

ETHYLENE OXIDE GAS (EtO) STERILIZERS



DE LAMA

more than fifty years of experience in sterilization

DE LAMA holds the Quality System certificates
ISO 9001 and EN 46001



ISO 9001 - Cert. n° 0351/2
EN 46001 - Cert. n° 1275/0





ISO 9001 - Cert. n° IT - 4018
EN 46001 - Cert. n° IT - 7773






Ethylene oxide gas (EtO) sterilizers

DE LAMA DLOG and DLOG/V

Ethylene oxide sterilizers of  **DE LAMA DLOG** and  **DE LAMA DLOG/V** series have been specifically designed for sterilization of products sensitive to high temperatures and to humidity (syringes, defluxers, catheters, cartridges for dialysis, plastic articles, bandages, sutures, etc.). Such autoclaves can be used even for sterilization of powders which deteriorate by heating exposure. For the wide range of product that can be treated, such sterilizers find application in parapharmaceutical and pharmaceutical industry, in laboratories and hospitals.

Ethylene oxide autoclaves can be realized in two versions to satisfy different requirements:

-  **DE LAMA DLOG** series for working under pressure (3,5 abs. bar + vacuum) with mixtures of ethylene oxide and carbon dioxide (usual composition 10% EtO + 90% CO₂)
-  **DE LAMA DLOG/V** series for working under vacuum (1,45 abs. bar + vacuum) with mixtures of ethylene oxide and carbon dioxide (usual composition 90% EtO + 10% CO₂) or with 100% ethylene oxide.



On request,  **DE LAMA** can supply EtO sterilizers which are able to perform even saturated steam cycles.



Sterilizer  DE LAMA DLOG/V-Ex 561 type,
capacity 14500 lts., with automatic sliding door

MAIN CONSTRUCTION FEATURES

Sterilizers are designed, manufactured and tested according to current Directives for construction of pressure vessels (PED), in full compliance with cGMP Guidelines, European Standards and **EN 1422**, with procedures fixed by **ISO 9001** and Quality Systems and are suitable to be validated according to European Standard **EN 550**.

DE LAMA  LOG (equipment under pressure) and **DE LAMA  DLOG/V** (equipment under vacuum) are distin-

- double wall body
- sterilization chamber in AISI 316 or AISI 316L stainless steel

- front panels and eventual side walls in satin finish AISI 304 stainless steel
- piping and valves directly connected with the chamber in stainless steel
- loop for heating and circulation of water inside the jacket, complete of pump
- efficient insulation with minimum heat loss and high power economies

Sterilizers are available with single or double door, hinged or automatic sliding type.

PROCESS CONTROL

All **DE LAMA** control systems are provided with **CE** marking and are in compliance with European Directive **EMC 89/336** relevant to electromagnetic compatibility.

To satisfy Customers' several production needs, **DE LAMA** has realized different and flexible control system configurations. All controllers give the possibility of data processing and to issue detailed process documentation.

DE LAMA MASTER 6

Distributed architecture modular control, processing and recording system with industrial PC connected to a PLC

- VGA colour LCD monitor (TFT 800x600)
- multifunction keyboard membrane type
- track-ball
- colour graphic printer with printout size A4
- interface Ethernet IEEE 802.3 and Profibus
- self-diagnostic and self-test
- graphic programming
- configurable dynamic synoptic panel
- human / machine interface (HMI) with graphic management
- Windows-NT® / 2000 Professional® operating system
- integrated management of all process parameters and sequences



PC/PLC integrated logic computerized control system

Master 6 type

- unlimited possibility of programmes configuration and memorization
- data holding in case of black-out
- software in compliance with GAMP3 Guidelines
- Multilevel password and full compliance with FDA Regulations
- Guidelines relevant to electronic signature (CFR 21-Part 11).

DE LAMA OLIMPIA/EXP3

Control, regulation, management and recording system equipped with high speed microprocessor:

- monitor LCD
- multifunction keyboard membrane type
- synoptic panel
- colour graphic printer with printout size A4
- serial interface
- wide programming and management of all process parameters

- up to 35 standard storable programmes
- self-diagnostic
- data holding in case of black-out
- possibility of connection to an external PC for real-time logger and data storage functions

On Customer's request, **DE LAMA** can supply:

- customized systems able to interface with supervisors (SCADA) and external control facilities
- independent recording system for process data (according to European Standard **EN 1422**)

STERILIZATION PROGRAMMES

High flexibility of control systems mounted on autoclaves **DE LAMA DLOG** and **DE LAMA DLOG/V** allows to perform cycles, automatic control cycles (vacuum leak test pressure leak test) and cycles free programmable by It is possible to choose operating parameters (time, humidity, gas concentration, etc.) according to type load, packaging and product placing inside the chamber.

Standard operating values are the following:

Sterilization time: usual gas exposure time is 3÷4 hours. Sterilization time depends on both type of packaging and other process parameters.

Product temperature: 40÷60°C

Set temperature value is non-stop holded by forced circulation of water inside the jacket and, optionally, inside the

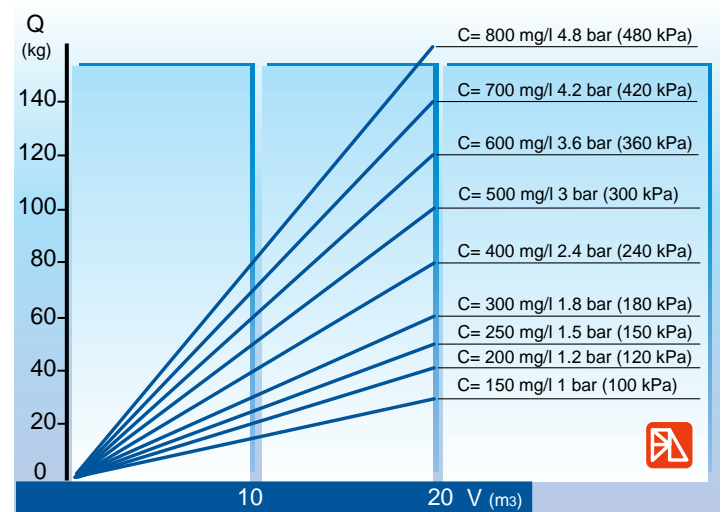
This system is very reliable with no risk of overheating and temperature differences by steam use.

Product humidity: 40÷70 RH%

Such value is obtained with sterilizer under vacuum condition to allow best conditioning of sterilization load.

Gas concentration inside the sterilizer: variable on the basis of used gas mixture and operating pressure.

Graphic of changes in mixture consumption (10% EtO + 90% CO₂) to different concentrations

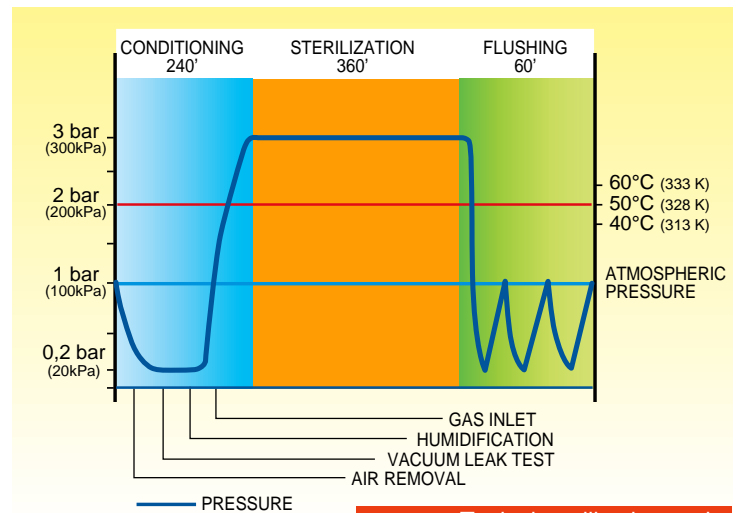


CYCLE BASIC PHASES

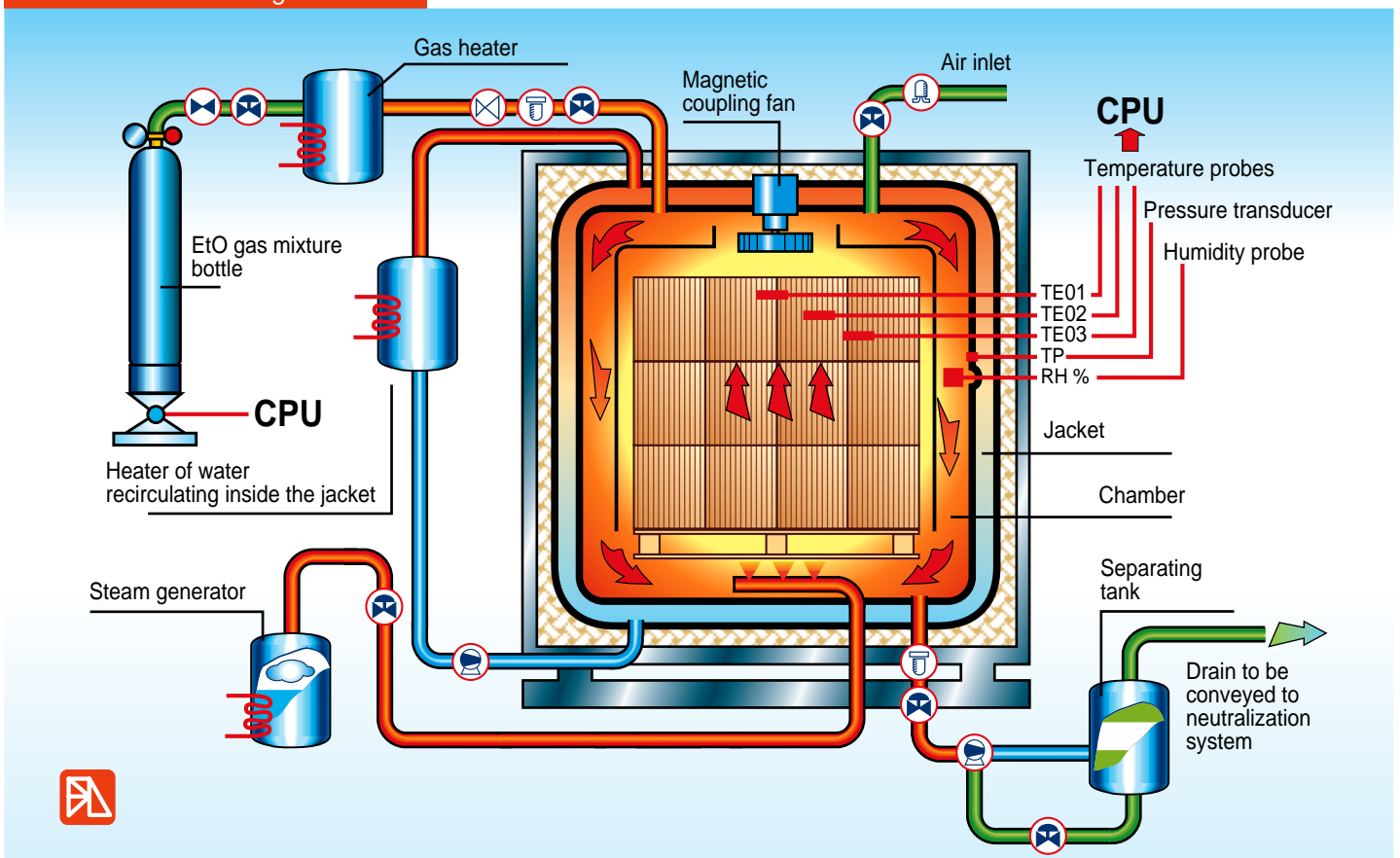


Sterilizer **DE LAMA DLOG 931** type,
capacity 37734 lbs., with hinged motorized door

- Load of product to be sterilized
- Product heating by heated water circulating inside the jacket and by internal fans preventing stratification which make heat exchange easier.
- Pre-vacuum with value that can be automatically set up to 40 mbar (4 kPa) max.
- Vacuum leak test of the chamber before gas inlet
- Product conditioning by humidification up to a preset value
- Inlet of preheated and vaporized gas up to selected pressure value
- Sterilization with gas pressure constant holding for a preset time (up to 24 hours)
- Flushing by gas evacuation through vacuum pump and sterile air inlet (pulsations) for a prefixed number of times.



Functional diagram





AUXILIARY EQUIPMENT

- Gas feeding, vaporizing and preconditioning equipment
- Microprocessor system for control of relative humidity
- Exhausted gas neutralization equipment
- Device for continuous monitoring of EtO pollution arising from eventual escapes of gas indoor

OPTIONALS

- Doors heating through hot water flushing
- Doors motorization system with electronic control
- Automatic translation system for doors opening/closing
- Internal ventilation system, with magnetic coupling fan groups, to optimize homogeneity conditions throughout the chamber (according to European Standard **EN 1422**)
- Gas injection pipes washing system by nitrogen flux
- Exhaust hoods for suction of eventual residual gas on doors opening
- Electronic gas weighing system
- ADPE explosion-proof execution for sterilizers under vacuum (**DE LAMA DLOG/V**)

QUALITY CONTROL AND VALIDATION

Equipment and relevant supervision systems are designed and manufactured to be easily validable in compliance with European Standard **EN 550** and with quality standards for pharmaceutical processes required by FDA.

Careful tests, specific controls and high technical professionalism in pre-validation activities assure that plants are fully in compliance with highest required standards.



Sterilizer **DE LAMA DLOG 631 type**,
capacity 23392 lts., with automatic product loading system



Sterilizer **DE LAMA DLOG 541 type**,
capacity 10875 lts., with hinged door

TECHNICAL DOCUMENTATION AND ADDITIONAL ACTIVITIES

To complete the supply, plants are always provided with following basic documentation:

- installation and operation manuals
- P&I and technological diagrams
- dimensional drawings and lay-out
- bill of materials and components
- materials and calibration certificates

On request, **DE LAMA** supplies:

- FAT and SAT protocols/documentation for pre-validation
- Validation documentation customizable by the end-users
- Full documentation for EN or FDA activity of validation
- Theoretical/practical trainings reserved to Customers' production and maintenance staff.

ASSOCIATED EQUIPMENT AND ACCESSORIES


TO COMPLETE THE PLANT

- Stainless steel trolleys for internal loading and external moving, trays and boxes
- Idle/motorized rollers internal conveyor for europallets
- Full customized systems for loads handling

TECHNICAL DATA


ETHYLENE OXIDE (EtO) GAS STERILIZERS DE LAMA DLOG and DLOG/V type

MODEL	CAPACITY lbs.	CHAMBER INTERNAL DIMENSIONS			MAXIMUM WORKING PRESSURE		LOADING CAPACITY IN EUROPALLETS (dimensions mm.800x1200)
		HEIGHT mm	WIDTH mm	DEPTH mm	abs. bar	kPa	
DLOG 101	640	800	800	1000	3,5	350	---
DLOG 201	800	1000	800	1000	3,5	350	---
DLOG 211	1000	1000	800	1250	3,5	350	---
DLOG 311	1250	1000	1000	1250	3,5	350	1
DLOG 411	2925	1300	900	2500	3,5	350	2
DLOG 501	3625	1450	1000	2500	3,5	350	2
DLOG 511	5510	1450	1000	3800	3,5	350	3
DLOG 521	7250	1450	1000	5000	3,5	350	4
DLOG 531	8990	1450	1000	6200	3,5	350	5
DLOG 541	10875	1450	1000	7500	3,5	350	6
DLOG 551	12470	1450	1000	8600	3,5	350	7
DLOG 561	14500	1450	1000	10000	3,5	350	8
DLOG 611	16864	1600	1700	6200	3,5	350	10
DLOG 621	20400	1600	1700	7500	3,5	350	12
DLOG 711	21675	1700	1700	7500	3,5	350	12
DLOG 631	23392	1600	1700	8600	3,5	350	14
DLOG 651	27200	1600	1700	10000	3,5	350	16
DLOG 811	24225	1900	1700	7500	3,5	350	12
DLOG 911	25994	2150	1950	6200	3,5	350	10
DLOG 931	37734	2150	1950	9000	3,5	350	14

Models indicated in above table are only some of standard sizing for  DE LAMA DLOG and DLOG/V.

Apart from the standard configurations indicated in the table, sterilizers can be proposed even with other dimensions, on request, according to Customer's production needs.

Working parameters are for indication only and can be modified in relation to Customer's working requirements.

 DE LAMA advises that technical data and features indicated in this folder are subject to without notice, owing to the continuous development of the technology and the research in the field.



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