



SAFE Sens™ IVM  
User Guide  
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English

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The logo for Origio, featuring the word "origio" in a lowercase, purple, sans-serif font. The letter "i" is stylized with a dot that forms a loop.

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# Explanation of Icons in the Instruction manual

| ICON  | MEANING  |
|---|--|
|  | Marks information in the instruction manual for optimizing use of the equipment. |
|  | Read the operating instructions  |
| <b>I</b>  | Unit ON [Appears next to the power switch]                                       |
| <b>0</b>  | Unit OFF [Appears next to the power switch]                                      |

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## 1.0 Introduction

|                   |  |
|-------------------|--|
|                   | <p>The SAFE Sens IVM is a simple tool that allows monitoring pH within a closed environment without opening and contaminating that environment. The overall system includes the SAFE Sens IVM instrument, described in this document, and a separate computer program for collection and presentation of results. SAFE stands for <b>S</b>terile, <b>A</b>utomated <b>F</b>luoroscopic <b>E</b>valuation. IVM stands for <b>i</b>n-vessel <b>m</b>onitoring.</p> <p>If the system is not already installed and operating, please see Appendix A, “Installation.”</p>   |
| <p><b>1.1</b></p> | <p><b>What the SAFE Sens IVM system does</b></p> <p>The system includes</p> <ul style="list-style-type: none"><li>• A small hand-held or desk-top machine with a simple user interface</li><li>• A fiber optic cable and probe that connect the reader to the SAFE Sens sv<sup>1</sup> sensor, which detects the pH of the sample</li><li>• Other supplies and equipment for installation (Appendix A) and for use in quality control (Section 2.1).</li></ul> <p>The SAFE Sens sv<sup>1</sup> sensor is a small clear tube into which you put a sample of the media whose pH you want to track. At the bottom of the sensor is a special membrane that contains a dye. This dye is affected by the pH of the media sample, and it reacts to light differently at different pH levels.</p> <p>The sensor fits onto the fiber optic probe. To make a measurement, the machine sends flashes of light of a certain wavelength through the fiber optic probe. The dye in the membrane reacts by sending back flashes of light at a different wavelength. The machine reads this result and calculates the pH of the media sample. You can set the timing of this measurement to be once per minute or once every 30 minutes.</p> <p>The SAFE Sens IVM's user interface is described in Section 1.3.</p> <p>For a more detailed explanation of how the SAFE Sens IVM uses fluorometric technology, see Appendix B, “The science behind SAFE Sens IVM.”</p> |
| <p><b>1.2</b></p> | <p><b>Features of the SAFE Sens IVM</b></p> <p>The SAFE Sens IVM system is easy to use, accurate, and reliable. You do not have to calibrate it—this step is done at the factory. It is easy to do quality-control checks on a routine basis, using a supplied standard.</p> <p>The SAFE Sens IVM provides you with several options for adjusting</p>  |

configuration and calibration. You can:

- Set the frequency with which pH readings are to be taken (at 1- or 30-minute intervals).
- Set the clock: Verify or edit the current instrument date/time settings.
- Set the QC (quality control) values: Update the internal quality-control test values in the instrument when you replace your quality-control standard with a new one. (See Section 3.3.)
- Edit offset values: Recalibrate the instrument's pH output to match that of another reference pH measurement instrument that you may have.
- Correctly replace the fiber optic cable. This process includes checking the instrument's reading of the regular QC sample with the new cable in place.
- Provide or edit settings for network communication from the instrument to the computer running the data presentation software.

### 1.3 How the user interface works

The SAFE Sens IVM has a simple keypad and a two-line display screen. (Figure 1-1.)



Figure 1-1 SAFE Sens IVM keypad and display

The keypad has 10 alphanumeric keys (0 through 9, with associated letters) and two function keys, Options and Enter. You use the alphanumeric keys to enter the test ID, the calibration code (pHID) or other information as needed. You use the function keys to navigate through the software and use various functions and options.

|              |  |
|--------------|--|
| <p>1.3.1</p> | <p><b>The alphanumeric keys</b></p> <p>To input a specific letter or number, press the appropriate key multiple times to scroll through the choices until the desired character is displayed. For example, to input the letter R, press the key marked PQR 6 four times, until the letter R is displayed.</p> <p>When the desired character is displayed, press a different alphanumeric key to accept this character and move the cursor one position to the right. Then you can enter the next character.</p> <p>You can also simply wait two seconds after the first character is correctly displayed. The character is accepted automatically after two seconds, and the cursor moves one space to the right. In this way, you can enter double letters or double digits (as in “XYYZ” or “12334”).</p> <p>You can backspace to erase a character by pressing the Options key.</p> |
| <p>1.3.2</p> | <p><b>The arrow keys</b></p> <p>Sometimes a menu provides you with several choices, but the display has only two lines and can display only one choice at a time. To scroll through the choices, use the Up Arrow key (which is the same as the ABC 1 key) and the Down Arrow key (GHI 3). When the correct choice is displayed, press Enter to select it.</p>   |
| <p>1.3.3</p> | <p><b>The Options key</b></p> <p>The Options key has two roles. Its first role is to move from the main menu to the Options menu, hence its name. However, the Options key more generally allows you to decide not to do something or to go back a level in the menus. In most situations it is like an Escape or Cancel key. If you type the wrong character, decide not to carry through an action, chose the wrong option by mistake, or want to return to the previous menu, press Options.</p>  |
| <p>1.4</p>   | <p><b>Process flow</b></p> <p>The SAFE Sens IVM has several functions, but in routine operation you use only a few of them repeatedly.</p>   |
| <p>1.4.1</p> | <p><b>Routine Operation</b></p> <p>The normal flow of work for pH testing is as follows:</p> <ol style="list-style-type: none"><li>1. Run a quality-control (QC) test before first use, and on a regular schedule (usually weekly) between pH testing runs. (See Section 2.1)</li><li>2. Before pH testing, set up and equilibrate the sample and sensor.</li><li>3. Start pH testing. The instrument then reads the pH at either 1- or 30-minute intervals (which you can set using the pH Frequency option).</li></ol>   |

|       |   |
|-------|---|
|       | 4. Stop testing by pressing the Options key.  |
| 1.4.2 | <p><b>Occasional Tasks</b></p> <p>The Options Menu navigation map below shows that from the Main menu, you can also access the Options menu by using the Options key.</p> <p style="text-align: center;">OPTIONS MENU</p> <ol style="list-style-type: none"> <li>1. pH FREQUENCY</li> <li>2. SET CLOCK</li> <li>3. SET QC VALUES</li> <li>4. OFFSET VALUES</li> <li>5. REPLACE FIBEROPTIC</li> <li>6. CONFIGURE NETWORK</li> </ol> <p>You will need to do these tasks only occasionally. To access any one of them, use the arrow keys, and then press Enter when the one that you want is displayed. The options and how to use them are all described in Section 3.0.</p> |
| 1.5   | <p><b>Data output</b></p> <p>Output from the SAFE Sens IVM can be directed to a networked computer running the data presentation software. See Section 3.6 for more information.</p>  |

## 2.0 The Run Test procedures

You access both of the routine test procedures, the QC test and the pH test, from the Run Test menu. As shown below, you start from the main menu. The screen displays:

```
TEST      <ENTER>
SETTINGS  <OPTIONS>
```

This display indicates that to reach the Run Test menu, you should press the Enter key; or to reach the Options menu, press the Options key.

Press the Enter key. The display changes to:

```
ENTER TEST ID:
<Entry field>
```

At this point, if you want to perform a QC test, you place the QC standard on the fiber optic probe, enter the letters “QC”, and press the Enter key. The QC test begins, as described in Section 2.1, later in this document.

|   |   |
|---|---|
|   | <p>To begin pH testing, enter an ID that you want to associate with the test. You can correct typing errors by using the Options key to backspace. When you are satisfied with your entry, press Enter to begin the pH test. The test is described more fully in Section 2.2, later in this document.</p>   |
| <p><b>2.1</b></p>  | <p><b>QC Test</b></p> <p>The quality-control (QC) standard is an aluminum tube containing a small amount of fluorescent dye. When you read it with the SAFE Sens IVM machine, it gives a known and stable reading. You use it to make sure the machine is operating correctly. You should take a QC measurement once a week.</p>  |
| <p><b>2.1.1</b></p>   | <p><b>Caring for the QC Standard</b></p> <p>Keep the standard protected in the provided bag when you are not using it. If it develops scratches or collects dust, it does not give a true reading.</p> <p>Replace the standard when it reaches its expiration date (typically one year).</p> <p>Never try to open or repair the standard.</p>   |
| <p><b>2.1.2</b></p>   | <p><b>Using the Standard</b></p> <p>You can use your QC standard with any SAFE Sens IVM machine. The machine is programmed for your QC standard using the Set QC Values menu described in section 3.3.</p> <p>For the qc<sup>1</sup> version of the standard, place the standard onto the fiber optic probe so that it clicks into place. For the qc<sup>2</sup> version of the standard place the standard where the sv<sup>2</sup> sensor is normally placed.</p>   |
| <p><b>2.1.3</b></p>   | <p><b>Running the QC Test</b></p> <p>When you enter “QC” as the Test ID and press the Enter key, the machine guides you through the steps of the QC process by displaying messages.</p> <p>Step 1: Cleaning the probe</p> <p>The following two messages are displayed alternately:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p>*** PERFORM QC ***<br/>PLEASE CLEAN PROBE</p> </div> <div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p>*** PERFORM QC ***<br/>PRESS ENTER</p> </div> </div> <p>Use a lint-free tissue to clean the fiber optic probe. Press Enter when you are ready to continue.</p> <p>Step 2: Placing the QC standard</p> <p>The screen alternates the following two messages:</p> |

\*\*\* PERFORM QC \*\*\*  
PUT QC XNNN ON PROBE

\*\*\* PERFORM QC \*\*\*  
PRESS ENTER

Place the QC standard identified onto the sample probe. Make sure it clicks into place. Press Enter when you are ready to continue. The following message is displayed:

\*\*\* RUN QC \*\*\*  
TESTING QC

Do not touch the standard while the measurement is taking place.

Step 3: QC check and test

The machine first tests to make sure the standard is seated correctly. If it is not, the following messages are displayed alternately:

\*\*\* PERFORM QC \*\*\*  
CHECK PLACEMENT

\*\*\* PERFORM QC \*\*\*  
PRESS ANY KEY

Remove the standard and replace it, making sure it clicks into place. Then press any key to continue the test. While the test is running, the machine may display:

\*\*\* RUN QC \*\*\*  
ADJUSTING

The display then reports the results of the test, alternating these messages:

\*\*\* QC PASSED \*\*\*  
QC CONFIDENCE XXXX

\*\*\* QC PASSED \*\*\*  
PRESS ANY KEY

The passing QC confidence level is displayed in the XXXX. It may be any value between 970 and 1030 (unless noted differently on the QC Standard Certificate of Compliance). If the value is less than 970 or more than 1030, the test fails, and the machine reports alternately:

\*\*\* QC FAILED \*\*\*  
QC CONFIDENCE XXXX

\*\*\* QC FAILED \*\*\*  
PRESS ANY KEY

Whether the test passed or failed, you exit the test by pressing any key. The main menu returns.

If the test failed, you should rerun the QC, paying careful attention to the cleanliness of the probe, and the correct placement of the standard on the probe. If failures persist, contact BCSI Technical Support. (See Section 4.1)

## 2.2 pH Test

### 2.2.1 Setting up and equilibrating the sample

Before you begin testing a media sample for pH, prepare the sensor and the sample as described here.

If the sensor is new, remove it aseptically from the sterilization pouch in which it arrived. A lot calibration number (pHID) is printed on the package, as shown in Figure 2-1. Keep this number to use when reading the pH. The LOT and hour glass refer to a lot number and the expiration date (prior to use) of the Sensor.

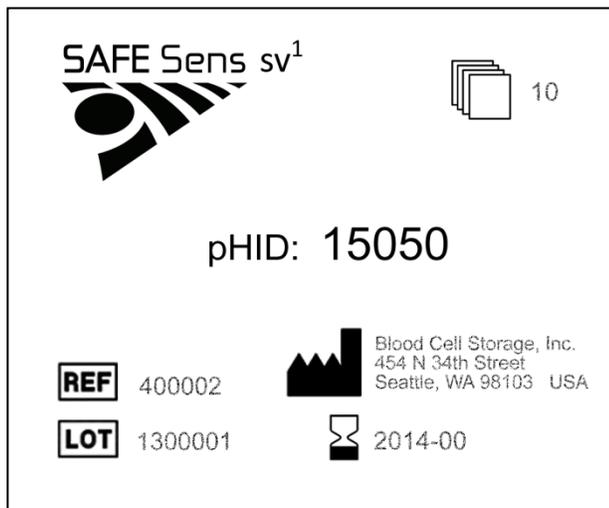


Figure 2-1 Example SAFE Sens sensor label with pHID code (15050 in this example)

Hold the sensor with the opening of the tube upward.

|          | sv <sup>1</sup> | sv <sup>2</sup> |
|----------|-----------------|-----------------|
| 1) Media | 50 µL           | 75 µL           |
| 2) Oil   | 35 µL           | 75 µL           |

Carefully pipette the appropriate amount of media onto the membrane according to the sensor type being used. Avoid adding bubbles while doing this step. Also avoid touching the pipette tip to the membrane.



Pipette an oil overlay onto the media. Again, avoid adding bubbles while doing so. The oil prevents the media from evaporating in the course of several days of pH monitoring. Make sure the meniscus of the oil does not touch the media, which would allow evaporation.

Increase the volume of oil if the meniscus of the oil is touching the media.

Place the sensor in the closed environment that will be monitored, and allow the sensor and the media to equilibrate with the environment. It can take up to two hours for the pH to rise from the low pH level of the dry sensor up to the pH level of the media being tested.

Depending on the media and the conditions of storage, it can take several hours for the media to equilibrate with an atmosphere containing different proportions of gases from that in ambient air. It is preferable to set up the sensor the night before to allow for the equilibration time. A Sensor with a 30 minute pH reading frequency will last for six days.



If you are replacing the media in a sensor that has already been used, remove the sensor from the fiber optic probe and from the closed environment. Using a pipette, carefully remove the contents of the sensor, taking care not to touch the membrane. Turn the sensor upside down and flick the bottom to remove any excess liquid. Replacing the media will not increase the six day usable lifetime of the sensor.

From this point, follow the procedure for filling the sensor with media and oil. This will not extend the normal life of the sensor but may be useful for procedures where the media used in culturing is exchanged.

### 2.2.2 Running the test

To begin measurements on a new sample, place the sensor on the fiber optic probe. Be sure to push the sensor down until it clicks into place on the probe.

From the main menu, press Enter to reach the Run Test menu.

ENTER TEST ID:  
<Entry field>

Enter a test ID with which to associate the pH records, or leave this field blank. A test ID can be an incubator number or some other identifier that should be associated with the six days of the Sensor's pH monitoring. Press the Enter key. See 2.2.3 about resuming tests using the test ID. The display changes to allow for the pHID to be entered.

ENTER PHID:  
<pHID that you entered>

Enter the pHID that was printed on the sensor packaging and press the Enter key to start testing (or Options to cancel the test). The SAFE Sens IVM performs a pH measurement and updates the screen to

display the result and the date and time:

pH: X.XX (pH measured)  
DD-MMM-YYYY HH:MM

At this point, the measured value and the date and time are output to a networked computer for data storage and analysis.

A graphic in the upper right rotates ( < ^ > v ) to indicate that the SAFE Sens IVM is continuing to function. The SAFE Sens IVM continues to take measurements every 30 minutes or each minute, depending on what you have set for the pH test frequency in the Options menu. You can stop testing at any time by pressing the Options key. You can also take an on-demand measurement at any time by pressing Enter.

### 2.2.3 Resuming a test



If you want to continue testing the same sensor with the same media sample after a test was stopped or interrupted, the procedure is similar. It is important to continue the test started because the Sensor's pH reading has a small dependence on the test time and reading frequency. It is only possible to resume the most recent test.

From the main menu, press Enter to reach the Run Test menu. Enter the test ID that you were using in the interrupted test in the screen below.

ENTER TEST ID:  
<test ID from previous test>

In either case, simply press Enter. The machine displays this question, identifying the pHID and the time and date of the most recent sample and alternately asks you to verify what you intend to do:

CONTINUE TEST?  
<test ID>HH:MM DD/MMM

YES <ENTER>  
NO <OPTION>

Press Enter to continue testing the same sample, or Options to cancel and return to the main menu.

## 3.0 The Options menu procedures

The Options menu, which you reach from the main menu by pressing Options, gives you access to several special functions. You must use the arrow keys (numbers 1 and 3) to scroll through the choices, as the

two-line screen can display only one at a time.

### 3.1 pH Frequency

The pH frequency feature allows you to set the testing interval for repeated pH tests.

```
***  OPTIONS MENU  ***
1.  pH FREQUENCY
```

Press Enter to confirm that this is the option you want. The display changes:

```
***  pH FREQUENCY  ***
[ ] 1                [*] 30
```

Each time the SAFE Sens IVM is powered on the default frequency is set to every 30 minutes with an asterisk in that field. This time interval is recommended for multiple-day evaluations of pH up to six days for each Sensor.



You can change the interval to one minute by using an arrow key to move the asterisk to the [ ] 1 field. The 1 minute testing frequency will reduce the useable lifetime of the Sensor to an estimated three to four days. Press Enter to record your choice. The SAFE Sens IVM reflects what you have entered:

```
***  pH FREQUENCY  ***
      SET TO NN MINUTES
```

Alternately, it displays a message asking you to confirm your choice:

```
***  pH FREQUENCY  ***
      PRESS ANY KEY
```

Press any key to confirm. The machine then displays the main menu.

You can press the Options key at any time during the frequency setting process to back up to the Options menu.

### 3.2 Set Clock

Use this function to verify or edit the current instrument date/time settings.

From the Options menu, use the arrow keys to scroll the list until the Set Clock option is displayed:

### 3.3 Set QC Values

```
*** OPTIONS MENU ***  
2. SET CLOCK
```

Press Enter to accept this selection. The following screen is displayed:

```
DATE: >YYYY< MMM DD  
TIME: HH : MM
```

YYYY, MMM, and DD represent the current year, month, and day. HH and MM represent the hour (0 through 23) and minute.

If no changes are needed, press Enter to return to the Options menu.

To edit values in this display, first note the angle brackets > < surrounding the year value. They indicate that your edits will affect the year field. If you need to change the year value, use the arrow keys to increase or decrease the year. Press the Options key to accept the value and move the brackets to the month field (MMM).

In the same way, edit values for the month, day, hour, and minute as necessary. In each case, pressing the Options key moves to the next field.

When all the displayed values are correct, press Enter to accept them and return to the Options menu.

---

### 3.3 Set QC Values

Approximately once a year, you should replace your QC standard with a new one. The QC standard has an expiration date on its label. When you replace it, the QC values stored in your instrument must be updated to match the values provided on the Certificate of Calibration for the new standard.

From the Options menu, use the arrow keys to scroll the list until the Set QC Values option is displayed:

```
*** OPTIONS MENU ***  
3. SET QC VALUES
```

Press Enter to select this function. The following screen is displayed:

```
*** SET QC VALUES ***  
____-____-____-____
```

Using the numeric keys, enter the string of numbers from the QC Certificate of Calibration sheet. Press Enter to accept the value.

The string of numbers includes a check value. If the instrument detects that the string is not correct, it displays the following alternating messages:

\*\*\* SET QC VALUES \*\*\*  
INVALID ENTRY

\*\*\* SET QC VALUES \*\*\*  
PRESS ENTER

Press Enter to acknowledge the message and return to the Options menu, from which you can repeat the process and correct the entered string.

Once the numeric string is accepted, the instrument updates its internal values and reports success, alternating these messages:

\*\*\* SET QC VALUES \*\*\*  
UPDATED SUCCESSFULLY

\*\*\* SET QC VALUES \*\*\*  
PRESS ENTER

If the internal update fails, the instrument displays:

\*\*\* SET QC VALUES \*\*\*  
PROGRAM FAIL

\*\*\* SET QC VALUES \*\*\*  
PRESS ENTER

In either case, pressing Enter returns to the Options menu. If the update failed, try the programming again. If this continues contact BCSI Technical Support. (See Section 4.1.)

### 3.4 Offset Values

You may decide to correlate the pH results from the SAFE Sens IVM with measurements from a separate reference pH measurement instrument. You can adjust the SAFE Sens IVM's calculations to match those of the other instrument.

Imagine that internally, the SAFE Sens IVM is using a graph with X and Y axes to find the pH that it reports:

$$\text{pH displayed} = \text{slope} * \text{pH measured} + \text{intercept}$$

By default, the slope is set to 1.000 and the intercept to 0.000. To adjust the result, you have to adjust the slope or intercept values of the graph. You do so by using the Offset Values function of the Options menu.

From the Options menu, use the arrow keys to scroll through the list until 4. OFFSET VALUES is displayed.

### 3.5 Replace Fiberoptic

```
*** OPTIONS MENU ***
```

```
4. OFFSET VALUES
```

Press Enter to select this function. The slope value is displayed:

```
*** OFFSET VALUES ***
```

```
SLOPE =          X.XXX
```

where X.XXX is the current value of the slope.

You can edit the slope value using the 1 and 3 keys to increase and decrease the value by 0.001, the 4 and 6 keys to increase and decrease by 0.010, and the 7 and 9 keys to increase or decrease by 0.050. The range of possible values for the slope is 0.200 to 2.400.

Press Enter to accept the desired value. The display changes to show the intercept value:

```
*** OFFSET VALUES ***
```

```
INTERCEPT =    X.XXX
```

where X.XXX is the current value of the intercept. Use the same procedure to adjust the intercept value. The range of possible values for the intercept is -1.000 to 1.000.

Press Enter to record both the new slope and the new intercept values. The system reports success or failure and asks you to press Enter, again. This returns to the Options menu.

To determine the slope and intercept values, collect a data set of comparison measurements with SAFE Sens and the separate reference pH instrument. These should cover a range of pH values. Using a data analysis tool, such as Excel, plot the data with SAFE Sens IVM on the X axis and reference instrument on the Y axis. Create a linear best fit line and record the slope and intercept.

---

## 3.5 Replace Fiberoptic



If you break a fiber optic cable and need to replace it with a new one, the new cable has slightly different optical characteristics, and the SAFE Sens IVM must recalibrate itself for the new cable. Each SAFE Sens IVM is intended to operate with one fiber optic cable. The pH measurement accuracy specification is not valid if one SAFE Sens IVM is moved between multiple fiber optic cables and Sensors.

To start the cable replacement process, from the Options menu, use the arrow keys to scroll until the following is displayed:

\*\*\* OPTIONS MENU \*\*\*  
5. REPLACE FIBEROPTIC

Press Enter to begin the process. The following two screen displays alternate:

\* REPLACE FIBEROPTIC \*  
CONNECT CABLE

\* REPLACE FIBEROPTIC \*  
PRESS ENTER

Replace the old cable with the new one, and then press Enter. The following two messages are displayed alternately:

\* REPLACE FIBEROPTIC \*  
PLEASE CLEAN PROBE

\* REPLACE FIBEROPTIC \*  
PRESS ENTER

Use a lint-free tissue to clean the fiber optic probe. Press Enter when you are ready to continue. The display directs you to put the QC standard on the probe:

\* REPLACE FIBEROPTIC \*  
PUT QC XNNN ON PROBE

and to press Enter once you have done so.

The SAFE Sens IVM first performs the recalibration. If this step is successful, the instrument displays

\* REPLACE FIBEROPTIC \*  
PERFORMING QC

If the QC process succeeds, the instrument reports:

\* REPLACE FIBEROPTIC \*  
REPLACEMENT COMPLETE

and asks you to press Enter, which returns you to the Main menu.

If either the recalibration or the QC test fails, the instrument alternates the displays:

\* REPLACE FIBEROPTIC \*  
REPLACEMENT ERROR!

\* REPLACE FIBEROPTIC \*  
CONSULT MANUAL

If the test failed, you should rerun the fiber optic replacement, paying careful attention to the connection of the new fiber optic, the cleanliness of the probe, and the correct placement of the standard on the probe. If failures persist, contact BCSI Technical Support. (See Section 4.1)

---

## 3.6 Network

Your SAFE Sens IVM can be configured to join an Internet Protocol (IP) based network so that it can report data to a laboratory information system (LIS) for storage and analysis.

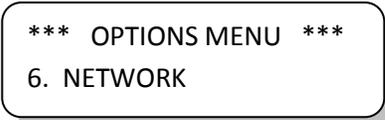
The instrument's Options menu offers a Network choice that allows you to configure network access in either of two ways: via the Dynamic Host Configuration Protocol (DHCP), or by specifying the literal IP address and netmask to be used.

If your network offers it, it is much simpler and more efficient to use DHCP. Your LIS administrator can tell you whether DHCP is available. Alternatively, the administrator must give you the values to use in configuring the IP address and netmask.

---

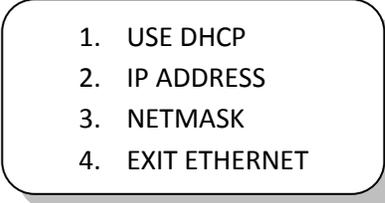
### 3.6.1 Enabling DHCP

To begin, in the Options menu, use the arrow keys to scroll the menu until the following appears:

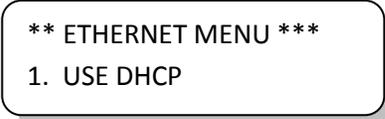


```
*** OPTIONS MENU ***
6. NETWORK
```

Press Enter. The Network menu appears, including these choices:

- 
- ```
1. USE DHCP
2. IP ADDRESS
3. NETMASK
4. EXIT ETHERNET
```

If you can use DHCP on your network, use the arrow keys to scroll until this display appears:



```
** ETHERNET MENU ***
1. USE DHCP
```

Press Enter. The following form is displayed:

```
* NET: USE DHCP? *
[*] YES      [ ] NO
```

Use the arrow keys to specify whether or not DHCP is to be used. Press Enter to set your choice.

If DHCP is not used select NO and follow the steps in Section 3.6.2 to manually set the network configurations.

If DHCP is used you can view the IP details automatically assigned to the SAFE Sens IVM by scrolling through the menus in Section 3.6.2.

### 3.6.2 Entering or viewing network addresses

If DHCP is not available, your LIS administrator must provide you with the correct addresses to use in configuring the IP address of your instrument, and also the appropriate netmask addresses. There is a network menu choice for each of these two values, but you enter all of them in the same way, described only once here.

In the Network menu, use the arrow keys to choose the parameter you want to configure or view (IP address or netmask). Press Enter to display a screen similar to the following:

```
*ENTER IP ADDRESS *
###.###.###.###
```

The cursor is placed below the first number, indicating that this value is available for editing. Enter the numeric value that your administrator has provided for this parameter. The address must include all three digits in each of the four segments of the address, including zeros if necessary.

A typical IP address is similar to the following example:

```
192.168.001.101
```

A netmask might have a form similar to

```
255.255.255.000
```

When you have entered and checked the value, press Enter to accept the address entry. If you are viewing the value, press Options to exit the entry without making changes. The display reports success or failure in recording your entries. Press Enter again to return to the Network menu.

## 4.0 Troubleshooting

### 4.1 Technical Support

For assistance regarding the use of the SAFE Sens IVM, please contact Technical Support. This is available from your local sales contact and from Blood Cell Storage, Inc. (BCSI).

Go to: [www.safesens.com/support](http://www.safesens.com/support) for the most up to date contact information for Blood Cell Storage, Inc.'s Technical Support.

Phone: +1-478-227-4006

Email: [support@safesens.com](mailto:support@safesens.com)

### 4.2 Error Messages

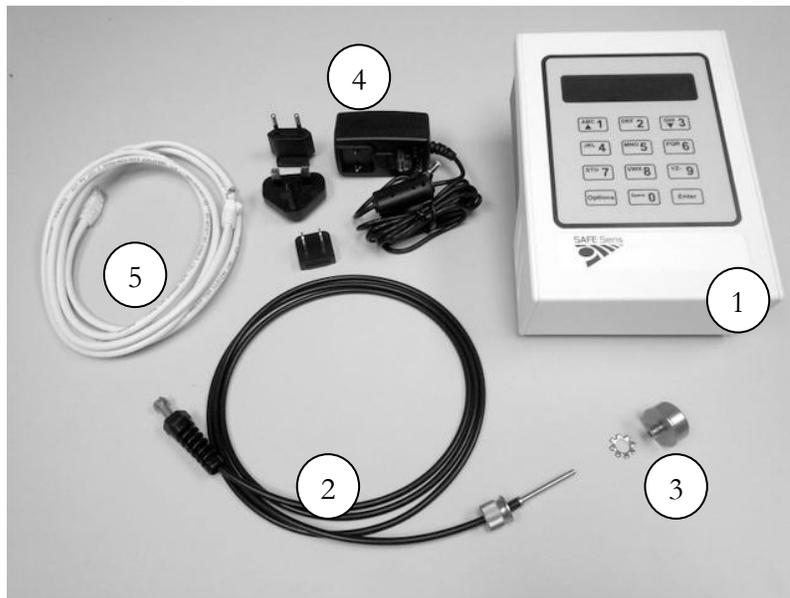
When the SAFE Sens IVM is unable to complete a specific task an alarm tone is emitted and an error message is displayed. Refer to the following list of error messages when troubleshooting.

| Message                                                    | Cause                                                                                      | Action                                                                                             |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| CALIBRATION FAULT!<br>CONSULT OPS MANUAL<br>Critical error | An internal checksum error was detected in the Reader data during Power-On Self-Test.      | Contact Technical Support for re-calibration servicing.                                            |
| RESETTING CLOCK!<br>PRESS KEY TO PROCEED                   | The clock is not running.                                                                  | Reset the time on the clock from the default value. Contact Technical Support if problem persists. |
| SETUP ERROR!                                               | Ethernet module was not set up properly.                                                   | Cycle the power. If problem persists contact Technical Support.                                    |
| * BAD IP ADDRESS!! *                                       | The IP address entered is not an allowable IP address.                                     | Enter an address in the range of 000:000:000:000 to 255:255:255:255.                               |
| TABLE NOT PROGRAMMED                                       | The pHID table is not available.                                                           | Contact Technical Support to upload additional pHID tables.                                        |
| ** QC FAILED **<br>QC Confidence: XXXX                     | The Quality Control test identified an issue but was not successful in correcting it.      | Repeat this procedure. (See section 2.1.) If the error persists contact Technical Support.         |
| *REPLACE FIBEROPTIC*<br>REPLACEMENT ERROR                  | The optical control and necessary adjustments were not successful for the new fiber optic. | Repeat the procedure. (See section 3.5.)                                                           |

## Appendix A: Installation and Cleaning

### A.1 Components

The SAFE Sens IVM is supplied with the following components for installation:



1. SAFE Sens IVM instrument.
2. Detachable fiber optic probe, which incorporates a nut, a spring, and a screw end.
3. A Washer and Detent, which will hold the SAFE Sens sv<sup>1</sup> Sensor. (The configuration for the sv<sup>2</sup> sensor is different from the one pictured.)
4. Universal power supply with country-specific pins.
5. Ethernet Cable.
6. Quick Start Guide (not pictured).
7. Certification Documents (not pictured).

The SAFE Sens IVM has consumable Sensors and QC standards as well as a replaceable fiber optic cable. Contact your local distributor for replacement items. The list below contains the part numbers and descriptions. Note that manufacturer and distributor part numbers may differ.

There are two configurations of fiber probes and sensors; check which configuration you require. Typically, cabinet-style incubators require the sv<sup>1</sup> and qc<sup>1</sup> configuration; whereas benchtop incubators require the sv<sup>2</sup> and qc<sup>2</sup> configuration (currently under development). Your distributor can assist you.

Accessories and Replacement Parts:

| Part Number | Description                                     |
|-------------|-------------------------------------------------|
| BCSI-400002 | 10 pack of SAFE Sens sv <sup>1</sup> Sensors    |
| BCSI-400004 | qc <sup>1</sup> Standard                        |
| BCSI-400006 | Replacement Fiber Optic (sv <sup>1</sup> style) |
| BCSI-150001 | Annual Basic Customer Support Package           |
| BCSI-150002 | Annual Express Customer Support Package         |
| BCSI-150003 | Annual Premium Customer Support Package         |

## **A.2 Directions**

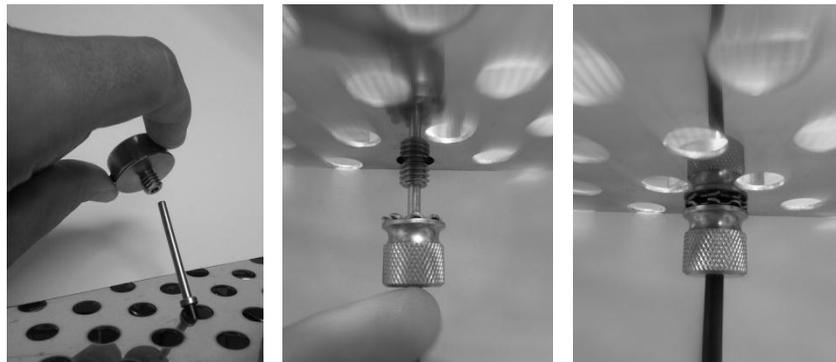
Unpack the box and verify that all parts are present and in good condition.

Set up the SAFE Sens IVM in the area where testing will be done.

Plug in the SAFE Sens IVM's power supply.

Connect the SAFE Sens IVM to the local Ethernet network.

To mount the probe in a cabinet style incubator, snake the fiber optic probe into the incubator using a back access port or through the seal in the incubator door.



Thread the washer onto the fiber optic cable so that it contacts the nut.

Thread the screw end of the fiber optic cable from the bottom through any hole in the incubator shelf and into the smaller end of the detent.

Tighten the nut firmly to hold the assembly in place.

**A.3 Use**

To use the probe, place the sv<sup>1</sup> Sensor vertically into the detent and push down until it clicks. The spring in the probe assembly holds the sensor in the correct position once it has been seated.

**A.4 Cleaning**

Cleaning solutions include 70% Ethanol, mild detergent, and peroxide solutions.

The SAFE Sens IVM can be wiped down with a cleaning solution

The fiber probe tip should only be cleaned with a dry lint free tissue. The fiber optic cable, washers and nut can be wiped down with a cleaning solution.

When decontaminating an incubator, remove the fiber optic from the incubator prior to starting the decontamination. Clean the fiber as instructed above for the decontamination process.

The SAFE Sens sv<sup>1</sup> and sv<sup>2</sup> Sensors cannot be cleaned or reused.

The exterior of the qc<sup>1</sup> and qc<sup>2</sup> devices may be wiped down with a cleaning solution. Do not put liquids into the inside of the QC standards. Do not attempt to open or clean the inside of the QC Standards.

**A.5 Data output**

Data is output via Ethernet connection. A computer on the same Local Area Network (LAN), can run the provided software to automatically download the SAFE Sens IVM data. Then you can view the data from a Web browser on the same LAN.

Instructions for the software are included with the software installation materials.

## **Appendix B: The science behind SAFE Sens IVM**

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The SAFE Sens technology is based on the principle that fluorescent dyes emit characteristic wavelength spectra at different pH levels.

The SAFE Sens sensor is a modified optical cuvette that creates a liquid well in which the pH of a media sample can be tracked. The sensor fits onto a fiber optic probe and includes a special membrane located at the bottom of the liquid well. The membrane is impregnated with a fluorescent dye that emits characteristic wavelength spectra at different pH levels. Periodically, the instrument measures the pH of the sensor. (You can choose the timing of this measurement to be at one or thirty-minute intervals.)

During measurement, the fiber optic probe delivers flashes of green light from a monochromatic light source to the sensor. The light excites the dye in the membrane and induces fluorescent light emission at two wavelengths. At 600nm, the intensity of light emission varies with the pH of the media. At the second, reference wavelength, 568 nm, the emission does not depend on the pH.

The intensities of emissions at these two wavelengths are collected by photo-detectors in the SAFE Sens IVM. The instrument calculates the ratio of the two wavelengths and converts it to the pH. Using a ratio of emission intensities allows determining the pH independently of any varying characteristics of the particular instrument used. The instrument also uses the reading frequency and the duration of the test to make small automatic corrections to the pH signal.

## Appendix C: Limited Warranty

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Blood Cell Storage, Inc. (BCSI) warrants that, at the time of shipment, the instrumentation provided to the customer is free from defects in material and workmanship.

This limited warranty is conditioned upon the customer giving BCSI notice of any defect within one (1) year after shipment. This limited warranty will not apply if the instrumentation (a) has not been installed, used, or maintained in accordance with applicable instructions and manuals; (b) has been repaired or altered by unauthorized persons or misused, abused, accidentally damaged or subjected to operation for which it was not intended; or (c) has had its serial number altered or removed. This limited warranty does not apply to consumable items. Except as expressly stated herein, BCSI makes no other warranties, express or implied, including warranties of merchantability or fitness for particular purpose.

Under this limited warranty, BCSI at its option, will repair or replace any defective instrumentation. This is the sole remedy for any breach of warranty. Any instrumentation to be returned for repair or replacement must be properly packaged and shipped via prepaid freight in accordance with BCSI instructions. This limited warranty does not apply to the use of the instrument other than as described herein.

This limited warranty contains BCSI's sole obligation and liability related to the customer's use of the BCSI products. BCSI shall not be liable to the customer for any other remedies of damages, including special, indirect, incidental, and consequential damages, including, but not limited to, lost profits, whether based upon warranty, strict liability, tort, contract or otherwise. This limited warranty may not be changed in any way without the express written permission of BCSI.

Each provision of this agreement that provides for a limitation of liability, disclaimer of warranties, or exclusion of damages is to allocate the risks between the parties. This allocation is reflected in the pricing offered by BCSI to the customer and is an essential element of the basis of the bargain between the parties. Each of these provisions is severable and independent of all other provisions of this agreement. The limitations in this section will apply notwithstanding the failure of essential purpose of any limited remedy in this agreement.

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### Warranty Registration

Check with your distributor about Warranty Registration

## Appendix D: System Specifications

| SAFE Sens IVM Specifications             |                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item                                     | Value                                                                                                                                                                                                                                                                                                                                                                 |
| Dimensions                               | L x W x H<br>19.7 cm x 13.9 cm x 7.2 cm<br>(7.7 in x 5.5 in x 2.9 in)                                                                                                                                                                                                                                                                                                 |
| Weight                                   | 0.8 kg (1.8 lbs)                                                                                                                                                                                                                                                                                                                                                      |
| External connections                     | <ul style="list-style-type: none"> <li>• Ethernet</li> <li>• Fiber optic</li> <li>• PS2</li> <li>• RS-232 DB-9 (male)</li> <li>• Power adaptor</li> </ul>                                                                                                                                                                                                             |
| Keypad                                   | 10 character alpha numeric keys<br>2 special function keys                                                                                                                                                                                                                                                                                                            |
| Display                                  | 2 line by 20 character liquid crystal display (LCD)                                                                                                                                                                                                                                                                                                                   |
| Power requirements<br>(AC power adapter) | Input power to power adapter: <ul style="list-style-type: none"> <li>• 100 – 240 V AC, 47 – 63 Hz, 0.6A max, 18W max</li> </ul> Adapter output power: <ul style="list-style-type: none"> <li>• 9 V DC, 2A max</li> </ul> Input current: <ul style="list-style-type: none"> <li>• 9 V DC, 1.7A</li> </ul> Note: input connectors are available for multiple countries. |
| Operating temperature                    | 5 – 40°C (41 – 104°F)                                                                                                                                                                                                                                                                                                                                                 |
| Operating humidity                       | 5-80% relative humidity, non-condensing<br>(For the SAFE Sens IVM outside of an incubator)                                                                                                                                                                                                                                                                            |
| Transport and storage conditions         | Temperature: -10 – 50 °C (14 – 122°F)<br>Humidity: 5 – 98% relative humidity, non-condensing<br>Atmospheric pressure: 50 kPa – 106 kPa (0.5 atm – 1 atm)                                                                                                                                                                                                              |
| Altitude                                 | Maximum altitude 4000 m (13,124 ft)                                                                                                                                                                                                                                                                                                                                   |
| Case                                     | Dust and splash resistant, chemical resistant                                                                                                                                                                                                                                                                                                                         |
| Pollution degree                         | Pollution degree 2 (BS EN 61010-1)                                                                                                                                                                                                                                                                                                                                    |
| Operating environment                    | Intended for indoor use only                                                                                                                                                                                                                                                                                                                                          |

**SAFE Sens IVM performance specifications**

| Item                    | Value                                                                                                                                                                                            |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| pH Range                | pH 6.00 to 8.00                                                                                                                                                                                  |
| pH measurement accuracy | 0.05 pH units (within pH 7.00 to 7.60)                                                                                                                                                           |
| pH resolution           | 0.01 pH units                                                                                                                                                                                    |
| pH Sensor lifetime      | 6 days of use with 30 minute reading frequency.<br>3-4 days of use with 1 minute reading frequency.<br>Shelf life is labeled on the packaging of sensor. (Typically one year from sterilization) |
| Optical control         | QC standard (qc <sup>1</sup> or qc <sup>2</sup> , minimum 12 month lifetime)                                                                                                                     |

**Certification**

| Item                | Value                     |
|---------------------|---------------------------|
| Safety class        | Class A                   |
| 2004/108/EC         | Electromagnetic compliant |
| 2006/95/EC          | Low voltage compliant     |
| EN 61010 revision 3 | Conforms                  |
| RoHS                | Compliant                 |

Specifications are subject to change without notice.

**Intellectual Property Disclaimer**

“SAFE Sens”™ and “Innovations that make a difference”™ are registered US, Canadian and/or European trademarks owned by Blood Cell Storage, Inc. (BCSI). The SAFE technology is covered by multiple issued and pending US and International equivalent Patents including but not limited to: 7,608,460, 7,968,346, 8,148,167, 8,183,052 and 8,497,134.