Safety Cabinet BIOHAZARD

STERILSafe 48_72

EN 12469:2000

Introduction

Designed for the situation where is requested the operator, product and environmental protection from dangerous effects due to uncontrolled diffusion of air-transported contaminants and, in the same time, to avoid any biological interference from the environmental to the product during its handling.

Applications

Normally used in laboratory of microbiology, virology, hematology and cell culture.
Furthermore, used in innovative fields of scientific research and above all in the manipulation of:

- Recombinant DNA
- Oncogenic Virus
- Pathogenic agents

For a correct use and application of the cabinet here described, it is necessary to refer to the appropriate standard norm and rules in force in the country where the cabinet is used.

Definition

STERILSafe cabinets produced by Steril Manufacturing Division of ANGELANTONI LIFE SCIENCE S.r.l. are defined:

Microbiological Safety Cabinet “BIOHAZARD” as designed to fulfil the above described application.

- Class II as designed with a frontal working opening for the aspiration of 30% of the total air involved, at a minimum velocity of 0,40 m/s, and the remaining 70% is recirculated through a HEPA filter in the working chamber with a mean laminar flow velocity of 0,40 m/s (as defined by European standard EN 12469:2000).
- Type A1 as, according to NSF 49 (U.S.A.) rules, designed to safely exhaust the amount of air from the front barrier in the room.
- Type A2 as, according to NSF 49 (U.S.A.) rules, designed to duct the exhaust air outside the room (for further technical information refers to paragraph “Technical Specifications”).

Standards and Certifications

STERILSafe cabinets produced by Steril Manufacturing Division of ANGELANTONI LIFE SCIENCE S.r.l. are designed to fulfil and satisfy the European Norm EN 12469:2000

Model:		
STERILSafe 48 & 72	Certification	GS (TŰV RHEINLAND)

Performances

- **Operator Protection**

- The containment index, evaluated on the total surface of the front working opening, is equal or less than 5 CFU for non-disturbance test or Apf equal or more than 1 x 105 according EN12469:2000.

- **Product Protection**

- Sterility in the working area higher than ISO Class 5 according to ISO EN 14644-1 (Class 100/M3.5 according to Federal Standard 209E).
- Equal or less than 5 CFU per test, according product protection test EN12469:2000 and
- Equal or less than 2 CFU per test, according cross contamination test EN12469:2000.

- **Environmental Protection**

- By filtration of the exhaust air through H14 HEPA filter with efficiency 99.995% MPPS as per EN 1822 (EU14 with efficiency 99,999% tested with DOP/DOS @ 0.3 µm).

Norms and Directives

The apparatus is developed in agreement with the following directives:

- MACHINERY DIRECTIVE 2006/42/CE, (when available)
- ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2004/108/CE
- LOW TENSION DIRECTIVE 2006/95/CE
- EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. (Part 1: General requirements)
- UNI EN ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction
- EN 61326-1 :2006 Electrical equipment for measurement, control and laboratory use - EMC requirements – (Part 1: General requirements)
- EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinets

IMPORTANT !!

The apparatus doesn't reenter in the field of application of the directive Us 93/42 about the medical devices, as it is deduced by the definition of "medical Device" at the art. 1 point 2 of the same directive.

ALS – Div. STERIL is not responsible for damages to people or things caused by an improper use of the system and, particularly, from the non-observance of the instruction of use and maintenance that accompany the same.

Technical Specification

Construction structure in steel epoxy-polyester powder coated, resistant to the most common industrial disinfectants.

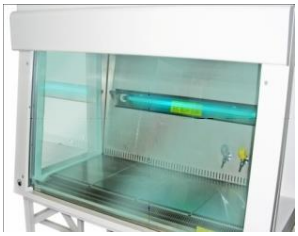
Work chamber and spillage tray in stainless steel AISI 304L "2B" finishing, smooth and sealed edges.

The front of the MSC with the only presence of a touch screen display, no buttons or keyboard, that result in an easy cleanable surface

Working surface in stainless steel AISI 304L "2B" finishing, 4 sectors removable and autoclavable. Available both in perforated and solid version.

Air barrier recovery obtained by means of built-in V-shaped on the work surface to total guarantee of maintaining the performance of containment as the operator cannot block the air intake slots on the arm (even without the use of rests arms).

Lighting on working surface by means of 2 fluorescent lamps fitted in non-contaminated area, both with electronic ballast.



UV lamp integrated in a retractable tilting system in the bottom panel room (see photo).

Front window (electrical driven provided), **tilted and pivoted** (movement with gas springs), in laminated safety glass (aluminium frame).
Tilt front MCS (front screen) 7°

For operational activities front screen tilt **down**

- In working condition barrier height 200 mm
- Height (working condition) opening/loading/unloading available passage with glass raised open 478 mm

For maintenance front screen tilt **up**

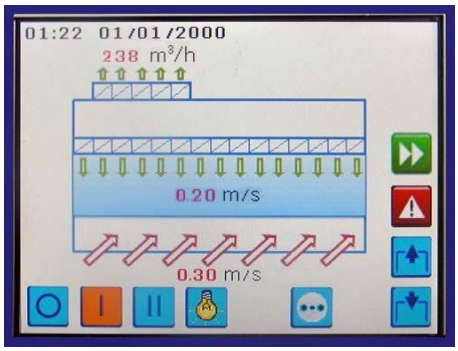
- Opening angle to 117° in relation to the floor (see photo)
- Height (maintenance) opening/loading/unloading step available with tilting screen open 675 ÷ 704 mm (Due to the presence of the protection grid than tilted 7°, the measure is calculated from the bottom of the hood at the beginning of the work plan)

Side Windows to guarantee a better visibility into the work area.

Ventilation system by means of n. 2 motor blowers dedicated to the one-way airflow in the working chamber, equal to 70% of the total involved air and the other dedicated to exhaust the remaining 30%.
The motor blower is centrifugal type, direct driven motor with double aspiration and protection factor IP55.
In case of failure of one fan, the other fan is able to guarantee, for period of emergency, a minimum efficiency of the protection of the front barrier.

Air filtration, both recirculate and exhaust air by means of **H14 HEPA filters with efficiency 99.995% MPPS as per EN 1822**. Both filters will be tested with scanning method for integrity with DOP/DOS test.

Low speed mode, for idle (pause day and night) fully lowering the screen activates automatically the speed of flow "reduced", guaranteeing the maintenance of sterility inside the cabin, allowing reactivation of activities without having to sanitize the inside room. In addition, the low speed you can use Uv lamp (see picture on the right)

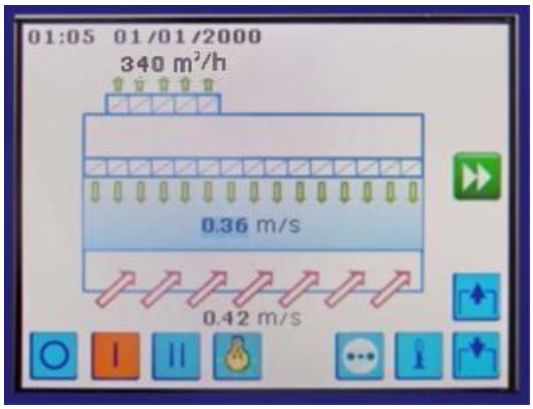


Protection grid, for main HEPA filter made by anodized aluminium.

Command and controls

User interface by means of a "**TOUCH SCREEN**" color panel, 5,7" wide. Only enabled function are shown to the operator.

Real time visualization of cabin working scheme with simultaneous display of laminar airflow speed, exhaust airflow rate and safety fence speed.



Air ventilation control by means of automatic regulation of the revolution velocity of the motor blower. **High-resolution flow rate volumetric device**, directly interfaced to **microprocessor**, achieve the automatic regulation. The microprocessor guarantees the activity of the motor blower and controls the optimal function even in presence of effects caused by progressive clogging of the HEPA filters.

Cabin wear level monitoring with visualization of filters' clogging level, UV lamp service life and cabin run hours.

Free contact to connect an external alarm.

Free contact to **control** a remote extraction fan.

RS232 connection port with Modbus protocol for remote monitoring of main function parameters (optional).

Calibration and maintenance mode protected with service password.

Automatic management of the sterilization cycle controlled by microprocessor with the possibility to control sterilizer activation and reduced airflow ventilation phases.

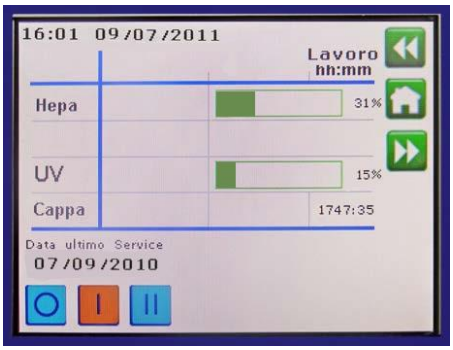
Alarm device optical and acoustic type, activated, at real time, by the **microprocessor**.
Acoustic alarm (dedicated) with a minimum duration of 10 seconds to report a black-out.

- Min LAF
- Max LAF
- Min EXAUST
- Max EXAUST
- Front window position
- Front window frame not closed

- LAF sensor
- EXAUST sensor
- Service alarm
- LAF Hepa filter run hours
- EXAUST Hepa filter run hours
- UV-C lamp run hours
- Front window limit
- Front window frame limit
- Incorrect UV lamp position

Touch Panel display showing:

- Laminar air flow speed in m/s (always visible)
- Exhaust air flow rate in m3/h (always visible)
- Front window speed in m/s (always visible)
- Date and time (always visible)
- Hours counters for cabinet life
- UV-C Lamp run hours
- HEPA filters run hours
- Date of last service
- Date of last power failure (date and time)



User can set following parameters:

- Setting MSC decontamination program
- Change password
- Change language (chose from IT, UK, FR, DE)
- UV-C lamp timer (on and off hour)
- Date and time
- Screensaver
- Display Brightness

Tests Control

According to our procedure WI-MFG-006 included in the Quality Manual of A.L.S. Srl. – Div. STERIL.
The Quality System of Steril Manufacturing Division is certified in compliance to **UNI EN ISO 9001-2000** with certificate nr "**CERT-26437-2008-AQ-ITA-SINCERT**" released by **DNV (Det Norske Veritas)**.
On request, validation tests at site with IQ/OQ protocols are available.

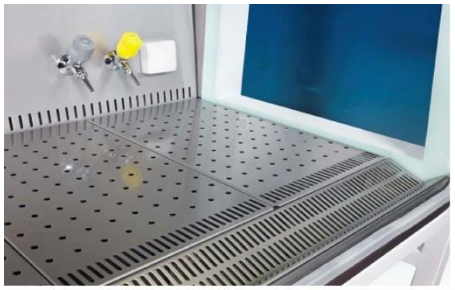
Standard Features

Ceiling with 2 fluorescent lights and electronic ballast

- Standard Italian and German duplex electric socket 4A IP 55 (internal back panel right side).
- Germicidal lamp, 253.7 nm wavelength (UV-C), integrated in a tilting system inside the bottom cabin panel.
- UV lamp timer (see picture on the right)
- DOP/DOS test port
- Sterilization program

Optional Features

- Internal working surface perforated or solid (see picture on the right)
- Empty circuit with tap (right side) as UNI/CIG standards with copper piping and 10 mm diam, (external) hose to delivery network connection
- Gas circulation and tap (right side) as UNI/CIG standards with copper piping and 10 mm diam, (external) hose to delivery network connection. Circuit is provided with an **automatic system that stop gas** delivery in event of power failure or an airflow reduction
- Compressed air line with manual tap
- Nitrogen line with manual tap
- Steel support stand
- Chest of 3 drawers on pivoting wheels in steel epoxy coated
- Bunsen burner with automatic foot switch ignition
- Bunsen burner with automatic switch ignition
- **Double HEPA** exhaust filter (total height increases of 245 mm). With this optional item the cabinet can be ducted to outside, only after inspection of authorized ALS Srl. – Div. STERIL personnel.
- **Activated carbon** exhaust filter (total height increases of 256 mm). With this optional item the cabinet can be ducted to outside, only after inspection of authorized ALS Srl. – Div. STERIL personnel.
- THIMBLE kit to conduct expulsion by remote fan
- Additional electrical power socket
- Arms support shelf kit



Maintenance

The replacement of HEPA filter filters (after decontamination) and UV-C lamp (with its starter) can be done from the front of the cabinet.
Simple scanning of the HEPA filter of expulsion through the simple removal of the protection cover.
Any other maintenance activity (control of the electric board, replacement fluorescent lamps) can be done from the front in non-contaminated area.

Installation of an eventual deportation channel

All biohazard cabinets is equipped with security arrangement for connecting outside. Below we will give directions concerning the maximum length of the channel connect, where you want, the data does not take into account any curves that would cause pressure loss.

	Flange diameter	Linear length
STERIL*Safe* 48	**mm 250**	**mt 15**

To determine the possible loss, you must calculate that each curve provides a load loss equivalent to a linear metre (ex. 15 Mt. three linear curves, determine a maximum length of 12 mt.).

Before you set up and maintain an installation, contact the technicians of A.L.S. Srl. – Div. STERIL, who will be on hand to evaluate the best configuration of expulsion in accordance with the characteristics of the Canal itself.
Technical characteristics

Technical characteristics

Model	Unit	STERILSAFE 48	STERILSAFE 72
CODE		**Cod. ST-003249000**	**Cod. ST-003250000**
Overall dimension (WxDxH)	**mm**	**1398x860x1784**	**2008x860x1784**
Internal dimension (WxDxH min/max) ****	**mm**	**1186x485x(675÷725)**	**1796x485x(675÷725)**
Safe working area dimension (WxD)	**mm**	**1086x420**	**1596x402**
Max front opening	**mm**	**478 -/- 704**	
Front opening height	**mm**	**200**	
Net weight	**Kg**	**281**	**365**
Recirculated flow rate	**m3/h**	**1000**	**1500**
Exhaust air flow rate in operating condition (Vb=0,42m/s)	**m3/h**	**340**	**540**
Minimum acceptable Exhaust air flow rate (alarm threshold) (Vb=0,40)	**m3/h**	**337**	**513**
Heat emission at 25 °C (1)	**Kcal/h**	**430**	**650**
Noise level	**dB (A)**	**<53**	**<56**
Lighting	**Lux**	**1470**	**1600**
Voltage	**V**	**230V AC P+N+P.E.**	
Frequency	**Hz**	**50**	

Energy consumption ***	**kWh/anno**	**1350**	**1670**
Electrical classification (with feeding cable)		**I**	
Protection category		**IP20**	
Power socket (protected by a single fuse 4A)		**2P+T 250V 10/16A**	
Fluorescent lamps	**W**	**2x54**	**2x80**

(*) Vb = 0,42 m/s
(**) Alarm threshold / Vb = 0,40 m/s
(***) Working hours: 5 days/week x 8 hours/day x 52 weeks/year= 2080 h
(****) Due to presence of the upper diffusor, measurement is calculated from the cabin's opposite end to the beginning of worktop

Other technical data

Product Name	**STERILSAFE** series STERIL™ is a brand name who belong to ANGELANTONI Group.
Manufacturer	Angelantoni Life Science S.r.l. Loc. Cimacolle, 464 06056 Massa Martana (PG) - Italy
CE marking ref.	MACHINERY DIRECTIVE 2006/42/CE (if applicable) EMC DIRECTIVE 2004/108/CE LOW TENSION DIRECTIVE 2006/95/CE EN 12100, EN 61326-1, EN 12469, EN61010-1, 2011/65UE.
Power supply	208 – 253 VAC 50 Hz single phase
Ambient conditions of use	Temperature: +10° ~ +32° C Relative humidity: 30 ~ 85% without condensation
Stocking condition	Temperature: +2° ~ + 50° C Relative humidity: 20 ~ 80% without condensation
Alarms types	Acoustic and Optical
In case of power black-out	System OFF
Warranty	Twenty-four months from shipping date (valid on defective spare parts only)

Reference layout

TECHNICAL DATA - REV. 1 - 08/02/2012	Net weigth (Kg)
STERIL*Safe* 48" (cod. ST-00324900000)	281
STERIL*Safe* 72" (cod. ST-00325000000)	365