

HEMEDEX, INC.

Bowman Perfusion Monitor Model 500 User Manual

for use with software version 3.0.4

Manufactured by:



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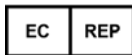
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Service and Support

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Warranty

Hemedex, Inc., warrants this product, and accessories, for a period of 1 year from the date of purchase, limited to parts and labor. The repaired unit will be covered for the period of 1 year following the date of repair.

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Preface

The Bowman Perfusion Monitor Model 500 is a user-friendly monitor for flexible, real-time measurements of tissue perfusion.

The Bowman Perfusion Monitor Model 500 allows unprecedented real-time monitoring of tissue perfusion in absolute units. It will automatically display and record these data. The Monitor is self-calibrating, requiring no operator intervention after initializing a measurement.

Purpose

This manual is designed to allow the clinician to quickly set up and begin using the Bowman Perfusion Monitor Model 500. Emphasis is placed on the essential components and tasks. Care should be taken to properly insert the probe in the patient and verify its placement—this is the most critical element in obtaining a valid measurement. For further details on using the QFlow™ 500 Probe, please see 'Instructions for Use' pamphlet that accompanies each probe.

This manual is intended to give general information about the utility and methodology of perfusion measurement. The manual provides specific instructions for the setup and operation of the Monitor, and raises awareness of the safety issues involved during use.

Indications for Use

The Bowman Perfusion Monitor Model 500 is intended for extravascular monitoring of microcirculation blood flow in buried tissues. Examples of this application include (but are not limited to) 1) Monitoring buried muscle or esophagus following free muscle transfer or esophageal reconstruction, 2) Monitoring soft tissue microcirculation following reconstructive surgery, such as oral and facial reconstruction, and 3) Monitoring cerebral blood flow during and following neurosurgery for head trauma.

Important Notes

Device Classifications and Standards

This instrument has been designed for constant use.

Electrical safety meets the following standards:

EN 60601-1:1994 including Amendments 1 and 2, for Defibrillation Proof type CF, Class 1 equipment.

UL2601-1, 2nd Edition (1997) including Amendments 1 and 2.

CAN/CSA C22.2 No. 601.1-M90 including C22.2 No. 601.1S1-94 (IEC601-1, Amendment 1:1991) Supplement No. 1-94 to CAN/CSA 22.2 No. 601-1-M90

Immunity from electromagnetic disturbance meets EN 60601-1-2:1993.

Maximum electromagnetic emission meets EN 60601-1-2:1993. Testing was performed to include demonstrated compliance, Group 1 Class B.













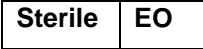




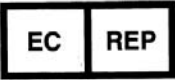
Warning Instructions

Failure to observe one or more of the following warnings could compromise the safety of the patient or result in measurement errors.

- The Bowman Perfusion Monitor Model 500 may only be used per the “Indications for Use” section of this document.
- The use of excessive force on the Monitor, umbilical cord and QFlow™ 500 Probe may cause serious damage. All mechanical features of the Monitor can be operated without the use of excessive force.
- The Monitor housing must not be opened and must be returned to the distributor or manufacturer for repair and service.
- The Monitor must be switched off before the power cable is disconnected.
- QFlow™ 500 Probes, umbilical cords, and power cords with damaged isolation jacketing must not be used.
- The Monitor and cable connectors must be protected against moisture and wetness.
- Connector contacts must be cleaned after coming into contact with saline solutions or body fluid. Connector contacts may not be used when they are wet or damp.
- Strong electrical interference (*e.g.* from electrocautery or cardioversion) can disturb the measurement.
- The Monitor should not be used in areas where there is a risk of explosion (*e.g.* in the presence of flammable anesthetics).

- Disposable QFlow™ 500 Probes are for single patient use only.
- If mounting the Monitor, the pole must have a wide enough base to provide a stable foundation.

Explanation of Symbols

	- Attention, see accompanying documents.
	- Defibrillation proof Type CF Applied Part.
	- Equipotential ground terminal.
	- Protective earth (ground)
	- Alternating current
	- AC (Mains) power on
	- AC (Mains) power off
	- Date of manufacture
	- Production lot number
	- Date of expiration
	- Sterilization by means of ethylene oxide gas
	- Single use only
	- Storage/transport temperature range
	- Storage/transport humidity range
	Manufacturer
	Authorized European community representative

Audience

The Bowman Perfusion Monitor Model 500 is designed for use by clinicians who wish to know perfusion. It is useful for correlating physiologic changes, treatment, and trauma to the tissue perfusion. The QFlow™ 500 Probe may be inserted in any perfused tissue: muscle, brain, liver, kidney, etc. This manual assumes a general background in medical practice and physiology on the user's part. Knowledge of expected and reasonable perfusion levels for the tissue is left to the discretion of the user.

Organization

This manual is organized into a Preface, six chapters, plus appendices. Chapter 1 reviews safety issues. Chapter 2 contains introductory information on perfusion and the Bowman Perfusion Monitor Model 500's ability to measure it. Chapter 3 covers setup of the Monitor. Chapter 4 explains how to take accurate perfusion measurements the first time you use the Monitor. Chapter 5 describes the basic procedures you will use to take perfusion measurements. Chapter 6 explains in detail the procedures you need to operate the Monitor.

Safety

The Bowman Perfusion Monitor Model 500 has built-in safety features, as well as some risks the user should be aware of.

The Bowman Perfusion Monitor Model 500 is designed with multiple levels of built-in safety features. The Monitor is designed with a switch to remove power from the QFlow™ 500 Probe if the Monitor checks indicate a faulty probe. This message is also relayed to the user interface. At another level of protection, the Monitor evaluates conditions for accurate measurements and issues warnings if required. Measurement error traps reduce the likelihood of an inaccurate measurement of perfusion from being made. System errors cause a safety shut down. The operator is alerted if the safety shutdown fails.

Risks

Contraindication

This device is not intended for use other than described below. Patients with contraindications for needle insertion into tissue, including coagulopathy and increased susceptibility to infection, should not be considered candidates for this device.

Risks and Complications

Maintenance of sterility during probe placement and subsequent handling is essential.

Sterile technique should be used at all times when inserting, correcting or adjusting the probe.

Precautions

- Bending of the Probe 1 cm from the tip can result in damage and can impair performance.
- Do not stretch or whip the probe.

- Exercise care when handling and inserting the Probe.
- Use aseptic technique throughout the procedure.
- Maintain the insertion site with regular redressing and use aseptic techniques.
- This device takes a local measurement of blood flow. Regional flow extrapolation from the local blood flow measurement is not claimed.
- This product may not be compatible with MRI diagnostic imaging equipment. **No MR imaging is recommended while this device is in place.**

Perfusion Probe

The QFlow™ 500 system should be used on the order of a physician only and it is assumed that the operator is knowledgeable of standard clinical practice, that the QFlow™ 500 Probe insertion is being performed in a sterile manner, and that the general precautions for implanting invasive probes are being followed. Further, therapeutic interventions should be based on the complete volume of relevant clinical data specific to each patient's pathology, and not solely upon the tissue perfusion values as measured by the Bowman Perfusion Monitor, Model 500. Contraindications for needle insertion into tissue also apply, including coagulopathy and increased susceptibility to infection.

Electrical

Table 1. Electrical Safety Parameters

Breakdown Voltage	Medical Grade Isolation: dielectric strength tested to 4000 V AC
Leakage current	< 10 μ A—meets IEC-6060-1-1 specifications for CF equipment

Monitor Malfunction

A malfunction in the Monitor may terminate the measurement. The Monitor will shut down electrical power to the Probe if contact is lost for more than six seconds. Contact Hemedex, Inc., to report the error description given by the interface.

Introduction

The ability to measure absolute perfusion continuously at the tissue level is unique to the Bowman Perfusion Monitor Model 500.

What is perfusion? Tissue blood flow, or perfusion, can be defined as the rate at which the quantity of blood in a given mass or volume of tissue is replenished at the level of the capillary network. It is measured in milliliters of blood per 100 grams of tissue per minute, or ml/100g–min. Perfusion is a primary factor in the local transport of heat, drugs, oxygen, nutrients, and waste products.

Why is Perfusion of Interest?

Perfusion monitoring is a leading indicator of change to tissue health. Perfusion monitoring aids in the assessment of tissue in general and in reaction to induced physiologic changes. The Bowman Perfusion Monitor Model 500 provides rapid detection of change in perfusion level, allowing early detection of changes, while also recording long-term perfusion levels to establish a baseline or to monitor changes over a course of treatment or study.

What is the Bowman Perfusion Monitor Model 500?

The technology to measure blood perfusion originated at the Massachusetts Institute of Technology (MIT), Cambridge, MA, under Dr. H. Frederick Bowman with support from the National Institutes of Health (NIH). The technology was further developed by Thermal Technologies, Inc., and Hemedex, Inc., both of Cambridge, MA.

The Bowman Perfusion Monitor Model 500 uses a QFlow™ 500 Probe to make real-time measurements of perfusion in absolute units and records data at 1 Hz. The procedure is safe, simple and rapid. The minimally invasive QFlow™ 500 Probe must be inserted within the tissue being examined.

Principles of the Perfusion Measurement

The QFlow™ 500 Probe contains two thermistors embedded at the tip of a polyurethane catheter. The QFlow™ 500 Probe comes sterilized and packaged for single patient use. The distal (heating) thermistor is heated to a small increment above the tissue temperature baseline (approximately 2.5°C, affecting only the immediate vicinity of the thermistor), while the proximal (sense) thermistor tracks the tissue baseline temperature. The power dissipated by the heated thermistor (5 to 20 mW) provides a measure of the tissue's ability to carry heat by thermal conduction in the tissue and by thermal convection due to tissue blood flow. The Monitor measures tissue perfusion by first determining the conductive properties of the tissue, calculated from the initial rate of propagation of the thermal field when the heat to the probe is first turned on. The Monitor calculates the thermal conductivity of the tissue and displays the constant as the K Value. Thermal convection from blood flow is then given as the difference between the total dissipated power and thermal conduction. The Monitor produces a real-time simultaneous measure of absolute perfusion and temperature at the measurement site.

Numerous validation experiments demonstrate the ability of the technique to measure perfusion throughout the physiologic range, from 0 to 200 ml/100g–min, with a flow sensitivity of better than 0.5 ml/100g–min in various tissues such as skin, tumor, muscle and liver. The Bowman Perfusion Monitor Model 500 technique is safe, simple, repeatable, and rapid and provides an absolute measure of perfusion.

Measurement Accuracy Considerations

The accuracy of perfusion measurement is highly dependent on proper probe placement, and on maintaining a stable probe placement against motion disturbances. The Bowman Perfusion Monitor is sensitive to motion artifact. If the motion causes the probe to be grossly displaced then the Monitor will go into recalibration to reassess the K Value. If the motion artifact detected is of a lesser degree then the Monitor will continue with perfusion measurement and will display the motion as spikes (Figure 1).

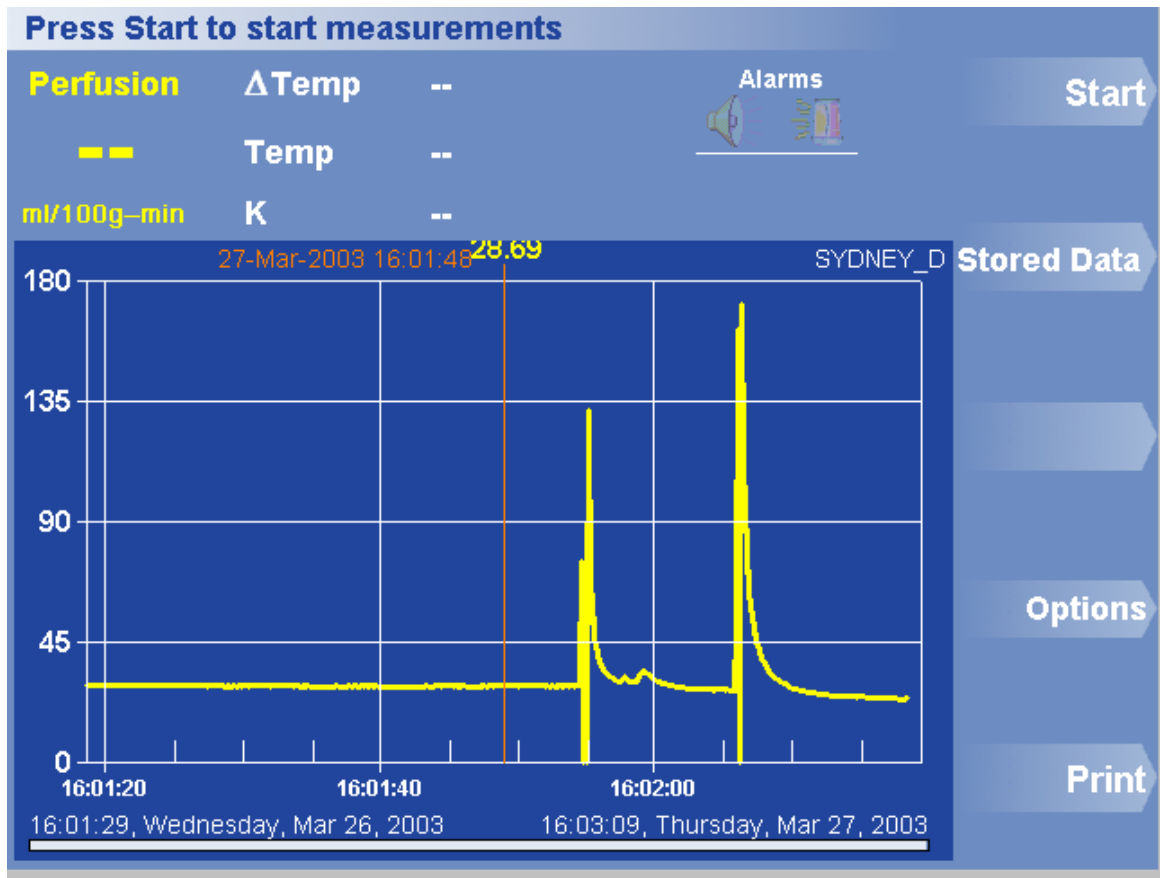


Figure 1. Motion Artifact

The perfusion measurement algorithm assumes a uniform distribution of blood flow in the tissue within a few millimeters of the probe tip. If the probe tip is near a thermally significant blood vessel, this vessel will preferentially absorb a significant fraction of the heat given off at the probe tip. This confounding case is detected by the Monitor when the measured K value (thermal conductivity) exceeds 6.5 mW/cm-°C. If this occurs, the user should reposition the probe until the K Value is below 6.5. To address this problem, slightly reposition the probe by sliding it approximately 1 mm in either direction along the insertion track. In extreme cases a high K Value will produce an error message and not allow the Monitor to continue into perfusion.

Periodic recalibration is required in living tissue because the baseline temperature and thermal conductivity (K value) may change over time. The Monitor automatically recalibrates after two hours or less, depending on a user-defined parameter (the default is one hour).

Setup

The Bowman Perfusion Monitor Model 500 is designed for rapid setup.

The Bowman Perfusion Monitor Model 500 is designed as a stand-alone unit with capability for linking to other systems. The Monitor connects directly to any standard RS-232 serial port. The analog output (BNC) connector of the Monitor may be attached to a user-selected auxiliary analog voltage data collection device. The QFlow™ 500 Probes must be inserted properly into the target tissue and attached to the Monitor.

Specifications

The Bowman Perfusion Monitor Model 500 requires the following interfaces to function.

Table 2. Electronics Hardware Specifications

Power	100-120 VAC, 200-240 VAC; 50/60 Hz, 65 VA Note to use the 120 VAC selection for 100 to 120 VAC and use the 240 VAC selection for 200 to 240 VAC. These voltages are selected by the Line Voltage Selector. See Figure 4 for a picture of the Line Voltage Selector on the rear panel of the Monitor.
Serial Cable	Any standard straight-through connecting cable with the proper pin configuration (DB-9) to match your Bowman Perfusion Monitor Model 500. The Monitor must be connected to a male connector at the Monitor end. (Computer serial ports typically require a female connector.)

European power setup is available upon request.

The Bowman Perfusion Monitor Model 500 also includes an analog output.

Table 3. Analog Output Specifications

Voltage Output	0 to 2 V DC (100 Ω impedance) Voltage floating and insulated from chassis ground
Output Scale	Fixed scale 100 ml/100g–min perfusion per V (0 to 200 ml/100g–min range)
Filtering	Analog output is filtered to the same degree as displayed perfusion measurement

Table 4. Physical Specifications

Dimensions	16.6 \times 11.9 \times 10.1 inches (42.2 \times 30.2 \times 25.7 cm)
Weight	10 lbs. (4.5 kg)
Operating Temperature Range	0° to 50° C
Storage Temperature Range	-25° to 60° C
Storage Humidity Range	20% to 90% RH

Setting up the System

Front Panel

The front panel of the Bowman Perfusion Monitor Model 500 (See Figure 2) holds the power switch, printer, display screen, menu buttons, and umbilical cord connector (for the perfusion probe). To take measurements, a QFlow™ 500 Probe must be connected to the umbilical cord, and the umbilical cord must be connected to the Monitor. The Monitor checks for a probe to start the measurement, and continues checking to ensure the probe is not disconnected during the measurement.

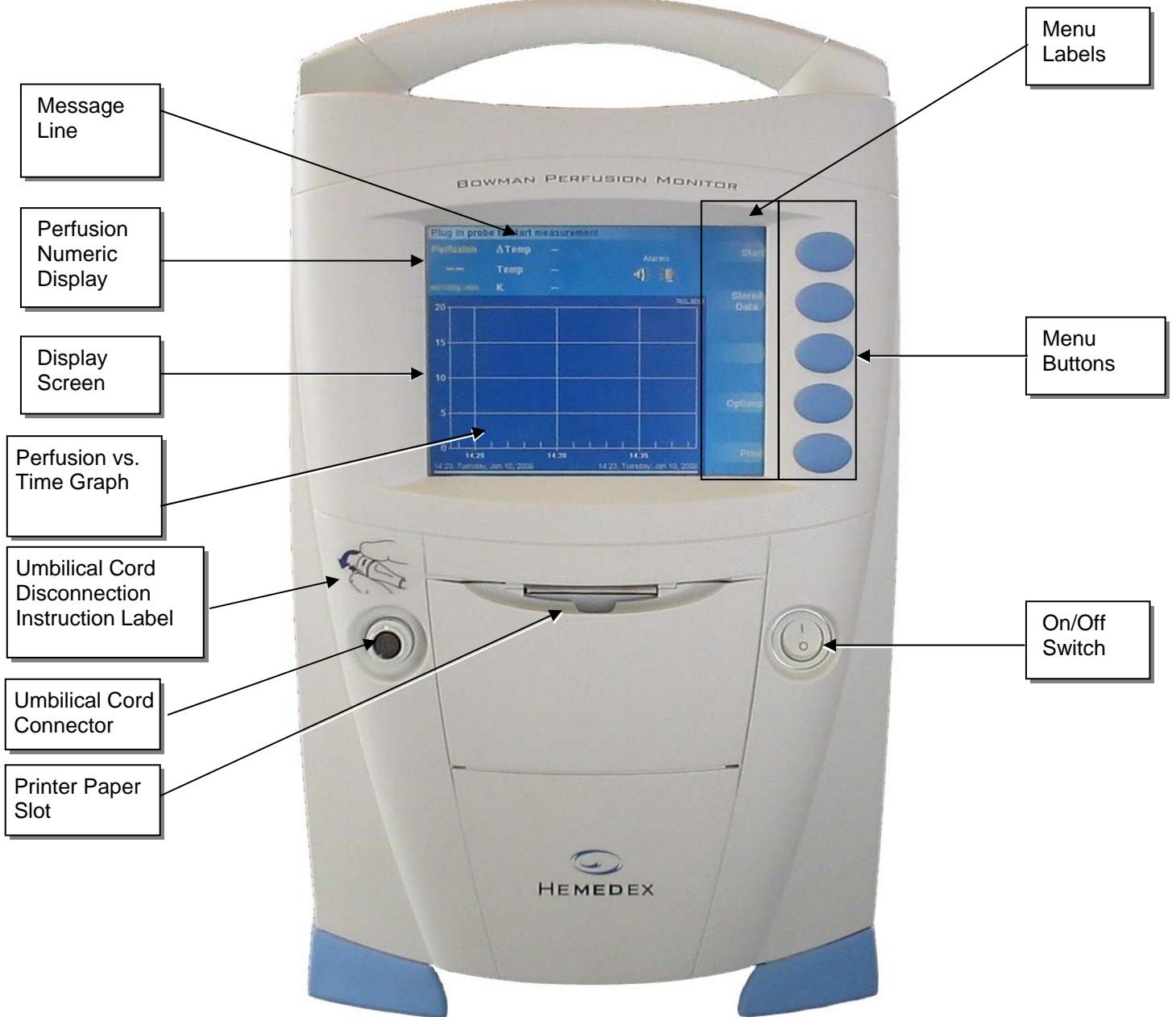


Figure 2. Front Panel of the Bowman Perfusion Monitor Model 500

Printer

The printer records the real-time perfusion measurements on paper for review by the Monitor operator. Printing is performed when requested by the user.

Load paper in the Bowman Perfusion Monitor Model 500 before operating. The printer uses standard 50 mm thermographic print rolls (Hemedex catalogue # 3605).

Use Procedure 1 to load paper in the printer.

Procedure 1. Load paper in the printer

1. Open printer access panel by flipping the door down.
2. Push black trigger on printer paper door end to access paper compartment.
3. Insert paper roll into opening with paper coming off the bottom side of the roll (see Figure 3).
4. Pull paper strip out to expose several inches of paper.
5. Close paper door and printer access door.

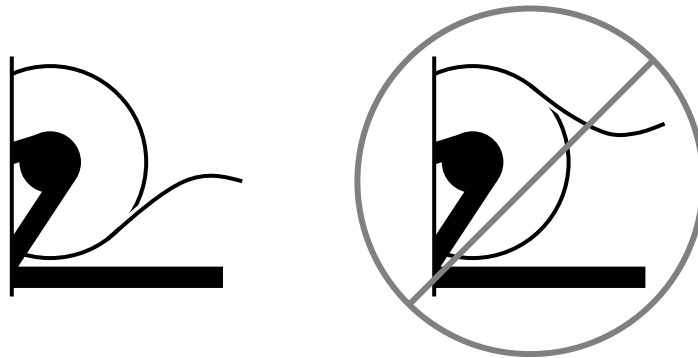


Figure 3. Correct (left) and incorrect (right) paper orientation

Rear Panel

The rear panel of the Bowman Perfusion Monitor Model 500 (see Figure 4) contains a BNC connector for the analog output, and a 9-pin female connector (DB-9) for serial communications (RS-232) to an outboard computer. The rear panel also contains the power cord connector and an indicator showing the power input compatible to the Monitor. This is the fuse and line voltage selector (see Figure 4). The switch must be set accordingly for the country of use.

Checking the AC Voltage Switch

The only two positions used are 120 VAC which covers the range from 100 to 120 VAC and 240 VAC which covers the range from 220 to 240 VAC. If the voltage is set incorrectly the monitor display lights up, and an error message occurs that prompts the user to Check that the AC line input switch is set correctly. If you need to change the switch, remove the AC Power Cord. Use a small flat blade screwdriver to pry open the slot in the power input module just above the section indicating the line voltage. Pull the drum with the voltage marked on it straight out and then reinsert it with the correct voltage.



Cables connected to the “RS232” Serial Port and the “ANALOG OUT” connector are intended for external monitoring and service access purposes only and must not be brought into the sterile patient field. Only the Perfusion Probe that is to be connected to the umbilical cord can be inserted into the patient operating field. The umbilical cord is not sterile but can be steam sterilized for use in the operating field.

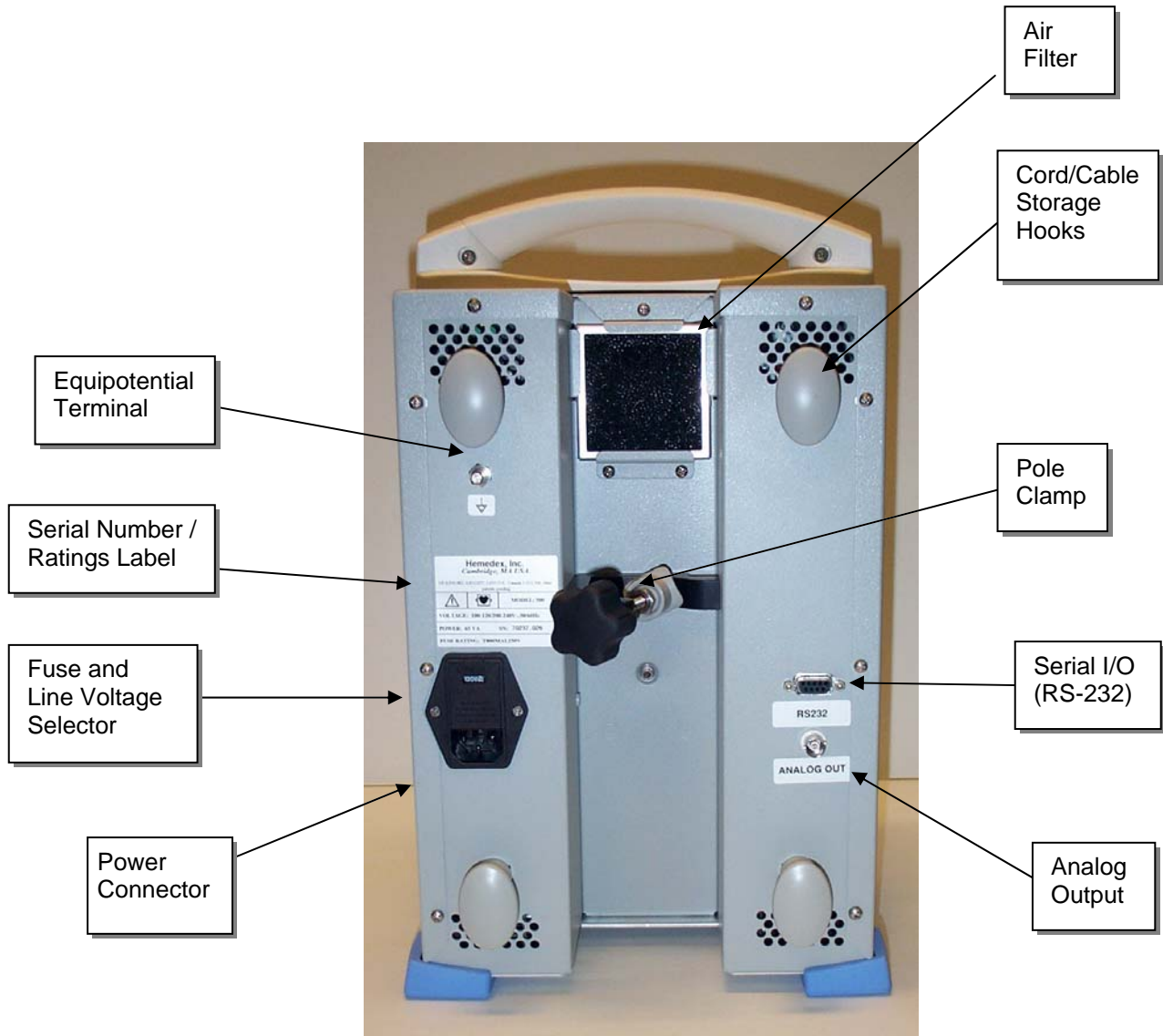


Figure 4. Rear Panel of the Bowman Perfusion Monitor Model 500

Mounting the Monitor

The Bowman Perfusion Monitor Model 500 is designed to be mounted on standard medical equipment holders, such as an IV pole. Simply place the rear mounting channel against the upright pole and screw the self-aligning mounting clamp tight. The pole needs to have a base wide enough to provide a stable foundation for the Monitor.

Sterilization and Cleaning



Perfusion Probe: The QFlow™ 500 Probe is intended for a single patient use of no longer than ten days. The probe is to be disposed of after use in accordance with established biohazard waste disposal practices.

Umbilical Cord: The QFlow™ 500 Probe Umbilical Cord can be used multiple times and must be cleaned or autoclave sterilized between uses in accordance with directions supplied with the cord. The cord may be autoclaved up to 20 times before replacement is necessary.

Monitor: The Bowman Perfusion Monitor Model 500 should be thoroughly wiped down with disinfectant after each use.

Maintenance and Servicing



There are no user serviceable parts in the Bowman Perfusion Monitor Model 500 System. All servicing and maintenance other than the changing of the paper roll, and the cleaning/sterilization described above must be performed by factory authorized personnel. All Hemedex, Inc. warranties expressed and implied will be void if the tamper evident seal shows signs of unauthorized servicing.

Routine visual inspection of the Umbilical Cord is recommended. If there is evidence of any degradation due to repeated use please contact Hemedex, Inc. for replacement/repair. In addition, the air filter mounted at the fan intake may need periodic cleaning with a small vacuum cleaner as necessary.

Getting Started

Chapter 4 explains how to take accurate perfusion measurements the first time you turn on the Bowman Perfusion Monitor Model 500.

The front panel of the Bowman Perfusion Monitor Model 500 contains a display screen that uses menus, dialog boxes, and measurement readouts to give and receive information. In addition, it uses five buttons to navigate the menu system and execute your instructions. Use the screen to enter information necessary to set up a perfusion measurement. Numeric and graphic displays let you monitor the measurement after it is underway. Figure 2 illustrates important items on the front panel of the Monitor.

Measurement Basics

The Bowman Perfusion Monitor Model 500 measurement cycle has three phases: temperature stabilization, calibration, and perfusion measurement. Figure 5 shows how these three parts of the measurement cycle fit together.

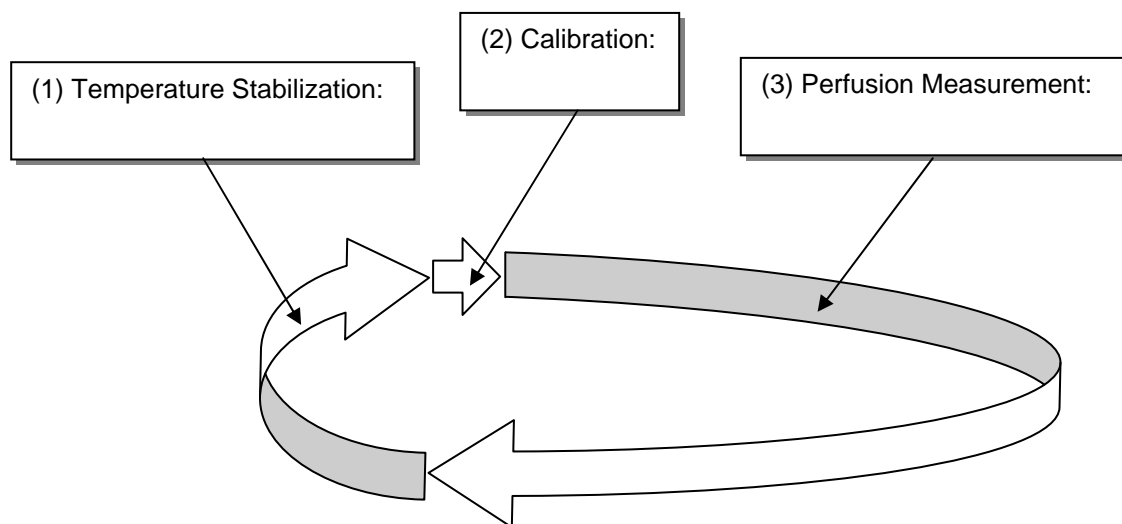


Figure 5. Three Phases of the Perfusion Measurement Cycle

The current phase of the measurement cycle is usually given in the message line at the top of the screen. During perfusion measurement, the numerical display in the upper left-hand corner of the screen shows perfusion in milliliters of blood per 100 grams of tissue per minute (ml/100g–min). This value is also plotted versus time on the graph area of the screen.

Temperature Stabilization

At the start of each new measurement, the system automatically begins with temperature stabilization. During the temperature stabilization phase, the Bowman Perfusion Monitor Model 500 confirms the tissue baseline temperature is stable. The stabilization period typically lasts several minutes. The Monitor takes no perfusion measurements during this phase. If thermal stability is not met the Monitor will not exit the temperature stabilization phase. A warning message will be displayed (see Figure 6) and the Monitor will continue to check for stability. Once thermal stability is reached an additional message will overwrite the original warning message and temperature stabilization period will end.

The temperature stabilization phase also includes a period of time to allow the heated tissue to cool down to baseline temperature before reheating; this is called Cool Down Time. It is necessary to allow the thermistor to cool so that any thermal energy introduced by the Monitor's heating cycle is completely dissipated before recalibration. No perfusion calculations are performed during the Cool Down Time; it is a waiting period. In software version 3.0.4 temperature stabilization period (including cool down time) is between 3 minutes, 30 seconds and 8 minutes 30 seconds, depending on the perfusion level. The user may also specify a longer temperature stabilization period, if desired, by changing the parameters under the Measurement Control Menu.

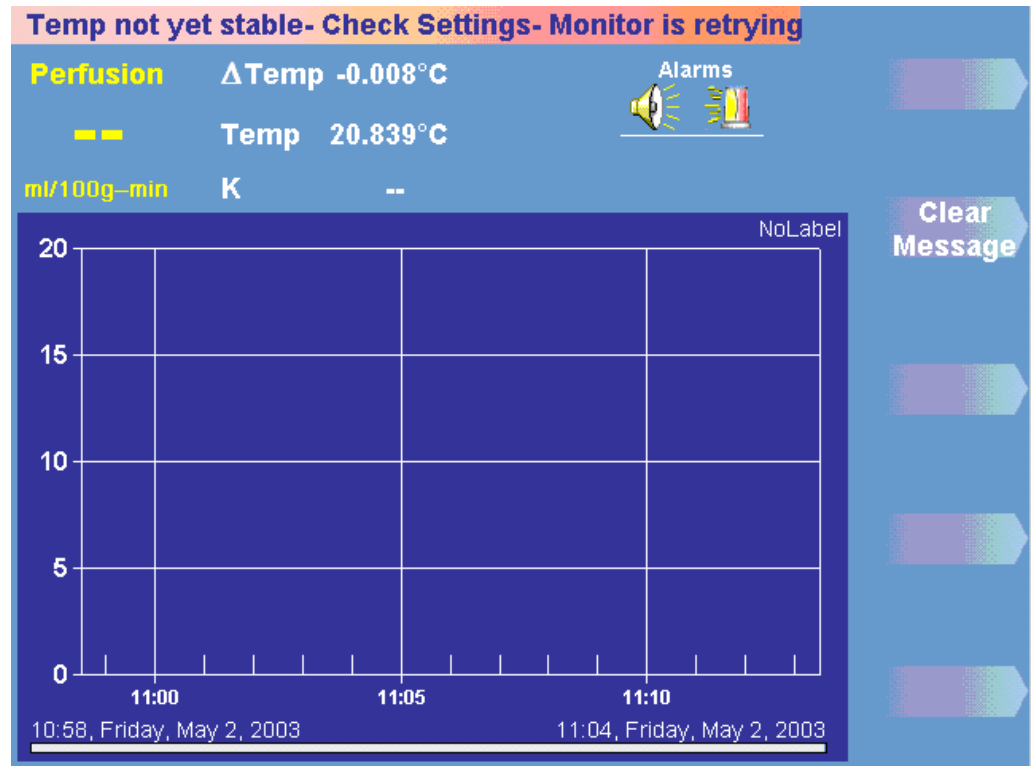


Figure 6. Unstable temperature warning message.

Calibration

The Monitor automatically calibrates during the period immediately after temperature stabilization and before perfusion measurement. During calibration, the Monitor calculates the thermal conductivity (K value) of the tissue. Calibration requires about 10 seconds. The Monitor takes no perfusion measurements while it calibrates.

Perfusion Measurement

Perfusion measurement begins after calibration is complete, but no reading appears until 50 seconds later (after blackout period) when the Monitor determines that the measurement is accurate. If the Monitor detects a problem with the measurement results, it automatically recalibrates, starting a new temperature stabilization phase to obtain a better reading.

A First Measurement

If you have followed the setup procedure in Chapter 3, the Bowman Perfusion Monitor Model 500 is unpacked and ready for use. Follow these steps to measure perfusion with the Monitor for the first time:

1. Plug the grounded power cord into an appropriate wall outlet.

2. Press the On/Off switch on the front of the Monitor to turn it on.

Notice the screen as the Monitor starts up. When the Monitor is ready, the screen in Figure 7 appears.

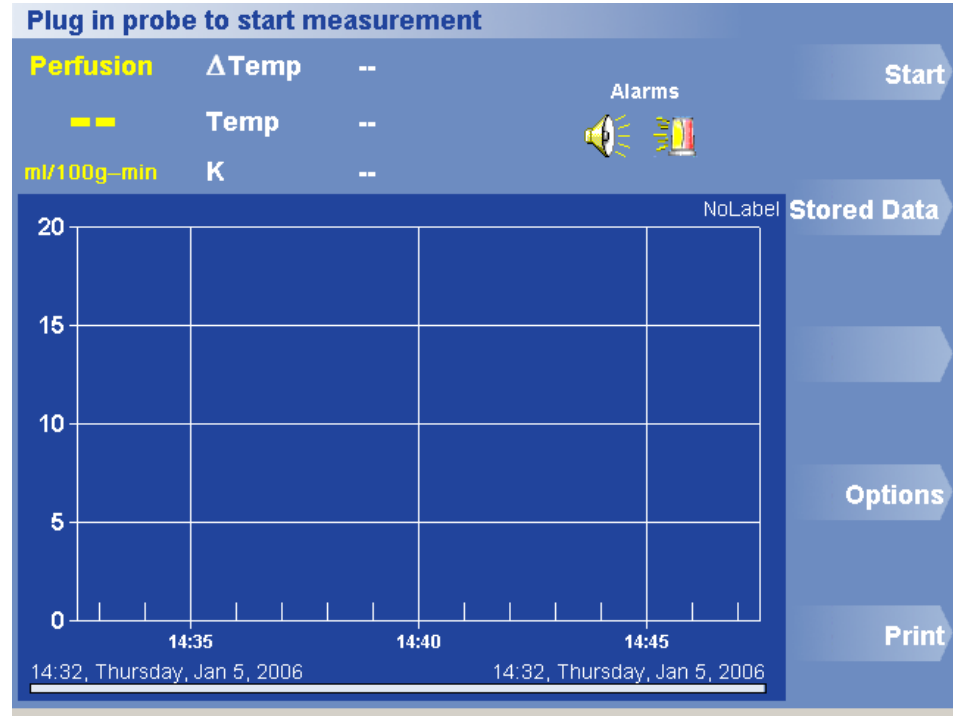


Figure 7. Initial Display-Start Menu

3. Remove the Probe from its sterile packaging.

The instructions that come with the Probe explain how to handle it properly.

4. Insert the Probe into the tissue where you want to monitor blood flow.

The instructions that accompany the Probe give step-by-step guidance for the proper insertion technique.



Caution: Once the Probe is in place, do not move it until the perfusion measurement is complete. You should move the Probe only if you want measurements at a different tissue site, or if the Monitor recommends moving the Probe.

5. Connect the Probe to its umbilical cord, and then connect the umbilical cord to the connector on the front of the Monitor. Make sure to place the cord out of traffic and in such a way as to prevent entanglement of the patient and undue stresses on the cord. Use the enclosed clips where helpful.
6. The Monitor will automatically start a measurement when the Probe is attached or you can press the Start button (the top menu button).

- The message line indicates that the Monitor is in the temperature stabilization phase of its measurement cycle. It also indicates the estimated time until perfusion measurement begins.
 - When the Monitor has verified that the tissue is thermally stable, it enters a calibration phase to determine the K value (thermal conductivity) of the tissue. Calibration lasts approximately 10 seconds.
 - Approximately 50 seconds after calibration is complete, accurate perfusion measurement begins.
7. Check the display to verify that perfusion measurement is satisfactorily underway:
- The value in the upper left-hand corner of the display shows perfusion in milliliters of blood per 100 grams of tissue per minute (ml/100g–min).
 - The graph in the display plots perfusion in real time. Figure 8 shows how the screen appears when perfusion measurement is in progress.

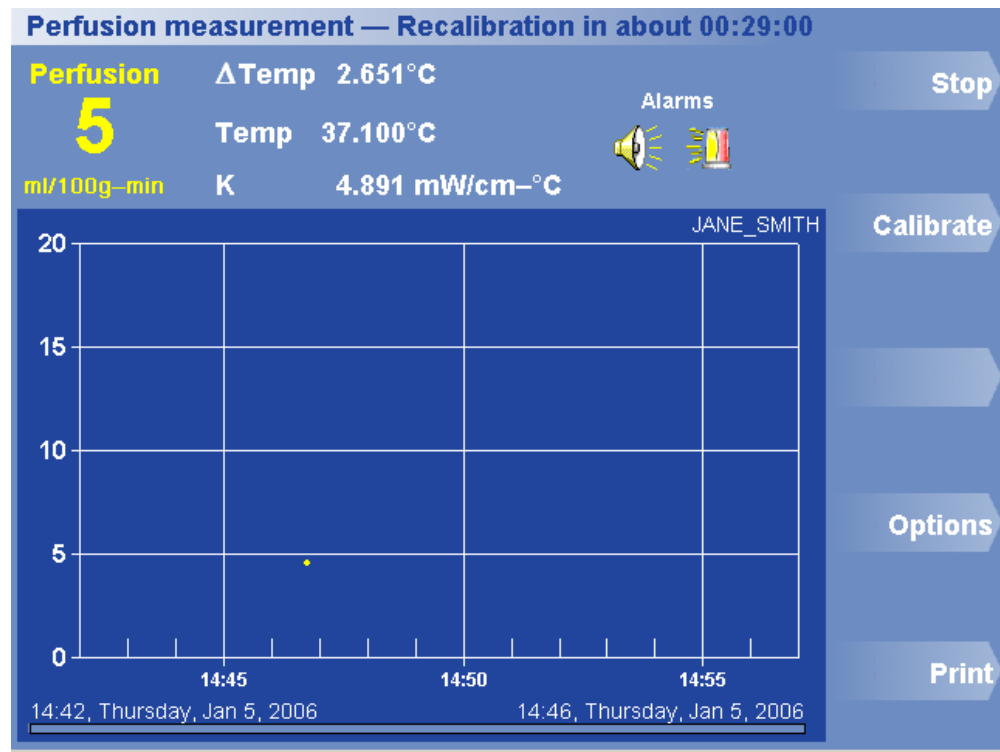
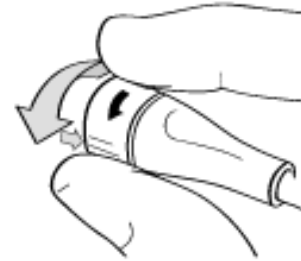


Figure 8. Perfusion Measurement Underway-Stop Menu

8. To stop the perfusion measurement, press the Stop button.

- If you press the Stop button, the value for perfusion disappears from the numeric display, and the plot of perfusion against time stops scrolling.
- Settings and options are stored on the Probe when you press start and during every transition from temperature stabilization to calibration.
- After pressing the Stop button, the Monitor will automatically start the measurement cycle after 5 minutes.

9. When disconnecting the umbilical cord, from the Monitor, make sure to turn the connector Locking Ring counterclockwise and then gently pull the connector away from the Monitor.



Saving settings and options

It is important to make note that no changes made to settings and options are saved until the user starts a measurement. The changes are stored to the probe and will be restored from the probe once it is connected to the Monitor. If you change settings on the Monitor and connect a probe that has already been used, the settings from the probe will override those from the Monitor. Conversely, if a new probe is connected then settings on the Monitor will overwrite the default settings on the probe.

Summary

A summary of important terms in this chapter follows:

Stabilize Temperature

The first phase of the perfusion measurement cycle is temperature stabilization. The Monitor measures the temperature of the tissue surrounding the Probe, and verifies that it is stable. Stable baseline temperature is a prerequisite for calibration.

Calibrate

The Monitor calculates the thermal conductivity (K value) of the tissue. When this calculation is complete, the Monitor is calibrated and ready to measure perfusion.

Measure Perfusion

The Monitor measures tissue blood flow and reports the results both in the numeric display and in the plot of perfusion vs. time. After about 60 minutes, measurement stops and the Monitor recalibrates before starting a new measurement cycle.

Message Line

The message line at the top of the screen communicates instructions and suggestions, Monitor status, and warning and error conditions.

Numeric Display

The numeric display in the upper left-hand corner of the screen shows the current perfusion level in units of milliliters of blood per 100 grams of tissue per minute (ml/100g–min). A number in this display indicates that accurate perfusion measurement is in progress. No reading appears in the numeric display when perfusion measurement is not in progress, or when any factor prevents the Monitor from taking accurate measurements.

Cool Down Time

The Cool Down Time is the amount of time necessary for the distal (heating) thermistor temperature to return to baseline temperature (equal to that of the proximal thermistor temperature). Normally, the Monitor automatically calculates this time and adds it into the temperature stabilization time. Though the user can override this time. If there is an inadequate amount of time between heating cycles the leftover thermal energy can confound the measurement.

Operation Overview

This chapter introduces the operation of the Bowman Perfusion Monitor Model 500. It explains how to interpret the information on the main screen, and gives an overview of the menu system.

The graphical interface that appears in the main screen of the Bowman Perfusion Monitor Model 500 contains data and system information in three display areas:

- The message line at the top of the main screen.
- The area just below the message line, which contains numerical data and status indicators.
- The graphical portion of the screen, which contains plots of perfusion and three thermal parameters over time (By default only the perfusion plot is displayed, to enable viewing of the thermal plots see Procedure 21).

In addition, the interface allows you to enter instructions and adjust settings via the menus on the right side of the screen. Chapter 5 explains how the menus are organized. Chapter 6 explains how to use the menus to adjust and control the Monitor.

Main Screen Layout

The main screen of the Bowman Perfusion Monitor Model 500 contains several types of data. Figure 9 identifies key information available in the message line, the area below the message line, and the data plots. It also highlights the Monitor controls available in the menu on the right side of the screen.

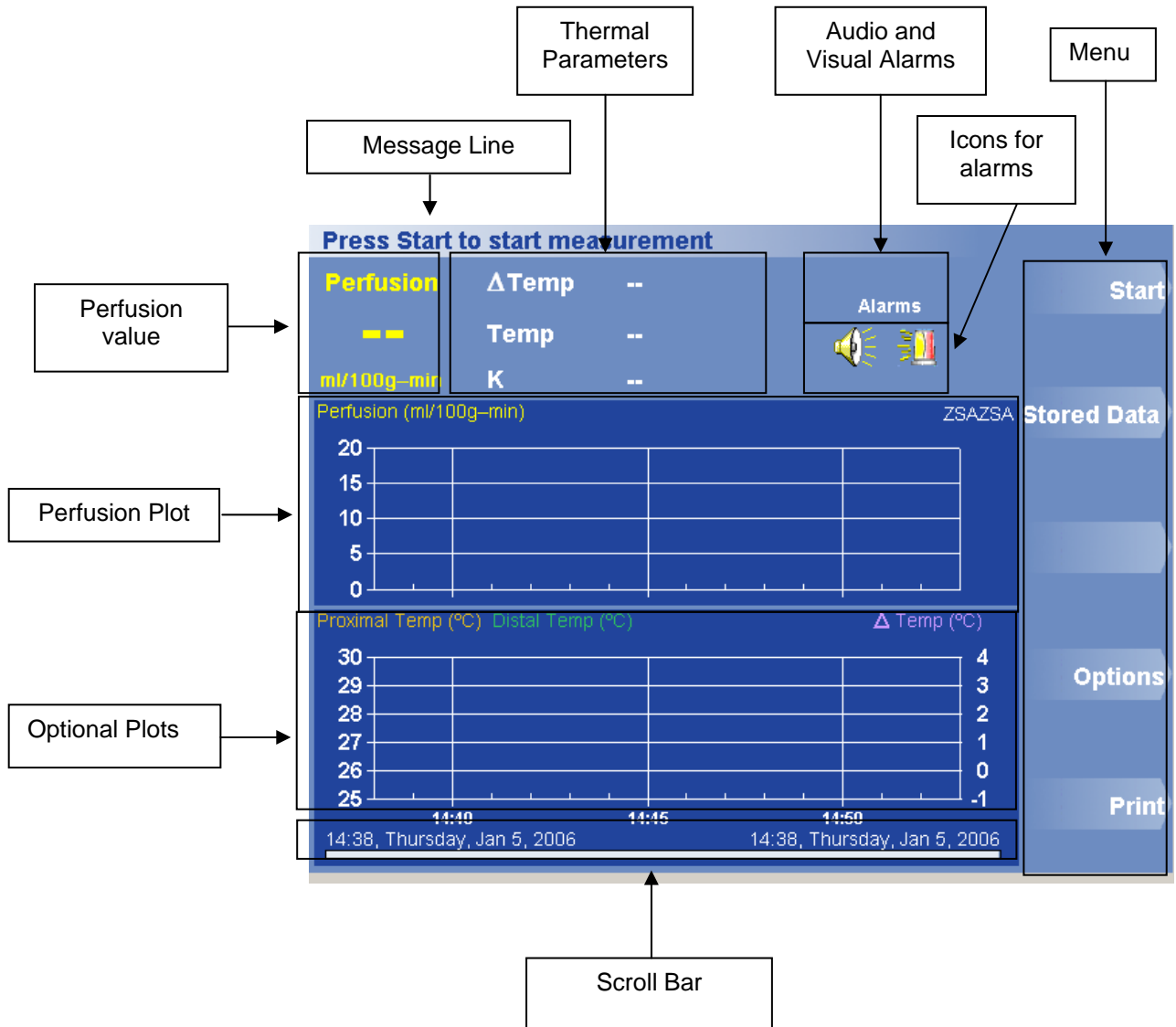


Figure 9. Main Screen of the Bowman Perfusion Monitor Model 500

Message Line

The information that appears in the message line depends on the current state of the Monitor. For example:

- If the Monitor is ready to begin perfusion measurement, an instructional message tells you to press Start.
- During temperature stabilization and calibration, the Monitor generally displays the estimated time until the start of perfusion measurement.
- During perfusion measurement, the Monitor generally displays the estimated time until the end of the current perfusion measurement phase and the beginning of the next measurement cycle.
- If an error or anomaly has occurred, the message line flashes between red and blue, and displays a message that alerts you to the problem.
- If perfusion in the tissue exceeds an alarm limit, the message line contains information about the alarm.
- Table 5 shows the on-screen indications for urgent messages and alarms. When the perfusion Monitor is in normal operation, the background of the main screen remains blue.

Table 5. Indications for Warnings, Error, and Alarm Messages

Indication	Type of Message	Explanation
The message line at the top of the main screen flashes between red and light blue.	Warning, error, or alarm message	Some anomaly or error has occurred. See the list of warning and error messages in Appendix A.
The main screen flashes between red and blue.	Perfusion alarm	Measured perfusion has exceeded the upper or lower bound of the perfusion alarm (and the visual alarm is enabled).

Perfusion Measurement

The most prominent part of the main screen is the numerical display in the upper left-hand corner. During normal operation, the current value for perfusion appears in the numerical display whenever perfusion measurements are taking place. No perfusion value appears during temperature stabilization and calibration, or when you scroll the data plots back in time.

Thermal Parameters

If perfusion measurement is underway and the plotted data are not scrolled back, a value for each thermal parameter listed in Table 6 appears above the graph area. The values for these three parameters do not appear when you review stored data.

Table 6. Thermal Parameters

Screen Label	Full Name	Definition
Δ Temp	Δ Temperature	<p>During temperature stabilization: The difference between the temperatures of the distal thermistor and the proximal thermistor.</p> <p>During calibration: Not measured.</p> <p>During perfusion measurement: The difference between the surface temperature of the distal thermistor during perfusion measurement mode and immediately prior to calibration.</p>
Temp	Baseline temperature	Baseline temperature of the tissue, which is the same as proximal (sense) temperature.
K	Thermal conductivity	Thermal conductivity of the tissue in mW/cm-°C. (This parameter is displayed only during perfusion measurement.)

Alarms

The Monitor contains both visual and audio perfusion limit alarms. If only the visual alarm is enabled when the alarm is triggered, the background color of the entire screen flashes between red and blue. If only the audio alarm is enabled when the alarm is triggered, a repeating beep sounds and only the background color of the message line flashes between red and blue.

The alarms can be set to trigger when they rise above an upper bound limit or below a lower bound limit. There are three different parameters that need to be defined for both the lower and upper bound limits.

- Value
- Trigger Time
- Suspend Time

The Value refers to the perfusion value which the user chooses as either an upper or lower bound limit. The Trigger Time specifies how long measured perfusion must lay outside the bound before the Monitor triggers the alarm. Once the alarm is triggered a menu appears that allows the user to temporarily suspend the alarm. The Suspend Time specifies how long a triggered alarm remains temporarily disabled. These three parameters are all user defined within a certain range.

It is important to note that if an alarm is suspended and the perfusion continues to violate the bounds, the Monitor will not alarm. When choosing suspend times, keep in mind that in suspend state the alarm mode is virtually turned off.

Measurement Control

Accurate measurement of perfusion depends on an accurate and periodic assessment of the tissue's thermal conductivity (K value). Therefore perfusion measurement lasts no longer than two hours to allow for a new cycle of thermal stabilization, calibration, and resumption of perfusion measurement. The temperature stabilization and perfusion measurement phases are set for user-adjustable, specified durations. The Monitor simply cycles through the temperature stabilization, calibration, and perfusion measurement phases based on the pre-set schedule. You can set the measurement control for an unlimited amount of cycles or for a specific number of cycles.

The screen indicators for the three measurement cycle control modes are summarized in Table 7.

Table 7. Measurement Control User-Adjustable Parameters

Mode	Indicator
Number of Cycles	This parameter allows the user to enter a limited number of cycles. By default the number of cycles is unlimited allowing the Monitor to measure continuously.
Temperature Period	This parameter is used to ensure that there has been adequate cooling of the probe before the next measurement begins. The user can adjust this parameter, however the Monitor automatically insures that there is at least sufficient cool down time for an accurate measurement. The greater the temperature period, the longer it takes the Monitor to reach perfusion.
Perfusion Period	This parameter allows the user to choose the length of time that the Monitor measures perfusion. The maximum is 2 hours to ensure accurate measurement.

Graphs

The graph area consists of one or two sections. The upper section displays a single plot for perfusion. The lower section, if present, displays plots for up to three thermal parameters. By default only the perfusion section is displayed. The user has the option of enabling the temperature section of the graph.

Perfusion Plot

Perfusion is plotted as a function of time. The plot displays a yellow line to indicate the current perfusion in units of milliliters of blood per 100 grams of tissue per minute (ml/100g–min). The horizontal axis shows the time of day. By default, the screen displays 15 minutes of perfusion data. If perfusion data are reviewed from stored data, the latest perfusion data are initially displayed in the plot.

No perfusion data are plotted during the temperature stabilization or calibration phases of the measurement cycle.

If you have scrolled the plotted data back in time, an orange vertical line appears at the center of the perfusion plot area. The plot shows the value for perfusion at the place where the plotted data intersect the vertical line. It also shows the corresponding date and time of the measurement.

Thermal Parameter Plots

The proximal thermistor temperature and distal thermistor temperature are individually selectable for plotting as a function of time. Proximal temperature is plotted in gold, distal temperature is plotted in dark green, and Δ temperature is plotted in lavender. The plot for Δ temperature, which is also selectable for plotting (with one of the thermistor temperatures), uses the vertical scale on the right-hand side of the graph. Distal temperature and Δ temperature are not available during calibration.

Table 8 summarizes the plots that appear in the graph area.

Table 8. Color Key for Data Plots

Color	Plot
Yellow	Perfusion
Dark Green	Distal Temperature (Distal Temp)
Gold	Proximal Temperature (Proximal Temp)
Lavender	Δ Temperature (Δ Temp)

Plot Scrolling

If perfusion measurement is underway, the perfusion plot scrolls automatically as new data points are added. If you have scrolled back to view data collected earlier, the plot does not scroll automatically as new measurements accumulate. The same conditions hold for the thermal parameter plots in the lower portion of the graph area.

Just below the x-axis of the graph there are two times displayed. The time to the far left of the graph is the earliest time that you can scroll back to. The time to the far right of the graph is the current system time. If no measurements are being taken then the time to the far right of the graph reflects when the Monitor was last running.

The graph area includes a scroll bar below the thermal parameter plots. The size of the small rectangular box in the scroll bar indicates what proportion of the data is actually displayed at the moment. The position of the box in the scroll bar indicates when the measurements for that portion of the data were taken. The left side of the box represents the earliest data in the display, and the right side represents the latest data.

Graph Scaling

The Bowman Perfusion Monitor allows the user to set a fixed perfusion scale (y-axis) or to use the autoscale option. Autoscale will automatically adjust the y-axis to best display the data being collected. The Time Range (x-axis) can also be adjusted by the user. The user can choose a time range from 30 seconds to 10 days.

Menus

Use the menu on the right-hand side of the main screen to control the Bowman Perfusion Monitor Model 500, to set measurement and device parameters, and to manipulate data. A menu shows up to five options at a time. The menus are arranged in a hierarchical tree, so selection of one option often opens a new set of menu items at the next level in the tree. Figure 10 illustrates key menus in this structure.

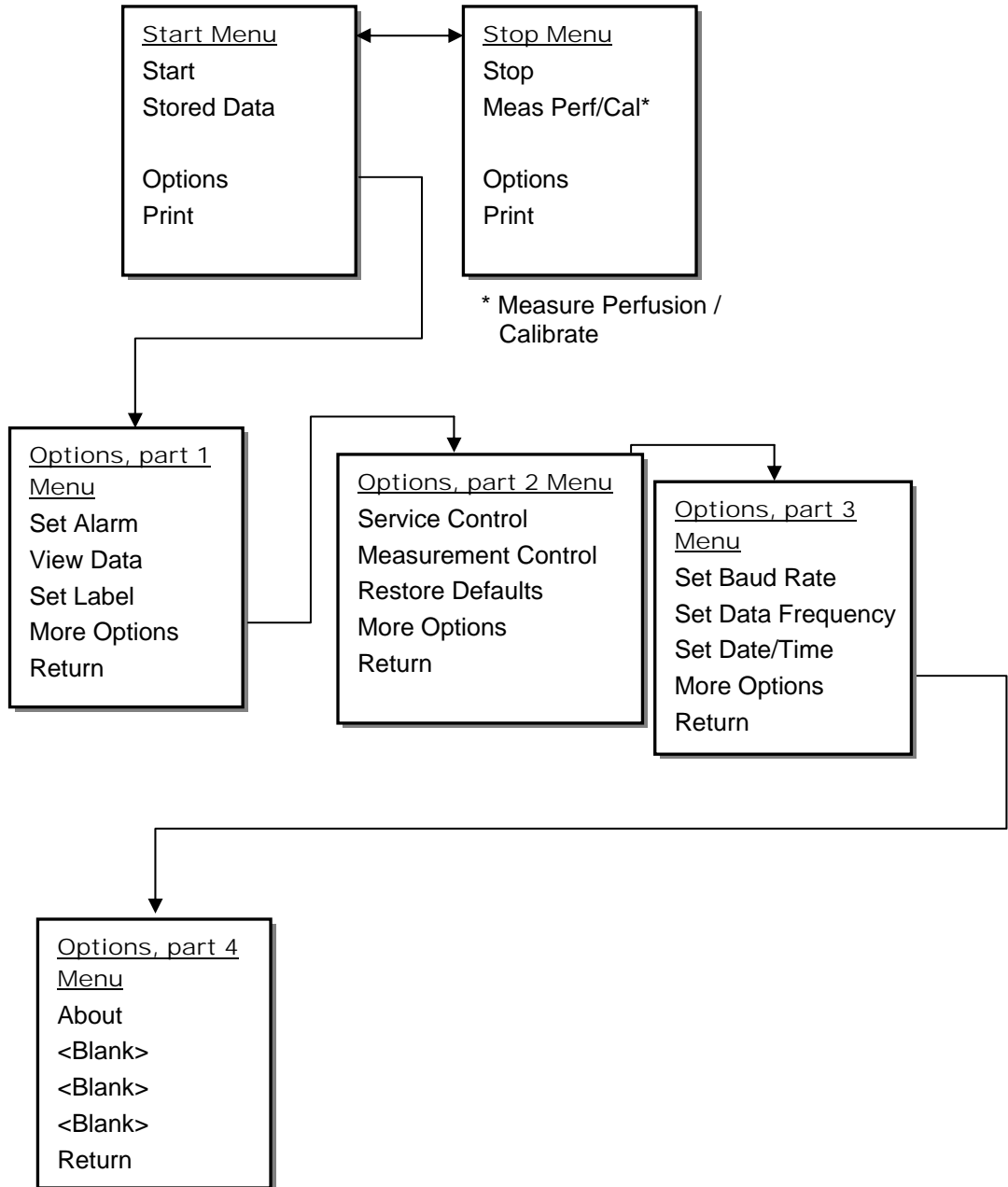


Figure 10. Menu Tree

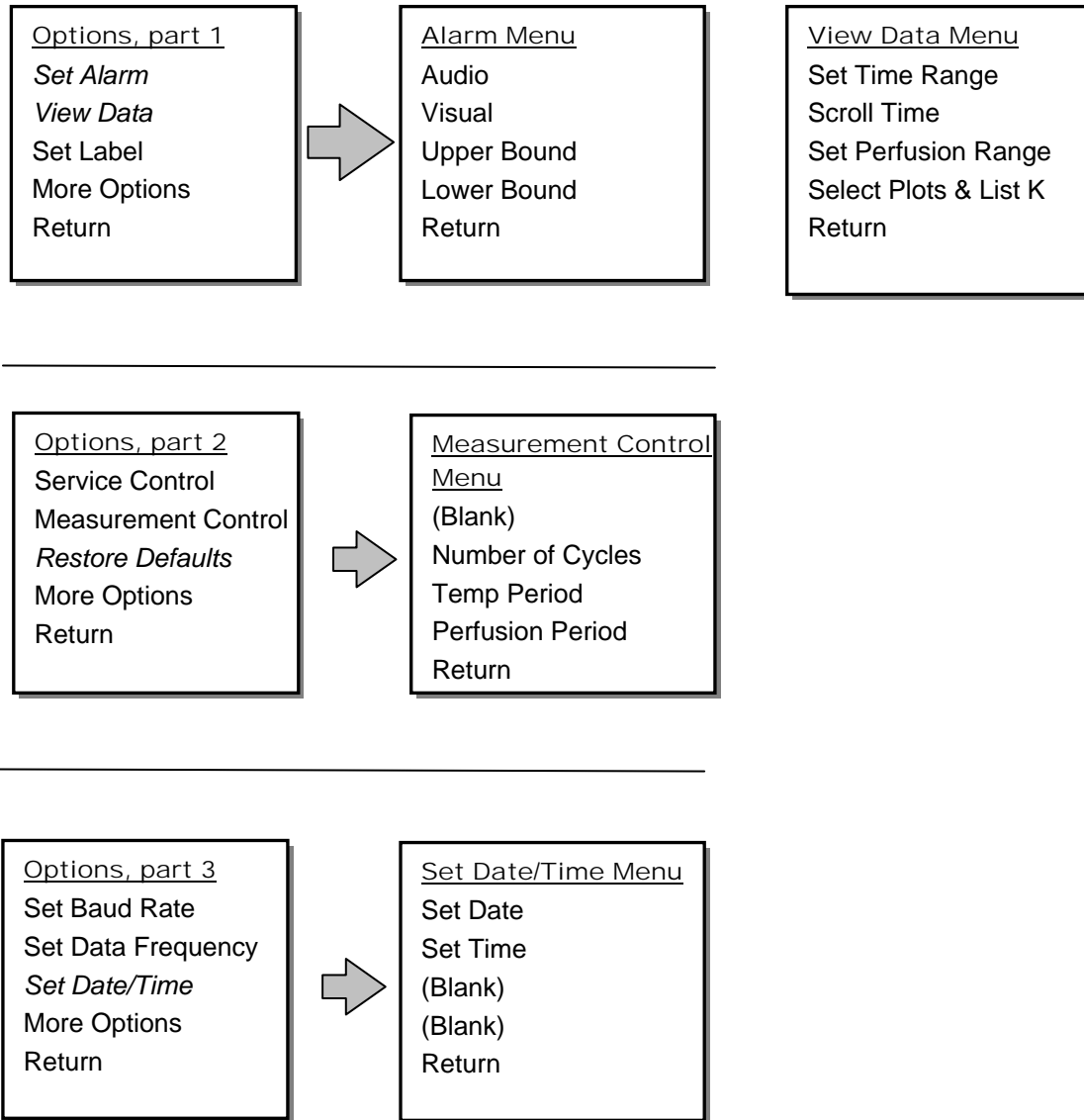


Figure 11. Menus Available from the Options Menus

Figure 11 shows a sample of menus available from the options menus. To set parameters from the Alarm menu, for example, press Alarm in the first options menu. To set measurement control parameters press Measurement Control in the second options menu.

Many of the menus below the Start and Stop menus at the top of the tree have a Return button in the fifth position. At any of these lower-level menus, press Return to return to the previous menu in the hierarchy. To move from the current menu to the Start or the Stop menu at the top of the menu tree, press Return as many times as necessary.

General Commands and Procedures

The general operations in this section apply to many of the specific procedures that follow. These general operations use several buttons that appear throughout the menu tree and dialog boxes.

OK	Close the current dialog box and accept whatever information you have entered.
Cancel	Close the current dialog box and cancel whatever information you have entered.
Return	Return to the previous menu.
↑	Increase the selected value by one, or move the cursor up.
↓	Decrease the selected value by one, or move the cursor down.
←	Move the cursor to the left.
→	Move the cursor to the right.

Arrow keys are the most common method you will use to adjust a setting after you have opened the appropriate dialog box. Suppose, for example, that you want to reduce the trigger time for the upper bound of the perfusion alarm from two minutes to 90 seconds. The procedure below illustrates how to use arrow buttons to adjust the setting.

Procedure 2. How to Use Arrow Buttons to Adjust a Setting

1. Press Options > Set Alarm > Upper Bound > Trigger Time. The Enter Upper Trigger Time dialog box opens (Figure 12).
2. Press the right arrow to move the cursor from hours to minutes.
3. Press the down arrow to change the minutes from 02 to 01.
4. Press the right arrow to move the cursor from minutes to seconds.
5. Press the up arrow multiple times to increase the seconds from 00 to 30.
6. Verify that the upper bound trigger time is set at 00:01:30. If it is not, use the arrow buttons to adjust it. If the trigger time is adjusted correctly, press OK.

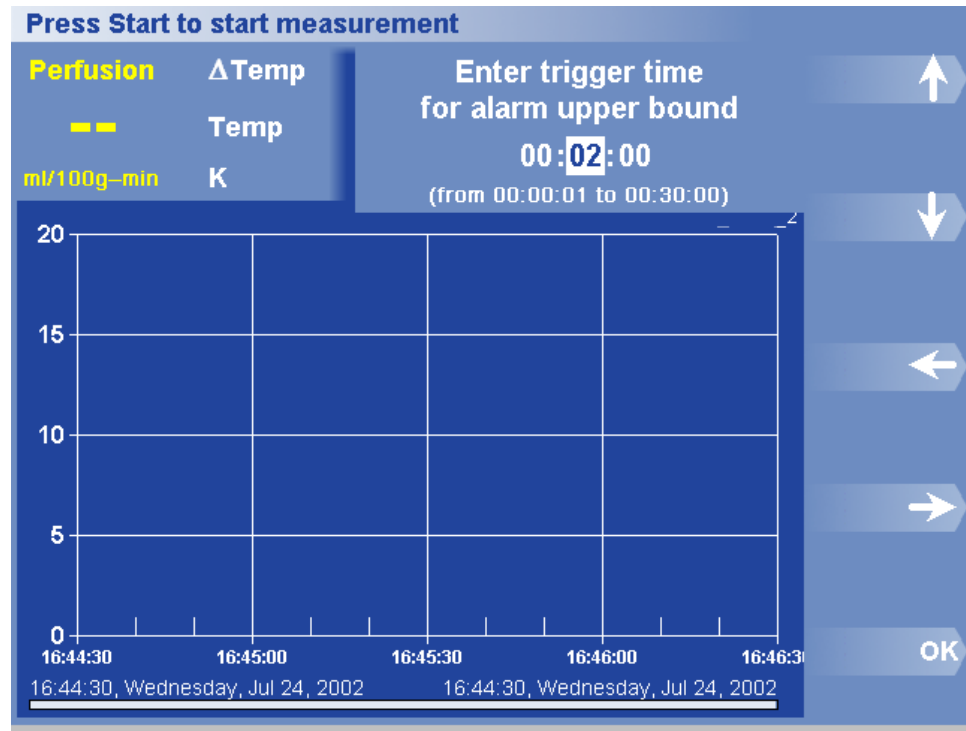


Figure 12. Alarm Upper Bound Trigger Time Dialog Box

When you adjust other operational settings for the Monitor, use the arrow buttons in the manner illustrated above.

Detailed Operation

This chapter explains each menu item in full detail. It will also review the procedures you need to know to operate the Bowman Perfusion Monitor Model 500.

Because the Bowman Perfusion Monitor Model 500 has a simple menu structure, the procedures used to operate the Monitor are easy to execute. This chapter begins with a look at the Start and Stop menus that reside at the top of the menu tree. Then it details some general commands and procedures used throughout the interface. The specific procedures used to operate the Monitor are divided into five sections:

- Measurement cycle control settings
- Alarm settings
- Viewing data
- Printing data
- Stored data operations
- Miscellaneous procedures

The chapter concludes with a table of the Monitor's default settings and a description of the 'About' dialog box.

Start and Stop Menus

When you turn on the Bowman Perfusion Monitor Model 500, it opens the Start menu in Figure 13. You do not need to adjust any settings before you start perfusion measurements. Once the Probe is connected the Monitor automatically starts or you can press Start to begin the measurement cycle if you have stopped it.

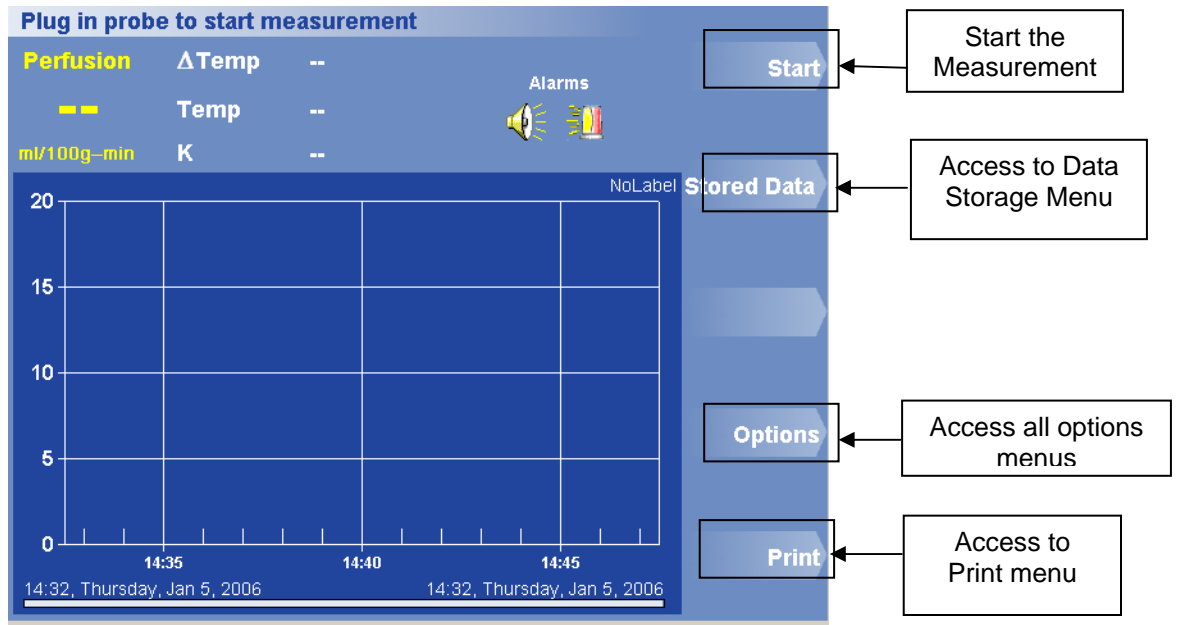


Figure 13. Start Menu

When you press Start, the Stop menu appears (See Figure 14). Press Stop to interrupt the measurement cycle and stop perfusion.

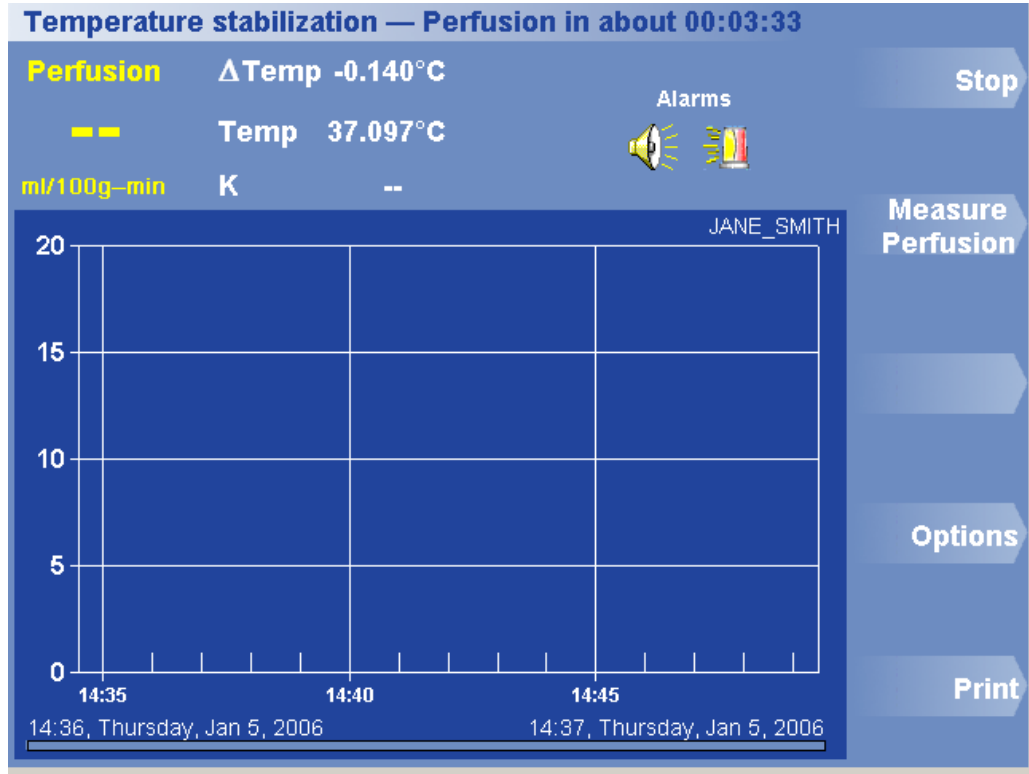


Figure 14. Stop Menu

You can use the Measure Perfusion/Calibrate button as a manual override to initiate the next Monitor phase. It is important to realize that the manual override should be used carefully. For example if the probe has already been in the tissue for some time, it is alright to select **Measure Perfusion** to cut temperature stabilization time from 2 minutes to 30 seconds. However, if there was any heating performed then the user should allow the Monitor to run through cool down time otherwise there will be left over thermal energy that may confound the measurement.

The list below summarizes the menu buttons available on the Start and Stop menus:

- Start – Starts a perfusion measurement. The measurement cycle always begins with a temperature stabilization phase.
- Stop – Stops a perfusion measurement. This action overrides the measurement control cycle. The Monitor takes a few moments to shut down the measurement process.
- Measure Perfusion – Manually overrides the Monitor when it is in the temperature stabilization phase and initiates a perfusion measurement phase. Measure Perfusion alternates with Calibrate as the second item in the Stop menu.
- Calibrate – Manually overrides the current perfusion measurement phase and initiates a new measurement cycle of temperature stabilization, calibration, and perfusion measurement.

Use the second button in the Stop menu as a manual override and initiate temperature stabilization or perfusion measurement, depending on the state of the instrument. The label of the button toggles between Measure Perfusion and Calibrate.

Stored Data

The Bowman Perfusion Monitor Model 500 saves data automatically. The Monitor creates a new perfusion file for each Probe. The maximum amount of perfusion data/probe is 15 days. If more than 15 days (21 MB) of data are collected from one probe the additional data will overwrite the first few days of data for that Probe. The Monitor can hold multiple files that total 25MB. Once the disk is totally full the Monitor will continue to measure perfusion but will no longer store data to the disk unless the current Probe is associated with a full file (21MB) in which case it will overwrite the first few days of data as described above.

Three different tags identify stored data from a patient.

- The user designated Label, which is entered in the Set Label menu.
- The date of the first use of the probe in the patient. (A probe may only be used in a single patient.)
- The time of the first use of the probe in the patient.

When reviewing the stored data list the user sees the above mentioned tags along with the size of the data file. The size is given in Kilobytes. It will take roughly two minutes to upload 1,000KB (1MB) of data. The data are uploaded as a binary file.

The procedures in this section explain how to perform the following operations on stored data:

- Review stored data.
- Delete stored data.
- Upload stored data from the Bowman Perfusion Monitor Model 500 to a computer.
- Set the baud rate for uploading data.

Review Data

Use Procedure 3 to review stored data:

Procedure 3. Review Stored Data

1. Press Stored Data. The Stored Data menu appears (Figure 15).
2. Press Review Data. A list of stored data (tagged with labels, dates, times, and file size) appears (Figure 16). The file with the asterisk (*) prefix is that of a connected probe.
3. Press the Up and Down arrows to select the stored data you want to review.
4. Press OK. The list of stored data closes and the data you selected are plotted on the screen.

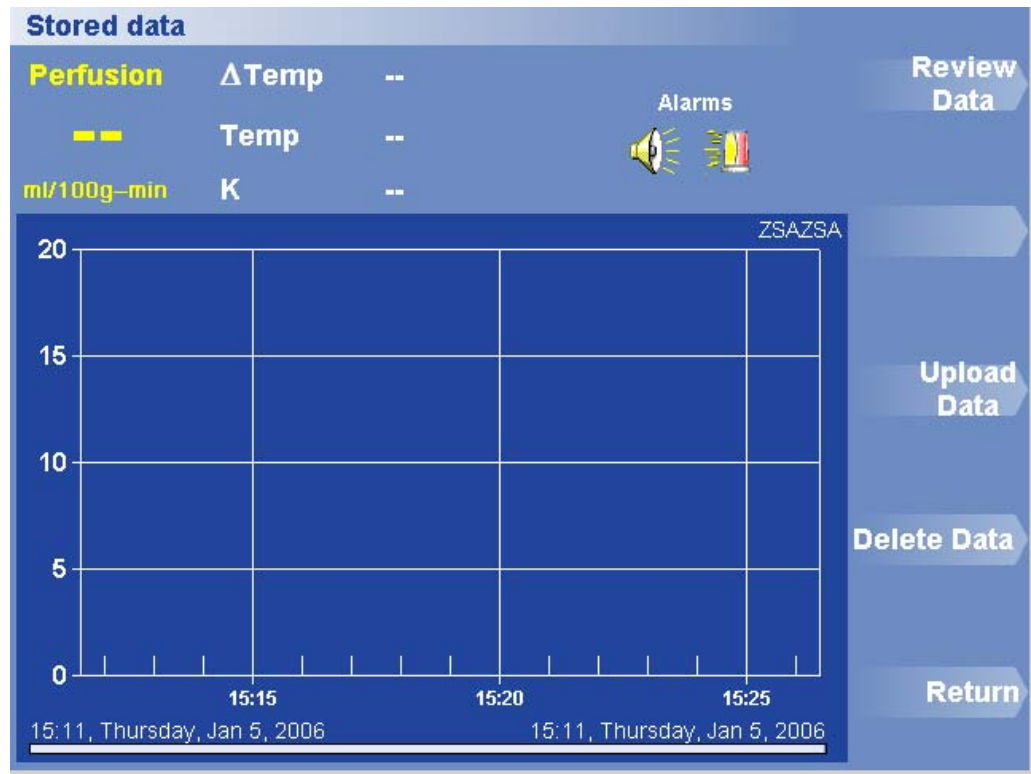


Figure 15. Stored Data Menu

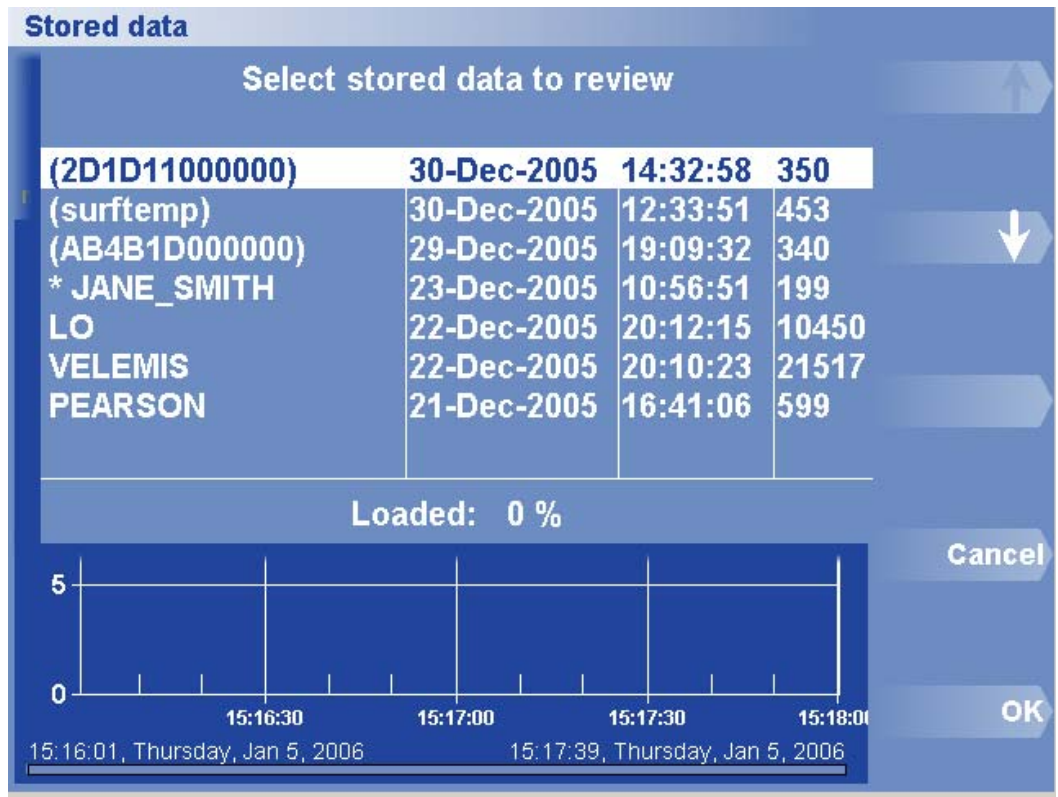


Figure 16. Review Data Dialog box and Menu

Delete Data

Use Procedure 4 to delete stored data:

Procedure 4. Delete Stored Data

1. Press Stored Data > Delete Data. The Delete Stored Data list appears (Figure 17).
2. Press the Up and Down arrows to select the stored data (tagged with labels, dates, and times) you want to delete. The file with the asterisk (*) prefix is that of a connected probe.
3. Press Select.
4. Repeat Steps 2 and 3 if you want to delete the stored data associated with multiple labels, dates, or times.
5. Press OK.
6. Press Confirm Delete to execute the deletion.

When the Monitor does not have enough storage space, it prompts you to delete some stored data sets.

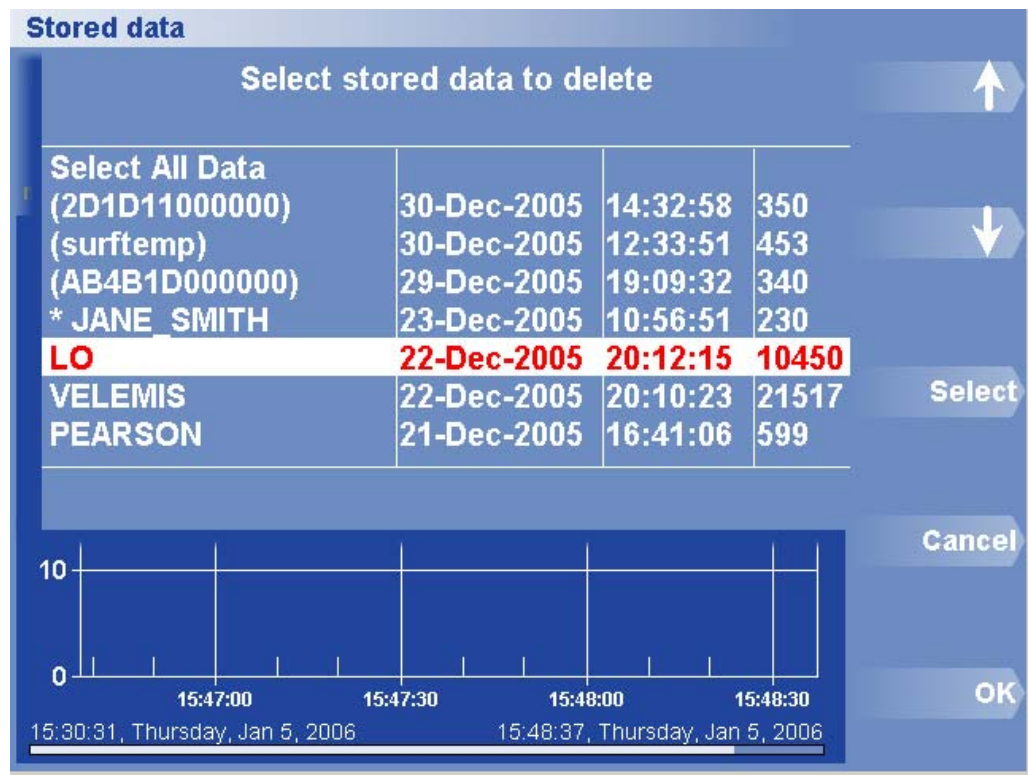


Figure 17. Delete Data Dialog Box and Menu

Upload Data

Upload typically takes about 2 minutes per megabyte of data (1MB=1000KB). The data will be uploaded in binary format. The file can be sent to data@hemedex.com for conversion to ASCII format. Also, data can be converted using Hemedex's Web Manager. Contact Hemedex about setting up an account (info@hemedex.com).

In order to Upload Data you will need a PC or a laptop attached to the Monitor with a straight through DB9 serial cable. The Monitor uses a communications software package that is standard on all Windows operating systems.

Procedure 5 explains how to configure HyperTerminal. This step should only need to be performed once. The user can then create a shortcut to HyperTerminal which can be used each time data upload is necessary.

When uploading data be sure that you have a secure connection between the Monitor and your computer.

Procedure 5. Configure Computer with HyperTerminal

1. Start the HyperTerminal application from your computer's start menu by going to Programs > Accessories > Communications > HyperTerminal.
2. Enter a name to make a new data transfer configuration, or select an existing one.
3. Select the communication port (typically COM1 or COM2) through which the Monitor is connected to the computer.
4. Select the computer port settings. For Bits per second, match the Monitor's baud rate (default is 115,200). Choose Data bits 8, Parity None, Stop bits 1, and Flow control Hardware.
5. From the menu bar, select Transfer > Receive File....
6. In the Receive File dialog box, select or name the folder for receiving the data file, choose Zmodem for the receiving protocol, and click the Receive button.

In the above procedure a default baud rate of 115,200 is recommended. This is a user settable parameter that should be based on the type of computer receiving the upload. It is not necessary to use 115,200; however, it is necessary to use the same baud rate on the monitor as you are using in HyperTerminal.

Procedure 6. Upload Stored Data to a Computer

1. Press the OK button on the Upload Data menu of the Monitor. (This is the last step of the previous procedure.)
2. Connect the Monitor to the destination computer. Connect the data transmission cable to the serial port at the back of the Monitor.
3. If desired, set the baud rate (see Procedure 7).
4. Press Stored Data > Upload Data. The Start Upload Stored Data menu appears (Figure 18).
5. Select Start Upload. The Stored Data list appears (Figure 19).
6. Use the arrow buttons to select the stored data you want to upload. The file with the asterisk (*) prefix is that of a connected probe.
7. Make sure the destination computer is connected to the Monitor's serial port and is properly configured for data transfer: Zmodem protocol.
8. Press OK. The Upload Stored Data list closes.

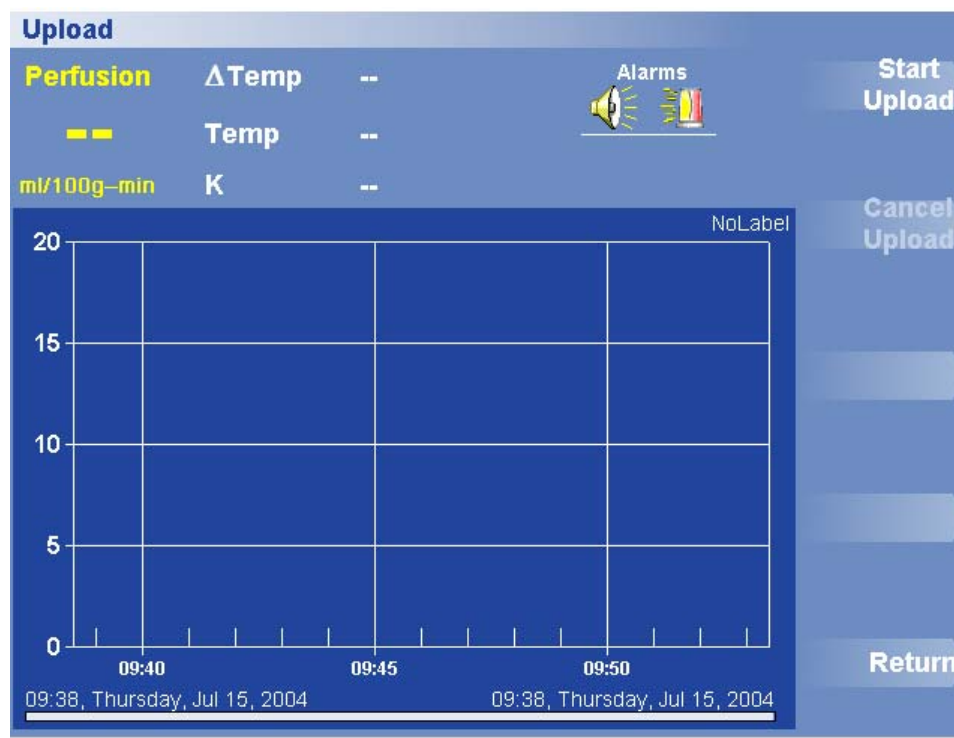


Figure 18. Start Upload Stored Data

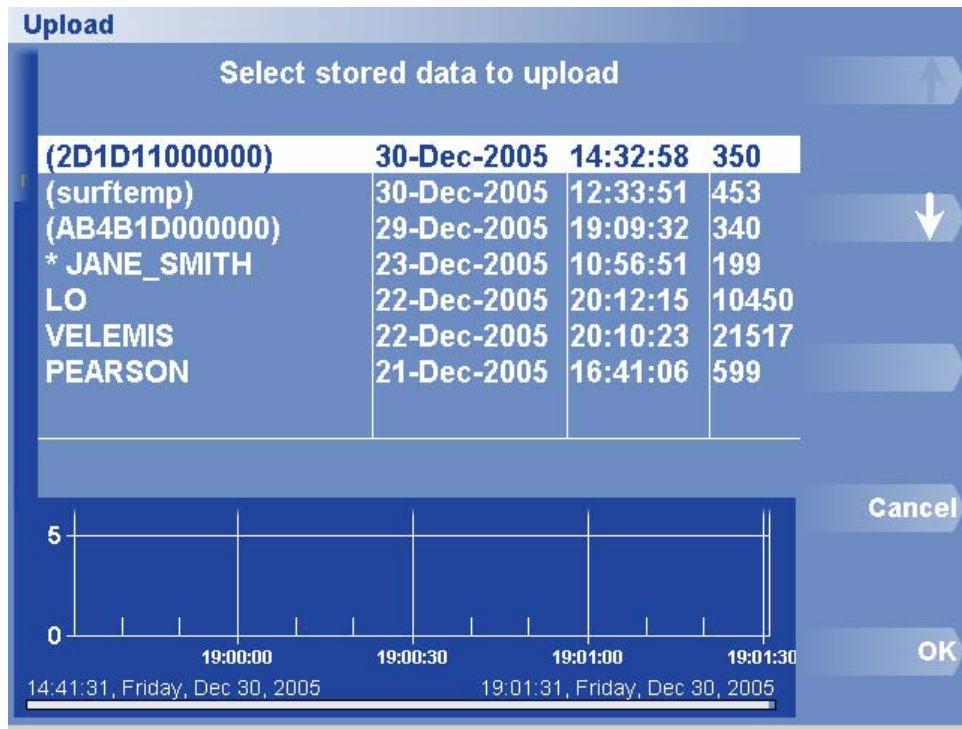


Figure 19. Upload Stored Data

Use Procedure 7 to set the port baud rate for uploading stored data from the Bowman Perfusion Monitor Model 500 to a computer:

Procedure 7. Set the Baud Rate for Uploading Data

1. Press Options>More Options> More Options> Set Baud Rate. The Set Upload Baud Rate dialog box appears (Figure 20).
2. Use the arrow buttons to select the desired baud rate.
3. Press OK. The dialog box closes and the new setting appears under Baud Rate in the third Options menu.

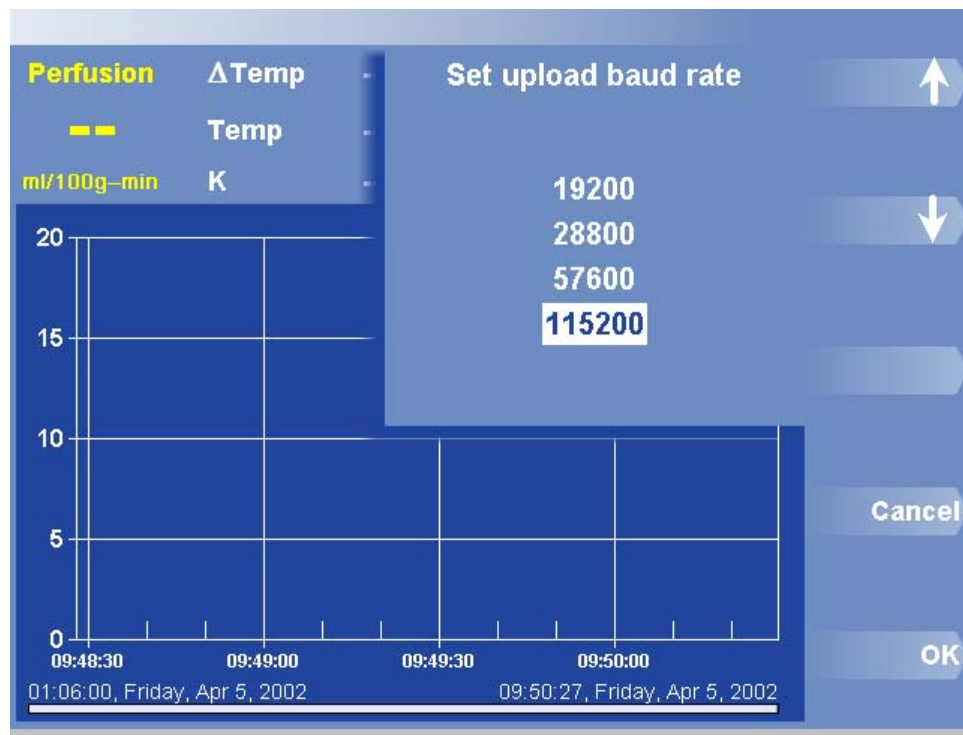


Figure 20. Set Upload Baud Rate Dialog Box and Menu

Print Data

Use Procedure 8 to print data:

Procedure 8. Print Data

1. Press Print at the bottom of the Stop menu. The Print menu appears (Figure 21).
2. Select one of the following options to print data:
 - Press Print Perfusion to print the perfusion trace that currently appears in the plot.
 - Press Perfusion & Temperature to print plots of perfusion and proximal temperature.
 - Press Print K Values to print all the values recorded for thermal conductivity, and the time and date they were recorded.
 - Press Print Settings to print all the settings currently in place.

See Chapter 2 for instructions about how to load paper in the printer.

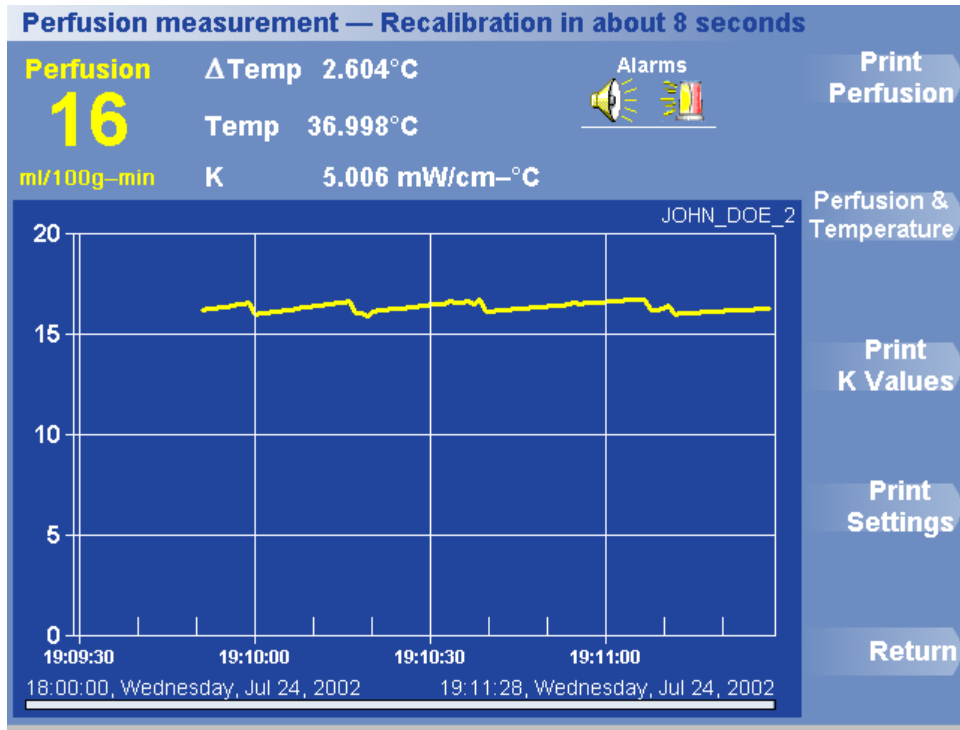


Figure 21. Print Menu

After you have printed the desired data, press Return to return to the Stop menu. Figure 22 shows a sample Perfusion & Temperature print-out.

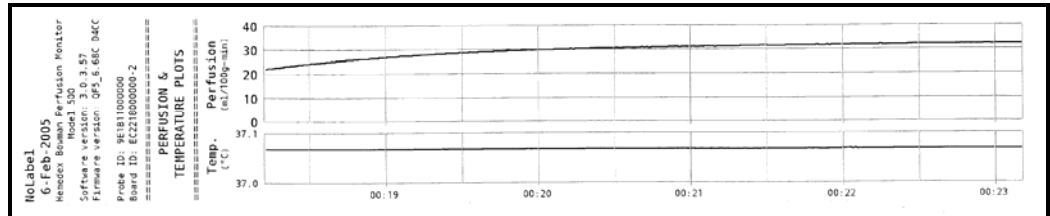


Figure 22. Perfusion & Temperature Print-out

Set Label

Use Procedure 9 to create a new label for the current data.

Procedure 9. Assign a Label to the Current Data

1. Press Options > Set Label. The Label dialog box appears (See Figure 23).
2. Use the arrow buttons to select the first character in the label.
3. Press OK to confirm the selection. The first character of the label appears in the white box.
4. Repeat steps 2 and 3 for each character in the label.
5. Move the cursor to Label complete and press OK when the patient label is complete.

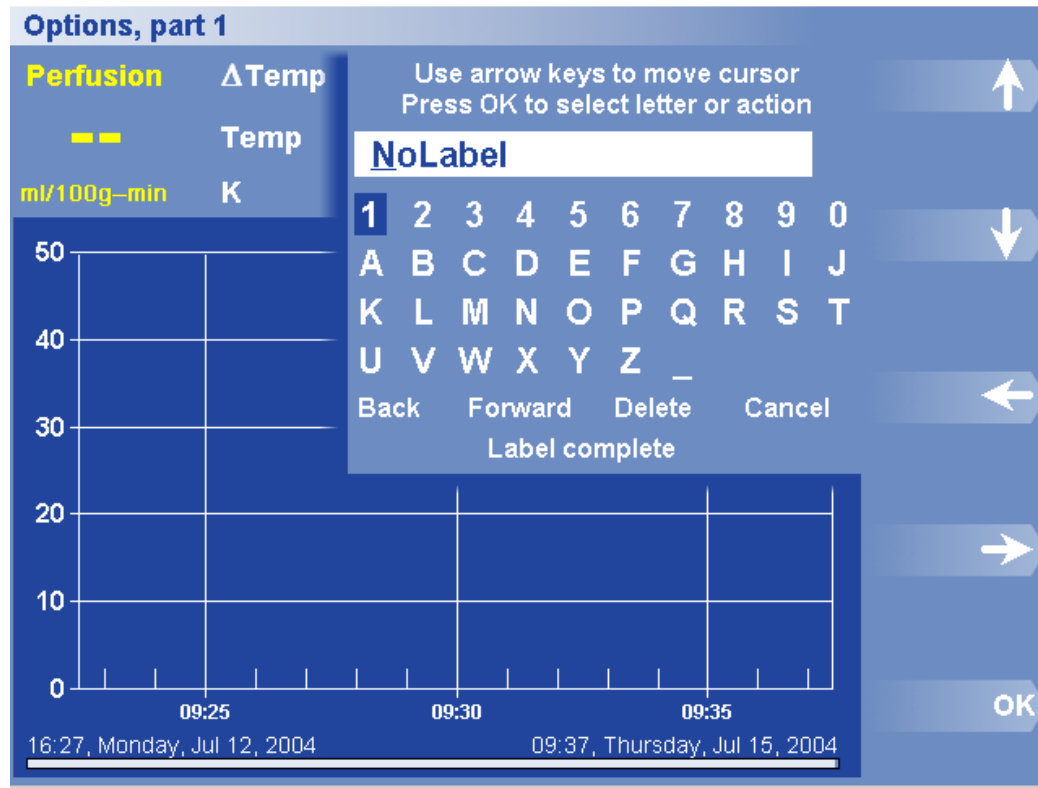


Figure 23. Set Label Dialog Box and Menu

Alarms

The Bowman Perfusion Monitor Model 500 includes audio and visual perfusion alarms. When perfusion drops below the alarm lower bound for a specified period of time, the Monitor triggers the alarm. Similarly, when perfusion rises above the alarm upper bound for a specified period of time, the Monitor triggers the alarm. This section explains how to enable the alarms, and how to set the parameters associated with each bound.

Use the following procedure to turn the audio and visual alarms on:

Procedure 10. Toggling the Audio and Visual Alarms

1. Press Options. The Options, part 1 menu appears.
2. Press Set Alarm. The Alarm menu appears (Figure 24).
3. Press Audio. The status indicator beneath the button label toggles between ON and OFF, and the speaker symbol brightens or dims.
4. Press Visual. The status indicator beneath the button label toggles between ON and OFF, and the siren symbol brightens or dims.

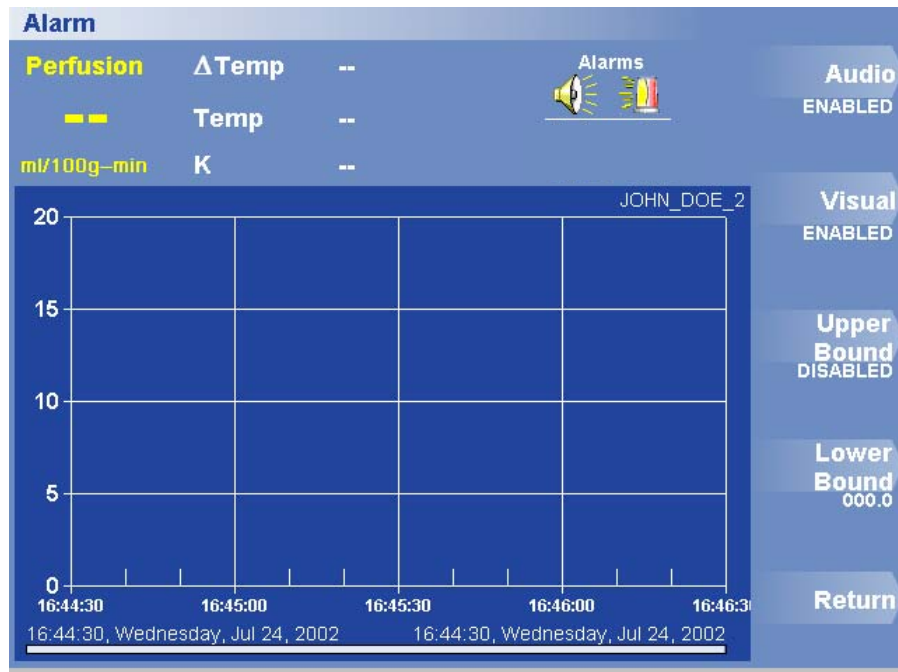


Figure 24. Audio and Visual Alarms Menu

The procedure used to set the upper bound of the perfusion alarm is the same as the procedure used to set the lower bound. Procedure 11 lists the four general steps required to set the upper or lower bound of the perfusion Monitor alarm.

Procedure 11. Set an Alarm Bound and its Associated Parameters

1. Set the Value of the bound.
2. Set the Trigger Time. The Trigger Time specifies how long measured perfusion must lay outside the bound before the Monitor triggers the alarm.
3. Set the Suspend Time. The Suspend Time specifies how long a triggered alarm remains suspended (temporarily disabled) after you acknowledge it.
4. Enable the bound.

Upper Bound

Use the Alarm Upper Bound menu to set the upper bound of the perfusion alarm. Procedure 12 explains how to set the alarm's upper bound:

Procedure 12. Set the Upper Bound of the Perfusion Monitor Alarm

1. Press Options > Set Alarm. The Alarm menu appears (Figure 24). The current value for the upper bound of the alarm appears below the Upper Bound label.
2. Press Upper Bound. The Alarm Upper Bound menu appears (Figure 25).
3. Press Value. The Upper Bound dialog box appears (Figure 26). Use the arrow buttons to set the upper bound of the alarm.
4. Press OK when the desired upper bound is set. The Upper Bound dialog box closes and the new value for the upper bound appears below Value in the Alarm Upper Bound menu.

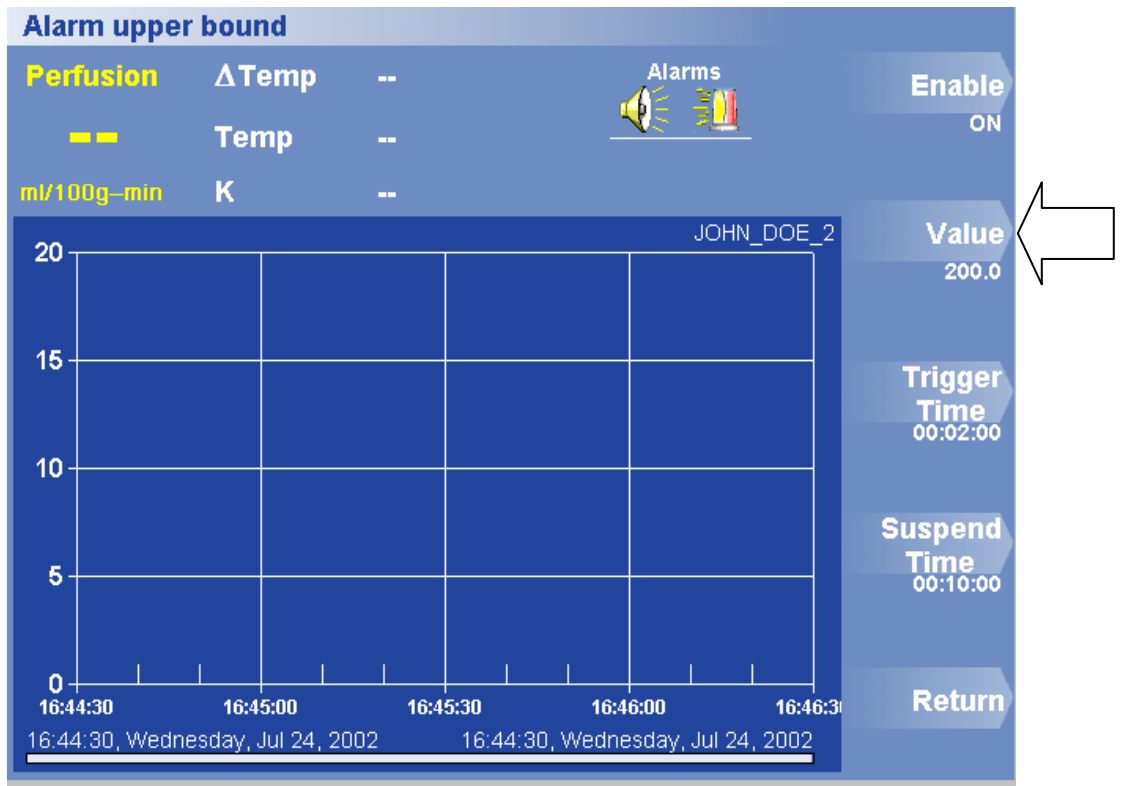


Figure 25. Set the Alarm Upper Bound Menu

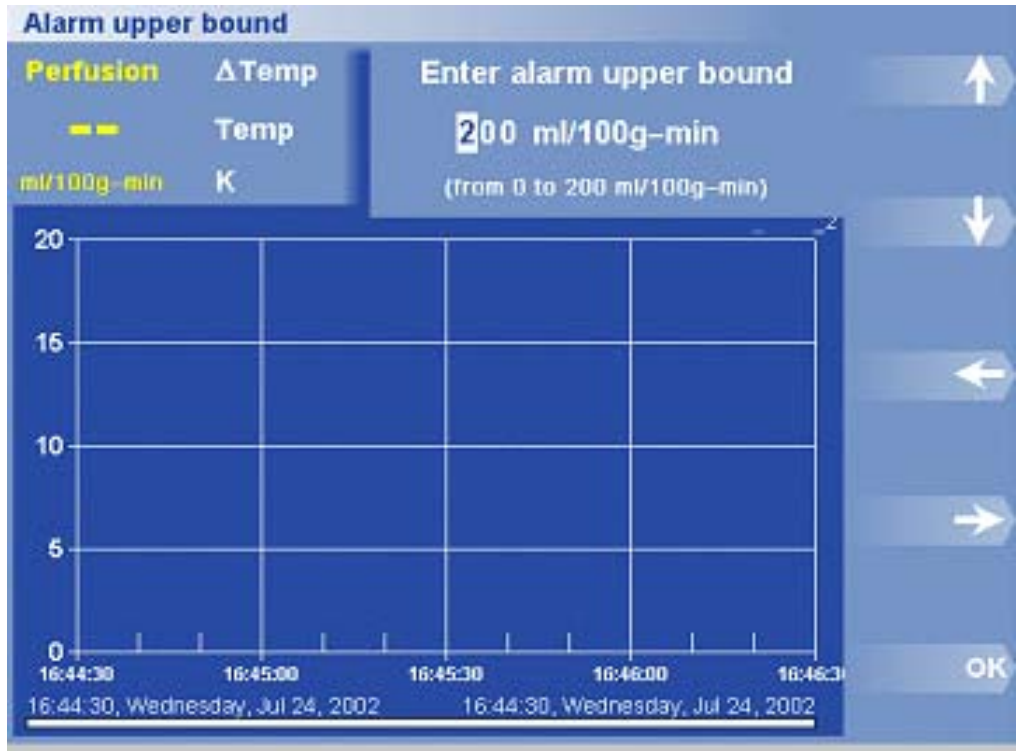


Figure 26. Alarm Upper Bound Dialog Box and Menu

Use Procedure 13 to set the Trigger Time for the Upper Bound. The Trigger Time specifies how long the measured perfusion must be outside the bound before the Monitor triggers the alarm

Procedure 13. Set the Trigger Time

1. Press Options > Set Alarm > Upper Bound. The Alarm Upper Bound menu appears (Figure 25).
2. Press Trigger Time. The Trigger Time dialog box appears (Figure 27).
3. Use the arrow buttons to enter the trigger time in the dialog box.
4. Press OK when the desired trigger time is set. The Trigger Time dialog box closes and the new setting appears below Trigger Time in the Alarm Upper Bound menu.

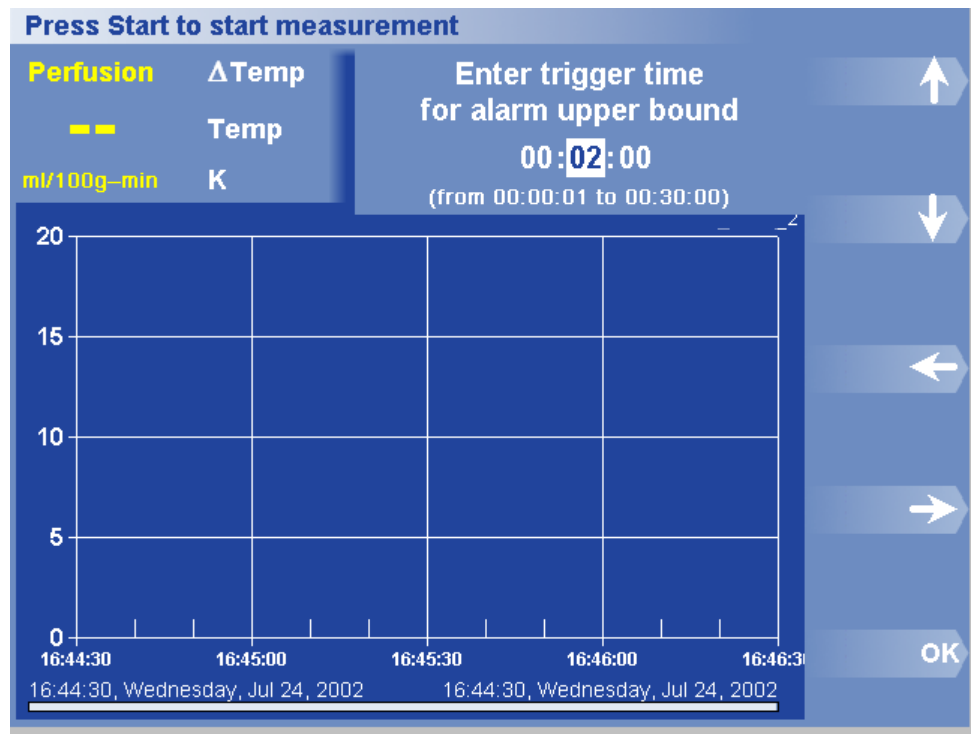


Figure 27. Upper Bound Trigger Time Dialog Box and Menu

Use Procedure 14 to set the Suspend Time for the upper bound. The Suspend Time specifies how long a triggered alarm remains suspended after the user acknowledges the alarm.

Procedure 14. Set the Suspend Time

1. Press Options > Set Alarm > Upper Bound. The Alarm Upper Bound menu appears (Figure 25).
2. Press Suspend Time. The Suspend Time dialog box appears (Figure 28).
3. Use the arrow buttons to enter the suspend time in the dialog box.
4. Press OK when the desired suspend time is set. The Suspend Time dialog box closes and the new setting appears below Suspend Time in the Alarm Upper Bound menu.

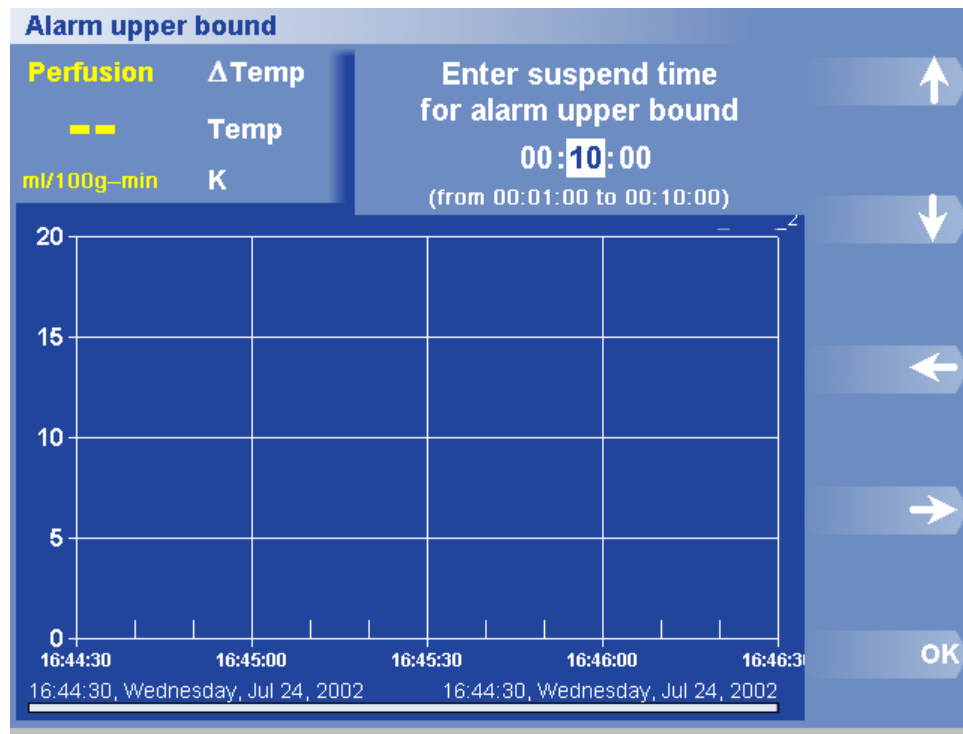


Figure 28. Alarm Upper Bound Suspend Time Dialog Box and Menu

Use Procedure 15 to enable the upper bound of the perfusion alarm:

Procedure 15. Enable the Alarm Upper Bound

1. Press Options > Set Alarm > Upper Bound. The Alarm Upper Bound menu appears (Figure 29).
2. Press Enable. The indicator below the button label toggles between ON and OFF. The current value of the upper bound appears under Value.

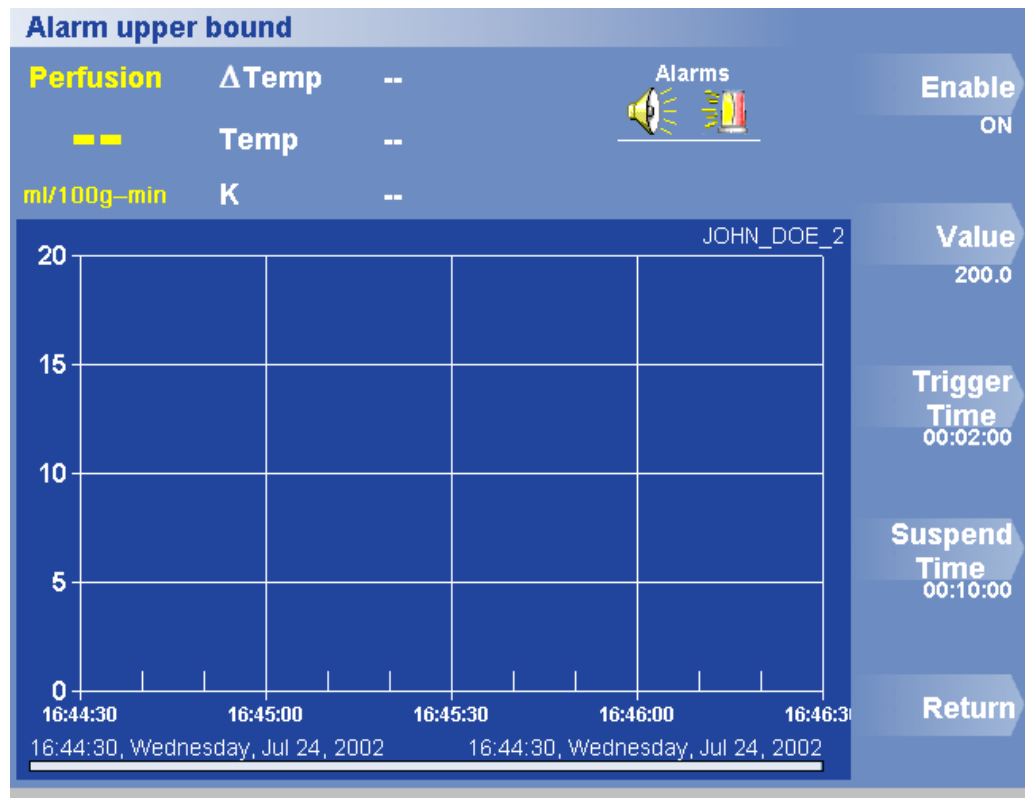


Figure 29. Alarm Upper Bound Menu

Table 9 lists the minimum, maximum, and default settings for the upper bound of the perfusion Monitor alarm.

Table 9. Alarm Upper Bound Settings

Setting	Minimum	Maximum	Default
Upper Bound Enable	N/A	N/A	OFF
Upper Bound Value	0 ml/100g–min	200 ml/100g–min	200 ml/100g–min
Upper Bound Trigger Time	1 second	30 minutes	2 minutes
Upper Bound Suspend Time	1 minute	10 minutes	10 minutes

Lower Bound

Use the Alarm Lower Bound menu to set the lower bound of the perfusion alarm. The following procedure consolidates all of the steps for setting the lower bound in a single list:

Procedure 16. Set Alarm Lower Bound

1. Press Options > Set Alarm. The Alarm menu appears. The current value for the lower bound of the alarm appears below the Lower Bound label.
2. Press Lower Bound. The Alarm Lower Bound menu appears (Figure 30).
3. Press Value. The Lower Bound dialog box appears.
4. Use the arrow buttons to set the lower bound of the alarm.
5. Press OK when the desired lower bound is set. The Lower Bound dialog box closes and the new value for the lower bound appears below Value in the Alarm Lower Bound menu.
6. Press Trigger Time. The Trigger Time dialog box appears.
7. Use the arrow buttons to enter the trigger time in the dialog box.
8. Press OK when the desired trigger time is set. The Trigger Time dialog box closes and the new setting appears below Trigger Time in the Alarm Lower Bound menu.
9. Press Suspend Time. The Suspend Time dialog box appears.
10. Use the arrow buttons to enter the suspend time in the dialog box.
11. Press OK when the desired suspend time is set. The Suspend Time dialog box closes and the new setting appears below Suspend Time in the Alarm Lower Bound menu.
12. Press Enable. The indicator below the button label toggles between ON and OFF.

The Trigger Time specifies how long perfusion must stay outside the bound before the monitor triggers the alarm.

The Suspend Time specifies how long a triggered alarm remains suspended after the user acknowledges it.

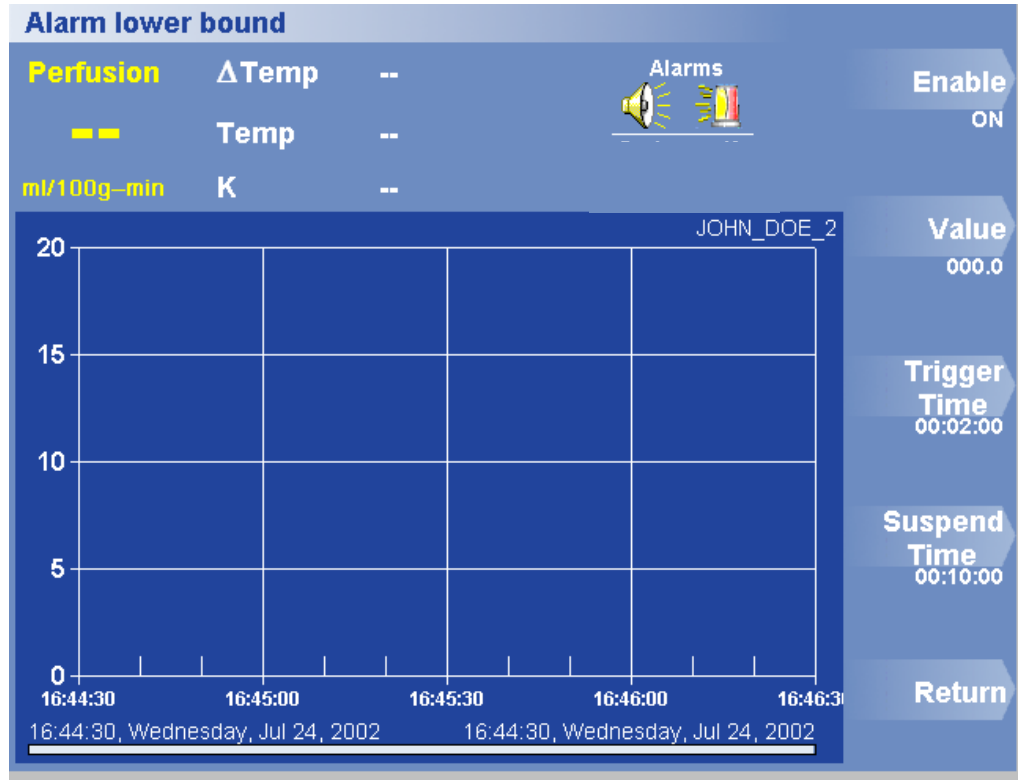


Figure 30. Alarm Lower Bound Menu

Table 10 lists the minimum, maximum, and default settings for the lower bound of the perfusion Monitor alarm. The table values are identical to those for the Upper Bound (Table 9), except for the default Lower Bound Value.

Table 10. Alarm Lower Bound Settings

Setting	Minimum	Maximum	Default
Lower Bound Enable	N/A	N/A	ON
Lower Bound Value	0 ml/100g-min	200 ml/100g-min	0 ml/100g-min
Lower Bound Trigger Time	1 second	30 minutes	2 minutes
Lower Bound Suspend Time	1 minute	10 minutes	10 minutes

Alarm Message

When the perfusion alarm is triggered, the message line displays an alarm message and the Suspend Alarm menu appears. Press Suspend Alarm to disable the alarm temporarily (Figure 31).

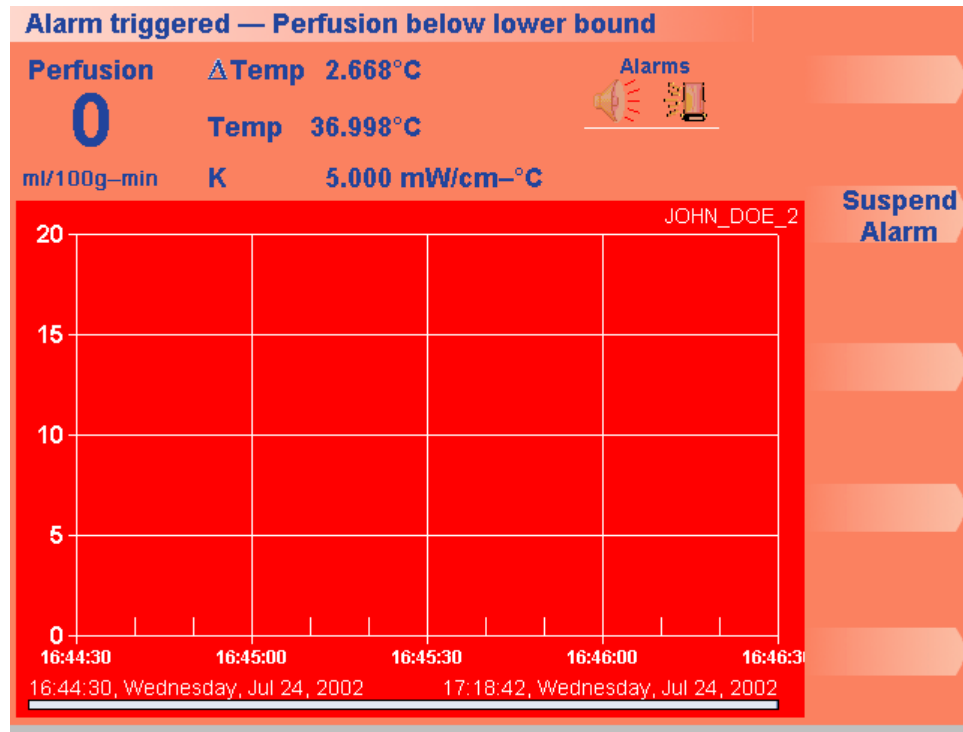


Figure 31. Suspend Alarm Screen and Menu

View Data

The Bowman Perfusion Monitor Model 500 makes perfusion data available via the main screen and in printed form. The procedures in this section explain how to perform the following data-related tasks:

- Select the time range displayed on the horizontal axis of the plots in the graph area.
- Scroll back to data recorded at an earlier time.
- Select the perfusion range displayed on the vertical axis of the perfusion plot in the graph area
- Select which thermal parameters appear in the graph area.
- List previously recorded values for thermal conductivity (K value).
- Print selected data or Monitor settings.

Set Time Range

Use Procedure 17 to select the time range displayed on the horizontal axis of the plots:

Procedure 17. Set the Time Range of the Plots

1. Press Options > View Data. The View Data menu opens (Figure 32).
2. Press Set Time Range. The Time Range dialog box appears (Figure 33).
3. Use the up and down arrow buttons to select the time range of the horizontal axis. The default value is 15 minutes.
4. Use the left and right arrow buttons to scroll the data.
5. Press OK. The Time Range dialog box closes and the plots adjust to reflect the time range you have set.

The left and right arrows in the Time Range menu are functionally the same as the coarse scroll buttons on the Scroll Time menu.

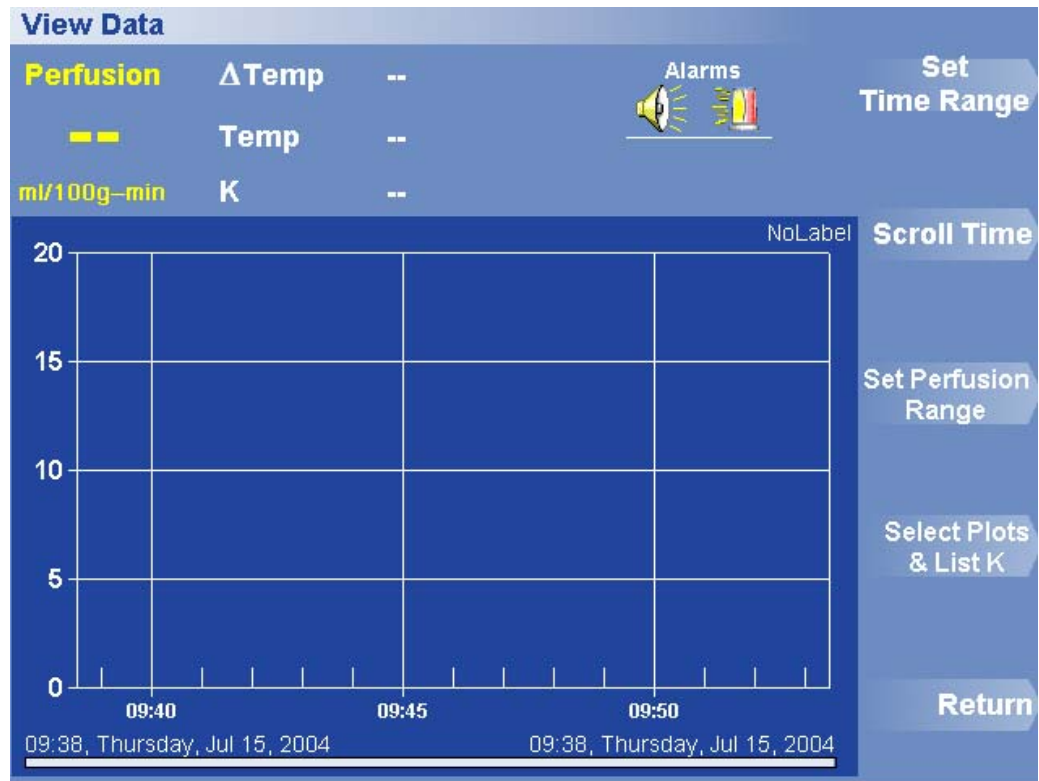


Figure 32. View Data Menu

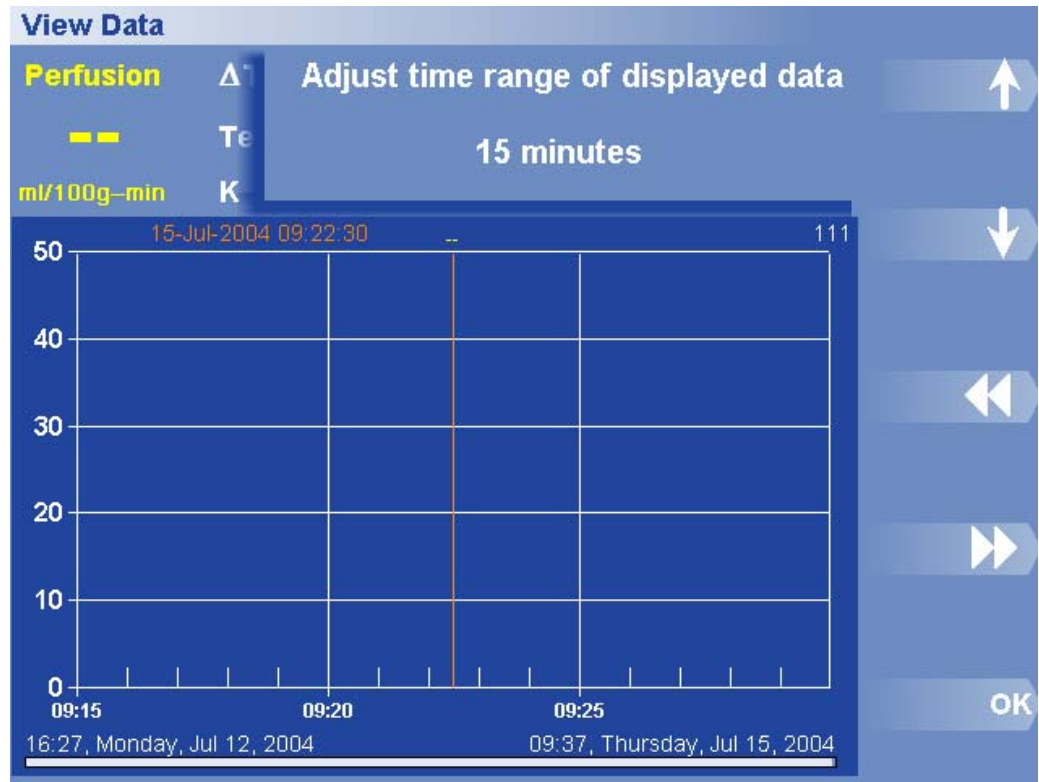


Figure 33. Set Time Range Dialog Box and Menu

Scroll Time

Use Procedure 18 to view data recorded earlier:

Procedure 18. Scroll Back to Data Recorded at Earlier Times

1. Press Options > View Data > Scroll Time. The Scroll Time screen appears (Figure 34).
2. Use the arrow buttons to select which portion of the data you want to display. A vertical orange line appears in the middle of the plot, with the value, date, and time of the perfusion trace where it intersects the vertical orange line.
3. Press OK.

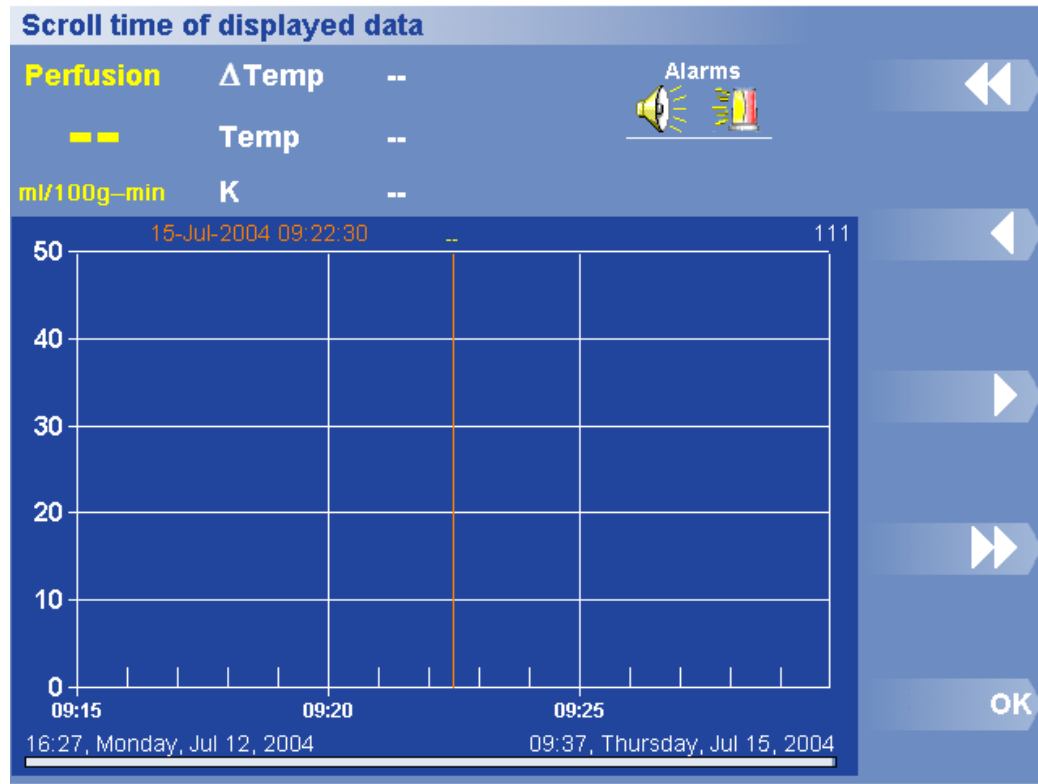


Figure 34. Scroll Time

Set Perfusion Range

Use Procedure 19 to set the perfusion range displayed on the vertical y-axis.

Procedure 19. Set the Perfusion Range of the Perfusion Plot

1. Press Options > View Data > Set Perfusion Range. The Set Perfusion Range dialog box appears (Figure 35).
2. Use the arrows to adjust the upper extent of the perfusion plot.
3. Press Autoscale to toggle between enabling autoscaling, and fixing the upper extent at your selected value.
4. Press OK. The Perfusion Range dialog box closes and the perfusion plot adjusts to reflect the perfusion range you have set.

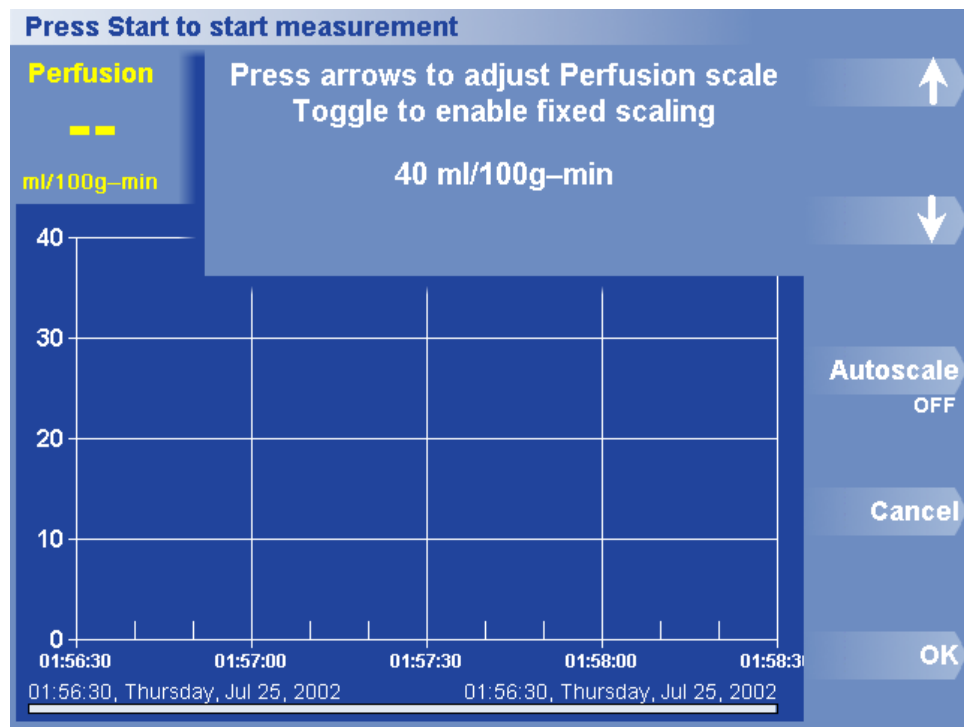


Figure 35. Set Perfusion Range Dialog Box and Menu

List K Values

Use Procedure 20 to list K values (thermal conductivity) and the times they were recorded:

Procedure 20. View a Record of Past K Values (Thermal Conductivity)

1. Press Options > View Data > Select Plots & List K -> List K. The List K dialog box appears (Figure 36). The list shows the date and time each value of K was recorded.
2. Use the arrow buttons to scroll through the list.
3. Press OK. The List K dialog box closes.

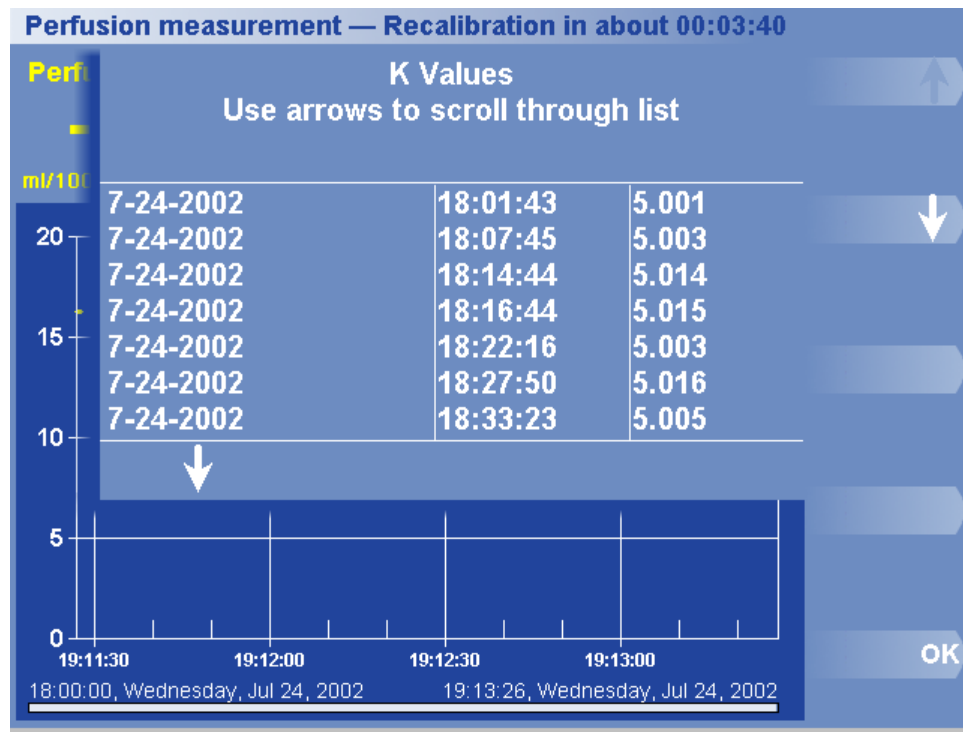


Figure 36. List K Values Dialog Box and Menu

Select Temperature Plots

Use Procedure 21 to select which plots appear in the the main screen:

Procedure 21. Plot Selection

1. Press Options > View Data > Select Plots & List K. The Select Plots menu appears (Figure 37).
2. Press one of three buttons to turn a trace on or off:
 - Press Proximal Temperature to show time series data for the tissue temperature measured at the proximal thermistor.
 - Press Distal Temperature to show the data for the tissue temperature measured at the distal thermistor.
 - Press Δ Temperature to show the data for the Δ temperature.
3. The ON/OFF indicator under the button label changes to reflect the new setting. The plots you select appear in the lower graph on the main screen.

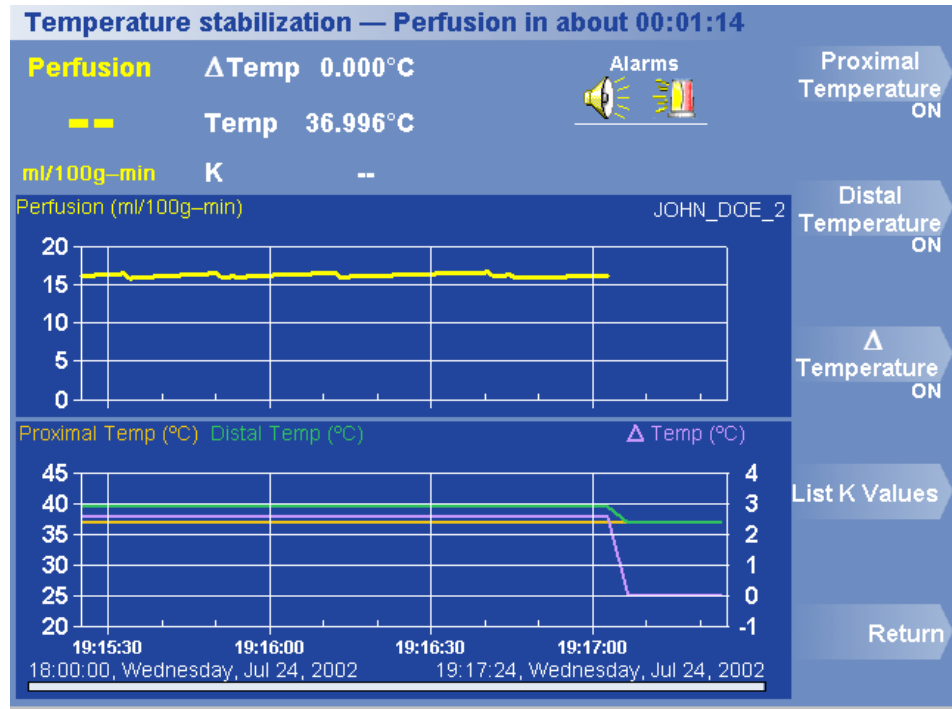


Figure 37. Select Plots Menu

Measurement Control Mode

Measurement Control allows the user to run the monitor continuously with options to change Temperature and Perfusion periods.

Measurement Cycle Control

The Monitor alternates pre-set periods of temperature measurement and perfusion measurement. You can determine the length of the temperature stabilization and perfusion measurement phases of the measurement cycle. After temperature stabilization, the Monitor can perform calibration and begin perfusion measurement.

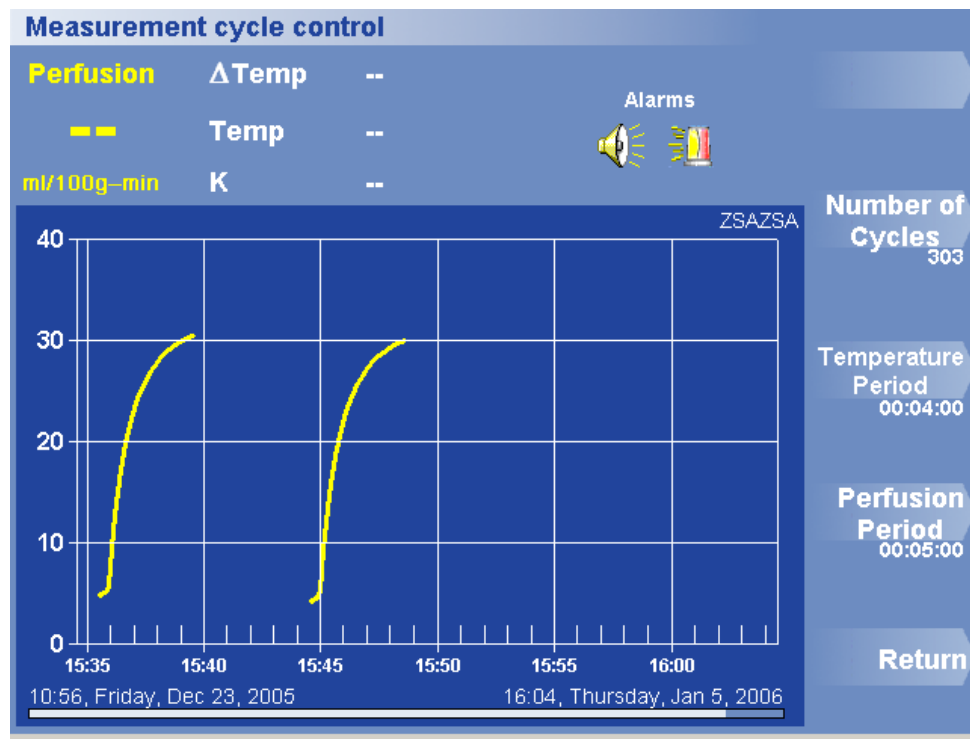


Figure 38. Measurement Cycle Control Menu

Under the Measurement Cycle Control Menu, the user can program the Monitor's measurement cycles in advance. To set the number of measurement cycles:

Procedure 22. Set the Number of Measurement Cycles

1. Press Options > More Options > Measurement Cycle Control. The Measurement Cycle Control menu appears (Figure 38). The number of cycles currently set appears under Number of Cycles.
2. Press Number of Cycles. The Number of Cycles dialog box appears (Figure 39).
3. Use the arrow buttons to enter the new setting for Number of Cycles, which is a number or Unlimited.
4. Press OK. The dialog box closes and the new setting appears under Number of Cycles.

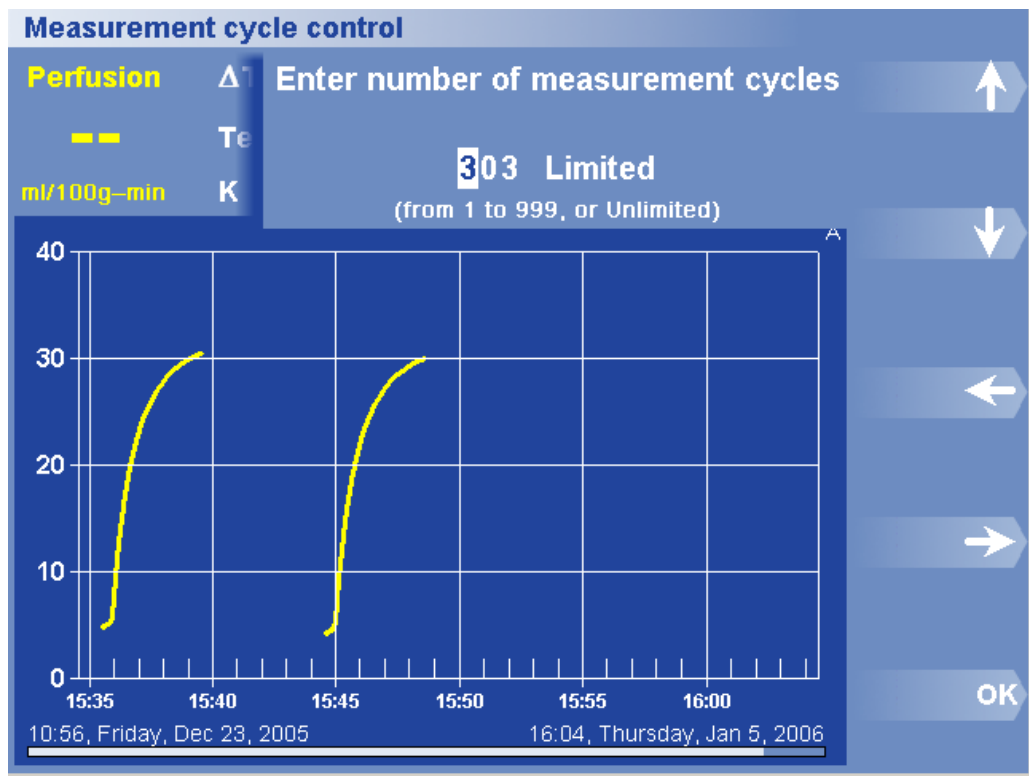


Figure 39. Number of Cycles Dialog Box and Menu

Use Procedure 23 to set the length of the temperature stabilization period :

Procedure 23. Set the Temperature Stabilization Period

1. Press Options > More Options > Measurement Cycle Control. The Measurement Cycle Control menu appears (Figure 38). The current length of the temperature stabilization period appears under Temperature Period.
2. Press Temperature Period. The Temperature Period dialog box appears (Figure 40).
3. Use the arrow buttons to enter the new setting for Temperature Period.
4. Press OK. The Temperature Period dialog box closes and the new setting appears under Temperature Period in the Measurement Cycle Control menu.

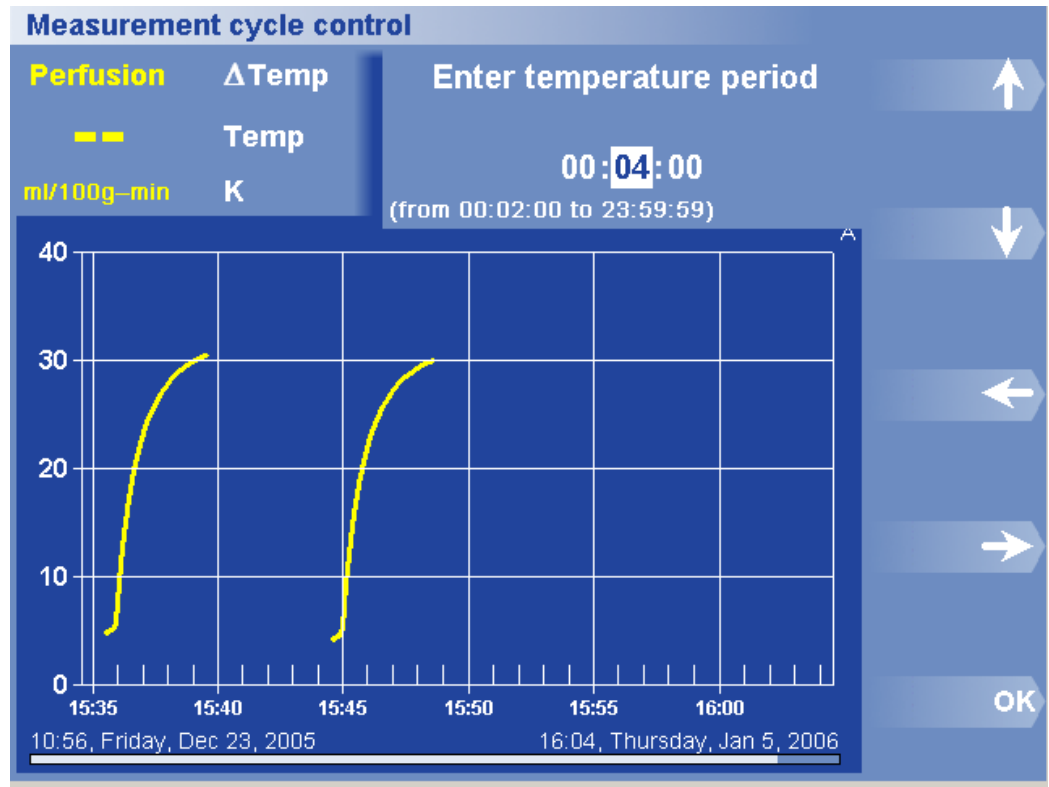


Figure 40. Temperature Period Dialog Box and Menu

The length of the calibration phase of the measurement cycle—approximately 10 seconds—is not adjustable.

Use Procedure 24 to set the length of the perfusion measurement period :

Procedure 24. Set the Perfusion Measurement Period

1. Press Options > More Options > Measurement Cycle Control. The Measurement Cycle Control menu appears (Figure 38). The current length of the perfusion measurement period appears under Perfusion Period.
2. Press Perfusion Period. The Perfusion Period dialog box appears (Figure 41).
3. Use the arrow buttons to enter the new setting for Perfusion Period.
4. Press OK. The Perfusion Period dialog box closes and the new setting appears under Perfusion Period in the Measurement Cycle Control menu.

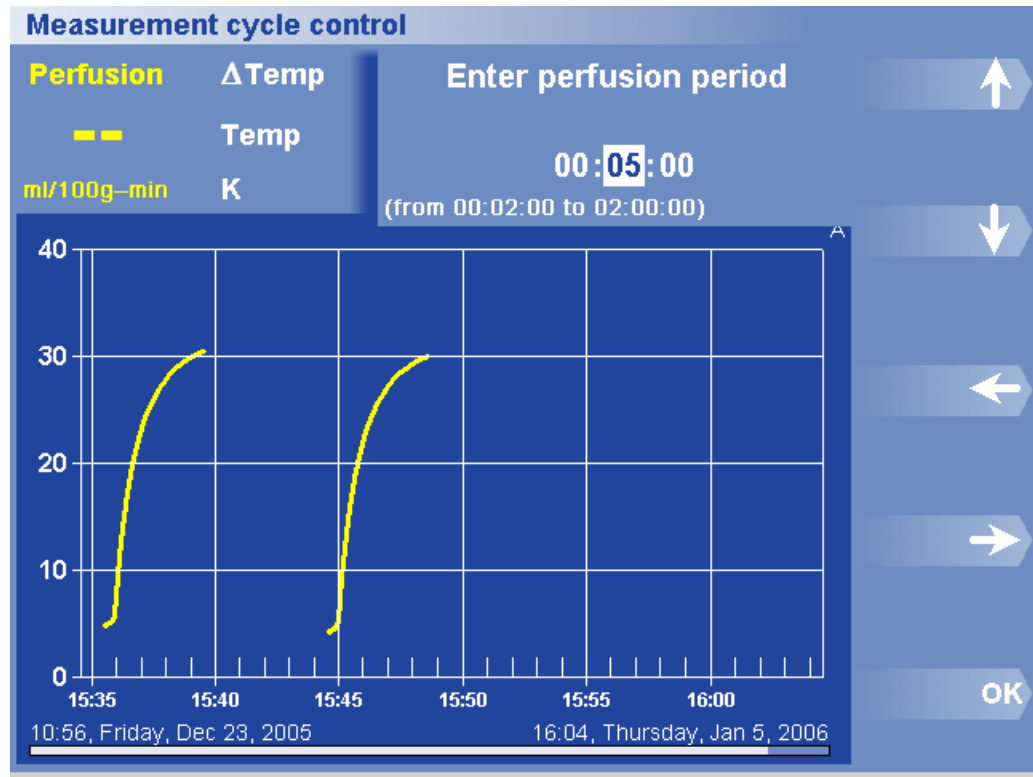


Figure 41. Perfusion Period Dialog Box and Menu

Table 11 lists the minimum, maximum, and default settings for the three adjustable parameters Measurement Control.

Table 11. Operating Parameters for Measurement Control

Parameter	Minimum	Maximum	Default
<i>Number of Cycles</i> – number of perfusion measurement cycles to conduct	1 cycle	999 cycles or Unlimited	Unlimited
<i>Temperature Period</i> – length of the temperature stabilization period	2 min	23:59:59	2 min
<i>Perfusion Period</i> – length of the perfusion measurement period	6 min	2 hrs	1 hr

Miscellaneous Procedures

Use the procedures in this section to accomplish the following tasks:

- Set the date and time.

Date and Time

Press Set Date/Time in the third options menu to open the Date/Time menu (Figure 42).

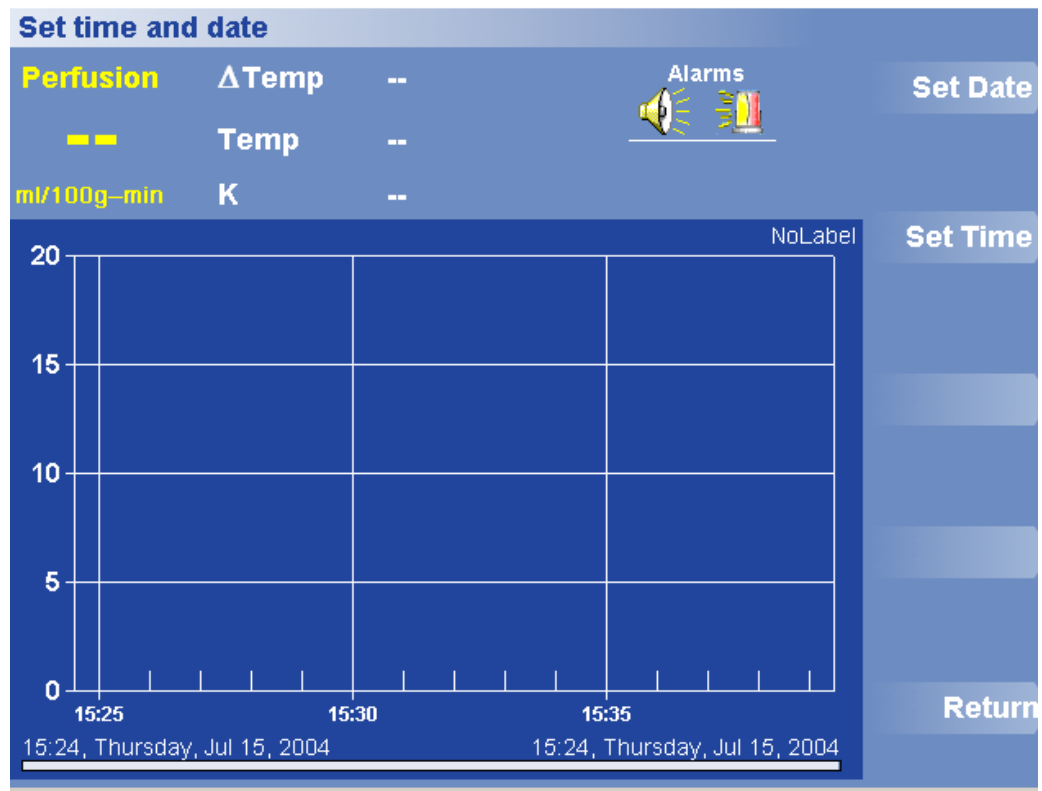


Figure 42. Date/Time Menu

Use the Date/Time menu to accomplish these tasks:

- Set the date on the Monitor.
- Set the time.

Use Procedure 25 to set the date:

Procedure 25. Set the Date

1. Press Options > More Options > More Options. The third options menu appears.
2. Press Set Date/Time. The Date/Time menu appears (Figure 42).
3. Press Set Date. The Enter Date dialog box appears (Figure 43).
4. Use the arrow buttons to enter the current date.
5. Press OK. The Enter Date dialog box closes and the new date appears at the bottom of the main screen.

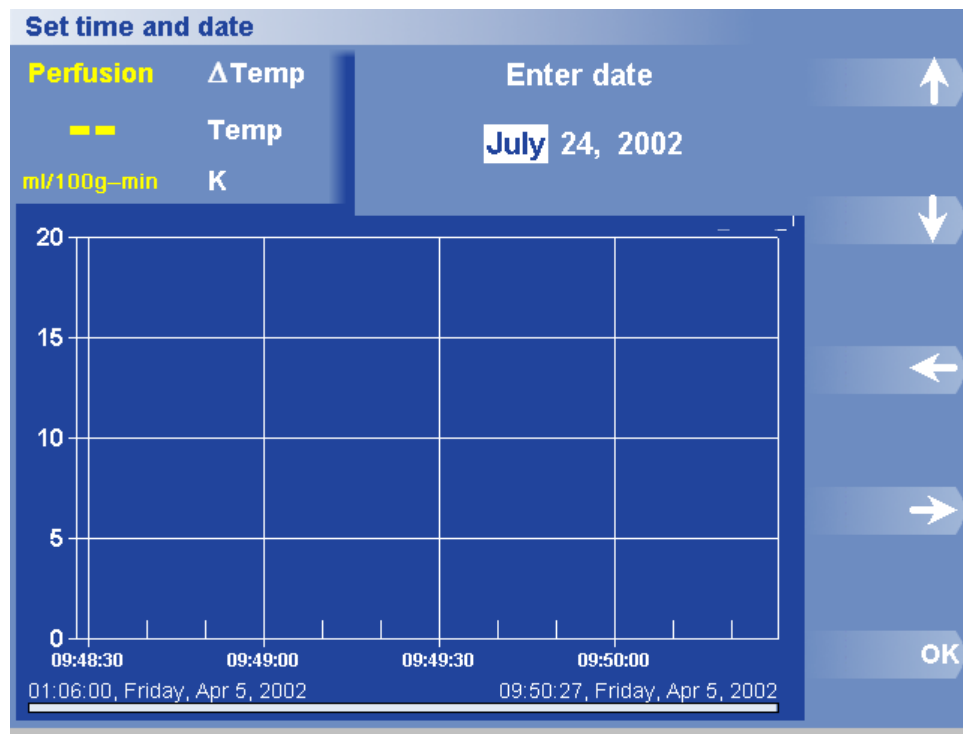


Figure 43. Set Date Dialog Box and Menu

Use Procedure 26 to set the time:

Procedure 26. Set Time

1. Press Options > More Options > More Options. The third Options menu appears.
2. Press Set Date/Time > Set Time. The Time dialog box appears (Figure 44).
3. Use the arrow buttons to enter the correct time.
4. Press OK. The Time dialog box closes and the new time appears at the bottom of the main screen.

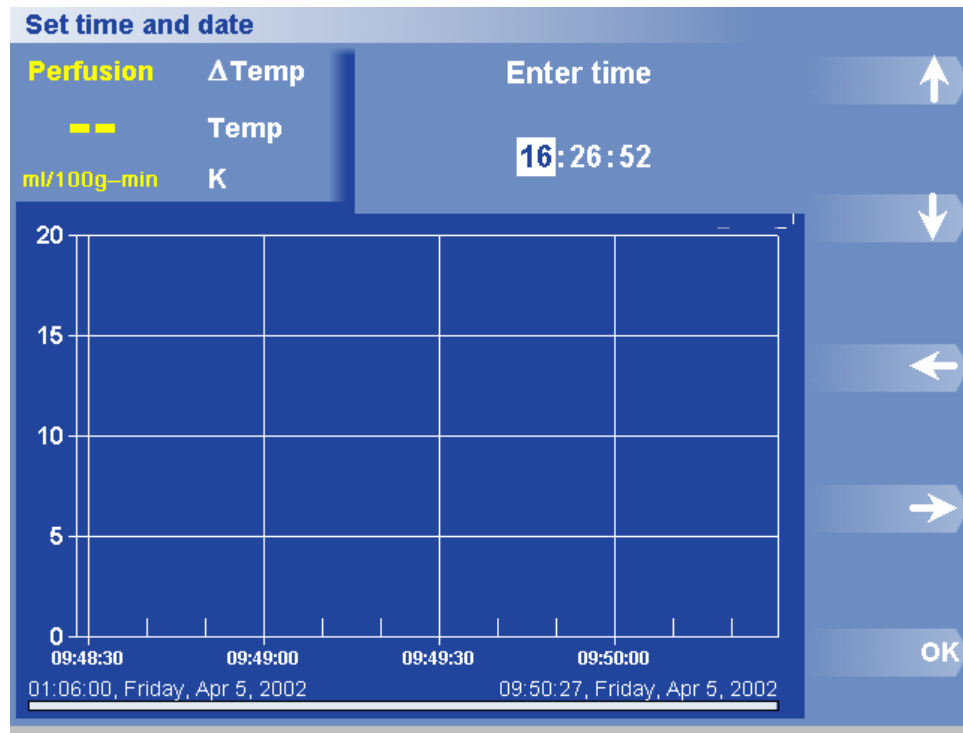


Figure 44. Set Time Dialog Box and Menu

Default Settings

The Bowman Perfusion Monitor Model 500 keeps all the settings used in the current measurement cycle for the next measurement cycle. To restore the manufacturer's defaults, stop all measurements, and press Options > More Options > Restore Defaults, and then Confirm Restore. The defaults cannot be restored while a measurement is in progress. Table 12 lists default settings for several parameters and functions in the Bowman Perfusion Monitor Model 500: Table 13 in Appendix B lists minimum, maximum, and default values for each of the Monitor's adjustable settings.

Table 12. Default Settings

Menu Item	Default Setting
Baud Rate	115,200
Proximal Temperature Plot	Off
Distal Temperature Plot	Off
Δ Temperature Plot	Off
Time Range	15 min
Audio Alarm	Enabled
Visual Alarm	Enabled
Alarm Upper Bound	Disabled
Alarm Lower Bound	Enabled
Perfusion Plot Upper Extent	20 ml/100g–min
Autoscale	On

About

Press Options > More Options > More Options > More Options > About to display the About dialog box, which informs you of the Monitor board identification number, the Probe identification number, the software version, the firmware version, and the amount of available data storage. The dialog box also contains contact information. Press OK to close the About dialog box.

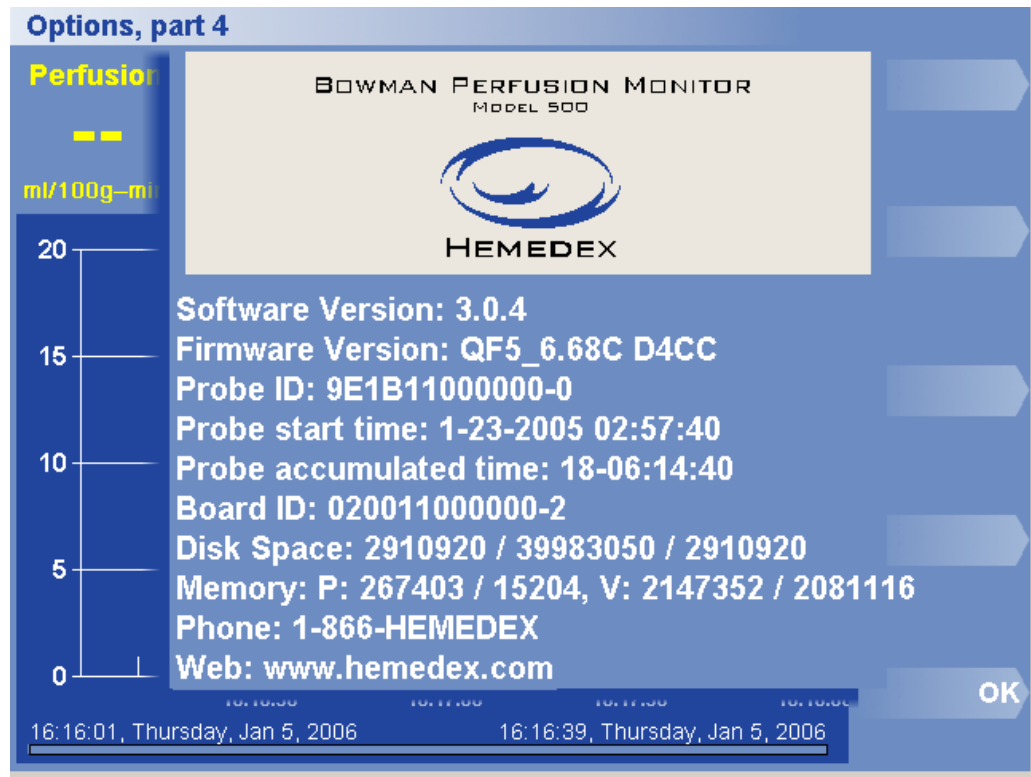


Figure 45. About Menu

Messages

Appendix A lists and explains the messages that appear in the message line of the Bowman Perfusion Monitor Model 500.

Status Messages

Status messages provide information about the status of the Monitor or measurement, but they do not require a response from the user.

Insufficient probe heating

The surface temperature of the distal (heating) thermistor of the QFlow™ 500 Probe was not heated sufficiently. The probe must be heated to at least one degree above the baseline temperature. Most likely the patient baseline temperature is above 39.5 degrees and heating the distal thermistor would exceed the safety limit of 40.7°C. The Monitor automatically recalibrates.

Performing Monitor self-test

Every time the Monitor is turned on it automatically performs an internal self test.

Reading probe information

The Monitor is reading all information stored on the probe, including calibration information and stored settings.

Plug in probe to start measurement

To start measurement, plug a perfusion QFlow™ 500 Probe into the Monitor and the Monitor will automatically start the measurement.

Press Start to start measurement

To start measurement, press the Start button.

Temperature stabilization—Perfusion in about *time*

The measurement cycle is in the temperature stabilization phase. The estimated time to the next displayed perfusion value may be given.

Calibration—Perfusion in about *time*

The measurement cycle is in the calibration phase. The estimated time to the next displayed perfusion value may be given.

Perfusion measurement in about *time*

Perfusion measurement—Recalibration in about *time*

Perfusion measurement phase ends in about *time*

The measurement cycle is in the perfusion measurement phase. The estimated time to the next displayed perfusion value or the estimated time to the end of the current perfusion measurement phase may be given.

Probe may have moved—Recalibrating

The Monitor detected a possible movement of the QFlow™ 500 Probe, and a calibration will be performed automatically.

Baseline temperature drifted—Recalibrating

The Monitor detected an excessive baseline temperature drift, and a calibration will be performed automatically.

Normal measurement termination by user

The user manually terminated measurement.

Cycle Run is complete

The selected number of measurement cycles to run has been successfully completed.

Probe life expired

The QFlow™ 500 Probe has been used for the duration of its allowed life, and measurement was automatically terminated.

Warning Messages

Warning messages describe conditions that may require user intervention to address, but the conditions do not cause measurement to stop. Some warning messages require explicit user acknowledgement (such as **Printer is out of paper**). Other Warning messages automatically clear themselves when the condition no longer exists (such as **Patient temp too high for perfusion measurement**).

Patient temp too low for perfusion measurement

The patient's temperature is too low to obtain a satisfactory K value. Make sure the probe is inserted in tissue.

Temperature outside calibrated range (*low to high* °C)

Each QFlow™ 500 Probe thermistor is calibrated to high accuracy over a specific temperature range. If the tissue temperature is outside that range, an accurate perfusion measurement may not be possible. The Monitor automatically recalibrates.

Patient temp too high for perfusion measurement

Temp too high for perfusion measurement

The surface temperature of the distal (heating) thermistor of the QFlow™ 500 Probe exceeded the safety limit of 40.7°C. The Monitor automatically recalibrates.

Temp gradient too high for perfusion measurement

The difference in temperature between the sense and heat thermistors is too high to make an accurate measurement of perfusion. Make sure the probe is properly inserted into the tissue.

Temperature not yet stable - monitor is retrying

The tissue temperature is too thermally unstable to make an accurate perfusion measurement. Monitor remains in Temperature Stabilization Phase until temperature becomes stable.

Temperature can't be set

The necessary set temperature for the distal (heating) thermistor of the QFlow™ 500 Probe is above its calibrated temperature range. The Monitor automatically recalibrates.

High K value—Suggest reposition perfusion probe

The calibrated tissue K value (thermal conductivity) is higher than that of water (6.5 mW/cm-°C), which is the theoretical upper bound for tissue K. The high K value is typically caused by the QFlow™ 500 Probe tip being too close to a thermally significant vessel, and the problem can be addressed by repositioning the Probe. Alternatively, probe-tissue periodic motion in such organs as the brain, heart and kidney, can cause a high K-value. Where periodic motion is suspected,

make sure the probe is properly inserted. In any case, the Monitor will automatically recalibrate after a high K value..

Low K value - make sure probe is in tissue

The K value is below 1.5 mW/cm-°C. The probe may not be in the tissue. Make sure the probe is properly inserted into tissue. The Monitor automatically recalibrates.

Calibration data too noisy– recalibrating

Significant noise in the signal (from motion, electrocautery, or some other source) prevented an accurate K value from being obtained. Monitor automatically recalibrates.

Baseline temperature drifted – recalibrating

The baseline tissue temperature has changed by more than 0.5 °C and the Monitor automatically recalibrates.

Probe may have moved

The Monitor detected a motion artifact and will monitor the perfusion response to determine if recalibration is necessary.

Probe may have moved – recalibrating

The Monitor detected a significant motion artifact and is automatically recalibrating.

Printer is out of paper

Reload printer paper, according to the instructions in Procedure 1.

Printer door is apparently open

Open and close the printer door, according to the instructions in Procedure 1. This message may occur even if the printer door appears closed.

Can't print—Warning code #number

An internal printer warning condition occurred. (The code number may be appended with text.) Contact Hemedex, Inc., if the warning persists.

Can't store data

The Monitor is unable to store data (Data measurement and display continue).

Can't upload data

The Monitor was unable to upload data. Check the serial communications cable connections and the download (receiving) device.

Probe life expires in *time*

The QFlow™ 500 Probe will reach the end of its allowed life in the indicated amount of time.

Warning code #number

An internal warning condition occurred, and the Monitor automatically recalibrates. (The code number may be appended with text.) Contact Hemedex, Inc., if the warning persists.

Error Messages

Error conditions occurring during a measurement will cause the measurement to stop. In some cases, the Monitor prints out a strip of paper containing useful error information. This **strip should be faxed to the Hemedex** as specified on the print-out. After printing the strip, the Monitor may reboot and will be automatically restart if the error is of a recoverable nature and not safety critical.

In case of Application errors, a pop-up box appears on the Monitor screen. Contact manufacturer with the information displayed in the pop-up.

Probe ID not matched for this device

The probe being used is not compatible with the Monitor being used.

Probe ID not available

Monitor is unable to read the serial number from the memory chip on the probe.

Board CRC failure

Different parts of the Monitor are having trouble communicating with each other.

Board mismatch

Different parts of the Monitor are having trouble communicating with each other.

Probe powered down, restarting...

The Monitor detected a possible fault in the probe and shut down automatically.

Probe powered down

The Monitor detected a possible fault in the probe and shut down automatically.

Insufficient storage available—Delete stored data

There is not enough space available to store new data. Delete stored data to make room for new data.

Can't review stored data

The selected stored data cannot be found or accessed.

Can't delete stored data

The selected stored data cannot be deleted.

Probe is disconnected or broken

Reconnect the QFlow™ 500 Probe, or replace QFlow™ 500 Probe .

Safety shutdown

The Monitor detected a possible fault in the QFlow™ 500 Probe circuit and shut down automatically.

Error code #number

An internal error condition occurred. (The code number may be appended with text.) Contact Hemedex with the Error code number.

Fatal Error

Turn the Monitor off and on again. This error message appears in a message box.

Alarm Messages

Alarm messages are given when the measured perfusion exceeds an alarm bound for the alarm bound trigger time.

Alarm triggered—Perfusion below alarm lower bound

The perfusion was less than the alarm lower bound continuously for the duration of the alarm lower bound trigger time. Press Suspend Alarm to suspend the alarm for the lower bound suspend time.

Alarm triggered—Perfusion above upper bound

The perfusion was greater than the alarm upper bound continuously for the duration of the alarm upper bound trigger time. Press Suspend Alarm to suspend the alarm for the upper bound suspend time.

Troubleshooting Tips

Problems due to instrument malfunction

- Power failure—If the building power supply is interrupted, the device powers up automatically after the power supply has been re-established. If the Monitor was connected to a probe the measurement will automatically start.
- Electrical disturbances—Strong electromagnetic disturbances can result in high frequency noise in the perfusion and temperature signals. These disturbances may occur when using a high-frequency scalpel, during cardioversion, or during electrocauterization.
- Damage to cable or connector—If a QFlow™ 500 Probe cable or umbilical cord is damaged, or a connector is damaged, measured values may be incorrect. The damaged Probe or umbilical cord must be replaced.
- Wet Probes and cable connectors—The QFlow™ 500 Probe connector is not waterproof. Do not allow liquids to contact the connector. Do not dip into liquids.
- Device defects—The Monitor displays an error message if it has an internal defect. The error message will give instructions to the user.

Fault in operation

- Bent Probe—Do not bend the tip of the QFlow™ 500 Probe excessively.
- It is important to have proper placement of the probe and to secure the probe to avoid dislodgement.

Troubleshooting guide
Bowman Perfusion Monitor, Model 500

For the reported Error Messages, follow the suggested actions.

If the suggested action is to contact Hemedex, Inc. (Voice: 1-866-HEMEDEX and 1-617-577-1759, FAX: 1-617-577-9328), please make note of as much detail as possible including any messages or error codes given by the Monitor. FAX any error printouts to Hemedex. Be sure to write in the name of your institution in the “location” field on the printout.

Error message	Description/Possible cause	Suggestions
<i>Can't Store Data</i>	<ul style="list-style-type: none"> There may not be enough space available to store new data 	<ul style="list-style-type: none"> Delete unnecessary stored data
<i>Can't review stored data</i>	<ul style="list-style-type: none"> The selected stored data cannot be found or accessed 	<ul style="list-style-type: none"> Contact manufacturer
<i>Can't delete stored data</i>	<ul style="list-style-type: none"> The selected stored data file cannot be deleted 	<ul style="list-style-type: none"> Contact manufacturer
<i>Probe is disconnected or broken</i>	<ul style="list-style-type: none"> Probe disconnected Faulty umbilical cord Faulty probe 	<ul style="list-style-type: none"> Ensure probe connected to umbilical cord Ensure umbilical cord connected to Monitor Replace umbilical cord Replace Probe
<i>Temp gradient too high for perfusion measurement</i>	<ul style="list-style-type: none"> Temperature difference between sense and heat thermistors is greater than 0.5°C Probe may not be properly inserted 	<ul style="list-style-type: none"> Check probe position If problem persists, consider moving probe.

Error message	Description/Possible cause	Suggestions
<i>Patient temp too high for perfusion measurement</i>	<ul style="list-style-type: none"> • Patient has a fever above 39.5°C 	<ul style="list-style-type: none"> • Monitor will automatically resume perfusion measurement when patient's temperature is below 39.5°C
<i>Temp too high for perfusion measurement</i>	<ul style="list-style-type: none"> • Monitor attempted to make a perfusion measurement but aborted the attempt because the patient temperature is too high. 	<ul style="list-style-type: none"> • Monitor will resume perfusion measurement when patient's temperature is below 39.5°C
<i>Patient temp too low for perfusion measurement</i>	<ul style="list-style-type: none"> • Tissue temperature is below 20 °C • Probe may not be in tissue. 	<ul style="list-style-type: none"> • Check to make sure probe is in tissue.
<i>Probe temp is too low – make sure probe is in tissue</i>	<ul style="list-style-type: none"> • Probe may not be in tissue. • Tissue may be too cold to permit a measurement 	<ul style="list-style-type: none"> • Check to make sure probe is in tissue.
<i>Temp outside calibrated range (20 to 46 °C)</i>	<ul style="list-style-type: none"> • Probe may not be in tissue. • Tissue may be too cold to permit a measurement 	<ul style="list-style-type: none"> • Check to make sure probe is in tissue.
<i>Set temp outside cal range (20 to 41 °C)</i>	<ul style="list-style-type: none"> • Probe may not be in tissue. • Tissue may be too cold to permit a measurement 	<ul style="list-style-type: none"> • Check to make sure probe is in tissue.
<i>Baseline temperature drifted – recalibrating</i>	<ul style="list-style-type: none"> • The patient's temperature changed by more than 0.5 °C during a perfusion measurement cycle 	<ul style="list-style-type: none"> • If message reoccurs, consider draping the area of probe insertion to insulate tissue from environmental temperature changes

Error message	Description/Possible cause	Suggestions
<i>Temperature not yet stable – Monitor retrying</i>	<ul style="list-style-type: none"> • The tissue temperature is changing too rapidly to accurately measure perfusion 	<ul style="list-style-type: none"> • If message reoccurs several times, consider draping the probe to insulate it from environmental temperature changes • Make sure the probe is inserted at least 1.5 cm into tissue
<i>Insufficient probe heating – recalibrating</i>	<ul style="list-style-type: none"> • The patient’s temperature is high and the chosen Temperature step was too high 	<ul style="list-style-type: none"> • Monitor will automatically retry measuring perfusion using a lower temperature step
<i>Low K value – make sure probe is in tissue</i>	<ul style="list-style-type: none"> • The probe has fallen out of the patient 	<ul style="list-style-type: none"> • Make sure probe is in tissue
<i>High K value – suggest reposition perfusion probe</i>	<ul style="list-style-type: none"> • Probe may be near a thermally significant vessel • Probe or tissue may be moving slightly 	<ul style="list-style-type: none"> • Check probe position • Consider repositioning the probe along the same insertion track
<i>Data too noisy to calibrate – recalibrating</i>	<ul style="list-style-type: none"> • Probe or tissue may be moving slightly • Electrocautery may be a source of such noise 	<ul style="list-style-type: none"> • Make sure probe is properly secured • Try to not run electrocautery during calibration
<i>Probe may have moved – recalibrating</i>	<ul style="list-style-type: none"> • Probe was moved relative to the tissue 	<ul style="list-style-type: none"> • Make sure probe is properly secured
<i>Board CRC failure</i>	<ul style="list-style-type: none"> • Parts of the Monitor are having trouble communicating 	<ul style="list-style-type: none"> • Contact manufacturer even if this is only an intermittent problem
<i>Board mismatch</i>	<ul style="list-style-type: none"> • Parts of the Monitor are having trouble communicating 	<ul style="list-style-type: none"> • Contact manufacturer

Error message	Description/Possible cause	Suggestions
<i>Probe powered down, restarting...</i>	<ul style="list-style-type: none"> The Monitor detected a possible fault in the probe circuit and shut down automatically 	<ul style="list-style-type: none"> If the message persists, replace the probe with a new probe
<i>Probe powered down</i>	<ul style="list-style-type: none"> The Monitor detected a possible fault in the probe circuit and shut down automatically 	<ul style="list-style-type: none"> If the message persists, replace the probe with a new probe
<i>Error code #</i>	<ul style="list-style-type: none"> An internal error condition occurred. (The code number may be appended with text) 	<ul style="list-style-type: none"> Record the code # or text and contact the manufacturer
<i>Warning code #</i>	<ul style="list-style-type: none"> An internal error condition occurred. (The code number may be appended with text) 	<ul style="list-style-type: none"> Record the code # or text and contact the manufacturer

Default Settings

The table below lists minimum, maximum, and default settings for Measurement Control, the Alarm Upper Bound, and the Alarm Lower Bound.

Table 13. Consolidated Listing of Default Settings

Setting	Minimum	Maximum	Default
Temperature Stability	0.005°C	0.100°C	0.025°C
Time Stability	10 secs	60 secs	30 secs
Number of Cycles	1 cycle	999 cycles or Unlimited	Unlimited
Temperature Period	2 mins	23:59:59	2 mins
Perfusion Period	2 mins	2 hrs	60 mins

Setting	Minimum	Maximum	Default
Alarm Upper Bound	N/A	N/A	Disabled
Alarm Upper Bound Value	0 ml/100g–min	200 ml/100g–min	200 ml/100g–min
Alarm Upper Bound Trigger Time	1 sec	30 mins	2 mins
Alarm Upper Bound Suspend Time	1 min	10 mins	10 mins
Alarm Lower Bound	N/A	N/A	Enabled
Alarm Lower Bound Value	0 ml/100g–min	200 ml/100g–min	0 ml/100g–min
Alarm Lower Bound Trigger Time	1 sec	30 mins	2 mins
Alarm Lower Bound Suspend Time	1 min	10 mins	10 mins
Baud Rate	19,200	115,200	115,200
Data Frequency	1 Hz	1 Hz	1 Hz
Proximal Temperature Plot	N/A	N/A	Off
Distal Temperature Plot	N/A	N/A	Off
Δ Temperature Plot	N/A	N/A	Off
Time Range	N/A	N/A	15 min
Audio Alarm	N/A	N/A	Enabled
Visual Alarm	N/A	N/A	Enabled
Perfusion Plot Upper Extent	10 ml/100g–min	200 ml/100g–min	Autoscale

Technical Specifications

Perfusion range	0 to 200 ml/100g–min
Perfusion resolution	< 0.5 ml/100g–min
Perfusion accuracy	10% at full scale (200 ml/100g–min)
Volume of measurement region	Approximately 0.1 ml
Temperature range for perfusion measurement	20 to 39.5°C
Temperature accuracy	0.3°C
Temperature resolution	0.005°C
Serial communication	RS-232 standard, DB-9 connector
BNC Analog output	0 to 2 V proportional to 0 to 200 ml/100g–min
Breakdown Voltage	Medical Grade Isolation: dielectric strength tested to 4000 V AC
Leakage current	< 10 μ A (meets IEC-60601 specifications for CF equipment)
Monitor warm-up time	10 minutes
Power Requirements	100-120 VAC or 200-240 VAC , 65 VA
Power Line Fuse	630 mA, Slow Blow
Physical Dimensions	16.6 \times 11.9 \times 10.1 inches (42.2 \times 30.2 \times 25.7 cm)
Weight	10 lbs. (4.5 kg)

Glossary

Δ temperature See Delta temperature.

Baseline temperature The tissue temperature measured by the sense (proximal) thermistor in the probe. The tissue temperature in the absence of the heating from the Probe.

Calibration The second and shortest phase of the measurement cycle (approximately 10 seconds), whose primary objective is to determine the tissue thermal conductivity (K value)—a prerequisite for perfusion measurement.

Conductivity Thermal conductivity.

Cycle control See Measurement cycle.

Measurement Control The way the Monitor cycles between the temperature stabilization, calibration, and perfusion measurement phases on a regular schedule, allowing perfusion measurements to be made at regular intervals. The measurement cycle can be repeated a fixed number of times, or indefinitely.

Δ temperature (Delta temperature) During temperature stabilization, Δ temperature is the difference between the temperatures of the distal (heating) and proximal (tracking) thermistors of the Probe. During perfusion measurement, Δ temperature is the difference between the current temperature of the distal thermistor and its temperature immediately before the beginning of calibration. (Δ temperature is not defined during calibration.)

Distal temperature The temperature of the distal (heating) thermistor of the Probe. This temperature is elevated over the baseline tissue temperature during calibration and perfusion measurement.

Heating thermistor The distal thermistor of the Probe.

K (value) The symbol for thermal conductivity.

Measurement cycle The cycle of three phases necessary to make perfusion measurements; *Temperature stabilization, calibration, perfusion measurement*. Accurate perfusion measurement requires knowledge of tissue thermal conductivity (K value). This value is determined during calibration, thus calibration precedes perfusion measurement. Tissue thermal conductivity measurement requires stable

tissue temperature, thus temperature stabilization precedes calibration. Over time tissue thermal conductivity and baseline temperature may change. Therefore, perfusion measurement must eventually cease to allow for recalibration, and the measurement cycle repeats.

Message Line The line at the top of the Monitor's screen where various status, warning, error, and alarm messages are displayed.

Perfusion Tissue blood flow, or blood flow in the microvasculature. This is the rate at which the quantity of blood in a given mass or volume of tissue is replenished at the level of the capillaries. Perfusion is often given in the units of milliliters of blood per 100 grams of tissue per minute, or ml/100g–min.

Perfusion Blackout Period is the first stage of perfusion mode. It is during this time period that the Monitor is processing all the information it needs to give an accurate perfusion value. Since perfusion values in this initial stage are not accurate the Monitor will black out the data. Once accurate measurements are obtained they are displayed numerically and graphically.

Perfusion measurement The third and last phase of the measurement cycle, during which the Monitor is able to measure perfusion.

Perfusion mode consists of the perfusion blackout period and perfusion measurement phase.

Proximal temperature The temperature of the proximal (tracking) thermistor of the Probe. The tracking thermistor tracks the baseline tissue temperature.

Recalibration The initiation of an automatic measurement cycle during the perfusion measurement phase of the measurement cycle. (See Measurement cycle also.)

Suspend time The time for which an alarm bound is temporarily disabled, after it has triggered an alarm and the alarm has been acknowledged by the user

Temperature stabilization The first phase of the measurement cycle, during which the stability of tissue temperature is evaluated. Temperature stability must be confirmed by the Monitor before calibration and perfusion measurement can take place.

Temperature stability This parameter is the maximum allowable change in temperature of either thermistor (over the time stability period) that is consistent with stable tissue temperature.

Thermal conduction The ability of a solid medium, such as tissue, to transport heat (thermal energy).

Thermal convection The ability of a fluid medium, such as blood, to transport heat (thermal energy).

Thermally significant vessel A blood vessel large enough to confound perfusion measurements by a nearby Probe. Such a vessel can be recognized by the unphysiologically high K values (thermal conductivity) it causes in calibration. This problem is addressed by repositioning the probe.

Thermistor An electrical element that changes its resistance in response to a temperature change.

Time stability The minimal time period over which tissue temperature must be assessed to confirm temperature stability. (See Temperature stability also.)

Tissue Perfusion See Perfusion.

Tracking thermistor The proximal thermistor of the Probe.

Trigger time The time for which perfusion must exceed an enabled alarm bound to trigger the alarm.

Umbilical cord A necessary extension cable for the Probe. The Probe connects to the umbilical cord, and the umbilical cord plugs into the Monitor.

Watchdog Timer An electronic device on the Monitor that will automatically end a measurement and turn off the power to the Probe if the Monitor has not communicated with the probe for more than 6 seconds.

Sample ASCII Data

A sample is given of data streamed from the Monitor.

Measurements made using the Bowman Perfusion Monitor Model 500 can be streamed (sent) to a computer. ASCII data are streamed essentially in real time while measurements are being made, and stored data can be uploaded after measurements are completed. These uploaded data can be sent to info@hemedex.com for conversion into ASCII format.

Communication through the external serial port takes place with user-selectable baud rates between 19,200 and 115,200, no parity, 8 data bits, 1 stop bit. If data are uploaded as they are being measured (called streaming data), the ASCII protocol is used; if data are uploaded from a file (perfusion data file), the Zmodem protocol is used. Note that streaming does not use flow control, but uploading data via the serial port requires the use of hardware flow control.

The format of the streamed data is given below. The vast majority of these data generally consists of lines containing five parameters: date, time, temperature, delta temperature, and perfusion. All other lines begin with the '#' character. For conciseness, the ':' character indicates a continuing (but not shown) series of lines identical in format to the previous line. Sample uploaded data are shown in Courier font, and annotations which do not appear in the data upload are shown in *italics*. NaN (not a number) indicates a measured parameter is not available at the given time.

Header information

#Label: JANE_SMITH
#Start time: 1-5-2006_14:21:58
#Probe number: 9E1B11000000
#Monitor number: 020011000000-2
#Software version: 3.0.4
#Firmware version: QF5_6.68C D4CC

Settings summary

#Alarm audio: ENABLED
#Alarm visual: ENABLED
#Alarm lower bound: Enabled
#Alarm lower bound value: 0.000000
#Alarm lower bound trigger time: 00:02:00
#Alarm lower bound suspend time: 00:10:00
#Alarm upper bound: Disabled
#Temperature stability: 0.025000
#Time stability: 30.000000
#Data frequency: 1 Hz
#Column headers: Date Time Temperature DeltaTemp Perfusion

Temperature mode header and data

#Temperature Stabilization
1-5-2006 14:22:06.7 37.097 -0.141 NaN
1-5-2006 14:22:07.7 37.097 -0.140 NaN
1-5-2006 14:22:08.7 37.097 -0.140 NaN
:
1-5-2006 14:22:23.7 37.097 -0.141 NaN

Calibration mode header and data

#Calibration
1-5-2006 14:22:46.1 37.097 NaN NaN
1-5-2006 14:22:46.2 37.097 NaN NaN
1-5-2006 14:22:46.3 37.097 NaN NaN
:
1-5-2006 14:22:55.5 37.097 NaN NaN

Measured thermal conductivity

#K: 4.887 (4.887) [0.104 (0.104)]

Perfusion mode header and data

#Perfusion Measurement
1-5-2006 14:22:56.0 37.099 NaN NaN
1-5-2006 14:22:57.0 37.099 NaN NaN
1-5-2006 14:22:58.0 37.099 NaN NaN

Appendix E

⋮
1-5-2006 14:23:46.0 37.099 NaN NaN
1-5-2006 14:23:47.0 37.099 2.647 4.67
1-5-2006 14:23:48.0 37.099 2.647 4.54
1-5-2006 14:23:49.0 37.099 2.647 4.57
1-5-2006 14:23:50.0 37.099 2.648 4.40
⋮
1-5-2006 14:23:56.0 37.099 2.644 5.45

Status, warning, or error message

#Message: "Normal measurement termination by user"

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