

Sterilisers ...

Vötsch
Industrietechnik



... design compliant with GMP and FDA requirements
Hot air sterilisers also under clean room conditions

Reliability by means of dry-heat sterilisation

In the manufacture of pharmaceuticals, active substances and products, the objective is a reliable product which consistently meets high demands on quality.



Absolute reliability is therefore a fundamental necessity in the spheres of pharmacy, medicine, gene technology, biotechnology, food industry and all research-intensive life science industries.

Regardless of whether for production purposes your requirement is for heating and drying ovens or dry heat sterilisers, Vötsch Industrietechnik offers you the appropriate product – compliant with GMP and FDA requirements.

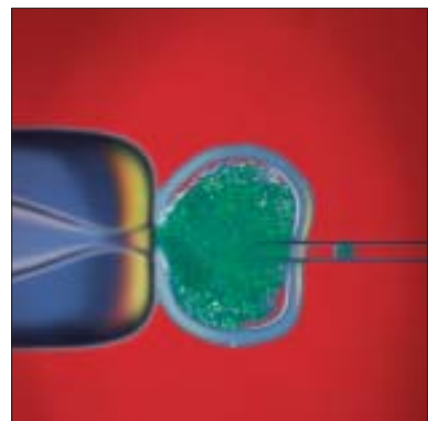
GMP
Good Manufacturing Practice

FDA
Food and Drug Administration

With its know-how and service, Vötsch assists the validation of pharmaceutical plants by providing documents and carrying out the qualification for the following phases:

- Design qualification (DQ)
- Installation qualification (IQ)
- Operation qualification (OQ)

The qualification documentation defined by FDA-GMP is available both for the unit and for the control system and software **SIMCON/32*-NET** and **SIMPATI*** (GAMP-GUIDE and 21 CFR, Part 11).



...and its application

Why use dry heat sterilisation?

If you wish to sterilise quickly, reliably and cost-effectively, the dry heat sterilisation method is an attractive alternative to other available systems.

The decisive advantage ...

This method only employs air, thus enabling sterilisation to be carried out at high temperatures. Dependent on the temperature level, the sterilisation process is considerably faster than with other methods and is thereby time-saving and economical. Furthermore, the investment costs are comparatively low.

Thanks to the high temperatures, the sterilisation process requires no chemicals, which results in further advantages:

- Easy handling of the system
- Simplified maintenance and cleaning
- Safe working conditions for operating staff, due to the fact that no risks can evolve from hazardous additives
- Environmentally friendly
- Low operating costs

Pyrogenic substances don't stand a chance ...

At temperatures of 250 °C and above, even highly resistant pyrogen (e. g. necrotised bacteria subsequent to sterilisation) is eliminated during the production of injection solutions.

The spheres of application ... whenever reliable and reproducible results are of importance!



- Pharmaceutical industry
- Biotechnology
- Gene technology
- Medical technology
- Microstructure technology
- Cosmetic industry
- Food industry
- Beverage industry
- Laboratories
- R & D



Product range and design

A comprehensive range of products ...

Vötsch offers dry heat sterilisers for the clean room specifications ISO 5 and 7 in accordance with DIN EN ISO 14644-1.

All series can be produced

- as a free-standing unit
- prepared for wall installation
- as a serving-hatch version, with front and rear doors for separation of sterile and non-sterile working areas.

The serving-hatch version is equipped with electric locks, thus ensuring that only one door at a time can be opened.

Series	Nominal temperature
VHS	250 (300) °C
VHSF	230 (300) °C
VHSF 1-4	350 °C

Series	Airflow direction
VHS	Horizontal
VHSF	Horizontal
VHSF 1-4	Vertical

Standard features for all series ...

- Sterilisation chamber in stainless steel (1.4301)
- Outer casing in brushed stainless steel (1.4301)
- Control system integrated in outer casing
- GMP-compliant design
- Permanent overpressure in sterilisation chamber
- Monitored overpressure
- Control system Vötsch-SIMCON/32*-NET, parameter input and programme monitoring via colour touch panel



- Single channel temperature recorder
- Fresh air fan (2-stage)
- Fresh air filtration via high-performance particulate filter, with preliminary filter
- Filter monitoring
- Electro-pneumatic flap valve for cooling operation
- DEHS filter test nozzle
- Nozzle for validation DN 25
- LED display for operating status
- Electric door locking unit for serving-hatch

Optional features ...

- Serving-hatch version
- Various programme controller
- Electric door locking unit (standard with serving-hatch version)
- Exhaust air filter (HEPA)
- Qualification documentation
- Proof of effective sterilisation with Vötsch sterilisers via bio-indicators
- Charging trolley
- Transport trolley
- Vötsch software package



Charging trolley with transport trolley

Sterilisers – Class ISO 7

The VHS series sterilisers comply with the clean room class ISO 7 requirements in accordance with DIN EN ISO 14644-1 (US Federal Standard Class 10.000)

The VHS series sterilisers comply with the clean room class ISO 7 requirements in accordance with DIN EN ISO 14644-1 (US Federal Standard Class 10.000).

The VHS sterilisers (VHS 75/100, 100/150 and 125/200) offer a variety of applications. Regardless if large containers or small components need to be sterilised, the large storage volume offers the appropriate solution for a whole range of applications. Three sizes are offered as standard: The standard steriliser has a work space volume of 3,100 litres. The nominal temperature is 250 °C.

Charging trolleys with racks facilitate flexible handling. Transport trolleys are available in order to ensure that no particles are carried into the sterilisation chamber.



Dry heat steriliser VHSD 150/150/150 GMP as serving-hatch version

The VHS series sterilisers (VHS 4-12) have been designed for standardised sterilisation units (Norm-StE).

Vötsch manufactures the VHS sterilisers in four sizes. Depending on the size, the sterilisation chamber offers capacity for 4 to 12 standard sterilisation units.

Furthermore, this series is ideal for sterilising small components and containers. An additional advantage is the small amount of space required.



Dry heat steriliser VHSD 4 GMP as serving-hatch version

ISO 5 Class sterilisers

The VHSF steriliser series fulfil the requirements of the clean air Class ISO 5 according to DIN EN ISO 14644-1 (US Federal Standard Class 100)

With the VHSF series, the requirements of clean air Class ISO 5 are fulfilled by the circulating air filters which are installed in the sterilisation chamber.

The high efficiency particulate filter is positioned immediately in front of the air inlet into the sterilisation chamber and is an absolute filter (HEPA).

All significant differential pressures and flow volumes are monitored.

The filters reliably ensure sterilisation at temperatures up to 230 °C (300 °C), this being maintained during the whole sterilisation cycle, i. e., not only during sterilisation but also during the heating and cooling phase.

The laminar flow technology ensures a laminar flow condition, with a particularly homogenous temperature distribution. Due to this, glass products such as ampoules, injection and infusion bottles or other thermostable materials, can be sterilised at temperatures up to 350 °C.

The high temperature is particularly useful in achieving a rapid and reliable dehydrogenation.

The dry heat sterilisers VHSF 1-4 are available in four sizes.

Unique two chamber steriliser VHSF-K

For time- and energy-saving cooling processes, the dry heat steriliser can be combined with an additional cooling chamber (optional). In this case and following the successful sterilisation, the charging trolley is automatically transported from the sterilisation chamber into the cooling chamber.

The advantage: The sterilisation chamber retains its sterilising temperature and whilst the sterilised products are cooling down in the cooling chamber, the sterilising chamber can be recharged. The unique two-chamber system facilitates a particularly economic sterilisation process and high throughput.

Depyrogenisation (Pyrogen sterilisation)

The VHSF 1-4 series dry heat sterilisers are also designed for use in clean room conditions.

This series is distinguished by the airflow, laminar flow technology and the higher sterilisation temperature for reliable depyrogenisation (pyrogen sterilisation).

In the VHSF 1-4 sterilisers, the air flows vertically downwards through the chamber.



Dry heat steriliser VHS 100/150 GMP



Dry heat steriliser VHS 100/150 GMP



Dry heat steriliser VHSF-K1 with optional cooling chamber (two chamber system) for **depyrogenisation**

Programme, function and safety . . .

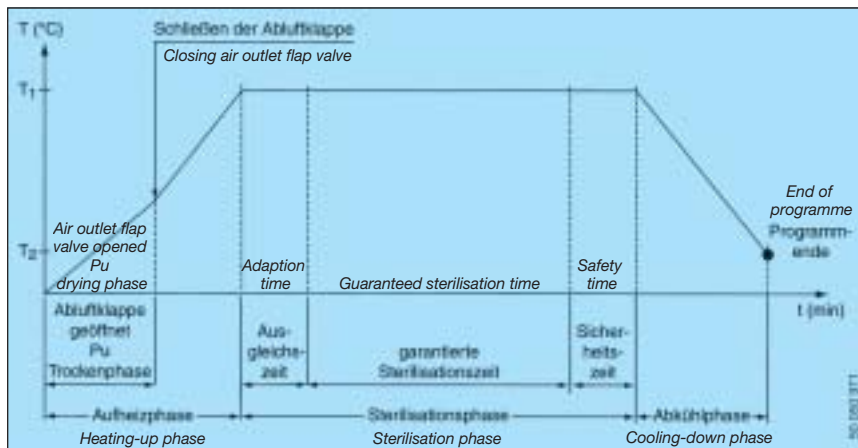
The individual sterilisation programme

Programming is carried out with the assistance of the programme editor via the colour touch panel (alternatively with the aid of the **SIMPATI*** PC software package.

The important process steps are:

- Charging
- Drying (where necessary)
- Heating-up
- Sterilising
- Cooling
- Discharging

Programme example



Operational messages

All operational and process steps are indicated in colour on the operating touch-panel. Parallel signals are given in the sterile area via indicator lamps.

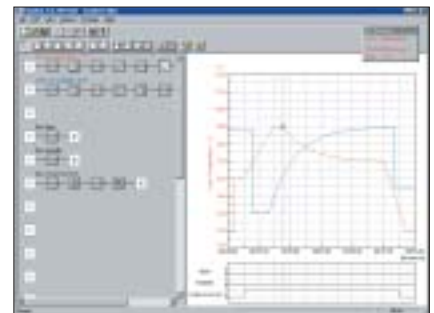


Error messages

All error messages are displayed on the touch-panel. Depending on the type of error, a direct return to the beginning of the sterilisation programme is effected.

The important error messages are:

- Failure of temperature sensors
- Motor overload
- Safety temperature limiter (STB), temperature selection limiter, software temperature limit cut-out (TWB)
- T_{min} of control and working space sensors
- Door locks
- Differential pressure in working space
- Differential pressure in the filter
- Positional error of exhaust air flap valve
- Emergency shut-off.



Safety features

Our sterilisers are manufactured in accordance with state of the art technology. This of course also applies to the safety features.

Significant components:

- Temperature limiter for protection of the system
- Temperature limit cut-out for protection of goods to be sterilised
- Continuous monitoring of overpressure in the sterilisation chamber (no contamination from the non-sterile area)
- Differential pressure monitoring of the high-performance particulate filter
- Serving hatch version with electrically lockable doors – only one door at a time can be opened
- Low surface temperature of outer housing.

... operating and controlling

...with regard to FDA 21 CFR, part 11

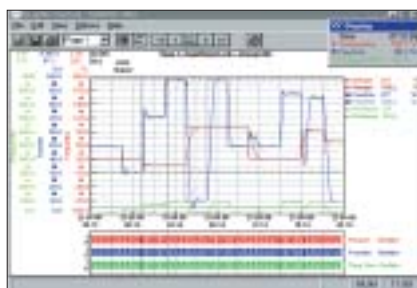
Operating and controlling with **SIMCON/32*-NET**...

All Vötsch dry heat sterilisers are equipped with the operating and control system **SIMCON/32*-NET**.

The **SIMCON/32*-NET** is a self-controlling, digital measuring and control system. The input of process parameters and programmes, as well as the output of actual values, operating and error messages, is carried out by means of a touch-panel.

Special features:

- Comfortable input of process values and programme operation, with graphic presentation of the set and actual values by means of the touch-panel
- Programme memory for up to 100 programmes, with a total of 1,000 sections
- Two-level password protection against unauthorised access
- Integrated limit value temperature control system
- Serial interfaces RS 232 C and RS 485, Ethernet
- Operating and failure messages are shown on the colour touch-panel
- Compatible with Vötsch PC software package **SIMPATI***, for convenient administration and archiving data records
- Special user interface for application in a production environment (simplified process start/stop mode).



Vötsch PC software package **SIMPATI***

The Vötsch software **SIMPATI*** ensures a complete documentation and graphical evaluation

If installed in an optional notebook or PC, the user can create programme profiles and document all process parameters. Parallel to this, the user can make full use of the PC's performance.

Software advantages:

- Up to 32 units can be networked
- Programming and selection of programmes for automatic processes; no costly programming required
- Not only operating and control but also documentation, visualisation and administration of sterilisation process data
- Print graphical presentation of process data and copy into other programmes. Internal interfaces ensure compatibility (with Microsoft Word, Microsoft Paint, Microsoft Excel, National Instruments Labview)
- Access via PC network and your Internet browser
- Transfer of messages per e-mail to an available mail-server (SMTP)
- Reads programmes, production data (product, operator, unit) via bar code (optional)
- Conforms with FDA 21 CFR, part 11.

Technical data...

ISO 7 Class clean room								
Series		VHS 75/100	VHS 100/150	VHS 125/200	VHS 4	VHS 6	VHS 9	VHS 12
Size		75/100	100/150	125/200	4	6	9	12
Internal dimensions								
Width	mm	750	1000	1250	700	700	700	700
Height	mm	1080	1580	2080	700	1050	1050	1300
Depth	mm	750	1000	1250	700	700	1000	1300
External dimensions								
Width	mm	1650	1900	2150	1400	1400	1400	1400
Height	mm	2280	2780	3280	2500	2650	2650	2400
Depth	mm	1065	1310	1565	1020	1020	1320	1620
Effective volume	litre	560	1500	3125	340	550	735	1180
Nominal temperature	°C	250 (300*)	250 (300*)	250 (300*)	250	250	250	250
Heating capacity	kW	16	27	36	11	11	16	19
Connected load	kW	18	29	39	12,5	12,5	17,5	20,5
Rated voltage	V	400	400	400	400	400	400	400
Air flow		←	←	←	←	←	←	←

ISO 5 Class clean room								
Series		VHSF 75/100	VHSF 100/150	VHSF 125/200	VHSF 1	VHSF 2	VHSF 3	VHSF 4
Size		75/100	100/150	125/200	1	2	3	4
Internal dimensions								
Width	mm	750	1000	1250	650	650	1000	1310
Height	mm	1080	1580	2080	1550	1550	1550	1550
Depth	mm	750	1000	1250	650	1310	1310	1310
External dimensions								
Width	mm	1880	2190	2440	1550	1550	1900	2210
Height	mm	2280	2780	3280	3050	3050	3050	3050
Depth	mm	1065	1310	1565	1150	1810	1810	1810
Effective volume	litre	560	1500	3125	660	1330	2130	2660
Nominal temperature	°C	230 (300*)	230 (300*)	230 (300*)	350	350	350	350
Heating capacity	kW	16	27	36	24	24	36	48
Connected load	kW	18	29	39	28	28	40	53
Rated voltage	V	400	400	400	400	400	400	400
Air flow		←	←	←	↓	↓	↓	↓

* Optional
 ← Horizontal air flow
 ↓ Vertical air flow



Quality guarantees

... Basic version, additional equipment

Series Size	ISO 7 Class clean room							ISO 5 Class clean room						
	VHS 75/ 100	VHS 100/ 150	VHS 125/ 200	VHS 4	VHS 6	VHS 9	VHS 12	VHSF 75/ 100	VHSF 100/ 150	VHSF 125/ 200	VHSF 1	VHSF 2	VHSF 3	VHSF 4
Constructional features														
External housing in 1.4301 brushed stainless steel	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Serving-hatch version	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Integrated base frame	—	—	—	●	●	●	—	—	—	—	—	—	—	—
External housing for clean room install.	●	●	●	●	●	●	●	●	●	●	●	●	●	●
GMP sterilisation chamber (jointless)	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Floor version for charging trolley	○	○	○	—	—	—	○	○	○	○	●	●	●	●
Switchbox integrated in external housing	●	●	●	●	●	●	●	●	●	●	—	—	—	—
Separate switch cabinet	○	○	○	○	○	○	○	○	○	○	●	●	●	●
DEHS filter-test support	●	●	●	●	●	●	●	●	●	●	●	●	●	●
DN 25 validation nozzle	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Other features														
Clean room Class ISO 5* sterilis. chamber	—	—	—	—	—	—	—	●	●	●	●	●	●	●
Clean room Class ISO 7* sterilis. chamber	●	●	●	●	●	●	●	—	—	—	—	—	—	—
2-stage fresh air fan	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Circulating air filter (HEPA)	—	—	—	—	—	—	—	●	●	●	●	●	●	●
Fresh air filter (HEPA)	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Exhaust air filter (HEPA)	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Filter monitoring	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Internal pressure monitoring	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Regulating and controlling														
Vötsch-SIMCON/32*-NET	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Vötsch software SIMPATI*	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Electrical door locking – standard unit	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Electrical door locking (with serving-hatch version)	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Electr. shut-off valve for cool. operation	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Accessories														
Qualification documentation	○	○	○	○	○	○	○	○	○	○	○	○	○	○
1-channel temperature recorder	●	●	●	●	●	●	●	●	●	●	●	●	●	●
6-channel temperature recorder	○	○	○	○	○	○	○	○	○	○	○	○	○	○
1.4541/GMP s/steel wire mesh shelves	○	○	○	○	○	○	○	○	○	○	—	—	—	—
Pair of 1.4301/GMP s/steel sup. brackets	○	○	○	○	○	○	○	○	○	○	—	—	—	—
1.4301/GMP s/steel charging trolley (CT)	○	○	○	—	—	—	○	○	○	○	○	○	○	○
1.4301/GMP s/steel transport trolley for CT	○	○	○	—	—	—	○	○	○	○	○	○	○	○
1.4301/GMP s/steel charging tray for CT	○	○	○	○	○	○	○	○	○	○	○	○	○	○
1.4541/GMP s/steel wire mesh shelves for CT	○	○	○	—	—	—	○	○	○	○	○	○	○	○
1.4301/GMP s/steel support. Brackets for CT	○	○	○	—	—	—	○	○	○	○	○	○	○	○

* conforming to DIN EN ISO 14644-1

● standard

○ optional

— not available

We reserve the right to make any technical changes.

Heat technology for all applications ...

Our service programme for specific applications ...

- Dry heat sterilisers
- Hot air tunnels for continuous dry heat sterilisation
- Heating and drying ovens
- Vacuum drying ovens
- Explosion proof drying ovens

... all systems comply with GMP/FDA regulations

Please contact us if you are interested in receiving further information.

A strong, competent and customer-oriented partner ...

- Individual consultation
- Project planning and development
- Production and installation
- Quality control
- Commissioning and instruction
- Documentation (DQ, IQ, OQ)
- Service (calibration, re-qualification, maintenance, spare parts, recycling redundant systems)
- Training and workshops

Further information and representatives world-wide see www.voetsch.info



GMP version vacuum drying oven

Vötsch

Industrietechnik

Vötsch Industrietechnik GmbH
Umweltsimulation · Wärmetechnik

Product Range Heat Technology

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