

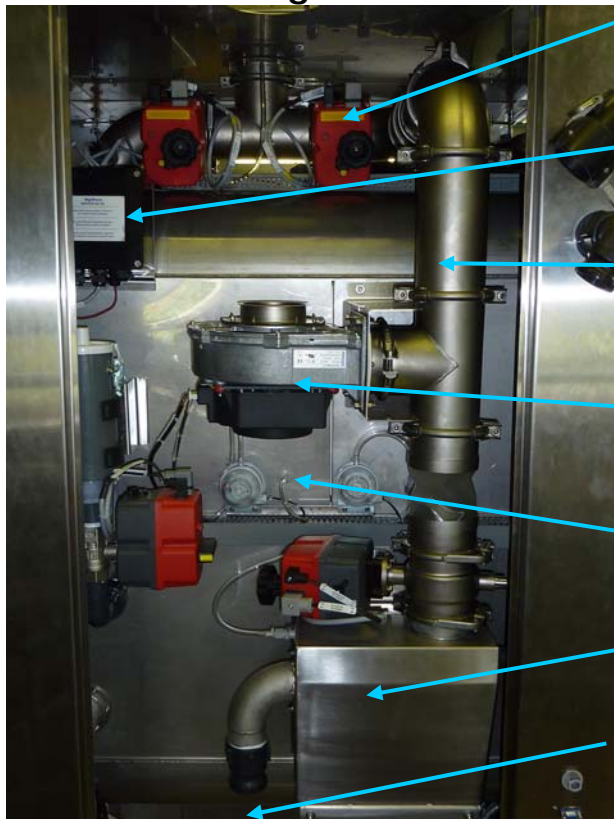
“Pass Through Chamber”
High Level HPV Disinfection Transfer Hatch
Including Integration of a Bioquell Clarus L2
hydrogen peroxide vapour (HPV) generator



HPV Transfer Hatch and HPV integrated system - Product overview.

The fumigation pass through hatch - 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 Transfer requires a hydrogen peroxide vapour generator attached that can be connected either room side or in a separate technical area.

Side view through chamber service panel



Monitored 24VDC valves with a 100mm butterfly valve

Heat trace for temperature control on the supply pipe to the injection nozzle.

Stainless steel ducting with compensators

High performance fan unit, with PWM signal for speed control

Pressure switches to monitor ducting and pressure drop across the filter.

H14 HEPA filter with stainless steel plenum chamber.

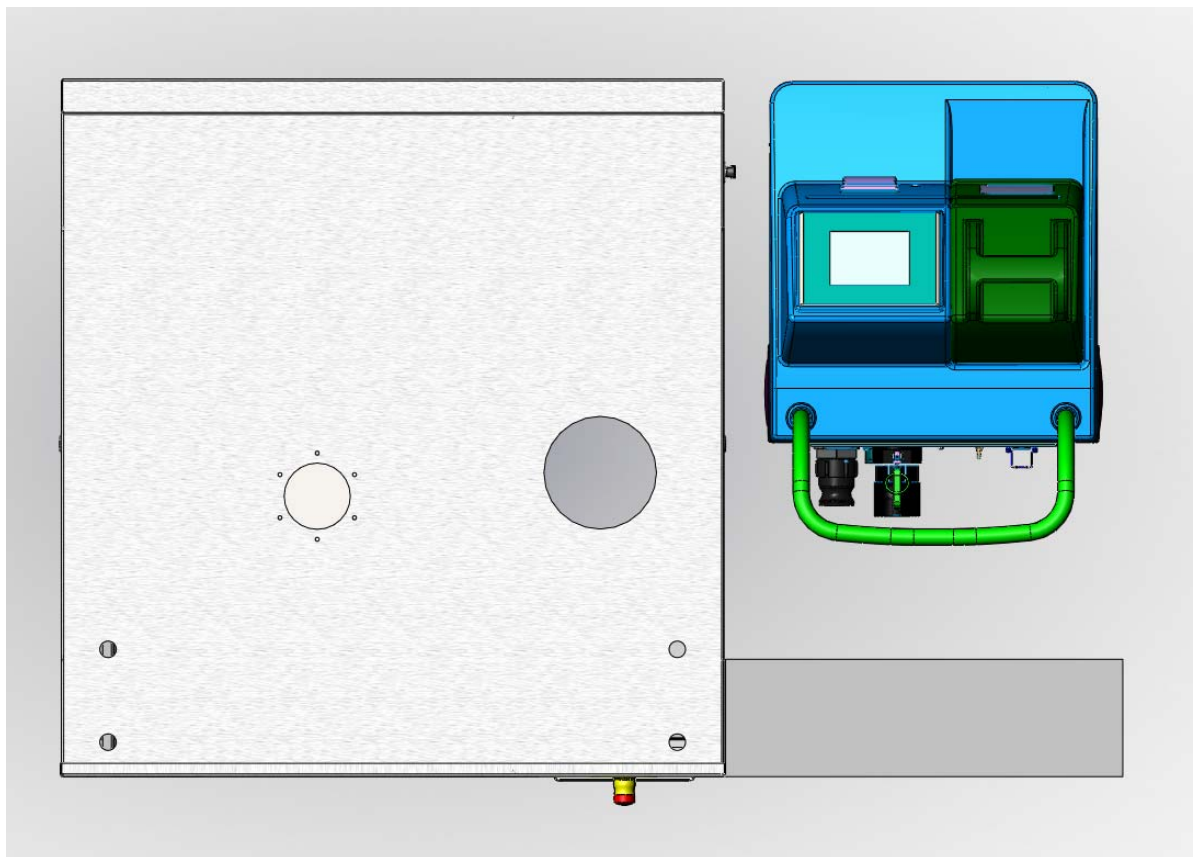
Re-circulating catalyst to assist with the aeration phase in the HPV cycle.

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

Clarus L2 Hydrogen peroxide vapour Generator used with the pass through hatch and is connected to the chamber on the fixings as shown below. It is possible to operate either side of the chamber (Loading or Unloading side).



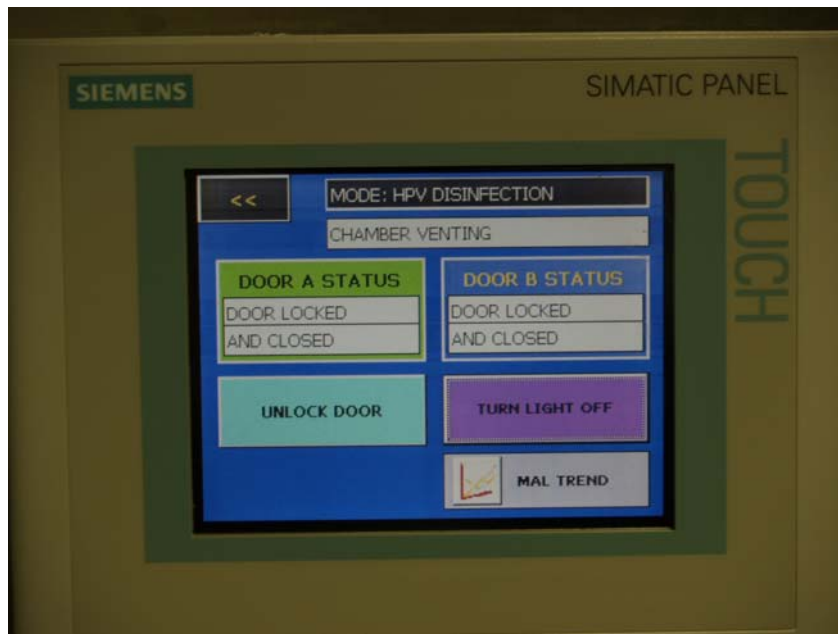
Above are the cam lock connections to the chamber



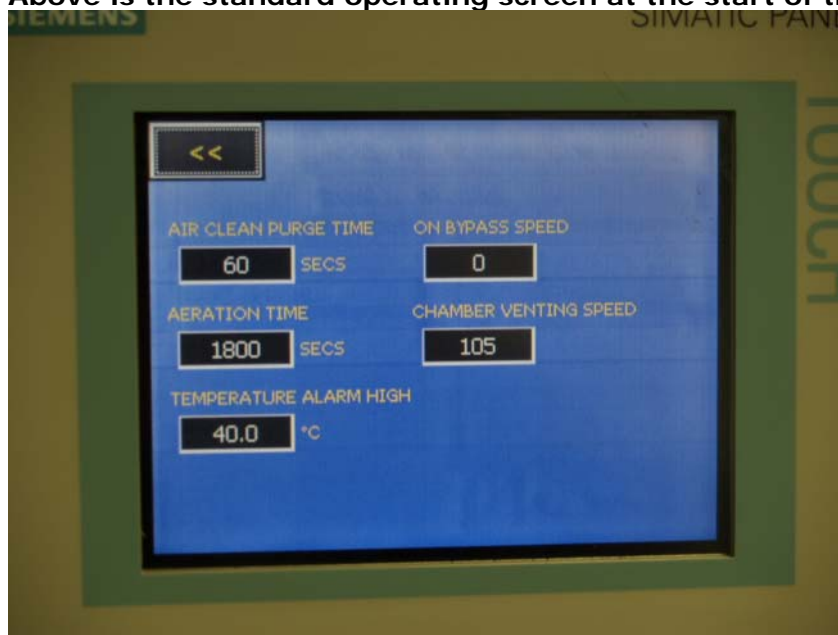
Above shows the standard position of the Clarus L2 next to the hatch.

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 supplied to both sides of the hatch in addition to the HMI soft touch screen.



Above is the standard operating screen at the start of the cycle



Above is a calibration screen for time and temperature settings

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

Process and transfer chamber operation overview

The HPV transfer 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 **transfer 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 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).

The chamber doors have an inflatable seals and an 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 transfer chamber.

The hydrogen peroxide vapour generator integrated with the transfer 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 Chamber this is a different Chamber product and not covered by this specification.



- 'Dual Circuit' technology for optimum cycle times
- Closed circuit operation – no external vent required
- Siemens MP177 colour touch screen
- GAMP compliant software
- Compact and highly portable design
- Easily cleanable external surface
- Volt free contacts for external signals
- Integral thermal paper printer
- Remote start/stop
- Simple connection, flexible supply / return hoses and pressure monitoring
- Supply and return hoses (2m long)
- Cycle edit and store facility for new applications
- Effective against a wide range of micro-organisms
- Hydrogen Peroxide gas sensor
- RH sensor
- Utilises 30 % w/w or 60% AnalaR grade H₂O₂ in standard format containers (500 mL or 1000mL)
- Maximum enclosure bio-decontamination 80m³
- Dimensions: 510(w) x 700(d) x 1135(h) mm.
- Weight: 80Kg

Overview of Transfer Hatch– 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 **transfer chamber** has 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 is 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 transfer 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 transfer 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 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 200 cubic metres per hour flow rate in conjunction with the APB (300 -400 cubic metres per hour).

Note: 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).

In the event of a pressure leak test the automated ball valve on the pressure balance filter will seal the leakage 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.



Airflow configuration

The hatch operates continuously draws a **constant** volume of air from the side of the hatch the Clarus is connected. The air is taken through the stainless steel ducting in the hatch in two methods depending on the condition of the hatch. The hatch requires an extract duct drawing a constant amount of air to be connected to the roof of the hatch. Below are two type of preparation which can be supplied. Please advise the type you required. The ducting connection at the top of the chamber is 100mmØ.

Air purge through the chamber

There are a number of conditions when the 3 No. valves on the chamber ducting system direct the air through the H14 filter on the hatch. These are below.

- At rest: To provide a continual particulate clean up in the hatch chamber.
- Air cycle: If the air cycle is selected a load can be passed through the hatch after the air purge has run for a set period of time. The air purge time is set via the master touch screen.
- Aeration: During the aeration phase of the HPV cycle the hatch, the air will be directed through hatch. Also the re-circulation unit at the bottom of the hatch will run for the aeration period.

Bypass of chamber

The air will by pass the chamber and vent directly to the exhaust during when a door is opened, conditioning phase, gassing phase and dwell phase



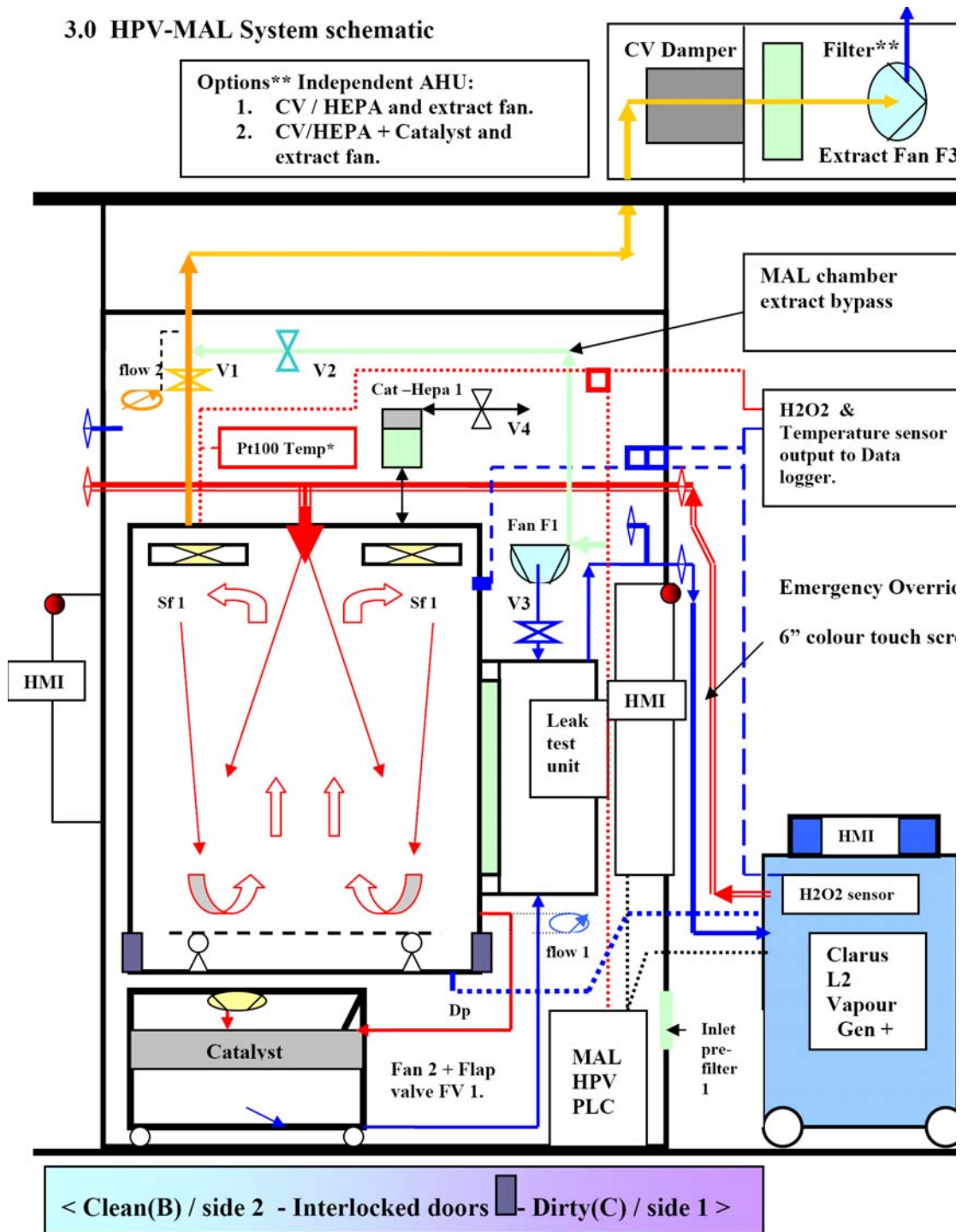
Above is with a return lip on the duct



Above is a duct with a straight duct

Transfer Chamber system schematic

3.0 HPV-MAL System schematic



Modes of operation: For Materials transfer; Bi-directional material flow.> <.

1. Air clean up (Grade C > B) door interlock timer control.
2. Hydrogen peroxide vapour (HPV) disinfection cycle door interlock control.

MAL over temperature monitored/alarmed and displayed (on MAL HMI).

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.



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. A recalculating aeration unit is also 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 a 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 by-pass.

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 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. – Optional extra if required



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.

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	Transfer - 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 Transfer 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 Transfer 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 Transfer PLC. 3 
Aeration complete and cycle complete acknowledge	On receipt of cycle complete signal Transfer 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 Transfer 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).



Electrical Services

Overview

The Transfer Chamber is supplied with mains flying lead connected into the electrical box of the chamber

PBSC Supplied

As standard a 'Commando' Type Plug is fitted to the end of the lead (See picture)
The flying lead is 3 meters long (wire specification is 4mm² x 3 core SY cable - See Data Sheet notes)

Refer to the approval drawing for the position of the cable exit from the control panel



Client Requirement

Wall Socket

A wall mounted socket is required to be fitted by the client (See picture)
This should be sited within 2 meters of the cable exit point from the control panel



Isolation: The client should consider machine isolation either near the machine or at the distribution panel Technical

Specifications

Voltage	Amp	Hz	Comments
220 > 240VAC Single Phase + Earth	32A	50	

Compressed Air Supply

Overview

The Chamber requires air to inflate the air seal doors

2 options are available:

- Optional Air Pump and reservoir fitted in the transfer chamber next to control panel
- Mains supplied from clients building supply

Optional Air Supply –

A pump and reservoir are fitted to provide a self sufficient air supply to the doors

Client Requirement

Mains Supply –

Client should supply a regulated @6 Bar (90 P.S.I) instrument quality air supply to the machine

The Outlet from the regulator or outlet should be a 6mm Push Type fitting to receive the supplied 6mm hose from the WiC Chamber. This should be positioned above the electrical panel

Mains Air Isolation of the supply can be achieved in the control panel

Operation

The WiC chamber monitors the incoming pressure. If mains air failure occurs the chamber will alarm

The door(s) will stay inflated until air is restored. An emergency air in port is provided and can be used if the monitored door pressure drops below recommended safe operating pressures



Consider position of regulator and access to it if failure occurs

Technical

Specifications

Air Supply	Grade	Comments
6 BAR (90 P.S.I)	Instrument Quality	

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

Specifications.

1. Transfer FRS / Functional requirement specification – Bioquell/PBSC Document
2. Transfer 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. Transfer user manual – PBSC/Bioquell document.
2. Clarus L2 user manuals – Bioquell documents.

