

AC-IS

THE MODULAR ASEPTIC
CONTAINMENT ISOLATOR SYSTEM



TEMA SINERGIE
High tech, high care

AC-IS

THE MODULAR ASEPTIC CONTAINMENT ISOLATOR SYSTEM

MODULAR BASED CONFIGURATION
GUARANTEED ASEPSIS
MAXIMUM SAFETY
INTEGRATED WASH-IN-PLACE (WIP)
AUTOMATIC LEAK TEST
EASE OF MAINTENANCE
ERGONOMIC DESIGN
GLOVE INTEGRITY TESTING
DATA MANAGEMENT
ENERGY SAVING



MODULAR BASED CONFIGURATION

The system is based on a versatile modular concept: the base isolator configuration is composed of a single 4-gloves working chamber which can be easily expanded with additional chambers/airlocks.

This makes AC-IS perfectly suitable to every need and process. A select number of available options may be added at a future date.



GUARANTEED ASEPSIS

The Aseptic Containment Isolator System assures the highest air quality of the isolated environment thanks to:

- an engineered filtration system composed of Efficiency Particulate Air (EPA E11) inlet and exhaust filters and High Efficiency Particulate Air (HEPA H14) unidirectional down flow and safe charge return filters (bag in/bag out);
- 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 Bio-Guardian®, with anti bacteria inhibitors.



MAXIMUM SAFETY

Maximizing operators' protection is the primary characteristic of a HPAPI containment isolator. The Aseptic Containment Isolator System assures very stringent HPAPI containment levels thanks to a perfect combination of design and manufacturing strategies. The system is equipped with inflatable and static seals to guarantee air tightness Class II (ISO 10648:2). The isolator is therefore the perfect solution for sterile processing of High Potent Active Pharmaceutical Ingredients (HPAPIs).



INTEGRATED WASH-IN-PLACE (WIP)

The system is provided with Integrated manual & automatic Wash-In-Place (WIP) for cleaning processes, thus improving safety for the operators involved in the production of potentially hazardous compounds and reducing the risk of possible cross contamination.



AUTOMATIC LEAK TEST

The AC-IS 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

An integrated sliding 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.



ERGONOMIC DESIGN

Maximizing operators' effectiveness is essential to minimize the risks of accidents, eliminate unscheduled downtime and boost production quality.

Operators are assured the most comfortable working conditions by the outstanding ergonomics of the AC-IS.

THE RIGHT PARTNER IN ASEPTIC PROCESSING OF HAZARDOUS COMPOUNDS

The Aseptic Containment Isolator System is a modular cGMP Class A/ISO 5 isolator system specifically designed for the Sterile processing of High Potent Active Pharmaceutical Ingredients (HPAPIs).



GLOVE INTEGRITY TESTING

The AC-IS can be equipped with an integrated Automatic Glove Leak Testing System (AGLTS) which performs an independent leak test cycle for each glove mounted on the isolator system according to the Positive Pressure Decay Method described in the international standard ISO 14644-7 Annex E.5. Wireless Wi-Fi data transmission based on a TCP/IP protocol. Recognition of the glove to be tested by means of Radio Frequency Identification (RFID) Technology. Detection of holes down to 100µm diameter.



DATA MANAGEMENT

The AC-IS 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.



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

AC-IS

THE MODULAR ASEPTIC CONTAINMENT ISOLATOR SYSTEM

KEY FEATURES

- Fully PLC controlled isolator system
- Modular configuration concept of the system
- Integrated manual & automatic Wash-In-Place (WIP)
- Integrated VPHP generator (HYPER) and distribution circuit
- VPHP resistant anemometer
- VPHP resistant relative humidity and temperature (rH%+T) sensor
- Integrated Sliding Control Cabinet made of AISI 316L stainless steel
- View/Access panel latches with integrated safety switches
- LED lighting system

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 ($<0,3 \mu\text{m}$), and Scotch Brite external finishing ($<0,8 \mu\text{m}$)
- Weldings ground, smoothed and polished

AUTOMATION

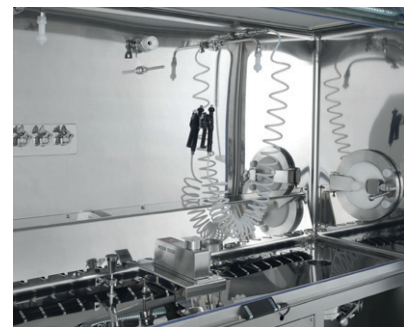
- SIMATIC IPC277E (Nanopanel PC), 7" Touch Panel with TFT colour widescreen display
- Tema Sinergie Data Management System (DataWall) available upon customer request as option
- PLC Siemens S7-1500
- 21 CFR part 11 compliant
- GAMP compliant software development
- Integrated SCADA – iFIX with Historian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

OPTIONAL INTEGRATED EQUIPMENT

- VPHP sensor for TLV environment (safety sensor)
- VPHP sensors for chamber(s) concentration monitoring
- External Catalytic Unit for H_2O_2 break down
- Rapid Transfer Port (RTP) and transfer container
- Aseptic Rapid Transfer System
- Integrated Weighing Scales and Operator Terminals
- Integrated High Containment Split Butterfly Valves (HCSBV's)
- Integrated Viable & Non-viable (Particle) monitoring system
- Integrated Automatic Glove Leak Testing System (AGLTS)
- Uninterruptable power supply (UPS)

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



REV. 01_20

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.