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SYM.	CHG. NO.	DESCRIPTION
D	91992	UPDATED RS232 SYMBOL
C	91988	MADE CLARIFICATIONS TO CHAPTER 9
B	91979	UPDATED CLEANING AND CHAPTER 9
		Refer to ECO

REVISIONS

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
Ann Arbor, Michigan

TITLE
CDI SYSTEM 550 OPERATORS MANUAL, TEXT

PART NUMBER 895230

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1 OF 1	895230	D

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What is the CDI® System 550?

The Terumo Cardiovascular Systems (Terumo CVS) CDI Blood Parameter Monitoring System 550 (CDI System 550) is a blood monitoring system to be used on a single patient during cardiopulmonary bypass procedures. It continuously monitors the blood in the extracorporeal circuit and provides ongoing information about the blood parameters. This information is displayed on the CDI System 550's easy-to-read screen.

The CDI System 550 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 550 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 ($\dot{V}O_2$)
- Oxygen delivery ($\dot{D}O_2$)

The CDI System 550 can display the blood parameters either at actual temperature or adjusted to 37°C.

The CDI System 550 and all related accessories are latex-free.

The CDI System 550 includes a built-in printer that can provide a printed copy of the displayed blood parameter values.

Indications for Use

The CDI System 550 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, oxygen delivery, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the systems integral printer provides a hard copy of displayed parameters.

Contraindications None

Operator Profile

This device is typically operated by a perfusionist and is not left unattended. A perfusionist usually possesses a degree with various levels of experience and perfusion-specific education. Some perfusionists may have other healthcare credentials. In some countries, the perfusionist completes a formal educational perfusion program followed by clinical practice prior to becoming certified and/or licensed to practice. In other countries, the perfusionist does not complete a formal perfusion education program, and learns the profession by practice and on-the-job training only.

Minimum Physical Requirements: Has physical ability to stand for long periods of time, and to stoop, bend, reach, grasp, or feel as needed; capable of lifting approximately 25 lb. from the floor location to countertop height; Normal visual and audible acuity (with correction if needed).

Training Requirements

Before you set up or operate the CDI System 550, 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 System 550 training.

How to use this manual

Before you set up or operate the CDI System 550, 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 550 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 550**

  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 USA
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 550. You must read these warnings before using the CDI System 550. ▲**

➤ Caution

- Cautions contain important information about the operation and maintenance of the CDI System 550. Read these carefully in order to avoid any problems. ➤

Note: Notes contain information that help with the operation of the CDI System 550.

How the CDI System 550 works

The CDI System 550 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 Arterial and one Venous (Optional) 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 550 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 Terumo 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 550 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:

- **The shunt sensor accessory 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 sensor is heparin treated and should not be used with heparin sensitive patients. Devices with heparin treated surfaces may cause an adverse reaction.**
- **Use of the following substances can potentially cause inaccuracies in displayed values: Indocyanine green (Cardiogreen), Methylene Blue, or other intravascular dyes, carboxyhemoglobin or situations such as dyshemoglobins, hemoglobinopathies, elevated bilirubinemia and/or icterus (jaundice).**
- **Verify the accuracy of displayed values with another source (i.e. laboratory or point of care blood gas analyzer) before initiating treatment.**

▲Warning

- **Possible explosion hazard. Do not use the CDI System 550 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 ensure that such interference will not occur, care must be taken in the selection of computer equipment or printers to be interfaced with the CDI System 550 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 modify this equipment without written authorization from the manufacturer.**
- **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.**
- **When Methylene Blue or similar dyes have been used prior to or during cardiopulmonary bypass, independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions. Readings obtained from the CDI System 550 for the following parameters should not be relied on to make therapeutic decisions when Methylene Blue has been used: pH, K^+, Base Excess, Bicarbonate, Oxygen Delivery, Oxygen Saturation, and Oxygen Consumption.**
- **Blood conditions such as hemoglobinopathies, thalassemia, and 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 550 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 Terumo CDI Shunt Sensor requires a minimum of 35 ml/min. Restoration of blood flow above the minimum through the CDI Shunt Sensor or the Terumo 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.**
- **Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions whenever intravascular dyes are administered or when dyshemoglobins or elevated bilirubin levels are present.**
- **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 with pH less than 7.0 or greater than 7.8 pH units can interfere in the accurate measurement of potassium.**
- **Exposure of the shunt sensor to prime solutions and/or blood with sodium measurement less than 120 or greater than 160 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 inhibit the system from achieving 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 after the initiation of cardiopulmonary bypass and when conditions are stable, 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 550 screen to indicate that the values are not accurate until an initial in vivo calibration is performed.**
- **After changes of blood temperature of > 6°C, the user must repeat an in vivo calibration of shunt sensor values once temperature stability has been achieved. Optimal system accuracy will be maintained by this practice.**
- **The temperature measured by the shunt sensor is local to the sensor and does not reflect the actual patient arterial or venous blood temperature. Do not use this measurement for patient management.**
- **To avoid risk of electrical shock and 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. ▲**

➤ **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.
- 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.

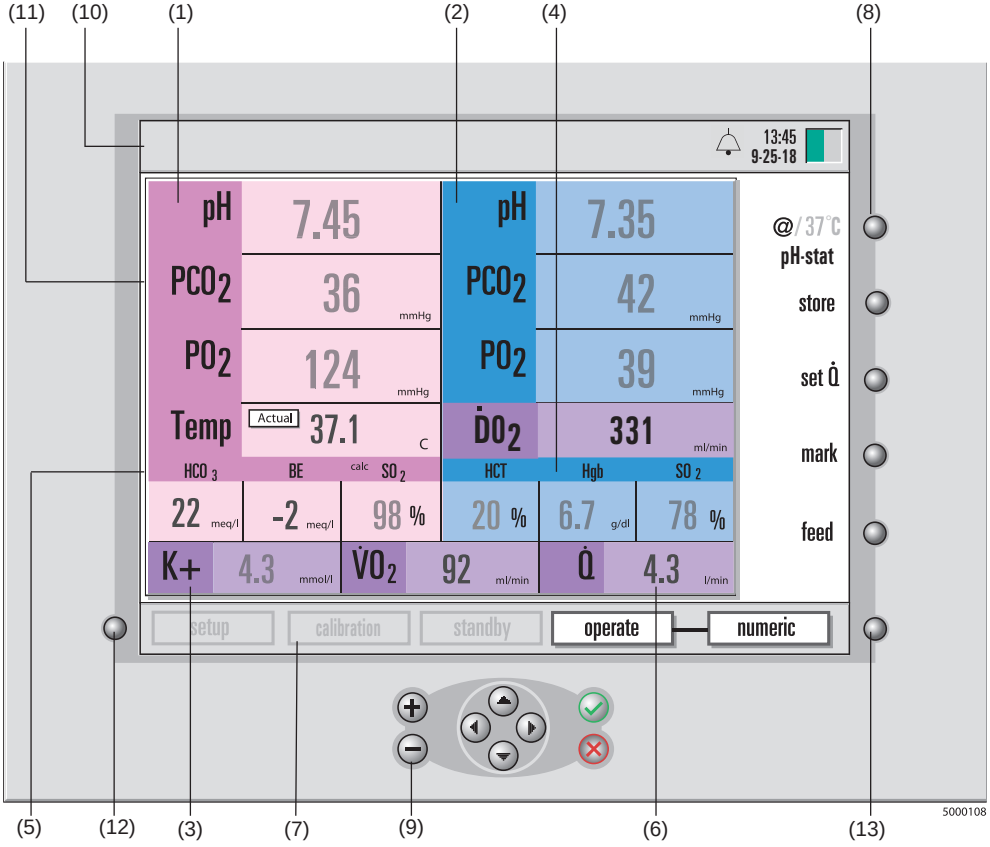
  The accuracy of the results is dependent upon the following:

  - 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 ➤

CDI System 550 components

Monitor

The next figure shows the front panel of the monitor (with $\dot{D}O_2$ enabled).
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 pink). 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/L.

(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/L. 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/L), bicarbonate (mEq/L), arterial oxygen saturation (%), oxygen delivery (ml/min or ml/min/m^2), 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, and Oxygen Delivery is entered either manually or through a pump connected to the CDI System 550's pump interface port.

(7) **System map.** Includes the labels for the different modes (setup, calibration, 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.

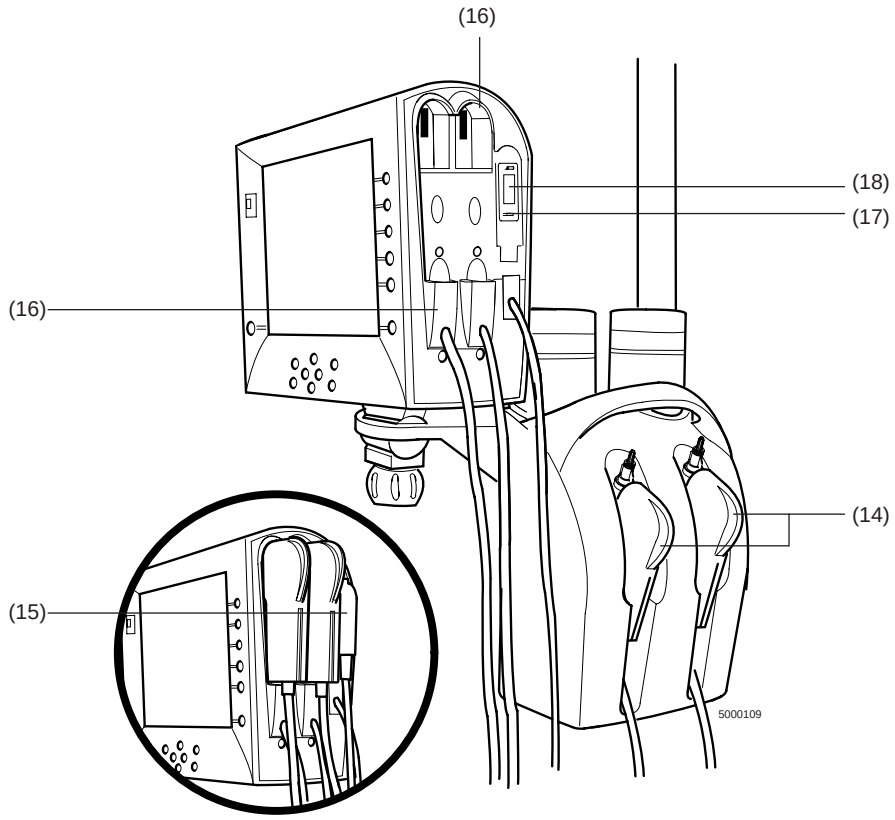
(10) **Message bar.** The area that displays current system status and alarms (above the parameter display window).

(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.

➤ **Caution**

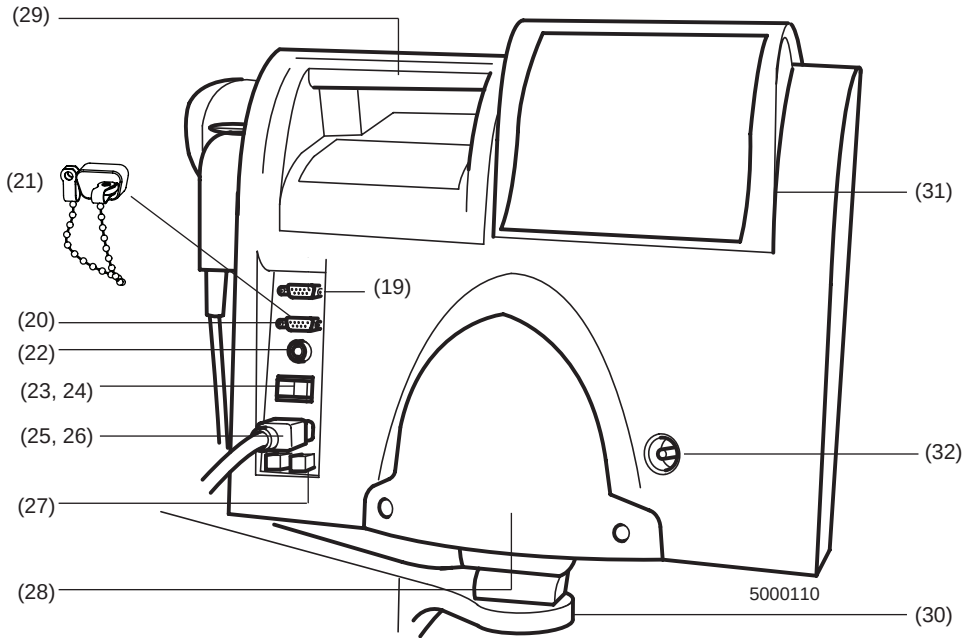
Do not stare directly into the light generated by the BPM LED. ➤

(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. This port is a low voltage communication port and is configured for data transmission. Application of voltages greater than 5 Volts will damage the monitor.

(20) **Pump interface port.** Allows the input of blood flow data from a Terumo System 1/CDI Interface Module (Terumo), Sarns 8000 Communications Module (Terumo), Sarns Centrifugal Pump (Terumo), BioConsole® 550/560 (Medtronic), S5/C5 (LivaNova/Sorin/Stöckert), HL 20/Rotaflow Console (Maquet/Jostra), NEO System (Terumo).

(21) **Protective cap for pump interface port.** Reduces the risk of ESD interference when the pump interface port is not in use.

(22) **Calibrator cable port.** The receptacle for attaching the Terumo CDI Model 540 Calibrator.

(23) **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.

(24) **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.

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

(26) **Power cord.** The CDI System 550 hospital grade AC power cord.

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

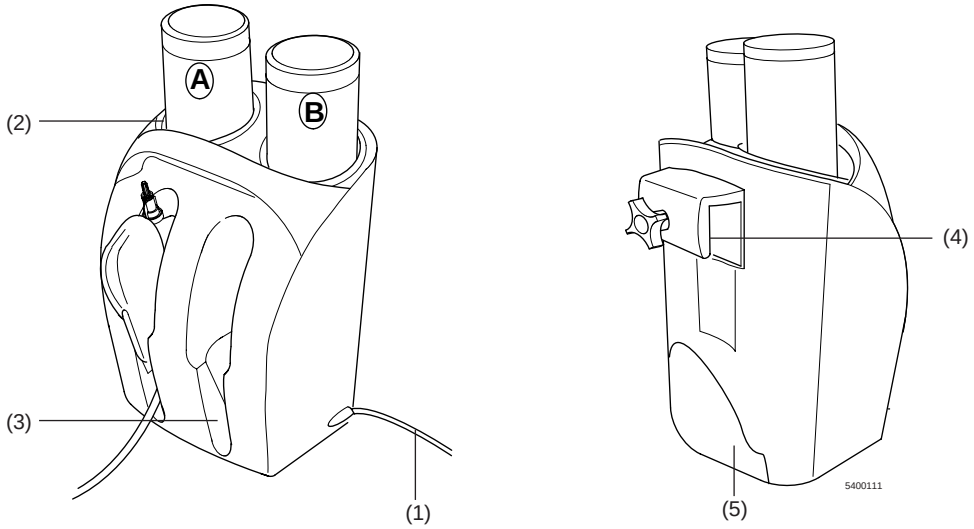
(28) **Cable guide.** Excess cable can be wrapped here for convenient storage when not in use or during transport of the monitor.

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

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

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

(32) **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 550 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 (Terumo CDI Model CDI506):	**Gas B** (Terumo CDI Model CDI507):
CO_2: 7.5 +/- 0.1%	CO_2: 2.8 +/- 0.1%
O_2: 27.5 +/- 0.1%	O_2: 4.0 +/- 0.1%
N_2: Balance	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

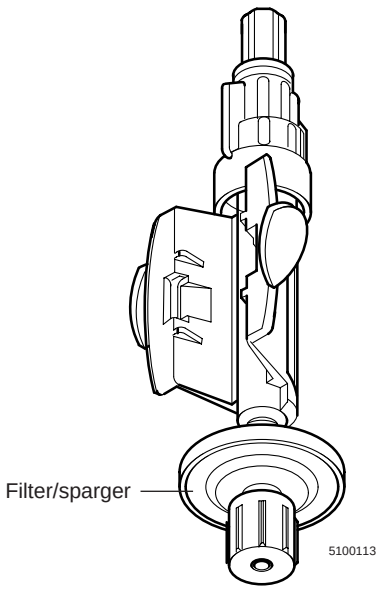
- Check the expiration date on the gas bottles before use. Use of the calibration gas bottles after expiration may result in inaccurate calibration. ➤

Terumo 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.

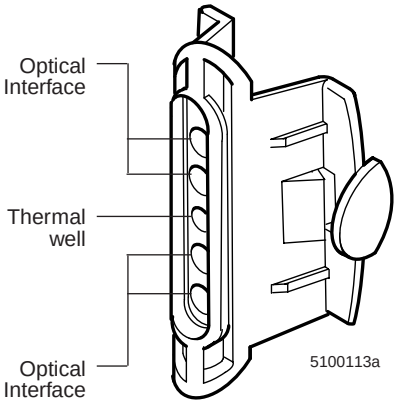
The heparin-coated, sterile CDI Shunt Sensors, Model CDI510H, are intended for placement into shunt lines, purge lines, sampling lines, shunt bypass lines, or any similar line that has blood flow. A minimum flow requirement of 35 ml/min is necessary for proper measurement.

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.



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 microsensors 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.



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.**

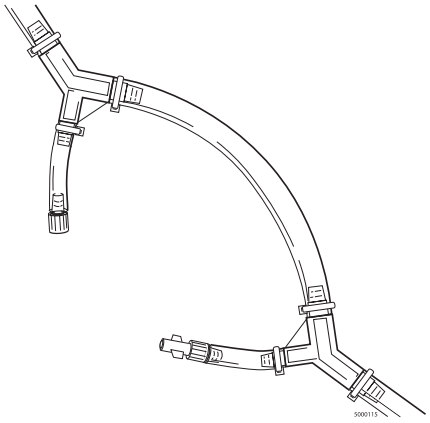
- **Elevated levels of blood substances including irregular cell morphologies, protein levels, plasma free hemoglobin and bilirubin may interfere with blood measurements. Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions.**
- **Independent external blood gas and blood chemistry analysis is required for accurate determination of all measured parameters needed to guide therapeutic decisions whenever intravascular dyes are administered or when dyshemoglobins or elevated bilirubin levels are present.**
- **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 550 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 ml/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

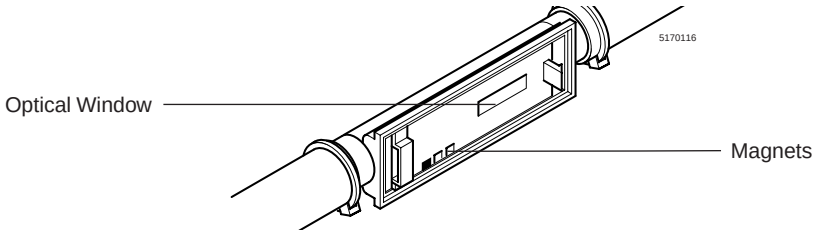
- For single sterile shunt bypass line assemblies. Do not use the shunt bypass line after the date printed on the package label. Use beyond the date may result in inaccurate performance.
- The shunt bypass lines, which are supplied sterile, will remain so as long as the package is unopened and undamaged.
- Secure all connections on the shunt bypass line with stay straps. ➢

Terumo 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.



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.

▲Warning

- **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 measure 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. ▲**

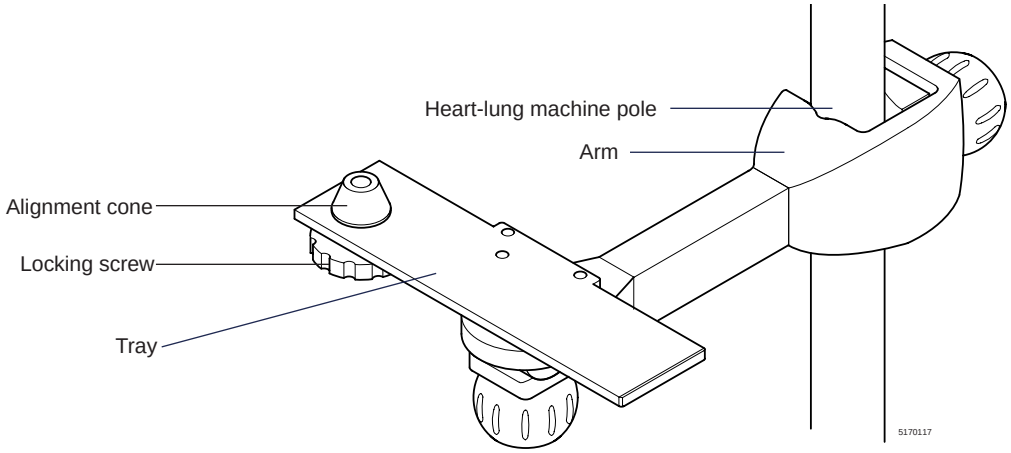
➤ Caution

- 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. ➤

Terumo 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.

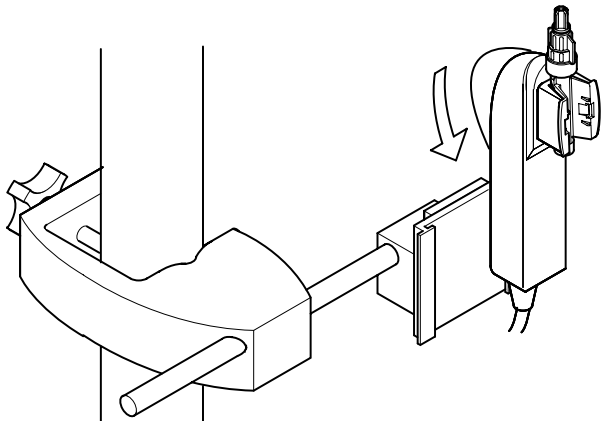


▲ Warning

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

Terumo 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.



This chapter gives a brief overview of the steps involved in setting up and using the Terumo Cardiovascular Systems CDI Blood Parameter Monitoring System 550. 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 550 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 setup 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 Option: 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.

8 Manually route cables such that they do not present a tripping hazard during operation of the CDI System 550.

Calibration

See Chapter 5 for calibration 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 "calibration" 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.

Note: Do NOT squeeze the plastic "wings" on the sensor.

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.)

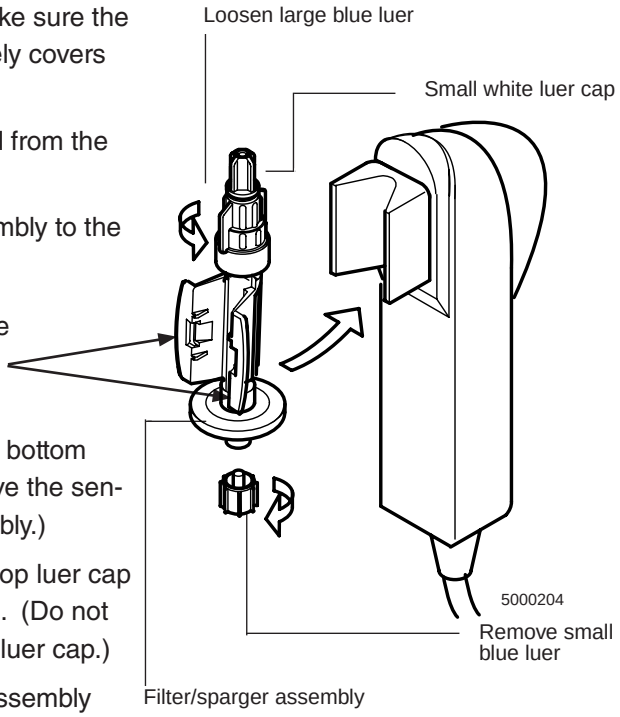
11 Place the cable-head assembly into the calibrator pocket.

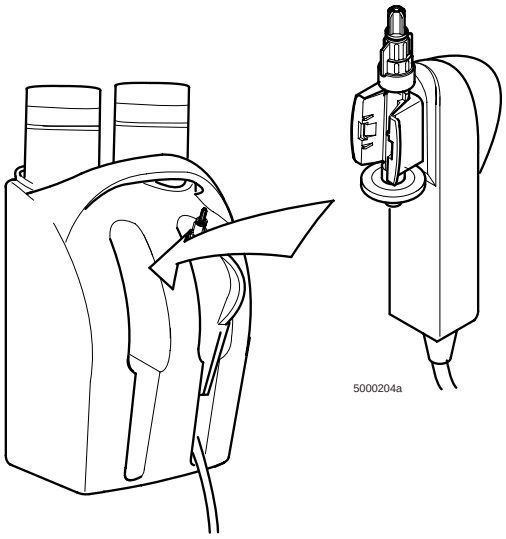
12 If the user is calibrating another sensor, repeat steps 6-10 for the second sensor.

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.





Installation

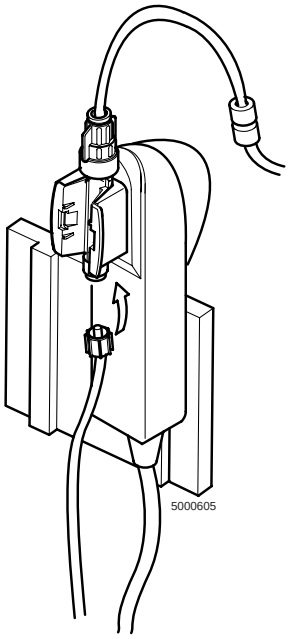
See Chapter 6 for installation warnings and more details on installation.

1 If the Terumo 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.



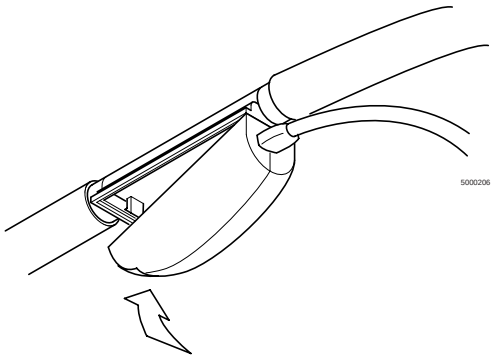
4 If you are using a shunt bypass line, install the CDI Shunt Sensor into the shunt bypass line using aseptic technique:

- 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), 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.



Operation

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

1 Set the monitor to “Operate” mode.

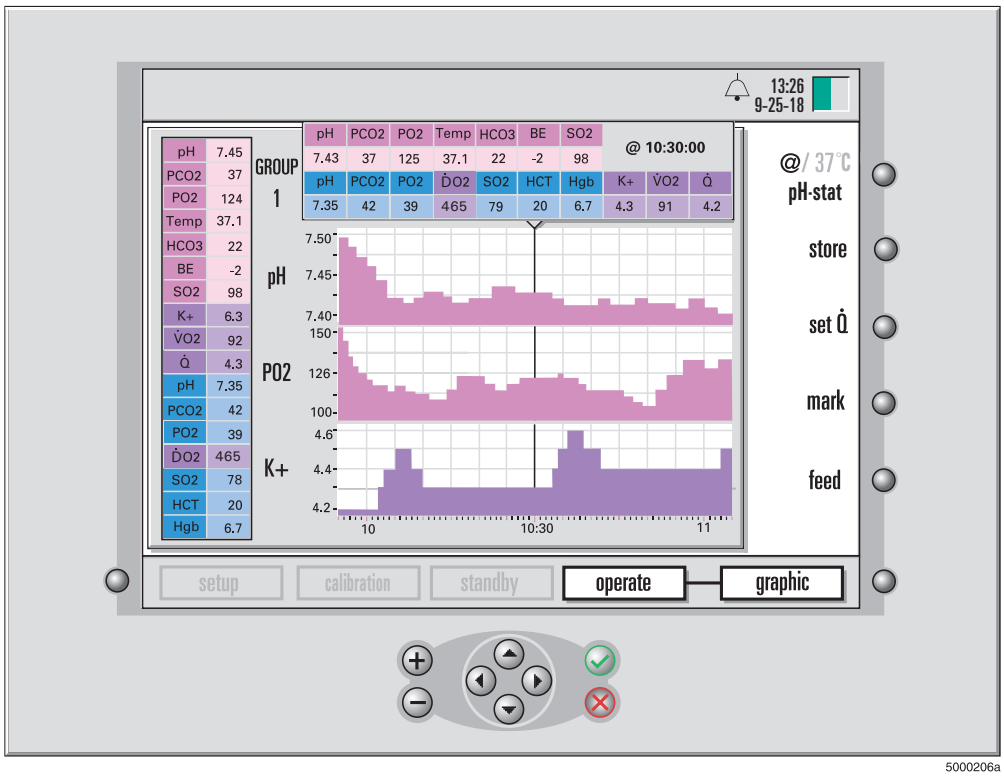
▲ Warning

Measured values prior to initial 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, and 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.



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Conclusion of case

See Chapter 8 for cautions and 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.

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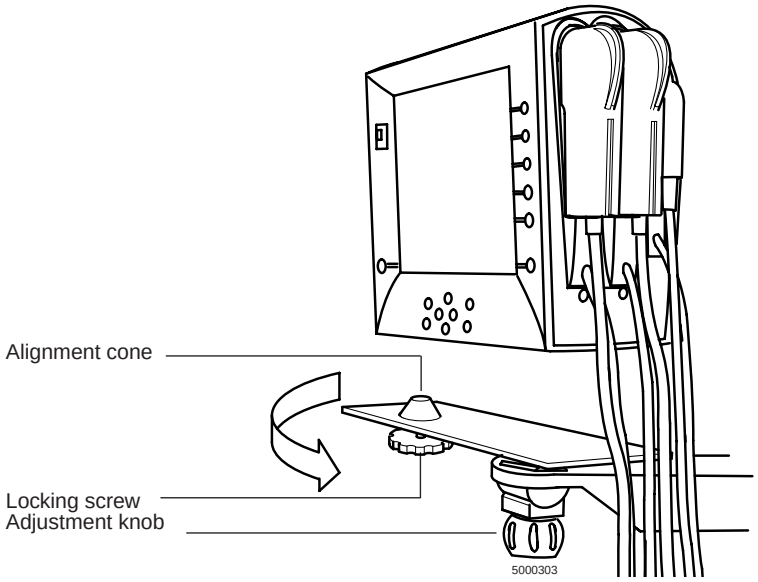
This chapter explains how to set up the Terumo Cardiovascular Systems CDI Blood Parameter Monitoring System 550 Monitor, printer, and Terumo CDI Model 540 Calibrator, and describes the process of powering up the monitor.

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 550 Monitor to the tray of the monitor pole clamp. Place the monitor on the tray, positioning it correctly on the alignment cone, then pushing 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.



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 550. 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.

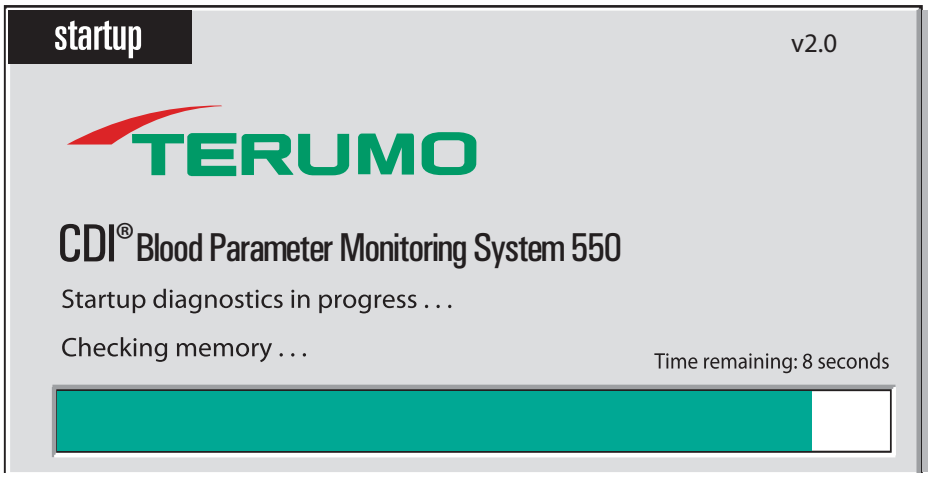
Turning on the monitor

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 550.

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.
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.
The startup sequence begins, and the following display appears:

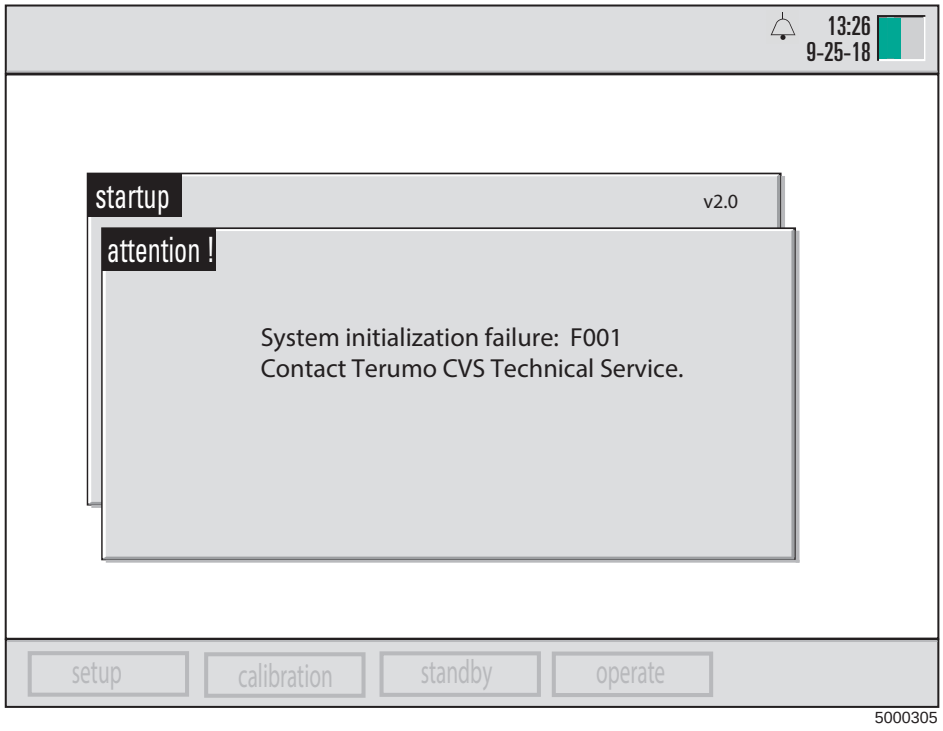


The system diagnostic testing takes about 40 seconds. During these diagnostics, the BPM self-test(s) and/or a CDI H/S Probe self-test are completed.

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

An audible tone shall be heard upon startup.

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



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 Terumo 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 Terumo Technical Service for assistance.

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

Note: If upon power-up, an extended audible alarm sound and/or the display remains blank, contact Terumo 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 CDI® 550

Blood Parameter Monitoring System

Date: 09/25/2018
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.

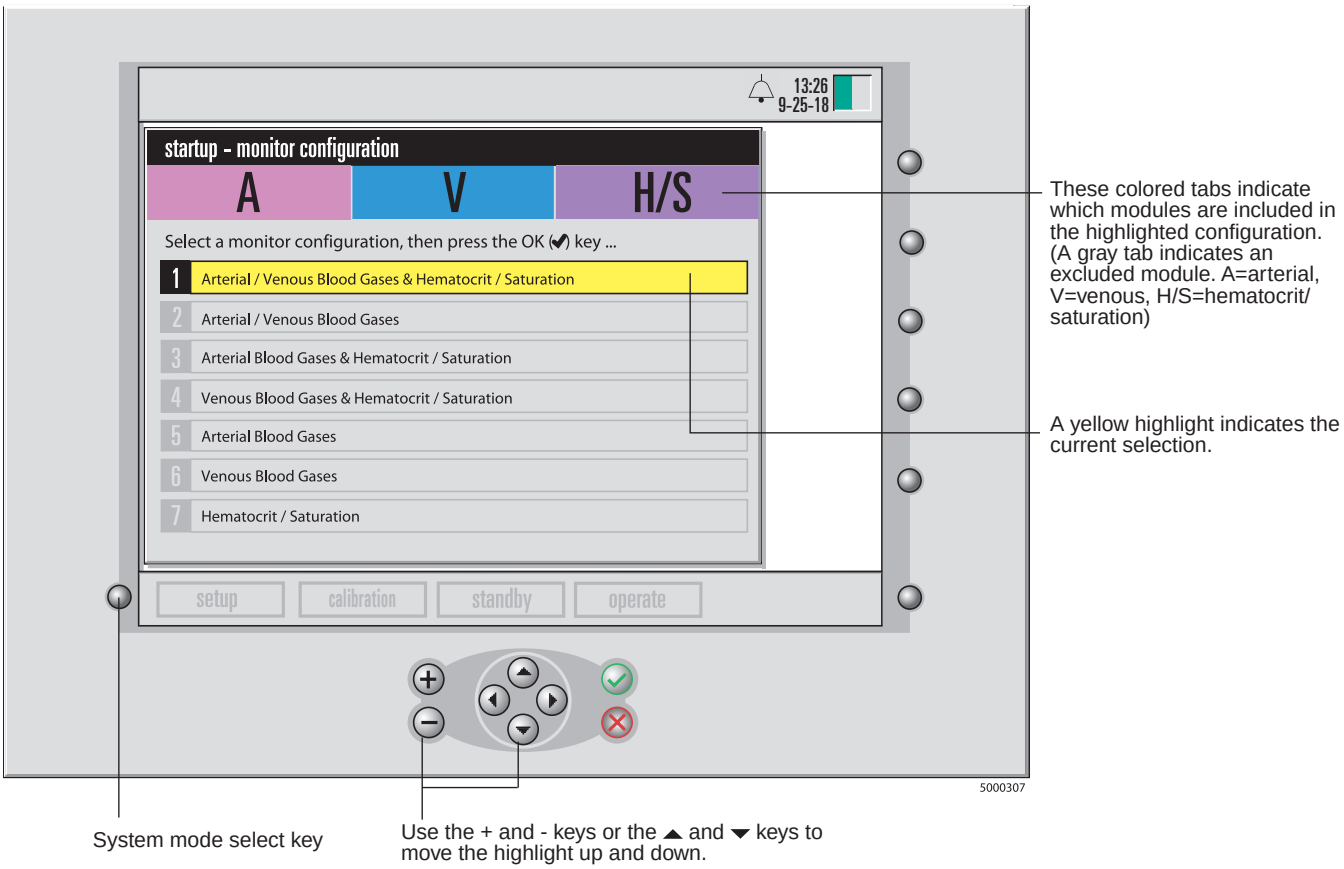
Note: The dimmed configurations indicate the required hardware is not available on your system for that particular configuration. Therefore the dimmed configurations cannot be selected.

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.



Note: If any module self-tests 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

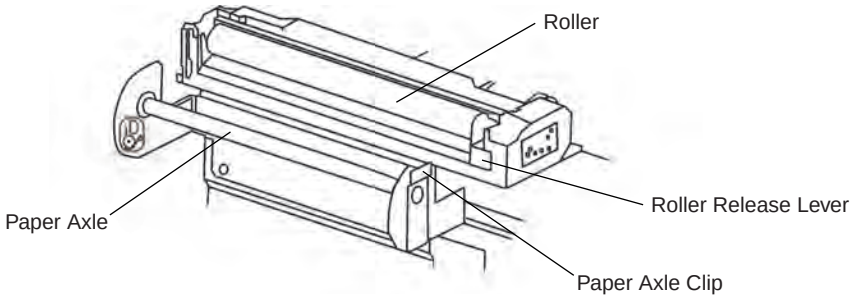
To load the printer paper into the Printer, follow these steps:

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 Terumo 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 (77°F) and 65% relative humidity.

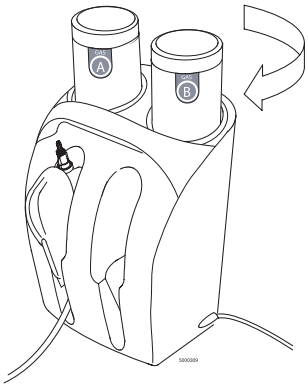
Preparing the calibrator

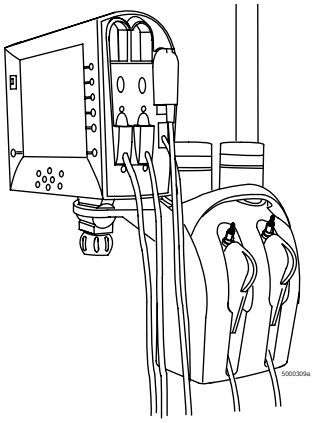
To prepare the Terumo CDI Model 540 Calibrator to perform a tonometered calibration of the sensors, you need the CDI Model 540 Calibrator, one Terumo CDI Gas A bottle (Model CDI506), and one Terumo CDI™ Gas B bottle (Model CDI507).

To install the gas bottles in preparation for calibration:

1 Connect the calibrator cable to the calibrator cable port on the back of the CDI550 monitor by aligning the red dots.
2 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.
3 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.
4 Remove the caps from the calibration gas bottles.
5 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.
6 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: Terumo 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:

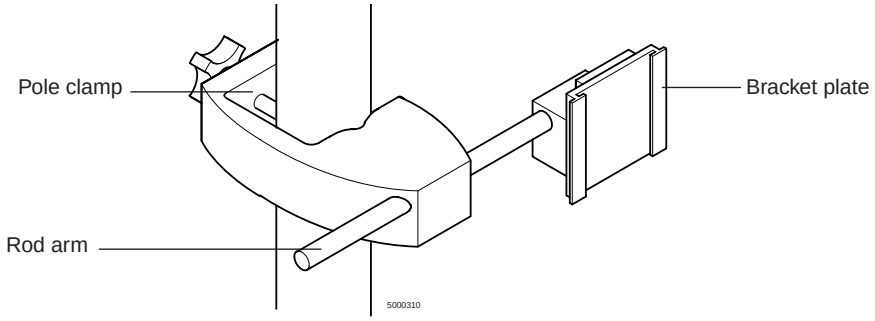
1 Make sure all residual gas is out of the bottle. For gases or mixtures containing less than 21% oxygen, this should be done in a well ventilated area to avoid asphyxiation by displacement of oxygen.

2 Remove or obliterate markings which indicated the cylinder contains hazardous material.

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.

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This chapter explains how to choose system settings — settings that customize your Terumo Cardiovascular Systems CDI System 550 for the way you plan to use it. You choose these settings on a series of numeric setup tabs that appear on the Terumo CDI System 550 Monitor. Here's a list of the setup tabs and a brief description of what you do with each one (the details are in the sections that follow):

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

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

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

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

5 **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.

6 **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.

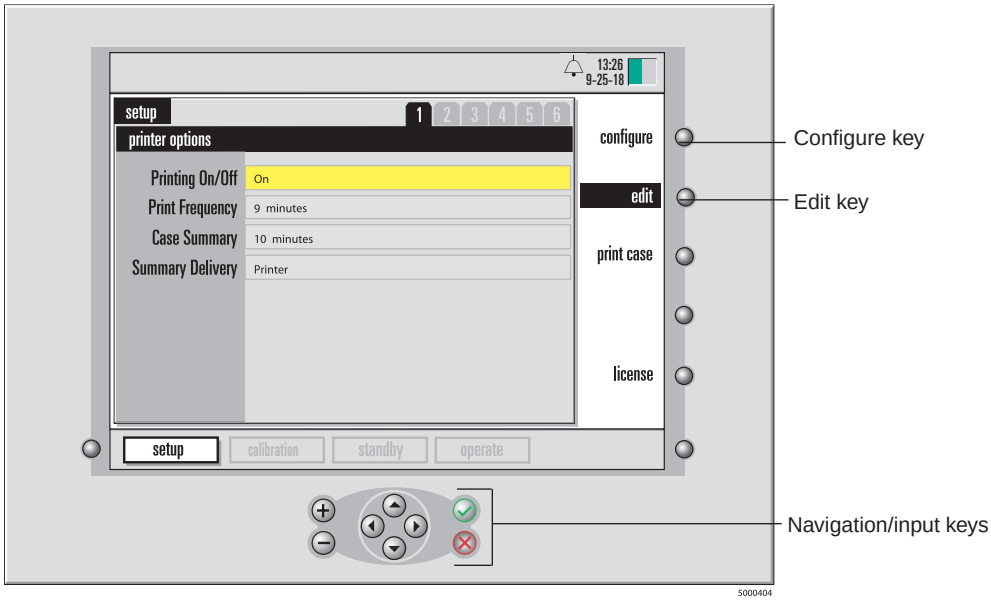
Selecting options on the setup screens

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.

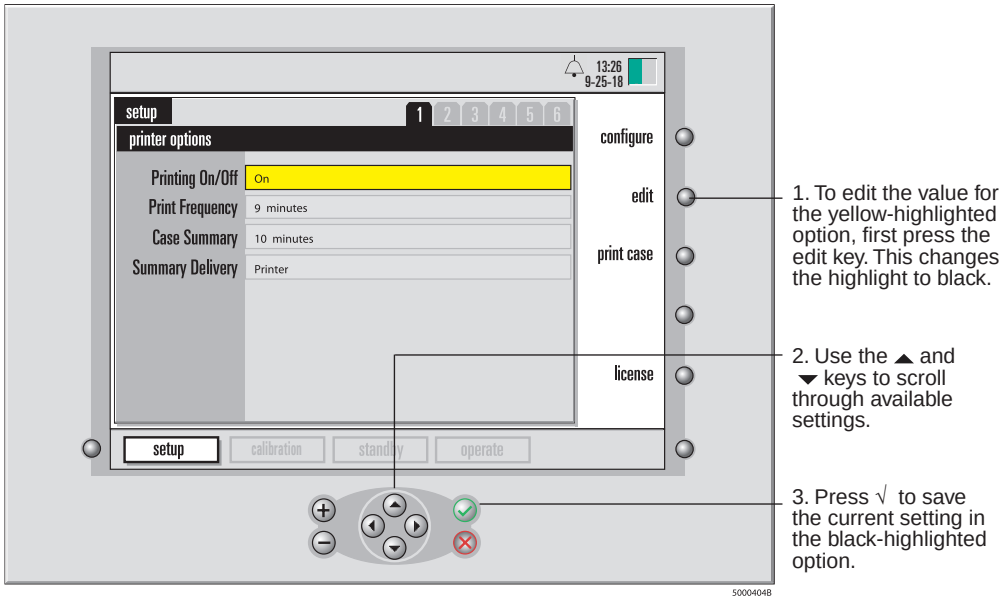
- When you've selected and confirmed all your choices on a screen, you can move on to the next screen by pressing the ▸ key.

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).



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.



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 one 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. Regardless of where the case summary is sent, the printing On/Off option must be set to "On." ***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 Terumo CVS. Use the ▲ and ▼ keys to view the entire license agreement.

System Notifications

System notifications consist of physiological alarms and technical alarms (status and error messages) and information messages. Physiological alarms are covered in detail in the next Section, "Setting Alarms". Technical alarms concern medium priority equipment and system issues that may require an operator response to resolve. A list of technical alarms can be found in Chapter 9.

Physiological Alarms

The Physiological Alarm System consists of audible and visual alarms to inform the user when monitored physiological parameter values are out of range. The specific parameters monitored are dependent on the modules that are part of the System. The alarms are activated if any of the monitored parameters are outside of the selected alarm limit ranges. There is no inherent delay in the determination of an alarm condition.

The minimum and maximum values for each of the monitored blood parameters are initialized with manufacturer-defined default alarm limits when the product is first shipped to the customer as shown in the table below.

Manufacturer-Defined Default Alarm Limits

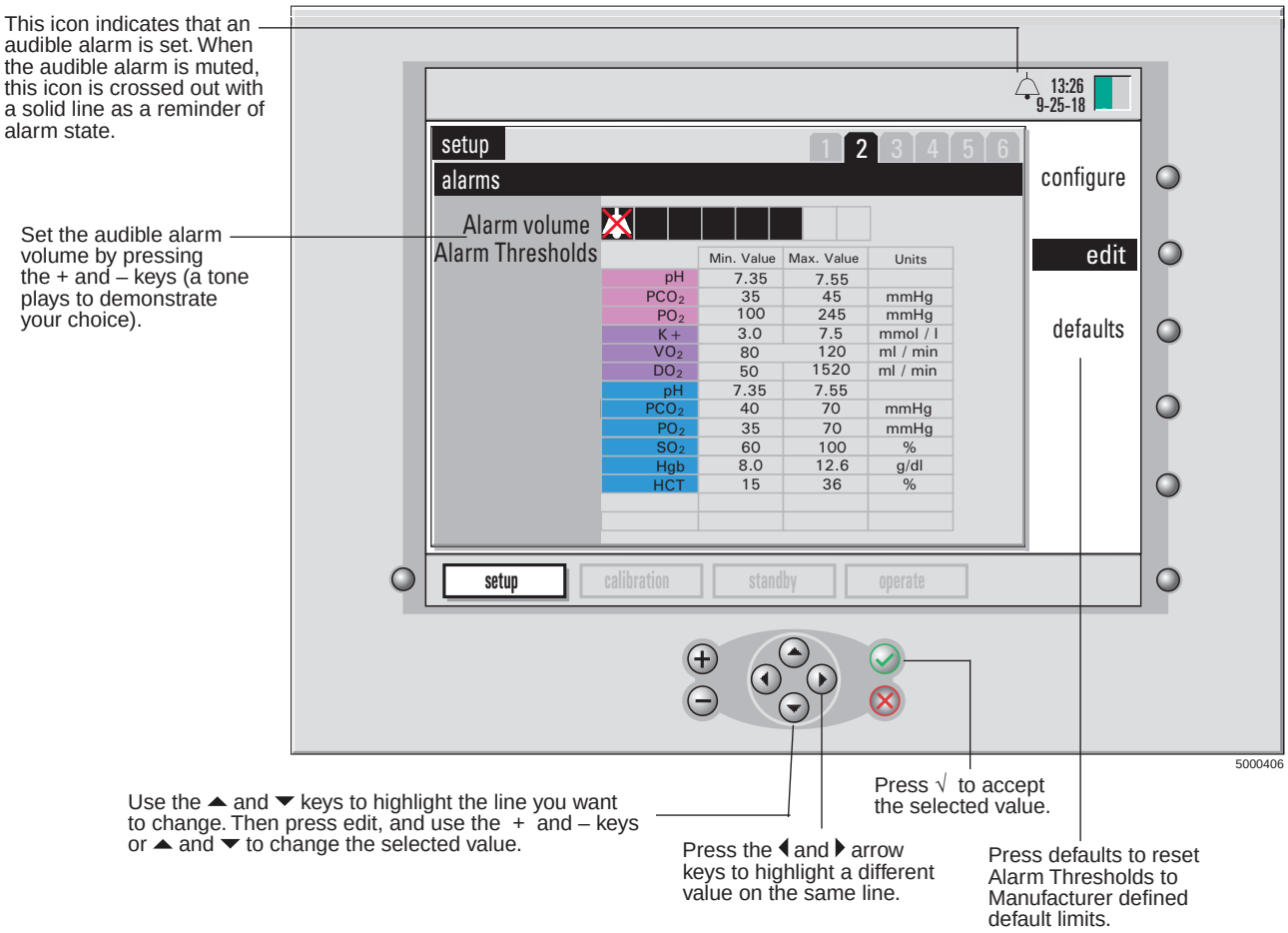
Parameter		Minimum Value	Maximum Value	Units
pH	Arterial	7.10	7.70	pH units
PCO_2	Arterial	30 (4.0)	55 (7.3)	mmHg (kPa)
PO_2	Arterial	85 (11.3)	500 (66.7)	mmHg (kPa)
K^+		3.0	7.0	mmol/L
$\dot{V}O_2$		20	400	ml/min
$\dot{D}O_2$		50	1500	ml/min
pH	Venous	7.00	7.70	pH units
PCO_2	Venous	35 (4.7)	60 (8.0)	mmHg (kPa)
PO_2	Venous	30 (4.0)	65 (8.7)	mmHg (kPa)
SO_2	Venous	60	95	%
HCT	Venous	24	38	%
Hgb	Venous	8.0	12.6	g/dl

The Manufacturer-defined default alarm limits have been determined to be medium or low priority based on the criteria described in Appendix B. The only low priority default alarm limits are associated with the $\dot{V}O_2$ parameter.

The manufacturer-defined default limits are derived from typical clinical values that occur during cardiopulmonary bypass where user intervention may be required. The Manufacturer-defined default limits are hard coded and cannot be changed.

The minimum and maximum values for each monitored parameter can be modified by the user as described below. Specific cases may require adjustment of these limits from the Manufacturer-defined alarm limits based on the clinical judgment of the user. The alarm priority does not change even if the alarm limits are changed by the user. The user should be aware that significant changes from the manufacturer-defined default limits may not be consistent with the priority alarm conditions listed in the Appendix B.

Setting Alarms



The second screen in setup mode — the alarms screen — allows you to set alarms 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 alarm that sounds when a patient's values fall outside the acceptable range.

Note: Operator should check that each current preset alarm threshold is appropriate prior to use on each patient.

Note: Although values outside the default ranges shown above may be displayed, the alarms limits can be set only within the maximum/minimum ranges in the table below.

Note: The lowest setting for the alarm volume is the mute setting indicated by a crossed out bell.

Note: The highest setting for the alarm volume is typically 53 dBa as measured at 1 meter from the monitor. The lowest setting for the audible alarm volume is typically 39 dBa as measured at 1 meter from the monitor.

Note: Press the button located next to the word "defaults" to reset alarm thresholds to the Manufacturer-defined default limits.

Note: The minimum and maximum values set will 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: No alarm is associated with HCO_3^-, BE, temperature and arterial SO_2.

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

Note: The CDI System 550 monitor is equipped with the capability to prohibit the user from muting the audible alarm through the use of a password in accordance with the international standard for alarm systems in medical electrical equipment.

The password makes the mute option available (crossed-out bell icon has a black background) or not available (crossed-out bell icon has a grey background). The setting is saved in the CDI System 550 monitor's memory and will remain until it is changed by the responsible person in the user's organization.

When muting is prohibited, the audible alarm can still be temporarily dismissed by pressing the X button in Operate Mode.

If the password protection feature is desired, contact Terumo Technical Service and instructions (Ref 878829) will be provided upon request. Instructions for the password are provided separately per the regulation.

If audible alarm muting is desired, it must be done prior to entering the Operate mode.

Note: The alarm settings are automatically stored into memory once the selections are confirmed.

The minimum and maximum values are provided in the table below.

Parameter		Minimum Value	Maximum Value	Maximum Resolution	Units
pH	Arterial	6.80	7.80	0.05	pH units
PCO_2	Arterial	10 1.3	80 10.7	5 0.5	mmHg kPa
PO_2	Arterial	20 2.7	500 66.7	10 1.0	mmHg kPa
K^+		3.0	8.0	0.5	mmol/L
$\dot{V}O_2$	(indexed)	1	994	1	ml/min/m^2
$\dot{V}O_2$	(non-indexed)	10	400	1	ml/min
$\dot{D}O_2$	(indexed)	1	20000	1	ml/min/m^2
$\dot{D}O_2$	(non-indexed)	10	2000	1	ml/min
pH	Venous	6.80	7.80	0.05	pH units
PCO_2	Venous	10 1.3	80 10.7	5 0.5	mmHg kPa
PO_2	Venous	20 2.7	500 66.7	10 1.0	mmHg kPa
SO_2	Venous	60	100	1	%
Hgb	Venous	5.0	15	0.1	g/dl
HCT	Venous	15	45	1	%

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 550 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.**

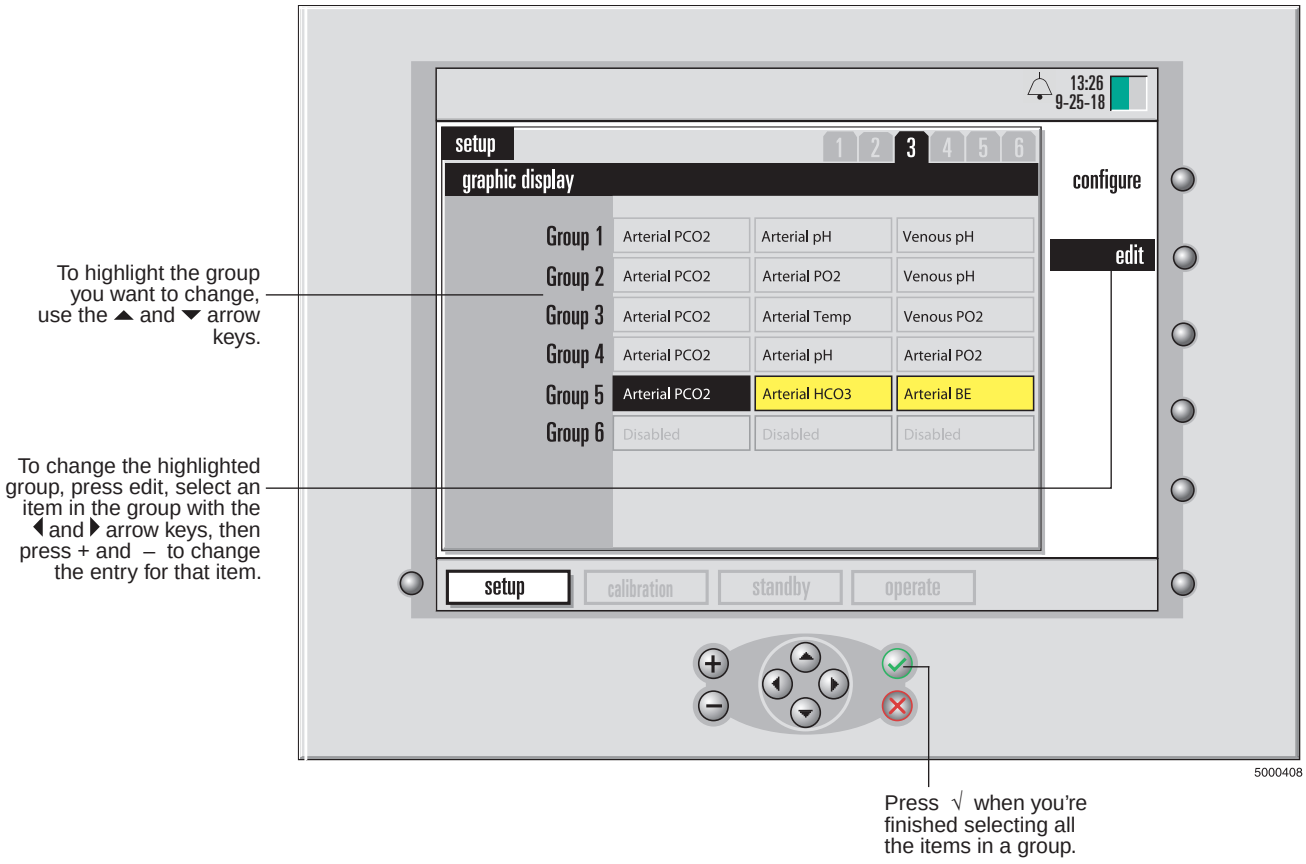
2 **Press edit.**

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.

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.

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



6 Repeat steps 1-5 for all the groups you want to set.

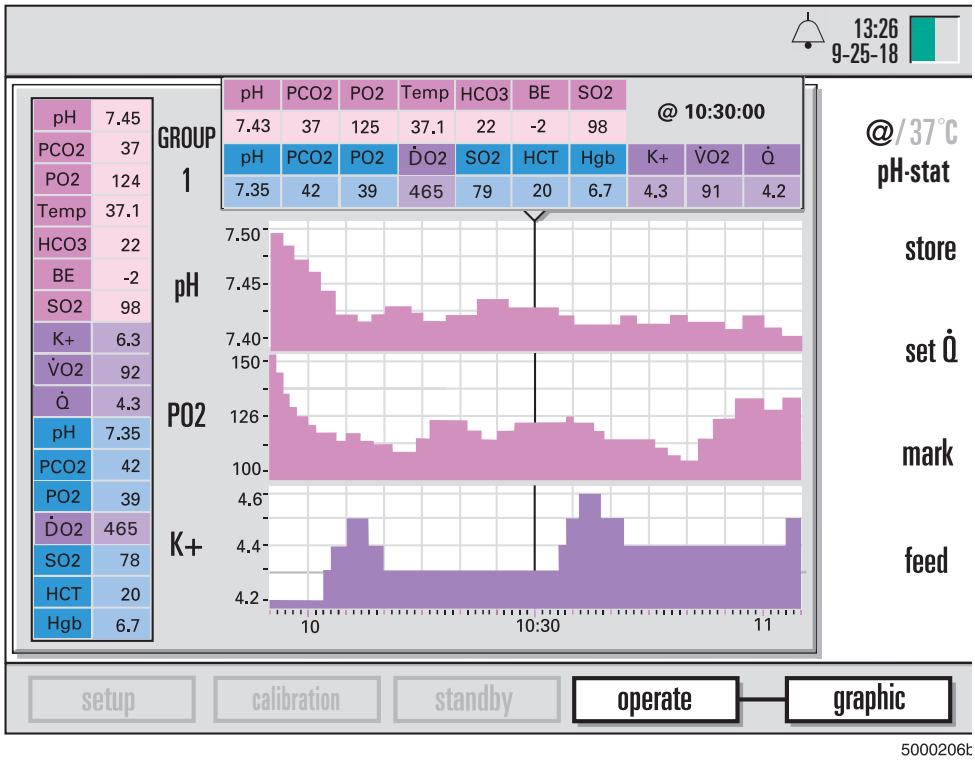
Depending on your chosen module configuration, you can select parameters available from the following group:

Arterial pH	Arterial PCO_2	Arterial PO_2
Arterial Temp	Arterial HCO_3^-	Arterial BE
Arterial SO_2	K^+	$\dot{V}O_2$
$\dot{Q}$	$\dot{D}O_2$	
	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.

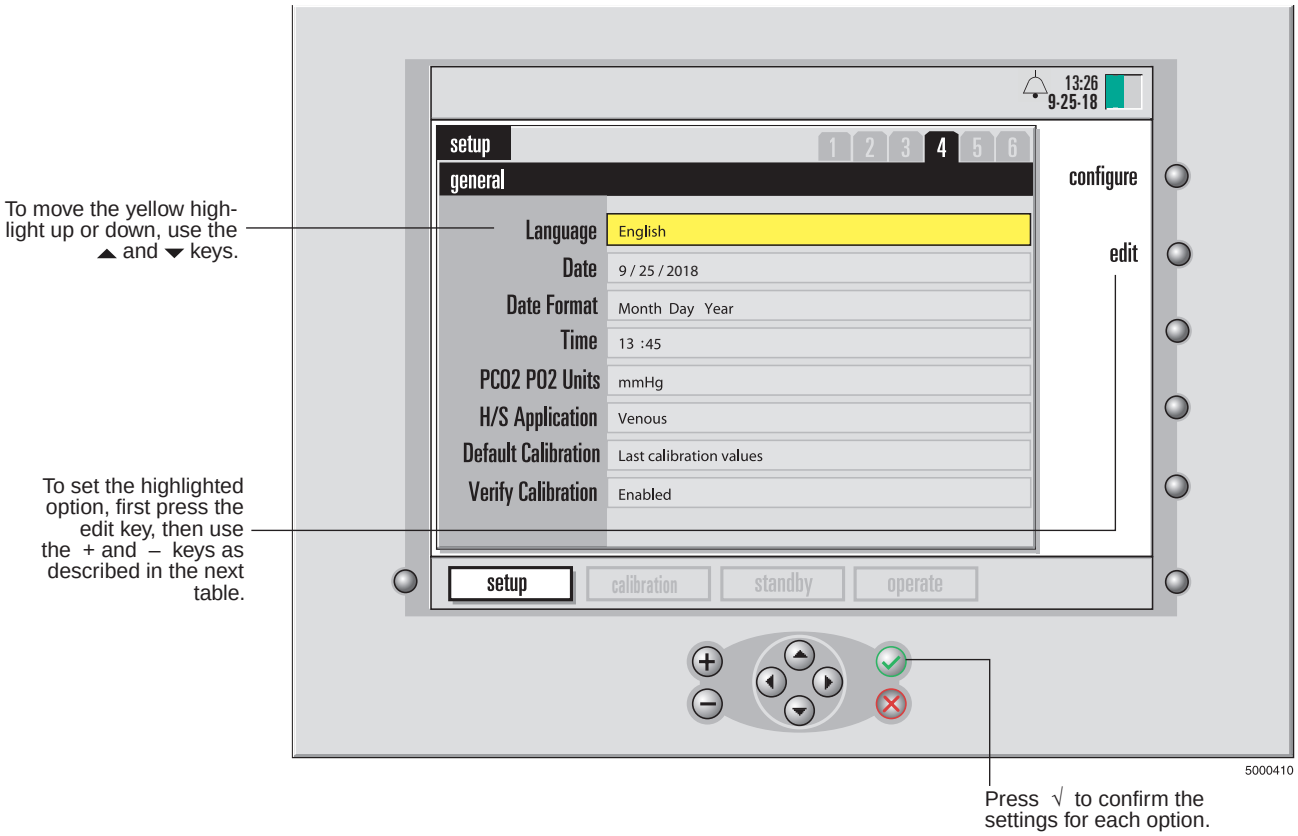
The following figure shows an example of bar graphs that display blood parameter values during an operation. The graphs make it easy to see the changes in the values over time. The graphed parameters are the ones you specify on the **graphic display** screen described above. During an operation, you 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).



The general options are:

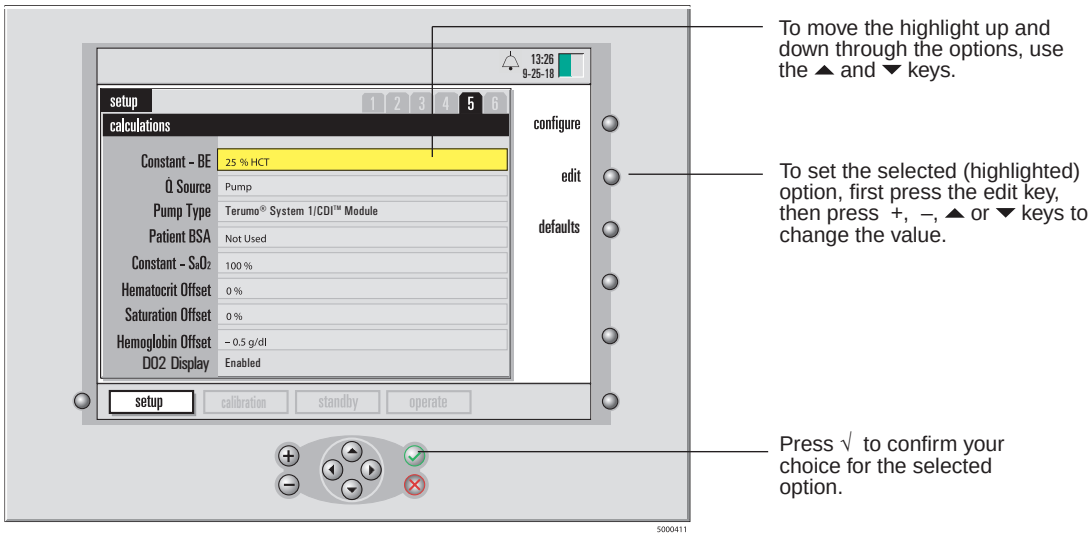
Language	Press the + and – or ▲ and ▼ keys to select a language. The choices are English, French, German, Italian, Japanese, Spanish, Swedish, Danish, and Dutch. ***Note:*** Once changed, the language setting will not take effect until the monitor is turned off and then on again.
Date	Use the ◀ and ▶ 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.
PCO_2 PO_2 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 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 check the 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.)



The following table explains the purpose and possible values for the settings on the calculations screen.

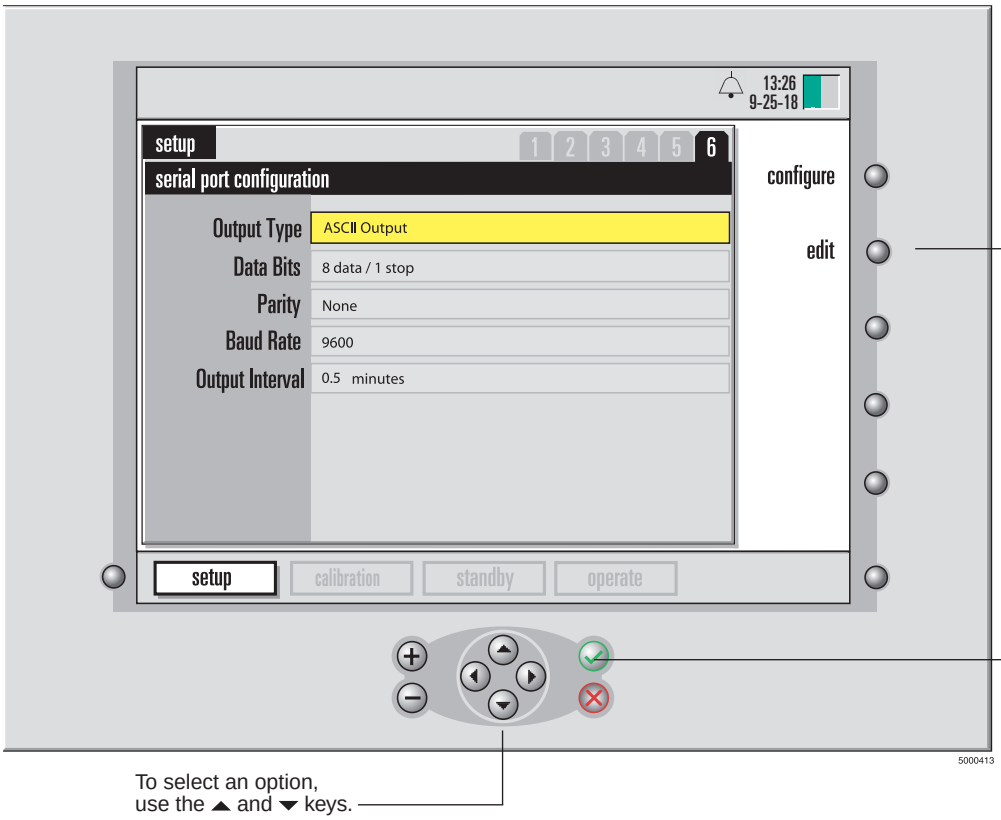
Constant - BE	Use the + and – or ▲ and ▼ keys to select a value between 10 and 47% Hematocrit. This value is used only for the calculation of Base Excess. The default value is 25%.
$\dot{Q}$ Source	Flow rate input source. Choices are None, Manual, or Pump (the default is Manual). Used in the oxygen consumption and oxygen delivery calculations (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, Terumo® System 1/CDI™ Module (Terumo), Sarns™ 8000 Communications Module (Terumo), Sarns™ Centrifugal Pump (Terumo), BioConsole® 550/560 (Medtronic), S5/C5 (LivaNova/Sorin/Stöckert), HL 20/Rotaflow Console (Maquet/Jostra), NEO System (Terumo)." The default is "Not Used" ***Note:*** If you select the (LivaNova/Sorin/Stöckert), S5/C5, 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 and oxygen delivery calculations. This value automatically resets to "Not Used" when you turn on the monitor.
Constant - SaO_2	Possible values are 50-100% in increments of 1%. The default is 99%. 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).
Oxygen Delivery	Possible options are Enabled and Disabled. The default setting is Enabled.

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 550. When values are entered for these offsets, they are stored in system memory. The offset is in effect until an in vivo calibration is performed. The offset is reinstated at the next power cycle. A message stating the current offset value prints when you enter Operate mode.

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 550 can send operational information and blood parameter values at a prescribed frequency or on demand.



To set the selected option, first press edit, then press + and – or ▲ and ▼ keys to change the value.

Press √ to confirm your choice for the selected option.

To select an option, use the ▲ and ▼ keys.

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

Output Type	Possible settings are "ASCII Output", "Terumo® Systems," or "Packet Mode."
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 550 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 "$\dot{Q}$ 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.**

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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 (Terumo) CDI System 550 Monitor, the Terumo 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. ▲**

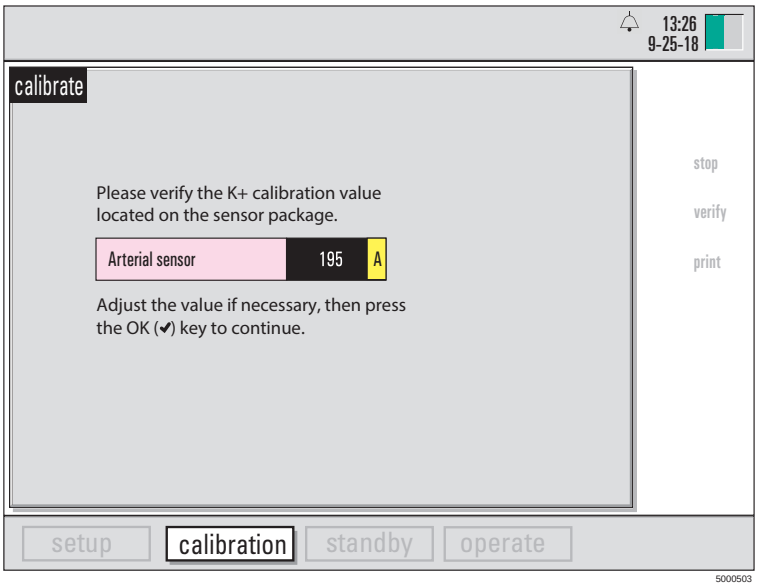
▲Warning

- **Failure to complete calibration as described in Chapter 7, Completing Calibration of the CDI System 550 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, and has been connected to the monitor, 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:

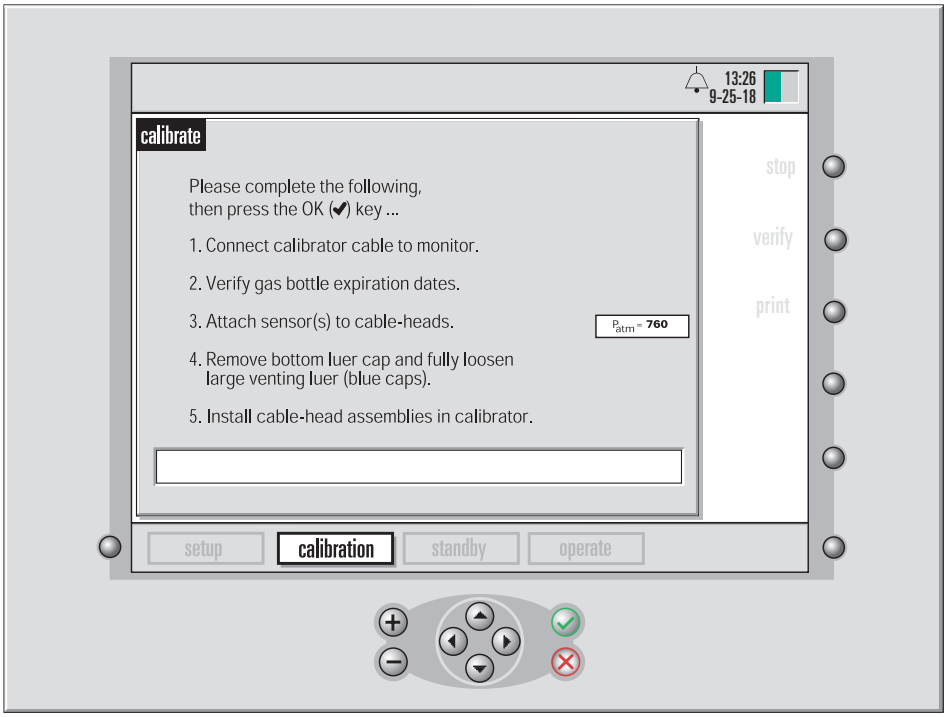


2 K^+ calibration value consists of a three digit number and a letter. Verify that the K^+ calibration value, from the sensor's foil pouch label, K^+ code matches what is shown on the screen.
If the calibration value on the foil pouch does not match the value on the screen, adjust the screen value by 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.

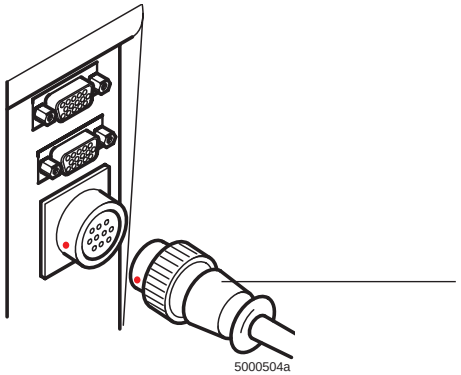
Press the √ when the calibration values match.

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.



5000504a

Connect the calibrator cable to the monitor by aligning the red dots on each of the connectors and pushing the calibrator cable connector onto the monitor connector.

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.

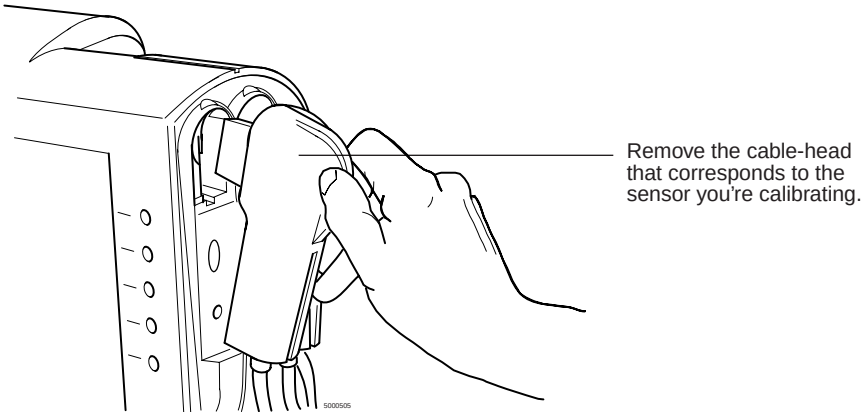
▲ Warning

- **Avoid touching the optical surfaces of the CDI Shunt Sensor and cable-head. 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. ▲**

➤ **Caution**

- 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 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.



7 Attach the sensor assembly to the cable-head.
See the figure after step 8.

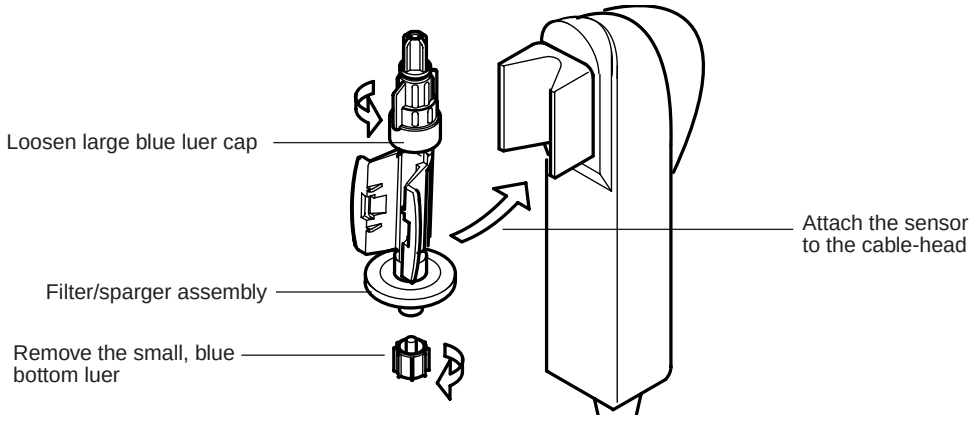
The sensor will snap securely onto the cable-head, and will fit only one way on the cable-head.

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. ▲**



10 Using sterile technique, fully loosen the large, blue top venting luer cap on the sensor(s).

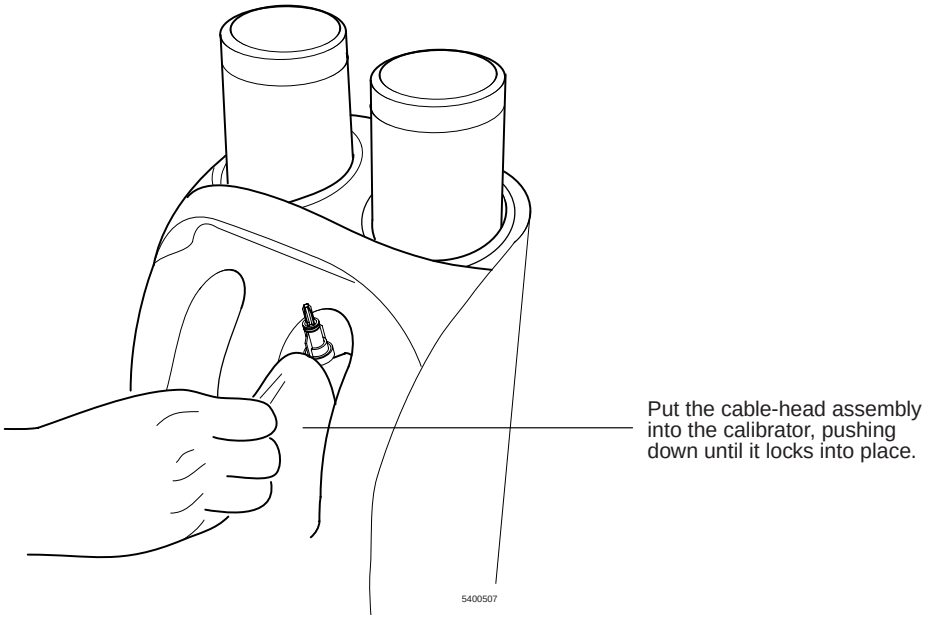
The cap will stay attached to the top of the sensor, allowing venting of the buffer solution without compromising the sterility.

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.



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.

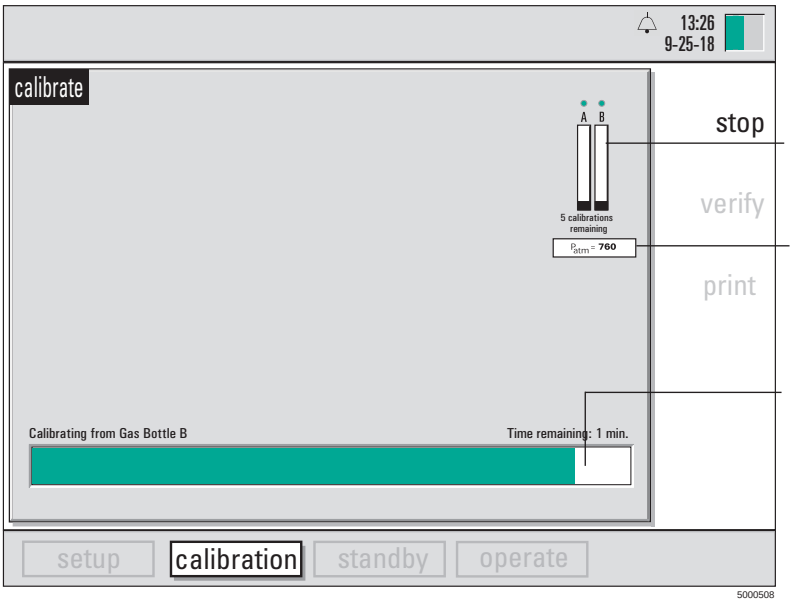
If no errors occur, the calibration proceeds and you see a screen like the one shown in the next figure.

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 CDI System 550 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.



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 550 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.

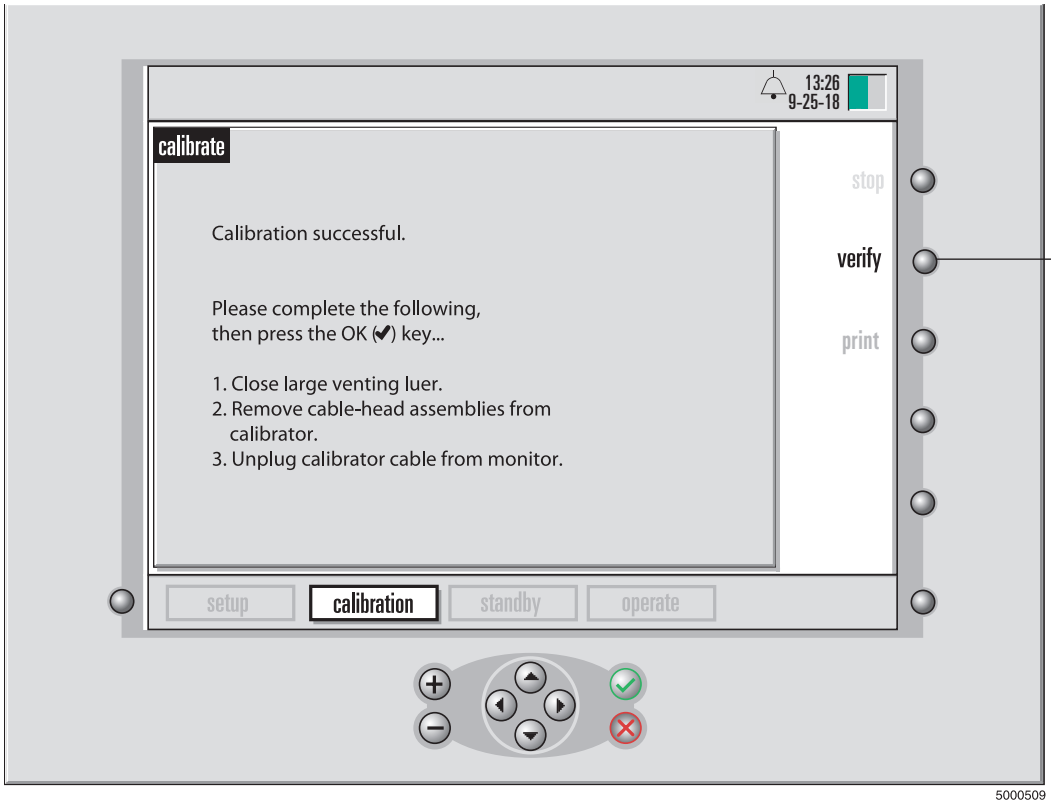
- If the last calibration values are suspect for any reason, it is recommended that you change the default setting to "Factory default values" before entering Operate mode.

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).



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. ▲**

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 550 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 is not available while the monitor is running on backup 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.

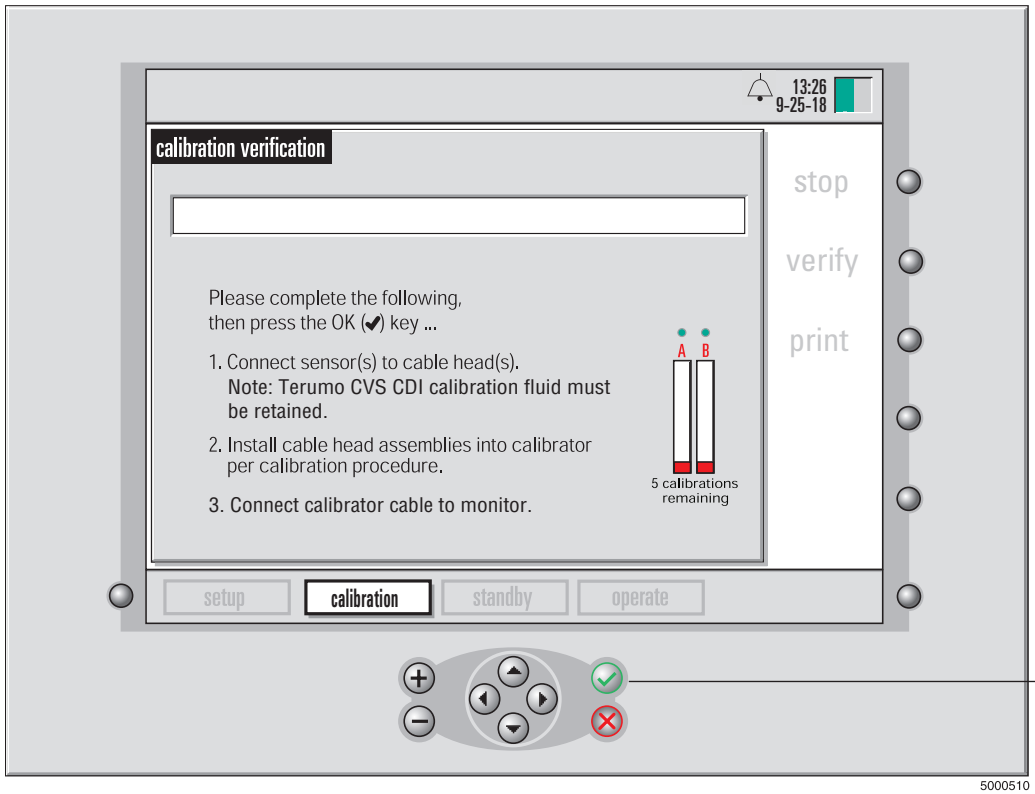
If you want to verify the calibration, follow these steps:

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.

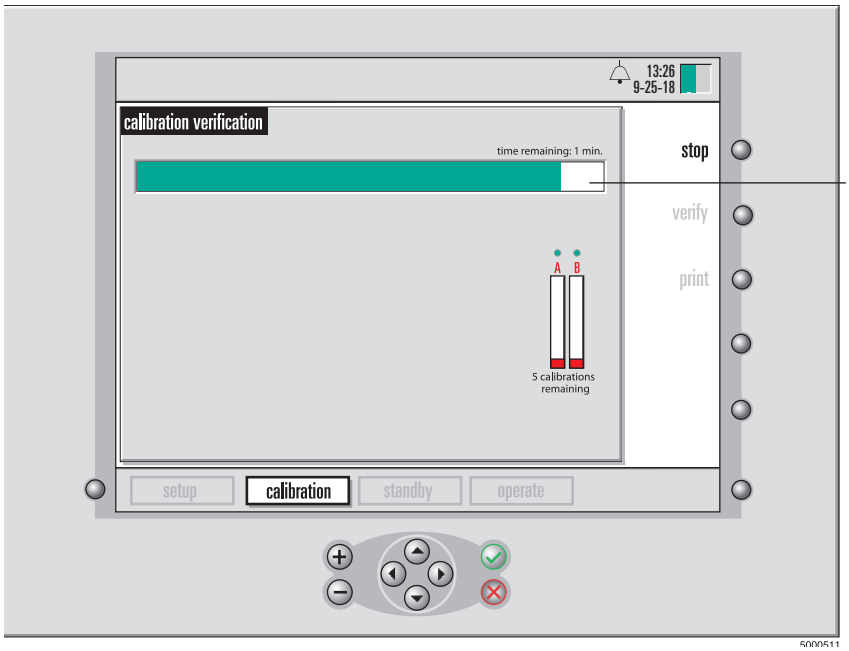
2 Press the “verify” key.

The following screen appears:



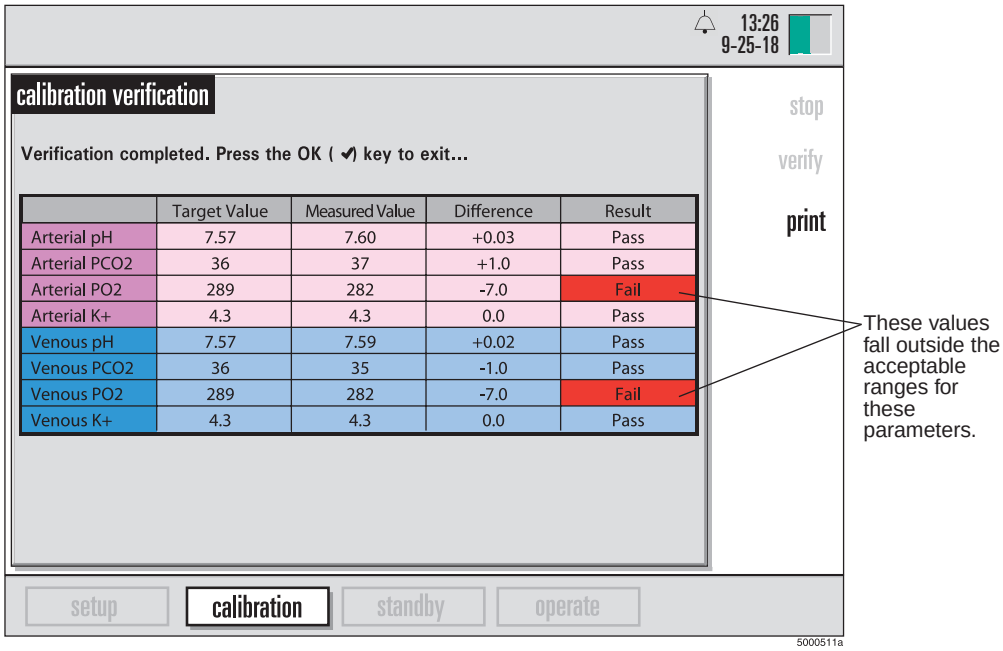
3 Press the √ key to begin the calibration verification.

The calibration verification takes about 5 minutes. The following screen appears during the process.



Note: At any time during calibration verification, you can press the stop key (in the upper-right corner of the monitor's front panel) to halt the calibration verification process. You can then resume calibration verification by pressing the √ (OK) key. If you run out of time and you need to abort the calibration verification, press the stop key. You can then press the cancel (X) key to exit and return to Standby.

When the calibration verification is finished, the results are reported:



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.
Note: Print soft key will be gray if the printer is disabled.

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 (Terumo) CDI Shunt Sensor(s) you're installing, Terumo CDI H/S Cuvette, and access to the bypass 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. If necessary, optical surfaces on the CDI H/S Cuvette and CDI H/S Probe can be cleaned with a soft, lint free cloth. ▲**

➢ **Caution**

- 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 Terumo 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 Terumo 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.
- Terumo 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. Terumo 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 up-stream 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.**

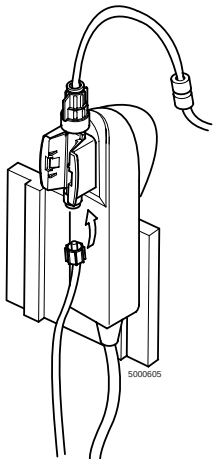
2 **Using sterile technique, remove the top luer cap (white) from the CDI Shunt Sensor and attach one end of the "shunt/purge" line to the top of the CDI Shunt Sensor. Make sure the large blue top venting luer is completely tightened.**

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

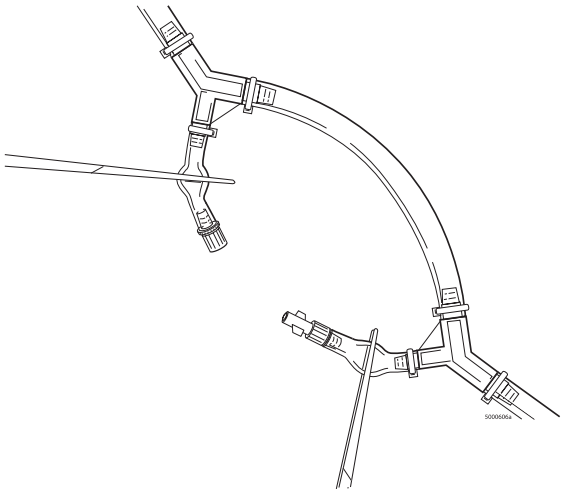
▲Warning

- **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. ➢

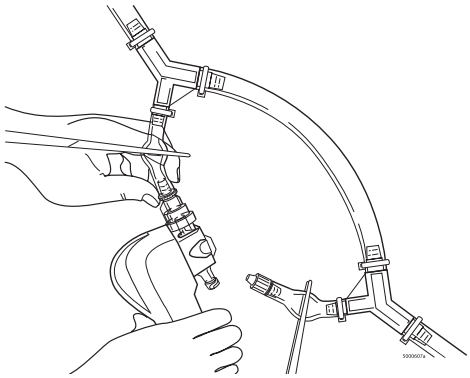
1 Stop the pump and/or clamp off the Shunt Bypass Line.



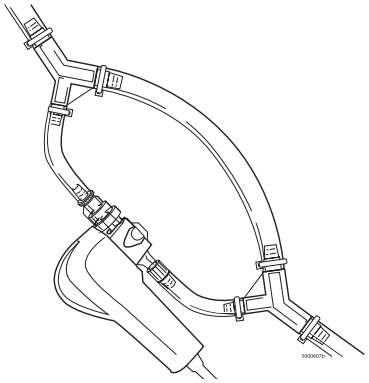
2 **Using sterile technique, remove the blue cap from the female luer end of the Shunt Bypass Line and the small top luer cap (white) from the top of the CDI Shunt Sensor. Attach the CDI Shunt Sensor to the female luer end of the Bypass Shunt Line.**

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. 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

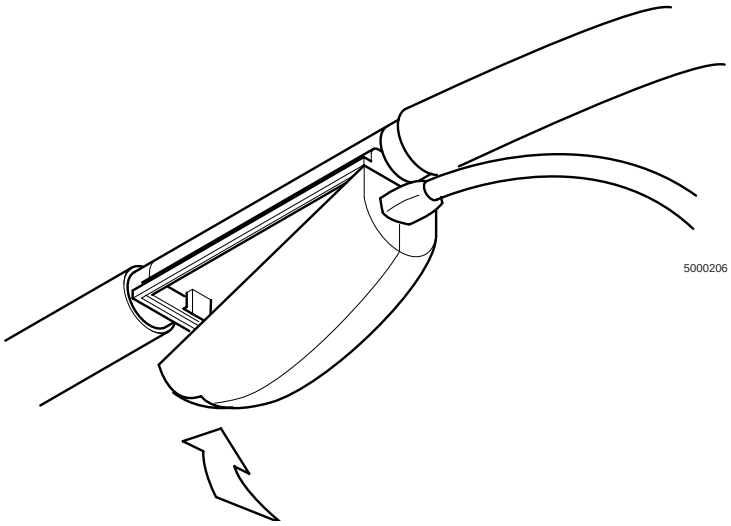
Follow these steps to attach the CDI H/S probe to the CDI H/S Cuvette for hematocrit, hemoglobin, and oxygen saturation measurement.

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.



▲ 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. If necessary, optical surfaces on the CDI H/S Cuvette and CDI H/S Probe can be cleaned with a soft, lint free cloth. ▲**

➢ 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 550.

Initiating "operate" mode

When you're ready to begin in-line measurement of blood parameters, set the CDI System 550 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 √.

Dashes appear for values that are out of the display range, which is located in Appendix B. In Numeric display mode, for a low priority alarm, if a value is outside the alarm limits specified on the alarms setup screen, a solid yellow box appears adjacent to the value with either a HIGH or LOW indication. In Numeric display mode, for a medium priority alarm, if a value is outside the alarm limits specified on the alarms setup screen, a flashing yellow box appears adjacent to the value with either a HIGH or LOW indication and an audible alarm sounds at the volume specified in the alarms setup screen.

▲ Warning

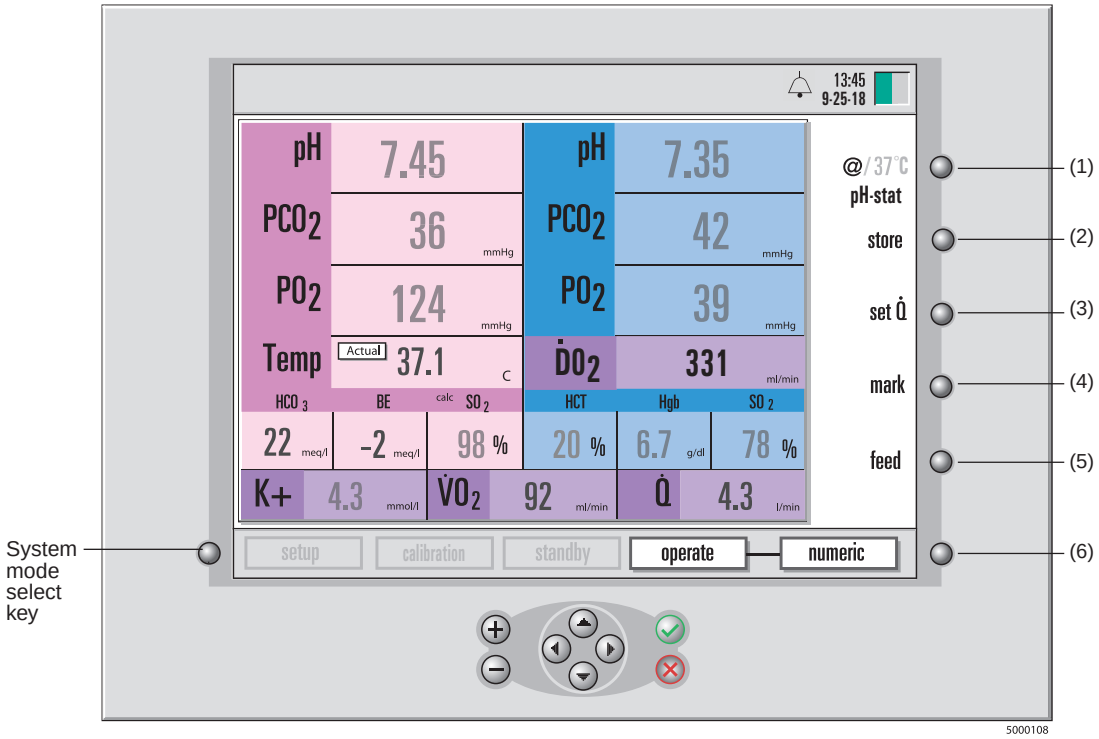
Measured values prior to initial in vivo calibration may not be accurate. Do not use values prior to initial in vivo calibration for patient management. ▲

Note: When an alarm is activated, an audible and visual alarm occurs. If the audible alarm is dismissed and a second alarm occurs, both an audible and visual alarm will be activated. Visual alarms indicating specific alarm conditions can be perceived at a distance of 1 meter from the front of the CDI 550 Monitor. No other intended position of the user with respect to the alarm signals is defined.

▲ Warning

- **Use of Halothane anesthetic will result in significant PO_2 inaccuracy.**
- **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 7.0 pH units 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 pH units. Exposure to acetate-containing prime solutions below 7.00 pH units for longer than a few minutes can cause significant PCO_2 inaccuracy.**
- **Exposure of the shunt sensor to prime solutions and/or blood with pH less than 7.0 or greater than 7.8 pH units can interfere in the accurate measurement of potassium.**
- **Exposure of the shunt sensor to prime solutions and/or blood with sodium measurement less than 120 or greater than 160 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.

Note: The screens in this manual reflect a particular configuration of modules ("Arterial/Venous Blood Gases & Hematocrit/Saturation") per statement on page 3-4. Only parameters that can be in vivo recalibrated will have numeric values that will be 'dimmed' prior to the completion of the recalibration process.

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 $\dot{Q}$.** You press this to enter the flow rate manually for the calculation of oxygen consumption and oxygen delivery. This key is available only if the "$\dot{Q}$ 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 550 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 values are dimmed on the screen until an initial in vivo recalibration is done.

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

▲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: 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: For calibrating the potassium sensor, and to ensure accuracy of the potassium value, the pH of the blood must be between 7.0 and 7.8 on the CDI System 550.

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.

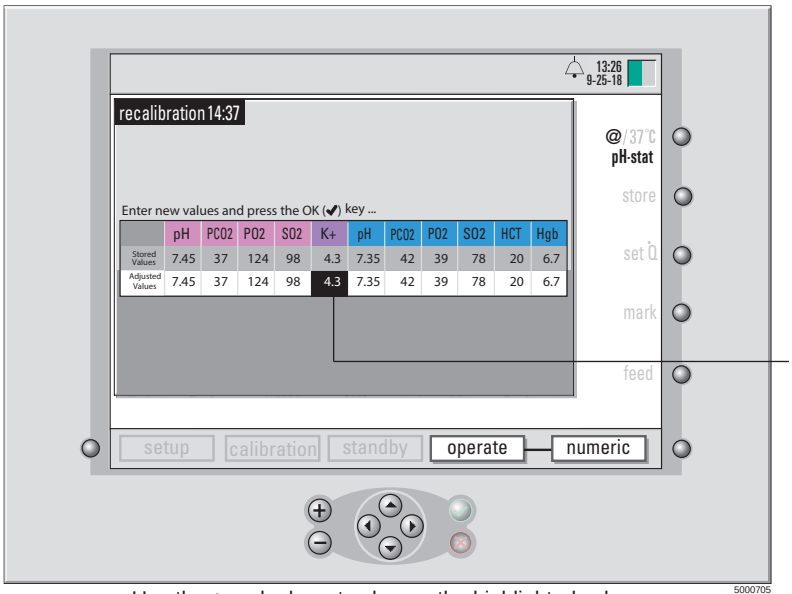
Note: If the laboratory blood gas values are 37°C, the monitor must be in 37°C mode. If the laboratory gas values are at patient temperature, the monitor must be in actual (@) mode. The stored temperature mode can be switched in the recalibration screen, however the temperature value used in the actual 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 will compromise 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.



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 √ when you've finished adjusting all values.

Or, press X to cancel the adjustment and leave the "recall" key active.

▲**Warning**

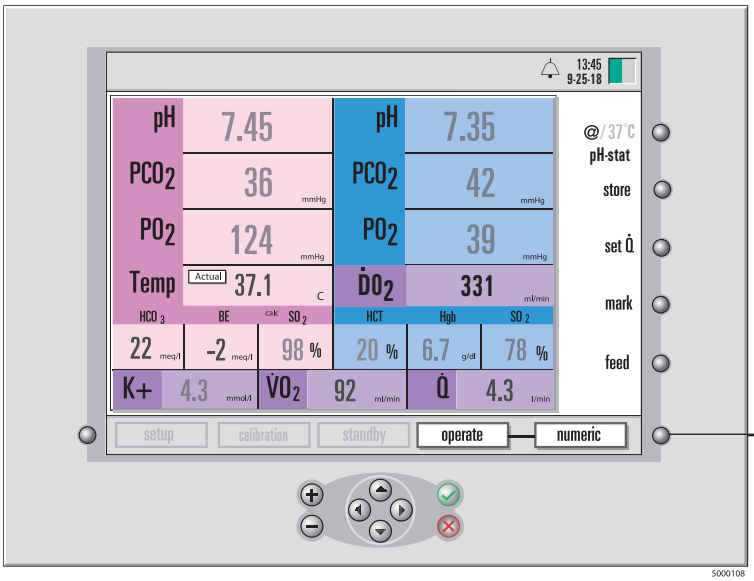
- **Measured values prior to initial in vivo calibration may not be accurate. Do not use values prior to initial in vivo calibration for patient management. Failure to perform a proper set-up, full two-point tonometered gas calibration, and initial in vivo calibration may result in compromised system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

Note: If you press √ without changing any values, the stored potassium value becomes 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 will also become the adjusted values. Upon returning to operate, the values will no longer appear dimmed.

Choosing display modes

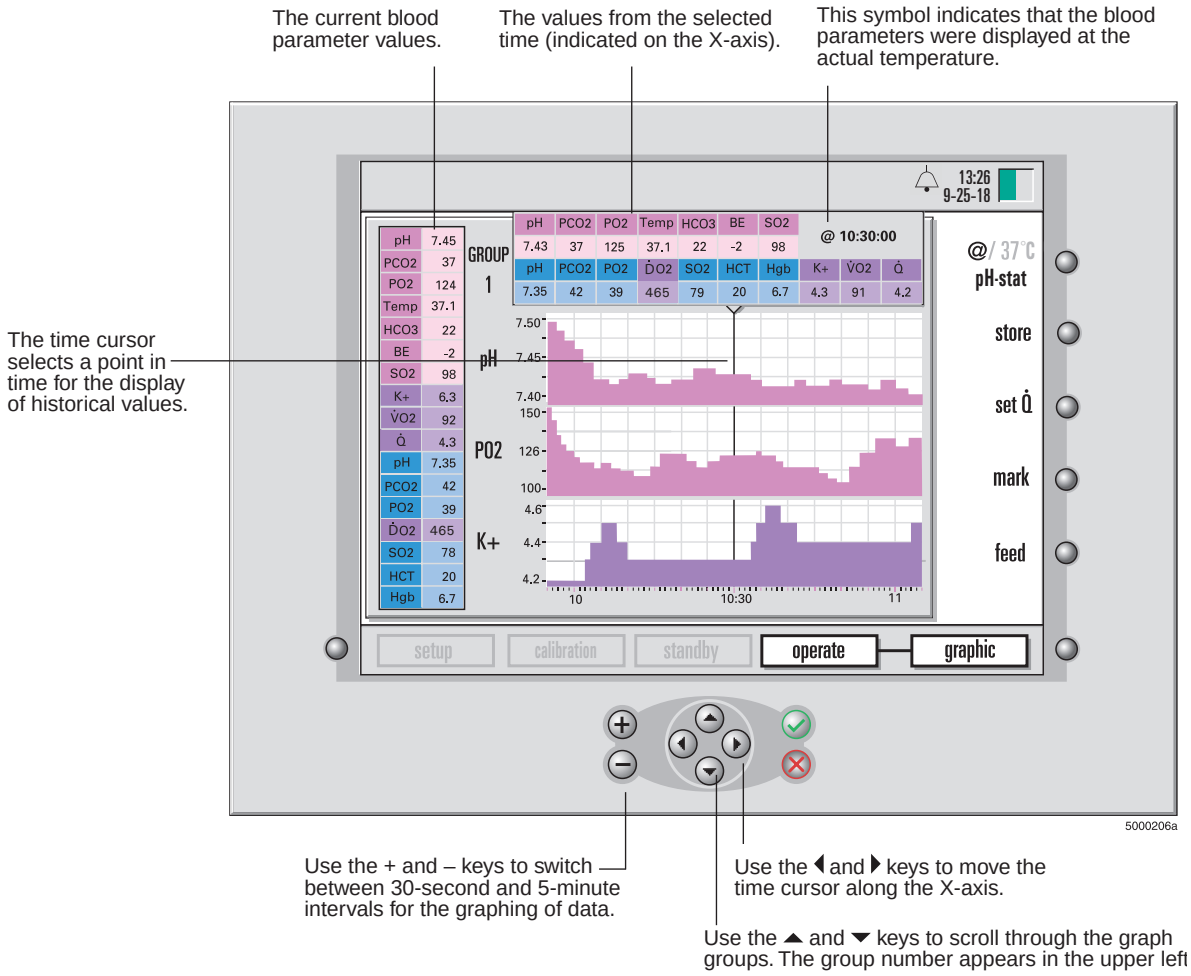
During a case, you can press the operate mode toggle key to switch among three display modes — numeric, graphic, and tabular. Continuous blood parameter values are shown in each display mode. The soft keys — @/37°C, store, set $\dot{Q}$, and feed — work the same way in the graphic and tabular display 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 larger than when displayed in graphic or tabular display mode.



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 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.

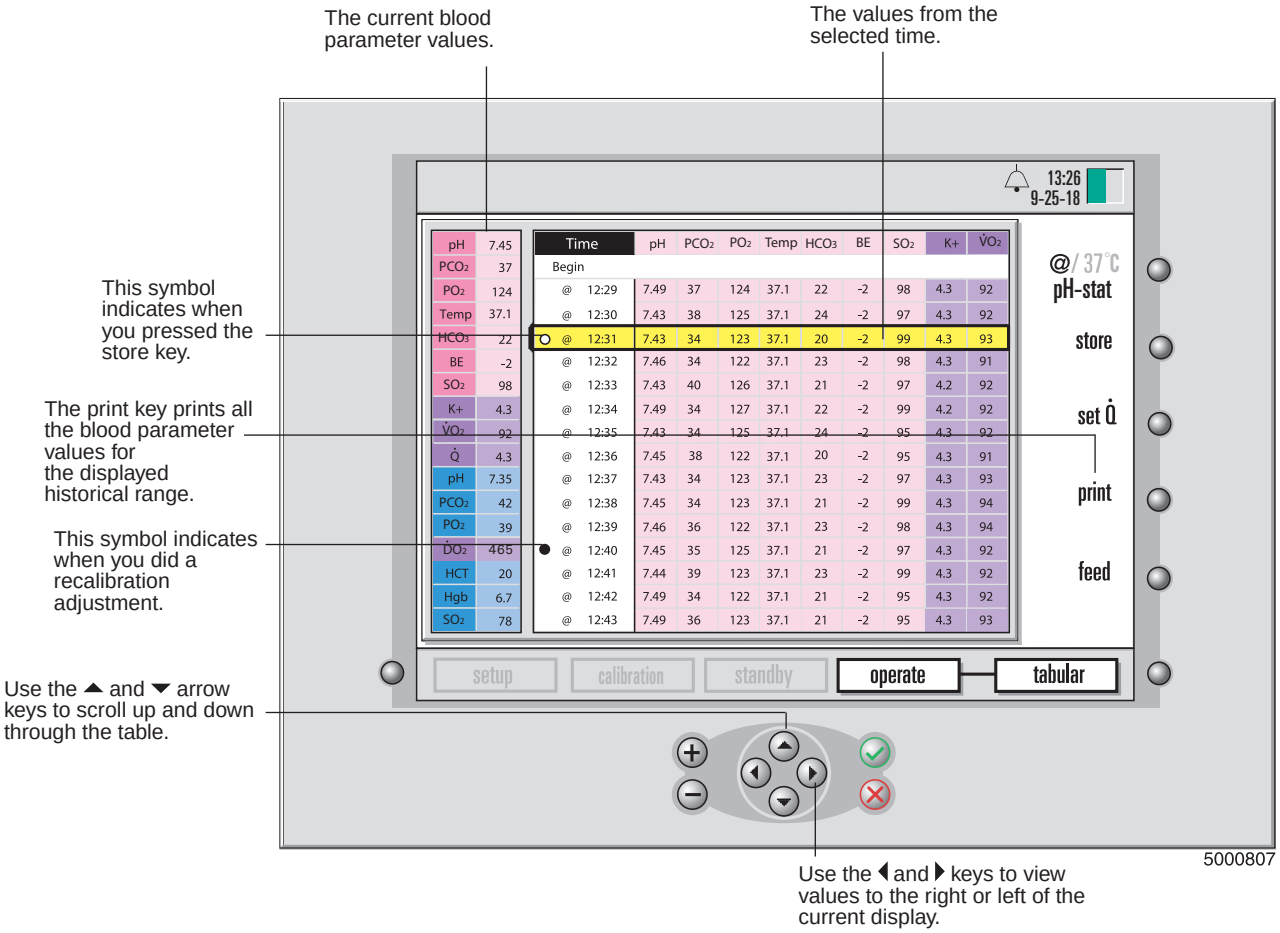
The range of the X-axis (time scale) is either 36 minutes (30 second intervals) or 6 hours (5 minute intervals).

The range of values along each graph's Y-axis is determined automatically by the alarm thresholds set on the alarms 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 be time stamped and added to the bottom (at 1 minute intervals).



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 low priority physiological alarm event occurs while in the graphic or tabular display modes, the background color of the affected parameter value will be solid yellow. If a medium priority physiological alarm event occurs while in the graphic or tabular display modes, the background color of the affected parameter value will flash yellow. 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) /pH-stat or corrected to 37°C /alpha-stat. Use the "@/37°C" 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 ($\dot{V}O_2$) and oxygen delivery ($\dot{D}O_2$). The user chooses 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 "Pump" is specified as the source of flow data (and the CDI System 550 is connected to a pump, as explained in Appendix C), the user will also need to specify the particular pump type in the same "calculations" setup screen.

If the "Manual" is specified as the source of flow data, the user 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 and oxygen delivery values will continue to recalculate using the same flow rate until the user enters a new flow rate.

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

Note: The user will 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 only a CDI H/S Probe and a venous BPM are 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: The user will need at a minimum one arterial BPM and either a venous BPM or a CDI H/S probe to get enough data to calculate oxygen delivery. If only an arterial and a venous BPM are used, a hematocrit value will need to be entered manually.

Note: The user 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 and oxygen delivery are desired when using 2 CDI BPMs (only), the user 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 the user. Blood flow data is obtained in the same way described above.

Recalibrating during a procedure

Recalibrate the monitor periodically during in-line operation if it is necessary for the monitor to correlate closer to the institution’s blood parameter laboratory measured values. (Each institution shall determine their allowable variance between these two sets of measurements.)

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

Note: After changes of blood temperature of > 6°C, repeat an in vivo calibration of shunt sensor values once temperature stability has been achieved. Optimal system accuracy will be maintained by this practice.

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 the laboratory values, 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. ➤

Note: If the stored values are outside of a parameter’s display range (showing dashes), the user can change the adjusted value within the display range.

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.

▲ 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 550 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). ▲**

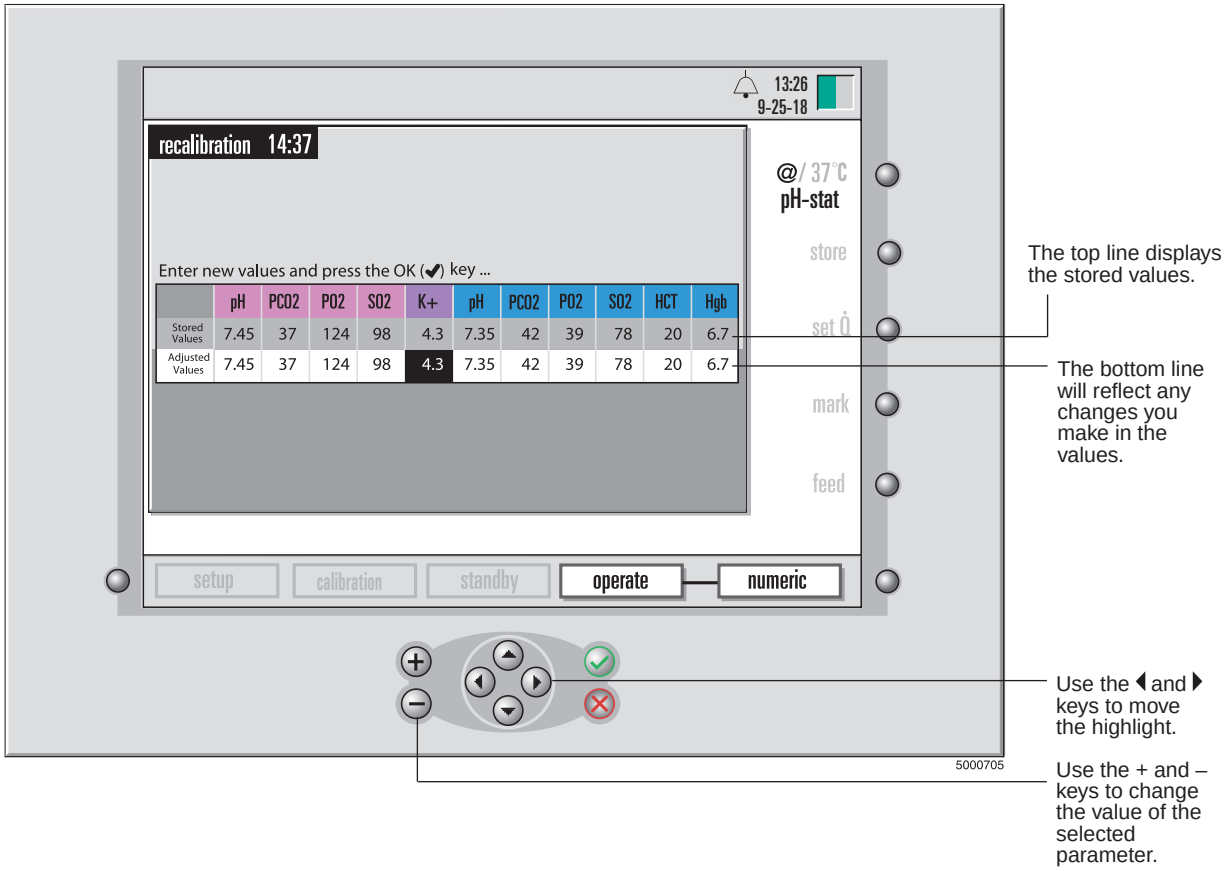
➤ Caution

- 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 the laboratory results are obtained, press the "recall" key.**

The recalibration screen opens, as shown in the next figure.



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 finished, to enter the adjusted values and return to display mode.**

Or press X to cancel the adjustments.

If the user presses √, 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.

Batteries contained within the CDI System 550

The CDI monitor contains two types of batteries: system batteries and a backup battery.

System Batteries

The system batteries power the monitor’s date, time and system error code memory. They are AA lithium batteries. If the battery life is diminished, the system informs the user during system initialization by providing an error code. The system will normally allow the user to continue (with certain provisions, such as loss of date and time) by accepting the condition. The user should contact Terumo CVS Technical Service for System battery replacement.

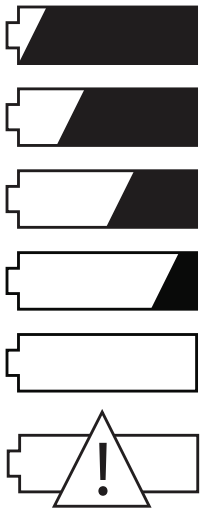
Operating on emergency battery power

The backup battery is 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 Terumo CDI Model 540 Calibrator and the Terumo CDI System 550 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, the user 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

Low battery (symbol flashes)

Service Battery Icon

The battery can be serviced only by trained, certified Terumo service technicians. Contact your Terumo 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 the user plugs 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, allow the battery to fully discharge on an occasional basis.

Note: When the low battery symbol appears, the system will be powered for at least 5 minutes provided the AC power is lost on a fully charged battery that is maintained per the information above.

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, the user can print a case summary that contains the data recorded during the case. The user 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 the user returns 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:

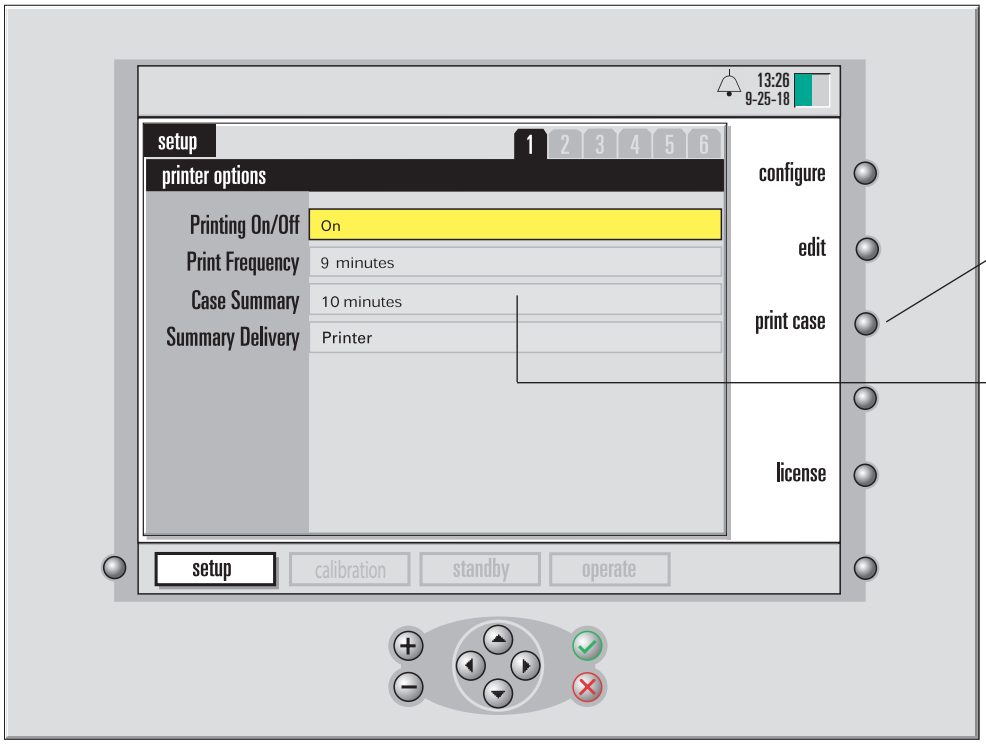
1 **Go to the setup mode.**
To do this, press the system mode select key, press the ◂ or ▸ key until “setup” mode label highlights, then press √.

2 **Make sure the “Printing On/Off” selection is set to “On”.**

3 **Choose the desired “Summary Delivery” option: “Printer,” “Serial Port,” or “Printer and Serial Port.”**

4 **Make sure the “Case Summary” data interval is set as previously determined.**

5 **Press the “print case” key.**



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Returning the monitor to “standby” mode

After printing or sending the case report, the Terumo Cardiovascular Systems CDI 550 Monitor can go to “standby” mode or be turned off.

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

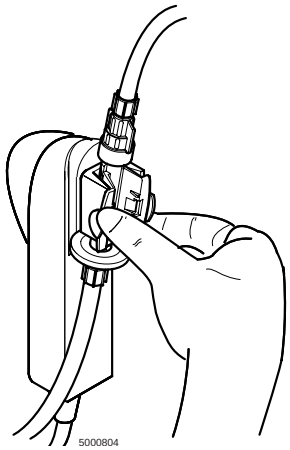
To go to standby mode:

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, the user 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.**



3 **Return the BPM cable-head(s) to their designated docking ports on the monitor.**
4 **Detach the Terumo CDI H/S Probe from the Terumo CDI H/S Cuvette, and return the Probe to its monitor docking mechanism.**
5 **Wipe down the CDI System 550 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.**

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).**

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This chapter can help the user solve problems that might occur with the Terumo Cardiovascular Systems CDI System 550. 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, you can call the Terumo troubleshooting hotline during normal business hours.

- 800-521-2818 — Customer Administration
- 800-441-3220 — Technical Support

Error messages and conditions

The CDI System 550 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 the user corrects 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 a 3.15 Ampere (5mm x 20mm, 250V) Slow Acting fuse. If the monitor still won't power on, contact your Terumo 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 Terumo Technical Service.**	This indicates that a software problem has occurred, and it cannot be corrected by you. Please contact your Terumo 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 Terumo 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 Terumo Technical Service representative to arrange for repair.
System initialization failure: _____ *Possible messages:* **Date & time lost and needs to be reset.** **Setup preferences and calibration lost.** **Previous patient case data has been lost.** **Contact Terumo 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 Terumo Technical Service Representative. Most failures will allow the user to continue (with certain provisions) by pressing the √ (OK) key. Examples are listed to the left. Failures that are not recoverable will have no option to continue. Please contact your Terumo Technical Service representative to arrange for repair. ***Note:*** Failure code "F00D" indicates one or more keys stuck down during startup. Ensure that 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 Terumo Technical Service.**	This indicates a module hardware failure in startup. The user has the option to continue using the system excluding the failed module. This failure should be reported to your Terumo 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 Terumo Technical Service.
Barometric pressure measurement failure: F050 **Contact Terumo 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 Terumo Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Arterial (or Venous) module SRS 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; 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 Terumo 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; 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 Terumo 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.	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 Terumo Technical Service representative to arrange for repair.
Printer failure detected: _____ **Printer will be disabled.** **Contact Terumo Technical Service.**	This error message appears during startup if printer hardware failure occurs. A specific identifying code will appear in the blank — save this number for later reporting to your Terumo Technical Service representative. This failure will disable further use of the printer although you may continue to use the system. Contact your Terumo Technical Service representative to arrange for repair.
Printer paper is 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 Terumo Technical Service representative to arrange for repair.
Printer paper jams.	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.

Message/Problem	Meaning and Corrective Action
Printer paper release lever is disengaged.	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 Terumo Technical Service representative to arrange for printer repair.

Calibration

Message/Problem	Meaning and Corrective Action
Calibration (or verification) procedure unavailable while on battery power. **Verify power source.**	Make sure the monitor is plugged into an AC power outlet. If the monitor is running on battery power only, calibration (or verification) 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 (or verification). If this message appears while the monitor is plugged into AC power, contact your Terumo Technical Service representative to arrange for repair.
Calibration function is unavailable. **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 Terumo Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
Calibrator failure detected: _____ **Contact Technical Service.**	This message refers to a detected calibrator hardware failure or communication failure with the monitor. An identifying error code appears in the blank. Record this error code for later reporting to Terumo Technical Service. At this time, you have the option to re-initiate the calibration procedure. If the error code persists, re-attempt calibration with a new calibrator if available. Success of the calibration process with another calibrator would indicate a hardware failure with the first calibrator. Press the X (cancel) key to exit calibration and return to standby. If no alternate calibrator is available, the system will allow continued use with application of the system default calibration values. Contact your Terumo Technical Service representative to arrange for repair.
Calibration (or verification) process stopped.	This message occurs when the “stop” soft key is pressed during calibration (or verification). Pressing the √ (OK) key will restart calibration (or verification); 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 Terumo 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. **Verify proper placement.**	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 is connected correctly and captured securely in the calibrator pocket. Verify the number of modules being used. If the error persists, contact your Terumo Technical Service representative to arrange for repair. ***Note:*** If the monitor configuration chosen has only one BPM while two are physically present, either one will be accepted by the system and will not cause this error message.
Insufficient gas pressure for Gas A (or Gas B). **Replace bottle.**	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 Terumo 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 Terumo Technical Service representative. You have the option of using the calibration default values by pressing the √ (OK) key. ***Note:*** If you press the √ (OK) key to substitute default calibration values, then a message stating "Calibration completed." will appear. ***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 Terumo 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 Terumo Technical Service representative. You have the option of substituting default calibration values for the failed microsensors by pressing the Cancel (X) 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 – 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 Terumo 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 $\dot{D}O_2$ or $\dot{V}O_2$). No values for $\dot{D}O_2$ 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 deactivated 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".

Message/Problem	Meaning and Corrective Action
Arterial (or Venous or H/S) module failure: _____ **Measurements from module will be discontinued.** **Contact Terumo 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 for later reporting to Terumo Technical Service. You may continue using the system although measurements from this module will be discontinued and will no longer be displayed. Contact your Terumo Technical Service representative to arrange for repair.
Monitor failure detected: _____ **Contact Terumo 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 Terumo Technical Service. You will not be able to continue use of the system. Contact your Terumo Technical Service representative to arrange for repair.

Message/Problem	Meaning and Corrective Action
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 can only 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 ml/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. ■ After changes of blood temperature of > 6°C, repeat an in vivo calibration of shunt sensor values once temperature stability has been achieved. Optimal system accuracy will be maintained with this practice. ■ 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, these include: 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 Terumo 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.	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 Terumo 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.
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. ***Note:*** The printer cover is designed to reduce the risk associated with fluids getting into the monitor. If fluids are suspected to have splashed into this area, unplug the device from the power source and contact Terumo for further support.

Message/Problem	Meaning and Corrective Action
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 Terumo 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 Terumo Technical Service Representative to arrange for battery replacement. ■ Has the service battery icon been noticed at startup? The battery has exceeded its manufacturers recommended replacement date.
H/S Disconnect at Cuvette.	Connect H/S probe to cuvette. ***Note:*** Connecting the H/S probe to the cuvette will deactivate the alarm.

Laboratory comparison troubleshooting table

The following table details information you can use to determine why your CDI System 550 values appear to be inaccurate with respect to laboratory values:

<table>
<tr><th>Issue</th><th>Meaning and/or Corrective Action</th></tr>
<tr><td>Make sure the circuit has stabilized before drawing a laboratory comparison sample.</td><td>

Wait approximately five minutes after making a change to blood flow rate, gas flow rate, FiO_2, temperature, etc. Watching the CDI System 550 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 ml/min in the CDI Shunt Sensor line may result in slower measurement response times. Restoration of the flow rate back above 35 ml/min will return the sensor readings to normal.
A minimum blood flow rate through the CDI H/S Cuvette may result in less than optimal saturation/ hematocrit readings. Restoration of the flow rate back above minimum requirement will return the CDI H/S Cuvette readings to normal. See the table below for reference:
<table>
<tr><th>H/S Cuvette Size</th><th>Min Flow</th><th>Max Flow</th></tr>
<tr><td>1/2"</td><td>1.0 LPM</td><td>7.0 LPM</td></tr>
<tr><td>3/8"</td><td>0.5 LPM</td><td>4.0 LPM</td></tr>
<tr><td>1/4"</td><td>0.2 LPM</td><td>1.5 LPM</td></tr>
</table>

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.

</td></tr>
</table>

Issue	Meaning and/or Corrective Action
Make sure the lab temperature matches the CDI System 550 temperature.	The temperature mode of the CDI System 550 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 550 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.
K^+ problems? What kind of prime are you using?	Exposure of the shunt sensor to prime solutions with pH less than 7.0 or greater than 7.8 pH units can interfere in the accurate measurement of potassium. To avoid K^+ 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. Monitor pH levels in the prime in order to ensure the pH is within the 7.0 - 7.8 pH units range.
K^+ problems? What kind of prime are you using?	Exposure of the shunt sensor to prime solutions with a sodium measurement less than 120 or greater than 160 mEq/L can interfere in the accurate measurement of potassium.

Issue	Meaning and/or Corrective Action
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 Terumo Customer Administration or your local Terumo Sales representative.
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.

▲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 Terumo Technical Service representative for any technical service needs.

Fuse replacement

The CDI System 550 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 used are identical:

3.15A @250 V, Slow Acting, High Breaking Capacity, 5mm X 20mm 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.▲**

Error Code Definitions

Error code (Non-recoverable)	Description	Cause	Recommendation
None	At start up (boot), Buzzer remains on	MCU (microcontroller) Error	Contact Terumo CVS Technical Service.
None	At start up (boot), Buzzer on, or keep on-off-on-off, blink DIAG LED	SRAM Error	Contact Terumo CVS Technical Service.
F001, F002, F003, or F004	Monitor resets	Software Fault	Contact Terumo CVS Technical Service.
F006	At start up, the monitor freezes	SBC board failure	Contact Terumo CVS Technical Service.
F007	At start up, the monitor freezes	SBC board failure	Contact Terumo CVS Technical Service.
F009	Monitor freezes at start up or run time.	Module error or no module detected	Contact Terumo CVS Technical Service.
F00A	At start up (boot), monitor freezes.	BPM LED current mismatched	Contact Terumo CVS Technical Service.
F00D	At start up (boot), monitor freezes.	Stuck key detected.	Contact Terumo CVS Technical Service.
F030	Display CDI error message at start up, system freezes.	Flash memory checksum error.	Contact Terumo CVS Technical Service.
F031	Display CDI error message at start up, loop forever, system freezes.	SBC board failure	Contact Terumo CVS Technical Service.
F032	Display CDI error message at start up, system freezes.	AUX board failure	Contact Terumo CVS Technical Service.

Error code (Recoverable)	Description	Cause	Recommendation
F033	Display CDI error message at start up.	Arterial PC card error.	Allow user to ignore error message. If ignored, arterial BPM is disabled. Venous BPM, if installed, and H/Sat Probe will still be available for use.
F034	Display CDI error message at start up.	Venous PC card error.	Allow user to ignore error message. If ignored, venous BPM is disabled. Arterial BPM and H/Sat Probe will still be available for use.
F035	Display CDI error message at start up.	HSAT Probe error.	Allow user to ignore error message. If ignored, H/Sat probe is disabled. Venous BPM, if installed, and arterial BPM will still be available for use.
F036	Display CDI error message at start up.	HSAT Servo card error.	Allow user to ignore error message. If ignored, H/Sat probe is disabled. Venous BPM, if installed, and arterial BPM will still be available for use.
F038	Display CDI error message at start up.	AUX board failure, or software update.	Allow user to ignore the error message. If ignored, all setup parameters will be set back to Factory Defaults.
F039	Display CDI error message at start up.	RTC (real time clock) checksum error.	Allow user to ignore the error message. If ignored, date settings will be set back to 1/1/1997, time will be set to 12:00. All the other functions are available.
F050	Display CDI error message at start up.	SBC board failure. Barometric pressure related	Allow user to ignore error message. If ignored, 760mmHg will be used for calibration.
F070	Display CDI error message at start up.	Arterial PC card Rev code error, or card is not plugged in.	Allow user to ignore error message. If ignored, Arterial BPM is disabled. Venous BPM, if installed, and H/Sat Probe will still be available for use.

Error code (Recoverable)	Description	Cause	Recommendation
F071	Display CDI error message at start up.	Venous PC card Rev code error, or card is not plugged in.	Allow user to ignore error message. If ignored, venous BPM is disabled. Arterial BPM and H/Sat Probe will still be available for use.
F072	Display CDI error message at start up.	HSAT servo card Rev code error, or card is not plugged in.	Allow user to ignore error message. If ignored, H/Sat probe is disabled. Venous BPM, if installed, and arterial BPM will still be available for use.
F101	Display CDI error message at runtime.	Arterial BPM error.	Allow user to ignore error message. If ignored, arterial BPM is disabled. All other functions are available
F102	Display CDI error message at runtime.	Venous BPM error.	Allow user to ignore error message. If ignored, venous BPM is disabled. All other functions are available.
F103	Display CDI error message at runtime.	HSAT 5V reference voltage out of range (5V +/- 30mV).	Allow user to ignore error message. If ignored, H/Sat probe is disabled. All other functions are available.
F120	Display CDI error message at start up, runtime.	Printer Failure.	Allow user to ignore, printer is disabled. All other functions are available.
F121	Display CDI error message at start up.	Incorrect printer software version or printer failure.	Allow user to ignore, printer is disabled. All other functions are available.
F133	Display CDI error message at start up.	Checksum failure for the Arterial BPM.	Allow user to ignore error message. If ignored, arterial BPM is disabled. All other functions are available.
F134	Display CDI error message at start up.	Checksum failure for the Venous BPM.	Allow user to ignore error message. If ignored, venous BPM is disabled. All other functions are available.

Error code (Recoverable)	Description	Cause	Recommendation
F233	Displayed in EEPROM dump.	Arterial BPM Probe EEPROM failure	Allow user to ignore error message. If ignored, arterial BPM is disabled. All other functions are available.
F234	Displayed in EEPROM dump.	Venous BPM Probe EEPROM failure	Allow user to ignore error message. If ignored, venous BPM is disabled. All other functions are available.
F0A0	Display CDI error message at start up.	Arterial BPM Probe ADC failure.	Allow user to ignore error message. If ignored, arterial BPM is disabled. All other functions are available.
F0A1	Display CDI error message at start up.	Arterial BPM Probe thermistor failure.	Allow user to ignore error message. If ignored, arterial BPM is disabled. All other functions are available.
F0A2	Display CDI error message at start up.	Venous BPM ADC failure.	Allow user to ignore error message. If ignored, venous BPM is disabled. All other functions are available.
F0A3	Display CDI error message at start up.	Venous BPM thermistor failure.	Allow user to ignore error message. If ignored, venous BPM is disabled. All other functions are available.

CF error code is for Calibrator (CDI 540)

Error code (Recoverable)	Description	Cause	Recommendation
CF01	Detected at calibration start up.	Calibrator I2C failure.	Exit calibration and contact Terumo CVS Technical Service.
CF02	Detected at calibration start up.	Calibrator ADC failure.	Exit calibration and contact Terumo CVS Technical Service.
CF03	Detected at calibration start up	Calibrator reference voltage error.	Exit calibration and contact Terumo CVS Technical Service.
CF04	Detected at calibration start up.	Bottle A valve failure or Calibrator leakage or bad transducer for bottle A.	Exit calibration and contact Terumo CVS Technical Service.
CF05	Detected at calibration start up.	Bottle B valve failure or Calibrator leakage or bad transducer for bottle B.	Exit calibration and contact Terumo CVS Technical Service.
CF06	Detected at calibration start up.	Bad exhaust valve or mix-line transducer	Exit calibration and contact Terumo CVS Technical Service.
CF07	Detected at calibration start up.	Mix line transducer failure or bottle A, B valve failure.	Exit calibration and contact Terumo CVS Technical Service.
CF08	Detected at calibration start up.	Bad bottle A pressure regulator or bad mix line transducer.	Exit calibration and contact Terumo CVS Technical Service.
CF09	Detected at calibration start up.	Bottle A valve failure, bottle A pressure regulator failure, large leak.	Exit calibration and contact Terumo CVS Technical Service.
CF0A	Detected at any time during calibration.	Bad exhaust valve.	Exit calibration and contact Terumo CVS Technical Service.
CF0B	Detected at calibration start up.	Bad bottle B pressure regulator or bad mix line transducer.	Exit calibration and contact Terumo CVS Technical Service.
CF0C	Detected at any time during calibration.	Bad calibrator memory or un-calibrated calibrator.	Restart calibration process and see if the error code persists. If the error code persists, exit calibration and contact Terumo CVS Technical Service.
CF11	Detected at calibration start up.	Bottle B valve failure, bottle B pressure regulator failure, large leak.	Exit calibration and contact Terumo CVS Technical Service.

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The Terumo Cardiovascular Systems CDI Blood parameter Monitoring System 550 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 Terumo 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 550 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 CDI H/S Probe face, and the optical reference color chips.

If these surfaces need cleaning, use a soft, lint-free, damp 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 and a soft, lint-free, damp cloth. 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 on a soft, lint-free, damp cloth.

Note: Ensure the printer cover is closed securely to maintain proper protection from liquids entering the printer area and disrupting the performance of the monitor.

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.
- Do not use chemical solvents such as ether, acetone, or anesthetics, such as Forane (isofluorane) as cleaning agents on any part of the system. These chemicals can be destructive to the device. ➤

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 550 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 Terumo CDI Model 540 Calibrator and the Terumo CDI System 550 Monitor printer will not operate while the CDI System 550 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. In order to charge the backup battery in the monitor, you must plug it into an AC outlet for at least 8 hours.

The battery can be serviced only by trained Terumo service technicians. Contact your Terumo 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 Terumo Technical Service if you suspect your battery needs to be replaced.

Note: The service battery icon will appear at boot-up if the battery has exceeded its manufacturer's recommended time.

➤ **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 Battery Icon

The service battery icon will alert the user, at startup, when a battery is nearing the end of its expected service life. The backup battery has an expected service life of 4 years from installation date. The system batteries (which power the monitor's date, time and system error code memory) have an expected service life of 8 years from installation date.

When the service battery icon appears on the screen at startup, contact your local Terumo Cardiovascular Group representative or call 1-800-521-2818 for service.

Monitor and Calibrator Disposal

The CDI System 550 monitor contains batteries. The monitor, calibrator, and batteries shall be disposed of in accordance with hospital policy regarding waste of electrical and electronic equipment.

Refer to page 8-3 for disposal of CDI Shunt Sensors, H/S Cuvettes and calibration gas cylinders.

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List of system components

Terumo Cardiovascular Systems Extracorporeal Blood Parameter Monitoring System

Description	Size	Catalog Number
MONITOR		
Terumo CDI Extracorporeal Blood Parameter Monitor		
Monitor with one blood parameter module and one H/S Probe		550AHCT
Monitor with two blood parameter modules and one H/S Probe		550AVHCT
DISPOSABLES		
Terumo CDI Shunt Sensor, (Sterile, Heparin-treated, case of 20 each)		CDI510H
Terumo CDI H/S Cuvette, (Sterile, case of 20 each)	1/4"	6914
	3/8"	6913
	1/2"	6912
Terumo CDI H/S Cuvette with 6” (15.2 cm) extension tube, (Sterile, case of 10 each)	1/4"	6934
	3/8"	6933
	1/2"	6932
ACCESSORIES		
Calibrator, for use with CDI Systems		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 CDI Systems		7310
Monitor Pole Clamp, Long, Calibrator Mount, for use with CDI Systems Monitor	7"	CDI517
Monitor Pole Clamp, Short, for use with CDI Systems Monitor	4.5"	CDI518
Cable-head Bracket for use with CDI Systems		CDI519

Description	Catalog Number
PUMP INTERFACE ACCESSORIES	
Note: CDI System 550 was designed to utilize existing CDI modules and interface cables.	
CDI Module for Terumo Advanced Perfusion System 1	803479
CDI interface cable for Terumo Advanced Perfusion System 1	804981
CDI Comm module for Terumo Sarns 8000	16417
Interface cable for Terumo NEO System	Accessory of Terumo NEO System

System Notification Specifications

Determination of Priorities for Physiological Alarms and Rationale for Manufacturer Defined Default Limits.

The CDI System 550 provides the user with alarm functionality for the parameters the system is capable of measuring in accordance with the IEC 60601-1-8:2006, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. Based on these requirements, and the known clinical use of the CDI System 550, manufacturer-defined default limits were established to provide alarm functionality at the medium and low priority level. Physiological alarm priorities were established for both “out of range –High” and “out of range – Low” blood parameter values based on the type of potential harm to the patient and the time to occurrence of harm if the user ignored the alarm. The following criteria were used to determine the appropriate ranges for the manufacturer-defined default limits.

Medium Priority conditions are defined in the standard as conditions which can:

- Result in reversible injury with a time period sufficient for manual corrective action,
- Result in death or irreversible injury within an unspecified time greater than specified as prompt,
- Result in minor injury or discomfort within a period of time not usually sufficient for manual corrective action.

Low Priority conditions are defined in the standard as conditions which can:

- Result in reversible injury within an unspecified time greater than specified as prompt,
- Result in minor injury or discomfort with a time period sufficient for manual corrective action,
- Result in minor injury or discomfort within an unspecified time greater than specified as prompt.

Manufacturer-Defined Default Alarm Limits

Parameter		Minimum Value	Maximum Value	Units
pH	Arterial	7.10	7.70	pH units
PCO_2	Arterial	30(4.0)	55(7.3)	mmHg (kPa)
PO_2	Arterial	85(11.3)	500(66.7)	mmHg (kPa)
K^+		3.0	7.0	mmol/L
$\dot{V}O_2$		20	400	ml/min
$\dot{D}O_2$		50	1500	ml/min
pH	Venous	7.00	7.70	pH units
PCO_2	Venous	35(4.7)	60(8.0)	mmHg (kPa)
PO_2	Venous	30(4.0)	65(8.7)	mmHg (kPa)
SO_2	Venous	60	95	%
HCT	Venous	24	38	%
Hgb	Venous	8.0	12.6	g/dl

System operating ranges

pH	6.80 to 7.80 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	15 % to 45%.
SO_2	60% to 100%
Hgb	5.0 to 15.0 g/dl
$\dot{D}O_2$	10 to 2000 ml/min
$\dot{V}O_2$	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 alarm will be triggered, except for HCO_3^-, BE, Temperature and Arterial SO_2.

System display ranges

pH	6.50 to 8.50 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
$\dot{V}O_2$ (Indexed)	1 to 999 ml/min/m^2
BE	-25 to 25 mEq/L
HCO_3^-	0 to 50 mEq/L
$\dot{D}O_2$	10 to 2000 ml/min
$\dot{D}O_2$ (Indexed)	1 to 20000 ml/min/m^2
Temperature	1.0 to 45.0°C
$\dot{Q}$	0.0 to 9.9 L/min

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 550 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 550. Accuracy values were generated by using the results from the CDI System 550 minus conventional analyzer results The following table shows the mean difference between the two measurement techniques, and the standard deviation of the distribution differences found.

pH Sensor (pH units):
Mean: 0.007
Standard Deviation: 0.014

PCO_2 Sensor (mmHg):
Mean: 0.0
Standard Deviation: 2.9

PO_2 Sensor – Arterial (>80 mmHg):
Mean: -0.5
Standard Deviation: 5.5

PO_2 Sensor - Venous (<80 mmHg):
Mean: -0.4
Standard Deviation: 0.8

Oxygen Saturation Value (%):
Mean: -0.5
Standard Deviation: 1.6

Total Hemoglobin Value (g/dl):
Mean: -0.17
Standard Deviation 0.54

Potassium Sensor (mmol/L):
Mean: 0.05
Standard Deviation: 0.18

Hematocrit Value (%):
Mean: -0.5
Standard Deviation: 1.7

Environmental and electrical specifications

Dimensions

Monitor:	
	BPM and H/S Probe mounted on monitor
H x W x D:	28 cm x 38 cm x 17 cm
	BPM and H/S Probe not mounted on monitor
H x W x D:	28 cm x 32 cm x 17 cm
	550AVHCT configuration
Mass:	7.9 kg
Pole Clamps:	
	CDI517
H x W x D:	12 cm x 56 cm x 24 cm
Mass:	2.4 kg
	CDI518
H x W x D:	12 cm x 50 cm x 24 cm
Mass:	2.3 kg
	CDI519
H x W x D:	8 cm x 30 cm x 22 cm
Mass:	1.0 kg
Calibrator:	
H x W x D:	32 cm x 21 cm x 26 cm
Mass:	3.81 kg
Display:	The maximum Horizontal viewing angle is +/-80 degrees as measured from Normal. The maximum Vertical viewing angle is +65, -80 degrees as measured from Normal.

Note: All dimensions are approximate and may vary slightly from product to product.

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 Terumo demonstrates that current flow through the patient would be well below the 10 microamp maximum specified in IEC 60601-1 and UL 60601-1.

Note: To provide isolation from supply mains, remove power cord from the CDI System 550 appliance coupler. Do not position the CDI System 550 so that it is difficult to isolate the appliance coupler from the supply mains.

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 60601-1-2:2014. 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 the receiving device for help.

In accordance with IEC 60601-1: 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. Anyone who connects additional equipment to the signal input port or signal output configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1. 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.

This system was tested with the following equipment connected as a worst case scenario; 550AVHCT, Sarns Centrifugal System, TLink Data Management System and 540 Calibrator.

Environment

Operating Temperature:	Monitor and Calibrator 15°C to 30°C (59°F to 86°F)
Storage/Transport Conditions:	
Temperature:	
Monitor/Calibrator:	-15°C to 40°C (5°F to 104°F)
Shunt Sensors:	0°C to 35°C (32°F to 95°F)
Calibration Gas A & B	Not to exceed 50°C (122°F)
Humidity:	
Operating range:	15% to 90% (non-condensing)
Storage/Shipping:	5% to 95% (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 at IPX2

EMC Tables

Table 1 – Guidance and manufacturer's declaration
electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The CDI System 550 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 550 shall assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions IEC CISPR 11:2009 +A1:2010	Group 1	The CDI System 550 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 IEC CISPR 11:2009 +A1:2010	Class A	The CDI System 550 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	

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Table 2 – Guidance and manufacturer's declaration
electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The CDI System 550 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 550 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The CDI System 550 is classified as level 4 for ESD compliance to ensure most installation and environments are considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	± 1 kV for power supply lines ±1 kV for input/output lines	The CDI System 550 should always be used with a power cord with the following specifications: Length: 3m Ampacity: 10A Termination: IEC 60320-C13 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. A temporary loss of function or degradation of performance, which ceases after the surge event ceases, could occur.

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 550 requires continued operation during power mains interruptions, it is recommended that the CDI System 550 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 3 – Guidance and manufacturer's declaration electromagnetic immunity for all EQUIPMENT and SYSTEMS that are not LIFE SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The CDI System 550 is intended for use in the electromagnetic environment specified below. The customer or the user of the CDI System 550 shall 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 550, 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 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 *MHz to* 800 *MHz* $d = 2.3\sqrt{P}$ 800 *MHz to* 2.7 *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 550 is used exceeds the applicable RF compliance level above, observe the CDI System 550 to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CDI System 550.

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

Verify the accuracy of displayed values with another source (i.e. laboratory or point of care blood gas analyzer) before initiating treatment if performance is lost or degraded due to EM disturbances.

Safe Working Loads

Monitor Pole Clamp, Long, Calibrator Mount, for use with the CDI System 550 Monitor	CDI517	32.5 lbs
Pole Clamp, Short, for use with the CDI System 550 Monitor	CDI518	23.0 lbs
Cable-head Bracket for use with the CDI System 550 Monitor	CDI519	7.0 lbs

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 or fluctuations in AC line voltage may compromise performance or damage the equipment. There are no precautions specific to the CDI System 550 to be taken when a cardiac defibrillator or high-frequency electrosurgical equipment is used on a patient. The typical recovery time from these events is less than 30 seconds.

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) communication equipment can affect this system. RF communications equipment include, but are not limited to, peripherals such as antenna cables, external antennas, cell phones, pagers, walkie-talkies, and Bluetooth devices. Portable RF communications equipment should be used no closer than 76 cm (30 inches) from the H/Sat probe head and no closer than 30 cm (12 inches) to any other part of the CDI System 550, including cables used with the CDI System 550.

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.

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 other objects.

The ground equalization stud on the Monitor is a 6mm diameter pin conforming to DIN 42801 part 1 Potential Equalization Leads - Connecting Pins. Use a connecting lead with a 6mm 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 2) that limit the ability of the CDI System 550 to perform as intended in the presence of electromagnetic disturbances.

Protection of the device against the effects from a discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

The label on the back side of the monitor is legible to the operator at distance of 35 cm or less.

Unpacking and inspection

The CDI System 550 Monitor has been packaged to prevent shipping damage. The carton contains the monitor, one operator's manual, power cable, 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.

O_2 Delivery ($\dot{D}O_2$) ml/min = 10 x ((1.36 x Hgb x SaO_2) + (0.0031 x PaO_2)) x $\dot{Q}$

Note: 1.36 is the constant used for ml O_2 per gram of hemoglobin. SaO_2 values are expressed in fractional form (i.e., 100% = 1.0). $\dot{Q}$ is expressed in L/min. 0.0031 is the constant used for partial pressure of oxygen in arterial blood. Partial pressure of oxygen (PaO_2) is expressed in mmHg.

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

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

Communication with other devices

The Terumo Cardiovascular Systems (Terumo) CDI System 550 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 550 is attached to an external device, you can send patient data (blood parameter values over the course of an operation) from the CDI System 550 to this device.

A second serial interface port, called the pump interface, allows the CDI System 550 to receive flow ($\dot{Q}$) data from selected pumps. These are the Terumo® Advanced Perfusion System 1, Terumo Sarns™ 8000, Terumo Sarns™ Centrifugal, Medtronic® Bio-Console® 550/560, LivaNova/Sorin/Stöckert S5/C5, Terumo NEO System and Maquet/ Jostra HL 20 / Rotaflow. When using the pump interface port with the Terumo® Advanced Perfusion System 1, data can also be sent from the CDI System 550, 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 ensure that such interference will not occur, care must be taken in the selection of computer equipment or printers to be interfaced with the Terumo CDI System 550 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 550, 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 550 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 550 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 550.**
Follow the instructions in the device's manual to set the appropriate baud rate and other communication parameters.

3 **Turn on the CDI System 550 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 550'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," "Terumo® Systems," or "Packet Mode"
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 550 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.

Data output port pin assignments

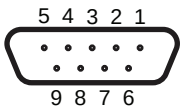
The CDI System 550 serial data output port is a female DB-9 connector. The data output port is set up as a DCE (Data Comm.) device at the factory, however, hardware handshaking is not supported.

The CDI System 550 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 550'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	CDI System 550 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 550 Monitor. Pin 5 is the ground return. Pin 3 carries serial data to the CDI System 550 Monitor.



Sending data to an external device

The CDI System 550 can be configured to send data using three different protocols:

- **ASCII Output**

  This selection will send all System 550 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 550 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.

- **Terumo® Systems**

  This selection offers compatibility with one of Terumo® System's Legacy product: Sarns 9000 Perfusion System. 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 Sarns 9000.

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 the serial port. The request packet is the following:

<X08Z36>

Upon receiving this packet, the CDI System 550 will get the latest parameter information and send it out 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, and 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:

	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	measured in pH units
3	Arterial CO_2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
4	Arterial O_2	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 HCO_3^-	xx	4	calculated in mEq/L
7	Arterial Base Excess	sxx	4	calculated in mEq/L
8	Calculated Oxygen Saturation	xxx%	4	parameter calculated if no HSAT module is operating
9	Potassium	x.x	4	measured in mEq/L
10	VO_2 (Oxygen Consumption)	xxx	4	measured in ml/min calculated in ml/min or ml/min/m^2
11	Q (Pump Flow)	x.x	4	measured in L/min - negative values are displayed as 0.0
12	BSA (Body Surface Area)	x.xx	4	measured in m^2
13	Venous pH	x.xx	4	measured in pH units
14	Venous CO_2	xxx/xx.x	4	xxx if monitor measuring in mmHg, xx.x if measuring in kPa
15	Venous O_2	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	xxx%	4	parameter measured when H/S module operating ONLY
18	Hematocrit	xx%	4	measured in percent Hematocrit
19	Hemoglobin	xx.x	4	measured in g/dL

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

Sample Output:

Note: Example 1 includes no Venous Module, Arterial pH out of operating range, no pump flow 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**
08:56:38	8.13	041	097	23.4	--	--	100%	7.9	--	0.0						078%	26%	8.8
08:56:44	8.13	041	097	23.4	--	--	100%	7.9	--	0.0						078%	26%	8.8
08:56:50	8.13	041	097	23.4	--	--	100%	7.9	--	0.0						078%	26%	8.8

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**
09:08:55	7.65	05.7	13.0	24.5	--	--	100%	8.0	065	2.5		7.37	03.5	06.2	23.9	078%	26%	8.8
09:09:01	7.65	05.7	13.0	24.5	--	--	100%	8.0	065	2.5		7.37	03.5	06.2	23.9	078%	26%	8.8
09:09:07	7.65	05.7	13.0	24.5	--	--	100%	8.0	065	2.5		7.37	03.5	06.2	23.9	078%	26%	8.8

Packet Mode Output

Hardware protocol.
The CDI System 550 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 CDI System 550.

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 550 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 550 is 'X'. All outgoing packets from the CDI System 550 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 CDI System 550	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 CDI System 550	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 CDI System 550	Indicates a problem with packet communications. See the SubCommand list of NAK conditions for more details.
'E'	Error	From CDI System 550	Indicates an error condition in the CDI System 550. The data portion of the packet will contain the error code, which should be the same as seen on the CDI System 550 screen.
'S'	Set	To/From CDI System 550	Sent to the CDI System 550 to set certain parameters, such as Arterial Flow or certain toggles. The CDI System 550 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 CDI System 550	Sent to the CDI System 550 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 CDI System 550 at the specified output interval. See Analyte Packet section for more information.
'1'	Mark Data Packet	Analyte Packet sent by CDI System 550 when the Mark key pressed.
'2'	Store Data Packet	Analyte Packet sent by CDI System 550 when the Store key pressed.
'3'	Recal Data Packet	Analyte Packet sent by CDI System 550 when the Recal key pressed.
'4'	Solicited Data Packet	Analyte Packet sent by CDI System 550 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 550) 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 550 for which this Acknowledge is made
S - SubCommand sent to the System 550 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 550, 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/ Terumo 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 CDI System 550, 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 CDI System 550 will return an Attention 4 Analyte data packet.
'1'	Analyte Output Interval	Request the CDI System 550 analyte output interval, in seconds. The CDI System 550 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 CDI System 550 system time. The CDI System 550 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 CDI System 550 to send EEPROM Dump data (Attention 7) packets.
'5'	Operate State	Request the Operate State. The CDI System 550 will return an Acknowledge packet with the data containing G5X where X is either 1 (CDI System 550 is in Operate mode) or 0 (CDI System 550 is not in Operate mode).

Set ('S'):

Value	Name	Description
'1'	Auto Output Interval	Sends the CDI System 550 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 CDI System 550 updates its internal database once every 6 seconds, any value sent to the CDI System 550 using this command will be rounded down to the closest value divisible by 6 (e.g., a 13 would become a 12). The CDI System 550 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 550 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 CDI System 550 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 550. Data is recorded every 6 seconds in the CDI System 550, 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 CO_2	01
Arterial O_2	02
Arterial Temp	03
Arterial SO_2	04
Arterial HCO_3^-	05
Arterial Base Excess	06
Potassium (K^+)	07
Consumption ($\dot{V}O_2$)	08
Venous pH	09
Venous CO_2	0A
Venous O_2	0B
Venous Temp	0C
Venous SO_2	0D
Venous HCO_3^-	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 O_2 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 550 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 550. Please see the following section on pump interfacing tips or contact your Terumo Technical Service Representative for assistance. ➤

If a pump is selected in the “setup” mode, the CDI System 550 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 550 supports the following pumping system interfaces: Terumo® Advanced Perfusion System 1, Terumo Sarns 8000 Communications Module, Terumo Sarns Centrifugal, Medtronic® Bio-Console® 550/560, Terumo NEO System, LivaNova/Sorin/Stöckert S5/C5 and the Maquet/ Jostra HL 20 / Rotaflow.

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 550 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 Terumo Customer Administration. The interface cable will always connect to the pump interface port (only) on the monitor. When an interface cable is not connected to the pump interface port, use the protective cap to cover the port. 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.

Pumping System	Special Instructions
Terumo® Advanced Perfusion System 1	Interfacing with the Terumo® Advanced Perfusion System 1 can only be done with the CDI interface module (Terumo part number 803479). The System 1 Perfusion screen must be configured to include the CDI module. See the System 1 Operator's Manual for instructions on adding the CDI module to a perfusion screen configuration. The physical connection between the CDI module of the System 1 to the CDI System 550 is the same process as the CDI System 500. Make sure the correct interface cable is used (Terumo 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 550 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 Terumo CDI Pump Interface.

Terumo Sarns 8000	Interfacing with the Sarns 8000 can only be done with the Sarns 8000 Communications Module (Terumo part number 16417) accessory. The Communications Module port must be set to the “DCE” setting. This is the default setting from the factory. Contact Terumo Technical Administration if you need to change the setting on your Communications Module. Make sure the correct interface cable is used and that it is connected in the proper orientation.
Terumo 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 550. Make sure the correct interface cable is used and that it is connected in the proper orientation.
Maquet/Jostra HL 20	The HL 20 must have a digital I/O module to be connected to the CDI System 550. Please contact your Maquet/Jostra Technical Service representative to setup the HL 20 software before interfacing. Make sure the correct interface cable is used.
LivaNova/Sorin/ Stöckert S5/C5	Interfacing with the LivaNova/Sorin/Stöckert S5/C5 pumping systems requires use of the LivaNova “interface DDD module.” ***Note:*** You must enter the position the arterial pump (1-6) along with the pump type in setup screen #5.
Medtronic Bio-Console® 550/560	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. ***Note:*** On the Medtronic connector, pin 2 is assumed to be RX (IN) and pin 3 is TX (OUT). Hardware handshaking is not supported.
Terumo NEO System	No special instruction available. The customized interface cable is accessory of Terumo NEO System. Follow the instruction of Terumo NEO System to make the connection between the CDI 550 and Terumo NEO System.

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 550 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 550 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 System 550 Pump Interface packet communication will have RS-232 parameters adjusted automatically based on the pump selected.

Software Support.
The CDI System 550 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 550 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 550 will produce a No-Acknowledge (NAK) packet. If no response is received from the CDI System 550 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 550 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 550 is 'X'. All outgoing packets from the CDI System 550 will have an 'X' in the Device ID field.
- All pumping systems connected to the CDI System 550 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 CDI System 550	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 CDI System 550	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 CDI System 550) to both confirm that the request came through successfully, and to provide any data associated with the request.
'N'	No Acknowledge	From CDI System 550	Indicates a problem with packet communications. See the SubCommand list of NAK conditions for more details.
'E'	Error	From CDI System 550	Indicates an error condition in the CDI System 550. The data portion of the packet will contain the error code, which will be the same as seen on the CDI System 550 screen.
'S'	Set	To CDI System 550	Sent to the CDI System 550 to set certain parameters, such as Arterial Flow or certain toggles.
'G'	Get	To CDI System 550	Sent to the CDI System 550 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.

Attention ('A'):

Value	Name	Description
'0'	Unsolicited Data Packet	Analyte Packet sent by CDI System 550 at the specified output interval. See Analyte Packet section for more information.
'1'	Mark Data Packet	Analyte Packet sent by CDI System 550 when the Mark key is pressed.
'2'	Store Data Packet	Analyte Packet sent by CDI System 550 when the Store key is pressed.
'3'	Recal Data Packet	Analyte Packet sent by CDI System 550 when the Recal key is pressed.
'4'	Solicited Date Packet	Analyte Packet sent by CDI System 550 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 CDI System 550 during calibration if requested and if in Service Mode.
'7'	EEPROM Dump Data	A line of the EEPROM Dump information sent by CDI System 550 in response to an EEPROM dump request, while in Service Mode.

Acknowledge ('K'):

Acknowledge packets are sent back to the requesting device (usually the pumping system, but for some commands, the CDI System 550) 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 550 for which this Acknowledge is made

S - SubCommand sent to the CDI System 550 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 550, 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/Terumo 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 Command	Sent when the Command character is not a valid one. For incoming packets to the CDI System 550, 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 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 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 CDI System 550 will return an Attention 4 Analyte data packet.
'1'	Analyte Output Interval	Request the CDI System 550 analyte output interval, in seconds. The CDI System 550 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 CDI System 550 system time. The CDI System 550 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 CDI System 550 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 CDI System 550 to send EEPROM Dump data (Attention 7) packets.
'5'	Operate State	Request the Operate State. The CDI System 550 will return an Acknowledge packet with the data containing G5X where X is either 1 (CDI System 550 is in Operate mode) or 0 (CDI System 550 is not in Operate mode).
'6'	Arterial Flow	Generated by the CDI System 550, this will be a way for the CDI System 550 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 CDI System 550, this will be a way for the CDI System 550 to request the body Surface Area, in m^2. The expected response would be a "Set 6" packet, setting the BSA.

Set ('S'):

Value	Name	Description
'0'	Arterial Flow	This sends the CDI System 550 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 CDI System 550 will respond with an Acknowledge packet, indicating that it got the flow input. The CDI System 550 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 CDI System 550 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 CDI System 550 updates its internal database once every 6 seconds, any value sent to the CDI System 550 using this command will be rounded down to the closest value divisible by 6 (e.g., a 13 would become a 12). The CDI System 550 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 CDI System 550 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 CDI System 550 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 CDI System 550 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 CDI System 550 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 VO_2. 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 CDI System 550 to a pumping system, this sets the interval, in seconds, that the CDI System 550 wants Arterial flow. The pumping system shall respond with an Acknowledge packet telling the CDI System 550 the negotiated value for Arterial Flow. A 0 value indicates that no unsolicited flow values shall be sent, and the CDI System 550 will send a "Get 6" packet to get the Arterial Flow. The CDI System 550 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 CDI System 550 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 CDI System 550 that flow will be sent every 12 seconds, and the timeout will be 3 x 12 or 36 seconds.

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 550. Data is recorded every 6 seconds in the CDI System 550, 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 CO_2	01
Arterial O_2	02
Arterial Temp	03
Arterial SO_2	04
Arterial HCO_3^-	05
Arterial Base Excess	06
Potassium (K^+)	07
Consumption ($\dot{V}O_2$)	08
Venous pH	09
Venous CO_2	0A
Venous O_2	0B
Venous Temp	0C
Venous SO_2	0D
Venous HCO_3^-	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:

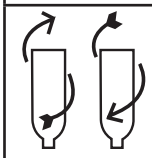
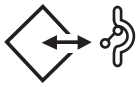
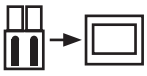
Arterial O_2 of 54 in mmHg at Actual Temperature with Low Alarm status: 022354
Potassium of 5.4 in mEq/L at 37 degree value with no alarms: 07505.4
Hematocrit in Percent unavailable while measuring in Actual Temperature: 104A--

Symbols Glossary

The following symbols may appear in the labeling, marking, or display of the Terumo Cardiovascular Systems (Terumo) CDI System 550 Blood Parameter Monitoring System. These symbols are in accordance with the internationally harmonized standards.

Symbol	Title	Description	Source
	Operator's manual; operating instructions	To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.	ISO 7000-1641
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.	ISO 7010-M002
	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
	"On" for a part of Equipment	"On" for a part of Equipment.	IEC 60417-5264
	"Off" for a part of Equipment	"Off" for a part of Equipment.	IEC 60417-5265
	Protective earth ground	Protective earth ground.	IEC 60417-5019
	Defibrillation - Proof Type CF Applied Part	Patient applied part.	IEC 60417-5336
	Alternating current	To indicate on the rating plate that the equipment 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	Protected against vertically falling water drops when enclosure tilted up to 15°	Drip proof in accordance with IEC 60529.	IEC 60529
	The PSE mark shall be on the fuse.	Design compliance to Law No.234 of 1961	Denan Guide for compliance with Japan Regulations

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 15223-1-5.1.7
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/ EEC and 98/79/EC.	ISO 15223-1-5.1.1
	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
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1-5.3.8
CE	CE Mark	Indicates conformity of the product to Council Directive 93/42/ EEC.	Council Directive 93/42/ EEC.
	Battery recycling (European)	Battery recycling (European).	WEEE 2012/19/EU.
	Battery recycling (USA)	Battery recycling (USA).	ISO 7000-1135
	Battery charge status	Battery charge status.	IEC 60417-5546

	1 Bottle per case	1 Bottle per case.	Terumo Cardiovascular Systems.
	Number of contents in carton	Identifies the number of contents.	Terumo Cardiovascular Systems.
	Gas A	Gas A.	Terumo Cardiovascular Systems.
	Gas B	Gas B.	Terumo Cardiovascular Systems.
	Twist to remove/tighten gas bottles	Twist to remove/tighten gas bottles.	Terumo Cardiovascular Systems.
	Monitor pump interface port	Monitor pump interface port.	Terumo Cardiovascular Systems.
	Calibrator connector to monitor	Calibrator connector to monitor.	Terumo Cardiovascular Systems.
	Monitor connector to calibrator	Monitor connector to calibrator.	Terumo Cardiovascular Systems.
	Connection to the serial data output port	Connection to the serial data output port.	Terumo Cardiovascular Systems.
	Audible alerts are active	Audible alerts are active.	Terumo Cardiovascular Systems.
	Audible alerts are temporarily silenced	Audible alerts are temporarily silenced.	Terumo Cardiovascular Systems.
	Audible alerts are disabled	Audible alerts are disabled.	Terumo Cardiovascular Systems.
	Non-ionizing radiation	Non-ionizing radiation.	IEC 60417-5140
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1-5.1.6
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.	ISO 15223-1-5.1.2
	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
	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
	Mass; Weight	To indicate mass. To identify a function related to mass.	ISO 7000-1321A
	Do not turn upside down	Indicates not to turn the UAS upside down.	Terumo Cardiovascular Systems.
	Service battery icon	Service battery icon.	Terumo Cardiovascular Systems.
	Do not reuse, Single use only	To indicate that the item is for single use only and must not be used more than once.	ISO 15223-1-5.4.2
	Do Not Resterilize	To indicate that the device should not be re-sterilized after it once has been sterilized.	ISO 7000-2608
	Do Not Use if Package is Damaged	To indicate that the device must not be used if the package holding the device is damaged.	ISO 7000-2606
	Fluid Path	On medical devices: to indicate the flow path for fluids.	ISO 7000-2722
	Sterilized using irradiation	To indicate that the device is provided sterile and has been sterilized using irradiation.	ISO 7000-2502
	Sterilized using ethylene oxide	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.	ISO 7000-2501
	Non-Pyrogenic	On medical devices: to indicate that the product is non-pyrogenic.	ISO 7000-2724

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.

ISO 7000: Standard for Graphical symbols for use on equipment -- Registered symbols.

WARRANTY: DISCLAIMER OF WARRANTY: LIMITATIONS OF REMEDIES

Warranties

Terumo Cardiovascular Systems (Terumo CVS) warrants that its CDI System 550 Monitors will be free from defects in materials and manufacturing for one year from the date they are shipped. Terumo CVS warrants that its Accessories will be free from defects in materials and manufacturing for 90 days from the date they are shipped. Terumo CVS warrants that its disposables will be free from defects in materials and manufacturing until the stated expiration date.

Terumo CVS also warrants that its monitors, disposables, and accessories will be fit for use in accordance with Terumo CVS's written instructions. Terumo CVS 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 Terumo CVS. Only service representatives authorized by Terumo CVS may service the monitors, disposables, and accessories. This warranty does not cover damage due to unauthorized service.

Because the operation of Terumo CVS's monitors, disposables, and accessories depends on factors which are out of Terumo CVS's control (such as the care of the products and the particular circumstances of the surgery), Terumo CVS does not warrant that its monitors, disposables, and accessories will be 100% effective in all circumstances.

Limitations of Remedies

Terumo CVS 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 Terumo CVS 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 Terumo CVS, CDI Products. The returned goods (RG) policy, as stated on the following page, must be followed.

THIS REMEDY IS YOUR EXCLUSIVE REMEDY. Terumo CVS 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 Terumo CVS CDI Blood Parameter Monitoring System 550 must be performed by Terumo CVS or an authorized service organization.

If you suspect instrument malfunction, please review the Troubleshooting section of this manual to determine the possible cause. Terumo CVS 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 Terumo CVS's authorization to return goods by calling Terumo CVS'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. Terumo CVS may give authorization at its discretion.

Terumo CVS 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 Terumo CVS's most recently published price list. Terumo CVS may inspect returned goods. If Terumo CVS determines that the returned goods are unacceptable, Terumo CVS may refuse to issue any credit. Terumo CVS 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 Terumo CVS will dispose of the returned goods.

Terumo CVS 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 Terumo CVS's shipping error, Terumo CVS will give 100% credit against the invoice price (less discounts). Otherwise, Terumo CVS will grant a 90% credit against the original invoice price (less discounts, freight, taxes, etc.). Terumo CVS 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.

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Software License

End User License Agreement
CDI System 550 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 550, 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-exclusive, non-transferable, non-assignable license to install and use one copy of the SOFTWARE on the CDI System 550. The SOFTWARE is intended specifically for use on the CDI System 550, 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 decompile, decrypt, disassemble, reverse engineer, or otherwise reduce the SOFTWARE to a human-perceivable form, even if such activity is expressly permitted by applicable law in the absence of an agreement. 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 550. 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 550. 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 550, 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 CONSEQUENTIAL 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.

8 EXPORT REGULATION. The SOFTWARE is subject to export control laws and regulations of the United States and may be subject to export or import regulations and laws of other countries. The SOFTWARE shall not be downloaded by, exported or re-exported to, any country currently under an embargo of the United States Government, including but not limited to Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria or to anyone on the U.S. Treasury Department's list of Specially Designated Nationals or the United States Department of Commerce's Table of Denial Orders.

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 Service, Terumo CVS, 6200 Jackson Rd., Ann Arbor, MI 48103, USA.

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Glossary

Note: These definitions are specific to the Terumo Cardiovascular Systems CDI Blood Parameter Monitoring System 550.

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 550 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 alarms.

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 Terumo CVS 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 Delivery ($\dot{D}O_2$)
The amount of oxygen delivered to the patient during CPB expressed in ml per minute.

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 550 Monitor's screen that contains case parameter data.

Potassium (K^+)

The major cation of intercellular fluid.

$\dot{Q}$

Blood flow value, in L/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.

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.

SRS

Standard reference sensor.

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 550. The gas concentrations used with the CDI System 550 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.