

Depyrogenation oven

depyrogenation and dry heat sterilization



Dry heat sterilization and depyrogenation

Dry heat sterilization and depyrogenation provide complete destruction of micro-organisms 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.

Design of Lytzen depyrogenation ovens

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. Due to our unique design, the chamber interior is welded to the outside cabinet, eliminating hidden hollows caused by the cover panels where particles and bacteria could otherwise hide. Only stainless steel is used for the reinforcement within the insulation.

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

Doors

Manual and semi-automatic door types are available for Lytzen depyrogenation ovens. Both door types are with double door gasket for low surface temperature and maximum sealing of chamber. The semi-automatic door type is suitable for the oven to be connected with isolators.

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.



Depyrogenation oven with transfer trolley and mobile rack

Customized sizes

In principle all sizes above 0.5 m³ are available. For ISO Class 5 depyrogenation ovens, a few combinations between height and depth are not available due to the fixed sizes of the internal filters.

For capacities and dimensions, please visit our website.

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. The temperature distribution is validated once and for all.

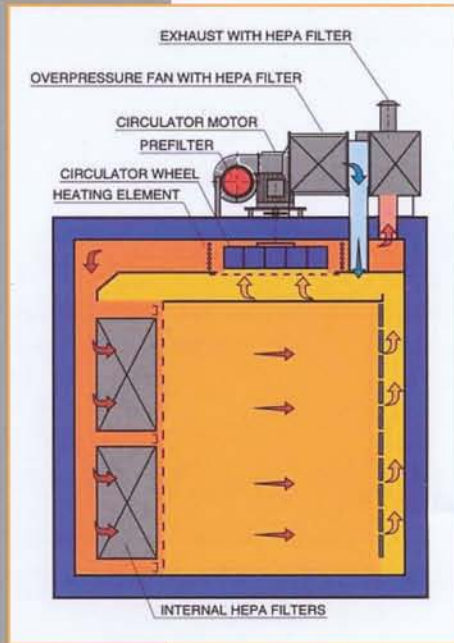
Fast cooling

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 closed during heating and sterilizing, saving energy.

Principle of air circulation



ISO Class 5			ISO Class 5		
Time	°C	0.5 µm	Time	°C	0.5 µm
D 16:12	52	2	17:39	272	1
H 16:18	143	0	17:44	272	2
16:23	177	1	C 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	2	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
S 17:14	271	0	18:40	57	4
17:19	271	0	18:45	60	1
17:24	271	1	E 18:51	53	0
17:29	272	4	18:56	48	1
17:34	272	0			

Particle nos. for depyrogenation oven type CF

ISO Class 5 (Class 100) up to 280 °C.

Lytzen depyrogenation ovens are now capable of conforming to ISO 14644-1 (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.



Depyrogenation oven sterile side / with manual box door

Lytzen first to maintain class 100 during an entire cycle

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).

ISO 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.

Lytzen is performing particle tests for all depyrogenation ovens and the test results are available to the customer before delivery of the oven.

The kit for particle counting is available from Lytzen.

ISO Class 7 (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 2 Control System

The Lytzen control system, Lytcon 2 with touch screens, provides a fully automatic cycle. Lytcon 2 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 2 control systems have password structures complying with FDA 21 CFR part 11 including the systems for storing process data on paper.

Lytcon 2 can be connected to local factory network.

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 depyrogenation 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.

Accessories

Lytzen Accessories are specially designed to fit the specific depyrogenation oven and the special cGMP requirements within the pharmaceutical industry.

The full package of accessories for the Lytzen oven comprises transfer trolley, mobile rack, wire trays and cassettes.

The transfer trolley is for transporting the mobile rack outside the oven. The transfer trolley is locked to the oven chamber 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 the special Lytzen wheel that runs very easily. The wheel stands a temperature up to 350 °C without any need for lubrications.



Perforated tray with lid

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.

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.



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 reliability, 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.

We look forward to serving you.

Lytzen A/S
Dynamovej 9
DK-2730 Herlev

Tel.: +45 4491 1200
E-mail: sales@lytzen.com
www.lytzen.com

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