

**“Walk in”
Modular Material Transfer Chamber
Including Integration of a Bioquell Clarus L2
hydrogen peroxide vapour (HPV) generator**

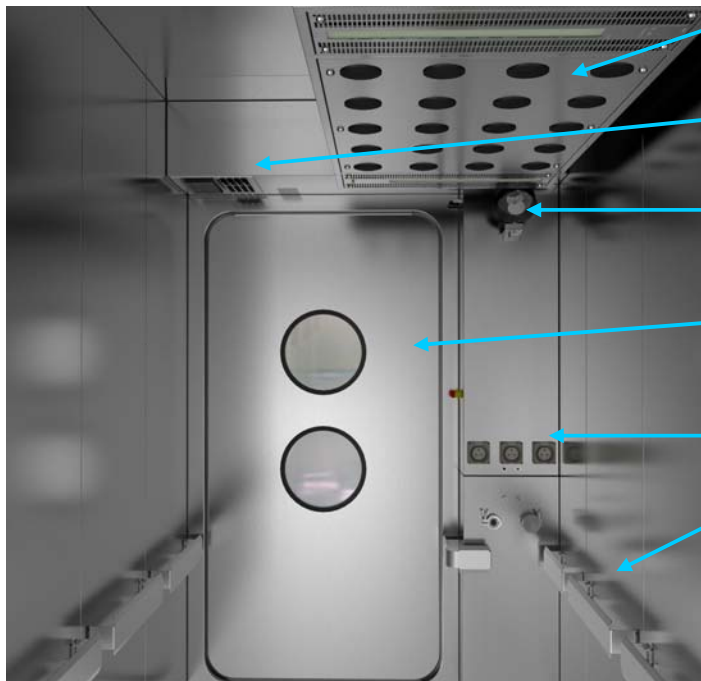


Walk in chamber and HPV integrated system - Product overview.

The Walk in - HPV (Materials Transfer solution) is an integrated through the wall transfer device for material transfers between different classification rooms where either an air particulate clean up or material surface bio-decontamination step is needed before transfer, in either direction.

The Walk in requires a hydrogen peroxide vapour generator attached that can be connected either room side or in a separate technical area.

Inside view of chamber HPV



Ceiling Mounted Aeration Unit

Air Purge By-pass System (APB)

Stirring Fan (tacho monitoring)

High performance inflatable seal door

Internal Power Sockets and comms for Clarus Self Decontamination

Stainless steel bumper rails to ensure product is 100mm from the wall for good air flow around the load.

Overview of integration of the Clarus L2 Hydrogen peroxide Vapour Generator.

Clarus L2 Hydrogen peroxide vapour Generator used with the Walk-in transfer chamber must be possible to connect and operate either side of the chamber (Loading or Unloading side).

Clarus L2 – multi-application H₂O₂ Vapour Generator for chambers, small rooms (up to 75 cu m) and isolators.

Overview of HMI integration

- The Chamber loading side will carry the master soft touch Siemens HMI with a slave on the unloading side.
- All HMI screens including Clarus L2(1) +Chamber(2) HMI be integrated into the Chamber master HMI.
- At the Master cycle parameters can be changed together with all other functions.
- At the Slave cycles can be selected, run but not modified.
- The HMI will replace push button features.
- An Emergency override is required in addition to the HMI soft touch screen.

Airflow configuration options – 4 optional configurations will be required (see walk in chamber system schematic)

1. Recirculation catalyst plus chamber Air Purge Boost system (APB).
2. Recirculation catalyst plus Building HVAC inlet and exhaust.
3. Building HVAC only under control of BMS (signal exchanges required during HPV cycle).
4. APB only.

Note: Recirculation catalysts to include ceiling mounted aeration unit and the Bioquell 'R' range. Options 3 and 4 have the ability to run a R range aeration unit.



2.0 Process and high level (6log) hydrogen peroxide vapour (HPV) disinfection requirements overview.

Process and walk in chamber operation overview

The walk in HPV chamber is a transfer device for through the wall material transfers between different classification rooms.

For GMP applications, transfers can be bi-directional between loading side, GMP EU Grade D/C and unloading side Grade C/B or the reverse (from the cleaner production side to the preparation side on the facility).

Interlocking direction/priority is to be selectable. In the case of GMP the priority is to be from the preparation side (lower classification room) to the production side (higher classification room), however the decontamination step should be selectable at the entry or exit side of the chamber.

For BSL/Cat-rooms exit decontamination will be the priority but it will also require bi-directional decontamination interlocking.

In addition materials can enter and exit from the same side after a disinfection or air clean up cycle.

The **walk in chamber** has two principal modes of operation:

- 1) **Air cleanup cycle** (Timed particulate clean-up with interlocked doors).
- 2) Hydrogen peroxide vapour high level **disinfection cycle** (disinfection of outer surfaces of materials placed in the walk in chamber for transfer).

The Air clean up cycle provides particulate clean up to EU Grade C/B particle conditions (as required), via H14 grade inlet HEPA filtration. The particulate clean up time is a validated time based on clean up from the actual environmental conditions on the loading or unloading side (as specified).

Walk in chamber doors are required to have an inflatable, interlocked function so that no two chamber doors are open at the same time. The clean up is completed after loading before the other side door is provided access for opening. Each time a chamber door is closed clean up will be completed automatically before re-entry (door opening) is possible. The chamber HVAC will remain in operation during standby to maintain room pressure balances.

The hydrogen peroxide vapour high level disinfection cycle

Is an automated cycle for high level disinfection of material outer surfaces, supported on point contact supports to maximise exposure, before transfer between rooms.



Type of vapour generator used with the walk in chamber.

The hydrogen peroxide vapour generator integrated with the walk in chamber, for automated disinfection cycles, will be the Bioquell Clarus L2.

When a combined room and chamber function is specified the Clarus L2 and Chamber PLCs will require communication capability with an interface PLC controller.

If a Clarus C is required for a larger room suite application combined with a Walk in Chamber this is a different Chamber product and not covered by this specification.



Overview of walk in chamber – HPV integrated control systems.

Clarus vapour generators have dedicated siemens S7 PLC programmed for disinfection cycle control and alarm management of a pre-defined cycle selectable from stored cycles (up to 99).

The Clarus L2 has an onboard User interface soft touch screen.

The **walk in chamber** requires a dedicated S7 PLC. Programmed to control and monitor the chamber configuration and devices. The devices include fans, APB, valves and pneumatics. The PLC will alarm if the devices are faulty or running outside of set parameters. Alarms and status functions will be detailed on the HMI. A HMI will be located beside the load and unload doors.

In addition the walk in chamber temperature will be monitored and is required to have automatic emergency venting (to cool the chamber/load) in the event of the maximum temperature alarm limit being reached during the cycle.

The user interface for starting cycles will be via soft touch buttons on the HMI. An emergency override will be required at each side of the Chamber to abort cycles in the event of unacceptable deviation. Safe recovery routines will be controlled in response to alarms or a cycle abort.

An emergency override is required inside the chamber.

The HPV Generator PLC and the walk in chamber PLC are to communicate via a profibus connection and digital signals.

High level disinfection cycle qualification and control

Outer material surfaces will be decontaminated before transfer via a validated 6log reduction using a hydrogen peroxide vapour sporicidal disinfection cycle.

Each HPV cycle will be developed based on defined load patterns and qualified with biological indicator challenges of *Geobacillus stearothermophilus*, highly resistant spore form inoculation on stainless steel carriers presented in a Tyvek primary pack.

Gassing cycle development protocols are specified to complement installations at defined sites.



Process and walk in chamber operation overview

The high level disinfection process phases controlled by the Clarus L2 include the following steps:

1. Conditioning phase: reduction in relative humidity (limited impact on process in small chambers) and temperature conditioning of the vapour delivery system.
2. Gassing: to process lethal conditions – achieving saturated vapour conditions, past dew point, where hydrogen peroxide molecules are delivered to surfaces (in a micron layer) starting the oxidation process and free radical release to affect bio-decontamination.
3. Gassing Dwell: contact time of decontamination agent for sporicidal activity. This phase may include further hydrogen peroxide injection, if required, otherwise the injected peroxide will maintain in circulation.
4. Aeration: re-evaporation of micron-layer of decontamination agent removal of gas residuals for a residue free process. This is a joint phase with gas residual removal by the vapour generator catalyst (20-30 cubic metres per hour flow rate) and a recirculation catalyst device i.e. a ceiling mounted aeration unit (2000 cubic metres per hour flow rate) or the R range aeration units in conjunction with the APB (300 cubic metres per hour) or building HVAC. The chamber exhaust vent system may also include a catalyst filter if there is a restriction or safety case not to vent peroxide outside.



Chamber pressure regulation and maintenance of room to room pressure differentials, during material transfers.

The APB will be running continuously with flow regulated by a local constant velocity damper. Interconnection to the chamber exhaust duct may be rigid or flexible connection (As required). The inlet air fan will have a speed control facility for adjustment during set up to establish chamber pressure neutral relative to the defined reference, loading side. During gassing phases the APB will be diverted to 'By-pass' via a change over valve system.

Pressure regulation of the chamber through consequential pressure changes, due to temperature variation through the disinfection process, is maintained by use of a Catalyst –Hepa pressure balance filter. This filter permits safe pressure release (via a catalyst/Hepa) or pressure make up via a Hepa filter so that pressure in the chamber stays neutral with respect to the reference side of the chamber (typically the lower classification loading side). The pressure balance filter (one single unit) will have facility of connecting the pressure reference line to either side of the chamber (specified for the defined application).

There is no automated Leak test required for Walk-in chambers, hence no valve on the pressure balance filter. However installation and re-qualification leak tests will be required and for these applications a manual valve is provided to close the leak path.



Leakage management from the chamber

Key safety considerations are that the chamber is always operated at neutral pressure with respect to the loading side and a very low passive pressure with respect to the unloading room side. In addition door seals are inflatable with continuous integrity monitoring required.

Therefore there is very limited motive force for leakage. In the event of unexpected leakage into either of the much larger volume, adjacent ventilated rooms it should be possible to support by risk assessment and calculation that the Operator Exposure Limit (OEL = 1ppm) will not be compromised in operation.

Door and valve configurations are to be monitored via positional sensors to assure HPV gas containment in cycle.

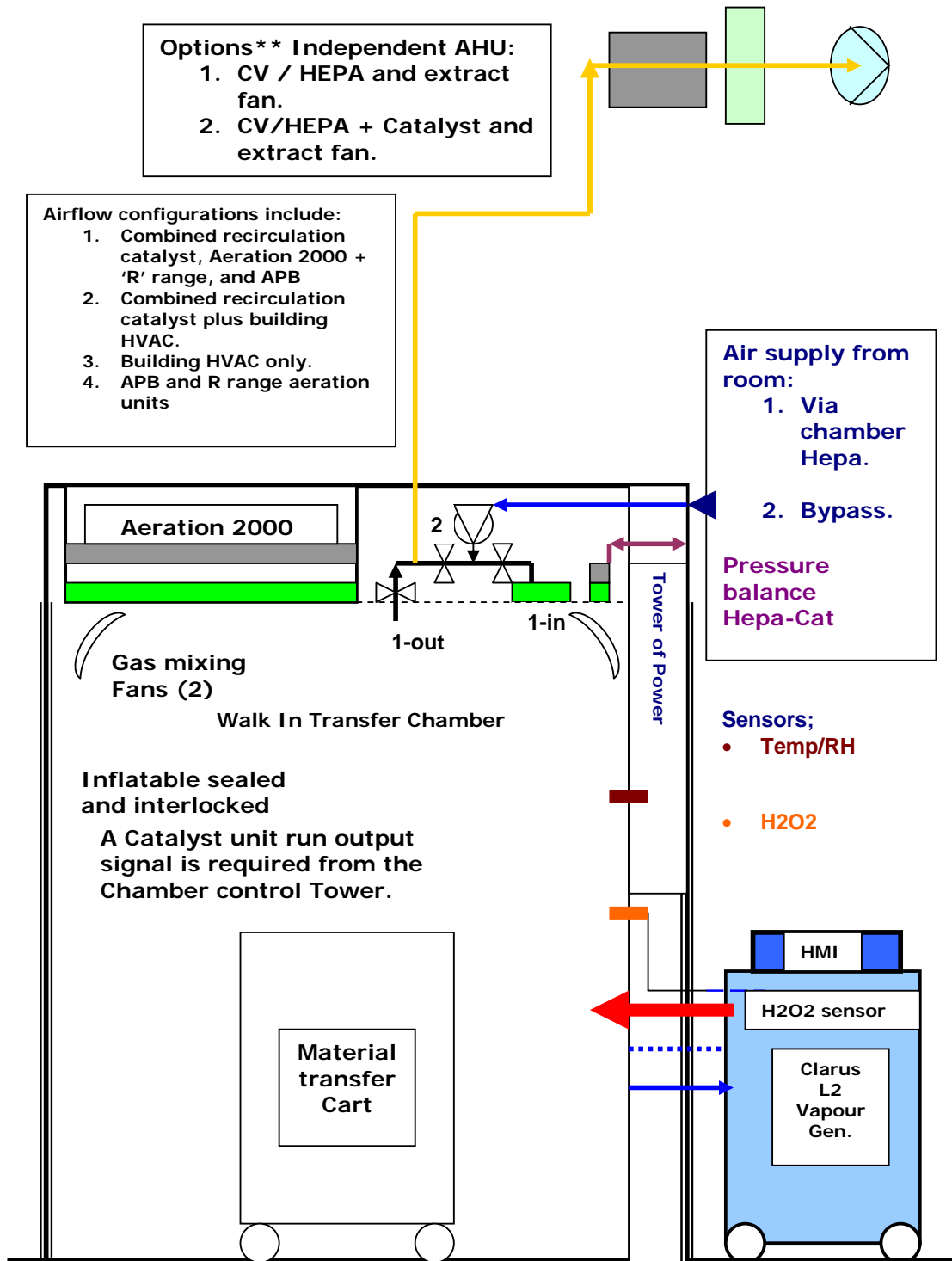
Based on safety considerations together with the fact that hydrogen peroxide molecules are subject to hydrogen bonding ('sticky molecules') hence the vapour is poor at passive diffusion a pre-gassing leak tests are not used at each cycle run.

Leak testing is completed as an operational qualification at installation and during routine environmental monitoring programmes.

A qualification leak test cycle is possible via the Clarus L2 controller. The onboard pressure transducer of the Clarus L2 is used for the leak test control. In this case the balance Filter sealing plates are fitted and a Leak test only cycle program used in the Clarus L2, from stored cycles.



Walk in Chamber system schematic



Chamber – HPV system functionality and control logic.

HPV Standby - overview

In standby with both transfer doors closed, with the APB unit air into the chamber is routed from the lower classification loading side through a H14 grade HEPA filter into the enclosure and around the chamber. Chamber air is then extracted to the outside via a dedicated air handling unit. Door open availability is indicated by an illuminated 'Green' Door open push button on the soft touch screen. The chamber status indicator on the soft touch screen is not illuminated in stand by.

HPV Disinfection cycle overview

In HPV mode entry access to the opposite barrier side transfer door is only possible after successful completion of an automated HPV cycle.

HPV - Disinfection operation will be selected by way of a password protected setup screen on the user screen.

The required Clarus L2 cycle can be selected from 'stored cycles' and advanced on the Clarus HMI screen to 'waiting for remote input'.

If both doors are locked and there are no alarms the HPV disinfection cycle can then be started by pressing the Chamber cycle start push button (the push button will be illuminated green). Door access will be disabled. The chamber display indicator will illuminate amber. The inlet air valves and extract valves will close isolating the chamber for receiving Hydrogen peroxide vapour. The chamber air inlet fan will remain in operation with air re-routed to extract via the by-pass. Gas mixing fans inside the chamber will be turned on. Gas mixing fans require rotation monitoring in operation.

The vapour generator automatically progresses the disinfection cycle through the conditioning and gassing phases.

Over pressure in the chamber (not expected due to pressure balance HEPA – Catalyst) will be monitored and if out of specification limits are reached the HPV cycle will be aborted and emergency aeration started.

Self disinfection of the Clarus L2.

A function is required for self disinfection of the Clarus L2.

As the L2 can be used for other room disinfections the L2 may need transfer into the clean room or containment room suite. In the case the disinfection cycle is completed with the L2 inside the chamber with all HPV and control connections required inside whilst maintaining cycle control from the chamber HMIs.



Chamber – HPV system functionality and control logic.

HPV Disinfection cycle overview

At the arrival of the aeration phase there is an operational change to combined system aeration. Aeration (gas residual removal) is completed by a combination of the APB or building HVAC. A recalculating aeration unit (Ceiling mounted aeration unit or the R range aerators) may be used.

At the completion of the timed aeration phase, reaching 1ppm or lower residual gas concentration, the operator is requested to acknowledge the end of cycle. To indicate an action is required by the operator the chamber status indicators on the touch screen flash amber and the cycle end acknowledge illuminates amber.

Transfer Mode –After an HPV Disinfection cycle.

On pressing the cycle end acknowledgement button on the touch screen the indicator light goes out and the vapour generator unit is automatically switched off. The chamber status indicator on the touch screen illuminates green and both door open access indicator lights are illuminated (green). The chamber ventilation will be running, with the extract route through the chamber.

When a door is requested to be opened the chamber ventilation switches to bypass.

If the unloading door is open there is no possible air exchange between the loading side and the unloading (GMP)/Production or BSL side.

The unloading side door can be opened and closed as many times as required. If the loading side door is opened a disinfection cycle must be repeated before the unloading side door can be opened. The chamber display indicator on the soft touch screen is to illuminate red if a chamber door is left open for longer than a preset access time.



Monitoring and HPV cycle deviation control.

HPV cycle – critical parameter/ condition monitoring.

The chamber PLC controller is required to control and monitor all associated devices including, fans, valves, door interlocks, seal inflation and sensors including hydrogen peroxide vapour gas concentration, flow and temperature.

The vapour generator PLC controls and monitors all critical control points of the disinfection cycle including monitoring (only) chamber pressure within set limits. If any critical parameter or condition reaches alarm limits or settings during the HPV cycle then the cycle will automatically abort (generator goes to Off mode).

At HPV cycle abort the chamber will be required to indicate alarm status. Depending at what point in the HPV cycle abort occurred the chamber status must be controlled for safe recovery to either hydrogen peroxide vapour clearance or a restart of a HPV cycle with successful completion.

HPV cycle abort (generator goes to Off mode) control responses:

1. Cycle abort once cycle started at Conditioning phase:
 - Chamber remains in set configuration with both doors locked and in alarm indication.
 - To clear the cycle either a cycle end signal is provided by completing a valid Aeration only or HPV cycle selected from the HPV generator and re-run or by emergency aeration via the chamber HVAC (selected from the chamber HMI).

A chamber emergency aeration function will be available for selection at the chamber. Emergency aeration, via the chamber extract air handling unit (only), is direct venting of HPV to the outside environment for dilution and natural breakdown to water and oxygen). The emergency aeration time is validated and pre-set as a default value.

Alarm messages relating to the HPV generator will be printed with time/date on the vapour generator printer. During operation event messages will also be required to be displayed on the vapour generator HMI.

Alarm messages relating to the chamber devices position, On-Off status and conditions of flow and temperature will require display on the chamber HMI. There will be no print out of chamber alarm events.

Refer to independent data logging option for temperature and Hydrogen peroxide vapour gas concentration via Yokagawa data logger.



HPV cycle abort by emergency override.

Operators can abort a HPV disinfection cycle by actuation of an emergency override button (one each side of the Chamber) or by activation of the abort button on the Clarus L2 HMI.

Room HPV environmental monitor interface.

ATI room monitors (monitoring for leakage at 1ppm) can be interfaced with the vapour generator via a BMS (building management system). If activated this will abort the HPV disinfection cycle.

Cycle End following Emergency Aeration

Following emergency aeration the operator will be prompted to take a gas concentration sample at a sample port provided on the chamber (sample taken with an independent hand held gas sensor instrument / device suitable for low level gas concentration measurement e.g. Portasens or drager peroxide tubes). Following confirmation the chamber concentration is at or below the operator exposure limit of 1ppm (one part per million for a time weighted average of 8 hours) then acknowledging cycle end (via push button – Green light) will advance the chamber status to open door access of the loading side only. Maintenance / repair may be needed before continued use.

Chamber fault conditions and recovery.

Gas mixing fans in the chamber have taco monitoring with failure an alarm condition that will abort the HPV cycle. Maintenance / repair may be needed before continued use.

Any flow fault of the chamber aeration support systems, Aeraflow or HVAC extract, will be alarmed via flow failure as the vapour generator aeration phase time will not be valid. In this event the vapour generator HPV cycle will be aborted with the vapour generator advancing to Off mode.

Maintenance / repair may be needed before continued use.



HPV cycle print record.

At each cycle phase transition, key control parameters will be printed on the Clarus L2 printer. Refer to the Clarus L2 User manual.

As standard the hydrogen peroxide gas concentration in the chamber will be measured and recorded on the Vapour Generator cycle print-out. Gas concentrations will be printed at phase transitions of:

- Cycle start at Conditioning phase
- Start of Gassing phase
- Peak concentration in Gassing phase.
- Start of Gassing Dwell phase.
- Peak concentration in Gassing Dwell phase.
- Start of Aeration Phase.
- Peak concentration in Aeration phase.
- At Aeration completion.
- At cycle end acknowledgement.

Clarus L2 location and print records.

The Clarus L2 must to be possible to install and operate from a remote location from the chamber (within specified restrictions).

A remote printer option is not required. All print records will be generated at the Clarus L2.

It is likely to maintain control of the critical print records the Clarus L2 will not be installed in an uncontrolled technical area (plant room) but will be installed in the locality of the chamber.

Chamber – HPV cycle temperature monitoring and control logic for out of specification deviations.

Temperature monitoring

The vapour generator has temperatures that are controlled monitored and alarmed in the event of deviation during the HPV cycle. Temperature control and monitoring includes the vaporiser, refrigeration dryer and re-heater temperatures and if outside set limits the HPV cycle will be aborted.

The chamber is fitted with a temperature sensor with default set point at 30 degrees C. At arrival of the Max temperature set point during the HPV disinfection cycle the chamber PLC will monitor this condition for a set length of time (0 to set hold time).

In the event of the maximum temperature (or above) maintaining for the set time this becomes an alarm condition with an automatic abort of the vapour disinfection cycle and start up of Emergency Aeration. The chamber APB will be automatically changed from by-pass mode to aeration mode to reduce the chamber temperature. The vapour generator will be aborted to Off mode.

Chamber pressure monitoring in the HPV cycle.



The vapour generator has a pressure sensor transducer and will monitor and record chamber pressures through the HPV cycle. In the event of low or high pressure alarms (not expected) the disinfection cycle will automatically abort.

Auxiliary power supplies inside the chamber.

During the HPV cycle process equipment may be part of the decontamination load. In this case the process equipment may require power supplies (single phase) to run internal fan or ventilation systems to assure full decontamination. Auxiliary power supplies are required from the Chamber control tower.



Optional independent temperature data logging.

The standard chamber system will include a facility for independent data logging of the chamber temperature with a 2-10 volt output signal for the purpose of independent data logging on a client supply data logger.

Optional independent hydrogen peroxide vapour gas concentration data logging.

The standard chamber system will include a facility for independent data logging of the chamber hydrogen peroxide vapour gas concentration with a 2-10 volt output signal for the purpose of independent data logging on a client supply data logger.

Recommended independent Data logger.

Data loggers are not included as part of the chamber package but a 'Paperless' Yokohama DX100P is recommended.

BMS pressure monitoring port

In some cases pressure differential monitoring of the Chamber in respect to adjacent rooms will be required. Such monitoring will be the function of the BMS and not included in the chamber control system. A pressure connection port is required in the chamber design in preparation for monitoring via the BMS, if specified.

Air Clean cycle overview

The Clean air cycle is a dedicated Air particulate clean up cycle only. Chamber doors are interlocked to ensure the opposite side barrier door can not be opened until a valid air clean up cycle is completed (expected to be just a few minutes – specific times validated and set at time of installation).

Air Clean mode operation will be selected by way of a password protected setup screen on the user screen.







On closure of the selected door the validated air clean up Air purge will be automatically completed before permitting further opening access to either door.

When a door is requested to be opened the chamber ventilation switches to by-pass.

The Chamber Display indicator is to illuminate Red if a chamber door is left open for longer than a preset access time.



Signal exchange summary table of signals between chamber PLC and vapour generator PLC.

Digital Input and Output to Isolator PLC – Digital Signal exchanges		
Mode Phase	Walk in - Chamber PLC	Vapour Generator PLC
Disinfection Mode selection cycle start, progressing to: Conditioning phase.	On disinfection selection, configuration verification the Disinfection mode is set and a Disinfection Start signal is provided to Vapour Generator. 1. 	Vapour Generator prepared for disinfection and cycle status advanced at Vapour Generator UMI to 'Waiting for remote input' On receipt of Start disinfection signal the Disinfection cycle advances to the first stage of Conditioning of Temperature and Relative humidity.
Gassing phase start and Run	At Gassing signal from Vapour Generator the GAS PRESENT display on the Walk in interface panel is illuminated - Amber.	Following completion of Conditioning phase the Vapour Generator automatically advances in Gassing phase . At arrival of Gassing phase the Vapour Generator provides a Gassing signal to the Walk in PLC. 2. 
Aeration phase	On receipt of Aeration signal the Air make up and exhaust valves, V1/V3 are opened with supply / exhaust fans switched on followed the bypass valve V2 closed.	At arrival of Aeration phase Vapour Generator provides Aeration signal to Walk in PLC. 3. 
Aeration complete and cycle complete acknowledge	On receipt of cycle complete signal Walk in PLC verifies exhaust flow status as alarm free and requests for operator acknowledgement of cycle end. Following the cycle end acknowledgement key operation a Cycle end signal is provided to the Vapour Generator. 5. 	At cycle complete (time controlled by Vapour Generator PLC) signal provided to Walk in PLC to acknowledge cycle End. 4.  On receipt of cycle end signal Vapour Gen goes to Off mode.
Cycle End: Clean door access provided	After minimum of (10) seconds remove Disinfection Start signal 6. 	Vapour Generator proceeds to Off mode waiting for further HPV cycles (as required).



Material Airlock (MAL) to HVAC interfacing.

'Start disinfection (in cycle)' signal - Output from chamber

'Alarm Signal' – Output from chamber

'Ready for disinfection' signal – Output from HVAC

'Start Aeration' signal – Output from chamber

Note: All signals are volt-free contacts.

In cycle logic will be as follows:

Mal signals ready to 'Start disinfection' and waits for 'Ready for disinfection' signal from HVAC.

On Receipt of the 'Ready for disinfection' signal the VHP Generator will transition through its cycle.

When the Aeration phase of the cycle is reached the Mal signals 'Start Aeration' to the HVAC. On completion of the Aeration phase the 'Start Aeration' signal is reset.

When the VHP cycle completes the 'Start disinfection' signal is reset.

Reset the 'Ready for disinfection' signal.

Alarm Logic will be follows.

HVAC:

Loss of 'Start disinfection (in cycle)' signal and 'Start Aeration' signal not received.

Loss of 'Start disinfection (in cycle)' signal less than 2 seconds after the 'Start Aeration' signal is reset.

Timeout waiting for 'Start Aeration' signal.

An alarm signal will be sent to the building HVAC in an event of a chamber or vapour generator critical alarm.

MAL

Loss of 'Ready for disinfection' signal and cycle not complete.

Timeout waiting for 'Ready for disinfection' signal.



Related Documentation either PBSC or BIOQUELL document formats (as stated).

Specifications.

1. Walk in FRS / Functional requirement specification – This document.
2. Walk in product specification – hardware – PBSC document.

Factory testing documents

1. SAT- Site acceptance test – PBSC document

Site testing documents

1. IQOQ Clarus L2 – Bioquell document
2. Chamber Mechanical Build sign off document – PBSC document.
3. Chamber electrical test sign off document – PBSC document.
4. Chamber commissioning document – PBSC document.
5. Gassing cycle PQ - Performance Qualification – Bioquell document.
6. Summary Qualification report – Bioquell document.

Manuals

1. Walk in user manual – PBSC/Bioquell document.
2. Clarus L2 user manuals – Bioquell documents.

