

# AB-PTC

ACTIVE BIO-DECON PASS THROUGH CHAMBER  
THE RELIABLE SUPPORT FOR YOUR ASEPTIC OPERATIONS



# AB-PTC

ACTIVE BIO-DECON  
PASS THROUGH CHAMBER

GUARANTEED ASEPSIS  
MAXIMUM SAFETY  
AUTOMATIC LEAK TEST  
EASE OF MAINTENANCE  
STANDARD AND CUSTOM DESIGN  
DATA MANAGEMENT  
ENERGY SAVING



## GUARANTEED ASEPSIS

The AB-PTC assures the highest air quality of the isolated environment thanks to:

- an engineered filtration system composed of High-Efficiency Particulate Air (HEPA H14) down flow and exhaust filters;
- HYPER, Tema Sinergie's integrated Vapour Phase Hydrogen Peroxide (VPHP) bio-decontamination system for very fast bio-decon cycle
- inflatable seals made of FDA-approved White Silicon

The integrated ventilation system of the chamber guarantees a pressure cascade between the adjoining rooms and the chamber itself. This cascade preserves the asepsis of the materials after the termination of bio-decontamination process prior to extraction into the cleanroom.



## MAXIMUM SAFETY

Maximizing operator protection is a key feature when handling BSL-1 through 4 organisms. AB-PTC assures the maximum safety thanks to the following features:

- HYPER, an integrated VPHP system for the decontamination of materials prior to extraction from the BSL facility
- pressure control strategy to prevent back flow of air between the BSL and non BSL boundaries.
- bio-sealed doors and sheathings to avoid any leak between BSL and non BSL boundaries.

The AB-PTC is therefore the perfect adaptable solution to decontaminate equipment/materials prior to taking it out of a BSL facility, to avoid leak of potentially hazardous organisms towards the external areas.



## AUTOMATIC LEAK TEST

The AB-PTC is equipped with a routine automatic leak testing system which performs an independent leak test cycle for each chamber according to the pressure change method (5.2) ISO 10648-2(E).



## EASE OF MAINTENANCE

A remote control module made of AISI 316L stainless steel, containing electrical and pneumatic components, allows direct access for all maintenance operations. A Virtual Private Network (VPN) connection allows a secure and private communication via Internet network and provides remote access and assistance, updates and maintenance any time, everywhere.



## STANDARD AND CUSTOM DESIGN

AB-PTC is available in different standard dimensions, including Walk-In models. Fully custom-designed Active Bio-decon Pass Through Chambers according to user requirements. Custom-designed carts and cart-to-cart systems available.



## DATA MANAGEMENT

The AB-PTC can also be upgraded with an Integrated Supervisory Control And Data Acquisition (SCADA) - iFIX with Historian Data Management Software (DMS) from GE Digital. DataWall, a software application developed by Tema Sinergie for data management, is also available upon request.

## THE SAFEST WAY OF TRANSFERRING MATERIAL

Active Bio-Decon Pass Through Chambers can be used for multiple applications, such as aseptic transfer of materials into cleanrooms or decontamination of equipment from BSL-1 through 4 organisms prior to extraction from the facility. In both cases, materials are sterilized in the Pass Through Chambers by means of the integrated VPHP system.



## ENERGY SAVING

Thanks to the new sustainable low voltage ventilation fans, the isolator has a very low energy consumption throughout its life



**TEMA** SINERGIE  
High tech, high care

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### KEY FEATURES

- Fully PLC controlled
- Integrated VPHP generator (HYPER) and distribution circuit
- VPHP resistant relative humidity and temperature (rH%+T) sensor
- View/Access panel latches with integrated safety switches
- LED lighting system

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### GENERAL CHARACTERISTICS

- Main shell structure made of high-grade AISI 316L stainless steel
- Sheathings and support structure made of AISI 316L stainless steel
- Mirror Brite internal finishing (<0,3 µm), and Scotch Brite external finishing (<0,8 µm)
- Weldings ground, smoothed and polished

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### AUTOMATION

- Integrated SCADA – iFIX with Historian DMS available upon customer request as option
- Tema Sinergie Data Management System (DataWall) available upon customer request as option
- SIMATIC IPC277E (Nanopanel PC), 7" Touch Panel with TFT colour widescreen display
- PLC Siemens S7-1500
- 21 CFR part 11 compliant
- GAMP compliant software development
- VPN connection for a secure and private communication via Internet network – remote access and assistance, updates, maintenance and training
- UPS for PLC reliability

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### OPTIONAL INTEGRATED EQUIPMENT

- VPHP sensor for TLV environment (safety sensor)
- VPHP sensors for chamber(s) concentration monitoring
- External Catalytic Unit for H<sub>2</sub>O<sub>2</sub> break down
- Uninterruptable power supply (UPS)

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### DOCUMENTATION & VALIDATION

- Complete documentation package according to Tema Sinergie standards
- Factory Acceptance Test (FAT) and Site Acceptance Test (SAT)
- Complete Validation package, Installation Qualification/Operational Qualification (IQ/OQ) protocols and execution upon request
- Performance Qualification (PQ) protocols and execution upon request



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The company Tema Sinergie S.p.A. has a Quality Management System certified by Kiwa Cermet Italia S.p.A. according to the ISO9001:2015 (since 2000) and ISO13485:2016 (since 2013) regulations.