

eBDS Oxygen Analyzer

*Device Operation
User Manual*

P/N COL_COPY000535_US(AB)



HAEMONETICS®
THE Blood Management Company™

Printed in USA

Consumer information

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Corporate headquarters

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184
U.S.A.
Tel.: +1 781 848 7100
Fax: +1 781 848 5106

International headquarters

Haemonetics S.A.
Rue des Fléchères
Signy Centre
P.O. Box 262
1274 Signy-Centre, Switzerland
Tel.: +41 22 363 9011
Fax: +41 22 363 9054

Disclaimer

This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Haemonetics Corporation products. This manual should be used in conjunction with instruction and training supplied by qualified Haemonetics personnel.

Any failure to following the instructions as described could result in impaired product function, injury to the operator or others, or void applicable product warranties. Haemonetics accepts no responsibility for liability resulting from improper use or maintenance of its products.

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Haemonetics worldwide

Haemonetics Austria

Handelsges.m.b.H.

Mariahilfer Strasse 123
3rd Floor
1060 Wien, Austria
Tel.: 0800 29 2777
Fax: 0800 29 2820

Haemonetics Belgium-NV

Braine-L'Alleud Parc de L'Alliance 9
Boulevard de France, bât A
1420 Braine L'Alleud
Belgium
Tel.: (FR): 0800 754 80
Fax: 0800 75512
Tel. (NL): 0800 754 82
Fax: 0800 755 12

Haemonetics BV

Claudius Prinsenhof
Verlengde Poolseweg 34-46
4818 CL Breda
The Netherlands
Tel.: 0800 0222 707
Fax: 0800 0223 066

Haemonetics CZ, spol. s.r.o.

Ptašínského 8
60200 Brno, Czech Republic
Tel.: 800 143 243
Fax: 800 143 250

Haemonetics France SARL

46 bis, rue Pierre Curie
Z.I. Les Gâtines
78370, Plaisir, France
Tel.: 0800 90 11 58
Fax: 0800 91 48 76

Haemonetics GmbH

Wolfratshauser Straße 84
81379 Munich, Germany
Tel.: 0800 180 8890
Fax: 0800 182 8064

Haemonetics (Hong Kong) Ltd.

Rooms 2202, 22/F
Harbour Centre, 25 Harbour Road
Wanchai, Hong Kong
Tel.: +852 2868 9218
Fax: +852 2801 4380

Haemonetics Hospitaler LTDA

Avenida Bernardino de Campos, 98
Sobreloja, Paraisio, CEP 04004-040
City of São Paulo
State of São Paulo, Brazil

India Representative Office

Haemonetics (Hong Kong) Ltd.

JMD Regent Square
Regus - Level 6
Mehrauli Gurgaon Road
Gurgaon - 122 001
Haryana (Delhi-NCR) India
Tel.: +91 124 471 1819
Fax: +91 981 027 3237

Haemonetics Italia SA

Via Senigalia 18/2 - Torre A
Milan 20161
Italy
Tel.: 800 870 200
Fax: 800 870 375

Haemonetics Japan GK

Kyodo Building, 16
Ichiban-cho, Chiyoda-ku
Tokyo 102-0082, Japan
Tel.: +81 3 3237 7260
Fax: +81 3 3237 7330

Haemonetics Korea, Inc.

30th Floor ASEM Tower
 159-1 Samsung-dong, Kangnam-ku
 Seoul 135-798, Korea
 Tel.: +82 2 6001 3280
 Fax: +82 2 6001 3281

Russia Representative Office

Haemonetics SA
 Smolenskaya Passage
 Smolenskaya Square 3
 121099 Moscow Russia
 Tel.: +7 495 937 8239

**Haemonetics Medical Devices
 (Shanghai) International Trading
 Company**

Room 1103-06 Evergo Mansion
 No. 1325 Middle Huaihai Road
 200031 Shanghai, China
 Tel.: +86 21 3406 0700
 Fax: +86 21 5466 8852

Haemonetics Scandinavia AB

Ideon
 223 70 Lund, Sweden
 Tel.: 020 797 150
 Fax.: 020 794 670

**Haemonetics Asia
 Incorporated Taiwan Branch**
 26F-1, No. 102, Roosevelt Road Sec.
 2
 Taipei, Taiwan
 Tel.: +886 2 2369 0722
 Fax: +886 2 2364 3698

United Kingdom Sales Office**Haemonetics Ltd.**

Suite 1/Building 5
 5 Hercules Way
 Leavesden Park
 Watford WD25 7GS
 United Kingdom
 Tel.: 0808 234 4817
 Fax: 0808 234 4845

Lebanon Representative Office

Haemonetics SA
 c/o The Regus Group
 Azarieh Bldg., Block 3,
 5th floor
 Regus, Beirut, Lebanon
 PO Box 11-503

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Chapter 1

Introduction

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Intended Use

The eBDS Oxygen analyzer is a component of the eBDS Bacteria Detection System. The eBDS Oxygen Analyzer measures the percent of oxygen in the headspace air of the sample pouch after 35 °C incubation. The eBDS Oxygen Analyzer and the eBDS Sample Set are used together in qualitative procedures for the recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria) for quality control testing of apheresis and single and pooled units of whole blood derived platelet products in plasma.

Analyzer Components

The primary Analyzer components are:

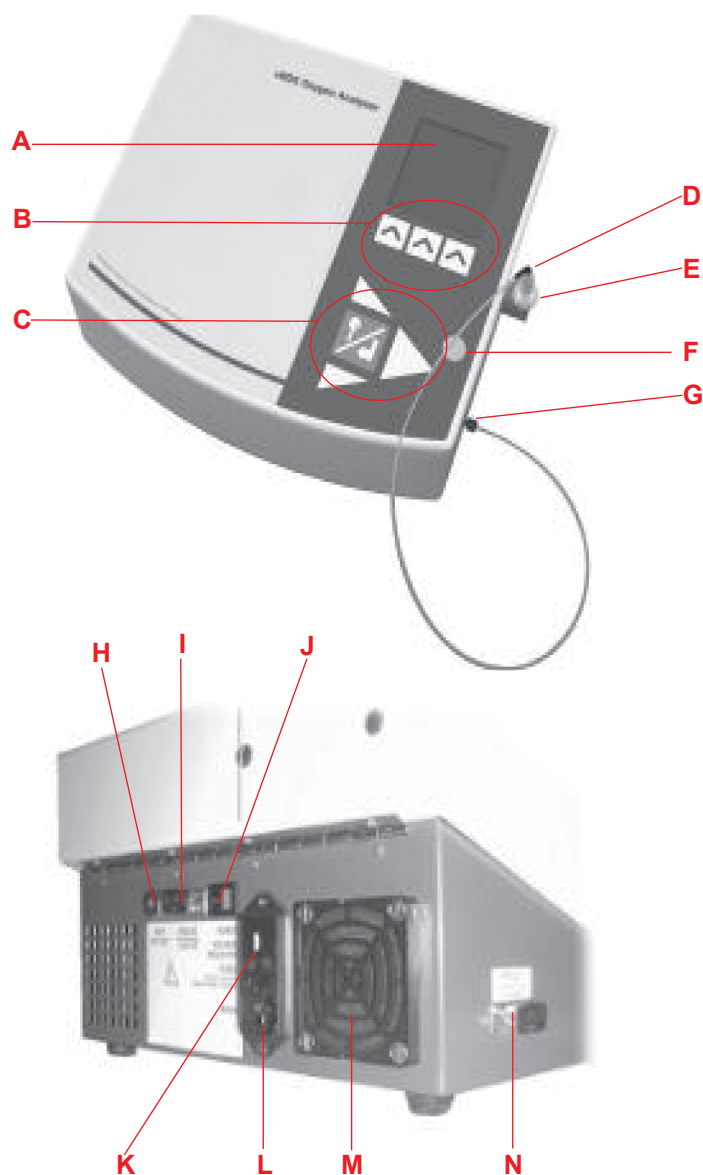


Figure 3-1, eBDS Oxygen Analyzer

Table 3-1, Analyzer Components

A	Display
B	Soft Keys
C	Fixed Keys
D	Sample Probe
E	Holder for Sample Probe
F	Rubber Disc for Leak Test
G	Sample Gas Inlet
H	Sample Gas Outlet
I	RS232C to Personal Computer
J	Main Switch
K	Mains Voltage Selector
L	Mains Inlet
M	Fan and Dust Filter (Gas outlet located on rear panel vents sample air to atmosphere)
N	RS232C to Barcode Scanner

International Symbols

International symbols referenced in this manual are:



Consult instructions for use



Caution



Warning: Maintain ground/earth to avoid electric shock



This equipment complies with the IVDD Directive, 98/79/EC



This equipment is certified to the Canadian Standards Association. Certificate
C_{US} No: 1263877

Safety Precautions

To protect your personal safety and ensure correct use of this equipment, make sure you read and understand this guide.

The following terms are used:



DANGER: To designate a condition which MAY involve mortal danger or serious injury



CAUTION: To designate a condition which MAY involve serious injury or destruction of the equipment involved



NOTE: To designate a condition which MAY involve faulty operation of the equipment thus causing faulty measuring results



IMPORTANT: Follow the instructions below carefully

Universal Precautions

Appropriate care should always be taken to guard against hazards when handling untested blood components. Use of personal protective equipment such as gloves, gowns and protective eye wear to help reduce the risk of exposure is recommended. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood.

Dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures.

BIOHAZARD safety procedures



DANGER:

Opening the eBDS Oxygen analyzer may involve mortal danger or serious injury as live high-voltage leads may be exposed. Only authorized personnel should open the cabinet.

When connecting to mains, Ground/Earth must always be connected.

**CAUTION:**

- Use only original parts
- For indoor use only
- If Analyzer is moved or transported, make sure it is not exposed to shocks or impact
- Analyzer should always be transported in the original box if warranty repair work is to be carried out
- Analyzer should never be used unless the enclosed probe filter is correctly fitted
- Buttons/keys on this equipment should only be finger touch operated, sharp objects will destroy the touch-sensitive film
- Only use water or a mild soap solution to clean the front panel
- The warranty is invalidated if the above instructions are not strictly adhered to
- Locate oxygen analyzer at least 5 cm (2.0 in.) from walls or other electronic equipment

Chapter 2

Preparing the system for use

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Assembly and setup

Initial Assembly

1. Remove the eBDS Oxygen Analyzer from the shipping box.



IMPORTANT: Save the shipping box. The eBDS Oxygen Analyzer must be transported in the original shipping box if warranty repairs are needed. Failure to do so invalidates the Warranty. Call your Haemonetics Sales Representative for instructions on how to return the eBDS Oxygen Analyzer.



Note: If the eBDS Oxygen Analyzer is to be used at altitudes between 1500 - 3000 meters (4900 - 9800 feet), contact a Haemonetics Service Representative prior to preparing the system for use.

2. Attach end of hose tubing to sample gas inlet, located on the side panel (Figure 4-1, G) of the Analyzer with finger screw. **Do not over-tighten.**

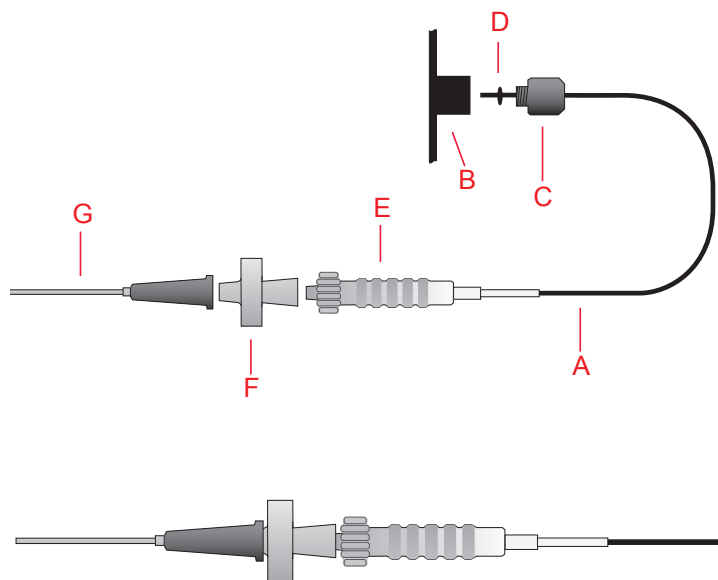


Figure 4-1, Sample Probe Assembly and Probe Pen

Table 4-1, Sampling Probe Components

A	Sample Hose
B	Gas Inlet of Analyzer
C	Finger Screw
D	O-Ring
E	Probe Pen Assembly
F	Probe Filter
G	Probe

5. Attach the probe filter to the probe pen. Attach the probe to the probe filter. Place the probe into the holder located on side of analyzer (Figure 4-1, E). Replace sample hose only when damaged. Conduct the Probe Leak Test after every probe, filter, or probe assembly change, as described in “Performing the Probe Leak Test” on page 50.

Selecting the appropriate voltage

To select the appropriate voltage for the eBDS Oxygen Analyzer:

1. Before the power cord is connected to the eBDS Oxygen Analyzer, check that the device is adjusted to the correct voltage. The user can select one of the following three voltages:
 - 230 V AC,
 - 115 V AC
 - 100 V AC (Figure 3, A).

The currently selected voltage for the eBDS Oxygen Analyzer appears in the small window in the fuse holder, which is located on the rear panel.

2. Depending on the selected voltage, two 5 x 20 mm fuses must be inserted into the fuse holder with the following rated current:

Device Voltage	Fuse
230 VAC	2 pcs. 0.63 AT
115 VAC or 100 V AC	2 pcs. 1.6 AT

* Additional fuse information is provided in “Power supply” on page 76.

3. If the eBDS Oxygen Analyzer is to be used with a barcode scanner or a PC running data-collection software, connect these devices to the eBDS Oxygen Analyzer BEFORE applying power to the eBDS Oxygen Analyzer.
4. Locate oxygen analyzer at least 5 cm (2.0 in.) from walls or other electronic equipment.

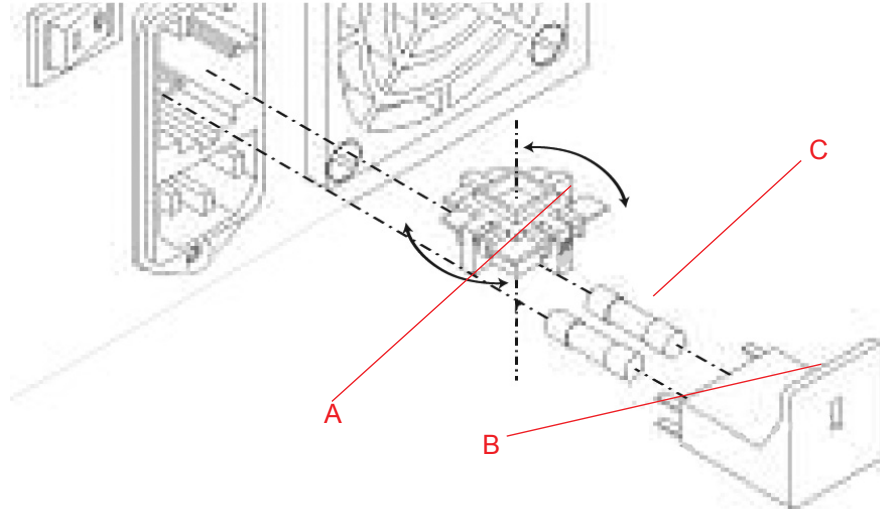
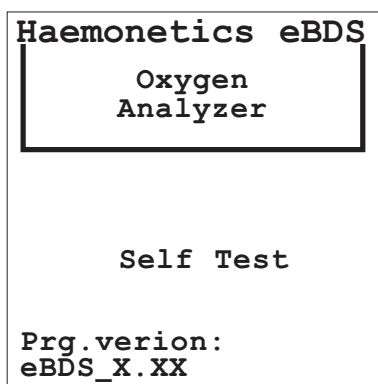


Figure 4-2, Selection of Voltage for the Device

Starting the eBDS Oxygen Analyzer

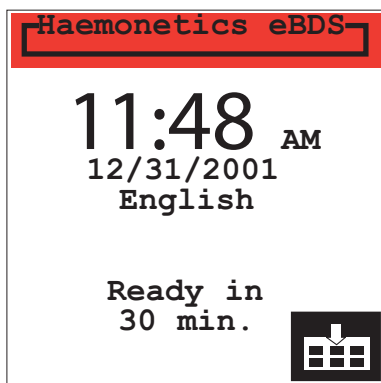
To start the eBDS Oxygen Analyzer:

1. After confirming that the correct voltage is selected, and the appropriate fuses are inserted, connect the power cord to the eBDS Oxygen Analyzer and then to the power outlet.
2. Turn on the device. The eBDS Oxygen Analyzer will begin operation with a short self test.

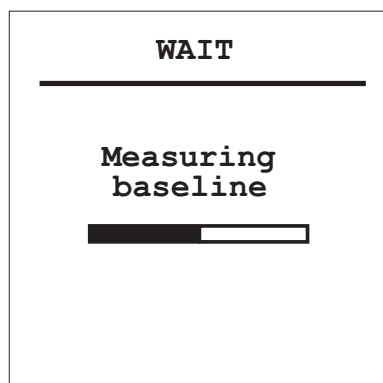


Note: If there is a problem confirming the baseline with the eBDS Oxygen Analyzer during or after the self test, refer to “Sample Test Procedure”, - “Possible Alarm and Alert Messages During Measuring”.

After the self test, a warm-up period of 30 minutes must elapse before the device is ready to measure.



3. Wait the stated time. The probe must be placed in the holder when not in use.
4. After completion of the warm-up period, the eBDS Oxygen Analyzer will automatically measure and reset the “Baseline” with the %O2 in atmospheric air.



5. If PC Handshake is enabled (“Enabling PC handshake and manual logging” on page 30) the eBDS Oxygen Analyzer will verify that a PC with data collection software is connected. If this is not the case, an “ALARM” message is displayed. If PC handshake is disabled, the eBDS Oxygen Analyzer will bypass this item.

The user may now be requested to carry out a Log On procedure before being able to initiate a sample test (“Sampling” on page 41).

After one hour of inactivity, the eBDS Oxygen Analyzer will automatically initiate a baseline confirmation. When confirmed, the baseline is reset. Automatic baseline confirmation will not be executed when the user is prompted, or when displaying “Pass” or “Fail” or if in a sub-menu.



When returning from one of these conditions, the baseline will be confirmed/ reset immediately if more than one hour has elapsed since the last baseline confirmation.

Functions of keys and icons

Soft keys

Soft keys are the  keys below the icon in the display. The following icons can be displayed above the soft keys.

-  Confirm/Accept
-  Cancel/previous menu/baseline measurement
-  Go to the diagnostic menu
-  Go to the setup menu
-  Go to the next screen
-  Resend data in Log data menu
-  Go to the Log data menu (only accessible when Manual logging is set to “Yes”)
-  Go to “Enter passcode” screen. Entering the valid passcode provides access to the Setup Menu and Diagnostic Menu

Fixed keys

-  Start measuring/ (select, enter)
-  Manual Probe Leak Test
-  Up (select previous or contrast up)
-  Down (select next or contrast down)
-  Right (next digit)

Setting up the eBDS Oxygen Analyzer

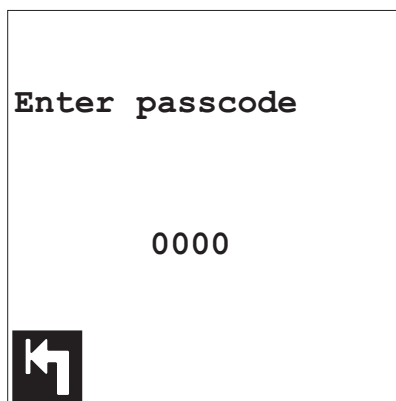


Set up the eBDS Oxygen Analyzer using the Setup Menu.

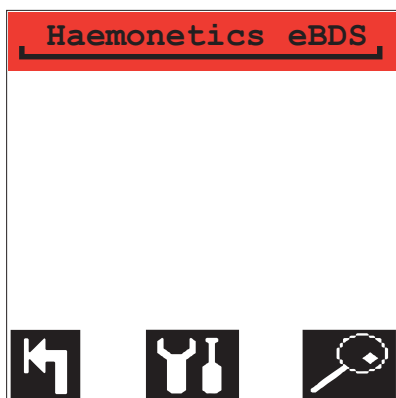
Note: Access to the Setup Menu requires the user to enter the User Supervisor passcode:

To set up the eBDS Oxygen Analyzer:

1. In the main display, press . The Enter passcode screen appears.



2. Using the fixed keys, enter the User supervisor passcode
3. Press  to confirm.
4. Icons  and  now appear, providing access to, respectively, the Setup Menu and the Diagnostic Menu.



5. Press  to go to the Setup Menu.

Setup 1	
Time:	11:48 AM
Time	AM/PM
Date:	MM/DD/YYYY
Date:	12/31/2001
Language:	English
Contrast:	25
Passcode:	****
	



Note: If the user enters an invalid input, an alert message appears. Additional information regarding the erroneous input may be displayed in some cases.

Press  to confirm and reenter the parameter correctly.

ALERT
Invalid input


This ALERT also is displayed if the setting of interrelated parameters conflict with each other.

Setting time, date, language, contrast, and passcode

To set system time, date, language, contrast, and passcode:

1. In the Setup Menu, press  if needed to go to Screen 1.

Setup 1	
Time:	11:48 AM
Time	AM/PM
Date:	MM/DD/YYYY
Date:	12/31/2001
Language:	English
Contrast:	25
Passcode:	****
	

2. Highlight the selection using the  and  keys.
3. Press  (enter).
4. Set the correct value using the , , and  keys.
5. Press  to accept the value.
6. Press  to return.

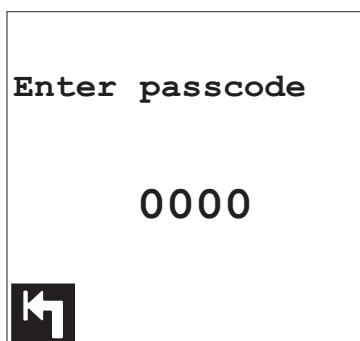
Setup items

- Time (1st) - Set current time.
- Time (2nd) - Select time format. Select between: "AM/PM" or "24 hr."
- Date (1st) - Select date format. Select between: "Month/Day/Year" or "Day/Month/Year."
- Date (2nd) - Set current date.

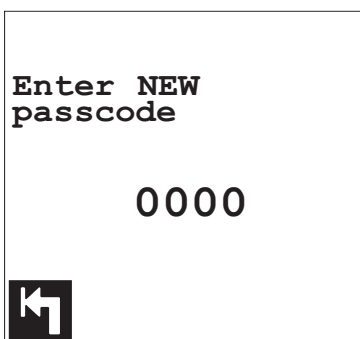


Note: Time and date can only be adjusted 24 hours back and forth after each power-up with a total limit of ± 5 days relative to the factory setting.

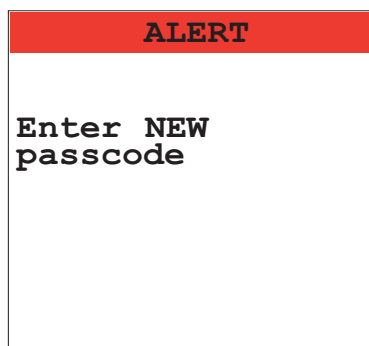
- Language - Selects language. After selecting a language, all menus, messages and printouts will be in the selected language.
- Contrast - Adjusts display contrast if necessary. In the main screen, the contrast can be adjusted by pressing the or the key.
- Passcode - Changes the 4-digit User Supervisor passcode. The eBDS Oxygen Analyzer will first prompt for the present passcode.



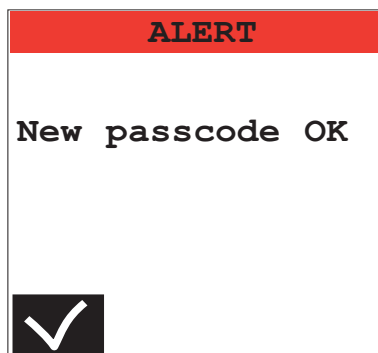
Enter the new passcode.



An ALERT is displayed, prompting the user to enter the new passcode once more.



If the procedure has been followed correctly, the following message will display.



Press  to confirm and return to Setup Menu screen 1.

Enabling PC handshake and manual logging

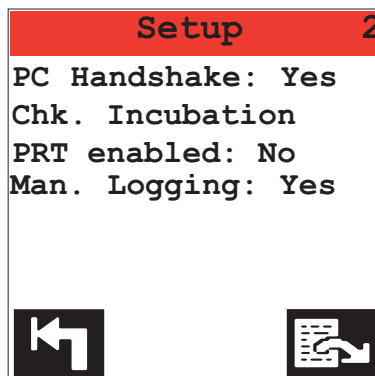
The user can enable or disable PC handshake or manual logging at any time.

Enabling PC handshake

If PC handshake is set to "Yes," the eBDS Oxygen Analyzer will verify that a PC with data collection software is connected. This check is performed continuously during the sample test procedure.

To enable or disable PC handshake:

1. In the Setup Menu, press  to go to screen 2.



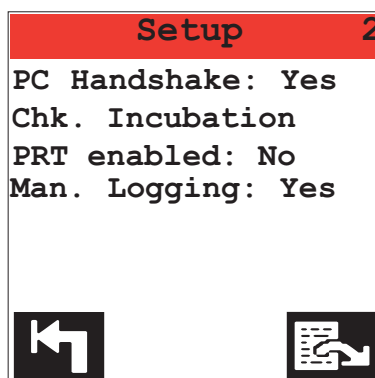
2. Highlight PC Handshake using the  and  keys.
3. Press  to toggle yes or no.
4. Press  to return.

Enabling Manual Logging

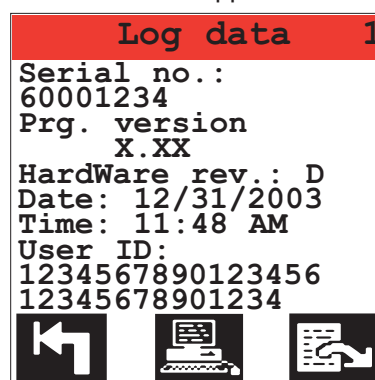
If manual logging is set to “Yes,” the user can initiate a retransmission of data to the PC, which is useful if a failing connection to the PC is re-established.

To enable manual logging:

1. In the Setup Menu, press  to go to screen 2.



2. Highlight Manual Logging using the  and  keys.
3. Press  to toggle yes or no.
4. Press  to return.
5. Access to Log Data Menu screens 1-5 is now possible by pressing  in any screen in which it appears.



The Log Data Menu screens provide the user with the same information that is transmitted to the PC. This enables the user to log data manually if a PC with data collection software is not available or in case the connection to the PC fails.

6. Press  in any of the five Log Data Menu screens to initiate a retransmission of data to the PC, which is useful if a failing connection to the PC is re-established.

Setting scanner options

To set scanner options:

1. In the Setup Menu, press  to go to screen 3.



2. Highlight your selection using the  and  keys. The options are:
 - User ID - If set to “No” the user will not be prompted to input a User ID. If set to “Yes” the user will be prompted to scan the User ID. If set to “LogOn” the user may freely choose to input the User ID either manually or by means of the scanner. If set to “Auto” the user will be prompted to scan the User ID if a scanner is connected. If set to “Auto” and a scanner is not connected, User ID is not requested.
 - Code - Barcode type. Two options are available: “Codabar” and “Free”, which is a simple string consisting from 3 to 20 characters. Code: appears only if Codabar is connected.
 - Max. length/Total length - Number of characters in the barcode string.
 - Start/Stop --appears for Codabar only. Five options are available: A,B,C,D.
3. Press .
4. Set the correct values using the , , and  keys.
5. Press  to accept the value.
6. Press  to return.

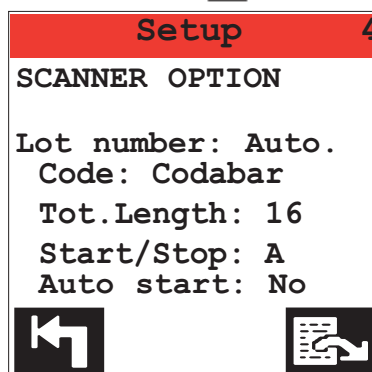
Setting the lot number



Note: Changing this parameter cannot be done by the user but requires the assistance of a Haemonetics Service Representative.

To set the lot number:

1. In the Setup Menu, press  to go to screen 4.



2. Highlight your selection using the  and  keys. The options are:

- Lot number:
 - If set to “No” the user will not be prompted to input a Lot number.
 - If set to “Yes” the user will be prompted to scan the Lot number.
 - If set to “Auto” the user will be prompted to scan the Lot number if a scanner is connected.
 - If set to “Auto” and a scanner is not connected, Lot number will not be requested.
- Code - Barcode type. Three options are available: “ISBT 128”, “Codabar” and “Free”, which is a simple string consisting of up to 30 characters.
- Max./Tot. Length - Number of characters in the barcode string.
- Start/Stop - Start/Stop code for Codabar only. Five options are available: A,B,C,D, and * (wildcard).
- Auto start - If set to “Yes” the eBDS Oxygen Analyzer will automatically start a measurement upon scanning a valid Lot number.

3. Press .

4. Set the correct values using the , , and  keys.

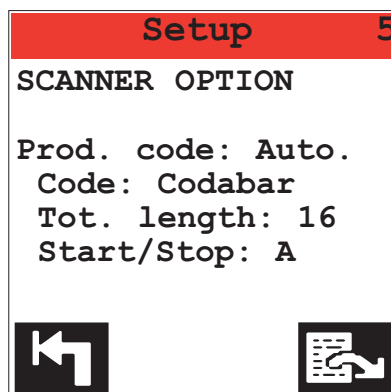
5. Press  to accept the value.

6. Press  to return.

Setting the product code

To set the product code:

1. In the Setup Menu, press  to go to screen 5.



2. Highlight your selection using the  and  keys. The options are:
 - Product code - If set to "No" the user will not be prompted to input a Product code.
 - If set to "Yes" the user will be prompted to scan the Product code.
 - If set to "Auto" the user will be prompted to scan the Product code if a scanner is connected.
 - If set to "Auto" and a scanner is not connected, Product code will not be requested.
 - Code - Barcode type. Four options are available: "
 - USS Codabar
 - ISBT 128
 - Codabar
 - Free, which is a string consisting of up to 30 characters.
 - Max. length/Total length - Number of characters in the barcode string.
 - Start/Stop - Start/Stop code, for Codabar only. Five options are available: A, B, C, D and * (wildcard).
3. Press .
4. Set the correct values using the , , and  keys.
5. Press  to accept the value.
6. Press  to return.

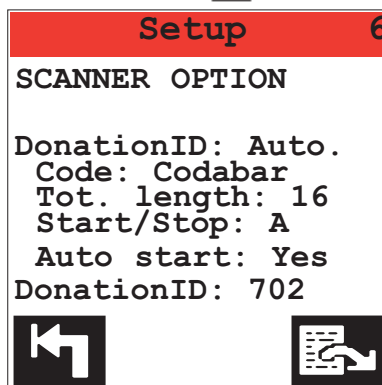
Setting the Donation ID



Note: Changing this parameter cannot be done by the user but requires the assistance of a Haemonetics service representative.

To set the Donation ID:

1. In the Setup Menu, press  to go to screen 6.



2. Highlight your selection using the  and  keys. The options are:
 - Donation ID - If set to “No” the user will not be prompted to input a Donation ID. The eBDS Oxygen Analyzer will automatically assign an internally generated number to represent the measurement (Figure 20).
 - If set to “Yes” the user will be prompted to scan the Donation ID
 - If set to “Auto” the user will be prompted to scan the Donation ID if a scanner is connected
 - If set to “Auto” and a scanner is not connected, Donation ID will not be requested
 - Code - Barcode type. Four options are available:
 - USS Codabar
 - ISBT 128
 - Codabar
 - Free, which is a string consisting of up to 30 characters
 - Max. length/Total length - Number of characters in the barcode string.
 - Start/Stop - Start/Stop code, for Codabar only. Five options are available: A, B, C, D, and * (wild card).
 - Auto start - If set to “Yes” the eBDS Oxygen Analyzer will automatically start a measurement upon scanning a valid Donation ID.

Chapter 3

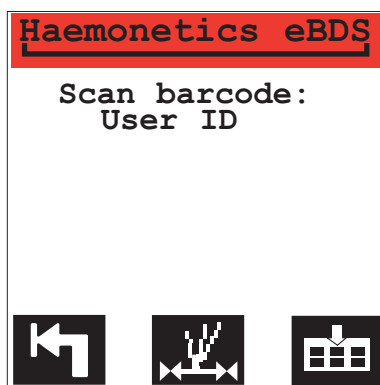
Sample test procedure

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Logging on

To log on to the eBDS Oxygen Analyzer:

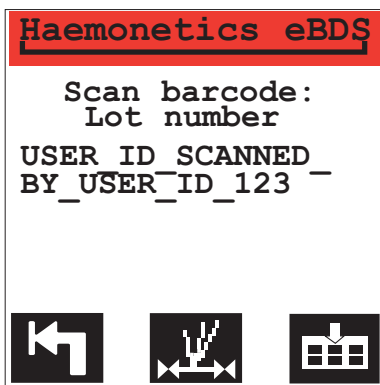
1. The user may be prompted to input a “User ID”.



Depending on the settings in the Setup Menu (“Setting up the eBDS Oxygen Analyzer” on page 25), three possibilities exist:

- User ID not required, in which case this item is bypassed.
- The user is prompted to input the User ID either manually using the “Up”, “Down” and “Right” keys, or by means of a scanner.
- The user is prompted to input the User ID using a scanner. When the eBDS Oxygen Analyzer receives a barcode from the scanner, two short beeps will sound.

2. The user may now be prompted to input a Lot number.”



Depending on the settings in the Setup Menu (“Setting up the eBDS Oxygen Analyzer” on page 25), three possibilities exist:

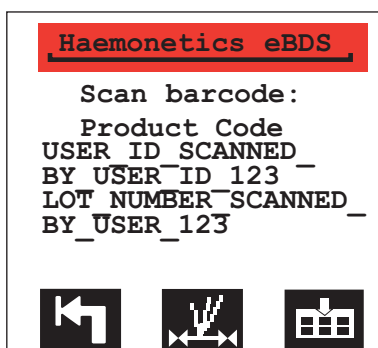
- Lot Number not required, in which case this item is bypassed.
- The user is prompted to input the Lot Number using a scanner.

- The user is prompted to input the Lot Number using a scanner after which the eBDS Oxygen Analyzer will automatically start a measurement. In this case the remaining items in this section are bypassed.

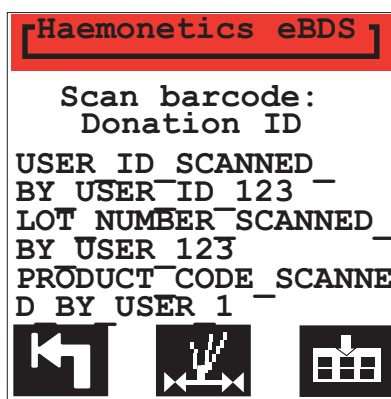
**IMPORTANT:**

Before attempting to start a measurement, perform preparatory steps 1-6 in “Sampling” on page 41.

3. The user may now be prompted to input a “Product code”.



4. Depending on the settings in the Setup Menu (see Section 5 “Setup Menu”), two possibilities exist:
 - Product code not required in which case this item is bypassed.
 - The user is prompted to input the Product code using a scanner.
5. The user is now prompted to input a Donation ID:



6. Depending on the settings in the Setup Menu (see Section 5 “Setup Menu”), two possibilities exist:
 - The user is prompted to input the Donation ID using a scanner.
 - The user is prompted to input the Donation ID using a scanner after which the eBDS Oxygen Analyzer will automatically start a measurement.

**IMPORTANT:**

Before attempting to start a measurement, perform preparatory steps 1-6 in “Sampling” on page 41.

The eBDS Oxygen Analyzer is now ready to measure sample pouch.

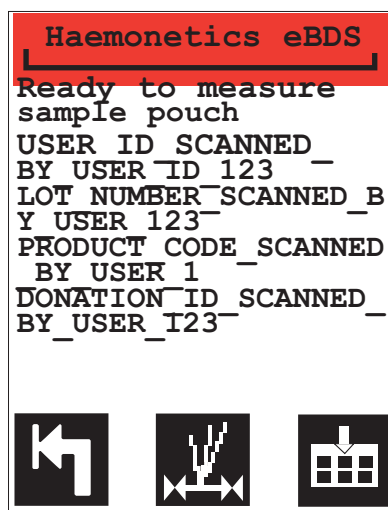


Caution: Universal Precautions: *Appropriate care should always be taken to guard against hazards when handling of untested blood components. Use of personal protective equipment such as gloves, gowns and protective eyewear to help reduce the risk of exposure is recommended. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood.*

Sampling

To perform a sample test procedure:

1. Verify that the eBDS Oxygen Analyzer displays the message “Ready to measure sample pouch” at the top of the screen.



2. Confirm that the probe filter is in place and the probe is securely attached.
3. Obtain the eBDS sample pouch to be tested. Slide the neck of the sample pouch into the holder and position securely. Scan barcodes as prompted either before or after placing the sample pouch in the holder.

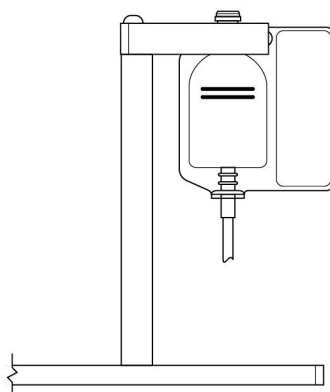


Figure 5-1, Setting up the sample pouch

4. Hold the sample pouch vertically and insert probe of the Oxygen Analyzer through the sampling site and protective membrane and into the head space air of the sample pouch. When you penetrate the

protective membrane you will hear a “click.” This means the probe has been inserted successfully.

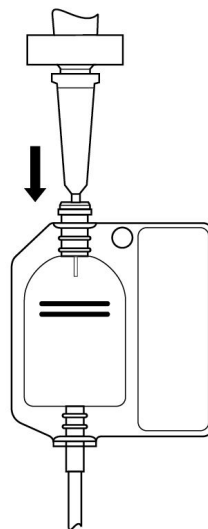


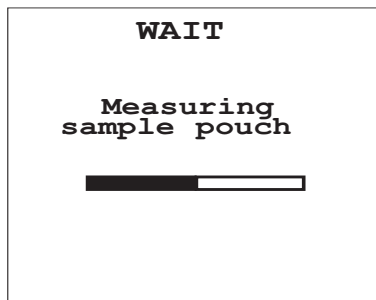
Figure 5-2, Inserting the probe into the sample pouch



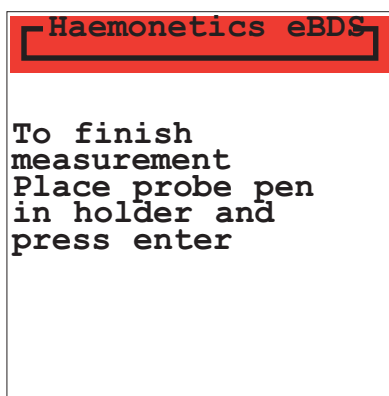
Caution:

- Contamination of probe and/or filter with liquid will result in no reading, the screen will display the alarm message: “Filter blocked.”
- Always dispose of blood - contaminated products in a manner consistent with established BIOHAZARD safety procedures.
- If probe filter is not attached fluid will enter the eBDS Oxygen Analyzer and cause damage. Contact Haemonetics Service Representative.
- Do not hold/squeeze sample pouch when inserting probe, pressure will force liquid up into probe.
- Do not insert probe into liquid.
- Do not use alcohol to cleanse sampling site or probe. The presence of alcohol near the sampling site could result in a “FAIL” determination, when there should have been a “Pass” i.e., a false positive for contamination.

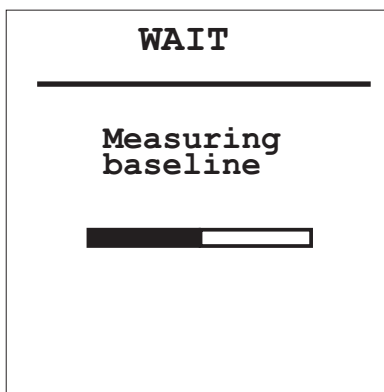
5. Once the probe is inserted, press  to start measuring or scan pouch Lot Number (or Donation ID) if “Auto Start” is enabled. While measuring, the eBDS Oxygen Analyzer displays:



6. After measuring the sample pouch, Analyzer must verify the baseline (atmospheric air). This screen is displayed:



7. Remove the probe from the sample set and place it in the probe holder located on the side of the eBDS Oxygen Analyzer.
8. Press  to start the verification of the baseline. The verification will take up to 50 seconds. This screen is displayed:



If the baseline can be confirmed, the result of the sample pouch measurement will display one of two screens:

Results of sample pouch measurement	
	If the green screen with the result "Pass" is displayed, the test did not detect bacteria contamination and indicates the sample is NEGATIVE at the time of measurement.
	A flashing "FAIL" on a red screen indicates that the platelet unit may be contaminated with bacteria and should be discarded after culturing to confirm results. This result indicates that the sample is POSITIVE.

After a "FAIL" reading the flow system will be flushed for an extended period of time and baseline verification will repeat.

9. If an "ALERT" message appears, follow the instructions on the eBDS analyzer display to enable a retest. Only one retest of the %O2 for a given eBDS Sample Set can be done. If a retest is desired, return to step 1 of this section. Should an error message be displayed and not resolved, or if for any other reason there is a question about the ability to obtain a proper "Pass" or "FAIL" indication for a given platelet component, the test should be considered invalid.
10. Record the results in normal manner.
11. Press  to confirm the result.
12. Discard the sample pouch. The eBDS Oxygen Analyzer is now ready to measure the next sample pouch.

Alarm and Alert Messages



Note: If an “Alarm” or “Alert” is displayed during sampling, the measurement is invalid.

This section lists the alarms and alerts that may occur.

Filter is blocked alarm

If liquid is drawn into the probe filter, the filter will become blocked. The “Filter blocked” alarm is displayed.

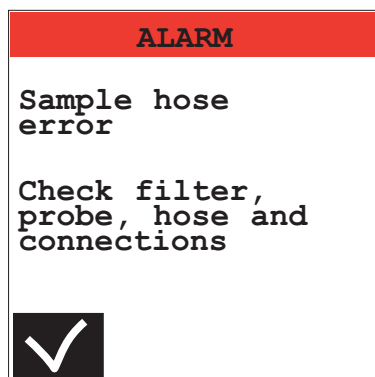


Remedy:

1. Change both the probe filter and the probe and place in the holder.
2. Press  to reset the eBDS Oxygen Analyzer.
3. Perform the Probe Leak Test (“Performing the Probe Leak Test” on page 50).

Sample hose error alarm

If the sample hose is detached or contains a leak, the alarm “Sample hose error” is displayed.

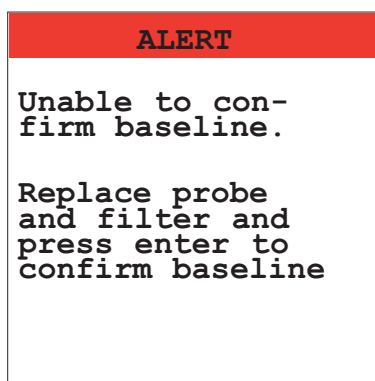


Remedy:

1. Check that the O-ring on the sample hose is mounted correctly.
2. Check all connections for leaks.
3. Press  to reset the eBDS Oxygen Analyzer.
4. Perform the Probe Leak Test (see “Performing the Probe Leak Test” on page 50).

Unable to confirm baseline alert

If the eBDS Oxygen Analyzer is unable to confirm a baseline, that is, it was not possible to measure $20.9\% \text{ O}_2 \pm 0.2$ while measuring atmospheric air, the Unable to confirm baseline alert is displayed.

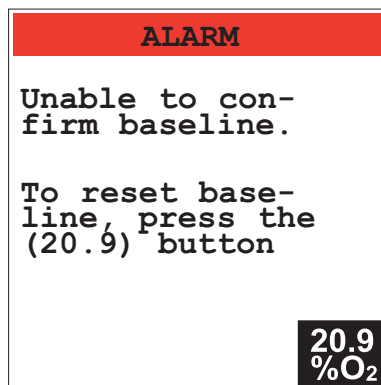


The cause can be either a partly blocked probe filter or probe.

Remedy:

1. Replace the probe and the probe filter.
2. Place assembly in the holder and Press to reset analyzer.
3. Perform the Probe Leak Test (“Performing the Probe Leak Test” on page 50).

If it is still not possible to confirm the baseline after replacing probe filter and probe, with the probe placed in the holder (see previous alert), it is therefore not possible to measure $20.9\% \text{ O}_2 \pm 0.2$ when sampling atmospheric air. It is therefore necessary to reset the baseline.

**Remedy:**

1. Press . The eBDS Oxygen Analyzer resets the baseline.
2. Perform the Probe Leak Test ("Performing the Probe Leak Test" on page 50).

Possible wrong measurement alert

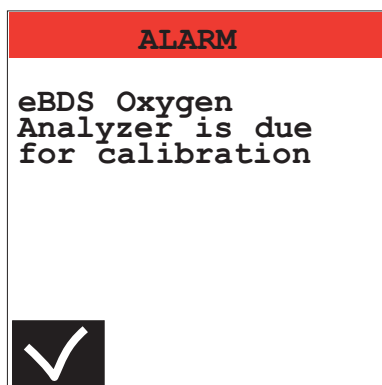
This alert appears when the sample pouch concentration is above 21.1% O₂. Expected O₂ concentration is 20.9% or lower.

**Remedy:**

Press  to reset the eBDS Oxygen Analyzer.

Calibration is due alert

Calibration is due.



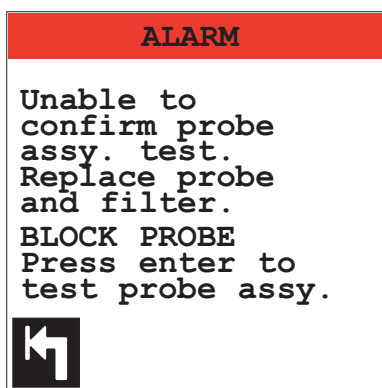
Remedy:

Contact a Haemonetics Service Representative. When 12 months have elapsed since the last calibration, this alert is displayed once every day at first user activity followed by the alarm "New calibration needed."

Press  to resume normal operation. The user can resume normal operation until 13 months have elapsed since the last calibration. After this date an alarm "New calibration needed" is displayed (page 67) and the eBDS Oxygen Analyzer is locked for further testing until a calibration has been performed.

Unable to confirm probe assay. test alert

If a leak is detected during a leak test, the "Unable to confirm probe assay. test." Alert is displayed.



Remedy:

Replace the probe and filter, then press .



IMPORTANT:

If "Unable to confirm probe assay." is displayed again, it indicates that a leak is still present.

**Remedy:**

1. Replace the complete probe assembly
2. Perform the probe leak test
3. Press .

If the test fails a third time, contact a Haemonetics service representative.

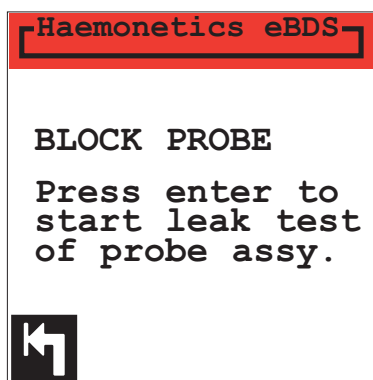
Performing the Probe Leak Test

Conduct the Probe Leak Test

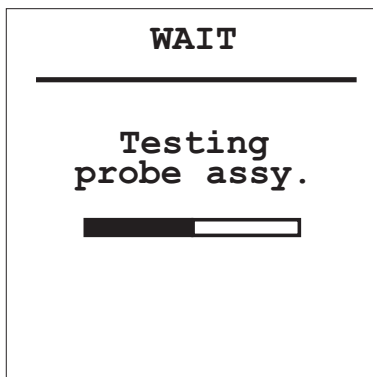
- A minimum of once a day
- After every probe and filter change

To perform the Probe Leak Test:

1. Press the leak test icon .
2. Block the probe by pressing the probe tip against the rubber disc located on the front of the eBDS Oxygen Analyzer.



3. Press  to start the leak test. The test will take approximately 10 seconds. Keep the probe tip against the rubber disc for the duration of the test..



If the leak test was successful, this screen is displayed:.



4. Press  to confirm the result.
5. If the leak test is unsuccessful, replace the probe and filter and repeat the test.



6. If the subsequent leak test was unsuccessful, replace entire sample probe assembly and repeat the test.



Chapter 4

Connecting to a PC or scanner

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Connecting to a personal computer

To connect the eBDS Oxygen Analyzer to a personal computer:

1. Locate the serial cable delivered with the eBDS Oxygen Analyzer. The connector pinout is:

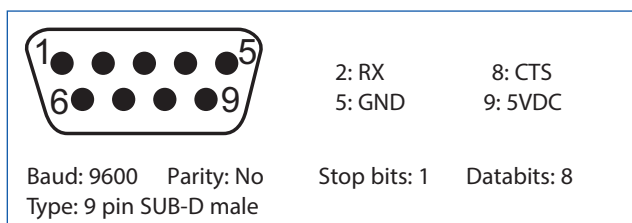


Figure 4-1, Serial Cable Pinout

2. Connect either end of the cable to the RS232C serial port on the rear of the eBDS Oxygen Analyzer.
3. Connect the other end of the serial cable to the RS232C port on the personal computer.

Connecting to a barcode scanner



IMPORTANT: The serial port on the left side of Analyzer has +5 VDC on pin no. 9, and is thus not a standard serial RS232C port. Draw max. 250 mA from this 5 V DC supply.

The user can connect a scanner directly to the serial port without the use of an external power supply if the scanner is able to use the 5 VDC from pin 9 in the serial port (max. 250 mA) as its power supply.

To connect the eBDS Oxygen Analyzer to a barcode scanner:

1. Locate the serial cable delivered with the eBDS Oxygen Analyzer. The connector pinout is:

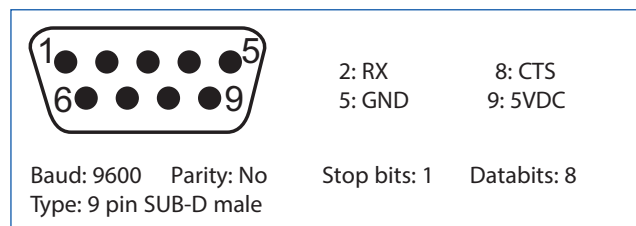


Figure 4-2, Serial Cable Pinout

2. Connect either end of the cable to the RS232C serial port on the left side of the eBDS Oxygen Analyzer.
3. Connect the other end of the serial cable to the RS232C port on the scanner.

Configuring the scanner



Note: This configuration procedure activates handshaking between the eBDS Oxygen Analyzer and the Metrologic Voyager Bar Code Scanner.

To configure the scanner:

1. Power up the **Voyager**.
2. Scan the four bar codes below, proceeding from code 1 to code 4.

Code 1	 3 9 9 9 9 9 9	Enter configuration mode (3 fast beeps)
Code 2	 3 9 9 9 9 9 8	Recall defaults (1 beep)
Code 3	 3 1 2 4 5 1 0	Invert RTS polarity (1 beep)
Code 4	 3 9 9 9 9 9 9	Exit configuration mode (3 slow beeps)

3. Press  to reset the eBDS Oxygen Analyzer.

Chapter 5

Performing diagnostics and data logging

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Performing Diagnostics



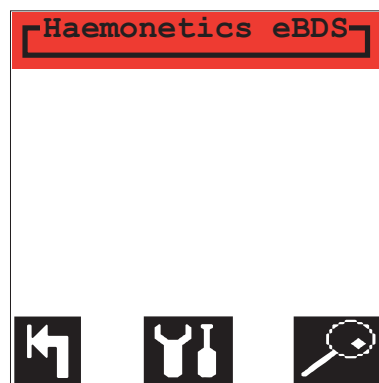
Note: Access to the Diagnostic Menu menu requires that the user enter the User Supervisor passcode.

To perform Analyzer diagnostics:

1. In the main display, press  to go to the “Enter passcode” screen.



2. Enter the User Supervisor passcode.
3. Press  to confirm.
4. Icons  and  appear providing access to the Setup Menu and the Diagnostic Menu, respectively.



5. Press  to go to screen 1 of the Diagnostic Menu.

Diagnostic		1
O2 EMF	-0.238	
O2	20.93	
Press.diff	209	
Device temp.	29	
Heat.t.dif	0	
O2 Offset	-0.002	
Scanner	Yes	
Prg.version:	X.XX	
		  



Note: In the Diagnostic Menu the user can start and stop the pump by pressing .

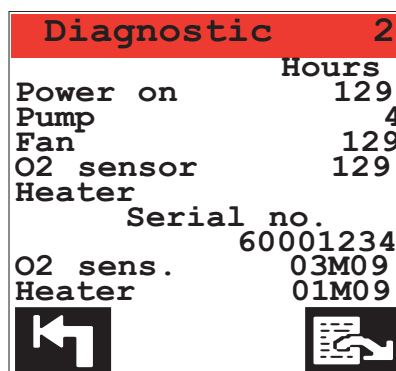
Diagnostics screen 1 displays these diagnostic results:

- O2 EMF - Sensor EMF (mV)
- O2 - Actual measured %O2
- Press.diff. - Actual pressure difference/pressure drop in sample hose, probe and probe filter. Read out should be less than 2 mbar with the pump stopped. Normally, with the pump running, the pressure difference should be between 200 and 230 mbar.
- Device temp. - Internal device temperature [°C]. Allowed range is 0 to 60 °C.
- Heat.t.dif - Heater temperature difference [°C]. Max. ±30 °C is allowed.
- O2 Offset - Read out of the current O2 offset/drift in mV compared to factory calibration with 20.9% O2. The O2 offset is measured every time the baseline is reset. Max allowable offset is ±3 mV.
- Scanner - Yes: Scanner detected. No: No scanner is detected. It is possible to scan barcodes while in this menu. Scanned bar code is written on the line below.
- Prg.version - Software program version.

6. The user now has three options:

- Press  to go to screen 2 in the diagnostic menu. Screen 2 in the diagnostic menu contains hour counters and serial numbers of major

parts in the eBDS Oxygen Analyzer.



- Press  to go back to screen 1 in the diagnostic menu.
- Press  to return to the previous screen
- Press  to go to the Log Data screen. See “Viewing data logging” on page 7-61 for information.

Sending diagnostic menu data to a peripheral device

To send diagnostic data to a peripheral device:

1. Ensure that PC Handshake is set to No (see Section 5, PC Handshake).
2. Press  to go to screen 1 of the Diagnostic Menu.
3. Press  to go to screen 2 in the diagnostic menu.
4. Press  to send the data to a peripheral device such as a PC with data collection software.



Note: If the user is using Data-5 Software, he or she may need to press



several times to allow all of the data to be transferred from the buffer. If there is any sample reading data or residual data in the buffer that has not been delivered, it will be delivered when the connection between the eBDS Oxygen Analyzer and the peripheral device is disconnected and then re-reconnected (see “Enabling PC handshake and manual logging” on page 4-30).

Viewing data logging

The eBDS Oxygen Analyzer is configured to log the following data:

- Serial_no_of_eBDS
- Software_version
- Hardware_revision
- Year
- Month
- Day
- Hours
- Minutes
- Seconds
- UserID
- Lot_Number
- Product_Code
- Donation_ID
- Pre_Baseline_mV
- Pre_Baseline_O2%
- Pre_Baseline_Pressure
- Pre_Baseline_DeviceTemp
- Pre_Baseline_Thermocouple_mV
- Test_O2_sensor_mV
- Test_O2%
- Test_Pressure
- Test_DeviceTemp
- Test_Thermocouple_mV
- Post_mV
- Post_Baseline_O2%
- Post_Baseline_Pressure
- Post_Baseline_DeviceTemp
- Post_Baseline_Thermocouple_mV
- Fail_level_
- O2%
- Result;CRC16

Hour: logged in 24 hrs. format.

Donation_ID: If a barcode is scanned before the measurement this code is logged. If not, the internal Donation ID is used.

Result:

0: FAIL.	O2_level = sample pouch
1: Pass.	O2_level = sample pouch
2: Baseline confirmed	O2_level = Baseline
3: Unable to confirm baseline	O2_level = Baseline
4: Probe filter blocked	O2_level = 0
5: Measuring hose error	O2_level = 0
6: Sample pouch above 21.1% O2	O2_level = 0
7: Manual leak test failure #1	Replace probe/filter
8: Manual leak test failure #2	Replace sample kit
9: Manual leak test OK	

Chapter 6

System Errors and Alarms

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Error no. 35	70
O2 sensor	
Error no. 61	70
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Alarms and Troubleshooting

Errors in eBDS Oxygen Analyzer are divided into two categories; alarms and System errors (see “System errors” on page 69).

Leak, Pump, and pressure gauge test

1. Go to screen 1 in the diagnostic menu (“Performing Diagnostics” on page 58). Read the Press. diff. It should be less than 2 mbar with the pump turned off.
2. Turn on the pump with the  key and read Press. diff. It should now be in the range 200 to 230 mbar.
3. Block the probe by pressing probe tip against rubber disc on top of analyzer and check that Press. diff. now increases to a value greater than 350 mbar. Typical pressure differences with the pump running:
 - Without measuring gas hose: 0 mbar
 - With measuring gas hose and probe pen: 200 mbar
 - With measuring gas hose, probe pen and probe filter: 203 mbar
 - With measuring gas hose, probe pen, probe filter and probe: 204 mbar
 - With blocked probe: > 350 mbar

If the pressure difference, with the pump running and with the probe blocked, is below 350 mbar, it indicates either a sample flow system leak or a defective pump. Perform the Probe Leak Test (“Performing the Probe Leak Test” on page 50). If this does not remedy the problem, contact a service representative.

Alarms

The filter is blocked. Change filter and probe

This alarm occurs when the pressure difference, with the pump running, is greater than the Press. max limit defined in the setup menu.

To remedy the problem:

1. Change probe and filter.
2. Perform the leak, pump and pressure gauge test ("Leak, Pump, and pressure gauge test" on page 65).
3. If changing the filter and probe did not solve the problem check that the sample hose is not blocked.
4. Perform leak, pump and pressure gauge test ("Leak, Pump, and pressure gauge test" on page 65).
5. If this does not remedy the problem, contact a Haemonetics service representative.

Sample hose error. Check filter, probe, hose, and connections

This alarm occurs when the pressure difference, with the pump running, is lower than the Press. min limit defined in the setup menu. To remedy the problem:

1. Check all connections for leaks.
2. Perform the Probe Leak Test ("Performing the Probe Leak Test" on page 50).
3. With the pump running and with the probe blocked, check that Analyzer is able to obtain a pressure difference bigger than 350 mbar. See "Leak, Pump, and pressure gauge test" on page 65.

Calibration data is invalid Please contact service representative

Each time the eBDS Oxygen Analyzer is turned on it checks to determine whether the calibration data is valid and intact. If not, all calibration data is reset and this alarm displays.

The User cannot use the eBDS Oxygen Analyzer until a new calibration has been performed.

If this alarm appears, contact a Haemonetics Service Representative.

**Error in setup data
Please contact service representative**

Each time the eBDS Oxygen Analyzer is turned on it checks to determine whether the setup data is valid and intact. If not, all setup data is preset to default values and this alarm displays.

The default values are:

- Scanner: Auto
- Lot number: Auto
- User ID: Auto
- Language: English

If this alarm displays, contact a Haemonetics service representative.

**No LF signal at last power down
Please contact service representative**

Each time the eBDS Oxygen Analyzer is turned off, hour counters, etc. are saved. Further, information is saved indicating that all hour counters, etc. were saved. If this information is missing when the eBDS Oxygen Analyzer is turned on, this alarm displays. The information is missing because of an error in the power supply or another hardware error.

To remedy this condition, turn the eBDS Oxygen Analyzer off and on again. If this alarm displays again contact a Haemonetics Service Representative.

**New calibration needed
Please contact service representative**

This alarm displays when more than 13 months have elapsed since the last calibration. This means that the accuracy of the instrument cannot be guaranteed. The user cannot use the eBDS Oxygen Analyzer until a new calibration has been performed.

To calibrate the eBDS Oxygen Analyzer, contact a Haemonetics Service Representative.

PC not connected

This alarm displays if PC Handshake is set to Yes in the Setup Menu, screen 2, and the eBDS Oxygen Analyzer cannot verify that a PC with data collection software is connected.

To remedy this condition

- If no PC is connected, set PC Handshake to No
- If a PC is connected, check that the cable is connected correctly and that the software is responding correctly

Communication problems with PC

This alarm displays if PC Handshake is set to Yes in the Setup Menu, screen 2, and the eBDS Oxygen Analyzer does not receive an acknowledgement upon sending sample data to the PC.

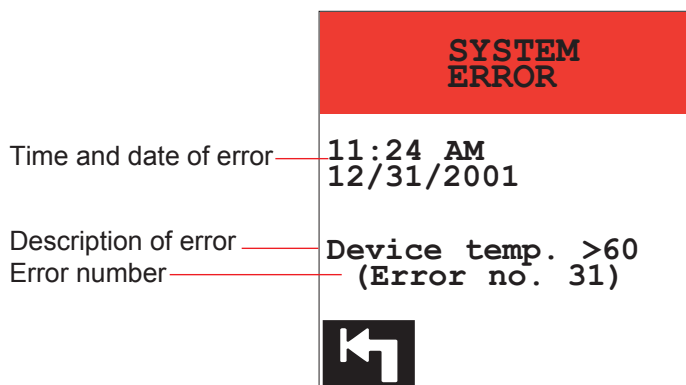
Remedy: Check that the PC software is responding correctly.

**Log data lost
Could not send data**

If the alarm Communication problems with PC has displayed because of a missing acknowledgment from the PC upon sending sample data, this alarm will follow shortly after. This indicates that the data being sent is not being collected by the PC and must be considered lost.

System errors

If a system error occurs, the error displays:



When a System Error is displayed:

1. Note the error time and date.
2. Note the error description.
3. Note the error numbers.
4. Press  to accept the error. When the user presses  the eBDS Oxygen Analyzer will restart when power is connected.

Response to a system error

When a system error occurs, restart the eBDS Oxygen Analyzer once (unless the error is Device temp. >60°C Error no. 31). If the same or a new system error displays after a restart, turn the eBDS Oxygen Analyzer off and contact a Haemonetics Service Representative.

Device temp. >60°C Error no. 31

the eBDS Oxygen Analyzer checks its internal temperature continuously. This error indicates that the internal device temperature is greater than 60 °C.

Possible causes:

1. The surrounding temperature is too high.
2. The filter in front of the fan on the rear of the eBDS Oxygen Analyzer is blocked.
3. The fan is defective.

Remedies:

1. Determine that the instrument's fan is not too close to a wall, or in an area where heat could build up.

2. Change the filter in front on the fan if it is dirty or otherwise is restricting airflow.
3. Activate back-up analyzer and contact a Haemonetics Customer Service Representative to obtain replacements to the unit displaying System Error.

Bad ROM checksum Error no. 32

Checked at start up. The program in the eBDS Oxygen Analyzer resides in a PROM together with a checksum. If the checksum is wrong this error displays, indicating a hardware error.

Remedy: Call a Haemonetics Customer Service Representative for return authorization and a replacement Analyzer. Substitute a backup Analyzer.

I2C Communic. bus Error no. 33

Checked continuously. Internal communication bus error. This error message indicates a hardware error.

Remedy: Call a Haemonetics Customer Service Representative for return authorization and a replacement Analyzer. Substitute a backup Analyzer.

LF signal Error no. 34

Checked at start up. The power supply is reporting a too-low secondary voltage. Reason: Power supply error or low primary voltage.

Remedy: Remove other electrical devices from the power line that contains the wall outlet supplying the Oxygen Analyzer or otherwise stabilize and verify the supply voltage.

Thermocouple Error no. 35

The thermocouple voltage is not in the range of -1 to 9 mV. Reason: The thermocouple is disconnected (hardware error).

Remedy: Call customer service for return authorization and replacement Analyzer. Substitute backup Analyzer.

O2 sensor Error no. 61

The heater temperature difference is not in the range ± 30 °C. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Analyzer. Substitute backup Analyzer.

Error no. 62

The O2 sensor voltage (EMF) is higher than 200 mV. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Oxygen Analyzer. Substitute backup Oxygen Analyzer.

Error no. 63

The O2 sensor voltage (EMF) is below -50 mV. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Oxygen Analyzer. Substitute backup Oxygen Analyzer.

Error no. 64

The O2 sensor is short-circuited. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Oxygen Analyzer. Substitute backup Oxygen Analyzer.

Error no. 65

The voltage reference to the ADC is not within the tolerance $1.45\text{ V} \pm 0.0725\text{ V}$ (5%). Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Oxygen Analyzer. Substitute backup Oxygen Analyzer.

Error no. 66

The O2 offset is outside the range: factory calibration with $20.946\% \text{ O}_2 \pm 3.0\text{ mV}$. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement Oxygen Analyzer. Substitute backup Oxygen Analyzer.

**Device temp. <0
Error no. 37**

Checked continuously. Internal device temperature is below 0 °C.

Remedy: Move Analyzer to a location where the temperature is greater than 0°C and wait until the temperature has stabilized.

**RAM
Error no. 41**

Error in internal RAM. Cannot detect internal clock. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement of the eBDS Oxygen Analyzer. Substitute backup Analyzer.

**AD7714
Error no. 42**

Error in internal ADC AD7714. Reason: Hardware error.

Remedy: Call customer service for return authorization and replacement of the eBDS Oxygen Analyzer. Substitute backup Analyzer.

Maintenance

- Calibration and service is to be provided by a factory authorized technician only.
- The device should be cleaned with a mild detergent solution; however, if the front panel (keys and display field) are seriously soiled, use isopropyl alcohol. No other solutions should be used to clean the front panel.

Service information

For service information call Customer Service or your local representative.

In the USA & Canada, call 800.537.2802

Chapter 7

Technical specifications

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Power supply

Electrical supply

Rated Input Voltage: 110/115/230 V AC

Rated Frequency: 50/60 Hz \

Rated Input Power: 70 VA

Mains supply voltage

Mains supply voltage fluctuations are not to exceed 10% of the normal supply voltage

Pollution classification

Degree 2

Environmental specifications

Installation category

Category II

Altitude

Up to 3,000 m (9,800 feet)

Temperature

Storage: -20 °C to 45 °C

Operating: 15 °C to 35 °C

Humidity

Storage: < 75% RH

Operating: < 95% RH (non-condensing)

Physical specifications

Dimensions

323 cm x 21 cm x 27 cm (Width x Depth x Height)

Weight

5.7 kg

O₂ concentration “pass-fail” threshold

9.4% (in configuration for platelets collected in plasma)

Headspace gas sample volume per test

1.7 mL +/- 0.01 mL

Testing time

(from start sample measurement to end of sample measurement)

Less than 15 seconds

Electrical requirements

Fuses

0.63 Ampere 250 Volt Alternating Current - 5 x 20 mm Time Lag Surge
withstand Glass Body

Cartridge Fuse designed to IEC Specification.

1.6 Ampere 250 Volt Alternating Current - 5 x 20 mm Time Lag Surge
withstand Glass Body

Cartridge Fuse designed to IEC Specification.

Device risk statement

All risk is reduced to tolerable risk level per IEC Test Requirements.