Sterilization & washing systems

Serving the pharma industry worldwide

high performance solutions
to resolve complex sterilization and
washing challenges

Infection control solutions for the global Pharmaceutical industry

Located in modern factories near Venice in Italy, ICOS Pharma, member of Steelco Group, is a major global supplier of infection control equipment and solutions for the laboratory, pharmaceutical and biotech sectors.

ICOS Pharma's success is demonstrated by its strong growth, becoming the partner of choice for many of the world's leading pharmaceutical companies who appreciate the company's:

Extensive product range

With over 3000 installations worldwide, ICOS Pharma offers a wide portfolio including:

- Innovative washing equipment (LM and LB series), customizing loading racks to customer needs.
- Diversified, steam and ETO sterilization range.
- Innovative fully automated closure processing equipment.
- Drying and depyrogenation ovens.
- Automation systems to maximize productivity and safety.

Flexible solutions

- Ability to meet the most challenging processing needs.
- Only using best proven readily available control systems and components.

Experience and knowledge

- Strong track record of establishing long term global partnerships.
- Integrated in-house operations from incoming raw materials to installation, validation and technical support.
- Fully certified quality systems with knowledge of pharmaceutical manufacturing standards

Global footprint

- Global HQ in Italy with regional customer support centres in North America and Asia.
- Network of factory trained agencies in over 100 countries worldwide.

Quality engineering process

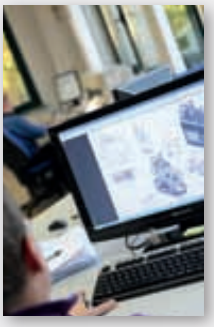
ICOS Pharma's engineering experience encompasses knowledge and understanding to be able to satisfy the most stringent requests from clients.

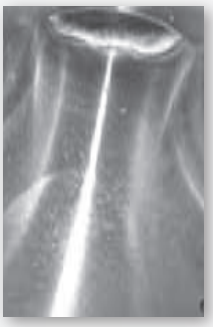
Technical consulting, design, engineering, project management, as well as commissioning and qualification services of our equipment is offered, with customers appreciating the cost effective high performance solutions offered to resolve complex washing and sterilization challenges.

Our respected engineering experience in the laboratory, pharmaceutical and biotech fields allows us to develop a proven approach that prioritizes the pharma manufacturing process and safety bearing in mind life cycle costs of the equipment.

Our methodical approach is to first develop an in-depth understanding of the project and the product goals in order to offer the best equipment and solution for the application.

Customers are always welcome to visit ICOS Pharma factories to see design and manufacturing methods and audit our processes.





Quality system certification

In addition to having a certified Quality System as per ISO 9001:2008 (and ISO 13485 for Medical Division), our products are subject to rigorous quality control systems and inspection.

This coupled with continuously training our technically specialized personnel ensures you receive best in class product solutions and support.

We constantly strive to improve on our high standards to enable us to deliver optimal solutions for our partners in the pharma industry.

3D project layouts

ICOS Pharma offers complete 'turnkey" solutions for washing and sterilization processes in the pharmaceutical sector, with the ability to undertake all stages of a project from concept to delivering solutions that exceed customer expectations.

ICOS Pharma's extensive experience assists customers to increase process productivity and quality with improved ergonomics whilst limiting costs.

Extensive customer support services

ICOS Pharma offers a comprehensive range of services to ensure the success of projects at each important step including:

- Process and workflow design
- Process equipment design and manufacture
- Automation and SCADA
- Installation and commissioning
- Training packages, from basic to in-depth
- Validation and documentation:
- cGMP compliance consultancy and assessment
- Training and assistance if requested by pharmaceutical companies as well as regulatory inspectors on GMP related topics
- Spare parts supply and first line service training
- Fully comprehensive and preventative maintenance contracts
- Periodic validation and re-qualification as required.

For all previously installed equipment ICOS Pharma can offer a range of customizable service packages and revamping activities if required. Customer service excellence is ICOS Pharma's commitment to our clients and a cornerstone of our success with emergency service support if needed available, 24 hours, 7 days a week.

Design warranty

Thanks to the design and quality of equipment, as well as the reliability of the components used, ICOS Pharma can offer extended warranties. Standard warranty is 10 years on pressure vessels. ICOS Pharma warrants all materials and workmanship to be free of defects for 18 months from shipment date. ICOS Pharma's pharma sterilizer door gasket design carries a 4 years warranty without any lubrication required.

Only the best available "Non-Proprietary" components such as valves are sourced. Components are selected for their reliability and availability to reduce running costs and down time.

ICOS Pharma can use customer preferred parts provided that these meet performance and reliability requirements.

Control system

User friendly control systems developed according to the latest GAMP and design for 21 CFR Part 11 available, sourced from the best available suppliers avoiding customized electronics.

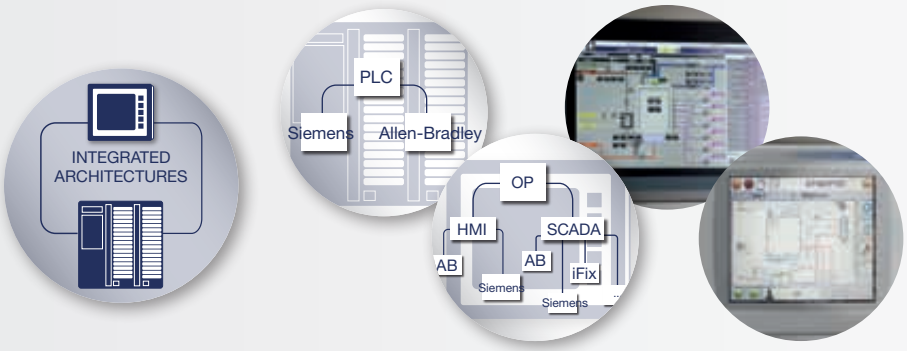
ICOS Pharma can provide software source codes, allowing its customers to become owners of the control system of the machine ("open source architecture").

System platforms available include Siemens and Allen-Bradley which are easily integrated with those already installed by pharmaceutical companies. The software is structured and commented in English to allow a better understanding of functionality. Multi Language tool for development software is also available.

Software is developed in compliance with current coding rules and programming and according to standard ISA 88, ISA 95, IEC 61131-3 standard & GAMP 5.

The structure is designed for straightforward validation by the end user.
Tools to simplify validation are also available (validation wizard).

Telemodem capabilities are available for all our controller solutions as well as remote diagnostic capabilities.



International standards:	
ISA 88	*Standard addressing batch process control*
ISA 95	*Enterprise-Control System Integration*
IEC 61131	*Programmable controllers*

Integrated architecture

ICOS Pharma can install new equipment into an existing automation system through the adoption of a simple (HMI) or more sophisticated (SCADA) man-machine interface.

Complete customization of access levels is available (local or domain users).

In compliance with the individual internal policies of each customer, ICOS Pharma offers remote service access by using virtual private networks to ensure the confidentiality and safety of all transferred data.

Safe remote access using UMTS/LTE/GPRS networks solutions are also available.

All ICOS Pharma machines share the same interface system: despite different functions of modes with a logical evolution based graphic to interface ensure easier training and use by operators.

Validation documents

User safety, product quality and data integrity are core values.

Equipment is developed and validated according to the latest GAMP and cGMP standards. ICOS Pharma "know-how" allows the client's to benefit from optimal solutions for their individual requirements, in order to perform effectively and reproducibility cleaning, sterilization and validation of pharma production components.

A risk based approach to comply with regulatory requirements is fundamental in the development of our validation documentation. An extensive package is available to minimize on-site validation time.

ICOS Pharma documents include but are not limited to the following:

- Hardware Design Specification
- Functional Design Specification
- Software Design Specification
- P&ID (Piping and Instrumentation Diagram)
- Component List
- General Arrangement Drawing
- Electrical Drawings
- Quality and Project Plan
- Traceability Matrix

ICOS Pharma is available to customize documentation packages according to customer standard requirements and to produce specific documents upon request.

Pre-validation of ICOS Pharma equipment ensures minimal project risk, less time and cost to qualify the units on site.

Acceptance Tests & on site activities

Factory Acceptance Test and Site Acceptance Tests.

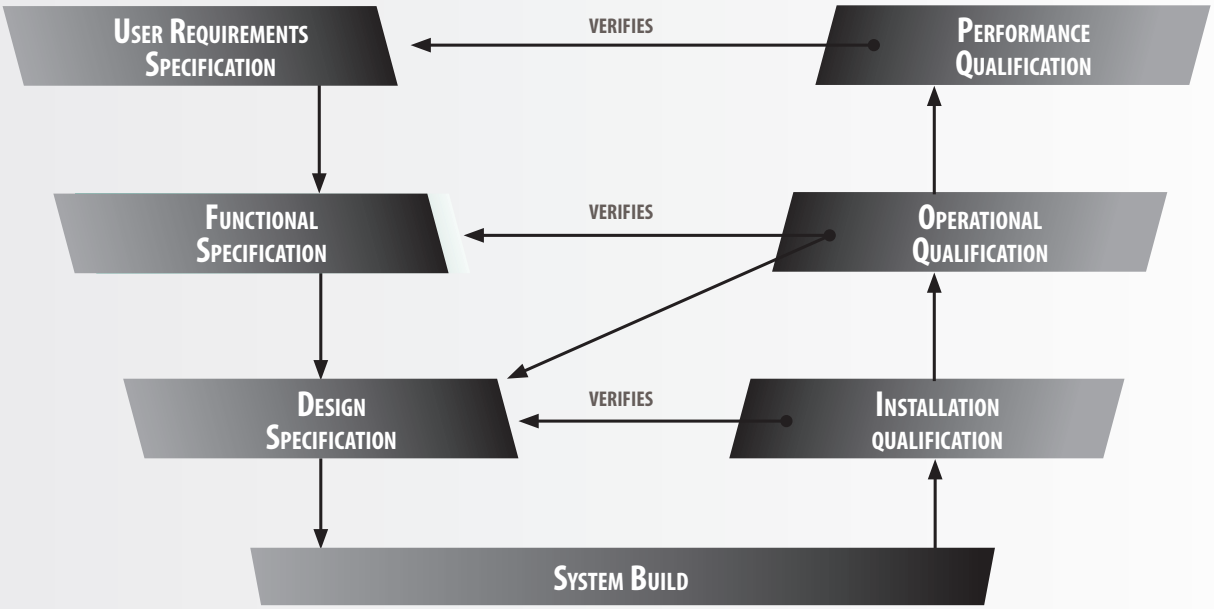
ICOS Pharma is available anytime to support customers during all acceptance on site including process development and mapping. All on site activities undertaken to pre-agreed written protocols according to GDP and HSE requirements.

ICOS keeps records of the technical file of each machine to enable full access in case of third party inspection to verify compliance with directives and regulations currently in force.

Expertise in Design Quality and Hazop is available to customers.

Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) are provided in standard version or customized according to the final scope of supply.

V-Model for specification, installation, start up and qualifications



Safety

Safety features and interlocks are mandatory requirements for a safe operating system and to maintain required quality. ICOS Pharma's ergonomically designed equipment includes appropriate alarms and other personnel protective devices.

Compliance and guidelines

ICOS Pharma complies with latest International requirements and guidelines, as well as local standards as applicable:

European Directives	
2006/42/EC	Safety of machinery
2004/108/EC and amendments	Electromagnetic compatibility
2006/95/EC and amendments	Low-voltage devices
97/23/CE	Pressure Equipment Directive-PED
ATEX 94/9/CE	Electrical equipment for explosive atmospheres

European standards	
EN 12100-1	Safety of machinery. Basic concepts, general principles for design. Part 1: Basic terminology, methodology.
EN 12100-2	Safety of machinery. Basic concepts, general principles for design.
EN 13857	Safety of machinery. Safety distances to prevent hazard zones being reached by upper and lower limbs.
EN 349	Safety of machinery. Minimum gaps to avoid crushing parts of the human body.
EN 61000-6-2 EN 61000-6-4	Electromagnetic compatibility (EMC). Generic standard. Part 6-2: Immunity for industrial environment. Part 6-4: Emission Standard for industrial environments (IEC 61000-6-4,modified); German version EN 61000-6-4.
EN 55011	Industrial, scientific and medical (ISM) radio-frequency equipment.
EN 61000-4-2 (IEC 1000.4.2) EN 61000-4-4 (IEC 1000.4.4)	Electromagnetic compatibility (EMC). Part 4: Testing and measurement techniques. Section 2: Electrostatic discharge immunity test. Section 4: Electrical fast transient/burst immunity test
AD 2000	Calculation code harmonized with Directive 97/23/EC
EN 60204-1 (IEC 204.1)	Safety of machinery. Electrical equipment of machines. Part 1: General requirement
EN ISO 11135	Specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process
EN 1422	Sterilizers For Medical Purposes. Ethylene Oxide Sterilizers. Requirements And Test Methods.

North American Standards
OSHA
NFPA
FDA
UL
when applicable:
ASME

Canadian Standards
CSA
CRN

Russian Standards
GOST

China Regulation
SELO

Closure Processing Systems

Completely integrated all in one solution

LST/LT Series
Closure processing equipment

Sterile continuity is the vision

ICOS Pharma aims at reducing manual contact to the minimum level. The LST/LT series is ideal for the treatment of closures for containers normally used in the pharmaceutical industry, where **continuous sterility has to be maintained** between different phases.

The LST Series offers **washing**, **rinsing**, **siliconizing**, **sterilizing**, **drying** and **cooling** all in one solution and is compatible with different loading/unloading systems, with the ability to interface with vaporized hydrogen peroxide isolator.

ICOS Pharma produces a "**Closure washer**" version - **LT series** - which only provides washing, rinsing, siliconizing, drying and cooling phases.

Thanks to an extended range of capabilities, ICOS Pharma now offers innovative customized stopper processor solutions for highly cost-effective projects.

Patent pending

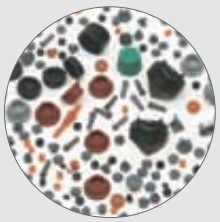
Chamber volume

from 40 litres / 1.4 cu.ft
to 480 litres / 17 cu.ft

Useful baskets volume (litres / cu. ft.)
40 / 1.4
80 / 2.8
120 / 4.2
180 / 6.4
240 / 8.5
480 / 17

Technical data, utilities consumptions and drawings are available upon request

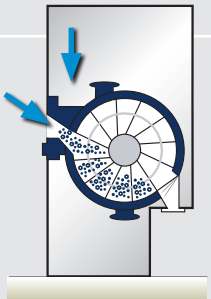
Field of application

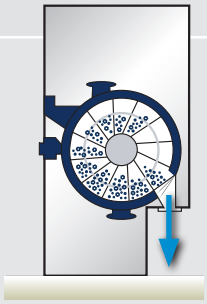


Designed for the complete treatment of closure devices for pharmaceutical products such as: **rubber stoppers**, **plastic stoppers**, **droppers**, **pistons**, **aluminium caps** and other similar components.

Closures loading options:

- manual
- automatic





Automatic unloading into:

- wheeled tanks
- containers
- sterile bags
- sterile bags through HPV (hydrogen peroxide vapor) isolator

"Assured productivity and sterility"

Advantages of ICOS Pharma technology

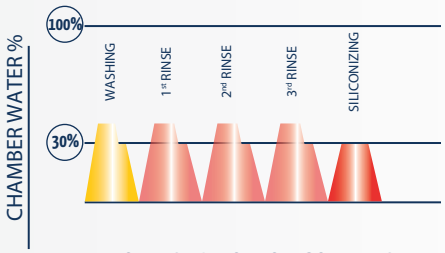
Physical separation of the load into different sub batches (basket) with uniform capacity offers the following advantages:

- capable of processing **different kinds of stoppers at the same time**
- **elimination of the excessive accumulation of material** during treatment phases
- **minimizing particle generation** due to mechanical stress and effective endotoxin reduction
- enhanced surface exposure to process fluids
- optimization of the washing process, with **effective endotoxin and particle reduction**
- **uniform silicone distribution** on individual stoppers and the entire batch
- optimization of the CIP phase
- more efficient cycle

Sterilizing quality process

The process consists of combined phases and actions designed to provide maximum process flexibility and efficiency.

The choice of time and phase succession allows the user to obtain the most appropriate cycle to match the characteristics of the material to be processed.



WASHING - RINSE - SILICONIZING

STERILIZATION - DRYING - COOLING

The **control system** manages the machine and its basic parameters, such as temperatures, F0, vacuum/pressure, times and level control, and other critical parameters.

The control system monitors, records, and controls the operation of the equipment.

Ethernet ports allow the downloading of data to a local computer or to a future plant data collection system.

Customized cycle according to client requirements.

Phases	Actions
Loading of material	through prearranged system
Washing	rotation, fluid bed, detergent
overflow	rotation, water diffuser
drain	rotation, water spraying
dripping	rotation

3 Rinsing phases	rotation, fluid bed
overflow	rotation, water diffuser
drain	rotation, water spraying
dripping	rotation
Siliconizing	rotation, fluid bed, silicone
drain	rotation, water spraying
dripping	rotation

Sterilization	steam at 121 °C
Drying	sterile air with HEPA filters
Cooling	sterile air with HEPA filters
Product discharge	in a sterile environment by means of prearranged system

LST/LT Series

Constructions features

The machine body and jacket are completely made of AISI 316L stainless-steel. The machine body is insulated with ceramic material and with an external cladding of stainless steel.

AISI 316L stainless steel piping is connected with ASME tri-clamp connections. The inner part of the chamber, the tubings, the baskets and all parts in contact with the product are polished to ≤ 0.5 µm / 20 µ/in.

All welds are continuous, ground and provided with a surface finish equal to the level of finish of the adjacent surfaces joined by the weld according to ASME BPE requirements. Gaskets, elastomers, sleeves, and other interior sealing components are FDA approved.

The stopper processor uses fluid bed washing technology, powered by a water recirculation pump. This sets the machine apart from other manufacturers by providing:

- A **gentler and more effective washing action**.
- No use of **compressed air during the washing cycle.**
- The recirculation pump also acts as an **emulsifier of the silicone oil injected and precisely dosed** into the recirculation pump loop system, allowing for the use of much lower levels of silicone oil per cycle than other solutions, making the CIP WIP cycle much more effective.

√ Highly **effective drying system** by air pulses and a rotating chamber canister.

√ Equipment is engineered and manufactured to **optimize running costs, saving utility costs**.

Sample points available for analysis

FIlters available for recycling phase

Electrical Panel in compliance with EU, UL and local standards as needed

"Advanced multitasking process"

Chamber features

Even distribution of load in separate baskets ensures better final results. **Washing by a simultaneous combination of basket rotation and fluid-bed action** is achieved by a recirculation pump and spray nozzles. It is designed for continuous effective operation without excessive adjustment or replacement due to wear.

The possibility **to visually check line clearance simplifies** the verification that no stoppers are left in the unit from previous cycles.

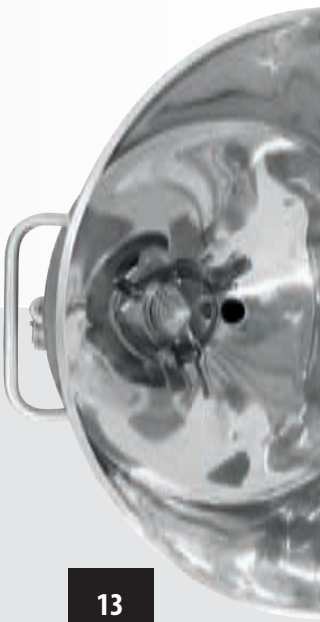
Suspended particles are skimmed off by side overflow drains. Appropriate sized relief valves are provided as required for each pressurized component.

- ☑ The chamber can be **completely inspected through a loading doo**r. The basket doors have automatic opening and closure.
- ☑ No presence of sharp edges in order to **prevent injuries to equipment operators or damaging of the closures**.
- ☑ **Ten different loading and unloading solutions** are offered.

Loading systems

Automatic loading is undertaken using a: stopper storage tank with mixer, suction tube, measuring tank with sanitary valves and aspirator.

Manual loading is carried out using AISI 304 stainless-steel containers of the same capacity as the machine baskets.



LST/LT Series

Unloading systems

Possibility to interface the unloading door with **wheeled tanks**, **containers**, **sterile transfer bags** and **HPV (hydrogen peroxide vapor) isolator**.

Unloading door equipped with a system for interfacing with clean area (bio-seal frame with "FDA approved facilities").

Chamber doors made in accordance with requirements for sterile environments.

Semiautomatic unloading into containers ("standard" application)
Unloading is semi-automatic and undertaken in stainless steel containers provided with a lid of the same capacity as the machine basket.
The unloading phase is protected by a sterile air flow originating from the inside of the chamber.

Automatic unloading into wheeled containers with Alfa Beta valve
Unloading is completely automatic and it is achieved with hermetically sealed wheeled containers of 100 liter capacity; the containers are built of AISI 316L stainless steel and are internally sterilizable.

Semiautomatic unloading into Sterile bags
Unloading is semiautomatic and it is discharged through sterilized PVC bags. The bags are treated at the stainless-steel station provided with a heat-sealing system for sealing the PVC bags. The unloading phase is protected by a sterile air laminar flow.

Automatic unloading into clean pre-sterilized bags through HPV Isolator

Unloading is completely automatic and it is carried out through HPV Isolator and transferring into alpha-beta sterilized bags.

The complete system includes:

- HPV isolator with alpha-beta port.
- HPV generator.
- Conveyor system from CPE port and alpha-beta port.
- Set of alpha-beta bags (each bag with the same capacity as each basket of the CPE – 10 litters of stoppers).
- Transferring trolley for bags.

Patent pending

Automatic unloading into Sartorius Stedim Biotech clean & pre-sterilized Biosafe® Bags through the Biosafe® Biosteam S Port

Unloading is completely automatic and is carried out through the Biosafe® Biosteam S Port transferring the closure into gamma-irradiated Biosafe® Bags.

The complete system includes:

- Biosafe® Biosteam Port ducted to the closure processing equipment.
- Biosafe® 110 Monolever Port ducted to the isolator of the filling machine.
- Disposable Biosafe® Bags.
- Transferring trolley for Biosafe® Bags filled with closure.

Biosafe and Biosteam are registered trademarks of Sartorius Stedim Aseptics S.A.

Saturated Steam Sterilization

Versatile cGMP Steam Sterilizers

AV Series

AV Series
Saturated steam sterilizers

Obtain the best results

In pharmaceutical production, the need to optimize sterilization processes is important to **increase safety** and **productivity**.

ICOS Pharma is able to offer an extremely diversified product range capable of meeting the requirements of the most varied applications and satisfy the strict standards of the pharmaceutical industry.

Due to our investments in the research of innovative solutions, ICOS Pharma sterilizers are **high performing**, **reliable** and **easy to use with excellent results**.

ICOS Pharma offers a wide selection of saturated steam sterilizers to exceed industry standards, available in single or pass-through versions, with hinged (AVL Series) or sliding doors (AVS Series).

Built to a very high standard, each unit is tailored to the customer's individual specifications.

Cart guides are welded into chamber floor.

Field of application

Used for sterilizing steam safe materials such as: **vials**, **bottles**, **glass items**, **fabric materials**, **sealed** or **vented containers**, **rubber parts**, **machine part and filters**, etc.

Chamber volume

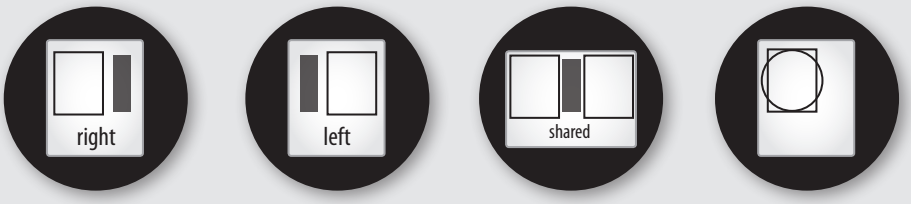
from 195 litres / 7 cu.ft
to 10.000 litres / 353 cu.ft

in several different dimensions with configurable options

Technical data, utilities consumption and drawings available upon request
Floor or pit mounted solutions

Flexible layout options

The AV Series offers **flexibility configuration** and **versatility**.The electrical panel can be integrated or remotely installed.



technical area | technical area | technical area | round or rectangular chamber

"Sterility Assurance"

Sterilizing quality process

The sterilization cycle has been specifically designed to reduce time and energy consumption, improving efficiency and throughput.

The preconditioning phase at the beginning of the cycle and the fractional vacuum phase at the end have been developed to maximize performance and minimize cycle time and energy use.

Each sterilizer can be equipped with any combination of cycles with complete flexibility to customize each phase and its parameters. Cycles are easily recalled from the HMI and are protected from unauthorized changes by a multi-level password system.

The following cycles are available depending on machine specification:

Service programs:
Vacuum leak test
Machine SIP
Bowie & Dick test
Automatic sterilization of machine and vacuum brake filter (SIP)
Predisposition for Automatic integrity test of vacuum brake filter (W.I.T.)

Working programs:
Fractioned vacuum
Rapid cooling by shower and counterpressure
Gravity purge and counter-pressure
Rapid cooling by shower and counterpressure + seal test by vacuum crush
Cooling by water injection in the jacket and counter-pressure
Air + steam mixture and counter-pressure
Tyndalization
Pharmacy with natural cooling
Slow heating with drying by slow vacuum
Drying by hot air

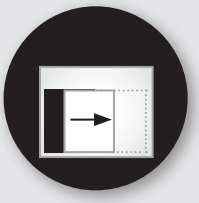
The **control system** manages the machine and its basic parameters, such as temperature, F0 and pressure; it enables easy interfacing with the operator and makes the customization of working cycles and maintenance operations possible.

Software used by ICOS Pharma is according to GAMP guidelines and designed for 21 CFR Part 11 where required.

SCADA system available for complete integration.

pit mounted
or floor loaded

vertical sliding down



horizontal sliding
left or right

hinged door
left or right

Construction features

In the standard version, the door seal is achieved by a pneumatically pressurized silicone gasket; ensuring the integrity of the door in any phase of operation.

Sliding doors are driven by an electromechanical system made in compliance with the requirements for clean areas and it is equipped with bio-seal or airtight separation.

Door seal system guaranteed for 4 years operational use without lubrication.

- The sterilizing chamber is entirely **covered by a full jacket system in AISI 316 L of dimple welded type** for fast heat transfer and to optimize chamber temperature distribution.
- **Single or twin air filters** installed in parallel, capable of being sterilized in place.
- Air detector following EN 285 **to detect the presence of air or non-condensable gases within pure steam**.
- All piping and ports in contact with the chamber are made of AISI 316L, are sloped and self draining. All components are of sanitary type where appropriate, including clamp fittings.
- The front loading side is fitted **with connection ports for validation testing**.
- **Airtight or bio-seal separation**.
- **Optimised for energy savings & low wastage**. Drain cooling system available to cool down all effluents prior to discharge into drains.

Low maintenance with long life proven components.

Safe applications

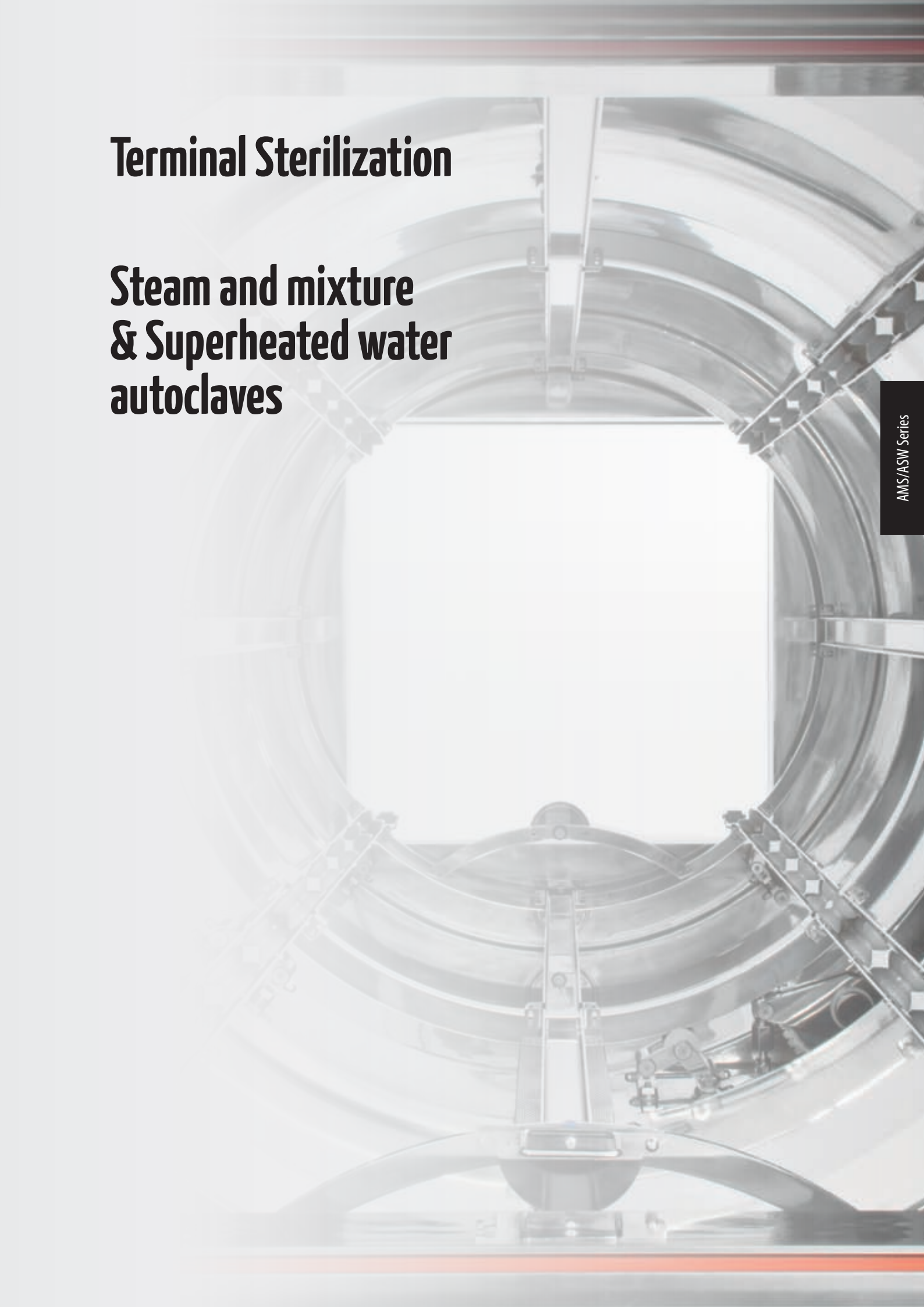
The unloading door can be interfaced with a HPV (hydrogen peroxide vapor) generator and/or isolation technology or with dedicated systems according to sterile requirements.

HPV generator

isolation technology

Terminal Sterilization

Steam and mixture & Superheated water autoclaves



AMS/ASW Series

AMS/ASW Series
Steam air mixture or Superheated water sterilizers

Different options for differing needs

ICOS Pharma's range autoclaves using **air + steam** or **superheated water** are for the terminal sterilization of injectable solutions.

Both methods of sterilization avoid any damage of the processed liquid material and their containers, including heat sensitive materials.

Thanks to an effective recirculation of air or water, uniform temperature is maintained in the sterilizing chamber, during all process phases.

Required pressure balance is achieved by using sterile compressed air in the chamber.

Field of application

Used to sterilize liquids in sealed or heat-sensitive containers such as: **bottles**, **ampoules**, **vials**, **semi-open containers, bags, blister packing**, **pre-filled syringes**, **pockets, contact lenses, LPV's, etc,** and also for the **pasteurization** of products like **blood plasma**.

Air-Steam or Superheated Water Process?
Selection depends on the products thermal lability, level of dryness to be reached, utilities available on site and running costs.

Chamber volume

from 830 litres / 29 cu.ft
to 25.000 litres / 883 cu.ft

in several different chamber sizes, configurations and accessories to tailor each unit to exact requirements

Technical data, utilities consumption and drawings available upon request
Floor or pit mounted solutions

Versatile loading/unloading systems and automation

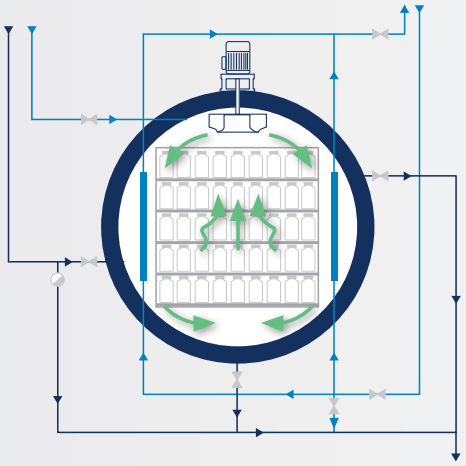
ICOS Pharma can provide a range of automated loading and unloading solutions including integration with robotic systems.

AMS Series

The sterilization program using an **air+steam mixture** is appropriate for different types of loads: bottles, ampoules and vials made in glass and plastic, multi-single bags, pre-filled sysringes, contact lens, blood bags.

It is also used in microbiological laboratories, particularly in the sterilization of sealed plastic containers.

The process includes the application of counterpressure to avoid permanent deformation of containers.

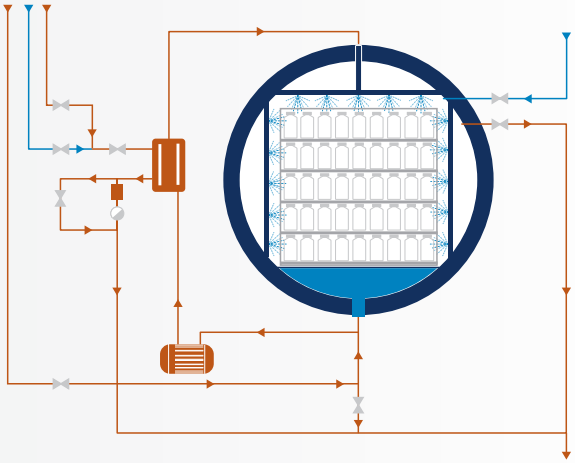


ASW Series

The sterilization program using **superheated water** is used mainly for sterilizing large containers, bottles, ampoules and vials made in glass and plastic, multi-single bags, although it can also be used for other types of loads.

The product is treated in counterpressure, in order to avoid deforming or breaking the containers

The ASW Series offers a rapid, safe and effective terminal sterilization process for high product throughput.



Sterile compressed air

Pure steam is used in the chamber for heating liquids and over-pressure filtered air is injected into chamber to compensate for the rising temperature and pressure inside products.

Internal fans ensure a uniform temperature distribution, between 110°C to 135°C, and to avoid cold spots across the chamber.

Rapid heating and cooling are standard phases. Products are completely dry at the end of the cycle.

Temperature distribution according to International Pharmacopeia.

High capacity pump

Water is continuously circulated through the system and cascades over the load using spray nozzles, high capacity pump and large diameter piping to ensure high water flow rates. The recirculating water is heated and cooled by external heat exchangers.

Meticulous control of heating and sterilization is achieved by superheating the water using modulated steam.

Compressed air at overpressure is injected to compensate for the rising temperature and pressure that builds inside the products when heated. The cooling phase brings the product down to ambient temperature by continuously spraying the recirculating water over the load.

To assist heat penetration and when fluids are liable to separation, the load can be rotated during the complete cycle.

Temperature distribution according to International Pharmacopeia

Chamber Seal

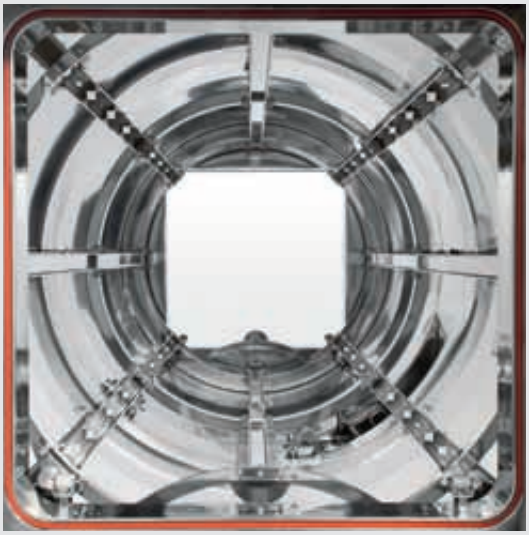
An automatic pressure sealing type door gasket is available upon request.

This system ensures the seal of the door in any condition of operation. ICOS Pharma guarantees these door seals for it 4 years.

Construction features

The machine body and jacket are completely made of AISI 316L stainless-steel. The machine body is insulated with ceramic material and with external cladding stainless steel. Pipings in compliance with ASME BPE made of AISI 316L stainless steel with tri-clamp fittings and all machine components of sanitary type.

The inner part of the chamber, the tubings, the baskets and all parts in contact with the product are polished to ≤0.5 µm.



The front loading side the machine is provided with the connection ports required for the validation tests.

The control system PLC is capable of storing and executing preprogrammed cycles and performing all self-diagnostics cycles.

Unique sealing of fan shaft for easy inspection and maintenance

Uniformity of temperature guaranteed by recirculation pump action

Flexible RTDs

Recircutlation system

Energy savings with recirculation water cooling system

Equipment is provided with a grounding lug for proper static grounding and seismic compliance if required

Useful combined solution

ICOS Pharma designs combined/modular systems sterilization, where heating and sterilization phases are carried out with saturated steam, like a normal sterilizer, or with a mixture of steam and air in the same autoclave.

Chemical Sterilization

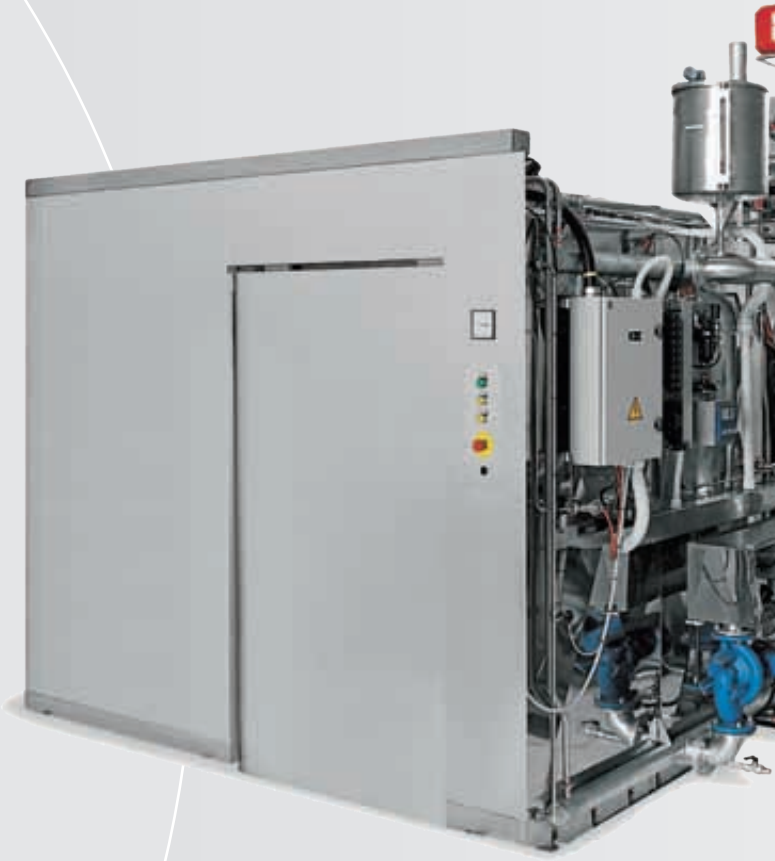
Ethylene oxide media

AGS/AGS-E Series
Ethylene oxide sterilization autoclave

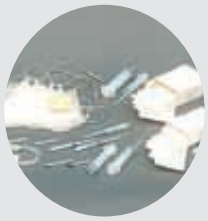
ICOS Pharma's latest range of sterilizing autoclaves using Ethylene Oxide increases performance and versatility.

Manufactured in our factories in Italy after a long research program and an extensive series of tests, the AGS/AGS-E series is **the best relationship between engineering, quality**, **price, operating running costs** and most important **safety of the system and operators**.

ICOS Pharma's range of ETO sterilizers use **thermal combustion** for **a complete breakdown of the sterilizing gas**.



Field of application



Used for low temperature sterilization of heat-sensitive products according to the EN 1422 Standards for the medical processing industry such as: **plastic syringes**, **perfusion sets**, **dialysis cartridges, heat-sensitive rubber products** and **special surgical instruments**.

Productivity and energy saving

The new range has been designed for best in class energy recovery in order to optimize consumption.

The vacuum system is provided with a water ring pump, which is supplied with water drawn from the separator by creating a closed circuit. The temperature is maintained at optimum levels by a heat exchanger. The pump outflow is directed to the separator, from where it is sent to the neutralizing system.

Chamber volume

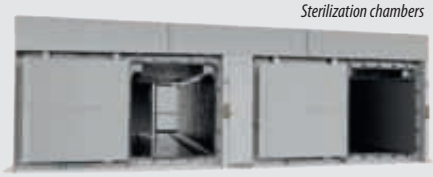
from 1000 litres / 35 cu.ft
to 63.000 litres / 2.225 cu.ft

Available in a wide range of chamber sizes and volume.

Technical data, utilities consumption and drawings available upon request

Following customer requests, dedicated chambers for separate processes can be supplied:

Conditioning chambers



Sterilization chambers

Degassing chambers

"Optimal cycles"

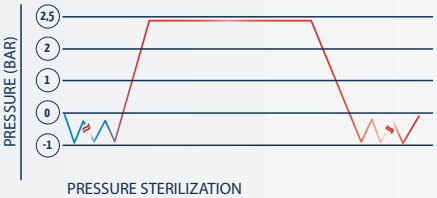
Effective and safe abatement of Ethylene Oxide at completion of sterilization process by thermal combustion

Process under optimized conditions

AGS series

Pressure sterilization program

up to 10% of Ethylene Oxide, with the remaining 90% made of inert gas (normally Nitrogen)

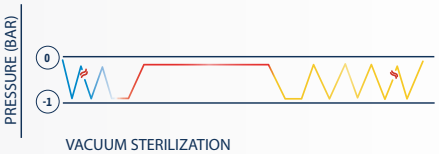


PRESSURE STERILIZATION
non explosive mixtures 10% EO 90% CO2

AGS-E series

Vacuum sterilization program

up to 90% of Ethylene Oxide, with the residual 10% made of inert gas (normally Nitrogen)



VACUUM STERILIZATION
explosive mixtures 90% EO 10% CO2

Process data

Phases	non explosive mixtures	explosive mixtures
Heating of load with hot water circulating in the heating jacket and alternating vacuum phases followed by the inflow of hot air	●	●
Humidification of load, with alternating phases of vacuum and steam inflow at low pressure	●	●
Sterilization of load by pressurization of the chamber with the gas mixture	●	with preset steam pressure
Gas discharge	●	by vacuum pump
Inflow of inert gas		●
Load degassing with alternating vacuum and hot-air inflow phases for a preset time	●	●

Sterilization temperature up to a max. of 60°C with temperature distribution of ± 1° C.
The right sterilization temperature must be matched to the type of the material to be processed.

Quality details in every phase of the process

The ETO gas is heated through evaporators, before being introduced into the chamber. Load moistened through the inflow of low-pressure clean steam supplied by a steam generator.

The air, which is supplied into the chamber in the degassing phase, is filtered through absolute filters to guarantee higher quality.

Manufactured with the highest industrial standards

ICOS Pharma's rectangular cross section sterilization chamber is completely surrounded by a high efficiency heating jacket for rapid and even heating of loads. Machine body is completely made of AISI 304 stainless-steel, insulated with high density ceramic material, and clad in stainless steel sheet. The chamber and the hydraulic system are completely built, and clad stainless steel. Panels and sterilization chamber are satin finished.

Process piping is made tri-clamps and flange connections. Pneumatic control of the valves is fitted.

Compliance and solutions

ICOS Pharma has developed an automatic horizontal sliding door system with a heated jacket, where the closure of the door is assured by a pneumatically pressurized gasket with a 4 year of warranty.

Dedicated to autoclaves that use a potentially explosive mixture, ICOS Pharma has specifically designed a safe hermetic closure guaranteed by a pressure-sealing device with automatic tie-rods.

All safety devices are in compliance with international standards with parameters continuously monitored to avoid the risk of explosion.

Machine provided with necessary connection ports for validation tests.

Design pressure

The chamber is dimensioned taking into account the following parameters: 1, 5 bar + vacuum working pressure; 2,7 bar + vacuum design pressure.

Complete protection of the environment

Abatement of Ethylene Oxide at completion of sterilization process: increasingly stringent parameters make it necessary to offer safe accepted abatement systems on every Ethylene Oxide sterilizer.

ICOS Pharma follows the ATEX, US, OSHA, NFPA and FDA regulations and complies with ISO 11135, EN 1422.

Dry Heat Sterilizers

Advanced solutions for special applications

SD Series
Class 100 static air depyrogenation sterilizers

ICOS Pharma designs and manufactures a wide range of Class 100 static depyrogenation sterilizers (ISO 14644-1 class 5) to meet the most challenging pharmaceutical requirements.

The depyrogenation process is aimed at the reduction in the level of pyrogens, with the use of hot air in temperature which range from 250°C up to 300°C.

The high performance Class 100 oven solution ensures an even distribution of hot air for the entire cycle including large loads, with the installed HEPA filters preventing cross contamination.

Field of application

Used for the sterilization and depyrogenation of heat resistant materials such as: **bottles, vials, glass containers, metal trays and production equipments** such as stainless steel vessel etc.

Laboratory glassware and instruments, materials sensitive to humidity, **thermostable basic pharmaceutical products** and **chemical compounds**, non aqueous liquid materials such us **oils, glycerines**, etc.

Chamber volume

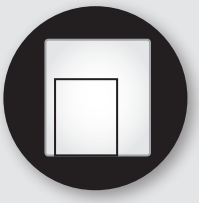
from 330 litres / 12 cu.ft
to10.000 litres / 353 cu.ft

A large range of chambers and configurations are available.

Technical data, utilities consumption and drawings available upon request

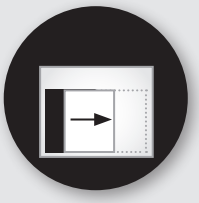
Complete layout versatility

Available with a choice of three types of doors: swing-out, horizontally sliding and vertically sliding, with the goal to always guarantee the door tightness, regardless of unit dimensions.



pit mounted and floor loaded

vertical sliding down



horizontal sliding left or right

hinged door left or right

"Drying without compromise"

Drying quality process

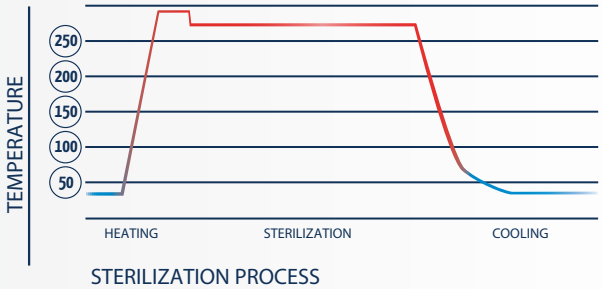
Fully compatible with the strict standards of the pharmaceutical industry, the SD Series is supplied with HEPA filters (99,99% efficiency) for filtration of pressurized air flow (EU 13), air recycling and exhaust chamber air (EU 12).

The HEPA filters abate the level of particle contamination in the chamber also during critical phases, such as heating and cooling.

Particular care is used to eliminate heat transmission points.

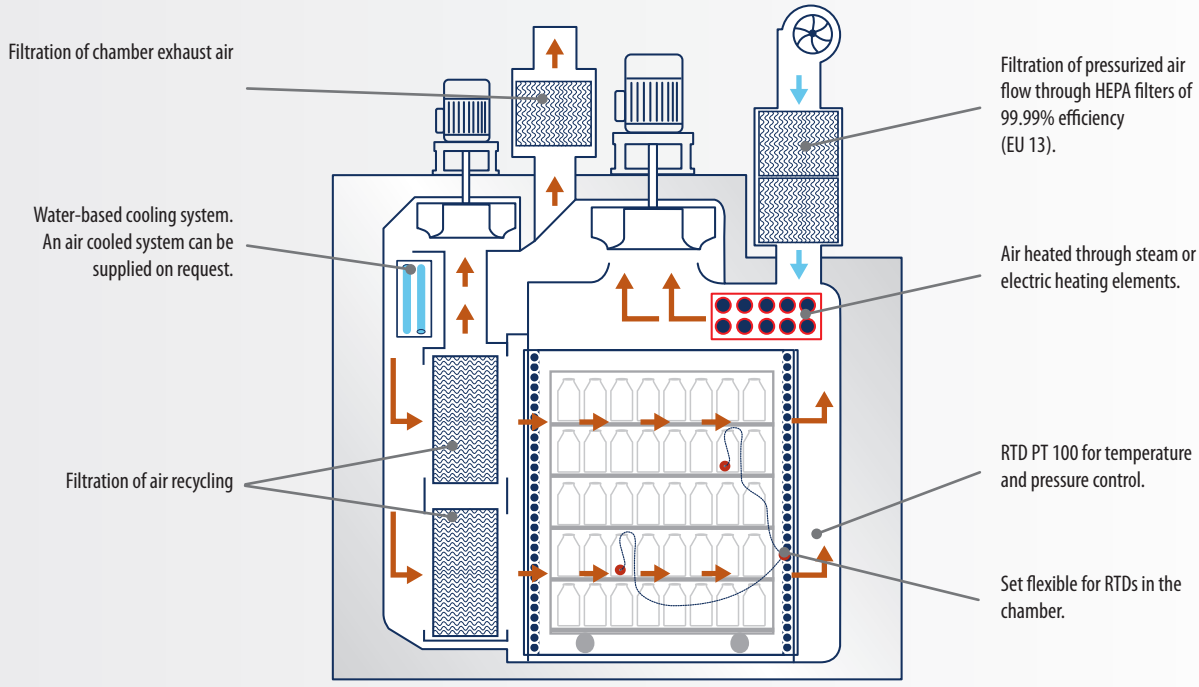
Specially designed filter retention system to minimise thermal stress.

The **control system** manages the machine and its basic parameters, such as temperature, Ft, Fh and pressures.
We guarantee excellent PID control of temperature and chamber pressure throughout all phases.



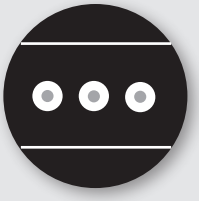
STERILIZATION PROCESS

Adjustable temperature ramp, sterilization plateau, cooling temperature, chamber pressure, cooling time are all available.



Perfect compatibilty

The SD series features connection ports on the front loading side for validation testing. Machines equipped with special product holding trays and handling trolleys, can be also interfaced with the isolation technology.



Inspection window in the front loading side

isolation technology

Construction features

Chamber, areaulic system, doors and other machine structural components are made of AISI 316 stainless steel.
Chamber insulated with high density ceramic insulating material and covered externally by AISI 316 stainless steel panel.

Uniform air distribution through differentially perforated walls, particularly suitable for varied loads.

Chamber with rounded internal angles and TIG welded smooth seams.

Uniform automatic chamber pressure and temperature control.

Chamber provided with a double bottom for even temperature distribution.

Inside of chamber polished to ≤ 0.5 µm.

Automatic pneumatic door locking mechanism.

Hermetically sealed doors with a special profile silicone gasket with double sealing strip. Gasket allows the formation of vacuum to guarantee perfect door seal during every phase of the cycle.

System designed to minimize cross contamination risk.

Norms and standards

The SD Series is in compliance with the following latest Norms and Directives:

cGMP - GAMP - FDA - EN 1822 - ISO 14644/1/2 - CFR's including 21 CFR parts, 201, 211 and part 11 available as option - EUROVENT - Technical Reports "Parenteral Drug Association" - 2004/108/CE, 2006/95/CE - plus other local and international standards as applicable.

"Drying without compromise"

EG Series
Tray drying ovens for granulates

Static tray drying ovens manufactured by ICOS Pharma are some of the most technically advanced machines in existence.

Thanks to a **long experience in hot air drying**, these machines are **designed for optimizing process parameters** for **effective**, **uniform** and **gentle** drying.

A wide range machines, fully compatible with the strict standards of the pharmaceutical industry (FDA, cGMP, GAMP 5, etc.) are offered.

Provision of tray handling trolleys, customized to suit end user requirements.

Chamber volume

from 330 litres / 11.5 cu.ft
to 10.000 litres / 308.5 cu.ft

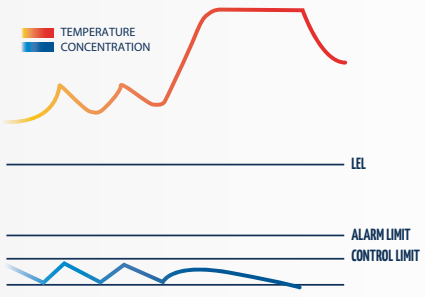
Technical data, utilities consumptions and drawings available upon request.

Field of application

This range of machines is used for drying by hot air of materials such as **granulates**, **pellets**, **powders** and **porous load** in pharmaceutical industry processes.

Special application

For the treatment of granules with presence of solvents, the dryer can be equipped to monitor flammability hazard by controlling LEL.



DRYING PROCESS

Main options

The hot air drying ovens can be supplied **with a self washing system** in the chamber and a device for the **removal** and **insertion of tray support carts**.

Upon request and for particular types of applications, the electrical system and components of the machine can be supplied to be compliant with **flameproof type** (ATEX regulation).

Drying quality process

The EG Series has even hot air distribution in the chamber. Special perforated walls and temperature control, ensure the drying quality process. The mechanical construction of the machine body is designed to resist temperatures of up to 300 °C. External panelling is made of AISI 316 stainless steel with the chamber having a polished finish.

The unit is provided with filters for the inlet and exhaust air flows in the chamber.
Steam and electric heated options are available with a maximum temperature of 120°C.

The machine body and aeraulic system are made of AISI 316 stainless steel.

The chamber has a rectangular cross section and is fitted with a rectangular hatch.

Fast-closing swing out doors and gaskets are made of silicone rubber.

Floor or pit mounted solutions.

Documentation/Validation

Comprehensive operating and maintenance manuals and IQ/OQ documentation is provided as standard. ICOS Pharma helps you to minimize the time needed for validation, with decreased breakdowns, increased production and operative lifetime achieved.

LB Series & ML Series

Bin and cabinet washers
Parts and glassware washers

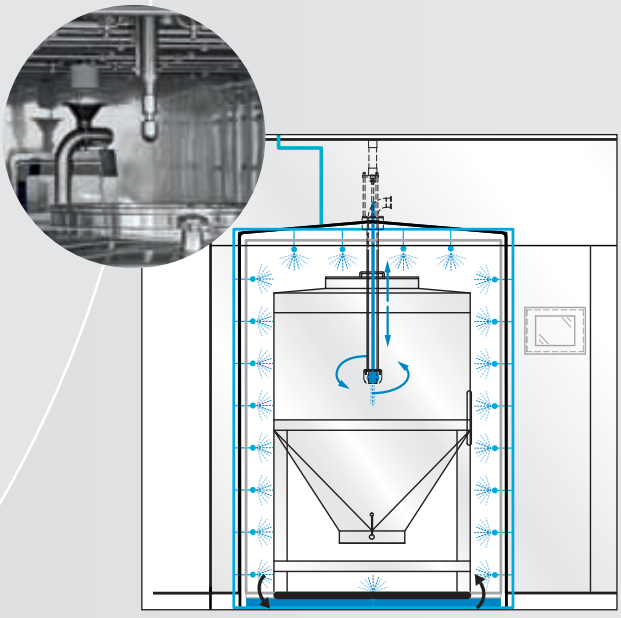
LB Series
Bin washer system

LB Series is a system specifically designed for the cleaning and drying of containers and drums in pharmaceutical validated processes.

Custom made for individual customer needs, these units feature the possibility to rotate both the container being cleaned and/or the spray nozzle arm 360° inside the object ensuring exceptional cleaning of all surfaces of the container.

Field of application

Bins, drums, tanks, IBV, IBC



Chamber volume

from 5.000 litres / 177 cu.ft
to 10.000 litres / 353 cu.ft

in several different dimensions with configurable options

Construction features

- √ *Highest cleaning performance*
- √ *Continuous moving top spray arms*
- √ *360° continuous bin rotating during operation*
- √ *Drying unit with 1000 m³/hour capacity*

ML Series
parts and glassware washers

Compact footprint & hinged door washer

This machine offers pre-washing, washing, rinsing, drying and cooling phases with optimal performance in a compact size and footprint solution.

Hinged type chamber doors with single or double door and double locking device made in accordance with requirements for clean environments.

Use of FDA approved components (valves, filters, piping, tri-clamp fittings, pumps, etc.). Use of 316L stainless steel with roughness less than 0.5 µm (20 micro inches) on all components in process contact (machine body, machine doors, spray nozzles bars, process piping, instruments, valves, racks, internal carts, baskets, etc.).

Drying by HEPA filtered hot air at max. 130°C.

Low running and life cycle costs.

Chamber volume

from 465 litres / 16 cu.ft
to 3800 litres / 134 cu.ft

in several different dimensions with configurable options

Field of application

Machines are designed for pharmaceutical products such as **glassware, pipettes, machine parts, tanks, glass bottles, pill stamps, carboys, tubes, needles**, etc.

Customized and engineered loading equipment: racks/carts and baskets.

Adjustable height transport trolleys. Possibility of interfacing unloading door with isolator.

Construction features

- √ *Orbital welding on all piping with tri-clamp fittings.*
- √ *Respecting 3-D dead legs with the application of Zero-Static (0-Dead legs) components.*
- √ *3 degree slope on process piping.*
- √ *All internal corners of the chamber have radiuses as per cGMP requirement.*
- √ *No. 3 Water supply of "pharma" type with last rinsing water sprayed directly onto spray nozzles/load.*

ICOS Pharma S.p.A.
Via E. Ellero, 15
33080 Cusano di Zoppola (PN)
ITALY

PHONE +39 0434 5772911
FAX +39 0434 5772900

sales@icospharma.com
www.icospharma.com

member of

Steelco GROUP

CE

DC-PD-02-ICOS PH ST EN Rev.01