



Depyrogenation Oven

depyrogenation and dry heat sterilization



Lytzen philosophy

The philosophy behind the Lytzen Depyroge-nation ovens is never to compromise on our high level of quality in every detail.

Several hundreds of depyrogenation ovens are delivered to all well known multinational pharmaceutical companies all over the world. Reference lists are available on request.

Continuous development ensures that we are in front and we intend to stay there.

Dry heat sterilization and depyrogenation

Dry heat sterilization and depyrogenation provide complete destruction of microorganisms by means of dry heat for a controlled period of time.

The Lytzen depyrogenation oven is mainly used for depyrogenation and sterilization of empty glass and metal such as ampoules, injection bottles, vials and stainless steel equipment. Other applications are sterilization of closed bottles with low aqueous liquids and powder medicaments.

cGMP

The Lytzen depyrogenation oven is fully stainless steel inside and outside. Stainless steel AISI 304 or 316 L is standard.

The chamber is fully welded inside, this negates the possibility of leakage to the insulation and also makes the chamber very easy to clean. All welds are visible and can be inspected.

Only stainless steel is used for the reinforcement within the insulation. The inside chamber is welded to the outside cabinet, making the design unique and completing the Lytzen cGMP-design.

The water cooling element is a continuous welded unit. It is pressure tested and is expected to last the life time of the depyrogenation oven. There are no joints in the water piping inside the depyrogenation oven boundary.



Depyroge-nation oven with transfer trolley and mobile rack

Door

The semi-automatic door type is standard for Lytzen depyrogenation ovens. All doors are equipped with double door gasket for low surface temperature and maximum sealing of chamber.

The pass through units are equipped with an interlock door system preventing operation failure and contamination through the chamber.

Single door units are also available.

Isolator

The Lytzen depyrogenation ovens are suitable for connection with isolators. The front will be pre-prepared for mounting of isolator flange. Our system is thoroughly pressure tested on cooperation with different Isolators manufactures.

Customized chamber sizes

In principle all sizes are available. Lytzen can customize the chamber size according to customers room layout and load configuration.

For capacities and dimensions, please contact us or visit our homepage.

Guaranteed temperature distribution

Lytzen depyrogenation ovens operate in accordance with the forced convection principle with fast heat transmission to the load.

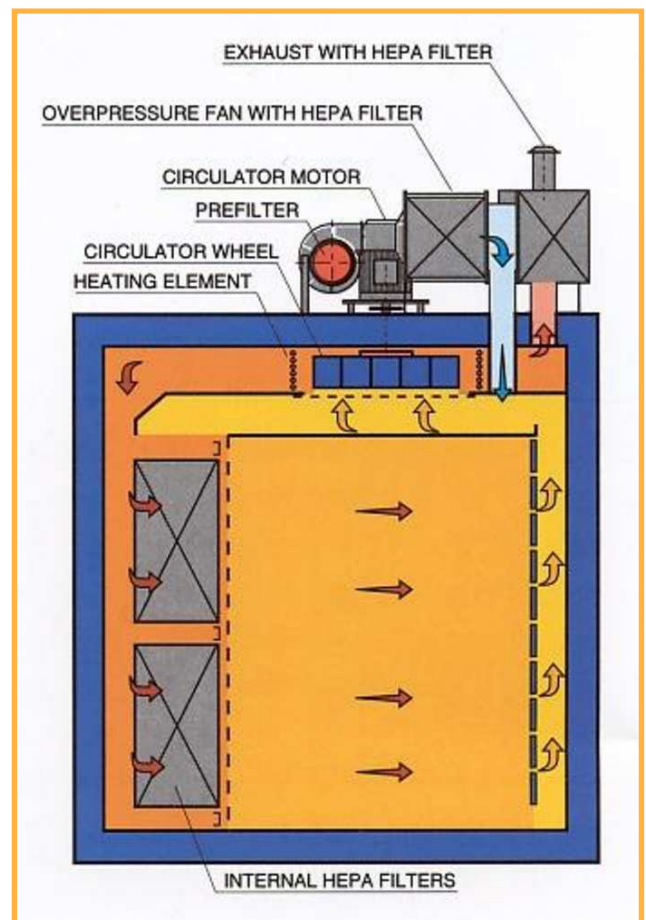
Together with the shape and position of the heating element and the computer designed air distribution plate, a unique temperature distribution inside the chamber is ensured. The temperature distribution is tested before delivery and guaranteed without any adjustments afterwards. Reducing the time used for validation considerably.

Fast cooling

Both forced air cooling and water cooling is available for Lytzen ovens, water cooling being the most efficient especially for larger models. As Lytzen has no problems with particles inside the chamber during heating and cooling, we can heat and cool at full speed without need of ramping.

Saving energy

The exhaust is equipped with a damper controlling the air exchange during the cycle. The damper will be open to secure a high air flow during drying and will be close during heating and sterilizing, saving energy.



ISO CLASS 5 (Class 100) up to 280 °C

Lytzen depyrogenation ovens are capable of conforming to ISO 14644-1, class 5 (former class 100 according to US Federal standard 209 E) up to a temperature of 280°C, during the entire cycle. We have achieved this, due to our unique chamber construction and filter suspension system, and our never ending work for further improvements.

Lytzen was the first company to be in compliance with the U.S. Federal standard for class 100 during an entire cycle (heating, sterilizing, and cooling).

The Lytzen ISO class 5 filters together with the special ISO class 5 design of the cabinet, secure a minimum of particles inside the chamber. As the particle counting on this page is showing - nearly no particles occur during sterilization and the number is well below the limit during temperature changes

The particle test is to be performed during a complete cycle, heating, sterilizing and cooling



Depyrogenation oven loading side with semi-automatic door

CLASS 100 (ISO CLASS 5) TEST RESULT

| Time | °C | 0.5µm | Time | °C | 0.5µm |
|-------|-----|-------|-------|-----|-------|
| 16:13 | 52 | 2 | 17:39 | 272 | 1 |
| 16:18 | 143 | 0 | 17:44 | 272 | 2 |
| 16:23 | 177 | 1 | 17:49 | 268 | 1 |
| 16:28 | 212 | 0 | 17:54 | 248 | 0 |
| 16:33 | 242 | 0 | 18:00 | 205 | 0 |
| 16:38 | 258 | 0 | 18:05 | 166 | 6 |
| 16:43 | 263 | 2 | 18:10 | 142 | 1 |
| 16:48 | 266 | 10 | 18:15 | 116 | 4 |
| 16:53 | 268 | 0 | 18:20 | 98 | 6 |
| 16:58 | 268 | 0 | 18:25 | 92 | 0 |
| 17:03 | 269 | 0 | 18:30 | 77 | 10 |
| 17:09 | 269 | 0 | 18:35 | 66 | 1 |
| 17:14 | 271 | 0 | 18:40 | 57 | 4 |
| 17:19 | 271 | 0 | 18:45 | 60 | 1 |
| 17:24 | 271 | 1 | 18:51 | 53 | 0 |
| 17:29 | 272 | 4 | 18:56 | 48 | 1 |
| 17:34 | 272 | 0 | | | |

Typical particle numbers for depyrogenation oven

Class 5 documentation before delivery

The critical phases for maintaining ISO class 5 are the heating and cooling phase due to the expansion and contracting of the frames around the filters. Particle counting during an entire cycle is therefore a necessity. Particle counting during sterilizing or at ambient temperature only, is worthless.

Each depyrogenation oven is factory tested under production-like conditions prior to shipping. A particle counter is used to test conformity with ISO Class 5 or 7 requirements. The chamber is tested for temperature distribution and pressure stability. Documentation of the testing is provided within the owner's manual at delivery.

The kit for particle counting is available from Lytzen.

ISO Class7 (Class 10,000) up to 350° C

The Lytzen ISO class 7 depyrogenation oven is without internal filters. Only filters on air inlet and exhaust are necessary. The chamber construction and the sealing of the chamber guarantee, that classification can be obtained throughout the cycle without use of internal HEPA-filters. The absence of internal filters reduces the overall price for the oven considerably.

Lytcon Control System

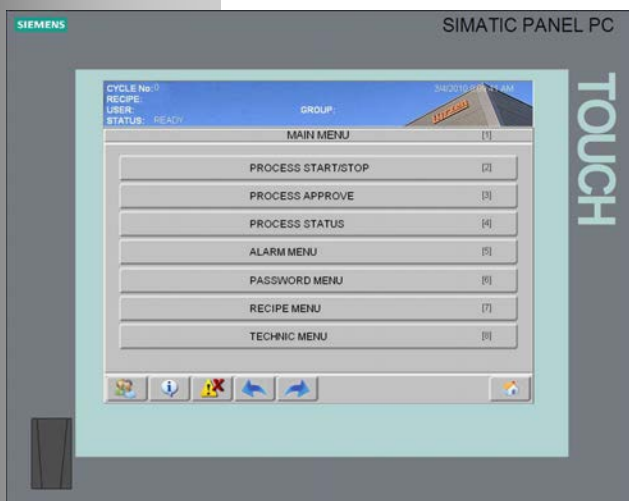
The Lytzen control system, Lytcon with touch screens, provides a fully automatic cycle. Lytcon is constructed to comply with the requirements for control of critical production units within the pharmaceutical industry. The system is available with Siemens or Allen-Bradley PLC, making it easy to get local support all over the world in case of hardware failure.

The system can be delivered for storing process data on paper or for storing process data on electronic media, ready to be integrated into a production complying with FDA 21 CFR part 11.

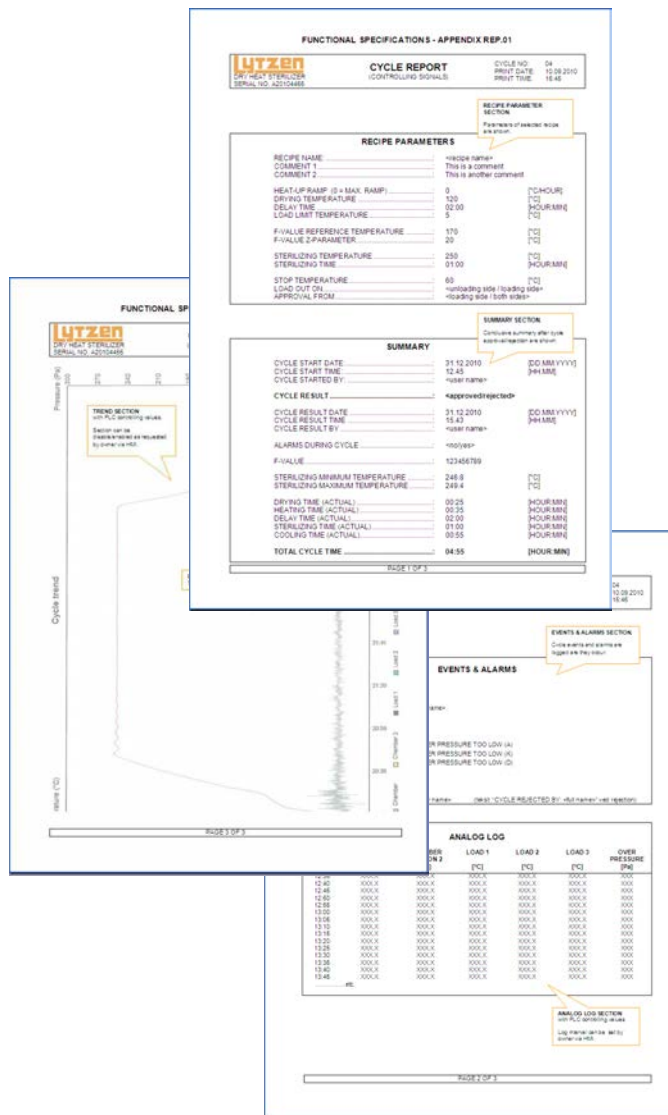
All Lytcon control systems have password structures complying with FDA 21 CFR part 11. Lytcon can be connected to local factory network.

Printer report

The printer report layout consists of two separate printer reports. Report number 1 (monitoring signals) contains raw data not used by the control system.



Lytcon with Siemens panel



Lytcon batch report (Siemens)

This report includes the recipe settings and the logs for temperature and over pressure. Report number 2 (controlling signals) contains the process data used by the soft PLC, controlling the unit.

This report includes recipe settings, logs for temperature and over pressure, summary report for the cycle and if present alarms during the cycle. Based on CSV-files, the system will automatically generate printer reports in PFD format to be stored on the PC-panel. Furthermore the system can automatically print out the reports on paper. The printer report will also be visible in the HMI-panel on loading side.

If the system is hooked up with Ethernet connection the PDF files can also be transferred to customer LAN or send by e-mail.

Documentation

As the demands from the regulatory authorities regarding documentation have become increasingly extended, the requirement for first class qualification & validation documentation is a necessity. Along with the comprehensive operation and maintenance manual, IQ/OQ qualification documents are standard when buying the Lytzen depyrogeneration oven.

Lytzen also offers QA-documentation.

GAMP

As an option Lytzen offers a complete package of qualification and validation documentation based on GAMP (Good Automated Manufacturing Practice).

An easy access to validation can save a lot of money and not to forget a lot of time. 1 week more for validation means 1 week less for production

A full documentation package from Lytzen including operation & maintenance manual, GAMP documentation and QA-documentation consists of approximately 2000 pages.

Qualification

Assistance for qualification of the depyrogeneration oven is available. The Lytzen technician will perform the qualification using either the standard qualification package or the extended qualification package based on GAMP.

On-line long distance support

Lytzen depyrogeneration ovens can be equipped with long distance support of the control system. The system allows a Lytzen engineer supporting and troubleshooting from our headquarter in Denmark. The client is always in full control of the access to the system and the connection is encrypted and secured according to international standards.

Accessories

Lytzen accessories are specially designed to fit the specific depyrogeneration oven and the special cGMP requirements within the pharmaceutical industry. The full package of accessories for the Lytzen depyrogeneration oven comprises transfer trolley, mobile rack wire trays and cassettes.

The transfer trolley is for transporting the mobile rack outside the depyrogeneration oven. The transfer trolley is locked to the depyrogeneration oven when the mobile rack is pushed into the chamber making the operation very easy and safe.

For storage, the trolley is provided with a unique floor saving feature.

The mobile rack is available with fixed or adjustable tray supports. The height between the tray supports can be adjusted to customer load configuration.

The mobile rack is equipped with special Lytzen designed wheels which run very easily. The lubrication free wheel stands a temperature up to 300°.

Cassettes are customized and are also available in perforated design. The cassettes are available with or without lid.

Mobile rack, wire trays and cassettes are always in stainless steel AISI 316.



Transfer trolley and mobile rack

Service/Spare parts

Lytzen offers service world wide. Through our world covering net of representatives and Lytzen's own service technicians, we can offer service anywhere in the world.

As Lytzen uses only high quality world-wide known brands whenever possible, it is very easy

for the customer to have access to most spare parts local. It also allows for assistance from locally representatives of Lytzen sub-suppliers in case of hardware problems with equipment on the depyrogenation oven.

Samples of chamber dimensions

| ISO CLASS 5 DRY HEAT STERILIZERS | | | | | | | | |
|----------------------------------|-----------------------------|------|------|----------------------|------|------|--------------------------------------|---------------------------|
| Type | Inside free dimensions [mm] | | | Outside Cabinet [mm] | | | Inside free volume [m ³] | Est. Capacity 10 ml vials |
| | w | d | h | W | D | H | | |
| LDF-590 | 700 | 800 | 1050 | 2205 | 1300 | 2405 | 0.59 | 8,800 |
| LDF-760 | 900 | 800 | 1050 | 2405 | 1300 | 2405 | 0.76 | 11,300 |
| LDF-920 | 800 | 800 | 1440 | 2305 | 1300 | 2795 | 0.92 | 13,800 |
| LDF-1540 | 1000 | 1070 | 1440 | 2505 | 1570 | 2795 | 1.54 | 23,000 |
| LDF-2020 | 1000 | 1400 | 1440 | 2505 | 1900 | 2795 | 2.02 | 30,000 |
| LDF-2390 | 1000 | 1450 | 1650 | 2505 | 1950 | 3005 | 2.39 | 36,000 |
| LDF-2680 | 900 | 2070 | 1440 | 2405 | 2570 | 2795 | 2.68 | 40,000 |
| LDF-3190 | 900 | 2150 | 1650 | 2405 | 2650 | 3005 | 3.19 | 48,000 |
| LDF-3480 | 900 | 2150 | 1800 | 2405 | 2650 | 3155 | 3.48 | 52,000 |
| LDF-4010 | 900 | 2700 | 1650 | 2405 | 3200 | 3005 | 4.86 | 73,000 |
| LDF-4860 | 2x1000 | 1400 | 1440 | 4525 | 1900 | 2795 | 4.03 | 60,000 |

| ISO CLASS 7 DRY HEAT STERILIZERS | | | | | | | | |
|----------------------------------|-----------------------------|------|------|----------------------|------|------|--------------------------------------|---------------------------|
| Type | Inside free dimensions [mm] | | | Outside Cabinet [mm] | | | Inside free volume [m ³] | Est. Capacity 10 ml vials |
| | w | d | h | W | D | H | | |
| LD-590 | 700 | 800 | 1050 | 1865 | 1300 | 2405 | 0.59 | 8,800 |
| LD-760 | 900 | 800 | 1050 | 2065 | 1300 | 2405 | 0.76 | 11,300 |
| LD-920 | 800 | 800 | 1440 | 1965 | 1300 | 2795 | 0.92 | 13,800 |
| LD-1540 | 1000 | 1070 | 1440 | 2165 | 1570 | 2795 | 1.54 | 23,000 |
| LD-2020 | 1000 | 1400 | 1440 | 2165 | 1900 | 2795 | 2.02 | 30,000 |
| LD-2390 | 1000 | 1450 | 1650 | 2165 | 1950 | 3005 | 2.39 | 36,000 |
| LD-2680 | 900 | 2070 | 1440 | 2065 | 2570 | 2795 | 2.68 | 40,000 |
| LD-3190 | 900 | 2150 | 1650 | 2065 | 2650 | 3005 | 3.19 | 48,000 |
| LD-3480 | 900 | 2150 | 1800 | 2065 | 2650 | 3155 | 3.48 | 52,000 |



Lytzen is a high-technology organization, operating in markets around the world. We are the market leader for the development, production, and installation of depyrogenation ovens and dry heat sterilizers for the pharmaceutical industry.

Lytzen depyrogenation ovens are known for their high quality and are capable of meeting the most stringent demands for cleanliness and accuracy required by the pharmaceutical industry.

Lytzen depyrogenation ovens are a perfect match for discerning customers who understand that a little extra cost for superior quality and reliability is most profitable in the long run.

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