

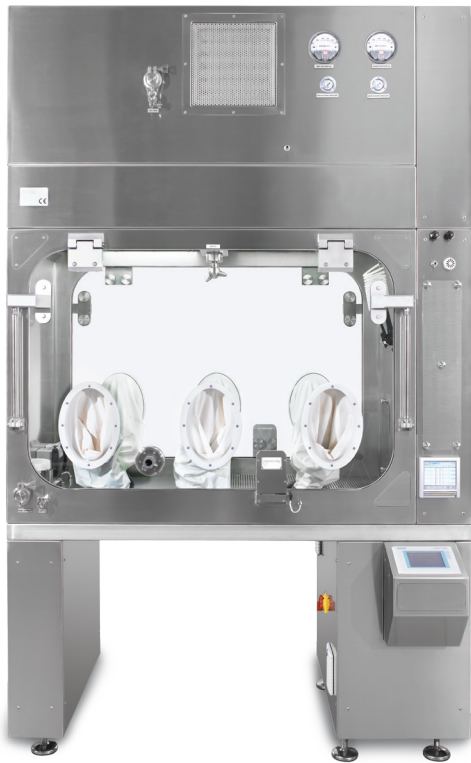


## Stand-Alone Isolators

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# STAND-ALONE ISOLATORS



Due to increasing market demand STERILINE has developed a new range of STAND ALONE ISOLATORS for the following applications:

- Quality Control
- Sterility Testing
- Dispensing
- Weighing
- Compounding
- R&D

The Isolators are designed to work with sterile products either toxic or not-toxic, granting the highest safety level for product and operator.

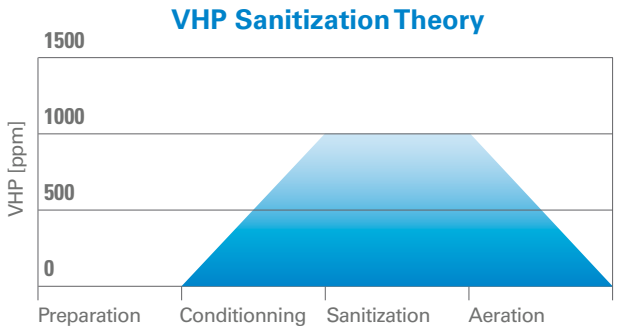
Stainless steel walls with high level surface finishing grant ease of cleaning and sanitization. ISO 5 environment is maintained inside the isolator with unidirectional or turbulent air flow according to process needs. The isolator is equipped with fans and HEPA filters to supply sterile air. In the return duct the exhaust air is again filtered by "Bag-In-Bag-Out" HEPA filters, easy to access for maintenance. The best components available on the market and the collaboration with the primary brands allow a complete integration for:

- Process automation
- Air pressure control
- VHP Sanitization

RTP ports enable In-Out product and waste transfer without safety or sterility failure. The cycle automation is achieved through the synoptic HMI for production phase, decontamination phase, aeration, integrity test and maintenance. Mock-up studies and tests allow perfect accessibility of the operator to all isolator functions.



STERILINE develops 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.

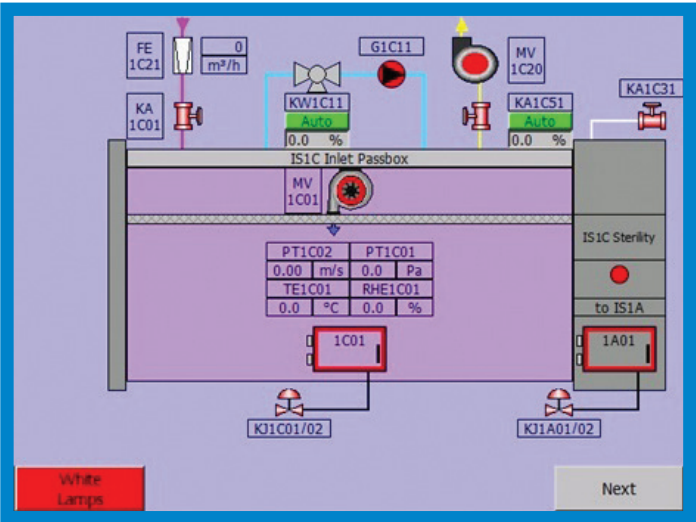
The HMI synoptic page highlights all main functions and monitors the following process parameters:

- 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.



STERILINE STAND ALONE ISOLATORS are designed in 3D CAD and built in standard modular construction allowing shorter delivery time and competitive price level. Installation, Start-Up and training on site with our experts, full Validation Protocols and assistance complete the STERILINE package. These isolators main features are:

- AISI304L or AISI316L stainless steel for 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;

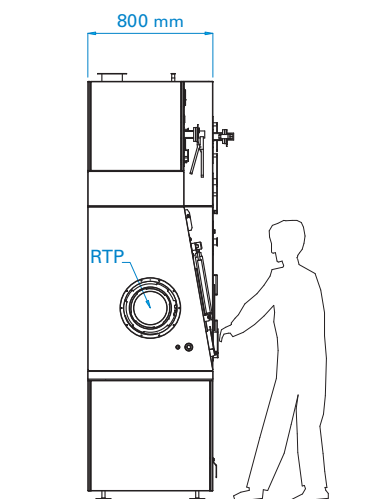
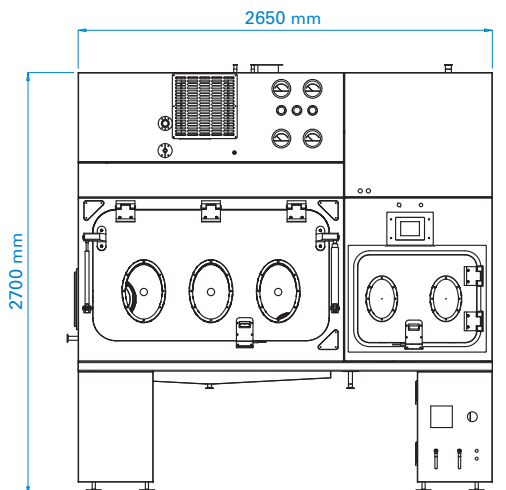
- AISI316L stainless steel for cleaning solution piping with tri-clamp fittings;
- Doors are made of thick security glass and sealed with inflatable gaskets. Gaskets are made of either silicone, Viton or EPDM;
- Gloves are incorporated into the design for aseptic applications. The quality and position of gloves is determined during the mock-up 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;

- 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.

## Overall Dimensions



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