PBS-3 Vertical-Wheel®

Reusable Sensors

Single-Use Bioreactor System

User Manual

Applicable Models: IA-3-B-501 | IA-3-B-502

Bioreactor Serial Number: ______________________

Bioreactor Name: ______________________

PBS Biotech, Inc.

This manual is intended as a guide to provide the user with necessary instructions on the proper use and maintenance of the PBS-3 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.

PBS Biotech, Inc.
4721 Calle Carga
Camarillo, California 93012
+1 (805) 482-7272
www.pbsbiotech.com

Contents

About This Manual

This user manual shows you how to install, configure, and use the PBS-3 Bioreactor System (PBS-3). This manual covers the Integrated Bioreactor, including the PBS Software package and the PBS-3 Bioreactor Single-Use Vessel assembly.

Configurations are standard as of the time at publication and the software features and instructions are applicable to version 3.2.1. The "Software Release Version" can be viewed in the "About" tab of the Desktop User Interface.

The contents include:

- An overview of the PBS-3's features, components, and controls (Chapter 1 on page 11)
- A high level system description to provide an understanding of the complete PBS-3 (Chapter 2 on page 24)
- Safety considerations (Chapter 3 on page 29)
- Product specifications (Chapter 4 on page 33)
- Instructions for installing the PBS-3 and configuring users, logger settings, and alarms (Chapter 5 on page 37)
- Day-to-day use of the PBS-3 (Chapter 6 on page 57)
- A detailed description of all PBS-3 features and functions (Chapter 7 on page 116)
- Information an IT department will need about the PBS-3 (Chapter 8 on page 152)

For More Information

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

Website	Login	Password	Date
outlook.com			
logmein.com			

PBS-3 at a Glance

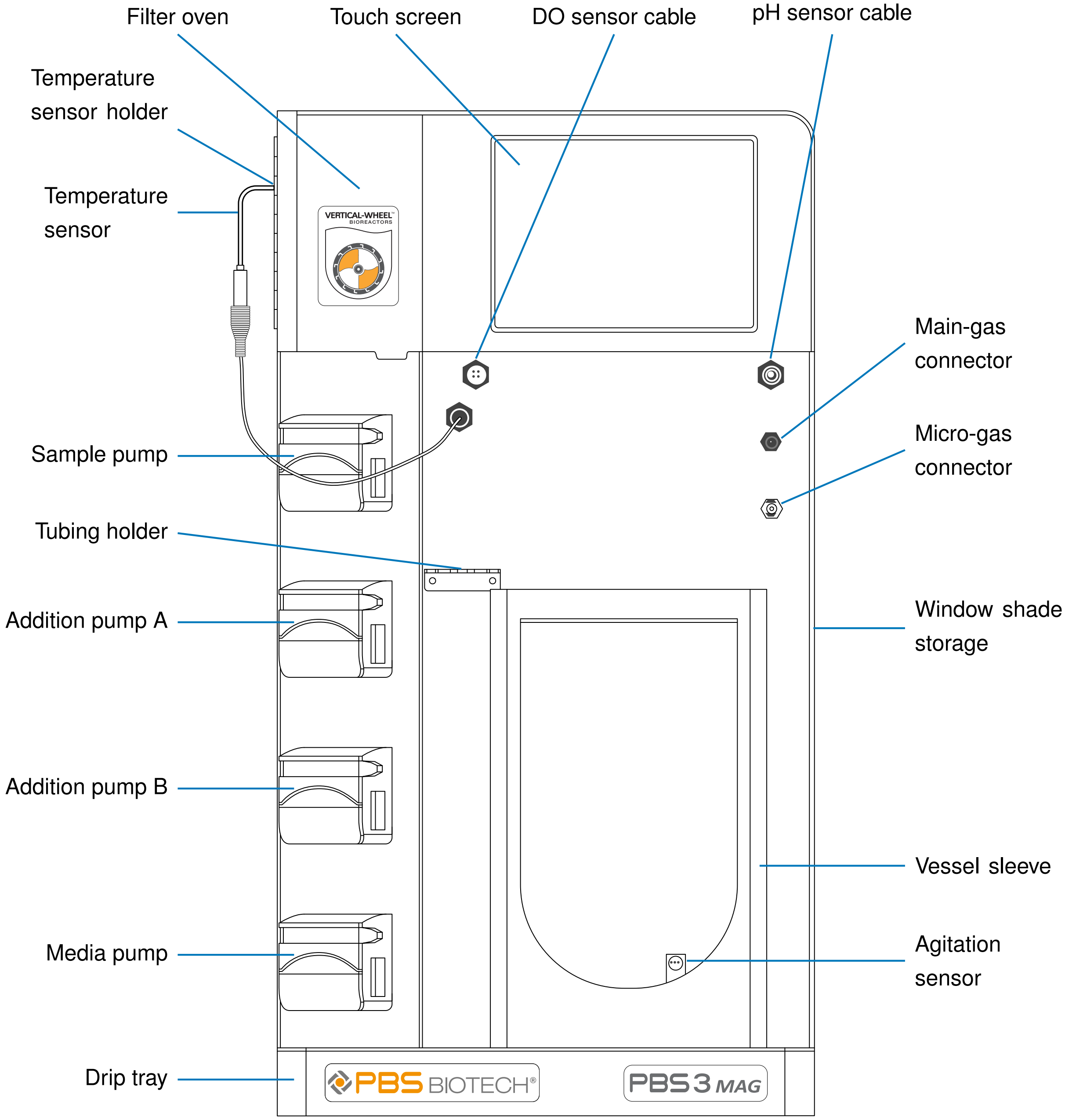
1

Use the illustrations in this chapter to become familiar with the basic features, components, and controls of the PBS-3.

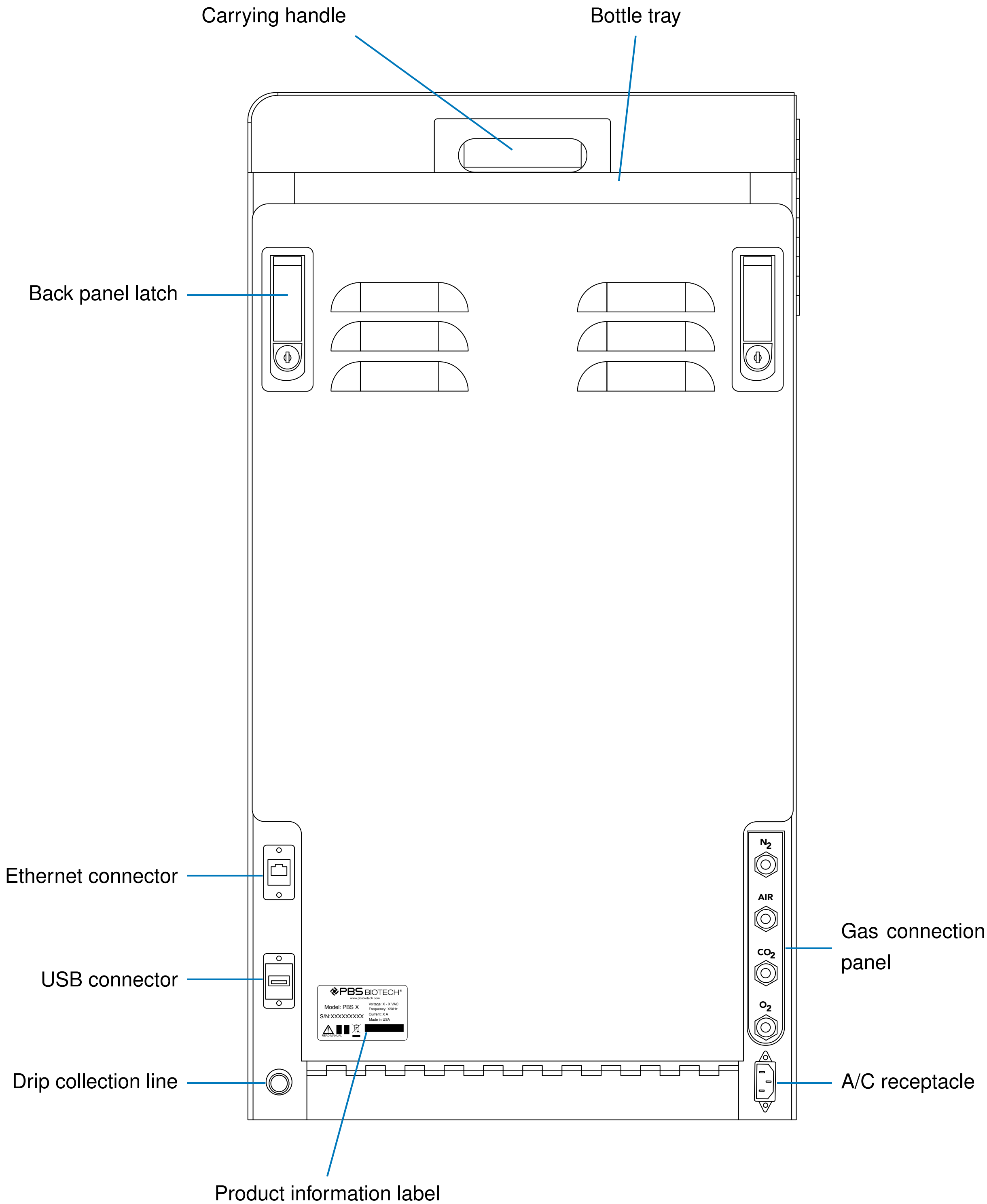
Note: Some components may be slightly different from the illustrations here, depending on the configuration you purchased.

Definitions

PV = Present Value
SP = Set Point
UI = User Interface
LPM = Liters Per Minute
mLPM = Milliliters Per Minute
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

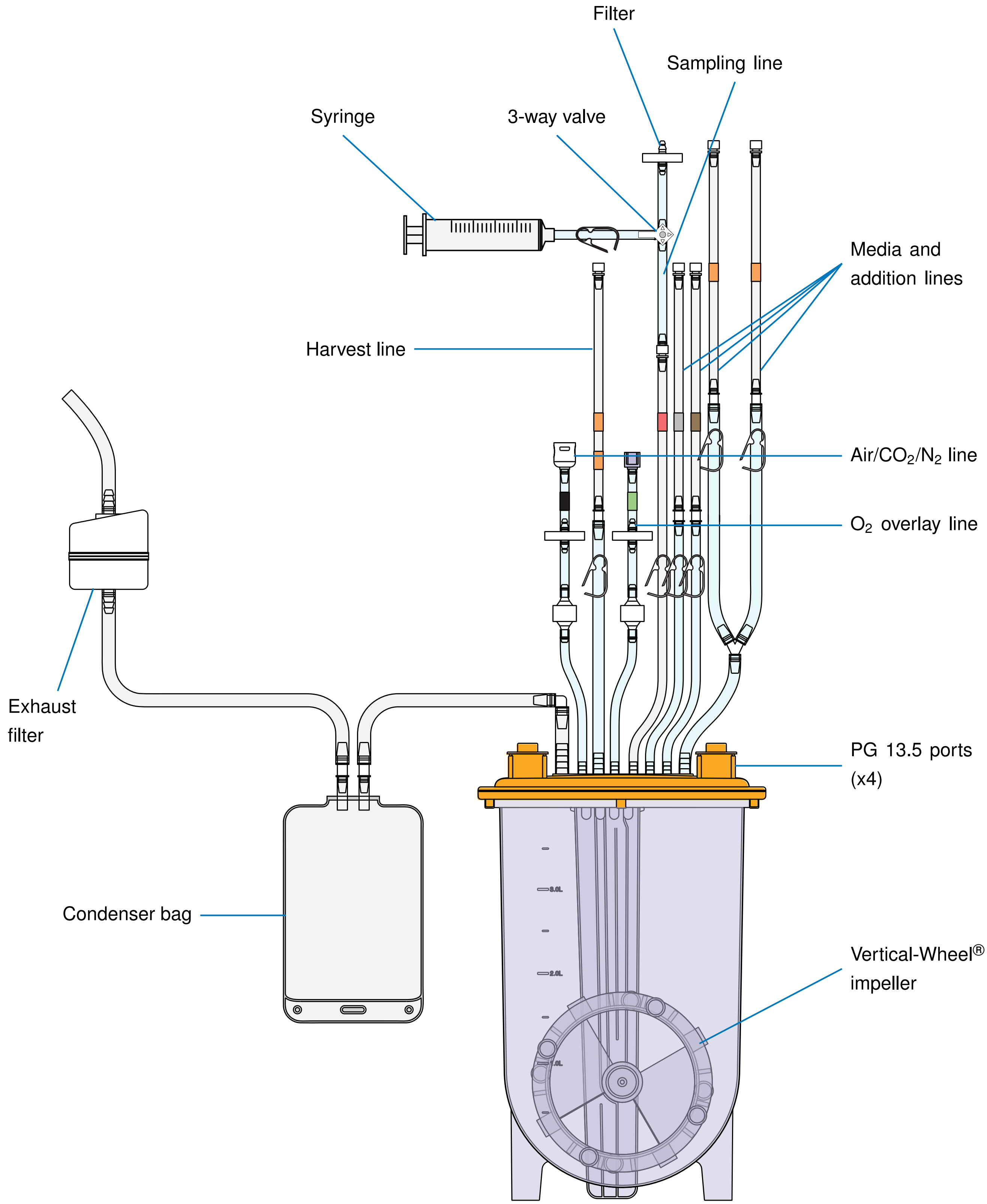

Filter oven
Touch screen
DO sensor cable
pH sensor cable
Temperature sensor holder
Temperature sensor
VERTICAL-WHEEL
BIOREACTORS
Main-gas connector
Micro-gas connector
Sample pump
Tubing holder
Addition pump A
Window shade storage
Addition pump B
Vessel sleeve
Agitation sensor
Media pump
Drip tray
PBS BIOTECH®
PBS 3 MAG

Filter oven Keeps the exhaust filter at an elevated temperature to prevent clogging due to condensation of moisture from the exhaust gas.
Touch screen Responds to bare fingers, latex/nitrile gloves, or a stylus.
Sensor cables Connected to the DO and pH sensors after they have been installed in the vessel.
Main-gas connector Connects the vessel's Air/CO_2/N_2 line to supplies of Air, CO2, and N_2, which are attached to the bioreactor via the gas connection panel (see "PBS-3 Bioreactor - Rear" on page 14).
Micro-gas connector Connects the vessel's O_2 overlay line to a supply of O_2, which is attached to the bioreactor via the gas connection panel (see "PBS-3 Bioreactor - Rear" on page 14). For information on sparging O_2, reach out to Applications Engineering at app.eng@pbsbiotech.com.
Window shade storage Stores the window shade by adhering to magnets in the PBS-3's side when not in use.
Vessel sleeve Insulates the vessel, and when used with the window shade, keeps it dark to protect light-sensitive media in the vessel. The sleeve must not be used to lift or carry the bioreactor - this could result in damage to the level sensor.
Agitation sensor Detects agitation using the Hall effect by sensing when magnets on the Vertical-Wheel® impeller pass it.
Drip tray Catches any media that leaks or overflows from the vessel. The media will then flow down a drain and into the drip collection line (see "PBS-3 Bioreactor - Rear" on page 14).
Media pump Used to fill or empty the vessel.
Addition pumps Used with the vessel's addition tubing to add base and other supplements/additions during a run.
Sample pump Used to draw a sterile sample from the vessel.
Tubing holder Helps prevent the sample line and exhaust tubing from becoming kinked or tangled.
Temperature sensor Installed in the thermal well in the vessel to provide accurate temperature readings.


Carrying handle
Bottle tray
Back panel latch
Ethernet connector
USB connector
Drip collection line
Product information label
Gas connection panel
A/C receptacle
N2
AIR
CO2
O2
PBS BIOTECH
Model: PBS X

Carrying handle Allows for convenience in moving the bioreactor.
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 37). **WARNING:** 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.
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.
Product information label Displays the bioreactor's serial and model numbers, as well as safety information.
Drip collection line Connects to a drip collection container to catch overflow/spills from the vessel. **WARNING:** As this is a gravity drain, ensure the collection container is below the level of the table and that the tubing runs downwards.
USB connector Allows connection of USB devices such as a keyboard, memory stick, or Wi-Fi adaptor. **WARNING:** Avoid using keyboards with a power button, to prevent accidentally turning the bioreactor's HMI computer off.
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 vessel is illustrative of general features and is not intended to represent any particular PBS product with 100% accuracy.



Sampling line
Used with the sample pump to remove a sterile sample and put it in the syringe. By manipulating the three-way valve and the pump correctly, sterile air from the filter is then used to clear the line to the syringe and back to the vessel.

Media and addition lines
Used with their respective pumps. The media line is used with the media pump to fill the vessel 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 line
Connects to the bioreactor's Main-gas connector, which connects to external gas sources via the gas connection panel (see "PBS-3 Bioreactor - Rear" on page 14). Air, CO_2, and N_2 flow through this line to the overlay to control dissolved oxygen and pH.

O_2 overlay line
Connects to the bioreactor's Micro-gas connector, which connects to external gas sources via the gas connection panel (see "PBS-3 Bioreactor - Rear" on page 14). O_2 flows through the O_2 overlay line to the overlay to control dissolved oxygen. For information on sparging O_2, reach out to Applications Engineering at app.eng@pbsbiotech.com.

PG 13.5 ports (x4)
Accommodate thermal well, pH sensor, DO sensor, along with optional sensors or pieces of equipment, such as a dip tube.

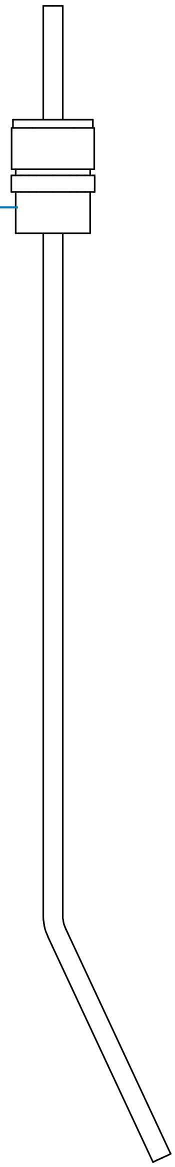
Vertical-Wheel® impeller
Coupled to a driving motor by a set of magnets around its circumference. It has vanes for multidirectional mixing and a pair of magnets for RPM sensing.

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

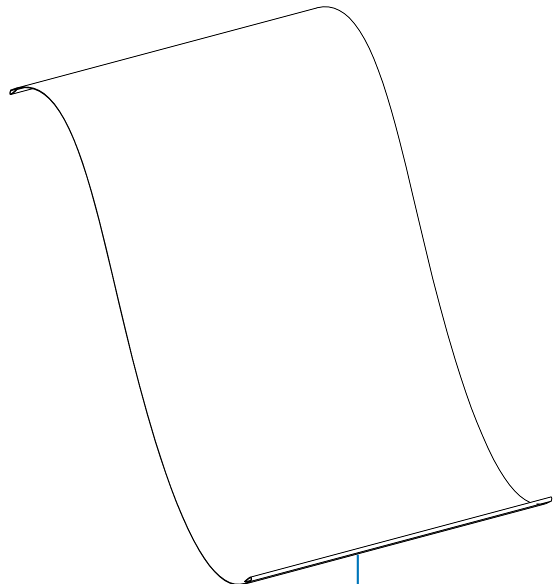
Exhaust filter
Filters the exhaust in order to maintain sterility of the vessel contents.

Harvest line
Used to empty the vessel during a harvest run, or to transfer the vessel's contents into a larger Vertical-Wheel® bioreactor. It is used with the media pump.

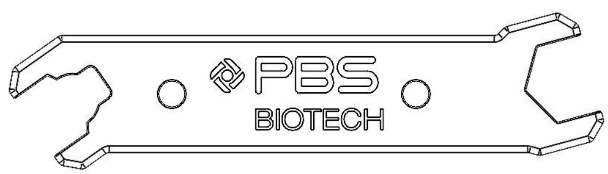
Note: Depending on the model of vessel being used, some of the tubing lines may not be compatible with the pumps installed on the PBS-3 and will require the use of an external pump.



Dip tube



Window shade



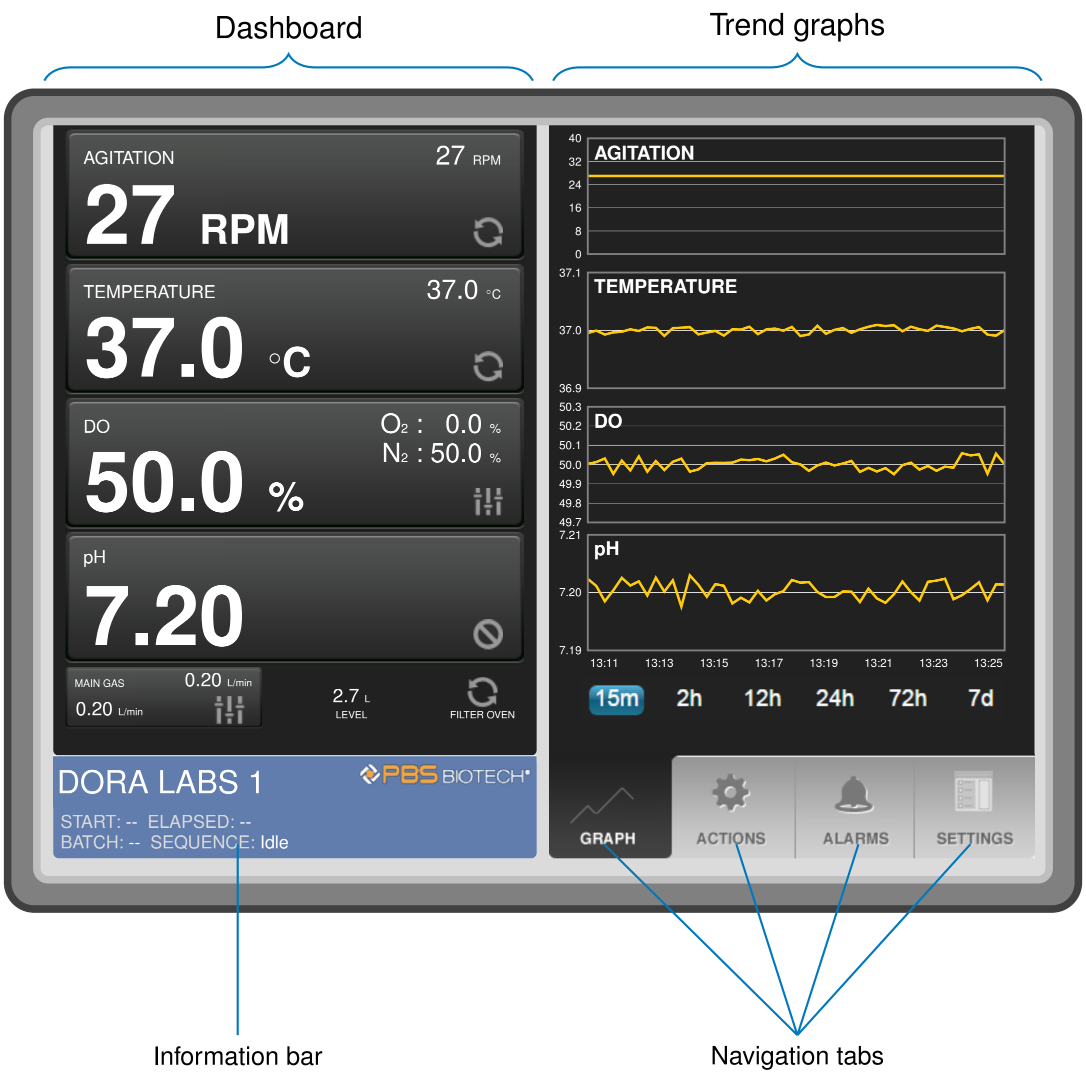
Wrench

Dip tube
Used to remove spent medium, add liquids to the vessel, and take samples.

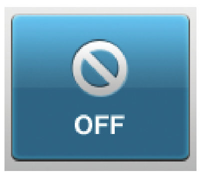
Window shade
Attaches to the sleeve to protect light-sensitive media in the vessel. Removable and stored by adhering to magnets in the PBS-3's side when not in use.

Wrench
Used for installing and removing port caps and accessories, such as the dip tube and sensors.

The Hello User Interface (Hello UI) opens automatically when the PBS-3 is powered on. It is the primary way of interacting with the PBS-3. Google Chrome and Safari for iOS are the only browsers supported. For more information, see “Hello User Interface” on page 116.



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

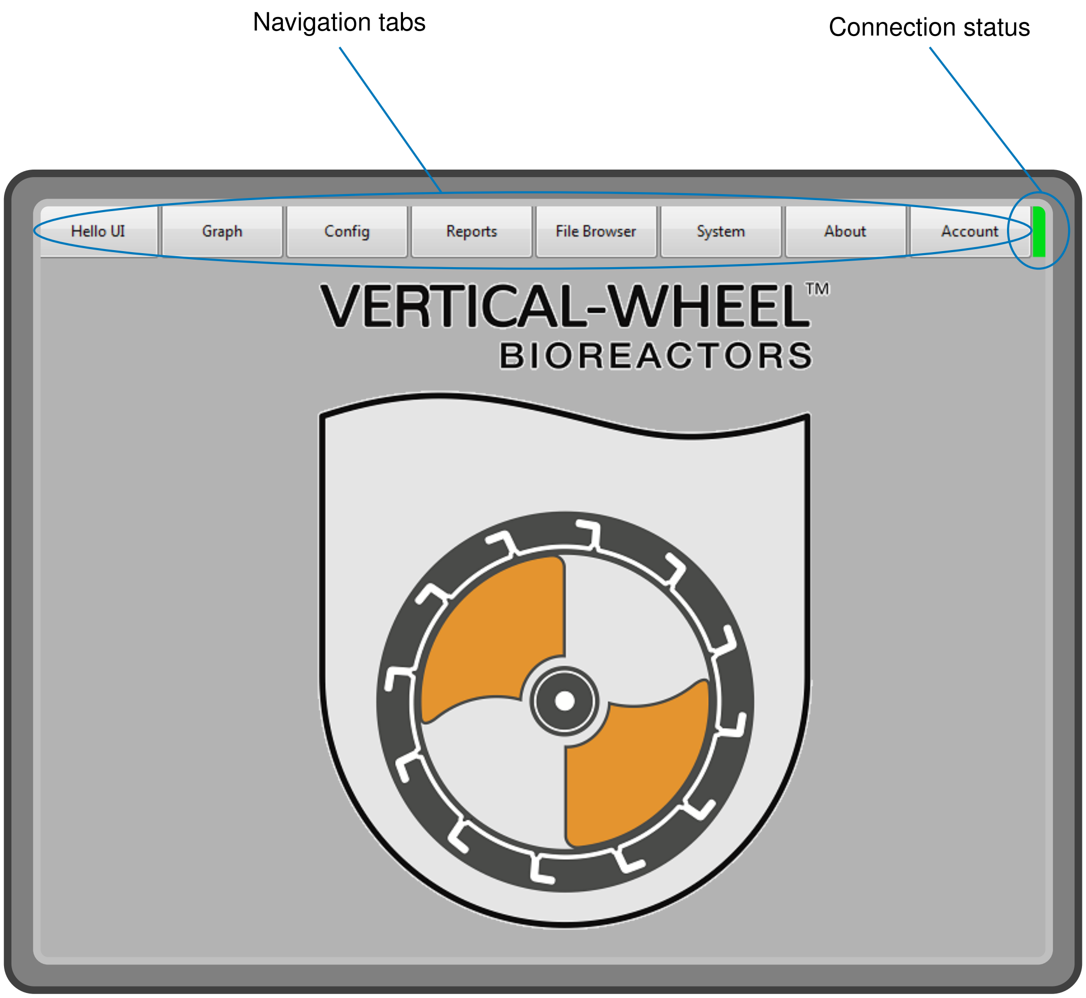
Mode Symbols	
Auto	
Manual	
Off	

Trend graphs
Show the agitation, temperature, DO, and pH PVs. The buttons below the graphs adjust the displayed time scale.

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

Information bar
Shows the PBS-3 name, the name of the current batch, the time the current batch was started, how long the current batch has been running, and the name of the recipe currently running.

The Desktop User Interface (Desktop UI) is used for performing operations the Hello UI cannot. For users, the Desktop UI will automatically launch upon startup of the PBS-3.



Navigation tabs Allows users to navigate to different pages within the Desktop UI.
Hello UI Launches the Hello UI. For more information, see “Hello User Interface” on page 116.
Graph Accesses graphs for each of the main controls on the PBS-3 - Agitation, Temp, DO, pH, Level, FiltOven, Gases, and Main Gas. In the “FiltOven” submenu, users can configure the mode and set point for the filter oven. For more information on enabling and disabling the filter oven, see “Filter Oven” on page 96.
Config Opens a drop-down menu from which users can navigate to the Alarm, Calibration, Logger, Recipe, and Settings configuration pages. For more information, see the following sections: “Configuring Logger Settings” on page 47, “Configuring Alarm Settings” on page 50, “Recipes” on page 97, “Settings/System Variables” on page 110, and “Other Calibrations” on page 114.
Reports Allows users to generate a report for process data, user events, errors, alarms, and recipe steps for individual batches, or a specified amount of time.
File browser Allows users to archive the current database, delete a report or archived database, copy files to a thumb drive, and configure the automatic backup feature.
System Opens a drop-down menu in which users can configure the PBS-3’s name, reboot the RIO, sync the RIO’s time, and test the alarm buzzer by selecting “Tools,” or shut down, reboot, or log out of the HMI computer by selecting “Power.”
About Displays the current system and vessel information, as well as the PBS-3’s database history.
Account Opens a drop-down menu, which allows users to either manage users and groups by selecting “Account,” or log out of the PBS-3 by selecting “Logout.”
Connection status Indicates the status of the connection between the HMI computer and the RIO. The light is green when there are no communication issues, and turns red when there is a communication problem.

System Description

2

This chapter gives an overview of the PBS-3 Bioreactor. It describes the high-level components and functionality of the PBS-3 and explains the principles of basic operation.

System Description

The PBS-3 Vertical-Wheel® Bioreactor System (PBS-3) 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-3 Bioreactor and a Vertical-Wheel® Bioreactor Single-Use Vessel Assembly (vessel). The PBS-3 Bioreactor and vessel are designed to interface closely with each other and to function as an integrated system.

This PBS-3 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-3 consists of: an interface for the vessel; an industrial controller; a four-gas module; a vessel heater; a vessel temperature sensor; DO and pH transducers; a level 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 Vessel is a uniquely shaped rectangular vessel with a round bottom incorporating the Vertical-Wheel® impeller, which has side paddles, vanes, and a hub. The vessel'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-3 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 vessel and impeller geometry, described above. The Vertical-Wheel® impeller is driven by a magnetically-coupled external motor.

Heating

The PBS-3 has a built-in temperature sensor which, when inserted in the stainless steel thermal well after installing it in the vessel, senses the temperature of the vessel contents. The PBS-3 also has permanently-mounted electric heaters positioned beneath the sleeve floor, which contacts the bottom surface of the vessel.

Dissolved Oxygen

The dissolved oxygen is monitored by a reusable DO sensor. The reusable sensors are intended to be calibrated with the PBS-3, autoclaved, and installed aseptically in the vessel during vessel installation. The PBS-3 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 Main-gas connector, through the Air/CO_2/N_2 line, and into the overlay. To increase DO levels, the software flows O_2 out of the O_2 overlay/O_2 sparge connector, which flows into the overlay via the O_2 overlay line. For information on sparging O_2, reach out to Applications Engineering at app.eng@pbsbiotech.com.

pH

The culture pH is monitored by a reusable pH sensor. The reusable sensors are intended to be calibrated with the PBS-3, autoclaved, and installed aseptically in the vessel during vessel installation. pH is usually regulated exclusively by CO_2%, and base should only be added if absolutely necessary. The PBS-3 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 Main-gas connector, through the Air/CO_2/N_2 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 weight of the vessel is continuously monitored by a load cell mounted inside the sleeve.

Filter Oven and Condenser Bag

To prevent clogging of the exhaust filter, each vessel is equipped with a condenser bag on the exhaust tubing to catch entrained medium droplets, and the PBS-3 has a temperature controlled oven to house the exhaust filter and prevent condensation of water vapor on the filter.

Overview of PBS Software Functionality and Architecture

Functionality

The PBS Software that is an integral part of your PBS-3 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 and Control
- Utilities

Sensing and Control

The PBS-3 has the ability to monitor and control agitation, temperature, dissolved oxygen, and pH in the vessel. It can also control the filter oven at a pre-determined temperature, as well as monitor the volume of the vessel contents. 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, broken sensor detection, and broken sensor 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 broken sensor 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, Recipe Steps, and Errors. All these data types are stored to a database on the HMI computer's hard drive (see "Architecture" on page 28), and can be exported via email or web-link to remotely connected computers 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-3, 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-3'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 "Auto Pilot" from the "Actions" tab brings you to the menu used to activate the recipe engine.

The recipe engine allows the user to automatically run sequences of instructions on the PBS-3. The recipes are programmed using the Recipe Editor available in the Desktop UI. Once saved, the recipes are available to be run from the Hello UI. Recipes 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 Hello UI is programmed as a web page and viewed with a web browser. The PBS-3 has a built-in web server that serves up the interface and handles two-way communications to and from the user. This architecture makes it easy for the user to open remote instances of the Hello UI by navigating their browser to the Hello server on the PBS-3. Multiple instances of the Hello UI can be opened simultaneously, although care should be taken to limit these remote instances to only one per device. These remote interfaces can be opened not only on remote computers, but also on mobile devices, such as the iPhone or iPad.

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, broken sensor detection, and running recipes. If the HMI were to fail (from a software crash or hardware failure), the control loops, interlocks, and recipes 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.

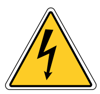
Finally, the RIO is in charge of detecting process and failure alarms, and the HMI communicates those alarms to the user. Alarm notifications would cease if the PC were not to run.

WARNING: 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 unit.

	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 unit. Only plug the instrument into a grounded outlet. To remove power from the unit, unplug the power cord. Do not position the unit in such a way that it is difficult to unplug the power cord.
	The back panel of the unit 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-3 has hot surfaces, as indicated by hot surface warning signs. Do not touch hot surfaces.
	Always allow the PBS-3 Vertical-Wheel® Bioreactor vessel to vent. Never clamp the product vessel outlet lines. This could result in dangerous pressure build-up in the vessel. Vertical-Wheel® Bioreactors are not designed for pressurized operation.
	Only use power cords provided by PBS Biotech. Only use vessels manufactured by PBS Biotech for the specific model of your bioreactor.
	Pumps may restart automatically if the power is restored after an interruption.
	When using external pumps to fill a vessel installed in the unit, use precautions to ensure that the vessel will not overfill, which could cause dangerous pressure build-up in the vessel.

	Biological substances, such as viruses, cells, and sera, have the potential to transmit infectious diseases. If biohazardous materials are used with this device, 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.

Electromagnetic Emissions

Supplier's Declaration of Conformity (USA)

FCC / 47 CFR § 2.1077 Compliance Information

Identification of Product: PBS 3
Responsible Party: PBS Biotech, Inc.
4721 Calle Carga
Camarillo, CA 93012 USA
1 (805) 482-7272

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: The PBS 3 has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Inspections and Preventative Maintenance

Inspections

This section describes the inspections that the user should perform on the PBS-3 Bioreactor to verify safety mechanisms are functional. For instructions on inspecting a Vertical-Wheel® Bioreactor vessel before use, see “Install Vessel in PBS-3” on page 66.

Drip Tray

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

Safety-Related Settings

Confirm that all settings in the “Safety” group match those listed in Appendix 1 on page 179, 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.

Preventative Maintenance

To keep your PBS-3 properly maintained, clean and decontaminate it after each run (see below). For other maintenance on the PBS-3, contact PBS Biotech Technical Support.

Cleaning and Decontamination

To clean and decontaminate the PBS-3, use 70% IPA or EtOH. Wipe down all surfaces of the PBS-3, including inside the vessel sleeve and drip collection tray. Be very gentle when cleaning the temperature sensor(s), level sensor, and door pressure sensor (if applicable). 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.

WARNING: Do not use abrasive materials on the PBS-3. 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-3 weighs approximately $<$ 40 kg (88 lbs). To prevent injury or damage to the product, it should only be lifted by two individuals from the pallet onto the bench. Proper lifting technique of bending at the knees and lifting with the legs should be used. Do not move the PBS-3 by its sleeve as this will cause damage to the load cell.

Product Specifications

4

Note: These specifications are for the standard PBS-3 configuration as of publication. Individual bioreactors may differ.

PBS-3 Specifications		
General	Size	Width: 38 cm (15.0 inches) Depth: 48 cm (18.5 inches) Height: 67 cm (26.5 inches)
	Weight	< 40 kg (88 lbs) without Vessel
	Space Requirements	Width: 51 cm (20 inches) Depth: 51 cm (20 inches) Height: 92 cm (36 inches)
	Electrical	2.5 A (max), 110-120 Vac, 50/60 Hz or 1.5 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	3.0 L
	Minimum Working Volume	1.8 L (top of wheel)
	Impeller Type	Vertically oriented mixing wheel
Controls	Control Interface	Integrated 8.4″ touch screen. Network connectivity capability
	Control Hardware/Software	Industrial embedded real-time control

PBS-3 Specifications		
Controls (continued)	Data Communication	Built-in data historian, remote control panel accessible over Ethernet
	Data Connection Ports	1x USB 2.0 1x RJ45 Ethernet
Agitation	Agitation Mechanism	Brushless DC motor drive, Magnetic coupling to vessel impeller
	Agitation Control Range (Accuracy)	10 – 50 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	30 – 500 mL/min for Air, N_2, O_2 30 – 100 mL/min for CO_2
Temperature	Temperature Control Range (Accuracy)	5 °C above ambient to 40 °C (± 0.5 °C)
	Temperature Sensor Type	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
pH	pH Control	Two-sided PID control with CO_2 and base addition pump or manual control

PBS-3 Specifications		
pH (continued)	pH Sensor Type	Broadley James FermProbe® electrochemical
Level	Level Sensor Type	Load cell
Pumps	Media	Watson Marlow 114DV series Unidirectional, Single-Speed, 200 RPM nominal
	Addition A	Watson Marlow 114DV series Unidirectional, 3-Speed, 200 RPM nominal
	Addition B	Watson Marlow 114DV series Unidirectional, 3-Speed, 200 RPM nominal
	Sample	Watson Marlow 114DV series Bidirectional, Single-Speed, 100 RPM nominal
Single-Use Vessel	Vessel Construction	Injection-molded polycarbonate
	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 Addition Line	Platinum-cured silicone/C-Flex® with female luer fitting and cap
	Exhaust Line	Platinum-cured silicone tubing with condenser bag and 0.2-micron exhaust filter
	Air/CO_2/N_2 Line	Platinum-cured silicone tubing with 0.2-micron filter
	O_2 Overlay Line	Platinum-cured silicone tubing with 0.2-micron filter

PBS-3 Specifications		
Single-Use Vessel (continued)	Sampling Line	Platinum-cured silicone and C-Flex® tubing with syringe, 3-way valve and 0.2-micron filter
	Harvest Line	Platinum-cured silicone and C-Flex® with female luer fitting and cap
	Configuration of Tubing and Filters	Refer to “Single-Use Vessel Configuration” for the vessel. Customizable in addition to the standard configurations
Service Life	Mechanical Drive Belt	Expected Service Life 1 year minimum
	Mechanical Drive Components (excepting belt)	Expected Service Life 3 year minimum
Safety and Regulatory	Markings (housing)	NRTL (NEMKO), CE

Installing the PBS-3

5

This chapter gives detailed instructions on how to install the PBS-3.

Integrated Bioreactor

Space Requirements

Before you begin, see “Space Requirements” on page 33 and confirm that your available bench space meets or exceeds the 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 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

WARNING: 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.

Gas Supply Pressures

Gas	Imperial	Metric
Air, O_2, N_2	20 – 40 psig	140 – 275 kPa
CO_2	14 – 16 psig	96.5 – 110 kPa

Unit Placement

To prevent bodily injury and/or damage to the product, see “Lifting and Handling” on page 32 and follow the safety instructions.

The unit should be placed on a tabletop or benchtop where the appropriate utilities have been prepared.

Once the unit is in place, 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 1.27 cm (0.50 in). The tubing should lead to a container below the bioreactor to allow overflow from the vessel to drain through the line by gravity.

Powering On the PBS-3

Install the appropriate power cord on the PBS-3. 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-3 will automatically power on, and the Hello UI will automatically load once the system has finished booting.

Configuring Users and Groups

Both the Hello UI and the Desktop UI require a user to log in before making any changes. This section describes how to create new users and modify user accounts.

The PBS-3 comes with two default 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-3 also comes with a user account “pbstech,” which will be used by PBS Biotech Technical Support if they need to log in to your bioreactor. 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.

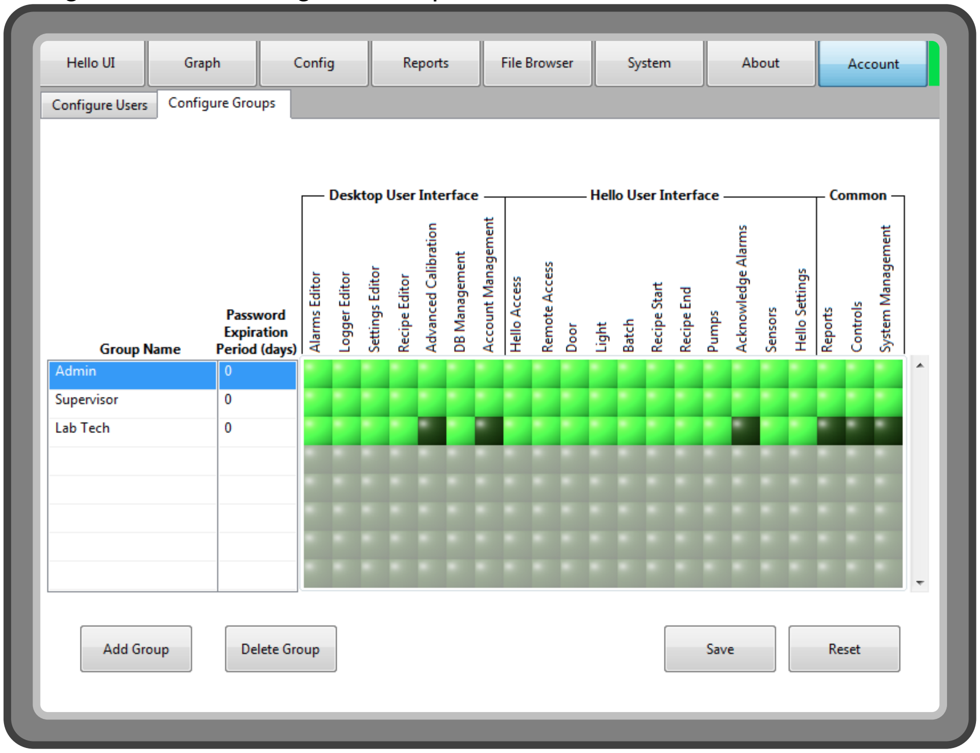
PBS Biotech Technical Support strongly suggests changing the username and password for the admin and user1 accounts to make them more secure, and adding accounts with unique usernames and passwords for each individual accessing the bioreactor. While all usernames and passwords should be as secure as 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. To ensure these usernames remain unknown, PBS Biotech Technical Support recommends disabling the “Hello Access” permission for all user groups with the “Account Management” permission to prevent the associated usernames from appearing on the Hello login screen, which is accessible to anyone with physical or remote access to the bioreactor.

Creating a New User Group

1. Log in to the Desktop UI using the user name and password of an account in a group with the “Account Management” permission.
2. Click “Account” and then “Manage.”

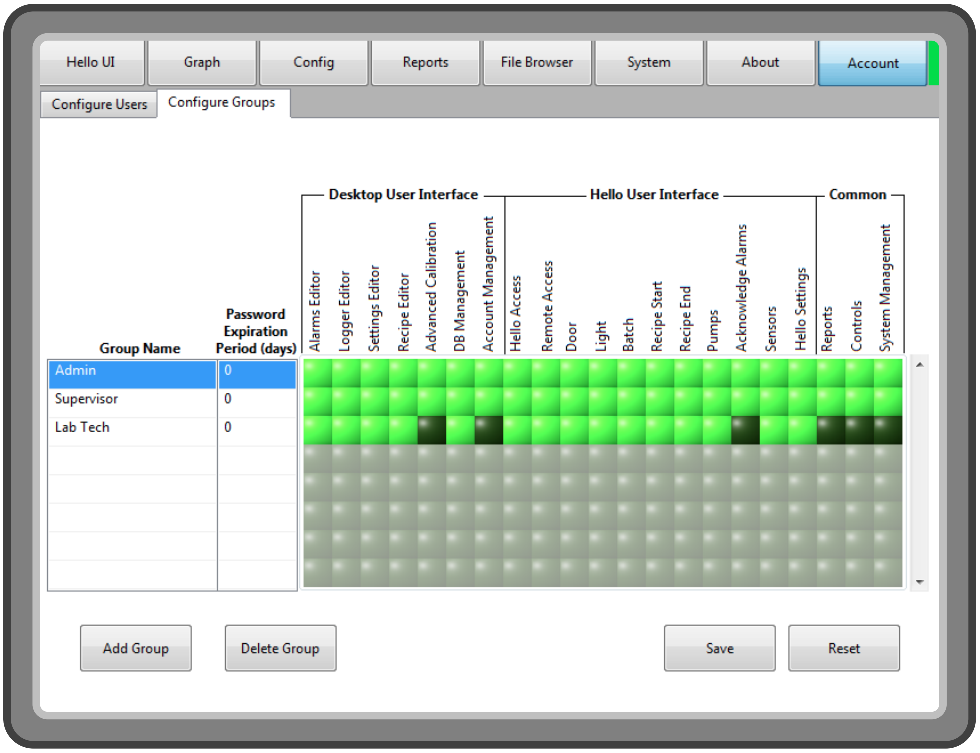
3. Navigate to the “Configure Groups” tab.



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 Group Permissions

Group permissions are divided into three categories: Desktop User Interface, Hello User Interface, and Common. To edit the permissions of a group, simply select the green square corresponding to the permission you wish to edit. Bright green indicates that the permission is granted, dark green indicates that the user group does not have that permission. For more information on group permissions, see “User Group Permissions” on page 149.

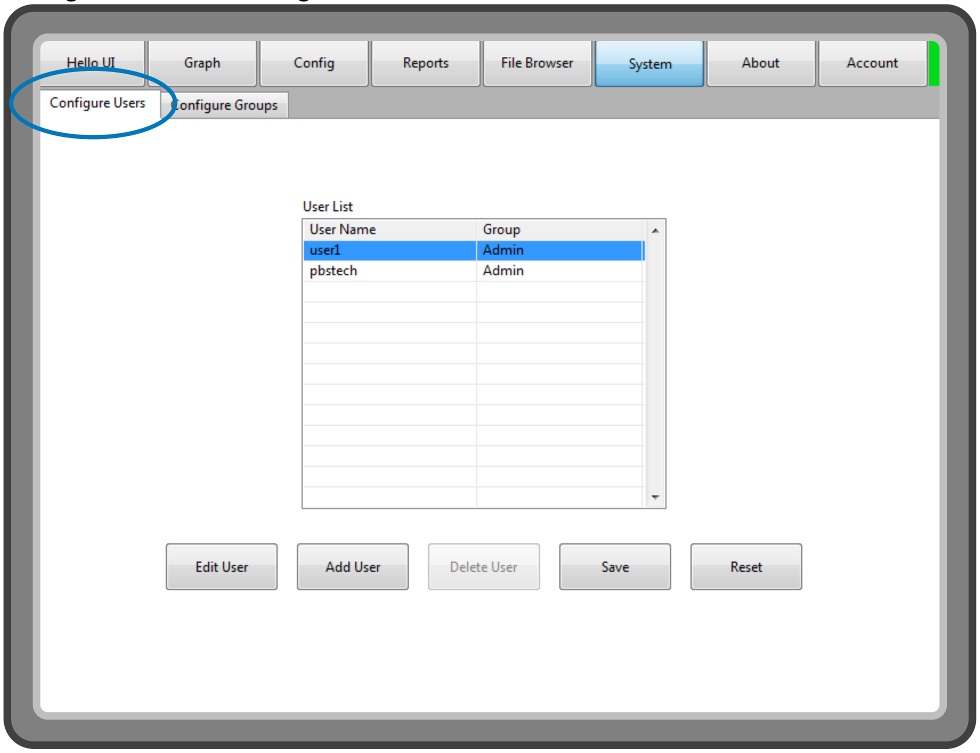


Editing Group Password Settings

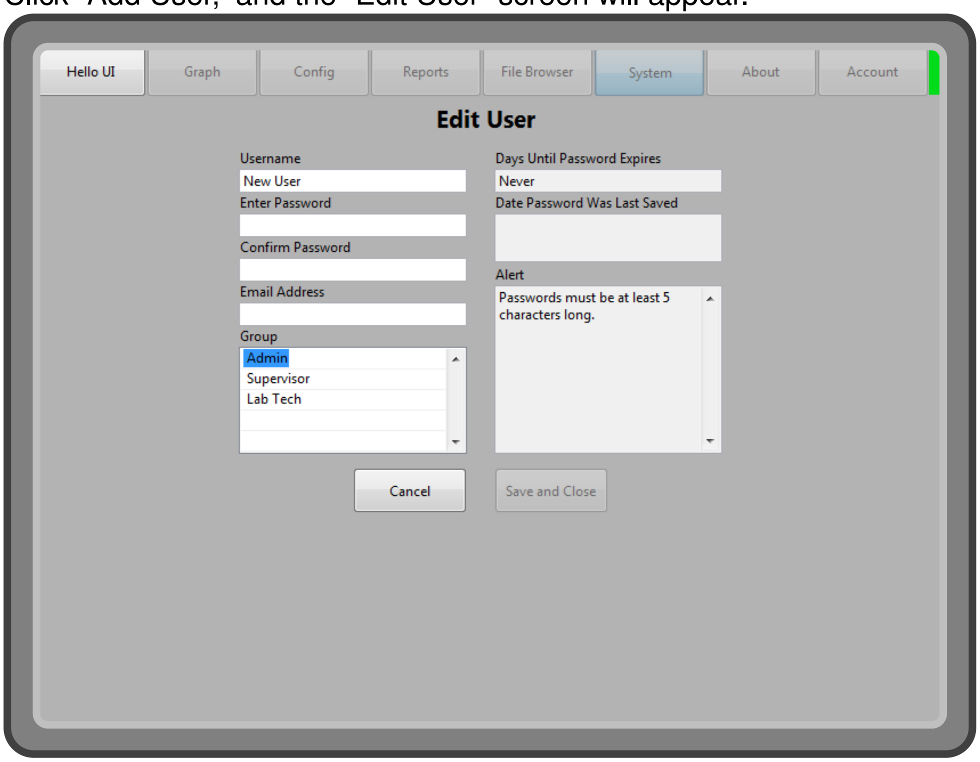
The default time period for password expiration is “0,” which means the password will never expire. To edit this value, double click the “Password Expiration Period (days)” box that corresponds to the Group Name. The Group Name can also be edited in this way.

Creating a New User

1. Navigate to the “Configure Users” tab.



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



3. To change the name from the default “New User,” 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 capital letters, spaces, or symbols.

4. To enter a password, select the "Enter Password" field and enter the new password, then click "Enter." When entering a password for an account in a group with the "Hello Access" permission, use only numbers. Do not use any letters, spaces, or symbols. Passwords must be at least 5 characters long, and have no maximum length. Users who desire more stringent password requirements may implement their own internal policies, which will not be enforced by the software.
5. (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 email reports generated in the Hello UI.
6. Select the user group that the user will be assigned to from the "Group" field.
7. The "Days Until Password Expires" field will reflect the "Password Expiration Period (days)" that is associated with the user group under the "Configure Groups" tab, and cannot be edited within the "Configure Users" tab.
8. When you are finished, click "Save and Close."

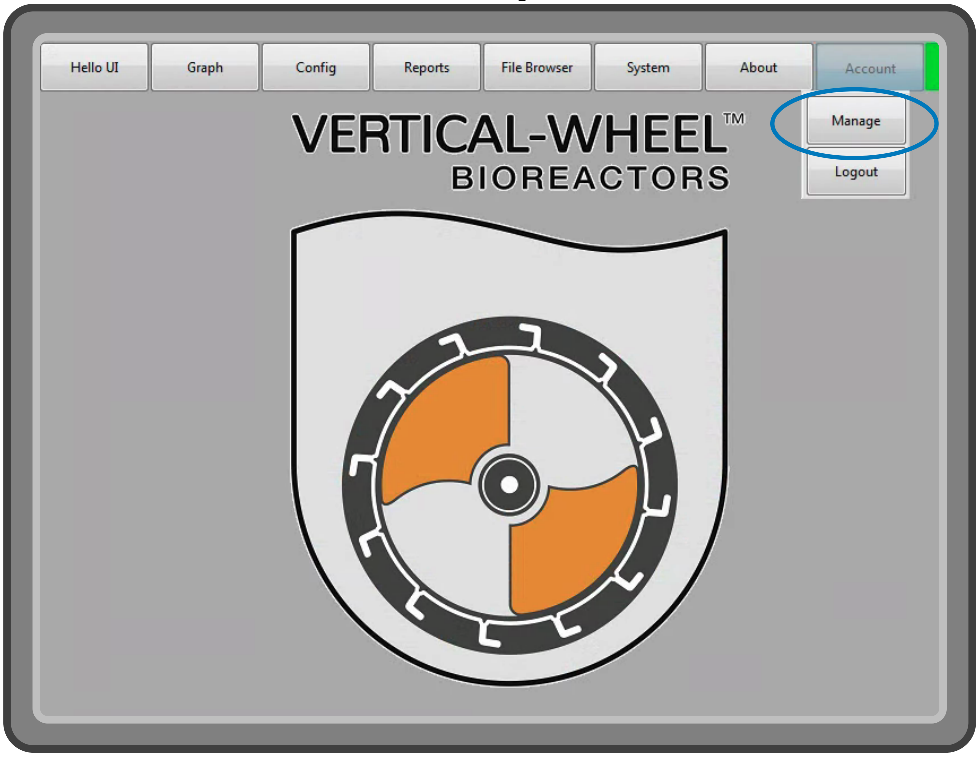
Modifying User Accounts

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 User" tab, and click the "Delete User" button. Click the "Save" button to save these changes.
3. To edit a user group, select the group in the "Group List" section under the "Configure Groups" tab. Change the Group Name, Password Expiration Period, 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.

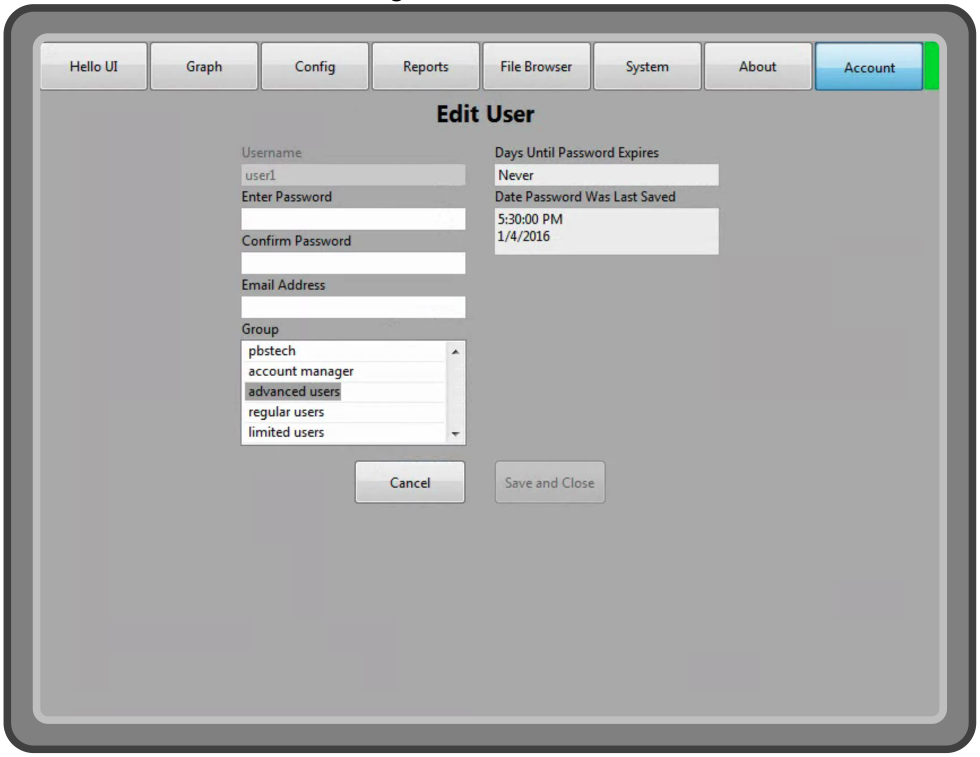
Users' Own Accounts

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.

1. Click "Account" and then select "Manage."



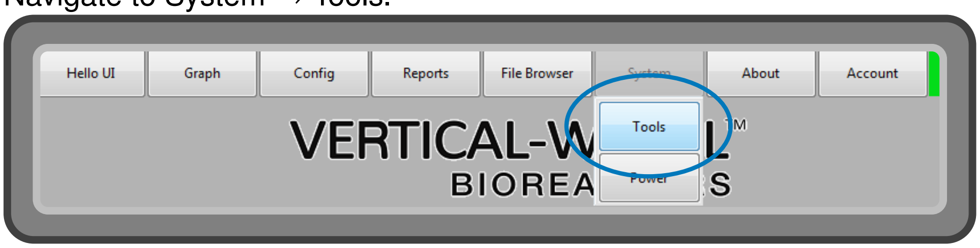
2. Make and save desired changes.



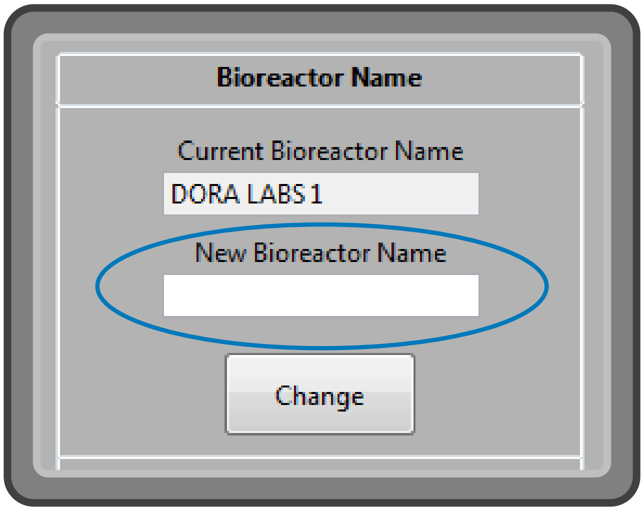
Naming the PBS-3

The PBS-3 ships with a generic name. However, PBS Biotech Technical Support suggests you change the name as you see fit.

1. Log in to the Desktop UI as a user with “System Management” permission.
2. Navigate to System → Tools.



3. Under “Bioreactor Name,” select the ‘New Bioreactor Name’ field.



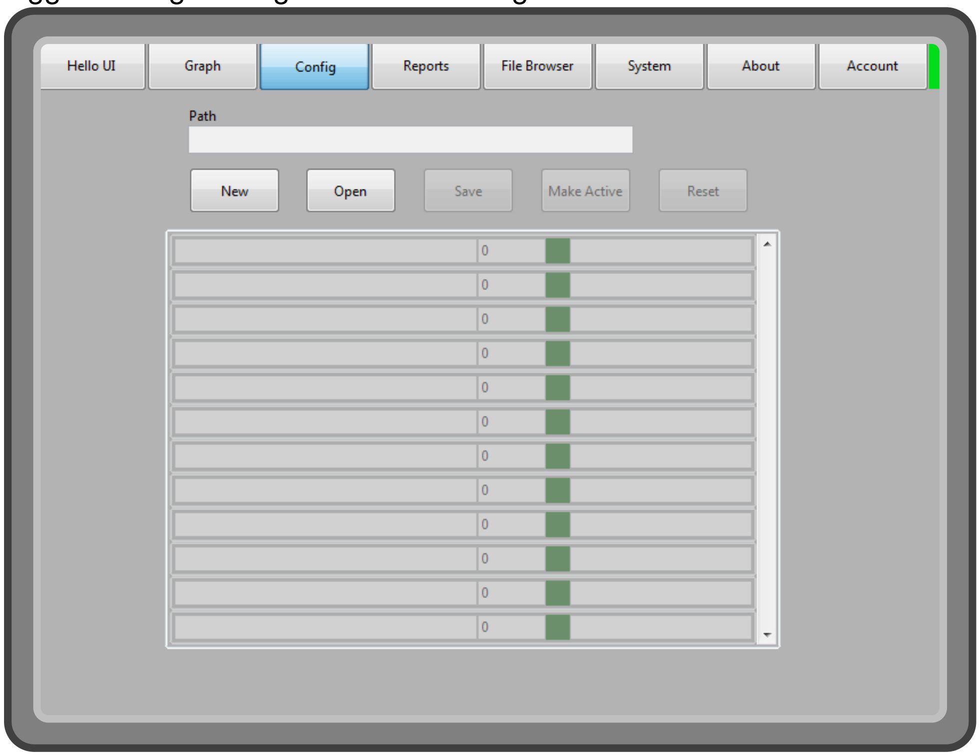
4. Enter the desired name using the on screen keyboard or an external keyboard and select “Enter.” The name you entered should now appear in the ‘New Bioreactor Name’ field.
5. Click “Change.” The ‘Current Bioreactor Name’ field should now match the ‘New Bioreactor Name’ field.

Configuring Logger Settings

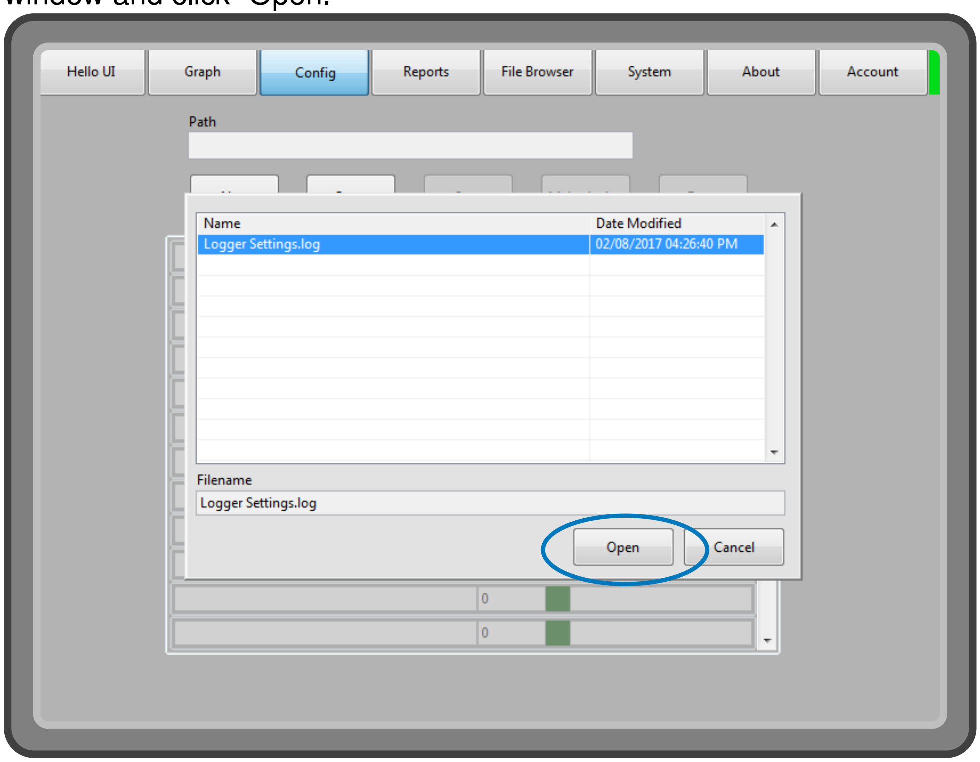
Before beginning a run, you should configure what data is recorded and how often. For an in-depth explanation for how data recording works, see “Process Data Recording” on page 142.

1. Log in to the Desktop UI as a user with the “Logger Editor” permission.
2. Navigate to Config → Logger.

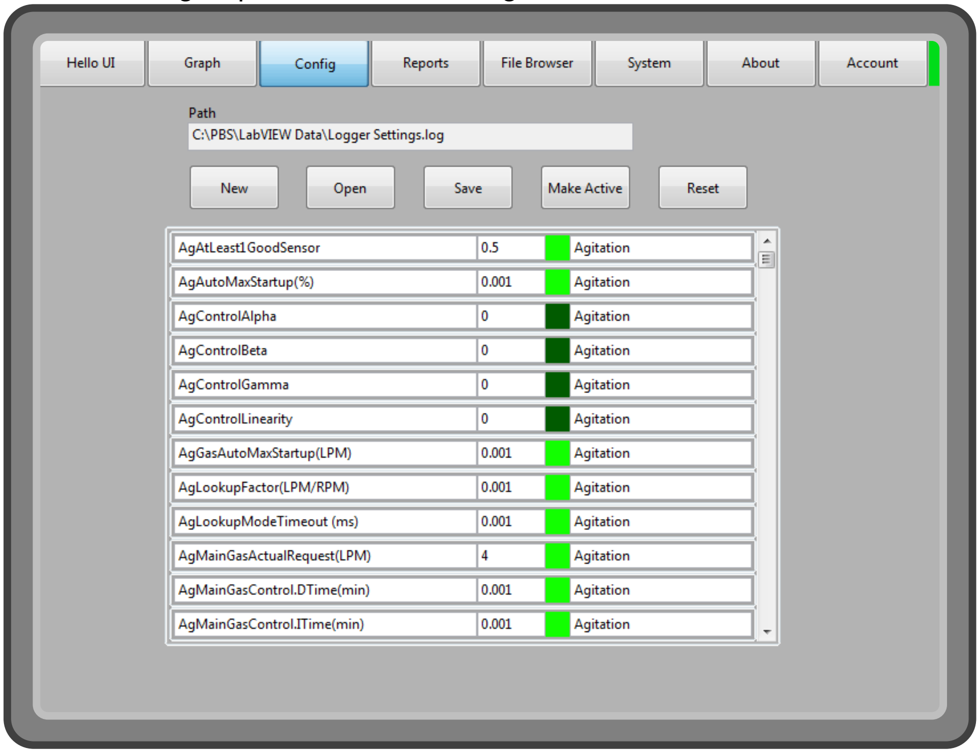
3. Click “Open” to edit an existing Logger Settings file, or “New” if you would like to create an entirely new Logger Settings file. You can create multiple logger settings configuration files and give them different names.



4. If opening an existing logger settings file, select the desired file in the window and click “Open.”



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



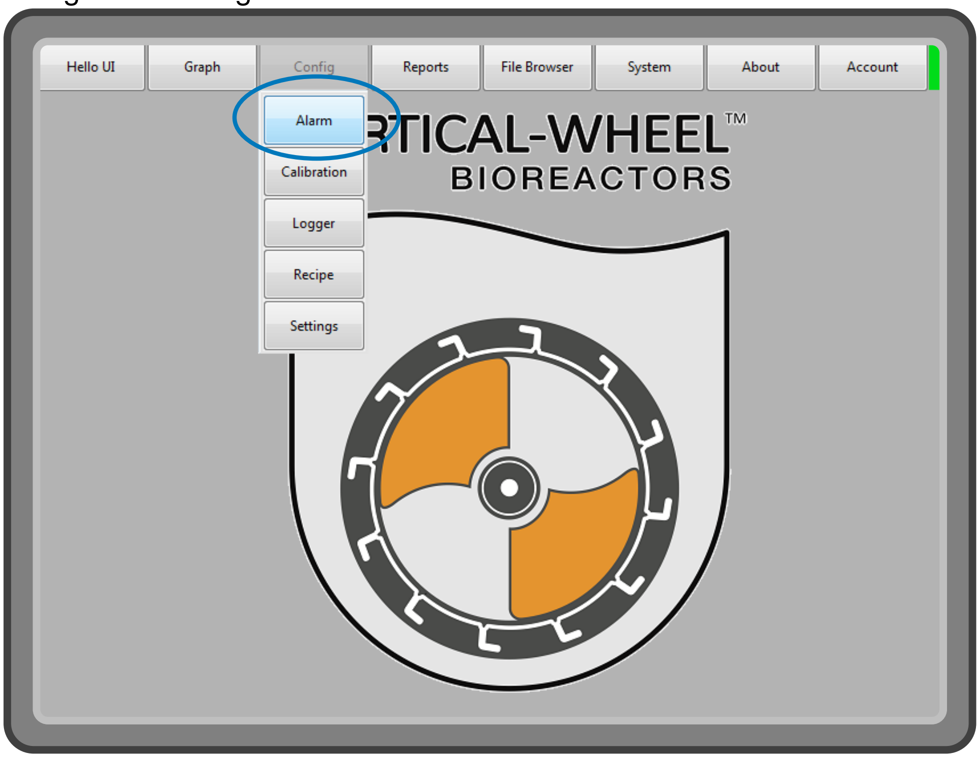
6. To change the value of the deadband for a variable, click the number field next to the corresponding variable and enter the desired value using the on-screen keypad or an external keyboard.
7. To change whether a variable is recorded or not, click the green square next to the deadband value. Bright green indicates that the variable will be recorded, while dark green indicates that it will not.
8. If you wish to reverse changes you have made, click “Reset” and the file will revert back to its original values.
9. When you are finished making your desired changes, click “Save” and either select “Save” again to overwrite the file, or change the file name to create a new one.
10. Click “Make Active” to make the selected file active on the RIO.

Configuring Alarm Settings

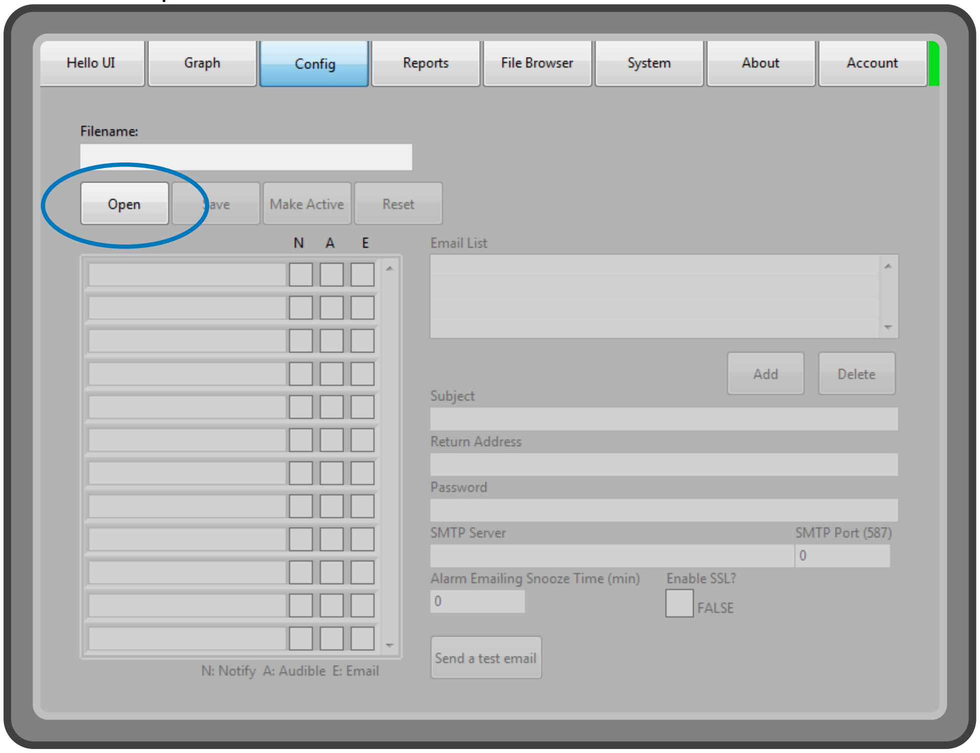
The PBS-3 comes with its Alarms Off.alm file loaded so the non-run conditions will not set off any alarms (disconnected sensors, temperature far below 37 °C, etc.). You can create and edit multiple Alarms configuration files using the Alarms Editor in the Desktop UI.

Creating and Editing Alarm Files

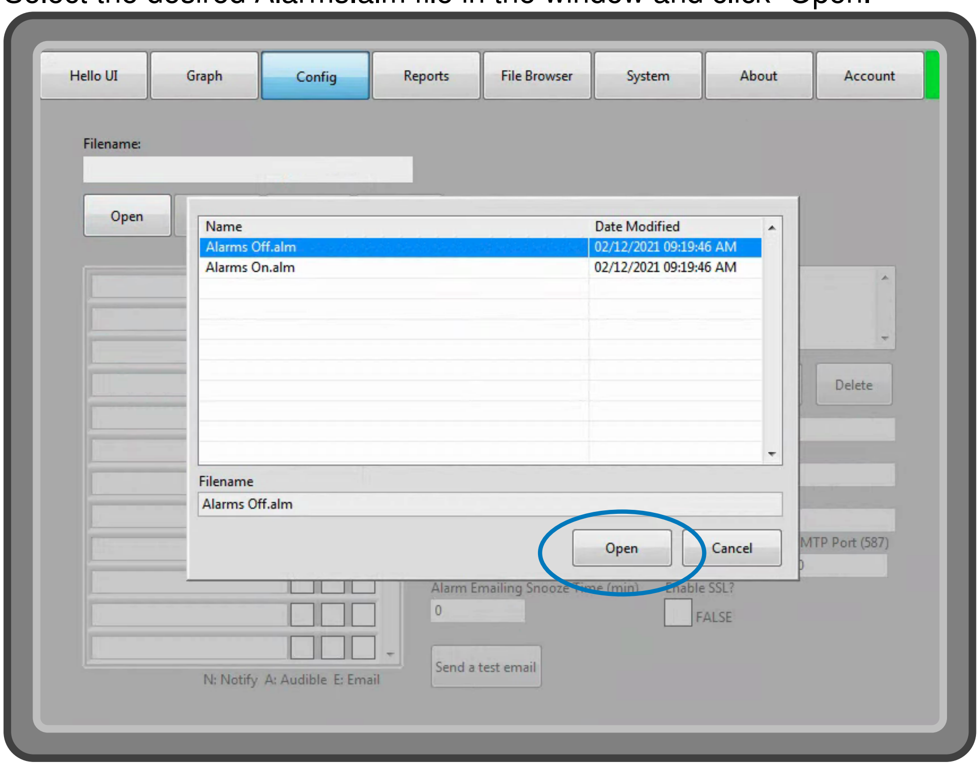
1. Log in to the Desktop UI as a user with the “Alarms Editor” permission.
2. Navigate to Config → Alarm.



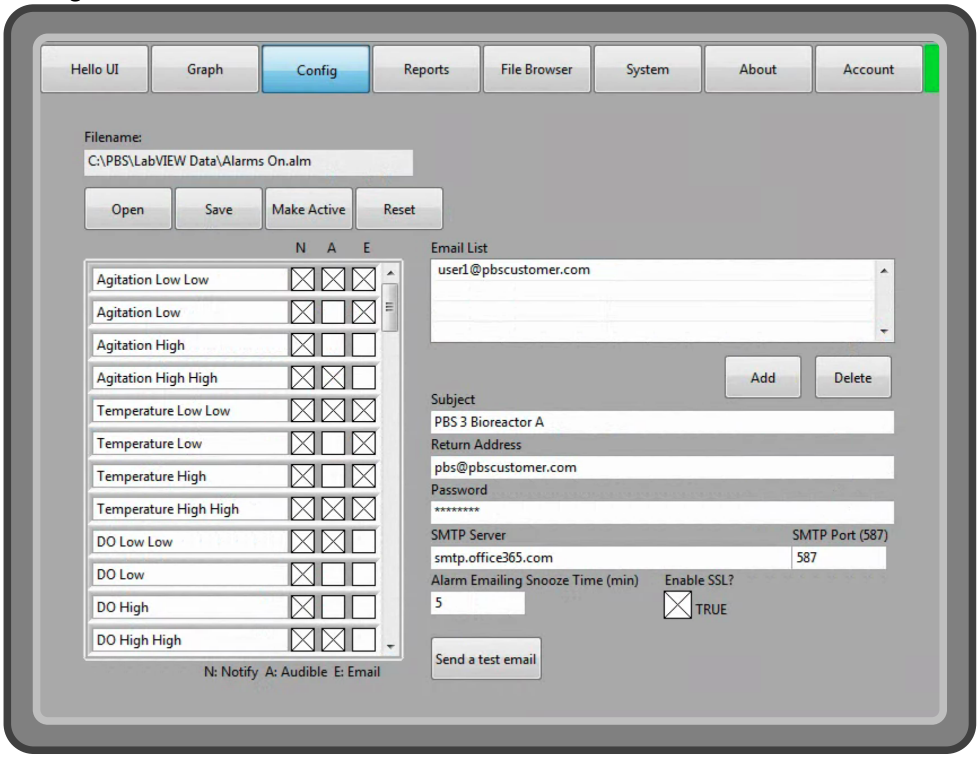
3. Click the “Open” button.



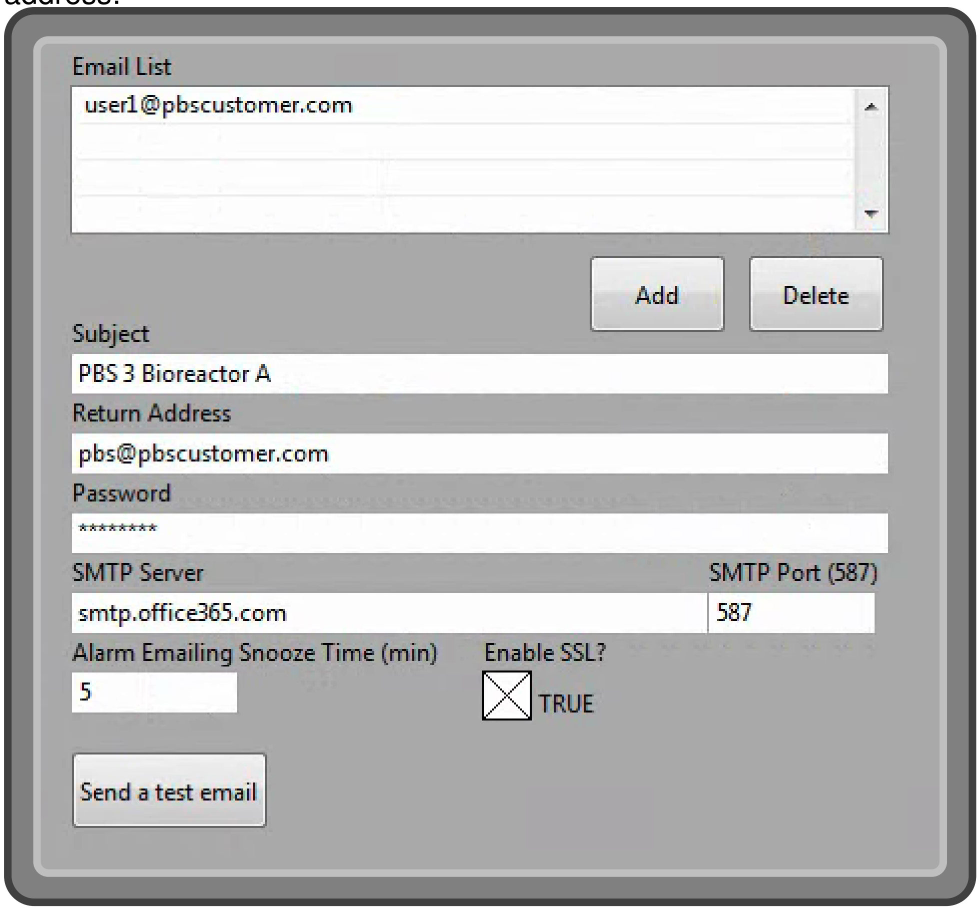
4. Select the desired Alarms.alm file in the window and click “Open.”



5. Configure alarms notifications by selecting “N,” “A,” and/or “E” for each alarm, where “N” is Notify (appears in the Alarms tab of the Hello UI), “A” is Audible (a buzzer sounds), and “E” is Email, where an email is sent to all of the email addresses in the “Email List” from the email address in the “Return Address” field. Note that an alarm that is not set to Notify will not sound a buzzer or be emailed, regardless of how “A” and “E” are configured.



6. Configure email notifications. The PBS-3 arrives with a PBS Biotech email address. The size limit for generating and emailing files is about 10 MB, due to CPU and memory limitations. To change the PBS-3's sending address:



(a) Fill in the 'Subject' field with a desired subject – PBS Biotech suggests using the PBS-3's name.

(b) Fill in the 'Return Address' field with the email address the PBS-3 will email users from.

(c) Fill in the 'Password' field with the password to that email account.

(d) Fill in the 'SMTP Server' field with the SMTP Server address for that email provider.

(e) Fill in the 'SMTP Port' field with the SMTP Port available on your network; 587 is the most common, but consult the network administrator if it does not work.

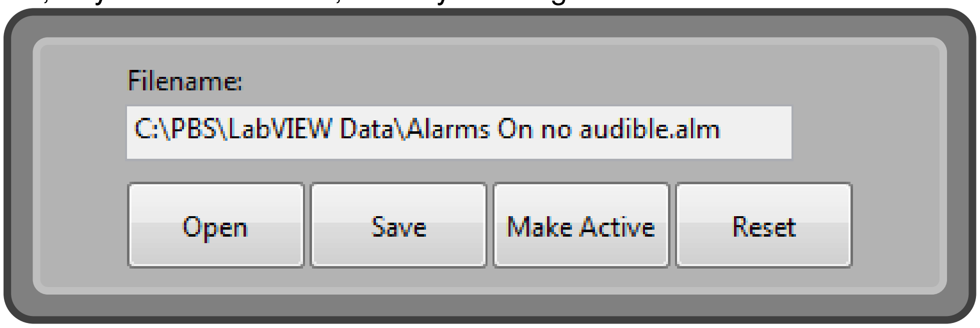
(f) Click "Enable SSL?" if you wish to enable an encrypted link between the server and the mail client.

(g) Enter email addresses in the 'Email List' to send alarm emails to.

Note: 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.

(h) Click “Send a test email” – a confirmation email should appear in the inboxes of the email accounts in the “Email List.” If there is no confirmation email, check the entries in all the fields, and confirm internet connectivity.

7. If you wish to reverse changes you have made, click “Reset” and the file will revert back to its original values.
8. Once you have made the desired changes, click “Save.” You can then choose to keep the current file name to save the changes made to that file, or you can rename it, thereby creating a new alarm file.



9. Click “Make Active” to make the selected file active on the RIO.

Configuring Automatic Backups

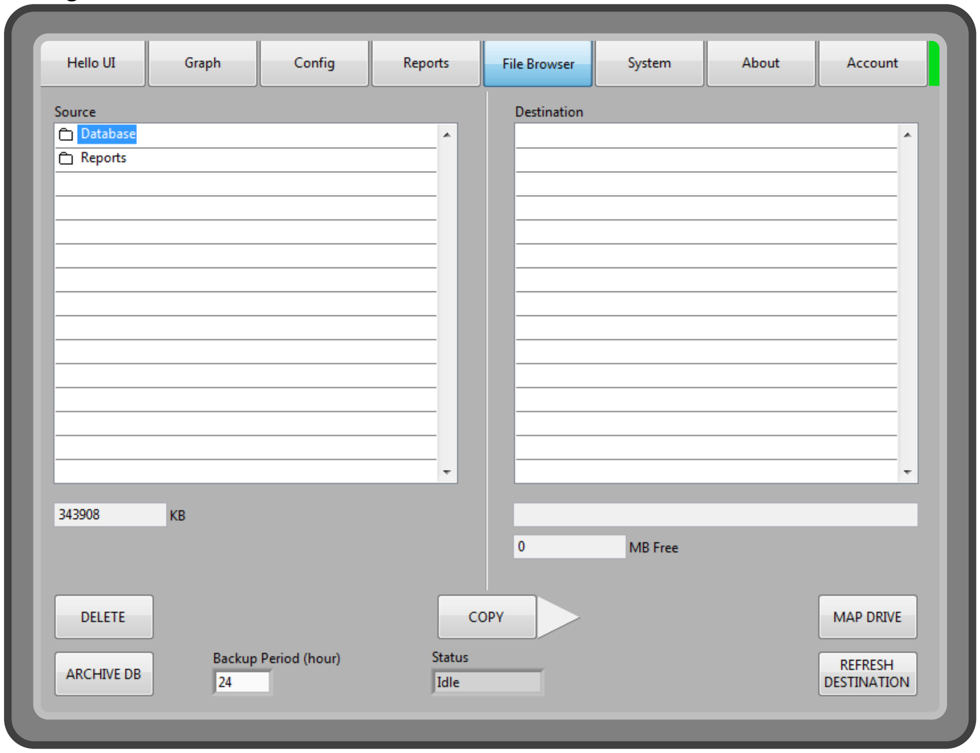
The PBS-3 can automatically back up the contents of the Database folder, including the active and archived databases and the Database History File.

Note: Users are responsible for their own backup and recovery.

Setting Automatic Backup Period

1. Log in to the Desktop UI with a user account with the “DB Management” permission.

2. Navigate to the File Browser menu.



3. Set the Backup Period (hour) to the desired number of hours. PBS Biotech Technical Support recommends backing up at least every 24 hours.

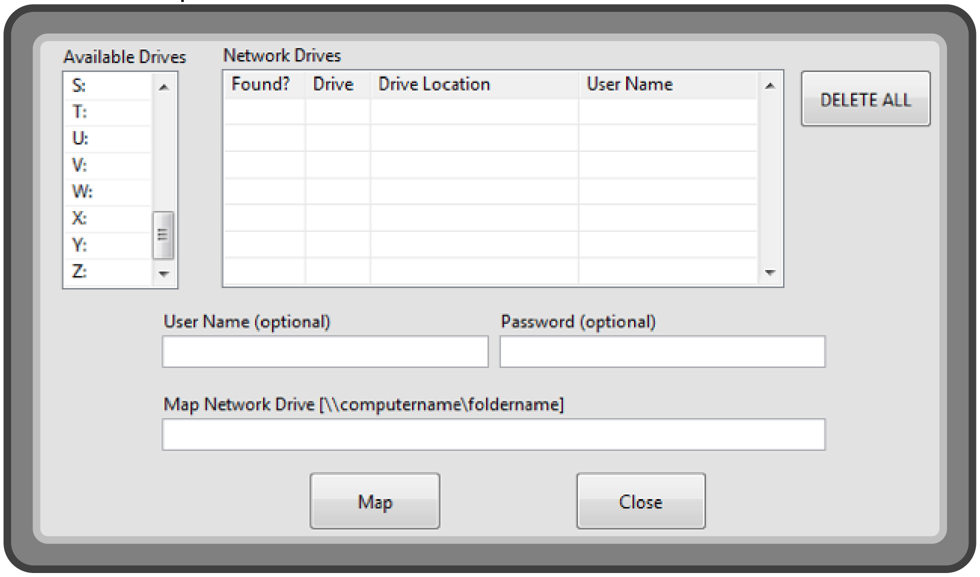
Note: To disable automatic backups, set the Backup Period (hour) to 0.

Note: If the Backup Period (hour) is set to 24, the backups will occur at midnight. Otherwise, the backup schedule will be set such that the first backup will occur at the top of the hour after changing the period or rebooting the HMI.

Setting Automatic Backup Location

1. Log in to the Desktop UI with a user account with the “DB Management” permission.
2. Navigate to the File Browser menu

3. Click the “Map Drive” button.



4. Select the Z drive and enter the appropriate information in the User Name, Password, and Map Network Drive fields, then click “Map” and “Close.”
5. The mapped network drive should appear in the list of Destinations. If not, check your network connection and consult your IT department.

Note: The PBS Software automatically backs up to the Z drive. Following the instructions above allows a user to map a networked drive to the Z drive. If users prefer using a physical external drive as the automatic backup location, have your IT department use their Administrator account on the HMI computer to configure a specific physical drive to be recognized as the Z drive.

Note: Although it is only possible to automatically back up databases to the Z drive, other networked drives may be mapped to other drive letters and used for manual backups of databases and/or reports.

Congratulations! You have now set up your PBS-3 and configured user accounts, logger settings, and alarms. Please see Chapter 6 for more details to begin using the PBS-3.

Using the PBS-3

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. Configure dip tube and tubing assembly (if using dip tube)
5. Autoclave reusable sensors, thermal well (and dip tube, if using)
6. Confirm gas source pressure matches specifications (see “Utility Requirements” on page 37)
7. Install reusable sensors, thermal well (and dip tube, if using) in vessel
8. Load Vessel
9. Install vessel in PBS-3
10. Level ‘Zero’ calibration
11. Add medium
12. Level ‘Span’ calibration (if necessary)
13. Control temperature, agitation, and main gas as for process. Control DO and pH in Manual mode.
14. Wait for equilibration
15. ‘One-point’/‘Span’ DO calibration
16. ‘One-point’ pH calibration
17. Control DO and pH in Auto mode
18. Load the Alarms On.alm file
19. Add cells
20. Start batch

During Run

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

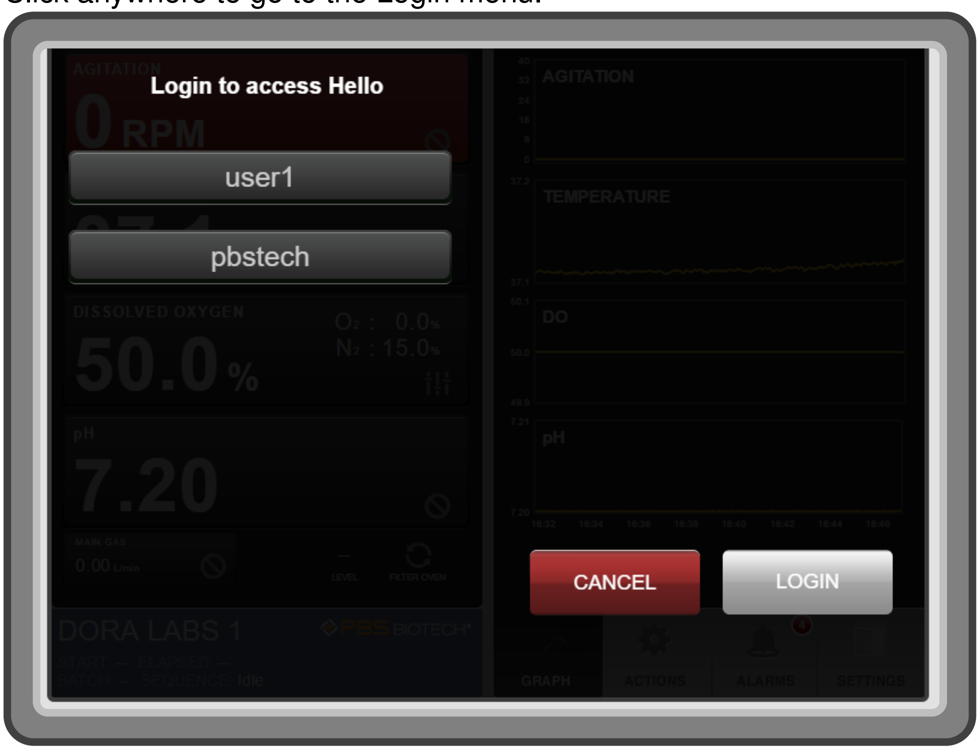
End Run

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

Before Starting a Batch Run

Log In to the Hello UI

1. If the screen is currently displaying the Desktop UI, click the “Hello UI” button to launch the Hello User Interface, and wait for the page to load.
2. Click anywhere to go to the Login menu.



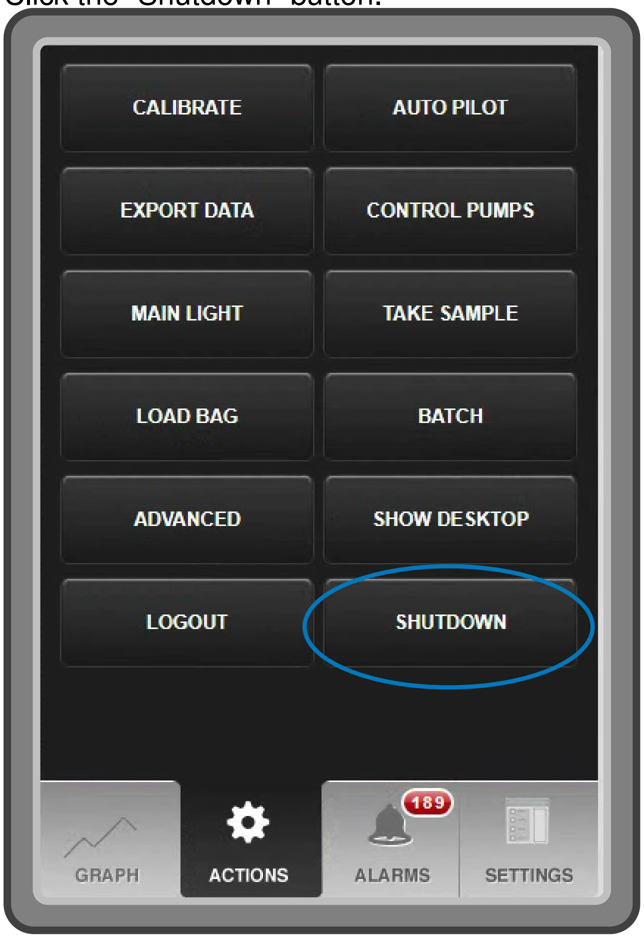
3. Select your user name from the menu.
4. Enter your password with the on-screen keypad, or with an external keyboard.
5. Click “Login.”

Restarting the HMI Computer

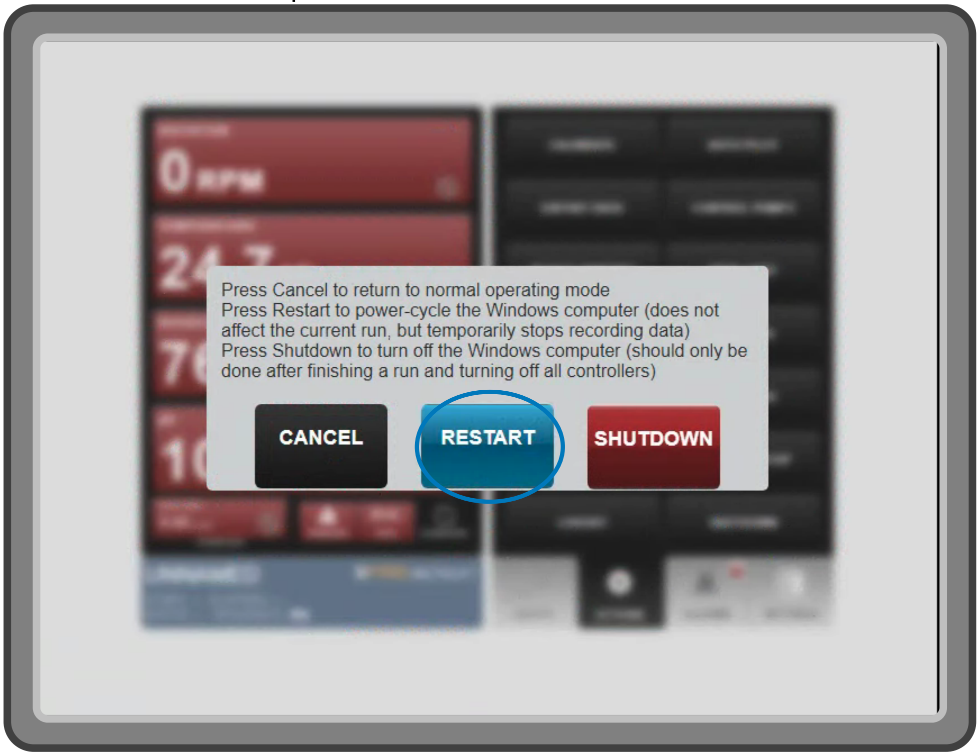
Like any computer, the bioreactor's HMI benefits from occasional reboots. Doing so before starting a run is especially beneficial if the bioreactor has been on for a significant amount of time.

To Restart the HMI with the Hello Interface:

1. Navigate to the "Actions" tab.
2. Click the "Shutdown" button.



3. Select the “Restart” option.



Calibrating Reusable pH Sensor

Before calibrating:

- Confirm the pH sensor is compatible with the PBS-3. The standard PBS-3 configuration is compatible with most combination electrodes with an S8 connector. If your PBS-3 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.
  Note: Do not twist the pH cable as this may damage it.

Two-point pH calibration with the Hello UI

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

3. Enter buffer temperature in the ‘Calibration Solution Temp’ field.
4. Enter buffer 1 value in the ‘Zero’ field.
5. Place pH sensor in buffer 1.
6. Wait for the graph to stabilize.
7. Click the “Calibrate 1” button.
8. Enter buffer 2 value in the ‘Span’ field.
9. Place pH sensor in buffer 2.
10. Wait for the graph to stabilize.
11. Click the “Calibrate 2” button.
12. Click “Save.”
13. Place pH sensor in buffer 1.
14. Confirm the displayed pH PV is close to the actual value of buffer 1.
15. Click “Close.”

For more information, see “‘One-point’ pH calibration” on page 80.

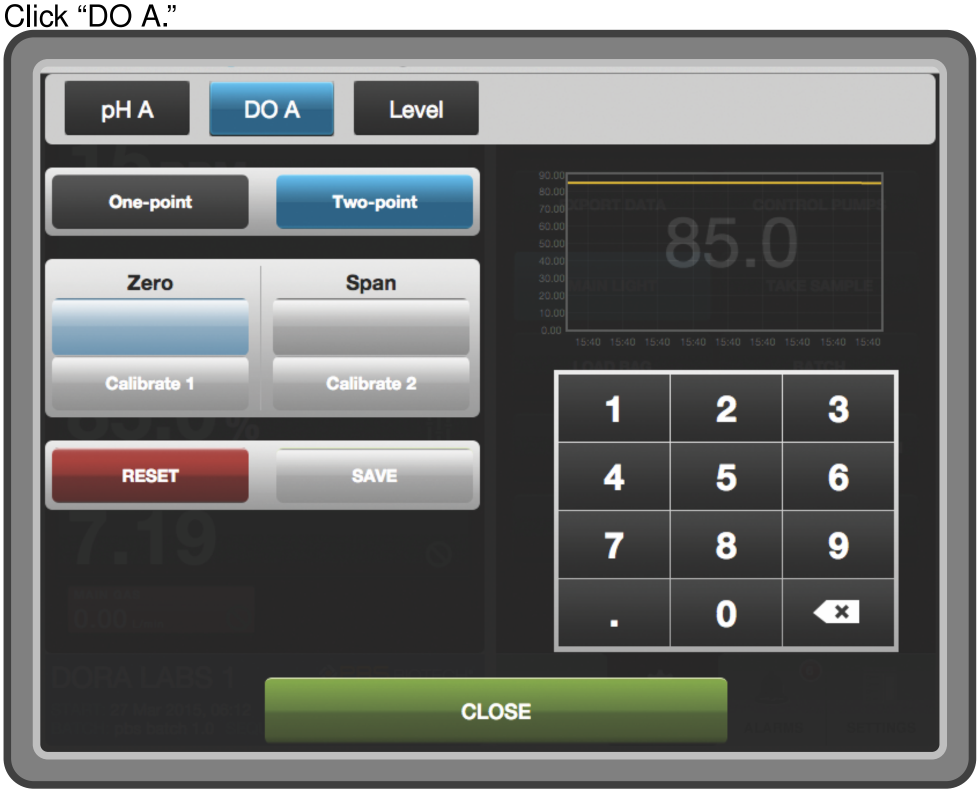
Calibrating Reusable Dissolved Oxygen Sensor

Before calibrating:

- Confirm the DO sensor is compatible with the PBS-3. The standard PBS-3 configuration is compatible with most polarographic DO electrodes with a D4 connector. If your PBS-3 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 with the Hello UI

1. Confirm the sensor is fully polarized.
2. Navigate to the “Actions” tab.
3. Click “Calibrate.”
4. Click “DO A.”



5. Enter ‘100’ in the ‘Zero’ field.
6. Click the “Calibrate 1” button.
7. Disconnect the polarized DO sensor.
8. Enter ‘0’ in the ‘Span’ field.
9. Wait for the graph to stabilize.
10. Click the “Calibrate 2” button.
11. Click “Save.”
12. Click “Close.”
13. Reconnect the sensor.
14. Wait for the graph to stabilize. It should read 100%.

Note: The operator could change the order, and calibrate to 0% for the ‘Zero’ field and 100% for the ‘Span’ 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 “‘One-point’/‘Span’ DO calibration” on page 78.

Configure Optional Dip Tube and Tubing Assembly

The dip tube can be used for the following purposes, among others:

- To remove spent medium, without removing settled cells
- To add liquids to the vessel, to minimize splashing
- To take a representative sample

The inner diameter of the tubing directly attached to the dip tube should be 3/16 inches. The dip tube itself should be configured so the maximum length of the dip tube extends into the vessel, beneath the compression fitting. After autoclaving, when it is installed in the vessel, the distance the dip tube extends into the vessel can be set.

All tubing branches should have clamps so the flow of liquid is controlled.

If the dip tube is being used for taking samples, it is recommended to separately prepare a small transfer flask with a short dip tube (see “Take Sample” on page 84), and connect it to the dip tube after the dip tube has been installed in the vessel.

If the dip tube is being used for taking samples of microcarrier culture or cell aggregates, it is best if the tubing and all connections are 3/16 inch inner diameter or larger. Tubing that is 1/4 inch inner diameter can be used instead, except for the connection directly to the dip tube. A reducer from 1/4 inch to 3/16 inch can be used to connect the tubing to the dip tube, or the 3/16 inch tubing can be stretched to fit over hose barbs meant for 1/4 inch inner diameter tubing. When preparing to autoclave, the tubing line(s) should not be plugged or clamped, so steam can fully penetrate the tubing.

Autoclaving Reusable Sensors, Thermal Well, and Optional Dip Tube

Prepare individual accessories to be autoclaved:

1. For a sensor, cover the part of the sensor that connects to the cables on the PBS-3, using the screw cap that came with the sensor.
2. Clean the accessory to be autoclaved, being sure to rinse with DI water.
3. Place the accessory to be autoclaved in an autoclave pouch, such that the nonsterile portion is easiest to access when the pouch is opened in the biosafety cabinet.
4. Seal the pouch.
5. Place the accessory 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.
6. 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.

Installing Reusable Sensors, Thermal Well, and Optional Dip Tube

Note: Wait until the reusable sensors, thermal well, and dip tube are cool to the touch before installing them in the vessel.

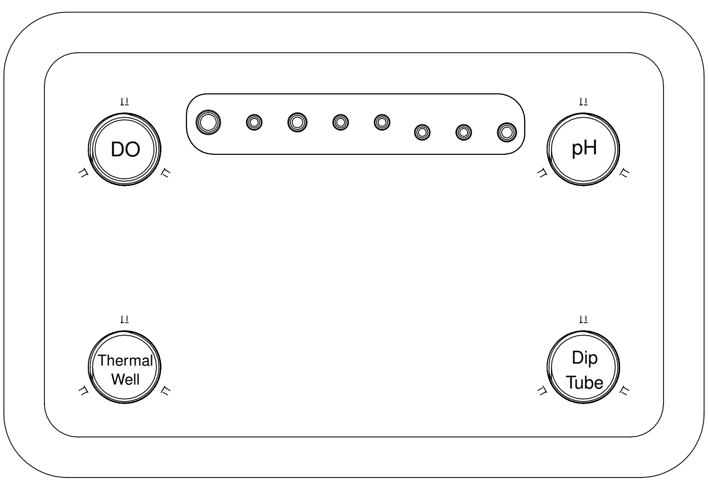
Note: The PBS Wrench can be used to assist in the installation or removal of port caps and accessories, such as sensors, the thermal well, and the dip tube.

1. Sanitize the autoclave pouches with 70% IPA or equivalent.
2. Transfer the autoclave pouches to biosafety cabinet.
3. Remove vessel outer packaging.
4. Sanitize vessel inner packaging with 70% IPA or equivalent.
5. Transfer packaged vessel into biosafety cabinet.
6. Remove vessel inner packaging.

7. Inspect the vessel and all tubing for damage inflicted during shipping.
8. Install the sensors, thermal well, and dip tube as follows:
   (a) Position the vessel so the port cap is accessible and tubing is not in the way. Use the image below to determine which port cap should be used for which accessory.
   (b) Loosen the port cap using the PBS Wrench.
   (c) Remove the accessory from the autoclave pouch, only touching the nonsterile portion.
   (d) Remove the port cap.
   (e) Guide the accessory through the port.
   (f) Thread the accessory tightly into the port.

   Note: The DO sensor must be positioned so its connector faces to the left, as you look at the front of the vessel. Otherwise, the cable on the PBS-3 will not reach the sensor.

   Note: If the dip tube is being used, PBS Biotech Technical Support recommends installing it after any other sensors and accessories, since its tubing can interfere with installing other accessories. Loosen the compression fitting on the dip tube, screw the dip tube into the vessel, adjust the height, and then tighten the compression fitting. The dip tube can be raised out of the vessel without compromising sterility, but cannot be pushed back down. This can also be done in the middle of a run, as long as the vesselis first placed in the biosafety cabinet. Ensure the angled tip of the dip tube does not interfere with the wheel.



9. Make connections to tubing as necessary. This will likely include connecting the dip tube to a transfer flask, if using.
10. Transfer the vessel out of the biosafety cabinet.

Load Vessel

To load a vessel:

1. Navigate to the “Actions” tab.
2. Click “Load Bag.”

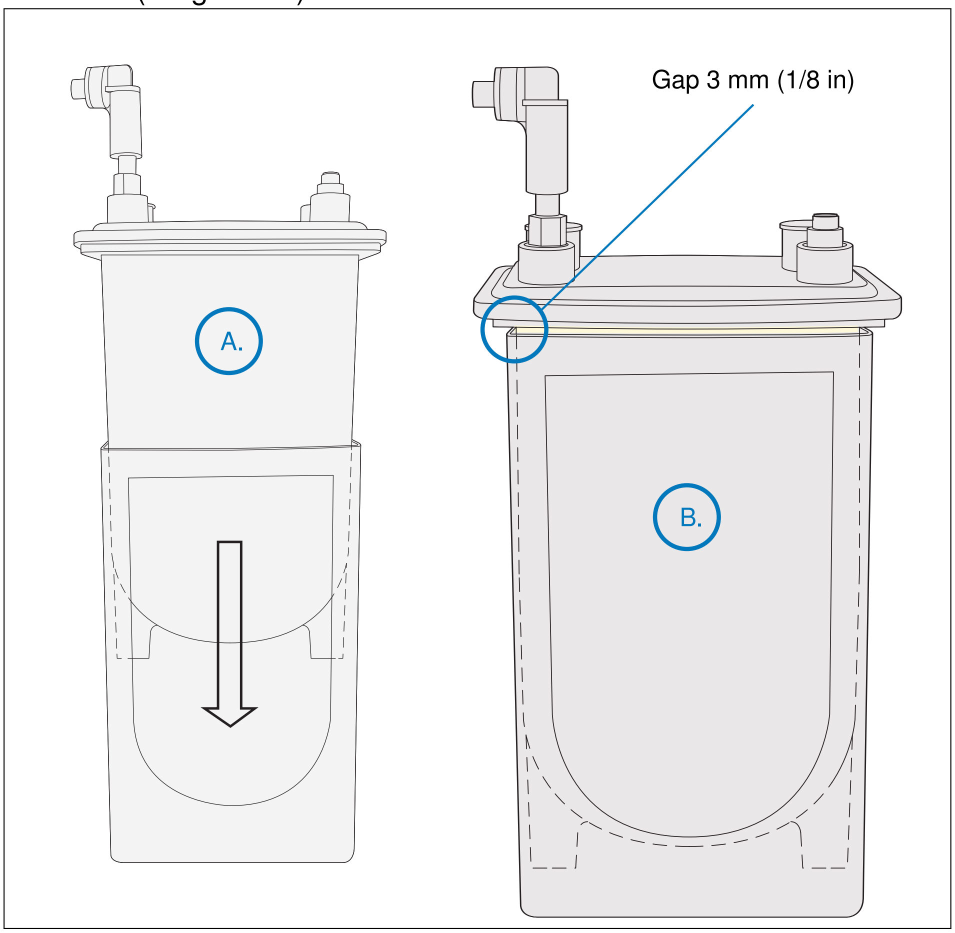
3. Enter the vessel gamma date.
4. Enter the vessel part number.
5. Enter the vessel serial number.
6. Do not enter calibration values for any reusable or single-use sensors that will be utilized.
7. Click “Load Bag.”

Install Vessel in PBS-3

Note: These instructions are for the standard PBS-3 Bioreactor vessel configuration. If your vessel is different, please consult its installation protocol.

1. Install all reusable sensors and connect optional extensions in a biosafety cabinet.
   Note: The PBS Wrench can be used to assist in the installation or removal of port caps and accessories, such as sensors and the dip tube.

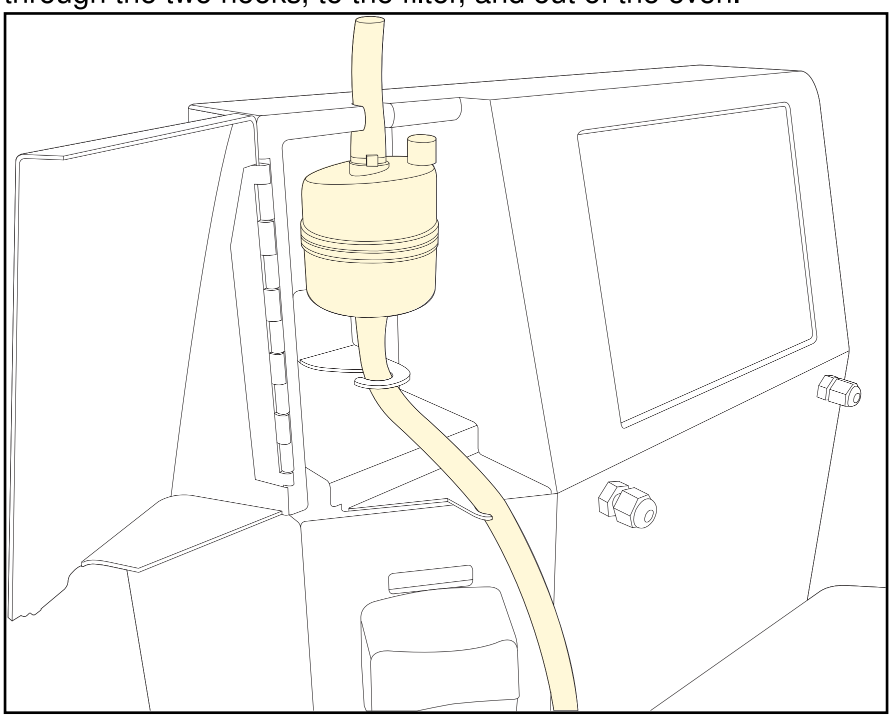
2. Hang the DO and pH sensor cables outside the vessel sleeve, and check that nothing is in the sleeve.
3. Hold the vessel so the back (i.e. the side with tubing coming out of it) faces away from you.
4. Slide the vessel into the sleeve, feet first. The bottom of the vessel should rest against the heaters (Diagram A.), and there should be a gap of approximately 3 mm (1/8 in) between the top of the sleeve and the vessel lid (Diagram B.).

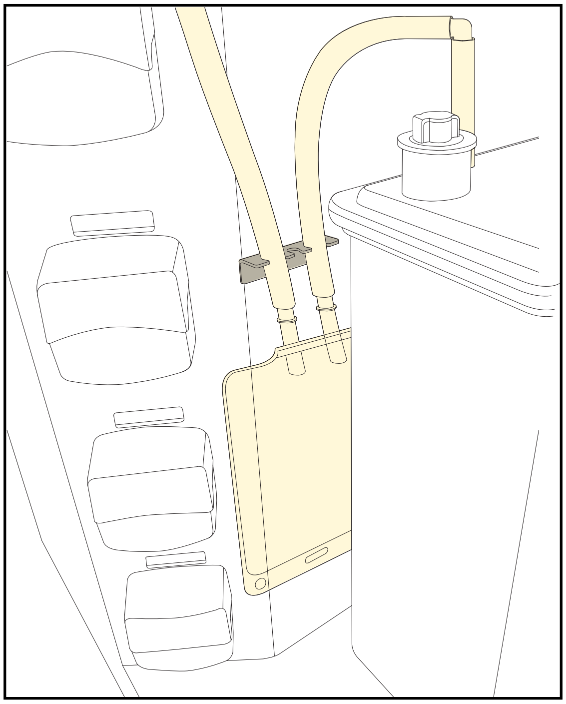


5. Remove the tubing sets from their bags. The tubing is color-coded to match the corresponding connectors and pumps on the PBS-3.

Connector/Pump	Tube Color
Main-gas	**Black**
Micro-gas	**Green**
Sample	**Red**
Addition A	**Brown**
Addition B	**Gray**
Media	**Orange**
Harvest	**Orange (x2)**

6. Leave the tubing lines on top of the PBS-3 so they do not get in the way during installation.
7. Install the exhaust filter tubing:
   (a) Secure the exhaust filter on the U-channel, so its tubing goes through the two hooks, to the filter, and out of the oven.

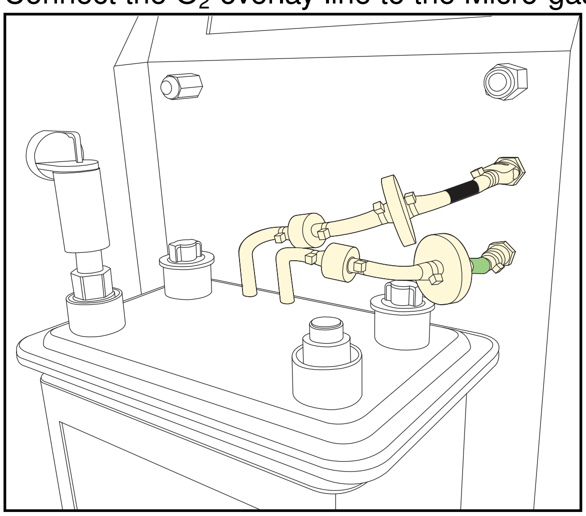




(b) Install the tubing by the condenser bag in the tubing holder.

(c) Close the filter oven door.

8. Connect the Air/CO_2/N_2 line to the Main-gas connector on the PBS-3.
9. Connect the O_2 overlay line to the Micro-gas connector on the PBS-3.

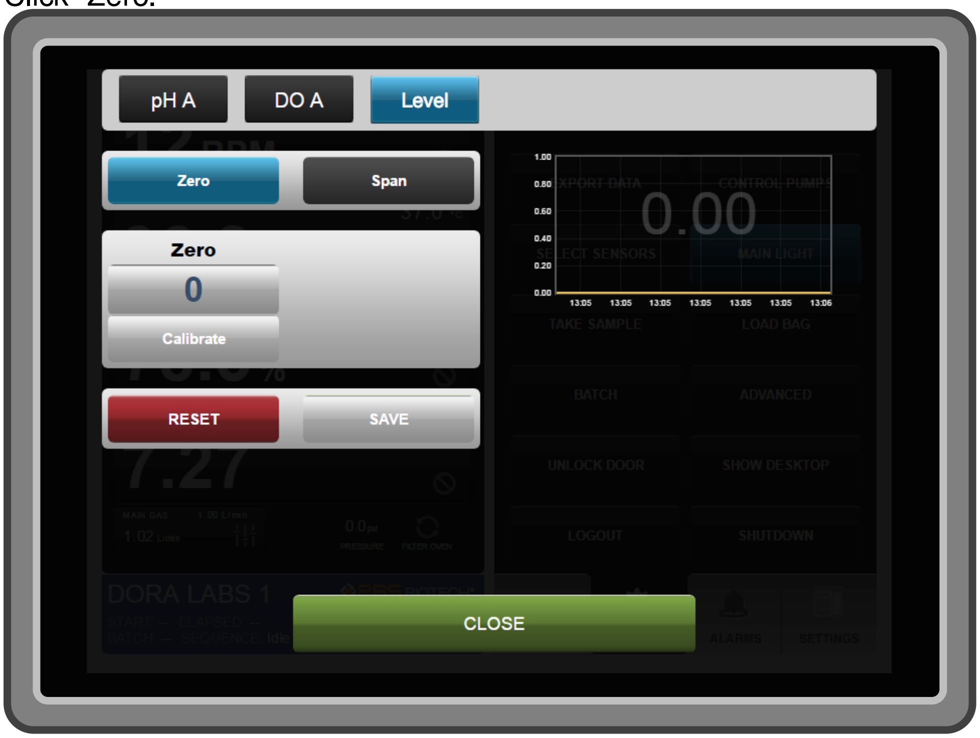


10. Connect the cables to the pH and DO sensors, as in “Calibrating Reusable pH Sensor” on page 60, and “Calibrating Reusable Dissolved Oxygen Sensor” on page 62.
    WARNING: When connecting the sensors, do not overtighten, as this may cause damage to the sensors.
11. Insert the temperature sensor in the thermal well.
12. Route addition lines, both media lines, and the harvest line behind the DO sensor and onto the bench next to the PBS-3.

Level ‘Zero’ Calibration

Level ‘Zero’ calibration with the Hello UI

1. Install empty vessel containing thermal well, all sensors and accessories, connect sensor cables, and install tubing in pumps as if during a run.
2. Navigate to the “Actions” tab.
3. Click “Calibrate.”
4. Click “Level.”
5. Click “Zero.”



6. Click the “Calibrate” button.
7. Click “Save.”
8. Click “Close.”

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.

Starting a Run

Using the Pumps

The tubing lines on the standard vessel have a silicone section, close to the vessel, 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 vessel. Only pump the silicone tubing.

Note: Depending on the model of vessel being used, some of the tubing lines may not be compatible with the pumps installed on the PBS-3 and will require the use of an external pump.

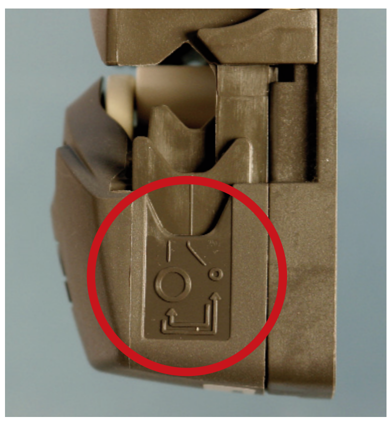
Tube holder positioning

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.

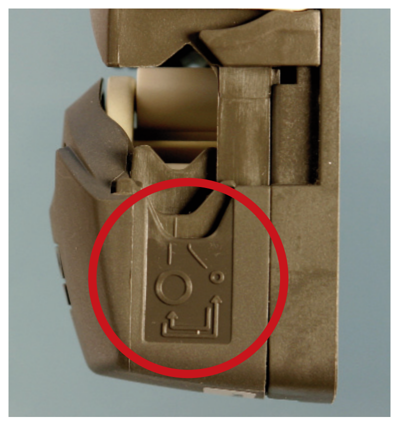
The pumphead can be adjusted to accommodate 1.6mm wall tubing in sizes from 0.5mm bore to 4.8mm bore.

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.

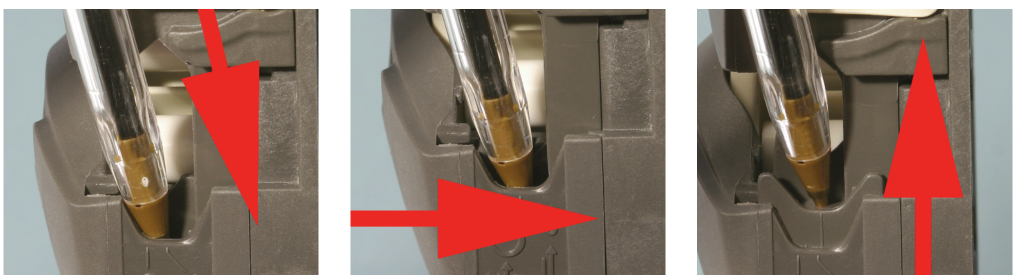
With the larger bore tubes of 4.0mm and 4.8mm the outer position must be used to prevent the flow rate being excessively reduced.

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

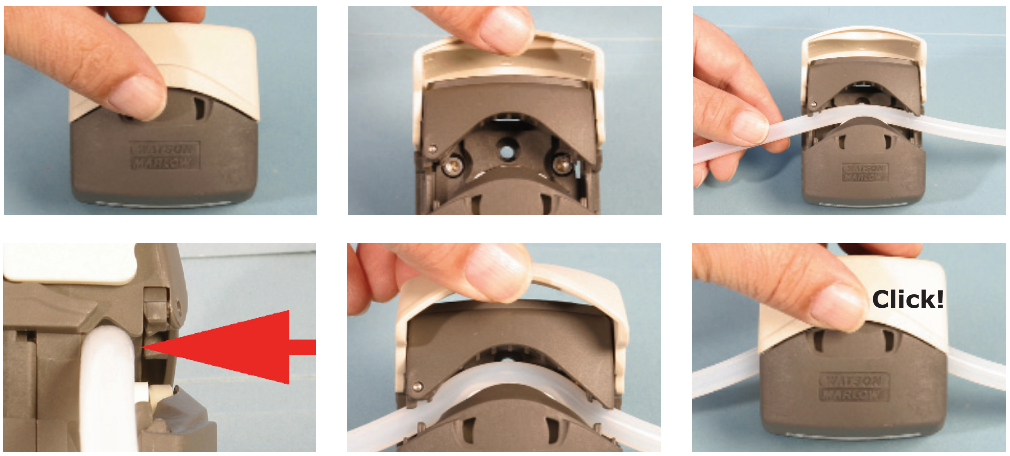
Carry out the procedure described above, but pushing towards the front of the pumphead.

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 loading

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.

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

To add medium:

1. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 73).
2. If the media pump is on, click the slider to turn it off.
3. 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.
4. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and vessel (see “Using the Pumps” on page 70).
5. Click the slider to turn the media pump on.
6. Click the slider to turn the media pump off after adding desired amount of medium.

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 vessel.

1. Confirm no gases are flowing and agitation is off.
2. Navigate to the “Actions” tab.
3. Click “Calibrate.”
4. Click “Level.”
5. Click “Span.”

6. Enter the actual level.
7. Click the “Calibrate” button.
8. Click “Save.”
9. Click “Close.”

Turning Controls On

After filling the vessel 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.

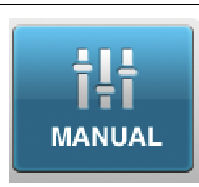
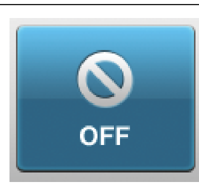
First, the agitation, temperature, and main gas controllers must be turned on. Then, the DO and pH controllers can be set to Manual mode, to achieve the desired process parameters you intend to use before inoculating. For an explanation why it is recommended to use DO and pH in Manual mode rather than Auto mode before the ‘span’/‘one-point’ calibrations are performed, see “Pre-Calibration Medium Conditioning Strategy” on page 131.

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 vessel 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 124.

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	50 °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 81.

Note: The dissolved oxygen and pH deadbands can be changed in the “Settings” tab. For more information, see “Settings/System Variables” on page 110.

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’ calibration 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 broken sensor may also necessitate using manual mode until a replacement can be sent. 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.

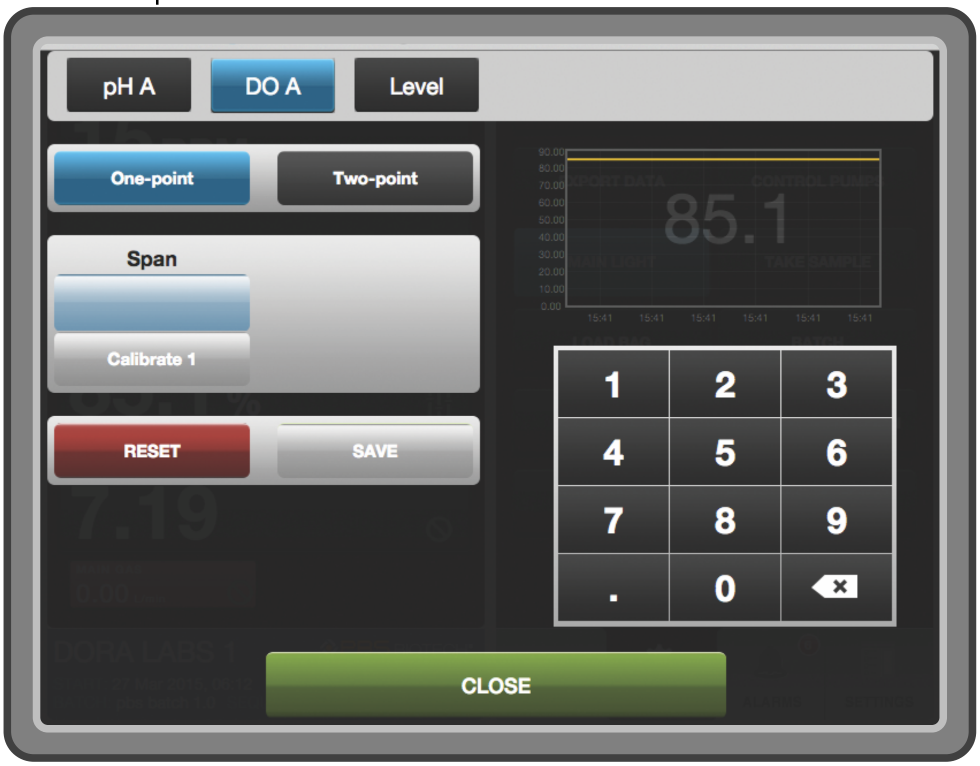
‘One-point’/‘Span’ DO calibration:

The following is recommended for DO calibrations:

- Only perform a ‘one-point’/‘span’ DO calibration before inoculating with cells
- Perform the ‘one-point’/‘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 133.

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 ‘one-point’/‘span’ calibration.
3. Navigate to the “Actions” tab.
4. Click “Calibrate.”
5. Click “DO A.”
6. Click “One-point.”



7. 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%.
8. Click the “Calibrate 1” button.
9. Click “Save.”
10. Click “Close.”
11. Set DO to Auto mode, if desired (see “Turning Controls On” on page 75).

‘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 84, “Take Sample” on page 143, and “Sampling for pH Measurement” on page 144). Note pH present value when taking sample.
2. Measure the pH of the sample (see “Sampling for pH Measurement” on page 144).
3. Navigate back to the “Actions” tab.
4. Click “Calibrate.”
5. Click “One-point.”

6. Click “Get Vessel Temp.”
7. Enter [(pH PV) – (pH PV when taking sample) + (actual pH of sample)] in the ‘Zero’ field.
8. Click the “Calibrate 1” button.
9. Click “Save.”
10. Click “Close.”
11. Set pH to Auto mode, if desired (see “Turning Controls On” on page 75 and “Selecting a Base Pump” on page 81).

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 73).
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 vessel as the pump rotates clockwise (see “Using the Pumps” on page 70).
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 vessel. 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 73).

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 vessel as the pump rotates clockwise (see “Using the Pumps” on page 70).
6. Confirm that the tubing is not clamped.
7. Set the desired addition speed.
8. Click the slider to turn the addition pump on.
9. Click the slider to turn the addition pump off after desired amount has been added, or leave the slider 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 Off.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 110.
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 50.
3. For how to view and acknowledge alarms, see “Alarms” on page 109.

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.

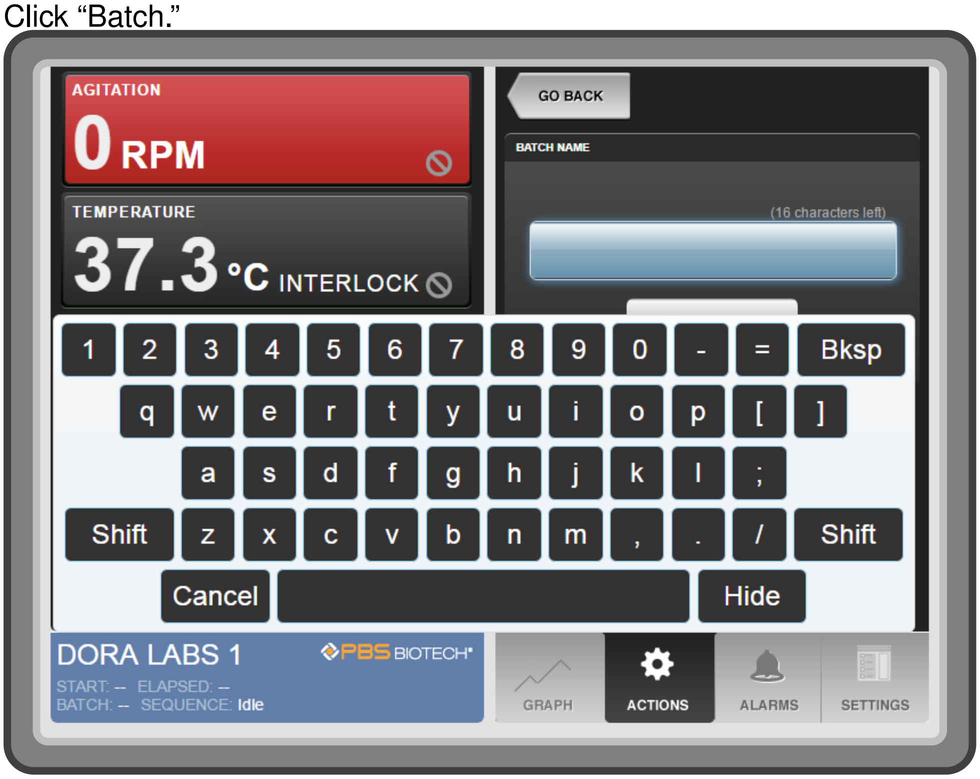
To inoculate:

1. Navigate to the Pumps menu (see “Accessing the Pumps menu” on page 73).
2. If the media pump is on, click the slider 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 vessel (see “Using the Pumps” on page 70).
5. Check that the tubing clamp is open, and its branched tubing clamp is closed, if applicable.
6. Click the slider to turn the media pump on.
7. Click slider 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 “End” in the overlay.
   (c) Click “Batch.”
4. Use the on-screen keyboard, or an external keyboard, to enter a batch name 16 characters or less.
5. Click the on-screen keyboard’s “Hide” button.
6. Click “Start Batch.”
7. Confirm by clicking “Start” in the overlay.
8. Observe that the Information Bar now displays the entered batch name, the start time, and the elapsed time.

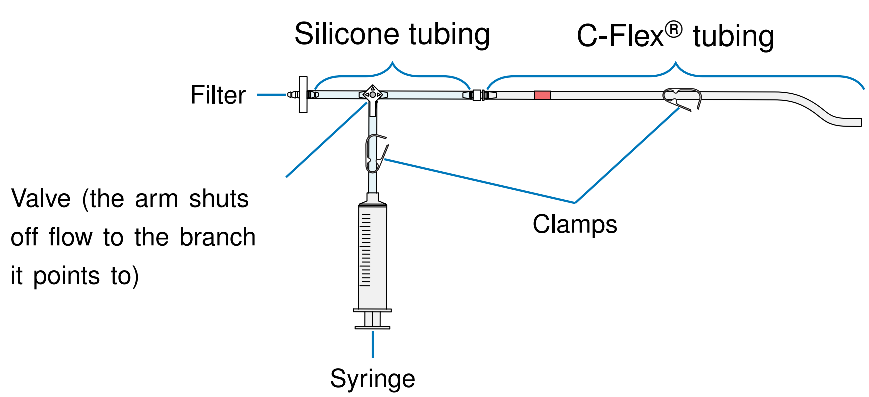
Take Sample

For information about concerns when taking a sample, handling the sample, and measuring a sample, see “Take Sample” on page 143.

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 vessel.

Note: A sample of 10 mL or larger is recommended for cell counts.

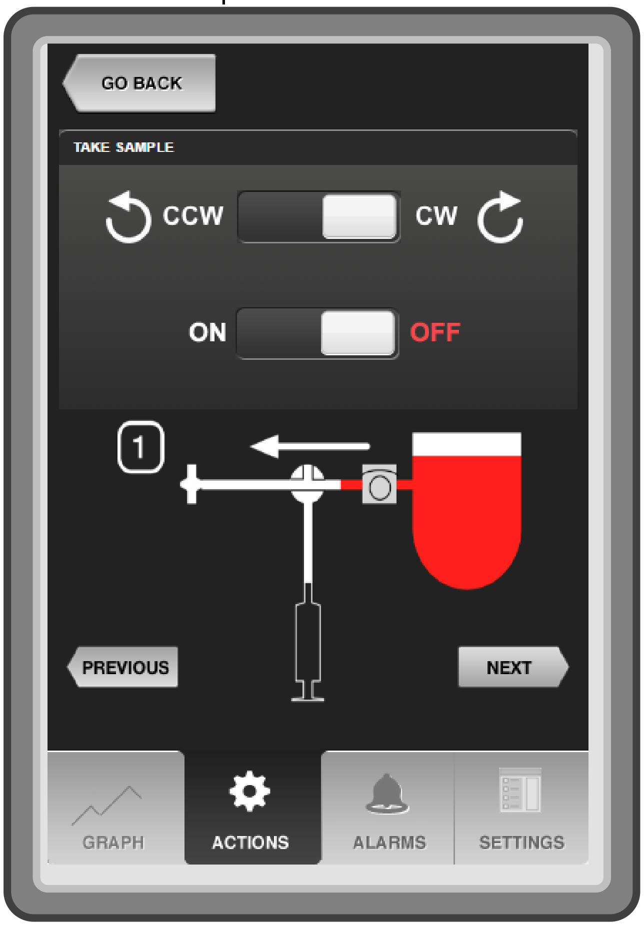
PBS-3 vessel’s sample line



To take a sample with the vessel’s sample line and a pump:

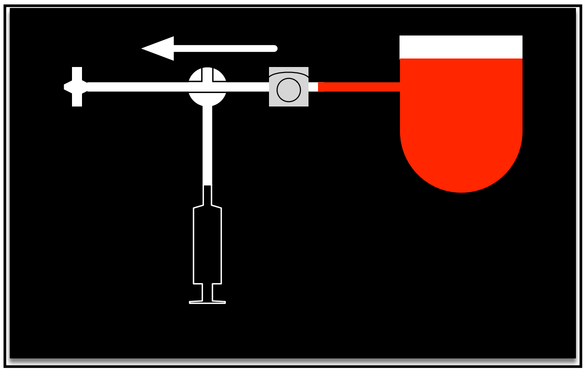
Using a pump to take a sample can decrease the sampling variability between operators. It can also, however, expose the sample to more shear stress. For instructions on how to take a sample without using a pump, see “To take a sample with the vessel’s sample line and dual-syringe pull” on page 88 and “To take a sample with the vessel's sample line, single-syringe pull, and gravity drain" on page 91.

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

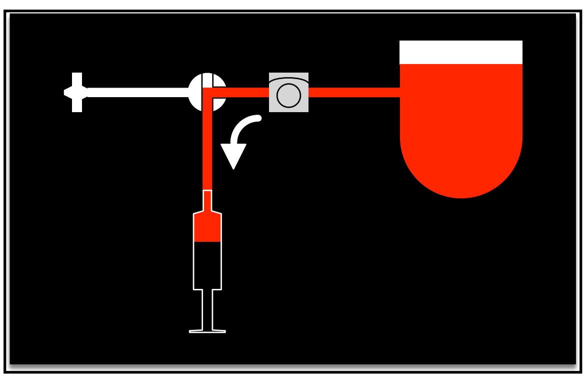


4. Unclamp all clamps on the sample line.

5. Clear the sample line of air, to minimize the amount of air that will end up in the syringe:
   (a) Install the silicone tubing between the valve and vessel in the sample pump as in the image below.
   (b) Configure the valve to block flow to the syringe. This will push the air in the sample line out of the filter.
   (c) Configure the sample pump to flow counter clockwise (CCW).
   (d) Turn the sample pump on. Be prepared to execute the next step.

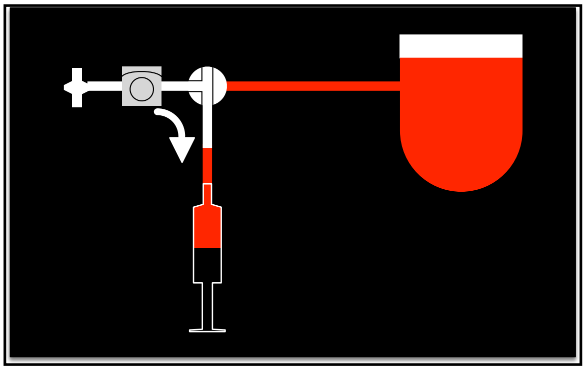


6. Bring the sample into the syringe:
   (a) Shortly before the liquid reaches the sample pump (as in the image above), change the direction of the valve to block flow to the filter. This will bring the liquid from the vessel into the syringe. Not changing the valve direction in time risks wetting the filter, which can clog it and prevent other samples from being taken.
   (b) When there is sufficient sample in the syringe, stop the sample pump.

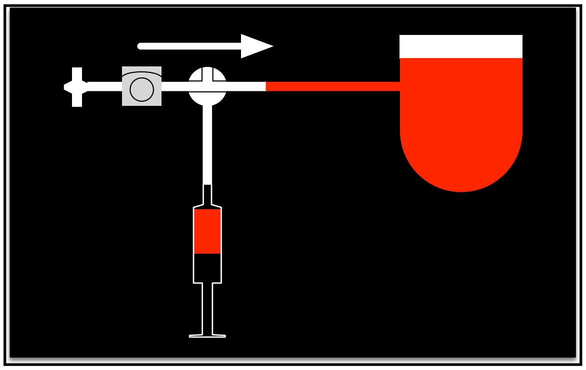


7. Clamp the line between the valve and syringe, and remove the tubing from the sample pump.

8. Push the remaining liquid between the valve and syringe into the syringe:
   (a) Install the tubing between the filter and valve in the sample pump as in the image below.
   (b) Configure the valve to block flow to the vessel. This will push filtered air into the syringe, clearing the line between the valve and syringe of liquid.
   (c) Unclamp the line between the valve and syringe.
   (d) Configure the sample pump to flow clockwise (CW).
   (e) Turn the sample pump on. Be prepared to execute the next step.



9. Push the remaining liquid between the valve and vessel back into the vessel:
   (a) When the line between the valve and syringe is clear of liquid, configure the valve to block flow to the syringe. This will push filtered air into the vessel, clearing the line between the valve and vessel of liquid.

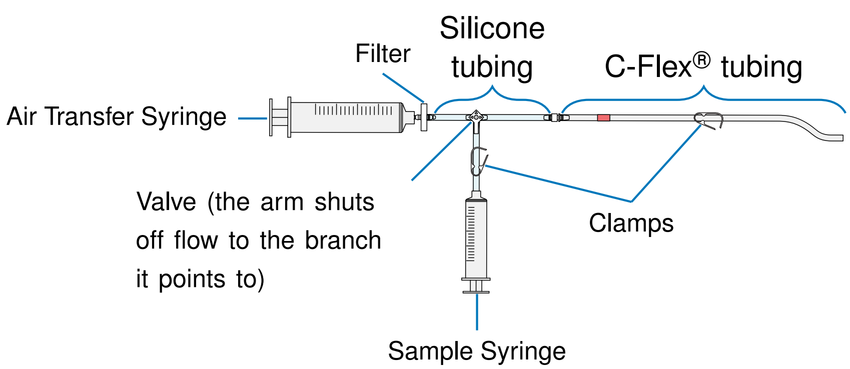


10. When bubbles form in the vessel it means the line is clear of liquid. Turn off the sample pump.
11. Clamp the sample line and replace the syringe with a sterile one, performing an alcohol dip for the transition.
12. If sampling to measure pH or DO, expel the head gas from the syringe, and cap it to make the sample more stable. Measure the pH or DO as soon as possible.

Note: Some users find that the Sample pump flows too quickly, and prefer using an Addition pump set to 'Slow' speed instead. The Addition pumps are controlled in the "Control Pumps" menu. Because they are not bi-directional, the tubing would have to be clamped and the manifold turned around at specific points in the Manual Sampling operation.

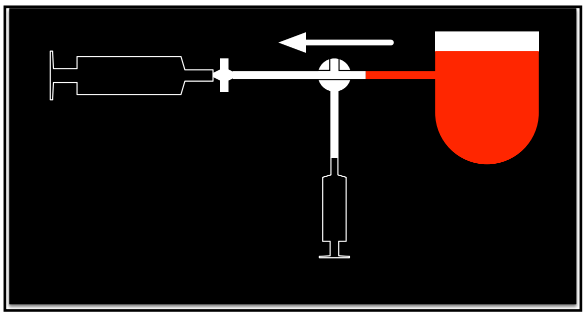
To take a sample with the vessel's sample line and dual-syringe pull:

This method requires a 60 mL syringe or similar, installed on the filter on the vessel's sample line. Taking a sample without using a pump can expose the sample to less shear stress. It can also, however, introduce more sampling variability between operators. For instructions on how to take a sample using a pump, see "To take a sample with the vessel's sample line and a pump" on page 84. For an alternative method for taking a sample without a pump, see "To take a sample with the vessel's sample line, single-syringe pull, and gravity drain" on page 91.

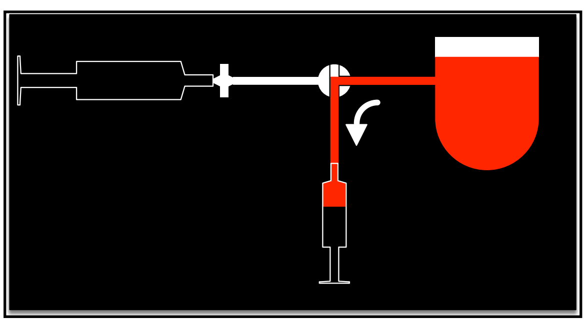


1. Install a 60 mL syringe or similar on the filter on the sample line. Instructions will refer to this as the "air transfer syringe."
2. Unclamp all clamps on the sample line.

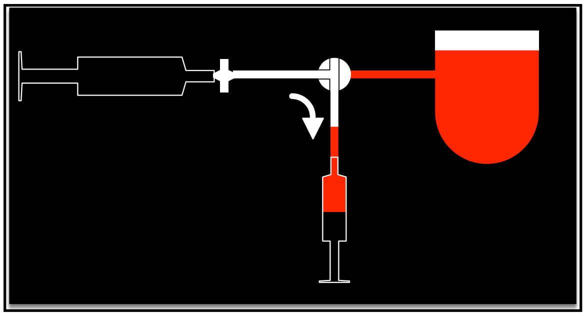
3. Clear the sample line of air, to minimize the amount of air that will end up in the sample syringe:
    (a) Configure the valve to block flow to the sample syringe. This will allow the air transfer syringe to pull the air in the sample line through the filter and into the air transfer syringe.
    (b) Using the air transfer syringe, pull air out of the sample line.
    (c) Stop before the liquid in the vessel gets to the valve. Continuing to pull liquid past the valve risks wetting the filter, which can clog it and prevent other samples from being taken.



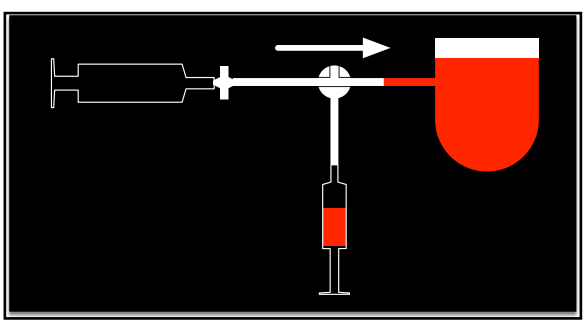
4. Bring the sample into the sample syringe:
    (a) Change the direction of the valve to block flow to the filter. This will allow the sample syringe to pull the liquid from the vessel into the sample syringe.
    (b) Pull the sample from the vessel using the sample syringe.
    (c) When there is sufficient sample in the syringe, stop pulling.



5. Push the remaining liquid between the valve and sample syringe into the sample syringe:
   (a) Configure the valve to block flow to the vessel. This will allow the air transfer syringe to push filtered air into the sample syringe, clearing the line between the valve and sample syringe of liquid.
   (b) Push air from the air transfer syringe through the filter and into the sample syringe.
   (c) Stop pushing air into the sample syringe once the line between the valve and sample syringe is clear of liquid.



6. Push the remaining liquid between the valve and vessel back into the vessel:
   (a) Configure the valve to block flow to the sample syringe. This will allow the air transfer syringe to push the air in the air transfer syringe through the filter and into the vessel, clearing the sample line.
   (b) Using the air transfer syringe, push air into the sample line. You will likely have to disconnect the air transfer syringe, pull more air into it, and reconnect it to the filter to completely clear the sample line. Because the air is being pushed through the filter, this will not compromise sterility.
   (c) When bubbles form in the vessel it means the sample line is clear of liquid. Stop pushing air through the air transfer syringe at this point.



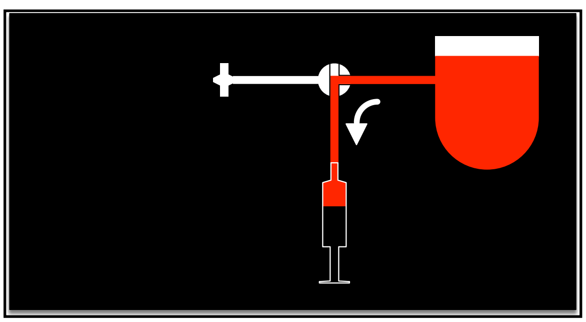
7. Clamp the sample line and replace the sample syringe with a sterile one, performing an alcohol dip for the transition.
8. If sampling to measure pH or DO, expel the head gas from the syringe,

and cap it to make the sample more stable. Measure the pH or DO as soon as possible.

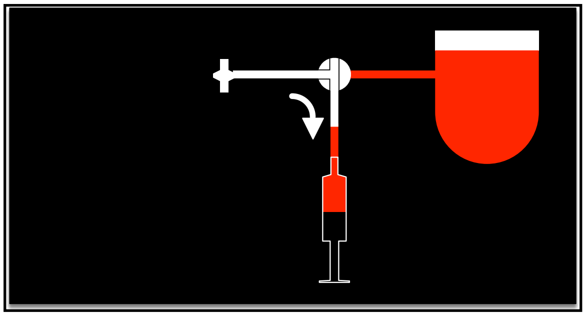
To take a sample with the vessel's sample line, single-syringe pull, and gravity drain:

Taking a sample without using a pump can expose the sample to less shear stress. It can also, however, introduce more sampling variability between operators. This method also exposes the sample much more air than the other methods using the sample line, and is therefore not appropriate for measuring the pH or DO of the sample. For an alternative method of taking a sample without using a pump, see "To take a sample with the vessel's sample line and dual-syringe pull" on page 88. For instructions on how to take a sample using a pump, see "To take a sample with the vessel's sample line and a pump" on page 84.

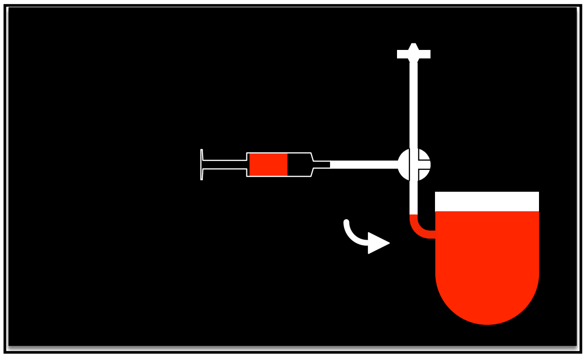
1. Unclamp all clamps on the sample line.
2. Pull the sample into the sample syringe:
    (a) Configure the valve to block flow to the filter. This will allow the sample syringe to pull the liquid from the vessel into the sample syringe.
    (b) Pull the sample from the vessel using the sample syringe. Note that you will first be pulling the air in the sample line into the syringe.
    (c) When there is sufficient sample in the syringe, stop pulling.



3. Pull the remaining liquid between the valve and sample syringe into the sample syringe:
   (a) Configure the valve to block flow to the vessel. This will allow the sample syringe to pull filtered air into the sample syringe, clearing the line between the valve and sample syringe of liquid.
   (b) Pull air from the air transfer syringe through the filter and into the sample syringe.
   (c) Stop pulling air into the sample syringe once the line between the valve and sample syringe is clear of liquid.



4. Drain the remaining liquid between the valve and vessel back into the vessel:
   (a) Hold the filter and valve above the liquid level line of the vessel.
   (b) Configure the valve to block flow to the sample syringe. This will allow air to pass through the filter and into the vessel, clearing the sample line.
   (c) Raise the sample line above the liquid level line of the vessel, to allow gravity to drain as much of the liquid as possible back into the vessel.



5. Clamp the sample line and replace the sample syringe with a sterile one, performing an alcohol dip for the transition.

To take a sample from the dip tube:

Note: Two operators are necessary for this section.

Note: This assumes the dip tube's tubing line routes 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 "Control Pumps."
4. Position the dip tube tubing in the Media pump so the flow is toward the transfer flask at the end of the dip tube assembly.
5. Put 2 50 mL conicals in the biosafety cabinet. Label one for 'Waste' and the other for 'Sample.'
6. Put the transfer flask at the end of the dip tube assembly in the biosafety cabinet.
7. Operator A: Remove the transfer cap and hold its dip tube over the 'Waste' conical.
8. Operator B: Unclamp the dip tube line and turn the pump on.
9. Operator A: Instruct Operator B to turn the pump off when 5 mL or more has gone into the 'Waste' conical. This clears the line of settled microcarriers and excess media.
10. Operator B: Turn the pump off when directed.
11. Operator A: Hold the transfer cap's dip tube over the 'Sample' conical.
12. Operator B: Turn the pump on.
13. Operator A: Instruct Operator B to turn the pump off when enough liquid has entered the 'Sample' conical.
14. Operator B: Turn the pump off when directed. Clamp the line.
15. Operator A: Install the transfer cap back in the transfer flask.
16. Operator B: Position the dip tube tubing in the Media pump so the flow is toward the vessel.
17. Operator B: Unclamp the dip tube line and turn the pump on.
18. Operator B: Turn the pump off and clamp the dip tube line when the line is clear and bubbles are pushed through the end of the dip tube in the vessel.

Exchanging Medium

1. Form a sterile connection between the dip tube line and the waste media bottle/bag destination by welding the tubing or using the sterile connectors. The end of the dip tube should be above the volume of settled cells.
2. Load the Alarms Off.alm file (see “Load the Alarms On.alm File” on page 82).
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 vessel to maintain a reasonable amount of pressure within the vessel.
5. Turn agitation off.
6. Sparging gas will interfere with the cells settling to the bottom of the vessel. If O_2 is being sparged, disconnect the O_2 sparge line being used, to prevent sparging gas while cells are settling. Route O_2 through the headspace.
7. Wait for the cells to settle to the bottom of the vessel. The aspiration port or the end of the dip tube should be above the settled volume of cells. If not, either change which aspiration line is connected to the waste media bottle/bag, or (if the dip tube is being used), bring the vessel into the biosafety cabinet, and (being careful not to insert the dip tube further into the vessel) loosen the dip tube, raise part out of the vessel, and re-tighten it.
8. Check that the aspiration line or dip tube line tubing clamp is open, and its branched tubing clamp is closed, if applicable.
9. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and waste media bottle/bag.
10. Remove the desired amount of spent medium.
11. Reattach the O_2 sparge line, if applicable.
12. Add fresh medium (see “Adding Medium” on page 74).
13. Turn agitation back on, and set DO and pH to the original desired modes.
14. When settled cells/aggregates/microcarriers are resuspended, turn temperature back on.

15. Load the Alarms On.alm file (see “Configuring Alarm Settings” on page 50 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 Off.alm file (see “Configuring Alarm Settings” on page 50).
2. Set all control modes to Off.
3. Navigate to the “Actions” tab.
4. Click “Control Pumps.”
5. If the media pump is on, click the slider to turn it off.
6. Form a sterile connection between the harvest line (two orange bands) and the harvest bottle/bag destination by welding the tubing or using the sterile connectors.
7. Check that the tubing clamp is open, and its branched tubing clamp is closed, if applicable.
8. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and harvest bottle/bag destination.
9. Click the slider to turn the media pump on.
10. Click the slider to turn the media pump off after removing culture.
11. Turn off all pumps.
12. Set base pump to “None.”
13. Turn off light.
14. End batch (see “Entering Batch Name” on page 83).
15. Remove the vessel.
    WARNING: When removing the DO and pH sensors from the vessel, 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 probe ports and be accidentally disposed of). Similarly, when removing the thermal well and dip tube from the vessel, be sure to retrieve the transparent o-rings necessary for sealing and keep them with the thermal well and dip tube (they can slide off and remain in the probe ports and be accidentally disposed of).

16. Turn the filter oven off, if desired (see “Filter Oven” on page 96).
17. Clean/decontaminate the PBS-3 (see “Cleaning and Decontamination” on page 31).

Note: If performing multiple harvests, reposition tubing through the pump head if it starts to wear out, to pump with a fresh piece.

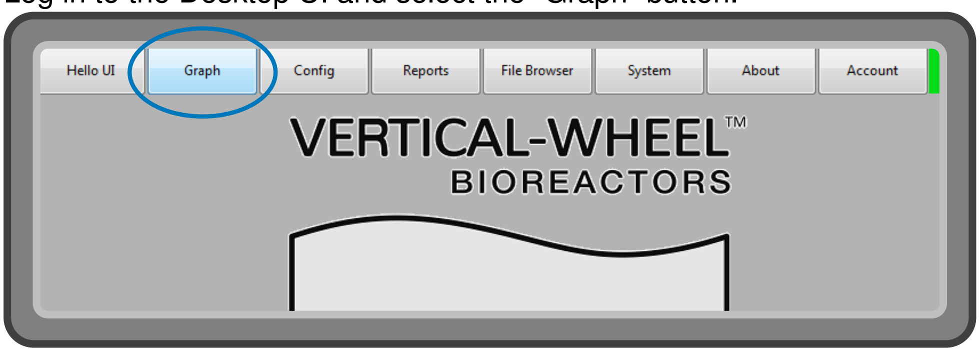
Other Features

Filter Oven

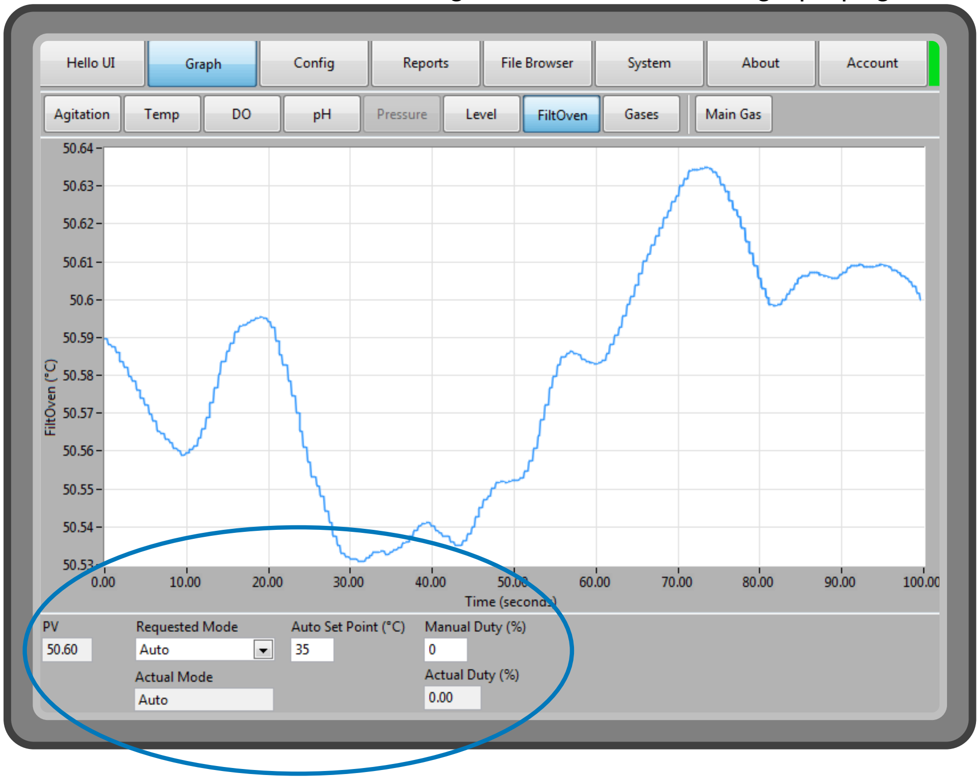
The Filter Oven heats the exhaust filter on the vessel, preventing moisture from accumulating in it and clogging it. The PBS-3 is designed to always have the Filter Oven in Auto mode, at 50 °C. If users still want to turn it off between runs, they need to make sure to turn it on before adding medium. PBS Biotech Technical Support does not recommend this, as there is no software alert or interlock to alert users that the Filter Oven is Off.

To change the filter oven mode:

1. Log in to the Desktop UI and select the “Graph” button.



2. Click the “FiltOven” button to navigate to the Filter Oven graph page.



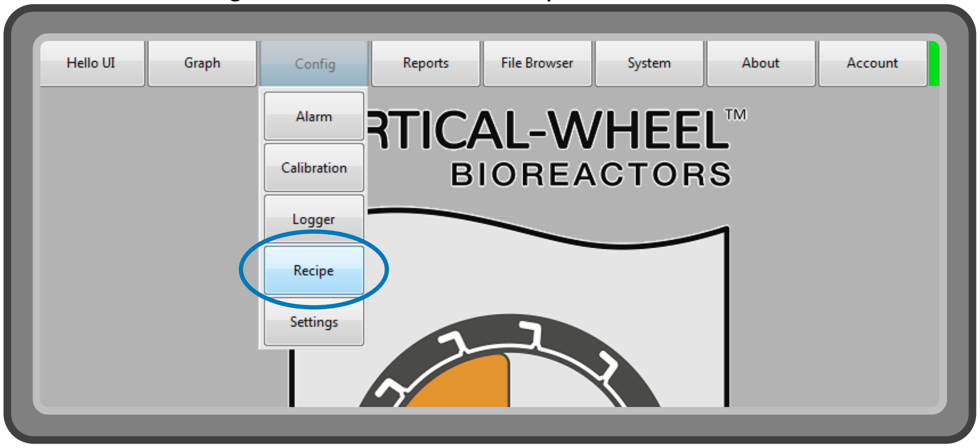
3. Select the desired mode from the ‘Requested Mode’ field.
4. To change the set point for the Filter Oven, select the ‘Auto Set Point (C)’ field. In the number pad that appears, enter an acceptable set point.

Recipes

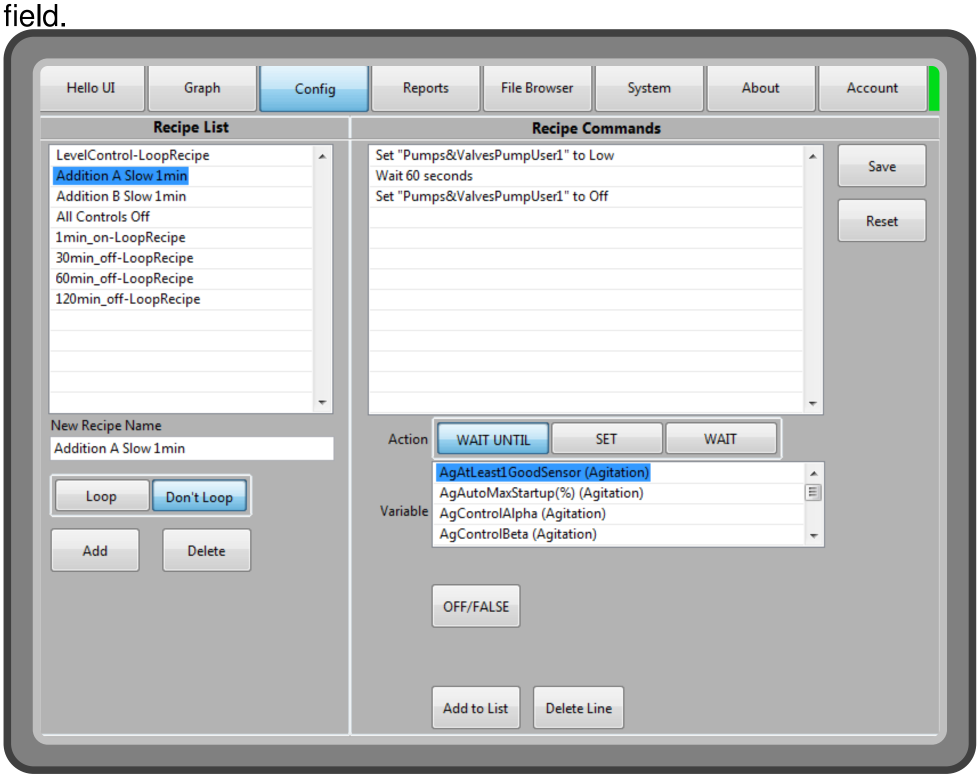
Creating or editing recipes

1. Log in to the Desktop UI with a user account with the “Recipe Editor” permission (for more information on user permissions, see “User Group Permissions” on page 149).

2. Select the “Config” tab, then select “Recipe.”



3. To edit an existing recipe, click on the recipe in the “Recipe List.” To add a new recipe, click “Add.”
4. The on-screen keyboard will appear, allowing you to name your new recipe. (Please note that the use of capital letters in the recipe name will not be reflected in the Hello UI). An existing recipe name may be edited at any time by selecting the recipe and clicking the ”New Recipe Name” field.



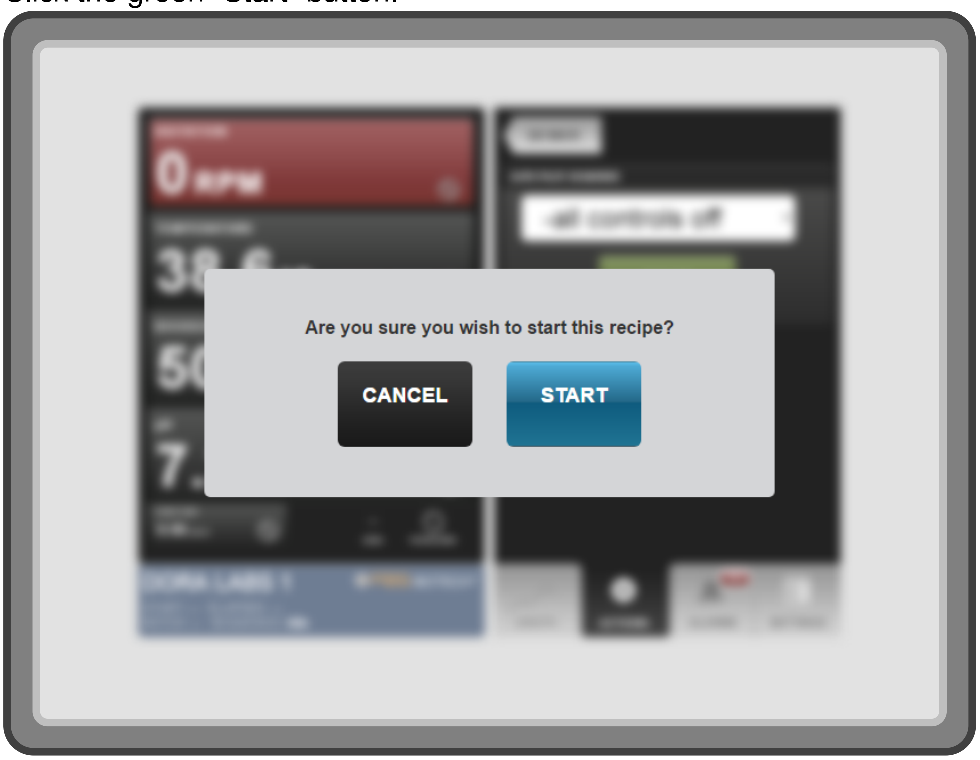
Configuring recipes

1. Select a recipe in the “Recipe List” field.

2. Recipe steps will be listed in order of operation in the "Recipe Commands" field. In a new recipe, this field will be blank.
3. To add a recipe step, select a variable in the "Variable" field, then select one of the buttons in the "Action" field (for more information on the variables listed, see Appendix 4 on page 195).
4. Select or enter the relevant data for the step, then click "Add to List."
5. To delete a step, click "Delete Line."
6. To rearrange steps, click and drag them.
7. To revert a recipe, click "Reset."
8. When you are finished configuring your recipe, click "Save."

Running recipes

1. Log in to the Hello UI.
2. Navigate to the "Actions" tab.
3. Click "Auto Pilot."
4. Click "SELECT RECIPE" and select the desired recipe.
5. Click the green "Start" button.



6. Click "Start" to confirm.

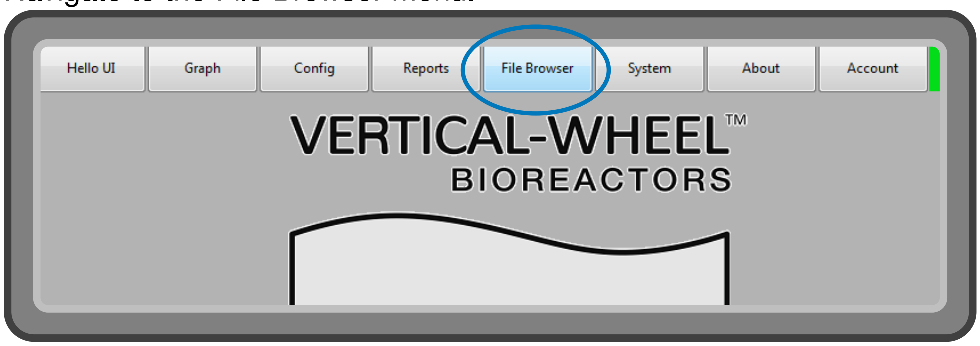
Note: If the Auto Pilot menu was open when a new recipe was created, close and re-open the menu by clicking “Go Back” and then “Auto Pilot.”

For more on recipes, see “Recipes” on page 139.

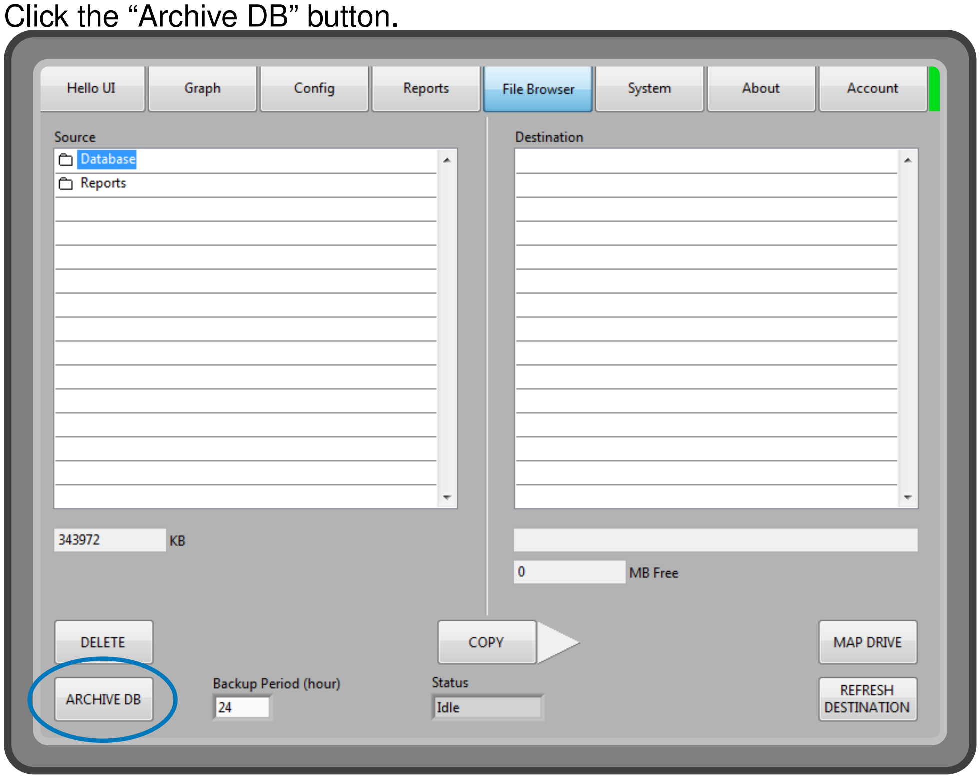
Manually Archiving DBs

The PBS Software automatically archives the active database based on its size. It checks every hour, and when a user stops a batch. However, if users desire, they can manually archive the active database.

1. Log in to the Desktop UI with a user account with the “DB Management” permission.
2. Navigate to the File Browser menu.



3. Click the “Archive DB” button.



Note: During the archive process, data recording is paused, and restarts after the archive process is complete. The data generated during this time is not lost, but is temporarily stored in memory. Access to all features is also restored once the archive process is complete. For more information on the archive process, see “Database” on page 143.

Managing Files

To copy databases and reports to external drives, and delete reports and archived databases, see “Generating Reports” on page 101. Users should only have to delete archived databases yearly. DO NOT delete archived databases until they have been securely backed up.

Generating Reports

Reports can be generated in both the Desktop and Hello User interfaces.

Note: 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.

To generate reports from the active database with the Hello UI (preferred method):

1. Log in to the Hello UI and navigate to the “Actions” tab.
2. Click “Export Data.”

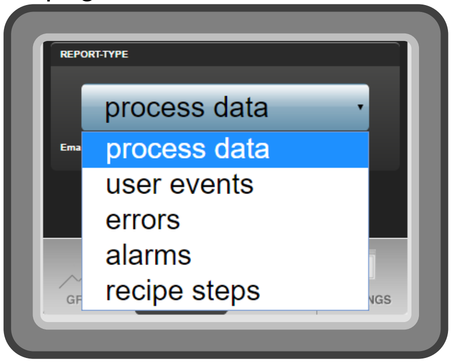
3. Choose a batch or time span:

(a) To select a batch by name, use the "Select Batch" dropdown menu.

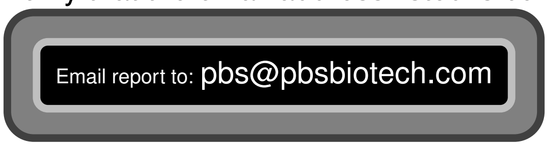
(b) To select a time span, click the 'From' field, choose the dates in the calendar, and use the sliders to select the hours and minutes. Click back into the Export Data window.

(c) Click the 'To' field, and choose a date and time.

4. Select “Report Type.” For more information on Report Types, see “Types” on page 141.



5. Verify that the email address listed is correct.



6. Click “Get Report.”
7. You can click the “Open Report” button to preview the raw contents of the report.
8. To access the report file:

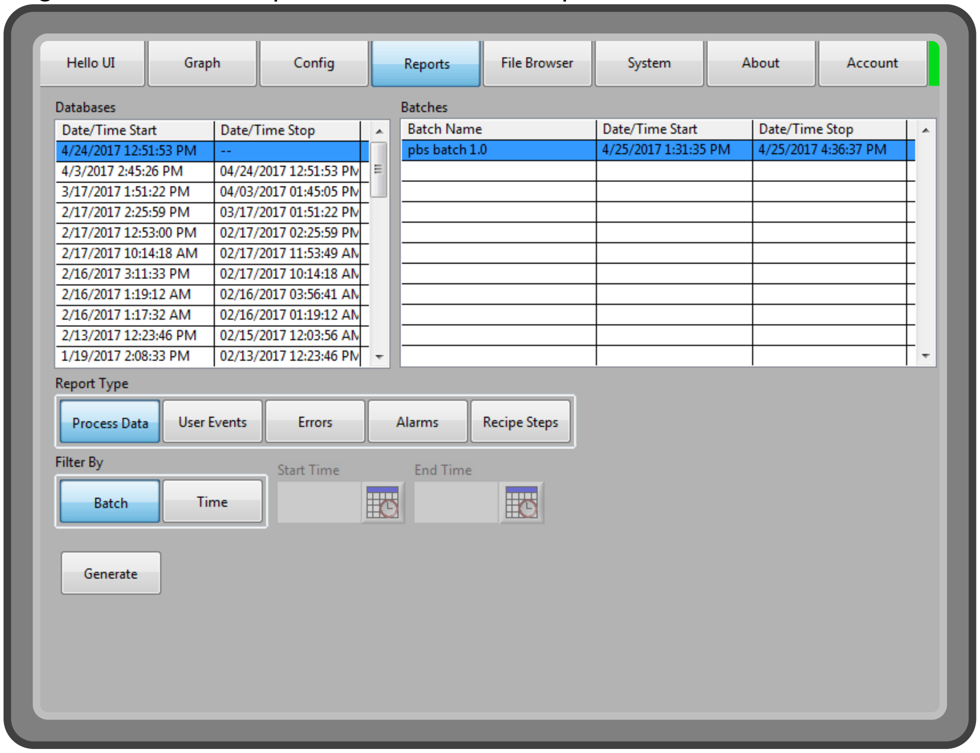
    (a) If email is configured correctly, the report will be in your inbox.

    (b) If you are accessing the PBS-3 from a remote client and would like to save the report directly to your computer, click the “Download Report” button to save the file. If the file’s “Save As” prompt suggests .txt format, change it to .csv.

    (c) If you are working directly on the bioreactor, note the name of the report, and see the instructions below for using the Desktop UI to copy reports to external drives.

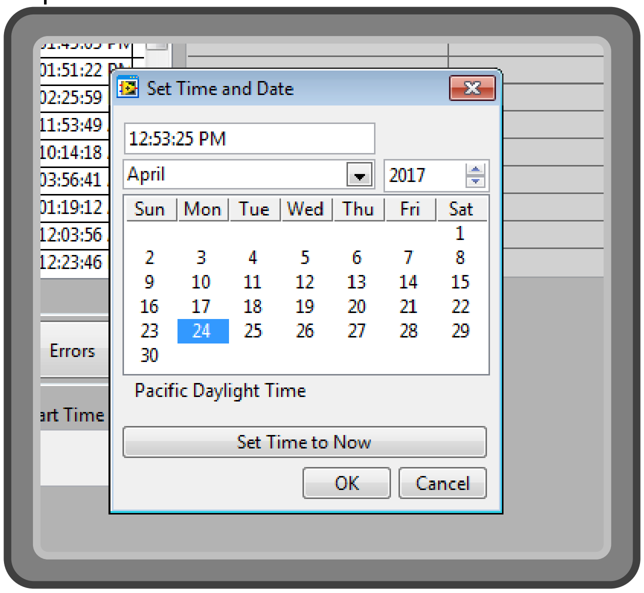
To generate reports with the Desktop UI (alternative method):

1. Log in to the Desktop UI and click the “Reports” button.

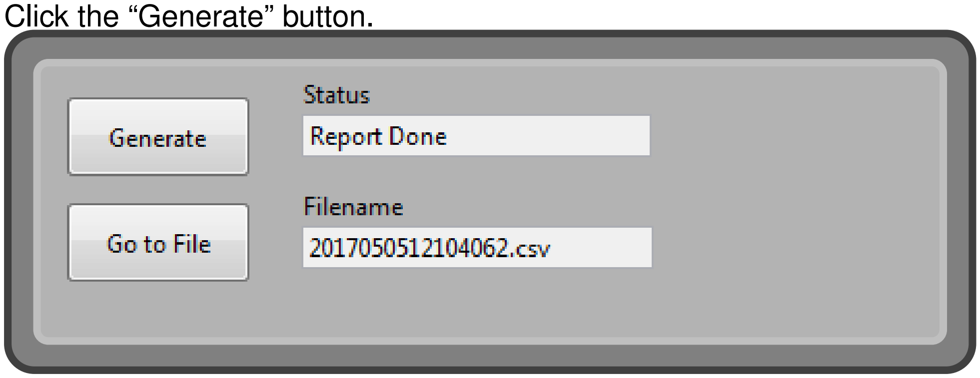


2. Select either the current database, which will be the first database listed in the “Databases” field, or an archived database listed below the current one.
3. Choose a “Report Type.”
4. Select whether you want to filter by “Batch,” or “Time.”
   (a) If selecting “Batch,” then choose a batch from those listed in the “Batches” field.

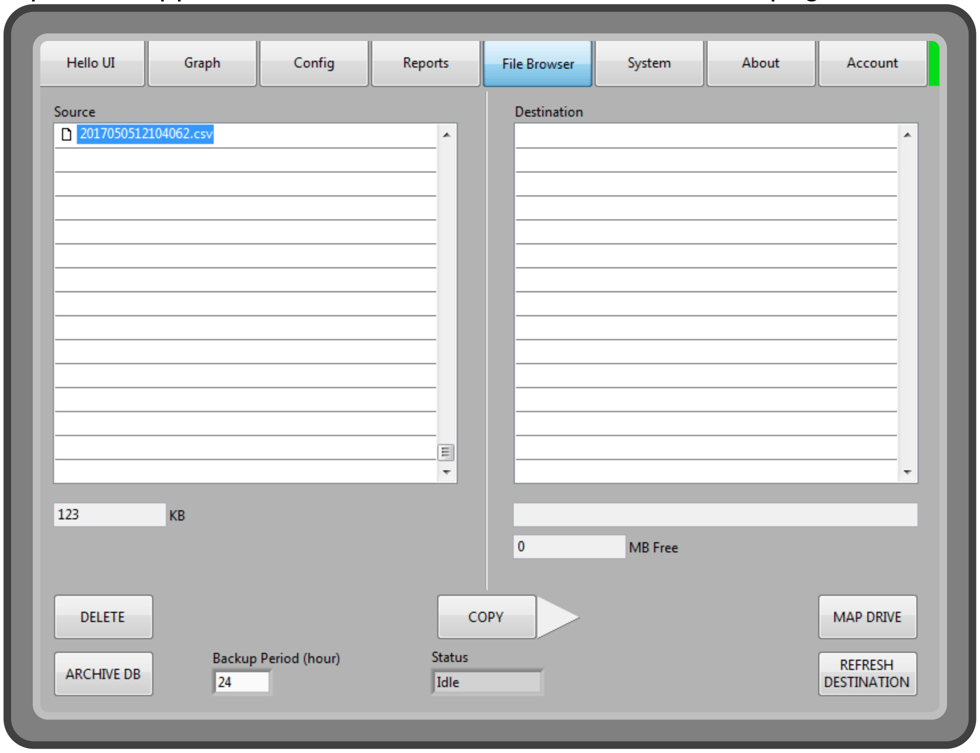
(b) If selecting “Time,” then select the calendar button beside the ‘Start Time’ field. In the menu that appears, select a time and date. Repeat with the ‘End Time’ field.



5. Click the “Generate” button.



6. Wait until the ‘Status’ field reads ‘Report Done,’ then click the “Go to File” button to navigate to the “File Browser” page on the Desktop UI. Your report will appear in the ‘Source’ field of the File Browser page.

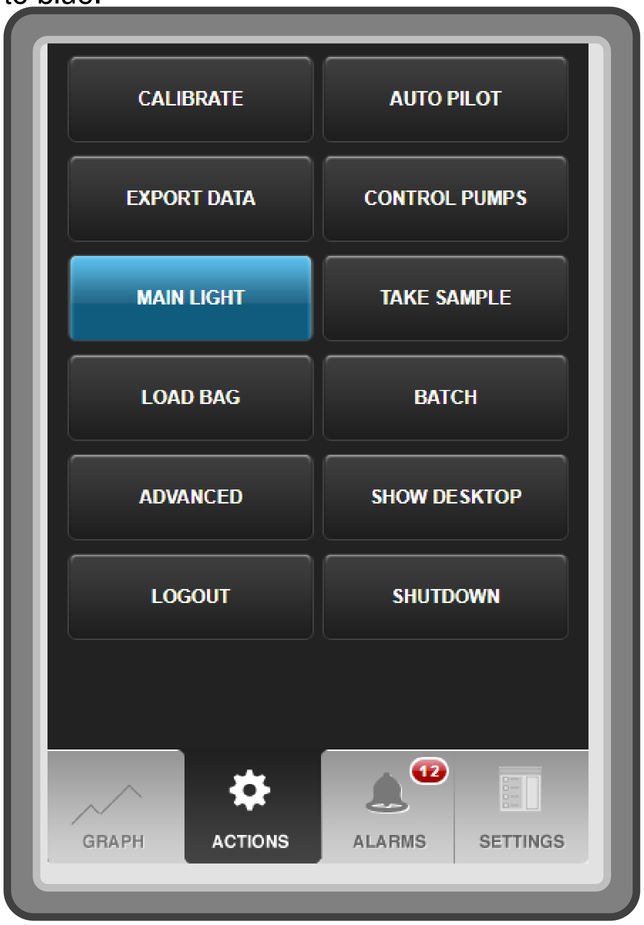


7. Any external drives, including mapped network drives, will be displayed under Destination. Navigate to the desired location, and click the “Copy” button to copy the file to it. Other reports, besides the last one generated, can also be copied to external media. After copying, reports can be deleted. Users may also navigate in the ‘Source’ field to the Database folder, where they may copy any of the contents, or delete databases which have been archived. Users should not delete archived databases until they have been securely backed up.

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 black to blue.



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

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 Controller 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.

Show Desktop

This button can be used to navigate to the Desktop UI.

Shutdown

Users can shut down the HMI computer from the Hello UI or from the Desktop UI. Note that the RIO controller will continue running as long as the PBS-3 has power. Because there is no "On" switch on the PBS-3, it is recommended that the HMI is only shut down after turning off all controllers, and when the PBS-3 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:

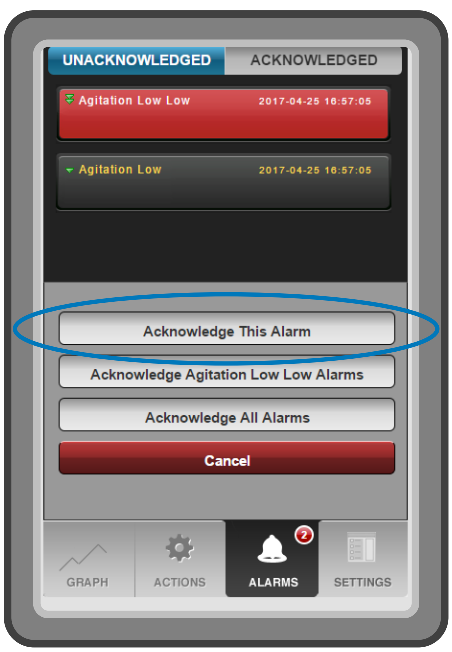
1. Initiate Shutdown from the Shutdown menu in the Hello UI. If the PBS Software is not running, shutdown can be initiated from the Start Menu instead.
2. Wait for the software to shutdown and display “No Signal” (or similar) on the monitor.
3. Wait an additional 10 seconds (or longer).
4. Unplug the power cord.

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

Alarms

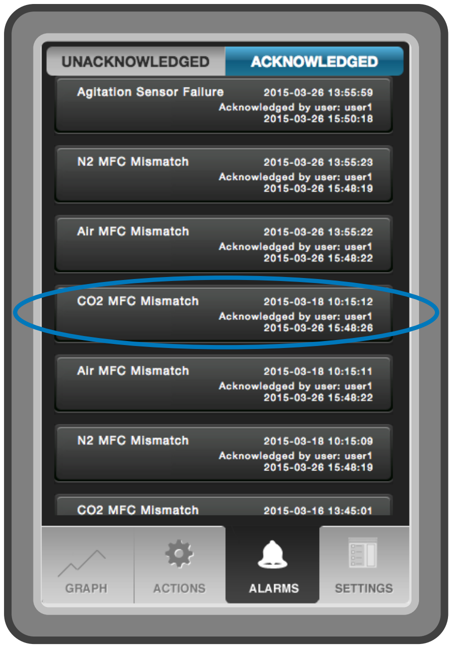
To acknowledge alarms:

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 186.

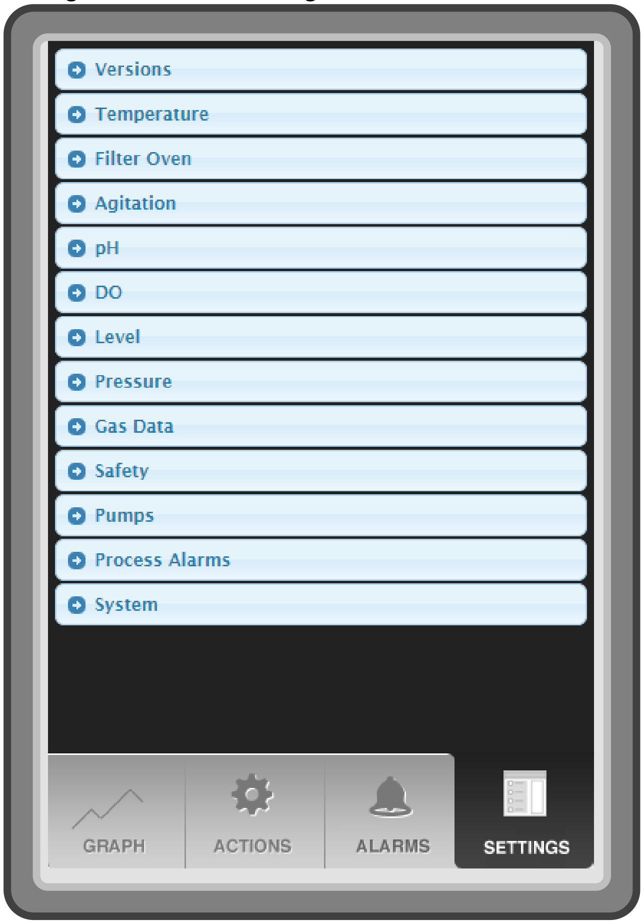
Settings/System Variables

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 159.

To change settings with the Hello UI (preferred method):

1. Log in to the Hello UI as a user with the “Hello User Interface - Hello Settings” permisison.

2. Navigate to the “Settings” tab.

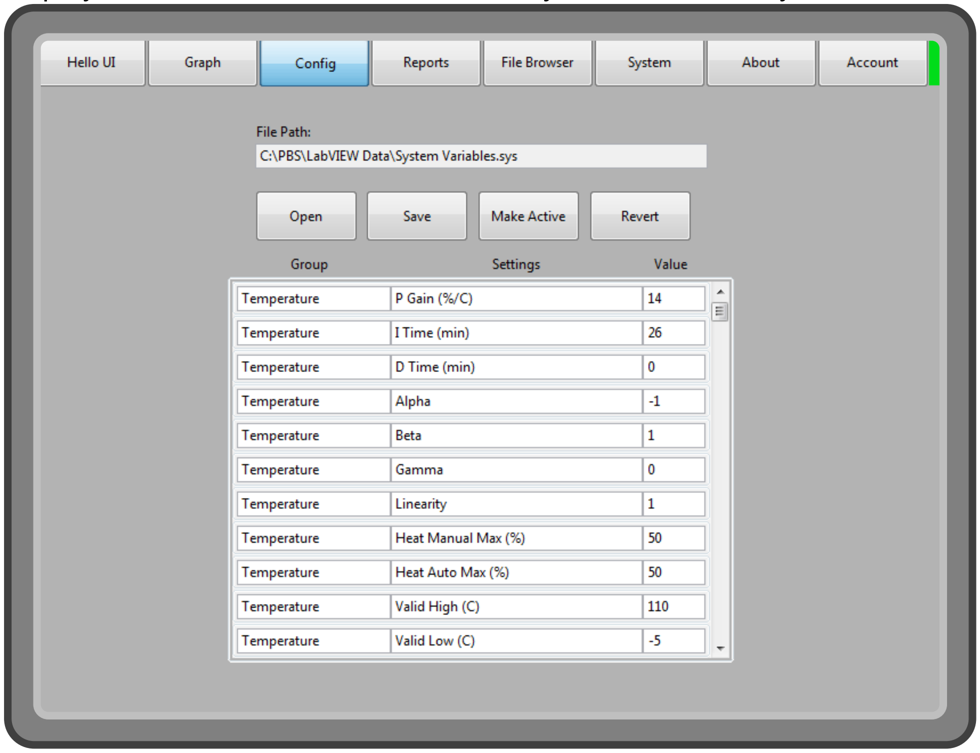


3. Click a submenu to expand it.
4. Scroll up or down and click a variable to change.
5. Use the keypad to enter a new value.
6. Click “OK.”

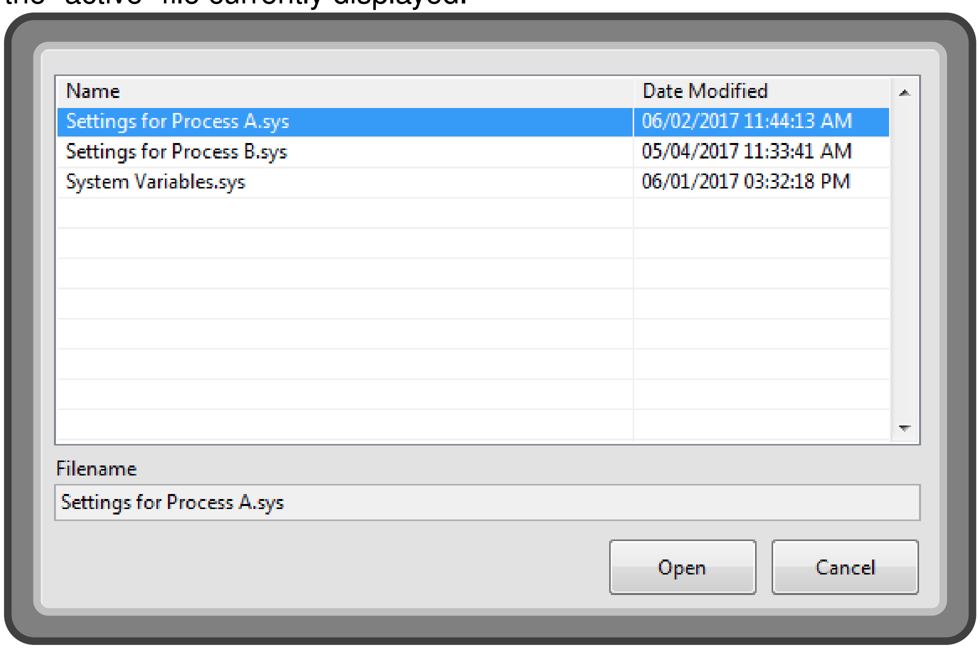
To change settings with the Desktop UI (alternative method):

1. Log in to the Desktop UI with an account with the “Desktop Settings – Settings Editor” permission.

2. Navigate to Config → Settings. The contents of the “active” file will be displayed, which match the file named System Variables.sys.



3. Click “Open” to edit an existing file, or simply begin making changes to the “active” file currently displayed.



4. Select a file to edit, then click “Open.”

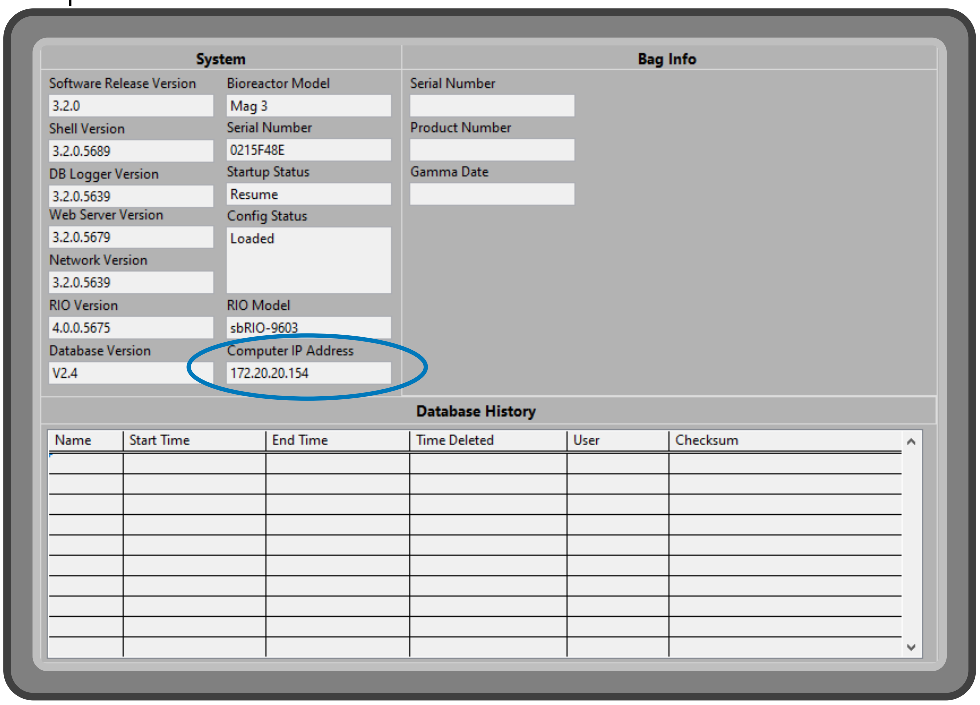
5. Scroll through the list and click a variable to change, then use the onscreen keyboard or an external keyboard to enter a new value.

6. If you wish to reverse changes you have made, click "Reset" and the file will revert back to its original values.
7. Once the desired changes have been made, click "Save."
   (a) To make the changes to the open file, click "Save" to overwrite it.
   (b) To create a new file, click the "Filename" field and enter a new name using the onscreen keyboard or an external keyboard, then click "Save." You can create multiple System Variables files and give them different names.
8. To make the new settings active, click "Make Active."

Remote Access

A computer on the same local network as the PBS-3 can open its Hello page from a browser.

1. In the Desktop UI, go to the About tab, and note what is displayed in the Computer IP Address field.



2. Using Google Chrome on a computer on the local network, navigate to https://<IP Address>/webservice/hello.html to remotely access the Hello UI. For security, https must be used instead of http. Because the certificate is self-signed by the Server on the PBS-3, Google Chrome will likely show a security alert, but this can be ignored.

If the computer accessing the PBS-3 remotely is in a different time zone, the graphs and alarms displayed in the Hello UI will be translated to that user's time zone, and if they generate a report by time span, they will specify the time span in their own time zone. However, actions performed by that user and recorded to the database will be in the bioreactor's system time, as will generated reports.

Sparging Oxygen

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. For information on sparging O_2, reach out to Applications Engineering at app.eng@pbsbiotech.com.

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 Desktop UI as a user with the "System Management" permission.
4. Navigate to System → Tools.
5. Click the "Reboot" button under "Reboot RIO," then click "YES."
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 should all be performed in the Hello UI - instructions are in the sections under "Before Starting a Batch Run" on page 58, and "Starting a Run" on page 70.

Additional calibration actions can be performed in the Desktop UI's "Calibration" configuration page, but such calibrations should only be performed after consulting with PBS Biotech Technical Support. The "Advanced Calibration" user permission is required to access this page. For more information on calibrations, see "Calibrating/Configuring Sensors" on page 131.

Understanding the PBS-3 7

Hello User Interface

The primary way of interacting with the PBS-3 is the Hello User Interface (Hello UI), which is automatically launched when the PBS-3 is turned on. It is served up as a website by the Hello server and is accessible through a web browser. Google Chrome and Safari for iOS are the only browsers supported. Because Hello is a website, it can also be accessed by another computer or mobile device on the same network as the PBS-3.

Desktop User Interface

While the Hello UI is the primary way of interacting with the PBS-3, the Desktop User Interface (Desktop UI) provides supplemental functions.

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				
		Agitation	**Temperature**	**Level**
Interlocked Controls	**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)”
	pH			Level PV > “Max Level (L)”
	Control Pumps			Level PV > “Max Level (L)”

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 broken sensor mode:

- Off mode
- Manual mode
- Auto mode
- Lookup mode (broken sensor 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 broken agitation sensor 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 setpoint.

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

Output Ranges

For agitation control range, see "Agitation Control Range" on page 34.

Agitation motor power range is 0 - 100%.

Relevant Settings

See Appendix 1 on page 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

<u>Agitation</u> (page 162)

- P Gain (%/RPM)
- I Time (min)
- D Time (min)
- Alpha
- Beta
- Gamma
- Linearity
- Minimum (RPM)
- Pulse Mode Timeout (s)
- 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

<u>Safety</u> (page 179)

- Min Ag Power (%)

<u>Process Alarms</u> (page 181)

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

Interlocks

The PBS-3 has no interlocks that prevent power output from the agitation motor.

Temperature

The temperature PV, reported in degrees celsius (°C), is determined by the built-in temperature sensor, which is inserted in the thermal well after installing it in the vessel. The software refers to it as "temperature sensor A."

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

- Off mode
- Manual mode
- Auto mode
- Broken sensor 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.

Broken Sensor Mode

When temperature is in Auto mode and the temperature sensor detects a PV outside the valid range, the software assumes the sensor is broken, 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 broken sensor mode.

Output Ranges

For temperature control range, see “Temperature Control Range” on page 34.

The recommended main heater duty output range is 0 – 50%.

Relevant Settings

See Appendix 1 on page 159 for each setting’s default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 159)

- 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)

Safety (page 179)

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

Process Alarms (page 181)

- 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 vessel. 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 shut off if the temperature PV is greater than or equal to the Safety "Max Temp (C)" setting. This protects the run against a broken sensor or an improperly entered setpoint.

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 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 vessel.

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 34. 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 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Gas Data (page 176)

- 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)

Process Alarms (page 181)

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

Interlocks

There are no interlocks preventing main gas flow in the PBS-3.

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 120.

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

- Off mode
- Manual mode
- Auto mode
- Broken sensor mode

Off Mode

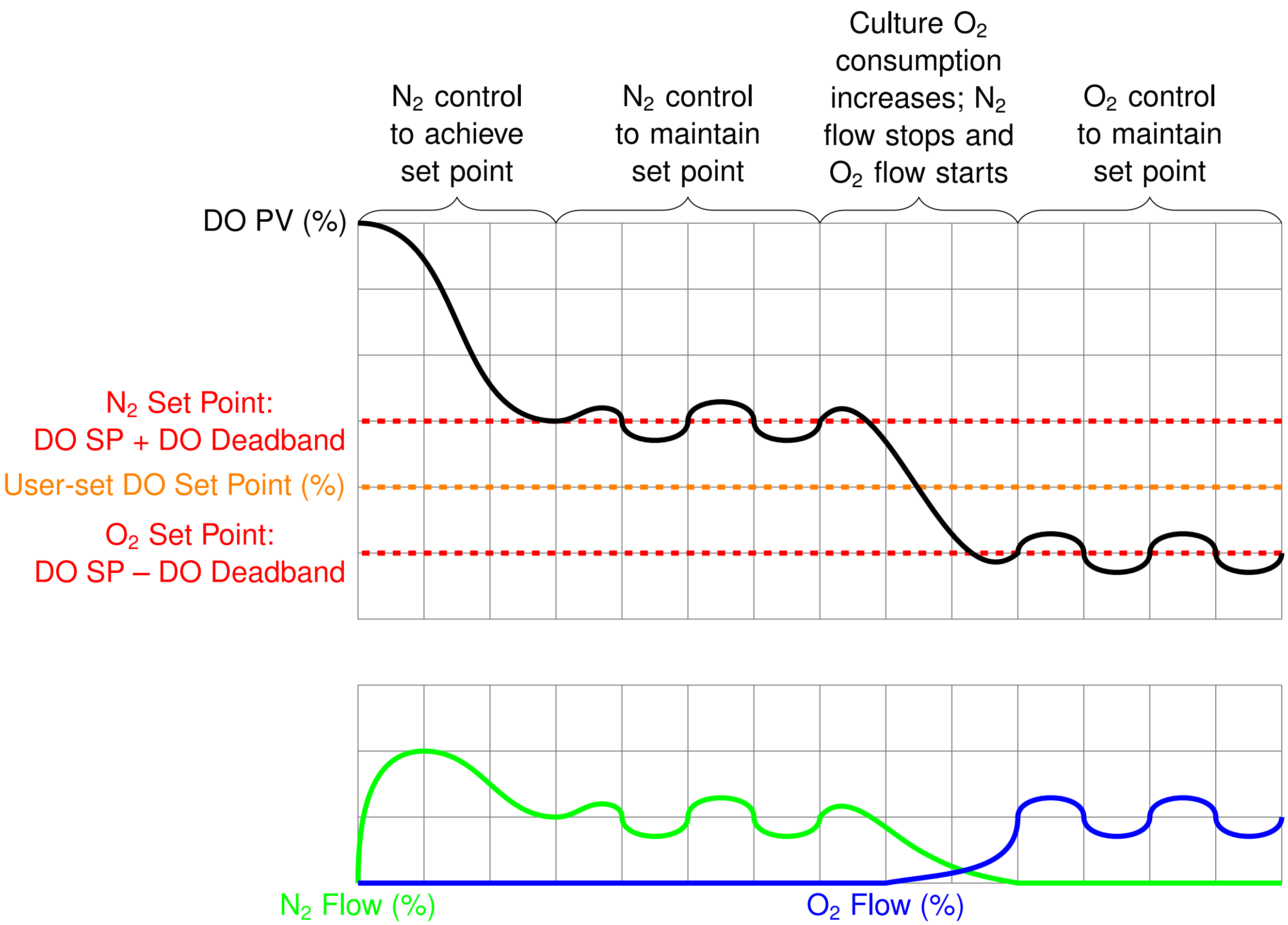
N_2 and O_2 are 0% of main gas flow.

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.



Broken Sensor Mode

When DO is in Auto mode and the DO sensor detects a PV outside the valid range, the software assumes the sensor is broken, and outputs the average of its N_2 and O_2 output values during the last 100 seconds before the software entered broken sensor 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 34. 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 34. 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 vessel or accessories when O_2 is being sparged.

Relevant Settings

See Appendix 1 on page 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

DO (page 170)

- 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%)

Gas Data (page 176)

- 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 181)

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

Interlocks

The PBS-3 has no interlocks that prevent N_2 or O_2 flow.

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 120.

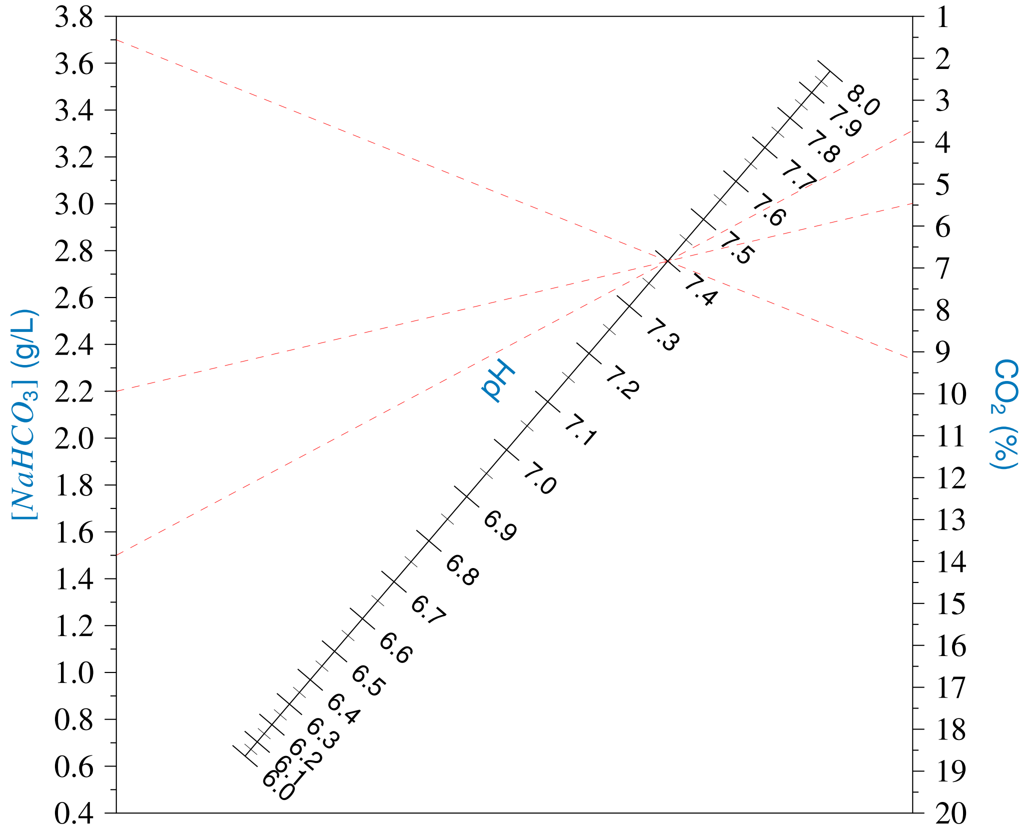
Before inoculating (i.e. when there is no metabolic activity), the pH has a predictable relationship with the concentration of sodium bicarbonate ($NaHCO_3$) in the medium and the % CO_2 composition. Below the following chart is the equation to calculate the resulting pH from a known concentration of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

- Off mode
- Manual mode
- Auto mode
- Broken sensor mode

Off Mode

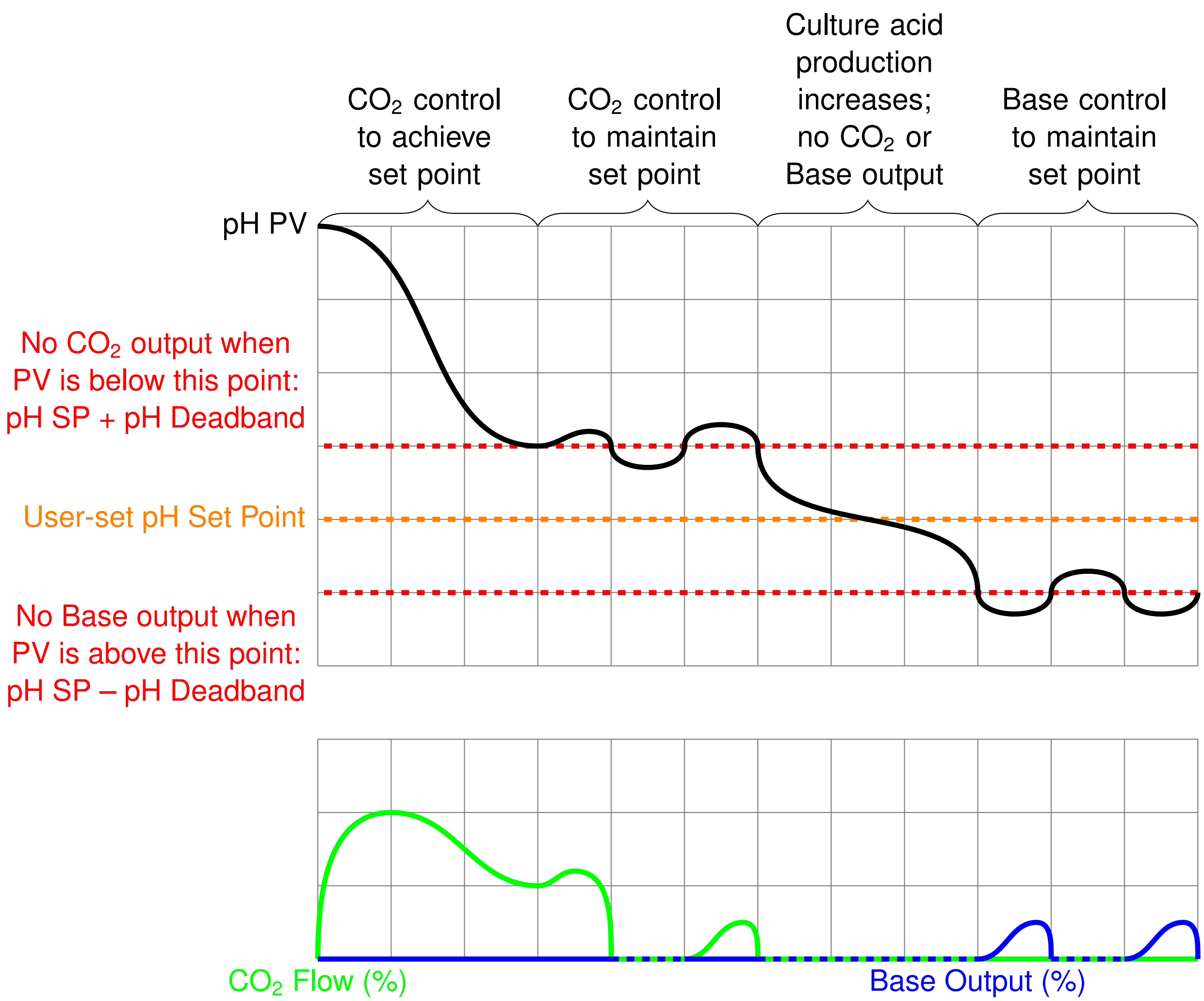
CO_2 is 0% of main gas flow and base pump duty is 0%.

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.



Broken Sensor 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 broken, and outputs the average of its CO_2 and base pump output values during the last 100 seconds before the software entered broken sensor 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 34. 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 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

pH (page 165)

- 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)

Gas Data (page 176)

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

Safety (page 179)

- Max Level (L)

Pumps (page 181)

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

Process Alarms (page 181)

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

Interlocks

The base pump will not turn on if the level PV is above the “Max Level (L).” This prevents base from being added to the point of overfilling the vessel.

The PBS-3 has no interlocks that prevent CO_2 flow.

Level Sensing

The vessel rests on a load cell in the vessel sleeve. The weight the load cell detects is displayed as the level PV in the software.

For the level sensor to work properly, the user must perform a ‘zero’ calibration at 0 L with an empty vessel, with all tubing and sensors configured as they will be during use. After filling the vessel 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 vessel.

The working level range of the PBS-3 is 1.8 – 3 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 0.6 L. Above the maximum there is the danger of overfilling the vessel, causing overflow.

Relevant Settings

See Appendix 1 on page 159 for each setting’s default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 174)

- Empty Level (V)
- Empty Level (L)
- Enable Sensor (0 or 1)
- CalLevelSlopeMax(psi/V)
- CalLevelSlopeMin(psi/V)
- CalLevelInterceptMax(psi)
- CalLevelInterceptMin(psi)

Safety (page 179)

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

Process Alarms (page 181)

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

Filter Oven

The filter oven keeps the exhaust filter at a temperature at least 10 °C above ambient temperature to prevent moisture from the exhaust line from clogging the filter. The factory default is 50 °C.

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

WARNING: The filter oven should only be set to Off mode when the PBS-3 is not in use. Otherwise it should be in Auto 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.

Broken Sensor 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 broken, and outputs the average of its output values during the last 100 seconds before the software entered broken sensor 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 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 159)

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

Filter Oven (page 161)

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

Process Alarms (page 181)

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

Interlocks

The PBS-3 has no interlocks that prevent the filter oven heater from turning on.

Control Pumps

Types (Media and Additions A and B)

The media pump is meant to be used for initially filling the vessel with medium and to empty the vessel when it is time to harvest.

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 159 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 174)

- Enable Sensor (0 or 1)

Safety (page 179)

- Max Level (L)

Pumps (page 181)

- 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 level PV is greater than the "Max Level (L)." This prevents medium or additions being added to the point of overfilling the vessel.

To empty the vessel when the level PV is above the "Max Level (L)," increase the value of the setting, empty the vessel using the harvest line and medium pump, and restore the "Max Level (L)" setting to its original value.

Main Light

The PBS-3 has a white LED light to illuminate the contents of the vessel. It can be turned on and off through the software.

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 vessel 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 124 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 124 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 vessel 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 143. 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.

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 'one-point'/'span' calibration before inoculation. It is generally not recommended that users perform additional 'one-point'/'span' calibrations during a run. 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.

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 effects 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 vessel, and the measured DO of the sample is not representative of the DO of the media in the vessel. For more information, see "Sampling for DO Measurement" on page 145. 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 145.

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 vessel at the beginning of a run. After filling the vessel 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 vessel. Level calibrations cannot be performed from the Hello UI while the agitation, main gas, or dissolved oxygen controls are on.

Temperature

The PBS-3 is shipped with its temperature sensor already calibrated. Users should not calibrate the temperature sensor without consulting PBS Biotech Technical Support.

Filter Oven Temperature

The PBS-3 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.

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

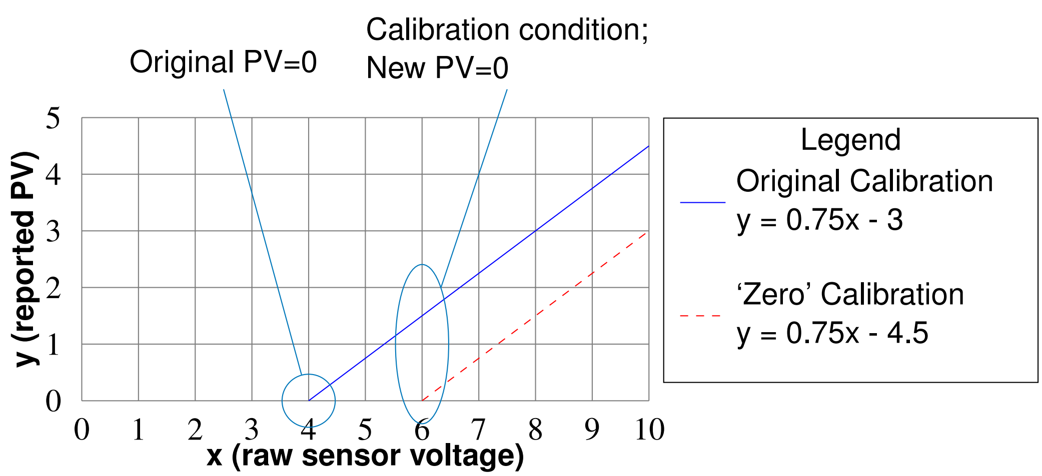
$$y = mx + b$$

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-3.

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.



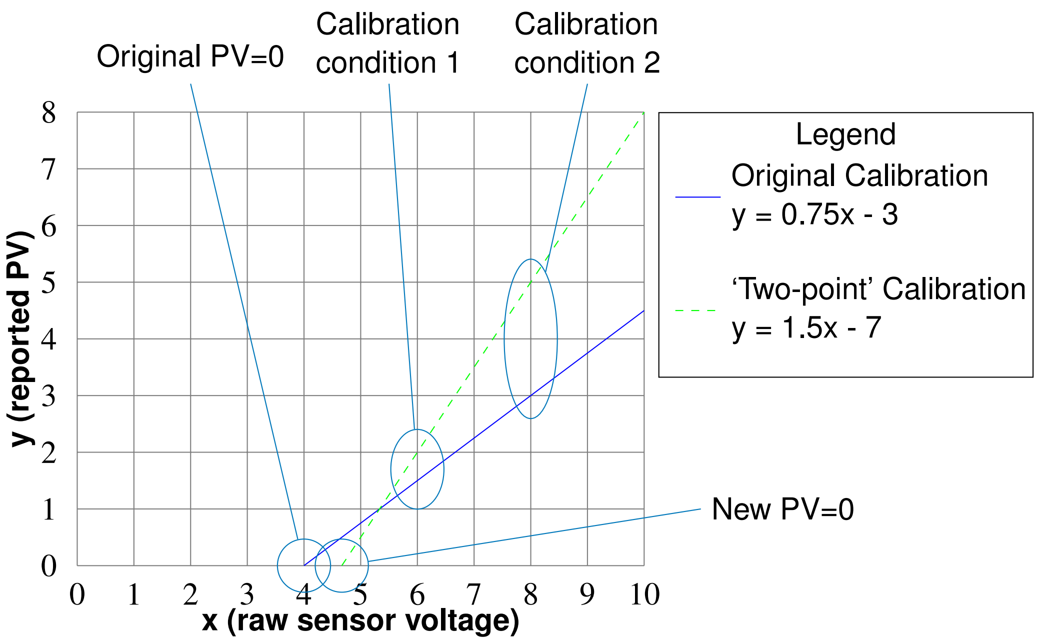
In the above example, the calibration would have been performed when the raw sensor voltage was 6. With the original calibration values, the PV would have been 1.5, but the operator knew that the actual PV should be 0 under that condition. The slope stayed at 0.75, but the intercept changed from -3 to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

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

- When an empty vessel is installed, the Level PV should be 0.

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.



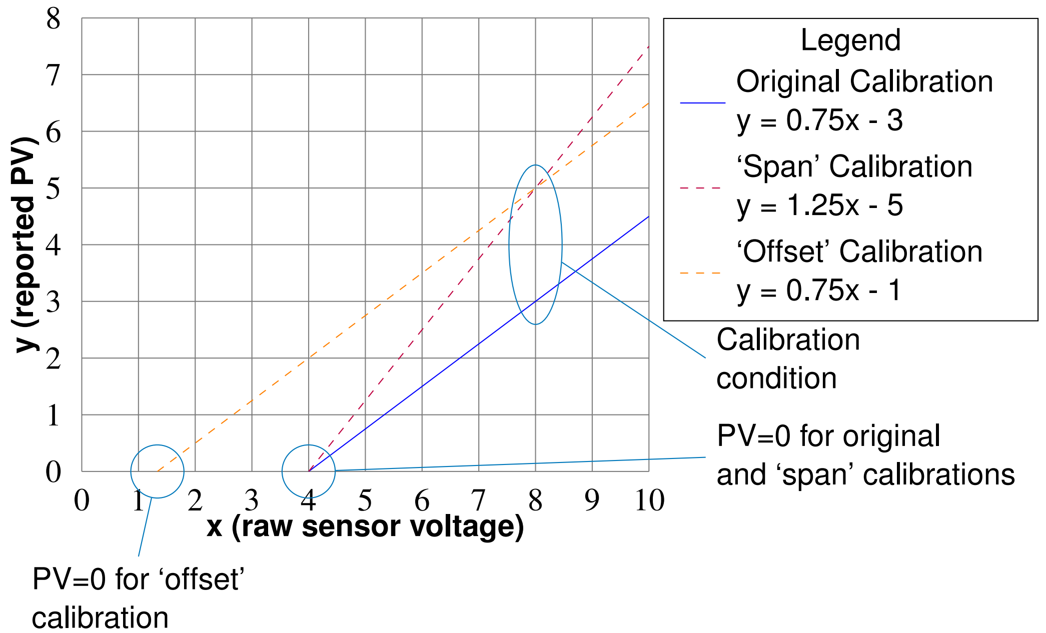
In the above example, the calibration would have been performed when the raw sensor voltage was 6 for the first point and 8 for the second point. With the original calibration values, the PV would have been 1.5 at the first point and 3 at the second point, but the operator knew that the actual PVs should 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, except what the software refers to as a 'one-point' DO calibration is actually a 'span' calibration.



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 a 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. While the button is labeled "One-point," the software performs a 'span' calibration.
- For the Level sensor, Level=0 L is a relevant condition, and should have been set by performing a 'zero' calibration on the empty vessel. Therefore after filling a vessel, a 'span' calibration is appropriate to perform. However, if during a run there is a change made to the tubing configuration or sensor cable positioning which would affect the weight of the vessel but not the actual volume of liquid inside, an an 'offset'/'one-point' calibration may be appropriate to perform. This would be somewhat unusual, so please consult PBS Biotech Technical Support with any questions.

Manual

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

Recipes

Recipes are configured in the Desktop UI and run in 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 recipe changing the agitation mode to "Auto."

"Wait" – Select this action when you want the recipe 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 'ValNum' field would result in the recipe 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 recipe 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 'ValNum' field would result in the recipe 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 recipe to loop until the user stops the recipe. To configure a recipe to loop, select the recipe in the 'Recipe List' field and click the "Loop" button. The recipe name will now have "–LoopRecipe" after it. To set a looping recipe to not loop, select the looping recipe and click the "Don't Loop" button.

Which Variable Types Recipes Can Change

For a complete list of variables the software uses, see Appendix 4 on page 195.

User Source

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

System Source

All variables which are "System" Source can be changed using a recipe. Changing calibration slopes and intercepts with a recipe 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 Hello UI's Settings tab or in the Settings editor of the Desktop UI. However, changing other "System" Source variables via recipe 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

All other variables can also be changed using a recipe, but may be immediately overridden by the software. These variables include calculated values such as PVs and raw sensor values.

Other Information About Recipes

Recipes can only be run one at a time, and cannot refer to other recipes.

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

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

If the above recipe 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 recipe, the pump can still be stopped in the "Control Pumps" menu.

Use caution with "Wait Until" steps involving PV, particularly when using the "equal to" comparison, as present values are often calculated as being very slightly above or below the set point. For example, a recipe with a step reading 'Wait Until "TempSP(C)" = 37' could stall on that step indefinitely if the temperature PV is 37.001. The step would be be better written as 'Wait until TempPV(C)" >= 37' to avoid this problem.

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

Reports

Reports contain data from a specified time span or from an individual batch. They are generated as .csv files with their creation time as their name. If generated through the Hello UI, these reports are automatically emailed to the user who generated them, if the user has a registered email address. If generated through the Hello UI on a remote computer, these reports can be downloaded using the generated link. All reports that are generated can be copied onto an external drive using the File Browser menu in the Desktop UI.

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, with the following exceptions: screen navigation, saving an Alarm file without making it active, saving a Logger file without making it active, saving a System Variables file that is not named System Variables.sys without making it active. When a config file is made active, a user event is generated and includes the contents of the file.

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

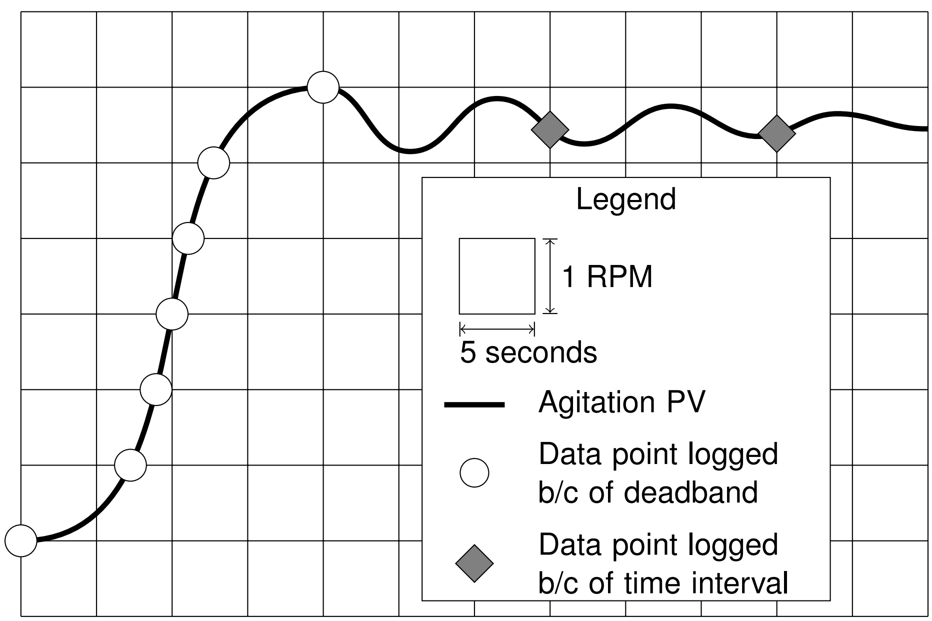
Alarms – Contains information about alarms that are generated, when they are acknowledged, and which user acknowledged them.

Recipe Steps – Contains all recipe steps executed by the software, and at what time they were started.

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 195.

Database

The active database is called PBSBioreactorDatabase.mdb and contains all data recorded by the system. Its contents are compatible with any application that can read MDB format.
The database will be automatically archived by the PBS Software when it reaches a certain size. It can also be manually archived by users (see “Manually Archiving DBs” on page 100). When the database is archived, a new .mdb file named “Archive000.mdb” will appear, where “000” is the next sequential number of archived databases that have been created. The Database History File.csv contains records of all the archived databases. The included information is: the database name, the Start Time, the End Time, the MD5 Checksum, the Time Deleted (if applicable), and the User who deleted the archived database (if applicable).

The MD5 Checksum is a unique text string generated at the time the database was archived. To confirm that a copy of a database has not been compromised, third-party software can be used to determine the MD5 Checksum of the copy, and compare the result to the MD5 Checksum of the original listed in the database history file (refer to your IT department for further assistance). The Database History File can be viewed in the Desktop UI’s “About” tab, or it can be copied from the Database folder to an external drive.

Take Sample

The sequence for taking a sample manually is illustrated in the Hello UI’s “Take Sample” menu. The images represent the following steps:

1. Bring liquid from the vessel to the 3-way valve, expelling the air out through the filter.
2. Bring liquid from the vessel to the syringe.
3. Push the liquid between the 3-way valve and syringe into the syringe, with air from the filter.
4. Push the liquid between the 3-way valve and vessel into the vessel with air from the filter.

For instructions to take a sample manually, see “Take Sample” on page 84.

Note: The Sample pump does not have speed control, and some users are more comfortable taking a manual sample using one of the Addition Pumps set to ‘Slow’ instead. They are controlled in the Hello UI’s “Control Pumps” menu, and because they are not bi-directional, the sample tubing must be removed and repositioned while taking a sample.

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 vessel. 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 vessel 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 vessel.

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 vessel 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 124, 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 vessel.

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 vessel 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 Bag

The Load Bag feature allows the database to store the vessel expiration date, part number, and serial number used for particular batches.

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 Desktop 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 or from the Desktop 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 59.

Alarms

The Alarms configuration file (Alarms.alm) is configured in the Desktop 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-3:

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 submenu of the “Settings” tab in Hello UI, or the “Settings” submenu of the “Config” tab in the Desktop UI.

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 186.

All alarms can be configured in the “Alarms” configuration page on the Desktop UI. There are three settings for alarms on the PBS-3: 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 and is also set to ‘Notify,’ 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” tab of the Hello UI, or the “Settings” configuration page of the Desktop UI.

Email – If the selected alarm is triggered and is also set to ‘Notify,’ a notification email will be sent to the list of entered email addresses in the ‘Email List’ field of the “Alarms” configuration page of the Desktop UI. For more information on how to configure email settings, see the “Configure email notifications” step of “Creating and Editing Alarm Files” on page 53.

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 109. For information on changing the Alarm “Snooze Time,” see see “Settings/System Variables” on page 110. For default alarms configurations, see Appendix 3 on page 191.

Settings

The System Variables configuration file (System Variables.sys) can be configured in the Desktop UI, or in the Hello UI’s “Settings” tab. You can navigate to the “Settings” page in the Desktop UI by clicking the “Config” tab, and then selecting the “Settings” button. While some settings are meant to be user-configurable, it is possible to severely impair functionality of the PBS-3 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 159.

User Accounts

Users are required to log in with an individual user name and password to access both the Hello UI and the Desktop UI. Using remote clients, multiple users can log in to the Hello UI at the same time, and one user can be logged in to the Hello UI from multiple locations. Users can choose to log out of the Hello UI, and are logged out automatically after ten minutes of inactivity. Only one user can log in to the Desktop UI at a time, and if they do not log out when they finish, they will be logged out after ten minutes of inactivity. Changes a user makes while they are logged in to either interface 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.

Users have user names, passwords, user groups, and optional email addresses to receive emailed reports. For information on configuring users and user groups, see “Configuring Users and Groups” on page 38.

User Group Permissions

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

Desktop User Interface Permissions

These control access to the features in the Desktop UI. They do not affect permissions in the Hello UI.

Alarms Editor – Allows users to configure alarms to be set to Notify, Audible, and/or Email, as well as advanced email settings. When this permission is not granted, the “Alarm” option under the “Config” button in the Desktop UI is grayed out and cannot be selected. Alarms permissions in the Hello UI are not affected.

Logger Editor – Allows users to configure what data is recorded and how often. When this permission is not granted, the “Logger” option under the “Config” button in the Desktop UI is grayed out and cannot be selected.

Settings Editor – Allows users to edit the values of system variables. When this permission is not granted, the “Settings” button under the “Config” option is grayed out and cannot be selected. It should be noted that settings can still be edited through the Hello UI if the user has the “Hello Access” and “Hello Settings” permissions under the Hello User Interface permissions.

Recipe Editor – Allows users to add and edit recipes. When this permission is not granted, the “Recipe” button under “Config” is grayed out and cannot be selected. The ability to start or stop recipes in the Hello UI is not affected.

Advanced Calibration – Allows users to calibrate the pH, DO, temperature, filter oven, level, and MFCs. It also allows users to enter calibration slope and intercept values manually, but this should not be done without consulting PBS Biotech Technical Support. When this permission is not granted, the “Calibration” button under “Config” is grayed out and cannot be selected.

DB Management – Allows users to archive the current database, copy databases onto external drives, delete archived databases, and map networked drives.

Account Management – Allows users to configure Users and User Groups settings, including permissions, password expiration periods, emails, assigned User Groups, and names. When this permission is not granted, the user only has access to “Edit User” under Account → Manage, and can only change the password and email address associated with their own account.

Hello User Interface Permissions

These permissions control access to the Hello UI:

Hello Access – Allows users to log in to the Hello UI. When this permission is not granted, the users assigned to the group do not appear on the Login menu of the Hello UI.

Remote Access – Allows users to log in to the Hello UI using a remote client. When this permission is not granted, the users assigned to the group do not appear on the Login list in the remote client, but do appear on the bioreactor and on LogMeIn.

Door – Not applicable for the PBS-3.

Light – Allows the user to turn the Main Light on and off. When this permission is not granted, the “Main Light” button under the “Actions” tab is grayed out and cannot be selected.

Batch – Allows users to start and end batches. When this permission is not granted, the “Batch” button under the “Actions” tab is grayed out and cannot be selected.

Recipe Start – Allows the user to start a recipe. When this permission is not granted, the “Auto Pilot” button under the “Actions” tab is grayed out and cannot be selected.

Recipe End – Allows the user to end a recipe that is currently running. When this permission is not granted, the “End” button in the “Auto Pilot” menu is grayed out and cannot be selected while a recipe is running.

Pumps – Allows the user to turn the pumps on and off, and change their direction and speed (if applicable).

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

Sensors – Allows users to perform applicable ‘one-point,’ ‘two-point,’ ‘zero,’ and ‘span’ calibrations on the DO, pH, and level sensors, and to use the Load Bag menu. When this permission is not granted, the “Calibrate” button under the “Actions” tab, and the “Load Bag” button in the “Load Bag” menu are grayed out and cannot be selected.

Hello Settings – Allows users to change the values of system variables. When this permission is not granted, users are unable to select the individual system variables to change them under the “Settings” tab, although they are able to view them.

Common Permissions

These permissions are shared by both the Desktop UI and the Hello UI.

Reports – Allows users to create and export reports. When this permission is not granted, the “Export Data” button in the Hello UI is grayed out and cannot be selected, as is the “Reports” button in the Desktop UI.

Controls – Allows users to set agitation, temperature, DO, pH, main gas, filter oven, and base pump. When this permission is not granted, the user is unable to select the corresponding buttons in the Dashboard and “Pumps” menu of the Hello UI, and the “Requested Mode,” “Auto Set Point (°C),” and “Manual Duty (%)” options under “FiltOven” in the “Graph” tab in the Desktop UI are grayed out and cannot be selected.

System Management – In the Desktop UI, this allows users to rename the bioreactor, reboot the RIO, sync the RIO time, test the alarm buzzer, and restart the RIO. It also allows the user to shutdown, reboot, and log off of the Windows/HMI computer. In the Hello UI, it allows the user to shutdown or restart the Windows/HMI computer. When this permission is not granted, the “Shutdown” button under the Actions tab in the Hello UI is grayed out and cannot be selected, as is the “System” button in the Desktop UI.

Instructions for IT

8

This chapter contains information a customer's IT department may need to install or maintain the PBS-3.

Bioreactor Computer Architecture

- The control system of the PBS-3 Vertical-Wheel® Bioreactor System (PBS-3) 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 responsiible for:
  - User Interfaces, 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 PBS Software
  - Running the Recipe engine

Operating System

The IPC runs on Windows Embedded Standard 7. Access to the operating system is granted to provide access to specific functions not implemented in the Hello UI application:

- 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.

WARNING: PBS Bioreactors are provided with a fully configured, embedded software package. PBS Biotech can only support system modifications made through the Hello UI 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-3. 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 unecessary for general use and must be done with extreme caution.

Note: To maintain data integrity, internal access to the bioreactor housing must be restricted to authorized personnel only. The BIOS security configuraiton 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

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

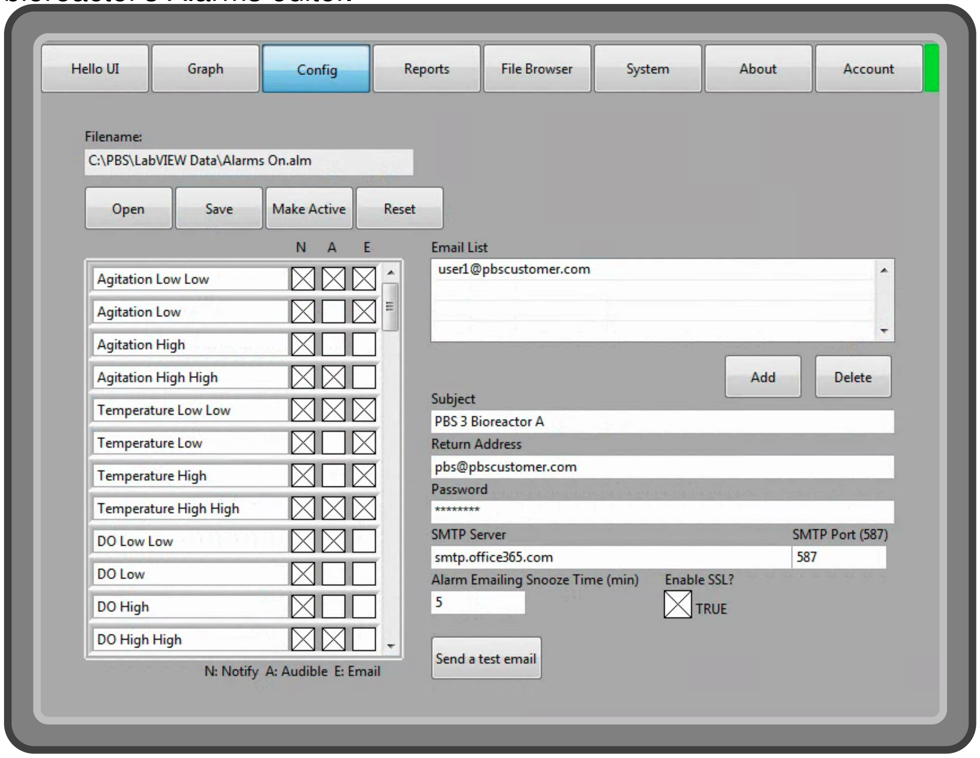
- The Bioreactor computer may be joined to a local network via the Ethernet port. That network connection may be configured as necessary.

By default, the bioreactor will automatically obtain an IP address and connect to the local network.

Email

- The PBS software can send emails for the following reasons:
  - To notify users about alarms
    - The active Alarm file must be configured for the alarm to be 'Notify'
    - 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 Desktop UI → Config → Alarm 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
    - A user who generates a report in the Hello UI will receive an email if their account has an associated email address

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



- 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.
    Note: 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

Remote Access (not LogMeIn)

- Computers on the same LAN as the bioreactor can access the Hello User Interface by pointing Google Chrome at
  https://<IP Address>/webservice/hello.html
  - Configuring the bioreactor’s IPC to have a static IP on the LAN is recommended for this reason (see “Network Connections” on page 153)
- Because the certificate is self-signed by the Server on the IPC, Google Chrome will likely show a security alert, but this can be ignored.
- If users wish to access the Hello User Interface even when they are not on the same LAN, the IT department can either set up a VPN or port forwarding.
- If users do not wish for the Hello User Interface to be accessible remotely, they can simply remove the “Hello User Interface – Remote Access” permission from all user groups. The Hello User Interface will still load on Google Chrome on a computer on the same LAN as the bioreactor, but users will not be able to log in or perform any actions.

Backups

- The PBS software automatically backs up the Database folders to the root of the Z: drive. The PBS software offers an interface to users to map a network location to the Z: drive, which should be used instead of configuring “net use” directly.
- Backing up to a physical drive:
  - If users desire to back up to a physical drive, configure Disk Management to recognize the physical drive as the Z: drive.
- Backing up to a network location:
  - If users desire to back up to a network location, the interface in the PBS Desktop UI should be used, by a user account with the “DB Access” permission. Log in and click “File Browser” → “Map Drive.”

- The “DELETE ALL” button in the “Map Drive” menu will remove all mapped network drives (including those configured with “net use” or some other method), not just those mapped using PBS software.
- The network configuration may need to be changed to successfully map a network drive - see “Network Connections” on page 153.

- The bioreactor ships with its “Backup Period (hour)” field in the “File Browser” menu set to 0, which disables automatic backups. Be sure to change this number after a Z: drive is made available.

McAfee Application and Change Control

- This is the security software used by the PBS-3
- It prevents non-whitelisted software from modifying the contents of the write-protected locations
  - For the GMP configuration, these are:
    - C:\Database
    - C:\PBS
    - C:\Reports
  - For the R&D configuration, these are:
    - C:\Database
    - C:\PBS\builds
    - C:\PBS\LabVIEW Data\System Variables.sys
    - C:\Reports
- It is configured to allow Windows Updates, Google Chrome, and LogMeIn to update their own software
- Contact PBS Biotech Technical Support for the password. GMP users of the bioreactor should not have access to this password.
- Commands
  - To install new software, or make modifications to the write-protected locations (these are listed above, although **modifying anything in write-protected locations is a violation of GMP compliance**):
    - Take the computer offline
    - Enter **sadmin bu** in the command line editor (begin update)
    - Install the desired software with an offline method
    - Enter **sadmin eu** in the command line editor (end update)
    - Put the computer back online

- To allow software to update itself:
  - Enter **sadmin updaters add** <**application**> in the command line editor, replacing <application> with either the path to the application, or the name of the .exe.
- To see a list of software allowed to perform updates:
  - Enter **sadmin updaters list** in the command line editor.
- To change the password:
  - Enter **sadmin passwd -d** in the command line editor to remove the current password.
  - Enter **sadmin passwd** to add a new password

- For more information, see McAfee Support for McAfee Application and Change Control.

Automatic Updates

- LogMeIn
  - As stated in “McAfee Application and Change Control” on page 157, McAfee is configured to allow LogMeIn to automatically update itself, provided it has access to the internet.
  - Preventing these automatic updates is not recommended.
- Windows
  - Windows is configured to automatically install updates.
  - If desired, this can be changed in the control panel.
- Google Chrome
  - Google Chrome is able to update itself automatically, provided it has access to the internet.
  - Preventing these automatic updates will require collaborating with PBS Biotech Technical Support to determine the best course of action.

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)	50.000	Proportional Gain for the temperature controller.	!	TempHeatDuty Control.PGain (min)
I Time (min)	26.000	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 setpoint 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 setpoint 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 (%)	50.000	The maximum main heater duty allowed in Manual mode.	!	TempHeatMan Max(%)
Heat Auto Max (%)	50.000	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 broken, 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 broken, 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)	N/A	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.	N/A	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 setpoint 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 setpoint 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 (%)	100.000	The maximum filter oven heater duty allowed in Manual mode.	X	FilterOvenDuty RangeManMax (%)
Heat Auto Max (%)	100.000	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 setpoint 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 setpoint 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)	60.000	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.	✓	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. Should be set equal to the Agitation "Pulse Mode Timeout (s)" setting, to disable Pulse Mode.	✓	AgLookupMode Timeout (ms)
Lookup Factor (%/RPM)	1.820	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 (%)	10.000	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(%)

AGITATION (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Number of Magnets	2.000	The number of magnets on the Vertical-Wheel® impeller.	!	AgWheelMagnet Count
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
Mismatch Thresh	N/A	For Vertical-Wheel® Bioreactors with dual pH sensors, if the sensors register measurements that differ by more than this amount, it triggers a pH Mismatch Alarm.	N/A	pHMismatch Thresh
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 broken, 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 broken, 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(%)

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
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)
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 setpoint 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 setpoint 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 (%)

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
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(%)
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 setpoint 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 setpoint value.	X	pHBaseDuty ControlGamma

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Base Linearity	1.000	Specifies the linearity of the error response. The valid range is 0 to 1.	X	pHBaseDuty ControlLinearity
Base Manual Max (%)	50.000	The maximum base pump duty allowed in Manual mode.	✓	pHBaseDutyMan Max(%)
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
B Use Temp Comp?	N/A	Use (1) or do not use (0) a temperature compensation factor for pH sensor B. Must be used for reusable pH sensors, and must not be used for single-use pH sensors.	N/A	pHBUseTemp 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

pH (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Valid High (pH)	14.000	If a pH sensor registers a measurement above this value, the software assumes the pH sensor is broken, 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 broken, 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 Desktop UI's or Hello UI's calibration menu.	!	pHSensor SamplesTo Average

DO

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Mismatch Thresh (DO%)	N/A	For Vertical-Wheel® Bioreactors with dual DO sensors, if the sensors register measurements that differ by more than this amount, it triggers a DO Mismatch Alarm.	N/A	DOMismatch Thresh(%)

DO (continued)

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 broken, 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 broken, and triggers a DO Sensor Failure (range) Alarm.	!	DOValidMin(%)
O2 P Gain (%/DO%)	1.500	Proportional Gain for the DO O_2 controller. The same value should be used whether O_2 is flowing through the overlay or being sparged.	!	DOO2Control Mag.PGain(%/%)
O2 I Time (min)	120.000	Integral Time for the DO O_2 controller. The same value should be used whether O_2 is flowing through the overlay or being sparged.	!	DOO2Control Mag.ITime(min)
O2 D Time (min)	0.000	Derivative Time for the DO O_2 controller. The same value should be used whether O_2 is flowing through the overlay or being sparged.	!	DOO2Control Mag.DTime(min)

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 setpoint 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 setpoint 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%)	-5.000	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)	50.000	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 setpoint 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 setpoint 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)	N/A	The radius of the base of the chamber. This is used in the nonlinear level calculation.	N/A	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)	0.000	If the level PV is below this value, the software recognizes the level PV = 0.	!	LevelCal Cluster.Level Empty(L)
cm/psi	N/A	The conversion from the pressure the level sensor reports to the height of the liquid. This is used in the nonlinear level calculation.	N/A	LevelCal Cluster.Cm/psi
Vessel Depth (cm)	N/A	The distance from the back of the chamber to the door. This is used in the nonlinear level calculation.	N/A	LevelCal Cluster.Depth

LEVEL (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Bottom Gap (cm)	N/A	Gap at the bottom of the chamber unaccounted for by the level sensor.	N/A	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)	9000	The maximum level slope value allowed during calibration.	!	CalLimits Level.CalLevel SlopeMax(psi/V)
CalLevelSlope Min(psi/V)	5000	The minimum level slope value allowed during calibration.	!	CalLimits Level.CalLevel SlopeMin(psi/V)
CalLevel InterceptMax (psi)	0.000	The maximum level intercept value allowed during calibration.	!	CalLimits Level.CalLevel InterceptMax(psi)
CalLevel InterceptMin (psi)	-10.000	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)	0.005	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)	N/A	The maximum pressure intercept value allowed during calibration.	N/A	CalLimits Pressure.Cal PressureIntercept Max(psi)
CalPressure InterceptMin (psi)	N/A	The minimum pressure intercept value allowed during calibration.	N/A	CalLimits Pressure.Cal PressureIntercept Min(psi)
CalPressure SlopeMax (psi/V)	N/A	The maximum pressure slope value allowed during calibration.	N/A	CalLimits Pressure.Cal PressureSlope Max(psi/V)
CalPressure SlopeMin (psi/V)	N/A	The minimum pressure slope value allowed during calibration.	N/A	CalLimits Pressure.Cal PressureSlope Min(psi/V)
Reusable Sensor (0 or 1)	0.000	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)	0.030	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)	0.030	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)	0.030	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)	0.030	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)	200.000	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)	0.010	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)	0.500	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 (%)	17.000	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 broken, 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)	N/A	The software will stop gas flow and pump activity if the pressure PV exceeds this pressure.	N/A	InterlockPressure Max(psi)
Max Pressure Door (psi)	N/A	The software will not allow the door to be unlocked if pressure PV exceeds this pressure.	N/A	InterlockDoor PressureMax(psi)

SAFETY (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Min Level (L)	0.500	The minimum level below which the temperature controller will be interlocked to avoid heating an empty vessel or heating in the absence of a vessel.	X	LevelMin(L)
Max Level (L)	4.000	The maximum level, above which the temperature controller will be interlocked to avoid heating an overfilled vessel. Additionally, pumps will be interlocked ot 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		At "Slow" speed, the addition pump will give this many "on" pulses out of 2^{16}, or 65,536 pulses in total.	✓	Pumps&Valves PumpLowAux Speed
sbRIO* 9641 or 9642:	20000			
sbRIO* 9603:	30000			
Aux Med Duty		At "Medium" speed, the addition pump will give this many "on" pulses out of 2^{16}, or 65,536 pulses in total.	✓	Pumps&Valves PumpMedAux Speed
sbRIO* 9641 or 9642:	30000			
sbRIO* 9603:	52000			
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)
Analog Base Speed (RPM)	N/A	For models with analog Additions pumps, when the base pump turns on, it is set to this RPM value. A higher Pumps "Base On Time (s)" setting makes it more likely the pump can reach a higher RPM.	N/A	Pumps&Valves AnalogBase Speed(RPM)
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 Desktop UI About tab.

PROCESS ALARMS

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

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Agitation Low Low (RPM)	10.000	If the PV is below this value, the alarm state is “error.”	✓	Limits.Agitation Low Low (RPM)
Agitation Low (RPM)	15.000	If the PV is below this value, the alarm state is “warning.”	✓	Limits.Agitation Low (RPM)
Agitation High (RPM)	35.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Agitation High (RPM)
Agitation High High (RPM)	38.000	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 (%)

PROCESS ALARMS (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
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
Pressure Low Low (psi)	N/A	If the PV is below this value, the alarm state is "error."	N/A	Limits.Pressure Low Low (psi)
Pressure Low (psi)	N/A	If the PV is below this value, the alarm state is "warning."	N/A	Limits.Pressure Low (psi)
Pressure High (psi)	N/A	If the PV is above this value, the alarm state is "warning."	N/A	Limits.Pressure High (psi)
Pressure High High (psi)	N/A	If the PV is above this value, the alarm state is "warning."	N/A	Limits.Pressure High High (psi)
Level Low Low (L)	0.500	If the PV is below this value, the alarm state is "error."	✓	Limits.Level Low Low (L)
Level Low (L)	1.300	If the PV is below this value, the alarm state is "warning."	✓	Limits.Level Low (L)
Level High (L)	3.250	If the PV is above this value, the alarm state is "warning."	✓	Limits.Level High (L)
Level High High (L)	3.500	If the PV is above this value, the alarm state is "warning."	✓	Limits.Level High High (L)
Filter Oven Low Low (C)	45.000	If the PV is below this value, the alarm state is "error."	✓	Limits.Filter Oven Low Low (C)

PROCESS ALARMS (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
Filter Oven Low (C)	47.000	If the PV is below this value, the alarm state is “warning.”	✓	Limits.Filter Oven Low (C)
Filter Oven High (C)	53.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Filter Oven High (C)
Filter Oven High High (C)	55.000	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Filter Oven High High (C)
Main Gas Low Low (LPM)	0.050	If the PV is below this value, the alarm state is “error.”	✓	Limits.Main Gas Low Low (LPM)
Main Gas Low (LPM)	0.100	If the PV is below this value, the alarm state is “warning.”	✓	Limits.Main Gas Low (LPM)
Main Gas High (LPM)	0.400	If the PV is above this value, the alarm state is “warning.”	✓	Limits.Main Gas High (LPM)
Main Gas High High (LPM)	0.450	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 adition to the logging by deadband as configured in the logger settings file.	✓	LoggerMaxLog Interval(ms)

SYSTEM (continued)

Setting Name	Default Value	Definition	User May Change	Corresponding Global Variable
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

Alarm Name	Alarm is Triggered When:
Agitation Low Low	Agitation PV drops below this value.
Agitation Low	Agitation PV drops below this value.
Agitation High	Agitation PV rises above this value.
Agitation High High	Agitation PV rises above this value.
Temperature Low Low	Temperature PV drops below this value.
Temperature Low	Temperature PV drops below this value.
Temperature High	Temperature PV rises above this value.
Temperature High High	Temperature PV rises above this value.
DO Low Low	DO PV drops below this value.
DO Low	DO PV drops below this value.
DO High	DO PV rises above this value.
DO High High	DO PV rises above this value.
pH Low Low	pH PV drops below this value.
pH Low	pH PV drops below this value.
pH High	pH PV rises above this value.
pH High High	pH PV rises above this value.
Pressure Low Low	(N/A on PBS-3) Pressure PV drops below this value.
Pressure Low	(N/A on PBS-3) Pressure PV drops below this value.
Pressure High	(N/A on PBS-3) Pressure PV rises above this value.
Pressure High High	(N/A on PBS-3) Pressure PV rises above this value.
Level Low Low	Level PV drops below this value.
Level Low	Level PV drops below this value.
Level High	Level PV rises above this value.
Level High High	Level PV rises above this value.
Filter Oven Low Low	Filter oven temperature PV drops below this value.
Filter Oven Low	Filter oven temperature PV drops below this value.
Filter Oven High	Filter oven temperature PV rises above this value.
Filter Oven High High	Filter oven temperature PV rises above this value.
Main Gas Low Low	Main gas flow drops below this value.
Main Gas Low	Main gas flow drops below this value.
Main Gas High	Main gas flow rises above this value.
Main Gas High High	Main gas flow rises above this value.

Alarm Name	Alarm is Triggered When:
Leak Detected	(N/A on PBS-3) The leak sensor detects a leak.
Sequence Resumed	The RIO lost power while a recipe was running, and attempted to restart the recipe when it booted up.
Temperature Sensor Mismatch	(N/A on PBS-3) The temperature sensors register measurements that differ by more than the Temperature “Mismatch Thresh (C)” setting.
DO Sensor Mismatch	(N/A on PBS-3) The DO sensors register measurements that differ by more than the DO “Mismatch Thresh (DO%)” setting.
pH Sensor Mismatch	(N/A on PBS-3) The pH sensors register measurements that differ by more than the pH “Mismatch Thresh” setting.
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.
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.
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.
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 Sensor Failure	The agitation motor is being powered but agitation PV = 0 RPM.
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.

Alarm Name	Alarm is Triggered When:
Temp Sensor B Failure (range)	(N/A on PBS-3) Temperature sensor B registers a measurement above the Temperature “Valid High (C)” or below the Temperature “Valid Low (C)” settings.
Temp Dual Sensor Failure	(N/A on PBS-3) Both temperature sensors register range failures.
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.
DO Sensor B Failure (range)	(N/A on PBS-3) DO sensor B registers a measurement above the DO “Valid High (DO%)” or below the DO “Valid Low (DO%)” settings.
DO Dual Sensor Failure	(N/A on PBS-3) Both DO sensors register range failures.
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 Sensor B Failure (range)	(N/A on PBS-3) pH sensor B registers a measurement above the pH “Valid High (pH)” or below the pH “Valid Low (pH)” settings.
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.
pH Sensor B Failure (rate)	(N/A on PBS-3) pH sensor B 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.
pH Dual Sensor Failure	(N/A on PBS-3) Both pH sensors register rate failures or range failures.
Pressure Sensor Disconnected	(N/A on PBS-3) 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 and the software detects that the pressure sensing line is disconnected.
Comb Plate Popped	(N/A on PBS-3) The bag has pressurized enough to lift the comb plate.
Dirty Startup	RIO was restarted using a method other than through the Desktop UI desktop (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.

Alarm Name	Alarm is Triggered When:
Clean Startup	RIO was restarted through the Desktop UI.
Resume	RIO was restarted using a method other than through the Desktop UI (usually just unplugging the bioreactor), but the last user-selected modes, set points etc. were recovered with no problems.
RT Mem Fragmented*	The largest contiguous block (LCB) of memory on the RIO computer is less than the System “LCB Mem Limit (KB)”.
RT Mem Nearly Full	The available memory on the RIO computer is less than the System “Available Mem Limit (KB)”.
NI 9205 Error*	Analog Input errors reading MFCs, DO, and pH.
NI 9425/Onboard Error	Digital Input errors reading leak sensor (N/A on PBS-3), pressure sensor connected (N/A on PBS-3), Door Pressure sensor (N/A on PBS-3), fuses, and RPM sensor. Digital Output errors writing to motor brake, media pump, and RTOS Run Status light.
NI 9219 Error	Error reading 9219 board (analog inputs for pressure sensor (N/A on PBS-3), load cell, and temperature sensors).
NI 9476 Error	Digital Output errors writing to temperature and filter oven heaters, door unlock(N/A on PBS-3, buzzer, sample pump, media pump, LED, addition pump A, addition pump B, and PBS 3 MAG agitation motor.
NI 9263 Error	(N/A on PBS-3) Analog Output errors writing to pumps with RPM input, and to agitation motors other than for the PBS-3.
12 Vdc Atom Fuse*	This fuse needs to be replaced.
12 Vdc Mezz Fuse*	This fuse needs to be replaced.
12 Vdc Mntr Fuse*	This fuse needs to be replaced.
12 Vdc User1 Fuse*	This fuse needs to be replaced.
12 Vdc User2 Fuse	This fuse needs to be replaced.
12 Vdc User3 Fuse	This fuse needs to be replaced.
24 Vdc Fill Pump Fuse	This fuse needs to be replaced.
24 Vdc Ind DO Fuse*	This fuse needs to be replaced.
24 Vdc Main Fuse*	This fuse needs to be replaced.
24 Vdc Mezz Fuse*	This fuse needs to be replaced.
24 Vdc MFC Fuse*	This fuse needs to be replaced.
24 Vdc sbRIO Fuse*	This fuse needs to be replaced.
24 Vdc User1 Fuse*	This fuse needs to be replaced.

Alarm Name	Alarm is Triggered When:
24 Vdc User2 Fuse	This fuse needs to be replaced.
24 Vdc User3 Fuse	This fuse needs to be replaced.
12 Vdc Supply Fuse†	This fuse needs to be replaced.
24 Vdc Supply Fuse†	This fuse needs to be replaced.
Pump Supply Fuse†	This fuse needs to be replaced.
24 Vdc Ctrl Main Fuse†	This fuse needs to be replaced.
Unknown Alarm	This is a placeholder alarm, and should never be generated.

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

† These alarms are only applicable to biroeactors with sbRIO model 9603 (as visible in the Desktop UI About tab). If these alarms are not applicable to your bioreactor, they will still appear in the Alarms Editor, but they will not be triggered.

Default Alarms Configurations

The PBS-3 comes with two default Alarms.alm files on the HMI. PBS Biotech Technical Support recommends loading the Alarms Off.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 50.

Note: The email setting is independent of the chosen alarm file. However, if an alarm is not configured to be Notify, the PBS-3 will not send an email alert for that alarm.

Alarm Name	Alarms Off		Alarms On		Email
	Notify	Audible	Notify	Audible	
Agitation Low Low			✓	✓	✓
Agitation Low			✓		
Agitation High			✓		
Agitation High High			✓	✓	✓
Temperature Low Low			✓	✓	✓
Temperature Low			✓		
Temperature High	✓		✓		
Temperature High High	✓		✓	✓	✓
DO Low Low			✓	✓	✓
DO Low			✓		
DO High			✓		
DO High High			✓	✓	✓
pH Low Low			✓	✓	✓
pH Low			✓		
pH High			✓		
pH High High			✓	✓	✓
Pressure Low Low					
Pressure Low					
Pressure High					
Pressure High High					
Level Low Low			✓	✓	✓

Alarm Name	Alarms Off		Alarms On		Email
	Notify	Audible	Notify	Audible	
Level Low			✓		
Level High			✓		
Level High High			✓	✓	✓
Filter Oven Low Low			✓	✓	✓
Filter Oven Low			✓		
Filter Oven High	✓		✓		
Filter Oven High High	✓		✓	✓	
Main Gas Low Low			✓	✓	✓
Main Gas Low			✓		
Main Gas High	✓		✓		
Main Gas High High	✓		✓	✓	✓
Leak Detected					
Sequence Resumed	✓		✓		✓
Temperature Sensor Mismatch					
DO Sensor Mismatch					
pH Sensor Mismatch					
Air Source Pressure Error	✓		✓	✓	✓
CO2 Source Pressure Error	✓		✓	✓	✓
N2 Source Pressure Error	✓		✓	✓	✓
O2 Source Pressure Error	✓		✓	✓	✓
Agitation Sensor Failure	✓		✓	✓	✓
Temp Sensor A Failure (range)	✓		✓	✓	✓
Temp Sensor B Failure (range)					
Temp Dual Sensor Failure					
DO Sensor A Failure (range)			✓	✓	✓
DO Sensor B Failure (range)					

Alarm Name	Alarms Off		Alarms On		Email
	Notify	Audible	Notify	Audible	
DO Dual Sensor Failure					
pH Sensor A Failure (range)			✓	✓	✓
pH Sensor B Failure (range)					
pH Sensor A Failure (rate)			✓	✓	✓
pH Sensor B Failure (rate)					
pH Dual Sensor Failure					
Pressure Sensor Disconnected					
Comb Plate Popped					
Dirty Startup	✓		✓		
Clean Startup	✓		✓		
Resume	✓		✓		
RT Mem Fragmented*	✓		✓		✓
RT Mem Nearly Full	✓		✓		✓
NI 9205 Error*	✓		✓		✓
NI 9425/Onboard Error	✓		✓		✓
NI 9219 Error	✓		✓		✓
NI 9476 Error	✓		✓		✓
NI 9263 Error					✓
12 Vdc Atom Fuse*	✓		✓		
12 Vdc Mezz Fuse*	✓		✓		
12 Vdc Mntr Fuse*	✓		✓		
12 Vdc User1 Fuse*	✓		✓		
12 Vdc User2 Fuse	✓		✓		
12 Vdc User3 Fuse	✓		✓		
24 Vdc Fill Pump Fuse	✓		✓		
24 Vdc Ind DO Fuse*	✓		✓		
24 Vdc Main Fuse*	✓		✓		

Alarm Name	Alarms Off		Alarms On		Email
	Notify	Audible	Notify	Audible	
24 Vdc Mezz Fuse*	✓		✓		
24 Vdc MFC Fuse*	✓		✓		
24 Vdc sbRIO Fuse*	✓		✓		
24 Vdc User1 Fuse*	✓		✓		
24 Vdc User2 Fuse	✓		✓		
24 Vdc User3 Fuse	✓		✓		
12 Vdc Supply Fuse†	✓		✓		
24 Vdc Supply Fuse†	✓		✓		
Pump Supply Fuse†	✓		✓		
24 Vdc Ctrl Main Fuse†	✓		✓		
Unknown Alarm	✓		✓		

* These alarms are only applicable to bioreactors with sbRIO model 9641 or 9642 (as visible in the Desktop UI About tab). If these alarms are not applicable to your bioreactor, they will still appear in the Alarms Editor, but they will not be triggered.
† These alarms are only applicable to biroeactors with sbRIO model 9603 (as visible in the Desktop UI About tab). If these alarms are not applicable to your bioreactor, they will still appear in the Alarms Editor, but they will not be triggered.

Default Logger Configurations and Global Variables Definitions

The PBS-3 ships with a default Logger file loaded. For more information, see “Configuring Logger Settings” on page 47.

AGITATION

Variable Name	Default Deadband	Default Record	Source	Definition
AgAtLeast1GoodSensor	0.500		Calc	Signals if the agitation sensor is functioning correctly.
AgAutoMaxStartup(%)	0.001		System	See Agitation “Auto Max Startup (%)” 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.
AgControlGamma	0.001		System	See Agitation “Gamma” setting in Appendix 1.
AgControlLinearity	0.001		System	See Agitation “Linearity” setting in Appendix 1.
AgGasAutoMaxStartup (LPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgLookupFactor (LPM/RPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgLookupModeTimeout (ms)	0.001		System	See Agitation “Lookup Mode Timeout (s)” setting in Appendix 1.
AgMainGasActualRequest (LPM)	0.100		Calc	(N/A on PBS-3) For AirDrive Bioreactors, the flow rate requested of the main gas MFCs.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AgMainGasControl.DTime (min)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasControl.ITime (min)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasControl.PGain (LPM/RPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasRangeAuto (LPM).Max	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasRangeAuto (LPM).Min	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasRangeManMax (LPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMainGasUser(LPM)	0.100		User	(N/A on PBS-3) For PBS AirDrive Bioreactors, the last user-defined main gas output used when agitation was in Manual mode.
AgMin(RPM)	0.001		System	See Agitation “Minimum (RPM)” setting in Appendix 1.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AgMinGasSum(V)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
AgMinPower(%)	0.001		System	See Safety "Min Ag Power (%)" setting in Appendix 1.
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.
AgMotorPWM.Duty	0.100		Calc	Not in use.
AgMotorPWM.OnTime (Cycle)	1.000		Calc	For the PBS 3 MAG (SUS), the time that the agitation motor stays on each period, in number of cycles of the hardware writing to the agitation motor. 1 Cycle ≈ 36 μs.
AgMotorPWM.Period (Cycle)	1.000		Calc	For the PBS 3 MAG (SUS), the pulse width modulation period for the agitation motor, in number of cycles of the hardware writing to the agitation motor. 1 Cycle ≈ 36 μs.
AgMotorPower(V)	0.100		Calc	Used by the system to calculate % power to output to the agitation motor.
AgPV(RPM)	0.500	✓	Calc	The speed of the wheel detected by the software.
AgPowerActualRequest(%)	2.000	✓	Calc	The % power being sent to the agitation motor.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AgPowerControl.DTime (min)	0.010		System	See Agitation “D Time (min)” setting in Appendix 1.
AgPowerControl.ITime (min)	0.010		System	See Agitation “I Time (min)” setting in Appendix 1.
AgPowerControl.PGain (%/RPM)	0.010		System	See Agitation “P Gain (%/RPM)” 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.
AgPowerUser(%)	0.100	✓	User	The last user-defined power output used when agitation was in Manual mode.
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.
AgRPMLoopTime (ticks/Cycle)	0.500		Sensor	The length of time, in ticks, of 1 cycle of the hardware reading the agitation sensor. 1 tick = 25 ns.
AgSP(RPM)	0.500	✓	User	The last agitation setpoint used when agitation was in Auto mode.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
AgWheelCount	1.000		Sensor	Raw count from input counter.
AgWheelLastPeriod(iter)	1.000		Sensor	How many iterations since the last completed wheel period. 1 iter ≈ 2400 ns.
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.
AgWheelSense	0.500		Sensor	True when the agitation sensor senses a Vertical-Wheel® impeller magnet.
AgWheelTimeSinceLast Mag(Cycle)	1.000		Sensor	Elapsed time since last magnet pass detected. 1 Cycle ≈ 2400 ns.
HarvestDelay(s)	0.001		System	(N/A on PBS-3) 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	(N/A on PBS-3) 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.

AGITATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
HarvestTimeout	0.500		Calc	(N/A on PBS-3) 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 MAG, or 40 seconds for other models.

ALARM

Variable Name	Default Deadband	Default Record	Source	Definition
AlarmBuzzerOnTime (Cycle)	10.000		Calc	The time that the buzzer stays on each period, in number of cycles of the hardware writing to the buzzer. 1 Cycle $\approx$ 36 μs. When the buzzer should sound, this is half the value of the period.
AlarmBuzzerPeriod(Cycle)	10.000		System	See Safety “Buzzer Period (ms)” setting in Appendix 1.
AlarmBuzzerUser	0.500		User	True when the user wants to test the buzzer.
AlarmFuseStatus	0.500		Sensor	Status of the fuses – when the number is above zero it means at least 1 fuse is blown.
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.

ALARM (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Alm_CombPlate	0.500		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a comb plate, true when the comb plate has popped up.

CALIBRATION

Variable Name	Default Deadband	Default Record	Source	Definition
CalDOA.Offset(%)	0.010		System	The offset of the raw voltage to DO sensor A PV conversion.
CalDOA.Slope	0.010		System	The slope of the raw voltage to DO sensor A PV conversion.
CalDOB.Offset(%)	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the offset of the raw value to DO sensor B PV conversion.
CalDOB.Slope	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the slope of the raw value to DO sensor B PV conversion.
CalFilterOvenTemp.Offset (C)	0.010		System	The offset for the raw resistance to filter oven temperature PV conversion.
CalFilterOvenTemp.Slope	0.010		System	The slope of the raw resistance to filter oven temperature PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalLevel.b	0.010		System	The offset of the raw voltage to level PV conversion.
CalLevel.m	0.010		System	The slope of the raw voltage to level 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.
CalMFCAir.b(LPM)	0.001		System	The offset of the raw voltage to Air flow (LPM) output conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalMFCAir.m(LPM/V)	0.001		System	The slope of the raw voltage to Air flow (LPM) output conversion.
CalMFCCO2.b(LPM)	0.001		System	The offset of the raw voltage to CO_2 flow (LPM) output conversion.
CalMFCCO2.m(LPM/V)	0.001		System	The slope of the raw voltage to CO_2 flow (LPM) output conversion.
CalMFCN2.b(LPM)	0.001		System	The offset of the raw voltage to N_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.
CalMFCO2.b(LPM)	0.001		System	The offset of the raw voltage to O_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.
CalPressure.Offset(psi)	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the offset of the raw voltage to pressure PV conversion.
CalPressure.Slope	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the slope of the raw voltage to pressure PV conversion.
CalTempA.Offset(C)	0.010		System	The offset of the raw resistance to temperature sensor A PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalTempA.Slope	0.010		System	The slope of the raw resistance to temperature sensor A PV conversion.
CalTempB.Offset(C)	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the offset of the raw resistance to temperature sensor B PV conversion.
CalTempB.Slope	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the slope of the raw resistance to temperature sensor B PV conversion.
CalpHA.Offset(%)	0.010		System	The offset of the raw voltage to pH sensor A PV conversion.
CalpHA.Slope	0.010		System	The slope of the raw voltage to pH sensor A PV conversion.
CalpHA.Temp(C)	0.010		System	The temperature at which pH sensor A was calibrated.
CalpHB.Offset(%)	0.010		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the offset of the raw voltage to pH sensor B PV conversion.

CALIBRATION (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
CalpHB.Slope	0.100		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the slope of the raw voltage to pH sensor B PV conversion.
CalpHB.Temp(C)	0.100		System	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate reusable pH sensors, the temperature at which pH sensor B was calibrated.

DO

Variable Name	Default Deadband	Default Record	Source	Definition
DOA(%)	2.000		Calc	The PV reported by DO sensor A.
DOAIsPrimaryActual	0.500		Calc	True when the software reports DO PV as what DO sensor A measures.
DOARaw(%)	0.100		Sensor	The raw voltage DO sensor A reports.
DOAisActive	0.500		Calc	True when DO sensor A is not failed.
DOAisPrimaryUser	0.500		User	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, true when the user prefers that the software reports DO PV as what DO sensor A measures.
DOAtLeast1GoodSensor	0.500		Calc	Indicates if at least 1 DO sensor has not failed.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DOB(%)	2.000		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the PV reported by DO sensor B.
DOBRaw(%)	0.100		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the raw voltage DO sensor B reports.
DOBisActive	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, true when DO sensor B has not failed.
DODeadband(%)	0.001	✓	System	See DO “Deadband (DO%)” setting in Appendix 1.
DOHardware	0.500		System	A configuration set at the factory to tell the software which DO sensors the hardware supports. This variable should not be modified via recipe.
DOInRange.A	0.500		Calc	True when DO sensor A is in valid range.
DOInRange.B	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, true when DO sensor B is in valid range.
DOMismatchThresh(%)	0.001		System	See DO “Mismatch Thresh (DO%)” setting in Appendix 1.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DOModeActual	0.500	✓	Calc	The actual DO mode: 0) Auto, 1) Manual, 2) Off, and 3) Broken Sensor.
DOModeUser	0.500		User	The user-requested DO mode: 0) Auto, 1) Manual, and 2) Off.
DON2Control.DTime(min)	0.001		System	See DO "N2 D Time (min)" setting in Appendix 1.
DON2Control.ITime(min)	0.001		System	See DO "N2 I Time (min)" setting in Appendix 1.
DON2Control.PGain(%/%)	0.001		System	See DO "N2 P Gain (%/DO%)" 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.
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.
DON2FlowController Request(%)	2.000		Calc	The N_2 flow output requested by the DO controller, in percent of main gas flow.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DON2FlowUser(%)	1.000	✓	User	The last user-defined N_2 output used when DO was in Manual mode.
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.
DOO2ControlAir.DTime (min)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
DOO2ControlAir.ITime (min)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
DOO2ControlAir.PGain (mLPM/%)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
DOO2ControlAlpha	0.001		System	See DO “O2 Alpha” setting in Appendix 1.
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.
DOO2ControlMag.DTime (min)	0.001		System	See DO “O2 D Time (min)” setting in Appendix 1.
DOO2ControlMag.ITime (min)	0.001		System	See DO “O2 I Time (min)” setting in Appendix 1.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DOO2ControlMag.PGain (%/%)	0.001		System	See DO "O2 P Gain (%/DO%)" setting in Appendix 1.
DOO2FlowController Request(%)	2.000		Calc	The O_2 flow output requested by the DO controller, in percent of main gas flow.
DOO2FlowController Request(mLPM)	5.000		Calc	(N/A on PBS-3) For PBS AirDrive Bioreactors, the O_2 flow output requested by the DO controller, in mL/min.
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.
DOO2FlowController RequestLimited(mLPM)	5.000		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.
DOO2FlowUser(%)	0.100	✓	User	The last user-defined O_2 output used when DO was in Manual mode.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
DOO2FlowUser(mLPM)	1.000		User	(N/A on PBS-3) For PBS AirDrive Bioreactors, the last user-defined O_2 output used when DO was in Manual mode.
DOO2RangeAutoMax(%)	1.000		System	See DO "O2 Auto Max (%)" setting in Appendix 1.
DOO2RangeAutoMax (mLPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
DOO2RangeManMax(%)	0.001		System	See DO "O2 Manual Max (%)" setting in Appendix 1.
DOO2RangeManMax (mLPM)	0.001		System	(N/A on PBS-3) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors.
DOPV(%)	2.000	✓	Calc	The DO value detected by the software.
DOSP(%)	1.000	✓	User	The last DO setpoint used when DO was in Auto mode.
DOUserConfig	0.500		User	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, a user configuration to tell the software which DO sensors the user has installed.
DOValidMax(%)	0.001		System	See DO "Valid High (DO%)" setting in Appendix 1.

DO (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a door, indicates if the user is attempting to unlock the door, and the door is not interlocked.
DoorPressureSafe	0.500		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a door pressure sensor, indicates if the door pressure sensor reports a safe value.
DoorPressureSensor	0.500		System	See Safety "Door PressureSensor (0 or 1)" setting in Appendix 1.
DoorUnlockUser	0.500		User	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a door, the user sets this to true to request the door to be unlocked.
ReusablePressure Connected	0.500		Sensor	(N/A on PBS-3) 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
FilterOvenDutyActual(%)	50.000	✓	Calc	The heater duty of the filter oven.
FilterOvenDuty Control.DTime(min)	0.001		System	See Filter Oven “D Time (min)” setting in Appendix 1.
FilterOvenDuty Control.Gain(%/C)	0.001		System	See Filter Oven “P Gain (%/C)” setting in Appendix 1.
FilterOvenDuty Control.ITime(min)	0.001		System	See Filter Oven “I 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.
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) Broken Sensor.
FilterOvenModeUser	0.500		User	The user-requested filter oven mode: 0) Auto, 1) Manual, and 2) Off.

FILTER OVEN (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
FilterOvenOnTime(Cycle)	10.000		Calc	The time that the filter oven stays on each period, in number of cycles of the hardware writing to the filter oven heater. 1 Cycle $\approx$ 36 μs.
FilterOvenPV(C)	5.000	✓	Calc	The temperature of the filter oven detected by the software.
FilterOvenPeriod(Cycle)	10.000		Calc	The pulse width modulation period for the filter oven heater, in number of cycles of the hardware writing to the main heater. Corresponds to 1 second. 1 Cycle $\approx$ 36 μs.
FilterOvenRaw(C)	5.000		Sensor	The raw resistance the filter oven sensor reports.
FilterOvenSP(C)	1.000	✓	User	The last filter oven setpoint used when filter oven was in Auto mode.
FilterOvenSensorActive	0.500		Calc	True when the filter oven temperature sensor has not failed.

GASES

Variable Name	Default Deadband	Default Record	Source	Definition
MFCAirFlowFeedback (LPM)	0.025	✓	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.
MFCAirMeasRaw(V)	0.100		Sensor	The raw voltage the Air MFC reports.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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.
MFCAirOutRaw(V).AO(V)	0.100		Calc	The voltage to request from the Air MFC when the pulse width modulation determines the Air MFC should be pulsing. This allows the MFC to deliver a flow which is effectively lower than its minimum flow rate.
MFCAirOutRaw(V).On(iter)	0.100		Calc	The time that the Air MFC stays on each period, in number of iterations of the hardware writing to the MFCs. 1 iter ≈ 8850 ns.
MFCAirOutRaw(V).Period (iter)	0.100		Calc	The pulse width modulation period for the Air MFC, in number of iterations of the hardware writing to the MFCs. 1 iter ≈ 8850 ns.
MFCCO2FlowFeedback (LPM)	0.020	✓	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.
MFCCO2MeasRaw(V)	0.100		Sensor	The raw voltage the CO_2 MFC reports.
MFCCO2Min(LPM)	0.001		System	See Gas Data “CO2 Min (LPM)” setting in Appendix 1.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MFCCO2Off(V)	0.001		System	See Gas Data "CO2 Off (V)" setting in Appendix 1.
MFCCO2OutRaw.AO(V)	0.100		Calc	The voltage to request from the CO_2 MFC when the pulse width modulation determines the CO_2 MFC should be pulsing. This allows the MFC to deliver a flow which is effectively lower than its minimum flow rate.
MFCCO2OutRaw.On(iter)	0.100		Calc	The time that the CO_2 MFC stays on each period, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.
MFCCO2OutRaw.Period (iter)	0.100		Calc	The pulse width modulation period for the CO_2 MFC, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.
MFCLoopTime(ticks/Cycle)	1.000		Sensor	The length of time, in ticks, of 1 cycle of the hardware writing to the MFCs and NI 9263. 1 tick = 25 ns.
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.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MFCN2FlowFeedback (LPM)	0.025	✓	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.
MFCN2MeasRaw(V)	0.100		Sensor	The raw voltage the N_2 MFC reports.
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.
MFCN2OutRaw(V).AO(V)	0.100		Calc	The voltage to request from the N_2 MFC when the pulse width modulation determines the N_2 MFC should be pulsing. This allows the MFC to deliver a flow which is effectively lower than its minimum flow rate.
MFCN2OutRaw(V).On(iter)	0.100		Calc	The time that the N_2 MFC stays on each period, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.
MFCN2OutRaw(V).Period (iter)	0.100		Calc	The pulse width modulation period for the N_2 MFC, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.

GASES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MFCO2FlowFeedback (LPM)	0.025	✓	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.
MFCO2MeasRaw(V)	0.100		Sensor	The raw voltage the O_2 MFC reports.
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.
MFCO2OutRaw.AO(V)	0.100		Calc	The voltage to request from the O_2 MFC when the pulse width modulation determines the O_2 MFC should be pulsing. This allows the MFC to deliver a flow which is effectively lower than its minimum flow rate.
MFCO2OutRaw.On(iter)	0.100		Calc	The time that the O_2 MFC stays on each period, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.
MFCO2OutRaw.Period (iter)	0.100		Calc	The pulse width modulation period for the O_2 MFC, in number of iterations of the hardware writing to the MFCs. 1 iter $\approx$ 8850 ns.
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	(N/A on PBS-3) For PBS Bioreactors size 15 and higher, this indicates whether the agitation motor will not turn on because it is interlocked.
InterlockAll	0.500		Calc	Not in use.
InterlockDoor	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a door, this indicates whether the door will not unlock because it is interlocked.
InterlockDoorPressureMax (psi)	0.001		System	See Safety “Max Pressure Door (psi)” setting in Appendix 1.
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.
InterlockPressureMax(psi)	0.001		System	See Safety “Max Pressure (psi)” setting in Appendix 1.
InterlockPumps	0.500		Calc	Indicates whether media and additions pumps will not turn on because they are interlocked.

INTERLOCKS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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
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)	0.100		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)	1.000		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the level net pressure times the cm/psi.
LevelNoCal(L)	0.150		Calc	Not in use.
LevelPV(L)	0.100	✓	Calc	The level of the vessel contents detected by the software.
LevelRaw(V)	0.100		Sensor	The raw voltage the level sensor reports.
LevelSensorEnable	0.500		System	See Level "Enable Sensor (0 or 1)" setting in Appendix 1.
LevelTotal(cm)	1.000		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the net level plus the bottom gap.

PROCESS ALARMS/LIMITS

Variable Name	Default Deadband	Default Record	Source	Definition
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.

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 Low Low (RPM)	0.001		System	See Process Alarms "Agitation Low Low (RPM)" 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.DO Low (%)	0.001		System	See Process Alarms "DO Low (%)" setting in Appendix 1.
Limits.DO Low Low (%)	0.001		System	See Process Alarms "DO Low Low (%)" 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.
Limits.Filter Oven Low (C)	0.001		System	See Process Alarms "Filter Oven Low (C)" 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.Level High (L)	0.001		System	See Process Alarms "Level High (L)" setting in Appendix 1.

PROCESS ALARMS/LIMITS (continued)

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

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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.Temp Low (C)	0.001		System	See Process Alarms "Temp Low (C)" setting in Appendix 1.
Limits.Temp Low Low (C)	0.001		System	See Process Alarms "Temp Low Low (C)" 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.
Limits.pH Low	0.001		System	See Process Alarms "pH Low" setting in Appendix 1.
Limits.pH Low Low	0.001		System	See Process Alarms "pH Low Low" setting in Appendix 1.
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) Broken Sensor Mode.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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) Broken Sensor 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) Broken Sensor Mode.
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.

PROCESS ALARMS/LIMITS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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) Broken Sensor 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) Broken Sensor Mode.

LOGGER

Variable Name	Default Deadband	Default Record	Source	Definition
LoggerLoadedCount	0.500		Calc	Tracks the number of times logger settings have been loaded from file.
LoggerMaxLogInterval(ms)	60.000		System	See System “Max Data Log Interval (min)” setting in Appendix 1.

MAIN GAS

Variable Name	Default Deadband	Default Record	Source	Definition
MainGasActualRequest (LPM)	0.100	✓	Calc	The gas flow output the controller requests of the main gas MFCs.
MainGasFeedback(LPM)	0.100		Calc	The sum of the actual flows of the Air, N_2, CO_2, and O_2 MFCs.

MAIN GAS (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
MainGasModeActual	0.500	✓	Calc	The actual main gas mode: 0) Auto, 1) Manual, and 2) Off.
MainGasModeUser	0.500		User	The user-requested main gas mode: 0) Auto, 1) Manual, and 2) Off.
MainGasRangeManMax (LPM)	0.001		System	See Gas Data “Manual Max (LPM)” setting in Appendix 1.
MainGasUser(LPM)	0.100	✓	User	The last user-defined flow rate used when main gas was in Manual mode.

PRESSURE

Variable Name	Default Deadband	Default Record	Source	Definition
PressureDisconnected(V)	0.001		System	See Pressure “Disconnected Pressure (V)” setting in Appendix 1.
PressurePV(psi)	0.050		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the pressure in the bag detected by the software.
PressureRaw(V)	0.100		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, the raw voltage the pressure sensor reports.
PressureSensorIsActive	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, this indicates if the pressure sensor is disconnected.

PRESSURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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&ValvesAddition AHardware.AllowAsBase	0.500		System	A configuration set at the factory to tell the software if the Addition A pump can be used as the Base pump. This variable should not be modified via recipe.
Pumps&ValvesAddition AHardware.Exists	0.500		System	A configuration set at the factory to tell the software if an Addition A pump is installed. This variable should not be modified via recipe.
Pumps&ValvesAddition AHardware.Reversible	0.500		System	A configuration set at the factory to tell the software if the Addition A pump hardware supports bi-directional flow. This variable should not be modified via recipe.
Pumps&ValvesAddition AHardware.SpeedControl	0.500		System	A configuration set at the factory to tell the software what method of speed control for the Addition A pump is supported by the hardware: 0) Off/On, 1) Slow/Medium/Fast, and 2) RPM control. This variable should not be modified via recipe.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesAddition BHardware.AllowAsBase	0.500		System	A configuration set at the factory to tell the software if the Addition B pump can be used as the Base pump. This variable should not be modified via recipe.
Pumps&ValvesAddition BHardware.Exists	0.500		System	A configuration set at the factory to tell the software if an Addition B pump is installed. This variable should not be modified via recipe.
Pumps&ValvesAddition BHardware.Reversible	0.500		System	A configuration set at the factory to tell the software if the Addition B pump hardware supports bi-directional flow. This variable should not be modified via recipe.
Pumps&ValvesAddition BHardware.SpeedControl	0.500		System	A configuration set at the factory to tell the software what method of speed control for the Addition B pump is supported by the hardware: 0) Off/On, 1) Slow/Medium/Fast, and 2) RPM control. This variable should not be modified via recipe.
Pumps&ValvesAnalogBase Speed(RPM)	1.000		System	See Pumps “Analog Base Speed (RPM)” setting in Appendix 1.
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 AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
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&ValvesFillMotor Raw(V)	0.100		Calc	(N/A on PBS-3) 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-3) 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	(N/A on PBS-3) 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&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 AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesFillSpeed (RPM) 2	5.000		User	(N/A on PBS-3) 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	(N/A on PBS-3) 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&ValvesMedia Hardware.AllowAsBase	0.500		System	A configuration set at the factory to tell the software if the Media pump can be used as the Base pump. This variable should not be modified via recipe.
Pumps&ValvesMedia Hardware.Exists	0.500		System	A configuration set at the factory to tell the software if a Media pump is installed. This variable should not be modified via recipe.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesMedia Hardware.Reversible	0.500		System	A configuration set at the factory to tell the software if the Media pump hardware supports bi-directional flow. This variable should not be modified via recipe.
Pumps&ValvesMedia Hardware.SpeedControl	0.500		System	A configuration set at the factory to tell the software what method of speed control for the Media pump is supported by the hardware: 0) Off/On, 1) Slow/Medium/Fast, and 2) RPM control. This variable should not be modified via recipe.
Pumps&Valves Pump1.Duty	1.000		Calc	The pulse-density modulation duty for addition pump A. 2^{16} would be 100% duty.
Pumps&ValvesPump1.On Time(Cycle)	10.000		Calc	The time that addition pump A stays on each period, in number of cycles of the hardware writing to addition pump A, when addition pump A is the base pump. 1 iter $\approx$ 36 μs.
Pumps&Valves Pump1.Period(Cycle)	10.000		Calc	The pulse-density modulation period for addition pump A, in number of iterations of the hardware writing to the pumps. 1 iter $\approx$ 36 μs.
Pumps&Valves Pump2.Duty	1.000		Calc	The pulse-density modulation duty for addition pump B. 2^{16} would be 100% duty.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesPump2.On Time(Cycle)	10.000		Calc	The time that addition pump B stays on each period, in number of cycles of the hardware writing to addition pump A, when addition pump B is the base pump. 1 iter $\approx$ 36 μs.
Pumps&Valves Pump2.Period(Cycle)	10.000		Calc	The pulse-density modulation period for addition pump B, in number of iterations of the hardware writing to the pumps. 1 iter $\approx$ 36 μs.
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&ValvesPumpSmpl	0.500		Calc	True when the Sample Pump is on.
Pumps&ValvesPumpSmpl Req	0.500		User	The user sets this to true to request the sample pump to run.
Pumps&ValvesPumpSmpl Revrs	0.500		Calc	This toggles the sample pump direction.
Pumps&ValvesPumpSmpl RevrsReq	0.500		User	The user can toggle this to change pump direction.
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&ValvesReverse CCandCW	0.500		System	See Pumps "Sample Reverse CW and CCW (0 or 1)" setting in Appendix 1.
Pumps&ValvesSample Hardware.AllowAsBase	0.500		System	A configuration set at the factory to tell the software if the Sample pump can be used as the Base pump. This variable should not be modified via recipe.
Pumps&ValvesSample Hardware.Exists	0.500		System	A configuration set at the factory to tell the software if a Sample pump is installed. This variable should not be modified via recipe.
Pumps&ValvesSample Hardware.Reversible	0.500		System	A configuration set at the factory to tell the software if the Sample pump hardware supports bi-directional flow. This variable should not be modified via recipe.

PUMPS AND VALVES (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Pumps&ValvesSample Hardware.SpeedControl	0.500		System	A configuration set at the factory to tell the software what method of speed control for the Sample pump is supported by the hardware: 0) Off/On, 1) Slow/Medium/Fast, and 2) RPM control. This variable should not be modified via recipe.

RECIPE

Variable Name	Default Deadband	Default Record	Source	Definition
PromptIssued(tick)	0.100		Calc	Not in use.
Recipe Index	0.500		Calc	The step the recipe is currently on. Value is -1 when no recipe is running, 0 for first step, 1 for second step, etc.
RecipeSkipSequence	0.500		User	True when the user wants to skip past the sequence in the recipe engine. The variable automatically changes back.
RecipeSkipStep	0.500		User	True when the user wants to skip past the current step in the recipe engine. The variable automatically changes back.

SYSTEM

Variable Name	Default Deadband	Default Record	Source	Definition
BioreactorModel	0.500		System	The model of the PBS Vertical-Wheel® Bioreactor. This variable should not be modified via recipe.
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.
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.
SysSessionID	0.500		System	A unique session handle – used to confirm the RIO computer rebooted successfully
SysStop	0.500		System	Used to initiate a request to reboot the RIO computer.
Sys_FPGAError.NI 9205	0.500		Sensor	The status used to trigger the "NI 9205 Error" alarm.
Sys_FPGAError.NI 9219	0.500		Sensor	The status used to trigger the "NI 9219 Error" alarm.
Sys_FPGAError.NI 9263	0.500		Sensor	The status used to trigger the "NI 9263 Error" alarm.
Sys_FPGAError.NI 9425/Onboard	0.500		Sensor	The status used to trigger the "NI 9425/Onboard Error" alarm.

SYSTEM (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
Sys_FPGAError.NI 9476	0.500		Sensor	The status used to trigger the “NI 9476 Error” alarm.
Sys_PWMLoopTime (ticks/Cycle)	1.000		Sensor	The length of time, in ticks, of 1 cycle of the hardware writing to the NI 9476. 1 tick = 25 ns.
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
TempA(C)	0.200		Calc	The PV reported by temperature sensor A.
TempAIsActive	0.500		Calc	True when temperature sensor A has not failed.
TempAIsPrimaryActual	0.500		Calc	True when the software reports temperature PV as what temperature sensor A measures.
TempAIsPrimaryUser	0.500		User	(N/A on PBS-3) 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.
TempARaw(C)	0.100		Sensor	The raw resistance temperature sensor A reports.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempAtLeast1GoodSensor	0.500		Calc	Indicates if at least 1 temperature sensor has not failed.
TempB(C)	0.200		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the PV reported by temperature sensor B.
TempBIsActive	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, true when temperature sensor B has not failed.
TempBRaw(C)	0.100		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the raw resistance temperature sensor B reports.
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.
TempHeatDutyActual(%)	2.000	✓	Calc	The heat duty of the main heater.
TempHeatDutyAutoMax(%)	0.001		System	See Temperature “Heat Auto Max (%)” setting in Appendix 1.
TempHeatDuty Control.DTime(min)	0.001		System	See Temperature “D Time (min)” setting in Appendix 1.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempHeatDuty Control.ITime(min)	0.001		System	See Temperature “I Time (min)” setting in Appendix 1.
TempHeatDuty Control.PGain(min)	0.001		System	See Temperature “P Gain (%/C)” 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.
TempHeatDutyUser(%)	1.000	✓	User	The last user-defined heat duty used when temperature was in Manual mode.
TempHeatManMax(%)	0.001		System	See Temperature “Heat Manual Max (%)” setting in Appendix 1.
TempHeatOnTime(Cycle)	1.000		Calc	The time that the main heater stays on each period, in number of cycles of the hardware writing to the main heater. 1 Cycle $\approx$ 36 μs.
TempHeatPeriod(Cycle)	1.000		Calc	The pulse width modulation period for the main heater, in number of cycles of the hardware writing to the main heater. Corresponds to 1 second. 1 Cycle $\approx$ 36 μs.
TempInRange.A	0.500		Calc	True when temperature sensor A is in valid range.

TEMPERATURE (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
TempInRange.B	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, true when temperature sensor B is in valid range.
TempMismatchThresh(C)	0.001		System	See Temperature “Mismatch Thresh (C)” setting in Appendix 1.
TempModeActual	0.500	✓	Calc	The actual temperature mode: 0) Auto, 1) Manual, 2) Off, and 3) Broken Sensor.
TempModeUser	0.500		User	The user-requested temperature mode: 0) Auto, 1) Manual, and 2) Off.
TempPV(C)	0.200	✓	Calc	The temperature value detected by the software.
TempSP(C)	0.100	✓	User	The last temperature setpoint used when temperature was in Auto mode.
TempUserConfig	0.500		User	(N/A on PBS-3) 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.

pH

Variable Name	Default Deadband	Default Record	Source	Definition
pHA	0.050		Calc	The PV reported by pH sensor A.
pHAIsActive	0.500		Calc	True when pH sensor A has not failed.
pHAIsPrimaryActual	0.500		Calc	True when the software reports pH PV as what pH sensor A measures.
pHAIsPrimaryUser	0.500		User	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, true when the user prefers that the software reports pH PV as what pH sensor A measures.
pHARaw	0.010		Sensor	The raw voltage pH sensor A reports.
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.
pHAtLeast1GoodSensor	0.500		Calc	Indicates if at least 1 pH sensor has not failed.
pHB	0.050		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the PV reported by pH sensor B.
pHBIsActive	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, true when pH sensor B has not failed.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHBRaw	0.010		Sensor	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the raw voltage pH sensor B reports.
pHBUseTempComp	0.500		System	See pH “B Use Temp Comp?” setting in Appendix 1.
pHBaseAutoMax	0.001		System	See pH “Base Auto Max (%)” setting in Appendix 1.
pHBaseDutyActual(%)	1.000	✓	Calc	The base pump output.
pHBaseDutyControl.DTime (min)	0.001		System	See pH “Base D Time (min)” setting in Appendix 1.
pHBaseDutyControl.ITime (min)	0.001		System	See pH “Base I Time (min)” setting in Appendix 1.
pHBaseDutyControl.PGain (%)	0.001		System	See pH “Base P Gain (%/pH)” 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.
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
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.
pHCO2AutoMax(%)	0.001		System	See pH “CO2 Auto Max (%)” setting in Appendix 1.
pHCO2Control.DTime(min)	0.001		System	See pH “CO2 D Time (min)” setting in Appendix 1.
pHCO2Control.ITime(min)	0.001		System	See pH “CO2 I Time (min)” setting in Appendix 1.
pHCO2Control.PGain(%)	0.001		System	See pH “CO2 P Gain (%/pH)” 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.
pHCO2ControlGamma	0.001		System	See pH “CO2 Gamma” setting in Appendix 1.
pHCO2ControlLinearity	0.001		System	See pH “CO2 Linearity” setting in Appendix 1.
pHCO2FlowController Request(%)	1.000		Calc	The CO_2 flow output requested by the pH controller, in percent of main gas flow.
pHCO2ManMax(%)	0.001		System	See pH “CO2 Manual Max (%)” setting in Appendix 1.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHCO2User(%)	1.000		User	The last user-defined CO_2 output used when pH was in Manual mode.
pHDeadband	0.001	✓	System	See pH “Deadband” setting in Appendix 1.
pHHardware	0.500		System	A configuration set at the factory to tell the software which pH sensors the hardware supports. This variable should not be modified via recipe.
pHInRange.A	0.500		Calc	True when pH sensor A is in valid range.
pHInRange.B	0.500		Calc	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, true when pH sensor B is in valid range.
pHMismatchThresh	0.001		System	See pH “Mismatch Thresh” setting in Appendix 1.
pHModeActual	0.500	✓	Calc	The actual pH mode: 0) Auto, 1) Manual, 2) Off, and 3) Broken Sensor.
pHModeUser	0.500		User	The user-requested pH mode: 0) Auto, 1) Manual, and 2) Off.
pHPV	0.050	✓	Calc	The pH value detected by the software.
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.

pH (continued)

Variable Name	Default Deadband	Default Record	Source	Definition
pHSP	0.010	✓	User	The last pH setpoint used when pH was in Auto mode.
pHSensorSamplesTo Average	0.500		System	See pH “Samples To Average” setting in Appendix 1.
pHUserConfig	0.500		User	(N/A on PBS-3) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, a user configuration to tell the software which pH sensors the user has installed.
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.