

# STEAM STERILIZERS

## DLOV & DLDM series



# DE LAMA

more than fifty years of experience in sterilization

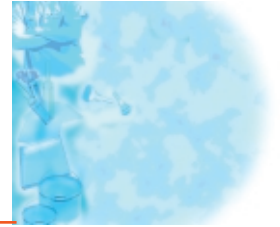
DE LAMA's Quality Management System is certified:




ISO 9001: 2000 - Cert. n° 0351  
ISO - UNI CEI EN 13485 - Cert. n° 1275

# Steam sterilizers

## DE LAMA DLOV series



 DE LAMA DLOV are the most versatile steam autoclaves designed to meet the widest requirements of the Pharmaceutical Industry. Sterilizers incorporate a high degree of operational flexibility that enable them to be used even for a wide range of industrial and laboratory applications (at biotechnology centers, research centers, universities and animal facilities).

### Typical applications:

- Empty and filled glassware (e.g. vials, ampoules, bottles)
- Stoppers and rubber materials
- Inox equipment, instruments, machine parts
- Filters and respective accessories
- Textiles
- Cages, beddings, feedstuffs and other products used at animal facilities



Autoclave  DE LAMA DLOV 30-10 2S type  
capacity 800 lts.

Thanks to high flexibility in design, lay-out configuration, chamber sizing and load handling systems, sterilizers DLOV can be offered in order to conform any specific requirement and meet User's production "critical load".

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

### APPLICABLE STANDARDS AND GUIDELINES:

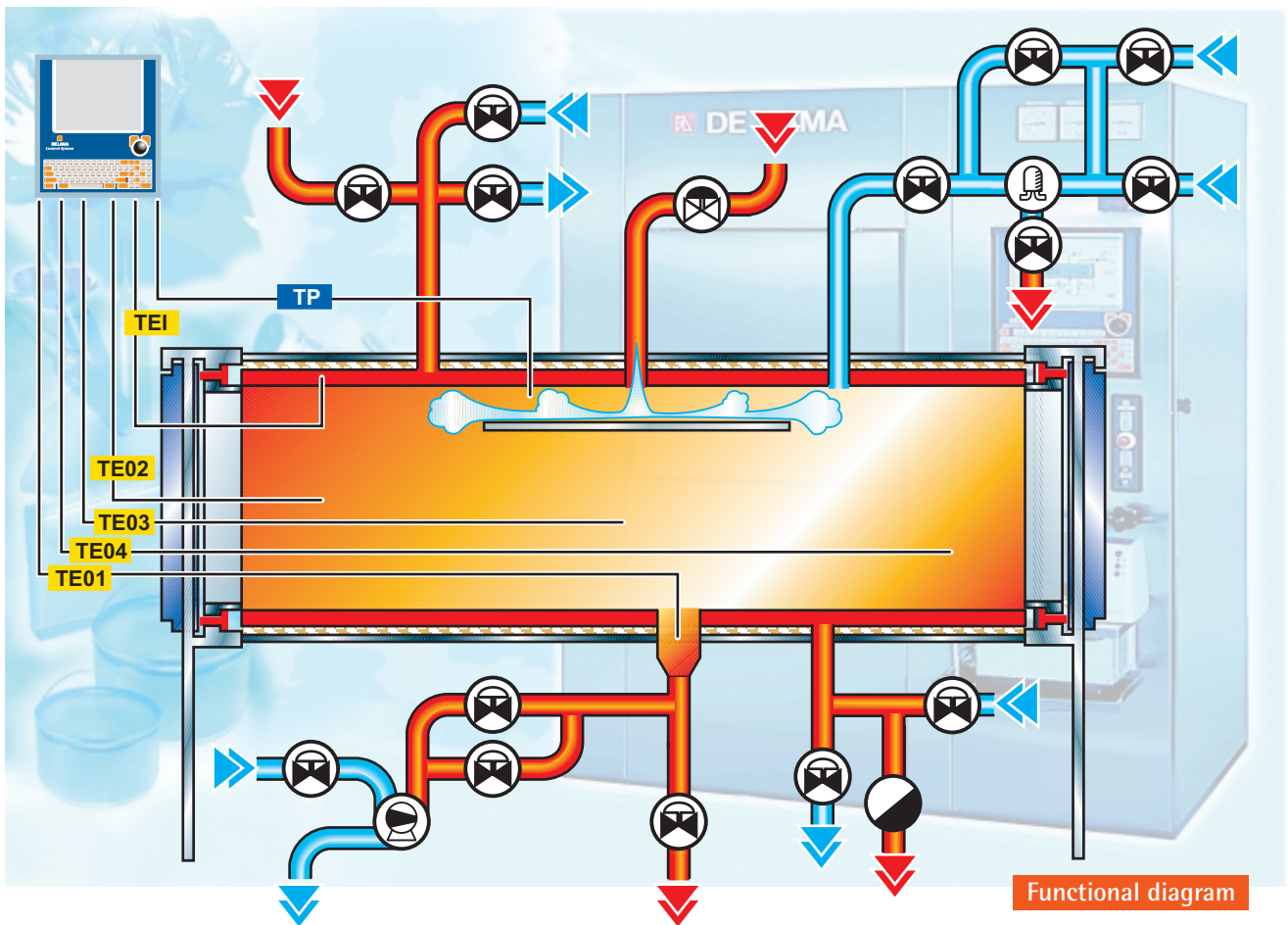
Sterilizers are designed, manufactured and tested in compliance with PED European Directive for construction of pressure vessels, according to ISO 9001:2000 Quality Management System procedures, following cGMP and cGAMP requirements, FDA Guidelines, European Standard EN 285 and HTM 2010.

On request,  DE LAMA can supply even autoclaves according to pressure vessels codes of extra-EEC Countries.

## STANDARD OPERATING PARAMETERS

- Pressure: max. 3,5 abs. bar (350 kPa)
- Temperature: max. 139°C (412K)

Note: Operating parameters can be modified according to Customer's requirements.



## DESIGN & CONSTRUCTION FEATURES

- parallelepiped chamber in highly satin finish AISI 316L stainless steel. Drainable execution. On request, cylindrical chamber
- jacket, in AISI 304 stainless steel, for heating, load drying and final cooling by recirculating water
- single or double door (pass-through execution for no-cross contamination), recessed semi-automatic hinged type or automatically sliding
- chamber pipings and fittings in AISI 316L stainless steel, tri-clamp connections. On request, sanitary execution
- vacuum pump group for vacuum phases, removal of air pockets and load drying
- device to cool drain
- absolute filter with 0,22 micron cartridge for air inlet, steam sterilizable, assembled to allow integrity test (e.g. W.I.T.)
- clamp connections for validation activities
- high grade thermal insulation
- built-in or separate electrical cabinet
- housing panels in satin finish AISI 304 stainless steel

Pressure transmitter for pressure control/regulation.  
Thermoresistances Pt 100 Ohm class A EN 60751/IEC 751 for temperature monitoring inside the chamber, the drain and the jacket.

Wide range of alarms and safety devices, conforming to European and International Rules, to assure operators' protection and equipment well-proven operation.

Sterilizers can be operated either through steam by factory utility line or through a dedicated steam generator (steam or electrically heated, built-in or externally located).

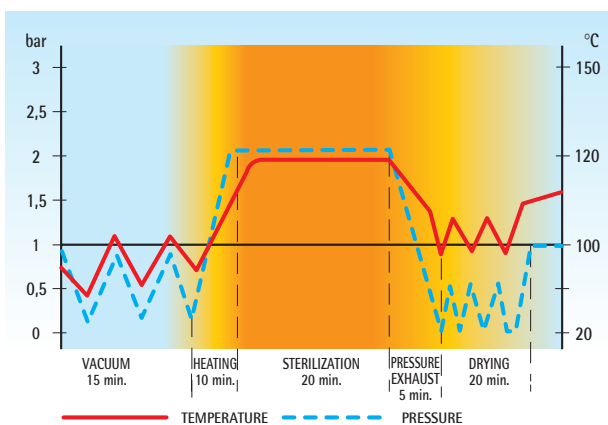


Autoclave DE LAMA DLOV 45-20 2H type  
capacity 2900 lts.

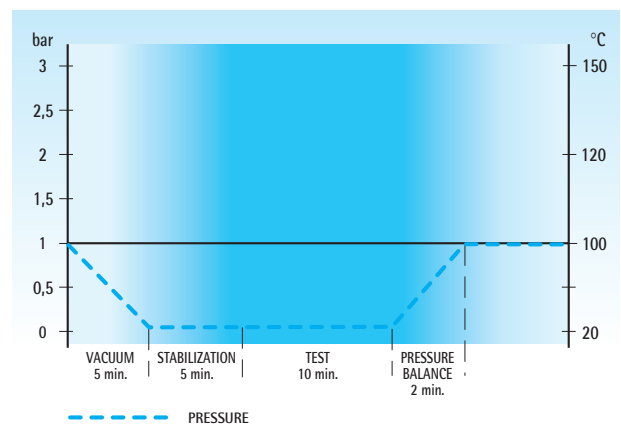
## PROGRAMS

The system memory stores a variety of working and control/utility programs out of which Customers can select the best ones to fit their own applications or kind of load. Some programs require suitable equipment options:

- sterilization of solids
- sterilization of porous materials
- sterilization of stoppers with final vacuum drying. Possibility of additional devices to optimize final drying process and assure very low percentages of residual humidity
- sterilization of membrane filters and accessories
- sterilization of ampoules with "seal test" performed either by rapid vacuum or by water flooding
- sterilization of liquid solutions in sealed/unsealed glass containers (ampoules, vials, bottles). Counterpressure inside the chamber and final cooling by demineralized water spray on load or water circulation inside the jacket
- tyndallization of products sensitive to high temperatures
- pasteurization for treatment of packed food products
- chamber vacuum/pressure leakage tests
- Bowie & Dick test, Helix test
- washdown treatments for removal of powder residuals, particulates and contaminants



Example of sterilization cycle for solids and porous materials



Vacuum leakage test conforming to EN 285

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

Possibility to program vacuum pulses, steam injections and trend of heating/cooling phases.

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

## Combined sterilizers DE LAMA DLOV-AV series

Sterilizers DLOV-AV series are designed to enable Customer to use the same equipment to run two different types of process cycles. The conventional steam sterilization is combined with the air/steam mixture sterilization.

Autoclaves DLOV-AV allow performance of all available programs for DLOV sterilizers plus the specific treatment of pressure/temperature sensitive products such as plastic containers, products in blister packs, pre-filled syringes, etc. by air/steam mixture.

This line of autoclaves features:

- maximum working pressure of 4,5 abs. bar
- ventilator group which provides for air/steam mixture forced recirculation and homogenization throughout the chamber, heat transfer during the heating phase, internal temperature uniform distribution during the cycle phases
- load cooling in counterpressure and drying

Sterilizers DLOV-AV type are usually in cylindrical chamber execution in order to house the ventilator group into the upper circular sector without affecting the available internal working area.



Autoclave  DE LAMA DLOV/C-AV 35-14 2S type  
useful capacity 1450 lts.


# Steam sterilizers

## DE LAMA DLOM series

Saturated steam sterilizers  DE LAMA DLOM are designed for applications at microbiology/virology laboratories and research institutes with programs suited to treatment of products addressed to such fields.

### Typical applications:

- containers
- culture media
- animal cages
- wastes which are not highly infected

Sterilizers DLOM have the general technical features of the sterilizers DLOV type and come with a cycles package suitable for the treatment of above-mentioned materials.  DE LAMA DLOM series normally range between 80 and 1500 lts.

Autoclave  DE LAMA DLOM 20-10 2S type  
capacity 640 lts.



# Combined sterilizers

## DE LAMA DLOM-HP series

The materials at high pathogenic risk have to be submitted to a specific treatment before being re-used, disposed or recycled in order to avoid any risk of pollution/contamination for the operators, the working area and the environment.

Sterilizers DLOM-HP series are designed to perform, in addition to sterilization programs of DLOM autoclaves, even the specific treatment of high pathogenic solids and liquids so that, after treatment, load is safe and ready to be re-used or disposed.

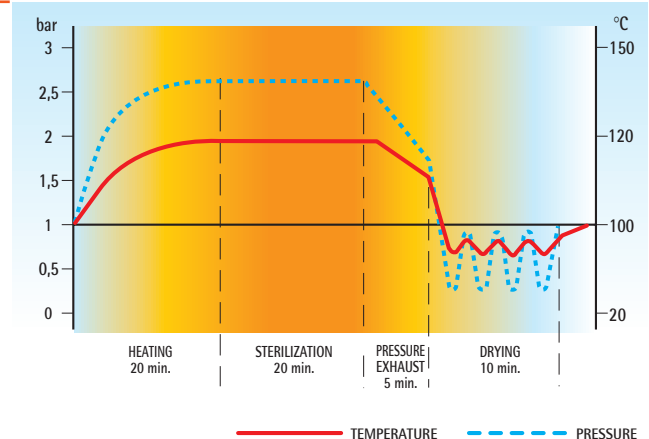
Such line of autoclaves combines the conventional sterilization by saturated steam with the air/steam mixture sterilization.

### Typical applications:

- materials coming from the pharmaceutical field (e.g. from laboratories for production of vaccines, serums, etc.)
- products coming from research and/or microbiology laboratories (e.g. diagnostic or biotechnological products or manufacturing wastes)
- products coming from the hospitals (e.g. materials outcoming from infectious diseases areas)
- highly resistant pathogenic organisms (e.g. from Creutzfeldt-Jakob disease – bovine spongiform encephalopathy well-known as “mad cow disease” – and from correlated syndromes)

### Main features:

- sterilization in overpressure (5 abs. bar) and overtemperature (148°C)
- no evacuation of fluids before being sterilized
- no venting of contaminated air till the end of the sterilization process
- homogenization of the air/steam mixture throughout the chamber by the application of a ventilator group which assures the internal temperature uniform distribution during the cycle phases
- cylindrical chamber to house the ventilator group into the upper circular sector without affecting the available internal working area
- application of pressure gauges with diaphragm seal and pressure transmitters with diaphragm separator

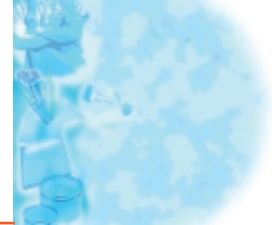


Example of sterilization cycle  
for solids at high pathogenic risk



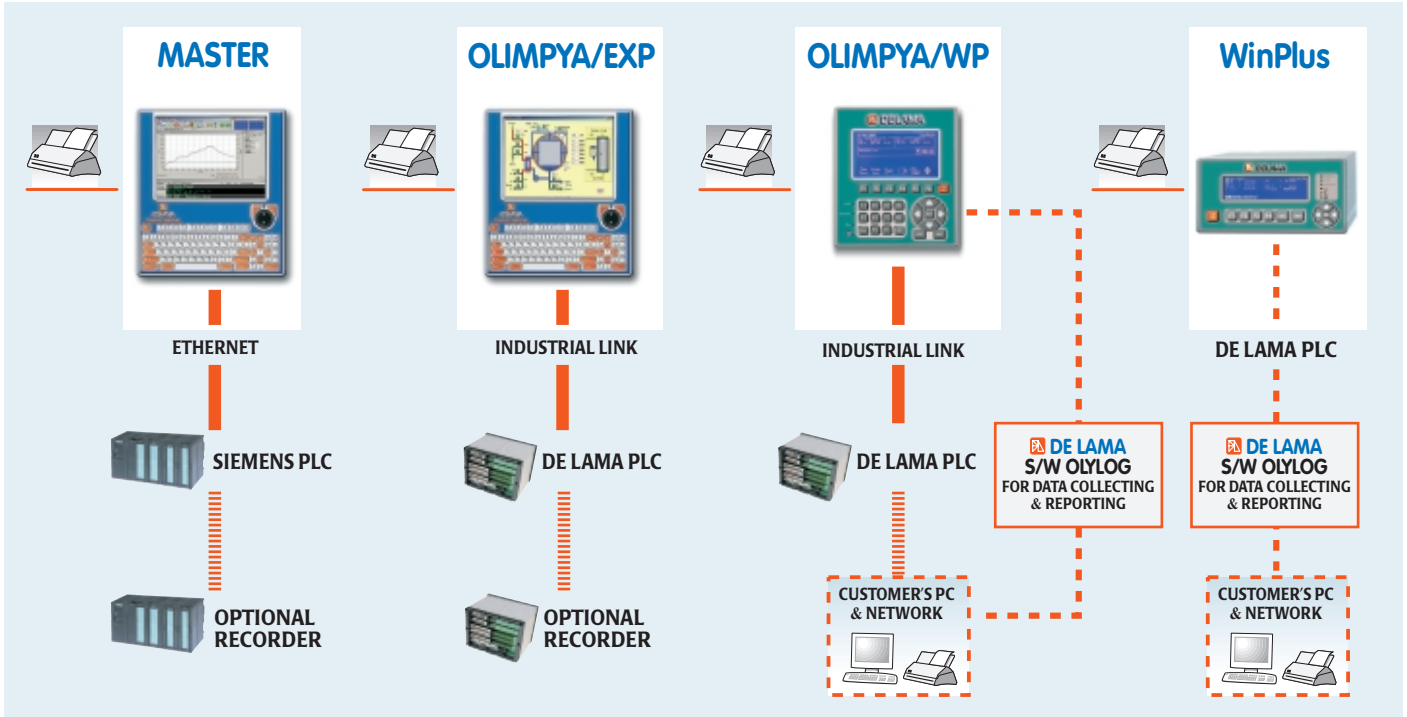
Autoclave  DE LAMA DLOM-HP 15-12 1S type  
useful capacity 545 lts.

# PROCESS CONTROLLERS



DE LAMA offers several alternative series of control systems, described in a separate leaflet, to meet Customer's requirements and fit any application. DE LAMA controllers are compliant with current applicable Standards/Directives, cGAMP and FDA Guidelines:

- MASTER** based on PC + PLC Siemens S7 controller
- OLIMPYA/EXP** based on PC + MultiProcessor integrated architecture
- OLIMPYA/WP** based on MultiProcessor integrated architecture
- WinPlus** based on MicroProcessor integrated architecture



Autoclave DE LAMA DLOV 45-30 2S type  
with automatic loading/unloading system



## QUALITY CONTROL & VALIDATION

Equipment and process controllers are designed and manufactured to be easily validable in compliance with FDA quality standards for pharmaceutical processes.

Careful tests, specific controls and high technical competence in pre-validation activities assure that plants are fully compliant with the strictest required standards.

## TECHNICAL DOCUMENTATION & ACTIVITIES

Sterilizers are always delivered with a full dossier of documentation:

- installation and operation manuals
- P&I and technological diagrams
- dimensional drawings and lay-out
- list of materials and components
- data sheets and certificates of critical components
- instruments calibration certificates
- conformity certificates

DE LAMA supplies, on request:

- FAT and SAT check-lists/reports
- Documentation to ensure quick and easy validation, customizable by the end-Users
- Manufacturer's data report
- Trainings to Customers' production and maintenance team



Autoclave DE LAMA DLOV 15-07 2S type  
capacity 305 lts.

## ACCESSORIES

- Wide range of load handling accessories, fully executed in stainless steel, conforming to ergonomic criteria and quality standards required for pharmaceutical and sanitary applications, detailed described in a separate leaflet:
  - shelf racks & trolleys for product loading inside the process chamber
  - trays, baskets, cassettes to house load
  - trolleys for load transfer outside the process chamber
- Integrated systems for load full handling



Autoclave DE LAMA DLOV 35-20 2S type + dry heat sterilizer DE LAMA DLST/L 60-27 2H type



**SEMI-AUTOMATIC  
HINGED DOOR**

MODEL	CAPACITY lbs.	CHAMBER INTERNAL DIMENSIONS			DOOR No.
		HEIGHT mm.	WIDTH mm.	DEPTH mm.	
DLOV 25-07 1H	439	950	660	700	1
DLOV 25-07 2H					2
DLOV 25-10 1H	627	950	660	1000	1
DLOV 25-10 2H					2
DLOV 25-13 1H	815	950	660	1300	1
DLOV 25-13 2H					2
DLOV 30-10 1H	800	1000	800	1000	1
DLOV 30-10 2H					2
DLOV 30-12 1H	1000	1000	800	1250	1
DLOV 30-12 2H					2
DLOV 35-10 1H	1000	1000	1000	1000	1
DLOV 35-10 2H					2
DLOV 35-12 1H	1250	1000	1000	1250	1
DLOV 35-12 2H					2
DLOV 35-15 1H	1500	1000	1000	1500	1
DLOV 35-15 2H					2
DLOV 35-20 1H	2000	1000	1000	2000	1
DLOV 35-20 2H					2
DLOV 40-13 1H	1521	1300	900	1300	1
DLOV 40-13 2H					2
DLOV 40-15 1H	1755	1300	900	1500	1
DLOV 40-15 2H					2
DLOV 40-18 1H	2106	1300	900	1800	1
DLOV 40-18 2H					2
DLOV 40-20 1H	2340	1300	900	2000	1
DLOV 40-20 2H					2
DLOV 40-24 1H	2808	1300	900	2400	1
DLOV 40-24 2H					2
DLOV 45-20 1H	2900	1450	1000	2000	1
DLOV 45-20 2H					2
DLOV 45-25 1H	3625	1450	1000	2500	1
DLOV 45-25 2H					2
DLOV 45-30 1H	4350	1450	1000	3000	1
DLOV 45-30 2H					2
DLOV 70-25 1H	6500	2000	1300	2500	1
DLOV 70-25 2H					2
DLOV 75-31 1H	6820	2200	1000	3100	1
DLOV 75-31 2H					2

Models indicated in the two tables are only some of standard sizing for DE LAMA DLOV.

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



Autoclave DE LAMA  
DLOV 30-12 2H type  
capacity 1000 lbs.

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



**AUTOMATIC  
SLIDING DOOR**

MODEL	CAPACITY lbs.	CHAMBER INTERNAL DIMENSIONS			DOOR No.
		HEIGHT mm.	WIDTH mm.	DEPTH mm.	
DLOV 05-07 1S	81	340	340	700	1
DLOV 05-07 2S					2
DLOV 05-10 1S	116	340	340	1000	1
DLOV 05-10 2S					2
DLOV 05-13 1S	150	340	340	1300	1
DLOV 05-13 2S					2
DLOV 10-07 1S	142	450	450	700	1
DLOV 10-07 2S					2
DLOV 10-10 1S	203	450	450	1000	1
DLOV 10-10 2S					2
DLOV 10-13 1S	263	450	450	1300	1
DLOV 10-13 2S					2
DLOV 15-07 1S	305	660	660	700	1
DLOV 15-07 2S					2
DLOV 15-10 1S	436	660	660	1000	1
DLOV 15-10 2S					2
DLOV 15-13 1S	566	660	660	1300	1
DLOV 15-13 2S					2
DLOV 20-10 1S	640	800	800	1000	1
DLOV 20-10 2S					2
DLOV 20-12 1S	800	800	800	1250	1
DLOV 20-12 2S					2
DLOV 25-07 1S	439	950	660	700	1
DLOV 25-07 2S					2
DLOV 25-10 1S	627	950	660	1000	1
DLOV 25-10 2S					2
DLOV 25-13 1S	815	950	660	1300	1
DLOV 25-13 2S					2
DLOV 30-10 1S	800	1000	800	1000	1
DLOV 30-10 2S					2
DLOV 30-12 1S	1000	1000	800	1250	1
DLOV 30-12 2S					2
DLOV 35-10 1S	1000	1000	1000	1000	1
DLOV 35-10 2S					2
DLOV 35-12 1S	1250	1000	1000	1250	1
DLOV 35-12 2S					2
DLOV 35-15 1S	1500	1000	1000	1500	1
DLOV 35-15 2S					2
DLOV 35-20 1S	2000	1000	1000	2000	1
DLOV 35-20 2S					2
DLOV 40-13 1S	1521	1300	900	1300	1
DLOV 40-13 2S					2
DLOV 40-15 1S	1755	1300	900	1500	1
DLOV 40-15 2S					2
DLOV 40-18 1S	2106	1300	900	1800	1
DLOV 40-18 2S					2
DLOV 40-20 1S	2340	1300	900	2000	1
DLOV 40-20 2S					2
DLOV 40-24 1S	2808	1300	900	2400	1
DLOV 40-24 2S					2
DLOV 45-20 1S	2900	1450	1000	2000	1
DLOV 45-20 2S					2
DLOV 45-25 1S	3625	1450	1000	2500	1
DLOV 45-25 2S					2
DLOV 45-30 1S	4350	1450	1000	3000	1
DLOV 45-30 2S					2
DLOV 70-25 1S	6500	2000	1300	2500	1
DLOV 70-25 2S					2
DLOV 75-31 1S	6820	2200	1000	3100	1
DLOV 75-31 2S					2