

CLARUS[®] PORT



- ✓ 6 log sporicidal reduction typically 15 minutes*
- ✓ 'Just-in-time' aseptic transfer for rapid processing
- ✓ Eliminates manual disinfectant spray and wipe
- ✓ Reduces equipment and processing space
- ✓ Improves production flexibility and throughput

Rapid H₂O₂ vapour aseptic transfer system



BIOQUELL
Bio-decontamination solutions

The Clarus® PORT** is the most advanced rapid bio-decontamination chamber using low temperature 'residue-free' hydrogen peroxide vapour.

The Process

Product, components or equipment are loaded into the PORT chamber. The chamber is automatically sealed and using the Clarus L hydrogen peroxide gas generator a high concentration of vapour is produced and distributed evenly throughout the load. Contact time for biological inactivation is very short. Hydrogen peroxide vapour is decomposed to oxygen and water at the end of the cycle leaving no residues. On completion the load can be withdrawn on a sliding trolley into an aseptic processing workstation or processing area. The entire process takes as little as 15 minutes.

Applications

The main applications for the PORT are when used as a bio-decontamination chamber between two aseptic processing workstations, such as isolators or laminar flow units, or as a pass through chamber into a cleanroom for:

- Pharmacy compounding of sterile products
- Small scale aseptic processing
- Sterility testing
- Material fumigation chamber
- 'Stand-alone' surface decontamination of materials, equipment, instruments and containers

Benefits

Because of the very rapid bio-decontamination cycle it is possible to utilise the very latest sporicidal gassing techniques recommended in EC GMPs for 'just-in-time' transfer of materials, equipment and components. This eliminates the labour-intensive, hazardous, difficult to control and non-validatable process of manual alcohol spray and wipe disinfection.

The PORT has the processing capacity to continuously serve two aseptic workstations increasing throughput and providing flexibility of operation. Because materials can be transferred only when they are required, other aseptic storage areas or devices such as bank isolators and transfer pods can be eliminated reducing space, equipment and cost.

The simplicity and ease of the PORT system makes it favourable with the operators whilst dramatically increasing the sterility assurance level. Hydrogen peroxide is safe and environmentally friendly leaving no residues and has excellent material compatibility with the cleanroom environment and sensitive electronics.

The Clarus PORT does not require any plant room installation and is easily installed into existing facilities without disruption.

Interfaces:

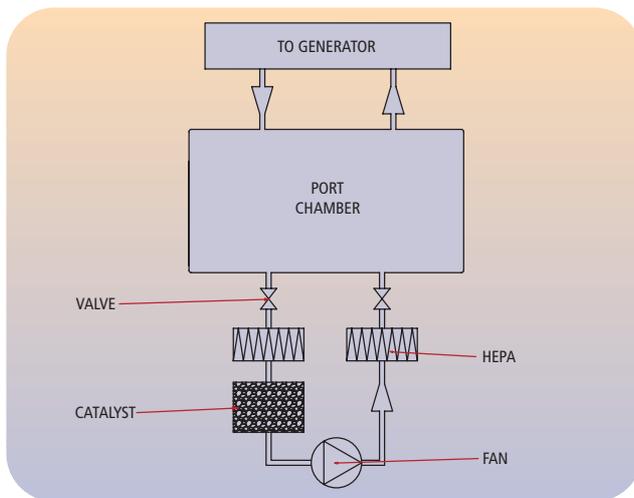
The Clarus PORT is available in 3 interface options:

- With a circular interface (565mm diameter) for permanent connection to flexible wall isolator canopies
- With a rectangular interface flange for permanent connection to rigid wall workstations or to rooms
- As a dockable unit for connection to a simple interface flange mounted on workstations or cleanroom walls

** Clarus PORT Patents pending

Key Benefits

- 6-log sporicidal reduction of bio-burden
- Circa 15 minute total cycle time
- Completely self-contained with no discharges
- No plant room installation required
- Safe, secure process, fully validatable
- Good ergonomics, easy to load and unload
- Easy to retrofit, no facility disruption
- Simple interfaces
- Only single phase electrical power required



Airflow schematic

Configuration

The bio-decontamination chamber has three doors interlocked with pneumatic seals. A mobile trolley supports the load and can pass through the end transfer door after surface sterilisation.

An integrated ventilation and filtration system is mounted below the chamber to remove hydrogen peroxide vapour and to provide HEPA filtered air through the chamber to achieve Class A particulate and microbial conditions.

Hydrogen Peroxide Vapour

Hydrogen peroxide vapour is the safest and fastest sporicidal agent recommended for aseptic processing, biotechnology and biomedical research bio-decontamination applications. H_2O_2 is extremely effective across a wide spectrum of bacteria (vegetative and spore forms), fungi, moulds and viruses. Hydrogen peroxide vapour reduces to oxygen and water leaving no harmful residues. The process operates at ambient conditions without any special environmental conditioning.



Because ideal vapour conditions are rapidly reached in the PORT to provide oxygen free radical activity, it is possible to achieve inactivation of micro-organisms in a few minutes. The system can be tested with a bacterial sporicidal challenge such as *Geobacillus stearothermophilus* and a 6-log reduction in bio-burden can easily be demonstrated.

Extensive testing of hydrogen peroxide vapour has shown no adverse effects on electronic circuits and materials used in aseptic processing facilities. Due to the very short exposure time, absorption of hydrogen peroxide into surfaces is virtually eliminated.

'Residue-free' rapid sporicidal gassing

CLARUS[®] PORT

The Clarus PORT uses 'state-of-the-art' hydrogen peroxide vapour technology to provide incredible bio-decontamination performance.



Illustration shows flexible canopy interface version

- On board ventilation and catalytic convertor removes particles and H₂O₂ vapour without any discharge to the room
- The Clarus PORT needs only a single phase power connection
No other utilities are required for system operation



Siemens control systems and interface



Unique nozzle vapour distribution system



Sliding trolley for ease of load transfer

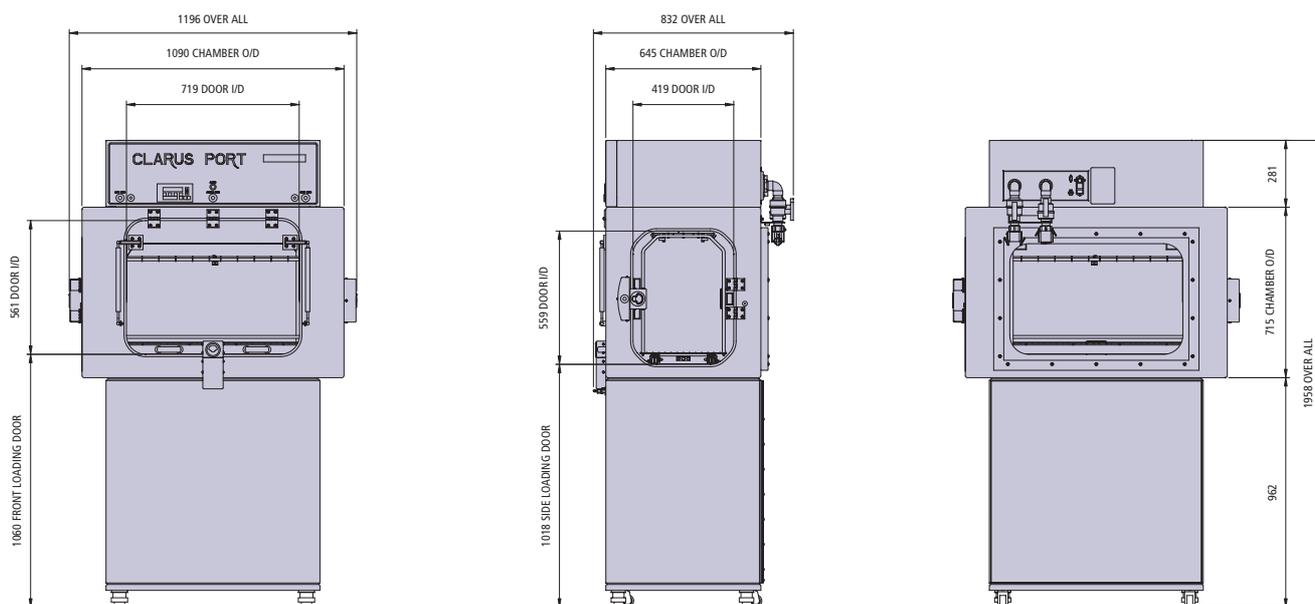


Connection panel for generator

The Clarus PORT is designed and configured to suit all major small scale aseptic processing needs. Although the chamber and unit size is standard, there are 3 interface configurations for rigid wall, flexible canopy and 'dockable' applications. Full details are available upon request.

Clarus PORT specifications		
Construction:		
Chamber		316L stainless steel
Lower Plenum		PVC
Windows and doors		toughned glass
Dimensions:		
External	(WxHxD) mm	1196 x 1966 x 813
Chamber	(WxHxD) mm	1090 x 645 x 995 (trolley 948 long)
Power requirement:		
AC 220 – 240V 50 Hz (Euro) 6amp / AC 115V 60Hz (US)		
Power consumption:		
Watts		1250
Operational conditions:		
Temperature	C	15 - 35 (for successful & repeatable decontamination)
Relative Humidity	%	85 - maximum
Storage conditions:		
Temperature	C	5 to 40 (safe to operate)
Relative Humidity	%	95 (non condensing)
Noise level:		
dB (A)		< 55 - at 1 metre (free field)
Control system:		
Siemens S7 PLC (Software compliant with GAMP)		
Consumables:		
H ₂ O ₂ liquid		"Typically 10 ml is required, 30% w/w"

Clarus L hydrogen peroxide gas generator		
Dimensions:		
External	(WxHxD) mm	505 x 870 x 578 (with lid closed, excluding handle)
Power requirement:		
AC 230V 50 Hz (Euro) 6amp		



Operation

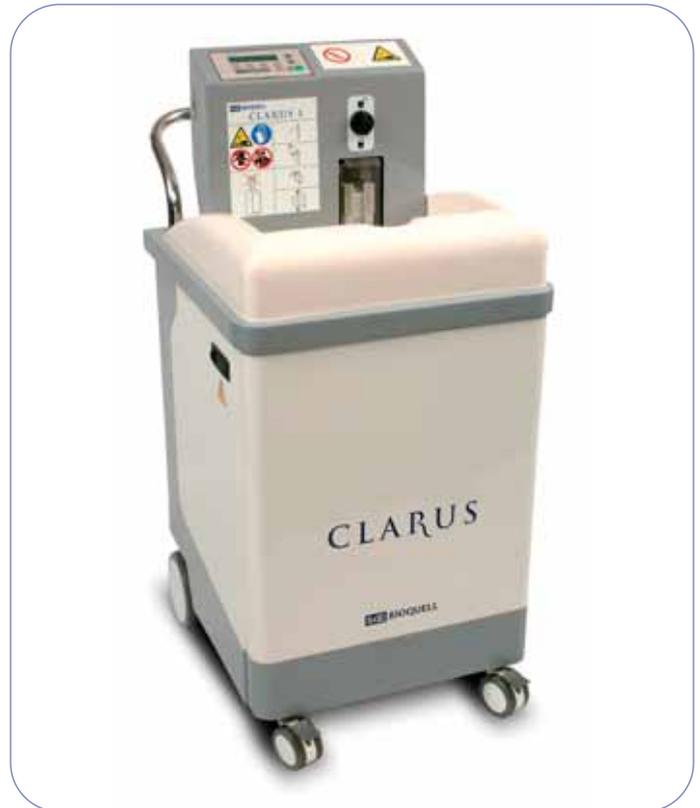
Operation of the Clarus PORT is simple and automatic. The PORT uses the industry standard Siemens PLC control system to communicate directly with the Clarus L generator.

Additional modes of operation are available to decontaminate the connected workstation isolators and for cleaning and maintenance.

The PORT can also be used as a conventional pass through using manual disinfection techniques.

Clarus L Hydrogen Peroxide Vapour Generator

The Clarus L gas generator is used with the Clarus PORT to provide high concentration hydrogen peroxide vapour. The unique 'dual loop' configuration of the small and highly mobile Clarus L generator provides rapid and secure bio-decontamination using very small quantities of H₂O₂. The generator can also be used to decontaminate suitable workstations and other chambers providing increased flexibility of use.



SERVICE

Commissioning, Validation and Maintenance

BIOQUELL provides a comprehensive support service including:

- Full validation service for equipment and cycle development and verification loads for GMP compliance. (using 6-log *G. stearothermophilus* biological challenge)
- Preventative maintenance contracts and after-sales service support for equipment.
- Supply of spare parts and consumables including pre-dispensed hydrogen peroxide solution for use in the Clarus L gas generator.

BIOQUELL also manufacture hydrogen peroxide vapour generators for room and chamber bio-decontamination and provide a routine or emergency bio-decontamination service for facilities, rooms and equipment for those customers who prefer the flexibility of a service.

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*subject to load and configuration, the cycle time likely to be in the range of 10-20 minutes.

Website: www.bioquell.com

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Bio-decontamination solutions