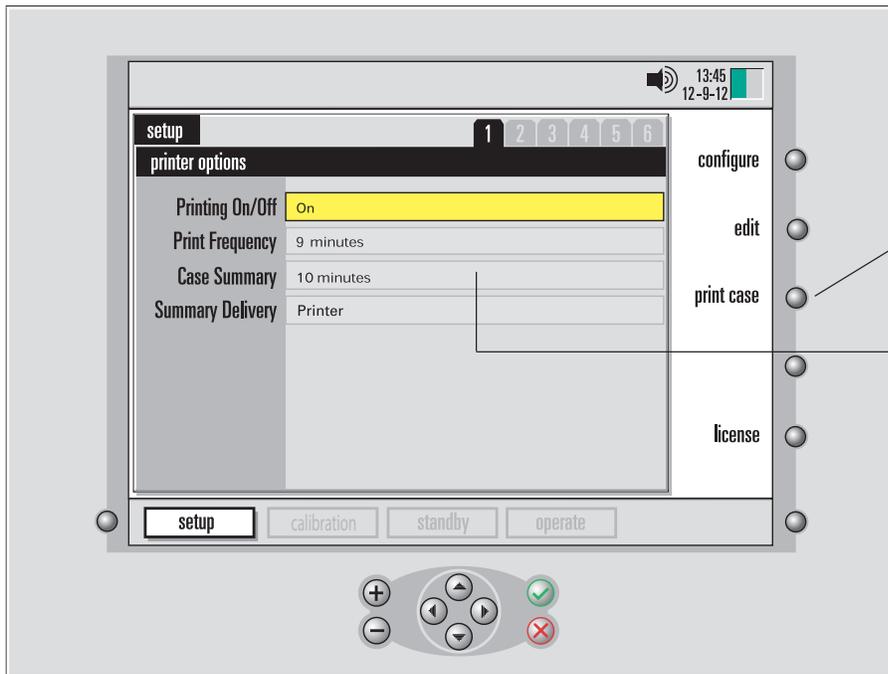
5000803

■ Returning the monitor to "standby" mode

After printing or sending the case report, you can either go to "standby" mode, or turn off the Terumo Cardiovascular Systems CDI System 500 Monitor.

Note: The monitor should be turned off when not in use.

To go to standby mode:

1   **Press the system mode select key.**
2   **Use the ◀ or ▶ keys (as needed) to highlight the "standby" label in the system map area.**
3   **Press √.**

■ Return the monitor to its pre-operation state

When the monitor is in standby mode or turned off, you can return it to its pre-operation state by following these steps:

1   **Detach the BPM cable-head(s) from the bracket.**
2   **Remove the CDI Shunt Sensor from the cable-head by pressing together the sensor wings and lifting the sensor off the cable-head.**

5000804
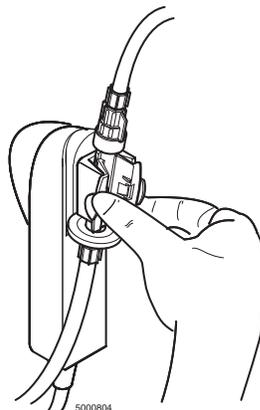
3   **Return the BPM cable-head(s) to their designated docking ports on the monitor.**
4   **Detach the TCVS CDI™ H/S Probe from the TCVS CDI™ H/S Cuvette, and return the Probe to its monitor docking mechanism.**
5   **Wipe down the CDI Model 500 Monitor and cables with an appropriate cleaning agent.**
    See the section "Routine cleaning" in Chapter 10 for cleaning instructions and precautions.

Disposal of waste products

Disposal of the CDI Shunt Sensors and CDI H/S Cuvette should be done along with the bypass tubing circuit. No disconnection or further handling of the CDI disposables is necessary. Use your standard hospital protocol for disposal of the bypass tubing circuit.

CDI gases are contained in disposable cylinders. These non-returnable cylinders contain non-toxic, non-flammable gases and gas mixtures.

To dispose of the cylinders:

1   **Open the valve slowly and allow all residual pressure to escape.**
    For gases or mixtures containing less than 21% oxygen, this should be done in a well ventilated area to avoid asphyxiation by displacement of oxygen.

2   **Remove or obliterate markings which indicated the cylinder contains hazardous material.**
    Do not remove markings prohibiting refill of the cylinder.

3   **Discard the cylinder as you would other metallic or hard goods trash as permitted by local authorities, rules or regulations.**

4   **For recycling, the valve would need to be removed from the cylinder because it is made from a different metal (steel valve in an aluminum cylinder).**

This chapter can help you solve problems that might occur with the Terumo Cardiovascular Systems CDI™ System 500. If you see an error message or have a problem with the system, consult this chapter for assistance.

If you can't solve a problem you're having with the system, or if you can't determine the cause of a problem, call the TCVS troubleshooting hotline during normal business hours.

- 800/521-2818 − Customer Administration
- 800/441-3220 − Technical Support

Error messages and conditions

The CDI System 500 can diagnose many of the problems that might occur during its use. When the system diagnoses a problem, an error message appears on the screen. In most cases, when you correct the error condition, the monitor returns to normal operation.

The following table lists the possible **error messages**, or an **error condition**, along with explanations of their meanings and what can be done to correct each situation.

Monitor Start Up

Message/Problem	Meaning and Corrective Action
Monitor won't power on	Make sure the monitor is securely plugged into an AC power outlet by checking to see if the green power indicator light located next to the on/off switch is illuminated. If the monitor is plugged in, still won't power on and the green indicator is not illuminated, have a trained person check the fuse located by the on/off switch. If a fuse is blown, replace it with the size fuse referenced on the monitor Name Plate/SN label (located on the back of the monitor). If the monitor still won't power on, contact your TCVS Technical Service representative to arrange for repair. Failure to power on with the monitor unplugged indicates a dead battery. Plug the monitor in (with the power switch off) for at least 8 hours to recharge the battery. The battery should provide power for up to 25 minutes on a full charge.
Monitor Failure Detected **Contact TCVS Technical Service**	This indicates that a software problem has occurred, and it cannot be corrected by you. Please contact your TCVS Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Detected module configuration has changed. **System will continue with valid modules** **Contact TCVS Technical Service**	This error occurs if the detected module availability does not match the modules that were installed at the factory. You will have the option to continue using any or all the valid modules. Please contact your TCVS Technical Service representative to arrange for repair.
System initialization failure: _____ *possible messages:* Date and time lost and need to be reset. Setup preferences and calibration lost. Previous patient case data has been lost. **Contact TCVS Technical Service**	There are many different system initialization failures that can occur. Each one has an identifying code that should be recorded for later reporting to your TCVS Technical Service Representative. Most failures will allow you to continue (with certain provisions) by pressing the $\sqrt{}$ (OK) key. Examples are listed to the left. Failures that are not recoverable will have no option to continue. Please contact your TCVS Technical Service representative to arrange for repair. *Note:* Failure code "F00D" indicates one or more keys stuck down during startup. You should make sure all keys on the front panel are disengaged and then reboot.
Arterial Module (or Venous Module or H/S Module) initialization failure: _____ **System will continue with remaining module(s).** **Contact TCVS Technical Service**	This indicates a module hardware failure in startup. You have the option to continue using the system excluding the failed module. This failure should be reported to your TCVS Technical Service representative to arrange for repair. *Note:* Excessive force applied to the sensor while attached (or attaching) to the BPM cable-head can cause the silver thermistor cap to break. The failed BPM will need to be repaired by TCVS Technical Service.
Barometric pressure measurement failure: F050 **Contact TCVS Technical Service**	This indicates an ambient pressure measurement outside the acceptable range. A hardware failure of the pressure reading circuit is suspected in this case. Please contact your TCVS Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Arterial (or Venous) module Self-test failure **Press "cancel" to return to configuration screen, or "retry" to repeat test.**	This failure indicates a module has failed its reference sensor test. Make sure that the module to be used is properly in place on the side panel and the cable-head surface is clean and undamaged; and then repeat the test. If this message appears again after verifying proper placement in the holder, you have the option of excluding the use of this module. Pressing "cancel" returns you to the configuration screen so you can choose a different configuration excluding the failed module. Pressing "retry" repeats the test. If the problem persists, contact your TCVS Technical Service representative to arrange for repair. *Note:* The printer records the final result of this test.
H/S module color chip failure. **Press "cancel" to return to configuration screen, or "retry" to repeat test.**	The CDI H/S Module has failed its color chip test. Make sure that the CDI H/S Module is properly in place on the monitor side panel and the color chip and module optical surfaces are clean and undamaged; and then repeat the test. If this message appears again after verifying proper placement in the holder, you will have to return to the configuration menu and exclude the CDI H/S Module from use. Pressing "cancel" returns you to the configuration screen so you can choose a different configuration. Pressing "retry" repeats the test. If the problem persists, contact your TCVS Technical Service representative to arrange for repair. *Note:* The printer records the final result of this test.

Printer

Message/Problem	Meaning and Corrective Action
Monitor won't print (Printer Style 1 only, see page 3-6 to identify printer style)	Make sure the "Printing on/off" selection in the Setup mode has "on" selected. Check to see if there is a paper jam in the printer. Make sure the printer paper is not installed backwards (Chapter 3). Make sure the paper release lever is all the way up. Make sure the monitor is plugged into an AC power outlet by checking to see if the green power light located by the on/off switch is illuminated. If the monitor is running on battery power alone, the printer won't work. If the monitor won't print while plugged into AC power, turn the monitor off, wait five seconds and turn it back on again. If the printer continues to malfunction, contact TCVS Technical Service representative to arrange for repair.
Monitor won't print (Printer Style 2 only, see page 3-6 to identify printer style)	Make sure the "Printing on/off" selection in the Setup mode has "on" selected. Check to see if there is a paper jam in the printer. Make sure the printer paper is not installed backwards. Make sure the roller is fully seated. If you are unsure, press the roller release lever to release the roller, and then snap it in place by pressing evenly on the top of the roller. Make sure the monitor is plugged into an AC power outlet by checking to see if the green power light located by the on/off switch is illuminated. If the monitor is running on battery power alone, the printer won't work. If the monitor won't print while plugged into AC power, turn the monitor off, wait five seconds and turn it back on again. If the printer continues to malfunction, contact TCVS Technical Service representative to arrange for repair.
Printer failure detected: _____ **Printer will be disabled.**	This error message appears during startup if printer hardware failure occurs. A specific identifying code will appear in the blank. Save this number to report to your TCVS Technical Service representative. This failure will disable further use of the printer although you may continue to use the system. Contact your TCVS Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Printer paper not detected.	This error message appears during startup if there is no paper detected in the printer. If absent, install new printer paper. If no print function is desired, press X (cancel), which sets the printer setting in Setup to "off." Pressing √ (OK) will allow the system to continue; however, a reminder message will occur in the message bar when the system tries to print and again detects no paper. If replacing the paper in the printer does not remove this error message, contact your TCVS Technical Service representative to arrange for repair.
Printer paper jams (Printer Style 1 only, see page 3-6 to identify printer style)	Push down the paper release lever located inside printer cover to release the paper engagement. Gently pull out and remove the jammed paper. Pull back the paper release lever to its original position (pointing up). With the monitor on, cut a straight edge on the paper and insert the straight edge into the printer. The printer's self-feeding mechanisms will pull the paper through if fed correctly (see the paper roll installation diagram located on the inside of the printer paper bracket). Follow the paper insertion directions in the section "Preparing the printer" in Chapter 3.
Printer paper jams (Printer Style 2 only, see page 3-6 to identify printer style)	Open the printer cover and press the roller release lever to release the roller. Remove the jammed paper. To load the printer paper, align the paper so that it will be positioned under the roller and place the roller on top of the paper. Press the roller down evenly to snap it into place.
Printer paper release lever is disengaged (Printer Style 1 only, see page 3-6 to identify printer style)	This error message appears during startup if the printer paper release lever is disengaged (held in release position). If so, pull lever up to engage paper. If no print function is desired, press X (cancel) which sets the printer setting in setup to "off." Pressing √ (OK) will allow the system to continue; however, a reminder message will occur in the message bar when the system tries to print and again detects the lever is down. If pulling up the release lever in the printer does not remove this error message, contact your TCVS Technical Service representative to arrange for printer repair.

Message/Problem	Meaning and Corrective Action
Printer paper release lever is disengaged (Printer Style 2 only, see page 3-6 to identify printer style)	This error occurs during startup if the roller is missing or incorrectly installed. If this occurs, make sure the roller is fully seated on the printer. Press the roller release lever to release the roller. Align the paper so that it will be positioned under the roller and place the roller on top of the paper. Press the roller down evenly to snap it into place. If no print function is desired, press X (cancel) which sets the printer setting in setup to "off." Pressing √ (OK) will allow the system to continue; however, a reminder message will occur in the message bar when the system tries to print and again detects that the roller is incorrectly installed. If re-installing the roller does not remove this error message, contact your TCVS Technical Service representative to arrange for printer repair.

Calibration

Message/Problem	Meaning and Corrective Action
Calibration procedure unavailable while on battery power	Make sure the monitor is plugged into an AC power outlet. If the monitor is running on battery power only, calibration won't begin. Turn the monitor off, plug it into an AC power outlet, wait 5 seconds, then turn it back on. After the startup diagnostics and configuration selection are completed, restart calibration. If this message appears while the monitor is plugged into AC power, contact your TCVS Technical Service representative to arrange for repair.
Calibration function is not available. **No BPMs are currently selected.**	The message appears if you try to calibrate and only have the CDI H/S Module selected in the Configuration screen. Go to the setup mode, press the "configure" soft key and select the correct configuration. If this message appears and the correct configuration including at least one BPM is selected, contact your TCVS Technical Service representative to arrange or repair.

Message/Problem	Meaning and Corrective Action
Calibrator failure detected: _____ **Contact Technical Service**	This message refers to a detected calibrator hardware failure or communications failure with the monitor. An identifying error code appears in the blank. Record this error code to report to TCVS Technical Service. You have the option of continuing use of the system; however, calibration will not be available. If you have another calibrator, you may try to restart the calibration process with the new calibrator. Success would indicate a hardware failure with the first calibrator. Press the X (cancel) key to exit calibration and return to standby. Contact your TCVS Technical Service representative to arrange for repair.
Calibration process stopped.	This message occurs when the "stop" soft key is pressed during calibration. Pressing the √ (OK) key will restart calibration; pressing the X (Cancel) key will exit calibration and will put the monitor in standby mode.
Calibrator not connected. **Check connection.**	The monitor did not detect the presence of a calibrator when it tried to initiate the calibration sequence. This occurs if the calibrator cable is not connected or is loosely connected. Check the connection and press the √ (OK) key to try calibration again. If the calibrator is still not detected after checking the connector, contact your TCVS Technical representative to arrange repair of the system. Use of the monitor can continue without the calibration function by pressing the X key (cancel) to exit calibration. You may try another calibrator if one is available. *Note:* If the calibrator has become disconnected during calibration, and reconnection has successfully occurred, the calibration will start over again.

Message/Problem	Meaning and Corrective Action
Chosen blood gas module configuration does not match placement of cable-heads in calibrator.	This occurs if the calibrator detects a different number of cable-heads in the calibrator than what was chosen during configuration selection. Check the circles over the gas bottle level indicators in the calibration screen. A green circle over the "A" and/or "B" indicator signifies a fully engaged cable-head and sensor in the associated calibrator pocket(s). A grey circle indicates no engagement. Check to make sure each cable-head and sensor are connected correctly and captured securely in the calibrator pocket. Verify the number of modules being used. If the error persists, contact your TCVS Technical Service representative to arrange for repair.
Insufficient gas pressure for Gas A, B	One or both of the gas bottles in the calibrator has insufficient gas to complete the calibration process. Replace the empty gas bottle(s).
No gas flow through sensor(s): A or B **Verify proper placement of sensor(s) and cable-head(s) in calibrator and that vent cap(s) have been loosened.**	The calibration gas is not flowing freely through the sensor during calibration. The "A" or "B" designation indicates which calibration pocket is affected. This can be caused by closed venting caps, blocked gas ports or blocked filter/sparger assemblies. Make sure the large blue venting cap(s) on the top of the sensor(s) are loosened and that the blue luer cap(s) on the filter(s) are removed. Check to make sure the sensor/cable-head(s) are securely captured in the calibrator pocket(s). Check the calibrator gas port for blockage. If there's any blockage, clean the port gently with a wet cotton-tipped swab. Press the √ (OK) to retry. If the problem persists, replace the sensor(s) and try again. You have the option of pressing the X (Cancel) key to exit Calibration and continue use of the system without completing calibration. ➤ **Caution** • If you suspect a blocked filter/sparger assembly, it is recommended not to try to remove it or clear it. This could result in a loss of sensor chamber sterility. ➤

Message/Problem	Meaning and Corrective Action
Gas pressure failure detected **Verify that gas bottles are securely tightened.**	This error message occurs if the calibrator gas pressure drops off, indicating either a loose gas bottle or a calibrator leak. Try tightening both gas bottles in the calibrator. If the problem persists after retrying, a calibrator failure error message will appear with a specific code for leak failure. In this case, you will need to contact your TCVS Technical Service representative to arrange for repair. You have the option of continuing use of the system without the calibration process or trying another calibrator (if available).
Calibration slope error on: _____ **Check sensors and gas bottles for correct placement and usage.** **Press √ (OK) to substitute default calibration values**	The specific microsensors failing calibration slope range appear in the blank. This includes one or more of the following: arterial pH, PCO_2, PO_2; venous pH, PCO_2, PO_2. This may be caused by incorrect installation of gas bottles, damaged or mishandled sensors, contaminated calibration solution, or poor placement of sensors onto gas nozzles. Make sure a Gas A calibration gas bottle is in the Gas A (orange) port and a Gas B calibration bottle is in the Gas B (blue) port. Check the sensor(s)/cable-head(s) for correct sensor engagement and correct placement in the calibrator. If you suspect the sensor has been damaged or improperly handled, replace the sensor. Retry calibration. If all of the above is checked and the problem persists, even with fresh sensors, save the failed sensor(s) and the printer failure report and contact your TCVS Technical Service representative. You have the option of using the calibration default values by pressing the √ (OK) key. *Note:* If you are calibrating both arterial and venous BPMs and only one side fails, the passing side will retain its new calibration data. If you decide to continue use without replacing the failed sensor, default calibration data will be applied to the failed sensor (only). In this case, it is recommended that you return to the configuration selection screen and exclude the failed sensor/BPM from use.

Message/Problem	Meaning and Corrective Action
CO$_2$ sensor air equilibration error on: Arterial PCO$_2$ and/or Venous PCO$_2$ **Replace sensor(s) and repeat calibration**	The monitor has detected a very low CO$_2$ level in the sensors. This could indicate that the sensor foil package had a leak in it, or that the sensor was exposed to room air (or out of the foil pouch) for greater than 24 hours. If the sensor has been exposed to room air for greater than 24 hours, discard that sensor and repeat calibration with a fresh sensor. If the foil pouch has a leak in it, please keep the foil pouch and sensor and contact TCVS Customer Administration for instructions.
Sensor intensity error on:_____ **Replace sensor(s) and repeat calibration**	The specific microsensors failing the calibration intensity range check appear in the blank. This includes one or more of the following: arterial pH, PCO$_2$, PO$_2$, K+; venous pH, PCO$_2$, PO$_2$, K+. Make sure the sensor(s) are fully and properly engaged with the cable-head(s). If the problem persists, you will need to replace the failing sensor(s) and repeat the calibration. Keep the failed sensor(s), along with the printed failed calibration results, and contact your TCVS Technical Service representative. You have the option of substituting default calibration values for the failed microsensors by pressing the √ (OK) key. *Note:* If you are calibrating both arterial and venous BPMs and only one side fails, the passing side will retain its new calibration data. If you decide to continue use without replacing the failed sensor, default calibration data will be applied to the failed sensor (only). If you choose to use the same sensor and factory default values without correcting the cause of the failure, be aware that the failed microsensor may not reflect accurate values. In this case, it is recommended that you return to the configuration selection screen and exclude the failed sensor/BPM from use.

Note: Most calibration failures will allow continued use of the system without successful completion of the calibration process. Continued use will then occur with the default calibration values, although a current tonometered gas calibration is always recommended. See Chapter 5 for more detail.

Operate Mode

Message/Problem	Meaning and Corrective Action
Pump Interface Failure, Check Setup	The monitor is set to get data from a specific pump but is not detecting the expected pump flow data at the pump interface port. Go to the setup mode, screen 5 (the "calculations" setup screen as described in Chapter 4) and make sure the correct pump has been entered in the "Pump Type" field, and that the "$\dot{Q}$ Source" selection to set to "Pump" field. Check to make sure you have the proper cable (from CDI), that the cable is connected to the right data ports, and that all connections are tight. If the error message persists, contact your TCVS Technical Service representative to arrange for repair. If you cannot get your pump interface working, your options are set to the "$\dot{Q}$ Source" to "Manual" (manually input flow values) or "None" (no calculation of $\dot{V}O_2$). No values for $\dot{Q}$ or $\dot{V}O_2$ will be displayed or printed if "None" is selected. *Note:* See Appendix C "Pump Interfacing tips" section for more information on pump interface troubleshooting. *Note:* The audible alarm can be inhibited by performing the following steps: 1. Check connection to pump port and reconnect if necessary. 2. Go to tab 5 in SETUP. Change $\dot{Q}$ source to "none" or "manual."
Arterial (or Venous or H/S) module failure detected: _____ **Measurements from module will be discontinued** **Contact TCVS Technical Service**	This message refers to a detected module hardware failure or communications failure with the monitor. This may occur due to sudden component failure or physical damage to the module, monitor or cable. An identifying error code appears in the blank. Record this error code to report to TCVS Technical Service. You may continue using the system although measurements from this module will be discontinued and will no longer be displayed. Contact your TCVS Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Monitor failure detected: _____ **Contact TCVS Technical Service**	This message refers to a detected monitor hardware failure. This may occur due to sudden physical damage to monitor, component failure, or failure of all modules. An identifying error code appears in the blank. Record this error code for later reporting to TCVS Technical Service. You will not be able to continue use of the system. Contact your TCVS Technical Service representative to arrange for repair.
Inaccurate values when compared to a laboratory	■ Verify that a successful sensor calibration has been done. For added assurance, verify the calibration using the system's calibration verification function. *Note:* Verification must be done after calibration but before operation. ■ Verify that proper blood sampling and lab procedures are followed. ■ Make sure there is a minimum flow rate of 35 cc/min through the shunt sensor. ■ Make sure the circuit has stabilized before drawing a comparison blood sample. Periods of dynamic movement of temperature and / or blood parameters make single-point (in time) comparisons difficult. ■ Check the shunt line. If it's too long, the blood in the line may have started equilibrating to room air values. ■ Make sure the laboratory and the monitor are correcting the blood gases to the same temperature, or both are using 37°C. ■ Make sure the sensor has not been exposed to acetate containing primes at low pH (<7.0) for more than a few minutes. This would produce elevated PCO_2 levels. ■ Make sure the sensor has not been exposed to fluids at high pH (> 7.8). This may affect K+ accuracy. ■ Check to make sure the "calculations" section of Setup has the appropriate settings for your application. See the following troubleshooting section: "Laboratory comparison troubleshooting chart." ■ Check for substances with known potential to cause inaccuracy, including: Indocyanine green (Cardiogreen), Methylene Blue, or other intravascular dyes, carboxyhemoglobin and other dyshemoglobins, hemoglobinopathies, elevated bilirubinemia and/or icterus (jaundice). ■ Check for any novel pharmacological agents that have potential effect on CDI sensors.

Message/Problem	Meaning and Corrective Action
Optical interface material is damaged, loose or peeled off of sensor or H/S cuvette.	The transparent optical interface material provides a means of consistent optical connection between the sensor and the BPM cable-head, and the CDI H/S Probe and CDI H/S Cuvette. This material reduces the risk of measurement errors caused by moisture or air trapped between the microsensors (or cuvette window) and module optics. If you have a sensor or cuvette whose optical interface material appears to be scratched or has peeled off, contact your TCVS Customer Service representative to report the incident. Do not use sensors or cuvettes with obvious optical interface material damage.
Cannot print case summary data after case.	Make sure the Printer is set to "On" in "setup" screen 1. You must print the case data before turning the monitor off, back on and returning to "operate" mode. Upon power-up and returning to "operate," the case data is erased from memory (new case begins). Case summary data will not print if the monitor is running on battery power.
Temperature measurement from BPM is significantly different from another temperature probe in the blood.	**▲ Warning** **The temperature measured by the shunt sensor is local to the sensor and does not reflect the actual patient arterial blood temperature. Do not use this measurement for patient management. ▲** Make sure the thermistor cap on the BPM is not stuck in the retracted position. The thermistor cap has some spring force to allow it to form a firm contact with the thermal well on the sensor. If it is stuck, the lack of firm contact will cause the temperature reading to be inaccurate. Call TCVS Technical Service to arrange for repair. *Note:* A shunt line will normally be different in temperature from the main line. Smaller diameter tubing and slower flow will increase the difference by allowing room temperature to affect the blood in the shunt line. Verify the actual difference between your shunt line temperature and main line using a reliable temperature probe.

Message/Problem	Meaning and Corrective Action
Fluid spilled onto monitor and/or calibrator	Clean the fluid off as soon as possible. The monitor calibrator has gaskets in the grooves and between panels to prevent fluid from seeping, but excess fluid can settle into joints and be difficult to remove.
Monitor lasts much less than 25 minutes on back-up battery power.	■ Make sure the monitor is plugged in with power off for a full 8 hours prior to use. The green light on rear panel indicates power being delivered to the battery. ■ Has the monitor been idle (uncharged) for two months or more prior to use? If so, battery performance may be permanently compromised. Call your TCVS Technical Service Representative to arrange for battery replacement. ■ Has the battery been used (fully discharged, then charged) repeatedly over years of service? The battery may exceed its normal life after about 200 complete cycles. In this case, call your TCVS Technical Service Representative to arrange for battery replacement.
H/S Disconnect at Cuvette	Connect H/S probe to cuvette. *Note:* Connecting the H/S probe to the cuvette will deactivate the alert.

Laboratory comparison troubleshooting chart

The following chart details information you can use to determine why your CDI System 500 values appear to be inaccurate with respect to laboratory values:

Issue	Meaning and/or Corrective Action
Make sure the circuit has stabilized before drawing a laboratory comparison sample	■ Wait approximately five minutes after making a change to blood flow rate, gas flow rate, FiO$_2$, temperature, etc. Watching the CDI System 500 parameter values for a minute or so will give you a good idea of whether the circuit has stabilized or not (the graphics display is also helpful for checking blood parameter stability).
	■ Check to see if the values measured $1 - 2$ minutes after storing have moved closer towards the corresponding Lab values. If so, this is a good indication that dynamic blood parameter changes and the system's time response are responsible for the comparison difference. Performing an in-vivo recalibration under these conditions is not recommended.
	■ A blood flow rate of less than 35 cc/min in the CDI Shunt Sensor line may result in slower measurement response times. Restoration of the flow rate back above 35 cc/min will return the sensor readings to normal.
	■ A blood flow rate of less than 100 cc/min through the CDI H/S Cuvette may result in less than optimal saturation/hematocrit readings. Restoration of the flow rate back above 100 cc/min will return the CDI H/S Cuvette readings to normal.
	■ Air bubbles or fluid other than blood (such as medication given in the shunt line, passing the shunt sensor) will affect the shunt sensor readings intermittently. As soon as the air or fluid clears the shunt sensor, values will return to normal.

Issue	Meaning and/or Corrective Action
Make sure the lab temperature matches the CDI System 500 temperature.	The temperature mode of the CDI System 500 recalled values must match that used by the Laboratory. If the Laboratory values are reported at 37°C, you have to either store the comparison values at 37°C or change them to 37°C values after recalling them. Likewise, if the Lab values are being reported at actual temperature, be sure the monitor values are stored in the Actual temperature mode or changed to actual after being recalled. You should verify that the Lab values are reported at the same temperature the monitor was using at the time the values were stored. Any differences will cause variation in the comparison. *Note:* The parameter values displayed in the recalibration screen are switchable to 37°C corrected or actual temperature values regardless of the temperature mode used when stored.
PCO_2 problems? What kind of prime are you using?	Certain primes, including Normosol-R, Plasmalyte-A and Isolyte-S, contain acetic acid ions (acetate) that may adversely affect the CDI System 500 CO_2 sensor. To avoid this contamination, do the following: Before putting the sensors in line: 1. Blow off enough CO_2 to raise the pH above 7.00 2. Add bicarbonate to the prime solution to raise the pH above 7.00 OR 3. Add the sensors at the last possible moment before going on bypass to limit exposure of the sensors to the acetic acid ions.
pH problems? What is the temperature like outside?	The buffer in the sensors can freeze if exposed to below freezing temperatures. This will result in a positive pH offset while on bypass. Check the freeze indicator on the sensor box to see if the sensors have been exposed to freezing temperatures. If the freeze indicator is positive, contact TCVS Customer Administration or your local TCVS Sales representative.

Issue	Meaning and/or Corrective Action
K+ problems? **What kind of prime are you using?**	Exposure of the shunt sensor to prime solutions and/or blood during CPB with pH greater than 7.8 or less than 7.0 pH units or a sodium measurement greater than 160 or less than 120 mEq/L can interfere in the accurate measurement of potassium. To avoid potassium problems, do one of the following: 1. Isolate the sensor by adding it just before the initiation of CPB or keep shunt lines closed. OR 2. Ensure the pH level in the prime solution is within the 7.0 - 7.8 range.
Are your PO$_2$ values much higher than the Lab?	■ Check to make sure Halothane is not being used as an anesthetic agent. Halothane presence in the blood will be measured as oxygen presence. ■ At very high PO$_2$ levels, some laboratory electrode signals can taper off showing lower than actual PO$_2$ values. Check to see if the Lab can be tested at high PO$_2$ calibration values.
Does your lab sample have air bubbles in it?	Air bubbles in the syringe can cause the PCO$_2$ and the PO$_2$ to go towards room air values (towards 0 mmHg for PCO$_2$ and towards 150 mmHg for PO$_2$). The longer it takes for the lab sample to be analyzed, the more pronounced the room air contamination will be.
$\dot{V}O_2$ calculation seems to be off?	■ Check screen 5 in the "setup" mode and make sure you have the correct patient BSA entered. ■ If using only venous side measurement modules, make sure your arterial side saturation is correctly set in screen 5 in the "setup" mode. ■ Check to make sure the Saturation, Hematocrit and flow ($\dot{Q}$) values used are correct. If you are using arterial and venous BPMs but no CDI H/S Module, the Hematocrit value must be supplied manually and the Saturation values used are calculated.
PCO$_2$ and PO$_2$ values have decimal points?	Check screen 4 in the "setup" mode and make sure your measurement units are correct (mmHg or kPa).
Saturation/Hemoglobin values are off?	■ Check screen 5 in the "setup" mode and make sure the Saturation, Hematocrit, and Hemoglobin offsets are being used correctly for your institution. ■ Check the Optical Interface Material on the CDI H/S Cuvette to make sure it is undamaged, fully attached and not contaminated by any debris. ■ Check the optical surface of the CDI H/S Probe to make sure it is not scratched, damaged or contaminated by any debris.

▉ Technical support and replacement procedures

▲ Warning

- **Before servicing the equipment, disconnect the monitor from the wall power source. ▲**

Aside from the fuses for the AC power line, there are no recommended maintenance or repair procedures to be done by hospital technical personnel. Please contact your TCVS Technical Service representative for any technical service needs.

Fuse replacement

The CDI System 500 fuses should be replaced only by people who are competent in electrical and mechanic repair, such as hospital Biomedical technicians. To test and/or change the fuses:

1   **Remove the fuse holder from the back of the monitor.**

2   **Test the continuity of the fuse(s), checking to see if they are blown.**

3   **Replace the fuse(s) as needed.**
     The two fuses are identical. Refer to the monitor Name Plate / Serial Number label (located on the back of the monitor) for the fuse size required for your monitor:

     The 3.15 Amp monitor requires 3.15 A @ 250 V, Slow Acting, High Breaking Capacity 5 mm x 20 mm fuses.

     The 2.0 Amp monitor requires 2.0 A @ 250 V, Slow Acting, High Breaking Capacity, 5 mm x 20 mm fuses.

     Make sure the fuses are correctly replaced in the monitor fuse holder.

▲ Warning

- **You must use replacement fuses of the correct size and rating to protect against the risk of fire. ▲**

The Terumo Cardiovascular Systems CDI™ Blood parameter Monitoring System 500 needs minimal routine maintenance including battery charging and surface cleaning. This chapter gives the instructions you need for these two tasks as well as recommended routine maintenance.

Note: If you suspect that the system isn't functioning properly, see Chapter 9, "Troubleshooting," for help. If you still need help after consulting Chapter 9, contact your TCVS representative or Customer Administration. Appendix E, "Warranty and service," describes the service policy and gives phone numbers you can call for help.

▲ Warning

- **Turn off the system power before inspection, cleaning, or storage. ▲**

➤ Caution

- Do not use chemical solvents such as alcohol, ether, and acetone − or anesthetics such as Forane (isoflurane) − as cleaning agents directly on any part of the system. These chemicals can be destructive to the device. Follow the cleaning procedure described in the next section. ➤

Routine cleaning

To keep the CDI System 500 working properly, make sure the optical pathways stay clean and free of surface cuts, abrasions, and contamination. Check the optical pathways regularly for damage and debris, paying special attention to the face of the BPM cable-head, the SRS chip, the CDI H/S Probe face, and the optical reference color chips.

If these surfaces need cleaning, use a soft, lint-free cloth with water to remove any foreign material. Dry the surface thoroughly with a clean, dry, and soft lint-free cloth.

For daily cleaning of the monitor enclosures, monitor pole clamp, tray and cables, use ordinary soap and water. If liquid accidentally spills onto the monitor or calibrator, clean up the spill as soon as possible to prevent the liquid from settling into the joints.

To disinfect the monitor and cables, use a 10% chlorine bleach solution.

Observe the following precautions during cleaning:

➤ **Caution**

- Do not expose the ends of the optical fibers in the cable-heads, the optical probe face or the optical reference color chip to chemicals such as organic solvents, acids, strong bases, or abrasives. They can cause degradation in the performance of the optical components. Use only water with a soft, lint-free cloth to clean these surfaces.

- Do not use harsh cleaning solutions on the monitor or the cable connectors. These can cause damage to the finish or the integrity of the surfaces. Use a 10% chlorine bleach solution to disinfect the monitor and cables.

- Do not use abrasive materials in cleaning the monitor front panel. This can cause removal of the keypad graphics. ➤

Note: Check the calibration fluid residue in the calibrator pockets, cable-head ports and on the BPM cable-heads themselves.

Note: Do not submerge any part of this device in any liquid.

Battery charging

The CDI System 500 comes with a 12 volt rechargeable sealed lead acid battery for backup power and transport operation. This backup battery can power the monitor continuously for up to 25 minutes with the thermal printer disabled.

Note: The TCVS CDI™ Model 540 Calibrator and the TCVS CDI System 500 Monitor printer will not operate while the CDI System 500 is on battery power.

When the monitor is working on battery power, a symbol appears in the message bar, indicating that the battery is in use and indicating approximately how much battery time is left. After the monitor battery runs down, you must plug it into an AC outlet for at least 8 hours to recharge the battery.

The battery can be serviced only by trained TCVS service technicians. Contact your TCVS Technical Service representative or Customer Administration if the battery needs to be replaced.

Note: The useful battery life will depend on how many full charge cycles it sees (fully discharged, then recharged). After about 200 cycles, the battery may need to be replaced in order to retain full 25 minute backup capability. Call TCVS Technical Service if you suspect your battery needs to be replaced.

➤ **Caution**

- Monitors left unused (and not plugged in) for 2 months or more may exhibit lower battery life, even after a full 8 hour charge. In this case, the battery will need to be replaced to regain full 25 minute capability. It is recommended that you leave the monitor plugged in overnight at least once a month if it could be left unused for periods exceeding 2 months. ➤

Note: For optimal battery performance over its lifetime, you should allow the battery to fully discharge on an occasional basis.

Routine Maintenance Requiring Service

System Batteries

The system batteries require periodic replacement. If system batteries are low, an Error Code will occur at startup prompting user to return monitor for service. Low voltage of system batteries will not affect performance during a case. System batteries are checked during service and replaced if 10 years old or older. Batteries are expected to last over 10 years. If you would like to check the last time system batteries were replaced or schedule maintenance, please contact your local Terumo Cardiovascular Systems representative or call 1-800-521-2818.

The battery must be removed for recycling prior to disposal of the device. Please contact TCVS for further instructions.

■ List of system components

Terumo Cardiovascular Systems Extracorporeal Blood Parameter Monitoring System

Description	Size	Model
MONITOR		
TCVS CDI™ Extracorporeal Blood Parameter Monitor		
Monitor with one blood parameter module		500A
Monitor with one blood parameter module and one H/S Probe		500AHCT
Monitor with two blood parameter modules		500AV
Monitor with two blood parameter modules and one H/S Probe		500AVHCT
DISPOSABLES		
TCVS CDI™ Shunt Sensor, (Sterile, Heparin-treated, case of 20 each)		CDI510H
TCVS CDI™ H/S Cuvette, (Sterile, case of 20 each)	1/4"	6914
	3/8"	6913
	1/2"	6912
TCVS CDI™ H/S Cuvette with 6" (15.2 cm) extension tube, (Sterile, case of 20 each)	1/4"	6934
	3/8"	6933
	1/2"	6932
ACCESSORIES		
Calibrator, for use with the CDI Model 500 Monitor		540
Gas A, calibration gas for use with the CDI Model 540 Calibrator		CDI506
Gas B, calibration gas for use with the CDI Model 540 Calibrator		CDI507
Printer paper for use with the CDI System 500		7310
Monitor Pole Clamp, Long, Calibrator Mount, for use with the CDI System 500 Monitor, SWL: 32.5 lbs.	7"	CDI517
Monitor Pole Clamp, Short, for use with the CDI System 500 Monitor, SWL: 23.0 lbs.	4.5"	CDI518
Cable-head Bracket for use with the CDI System 500 Monitor, SWL: 7.0 lbs.		CDI519

Description	Size	Model
PUMP INTERFACE ACCESSORIES		
CDI 500 Module for Terumo Advanced Perfusion System 1		803479
CDI 500 interface cable for Terumo Advanced Perfusion System 1		804981
CDI 500 interface cable for TCVS Sarns 9000		154481 (no longer sold)
CDI 500 data receiver for TCVS Sarns 9000		158810 (no longer sold)
CDI 500 Comm module for TCVS Sarns 8000		16417
Interface cable for TCVS Sarns 8000		151829
Interface cable for TCVS Sarns Centrifugal Pump		151853
Interface cable for Jostra HL 20		158828
Interface cable for Stöckert SIII/SC		158801 (no longer sold)
Interface cable for Medtronic Bio-Console 550		151861

System operating ranges

pH	6.8 to 7.8 pH units
PCO_2	10 to 80 mmHg (1.3 to 10.7 kPa)
PO_2	20 to 500 mmHg (2.7 to 66.7 kPa)
K+	3.0 to 8.0 mmol/l
HCT	17 to 38%
Hgb	5.6 to 12.6 g/dl
SO_2	60 to 100%
$\dot{V}O_2$	10 to 400 ml/min
BE	-25 to 25 meq/l
HCO_3^-	0 to 50 meq/l
Temperature	15°C to 40°C

Note: The monitor is intended to be used only within the above "System Operating Ranges" for the System Accuracy Limits. Values outside of these ranges will be displayed and an alert will be triggered. The display range is defined in the chart to follow.

System display ranges

pH	6.5 to 8.5 pH units
PCO_2	10 to 200 mmHg (1.3 to 26.7 kPa)
PO_2	10 to 700 mmHg (1.3 to 93.3 kPa)
K+	1.0 to 9.9 mmol/l
HCT	12 to 45%
Hgb	4.0 to 15.0 g/dl
SO_2	35 to 100%
$\dot{V}O_2$	10 to 400 ml/min
BE	-25 to 25 meq/l
HCO_3^-	0 to 50 meq/l
Temperature	1°C to 45°C

◼ Priming volumes

Model CDI510H Shunt Sensor — 1.2 ml
1/4" CDI H/S Cuvettes — 4 ml
3/8" CDI H/S Cuvettes — 9 ml
1/2" CDI H/S Cuvettes — 16 ml

System accuracy limits

The CDI System 500 has been subjected to rigorous bench tests to simulate the clinical use of the device and assessed its accuracy and precision over the system operating ranges of the measured parameters. Blood samples taken from the test circuit were analyzed in conventional analyzers, and these results were compared (on a sample-by-sample basis) to analyses provided by the CDI System 500. The following table shows the mean difference between the two measurement techniques, and the standard deviation of the differences found.

pH Sensor:
Mean: -0.018
Standard Deviation: 0.023

Temperature:
Mean: -0.07
Standard Deviation: 0.22

PCO_2 Sensor:
Mean: -0.2
Standard Deviation: 2.2

Total Hemoglobin Value:
Mean: -0.09
Standard Deviation 0.38

PO_2 Sensor − Arterial: (>80 mmHg)
Mean: 6.1
Standard Deviation: 17.6

Potassium Sensor:
Mean: -0.06
Standard Deviation: 0.19

PO_2 Sensor − Venous: (<80 mmHg)
Mean: 1.3
Standard Deviation: 2.3

Hematocrit Value:
Mean: -0.4
Standard Deviation: 1.2

Oxygen Saturation Value:
Mean: -0.4
Standard Deviation: 1.6

▉ Environmental and electrical specifications

Dimensions

Monitor:	
H x W x D:	11" x 12.5" x 6"
Weight:	16.1 lbs.
Calibrator:	
H x W x D:	12.5" x 8" x 8"
Weight:	8.4 lbs.

Electrical

Monitor Power:	100-240V~, 50/60 Hz, 75 VA continuous duty, 95 VA momentary duty. 12 volt lead acid battery backup.
Calibrator Power:	Supplied via connection with monitor.
Leakage Current:	In the event of the failure of a line-powered instrument attached to the monitor serial port, causing AC line power (120 VAC) to be applied to the monitor circuitry, testing on file at TCVS demonstrates that current flow through the patient would be well below the 10 microamp maximum specified in IEC 60601-1 and UL 60601-1.
Classifications:	This equipment is Type CF and Class 1. Classified by Underwriters Laboratories with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 <5P30>
	In accordance with UL 60601-1: This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer of field service technician for help.

In accordance with IEC 60601-1-1: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

Restrict use of IEC 950 certified data processing equipment to those with covers that can only be removed with the use of a tool.

When using IEC 950 compliant data processing equipment do not simultaneously contact patient and parts of data processing equipment that may be electrically energized.

Environment

Operating Temperature:	Monitor and Calibrator 15 to 30°C (59 to 86°F)

Storage/Transport Conditions:
Temperature:
  Monitor/Calibrator:
  Shunt Sensors:
	-15°C to 40°C (5°F to 104°F)
	0°C to 35°C (32°F to 95°F)

Humidity:	5 to 90% (non-condensing)
Atmospheric Pressure:	500 to 800 mmHg
Vibration/Shock:	Proper performance of the system depends upon high fidelity optical alignment. Avoid vibration or dropping the monitor or cable-heads.
Ingress Protection:	Rated IPX2

EMC Tables

Table 201 – Guidance and manufacturer's declaration
electromagnetic emissions for all EQUIPMENT and SYSTEMS
(see 6.8.3.201 a) 3))

Guidance and manufacturer's declaration – electromagnetic emissions		
The CDI System 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 500 shall assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 1	The CDI System 500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CDI System 500 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 202 – Guidance and manufacturer's declaration
electromagnetic immunity for all EQUIPMENT and SYSTEMS
(see 6.8.3.201 a) 6)

Guidance and manufacturer's declaration – electromagnetic immunity			
The CDI System 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 500 shall assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD)

IEC 61000-4-2 | ±6 kV contact

±8 kV air | ±6 kV contact

±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst

IEC 61000-4-4 | ±2 kV for power supply lines

±1 kV for input/output lines | +1 kV /-2 kV for power supply lines

±1 kV for input/output lines | The CDI System 500 should always be used with a power cord with the following specifications: Length: 3 m Capacity: 10 A Termination : IEC 320 Connector Mains power quality shall 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 shall be that of a typical commercial or hospital environment. |

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
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 sec	>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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CDI System 500 requires continued operation during power mains interruptions, it is recommended that the CDI System 500 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Table 204 – Guidance and manufacturer's declaration
electromagnetic immunity for all EQUIPMENT and
SYSTEMS that are not LIFE SUPPORTING (see 6.8.3.201 b))

Guidance and manufacturer's declaration – electromagnetic immunity			
The CDI System 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the CDI System 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 *MHz to* 800 *MHz* $d = 2.3 \sqrt{P}$ 800 *MHz to* 2,5 *GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength 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, consider conducting an electromagnetic site survey. If the measured field strength in the location in which the CDI System 500 is used exceeds the applicable RF compliance level above, observe the CDI System 500 to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CDI System 500.

[b]   Over the frequency range 150 kHz to 80 MHz, field strengths shall not exceed 3 V/m.

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT and SYSTEMS - for EQUIPMENT and SYSTEMS that are not LIFE SUPPORTING (see 6.8.3.201 b)

Recommended separation distances between portable and mobile RF communications equipment and the CDI System 500

The CDI System 500 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CDI System 500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CDI System 500 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1   At 80 MHz and 800 MHz, the separation distance for 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.

Additional Warnings and Precautions

Following standard practices for electronic devices, monitor this equipment closely when it is exposed to intense electrical noise or fluctuating line voltage. Strong electromagnetic fields radiated from equipment elsewhere in the operating room (particularly defibrillators and electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.

This device needs special precautions regarding electro-magnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this appendix.

Portable and mobile radio frequency (RF) communications equipment can affect this system.

Use only those accessories, transducers or cables specified, as use of non-specified items may result in increased emissions or decreased immunity of this system.

It is not recommended to use this system adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the system closely to verify normal operation in the configuration in which it will be used.

There are no precautions specific to the system to be taken when a cardiac defibrillator is used on a patient. There are no adverse effects on the system from the discharge of a cardiac defibrillator.

There are no additional precautions specific to the system when high-frequency surgical equipment is used on a patient. The ground equalization stud is used for external grounding of the device. In some countries, regulations require potential compensation; in this case, connect the cable from the potential compensation network to the ground equalization stud. The purpose of additional potential equalization is to equalize potentials between different metal parts that can be touched simultaneously or to reduce differences of potential which can occur during operation between the bodies of medical electrical devices and conductive parts of their objects.
The ground equalization stud on the monitor is a 6 mm pin conforming to DIN 42801 part 1 Potential Equalization Leads − Connecting Pins. Use a connecting lead with a 6 mm socket conforming to DIN 42801 part 2 Potential Equalization Leads − Connecting Sockets.
The compliance level for electrical Fast Transient/Burst is lower than the IEC test level (see table 202) due to physical constraints that limit the ability of the CDI System 500 to perform as intended in the presence of electromagnetic disturbances.

Unpacking and inspection

The CDI System 500 Monitor has been packaged to prevent shipping damage. The carton contains the monitor, one operator's manual, and one roll of printer paper. The CDI Model 540 Calibrator carton contains only the calibrator. The calibration gas bottles are packaged separately. Be sure to keep all cartons and fillers.

If any items are missing, or if there is visible damage to any of the contents, notify the Customer Administration Department at Terumo Cardiovascular Systems promptly (800/521-2818). They will provide instructions and make arrangements to resolve the problem.

Calculations

O_2 Consumption ($\dot{V}O_2$) ml/min = (SaO_2 - SvO_2) x 1.39 x Hgb x $\dot{Q}$ x 10

Note: 1.39 is the constant used for ml O_2 per gram of hemoglobin. SO_2 values are expressed in fractional form (i.e. 100% = 1.0). $\dot{Q}$ is expressed in L/min.

Indexed $\dot{V}O_2$ ml/min/m² = $\dot{V}O_2$/BSA

Note: BSA is patient's body surface area − expressed in m².

Communication with other devices

The Terumo Cardiovascular Systems (TCVS) CDI™ System 500 has a serial data output port, which allows you to use it with an external serial printer, computer, or data acquisition system. When the CDI System 500 is attached to an external device, you can send patient data (blood parameter values over the course of an operation) from the CDI System 500 to this device.

A second serial interface port, called the pump interface, allows the CDI System 500 to receive flow ($\dot{Q}$) data from selected pumps. These are the Terumo® Advanced Perfusion System 1, TCVS Sarns™ 9000, TCVS Sarns™ 8000, TCVS Sarns™ Centrifugal, Medtronic® Bio-Console® 550, Stöckert SIII/SC, and Jostra HL20. When using the pump interface port with the Terumo® Advanced Perfusion System 1, data can also be sent from the CDI System 500, to display blood parameter values on the Central Control Monitor.

▲ Warning

- **Computer equipment in the operating room environment may interfere with the operation of existing monitoring or therapeutic devices and may be susceptible to interference from such devices. To insure that such interference will not occur, care must be taken in the selection of computer equipment or printers to be interfaced with the TCVS CDI™ System 500 Monitor and in the manner in which this interface is accomplished.**

- **Equipment connected to the monitor's serial port shall be certified according to IEC 60601-1 for medical equipment. All configurations shall be checked for combined system leakage current within IEC 60601-1 leakage current specifications. ▲**

Note: Computer devices can generate radio frequency interference. When selecting an external device to use with the CDI System 500, make sure the device can be set up and used in a way that doesn't interfere with the monitors or therapeutic devices used in the operating room. Check the documentation that comes with the external device, or contact the manufacturer, to find out about potential radio frequency interference problems.

Connecting an external device to the data output port

This section explains how to connect an external serial device to the CDI System 500 data output port and tells how to set the communication parameters.

1   **Use a 9-pin, D-type, RS-232 cable to attach the CDI System 500 Monitor to the external device.**
    The cable must have a male connector to attach to the monitor. The length of the cable and the type of connector that attaches to the external device depends on the needs of that device.

    Check to make sure the connections are secure.

2   Configure the device to communicate with the CDI System 500.
Follow the instructions in the device's manual to set the appropriate baud rate and other communication parameters.

3   Turn on the CDI System 500 and access the "setup" mode.
The setup label (at the bottom of the screen) is highlighted when the monitor is in setup mode.

4   Go to screen #6, the "serial port configuration" screen.
Use the right-arrow key to get to the serial port configuration screen.

5   Set the CDI System 500's serial communication parameters to match those of the external device.
Chapter 4, "Choosing system settings," gives instructions for setting these parameters:

Output Type	"ASCII Output," "TCVS Sarns 9000" or "Packet Mode" (if Sarns 9000 is selected, all other values on the screen become unchangeable).
Data Bits	"8 data/1 stop" or "7 data/2 stop"
Parity	"none," "even," or "odd"
Baud Rate	1200, 2400, 4800, 9600, 19200, or 38400
Output Interval	0, 0.1, 0.5 minutes, or 1-10 minutes ("0" means the CDI System 500 will send data on demand only).

Note: The values sent to the external device at the specified interval are not averaged blood parameter values − they are the values that are displayed on the screen at the moment the data is sent.

Note: If setting "Output Type" to "TCVS Sarns 9000" the cable should be connected to the Sarns 9000 CDI interface port only (port "A"). See Appendix A, A-2.

Data output port pin assignments

The CDI System 500 serial data output port is a female DB-9 connector. The data output port is set up as a DCE (Data Comm.) device at the factory; however, hardware handshaking is not supported.

The CDI System 500 Monitor has two levels of protection to isolate the patient from shocks caused by AC line faults occurring in devices attached to the serial interface. An optical isolator provides electrical isolation in the monitor's communication interface. In addition, the thermistor contact is mechanically isolated from the instrument electronics.

The CDI System 500's serial interface has the same pin assignments as the RS-232 standard. The next table defines the pin assignments for the serial data output port.

Pin Number	RS-232 Name	System 500 Connection (DCE)
1	Data Carrier Detect	Force True
2	Receive Data	Transmit Data
3	Transmit Data	Receive Data
4	Data Terminal Ready	Looped to pin 6 (DSR)
5	Ground	Ground
6	Data Set Ready	Looped from pin 4 (DTR)
7	Request to Send	Looped from pin 8 (CTS)
8	Clear to Send	Looped from pin 7 (RTS)
9	Ring Indicator	Force True

Note: The pins in the top row of the DB-9 connector are numbered 5, 4, 3, 2, and 1. The pins in the bottom row are numbered 9, 8, 7, and 6. The higher-numbered pins are to the left. Pin 2 carries the serial data from the CDI System 500 Monitor. Pin 5 is the ground return. Pin 3 carries serial data to the CDI System 500 Monitor.
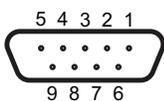
Female DB-9 mating face.

Sending data to an external device

The CDI System 500 can be configured to send data using three different protocols:

- **TCVS Sarns 9000**

  This selection will send data specially formatted to be received by the Sarns 9000 Perfusion System. Selected values can then be displayed on the Sarns 9000 display and packaged with data sent to a data acquisition system.

Note: Potassium (K+) and Hematocrit/Hemoglobin values will not be received by the 9000.

- **ASCII Output**

  This selection will send all System 500 data out the serial port in a simple ASCII string format. This string format is described in detail below. Data will be sent at intervals you select in the "setup" screen or by receiving a command from the external device to send data now.

- **Packet Mode**

  This selection will send all System 500 data out the serial port in packets designed to give the receiving device much more flexibility and quality assurance in receiving data than the simple ASCII string. The packet mode is intended for more sophisticated devices that can be more interactive with the monitor, such as how, when and what it wants in receiving data. The packet mode is described in detail below.

ASCII Output

Communications Setup.
The user may configure the communication parameters as follows:

Baud Rate:	2400, 4800, 9600, 19200, or 38400
Parity:	None, Odd, or Even
Stop Bits:	1, 2
Data Bits:	7, 8
Output Interval:	0, 0.1, 0.5, and 1-10 minutes in 1 minute increments.

The first four parameters configure the RS-232 interface, while the last parameter indicates the interval that data will be sent out through the serial port. Intervals are measured in minutes, so an interval of 1.0 is once a minute and an interval of 0.1 is once each six seconds. If the output interval is set to 0.0 no data will be sent out the port unless the user sends an output request packet, which is described later in this appendix.

Data output events.
A header line will print out every 50 lines of data for viewing convenience. Data will be sent out the serial port when any of the following events occur:

- Specified output interval has been reached

- User marks data by pressing the "mark" button during operation

- User stores data by pressing the "store" button during operation

- User returns from the "recalibration" screen

- User sends a request via the serial port for a line of data

While in ASCII Output mode, a line indicating temperature display value will be output initially and every time the user changes temperature modes. This line will either be "@ Temp Data" or "37C Temp Data" depending on the condition of the monitor at the time.

User request for data.
You can send a packet to request that a line of data be sent out of the serial port. The request packet is the following:

<X08Z36>

Upon receiving this packet, the CDI System 500 will get the latest parameter information and send it out of the serial port. The format will be identical to lines of data sent out at timer intervals, marks and recalibrations.

ASCII Output Format.
Blood parameter values are sent out the serial port as configured when the system is in "operate" mode. All values are delimited by tabs, and the packet is terminated by a Carriage Return <CR>. Additionally, if a parameter is out of bounds (as configured in the setup screen for each parameter), the numbers will be displayed as dashes. If a parameter is not available (based on the configuration of the monitor), the field will be filled with blanks. If the format is smaller than the field size, it is prepended with blanks. The format of the output is as follows:

Field	Parameter	Format	Field Size	Description
0	Header		1	Blank if normal, "*" if marked data, "S" if stored data, "o" if recal data
1	Time	xx:xx:xx	8	Military time is used as hh:mm:ss - i.e., 15:00:00 is 3:00PM
2	Arterial pH	x.xx	4	
3	Arterial CO2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
4	Arterial O2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
5	Arterial Temp	xx.x	4	calculated in Celsius
6	Arterial HCO3	xxx	4	calculated in meq/l
7	Arterial Base Excess	sxx	4	calculated in meq/l
8	Calculated Oxygen Saturation	xx%	4	parameter calculated if no HSAT module is operating
9	Potassium	x.x	4	measured in meq/1
10	VO2 (Oxygen Consumption)	xxx	4	
11	Q (Pump Flow)	x.x	4	measured in l/min - negative values are displayed as 0.0
12	BSA (Body Surface Area)	x	4	measured in m²
13	Venous pH	x.xx	4	
14	Venous CO2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
15	Venous O2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
16	Venous Temp	xx.x	4	measured in Celsius
17	Measured Oxygen Saturation	xx%	4	parameter measured when H/S module operating ONLY
18	Hematocrit	xx%	4	
19	Hemoglobin	x.x	4	measured in g/dL

x - a number (0-9)   s - sign indicator (+ or −)

Sample Output:

Note: Example 1 includes no Venous Module and measurements in mmHg.

@ Temp Data																	
	ARTERIAL										**VENOUS**						
Time	**pH**	**CO2**	**O2**	**Temp**	**HCO3**	**BE**	**cSO2**	**K+**	**VO2**	**Q**	**BSA**	**pH**	**CO2**	**O2**	**Temp**	**SO2**	**HCT**	**HGB**
10:06:02	7.41	40	172	23.9	24	2	100%	4.2	57	4.3	1.8					76%	24%	7.1
10:06:08	7.41	41	176	23.9	25	2	100%	4.2	57	4.3	1.8					76%	24%	7.1
10:06:14	7.41	41	177	23.9	24	2	100%	4.2	58	4.3	1.8					76%	24%	7.2

Note: Example 2 uses all modules, measurements in kPa.

37C Temp Data																	
	ARTERIAL										**VENOUS**						
Time	**pH**	**CO2**	**O2**	**Temp**	**HCO3**	**BE**	**cSO2**	**K+**	**VO2**	**Q**	**BSA**	**pH**	**CO2**	**O2**	**Temp**	**SO2**	**HCT**	**HGB**
10:06:02	7.34	5.3	49.5	23.9	24	2	100%	4.2	47	3.6	1.8	7.12	01.6	10.2	23.3	76%	24%	7.1
10:06:08	7.34	5.3	49.5	23.9	25	2	100%	4.2	49	3.6	1.8	7.12	01.6	10.2	23.3	75%	24%	7.1
10:06:14	7.34	5.3	49.5	23.9	24	2	100%	4.2	50	3.6	1.8	7.12	01.6	10.2	23.3	75%	24%	7.2

Packet Mode Output

Hardware protocol.
The CDI System 500 hardware supports RS-232 signals on the Serial Port, and is used for communication with any device with an RS-232 interface for the purposes of capturing analyte data from the System 500.

RS-232 Parameters.
Communication parameters for the serial port such as baud rate, data and stop bits and parity are all configured in Page 6 of the Setup screen.

Software Support.
The CDI System 500 will support both sending and receiving of messages to/from an external device.

- The communication packet infrastructure will have start and stop characters in binary, with the rest of the packet in ASCII. Binary data transfers are not currently supported.

- The communication packet will contain an 8-bit CRC for error detection. Upon failing the CRC, a NAK packet will be retained indicating the CRC failure.

- The packet will contain an 8-bit sequence counter that will define the order in which packets are sent and received. The sequence of outgoing packets will be independent of the sequence of incoming packets.

Serial Packet Interface Structure.

The format of a packet will be:

\<STX\>ABBLLLLCSD...DZZ\<ETX\>

where:

   \<STX\>   -   Start of packet character, which will be character 0x02 (binary, not ASCII '2').

   A   -   Single Character defining the device ID. See Device ID section for details.

   BB   -   8-bit ASCII hex-encoded sequence value.

   LLLL   -   16-bit ASCII hex-encoded length value. Length is calculated as the length of the entire packet from the \<STX\> to the \<ETX\> inclusive.

   C   -   Single ASCII character Command. This will define the major category for the packet. See the Command list section for definitions.

   S   -   Single ASCII number SubCommand. This will define the specific request or action under the category of the previously defined Command character. See the SubCommand list section for definitions.

   D...D   -   Variable-length data field in ASCII format. The data field will be used to pass parameters if necessary. If no data is necessary, this field will be omitted.

   ZZ   -   8-bit ASCII hex-encoded CRC. This CRC is calculated using the entire packet up to, but not including, the CRC field. Refer to the CRC calculation section for how to calculate the CRC.

   \<ETX\>   -   End of packet character, which will be character 0x03 (binary, not ASCII '3').

Device IDs.
Device IDs are single ASCII characters denoting specific device types for communication. Since communication on the Serial Port using the Packet protocol could be with any type of device capable of receiving analyte information, the Device IDs for incoming Packets are ignored and are only kept in the packet for compatibility with the CDI Pump Interface Protocol (see pump interface section).

The Device ID chosen for the System 500 is 'X'. All outgoing packets from the CDI System 500 will have an 'X' in the Device ID field.

Command List.

The following is a table of major Command values. These are identical to the CDI Pump Interface Protocol commands:

Value	Name	Direction	Description
'A'	Attention	From S500	Information sent out in response to a request or a timed action, such as calibration data, or sending out a line of analyte data during operate mode.
'K'	Acknowledge	From S500	Acknowledge a request by echoing back the Command and SubCommand along with the requested information in the Data portion of the packet.
'N'	No Acknowledge	From S500	Indicates a problem with packet communications. See the SubCommand list of NAK conditions for more details.
'E'	Error	From S500	Indicates an error condition in the System 500. The data portion of the packet will contain the error code, which should be the same as seen on the S500 screen.
'S'	Set	To/ FromS500	Sent to the S500 to set certain parameters, such as Arterial Flow or certain toggles. The S500 also sends a Set type packet to try and set the frequency that Arterial Flow packets will come from the pumping device.
'G'	Get	To S500	Sent to the S500 to request information about the state of an element in the system, such as the time or the operate state.

SubCommand List.

Each major Command type has a list of ASCII numeric SubCommand values used to produce a specific action. Below are the SubCommands listed for each Command.

Attention ('A') :

Value	Name	Description
'0'	Unsolicited Data Packet	Analyte Packet sent by S500 at the specified output interval. See Analyte Packet section for more information.
'1'	Mark Data Packet	Analyte Packet sent by S500 when the Mark key pressed.
'2'	Store Data Packet	Analyte Packet sent by S500 when the Store key pressed.
'3'	Recal Data Packet	Analyte Packet sent by S500 when the Recal key pressed.
'4'	Solicited Data Packet	Analyte Packet sent by S500 in response to a Data Request.

Acknowledge ('K'):

Acknowledge packets are sent back to the requesting device (usually the pumping system, but for some commands, the CDI System 500) to both confirm that the request came through successfully, and to provide any data associated with the request. The description portion of any given Command/SubCommand item will describe when an Acknowledge packet is to be used.

SubCommand for an Acknowledge packet will always be '0,' but the data portion will be of the format CSD..D where:

C — Command sent to the System 500 for which this Acknowledge is made
S — SubCommand sent to the System 500 for which this Acknowledge is made
D..D — Data associated with the Acknowledge. Data content is request-specific

For example, if a Get Time (G2) packet is sent to the System 500, the response would be an Acknowledge packet in the form:

<STX>ABBLLLLK0G2HH:MM:SSZZ<ETX>

The Command is Acknowledge	—	**K**
The SubCommand is always 0 for Acknowledge	—	**0**
The data portion is the Command/SubCommand sent, plus the data requested	—	**G2HH:MM:SS**

No Acknowledge ('N'):

Value	Name	Description
'0'	Invalid Packet Length	Sent when the driver detects more or less characters than the length field indicated.
'1'	Invalid Device ID	Sent when the Pump ID character is not valid for incoming packets to the CDI Monitor. For the System 1/NEO Pump Interface, the Device ID must be 'A'
'2'	Invalid CRC Value	Sent when the CRC calculation doesn't match the CRC value sent in the packet.
'3'	Invalid	Sent when the Command character is not a valid one. Command for incoming packets to the S500, the Command character must be one of: ('S,''G').
'4'	Invalid SubCommand	Sent when the SubCommand character is not valid for the given Command character. In all cases, the SubCommand character must be one of: ('0'..'7').
'5'	Invalid Number of Parameters	Sent when the number of parameters specified in the data field is incorrect, or if no parameters were sent, but at least one was required.
'6'	Parameter(s) out of bounds	Sent when one or more of the parameters in the data field is out of the given range.
'7'	Operation Failure	Sent when a requested operation fails, for example, if assigning the arterial flow results in an error even though the value was within the correct range.

Error ('E'):

Value	Name	Description
'0'	System Error	An error packet will always send a '0' in the SubCommand field. The 4-digit ASCII error code displayed on the screen will be included in the data field (e.g., "F038").

Get ('G'):

Value	Name	Description
'0'	Single Record	Request a single line of data. The S500 will return an Attention 4 Analyte data packet.
'1'	Analyte Output Interval	Request the S500 analyte output interval, in seconds. The S500 will respond with an Acknowledge packet with the data containing G1X where X is an integer value between 0 and 6000 (0 is disabled).
'2'	Time	Request the S500 system time. The S500 will return an Acknowledge packet with the data containing G2HH:MM:SS (military format time string).
'4'	EEPROM Dump	Request the EEPROM dump form to be sent in packet format, 1 line at a time. This will cause the S500 to send EEPROM Dump data (Attention 7) packets.
'5'	Operate State	Request the Operate State. The S500 will return an Acknowledge packet with the data containing G5X where X is either 1 (S500 is in Operate mode) or 0 (S500 is not in Operate mode).

Set ('S'):

Value	Name	Description
'1'	Auto Output Interval	Sends the S500 data on how often Analyte packets should be sent out automatically. 0 is disabled, so that packets will only be sent when requested. The range is from '0,' '6'−'6000,' and is sent in the data portion of the packet. Default is 6 seconds. Since the S500 updates its internal database once every 6 seconds, any value sent to the S500 using this command will be rounded down to the closest value divisible by 6 (e.g., a 13 would become a 12). The System 500 will send an Acknowledge packet with the desired output interval to indicate that it received the request.
'2'	Store/Recal Output Toggle	Indicates if Store/Recal data should be sent. A '0' in the data portion indicates that it should not, a '1' indicates that it should be sent. The CDI System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 1.
'5'	CRC Usage Toggle	Specifies whether the CRC is used to determine the validity of a packet. A '0' disables the use of the CRC, a '1' enables it. The System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 1.

CRC Information.

The 8-bit CRC is generated using the following algorithm:

```
const uchar CPIP_crc_table[]=

{

0x00, 0xcd, 0xd9, 0x14, 0xfl, 0x3c, 0x28, 0xe5,

0xal, 0x6c, 0x78, 0xb5, 0x50, 0x9d, 0x89, 0x44

};

unsigned char CPIP_crc(uchar *start_adr, int count)

{

int i;

uchar crc,idx;

uchar *byte_ptr;

byte_ptr = start_adr ;

crc=0 ;

for (i=0; i<count ; i++)

{

idx=(crc^(*byte_ptr) ) & 0x0f;

crc=( (crc>>4) & 0x0f)^CPIP_crc_table[idx];

idx=(crc^( *byte_ptr >>4)) & 0xf;

crc=((crc >>4)&0xf)^CPIP_crc_table[idx];

++byte_ptr;

}

return(crc);

}
```

The start_adr indicates the starting address of the packet (should be pointing to the 0x02 STX value). The count indicates how many bytes, and should include the count of all parts of the packet up to but not including the CRC field. The function returns the CRC value, which should be converted to a two-character hex-encoded ASCII value for inclusion in the packet.

Analyte Data Information.

When the system sends an analyte data packet while in Operate mode, the data portion of the packet will be of a specific format:

HH:MM:SS<tab>AABCD..D<tab>AABCD..D<tab>...<tab>

The entire analyte packet is in ASCII, and fields are tab-delimited. The first field indicates the time in military format that the data was recorded on the CDI System 500. Data is recorded every 6 seconds in the CDI System 500, so it is possible to get the same record more than once if requesting a packet "<" every 6 seconds.

The analyte information follows, using the following notation:

AA − Analyte descriptor − hex-encoded ASCII value indicating which analyte the value is for. Use the following table for definitions:

Analyte	Analyte Code
Arterial pH	00
Arterial CO2	01
Arterial O2	02
Arterial Temp	03
Arterial SO2	04
Arterial HCO3	05
Arterial Base Excess	06
Potassium (K+)	07
Consumption (V̇O2)	08
Venous pH	09
Venous CO2	0A
Venous O2	0B
Venous Temp	0C
Venous SO2	0D
Venous HCO3	0E
Venous Base Excess	0F
Hematocrit	10
Hemoglobin	11
Arterial Flow	12
Body Surface Area	13

B − Unit descriptor − hex-encoded ASCII value indicating the units for this analyte. Use the table below for definitions:

Unit	Unit Code
No Unit	'0'
Degrees C	'1'
mmHg	'2'
kPa	'3'
Percent	'4'
Milliequivalents/Liter	'5'
Grams/Deciliter	'6'
Millimoles/Liter	'7'
Milliliters/Minute	'8'
Milliliters/Minute/Meter^2	'9'
Liters/Minute	'A'

C – Analyte Status Bitmap – hex-encoded ASCII bitmap value indicating various status information. Since it is only a single character, there are only 4 bits of status.

Bit 0 (LSB)	-	0: 37 degree value,	1: Actual temperature value
Bit 1	-	0: Normal data,	1: Low alarm status
Bit 2	-	0: Normal data,	1: High alarm status
Bit 3 (MSB)	-	0: Normal data,	1: Analyte unavailable

This means that if the status value is in the range 0x8–0xF, the analyte is unavailable due to a configuration selection.

D..D – Analyte Value – The value of the analyte will be displayed in one of three possible formats:

- Integer 2 or 3 digit
- Floating point x.xx or xx.x
- Dashes of the above formats

Examples:

Arterial O2 of 54 in mmHg at Actual Temperature with Low Alarm status:	022354
Potassium of 5.4 in meq/l at 37 degree value with no alarms:	07505.4
Hematocrit in Percent unavailable while measuring in Actual Temperature:	104A--

Receiving blood flow data from pumps

The CDI System 500 pump interface port is a male DB-9 connector. The communications protocol is set up automatically through the selection of the specific pump being connected to (see Chapter 4, Choosing System Settings, for options and instructions). Selections are made in the "setup" mode, screen 5.

> ➤ **Caution**
> - Each type of pumping system will require a separate interface cable specially configured for that device and the CDI System 500. Please see the following section on pump interfacing tips or contact your TCVS Technical Service Representative for assistance. ➤

If a pump is selected in the "setup" mode, the CDI System 500 Monitor will begin looking for pump flow data from the pump interface port upon entering the "operate" mode. If no data is received within a specific time period, a pump interface failure warning will appear in the message bar. The monitor will keep trying to receive flow data at specified intervals until the selection in setup is changed or the monitor is switched to another mode.

Pumping systems supported. The CDI System 500 supports the following pumping system interfaces: Terumo® Advanced Perfusion System 1, TCVS Sarns™ 9000, TCVS Sarns™ 8000 Communications Module, TCVS Sarns™ Centrifugal, Medtronic® Bio-Console® 550, Stöckert SIII/SC and the Jostra HL 20.

CDI Pump Interface. The CDI Pump Interface is a 2-way communications protocol designed for future pumping systems, including the Terumo® Advanced Perfusion System 1. It provides a flexible format to allow the System 500 to get flow data as desired from the pump and for the pump to request data as desired from the monitor. The interface protocol is fully described later in the appendix section.

Pump interfacing tips

Any pump interface cable used is specific to each pump and should be ordered from TCVS Customer Administration. The interface cable will always connect to the pump interface port (only) on the monitor. The data output port (located just above the pump interface port) is reserved for sending data to computers or data acquisition systems.

Note: Please consult the Operator's manual of the specific pumping system being used for instructions on how to properly setup the pump for sending data through its serial interface.

Note: Some parts listed in table below are no longer available. These items are identified in table below. See List of System Components in Appendix A for complete list with availability information.

Pumping System	Special Instructions
Terumo® Advanced Perfusion System 1	Interfacing with the Terumo® Advanced Perfusion System 1 can only be done with the interface module for CDI System 500 (TCVS part number 803479). The System 1 Perfusion screen must be configured to include the CDI 500 module. See the System 1 Operator's Manual for instructions on adding the CDI 500 module to a perfusion screen configuration, and how to physically connect the CDI 500 module to the System 1 and the CDI System 500.
	Make sure the correct interface cable is used (TCVS part number 804981), and that it is connected in the proper orientation (see labels on cable to determine correct orientation).
	Set up the CDI System 500 as follows: use the system mode select key and the direction keys to access screen number 5 in setup mode, the calculations screen. Set the $\dot{Q}$ source to pump and the pump type to TCVS CDI Pump Interface.

TCVS Sarns 9000	To get blood flow from the Sarns 9000, connect the interface cable (TCVS part number 154481- no longer sold) to Port "B." The 9000 normally sends flow data in 60 second intervals, so you may need to wait 1 or 2 minutes to catch the next data string. Pressing "log star" on the 9000 screen will send data immediately. *Note:* Port "A" on the Sarns 9000 can be used to receive data from the System 500. A separate cable (TCVS part number 158810- no longer sold), connecting to the data output port on the 500 is used for this purpose.
TCVS Sarns 8000	Interfacing with the Sarns 8000 can only be done with the Sarns 8000 Communications Module (TCVS part number 16417) accessory. The Communications Module port must be set to the "DCE" setting. This is the default setting from the factory. Contact TCVS Technical Administration if you need to change the setting on your Communications Module. Make sure the correct interface cable is used (TCVS part number 151829), and that it is connected in the proper orientation (see labels on cable to determine correct orientation).
TCVS Sarns Centrifugal	Some Sarns Centrifugal pumps may have two 9-pin connectors on the console. If this is the case, connect only the one marked "RS-422" to CDI System 500. Make sure the correct interface cable is used (TCVS part number 151853), and that it is connected in the proper orientation (see labels on cable to determine correct orientation).
Jostra HL 20	The HL 20 must have a digital I/O module to be connected to the System 500. Please contact your Jostra Technical Service representative to setup the HL 20 software before interfacing. Make sure the correct interface cable is used (TCVS part number 158828).
Stöckert SIII/SC	Interfacing with the Stöckert SIII/SC pumping system requires use of the Stöckert "interface DDD module." The System 500 will also send data to the SIII/SC via this interface and cable. Make sure the correct interface cable is used (TCVS part number 158801- no longer sold or Stöckert part number 45-11-03). *Note:* You must enter the position the arterial pump (1-6) along with the pump type in setup screen #5.

Medtronic Bio-Console® 550	The Bio-Console interface protocol must be set to:
	  9600 baud
	  8 bits
	  no parity
	  1 stop bit
	
	This is the default setting from the factory. If you believe the setting has changed, contact Medtronic Technical Service to make adjustments. Make sure the correct interface cable is used (TCVS part number 151861).
	
	Note: On the Medtronic connector, pin 2 is assumed to be RX (IN) and pin 3 is TX (OUT). Hardware handshaking is not supported.

CDI Pump Interface Protocol

The CDI Pump Interface is a 2-way communications protocol designed for future pumping systems, including the Terumo® Advanced Perfusion System 1. It provides a flexible format to allow the CDI System 500 to get flow data as desired from the pump and for the pumping system to request data as desired from the monitor.

Hardware protocol.
The CDI System 500 hardware supports RS-232 and RS-485 signals on the Pump Port, which is used for communication with pumping systems. Since only one type of communication is necessary, the CDI Pump Interface Protocol will support RS-232 only.

RS-232 Parameters.
The CDI Pump Interface packet communication will have RS-232 parameters fixed at 19200 baud, 8 data bits, 1 stop bit and no parity.

Software Support.
The CDI System 500 will support both sending and receiving of messages to/from a pumping system or other device.

- The communication packet infrastructure will have start and stop characters in binary, with the rest of the packet in ASCII. Binary data transfers are not currently supported.

- The communication packet will contain an 8-bit CRC for error detection. Upon failing the CRC, a NAK packet will be returned. The behavior for acting on a NAK will be to re-transmit.

- The packet will contain an 8-bit sequence counter that will define the order in which packets are sent and received. The sequence of outgoing packets will be independent of the sequence of incoming packets.

- The packet sent to the CDI System 500 will, when successfully received, produce output in the form of an Acknowledge packet or Attention packet, depending on the command. If there is a problem with the packet structure, command combination, packet length, CRC or parameter value, the CDI System 500 will produce a No-Acknowledge (NAK) packet. If no response is received from the CDI System 500 after a packet is sent, it can be assumed that a communication error has occurred and a re-transmit is required.

CDI Pump Interface Packet Structure.
The format of the packet will be:

<STX>ABBLLLLCSD...DZZ<ETX>

where:

<STX>	—	Start of packet character, which will be character 0x02 (binary, not ASCII '2').
A	—	Single Character defining the device ID. See Device ID section for details.
BB	—	8-bit ASCII hex-encoded sequence value.
LLLL	—	16-bit ASCII hex-encoded length value. Length is calculated as the length of the entire packed from the <STX> to the <ETX> inclusive.
C	—	Single ASCII character Command. This will define the major category for the packet. See the Command list section for definitions.
S	—	Single ASCII number SubCommand. This will define the specific request or action under the category of the previously defined Command character. See the SubCommand list section for definitions.
D...D	—	Variable-length data field in ASCII format. The data field will be used to pass parameters if necessary. If no data is necessary, this field will be omitted.
ZZ	—	8-bit ASCII hex-encoded CRC. This CRC is calculated using the entire packet up to, but not including, the CRC field. Refer to the CRC calculation section for how to calculate the CRC.
<ETX>	—	End of packet character, which will be character 0x03 (binary, not ASCII '3').

Device IDs.
Device IDs are single ASCII characters denoting specific device types for communication. Although the CDI System 500 does not connect with more than one device on the Pump Interface port, specifying a device type may benefit other devices that do have multiple connections.

- The Device ID chosen for the CDI System 500 is 'X.' All outgoing packets from the CDI System 500 will have an 'X' in the Device ID field.
- All pumping systems connected to the CDI System 500 are capable of providing arterial flow. Since no benefit is gained by requiring each pumping system to have a unique ID, all incoming packets are required to have a device ID of 'A,' denoting an Arterial Pump.

Command List.

The following is a table of major Command values:

Value	Name	Direction	Description
'A'	Attention	From S500	Information sent out in response to a request or a timed action, such as calibration data, or sending out a line of analyte data during Operate mode.
'K'	Acknowledge	From S500	Acknowledge a request by echoing back the Command and SubCommand, along with the requested information in the Data portion of the packet. Acknowledge packets are sent back to the requesting device (usually the System 500) to both confirm that the request came through successfully and to provide any data associated with the request.
'N'	No Acknowledge	From S500	Indicates a problem with packet communications. See the SubCommand list of NAK conditions for more details.
'E'	Error	From S500	Indicates an error condition in the System 500. The data portion of the packet will contain the error code, which will be the same as seen on the S500 screen.
'S'	Set	To S500	Sent to the S500 to set certain parameters, such as Arterial Flow or certain toggles.
'G'	Get	To S500	Sent to the S500 to request information about the state of an element in the system, such as the time or the operate state.

SubCommand List.

Each major Command type has a list of numeric SubCommand values used to produce a specific action. Below are the SubCommands listed for each Command. Values denoted with an "*" are not supported in software version 1.4 and lower.

Attention ('A'):

Value	Name	Description
'0'	Unsolicited Data Packet	Analyte Packet sent by S500 at the specified output interval. See Analyte Packet section for more information.
'1'	Mark Data Packet	Analyte Packet sent by S500 when the Mark key is pressed.
'2'	Store Data Packet	Analyte Packet sent by S500 when the Store key is pressed.
'3'	Recal Data Packet	Analyte Packet sent by S500 when the Recal key is pressed.
'4'	Solicited Date Packet	Analyte Packet sent by S500 in response to a Data Request.
'5' *	Case Summary Data	A line of the Case Summary stored during a case. Multiple lines of this type of packet will be sent when the "Print Case" key is pressed.
'6' *	Calibration Data	Calibration Data Packet sent by S500 during calibration if requested and if in Service Mode.
'7'	EEPROM Dump Data	A line of the EEPROM Dump information sent by S500 in response to an EEPROM dump request, while in Service Mode.

* - not supported in software version 1.4 or lower.

Acknowledge ('K'):

Acknowledge packets are sent back to the requesting device (usually the pumping system, but for some commands, the CDI System 500) to both confirm that the request came through successfully, and to provide any data associated with the request. The description portion of any given command/subcommand item will describe when an Acknowledge packet is to be used. The SubCommand for an Acknowledge packet will always be '0,' but the data portion will be of the format CSD..D where:

C   —   Command sent to the CDI System 500 for which this Acknowledge is made

S   —   SubCommand sent to the CDI System 500 for which this Acknowledge is made

D..D   —   Data associated with the Acknowledge. Data content is request-specific.

For example, if a Get Time (G2) packet is sent to the System 500, the response would be an Acknowledge packet in the form:

<center>**<STX>ABBLLLLK0G2HH:MM:SSZZ<ETX>**</center>

The command is Acknowledge   –   **K**

The subcommand is always 0 for Acknowledge   –   **0**

The data portion is the command/subcommand sent, plus the
data requested   –   **G2HH:MM:SS**

No Acknowlege ('N'):

Value	Name	Description
'0'	Invalid Packet Length	Sent when the driver detects more or less characters than the Length field indicated.
'1'	Invalid CRC Value	Sent when the CRC calculation doesn't match the CRC value sent in the packet.
'2'	Invalid Command	Sent when the Command character is not a valid one. For incoming packets to the S500, the Command character must be one of: ('S', 'G').
'3'	Invalid SubCommand	Sent when the SubCommand character is not valid for the given Command character. In all cases, the SubCommand character must be one of: ('0'..'7').
'4'	Invalid Number of Parameters	Sent when the number of parameters specified in the data field is incorrect, or if no parameters were sent, but at least one was required.
'5'	Parameter(s) out bounds	Sent when one or more of the parameters in the data field is out of the given range.
'6'	Operation Failure	Sent when a requested operation fails, for example if assigning the arterial flow results in an error even though the value was within the correct range.

Error ('E'):

Value	Name	Description
'0'	System Error	An error packet will always send a '0' in the SubCommand field. The 4-digit ASCII error code will be included in the data field (e.g., "F038")

Get ('G'):

Value	Name	Description
'0'	Single Record	Request a single line of data. The S500 will return an Attention 4 Analyte data packet.
'1'	Analyte Output Interval	Request the S500 analyte output interval, in seconds. The S500 will respond with an Acknowledge packet with the data containing G1X where X is the integer value between 0 and 6000 (0 is disabled).
'2'	Time	Request the S500 system time. The S500 will return an Acknowledge packet with the data containing G2HH:MM:SS (military format time string).
'3' *	Summary Buffer	Request the Case Summary buffer be dumped in packet format. This will cause the S500 to send Case Summary data (Attention 5), each packet a separate line.
'4'	EEPROM Dump	Request the EEPROM dump form to be sent in packet format, one line at a time. This will cause the S500 to send EEPROM Dump data (Attention 7) packets.
'5'	Operate State	Request the Operate State. The S500 will return an Acknowledge packet with the data containing G5X where X is either 1 (S500 is in Operate mode) or 0 (S500 is not in Operate mode).
'6'	Arterial Flow	Generated by the System 500, this will be a way for the S500 to request the arterial flow from a pumping system. The expected response would be a "Set 0" packet, setting the Arterial flow.
'7'	BSA	Generated by the System 500, this will be a way for the S500 to request the body Surface Area, in m^2. The expected response would be a "Set 6" packet, setting the BSA.

* - not supported in software version 1.4 or lower.

Set ('S'):

Value	Name	Description
'0'	Arterial Flow	This sends the S500 an ASCII floating-point value between '0.0' and '10.0' in 1/min (inclusive) indicating the arterial flow on the pumping system. The flow value shall be located in the Data portion of the packet. Arterial flow can be updated as often as once every six seconds. The S500 will respond with an Acknowledge packet, indicating that it got the flow input. The S500 will produce an error on the status bar if the Arterial Flow hasn't been sent in the timeout period, which is 3x the Arterial Flow Auto-Interval. (See Set '7').
'1'	Auto Output Interval	Sends the S500 data on how often Analyte packets shall be sent out automatically. 0 is disabled, so that packets will only be sent when requested. The range is from '0,' '6'– '6000,' and is sent in the data portion of the packet. Default is 6 seconds. Since the S500 updates its internal database once every 6 seconds, any value sent to the S500 using this command will be rounded down to the closest value divisible by 6 (e.g., a 13 would become a 12). The System 500 will send an Acknowledge packet with the desired output interval to indicate that it received the request.
'2'	Store/Recal Output Toggle	Indicates if Store/Recal data shall be sent. A '0' in the data portion indicates that it shall not, a '1' indicates that is shall be sent. The System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 1.
'3' *	Calibration Output Toggle	Indicates if data shall be output as packets during calibration. A '0' in the data portion specifies that data shall not be sent. A '1' indicates that it shall be. Service mode must be enabled to enable Calibration output. The System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 0.
'4' *	Service Mode	Sets the communication in a special mode allowing additional commands. A '0' disables Service mode, while a '1' enables service mode. The System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 0.
'5'	CRC Usage Toggle	Specifies whether the CRC is used to determine the validity of a packet. A '0' disables the use of the CRC, a '1' enables it. The System 500 will send an Acknowledge packet with the desired setting to indicate that it received the request. Default is 1.
'6'	BSA	Sets the value of Body Surface Area in m2. The data portion of the packet contains the value. Data values can range from 0.0 to 20.0. A value of 0.0 indicates that BSA is not to be used in the calculation of VO2. For example, sending '2.30' in the data portion would set the BSA value to 2.30m2.
'7'	Arterial Flow Auto Interval	Sent by the System 500 to a pumping system, this sets the interval, in seconds, that the S500 wants Arterial flow. The pumping system shall respond with an Acknowledge packet telling the S500 the negotiated value for Arterial Flow. A 0 value indicates that no unsolicited flow values shall be sent, and the S500 will send a "Get 6" packet to get the Arterial Flow. The S500 always requests that Arterial Flow be sent every 6 seconds, but will use the value sent back from the pump as a basis for its timeout value for Arterial Flow. For example, if the System 500 sends a S712, indicating that the Arterial Flow Auto Interval shall be 12 seconds, the expected response from the pump would be a K0S712, where the S712 is the data portion of the packet. This would then tell the S500 that flow will be sent every 12 seconds, and the timeout will be 3 x 12 or 36 seconds.

* - not supported in software version 1.4 or lower.

CRC Information.
the 8-bit CRC is generated using the following algorithm

const uchar CPIP_crc_table[]=

{

0x00, 0xcd, 0xd9, 0x14, 0xf1, 0x3c, 0x28, 0xe5,

0xa1, 0x6c, 0x78, 0xb5, 0x50, 0x9d, 0x89, 0x44

};

unsigned char CPIP_crc(uchar *start_adr, int count)

{

int i;

uchar crc,idx;

uchar *byte_ptr;

byte_ptr = start_adr ;

crc = 0 ;

for (i=0 ; i<count ; i++)

{

idx=(crc^(*byte_ptr)) & 0x0f ;

crc = ((crc>>4) & 0x0f)^CPIP_crc_table[idx];

idx=(crc^(*byte_ptr >> 4)) & 0xf ;

crc = ((crc>>4) & 0xf)^CPIP_crc_table[idx];

++byte_ptr;

}

return(crc);

}

The start_adr indicates the starting address of the packet (should be pointing to the 0x02 STX value). The count indicates how many bytes, and includes the count of all parts of the packet up to but not including the CRC field. The function returns the CRC value, which shall be converted to a two-character hex-encoded ASCII value for inclusion in the packet.

Analyte Data Information.
When the system sends an analyte data packet while in Operate mode, the data portion of the packet will be of a specific format:

HH:MM:SS<tab>AABCD..D<tab>AABCD..D<tab>...<tab>

The entire analyte packet is in ASCII, and fields are tab-delimited. The first field indicates the time in military format that the data was recorded on the CDI System 500. Data is recorded every 6 seconds in the CDI System 500, so it is possible to get the same record more than once if requesting a packet "<" every 6 seconds.

The analyte information follows, using the following notation:
AA − Analyte descriptor − hex-encoded ASCII value indicating which analyte the value is for. Use the following table for definitions:

Analyte	Analyte Code
Arterial pH	00
Arterial CO2	01
Arterial O2	02
Arterial Temp	03
Arterial SO2	04
Arterial HCO3	05
Arterial Base Excess	06
Potassium (K+)	07
Consumption (V̇O2)	08
Venous pH	09
Venous CO2	0A
Venous O2	0B
Venous Temp	0C
Venous SO2	0D
Venous HCO3	0E
Venous Base Excess	0F
Hematocrit	10
Hemoglobin	11
Arterial Flow	12
Body Surface Area	13

B − Unit descriptor − hex-encoded ASCII value indicating the units for this analyte.
Use the table below for definitions:

Unit	Unit Code
No Unit	'0'
Degrees C	'1'
mmHg	'2'
kPa	'3'
Percent	'4'
Milliequivalents/Liter	'5'
Grams/Deciliter	'6'
Millimoles/Liter	'7'
Milliliters/Minute	'8'
Milliliters/Minute/Meter^2	'9'
Liters/Minute	'A'

C – Analyte Status Bitmap – hex-encoded ASCII bitmap value indicating various status information. Since it is only a single character, there are only 4 bits of status.

Bit 0 (LSB)	–	0: 37 degree value, 1: Actual temperature value
Bit 1	–	0: Normal data, 1: Low alarm status
Bit 2	–	0: Normal data, 1: High alarm status
Bit 3 (MSB)	–	0: Normal data, 1: Analyte unavailable

This means that if the status value is in the range 0x8 – 0xF, the analyte is unavailable due to a configuration selection.

D..D – Analyte Value – The value of the analyte will be displayed in one of three possible formats:

- Integer 2 or 3 digit
- Floating point x.xx or xx.x
- Dashes of the above formats

Examples:

Arterial O2 of 54 in mmHg at Actual Temperature with Low Alarm status: 022354
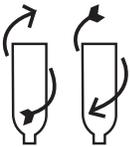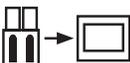Potassium of 5.4 in meq/l at 37 degree value with no alarms: 07505.4
Hematocrit in Percent unavailable while measuring in Actual Temperature: 104A--

Symbols Glossary

The following symbols may appear in the labeling, marking, or display of the Terumo Cardiovascular Systems (TCVS) CDI System 500 Blood Parameter Monitoring System. These symbols are in accordance with the internationally harmonized standards.

Symbol	Title	Description	Source
	Consult instructions for use.	Indicates the need for the user to consult the instructions for use.	ISO 15223-1-5.4.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1-5.4.4
	Uninsulated voltage within the unit may have sufficient magnitude to cause electric shock.	It is dangerous to make any kind of contact with any inside part of this unit.	IEC 60417-6042
	"On" for a part of Equipment.	"On" for a part of Equipment.	IEC 60601-1
	"Off" for a part of Equipment.	"Off" for a part of Equipment.	IEC 60601-1
	Protective earth ground.	Protective earth ground.	IEC 60417-5019
	Type CF equipment.	Type CF equipment.	IEC 60417-5335
	Alternating current.	To indicate on the rating plate that the equpiment is suitable for alternating current only; to identify relevant terminals	IEC 60417-5032
	Direct current.	Direct current.	IEC 60417-5031
	Equipotentiality	Equipotentiality	IEC 60417-5021
	Fuse.	Fuse.	IEC 60417-5016
IPX2	Protect against dripping water when tilted up to 15 degrees.	Drip proof in accordance with IEC 60529	IEC 60529

T	Type T	Type T	UL248-14
Hz	Hertz	Hertz	The International System of Units (SI)
A	Ampere	Ampere	The International System of Units (SI)
V	Volt	Volt	The International System of Units (SI)
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1-5.1.4
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15223-1-5.1.2
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 15223-1-5.3.1
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1-5.3.4
	This way up.	This way up	ISO 7000-0623
	Date of manufacture.	Indicates the date when the medical device was manufactured.	ISO 15223-1-5.1.3
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1-5.3.7
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	ISO 15223-1-5.3.6
CE	CE Mark	Indicates conformity of the product to Council Directive 93/42/ EEC	Council Directive 93/42/ EEC
Pb	Battery recycling (European).	Battery recycling (European).	WEEE 2012/19/EU
Pb	Battery recycling (USA).	Battery recycling (USA).	ISO 7000-1135

(battery symbol)	Battery charge status.	Battery charge status.	IEC 60417-5546
1 (bottle) /	1 Bottle per case.	1 Bottle per case.	Terumo Cardiovascular Systems
(# carton symbol)	Number of contents in carton.	Identifies the number of contents	Terumo Cardiovascular Systems
GAS (A)	Gas A.	Gas A	Terumo Cardiovascular Systems
GAS (B)	Gas B	Gas B	Terumo Cardiovascular Systems
(twist bottles symbol)	Twist to remove/tighten gas bottles	Twist to remove/tighten gas bottles	Terumo Cardiovascular Systems
(monitor pump interface symbol)	Monitor pump interface port.	Monitor pump interface port.	Terumo Cardiovascular Systems
(calibrator connector symbol)	Calibrator connector to monitor	Calibrator connector to monitor	Terumo Cardiovascular Systems
(monitor connector symbol)	Monitor connector to calibrator	Monitor connector to calibrator	Terumo Cardiovascular Systems
(RS 232 symbol) RS 232	Connection to the serial data output port	Connection to the serial data output port	Terumo Cardiovascular Systems
(speaker symbol)	Audible alerts are active	Audible alerts are active	Terumo Cardiovascular Systems
(muted speaker symbol)	Audible alerts are temporarily silenced	Audible alerts are temporarily silenced	Terumo Cardiovascular Systems
(disabled speaker symbol)	Audible alerts are disabled	Audible alerts are disabled	Terumo Cardiovascular Systems
(non-ionizing radiation symbol)	Non-ionizing radiation	Non-ionizing radiation	IEC 60417-5140
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1-5.1.6
EC | REP	Authorized representative in the European Community	Indicates the Authorized representative in the European Community	ISO 15223-1-5.1.2

CLASSIFIED c (UL) us	UL Mark	Classified by Underwriters Laboratories. With respect to electrical shock, fire and mechanical hazards only in accordance with UL IEC 60601-1 and CAN/CSA C22.2 No 601.1.	Underwriters Laboratories
	WEEE	This standard applies to Electronic equipment in accordance with article 11(12) of Directive 2002/96/EC	Directive 2002/96/EC
Rx ONLY	Prescription only	Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician	21 CFR 801.109
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1-5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1-5.1.4
%	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed	15223-1: 5.3.8
	Mass; Weight	To indicate mass. To identify a function related to mass.	ISO 7000:1321A

Standards:
ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements
BS EN 15986: Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing phthalates
IEC 60417: Graphical symbols for use on equipment
IEC 60529: Degrees of protection provided by enclosures (IP Code)
UL248-14: Standard for Safety Low-Voltage Fuses - Part 14: Supplemental Fuses
ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
ISO 7000:2014 - Graphical symbols for use on equipment -- Registered symbols

WARRANTY: DISCLAIMER OF WARRANTY:
LIMITATIONS OF REMEDIES

Warranties

Terumo Cardiovascular Systems (TCVS) warrants that its TCVS CDI™ System 500 Monitors will be free from defects in materials and manufacturing for one year from the date they are shipped. TCVS warrants that its Accessories will be free from defects in materials and manufacturing for 90 days from the date they are shipped. TCVS warrants that its disposables will be free from defects in materials and manufacturing until the stated expiration date.

TCVS also warrants that its monitors, disposables, and accessories will be fit for use in accordance with TCVS's written instructions. TCVS does not warrant that they are fit for any other use.

This warranty does not cover monitors, disposables, or accessories which are damaged through no fault of TCVS. Only service representatives authorized by TCVS may service the monitors, disposables, and accessories. This warranty does not cover damage due to unauthorized service.

Because the operation of TCVS's monitors, disposables, and accessories depends on factors which are out of TCVS's control (such as the care of the products and the particular circumstances of the surgery), TCVS does not warrant that its monitors, disposables, and accessories will be 100% effective in all circumstances.

Limitations of Remedies

TCVS at its option will repair, replace, or refund the purchase price of any monitor, disposables, and accessories which are defective in materials or manufacturing during the appropriate warranty periods.

The customer must notify TCVS of the defect within 30 days of discovering any defect, and no later than 30 days after the end of the appropriate warranty period. The customer must then return the monitor, disposable, or accessory, freight prepaid, to TCVS, CDI Products. The returned goods (RG) policy, as stated on the following page, must be followed.

THIS REMEDY IS YOUR EXCLUSIVE REMEDY. TCVS will not be liable for any consequential or incidental damages, including lost profits.

Service

Except for routine cleaning, battery charging and fuse replacement, any servicing of the components of the TCVS CDI Blood Parameter Monitoring System 500 must be performed by TCVS or an authorized service organization.

If you suspect instrument malfunction, please review the Troubleshooting section of this manual to determine the possible cause. TCVS maintains a Technical Service Hotline to assist you in troubleshooting the system. Should repair be necessary, a Technical Service or Customer Administration representative will authorize a replacement instrument. In order to expedite this process, please have the product serial or lot number and a detailed description of the abnormal behavior of the product available when calling. For the most efficient use of the troubleshooting process, the product should be close at hand for the execution of some simple tests during the telephone conversation.

> **Phone:**   800/521-2818 Customer Administration
>
> 800/441-3220 Technical Support

Returned Goods Policy

The customer must receive TCVS's authorization to return goods by calling TCVS's Customer Administration Department. Please be prepared to provide the product description, the quantity of product to be returned, the lot or serial numbers, and the reason for the return. TCVS may give authorization at its discretion. TCVS will not authorize the return of goods which are not in new and resalable condition, which have fewer that 90 days remaining prior to the expiration date, or which do not appear on TCVS's most recently published price list. TCVS may inspect returned goods. If TCVS determines that the returned goods are unacceptable, TCVS may refuse to issue any credit. TCVS will notify the customer that it will no issue credit and will hold the returned goods for 30 days for the customer's inspection. After that time TCVS will dispose of the returned goods. TCVS will identify which products it authorizes the customer to return and will give a returned goods (RG) number. The RG number must appear on the shipping container of all returned products. If the return is due to TCVS's shipping error, TCVS will give 100% credit against the invoice price (less discounts). Otherwise, TCVS will grant a 90% credit against the original invoice price (less discounts, freight, taxes, etc.). TCVS Sales Representatives are not authorized to accept returned goods from customers.

Patent Information

U.S. Patents: 5,296,381; 5,508,509; 5,591,400.

Software License

End User License Agreement
CDI System 500 Software

Important/read carefully: This License Agreement ("Agreement") is a legal agreement between you and Terumo Cardiovascular Systems ("Terumo CVS") for the computer software included with the CDI System 500, which includes computer software and associated documentation ("SOFTWARE"). By using the SOFTWARE, you agree to be bound by the terms of this Agreement.

The SOFTWARE is protected by copyright laws and treaties, as well as other intellectual property laws. The SOFTWARE is licensed, not sold, to you.

1   GRANT OF LICENSE. You are hereby granted a non-transferable, non-assignable license to install and use one copy of the SOFTWARE on the CDI System 500. The SOFTWARE is intended specifically for use on the CDI System 500, and may not under any circumstances be utilized or operated on any other processor without the express written permission of Terumo CVS.

2   LIMITATIONS. You agree to not reverse engineer, decompile, decrypt, disassemble, or otherwise reduce the SOFTWARE to a human-perceivable form, even if such activity is expressly permitted by applicable law notwithstanding this limitation. You may not rent or lease the SOFTWARE.

3   UPGRADES. If you receive an upgrade or other revision to the SOFTWARE you agree to immediately install the upgrade on the CDI System 500. The upgrade will be considered SOFTWARE for the purposes of this Agreement

4   COPYRIGHT. All title and copyrights in and to the SOFTWARE (including but not limited to any source code, object code, images, and text incorporated into the SOFTWARE), the accompanying printed materials, and any copies of the SOFTWARE are owned by Terumo CVS. As the SOFTWARE is copyrighted, you must treat the SOFTWARE as you do any other copyrighted material except that you may make one copy of the SOFTWARE for backup purposes. You may not copy the printed materials accompanying the SOFTWARE.

5   TERMINATION. You may terminate this Agreement at any time without notice to Terumo CVS. This Agreement will terminate immediately without notice to you if you fail to strictly comply with the terms of this Agreement. This Agreement will also terminate should there be an unremedied breach of your obligations under any Bundle Purchase Agreement, Equipment Loan Agreement, or other agreement with Terumo CVS pertaining to the CDI System 500. Upon any such termination, you will immediately cease utilizing the SOFTWARE and return the SOFTWARE to Terumo CVS. These termination provisions shall be in addition to any other remedies available to Terumo CVS at law or equity.

6   LIMITED WARRANTY. Terumo CVS warrants only that the SOFTWARE will, for a period of one year following shipment of the CDI System 500, function in accordance with the instructions furnished with the SOFTWARE. Should the SOFTWARE fail to properly function, Terumo CVS's sole obligation will be to utilize reasonable commercial efforts to resolve the problem, or at the option of Terumo CVS, to replace the SOFTWARE. To obtain warranty service, contact Terumo CVS at the address listed in "Notices" below. TERUMO CVS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TERUMO CVS DOES NOT WARRANT THAT THE SOFTWARE WILL BE ERROR-FREE, OR THAT THE SOFTWARE WILL BE FREE OF VIRUSES AND OTHER HARMFUL ELEMENTS.

7   LIMITATION OF LIABILITY. IN NO EVENT WILL TERUMO CVS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUEN-TIAL DAMAGES BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, TORT, STRICT LIABILITY OR OTHER LEGAL THEORY ARISING OUT OF THE INSTALLATION OF, USE OF, OR INABILITY TO USE THE SOFTWARE, EVEN IF TERUMO CVS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. TERUMO CVS'S LIMIT OF LIABILITY FOR DIRECT DAMAGES HEREUNDER, REGARDLESS OF LEGAL THEORY OR CAUSE OF ACTION, SHALL BE LIMITED TO THE LICENSE FEE PAID TO TERUMO CVS.

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9   GOVERNMENT END USERS. The SOFTWARE is considered "Commercial Items" as defined in 48 C.F.R.2.101, consisting of "Commercial Computer Software" and "Commercial Computer Software Documentation" as defined in 48 C.F.R.12.212 or 48 C.F.R.227.7202 as applicable. The SOFTWARE is being licensed to U.S. Government end users (A) only as Commercial Items and (b) with only those rights granted to all other end users pursuant to the Agreement.

10   GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the United States and the State of Michigan, as applied to agreements entered into and to be performed entirely within Michigan by Michigan residents. If you acquire this Software outside of the United States, the laws of the United States and the State of Michigan shall apply to this Agreement.

11   SEVERABILITY. If for any reason a court of competent jurisdiction finds any provision of this Agreement, or portions thereof, to be unenforceable, that provision of the Agreement shall be enforced to the maximum extent permissible so as to affect the intent of the parties, and the remainder of this Agreement shall continue in full force and effect.

12   COMPLETE AGREEMENT. This Agreement constitutes the entire agreement between the parties with respect to the SOFTWARE. No amendment to or modification of this Agreement will be binding unless in writing and signed by a duly authorized representative of Terumo CVS.

13   NOTICES. Notices required to be sent to Terumo CVS under the terms of this Agreement should be sent to: Customer Administration, Terumo Cardiovascular Systems, 6200 Jackson Rd., Ann Arbor, MI 48103, USA.

Glossary

Note: These definitions are specific to the Terumo Cardiovascular Systems (TCVS) CDI™ Blood Parameter Monitoring System 500.

Alpha-Stat
Maintenance of a constant OH−/H+ ratio; accomplished by measuring blood gas values at 37°C and keeping a constant pH of 7.40 and PCO_2 of 40 mmHg.

Aseptic technique
A particular method to be used when placing a sterile CDI H/S Cuvette or CDI Shunt Sensor into the extracorporeal circuit. To use aseptic technique, you can have a sterile team member place the sterile CDI component into the line, or use a sterile blade to cut into a sterilized circuit.

Base Excess (B.E.)
The sum of all the conjugate bases in one liter of whole blood.

Bicarbonate (HCO_3^-)
The primary buffering system of the body. It minimizes changes in pH when either acids or bases are added to the blood.

BPM
Blood Parameter Module. Arterial and/or Venous cable modules that measure pH, PCO_2, PO_2, K+ and temperature.

Buffer solution
A specific solution in the sensor. It stabilizes the microsensors during storage. It also reacts with the tonometered gases during calibration to establish predictable pH, PCO_2, PO_2, and K+ values. It cannot be replaced with other solutions.

Hematocrit
The volume percentage of red blood cells in the blood.

Hemoglobin
The iron-containing protein complex in the red blood cells which can combine with oxygen and carbon dioxide.

In-vivo recalibration
Recalibrating the CDI System 500 Monitor during on-line operation so that its measured values correlate more closely with those from the institution's blood parameter laboratory.

LEDs
Light Emitting Diodes.

Mean (average)
The numerical average of all the values in a data set. The mean is calculated as the sum of the values in the set divided by the number of values in the set.

Message bar
The area above the parameter display window that's used to convey current system status and alerts.

Microsensors
Located on the sensor body, these are small dots of fluorescent chemicals which emit light in response to flashes of light from the LED's correlating to the amount of substrate present.

Navigation/input keys
The keys located at the bottom of the monitor's front panel. They include the + (Plus), - (Minus), √ (OK), X (Cancel), and ◀, ▶, ▲, and ▼ (left-, right-, up- and down-arrow) keys.

Non-toxic
Not poisonous.

Non-pyrogenic
Not fever-producing.

Operate mode toggle key
The key you press during operate mode to switch among the three types of displays − Numeric, Tabular, and Graphic. (This key is near the lower-right corner of the monitor's front panel).

Optical Interface Material
A transparent material found on the back side of the TCVS CDI™ Model CDI510H Shunt Sensor. This material provides a means of consistent optical connection between the sensor and the fiberoptic cable connector. The transparent optical interface material reduces the risk of measurement errors caused by moisture or air trapped between the microsensors and the fiber optics.

Oxygen saturation
The amount of oxygen bound to hemoglobin in the blood, expressed as a percentage of the maximal binding capacity.

Oxygen consumption ($\dot{V}O_2$)
A measurement of the amount of oxygen transferred to the tissues, expressed in ml O_2/minute.

pH

The unit for measuring the degree of acidity or alkalinity of a substance, directly related to the concentration of hydrogen ions in the substance.

pH Stat

Maintenance of a constant pH at 7.40 and PCO_2 at 40 mmHg, over varying temperatures; accomplished by measuring blood gas values at actual (patient) temperature.

PO_2

Partial pressure of oxygen. The pressure exerted by oxygen gas in the blood.

PCO_2

Partial pressure of carbon dioxide. The pressure exerted by carbon dioxide gas in the blood.

Parameter display window

The window on the CDI System 500 Monitor's screen that contains case parameter data.

Potassium (K+)

The major cation of intercellular fluid.

$\dot{Q}$

Blood flow value, in 1/min obtained manually or via the pump interface port.

Soft keys

Software-driven function keys located along the right side of the monitor's front panel.

Standard deviation (precision)

A measure of how spread out the values in a data set are. This measure tells whether most of the values in a data set are close to the average or widely distributed around the average. This is the most common measure of variability. Variance is the average squared deviation from the mean. Standard deviation is the square root of the variance. In a normal distribution of values − that is, a set of values that are distributed evenly around the mean of the data set − 68% of the values are between +/− 1 standard deviation, and about 95% of the values are between +/− 2 standard deviations. The goal of quality control when studying precision is to keep standard deviations as small as possible.

SWL: Safe Working Load

System map

The area underneath the parameter display window that displays the labels for the different modes (setup, calibrate, standby, and operate) and the label for the operate mode display choice (numeric, tabular, or graphic).

System mode select key

The key that activates the system map. This key is near the lower-left corner of the monitor's front panel.

Thermistor

A silver cap located on the cable-head. It measures the temperature of the blood when connected to a sensor.

Tonometered

A measurement characteristic of the calibration gases used with the CDI System 500. The gas concentrations used with the CDI System 500 meet guaranteed specifications, which ensure that every gas bottle delivers specific gas concentrations, providing a consistent calibration.

Two-point tonometered gas calibration

A calibration procedure that uses the supplied gas bottles to deliver a precise mixture of CO_2 and O_2 gas in order to expose the sensors to well-defined pH, PCO_2, and PO_2 values. The monitor determines the intensities related to these specific points, and draws a slope and intercept value from them.