

# **User Manual**

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#### **Quick Description**

The FloChec<sup>TM</sup> System provides graphical information about pulsatile blood flow in an extremity. This enables assessment of effects on blood flow, such as partial or total occlusion on vasculature proximal to the extremity being monitored.

FloChec uses an infrared sensor to collect light measurements of the pulsed blood flow from fingers and toes, and then employs an algorithm to convert these measurements into a digital signal which is displayed on a workstation. The display shows changes in the pulsed blood flow in the extremity during an adjustable time period, and since the information is displayed while the patient is being monitored, effects on pulsed blood flow, such as the Valsalva maneuver, changes in proximal occlusion of a blood vessel (including external compression), or other vascular flow-affecting events may be observed in real time. This helps measure the effect on distal blood flow resulting from such events.

Once the information is collected and the test is complete, the results display on a PDF file that can be stored or printed out.

| Included Devices<br>Reusable Sensor  | Netbook PC  | Printer          |
|--|---|------------------|
| -  |   |                  |
| Infrared sensor used to collect<br>light measurements of the<br>blood flow from fingers and<br>toes. | Portable, wireless PC<br>specially configured with<br>the FloChec Application | Wireless printer |

### **Caution Statement**

Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.

#### Intended Use

This system is intended to measure arterial blood in the extremities.

#### **Indications for Use**

To monitor relative blood flow changes distal to the occlusion of a brachial, radial, ulnar, or femoral artery.

From the physician history and clinical findings, the person has pain, claudication, or changes in blood flow to an extremity.

#### **Contraindications for Use**

The device cannot be used on persons with no fingers or toes, or any person under 18 years of age.

# **Installation Instructions**

The application can either be installed on a workstation or run from the Software Drive. Running the application from the Software Drive means that you can run the application on any workstation (that meets the specified requirements) by simply inserting the Software Drive into a USB port.

#### Running the Application from the Software Drive

(also listed on the Quick Start Guide)

- **1.** Insert the Software Drive into a USB port.
- **2.** Two autoplay windows will appear: the U3 System window and the FloChec App window.
  - If the autoplay windows do not appear:
    - Select Start/Windows icon> Computer in MS Windows. This will open a window that displays any removable devices attached to the workstation.
    - Open the option labels "U3 System."
    - Select Launch U3.
    - Skip to Step 5.
- **3.** Select "Run U3 Launchpad" from the U3 System window.
- **4.** The program will initialize and then add a U3 icon to the bottom right hand corner of the MS Windows taskbar.
- **5.** Click on the U3 icon to open the U3 Launchpad.

- If the U3 icon does not appear on the MS Windows taskbar, select "Open folder to view files" on the FloChec App window, then select Launch U3 from the new window that opens. This will open the U3 Launchpad.
- 6. Select Install Drivers if this is the first time the application has been run on the workstation. This will install the drivers on the workstation.
  - If the drivers are not installed, you will receive an error when you try to Start a measurement
- **7.** Select FloChec Application on the U3 Launchpad menu. The FloChec application will begin.

# Installing the Application on a Workstation

(also listed on the Quick Start Guide)

- **1.** Insert the Software Drive into a USB port.
- **2.** Two autoplay windows will appear: the FloChec application window and the U3 System window.
- **3.** Select "Open folder to view files" from the FloChec App window. This will open a new window.
- **4.** Select FloChec Installation. This will begin the Setup Wizard.
- **5.** Proceed through the steps of the Setup Wizard, entering any required information.
  - Agree to the license agreement.
  - Select the path where you would like the application installed, or leave it set to the default location.
  - Select the **Everyone** toggle if all users on the workstation should have access to the FloChec application.
  - Proceed to the final step.
- **6.** A window will appear, confirming that the FloChec application is allowed to write files to your workstation. Click Accept to proceed.
- **7.** Another window will appear, confirming that you would like to install the FloChec drivers. Click the Install Drivers button.
- **8.** Once the Installation Wizard is successfully complete and the drivers have been installed, a FloChec icon will be added to the desktop.
- **9.** Click on the FloChec icon to launch the application.

# Instructions for Use

# Setting up the Application

Once the application is installed, follow the steps in this section to configure the software.

- 1. Setup the basic features of the application.
  - Open the application by clicking on the FloChec icon ☑ on the MS Windows desktop.

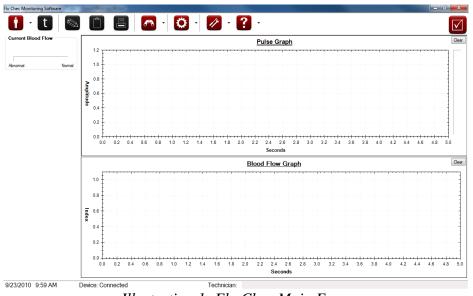


Illustration 1: Flo Chec Main Form

• Open the Options Form ( Blood Flow window). Settings >Options from the main FloChec

• Open the General tab.

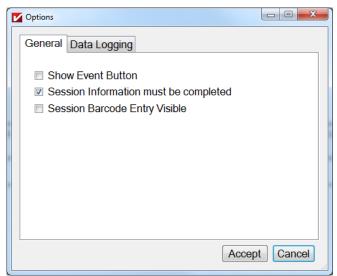


Illustration 2: Options Form (General Settings)

- The functionality of the **Show Event button** toggle is covered in the Advanced Users section of the user manual.
  - Leave this toggle unchecked or see the user manual section titled Using the Event and Data Logging features.
- Check the **Session Information must be completed** toggle if all patient and technician information must be entered before a test can be performed.
  - When this toggle is checked, the patient's First and Last Name or ID, Sex, and Birth Date, and a technician name must be entered into the Session Form before measurements can be taken.
  - When this toggle is not checked, no patient or technician information is required before a test is performed.
- Check the **Session Barcode Entry Visible** toggle if you would like the option of entering a barcode when entering patient information.
  - When this toggle is checked, a **Barcode** field will be added to the Session Form (Open Session button from the main FloChec Blood Flow window). The technician can tab to the **Barcode** field, scan a barcode, and the barcode will be stored in the field.
- The Data Logging tab is covered in the Advanced Users section of the user manual.
  - For information on Data Logging, see the section titled Using the Event and Data Logging features.
- Click the **Accept** button when complete to save the selections.
  - If you click the **Cancel** button, no changes to the Directory Settings Form will be saved.
- 2. Enter your company information into the application.
  - The Company Information Form ( O Settings> Company) is used to enter

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your company information into the application. Depending on how you setup the report that displays the test results, some or all of this information will display on that report.

• Setting up the report will covered during the user manual section titled Performing a test.

| Company Information Form     |             |       |        |        |
|------------------------------|-------------|-------|--------|--------|
| Company Name                 | -           |       |        |        |
| Semler Scientific, Inc.      |             |       |        |        |
| Street Address               |             |       |        |        |
| 2330 NW Everett St.          |             |       |        |        |
| City                         | State       | Zip   |        |        |
| Portland                     | OR 👻        | 97210 |        |        |
| Country                      |             |       |        |        |
| United States                |             |       |        |        |
| Phone Number                 | Fax Number  |       |        |        |
| 503-297-8608                 | 503-297-010 | 7     |        |        |
| E-Mail Address               |             |       |        |        |
| support@SemlerScientific.com |             |       |        |        |
| Website Address              |             |       |        |        |
| www.SemlerScientific.com     |             |       | Accept | Cancel |

Illustration 3: Company Information Form

- Open the Company Information Form by selecting Settings and Company Information from the FloChec Blood Flow main application window.
- Enter your company information into the window.
- **3**. The basic setup is now complete. Proceed to the manual section titled Creating and Editing protocols to define how tests should be performed.

## **Creating and Editing Protocols**

Protocols are the parameters used when taking measurements during a test, such as which appendages should be measured and the length of time they should be recorded. Use the Protocol Edit Form to create new protocols or modify existing ones.

| Protocol Edit Form  |  |   |
|---|--|---|
| Current Protocols Digital ABI Continuous up down + - Edit | Settings<br>Protocol Name Digital ABI<br>Pulse Graph Length 6<br>Blood Flow Graph Length 6<br>Measurements<br>Left Hand Index<br>Left Foot Big<br>Right Foot Big<br>Right Foot Big | Measurement Attributes Part Hand Location Left Finger Index Duration 15 |
|   | + - Edit Cancel  | Accept Cancel   |
|   | Close  |   |

Illustration 4: Protocol Edit Form

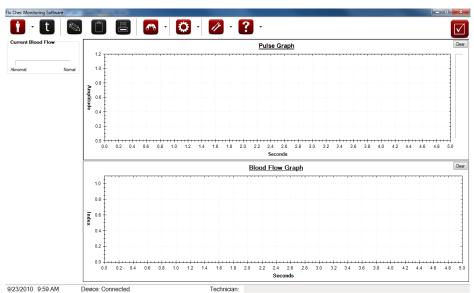
- Open the Protocol Edit Form by selecting <sup>(2)</sup> Settings, then Protocols from the main FloChec Blood Flow window.
  - This window can also be opened just before performing a test so that measurements can be customized for specific patients by clicking the Edit Protocol link on the New Test Form while opening a new session (Open Session button> Start Session button).
- The **Current Protocols** field displays all of the saved protocols.
  - Select a protocol and the fields in the window will populate with the settings of that protocol.
  - Click the **Edit** button if you would like to edit the selected protocol. This will enable the fields in the window.
  - Click the **Plus** button to create a new protocol, and then click the **Edit** button to modify the new protocol.
  - Click the **Minus** button to delete the selected protocol.
  - The **Up** and **Down** buttons are used to change the placement of the protocol on the drop down menu when a new test is being performed. For example, you might want the protocol that is performed the most often to be at the top of the list.
- The **Protocol Name** field is the name of the protocol.
  - This is the name that will display in the **Protocol to Use** drop down menu on the New Test Form window when a new test is being performed.

- $\circ$   $\,$  The name entered in this field should be something a technician can easily identify.
- The **Pulse Graph Length** field is used to select the length of the x-axis on the Pulse Graph that will display on the screen and on the reports generated during the test. This is a length of time in seconds.
  - For example, if you would like fifteen seconds of recorded measurements to display on the screen and on the report, select 15 from the drop down menu.
  - **HINT:** The selection in this field does not affect the duration of the measurement, it only affects the amount of information that will be displayed on the screen and on the report. For example, if the duration of the measurement is 30 seconds but the Pulse Graph Length is 15 seconds, the screen and report will only display the last fifteen seconds of measurements. If you would like the entire duration of the measurement to display on the graph, the **Duration** field and the **Pulse Graph Length** field should be set to the same value.
  - The value selected in this field is only the default value for the protocol. You can use the Graph Settings Form ( Settings) to modify the length of the Pulse Graph and Blood Flow Graph before the measurements are made to customize a test.
- The **Blood Flow Length** field determines the length of the x-axis of the Blood Flow graph and it functions the same way as the **Pulse Graph Length** field.
- The **Measurements** field is used to modify the measurements that will be made during the test. For example, if the left hand should be measured for 30 seconds during this protocol, this is the place to add that information. The function of this field is very similar to the **Current Protocols** field.
  - Click the **Plus** button to add a new measurement. This will add a record to the **Measurements** field and enable the fields in the Measurement Attributes section.
  - Highlight a record in the **Measurements** field and the fields in the **Measurements Attributes** section will populate with the values of the selected measurement.
  - Click the **Edit** button to enable the fields in the **Measurement Attributes** section and modify the values.
  - Highlight a record and click the **Minus** icon to delete the selected measurement.
- The fields in the **Measurement Attributes** section are used to modify the measurement selected in the **Measurements** field. These fields are only enabled when a measurement is highlighted and the **Edit** button is clicked.
  - The **Location** field is used to select the location of the measurement. For example, foot or hand.
  - $\circ$  The **Side** field is used to select which side, left or right, the measurement should be performed on.
  - The **Digit (Finger/Toe/etc)** field is used to select which digit the measurement should be performed on.

- The **Duration** field is used to select the duration of the measurement. For example, if the appendage should be measured for 30 seconds, select 30 from the drop down menu.
  - If the value selected in this field is greater than the value in the **Pulse Graph Length** and **Blood Flow Graph Length** fields, all of the measurement will not display on the screen and the reports when the protocol is performed. For example, if the duration is set to 30 seconds but the graph lengths are set to 15, only the last fifteen seconds of measurements will show on the screen and on the report when the measurement is complete.
  - Select Infinity from the drop down menu if the technician should be allowed to control the length of the measurement. When the measurement is being gathered, a timer will display on the screen showing how many seconds have elapsed. The technician will be able to stop the measurement once they feel enough data has been gathered.
- Click the Accept button in the Measurement Attributes section to save the entered data.
  - If you click the **Cancel** button, all changes to the Measurement Attribute fields will be lost.
- Once all of the measurements have been added to a protocol and all changes have been made, click the **Accept** button next to the **Measurements** field. This will save all of the information associated with the protocol selected in the **Current Protocols** field.
  - If you click the **Cancel** button, all changes made will be lost.
- Click the **Close** button once all protocols have been setup. This will close the Protocol Edit Form.

# Performing a Test

Once the software has been installed and configured, and the protocols have been defined, you are ready to perform a test. Follow the steps below to take measurements and perform a test.



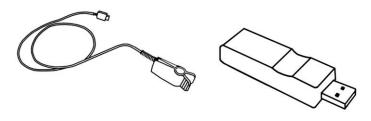
1. Open a New Patient and Start Test

Illustration 5: Flo Chec Main Form

- Plug the USB Signal Acquisition device into a USB drive on the workstation, and then plug the Reusable Sensor into the USB Signal Device. The status of the Device Connection is shown in several manners.
  - The Connection status is displayed in the status bar at the bottom of the screen.
  - A checkbox symbol is shown in the top right corner



- Indicates that the device is
  - Disconnected
- Indicates that the device is **Connected**
- $\circ~$  If you are still having trouble, see the troubleshooting section of the user manual.



#### Reusable Sensor and USB Signal Acquisition Device

Once the Reusable Sensor is connected, start a Session by Creating a new Patient by clicking the Patient Patient >New Patient on menu bar. This will open the Information Form, which is used to enter the patient information. The patient information entered into this window will display on all reports generated during this session.

| Patient Information Form |           |    |        |
|--------------------------|-----------|----|--------|
| First Name               | Last Name | ID |        |
| Sex                      |           |    |        |
| М -                      |           |    |        |
| Birth Date               |           |    |        |
| 9/23/2010                |           |    |        |
| Technician               |           |    |        |
|                          |           |    | Accept |
|                          |           |    | Cancel |

Illustration 6: Patient Information Form

- If the **Patient Information must be completed** toggle on the Option Settings window is checked, the fields in this window must be complete before proceeding to the next step.
  - Only the Full Name or ID must be entered not all three.
- Enter the Name or ID or both, and select a Sex from the drop down menu.
- The **Birth Date** field is a calendar field used to select the patient's birth date.
  - Enter a birth date using the arrow keys to move between month, date, and year, or click the Calendar icon to select a birth date using a graphical calendar.
  - HINT: When using the graphical calendar, click on the calendar heading to change what is displayed and quickly select data.
- The **Technician** field is used to enter the name of the technician performing the test.
  - This field is automatically filled with the last Technician used while the application is opened.

- The **Barcode** field is an optional field used to enter a barcode associated with the patient.
  - If there is a barcode scanner attached to the workstation, tab to the **Barcode** field and scan the barcode. The barcode will populate in the **Barcode** field.
  - This field will only display if the **Session Barcode Entry Visible** toggle is checked on the Options Settings window (Settings> Options> General).
- Click the **Accept** button when complete.
  - If all of the required information has not been entered, the Missing Information window will display. Click the OK button to return to the Session Form and then complete the information.
- If you click the **Cancel** button, all information entered into the window will be lost and the Patient Information Form window will close.

| New Test Form                                    |   |           |
|--|---|-----------|
| Protocol to Use<br>Digital ABIs<br>Edit Protocol | • | OK Cancel |

Illustration 7: New Test Form

# 2. Select a test to perform

- The New Test Form window is used to select which test to perform on the patient.
- Select a protocol in the **Protocol to Use** drop down menu to select a test.
- Click on the **Edit Protocol** link below the drop down menu if you would like to view the settings of the selected protocol or you would like to create a new protocol. This will open the Protocol Edit Form window.
  - This is the same window that opens when you select Settings> Protocols from the toolbar at the top of the FloChec Blood Flow window. For more information on the Protocol Edit Form, see the user manual section titled Creating and Editing Protocols.
- Click the OK button on the New Test Form once a protocol has been selected.
  - If you select Cancel, the New Test Form window will close and all patient information will be lost.

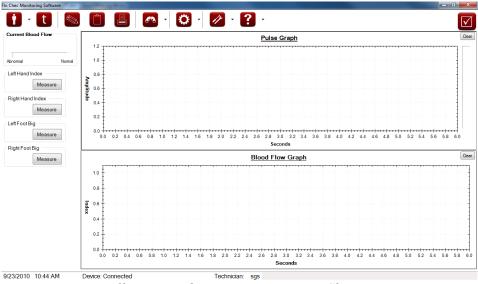


Illustration 8: Test Measurement Shown

- 3. Perform the selected test.
  - The toolbar on the left hand side of the FloChec Blood Flow window will vary depending on the test selected and how that test is setup. For example, if you are performing the standard Digital ABIs test, there will be an option to measure the left and right foot, and left and right hand.
    - For more information on defining how tests are performed, see the user manual section titled Creating and Editing Protocols.
  - Click on a **Measure** button to record the measurements of a selected appendage.
    - The left hand toolbar will change, displaying instructions on how to record the measurement.



Illustration 9: Measure Controls

• Place the Reusable Sensor on the selected appendage, making sure the correct side is facing up.



Illustration 10: Reusable Sensor

- Controls •
  - The **Event button** will display on the toolbar if you have enabled the Event feature (Settings> Options> General tab> Show Event Button toggle). This is an optional feature covered in the Advanced Users section of the user manual.
  - The Event button when pressed will store an event in the log file

|      | • The Start button is used to start the measurement.<br>Make sure the sensor is attached to correct appendage. |
|------|--|
| STOP | • The Stop button is used to stop a measurement when it is active.   |
| X    | • The Cancel button is used to Cancel the measurement if it is active or not.                                  |

- When a measurement is started, there may be a pause before the Pulse Graph ٠ shows data. The device is adjusting to the patient during this time.
- If the device cannot adjust for the patient, the measurement will be canceled after 40 seconds.

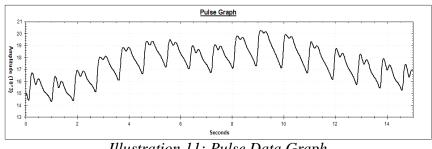
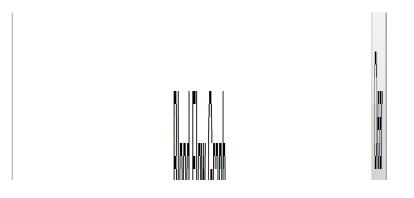


Illustration 11: Pulse Data Graph

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• There is an 8 second delay for the Blood Flow Data to be calculated.



- If either the Pulse Graph or Blood Flow Graph do not display on the FloChec Blood Flow window, select a check next to the add the selected graph to the main application window.
   If either the Pulse Graph or Blood Flow Graph do not display on the FloChec View> Graphs from the main menu and graph you would like displayed. This will
- The protocols of the selected test will determine how the measurements will end.
  - If the duration of the measurement is continuous, a **Stop** button will appear as well as a timer indicating the duration of the measurement being taken. Click the **Stop** button once the necessary data has been collected.
  - If the duration of the measurement is a specific length of time, for example 15 seconds, the toolbar will display a countdown until the data has been collected.
  - The duration of the measurement is defined when the protocol is created using the Protocol Edit Form (Settings> Protocols> **Duration** field). For more information on protocols options, see the user manual section titled Creating and Editing Protocols.
- The Blood Flow number listed for each measurement is an average of the Blood Flow during the measurement (calculations are performed once a second)
- Once data has been collected from one appendage, take measurements on the remaining appendages to complete the test.
- The **Current Blood Flow** field at the top of the left hand toolbar will always display the current blood flow of the last appendage measured.
  - For example, if you start with the left hand and then move to the right hand, the blood flow of the right hand will display once the measurement on the right hand is complete.
- The Notes button is used to add notes to the test which will display on report.
  - Click the **o**pen. **Notes** button and the Session Notes Form will
  - Enter any information that you would like to display on the report into the Session Notes Form.
  - Click the Save button when complete.

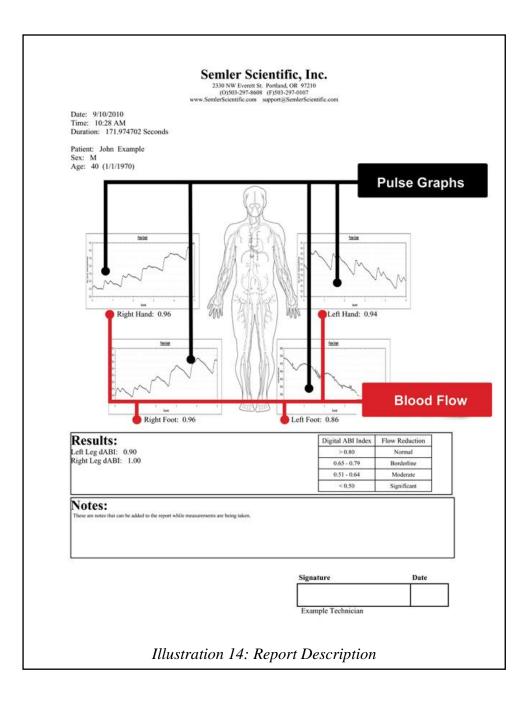
- **HINT**: The **Notes** field on the report is limited to seven lines of text, so any information added after the seventh line in this window will not display on the report.
- 4. View/Save/Print a report.
  - At any time during a session a report can be created, saved or printed with the available data.
    - The Show Report button opens a preview of the Report
    - The preview screen is shown in Illustration 13.

| I Size Full Page Best Fit                               | ⊖                                   | Print Create PDF  | Export PDF                              | Report Settings  |
|---|-------------------------------------|---|---|--|
|   | 2330 NW Everett S<br>(O)503-297-860 | entific, Inc.<br>Portand, OR 97200<br>6(7)503-397-0007<br>JerScientific.com |   |  |
| Date: 9/23/2010<br>Time: 2:08 P M                       |                                     |   |   |  |
| Patient: John Doe<br>ID: 12345<br>Sex: M<br>Age: 0      |                                     |   |   |  |
| Right Hand: 1.00  |                                     |   | Hand: 1.00                              |  |
| Right Foot: 1   |                                     | Left Foot: 0.95   |   |  |
| Results:<br>Left Lag dABI: 1.00<br>Right Lag dABI: 1.00 |                                     | 0   | > 0.75<br>5 - 0.74 Mild<br>25 - 0.49 Si | v Reduction<br>Normal<br>to Moderate<br>golficant<br>Seven |
| Notes:  |                                     |   |   |  |

Illustration 13: Report Preview Screen

- The user can change the Zoom Level using the options in the toolbar
  - Click the **Larger** or **Smaller** buttons to zoom in or zoom out of the report.
  - This will only affect how the report displays in the window, not how the report prints out.
- $\circ$  If the format of the report is good, then either print the report or save it.

- Click the **Print** button to print the report. This option will only work if there is a printer attached to the workstation and that printer is also installed in MS Windows.
  - You can view the printers installed on a workstation by opening the Devices and Printers folder in MS Windows (Windows icon on the Windows taskbar> Select **Devices and Printers**).
- The user can create a PDF document and open it in Adobe by clicking the Create Report Icon
- The user can Save a PDF document by clicking the Export Report Icon
- The user can modify what is displayed on the report by clicking the Report Settings Icon (see the Modifying Report Section below for more details).
- The report is a single page document that displays the collected data.



- Once the report has been printed or saved, then the test is complete and you can skip the last step of this user manual section.
  - If you would like to change the format of the report, then move to the next step.
- 5. Modifying the report.
  - Click the **Report Settings** button if you would like to modify how the information displays on the report. This will open the Report Configuration window.

| Phone Number<br>ax Number |
|---------------------------|
|                           |
|                           |
|                           |
|                           |
| All Ratios                |
|                           |
| r Box                     |
|                           |
|                           |
| Accept<br>Cancel          |
|                           |

Illustration 15: Report Configuration Form

- Changes made in this window will not only affect the current report, but it will affect all reports created in the application, so you will probably only need to do this once.
- Check the **Show Company Information** toggle if you would like your company information, such as address, phone number, and/or website URL to show up on the report. This will enable the fields in the Company Information section.
  - Company information is entered using the Company Information Form (Settings> Company Information).
  - For more information on entering your company information into the application, see the user manual document titled Setting up the Application.
- The following toggles will only be enabled if the **Show Company Information** toggle is checked.
  - Check the **Show Address** toggle if you would like the Street Address, City, State, and Zip Code to display on the report below the company name.
  - Check the **Show Phone Number** and/or **Show Fax Number** toggles if you would like to include the phone and/or fax number on the report. This information will display on the line below the address at the top of the report if the address is included.

- Check the **Show E-Mail Address** and/or **Show Web Address** toggles if you would like to include that information on the report.
- If you check the **Show Company Information** toggle, but leave all of the other toggles in the Company Information section unchecked, only the company name will display on the report.
- Check the **Show Body Image** toggle if you would like to include a simple body silhouette in the center of the report. If this toggle is not checked, nothing will display in its location.
- Check the **Show Captured Images** toggle if you would like to include the Pulse Graph on the report.
  - A Pulse Graph will display on the report for each appendage measured during the test.
  - The x-axis of the Pulse Graph (time in seconds) that will display on the report is setup using the Protocol Edit Form (Settings> Protocols). For more information on the Protocol Edit Form, see the user manual section titled Creating and Editing Protocols.
- The **Ratios** section is used to select which ratios you would like to display on the report.
  - Check the **Show Only Known Ratios** if only ratios with adequate data should be included on the report.
    - For example, if only the right hand and left hand are measured, the left leg and right leg dABI ratios will not display on the report.
  - Check **Show All Ratios** toggle if all ratios should be included on every report.
- Check the **Show Signature Box** toggle if you would like to include a signature box at the bottom of the form. This allows the technician to sign the report.
  - Check the **Show Physician/Technician Name under Box** toggle if you would also like to include the technician name entered when the session was created on the report below the signature box.
    - This toggle will only be enabled when the **Show Signature Box** toggle is checked.
- The **Session Information** section is used to select which information entered during the session should be included on the report.
  - Check the **Show Patient Age** toggle if you would like the patient's age included on the report. The application will calculate the patient's age based on the session date and the patient's birth date.
    - The patient's age will display below the patient's name and sex at the top of the report.
  - Check the **Show Patient Birth Date** toggle if you would like the patient's birth date included on the report. This will display under the patient's name and sex at the top of the report.
  - Check the Show Session Date, Show Session Time, and/or Show Session Duration toggles if you would like to include this information on the report.
    - When these toggles are checked, this information will display just above the patient information on the report.

- The Session Duration will display on the report in seconds. It is the length of time between when the session is opened and closed. If a session is still open while you are viewing the report, the Session Duration will continue to increase each time you view the report.
- Click the Accept button when complete. This will return you to the report.
   If you click the Cancel button, all changes will be lost.
- Once the report is formatted correctly, print or save it.

# **Advanced Features**

The features covered in this section are optional features for advanced users.

# Using the Event and Data Logging Features

1. Choosing to use the Event feature.

- The application displays changes in pulsed blood flow, and since the information is displayed while the patient is being monitored, the effects on pulsed blood flow, such as a Valsalva's maneuver, changes in proximal occlusion of a blood vessel (including external compression), and other vascular flow-affecting events can be observed in real time.
- The Event feature is used to highlight an event that takes place while a measurement is being taken, such as highlighting the effects on blood flow when external compression is applied to an extremity. This highlighted information can then be viewed using the Data Analyzer, an optional graphing feature that allows you to zoom in and print out specific portions of a chart that includes pulse and blood flow information.
- How it works:
  - Enabling the Event feature will add an Event button to the application when measurements are being taken. A technician can then click the Event button, which will begin recording the event. A clock will appear, displaying the seconds that have elapsed since the event began. The technician can then click the Event button again to stop recording. When the measurements are complete, the technician can view the information gathered during the test using the Data Analyzer. The data recorded during the event will be highlighted on the graph.
  - Any event highlighted during a measurement will only display when opening the test data in the Data Analyzer. Events will not display on the Pulse Graph on the report that prints out when the test is complete.
- In order to use the Event feature, all tests must be saved using the Data Logging feature. This saves all tests to a specific directory on a workstation or on a network.
- 2. Setting up the Event and Data Logging features.
  - If you would like to use the Event and Data Logging features, open the Options Form using the toolbar at the top of the main application window (Settings> Options).

| Options                               |       |
|---------------------------------------|-------|
| General Data Logging                  |       |
| Show Event Button                     |       |
| Session Information must be completed |       |
| Session Barcode Entry Visible         |       |
|                                       |       |
|                                       |       |
|                                       |       |
|                                       |       |
|                                       |       |
|                                       |       |
|                                       |       |
|                                       |       |
| Accept                                | ancel |

Illustration 16: Options Form

• Check the **Show Event Button**. This will add the Event button to the application window when measurements are being taken. The technician can then click this button to record the event.

| Options  |           |
|--|-----------|
| General Data Logging                               |           |
| Enable Data Logging (csv format)<br>Path           |           |
| C:\Projects\FloChec\Software\FloChec Monitoring Sc | Browse    |
|  |           |
|  |           |
|  |           |
| Acce   | pt Cancel |

Illustration 17: Options Form (Data Logging)

- Open the Data Logging tab.
- Check the **Enable Data Logging** toggle.
  - The data logging feature saves all pulse and blood flow data in a .csv file. These files can then be opened using the Data Analyzer feature (Tools> Data Analyzer), where the information can be viewed and printed.
  - The **Enable Data Logging** toggle must be checked if you are using the event feature.

- The **Path** field is used to select where the data logs will be stored. The application will create a folder in the selected path titled DataLog.
- Click the **Accept** button to save the selections.

3. Record an event.

- Open a new session from the main application window.
- Enter the patient information into the Session Form window.
- Select a test to perform in the New Test Form.
- Click on a **Measure** button to take a measurement.

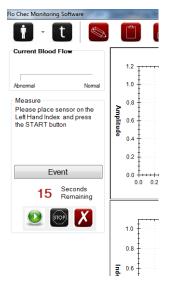


Illustration 18: Measure

- Click the **Start** button to begin taking measurements on an appendage.
- Click the **Event** button to begin recording an event.
  - A timer will display, showing the number of seconds that have elapsed since you began recording the event.
- Click the **Event** button again to stop recording.

# **Using the Session Viewer**

All Patient Sessions can be saved using the Patient >Save option. The user can then choose the name and location to save the session file.

To open or review a session you can use the Session Viewer tool. To open the Viewer select **⊘** Tools >Session Viewer. The Session Viewer is shown in Illustration 19.

| 🖳 Session Viewer   |  |  | - 0 <b>X</b>   |
|--|--|--|--|
| File Help  |  |  |  |
| Patient Info<br>Name: Shawn Scott<br>ID: 12345<br>Age: 32<br>Birth Date: 2/18/1978 | Session Info<br>Date: 9/22/2010<br>Start Time: 2:14 PM<br>Stop Time: 12:00 AM<br>Duration: 0<br>Technician: sgs<br>Left ABI: 1.00<br>Right ABI: 0.99 | <ul> <li>✓ Left Hand Index</li> <li>✓ Right Hand Index</li> <li>✓ Left Foot Big</li> <li>✓ Right Foot Big</li> </ul> |  |
|  | Pulse Data   |  |  |
| (10.2)   | ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷ ÷  |  | Left Hand Index<br>Right Hand Index<br>Left Foot Big<br>Right Foot Big |
|  | Blood Flow Data  |  |  |
|  | i i i i i i i i i i i i i i i i i i i  | ·····  | Left Hand Index<br>Right Hand Index<br>Left Foot Big<br>Right Foot Big |
| • m  | lime (sec)   |  | •  |
|  |  |  |  |

Illustration 19: Session Viewer

- Open a file: Select File >Open to open a recorded session file.
  - The file shall open if it a true Session file
  - Displayed are:
    - Patient Information
    - Session Information
    - Measurements recorded (checkbox)
    - Pulse Data Graph
    - Blood Flow Graph
- The user can show or hide Measurements by checking or unchecking the measurements listed in the top right box
- The user can scroll through the recording using the scroll bar at the bottom of the form.
- To close the current Session select File >Close.
- To close the Session Viewer select File >Exit.
- To view the revision of the Viewer select Help >About

# **Trouble Shooting**

# Connecting the Reusable Sensor to the Workstation

When the Reusable Sensor is properly connected to the workstation, **Connected** will appear at the bottom of the main FloChec Blood Flow application window. If **Connected** does not appear, make sure the Reusable Sensor is connected to the USB Signal Acquisition Device, and the USB Signal Acquisition Device is plugged into a USB port on the workstation. If the devices are properly connected and **Disconnected** still appears at the bottom of the main application window, try the following:

- **1.** Close the FloChec application.
- **2.** Unplug the USB Signal Acquisition Device from the workstation.
- **3.** Restart the FloChec application.
- **4.** Plug the USB Signal Acquisition Device back into the workstation, making sure it is still connected to the Reusable Sensor.

If this does not work, contact Technical Support at 1.877.SSI.4211.

# **Recommended Cleaning Instructions**

The Reusable Sensor and USB Signal Acquisition Device can be cleaned using a T-Spray Transducer Detergent Disinfectant Spray. Other forms of cleaning material may damage or cause them to function incorrectly. When cleaning the USB Signal Acquisition Device, make sure it is not connected to the workstation.

# Warnings

The device possesses cables between different parts of the device. Precaution should be taken towards the placement and movement of the device. These cables may also present a tripping hazard and precaution should be taken for placement and movement around device.

If any damage occurs to the device, unplug it and return it to the manufacturer.

Do not tamper or open the device as harm may occur to you.

The device is an indicator and should be used in correlation with other information about the patient. It is not a diagnostic device.

User intervention may be required under certain electrostatic conditions.

The device is not specified for use at high atmospheric pressures.

The device should not come in contact with liquid except as instructed for cleaning. If liquid comes into contact with any connectors or is believed to have entered the USB Signal Acquisition Device or Usable Sensor, do not use it. Contact the manufacturer and return the device.

The results may be subject to motion or movement artifacts. The device was not tested on patients with gross tremors.

In some cases in diminished pulsatility and bright light, it is advisable to cover the Usable Sensor with a dark cloth.

| Hardware  | Software  |
|---|---|
| <ul> <li>1GHz or faster processor with at least 256 MB of RAM</li> <li>A 32 or 64 bit architecture</li> <li>At least 100 MB's of free hard drive space, plus additional space if any log data will be stored</li> <li>At least (1) USB drive for the USB Signal Acquisition Device</li> </ul> | <ul> <li>Windows XP, Windows Vista, or<br/>Windows 7</li> <li>Microsoft .NET 3.5 Framework</li> <li>Adobe Acrobat Reader 9.0 or<br/>higher</li> </ul> |

# **Environmental Conditions**

- Operating Conditions
  - $\circ \quad 40-90 \; F$
  - 5% 95% Humidity (non condensing)
  - Storage Conditions
  - $\circ$  20 110 F
    - 5% 95% Humidity (non condensing)

### **Contact Information**

If you have any questions, contact Technical Support at 1.877.SSI.4211.

# Notes