



Labor- und Pharmatechnik



HOT-AIR STERILIZERS Class 100
HOT-AIR STERILIZERS Class 10 000



Pharmaceutical Technology



EHRET LIFE SCIENCE SOLUTIONS

GMP- conform HOT-AIR Sterilizers

EHRET Hot-Air Sterilizers

are developed to fulfil the high demands on hot-air sterilization and depyrogenation especially for pharmaceutical production as well as for hospital and pharmacy purposes.

With this, various solutions for dry heat sterilization methods under GMP conditions are at customers hands.

Hot-Air Sterilizers differ generally from Drying Ovens in view of construction as well as in view of control technique.

Basis and leading idea of construction and design are the regulations for the pharmaceutical production (GMP, PIC/s, ISO 14644, etc.).

Sterile Products by EHRET Know-How

The fabrication of Hot-Air Sterilizers is carried out entirely in the EHRET factory in accordance to ISO-certified work flow and basing on corresponding SOPs for design, production, qualification and documentation.

The conversions of these standards result in:

High economic efficiency	<ul style="list-style-type: none"> ■ Energy savings by high-quality insulation and optimised process flow ■ High productivity by maximal batches ■ Universal daily use; for most different drying processes
Reproducibility	<ul style="list-style-type: none"> ■ Validation of parameters ■ Automatic process control ■ Perfected control and safety systems ■ Temperature test protocols
Easy to use	<ul style="list-style-type: none"> ■ Easy cleaning and disinfecting ■ Ergonomics in handling, charging and operating ■ Long service intervals ■ Easy to maintain construction

HOT-AIR Sterilizers Class 100 and 10 000

EHRET Hot-Air Sterilizers class 100 and 10 000 are manufactured in accordance to the FDA and GMP standards and the relevant standards in effect.

The stated cleanroom class conditions are granted during the complete sterilisation cycle at a temperature range from +5°C above ambient temperature up to +200°C with all units, optionally up to +280°C.

STANDARD design

- Chamber: stainless steel AISI 304 brushed, surface roughness Ra ≤1,2 µm
- Chamber: stainless steel AISI 304 mat, surface roughness Ra ≤0,8µm
- Temperature range: +5°C above ambient up to +200°C, optionally up to +280°C
- Spatial temperature deviations: ±4°C at +250°C
- Temporal temperature differences: ±1,5°C at +250°C

Temperature and process control

Selection between two different PLC controls:

- STERICOMP control on microprocessor basis with LCD screen display
- Siemens S7 control and Siemens operator panels

Equipment

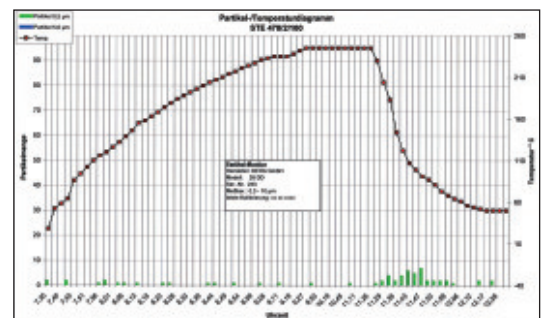
- High-temperature control: temperature limiter with optical indication (TWB)
- Fully armoured, broad-surface stainless steel heating elements
- Chamber cooling by HEPA filtered fresh air (class H 13) and circulating air combined with an air/water heat exchanger
- Indication of process end by an optical signal
- Air circulation by an radial ventilator in the upper part of the chamber with mixed vertical/horizontal airflow
- Fresh air supply by a radial ventilator and HEPA filter class H 13
- Program controlled exhaust
- Insulation by mineral insulation plates
- Integrated extensile switch cabinet
- Recessed door construction with optional door catch DIN left/right
- Door on one side or on both sides
- Validation port integrated in the operational side door
- DEHS-ports for filter integrity tests



Chamber class 100 and class 5 as per ISO 14644 - part 1 respectively

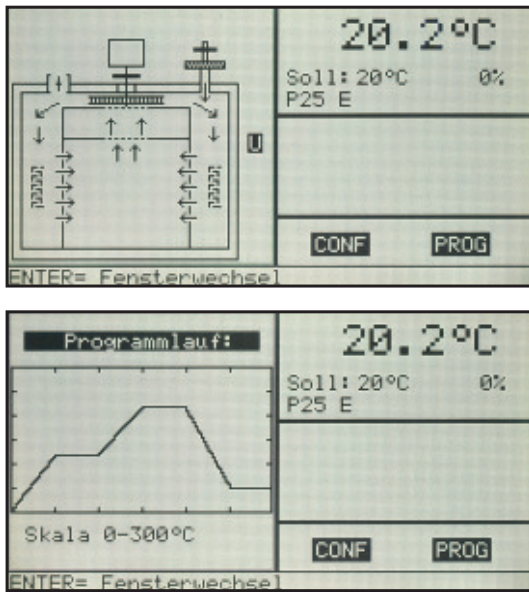
EHRET guarantees class 100 conditions throughout the complete cycle, not only during the sterilising phase!

- up to +200°C with HEPA filters H 13 or
- up to +280°C with HEPA filters H 13 with fibre glass gasket, ceramic filter frame and additional cooling of the front door gasket



STERICOMP control with microprocessor based PLC system

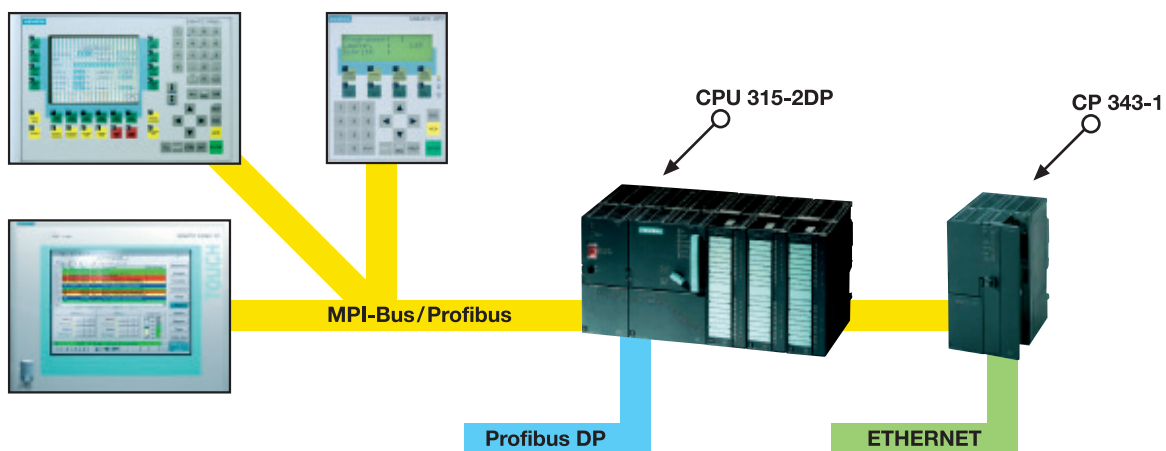
- Up to 25 programs can be stored with different parameters, for instance sterilization temperature, exhaust flap closing temperature, process end, etc.
- Process monitoring with electric door lock system
- Extensive password protection and access control
- The actual program status is displayed at the LCD screen
- Control panel: soft-touch keyboard integrated in the STERICOMP control



STERICOMP control

SIEMENS control S7-300

Siemens operator panels OP 270, MP 270 B (non-sterile side), Siemens OP 7 (sterile side)



The Siemens control S7-300 using the components CPU 315-2DP and operator panels OP 270 or MP 270 B and OP 7 is installed to fulfil all requirements of GMP, GAMP and PIC/s. With further options the requirements on electronic signature and electronic records according to 21 CFR Part 11 are secured.

Performance features

- Temperature and process control is carried out by CPU 315-2DP and the extended software package PID Control with self-tuning function
- Simple menu-guidance for easy operation
- 10 free configurable programs
- Free configuration of parameters, for instance gradients for heating-up, temperatures and time for drying and sterilizing steps, cooling-down gradients, process end temperature
- 4 different password protected user levels
- Batch recording with batch number
- ETHERNET or Profibus DP interface
- Complete process supervision
- Plain text messages on all failure situations

Registration options with process recorder

With the installation of different process recorders various possibilities are available for batch recording.

- Paper recorder Jumo Logoprint 500
- Paper recorder Yokogawa μ R10 000
- Electronic screen recorder JUMO Logoscreen
- Electronic screen recorder E+H Memograph S (21 CFR Part 11)

All recorders are configured in a way that printout of program start and stop, sterilization start and end as well as a common alarm message, each with date and time, is possible.

Configuration and display of the 6 channels with

- Pt 100, DIN 1/3 B with three-wire circuit
- 1 thereof fixed for temperature
- 5 thereof flexible (goods sensors)
- alternatively with differential chamber pressure sensor and 4 flexible goods sensors



Further control and recorder options

- Tying to a SCADA system by Profibus DP or ETHERNET
 - Registration of the chamber pressure
 - Variable chamber pressure control from 20 up to 200 Pa
 - Process control with F-value calculation
- round off the manifold possibilities in equipment of the EHRET Hot-Air Sterilizers.

Further Options

■ Pneumatic door gasket

The inflatable door gasket of high temperature resistant silicone, temperature up to +300°C, is especially suitable when connecting a Transfer Isolator to a 2-door pass-through Sterilizer; the complete and hermetic separation of the chamber from the ambience increases the process security.

■ Heat resistant HEPA exhaust air filter H 13

■ Chamber from stainless steel AISI 316 Ti or AISI 316 L

■ Perforated stainless steel shelves AISI 304,

optionally from AISI 316 Ti or AISI 316 L,
with variably adjustable shelf rails

■ Transport and charging trolley

from stainless steel AISI 304, optionally AISI 316 Ti or AISI 316 L
for easy charge and discharge of the Hot-Air Sterilizer



■ GMP conform qualification and extensive documentation

Preparation of the extensive qualification documents of
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)

The qualification of all components up to GAMP conform qualification of the Siemens control is optionally available.

Technical data, standard equipment and options			
Model STE, example 2-door design	700/2	1500/2	2500/2
Cleanroom class 100 [HEPA-Filter H13] ISO 14644-1 class 5, up to +200°C	●	●	●
Cleanroom class 100 [HEPA-Filter H13] ISO 14644-1 class 5, up to +280°C	○	○	○
Cleanroom class 10 000, ISO 14644-1 class 7, up to +200°C	●	●	●
Cleanroom class 10 000, ISO 14644-1 class 7, up to +280°C	○	○	○
Chamber			
Width [mm]	980	1250	1250
Height [mm]	1066	1372	2028
Depth [mm]	756	908	908
Outer dimensions			
Width [mm]	1995	2265	2265
Height [mm]	1965	2302	2958
Depth [mm] [plus 61 mm for each door handle]	1056	1208	1208
Chamber volume [l]	790	1557	2302
Connected power 400V/50 Hz [kW]	16	28	40
Heating capacity [kW]	14,4	25,6	36,8
Supply air filter H 13	305 x 305	457 x 457	457 x 457
Net weight approx. [kg]	850	1350	1700
Airflow cleanroom class 100, ISO 14644-1 class 5	horizontally	horizontally	horizontally
Airflow cleanroom class 10 000, ISO 14644-1 class 7	horizontally/vertically	horizontally/vertically	horizontally/vertically
Air/water cooling system	●	●	●
Maximum capacity [kg]	300	400	450
Exhaust air volume approx. [m ³ /h]	100	150	200
Overpressure inside the chamber approx. [Pa]	up to 320	up to 420	up to 420
Warmth radiation approx. [kcal/h]	300	780	1000
Control and Recorder Options			
Siemens control S7-300; Operator Panel OP270, MP 270 B, OP7	○	○	○
DC-UPS to maintain the PLC control	○	○	○
UPS (Uninterruptible Power Supply unit) to maintain safe condition [GMP-conform] of the complete installation	○	○	○
PLC - STERICOMP with LCD display	○	○	○
Paper recorder Jumo Logoprint 500	○	○	○
Paper recorder Yokogawa μ R 10 000	○	○	○
Screen recorder JUMO Logoscreen	○	○	○
Data manager and paperless recorder E+H Memograph S [21CFR part 11]	○	○	○
Tying to SCADA system [Profibus DP]	○	○	○
Tying to SCADA System [ETHERNET]	○	○	○
Chamber pressure registration	○	○	○

continuation»



Labor- und Pharmatechnik

continuation»

Modell STE, example 2-door design	700/2	1500/2	2500/2
Chamber pressure control	○	○	○
F-value calculation	○	○	○
Additional Options			
Pneumatic door gasket	○	○	○
Exhaust air filter H 13	○	○	○
Chamber from stainless steel AISI 316 Ti or AISI 316 L	○	○	○
Perforated stainless steel shelves AISI 304, AISI 316 Ti or AISI 316 L	○	○	○
Stainless steel transport trolley AISI 304	○	○	○
Stainless steel charging trolley AISI 304, AISI 316 Ti or AISI 316 L	○	○	○
Facing of the installation from stainless steel AISI 304	○	○	○
GMP conform qualification DQ / FAT / IQ / OQ / SAT	○	○	○
Standard-Documentation	●	●	●
GAMP 4 compliance, basis documentation	○	○	○
GAMP 4 compliance, extended documentation	○	○	○

● = Standard ○ = Option