

HEMEDEX, INC.

# **Addendum to Bowman Perfusion Monitor Model 500 User Manual**

for use with software version 3.0.6

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Manufactured by:



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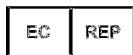
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## **User Manual Update New in 3.0.6**

### **New Features**

#### **Space Remaining Warning**

Space Remaining Warning is an indication to the user of how much storage space is available on the hard disk. If there is not enough storage space on the hard disk, one of two things will happen: One: if the file maximum size is reached: the monitor will over write, Two: if the disk space maximum is reached: the monitor will continue to monitor, but will have no place to store the data. Before the probe is inserted, a message will display on the monitor underneath the graph indicating, "storage remaining about xx.x days". This information is also available on the view settings screen.

#### **Time on Screen**

Hemedex recommends that users properly set the monitor time. The monitor time is displayed on the lower right hand corner of the screen for easy recognition and ease of notification.

Note: so as not to interfere with data collection, the monitor will not reset the time for daylight savings time. This must be changed by the user.

#### **Probe Placement Assistant (PPA)**

The Probe Placement Assistant is a feature to assure optimal placement of the perfusion probe for the most accurate quantification of tissue perfusion. The output of the PPA is a number which ranges from 0.0 to 10 and indicates the relative level of perfusion artifact induced by brain pulsatility. A value of 0.0 indicates ideal measurement conditions. A value above 2 but less than 5 indicates a less than ideal placement, Hemedex suggests that the probe be repositioned. A value greater than 5 indicates that the level of potential artifact in the measurement is unacceptable, the measurement will be terminated and the user instructed to reposition the probe.

In addition to the numeric output, the PPA provides feedback by presenting the number on green (0.0 to 2.0), yellow (2.1 to 4.9) or red (5 to 10) background behind the numeric value. When the placement is good, the background is green. When the placement is acceptable the background is yellow. Repositioning the probe may improve placement to green. For unacceptable placements, the background is red.

#### **Grayout**

The grayout flashing number gives the user an indication of the perfusion level. The measurement of perfusion depends upon a fully developed thermal field. The grayout value is the value before this field is fully developed. It is presented as a flashing number and is not graphed on the screen. After the "grayout" period, once the thermal field is fully developed the perfusion number will stop blinking and remain solid.

#### **Perfusion Change Verifier (PCV)**

The Perfusion Change Verifier is a user selectable feature designed to provide greater data integrity. This feature will automatically recalibrate if the perfusion value increases by 7.5 ml/100g-min or decreases by 5 ml/100g-min within one perfusion measurement cycle. This recalibration is to verify that the perfusion change is either real or induced by a change in tissue thermal conditions, primarily the tissue temperature gradient between the two sensors. When the PCV feature is enabled, recalibration is automatic. The user may enable/disable this feature by navigating to the "Overview" Menu. (From the main menu, press Options and then Overview.) The user will want to disable this function when large changes in perfusion are expected such as during challenges. "PCV" just after the "Continuous Mode" label near the top of the screen indicates that the feature is enabled. The threshold level of perfusion for automatic recalibration may be increased or decreased from the default level by the user.

#### **Trend Mode**

In Trend Mode, the monitor is configured to provide "snapshots" of averaged perfusion, 2 minutes in length, approximately every 15 minutes. Trend Mode forces frequent recalibration and minimizes the effects of a changing thermal gradient during the measurement. It presents the user with maximum frequency of independent perfusion measurements.

The factory default setting for Trend Mode is "off." The user may enable this function by navigate to the "Overview" Menu. (From the main menu, press Options and then Overview.)

## Overview Menu

**Trend Mode = On/Off**

**Perfusion Change Verifier = On/Off**

### Show PPA Details

The background data used for the Probe Placement Assistant is available on this screen for troubleshooting purposes. Please contact Hemedex for assistance.

### View Settings

This screen allows the user to view the basic monitor information (date, file version, probe ID, start time, temperature and delta temperature criteria.) In addition, any user changeable setting that has been changed from the default will be listed.

## Research Settings

Research settings are designed with research in mind.

Before changing any of these settings, please read the User Manual to be sure that the change is desired. If set improperly, these setting changes can limit the collection of data. Consult with Hemedex before proceeding with these settings.

### Set Temperature Stabilization Period = 2 minutes to 2 hours (default is 2 minutes)

The selected temperature stabilization period is the minimum amount of time the user requests to wait for temperature stabilization. The monitor will extend the temperature measurement phase as necessary to reestablish a new thermal field.

### Storage Frequency = 1 Hz or 10 Hz

As an option for research applications, data may be stored and streamed at 10 Hz as opposed to the default value of 1 Hz. Although in 1 Hz mode, thermal measurements are made at 10 Hz and perfusion is calculated at this rate, the screen is updated only once per second and median perfusion data is stored to the data file at this 1 Hz rate. If the option is engaged to store data at 10 Hz, the data file will be ten times larger and, therefore, the storage space will be limited to 1.5 days instead of 15.

The factory default setting is for 1 Hz storage. Note that the data storage rate cannot be changed during a measurement. If data has been stored at one rate for a particular probe, this file must be deleted from the monitor in order to change the data collection rate for that particular probe.

### Cycle Limit = 1-999 or unlimited

The Cycle Limit sets the number of consecutive, independent perfusion measurement cycles. The default value is UNLIMITED. Once changed to a number of cycles (1-999), the monitor will collect data for the selected number of cycles and then stop monitoring. The monitor will not begin again until the user presses the start button.

### Perfusion Change Verifier Limits

Upper Limit = 1 – 99 ml/100g-min

Lower Limit = automatically set to 2/3 of upper limit.

The Perfusion Change Verifier Limits control the amount of perfusion change that will trigger recalibration.

## **Advanced Settings**

These settings should be changed only as instructed by Hemedex.

### **K Max Value**

This value sets the upper limit for the acceptable range of thermal conductivity (K). If the K measurement is above this limit, the monitor will present an error message and automatically recalibrate. The default setting for this value is 6.5 mW/cm-C.

### **PPA Cutoff**

This cutoff controls the upper limit of PPA value that will trigger recalibration. The default value is 5.0.

### **Set Temperature Slope**

This value controls the maximum allowable magnitude of the slope of temperature vs. time for the temperature to be considered stable enough for perfusion measurement. The default value is 0.040 °C/min.

### **Set Delta Temp Slope**

This value controls the maximum allowable magnitude of the slope of delta temperature vs. time for the temperature to be considered stable enough for perfusion measurement. The default value is 0.020 °C/min.

## **Real Time verses Stored Data Indication**

When collecting Real Time Data the background of the screen is blue. When viewing recalled or previously stored data, the background becomes lighter blue, indicating that the user is not looking at real time, current data, but rather older data in the file. Move the cursor forward to return to real time data collection screen.