

## Appendix 1 - Equipment Specifications & Descriptions

### 1.1 Clarus™ PORT Rapid Gassing System

The industry has identified a need to achieve very rapid bio-decontamination cycles for small loads for aseptic processing in isolator enclosures as the time for surface decontamination of product enclosures is a rate limiting factor for overall processing capacity.

A configuration has been identified where a rapid decontamination chamber attached to process isolators can maintain continuous processing capacity by achieving at least two load decontamination cycles per hour, providing the load represents at least one hour of processing time. In recognition of this Bioquell has developed the Clarus PerOxide Rapid Transfer (PORT) System to fulfil these processing requirements.

The Clarus PORT can also be used as a double-ended rapid bio-decontamination pass through chamber to surface sterilise and transfer materials into cleanrooms.

The PORT System bio-decontamination chamber is manufactured from stainless steel with toughened glass doors and vision panels.

The unit has a full front glass opening panel which is hinged upwards and secured on gas struts to assist with opening and closing. Each end of the chamber is fitted with a circular door on an interface housing onto which an isolator can be attached. The rear of the chamber is fitted with a fixed glass panel to provide light from the room and to provide vision through the chamber. Within the gassing chamber is located a product load trolley mounted on a rail system which can transfer either to the left or right for unloading.

Above the decontamination chamber is mounted the gas distribution system comprising the unique active rotating distribution nozzle and the control system and display panel. The ventilation system is housed below the chamber. Supply and exhaust air is fully HEPA filtered. A catalytic filter system is fitted on the exhaust air from the chamber to remove all traces of hydrogen peroxide vapour before the air stream is then HEPA filtered and supplied back into the chamber. A separate diaphragm pump is used for pressure control of the chamber during the aeration phase until the sterilised load is transferred into the isolators.

The doors are clear toughened glass with an inflatable seal around the perimeter to ensure a full air seal and also to act as an interlock when the door is closed. In addition the door has a





mechanical latch that will prevent accidental opening of the door in the unlikely event of loss of compressed air supply.

The gas generator (Clarus L2) is normally located at one end of the chamber. It is connected to the PORT System by gas supply and return hoses, a communication cable and chamber pressure sensor hose. The operation of the Clarus L2 generator controls and the PORT System are fully integrated when the generator is docked. Cycle status is displayed on the PORT controls, together with any warning or alarm condition. All generator commands are displayed at the generator and printed reports are output on the gas generator printer. The sterilisation cycle can be initiated either from the gas generator or from the PORT control panel.



Loading door open



Transfer trolley



## Technical Specification

Materials of Construction	External	:	Chamber – 316L stainless steel Lower plenum – PVC Windows and doors – toughened glass
Operating Temperature		:	15°C - 35°C (For successful & repeatable decontamination) 5°C to 40°C (Safe to operate)
Relative Humidity	Operating Storage	:	85% RH maximum 95% RH (non condensing)
Power requirement		:	AC 220 – 240V 50 Hz (Euro) 6amp
Power consumption		:	1250W
Dimensions (WxHxD)	External Chamber	:	1214 x 1966 x 798 1050 x 715 x 615
Maximum H <sub>2</sub> O <sub>2</sub> liquid volume		:	175 ml (Two bottle sizes with a range of fills) Typically 10 ml is required
H <sub>2</sub> O <sub>2</sub> Liquid		:	30-35% w/w or 60% w/w
Interface flange		:	Door aperture 559mm x 430mm
Control System		:	Siemens S7 PLC (Software compliant with GAMP)
Airflow rate	Aeration	:	750 cu.m /hr
	Set back	:	200 cu.m/hr
H <sub>2</sub> O <sub>2</sub> evaporation rate		:	3.8 g/min
HEPA filter efficiency		:	99.997%
Pressurisation System range		:	0 to +100 Pa
Catalytic filters		:	Activated carbon



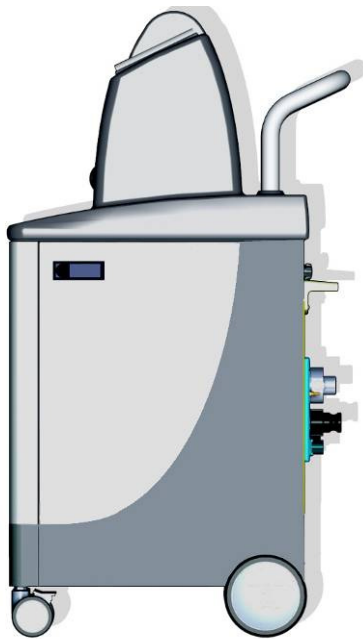
Noise	:	Less than 55 dBA at 1 metre (free field)
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**Design and Specification subject to change without notice**

## 1.2 Clarus™ L2 Hydrogen Peroxide Vapour Generator



- '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 H<sub>2</sub>O<sub>2</sub> in standard format containers (500 mL or 1000mL)
- Maximum enclosure bio-decontamination 80m<sup>3</sup>
- Dimensions: 510(w) x 700(d) x 1135(h) mm.
- Weight: 80Kg





## Technical Specification

External materials of construction	: Top cover – polypropylene : Side panels – polyurethane coated aluminium
Temperature – Operating	: 15°C to 30°C
- Storage	: -15°C to 50°C
Relative Humidity – Operating	: 75% RH maximum
- Storage	: 85% RH at 38°C maximum
Power requirement / Consumption	: AC 220 – 240V 50 Hz (Euro), 6 Amp : AC 110 – 120V 60 Hz (USA), 12 Amp : AC 91 – 110V 50/60 Hz (Japan), 12 Amp
Operating position	: Upright only
Dimensions (WxHxD) – Open	: 510 x 1135 x 700mm
Shipping carton	: 600 x 1250 x 810mm
Weight	: 80 kg, Gross shipping weight 100kg
Maximum H <sub>2</sub> O <sub>2</sub> liquid volume	: Up to 1000 ml
H <sub>2</sub> O <sub>2</sub> Liquid concentration	: 30-60% w/w
Gas hoses	: 25mm I/D x 2m long
Gas hose connections	: 1.5" male/female Camlock fittings
Control system	: Siemens S7 PLC (software compliant with GAMP)
Airflow rate – Gassing	: 25m <sup>3</sup> /hr
- Conditioning/aeration	: Greater than 25m <sup>3</sup> /hr at 800Pa external pressure
Pressure available at outlet	: 1200Pa
Temperature of supply gas at outlet	: Greater than 50°C to 75°C
H <sub>2</sub> O <sub>2</sub> liquid injection rate	: Approximate 2 - 6g/min
Refrigeration System off coil Temperature	: Approx. 2°C (from 20°C return)
Condensate removal	: Evaporation to atmosphere
Inlet air HEPA filter efficiency	: 99.99%
Circuit A and B HEPA filter efficiency	: 99.99%
Pressurisation System flow rate	: 100 l/min (max)
Pressurisation System range	: -70Pa to -10Pa, +10Pa to +70Pa
Catalytic filters	: Carbon



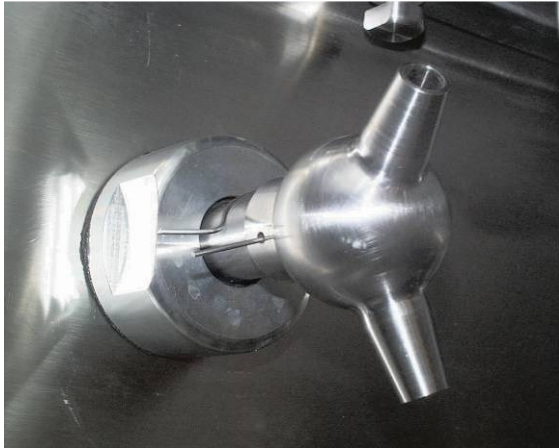


Noise level	:	Less than 60dBa at 1 metre
Enclosure decontamination capacity	:	Up to 75m <sup>3</sup> (subject to configuration and loading)

**Design and Specification subject to change without notice**

### 1.3 Isolator Direct Injection System

The Direct Gas Injection system comprises of a series of assemblies designed to work in conjunction with the Clarus™ gas generator to bio-decontaminate Isolators by direct injection. The assemblies allow a standard Clarus™ unit to inject Hydrogen Peroxide directly into the isolator work chamber through a distribution nozzle.

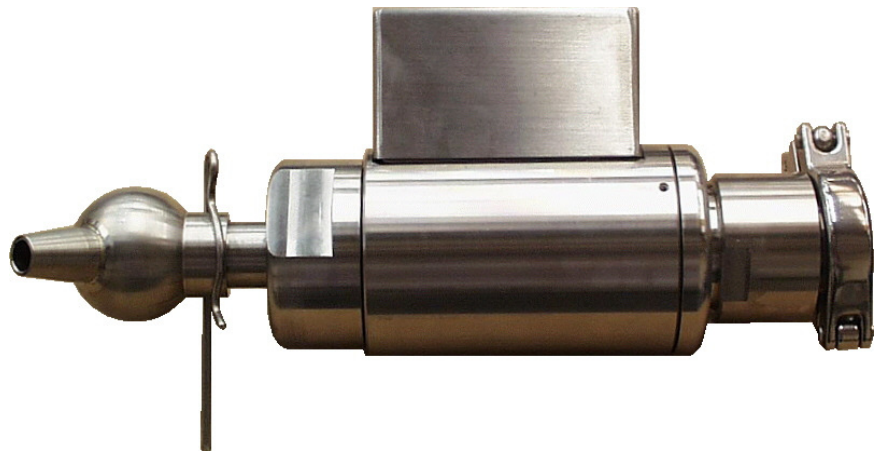


#### Gas Distribution Dynamic Nozzle, Part No. TS290-1000

A unique patented system for effective gas distribution in isolators or awkward geometries is available. H<sub>2</sub>O<sub>2</sub> vapour is delivered to the motorised nozzle, rotating in single fixed speed axis, releasing gas at a high velocity. The high energy and turbulence created by the nozzle system effectively distributes the hydrogen peroxide vapour over all surfaces.

The distribution nozzle comprises of a detachable head that can be configured for the specific chamber volume and geometry. The main body of the nozzle includes a 24V DC

motor assembly that is located externally to the chamber being decontaminated. The nozzle is supplied with a 1½" BSP male parallel thread as standard. (shown here with triclover adapter H16030035 attached) The nozzle has a switch that provides a feedback signal to indicate that the nozzle is rotating.





**Typical Distribution Nozzle Head  
Part No. TS290-1200**

The appropriate distribution nozzle head will be specified by Bioquell Engineering / Validation department according to the application and will be added to the sales order as a separate line item. In a typical single-nozzle application, the TS290-1200 is used.

## 1.4 Pressure Control Connection

As the Clarus L2 has a pressure control function, it is necessary to provide a pressure monitoring point on the enclosure. If no suitable connection is currently fitted, we recommend the use of a self-sealing connector, with a quick-connect function.

### Part No. H16010057

Typical pressure connection. One to be fitted to each discrete chamber

Coupling Body, Bulkhead panel mount, hose barb - valved

1/4" flow, with shut off valve

- Hole size – 18mm



### - Part No. H16010034

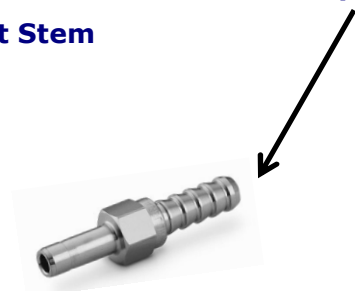
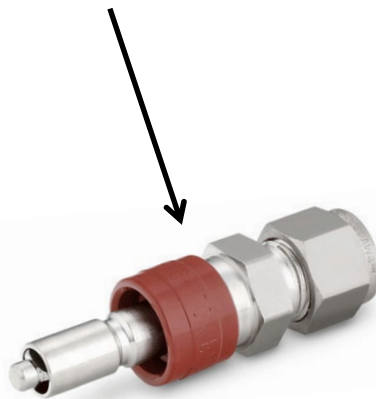
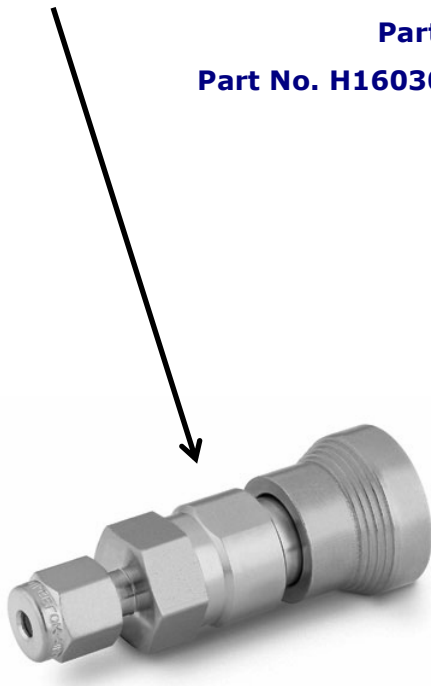
Coupling insert in-line hose barb, 1/4" tubing ID, straight through no valve, to be fitted to Clarus™ pressure control hose

## 1.5 Sampling Connection

### Part No. H16030004 Swagelok Quick-Connect Body

### Part No. H16030005 Swagelok Quick-Connect Hose Coupling

### Part No. H16030006 Swagelok Quick-Connect Stem



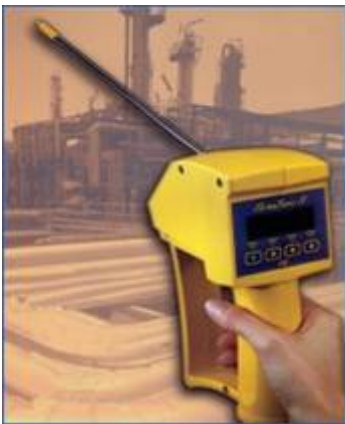


The three items shown are used together with a sampling device (e.g. Portasens or Dräger hand-pump) to allow measurement of the vapour concentration in the enclosure to determine the true end-point of the decontamination cycle. The sampling device (E.g. Portasens, below) may be connected to the Hose Coupling using a short piece of plastic tube. This is then locked into the Stem, which opens the sampling valve when inserted into the Body. The hole size required for fitting the body into the enclosure wall is 12mmDia.

## 1.6 Gas Detection

### PortaSens C16 - Hand Held Low Level H<sub>2</sub>O<sub>2</sub> Gas Detector Part No. H19010003 (Universal Voltage)

Low-level gas leak detection is an important part of every plant safety program. Bio-decontamination with Hydrogen Peroxide as a process requires the use of a potentially toxic gas, with the OEL typically less than 1 ppm. Such a hazard can be managed through careful equipment maintenance and regular monitoring for early signs of low-level leakage.



- Internal sample pump and external sample wand
- One-handed pistol grip design
- Standard "D" cell battery and rechargeable backup battery
- Easy to read back-lit graphics liquid crystal display
- Instantaneous and timed-sampling modes of operation
- Visual and Audible alarms
- Internal data-logger with RS-232 output

The C16 hand held portable gas leak detector is a versatile tool for performing regular instantaneous low level leak checks. Designed for easy one-hand operation, the detector contains an internal sample pump and a flexible sampling wand to allow pinpoint location of the source of possible H<sub>2</sub>O<sub>2</sub> leakage. A large character display insures that measured values are easily visible, and a backlight for the display insures readability in low or no light conditions.