LYTZEN DRY HEAT STERILIZER
MODEL C/1300

Temperature range up to 280°C

GENERALLY:
The Lytzen Dry Heat Sterilizer is designed for depyrogenation applications in clean room areas.

The sterilizer is a single-door unit designed for non pass-through operations. The sterilizer conforms with the requirements of current Good Manufacturing Practices (FDA) and Federal Standard 209 E for contamination control.

<table>
<thead>
<tr>
<th>DIMENSIONS</th>
<th>WIDTH</th>
<th>DEPTH</th>
<th>HEIGHT</th>
<th>VOLUME</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAMBER</td>
<td>700 mm</td>
<td>810 mm</td>
<td>1300 mm</td>
<td>0.73 m³</td>
</tr>
<tr>
<td>EXTERIOR (OVERALL)</td>
<td>1865 mm</td>
<td>1110 mm</td>
<td>2655 mm</td>
<td></td>
</tr>
<tr>
<td>SEAWORTHY PACKING</td>
<td>2115 mm</td>
<td>1560 mm</td>
<td>2975 mm</td>
<td>9.82 m³</td>
</tr>
</tbody>
</table>

Total weight: 800 kg excluded of packing.

1. EXTERIOR PANELS:

1.1 Made of stainless steel AISI 304. Visible sheets with 180 grit polish.

1.2 The front panels are welded and fitted without need for rivets, screws, or other fastener, to avoid unnecessary dust catchers.

2. CHAMBER:

2.1 The chamber and all interior components including fan, fan shaft and heater conjunction box are constructed of stainless steel AISI 304.

The chamber is with a 2B mill finish.

2.2 All sheet joints and ports contacting the insulation are seal welded, to avoid particles in the chamber. No rivets, screws, or other fasteners are used in the construction of the chamber.

2.3 Internal air distribution plates and cart rails are removable for easy cleaning.
3. INSULATION:

3.1 The chamber walls and doors are insulated with mineral wool.

3.2 Thickness of insulation: 150 mm

4. FRAME:

4.1 Legs with adjustable feet in stainless steel AISI 304 are provided for levelling of the sterilizer. The height between floor and rails for mobile rack inside chamber is 215 mm.

6. DOORS:

6.1 The swing type doors are manually operated
Left hand hinged.

6.2 The drawing handles are in heavy duty execution and in stainless steel AISI 304.

6.3 The door hinges are executed in stainless steel AISI 304.

6.4 The door frame is completely welded with no rivets, screws, or other fasteners to eliminate dust collection sites and to provide easy cleaning.

7. DOOR GASKET:

7.1 The door sealing is accomplished with a single gasket arrangement.
The gasket is constructed of heat resistant silicone.

8. CHAMBER PORTS FOR VALIDATION/TEST:

8.1 Port with tri-clover clamp (ISOØ 1½") for thermocouples.

9. RECIRCULATION AIR:

A centrally located circulator fan, made of stainless steel, AISI 304 or AISI 316 to match interior surface, secures the forced air circulation in the dry heat sterilizer. Combined with the construction of the chamber, a superior temperature distribution is provided.

9.1 The fan utilizes direct drive motor. This system has been developed for temperatures up to more than 400°C. The system needs no maintenance or service and it prolongs the lifetime of the entire fan system.

9.3 Horizontal air circulation in the chamber
10 AUTOMATIC DOOR INTERLOCK:

10.1 The electro-mechanical door interlock device is located on the top of the sterilizer sealed off from the clean room, and is serviced from the maintenance area.

The electro-mechanical interlocks prevent improper or accidental door operation even during power loss.

The door locks automatically upon initiation of a cycle.

Cycle approval must be granted before the door can be opened.

11. AIR INLET/OVERPRESSURE CONTROL:

11.2A Electronic over-pressure control conducted by an electronic controller integrated into the PLC and a transmitter, providing a precise control of the over-pressure.

A pressure controller automatically controls the amount of the replacement air, securing a constant over-pressure independent of the position of the exhaust damper, the condition of the sterile filter, and any leaks. A HEPA filter is built in, filtering 99.997% of all particles above 0.3 micron size contend in the inlet air, providing clean substitution air for the chamber.

The filter can be DOP tested and checked for pin holes and/or average tested by the customer, at any time.

The over-pressure is adjusted between 20 - 70 Pascal indicated on the pressure differential gauge 0-100 Pascal.

11.4 The inlet air is provided with a pre-filter with an average arrestance of 60-65% based on ASHRAE 52-76 test method to prolong the lifetime of the HEPA filter.

12. EXHAUST:

12.1.1A Servo-controlled tip-up damper in the exhaust, will automatically open to facilitate drying during heating, and open after sterilization to facilitate cooling, and will stay closed during the remaining of the cycle. The damper closes automatically after cooling.

13. ELECTRIC HEATING ELEMENT:

13.1 The electric circular heating elements are located around the circulator fan. The ends of the heating elements are fitted into a fully welded stainless steel junction box for extended lifetime.

Material: AISI 321 for heating element

Junction box is supplied in stainless steel AISI 304 or AISI 316 to match interior surface.

14. COOLING:

14.1 Cooling is effected by means of HEPA filtered substitution air.

15. SAFETY THERMOSTAT:

15.1 Safety thermostat discontinuing the process in case of failure of temperature control.

The safety thermostat is also connected to alarm.

16. EQUIPMENT FOR CONTROL BOARD:

Visible Genetics - Lytzen Ovens Technical Description
16.1A  **LYTCON 2 CONTROL SYSTEM (Allen Bradley)**

Lytcon 2 is the med-sized control system in the Lytcon series. It is designed for easy operation, has an extended line of storing and controlling facilities with possibilities for connection to PC and printer. It allows for an outstanding traceability of the entire sterilizing process. Furthermore the system can be an integrated part of a centrally located control system.

**Control Board:**

- PLC control system LYTCON 2 (PLC: Allen Bradley SLC 5/04 )
- user interface panel on non-sterile side: PanelView 900
- user interface panel on sterile side: PanelView 550
- passwords in 3 levels
- alarm buzzer
- ammeters (option)
- main switch
- circuit breakers
- 3 load sensors
- the sterilizer is provided with a potential free output relay for NO (Normaily Open) for connection for external alarm circuit/alarm central.
- relays for heat regulation: Solid state relays 90 A/600 V, included suitable cooling profiles. A conventional contactor is mounted in connection with the solid state relay to secure maximum security.

The temperature controller has been built into the PLC:

The pressure controller has been built into the PLC.

thermostats are also fitted in the PLC.

- Damper thermostat - for drying
- Filter thermostat - for protection of internal filters
- Door thermostat - to secure against opening the door the sterilizer being too hot
- Stop thermostat - for automatic stop after cooling.

The safety thermostat is a mechanical thermostat which is wired into the electrical circuit. In this way we achieve the utmost security against over-temperatures, even if the PLC should fail.

The PLC is provided with inputs from external components/systems/switches so messages about other systems upon which our sterilizer might be dependent can be given by LYTCON.

The PLC is provided with a communication port for DH485 Data Highway.

16.3A  Three ammeters for indication of phase current for heater.

16.4  Single channel recorder **CHESSELL 4102**, provides a permanent recording of the process temperature for the facility files.
16.5 Board ventilation with dust filter

17. PRESSURE INDICATOR:

17.1 A DWYER Magnehelic pressure gauge has been fitted for the following indications:

1. Indication of Chamber pressure 0-100 Pascal.

17.2.1 The Magnehelic(s) has been located on the upper front panel on the non-sterile side.

21. CE-CONFORMITY:

21.1 The sterilizer is constructed in full accordance with the following EEC directives:

Machinery Directive: 98/37/EEC with amendments
(formerly 89/392/EEC with amendments)

Low voltage Directive: 73/23/EEC with amendments

EMC Directive: 89/336/EEC with amendments

and are accordingly meeting harmonized standards: EN292-1, EN292-2, EN60204-1, EN50081-2, EN50082-1 and EN50082-2.

The sterilizer is supplied CE labelled and with declaration of conformity.

22. PREVALIDATION/TESTING:

22.1.1 Each sterilizer is factory tested under production-like conditions prior to shipping. The chamber is tested for temperature distribution and pressure stability. Documentation of the testing is provided within the owner's manual at delivery.

24. DOCUMENTATION:

24.1 Three (3) copies of Operation & Maintenance (O&M) manuals in English containing:

Installation
Descriptions
Daily operation
Trouble shooting
Maintenance
Factory test reports
Special description
Data sheets
Electrical wiring diagramme
Process & Instrumentation (P&I-Diagram)
24.2 Machine qualification documents in English for IQ and OQ are included in the basic price. The documents are for customer validation purposes, to be used after installation. The documents are to be filled in by customer.

<table>
<thead>
<tr>
<th>DATA SHEET FOR DRY HEAT STERILIZER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilizer type</td>
</tr>
<tr>
<td>Electric heating effect</td>
</tr>
<tr>
<td>Electric Motor (circulator)</td>
</tr>
<tr>
<td>Electric Motor (over-pressure fan)</td>
</tr>
<tr>
<td>Operating Voltage</td>
</tr>
<tr>
<td>Pilot Voltage</td>
</tr>
<tr>
<td>Max. Air change by basic air cooling</td>
</tr>
<tr>
<td>Heating time (empty chamber)</td>
</tr>
<tr>
<td>Cooling time, basic air cooling</td>
</tr>
<tr>
<td>250° C ≤ 60° Inlet air temperature: 20° C.</td>
</tr>
</tbody>
</table>

Re: installation you will have to supply to the sterilizer:

1. Electricity
2. Exhaust Connection (remember make-up air)