



In-line cRABS and Isolators



In-line cRABS AND ISOLATORS



STERILINE closed Restricted Access Barrier Systems (cRABS) are designed for the production of sterile products, either toxic or non-toxic. These systems provide protection for operator from product and for

product from operator and they prevent contamination by keeping the production process enclosed in a confined area.

The cRABS enclose a space where HEPA filtered, unidirectional air vertically flows over the process area. Pressure difference between the

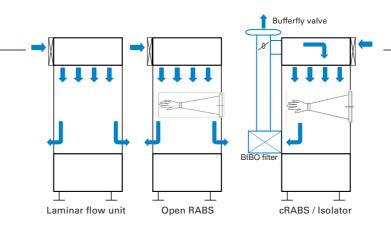
interior and the exterior is maintained by the exhaust fan. The exhaust air is HEPA filtered by "Bag-in Bag-out" (BIBO) filters.

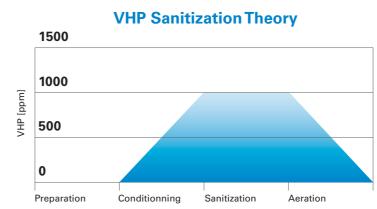
cRABS must be installed in Class B rooms.

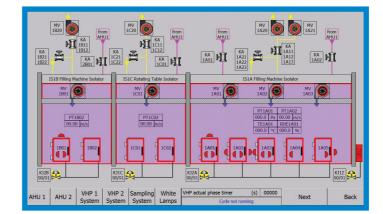
STERILINE isolators can be installed in Class C or D rooms. They can be either stand alone equipment (quality control, research and development, sampling, compounding, sterility test, etc.) or specially designed for fully integrated aseptic production line, in

compliance with cGMP regulations. The Isolators are designed for production of sterile products, either toxic or non toxic, maintaining uncompromised, continuous isolation of its interior from the external environment.

ISO 5 environment is achieved by HEPA filtered, unidirectional air that vertically flows over the process area. Pressure difference between the interior and the exterior is maintained by the exhaust fan. The exhaust air is HEPA filtered by BIBO filters.







The STERILINE cRABS and isolators main features are:

- AISI304L or AISI316L stainless steel for metal contact surfaces with finishes of at least Ra=0,5µm;
- AISI304L stainless steel for panels, guards, etc. not in contact with the product and sanitizing solution, with thickness from 1,5 to 2,0 mm;
- AISI316L stainless steel for cleaning solution piping with triclamp fittings;
- Doors are made of thick security glass and sealed with inflatable

gaskets. Gaskets are made of either silicone, Viton or EPDM;

- test;
 - Rapid Transfer Ports (RTP) are available in 105mm, 190mm, 270mm, 350mm diameters;
 - CIP of the internal surfaces is achieved by means of spray gun fed by WFI or WFI mixed with inactivation agent;



STERILINE provides standard laminar flow units that provide an ISO5 environment to the critical area. These systems are upgraded either to open RABS or closed RABS or to isolators in order to provide uncompromised, continuous isolation of the interior to the external environment, such as personnel and surrounding room.

STERILINE has decided to deliver a fully integrated isolators package with VHP (Vaporized Hydrogen Peroxide) generator for the sanitization cycle.

The isolator sanitization is achieved by means of VHP condensation or VHP in vapour status.

VHP sanitization is based on the following approach: • PREPARATION, including tightness test;

- CONDITIONING by increasing the VHP concentration to the set point;
- SANITIZATION at constant VHP concentration;
- AERATION to lower the VHP concentration less than 1 ppm.

The HMI synoptic page highlights all main functions and monitors the following process parameters:

- Speed of the vertical air flow;
- Differential pressure between the confined area and the surrounding room;
- Temperature and relative humidity.
- The PLC controls the following process parameters:
- Speed of the vertical air flow:
- Differential pressure between the confined area and the surrounding room by means of the exhaust fan;
- Temperature and relative humidity.

STERILINE designs and delivers HVAC systems to complete the RABS, cRABS and isolators packages.

- Gloves are incorporated into the design for aseptic applications. The quantity and position of gloves is determined during the mock-up
- VHP sanitization by condensation or by VHP in vapour status:
- Continuous monitoring of viable and non viable particles.

The integrated control system of cRABS and isolators is composed of PLC and touch screen operation panel for operator interface (HMI). The electrical cabinet can be located in the technical area, while the HMI is located close to the process unit. 21CFR Part11 compliance is achieved by means of a separate PC.



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