VERTICAL-WHEEL®
BIOREACTORS

PBS-80 Vertical-Wheel®

Reusable Sensors

Single-Use Bioreactor System

User Manual

Applicable Models: IA-80-B-531 | IA-80-B-532

PBS Biotech, Inc.

This User Manual reflects the latest product updates available at the time of publication. While every effort has been made to ensure accuracy, specifications and features may change. Please refer to the most recent product information on our website for the most up-to-date details regarding your bioreactor system.

PBS Biotech, Inc. is not responsible for printing or clerical errors.

This manual is intended as a guide to provide the user with necessary instructions on the proper use and maintenance of the PBS-80 Bioreactor System. This manual should be used in conjunction with instruction and training supplied by qualified PBS Biotech, Inc. personnel.

Any failure to follow the instructions as described, including use of materials or products not approved or recommended by PBS Biotech, Inc., could result in impaired product function, injury to the user or others, or void applicable product warranties. PBS Biotech, Inc. accepts no responsibility for liability resulting from improper use or maintenance of its products.

Utilization of PBS Biotech, Inc. products may require the user to handle and dispose of biohazardous materials. Users must fully understand and implement all regulations regarding the safe handling of biohazardous products and waste, including the policies and procedures of their facility.

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Contents

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About This Manual

This user manual shows you how to install, configure, and use the PBS-80 Bioreactor System (PBS-80). This manual covers the Integrated Bioreactor, including the PBS Software package and the PBS-80 Bioreactor Single-Use Bag assembly.

Configurations are standard as of the time of publication and the software features and instructions are applicable to version 4.2.x. The “Software Release Version” can be viewed in the “About” menu from the triple bar ≡ menu (top right corner).

The contents include:

- An overview of the PBS-80’s features, components, and controls (Chapter 1 on page 13)
- A high level system description to provide an understanding of the complete PBS-80 (Chapter 2 on page 28)
- Safety considerations (Chapter 3 on page 33)
- Product specifications (Chapter 4 on page 37)
- Instructions for installing the PBS-80 and configuring users, logger settings, and alarms (Chapter 5 on page 41)
- Day-to-day use of the PBS-80 (Chapter 6 on page 70)
- A detailed description of all PBS-80 features and functions (Chapter 7 on page 141)
- Information an IT department will need about the PBS-80 (Chapter 8 on page 183)

Note: Screenshots are illustrative of the Hello UI features and are not intended to show actual or recommended settings.

For More Information

For Frequently Asked Questions and more troubleshooting information, visit the PBS Biotech website at www.pbsbiotech.com, then navigate to Resources → FAQ.
For specific questions, email app.eng@pbsbiotech.com.

PBS-80 at a Glance

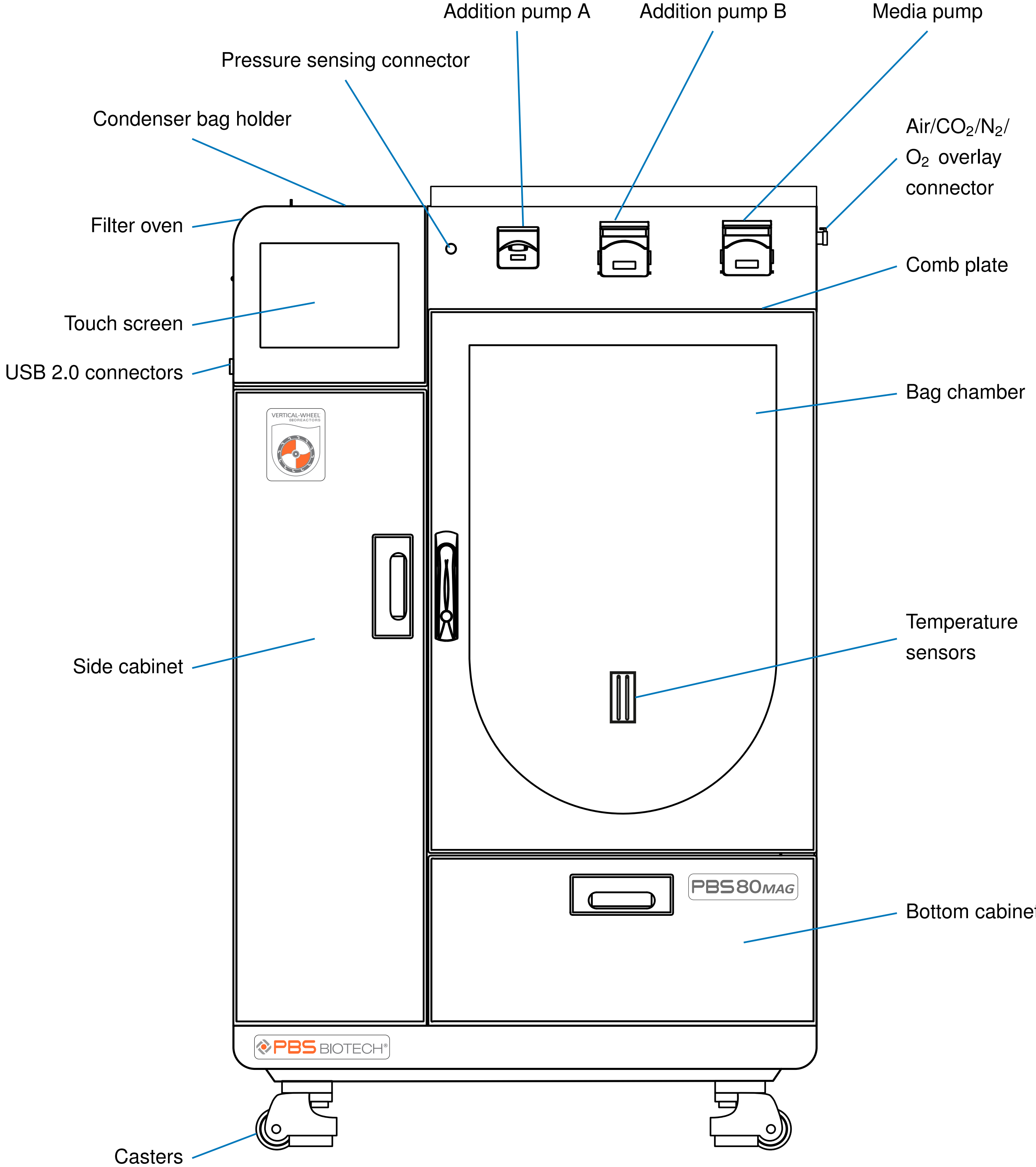
1

Use the illustrations in this chapter to become familiar with the basic features, components, and controls of the PBS-80.

Note: Some components may be slightly different from the illustrations here, depending on the configuration you purchased.

Definitions

PV = Present Value
SP = Set Point
UI = User Interface
LPM = Liters Per Minute
mLPM = Milliliters Per Minute
mL/min = Milliliters Per Minute
RPM = Revolutions Per Minute
CO_2 = Carbon Dioxide
N_2 = Nitrogen
O_2 = Oxygen
IPA = Isopropyl Alcohol
EtOH = Ethanol
MFC = Mass Flow Controller
RIO = Reconfigurable Input/Output
HMI = Human Machine Interface
BSC = Biosafety Cabinet


Addition pump A
Addition pump B
Media pump
Pressure sensing connector
Condenser bag holder
Air/CO_2/N_2/
O_2 overlay
connector
Filter oven
Comb plate
Touch screen
USB 2.0 connectors
Bag chamber
VERTICAL-WHEEL
Temperature
sensors
Side cabinet
PBS80MAG
Bottom cabinet
PBS BIOTECH
Casters

Touch screen
Responds to bare fingers, latex/nitrile gloves, or a capacitive stylus.

Filter oven
Keeps the exhaust filter at an elevated temperature to prevent clogging due to condensation of moisture from the exhaust gas.

Condenser bag holder
Stores the condenser bag.

Pressure sensing connector
Connects to the pressure sensing line on the bag. The software determines/detects a connection through a Hall effect sensor.

Addition pumps
Used with the bag's addition tubing to add base and other supplements/additions during a run.

Media pump
Used to fill the bag.

Air/CO_2/N_2/ O_2 overlay connector
Connects the bag's Air/CO_2/N_2/ O_2 overlay line to supplies of Air, CO2, N_2, and O_2, which are attached to the bioreactor via the gas connection panel (see "PBS-80 Bioreactor - Rear" on page 18).

Comb plate
Prevents critical bag failure in the event of over-pressurization due to software error. The over-inflated bag will push this plate away from magnets holding it in place, resulting in power being cut to the MFCs, pumps, heaters and agitation.

Bag chamber
Holds the bag in place. Once the chamber door is opened, the bag is loaded through the front of the chamber.

Temperature sensors
Rest against the back of the bag to provide accurate temperature readings.

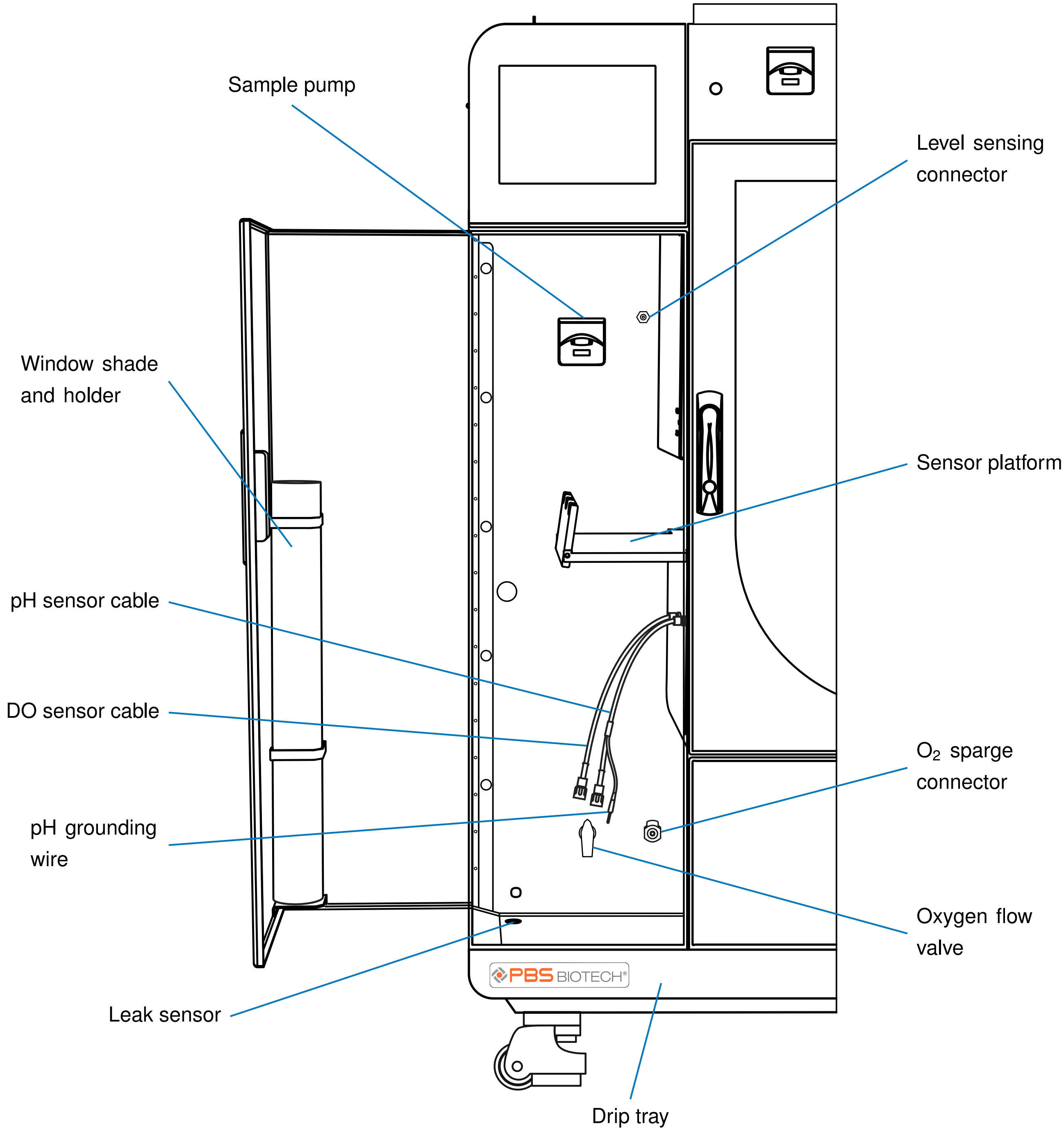
Bottom cabinet
Allows access to the harvest line.

Casters
Allows the bioreactor to be moved when unlocked and prevents movement when locked.

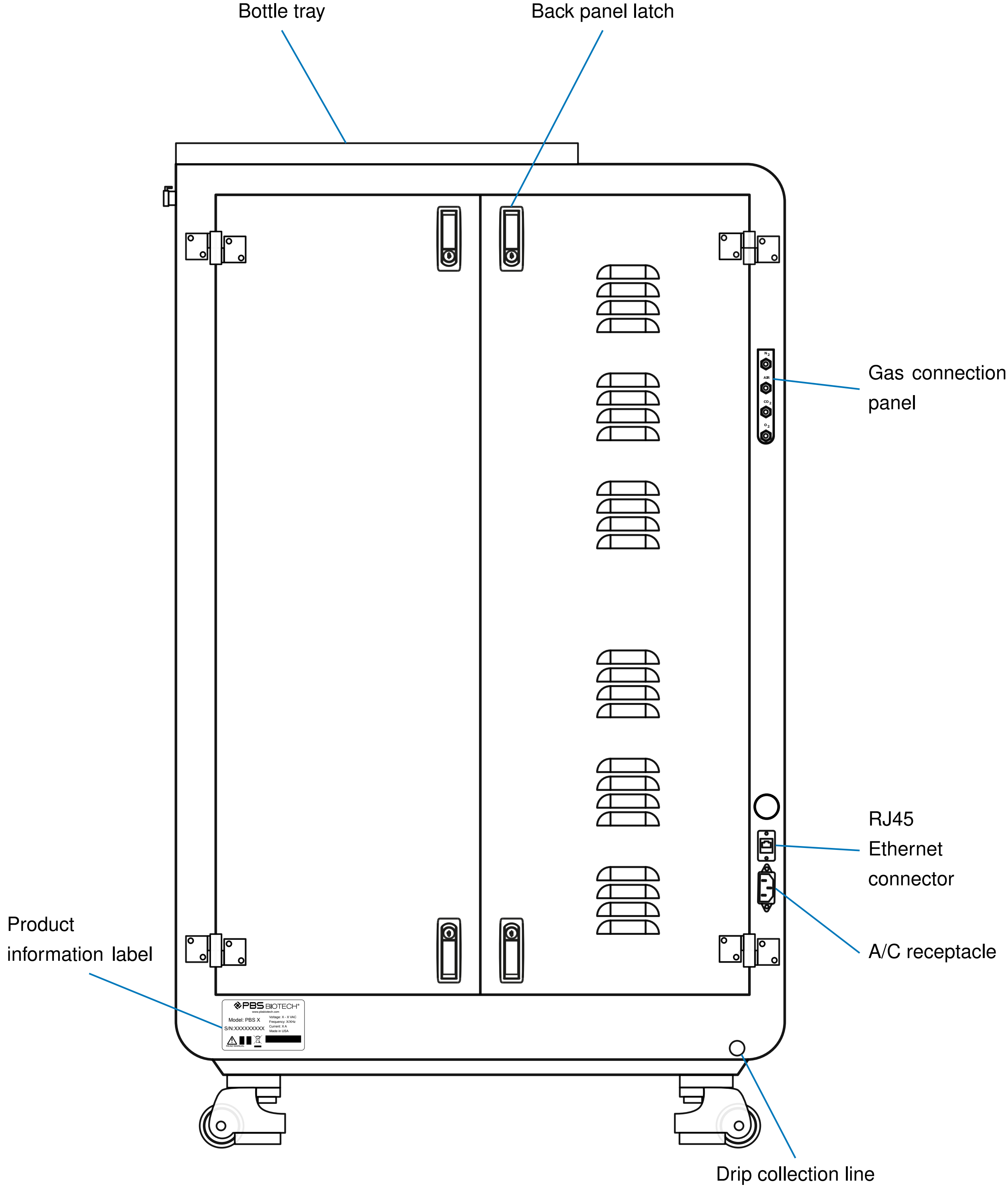
Side cabinet
Stores and allows access to sensors and equipment that may be used less regularly.

USB 2.0 connectors
Allow connection of USB devices such as a keyboard, memory stick, or Wi-Fi adaptor.

NOTICE Avoid using keyboards with a power button, to prevent accidentally turning the bioreactor's HMI computer off.


Sample pump
Level sensing connector
Window shade and holder
Sensor platform
pH sensor cable
DO sensor cable
O_2 sparge connector
pH grounding wire
Oxygen flow valve
Leak sensor
PBS BIOTECH
Drip tray

Sample pump Used to draw a sterile sample from the bag.
Sensor platform Holds the DO and pH sensors at an angle so they can provide accurate readings of the bag's contents.
Sensor cables Connected to the DO and pH sensors after they have been installed in the bag.
pH grounding wire Grounds the pH sensor's transmitter to the measured liquid, using the metal body of the DO sensor as a conduit.
Level sensing connector Attaches to the level sensing line on the bag.
Oxygen flow valve Controls how O_2 is delivered to the bag. When the valve is set to "Overlay," O_2 flows through the Air/CO_2/N_2/ O_2 overlay line into the overlay. When the valve is set to "Sparger," O_2 is diverted from the Air/CO_2/N_2/ O_2 overlay line to the O_2 sparge line, where it is sparged from the bottom of the bag.
O_2 sparge connector Connects the bag's O_2 sparge line to a supply of O_2, which is attached to the bioreactor via the gas connection panel (see "PBS-80 Bioreactor - Rear" on page 18).
Drip tray Catches any media that leaks or overflows from the bag. The media will then flow down a drain and into the drip collection line (see "PBS-80 Bioreactor - Rear" on page 18).
Leak sensor Detects leaks based on the presence of liquid in the drip tray. Stops reporting a leak once sensor contacts are dry.
Window shade and holder Stores the Window shade in this holder when not in use.


Bottle tray
Back panel latch
Gas connection panel
RJ45 Ethernet connector
A/C receptacle
Product information label
Drip collection line

Bottle tray
Stores reagent or media addition bottles during a run.

Gas connection panel
Connects the external N_2, Air, CO_2, and O_2 supplies to the bioreactor (for specifics, see “Utility Requirements” on page 41).

NOTICE The gas connectors on the back of the bioreactor are push-to-connect connectors. Disconnecting the tubing requires pushing in the orange or gray connector, then pulling out the tubing. Improper removal of tubing can break the retaining clip and impact the holding capability/seal when tubing is reinstalled.

Drip collection line
Connects to a drip collection container to catch overflow/spills from the bag.

WARNING! As this is a gravity drain, ensure the collection container is below the level of the table and that the tubing runs downwards.

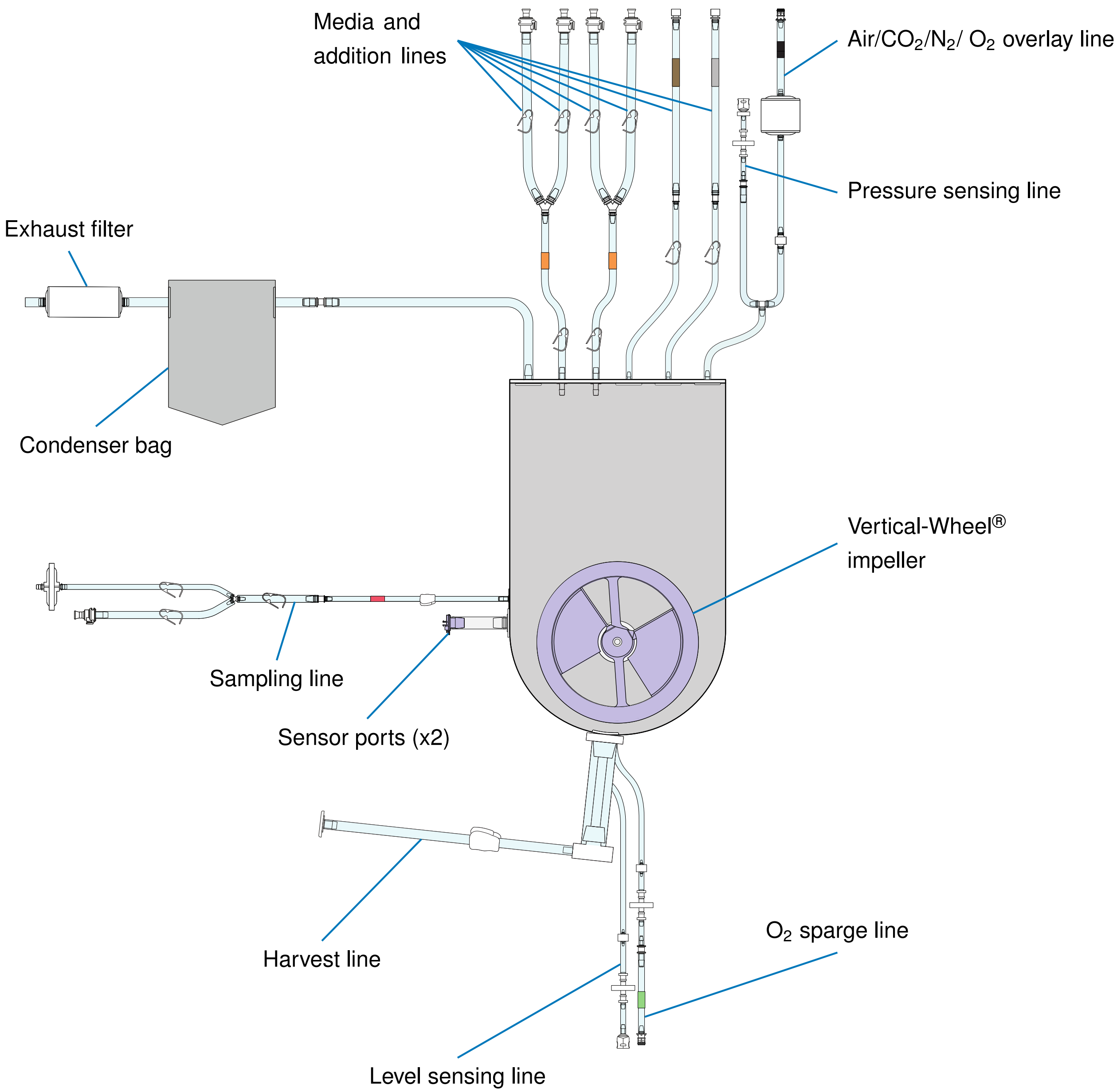
Product information label
Displays the bioreactor’s serial and model numbers, as well as safety information.

A/C receptacle
Connects to a grounded outlet through a desired power cord to start up the bioreactor. There is no power switch on the bioreactor, to prevent it from being turned off accidentally.

RJ45 Ethernet connector
Used to connect the bioreactor to a high-speed Ethernet network.

Back panel latch
Secures the bioreactor’s back cover and can be locked/unlocked with a supplied key.

This drawing of the bag is illustrative of general features and is not intended to represent any particular PBS product with 100% accuracy.



Exhaust filter
Filters the exhaust in order to maintain sterility of the bag contents.

Condenser bag
Catches droplets entrained in the exhaust, preventing them from clogging the exhaust filter.

Media and addition lines
Used with their respective pumps. The media line is used with the media pump to fill the bag at the start of a run or to add medium during a medium exchange. The addition lines are used to add base and other additions during a run.

Air/CO_2/N_2/ O_2 overlay line
Connects to the bioreactor's Air/CO_2/N_2/ O_2 overlay connector, which connects to external gas sources via the gas connection panel (see "PBS-80 Bioreactor - Rear" on page 18). Air, CO_2, N_2, and O_2 flow through this line to the overlay to control dissolved oxygen and pH. O_2 only flows through this line if the oxygen flow valve is set to "Overlay" (see "PBS-80 Bioreactor - Side Cabinet" on page 16).

Pressure sensing line
Senses the pressure inside the bag and provides data for the software's safety interlocks.

Corner protective sleeve
This is an additional layer of film meant to protect the top of the bag from damage. It is not to be removed.

Vertical-Wheel® impeller
Coupled to a driving motor by a set of magnets around its circumference. It has vanes for multidirectional mixing and a pair of magnets for RPM sensing.

O_2 sparge line
Connects to the bioreactor's O_2 sparge connector, which connects to external gas sources via the gas connection panel (see "PBS-80 Bioreactor - Rear" on page 18). O_2 is diverted from the Air/CO_2/N_2/ O_2 overlay line to flow through this line to the sparger when the oxygen control valve is set to "Sparger" (see "PBS-80 Bioreactor - Side Cabinet" on page 16) to control dissolved oxygen.

Level sensing line
Senses the liquid level inside the bag by measuring the pressure required to push a small amount of air through the line. The line must be filled with air to work properly.

NOTICE Users must not allow this line to fill with liquid. If it must be disconnected while the bag contains liquid, first make sure there is no O_2 flow out of the O_2 sparge line. Next clamp the line as close to the bag as possible, then disconnect it.
Reconnect the line while it is still clamped and O_2 sparge flow is off. Then wait 1 to 2 minutes, then un-clamp the line. This allows air pressure to build up in the line, and when the clamp is opened the pressurized air will prevent liquid from entering the line. For more information, see "Disconnecting the Level Sensing Line" on page 154.

Harvest line
Used to remove liquid during a medium exchange, empty the bag during a harvest run, or to transfer the bag's contents into a larger Vertical-Wheel® bioreactor. It can be drained with an external pump or drained by gravity.

Sensor ports (x2)
Accommodates one DO and one pH sensor in each port. They are installed using Kleenpak™ connectors to maintain sterility.

Sampling line
Used with the sample pump to remove a sterile sample.

NOTICE Depending on the model of bag being used, some of the tubing lines may not be compatible with the pumps installed on the PBS-80 and will require the use of an external pump.

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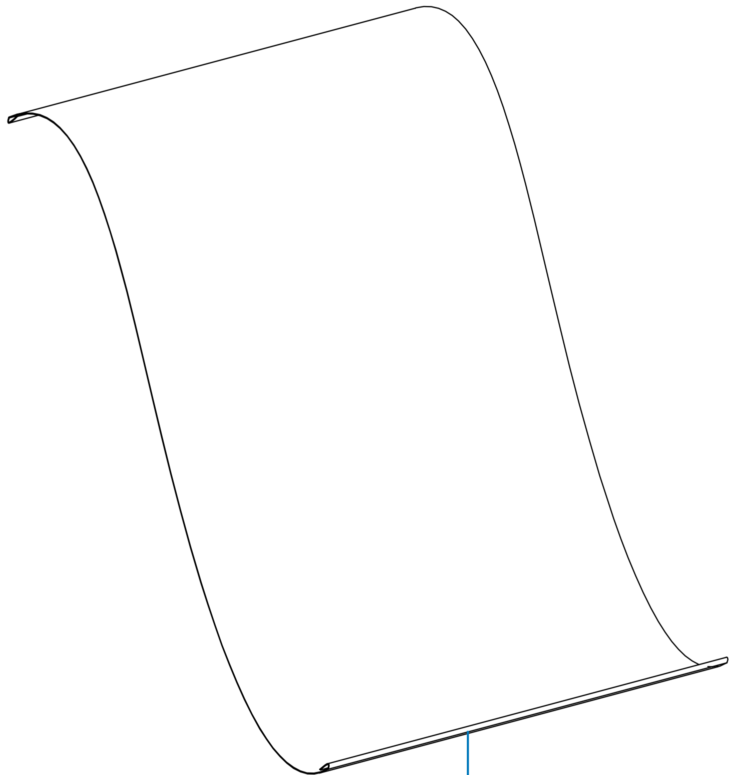
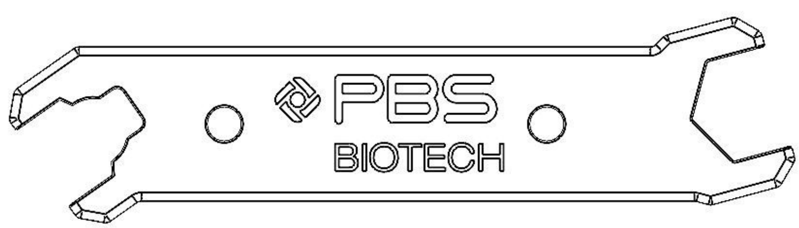


Window shade



Wrench

Window shade
Attaches to the door to protect light-sensitive media in the bag. Removable and stored in the Window shade holder when not in use. If it gets lost or damaged, the replacement part number is IA-80-BA-001.

Wrench
Used for installing and removing sensors. If it gets lost or damaged, the replacement part number is IA-UNI-BA-005.

The Hello User Interface (Hello UI) opens automatically when the PBS-80 is powered on. It contains all control panels, configurations, and other features needed to operate the bioreactor's control system. For more information, see "Hello User Interface" on page 141.

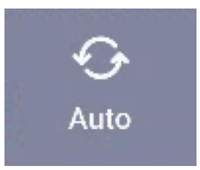
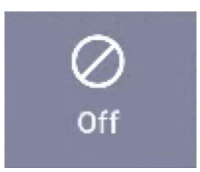
Information bar
Shows the name of the current batch, the time the current batch was started, how long the current batch has been running, the name of the sequence currently running, the name of the loaded Alarm Settings file and number of enabled alarms, the name of the loaded Logger Settings file and number of enabled parameters, and the PBS-80 name.

Side Menu
Displays additional menus.

Trend graphs
Show the agitation, temperature, DO, and pH PVs. The buttons below the graphs adjust the displayed time scale. Clicking on a graph brings up a full-screen graph menu, where graphs of Level, Filter Oven, Pressure, and Gases are also visible.

Navigation tabs
Used to navigate to view Graphs, perform Actions, and view and acknowledge Alarms. The Alarms tab shows the number of unacknowledged alarms.

Dashboard
Consists of the “Agitation,” “Temperature,” “Dissolved Oxygen,” “pH,” and “Main Gas” buttons, along with three boxes showing the pressure, level, and filter oven mode. The buttons show the present value, set point, and mode.

Mode Symbols	
Auto	
Manual	
Off	

Button/Box Color	Possible Causes
Gray	• The PV is between the ‘Low’ and ‘High’ Process Alarm limits
Yellow	• The PV is below the ‘Low’ Process Alarm limit • The PV is above the ‘High’ Process Alarm limit
Red	• The PV is below the ‘Low Low’ Process Alarm limit • The PV is above the ‘High High’ Process Alarm limit • The sensor is in an error state

System Description

2

This chapter gives an overview of the PBS-80 Bioreactor System. It describes the high-level components and functionality of the PBS-80 and explains the principles of basic operation.

System Description

The PBS-80 Vertical-Wheel® Bioreactor System (PBS-80) is a single-use bioreactor intended primarily for the culture of mammalian cells and the production of cell-derived biologicals. It consists of a non-disposable PBS-80 Bioreactor and a Vertical-Wheel® Bioreactor Single-Use Bag Assembly (bag). The PBS-80 Bioreactor and bag are designed to interface closely with each other and to function as an integrated system.

This PBS-80 Vertical-Wheel® Bioreactor System provides all of the necessary process measurement and control features to ensure necessary conditions for the successful cultivation of cells. The PBS-80 consists of: an interface for the bag; an industrial controller; a four-gas module; a bag heater; a bag temperature sensor; DO and pH sensor heads; a level sensor; a pressure sensor; sampling, medium, and addition pumps; a touchscreen interface; and an exhaust filter oven. It is able to control all critical cell culture parameters, such as agitation, temperature, DO, and pH.

The Vertical-Wheel® Bioreactor Single-Use Bag is a uniquely shaped rectangular bag with a round bottom incorporating the Vertical-Wheel® impeller, which has side paddles, vanes, and a hub. The bag's shape is designed to work with the vertical impeller to offer excellent mixing and homogeneous particle suspension with very low shear stress using minimal power input.

Principles of Operation

Agitation

The PBS-80 falls into the category of stirred bioreactors. The biggest difference between PBS Biotech's Vertical-Wheel® Bioreactors and traditional stirred bioreactors, whether single-use or reusable, lies in the unique bag and impeller geometry, described above. The Vertical-Wheel® impeller is driven by a magnetically-coupled external motor.

Heating

The PBS-80 has two permanently-mounted temperature sensors in the back of the chamber which sense the temperature of the bag contents. The PBS-80 also has permanently-mounted electric heaters positioned beneath the chamber, which contact the bottom surface of the bag.

Dissolved Oxygen

The dissolved oxygen is monitored by a reusable DO sensor. The reusable sensors are intended to be calibrated with the PBS-80, autoclaved, and installed aseptically in the bag during bag installation. The PBS-80 controls the DO by using a two-sided PID (proportional-integral-derivative) controller. To decrease DO levels, the software increases the percent composition of N_2 flowing out of the Air/CO_2/N_2/ O_2 overlay connector, through the Air/CO_2/N_2/ O_2 overlay line, and into the overlay. To increase DO levels, the software flows O_2 through the Air/CO_2/N_2/ O_2 overlay line into the overlay, or through the O_2 sparge line to be sparged through the medium (depending on how the O_2 flow valve is configured).

pH

The culture pH is monitored by a reusable pH sensor. The reusable sensors are intended to be calibrated with the PBS-80, autoclaved, and installed aseptically in the bag during bag installation. pH is usually regulated exclusively by CO_2%, and base should only be added if absolutely necessary. The PBS-80 controls the pH by using a two-sided PID controller. To decrease the pH, the software increases the percent composition of CO_2 flowing out of the Air/CO_2/N_2/ O_2 overlay connector, through the Air/CO_2/N_2/ O_2 overlay line, and into the overlay. To increase pH, the software increases the duty of an addition pump that the user has selected to be the base pump, and supplied with a source of base.

Level

The PBS-80 has a built-in sensor that monitors how much pressure is necessary to push a very low gas flow from the bottom of the bag. The software converts this pressure to a height, and using the geometry of the chamber, converts the height to a volume.

Filter Oven and Condenser Bag

As sterile gas flows into the bag, it must also leave to prevent the bag from over-pressurizing. Each bag has an exhaust tubing line for this purpose. The exhaust tubing line has an in-line filter to maintain the sterility of the bag contents. To prevent clogging of the exhaust filter, each bag is equipped with a condenser bag on the exhaust tubing to catch entrained medium droplets, and the PBS-80 has a temperature controlled oven to house the exhaust filter and prevent condensation of water vapor on the filter.

Pressure

The PBS-80 has a built-in sensor to measure the pressure in the overlay of the Vertical-Wheel® Bioreactor bag.

Overview of PBS Software Functionality and Architecture

Functionality

The PBS Software that is an integral part of your PBS-80 is multifunctional. Its capabilities can be grouped in the following categories:

- Sensing and Control
- Data Acquisition and Reporting
- Process and Failure Alarms
- Task Automation
- Remote Monitoring (standard) and Control (add-on)
- Administration

Sensing and Control

The PBS-80 has the ability to monitor and control agitation, temperature, dissolved oxygen, and pH in the bag. It can also control the filter oven at a pre-determined temperature, as well as monitor the volume of the bag contents and monitor the pressure of the bag headspace. The four main control loops (agitation, temperature, DO, and pH) each have three user-selectable modes: Automatic, Manual, and Off. The main gas controller, which must be on for the DO and pH controls to function, only has a Manual and Off mode. In Automatic mode, the control loops implement PID feedback control with a set point determined by the user. In Manual mode, the control loops implement an open loop scheme where the user directly selects controller output. In Off mode, the controller's output is set to zero.

Also falling under the scope of Sensing and Control are interlocks, sensor error detection, and sensor error modes. The purpose of the interlocks is to prevent the creation of unsafe conditions or conditions that would hinder the growth of cells. The purpose of the sensor error detection and mode features is to minimize the problems that could arise due to sensor failure.

Data Acquisition and Reporting

The PBS Software has the ability to collect and report multiple types of data. Data types include Process Data, User Events, Alarms, Sequence Steps, and Errors. All these data types are stored to a database on the HMI computer's hard drive (see "Architecture" on page 32), and can be exported via email as .csv (comma-separated value) files. Process data includes over 300 variables. For each Process data variable, the user can select whether or not to log them, as well as how frequently to log them. The other data types always get logged to the database.

Process and Failure Alarms

To assist you in monitoring the performance of the PBS-80, a comprehensive set of parameters is continuously monitored. If any parameter falls outside of a pre-defined range, an alarm event will be generated and communicated to you. Process alarms monitor your process variables, while Failure alarms monitor the PBS-80's sensors and other hardware.

Each alarm can be individually configured to be displayed, made to sound a buzzer, emailed, or ignored. The sensitivity of the failure alarms can be configured by the user. In addition, the process alarm limits are entirely selectable by the user according to their particular process conditions.

Task Automation

Clicking "Sequence" from the "Actions" tab brings you to the menu used to activate the sequence engine.

The sequence engine allows the user to automatically run sequences of instructions on the PBS-80. The sequences are programmed using the Sequence Editor. Once saved, the sequences are available to be run from the Hello UI. Sequences can be used for a variety of tasks, such as setting all the controller modes and set points at once, or for changing a set point at some time in the future when no user will be present.

Remote Monitoring and Control

The default PBS software offers the ability to remotely monitor process parameters etc. via REST API. For more information, see "Configuring REST API Connectivity" on page 189.

There is also an optional add-on which allows for remotely monitoring and controlling the bioreactor via OPC-UA. For more information, see "Configuring OPC UA Connectivity" on page 189.

Administration

In addition to all of the above, the software allows the user to perform additional direct control functions, such as turning pumps on and off. It also offers the user administrative capabilities to add user accounts, configure user permissions, and configure system variables.

Architecture

The Vertical-Wheel® Bioreactor control system is a hybrid consisting of an industrial automation controller (the RIO controller) paired with a human machine interface computer (HMI).

The RIO is in charge of all sensing and control functions, including interlocks, sensor error detection, and running sequences. If the HMI were to fail (from a software crash or hardware failure), the control loops, interlocks, and sequences would continue as normal and maintain current operating conditions.

The RIO is also in charge of the logic that captures the data points to be recorded, whereas the database engine and the database are on the HMI. If the HMI were to fail, data logging would stop, and would resume when the database engine resumed operation.

Finally, the RIO is in charge of detecting process and failure alarms, and the HMI communicates those alarms to the user. Alarm notifications would cease if the HMI were not to run.

NOTICE Users should not install additional software on the HMI without first consulting PBS Biotech Technical Support.

Safety

3

Review the following safety information before installing the system.

	Customer-provided safety-straps may be used to reduce the risk of tipping or damage in the event of earthquake. Do not drill into the equipment or use screws to attach straps. Industrial-strength self-adhesive straps may be affixed to the metal sides of the system.
	If any PBS Biotech equipment is used with accessories not provided or recommended by PBS Biotech or used in a manner not specified by PBS Biotech, the protection provided by the equipment may be impaired.
	The power cord is the main electrical disconnect for the equipment. To remove power from the equipment, unplug the power cord. Do not position the equipment in such a way that it is difficult to unplug the power cord. Do not apply tension on the power cord, to avoid sudden electrical disconnects.
	To provide continued protection against risk of electric shock, the equipment must be connected to a properly grounded outlet. Only use power cords provided by PBS Biotech. Do not use an adapter.
	The back panel of the equipment must only be removed by a trained technician. High voltage circuits are accessible inside and there is a danger of lethal electric shock.
	Use caution when working near peristaltic pumps. Keep fingers, jewelry, loose clothing, etc. free of the rotating pumps to prevent injury.
	The PBS-80 has hot surfaces, as indicated by hot surface warning signs. Do not touch hot surfaces.
	Vertical-Wheel® Bioreactors are not designed for pressurized operation. Always allow the bioreactor bag to vent. Never clamp the bag outlet lines. This could result in dangerous pressure build-up in the bag.
	Only use bags manufactured by PBS Biotech for the specific model of your bioreactor system.

	Pumps may restart automatically if the power is restored after an interruption.
	When using external pumps to fill a bag installed in the bioreactor, use precautions to ensure that the bag will not overfill, which could cause dangerous pressure build-up.
	Biological substances, such as viruses, cells, and sera, have the potential to transmit infectious diseases. If biohazardous materials are used with this equipment, follow all applicable local, state/provincial, and/or national regulations, including identification of samples with the biohazard symbol. Wear appropriate protective eyewear, clothing, and gloves.
	If the equipment has been used in a biohazardous environment, it must be decontaminated according to all applicable local, state/provincial, and/or national regulations prior to any shipment, or disposal.
	Customers are to follow local regulatory guidelines for proper recycling and disposal of PBS products.

Inspections and Preventative Maintenance

Inspections

This section describes the inspections that the user should perform on the PBS-80 Bioreactor system to verify safety mechanisms are functional. For instructions on inspecting a Vertical-Wheel® Bioreactor bag before use, see “Integrity Test” on page 91.

Drip Tray

Confirm that a drip collection container is properly connected to the drip collection line, to catch liquid in the event of spills.

Leak Sensor

Drip a small amount of water onto the leak sensor. The LED should change from green to amber. Dry off its contacts, and it should change back to green. If the “active” Alarms.alm file is configured correctly, the buzzer will sound when the leak sensor’s contacts are wet. For more information, see “Configuring Alarm Settings” on page 57.

Door Lock

Attempt to open the door without using the software or manually overriding the door latch. This confirms that the door latch works, and that the door can only open if the user unlocks it through the software, or manually overrides it.

Safety-Related Settings

Confirm that all settings in the “Safety” group match those listed in Appendix 1 on page 216, or that the values have been confirmed with PBS Biotech Technical Support. Do not attempt to verify the functionality of any interlocks - that should only be performed by a representative of PBS Biotech.

Comb Plate

Confirm that nothing is resting on top of the comb plate, as this would prevent the bag from pushing the comb plate up if the bag became over pressurized. The functionality of the kill switch beneath the comb plate may be verified by lifting the comb plate away from the magnets holding it in place. Restore the comb plate to its original position after confirming that the MFCs and pumps will not operate.

The pressure at which the comb plate is pushed up should only be verified by a representative of PBS Biotech.

Preventative Maintenance

To keep your PBS-80 properly maintained, clean and decontaminate it after each run (see below). For other maintenance on the PBS-80, contact PBS Biotech Technical Support.

Cleaning and Decontamination

To clean and decontaminate the PBS-80, use 70% IPA or EtOH. Apply the cleaning solution to a clean, soft cloth - do not spray or apply cleaning solution directly onto the PBS-80. Wipe down all surfaces of the PBS-80, including inside the bag chamber and drip collection tray. Be very gentle when cleaning the temperature sensors and level sensor. If a leak occurred, flush the drip collection line and decontaminate or replace the contaminated components of the liquid containment system it leads to. Contact the manufacturers of other equipment in use, such as a keyboard or Uninterruptible Power Supply (UPS), for cleaning and decontamination instructions.

NOTICE Do not use abrasive materials on the PBS-80. It is the user's responsibility to avoid use of decontamination or cleaning agents that could cause a hazard as a result of a reaction with parts of the equipment or material contained in it. Contact PBS Biotech Technical Support if there is any doubt about the compatibility of decontamination or cleaning agents.

This protocol is appropriate to clean and decontaminate equipment in contact with materials assigned to Biosafety Level 1. In case of operation in a higher Biosafety Level facility, please contact PBS Biotech Technical Support.

Lifting and Handling

The PBS-80 weighs approximately 223 kg (490 lbs). To prevent bodily injury and/or damage to the product, it should only be moved by at least two individuals using the built-in casters. Unlock the casters and roll the bioreactor down a ramp off the pallet and to its final destination. Avoid pushing on the monitor or door window and do not attempt to lift or carry the bioreactor.

Product Specifications

4

Note: These specifications are for the standard PBS-80 configuration as of publication. Individual bioreactors may differ.

PBS-80 Specifications		
General	Size	Width: 93 cm (36.5 inches) Depth: 56 cm (22 inches) Height: 146 cm (57.5 inches)
	Weight	223 kg (490 lbs) without Bag
	Minimum Space Requirements	Width: 147 cm (58 inches) Depth: 147 cm (58 inches) Height: 168 cm (65 inches)
	Electrical	6 A (max), 110-120 Vac, 50/60 Hz or 3 A (max), 200-240 Vac, 50/60 Hz, depending on model Overvoltage Category II
	Environmental Rating	Indoor use, Ambient Temperature: 16 - 32 °C (61 - 90 °F) Humidity: 10 - 80% RH Altitude: 2,000 m (6,500 ft) max Pollution Degree: 2
Bioreactor Geometry	Rated Working Volume	80 L
	Minimum Working Volume	45 L (top of wheel)
	Impeller Type	Vertical-Wheel® mixing technology
Controls	Control Interface	Integrated 10.4″ touch screen. Network connectivity capability.
	Control Hardware/Software	Industrial embedded real-time control

PBS-80 Specifications		
Controls (continued)	Data Communication	Built-in data historian Standard configuration: remote monitoring via REST API Optional upgrade: remote monitoring and control via OPC-UA
	Data Connection Ports	2x USB 2.0 1x RJ45 Ethernet
Agitation	Agitation Mechanism	Brushless DC motor drive, Magnetic coupling to bag impeller
	Agitation Control Range (Accuracy)	2 – 34 RPM (± 1 RPM)
	Agitation Sensor Type	Hall effect (magnetic sensing)
Gassing	Gassing Mode	Headspace overlay with an optional sparger
	Gas Control	4 mass flow controllers (for Air, N_2, O_2, CO_2 gases) Manual control of total gas flow rate Individual gas outputs as determined by Dissolved Oxygen and pH controls
	Gas Flow Rate Range	300 – 10,000 mL/min for Air, N_2, O_2 80 – 2,000 mL/min for CO_2
Temperature	Temperature Control Range (Accuracy)	5 °C above ambient to 40 °C (± 0.5 °C)
	Temperature Sensor Type	Dual (redundant) Class A Platinum RTD
Dissolved Oxygen	DO Control	Two-sided PID control with N_2 and O_2 or manual control
	DO Sensor Type	Broadley James OxyProbe® polarographic

PBS-80 Specifications		
pH	pH Control	Two-sided PID control with CO_2 and base addition pump or manual control
	pH Sensor Type	Broadley James FermProbe® electrochemical
Level	Level Sensor Type	Pressure differential via precision industrial pressure sensor
Pressure	Pressure Sensor Type	Precision industrial pressure sensor
Pumps	Media pump	Watson Marlow 313D Series Unidirectional, Variable-Speed, 400 RPM max. continuous speed
	Addition pump A	Watson Marlow 114DV Series Unidirectional, 3-Speed, 200 RPM max. continuous speed
	Addition pump B	Watson Marlow 313D Series Unidirectional, Variable-Speed, 400 RPM max. continuous speed
	Sample	Watson Marlow 114DV Series Bidirectional, Single-Speed, 100 RPM
Single-Use Bag	Bag Construction	Polyvinylidene fluoride (PVDF)
	Impeller Construction	Injection-molded polycarbonate
	Product Contact Materials	All product contact materials meet requirements for USP Class VI Testing for Plastics <88> and/or ISO 10993
	Gamma Radiation Absorbed Dose	25 – 40 kGy
	Media and Addition Lines	Silicone and C-Flex®

PBS-80 Specifications		
Single-Use Bag (continued)	Exhaust Line	Platinum-cured silicone tubing with condenser bag and 0.2-micron exhaust filter
	$Air/CO_2/N_2$ / O_2 Overlay Line	Platinum-cured silicone tubing with 0.2-micron filter
	O_2 Sparge Line	Platinum-cured silicone tubing with 0.2-micron filter
	Sampling Line	Platinum-cured silicone and C-Flex® tubing with syringe, 3-way valve and 0.2-micron filter
	Harvest Line	Variable-height sampling port. Polycarbonate, Platinum-cured silicone and C-Flex®
	Level-Sensing Line	Platinum-cured silicone tubing with 0.2-micron filter
Service Life	Mechanical Drive Belt	Expected Service Life 1 year minimum
	Mechanical Drive Components (excepting belt)	Expected Service Life 3 year minimum

FermProbe® is a registered trademark of Broadley-James Corporation.
OxyProbe® is a registered trademark of Broadley-James Corporation.
C-FLEX® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

Installing the PBS-80

5

This chapter gives detailed instructions on how to install the PBS-80.

Integrated Bioreactor

Minimum Space Requirements

Before you begin, see “Minimum Space Requirements” on page 37 and confirm that your available floor space meets or exceeds the minimum space requirements listed.

Utility Requirements

General Electrical Requirements

- Outlets must be properly grounded.
- The power cord must be provided by PBS Biotech, Inc.

For other electrical requirements, see “Electrical” on page 37, and the Safety information in Chapter 3 starting on page 33.

General Gas Requirements

- The gases supplied must be clean, dry, particulate-free, and oil-free to prevent MFC damage from contaminated gases.
- All gases must be connected to their corresponding gas connector inlets on the gas connection panel unless instructed otherwise by PBS Biotech Technical Support.

Gas Tubing Outer Diameter

Depending on the bioreactor’s configuration, it will require one of the following tubing sizes for all gases:

- 1/4 inch OD tubing
- 6 mm OD tubing

Gas Tubing Material

The following materials (or equivalent) are appropriate for the gas tubing:

- Polyethylene
- Polyurethane

NOTICE The gas connectors on the back of the bioreactor are push-to-connect connectors. Disconnecting the tubing requires pushing in the orange or gray connector, then pulling out the tubing. Improper removal of tubing can break the retaining clip and impact the holding capability/seal when tubing is reinstalled.

Gas Supply Pressures

Note: To ensure proper operation, gases must be regulated near the bioreactor system to a consistent pressure within the ranges specified below. Fluctuating inlet gas pressure may cause MFC flow rates to become unstable.

Gas	Imperial	Metric
Air, CO_2, O_2, N_2	25 – 40 psig	175 – 275 kPa

Unit Placement

To prevent bodily injury and/or damage to the product, see “Lifting and Handling” on page 36 and follow the safety instructions.

The PBS-80 should be placed in a clear floor space where the appropriate utilities have been prepared, and its casters should be locked. At that point, the utilities and liquid containment system may be connected.

Connecting the Drip Collection Line

The drip collection line is located behind the bioreactor. It must be attached to tubing with an internal diameter of 1.91 cm (0.75 in). The tubing should lead to a container below the bioreactor to allow overflow from the bag to drain through the line by gravity.

Powering On the PBS-80

Install the appropriate power cord on the PBS-80. It is recommended to plug it into an Uninterruptible Power Supply (UPS), to allow control to be maintained in the event of a power failure. A grounded outlet is required. The PBS-80 will automatically power on, and the Hello UI will automatically load once the system has finished booting.

Configuring Local Users and Groups

The Hello UI requires a user to log in before making any changes. This section describes how to create new local users and modify local user accounts.

The bioreactor can also be configured so users can log in to the bioreactor with domain credentials. When the Domain login option is enabled, users can still log in using local user accounts; this is useful for maintenance accounts, local administration, and fallback during network issues. For IT instructions to enable the Domain login option on the bioreactor and configure the domain, see “Configuring Domain Login” on page 186.

The PBS-80 comes with two default local user accounts for you to start with:

Username: user1
Password: 12345
Permissions: All but “Account Management”

Username: admin
Password: 12345
Permissions: None but “Account Management”

The PBS-80 also comes with a local user account “pbstech,” which will be used by PBS Biotech Technical Support if they need to log in to your bioreactor system. This is the only account in the “pbstech” user group. Do not delete or change this account or user group, and do not add other users to the user group.

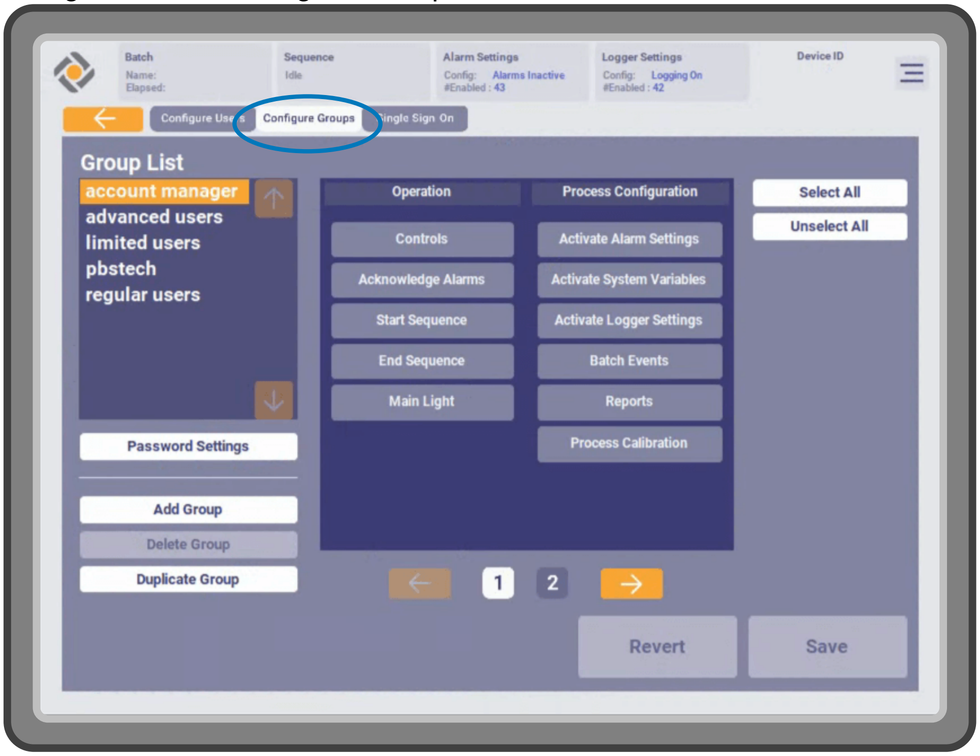
PBS Biotech Technical Support strongly suggests changing the username and password for the user1 and admin accounts to make them more secure, and adding accounts with unique usernames and passwords for each individual accessing the bioreactor system.
While all usernames and passwords should be as secure as possible, it is particularly important to change the admin account username and password to something that is difficult to guess in order to prevent malicious users from accessing that account to give themselves extra permissions they are not authorized to have.

In order to prevent users from being permanently locked out of their bioreactor, the PBS Software prohibits password expiration for user groups with the Account Management permission, and users within these user groups (i.e. Account Managers) cannot be locked out after multiple failed login attempts. For security purposes, the usernames associated with these user groups should remain unknown to all other users. The software requires that at least one local Account Manager account remains Active. Local Account Manager accounts cannot delete or disable their own account, change their own group, or remove their own group's account management permission. Domain logins with the Account Management permission cannot delete or disable the last Active local Account Manager. Domain Account Managers cannot change the last local Account Manager's group assignment or remove the Account Management permission from a group in a way that results in there being no local Account Managers. And, if no local Account Managers exist when the application starts, the Domain login option will be enabled automatically.

Creating a New Local User Group

1. Log in to the Hello UI using the user name and password of an account in a group with the "Account Management" permission.
2. Click the triple bar ≡ (top right corner) and then "Administration."

3. Navigate to the “Configure Groups” tab.



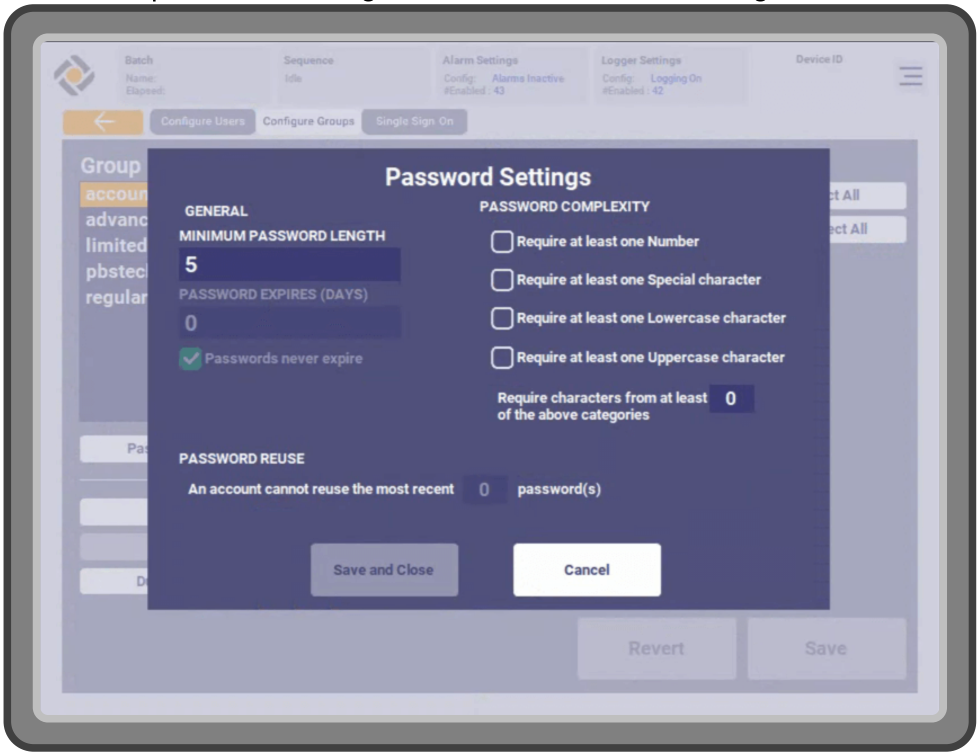
4. Click “Add Group” and enter a name using the on-screen keyboard or an external keyboard. Groups with blank names cannot be saved. Click “Enter.”

Editing Local Group Permissions

Group permissions are divided into four categories: Operation, Process Configuration, Advanced Configuration, and Administration. To edit the permissions of a group, select the group from the Group List, and click the button of the permission. Bright green indicates that the permission is granted, gray indicates that the user group does not have that permission. For more information on group permissions, see "User Group Permissions" on page 179.

Editing Local Group Password Settings

1. To edit the password settings, click the “Password Settings” button.



2. New groups have the following default password settings:

   (a) A minimum password length of 5

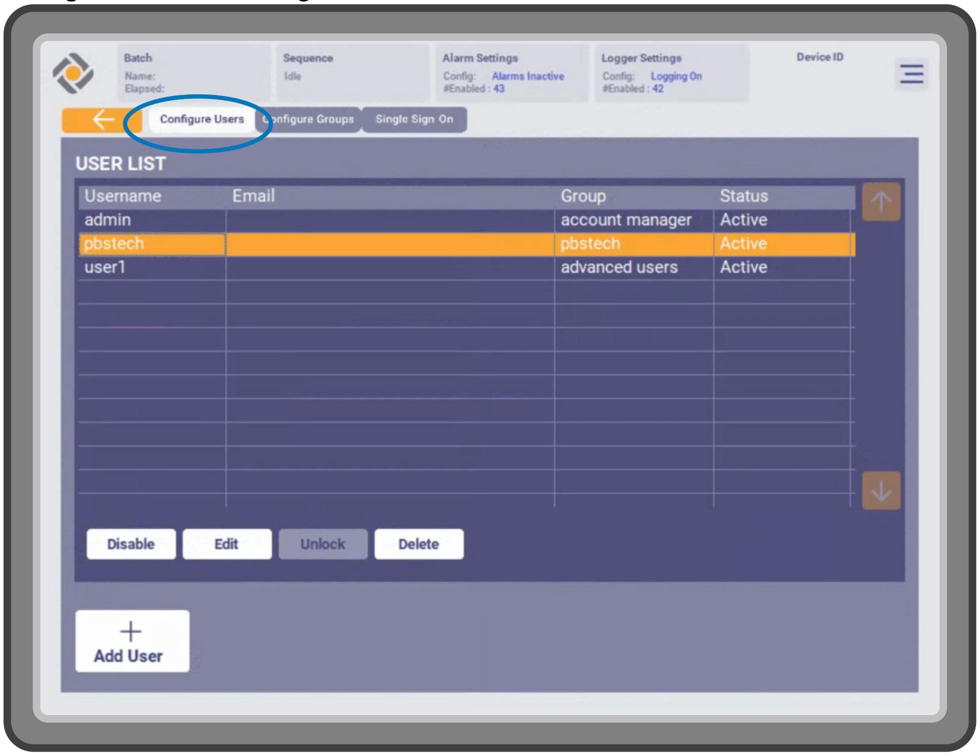
   (b) Passwords never expire

   (c) There are no limits on password reuse

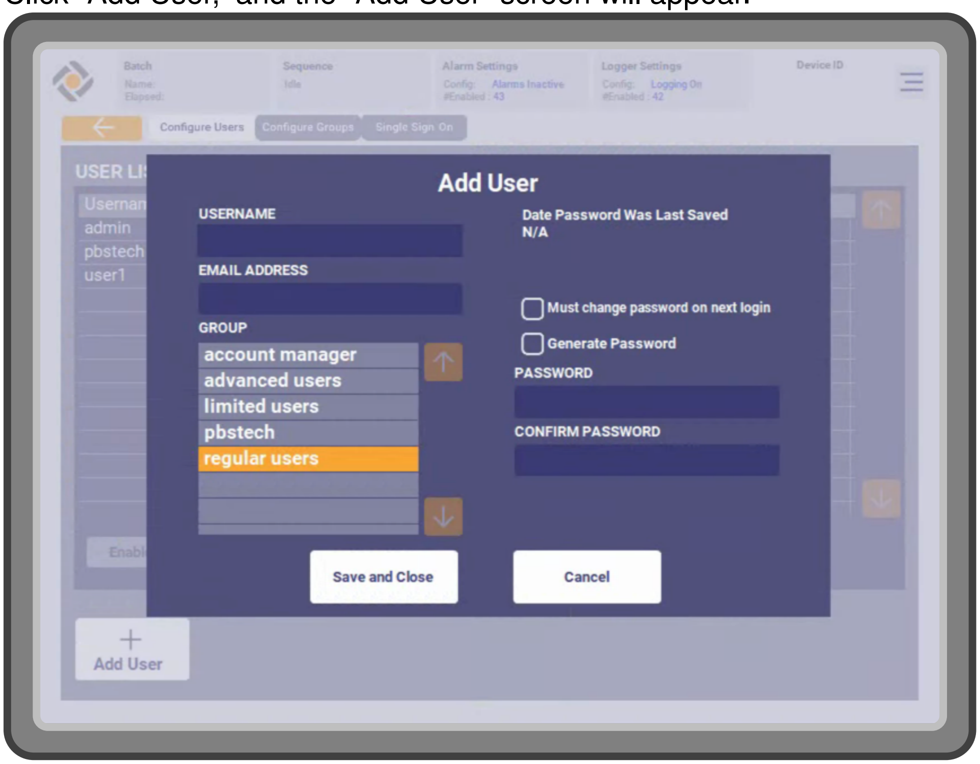
   (d) Simplest password complexity: there is no requirement to use numbers, special characters, lowercase characters, or uppercase characters.

Creating a New Local User

1. Navigate to the “Configure Users” tab.



2. Click “Add User,” and the “Add User” screen will appear.



3. To change the name, click the text field under “Username” and use the

on-screen keyboard or an external keyboard to enter a new name, then click “Enter.” Usernames must be unique, cannot be blank, and cannot contain spaces.

4. (Optional) To link an email address to the user, click the “Email Address” field and enter a valid email address. The account’s email address is used to send alerts about failed login attempts and to simplify emailing reports.
5. Select the user group that the user will be assigned to from the “Group” list.
6. The account manager can either enter a new password for the user, or check the “Generate Password” box, so the PBS Software will generate a password for the user on saving. Passwords must meet the requirements for the selected group.
7. The account manager can also require that the user change their password the next time they log in.
8. When you are finished, click “Save and Close.”

Modifying Local User Accounts

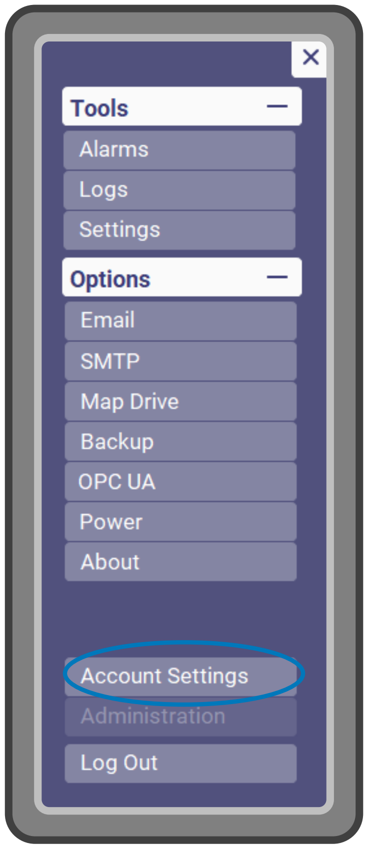
1. To edit a user, select the user in the “User List” section under the “Configure Users” tab, and then click “Edit.” Change the User Name, Password, Email Address, or Group. Click the “Save and Close” button to save the new user settings.
2. To delete a user, select the user in the “User List” section under the “Configure Users” tab, and click the “Delete” button.
3. To edit a user group, select the group in the “Group List” section under the “Configure Groups” tab. Change the Password Settings or Permission Options. Click the “Save” button to save any changes.
4. To delete a user group, select the group in the “Group List” section under the “Configure Groups” tab, click the “Delete Group” button, and click the “Save” button. Note that groups with users still assigned to them cannot be deleted.

Users' Own Accounts

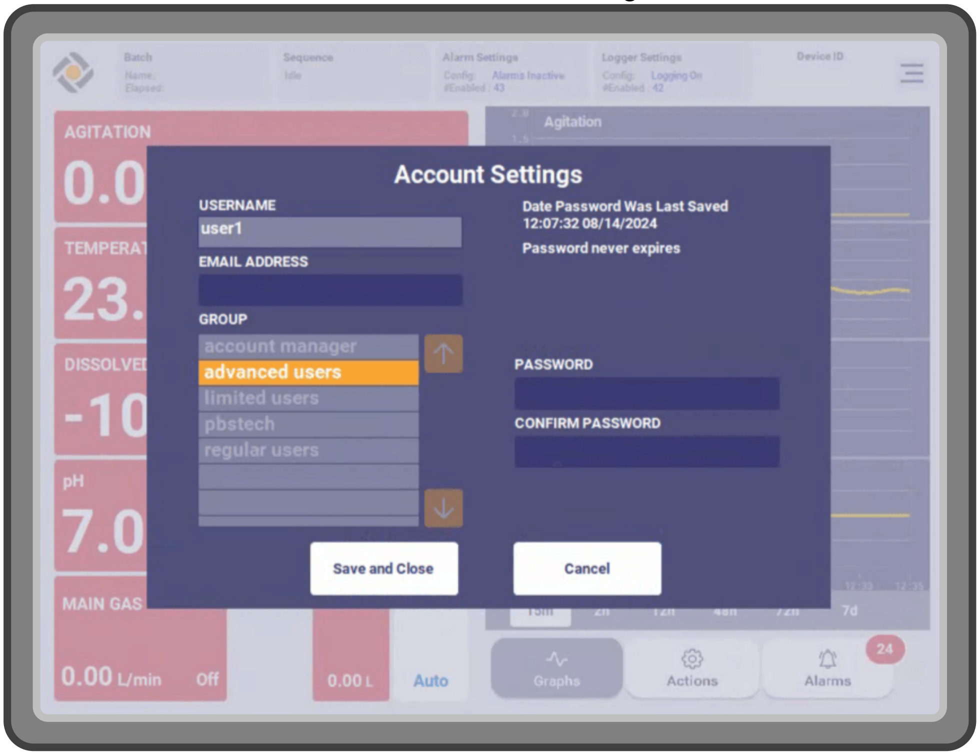
Local users without the "Account Management" permission can modify their own password (to prevent it from expiring) and their own email address. They will not be able to modify anything else in their account, or see any information about any other user account.

Domain users cannot make changes to their accounts, but they will be able to see which permissions are assigned to them.

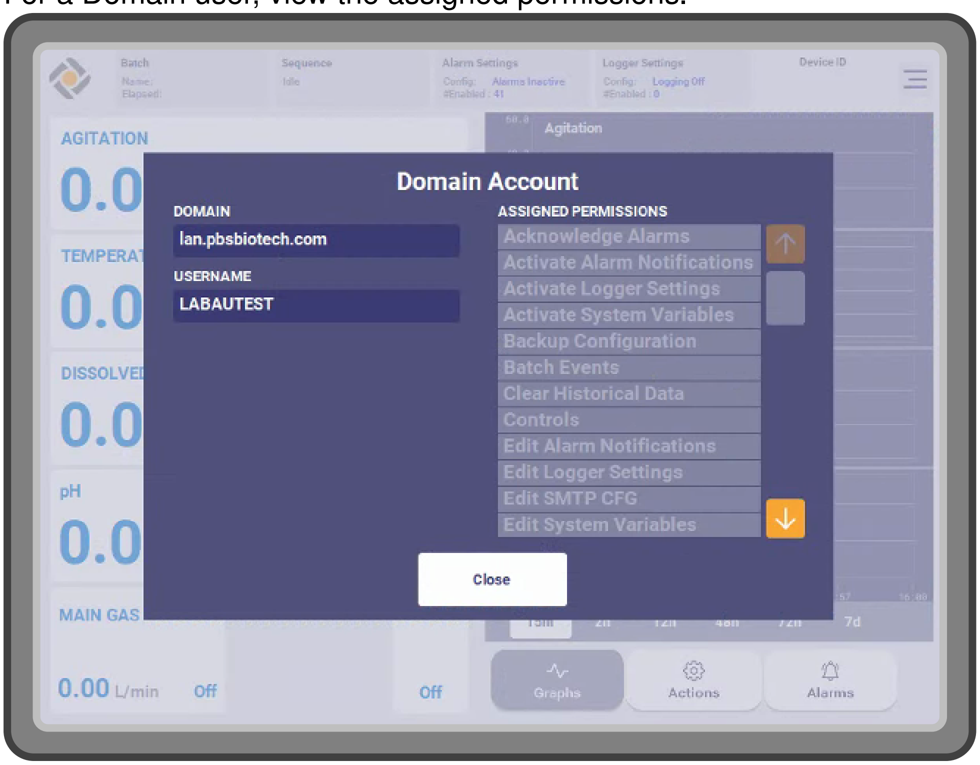
1. Click the triple bar ≡ (top right corner) and then "Account Settings."



2. For a Local user, make and save desired changes.



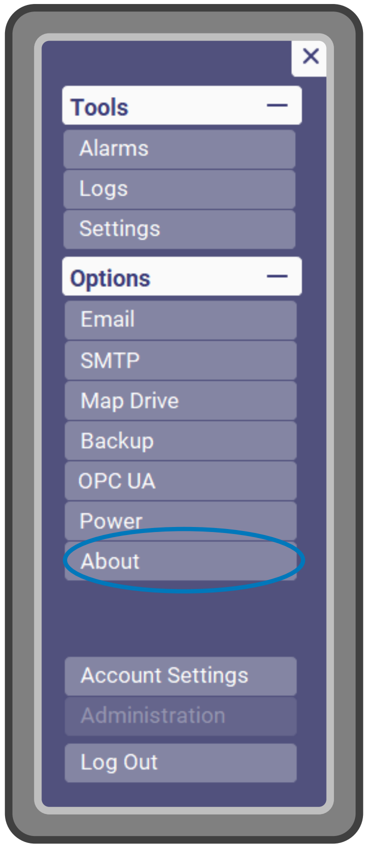
For a Domain user, view the assigned permissions.



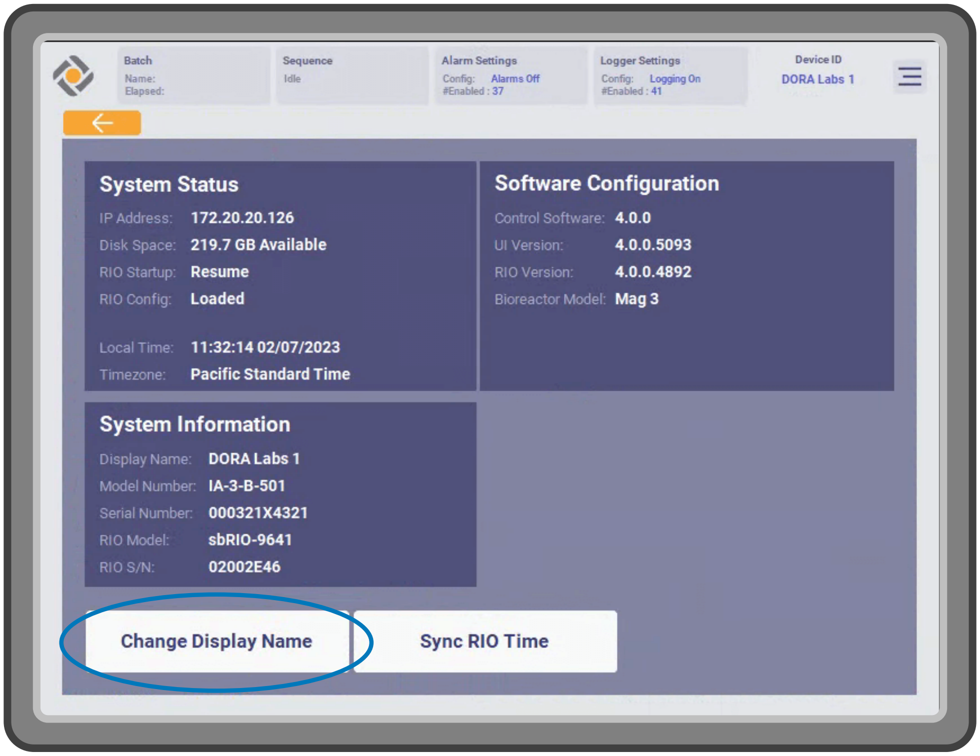
Naming the PBS-80

The PBS-80 ships with a generic name. However, PBS Biotech Technical Support suggests you change the name as you see fit.

1. Log in to the Hello UI as a user with “System Management” permission.
2. Click the triple bar ≡ (top right corner) and then “About.”



3. Click “Change Display Name.”

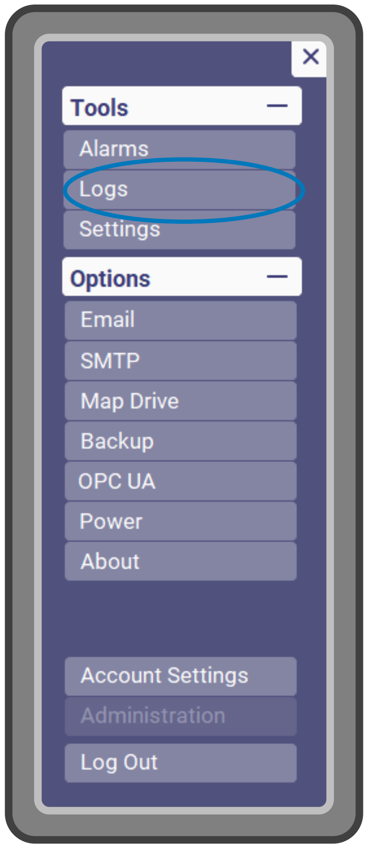


4. Enter the desired name using the on screen keyboard or an external keyboard and select “Enter.”

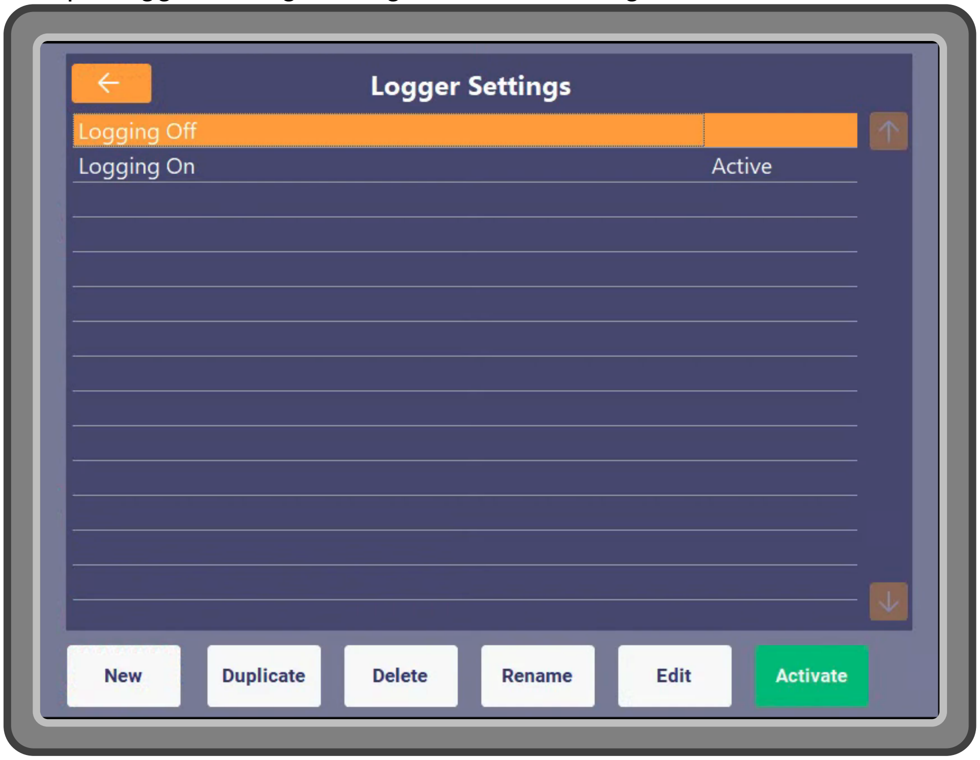
Configuring Logger Settings

Before beginning a run, you should configure what data is recorded and how often. For an in-depth explanation for how data recording works, see “Process Data Recording” on page 171.

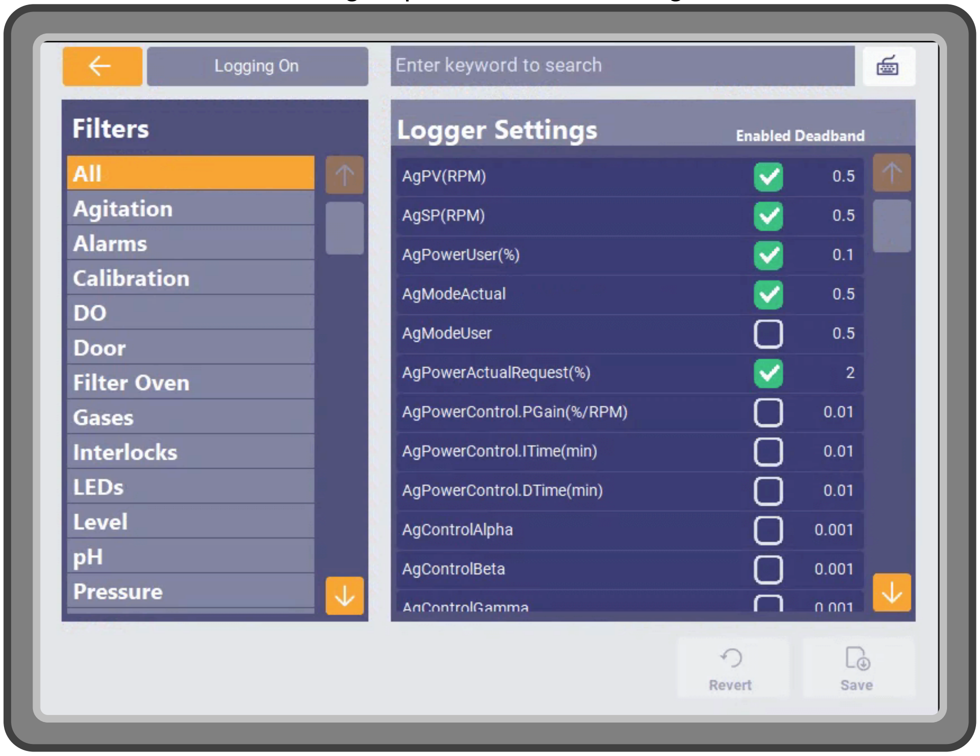
1. Log in to the Hello UI as a user with the “Logger Settings Editor” and “Activate Logger Settings” permissions. The “Logger Settings Editor” permission allows the user to create, modify, and delete Logger Settings files, whereas the “Activate Logger Settings” permission allows the user to make a particular Logger Settings file active.
2. Click the triple bar ≡ (top right corner) and then “Logs.”



3. Click “New” if you would like to create an entirely new Logger Settings file. Select an existing file to duplicate, delete, rename, or edit it. You cannot delete or rename the active Logger Settings file. You can create multiple logger settings configuration files and give them different names.



4. The screen will display the variable name, a green checkbox, the deadband value, and the group the variable belongs to.



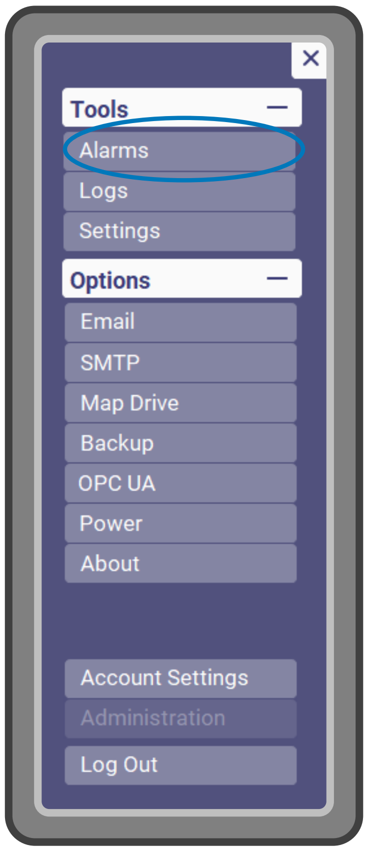
5. To change the value of the deadband for a variable, click the number field next to the corresponding variable and enter the desired value using the on-screen keypad or an external keyboard.
6. To change whether a variable is recorded or not, click the “Enabled” square. Green with a white checkbox indicates that the variable will be recorded, while an empty box indicates that it will not.
7. If you wish to reverse changes you have made, click “Revert” and the file will revert back to its original values.
8. When you are finished making your desired changes, click “Save.” Click the arrow in the top left corner to return to the main Logger Settings menu.
9. Click “Activate” to make the selected file active on the RIO. The active Logger file name and number of enabled parameters will be displayed in the Information Bar.

Configuring Alarm Settings

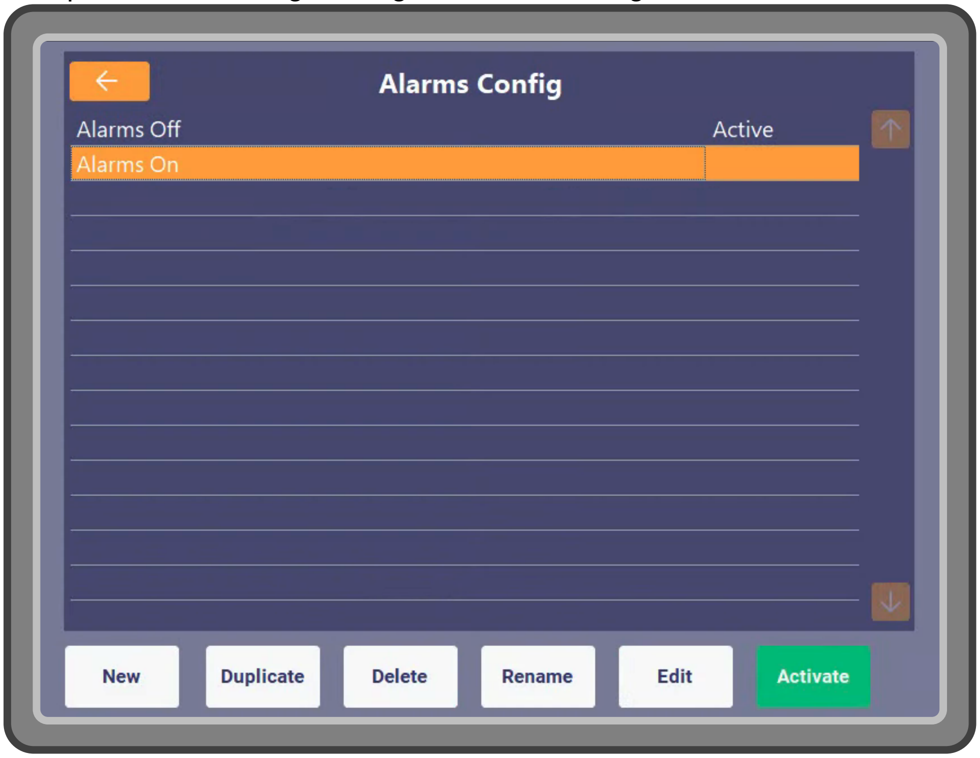
The PBS-80 comes with its Alarms Inactive file loaded so the non-run conditions will not set off any alarms (disconnected sensors, temperature far below 37 °C, etc.). You can create and edit multiple Alarms configuration files using the Alarms Editor in the Hello UI.

Creating and Editing Alarm Files

1. Log in to the Hello UI as a user with the "Alarm Settings Editor" and "Activate Alarm Settings" permissions. The "Alarm Settings Editor" permission allows the user to create, modify, and delete Alarm Settings files, whereas the "Activate Alarm Settings" permission allows the user to make a particular Alarm Settings file active.
2. Click the triple bar ≡ (top right corner) and then "Alarms."



3. Click “New” if you would like to create an entirely new Alarms Settings file. Select an existing file to duplicate, delete, rename, or edit it. You cannot delete or rename the active Alarms Settings file. You can create multiple alarms settings configuration files and give them different names.



4. Configure alarms notifications by selecting “Notify,” “Audible,” and/or “Email” for each alarm, where “Notify” means the alarm appears in the Alarms tab of the Hello UI when the alarm is triggered, “Audible” means a buzzer sounds when the alarm is triggered, and “Email” means an email is sent to all of the email addresses in the “Email List” from the email address in the “Return Address” field (see “Configuring Email Function” on page 59). Note that for an alarm to be emailed or audible, it must also be set to “Notify.”

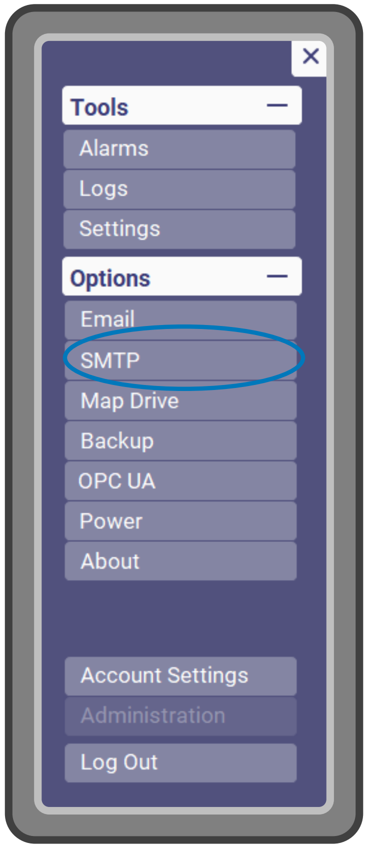
5. If you wish to reverse changes you have made, click “Revert” and the file will revert back to its original values.
6. When you are finished making your desired changes, click “Save.” Click the arrow in the top left corner to return to the main Alarm Settings menu.
7. Click “Activate” to make the selected file active on the RIO. The active Alarms file name and number of enabled alarms will be displayed in the Information Bar.

Configuring Email Function

The PBS-80 arrives with a PBS Biotech email address for sending emails. The size limit for generating and emailing files is 35 MB using the default office365 account configured at factory.

Configuring Sending Email

1. Log in to the Hello UI as a user with the “Email Settings” permission.
2. Click the triple bar ≡ (top right corner) and then “SMTP.”



3. Configure the SMTP Settings as desired.

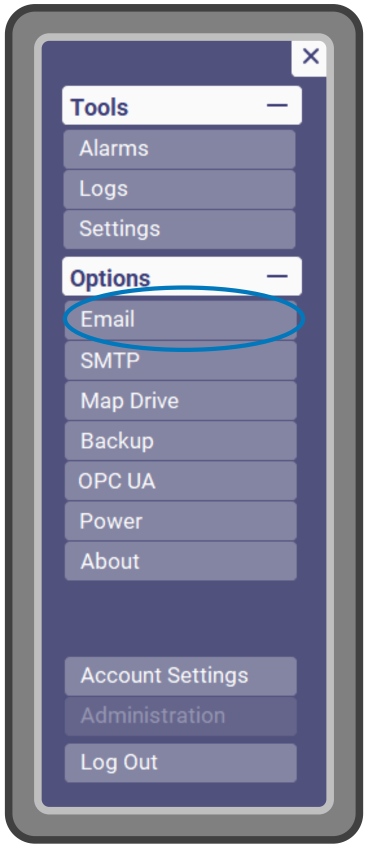
4. Click “Send Test Email” and enter a valid email address as the recipient, to verify that the email settings are configured correctly.
5. If you wish to reverse changes you have made, click “Revert” and the settings will revert back to their original values.
6. When you are finished making your desired changes, click “Save.” Click the arrow in the top left corner to return to the main menu.

Configuring Alarms Email List

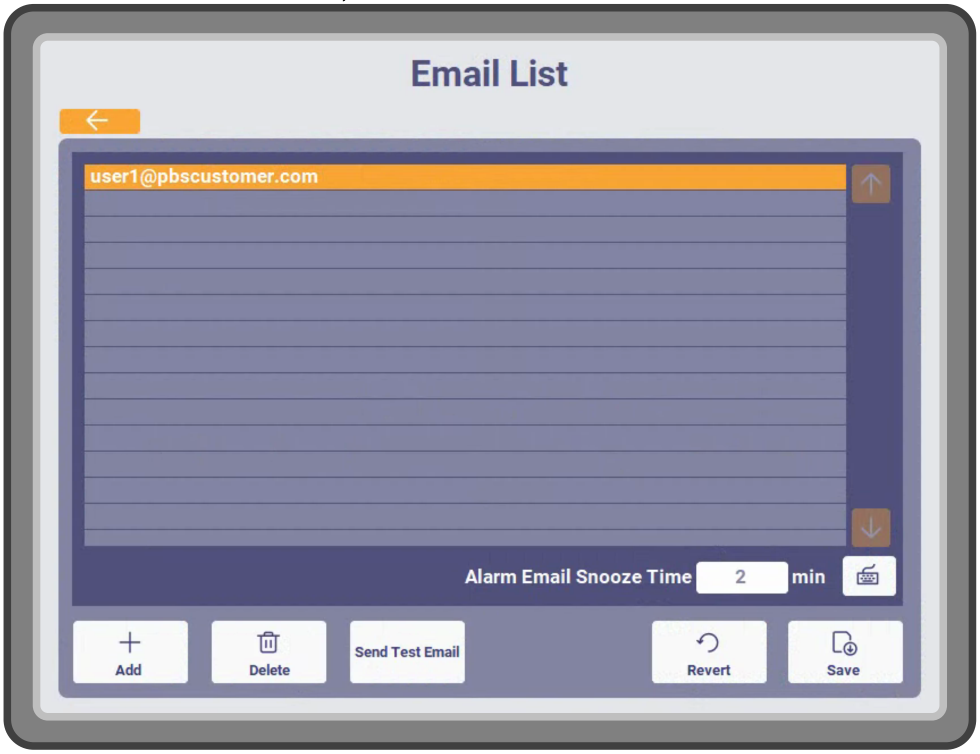
When an alarm configured to be emailed is triggered, the email addresses on this list will receive an email. If more than one alarm of the same type is triggered within the “Alarm Email Snooze Time,” only the first alarm triggered will be emailed.

1. Log in to the Hello UI as a user with the “Email Settings” permission.

2. Click the triple bar ≡ (top right corner) and then “Email.”



3. Click “Add” to add a new email address to the list. Select an existing email address to delete it, or to send a test email to it.



NOTICE You can get alarm notifications as text messages. PBS Biotech Technical Support suggests researching SMS gateways to learn which email address to use for your phone number, or contacting your IT department for assistance.

4. To change the “Alarm Email Snooze Time,” click the number and use an external keyboard or use the on-screen keyboard.
5. If you wish to reverse changes you have made, click “Revert” and the file will revert back to its original values.
6. When you are finished making your desired changes, click “Save.” Click the arrow in the top left corner to return to the main menu.

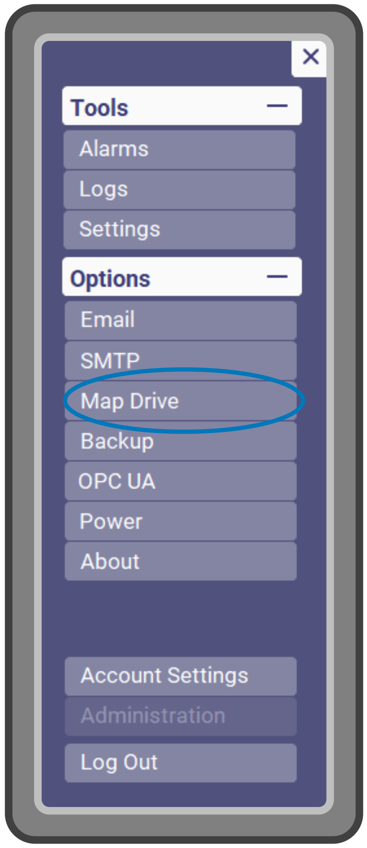
Configuring Automatic Backups

The PBS-80 can automatically back up either just the Historical Records database, or the Historical Records database along with the User Configurations database and all the configuration files and reports.

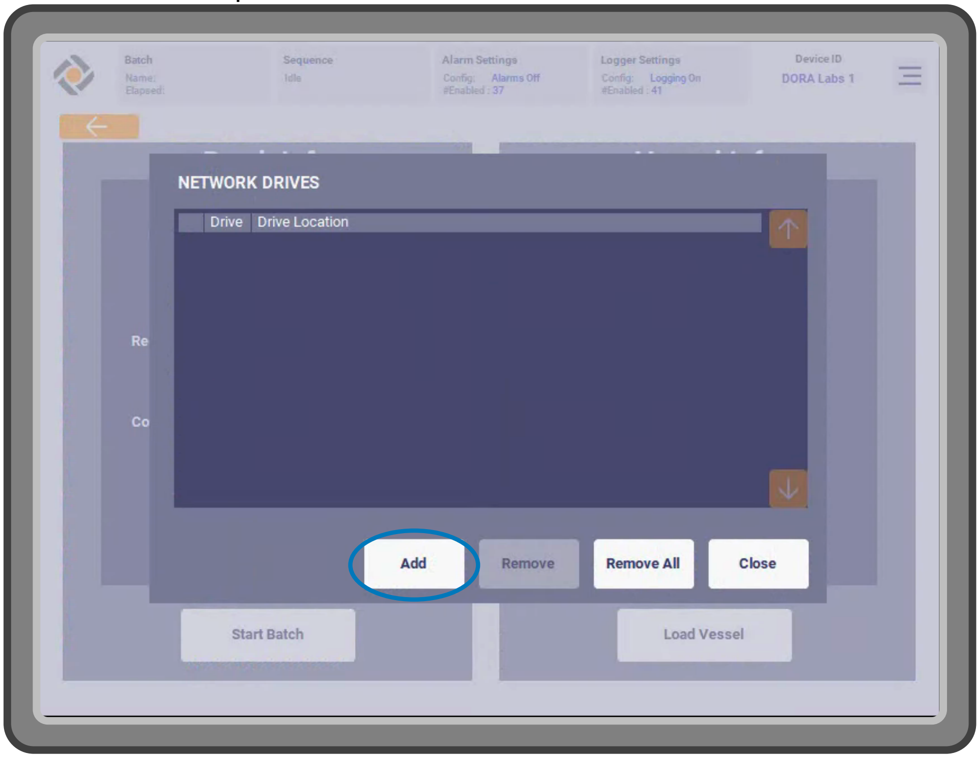
NOTICE Users are responsible for their own backup and recovery.

Mapping Network Drives for Automatic Backup

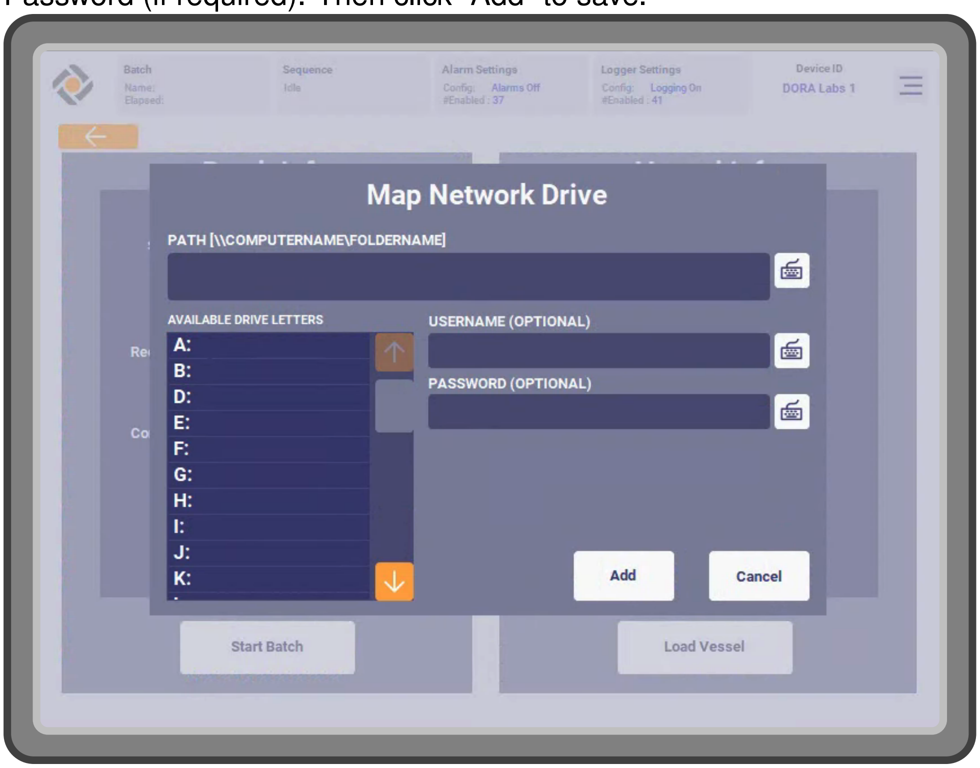
1. Log in to the Hello UI with a user account with the “Backup Configuration” permission.
2. Click the triple bar ≡ (top right corner) and then “Map Drive.”



3. Click “Add” to map a new network location.



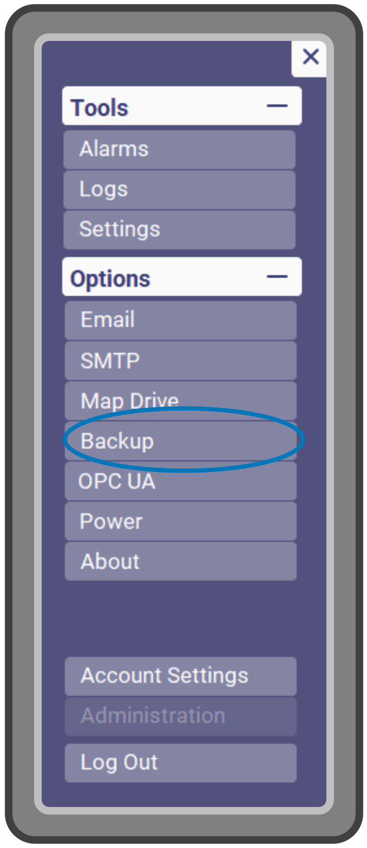
4. Input the Path, assign a Drive Letter, and input the Username and Password (if required). Then click “Add” to save.



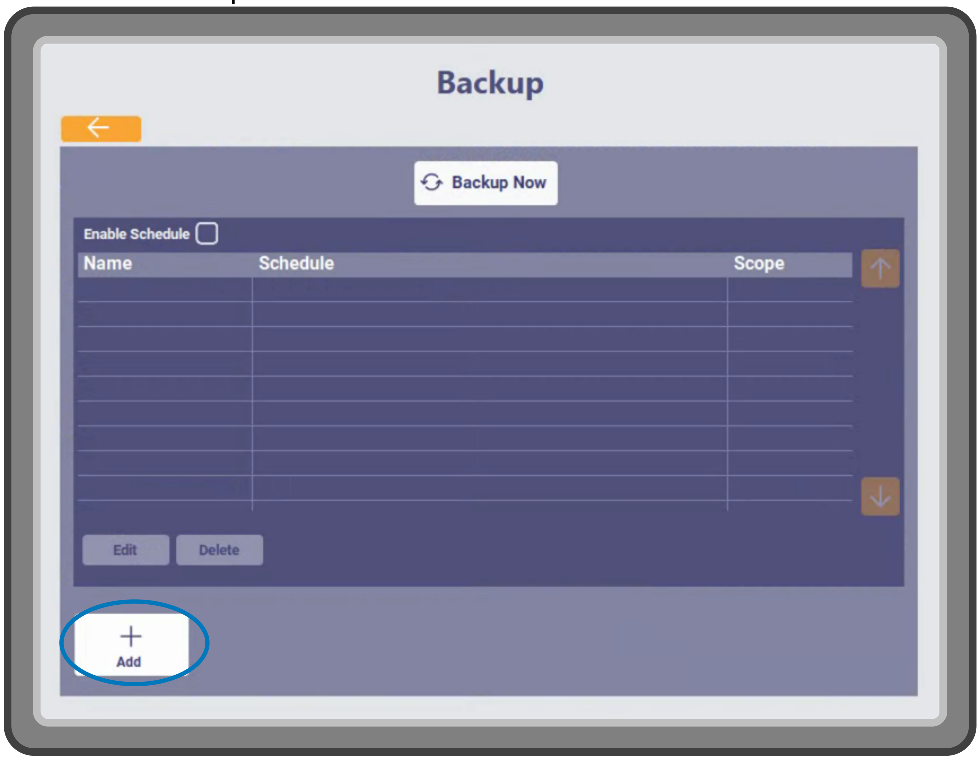
5. Click the “Close” button to return to the main menu.

Scheduling Automatic Backups

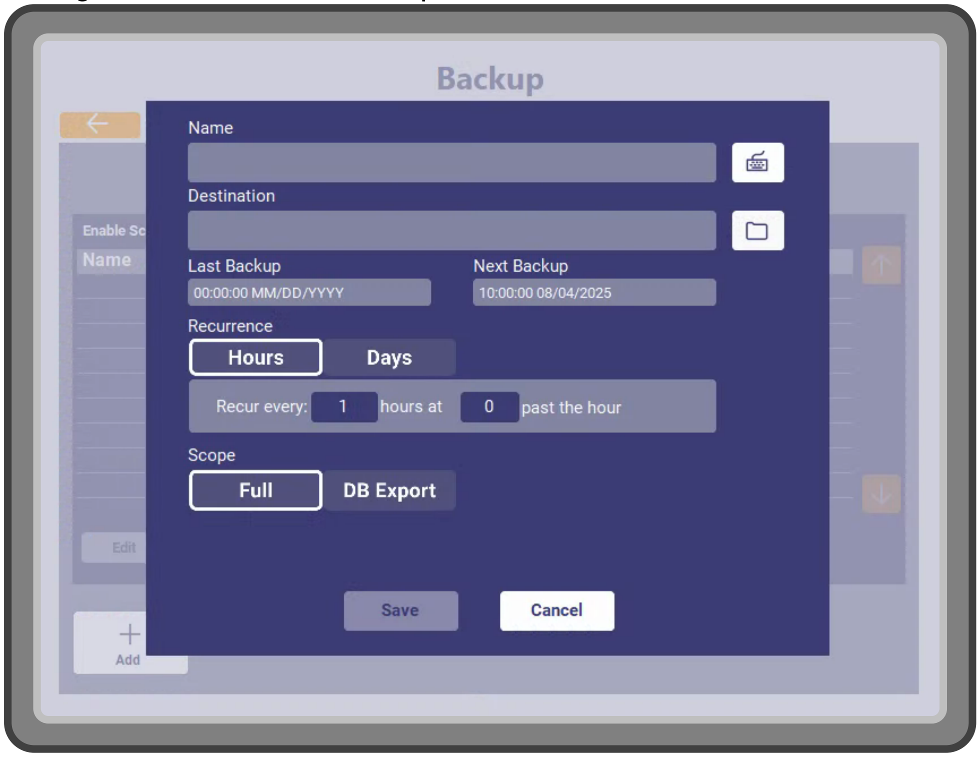
1. Log in to the Hello UI with a user account with the “Backup Configuration” permission.
2. Click the triple bar ≡ (top right corner) and then “Backup.”



3. Click “Add” to create a new scheduled backup. Select an existing scheduled backup to edit or delete it.



4. Configure the scheduled backup.



   (a) Name - this must be unique. The backup file name will start with this, and have a date and time at the end, in form name_YYYY-MM-DD_hh-mm-ss
   (b) Destination - this can be a mapped network drive (see "Mapping Network Drives for Automatic Backup" on page 64) or a physical drive attached via USB.
   (c) Recurrence - Frequency of backup. If "Hours" is selected, the number of minutes past the hour can be specified, to avoid having multiple bioreactors all performing their backup at the same time and overloading the network. If "Days" is selected, then a specific time for the backup is set. The "Next Backup" field updates based on how Recurrence is configured.
   (d) Scope - "DB Export" backs up the Historical Records database. "Full" backs up the Historical Records database along with the User Configurations database and all the configuration files and reports.

5. Click "Save" to save the scheduled backup.

6. Click the arrow in the top left corner to return to the main menu.

Note: The automatic backup function can be disabled by un-checking the "Enable Schedule" checkbox in the Backup menu.
Note: Backups can also be performed manually from the Backup menu by

clicking “Backup Now” and setting the Name, Destination, and Scope.

Congratulations! You have now set up your PBS-80 and configured user accounts, logger settings, and alarms. Please see Chapter 6 for more details to begin using the PBS-80.

Using the PBS-80

6

Before You Begin

This chapter will explain how to perform all the steps associated with a typical run, as well as tasks that a user may want to perform at any time from start to finish. Reading the preceding chapters is highly recommended before continuing.

Suggested Order of Operations

Set Up Run

1. HMI Computer Restart
2. ‘Two-point’ pH calibration
3. ‘Two-point’ DO calibration
4. Autoclave reusable sensors
5. Confirm gas source pressure matches specifications (see “Utility Requirements” on page 41)
6. Load Bag
7. Install bag in PBS-80
8. Check oxygen flow valve position
9. Check harvest valve alignment
10. Pressure ‘Zero’ calibration
11. Level ‘Zero’ calibration
12. First integrity test
13. Install reusable sensors in bag
14. Second integrity test
15. Add medium
16. Prime the harvest line
17. Level ‘Span’ calibration (if necessary)
18. Control temperature, agitation, and main gas as for process. Control DO and pH in Manual mode.
19. Wait for equilibration
20. ‘Span’ DO calibration
21. ‘One-point’ pH calibration

22. Control DO and pH in Auto mode
23. Load the Alarms On.alm file
24. Add cells
25. Start batch

During Run

1. Take Sample
2. Perform Medium feed/exchange (if applicable)

End Run

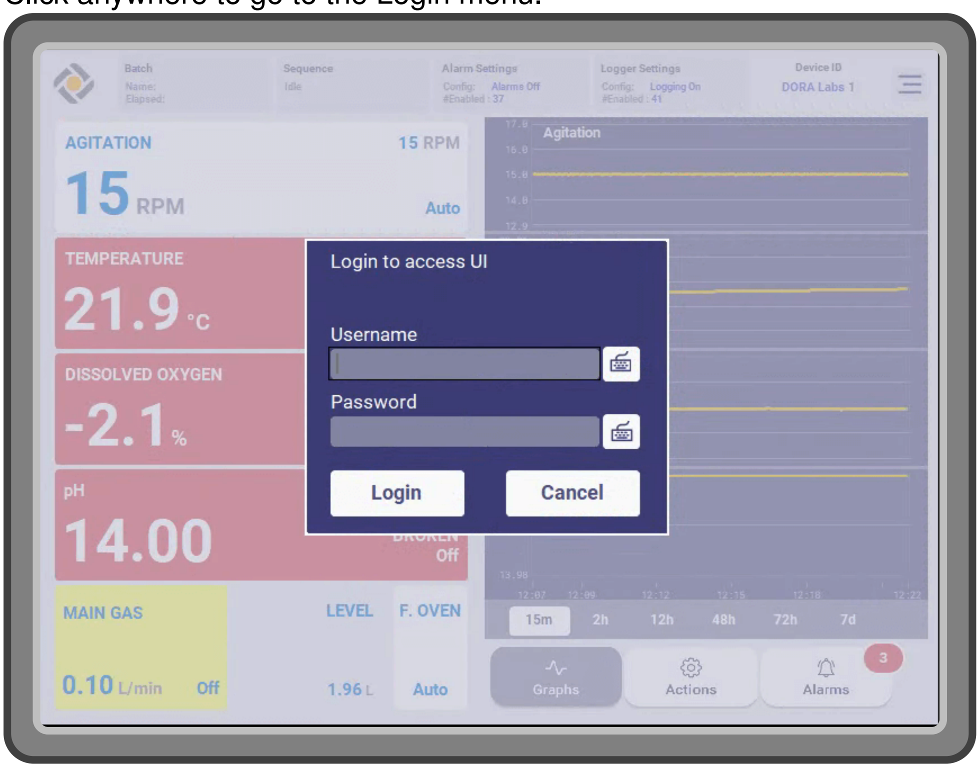
1. Load the Alarms Inactive.alm file
2. Harvest
3. End batch
4. Clean/decontaminate the PBS-80

Before Starting a Batch Run

Log In to the Hello UI

Local Login Only (default):

1. Click anywhere to go to the Login menu.



2. Enter your Username and Password with the on-screen keypad, or with an external keyboard.
3. Click “Login.”

Domain Enabled:

Logging in to a Domain account requires the feature to be enabled and configured on the bioreactor, requires the Domain to be configured appropriately, and requires that the Domain account has at least one (1) PBS permission associated with the account. For IT instructions to enable the Domain login option on the bioreactor and configure the domain, see “Configuring Domain Login” on page 186.

Note: Failed Domain login attempts are processed by the Domain controller, and may lock the account out on other systems.

1. Click anywhere to go to the Login menu.

2. For a Domain login, enter your Username and Password with the on-screen keypad, or with an external keyboard.
   The Usernames and Passwords for Domain accounts are corporate credentials, assigned and managed by the customers’ IT team.
   The entered username should not have domain prefix or UNC suffix. For

example, the user should enter "`johnsmith`" and not "`EXAMPLE\johnsmith`" or "`johnsmith@example.com`"

3. Click "Login."

Note: The 'Domain' field is automatically populated with the default specified when the bioreactor was configured to use this feature. It can be modified, if different from the default.

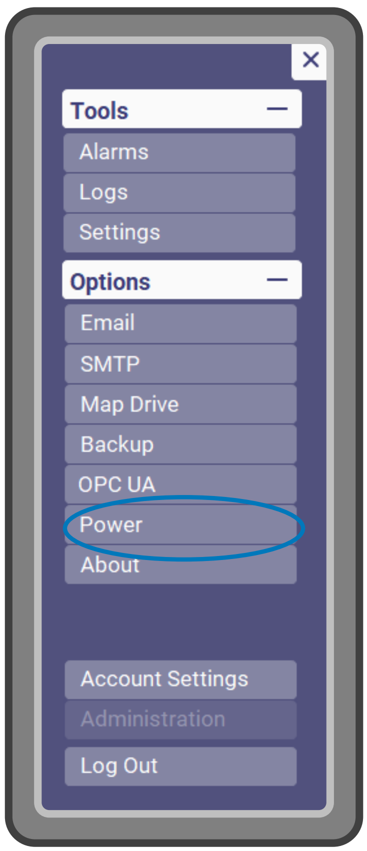
Note: To log in to a Local account while the Domain login feature is enabled, click "LOCAL" and enter your Username and Password.

Restarting the HMI Computer

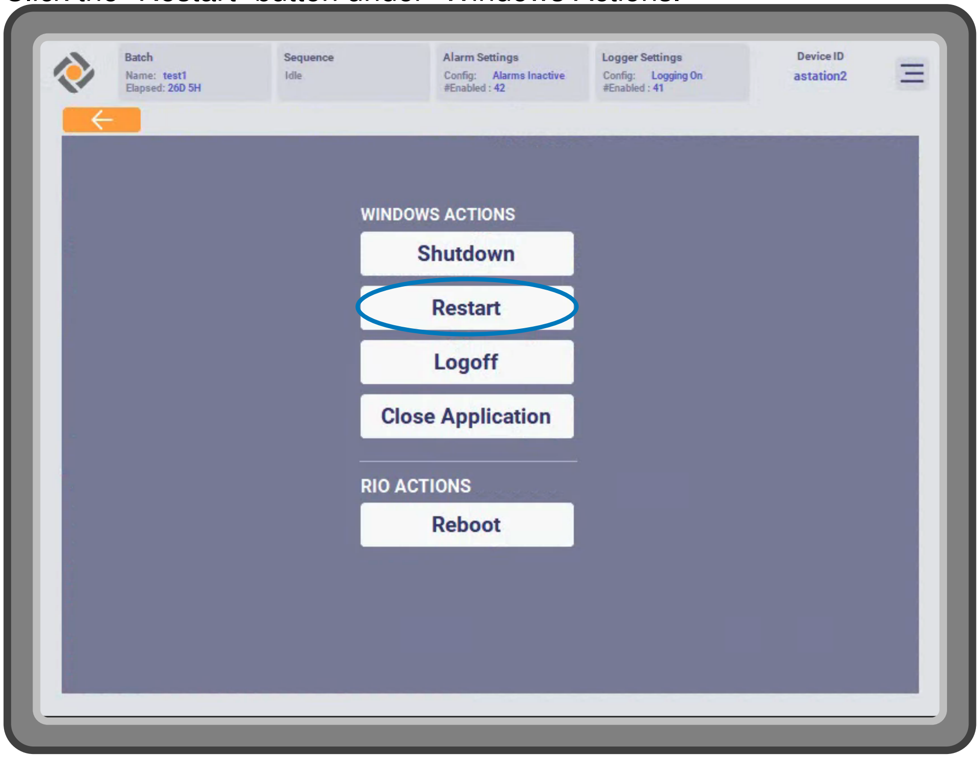
Like any computer, the bioreactor's HMI benefits from occasional reboots. Doing so before starting a run is especially beneficial if the bioreactor has been on for a significant amount of time.

To Restart the HMI with the Hello UI:

1. Click the triple bar ≡ (top right corner) and then "Power."



2. Click the “Restart” button under “Windows Actions.”



Calibrating Reusable pH Sensor

Before calibrating:

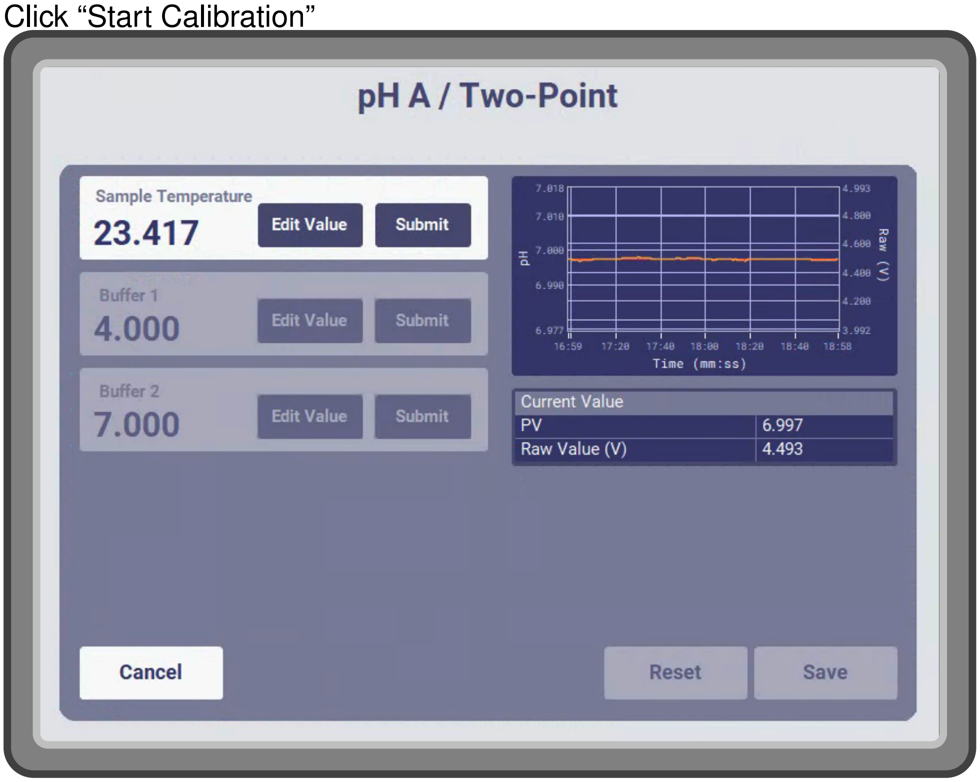
- Confirm the pH sensor is compatible with the PBS-80. The standard PBS-80 configuration is compatible with most combination electrodes with an S8 connector. If your PBS-80 has been custom built for different pH sensors, please consult PBS Biotech Technical Support to determine compatible sensors.
- Inspect the pH sensor. Confirm the sensor tip is filled with electrolyte solution and there are no bubbles.
- Connect the pH cable to the pH sensor by mating the two together and threading the articulating collar completely to secure.

  NOTICE Do not twist the pH cable as this may damage it.

Two-point pH calibration

1. Navigate to the “Actions” tab.
2. Click “Calibrate” and then “Two-Point.”

3. Click “Start Calibration”



4. If the number in the ‘Sample Temperature’ field does not match the buffer temperature, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter the correct value. Click the “Submit” button for ‘Sample Temperature’ once it is correct.
5. If the number in the ‘Buffer 1’ field does not match the buffer 1 value, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter the correct value.
6. Place pH sensor (and grounding wire, if applicable) in buffer 1.
7. Wait for the graph to stabilize.
8. Click the “Submit” button for ‘Buffer 1.’
9. If the number in the ‘Buffer 2’ field does not match the buffer 1 value, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter the correct value.
10. Place pH sensor (and grounding wire, if applicable) in buffer 2.
11. Wait for the graph to stabilize.
12. Click the “Submit” button for ‘Buffer 2.’
13. Verify the new calibration values are appropriate.
14. Click “Save.”
15. Place pH sensor (and grounding wire, if applicable) in buffer 1.
16. Confirm the displayed pH PV is close to the actual value of buffer 1.
17. Click the arrow in the top left corner to return to the main menu.

For more information, see “‘One-point’ pH calibration” on page 112.

Calibrating Reusable Dissolved Oxygen Sensor

Before calibrating:

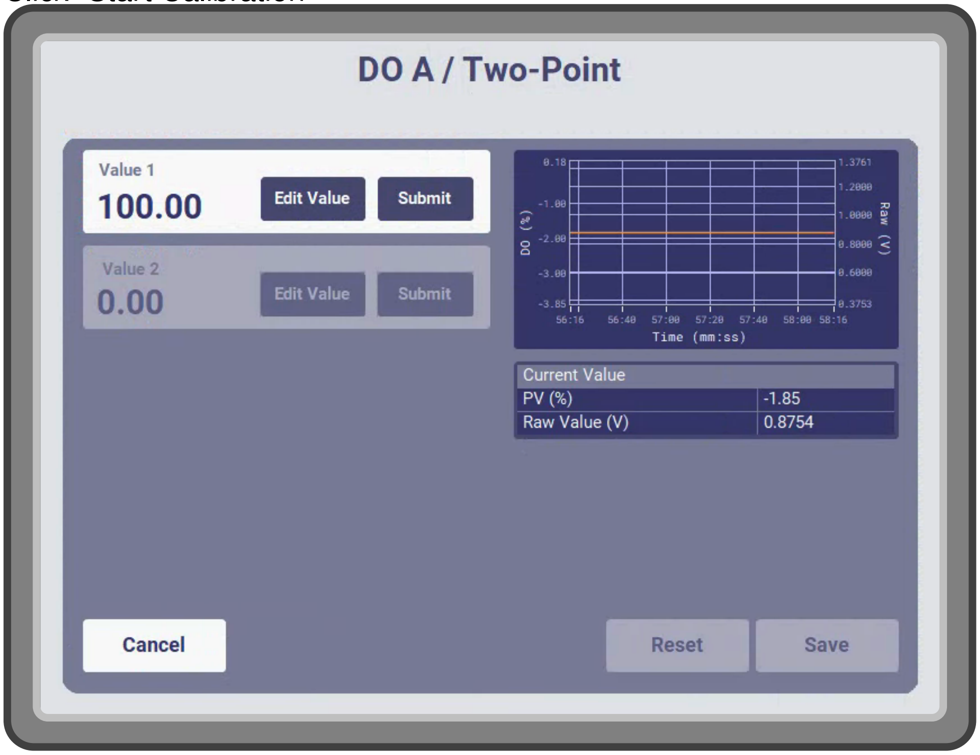
- Confirm the DO sensor is compatible with the PBS-80. The standard PBS-80 configuration is compatible with most polarographic DO electrodes with a D4 connector. If your PBS-80 has been custom built for different DO sensors, please consult PBS Biotech Technical Support to determine compatible sensors.
- Confirm that within the last 6 months, the electrolyte solution in the tip has been changed, and the anode has been confirmed to be free of corrosion.

- Connect the DO cable to the DO sensor by aligning the keys on the cable adapter and pushing the two components together. Then twist the articulating collar to secure.
- For polarographic sensors, ensure the sensor has been connected at least 6 hours before performing calibration.

Two-point DO calibration

1. Confirm the sensor is fully polarized.
2. Navigate to the "Actions" tab.
3. Click "Calibrate."
4. Click "DO" and then "Two-Point" if it is not already selected.

5. Click “Start Calibration”



6. If the number in the ‘Value 1’ field is not 100, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter 100.
7. Click the “Submit” button for ‘Value 1.’
8. Disconnect the polarized DO sensor.
9. If the number in the ‘Value 2’ field is not 0, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter 0.
10. Wait for the graph to stabilize.
11. Click the “Submit” button for ‘Value 2.’
12. Verify the new calibration values are appropriate.
13. Click “Save.”
14. Click the arrow in the top left corner to return to the main menu.
15. Reconnect the sensor.
16. Wait for the graph to stabilize. It should read 100%.

Note: The operator could change the order, and calibrate to 0% for the ‘Value 1’ field and 100% for the ‘Value 2’ field. However, the method suggested above has the advantage of calibrating to 100% when the sensor has been polarized for hours.

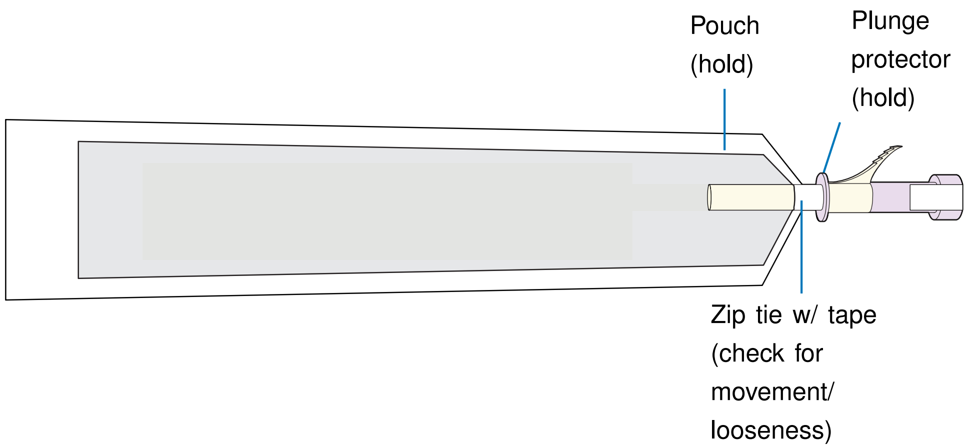
Note: When the DO sensor is disconnected, present value should be 0%.

For more information, see "'Span' DO calibration" on page 110.

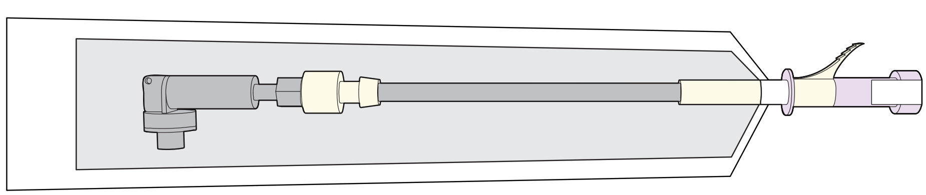
Autoclaving Reusable Sensors

Prepare individual sensors to be autoclaved:

1. Check that the Kleenpak™ pouch's zip tie is tight enough. Hold the pouch with one hand and the plunge protector with the other hand, and gently pull them in opposite directions to check whether the zip tie (covered with tape) moves or is loose. If the tube does not stay firmly in place, discard that Kleenpak™ pouch and use a backup.



2. Cover the part of the sensor that connects to the cables on the PBS-80, using the screw cap that came with the sensor.
3. Clean the sensor, being sure to rinse with DI water.
4. Screw the sensor into the converter that came with the Kleenpak™ pouch.
5. Gently tighten the sensor to compress the O-ring using a crescent wrench.
6. Place the sensor in the autoclave pouch, with the sensor tip in the silicone tubing.



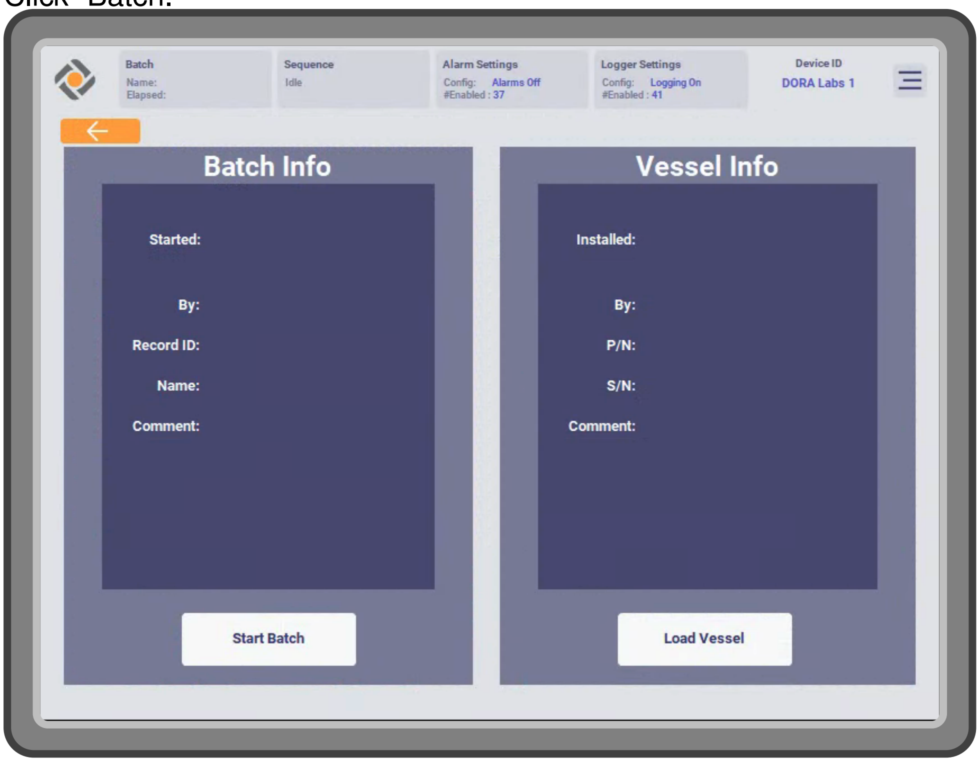
7. Seal the pouch.

8. Place the sensor in the autoclave. Arrange sensors so they are angled with the sensor tip lower than the part of the sensor that connects to the cable.
9. Autoclave per Standard Operating Procedure of your bioprocessing facility, using either slow exhaust or liquid cycle. The temperature should be 121 °C for at least 30 minutes.

Load Bag

To load a bag:

1. Navigate to the “Actions” tab.
2. Click “Batch.”



3. Click “Load Vessel.”

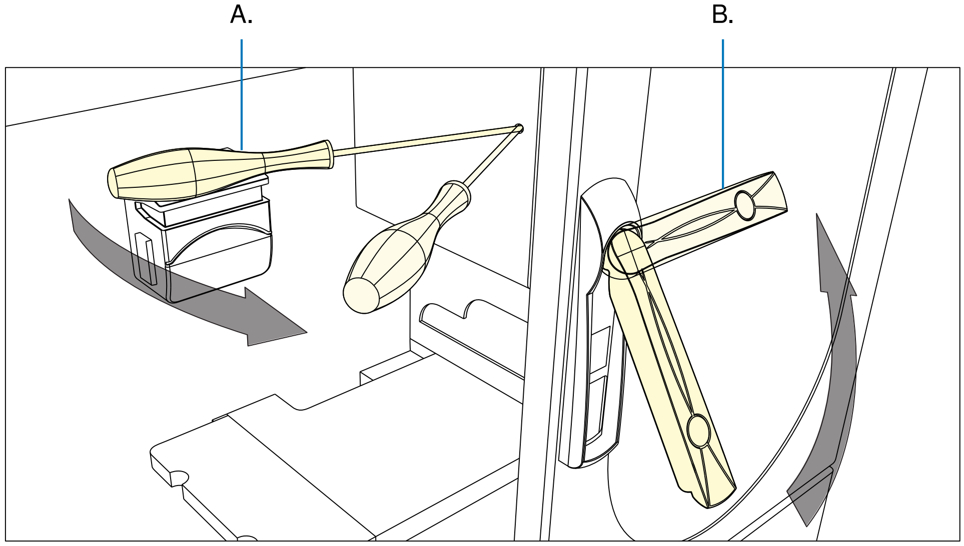
4. Enter the bag part number.
5. Enter the bag serial number.
6. Enter a comment, if desired.
7. Click “Submit.”

Install Bag in PBS-80

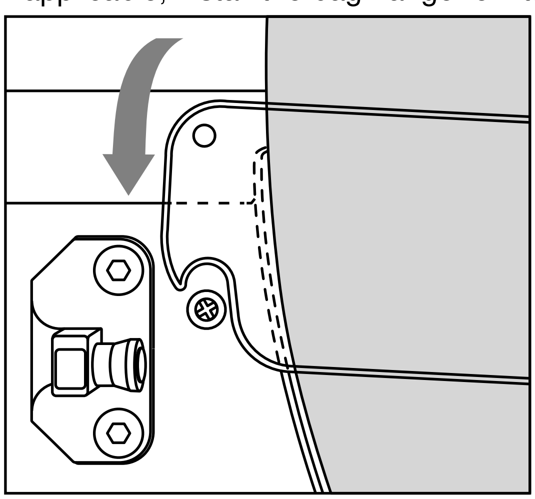
Note: These instructions are for the standard PBS-80 Bioreactor bag configuration. If your bag is different, please consult its installation protocol.

1. Remove the PBS-80 Bioreactor bag from the outer packaging.
2. If applicable, make connections to tubing in a biosafety cabinet. This could include connecting the sample line to a transfer flask (see “Take Sample” on page 118).

3. Use a screwdriver to mechanically override the door lock (A. pictured below), and open the door (B. pictured below).



4. Check that nothing is in the chamber.
5. Holding the bag upright by the side tabs, slide the bag into the chamber, aligning the ports at the side and bottom of the bag with the slotted openings of the chamber. Make sure the top of the harvest valve is properly inserted into the matching support at the bottom of the bag. Fold the side tabs down to the side of the bag.
6. Slide each tube at the top of the bag into its designated slot on top of the chamber.
7. If applicable, install the bag hanger on its support screws.



8. Close the door, making sure the tubing is not in the way.

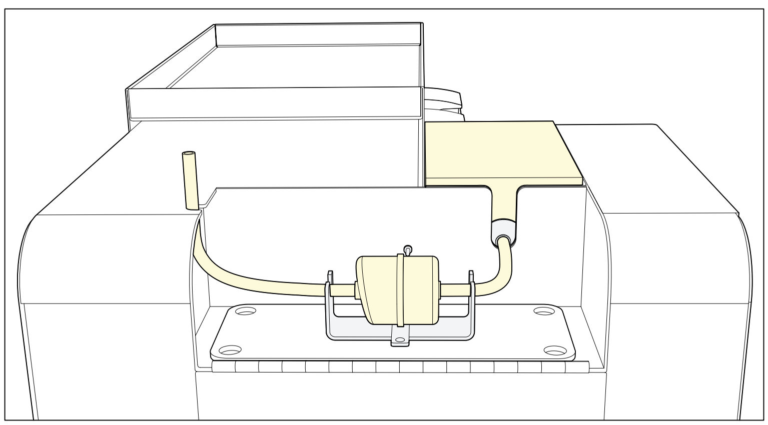
9. Remove the tubing sets from their bags. The tubing is color-coded to match the corresponding connectors and pumps on the PBS-80.

Connector/Pump	Tube Color
Air/CO_2/N_2/ O_2 overlay connector	**Black**
O_2 sparge connector	**Green**
Sample	**Red**
Addition A	**Brown**
Addition B	**Gray**
Media	**Orange**

10. Leave the tubing lines on top of the PBS-80 so they do not get in the way during installation.

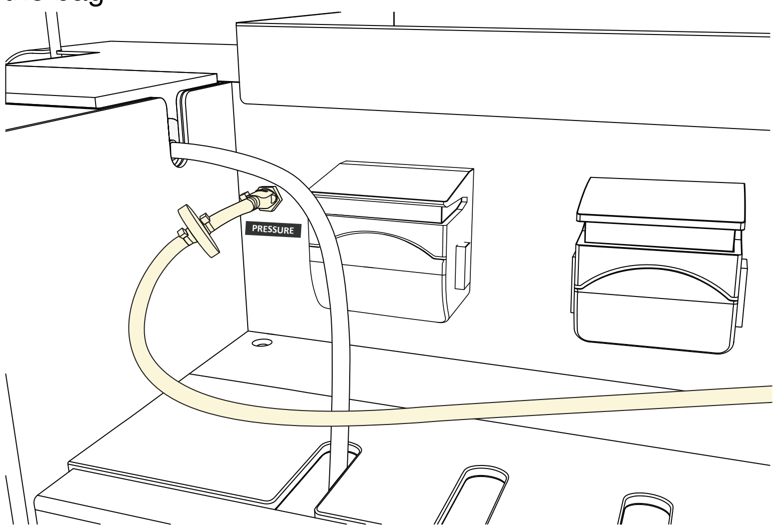
11. Install the exhaust filter tubing:

    (a) Install the condenser bag in the receptacle and the exhaust filter in the filter oven.



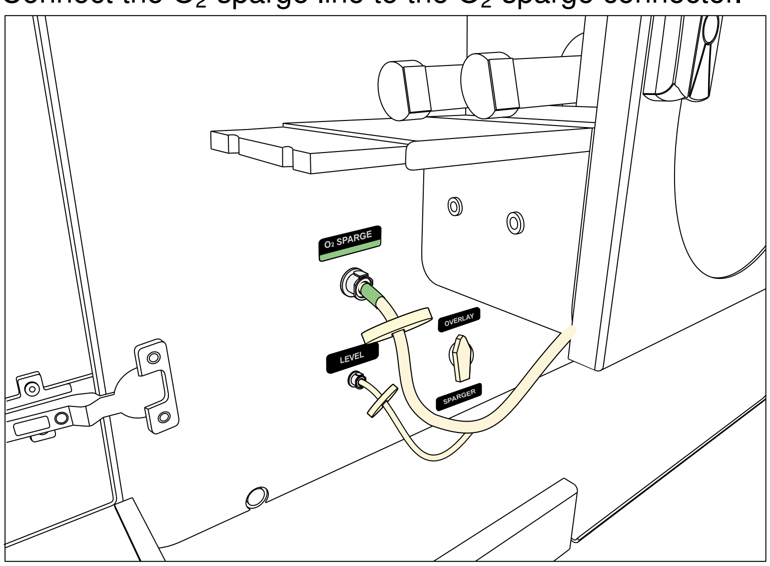
(b) Close the filter oven door.

(c) Attach the pressure sensing line to the pressure sensing connector, routing it in front of the other tubing lines coming out of the top of the bag.



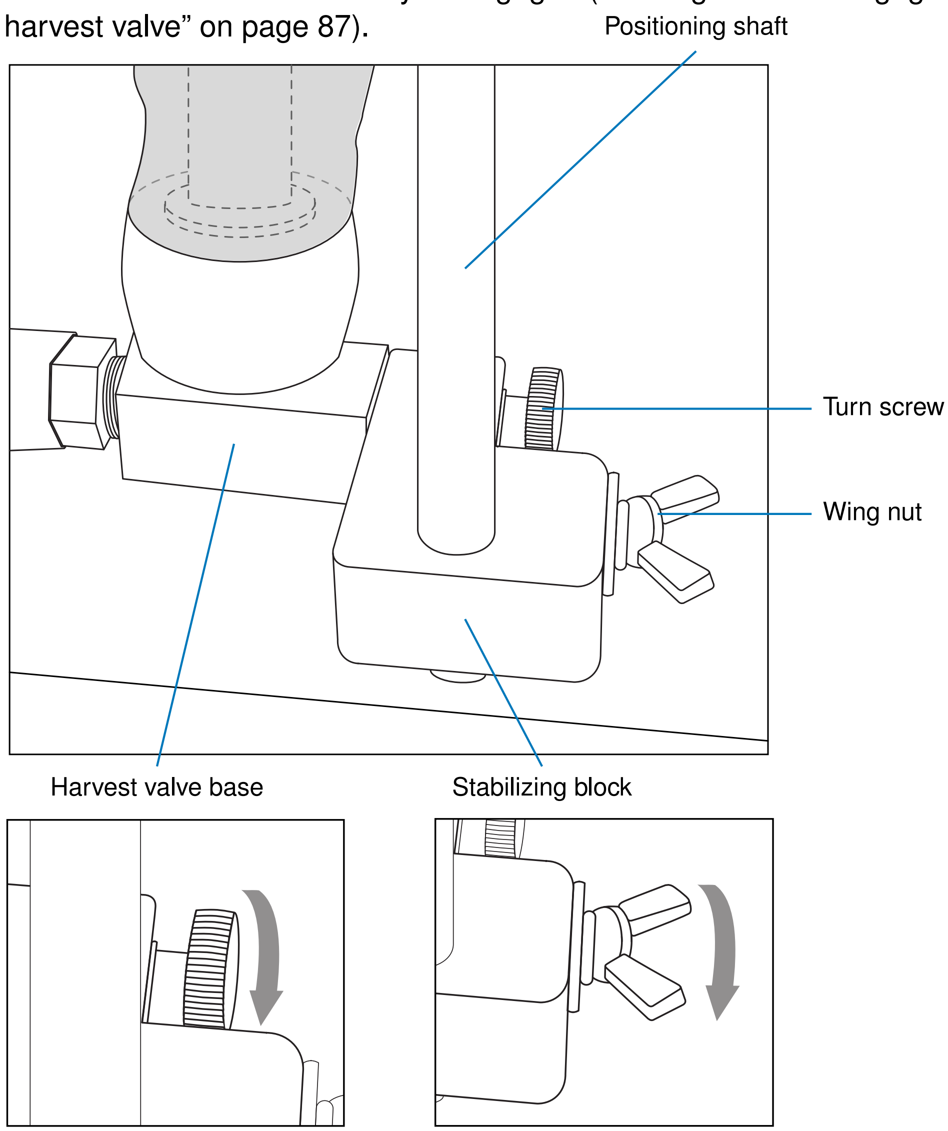
12. Connect the Air/CO_2/N_2/ O_2 overlay line to the Air/CO_2/N_2/ O_2 overlay connector.

13. Connect the O_2 sparge line to the O_2 sparge connector.



14. Connect the level sensing line to the level sensing connector. Be sure to read the “Level sensing line” warning on page 21.

15. Connect the harvest valve base to the stabilizing block using the turn screw. Tighten the stabilizing block to the positioning shaft with the wing nut so the harvest valve is fully disengaged (see “Figure A: Disengaged harvest valve” on page 87).



Check Oxygen Flow Valve Configuration

At the beginning of a run, even for a process with a high O_2 consumption rate, O_2 should be configured to flow through the overlay, instead of sparging.

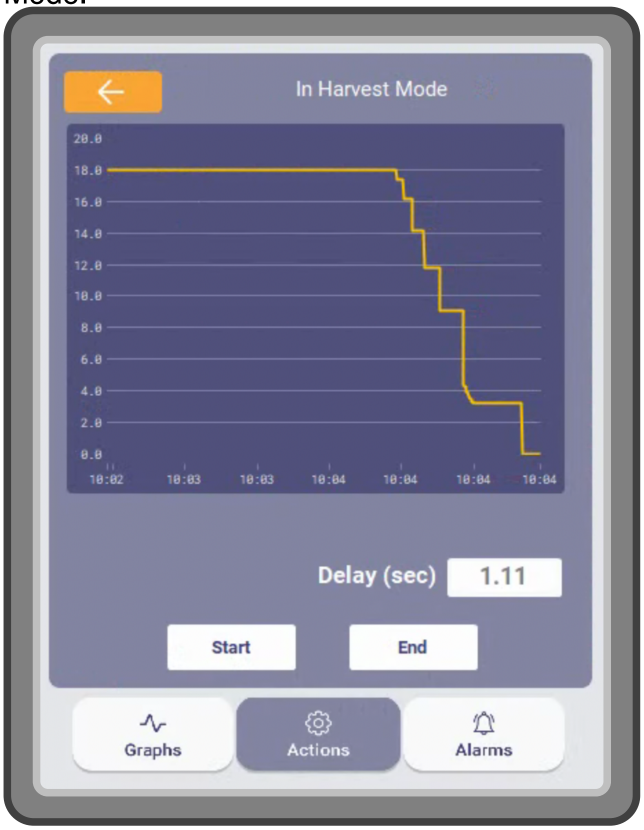
1. Set the oxygen flow valve to “Overlay.”
2. Set the DO “O2 P Gain (%/DO%),” “O2 I Time (min),” and “O2 D Time (min)” settings to the correct value for the configuration (see Appendix 1 “DO” section on page 207).

For more information, see “Oxygen Flow Valve” on page 182.

Check Harvest Valve Alignment with Harvest Mode

Confirm the harvest valve alignment feature works:

1. In the “Actions” tab, click “Harvest.”
2. Click “Start” and then “Confirm,” then wait until the menu says “In Harvest Mode.”



3. Confirm that when the Vertical-Wheel® impeller stops, one of its open channels is directly aligned with the harvest port in the bag (see Figure A below). If the opening is to the left of the harvest port, decrease the Delay (s) value. If it is to the right of the harvest port, increase the Delay (s) value. Then repeat step 2.

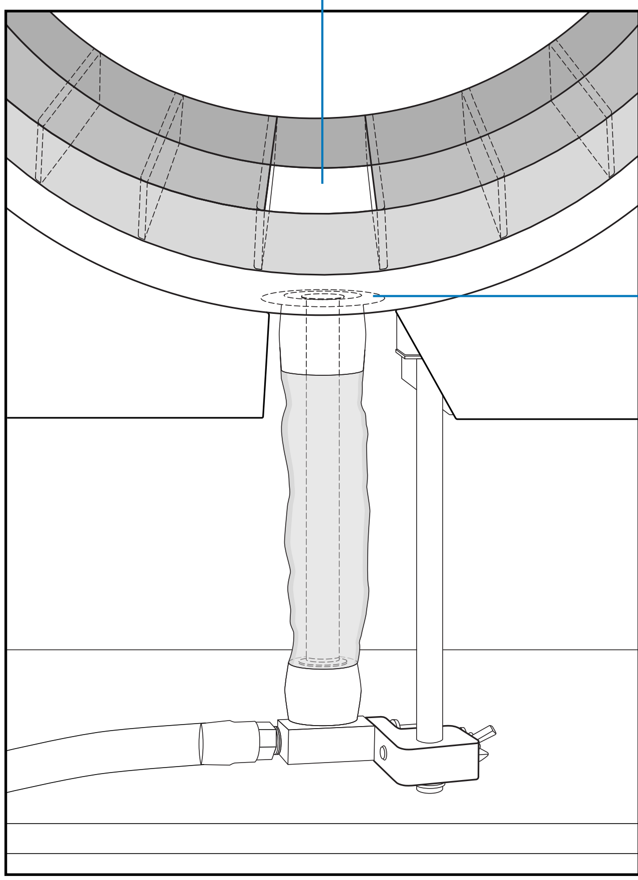


Figure A: Disengaged harvest valve

4. Make sure the harvest mode positioning allows the harvest valve to be fully engaged (see Figure B below):
   (a) Loosen the stabilizing block from the positioning shaft by turning the wing nut.
   (b) Slide the harvest valve up and through the Vertical-Wheel® impeller to confirm its path is not obstructed.

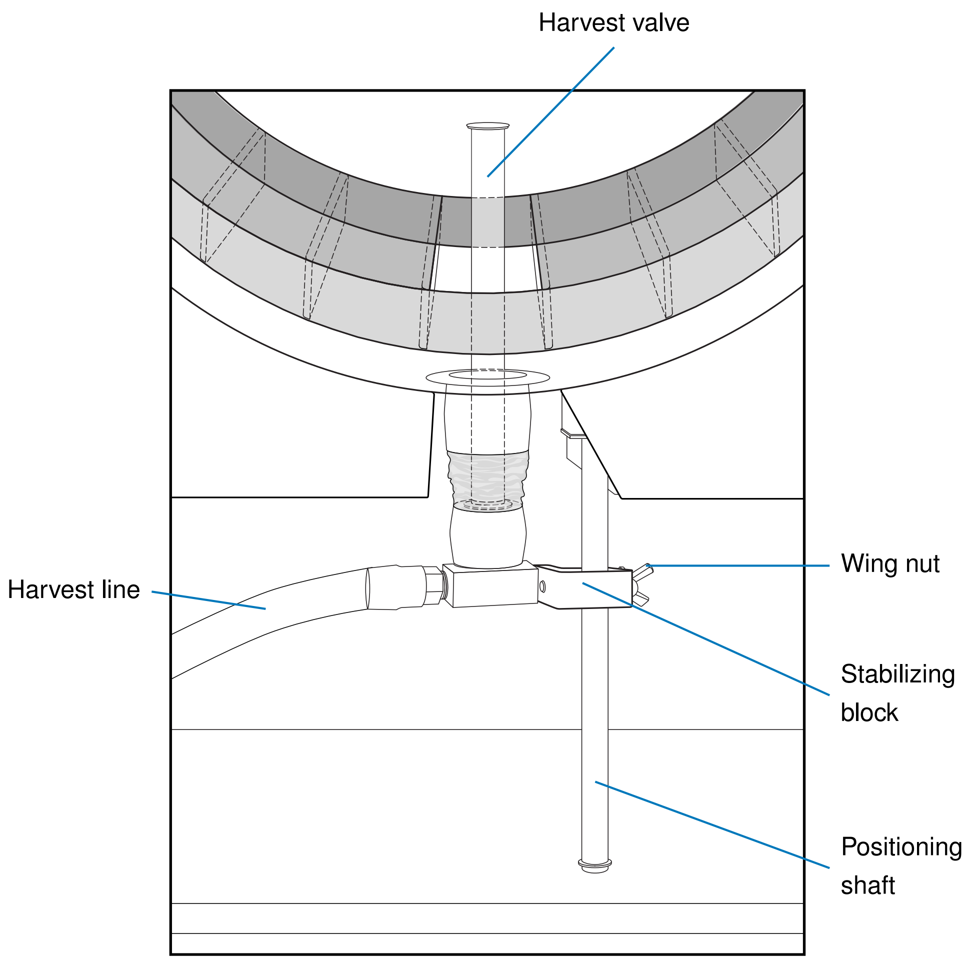


Figure B: Engaged harvest valve

5. Return the harvest valve to its fully disengaged starting position and tighten the stabilizing block to the positioning shaft with the wing nut.
6. Click the “End” button in the Harvest menu, and confirm.

Pressure ‘Zero’ Calibration

1. Confirm the pressure sensing line is connected to the PBS-80 and is not clamped or kinked.
2. Confirm the bag is completely depressurized and no gases are flowing.
3. Navigate to the “Actions” tab.

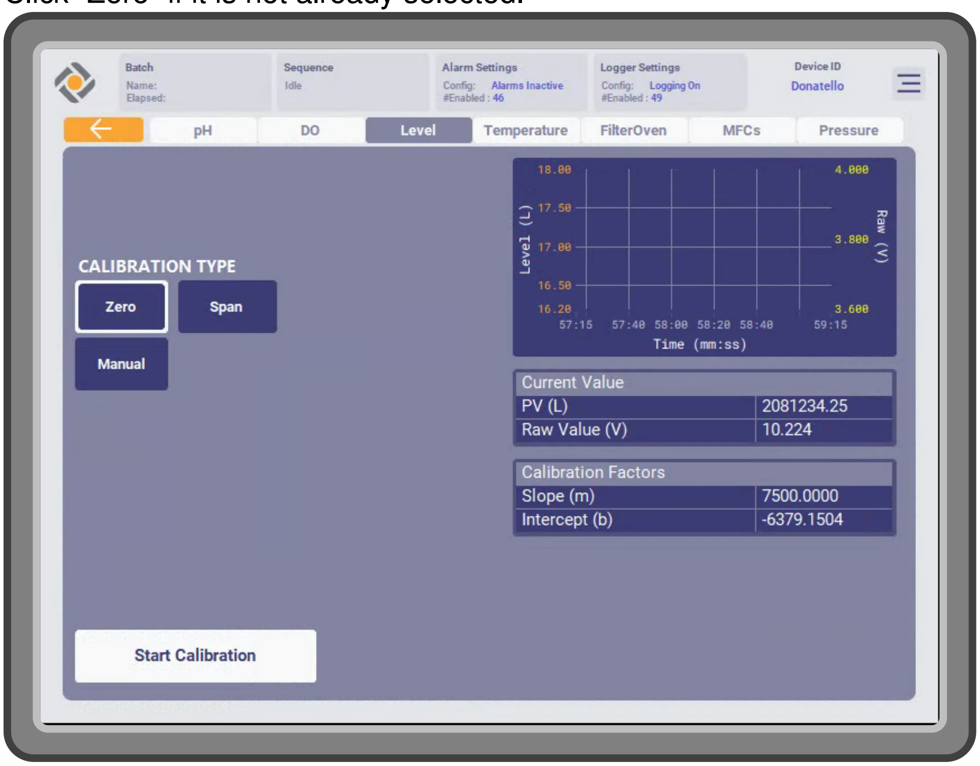
4. Click “Calibrate.”
5. Click “Pressure.”
6. Click “Zero” if it is not already selected.

7. Click “Start Calibration”

8. Click “Submit.”
9. Verify the new calibration values are appropriate.
10. Click “Save.”
11. Click the arrow in the top left corner to return to the main menu.

Level ‘Zero’ Calibration

1. Confirm the level sensing line and pressure sensing line are connected to the PBS-80 and are not clamped or kinked.
2. Confirm the bag is empty and completely depressurized, no gases are flowing, agitation is off, and the pressure PV is 0 (re-calibrate the pressure sensor, if necessary).
3. Navigate to the “Actions” tab.
4. Click “Calibrate.”
5. Click “Level.”
6. Click “Zero” if it is not already selected.



7. Click “Start Calibration”

8. Click “Submit.”
9. Verify the new calibration values are appropriate.
10. Click “Save.”
11. Click the arrow in the top left corner to return to the main menu.

Note: Outside of the calibration menu, the Hello UI will report the level PV as “--” when the software recognizes the level PV as exactly 0.0 L. This behavior should be expected after performing a ‘Zero’ calibration or below empty level setting.

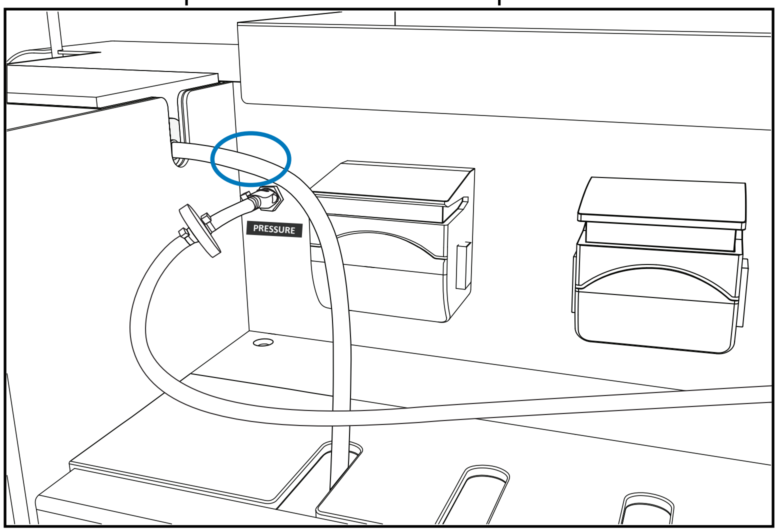
Integrity Test

Confirm that the bag was not damaged in shipping by performing the following integrity test. If using reusable sensors, perform the integrity test once before installing the sensors, and once after installing them.

Note: The acceptance criteria specified in step 7 should be treated as a guideline. Users can create their own protocol and acceptance criteria to confirm their bags were not damaged in shipping.

1. Allow the bag to completely depressurize and confirm that when the pressure sensing line is connected, the pressure PV reads 0.0 psi.

2. Set up for the test:
   (a) Confirm that the Safety “Max Pressure (psi)” setting is 0.5.
   (b) Disconnect the O_2 sparge line.
   (c) Clamp all lines except the Air/CO_2/N_2/ O_2 overlay line and pressure sensing lines. The exhaust line does not have a built-in clamp so an external clamp must be used to clamp it.



   (d) The level sensing line should also be clamped and disconnected. Clamp sensor ports which do not have sensors installed. Do not clamp the tubing on any sensor port with an installed sensor.
3. Navigate to the “Actions” tab and click “Integrity Test.”

4. Click the “Start” button, and then click “Confirm” to confirm and start the test.
5. Observe the graph as the test progresses. During the test, do not turn agitation, DO, pH, pumps, or Main Gas on, or change the Main Gas set point, as it will cancel the test.
6. When the test progresses from “Ramp” to “Settle,” disconnect the Air/CO_2/N_2/ O_2 overlay line.

7. After the test has finished, the software will show whether the test passed or failed. Additionally, confirm the following values:

Start Pressure:	0.4 psi or higher
Decay:	0.0020 psi/min or lower

The “Start Pressure,” “End Pressure,” “Delta,” “Start Time,” “End Time,” “Elapsed,” and “Decay” values will be displayed in the Integrity Test menu’s History tab, and will also be recorded in a user event when the test finishes.
8. If the starting pressure or decay rate was not acceptable according to the above criteria, run the test again. First, remove the clamp from the exhaust line to release the pressure in the bag. When the pressure has returned to 0.0 psi, re-clamp the exhaust line and confirm that all clamps are properly tightened. If performing the test after installing reusable sensors, confirm that the clamps around the sensors are fully actuated and that the Kleenpak™ connectors are fully locked.
9. If the test results were still not acceptable, try restarting the RIO and HMI computers (see “Reboot RIO” on page 138 and see “Restarting the HMI Computer” on page 73).
10. Remove the clamp from the exhaust line to release the pressure in the bag. When the pressure has returned to 0.0 psi, you can remove the other clamps and reconnect the level sensing line.
11. Reconnect the Air/CO_2/N_2/ O_2 overlay line and O_2 sparge line.

For more information, see “Integrity Test” on page 175.

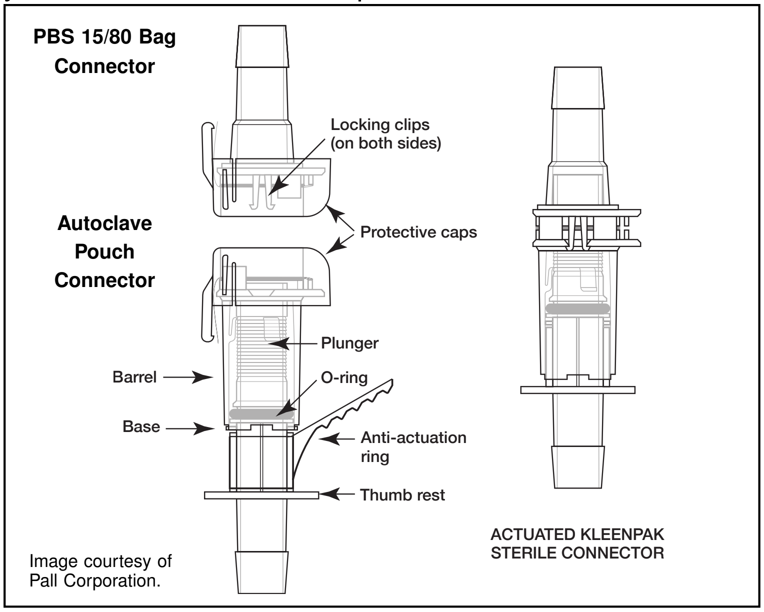
Install Sensors

After the installed bag passes the first integrity test, remove the clamps on the sensor ports and install the autoclaved reusable sensors.

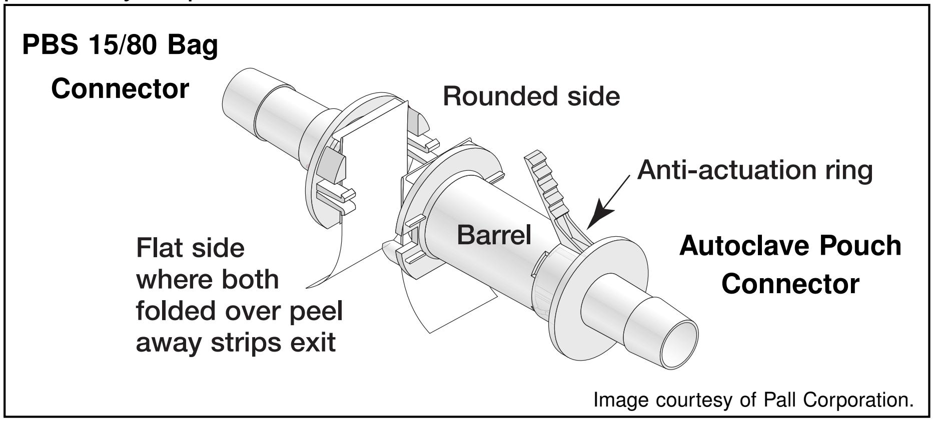
CAUTION! Wait until the reusable sensors are cool to the touch before installing them in the bag.

To install a reusable DO sensor:

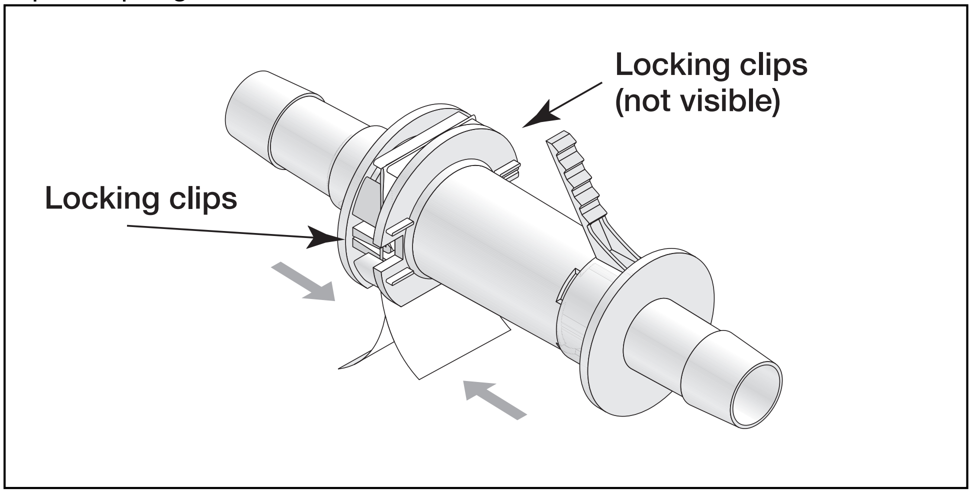
1. Remove the protective cap (NOT the paper) from the Kleenpak™ connectors on the PBS-80 Bioreactor bag's sensor port furthest from you, and on the autoclave pouch.



2. Holding both connectors, orient them so the flat sides are aligned and the peel away strips are folded and exit the same side.



3. Press the two Kleenpak™ connectors firmly together until both locking clips snap together.



4. Continuing to hold both connectors as positioned in step 3, remove the beige anti-actuation ring from the autoclave pouch by pulling the tab away from the PBS-80 Bioreactor bag.

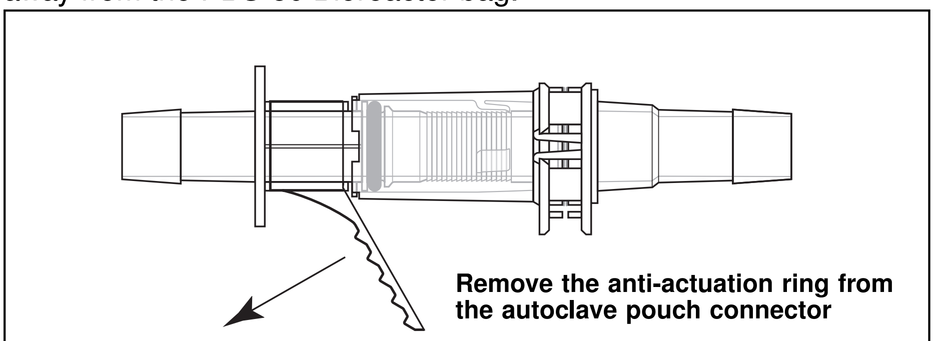
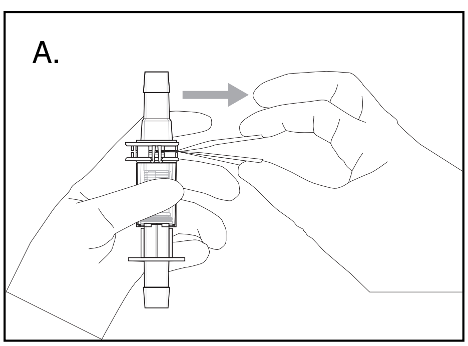
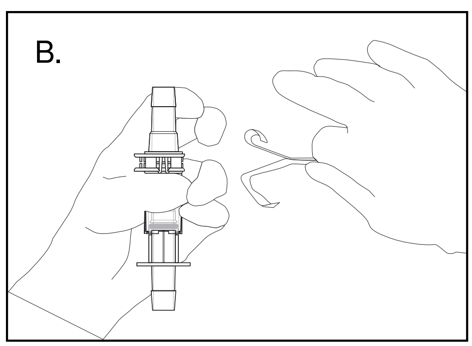


Image courtesy of Pall Corporation.

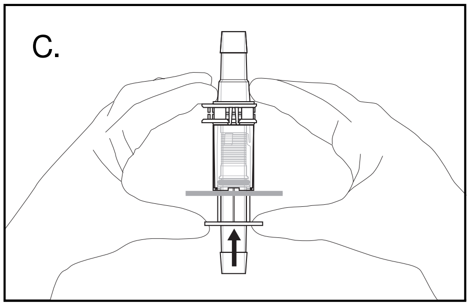
5. Make the sterile connection:

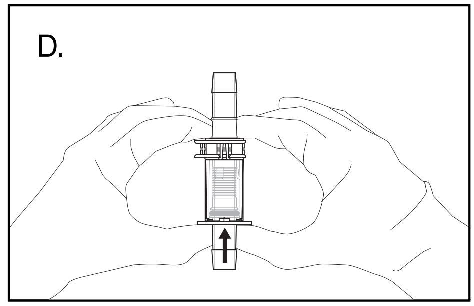
    - Continuing to hold both connectors in one hand, remove both peel away strips at the same time (A. and B. pictured below).



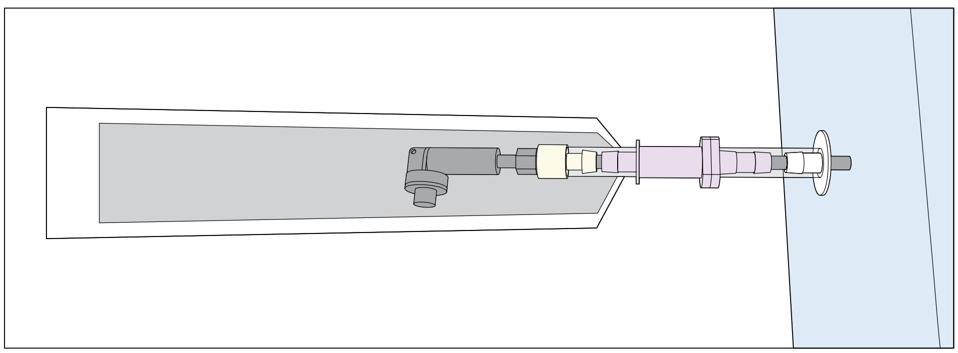


- Immediately push the thumb rest of the autoclave pouch's connector down towards the base of the barrel until they meet. Verify that the plunger is fully inserted in the connector by pushing until a hard stop is reached (C. and D. pictured below).



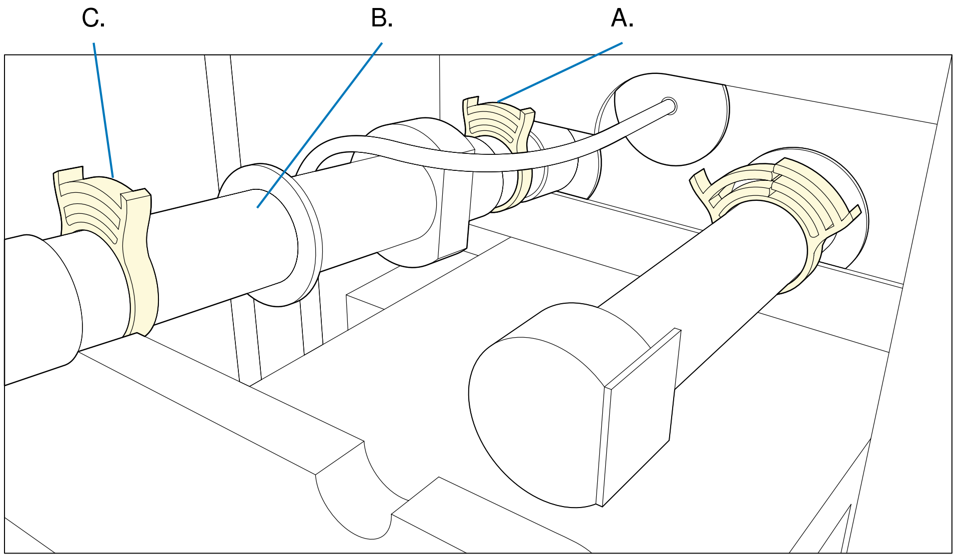


6. Push the sensor in the pouch through the new connection until the barbed end of the converter is fully in the silicone tubing.



7. Tighten the black clamp midway between the two zip ties, using adjustable pliers if necessary. For optimal tightness, all teeth on the clamp should be engaged.

8. Cut away the autoclave pouch with a pair of scissors, being careful around the PBS-80 Bioreactor bag. Apply the second black clamp so it tightens the silicone tubing from the autoclave pouch around the sensor.
   - Tighten the clamp around the sensor (A. pictured below) – all teeth should be engaged.
   - Remove pouch (B. pictured below).
   - Apply and tighten the clamp around the barbed end of the converter (C. pictured below). Not all teeth will be engaged.

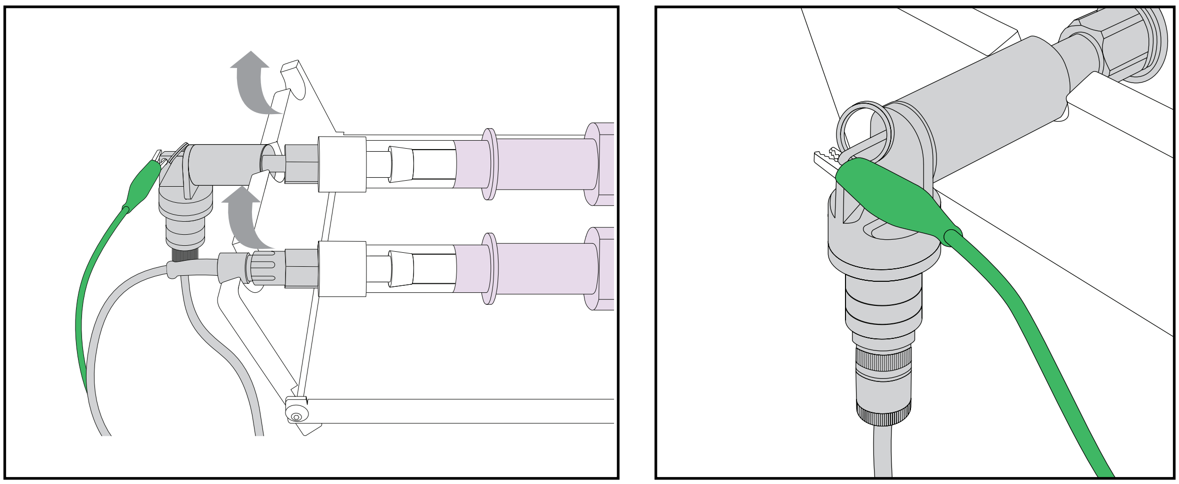


To install a reusable pH sensor:

Repeat the steps in the above “To install a reusable DO sensor” section (starting on page 94) using the other sensor port in the PBS-80 Bioreactor bag.

Finish sensor installation:

Connect the cables to the pH and DO sensors, as in “Calibrating Reusable pH Sensor” on page 74, and “Calibrating Reusable Dissolved Oxygen Sensor” on page 76. If the pH cable has a grounding wire, attach it to the DO sensor so it will be grounded in the medium. Flip up the holder on the sensor platform so the sensors can rest on it at the proper angle.



Second Integrity Test

Repeat the integrity test with the reusable sensors installed to confirm that the sensors were installed correctly. For more information, see “Integrity Test” on page 91.

Starting a Run

Using the Pumps

This section includes instructions for actually using the pumps. For more information about how they work, see “Control Pumps” on page 158.

The tubing lines on the standard bag have a silicone section, close to the bag, and a C-Flex® section, at the end. The C-Flex® is weldable, but not pumpable, and attempting to pump it can compromise the sterility of the bag. Only pump the silicone tubing.

NOTICE Depending on the model of bag being used, some of the tubing lines may not be compatible with the pumps installed on the PBS-80 and will require the use of an external pump.

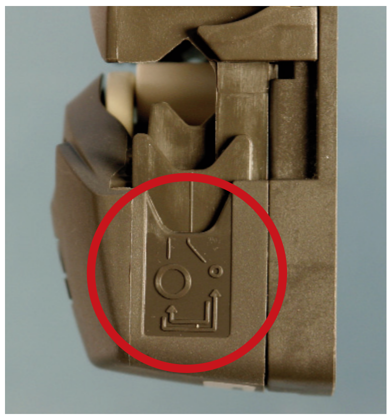
Tube holder positioning for smaller pumps

The pumps must be adjusted for the size of tubing being used. If the outer diameter of the tubing is 1/4 in. or smaller, the “inner” position should be used. For tubing with outer diameter of 5/16 in., the “outer” position should be used.

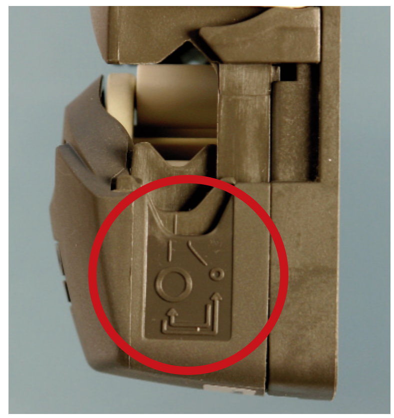
The pumphead can be adjusted to accommodate 1.6mm wall tubing in sizes from 0.5mm bore to 4.8mm bore.

Tube holder position

Tube bore size	0.5mm	0.8mm	1.6mm	2.4mm	3.2mm	4.0mm	4.8mm
Inner	✓	✓	✓	✓	✓	✗	✗
Outer	✗	✗	✗	✓	✓	✓	✓



Inner position, for small tubing



Outer position, for large tubing

With the smaller bore tubes of 0.5mm, 0.8mm and 1.6mm the inner position must be used to prevent the risk of tube slipping through the clamps and wandering across the rollers causing premature tube rupture.

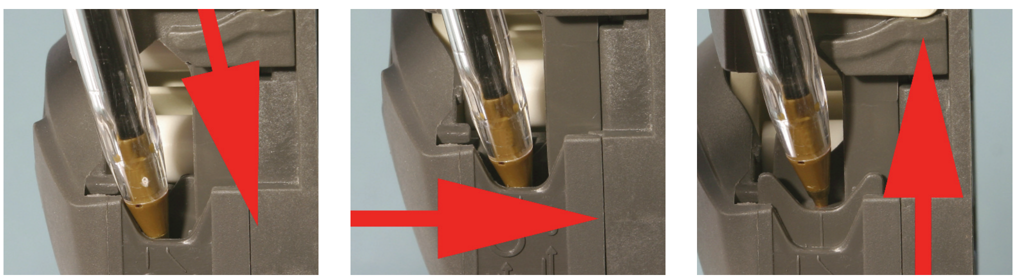
With the larger bore tubes of 4.0mm and 4.8mm the outer position must be used to prevent the flow rate being excessively reduced.

For tubing bores of 2.4mm and 3.2mm either setting may be used, as appropriate for the application. The inner setting will clamp the tube harder, reducing tube slip but has the potential to marginally reduce flow rate. The outer setting will optimise flow rate but the risk of tube slip is increased.

To change from the large tube to the small tube setting

Switch off the pump before changing the tube holder position. Use a pointed device such as a ball-point pen to reposition the lower tube holders **on both sides** of the pumphead.

- Lift the flip top until fully open.
- Place the pointed device pointing down into the small depression pictured here.



- Press down and slightly away from the front of the pumphead, as shown in the first picture above.
- Maintain the angled downward pressure and push away from the front of the pumphead. The jaw clicks into a new position.
- Release the pressure. The jaw rises into its correct alignment. If it does not rise, repeat the procedure, being sure to maintain downward pressure until release.
- Adjust the tube holder on the other side of the pumphead in the same way.

To change from the small tube to the large tube setting

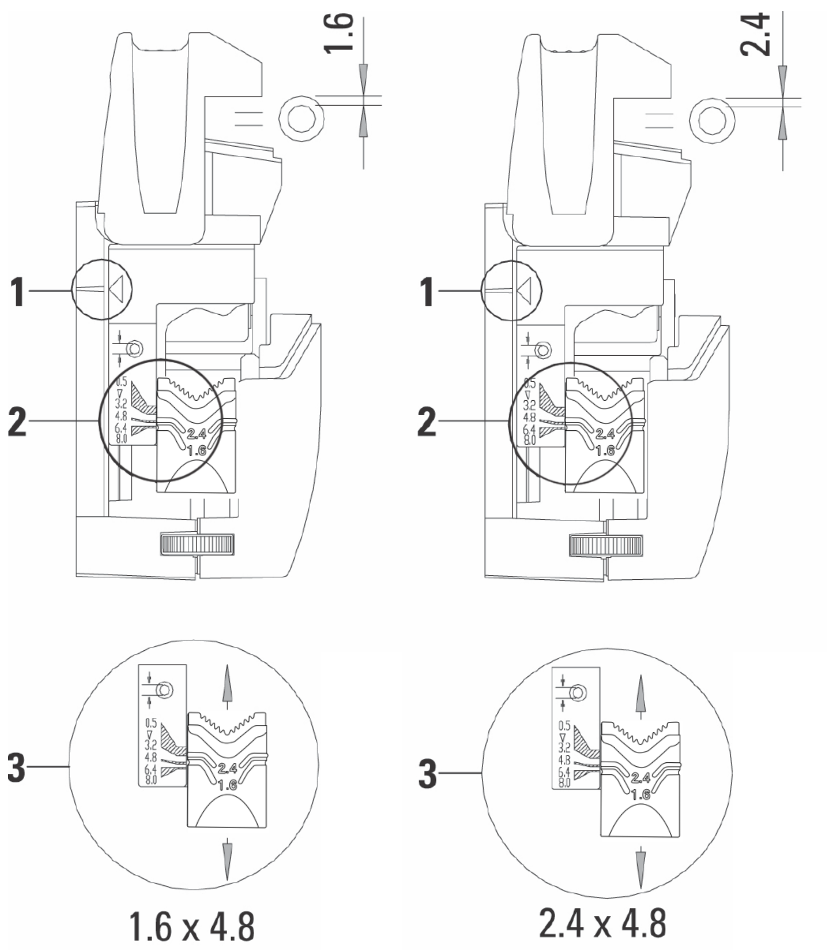
Carry out the procedure described above, but pushing towards the front of the pumphead.

Note: The pictures on the previous page show the tube holders' correct positions for small and large tubing. If a tube holder is not vertical relative to the body of the pumphead, it is wrongly positioned. Follow the instructions above to reposition it.

Tube holder positioning for larger pumps

For the larger pumps, the tube holder should be positioned to either the 1.6 or 2.4 setting, depending on the tube bore size.

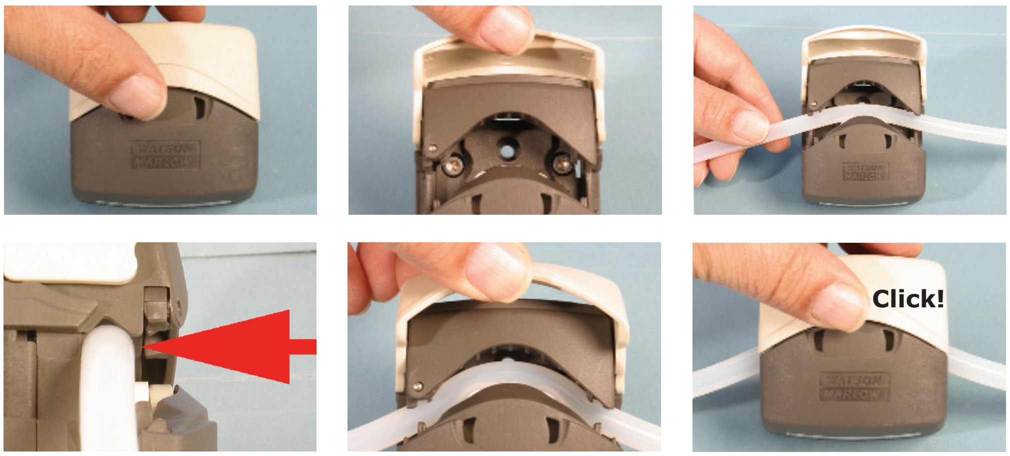
1. Tube clamp setting 2. Tube wall thickness 3. Set for tube bore size



Tube loading for smaller pumps

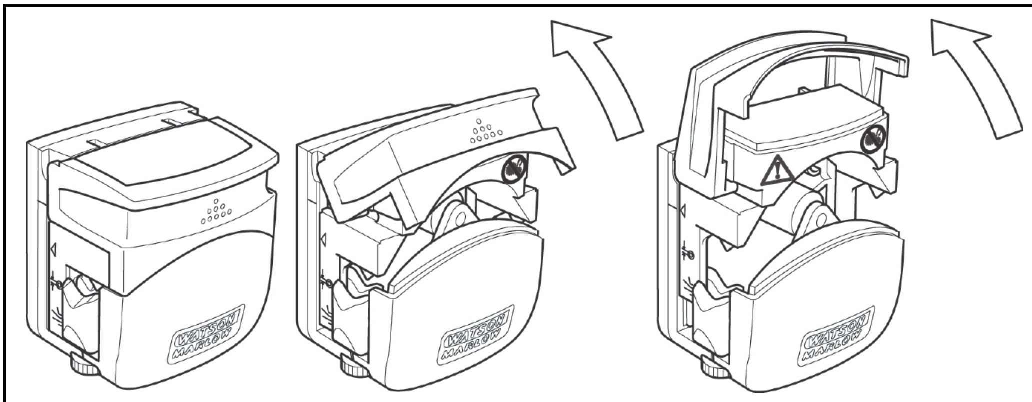
Switch off the pump before tube loading.

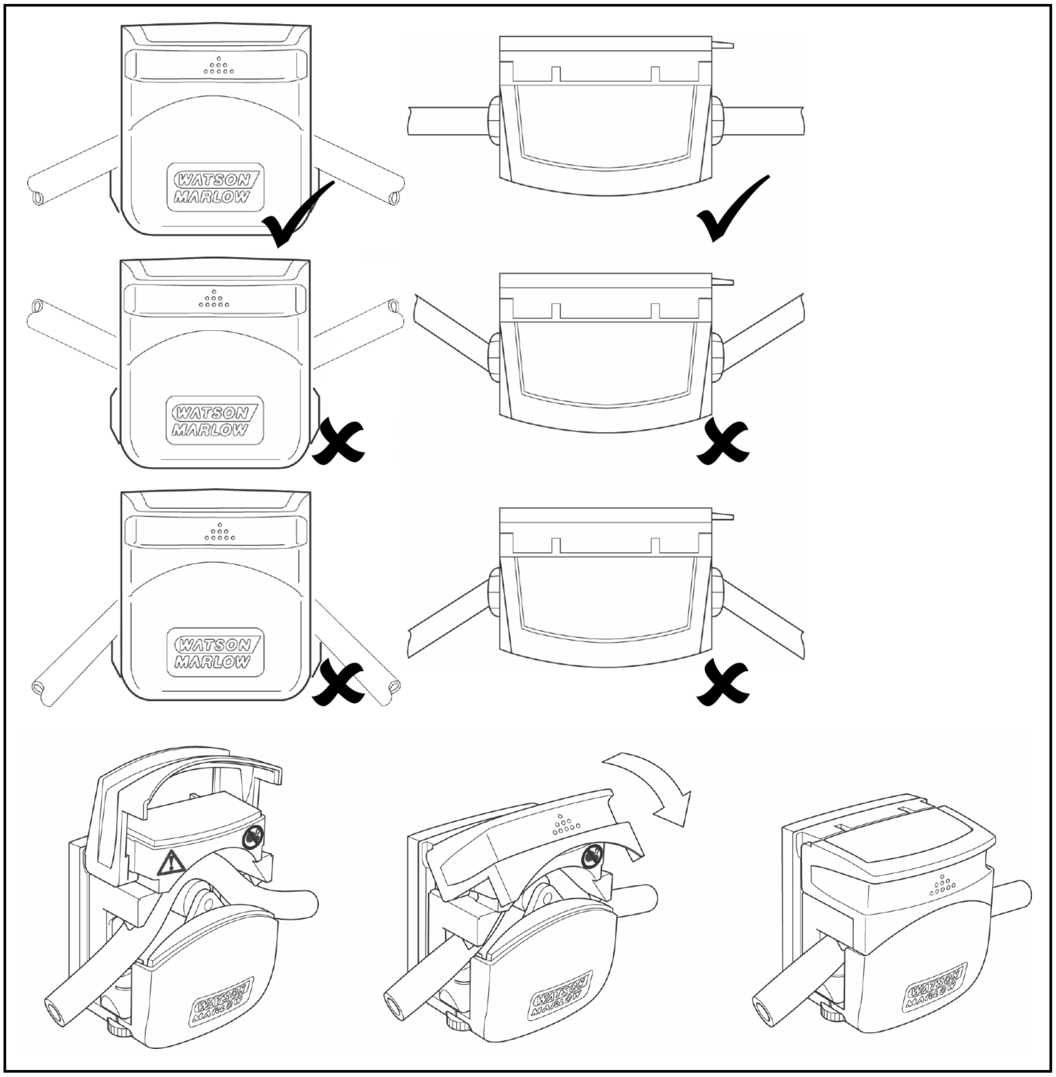
Check that the tube holders on both sides of the pumphead are correctly set for the size of tube you are using.



- Lift the flip top until fully open.
- Select enough tube length for the curve of the pump track. Place the tube between the rotor rollers and the track, pressed against the pumphead inner wall. The tube must not be twisted or stretched against the rollers.
- Lower the flip top until it clicks into its fully closed position. The track closes automatically and the tube is stretched correctly as it does so.

Tube loading for larger pumps





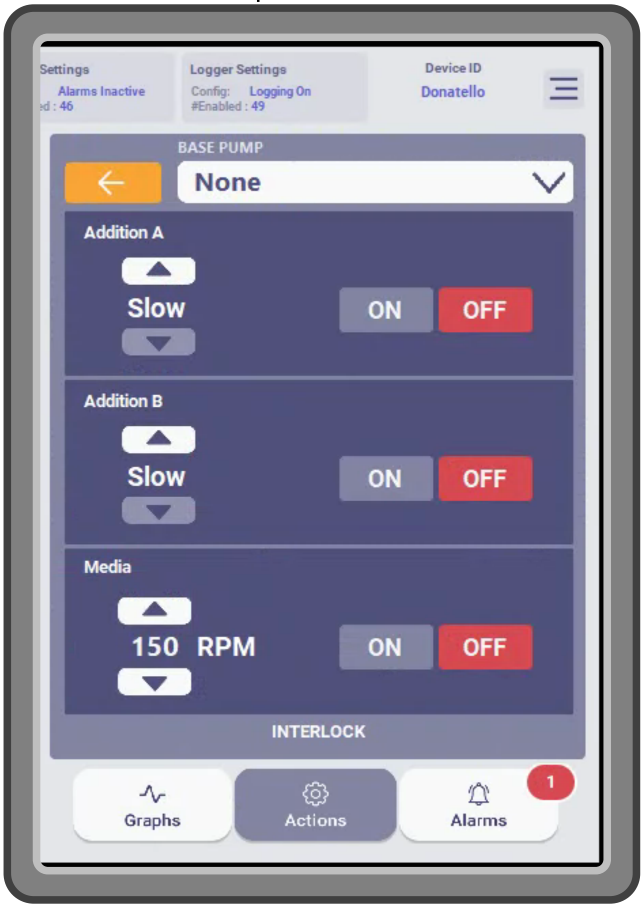
Using gravity

To avoid unnecessary wear on the silicone tubing, and exposing cells to unnecessary shear stress, use the pumps only to prime the tubing, and then use gravity for the rest of the liquid transfer when possible.

Accessing the Pumps menu

1. Log in to the Hello UI as a user with the “Controls” permission.
2. Navigate to the “Actions” tab.

3. Click “Control Pumps.”



Adding Medium

NOTICE If medium is in the bag and the level sensing line is disconnected and not clamped, medium will flow back through the line. Be sure to read the “Level sensing line” notice on page 21.
If the harvest line is not clamped, medium will flow past the harvest valve and into the harvest line.

To add medium:

1. Check for creases in the bag. If any need to be fixed, open the door, rearrange the bag, and close the door. Pressurize the bag by repeating the integrity test (see “Integrity Test” on page 91), and confirm the creases have been fixed. Repeat as necessary.
2. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 103).
3. If the media pump is on, click the button to turn it off.

4. Form a sterile connection between an unused medium addition line (one orange band) and the medium bottle/bag source, by welding the tubing or using the connectors.
5. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and bag (see "Using the Pumps" on page 98).
6. Adjust the media pump RPM using the up and down arrows.
7. Click the button to turn the media pump on.
8. Click the button to turn the media pump off after adding desired amount of medium.

Priming the Harvest Line

After adding medium, the air in the harvest line should be displaced with medium. This prevents a vacuum effect from taking place as the harvest valve moves through settled cells and micro carriers, which would cause them to enter the harvest line.

1. Confirm the harvest line is clamped.
2. Stop Agitation.
3. Partially engage the harvest valve (see "Harvesting a Run" on page 122 and follow the relevant instructions). Medium will enter the harvest line and displace the air inside.
4. Return the harvest valve to its fully disengaged starting position (see "Check Harvest Valve Alignment with Harvest Mode" on page 86 and follow the relevant instructions).

Level 'Span' Calibration

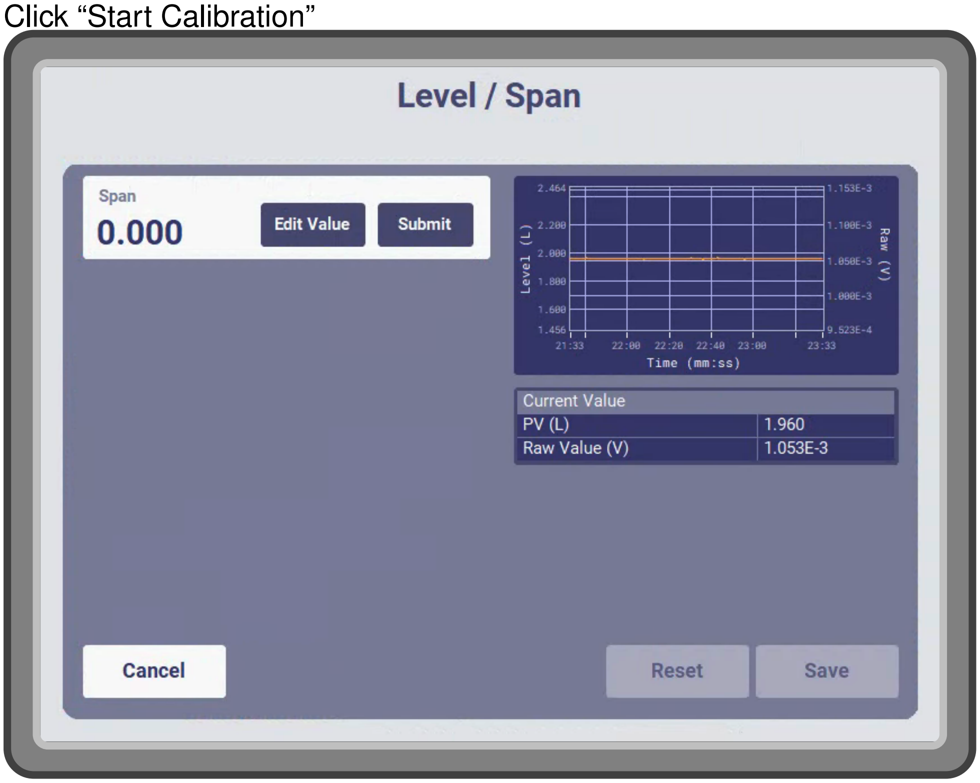
Level 'Span' Calibration with the Hello UI:

Note: This should only be performed if the Level reading reported by the software is significantly different from the actual volume in the bag.

1. Confirm the level sensing line and pressure sensing line are connected to the PBS-80 and are not clamped or kinked.
2. Confirm the Vertical-Wheel® Impeller is at least half-covered by medium, the bag is completely depressurized, no gases are flowing, agitation is off, and the pressure PV is 0 (re-calibrate the pressure sensor, if necessary).
3. Navigate to the "Actions" tab.
4. Click "Calibrate."

5. Click “Level.”
6. Click “Span.”

7. Click “Start Calibration”



8. Click “Edit Value” and use the on-screen keyboard or an external

keyboard to enter the correct value in the ‘Span’ field.

9. Click “Submit.”
10. Verify the new calibration values are appropriate.
11. Click “Save.”
12. Click the arrow in the top left corner to return to the main menu.

Note: A ‘Span’ calibration cannot be performed if the Vertical-Wheel® impeller is less than half covered.

Turning Controls On

After filling the bag with medium, the controls need to be turned on, to condition the medium. This accomplishes 3 things: (1) it allows the DO and pH sensors to polarize and equilibrate, so ‘span’/‘one-point’ calibrations can be performed, (2) it brings the PVs to within the appropriate ranges for the cell process, and (3) it acts as a sterility hold, so operators have the opportunity to determine whether the medium has been contaminated before inoculating.

First, the agitation, temperature, and main gas controllers must be turned on. Then, the DO and pH controllers can be set to Manual mode, to achieve the desired process parameters you intend to use before inoculating. For an explanation why it is recommended to use DO and pH in Manual mode rather than Auto mode before the ‘span’/‘one-point’ calibrations are performed, see “Pre-Calibration Medium Conditioning Strategy” on page 160.

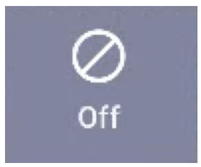
To control the DO in Manual mode, first remember that the DO is scaled so 100% equals atmospheric O_2 conditions. The amount of air entering the bag and therefore saturating the medium can be displaced with either CO_2 or N_2. For example, to control to a DO PV of 50% with pH set to 5% CO_2, set N_2 to 45% and O_2 to 0%.

To control the pH in Manual mode, set Base to 0% and CO_2% to the value that will provide the desired pH, using the “$NaHCO_3$, CO_2%, and pH at 37 °C” chart on page 150.

Using controls:

1. Click one of the dashboard buttons (“Agitation,” “Temperature,” “Dissolved Oxygen,” “pH,” or “Main Gas”).

2. Select a mode (Auto, Manual, or Off).

Mode Symbols	
Auto	
Manual	
Off	

3. If Auto mode, enter a set point using the on-screen keypad.

Auto Mode Variables and Set Point Units	
Agitation	Vertical-Wheel® Impeller Revolutions Per Minute
Temperature	Degrees Celsius (°C)
Main Gas	N/A - only Manual mode available
Dissolved Oxygen	% Air Saturation
pH	pH units

Recommended Auto Mode Set Points	
Agitation	15 – 35 RPM if Vertical-Wheel® impeller is fully submerged. 15 – 25 RPM if not.
Temperature	37 °C
Main Gas	N/A - only Manual mode available
Dissolved Oxygen Set Point	25 – 100% Dissolved Oxygen
Dissolved Oxygen Deadband	0 – 5% Dissolved Oxygen
pH Set Point*	6.8 – 7.4 pH units
pH Deadband	0 – 0.05 pH units
Filter Oven	38 °C

*The user must select a base pump from the “Control Pumps” menu for the pH base controller to operate. For more information, see “Selecting a Base Pump” on page 114.

Note: The dissolved oxygen and pH deadbands can be changed in the “Settings” tab. For more information, see “Settings/System Variables” on page 134.

4. If Manual mode, enter a controller output using the on-screen keypad.

   Note: Other than setting DO and pH to Manual mode before the first ‘span’/‘one-point’ calibrations can be performed, Manual mode is for advanced users ONLY. It is rarely necessary to operate outside of Auto mode, except in the case of the main gas controller, as it has no Auto mode. A sensor error may also necessitate using manual mode until the issue can be resolved, potentially after the cell culture run. Contact PBS Biotech Technical Support for assistance.

Manual Mode Variables and Controller Output Units	
Agitation	Motor % power
Temperature	Main heater % duty
Main Gas	Total gas liters per minute
Dissolved Oxygen – N_2	Total gas % N_2 composition
Dissolved Oxygen – O_2	Total gas % O_2 composition
pH – CO_2	Total gas % CO_2 composition
pH – Base	Base pump % duty

Note: When switching from Manual mode to Auto mode, the controller output will gradually increase or decrease to transition from the user-selected output in Manual mode to the PID-calculated output.

5. Click “Save.”
6. Observe that the dashboard button shows the selected mode and set point or controller output.

‘Span’/‘One-Point’ Calibrations After Equilibration

After the medium has been conditioned and the temperature, DO, and pH have equilibrated, PBS Biotech recommends performing ‘span’/‘one-point’ calibrations on the DO and pH sensors. It is recommended to calibrate the DO sensor first, because calibrating the pH sensor requires taking a sample, and clearing the sample line with air can temporarily change the DO PV.

‘Span’ DO calibration:

The following is recommended for DO calibrations:

- Only perform a ‘span’ DO calibration before inoculating with cells
- Perform the ‘span’ DO calibration using the headspace gas composition as the reference, rather than the measured DO of a sample
- Do not perform additional DO calibrations of any type during a cell culture run

For an explanation, see “Dissolved Oxygen” on page 163.

1. Confirm sensor is fully polarized.

2. Confirm DO present value has stabilized.
   Note: If the medium is 100% air saturated, the DO PV should be between 80% and 120% before performing ‘span’ calibration.

3. Navigate to the “Actions” tab.
4. Click “Calibrate.”
5. Click “DO.”
6. Click “Span.”

7. Click “Start Calibration”

8. Enter the correct DO PV in the ‘Span’ field. If the only gas flowing into the bioreactor was air, then the medium is 100% air saturated. Otherwise, before inoculating, the DO PV should equal 100 - CO_2% - N_2%.
9. Click the “Submit” button.
10. Verify the new calibration values are appropriate.
11. Click “Save.”
12. Click the arrow in the top left corner to return to the main menu.
13. Set DO to Auto mode, if desired (see “Turning Controls On” on page 107).

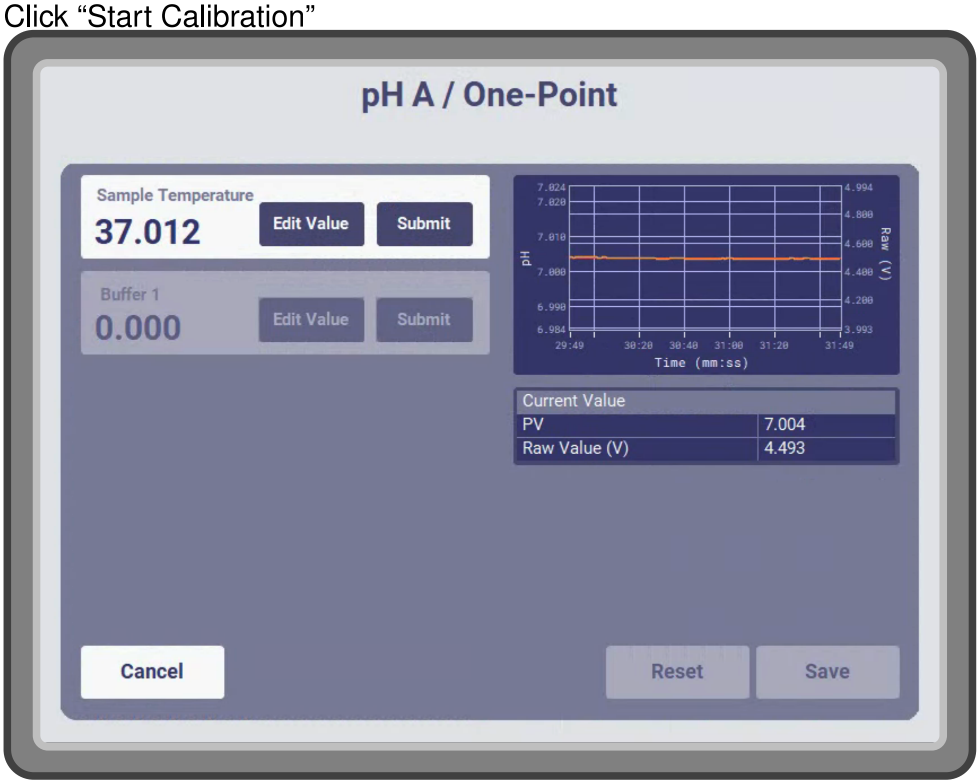
‘One-point’ pH calibration:

It is recommended to do this before inoculating with cells, and regularly throughout a cell culture run to counteract the pH sensor drift.

1. Take a sample (see “Take Sample” on page 118, “Take Sample” on page 172, and “Sampling for pH Measurement” on page 173). Note pH present value when taking sample.
2. Measure the pH of the sample (see “Sampling for pH Measurement” on page 173).
3. Navigate back to the “Actions” tab.

4. Click “Calibrate.”
5. Click “One-point” if it is not already selected.

6. Click “Start Calibration”



7. If the number in the ‘Sample Temperature’ field does not match the

sample temperature, click “Edit Value” and use the on-screen keyboard or an external keyboard to enter the correct value. Click the “Submit” button for ‘Sample Temperature’ once it is correct.

8. Enter [(pH PV) – (pH PV when taking sample) + (actual pH of sample)] in the ‘Buffer 1’ field.
9. Click the “Submit” button for ‘Buffer 1.’
10. Verify the new calibration values are appropriate.
11. Click “Save.”
12. Click the arrow in the top left corner to return to the main menu.
13. Set pH to Auto mode, if desired (see “Turning Controls On” on page 107 and “Selecting a Base Pump” on page 114).

Selecting a Base Pump

PBS Biotech Technical Support recommends configuring the base pump after performing a one-point calibration on the pH sensor and adding cells.

Because pH is usually regulated exclusively by CO_2, base should only be added if absolutely necessary.

The pH controller is configured to expect a solution of 0.5 M of $NaHCO_3$.

To select a base pump:

1. Set pH to “Off” mode.
2. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 103).
3. Click the drop-down menu beneath “Base Pump” and select “None.”
4. If the desired base pump (Addition A or Addition B) is on, turn it off.
5. Form a sterile connection between the Addition A (one brown band) or B (one gray band) line and the base bottle/bag source, by welding the tubing or using the connectors.
6. Install the silicone section of the addition line in the corresponding addition pump (A or B) to allow the base to flow into the bag as the pump rotates clockwise (see “Using the Pumps” on page 98).
7. Confirm that the tubing is not clamped.
8. Set the addition speed to “Slow.”
9. Turn the addition pump on to prime the line.
10. Turn the addition pump off when tubing is primed.

11. Click the drop-down menu beneath “Base Pump” and select the desired addition pump.
12. Select the desired pH mode and set point or controller outputs.

Adding Additional Fluids

It may be necessary to add other fluids throughout a run, such as antifoam solution to control the amount of foam in the bag. Users can either add additions all at once, or slowly titrate them over a period of time.

To add additional fluids:

1. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 103).
2. Confirm the desired addition pump is not set to be the base pump.
3. If the desired addition pump (A or B) is on, turn it off.
4. Form a sterile connection between the Addition A (one brown band) or B (one gray band) line and the addition bottle/bag source, by welding the tubing or using the connectors.
5. Install the silicone section of the addition line in the corresponding addition pump (A or B) to allow the fluid to flow into the bag as the pump rotates clockwise (see “Using the Pumps” on page 98).
6. Confirm that the tubing is not clamped.
7. Set the desired addition speed.
8. Click the button to turn the addition pump on.
9. Click the button to turn the addition pump off after desired amount has been added, or leave the button in the “on” position to continue titrating.

Load the Alarms On.alm File

After sensors have been calibrated and the important variables are within the appropriate ranges for your cell line/process, it is important to activate alarm notification before inoculating.

Alarm notification is activated by loading a different Alarms.alm file. Until this point, the Alarms Inactive.alm file should have been loaded. This file ignores the alarms which would be triggered while setting up for a run, such as the PVs being too low or too high before turning on controls, or the pH PV changing too rapidly during a two-point calibration. Because these alarms should not be ignored during a run, the Alarms On.alm file, or another Active alarms file that a user has configured and saved for this purpose, should be loaded at this time.

1. Confirm the Process Alarms settings for your run. Note that if a setting is configured such that the PV is outside the appropriate range, an alarm will be generated immediately after loading the Alarms On.alm file. For more information, see “Settings/System Variables” on page 134.
2. Load the Alarms On.alm file, or other desired Active file a user has configured and saved for this purpose. For more information, see “Configuring Alarm Settings” on page 57.
3. For how to view and acknowledge alarms, see “Alarms” on page 133.

Inoculate with Cells

When sensors have been calibrated and important variables are within the appropriate ranges for your cell line, it is safe to add the cells.

To inoculate:

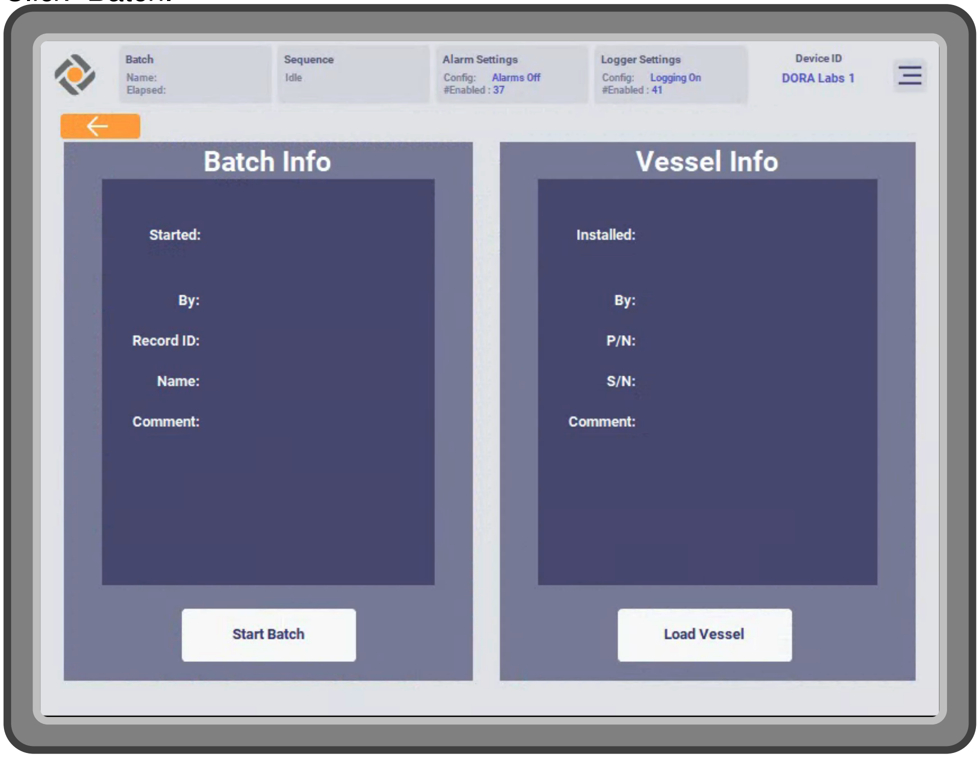
1. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 103).
2. If the media pump is on, click the button to turn it off.
3. Form a sterile connection between an unused medium addition line (one orange band) and the cell bottle/bag source, by welding the tubing or using the connectors.
4. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and bag (see “Using the Pumps” on page 98).
5. Check that the tubing clamp is open, and its branched tubing clamp is closed, if applicable.
6. Click the button to turn the media pump on.
7. Click button to turn the media pump off after adding cells.

Entering Batch Name

To name a batch:

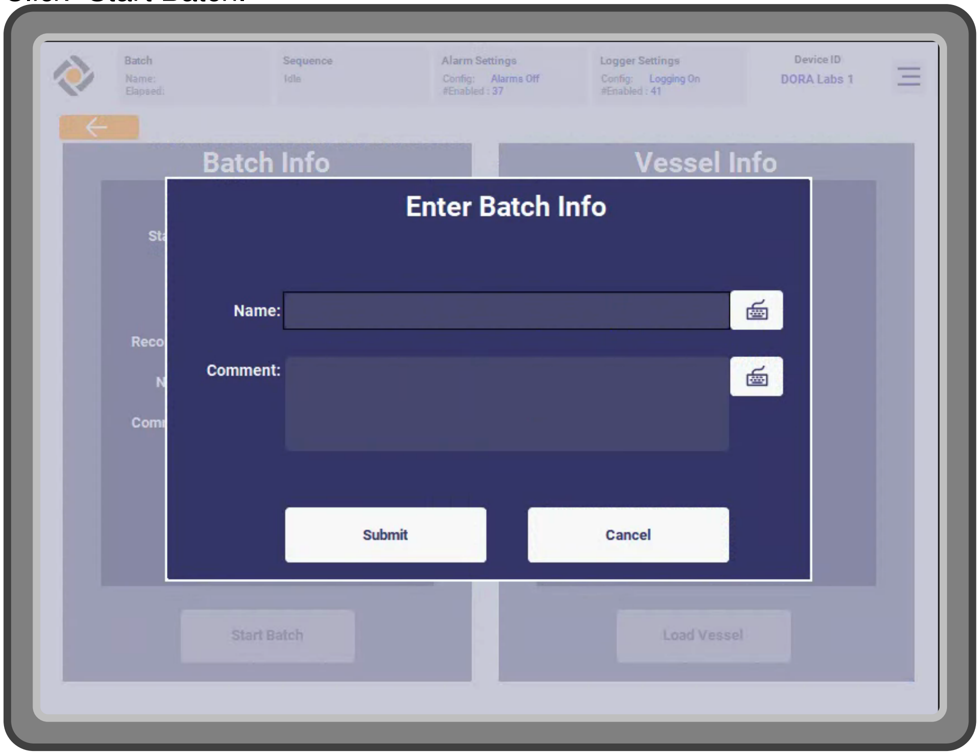
1. Navigate to the “Actions” tab.

2. Click “Batch.”



3. If a batch is running, end it:
   (a) Click “End Batch.”
   (b) Confirm by clicking “Confirm” in the overlay.

4. Click “Start Batch.”



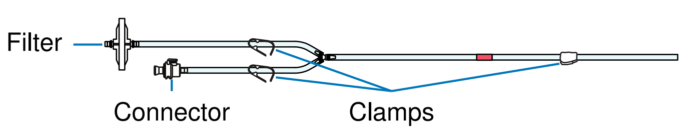
5. Use the on-screen keyboard, or an external keyboard, to enter a batch name 16 characters or less.
6. Enter a comment, if desired.
7. Click “Submit.”
8. Observe that the Information Bar now displays the entered batch name, the start time, and the elapsed time.

Take Sample

For information about concerns when taking a sample, handling the sample, and measuring a sample, see “Take Sample” on page 172.

The following sub-sections are not exhaustive, and there are likely many additional ways for operators to take a sample out of the bioreactor without compromising the sterility of the bag.

PBS-80 bag’s sample line



To take a sample with the bag's sample line and a pump:

Using a pump to take a sample can decrease the sampling variability between operators. It can also, however, expose the sample to more shear stress.
Note: Proximity to a BSC is required for this procedure.

Note: This assumes the sample line is connected to a small (250 mL – 500 mL) transfer flask, i.e. one with a short dip tube.

1. Log in to the Hello UI.
2. Navigate to the "Actions" tab.
3. Click "Sample."

4. Configure the sample pump to run clockwise (CW). Do not turn it on yet.
5. Install the sample line's section of tubing between the filter and the Y-connector in the sample pump so the filter is to the left.
6. Open the clamp on the sample line's section of tubing between the filter and the Y-connector.
7. Put 2 50 mL conicals in the biosafety cabinet. Label one for 'Waste' and the other for 'Sample.'

8. Put the transfer flask at the end of the sample line in the biosafety cabinet.
9. Remove the transfer cap and hold its dip tube over the ‘Waste’ conical.
10. Open the clamps on the sample line’s section of tubing between the bag and the Y-connector, and the section of tubing between the transfer flask and the Y-connector. Liquid will flow due to gravity.
11. After 5 mL or more has gone into the ‘Waste’ conical, re-clamp the sample line’s section of tubing between the bag and the Y-connector, and the section of tubing between the transfer flask and the Y-connector. This clears the line of settled microcarriers and excess media.
12. Hold the transfer cap’s dip tube over the ‘Sample’ conical.
13. Open the clamp on the sample line’s section of tubing between the transfer flask and the Y-connector.
14. Confirm the sample pump is configured to run clockwise, then start the pump to aliquot the sample.
15. Once the line is clear, stop the pump and clamp the section of tubing between the transfer flask and the Y-connector. The sample should be 20-30 mL, depending on the length of the sample tubing.
16. Install the transfer cap back in the transfer flask.
17. Open the clamp on the section of tubing between the bag and the Y-connector, and turn on the sample pump to clear the line.
18. Run the pump until bubbles come out of the sample port in the bag.
19. Once the line is clear, stop the pump, close all clamps, and remove the section of tubing from the sample pump.

Exchanging Medium

1. Form a sterile connection between the harvest line and the waste media bottle/bag destination by welding the tubing or using the sterile connectors.
2. Load the Alarms Inactive.alm file (see “Load the Alarms On.alm File” on page 115).
3. Turn temperature off, and wait 2 minutes before turning agitation off (below). This is to allow the heater plate(s) to cool before cells settle on it.
4. Change DO and pH from Auto mode to Manual mode, setting the requested N_2, O_2, and CO_2 flows to match what was called for while in Auto mode.

   Users should continue to request gas flow while removing medium from the bag to maintain a reasonable amount of pressure within the bag. This will prevent the top corners of the bag from collapsing inward due to the sudden drop in pressure that may occur if medium is removed rapidly.

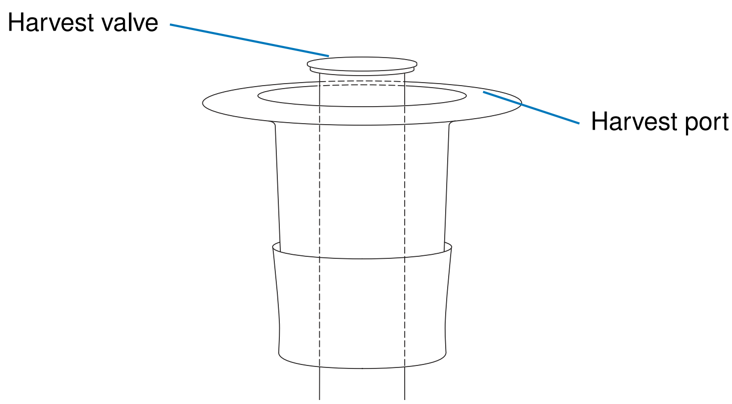
5. Turn agitation off.
6. Sparging gas will interfere with the cells settling to the bottom of the bag. Clamp the O_2 sparge line and level sensing line as close to the bag as possible, then disconnect both the O_2 sparge connector and level sensing connector from the bioreactor. Be sure to read the “Level sensing line” warning on page 21. Route O_2 through the headspace.
7. Align one of the open channels in the Vertical-Wheel® impeller with the harvest port at the bottom of the bag, and fully activate the harvest valve (see “Check Harvest Valve Alignment with Harvest Mode” on page 86 and follow the relevant instructions).
8. Tighten the harvest valve stabilizing block to the positioning shaft with the wing nut.
9. Wait for the cells to settle to the bottom of the bag.
10. Check that the harvest line tubing clamp is open, and its branched tubing clamp is closed, if applicable.
11. Remove the desired amount of spent medium, either by gravity or by installing the silicone section of the tubing in an external pump. Remove the tubing from the external pump when finished, if applicable.
12. Clamp the harvest line and loosen the stabilizing block from the positioning shaft using the wing nut.
13. Disengage the harvest valve and leave harvest mode (see “Check Harvest Valve Alignment with Harvest Mode” on page 86 and follow the relevant instructions).
14. Follow the instructions in the “Level sensing line” warning on page 21 to reattach the O_2 sparge line and level sensing line and open the clamp.
15. Add fresh medium (see “Adding Medium” on page 104).
16. Turn agitation back on, and set DO and pH to the original desired modes.
17. When settled cells/aggregates/microcarriers are resuspended, turn temperature back on.
18. Load the Alarms On.alm file (see “Configuring Alarm Settings” on page 57 and follow the relevant instructions).

Note: If performing multiple medium exchanges, reposition tubing through the pump head if it starts to wear out in order to pump with a fresh section of tubing.

Harvesting a Run

To harvest:

1. Load the Alarms Inactive.alm file (see “Load the Alarms On.alm File” on page 115).
2. Set all control modes to Off.
3. Form a sterile connection between the harvest line and the harvest bottle/bag destination by welding the tubing or using the sterile connectors.
4. Loosen the stabilizing block from the positioning shaft, partially engage the harvest valve by raising it slightly above the harvest port (as shown below), and then tighten the stabilizing block to the positioning shaft.



5. Check that the tubing clamp is open, and its branched tubing clamp is closed, if applicable.
6. Remove the entire bag contents, either by gravity or by installing the silicone section of the tubing in an external pump. Remove the tubing from the external pump when finished, if applicable.
7. Turn off all pumps.
8. Set base pump to “None.”
9. Turn off the light, if it is on.
10. End batch (see “Entering Batch Name” on page 116).
11. Go to the “Actions” tab and click “Unlock Door.”
12. Remove the bag.

NOTICE When removing the DO and pH sensors from the bag, be sure to retrieve the black o-rings necessary for sealing and keep them with the sensors (they can slide off and remain in the sensor ports and be accidentally disposed of).

13. Go to the "Actions" tab, click "Batch," and click "End Batch" and then "Unload Vessel."
14. Clean/decontaminate the PBS-80 (see "Cleaning and Decontamination" on page 35).

Note: No door interlocks may be in place after harvesting if the user wishes to open the door (see "Interlocks" on page 160).

Other Features

Filter Oven

The Filter Oven heats the exhaust filter on the bag, preventing moisture from accumulating in it and clogging it. The PBS-80 is designed to always have the Filter Oven in Auto mode, at 38 °C. The Filter Oven interlock effectively turns off the Filter Oven between cell culture runs (see "Interlocks" on page 141 and "Filter Oven" on page 156). For this reason, PBS Biotech Technical Support does not recommend setting the Filter Oven to Off mode. If users still want to turn it off between runs, they need to make sure to turn it on before adding medium.

To change the filter oven mode:

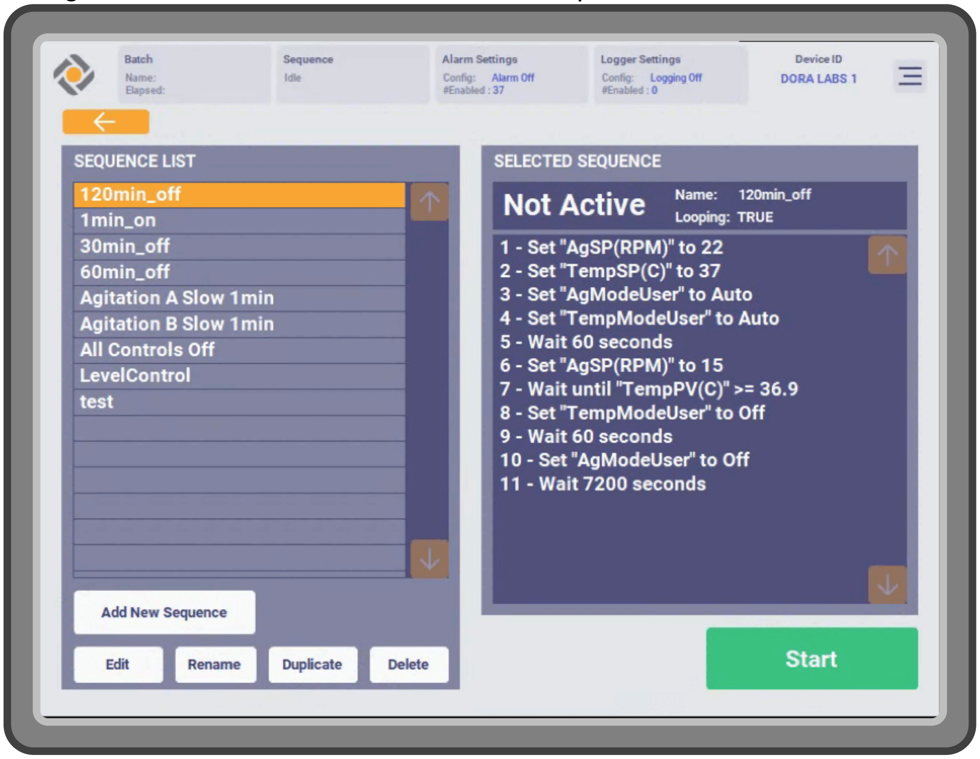
1. Navigate to the "Actions" tab.
2. Click "Advanced" (see "Advanced View" on page 132).
3. Click the "Filter Oven" button.
4. Change the mode and/or set point, like with the other controllers.

Sequences

Creating or editing sequences

1. Log in to the Hello UI as a user with the "Sequence Editor" permission.

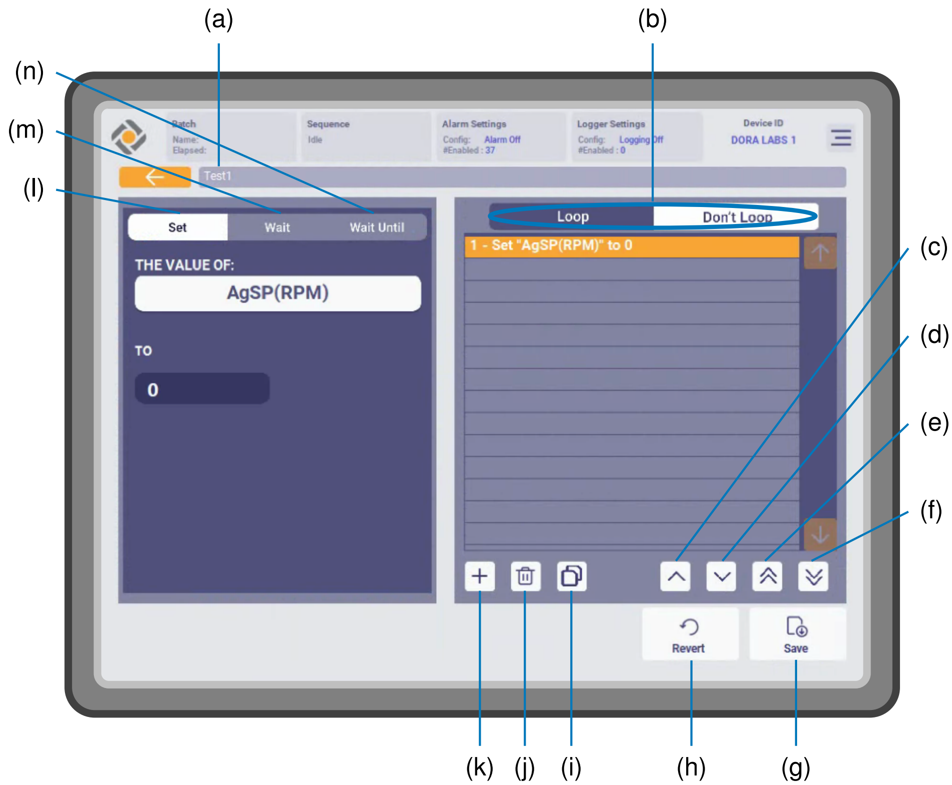
2. Navigate to the “Actions” tab and click “Sequence.”



3. Click “Add New Sequence” to create a new sequence. Select an existing sequence to edit, rename, duplicate, or delete it. You cannot edit, rename, or delete a sequence while it is running.

4. When creating a new sequence or renaming or duplicating an existing one, use either the on-screen keyboard or an external keyboard to enter the name.

5. This is the editor.



(a) The name of the sequence being edited
(b) Whether the sequence will run once, or run in a loop
(c) Move the selected step up by 1
(d) Move the selected step down by 1
(e) Move the selected step to be first
(f) Move the selected step to be last
(g) Save the changes
(h) Revert the changes
(i) Duplicate the selected step
(j) Delete the selected step
(k) Add a step after the selected step
(l) 'Set' steps change the value of a parameter to a number
(m) 'Wait' steps wait a specific amount of time before proceeding
(n) 'Wait Until' steps wait until a parameter's value meets a comparison condition before proceeding

6. Configure the sequence as desired, and save it.

Running sequences

1. Log in to the Hello UI as a user with the "Start Sequence" permission. The "End Sequence" permission is required to end a sequence while it is running.

2. Navigate to the “Actions” tab and click “Sequence.”
3. Select a sequence from the list. You will be able to review its steps before running.
4. Click the “Start” button to start the selected sequence.

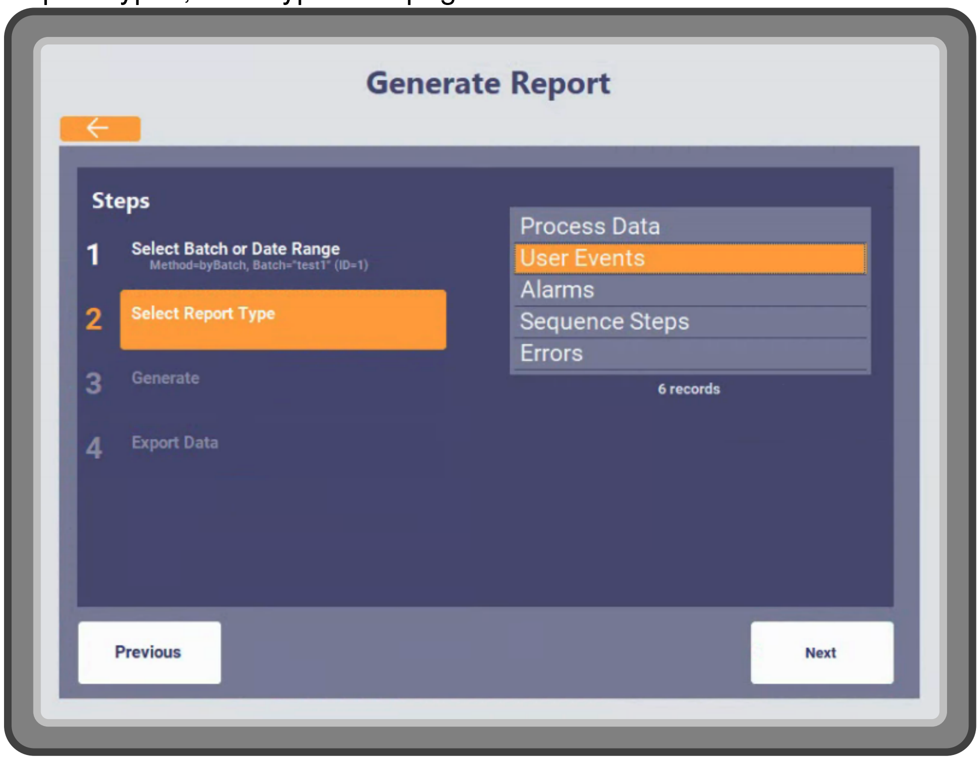
For more on sequences, see “Sequences” on page 169.

Generating Reports

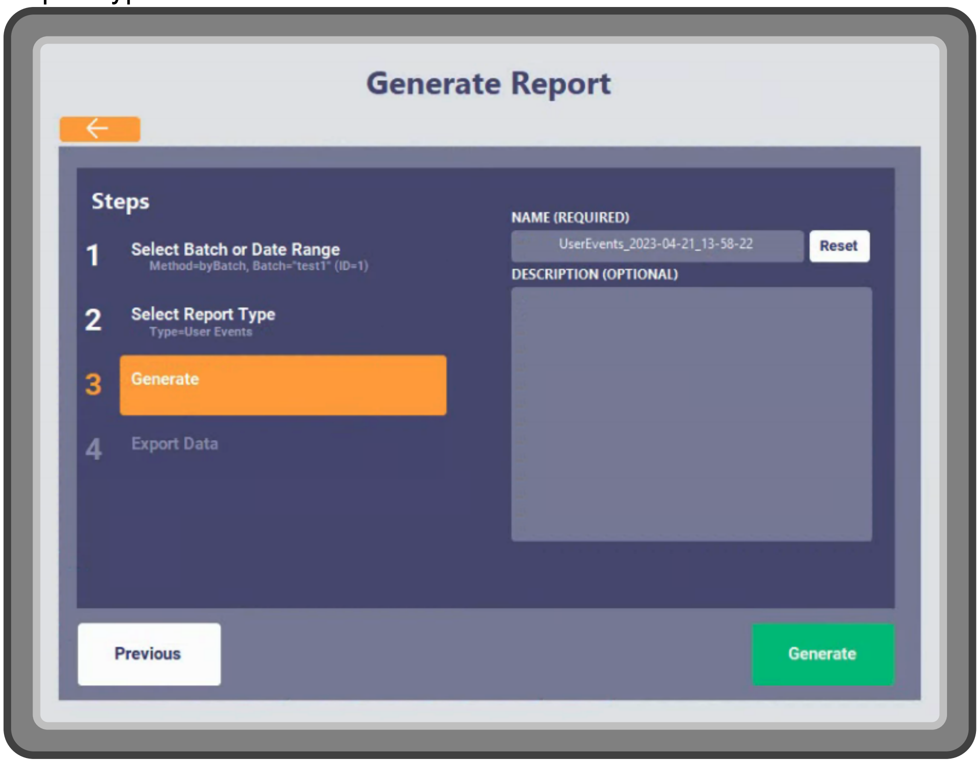
NOTICE The reports are generated in .csv format. Because many spreadsheet applications, such as Excel, have limited .csv functionality (they may not save the timestamp values properly in a .csv file, for example), once users open the .csv file in their preferred spreadsheet application, they should “Save As” an application-specific file type (e.g. .xls), and graph and analyze the data in that file rather than in the .csv file.

1. Log in to the Hello UI as a user with the “Reports” permission.
2. Navigate to the “Actions” tab.
3. Click “Reports.”
4. Choose a batch or time span.

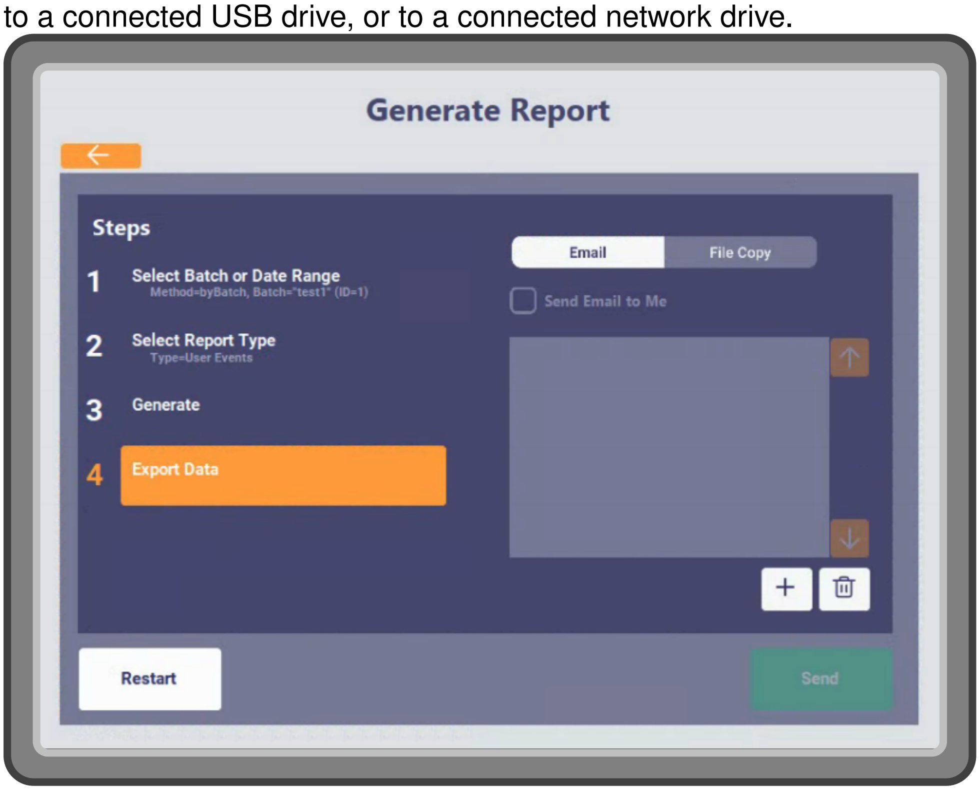
5. Select a Report Type. The number of records for the selected report type in the selected batch or time span will be displayed on the screen. If there are no records for the selected report type in the selected batch or time span, the report cannot be generated. For more information on Report Types, see “Types” on page 171.



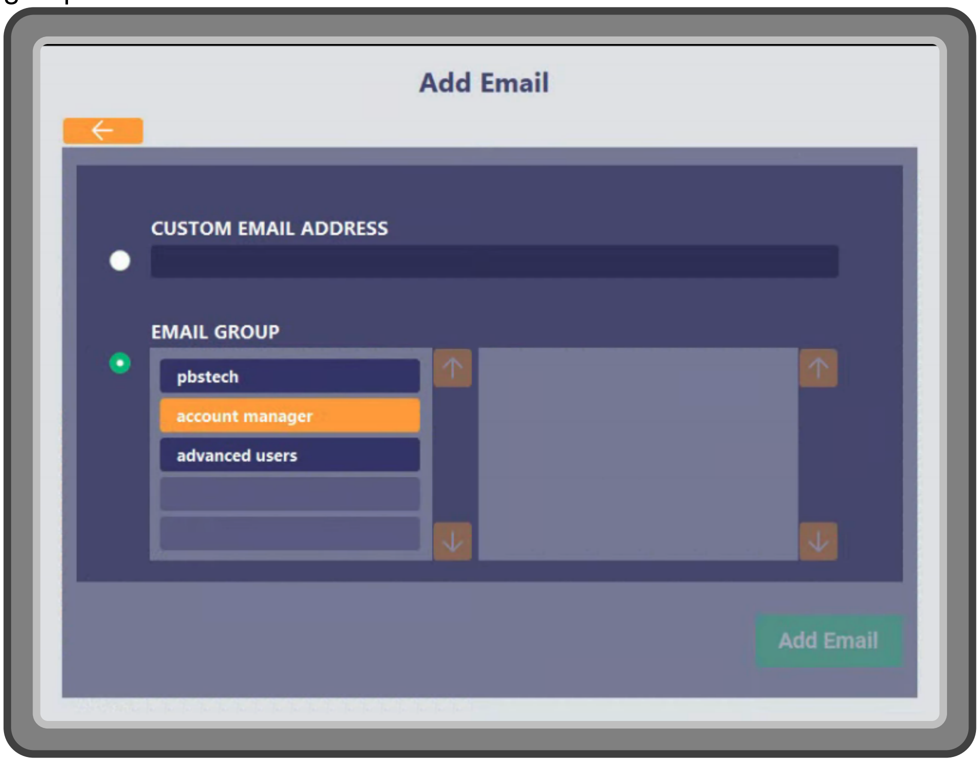
6. Modify the name and/or description, if desired, then generate the report. The default name is formatted as follows:
ReportType_YYYY-MM-DD_hh-mm-ss



7. After the report has been generated, it can be exported, either via email, to a connected USB drive, or to a connected network drive.



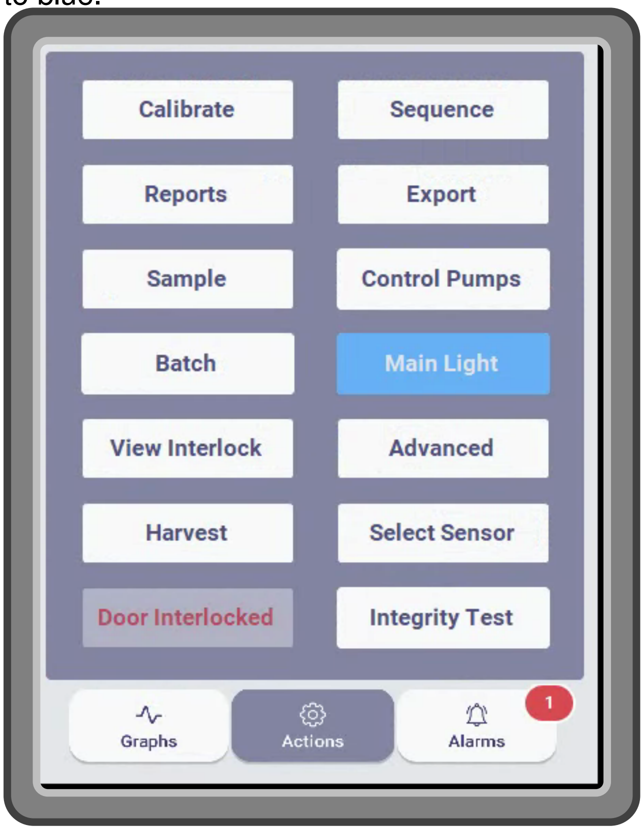
You can email it to the address associated with your user account, enter individual email addresses, or email the report to all users in a user group.



Light

To use the light with the Hello UI:

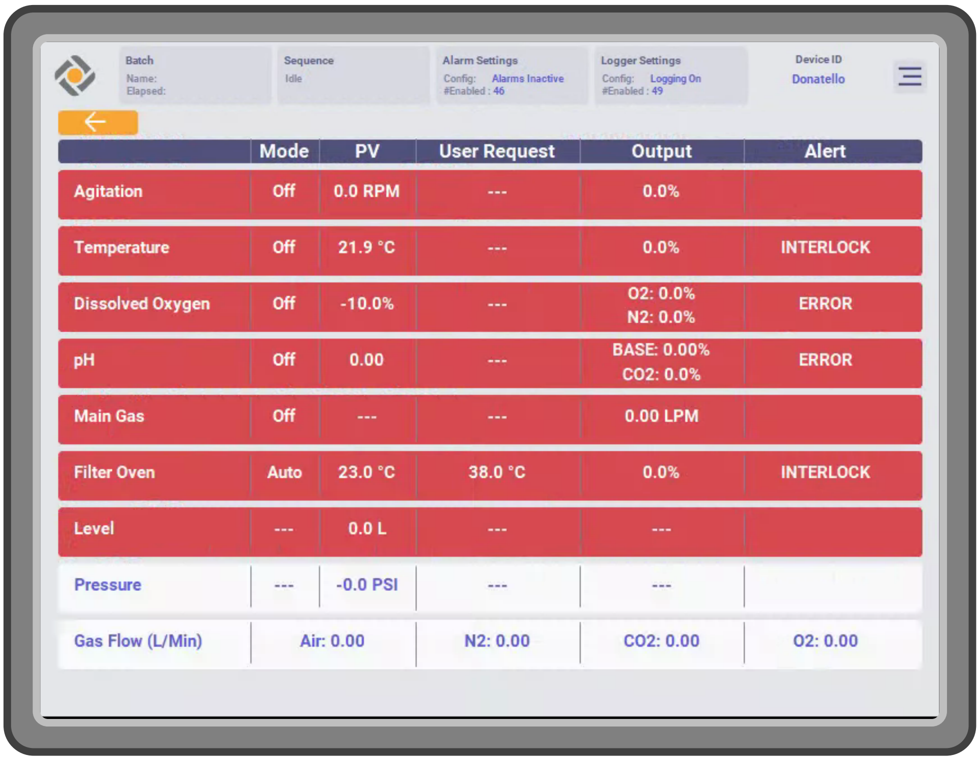
1. Navigate to the “Actions” tab.
2. Click “Main Light” to turn the light on. The button will change from white to blue.



3. Click “Main Light” to turn the light off. The button will change from blue to white.

Advanced View

In addition to all the data displayed in the Dashboard and button functions, the Advanced View menu also displays the Controller Outputs for each controller, and the filter oven temperature. The Output column shows the controller output being requested by the software for each controller. The actual flow rates for each MFC are reported in the row at the bottom of the menu. For example, if the user requests 50% N_2 flow but there is no source pressure to the N_2 MFC, the Dissolved Oxygen Controller Output will show 50% N_2, but the N_2 MFC flow will show 0 L/min.



Shutdown

Users can shut down the HMI computer from the Hello UI. Note that the RIO controller will continue running as long as the PBS-80 has power. Because there is no “On” switch on the PBS-80, it is recommended that the HMI is only shut down after turning off all controllers, and when the PBS-80 is going to be unplugged and stored.
After performing a clean shutdown, the HMI can be restarted by reconnecting power to the bioreactor.

The following power-off procedure **MUST** be used when removing power:

1. Initiate Shutdown from the Power menu in the Hello UI. If the Hello UI is not running, shutdown can be initiated from the Start Menu instead.

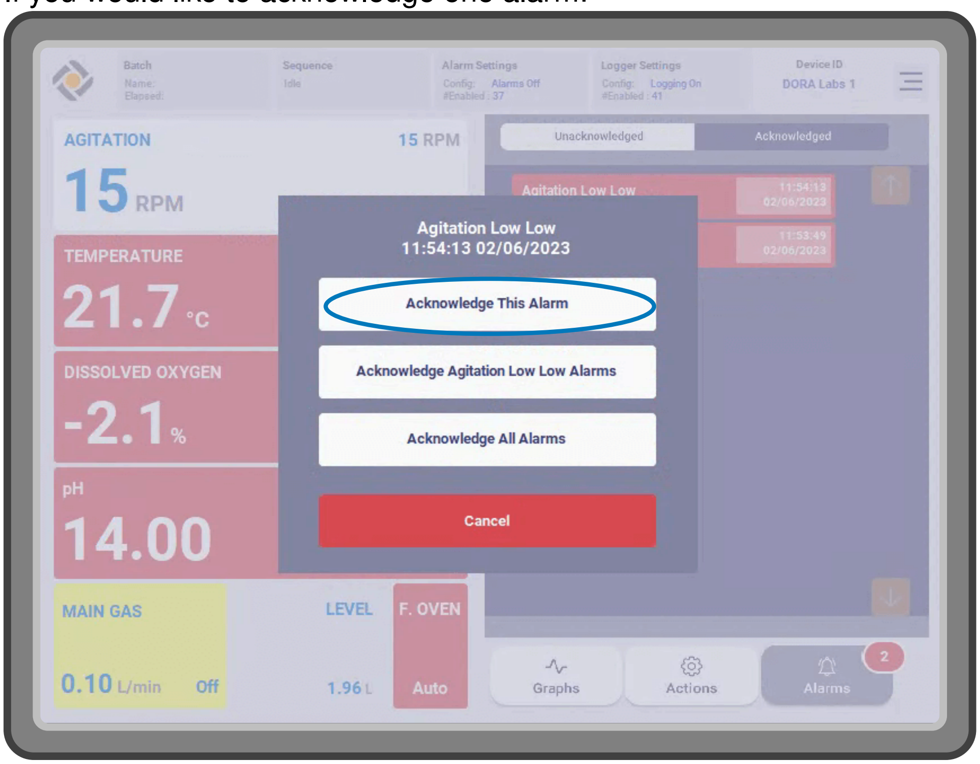
2. Wait for the software to shutdown and display “No Signal” (or similar) on the monitor.
3. Wait an additional 10 seconds (or longer).
4. Unplug the power cord.

NOTICE Unplugging the bioreactor without following the correct power-off procedure risks corrupting files that are critical for bioreactor system operation, including loss of historical data and user account information.

Alarms

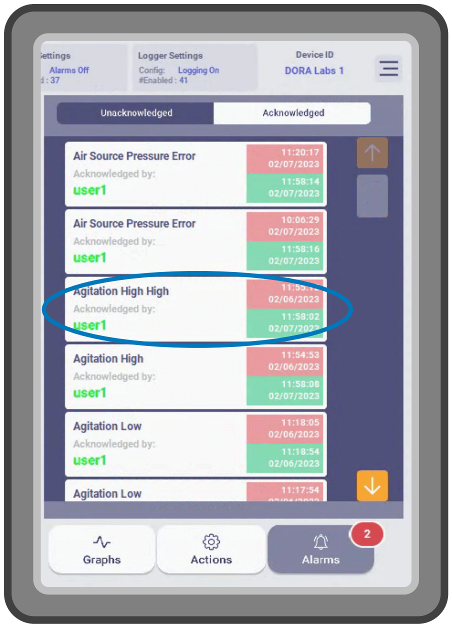
To acknowledge alarms:

1. Navigate to the “Alarms” tab.
2. If you would like to acknowledge one alarm:



   (a) Click the alarm.
   (b) Click “Acknowledge This Alarm.”
   (c) The alarm disappears from the “Unacknowledged” list and appears in the “Acknowledged” list. The alarm now also includes which user acknowledged it and when.

3. If you would like to acknowledge all alarms of one type:



   (a) Click one alarm of that type.
   (b) Click “Acknowledge <*Alarm Name*> Alarms.”
   (c) All alarms of that type disappear from the “Unacknowledged” list and appear in the “Acknowledged” list. The alarms now also include which user acknowledged them and when.

4. If you would like to acknowledge all alarms:

   (a) Click any alarm.
   (b) Click “Acknowledge All Alarms.”
   (c) All alarms disappear from the “Unacknowledged” list and appear in the “Acknowledged” list. The alarms now also include which user acknowledged them and when.

For definitions of all alarms, see Appendix 2 on page 222.

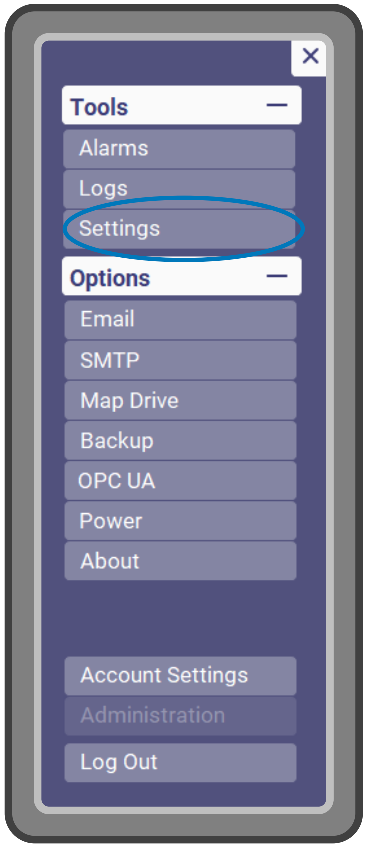
Settings/System Variables

WARNING! There are many settings PBS Biotech Technical Support does not recommend users change. For a complete list of all settings, their definitions, and whether PBS Biotech Technical Support recommends changing them, see Appendix 1 on page 197.

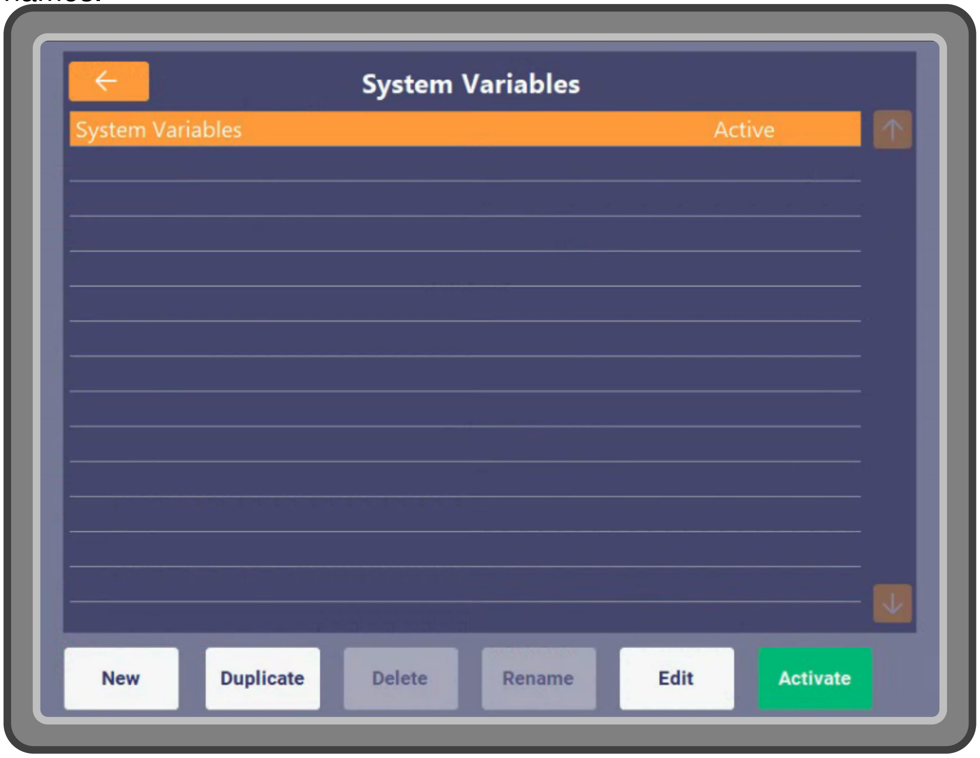
To change settings:

1. Log in to the Hello UI as a user with the “System Variables Editor” and “Activate System Variables” permissions. The “System Variables Editor” permission allows the user to create, modify, and delete System Variables files, whereas the “Activate System Variables” permission allows the user to make a particular System Variables file active.

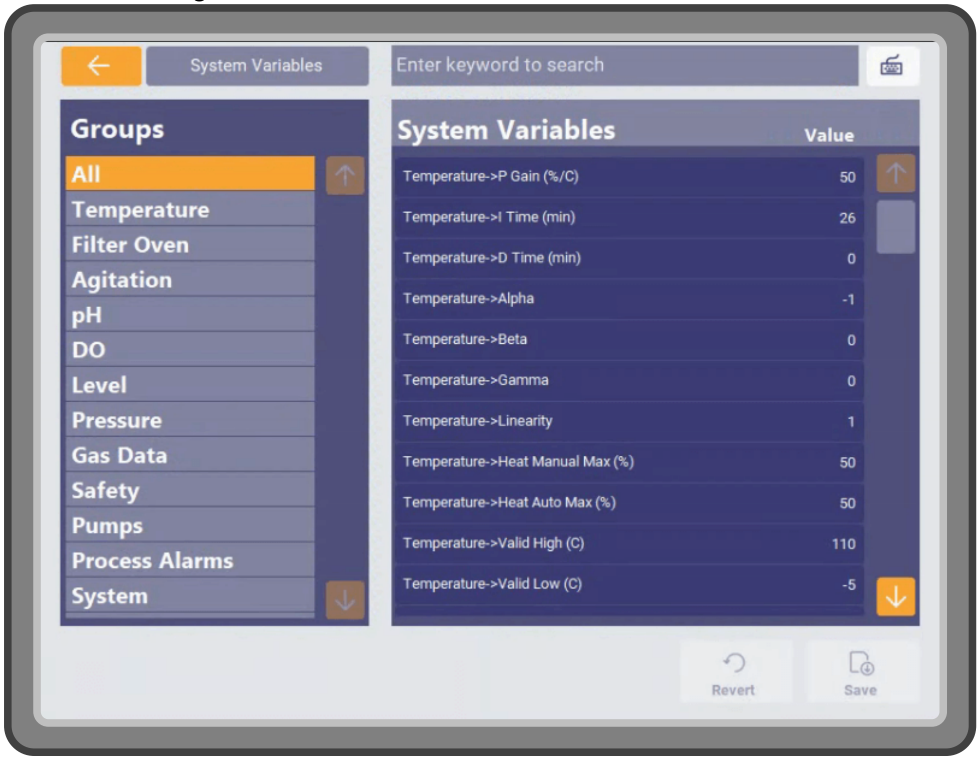
2. Click the triple bar ≡ (top right corner) and then "Settings."



3. Click “New” if you would like to create an entirely new System Variables file. Select an existing file to duplicate, delete, rename, or edit it. You cannot delete or rename the active System Variables file. You can create multiple system variables configuration files and give them different names.



4. The screen will display the variable name, the value, and the group the variable belongs to.



5. To change the value of a variable, click the number field next to the corresponding variable and enter the desired value using the on-screen keypad or an external keyboard.
6. If you wish to reverse changes you have made, click "Revert" and the file will revert back to its original values.
7. When you are finished making your desired changes, click "Save." Click the arrow in the top left corner to return to the main System Variables menu.
8. Click "Activate" to make the selected file active on the RIO.

Oxygen Flow Valve

For processes with high O_2 consumption rates, the O_2 transfer only through the overlay may not be enough at some point in the run. Switch to sparging O_2 when the DO controller is requesting the maximum possible O_2 flow, but the DO value is still less than the set point. To switch from flowing O_2 through the overlay to sparging:

1. Set the DO control to ‘Off.’
2. Set the oxygen flow valve to “Sparger.”
3. Set the DO “O2 P Gain (%/DO%),” “O2 I Time (min),” and “O2 D Time (min)” settings to the correct value for the configuration (see Appendix 1 “DO” section on page 207).
4. Set the DO control back to ‘Auto’ or ‘Manual.’

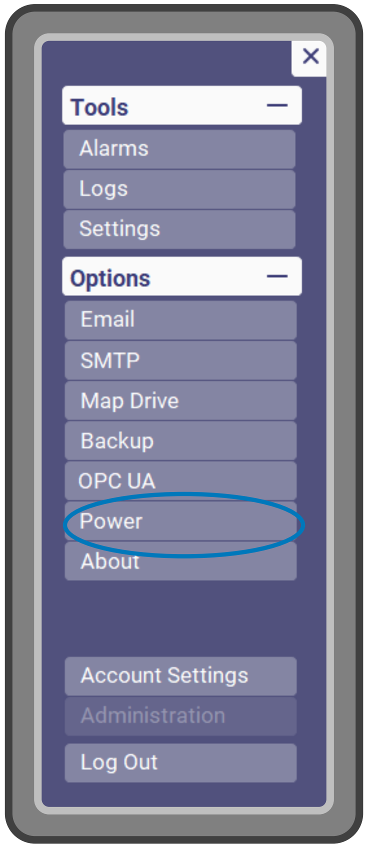
For more information, see “Oxygen Flow Valve” on page 182.

Reboot RIO

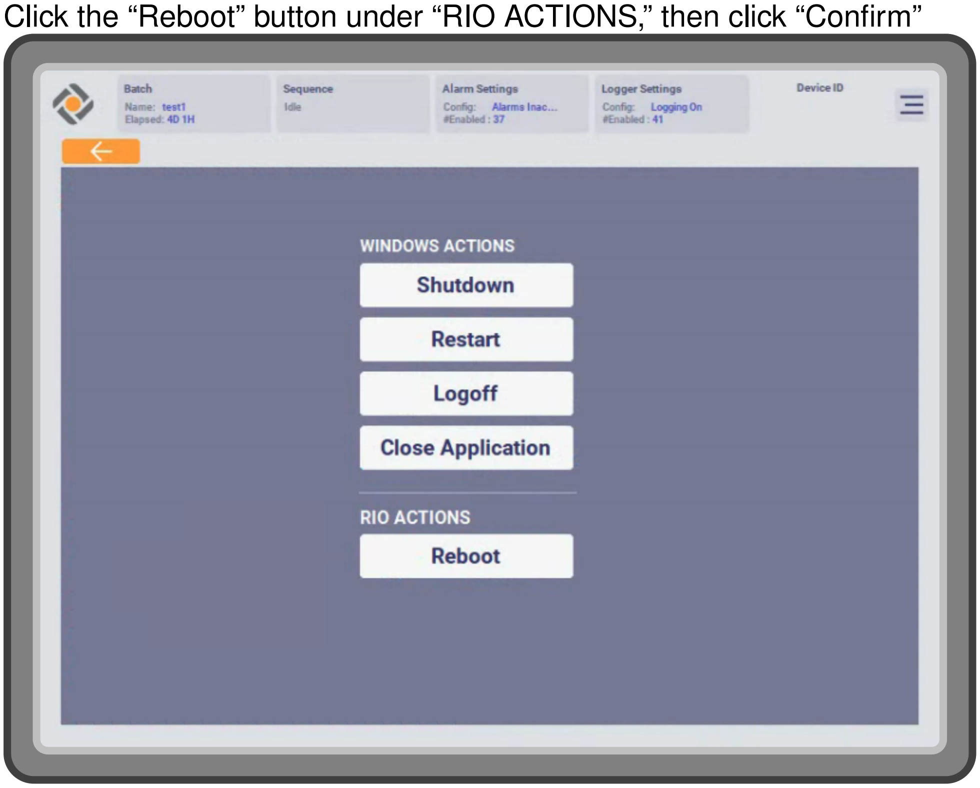
Users should not have to reboot the RIO under normal circumstances. However, if advised to do so by PBS Biotech Technical Support or as a troubleshooting measure, the following steps should be performed:

1. Note the modes all controllers are in. For controllers in Auto mode, note the controller outputs.
2. Set all controllers to Off mode.
3. Log in to the Hello UI as a user with the “System Management” permission.

4. Click the triple bar ≡ (top right corner) and then “Power.”



5. Click the “Reboot” button under “RIO ACTIONS,” then click “Confirm”



6. Wait for the RIO to finish rebooting (the “Reboot” button will no longer be grayed out).
7. When the RIO has finished rebooting, set all controllers which had been in Manual mode back to Manual mode. Set all controllers which had been in Auto mode to Manual mode, with the manual set point equal to the controller outputs noted in step 1.
8. Set all controllers which had been in Auto mode back to Auto mode.

Note: The controllers should be set to Manual mode before switching back to Auto to avoid the time lag in ramping up output.

Other Calibrations

The calibrations which users will have to perform before and during a batch run are described, with instructions, in the sections under “Before Starting a Batch Run” on page 71, and “Starting a Run” on page 98. They require the “Process Calibration” permission. Additional calibrations can be performed using the “Equipment Calibration” permission, but such calibrations should only be performed after consulting with PBS Biotech Technical Support. For more information on calibrations, see “Calibrating/Configuring Sensors” on page 160.

Understanding the PBS-80 7

Hello User Interface

The software interface of the PBS-80 is the Hello User Interface (Hello UI). It is automatically launched when the PBS-80 is turned on.

Interlocks

To prevent unsafe conditions or conditions that would hinder the growth of cells, the software interlocks the controllers when certain conditions are met.

Conditions Causing Interlocks

Interlocked Controls	Agitation	Temperature	Level	Main Gas	Pressure	Pressure Line Sensing	Comb Plate
Agitation	Agitation is in Harvest Mode						Comb plate has popped
Temperature	Agitation PV = 0 RPM and power output to the motor < "Min Ag Power (%)"	Temperature PV > "Max Temp (C)"	Level PV < "Min Level (L)" or Level PV > "Max Level (L)"				Comb plate has popped
Filter Oven		Temperature PV < 32 °C and Main Gas is Off		Main Gas is Off and Temperature PV < 32 °C			Comb plate has popped
Main Gas					Pressure PV > "Max Pressure (psi)"	Pressure sensing line is disconnected	Comb plate has popped
DO					Pressure PV > "Max Pressure (psi)"	Pressure sensing line is disconnected	Comb plate has popped
pH			Level PV > "Max Level (L)"		Pressure PV > "Max Pressure (psi)"	Pressure sensing line is disconnected	Comb plate has popped
Control Pumps			Level PV > "Max Level (L)"		Pressure PV > "Max Pressure (psi)"	Pressure sensing line is disconnected	Comb plate has popped
Door	Agitation PV > 0 RPM		Level PV > 0.001 L		Pressure PV > "Max Pressure (psi)"	Pressure sensing line is disconnected	Comb plate has popped

Agitation

The agitation PV is determined by a Hall effect sensor which detects the passage of magnets on the Vertical-Wheel® impeller. The period between magnet passes is used to calculate a value in RPM. The calculation is averaged over a configurable number of samples to report an accurate, stable value.

The Vertical-Wheel® impeller is magnetically coupled to a motor in the bioreactor which controls agitation output.

The agitation controller has three user modes and one sensor error mode:

- Off mode
- Manual mode
- Auto mode
- Lookup mode (sensor error mode)

Off Mode

No power is supplied to the motor.

Manual Mode

User selects a power output as a percentage of the motor's maximum.

Auto Mode

User selects a set point in units of RPM. A PID controller adjusts the motor's power output to achieve a stable set point.

Lookup Mode

This is the agitation sensor error mode. Lookup mode is triggered if too much time has passed in Auto Mode since the last magnet pass was detected. The controller assumes that the sensor has failed, and attempts to estimate the output required to achieve the set point.

The timeout can be adjusted by changing the "Lookup Mode Timeout (s)" setting. The power output estimation is calculated as: Set Point × "Lookup Factor (%/RPM)."

Harvest Mode

When the user clicks the "Harvest" button in the "Actions" tab, the following events occur:

1. The Harvest Status is set to "Ramping down speed" while agitation is set to Auto mode with a set point of 0 RPM.
2. When the agitation PV is low enough, agitation is set to Manual mode at a very low output.
3. The Harvest Status is set to "Attempting to align wheel" while the software checks that a magnet passes the Hall Effect sensor.

4. If a magnet passes the Hall Effect sensor, the software continues outputting the low Manual output for the Harvest “Delay (s)” time. Otherwise, it reports that the Harvest timeout was reached.
5. The Harvest Status is set to “In Harvest Mode” while agitation is set to Off mode, and the Auto and Manual set points are restored to their original values (from when the user first clicked the “Harvest” button).

Any changes a user makes to the agitation mode or set point during this sequence of events could prevent it from completing successfully.

Output Ranges

For agitation control range, see “Agitation Control Range” on page 38.

Agitation motor power range is 0 - 100%.

Relevant Settings

See Appendix 1 on page 197 for each setting’s default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Agitation (page 200)

- P Gain (%/RPM)
- I Time (min)
- D Time (min)
- Alpha
- Beta
- Gamma
- Linearity
- Minimum (RPM)
- Lookup Mode Timeout (s)
- Lookup Factor (%/RPM)
- Power Auto Max (%)
- Power Auto Min (%)
- Auto Max Startup (%)
- Power Manual Max (%)
- Number of Magnets
- Samples to Average

Safety (page 216)

- Min Ag Power (%)

Process Alarms (page 218)

- Agitation Low Low (RPM)
- Agitation Low (RPM)
- Agitation High (RPM)
- Agitation High High (RPM)

Interlocks

The agitation motor will not turn on if the comb plate has popped.

The agitation motor will not turn on if it is in Harvest mode.

Temperature

The temperature PV, reported in degrees celsius (°C), is determined by one of two temperature sensors positioned behind the bag at the back of the chamber. The software refers to them as temperature sensors “A” and “B.”

The temperature controller has three user modes and one sensor error mode:

- Off mode
- Manual mode
- Auto mode
- Sensor error mode

Off Mode

The main heater is off.

Manual Mode

User selects a main heater duty as a percentage of its maximum power.

Auto Mode

User selects a set point in °C. A PID controller adjusts the main heater duty to attempt to achieve the set point.

Sensor Error Mode

When temperature is in Auto mode and the temperature sensor detects a PV outside the valid range, the software assumes the sensor is experiencing an error condition, and in its best attempt at maintaining control the software outputs the average of its output values during the last 100 seconds before the software entered sensor error mode.

Output Ranges

For temperature control range, see “Temperature Control Range” on page 38.

The recommended main heater duty output range is 0 – 100%.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 197)

- P Gain (%/C)
- I Time (min)
- D Time (min)
- Alpha
- Beta
- Gamma
- Linearity
- Heat Manual Max (%)
- Heat Auto Max (%)
- Valid High (C)
- Valid Low (C)
- Mismatch Thresh (C)

Safety (page 216)

- Min Ag Power (%)
- Max Temp (C)
- Min Level (L)
- Max Level (L)

Process Alarms (page 218)

- Temp Low Low (C)
- Temp Low (C)
- Temp High (C)
- Temp High High (C)

Interlocks

The main heater will not turn on if the agitation PV is below the Agitation "Minimum (RPM)" setting unless the power output to the agitation motor is greater than the Safety "Min Ag Power (%)" setting. This is to avoid overheating cells which settle at the bottom of the bag. The main heater will continue to heat as long as the agitation controller is outputting sufficient power, even if the Hall effect sensor fails.

The main heater will not turn on if the temperature PV is greater than or equal to the Safety "Max Temp (C)" setting. This protects the run against a sensor error or an improperly entered set point.

The main heater will not turn on if the level PV is below the Safety "Min Level (L)" setting. This prevents damage to the disposable or its contents when the bioreactor system cannot properly control temperature at low volumes.

The main heater will not turn on if the level PV is above the Safety "Max Level (L)" setting. This is to prevent the heater from burning any medium which would spill out of an overfull bag.

Main Gas

The main gas PV, reported in liters per minute (LPM), is determined by reading the feedback voltages from the four gas mass flow controllers (MFCs): Air, N_2, O_2, and CO_2. Main gas only has two modes: Off, where no gas flows, and Manual, where the gas flows at the rate requested by the user.

The gas flow rate ranges for the MFCs are defined in "Gas Flow Rate Range" on page 38. If the requested flow rate for an individual gas is less than the MFC's minimum flow rate, the MFC will "pulse" its output to meet the request. The software prioritizes the gas composition to meet the pH and DO controller requests in the following order:

1. CO_2
2. O_2
3. N_2
4. Air (remainder of request)

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Gas Data (page 213)

- CO2 Min (LPM)
- CO2 Off (V)
- N2 Min (LPM)
- N2 Off (V)
- Air Min (LPM)
- Air Off (V)
- O2 Min (LPM)
- O2 Off (V)
- PWM On Time (s)
- PWM Max Period (s)
- Mismatch Thresh (V)
- Manual Max (LPM)

Safety (page 216)

- Max Pressure (psi)

Process Alarms (page 218)

- Main Gas Low Low (LPM)
- Main Gas Low (LPM)
- Main Gas High (LPM)
- Main Gas High High (LPM)

Interlocks

Gases will not flow if the pressure PV is above the Safety "Max Pressure (psi)" setting. This is to prevent the bag from becoming over pressurized.

Gases will not flow if the software detects that the pressure sensing line is disconnected. This is to prevent the bag from becoming over pressurized.

Dissolved Oxygen

The dissolved oxygen PV is reported as a percent of Air Saturation [(%) or (DO%)] and is determined by a DO sensor. The software refers to it as “DO sensor A.” A measurement of 100% DO does not mean the media is fully saturated with Oxygen, but instead that the media is fully saturated with Air.

The DO is controlled by varying the N_2 and O_2 gas flow as a percentage of main gas flow. The DO PV is lowered by increasing the % N_2 composition, and is raised by increasing the % O_2 composition. To understand how the software determines which gases to flow, see “Main Gas” on page 146.

The DO controller has three user modes and one sensor error mode:

- Off mode
- Manual mode
- Auto mode
- Sensor error mode

Off Mode

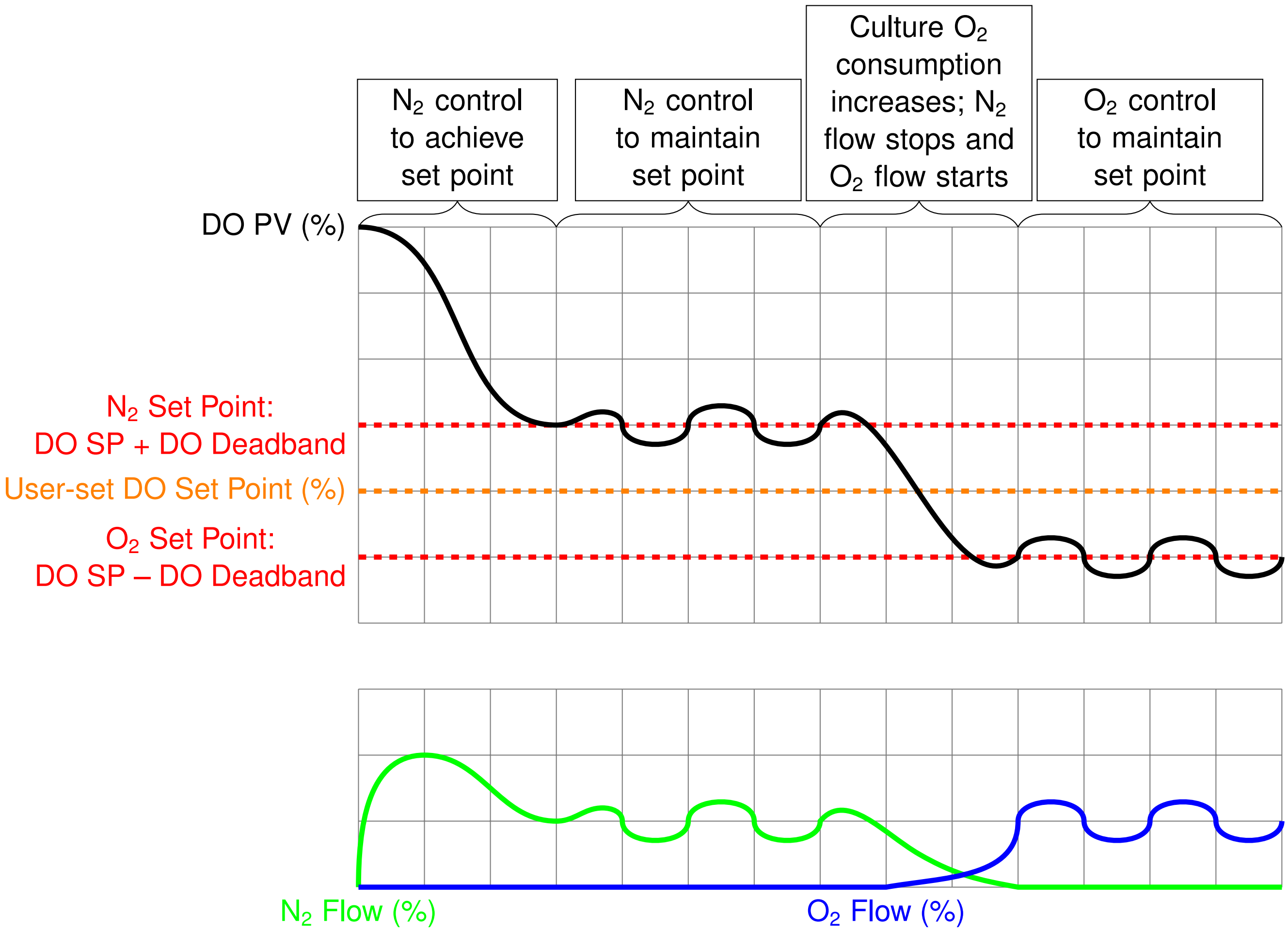
N_2 and O_2 are 0% of main gas flow.

Manual Mode

User selects N_2 and/or O_2 flow as a percentage of main gas flow.

Auto Mode

User selects a set point in units of % dissolved oxygen, which the software achieves by adjusting N_2 flow and O_2 flow. Each gas uses its own PID loop: the N_2 loop controls to the DO set point plus the DO "Deadband (DO%)" setting, and the O_2 loop controls to the DO set point minus the DO "Deadband (DO%)" setting.



Sensor Error Mode

When DO is in Auto mode and the DO sensor detects a PV outside the valid range, the software assumes the sensor is experiencing an error condition, and outputs the average of its N_2 and O_2 output values during the last 100 seconds before the software entered sensor error mode. Note that this is only intended to preserve short term stability – users should still take appropriate action in the event of sensor failure.

Output Ranges

The recommended N_2 output is 0 - 100% of main gas flow. The N_2 MFC output is stated in “Gas Flow Rate Range” on page 38. N_2 “pulsing” at the minimum value takes effect if the N_2 % called for represents less than the MFC’s minimum flow rate.

The O_2 MFC output is stated in “Gas Flow Rate Range” on page 38. O_2 “pulsing” at the minimum value takes effect if the O_2 % called for represents less than the MFC’s minimum flow rate. The software will not request more than the O_2 MFC minimum flow until the net volume of O_2 output since turning DO on is greater than the Gas Data “O2 Min Volume (L)” setting. This is known as the “O_2 Slow Start” feature, and is intended to prevent damage to the bag or accessories when O_2 is being sparged.

Relevant Settings

See Appendix 1 on page 197 for each setting’s default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

DO (page 207)

- Valid High (DO%)
- Valid Low (DO%)
- O2 P Gain (%/DO%)
- O2 I Time (min)
- O2 D Time (min)
- O2 Alpha
- O2 Beta
- O2 Gamma
- O2 Linearity
- O2 Manual Max (%)
- O2 Auto Max (%)
- N2 P Gain (%/DO%)
- N2 I Time (min)
- N2 D Time (min)
- N2 Alpha
- N2 Beta
- N2 Gamma
- N2 Linearity
- N2 Manual Max (%)
- N2 Auto Max (%)
- Deadband (DO%)

Pressure (page 212)

- Disconnected Pressure (V)
- Reusable Sensor (0 or 1)

Gas Data (page 213)

- N2 Min (LPM)
- N2 Off (V)
- O2 Min (LPM)
- O2 Off (V)
- PWM On Time (s)
- PWM Max Period (s)
- Mismatch Thresh (V)
- O2 Min Volume (L)

Process Alarms (page 218)

- DO Low Low (%)
- DO Low (%)
- DO High (%)
- DO High High (%)

Interlocks

Conditions which interlock the main gas will also prevent N_2 and O_2 from flowing. For more information, see the “Interlocks” subsection of “Main Gas” on page 146.

pH

The pH PV is determined by a pH sensor. The software uses temperature compensation to provide more accurate pH readings. The software refers to it as “pH sensor A.”

The pH is controlled by varying the CO_2 flow in % composition of main gas flow and varying the percent of time the base pump is on. Increasing CO_2 flow decreases pH PV, and increasing base pump duty increases pH PV. To understand how the software determines which gases to flow, see “Main Gas” on page 146.

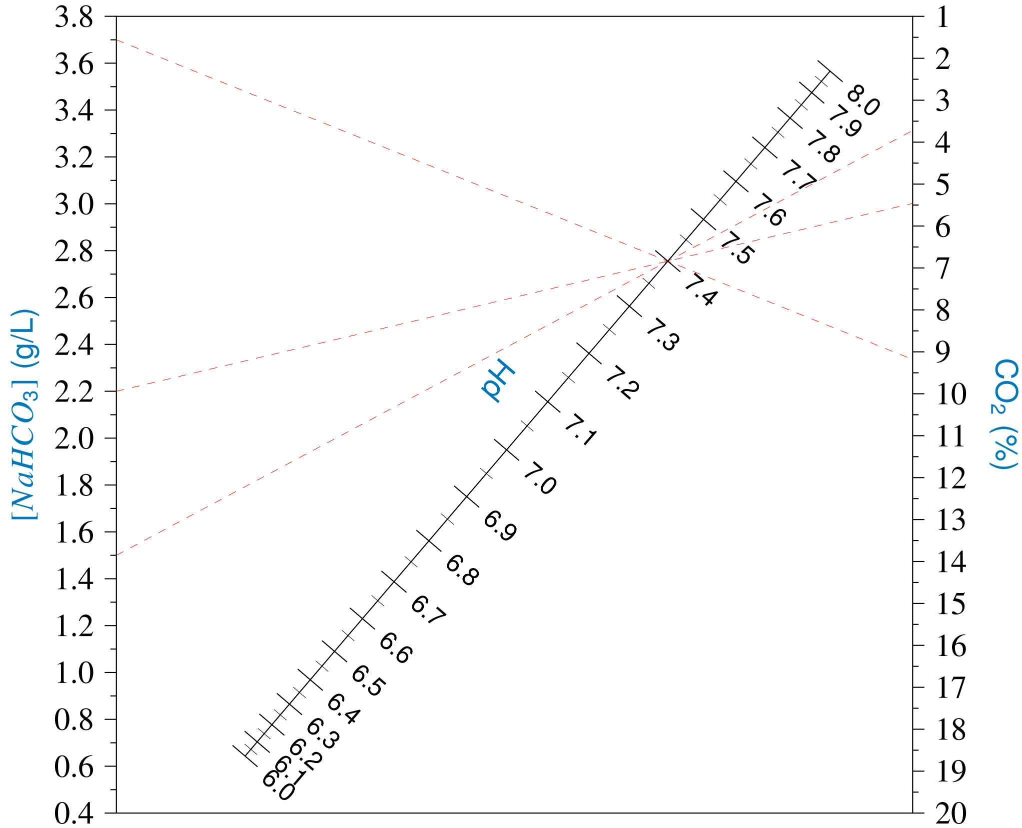
Before inoculating (i.e. when there is no metabolic activity), the pH has a predictable relationship with the concentration of sodium bicarbonate ($NaHCO_3$) in the medium and the % CO_2 composition. Below the following chart is the equation to calculate the resulting pH from a known concentration of sodium bicarbonate and a known % CO_2 composition. However, the following chart can be simpler to use.

To find the pH that would result from a known concentration of sodium bicarbonate and a known % CO_2 composition, draw a straight line between the points on the sodium bicarbonate and CO_2 axes. The line will cross the pH axis at the pH value. In fact, the chart can be used to find the third variable if any of the other two are known.

For example, if the medium being used has a sodium bicarbonate concentration of 3.7 g/L and the desired pH is 7.4, draw a straight line between those points on the corresponding axes, and extend the line to the CO_2 axis. You can see that a % CO_2 composition of just over 9% will result in the desired pH.

You can also see that to get the same pH using sodium bicarbonate concentrations of 2.2 g/L and 1.5 g/L will require % CO_2 compositions of about 5.5% and 3.5%, respectively.

CO_2%, $NaHCO_3$, and pH at 37 °C



$$pH = 6.1 + log_{10}(([NaHCO_3](g/L) * \frac{52}{CO_2\ (\%)}) - 1)$$

The pH controller has three user modes and one sensor error mode:

- Off mode
- Manual mode
- Auto mode
- Sensor error mode

Off Mode

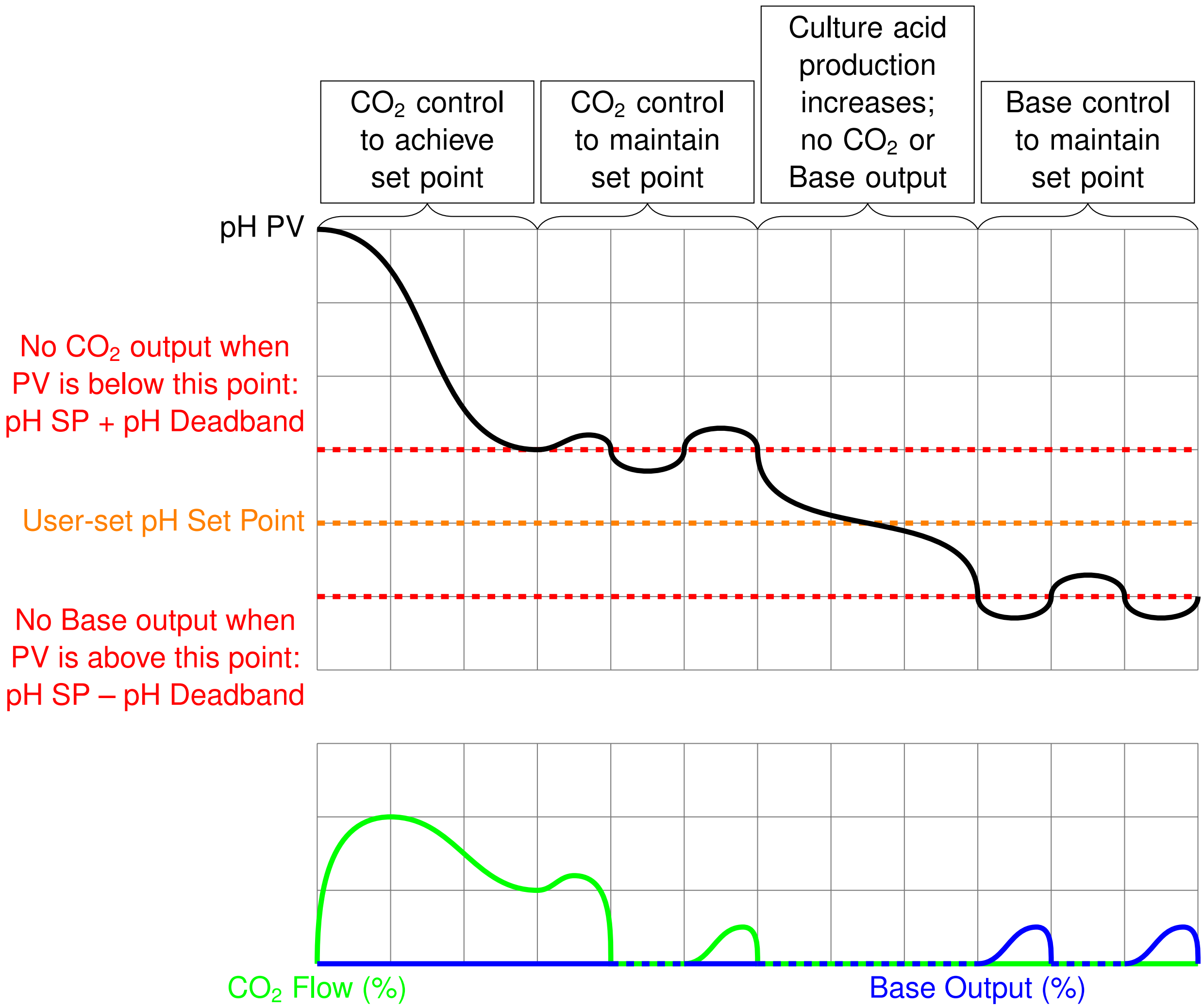
CO_2 is 0% of main gas flow and base pump duty is 0%.

Manual Mode

User selects a CO_2 flow in % composition of main gas flow, and/or a base pump duty in % (the user must select the base pump as well).

Auto Mode

User selects a set point in pH units. If it will be necessary to use base, the user also selects a base pump. The software achieves the set point by adjusting CO_2 flow and base pump duty. Each has its own PID loop: while both the CO_2 loop and the base loop control to the pH set point, the CO_2 will only output if the pH PV is greater than the pH set point plus the pH “Deadband” setting, and the base will only output if the pH PV is less than the pH set point minus the pH “Deadband” setting.



Sensor Error Mode

When pH is in Auto mode and the pH sensor detects a PV outside the valid range, or the PV has changed by more than the “Rate Fail Delta PV” in the time “Rate Fail Delta Time (s),” the software assumes the sensor is experiencing an error condition, and outputs the average of its CO_2 and base pump output values during the last 100 seconds before the software entered sensor error mode. Note that this is only intended to preserve short term stability – users should still take appropriate action in the event of sensor failure.

Output Ranges

The recommended CO_2 output is 0 - 100% CO_2 composition of main gas flow. The CO_2 MFC output is stated in "Gas Flow Rate Range" on page 38. CO_2 "pulsing" at the minimum value takes effect if the CO_2 % called for represents less than the MFC minimum flow rate.

The base pump output is technically 0 - 100% duty, however PBS Biotech Technical Support recommends using a range only up to your expected base consumption.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

pH (page 203)

- Rate Fail Delta PV
- Rate Fail Delta Time (s)
- CO2 P Gain (%/pH)
- CO2 I Time (min)
- CO2 D Time (min)
- CO2 Alpha
- CO2 Beta
- CO2 Gamma
- CO2 Linearity
- CO2 Manual Max (%)
- CO2 Auto Max (%)
- Base P Gain (%/pH)
- Base I Time (min)
- Base D Time (min)
- Base Alpha
- Base Beta
- Base Gamma
- Base Linearity
- Base Manual Max (%)
- Base Auto Max (%)
- Base Wait Time (s)
- A Use Temp Comp?
- Deadband
- Valid High (pH)
- Valid Low (pH)

Pressure (page 212)

- Disconnected Pressure (V)
- Reusable Sensor (0 or 1)

Gas Data (page 213)

- CO2 Min (LPM)
- CO2 Off (V)
- PWM On Time (s)
- PWM Max Period (s)
- Mismatch Thresh (V)

Safety (page 216)

- Max Level (L)

Pumps (page 218)

- Base On Time (s)
- Base Max Period (s)

Process Alarms (page 218)

- pH Low Low
- pH Low
- pH High
- pH High High

Interlocks

Conditions which interlock the pumps will also prevent the Base Pump from turning on. See the “Interlocks” subsection of “Control Pumps” on page 159.

Conditions which interlock the Main Gas will also prevent CO_2 from flowing. See the “Interlocks” subsection of “Main Gas” on page 146.

Level Sensing

The PBS-80 has a built-in level sensor, which measures the difference in pressure between the top and bottom of the bag. Pressure at the top is measured through the pressure line, while pressure at the bottom is measured by a tubing line which slowly bubbles air into the bag. The software converts the net pressure to a height, and uses the geometry of the bag chamber to convert the height to a volume.

For the level sensor to work properly, the user must perform a ‘zero’ calibration at 0 L with an empty bag. After filling the bag with medium, before turning any controls on, the user should perform a ‘span’ calibration if the Level reading reported by the software is significantly different from the actual volume in the bag.

The working level range of the PBS-80 is 50 – 80 L. Below the minimum, the Vertical-Wheel® impeller is not fully covered and may not function optimally, but certain processing steps may be performed with volumes as low as 16 L. Above the maximum there is the danger of overfilling the bag, causing overflow.

Disconnecting the Level Sensing Line

This expands on the “Level sensing line” warning on page 21. The level sensing line cannot be allowed to fill with liquid, and the level sensing line cannot be connected to the PBS-80 while gas flows through the O_2 sparge line and the line is clamped.

When the bag is filled with liquid, and the level sensing line is not clamped and is then disconnected from the PBS-80, liquid will fill the level sensing line up to the check valve. When the level sensing line is then reconnected to the PBS-80, a small amount of air will again flow into the level sensing line.

Because there is now liquid on the ‘bag’ side of the check valve instead of air, more pressure is required to open the check valve, and the calculated level is then less accurate. Additionally, because there is only a small amount of air flowing in to the level sensing line, a critical mass of liquid flows back through the check valve, eventually wetting and clogging the filter in the line. The amount of air flow is too small to ever displace the liquid that settles in the line.

The other important consideration is the level sensor itself. If the line is clamped, and the level sensing connector and the O_2 sparge connector are both connected to the PBS-80, and gas flows into the O_2 sparge line, there is a risk of exposing the level sensor to a pressure high enough to damage it. The check valve in the level sensing line should not be relied on to prevent the level sensor from being exposed to this high pressure from gas flowing from the O_2 sparge line.

To disconnect the level sensing line:

1. Prevent gas from flowing out of the O_2 sparge connector on the PBS-80. The simplest way is to turn DO Off.
2. Clamp the level sensing line as close to the bag as possible.
3. Disconnect the level sensing line and O_2 sparge line.

To reconnect the level sensing line:

1. Prevent gas from flowing out of the O_2 sparge connector on the PBS-80.
2. Reconnect the level sensing line and O_2 sparge line.
3. Wait 1 – 2 minutes.
4. Open the clamp on the level sensing line.
5. Allow gas to flow out of the O_2 sparge connector on the PBS-80.

Waiting between reconnecting the level sensing line and opening the clamp allows air pressure to build up in the line. When the clamp is opened, the pressurized air then prevents liquid from entering the line.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 211)

- Radius (cm)
- Empty Level (V)
- Empty Level (L)
- cm/psi
- Vessel Depth (cm)
- Bottom Gap (cm)
- Enable Sensor (0 or 1)
- CalLevelSlopeMax(psi/V)
- CalLevelSlopeMin(psi/V)
- CalLevelInterceptMax(psi)
- CalLevelInterceptMin(psi)

Safety (page 216)

- Min Level (L)
- Max Level (L)

Process Alarms (page 218)

- Level Low Low (L)
- Level Low (L)
- Level High (L)
- Level High High (L)

Filter Oven

The filter oven keeps the exhaust filter at an elevated temperature to reduce moisture accumulation in the exhaust filter. The factory default is 38 °C.

The filter oven's temperature PV is determined by a temperature sensor positioned inside the filter oven.

NOTICE If operators insist on setting the filter oven to Off when the PBS-80 is not in use, they need to be very careful to ensure they have set it to Auto mode when using the PBS-80. Because of the way the filter oven interlock works (see below), it is actually not necessary nor recommended to ever set the filter oven to Off mode.

Off Mode

The filter oven heater is off.

Manual Mode

User selects a filter oven heater duty as a percentage of its maximum power.

Auto Mode

User selects a set point in °C. A PID controller varies the filter oven heater duty to attempt to achieve the set point.

Sensor Error Mode

When filter oven is in Auto mode and the filter oven temperature sensor detects a PV outside the valid temperature range, the software assumes the sensor is experiencing an error condition, and outputs the average of its output values during the last 100 seconds before the software entered sensor error mode. Note that this is only intended to preserve short term stability – users should still take appropriate action in the event of sensor failure.

Output Ranges

The filter oven heater duty range is 0 - 100%.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 197)

- Valid High (C)
- Valid Low (C)

Filter Oven (page 199)

- P Gain (%/C)
- I Time (min)
- D Time (min)
- Alpha
- Beta
- Gamma
- Linearity
- Heat Manual Max (%)
- Heat Auto Max (%)

Process Alarms (page 218)

- Filter Oven Low Low (C)
- Filter Oven Low (C)
- Filter Oven High (C)
- Filter Oven High High (C)

Interlocks

The filter oven heater will not turn on if the main temperature PV is below 30 °C and no gas flow is requested. This is why it is recommended to operators to always leave filter oven in Auto mode - then, the filter oven will only turn on if necessary. If the main temperature PV is greater than or equal to 30 °C, or gas is flowing, there is a risk of the exhaust filter getting clogged, unless the filter oven is on.

Pressure Sensing

The PBS-80 has a built-in pressure sensor which monitors the pressure in the line between the bag and condenser bag. The pressure detected is displayed as the pressure PV in the software.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Pressure (page 212)

- Disconnected Pressure (V)
- CalPressureInterceptMax (psi)
- CalPressureInterceptMin (psi)
- CalPressureSlopeMax (psi/V)
- CalPressureSlopeMin (psi/V)
- Reusable Sensor (0 or 1)

Safety (page 216)

- Max Pressure (psi)
- Max Pressure Door (psi)

Process Alarms (page 218)

- Pressure Low Low (psi)
- Pressure Low (psi)
- Pressure High (psi)
- Pressure High High (psi)

Leak Sensing

The PBS-80 comes with a sensor to detect if a bag leaks based on the presence of liquid. It will stop reporting a leak once its contacts are dry.

Control Pumps

Types (Media and Additions A and B)

The media pump is meant for large scale additions of medium before or during a run.

The additions pumps are meant to be used throughout the run, for slow, medium, or fast titrations or quick one-time additions. Their pump speeds are adjustable. It is also an addition pump that the user must choose as the base pump if they desire base control – neither addition pump is automatically selected.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 211)

- Enable Sensor (0 or 1)

Pressure (page 212)

- Disconnected Pressure (V)
- Reusable Sensor (0 or 1)

Safety (page 216)

- Max Pressure (psi)
- Max Level (L)

Pumps (page 218)

- Aux Low Duty
- Aux Med Duty
- Base On Time (s)
- Base Max Period

Interlocks

The media and addition pumps will not turn on if the pressure PV is greater than the Safety "Max Pressure (psi)" setting, the software detects the pressure sensing line is disconnected, or the level PV is greater than the "Max Level (L)." This prevents medium or additions being added to the point of overfilling the bag or causing it to become over pressurized.

Main Light

The PBS-80 has a white LED light to illuminate the contents of the bag. It can be turned on and off through the software.

Door

The door on the PBS-80 only unlocks when it would be safe for the user to open it. There is no need for a user to open the door, other than to install an empty bag or to remove an empty bag.

Relevant Settings

See Appendix 1 on page 197 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 211)

- Enable Sensor (0 or 1)

Pressure (page 212)

- Disconnected Pressure (V)
- Reusable Sensor (0 or 1)

Safety (page 216)

- Max Pressure Door (psi)

Interlocks

The door will not unlock if the pressure PV is above the Safety "Max Pressure Door (psi)" setting.

The door will not unlock if the software recognizes that the pressure sensing line is disconnected.

The door will not unlock if the level PV is greater than 0.00 L.

The door will not unlock if the agitation PV is greater than 0 RPM.

Calibrating/Configuring Sensors

Pre-Calibration Medium Conditioning Strategy

After adding cell culture medium but before inoculating with cells, the DO and pH sensors must be calibrated. This is because autoclaving the sensors affects their calibration. Before the DO and pH sensors are calibrated, their reported measurements should not be considered accurate or reliable. In order to calibrate these sensors, the cell culture medium first needs to be conditioned, and the reported sensor PVs need to equilibrate. The controls should be set so the medium is in the ideal condition for the cells being cultured.

One reason for this is that if the medium is already in the ideal condition for the cells being cultured, the operators will not have to wait any time between calibrating the DO and pH sensors and inoculating with the cells. For example, if the operator were to set pH in Auto mode before calibrating, with a set point of pH=7.4, the software will adjust the percent of CO_2 in the headspace until the pH sensor reports a measurement of 7.4. However, because the sensor has not been calibrated yet, and autoclaving affects sensor response (which is why calibrating them is necessary), the actual pH of the media in the bag is very unlikely to be 7.4. If it is actually 7.5 or 7.3, for example, then after performing a calibration, the operator will have to wait to inoculate until the software adjusts the percent of CO_2 in the headspace and the pH sensor again reports a measurement of 7.4. Otherwise the bioreactor wouldn't be an optimal environment for the cells. But if the operator knew that the cell culture medium will have a pH of 7.4 from running 5% CO_2 in the headspace, the operator could set pH to Manual mode at 5% CO_2 to equilibrate (see the "$NaHCO_3$, CO_2%, and pH at 37 °C" chart on page 150 for more information). After equilibration and before calibration, it would not matter if the pH sensor reports 7.3 or 7.5, because the operator would calibrate it to be 7.4 (after verifying by taking a sample and measuring its pH). The operator could then immediately inoculate because the bioreactor would already be an optimal environment for the cells.

A second reason is that the DO and pH sensors should be calibrated to a measurement that is as close as possible to the condition the software will be controlling to during the cell culture run. This will minimize inaccuracy in the reported sensor measurement. Calibrating to a measurement which will not actually be controlled to introduces unnecessary inaccuracy in the reported sensor measurement. While the software uses a straight line $y = mx + b$ as the relationship between the sensor's raw output and the calculated PV, no sensor is 100% perfect, and there are inaccuracies. In the above example, when the operator put pH in Auto mode with a set point of 7.4 before calibrating, let's say that the actual PV was 7.3. When the operator then calibrates the pH to read 7.3, the sensor's reading at that single point has less inaccuracy than it would for any other pH PV. But because the operator intends to control the pH at 7.4 during the cell culture run via Auto mode, it would be in their best interest to manually control pH to conditions that will result in the pH being 7.4 before that first calibration. This can be accomplished by using the "$NaHCO_3$, CO_2%, and pH at 37 °C" chart on page 150 and setting the CO_2% by putting pH in Manual mode. Then, the operator could calibrate the pH reading to equal 7.4, and the running condition will match the PV where sensor inaccuracy has been minimized.

The agitation and main gas controls need to be on, so the contents of the bag are mixed homogenously, the Temperature is not interlocked, and the gases flowing through the headspace are able to efficiently diffuse into the medium. The agitation can be set to control to a higher RPM during this stage than when the bioreactor is inoculated, to speed up the process of conditioning the medium. Similarly, setting main gas flow to a higher flow rate during this stage than when the bioreactor is inoculated will also speed up the process of conditioning the medium. Or, operators could instead choose to set the main gas flow to a lower flow rate, to minimize gas use before inoculation. This may require additional time to condition the medium. The temperature control should be set to the temperature optimal for the cells. For most applications, this is 37 °C. This is important because the temperature of the medium has an effect on both the DO and pH of the medium.

It is recommended to condition the medium before these first calibrations by controlling DO and pH in Manual mode, rather than Auto mode. As explained above, this saves time and also minimizes calibration inaccuracy. Additionally, if DO is controlled in Auto mode, then the operator would be required to measure the DO of a sample to use as a reference when performing the calibration. For both pH and DO, regardless of whether the controller is in Auto or Manual mode, care must be taken when taking the sample and measuring it to ensure accuracy, as off-gassing can result in the sample's gas composition changing to be different from that of the medium. This is especially difficult to avoid for the DO. For more information, see “Take Sample” on page 172. This off-gassing can lead to the measurement of the sample not being accurate, and calibrations being performed to inaccurate or non-representative reference measurements can result in the calibrated sensor measurements being less accurate.

While it is technically possible to use DO and/or pH in Auto mode when conditioning the medium before performing the ‘span’/‘one-point’ calibrations, it is not recommended for the reasons explained above. Before inoculation, the gas composition of the headspace has a reliable and predictable effect on the gas composition of the medium. This means that putting DO and pH in Manual mode allows the operator to directly control the actual DO and pH of the medium. This allows the operator to use a very reliable and accurate reference when performing the ‘span’/‘one-point’ calibrations after the medium is conditioned and the sensor readings equilibrate.

Selecting Sensors

Sensors fail by registering PVs outside a valid range. Additionally, pH sensors can fail by registering a rapid PV change. When a sensor is failed, it is considered “Bad” by the software, and appears in red in the Select Sensors menu. If the control is in Auto mode but there is no “Good” sensor, the control will enter sensor error mode.

If a sensor type has no duplicate sensor, when that sensor stops failing (it is back in valid range, or for pH its PV stabilizes), it is “Good” again.

For duplicate sensors, a sensor which stops failing will remain “Suspect” until the user reactivates it, or its sibling sensor fails. The software will use the PV of the user-preferred sensor if it is “Good” or if both sensors are failing. Otherwise it will use the PV of the other sensor. Users can perform the following actions in the Select Sensors menu, which can affect which sensor PV the software will use:

- Tell the software which sensor they prefer (clicking the corresponding button).
- Reactivate a sensor that has gone out of range and come back into range, and which the user knows is trustworthy.
- Change the mode for a sensor set to be either “Single” (only the User Preferred sensor should be used) or “Dual” (automatically switch from using the User Preferred sensor to the other sensor if the User Preferred sensor fails).

Which Sensors Can Be Calibrated

It is possible to perform calibrations on the following sensors. Their calibration slope and intercept (m and b) values can also be manually entered; however, this should not be done without consulting PBS Biotech Technical Support.

Dissolved Oxygen

For a reusable DO sensor, the user should perform a ‘two-point’ calibration before autoclaving it, and an additional ‘span’ calibration before inoculation. It is generally not recommended that users perform additional ‘span’ calibrations during a run. Users should not perform additional ‘two-point’ calibrations during a run, perform any ‘zero’ calibrations, or manually enter calibration slope and intercept (m and b) values, without consulting PBS Biotech Technical Support.

This is because before inoculating with cells, the gas composition of the headspace has a reliable and predictable effect on the actual DO of the medium, so the operator can directly control the DO by putting pH and DO in Manual mode. This is the best reference to use when calibrating the DO sensor.

After inoculating with cells, the cells’ oxygen consumption additionally affects the actual DO of the medium, and so it can no longer be determined only based on the gas composition of the headspace. This means that a reference sample will have to be taken and measured, and the DO would have to be calibrated to that reference measurement. Taking the sample and handling it afterwards can introduce additional air to the sample and result in off-gassing, so the sample’s gas composition no longer matches that of the media in the bag, and the measured DO of the sample is not representative of the DO of the media in the bag. For more information, see “Sampling for DO Measurement” on page 174. Calibrating to an inaccurate or non-representative reference measurement can result in the calibrated sensor measurements being less accurate.

Additionally, for most applications, the DO sensor drift is minimal throughout a cell culture run. If sensor drift is suspected to be an issue for a process, it needs to be confirmed by isolating as many variables as possible when taking reference samples. Contact Applications Engineering at app.eng@pbsbiotech.com for additional information. If sensor drift is confirmed to be an issue for a process, the methods of collecting a sample and measuring it need to be confirmed to change the DO of the sample as little as possible for the reference measurement to be reliable. For more information, see “Sampling for DO Measurement” on page 174.

pH

For a reusable pH sensor, the user should perform a ‘two-point’ calibration before autoclaving it. Users should perform ‘one-point’ calibrations throughout a run if the measured pH of a sample shows that the sensor has drifted. Users should not perform additional ‘two-point’ calibrations during a run, or manually enter calibration slope and intercept (m and b) values without consulting PBS Biotech Technical Support.

Level

Users should perform a ‘zero’ calibration on an empty bag at the beginning of a run. After filling the bag with medium, before turning any controls on, the user should perform a ‘span’ calibration if the Level reading reported by the software is significantly different from the actual volume in the bag. Level calibrations cannot be performed from the Hello UI while the main gas control is on.

Temperature

The PBS-80 is shipped with its temperature sensors already calibrated. Users should not calibrate the temperature sensor without consulting PBS Biotech Technical Support.

Filter Oven Temperature

The PBS-80 is shipped with its filter oven temperature sensor already calibrated. Users should not calibrate the filter oven temperature sensor without consulting PBS Biotech Technical Support.

Pressure

Users should perform a ‘zero’ calibration on the pressure sensor before starting a run. No other calibrations should be performed on this sensor without consulting PBS Biotech Technical Support. Pressure calibrations cannot be performed from the Hello UI while the main gas control is on.

Temperature Compensation

The temperature of the pH sensor has a predictable effect on the sensor’s response. If the temperature PV differs from the temperature of the pH sensor when it was calibrated, the software is able to compensate for this, using the Nernst equation.

Calibration Types

The PBS software supports multiple calibration types for each sensor. However, not all calibration types are appropriate for all sensors or all situations.

All the calibrations rely on there being a linear relationship between the sensor’s raw voltage signal and the reported Present Value. This means the calibration curves take the form of

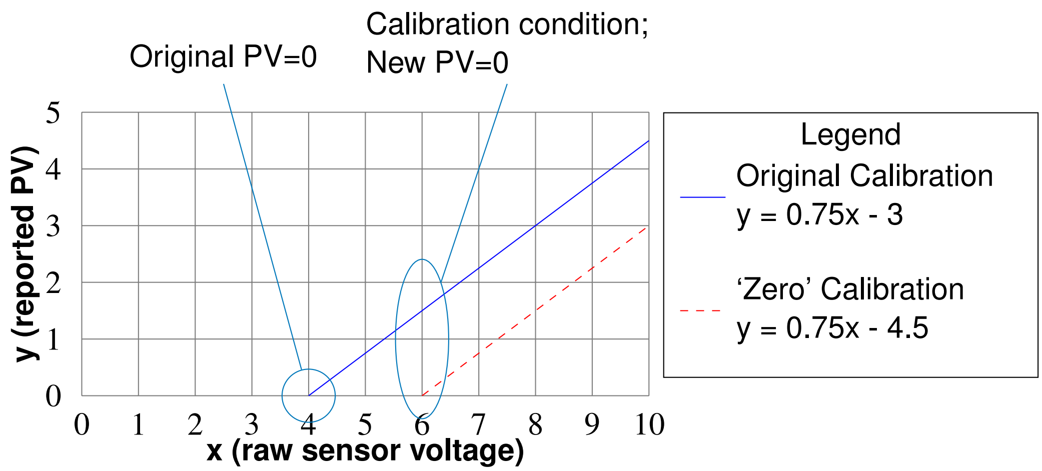
$$y = mx + b$$

where y is the final calculated Present Value (PV) (% for DO, L for Level, etc.), m is the calibration slope, x is the sensor’s raw voltage signal, and b is the intercept. All calibration operations involve changing the slope and/or intercept so when the sensor reports a particular raw voltage value, the calculated Present Value is different than it would have been when the original calibration values were in use.

In all the examples below, the calibration slope and intercept values do not correspond to the expected calibration values for any actual sensors on the PBS-80.

Zero

A ‘zero’ calibration involves keeping the original calibration’s slope, and adjusting the intercept so the PV equals zero at the calibration condition. This requires being able to reliably create conditions where the PV for that sensor type should equal 0.



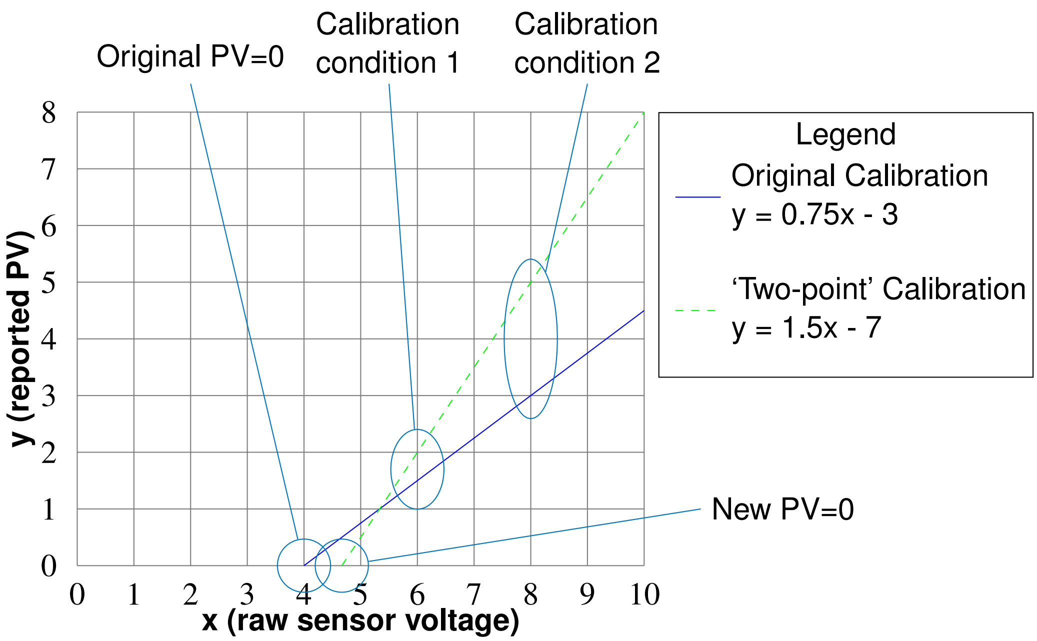
In the above example, the calibration would have been performed when the raw sensor voltage was 6. With the original calibration values, the PV would have been 1.5, but the operator knew that the actual PV should be 0 under that condition. The slope stayed at 0.75, but the intercept changed from -3 to -4.5.

This calibration type is applicable to sensors whose PV=0 condition is relevant and easily and reliably achieved:

- When an empty bag is installed, the Level PV should be 0.
- For the pressure sensor, PV=0 is achieved when the bag is not under any pressure and no gas is flowing.
- For the DO sensor, the PV=0 condition can be achieved most easily by disconnecting the sensor from the bioreactor. Before autoclaving, it can also be achieved by installing the nonsterile sensor in a small container that is flooded with N_2. After autoclaving and installing the DO sensor in the bag, the PV=0 condiiton can only be achieved while maintaining sterility by flooding the bag with N_2, which is a time-consuming process.

Two-point

A 'two-point' calibration involves quickly changing between two created calibration conditions, where the operator reliably knows what the PV should be at each condition. Usually, both the slope and intercept change as a result of performing a 'two-point' calibration.



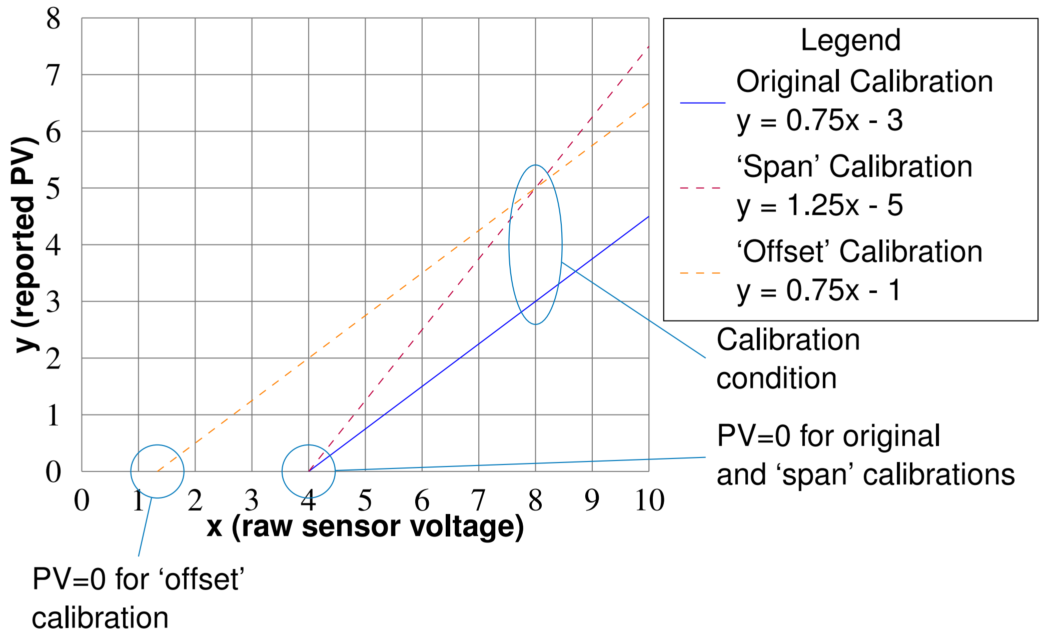
In the above example, the calibration would have been performed when the raw sensor voltage was 6 for the first point and 8 for the second point. With the original calibration values, the PV would have been 1.5 at the first point and 3 at the second point, but the operator knew that the actual PVs should be 2 under the first condition, and 5 under the second condition. This calibration type resulted in the slope, intercept, and PV=0 all changing.

This calibration type is applicable to sensors for which 2 conditions can be quickly and reliably created:

- For the pH sensor, this calibration is performed by using 2 different calibration buffer solutions, before autoclaving the sensor.
- For the DO sensor, this calibration is performed by keeping the DO sensor connected and exposed to a known gas composition for one of the points, and disconnecting the DO sensor to mimic the PV=0 condition for the other point.

Span and Offset

Both 'span' and 'offset' calibrations take a single new PV from the operator under a specific condition. A 'span' calibration preserves the PV=0 condition from the original calibration by changing the slope and intercept, whereas an 'offset' calibration preserves the slope from the original calibration, and the intercept and PV=0 condition change. The software refers to 'offset' calibrations as 'one-point' calibrations.



In the above example, the calibration would have been performed when the raw sensor voltage was 8. With the original calibration values, the PV would have been 3, but the operator knew that the actual PV should be 5 under that condition. If the operator had chosen to perform a 'span' calibration, the PV=0 condition would have been preserved, and the slope and intercept would have changed. If the operator instead had chosen to perform an 'offset'/'one-point' calibration, the original slope of 0.75 would have been preserved, and the intercept and PV=0 condition would have changed.

Whether it is more important to preserve the original calibration's slope by performing an 'offset'/'one-point' calibration, or it is more important to preserve the original calibration's PV=0 condition by performing a 'span' calibration, depends on the sensor, and how relevant the PV=0 condition is:

- For the pH sensor, pH=0 is not a relevant condition, and therefore 'offset'/'one-point' calibrations, and not 'span' calibrations, should be performed.
- For the DO sensor, DO=0% is a relevant condition, and therefore 'span' calibrations, and not 'offset'/'one-point' calibrations, should be performed.
- For the Level sensor, Level=0 L is a relevant condition, and should have been set by performing a 'zero' calibration on the empty bag. Therefore after filling a bag, a 'span' calibration is appropriate to perform.

Manual

Calibration slope and intercept values can also be manually entered; however, this should not be done without consulting PBS Biotech Technical Support.

Sequences

Sequences are configured and run from the Hello UI. The engine uses a simple interpreter which reads and writes directly to the bioreactor's internal state.

Actions and Looping

"Set" – Select this action when you want to set a variable to a specific value. For example, selecting the variable "AgModeUser (Agitation)" and then selecting the "Auto" button would result in the sequence changing the agitation mode to "Auto."

"Wait" – Select this action when you want the sequence to wait for a specified period of time before moving on to the next step. For example, selecting this action and then entering "10" in the 'Seconds' field would result in the sequence waiting for 10 seconds before moving on to the next step.

"Wait Until" – Select this action when you want a variable to reach a specific value or state before the sequence moves on to the next step. For example, selecting the variable "AgPV(RPM) (Agitation)," selecting ">= (greater than or equal to)" in the 'Compare' field, and then entering "10" in the number field would result in the sequence waiting until the agitation present value equaled 10 RPM before moving on to the next step.

"Loop" – Select this action when you want the entire sequence to loop until the user stops the sequence. To configure a sequence to loop, edit the sequence, click 'Loop,' and then save.

Which Variable Types Sequences Can Change

For a complete list of variables the software uses, see Appendix 4 on page 233.

User Source

All variables which are "User" Source can be changed using a sequence. This includes variables such as modes, set points, and pump speeds. Changing these variables with a sequence works the same as changing them through the Hello UI.

System Source

All variables which are "System" Source can be changed using a sequence. Changing calibration slopes and intercepts with a sequence is the same as changing them by performing a calibration, and changing "System" Source variables with a corresponding System Variable are the same as changing a setting in the Settings editor. However, changing other "System" Source variables via sequence should be treated as temporary; if the RIO is rebooted or loses power, the changes will be reverted when it is booted up again.

Sensor and Calculated Sources

Other variables cannot be changed using a sequence. These variables include calculated values such as PVs and raw sensor values.

Other Information About Sequences

Sequences can only be run one at a time, and cannot refer to other sequences.

Ending a sequence prematurely causes the sequence to end at the current step, and does not reset anything. Consider the following sequence:

1. Set "Pumps&ValvesPumpUser1" to Slow
2. Wait 60 seconds
3. Set "Pumps&ValvesPumpUser1" to Off

If the above sequence were stopped after only 30 seconds, the pump would continue to run, until a user stopped the pump themselves in the "Control Pumps" menu. Similarly, after a user starts that sequence, the pump can still be stopped in the "Control Pumps" menu.

Users should also remain conscious of any user-selectable parameters that may interfere with a sequence step.

Reports

Reports contain data from a specified time span or from an individual batch. They are generated as .csv files with the report type and creation time as their default name. As part of the report generation process, reports can be exported via email, to a connected USB drive, or to a connected network drive. They can be emailed to the user who generated them (if the user has a registered email address), individual email addresses manually entered, or to all users in a user group who have a registered email address. Reports can also be exported any time after they were generated using the "Export" menu from the "Actions" tab.

Types

Process Data – Contain process data logged for variables specified in the Logger Settings.log file. See below for more information.

User Events – Contains all actions a user takes, except screen navigation. When a configuration file is created, its name and contents are included in the user event. For additional edits to a configuration file, its name and the changes are included in the user event. When a configuration file is made active, its name is included in the user event.

Errors – Contains information used for debugging, and is not necessary for users under ordinary circumstances.

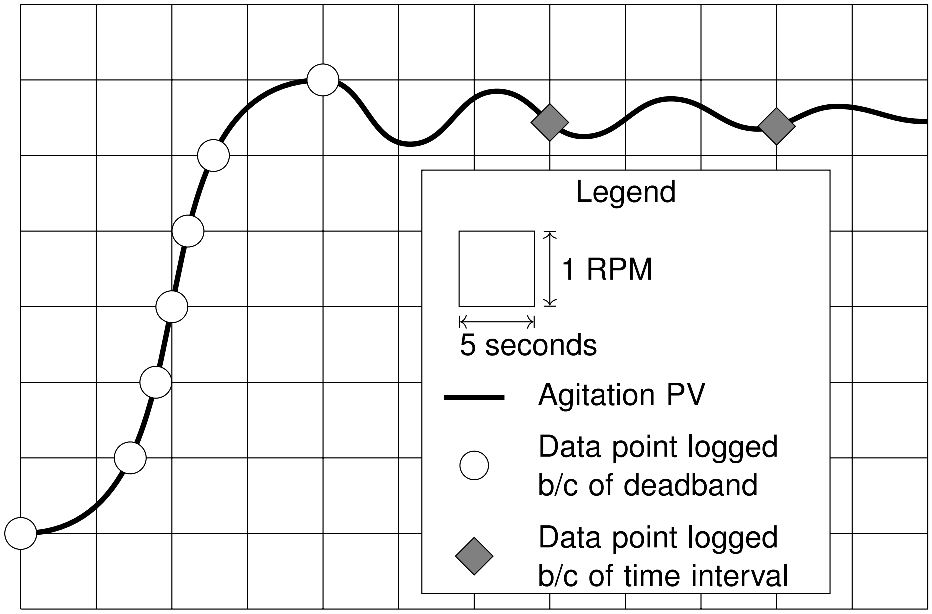
Alarms – Contains information about alarms that are generated, when they are acknowledged, and which user acknowledged them.

Sequence Steps – For each sequence ran, contains the start time of the sequence, all sequence steps executed by the software, what time the steps were started, and the time the sequence ended.

Process Data Recording

The Logger Settings.log file determines which variables' process data will be recorded. In addition to selecting what data to record, each variable has a "deadband" that says its value will be recorded if it changes by the deadband amount. The System "Max Data Log Interval (min)" setting determines how frequently the data will be recorded if it is changing less than the deadband.

For example, if the agitation PV is set to be recorded with a deadband of 1 RPM, and the “Max Data Log Interval” is 15 seconds, the following chart shows when the PV will be recorded:



The combination of time-dependent data recording and change-related data recording can be used to ensure that useful data is recorded without flooding the database.

For definitions of all logger variables and default deadbands, see Appendix 4 on page 233.

Database

The active database is called Historical Records.db and contains all data recorded by the system. Its contents are compatible with any application that can read SQLite format.

Take Sample

For instructions to take a sample manually, see “Take Sample” on page 118.

Do not attempt to combine samples for different types of analyses, for example measuring the pH of a sample that is going to be processed for cell counts. This will introduce more variability and error into the cell count. Each sample should be unique.

When validating any sampling and measurement method, multiple samples should be taken and compared to understand the inherent variation.

Sampling for Cell Counting

Sample should be representative of the culture – A representative sample should have the same proportion of healthy cells as in the bag. If the cells are growing in aggregates or microcarrier clumps, those amounts and morphologies should be reflected in the sample as well.

Volume – A sample of 10 mL or larger is recommended for cell counts.

Sample Method – Factors which impact how representative a sample is are the shear force the sample is subjected to as it is taken, the speed at which the sample is taken, and the location in the bag from which the sample is taken. Passing a sample through a pump or small connectors can subject the sample to shear force and affect cell health/viability, and affect the size/shape of aggregates or microcarrier clumps. Sampling speed and location can impact the number of total cells contained in a sample.

Handling Sample – For viability counts, the sample should be handled and processed as quickly and gently as possible to avoid artificially increasing the percent of dead or unhealthy cells.

Counting Cells in Sample – Users should validate their cell count method by taking multiple samples and comparing them, to understand the inherent variation.

Sampling for pH Measurement

Concerns – As a sample is removed and manipulated, CO_2 in the cell culture medium can be stripped out and replaced with air, which will increase the pH. A sample which is left to sit in ambient conditions will also experience off-gassing, which will have the same effect as actively stripping out the CO_2. The reverse can also happen; cellular metabolic activity may continue in the sample, causing the CO_2 and/or lactic acid to be higher than the concentration in the bag.

Volume – A sample of sufficient size for the offline pH meter to read it should be taken.

Sample Method – Minimize turbulence and air exposure while taking the sample. The bioreactor tubing is gas permeable, so as soon as liquid leaves the bag environment it is changing from its in situ conditions.

Handling Sample – Minimize turbulence and air exposure while handling the sample - perform the measurement as quickly as possible.

Measuring Sample – Getting a measurement as quickly as possible should be the priority. A dedicated benchtop pH meter will give a measurement more quickly than a metabolite analyzer, for example. The sampling and pH measurement methods can also be validated. Before inoculating with cells, when the % CO_2 composition is manually set and the pH PV has stabilized, the measured pH should match the expected pH from the "$NaHCO_3$, CO_2%, and pH at 37 °C" chart on page 150, given the % CO_2 composition and sodium bicarbonate concentration of the medium. Taking a sample can introduce air and strip out CO_2, causing the sample's measured pH to be higher than that in the actual bioreactor. Comparing the sample's measured pH to the theoretical pH based on the % CO_2 composition and sodium bicarbonate concentration of the medium is a good way to verify that the samples are being taken and handled appropriately.

Sampling for DO Measurement

Sampling for measuring the DO can be done regularly, but DO calibration should only be performed if DO sensor drift has been confirmed to be a significant issue. It's possible to introduce significant error by measuring the DO of a sample, and this concern should be weighed against concerns about sensor drift.

Concerns – As a sample is removed and manipulated, it will be rapidly equilibrating to the gas composition of atmospheric air, which will result in the DO of the sample rapidly approaching 100%. A sample which is left to sit in ambient conditions will also experience off-gassing, which will have the same effects as actively stripping out the other gases. Cellular metabolic activity might also continue in the sample, causing the O_2 to be lower than that of the media in the bag.

Volume – A sample of sufficient size for the offline gas analyzer to read it should be taken.

Sample Method – Minimize turbulence and air exposure while taking the sample. The bioreactor tubing is gas permeable, so as soon as liquid leaves the bag environment it is changing from its in situ conditions.

Handling Sample – Minimize turbulence and air exposure while handling the sample - perform the measurement as quickly as possible.

Measuring Sample – Getting a measurement as quickly as possible should be the priority. A blood gas analyzer will give a measurement more quickly than a metabolite analyzer, for example. The sampling and DO measurement methods can also be validated. Before inoculating with cells, when the % composition of the CO_2 and N_2 in the headspace is manually set and the DO PV has stabilized, the measured DO should match the percent of air entering the headspace. Comparing the sample's measured DO to the theoretical DO is a good way to verify that the samples are being taken and handled appropriately.

Load Vessel

The Load Vessel feature allows the database to store the bag part number and serial number used for particular batches.

Integrity Test

These are the steps the Integrity Test takes:

1. **Ramp:** To pressurize the bag, the software turns the Main Gas on at the "Ramp Flowrate (LPM)" until the Pressure PV is greater than or equal to the "Ramp Pressure (psi)."
2. **Settle:** To account for the bag and its tubing expanding as it is exposed to increased pressure from the 'Ramp step, the software waits for the "Settle Time (sec)" before proceeding with the actual test.
3. **Test:** The software records the system timestamp and the Pressure PV at the time the test begins. Provided nothing interrupts the test, it proceeds for the "Test Time (sec)," at which point the software again records the system timestamp and Pressure PV, and calculates the Decay.

These are the default values of the Integrity Test parameters:

Parameter	Definition	Value
Ramp Flowrate (LPM)	This is the flowrate the software uses to fill the bag during the 'Ramp' period of the test.	5
Ramp Pressure (psi)	This is the target pressure that the software is trying to fill the bag to during the 'Ramp' period of the test.	0.5
Ramp Timeout (sec)	If the pressure PV does not meet the Ramp Pressure (psi) after the 'Ramp' period of the test has lasted this long, the test will timeout and the software will end the test.	500

Parameter	Definition	Value
Settle Time (sec)	This is the amount of time the 'Settle' period of the test will last.	600
Min Settle Pressure (psi)	This is the lowest value the Pressure PV is allowed to be during the 'Settle' period of the test. If the Pressure PV is below this value for the "Settle Abort Delay (sec)" time during the 'Settle' period, the test will be cancelled. If the Pressure PV is below this value at the start of the 'Test' period, the test will be cancelled.	0.4
Settle Abort Delay (sec)	This is a delay to account for signal noise from the Pressure sensor. The Pressure PV has to be below the "Min Settle Pressure (psi)" for this amount of time for the test to be cancelled. If the Pressure PV quickly dips below this value and then recovers, the test will not be cancelled.	5
Test Time (sec)	This is the amount of time the 'Test' period of the test will last.	600
Max Decay Rate (psi/min)	This is the largest value the pressure decay can be - any larger and the software will report that the test failed.	0.0020

Batch

Rather than manually recording the start and end dates of various runs, users can start a new batch when they start a new run and end it after harvest. This makes it easier to access the relevant data for generating a report.

Advanced View

The “Advanced” menu allows the user to see more detailed information than is displayed in the Dashboard.

Windows/HMI Log Off

Users can log out of the HMI computer from the Hello UI. This feature is used when a customer’s IT department requires access to their Admin account on the Windows/HMI computer. Internal protocols must be followed to ensure that nobody with access to the Windows Admin account modifies or deletes any data.

Restart

Users can restart the HMI computer from the Hello UI. Because of the unique architecture combining the RIO controller and HMI, the user is able to reboot the HMI without interrupting run control. If the HMI stops responding or a software update requires a restart, the user can reboot the HMI without losing crucial functionality. For instructions to restart the HMI, see “Restarting the HMI Computer” on page 73.

Alarms

The Alarms configuration file (Alarms.alm) is configured in the Hello UI. Alarm monitoring is handled by the RIO, while user alerts are displayed in the Hello UI, and emails about alarms are sent by the HMI computer.

There are two types of alarms on the PBS-80:

Process Alarms – Triggered when the PV deviates outside the user-defined High and Low range, or High High and Low Low range, for each variable. These ranges are defined in the Process Alarms group of the “System Variables” editor.

Failure Alarms – Triggered when parameters fall outside pre-defined ranges, which indicates that sensors or other hardware have failed. For definitions of all alarms, see Appendix 2 on page 222.

All alarms can be configured in the Alarms editor. There are three settings for alarms on the PBS-80: Notify, Audible, and Email. Users can select all three alarm settings for all alarm variables.

Notify – If the selected alarm is triggered, an alert will appear in the “Alarms” tab of the Hello UI.

Audible – If the selected alarm is triggered, the software will alert users to a failure by sounding the built-in buzzer. The sound of the buzzer can be adjusted by changing the “Buzzer Period” setting in the Settings editor.

Email – If the selected alarm is triggered, a notification email will be sent to the list of entered email addresses in the ‘Email List’ (see “Configuring Alarms Email List” on page 61). For more information on how to configure email settings, see “Configuring Email Function” on page 59.

Users may acknowledge an alarm while the condition which triggered it is still being met. The alarm will regenerate once the amount of time specified in the Alarm “Snooze Time” setting has elapsed.

When a user clicks “Acknowledge All” to acknowledge all alarms, alarms of all types will be snoozed until the amount of time specified in the Alarm “Snooze Time” setting has elapsed. This also applies to alarm types which were not previously triggered.

For more information on acknowledging alarms, see “Alarms” on page 133. For information on changing the Alarm “Snooze Time,” see “Settings/System Variables” on page 134. For default alarms configurations, see Appendix 3 on page 228.

Settings

The System Variables configuration file (System Variables.sys) is configured in the System Variables editor (see “Settings/System Variables” on page 134). While some settings are meant to be user-configurable, it is possible to severely impair functionality of the PBS-80 by changing certain settings. For a complete list of all settings, their definitions, and whether PBS Biotech Technical Support recommends changing them, see Appendix 1 on page 197.

User Accounts

Users are required to log in with an individual user name and password to access the Hello UI. Users can choose to log out of the Hello UI, and local users are logged out automatically after ten (10) minutes of inactivity (the automatic logout time is configurable for domain users). Changes a user makes while they are logged in are recorded in the database and can be exported in a User Events report.

Use of shared or generic accounts is not recommended in regulated environments or when traceability of user actions is desired. Users in regulated environments are responsible for ensuring that any such use of accounts is managed appropriately.

Local users have user names, passwords, user groups, and optional email addresses to receive emailed reports. Domain account details are managed on the domain controller by the customer's IT team. Only username and permission assignments are used by the PBS Software. For information on configuring users and user groups, see "Configuring Local Users and Groups" on page 43.

User Group Permissions

Permission groups can be configured to have a combination of the following permission options:

Operation

These control access to the features required for day-to-day operations of the PBS-80.

Controls – Allows users to set agitation, temperature, DO, pH, main gas, and filter oven, and to turn pumps on and off, and change their direction and speed (if applicable). When this permission is not granted, the user is unable to click the corresponding buttons in the Dashboard and the "Advanced View," "Control Pumps," and "Sample" menus of the Hello UI.

Acknowledge Alarms – Allows the user to acknowledge alarms. When this permission is not granted, the user is unable to click any of the unacknowledged alarms under the "Alarms" tab.

Start Sequence – Allows the user to start a sequence. When this permission is not granted, the user is unable to click the "Start" button in the "Sequence" menu.

End Sequence – Allows the user to end a sequence. When this permission is not granted, the user is unable to click the "Stop" button in the "Sequence" menu.

Main Light – Allows the user to turn the Main Light on and off. When this permission is not granted, the user is unable to click the "Main Light" button in the "Actions" tab.

Unlock Door – Allows the user to unlock the door on the PBS-80. When this permission is not granted, the user is unable to click the "Unlock Door" button in the "Actions" tab.

Harvest – Allows the user to start and end Harvest Mode for Agitation. When this permission is not granted, the user is unable to click the "Harvest" button in the "Actions" tab.

Integrity Test – Allows the user to start and end an Integrity Test. When this permission is not granted, the user is unable to click the “Start” and “End” buttons in the “Integrity Test” menu.

Process Configuration

These control access to the features required to start and end a batch run on the PBS-80.

Activate Alarm Settings – Allows users to Activate Alarms files, and to test the buzzer. The “Alarm Settings Editor” permission is required to edit the Alarms files.

Activate System Variables – Allows users to make System Variables files active. The “System Variables Editor” permission is required to edit the System Variables files.

Activate Logger Settings – Allows users to make Logger Settings files active. The “Logger Settings Editor” permission is required to edit the Logger Settings files.

Batch Events – Allows users to start and end batches, and load and unload vessels.

Reports – Allows users to create and export reports.

Process Calibration – Allows users to perform ordinary calibrations on pH, DO, Level, and Pressure. Only ‘two-point’ and ‘span’ calibrations should be performed on reusable DO sensors. Other DO calibration types should not be performed without consulting PBS Biotech Technical Support.

Select Sensor – Allows users to select whether Sensor A or Sensor B will be used, when duplicate sensor hardware is available. When this permission is not granted, the user is unable to click any of the buttons in the “Select Sensors” menu.

Advanced Configuration

These control access to the features required to perform advanced configurations on the PBS-80. These functions are typically used during initial configuration or process development, but not day-to-day operation.

Sequence Editor – Allows users to add, edit, and delete sequences.

Email Settings – Allows users to configure the email settings for the PBS-80. This includes the SMTP server or Email server settings, the email list for alarm notifications, and the ‘Alarm Email Snooze Time.’

Alarm Settings Editor – Allows users to configure alarms to be set to Notify, Audible, and/or Email, and to test the buzzer. Users with this permission can create new Alarms files, edit existing Alarms files, and delete Alarms files. The "Activate Alarm Settings" permission is required to edit the Alarms file that is currently active.

System Variables Editor – Allows users to edit the values of system variables. Users with this permission can create new System Variables files, edit existing System Variables files, and delete System Variables files. The "Activate System Variables" permission is required to edit the System Variables file that is currently active.

Logger Settings Editor – Allows users to configure what data is recorded and how often. Users with this permission can create new Logger Settings files, edit existing Logger Settings files, and delete Logger Settings files. The "Activate Logger Settings" permission is required to edit the Logger Settings file that is currently active.

Equipment Calibration – Allows users to perform calibrations on Temperature, Filter Oven, and the MFCs. Also allows users to perform 'Span' Pressure calibrations, and to enter calibration slope and intercept values manually. These operations should not be performed without consulting PBS Biotech Technical Support.

Integrity Test Settings – Allows users to configure the parameters for the Integrity Test feature. When this permission is not granted, the user is unable to change any of the parameters in the "Settings" tab in the "Integrity Test" menu.

Administration

These control access to features required for administrative actions on the PBS-80.

Account Management – Allows admins to configure Users and User Groups settings, including permissions, passwords, password rules, emails, and assigned User Groups, and configure Domain login settings.

Backup Configuration – Allows users to schedule automatic backups and to perform manual backups.

System Management – Allows users to rename the bioreactor, reboot the RIO, sync the RIO time, and shutdown, reboot, and log off of the Windows/HMI computer.

Map Drive – Allows users to manage mapped network drives.

OPC UA Settings – Allows users to configure the bioreactor to connect to other software systems via OPC UA. When this permission is not granted, changes cannot be made in the OPC UA menu, accessed via the “OPC UA” button in the triple bar ≡ (top right corner) menu.

Oxygen Flow Valve

The oxygen flow valve allows users to change the method of delivering O_2 to the bag by switching between the Air/CO_2/N_2/ O_2 overlay line or the O_2 sparge line. When the valve is set to “Overlay,” O_2 is mixed with the other gases that enter the bag through the Air/CO_2/N_2/ O_2 overlay line into the overlay, and setting it to “Sparger” sparges pure O_2 through the O_2 sparge line at the bottom of the bag.

While sparging O_2 is more efficient and allows higher rates of gas transfer due to the higher surface area to volume ratio of the sparged bubbles compared to the overlay, it may also cause foaming in the bag, which can damage cells. To reduce cell damage, PBS Biotech generally recommends that users only set the valve to “Sparger” when O_2 delivery through the overlay is insufficient to meet oxygen demand. This condition is reached when the O_2 flow has reached maximum output and the DO PV begins to drop. For information on O_2 output, see “Output Ranges” on page 149.

As there are no sensors to inform the software of the O_2 valve setting, users must always turn DO off before changing from “Overlay” to “Sparger” in order to activate the ‘slow start’ gas flow feature. This prevents a sudden surge of pressure within the O_2 sparge line that may damage the sparger.

When changing from overlay O_2 to sparging, or vice versa, it is necessary to change the DO “O2 P Gain (%/DO%),” “O2 I Time (min),” and “O2 D Time (min)” settings to account for the differences in the rate and mechanism of O_2 delivery.

Instructions for IT

8

This chapter contains information a customer's IT department may need to install or maintain the PBS-80.

Bioreactor Computer Architecture

- The control system of the PBS-80 Vertical-Wheel® Bioreactor System (PBS-80) is accessed through a touchscreen HMI located on the front of the bioreactor housing. Internally, an industrial process computer (IPC) controls UI, data, and configuration, while equipment control and monitoring is performed by an industrial automation controller (RIO)
- The IPC operates PBS Biotech's Hello UI software. This software is responsible for:
  - User Interface, including control panel, readouts, and configuration
  - Data and event logging
  - Enforcing data integrity and security, including access controls and audit trails
  - Sending emails
  - Sending user commands to the RIO controller
- The RIO controller is in charge of:
  - Sensing and control functions
  - Process monitoring, including interlocks and equipment failures
  - Generating the data and event records logged by the Hello UI
  - Running the Sequence (automation) engine

Operating System

The IPC runs on Windows 10 IoT Enterprise LTSC 2021. Access to the operating system is granted to provide access to specific functions not implemented in the PBS Software:

- Date/Time configuration
- NTP server configuration
- Manual import/export of configuration files
- Database archiving
- Static IP configuration

Access to the OS may also be used for configuration and security auditing.

NOTICE PBS Bioreactors are provided with a fully configured, embedded software package. PBS Biotech can only support system modifications made through the PBS Software or performed by PBS Biotech. Installation of any third-party software to the system may void the warranty and cause unexpected failures and data loss.

BIOS

The IPC's BIOS is configured at the factory to prevent booting from any media other than the hard drive installed on the PBS-80. The BIOS must not be configured to allow booting from any other media. This is to prevent a malicious user from gaining access to the database files and modifying or deleting records, thus violating GMP standards for data integrity.

Reconfiguring the BIOS may result in loss of functionality and compromise data integrity.

The BIOS is provided with a secure, factory default password. It may be changed for security purposes, but this is unnecessary for general use and must be done with extreme caution.

NOTICE To maintain data integrity, internal access to the bioreactor housing must be restricted to authorized personnel only. The BIOS security configuration does not protect against intentional misuse by a person with physical access to the IPC's motherboard or SSD.

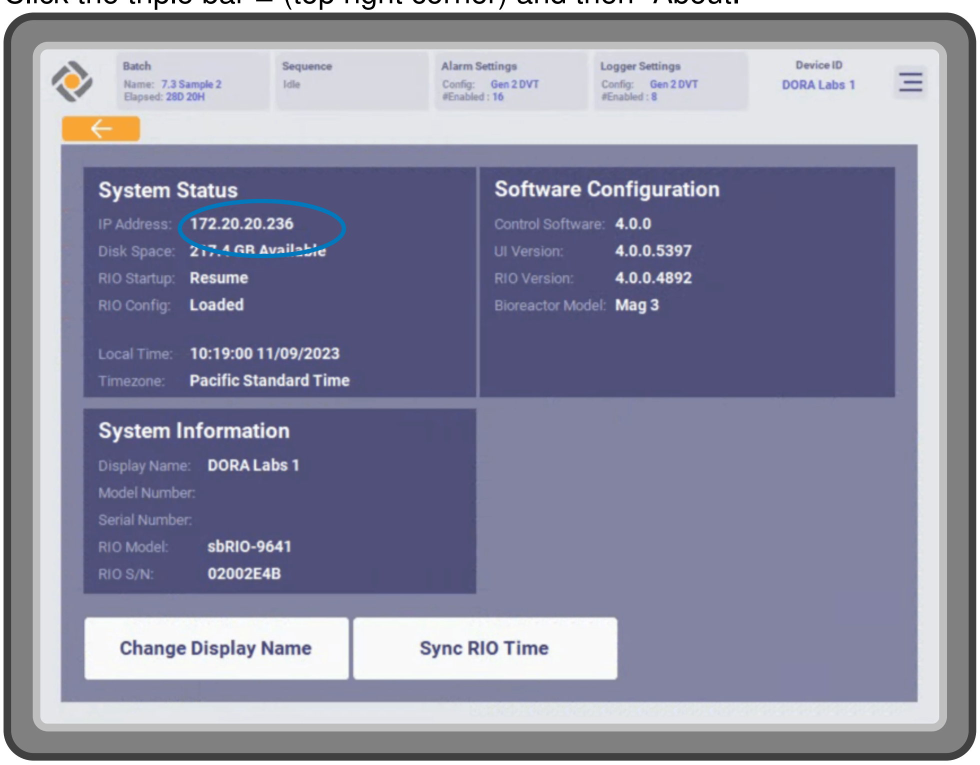
Network Connections

- The IPC and RIO communicate through an internal, link-local network connection configured with static IP settings. These settings must not be modified under any circumstance.
- The Local Area Connection to the RIO controller is configured as follows:

IPv4 Address:	100.100.100.5
IPv4 Subnet Mask:	255.255.255.0
IPv4 Default Gateway:	undefined
IPv4 DNS Server:	undefined

NOTICE Do not disable the above network connection, or modify any of its configurations, as that will disrupt communication with the RIO controller.

- The Bioreactor computer may be joined to a local network via the Ethernet port. That network connection may be configured as necessary. By default, the bioreactor will automatically obtain an IP address and connect to the local network.
- The bioreactor's local network address can be found in the About menu. Click the triple bar ≡ (top right corner) and then "About."

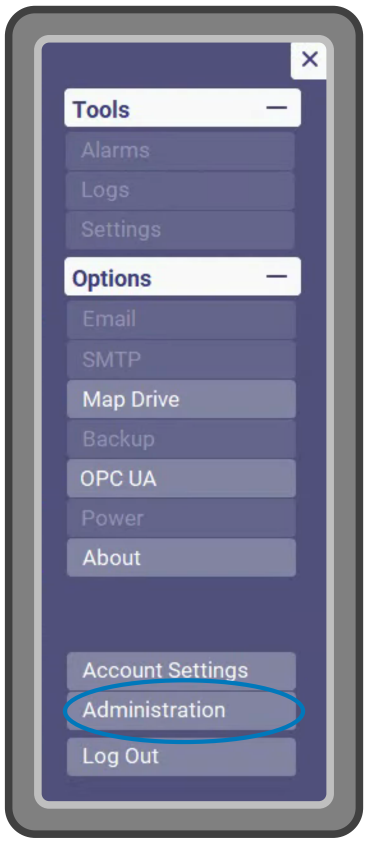


Configuring Domain Login

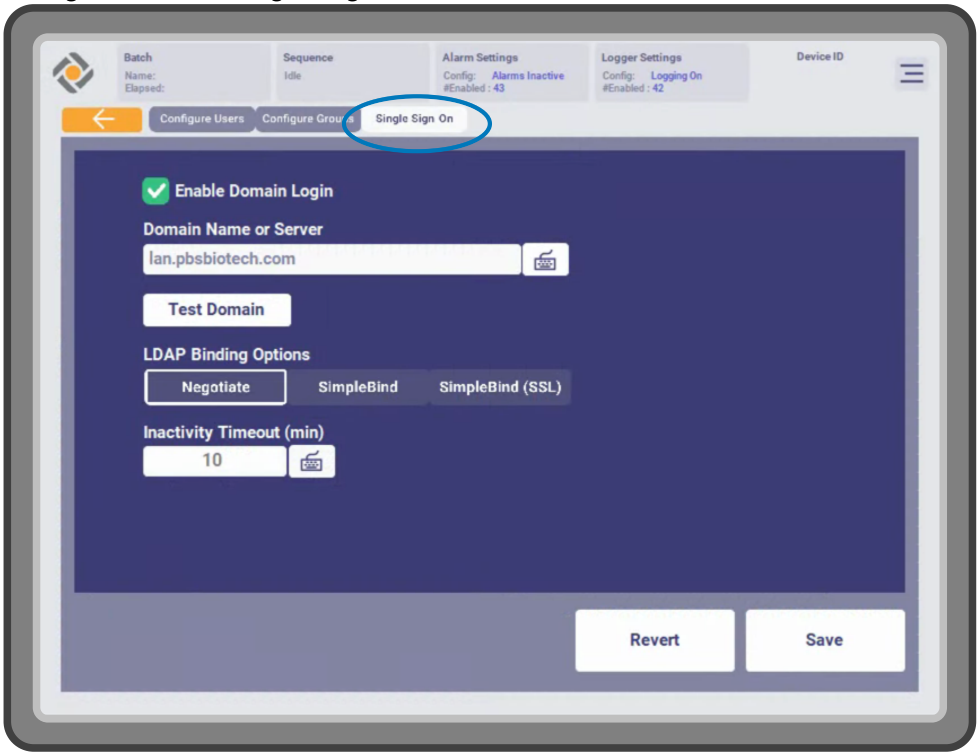
The bioreactor can be configured so users can log in to the bioreactor with domain credentials. When the Domain login option is enabled, users can still log in using local user accounts; this is useful for maintenance accounts, local administration, and fallback during network issues.

To configure the bioreactor:

1. Log in to the Hello UI using the user name and password of a local account in a group with the "Account Management" permission.
2. Click the triple bar ≡ (top right corner) and then "Administration."

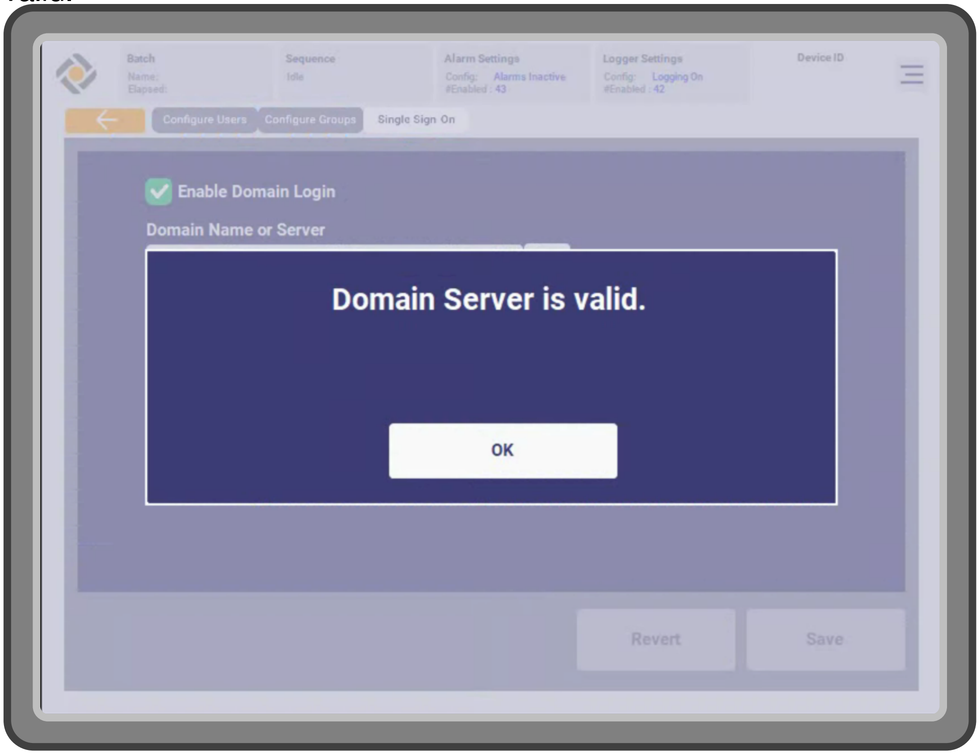


3. Navigate to the “Single Sign On” tab.



4. Check the “Enable Domain Login”
5. Configure the “Domain Name or Server”
6. Configure the “Inactivity Timeout (min)” if desired
7. Configure the “LDAP Binding Options” if desired

8. Click “Test Domain” - if the software is able to interact with the entered Domain Name or Server, a message will appear, “Domain Server is valid.”



9. Click “Save.”

To configure the domain:

Permissions are associated with domain accounts by group assignments queried from the Domain Controller. All permissions supported by the PBS Bioreactor can be granted to domain accounts. Domain accounts with no PBS permissions assigned cannot log in.

For further details, see Document VV-02827 “Bioreactor Single Sign-On Configuration Guide.”

For an explanation of what each Permission does, see “User Group Permissions” on page 179.

Configuring REST API Connectivity

The default PBS Software has an HTTP/REST interface accessed using the following URL format:

https://<IP Address>/v0/mainvalues

Configuring the bioreactor's IPC to have a static IP address on the LAN is recommended for this reason (see "Network Connections" on page 185).

Full instructions and documentation can be found in Document VV-04265 "REST API Programming Guide."

Configuring OPC UA Connectivity

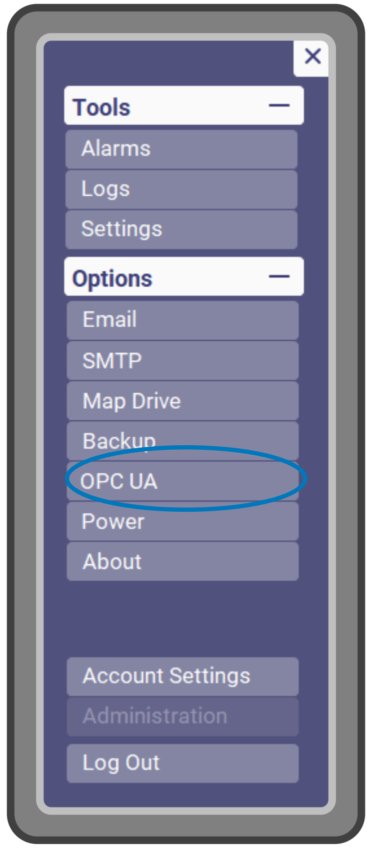
The bioreactor can be configured so it can be monitored and controlled via OPC UA by client software systems such as Data Historians, Distributed Control Systems (DCS), Supervisory Control and Data Acquisition (SCADA) systems, and/or Process Information Management Systems (PIMS). This requires applying an optional OPC UA upgrade with a license. Contact sales@pbsbiotech.com for a quote.

Instructions to configure the bioreactor via the Hello UI are below. See Document VV-04264 "OPC-UA Programming Guide" for a full description of the OPC interface.

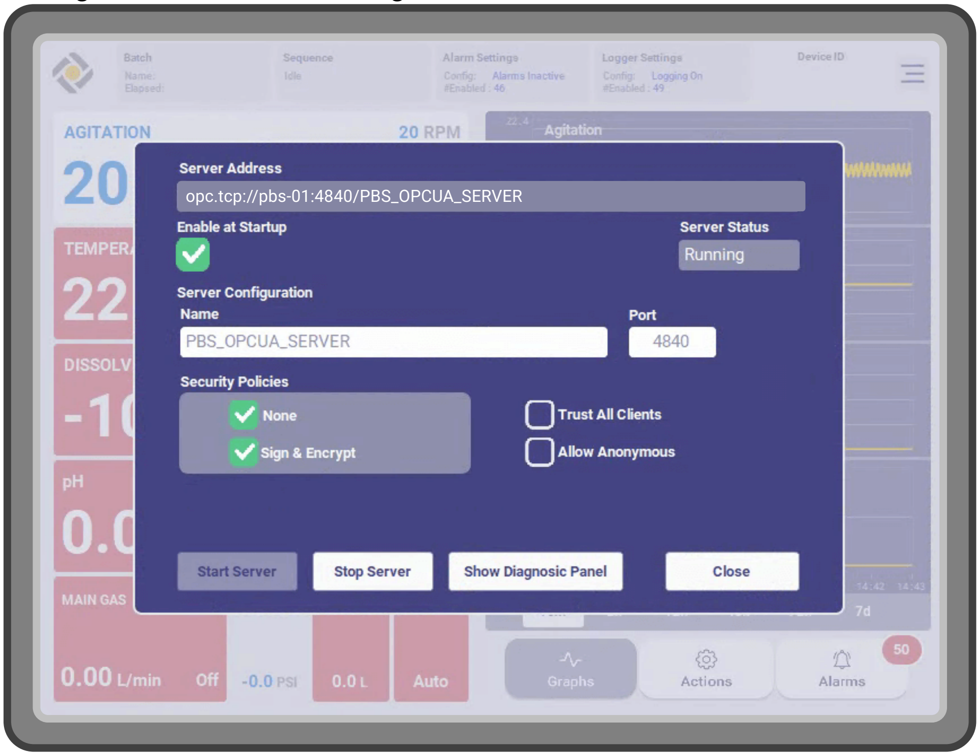
To configure the bioreactor:

1. Log in to the Hello UI using the user name and password of an account with the "OPC UA Settings" permission.

2. Click the triple bar ≡ (top right corner) and then “OPC UA.”



3. Configure the OPC UA settings as desired.



Indicators:

Server Address – This is the address of the OPC-UA server on the bioreactor, which clients will connect to. It is empty when the server is not started. The format is:

opc.tcp://<Host Address>:<Port>/<Server Name>

Server Status – Indicates whether the server is currently Running or Idle. If the optional OPC-UA upgrade has not been applied, it will indicate that a license is needed.

Software Configuration:

Enable at Startup – Check this box to configure the PBS Software to run the OPC-UA server when it starts up.

Server Configuration:

Name – While this is user-configurable, it is not recommended to edit this value.

Port – This is the port used by the server. 4840 is the default value.

Security Policies:

None – When checked, a client does not have to provide a certificate to connect to the server, and the communication is not encrypted.

Sign & Encrypt – When checked, a client has to provide a signed certificate to connect to the server, and the communication is encrypted.

Client Options:

Trust All Clients – When this box is checked, the server will trust certificates from clients even if they are not included in the local trust list (which is separately configured and maintained by IT).

Allow Anonymous – Checking this box allows clients to connect to the server without providing credentials. Any client which does this will only have read access granted to them; they will not be able to make any changes on the bioreactor.

Buttons:

Start Server – Starts the server if it is not running.

Stop Server – Stops the server if it is running.

Show Diagnostic Panel – Shows the actual server with the internal nodes populated, address of the server running, etc.

Close – Closes the OPC UA Settings menu.

4. Click "Close."

Email

- The PBS software can send emails for the following reasons:
  - To notify users about alarms
    - The email settings file must be configured for the alarm to be 'Email'
    - Either the Alarm Emailing Snooze Time is 0, or more time has passed since the last alarm of that type was emailed
    - An email is sent to every address in the "Email List" in the triple bar ≡ menu (top right corner) → Email menu
  - To notify users about failed login attempts
    - The user account will receive an email if it has an associated email address
    - All user accounts with the "Account Management" permission and which have an associated email address will receive an email
  - To send report files to users
    - When generating or exporting reports, it is simple to email a copy of the report to the user if the user account has an associated email address

- The network must allow access to an SMTP relay configured in the bioreactor's SMTP Settings menu.

  - Authentication: The system authenticates with the server using the provided sender address and password. If the password is blank, then authentication is not performed.
  - Supported SSL Protocols: The system supports TLS 1.2 and TLS 1.3.
  - Encryption (SSL=True): SSL protocol will be negotiated with the server and rejected if negotiation fails. If the provided port is 465, the connection will be initiated using ImplicitTls. Otherwise, it will be initiated using STARTTLS.
  - When SSL is False, the connection always will be made in plaintext and will not attempt to negotiate encryption.

- Troubleshooting:

  - The PBS Error log may contain additional information regarding errors encountered when configuring SMTP settings.
  - Additional network-level configurations may be necessary to ensure email can be sent.

- Bioreactors are shipped with a default SMTP server configuration using an @pbscustomer.com email specific to the customer.

  - There is an attachment size limit of 35 MB for the default sending email address. Process data reports may be too large to be emailed, depending on the date range.

- SMS and MMS Gateways:
  - Users can receive alarm notifications as text messages, if the configured SMTP server supports SMS or MMS Gateway.
    NOTICE The default SMTP relay provided by PBS Biotech is not guaranteed to support SMS or MMS.
  - This requires entering the user's mobile phone number as an email address using the SMS gateway domain or MMS gateway domain of their mobile carrier. For example, 8055557272@txt.att.net would be used to send a message to an AT&T mobile with number +1 805-555-7272.
  - The Wikipedia "SMS gateway" page has more information, including a list of gateway domains for US and Canadian carriers:
  https://en.wikipedia.org/wiki/SMS_gateway#Email_clients

Backups

- The PBS software has a backup feature, which supports two types of backup:
  - Full Backup: This backs up the Historical Records database, the User Configurations database, and all the configuration files and reports.
  - DB Export: This only backs up the Historical Records database.
- Backups can be scheduled to be performed automatically, or they can be performed manually.
- Backups can be saved to any USB drive or network location accessible as a mountaid volume (drive letter).
  NOTICE PBS Software is only verified to support USB flash drives and network drive locations mapped through the Map Drive feature.
- The "Backup Configuration" permission is required to configure automatic scheduled backups, or to perform manual backups.
- Backing up to a network location:
  - If users desire to back up to a network location, the interface in the Hello UI should be used, by a user account with the "Map Drive" permission. Log in and click the triple bar ≡ menu (top right corner) → Backup menu
  - Users should not configure "net use" directly.

- The network configuration may need to be changed to successfully map a network drive - see "Network Connections" on page 185.

Manually Archiving DBs

The Historical Records database can be manually archived as follows:

1. Make sure the PBS Software is not running. For bioreactors with the GMP configuration, this will require logging in to the 'Admin' Windows account.
2. Remove or rename the database file:
   C:\ProgramData\PBS Biotech\Database\Historical Records.db
   Do not change anything else in the folder.
   NOTICE It is recommended that you back up this file so the data can be accessed in future.
3. Reboot the IPC. When the PBS Software opens, it will see it is missing the database, and it will create a new empty one. An alert will be displayed:

   ```
   Error occurred opening Historical Records database.
   Administrator action needed.
   ```

   To acknowledge the error, click "hide" to close the notification, log in to the Hello UI as any user, and click "dismiss."

Automatic Updates

- LogMeIn
  - LogMeIn is installed on bioreactors with the R&D configuration. It updates itself automatically, provided it has access to the internet.
  - Preventing these automatic updates is not recommended.
- Windows
  Microsoft Service Pack releases and other Windows operating system updates introduce new software that could affect the operation of the system. Updates can cause unexpected behaviors, including automatically restarting the IPC.

  PBS bioreactors prevent updates through the following configurations:
  - Automatic updates are disabled
  - Manual updates through Windows settings are disabled
  - The Windows Update Service is disabled

For more information about Windows Updates or cybersecurity considerations, please contact PBS Biotech Technical Support for assistance.

Settings/System Variables

While all system variable settings can technically be changed by the user, many should remain in their default values unless advised by PBS Biotech Technical Support, or unless the user is confident they know what they are doing. Consult the "User May Change" column to determine which of the following categories each system variable falls into:

X = Should always remain in default value. Do not change unless specifically instructed by PBS Biotech Technical Support.
✓= User may change from default value.
! = Use caution. User must be familiar with bioreactor operations. If in doubt, consult PBS Biotech Technical Support.
N/A = Not applicable for this bioreactor model.

TEMPERATURE

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
P Gain (%/C)	60.000	Proportional Gain for the temperature controller.	!	TempHeatDuty Control.PGain (min)
I Time (min)	20.000	Integral Time for the temperature controller.	!	TempHeatDuty Control.ITime (min)
D Time (min)	0.000	Derivative Time for the temperature controller.	!	TempHeatDuty Control.DTime (min)
Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	TempHeatDuty ControlAlpha
Beta	0.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	TempHeatDuty ControlBeta

TEMPERATURE (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	TempHeatDuty ControlGamma
Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	TempHeatDuty ControlLinearity
Heat Manual Max (%)	100.000	The maximum main heater duty allowed in Manual mode.	!	TempHeatMan Max(%)
Heat Auto Max (%)	100.000	The maximum main heater duty allowed in Auto mode.	!	TempHeatDuty AutoMax(%)
Valid High (C)	110.000	If a temperature sensor registers a measurement above this value, the software assumes the temperature sensor is experiencing an error condition, and triggers a Temperature Sensor Failure (range) Alarm.	!	TempValidMax(C)
Valid Low (C)	-5.000	If a temperature sensor registers a measurement below this value, the software assumes the temperature sensor is experiencing an error condition, and triggers a Temperature Sensor Failure (range) Alarm.	!	TempValidMin(C)

TEMPERATURE (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Mismatch Thresh (C)	0.400	For Vertical-Wheel® Bioreactors with dual temperature sensors, if the sensors register measurements that differ by more than this amount, it triggers a Temperature Mismatch Alarm.	!	TempMismatch Thresh(C)

FILTER OVEN

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
P Gain (%/C)	100.000	Proportional Gain for the filter oven controller.	X	FilterOvenDuty Control.Gain (%/C)
I Time (min)	0.030	Integral Time for the filter oven controller.	X	FilterOvenDuty Control.ITime (min)
D Time (min)	0.000	Derivative Time for the filter oven controller.	X	FilterOvenDuty Control.DTime (min)
Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	FilterOvenDuty ControlAlpha
Beta	1.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	FilterOvenDuty ControlBeta

FILTER OVEN (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	FilterOvenDuty ControlGamma
Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	FilterOvenDuty ControlLinearity
Heat Manual Max (%)	50.000	The maximum filter oven heater duty allowed in Manual mode.	X	FilterOvenDuty RangeManMax (%)
Heat Auto Max (%)	50.000	The maximum filter oven heater duty allowed in Auto mode.	X	FilterOvenDuty RangeAutoMax (%)

AGITATION

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
P Gain (%/RPM)	0.100	Proportional Gain for the agitation controller.	!	AgPower Control.PGain (%/RPM)
I Time (min)	0.010	Integral Time for the agitation controller.	!	AgPower Control.ITime (min)
D Time (min)	0.000	Derivative Time for the agitation controller.	!	AgPower Control.DTime (min)

AGITATION (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	AgControlAlpha
Beta	0.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	AgControlBeta
Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	AgControlGamma
Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	AgControl Linearity
Minimum (RPM)	3.000	If the agitation rate is below this value the software will consider the agitation PV = 0.	!	AgMin(RPM)

AGITATION (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Pulse Mode Timeout (s)	N/A	(N/A for PBS-80) If the software fails to detect agitation in Auto mode for this length of time, it goes into Pulse mode. Should be set equal to the Agitation “Lookup Mode Timeout (s)” setting, to disable Pulse Mode.	N/A	AgPulseMode Timeout(ms)
Lookup Mode Timeout (s)	60.000	If the software fails to detect agitation in Auto mode for this length of time, it goes into Lookup mode.	✓	AgLookupMode Timeout (ms)
Lookup Factor (%/RPM)	2.924	In Lookup mode, the agitation set point is multiplied by this factor to determine the power output to be used.	✓	AgPwrLookup Factor(%/RPM)
Power Auto Max (%)	100.000	The maximum power output allowed in Auto mode while the PV is above 0.	✓	AgPowerRange Auto(%).Max
Power Auto Min (%)	3.500	The minimum power output allowed in Auto mode.	!	AgPowerRange Auto(%).Min
Auto Max Startup (%)	20.000	The maximum power output allowed in Auto mode until the PV is above 0.	!	AgAutoMax Startup(%)
Power Manual Max (%)	100.000	The maximum power output allowed in Manual mode.	✓	AgPowerRange ManMax(%)
Number of Magnets	2.000	The number of magnets on the Vertical-Wheel® impeller.	!	AgWheelMagnet Count

AGITATION (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Samples To Average	3.000	The number of time periods averaged when calculating the agitation.	X	AgWheelSamples ToAverage

pH

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Rate Fail Delta PV	1.000	If the pH changes by more than this value in the pH "Rate Fail Delta Time (s)" time, the software assumes the pH sensor is experiencing an error condition, and triggers a "pH Sensor Failure (rate)" alarm.	✓	pHRateFailDelta PV
Rate Fail Delta Time (s)	60.000	If the pH changes by more than the pH "Rate Fail Delta PV" value in this time, the software assumes the pH sensor is experiencing an error condition, and triggers a "pH Sensor Failure (rate)" alarm.	✓	pHRateFailDelta Time(ms)
CO2 P Gain (%/pH)	-200.000	Proportional Gain for the pH CO_2 controller.	!	pHCO2 Control.PGain(%)
CO2 I Time (min)	10.000	Integral Time for the pH CO_2 controller.	!	pHCO2 Control.ITime (min)
CO2 D Time (min)	0.000	Derivative Time for the pH CO_2 controller.	!	pHCO2 Control.DTime (min)

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
CO2 Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	pHCO2Control Alpha
CO2 Beta	1.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	pHCO2Control Beta
CO2 Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	pHCO2Control Gamma
CO2 Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	pHCO2Control Linearity
CO2 Manual Max (%)	100.000	The maximum CO_2 composition in the main gas flow allowed in Manual mode.	✓	pHCO2ManMax (%)
CO2 Auto Max (%)	30.000	The maximum CO_2 composition in the main gas flow allowed in Auto mode.	✓	pHCO2AutoMax (%)
Base P Gain (%/pH)	10.000	Proportional Gain for the pH base controller.	!	pHBaseDuty Control.PGain(%)

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Base I Time (min)	50.000	Integral Time for the pH base controller.	!	pHBaseDuty Control.ITime (min)
Base D Time (min)	0.000	Derivative Time for the pH base controller.	!	pHBaseDuty Control.DTime (min)
Base Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	pHBaseDuty ControlAlpha
Base Beta	1.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	pHBaseDuty ControlBeta
Base Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	pHBaseDuty ControlGamma
Base Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	pHBaseDuty ControlLinearity
Base Manual Max (%)	100.000	The maximum base pump duty allowed in Manual mode.	✓	pHBaseDutyMan Max(%)

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Base Auto Max (%)	50.000	The maximum base pump duty allowed in Auto mode.	✓	pHBaseAutoMax
A Use Temp Comp?	1.000	Use (1) or do not use (0) a temperature compensation factor for pH sensor A. Must be used for reusable pH sensors, and must not be used for single-use pH sensors.	X	pHAUseTemp Comp
Deadband	0.020	The internal deadband of the pH controller. CO_2 only flows when the pH PV is greater than the pH set point + deadband. Base only flows when the pH PV is less than the pH set point - deadband.	✓	pHDeadband
Valid High (pH)	14.000	If a pH sensor registers a measurement above this value, the software assumes the pH sensor is experiencing an error condition, and triggers a pH Sensor Failure (range) Alarm.	!	pHValidMax
Valid Low (pH)	0.000	If a pH sensor registers a measurement below this value, the software assumes the pH sensor is experiencing an error condition, and triggers a pH Sensor Failure (range) Alarm.	!	pHValidMin

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Samples To Average	10.000	The number of samples used to calculate a moving average of the pH signal. pH is sampled once per second, meaning a value of 10 Samples To Average corresponds to 10 seconds of data. Note: The corresponding global variable for this value is coerced between 1 and 3600 samples (inclusive). Note: Sampling data is reset when this setting is changed. Allow one second per sample (e.g. 10 seconds for 10 Samples To Average) for the setting to fully take effect. Note: This setting does not apply to data displayed in the Hello UI's calibration menu.	!	pHSensor SamplesTo Average

DO

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Valid High (DO%)	200.000	If a DO sensor registers a measurement above this value, the software assumes the DO sensor is experiencing an error condition, and triggers a DO Sensor Failure (range) Alarm.	!	DOValidMax(%)
Valid Low (DO%)	-10.000	If a DO sensor registers a measurement below this value, the software assumes the DO sensor is experiencing an error condition, and triggers a DO Sensor Failure (range) Alarm.	!	DOValidMin(%)
O2 P Gain (%/DO%)		Proportional Gain for the DO O_2 controller.	!	DOO2Control Mag.PGain(%/%)
Overlay:	3.000			
Sparger:	TBD			
O2 I Time (min)		Integral Time for the DO O_2 controller.	!	DOO2Control Mag.ITime(min)
Overlay:	70.000			
Sparger:	TBD			
O2 D Time (min)		Derivative Time for the DO O_2 controller.	!	DOO2Control Mag.DTime(min)
Overlay:	0.000			
Sparger:	TBD			

DO (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
O2 Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	DOO2Control Alpha
O2 Beta	0.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	DOO2Control Beta
O2 Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	DOO2Control Gamma
O2 Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	DOO2Control Linearity
O2 Manual Max (%)	100.000	The maximum O_2 composition in the main gas flow allowed in Manual mode.	✓	DOO2RangeMan Max(%)
O2 Auto Max (%)	100.000	The maximum O_2 composition in the main gas flow allowed in Auto mode.	✓	DOO2RangeAuto Max(%)
N2 P Gain (%/DO%)	-3.000	Proportional Gain for the DO N_2 controller.	!	DON2 Control.PGain (%/%)

DO (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
N2 I Time (min)	70.000	Integral Time for the DO N_2 controller.	!	DON2 Control.ITime (min)
N2 D Time (min)	0.000	Derivative Time for the DO N_2 controller.	!	DON2 Control.DTime (min)
N2 Alpha	-1.000	Specifies the derivative filter time constant. Increasing this value increases damping of derivative action. It can be a value between 0 and 1, or less than 0, which specifies that no derivative filter is applied.	X	DON2Control Alpha
N2 Beta	0.000	Specifies the relative emphasis of set point tracking to disturbance rejection.	X	DON2Control Beta
N2 Gamma	0.000	Specifies an amount by which to weight the error applied to derivative action. A value of 0 avoids derivative kick, which is the sudden change in controller output that can occur after a change in the set point value.	X	DON2Control Gamma
N2 Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	DON2Control Linearity
N2 Manual Max (%)	100.000	The maximum N_2 composition in the main gas flow allowed in Manual mode.	✓	DON2RangeMan Max(%)

DO (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
N2 Auto Max (%)	100.000	The maximum N_2 composition in the main gas flow allowed in Auto mode.	✓	DON2RangeAuto Max(%)
Deadband (DO%)	1.000	The internal deadband of the DO controller. N_2 set point is DO set point + deadband, and O_2 set point is DO set point - deadband.	✓	DODeadband(%)

LEVEL

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Radius (cm)	24.500	The radius of the base of the chamber. This is used in the nonlinear level calculation.	X	LevelCal Cluster.Radius (cm)
Empty Level (V)	0.000	If the level sensor is below this voltage, the system recognizes the level PV = 0.	!	LevelCal Cluster.Level Empty(V)
Empty Level (L)	8.000	If the level PV is below this value, the software recognizes the level PV = 0.	!	LevelCal Cluster.Level Empty(L)
cm/psi	70.358	The conversion from the pressure the level sensor reports to the height of the liquid. This is used in the nonlinear level calculation.	!	LevelCal Cluster.Cm/psi
Vessel Depth (cm)	26.000	The distance from the back of the chamber to the door. This is used in the nonlinear level calculation.	X	LevelCal Cluster.Depth

LEVEL (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Bottom Gap (cm)	0.000	Gap at the bottom of the chamber unaccounted for by the level sensor.	X	LevelCal Cluster.Bottom Gap (cm)
Enable Sensor (0 or 1)	1.000	If the level sensor is enabled (1), the “Level” box is displayed in the dashboard and all level-related interlocks are in place. Disabled (0), there is no “Level” box in the dashboard, and no level-related interlocks.	✓	LevelSensor Enable
CalLevelSlope Max(psi/V)	10000	The maximum level slope value allowed during calibration.	!	CalLimits Level.CalLevel SlopeMax(psi/V)
CalLevelSlope Min(psi/V)	-10000	The minimum level slope value allowed during calibration.	!	CalLimits Level.CalLevel SlopeMin(psi/V)
CalLevel InterceptMax (psi)	10000	The maximum level intercept value allowed during calibration.	!	CalLimits Level.CalLevel InterceptMax(psi)
CalLevel InterceptMin (psi)	-10000	The minimum level intercept value allowed during calibration.	!	CalLimits Level.CalLevel InterceptMin(psi)

PRESSURE

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Disconnected Pressure (V)	1.000	If the absolute value of the voltage associated with pressure PV is greater than the disconnected pressure voltage, the software recognizes the pressure sensor is disconnected.	X	Pressure Disconnected(V)
CalPressure InterceptMax (psi)	1.500	The maximum pressure intercept value allowed during calibration.	!	CalLimits Pressure.Cal PressureIntercept Max(psi)
CalPressure InterceptMin (psi)	-1.500	The minimum pressure intercept value allowed during calibration.	!	CalLimits Pressure.Cal PressureIntercept Min(psi)
CalPressure SlopeMax (psi/V)	250.000	The maximum pressure slope value allowed during calibration.	!	CalLimits Pressure.Cal PressureSlope Max(psi/V)
CalPressure SlopeMin (psi/V)	150.000	The minimum pressure slope value allowed during calibration.	!	CalLimits Pressure.Cal PressureSlope Min(psi/V)
Reusable Sensor (0 or 1)	1.000	Tells the software what kind of pressure sensor is used on the bioreactor.	X	Reusable Sensor (0 or 1)

GAS DATA

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
CO2 Min (LPM)	0.080	This corresponds to the shutoff flowrate of the CO_2 MFC - the MFC cannot flow reliably below this rate. Any requested flows below this will be delivered by the software as time metered pulses at this flow rate.	X	MFCCO2Min (LPM)
CO2 Off (V)	0.000	This is the voltage sent to the CO_2 MFC when no gas flow is being requested.	X	MFCCO2Off(V)
N2 Min (LPM)	0.250	This corresponds to the shutoff flowrate of the N_2 MFC - the MFC cannot flow reliably below this rate. Any requested flows below this will be delivered by the software as time metered pulses at this flow rate.	X	MFCN2Min(LPM)
N2 Off (V)	0.000	This is the voltage sent to the N_2 MFC when no gas flow is being requested.	X	MFCN2Off(V)
Air Min (LPM)	0.250	This corresponds to the shutoff flowrate of the Air MFC - the MFC cannot flow reliably below this rate. Any requested flows below this will be delivered by the software as time metered pulses at this flow rate.	X	MFCAirMin(LPM)

GAS DATA (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Air Off (V)	0.000	This is the voltage sent to the Air MFC when no gas flow is being requested.	X	MFCAirOff(V)
O2 Min (LPM)	0.300	This corresponds to the shutoff flowrate of the O_2 MFC - the MFC cannot flow reliably below this rate. Any requested flows below this will be delivered by the software as time metered pulses at this flow rate.	X	MFCO2Min(LPM)
O2 Off (V)	0.000	This is the voltage sent to the O_2 MFC when no gas flow is being requested.	X	MFCO2Off(V)
PWM On Time (s)	10.000	Pulse Width Modulation On Time of the MFCs.	!	MFCOnTime(s)
PWM Max Period (s)	500.000	Maximum Pulse Width Modulation Period of the MFCs (period may be smaller, depending on pulsing called for and Gas Data “PWM On Time (s)” setting.	!	MFCMaxPeriod (s)
Mismatch Thresh (V)	0.100	If the voltage the software requests the MFC to deliver is different from the actual voltage the MFC delivers by this value or more, it triggers a Source Pressure Error Alarm.	✓	MFCMismatch Thresh(V)

GAS DATA (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
O2 Min Volume (L)	0.060	O_2 cannot flow above the MFC's minimum until at least this much net volume of O_2 has flowed since turning DO on. This is known as the "O_2 Slow Start" feature.	!	O2 Min Volume (L)
Manual Max (LPM)	10.000	The maximum main gas flow allowed in Manual mode.	✓	MainGasRange ManMax(LPM)

SAFETY

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Min Ag Power (%)	10.000	If the agitation PV = 0 but the power output to the agitation motor is greater than this value, the software will assume the agitation sensor is experiencing an error condition, and will not interlock the main heater.	X	AgMinPower(%)
Max Temp (C)	45.000	The main heater will be interlocked if temperature PV exceeds this temperature.	✓	InterlockTemp Max(C)
Max Pressure (psi)	0.500	The software will stop gas flow and pump activity if the pressure PV exceeds this pressure.	X	InterlockPressure Max(psi)
Max Pressure Door (psi)	0.100	The software will not allow the door to be unlocked if pressure PV exceeds this pressure.	X	InterlockDoor PressureMax(psi)

SAFETY (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Min Level (L)	10.000	The minimum level below which the temperature controller will be interlocked to avoid heating an empty bag or heating in the absence of a bag.	X	LevelMin(L)
Max Level (L)	85.000	The maximum level, above which the temperature controller will be interlocked to avoid heating an overfilled bag. Additionally, pumps will be interlocked to avoid overfilling.	X	LevelMax(L)
Buzzer Period (ms)	100.000	This value affects the quality of sound of the alarm buzzer.	✓	AlarmBuzzer Period(Cycle)
DoorPressure Sensor (0 or 1)	0.000	Tells the software the bioreactor has a door pressure sensor.	X	DoorPressure Sensor

PUMPS

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Aux Low Duty sbRIO* 9641 or 9642: sbRIO* 9603:	 20000 30000	At "Slow" speed, a small addition pump will give this many "on" pulses out of 2^{16}, or 65,536 pulses in total.	✓	Pumps&Valves PumpLowAux Speed
Aux Med Duty sbRIO* 9641 or 9642: sbRIO* 9603:	 30000 52000	At "Medium" speed, a small addition pump will give this many "on" pulses out of 2^{16}, or 65,536 pulses in total.	✓	Pumps&Valves PumpMedAux Speed
Base On Time (s)	0.100	The base pump turns on in increments of this number.	!	Pumps&Valves BaseOnTime(s)
Base Max Period (s)	240.000	Maximum base pump period (period may be smaller, depending on base pump duty called for and Pumps "Base On Time (s)" setting.	!	Pumps&Valves BaseMaxPeriod (s)
Sample Reverse CW and CCW (0 or 1)	0.000	This value affects the rotation direction of the sample motor.	X	Pumps&Valves ReverseCCand CW

* The sbRIO model is displayed in the Hello UI About menu.

PROCESS ALARMS

These values are meant to be user configurable and used as process deviation alarms. If the PVs exceed the values, alarm events will be triggered.

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Agitation Low Low (RPM)	7.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Agitation Low Low (RPM)
Agitation Low (RPM)	9.000	If the PV is below this value, the alarm state is "warning."	✓	Limits.Agitation Low (RPM)
Agitation High (RPM)	18.000	If the PV is above this value, the alarm state is "warning."	✓	Limits.Agitation High (RPM)

PROCESS ALARMS (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Agitation High High (RPM)	20.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Agitation High High (RPM)
Temp Low Low (C)	35.000	If the PV is below this value, the alarm state is “error.”	✓	Limits.Temp Low Low (C)
Temp Low (C)	36.000	If the PV is below this value, the alarm state is “warning.”	✓	Limits.Temp Low (C)
Temp High (C)	38.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Temp High (C)
Temp High High (C)	39.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Temp High High (C)
DO Low Low (%)	30.000	If the PV is below this value, the alarm state is “error.”	✓	Limits.DO Low Low (%)
DO Low (%)	40.000	If the PV is below this value, the alarm state is “warning.”	✓	Limits.DO Low (%)
DO High (%)	60.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.DO High (%)
DO High High (%)	70.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.DO High High (%)
pH Low Low	7.100	If the PV is below this value, the alarm state is “error.”	✓	Limits.pH Low Low
pH Low	7.150	If the PV is below this value, the alarm state is “warning.”	✓	Limits.pH Low
pH High	7.250	If the PV is above this value, the alarm state is “warning.”	✓	Limits.pH High
pH High High	7.300	If the PV is above this value, the alarm state is “warning.”	✓	Limits.pH High High

PROCESS ALARMS (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Pressure Low Low (psi)	-1.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Pressure Low Low (psi)
Pressure Low (psi)	-0.500	If the PV is below this value, the alarm state is "warning."	✓	Limits.Pressure Low (psi)
Pressure High (psi)	0.200	If the PV is above this value, the alarm state is "warning."	✓	Limits.Pressure High (psi)
Pressure High High (psi)	0.300	If the PV is above this value, the alarm state is "warning."	✓	Limits.Pressure High High (psi)
Level Low Low (L)	10.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Level Low Low (L)
Level Low (L)	35.000	If the PV is below this value, the alarm state is "warning."	✓	Limits.Level Low (L)
Level High (L)	80.000	If the PV is above this value, the alarm state is "warning."	✓	Limits.Level High (L)
Level High High (L)	85.000	If the PV is above this value, the alarm state is "warning."	✓	Limits.Level High High (L)
Filter Oven Low Low (C)	33.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Filter Oven Low Low (C)
Filter Oven Low (C)	35.000	If the PV is below this value, the alarm state is "warning."	✓	Limits.Filter Oven Low (C)
Filter Oven High (C)	41.000	If the PV is above this value, the alarm state is "warning."	✓	Limits.Filter Oven High (C)
Filter Oven High High (C)	43.000	If the PV is above this value, the alarm state is "warning."	✓	Limits.Filter Oven High High (C)
Main Gas Low Low (LPM)	1.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Main Gas Low Low (LPM)

PROCESS ALARMS (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Main Gas Low (LPM)	2.000	If the PV is below this value, the alarm state is “warning.”	✓	Limits.Main Gas Low (LPM)
Main Gas High (LPM)	8.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Main Gas High (LPM)
Main Gas High High (LPM)	9.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Main Gas High High (LPM)

SYSTEM

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Max Data Log Interval (min)	60.000	This is the maximum time that will elapse between the logging of two subsequent timepoints of a logged variable. This is in addition to the logging by deadband as configured in the logger settings file.	✓	LoggerMaxLog Interval(ms)
Alarm Snooze Time (s)	300.000	If a Process Alarm is audible, acknowledging the alarm will silence the buzzer for the given period of time.	✓	AlarmSnooze Time(ms)
Available Mem Limit (KB)	2000	If available memory on the RIO computer is less than this value, the “RT Mem Nearly Full” alarm is triggered.	X	SysAvailableMem Limit(KB)
LCB Mem Limit (KB)	2000	If available LCB on the RIO is less than this value, the “RT Mem Fragmented” alarm is triggered.	X	SysLCBMemLimit (KB)

Alarms Definitions

Group	Alarm Name	Alarm is Triggered When:
Agitation	Agitation Low Low	Agitation PV drops below this value.
Agitation	Agitation Low	Agitation PV drops below this value.
Agitation	Agitation High	Agitation PV rises above this value.
Agitation	Agitation High High	Agitation PV rises above this value.
Temperature	Temperature Low Low	Temperature PV drops below this value.
Temperature	Temperature Low	Temperature PV drops below this value.
Temperature	Temperature High	Temperature PV rises above this value.
Temperature	Temperature High High	Temperature PV rises above this value.
DO	DO Low Low	DO PV drops below this value.
DO	DO Low	DO PV drops below this value.
DO	DO High	DO PV rises above this value.
DO	DO High High	DO PV rises above this value.
pH	pH Low Low	pH PV drops below this value.
pH	pH Low	pH PV drops below this value.
pH	pH High	pH PV rises above this value.
pH	pH High High	pH PV rises above this value.
Pressure	Pressure Low Low	Pressure PV drops below this value.
Pressure	Pressure Low	Pressure PV drops below this value.
Pressure	Pressure High	Pressure PV rises above this value.
Pressure	Pressure High High	Pressure PV rises above this value.
Level	Level Low Low	Level PV drops below this value.
Level	Level Low	Level PV drops below this value.
Level	Level High	Level PV rises above this value.
Level	Level High High	Level PV rises above this value.
Filter Oven	Filter Oven Low Low	Filter oven temperature PV drops below this value.

Group	Alarm Name	Alarm is Triggered When:
Filter Oven	Filter Oven Low	Filter oven temperature PV drops below this value.
Filter Oven	Filter Oven High	Filter oven temperature PV rises above this value.
Filter Oven	Filter Oven High High	Filter oven temperature PV rises above this value.
Main Gas	Main Gas Low Low	Main gas flow drops below this value.
Main Gas	Main Gas Low	Main gas flow drops below this value.
Main Gas	Main Gas High	Main gas flow rises above this value.
Main Gas	Main Gas High High	Main gas flow rises above this value.
System	Leak Detected	The leak sensor detects a leak.
System	Sequence Resumed	The RIO lost power while a sequence was running, and attempted to restart the sequence when it booted up.
Temperature	Temperature Sensor Mismatch	The temperature sensors register measurements that differ by more than the Temperature “Mismatch Thresh (C)” setting.
Gas Flow	Air Source Pressure Error	The voltage corresponding to the flow rate being delivered by the Air MFC differs from the voltage corresponding to the flow rate being requested of the Air MFC by the Gas Data “Mismatch Thresh (V)” setting. Usually caused by a tank being empty, but could also be from the source pressure being too high.
Gas Flow	CO2 Source Pressure Error	The voltage corresponding to the flow rate being delivered by the CO_2 MFC differs from the voltage corresponding to the flow rate being requested of the CO_2 MFC by the Gas Data “Mismatch Thresh (V)” setting. Usually caused by a tank being empty, but could also be from the source pressure being too high.
Gas Flow	N2 Source Pressure Error	The voltage corresponding to the flow rate being delivered by the N_2 MFC differs from the voltage corresponding to the flow rate being requested of the N_2 MFC by the Gas Data “Mismatch Thresh (V)” setting. Usually caused by a tank being empty, but could also be from the source pressure being too high.

Group	Alarm Name	Alarm is Triggered When:
Gas Flow	O2 Source Pressure Error	The voltage corresponding to the flow rate being delivered by the O_2 MFC differs from the voltage corresponding to the flow rate being requested of the O_2 MFC by the Gas Data “Mismatch Thresh (V)” setting. Usually caused by a tank being empty, but could also be from the source pressure being too high.
Agitation	Agitation Sensor Failure	The agitation motor is being powered but agitation PV = 0 RPM.
Temperature	Temp Sensor A Failure (range)	Temperature sensor A registers a measurement above the Temperature “Valid High (C)” or below the Temperature “Valid Low (C)” settings.
Temperature	Temp Sensor B Failure (range)	Temperature sensor B registers a measurement above the Temperature “Valid High (C)” or below the Temperature “Valid Low (C)” settings.
Temperature	Temp Dual Sensor Failure	Both temperature sensors register range failures.
DO	DO Sensor A Failure (range)	DO sensor A registers a measurement above the DO “Valid High (DO%)” or below the DO “Valid Low (DO%)” settings.
pH	pH Sensor A Failure (range)	pH sensor A registers a measurement above the pH “Valid High (pH)” or below the pH “Valid Low (pH)” settings.
pH	pH Sensor A Failure (rate)	pH sensor A registers a change in measurements greater than or equal to the pH “Rate Fail Delta PV” value over the pH “Rate Fail Delta Time (s)” time period.
Pressure	Pressure Sensor Disconnected	The absolute value of the raw voltage associated with the pressure PV is greater than or equal to the Pressure “Disconnected Pressure (V)” setting. Also triggered when the Pressure “Reusable Sensor (0 or 1)” setting is 1 (default for PBS-80) and the software detects that the pressure sensing line is disconnected.
Pressure	Comb Plate Popped	The bag has pressurized enough to lift the comb plate.

Group	Alarm Name	Alarm is Triggered When:
System	Dirty Startup	RIO was restarted using a method other than through the Hello UI (usually just unplugging the bioreactor), and there was a problem recovering the last user-selected modes, set points etc. If this alarm was triggered, generate an errors report spanning the time this alarm was generated for more detailed information.
System	Clean Startup	RIO was restarted through the Hello UI.
System	Resume	RIO was restarted using a method other than through the Hello UI (usually just unplugging the bioreactor), but the last user-selected modes, set points etc. were recovered with no problems.
System	RT Mem Fragmented*	The largest contiguous block (LCB) of memory on the RIO computer is less than the System “LCB Mem Limit (KB)”.
System	RT Mem Nearly Full	The available memory on the RIO computer is less than the System “Available Mem Limit (KB)”.
Hardware Fault	NI 9205 Error*	Analog Input errors reading MFCs, DO, and pH.
Hardware Fault	NI 9425 Onboard Error	Digital Input errors reading leak sensor, pressure sensor connected, Door Pressure sensor (N/A on PBS-80), fuses, and RPM sensor. Digital Output errors writing to motor brake, media pump, and RTOS Run Status light.
Hardware Fault	NI 9219 Error	Error reading 9219 board (analog inputs for pressure sensor, load cell (N/A on PBS-80), and temperature sensors).
Hardware Fault	NI 9476 Error	Digital Output errors writing to temperature and filter oven heaters, door unlock, buzzer, sample pump, media pump, LED, addition pump A, addition pump B, and PBS 3 MAG agitation motor.
Hardware Fault	NI 9263 Error	Analog Output errors writing to pumps with RPM input, and to agitation motors other than for the PBS-3.
Hardware Fault	12 Vdc Atom Fuse*	This fuse needs to be replaced.

Group	Alarm Name	Alarm is Triggered When:
Hardware Fault	12 Vdc Mezz Fuse*	This fuse needs to be replaced.
Hardware Fault	12 Vdc Mntr Fuse*	This fuse needs to be replaced.
Hardware Fault	12 Vdc User1 Fuse*	This fuse needs to be replaced.
Hardware Fault	12 Vdc User2 Fuse	This fuse needs to be replaced.
Hardware Fault	12 Vdc User3 Fuse	This fuse needs to be replaced.
Hardware Fault	24 Vdc Fill Pump Fuse	This fuse needs to be replaced.
Hardware Fault	24 Vdc Ind DO Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc Main Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc Mezz Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc MFC Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc sbRIO Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc User1 Fuse*	This fuse needs to be replaced.
Hardware Fault	24 Vdc User2 Fuse	This fuse needs to be replaced.
Hardware Fault	24 Vdc User3 Fuse	This fuse needs to be replaced.
Hardware Fault	12 Vdc Supply Fuse†	This fuse needs to be replaced.
Hardware Fault	24 Vdc Supply Fuse†	This fuse needs to be replaced.
Hardware Fault	Pump Supply Fuse†	This fuse needs to be replaced.

Group	Alarm Name	Alarm is Triggered When:
Hardware Fault	24 Vdc Ctrl Main Fuse†	This fuse needs to be replaced.

* These alarms are only applicable to bioreactors with sbRIO model 9641 or 9642 (as visible in the Hello UI About menu). If these alarms are not applicable to your bioreactor, they will not appear in the Alarms Editor.

† These alarms are only applicable to bioreactors with sbRIO model 9603 (as visible in the Hello UI About menu). If these alarms are not applicable to your bioreactor, they will not appear in the Alarms Editor.

Default Alarms Configurations

The PBS-80 comes with two default Alarms.alm files on the HMI. PBS Biotech Technical Support recommends loading the Alarms Inactive.alm file when you are not running a process, and before storing. It is configured to not notify about the alarms which would otherwise be triggered. PBS Biotech Technical Support recommends loading the Alarms On.alm file during a run. For more information, see “Configuring Alarm Settings” on page 57.

Group	Alarm Name	Alarms Inactive			Alarms On		
		Notify	Audible	Email	Notify	Audible	Email
Agitation	Agitation Low Low				✓	✓	✓
Agitation	Agitation Low				✓		
Agitation	Agitation High				✓		
Agitation	Agitation High High				✓	✓	✓
Temperature	Temperature Low Low				✓	✓	✓
Temperature	Temperature Low				✓		
Temperature	Temperature High	✓			✓		
Temperature	Temperature High High	✓		✓	✓	✓	✓
DO	DO Low Low				✓	✓	✓
DO	DO Low				✓		
DO	DO High				✓		
DO	DO High High				✓	✓	✓
pH	pH Low Low				✓	✓	✓
pH	pH Low				✓		
pH	pH High				✓		
pH	pH High High				✓	✓	✓
Pressure	Pressure Low Low			✓	✓	✓	✓
Pressure	Pressure Low				✓		
Pressure	Pressure High				✓		

Group	Alarm Name	Alarms Inactive			Alarms On		
		Notify	Audible	Email	Notify	Audible	Email
Pressure	Pressure High High			✓	✓	✓	✓
Level	Level Low Low				✓	✓	✓
Level	Level Low				✓		
Level	Level High				✓		
Level	Level High High				✓	✓	✓
Filter Oven	Filter Oven Low Low				✓	✓	✓
Filter Oven	Filter Oven Low				✓		
Filter Oven	Filter Oven High	✓			✓		
Filter Oven	Filter Oven High High	✓			✓	✓	
Main Gas	Main Gas Low Low				✓	✓	✓
Main Gas	Main Gas Low				✓		
Main Gas	Main Gas High	✓			✓		
Main Gas	Main Gas High High	✓		✓	✓	✓	✓
System	Leak Detected	✓	✓	✓	✓	✓	✓
System	Sequence Resumed	✓		✓	✓		✓
Temperature	Temperature Sensor Mismatch			✓	✓	✓	✓
Gas Flow	Air Source Pressure Error	✓		✓	✓	✓	✓
Gas Flow	CO2 Source Pressure Error	✓		✓	✓	✓	✓
Gas Flow	N2 Source Pressure Error	✓		✓	✓	✓	✓

Group	Alarm Name	Alarms Inactive			Alarms On		
		Notify	Audible	Email	Notify	Audible	Email
Gas Flow	O2 Source Pressure Error	✓		✓	✓	✓	✓
Agitation	Agitation Sensor Failure	✓		✓	✓	✓	✓
Temperature	Temp Sensor A Failure (range)	✓		✓	✓	✓	✓
Temperature	Temp Sensor B Failure (range)	✓		✓	✓	✓	✓
Temperature	Temp Dual Sensor Failure	✓		✓	✓	✓	✓
DO	DO Sensor A Failure (range)				✓	✓	✓
pH	pH Sensor A Failure (range)				✓	✓	✓
pH	pH Sensor A Failure (rate)				✓	✓	✓
Pressure	Pressure Sensor Disconnected			✓	✓	✓	✓
Pressure	Comb Plate Popped	✓		✓	✓		✓
System	Dirty Startup	✓			✓		
System	Clean Startup	✓			✓		
System	Resume	✓			✓		
System	RT Mem Fragmented*	✓		✓	✓		✓
System	RT Mem Nearly Full	✓		✓	✓		✓
Hardware Fault	NI 9205 Error*	✓		✓	✓		✓
Hardware Fault	NI 9425 Onboard Error	✓		✓	✓		✓
Hardware Fault	NI 9219 Error	✓		✓	✓		✓
Hardware Fault	NI 9476 Error	✓		✓	✓		✓
Hardware Fault	NI 9263 Error	✓		✓	✓	✓	✓

Group	Alarm Name	Alarms Inactive			Alarms On		
		Notify	Audible	Email	Notify	Audible	Email
Hardware Fault	12 Vdc Atom Fuse*	✓			✓		
Hardware Fault	12 Vdc Mezz Fuse*	✓			✓		
Hardware Fault	12 Vdc Mntr Fuse*	✓			✓		
Hardware Fault	12 Vdc User1 Fuse*	✓			✓		
Hardware Fault	12 Vdc User2 Fuse	✓			✓		
Hardware Fault	12 Vdc User3 Fuse	✓			✓		
Hardware Fault	24 Vdc Fill Pump Fuse	✓			✓		
Hardware Fault	24 Vdc Ind DO Fuse*	✓			✓		
Hardware Fault	24 Vdc Main Fuse*	✓			✓		
Hardware Fault	24 Vdc Mezz Fuse*	✓			✓		
Hardware Fault	24 Vdc MFC Fuse*	✓			✓		
Hardware Fault	24 Vdc sbRIO Fuse*	✓			✓		
Hardware Fault	24 Vdc User1 Fuse*	✓			✓		
Hardware Fault	24 Vdc User2 Fuse	✓			✓		
Hardware Fault	24 Vdc User3 Fuse	✓			✓		
Hardware Fault	12 Vdc Supply Fuse†	✓			✓		
Hardware Fault	24 Vdc Supply Fuse†	✓			✓		

Group	Alarm Name	Alarms Inactive			Alarms On		
		Notify	Audible	Email	Notify	Audible	Email
Hardware Fault	Pump Supply Fuse†	✓			✓		
Hardware Fault	24 Vdc Ctrl Main Fuse†	✓			✓		

* These alarms are only applicable to bioreactors with sbRIO model 9641 or 9642 (as visible in the Hello UI About menu). If these alarms are not applicable to your bioreactor, they will not appear in the Alarms Editor.

† These alarms are only applicable to bioreactors with sbRIO model 9603 (as visible in the Hello UI About menu). If these alarms are not applicable to your bioreactor, they will not appear in the Alarms Editor.

Default Logger Configurations and Global Variables Definitions

The PBS-80 ships with a default Logger file loaded. For more information, see “Configuring Logger Settings” on page 54.

AGITATION

Variable Name	Default Deadband	Default Record	Source	Definition
AgPV(RPM)	0.500	✓	Calc	The speed of the wheel detected by the software.
AgSP(RPM)	0.500	✓	User	The last agitation set point used when agitation was in Auto mode.
AgPowerUser(%)	0.100	✓	User	The last user-defined power output used when agitation was in Manual mode.
AgModeActual	0.500	✓	Calc	The actual agitation mode: 0) Auto, 1) Manual, 2) Off, 3) Lookup, and 4) Pulse.
AgModeUser	0.500		User	The user-requested agitation mode: 0) Auto, 1) Manual, and 2) Off.
AgPowerActualRequest(%)	2.000	✓	Calc	The % power being sent to the agitation motor.
AgPowerControl.PGain (%/RPM)	0.010		System	See Agitation “P Gain (%/RPM)” setting in Appendix 1.
AgPowerControl.ITime (min)	0.010		System	See Agitation “I Time (min)” setting in Appendix 1.
AgPowerControl.DTime (min)	0.010		System	See Agitation “D Time (min)” setting in Appendix 1.
AgControlAlpha	0.001		System	See Agitation “Alpha” setting in Appendix 1.
AgControlBeta	0.001		System	See Agitation “Beta” setting in Appendix 1.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AgControlGamma	0.001		System	See Agitation “Gamma” setting in Appendix 1.
AgControlLinearity	0.001		System	See Agitation “Linearity” setting in Appendix 1.
AgAutoMaxStartup(%)	0.001		System	See Agitation “Auto Max Startup (%)” setting in Appendix 1.
AgLookupModeTimeout (ms)	0.001		System	See Agitation “Lookup Mode Timeout (s)” setting in Appendix 1.
AgMin(RPM)	0.001		System	See Agitation “Minimum (RPM)” setting in Appendix 1.
AgMinPower(%)	0.001		System	See Safety “Min Ag Power (%)” setting in Appendix 1.
AgPowerRangeAuto (%).Max	0.010		System	See Agitation “Power Auto Max (%)” setting in Appendix 1.
AgPowerRangeAuto (%).Min	0.010		System	See Agitation “Power Auto Min (%)” setting in Appendix 1.
AgPowerRangeManMax (%)	0.010		System	See Agitation “Power Manual Max (%)” setting in Appendix 1.
AgPulseModeTimeout(ms)	1.000		System	See Agitation “Pulse Mode Timeout (s)” setting in Appendix 1.
AgPwrLookupFactor (%/RPM)	0.001		System	See Agitation “Lookup Factor (%/RPM)” setting in Appendix 1.
AgWheelMagnetCount	0.500		System	See Agitation “Number of Magnets” setting in Appendix 1.
AgWheelSamplesTo Average	0.500		System	See Agitation “Samples To Average” setting in Appendix 1.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
HarvestDelay(s)	0.001	✓	System	For PBS Bioreactors size 15 and higher, when aligning the wheel for harvest, this is the number of seconds to continue turning the wheel after the agitation sensor senses a magnet pass.
HarvestMode	0.500	✓	User	For PBS Bioreactors size 15 and higher, 0) not in Harvest mode, 1) ramping down agitation, 2) aligning the wheel, or 3) harvesting. For other models, this variable should not be modified via recipe.
HarvestTimeout	0.500	✓	Calc	For PBS Bioreactors size 15 and higher, true if while aligning the wheel for harvest, the sensor has not detected a magnet pass in 20 seconds for PBS-15, or 40 seconds for PBS-80.

ALARM

Variable Name	Default Deadband	Default Record	Source	Definition
AlarmBuzzerUser	0.500		User	True when the user wants to test the buzzer.
AlarmBuzzerPeriod(Cycle)	10.000		System	See Safety “Buzzer Period (ms)” setting in Appendix 1.
AlarmFuseStatus	0.500		Sensor	Status of the fuses – when the number is above zero it means at least 1 fuse is blown.

ALARM (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AlarmLeak	0.500		Sensor	True when the software detects a leak.
AlarmSnoozeTime(ms)	1.000		System	See System "Alarm Snooze Time (s)" setting in Appendix 1.
Alm_CombPlate	0.500		Sensor	For PBS Vertical-Wheel® Bioreactors with a comb plate, true when the comb plate has popped up.

PROCESS ALARMS/LIMITS

Variable Name	Default Deadband	Default Record	Source	Definition
SensorStates.Agitation	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) Sensor Error Mode.
SensorStates.DO	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) Sensor Error Mode.
SensorStates.Filter Oven	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) Sensor Error Mode.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
SensorStates.Level	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low.
SensorStates.Main Gas	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low.
SensorStates.Pressure	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low.
SensorStates.Temperature	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) Sensor Error Mode.
SensorStates.pH	0.500		Calc	The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) Sensor Error Mode.
Limits.Agitation Low Low (RPM)	0.001		System	See Process Alarms “Agitation Low Low (RPM)” setting in Appendix 1.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Limits.Agitation Low (RPM)	0.001		System	See Process Alarms "Agitation Low (RPM)" setting in Appendix 1.
Limits.Agitation High (RPM)	0.001		System	See Process Alarms "Agitation High (RPM)" setting in Appendix 1.
Limits.Agitation High High (RPM)	0.001		System	See Process Alarms "Agitation High High (RPM)" setting in Appendix 1.
Limits.DO Low Low (%)	0.001		System	See Process Alarms "DO Low Low (%)" setting in Appendix 1.
Limits.DO Low (%)	0.001		System	See Process Alarms "DO Low (%)" setting in Appendix 1.
Limits.DO High (%)	0.001		System	See Process Alarms "DO High (%)" setting in Appendix 1.
Limits.DO High High (%)	0.001		System	See Process Alarms "DO High High (%)" setting in Appendix 1.
Limits.Filter Oven Low Low (C)	0.001		System	See Process Alarms "Filter Oven Low Low (C)" setting in Appendix 1.
Limits.Filter Oven Low (C)	0.001		System	See Process Alarms "Filter Oven Low (C)" setting in Appendix 1.
Limits.Filter Oven High (C)	0.001		System	See Process Alarms "Filter Oven High (C)" setting in Appendix 1.
Limits.Filter Oven High High (C)	0.001		System	See Process Alarms "Filter Oven High High (C)" setting in Appendix 1.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Limits.Level Low Low (L)	0.001		System	See Process Alarms "Level Low Low (L)" setting in Appendix 1.
Limits.Level Low (L)	0.001		System	See Process Alarms "Level Low (L)" setting in Appendix 1.
Limits.Level High (L)	0.001		System	See Process Alarms "Level High (L)" setting in Appendix 1.
Limits.Level High High (L)	0.001		System	See Process Alarms "Level High High (L)" setting in Appendix 1.
Limits.Main Gas Low Low (LPM)	0.001		System	See Process Alarms "Main Gas Low Low (LPM)" setting in Appendix 1.
Limits.Main Gas Low (LPM)	0.001		System	See Process Alarms "Main Gas Low (LPM)" setting in Appendix 1.
Limits.Main Gas High (LPM)	0.001		System	See Process Alarms "Main Gas High (LPM)" setting in Appendix 1.
Limits.Main Gas High High (LPM)	0.001		System	See Process Alarms "Main Gas High High (LPM)" setting in Appendix 1.
Limits.Pressure Low Low (psi)	0.001		System	See Process Alarms "Pressure Low Low (psi)" setting in Appendix 1.
Limits.Pressure Low (psi)	0.001		System	See Process Alarms "Pressure Low (psi)" setting in Appendix 1.
Limits.Pressure High (psi)	0.001		System	See Process Alarms "Pressure High (psi)" setting in Appendix 1.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Limits.Pressure High High (psi)	0.001		System	See Process Alarms “Pressure High High (psi)” setting in Appendix 1.
Limits.Temp Low Low (C)	0.001		System	See Process Alarms “Temp Low Low (C)” setting in Appendix 1.
Limits.Temp Low (C)	0.001		System	See Process Alarms “Temp Low (C)” setting in Appendix 1.
Limits.Temp High (C)	0.001		System	See Process Alarms “Temp High (C)” setting in Appendix 1.
Limits.Temp High High (C)	0.001		System	See Process Alarms “Temp High High (C)” setting in Appendix 1.
Limits.pH Low Low	0.001		System	See Process Alarms “pH Low Low” setting in Appendix 1.
Limits.pH Low	0.001		System	See Process Alarms “pH Low” setting in Appendix 1.
Limits.pH High	0.001		System	See Process Alarms “pH High” setting in Appendix 1.
Limits.pH High High	0.001		System	See Process Alarms “pH High High” setting in Appendix 1.

CALIBRATION

Variable Name	Default Deadband	Default Record	Source	Definition
CalpHA.Slope	0.010		System	The slope of the raw voltage to pH sensor A PV conversion.
CalpHA.Offset(%)	0.010		System	The offset of the raw voltage to pH sensor A PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalpHA.Temp(C)	0.010		System	The temperature at which pH sensor A was calibrated.
CalDOA.Slope	0.010		System	The slope of the raw voltage to DO sensor A PV conversion.
CalDOA.Offset(%)	0.010		System	The offset of the raw voltage to DO sensor A PV conversion.
CalLevel.m	0.010		System	The slope of the raw voltage to level PV conversion.
CalLevel.b	0.010		System	The offset of the raw voltage to level PV conversion.
CalTempA.Slope	0.010		System	The slope of the raw resistance to temperature sensor A PV conversion.
CalTempA.Offset(C)	0.010		System	The offset of the raw resistance to temperature sensor A PV conversion.
CalTempB.Slope	0.010		System	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the slope of the raw resistance to temperature sensor B PV conversion.
CalTempB.Offset(C)	0.010		System	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the offset of the raw resistance to temperature sensor B PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalFilterOvenTemp.Slope	0.010		System	The slope of the raw resistance to filter oven temperature PV conversion.
CalFilterOvenTemp.Offset (C)	0.010		System	The offset for the raw resistance to filter oven temperature PV conversion.
CalMFCAir.m(LPM/V)	0.001		System	The slope of the raw voltage to Air flow (LPM) output conversion.
CalMFCAir.b(LPM)	0.001		System	The offset of the raw voltage to Air flow (LPM) output conversion.
CalMFCCO2.m(LPM/V)	0.001		System	The slope of the raw voltage to CO_2 flow (LPM) output conversion.
CalMFCCO2.b(LPM)	0.001		System	The offset of the raw voltage to CO_2 flow (LPM) output conversion.
CalMFCN2.m(LPM/V)	0.001		System	The slope of the raw voltage to N_2 flow (LPM) output conversion.
CalMFCN2.b(LPM)	0.001		System	The offset of the raw voltage to N_2 flow (LPM) output conversion.
CalMFCO2.m(LPM/V)	0.001		System	The slope of the raw voltage to O_2 flow (LPM) output conversion.
CalMFCO2.b(LPM)	0.001		System	The offset of the raw voltage to O_2 flow (LPM) output conversion.
CalPressure.Slope	0.010		System	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the slope of the raw voltage to pressure PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalPressure.Offset(psi)	0.010		System	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the offset of the raw voltage to pressure PV conversion.
CalLimitsLevel.CalLevel InterceptMax(psi)	0.001		System	See Level "CalLevel InterceptMax(psi)" setting in Appendix 1.
CalLimitsLevel.CalLevel InterceptMin(psi)	0.001		System	See Level "CalLevel InterceptMin(psi)" setting in Appendix 1.
CalLimitsLevel.CalLevel SlopeMax(psi/V)	0.001		System	See Level "CalLevel SlopeMax(psi/V)" setting in Appendix 1.
CalLimitsLevel.CalLevel SlopeMin(psi/V)	0.001		System	See Level "CalLevel SlopeMin(psi/V)" setting in Appendix 1.
CalLimitsPressure.Cal PressureInterceptMax(psi)	0.001		System	See Pressure "Cal PressureInterceptMax (psi)" setting in Appendix 1.
CalLimitsPressure.Cal PressureInterceptMin(psi)	0.001		System	See Pressure "Cal PressureInterceptMin (psi)" setting in Appendix 1.
CalLimitsPressure.Cal PressureSlopeMax(psi/V)	0.001		System	See Pressure "Cal PressureSlopeMax (psi/V)" setting in Appendix 1.
CalLimitsPressure.Cal PressureSlopeMin(psi/V)	0.001		System	See Pressure "Cal PressureSlopeMin (psi/V)" setting in Appendix 1.

DO

Variable Name	Default Deadband	Default Record	Source	Definition
DOPV(%)	2.000	✓	Calc	The DO value detected by the software.
DOSP(%)	1.000	✓	User	The last DO set point used when DO was in Auto mode.
DON2FlowUser(%)	1.000	✓	User	The last user-defined N_2 output used when DO was in Manual mode.
DOO2FlowUser(%)	0.100	✓	User	The last user-defined O_2 output used when DO was in Manual mode.
DOModeActual	0.500	✓	Calc	The actual DO mode: 0) Auto, 1) Manual, 2) Off, and 3) Sensor Error.
DOModeUser	0.500		User	The user-requested DO mode: 0) Auto, 1) Manual, and 2) Off.
DOO2FlowController RequestLimited(%)	2.000	✓	Calc	The O_2 flow output the software actually requests from the O_2 MFC, in percent of main gas flow. It limits the O_2 flow the DO controller requests by taking the maximum O_2 MFC flow, the Gas Data "O2 Min Volume (L)" setting, and the requested CO_2 flow into account.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DON2FlowActualRequest (%)	2.000	✓	Calc	The N_2 flow output the software actually requests from the N_2 MFC, in percent of main gas flow. It limits the N_2 flow the DO controller requests by taking the maximum N_2 MFC flow, the CO_2 flow request, and the O_2 flow request into account.
DOA(%)	2.000		Calc	The PV reported by DO sensor A.
DOARaw(%)	0.100		Sensor	The raw voltage DO sensor A reports.
DOAisActive	0.500		Calc	True when DO sensor A is not failed.
DOInRange.A	0.500		Calc	True when DO sensor A is in valid range.
DOO2FlowController Request(%)	2.000		Calc	The O_2 flow output requested by the DO controller, in percent of main gas flow.
DON2FlowController Request(%)	2.000		Calc	The N_2 flow output requested by the DO controller, in percent of main gas flow.
DOO2FlowController RequestLimited(mLPM)	100.000		Calc	The O_2 flow output the software actually requests from the O_2 MFC, in mL/min. It limits the O_2 flow the DO controller requests by taking the maximum O_2 MFC flow, the Gas Data "O2 Min Volume (L)" setting, and the requested CO_2 flow into account.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DODeadband(%)	0.001	✓	System	See DO “Deadband (DO%)” setting in Appendix 1.
DON2Control.PGain(%/%)	0.001		System	See DO “N2 P Gain (%/DO%)” setting in Appendix 1.
DON2Control.ITime(min)	0.001		System	See DO “N2 I Time (min)” setting in Appendix 1.
DON2Control.DTime(min)	0.001		System	See DO “N2 D Time (min)” setting in Appendix 1.
DON2ControlAlpha	0.001		System	See DO “N2 Alpha” setting in Appendix 1.
DON2ControlBeta	0.001		System	See DO “N2 Beta” setting in Appendix 1.
DON2ControlGamma	0.001		System	See DO “N2 Gamma” setting in Appendix 1.
DON2ControlLinearity	0.001		System	See DO “N2 Linearity” setting in Appendix 1.
DON2RangeAutoMax(%)	0.001		System	See DO “N2 Auto Max (%)” setting in Appendix 1.
DON2RangeManMax(%)	0.001		System	See DO “N2 Manual Max (%)” setting in Appendix 1.
DOO2ControlMag.PGain (%/%)	0.001		System	See DO “O2 P Gain (%/DO%)” setting in Appendix 1.
DOO2ControlMag.ITime (min)	0.001		System	See DO “O2 I Time (min)” setting in Appendix 1.
DOO2ControlMag.DTime (min)	0.001		System	See DO “O2 D Time (min)” setting in Appendix 1.
DOO2ControlAlpha	0.001		System	See DO “O2 Alpha” setting in Appendix 1.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DOO2ControlBeta	0.001		System	See DO “O2 Beta” setting in Appendix 1.
DOO2ControlGamma	0.001		System	See DO “O2 Gamma” setting in Appendix 1.
DOO2ControlLinearity	0.001		System	See DO “O2 Linearity” setting in Appendix 1.
DOO2RangeAutoMax(%)	1.000		System	See DO “O2 Auto Max (%)” setting in Appendix 1.
DOO2RangeManMax(%)	0.001		System	See DO “O2 Manual Max (%)” setting in Appendix 1.
DOValidMax(%)	0.001		System	See DO “Valid High (DO%)” setting in Appendix 1.
DOValidMin(%)	0.001		System	See DO “Valid Low (DO%)” setting in Appendix 1.

DOOR

Variable Name	Default Deadband	Default Record	Source	Definition
DoorLockActual	0.500		Calc	For PBS Vertical-Wheel® Bioreactors with a door, indicates if the user is attempting to unlock the door, and the door is not interlocked.
DoorUnlockUser	0.500		User	For PBS Vertical-Wheel® Bioreactors with a door, the user sets this to true to request the door to be unlocked.

DOOR (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
ReusablePressure Connected	0.500	✓	Sensor	For PBS Vertical-Wheel® Bioreactors with a reusable pressure sensor, indicates if the reusable pressure sensor is connected.

FILTER OVEN

Variable Name	Default Deadband	Default Record	Source	Definition
FilterOvenPV(C)	5.000	✓	Calc	The temperature of the filter oven detected by the software.
FilterOvenSP(C)	1.000	✓	User	The last filter oven set point used when filter oven was in Auto mode.
FilterOvenDutyUser(%)	1.000	✓	User	The last user-defined heater duty used when filter oven was in Manual mode.
FilterOvenModeActual	0.500	✓	Calc	The actual filter oven mode: 0) Auto, 1) Manual, 2) Off, and 3) Sensor Error.
FilterOvenModeUser	0.500		User	The user-requested filter oven mode: 0) Auto, 1) Manual, and 2) Off.
FilterOvenDutyActual(%)	25.000	✓	Calc	The heater duty of the filter oven.
FilterOvenRaw(C)	5.000		Sensor	The raw resistance the filter oven sensor reports.
FilterOvenSensorActive	0.500		Calc	True when the filter oven temperature sensor has not failed.
FilterOvenDuty Control.Gain(%/C)	0.001		System	See Filter Oven “P Gain (%/C)” setting in Appendix 1.

FILTER OVEN (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
FilterOvenDuty Control.ITime(min)	0.001		System	See Filter Oven “I Time (min)” setting in Appendix 1.
FilterOvenDuty Control.DTime(min)	0.001		System	See Filter Oven “D Time (min)” setting in Appendix 1.
FilterOvenDutyControl Alpha	0.001		System	See Filter Oven “Alpha” setting in Appendix 1.
FilterOvenDutyControlBeta	0.001		System	See Filter Oven “Beta” setting in Appendix 1.
FilterOvenDutyControl Gamma	0.001		System	See Filter Oven “Gamma” setting in Appendix 1.
FilterOvenDutyControl Linearity	0.001		System	See Filter Oven “Linearity” setting in Appendix 1.
FilterOvenDutyRangeAuto Max(%)	0.001		System	See Filter Oven “Heat Auto Max (%)” setting in Appendix 1.
FilterOvenDutyRangeMan Max(%)	0.001		System	See Filter Oven “Heat Manual Max (%)” setting in Appendix 1.

GASES

Variable Name	Default Deadband	Default Record	Source	Definition
MainGasFeedback(LPM)	2.000		Calc	The sum of the actual flows of the Air, N_2, CO_2, and O_2 MFCs.
MainGasUser(LPM)	2.000	✓	User	The last user-defined flow rate used when main gas was in Manual mode.
MainGasModeActual	0.500	✓	Calc	The actual main gas mode: 0) Auto, 1) Manual, and 2) Off.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MainGasModeUser	0.500		User	The user-requested main gas mode: 0) Auto, 1) Manual, and 2) Off.
MainGasActualRequest (LPM)	2.000	✓	Calc	The gas flow output the controller requests of the main gas MFCs.
MFCAirFlowFeedback (LPM)	0.500	✓	Calc	The voltage feedback from the Air MFC converted to a flow rate with its slope and offset, representing the actual flow out of the Air MFC.
MFCCO2FlowFeedback (LPM)	0.400	✓	Calc	The voltage feedback from the CO_2 MFC converted to a flow rate with its slope and offset, representing the actual flow out of the CO_2 MFC.
MFCN2FlowFeedback (LPM)	0.500	✓	Calc	The voltage feedback from the N_2 MFC converted to a flow rate with its slope and offset, representing the actual flow out of the N_2 MFC.
MFCO2FlowFeedback (LPM)	0.500	✓	Calc	The voltage feedback from the O_2 MFC converted to a flow rate with its slope and offset, representing the actual flow out of the O_2 MFC.
MFCAirMeasRaw(V)	0.100		Sensor	The raw voltage the Air MFC reports.
MFCCO2MeasRaw(V)	0.100		Sensor	The raw voltage the CO_2 MFC reports.
MFCN2MeasRaw(V)	0.100		Sensor	The raw voltage the N_2 MFC reports.
MFCO2MeasRaw(V)	0.100		Sensor	The raw voltage the O_2 MFC reports.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MainGasRangeManMax (LPM)	0.001		System	See Gas Data “Manual Max (LPM)” setting in Appendix 1.
MFCAirMin(LPM)	0.001		System	See Gas Data “Air Min (LPM)” setting in Appendix 1.
MFCAirOff(V)	0.001		System	See Gas Data “Air Off (V)” setting in Appendix 1.
MFCCO2Min(LPM)	0.001		System	See Gas Data “CO2 Min (LPM)” setting in Appendix 1.
MFCCO2Off(V)	0.001		System	See Gas Data “CO2 Off (V)” setting in Appendix 1.
MFCMaxPeriod(s)	0.001		System	See Gas Data “PWM Max Period (s)” setting in Appendix 1.
MFCMismatchThresh(V)	0.001		System	See Gas Data “Mismatch Thresh (V)” setting in Appendix 1.
MFCN2Min(LPM)	0.001		System	See Gas Data “N2 Min (LPM)” setting in Appendix 1.
MFCN2Off(V)	0.001		System	See Gas Data “N2 Off (V)” setting in Appendix 1.
MFCO2Min(LPM)	0.001		System	See Gas Data “O2 Min (LPM)” setting in Appendix 1.
MFCO2Off(V)	0.001		System	See Gas Data “O2 Off (V)” setting in Appendix 1.
MFCOnTime(s)	0.001		System	See Gas Data “PWM On Time (s)” setting in Appendix 1.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
O2 Min Volume (L)	0.001		System	See Gas Data “O2 Min Volume (L)” setting in Appendix 1.

INTERLOCKS

Variable Name	Default Deadband	Default Record	Source	Definition
InterlockAgMotor	0.500		Calc	For PBS Bioreactors size 15 and higher, this indicates whether the agitation motor will not turn on because it is interlocked.
InterlockDoor	0.500		Calc	For PBS Vertical-Wheel® Bioreactors with a door, this indicates whether the door will not unlock because it is interlocked.
InterlockGasFlow	0.500		Calc	Indicates whether gases will not flow because they are interlocked.
InterlockHeater	0.500		Calc	Indicates whether main heater will not turn on because temperature is interlocked.
InterlockPumps	0.500		Calc	Indicates whether media and additions pumps will not turn on because they are interlocked.
InterlockDoorPressureMax (psi)	0.001		System	See Safety “Max Pressure Door (psi)” setting in Appendix 1.
InterlockPressureMax(psi)	0.001		System	See Safety “Max Pressure (psi)” setting in Appendix 1.
InterlockTempMax(C)	0.001		System	See Safety “Max Temp (C)” setting in Appendix 1.

LEDS

Variable Name	Default Deadband	Default Record	Source	Definition
LEDWhiteLEDOn	0.500		User	The user can set this to true to turn on the white light in the chamber.

LEVEL

Variable Name	Default Deadband	Default Record	Source	Definition
LevelPV(L)	2.500	✓	Calc	The level of the bag contents detected by the software.
LevelRaw(V)	0.100		Sensor	The raw voltage the level sensor reports.
LevelCalCluster.Bottom Gap (cm)	0.001		System	See Level "Bottom Gap (cm)" setting in Appendix 1.
LevelCalCluster.Cm/psi	0.001		System	See Level "cm/psi" setting in Appendix 1.
LevelCalCluster.Depth	0.001		System	See Level "Vessel Depth (cm)" setting in Appendix 1.
LevelCalCluster.Level Empty(L)	0.001		System	See Level "Empty Level (L)" setting in Appendix 1.
LevelCalCluster.Level Empty(V)	0.001		System	See Level "Empty Level (V)" setting in Appendix 1.
LevelCalCluster.Radius (cm)	0.001		System	See Level "Radius (cm)" setting in Appendix 1.
LevelColumn(psi)	0.500		Calc	The raw voltage times level slope plus level intercept. For the PBS 3 models, this is the level PV. For larger models, this corresponds to the pressure the level sensor measures.

LEVEL (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
LevelMax(L)	0.001		System	See Safety "Max Level (L)" setting in Appendix 1.
LevelMin(L)	0.001		System	See Safety "Min Level (L)" setting in Appendix 1.
LevelNet(cm)	5.000		Calc	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the level net pressure times the cm/psi.
LevelNoCal(L)	4.000		Calc	Not in use.
LevelSensorEnable	0.500		System	See Level "Enable Sensor (0 or 1)" setting in Appendix 1.
LevelTotal(cm)	5.000		Calc	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the net level plus the bottom gap.

pH

Variable Name	Default Deadband	Default Record	Source	Definition
pHPV	0.050	✓	Calc	The pH value detected by the software.
pHSP	0.010	✓	User	The last pH set point used when pH was in Auto mode.
pHCO2User(%)	1.000	✓	User	The last user-defined CO_2 output used when pH was in Manual mode.
pHBaseDutyUser(%)	1.000	✓	User	The last user-defined base pump output used when pH was in Manual mode.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHModeActual	0.500	✓	Calc	The actual pH mode: 0) Auto, 1) Manual, 2) Off, and 3) Sensor Error.
pHModeUser	0.500		User	The user-requested pH mode: 0) Auto, 1) Manual, and 2) Off.
pHCO2ActualRequest(%)	1.000	✓	Calc	The CO_2 flow output the software actually requests from the CO_2 MFC, in percent of main gas flow. It limits the CO_2 flow the pH controller requests by taking the maximum CO_2 MFC flow and the requested main gas flow into account.
pHBaseDutyActual(%)	1.000	✓	Calc	The base pump output.
pHA	0.050		Calc	The PV reported by pH sensor A.
pHARaw	0.010		Sensor	The raw voltage pH sensor A reports.
pHAIsActive	0.500		Calc	True when pH sensor A has not failed.
pHInRange.A	0.500		Calc	True when pH sensor A is in valid range.
pHAUseTempComp	0.500		System	See pH “A Use Temp Comp?” setting in Appendix 1.
pHActiveMode	0.500		Calc	In Auto mode, indicates if the controller is: 0) lowering the pH, 1) in the deadband, or 2) raising pH.
pHCO2FlowController Request(%)	1.000		Calc	The CO_2 flow output requested by the pH controller, in percent of main gas flow.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHBaseDutyControl.PGain (%)	0.001		System	See pH “Base P Gain (%/pH)” setting in Appendix 1.
pHBaseDutyControl.ITime (min)	0.001		System	See pH “Base I Time (min)” setting in Appendix 1.
pHBaseDutyControl.DTime (min)	0.001		System	See pH “Base D Time (min)” setting in Appendix 1.
pHBaseDutyControlAlpha	0.001		System	See pH “Base Alpha” setting in Appendix 1.
pHBaseDutyControlBeta	0.001		System	See pH “Base Beta” setting in Appendix 1.
pHBaseDutyControl Gamma	0.001		System	See pH “Base Gamma” setting in Appendix 1.
pHBaseDutyControl Linearity	0.001		System	See pH “Base Linearity” setting in Appendix 1.
pHBaseDutyManMax(%)	0.001		System	See pH “Base Manual Max (%)” setting in Appendix 1.
pHBaseAutoMax	0.001		System	See pH “Base Auto Max (%)” setting in Appendix 1.
pHCO2Control.PGain(%)	0.001		System	See pH “CO2 P Gain (%/pH)” setting in Appendix 1.
pHCO2Control.ITime(min)	0.001		System	See pH “CO2 I Time (min)” setting in Appendix 1.
pHCO2Control.DTime(min)	0.001		System	See pH “CO2 D Time (min)” setting in Appendix 1.
pHCO2ControlAlpha	0.001		System	See pH “CO2 Alpha” setting in Appendix 1.
pHCO2ControlBeta	0.001		System	See pH “CO2 Beta” setting in Appendix 1.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHCO2ControlGamma	0.001		System	See pH "CO2 Gamma" setting in Appendix 1.
pHCO2ControlLinearity	0.001		System	See pH "CO2 Linearity" setting in Appendix 1.
pHCO2ManMax(%)	0.001		System	See pH "CO2 Manual Max (%)" setting in Appendix 1.
pHCO2AutoMax(%)	0.001		System	See pH "CO2 Auto Max (%)" setting in Appendix 1.
pHDeadband	0.001	✓	System	See pH "Deadband" setting in Appendix 1.
pHRateFailDeltaPV	0.001		System	See pH "Rate Fail Delta PV" setting in Appendix 1.
pHRateFailDeltaTime(ms)	1.000		System	See pH "Rate Fail Delta Time (s)" setting in Appendix 1.
pHSensorSamplesTo Average	0.500		System	See pH "Samples To Average" setting in Appendix 1.
pHValidMax	0.001		System	See pH "Valid High (pH)" setting in Appendix 1.
pHValidMin	0.001		System	See pH "Valid Low (pH)" setting in Appendix 1.

PRESSURE

Variable Name	Default Deadband	Default Record	Source	Definition
PressurePV(psi)	0.050	✓	Calc	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the pressure in the bag detected by the software.

PRESSURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
PressureRaw(V)	0.100		Sensor	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the raw voltage the pressure sensor reports.
PressureSensorIsActive	0.500		Calc	For PBS Vertical-Wheel® Bioreactors with a pressure sensor, this indicates if the pressure sensor is disconnected.
PressureDisconnected(V)	0.001		System	See Pressure "Disconnected Pressure (V)" setting in Appendix 1.
Reusable Sensor (0 or 1)	0.500		System	See Pressure "Reusable Sensor (0 or 1)" setting in Appendix 1.

PUMPS AND VALVES

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesFillSpeed (RPM)	5.000		User	For PBS Vertical-Wheel® Bioreactors with an RPM-controllable media pump, this is the speed at which the user wants the media pump to turn. For other models, a value of 0 means the media pump is off and a higher number means it is on.
Pumps&ValvesPumpUser1	0.500	✓	User	For PBS Vertical-Wheel® Bioreactors with speed-controllable addition pumps, this is the user-requested addition pump A speed: 0) Off, 1) Slow, 2) Medium, 3) Fast.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesPumpUser2	0.500	✓	User	For PBS Vertical-Wheel® Bioreactors with speed-controllable addition pumps, this is the user-requested addition pump B speed: 0) Off, 1) Slow, 2) Medium, 3) Fast.
Pumps&ValvesFillSpeed (RPM) 2	5.000		User	(N/A on PBS-80) For PBS Vertical-Wheel® Bioreactors with an RPM-controllable addition pump A, this is the speed at which the user wants the addition pump A to turn. For other models, this variable should not be modified via recipe.
Pumps&ValvesFillSpeed (RPM) 3	5.000		User	For PBS Vertical-Wheel® Bioreactors with an RPM-controllable addition pump B, this is the speed at which the user wants the addition pump B to turn. For other models, this variable should not be modified via recipe.
Pumps&ValvesBasePump Selection	0.500	✓	User	The selector of which pump is the base pump: 0) No base pump selected, 1) addition pump A, or 2) addition pump B.
Pumps&ValvesPumpSmpl Req	0.500		User	The user sets this to true to request the sample pump to run.
Pumps&ValvesPumpSmpl RevrsReq	0.500		User	The user can toggle this to change pump direction.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesPumpSmpl	0.500		Calc	True when the Sample Pump is on.
Pumps&ValvesPumpSmpl Revrs	0.500		Calc	This toggles the sample pump direction.
Pumps&ValvesFillMotor Raw(V)	0.100		Calc	For PBS Vertical-Wheel® Bioreactors with an RPM-controllable media pump, this is the voltage to output to the media pump motor.
Pumps&ValvesFillMotor Raw(V) 2	0.100		Calc	(N/A on PBS-80) For PBS Vertical-Wheel® Bioreactors with an RPM-controllable addition pump A, this is the voltage to output to the addition pump A motor.
Pumps&ValvesFillMotor Raw(V) 3	0.100		Calc	For PBS Vertical-Wheel® Bioreactors with an RPM-controllable addition pump B, this is the voltage to output to the addition pump B motor.
Pumps&Valves Pump1.Duty	1.000		Calc	The pulse-density modulation duty for addition pump A. 2^{16} would be 100% duty.
Pumps&Valves Pump2.Duty	1.000		Calc	The pulse-density modulation duty for addition pump B. 2^{16} would be 100% duty.
Pumps&ValvesPumpLow AuxSpeed	1.000		System	See Pumps “Aux Low Duty” setting in Appendix 1.
Pumps&ValvesPumpMed AuxSpeed	1.000		System	See Pumps “Aux Med Duty” setting in Appendix 1.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesBaseMax Period(s)	0.001		System	See Pumps "Base Max Period (s)" setting in Appendix 1.
Pumps&ValvesBaseOn Time(s)	0.001		System	See Pumps "Base On Time (s)" setting in Appendix 1.
Pumps&ValvesReverse CCandCW	0.500		System	See Pumps "Sample Reverse CW and CCW (0 or 1)" setting in Appendix 1.

SEQUENCE/RECIPE

Variable Name	Default Deadband	Default Record	Source	Definition
Recipe Index	0.500		Calc	The step the sequence is currently on. Value is -1 when no sequence is running, 0 for first step, 1 for second step, etc.

LOGGER

Variable Name	Default Deadband	Default Record	Source	Definition
LoggerMaxLogInterval(ms)	60.000		System	See System "Max Data Log Interval (min)" setting in Appendix 1.

SYSTEM

Variable Name	Default Deadband	Default Record	Source	Definition
SysAvailableMem(KB)	0.001		System	Available memory on the RIO computer (kilobytes).
SysAvailableMemLimit(KB)	0.001		System	See System "Available Mem Limit (KB)" setting in Appendix 1.

SYSTEM (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
SysLCBMem(KB)	0.001		System	Size (kilobytes) of the largest contiguous block (LCB) of memory on the RIO computer.
SysLCBMemLimit(KB)	0.001		System	See System "LCB Mem Limit (KB)" setting in Appendix 1.
Sys_StartupCond	0.500		System	Outputs how the last shutdown of the RIO computer occurred. Used to trigger "Dirty Startup", "Clean Startup", and "Resume" alarms.

TEMPERATURE

Variable Name	Default Deadband	Default Record	Source	Definition
TempPV(C)	0.200	✓	Calc	The temperature value detected by the software.
TempSP(C)	0.100	✓	User	The last temperature set point used when temperature was in Auto mode.
TempHeatDutyUser(%)	1.000	✓	User	The last user-defined heat duty used when temperature was in Manual mode.
TempModeActual	0.500	✓	Calc	The actual temperature mode: 0) Auto, 1) Manual, 2) Off, and 3) Sensor Error.
TempModeUser	0.500		User	The user-requested temperature mode: 0) Auto, 1) Manual, and 2) Off.
TempHeatDutyActual(%)	2.000	✓	Calc	The heat duty of the main heater.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempA(C)	0.200		Calc	The PV reported by temperature sensor A.
TempARaw(C)	0.100		Sensor	The raw resistance temperature sensor A reports.
TempAIsActive	0.500		Calc	True when temperature sensor A has not failed.
TempInRange.A	0.500		Calc	True when temperature sensor A is in valid range.
TempB(C)	0.200		Calc	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the PV reported by temperature sensor B.
TempBRaw(C)	0.100		Sensor	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the raw resistance temperature sensor B reports.
TempBIsActive	0.500		Calc	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, true when temperature sensor B has not failed.
TempInRange.B	0.500		Calc	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, true when temperature sensor B is in valid range.
TempAIsPrimaryActual	0.500	✓	Calc	True when the software reports temperature PV as what temperature sensor A measures.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempAIsPrimaryUser	0.500		User	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, true when the user prefers that the software reports temperature PV as what temperature sensor A measures.
TempAtLeast1GoodSensor	0.500		Calc	Indicates if at least 1 temperature sensor has not failed.
TempHardware	0.500		System	A configuration set at the factory to tell the software which temperature sensors the hardware supports. This variable should not be modified via recipe.
TempHeatDuty Control.PGain(min)	0.001		System	See Temperature “P Gain (%/C)” setting in Appendix 1.
TempHeatDuty Control.ITime(min)	0.001		System	See Temperature “I Time (min)” setting in Appendix 1.
TempHeatDuty Control.DTime(min)	0.001		System	See Temperature “D Time (min)” setting in Appendix 1.
TempHeatDutyControl Alpha	0.001		System	See Temperature “Alpha” setting in Appendix 1.
TempHeatDutyControlBeta	0.001		System	See Temperature “Beta” setting in Appendix 1.
TempHeatDutyControl Gamma	0.001		System	See Temperature “Gamma” setting in Appendix 1.
TempHeatDutyControl Linearity	0.001		System	See Temperature “Linearity” setting in Appendix 1.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempHeatManMax(%)	0.001		System	See Temperature “Heat Manual Max (%)” setting in Appendix 1.
TempHeatDutyAutoMax(%)	0.001		System	See Temperature “Heat Auto Max (%)” setting in Appendix 1.
TempMismatchThresh(C)	0.001		System	See Temperature “Mismatch Thresh (C)” setting in Appendix 1.
TempUserConfig	0.500		User	For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, a user configuration to tell the software which temperature sensors the user has installed.
TempValidMax(C)	0.001		System	See Temperature “Valid High (C)” setting in Appendix 1.
TempValidMin(C)	0.001		System	See Temperature “Valid Low (C)” setting in Appendix 1.