

Ethylene oxide (EtO) sterilizers

DLOG & DLOG/V series



 **DE LAMA**

more than sixty years of experience in sterilization

DE LAMA's Quality Management System is certified:



UNI EN ISO 9001 - Cert. n° 0351
UNI EN ISO 13485 - Cert. n° 1275

Ethylene oxide (EtO) sterilizers

DE LAMA DLOG & DLOG/V series

 DE LAMA ethylene oxide autoclaves are designed to perform sterilization treatment of medical and pharmaceutical products sensitive to temperature/humidity.

Main applications:

- syringes, defluxers, catheters, cartridges for dialysis
- plastic articles
- bandages, sutures
- furnitures, archives and books
- powders which deteriorate by heating exposure

Sterilizers high flexibility in design, lay-out configuration, chamber sizing along with relevant load handling systems, conform with any User Requirement Specification.

Components are of the highest quality and reliability, world-wide available for easy replacement and assure the equipment longest lifetime.




Sterilizer  DE LAMA DLOG 65-62 2H type
capacity 16864 lts.

According to type of sterilant to be used, following configurations are available:

- autoclaves **working above atmospheric pressure** designed to operate with a **sterilant having a typical EtO concentration of 10% and 90% CO₂** (model **DLOG**)
- autoclaves **working below atmospheric pressure** designed to operate with a **sterilant having EtO concentration higher than 90%** (model **DLOG/V**)

Since EtO sterilizers operate with a sterilant which is potentially explosive, autoclaves incorporate design features, devices and additional means of protection in order to operate in potentially explosive atmospheres in conformity with the established parameters ensuring a very high level of protection against explosions.

EtO sterilizers are, therefore, designed in  execution for use in potentially explosive condition for security of people as well as security of the process itself.

APPLICABLE STANDARDS & GUIDELINES

Sterilizers are designed, manufactured and tested in compliance with **PED** European Directive for construction of pressure vessels, according to **UNI EN ISO 9001** and **UNI EN ISO 13485** Quality Management Systems procedures, following **cGMP** requirements and **cGAMP** Guidelines.

De Lama's EtO sterilization systems can meet and exceed even applicable standards for EtO sterilizers, including **EN 1422** and **EN 550**.

On request,  DE LAMA can supply even autoclaves according to pressure vessels codes other than **PED**.

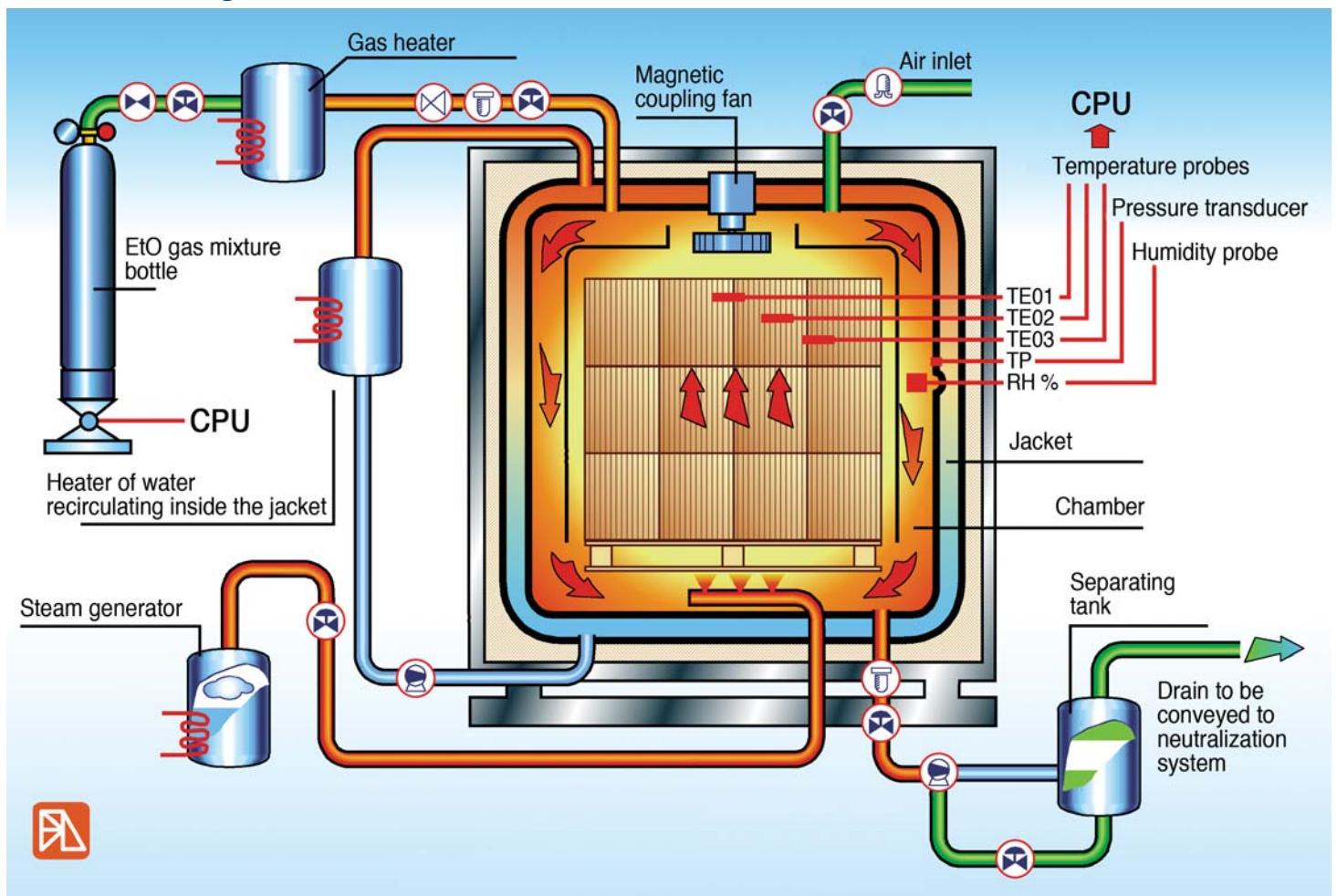
STANDARD OPERATING PARAMETERS

- Pressure: max. 3,5 bar abs. (model **DLOG**)
0,45 barg + full vacuum (model **DLOG/V**)
- Temperature: max. 80°C

DESIGN, CONSTRUCTION & FUNCTIONAL FEATURES

- design for installation on the floor or pit-mounted (for load direct introduction into the chamber)
- parallelepiped chamber in stainless steel
- jacket to optimize the temperature uniformity into the chamber through an original system for hot water circulation
- single or double door, hinged or automatically sliding, eventually heated through circulation of hot water coming from jacket. On request, hinged motorized door/s with automatic opening/closing system
- ventilator system, with revolution detector, to favour the best sterilant distribution inside the chamber and prevent sterilant stratification (**for autoclaves working above atmospheric pressure only**)
- chamber piping and fittings in stainless steel
- circuit to heat water circulating inside the jacket
- sterilant pre-conditioning group for sterilant controlled evaporation from liquid to gas status
- steam generator for load humidification/conditioning, prior to sterilant injection into the chamber, to allow sterilant best penetration into the load
- group for EtO and water separation on the exhaust line, inclusive of reduction and stabilization group for the gas conveyed to a combustor system
- air inlet absolute filter with 0,22 micron cartridge for chamber vent
- gas inlet filter with 50 micron cartridge for sterilant injection into the chamber
- entry connections for thermometry, vacuum test and sampling port to determine EtO concentration or RH value
- high grade thermal insulation
- built-in or separate electrical cabinet
- external panel/s in stainless steel
- pressure transmitter for pressure monitoring inside the chamber
- thermoresistances Pt 100 Ohm class A EN 60751/IEC 751 for temperature monitoring/regulation inside the chamber
- humidity/temperature transmitter for humidity monitoring inside the chamber
- wide range of alarms and safety devices to assure Operator protection and proper equipment operation
- thermal combustor system for exhausted gas elimination for environmental protection (available on request)
- gas detector set up at different locations to monitor and alarm any leak of EtO (available on request)

Functional diagram



PROGRAMS

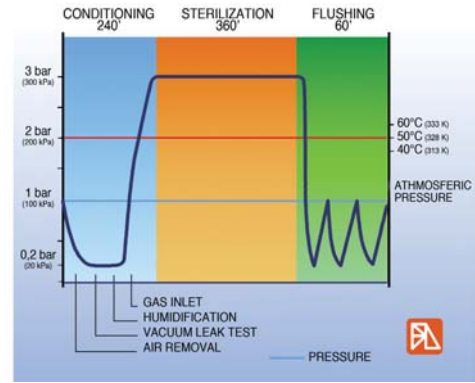
Customer can choose the more suitable operating parameters (time, temperature, humidity, etc.) to fit each program to requirements of type of load and relevant packaging.

Autoclave job parameters can be changed by the Operator according to the need. Different jobs can be stored and retrieved at any time for an easy and quick autoclave set up.

Reproducibility of cycles and process parameters enables Customers to perform easy and full validation.

Autoclaves come, as a standard, with control/utility programs (chamber vacuum leakage test and chamber pressure leakage test **for autoclaves working above atmospheric pressure only**) which can be used as stand-alone cycles or integrated in the sterilization cycle as required by the applicable European Standards.

A degassing program is always provided as a standard.



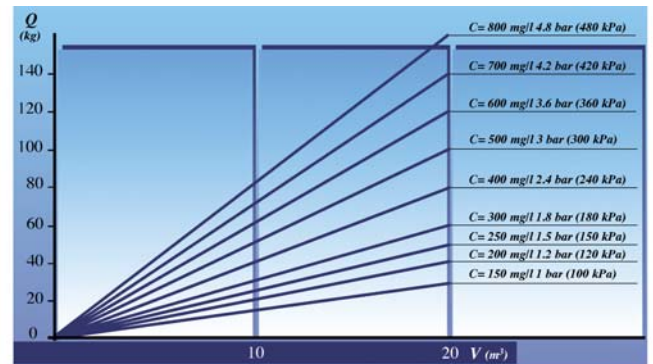
Typical sterilization cycle

PROCESS CONTROLLERS

DE LAMA offers a complete range of control systems, described in a separate leaflet, able to meet the most demanding Customer requirements and fit the widest variety of application. **DE LAMA** controllers are fully compliant with FDA CFR 21-PART 11 and cGAMP:

- **MASTER** based on industrial PC + PLC Siemens S7
- **OLIMPYA/EXP** based on industrial PC + PLC
- **OLIMPYA/WP-TS** based on embedded PC + PLC

Customized design and configurations are available on request.

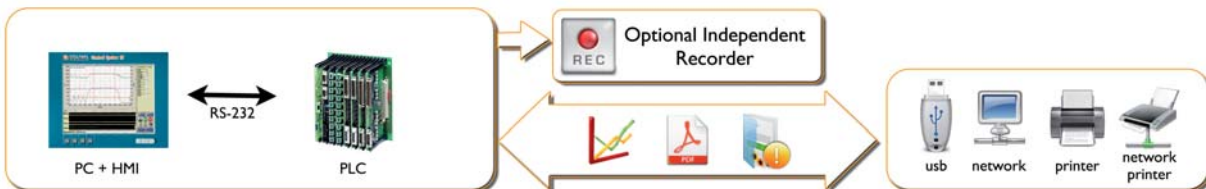


Graphic of changes in mixture consumption (10% EtO + 90% CO₂) to different concentration

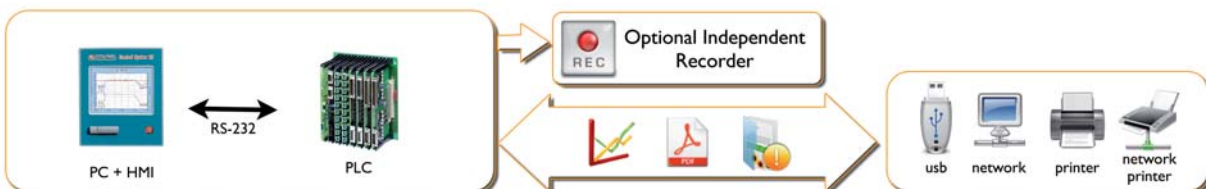
MASTER



OLIMPYA/EXP



OLIMPYA/WP-TS



QUALITY CONTROL & VALIDATION

Equipment and process controllers are designed and manufactured to be easily validated in compliance with FDA quality standards for pharmaceutical processes. Careful tests, specific controls and high technical skill in pre-validation activities assure that plants are fully compliant with the strictest standards.

TECHNICAL DOCUMENTATION & ACTIVITIES

Standard documentation:

- User and Control System User Manual
- P&ID general diagram
- Equipment data sheet and lay-out
- Equipment materials list
- Sub-vendor technical documentation
- Calibration manual
- Conformity certificate
- FAT protocol

 **DE LAMA** supplies, on request:

- SAT protocol
- cGAMP and IQ/OQ/PQ validation support documentation customizable by the end-Users
- Additional specific documentation
- Training to Customer personnel



Sterilizer  **DE LAMA DLOG 66-75 2H type**
capacity 21675 lts.

ACCESSORIES

- Wide range of load handling accessories, made of stainless steel, conforming to ergonomic criteria and high quality standards:
 - ✓ in-chamber shelf racks & trolleys
 - ✓ trays, baskets, cassettes to house load
 - ✓ transfer trolleys
- Semi-automatic/fully automatic loading/unloading systems for load handling

Further information in a separate leaflet.



Sterilizer  **DE LAMA DLOG 65-86 2H type**
capacity 23392 lts. with automatic loading system

TECHNICAL DATA


| MODEL | CAPACITY (gross) | CHAMBER INTERNAL DIMENSIONS (gross) | | | LOADING CAPACITY IN EUROPALLETS (*) |
|-------------|---------------------|---|--------------|--------------|---|
| | lbs. | HEIGHT mm. | WIDTH mm. | DEPTH mm. | No. |
| DLOG 20-10 | 640 | 800 | 800 | 1000 | --- |
| DLOG 30-10 | 800 | 1000 | 800 | 1000 | --- |
| DLOG 30-12 | 1000 | 1000 | 800 | 1250 | --- |
| DLOG 35-12 | 1250 | 1000 | 1000 | 1250 | 1 |
| DLOG 40-25 | 2925 | 1300 | 900 | 2500 | 2 |
| DLOG 45-25 | 3625 | 1450 | 1000 | 2500 | 2 |
| DLOG 45-38 | 5510 | 1450 | 1000 | 3800 | 3 |
| DLOG 45-50 | 7250 | 1450 | 1000 | 5000 | 4 |
| DLOG 45-62 | 8990 | 1450 | 1000 | 6200 | 5 |
| DLOG 45-75 | 10875 | 1450 | 1000 | 7500 | 6 |
| DLOG 45-86 | 12470 | 1450 | 1000 | 8600 | 7 |
| DLOG 45-100 | 14500 | 1450 | 1000 | 10000 | 8 |
| DLOG 65-62 | 16864 | 1600 | 1700 | 6200 | 10 |
| DLOG 65-75 | 20400 | 1600 | 1700 | 7500 | 12 |
| DLOG 66-75 | 21675 | 1700 | 1700 | 7500 | 12 |
| DLOG 65-86 | 23392 | 1600 | 1700 | 8600 | 14 |
| DLOG 65-100 | 27200 | 1600 | 1700 | 10000 | 16 |
| DLOG 68-75 | 24225 | 1900 | 1700 | 7500 | 12 |
| DLOG 74-62 | 25994 | 2150 | 1950 | 6200 | 10 |
| DLOG 74-90 | 37734 | 2150 | 1950 | 9000 | 14 |

* Calculation refers to europallets (size mm. 800 x 1200) loaded with transpallet

DLOG IN. 06-12



Sterilizer  DE LAMA DLOG/V 40-25 2S type
capacity 2925 lbs.

Table shows standard sizes. Other dimensions available on request.
The technical contents of present brochure are not binding and can be varied by  DE LAMA without any prior notice.

