

# DRY HEAT STERILIZATION

DEPYROGENATION



**LYTZEN**

## Dry heat sterilizing and depyrogenation

Dry heat sterilization and depyrogenation are pure heat treatment, suitable for glassware and metal as well as liquids with low moisture content.

This method is also very suitable for heat treatment of powder medicaments.

Dry heat sterilization and depyrogenation is a complete destruction of micro-organisms by means of dry heat for a controlled period of time. Dry heat sterilization and depyrogenation is environmentally safe. It causes no waste problems or inconvenience for surroundings and personnel. At the same time this process is designed to meet the most stringent requirements.



Display

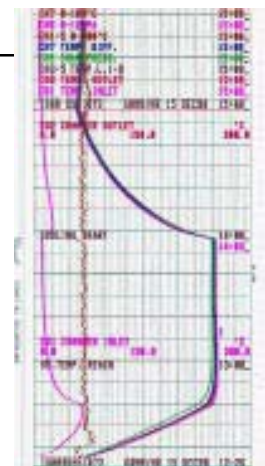


Sterilizer type H1 (Lytcon-1-PLC controlled) seen from non-sterile side. Here the sterilizer is shown during loading with glass bottles. Mobile racks are transported on transfer trolleys.

## Applications for Lytzen dry heat sterilizers

- preparation packings of glass and metal, such as ampoules, injection bottles, infusion bottles etc.
- production equipment such as stainless steel vessels etc.
- laboratory glassware - instruments.
- bottles containing low aqueous liquids such as glycerin.
- powder medicaments like talcum powder and sulphonamides.

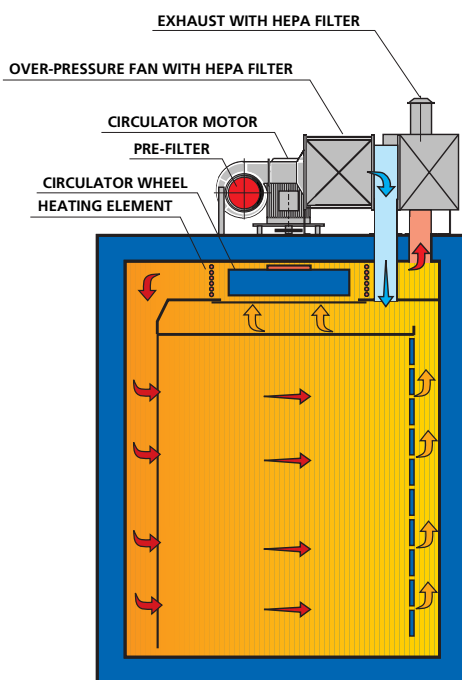
Typical curve for time/temperature course.





# Advantages when using Lytzen dry heat sterilizers

- The construction of the chamber is of course in full compliance with cGMP and very easy to clean. The chamber is seal welded and the front plate is seal welded to the chamber. All external sheets are welded, accordingly no screws and rivets are used in the construction of the cabinet at all. There are no hollow spaces behind the front plate.
- Lytzen sterilizers can be equipped with special draw hinges preventing the door gaskets from being twisted, due to repeated closing and opening the door. This will prolong the life time of the gaskets considerably.
- The dry heat sterilizer can be equipped with forced air cooling or watercooling, insuring a short cooling phase. The water cooling arrangement can be manual or automatical leak tested. Automatic leak test is executed from the PLC user interface.
- The door locking arrangement has built-in optimum safety. All maintenance can be done from maintenance area.
- The pressure inside the Lytzen sterilizer is kept constant during the entire cycle by means of HEPA filtered replacement air, controlled by dampers on air inlet and exhaust. The advanced interaction between the two dampers prevents large volumes of air entering or leaving the sterile room through the exhaust and air inlet openings, which can be destabilizing to the pressure there. As a bonus the system provides a low air-exchange, saving energy.
- The sterilizer is extremely reliable in operation and requires a minimum of maintenance.
- Fully automatic cycle controlled by PLC.



Principle of air circulation



Dry heat sterilizer with Lytcon 2 Allen-Bradley PLC, sterile side.

- Extended documentation package as well as complete sets of test reports for the specific dry heat sterilizer. Included in the test reports to be required before delivery is a particle test for a complete cycle according to the ordered classification (class 100 / class 10,000).

## Generally about our sterilizers

- Lytzen sterilizers are available in the following classifications: Class 100, Class 10,000 and non classified
- Temperature range from 50 - 400°C
- The dimensions of each sterilizer can be adapted to customer requirements
- There are two methods of loading: with fixed tray supports or by mobile racks. The mobile racks can be entered either directly from the floor into the chamber or on transfer trolleys.

## Description of dry heat sterilizer

Lytzen dry heat sterilizers operate in accordance with the forced convection principle with fast air circulation securing a fast heat transmission to the load. Together with the shape and position of the electrical heating element, it ensures a unique temperature distribution in the sterilization chamber. The dry heat sterilizers are constructed in a stainless steel design. Insulation between the sheets are made by mineral wool bats.

The sterilizers are provided with double doors for pass through operation between the non-sterile and sterile areas.

# Lytzen Control system

The Lytzen Control systems are available with both Siemens and Allen-Bradley PLC. The system construction enables an easy and logical operation with graphic user interface, menu driven display, and passwords at several levels. The systems provide the possibility of pre-programmed sterilizing programmes. Printer and PC can be connected directly to the control systems.

## User interfaces LYTCON 2, Siemens PLC:



Non-steriled side, User-panel



Sterile side, User-panel

## User interfaces LYTCON 2

### Allen-Bradley PLC



Non-sterile side, User-panel



Sterile side, User-panel

## Cycle Description:

The full automatic sterilizing cycle starts with the drying-phase removing humidity from the chamber through the exhaust damper until the pre-programmed set-point temperature is reached. At this time the damper will close and the sterilizer will start the heating-phase until the set-point temperature for sterilizing is reached. This will trigger the sterilizing timer and start the pre-programmed sterilizing-phase.

The cycle is completed with the cooling-phase. During the cooling-phase the exhaust damper will be open, minimizing the cooling time.

## Documentation

As the demands from the regulatory authorities regarding documentation have become increasingly extended, the requirement for first class validation documentation is now a necessity.

Lytzen provides IQ and OQ validation documents as standard. For our more advanced PLC control system Lytcon 2, we can provide full validation documentation in accordance with the GAMP regulations.

It is possible to acquire assistance from Lytzen for completion of IQ, OQ and PQ-documents.



Dry heat sterilizer with LYTCON 2, Allen-Bradley PLC. Non-sterile side.

## Accessories

A comprehensive range available

- mobile racks.
- transfer trolleys for external transportation of mobile racks.
- plate trays, wire trays, wire baskets etc.

## Special applications

- Lytzen class 100 dry heat sterilizers are equipped with Lytzen patented HEPA filter suspension system and Lytzen patented air shaft seal precluding introduction of particles into the chamber.
- Ovens for Ex-proof applications



Mobile rack placed on transfer trolley

### Types of Dry Heat Sterilizers

STERILIZER TYPE	INSIDE FREE DIMENSIONS			OUTSIDE DIMENSIONS		
	W mm	D mm	H mm	W mm	D mm	H mm
C	685	810	1500	1850	1110	2855
E	2x685	810	1500	2965	1110	2855
H1	900	1200	1500	2065	1500	2855
H2	900	2400	1500	2065	2700	2855
J1	1500	1200	1500	2665	1500	2855
J1d	2x685	1200	1500	2465	1500	2855
J2	1500	2400	1500	2665	2700	2855

The above listed types of sterilizers are our standard types. Standard heights for inside chamber from 1000 - 2000mm. In principle all chamber sizes are available. Outside width include control box (575mm). Control box can be removed if required.

### Indication of capacity

STERILIZER TYPE	AMPOULES		INJECTION BOTTLES		INFUSION BOTTLES	
	1 ml	5 ml	10 ml	100 ml	500 ml	1000 ml
C	40,000	19,000	8,600	1,500	400	200
E	80,000	38,000	17,200	3,000	900	400
H1	80,000	38,000	17,500	3,100	900	400
H2	160,000	76,000	35,000	6,200	1,800	800
J1/J1d	120,000	56,000	25,000	4,400	1,400	600
J2	240,000	112,000	50,000	8,800	2,800	1,200

Capacity indications for dry heat sterilizers with inside free height of 1500 mm.



# LYTZEN

## - A WORLDWIDE SPECIALIST



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**Lytzen is a high-technology organization, operating in all world markets. We are the market leader for development, production, and installation of ovens and sterilization equipment for the pharmaceutical industry.**

**Dry heat sterilizers from Lytzen are used by the pharmaceutical industry worldwide. They are known for their high quality and are capable of meeting the stringent demands for cleanliness and accuracy required by the pharmaceutical industry.**

**Lytzen dry heat sterilizers are a perfect match for discerning customers who understand that a little extra cost for superior quality and reliability is the best insurance against possible production loss due to equipment down time.**