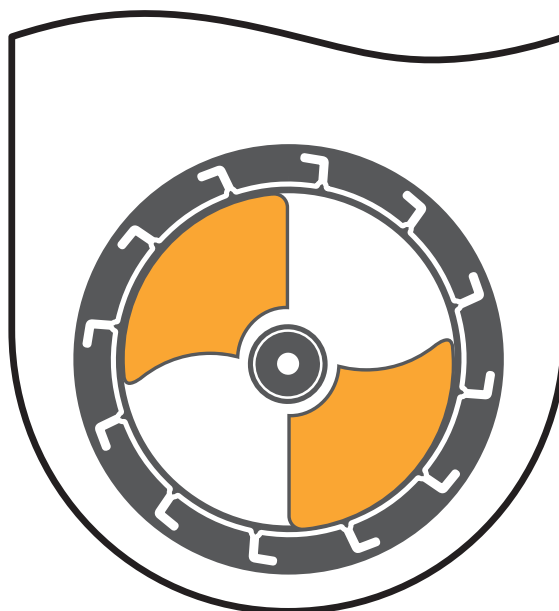


VERTICAL-WHEEL™ BIOREACTORS



PBS 3 MagDrive Vertical-Wheel®

Single-Use Sensors

Single-Use Bioreactor System

User Manual

Bioreactor Serial Number:

Bioreactor Name:



PBS Biotech, Inc.

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About This Manual

This user manual shows you how to install, configure, and use the PBS 3 MagDrive Vertical-Wheel® Bioreactor System with the Single-Use Sensor configuration (PBS 3 MAG-SUS). This manual covers the Integrated MagDrive Bioreactor, including the PBS Software package and the PBS 3 MAG-SUS Bioreactor Single-Use Vessel assembly.

Configurations are standard as of the time at publication and the software features and instructions are applicable to version 3.1.0. 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 MAG-SUS’s features, components, and controls (Chapter 1 on page 11)
- A high level system description to provide an understanding of the complete PBS 3 MAG-SUS (Chapter 2 on page 26)
- Safety considerations (Chapter 3 on page 31)
- Product specifications (Chapter 4 on page 35)
- Instructions for installing the PBS 3 MAG-SUS and configuring users, logger settings, and alarms (Chapter 5 on page 39)
- Day-to-day use of the PBS 3 MAG-SUS (Chapter 6 on page 56)
- A detailed description of all PBS 3 MAG-SUS features and functions (Chapter 7 on page 98)
- Information an IT department will need about the PBS 3 MAG-SUS (Chapter 8 on page 123)

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 |
|--|-------|----------|------|
| pbsbiotech.com | | | |
| webmail.1and1.com | | | |
| logmein.com | | | |

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

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

CO₂ = Carbon Dioxide

N₂ = Nitrogen

O₂ = Oxygen

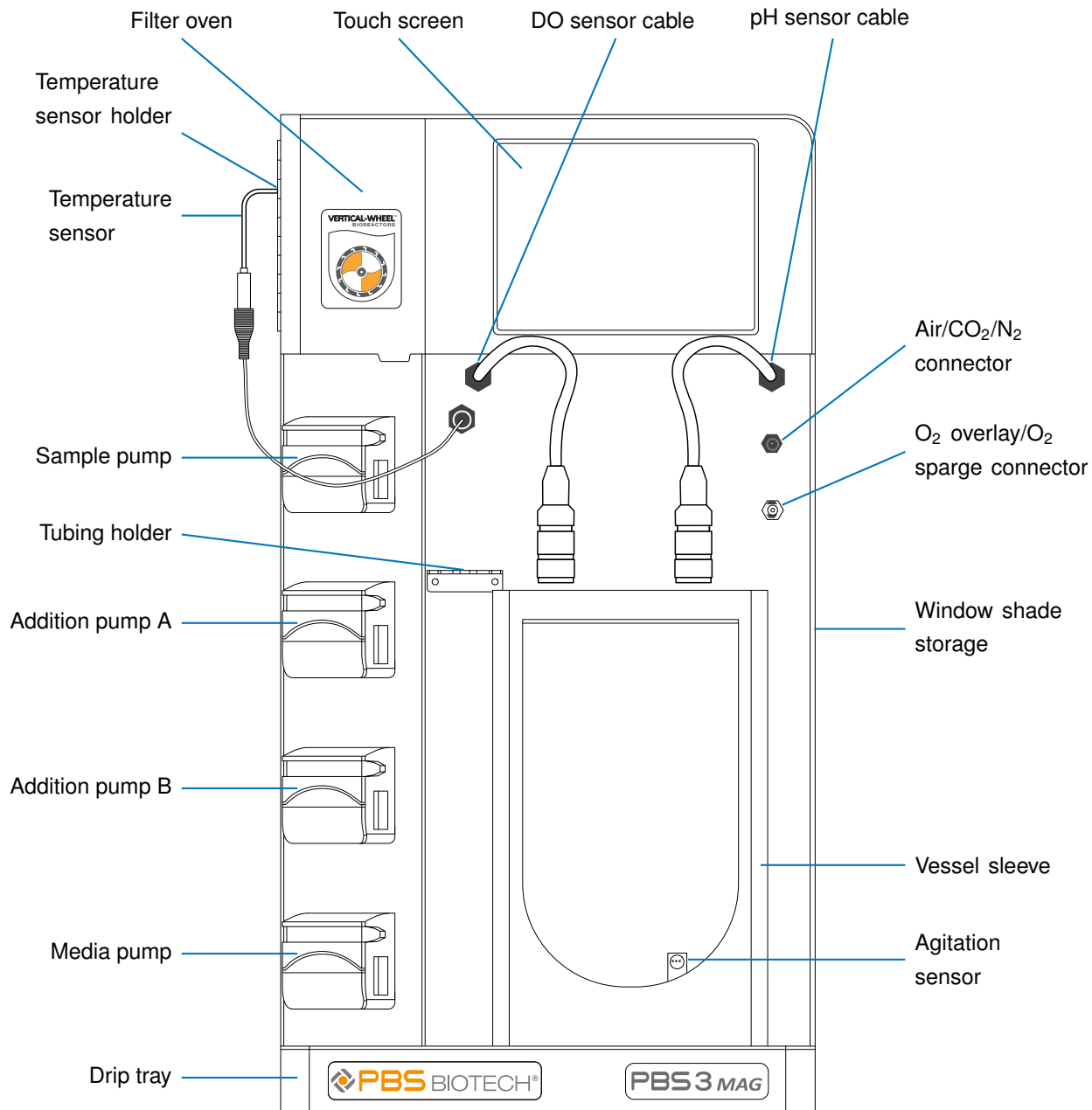
IPA = Isopropyl Alcohol

EtOH = Ethanol

MFC = Mass Flow Controller

RIO = Reconfigurable Input/Output

SUS = Single Use Sensor



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.

DO sensor cable

Connects the DO sensor head to the bioreactor.

pH sensor cable

Connects the pH sensor and sensor head to the bioreactor.

Air/CO₂/N₂ connector

Connects the vessel's Air/CO₂/N₂ line to supplies of Air, CO₂, and N₂, which are attached to the bioreactor via the gas connection panel (see "PBS 3 MAG-SUS Bioreactor - Rear" on page 14).

O₂ overlay/O₂ sparge connector

Connects the vessel's O₂ overlay or O₂ sparge line to a supply of O₂, which is attached to the bioreactor via the gas connection panel (see "PBS 3 MAG-SUS Bioreactor - Rear" on page 14).

Window shade storage

Stores the window shade by adhering to magnets in the PBS 3 MAG-SUS'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 MAG-SUS 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

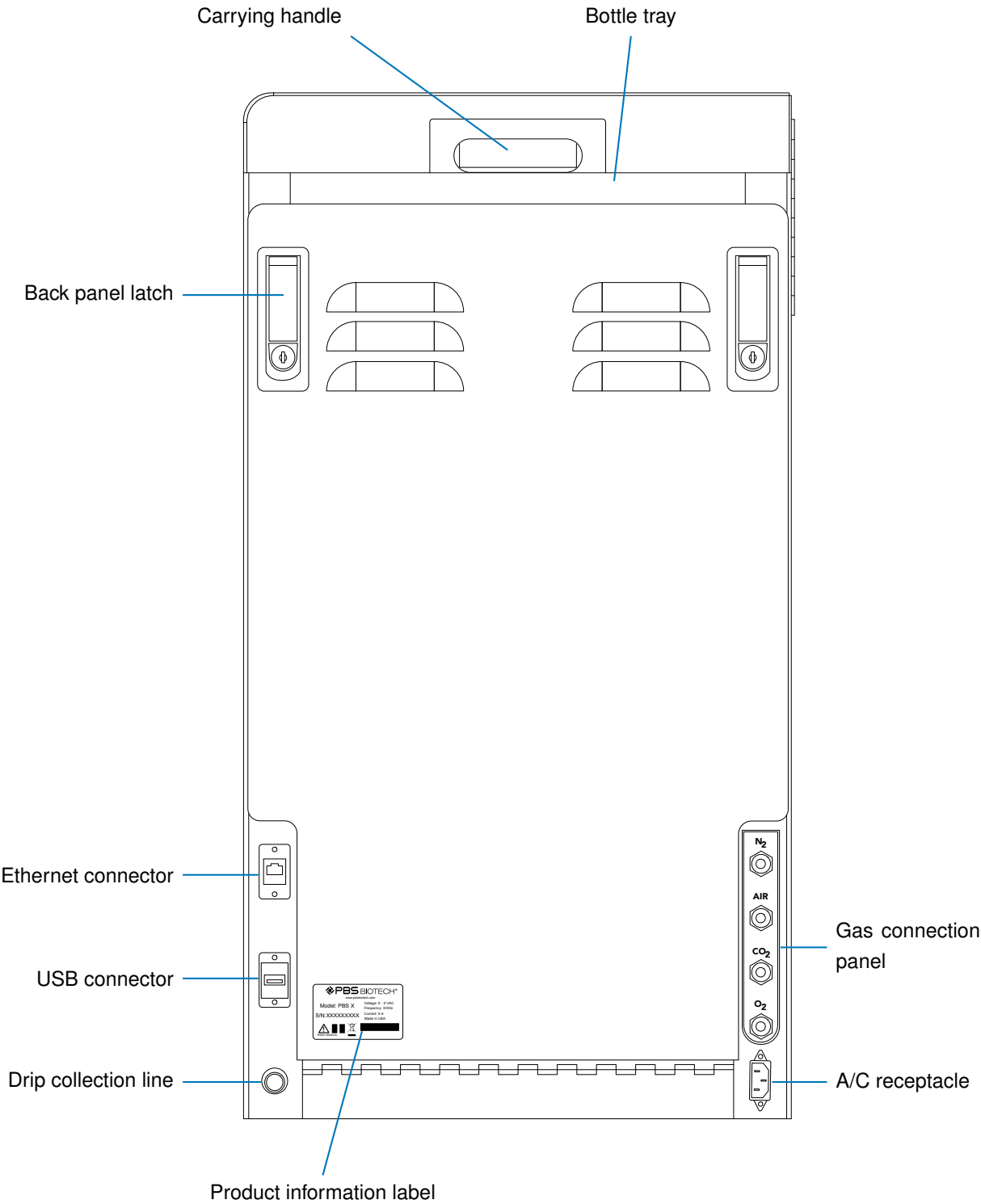
Used to draw a sterile sample from the vessel.

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

Allows for convenience in moving the bioreactor.

Bottle tray

Stores reagent or media addition bottles during a run.

Gas connection panel

Connects the external N₂, Air, CO₂, and O₂ supplies to the bioreactor.

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.

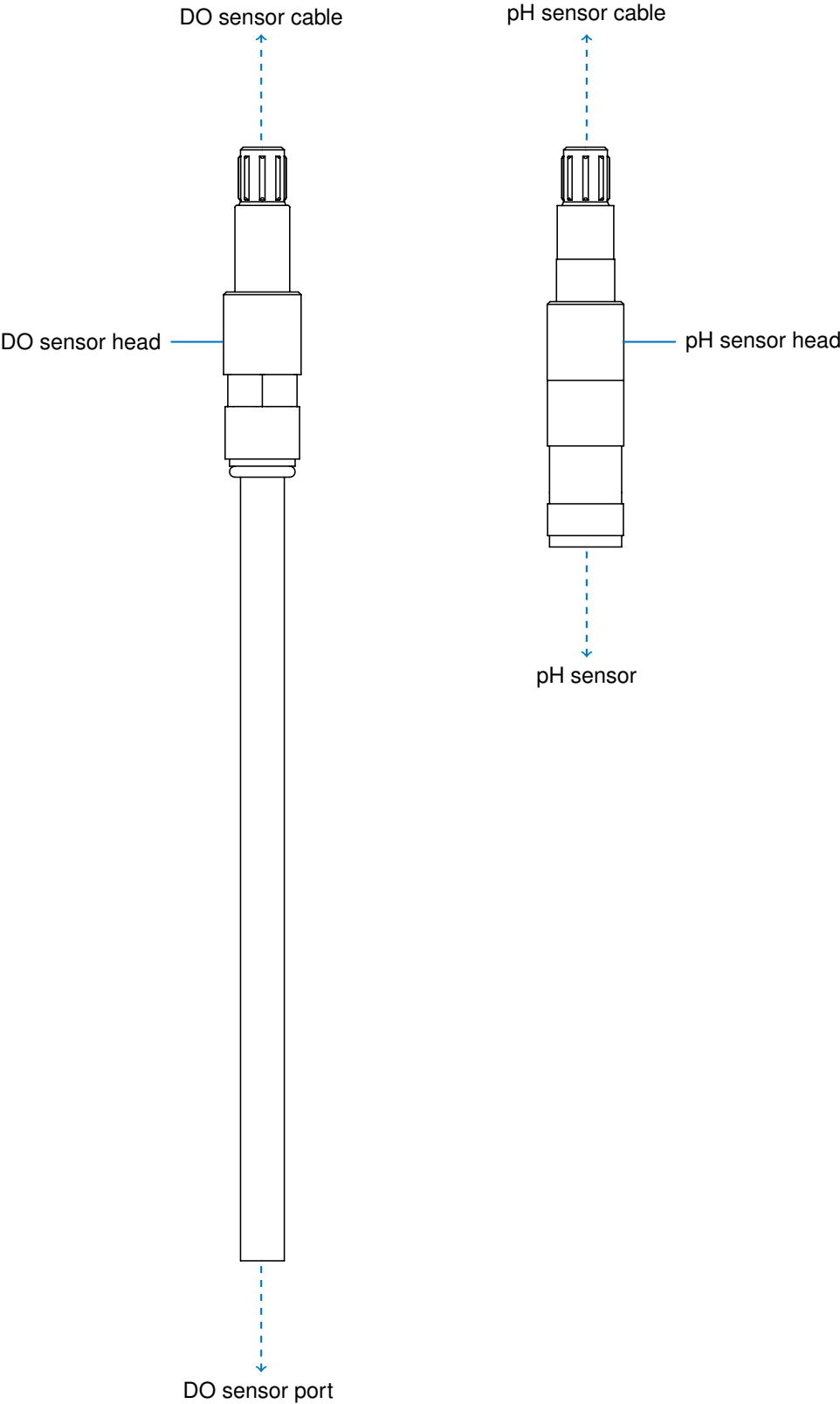
WARNING: Avoid using keyboards with a power button, to prevent accidentally turning the bioreactor's Windows computer off.

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.

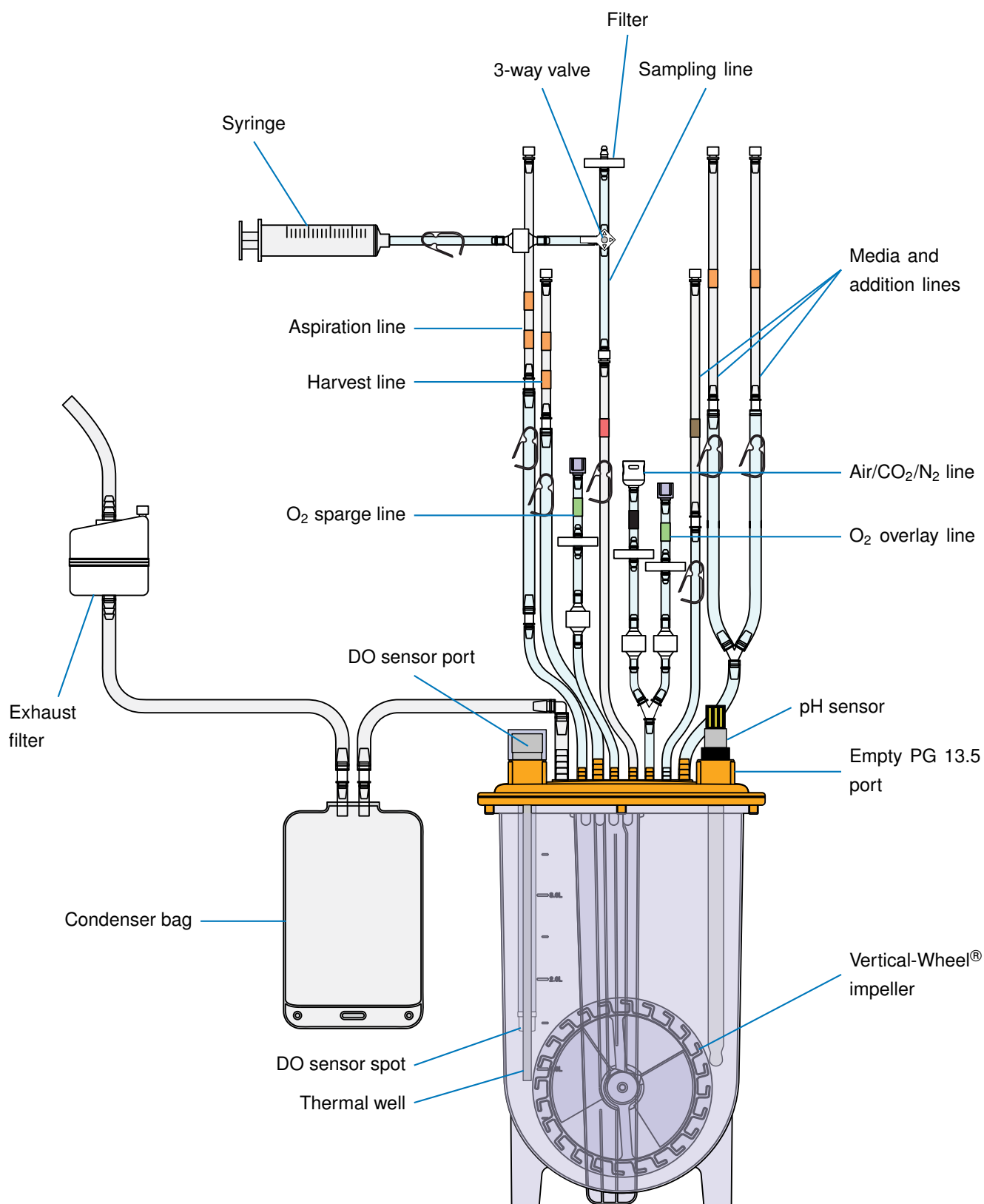


DO sensor head

Inserts into the DO sensor port pre-installed in the vessel and connects to the DO sensor cable on the bioreactor.

pH sensor head

Connects to the pH sensor pre-installed in the vessel and to the pH sensor cable on the bioreactor.



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. The addition line is used to add base and other additions during a run.

Air/CO₂/N₂ line

Connects the vessel to the bioreactor, which connects to external gas sources via the gas connection panel (see “PBS 3 MAG-SUS Bioreactor - Rear” on page 14). Air, CO₂, and N₂ flow through this line to the overlay to control dissolved oxygen and pH.

O₂ overlay/O₂ sparge lines

Connect the vessel to the bioreactor, which connects to external gas sources via the gas connection panel (see “PBS 3 MAG-SUS Bioreactor - Rear” on page 14). O₂ flows through the O₂ overlay line to the overlay or through the O₂ sparge line to the sparger to control dissolved oxygen.

pH sensor

Comes pre-installed and sterilized in the vessel. The probe connects to the pH sensor head, which is then attached to the pH sensor cable on the bioreactor.

Empty PG 13.5 port

Accommodates one optional sensor or piece 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.

Thermal well

Accommodates the temperature sensor to read the temperature of cell culture medium.

DO sensor spot

Located at the tip of the DO sensor port sleeve. The spot works in conjunction with the DO sensor head to read the DO value of cell culture medium in the vessel.

Condenser bag

Catches medium and condensate droplets entrained in the exhaust, preventing them from clogging the exhaust filter.

DO sensor port

Allows insertion and removal of the DO sensor head while providing a sterile barrier for the vessel.

Exhaust filter

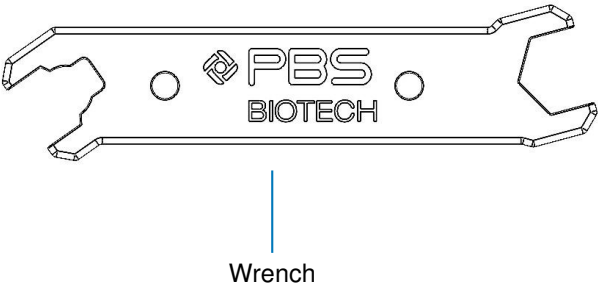
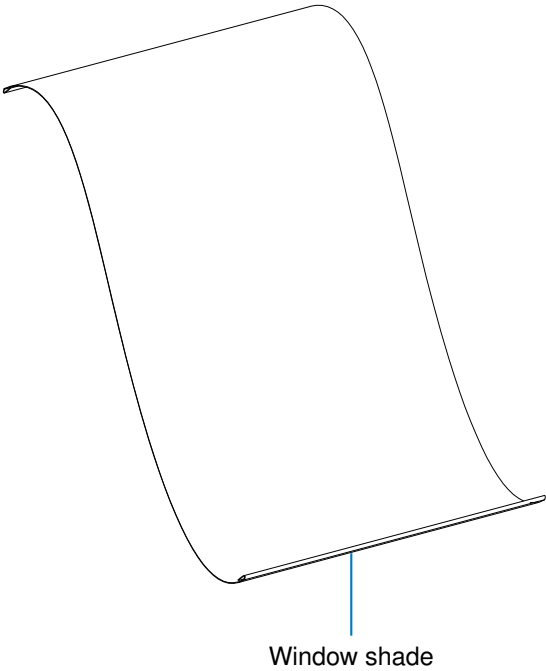
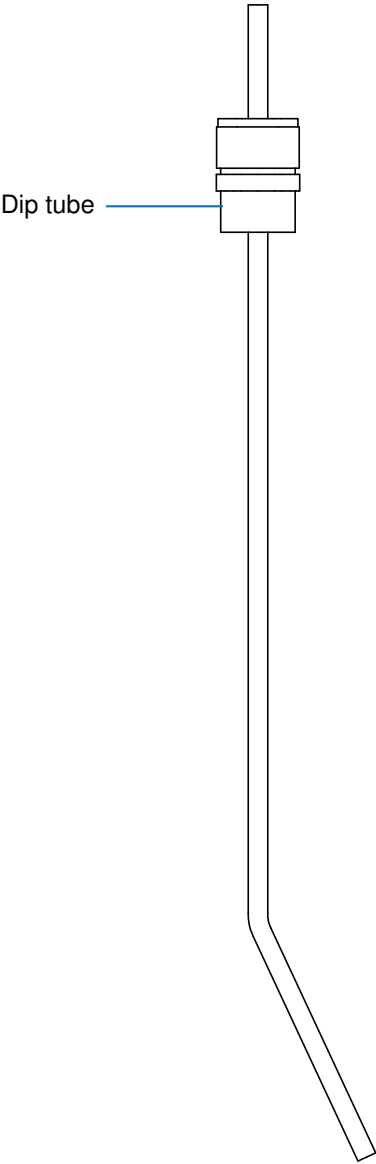
Filters the exhaust in order to maintain sterility of the vessel contents.

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.

Aspiration line

Used to draw a sample or remove spent culture medium during medium exchanges.



Dip tube

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

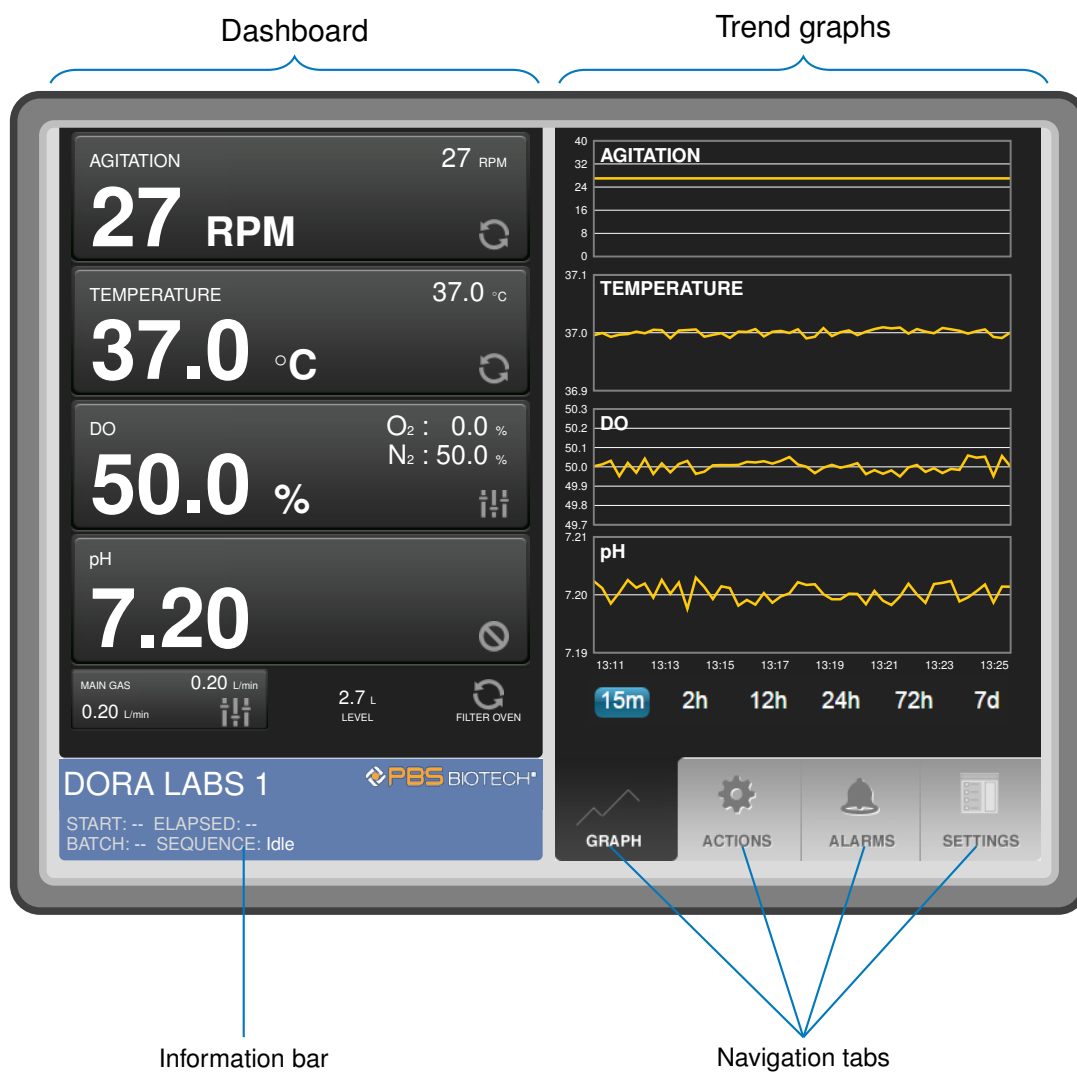
Window shade

Attaches to the sleeve to protect light-sensitive media in the vessel. Removable and stored by adhering to magnets in the PBS 3 MAG-SUS'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 MAG-SUS is powered on. It is the primary way of interacting with the PBS 3 MAG-SUS. Google Chrome and Safari for iOS are the only browsers supported. For more information, see “Hello User Interface” on page 98.



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.

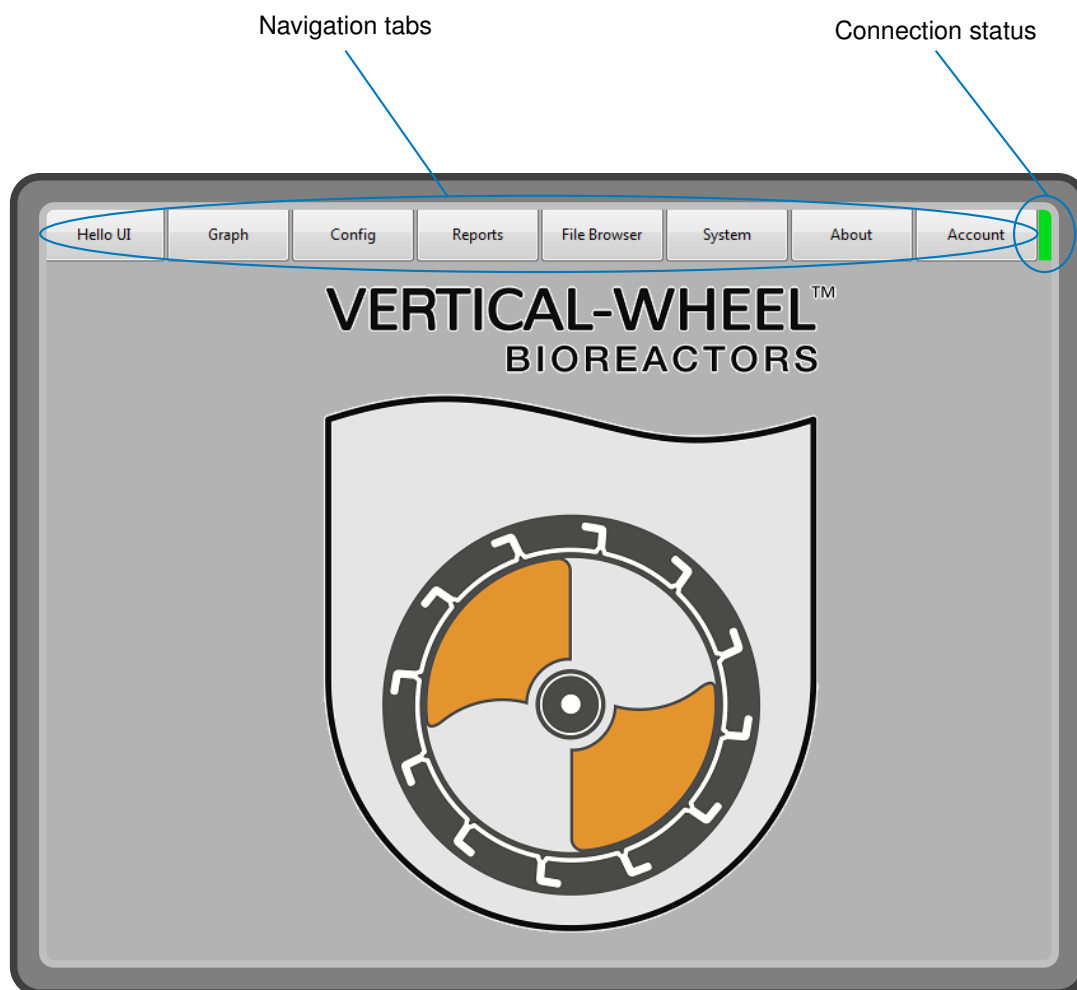
Navigation tabs

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 MAG-SUS 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 MAG-SUS.



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 98.

Graph

Accesses graphs for each of the main controls on the PBS 3 MAG-SUS - 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 79.

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 46, “PBS 3 MAG-SUS Alarms” on page 49, “Recipes” on page 80, “Settings/System Variables” on page 93, and “Other Calibrations” on page 97.

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 MAG-SUS’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 Windows computer by selecting “Power.”

About

Displays the current system and vessel information, as well as the PBS 3 MAG-SUS’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 MAG-SUS by selecting “Logout.”

Connection status

Indicates the status of the connection between the Windows computer and the RIO. The light is green when there are no communication issues, and turns red when there is a communication problem.

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

System Description

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

This PBS 3 MAG-SUS 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 MAG-SUS consists of: an interface for the vessel; an industrial controller; a four-gas module; a vessel heater; a vessel temperature sensor; single-use 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. The vessel comes pre-installed with a DO port, DO sensor spot, single-use pH probe, and single-use thermal well.

Principles of Operation

Agitation

The PBS 3 MAG-SUS 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 MAG-SUS has a built-in temperature sensor which, when inserted in the thermal well, senses the temperature of the vessel contents. The PBS 3 MAG-SUS 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 single-use DO sensor. Single-use sensors are intended to be calibrated with the PBS 3 MAG-SUS after the vessel has been filled with medium and equilibrated. The PBS 3 MAG-SUS controls the DO by using a two-sided PID (proportional-integral-derivative) controller. To decrease DO levels, the software increases the percent composition of N₂ flowing out of the Air/CO₂/N₂ connector, through the Air/CO₂/N₂ line, and into the overlay.

To increase DO levels, the software flows O₂ out of the O₂ overlay/O₂ sparge connector, which either flows into the overlay via the O₂ overlay line, or is sparged through the medium via the O₂ sparge line.

pH

The culture pH is monitored by a single-use pH sensor. pH is usually regulated exclusively by CO₂%, and base should only be added if absolutely necessary. Single-use sensors are intended to be calibrated with the PBS 3 MAG-SUS after the vessel has been filled with medium and equilibrated. The PBS 3 MAG-SUS controls the pH by using a two-sided PID controller. To decrease the pH, the software increases the percent composition of CO₂ flowing through the Air/CO₂/N₂ line 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 MAG-SUS 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 MAG-SUS 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 MAG-SUS 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 Windows computer's hard drive (see "Architecture" on page 30), 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 MAG-SUS, 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 MAG-SUS'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 MAG-SUS. 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 MAG-SUS 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 MAG-SUS. 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 Windows PC.










The RIO is in charge of all sensing and control functions, including interlocks, broken sensor detection, and running recipes. If the PC 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 PC. If the PC 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 PC 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 Windows PC without first consulting PBS Biotech Technical Support.

Important Safety Information - read 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 MAG-SUS has hot surfaces, as indicated by hot surface warning signs. Do not touch hot surfaces. |
|  | Always allow the PBS 3 MAG-SUS 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. |
|  | 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.

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 MAG-SUS Bioreactor to verify safety mechanisms are functional. For instructions on inspecting a Vertical-Wheel® Bioreactor vessel before use, see "Install Vessel in PBS 3 MAG-SUS" on page 60.

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

Cleaning and Decontamination

To clean and decontaminate the PBS 3 MAG-SUS, use 70% IPA or EtOH. Wipe down all surfaces of the PBS 3 MAG-SUS, 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 MAG-SUS. 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 MAG-SUS 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, while still in the original shrink-wrap. Proper lifting

technique of bending at the knees and lifting with the legs should be used. Do not move the PBS 3 MAG-SUS by its sleeve as this will cause damage to the load cell.

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

| PBS 3 MAG-SUS 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, varies by configuration |
| | 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, 50/60Hz, 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 MAG-SUS 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 | Single-Use Hamilton VisiFerm® fluorometric |
| pH | pH Control | Two-sided PID control with CO ₂ and base addition pump or manual control |

| PBS 3 MAG-SUS Specifications | | |
|------------------------------|--|---|
| pH (continued) | pH Sensor Type | Single-Use Hamilton OneFerm® 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 |

| PBS 3 MAG-SUS Specifications | | |
|--------------------------------------|--|--|
| Single-Use Vessel (continued) | O ₂ Overlay and O ₂ Sparge Lines | Platinum-cured silicone tubing with 0.2-micron filter |
| | Sampling Line | Platinum-cured silicone and C-Flex [®] tubing with syringe, 3-way valve and 0.2-micron filter |
| | Harvest Line | 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 |

FermProbe[®] is a registered trademark of Broadley-James Corporation.
 OxyProbe[®] is a registered trademark of Broadley-James Corporation.
 VisiFerm[®] and OneFerm[®] are owned and/or registered by Hamilton Company in the U.S. and/or other countries.

C-FLEX[®] is a registered trademark of Saint-Gobain Performance Plastics Corporation

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

Integrated MagDrive Bioreactor

Space Requirements

Before you begin, see “Space Requirements” on page 35 and confirm that your available bench space meets or exceeds the space requirements listed.

Utility Requirements

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

General Electrical Requirements

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

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 |

Electrical

Depending on the bioreactor's part number, it will require one of the following configurations:

- 110 – 120 V, 50 – 60 Hz, 2.5 A
- 200 – 240 V, 50 – 60 Hz, 1.5 A

Unit Placement

To prevent bodily injury and/or damage to the product, see “Lifting and Handling” on page 33 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, carefully remove the shrink-wrap by cutting sections away with a utility knife. Use caution when cutting the shrink-wrap to prevent harm to yourself and the unit. Once the unit has been unwrapped, 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 MAG-SUS

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

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 MAG-SUS 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 MAG-SUS 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.

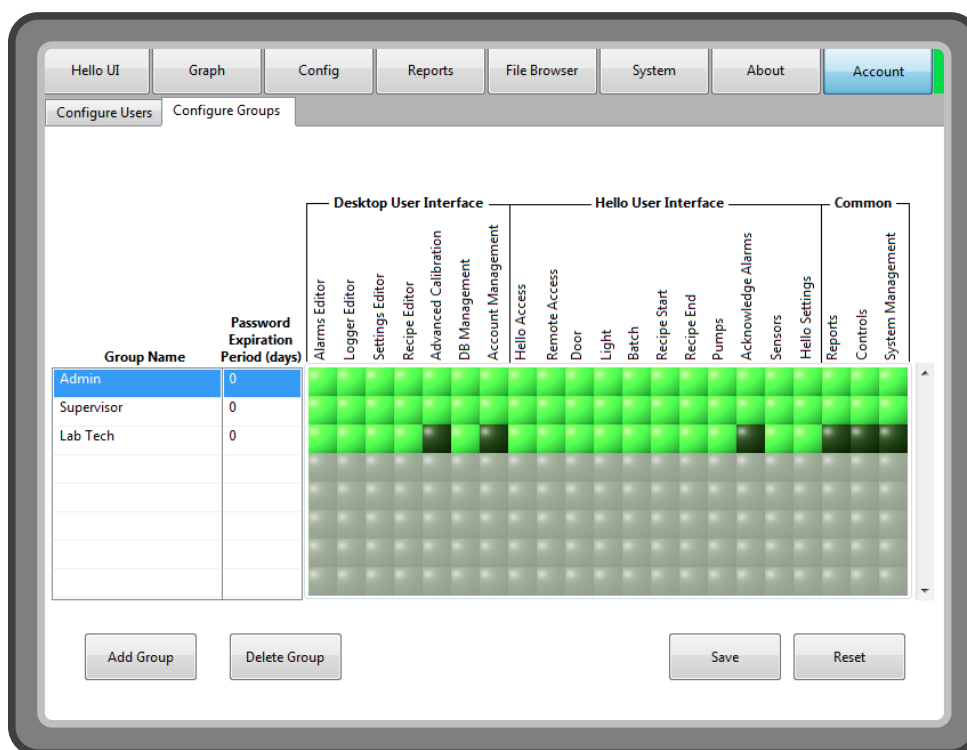
In order to prevent users from being permanently locked out of their bioreactor, the PBS Software prohibits password expiration for user groups with the Account Management permission, and users within these user groups cannot be locked out after multiple failed login attempts. For security purposes, 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.”
5. 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.

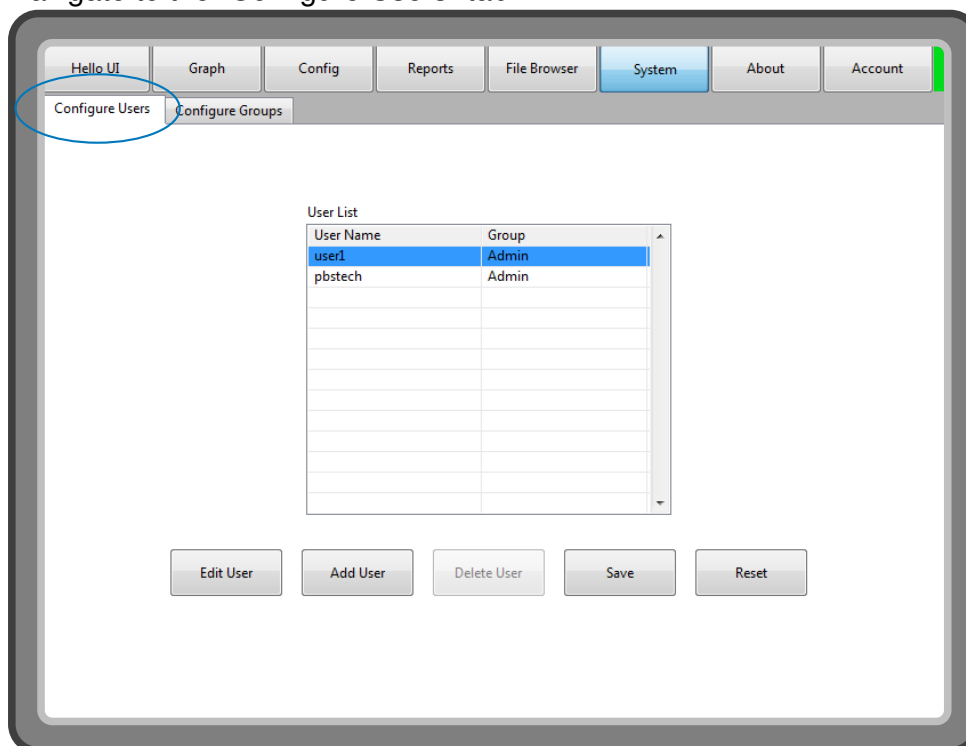
Editing Group Permissions

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 120.

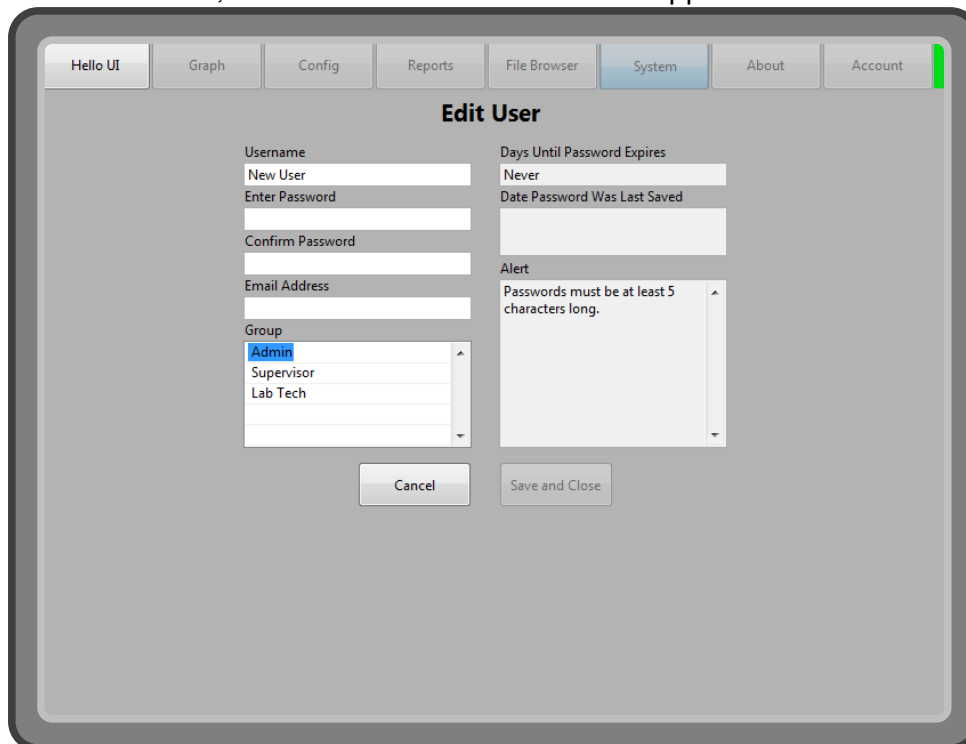


Creating a New User

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. To link an email address to the user, click the “Email Address” field and enter a valid email address. While a user can be saved without adding an email, the user will not be able to receive emailed reports or notifications about failed login attempts to their account without a valid email address entered in this field.
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. Log in to the Desktop UI as in the previous section, click “Account” and then select “Manage” to navigate to the “Configure Users” page.
2. To edit a user, select the user in the “User List” section under the “Configure User” tab. Change the User Name, Password, Email Address, or Group. Click the “Save and Close” button to save the new user settings.
3. 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.
4. To edit a user group, select the group in the “Group List” section under the “Configure Group” tab. Change the Group Name, Password Expiration Period, or Permission Options. Click the “Save” button to save any changes.
5. To delete a user group, select the group in the “Group List” section under the “Configure Group” tab, click the “Delete Group” button, and click the

“Save” button. Note that groups with users still assigned to them cannot be deleted.

Note: Users without the “Account Management” permission can modify their own password (to prevent it from expiring) and email address, when they click “Account” and then select “Manage.” They will not be able to modify anything else in their account or see any information about any other user account.

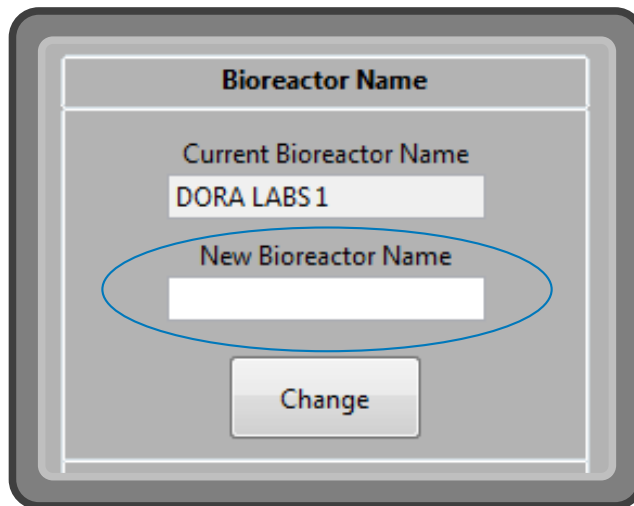
Naming the PBS 3 MAG-SUS

The PBS 3 MAG-SUS 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.

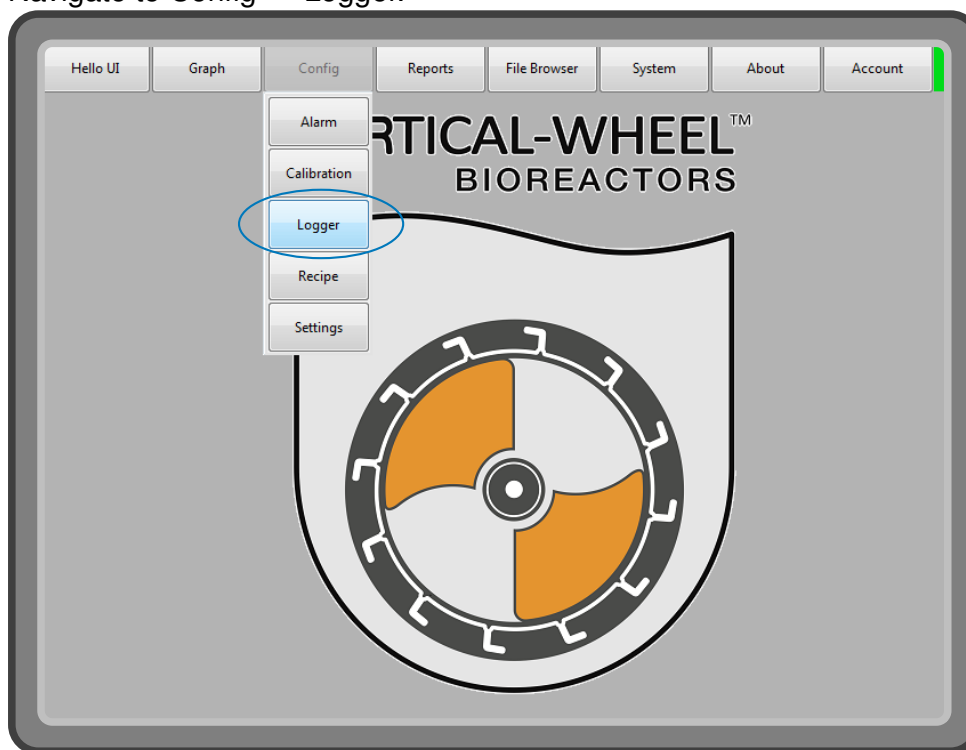


4. Enter the desired name using the on screen keyboard or an external keyboard and select “Enter.” The name you entered should now appear in the ‘New Bioreactor Name’ field.
5. Click “Change.” The ‘Current Bioreactor Name’ field should now match the ‘New Bioreactor Name’ field.

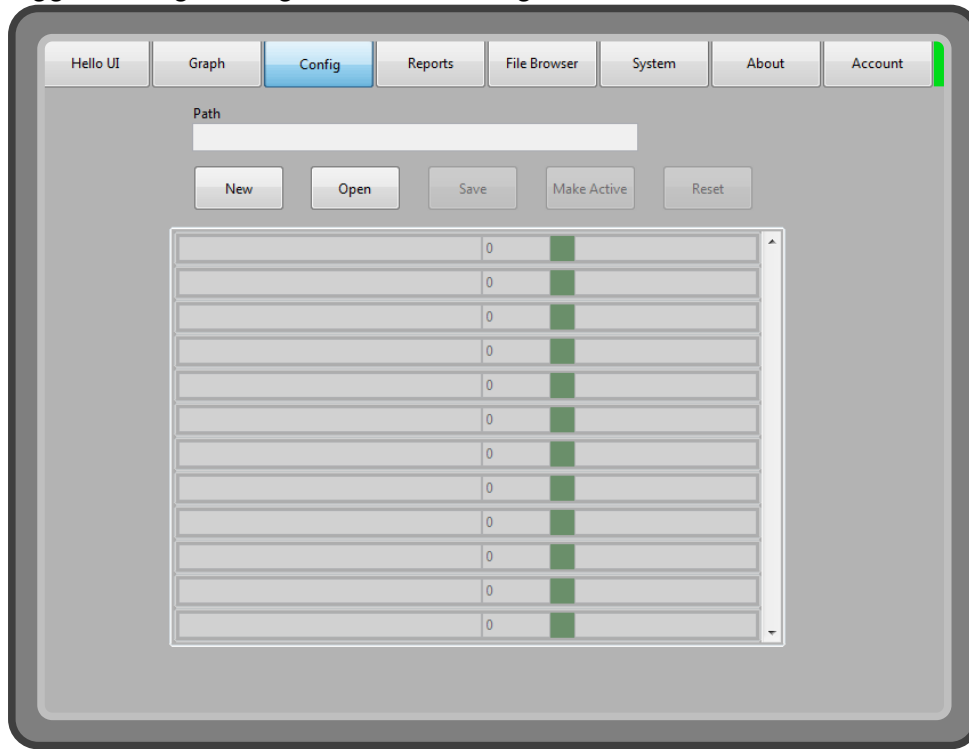
Configuring Logger Settings

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 115.

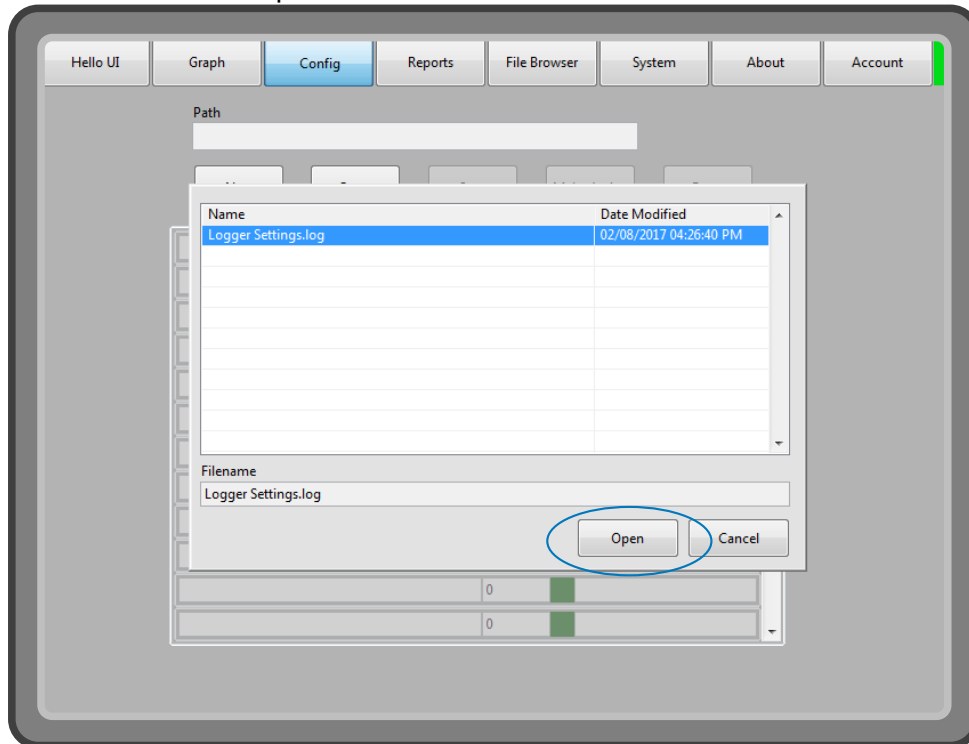
1. Log in to the Desktop UI as a user with the “Logger Editor” permission.
2. Navigate to Config → Logger.



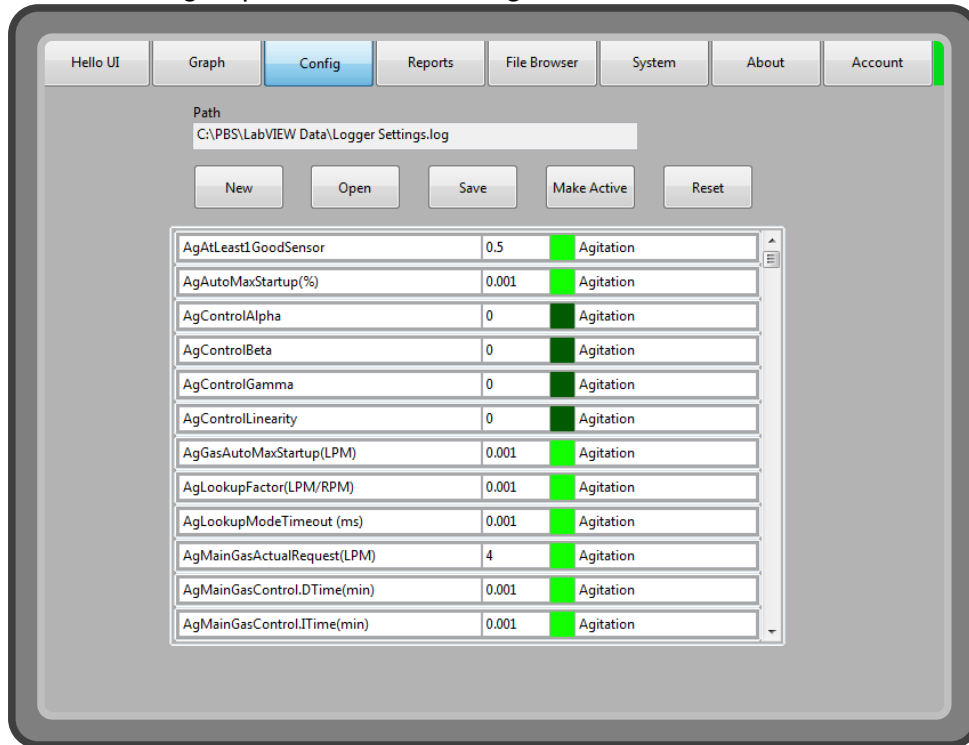
- Click “Open” to edit an existing Logger Settings file, or “New” if you would like to create an entirely new Logger Settings file. You can create multiple logger settings configuration files and give them different names.



- 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 file active on the RIO.

PBS 3 MAG-SUS Alarms

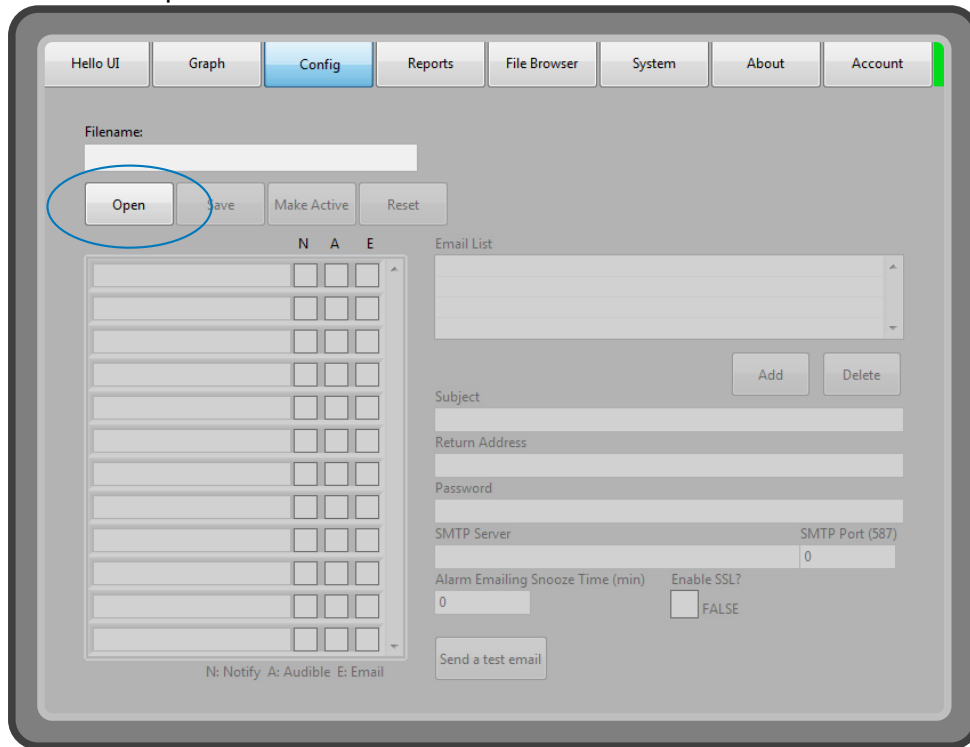
The PBS 3 MAG-SUS comes with its Alarms Off.alm file loaded so the non-run conditions will not set off any alarms (disconnected sensors, temperature far below 37 °C, etc.). You can create and edit multiple Alarms configuration files using the Alarms Editor in the Desktop UI.

Creating and Editing Alarm Files

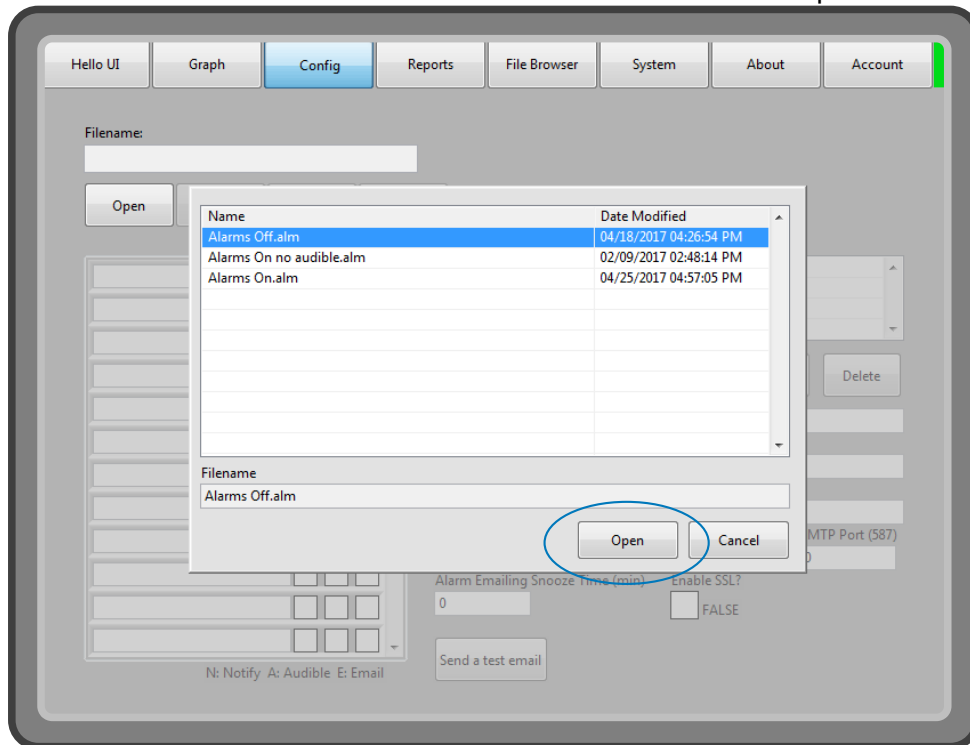
1. Log in to the Desktop UI as a user with the “Alarms Editor” permission.
2. Navigate to Config → Alarm.



- Click the “Open” button.



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



- 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.

Filename: C:\PBS\LabVIEW Data\Alarms On.alm

Open Save Make Active Reset

| | N | A | E |
|-----------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Agitation Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Main Gas Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Temperature Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| DO Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| pH Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Pressure Low Low | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Level Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Filter Oven Low Low | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Leak Detected | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Temperature Sensor Mismatch | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| DO Sensor Mismatch | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| pH Sensor Mismatch | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

N: Notify A: Audible E: Email

Email List

user1@pbsbiotech.com

Add Delete

Subject
PBS 3 Bioreactor A

Return Address
pbs@pbsbiotech.com

Password

SMTP Server
smtp.1and1.com

SMTP Port (587)
587

Alarm Emailing Snooze Time (min)
2

Enable SSL?
☒ TRUE

Send a test email

6. Configure email notifications. The PBS 3 MAG-SUS 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 MAG-SUS's sending address:

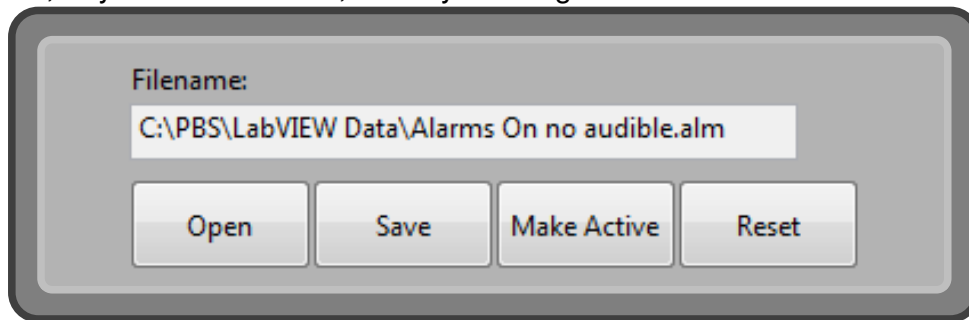
The screenshot shows a web-based configuration window for email notifications. At the top is an 'Email List' section with a text area containing 'user1@pbsbiotech.com' and two buttons, 'Add' and 'Delete'. Below this is the 'Subject' field with the text 'PBS 3 Bioreactor A'. The 'Return Address' field contains 'pbs@pbsbiotech.com'. The 'Password' field is masked with '*****'. The 'SMTP Server' field contains 'smtp.1and1.com' and the 'SMTP Port (587)' field contains '587'. The 'Alarm Emailing Snooze Time (min)' field contains '2'. The 'Enable SSL?' checkbox is checked, and the text 'TRUE' is displayed next to it. At the bottom left is a button labeled 'Send a test email'.

- Fill in the 'Subject' field with a desired subject – PBS Biotech suggests using the PBS 3 MAG-SUS's name.
- Fill in the 'Return Address' field with the email address the PBS 3 MAG-SUS will email users from.
- Fill in the 'Password' field with the password to that email account.
- Fill in the 'SMTP Server' field with the SMTP Server address for that email provider.
- 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.
- Click "Enable SSL?" if you wish to enable an encrypted link between the server and the mail client.
- 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. 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.



- 8. Click “Make Active” to make the configurations active on the RIO.

Configuring Automatic Backups

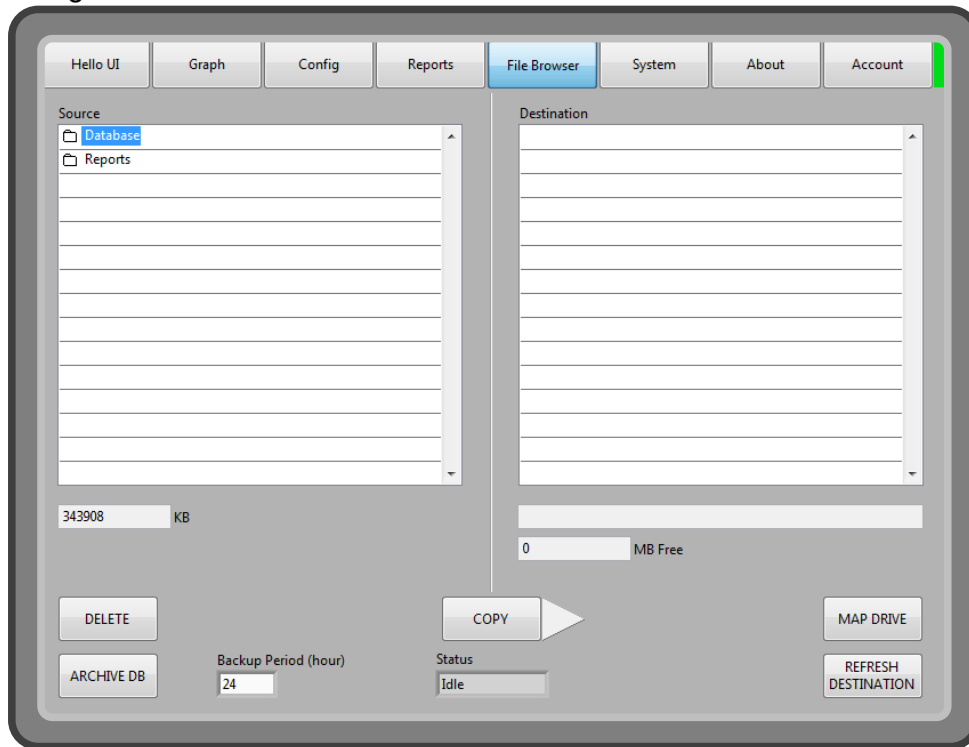
The PBS 3 MAG-SUS can automatically back up the contents of the Database folder, including the active and archived databases and the Database History File.

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.

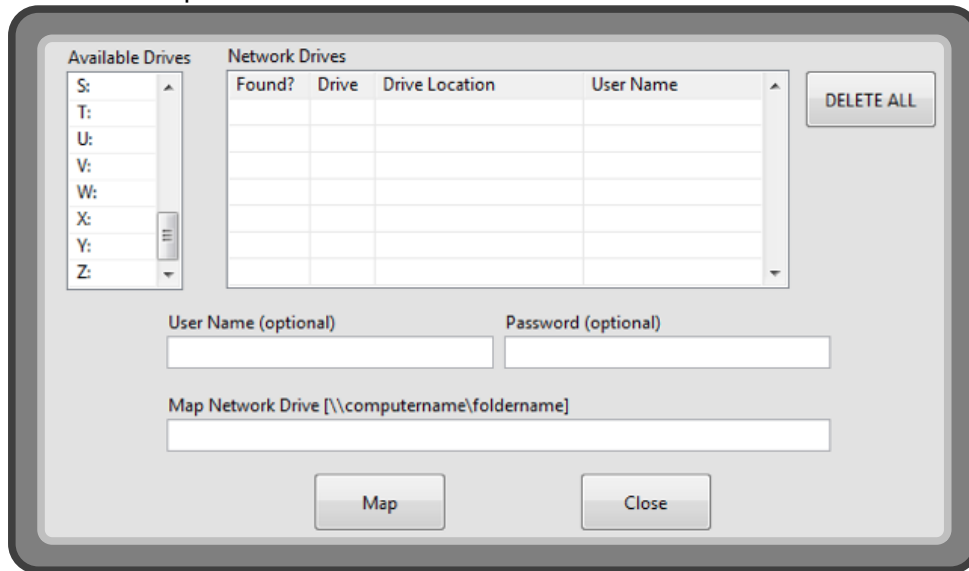
Note: To disable automatic backups, set the Backup Period (hour) to 0.

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 Windows computer.

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

- Click the “Map Drive” button.



- Select the Z drive and enter the appropriate information in the User Name, Password, and Map Network Drive fields, then click “Map” and “Close.”
- 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 Windows 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 MAG-SUS and configured user accounts, logger settings, and alarms. Please see Chapter 6 for more details to begin using the PBS 3 MAG-SUS.

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.

The aspiration port is positioned at the 300 mL liquid fill level in the standard vessel configuration. To change this position, a custom vessel configuration will need to be created. Please contact PBS Applications Engineering (app.eng@pbsbiotech.com) for more details.

Suggested Order of Operations

Set Up Run

1. Configure dip tube and tubing assembly (if applicable)
2. Autoclave dip tube (if applicable)
3. Confirm gas source pressure matches specifications(see “Utility Requirements” on page 39)
4. Install dip tube in vessel (if applicable)
5. Load Vessel
6. Install vessel in PBS 3 MAG-SUS
7. Level ‘Zero’ calibration
8. Add medium
9. Level ‘Span’ calibration (if necessary)
10. Control temperature, agitation, and main gas
11. One-point pH calibration
12. One-point DO calibration
13. Control pH and DO
14. Load the Alarms On.alm file
15. Add cells
16. Start batch

During Run

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

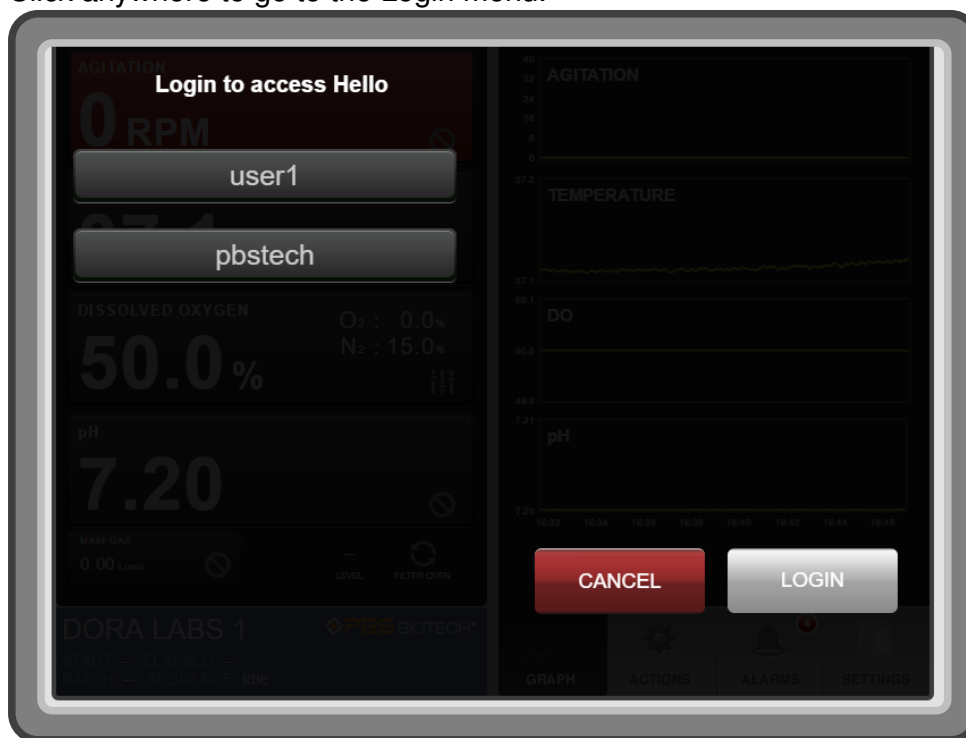
End Run

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

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.”

Configure Dip Tube and Tubing Assembly

The dip tube can be used in addition to or in place of the aspiration port (e.g. if the location of the aspiration port is not desirable).

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.

Autoclaving Dip Tube

1. Clean the dip tube, being sure to rinse with DI water.
2. Place the dip tube in an autoclave pouch, such that the nonsterile portion is easiest to access when the pouch is opened in the biosafety cabinet.
3. Seal the pouch.
4. Place the dip tube in the autoclave.
5. 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.

Install Dip Tube

Note: Wait until the dip tube is cool to the touch before installing in the vessel.

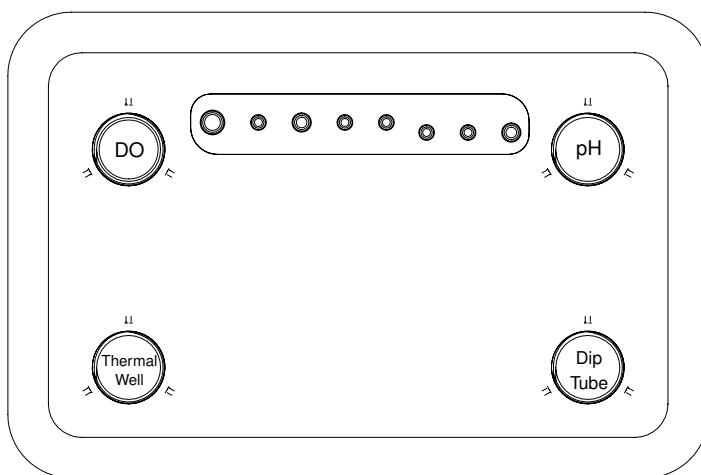
Note: The wrench can be used to assist in the installation or removal of port caps and accessories, such as the dip tube.

1. Sanitize the autoclave pouch with 70% IPA or equivalent.
2. Transfer the autoclave pouch 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 dip tube as follows:

- (a) Position the vessel so the port cap is accessible and tubing is not in the way. The dip tube will be installed in the front right port cap (see image below).
- (b) Loosen the port cap.
- (c) Remove the dip tube from the autoclave pouch, only touching the nonsterile portion.
- (d) Remove the port cap.
- (e) Guide the dip tube through the port.
- (f) Thread the dip tube tightly into the port.

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 be done, in the biosafety cabinet, in the middle of a run as well. 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 liquid transfer line of the dip tube to a transfer flask.
10. Transfer vessel out of biosafety cabinet.

Load Vessel

To load a vessel:

1. Navigate to the “Actions” tab.

- Click “Load Bag.”



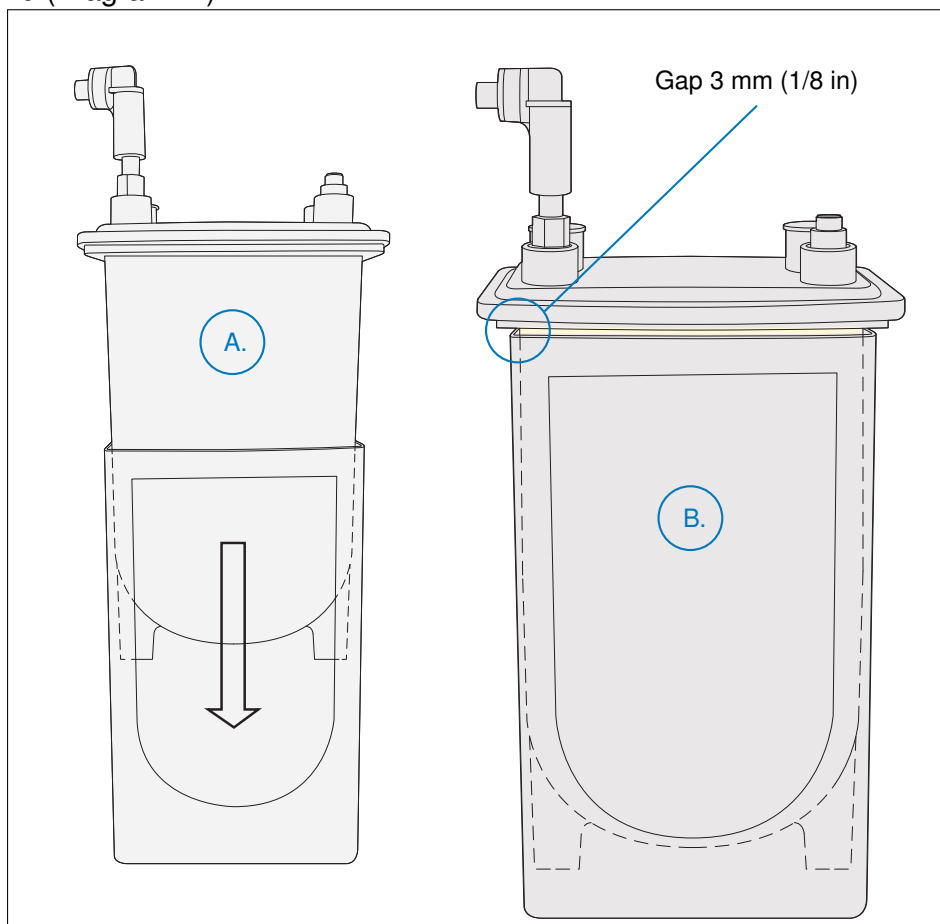
- Enter vessel expiration date.
- Enter vessel part number.
- Enter vessel serial number.
- Do not enter calibration values for any reusable or single-use sensors that will be utilized.
- Click “Load Bag.”

Install Vessel in PBS 3 MAG-SUS

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

- Connect any optional extensions in a biosafety cabinet.
Note: The wrench can be used to assist in the installation or removal of port caps and accessories, such as the dip tube.
- Hang the DO and pH sensor cables outside the vessel sleeve, and check that nothing is in the sleeve.
- Hold the vessel so the back (i.e. the side with tubing coming out of it) faces away from you.

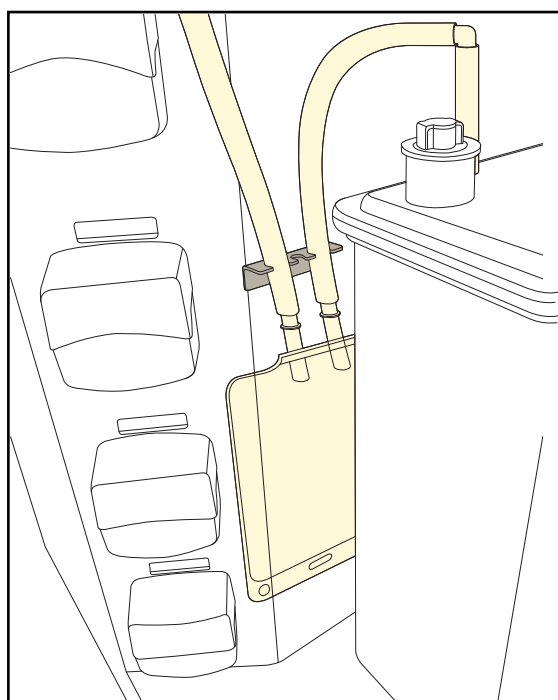
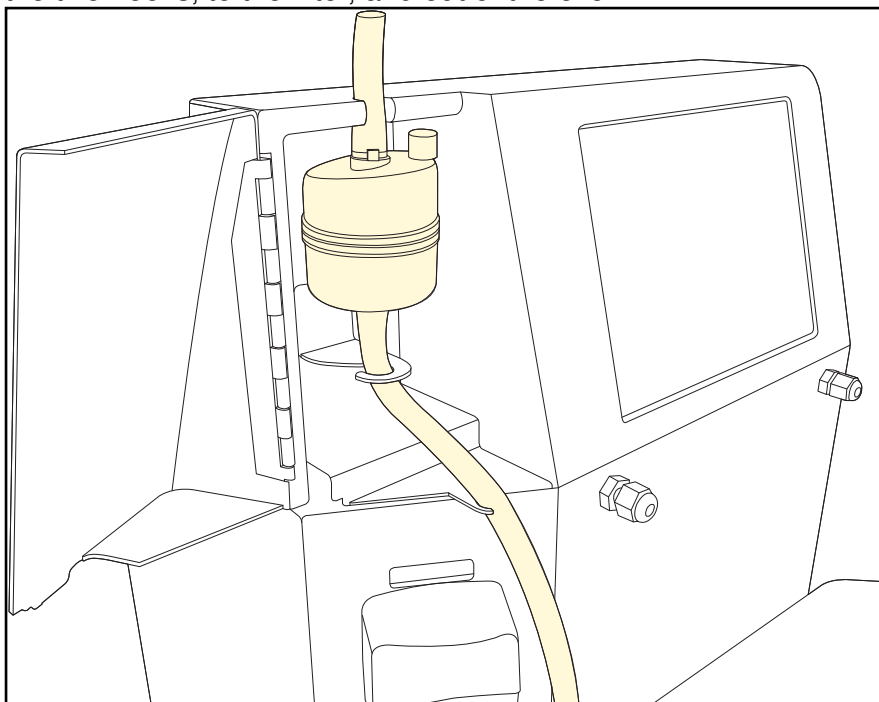
4. Slide the vessel into the sleeve, feet first. The bottom of the vessel should rest against the heaters (Diagram A.), and there should be a gap of approximately 3 mm (1/8 in) between the top of the sleeve and the vessel lid (Diagram B.).



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

| Connector/Pump | Tube Color |
|--|-------------|
| Air/CO ₂ /N ₂ | Black |
| O ₂ Overlay/O ₂ Sparge | Green |
| Sample | Red |
| Addition | Brown |
| Aspiration | Orange (x2) |
| Media | Orange |
| Harvest | Orange (x2) |

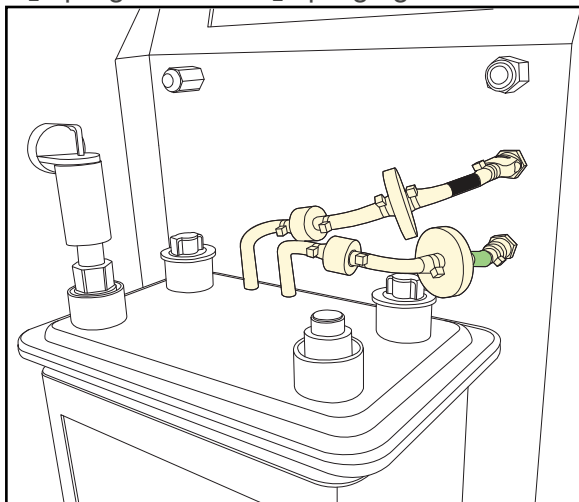
6. Leave the tubing lines on top of the PBS 3 MAG-SUS so they do not get in the way during installation.
7. Install the exhaust filter tubing:
 - (a) Secure the exhaust filter on the U-channel, so its tubing goes through the two hooks, to the filter, and out of the oven.



- (b) Install the tubing by the condenser bag in the tubing holder.
- (c) Close the filter oven door.

8. Connect the Air/CO₂/N₂ line to the Air/CO₂/N₂ connector on the PBS 3 MAG-SUS.
9. Connect the O₂ overlay or O₂ sparge line to the O₂ overlay/O₂ sparge connector on the PBS 3 MAG-SUS.

Note: Connect the O₂ overlay line for O₂ flow through the overlay and the O₂ sparge line for O₂ sparging.



10. Connect single-use pH and DO sensors:

Note: Remove the yellow protective cover from the electrical connectors on the sensors and sensor heads before making any connections.

Note: The single-use pH sensor and DO sensor port come pre-installed in the vessel and sterilized. They do not need to be removed, inserted, or autoclaved.

- (a) Connect the pH sensor head onto the pH sensor.

Note: Salt deposits may form on the glass surface of the pH sensor probe during dry storage, particularly near the tip, from the electrolyte solution within the sensor. This is considered normal and will dissipate once wetted. The deposit will not cause any cytotoxicity in volumes greater than 250 mL and meets all biocompatibility standards.

- (b) Insert the DO sensor head into the DO sensor port. The sensor will insert into a plastic tube that maintains the sterility of the vessel.

- (c) Thread the DO sensor head into the port by gently pressing and rotating the entire body of the sensor head clockwise until it stops. Do not overtighten the sensor.

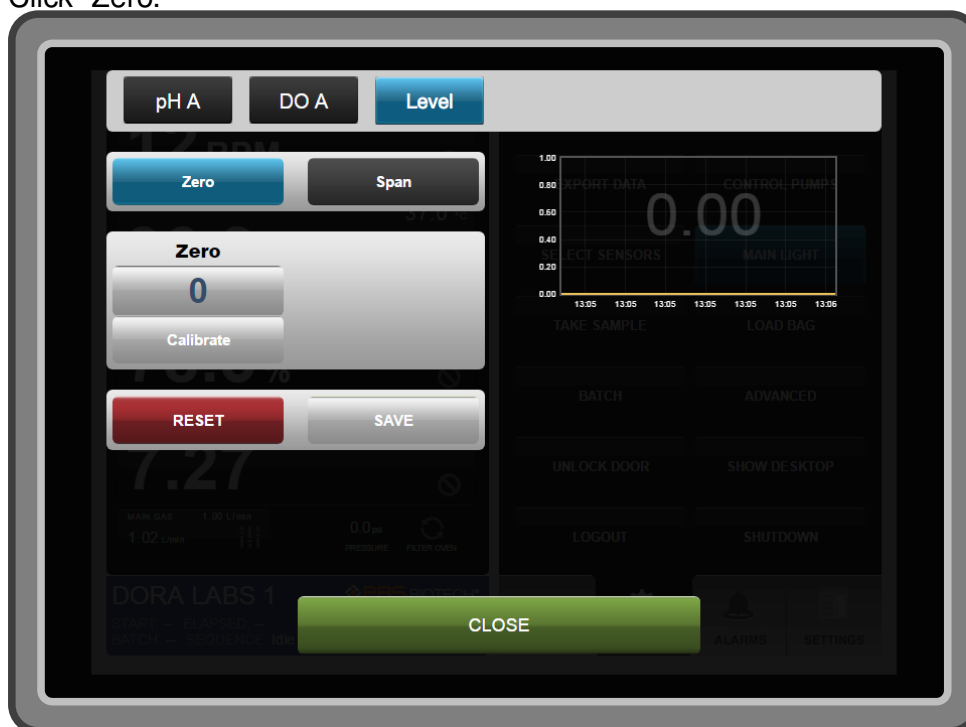
Note: The sensor head is retained in the port by threads at the tip of the sensor. Some sensor heads may have a PG13.5 threaded nut near the top of the sensor. This nut is not intended to engage with the vessel and will rotate freely when the sensor is installed.

11. Connect the cables to the DO and pH sensors.
WARNING: When connecting the sensors, do not overtighten, as this may cause damage to the sensors.
12. Insert the temperature sensor in the thermal well.
13. Route the addition line, aspiration line, both media lines, and the harvest line behind the DO sensor and onto the bench next to the PBS 3 MAG-SUS.

Level 'Zero' Calibration

Level 'Zero' calibration with the Hello UI

1. Install empty vessel containing thermal well and all sensors, 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

Adding Medium

To add medium:

1. Navigate to the “Actions” tab.
2. Click “Control Pumps.”



3. If the media pump is on, click the slider to turn it off.
4. Form a sterile connection between an unused medium addition line (one orange band) and the medium bottle/bag source, by welding the tubing or using the connectors.
5. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and vessel.

- Click the slider to turn the media pump on.
- 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.

- Confirm no gases are flowing and agitation is off.
- Navigate to the “Actions” tab.
- Click “Calibrate.”
- Click “Level.”
- Click “Span.”



- Enter the actual level.
- Click the “Calibrate” button.
- Click “Save.”
- Click “Close.”

Turning Controls On

After filling the vessel with medium, the controls need to be turned on, to equilibrate the medium. This accomplishes 2 things: (1) it allows the DO and pH sensors to polarize and equilibrate, so one-point calibrations can be performed, and (2) it brings the PVs to within the appropriate ranges for the cell process.

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. DO and pH can also be set to Auto mode before the one-point calibrations are performed, but it may take more time to achieve the desired process parameters after calibrating and before inoculating.




To control the pH in Manual mode, set Base to 0% and CO₂% to the value that will provide the desired pH, using the “NaHCO₃, CO₂%, and pH at 37 °C” chart on page 106.

To control the DO in Manual mode, first remember that the DO is scaled so 100% equals atmospheric O₂ conditions. The amount of air entering the vessel and therefore saturating the medium can be displaced with either CO₂ or N₂. For example, to control to a DO PV of 50% with pH set to 5% CO₂, set N₂ to 45% and O₂ to 0%.

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 72.

Note: The dissolved oxygen and pH deadbands can be changed in the “Settings” tab. For more information, see “Settings/System Variables” on page 93.

- 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 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 – N₂ | Total gas % N ₂ composition |
| Dissolved Oxygen – O₂ | Total gas % O ₂ composition |
| pH – CO₂ | 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.

One-Point Calibrations After Equilibration

After the temperature, pH, and DO have equilibrated, PBS Biotech recommends performing one-point calibrations on the pH and DO sensors.

One-point pH calibration with the Hello UI:

1. Take a sample (see “Take Sample” on page 76). Note pH present value when taking sample.
2. Measure the pH of the sample.
If this is before inoculating with cells, and the % CO₂ composition was manually set, confirm the measured pH matches the expected pH from the “NaHCO₃, CO₂%, and pH at 37 °C” chart on page 106, given the % CO₂ composition and sodium bicarbonate concentration of the medium.
3. Navigate back to the “Actions” tab.
4. Click “Calibrate.”

- Click “One-point.”

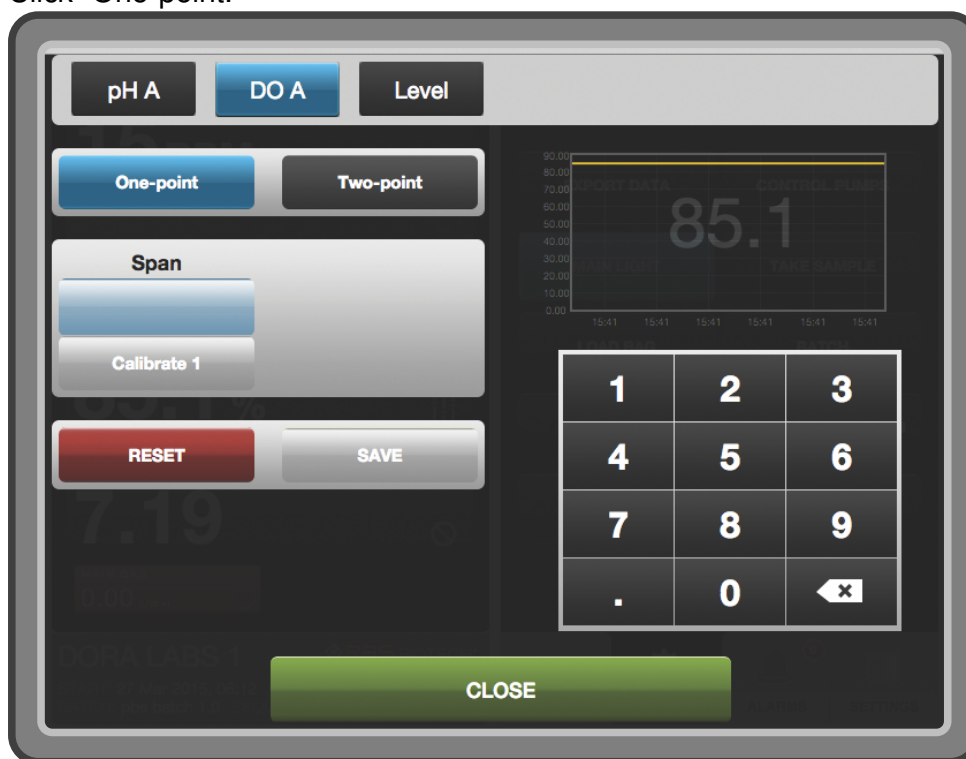


- Click “Get Vessel Temp.”
- Enter $[(\text{pH PV}) - (\text{pH PV when taking sample}) + (\text{actual pH of sample})]$ in the ‘Zero’ field.
- Click “Calibrate 1.”
- Click “Save.”
- Click “Close.”
- Turn on the pH control (see “Turning Controls On” on page 67 and “Selecting a Base Pump” on page 72).

One-point DO calibration:

- 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 calibration.
- Navigate to the “Actions” tab.
- Click “Calibrate.”
- Click “DO A.”

- Click “One-point.”



- 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 $100 - \text{CO}_2\% - \text{N}_2\%$.
- Click the “Calibrate 1” button.
- Click “Save.”
- Click “Close.”
- Turn on the DO control (see “Turning Controls On” on page 67).

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:

- Set pH to “Off” mode.
- Navigate to the “Actions” tab.

3. Click “Control Pumps.”
4. Click the drop-down menu beneath “Base Pump” and select “None.”
5. If the desired pump (Addition A or Addition B) to use for base addition is on, turn it off.
6. Form a sterile connection between the addition line and the base bottle/bag source, by welding the tubing or using the connectors.
7. Install the silicone section of the addition line in the desired addition pump to allow the base to flow into the vessel as the pump rotates clockwise.
8. Confirm that the tubing is not clamped.
9. Set addition speed to “Slow.”
10. Turn addition pump on to prime the line.
11. Turn addition pump off when tubing is primed.
12. Click the drop-down menu beneath “Base Pump” and select the desired addition pump.
13. 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 “Actions” tab.
2. Click “Control Pumps.”
3. Confirm the desired addition pump is not set to be the base pump.
4. If the desired addition pump is on, turn it off.
5. Form a sterile connection between the addition line and the addition bottle/bag source, by welding the tubing or using the connectors.
6. Install the silicone section of the addition line in the desired pump to allow the fluid to flow into the vessel as the pump rotates clockwise.
7. Confirm that the tubing is not clamped.
8. Set desired addition speed.
9. Click the slider to turn the addition pump on.
10. 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, 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 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 93.
2. Load the Alarms On.alm file. For more information, see “PBS 3 MAG-SUS Alarms” on page 49.
3. For how to view and acknowledge alarms, see “Alarms” on page 92.

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 “Actions” tab.
2. Click “Control Pumps.”
3. If the media pump is on, click the slider to turn it off.
4. 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.
5. Install the silicone section of the tubing in the media pump so the arrow points toward the tubing between the pump and vessel.
6. Check that the tubing clamp is open, and its branched tubing clamp is closed, if applicable.
7. Click the slider to turn the media pump on.
8. 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.”



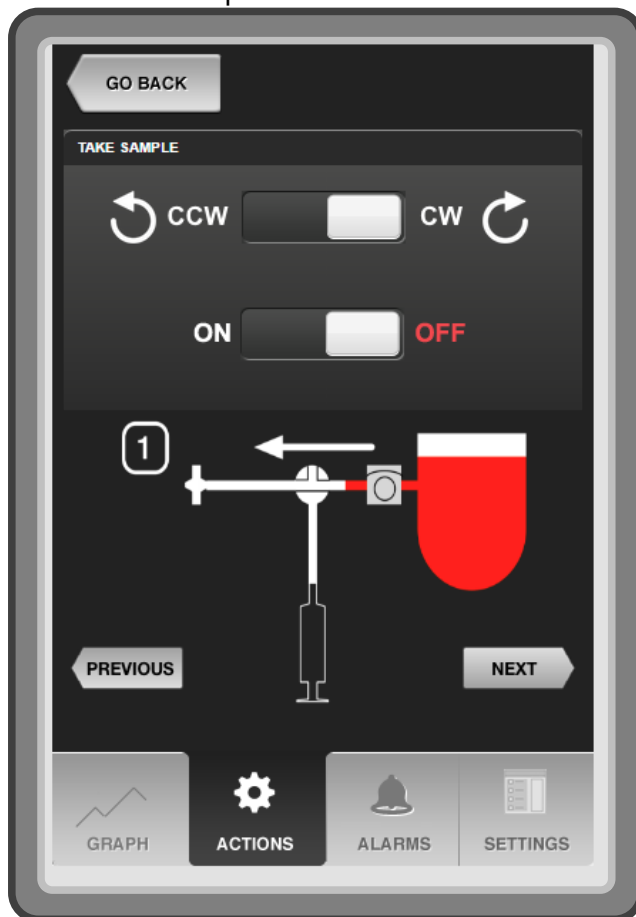
3. If a batch is running, end it:
 - (a) Click “End Batch.”
 - (b) Confirm by clicking “End” in the overlay.
 - (c) Click “Batch.”
4. Use the on-screen keyboard, or an external keyboard, to enter a batch name 16 characters or less.
5. Click the on-screen keyboard’s “Hide” button.
6. Click “Start Batch.”
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

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

To take a sample with the vessel's sample line:

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



4. Follow the on-screen instructions for manual sampling.
5. After the sample has been removed and the line has been cleared, clamp the sample line and replace the syringe with a sterile one, performing an alcohol dip for the transition.
6. Expel the head gas from the syringe, and cap it to make the sample more stable. Measure the pH 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 from the dip tube:

Note: Two operators are necessary for this section.

Note: This assumes the dip tube's liquid transfer 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 aspiration line and the waste media bottle/bag destination by welding the tubing or using the sterile connectors.
2. Load the Alarms Off.alm file (see “Load the Alarms On.alm File” on page 74).
3. Change DO and pH from Auto mode to Manual mode, setting the requested N₂ and CO₂ flows to match what was called for while in Auto mode.
Set O₂ to 0%, or if no N₂ was being called for, set DO to Off.
Users should continue to request gas flow while removing medium from the vessel to maintain a reasonable amount of pressure within the vessel.
4. Disconnect the O₂ sparge line, if being used to sparge O₂, to prevent sparging gas while cells are settling. Sparging gas will interfere with the cells settling to the bottom of the vessel.
5. Wait for the cells to settle to the bottom of the vessel. The aspiration port or end of the dip tube should be above the settled volume of cells. If not, and 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.
6. Check that the aspiration line harvest line tubing clamp is open, and its branched tubing clamp is closed, if applicable.
7. 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.
8. Remove the desired amount of spent medium.
9. Reattach the O₂ sparge line, if applicable.
10. Add fresh medium (see “Adding Medium” on page 65).
11. Turn agitation back on, and set DO and pH to the original desired modes.
12. Load the Alarms On.alm file (see “PBS 3 MAG-SUS Alarms” on page 49 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 “PBS 3 MAG-SUS Alarms” on page 49).

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 75).
15. Remove the vessel.
16. Turn the filter oven off, if desired.
17. Clean/decontaminate the PBS 3 MAG-SUS (see “Cleaning and Decontamination” on page 33).

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

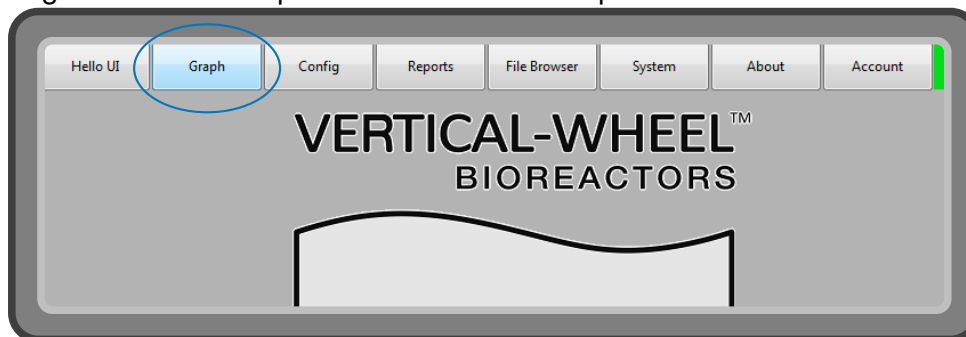
Other Features

Filter Oven

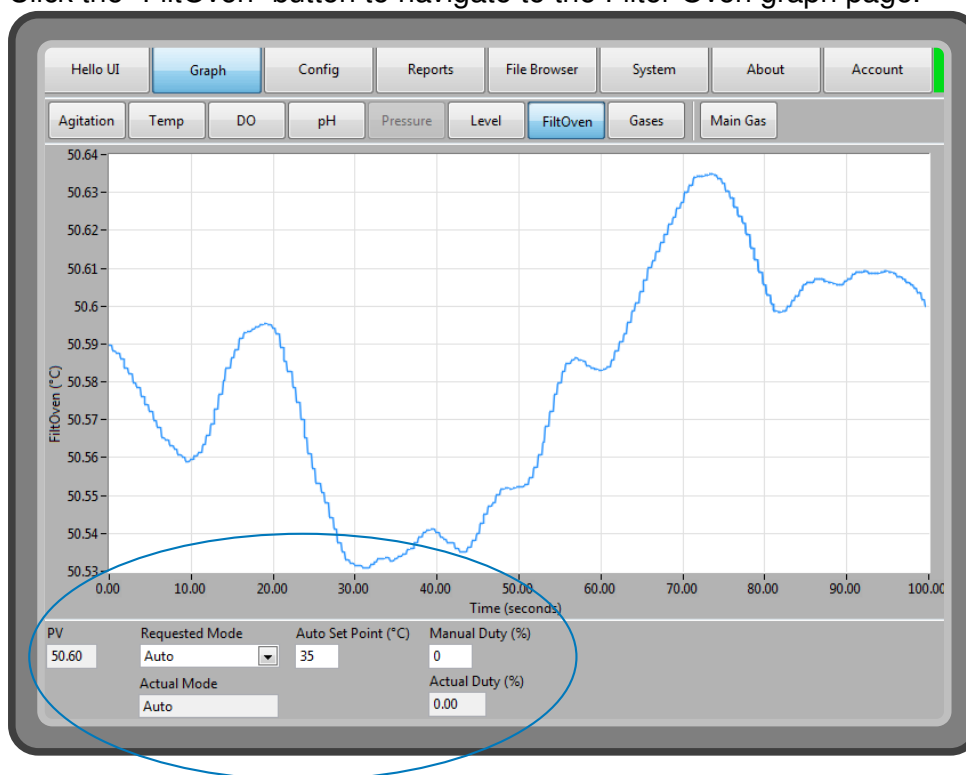
The Filter Oven heats the exhaust filter on the vessel, preventing moisture from accumulating in it and clogging it. The PBS 3 MAG-SUS is designed to always have the Filter Oven in Auto mode, at 50 °C. If users still want to turn it off between runs, they need to make sure to turn it on before adding 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

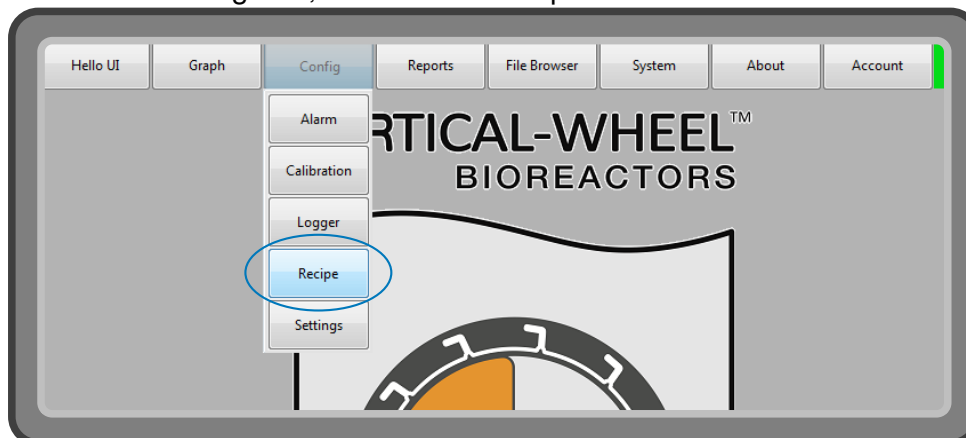
WARNING: Do NOT edit the “Integrity Test” recipe without consulting PBS Biotech Technical Support.

Creating or editing recipes

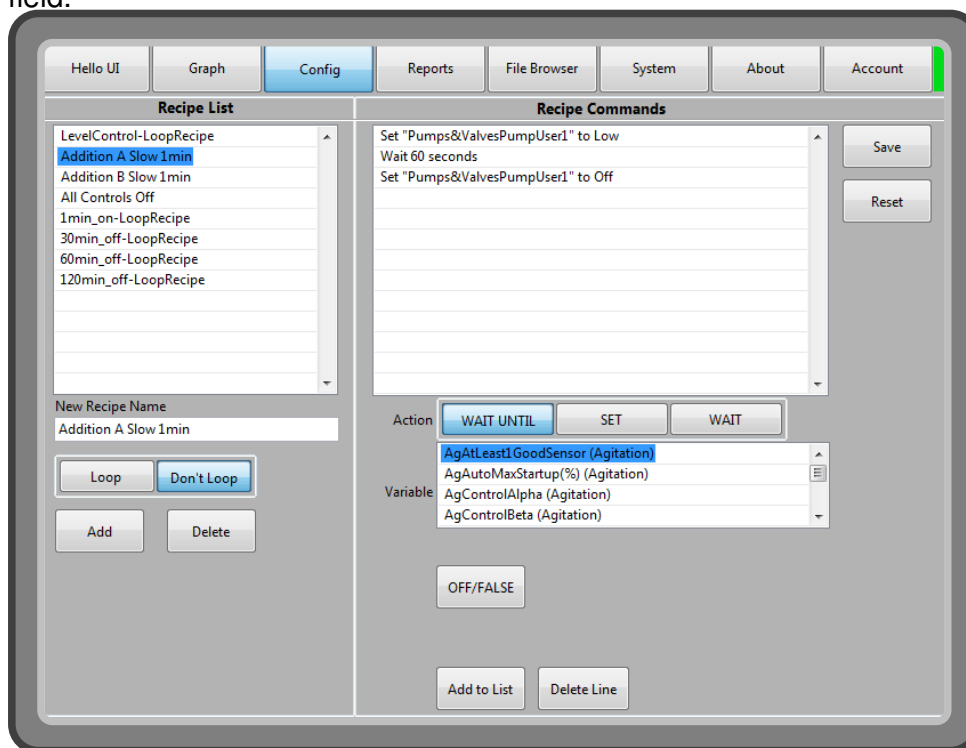
1. Log in to the Desktop UI with a user account with the “Recipe Editor”

permission (for more information on user permissions, see “User Group Permissions” on page 120).

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.

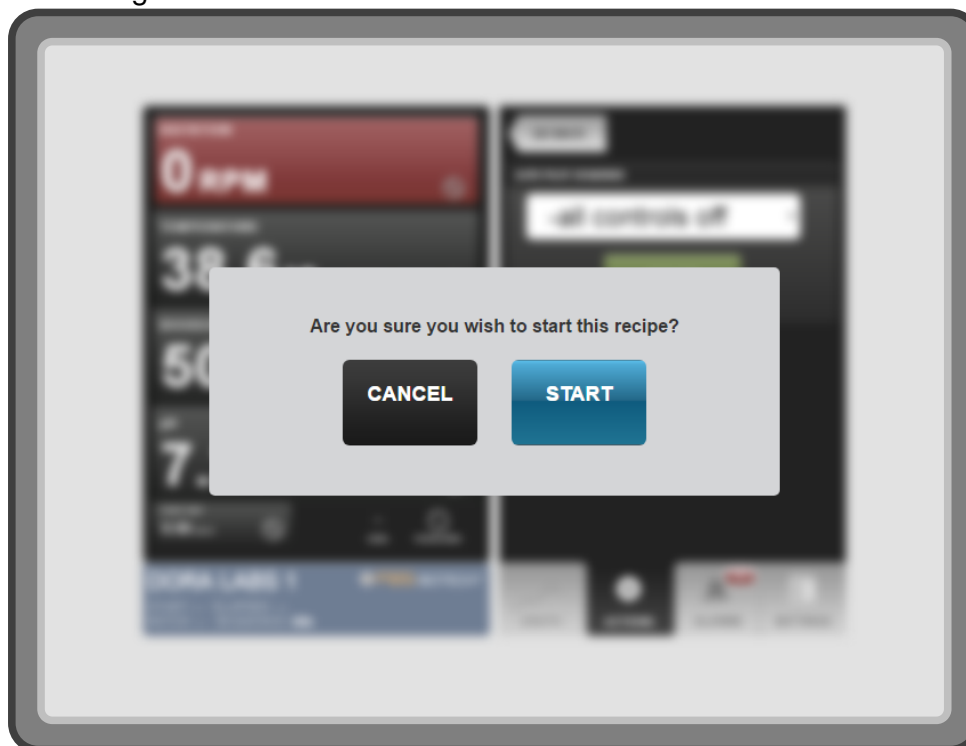


Configuring recipes

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 163).
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.



- Click “Start” to confirm.

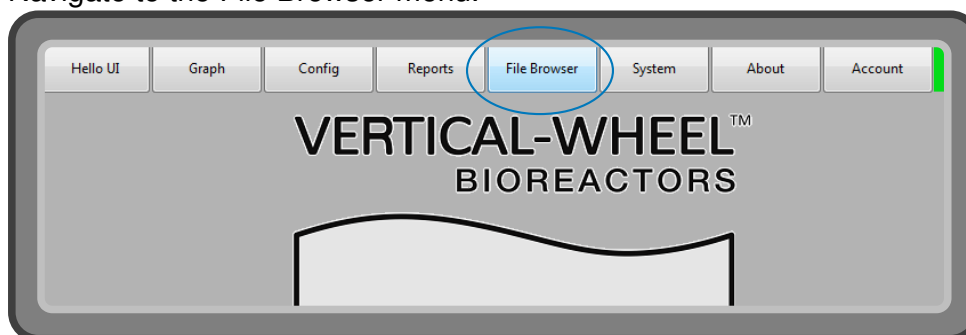
Note: If the Auto Pilot menu was open when a new recipe was created, close and re-open the menu by clicking “Go Back” and then “Auto Pilot.”

For more on recipes, see “Recipes” on page 113.

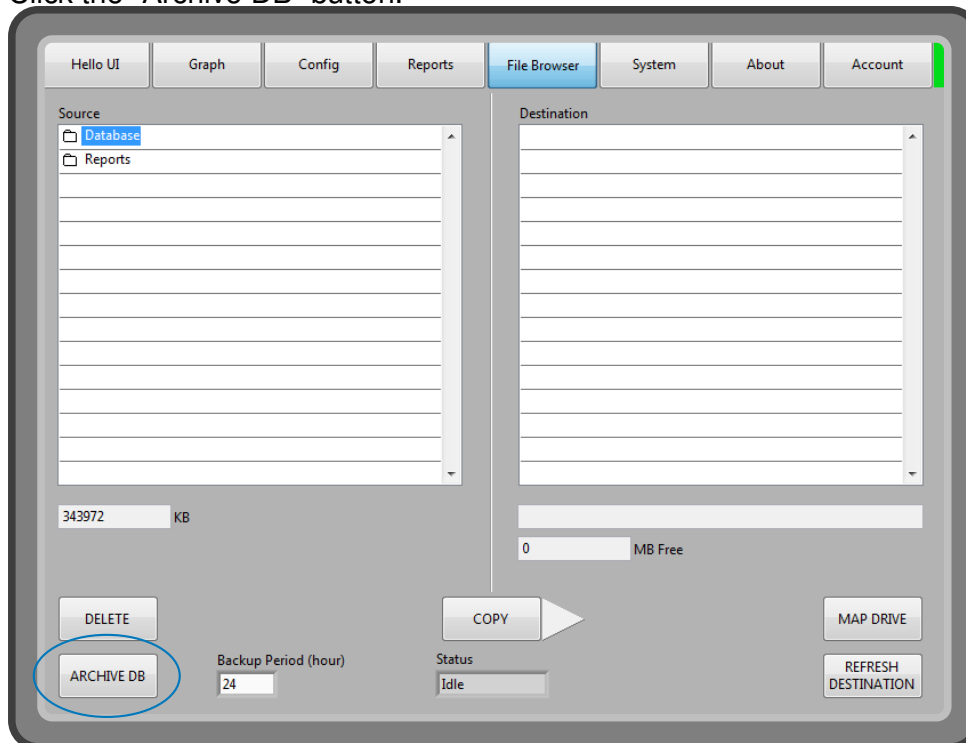
Manually Archiving DBs

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.

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



- 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 116.

Managing Files

To copy databases and reports to external drives, and delete reports and archived databases, see “Generating Reports” on page 84. 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:

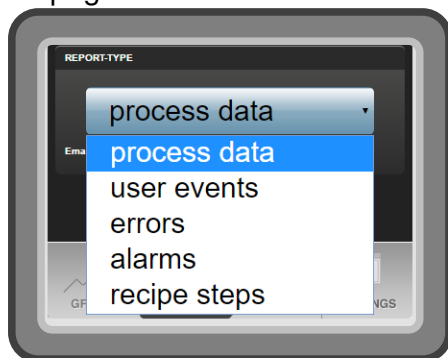
The screenshot shows the 'SELECT BATCH' dropdown menu set to 'Use Date'. Below it, the 'SELECT DATES' section has 'From:' and 'To:' input fields. The 'REPORT-TYPE' dropdown is set to 'process data'. The email report address is 'pbs@pbsbiotech.com'. At the bottom, there is a 'GET REPORT' button and a navigation bar with icons for GRAPH, ACTIONS, ALARMS, and SETTINGS.

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

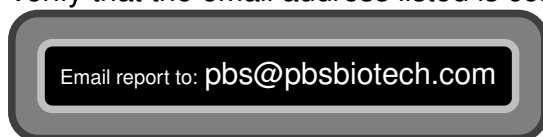
The screenshot shows the 'SELECT DATES' section with a calendar overlay. The 'From:' field is set to '2017-05-09 12:25'. The 'To:' field is empty. The calendar shows the month of May 2017, with the 9th highlighted. Below the calendar, there are sliders for 'Hour' and 'Minute' to select the time. The 'REPORT-TYPE' dropdown is set to 'process data'. The email report address is 'pbs@pbsbiotech.com'. At the bottom, there is a 'GET REPORT' button and a navigation bar with icons for GRAPH, ACTIONS, ALARMS, and SETTINGS.

- (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 115.



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 MAG-SUS 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.

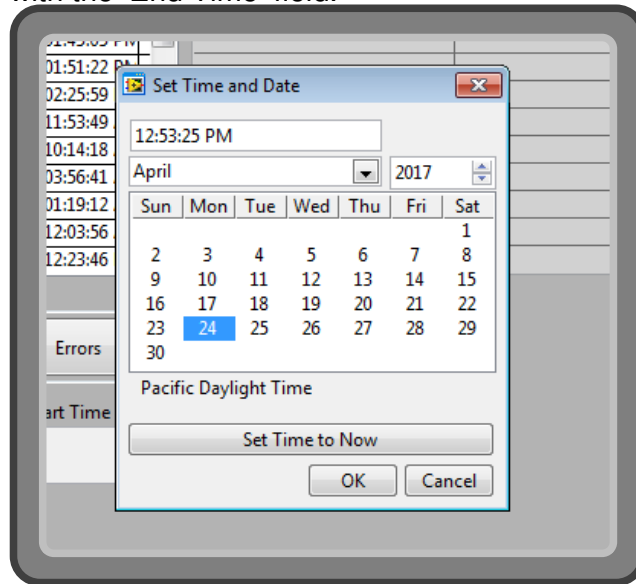
To generate reports with the Desktop UI (alternative method):

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

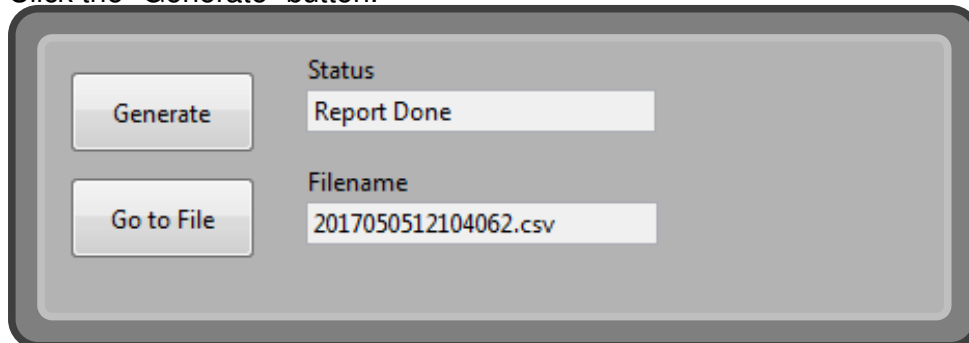
The screenshot shows the 'Reports' section of the PBS 3 MAG-SUS Desktop UI. The 'Databases' table lists various databases with their start and stop times. The 'Batches' table lists specific batches, with 'pbs batch 1.0' selected. The 'Report Type' section has 'Process Data' selected. The 'Filter By' section has 'Batch' selected. The 'Generate' button is visible at the bottom.

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.

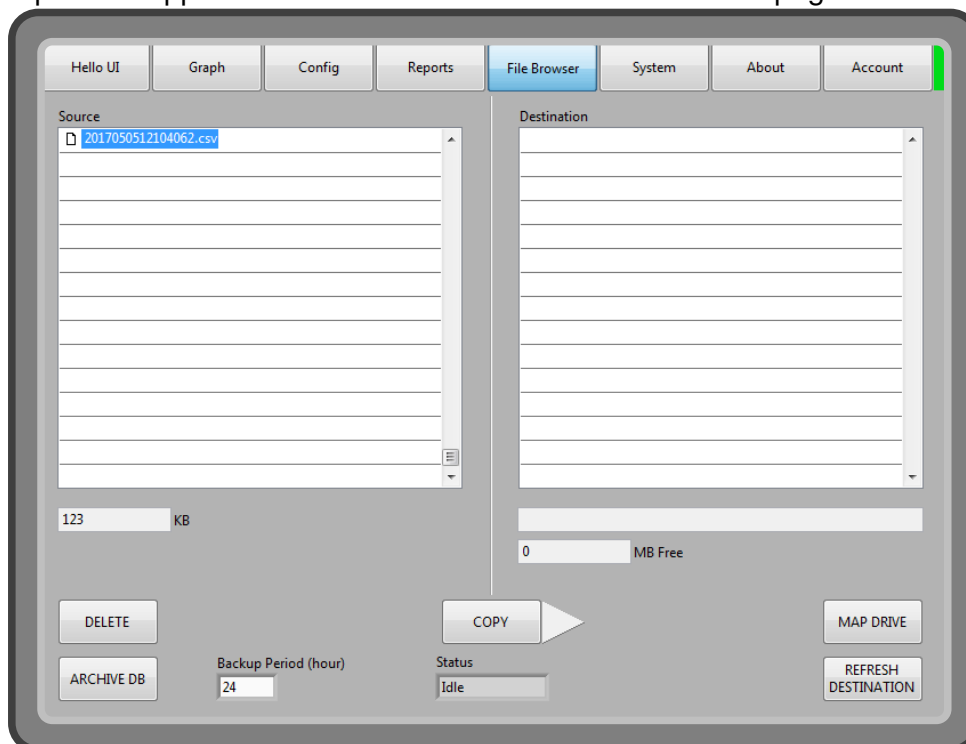
- (b) If selecting “Time,” then select the calendar button beside the ‘Start Time’ field. In the menu that appears, select a time and date. Repeat with the ‘End Time’ field.



5. Click the “Generate” button.



- 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.



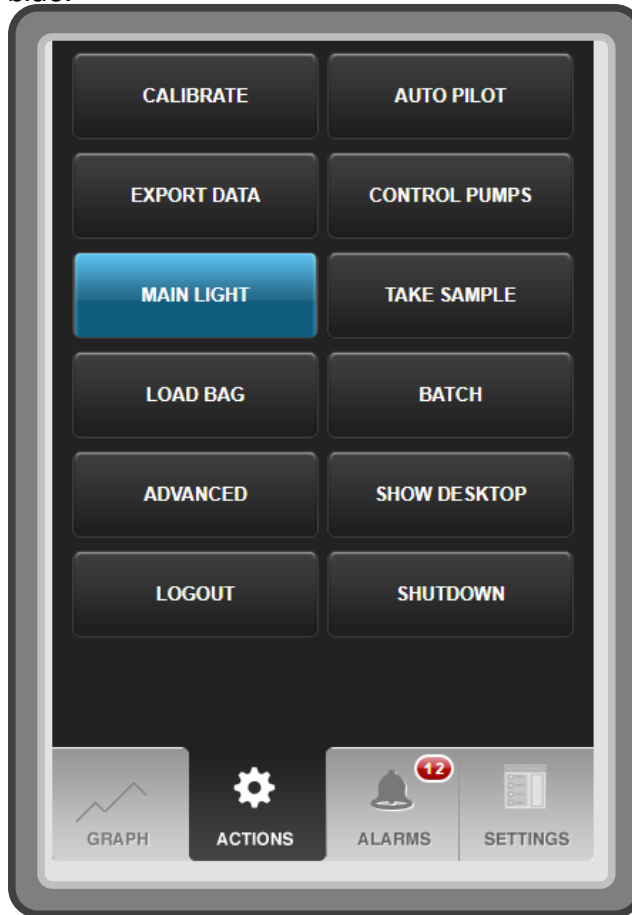
- Any external drives, including mapped network drives, will be displayed under Destination. Navigate to the desired location, and click the "Copy" button to copy the file to it. Other reports, besides the last one generated, can also be copied to external media. After copying, reports can be deleted. 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:

- 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, 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% N₂ flow but there is no source pressure to the N₂ MFC, the Dissolved Oxygen Controller Output will show 50% N₂, but the N₂ MFC flow will show 0 L/min.



| | Mode | PV | Set Point | Controller Output | ALERT |
|--|------|---------|-------------------------|----------------------------|--------|
| Agitation | 🔄 | 32 RPM | 32 RPM | 57.4 % | — |
| Temperature | 🚫 | 35.5 °C | — | 0.0 % | — |
| Dissolved Oxygen | 📊 | 41.1 % | O2: 0.0 % N2: 60.0 % | O2: 0.0 % N2: 60.0 % | — |
| pH | 🔄 | 0.00 | 7.20 | BASE%: 0.0 % CO2: 6.3 % | BROKEN |
| Main Gas | 📊 | N/A | 0.41 L/min | 0.41 L/min | — |
| Filter Oven | 🔄 | 30.1 °C | 35.0 °C | 50.0 % | — |
| Level | N/A | 2.40 L | N/A | N/A | — |
| Gas Flow (L/min) Air: 0.14 N2: 0.25 CO2: 0.03 O2: 0.00 | | | | | |

Below the table, there is a summary section with a 'CLOSE' button and 'ALARMS' and 'SETTINGS' links.

Show Desktop

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

Restarting the Windows Computer

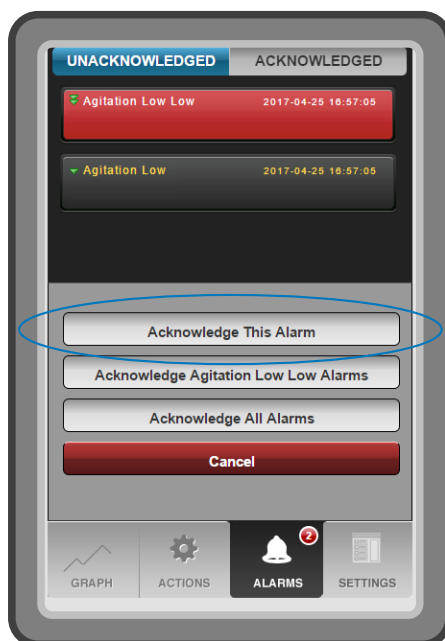
To Restart the Windows Computer with the Hello Interface:

1. Navigate to the “Actions” tab.
2. Click the “Shutdown” button.
3. Select the “Restart” option.

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.

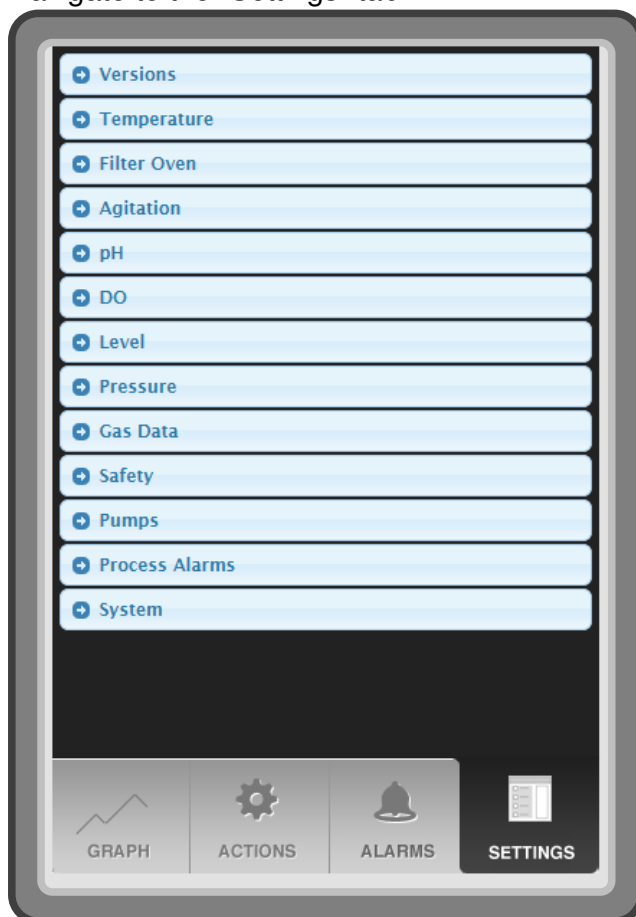
For definitions of all alarms, see Appendix 2 on page 154.

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 129.

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

1. Log in to the Hello UI with an account with “Hello User Interface - Hello Settings” permissions.
2. Navigate to the “Settings” tab.

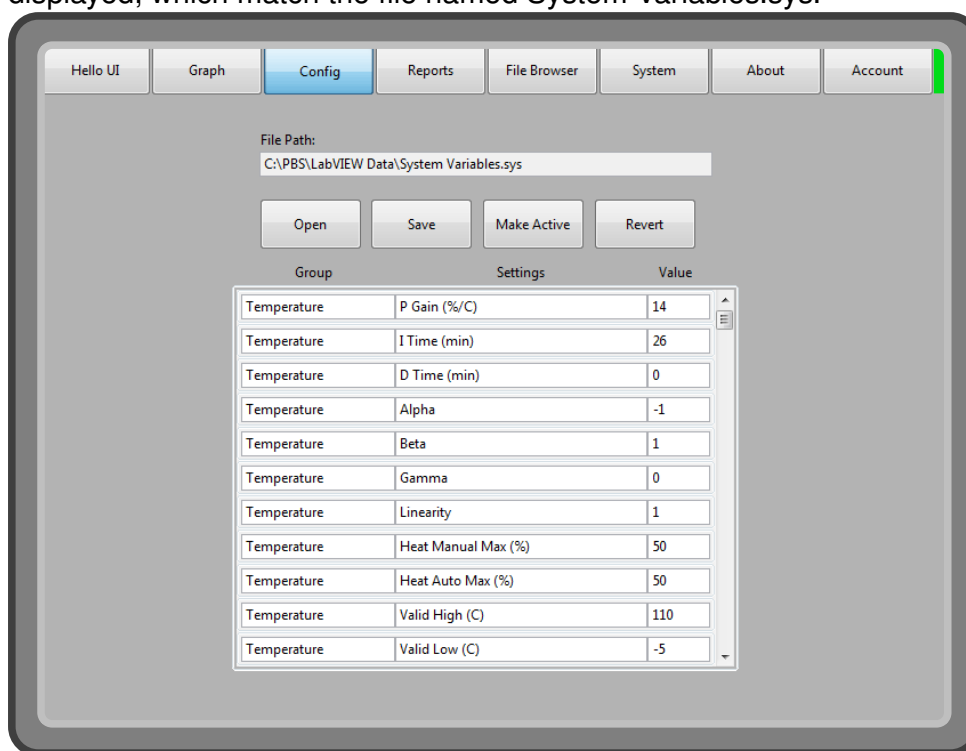


3. Click a submenu to expand it.

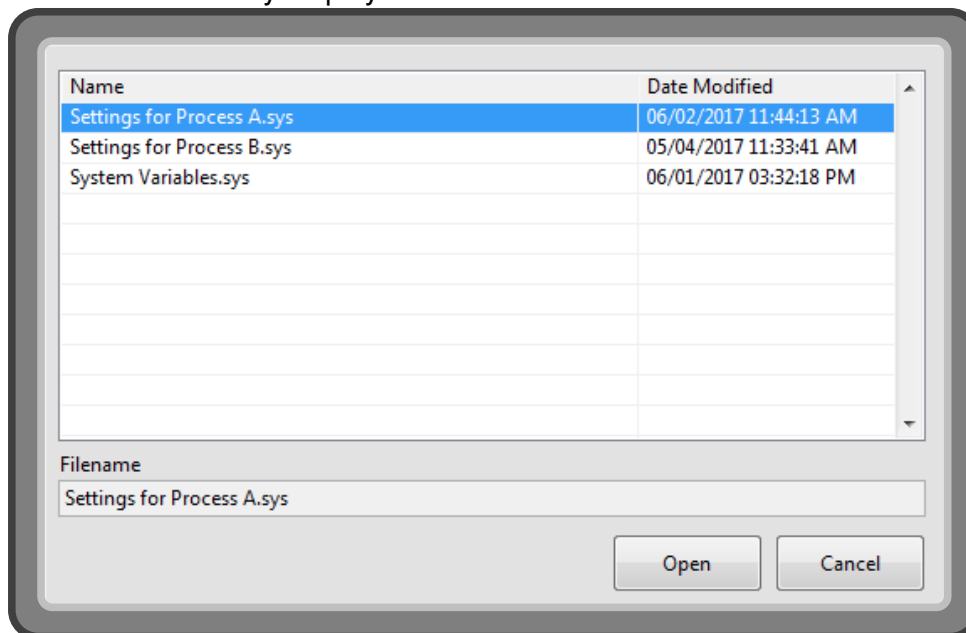
4. Scroll up or down and click a variable to change.
5. Use the keypad to enter a new value.
6. Click “OK.”

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.



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



- Select a file to edit, then click “Open.”
- Scroll through the list and click a variable to change, then use the onscreen keyboard or an external keyboard to enter a new value.
- If you wish to reverse changes you have made, click “Reset” and the file will revert back to its original values.
- Once the desired changes have been made, click “Save.”
 - To make the changes to the open file, click “Save” to overwrite it.
 - 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.
- To make the new settings active, click “Make Active.”

Remote Access

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

- In the Desktop UI, go to the About tab, and note what is displayed in the Computer IP Address field.
- 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 MAG-SUS, Google Chrome will likely show a security alert, but this can be ignored.

If the computer accessing the PBS 3 MAG-SUS 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 O₂ consumption rates, the O₂ transfer only through the overlay may not be enough at some point in the run. Switch to sparging O₂ when the DO controller is requesting the maximum possible O₂ flow, but the DO value is still less than the set point. To switch from flowing O₂ through the overlay to sparging:

1. Turn DO off.
2. Connect the O₂ sparge line to the O₂ overlay/O₂ sparge connector on the PBS 3 MAG-SUS.
3. Turn DO back on.

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 "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 57, and “Starting a Run” on page 65. 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 112.

Hello User Interface

The primary way of interacting with the PBS 3 MAG-SUS is the Hello User Interface (Hello UI), which is automatically launched when the PBS 3 MAG-SUS 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 MAG-SUS.

Desktop User Interface

While the Hello UI is the primary way of interacting with the PBS 3 MAG-SUS, 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 | | | | |
|-------------------------------|---------------|---|---------------------------------|--|
| Interlocked Controls | | Agitation | Temperature | Level |
| | 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: $\text{Set Point} \times \text{"Lookup Factor (\%/RPM)."}$

Output Ranges

For agitation control range, see "Agitation Control Range" on page 36.

Agitation motor power range is 0 - 100%.

Relevant Settings

See Appendix 1 on page 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Agitation (page 132)

- 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

Safety (page 148)

- Min Ag Power (%)

Process Alarms (page 150)

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

Interlocks

The PBS 3 MAG-SUS 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 36.

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

Relevant Settings

See Appendix 1 on page 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 129)

- 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 148)

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

Process Alarms (page 150)

- 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, N₂, O₂, and CO₂. 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 36. 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. CO₂
2. O₂
3. N₂
4. Air (remainder of request)

Relevant Settings

See Appendix 1 on page 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Gas Data (page 145)

- 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 150)

- 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 MAG-SUS.

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.”

The DO is controlled by varying the N₂ and O₂ gas flow as a percentage of main gas flow. The DO PV is lowered by increasing the % N₂ composition, and is raised by increasing the % O₂ composition. To understand how the software determines which gases to flow, see “Main Gas” on page 102.

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

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

Off Mode

N₂ and O₂ are 0% of main gas flow.

Manual Mode

User selects N₂ and/or O₂ 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 N₂ flow and O₂ flow. Each gas uses its own PID loop: the N₂ loop controls to DO set point and DO “Deadband (DO%)” setting, and the O₂ loop controls to DO set point – 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 N₂ and O₂ 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 N₂ output is 0 - 100% of main gas flow. The N₂ MFC output is stated in “Gas Flow Rate Range” on page 36. N₂ “pulsing” at the minimum value takes effect if the N₂ % called for represents less than the MFC’s minimum flow rate.

The O₂ MFC output is stated in “Gas Flow Rate Range” on page 36. O₂ “pulsing” at the minimum value takes effect if the O₂ % called for represents less than the MFC’s minimum flow rate. The software will not request more than the O₂ MFC minimum flow until the net volume of O₂ output since turning DO on is greater than the Gas Data “O2 Min Volume (L)” setting. This is known as the “O₂ Slow Start” feature, and is intended to prevent damage to the vessel or accessories when O₂ is being sparged.

Relevant Settings

See Appendix 1 on page 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

DO (page 139)

- Valid High (DO%)
- Valid Low (DO%)
- O2 P Gain (%/DO%)
- O2 I Time (min)
- O2 D Time (min)
- O2 Alpha

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

Gas Data (page 145)

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

Process Alarms (page 150)

- | | |
|------------------|--------------------|
| • DO Low Low (%) | • DO High (%) |
| • DO Low (%) | • DO High High (%) |

Interlocks

The PBS 3 MAG-SUS has no interlocks that prevent N₂ or O₂ flow.

pH

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

The pH is controlled by varying the CO₂ flow in % composition of main gas flow and varying the percent of time the base pump is on. Increasing CO₂ 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 102.

Before inoculating (i.e. when there is no metabolic activity), the pH has a predictable relationship with the concentration of sodium bicarbonate (NaHCO₃) in the medium and the % CO₂ composition. Below the following chart is the equation to calculate the resulting pH from a known concentration of sodium bicarbonate and a known % CO₂ composition. However, the following chart can be simpler to use.

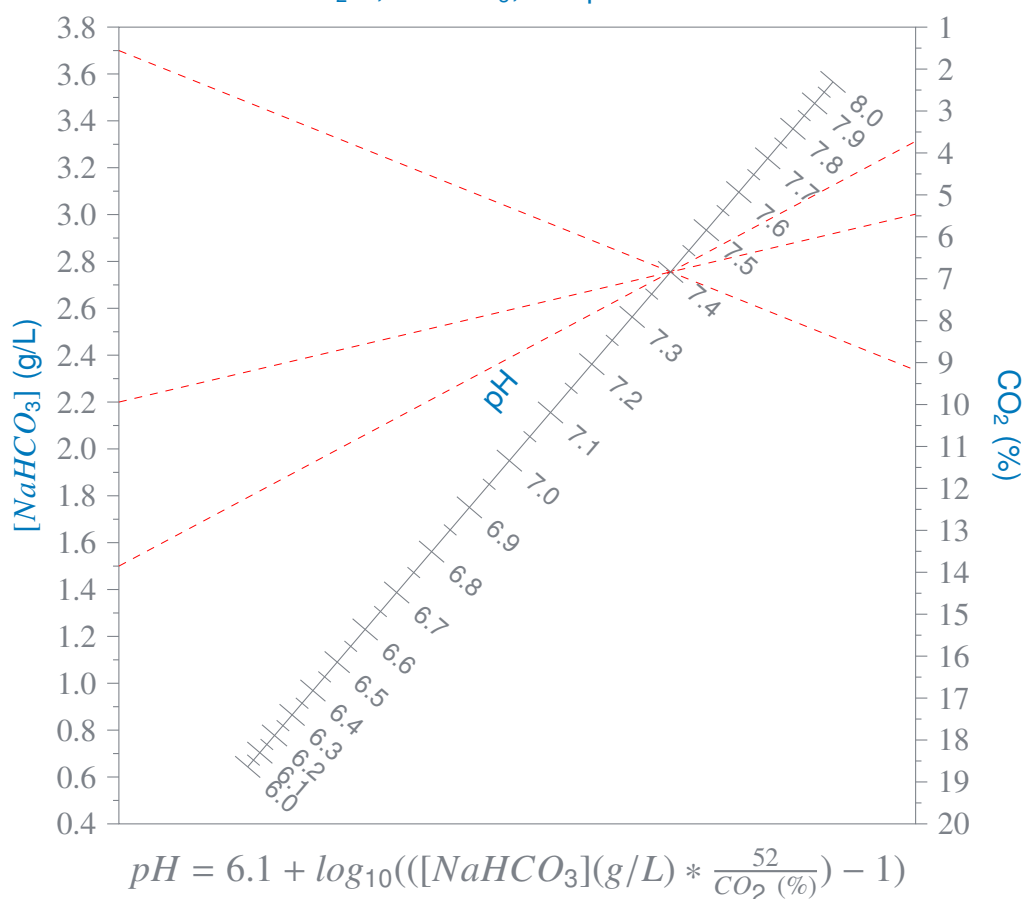
To find the pH that would result from a known concentration of sodium bicarbonate and a known % CO₂ composition, draw a straight line between the

points on the sodium bicarbonate and CO₂ 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 CO₂ axis. You can see that a % CO₂ 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 % CO₂ compositions of about 5.5% and 3.5%, respectively.

CO₂%, NaHCO₃, and pH at 37 °C



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

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

Off Mode

CO₂ is 0% of main gas flow and base pump duty is 0%.

Manual Mode

User selects a CO₂ 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 CO₂ flow and base pump duty. Each has its own PID loop: the CO₂ loop controls to pH setpoint and pH “Deadband” setting, and the base loop controls to pH set point – 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 CO₂ 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 CO₂ output is 0 - 100% CO₂ composition of main gas flow. The CO₂ MFC output is stated in “Gas Flow Rate Range” on page 36. CO₂ “pulsing” at the minimum value takes effect if the CO₂ % 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 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

pH (page 135)

- 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 145)

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

Safety (page 148)

- Max Level (L)

Pumps (page 149)

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

Process Alarms (page 150)

- 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 MAG-SUS has no interlocks that prevent CO₂ 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. They must then perform a 'Span' calibration after filling the vessel with medium, before turning any controls on.

The working level range of the PBS 3 MAG-SUS is 1.8 – 3 L. Below 1.8 L, 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 3 L there is the danger of overfilling the vessel, causing overflow.

Relevant Settings

See Appendix 1 on page 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 143)

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

Safety (page 148)

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

Process Alarms (page 150)

- 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 the liquid in the vessel 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 MAG-SUS 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 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Temperature (page 129)

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

Filter Oven (page 131)

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

Process Alarms (page 150)

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

Interlocks

The PBS 3 MAG-SUS 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 129 for each setting's default value, definition, and whether users can safely change the value without consulting PBS Biotech Technical Support.

Level (page 143)

- Enable Sensor (0 or 1)

Safety (page 148)

- Max Level (L)

Pumps (page 149)

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

Speeds and Associated Flow Rates

Each addition pump motor varies slightly, and these values thus are not the same for all PBS 3 MAG-SUS Bioreactors. Generally, however, the “Slow” speed corresponds to a flow rate of 30 mL/min, the “Medium” speed corresponds to a flow rate of 50 mL/min, and the “Fast” speed corresponds to a flow rate of 100 mL/min.

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 MAG-SUS 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

Which Sensors Can Be Calibrated

It is possible to perform calibrations on the following sensors.

Dissolved Oxygen

For a single-use DO sensor, users should perform a one-point calibration before inoculation. Users can perform additional one-point calibrations during the run. Users should not perform two-point calibrations or manually enter calibration values.

pH

For a single-use pH sensor, users should perform a one-point calibration before inoculation, and throughout a run if the measured pH of a sample shows that the sensor has drifted. Users should not perform two-point calibrations or manually enter calibration values.

Level

The user should perform a ‘Zero’ calibration on an empty vessel at the beginning of a run, and a ‘Span’ calibration after filling the vessel with medium, before starting any controls. Level calibrations cannot be performed from the Hello UI while the agitation, main gas, or dissolved oxygen controls are on.

Temperature

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

Filter Oven Temperature

The PBS 3 MAG-SUS is shipped with its filter oven temperature sensor already calibrated. The user should not calibrate the filter oven temperature sensor 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

“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.

“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.

“Loop” – Select this action when you want the entire recipe to loop indefinitely. 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 163.

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 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.

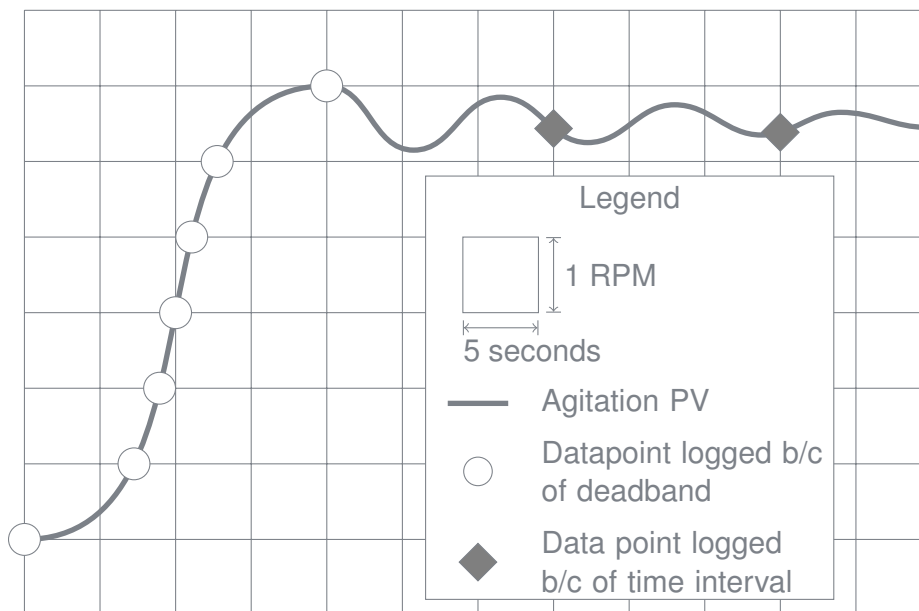
Alarms – Contains information about alarms that are generated, when they are acknowledged, and which user acknowledged them.

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 163.

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 83). 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.

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.

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 Log Off

Users can log out of the Windows computer from the Desktop UI. This feature is used when a customer's IT department requires access to their Admin account on the Windows 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 Windows computer from the Hello UI or from the Desktop UI. Because of the unique architecture combining the RIO controller and Windows PC, the user is able to reboot the PC without interrupting run control. If Windows stops responding or a software update requires a restart, the user can reboot the PC without losing crucial functionality.

Shutdown

Users can shut down the Windows computer from the Hello UI or the Desktop UI. There is no "On" switch on the PBS 3 MAG-SUS, so this feature should only be used after turning off all controllers, and when the PBS 3 MAG-SUS is going to be unplugged and stored.

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 Windows computer.

There are two types of alarms on the PBS 3 MAG-SUS:

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 154.

All alarms can be configured in the "Alarms" configuration page on the Desktop UI. There are three settings for alarms on the PBS 3 MAG-SUS: 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 52.

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. For more information on acknowledging alarms, see “Alarms” on page 92. For information on changing the Alarm “Snooze Time,” see “Settings/System Variables” on page 93. For default alarms configurations, see Appendix 3 on page 159.

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 MAG-SUS 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 129.

Users

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, although sharing a user name is not recommended. 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.

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 40.

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 MAG-SUS.

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 one- and two-point calibrations on the pH, DO, 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.

Note: Only one-point calibrations should be performed on single-use pH and DO sensors.

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 Windows. In the Hello UI, it allows the user to shutdown or restart the Windows 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.

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

Bioreactor Computer Architecture

- The PBS 3 MAG-SUS Vertical-Wheel® Bioreactor System (PBS 3 MAG-SUS) is a hybrid consisting of an industrial automation controller (the RIO controller) paired with a Windows computer via a network connection.
- The Windows computer is what users and IT interface with. The monitor, USB port, and Ethernet port connect to it. It is in charge of:
 - Displaying the user interfaces
 - Reading from and writing to the database
 - Sending emails
 - Sending user commands to the RIO controller
 - Receiving confirmation of user commands from the RIO controller
 - Receiving data to record (process data points, alarms, recipe steps, and errors) from the RIO controller
- The RIO controller is in charge of:
 - Sensing and control functions, including interlocks, broken sensor detection, and running recipes
 - The logic that captures the process data points to be recorded
 - Detecting process and failure alarms

Operating System

- The Windows computer runs Windows Embedded Standard 7
- The bioreactor should be treated as a piece of laboratory or manufacturing equipment, not a computer with installed control software. OS level configurations or software installations of any kind should not occur without consulting PBS Biotech Technical Support.

BIOS

The BIOS is configured at the factory to prevent booting from any media other than the hard drive installed on the PBS 3 MAG-SUS. 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.

Network Connections

- 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 |

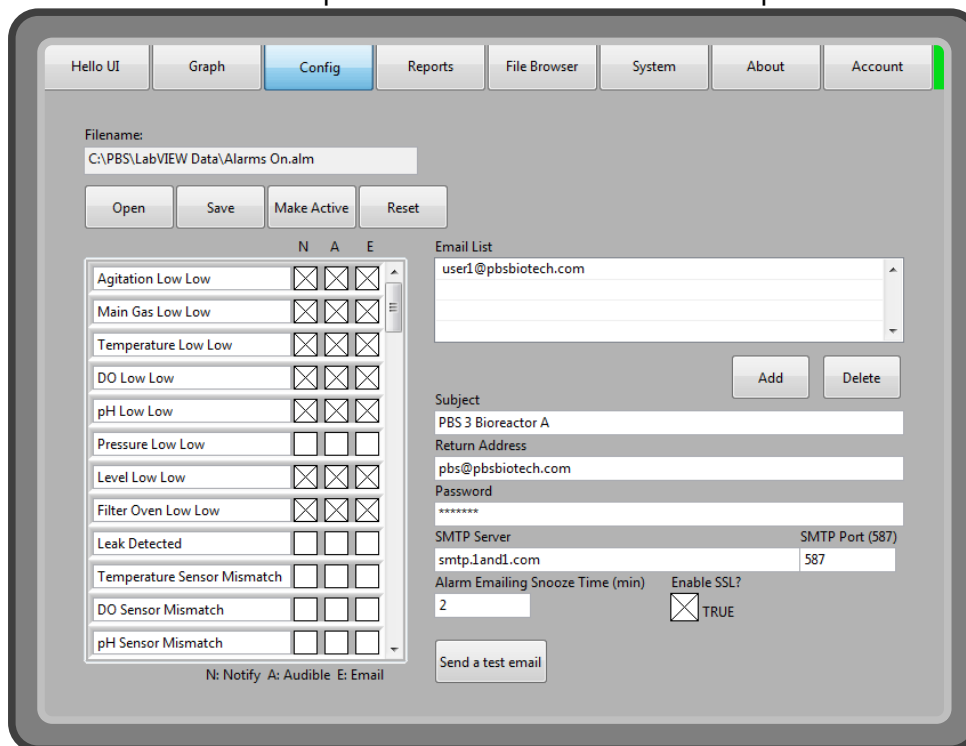
- Do not modify any configurations for the above network configuration, as it will disrupt communication with the RIO controller.
- The Windows computer may be joined to a local network via the Ethernet port or a USB/WiFi adapter. That network connection may be configured as necessary. By default, the Windows computer will:
 - Obtain an IP address automatically
 - Obtain DNS server addresses automatically
 - Treat networks as ‘Public’

Note: It may be required to configure the connection as ‘Work/Private’ to successfully join and/or map a network drive on a secure network (see “Backups” on page 126)

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 software sends emails via SMTP
- For the email function to work, the network needs to be configured to allow the Windows computer to access at least 1 SMTP port



- The following email settings can be configured in the Desktop UI → Config → Alarm menu, after opening an Alarm file:
 - SMTP port (the default is 25)
 - Whether to enable SSL (the default is TRUE)
 - The sending email address (the default is a customer-specific pbsbiotech.com email address)
 - The password for the sending email address (the default is the password for the pbsbiotech.com email address)
 - The SMTP server (the default is the SMTP server used by the pbsbiotech.com email address)
 - Subject (the default is the bioreactor name, which allows users with multiple bioreactors to distinguish which bioreactor is sending the email)
 - Email List, which is the list of email addresses that receive an email for alarms which are configured to be emailed

- SMS and MMS Gateways:
 - Users can receive alarm notifications as text messages
 - 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 Windows computer to have a static IP on the LAN is recommended for this reason (see "Network Connections" on page 124)
- Because the certificate is self-signed by the Server on the Windows computer, 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 124.
- 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 MAG-SUS
- 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 127, 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.

While all system variable settings can technically be changed by the user, many should remain in their default values unless advised by PBS Biotech, 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. | ! | TempHeatDutyControl.PGain (min) |
| I Time (min) | 26.000 | Integral Time for the temperature controller. | ! | TempHeatDutyControl.ITime (min) |
| D Time (min) | 0.000 | Derivative Time for the temperature controller. | ! | TempHeatDutyControl.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 | TempHeatDutyControlAlpha |
| Beta | 0.000 | Specifies the relative emphasis of setpoint tracking to disturbance rejection. | X | TempHeatDutyControlBeta |

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 | TempHeatDutyControlGamma |
| Linearity | 1.000 | Specifies the linearity of the error response. The valid range is 0 to 1. | X | TempHeatDutyControlLinearity |
| Heat Manual Max (%) | 50.000 | The maximum main heater duty allowed in Manual mode. | ! | TempHeatManMax(%) |
| Heat Auto Max (%) | 50.000 | The maximum main heater duty allowed in Auto mode. | ! | TempHeatDutyAutoMax(%) |
| 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 | FilterOvenDutyControlGamma |
| Linearity | 1.000 | Specifies the linearity of the error response. The valid range is 0 to 1. | X | FilterOvenDutyControlLinearity |
| Heat Manual Max (%) | 100.000 | The maximum filter oven heater duty allowed in Manual mode. | X | FilterOvenDutyRangeManMax (%) |
| Heat Auto Max (%) | 100.000 | The maximum filter oven heater duty allowed in Auto mode. | X | FilterOvenDutyRangeAutoMax (%) |

AGITATION

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|----------------|---------------|---|-----------------|-------------------------------|
| P Gain (%/RPM) | 0.100 | Proportional Gain for the agitation controller. | ! | AgPowerControl.PGain (%/RPM) |
| I Time (min) | 0.010 | Integral Time for the agitation controller. | ! | AgPowerControl.ITime (min) |
| D Time (min) | 0.000 | Derivative Time for the agitation controller. | ! | AgPowerControl.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 | AgControlLinearity |
| 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. | ✓ | AgLookupMode Timeout (ms) |
| Lookup Factor (%/RPM) | 0.550 | 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(%) |
| Number of Magnets | 2.000 | The number of magnets on the Vertical-Wheel® impeller. | ! | AgWheelMagnet Count |

AGITATION (continued)

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

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 | pHMismatchThresh |
| 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. | ✓ | pHRateFailDeltaPV |
| 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. | ✓ | pHRateFailDeltaTime(ms) |
| CO2 P Gain (%/pH) | -200.000 | Proportional Gain for the pH CO ₂ controller. | ! | pHCO2Control.PGain(%) |
| CO2 I Time (min) | 10.000 | Integral Time for the pH CO ₂ controller. | ! | pHCO2Control.ITime(min) |

pH (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|--------------------|---------------|--|-----------------|---------------------------------------|
| CO2 D Time (min) | 0.000 | Derivative Time for the pH CO ₂ controller. | ! | pHCO ₂ 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 | pHCO ₂ Control Alpha |
| CO2 Beta | 1.000 | Specifies the relative emphasis of setpoint tracking to disturbance rejection. | X | pHCO ₂ Control 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 | pHCO ₂ Control Gamma |
| CO2 Linearity | 1.000 | Specifies the linearity of the error response. The valid range is 0 to 1. | X | pHCO ₂ Control Linearity |
| CO2 Manual Max (%) | 100.000 | The maximum CO ₂ composition in the main gas flow allowed in Manual mode. | ✓ | pHCO ₂ ManMax (%) |
| CO2 Auto Max (%) | 30.000 | The maximum CO ₂ composition in the main gas flow allowed in Auto mode. | ✓ | pHCO ₂ AutoMax (%) |

pH (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|---------------------|---------------|--|-----------------|-------------------------------|
| Base P Gain (%/pH) | 10.000 | Proportional Gain for the pH base controller. | ! | pHBaseDutyControl.PGain(%) |
| Base I Time (min) | 50.000 | Integral Time for the pH base controller. | ! | pHBaseDutyControl.ITime (min) |
| Base D Time (min) | 0.000 | Derivative Time for the pH base controller. | ! | pHBaseDutyControl.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 | pHBaseDutyControlAlpha |
| Base Beta | 1.000 | Specifies the relative emphasis of setpoint tracking to disturbance rejection. | X | pHBaseDutyControlBeta |
| 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 | pHBaseDutyControlGamma |
| Base Linearity | 1.000 | Specifies the linearity of the error response. The valid range is 0 to 1. | X | pHBaseDutyControlLinearity |
| Base Manual Max (%) | 50.000 | The maximum base pump duty allowed in Manual mode. | ✓ | pHBaseDutyManMax(%) |

pH (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|-------------------|---------------|---|-----------------|-------------------------------|
| Base Auto Max (%) | 50.000 | The maximum base pump duty allowed in Auto mode. | ✓ | pHBaseAutoMax |
| A Use Temp Comp? | 0.000 | 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 | pHAUseTempComp |
| 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 | pHBUseTempComp |
| Deadband | 0.020 | The internal deadband of the pH controller. CO ₂ only flows when the pH PV is greater than the pH set point + deadband. Base only flows when the pH PV is less than the pH set point - deadband. | ✓ | pHDeadband |
| Valid High (pH) | 14.000 | If a pH sensor registers a measurement above this value, the software assumes the pH sensor is broken, and triggers a pH Sensor Failure (range) Alarm. | ! | pHValidMax |

pH (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|--------------------|---------------|--|-----------------|-------------------------------|
| 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 |
| 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 | DOMismatchThresh(%) |
| 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. | ! | DOO2ControlMag.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. | ! | DOO2ControlMag.ITime(min) |

DO (continued)

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

DO (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|-------------------|---------------|--|-----------------|-------------------------------|
| 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 (%/%) |
| 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 |

DO (continued)

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

LEVEL (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|-----------------------------|---------------|---|-----------------|--|
| 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 |
| 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 an MFC Mismatch Alarm. | ✓ | MFCMismatch Thresh(V) |

GAS DATA (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|-------------------------------|---------------|--|-----------------|-------------------------------|
| O ₂ 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. | ! | O ₂ 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 to avoid overfilling. | X | LevelMax(L) |
| Buzzer Period (ms) | 100.000 | This value affects the quality of sound of the alarm buzzer. | ✓ | AlarmBuzzer Period(Cycle) |
| DoorPressure Sensor (0 or 1) | 0.000 | Tells the software the bioreactor has a door pressure sensor. | X | DoorPressure Sensor |

PUMPS

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|------------------|---------------|---|-----------------|-------------------------------|
| Aux Low Duty | 20000 | 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 |
| Aux Med Duty | 30000 | 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 |
| Base On Time (s) | 0.100 | The base pump turns on in increments of this number. | ! | Pumps&Valves BaseOnTime(s) |

PUMPS (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|------------------------------------|---------------|---|-----------------|------------------------------------|
| 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 |

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) |

PROCESS ALARMS (continued)

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

PROCESS ALARMS (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|---------------------------|---------------|--|-----------------|----------------------------------|
| 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) |
| 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) |

PROCESS ALARMS (continued)

| Setting Name | Default Value | Definition | User May Change | Corresponding Global Variable |
|--------------------------|---------------|--|-----------------|---------------------------------|
| 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 addition to the logging by deadband as configured in the logger settings file. | ✓ | LoggerMaxLog Interval(ms) |
| Alarm Snooze Time (s) | 300.000 | If a Process Alarm is audible, acknowledging the alarm will silence the buzzer for the given period of time. | ✓ | AlarmSnooze Time(ms) |
| Available Mem Limit (KB) | 2000 | If available memory on the RIO computer is less than this value, the "RT Mem Nearly Full" alarm is triggered. | X | SysAvailableMem Limit(KB) |
| LCB Mem Limit (KB) | 2000 | If available LCB on the RIO is less than this value, the "RT Mem Fragmented" alarm is triggered. | X | SysLCBMemLimit (KB) |

| 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 MAG-SUS) Pressure PV drops below this value. |
| Pressure Low | (N/A on PBS 3 MAG-SUS) Pressure PV drops below this value. |
| Pressure High | (N/A on PBS 3 MAG-SUS) Pressure PV rises above this value. |
| Pressure High High | (N/A on PBS 3 MAG-SUS) 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. |

| Alarm Name | Alarm is Triggered When: |
|-----------------------------|--|
| Main Gas High | Main gas flow rises above this value. |
| Main Gas High High | Main gas flow rises above this value. |
| Leak Detected | (N/A on PBS 3 MAG-SUS) The leak sensor detects a leak. |
| Restarted Recipe | 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 MAG-SUS) The temperature sensors register measurements that differ by more than the Temperature "Mismatch Thresh (C)" setting. |
| DO Sensor Mismatch | (N/A on PBS 3 MAG-SUS) The DO sensors register measurements that differ by more than the DO "Mismatch Thresh (DO%)" setting. |
| pH Sensor Mismatch | (N/A on PBS 3 MAG-SUS) The pH sensors register measurements that differ by more than the pH "Mismatch Thresh" setting. |
| Air MFC Mismatch | 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 MFC Mismatch | 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 MFC Mismatch | 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 MFC Mismatch | 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. |

| Alarm Name | Alarm is Triggered When: |
|-------------------------------|--|
| 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. |
| Temp Sensor B Failure (range) | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) Both pH sensors register rate failures or range failures. |
| Pressure Sensor Disconnected | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) The bag has pressurized enough to lift the comb plate. |

| Alarm Name | Alarm is Triggered When: |
|-----------------------|--|
| 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. |
| 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 MAG-SUS), pressure sensor connected (N/A on PBS 3 MAG-SUS), Door Pressure sensor (N/A on PBS 3 MAG-SUS), 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 MAG-SUS), 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 MAG-SUS, 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 MAG-SUS) Analog Output errors writing to pumps with RPM input, and to agitation motors for the MagDrive other than the PBS 3 MAG. |
| 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. |

| Alarm Name | Alarm is Triggered When: |
|-----------------------|---|
| 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. |
| 24 Vdc User2 Fuse | This fuse needs to be replaced. |
| 24 Vdc User3 Fuse | This fuse needs to be replaced. |
| Unknown Alarm | This is a placeholder alarm, and should never be generated. |

Default Alarms Configurations

The PBS 3 MAG-SUS comes with two default Alarms.alm files on the Windows computer. 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 “PBS 3 MAG-SUS Alarms” on page 49.

Note: The email setting is independent of the chosen alarm file. However, if an alarm is not configured to be Notify, the PBS 3 MAG-SUS 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 | | | ✓ | ✓ | ✓ |

Appendix 3 - Default Alarms Configurations

| 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 | | | | | |
| Restarted Recipe | ✓ | | ✓ | | ✓ |
| Temperature Sensor Mismatch | | | | | |
| DO Sensor Mismatch | | | | | |
| pH Sensor Mismatch | | | | | |
| Air MFC Mismatch | ✓ | | ✓ | ✓ | ✓ |
| CO2 MFC Mismatch | ✓ | | ✓ | ✓ | ✓ |
| N2 MFC Mismatch | ✓ | | ✓ | ✓ | ✓ |
| O2 MFC Mismatch | ✓ | | ✓ | ✓ | ✓ |
| 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) | | | | | |

Appendix 3 - Default Alarms Configurations

| 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 | ✓ | | ✓ | | |

Appendix 3 - Default Alarms Configurations

| 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 | ✓ | | ✓ | | |
| Unknown Alarm | ✓ | | ✓ | | |

Default Logger Configurations and Global Variables Definitions

The PBS 3 MAG-SUS ships with a default Logger file loaded. For more information, see “Configuring Logger Settings” on page 46.

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 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgLookupFactor (LPM/RPM) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasControl.ITime (min) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasControl.PGain (LPM/RPM) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasRangeAuto (LPM).Max | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasRangeAuto (LPM).Min | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasRangeManMax (LPM) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| AgMainGasUser(LPM) | 0.100 | | User | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 $\approx 36 \mu\text{s}$. |
| 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 $\approx 36 \mu\text{s}$. |
| AgMotorPower(V) | 0.100 | | Calc | For PBS MagDrive Bioreactors, 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. |

AGITATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|------------------------------|------------------|----------------|--------|--|
| AgPowerActualRequest(%) | 2.000 | ✓ | Calc | For PBS MagDrive Bioreactors, the % power being sent to the agitation motor. |
| 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 | For PBS MagDrive Bioreactors, 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. |

AGITATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------------------|------------------|----------------|--------|---|
| AgSP(RPM) | 0.500 | ✓ | User | The last agitation setpoint used when agitation was in Auto mode. |
| 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 \approx 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 \approx 2400 ns. |
| HarvestDelay(s) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) For PBS MagDrive 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. |

AGITATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|----------------|------------------|----------------|--------|--|
| HarvestMode | 0.500 | | User | (N/A on PBS 3 MAG-SUS) For PBS MagDrive Bioreactors size 15 and higher, 0) not in Harvest mode, 1) ramping down agitation, 2) aligning the wheel, or 3) harvesting. For other models, this variable should not be modified via recipe. |
| HarvestTimeout | 0.500 | | Calc | (N/A on PBS 3 MAG-SUS) For PBS MagDrive 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 μ s. 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. |

ALARM (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------|------------------|----------------|--------|---|
| 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. |
| Alm_CombPlate | 0.500 | | Sensor | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the offset of the raw value to DO sensor B PV conversion. |

CALIBRATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---|------------------|----------------|--------|--|
| CalDOB.Slope | 0.010 | | System | (N/A on PBS 3 MAG-SUS) 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. |
| 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.CallLevel InterceptMax(psi) | 0.001 | | System | See Level “CallLevel InterceptMax(psi)” setting in Appendix 1. |
| CalLimitsLevel.CallLevel InterceptMin(psi) | 0.001 | | System | See Level “CallLevel InterceptMin(psi)” setting in Appendix 1. |
| CalLimitsLevel.CallLevel SlopeMax(psi/V) | 0.001 | | System | See Level “CallLevel SlopeMax(psi/V)” setting in Appendix 1. |
| CalLimitsLevel.CallLevel SlopeMin(psi/V) | 0.001 | | System | See Level “CallLevel SlopeMin(psi/V)” setting in Appendix 1. |
| CalLimitsPressure.Cal PressureInterceptMax(psi) | 0.001 | | System | See Pressure “Cal PressureInterceptMax (psi)” setting in Appendix 1. |

CALIBRATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---|------------------|----------------|--------|--|
| 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. |
| 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. |

CALIBRATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------|------------------|----------------|--------|--|
| CalPressure.Offset(psi) | 0.010 | | System | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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. |
| 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, the offset of the raw resistance to temperature sensor B PV conversion. |

CALIBRATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|------------------|------------------|----------------|--------|---|
| CalTempB.Slope | 0.010 | | System | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the offset of the raw voltage to pH sensor B PV conversion. |
| CalpHB.Slope | 0.100 | | System | (N/A on PBS 3 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, the slope of the raw voltage to pH sensor B PV conversion. |

CALIBRATION (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|----------------|------------------|----------------|--------|---|
| CalpHB.Temp(C) | 0.100 | | System | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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. |
| DOB(%) | 2.000 | | Calc | (N/A on PBS 3 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate DO sensors, the PV reported by DO sensor B. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------|------------------|----------------|--------|--|
| DOBRaw(%) | 0.100 | | Sensor | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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. |
| DOModeActual | 0.500 | ✓ | Calc | The actual DO mode: 0) Auto, 1) Manual, 2) Off, and 3) Broken Sensor. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------------|------------------|----------------|--------|---|
| 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, for PBS MagDrive Bioreactors, 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. |
| DON2FlowUser(%) | 1.000 | ✓ | User | The last user-defined N ₂ output used when DO was in Manual mode. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------------|------------------|----------------|--------|--|
| 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 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| DOO2ControlAir.ITime (min) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| DOO2ControlAir.PGain (mLPM/%) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) 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. |
| DOO2ControlMag.PGain (%/DO%) | 0.001 | | System | See DO “O2 P Gain (%/DO%)” setting in Appendix 1. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---|------------------|----------------|--------|--|
| DOO2FlowController Request(%) | 2.000 | | Calc | For PBS MagDrive Bioreactors, 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 MAG-SUS) 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, for PBS MagDrive Bioreactors, 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, for PBS MagDrive Bioreactors, the requested CO ₂ flow into account. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------|------------------|----------------|--------|---|
| DOO2FlowUser(%) | 0.100 | ✓ | User | For PBS MagDrive Bioreactors, the last user-defined O ₂ output used when DO was in Manual mode. |
| DOO2FlowUser(mLPM) | 1.000 | | User | (N/A on PBS 3 MAG-SUS) For PBS AirDrive Bioreactors, the last user-defined O ₂ output used when DO was in Manual mode. |
| DOO2RangeAutoMax(%) | 1.000 | | System | See DO “O ₂ Auto Max (%)” setting in Appendix 1. |
| DOO2RangeAutoMax (mLPM) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) Corresponds to a System Variable only applicable to PBS AirDrive Bioreactors. |
| DOO2RangeManMax(%) | 0.001 | | System | See DO “O ₂ Manual Max (%)” setting in Appendix 1. |
| DOO2RangeManMax (mLPM) | 0.001 | | System | (N/A on PBS 3 MAG-SUS) 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. |

DO (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------|------------------|----------------|--------|--|
| DOUserConfig | 0.500 | | User | (N/A on PBS 3 MAG-SUS) 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. |
| 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 MAG-SUS) 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 MAG-SUS) 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. |

DOOR (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|----------------------------|------------------|----------------|--------|---|
| DoorUnlockUser | 0.500 | | User | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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. |

FILTER OVEN (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------------------|------------------|----------------|--------|--|
| 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. |
| 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 μ s. |
| 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 μ s. |
| FilterOvenRaw(C) | 5.000 | | Sensor | The raw resistance the filter oven sensor reports. |

FILTER OVEN (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|------------------------|------------------|----------------|--------|---|
| 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. |
| 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 \approx 8850 ns. |

GASES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------------|------------------|----------------|--------|--|
| 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 \approx 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 “CO ₂ Min (LPM)” setting in Appendix 1. |
| MFCCO2Off(V) | 0.001 | | System | See Gas Data “CO ₂ 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. |

GASES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---|------------------|----------------|--------|--|
| MFC _{CO2} OutRaw.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 ≈ 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. |
| MFCN ₂ FlowFeedback (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. |
| MFCN ₂ MeasRaw(V) | 0.100 | | Sensor | The raw voltage the N ₂ MFC reports. |
| MFCN ₂ Min(LPM) | 0.001 | | System | See Gas Data “N ₂ Min (LPM)” setting in Appendix 1. |
| MFCN ₂ Off(V) | 0.001 | | System | See Gas Data “N ₂ Off (V)” setting in Appendix 1. |

GASES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|------------------------------|------------------|----------------|--------|--|
| 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. |
| 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. |

GASES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------------|------------------|----------------|--------|--|
| 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. |
| 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 MAG-SUS) For PBS MagDrive Bioreactors size 15 and higher, this indicates whether the agitation motor will not turn on because it is interlocked. |

INTERLOCKS (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------------|------------------|----------------|--------|--|
| InterlockAll | 0.500 | | Calc | Not in use. |
| InterlockDoor | 0.500 | | Calc | (N/A on PBS 3 MAG-SUS) 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. |
| 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. |
| 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 MAG-SUS) 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. |

LEVEL (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------|------------------|----------------|--------|---|
| 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 MAG-SUS) 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. |
| 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. |

PROCESS ALARMS/LIMITS (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|----------------------------------|------------------|----------------|--------|---|
| 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. |
| 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. |

PROCESS ALARMS/LIMITS (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------------------|------------------|----------------|--------|--|
| 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. |
| 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. |

PROCESS ALARMS/LIMITS (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------|------------------|----------------|--------|--|
| 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. |
| 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. |

PROCESS ALARMS/LIMITS (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------|------------------|----------------|--------|--|
| SensorStates.Level | 0.500 | | Calc | The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low. |
| SensorStates.Main Gas | 0.500 | | Calc | The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low. |
| SensorStates.Pressure | 0.500 | | Calc | The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, and 5) Below Low Low. |
| SensorStates.Temperature | 0.500 | | Calc | The state of the sensor with regard to Process Alarms and failures: 1) In Range, 2) Above High, 3) Below Low, 4) Above High High, 5) Below Low Low, and 6) 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 | For PBS MagDrive Bioreactors, the gas flow output the controller requests of the main gas MFCs. |
| MainGasFeedback(LPM) | 0.100 | | Calc | For PBS MagDrive Bioreactors, the sum of the actual flows of the Air, N ₂ , CO ₂ , and O ₂ MFCs. |
| MainGasModeActual | 0.500 | ✓ | Calc | For PBS MagDrive Bioreactors, the actual main gas mode: 0) Auto, 1) Manual, and 2) Off. |
| MainGasModeUser | 0.500 | | User | For PBS MagDrive Bioreactors, 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 | For PBS MagDrive Bioreactors, 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with a pressure sensor, this indicates if the pressure sensor is disconnected. |
| 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 AND VALVES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--|------------------|----------------|--------|---|
| 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&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 AND VALVES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--|------------------|----------------|--------|---|
| 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&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 AND VALVES (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------------|------------------|----------------|--------|---|
| Pumps&ValvesFillMotor Raw(V) | 0.100 | | Calc | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 $\approx 36 \mu s$. |
| 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 $\approx 36 \mu s$. |
| 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 $\approx 36 \mu\text{s}$. |
| 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 $\approx 36 \mu\text{s}$. |
| 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. |
| TempAlsActive | 0.500 | | Calc | True when temperature sensor A has not failed. |
| TempAlsPrimaryActual | 0.500 | | Calc | True when the software reports temperature PV as what temperature sensor A measures. |
| TempAlsPrimaryUser | 0.500 | | User | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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 MAG-SUS) 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. |

TEMPERATURE (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------------|------------------|----------------|--------|---|
| TempHeatDutyControl.DTime(min) | 0.001 | | System | See Temperature “D Time (min)” setting in Appendix 1. |
| TempHeatDutyControl.ITime(min) | 0.001 | | System | See Temperature “I Time (min)” setting in Appendix 1. |
| TempHeatDutyControl.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 μ s. |
| 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 μ s. |

TEMPERATURE (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-----------------------|------------------|----------------|--------|--|
| TempInRange.A | 0.500 | | Calc | True when temperature sensor A is in valid range. |
| TempInRange.B | 0.500 | | Calc | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate temperature sensors, a user configuration to tell the software which temperature sensors the user has installed. |

TEMPERATURE (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-----------------|------------------|----------------|--------|---|
| 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 MAG-SUS) 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. |

pH (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-------------------------------|------------------|----------------|--------|---|
| pHB | 0.050 | | Calc | (N/A on PBS 3 MAG-SUS) 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 MAG-SUS) For PBS Vertical-Wheel® Bioreactors with duplicate pH sensors, true when pH sensor B has not failed. |
| pHBRaw | 0.010 | | Sensor | (N/A on PBS 3 MAG-SUS) 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. |

pH (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|-----------------------------|------------------|----------------|--------|--|
| 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. |
| 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 “CO ₂ Auto Max (%)” setting in Appendix 1. |
| pHCO2Control.DTime(min) | 0.001 | | System | See pH “CO ₂ D Time (min)” setting in Appendix 1. |
| pHCO2Control.ITime(min) | 0.001 | | System | See pH “CO ₂ I Time (min)” setting in Appendix 1. |
| pHCO2Control.PGain(%) | 0.001 | | System | See pH “CO ₂ P Gain (%/pH)” setting in Appendix 1. |
| pHCO2ControlAlpha | 0.001 | | System | See pH “CO ₂ Alpha” setting in Appendix 1. |

pH (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|--------------------------------|------------------|----------------|--------|--|
| 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. |
| 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 MAG-SUS) 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. |

pH (continued)

| Variable Name | Default Deadband | Default Record | Source | Definition |
|---------------------------|------------------|----------------|--------|--|
| pHModeActual | 0.500 | ✓ | Calc | The actual pH mode: 0) Auto, 1) Manual, 2) Off, and 3) 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. |
| 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 MAG-SUS) 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. |