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pH SAFE™ Reader

Model: BCSI pH1000

Operator Manual

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Doc. No. 120001-10

Issue Date 30 August 2023

IVD

Blood Cell Storage, Inc.

4203 23rd Ave W

Seattle, WA 98199 USA

| EC | REP |

MedEnvoy Global B.V.

Prinses Margrietplantsoen 33 - Suite 123

2595 AM The Hauge

The Netherlands

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1   Introduction

1.1   Intended Use

The **pH SAFE Reader** (**S**terile, **A**utomated **F**luoroscopic **E**valuation) is an *in vitro* diagnostic (IVD) medical device that provides a rapid, non-invasive method to measure the pH of fluid contained in platelet storage bags. The **pH SAFE Reader** (Model: BCSI pH1000) reports the pH at a temperature of 22°C. Platelets collected in storage bags retain function over time. During storage of platelets, the pH of the fluid in a platelet storage bag will change over time. The measurement range for pH is 6.2 to 7.8 with an accuracy of 0.1 pH units. Regular pH monitoring of stored platelet units can be used to verify the quality of platelet units before use in transfusion.

Current guidelines for acceptable pH range of stored platelets are established by the Council of Europe, the International Society of Blood Transfusion (ISBT), and the AABB. Users should refer to local protocols for additional guidance on pH measurement. Clinical Decisions based on the pH measurements are the responsibiliy of the users of the **pH SAFE Reader**.

The **pH SAFE Reader** is intended for use in hospital laboratories and blood banks to monitor pH of platelet storage bags. Intended users are trained laboratory and blood bank personnel; device is not intended for self-testing by lay-users.

1.2   Using this Manual

Chapters in this manual provide comprehensive information describing the technology and operation of the **pH SAFE Reader**:

Chapter 1, Introduction – (this chapter) contains introductory, safety, and warranty information.

Chapter 2, System Description – contains a description about the principles of the device technology, the components of the system, and the system specifications.

Chapter 3, Unpacking and Installation – contains installation and setup information.

Chapter 4, Using the pH SAFE Reader Software – contains a description of the BCSI software application structure and detailed usage and configuration information for all software features.

Chapter 5, Run Test Operation – contains instructions for performing the specific tasks required for the typical daily use of the **pH SAFE Reader**.

Chapter 6, Using the Options Menu – contains procedures used to configure and use functions available from the Options Menu.

Chapter 7, Maintenance – contains a description of the recommended maintenance and quality control test procedures.

Chapter 8, Troubleshooting – contains BCSI Service and Technical Support contact information and a list of possible error messages with a description of the probable cause for each message and suggested resolution procedures.

Appendix A, Power-On Self Check (SELF-CHK)

Appendix B, Serial Port Results Upload

Appendix C, Ethernet Setup

1.3 Warnings

Conventions

This symbol indicates a potential hazard where misuse of the system could result in damage to the equipment.

This symbol indicates a potential hazard where misuse of the system could result in electric shock or fire.

Shock Potential when Power Improperly Applied

Ensure that the system is connected to a power receptacle that provides voltage and current within the specified operating range. Use of an incompatible power source may produce electrical shock and fire hazards.

Shock Potential from Spilled Liquids

If liquid is spilled onto the instrument, fluid seepage into internal components creates a potential shock hazard. If liquid is spilled onto the instrument, disconnect power and clean/dry the instrument surfaces.

Do Not Remove Instrument Cover

The **pH SAFE Reader** contains no user-serviceable components. The manufacturer warranty is voided if the instrument cover is removed.

Use only Supplied AC Power Adapter Cables for pH SAFE Reader and Printer

A power adapter is supplied for specific use with the **pH SAFE Reader**. If the optional Printer accessory will be used, an additional power adapter is also supplied for specific use with the Printer.

DO NOT interchange the **pH SAFE Reader** and Printer AC power adapters. Always ensure the proper supplied AC power adapter is used for each device. Failure to do so may result in damage to the instrument and/or the Printer.

⚠

Ensure Instrument Power is OFF before connecting Bar Code Scanner

DO NOT connect the Bar Code Scanner to the **pH SAFE Reader** after the instrument is turned ON. Doing so may result in damage to the Bar Code Scanner.

⚠

Reporting Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and where relevant for use in the European Union to the competent authority of a Member State.

1.4   Precautions

Read the entire contents of this Operator Manual prior to using the **pH SAFE Reader**.

Observe the following precautions when operating the **pH SAFE Reader**:
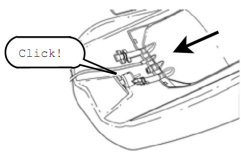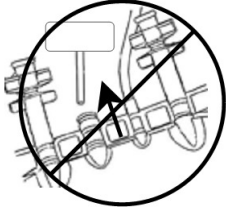
• Unplug the instrument before cleaning.

• Clean only external surfaces using 70% ethanol or a mild detergent or non-organic laboratory disinfectant and a damp cloth. DO NOT USE STRONG BLEACH (> 0.1% solution) OR ORGANIC SOLVENTS!

• Use only BCSI supplied or approved platelet storage bags with the ***pH SAFE Reader***.

• If the instrument is used in a manner not specified by the installation/operation procedures included in this manual the safety protections provided by the equipment may be impaired.

1.5   Informational Symbols

The following informational symbols are displayed on the **pH SAFE Reader** and the **pH SAFE Reader Quick Reference Guide**.

Symbol	Location	Meaning
⚠	Bottom Instrument Panel	CAUTION: Electric Shock Hazard. Refer servicing to qualified personnel. Consult accompanying documents.
|	Power Switch (Right Side Panel)	On (Power Supply)
0	Power Switch (Right Side Panel)	Off (Power Supply)
| o ⚡	Quick Reference Guide	Power Switch with **|** (On) and **o** (Off)

Symbol	Location	Meaning
	Quick Reference Guide	Put the pH sensor all the way onto the probe until a click sound or feeling.
	Quick Reference Guide	Inspect the probe for scrapings (see Chapter 7.1)
	Quick Reference Guide	Ensure pH SAFE Sensor is aligned with fiber optic probe on pH SAFE Reader. Avoid scraping the sensor on the probe.
	Quick Reference Guide	Check the information on the pH SAFE Reader Screen and the barcoded information for correct barcode scanning or keyboard entry.
	Quick Reference Guide	Save the pH Record
	Quick Reference Guide	Print the pH Record via the RS 232 Serial Port
	Quick Reference Guide	Delete the pH Record

1.6   Limited Warranty

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.

1.7   Trade Marks and Intellectual Property

pH SAFE® and BCSI "…it's in the bag"® are registered US, Canadian and/or European trademarks. The pH SAFE technology is covered by multiple issued and pending US and International equivalent Patents including but not limited to: US Pat. No. 7,608,460, 7,968,346, 8,148,167, 8,183,052, 8,497,134, 9,040,307, 9,062,205, 9,217,170; AU Pat. No. 2005277258; JP Pat. No. 5017113; CN Pat. No. ZL200580033961.1; IN Pat. No. 257667

1.8   Change log for recent revisions

Revision 10 30 August 2023

Added items for IVDR compilance

Revision 9   28 June 2022

Update Authorized Representative and additional items for IVDR compliance

2   System Description

2.1   Theory of Operation

The **pH SAFE^{TM}** (**S**terile, **A**utomated **F**luoroscopic **E**valuation) technology is based upon the principle that fluorescent dyes emit characteristic wavelength spectra at different pH levels.

BCSI Platelet Storage Bags

Concentrated platelets, a cellular component of blood, are stored in **BCSI Platelet Storage Bags** intended for specific use with the **pH SAFE Reader**.

BCSI Platelet Storage Bags are manufactured to be identical to standard platelet storage bags, in form and function, while providing an additional, embedded **pH SAFE Sensor**. This port allows non-invasive pH monitoring of the fluid in the bag using the **pH SAFE Reader**.

NOTE: BCSI Platelet Storage Bags may be used in exactly the same manner as standard platelet storage bags for platelet collection and transfusion purposes. Refer to the *BCSI Platelet Storage Bag* package insert for complete information about the characteristics and intended use of the BCSI Platelet Storage Bags.
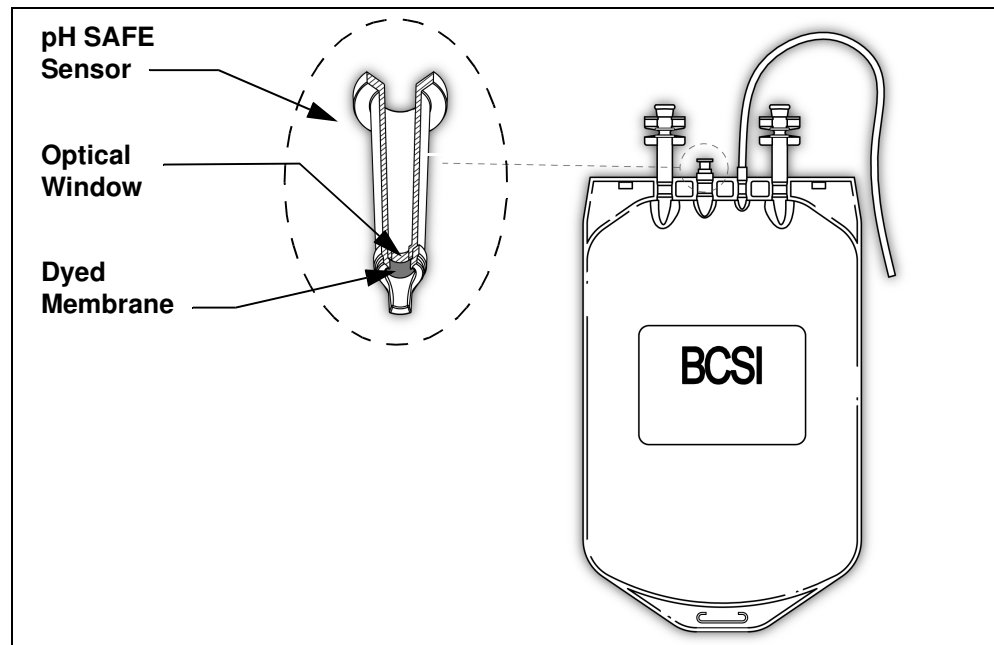
Figure 2-1   BCSI Platelet Storage Bag and pH SAFE Sensor

pH SAFE Sensor

The **pH SAFE Sensor** is a modified optical cuvette component which allows non-invasive insertion of a Fiber Optic Probe and provides a special membrane located at the lower end of the sensor. The membrane is impregnated with a fluorescent dye which emits a characteristic wavelength spectra at different pH, sealed inside the bag and immersed in the fluid contained by the bag. The dyed membrane is positioned adjacent to a transparent optical window such that fluorescent light emitted by the dye can be measured by the **pH SAFE Reader** without removing any fluid, opening the bag, or otherwise compromising the bag integrity and sterility of the platelet product.

pH SAFE Reader
Model: BCSI pH1000

To measure pH, the **Fiber Optic Probe** of the **pH SAFE Reader** is inserted into the pH SAFE Sensor of the BCSI platelet storage bag. When directed by the user, the Fiber Optic Probe delivers flashes of green light from a monochromatic light source to the bag to excite and induce fluorescent light emission from the dye in the membrane. When excited to fluorescence the dye produces a characteristic wavelength spectrum of emission light. At one wavelength (600nm, Fp), the intensity of light emission is variable and dependent upon the pH of the fluid in the bag. At a second reference wavelength (568nm Fr), the relative emission intensity is constant regardless of the pH of the fluid in the bag.

The intensities of the two wavelengths of interest are collected by photodetectors in the **pH SAFE Reader**. A ratio of the two wavelengths is calculated and converted into a pH. By using a ratio of the emission intensities, the pH can be determined independent of factors such as excitation intensity, optical transmission quality, or dye concentration. If either the intensity measurement or the calculated ratio value fall outside acceptable ranges, an alarm message is displayed on the instrument screen and the pH result value for this bag is not stored. The **pH SAFE Reader** includes a Quality Control Test, which measures the fluorescent signals of the device and compares the relative signals to the levels initially set at the Factory. The factory fluorescent signals can be traced to pH measurements of platelets with a NIST traceable blood gas analyzer's pH measurements.

2.2   Reader Components
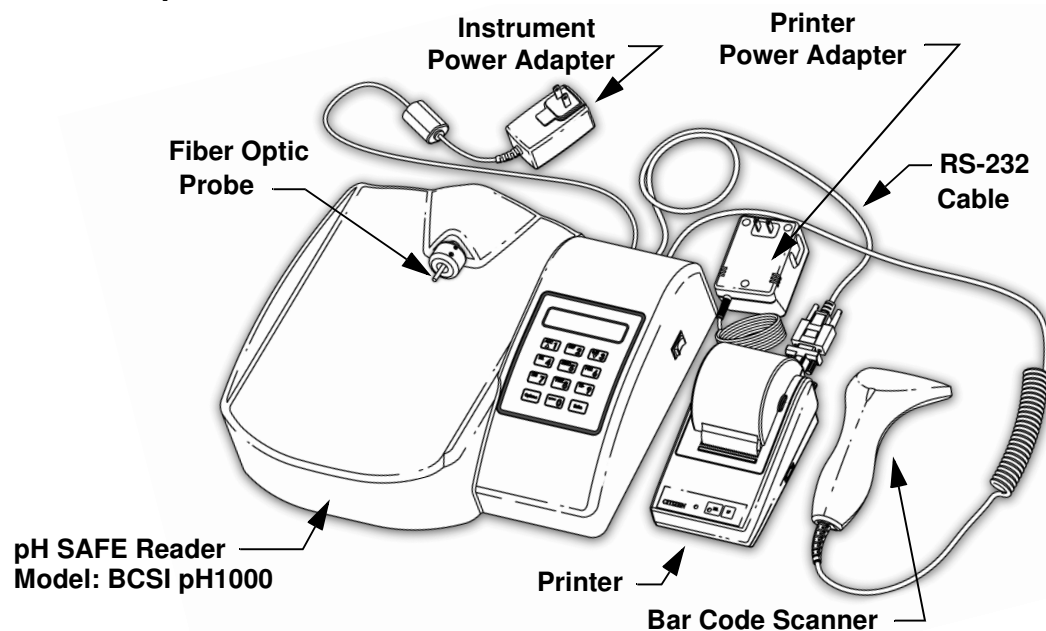
Figure 2-2   pH SAFE Reader Components

The **pH SAFE Reader** consists of the following components:

*   **pH SAFE Reader** (Model: BCSI pH1000), power adapter (GlobTek, GT-41052-1509), Ethernet cable, RS-232 Serial cable

- Bar Code Scanner

- Printer, power adapter, RS-232 Serial adapter (optional)

These individual components are described next.

pH SAFE Reader
Model: BCSI pH1000

The **pH SAFE Reader** is a fluorometric instrument which includes the following:

- **Fluorometer** - The instrument includes internal optical components used for photometric measurement, an excitation light source, and a Fiber Optic Probe, which is inserted into the pH SAFE Sensor in the Platelet Storage Bag being tested, to deliver excitation light to induce fluorescence and subsequently collect resulting emission light at 568nm and 600nm.

- **System Software -** The system software includes a user interface which displays information on the liquid crystal display (LCD) screen and is directed by the user via the keypad, data analysis functions, and a database for storing User ID and pH test results information.

- **Communication Capability -** The instrument provides the following connection ports for data transfer with external devices:

    - Bar Code Scanner port, for data entry of bar-coded platelet storage bag ID and User ID information.
    - Keypad, for data entry of platelet storage bag ID and User ID information and menu navigation.
    - RS-232 Serial port, for output of results data to a Printer, or for upload of results data to an external personal computer (PC) or laboratory information system (LIS).
    - Ethernet port, for upload of results to an external PC or LIS.

Bar Code Scanner

A handheld **Bar Code Scanner** device may be used to enter platelet bag ID and User ID information from bar codes. The Bar Code Scanner will be provided with the **pH SAFE Reader** if appropriate for use in your facility.

The Bar Code Scanner is pre-configured to identify the ISBT 128 platelet storage bag ID character format and User ID bar code symbologies.

The Bar Code Scanner is connected to the Bar Code Scanner port provided on the back panel of the instrument. The Bar Code Scanner is continuously powered via the Bar Code Scanner port, but the instrument will only accept data sent by the Bar Code Scanner at certain times during the measurement procedure.

Printer

An optional Citizen iDP-3110 Printer can be connected to the RS-232 Serial port to generate a printed results report containing pH results for one or more tested platelet storage bags.

2.3   Specifications

Dimensions	L x W x H 35 cm x 39.5 cm x 11 cm (13.8 in x 15.5 in x 4.3 in)
Weight	2.35 kg (5.2 lbs)
External Connections	• PS2, for Bar Code Scanner • RS-232 DB-9 (male), for serial communication • Ethernet
Power Requirements (AC Power Adapter)	Input power to power adapter: • 100 - 240V AC, 50 - 60Hz, 0.6A max, 15W max • Main supply voltage fluctuations must not exceed ± 10% of nominal value • Transient over voltages typically present on the main supply is expected to be impulse withstand (over voltage) category II of IEC 60364-4-443 Adapter output power: 9V DC, 1.7A max *(NOTE*: Input connectors are available for: Continental Europe, the United Kingdom, North America and Australia)
Operating Temperature Range	5 - 40°C (41 - 104°F)
Operating Humidity Range	5 – 80% relative humidity, non-condensing
Operating Altitude	Maximum altitude 2000 m (6562 ft)
Pollution Degree Classification	Pollution Degree 2
Operating Environment	The instrument is intended for indoor use only
Transport and Storage Conditions	Temperature: -10 - 50ºC (14 - 122ºF) Humidity: 5 - 98% relative humidity, non-condensing Atmospheric pressure: 50 kPa - 106 kPa (0.5 atm - 1 atm)
Keypad	10 character alphanumeric keys 2 special function keys
Display	2 line by 20 character Liquid Crystal Display (LCD)

Compliance with Standards	The **pH SAFE Reader** is in compliance with medical device equipment operation requirements as specified in the following regulatory standards documents:
	• CAN/CSA-C22.2 No. 61010-1-04 - Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
	• UL Std. No. 61010-1 - Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
	• IEC 61010-1 - Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
	• EN 61010-1 - Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
	• CAN/CSA-C22.2 No. 61010-2-101-04 - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
	• IEC 61010-2-101 - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
	• EN 61010-2-101 - Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
	• EN 61326-1 - Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements

3 Unpacking and Installation

3.1 Unpacking

The **pH SAFE Reader** is shipped in one (1) box, as follows

Box 1 contains:

* 1 - **pH SAFE Reader** (Model: BCSI pH1000)
* 1 - pH SAFE QC Standard
* 1 - Instrument power adapter
* 1 - Ethernet cable
* 1 - Instrument to printer serial cable
* 1 - **pH SAFE Reader** *Operator Manual*
* 1 - **pH SAFE Reader** *Quick Reference Guides*
* 1 - Bar code scanner box, containing: the Bar Code Scanner and the Bar Code Scanner *User's Manual.*

If the optional Printer is purchased, a second box will also be shipped.

Box 2 contains:

* 1 - Printer box, containing: the Printer, the printer power adapter, printer paper, ink ribbon, and the printer *User's Manual.*
* 1 - Serial cable adapter

After unpacking all components, save the packaging materials and boxes for reuse in the unlikely event that it is necessary to return any damaged components.

3.2 Hardware Installation

3.2.1 Materials Required

1 - **pH SAFE Reader** and power adapter

1 - Printer and power adapter (optional)

1 - Bar code scanner

1 - Instrument to printer serial cable and adapter (optional)

1 - Ethernet cable

3.2.2   Procedure

Refer to the figure below and perform the following steps:
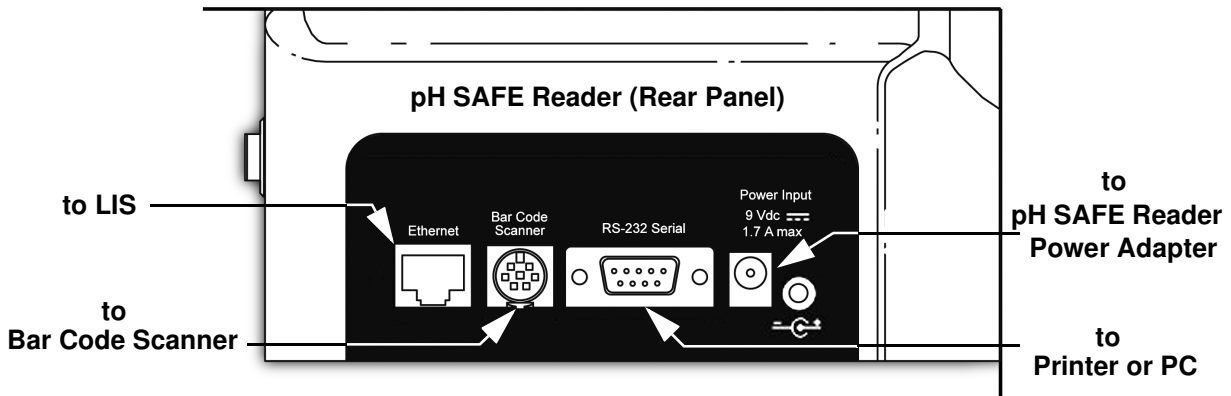
Figure 3-1   Hardware Connections

1. Position the **pH SAFE Reader** so that the power adapter(s) can be quickly disconnected from the facility AC power source if necessary in the unlikely event of an electrical fire.

CAUTION: Use only the supplied power adapters for the **pH SAFE Reader** and the (optional) Printer device.
DO NOT interchange for use the **pH SAFE Reader** and Printer AC power adapters. Always ensure the proper AC power adapter is used for each device. Failure to do so may result in damage to the instrument and/or the Printer.

2. Connect the instrument power adapter to the **Power Input** port on the back panel of the instrument and to the facility AC power source.

3. If the Bar Code Scanner will be used, connect the Bar Code Scanner to the **Bar Code Scanner** port of the instrument.

4. If the optional Printer will be used, connect the Printer to the **RS-232 Serial** port of the instrument using an RS-232 cable. Connect the Printer power adapter to the Printer and to the facility AC power source.

5. If an Ethernet connection will be used, connect an Ethernet cable from the external PC, or Ethernet drop wall jack, to the **Ethernet** port of the instrument.

3.3   Software Setup

3.3.1   Configure *pH SAFE Reader* Options

Before using the **pH SAFE Reader**, configure the System Settings parameters as desired. Refer to Section 6.5, System Settings.

4   Using the *pH SAFE Reader* Software

4.1   Overview
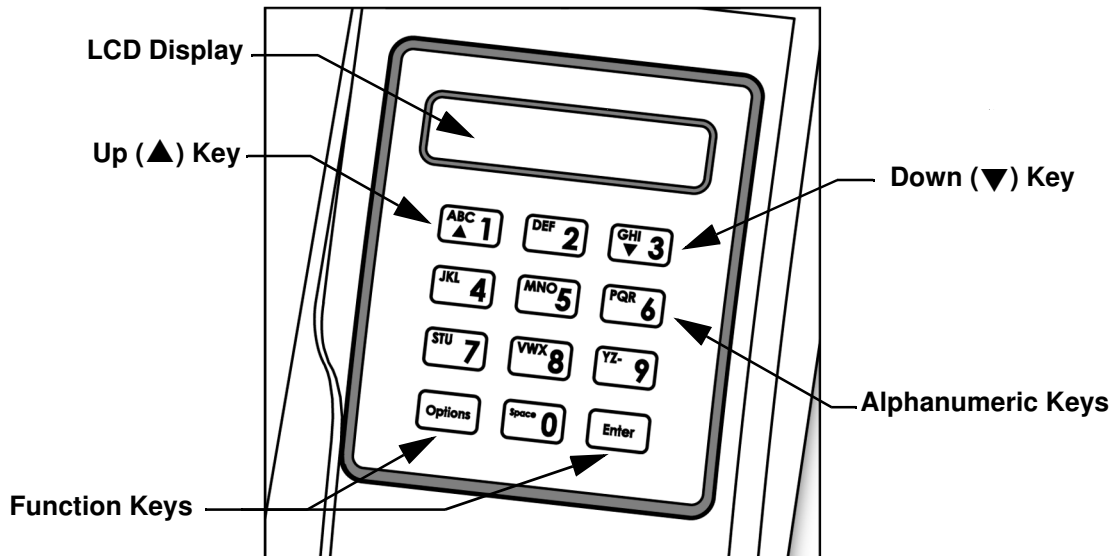
Figure 4-1   pH SAFE Reader Screen and Keypad

From the **pH SAFE Reader** the user observes information displayed on the LCD screen and manipulates the **pH SAFE Reader** software functions using the keypad. Additionally, at appropriate times during the testing process, the user may use the Bar Code Scanner to input platelet storage bag ID and User ID information if desired.

The LCD screen displays current software function status information and updates automatically to report: function progress/completion, and response to input by the user from either the keypad or the Bar Code Scanner.

4.1.1   Power-On Self Check (SELF-CHK)

Whenever power is applied to the instrument using the ON/OFF switch (located on the right side panel of the instrument, Figure 2-2) the software executes a startup sequence, the Power-On Self Check (SELF-CHK). This automatic test completes in 5 seconds. During SELF-CHK the keypad is inactive. The sequence of the SELF-CHK is as follows:
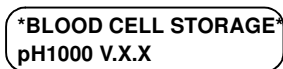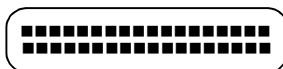
1.   First the LCD screen pixels are exercised. All screen pixels are turned on for one second. The screen should display two rows of 20 black squares indicating all pixels are functioning in each character block.

2.   Next the LCD screen updates to display the Software Version information while concurrently the software initializes the internal photometer hardware components and performs a series of function tests to verify system performance. (Refer to Appendix A for a full description of the SELF-CHK test process, SELF-CHK error conditions, and SELF-CHK error recovery procedures.)

3. After the SELF-CHK procedure is complete the LCD screen updates to the Ethernet setup screen. During Ethernet setup the instrument verifies that the Ethernet module is functioning and synchronizes stored data.

When Ethernet setup is successfully concluded the LCD screen updates to display the **Run/Options** prompt. Use of the **Run/Options** prompt is described next.

4.1.2   Run / Options Prompt

> RUN TEST: <Enter>
> OPTIONS: <Options>

Whenever the **Run/Options** prompt is displayed on the LCD screen, the instrument is in an <u>idle state</u> awaiting direction from the user.

From this screen the user may access the following functions:

Run Test - From the **Run/Options** prompt, when the **<Enter>** key is pressed the instrument begins a pH measurement test. The LCD screen updates to display a prompt to begin the measurement process. The **Run Test** process is fully described in Chapter 5, Run Test Operation.

Options Menu - From the **Run/Options** prompt, when the **<Options>** key is pressed the instrument enters the **Options Menu**. The **Options Menu** provides access to a list of functions used to review/print results records and configure system operation parameters. The LCD screen updates to display access to the first function available from the menu. Use of the **Options Menu** functions is fully described in Chapter 6, Using the Options Menu.

Automatic Results Upload

The system may be configured to automatically transfer results data to an external computer or LIS via an Ethernet connection. If Ethernet communication is setup from the **Options/System Settings/Ethernet Setup** menu, the external computer or LIS can be configured to automatically upload the test results stored in the instrument memory at periodic intervals. All instrument functions behave normally when test results are being uploaded via Ethernet except in the case where a new measurement test result is ready to be saved. In this case the instrument will pause until the upload is complete (typically the pause will be less than 2-3 seconds) before saving the latest test result in the instrument memory. (Refer to Section 6.5.8, Ethernet Setup.)

Alternatively results may be uploaded to an external computer or LIS by output through the serial port. (Refer to Appendix B, Serial Port Results Upload, for complete information.)

4.1.3   Power Down

To turn off the **pH SAFE Reader** ensure all testing or test uploading process are complete, return to the **Run/Options** prompt, and toggle the ON/OFF switch located on the right side panel of the instrument.

4.2   Keypad Usage

The keypad consists of ten **alphanumeric** character keys, **<0>** - **<9>**, and two **Function** keys, **<Options>** and **<Enter>**.

The alphanumeric keys are used to enter User ID/PIN, Supervisor PIN, and platelet storage bag ID information as needed.

The function keys are used to navigate through the software and manipulate the use of functions.
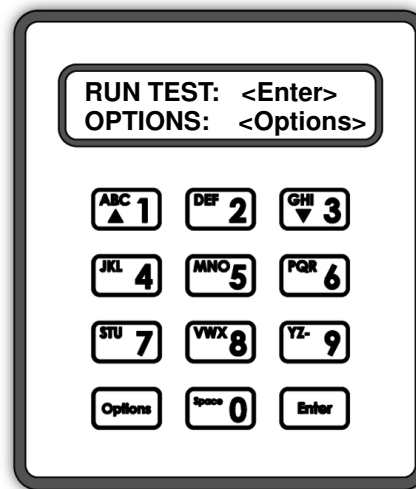
Entering Alphanumeric Characters

The **alphanumeric** keys are used to input a sequence of number and/or letter characters when entering User ID/PIN, Supervisor PIN, or platelet storage bag ID information.

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.

When the desired character is displayed, press a different alphanumeric key (other than the key initially pressed) to accept the first character and move the cursor one character position to the right for entry of the next desired character.

Alternatively, once the first desired character is displayed, wait, and after a two-second delay the displayed character is accepted automatically and the cursor moves one space to the right. This provides a means of entering double-letters or double-digits.

Pressing the **<Options>** key causes the character currently displayed to be erased and the cursor to move one space to the left. This provides a backspace or correction function.

If either the **<Options>** or **<Enter>** key is pressed when no characters are shown on the display, the test is aborted and the system returns to the **Run/Options** prompt.

Scrolling Menu Lists
Up Arrow

Down Arrow

At several points when using the software a menu of several function choices is provided. The two line LCD display displays only one menu item at a time. To scroll the display through choices available from a menu, use the **Up Arrow** key **<ABC 1>** and the **Down Arrow** key **<GHI 3>** as necessary.

When a particular function is displayed on the screen, press the **<Enter>** key to access use of that function.

Exit a Menu or Cancel a Function

<Options>

To exit from a menu list or cancel use of a selected function press the **<Options>** key. The system returns to either a previous menu list screen or to the **Run/Options** prompt, as appropriate.

4.3   Bar Code Scanner Usage

The Bar Code Scanner supplied with the instrument has been specially programmed to recognize the ISBT 128 standard barcodes. It will trim the User ID, Bag ID and pH ID to report only the eye readable text from the bar code. Also if an ISBT 128 bar code that is not a User ID, Bag ID or pH ID is scanned it will alert the **pH SAFE Reader** that an incorrect bar code has been scanned.

In the **Run Test** function of the **pH SAFE Reader**, two additional functional bar codes are recognized by the specially programmed bar code scanner so that when the **ENTER** or **OPTIONS** codes below are scanned the instrument will proceed as if the **<Enter>** or **<Options>** key were pressed. This functionality is provided so the bar code reader alone can be used in the course of running a normal pH test. Adhesive labels with these two codes on them are also provided for convenience.

ENTER   OPTIONS

4.4   Software Security

The software may be configured to allow or restrict user access to the **Run Test** and/or the **Options/System Settings** functions as desired.

4.4.1   Security Access to 'Run Test'

Security procedures required to access the **Run Test** function are specified by the current setting of the **Options / System Settings / Enable User ID/PIN** parameter.

Three security access settings are available for definition of the **Options / System Settings / Enable User ID/PIN** parameter:

1.   **DISABLE ID & PIN -** Security features are off with this setting. Access to the **Run Test** function is unrestricted. Any user may access the **Run Test** function. No User ID information is stored with pH test results.

2.   **ENABLE ID ONLY -** Security features are at a minimum with this setting. The user is required to input a User ID before accessing the **Run Test** function. The User ID may be selected from a list of previously stored User IDs, or a new User ID may be input using the keypad or Bar Code Scanner. The User ID information is reported and stored with the pH test results.

3.   **ENABLE ID & PIN -** Security features are at a maximum with this setting. The user is required to input a stored User ID and PIN (Personal Identification Number) value before accessing the **Run Test** function. The PIN value must

be recognized by the software as a valid PIN assigned to the previously defined User ID stored in the instrument memory. The User ID information is reported and stored with the pH test results. Up to eight (8) User IDs and PIN values may be defined and stored.

Refer to Section 6.5.4, Enable User ID and PIN, for complete procedural information about configuration of this parameter setting.

4.4.2 Security Access to 'Options / System Settings'

Security access to the **Options / System Settings** functions is specified by the current setting of the **Options / System Settings / Supervisor PIN** parameter.

When the **Supervisor PIN** value is disabled or the value is left undefined, set to **00000** (five zeros), access to the **System Settings** functions is unrestricted. Any user may access the **System Settings** functions.

When the **Supervisor PIN** value is enabled and defined, by input of a sequence of 5 digits, the user is required to input this PIN value before accessing the **System Settings** functions. The PIN value must be recognized by the software as the valid **Supervisor PIN** value previously defined and stored in the instrument memory.

Refer to Section 6.5.2, Supervisor PIN, for complete procedural information about configuration of this parameter setting.

5   Run Test Operation

5.1   Overview

From the **Run/Options** prompt, press the **<Enter>** key to begin a pH measurement test for a platelet storage bag.

Next, the software displays a series of prompts to guide the user through the test process. The sequence of steps to perform a pH measurement test are as follows:

Security Access

Enter Platelet Storage Bag ID

Enter pHID

Measure pH

Save/Print Test Results

Automatic Ethernet Results Upload

These steps are described in detail in the following sections.

5.2   Security Access

When the **<Enter>** key is pressed from the **Run/Options** prompt to access the **Run Test** function the first prompt displayed will vary, depending on the currently defined security access setting of the instrument. (Refer to Section 4.4.1, Security Access to 'Run Test', and Section 6.5.4, Enable User ID and PIN.)

Three security access settings are available for definition of the **Options / System Settings / Enable User ID/PIN** parameter. The software functions as follows for each parameter setting:

DISABLE ID & PIN - When this setting is selected, no security access prompt is displayed. Proceed to Section 5.3, Enter Platelet Storage Bag ID.

ENABLE ID ONLY - When this setting is selected the user is required to input a User ID before accessing the **Run Test** function. Proceed to Section 5.2.1, Select/Enter User ID.

ENABLE ID & PIN - When this setting is selected the user is required to input a User PIN before accessing the **Run Test** function. Proceed to Section 5.2.2, Enter User PIN.

5.2.1   Select/Enter User ID

If the currently defined setting of the **Options / System Settings / Enable User ID/PIN** parameter is specified as **ENABLE ID ONLY,** the first prompt displayed when the **Run Test** function is accessed will be:

```
> SELECT USER ID
  ENTER USER ID
```

From this screen the user may choose to either:

• Select a User ID from the list of current users stored in the instrument memory.

• Enter a User ID for use with this test via the keypad or by using the Bar Code Scanner.

Use the **Down Arrow** key or the **Up Arrow** key as necessary to move the cursor (**>**) down or up, to select the desired method of User ID entry, then press the **<Enter>** key to select use of this method.

Select User ID

User ID definitions for up to eight (8) users may be previously defined and stored in the instrument memory using the **Options** / **System Settings** / **Edit User ID** function. (Refer to Section 6.5.5, Edit User ID/PIN.) To select a User ID from the list of users currently stored in the instrument memory proceed as follows:

1. From the **Select User ID/Enter User ID** prompt, ensure the cursor (**>**) is positioned on the upper line pointing to **Select User ID,** then press the **<Enter>** key. The screen updates to display the following prompt:

> **SELECT USER ID:**
> **#. User Name**

Where **#. User Name** on the lower line indicates the most recently accessed User ID stored in the User List.

NOTE: The default User ID definitions contained in the list are **USER1** - **USER8**. Refer to Section 6.5.5, Edit User ID/PIN, for complete information about editing User ID definitions in the User List.

2. If the User ID information displayed on the lower line is correct, press the **<Enter>** key to continue.

3. To select a different User ID, use the **Up**/**Down Arrow** keys to scroll the list as necessary. When the correct User ID is displayed on the lower line, press the **<Enter>** key to continue.

The screen updates to display the **Enter Bag ID** prompt. Proceed to Section 5.3, Enter Platelet Storage Bag ID.

Enter User ID

Alternatively, the User ID may be input using the keypad or Bar Code Scanner. To enter a User ID for use with this pH measurement test, proceed as follows.

1. From the **Select User ID/Enter User ID** prompt, ensure the cursor (**>**) is positioned on the lower line pointing to **Enter User ID,** then press the **<Enter>** key. The screen updates to display the following prompt:

> **ENTER USER ID:**
> _

Enter the appropriate User ID information by either using the keypad (proceed to step 2), or by using the Bar Code Scanner (proceed to step 3).

Keypad

2. Using the keypad, enter any combination of up to eleven (11) alphanumeric characters, then press the **<Enter>** key to continue.

NOTE: The User ID may not begin with a **<Space>** character.

When entering User ID information the **<Options>** key may be used as a backspace/correction key. Pressing the **<Options>** key with no User ID information entered causes the display to return to the **Run/Options** prompt.

Bar Code Scanner 3. Use the Bar Code Scanner to input User ID data from a bar code. When acceptable data is received from the Bar Code Scanner, any characters previously entered via the keypad are deleted from the screen and replaced by the bar-coded User ID information

ERROR: If the Bar Code Scanner reads an ISBT standard bar code that is not a User ID, the following message is briefly displayed:

```
ID SCAN ERROR
PLEASE RESCAN
```

Next, the screen returns to the **Enter User ID** prompt.

NOTE: When entering User ID information from the Bar Code Scanner, the **<Options>** key may be used as a delete key after a scanned User ID is displayed. The screen returns to the **Enter User ID** prompt.

When the appropriate User ID information has been entered via either the keypad or the Bar Code Scanner, the screen updates to display the **Enter Bag ID** prompt. Proceed to Section 5.3, Enter Platelet Storage Bag ID.

5.2.2   Enter User PIN

No User Currently Logged On

If the currently defined setting of the **Options / System Settings / Enable User ID/PIN** parameter is specified as **ENABLE ID & PIN,** and no user is currently "logged on," the first prompt displayed when the **Run Test** function is accessed will be:

```
ENTER USER PIN:
_       ***************
```

Proceed as follows:

1. Using the keypad, enter your previously defined 1-5 digit numeric PIN value. (Refer to Section 4.4.1, Security Access to 'Run Test', and Section 6.5.4, Enable User ID and PIN. for more information about PIN value definition procedures and requirements.)

2. When the correct PIN value is displayed on the screen press the **<Enter>** key to continue.

NOTE: Bar code scanning is disabled during PIN entry.

When entering a PIN, the keypad function is restricted to numeric data entry only (alphabetic character functions are disabled). When typing the PIN, the digits are hidden and indicated as "X"s on screen.

The **<Options>** key may be used as a backspace or correction key. Pressing the **<Options>** key with no digits entered causes the display to return to the **Run/Options** prompt.

3. When a correct PIN value has been entered, the screen updates to display the **Enter Bag ID** prompt. Proceed to Section 5.3, Enter Platelet Storage Bag ID.

NOTE: This user is now "logged on." A user remains logged on until either: a) the user logs out via the **Options Menu** (refer to Section 6.2, Log

Off User).
b) the user does not initiate another test within 5 minutes.
c) another user logs on via the User ID confirmation screen
(as described subsequently in the User Currently Logged On topic)

4. If the PIN associated with the specified user does not match any PIN currently stored in the instrument memory, the following screen is displayed:

> PIN IS INCORRECT!
> PRESS KEY TO PROCEED

Upon pressing any key, the display returns to the **Run/Options** prompt.

User Currently Logged On

When an user is currently logged on and the **<Enter>** key is pressed from the **Run/Options** prompt to begin another pH measurement test, the screen displays a User ID confirmation prompt, e.g.:

> You are user   >YES
> "MAP" ?   NO

From this screen proceed as follows:

1. If the User ID shown on the lower line is correct, press the **<Enter>** key to continue. The screen updates to display the **Enter Bag ID** prompt. Proceed to Section 5.3, Enter Platelet Storage Bag ID.

2. If the User ID shown on the lower line is incorrect, use the **Down Arrow** key to move the cursor (**>**) down to select **>NO**, then press the **<Enter>** key.

3. The instrument will log off the current user and display the following screen:

> ENTER USER PIN:
> _***************

From this screen proceed as described in the previous topic, No User Currently Logged ON.

5.3   Enter Platelet Storage Bag ID

After initiation of a pH measurement test for a platelet storage bag, the screen updates to display the following prompt:

> ENTER BAG ID:
> _

Enter the appropriate platelet storage bag ID information by using either the keypad (proceed to step 1) or the Bar Code Scanner (proceed to step 2).

Keypad

1. Using the keypad, enter any combination of up to twenty (20) alphanumeric characters, then press the **<Enter>** key to continue.

NOTE: When entering platelet storage bag ID information the **<Options>** key may be used as a backspace/correction key. Pressing the **<Options>** key with no platelet storage bag ID information entered causes the display to return to the **Run/Options** prompt.

Bar Code Scanner

2. Use the Bar Code Scanner to input platelet storage bag ID data from a bar code. When acceptable data is received from the Bar Code Scanner, any

characters previously entered via the keypad are deleted from the screen and replaced by the bar-coded platelet storage bag ID information.

ERROR: If the Bar Code Scanner reads an ISBT standard bar code that is not a platelet storage bag ID, the following message is briefly displayed:

> **BAG ID SCAN ERROR**
> **PLEASE RESCAN**

Next, the screen returns to the **Enter Bag ID** prompt.

When the appropriate platelet storage bag ID information has been entered via either the keypad or the Bar Code Scanner, the screen updates to display the **Enter pH ID** prompt. Proceed to Section 5.4, Enter pHID.

5.4   Enter pHID

After entering the platelet storage bag ID the screen will update to display the following prompt:

> **ENTER PHID:**
> **_ *****************

Enter the appropriate pHID information by using either the keypad (proceed to step 1) or the Bar Code Scanner (proceed to step 2).

Keypad

1. Using the keypad, enter the designated (5) alphanumeric characters, then press the **<Enter>** key to continue.

NOTE: When entering pHID information the **<Options>** key may be used as a backspace/correction key. Pressing the **<Options>** key with no pH ID information entered causes the display to return to the **Run/Options** prompt.

Bar Code Scanner

2. Use the Bar Code Scanner to input pHID data from a bar code. When acceptable data is received from the Bar Code Scanner, any characters previously entered via the keypad are deleted from the screen and replaced by the bar-coded pHID information.

ERROR: If the Bar Code Scanner reads an ISBT standard bar code that is not a pHID, the following message is briefly displayed:

> **PHID SCAN ERROR**
> **PLEASE RESCAN**

Next, the screen returns to the **Enter pHID** prompt.

NOTE: When the Bar Code Scanner is used to enter pHID information, the **<Options>** key may be used to delete the displayed pHID entry. The screen will return to the **Enter Bag ID** prompt.

A pHID must be entered before a measurement will be carried out. The menu will return to the **Enter Bag ID** prompt if an improper value for the pHID is entered.

When the appropriate pHID information has been entered via either the keypad or the Bar Code Scanner, the screen will update to display the entered values. The user should check the displayed values and confirm they match the values from the bag label. After confirmation, press the **<Enter>** key to continue.

If a pHID has not been programmed into the instrument a warning will be displayed. Please contact technical support to enable the appropriate pHID.

Next, the screen will advance to display the **Read pH** prompt. Proceed to Section 5.5, Read pH.

5.5   Read pH

Following the entry of the necessary identification information for the pH measurement test of a platelet storage bag, the screen will display the following prompt:

```
READ pH: <Enter>
ABORT:    <Options>
```

Proceed as follows:

3.   Refer to Figure 5-1. Place the platelet storage bag onto the instrument measurement platform and insert the Fiber Optic Probe of the instrument into the opening at the top of the pH SAFE Sensor of the bag.
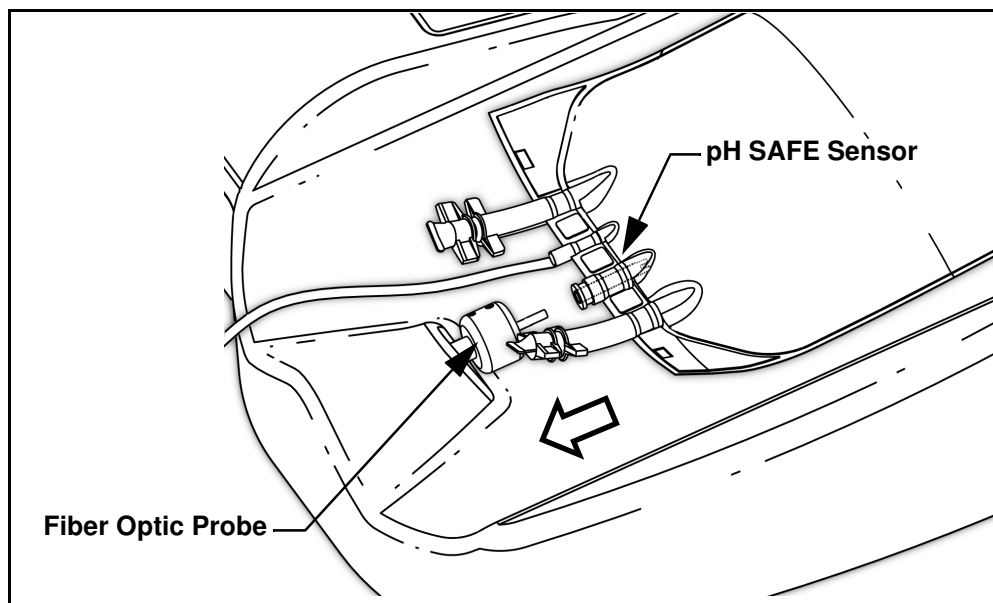
Figure 5-1   Insert Fiber Optic Probe into pH SAFE Sensor

4.   Slide the pH SAFE Sensor of the platelet storage bag onto the pH SAFE Reader Fiber Optic Probe until it snaps into place at the top of the sensor. Ensure sensor is aligned with probe on reader. Avoid scraping the sensor on the probe. When the test is successfully completed the screen updates to display the platelet storage bag ID and the calculated pH test result, for example:

```
ID:   ST13578A004MT
pH:  6.87
```

5.   From this screen, press any key to continue and display the Save/Print/ Discard Result menu. Proceed to Section 5.6, Save/Print Test Results.

NOTE: If the measured pH value is higher than the instrument measurement range the instrument will report the result as pH > 7.8.

If the measured pH value is lower than the instrument measurement range the instrument will report the result as pH < 6.2.

ERROR: If the instrument detects an error during the pH measurement process an error message is displayed:

> **MEASUREMENT ERROR!**
> **PRESS A KEY....**

At 2 second intervals the upper line of the display alternates to display the **MEASUREMENT ERROR!** message and a description of the fault, as follows:

Error message displayed	Meaning
LOW REF SIGNAL	The calculated mean of the signal data values collected from the reference channel is to low.
HIGH REF SIGNAL	The calculated mean of the signal data values collected from the reference channel is too high.
LOW PH SIGNAL	The calculated mean of the signal data values collected from the pH channel is to low.
HIGH PH SIGNAL	The calculated mean of the signal data values collected from the pH channel is too high.
LOW RATIO	The calculated fluorescence ratio between the two channels is too low.
HIGH RATIO	The calculated fluorescence ratio between the two channels is too high.

From the error message screen, press any key to return to the **Run/Options** prompt. The measurement result data for this test is not stored.

5.6   Save/Print Test Results

Upon conclusion of a successful pH measurement test, the instrument provides the user with options to save, print, or discard the results data for this test. From the test result screen

> **ID: ST13578A004MT**
> **pH: 6.87**

Press any key to continue. The screen updates to display the Results menu, with the first option in the menu displayed on the lower line:

> **SELECT OPTION:**
> **1. SAVE pH**

There are four options available from this menu:

1. SAVE pH

2. PRINT pH

3. SAVE & PRINT pH

4. DISCARD RESULT

Proceed as follows:

1. From the Result menu, use the **Up** / **Down Arrow** keys as necessary to scroll the list until the desired option is displayed on the lower line of the screen.

2. When the desired option is displayed, press the **<Enter>** key. The instrument performs the function and returns to the **Run/Options** prompt.

The use of these options is described in detail in the following subsections.

5.6.1   Save pH

> **SELECT OPTION:**
> **1. SAVE pH**

Use this option to save the test result for this platelet storage bag in the instrument memory. Up to 100 results may be stored. Stored results may be reviewed, printed or uploaded to an external computer or LIS at a later time.

When the **<Enter>** key is pressed to select use of this option, the screen updates to briefly display a message similar to the following example:

> **RECORD # 8 SAVED**
> **RECORDS AVAIL.: 92**

The upper line indicates which memory slot the test result has been recorded to. The lower line indicates the number of memory locations remaining for additional test results. In the above example, 92 additional measurements can be performed and saved before the memory is full. After displaying the above screen for approximately two seconds, the screen returns to the **Run/Options** prompt.

Memory Full

In the event that the last record space is utilized in the instrument memory when a result is saved, the screen briefly displays the following additional warning message, before returning to the **Run/Options** prompt:

> **RECORD # 100 SAVED**
> **MEMORY NOW FULL!**

ERROR: If, after a subsequent test the **SAVE pH** or **SAVE & PRINT pH** option is selected with no record space available, the test result is not saved and the following error message is displayed:

> **ERROR MEMORY FULL!**
> **PRESS A KEY. . .**

From this error screen when any key is pressed, the test result screen is re-displayed:

> **ID: ST13578A004MT**
> **pH: 6.87**

This allows the user to review and possibly write down the result. From this screen press any key to return to the Results menu.

> **SELECT OPTION:**
> **1. SAVE pH**

NOTE: To erase results from the instrument memory, in order to make room for storing new results, use the **Options/View Results** function to erase results one at a time (refer to Section 6.3, View Records), or use the

Options/System Settings/Erase Memory function to erase all results currently stored in the instrument memory (refer to Section 6.5.6, Erase Memory).

5.6.2   Print pH

> SELECT OPTION:
> 2. PRINT pH

Use this option to output the test result to a Printer (or other receiving device, see *Note*: below) connected to the RS-232 Serial port of the instrument. The result is <u>not</u> <u>stored</u> in the instrument memory.

When the **<Enter>** key is pressed to select use of this option, the screen updates to briefly display the following message:

> OUTPUTTING
> TEST RECORD

The data output from the serial port will be in the format illustrated in the following example:
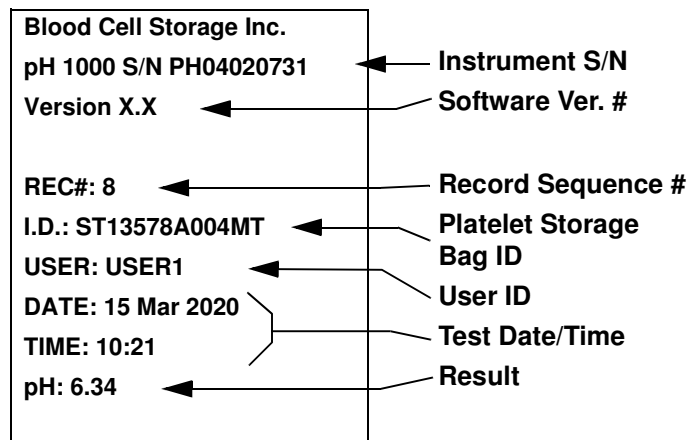
Figure 5-2   pH Result Printout

When the serial output has completed the screen briefly displays the following message:

> OUTPUT COMPLETED

After displaying this message for approximately two seconds, the screen returns to the **Run/Options** prompt.

NOTE: The RS-232 Serial port hardware and corresponding firmware of the **BCSI pH1000** are designed to operate with a CBM Citizen model iDP-3110 serial Printer. Alternatively, the instrument's RS-232 Serial port may be connected to a COM Port of an external computer using a suitable RS-232 cable. The results output produced by the **BCSI pH1000** can then be received using the Windows® HyperTerminal application, or other serial data communication application. Refer to Appendix A for complete information about serial communication configuration requirements for this usage.

Printer Off-line   Upon initiating data output via the RS-232 Serial port, the instrument monitors the port for a communication response signal from the receiving device (Printer or external computer).

ERROR: If a receiving device is not detected after 4 seconds, the instrument sounds an alarm tone and displays the following error message:

```
********** ERROR! **********
PRINTER PORT OFF-LINE
```

After displaying this message for approximately four seconds, the screen returns to the test result screen:

```
ID:   ST13578A004MT
pH:  6.87
```

From this screen press any key to again enter the Results menu.

```
SELECT OPTION:
1. SAVE pH
```

Verify that the Printer/receiving device is turned on and properly connected to the **BCSI pH1000** before attempting to output the result a second time.

5.6.3   Save & Print pH

```
SELECT OPTION:
3. SAVE & PRINT pH
```

Use this option to output the test result to a Printer/receiving device and also save the result in the instrument memory.

When the **<Enter>** key is pressed to select use of this option, the screen updates to briefly display a message similar to the following example:

```
RECORD #  8 SAVED
RECORDS AVAIL.:  92
```

This function proceeds in the same manner described in Section 5.6.1, Save pH.

Additionally, after the result is saved but before the screen returns to the **Run/Options** prompt, the instrument outputs the result via the serial port to a connected Printer/receiving device. This function proceeds in the same manner described in Section 5.6.2, Print pH.

5.6.4   Discard Result

```
SELECT OPTION:
4. DISCARD RESULT
```

Use this option to discard the test result. When the **<Enter>** key is pressed to select use of this option, the screen discards the result information and returns to the **Run/Options** prompt. The result is not stored in the instrument memory.

5.7   Automatic Ethernet Results Upload

If Ethernet communication is setup from the **Options/System Settings/Ethernet Setup** menu (see Section 6.5.8, Ethernet Setup), at periodic intervals an external computer or LIS can download all results currently stored in the instrument memory.

All instrument functions behave normally when test results are being uploaded via Ethernet except in the case where a new measurement test result is ready to be saved. In this case the instrument will pause until the upload is complete and display the following message:

```
ETHERNET TRANSFER IN
PROGRESS . . . . . . . . . . .
```

After the pause (typically less than 2-3 seconds) the latest test result will be saved to the instrument memory.

NOTE: After the data transfer is completed these results are automatically deleted from the instrument memory.

If the data transfer is initiated while the user is in the **Options** menu, the stored results will not be deleted until the system returns to the **Run/Options** prompt.

6   Using the Options Menu

6.1   Overview

The **Options Menu** provides access to a list of functions used to review/print results records and configure system operation parameters.

From the **Run/Options** prompt, press the **<Options>** key to enter the **Options Menu**. The screen updates to display access to the first function available from the menu on the lower line of the screen.

```
*** OPTIONS MENU ***
1.   LOG OFF USER
```

The following functions are available from the **Options Menu**:

1.   **LOG OFF USER**
2.   **VIEW RECORDS**
3.   **OUTPUT RECORDS**
4.   **SYSTEM SETTINGS**
5.   **RUN QC TEST**
6.   **EXIT OPTIONS**

Proceed as follows:

1.   From the **Options Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the desired option is displayed on the lower line of the screen.

2.   When the desired option is displayed, press the **<Enter>** key to access the use of this function.

3.   To return to the **Run/Options** prompt from the **Options Menu**, press the **<Options>** key.

Use of these functions is described in detail in the subsequent sections.

6.2   Log Off User

```
*** OPTIONS MENU ***
1.   LOG OFF USER
```

Use this function to log out as the active user, if you have previously logged in using a User PIN value when beginning a pH test measurement (refer to Section 5.2.1, Select/Enter User ID).

Proceed as follows.

1.   From the **Options Menu** screen, use the **Up / Down Arrow** keys (if necessary) to scroll the list until the **1. LOG OFF USER** option is displayed on the lower line of the screen.

2.   Press the **<Enter>** key to select use of this function. The instrument will log off the currently active user. The following message is briefly displayed:

```
USER LOGGED OFF
```

After displaying this message for approximately two seconds, the screen returns to the **Options Menu**.

6.3   View Records

```
*** OPTIONS MENU ***
2.    VIEW RECORDS
```

Use this function to review/print/delete individual results stored in the instrument memory.

Proceed as follows.

1. From the **Run/Options** prompt, press the **<Options>** key to enter the **Options Menu**. The screen updates to display access to the first function available from the menu on the lower line of the screen.

2. From the **Options Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **2. VIEW RECORDS** option is displayed on the lower line of the screen.

3. Press the **<Enter>** key to select use of this function. Proceed to Section 6.3.1, pH Test Results List.

NOTE: If there are no test results stored in the instrument memory, the instrument emits an alarm tone and displays the following message:

```
NO TEST RECORDS IN
MEMORY! PUSH A KEY
```

After any key is pressed, the screen returns to the **Options Menu**.

6.3.1   pH Test Results List

4. When the **Options/View Records** function is selected the screen updates to display the list of currently stored pH measurement test results. The most recently stored record in the list is displayed:

```
TEST RECORD #  8
ID:  ST13578A004MT
```

The top line indicates the sequence number of the stored result record. The lower line indicates the platelet storage bag ID associated with the stored result. The instrument memory can store up to 100 pH test results.

5. Use the **Down/Up Arrow** keys to scroll through the list of all stored records. When the desired record is displayed press the **<Enter>** key to view results for this platelet storage bag. The screen updates to display the first line of result information for this platelet storage bag on the lower line:

```
ID:  ST13578A004MT
pH:  6.34                ◄──────  Test Result
```

6. Press the **<Enter>** key, two more times, to scroll through the result information stored for this platelet storage bag:

> pH: 6.34
> 15 Mar 2012 - 10:21 ◄───── **Test Date/Time**

> USER ID: USER1 ◄───── **User ID**

Proceed to Section 6.3.2, Print Record?.

NOTE: To cancel the review of this record and return to the list of pH test results records press the **<Options>** key.

6.3.2   Print Record?

7. Press the **<Enter>** key again to continue. The following prompt is displayed:

> PRINT RECORD?> NO
>   YES

From this screen proceed as follows:

a. If you do not wish to print a copy of the record, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen updates as follows:

  - If the current setting of the **Options/System Settings/Enable User ID/ PIN** parameter is set to '**Enable User ID and PIN**', and the current user's PIN does not match the Supervisor PIN the screen returns to the list of pH test results records. If the current user PIN does match the Supervisor PIN, the **Delete Record?** prompt is displayed. Proceed to Section 6.3.3, Delete Record?.

  - If the current setting of the **Options/System Settings/Enable User ID/ PIN** parameter is set to <u>either</u>: '**Disable User ID and PIN**' or '**Enable User ID Only**', next the screen displays the **Delete Record?** prompt. Proceed to Section 6.3.3, Delete Record?.

b. If you do wish to print a copy of the record, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The instrument will output the result to the Printer or other receiving device connected to the RS-232 Serial port. (An example of a pH test result report is illustrated in Figure 5-2.)
   When the result output is completed the screen will return to the **Print Record?** prompt.

Printer Off-line   *ERROR:* If a receiving device is not connected, the instrument sounds an alarm tone and briefly displays the following error message:

> ********** ERROR! **********
> PRINTER PORT OFF-LINE

Next, the screen will return to the **Print Record?** prompt.

6.3.3   Delete Record?

8. If appropriate, according to the current security access configuration of the **Options/System Settings/Enable User ID & PIN** parameter (refer to Section 6.5.4, Enable User ID and PIN), after the **Print Record?** prompt, the screen updates to display the following prompt:

> DELETE RECORD? > NO
>   YES

From this screen proceed as follows:

a. If you do not wish to delete the record, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the list of pH Results records.

b. If you do wish to delete the record, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following prompt is displayed:

> DELETE RECORD! > NO
> ARE YOU SURE?   YES

From this screen proceed as follows:

- If you do not wish to delete the record, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the list of pH test results records.

- If you do wish to delete the record, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following message is briefly displayed:

> * TEST RECORD #   8 *
> * HAS BEEN DELETED *

Next the screen returns to the list of pH test results records.

6.4   Output Records

> *** OPTIONS MENU ***
> 3. OUTPUT RECORDS

Use this function to output records stored in the instrument memory to a Printer or other receiving device connected to the instrument serial port.

NOTE: The RS-232 Serial port is designed to operate with a CBM Citizen model iDP-3110 serial Printer. Alternatively, the instrument's RS-232 Serial port may be connected to a COM Port of an external computer using a suitable RS-232 cable. The results output can then be received using the Windows® HyperTerminal application, or other serial data communication application. Refer to Appendix B for complete information about serial communication configuration requirements for this usage.

Proceed as follows:

1. From the **Run/Options** prompt, press the **<Options>** key to enter the **Options Menu**. The screen updates to display access to the first function available from the menu on the lower line of the screen.

2. From the **Options Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **3. OUTPUT RECORDS** option is displayed on the lower line of the screen.

3. Press the **<Enter>** key to select use of this function. Proceed to Section 6.4.1, Select Records to Output.

NOTE: If there are no test results stored in the instrument memory, the instrument emits an alarm tone and displays the following message:

> **NO TEST RECORDS IN**
> **MEMORY! PUSH A KEY**

After any key is pressed, the screen returns to the **Options Menu**.

6.4.1   Select Records to Output

4. When the **Options/Output Records** function is selected the following screen is displayed:

> **> ALL RECORDS**
> **SELECTED RECORDS**

From this screen proceed as follows:

a. To output all stored records, ensure the cursor (**>**) is positioned on the top line pointing to **>ALL RECORDS**, then press the **<Enter>** key. Proceed to Step 5.

b. To output only selected records, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>SELECTED RECORDS**, then press the **<Enter>** key. The following prompt is displayed:

> **OUTPUT LAST 2**
> **TEST RECORDS**

From this screen proceed as follows:

‒ Use the **Up/Down Arrow** keys to increment/decrement the number of records to be output, then press the **<Enter>** key. (Records are selected in sequence beginning with the most recently stored records). Proceed to Step 5.

c. To cancel the use of the **Output Records** function, press the **<Options>** key. The display returns to the **Options Menu** screen.

5. When the **<Enter>** key is pressed to begin transmission of records from the serial port, the screen updates to briefly display the following message:

> **OUTPUTTING**
> **TEST RECORDS**

The data output from the serial port will be in the format illustrated below:

```
Blood Cell Storage Inc.
BCSI pH1000 S/N PH04020731
Version X.X

REC#: 8
I.D.: ST13578A004MT
USER: USER1
DATE: 16 Mar 2020
TIME: 13:26
pH: >7.8

REC#: 7
I.D.: B812345AX2
USER: USER1
DATE: 15 Mar 2020
TIME: 10:19
pH: <6.2

REC#: 6
I.D.: QC TEST
USER: V
DATE: 14 Mar 2020
TIME: 14:42
QC: 1002

- - - - - -
- - - - - -
REC#: 1
I.D.: CSB8007
USER:V
DATE: 14 Mar 2020
TIME: 08:55
pH: 6.74

END OF DATA
```

pH Test Results

Figure 6-1   Output Records Format

6. When the serial output has completed the screen briefly displays the following message:

> **OUTPUT COMPLETED**

When the result output is completed the screen updates as follows:

- If the current setting of the **Options/System Settings/Enable User ID/ PIN** parameter is set to '**Enable User ID and PIN**' (refer to Section 6.5.4, Enable User ID and PIN), and the current user PIN does not match the Supervisor PIN, the screen returns to the **Options Menu**. If the

current user PIN does match the Supervisor PIN next the screen displays the **CLEAR MEMORY?** prompt. Proceed to Step 7.

- If the current setting of the **Options/System Settings/Enable User ID/ PIN** parameter is set to either: '**Disable User ID and PIN**' or '**Enable User ID Only**', next the screen displays the **CLEAR MEMORY?** prompt. Proceed to Step 7.

Clear Memory?   7. If appropriate, according to the current security access configuration of the **Options/System Settings/Enable User ID & PIN** parameter (refer to Section 6.5.4, Enable User ID and PIN), after the results output has completed the screen updates to display the following prompt:

> CLEAR MEMORY?   > NO
> YES

NOTE: If the **CLEAR MEMORY** function is selected, ALL records of this result type are cleared from the instrument memory.

From this screen proceed as follows:

a. If you do not wish to erase the results records, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the **Options Menu**.

b. If you do wish to erase the results records from the instrument memory, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following prompt is displayed:

> ARE YOU SURE?   > NO
> YES

From this screen proceed as follows:

- If you do not wish to erase the results records, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the **Options Menu**.

- If you do wish to erase the results records, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following message is briefly displayed:

> MEMORY HAS BEEN
> CLEARED

Next the screen returns to the **Options Menu**.

Printer Off-line   Upon initiating data output via the RS-232 Serial port, the instrument monitors the serial port for a communication response signal from the receiving device (printer or external computer). If a receiving device is not detected after 4 seconds, the instrument sounds an alarm tone and displays the following error message:

> ********** ERROR! **********
> PRINTER PORT OFF-LINE

After displaying this message for approximately four seconds, the screen returns to the **Options Menu**.

6.5   System Settings

> ┌─────────────────────────┐
> │ *** OPTIONS MENU *** │
> │ **4. SYSTEM SETTINGS** │
> └─────────────────────────┘

Use this function to access a menu of configuration functions.

Proceed as follows.

1. From the **Run**/**Options** prompt, press the **<Options>** key to enter the **Options Menu**. The screen updates to display access to the first function available from the menu on the lower line of the screen.

2. From the **Options Menu** screen, use the **Up** / **Down Arrow** keys as necessary to scroll the list until the **4. SYSTEM SETTINGS** option is displayed on the lower line of the screen.

3. Press the **<Enter>** key to select use of this function. If the use of a Supervisor PIN is enabled proceed to Step 4. If a Supervisor PIN will not be required, proceed to Section 6.5.1, System Menu.

Enter Supervisor PIN

4. If the **Options/System Settings/Set Master PIN** function is currently enabled the following screen is displayed:

> ┌─────────────────────────┐
> │ **ENTER PIN:** │
> │ _   * * * * * * * * * * * * * * │
> └─────────────────────────┘

5. Type the appropriate 5 digit PIN value that has been previously assigned (refer to Section 6.5.2, Supervisor PIN). If the PIN value is correct the screen updates to display the **System Menu**. Proceed to Section 6.5.1, System Menu.

Incorrect PIN

6. If the entered PIN value does not match the currently defined Supervisor PIN value, the following message is displayed:

> ┌─────────────────────────┐
> │ **PIN IS INCORRECT!** │
> │ **PRESS KEY TO PROCEED** │
> └─────────────────────────┘

From this screen press any key to proceed. The following prompt is displayed:

> ┌─────────────────────────┐
> │ **> RE-ENTER PIN** │
> │ **OVERRIDE PIN** │
> └─────────────────────────┘

7. From this screen proceed as follows:

    a. To re-enter the Supervisor PIN value, ensure the cursor (**>**) is positioned on the top line pointing to **>RE-ENTER PIN**, then press the **<Enter>** key. The display returns to the **ENTER SUPERVISOR PIN** screen.

    b. If you do not know the correct Supervisor PIN and wish to override this requirement, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>OVERRIDE PIN**, then press the **<Enter>** key.   A message similar to the following is displayed:

> ┌─────────────────────────┐
> │ **CONTACT TECH SUPPORT** │
> │ **WITH PERMIT #: #####** │
> └─────────────────────────┘

The Permit # is a randomly generated value, based on the current instrument clock time. From this screen proceed as follows:

    -   <u>Leave the instrument in this state, showing the **Permit #**</u>. Contact BCSI Technical Support (refer to Section 8.1, BCSI Technical Support). Using the **Permit #** value BCSI Technical Support will generate an

Override Code for temporary use to access the **System Settings** functions.

- Return to the instrument and press any key to continue. The following prompt is displayed:

```
ENTER OVERRIDE CODE:
_     * * * * * * * * * * * *
```

- Type the **Override Code** supplied by BCSI Technical Support, then press the **<Enter>** key. If the code is accepted, the screen updates to display the **System Menu** screen. Proceed to Section 6.5.1, System Menu.

ERROR: If the entered Override Code is incorrect, the following message is briefly displayed, then the screen returns to the **Options Menu**.

```
OVERRIDE CODE
IS INCORRECT!
```

c. To cancel the request to enter the **System Settings** functions, press the **<Options>** key. The screen returns to the **Run/Options** prompt.

6.5.1   System Menu

When the **System Settings** function is accessed the **System Menu** screen is displayed. The first function available from the menu is displayed on the lower line of the screen.

```
*** SYSTEM MENU ***
1.    SUPERVISOR PIN
```

The following functions are available from the **System Menu**:

1.   **SUPERVISOR PIN**
2.   **SET CLOCK**
3.   **ENABLE USER ID/PIN**
4.   **EDIT USER ID/PIN**
5.   **ERASE MEMORY**
6.   **PACK MEMORY**
7.   **ETHERNET SETUP**
8.   **READ RATIO**
9.   **SET QC VALUES**
10. **SET UCV VALUES**
11. **SERVICE REPORT**
12. **EXIT SETTINGS**

Use of these functions is described in the subsequent subsections.

6.5.2   Supervisor PIN

```
*** SYSTEM MENU ***
1.    SUPERVISOR PIN
```

Use this function to specify security requirements to access the **Options** / **System Settings** functions.

When the **Supervisor PIN** value is disabled (set to **00000** (five zeros)) access to the **System Settings** functions is unrestricted. Any user may access the **System Settings** functions.

When the **Supervisor PIN** value is enabled and defined, by input of a sequence of one to five digits, the user is required to input this PIN value before accessing the **System Settings** functions. The PIN value must be recognized by the software as the valid **Supervisor PIN** value previously defined and stored in the instrument memory.

Proceed as follows:

1. From the **System Menu** screen, if necessary use the **Up / Down Arrow** keys to scroll the list until the **1. SUPERVISOR PIN** option is displayed on the lower line of the screen.

    Press the **<Enter>** key to select use of this function. The following screen is displayed:

    ```
    PIN:  > EDIT
            DISABLE
    ```

2. From this screen proceed as follows:

    a. To <u>edit</u> the definition of the **Supervisor PIN** value, ensure the cursor (**>**) is positioned on the top line pointing to **>EDIT**, then press the **<Enter>** key. A screen similar to the following is displayed:

    ```
    EDIT PIN:   35121
    _         * * * * * * * * * * *
    ```

    The currently defined PIN value is displayed on the top line. Proceed as follows:

    -   To edit the PIN value type a new 5 digit value (numeric characters only) then press the **<Enter>** key. The display returns to the **System Menu** screen.
    -   To leave the PIN value unchanged, press either the **<Enter>** key or the **<Options>** key. The display returns to the **System Menu** screen.
    -   To disable use of the Supervisor PIN function, enter the disabled PIN value definition; type **00000** (five zeros) then press the **<Enter>** key. The display returns to the **System Menu** screen.

    b. To disable use of the Supervisor PIN function, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>DISABLE**, then press the **<Enter>** key. The following confirmation prompt is displayed:

    ```
    PROCEED: >YES
              NO
    ```

    Proceed as follows:

    -   To confirm disabling use of the Supervisor PIN function, ensure the cursor (**>**) is positioned on the top line pointing to **>YES**, then press the **<Enter>** key. The Supervisor PIN value is reset to the disabled value, 00000, and the display returns to the **System Menu** screen.
    -   To cancel the request to disable use of the Supervisor PIN function, use the **Down Arrow** key to move the cursor to the lower line so as to point

to **>NO**, then press the **<Enter>** key. The display returns to the **System Menu** screen without changes to the parameter value definition.

___

6.5.3   Set Clock

> ***** SYSTEM MENU *****
> **2.   SET CLOCK**

Use this function to verify and/or edit the current instrument date/time settings. Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **2. SET CLOCK** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The following screen is displayed:

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

where **YYYY**, **MMM**, **DD**, **HH** and **MM** are the current Year, Month, Day, Hour, minute values currently set in the instrument system clock. Proceed as follows:

3. If no date/time values require editing press the **<Enter>** key to accept all values and return to the **System Menu**.

4. Notice the **> <** selection characters surrounding the Year value, this indicates that this value is currently available for editing.

    a. If the Year value does not require editing, press the **<Options>** key to move the selection characters to the Month parameter.

    b. If the Year value does require editing, use the **Up/Down Arrow** keys to select a new year value, then press the **<Options>** key to accept the value and move the selection characters to the Month parameter.

5. In the same manner edit values for the Month, Day, Hour and Minute as necessary.

6. When all displayed values are correct, press the **<Enter>** key to accept all values and return to the **System Menu**.

___

6.5.4   Enable User ID and PIN

> ***** SYSTEM MENU *****
> **3. ENABLE USER ID/PIN**

Use this function to specify security requirements to access the **Run Test** function and also to allow user deletion of results records from the **Options/View Records** and/or **Options/Output Records** functions.

Three security access settings are available for definition of the **Options / System Settings / Enable User ID/PIN** parameter. The software functions as follows for each parameter setting:

DISABLE ID & PIN - When this setting is selected, access to the **Run Test** and records deletion functions is unrestricted.

ENABLE ID ONLY - When this setting is selected the user is required to input a **USER ID** before accessing the **Run Test** function. The User ID may be selected from a list of previously entered users (refer to Section 6.5.5, Edit

User ID/PIN) or entered from the keypad or Bar Code Scanner. Deletion of results records is unrestricted.

ENABLE ID & PIN - When this setting is selected the user is required to input a **USER PIN** before accessing the **Run Test** function. Results records may be deleted only by a User whose PIN matches the Supervisor PIN (refer to Section 6.5.2, Supervisor PIN) from the **Options/View Records** and/or **Options/Output Records** functions.

Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **3. ENABLE USER ID/PIN** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The following screen is displayed:

    > **SET ID/PIN FUNCTION:**
    > **1. DISABLE ID & PIN**

    Proceed as follows:

    a. Use the **Up/Down Arrow** keys to scroll through the list of security access settings. When the desired setting is displayed on the lower line of the screen, press the **<Enter>** key to select this setting and return to the **System Menu**.

    b. To cancel use of this function and leave the current security access setting unchanged, press the **<Options>** key. The screen returns to the **System Menu**.

6.5.5   Edit User ID/PIN

> ***** SYSTEM MENU *****
> **4. EDIT USER ID/PIN**

Use this function to edit User ID and PIN definitions. Up to eight (8) User IDs and PINs may be stored in the instrument memory. Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **4. EDIT USER ID/PIN** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The following screen is displayed:

    > **SELECT USER ID:**
    > **#. *User Name***

    Where **#. User Name** on the lower line indicates the most recently accessed User ID stored in the User List.

NOTE: The default User ID definitions contained in the list are **USER1** - **USER8**.

Proceed as follows:

a. To select this User ID for editing press the **<Enter>** key.

b. To select a different User ID for editing, use the **Up/Down Arrow** keys to scroll the list as necessary. When the correct User ID is displayed on the lower line, press the **<Enter>** key to continue.

3. The following screen is displayed:

> EDIT USER ID:
> _   ************

Enter the appropriate User ID information by either using the keypad (proceed to step 4), or by using the Bar Code Scanner (proceed to step 5).

Keypad

4. Using the keypad, enter any combination of up to eleven (11) alphanumeric characters, then press the **<Enter>** key to continue.

NOTE: When entering User ID information the **<Options>** key may be used as a backspace/correction key. Pressing the **<Options>** key with no User ID information entered causes the display to return to the **Run/Options** prompt.

Bar Code Scanner

5. Use the Bar Code Scanner to input User ID data from a bar code. When acceptable data is received from the Bar Code Scanner, any characters previously entered via the keypad are deleted from the screen and replaced by the bar-coded User ID information.

ERROR: If the Bar Code Scanner reads an ISBT 128 standard bar code that is not a User ID, the following message is briefly displayed:

> ID SCAN ERROR
> PLEASE RESCAN

Next, the screen returns to the **Enter User ID** prompt.

NOTE: When entering User ID information from the Bar Code Scanner, the **<Options>** key may be used as a delete key after a scanned User ID is displayed. The screen returns to the **Enter User ID** prompt.

6. When the User ID has been entered the following screen is displayed:

> EDIT PIN: 00000
> _   * * * * * * * * * *

If the User ID has a previously defined PIN, this value is displayed on the top line. Proceed as follows:

-   To edit the PIN value type a new 5 digit value (numeric characters only) then press the **<Enter>** key. The display returns to the **System Menu** screen.

-   To leave the PIN value unchanged, press either the **<Enter>** key or the **<Options>** key. The display returns to the **System Menu** screen.

NOTE: To access supervisor functions when the Supervisor PIN is enabled one user must have a PIN that matches the value set in Section 6.5.2, Supervisor PIN.

ERROR: Each user PIN must be unique, if a PIN is already used after entering a value as in (6) above, the following error message is displayed:

> PIN IS IN USE!
> PRESS KEY TO REENTER

Press any key to return to the screen as in Step 6, above.

6.5.6   Erase Memory

```
*** SYSTEM MENU ***
5.  ERASE MEMORY
```

Use this function to delete results records from the instrument memory. Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **5. ERASE MEMORY** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function. Proceed to Step 2.

2. Next, the following screen is displayed:

```
CLEAR MEMORY?  >NO
               YES
```

From this screen proceed as follows:

a. If you do not wish to erase the results records, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the **System Menu**.

b. If you do wish to erase the results records from the instrument memory, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following prompt is displayed:

```
ARE YOU SURE?    > NO
                 YES
```

From this screen proceed as follows:

-   If you do not wish to erase the results records, ensure the cursor (**>**) is positioned on the top line pointing to **>NO**, then press the **<Enter>** key. The screen returns to the **System Menu**.

-   If you do wish to erase the results records, use the **Down Arrow** key to move the cursor to the lower line so as to point to **>YES**, then press the **<Enter>** key. The following message is briefly displayed:

```
       MEMORY
 HAS BEEN CLEARED
```

Next the screen returns to the **System Menu**.

NOTE: After the memory has been cleared the Ethernet Module will automatically clear the contents of its comma separated values (CSV) data file.

6.5.7   Pack Memory

```
*** SYSTEM MENU ***
6.  PACK MEMORY
```

Use this function to defragment the instrument memory. This function should be used occasionally if results are frequently deleted one at a time using the **Options**/**View Records** function.

Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **6. PACK MEMORY** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The following screens are briefly displayed in succession:

> UPDATING ETHERNET
> PLEASE WAIT

> PACKING MEMORY . . . .

ERROR: If there are no records stored in the memory the following error
message will be displayed:

> NO TEST RECORDS IN
> MEMORY! PUSH A KEY.

Pressing any key will return you to the **System Menu**.

When the packing process is completed the following message is briefly
displayed:

> MEMORY HAS BEEN
> PACKED

Next the display returns to the **System Menu**.

6.5.8   Ethernet Setup

> *** SYSTEM MENU ***
> 7. ETHERNET SETUP

Use this function to configure Ethernet communication parameters to enable
automatic upload of results data to an external computer or LIS.

NOTE: When configuring Ethernet communication parameter enter specific
values for each parameter as provided by the site's LIS System
Administrator.

Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to
scroll the list until the **7. ETHERNET SETUP** option is displayed on the lower
line of the screen. Press the **<Enter>** key to select use of this function.

2. The screen updates to display the **Ethernet Menu**, with the first setup
parameter in the menu displayed on the lower line:

> * *   ETHERNET MENU   * *
> 1.   IP ADDRESS

3. There are three Ethernet setup parameters and an exit option available from
this menu:

1. IP ADDRESS

2. NETMASK

3. DEFAULT GATEWAY

4. EXIT ETHERNET

Proceed as follows:

IP Address

4. From the **Ethernet Menu** screen, use the **Up / Down Arrow** keys if necessary to
scroll the list and ensure the **1. IP ADDRESS** parameter is displayed on the

lower line of the screen, then press the **<Enter>** key. The following screen is displayed:

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

Where **###.###.###.###** indicates the current setting for the IP address. The cursor is placed below the first number in the first segment indicating that this value is available for editing.

From this screen enter the numeric IP address for this instrument, as assigned by the LIS System Administrator. The IP address must be a series of numeric characters in the format **###.###.###.###**. The address must include all three (3) numbers for each of the four segments of the address, including zeros if necessary. A typical IP address will be similar to the following example: **192.168.001.101**.

When the appropriate IP address has been entered, press the **<Enter>** key to accept the address entry and return to the **Ethernet Menu**.

NOTE: If you make an error when entering the IP address information, press the **<Options>** key to clear the current entry and start over.

To cancel use of this function, press the **<Options>** key again to return to the **System Menu**.

Netmask

5. From the **Ethernet Menu** use the **Up / Down Arrow** keys as necessary to scroll the list until the **2. Netmask** option is displayed on the lower line of the screen.

```
* *   ETHERNET MENU  * *
  2.  NETMASK
```

6. From this screen press the **<Enter>** key. The following screen is displayed:

```
*   ENTER NETMASK *
  ###.###.###.###  * * * * *
```

Where **###.###.###.###** indicates the current setting for the Netmask address. The cursor is placed below the first number in the first segment indicating that this value is available for editing.

From this screen enter the numeric Netmask value for the site's LIS network, as specified by the LIS System Administrator. The Netmask must be a series of numeric characters in the format **###.###.###.###**. The address must include all three (3) numbers for each of the four segments of the address, including zeros if necessary. A typical Netmask value will be similar to the following example: **255.255.255.000**.

When the appropriate Netmask value has been entered, press the **<Enter>** key to accept the entry and return to the **Ethernet Menu**.

NOTE: If you make an error when entering the Netmask information, press the **<Options>** key to clear the current entry and start over.

To cancel use of this function, press the **<Options>** key again to return to the **System Menu**.

Gateway Address

7. From the **Ethernet Menu** use the **Up** / **Down Arrow** keys as necessary to scroll the list until the **3. DEFAULT GATEWAY** option is displayed on the lower line of the screen.

> * *   ETHERNET MENU * *
> 3.   GATEWAY ADDRESS

8. From this screen press the **<Enter>** key. The following screen is displayed:

> *   ENTER GATEWAY ADDRESS *
> *###.###.###.###*   * * * * * * *

Where **###.###.###.###** indicates the current setting for the gateway address. The cursor is placed below the first number in the first segment indicating that this value is available for editing.

From this screen enter the numeric **Default Gateway** value for the site's LIS network, as specified by the LIS System Administrator. The **Default Gateway** must be a series of numeric characters in the format **###.###.###.###**. The address must include all three (3) numbers for each of the four segments of the address, including zeros if necessary. A typical **Default Gateway** value will be similar to the following example: **192.168.001.001**.

When the appropriate **Default Gateway** value has been entered, press the **<Enter>** key to accept the entry and return to the **Ethernet Menu**.

NOTE: If you make an error when entering the **Default Gateway** information, press the **<Options>** key to clear the current entry and start over.

To cancel use of this function, press the **<Options>** key again to return to the **System Menu**.

Exit Ethernet

9. When all Ethernet parameters have been defined, from the **Ethernet Menu** use the **Up** / **Down Arrow** keys as necessary to scroll the list until the **4. EXIT ETHERNET** option is displayed on the lower line of the screen.

> * *   ETHERNET MENU * *
> 4.   EXIT ETHERNET

10. From this screen press the **<Enter>** key. The display returns to the **System Menu**.

6.5.9   Read Ratio

> *** SYSTEM MENU ***
> 8. READ RATIO

This function is provided to allow experimental investigators to acquire data from test samples for research purposes.

The **Read Ratio** function causes the instrument to execute the fluorescence measurement algorithm, without requiring the user to first enter a platelet storage bag ID or User ID. The measurement results are not stored in the instrument memory, however, the data is shown on the display and is automatically transmitted from the serial port for capture by a Printer or personal computer running the Windows® HyperTerminal application. Windows® HyperTerminal can then be used to save the acquired data to a file.

Proceed as follows:

1. From the **System Menu** screen, use the **Up** / **Down Arrow** keys as necessary to scroll the list until the **8. READ RATIO** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function. The screen will update to display the following prompt:

```
ENTER PHID:
_  ********************
```

Use the keypad or barcode reader to enter the appropriate pHID.

NOTE: If the user proceeds without entering a pHID, the system will either use the default value (05050) or the pHID value that was entered for the previous read.

2. After entering the pHID, the following screen is displayed:

```
READ pH:  <Enter>
EXIT:        <Options>
```

3. Refer to Figure 6-2. Place the platelet storage bag onto the instrument measurement platform and insert the Fiber Optic Probe of the instrument into the opening at the top of the pH SAFE Sensor of the bag

4. Slide the pH SAFE Sensor of the platelet storage bag onto the pH SAFE Reader Fiber Optic Probe until it snaps into place at the top of the sensor. Ensure sensor is aligned with probe on reader. Avoid scraping the sensor on the probe.

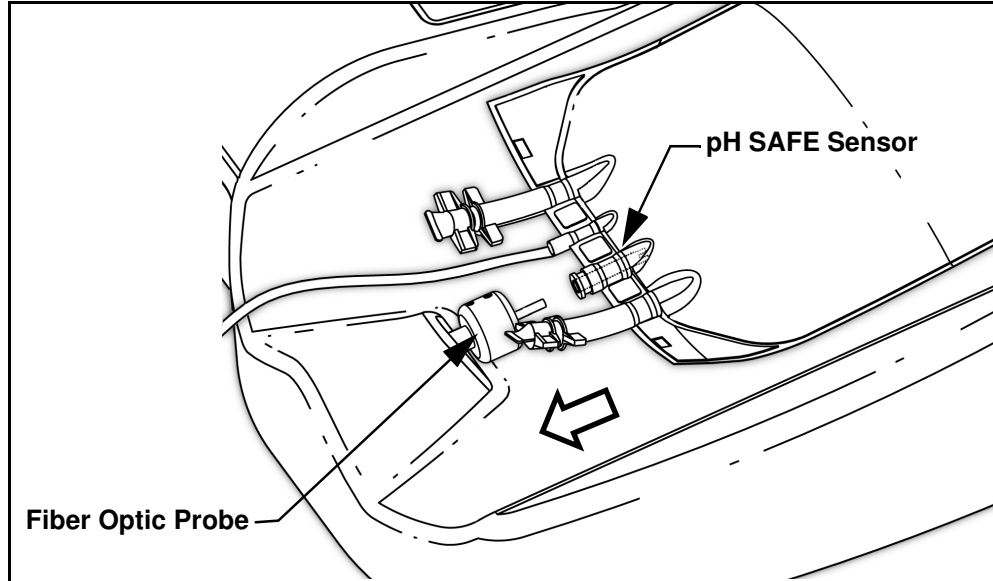*Figure 6-2   Insert Fiber Optic Probe into pH SAFE Sensor*

5. Press the **<Enter>** key to begin the measurement test.

NOTE: If the **<Options>** key is pressed at this time, the test is aborted and the screen returns to the **System Menu**.

6. When the test is successfully completed the screen updates to display the test results, for example:.

```
-Fr-  -Fp-   -Rp-   -pH-
1027  2145  2.091  6.24
```

Where:

Fr.:	The calculated mean of the signal data values collected from the reference channel.
Fp:	The calculated mean of the signal data values collected from the measurement channel.
Rp:	The calculated fluorescence ratio between the 2 channels.
pH:	The calculated pH measurement for this bag

Additionally the results are automatically output to the instrument serial port (see Note below). The results are output as a single line of 4 values separated by commas and spaces, for example:**1027, 2148, 2.091, 6.24**

7. From the test results screen, press any key to continue. The screen updates to re-display the **Read pH/Exit** screen.

8. To exit the **Read Ratio** function, press the **<Options>** key. The software returns to the **System Menu**.

NOTE: When using the **Read Ratio** function, after the first pH measurement is completed the instrument will automatically attempt to output the result information to the serial port. The result information is then discarded.

If there is no device currently connected to the serial port, the test result is not output. The instrument <u>does not</u> display an "OFF-LINE" error message when the **Read Ratio** function is in use. Additionally, on completion of any subsequent measurement tests using the **Read Ratio** utility, the instrument will not again attempt output of results to the serial port.

If a serial device is later connected to the instrument, in order to output new results generated using the **Read Ratio** function it is necessary to:
a. Exit the **Read Ratio** function by pressing the **<Options>** key.
b. From the **System Menu**, select and restart the **Read Ratio** utility.

For more information regarding the use of the **Read Ratio** function contact BCSI Technical Support.

6.5.10 Set QC Values

```
*** SYSTEM MENU ***
9.  SET QC VALUES
```

Use this function to update the QC values stored in the instrument to match those values provided with the certificate of calibration for the QC standard following a recertification of the standard.

Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll through the list until the **9. SET QC VALUES** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The screen updates to allow entry of the new QC information:

> ENTER/SCAN QC LABEL

The value can be scanned from a barcode or manually entered with the keypad, duplicating the string of numbers on the QC Certificate of Calibration sheet. If using the keypad for entry, press **<Enter>** to accept the entered value.

A check value is included in the QC label, if the value was input incorrectly the instrument will identify the incorrect data and alert the user of an ID scan error.

3. After the QC values are stored in memory, the screen updates to:

> Program Successful
> Press A Key

4. Press a key to return to the **System Menu**.

6.5.11   Set User Correction Values

> *** SYSTEM MENU ***
> 10. SET UCV VALUES

Use this function to update the User Correction Values (UCV) stored in the instrument. The UCV_SLOPE and UCV_INTR are a pair of slope and intercept terms which are applied to the pH reported by the **pH SAFE Reader**. These can be set by the user if needed to adjust the pH output from the **pH SAFE Reader** to match pH values from a separate reference pH measurement instrument as follows:

pH displayed = UCV_SLOPE * pH measurement + UCV_INTR

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll through the list until the **10. SET UCV VALUES** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

2. The UCV_SLOPE (slope) value can be edited using the 1 and 3 keys to increase and decrease the values by 0.001, the 4 and 6 keys to increase and decrease the values by 0.010, or the 7 and 9 keys to increase or decrease the values by 0.050.

3. Once the desired value is set press the **<Enter>** key to store the value and press another key to confirm that the value has been stored.

4. Follow the same procedure to adjust the UCV_INTR (intercept).

5. By default these values are set to 1.000 and 0.000. They can range from 0.600 to 1.400 for the UCV_SLOPE and -1.000 to 1.000 for the UCV_INTR.

6.5.12   Print Service Report

> *** SYSTEM MENU ***
> 11. SERVICE REPORT

Use this function to print out a summary of what the current instrument settings are for the QC values and the photodetector gains. This function is used in situations where servicing of the instrument is required.

Proceed as follows:

1. Connect a printer or PC to the serial port of the **pH SAFE Reader** and enable communication with the instrument.

2. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **11. SERVICE REPORT** option is displayed on the lower line of the screen. Press the **<Enter>** key to begin the printout. The screen will update to:

> OUTPUTTING
> SERVICE REPORT

3. The **pH SAFE Reader** will print out the instrument serial number (S/N) and firmware revision number followed by a table of technical data needed by your service representative. Following output, the screen will display a confirmation message:

> PRINTING COMPLETE

The software will then return to the **System Menu** screen.

6.5.13   Exit System Settings

> *** SYSTEM MENU ***
> 12. EXIT SETTINGS

Use this function to exit the **System Menu** and return to the **Options Menu**.

Proceed as follows:

1. From the **System Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **12. EXIT SETTINGS** option is displayed on the lower line of the screen. Press the **<Enter>** key to select use of this function.

The software returns to the **Run/Options** prompt.

6.6   Run QC Test

Use this function, along with the supplied QC Standard, to perform the QC Test on the **pH SAFE Reader**.

This function is described in detail in Section 7.2, Quality Control Test.

6.7   Exit Options

> *** OPTIONS MENU ***
> 6. EXIT OPTIONS

Use this function to exit the **Options Menu** and return to the **Run/Options** prompt. Proceed as follows:

1. From the **Options Menu** screen, use the **Up / Down Arrow** keys as necessary to scroll the list until the **6. EXIT OPTIONS** option is displayed on the lower line of the screen.

2. Press the **<Enter>** key to select use of this function. The screen returns to the **Run/Options** prompt.

7   Maintenance

7.1   Daily Fiber Optic Probe Tip Inspection

The tip of the instrument Fiber Optic Probe is a clear optical surface which must be kept free of dust and debris to ensure optimum instrument performance.

Each day, prior to beginning use of the **pH SAFE Reader**, inspect the surface of the tip of the instrument Sample Probe. If any dust and/or debris material has accumulated it is necessary to clean the Fiber Optic Probe tip surface.

⚠

CAUTION: To prevent damage to the optical surface of the Fiber Optic Probe tip observe the following precautions:

- Do not perform this procedure if a visual inspection of the FIber Optic Probe tip surface does not indicate cleaning is necessary. Clean the probe tip only if dust and/or debris particles are obviously visible on the probe tip surface.

- Never use solvents or water when cleaning the tip surface.

- Avoid touching the optical surface at the tip of the Fiber Optic Probe with your fingers.

Materials Required

Lint-free tissues.

Procedure

1. Visually inspect the tip of the instrument Fiber Optic Probe to determine if any particles of dust and/or other debris material are present on the optical surface.

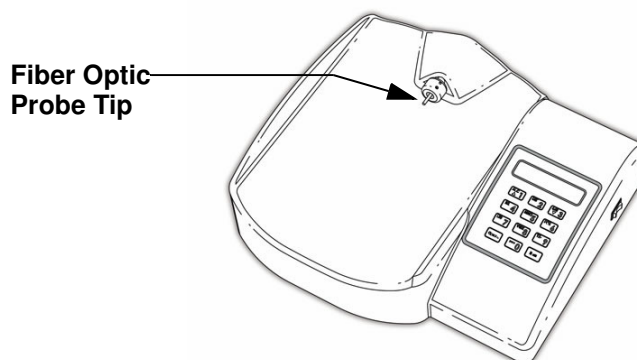*Figure 7-1   Cleaning Fiber Optic Probe Tip*

2. Proceed as follows:

- **If any dust and/or debris particles are seen**, carefully remove these particles by very gently dabbing or wiping the optical surface of the probe tip with a dry, lint-free tissue.
- **If no dust and/or debris particles are seen**, sample probe tip cleaning is not required.

The instrument is now ready for use.

7.2   Quality Control Test

Quality Control for the **pH SAFE Reader** utilizes a fluorescent dye fixed in an aluminum tube. The fluorescent dye in the standard will give a stable reading on the **pH SAFE Reader** if handled appropriately. When using the QC Standard, follow these general guidelines:

- Place the standard onto the instrument so that it clicks into place.
- The standard is temperature sensitive and care should be taken to use the standard at 22.0 ± 2.0°C.
- Because the optics in the standard are prone to scratches and collection of dust, the standard should remain protected when not in use.
- Replace when indicated expiration date is reached (typically one year).
- Due to the complex optical pathways in each instrument, it is important to keep each standard with the **pH SAFE Reader** it is supplied. Not all **pH SAFE Reader** will read an identical fluorescent value for a given standard.
- **<u>NEVER</u>** attempt to open or repair the QC standard.

The user should determine at what frequency the standard is used to ensure proper operation of the **pH SAFE Reader**. BCSI recommends the standard be used once a week.

Materials Required

QC Standard associated with the **pH SAFE Reader**

Lint-free tissues

Procedure

From the **Options Menu** screen, use the **Up** / **Down Arrow** keys as necessary to scroll the list until the **5. RUN QC TEST** option is displayed on the lower line of the display. Press the **<Enter>** key to select use of this function.

Next the software displays a series of prompts to guide the user through the QC Test process. The sequence of steps to perform a QC Test include:

> **Security Access**
> **Clean Sample Probe**
> **Put QC Standard on Sample Probe**
> **QC Check**
> **Save/Print QC Results**

And, if necessary:
> **Fix QC Confidence**
> **Save/Print QC Results**

The software will direct the user in the following manner:

Security Access

Upon entering the **Run QC Test** function the user will be prompted to enter a User ID or PIN, if this function has been enabled.

Refer to Section 6.5.4, Enable User ID and PIN.

The prompts will be similar to those displayed in the **Run Test** function.

Refer to Section 5.2, Security Access.

Clean Fiber Optic Probe

After the User ID or PIN has been entered, the instrument directs the user to clean the sample probe. This should be done with a lint-free tissue.

Refer to Section 7.1, Daily Fiber Optic Probe Tip Inspection.

Press the **<Enter>** key to continue.

Put QC Standard on Fiber Optic Probe

The screen will display the following prompt:

```
PUT B### ON PROBE
THEN PRESS ENTER
```

Place the QC Standard, with the displayed serial number, onto the sample probe. Ensure the standard was placed far enough onto the probe so that it clicks into the detent. Press the **<Enter>** key to initiate the QC Check.

NOTE: BCSI has matched each **pH SAFE Reader** to a specific QC Standard as referenced on the QC Standard's label. The standards are not interchangeable between instruments. It is important to ensure the standard and instrument that is supplied together is also used together.

For best results, do not touch the standard while measuring. Heat from the user's fingers can cause the fluorescent signal of the standard to change slightly.

QC Check

After initiation of a QC Test the **pH SAFE Reader** will check the QC Confidence value by measuring the fluorescent signal of the standard and comparing it to the set QC value. A QC Confidence value is measured and if the value is 1000 ± 10 the **pH SAFE Reader** is determined to be within specification. The result of the test is displayed as:

```
QC Check Complete
QC Confidence:   1001
```

During this test, if the instrument determines the standard is not placed onto the probe far enough the screen will display the following prompt:

```
CHECK PLACEMENT
THEN PRESS ENTER
```

If the QC Confidence value is outside of specification the instrument will beep and report a QC Check Failure. Leave the QC standard in place on the probe. In subsequent steps of the test, the **pH SAFE Reader** will automatically adjust the photodetector gains to repair the QC Confidence.

Save/Print QC Results

Following the QC check of either a successful or failing QC Confidence, the instrument provides options to save, print, save and print, or discard the results for the test. Proceed in the same manner as described in Section 5.5, Save/Print Test Results. The ID for a QC Test is designated as 'QC TEST' and the QC Confidence value is treated like a pH Test result record.

If a failure has occurred, it may be useful to keep track of the QC Confidence values and use a Levy Jennings type plot to determine if failures are continually in one direction or the other.

If the QC Confidence is in the acceptable range then this is the end of the QC Test. The instrument will return to the **Options Menu**.

If a failure has occurred the instrument will attempt to fix the QC value as described in the subsequent sections.

> *NOTE:* A QC Test failure will disable the **Run Test** function of the instrument until the QC Confidence has been repaired.

Fix QC Confidence

If the QC Confidence is outside of acceptable ranges, after the test results are saved or printed the screen updates the following two displays:

```
FIXING: REF CHANNEL
QC Confidence:   1053
```
```
FIXING: PH CHANNEL
QC Confidence:   931
```

During this step, the light collecting photodetectors in the instrument are automatically adjusted so that the QC Confidence number changes and reaches the appropriate value (1000 ± 10). First the Reference Channel is adjusted, then the pH Channel is adjusted. Finally the result of the fixed QC Confidence is displayed. If the QC Test fails to adjust itself correctly, something could be wrong with the placement of the standard or the instrument. Rerun the QC Test paying careful attention to temperature of the standard (22 ± 2°C), cleanliness of the probe tip and correct placement of the standard on the probe. If failures persist contact BCSI Technical Support.

Save/Print QC Results

Following the Fix QC Confidence step, the user is given the option to save, print, save and print, or discard the new QC Confidence value. Proceed in the same manner as described in Section 5.6, Save/Print Test Results.

Following this step the software returns to the **Options Menu**.

Metrological Information

The QC test confirms the fluorescent signals are within 1% of their target levels as set at the Factory. Fluorescence is a relative measurement and traceability is provided by measuring and setting target values on a Factory reference **pH SAFE Reader** which has been calibrated for pH measurements against a blood gas analyzer to ± 0.1 pH units of accuracy. The blood gas analyzer's pH readings are NIST traceable for pH levels with controlled calibration buffers and reference QC measurements. The 1% fluorescent level target corresponds to 0.03 pH units of variation for the measurement system. Any variation outside of the 1% level is corrected by the **pH SAFE Reader** during the QC test.

7.3   Routine Cleaning

The **pH SAFE Reader** does not require any other routine or preventative maintenance other than occasional cleaning of external surfaces.

When cleaning the **pH SAFE Reader** housing, use 70% ethanol, a mild detergent or a non-organic laboratory disinfectant and a damp cloth.

DO NOT USE STRONG BLEACH (> 0.1% solution) OR ORGANIC SOLVENTS!

DO NOT CLEAN THE FIBER OPTIC PROBE TIP WITH SOLVENTS OR WATER!

7.4   Disposal Precautions

The **pH SAFE Reader** contains printed circuit board components which may prohibit disposal in uncontrolled solid waste. Refer to local regulations for proper disposal and/or recycling of the instrument.

8   Troubleshooting

8.1   BCSI Technical Support

For assistance regarding the use of the **pH SAFE Reader** system or to report any serious incidences that have occurred in relation to the device, please contact Technical Support at Blood Cell Storage Inc. as follows:

In the United States:

Phone: 1-425-654-8455

Fax: 1-425-654-8461

E-mail: support@safesens.com

Other countries:

Distributor contact information is available at:
www.safesens.com/support/

Additionally, please refer to the Blood Cell Storage website:
www.safesens.com/support/
which contains support and contact information.

8.2   Error Messages

When the **pH SAFE Reader** 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
pH1000 CALIBR FAULT! **CONSULT OPS MANUAL** **Critical error**	A "checksum" mismatch was detected in Reader calibration data during Power-On Self-Test.	Contact Technical Support for re-calibration servicing.
RESETTING CLOCK! **PRESS KEY TO PROCEED**	The clock is not running.	Clock will be reset to the default time. Use the System Settings/Set Clock function to adjust to the correct time and date.
SETUP ERROR!	Ethernet module was not setup properly.	Contact Technical Support for servicing.
ERROR! NO PINs HAVE **BEEN ENTERED YET...**	User ID and PIN is enabled but no PINs have been defined for users	Define at least one PIN for one of the defined Users.
* BAD IP ADDRESS!! *	The IP address entered is not an allowable IP address	Enter an allowed IP address in the range of 000:000:000:000 and 255:255:255:255.
PIN IS INCORRECT! **PRESS KEY TO PROCEED**	Entered PIN does not match the PINs stored for any of the defined users.	Enter a correct PIN.

Message	Cause	Action
OVERRIDE CODE **IS INCORRECT!**	An incorrect override code has been entered when trying to override the supervisor's PIN.	Return to the override Supervisor PIN and get a new permit number from Technical Support.
PIN IS IN USE! **PRESS KEY TO REENTER**	The entered PIN is already assigned to a different user.	Enter a different PIN for the current user.
NO TEST RECORDS IN **MEMORY! PUSH A KEY.**	There are no records in memory to print or view.	Push a key.
****** ERROR! ****** **PRINTER PORT OFF-LINE**	The serial Printer is unavailable for communication.	Ensure that the Printer is turned on, connected and online.
MEASUREMENT ERROR! **w/ one of** **LOW REF SIGNAL** **HIGH REF SIGNAL** **LOW PH SIGNAL** **HIGH PH SIGNAL** **LOW RATIO** **HIGH RATIO**	Measurement of fluorescent dye gave a result that is outside of acceptable range. The probe could be improperly inserted into the platelet storage bag.	Remove platelet storage bag and repeat measurement. If problem persists a pH measurement for this platelet storage bag is not possible.
MEMORY NOW FULL!	100 tests have been stored in memory.	Print out the records and erase them from memory or Consult supervisor to pack memory or delete records.
ERROR: MEMORY FULL! **PRESS KEY TO PROCEED**	100 tests have been stored in memory.	Print out the records and erase them from memory or Consult supervisor to pack memory or delete records.
ETHERNET TRANSFER IN **PROGRESS..PLS WAIT..**	pH test result records are being downloaded via Ethernet.	After a few seconds the transfer will be complete and the test record will be saved.
TABLE NOT PROGRAMMED **PRESS KEY TO RETURN**	The scanned pHID has not been programmed into the memory.	Contact Technical Support to upload additional pHID lookup tables.
ID SCAN ERROR **PLEASE RESCAN**	The scanned bar code was recognized as an ISBT 128 code that is not a User ID or platelet storage bag ID.	Scan the correct User ID or platelet storage bag ID again. If problem persists manually enter ID or consult technical support.

Appendix A   Power-On Self Check (SELF-CHK)

The power-on self check (SELF-CHK) is an internal quality assurance procedure executed by the **pH SAFE Reader** each time the instrument is turned on. The SELF-CHK algorithm performs the following sequential series of tests which exercise and evaluate the performance of individual instrument functions:

- **pH SAFE Reader** Calibration Self-Test

- Real Time Clock Test

- Initialization of Ethernet Module

If a test fails, an error message is displayed. Some test failures will prevent further operation of the **pH SAFE Reader** instrument. The individual tests are described next.

A.1   pH SAFE Reader Calibration Self-Test

This test verifies the calibration and configuration settings of the instrument. A checksum value is calculated, which is compared to an internally stored value.

ERROR: If a checksum mismatch is detected, the instrument sounds an alarm tone and the screen displays the following error message:

> **METER CALIBR FAULT!**
> **CONSULT OPS MANUAL**

Further operation of the instrument is prohibited at this point. In this case, the instrument requires repair servicing and/or a re-calibration. Contact BCSI Technical Support for assistance.

A.2   Real-Time Clock Test

This test verifies the correct operation of the internal real-time clock of the **pH SAFE Reader** instrument. The current clock date and time is validated, and the clock function is tested to verify accurate continuous "ticking" once per second. If an invalid date/time or a stopped clock is detected, the instrument sounds an alarm tone and the screen displays the following error message:

> **RESETTING CLOCK!**
> **PRESS KEY TO PROCEED**

In this case, the clock is automatically reset to the default date/time: 09:00 Jan 01 2005. Next the system automatically enters the **Options/System Settings/Set Clock** function to allow manual reset to the correct date and time (see Section 6.5.3, Impostazione orologio).

The above alarm condition implies that the clock backup battery may have failed. Under normal circumstances, the clock backup battery is expected to have an

operating lifetime of at least 5 years. If the clock alarm occurs during the SELF-CHK, contact BCSI Technical Support for assistance.

A.3   Initialization of Ethernet Module

After completing the Real-Time Clock test, the Ethernet Module is loaded with the three network addresses (IP, netmask and gateway) currently stored in the instrument memory (refer to Section 6.5.8, Ethernet Setup).

Next the system checks the current contents of the Test Record memory. If the instrument was not able to send accumulated results records to the LIS before last being powered down the Test Record memory will not be empty when the instrument is next powered up. If the Test Record memory is not empty, it is copied to the CSV data file which is stored in the Ethernet Module.

Following this initialization, the Ethernet Module will set up a socket for TCP/IP and will initiate the FTP (or HTTP) Server protocol. The Ethernet Module is thereby prepared to receive a file transfer request from the LIS. When such a request is received the CSV data file is sent to the LIS and the CSV data file and Test Record memory contents are erased.

NOTE: Test Records are not erased when the instrument is in the **Options** menu. Once the system returns to the **Run/Options** prompt the transferred records will be erased.

When the SELF-CHK is successfully completed, the display returns to the **Run/Options** prompt.

Appendix B   Serial Port Results Upload

The **pH SAFE Reader** may be connected to a Printer or computer for transferring data via the RS-232 Serial port. Output configuration is as follows:

- 9600 baud

- 8 data bits

- No Parity

- 1 Stop Bit.

This output is designed to be compatible with small 40 character serial Printers such as those available from Citizen (Model: iDP-3110 - Dot Matrix Printer). The output is also compatible with some other Printers and computer serial ports.

If connected to a Printer, the instrument uses the DTR line (DB9 pin 4) as a handshaking signal.

If the connected device is a personal computer maintain the DTR or RTS line (DB9 pin 7) in the active (logic high) state to receive data from the instrument.

Appendix C   Ethernet Setup

The **pH SAFE Reader** may be connected to a LIS network for transferring data via a 10Base-T Ethernet output port. The BCSI software is setup so the LIS will pull data from the instrument.

The **pH SAFE Reader** is setup to run as an anonymous FTP server. The static IP address of the instrument and network addresses are specified in Section 6.5.8, Ethernet Setup.

The instrument will maintain two text files on the server. One file, named **README,** contains the serial number of the unit in the following format:

BCSI pH 1000

Serial #(12 char serial no)

The second file, named **test_info**, is a CSV data file that contains the test results in the following format.

1234567890abcdefghij,USER1   ,30 Nov 2020,11:51:00,6.87

QC Test   ,USER1   ,30 Nov 2020,12:32:00,1003

Bag ID   ,User ID   ,Test Date   ,Time   ,pH (or QC) reading

20 Chars   ,11 Chars ,11 Chars   ,8 Chars ,4 Chars

As additional test records are saved they are added to the data file. If the instrument is busy communicating via Ethernet, it will block the saving of new test records until the Ethernet communication has finished. Once the CSV data file has been uploaded to the LIS, the results stored in the instrument's non-volatile memory are deleted and newly saved results can be stored in memory.

The LIS should be setup so that it logs onto the FTP server of the **pH SAFE Reader**, copies the data file from the instrument and then logs off. This should be done on a timed basis. The instrument's memory can hold up to 100 records which takes over an hour of constant measurements to generate and save.