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Life Sciences

Instructions for Use

USD3238

mPath™ Bioreactor Control Tower





Filtration. Separation. Solution.SM

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The following Instructions for Use (IFU) contain important information on the installation, operation and maintenance of your mPath bioreactor control tower. To get the best results in operation and performance, please take the time to read this IFU thoroughly. The IFU related to the Pall bioreactor connected to the mPath bioreactor control tower should be read in addition to this IFU.

It is important to work with your IT department if connecting Pall Link and mPath bioreactor control towers to your local network. Please consult the Pall IT Technical Note reference USD 3222 and review requirements for static IP addresses for the mPath bioreactor control tower and bench top Pall Link server.

1. Warnings

1.1. Hazard Icons

	Caution! Documentation must be consulted in all cases where this symbol is marked!
	Warning! Possibility of electric shock!
	Caution! Risk of crush injury!
	Caution! Hot surface!

1.2. Danger Levels

The following danger levels are used in safety messages throughout this manual:

DANGER:	Will lead to severe injuries or death
WARNING:	May lead to severe injuries or death
CAUTION:	May lead to light or moderate injuries
ALERT:	May lead to material damage

 **Please read all Warnings carefully and ensure that they are adhered to.**

Safety is the responsibility of the individual installing, using or maintaining the equipment and any others who may be involved in the operation. It is important that the safety instructions are read and followed.

If the equipment or the packaging in which the equipment is supplied is damaged on receipt do not attempt to install or use the equipment, but instead contact Pall Corporation for advice.

DO NOT use the equipment in any way other than is stated in this manual. Doing so could result in personal injury and damage to the equipment.

DO NOT block equipment ventilation holes. Doing so could cause the equipment to overheat.

DO NOT power up the equipment or attempt to use the equipment if it is damaged in any way. Contact Pall for advice.

DO NOT use the equipment if you suspect a fault. Switch off and disconnect power to the equipment immediately and contact Pall for advice.

2. System Overview

2.1. Introduction

Your mPath bioreactor control tower has been designed to be used with Pall bioreactor products. It is intended for use in research & development, process development and small scale cGMP manufacturing.

The mPath bioreactor control tower system is capable of supporting cGMP cell culture processes on the iCELLis® Nano bioreactor, PadReactor® Mini bioreactor, Xpansion® multiplate bioreactor and Allegro™ XRS 25 single-use bioreactor systems. The mPath control tower also includes four extra Input / Output (I/O) ports to allow user configuration.

The mPath bioreactor control tower does not have a user interface (UI) present on the casing. It has been designed to work with Pall Link, a supervisory control and data acquisition (SCADA) platform where the user can remotely view and control their bioreactor from a network enabled device. Access to full features of Pall Link is dependent on the IT environment in which the software is installed. For further details, consult the Pall IT Technical Advisory Note reference USD 3222.

Pall Link UI and SCADA software is delivered as standard on a Pall Link server (P/N MPATHLINK) which is configured as a server. All required software is pre-installed with default recipes to aid the user in a quick start scenario.

The design of the software is such that up to 20 mPath bioreactor control towers and user interfaces can be supported from one server. Additional bioreactors may reduce performance. To support larger installs a more powerful server or multiple server may be required.

The software is recipe focused allowing the user to create, save, edit, delete, archive and duplicate recipes. The recipe then can be scheduled against an integrated calendar within the software to allow lab managers to arrange bioreactor availability and plan resource requirements.

The mPath bioreactor control tower can provide two mixed gas supplies – primary and secondary – to the bioreactor. Each mixture may be generated from four compressed gases: carbon dioxide, nitrogen, oxygen and air which are supplied to the tower.

Primary is typically a mix of carbon dioxide, oxygen and air or nitrogen (air and nitrogen are interchangeable without an impact on calibration).

Secondary is typically a mix of carbon dioxide, air or nitrogen.

An additional feature on the mPath bioreactor control tower is a rapid inflate option which allows the operator to quickly inflate their biocontainer with compressed air.

The mPath bioreactor control tower can be delivered with or without peristaltic pumps depending on the bioreactor being connected to the tower. If the pump option is chosen, three variable speed Watson Marlow♦ 314D pump heads, accommodating tubing with bore sizes of up to 8 mm are fitted as standard.

2.2. Equipment Overview

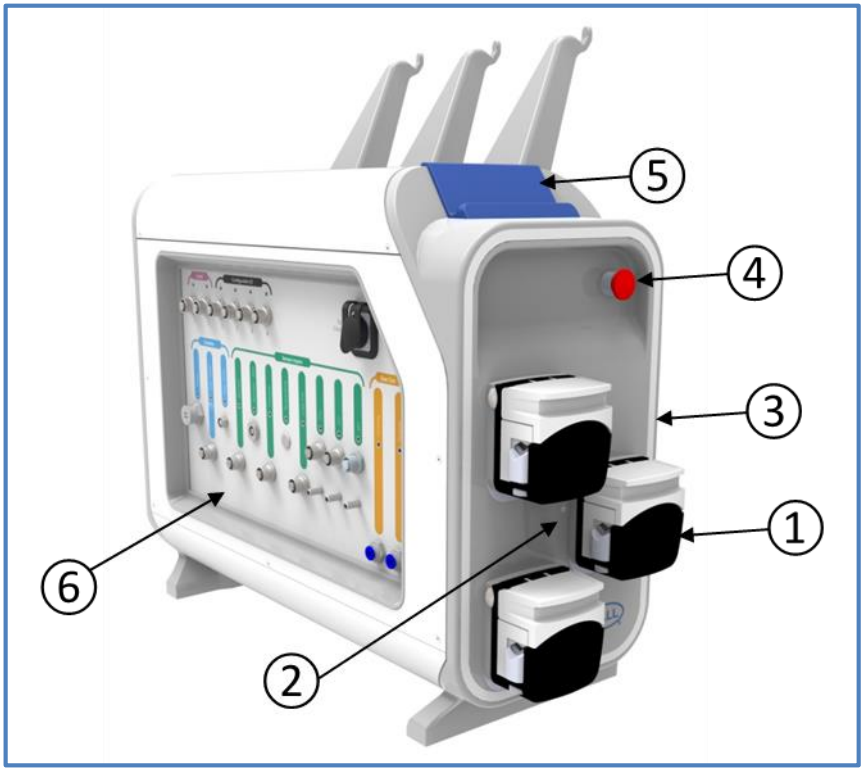


Figure 1: mPath bioreactor control tower;
(1) peristaltic pumps; (2) LED pump status (on selected models); (3) system alarm status illumination; (4) emergency stop; (5) tablet dock and (6) bioreactor connection panel

3. Site Requirements

3.1. Responsibilities

A Pall engineer will be responsible for installing and commissioning the hardware to ensure that it is properly installed and operational. The user is responsible for ensuring that the workspace is prepared in advance to allow the Pall engineer to carry out the installation efficiently.

Important: The installation of the hardware cannot begin until the checklist has been completed and returned to the Pall engineer. The site preparation checklist must be completed as accurately as possible to help minimize installation time.

Important: A user who has been designated to be responsible for the normal use and upkeep of the hardware must be present during the installation. This allows the user to be trained on the basic hardware operation.

3.2. Size and Weight of Equipment

Table 1: Size and weight of the mPath equipment

Dimensions (W x D x H)	230 mm x 600 mm x 450 mm (H = 590 mm with hangers attached)
Weight	20 kg

3.3. Space Requirements for Equipment Operation

The mPath bioreactor control tower is intended for indoor use only. Choose an appropriate location to install the equipment taking into consideration the following:



- The equipment should be placed on a solid, level and even surface to minimize the risk of the equipment falling over.
- When using hanging load cells ensure control tower is placed on an even surface, which is not subject to vibration.
- Ensure the space around the equipment is clear to allow ventilation through the underside and rear of the equipment.
- No exposure to direct sunlight.



- Not positioned near any water sources or heat sources. In the event of a major liquid spillage in or near the bioreactor control tower, isolate the system from the electricity supply.
- Ensure a well illuminated and well-ventilated working environment.
- The equipment will require access to the rear and left side panels during installation and setup.
- Access to the left, front and right panels will be required in normal use.
- The equipment needs to be powered from an AC power supply.
- The AC power supply should provide a safety earth connection.
- The AC switch on the rear of the equipment should be easily accessible without having to move the equipment.

3.4. Power Requirements



- When connecting the instrument, check the electrical cable for damage. If the cable is undamaged then first connect the cable to the instrument, and then connect the cable to the electricity supply.
- The mPath bioreactor control tower should only be connected to an AC current limited (16A) supply that has protective ground using the IEC power supply cord provided. Do not replace the detachable power supply cord with an inadequately rated cord. Doing so could compromise safety.
- The detachable power supply cord is used as an electrical disconnect device. Do not position the equipment so that it is difficult to remove the supply cord from the AC supply.
- The equipment has an AC power switch on the rear. The power switch has two positions indicated by graphical symbols:
- | On – equipment powered ○ Off – equipment powered off
- The AC power switch is illuminated when in the on position.
- Avoid contact with water and other solvents.
- In the event of a major liquid spillage in or near to the bioreactor control tower, isolate the unit from the electricity supply.
- The equipment contains no internal user-serviceable parts. Do not remove covers or attempt to repair the equipment. Doing so will void the warranty.
- Repairs must be undertaken by Pall authorized service personnel only. Faulty unqualified repair work may cause accidents or injury to the operator.
- Do not use extension cords.
- The plug must be disconnected from the power source before changing the fuse.
- The fuse in the AC power inlet must only be replaced with the type and rating marked on the equipment.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

3.5. Gases



- It is the user's responsibility to provide a clean, dry, oil free, analytical grade source of each compressed gas regulated from 2 (29 psi) to 6 bar (87 psi) or below as mass flow controllers are sensitive to dirt and pressure spikes.
  - Gases from local compressors or generators must be filtered and dried.
  - It is recommended that Pall sub-micron filters are installed in each gas line. Recommended: Pall Gaskleen® GLF6101FP4 filters.
    Note: When using the stated filter, male ¼ in. NPT to 6 mm push to connect stubs are also required.
- The mPath bioreactor control tower is designed for use with and calibrated for the gases carbon dioxide, oxygen, nitrogen and air at pressures between 2 bar (29 psi) and 6 bar (87 psi). Use caution when working with the gases and ensure all gas tubing is fully inserted into the push to connect fittings on the bioreactor control tower.
- The use of gases other than those listed above is not recommended.
- The maximum inlet pressure of 6 bar (87 psi) must not be exceeded.
- All pneumatic tubing used must be rated to withstand the gas pressures used (up to 6 bar / 87 psi).
- The operator should check the tubing and connectors for damage before each use.
- Ensure the environment in which the mPath bioreactor control tower is being operated has appropriate gas alarms enabled.

Table 2: Gases connections overview

Gases	Mains Gas in Connection Type	Gas Out / Delivery Connection Type	Recommended Tubing for Gas Connections
Air, oxygen, nitrogen and carbon dioxide	Pneumatic push-fit connector (for each gas)	Quick connectors 6 mm	Pneumatic tubing 6 mm OD

The optional with PN CCTOOLKIT1 supplied by Pall includes tubing and tubing connectors to enable the easy installation of the hardware and connection of gas lines.

3.6. Environment



ALERT! Risk of damage to equipment!
This equipment was designed for indoor use only (ambient temperatures of +16 °C to +30°C). It may occasionally be subjected to temperatures between +5 °C and +40 °C without degradation of its safety.

The mPath control system can be operated under the following ambient environmental condition:

- Indoor use only.
- Altitude up to 2000 m.
- The ambient temperatures must be between 5 °C (41 °F) and 40 °C (104 °F).
- Maximum relative humidity of 80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40 °C.
- Electrical supply voltage fluctuations allowable of up to +/- 10% of the nominal voltage.

4. Unpacking and Installing

4.1. Packaging Details

The mPath bioreactor control tower is supplied in packaging to help reduce the risk of damage to the equipment during transit. The equipment is heavy and suitable precautions should be taken when lifting or moving the packaged equipment to help prevent personal injury or damage to the equipment. It is recommended that the packaged equipment be lifted by two people.

Inspect the packaging for signs of damage. Place the packaging on a solid and even surface with the arrows pointing in the up direction. Open the packaging from the top. Before attempting to remove the equipment, check the internal packaging for signs of damage.

Carefully lift the equipment from the packaging and place it on a solid and even surface. Check the equipment for any signs of damage.

If the packaging or equipment is damaged in any way, contact Pall for advice.

Ensure the equipment AC on/off switch on the rear panel is in the **off** position, and the switch on the AC power supply socket is **off** if one is fitted.

Table 3: Packaging details

Dimensions (packaging)	H = 610 mm, L = 699 mm, W = 330 mm
Weight	25 kg

4.2. Installation



- The mPath bioreactor control tower should be handled with care as appropriate for a sensitive electronic instrument.
- The mPath bioreactor control tower weighs 20 kg when fully assembled; care should be taken when lifting. Only lift or move the equipment using the rear hand hold at the bottom and lip at the top of the top face. It is recommended that the equipment be lifted or moved by two people.
- Before attempting to move the mPath bioreactor control tower, disconnect from power supply, disconnect gas lines, remove hanging biocontainers, remove cables connecting control tower and bioreactor as well as any tubing from peristaltic pumps.
- To connect the bioreactor control tower to a network, please refer to the Pall IT Technical Advisory Note reference USD 3222.
- A Pall service engineer will aid with the first installation of the bioreactor control tower. *Warranty may be void if installation is carried out without Pall specialist present.

4.3. Hardware Overview

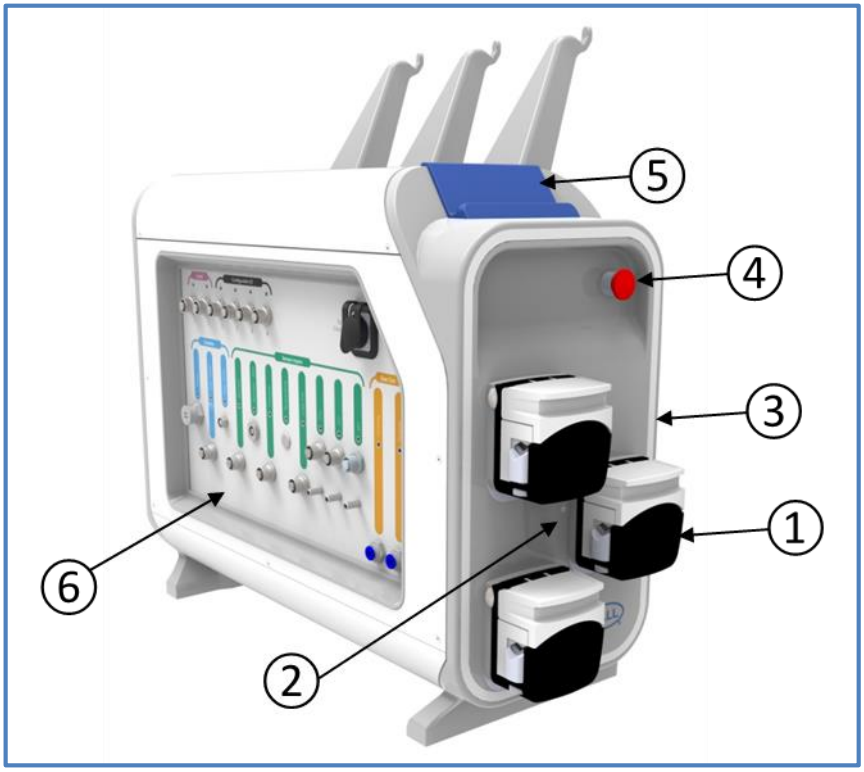


Figure 2: mPath bioreactor control tower – see key below

	Item	Description
1	Peristaltic pumps. *Only on part numbers: MPATHBRXPS2P3 MPATHBRXPS0P3*	Three variable speed Watson Marlow 314D pump heads are located on the front of the control tower. These pumps are designed to operate with tubing bore sizes in the range 0.5 mm to 8 mm
2	Pump status LEDs. *Only on part numbers: MPATHBRXPS2P3 MPATHBRXPS0P3*	Three LEDs provide the user with information on the status of the pumps
3	Status illumination	An illuminated ring is located on the front of the control tower to provide the user with general alarm status
4	Emergency stop	An E-stop is located on the front of the control tower. This is an E-stop for the control tower only!
5	Tablet dock	The user can set up recipes and monitor progress through a tablet computer or HDMI touchscreen that may be docked on top of the control tower. A charging point is available on the connector panel and an HDMI output on the rear of the instrument
6	Connector panel	The connector panel provides for a range of sensor inputs (both electrical and optical) and control outputs

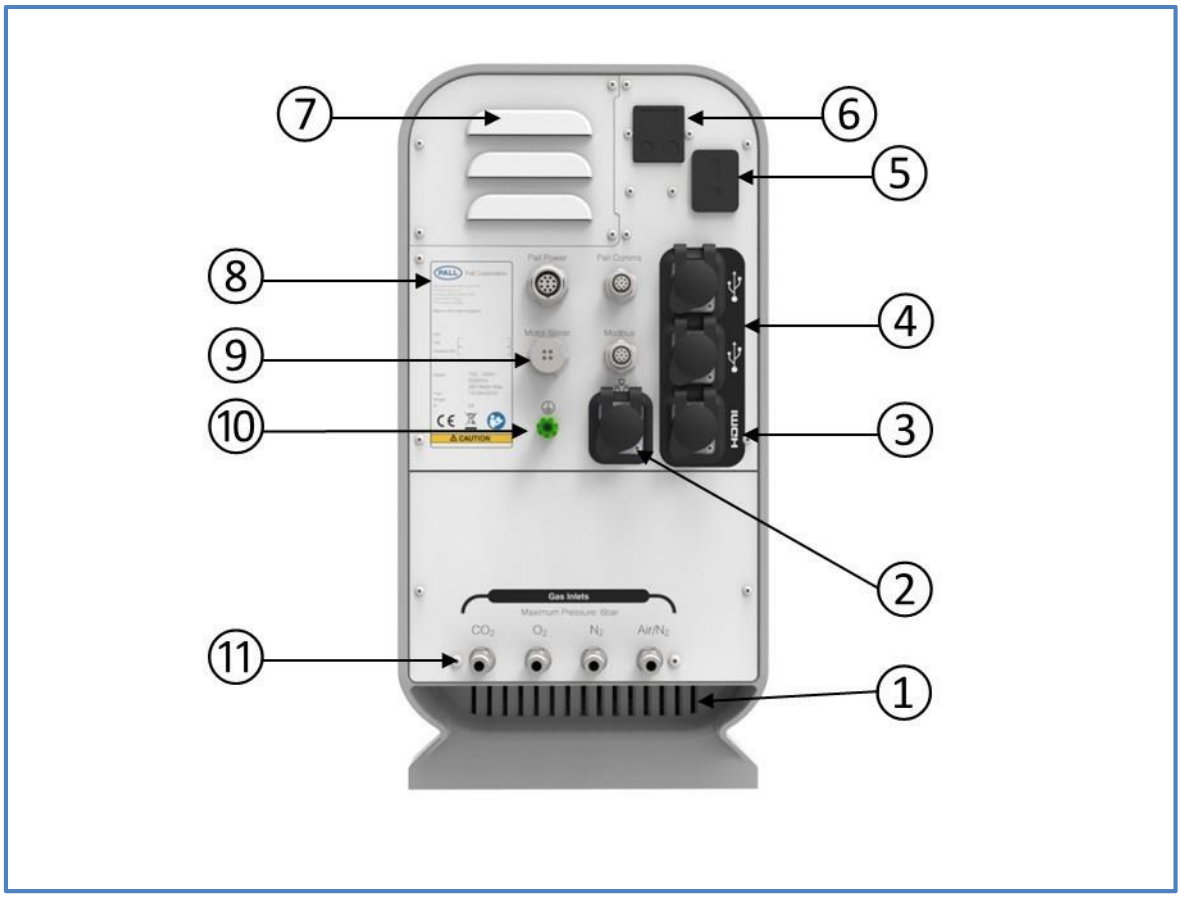


Figure 3: mPath bioreactor control tower rear panel – see key below

	Item	Description
1	Ventilation exhaust	To allow air used for cooling to exit the mPath control tower
2	Ethernet	Network connection
3	HDMI	Monitor connection
4	USB (x2)	Keyboard and mouse connections
5	AC on / off switch	The equipment can be switched on/off using the AC on/off switch on the rear panel
6	AC Inlet and fuse	Power to the equipment is provided through the AC inlet using one of the three supplied detachable power cords (UK, EU or US power plugs)
7	Ventilation inlet	To allow external air to be drawn into the mPath control tower for cooling
8	Product label	Product and safety information
9	Bioreactor connections	Connectors that allow a variety of Pall range laboratory scale bioreactors to interface with the mPath control tower
10	Ground	For peripheral equipment requiring a ground connection
11	Gas inlets	Four 6 mm quick-fit connectors that can be connected to pressurised supplies of air, nitrogen, carbon dioxide and oxygen, 2 (29 psi) - 6 bar (87 psi) supply pressure.

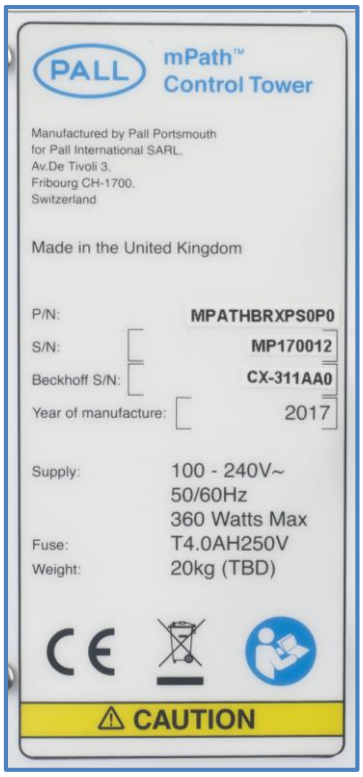


Figure 4: Product safety label

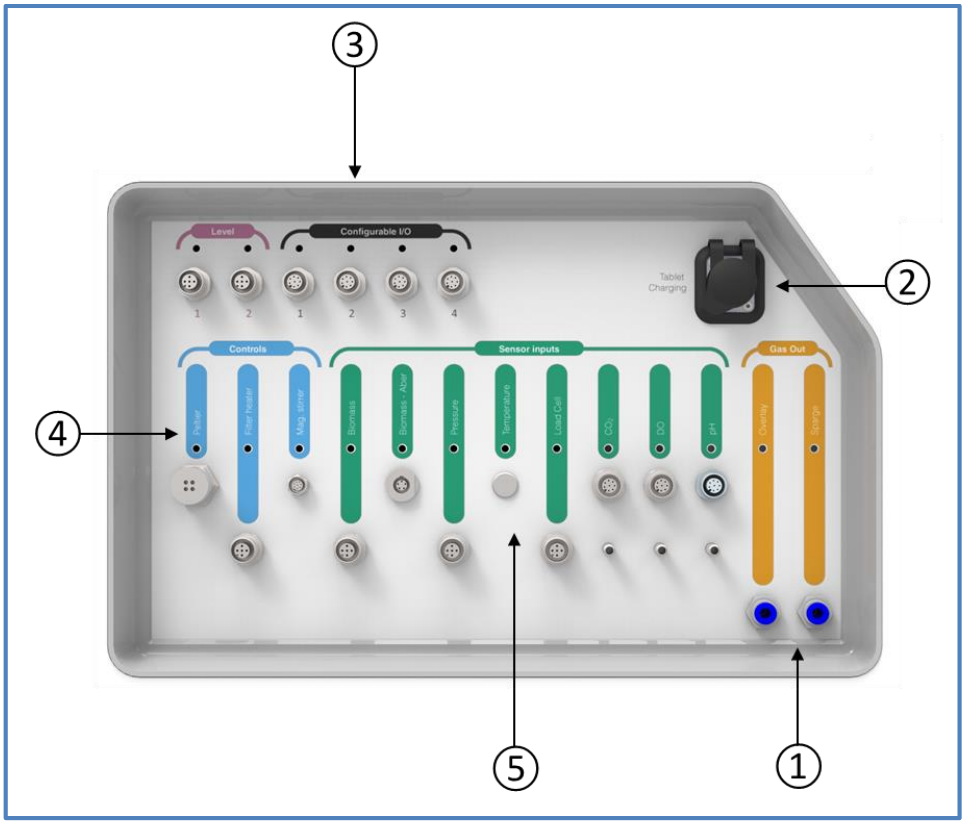


Figure 5: Side panel – see key below

	Item	Description
1	Gas outlets	The control tower provides two gas outlets (Primary and Secondary) which provide a controlled flow/mixture of the inlet gases: Primary provides gas mixes of CO_2, Air/N_2, N_2 and O_2 Secondary provides gas mixes of CO_2 and Air/N_2
2	Tablet charging connection	A USB charging port that can be used to charge a docked tablet is also provided (No data transfer capability)
3	Configurable I/O	The control tower provides four M12 A-coded 8-way female connectors that offer a range of I/O signals
4	Bioreactor control connections	Electrical connections that control bioreactor functions such as heaters and stirring systems Mag Stirrer - 2Mag bioMIX drive stirrer connection Filter Heater - M12, A-coded, 5-way, female connector, 0 - 24 V Peltier - controllable supply for Peltier heater/cooler or resistive heater - output is presented on an M12 T-coded 4-way female connector, 0 to +/-21 V, 0 to +/-4 A.
5	Bioreactor sensor connections	Electrical and optical connections pH and DO – electrochemical and fiber optic CO_2 – electrochemical Load Cell – M12, A-coded, 5-way, female connector, 24 V supply, 1 x 0 - 20 mA input. Temperature – PT 100 Pressure – M12, A-coded, 5-way, female connector, 24 V supply, 1 x 0 - 20 mA input or 1 x 0 - 10 V input Biomass – M12, A-coded, 5-way, female connector, 0 - 20 mA. Biomass – amber biomass Modbus communication

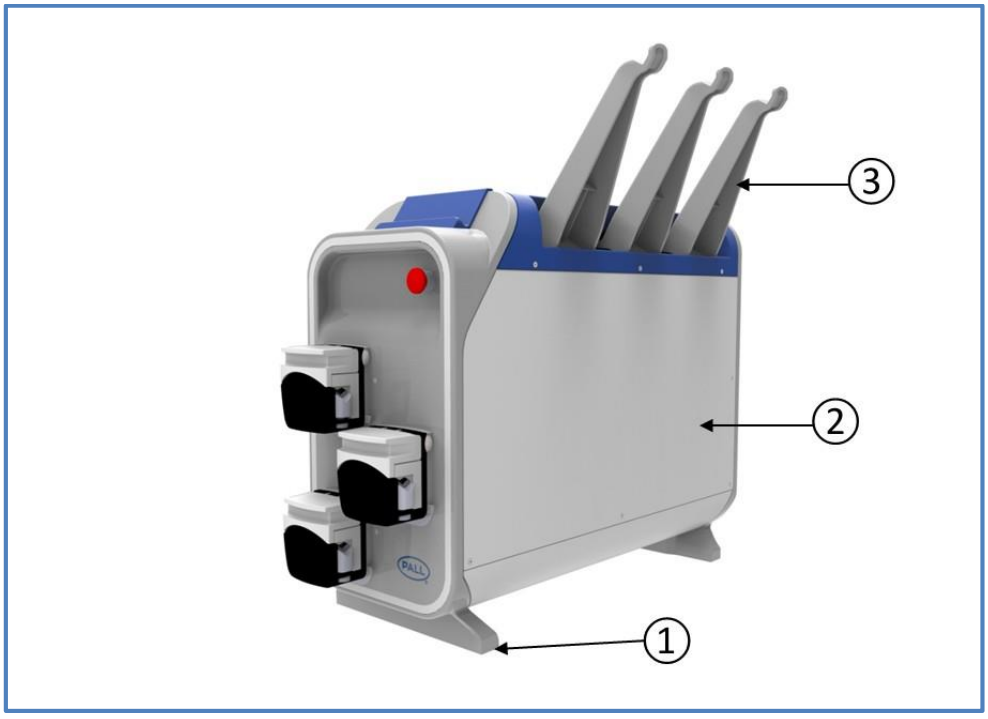


Figure 6: Right side of control tower – see key below

	Item	Description
1	Instrument feet	The instrument is mounted on feet that elevate the instrument to allow access to all surfaces for cleaning and for convenience in routing control cables to bioreactor vessels placed on the opposite side of the controller
2	Maintenance access panel	Pall qualified service engineers can access the control tower through removable panels on both sides
3	Biocontainer weighing system	The weighing system consists of load cells within the instrument and removable hangers that provide a method for monitoring the weight of up to 3 biocontainers – maximum volume 2 liter per biocontainer hanger – maximum total volume 4.5 liters.

4.4. Connecting the mPath Control Tower

ALERT!
Make sure the power is switched off on mPath controller before making connections between controller and bioreactors.

4.4.1. Communications



Figure 7: Rear panel Ethernet connection

1. Ethernet connection

Depending on your choice of network communications determined from the Pall IT Technical Note reference USD 3222:

- Use the Ethernet port on the rear of the mPath control tower and connect it to the appropriate network point via a CAT6 Ethernet patch cable or directly connect to the Pall Link server as shown by the options above.
- Perform the same task with the Pall Link server. Connect CAT6 Ethernet patch cable to the Ethernet port located at the rear of the unit to the appropriate network point.

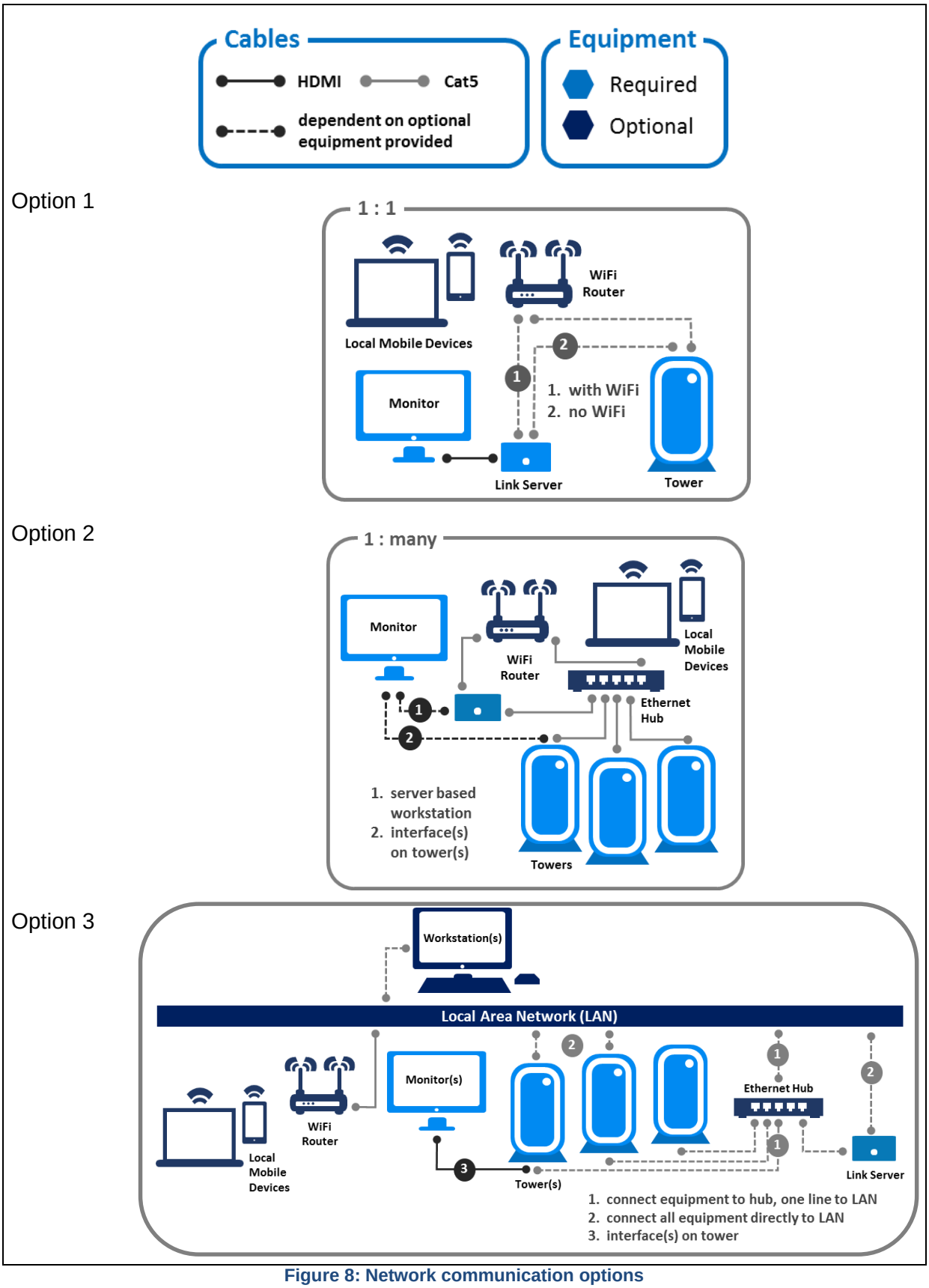


Figure 8: Network communication options

From the instructions in the Pall IT Technical Advisory Note reference USD 3222, the Pall bioreactor installation specialist will use the IP address set by your IT department to configure the mPath bioreactor control tower.

The Pall Link server along with each bioreactor control tower require a unique static IP address when networked. All IP addresses must be within the same domain range. When adding new control towers to an existing Pall Link system, ensure domain ranges match.

If connecting a monitor to the mPath control tower the user should sign in via the user account with password **PallmPath**. It is important to plug the keyboard and mouse in first before making the HDMI connection.

4.4.2. Gas Connections

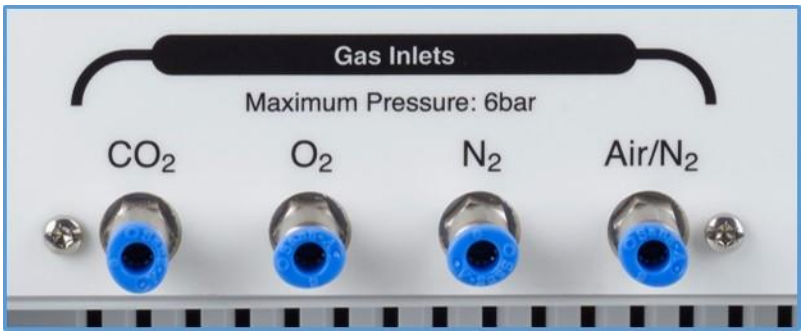


Figure 9: Rear panel gas connections

The gas specifications are described in Section 3.5 Gases.

Using 6 mm, 6 bar rated gas tubing and tubing connectors (optional PN CCTOOLKIT1) gases should be connected from the utilities gas regulators (2 - 6 bar) to the rear panel gas connections on the control system and from the control system to the bioreactor.

Connect the Primary and Secondary outlet ports, if required, from the left hand side of the mPath bioreactor control tower to the bioreactor in use with 6 mm pneumatic tubing.

- Primary provides gas mixes of CO_2, air/N_2, N_2 and O_2.
- Secondary provides gas mixes of CO_2 and air/N_2.

To safely connect gas outlets to the bioreactor gas inlet line, push-to-connect to ¼ inch hose barb connectors should be used (included in PN CCTOOLKIT1).

4.4.3. Rear Panel Bioreactor Connections

Certain permanent connections to your chosen bioreactor are located on the rear panel of the tower. **Connect these at this point.**

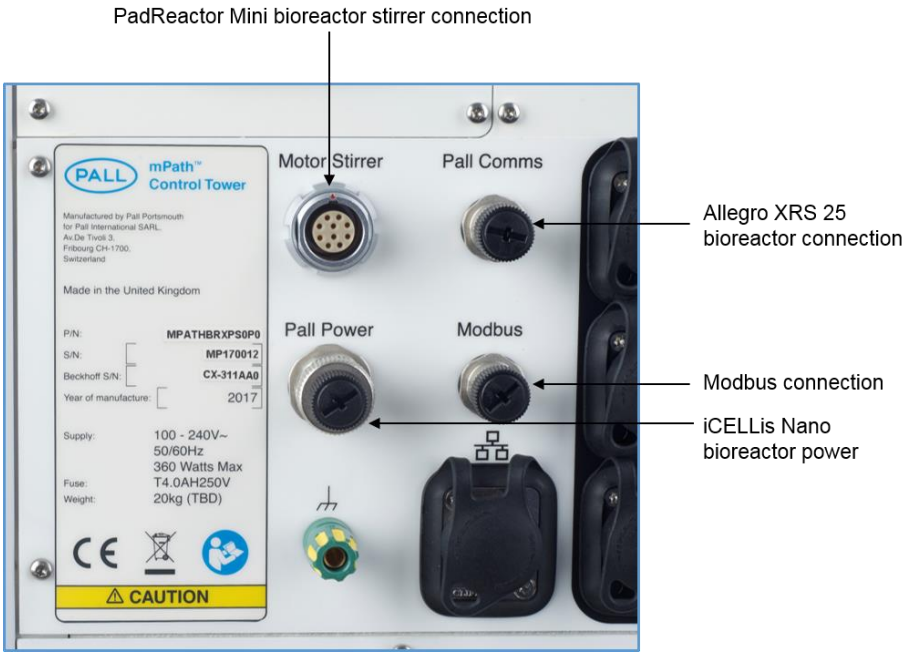


Figure 10: Rear panel bioreactor connections

Allegro XRS 25 bioreactor – Ensure the Allegro XRS 25 bioreactor is powered off before making any connections. Connect the communication cable to the Pall Comms port.

iCELLis Nano bioreactor – Connect the docking station communication cable to Pall Power and connect the Modbus cable to the Modbus port on the rear panel of the mPath control tower.

Note: The iCELLis Nano bioreactor docking station does not have a power button. It will power on once the mPath control tower is powered on.

PadReactor Mini bioreactor – Connect the paddle drive cable to the Motor Stirrer port on the rear panel of the mPath control tower.

Xpansion bioreactor – No connections from the rear of the bioreactor are made.

4.4.4. Side Panel Connections

Ensure single-use bioreactor vessel is installed before proceeding. Please refer to the respective product installation guide for detailed instructions on the required connections. Connect all required inputs and outputs at this point.



Allegro XRS 25 bioreactor system



Xpansion multiplate bioreactor system



iCELLis Nano bioreactor system



PadReactor Mini bioreactor system

Figure 11: Side panel connections

4.5 Power on the Bioreactor Control Tower

After completing the previous steps, connect the control tower AC inlet to an AC supply using one of the supplied detachable power cords (UK, EU or US power plugs). Once the control tower is connected, switch on the power via the AC on / off switch shown in Figure 3.

The status ring on the front of the equipment will flash blue when the equipment is switched on. After approximately 40 seconds the status ring will display a solid blue color.

If the status ring does not show a solid blue color after approximately 40 seconds, refer to Troubleshooting in Section 8.6.

The iCELLis Nano and Xpansion bioreactors will power on together with the mPath controller. The Allegro XRS 25 bioreactor and the PadReactor Mini bioreactor should now be powered on by their respective power switches (see the product user manuals).

4.6 Enabling Network Communications

At this point, network communications between the mPath bioreactor control tower and the Pall Link Server are to be established.

Note: Please ensure you have read the Pall IT Technical Advisory Note reference USD 3222 before proceeding.

Pall Link Windows♦ log in password is Pall Link

The Pall installation engineer will assist during the following steps to ensure that the mPath bioreactor control tower and the Pall Link server are communicating via the IP addresses provided on the network configuration you have chosen.

- Connect a monitor or touch screen to the HDMI port on the rear of the bioreactor control tower.
- Connect a monitor to the HDMI port on the Pall Link server.
- The Pall engineer, using their unique passcodes, will set the IP address and Sub Net mask for the mPath bioreactor control tower that you have provided.
- The Pall engineer will then ensure the Pall Link server is set with the IP address provided.

Note: The Pall Link server does not need to be next to the mPath control tower. It is only required to be on the same network as the control tower.

The software to run Pall Link is pre-installed on a Pall Link server. The Pall installation engineer will show you how to access it. Please consult the Pall IT Technical Note reference USD 3222.

Step 1

- The screen will load to the Control Tower Setup screen. Press “+ New Control Tower” to begin.



Figure 12: Adding a bioreactor control tower

Fields that are mandatory are marked with an asterisk.

Step 2

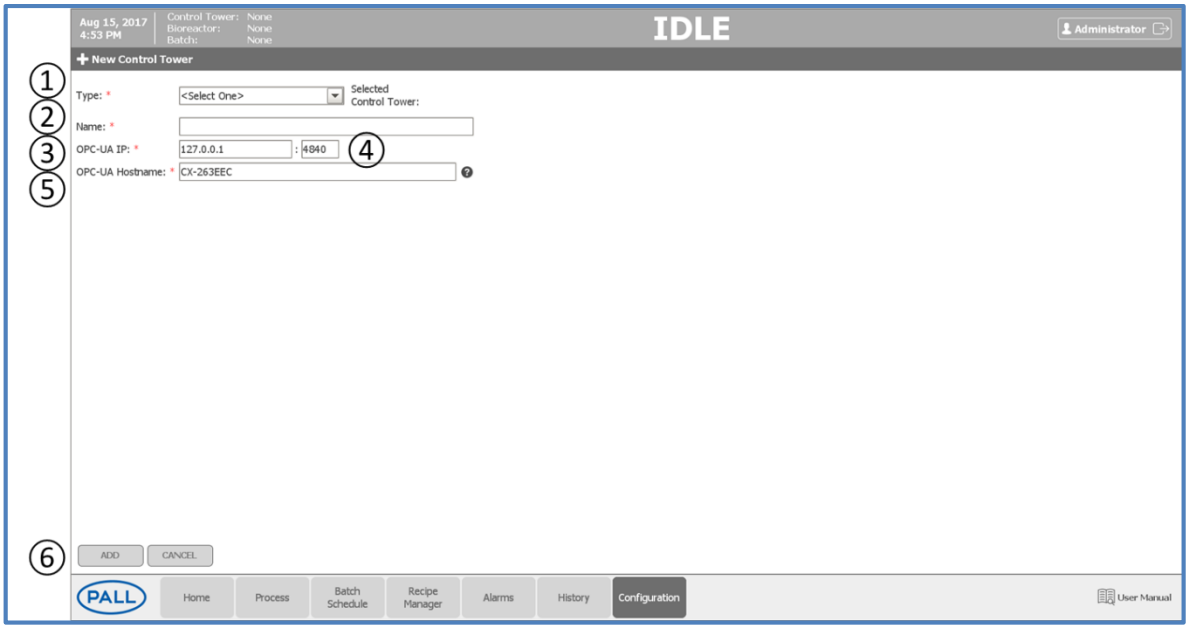


Figure 13: Creating a new control tower

1. Select the correct control tower from the drop down list, either with or without pumps. An image of the selected tower will appear.
2. Give the control tower a name or identifier using alpha-numeric characters.
3. Enter the static IP address generated by your IT department for the control tower for OPC-UA IP.
4. Enter the port, usually 4 digits to the box next to the previously entered IP address.
5. Enter the CX number of the single board computer within the control tower into the OPC-UA Hostname box. (The CX number is located on the rear of the tower. Clicking the ? icon next to the OPC-UA name box shows the location of the CX number).
6. Press “ADD” to save the configuration:
    - An option box will pop up asking if you wish to create a bioreactor.
    - Pressing “No” will return to the Control Tower Setup page.
    - Pressing “Yes” will open the Bioreactor Setup page (Section 4.7).

If you have multiple mPath bioreactor control towers you can add them now by repeating the instructions above.

4.7 Connecting to the Bioreactor System

When the bioreactor has been connected to the control tower, follow the steps below to establish Pall Link communications between the mPath control tower and the chosen bioreactor.

Step 1

- If “NO” was pressed in the instructions above, navigate to the configuration tab, click on Bioreactor Setup and press “+New Bioreactor”

Step 2

- Select the control tower that will control the bioreactor that is being connected from the drop-down list.
- Select the type of bioreactor required from the drop-down list. Options available are Allegro XRS 25 bioreactor, Xpansion multiplate bioreactor, iCELLis Nano bioreactor, PadReactor Mini bioreactor and other*.

- Enter a name for your bioreactor in the name option box.
- To add password access specific to this bioreactor, click the “Yes” tick box and enter in the password of choice. To add specific user access to this bioreactor, click the “Yes” tick box next to Only User Access and select the users to gain access.
- If there is no requirement for a password or specific user access proceed to next step.
- Navigate to the I/O configuration tab by pressing “NEXT” or by selecting the I/O configuration tab.

* *When selecting a bioreactor type from the drop-down list, the other option allows the user to create a fully customizable bioreactor. The user will have an additional option to choose if they wish to use electrochemical or fiber optic sensors.*

Step 3

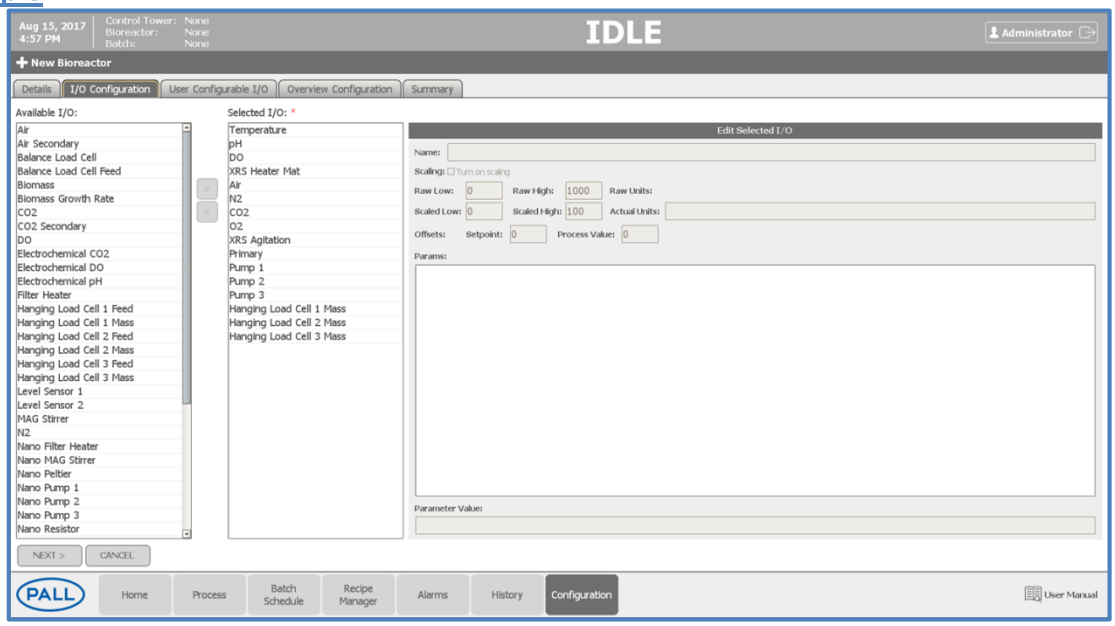


Figure 14: Configuring bioreactor I/O

The selected I/O list will populate based on the bioreactor that was selected in the previous tab. To allow the user to customize their batch, the name of the I/O can be changed in number 1, the attached I/O can be scaled in number 2 and there is an option to create an offset on setpoint and present value as shown in number 3 (Figure 15: Scaling of I/OFigure 15).

To scale the I/O (Figure 15):

- Click the ‘Turn on scaling’ check box.
- The raw low and high values will be present as per the raw values of the I/O.
- Use the scaled low and high boxes to define scaling for the unit of measurement of the sensor. e.g. To change Air flow rate from mL/min to L/min, Raw low = 0 mL/min, Raw high = 1000 mL/min, scaled low = 0 L/min, scaled high = 1 L/min.
- The offset feature will scale the setpoint or process value to a set positive or negative value. Example, a heater mat setpoint of 20 °C with an offset of + 1 °C means that the heater mat will show 20 °C but will actually be heating to 21 °C.
- If an offset is required on setpoint or process value, enter in the positive or negative offset amount into the fields shown by number 3. The offset will be applied to the inputted setpoint or process value!

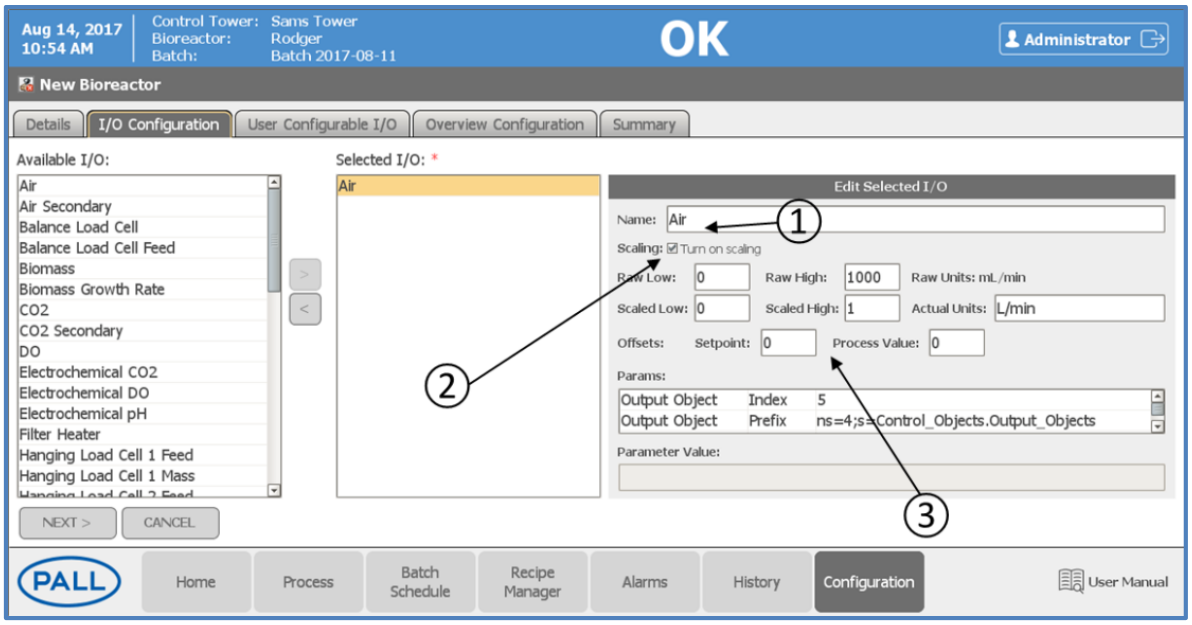


Figure 15: Scaling of I/O

The Allegro XRS 25 bioreactor temperature input has a default offset of +0.5 °C because the PT100 which monitors fluid temperature is outside of the biocontainer. At 25 L the distance between the PT100 and the fluid inside the biocontainer causes a temperature offset of 0.5 °C. The fluid is required to be maintained at 37 °C, therefore the default setpoint offset of 0.5 °C allows the fluid temperature to remain at 37 °C whilst the heater mat is actually heating to 37.5 °C.

Offsets for lower operating volumes will need to be calculated by the user. **PID terms may also need to be re-calculated.**

- To add extra I/O, select the control element in the left-hand column and press the “>” button to move it to the selected I/O column.
- To remove any selected control elements, press the “<” button.
- Biomass, Biomass growth rate, Level sensor 1, Level sensor 2 and Pressure require additional configuration as these connections are customer specific.
    - If any of the above are required, select them and move to the selected I/O column.
    - Click the ‘Turn on scaling’ check box.
    - Enter the raw low and high values from the table 4 into the raw low and high boxes. Press “enter” after each entry.
    - Use the scaled low and high boxes to define scaling for the unit of measurement of the sensor. E.g. Mag Stirrer, Raw low = 0 V, Raw high= 10 V, scaled low = 0 rpm, scaled high = 250 rpm. This means that at 10 V the Mag stirrer will be rotation at 250 rpm.

Table 4: I/O Raw low and Raw high values

I/O	Raw Low	Raw High
Biomass	0 mA	20 mA
Biomass growth rate	0 mA	20 mA
Level 1	0 mA	20 mA
Level 2	0 mA	20 mA
Pressure	0 mA	20 mA
Pressure	0 V	10 V

- Navigate to the User Configurable I/O tab by pressing “NEXT” or selecting the User Configurable I/O tab. (If no additional I/O are being added proceed to Step 5).

*A full I/O list can be found in Appendix C.

Step 4 – Creating User Configurable I/O (Inputs/Outputs)

These ports can be used to connect inputs such as sensors or switches and outputs such as additional pumps or balances.

- Four user configurable I/O are available for selection. Each configurable I/O connection is a M12 A-coded 8-way female connector.
- M12 A-coded 8-way male connectors (user supplied) will be required to connect to these ports.
- Each port can be configured as either analog or digital.
- Each port can also be configured as an input or output.
- The pins are set according to the Table 5.

Table 5: User configurable I/O connection pins

Pin Number	Signal	Values
1	Digital output	24 Volt
2	Digital input	24 Volt
3	Ground	0 Volt
4	Analog input	0 - 10 Volt
5	Analog input	0 / 4 - 20 mA
6	Analog output	0 - 10 Volt
7	Analog output	0 / 4 - 20 mA
8	Screen	None

- Pin 1 can be used as either a 24 V digital output or power source to an external sensor. Pin 3 is the 0 V reference/return for all I/O signals.
- Select from the drop down list under each I/O what type of signal is required.
- Set a I/O name.
- Select the ‘calculate scaling’ icon  and enter in the raw low and high scale of the item being connected. E.g. Raw Low = 0 mA and Raw High = 20 mA.
- Below enter in the scaled low and high values required, eg: low = 0 and high = 1000
- Press close and then enter the units required. As per the example about the units would be grams.
- Repeat for the remaining configurable I/O if required.
- Press “SET CONFIGURABLE I/O” button.
- Navigate to the Overview Configuration tab by pressing NEXT or pressing the Overview Configuration tab.
- If no user configurable I/O is required, navigate to the Overview Configuration tab.

If a PadReactor Mini bioreactor is being configured, you must select ‘PadReactor Mini Temperature’ from the drop-down list on User Configurable 1. Once selected, the screen will show In, Out and Digital Out. This configuration allows control of the heater mat around the PadReactor Mini bioreactor from the mPath control tower.

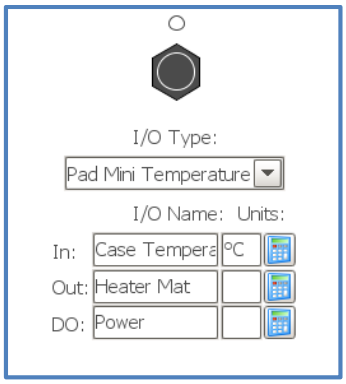


Figure 16: PadReactor Mini bioreactor user I/O configuration

Step 5

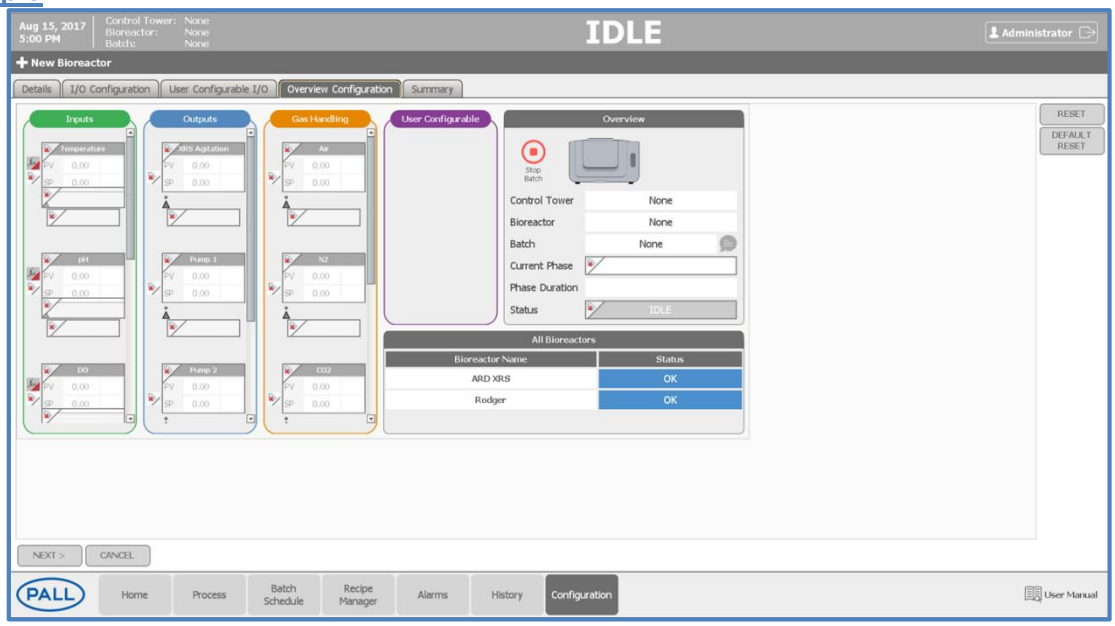


Figure 17: Overview configuration

The Overview Configuration screen allows customization of the appearance of selected display boxes.

- Display boxes can be moved around and resized to meet the user's needs by:
  - Clicking the display box and dragging it.
  - Clicking the display box and resizing using the double-headed arrows.

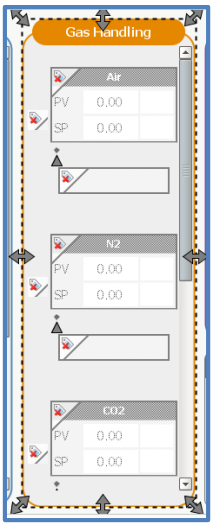


Figure 18: Configuration of control elements

- Reordering of the control elements within the display boxes can be achieved via the Process Overview screen once an experiment/batch has been started.
- Once customization is complete, press “NEXT” or select the Summary tab to complete bioreactor set up.

Step 6

- A review of the settings selected in the previous steps is shown.
- Three options are presented:
    - Save – The configuration is saved and the user is returned to the bioreactor set-up page.
    - Save and View Overview – The configuration is saved and the system navigates to the main process screen where a default recipe will be loaded and an experiment/batch started (Section 5.3).
    - Cancel – The configuration will not be saved and user will be returned to bioreactor set up page.

4.8. Editing and Deleting Control Towers and Bioreactors

4.8.1. Editing a Previously Created Bioreactor Control Tower

- Navigate to the control tower set up screen via the Configuration tab.
- Press “SELECT” on the control tower you wish to edit.
- Make the changes required and press “SAVE”.

4.8.2. Removing a Bioreactor Control Tower

- Navigate to the control tower set up screen via the Configuration tab.
- Press “SELECT” on the control tower that is to be deleted.
- Press the “REMOVE” button and confirm the pop up message.

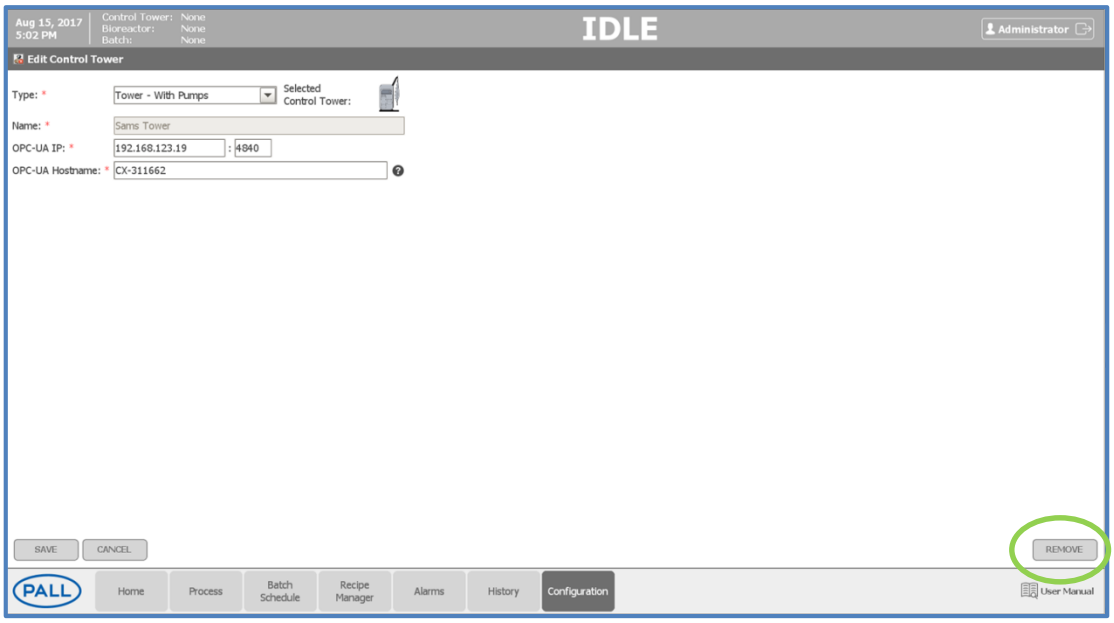


Figure 19: Removing a bioreactor control tower

4.8.3. Editing a Bioreactor

- To make changes to a bioreactor, navigate to the Configuration tab and click on “Bioreactor Setup”.
- Press “SELECT” on the bioreactor to be edited.
- Make the changes require and press “SAVE”.

4.8.4. Deleting a Bioreactor

- To delete a bioreactor, navigate to the Configuration tab and click on Bioreactor Setup.
- Press “SELECT” on the bioreactor to be deleted.
- Press the “REMOVE” button and confirm the pop up message.

4.9. Fluid Handling

- The mPath bioreactor control tower can be delivered with or without peristaltic pumps depending on the bioreactor being connected to the tower. If the pump option is chosen, peristaltic pumps can present a pinch hazard if the mechanisms are open when operational.



- Peristaltic tubing should be checked regularly for damage and only be loaded into or removed from the peristaltic pumps when the equipment is powered off to prevent injury due to moving parts.
- Follow the appropriate MSDS guidelines for the safe handling of fluids used with the equipment.



- DO NOT place containers with fluids on top of the equipment.
- If fluid is spilt on the equipment, disconnect the equipment from the electrical supply via the cord supplied. Wipe the fluid off the equipment using a dry cloth. If it is believed that fluid has entered the equipment, then contact Pall for advice.

5. User Interface Interaction

5.1. User Interface Overview

Next is described how to establish communications and interact with the Pall Link user interface. The screen layout is divided into three main layers (Figure 20):

1) **Header**: Status bar
2) **Main window**
3) **Footer:** Navigation pane

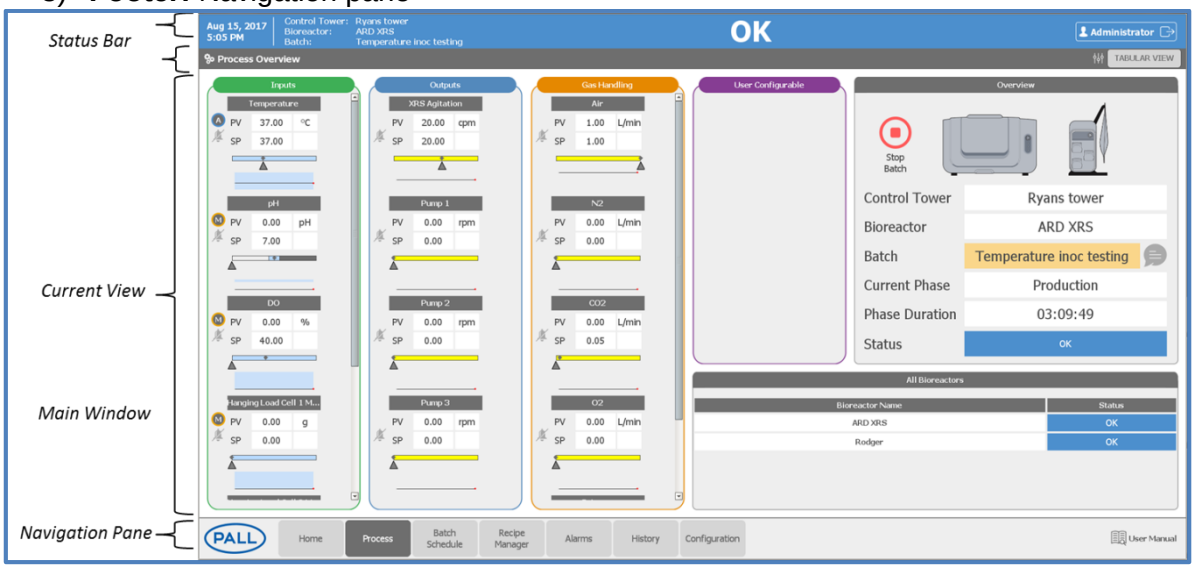


Figure 20: User interface overview

5.2. User Management

Pall Link Windows log in password is ***PallLink.*** If connecting a monitor to the mPath control tower the user should sign in via the user account with password ***PallmPath***.

Pall Link comes with the option of enabling or disabling good manufacturing process (GMP) mode. This mode allows Pall Link to be either set up with user roles which have specific rights or to be open to all created users. Upon receipt of Pall Link, GMP mode is set to off.

Pall Link has 3 default users created, Administrator, Operator 1 and Supervisor 1.

Table 6: Defined user passwords

User Name	Password
Administrator	Palladmin
Supervisor1	Pallsuper
Operator1	Pallop

Operator and Supervisor do not have access to user management or system settings. Please refer to the table in Appendix D for full list of user rights.

5.2.1. Adding / Deleting Users

The administrator user can only be used to add, edit or delete users.
To create a new user:

- Navigate to the “User Management” tab via “Configuration”.
- Press the green ‘+’ button on the right-hand side to open the “Add User” screen.

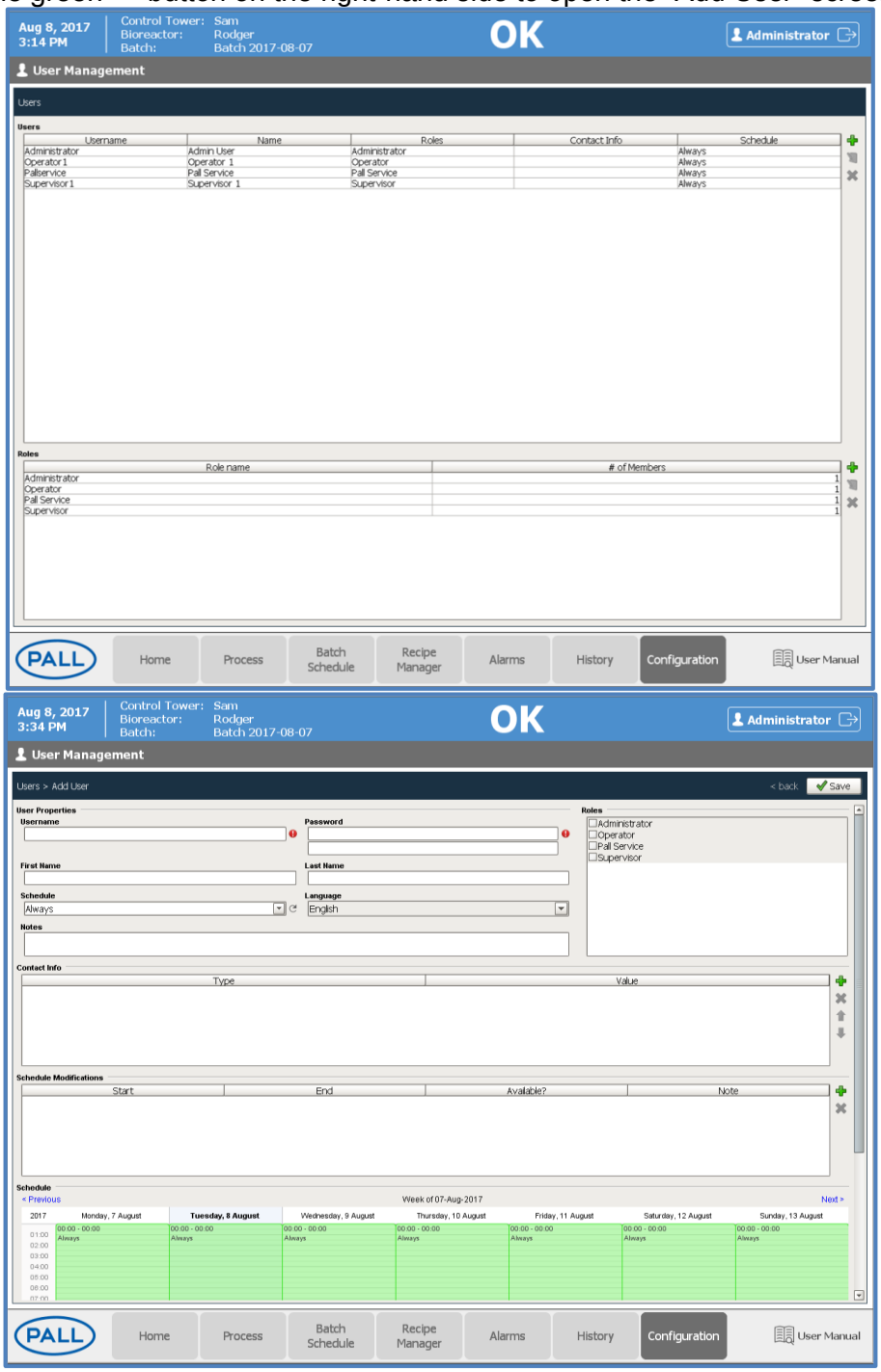


Figure 21: Adding users

- Enter a Username.
- Select the Role for the user from the right hand column.
- Create a password for the user.
- Click the “Save” button.

To edit an existing user:

- Double click on the user name or press the edit icon to open the selected user.
- The password and user roles can be changed but the user name cannot.
- Click the “Save” button to save the changes.

To delete an existing user:

- Highlight the user to be deleted from the user list and press the red ‘x’ button.
- A confirmation box will pop up before the user is deleted.

5.2.2. Non GMP Mode

When non GMP mode is activated all screen elements are open to view and edit by an Administrator user. Operate and Supervisor users can view and edit all screen elements except user management and system settings. In this mode the audit trail is updated with every change.

5.2.3. GMP On

To enable or disable GMP mode you will need to be signed in as an Administrator.

- Navigate to “Configuration” and the select “System Settings”
- Select Admin and then GMP.
- Switch the toggle to mode “On” and press “SAVE”.



Figure 22: GMP activation

When enabled each element appears with a grey padlock to show the user that GMP mode is on.

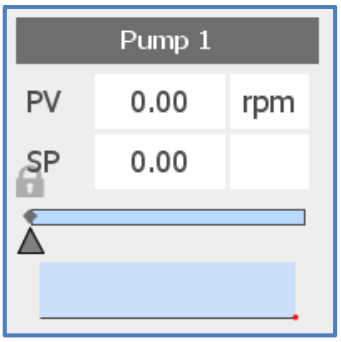


Figure 23: GMP activated showing locked elements

In this mode the Administrator can only access system settings and user configuration.

Supervisor does not have access to system settings or user configuration but can schedule batches, write recipes, change setpoints, calibrate, create and edit trends and export data.

The operator does not have access to system settings or user configuration but only has rights to start a scheduled batch and monitor the batch by view only on certain screens.

For more details, refer to the table in Appendix D for full list of user rights.

5.3. Quick Start Experiment / Batch – from a Pall Default Recipe

The mPath bioreactor control tower software has been designed to allow as much or as little customization as the user wishes.

The software includes standard default recipes for each supported bioreactor. The default recipes can be viewed, edited or duplicated. Using or editing a default recipe reduces set up time allowing an experiment/batch to be run quickly with little configuration.

The other option is to create a new recipe. (For instructions on creating a new recipe see Section 6.1).

5.3.1. Running an Experiment / Batch from a Pall Default Recipe

After connecting a bioreactor in Section 4.7, if Save and View Overview was chosen as a save option in Step 6, the main process screen will load with a default recipe specific to the chosen bioreactor, and the experiment/batch will be **started** automatically. Alternatively, you can find default recipes in the recipe manager (Section 6.1).

The default recipe loaded allows the user to set setpoints, select control options and alarms manually. All control is as per the created recipe. Default recipes can be edited as is descried in Section 6.1)

5.3.2. Calibration

- Navigate to I/O Calibration tab from the Process Overview tab and enter in the calibration parameters required for your process. Press Enter key after entering each parameter.
- Once entered press Calibrate button. Calibration can take up to 30 seconds to complete on pH and DO.
- Navigate back to the Overview screen.

(Calibration can also be found on certain control element pop up views).

5.3.3. Control Element Parameter Setting

- Clicking on any of the control elements and its pop up screen will allow the user to enter setpoints and other desired parameters.
- Click on the “Manual” button to activate manual control or select a control parameter linked to the input.
- Press the close button to exit out of the pop up.

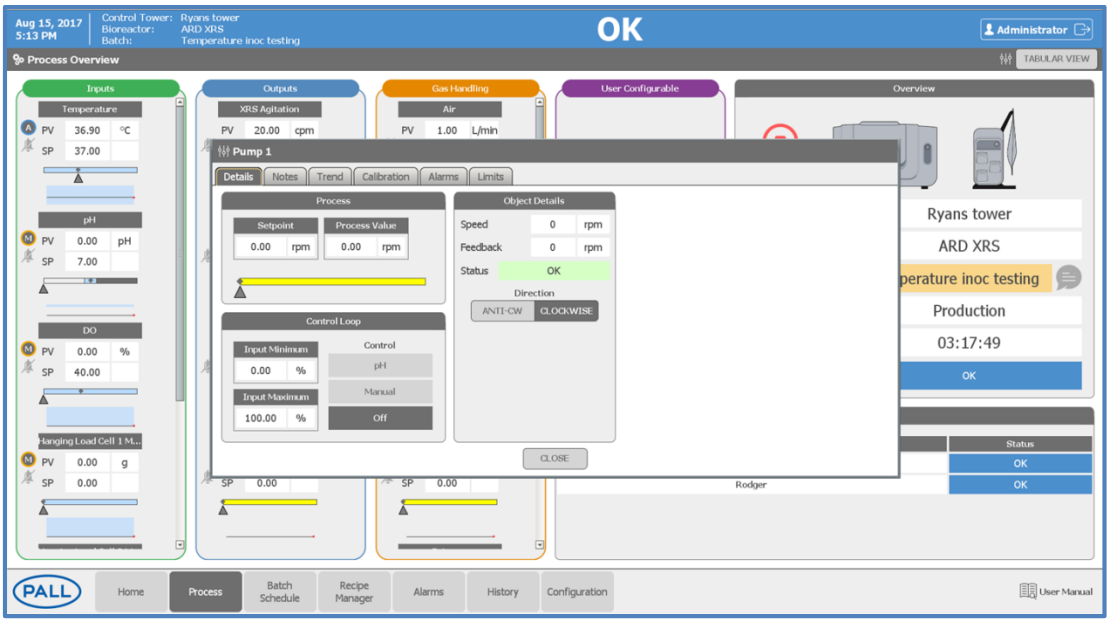


Figure 24: Control element parameter settings

5.3.4. Trending

- To display data, select the Process Tab and navigate to the Trends tab.
- The Trends tab displays customizable trending explained below.
  - The “All Tags” tab allows the user to trend any parameter.
  - Select from the drop down filter the parameters required. All parameters can be selected to view.
  - Scroll through the listed parameters and click in the check box next to a parameter, to automatically plot the trend. To change color of the trend line, click the colored box on the left hand side of the selected parameter and select a color from the pallet displayed.
  - Multiple trends can be plotted on the same graph.
- To return to the overview screen, navigate to the Process Overview.

Table 7: Trends tab display button overview

Button	Functionality
	Filter option allowing the user to configure a list of parameters to trend
	Toggle between all the trends on one graph or split into multiple
	Click this button and then click the trend line to add a vertical read line to the trend
	Zoom functionality. Click on the “+“button and then select an area to zoom on the graph by dragging a box The “–“(zoom out) button can be pressed to zoom out
	Click this button and then click the trend line to add a cross read line to the trend
	Pressing this button will clear all read lines added to the trend
	Auto scaling options

	Stop or run a live trend
	Toggle between real time or calendar view
	Click this button to export trended data

Note: Trending live data for a batch/experiment which has been running for many days can cause delays when loading the data to the trend screen. To prevent this press the “Stop” button at the top of the trend screen and select the data to trend.

5.3.5. Overview Configuration

- A tabular view of the Process Overview screen can be selected by pressing the “tabular view” button located in the top right hand corner of the screen.
- To rearrange the order of the on screen elements, click the  icon in the top right hand corner, select the element to move and click UP or DN. Upon closing the elements will re-order.

5.3.6. Export Data

- To export trended data, navigate to the trends tab, select the parameters to be trended and press the save icon.
- The save icon will present two options:
  - Natural – data recorded every 30 seconds.
  - Raw – raw data recorded when data points are changing. If data points are changing the log rate is approx. every 5 seconds.
- Select an option then select a save location.

5.3.7. Experiment / Batch Stop

- To stop the experiment/batch, press the stop batch button. A prompt to enter a comment will be displayed on screen.

6. Operation

6.1. Configuring Recipes

Recipes allow the user to run experiments/batches using customized control loops, parameters, alarms and trends. Control loops, setpoints, alarm values and trend parameters are all created within the recipe manager.

The software holds default recipes which can be used once the bioreactor and control tower have been installed. The default recipes can be viewed, edited or duplicated. Using or editing a default recipe reduces set up time allowing an experiment/batch to be run quickly with little configuration.

If a fully customized process is required, a new recipe can be created. Once a recipe has been created, it can be edited, duplicated, retired or removed.

6.1.1. Creating a New Recipe

Creating a new recipe should only be undertaken by experienced users.

Step 1

- Navigate to Recipe Manager.
- Select “new”.
- Select a bioreactor from the drop-down list to run this recipe. *(Only previously created bioreactors will show in this list. If a bioreactor is not present, please refer to Section 4.7 before proceeding).*
- The recipe must be given a name or identifier; a revision can be set along with a description if required.
- Select the state of released, retired or unreleased from the drop down.
- Navigate to the Control loop configuration tab by pressing “NEXT” or by selecting the control loops tab.

Step 2 – Control loop configuration

- Allowable parameters (input objects) will self-populate. The input objects in the list are linked to the I/O that was selected when the bioreactor was created.
- Once an available input object has been selected a list of available slave outputs will populate.
- From the list, select a control action (slave output) to move to the positive or negative columns. For positive control, the control action will increase the parameter under control from the present value towards the setpoint. For negative control, the control action will decrease the parameter under control from the present value towards the setpoint.
- Multiple control actions can be added to the positive or negative columns. The Up and Down (Dn) buttons are used to set the priority of the control parameters.
- Navigate to I/O Values tab by pressing “NEXT” or the I/O Values tab.

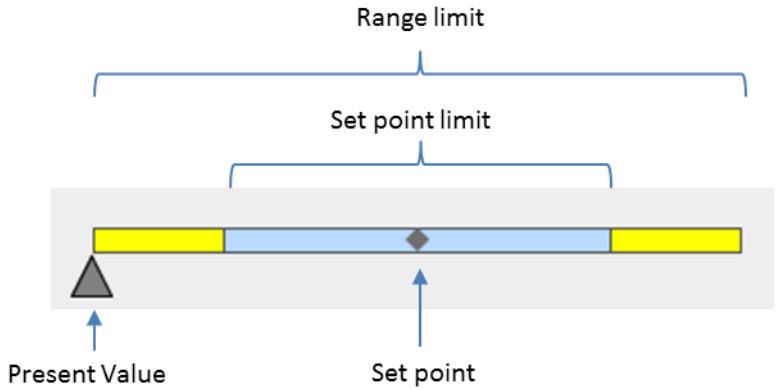
Step 3 – Control parameter data entry

The I/O values screen is used to enter setpoints, range and alarm values for each of the selected I/O. The values set here will automatically load once the recipe is selected when an experiment/batch is started.

- Click on a parameter in the table, it will highlight grey and then enter the desired value into the value box.

- The value is saved by pressing “enter”. The value can be changed by re-selecting the box; entering a new value and pressing “enter”.
- Below is a table describing each parameter.

Table 8: I/O Values screen displays overview

Tab	Parameter	Description
Setpoints	Units	Enter the units required for the specific control parameter
Setpoints	Setpoint/ setpoint value	Enter the control setpoint that is required once the experiment/batch is started
Setpoints	Process limit setpoint low	This value creates a low visual indicator on the progress bar of each I/O
Setpoints	Process limit setpoint high	This value creates a high visual indicator on the progress bar of each I/O
Setpoints	Process limit range low	This value depicts a range bar on the process screen allowing quick visualization showing how close or far away the process value is from the set point
Setpoints	Process ;limit range high	Like above but this setting completes the range bar
		
Setpoints	Input maximum	100% for single control action
Setpoints	Input minimum	0% for single control action
Setpoints	Output maximum	This allows the user to set the maximum output of a parameter. For example, oxygen gas has a maximum flow rate of 1 L/min but the user can set it to 500 mL/min using the output maximum
Setpoints	Output minimum	This allows the user to set the output minimum of a parameter
Setpoints	Name	The user can give a specific name to each I/O
PID	KD	Enter the value required for derivative control of the PID loop
PID	KI	Enter the value required for integral control of the PID loop
PID	KP	Enter the value required for proportional control of the PID loop
Alarms	Process value alarm low setpoint	This value depicts a portion of the range bar showing grey for alarm limits and yellow when the process value falls into this band. For example, using a temperature setpoint of 37 °C, the process value alarm low setpoint could be 30, allowing the visual indicator to show an alarm range from 20 °C - 30 °C
Alarms	Process value alarm high setpoint	This value depicts a portion of the range bar showing grey for alarm limits and yellow when the process value rises into this band. For example, using a temperature set point of 37 °C, the process value alarm high setpoint could be 38, allowing the visual indicator to show an alarm range from 38 °C - 40 °C
Alarms	High high/ high/ low/low low alarm deadband	Once triggered, the alarm will only become untriggered once the present value crosses the set point + the set deadband
Alarms	High high/ high/ low/low low alarm display path	User can create their own alarm identifiers. If text is entered into this field it will display in the alarm list if that alarm occurs

Alarms	High high/ high/ low/low low alarm Off delay	User configurable. Minimum time that the 'alarm off' condition needs to be met before the alarm transitions to the untriggered state in milliseconds
Alarms	High high/ high/ low/low low alarm On delay	User configurable. Minimum time that the 'alarm on' condition needs to be met before the alarm transitions to the triggered state in milliseconds
Alarms	High high/ high/ low/low low alarm priority	Options of diagnostic, low, medium, high or critical
Alarms	High high/ high/ low/low low alarm setpoint	Enter a setpoint where the alarm will be activated if the setpoint is reached
Alarms	High high/ high/ low/low low alarm suppressed	The user is presented with the option to suppress alarms
Alarms	High high/ high/ low/low low alarm variable	This shows the present value of the control parameter
Object Specific	Direction	Pumps – clockwise or anti-clockwise
Object Specific	Speed	This is the raw speed value being reported from the control parameter
Object Specific	Max X angle	Set the maximum angle of the X axis on the Allegro XRS 25 bioreactor platform
Object Specific	Max Y angle	Set the maximum angle of the Y axis on the Allegro XRS 25 bioreactor platform
Object Specific	Park X angle	Set the park angle of the X axis on the Allegro XRS 25 bioreactor platform
Object Specific	Park Y angle	Set the park angle of the Y axis on the Allegro XRS platform

- Once all the setpoints are entered, select the Alarms tab and complete as required.
- Repeat for the PID and object specific tab if required.
- Move onto the next control parameter and repeat.
- Navigate to the Trends tab by pressing "NEXT" or by clicking the trends tab.

Step 4 – Trend configuration

Within the recipe set up a trend can be created which will be plotted every time the recipe is used.

If trends are required specific to the recipe they can be created in the following steps. If not proceed to the Summary tab.

- Give the trend a name in the trend name box.
- X and Y axis name boxes can both be edited.
- Press "ADD".
- Once added, a list of parameters is created. Click on a parameter to establish a trend and select data points for the trend.
- Once selected navigate the three tabs, Process Values, Object Specific and Alarms to select a parameter to plot.
- Once selected press "ADD TAG".
- The name, color, line style and shape can be changed. (See Section **Error! R eference source not found.**)
- Multiple data points can be added from multiple control parameters to the same graph if desired. (See Section **Error! Reference source not found.**).
- To create a new trend press "ADD NEW TREND" and repeat steps above.
- Once finished navigate to the Summary tab or press the Summary button at the bottom of the screen.

Step 5 – Completion

- The user will be given four options:
  - Save (The recipe will save and return the user to the recipe manager).
  - Save and schedule* (Scheduling opens a calendar view with a pop up prompting the user to plan a time to run the recipe at a later date).
  - Save and Run (Saves the recipe and opens up a check screen before an experiment/batch will begin).
  - Cancel (Returns to recipe manager screen. Recipe is not saved).

**Scheduling an experiment/batch to run on a specific date is to allow users to plan equipment availability and resources, the experiment/batch will not start automatically on the selected date.*

6.1.2. Editing and Duplicating a Previously Created Recipe

Default recipes can be viewed and the parameters can be changed to suit user processes. Editing recipes is a rapid method allowing an experiment/batch to be run quickly with little configuration.

- Navigate to Recipe Manager.
- Select the recipe you wish to view, edit or duplicate by clicking on it. The recipe will highlight.
- Click “view, edit or duplicate”.
- Edit allows the user to make changes to a current recipe but upon acknowledging those changes the recipe will be saved as the next revision.
- Duplicating a recipe allows the user to make changes but upon acknowledging those changes the recipe must be saved under a different name. The revision will be set at revision 1 for the new recipe. The original recipe will remain unchanged.

6.1.3. Removing or Retiring a Previously Created Recipe

Recipes can be removed or retired from the listed view by selecting the desired recipe and pressing either “REMOVE” or “RETIRE”.

Remove acts as if the recipe is deleted but it will remain in the database and can be found by selecting removed from the filter column.

Retire allows the user to hide the desired recipe from the recipe list. The recipe is not deleted and can be found by selecting retired from the filter column.

6.1.4. Search Feature within Recipe Manager

Saved recipes may be searched using the search filter to the left hand side of the recipe manager screen. By selecting from the filter options detailed below the recipe list will update for a concise view.

There are four search options:

- **Bioreactor** – This option allows the user to search for recipes created for a certain bioreactor. Select the bioreactor from the drop down box.
- **State** – The user can search for released, unreleased, retired or all recipes. Select the state required and the recipe list will update.
- **Add by** – Recipes created by the current or other users can be viewed by selecting either Me or All.
- **Removed** – Locate previously removed recipes. Click either Yes or No under the removed option.

6.2. Starting an Experiment / Batch

Experiments / batches may be scheduled for the future or started immediately. In Section 5.3 and 6.1 the options to do a quick start based on a default recipe or after new recipe creation was already described. Here is described how to schedule and start a default recipe, a recipe which has been saved or that has been saved and scheduled during the recipe creation process.

6.2.1. Scheduling an Experiment / Batch Linked to a Recipe

The scheduling view allows users to create experiments/ batches linked to previously created recipes which can be scheduled from the current time or scheduled for use in the future.

Note: The experiment/ batch will not automatically start on its scheduled time. The user must select and start the experiment/batch.

The scheduling view allows lab custodians or lab users to plan experiments/batches, view usage on bioreactors and schedule resources.

- Click on the Batch Schedule tab. *(Not required if save and schedule was chosen when creating a recipe)*
- The schedule screen has 4 views:
    - Table – Tabular view of created experiments/batches.
    - Day – Current selected day view.
    - Week – Current selected week view.
    - Month – Current selected month view.

In table view, date selector boxes on the left-hand side of the screen allow the user to view a period of time by selecting a start date in the top box and an end date in the bottom box.

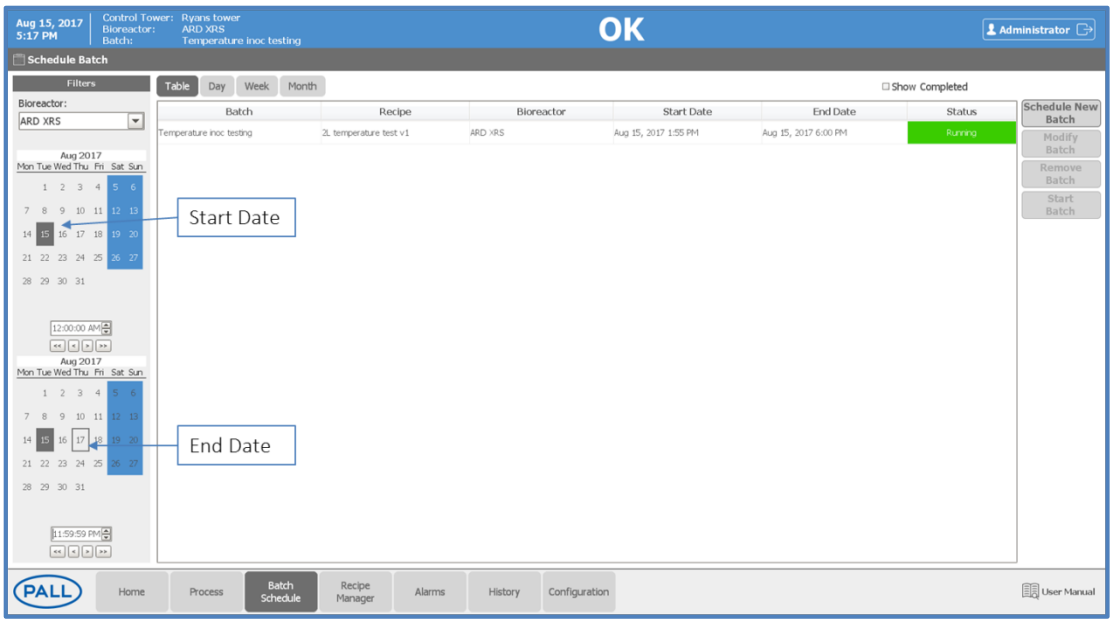


Figure 25: Schedule view – table tab

In Day, Week and Month views the date selector box can be used to select required dates of view.

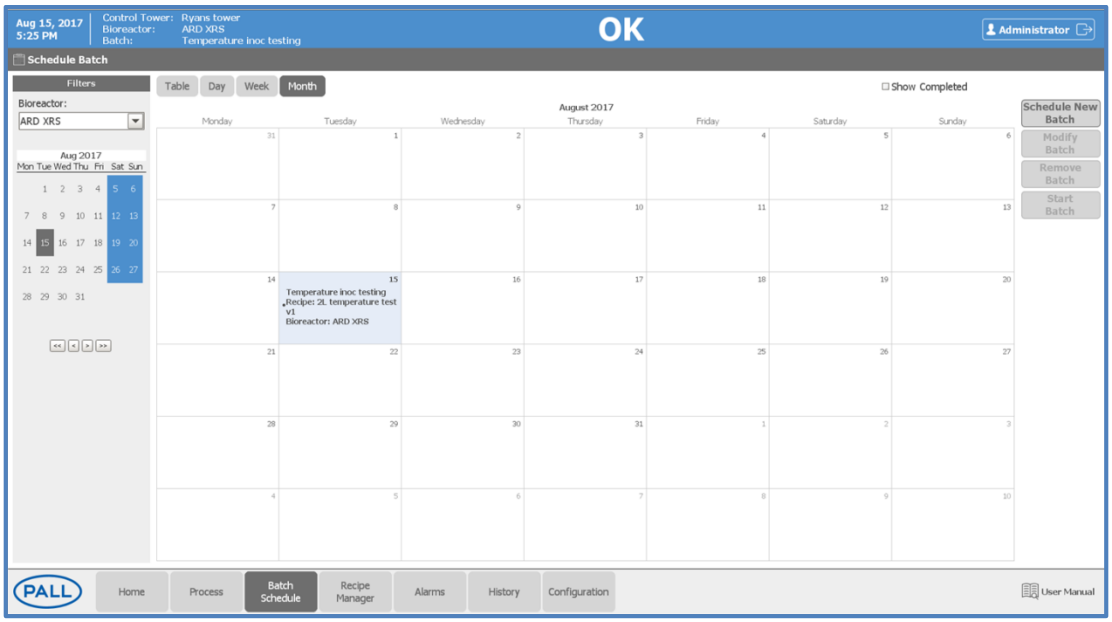


Figure 26: Schedule view

- Click “Schedule New Batch”. A pop up will appear. *(Not required if save and schedule was chosen when creating a recipe).*

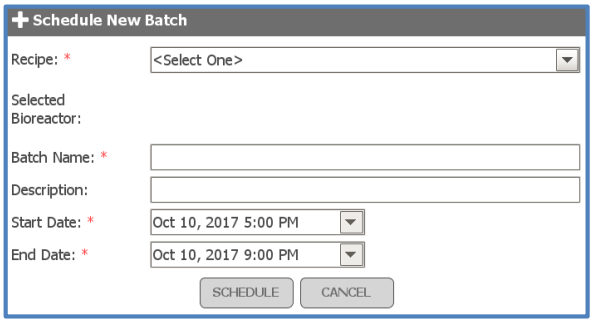


Figure 27: Schedule new batch pop up

- Select a recipe from the drop down list. *(Note: Only recipes that have been created will appear here).*
- An image of the bioreactor and control tower will appear beside selected bioreactor.
- Enter an experiment/batch name in the batch name option box.
- A description in the description box is not required to run the experiment/batch but may be used to add extra information for operators.
- Schedule a start and end date and time for the experiment/batch from the drop down.
- Press “SCHEDULE”.
- Multiple experiments/batches can be scheduled by repeating the steps above.

6.2.2. Editing a Scheduled Experiment / Batch

- If changes are required to the scheduled time, click the scheduled experiment/batch and then press the “Modify Batch” on the right hand side of the screen. The pop up box used for scheduling will pop up allowing changes to be made.
- The experiment/batch cannot be edited once it has started.

(Note the experiment/batch will not automatically start on the times chosen. The experiment/batch will also not end on the time stated. The user is required to start and end the experiment/batch. Scheduling an experiment/batch will place an entry into the calendar allowing users to observe the duration of scheduled experiment/batch as well as the bioreactor that the experiment/batch is run on).

6.2.3. Deleting a Schedule Experiment / Batch

- To delete a scheduled entry, click on the experiment/batch and click “Remove Batch”.
- A confirmation pop up will appear asking to confirm deletion.
- An experiment/batch cannot be deleted once it has been started.

6.2.4. Starting an Experiment / Batch

After the steps above, select the experiment/batch to be started by clicking on it from the scheduler.

- Click on “Start Batch”. A confirmation pop up will appear asking to confirm the batch start. Pressing “NO” will return the user to the schedule. “YES” will open a phase selection screen where the experiment/batch can be started.

6.2.5. Starting an Experiment / Batch Step 2

- The phase selection screen displays the parameters selected.

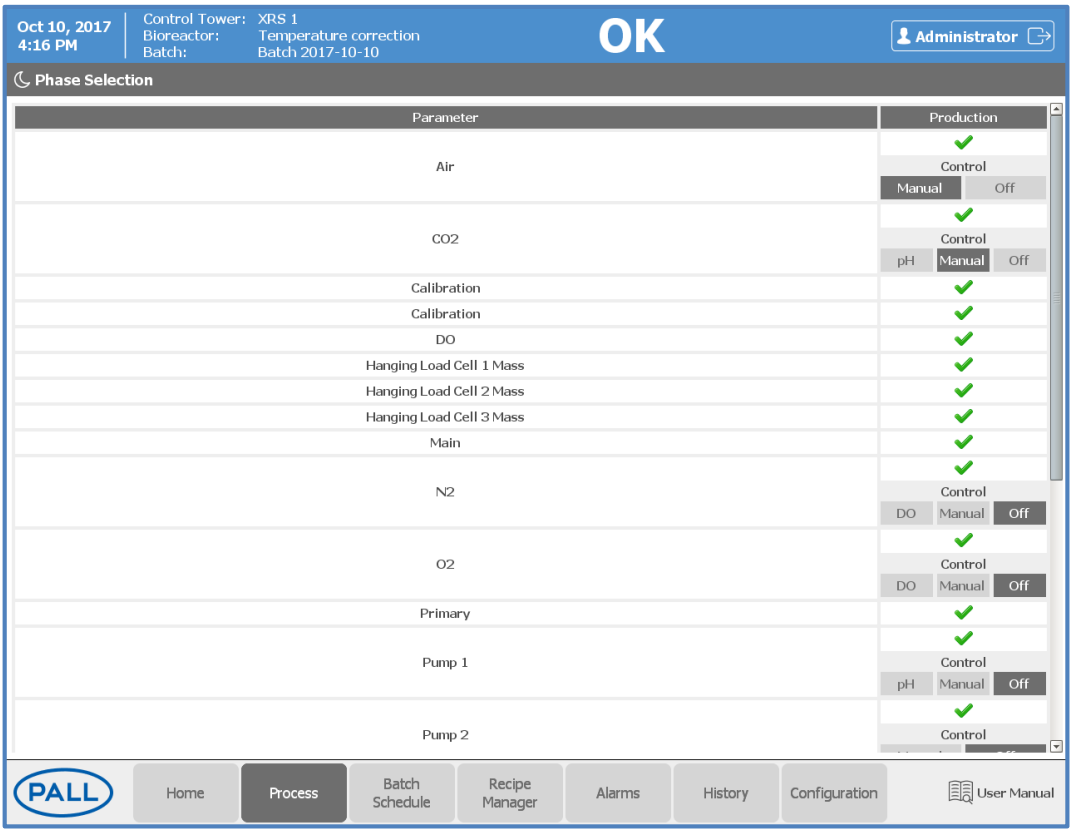


Figure 28: Phase selection screen

- Configure each parameter as required by selecting “Off”, “Manual” or connecting to a loop.
- Press “Begin”.
- Confirm that the experiment/batch should start.
- The screen will progress to the Process Overview screen where all the setpoints and control loops created in the recipe will have been pre-loaded.
- Enable control loops and set any I/O not linked to control loops to manual if required.
- Experimental/batch information is populated on the right hand side of the Process Overview screen. Phase duration will begin as soon as the experiment/batch has started.

6.3. Calibration

Sensors, pumps and internal load cells may all be calibrated. For specific calibration guidance linked to a particular bioreactor, please consult the corresponding bioreactor IFU.

When in Process Overview, select the parameter that requires calibration and then select the I/O calibration tab from the pop up window or select the I/O Calibration tab found within the Process tab.

Calibration parameters will only be present for the I/O that was added when creating the bioreactor.

6.3.1. Calibrating PreSens pH and DO Sensors

The pH fiber optic cable provided with the Allegro XRS 25 bioreactor and Xpansion multiplate bioreactors is a reusable cable, which works in conjunction with a disposable optical pH sensor. To ensure proper calibration of the sensor and to compensate for any discrepancy, you will need a calibrated offline benchtop pH meter.

- Enter the values for Lmin, Lmax, pH0, dpH and Temperature in their respective edit boxes, as marked on the label on the top of your biocontainer or on the biocontainer box. Press the box for the parameter, use the keypad to type the value then press “OK” button or enter.
- When all values have been entered, press the Trigger Calibration “DONE” button. The screen will display “CALIBRATE”. *Note: Calibration can take up to 30 seconds to complete.*
- Take a sample of growth medium from the bioreactor and measure the pH using the external meter.
- Enter the offline value into the pH offline value box and press confirm.
- The offset is calculated automatically.
- Navigate back to the process screen or complete DO calibration as described below.

The DO fiber optic cable provided with Allegro XRS 25 bioreactor and Xpansion multiplate bioreactors is a reusable cable, which works in conjunction with a disposable optical DO sensor.

- In their respective edit boxes, enter the DO Calibration Factors that are marked on the biocontainer’s label (and its box): Cal 0%, Cal 100%, Temp (degC) and Press (hPa).
- To enter the numbers, press inside each edit box, use the keypad to type the number, then press enter or the OK button.
- When all values have been entered, press the Trigger calibration “DONE” button. *Note: Calibration can take up to 30 seconds to complete.*
- Navigate back to the process screen or complete pump and hanging load cell calibration if required as described below.

6.3.2. Calibrating Electrochemical pH and DO Sensors

Electrochemical pH is a two-point calibration.

- Navigate to “Process” followed by “I/O Calibration”.
- Select Electrochemical pH from the list on the left-hand side of the screen.
- Take an offline pH measurement and enter the value into “Calibrate 1” box.
- Press “CALIBRATE” button.
- Perform another offline measurement and enter the value in to the “Calibrate 2” box.
- Press “CALIBRATE” button.
- Calibration is complete.
- When performing an offset type the correct pH reading into the “Value” box.
- Press “CONFIRM”.

- The offset box will display the offset value.

Electrochemical DO is also a two-point calibration.

- Navigate to “Process” followed by “I/O Calibration”.
- Select Electrochemical DO from the list on the left-hand side of the screen.
- Take an offline DO measurement and enter the value into “Calibrate 0%” box.
- Press “CALIBRATE” button.
- Perform another offline measurement and enter the value in to the “Calibrate 100%” box.
- Press “CALIBRATE” button.
- Calibration is complete.
- When performing an offset type the correct DO reading into the “Value” box.
- Press “CONFIRM”.
- The offset box will display the offset value.

6.3.3. Calibrating Pumps

Single point calibration. To calibrate pump flow additional equipment is required. Please source a measurement container which can hold liquid. E.g. measuring cylinder.

- Connect a section of tubing, equivalent to that being used under sterile conditions to the pump of choice.
- Ensure one end is in fluid of similar viscosity to fluid used during cell culture.
- Ensure the opposite end of the tubing is located in the measuring container.
- Prime pump by ensuring tube is full of liquid before calibrating.
- Set a setpoint (speed).
- Click the “START” button.
- A timer will begin on screen.
- Press the “STOP” button and observe what volume of the measuring container has been reached.
- Enter this value into the total volume box. (Units are mL).
- Press “CALCULATE” to complete calibration.
- Perform for additional pumps if required.

6.3.4. Calibrating Load Cell Hangers

Ensure an offline balance is available to weigh the hanging biocontainer. Follow the onscreen instructions to perform calibration of the hanging load cells. All parameters are in grams.

- Type in an empty weight value in step one, press enter. Press Calibrate and step 2 will appear.
- Hang the heaviest weight from the load cell and type in its value in grams. Press Enter. Press Calibrate.

6.4. Monitoring a Running Experiment / Batch

The Process tab links to the following tabs: Overview, Phases, I/O Calibration and Trends.

6.4.1. Overview Screen

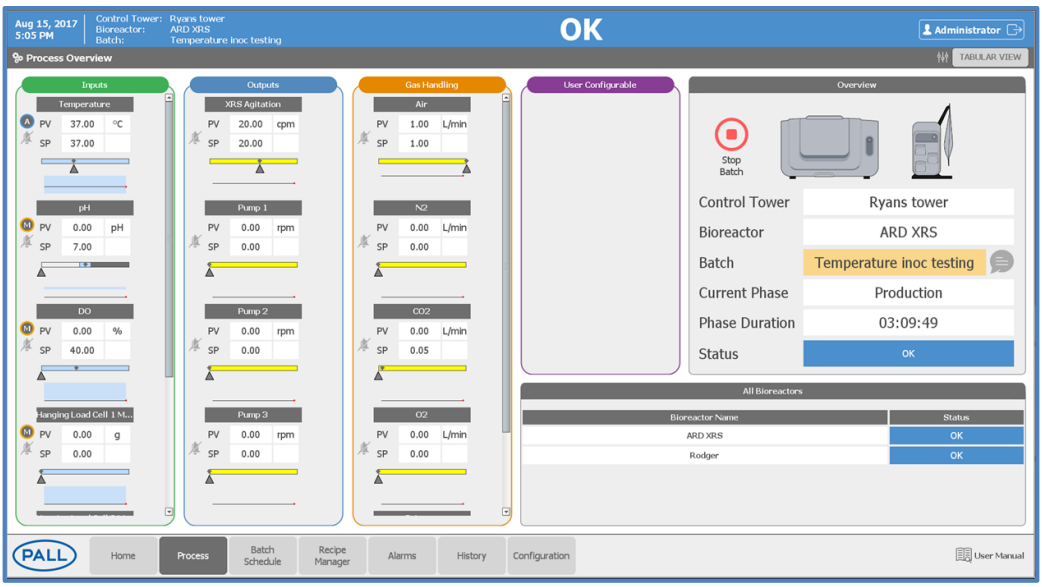


Figure 29: Process overview screen

The layout of the main window is displayed as configured when the bioreactor was created. If changes to the layout of the screen are required please refer to step 5 in Section 4.7 or to reorder the layout of Inputs, Outputs, Gas Handling or User Configurable press the  icon next to the tabular view button.

A pop up window will appear allowing the user to select an input, output, gas or user configurable I/O entry and move it up or down within its section.

- Press “UP” or “DN” to move that parameter.
- Once the pop window is closed the parameters will reorder.



The “Stop Batch” button on screen is an experiment/batch stop, NOT an emergency stop.

The stop batch button will set all loops to idle, set all assigned outputs to off and completes experiment/batch logging. Once pressed the user will be asked to acknowledge the completion of the experiment/batch.

6.4.2. Input / Output / Gas Handling and User Configurable Pop Up Screens

Configuration of control loops, setpoints, limits, and trends for each control parameter is carried out by pressing on that parameter from the overview screen.

Press the control parameter to open a pop up screen as shown below:

Bioreactor Inputs Pop Up

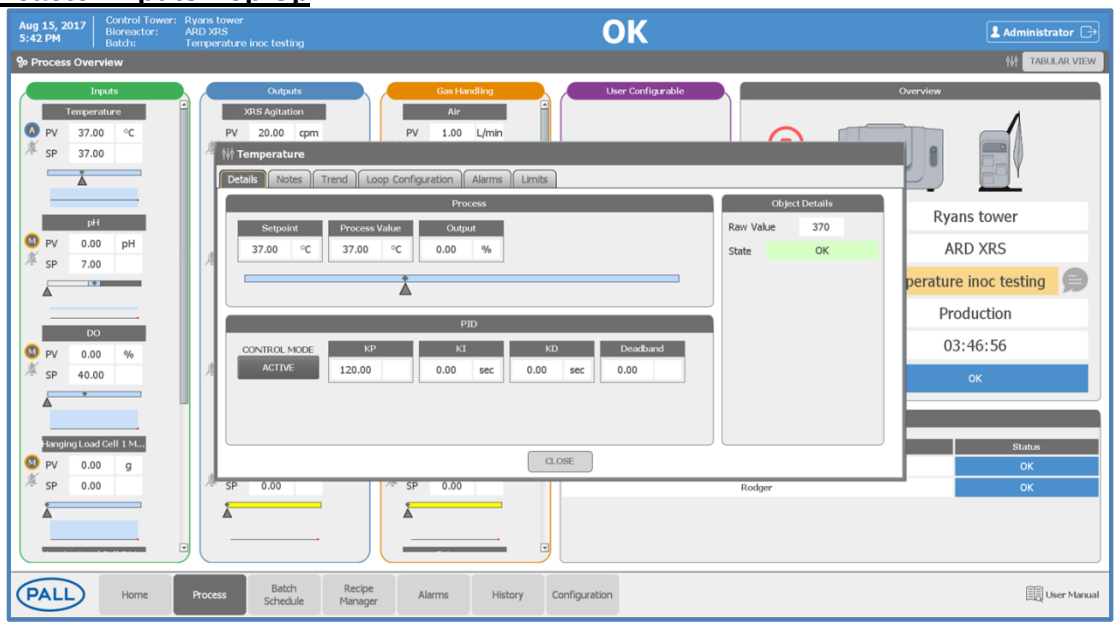


Figure 30: Bioreactor inputs pop up

Tab	Description
Details	Setpoint – User editable.
Details	Process Value – This is the value that is being read by the sensor.
Details	Output – Percentage power used when attached to a control loop
Details	Visual indicator bar.
Details	KP, KI, KD and deadband parameters (User editable).
Details	Control Mode – Active or Idle (User selectable).
Notes	Allows the user to add notes to each I/O pop up.
Trend	Shows the PID values, control mode, output, process value and setpoint on a trend specific to the input. Functionality to zoom in and out and define view period. Specific parameter data can be exported from here by pressing the save icon.
Loop Configuration	Shows the user the control variables they have connected to the bioreactor input.
Loop Configuration	User configurable to change control variable state. Input, Manual or Off.
Calibration	Copy of the calibration screen shown in the process tab.
Alarms	High high, high, low, low low, alarm configuration possible in this tab. User editable: Suppressed Yes/No, Variable, Setpoint, Deadband, On delay, Off Delay, State of the alarm and Acknowledged Yes/No.
Limits	Range limits - Total length of the visualisation bar.
Limits	Setpoint limits – A limiting feature which is user configurable to prevent certain values entered.
Limits	Scalar limits: Input Minimum, Input Maximum, Output Minimum and Output Maximum. Input Min and Max is the % of the control loop that this parameter operates within. Output Min and Max is a limit on the output of that control action.

Bioreactor Outputs Pop Up

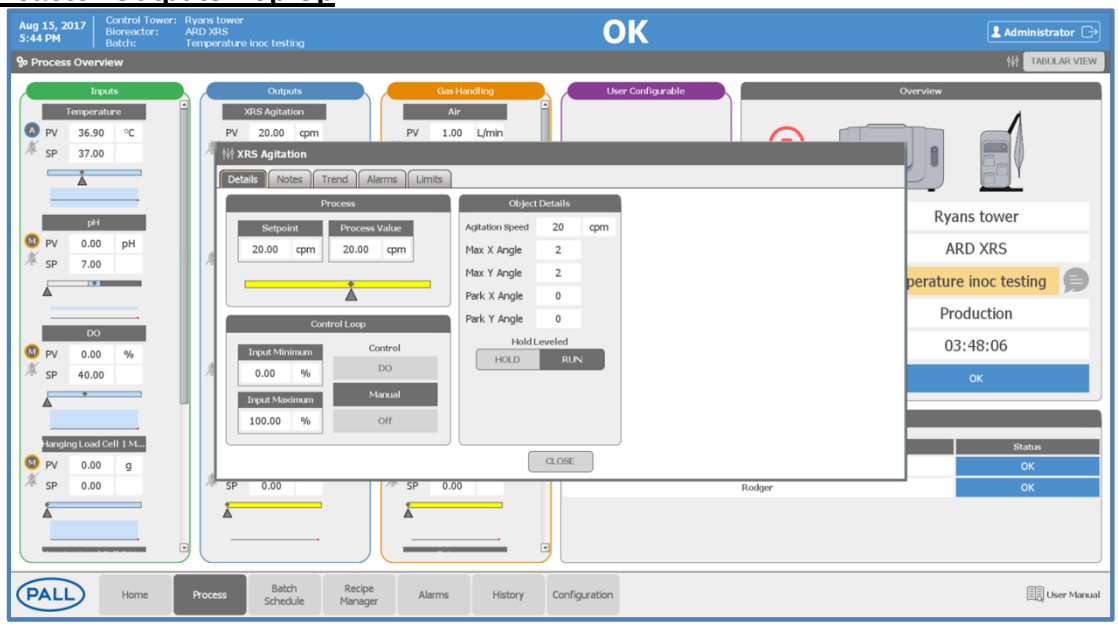


Figure 31: Bioreactor output pop up

Tab	Description
Details	Setpoint – User editable.
Details	Process Value – The value being read by the sensor.
Details	Visual indicator bar.
Details	Control Loop – Input minimum and maximum allows the user to define what percentage of the loop is used for this parameter. Control Loop – User selectable “Manual” or “Off”.
Details	Object Details – User editable details specific for this parameter.
Notes	Allows the user to add notes to each I/O pop up.
Trend	Shows the PID values, control mode, output, process value and setpoint on a trend specific to the particular pop up. It is possible to zoom in and out and define the view duration. Specific parameter data can be exported from here by pressing the save icon.
Alarms	High high, high, low, low low, alarm configuration possible in this tab. User editable: Suppressed Yes/No, Variable, Setpoint, Deadband, On delay, Off Delay, State of the alarm and Acknowledged Yes/No.
Limits	Tab contains: Range limits - Total length of the visualisation bar. Setpoint limits – A limiting feature which is user configurable to prevent certain values entered. Scalar limits: Input Minimum, Input Maximum, Output Minimum and Output Maximum.

Gas Handing Pop Up

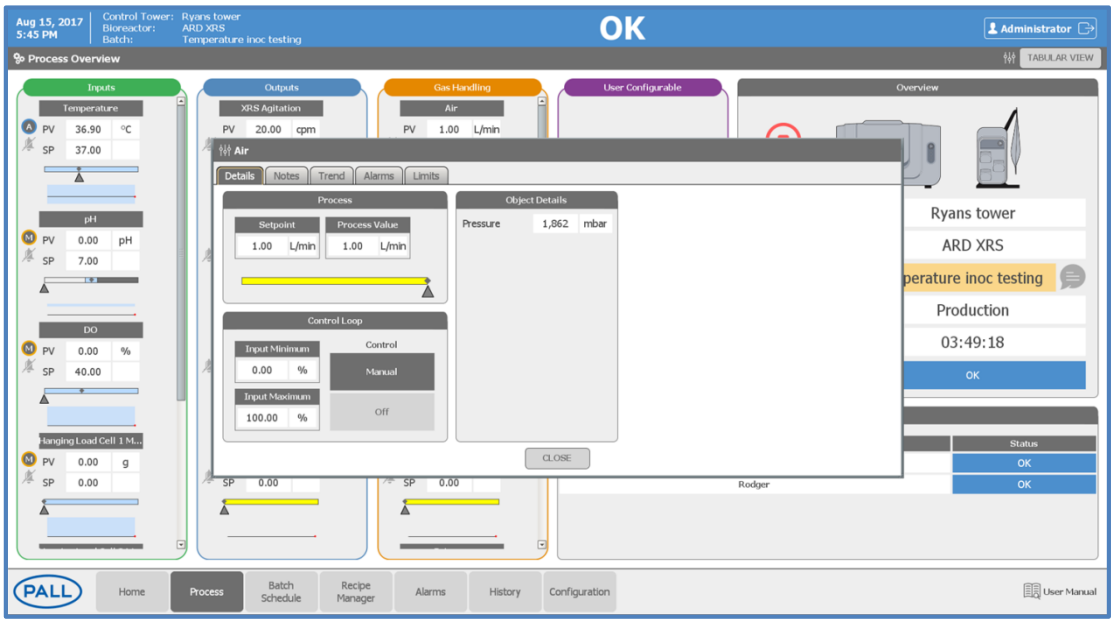


Figure 32: Gas handling pop up

Tab	Description
Details	Setpoint – User editable
Details	Process Value – The value being read by the sensor.
Details	Visual indicator bar.
Details	Control Loop – Input minimum and maximum allows the user to define what percentage of the loop is used for this parameter. Control Loop – User editable Manual or off.
Details	Object Details – User editable details specific for this parameter.
Notes	Allows the user to add notes to each I/O pop up.
Trend	Shows the PID values, control mode, output, process value and setpoint on a trend specific to the particular pop up. Functionality to zoom in and out and define view period. Specific parameter data can be exported from here by pressing the save icon.
Alarms	High high, high, low, low low, alarm configuration possible in this tab. User editable: Suppressed Yes/No, Variable, Setpoint, Deadband, On delay, Off Delay, State of the alarm and Acknowledged Yes/No.
Limits	Tab contains: Range limits – Total length of the visualisation bar. Setpoint limits – A limiting feature which is user configurable to prevent certain values entered. Scalar limits: Input Minimum, Input Maximum, Output Minimum and Output Maximum.

Primary Gas Pop Up

The Primary gas pop up screen shows a visual representation of the gas mixes flowing out of the primary gas port.

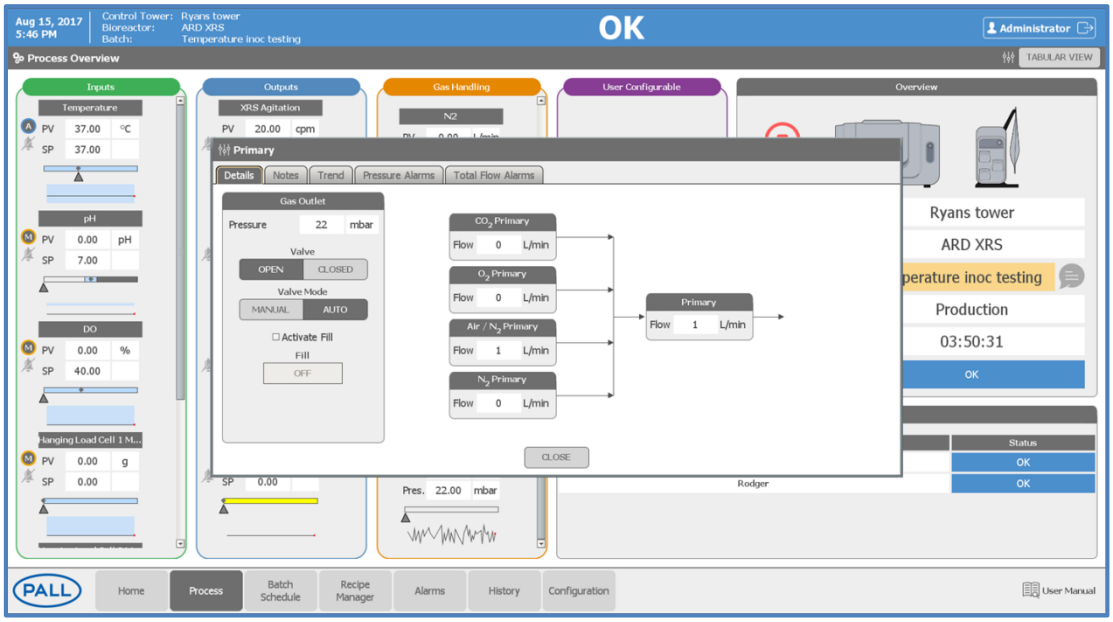


Figure 33: Gas handling – primary pop up

Tab	Description
Details	Gas Outlet – Shows pressure and total flow through the primary port
Details	Gas Outlet – Valve allows the user to close the outlet value preventing gas flow through the primary port.
Details	Gas Outlet – Valve mode allows the user to place the valve action into manual or auto. For optimum use leave in auto as shown above.
Details	Gas Outlet – Fill. The fill button is a press and hold button which allows air only to flow through the primary port. Once the button is released air will stop flowing. This function is not flow controlled so care should be taken when using. This feature is designed to inflate biocontainers with air or top up with air. As a safety feature the user must select the activate fill tick box, a pop up message will appear saying 'Are you sure you want to activate fill?' When yes is pressed the filled button is selectable. If the button is not pressed within 30 seconds it will return to an un-selectable state.
Details	Flow diagram is a visual indication to show exactly which gas and flow rate is supplied through the primary port.
Notes	Allows the user to add notes to each I/O pop up.
Trend	Shows the PID values, control mode, output, process value and setpoint on a trend specific to the primary output. Functionality to zoom in and out and define view period. Specific parameter data can be exported from here by pressing the save icon.

Fill Feature: As explained in the table above this button allows for rapid flow of air only, to aid in filling biocontainers. The button must be held down to allow air to flow. Once released the air flow will stop.

Secondary Pop Up

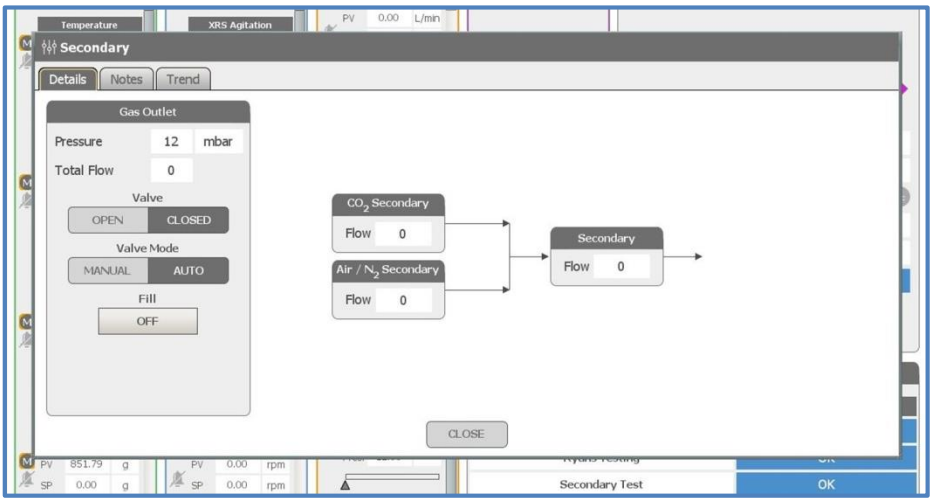


Figure 34: Gas handling – secondary pop up

The Secondary gas pop up screen shows a visual representation of gas mixes flowing out of the secondary gas port.

Tab	Description
Details	Gas Outlet – Shows pressure and total flow being passed through the primary port.
Details	Gas Outlet – Valve allows the user to close the outlet value preventing gas flow through the primary port.
Details	Gas Outlet – Valve mode allows the user to place the valve action into manual or auto. For optimum use leave in auto as shown above.
Details	Flow diagram is a visual indication for the user to show exactly what gas and how much flow is leaving the primary port.
Notes	Allows the user to add notes to each I/O pop up.
Trend	Shows the PID values, control mode, output, process value and setpoint on a trend specific to the secondary output. Functionality to zoom in and out and define view period. Specific parameter data can be exported from here by pressing the save icon.

Press “CLOSE” to return to the Process Overview screen.

Bioreactor Image Pop Up

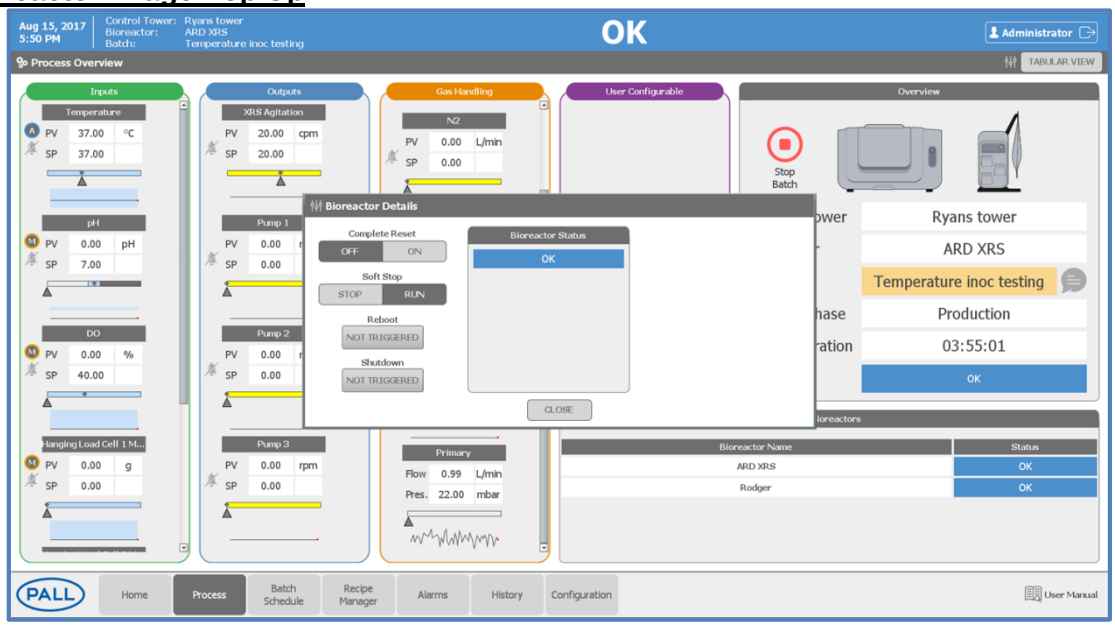


Figure 35: Bioreactor details

Clicking on the bioreactor image will open a pop up window to allow users to reset, reboot or shut down the system.

Note Pressing Complete Rest "ON" will set all setpoints to a default and will set all control to off.

6.4.3. Tabular View

The tabular view can be accessed by pressing the Tabular view button in the top right hand corner of the Process Overview screen. Setpoints can be changed from this screen.

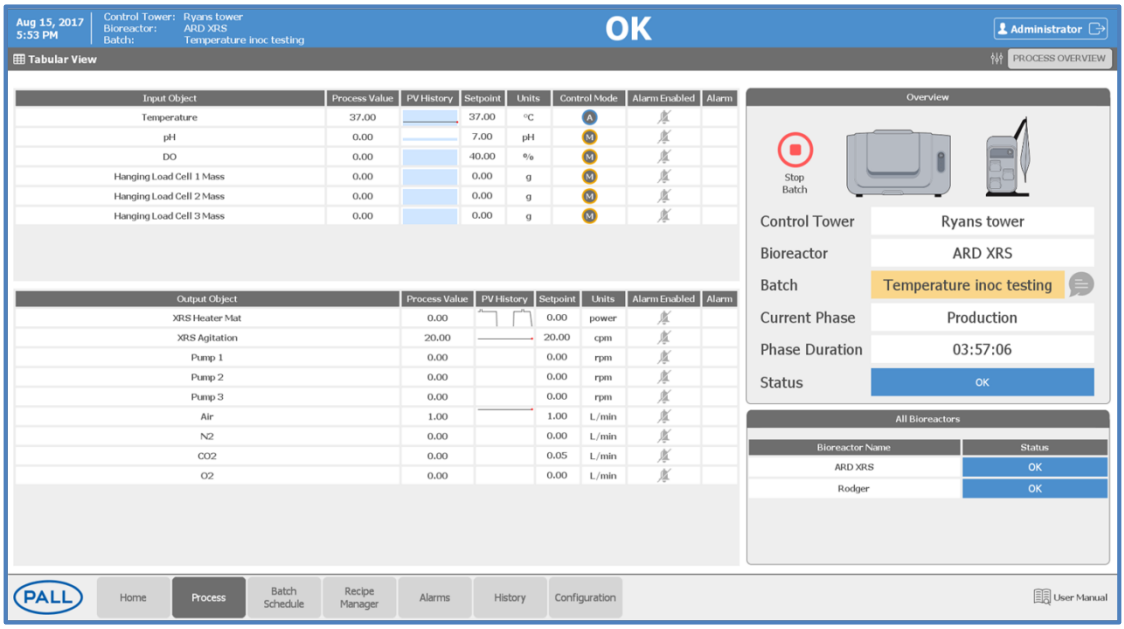


Figure 36: Tabular view

6.4.4. Trends

The trends tab displays trends previously created in a recipe as well a fully customizable trending options explained below. Navigate to “Process” and then click the “Trends” button.

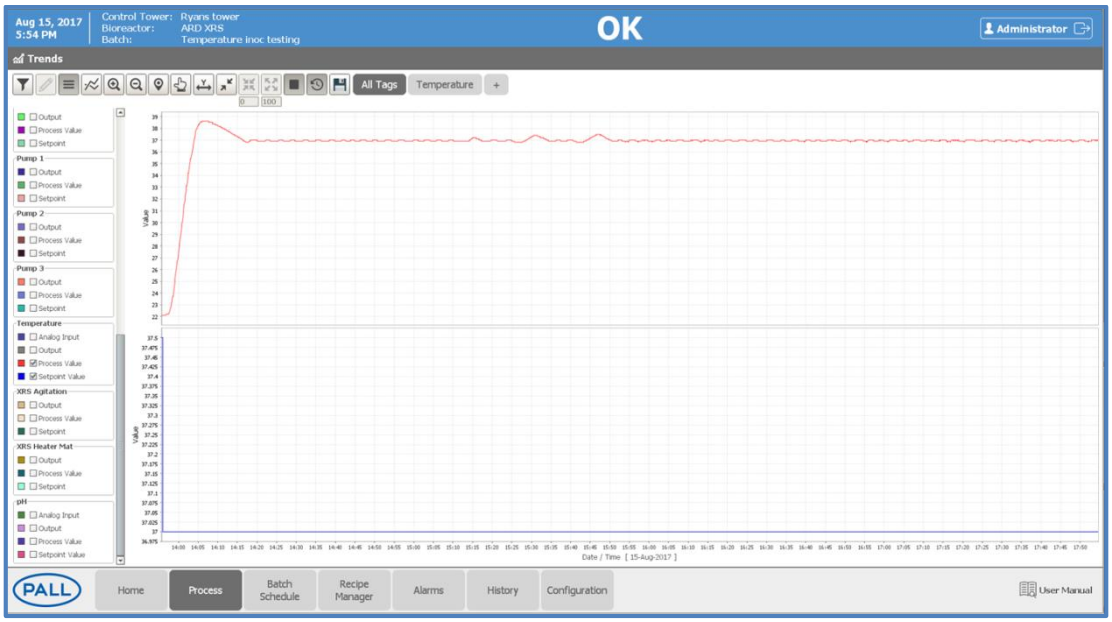


Figure 37: Trend screen

The “All Tags” tab allows the user to trend any parameter selected when a recipe was created. Scroll through the listed parameters or simplify the list by filtering to the desired parameters. Select the check box next to a value to add it to the trend. To change color of the trend line, click the colored box on the left-hand side of the selected parameter and select a color from the pallet displayed.

Multiple trends may be plotted on the same graph. Trends which were created during recipe customization will be displayed next to the “All Tags” button. Click the created trend to navigate to it. To add a trend to a currently running experiment/batch press the + button and follow the steps as described in step 4 of Section **Error! Reference source not found.**.

Table 9: Trends display button overview

Button	Functionality
	Filter option to filter the list showing potential parameters to trend.
	Toggle between all the trends on one graph or split into multiple graphs.
	Click this button and then click the trend line to add a vertical read line to the trend.
	Zoom functionality. Click on the + button and then select and area to zoom on the graph by dragging a box with a computer mouse. The – (zoom out) button can be pressed to zoom out.
	Click this button and then click the trend line to add a cross read line to the trend.
	Pressing this button will clear all read lines added to the trend.
	Auto scaling options. Once selected the auto range feature allows users to define the range of the Y axis.
	Stop or run a live trend.
	Switch between real time or calendar view.
	Click this button to export trended data.
	Pressing this button will open a pop up window allowing the user to create a trend which will be added as a tab to the trending screen.

7. Detailed Configuration and Batch Management

7.1. Control Loop Configuration

As described in Step 2 of Section 6.1 the control loop is created within a recipe.

The control of pH, Dissolved Oxygen and Temperature are achieved using a proportional, integral and derivative (PID) controller.

Default control parameters have been set by Pall using Pall standard operating procedures and representative cell lines. If your cell line has consumption and production dynamics which vary significantly from the cell lines used in tuning then custom tuning may be required. Further details are available on request. Contact your Pall applications specialist.

When a loop is created, the maximum and minimum input values relate to how much of the loop in percent is used to control to the desired setpoint.

Each output parameter connected to a loop is shown on its pop up screen.

- Select an output parameter from the Process Overview screen.
- The connected loop is shown in the Details tab.

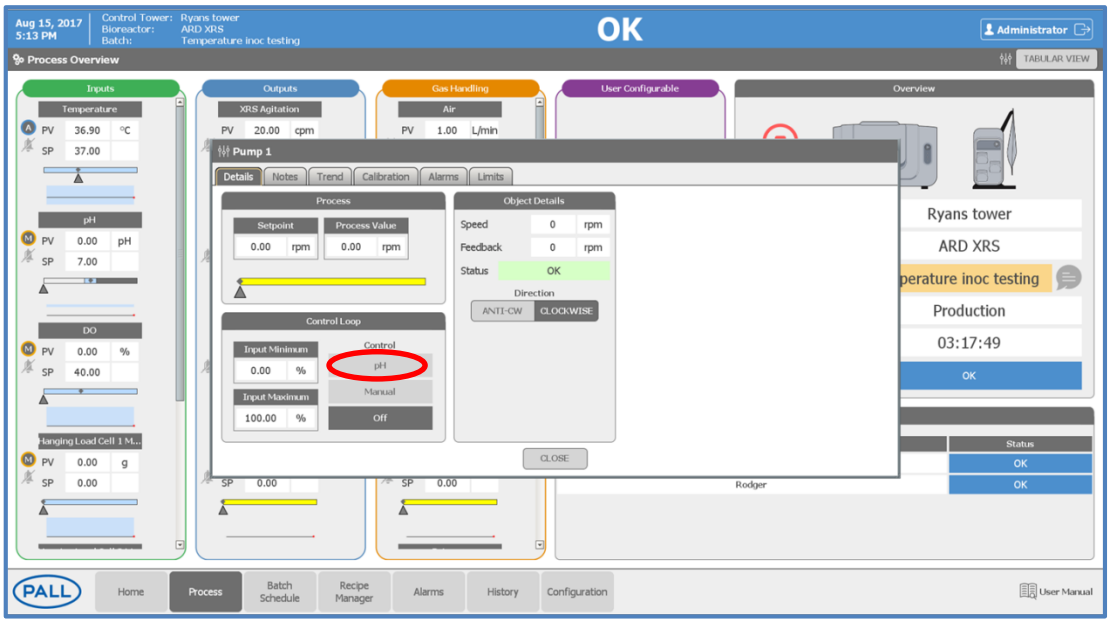


Figure 38:Active control loops

- To activate the loop, select the control actuator from the control loop column. *Note: Options displayed in the control loop column are configured during recipe set up.*
- A dark grey box represents a selected item.
- In the example above, pump 1 can be linked to pH by clicking the pH control loop box. To activate pH control, navigate to the pH pop up from the process overview screen and set control mode to active.

7.1.1. Single Parameter Control

If a loop has been created with only one positive control parameter, the minimum input is 0% and the maximum input is 100%. This means that the control parameter is used the entire time the loop is active to control to the desired setpoint.

For negative control, the maximum and minimum values range from 0% to -100%.

Important: When creating negative control loops ensure a negative value is written to the input minimum and maximum parameters.

These parameters can be set by the user in the recipe to suit the needs of the experiment/batch. A single parameter control loop does not need to be 0 - 100% if the user does not require full use of that output.

Note: If an output minimum and maximum is not set for a control parameter the parameter will run at 100% power/speed or flow rate.

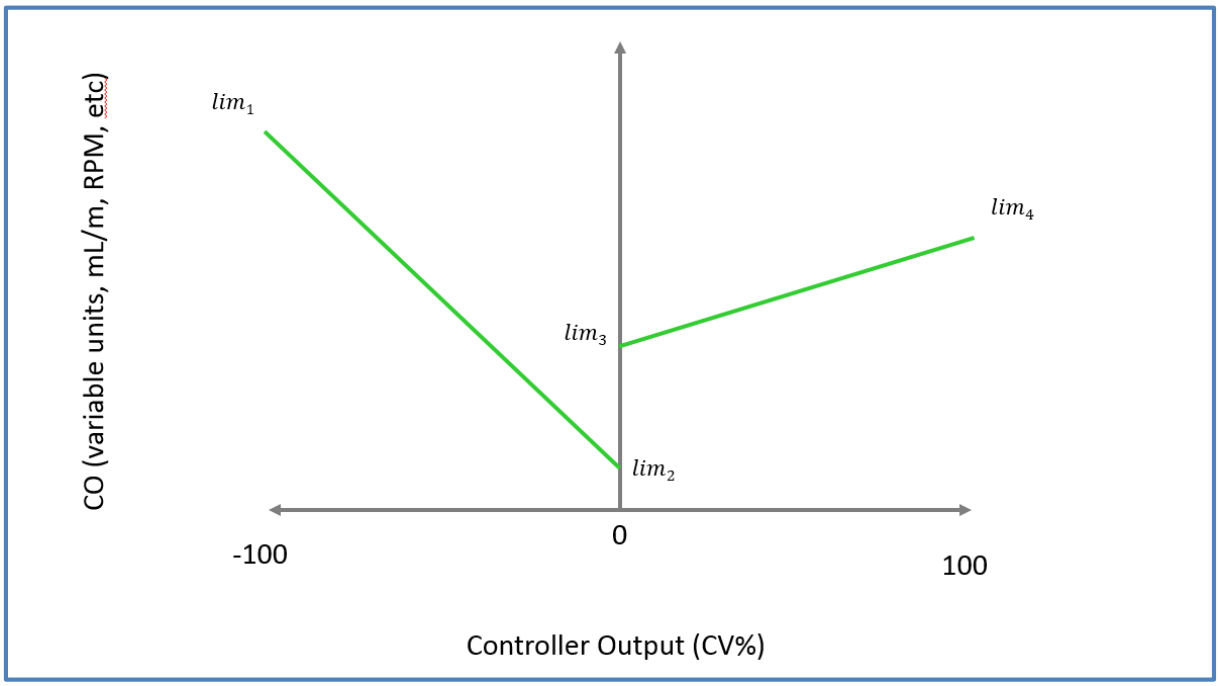


Figure 39: Single parameter control graph

7.1.2. Multiple Parameter Control

If two or three control parameters have been selected, the minimum and maximum inputs depend on the order of the desired control. As described in Step 2 of **Error! Reference s ource not found.**, the up and down buttons are used to set a priority of which control parameter is used before the next, to control to the desired setpoint.

The explanations below are examples only; all settings are user editable in recipe set up.

Two control parameters

Positive control – The control parameter selected first should have a minimum input range of 0% and a maximum input of 50%. The second control parameter should have a minimum input of 50% and a maximum input of 100%.

Negative control – First control parameter 0% minimum and -50% maximum. Second control parameter -50% minimum and -100% maximum.

Three control parameters

Positive control – The control parameter selected first should have a minimum input range of 0% and a maximum input of 33%. The second control parameter should have a minimum input of 33% and a maximum input of 66%. The third control parameter should have a minimum input of 66% and a maximum input of 100%.

Negative control – First control parameter 0% minimum and -33% maximum. Second control parameter -33% minimum and -66% maximum. Third control parameter -66% minimum and -100% maximum.

The percentages allow the control tower to switch control parameters if the desired setpoint cannot be reached using the initial control parameter.

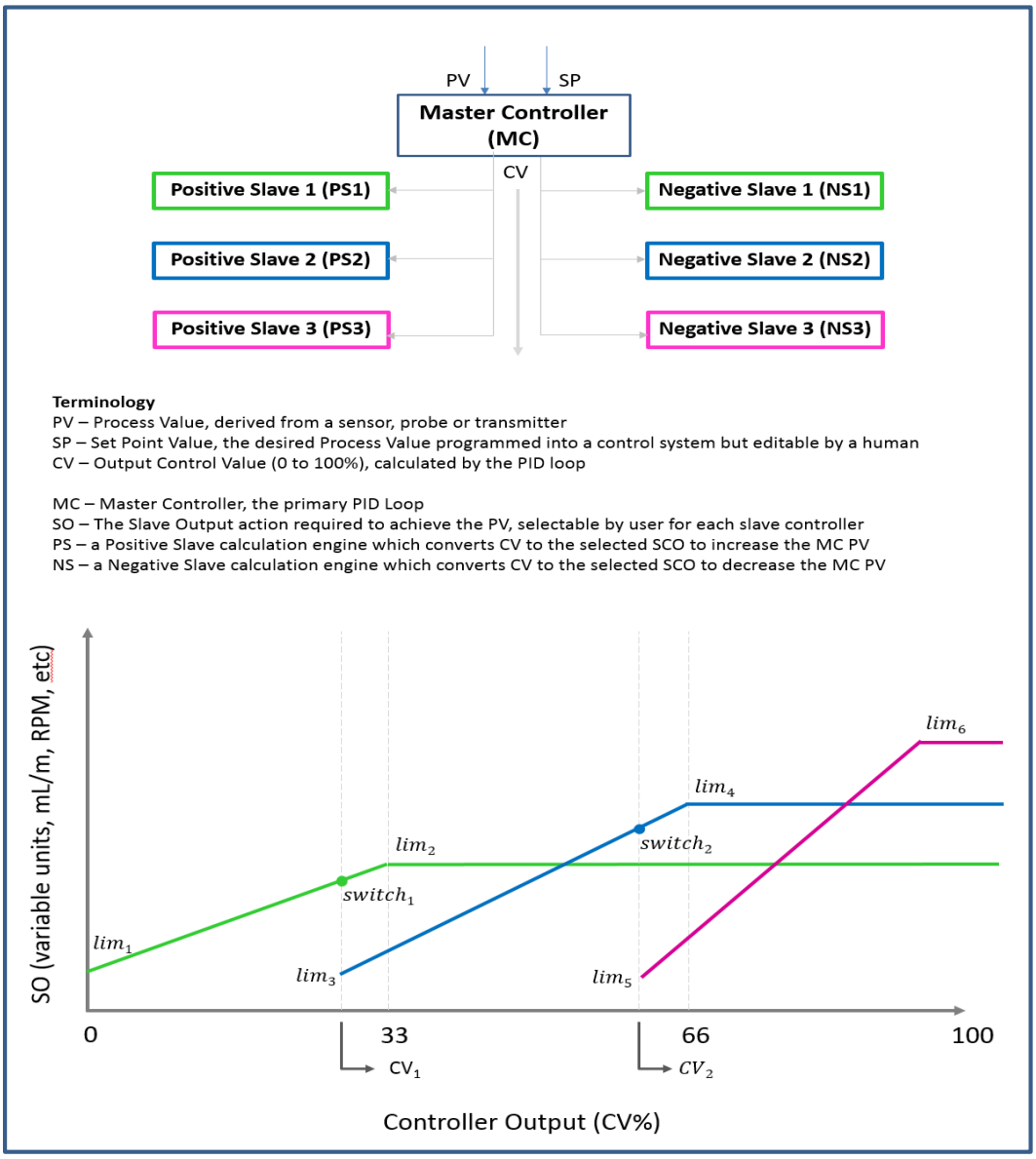


Figure 40: Multiple parameter control graph

7.1.3. DO and pH Control Philosophy

Dissolved Oxygen

Dissolved oxygen can be controlled via positive and negative control parameters enabled during recipe setup. The P, I and D terms represent one control loop controlling to a user defined setpoint. The positive and negative control parameters are activated when the present value is either higher or lower than the desired setpoint.

- Positive control is active when process value is lower than the setpoint.
- Negative control is active when the process value is higher than the setpoint.

The accuracy range for dissolved oxygen is +/- 5% of the setpoint.

pH

Like DO, pH can be controlled by positive and negative control parameters to a setpoint with a common deadband. The deadband is equidistant to the setpoint. pH will be controlled by 2 sets of P,I and D parameters. One set for the acidic setpoint (positive side of the deadband from the setpoint) and one set for the basic setpoint (negative side of the deadband from the setpoint). The user interface will display both sets of P,I and D values which are editable.

7.2. Event Log

Navigate to the History tab and click on “Event Log”.

The event log is a screen, which displays in a tabular format, all actions made by the user when commands are written to the programmable logic controller.

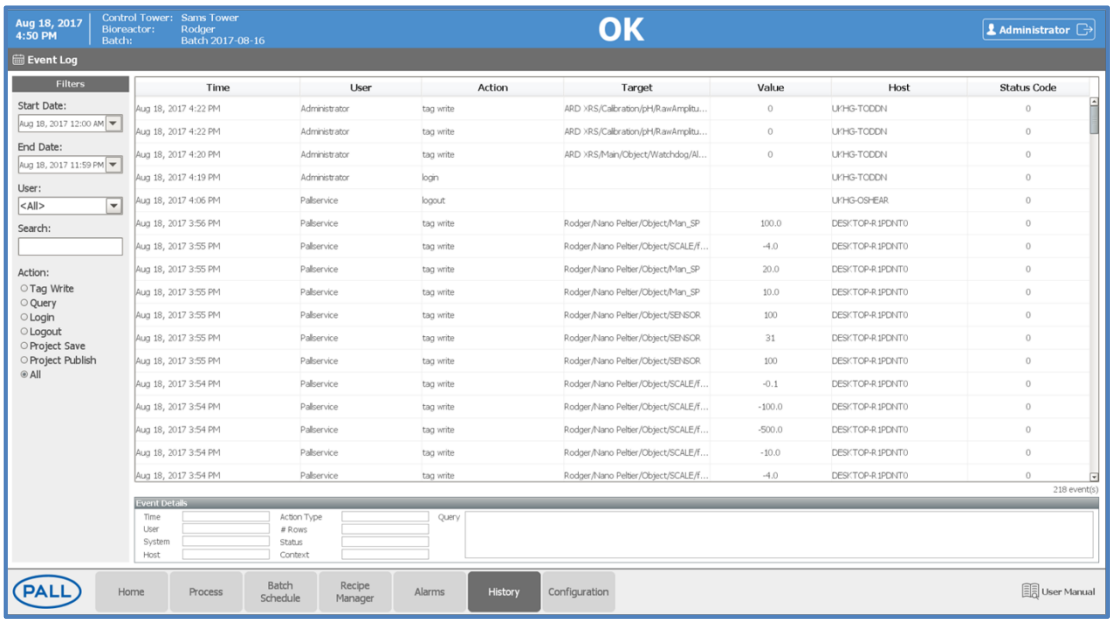


Figure 41: Event log screen

The event log displays the event time, user, action, target, value and host in a tabular format. The screen comes with advanced search filters allowing the user to search by date, user, specific terms and actions. Selecting a search option will populate the table view as per the set parameters.

When clicking on an entry, the event details will populate the event details box at the bottom of the screen. The event details box displays time, user, system, host, action type, number of rows affected, status, context and query.

7.2.1. Experiment / Batch History and Export Data

Navigate to the History tab and click on the batch history tab to find reports of all experiments/batches run. The screen is displayed in a tabular format allowing the user to search using the filters on the left hand side, which will update the view accordingly.

Filters available are bioreactor, recipe, start date, end date, state and added by. Each filter can be selected using the drop down arrow or by selecting the appropriate search term.

From the batch history screen users can view completed experiments/batches, view reports and export data.

7.2.2. View

View allows the user to view a window of many tabs detailing key experimental/batch information.

- Select the batch report to be viewed by clicking on it. It will highlight orange and press the “View” button.
- Navigate each tab to view information.

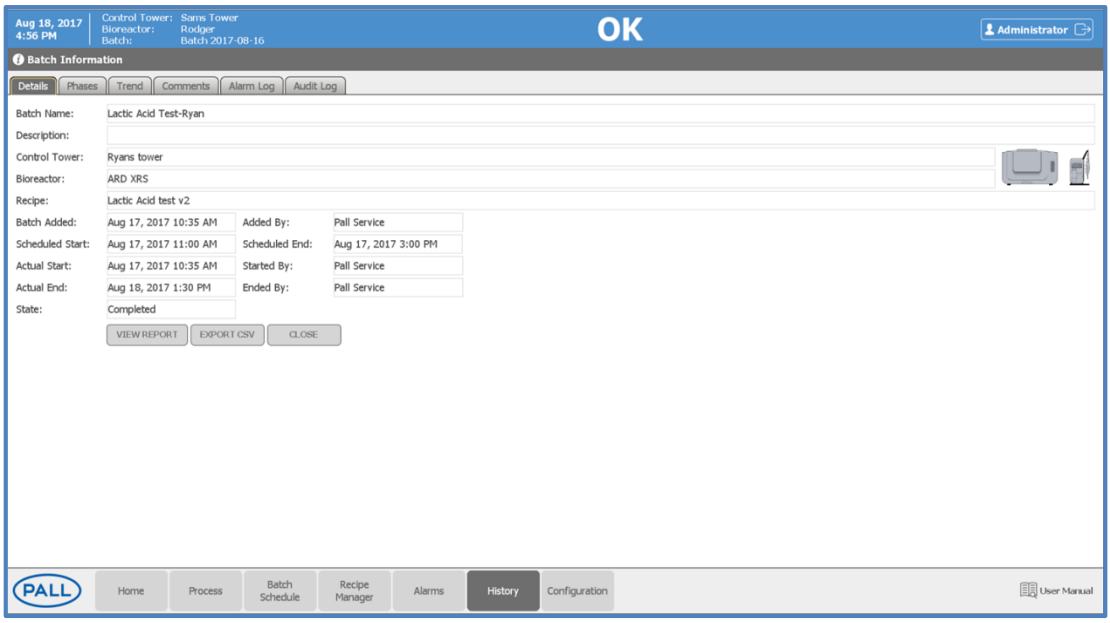


Figure 42: Batch review

- Phases tab shows the phase run, its start date, end date, the user that started the batch and the user that ended it.
- The Trend tab will display all trended data from the batch. Click on the parameters to plot the trend. The data can also be exported from this screen as described in the trending sections above.
- The Comments tab shows any comments recorded during the running of the batch.
- The Alarm Log and Audit Log show all activity recorded during the batch.
- A report of the experiment/batch can be generated from this screen by clicking the “View Report” button. *Note: The report may take some time to load.*
- The report can be printed or saved to a folder as a PDF.
- The report can also be exported as a CSV file. *Note: This is not the experimental/batch trends.*

7.2.3. Data Export

- To export data navigate to the trends tab, select the data to be plotted using the selection boxes to the left of the graph.
    - *It is possible to export all data points if none of the parameter boxes are selected from the left of the graph. Note: after a long batch run the vast amount of data collected may cause Pall Link and Excel to perform slowly.*
- Use the save functionality at the top of the screen by clicking the save icon.
- Two options will be presented:
    - Natural – data recorded every 30 seconds. The user has 4 options on what data to export. They can export minimum value, maximum value and the average value during the 30 second capture or last value which is the value recorded on second 30. You can Click one or multiple options when exporting.

- Raw – Raw data recorded when data points are changing. If data points are changing the log rate is approx. every 5 seconds.
- Select an option then select a save location.

7.2.4. Viewing and Printing a Report

A report is a printable document, time stamped detailing experimental/batch information including: experiment/batch name, description, control tower name, bioreactor name, start and end dates, phase durations, trended data, alarm log, comments and audit logs etc.

- From the Batch History tab select the report to be viewed by clicking on it. It will highlight orange.
- Press the “View Report” button on the right hand side of the screen.
- A pop up screen will appear of the selected report.
- The report is user configurable by selecting additional information to be added by clicking on the 4 tick boxes at the top of the pop up window.
- Users can navigate through the report by pressing the left and right arrows.
- To print the report, press print and select the appropriate method.
- Press close to close the report and return to the tabular view.

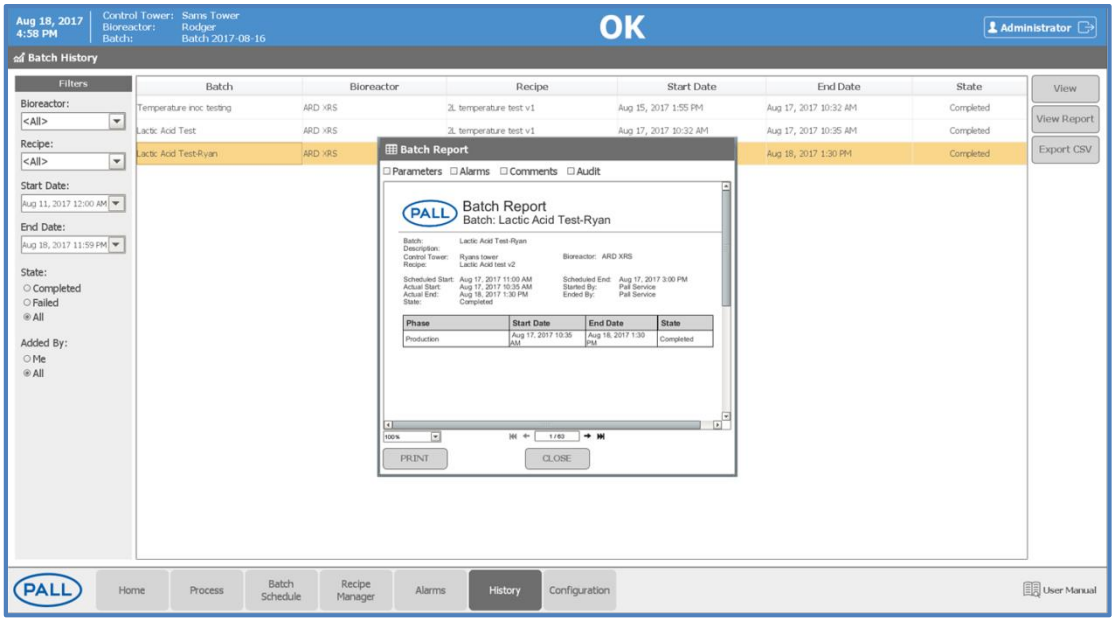


Figure 43: Batch report export

7.2.5. Export via CSV

Experiment/batch data can be exported as CSV.

- Select the report to be viewed by clicking on it. It will highlight orange.
- Press the export CSV button on the right hand side of the screen.
- A pop up screen will appear to select the location to save to. *Note: This may take some time depending on the report size.*

8. Alarms, Diagnostics and Troubleshooting

8.1. Alarm Log

During an experiment/batch the status ring encircling the face of the control tower will change color depending on the status of the experiment/batch.



Figure 44: LED light ring colors

If there is an alarm detected:

- The status ring will be colored orange or red depending on criticality, OR
- Magenta if a system alarm is detected.

8.2. Alarm Screen Description

To access the alarm log, navigate to the Alarms tab or click on the status indicating text in the status bar.

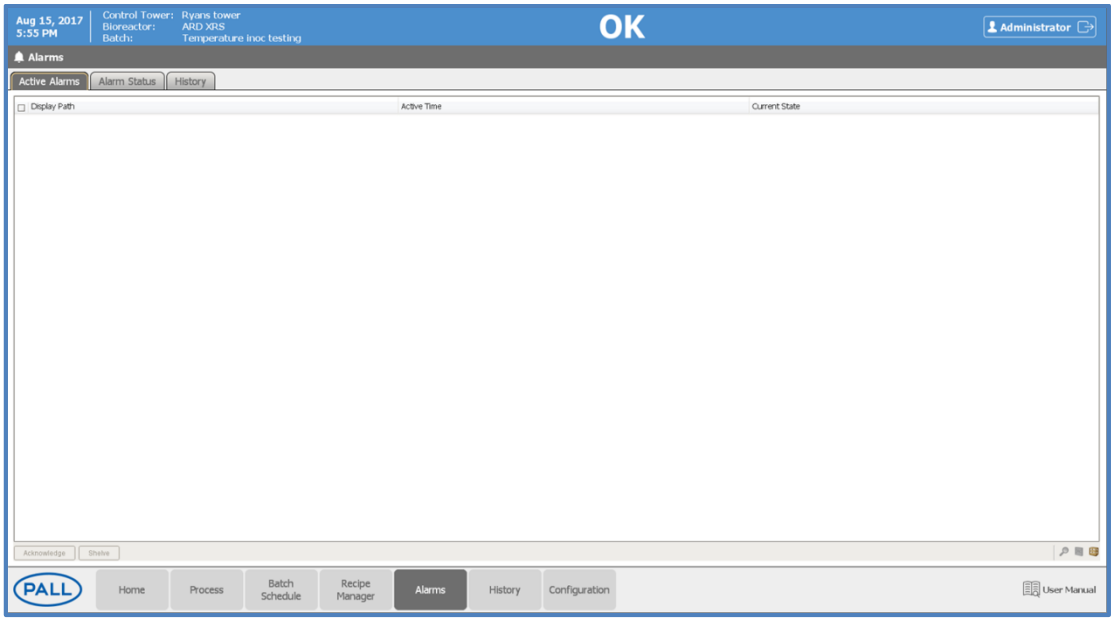


Figure 45: Alarm log screen

The alarm log displays current alarms, general alarm status and historical alarms in three tabs. The screen is set out in a tabular format showing the alarm name, priority, active time and current state.

Within the current alarms tab there is an acknowledge button which allows the user to acknowledge each alarm. Once the alarm is acknowledged the light ring will stop flashing but will remain the color of the alarm until the alarm is dealt with by the user.

The alarm status tab shows the status of all the alarms for the current experiment/batch. This screen can be used to view all status alarms, e.g. loss of communication, specific to the created bioreactor as well allowing the user to suppress and/or acknowledge active alarms.

The user can filter the alarm view by selecting system or I/O alarms, selecting alarm state and selecting how many alarms show per page.

The historical tab displays all past alarms with information on alarm name, event time, event state, acknowledged by and priority. There is a search feature on the left-hand side of the screen to allow the user to filter the main history view. Filtering can be achieved by selecting start and end dates, setting priority levels or by ticking active and cleared events.

8.2.1. Setpoint Alarms

Alarm setpoints can be viewed and edited during an experiment/batch by selecting the desired parameter from the Process Overview screen.

- When an alarm is present, navigate to the Alarms tab by either pressing the Alarms tab or by clicking the status indicating text in the status bar (e.g. Alert). The table will show the location of the alarm and criticality level. If an alarm is present on a pump or any of the side connections the respective LED will illuminate according to the criticality of the alarm.
- Acknowledge the alarm if it is safe to do so or to investigate further navigate to the Process Overview screen and select the parameter where the alarm is present.
- On the pop up screen navigate to the alarms tab.
- This tab will show if there is a low, low low, high or high high alarm.

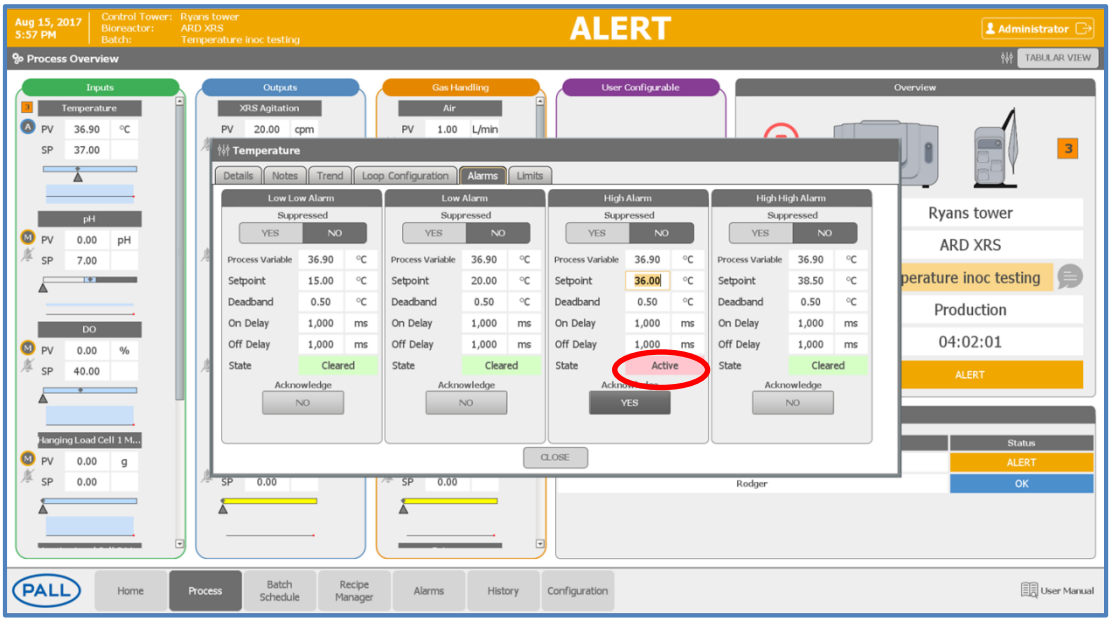


Figure 46: Alert alarm

- The image above shows that an alert is raised due to a temperature high alarm as the alarm setpoint was 37 °C but the process variable is 37.3 °C. *Note: the state is active.*

- The alarm is acknowledged meaning the status banner is no longer flashing but until the alarm is cleared the banner will display the orange alert.
- Take action to remove the alarm or if the alarm is process dependant it will self-clear once the process variable is within the alarm limits.
- If action cannot be taken and the requirement is to suppress the alarm, click the suppressed “YES” button and then re-acknowledge.
- The top banner will turn blue and read OK.

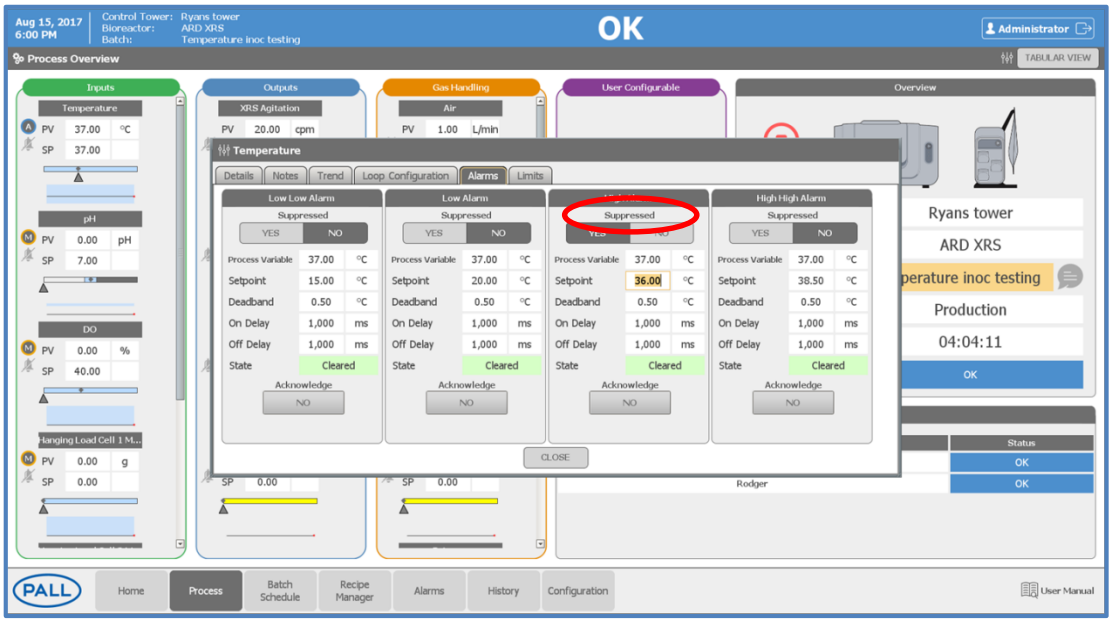


Figure 47: Alarm suppression

A full list of potential alarms is attached in Appendix E.

8.2.2. System Alarms

System alarms will present when issues occur which are not related to user set alarms in a recipe, for example, loss of communication between control tower and Pall Link computer.

System alarms will display a flashing magenta color status ring on the control tower front and header bar on screen.

- Navigate to the Alarm tab and then select the alarm status tab.
- There are 3 options present to enhance searching: Active, All and cleared. Active alarms are selected as default.
- Scroll through the list to identify which alarms are present.
- Depending on the alarm description, acknowledging the alarm will cause the LED light ring to remain static.
- Many system alarms can be cleared by ensuring all connections are connected securely and communications between tower and bioreactor are active.
- If all connections are properly connected the alarm should self-clear. *Note: Alarm will only self-clear if acknowledge button was selected previously.*
- If the alarm does not clear, and it is safe to do so, suppressing the alarm will allow continuation of the experiment/batch and the LED light ring will return to blue.
- If the alarm status lists have been checked and no apparent reasons for the alarm can be seen, navigate to the process overview screen, click the bioreactor image and press *complete Rest “ON”. Note: This will set all setpoints to 0 and will set all control to off.*
- If the system alarm is not removed, please see troubleshooting in Section **Error! R eference source not found.**.

If an alarm is present and the bioreactor is deleted from the Pall Link software, the alarm will remain on the control tower. To remove this alarm, navigate to the process overview screen, click the bioreactor image and press *complete Rest "ON".*

To avoid this, remove or acknowledge all alarms before deleting a bioreactor.

8.3. Suppressing Alarms on Experiment / Batch Start

When an experiment/batch is running, all alarms are active. The mPath control tower will display alert and critical alarms due to the high high, high, low low and low setpoints as well as system alarms.

During preparation of an experiment/batch, present values of many parameters will be either above or below the setpoint. In this case the mPath control tower will display alert and critical alarms on the Pall Link Server and via the LED light ring.

Alarms at this stage in an experiment/batch may be bothersome to the user due to the duration of the preparation stage.

To suppress alarms for this stage of the experiment/batch the user can acknowledge and enable suppression.

Acknowledging and supressing alarms should only be undertaken by experienced users.

- Navigate to the "Alarms" tab.
- The "Active Alarms" tab is selected.
- Tick the alarms to be acknowledged by selecting the box next to the alarm description.

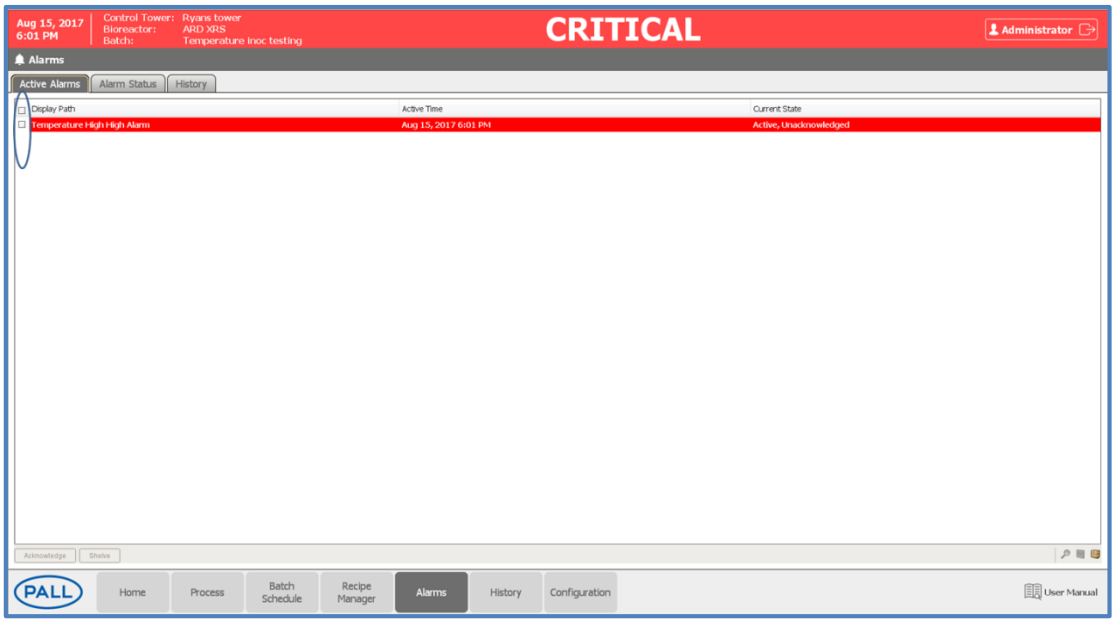


Figure 48: Active alarm screen

- Press the "Acknowledge" button at the bottom of the screen. Acknowledge will stop the flashing of the alarm but the alarm will remain.
- Navigate to the "Alarm Status" tab.
- Scroll through the alarm list and enable suppression on the active alarms.
- Unselect "System Alarms" and Select "I/O Alarms".
- Scroll through the alarm list and enable suppression on the active alarms.

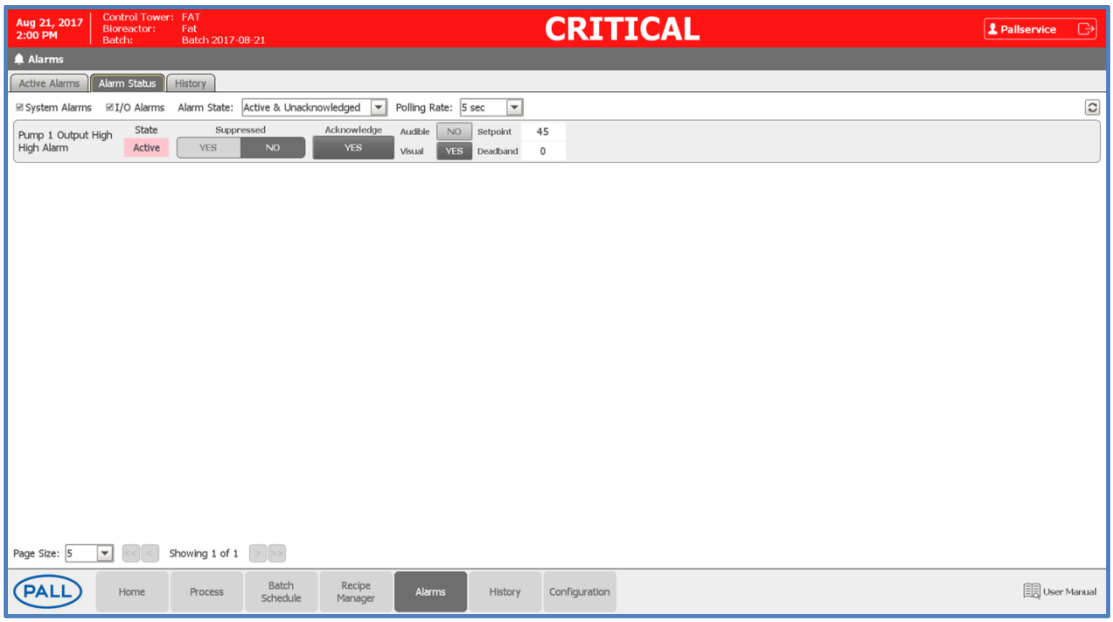


Figure 49: Alarm status screen

- Once all alarms are suppressed the Pall Link Server top banner will turn blue and present “OK” and the LED light ring will also display blue.
- The Process Overview screen will show a bell icon, depicting that the alarm is suppressed.



Figure 50: Bell icon on process overview screen

8.4. Removing Alarm Suppression

When an experiment/batch is running, alarming is used to notify the user if there are any issues that need addressing.

- To set the alarm status to unsuppressed for particular control elements, navigate to the Process Overview screen.
- Click on the control element and navigate to the Alarms tab.
- Click the “NO” option in the suppression box.



Figure 51: Un-suppression of alarms

- Press “CLOSE” and repeat for the remaining control elements.

8.5. Diagnostics

The performance and diagnostics of the Pall Link system can be observed and monitored during use from the diagnostics screen located in the configuration tab.

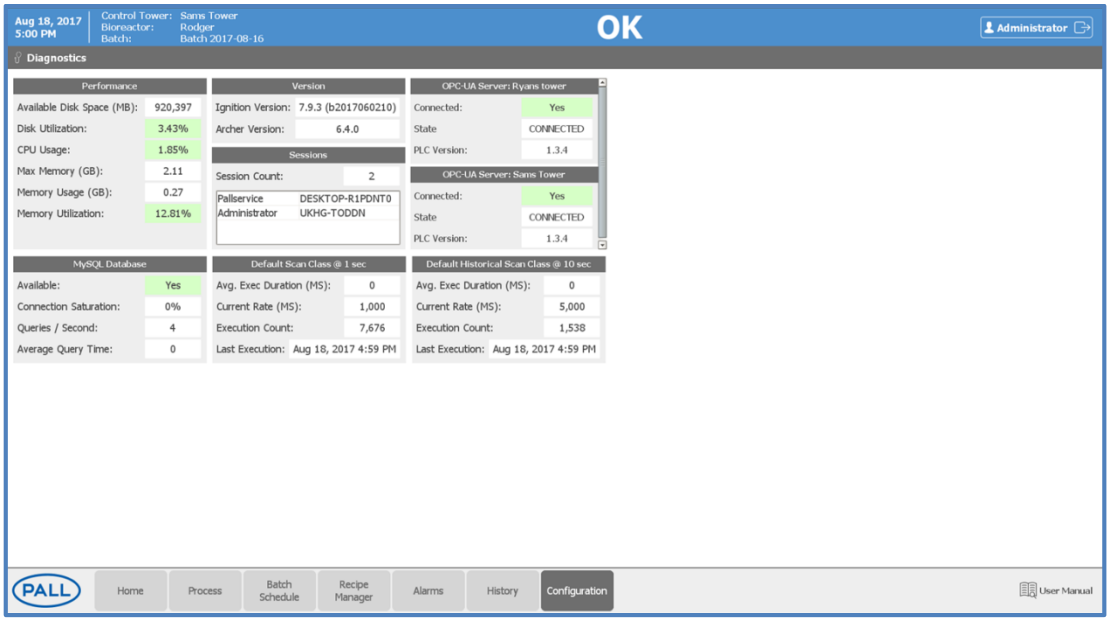


Figure 52: Diagnostic screen

The screen is a visual representation showing the OPC UA server status, the number of people logged into Pall Link, software versions of Pall Link and the PLC and the performance of the server computer along with its databases.

8.6. Trouble Shooting

Table 10: Troubleshooting overview

Issue / Error	Troubleshoot
Status ring is not static after 40 seconds	Issue – Control tower computer not booting properly. Turn off power to mPath control tower and leave powered off for 2 minutes due to retentive memory. Re-connect power and switch on mPath control tower. If status ring does not remain static after 40 seconds, there may be an issue with the PLC license. Please contact Pall.
Magenta light right upon start up	System error present from uncontrolled shut down. Navigate to “Alarm Status” tab and scroll to find shutdown alarms. Press Acknowledge button. If the alarm is not cleared click on the image of the bioreactor on the process screen. Press “Complete Reset” which will remove the system error.
Bioreactor control tower connection faulted	Check network connections. Check IP address and port configuration entered into Pall Link is correct for the mPath control tower. Check that the CX number is entered correctly. Press “Save” after editing or confirming IP addresses, port configuration and CX number in control tower setup. If the connection remains faulted contact your IT department to check the IP address of the control tower and Pall Link server computer.
Loss of communication to bioreactor	Check the status of the OPC UA server. If communications are still lost to the bioreactor check all connections are correct between the control tower and bioreactor. Repeat steps in ‘mPath control tower connection faulted’ issue.
Loss of communication to Allegro XRS 25 bioreactor	System alarm will be present. Click on the Allegro XRS 25 bioreactor image on the process overview screen. The object details will display the communications status. If there is a “Comms Fault” ensure the Allegro XRS 25 bioreactor is turned on and the communications cable is connected between mPath control tower and Allegro XRS 25 bioreactor. Navigate to the “Alarm Status” tab, scroll through the list and acknowledge all Allegro XRS 25 bioreactor status alarms. If communication status does not read OK, shut down the control tower and Allegro XRS 25 bioreactor. After 30 seconds power up the control tower followed by the Allegro XRS 25 bioreactor. Clear the system error due to uncontrolled shut down as described above.
Input and output connections not sending readings to user interface	Ensure all input and output connections are connected securely to the control tower and are in the correct ports.
Input and output connections not reading correctly	Ensure all input and output connections are connected securely to the control tower in the correct ports. Perform calibration.
Loss of on screen functionality	If the on screen view displays control parameters shown with red X’s and greyed out text, check the status of the OPC server and that all connections are correct. Ensure the bioreactor control tower is showing connected on the diagnostics page. Ensure the Pall Link Server is powered on and the software is operating.
Control tower connection status faulted	Check IP address has been entered correctly. Ensure the port information is correct. Ensure CX-number is correct. Press “SAVE” to save updates.

	Note: connection may take up to 60 seconds to complete.
Low pressure	There is insufficient inlet pressure to the gas mixing block. Pressure supplied should be 2 bar (29 psi) minimum.
Incorrect gas mixing	Ensure the correct gas lines are connected to the inlet and outlet ports on the mPath control tower. Ensure that the gas supply to mPath control tower is the correct gas from the regulator. Re-calibration of the gas block may be required. Contact Pall.
mPath control tower will not power on	Ensure all electrical connections to the electrical supply are completed and that the appropriate provided power cables are used. For further support please contact bioreactors@pall.com.
Alarm present but bioreactor deleted	If a bioreactor was deleted before its alarms were acknowledged or cleared navigate to a created bioreactor's "Process Overview" screen created on the same mPath control tower. Select the bioreactor image and press Complete Reset "On".
Unable to launch application error message	If an error message stating 'Unable to launch application' appears when clicking on the icon to launch the software, ensure the web server and gateway are running. Open the gateway control utility on the Pall Link server, and wait until the web server and gateway show green ticks. Re-launch the application.
Pall Link web server and gateway not started.	Open the gateway control utility on the Pall Link server and press the green start button in the top right hand corner.
Freezing of alarm screen	If the alarm screen freezes the server may not be able to handle the read/write requests to update a large number of alarms as well as log data. Reduce the number of alarms displayed per page.
Pall Link operates slow	When plugging in a screen in the back of the mPath controller, you might not see sufficient performance, as the controller PC is acting both as a client to the Pall Link SCADA as well as running the PLC. To improve performance, close the Pall Link Window and re-open it again. When the mPath controller is attached to a LAN network with the Pall Link server also on the LAN, with a tablet to view the HMI, the network and Wi-Fi speed will impact the performance. The Wi-Fi strength is displayed with a green, orange or red Wi-Fi symbol on the SCADA HMI.

9. Cleaning and Maintenance

9.1. Cleaning

The ingress protection rating of the mPath control tower is IP 54. To clean the mPath bioreactor control tower wipe down the instrument externally with a non-fiber releasing IPA wipe or IPA spray.

9.2. Preventive Maintenance

Pall provides maintenance and repairs for all bioreactor systems, including preventive maintenance services. Please consult datasheet USD 3078: Pall Single-Use Bioreactor Systems Support and Maintenance Services on www.pall.com or contact your Pall sales representative. In order to keep the bioreactor system up and running a minimum of one preventive maintenance a year is recommended.

9.3. Critical Spare Parts

Table 11: critical spare parts

KMPATHLOAD	mPath bioreactor control tower loadcell hanger
KMPATHCLIP	mPath bioreactor control clip for screen
KMPATHCBLXRS	Communication cable kit Allegro XRS 25 bioreactor
KMPATHCBLICLN	Communication cable kit for iCELLis Nano bioreactor

9.4. End of Life Disposal

In order to dispose of the mPath bioreactor control tower, the relevant local legal regulations must be observed. Within the European Community, the disposal of electrical devices is regulated by national regulations based on EU directive 2002/96/EC pertaining to waste electrical and electronic equipment (WEEE). According to these regulations, any device supplied after August 13, 2005, in the business-to-business sphere (to which this product is assigned), may no longer be disposed of in municipal or domestic waste. To document this, they have been marked with the following symbol:



Please visit our website for more information and local instructions on disposing of the product at https://www.pall.com/en/about-pall/corporate-sustainability/weee-compliance.html.

10. Technical Specifications Summary

Table 12: mPath controller technical specifications

Models	KMPATHBRXPS2P3 KMPATHBRXPS2P0 KMPATHBRXPS0P3 KMPATHBRXPS0P0 -	mPath control tower, PreSens pH/DO, pumps x 3 mPath control tower, PreSens pH/DO, pumps x 0 mPath control tower, PreSens x 0, pumps x 3 mPath control tower, PreSens x 0, pumps x 0
Facility	Dimensions (W x D x H)	230 x 600 X 450 mm (590 mm with hangers attached)
	Weight kg	20 kg
	Materials of construction	Polymer, stainless steel, aluminum
	Electrical supply	Voltage: Automatically adjusted between 100 – 240 V AC Input Frequency: 50 Hz/60Hz
	Electrical connection	Supplied with US, EU and UK cables
Utilities	Power consumption	360 W maximum
	Gas supply	2.0 – 6.0 bar / 29 – 87 psi
	Control architecture	Beckhoff♦ PLC, SBC Pall Link SCADA
	Operating system	Pall Corporation SCADA Pall Link server: Microsoft♦ Windows 10 Pro Control Tower: Microsoft Windows Embedded Compact Oracle♦: MySQL♦ and Java♦
Control System	Automation design	Developed and tested in accordance with GAMP 5
	Electronic records and electronic signatures	Compatible with FDA 21 CFR Part 11 & EudraLex Annex 11
	Network compatibility	Integrated OPC-UA server
	Data export / communication	USB, OPC-UA over Ethernet
	Remote operation	Yes, support for remote desktop and mobile clients through Pall Link SCADA software
	Standalone operation	No, requires Pall Link SCADA software for operation
Gas	Gas connections	6 mm push to connect fittings 6 mm OD pneumatic tubing
	Gas flow control	6 TMFCs
	Input gases supported	N_2, O_2, air and CO_2
	Pressure regulation	Onboard preset regulators, inputs from 2.5 bar (36.3 psi) – 6.0 bar (87 psi) accepted
Pumps	Pumps (on selected models)	3 variable speed pumps (14 - 211 rpm), control requiring speeds less than 14 rpm achieved through pulse width modulation (PWM)
	Compatible tubing	Up to ID 8 mm and 1.6 mm wall thickness
	Maximal flow rate	Up to 844 mL/min (tubing with ID 8 mm and OD 11.2 mm)
	Flow rate with standard SUS	1 line up to 844 mL/min (tubing with ID 8 mm and OD 11.2 mm) 2 lines up to 633 mL/min (tubing with ID 6.4 mm and OD 9.6 mm)

	External pump support	Up to 4 via user configurable I/O
Sensors	Single use sensors (on selected models)	Integrated PreSens – 1 pH / 1 DO
	Temperature	Pt100
	Pressure	Gas input, 4 input lines Gas output / biocontainer pressure, 2 output lines
	Weight	3 biocontainer load cells; each hanging load cell can hold a max weight of 2 kg. A combined max total weight of 4.5 kg can be hung from the mPath control tower
Auxillary	User configurable I/O	4 ports, M12 A coded 8-way female
	Power output	1 USB, power only, 2.1A
	Data I/O	3 USB 2.0
	Display output	1 HDMI
Safety	E-stop & interlocks	Hard emergency stop on both platform and tower, soft stops on all user interfaces, programmable and preconfigured safety interlocks
	CE marked	WEEE Directive – 2012/19/EU UL and CSA optional available
	EMC Directive 2014/30/EU	BS EN 61326-1: 2013
	Low Voltage Directive (LVD) 2014/35/EU	BS EN 61010-1: 2010
	Machinery Directive 2006/42/EC	BS EN ISO 12100:2010
	RoHS Directive	2011/65/EU
	IP rating	IP54, IEC 60529 Ed 2.2 b 2013
	Operating conditions	Laboratory environment The ambient temperatures must be between 5 °C (41 °F) and 40 °C (104 °F). Maximum relative humidity of 80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40 °C.

11. Technical Assistance and Important Contact Details

The mPath bioreactor control tower is manufactured by:

Pall Portsmouth for Pall international SARL, Avenue de Tivoli 3, 1700 Fribourg Switzerland.

For technical assistance, please contact:

Corporate Headquarters 25 Harbor Park Drive Port Washington, NY 11050, USA +1.800.717.7255 toll free (USA) +1.516.484.5400 phone biopharm@pall.com e-mail	European Headquarters Avenue de Tivoli 3, 1700 Fribourg, Switzerland +41 (0)26 350 53 00 phone LifeSciences.EU@pall.com e-mail	Asia-Pacific Headquarters 1 Science Park Road, #05-09/15 East Wing, The Capricorn, Singapore Science Park II, Singapore, 117528. +65 6389 6500 phone sgcustomerservice@pall.com e-mail

Or

- Contact your local Pall representative
- Visit the support section on www.pall.com
- E-mail your enquiry to lapplsupport@pall.com

Appendix A: Abbreviations

DO	Dissolved Oxygen
I/O	Inputs and Outputs
IFU	Instructions for use
IPA	Isopropyl alcohol
MSDS	Material safety data sheet
pH	Potential of Hydrogen
SCADA	Supervisory Control and Data Acquisition
UI	User Interface
CSA	Canadian Standards Association
HMI	Human-Machine Interface
Hz	Hertz
ID	Inner Diameter
I/O	Input/Output
OD	Outer Diameter
PID	Proportional Integral Derivative
PV	Process Variable
rpm	Revolutions per minute
RTD	Resistance Temperature Detector
SCADA	Supervisory Control And Data Acquisition Software
slpm	Standard Liters per Minute
SP	Set point
TMFC	Thermal Mass Flow Controller
V	Volts
WxDxH	Width x Depth x Height

Appendix B: Connecting to Additional Networked Computers and Tablets

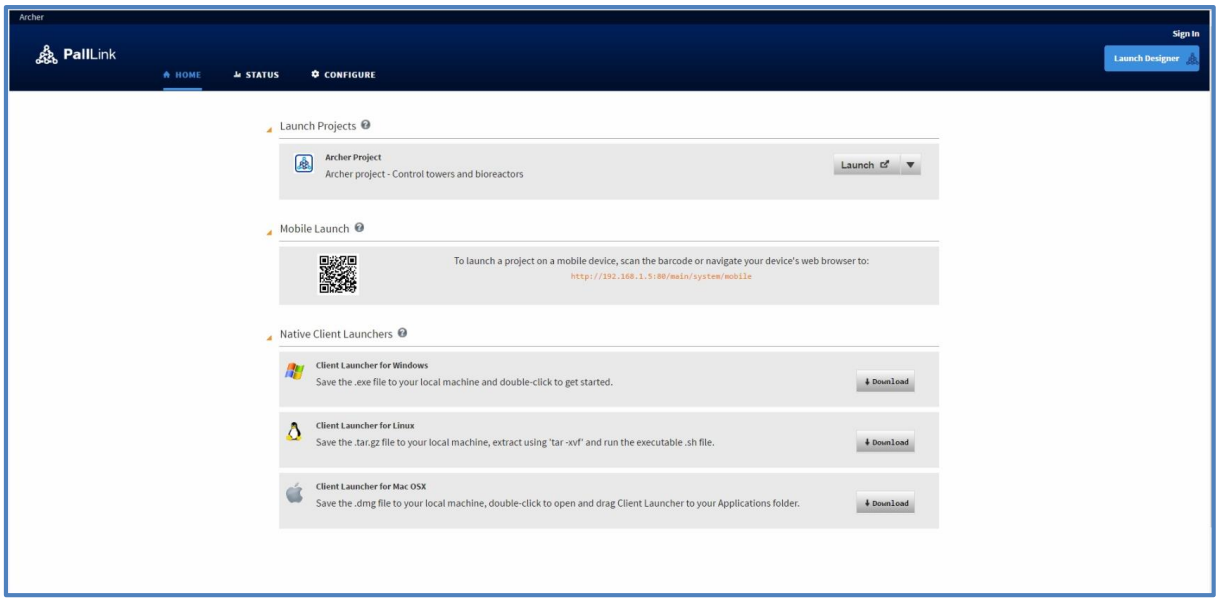
To connect to additional networked devices, the Pall Link system must be connected to a local area network.

If the air-gapped approach has been used, no additional viewing platforms can be used other than the Pall Link server supplied.

If the Pall Link server supplied is connected to a local area network or a wider area network which allows traffic, enter the IP address of the Pall Link server into the browser of your networked device.

Computers:

The Pall Link page will open giving the user the options on how to download the SCADA screens.



- Press launch to download the SCADA screens.
- Log in using the details created within user management.

Tablets

- The login page of the SCADA screen will open.
- Log in using the details created within user management.

Appendix C: I/O List

Table shows the full I/O list and the default I/O (ticked) in Pall Link as per bioreactor.

I/O	Description	Allegro XRS 25 Bioreactor	Xpansion Multiplate Bioreactor	iCELLis Nano Bioreactor	PadReactor Mini Bioreactor
Air	6 mm gas supply to primary outlet.	✓	✓	✓	✓
Air Secondary	6 mm gas supply to secondary outlet.				✓
Balance Load Cell	M12, A-coded, 5-way, female connector, 24 V supply, 0-20 mA input. Units: grams				
Balance Load Cell Feed	M12, A-coded, 5-way, female connector, 24 V supply, 0-20 mA input. Units: grams/second				
Biomass	M12, A-coded, 5-way, female connector, 0-20 mA.			✓	
Biomass Growth Rate	M12, A-coded, 5-way, female connector, 0-20 mA.				
CO_2	6 mm gas supply to primary outlet.	✓	✓	✓	✓
CO_2 Secondary	6 mm gas supply to secondary outlet.				✓
DO	Dissolved oxygen fibre optic	✓	✓		
Electrochemical CO_2	Electrochemical CO_2				
Electrochemical DO	Electrochemical DO			✓	✓
Electrochemical pH	Electrochemical pH			✓	✓
Filter Heater	M12, A-coded, 5-way, female connector. 0-24 V				✓
Hanging Load Cell 1 Feed	Hanging load cell feed measured in g/s				
Hanging Load Cell 1 Mass	Hanging load cell mass measured in g.	✓	✓		
Hanging Load Cell 2 Feed	Hanging load cell feed measured in g/s				
Hanging Load Cell 2 Mass	Hanging load cell mass measured in g.	✓	✓		
Hanging Load Cell 3 Feed	Hanging load cell feed measured in g/s				
Hanging Load Cell 3 Mass	Hanging load cell mass measured in g.	✓	✓		
Level Sensor 1	M12, A-coded, 5-way, female connector. 1 x 0-20 mA input; 1 x 24 V digital input				
Level Sensor 2	M12, A-coded, 5-way, female connector. 1 x 0-20 mA input; 1 x 24 V digital input				
MAG Stirrer	2Mag stirrer plate.		✓		

I/O	Description	Allegro XRS 25 Bioreactor	Xpansion Multiplate Bioreactor	iCELLis Nano Bioreactor	PadReactor Mini Bioreactor
N_2	6 mm Gas supply to primary outlet.	✓	✓	✓	✓
Nano Filter Heater	0-24 V			✓	
Nano MAG Stirrer	Internal connection. Measured in rpm			✓	
Nano Peltier	Internal connection. Measured in %.			✓	
Nano Pump 1	Pump speed measured in rpm.			✓	
Nano Pump 2	Pump speed measured in rpm.			✓	
Nano Pump 3	Pump speed measured in rpm.			✓	
Nano Resistor	Internal connection. Degrees C.			✓	
Nano Temperature	PT 100 measured in Degrees C.			✓	
O_2	6 mm Gas supply to primary outlet.	✓	✓	✓	✓
Peltier	M12, T-coded, 4-way, female.				
pH	pH fibre optic	✓	✓		
Pressure Sensor Current	M12, A-coded, 5-way, female. 0-20 mA				
Pressure Sensor Voltage	M12, A-coded, 5-way, female. 0-10 V				
Primary	Outlet gas flow of all primary gas flows. 6 mm	✓	✓	✓	✓
Pump 1	Pump on mPath controller. Measured in rpm	✓			
Pump 2	Pump on mPath controller. Measured in rpm	✓			
Pump 3	Pump on mPath controller. Measured in rpm	✓			
Secondary	Outlet gas flow of both secondary gas flows. 6mm				✓
Stirrer	PadReactor Mini bioreactor paddle stirrer. Measured in rpm.				✓
Temperature	PT 100 measured in Degrees C.	✓	✓		✓
Allegro XRS Agitation	Agitation to Allegro XRS 25 bioreactor measured in CPM.	✓			

Appendix D: User Management (Default List)

<table>
<tr><th colspan="2" rowspan="3"></th><th colspan="4">Access Control OFF - Non GMP Use</th><th colspan="5">Access Control ON - GMP Use</th></tr>
<tr><th colspan="4">Generic Username / Password Combination at Pall Link launch</th><th colspan="5">All changes require password entry to confirm on save.</th></tr>
<tr><th>OPERATOR</th><th>SUPERVISOR</th><th>ADMINISTRATOR</th><th>PALL SERVICE</th><th>DEFAULT (logged out)</th><th>OPERATOR</th><th>SUPERVISOR</th><th>ADMINISTRATOR</th><th>PALL SERVICE</th></tr>
<tr><td colspan="2">SCREEN</td><td colspan="4"></td><td colspan="5"></td></tr>
<tr><td></td><td>Home</td><td colspan="4">OPEN</td><td>Read Only</td><td colspan="4">Password Access</td></tr>
<tr><td colspan="10">Configuration</td></tr>
<tr><td></td><td>System Settings</td><td colspan="2">No Access</td><td rowspan="2">Password Access</td><td rowspan="5">No Access</td><td rowspan="3">No Access</td><td rowspan="2">No Access</td><td colspan="2">Password Access</td></tr>
<tr><td></td><td>User Management</td><td colspan="2">No Access</td><td>Password Access</td><td>No Access</td></tr>
<tr><td></td><td>Add Control Tower</td><td colspan="4" rowspan="3">OPEN</td><td rowspan="3">No Access</td><td rowspan="3">Password Access</td><td rowspan="3">No Access</td><td rowspan="3">Password Access</td></tr>
<tr><td></td><td>Add Bioreactor</td></tr>
<tr><td></td><td>Bioreactor Default Recipe Editor</td></tr>
<tr><td></td><td>Diagnostics</td><td colspan="4">OPEN</td><td colspan="4">Read Only</td></tr>
<tr><td colspan="10">Set up</td></tr>
<tr><td></td><td>Experiment Identifier</td><td colspan="4" rowspan="6">OPEN</td><td rowspan="6">No Access</td><td rowspan="5">No Access</td><td rowspan="6">Password Access</td><td rowspan="6">No Access</td><td rowspan="6">Password Access</td></tr>
<tr><td></td><td>I/O Configuration</td></tr>
<tr><td></td><td>Calibration</td></tr>
<tr><td></td><td>Process</td></tr>
<tr><td></td><td>Phase Selection</td></tr>
<tr><td></td><td>Batch Start</td><td>Password Access</td></tr>
<tr><td colspan="10">Process</td></tr>
<tr><td></td><td>Synoptic View</td><td colspan="4" rowspan="6">OPEN</td><td rowspan="6">No Access</td><td rowspan="3">Read Only</td><td rowspan="6">Password Access</td><td rowspan="6">No Access</td><td rowspan="6">Password Access</td></tr>
<tr><td></td><td>Tabular View</td></tr>
<tr><td></td><td>I/O Items</td></tr>
<tr><td></td><td>Loops</td></tr>
<tr><td></td><td>Calibration</td><td>Password Access</td></tr>
<tr><td></td><td>Export Data</td><td>No Access</td></tr>
<tr><td></td><td>Trends</td><td>Read Only</td></tr>
</table>

	Access Control OFF - Non GMP Use				Access Control ON - GMP Use				
	Generic Username / Password Combination at Pall Link launch				All changes require password entry to confirm on save.				
	OPERATOR	SUPERVISOR	ADMINISTRATOR	PALL SERVICE	DEFAULT (logged out)	OPERATOR	SUPERVISOR	ADMINISTRATOR	PALL SERVICE
SCREEN									
Batch Schedule									
Schedule New Batch	OPEN				No Access	Read Only	Password Access	No Access	Password Access
Modify Batch									
Remove Batch									
Start Batch						Password Access			
Recipe Manager									
Create New Recipe	OPEN				No Access	No Access	Password Access	No Access	Password Access
View Recipe						Read Only			Read Only
Edit Recipe						No Access			
Duplicate Recipe									
Remove Recipe									
Retire Recipe									
Alarms									
Active Alarms	OPEN				No Access	Read Only	Password Access	No Access	Password Access
Alarm Status									
Alarm History						Read Only			
History									
Batch History	OPEN				No Access	Read Only	Password Access	No Access	Password Access
Batch Trends									
Event Log - Audit Trail						Read Only			

Appendix E: Alarm List

Alarm	SCADA Description
Input_Object (pH) Alarm LowLow	pH Low Low – Optical Sensor
Input_Object (pH) Alarm Low	pH Low – Optical Sensor
Input_Object (pH) Alarm High	pH High – Optical Sensor
Input_Object (pH) Alarm HighHigh	pH High High – Optical Sensor
Input_Object (O_2) Alarm LowLow	Dissolved Oxygen Low Low – Optical Sensor
Input_Object (O_2) Alarm Low	Dissolved Oxygen Low – Optical Sensor
Input_Object (O_2) Alarm High	Dissolved Oxygen High – Optical Sensor
Input_Object (O_2) Alarm HighHigh	Dissolved Oxygen High High – Optical Sensor
Input_Object (TMP) Alarm LowLow	Temperature Low Low
Input_Object (TMP) Alarm Low	Temperature Low
Input_Object (TMP) Alarm High	Temperature High
Input_Object (TMP) Alarm HighHigh	Temperature High High
Input_Object (Under Vessel Load Cells - Mass) Alarm LowLow	Mass Low Low – Under Vessel Load Cell
Input_Object (Under Vessel Load Cells - Mass) Alarm Low	Mass Low – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Mass) Alarm High	Mass High – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Mass) Alarm HighHigh	Mass High High – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Feed) Alarm LowLow	Feed Low Low – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Feed) Alarm Low	Feed Low – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Feed) Alarm High	Feed High – Under Vessel Load cell
Input_Object (Under Vessel Load Cells - Feed) Alarm HighHigh	Feed High High – Under Vessel Load cell
Input_Object (Hanging Load Cells 1 - Mass) Alarm LowLow	Mass Low Low – Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Mass) Alarm Low	Mass Low – Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Mass) Alarm High	Mass High - Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Mass) Alarm HighHigh	Mass High High – Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Feed) Alarm LowLow	Feed Low Low – Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Feed) Alarm Low	Feed Low – Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Feed) Alarm High	Feed High - Hanging Load Cell 1
Input_Object (Hanging Load Cells 1 - Feed) Alarm HighHigh	Feed High High – Hanging Load Cell 1
Input_Object (Hanging Load Cells 2 - Mass) Alarm LowLow	Mass Low Low – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Mass) Alarm Low	Mass Low – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Mass) Alarm High	Mass High – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Mass)	Mass High High – Hanging Load Cell 2

Alarm HighHigh	
Input_Object (Hanging Load Cells 2 - Feed) Alarm LowLow	Feed Low Low – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Feed) Alarm Low	Feed Low – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Feed) Alarm High	Feed High – Hanging Load Cell 2
Input_Object (Hanging Load Cells 2 - Feed) Alarm HighHigh	Feed High High – Hanging Load Cell 2
Input_Object (Hanging Load Cells 3 - Mass) Alarm LowLow	Mass Low Low – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Mass) Alarm Low	Mass Low – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Mass) Alarm High	Mass High – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Mass) Alarm HighHigh	Mass High High – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Feed) Alarm LowLow	Feed Low Low – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Feed) Alarm Low	Feed Low – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Feed) Alarm High	Feed High – Hanging Load Cell 3
Input_Object (Hanging Load Cells 3 - Feed) Alarm HighHigh	Feed High High – Hanging Load Cell 3
Input_Object (UCI 1 - Current) Alarm LowLow	"UCI 1 Current – Item Label Name" + Low Low
Input_Object (UCI 1 - Current) Alarm Low	"UCI 1 Current – Item Label Name" + Low
Input_Object (UCI 1 - Current) Alarm High	"UCI 1 Current – Item Label Name" + High
Input_Object (UCI 1 - Current) Alarm HighHigh	"UCI 1 Current – Item Label Name" + High High
Input_Object (UCI 1 - Voltage) Alarm LowLow	"UCI 1 Voltage – Item Label Name" + Low Low
Input_Object (UCI 1 - Voltage) Alarm Low	"UCI 1 Voltage – Item Label Name" + Low
Input_Object (UCI 1 - Voltage) Alarm High	"UCI 1 Voltage – Item Label Name" + High
Input_Object (UCI 1 - Voltage) Alarm HighHigh	"UCI 1 Voltage – Item Label Name" + High High
Input_Object (UCI 2 - Current) Alarm LowLow	"UCI 2 Current -– Item Label Name" + Low Low
Input_Object (UCI 2 - Current) Alarm Low	"UCI 2 Current – Item Label Name" + Low
Input_Object (UCI 2 - Current) Alarm High	"UCI 2 Current – Item Label Name" + High
Input_Object (UCI 2 - Current) Alarm HighHigh	"UCI 2 Current – Item Label Name" + High High
Input_Object (UCI 2 - Voltage) Alarm LowLow	"UCI 2 Voltage – Item Label Name" + Low Low
Input_Object (UCI 2 - Voltage) Alarm Low	"UCI 2 Voltage – Item Label Name" + Low
Input_Object (UCI 2 - Voltage) Alarm High	"UCI 2 Voltage – Item Label Name" + High
Input_Object (UCI 2 - Voltage) Alarm HighHigh	"UCI 2 Voltage – Item Label Name" + High High
Input_Object (UCI 3 - Current) Alarm LowLow	"UCI 3 Current – Item Label Name" + Low Low
Input_Object (UCI 3 - Current) Alarm Low	"UCI 3 Current – Item Label Name" + Low
Input_Object (UCI 3 - Current) Alarm High	"UCI 3 Current – Item Label Name" + High
Input_Object (UCI 3 - Current) Alarm HighHigh	"UCI 3 Current – Item Label Name" + High High

Input_Object (UCI 3 - Voltage) Alarm LowLow	"UCI 3 Voltage – Item Label Name" + Low Low
Input_Object (UCI 3 - Voltage) Alarm Low	"UCI 3 Voltage – Item Label Name" + Low
Input_Object (UCI 3 - Voltage) Alarm High	"UCI 3 Voltage – Item Label Name" + High
Input_Object (UCI 3 - Voltage) Alarm HighHigh	"UCI 3 Voltage – Item Label Name" + High High
Input_Object (UCI 4 - Current) Alarm LowLow	"UCI 4 Current – Item Label Name" + Low Low
Input_Object (UCI 4 - Current) Alarm Low	"UCI 4 Current – Item Label Name" + Low
Input_Object (UCI 4 - Current) Alarm High	"UCI 4 Current - Item Label Name" + High
Input_Object (UCI 4 - Current) Alarm HighHigh	"UCI 4 Current – Item Label Name" + High Hgih
Input_Object (UCI 4 - Voltage) Alarm LowLow	"UCI 4 Voltage – Item Label Name" + Low Low
Input_Object (UCI 4 - Voltage) Alarm Low	"UCI 4 Voltage – Item Label Name" + Low
Input_Object (UCI 4 - Voltage) Alarm High	"UCI 4 Voltage – Item Label Name" + High
Input_Object (UCI 4 - Voltage) Alarm HighHigh	"UCI 4 Voltage – Item Label Name" + High Hgih
Input_Object (EC_PH) Alarm LowLow	pH Low Low – Electrochemical Sensor
Input_Object (EC_PH) Alarm Low	pH Low – Electrochemical Sensor
Input_Object (EC_PH) Alarm High	pH High – Electrochemical Sensor
Input_Object (EC_PH) Alarm HighHigh	pH High High – Electrochemical Sensor
Input_Object (EC_PH_T) Alarm LowLow	pH Probe Temperature Low Low – Electrochemical Sensor
Input_Object (EC_PH_T) Alarm Low	pH Probe Temperature Low – Electrochemical Sensor
Input_Object (EC_PH_T) Alarm High	pH Probe Temperature High – Electrochemical Sensor
Input_Object (EC_PH_T) Alarm HighHigh	pH Probe Temperature High High – Electrochemical Sensor
Input_Object (EC_CO2) Alarm LowLow	CO_2 Low Low – Electrochemical Sensor
Input_Object (EC_CO2) Alarm Low	CO_2 Low – Electrochemical Sensor
Input_Object (EC_CO2) Alarm High	CO_2 High High – Electrochemical Sensor
Input_Object (EC_CO2) Alarm HighHigh	CO_2 High High – Electrochemical Sensor
Input_Object (EC_CO2_T) Alarm LowLow	CO_2 Probe Temperature Low Low – Electrochemical Sensor
Input_Object (EC_CO2_T) Alarm Low	CO_2 Probe Temperature Low – Electrochemical Sensor
Input_Object (EC_CO2_T) Alarm High	CO_2 Probe Temperature High – Electrochemical Sensor
Input_Object (EC_CO2_T) Alarm HighHigh	CO_2 Probe Temperature High High – Electrochemical Sensor
Input_Object (EC_DO) Alarm LowLow	Dissolved Oxygen Low Low – Electrochemical Sensor
Input_Object (EC_DO) Alarm Low	Dissolved Oxygen Low – Electrochemical Sensor
Input_Object (EC_DO) Alarm High	Dissolved Oxygen High High – Electrochemical Sensor
Input_Object (EC_DO) Alarm HighHigh	Dissolved Oxygen High High – Electrochemical Sensor
Input_Object (EC_DO_T) Alarm LowLow	Dissolved Oxygen Probe Temperature Low Low – Electrochemical Sensor
Input_Object (EC_DO_T) Alarm Low	Dissolved Oxygen Probe Temperature Low – Electrochemical Sensor
Input_Object (EC_DO_T) Alarm High	Dissolved Oxygen Probe Temperature High – Electrochemical Sensor

Input_Object (EC_DO_T) Alarm HighHigh	Dissolved Oxygen Probe Temperature High High – Electrochemical Sensor
Input_Object (BIOMASS) Alarm LowLow	Low Low – Biomass
Input_Object (BIOMASS) Alarm Low	Low – Biomass
Input_Object (BIOMASS) Alarm High	High – Biomass
Input_Object (BIOMASS) Alarm HighHigh	High High – Biomass
Input_Object (BIOMASS_RATE) Alarm LowLow	Low Low – Biomass
Input_Object (BIOMASS_RATE) Alarm Low	Low – Biomass
Input_Object (BIOMASS_RATE) Alarm High	High – Biomass
Input_Object (BIOMASS_RATE) Alarm HighHigh	High High – Biomass
Input_Object (BIOMASS) Alarm LowLow	Low Low – Aber Biomass
Input_Object (BIOMASS) Alarm Low	Low – Aber Biomass
Input_Object (BIOMASS) Alarm High	High – Aber Biomass
Input_Object (BIOMASS) Alarm HighHigh	High High – Aber Biomass
Input_Object (BIOMASS_RATE) Alarm LowLow	Low Low – Aber Biomass
Input_Object (BIOMASS_RATE) Alarm Low	Low – Aber Biomass
Input_Object (BIOMASS_RATE) Alarm High	High – Aber Biomass
Input_Object (BIOMASS_RATE) Alarm HighHigh	High High – Aber Biomass
Input_Object (LEVEL_1_RATE) Alarm LowLow	Level 1 Low Low
Input_Object (LEVEL_1_RATE) Alarm Low	Level 1 Low
Input_Object (LEVEL_1_RATE) Alarm High	Level 1 High
Input_Object (LEVEL_1_RATE) Alarm HighHigh	Level 1 High High
Input_Object (LEVEL_2_RATE) Alarm LowLow	Level 2 Low Low
Input_Object (LEVEL_2_RATE) Alarm Low	Level 2 Low
Input_Object (LEVEL_2_RATE) Alarm High	Level 2 High
Input_Object (LEVEL_2_RATE) Alarm HighHigh	Level 2 High High
Input_Object (PRESSURE_CURR) Alarm LowLow	Pressure Low Low
Input_Object (PRESSURE_CURR) Alarm Low	Pressure Low
Input_Object (PRESSURE_CURR) Alarm High	Pressure High
Input_Object (PRESSURE_CURR) Alarm HighHigh	Pressure High High
Input_Object (PRESSURE_VOLT) Alarm LowLow	Pressure Low Low
Input_Object (PRESSURE_VOLT) Alarm Low	Pressure Low
Input_Object (PRESSURE_VOLT) Alarm High	Pressure High
Input_Object (PRESSURE_VOLT) Alarm HighHigh	Pressure High High
Gas handling module (GHM) Status Alarm	Power Failure – Gas Handling Module
GHM Status Alarm	Comms Failure – Gas Handling Module
GHM Status Alarm	CO2 Valve PV1 Failed to Open – Gas Handling

	Module Primary
GHM Status Alarm	CO2 Valve PV1 Failed to Close – Gas Handling Module Primary
GHM Status Alarm	O2 Valve PV2 Failed to Open – Gas Handling Module
GHM Status Alarm	O2 Valve PV2 Failed to Close – Gas Handling Module
GHM Status Alarm	Air / N2 Valve PV3 Failed to Open – Gas Handling Module Primary
GHM Status Alarm	Air / N2 Valve PV3 Failed to Close – Gas Handling Module Primary
GHM Status Alarm	Rapid Inflation Valve SV1 Failed to Open – Gas Handling Module
GHM Status Alarm	Rapid Inflation Valve SV1 Failed to Close – Gas Handling Module
GHM Status Alarm	CO2 Valve PV4 Failed to Open – Gas Handling Module Secondary
GHM Status Alarm	CO2 Valve PV4 Failed to Close – Gas Handling Module Secondary
GHM Status Alarm	Air / N2 Valve PV5 Failed to Open – Gas Handling Module Secondary
GHM Status Alarm	Air / N2 Valve PV5 Failed to Close – Gas Handling Module Secondary
GHM Status Alarm	N2 Valve PV6 Failed to Open - Gas Handling Module Primary
GHM Status Alarm	N2 Valve PV6 Failed to Close – Gas Handling Module Primary
GHM Status Alarm	Primary Outlet Shutoff Valve SV2 Failed to Open – Gas Handling Module
GHM Status Alarm	Primary Outlet Shutoff Valve SV2 Failed to Close - Gas Handling Module
GHM Status Alarm	Secondary Outlet Shutoff Valve SV3 Failed to Open – Gas Handling Module
GHM Status Alarm	Secondary Outlet Shutoff Valve SV3 Failed to Close – Gas Handling Module
GHM Air Inlet Pressure Alarm LowLow (Units are mBar)	Air Inlet Pressure Low Low – Gas Handling Module
GHM Air Inlet Pressure Alarm Low	Air Inlet Pressure Low – Gas Handling Module
GHM Air Inlet Pressure Alarm High	Air Inlet Pressure High – Gas Handling Module
GHM Air Inlet Pressure Alarm HighHigh	Air Inlet Pressure High High – Gas Handling Module
GHM O2 Inlet Pressure Alarm LowLow	O2 Inlet Pressure Low Low – Gas Handling Module
GHM O2 Inlet Pressure Alarm Low	O2 Inlet Pressure Low – Gas Handling Module
GHM O2 Inlet Pressure Alarm High	O2 Inlet Pressure High – Gas Handling Module
GHM O2 Inlet Pressure Alarm HighHigh	O2 Inlet Pressure High High – Gas Handling Module
GHM CO2 Inlet Pressure Alarm LowLow	CO2 Inlet Pressure Low Low – Gas Handling Module
GHM CO2 Inlet Pressure Alarm Low	CO2 Inlet Pressure Low – Gas Handling Module
GHM CO2 Inlet Pressure Alarm High	CO2 Inlet Pressure High – Gas Handling Module
GHM CO2 Inlet Pressure Alarm HighHigh	CO2 Inlet Pressure High High – Gas Handling Module
GHM N2 Inlet Pressure Alarm LowLow	N2 Inlet Pressure Low Low – Gas Handling Module
GHM N2 Inlet Pressure Alarm Low	N2 Inlet Pressure Low – Gas Handling Module
GHM N2 Inlet Pressure Alarm High	N2 Inlet Pressure High – Gas Handling Module
GHM N2 Inlet Pressure Alarm HighHigh	N2 Inlet Pressure High High – Gas Handling Module
GHM Outlet Pressure Alarm LowLow	Primary Outlet Pressure Low Low – Gas Handling Module
GHM Outlet Pressure Alarm Low	Primary Outlet Pressure Low – Gas Handling Module

GHM Outlet Pressure Alarm High	Primary Outlet Pressure High – Gas Handling Module
GHM Outlet Pressure Alarm HighHigh	Primary Outlet Pressure High High – Gas Handling Module
GHM Outlet Pressure Alarm High	Secondary Outlet Pressure Low Low – Gas Handling Module
GHM Outlet Pressure Alarm Low	Secondary Outlet Pressure Low – Gas Handling Module
GHM Outlet Pressure Alarm HighHigh	Secondary Outlet Pressure High – Gas Handling Module
GHM Outlet Pressure Alarm LowLow	Secondary Outlet Pressure High High – Gas Handling Module
GHM Outlet TotalFlow Alarm High	Primary Outlet Total Flow High
GHM Outlet TotalFlow Alarm Low	Primary Outlet Total Flow Low
GHM Outlet TotalFlow Alarm HighHigh	Primary Outlet Total Flow High High
GHM Outlet TotalFlow Alarm LowLow	Primary Outlet Total Flow Low Low
GHM Outlet TotalFlow Alarm High	Secondary Outlet Total Flow High
GHM Outlet TotalFlow Alarm Low	Secondary Outlet Total Flow Low
GHM Outlet TotalFlow Alarm HighHigh	Secondary Outlet Total Flow High High
GHM Outlet TotalFlow Alarm LowLow	Secondary Outlet Total Flow Low Low
Allegro XRS 25 bioreactor status alarm	Allegro XRS 25 bioreactor Power Failure
Allegro XRS 25 bioreactor status alarm	Allegro XRS 25 bioreactor Comms Failure
Allegro XRS 25 bioreactor status alarm	X Axis Servo Failure
Allegro XRS 25 bioreactor status alarm	Y Axis Servo Failure
Allegro XRS 25 bioreactor status alarm	Lid Open
PT100 Status Alarm (out of bounds)	PT100 Sensor Open Circuit - Failed Sensor or Broken Wire / Connector
PT100 Status Alarm (out of bounds)	PT100 Sensor Overrange
Presens Module 1 status alarm	Presens Module 1 – Power Failure
Presens Module 1 status alarm	Presens Module 1 – Comms Failure
Presens Module 1 status alarm	Presens Module 1 – Open Circuit
Presens Module 1 status alarm	Presens Module 1 – Overrange
Presens Module 2 status alarm	Presens Module 2 – Power Failure
Presens Module 2 status alarm	Presens Module 2 – Comms Failure
Presens Module 2 status alarm	Presens Module 2 – Open Circuit
Presens Module 2 status alarm	Presens Module 2 – Overrange
E-Stop status Alarm	Emergency Stop Pushbutton Activated
E-Stop status Alarm	Emergency Stop Self Test – Pushbutton Failed
Cooling FAN status alarm	Control Tower Cooling Fan Failed – Running at Low Speed
Cooling FAN status alarm	Control Tower Cooling Fan – Power Failure
Cooling Temperature alarm	Control Tower Internal Temperature High

Life Sciences

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