

PennTech Sterilizing and Depyrogenation Tunnels

*Uniquely Engineered
to Outperform™*



PennTech
Machinery Corporation

PennTech's Unique Sterilizing and Depyrogenation Tunnels are Engineered for Increased Energy Efficiency and Smaller Footprint

PennTech laminar air flow tunnels have been designed to continuously sterilize and depyrogenate pharmaceutical glass containers in a class 100 environment according to US Federal Standard 209d.

The Tunnels are comprised of three chambers:

- The Infeed Chamber
- The Sterilizing Chamber
- The Cooling Chamber

Infeed Chamber

The Infeed Chamber creates a thermal barrier between the vial washing room and the Sterilizing Chamber, to protect the vials from contamination and to pre-heat the vials.

Vertical unidirectional HEPA-filtered air blows over the vials at 0.5m/s. The Infeed Chamber is pressurized to 28Pa (1Pa=0.1mm), one Pa less than the Sterilizing Chamber. This small pressure drop allows for some hot air to flow from the Sterilizing Chamber to the Infeed Chamber for drying and pre-heating of the vials.

Sterilizing Chamber

The Sterilizing Chamber is fully insulated and can be heated up to temperatures of 350°C (660°F). Heat is generated by stainless steel, SCR-controlled heating elements. The sterilization time of the vials is a function of the air temperature and air velocity. The air velocity is adjustable. The thermal cycle is designed to obtain a 3-log pyrogen reduction in 15 minutes (D-value) at a temperature of 250°C. Every 46.4°C increase in temperature (referred to E.colli endotoxin), reduces the D-value by 1-log cycle.

| | | 1-log cycle | 2-log cycle | 3-log cycle | 4-log cycle |
|--------|---|-------------|-------------|-------------|-------------|
| Z250 | → | D5min. | D10min. | D15min. | D20min. |
| Z296.4 | → | D30sec. | D60sec. | D90sec. | D120sec. |
| Z342.8 | → | D3sec. | D6sec. | D9sec. | D12sec. |

The Sterilizing Chamber is pressurized to 29Pa, one Pa less than the Cooling Chamber. This small pressure drop causes a counter flow from the Cooling Chamber to the Sterilizing Chamber.

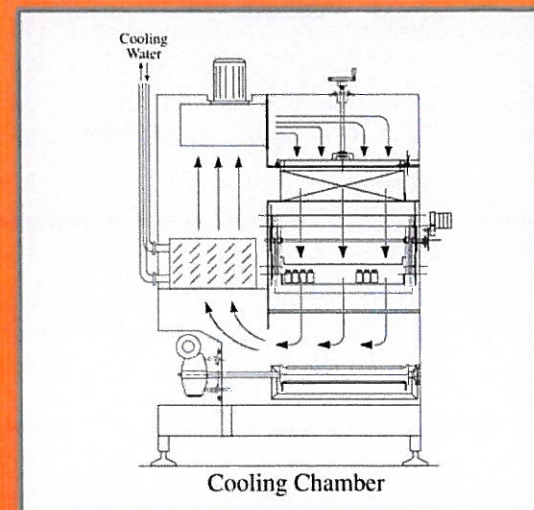
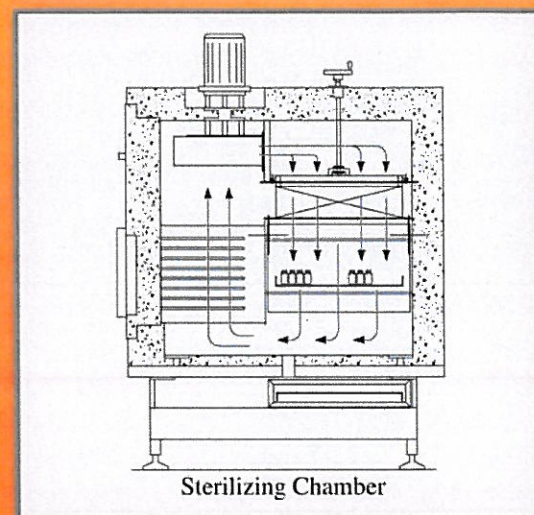
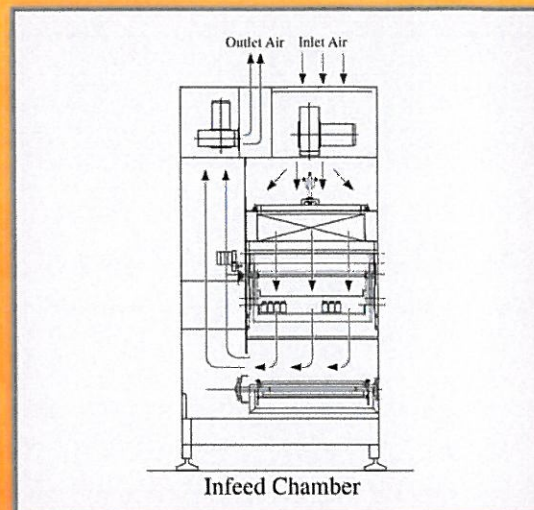
Some options include:

- DOP testing of HEPA filters
- Automatic height setting of infeed and outfeed door

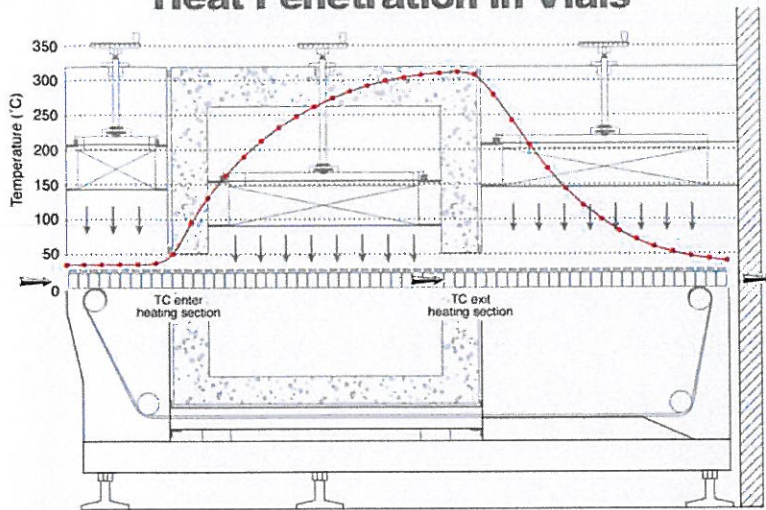
Cooling Chamber

Depending on the tunnel size, one or two cooling coils assist in the cooling of the vials to ambient temperature. Regular tap water or chilled water may be used. Depending on the format, vials stay in the Cooling Chamber for 15-20 minutes.

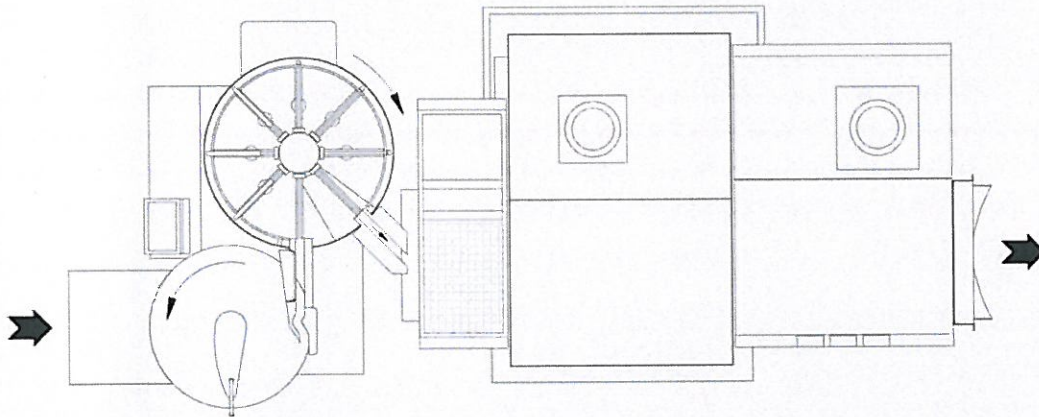
Optionally, the Cooling Chamber can be heat sterilized by HEPA-filtered hot air of 200°C for a D-value of 7.2 minutes at a temperature of 170°C. The air pressure in the Cooling Chamber is 30Pa.



Heat Penetration in Vials



PennTech Rotary Vial Washer & Sterilization Tunnel



Control System

PennTech's sterilizing tunnels are standard equipped with Allen Bradley® SLC-series or ControlLogix PLC's in combination with an Allen Bradley® PanelView or Siemens HMI (Human Machine Interface). The HMI displays alarm conditions when they occur. GE's Fanuc Intellution iFIX software package is used for system validation according to Title 21 Code of Federal Regulations (21 CFR part 11).

Night Mode

When the tunnel is not being used, it can be operated in the "night-mode" to save energy while avoiding contamination.

Specifications of PennTech Sterilizing Tunnels

| Model | Output in vials/min. (A=Tubular H=molded) | | | | | |
|-----------------|---|--------|---------|---------|---------|----------|
| | 2ml(A) | 5ml(A) | 10ml(A) | 30ml(A) | 50ml(H) | 100ml(H) |
| ST1/450/1980* | 240 | 125 | 100 | 67 | 21 | 12 |
| ST1L/450/2130 | 296 | 155 | 125 | 80 | 26 | 14 |
| ST2/450/2285 | 390 | 200 | 170 | 100 | 34 | 18 |
| ST2L/450/2435 | 480 | 250 | 200 | 130 | 40 | 23 |
| ST3/600/2485 | 550 | 285 | 235 | 150 | 48 | 26 |
| ST4/600/2800 | 640 | 335 | 275 | 175 | 55 | 31 |
| ST5/600/3075 | 730 | 380 | 315 | 200 | 63 | 35 |
| ST6/800/2925 | 800+ | 430 | 355 | 225 | 71 | 39 |
| ST7/800/3260 | 800+ | 480 | 395 | 250 | 79 | 44 |
| ST8/800/3565 | 800+ | 525 | 430 | 275 | 87 | 47 |
| ST9/800/3870 | 800+ | 600 | 500 | 300 | 100 | 53 |
| ST12/1250/3160 | 800+ | 670 | 555 | 350 | 110 | 60 |
| ST13/1250/3460 | 800+ | 750 | 620 | 390 | 125 | 68 |
| ST13B/1250/3920 | 800+ | 750+ | 680 | 430 | 140 | 75 |
| ST14/1250/4200 | 800+ | 750+ | 680+ | 550 | 170 | 95 |
| ST15/1250/4560 | 800+ | 750+ | 680+ | 550+ | 240 | 133 |
| ST18/1600/4680 | 800+ | 750+ | 680+ | 550+ | 240+ | 133+ |

*ST1/450/1980 = Belt width 450mm, Overall Tunnel Length 1980mm

Technical Specifications

| Model | Infeed Chamber | | Sterilizing Chamber | | Cooling Chamber-1 | | Cooling Chamber-2 | |
|-----------------|----------------|------------------------------|-------------------------|------------------------------|-----------------------|------------------------------|-------------------|------------------------------|
| | HEPA filters | airflow (m ³ /hr) | HEPA filters | airflow (m ³ /hr) | HEPA filters | airflow (m ³ /hr) | HEPA filters | airflow (m ³ /hr) |
| ST1/450/1980* | 457X305 | 418 | 457X610 | 1002 | 457x610 | 1066 | N/A | N/A |
| ST1L/450/2130 | 457X305 | 418 | 457X610 | 1002 | 457x610 | 1303 | N/A | N/A |
| ST2/450/2285 | 457X305 | 418 | 457x762 | 1210 | 457x762 | 1303 | N/A | N/A |
| ST2L/450/2435 | 457X305 | 418 | 457x762 | 1210 | 457x914 | 1539 | N/A | N/A |
| ST3/600/2485 | 610x305 | 546 | 610x762 | 1593 | 610x914 | 1967 | N/A | N/A |
| ST4/600/2800 | 610x305 | 546 | 2@610x457 | 1940 | (610x610)+(610x457) | 2271 | N/A | N/A |
| ST5/600/3075 | 610x305 | 546 | (610x610)+(610x457) | 2214 | 610x1219 | 2573 | N/A | N/A |
| ST6/800/2925 | 762x305 | 716 | 2@762x610 | 2561 | 762x1219 | 3319 | N/A | N/A |
| ST7/800/3260 | 762x305 | 716 | (762x457)+(762x762) | 2922 | (762x610)+(762x762) | 3814 | N/A | N/A |
| ST8/800/3565 | 762x305 | 716 | 2@762x610 | 3286 | 2@762x762 | 4203 | N/A | N/A |
| ST9/800/3870 | 762x305 | 716 | (762x610)+(762x762) | 3647 | (762x762)+(762x914) | 4593 | N/A | N/A |
| ST12/1250/3160 | 2@610x457 | 1524 | 4@610x457 | 3958 | 1219x610 | 2647 | 1219X610 | 2647 |
| ST13/1250/3460 | 2@610x457 | 1524 | 2@(610x610)+2@(610x457) | 4516 | 1219x762 | 3234 | 1219X610 | 2647 |
| ST13B/1250/3920 | 2@610x457 | 1524 | 4@610x610 | 5078 | 1219x914 | 3820 | 1219X762 | 3234 |
| ST14/1250/4200 | 2@610x457 | 1524 | 2@(610x610)+2@(610x762) | 5636 | 1219x914 | 3820 | 1219X914 | 3820 |
| ST15/1250/4560 | 2@610x457 | 1524 | 4@610x762 | 6194 | (1219x610)x(1219x457) | 4565 | 1219X914 | 3820 |
| ST18/1600/4680 | 2@763x457 | 1937 | 4@762x762 | 7895 | 2@762x1219 | 6303 | 2@762x914 | 4818 |

Power Consumption

| Model | Belt (kW) | Infeed Chamber | | Sterilizing Chamber | | Cooling Chamber-1 | | Cooling Chamber-2 | | Total Power Consumption (kW) |
|-----------------|-----------|-----------------|-----------------|---------------------|--------------|-------------------|-----------------|-------------------|-----------------|------------------------------|
| | | Recirc. fan(kW) | Exhaust fan(kW) | Recirc. fan(kW) | Heaters (kW) | Recirc. fan(kW) | Exhaust fan(kW) | Recirc. fan(kW) | Exhaust fan(kW) | |
| ST1/450/1980* | 0.11 | 0.37 | 0.25 | 1.5 | 21.0 | 0.55 | 0.12 | N/A | N/A | 22 |
| ST1L/450/2130 | 0.11 | 0.37 | 0.25 | 1.5 | 21.0 | 0.55 | 0.12 | N/A | N/A | 22 |
| ST2/450/2285 | 0.11 | 0.37 | 0.25 | 1.5 | 24.6 | 0.55 | 0.12 | N/A | N/A | 28 |
| ST2L/450/2435 | 0.11 | 0.37 | 0.25 | 1.5 | 24.6 | 0.55 | 0.12 | N/A | N/A | 28 |
| ST3/600/2485 | 0.11 | 0.37 | 0.25 | 1.5 | 28.8 | 0.75 | 0.12 | N/A | N/A | 33 |
| ST4/600/2800 | 0.18 | 0.37 | 0.25 | 1.5 | 31.5 | 0.75 | 0.12 | N/A | N/A | 37 |
| ST5/600/3075 | 0.18 | 0.37 | 0.25 | 3.0 | 36.0 | 1.1 | 0.12 | N/A | N/A | 41 |
| ST6/800/2925 | 0.18 | 0.55 | 0.37 | 3.0 | 40.5 | 1.1 | 0.12 | N/A | N/A | 48 |
| ST7/800/3260 | 0.18 | 0.55 | 0.37 | 3.0 | 45.0 | 1.5 | 0.12 | N/A | N/A | 51 |
| ST8/800/3565 | 0.18 | 0.55 | 0.37 | 3.0 | 48.6 | 2.2 | 0.12 | N/A | N/A | 55 |
| ST9/800/3870 | 0.18 | 0.55 | 0.37 | 3.0 | 51.6 | 2.2 | 0.12 | N/A | N/A | 61 |
| ST12/1250/3160 | 0.37 | 0.55 | 0.55 | 4.0 | 54.0 | 1.1 | 0.25 | 1.1 | N/A | 63 |
| ST13/1250/3460 | 0.37 | 0.55 | 0.55 | 4.0 | 63.0 | 1.1 | 0.25 | 1.1 | N/A | 70 |
| ST13B/1250/3920 | 0.37 | 0.55 | 0.55 | 4.0 | 67.5 | 2.2 | 0.25 | 1.1 | N/A | 83 |
| ST14/1250/4200 | 0.37 | 0.55 | 0.55 | 4.0 | 72.0 | 2.2 | 0.25 | 1.5 | N/A | 92 |
| ST15/1250/4560 | 0.37 | 0.55 | 0.55 | 4.0 | 72.0 | 2.2 | 0.25 | 2.2 | N/A | 92 |
| ST18/1600/4680 | 0.37 | 0.55 | 0.55 | 6.0 | 81.0 | 2.2 | 0.75 | 2.2 | N/A | 114 |

*ST1/450/1980 = Belt width 450mm, Overall Tunnel Length 1980mm

Information subject to change

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