COOL ZONE STERILIZING IN DEPYROGENATION TUNNEL

Background:

COOLING CHAMBER HEATING ELEMENTS

AUTOMATIC TIGHT DOOR

HIGH TEMPERATURE RESISTANT INFLATABLE GASKETS

AUTOMATIC DISCHARGE BAR

Concept of cool zone sterilization is not exist is old tunnel technology. There are two types of dry-heat sterilizers: the static-air type and the forced-air type. The static-air type is referred to as the oven type sterilizer as heating coils in the bottom of the unit cause the hot air to rise inside the chamber via gravity convection. This type of dry-heat sterilizer is much slower in heating, requires longer time to reach sterilizing temperature, and is less uniform in temperature control throughout the chamber than is the forced-air type. The forced-air or mechanical convection sterilizer is equipped with a motor-driven blower that circulates heated air throughout the chamber at a high velocity, permitting a more rapid transfer of energy from the air to the instruments.

Initially hot air ovens are used to depyrogenated the glass containers and after completion of depyrogenation cycle containers unloaded under the celling LAF and transfer for aseptic filling line.

Concept of tunnel is came into the existence to reduce the aseptic intervention. As per current technology washed containers are travelled through preheating zone, hot/sterilizing zone and cooling zone of tunnel to filling machine automatically with predefined validated recipe.

Figure 1: Demonstrated from STERILINE ST

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System Description:

The depyrogenating tunnels with sterilizable cooling chamber have the following features:

- Heating elements for sterilizing the cooling chamber by means of dry heat;
- Cooling chamber insulation to provide protection at temperatures up to 230°C;
- Insulated airtight door at the tunnel exit, equipped with high temperature resistant inflatable gaskets, to protect the isolator during the cooling chamber sterilization and to enable the isolator to be sterilized without any leak of VHP into the tunnel.

Figure 2: Vertically directed hot air

The cooling chamber is sterilized by HEPA filtered hot air at a temperature of approximately 200°C. The cycle time is defined during the pre-testing phase, calculated in order to ensure the coldest point sterilization. The minimum surface temperature anywhere in the cooling chamber on any material should be above 170°C. The coldest point shall stay at a temperature of 170°C as long as necessary to achieve bacterial reduction of 6 log according to the following formula:

$$F_H = \int_0^t 10^{\frac{T-170}{20}} dt$$

Once the cooling chamber sterilization cycle has been started:

- The airtight door closes and the insulated gaskets inflate;
- The cooling water circuit drains;
- All tunnel heaters start;
- The cooling chamber temperature raises up to the predefined set point, which is maintained for the predefined sterilization time.

Acceptance criteria:

Temperature not less than 170 °C for 1 hr to be observed. The most common time-temperature relationships for sterilization with hot air sterilizers are 170 °C (340 F) for 60 minutes, 160 °C (320 F) for 120 minutes, and 150 °C (300 F) for 150 minutes. Bacillus atrophaeus spores should be used to monitor the sterilization process for dry heat because they are more resistant to dry heat than are G. stearothermophilus spores. Minimum 6 log reduction of biological indicator Bacillus atrophaeus.

Recommendation for cool zone sterilization cycle:

Considering Cool Zone sterilization cycle is a good practice to avoid the microbial contamination after sudden stoppage of machine or breakdown maintenance. In routine it is recommended to switch on the tunnel in Blower On/Night mode to maintain the Grade A (ISO 5) condition after completion of batch activity. When machine is completely stopped for performing preventive maintenance or sudden break down maintenance cool zone sterilization cycle need to be considered. Irrespective of maintenance a periodic sterilization cycle will keep the tunnel healthy.

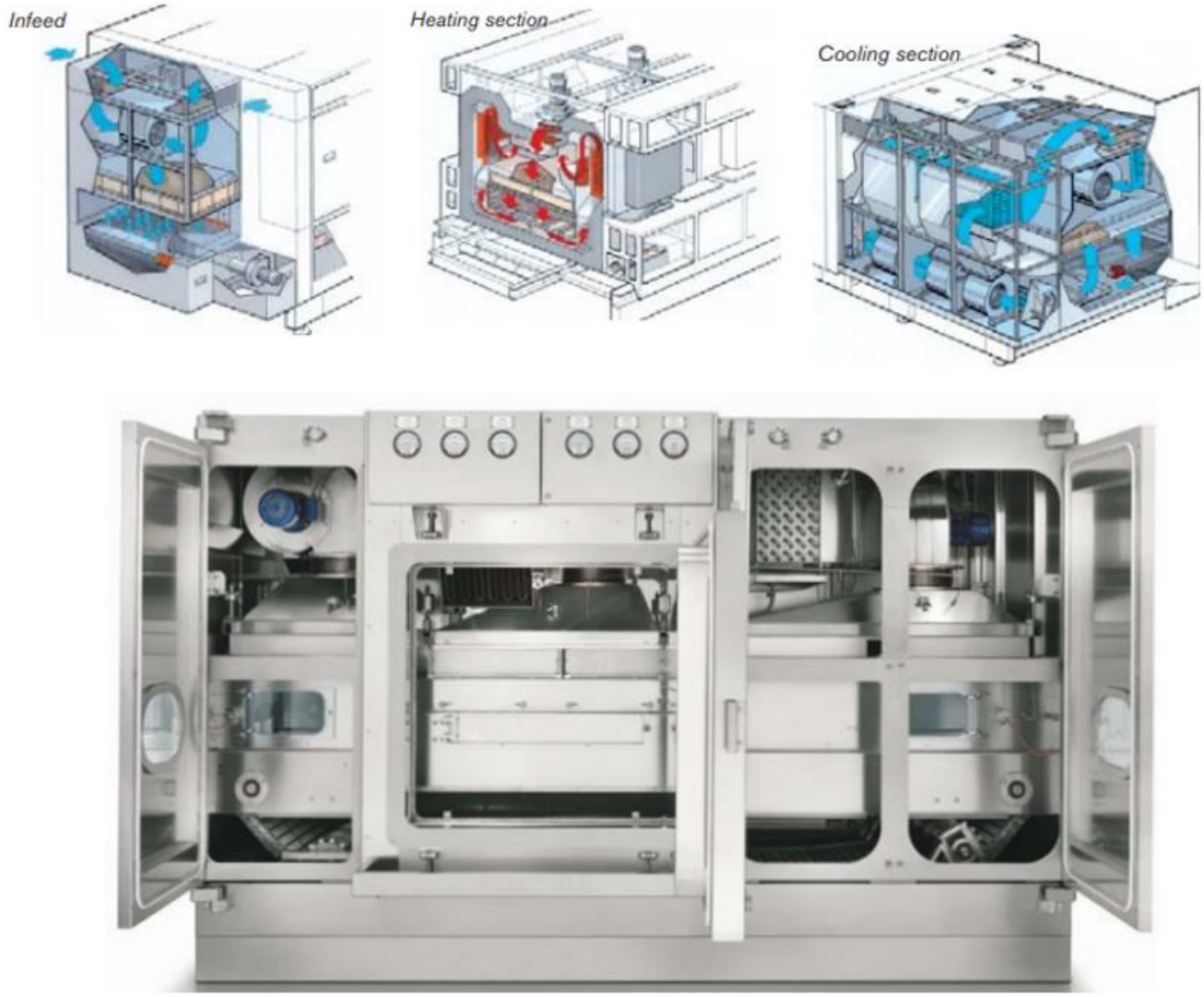

Figure 3: Depyrogenating Tunnel demonstrated from IMA LIFE

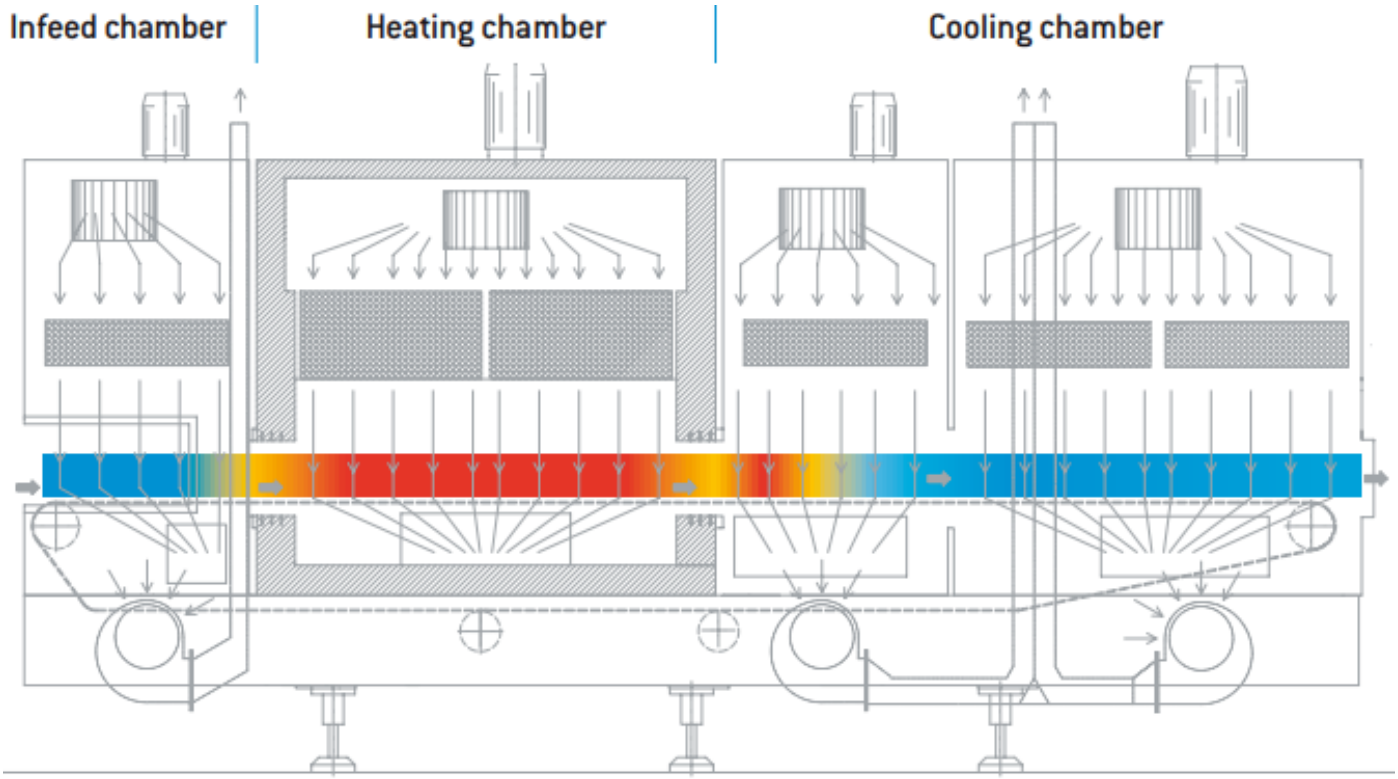

Figure 4: Air flow direction demonstrated from Romaco Macofar

Reference:

1. *PDA Technical Report No. 3, Validation of Dry Heat Process Used for Depyrogenation and Sterilization*
2. *Journal of Hygiene sciences, Volume-VI, Issue-II, June-Jul 2013*
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