Codman
a Johnson & Johnson company

HEMEDEX® Cerebral Blood Flow Monitoring System

TECHNICAL **USER GUIDE**

HEMEDEX

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INTRODUCTION

Purpose

The purpose of this guide is to aid BOWMAN PERFUSION MONITOR® users with technical knowledge of BOWMAN PERFUSION MONITOR, the placement and fixation of the QFLOW 500™ Perfusion Probe, and to help in understanding the data recorded by the BOWMAN PERFUSION MONITOR. This Technical Manual provides a general technical overview and is not intended to replace the User Manual or IFUs for individual products. For detailed information, please refer to the User Manual of the BOWMAN PERFUSION MONITOR and IFU for the QFLOW 500 Perfusion Probes. The successful use of the BOWMAN PERFUSION MONITOR requires that:

- The probe is inserted at the proper site and at the proper depth for the given indication
- The probe is kept fixed at this location
- The data is properly interpreted and utilized by physicians to aid them in patient management

The following sections should aid in this process.

Audience

This guide is intended for BOWMAN PERFUSION MONITOR and QFLOW 500 Perfusion Probe users. Basic knowledge of neuroanatomy and procedures is assumed.

Background

The QFLOW 500 is intended for extravascular monitoring of microcirculation blood flow in buried tissues.

HEMEDEX® CBF Monitoring System consists of the BOWMAN PERFUSION MONITOR, the QFLOW 500 Perfusion Probe, connecting umbilical cable and power cable. It is FDA cleared for measuring cerebral blood flow in brain white matter.

HEMEDEX CBF Monitoring System is developed based on thermal diffusion technology, and is currently the only minimal invasive technology available that measures cerebral blood flow in absolute unites continuously. The monitor has an intuitive graphical user interface, a color display screen, and a thermal printer. The probe's diameter is 1.1mm.

As of early 2007, Codman and Shurtleff, Inc. acquired exclusive rights to distribute the HEMEDEX CBF Monitoring System and accessory products in United States for measurement of cerebral blood flow.

BOWMAN PERFUSION MONITOR

(Please refer to the User Manual for complete and detailed instructions)

Section 1: BOWMAN PERFUSION MONITOR General Overview

The BOWMAN PERFUSION MONITOR is designed as a stand-alone unit for patient bedside use. It has capabilities for linking to other systems. The monitor connects directly at 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. The electronic hardware specifications are as follows:

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.)

The physical specifications for the BOWMAN PERFUSION MONITOR are as follows:

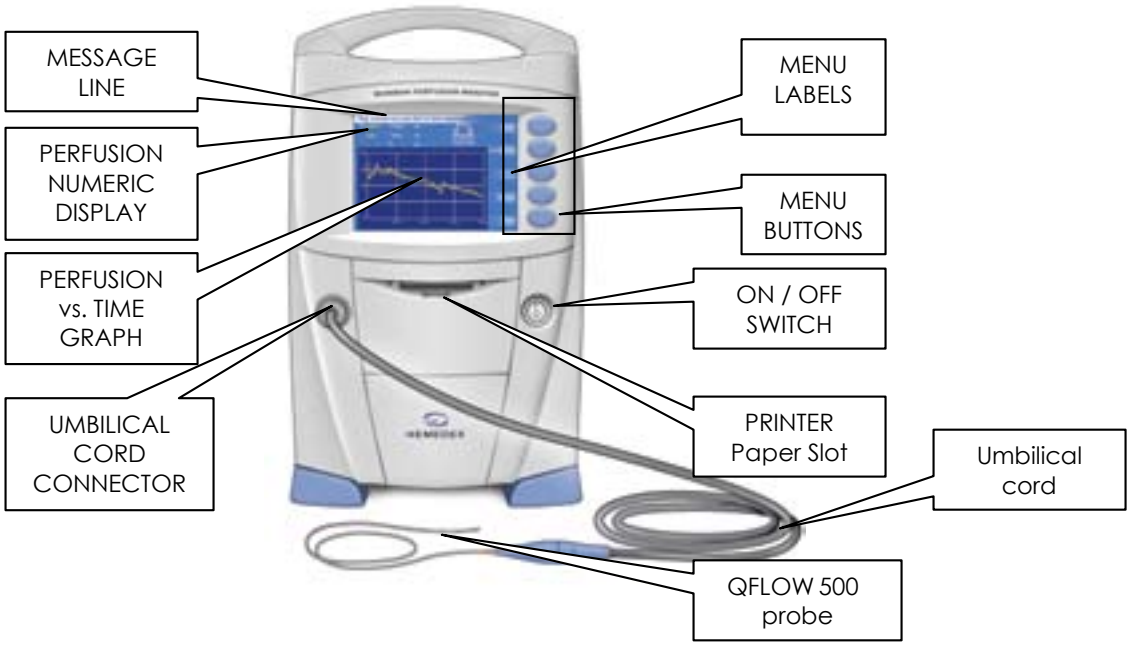
Dimensions	16.6 X 11.9 X 10.1 inches (42.2 X 30.2 X 25.7 cm)
Weight	10 lbs. (4.5 kg)
Operating Temperature Range	32° to 122°F (0° to 50°C)
Storage Temperature Range	-4° to 140°F (-25° to 60°C)
Storage Humidity Range	20% to 90% RH

Analog output specifications are as follows:

Voltage Output	0 to 2 V DC (100 Ω impedance) Voltage floating and insulted 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

Front Panel

The front panel of the BOWMAN PERFUSION MONITOR (Model 500) holds the power switch, printer, display screen, menu buttons, and umbilical cord connector (for the QFLOW 500 probe). To take measurement, a QFLOW 500 probe must be properly placed in the target tissue, and 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. **The message line at the top of the display screen will indicate the progress in measurement cycle as well as warning messages if there is any problem with the probe, the monitor, or performing perfusion measurements.**



Printer and Load Paper

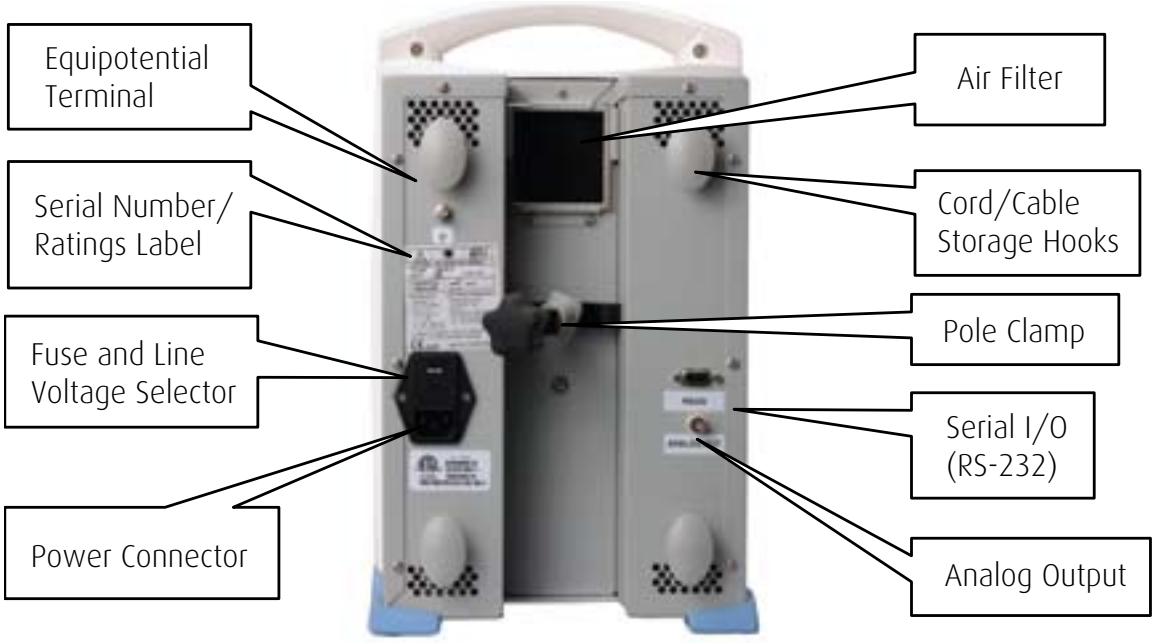
The printer records the real-time perfusion measurements on paper for review and record keeping. When "**Print**" option is requested, the data shown on the display screen will be printed with the probe label and the unique probe ID number with options to Print Perfusion; Print Perfusion & Temperature; Print K Values; or Print Settings.

Load paper in the BOWMAN PERFUSION MONITOR before operating. The printer uses standard 50mm thermographic print rolls. To load paper in the printer:

1. Open printer access panel by flipping door down.
2. Push black trigger on lower right side to access paper compartment.
3. Insert paper roll into opening with paper coming off the bottom.
4. Close paper door and printer access door.

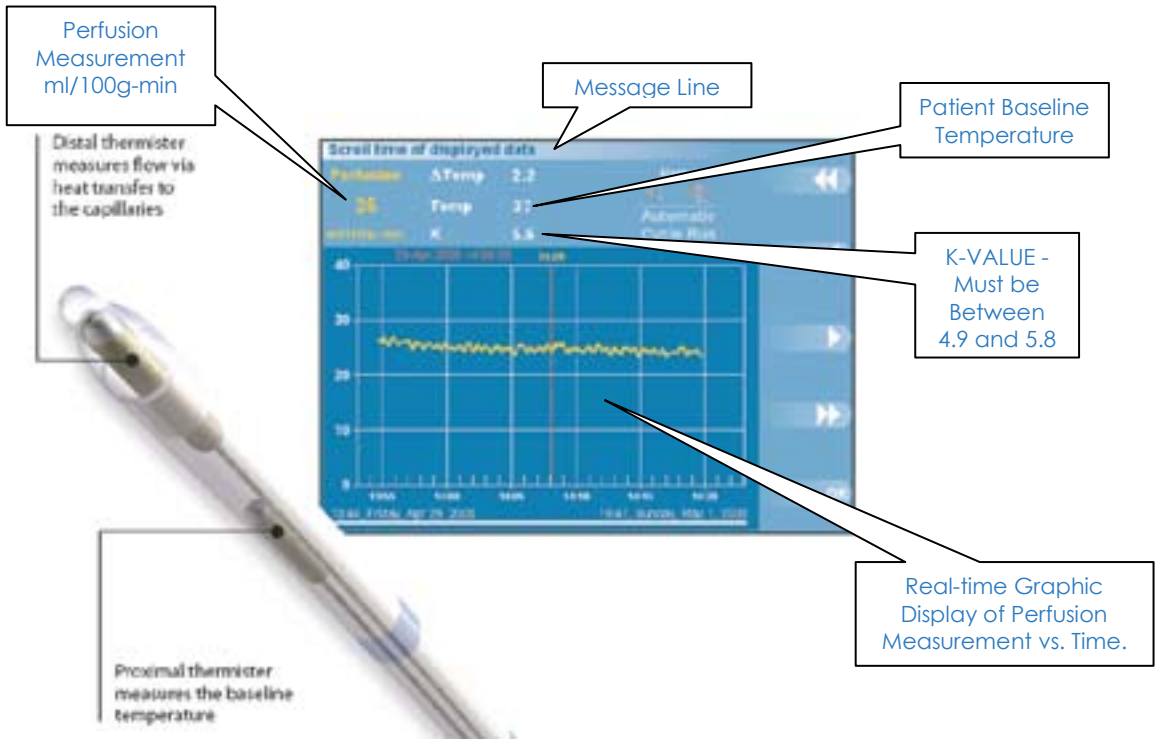
Rear Panel

The rear panel of the BOWMAN PERFUSION MONITOR 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. The switch must be set accordingly for the country of use.



Section 2: Monitor Set Up

1. Place monitor on shelf or securely mount on IV pole.
2. Plug power cord into back of monitor and opposite end into wall power outlet. Please note that the monitor does not have battery capabilities. However, when the monitor is not plugged into the wall, or is turned off, it will not lose previously recorded data. The monitor will retain in total 15 days of data.
3. Connect umbilical cord into connector on front left panel of the monitor. The umbilical cord is 12 feet long. Connect the umbilical cord to the properly placed QFLOW 500 probe.
4. Press ON/OFF switch on front right panel of the monitor.
5. The display screen of the monitor should turn on. Message line is on the top of the display screen.
6. Measurement of tissue temperature and K-value will begin automatically. Correct K value in brain white matter should be between 4.9 and 5.8.
7. If the probe has been placed correctly in the white matter, perfusion measurement will begin in 3-5 minutes after the automatic calibration process is completed.
8. Perfusion measurement is displayed in absolute units of ml/100g/min.
9. The graphic display will show perfusion measurement in real time.



Section 3: Measurement Cycle

The BOWMAN PERFUSION MONITOR measurement cycle has three phases: temperature stabilization, calibration and perfusion measurement. It takes in total about 3-5 minutes on average for the monitor to go through the temperature stabilization and calibration phases. During these two phases, no perfusion measurement will be taken. Recalibration happens automatically at end of the preset perfusion measurement time, which ranges from 2 minutes to 2 hours. The message line at the top of the screen will indicate which phase of the measurement cycle the monitor is in.

Temperature Stabilization

At the start of each new measurement, the monitor will automatically begin with temperature stabilization. During this phase, the monitor is confirming the stability of the tissue baseline temperature, which usually takes several minutes, and no perfusion measurement is taken at this time. If the patient's tissue temperature is not stable, or is undergoing dramatic changes, a warning message will display as "Temp not yet stable – Check Settings – Monitor is trying"; the monitor will continue to check for temperature stability, and no perfusion measurement will be taken. Once the tissue temperature is stabilized, the HEMEDEX CBF Monitoring system will continue to the calibration phase, followed by measuring perfusion.

Calibration

The calibration for the BOWMAN PERFUSION MONITOR and the QFLOW 500 probe are done automatically in-vivo. The monitor automatically calibrates during the period immediately after temperature stabilization and before perfusion measurement while the probe is implanted in the target tissue. During calibration, the monitor calculates the thermal conductivity (K) value. The proper K value for the brain white matter is between 4.9 and 5.8. The monitor has the capability to automatically re-calibrate within a pre-set time interval ranging every 2 min to 2 hours. The default setting in the monitor for re-calibration is every 60 minutes. Re-calibration may last 3-5 minutes. During this time, no perfusion measurement is taken. To manually set the Re-Calibration time interval (for more detail see 6.3.2.2 for Options Menu 2)**,** begin at the **Start Menu**, press buttons **OPTIONS** > **MORE OPTIONS** > **MEASUREMENT CONTROL** > **PERFUSION PERIOD,** then use arrow keys to adjust time parameters, and press OK to allow the monitor to close out the dialogue box. This means the monitor will automatically recalibrate at the time interval set for the perfusion period.

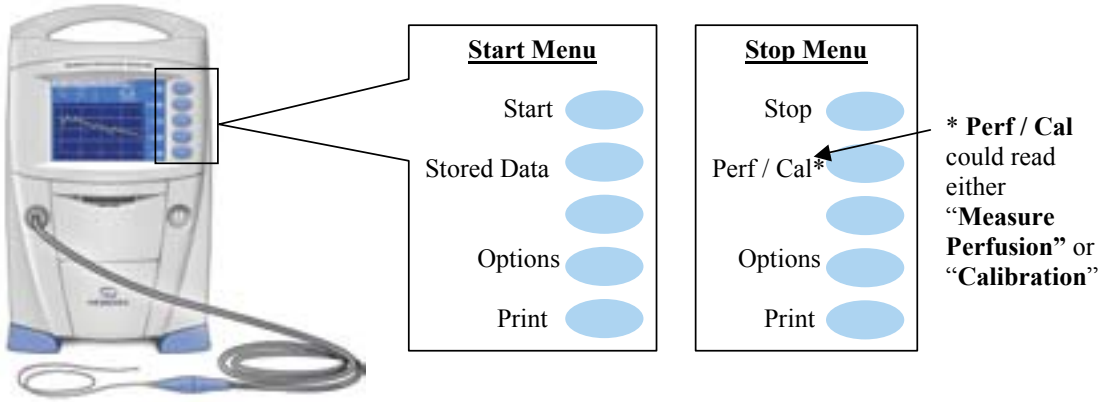
Perfusion Measurement

Perfusion measurement begins after the calibration is complete, but no reading appears until 50 seconds later, when the monitor determines that the measurement is accurate. If the monitor detects a problem with the measurement results, it automatically re-calibrates, starting a new temperature stabilization phase to obtain a better reading. During perfusion measurement phase, the user has the option to choose force calibration by pressing the "Calibration" button, which initiates the calibration phase immediately. BOWMAN PERFUSION MONITOR is capable of detecting cerebral blood perfusion ranging from 0 to 200 ml/100g/min. To stop perfusion measurement, simply press the "Stop" button.

Section 4: User Interface Menu

Use the menu on the right-hand side of the main screen to control the BOWMAN PERFUSION MONITOR, 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.

Start / Stop Menu



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.

Stored Data: Stored Data option allows the user to "review", "delete", "upload" or "set the baud rate for uploading" data. The BOWMAN PERFUSION MONITOR saves data automatically with maximum limit as 15 days of data. The monitor creates a new perfusion file for each probe. If more than 15 days of data are collected, the additional data will overwrite the first few days of data for that probe. Data can be uploaded to a computer. For individual data management support, please contact your local Codman representative. The stored data is identified with three different tags:

1. The user designated label, which is entered in the **Set Label** menu.
2. The date of the first use of the probe in the patient. The probe is approved for single-patient use.
3. The time of the first use of the probe in the patient.

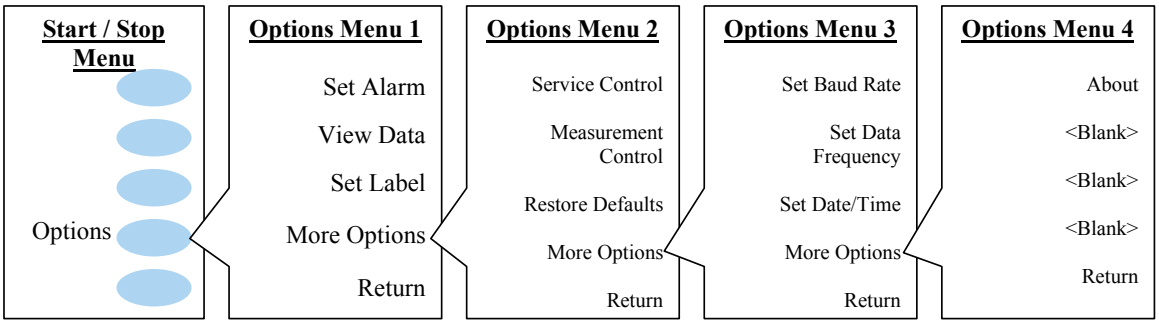
Measure Perfusion: Manually overrides the monitor when it is in the temperature stabilization phase and initiates a perfusion measurement phase. **Measure Perfusion** alternates with **Calibrate** as the second item in the Stop Menu.

Calibration: 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**.

Print: Press **Print** to request printing of data. All printed strips of data include Label information and the unique probe ID. Select one of the 4 options to print data:
1. Print Perfusion: Print the perfusion trace plot that currently appears in the display screen.
2. Print Perfusion & Temperature: Print plots of perfusion and proximal temperature (patient's base line temperature).
3. Print K Values: Print all the values recorded for thermal conductivity and the time and date they were recorded.
4. Print Settings: Print all the settings currently in place.

Options Menu



Options Menu 1

Set Alarm: The BOWMAN PERFUSION MONITOR 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. Similarily, when perfusion rises above the alarm upper bound for a specified period of time, the monitor triggers the alarm. To enable the alarm:

- Press **Audio** to turn audio alarm ON or OFF. The speaker symbol on the display screen brightens or dims.
- Press **Visual** to turn visual alarm ON or OFF. The siren symbol on the display screen brightens or dims.
- To set **Upper Bound** or **Lower Bound** for perfusion alarm, the user can set the value of the bound, trigger time and suspend time. **Trigger Time** specifies how long measured perfusion must lie outside the bound before the monitor triggers the alarm. **Suspend Time** specifies how long a triggered alarm remains suspended (temporarily disabled) after you acknowledge it. **Enable** the bound to ensure the activation of the alarm.
- **Return** three times to get back to the main screen.

View Data:

- Press **Set Time Range**, and use **up and down arrow** buttons to select the time range of horizontal axis. The default value is 15 minutes. Use left and right arrow buttons to scroll the data. Press **OK** to allow the time range dialog box to close and the plots on the display screen adjust to reflect the time range of the user's choice
- Press **Scroll Time**, and use arrow buttons to select which portion of the data you want to display.
- Press **Set Perfusion Range** and use arrow buttons to adjust the upper extend of the perfusion plot shown on the display screen. Press **Autoscale** to turn ON or OFF autoscale. When autoscale is on, the monitor to automatically adjust the displayed plot to allow for the highest range of perfusion detected.
- Press **Select Plots & List K** to view various Temperature plots and list of K values.

Set Label: Use arrow keys to select **Delete** old label if appropriate, or to enter patient name by pressing **O.K**. for each selected character. Choose **Label Complete** when finished. Be sure to press **Return** to get back to the main screen.

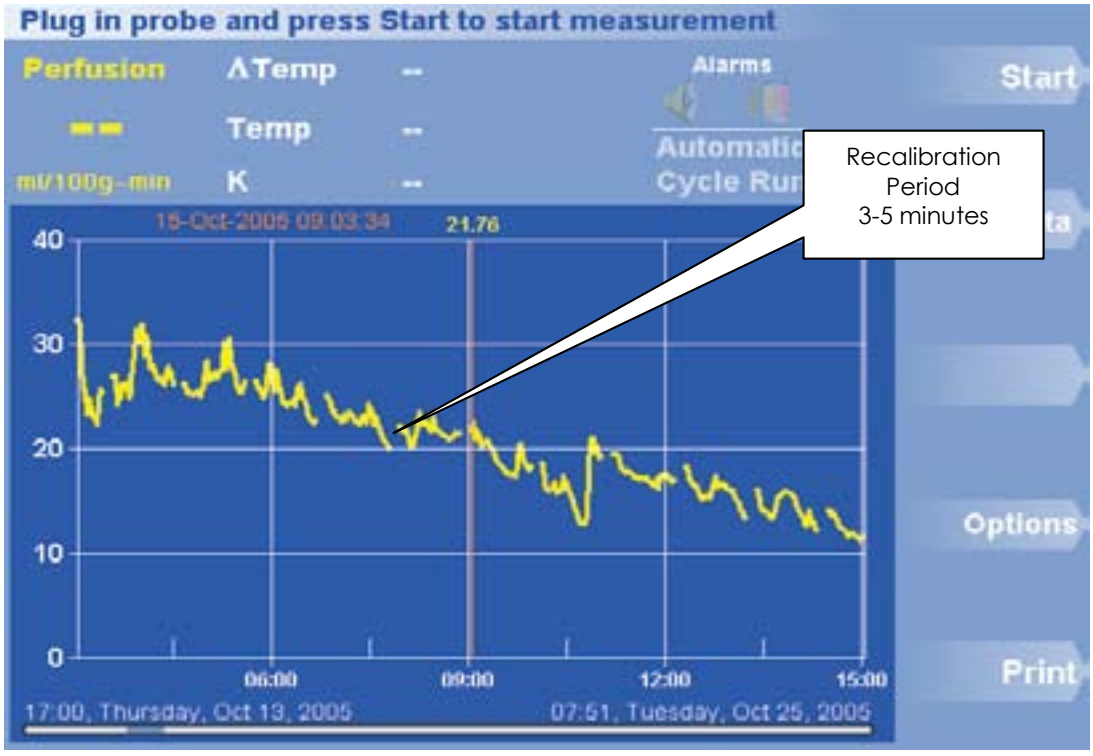
Options Menu 2

Measurement Control: The **Measurement Control** Menu allows you adjust the **Number of Cycles**; **Temp Period** and **Perfusion Period**. See the following chart for the definition and limits of each parameter. The important option here is **Perfusion Period**.

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.

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

Press **Perfusion Period** and use arrow keys to adjust time parameters. Once the time parameters are set, the monitor will automatically re-calibrate at the interval user set for the perfusion period. For example, if the time parameter is set at 45 minutes, then the monitor will recalibrate for every 45 minutes of perfusion period measured. Usually re-calibration takes 3-5 minutes, at which time no perfusion measurement will be taken. On the display screen, the breaks in the perfusion vs. time graph represent these re-calibrations.



Restore Defaults: To restore manufacturer's defaults, stop all measurements and press **Restore Defaults**, and then **Confirm Restore**. Below is a comprehensive list of default settings, including the minimum and maximum limits of each parameter.

SETTING	MINIMUM	MAXIMUM	DEFAULT
Temperature Stability	0.005°C	0.100°C	0.025°C
Time Stability	10 sec	60 sec	30 sec
Number of cycles	1	999 or Unlimited	Unlimited
Temperature Period	2 min	23:59:59	2 min
Perfusion Period	2 min	2 hrs	60 min
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 min	2 min
Alarm Upper Bound Suspend Time	1 min	10 min	10 min
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 min	2 min
Alarm Lower Bound Suspend Time	1 min	10 min	10 min
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

Options Menu 3

Set Date/Time: Use this option to set the date and time for the monitor.

PROBE PLACEMENT IN THE O.R.

Proper probe insertion requires consideration of the following:

- The probe measures focal perfusion in a volume of approximately 0.27ml. This focal measurement, in absolute units (ml/100mg/min), represents the cerebral blood flow delivered by the supplying vasculature to that territory.
- Placement should be in the brain white matter, and in the tissue or vascular territory of interest.
- The probe uses a thermal technique for quantification of perfusion.
- The measurement may be affected by rapid changes in tissue temperature (irrigation, rapid infusion of fluids, etc.).
- Motion of the probe will cause artifact and possibly recalibration if severe enough.
- The probe should be properly fixed to the bolt or sutured to the scalp.

Section 1: Intra-operative indications and suggested site for Probe insertion

Aneurysm Repair Surgery

According to the published article "Continuous monitoring of regional cerebral blood flow during temporary arterial occlusion in aneurysm surgery", by Thome, Vajkoczy, Horn et al (J. Neurosurg./ Volume 95/September, 2001), the implantation site of the bolt was chosen according to the vascular territory of interest parasagitally, either 2 cm lateral to the midline for aneurysms of ACD or 6 cm lateral to the midline for aneurysms of the MCA or ICA.

EC/IC Bypass Surgery

The probe should be inserted in the vascular territory that is most affected by the bypass to assess the adequacy of flow.

Section 2: Insertion through a burr hole adjacent to the craniotomy

Create Burr Hole

a. At the site for probe insertion, use a scalpel with a #15 blade to make a linear incision 2-3 cm long and carry it to the bone.
b. Use a self-retaining retractor to provide bone exposure.
c. Using a 2.7 mm drill bit, drill through the outer and inner tables of the skull taking care to minimize any potential for damage to the dura or the underlying structures.
d. If necessary, use a sterile flush to enhance visibility.
e. Make an incision in the dura using a #11 blade or bipolar, securing hemostasis as necessary.

Create Tunnel

a. Use a 14-gauge Touhy needle to tunnel the probe under the scalp by inserting the needle from the site of the burr hole, under the scalp to exit at the desired location approximately 6 cm from the burr hole.

b. NOTE: The needle cannot slide over the blue connector at the end of the probe. Therefore, it is necessary to feed the needle from inside the incision site out towards the exit site.

c. Remove any trocar that may be in the needle lumen.

d. Pass the probe tip through the lumen in the distal end of the Touhy needle and advance the probe tip toward the burr hole.

e. While holding the probe in place, slide the Tuohy needle out from under the scalp and discard.

Insert Probe

a. Using the blue centimeter markings on the probe shaft as a guide, insert the probe through the burr hole to a depth of 25 mm below the level of the dura into the white matter.

b. Suture scalp over burr hole as necessary.

c. Loop 4-5 cm of probe slack in a circle around the site where the probe exits from under the scalp and secure the probe shaft with three sutures spaced evenly apart.

d. Connect the probe to the BOWMAN PERFUSION MONITOR. Confirm adequate placement of the probe by checking the K value. Normal range for K value in brain white matter is between 4.9 and 5.8.

Figure 1 below is a graphic depiction of the placement of the probe though a burr hole adjacent to the craniotomy. In the event that post-operative monitoring is desired, it is best to forward tunnel the probe.

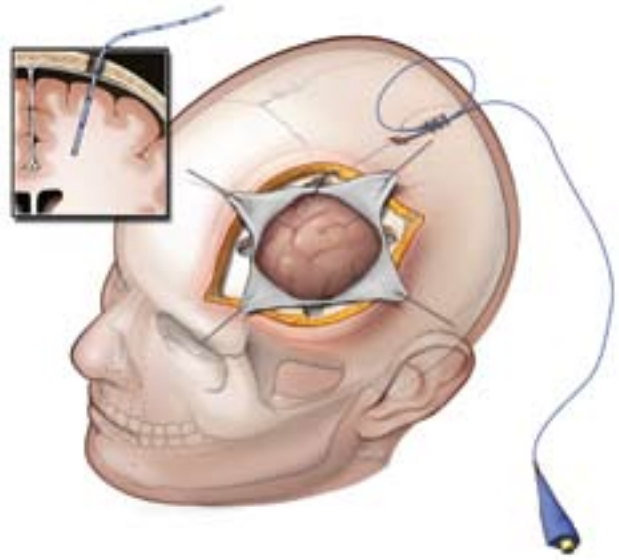


Figure 1: Drawing of the QFLOW 500 Probe placed via a burr hole and tunneled adjacent to a craniotomy.

Section 3: Insertion Through the Craniotomy

Based on neurosurgeon preference, the intra-operative placement of the probe through a burr hole may not be desirable. In this case, the probe may still be placed through an open craniotomy. However, extra care must be taken to position the probe at the edge of the craniotomy away from the main surgery site to minimize artifact from retraction, irrigation and mechanical interference.

The figure below shows a rendition of the placement of the probe though the craniotomy. In the event that post-operative monitoring is desired, it is best to forward tunnel the probe. Also make sure to insert the probe through the site of one of the burr holes that was used to create the craniotomy. In this way, when the bone flap is put back in place, there will be an opening for the probe shaft to exit. The procedural steps for the probe placement through a craniotomy with tunneling are as follows:

Create Tunnel

Use a 14-gauge Touhy needle to tunnel the probe under the scalp by inserting the needle from the edge of the craniotomy, under the scalp to exit at the desired location approximately 6 cm away. ***NOTE: The needle cannot slide over the blue connector at the end of the probe. Therefore, it is necessary to feed the needle from inside the incision site out towards the exit site.***

a. Remove any trocar that may be in the needle lumen.
b. Pass the probe tip through the lumen in the distal end of the Tuohy needle and advance the probe tip toward the craniotomy.
c. While holding the probe in place, slide the Tuohy needle out from under the scalp and discard.

Insert Probe

d. Using the blue centimeter markings on the probe shaft as a guide, insert the probe to a depth of 25 mm below the level of the dura into the white matter.
e. Loop 4-5 cm of probe slack in a circle around the site where the probe exits from under the scalp and secure the probe shaft with three sutures spaced evenly apart.
f. Connect the probe to the BOWMAN PERFUSION MONITOR via the umbilical cord. Once the probe is properly connected to the BOWMAN PERFUSION MONITOR, power on the monitor. The monitor will automatically calibrate the implanted probe through checking for temperature stabilization and K value. Confirm adequate placement of the probe by checking the K value. Normal range for K value in brain white matter is between 4.9 and 5.8. ***NOTE: Do not break the sterile environment without confirming the proper K Value. If K value is not within the normal range, please check the Troubleshooting Guide section of this manual.***

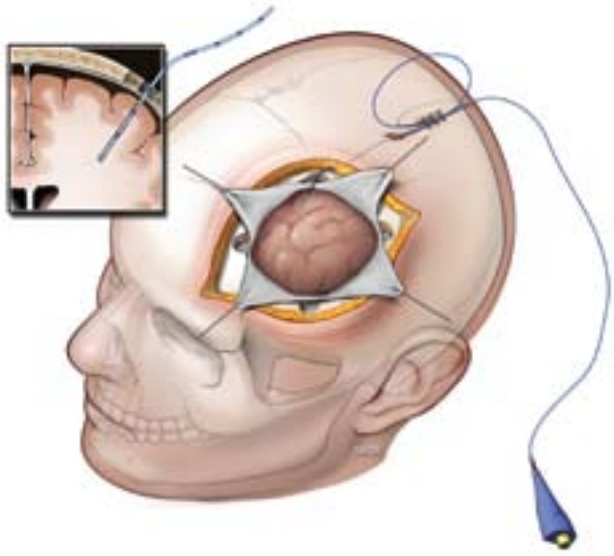


Figure 2: The placement of the QFLOW 500 Probe placed via craniotomy and tunneled.

Section 4: Confirm K Value

Confirm adequate placement of the probe by checking the K Value. Connect the probe to the umbilical cord and Monitor and the measurement will automatically begin. After about 3 minutes, the Monitor will go into calibration and display a K Value. Normal range for K value in brain white matter is between 4.9 and 5.8. If the K value is out of range, an error message will appear on top of the display screen. The monitor will not deliver cerebral blood flow measurements.

a. If you have a high K Value (>5.8), move the probe 1 mm by either advancing or retract it.
b. The monitor will automatically try to recalibrate. However, if Temperature Stabilization Phase is taking too long, press "Measure Perfusion" to request an earlier calibration.
c. After confirming placement with a good K Value (4.9 <= K <= 5.8), allow the measurement to continue and fix the probe.

Section 5: Potential Sources of Interference

During intra-operative procedures, the measurement of perfusion may be affected by:

- Thermal instability from tissue cooling via the open craniotomy;
- Thermal instability from fluid irrigation;
- Probe motion from tissue retraction;
- Reduced perfusion from tissue compression via retraction;
- Probe motion from external interference;
- Electrocautery, especially unipolar (Bovie).

Based on these considerations, it is recommended that the probe be inserted though a burr hole just adjacent to the craniotomy to reduce thermal and mechanical interference to the probe.

Irrigation

Tissue irrigation close to the entry location of the probe may cause thermal instability in the reading and prevent an accurate measurement of blood flow and/or induce a longer stabilization time.

Retraction

Retraction can affect the measurement by 1) inducing the cerebral tissue to move relative to the probe, thus causing a motion artifact; and 2) by decreasing the blood flow by compression of the tissue behind the retractor. Therefore it is suggested that the probe be placed away from the site of retraction.

Electrocautery

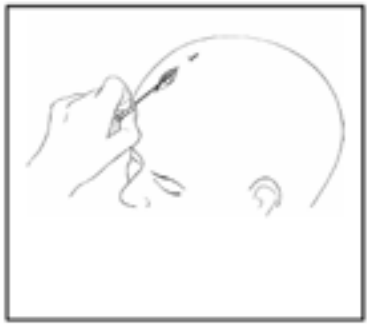
Electrocautery, both unipolar (Bovie) and bipolar, can cause electrical interference with the Monitor. This interference can introduce noise into the perfusion data and possibly cause the monitor to automatically recalibrate. The operation of the device should return to normal, as soon as the electrocautery ceases.

Probe movement

Probe movement may be caused by retraction or by external interference with the probe shaft. Linear movement of the probe along the insertion track causes a characteristic artifactual spike in the perfusion measurement. This is recognized by the Monitor which then produces an error message. If the motion is significant enough, the monitor will automatically recalibrate.

PROBE PLACEMENT IN THE ICU

Section 1: Probe Insertion and Fixation Protocol with Tunneling



Create burr hole

a. Shave and prep the determined site and exit area (for tunneling) using aseptic technique.
b. Drape the shaved, prepped area.
c. Mark the incision site with a marking pen and ruler.
   - Consider injecting the area with a local anesthetic.
   - Use the #15 blade/scalpel to make a linear incision 2 – 3 cm long and carried to the bone.
d. Use the self-retaining retractor to expose bone
e. Prepare drill according to manufacture's instruction.
f. Using a 2.7 mm twist drill, drill through the outer and inner tables of the skull taking care to prevent any damage to the dura or underlying structures.
g. If necessary, use sterile saline to flush the site for better visibility.
h. Make an incision in the dura using a # 11 blade/scalpel or bipolar, securing hemostasis as necessary. Visually confirm that there are no obstructions to probe insertion.

Create tunnel

a. Use a 14 gauge Tuohy needle to tunnel the probe under the scalp by inserting the needle into incision site and moving under the scalp to exit 6 cm from scalp incision.
b. NOTE: The needle can not slide over the blue connector at the end of the probe. Therefore, it is necessary to feed the needle from inside the incision site out towards the exit site.
c. Remove and discard any trocar.
d. Pass the Probe tip into distal end of needle (exit site) and out proximal end (incision site); slide the needle from the Probe and discard.

Insert probe

a. Using the centimeter markings on the Probe as a guide, insert the Probe to a depth of 25 mm subdurally into the target (white matter) tissue.
b. Before breaking the sterile field, confirm adequate placement of the probe by checking the K Value (see Section 5.2.2.3).
c. After confirming placement with a good K Value, allow measurement to continue and suture dura and scalp as necessary.

d. Clean and dry the Probe site.
e. If desired, attach the HEMEDEX Fixation Disk.
   - If desired, attach the probe shaft to the scalp using the HEMEDEX Fixation Disk.
   - Position the disk onto the Probe via the slit (as described in the Disk instructions for use).
   - Slide the Disk onto the scalp and secure Disk in place with sutures.
   - Close the clamp completely, ensuring that the Probe is still adequately positioned (25 mm deep, subdurally).
   - If necessary, apply adhesive dressing.

f. Loop 4-5 cm of probe slack in a circle around the probe exit site and secure shaft to scalp with three (3) sutures spaced evenly apart.
g. Apply appropriate dressing to burr hole and probe exit site.
h. If appropriate, tape the blue probe connector to the patient's neck or shoulder to minimize movement.
i. Be sure to position the umbilical cord in such a fashion to prevent accidents and minimize movement.

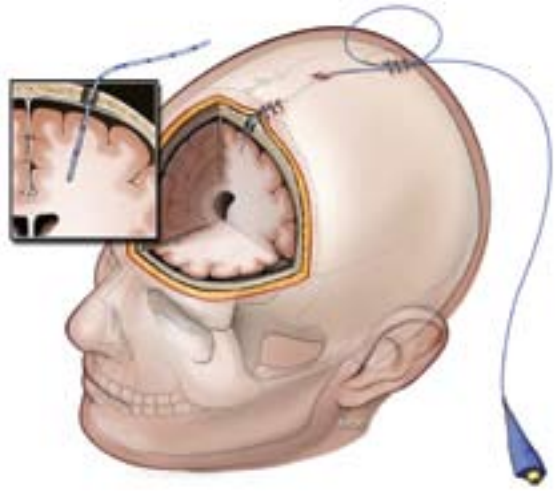


Figure 4: Insertion of the QFLOW 500 Perfusion Probe via a burr hole and tunneled

Section 2: Probe Insertion and Fixation Protocol with Bolt

Create burr hole

a. Shave, prep, and drape the insertion site using aseptic technique.
b. Mark the insertion site with a marking pen and ruler.
c. Consider injecting the area with a local anesthetic.
d. Use the #15 blade/scalpel to make a linear incision 2 – 3 cm long and carried to the bone.
e. Use the self-retaining retractor to provide bone exposure.
f. Prepare drill according to manufacturer's instruction.
g. Drill through the outer and inner tables of the skull taking care to minimize any potential for damage to the dura or underlying structures.
h. If necessary, use sterile saline to flush the site for better visibility.

i. Make a cruciate incision, in the dura using a # 11 blade/scalpel or bipolar, securing hemostasis as necessary. If the opening in the dura is not sufficient, the probe will not properly track into the cerebral tissue.
j. Visually confirm that there are no obstructions to probe insertion on the tissue surface.

Insert the cranial bolt
Follow manufacturer's instructions. Be sure to attach the compression cap for the QFLOW 500 Probe.

Insert probe
a. Remove QFLOW 500 Probe from package. Be sure to mark the probe for adequate depth insertion.
b. Feed the Probe through the corresponding port of the bolt, being careful not to bend the rigid tip of the Probe.
c. Using the centimeter markings on the Probe, glide the Probe to a depth of 25 mm subdurally into the target (white matter) tissue. Make sure to account for any space left between the end of the bolt and the dura.
d. Before breaking the sterile field, confirm adequate placement of the probe by checking the K Value. See Section 5.2.2.3 for instructions.
e. Secure the bolt locking mechanism as described by bolt manufacturer.

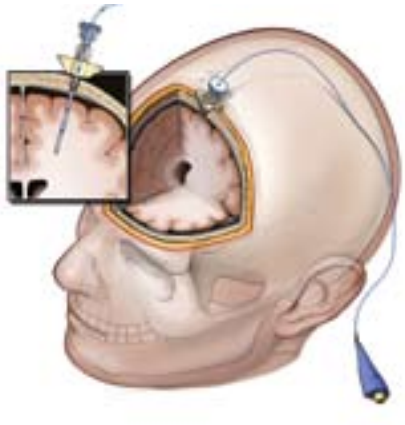


Figure 5: Drawing of the QFLOW 500 Perfusion Probe fixed with a cranial bolt

Section 3: Confirm K Value

Before breaking the sterile field, confirm adequate placement of the probe by checking the K Value. The K value for white matter should be 4.9 to 5.8 mW/cm-C. Connect the probe to the umbilical cord and Monitor and the measurement will automatically start. After a few minutes, the Monitor will go into calibration and display a K Value. If the probe is not in a good location you will receive an error message on the top of the display screen. If you have a high K Value (>5.8):

- Move the probe 1 mm by either pulling it back or advancing it.
- The monitor will automatically try to recalibrate. However, if Temperature Stabilization Phase is taking too long, press "Measure Perfusion" to request calibration earlier.
- After confirming placement with a good K Value, allow the measurement to continue and fix the probe to the bolt or the dressing; cover with tape.

- If appropriate, tape the blue probe connector to the patient's neck or shoulder to minimize movement.
- Position the umbilical cord in such a fashion as to prevent dislodgment and minimize movement.

Section 4: Potential Sources of Interference

Fever

The BOWMAN PERFUSION MONITOR automatically suspends measuring perfusion when the tissue temperature reaches 39.5 °C or above. Perfusion measurement is automatically resumed when the tissue temperature drops below this level. The device is designed to operate in this way because the FDA mandates that tissue must not be heated above 41 °C. The probe will not heat the tissue when patient's baseline temperature reaches 39.5 °C, and the monitor will automatically stop measurement.

Rapidly changing temperature

The probe does contain a reference temperature sensor that permits the monitor to compensate the signal for changes in patient temperature. During calibration period, the probe will start measurement when the tissue temperature environment has been stable for a period of 2 minutes. If temperature stable environment is not detected, the monitor will continue to recalibrate and not able to deliver cerebral blood flow measurement.

Probe movement

Probe motion causes an artifact in the measurement with an apparent and characteristic spike upward in perfusion measurement. This is caused by the fact that the distal sensor must rapidly re-establish the thermal field in the tissue at the site where the sensor has been translated to. If the perfusion measurement does not return to the pre-motion level, the monitor will automatically recalibrate.

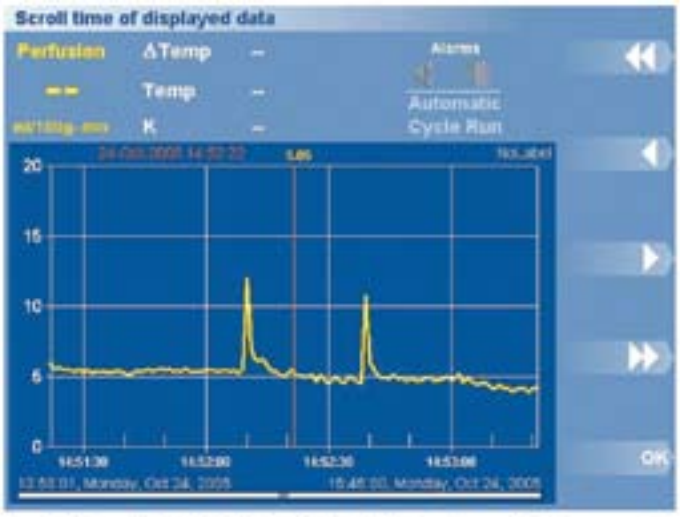


Figure 7: Motion artifacts (at 14:52:10 and 14:52:38) which temporarily cause the CBF measurement to artifactually increase. For small motions, the CBF value returns to its level prior to motion. In the event that the CBF does not return to its pre-motion level, the monitor will automatically recalibrate.

FREQUENTLY ASKED QUESTIONS (FAQs)

1. How do you insert the Monitor's QFLOW 500 Probe?

a. Similar to other cerebral probes, e.g. intraparenchymal ICP probes, which are inserted via a burr hole.
b. The probes can also be tunneled under the scalp.
c. For full details see Section 5.1 and 5.2.

2. Where do you implant the probe?

a. The probe should be placed in the vascular territory at risk for ischemia, or in the area of interest for measuring CBF.
b. The probe tip should be completely surrounded by white matter.

3. What risks are there in implanting the Probe?

a. Same as implanting other minimally invasive, intraparenchymal probes.
b. Contraindications are the same as catheter insertion into tissue.
c. Histological studies reveal only minimal tissue destruction, and no bleeding around insertion track.
d. There have been no signs of inflammation, edema, or thermal damage (tissue temperature is never heated above 41 ˚C (105.8 ˚F), as mandated by the FDA.

4. At what depth is the probe tip placed?

a. The probe tip should be placed approximately 20-25 mm below the dura in the white matter of the brain.

5. How do I know I have the probe tip in a good location?

a. Good placement is determined by the K Value. Normal range for K value in the brain white matter is between 4.9 and 5.8. If your K Value is too high, the probe tip may be next to a thermally significant vessel which flow is confounding the measurement or the brain may be periodically moving against the probe from the cardiac cycle.
b. If the K Value is not in the suggested range, the Monitor will alert the user. It is for this reason you should check your K Value prior to securing the probe in place or breaking sterile field. To obtain a good K Value, move the probe by either advancing it or pulling it back 1 mm.
c. Another way to ensure proper depth placement is with a CT scan. The probe is radio-opaque and, although you will not be able to see the depth markings, you will be able to see the probe tip.

6. What are the technique sensitivities of the QFLOW 500 Probe?

a. The probe will calibrate itself by measuring tissue temperature and conductivity (K) prior to measuring perfusion. This process typically lasts a few minutes (approximately 4 minutes depending on the level of perfusion).
b. If the probe is moved, it will automatically recalibrate itself.
c. Placing the probe near a thermally significant vessel will give a high K Value.
d. During recalibration you cannot obtain perfusion measurements. Recalibration will be performed after 30 minutes (unless the default settings are changed), and will be done automatically.

e. The Monitor is sensitive to electrical noise such as that produced by electrocautery equipment. If the interference is great enough the Monitor will need to recalibrate.
f. The tissue being measured must be thermally stable; therefore, external influences such as irrigation may cause a thermally unstable environment and inhibit perfusion measurement.

7. Does the Probe need to be calibrated or zeroed?

a. No, the probe does not need to be zeroed or calibrated like other catheters. However, the monitor does automatically go through a calibration phase to ensure accuracy of the measurement. The user does not need to do anything to calibrate the probe.

8. How long does Calibration take?

a. Calibration typically takes a few minutes depending on blood flow; the higher the flow the quicker the calibration process and vice versa.

9. Is the probe sensitive to motion artifact?

a. Yes, the probe is sensitive to motion artifact. If the probe tip is moved significantly in relation to the tissue where it's implanted, the monitor will be forced into recalibration. However, if the motion is minor then the monitor will not be forced into recalibration but, you will see sharp spikes in on the monitor graph; these spikes can range from 0 – 250 ml/100g-min.
b. In the ICU environment it is less likely to experience motion artifact than in the OR setting. When using the probe intra-operatively there are challenging factors such as irrigation, retraction, and surgical manipulation. These factors may lead to probe displacement and, in turn, motion artifact.

10. What is the maximum time a Probe can be left in situ?

a. The probe is indicated for 10 days implantation. The BOWMAN PERFUSION MONITOR will automatically not record any data from a probe that is used longer than 20 days.

11. Are the probes reusable?

a. No, the QFLOW 500 Probe is a disposable, single-use item.

12. Is the Probe MRI compatible?

a. No, the QFLOW 500 Probe is not MRI compatible.
b. If the patient needs an MRI, it will be necessary to remove the probe.

13. How sensitive is the QFLOW 500 Probe?

a. 0.1 ml/100g-minute.

14. What is the operating temperature range of the probe?

a. The probe will be able to measure accurate cerebral blood flow with in temperature range of 20°C (68°F) to 39.5°C (103.1°F). When the tissue temperature is outside of this range, the probe will automatically stop measurement, and an error message will appear on the top of the display screen.

15. Can the Monitor accommodate more than one probe?

a. The monitor is a single channel device. If you want to simultaneously monitor more than one QFLOW 500 Probe you will need additional Monitors. Alternatively, 2 Probes could be intermittently measured with a single Monitor.

16. Can the BOWMAN PERFUSION MONITOR interface with other patient monitors?

a. The Monitor provides both analog and digital outputs which can be interfaced with other patient monitors and data acquisition systems by the user.
b. Digital data is streamed through a serial port and can be uploaded to a laptop.
c. The analog output can be connected to a Philips bedside monitor with an Open Link module. Contact your local Codman representative for assistance.

17. Does the Monitor have alarms?

a. Yes, the Monitor can be set to alarm if the perfusion reaches above or below a certain threshold for a user-defined time period (i.e., a quick "spike" above or below the alarm thresholds will not set off the alarm). The Alarms are not enabled by default; the user needs to enable the alarms and set the bounds.

18. How much data can be stored/retrieved?

a. The monitor can collect data at a rate of once a second and there is enough memory to store this data for 15 days.

19. Can you print a trend or just the numerical values?

a. You have the option to print the following 4 items:
   - Print perfusion, i.e., what you see on the monitor graph
   - Print perfusion and temperature (on the same strip)
   - Print a list of the K Values
   - Print the current Monitor settings

20. Can the data be smoothed?

a. No, at this point in time the data cannot be smoothed. However, the time range can be adjusted so that the data can be spread out over time, which allows for more detailed viewing at specific points in time.

21. Can the average or mean be displayed or printed?

a. No, the monitor gives perfusion measurements in real time only and, currently, does not have the capability to display a mean or average CBF measurement.
b. However, if you printout the data it is easier to see what the average value was for the last 30 minutes perfusion run.

22. What other limitations are present?

a. The Monitor will not heat tissue above 41 ˚C (105.8 ˚F); therefore, if a patient has a temperature around 39.5 ˚C (103.1 ˚F) the Monitor will not be able to measure cerebral blood flow. Once the patient's temperature is below this threshold, the Monitor will automatically start measuring again.

b. The measurement is focal in nature; specifically, the probe measures cerebral blood flow in the small, spherical volume of tissue surrounding the distal tip of the probe, a sphere of tissue about 4-5 mm in diameter, approximately equivalent to a volume of 0.27ml.

TROUBLESHOOTING GUIDE

Measurement Step	Possible Problems	Possible Causes	Possible Solutions
Insert Probe ▼ Start Measurement ▼			
Temperature Stabilization	Temperature not stable	Probe recently inserted	Wait 10 minutes
		Probe not deep enough	Verify probe is at proper depth (25 mm subdural)
	Thermal gradient too high	Probe not deep enough	Verify probe is at proper depth
		○ Probe is epidural	Confirm probe location with CT
		○ Probe is not in white matter	
	Patient temperature too high	Fever above 39.5 ℃	When patient temperature goes below 39.5℃, CBF measurement will automatically restart
Calibration	Low Km (<4.8)	Probe pulled out of tissue (K<1.5)	Verify probe is in tissue at proper depth (25 mm subdural)
		Probe is not in white matter	Confirm probe location with CT
	○ High Km (>5.8) ○ Data too noisy	Probe motion or electrocautery	Recalibrate
		○ Probe may be too deep ○ Probe may be in the ventricle ○ Probe may be sub/epidural	○ Verify probe tip is at proper depth (25 mm subdural) ○ Confirm probe location with CT
		Probe may be near a vessel	Move the probe about 1mm along the insertion track

Measurement Step	Possible Problems	Possible Causes	Possible Solutions
▼			
CBF measurement		Probe may be in gray matter	○ Verify probe is at proper depth ○ Confirm probe location with CT
	CBF > 50 ml/min-100g		
	CBF < 10 ml/min-100 g	Probe may be in infarcted tissue	
	CBF varies ±10 ml/min-100g with respiration rate and/or heart rate	○ Probe may be too deep ○ Probe may be in the ventricle ○ Probe may be epidural	○ Verify probe is at proper depth (25 mm subdural) ○ Confirm probe location with CT
	CBF varies ±10 ml/min-100g over minute(s)	Slow variations may be due to reduced autoregulation	Compare CBF variations with ICP, CPP and MAP variations
	CBF drift	Temperature is rapidly changing	Manually recalibrate
▼			
Recalibration	Motion artifact	Probe has moved	Make sure probe is secured and at correct depth
	Temperature drift	Temperature is rapidly changing	Monitor automatically recalibrates

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