

MSTI
MODULAR STERILITY TESTING ISOLATOR



***Sterility testing...
is moving ahead***

Sterility testing: why isolator instead of laminar flow hood?

- Suggested and preferred by the regulatory bodies
- No risk of contamination from operator and external environment
- Contained volume suitable for toxic product
- Decontamination through an automated and validated cycle
- Installed in a class D environment, no gowning for operator
- Reduced operational cost up to 30% of conventional class B clean room

A real modular approach

Available modules includes different size of working chambers as well as two kinds of pre-chamber (one larger with laminar airflow, one smaller with turbulent airflow) and VPHP generator. Desired configuration based on the specific customer need is reached combining the different modules.

AVAILABLE MODULES

CHAMBER 1200

CHAMBER 1350

CHAMBER 2000

PRECHAMBER 800L

PRECHAMBER 500T

VPHP

SAMPLE CONFIGURATIONS

VPHP+CHAMBER 1200+PRECHAMBER 500T

VPHP+CHAMBER 1350

VPHP+PRECHAMBER 800L+CHAMBER 2000+PRECHAMBER 800L

VPHP+CHAMBER 2000+PRECHAMBER 800L

Customized internal solutions

The MSTI can be equipped with customized racks, accessories and tools in order to answer any specific requirement. A dedicated load study is carried out to correctly host and position all the samples, such as vials, ampoules, bags, syringes as well as consumables like saline solution, culturing media, petri dishes.



The heart of MSTI: integrated VPHP decontamination system

An integrated VPHP generator assures the 6-log decontamination of all the internal volumes in the shortest time. Full cycle reporting is provided through the main isolator HMI. The Cycle Development and PQ at the customer's premises is performed by Comecer experienced personnel using reference calibrated instruments and following optimized protocols.

- The system includes on board:

 - dehumidifier
 - HEPA filter
 - vaporizer
 - double stage catalytic converter

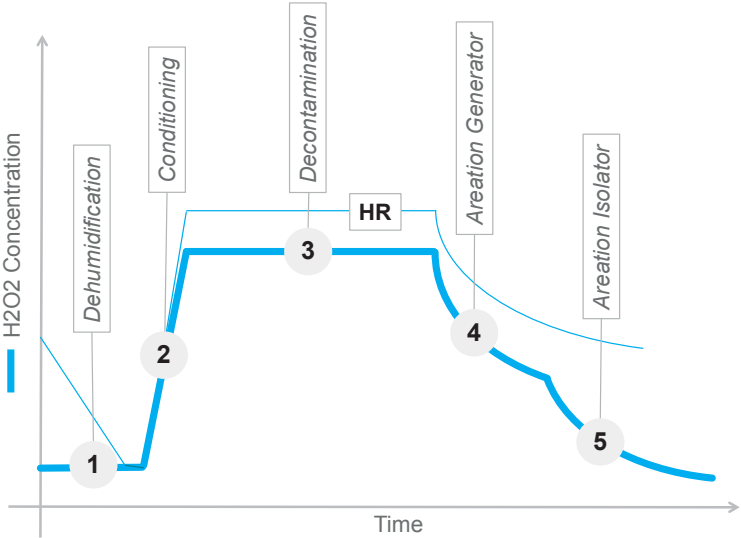
Full cycle time

CHAMBER + PRE-CHAMBER

100 min

PRE-CHAMBER ONLY

45 min



General process cycle

Each phase of sterility testing, either following Direct Inoculation method or Membrane Filtration method, has its own need. MSTI is configured in order to assist the operator step by step, always ensuring the best performances and maximum comfort.

1. Materials loading

2. Decontamination cycle

3. Sterility testing

4. Materials loading during sterility testing



State of the art features

- Stainless steel AISI 316L enclosure with external Scotch-Brite and internal Mirror-Brite
- Laminar airflow on working area with highest recirculation rate
- Integrated VPHP generator
- Peristaltic pump
- Liquid waste container (circuit internally sanitizable)
- Viable and non viable monitoring system (circuit internally sanitizable)
- Anemometer
- Humidity and temperature sensor
- HEPA H14 filters on inlet
- Glove extenders
- 7" widescreen HMI with user-friendly interface including USB and ethernet port

Further optional

- AGT onboard
- Rapid transfer port (RTP)
- VPHP concentration sensors low/high level
- HEPA H14 filters on outlet
- Filtration manifold
- SCADA
- Paperless graphic recorder
- Operation with positive/negative pressure
- Others on request



Technical data

Material

Shell structure	AISI 316 L
Stainless steel finish	external: Scotch-Brite internal: Mirror-Brite

Air classification

Main chamber	class A (after decontamination)
Pre-chamber	class A (after decontamination)

Working internal pressure

Main chamber	50-100 Pa
Pre-chamber	25-50 Pa

Filters

Main chamber	H14 inlet and outlet
Pre-chamber	H14 inlet and outlet

Make up air flow rate

	732 m ³ /h
--	-----------------------

Overall dimensions (w x d x h)

	3750 x 1050 x 2500 mm
--	-----------------------

Internal dimensions (w x d x h)

Main chamber	2000 x 525 x 730 mm
Pre-chamber	800 x 525 x 730 mm

Net weight

	1730 kg
--	---------

Utilities requirements

Compressed air	6 bar, 25 nL/min
----------------	------------------

Power supply

Isolator	230V (1Ph+N+PE) 50/60Hz 32A TN-S
VPHP generator	230V (1Ph+N+PE) 50/60Hz 25A TN-S
Installed power	8900 W

All data refer to the configuration "MSTI: VPHP+CHAMBER 2000+PRECHAMBER 800L"



www.comecer.com/MSTI

Kontakt / Contact:



COMECER S.p.A. - Via Maestri del Lavoro, 90
48014 - Castel Bolognese (RA) - Italy
t: +39 0546 656375 - f: +39 0546 656353
comecer@comecer.com - www.comecer.com

Part of COMECERGROUP



WINKGEN MEDICAL SYSTEMS GmbH & Co. KG
Eichendorffstraße 3
D-35584 Wetzlar
Telefon: +49(0)6441 / 381437
Telefax: +49(0)6441 / 381442
www.winkgen.de / email@winkgen.de