

The static depyrogenation sterilizers in Class 100 (ISO 5) manufactured by ICOS rank with the most technologically advanced machines in the field.

The company's long experience with air sterilizers, the large number of laboratory tests carried out and the use of equipment specifically designed for optimizing the process parameters give us the possibility of proposing a range of high-performance and full comply with the strictly standards of pharmaceutical industry (FDA, cGMP, GAMP 5, etc.) machines on the market.

These machines are identified as follows:

- STATIC AIR DEPYROGENATION STERILIZERS, SD SERIES



FIELD OF APPLICATION

The machines in this range are used for the sterilization and depyrogenation of heat-resistant materials such as: bottles, vials, glass containers, metal trays and machine parts.

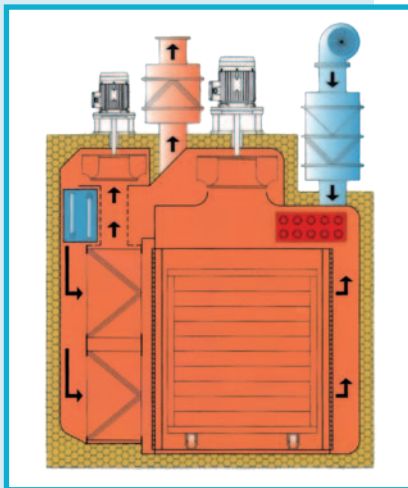
LOADING SIDE - TYPE SD 602



LOADING SIDE - TYPE SD 1001

MAIN FEATURES

- Filtration of pressurization air flow into the chamber through HEPA filters of 99,99% efficiency (EU 13)
- Filtration of chamber exhaust air through HEPA filters of 99,99% Efficiency (EU 13)
- Filtration of air recycling in the chamber through HEPA filters of 99,99% Efficiency (EU 12)
- Automatic chamber pressure control
- Automatic chamber temperature control
- Uniform air distribution through differentially perforated walls, particularly suitable also for differentiated loads
- Uniform temperature on the product $\pm 3^{\circ}\text{C}$
- Automatic door locking mechanism through a device of pneumatic type
- Hermetically sealed doors with a special-profile silicone gasket with double sealing strip. Gasket allowing the formation of vacuum to guarantee perfect door tightness in every cycle phase. This ICOS-designed system avoids any possible contamination
- Chamber provided with a double bottom, which further improves an even temperature distribution
- Mechanical construction designed to withstand temperatures up to 300°C
- On the front - loading side - the machine is provided with the connections required for the validation tests
- The machine can be interfaced with the isolator



FUNCTIONAL SKETCH

CONSTRUCTION FEATURES

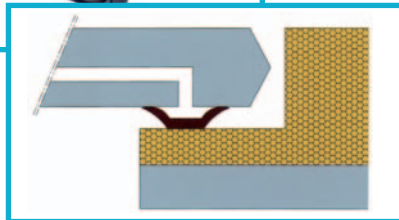
- Machines available with a choice of three types of doors: swing-out, sideways sliding and vertically sliding
- Water-based cooling system; an air cooled system can be supplied on request
- Chamber, aeraulic system, doors and other machine structural components made of AISI 304 stainless steel, on request, they can be made of aisi 316 stainless steel
- All the chamber internal angles are rounded
- Chamber welding seams of tig type
- Inside of chamber polished with a degree of roughness of 0.5 μm
- Chamber insulated with high-density ceramic insulating material and covered externally by AISI 304 stainless steel panel. Particular care is used to eliminate heat transmission points
- Particular care is used to eliminate heat transmission points

STATIC AIR DEPYROGENATION STERILIZERS IN CLASS 100

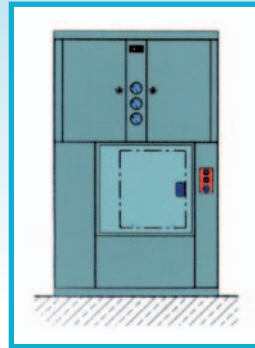
SD
Series



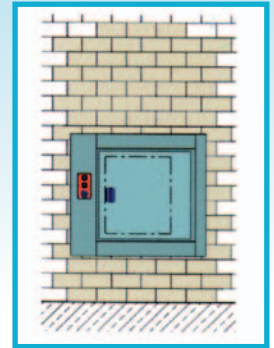
UNLOADING SIDE - TYPE SD 803



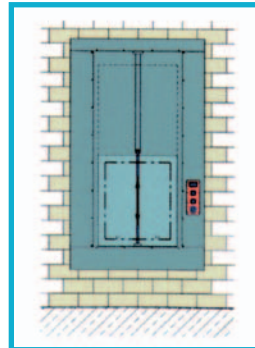
DETAIL OF DOOR GASKET TIGHTNESS



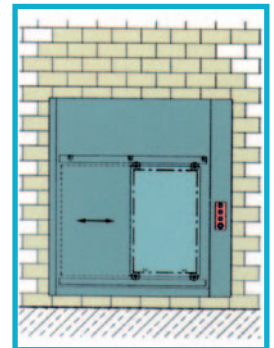
LOADING SIDE / HINGED TYPE DOOR



UNLOADING SIDE / HINGED TYPE DOOR



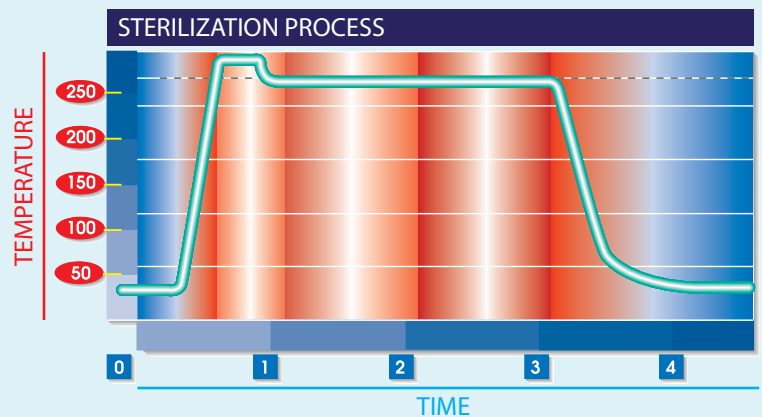
UNLOADING SIDE / VERTICAL
SLIDING TYPE DOOR



UNLOADING SIDE / SIDE SLIDING
TYPE DOOR

PROCESS DATA

- Process temperature adjustable to a maximum of 250°C
- Adjustable temperature ramp
- Adjustable treatment time
- Adjustable cooling temperature
- Adjustable chamber pressure
- Adjustable cooling time



CONTROL SYSTEM

The machines of "SD" series are provided with a control system made up of a programmable controller (PLC), operating panel (OP) or industrial computer (PC) and printer. The control system manages the machine and its basic parameters, such as temperature, Ft, Fh and pressures. It allows an easy interfacing with the operator and makes it possible to customize the working cycles and maintenance operations. The system provides a complete process documentation and assists in the validation procedures.

Note: A full description of the control system is contained in the relative booklet.

In the quality of the materials used, and in their accurate finish, construction and process characteristics, all the ICOS machines are in compliance with the most up-to-date standards.



CONTROL BOARD



ICOS RESERVES THE RIGHT TO MAKE
PRODUCT CHANGES WITHOUT PRIOR
NOTIFICATION



UNI EN ISO 9001



SD SERIES - STATIC AIR DEPYROGENATION STERILIZERS IN CLASS 100

Type	Capacity (litres / cu. ft.)	Chamber dimensions (mm / inches)			Overall dimensions (mm / inches)		
		Width	Height	Length	Width	Height	Length
SD 601	330 / 11.5	660 / 26	730 / 28.5	695 / 27	1650 / 65	2850 / 112	1210 / 47.5
SD 602	645 / 22.5	660 / 26	730 / 28.5	1345 / 53	1650 / 65	2850 / 112	1860 / 73
SD 801	785 / 27.5	800 / 31.5	730 / 28.5	1345 / 53	2085 / 82	2850 / 112	1860 / 73
SD 802	975 / 34.5	800 / 31.5	730 / 28.5	1670 / 65.5	2085 / 82	2850 / 112	2185 / 86
SD 803	1460 / 51.5	800 / 31.5	1360 / 53.5	1345 / 53	2085 / 82	3350 / 132	1860 / 73
SD 804	1810 / 64	800 / 31.5	1360 / 53.5	1670 / 65.5	2085 / 82	3350 / 132	2185 / 86
SD 805	2140 / 75.5	800 / 31.5	1360 / 53.5	1975 / 77.5	2085 / 82	3350 / 132	2490 / 98
SD 1001	2680 / 94.5	1000 / 39	1360 / 53.5	1975 / 77.5	2285 / 90	3350 / 132	2490 / 98
SD 1002	3320 / 117	1000 / 39	1685 / 66	1975 / 77.5	2285 / 90	3450 / 136	2490 / 98
SD 1003	3870 / 136.5	1000 / 39	1685 / 66	2300 / 90.5	2285 / 90	3450 / 136	2815 / 110
SD 1004	4390 / 115	1000 / 39	1685 / 66	2605 / 102.5	2285 / 90	3450 / 136	3120 / 122.5
SD 1501	6580 / 232	1500 / 59	1685 / 66	2605 / 102.5	2785 / 109.5	3450 / 136	3120 / 122.5
SD 1502	7400 / 261	1500 / 59	1685 / 66	2930 / 115	2785 / 109.5	3450 / 136	3445 / 135.5
SD 1503	7770 / 247	1500 / 59	1990 / 78	2605 / 102.5	2785 / 109.5	3750 / 147.5	3120 / 122.5
SD 1504	8740 / 308.5	1500 / 59	1990 / 78	2930 / 115	2785 / 109.5	3750 / 147.5	3445 / 135.5

ICOS ICOS IMPIANTI GROUP S.p.A. - *Pharmaceutical Division*

Via E. Ellero, 15 - Zona Industriale - 33080 Cusano di Zoppola (PN) - Italy - Phone +39 0434 979596 - Fax +39 0434 574080
e-mail: sales@icosimpianti.com