Design Specification and Function Specification

ADV-12.09.12/2

VAKUTHERM Sterilizer

- -

Function	Name	Division	Position / Company	Date
Author	F. Goulabert	PAAT/PJM	Project manager / SBM	16. Jul. 2012
Reviewed	G. Friesenbichler	PAAT/SVC	Qualification / SBM	

Document history:

Rev.	Date	Description	Author	Reviewed
2	16. Jul. 2012	Update following customer visit 3.7 & 4.7.3: KS Vario connection in the front paneling not necessary (remote control tool used) Sensors are used in the product (no reference bottles) 4.7.5: Analog modem instead of digital	F.Goulabert	G.Friesenbichler
1	26. Apr. 2012	Minimum distance between trays = 10cm Door release at 80°C, not 70°C	F.Goulabert	G.Friesenbichler
0	11. Apr. 2012	First release	F.Goulabert	G.Friesenbichler

Table of Contents

1 GENERAL

This technical specification details the technical properties and the scope of services of the steam sterilizer VAKUTHERM type ADV-12.09.12/2.
This project specification is based on SBM Master Document “Technical specification Type designation: ADV, ADV-F and SDT” Revision 1.0 dated 13.Jan.2012.

1.1 Intended use of the machinery of the type SDT

The sterilizer VAKUTHERM type ADV-12.09.12/2 is used for sterilization of:

- solid and porous goods as well as liquids in open or in pressure- and vacuum-resistant closed containers up to a volume of 50ml (vacuum mode)
- Liquid in open or closed containers (liquid mode)

All liquids should be sterilized in liquid mode for a clear product separation.

1.2 Standards including PED

The performance of the project (design, manufacture and servicing) is approved and certified according to EN ISO 9001

The design and assembly are based on the following technical standards:

- DIN 58950-2: 2011-01: Steam-sterilizers for pharmaceutical products; Technical requirements
- DIN EN 285: 2009-08 Sterilization - Steam sterilizers - Large sterilizers
- EN 60204-1: 6.2007: Electrical equipment of machines
- EN ISO 12100: 2010: Safety of machinery - General principles for design - Risk assessment and risk reduction
- Maximal noise level requested 72 dB
- DIN EN ISO 13850:2008-09: Safety of machinery - Emergency stop
- DIN EN ISO 13849-1: 2008-12: Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design
- 97/23/EC pressure equipment directive, AD2000
- 2006/42/EC Machinery directive
- 2006/95/EC Low voltage directive
- 2004/108/EC EMC directive
- cGMP - EU / FDA
- SBM Lifecycle Model based on GAMP 5

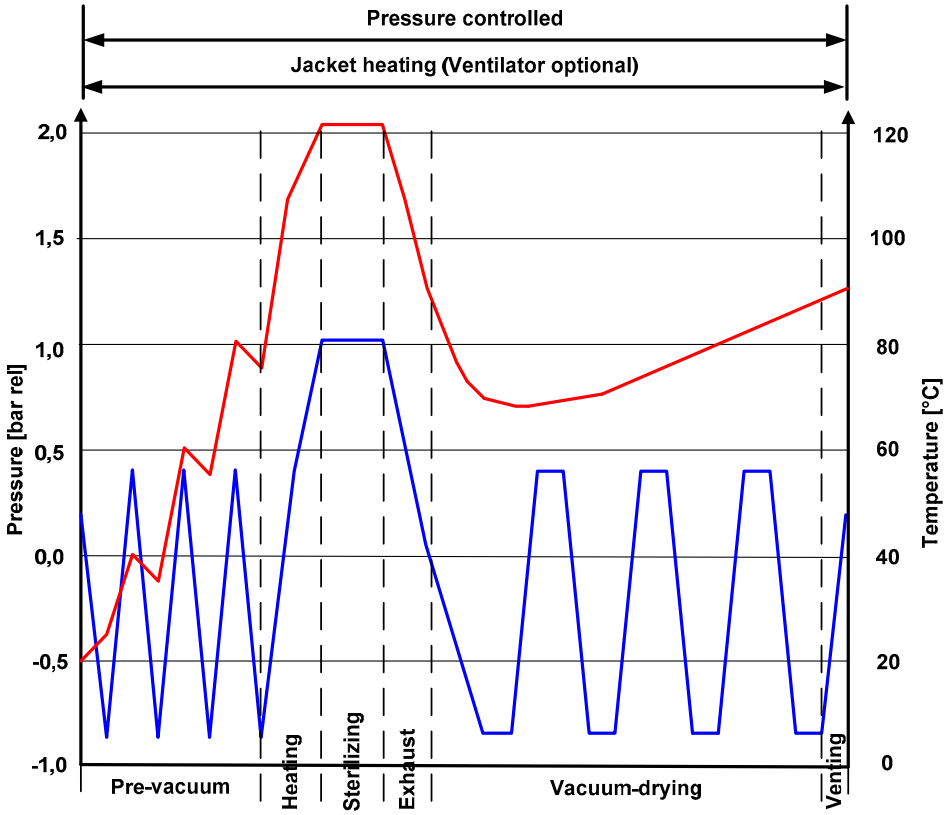
2 DESCRIPTION OF THE STERILIZATION PROCESS

2.1 Fractionated pre-vacuum process with Fractionated vacuum-drying with fan

The following products can be sterilized with this process:

- Solid and porous goods (e.g. machine parts, textiles, glassware, filters, rubber stoppers)
- Liquids in open containers ≤ 50ml (only with single pre-vacuum process)
- Liquids in pressure- and vacuum-resistant closed containers up to a volume of 50ml (only with single pre-vacuum process)

Graphical example



Fundamental recipe sequence:

- Jacket preheating to a pre-set temperature (default 100°C)
- Fractionated pre-vacuum
  Evacuating the chamber till a pre-set pressure.
  “Vacuum pulses” to penetrate the steam into the product (optional recipe step) followed by heating with steam till a pre-set pressure. This procedure is to eliminate air from the chamber and product. Therefore a flawless heating and sterilization process is guaranteed. The amount of vacuum- and steam-pulse cycles is programmable during the creation of a recipe. The jacket is heated with steam.
- Heating the chamber with steam. This causes a rapid and uniform temperature increase. The jacket is heated with steam.
- Sterilizing for a pre-set time at a pre-set temperature with a guaranteed temperature distribution of +2,0/-0,0 °C (in a empty chamber). The sterilization process is pressure controlled. The jacket is heated with steam.
- Pressure release of the chamber (exhaust) till a pre-set pressure.

- Vacuum-drying
  Drying the product by evacuating the chamber till a pre-set vacuum followed by evacuating for a pre-set time. Venting with sterile air till a pre-set pressure followed by a holding time. The amount of vacuum and venting cycles is programmable during the creation of a recipe. The option “Fractionated vacuum-drying” is implemented to optimize the drying result for special applications (e.g. rubber stoppers). This option can be activated in a recipe if required. The jacket is heated with steam.
- Pressure release of the chamber (venting) till atmospheric pressure

The fan can be turned on or off separately for every recipe step when creating a recipe.

This procedure is a typical recipe sequence.
The flexible creation of a recipe allows combining recipe steps with the corresponding parameters, to apply to the requirements and relevant standards.

The following combinations are possible (examples):
- Single pre-vacuum process - Vacuum-drying
- Single pre-vacuum process - Fractionated vacuum-drying
- Fractionated pre-vacuum process - Vacuum-drying
- Fractionated pre-vacuum process - Fractionated vacuum-drying (like described before)
- Single pre-vacuum process - Pressure release (exhaust) till atmospheric pressure

Switch-points can be set with the following limits:

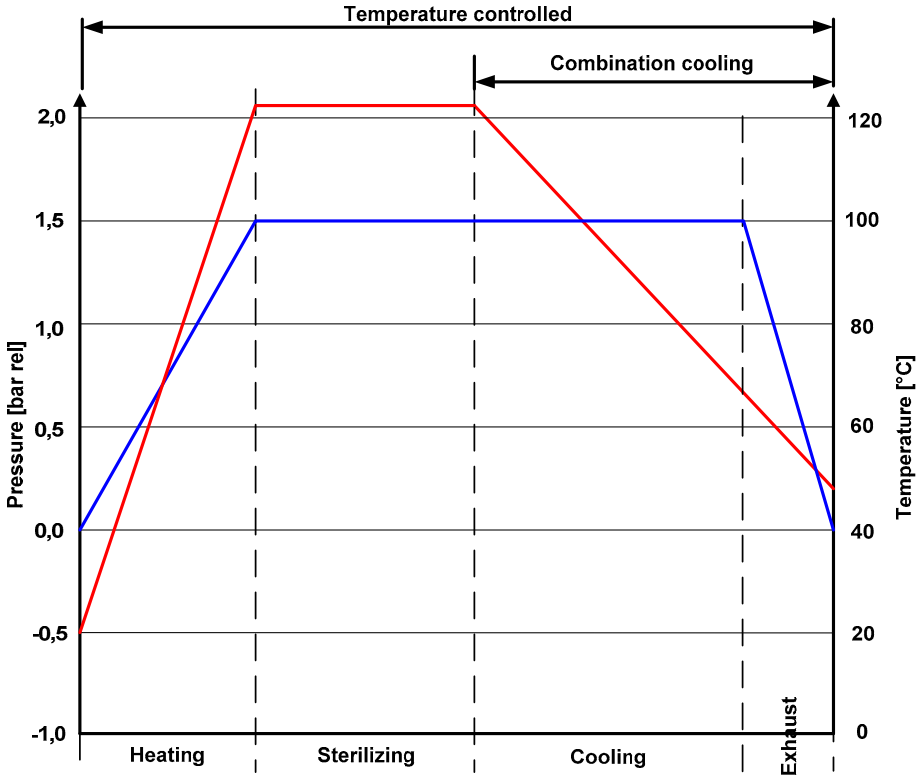
Heating and sterilization temperature	110,0 – 137,0 °C
Amount of vacuum pulses	1 – 9
Chamber pressure	-0,98 – +2,50 bar(g)
Sterilization time	1 – 999 min
Temperature ramp (heating)	0,0 – 10,0 °C/min
Pressure ramp (increase and decrease)	0,0 – 1,0 bar/min
Fan	On / Off

2.2 Steam-air mixture process with combination cooling

The following products can be sterilized with this process:

- Liquids in open or closed containers

Graphical example



Fundamental recipe sequence:

- Jacket preheating to a pre-set temperature (default 100°C)
- The chamber is heated with steam which is circulated by (a) built-in fan(s). Therefore a rapid and uniform temperature increase is guaranteed. A regulated differential support pressure is created with compressed air during heating to protect the product containers against deformation.
- Sterilizing for a pre-set time or F_0-Value with a pre-set support pressure with a guaranteed temperature distribution of ±1,0 °C in a empty chamber and ±0,5 °C inside the product. The sterilization process is temperature controlled.
- Cooling the chamber by circulating the steam-air mixture and to admit cooling medium to the internal heat exchanger and the jacket. A differential or a fix pressure regulation for the support pressure during the cooling phase can be set in the recipe. The support pressure prevents damage to the product containers in the cooling phase.
- Pressure release of the chamber (exhaust) till atmospheric pressure

This procedure is a typical recipe sequence.
The flexible creation of a recipe allows combining recipe steps with the corresponding parameters, to apply to the requirements and relevant standards.

Switch-points can be set with the following limits:

- Heating and sterilization temperature 110,0 – 125,0 °C
- Chamber pressure -0,98 – +2,50 bar(g)
- Sterilization time 1 – 999 min

- o F_0-Value 0 – 99,9 min
- o Temperature ramp (heating and cooling) 0,0 – 10,0 °C/min
- o Pressure ramp (increase and decrease) 0,0 – 1,0 bar/min
- o Chamber temperature for cooling end (temperature sensor in the product or 0,0 – 125,0 °C

2.3 Bowie-Dick Test

According to DIN EN 285 the Bowie and Dick test was developed to test for successful air removal of sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack.
Remaining air in the test indicator (e.g. referable to an inefficient air removal stage, the presence of an air leak during the air removal stage or the presence of non-condensable gases in the steam supply) are circumstances which can lead to failure of the test.

To use a positive Bowie and Dick test result, the Bowie and Dick test recipe should be programmed with the same recipe steps and recipe parameters till the recipe step sterilizing as the production recipe.

The necessary test indicators are not in the scope of supply.

Switch-points can be set with the following limits:
- o See chapter “Fractionated pre-vacuum process with Fractionated vacuum-drying”

2.4 Vacuum test

The vacuum test (based on the DIN 58950 respectively DIN EN285) is used to test the chamber for tightness.

Fundamental recipe sequence:
- o Evacuating the chamber till a pre-set pressure of < 70mbar
- o Stabilization time between 5min and 10min
- o Holding time of 10 min where the chamber pressure is not allowed to rise more than 13mbar.
- o Venting till atmospheric pressure

The evaluation of the test is done automatically.
An alarm message is shown when the vacuum test is negative.

Switch-points can be set with the following limits:
- o Chamber pressure -0,98 – +0,30 bar(g)
- o Time 0,0 – 999,9min

2.5 Automatic inline filter sterilization

The automatic inline filter sterilization is used to sterilize the air filter in the compressed air line.

Fundamental recipe sequence:

- Heating the filter with steam till a pre-set temperature (121,1 °C)
- Sterilizing for a pre-set time (15min)
- Cooling the filter with compressed air till a preset temperature.

An alarm message is shown when a failure occurred during the sterilization process.

Switch-points can be set with the following limits:

- Heating and sterilization temperature 0,0 – 137,0 °C
- Sterilization time 1 – 999min

3 MECHANICAL DESIGN

3.1 Dimensions, weights and utility consumption

The following points are quoted in the attachment 1 “Key data standard ADV/ADV-F/SDT”.

- Dimension of useable space inside the chamber (height, width, depth[mm])
- Dimension of the inside of the chamber (height, width, depth[mm])
- External dimensions(height, width*, depth[mm])
- Loading height[mm]
- Weight (empty, pressure test[kg])
- Minimum opening for transportation (height, width[mm])
- Amount of fans **

* Depending of switch cabinet position
** Optional

The consumption and pressure requirements are guidelines and are based on average loading.
See the attachment 2 “Media and interface list” for the utility consumption.

3.2 Chamber made of 1.4404 (316L), 0,8µm, polished

Chamber: cubical design with rectangular door opening(s) and a jacket for heating and cooling (when implemented)

Design pressure and temperature:

- Maximum working pressure chamber: 1,0 / +2,5 bar(g)
- Maximum working pressure jacket: 0,0 / +2,5 bar(g)
- Design pressure chamber: -1,0 / +3,0 bar(g)
- Design pressure jacket: 0,0 / +3,0 bar(g)
- Design temperature: 150 °C

Material and surface finish:

- Material: 1.4404 (316L)
- Interior surface: Ra ≤ 0,8 µm; polished
- The bottom of the chamber is designed with a decline to the chamber drain. Removal of all condensate drops on the chamber bottom can not be guaranteed (e.g. vacuum drying time to short)

The chamber is insulated with an 80mm thick asbestos free mineral wool and a 0,8mm thick aluminum sheet.
For qualification and validation purposes an aseptic blind flange DN50 is provided to lead PT-100 sensors or thermo elements into the chamber
The chamber is protected against overpressure with a safety valve with a set-point pressure of 3,0 bar(g).
The jacket is protected against overpressure with a safety valve with a set-point pressure of 3,0 bar(g).
All utility lines connected to the chamber are fixed with aseptic-flanges according to DIN 11864-2.
The inside of the chamber can be easily cleaned.

3.3 Chamber door(s) made of 1.4404 (316L), 0,8µm, polished

Material and surface finish:

- Material: 1.4404 (316L)
- Interior surface: Ra ≤ 0,8 µm; polished

The automatic horizontal sliding door(s) are driven by an encapsulated linear drive.
The sealing between the chamber and the door is done with a silicone o-seal.
The door(s) is (are) insulated with asbestos free mineral wool and a cover plate made of 1.4301.

3.4 Chamber construction with fan

The ceiling and the sides of the chamber are covered with paneling which protects the product for drops of condensate. It also ensures a targeted streaming of the chamber atmosphere.

Special constructed rails are available to guide the loading cart into the chamber.
The rails can be removed for maintenance purposes.

- Material See chapter “Chamber”

3.5 Sterilizer frame

The sterilizer is mounted in a frame.
This frame supports the chamber and other components and forms the complete service area.

- Material (frame parts): 1.4301

3.6 Service area loading side right

The service area is on the right side of the chamber and accessible via a service door provided by the customer.
The service area is only to be entered by authorized personnel.

3.7 Sterilizer paneling up to sterilizer height on operating side(s)

The sterilizer is equipped with stainless steel paneling on the operating side(s) up to sterilizer height (see attachment 1 “Key data standard ADV/ADV-F/SDT“)
Paneling on the sides are not provided.
The paneling is hygienically designed and can be easily cleaned with a suitable cleaning agent (GMP compliant)
Note: an additional connection to the KS-Vario multi-transmitter was first foreseen in the paneling. This is not necessary anymore: instead of, an Ethernet switch will be installed in the switch cabinet in the service room. Thus it is possible to connect a laptop to the network and take control of the sterilizer through VNC tools.

Material and surface finish:

- Material: 1.4301
- Surface: Ra ≤ 1,2 µm

3.8 Clean-room concept – double gas tight design; aluminum

The sterilizer is used as a hatch-sterilizer between rooms with different clean-room classes. A barrier (bio-seal) is installed **at both sides**.
The gaps are sealed with silicone.

- Material: Aluminum

The special door interlocks due to the gas-tight design are described in chapter “Door functions”.

Pressure switch and function:

Pressure switch	Function
1 piece in the door sealing piping for the loading side door sealing	Triggers an alarm when the door sealing pressure is low for the loading door
1 piece in the door sealing piping for the unloading side door sealing	Triggers an alarm when the door sealing pressure is low for the unloading door

3.9 Available utilities on site

Clean steam

- Nitrate ≤ 0,2 ppm
- Conductivity ≤ 1,1 µScm-1
- TOC ≤ 0,5 mg/l
- Pressure 3 – 4 barg

Process air

- Pressure ~ 7 barg

Cooling water

- Pressure 5 - 6 bar
- Temperature 10 – 20°C

Power supply

- 3 x 380V +N+PE, tol. -6 + 10%
- 10 amp
- 50 Hz

3.10 Mechanical main components

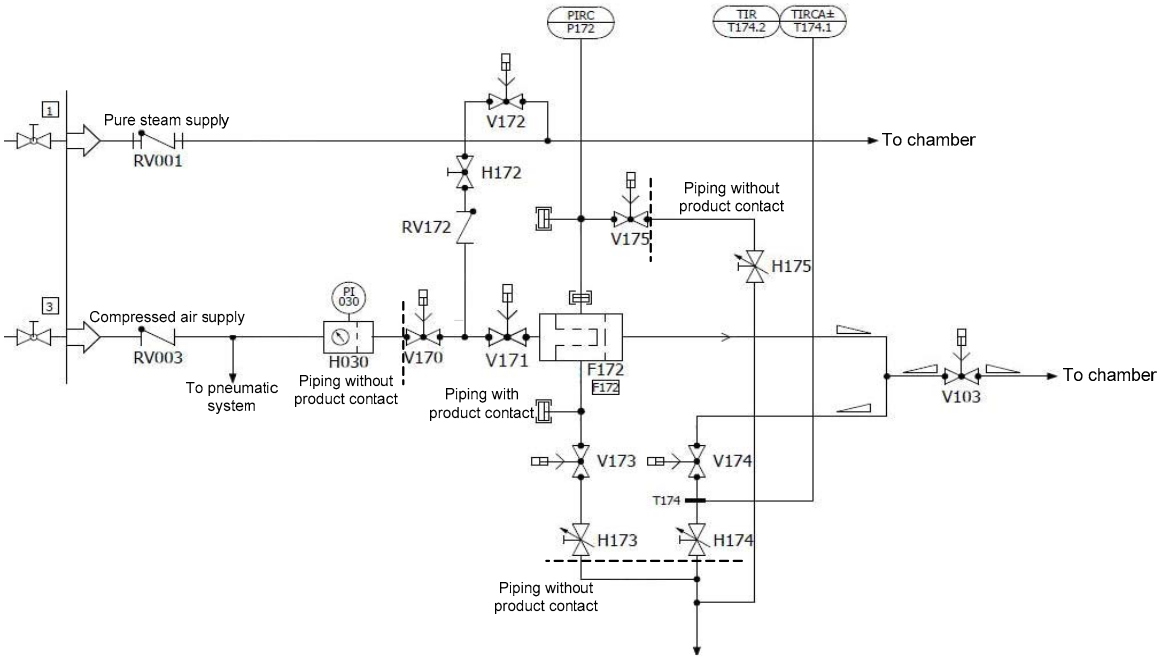
3.10.1 Sterile filter with housing made of stainless steel, automatic filter sterilization and connections for external WIT

A sterile filter with a absolute hold-back-rate of 0,2 µm is used for compressed air.
The connections of the housing are weld-ends and clamp couplings.
Enough space is available to perform a filter change.
The filter change can be activated with a button on the visualization.

Material:

- Housing 1.4404/1.4435
- Filter element PTFE

Schematic view of the filter system



The equipment consists of the necessary piping including fittings as well as the corresponding software to perform an automatic inline filter sterilization of the compressed air filter.
See chapter “Automatic inline filter sterilization” for the recipe sequence.

Connections (2 Clamps) and additional fittings (valves) are provided in the service room to perform an integrity test with external equipment (not scope of supply). The test is started with a button on the visualization.

Temperature sensors and function:
Double PT-100 sensors Class AA according to EN60751 are used.

Temperature sensor	Function element 1	Function element 2
1 piece in the filter system (fix) as a filter sensor	-Used as a switch-point for heating end and sterilization begin; -Triggers an alarm when the sterilization temperature is too low or too high; -Used as a switch-point for cooling end; -Data recording for the batch protocol (when implemented)	-Redundant data recording for the recorder (when implemented, otherwise not used)

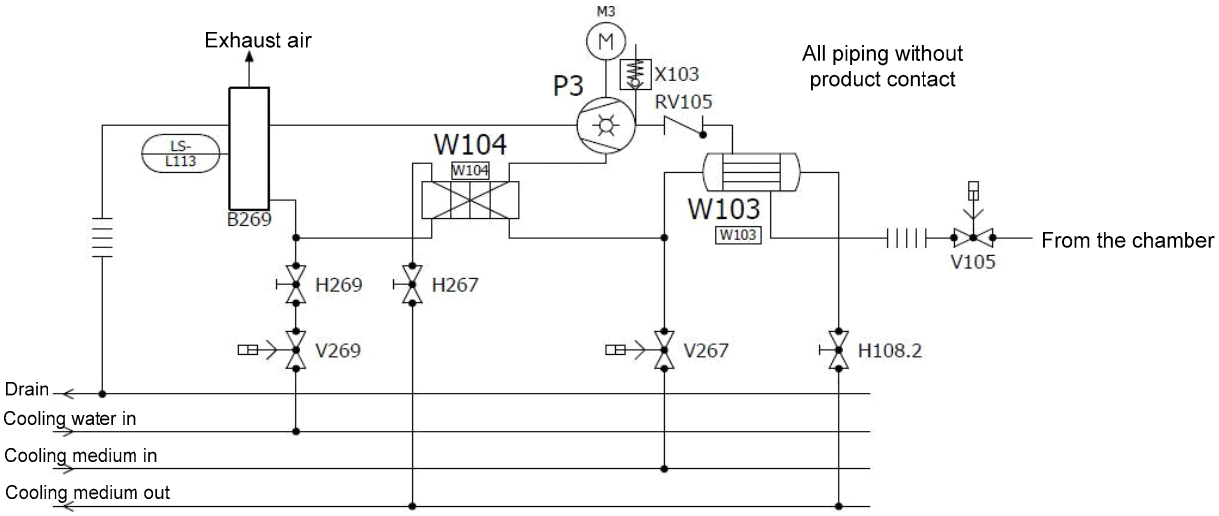
Pressure sensor and function:
Class 0.6 pressure sensors are used

Pressure sensor	Function
1 piece on the filter housing as a filter pressure sensor	-Regulates the pressure in pressure controlled steps

3.10.2 Vacuum pump type Speck made of gray cast iron with water safe circuit

The vacuum pump is used to depressurize the chamber.
The pump is equipped with a liquid separator to separate the liquid and the gas on the pressurized side. The pressureless liquid separator is filled up to a defined level (switch-point: level switch). The liquid is flown during operation trough a plate heat exchanger (closed system). The heat exchanger is connected to the on-site cooling water supply which can dissipate the heat generated by the vacuum pump system. When the vacuum pump stops, eventual excess liquids are discarded via the overflow of the liquid separator into the drain. The liquid separator is automatically filled when the level inside the separator is falling short. A condensate cooler is integrated in the vacuum piping.

Schematic view of the vacuum pump system



Material and manufacturer:

- o Manufacturer: Speck
- o Cavitation protection: Vacuum check valve directly on the pump
- o Material pump: Gray cast iron (GG25)
- o Material liquid separator: 1.4301

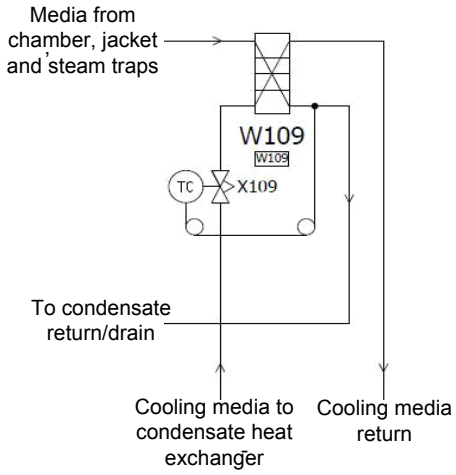
Level switch and function:

Level switch	Function
1 piece on the liquid separator	-Used as a switch-point for filling the liquid separator -Used as a switch-point to discard the eventual excess liquids when the vacuum pump stops

3.10.3 Condensate cooling with heat exchanger

Steam respectively condensate from the chamber and jacket is discarded via a plate heat exchanger to the condensate return / drain. The condensate is cooled by the heat exchanger and thermostat valve. The heat exchanger is cooled via a thermostat valve and therefore the condensate is cooled before entering the drain.
Heat exchanger material: 1.4401 / 316

Schematic view of the condensate cooling system



3.10.4 Drain with air gap

The air gap between the drain of the sterilizer and the on-site drain is 60mm. The air gap guarantees that no germs in the on-site drain can contaminate the piping system of the sterilizer.

3.10.5 Fan

The radial fan(s) is (are) mounted on the chamber ceiling for an intensive circulation of the air inside the chamber.
Material: 1.4404
The amount of fans depends on the chamber size and is quoted in the attachment 1 “Key data standard ADV/ADV-F/SDT“.
The drive shaft of the fan is sealed with a shaft sealing.

3.10.6 Jacket cooling as closed system with no discard

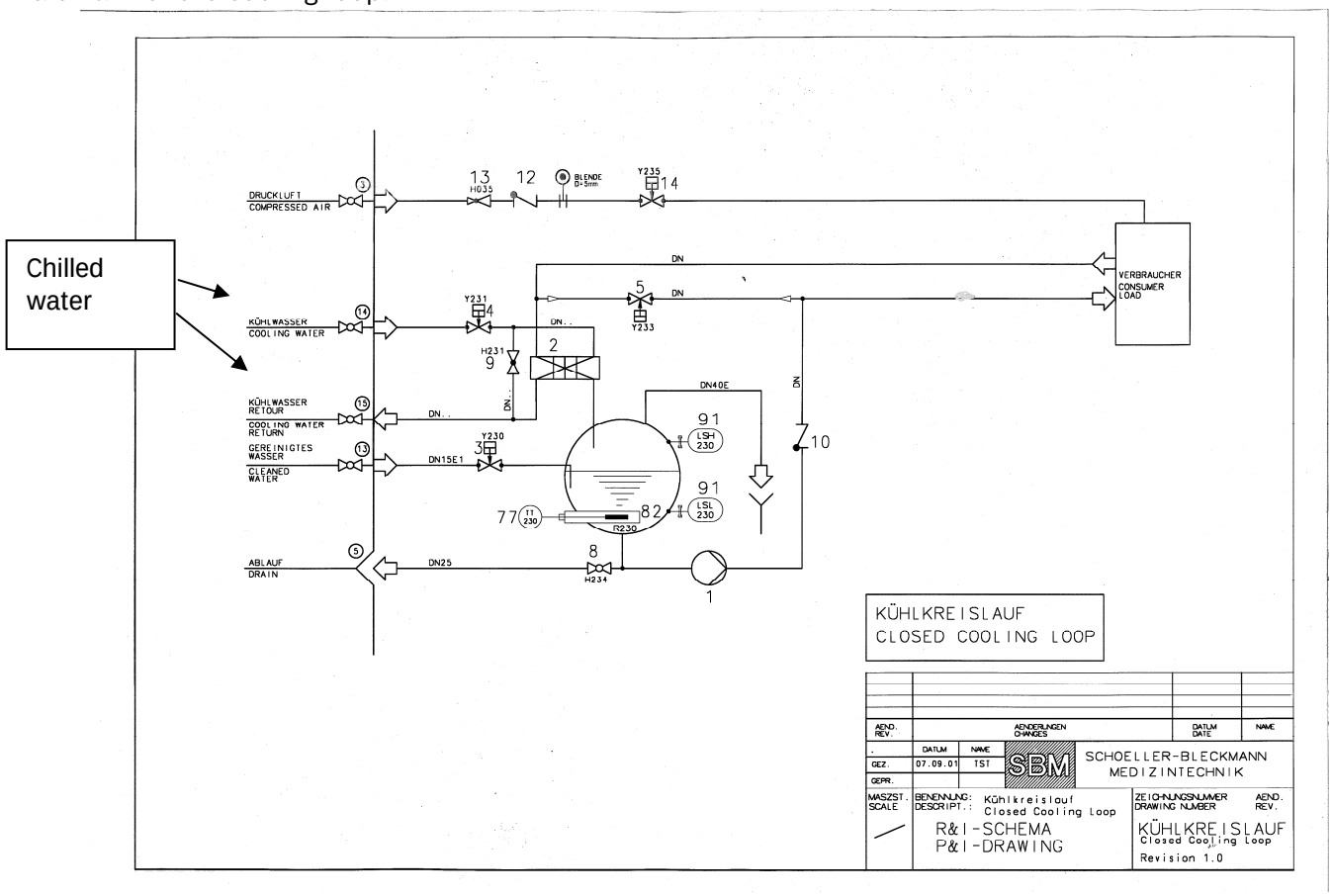
Cooling water is flown through the jacket. The cooling is active until a pre-set temperature is reached. The relevant temperature sensor for triggering the switch-point is depending on the sterilization process (see chapter “Description of the sterilization process”).
In this system no cooling water is discarded to the drain. After the cooling phase, the remaining water left in the jacket is pushed out with compressed air to the cooling water return system (no cooling water wasted). The jacket draining will be done for a pre-set time.
The cooling process is enhanced by a small compressed air flown through the chamber maintaining the support pressure (when implemented) and the circulation of the air inside the chamber by the fan(s) (when implemented).

3.10.7 Closed secondary cooling loop with tank

In order to save cooling water the jacket cooling device is additionally equipped with a closed cooling water loop. This equipment consists of a buffer tank, level controlled, a chilled water cooled plate heat exchanger, a circulating pump and the required pipe work system with valves. Further all required control devices for a full automatic operation are provided.

The required equipment will be installed in the maintenance area of the autoclave.

Draft P&ID of the cooling loop:



3.10.8 Steam supply with two utilities

The chamber and jacket are supplied separately with steam with different qualities.
See the attachment 2 “Media and interface list” for the utility consumption.

3.10.9 Support pressure equipment

The sterilizer is equipped with the necessary piping including fittings as well as the corresponding software to generate the correct support pressure.
Depending on the sterilization mode a support pressure is necessary to prevent damage to the product containers respectively to avoid boil over of liquids.

Lamellar heat exchangers on both sides of the chamber are used for cooling. These heat exchangers are admitted with cooling water during the cooling phase.
The design pressure of the heat exchangers is 10,0 bar(g) and are protected against overpressure with a safety valve with a set-point pressure of 9,0 bar(g)

Material:

- Lamellar heat exchanger inside the chamber Piping class PC02 (1.4404 / 1.4408)
- Piping outside of the chamber Piping class PC01 (1.4301 or better)

3.10.11 Steam sampling point, not implemented

The option steam sampling point is not implemented in this project.

3.10.12 Base frame without drip-pan

The installation of the sterilizer on a plain floor is done with a base frame.
The option base frame with drip-pan is not implemented in this project.

3.11 Piping

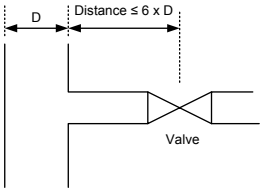
3.11.1 General

The sterilizer is equipped with piping system that's annotated in regulatory requirements regarding equipment for steam vessels and relevant piping system including all aggregate, fitting and instruments.
The internal piping is according to DIN EN ISO 1127.
The connections of the sterilizer to the customer utility piping are defined in the attachment 2 "Media and interface list".
The connection between sterilizer and the customer utility piping is done by the customer.
Welding joints in the piping are executed as much as possible with orbital-welds.
Piping with piping class PC01 can be crimped according to SBM standards.
Valves with weld-ends are used as much as possible.
All utility supply lines at site to the sterilizer have to be equipped with manual shut off valves by the customer.
The piping is supported sufficient and are connected free from tension.
The piping is installed with a slope of ≥1%.
The utility piping is designed to withstand the temperatures and pressures inside the piping.
All valves are pneumatically actuated open/close valves with an optical position indicator.

3.11.2 Piping and components with contact to the product made of piping class PC03

As components in contact with the product all components in steam pipe to the chamber, the compressed air pipe after the sterile filter and the discharge piping from the chamber till the first valve are defined. All connections are welded. The 6-D regulation is ensured.

Definition of the 6-D regulation:



Piping:

Material:	1.4435 (316L)
Material roughness:	< 0,8µm
Gaskets:	EPDM, PTFE, Gylon
Certificates:	EN10204-3.1 and FDA possible See chapter "Welding documentation"

Valves:

Material:	1.4435 (316L)
Material roughness:	< 0,6µm
Gaskets:	EPDM, PTFE, Gylon
Certificates:	EN10204-3.1 and FDA possible See chapter "Welding documentation"

Pressure gauge with diaphragm seal:

Material:	1.4571 (316Ti) and 1.4435 (316L)
Gaskets:	Diaphragm seal: 1.4435 (316L)
Certificates:	EN10204-3.1 and FDA possible See chapter "Welding documentation"

A detailed component list can be seen at SBM

3.11.3 Piping and components without contact to the product made of piping class PC01

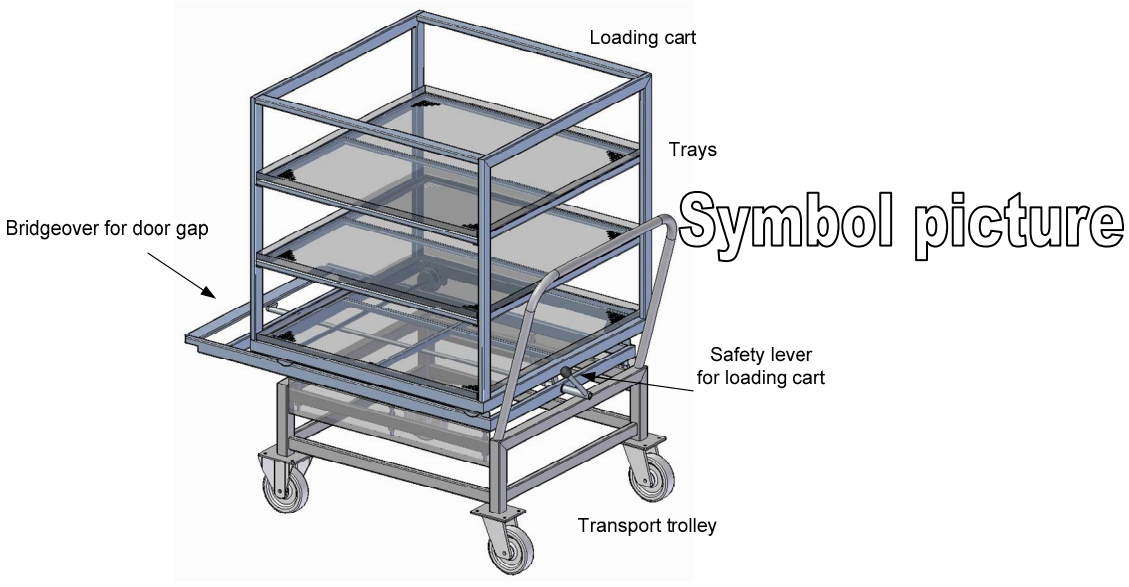
All connections are welded, clamped respectively screw-fastened.

Piping:	
Material:	1.4404 (316), 1.4401 (316), 1.4571 (316Ti), Gray cast iron
Material roughness:	Steel bright metal, no defined roughness
Gaskets:	EPDM, PTFE, Gylon, metallic sealed
Certificates:	See chapter “Welding documentation”
Valves:	
Material:	1.4401 (316) and 1.4408 (316)
Material roughness:	Steel bright metal, no defined roughness
Gaskets:	EPDM, PTFE, Gylon
Certificates:	See chapter “Welding documentation”

A detailed component list can be seen at SBM

3.12 Handling system

Loading and unloading the sterilizer is done with a transport trolley and a loading cart.
The product can be placed on the perforated trays on the transport trolley.
The transport trolley with the loaded loading cart is docked to the sterilizer. The transport trolley is designed to bridge the door gap. The loading cart can be pushed into the sterilizer when the transport trolley has been unlocked with the safety lever.
A second transport trolley can be used to unload the loading cart on the unloading side (two-door model) or the same transport trolley is used on the loading side (one-door model)



3.12.1 Transport trolley (2 pieces)

The transport trolley consists of a special section tube frame with two steering and two guiding rollers.

The transport trolley is adjustable in height and can be locked for a safe transport of the loading carts.

Material:

- Special section tube frame: 1.4301 (304)
- Rollers: Plastic
- Dimensions: Depends on usable space and loading height of the sterilizer (see attachment 1 “Key data standard ADV/ADV-F/SDT”)

3.12.2 Loading cart (1 piece)

The loading cart is used to intake the product and to transfer it into the chamber. It consists of a special section tube frame on which the perforated trays are placed.
The height of the trays is adjustable: minimum distance 10cm.

Material:

- Tubular frame: 1.4404 (316L)
- Trays: 1.4404 (316L)
- Rollers: 1.4404 (316L)
- Material roughness: < 0,8µm
- Dimensions: Depends on usable space of the sterilizer (see attachment 1 “Key data standard ADV/ADV-F/SDT”)

3.12.3 Trays for the loading cart (4 pieces)

The trays are perforated and can be placed into the loading cart.

Material:

- Trays: 1.4404 (316L)
- Material roughness: < 0,8µm
- Dimensions: Depends on usable space of the sterilizer (see attachment 1 “Key data standard ADV/ADV-F/SDT”)

4 ELECTRICAL DESIGN

4.1 Installation technology

4.1.1 Switch cabinet as stand-alone type made of steel panel

The lockable switch cabinet is placed separately on the loading side. All energized components, electrical control components as well as operating and recording components are built in the switch cabinet front door.
The switch cabinet and therein laid cable channels are dimensioned in a way, that after completion of the cabling, a spare of at least 20% is available.

Switch cabinet material:	Steel sheets varnished in RAL7035 (gray)
Switch cabinet protection class:	IP55
Switch cabinet dimensions (mm):	H x W x D = 2000 x 800 x 600

The switch cabinet is equipped with a built-in fan and a filter to ensure that the temperature inside the cabinet doesn't exceed 40 °C. A switch cabinet climate control (when placed in a clean-room area) is available for gas-tight designed sterilizers.
A disturbance free switch cabinet illumination and a power socket are available. The switch cabinet illumination is triggered by a motion controlled sensor. This power circuit is protected with a 6A circuit breaker which is connected before the main power switch.
The cabling is short circuit proof till the circuit breaker.
All terminals and components in this circuit are labeled clearly and durably fixed with warning signs.
All terminals and solenoid valves cabinets are located behind the front paneling in the service room. A good accessibility is guaranteed.
All terminal boxes are labeled with identification plates.
The cables of the motors are not laid in a collecting pipe. The separation of the power and signal cables is adhered to.
All analog signal cables connection are screw connected.
Terminal clamps for the outer cable, neutral wire and the earth wire are available inside the switch cabinet.
The switch cabinet is equipped with a main power switch. This main switch complies with the requirements stated in the EN 60204-1 regulation.
The earth and the neutral wire inside the switch cabinet are starred wired. PE and N -clamps are used for this purpose.
The power supply is monitored for power failure and phase sequence by a power monitoring relay.

4.1.2 Power supply

The power supply of the sterilizer is delivered from the on-site main distributor.

o	Line current:	3/N/PE 400VAC 50Hz	
o	Main power circuit:	3/N/PE 400VAC 50Hz	
o	Control power circuit	1/N/PE 230VAC 50Hz	is powered via a safety transformer when not available on-site
		24VDC	is powered via a power supply
o	Anticipated short circuit current:		Power consumption < 30kW min 10kA eff.

The over current protection (primary fuse), the power supply cable and the installation of the cable is not in the scope of supply of SBM.
All control and visualization components as well as all sensors and signal devices are connected to an uninterruptible power supply (UPS)

Customer requirements AC power supply (from the DIN-EN 60204-1, IEC 60204-1:2005)

Steady state voltage:	0,9 to 1,1 of nominal voltage.
Frequency:	0,99 to 1,01 of nominal frequency continuously; 0,98 to 1,02 short time.
Harmonics:	Harmonic distortion not exceeding 10 % of the total r.m.s. voltage between live conductors for the sum of the 2nd through to the 5th harmonic. An additional 2 % of the total r.m.s. voltage between live conductors for the sum of the 6th through to the 30th harmonic is permissible.
Voltage unbalance:	Neither the voltage of the negative sequence component nor the voltage of the zero sequence component in three-phase supplies exceeding 2 % of the positive sequence component.
Voltage interruption:	Supply interrupted or at zero voltage for not more than 3 ms at any random time in the supply cycle with more than 1 s between successive interruptions.
Voltage dips:	Voltage dips not exceeding 20 % of the peak voltage of the supply for more than one cycle with more than 1 s between successive dips.

Information:
It is recommended that Annex B of the EN 60204-1 is used as a part of design specification to facilitate an appropriate agreement between the user and the supplier(s) on basic conditions and additional user specifications related to the electrical equipment. Those additional specifications are to:

- provide additional features that are dependent on the type of machine (or group of machines) and the application;
- facilitate maintenance and repair; and
- improve the reliability and ease of operation.

4.1.3 Installation

Heavy current installations are installed in separate cable trays or channel systems.
Low voltage current e.g. communication and measurement cables, safety installations, optic fiber cable as well as pneumatic installations are properly separated in separate cable trays and channel systems.
The cable trays and channel systems of the sterilizer are installed in a way to minimize obstructions or stumbling points and therefore maximize the accessibility.
The cable trays and channel systems are filled for 80% maximum.
A dividing wall is used when separate cable trays or channel systems is not possible. The accessibility of the cable trays and channel systems is guaranteed.
The connection cable between switch cabinet and sterilizer is in the scope of supply and is installed by SBM.
The lead through inside the switch cabinets are done with flange plates.

4.1.4 Wiring without single-wire designation

An adequate installation of the wiring is respected. Inductive, capacitive or magnetic cross interference of signals are avoided by taking adequate measures.
Shielded cables are used when, despite separate wiring, a threat of cross interference exists.
Shielded cables are also used for frequency convertors (including control wires).
For control wires (except for flat cables), measurement and communication cables and temperature resistant cables numbered leads are used.
Special cables e.g. temperature resistant cables are used when necessary.
Low voltage and high voltage cables are not laid in the same cable channels.
Separate lines are installed for motors and control lines.

Cables / wires (cable type)	Ölflex-110
	LiYCY
	Unitronic

4.2 Protective measures electrical equipment

4.2.1 Earthing / potential equalization

Measures according to EN 60204 regarding potential equalization are implemented.
All casings of the electrical equipment and the sterilizer are connected to the earth wire system.
Removal of a component doesn't influence the earth wire system.
The frame and the mounting plates of the incoming feeder terminal are directly connected with the earth wire input terminal. Screwable, fitted with electrical components, doors and adjoining switch cabinet parts are connected to each other with earth straps. The size and the patency of the earth cabling are considered.
The connection points of the earthing system are not used for other purposes (e.g. connecting or mounting of other components).
The connection points of the earthing system are secured again loosening and labeled.
The main earthing point of the sterilizer is connected with a potential equalization terminal strip, whereby a proper potential equalization is guaranteed.
The connection between main earthing point of the sterilizer and the potential equalization is not in the scope of supply of SBM.

4.2.2 Protection against electric shocks

The electrical equipment is protected against electric shocks according to EN 60204-1.
All parts are covered according to protection class "IP2X" or "IPXXB" or "Finger-proof".
Parts that are remaining energized when the main switch is switched off are labeled clearly and durably fixed with warning signs (not on the cable channel cover).

4.2.3 Control circuit

The AC (Alternating Current) control circuit is supplied via a single-phase transformer.
The transformer is protected against over current by circuit breakers with the corresponding characteristics on the primary and secondary side. These are used for AC as well as DC (Direct Current) circuits.
Transformers and power supplies are according to the regulations and the test voltages stated in the EN 61558 and EN 50178.
The control circuits are protected selective against over current with the use of a circuit breaker.
Every control circuit is protected against overload current.

4.2.4 Electrical motors

Motors with the following power supply are used:
- o Door motor nominal voltage 3/PE 400VAC, 50 Hz (one motor for each chamber door)
- o Vacuum pump nominal voltage 3/PE 400VAC, 50 Hz
- o Each fan motor with a nominal voltage 3/PE 400VAC, 50Hz (when applicable, see chapter “Fan”)
- o Circulation pump for the jacket cooling system with a nominal voltage 3/PE 400VAC, 50Hz (when applicable, see chapter “Jacket cooling”)

The motors are hardware protected.
The circuit breakers of the motors are monitored. An alarm message is shown on the visualization when a circuit breaker is triggered.

Energy efficiency class:
The motors are categorized in energy-efficiency classes IE1, IE2 and IE3 according to IEC 60034-30. The country specific statutory regulations regarding the energy efficiency classes are adhered to.

4.3 Visualization and operating instrumentation

4.3.1 Loading side instrumentation

The touch panel PC and all instrumentation are mounted on the paneling in an ergonomically height and can be easily maintained.
- o SIEMENS Simatic Panel PC 677B with a 15,1“-TFT-Touch-Bildschirm
- o The keyboard with integrated trackball is not integrated in the paneling
- o Printer (type and configuration see chapter “Printer”)
- o Recorder (type and configuration see chapter “Recorder”)
- o Emergency stop button that can be locked
- o Key switch “CONTROL POWER OFF/ON”
- o Buzzer
- o Button “BUZZER ACKN.”
- o Button “E-STOP ACKN.” (acknowledge emergency stop)
- o Key switch “STEP OVER BUTTON” to step over recipe steps

4.3.2 Loading side instrumentation integrated in front paneling with switch cabinet as stand-alone type

The visualization and instrumentation mounted in the front paneling. The switch cabinet is placed according to the installation plan. No further instrumentation is mounted on the front paneling.

4.3.3 Unloading side instrumentation

All instrumentation are mounted into the paneling in an ergonomically height and can be easily maintained.
- o SIEMENS operating panel “TP177B 4” as visualization
- o Emergency stop button that can be locked

4.3.4 Door drive safety switch, lockable

The door motor(s) is (are) equipped with a safety switch when the chamber height is ≥ 1450mm. This safety switch “DOOR DRIVE OFF/ON” disconnects the power supply of the door motors to prevent door operation.

4.3.5 Jumo Logoprint 500 paper recorder

A 6-channel Jumo Logoprint 500 recorder is used to record the temperature and pressure values.

Type:	70.6030/15/888/888/00/22/020.259
	21 CFR Part 11 conformity, comply with the specification of DIN EN 58950
Dimensions (mm):	144 x 144 (Panel cutout dimensions: 138 x 138)
Recorder:	6 analog inputs
	Power supply 24VDC, UL certified
	Lithium battery for buffer storage#
	8 binary inputs
Paper:	100mm endless

Recorded data: Program start, program end, start sterilization and sterilization end.

4.3.6 Recorder configuration

Recorder configuration:

Channel	
1	Pressure chamber
2	Temperature permanent drain
3	Temperature product 1
4	Temperature product 2
5	Temperature product 3
6	Temperature product 4

4.3.7 Network Printer

A HP printer is used to print out relevant data.
The printer is connected through the Ethernet network.
See chapter “Data acquisition - Protocols”

4.4 Hardware configuration

4.4.1 Control system

The sterilizer is controlled with a control system developed by SBM. The PLC is responsible for controlling the sterilizer and the recipes.
This control system is based on a SIEMENS S7-300 PLC with a 315-2DP CPU and a 512kB Memory Card as well as multiple digital & analog in- and output modules (S7-300 Series).
The in- and output modules are connected with a front plug and are labeled with bit-addresses. The communication with the operating panels, valve terminals, the visualization, etc is done with the integrated DP interface (Profibus) with a bitrate of 1.5MBaud.

4.4.2 Visualization with PC and TP177B

The sterilizer is operated via the visualization on the loading side with a Simatic Panel PC677B Core2Duo with at least 1,5GB RAM with a 15,1” TFT-Touchscreen including keyboard with integrated trackball.

The sterilizer can be operated on the unloading side with a SIEMENS TB177B 4” with an alphanumeric display (e.g. alarm messages) and a membrane keyboard.
The unloading door can be operated with the TB177B as well as basic observation purposes like read out current process step, common alarm indication, chamber pressure indication.

The display’s of the PC677B and the TP177B as well as the membrane keyboard are dust and water proof (IP65). The operating panel and all instrumentation are mounted at an ergonomically height and can be easily maintained.

4.4.3 Emergency power supply integrated in the switch cabinet

An uninterrupted power supply (UPS) with 750VA/450W is installed inside the switch cabinet to maintain power for the control system and visualization in case of a power failure.

4.5 Measurement and control equipment

4.5.1 General

The analog signals from and to the control system are in a range of 4 - 20 mA except for the PT100 temperature sensors (standard PT100 signal). A wire break is recognized by the system and a corresponding alarm is shown on the visualization. The power supply of the sensors is done with 24V. All analog signals are handled with a multi purpose transmitter (a microprocessor controlled KS-Vario). The communication between multi transmitter and PLC is done with Profibus.

4.5.2 Used sensors for the type SDT

Longer sensor cables are foreseen, so that it is possible to get the sensors through the measuring or validation flange to the loading side (for calibration purposes)

Temperature sensors and functions:
Double PT-100 sensors Class AA according to EN60751 are used: straight sensors, length 100mm

Temperature sensor	Function element 1	Function element 2
1 piece in the chamber drain (fix) as a drain sensor	ADV Mode: -Used as a switch-point for heating end and sterilization begin; -Triggers an alarm when the sterilization temperature is too low or too high; -Data recording for the batch protocol (when implemented) SDT Mode: -No function	ADV Mode: -Redundant data recording for the recorder (when implemented, otherwise not used) SDT Mode: -No function
1 piece in the chamber (flexible) as a safety thermostat	ADV Mode: -No function SDT Mode: -Door release when the chamber temperature is <80 °C -Used to regulate and as a switch-point for cooling end when the load temperature sensors are defective	ADV Mode: -No function SDT Mode: -Temperature indication on the visualization -Used as a switch-point for cooling end when the load temperature sensors are defective
4 pieces in the chamber (flexible) as a load temperature sensor	ADV Mode: -No function SDT Mode: -Used as a switch-point for heating end and sterilization begin (switch-point = T_{min}); -Triggers an alarm when the sterilization temperature is too low or too high; -Used as a switch-point for cooling end (switch-point = T_{max}); -Used as a F_0-value switch-point for sterilization end (switch-point = F_0-value$_{min}$); -Data recording for the batch protocol (when implemented)	ADV Mode: -No function SDT Mode: -Redundant data recording for the recorder (when implemented, otherwise not used) SDT Mode: -No function
1 piece in the chamber (fix) as a chamber sensor	ADV Mode: -No function SDT Mode: -Regulates the chamber temperature -Data recording for the batch protocol (when implemented)	ADV Mode: -No function SDT Mode: -Redundant data recording for the recorder (when implemented, otherwise not used)

- Additional temperature sensors see chapter “Sterile filter” (when applicable)

Pressure sensors and functions:
Class 0.6 pressure sensors are used

Pressure sensor	Function
1 piece on the chamber as a chamber pressure sensor 1	ADV Mode: -Regulates the chamber pressure; -Triggers an alarm when the chamber pressure is too high; -Used as a switch-point in pressure controlled steps; -Data recording for the batch protocol (when implemented) SDT Mode: -Regulates the support pressure; -Triggers an alarm when the chamber pressure is too high; -Data recording for the batch protocol (when implemented)
1 piece on the chamber as a chamber pressure sensor 2	ADV Mode: -Regulates the chamber pressure (when chamber pressure sensor 1 is defective); -Triggers an alarm when the chamber pressure is too high (when chamber pressure sensor 1 is defective); -Used as a switch-point in pressure controlled steps (when chamber pressure sensor 1 is defective); -Redundant data recording for the recorder (when implemented) SDT Mode: -Regulates the support pressure (when chamber pressure sensor 1 is defective); -Triggers an alarm when the chamber pressure is too high (when chamber pressure sensor 1 is defective); -Redundant data recording for the recorder (when implemented)
1 piece on the jacket as a jacket pressure sensor	ADV and SDT Mode: -Regulates the jacket pressure; -Triggers an alarm when the jacket pressure is too high;

- Additional pressure sensors see chapter “Sterile filter” (when applicable)
  “Utility monitoring”

Pressure switches and functions:

Pressure switch	Function
2 pieces on the chamber with a pressure indication inside the switch cabinet as a chamber pressure switch	-Door release when the chamber pressure is <0,15 bar(g)

- Additional pressure switches see chapter “Clean-room concept”
  “Utility monitoring”

Pressure gauges and functions:

Pressure gauge	Function
1 piece on the chamber	-Indication of the chamber pressure
1 piece on the jacket	-Indication of the jacket pressure
1 piece on each utility supply conduct	-Indication of the utility pressure

Level switch:

- Used level switch: -None
  -additional level switches see chapter “Vacuum pump - Water safe circuit” (when applicable)

4.5.3 Nameplates, signs and tag numbers

The components are clearly labeled with the P&ID designation according to the SBM standard.
If possible, the tag number is placed close to the component and not on the components itself.

4.6 Calibration

The sterilizer is designed to ensure the accessibility to the different sensors for the necessary calibration and maintenance work.
The used sensors can be easily removed. The length of the connection cable is sufficient to calibrate the sensors without dismounting.
The calibration is done for the complete measuring chain.
The analog values can be read from the visualization.
A pre-calibration is done during commissioning by a SBM technician. The calibration is done with equipment that can be traced to national standards.
The first calibration is done on-site under supervision of the customer. The calibration is done by trained SBM technicians.

Remark: The customer is responsible for the necessary calibration equipment.

4.7 Software Configuration

4.7.1 Control system

The PLC software is programmed with SIEMENS system software Step 7.
The necessary software respectively Runtime and library-licenses to run the sterilizer is in the scope of supply.
The PLC software is engineered and programmed according to GAMP5 guidelines based on the SBM life cycle model.
The maximum load of the PLC is defined with 60%.
The PLC is programmed in a way to remain 30% of the digital in- and outputs, timers, memory usage and so forth, as spare.
The communication cables between operator panels are monitored with a watchdog-signal. An alarm message is shown on the visualization when a communication failure occurs.
Predefined basic settings are recovered during a new start-up of the PLC. The functions of the PLC are set in a predefined operating mode. The communication is synchronized independently after a new start-up.
The software interlocks are programmed in the control system.

4.7.2 Visualization with PC (WinCC7 on Windows 7) and TP177B

The visualization software on the loading side (WinCC) is programmed with SIEMENS WinCC7 and Windows 7.
The visualization software on the unloading side (TP177B) is programmed with SIEMENS WinCC flexible.
The necessary software respectively runtime and library-licenses to run the sterilizer is in the scope of supply.
The visualization software is engineered and programmed according to GAMP5 guidelines based on the SBM life cycle model.
The measured and displayed analog values have sufficient resolution to correspond with the demanded accuracy.
The high resolution guarantees a calibration within the predefined tolerances.
Every sensor and actuator is displayed on the visualization with the corresponding P&ID designation.
The logged in user is shown in every menu of the visualization.
The date/time format is DD/MM/YYYY, hh:mm:ss (24h).
The process menu can be entered with 2 clicks via the easily build-up menu structure.
The analog values can be displayed in a graph.
The basic settings of the graph are predefined to cover the complete working range of the sensors.

Recipe editor:

- Creating recipes (sterilization programs) with the available recipe steps (e.g. prevacuum, heating, and sterilizing) by trained employees without a program device.
- Changing the sterilization product can be done easily by adapting the parameters in existing recipes.
- Maximum input limits are defined to reject illogical values. An info screen pops up when an input value is rejected. The value is automatically set to the nearest allowable value.

An I/O-Test-menu is available to test the digital & analog in- and outputs.

4.7.3 Interface overview

Designated interfaces: Potential-free (floating) contact for common alarm

An Ethernet switch is foreseen in the electrical cabinet in order to connect an external laptop on the network.

4.7.4 Option data transfer to an external control system; not implemented

This option is not implemented in this project.

4.7.5 Option analog modem

A analog modem is installed for remote diagnosis and servicing of the control system

5 SYSTEM FUNCTIONS

5.1 Operating modes

The following operating modes are implemented:

- Off (sterilizer is shut down and in a safe state)
- Production: Functions, programs etc. are started manually and handled by the control system automatically.
- Service: I/O Test for testing components (valves, end switches, temperature sensors, pressure sensors, etc.) as well as setting for user-management and calibrating / adjusting temperature sensors.

5.2 Commissioning

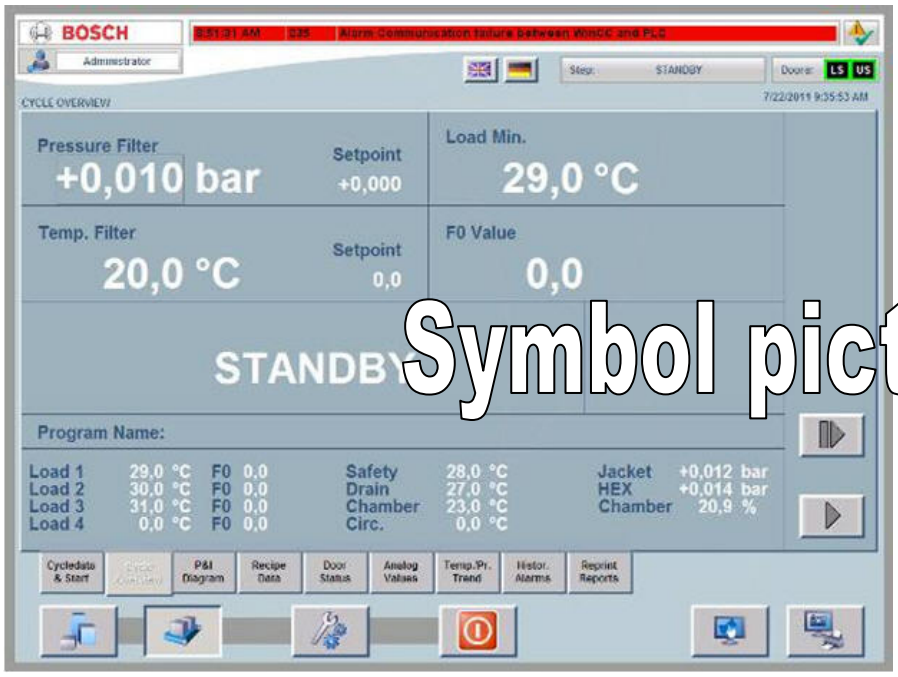
The control system and the visualization starts up automatically when the sterilizer is switch on (main power switch and control power key switch).
The operator is automatically asked to log in when the when the visualization has been started up completely. The operator is asked to enter his username and password when the button “Log in” has been pressed. Additionally the SIEMENS virtual keyboard appears.

5.3 Door functions – two-door model, gastight design

Both doors opens and closes automatically considering the door interlocks by pressing the corresponding button.
The doors can’t be opened simultaneous during normal operation.
After the loading the loading door will be closed. When the loading door is completely closed and no alarm is active the start of a recipe after choosing a recipe (loading of a recipe into the PLC) is released. The status of the sterilizer (shown on the visualization) changes to “Ready for operation” and the program can be started. The door sealings are pressurized with the use of compressed air. The status of the sterilizer changed to “Program end” when the program has been executed. The unloading door can be opened with the used of TP177B on the unloading side when no process relevant alarms occurred during the process. The door sealings are not pressurized with compressed air anymore.
The unloading door can be opened and closed freely.
The loading door can only be opened to reload the sterilizer when the unloading door is completely closed. The door sealing is retracted with the use of an air jet pump to prevent damage to the door sealing during the opening and closing process of the door. The unloading door is blocked when process relevant alarms occurred during the process. The loading side door can be opened, only.
The handling process of non sterile products, when products are loaded and unloaded from the loading side, is to be determined by the customer with a SOP.

5.4 Visualization features of PC

The production menu is shown when the start-up process is completed.
The first level menu contains the recipe menu, the production menu and the service menu. Multiple second level menus can be selected by pressing the corresponding buttons.



5.4.1 Production menu

The following functions can be done in the production menu:

- o Batch data and start — Enter the production batch data and load a recipe into the PLC
- o Overview — Display of the recipe specific analog values (temperature, pressure) and information about the sterilization process (recipe step, switch-point, etc)
- o Recipe data — Display of the recipe data that's been loaded into the PLC with the according parameters.
- o Door status — Display of the door status and door sealing(s) The loading door can be operated.
- o Analog values — Display of the analog values (temperature and pressure)
- o °C / bar graph — Display of the analog values (temperature and pressure) in a graphical illustration.
- o Historical alarms — Display of the historical alarms in a long-term archive.
- o Reports — Reprint the batch protocol, the alarm protocol, the °C / bar graph and the audit trail protocol.

5.4.2 Recipe menu

New recipes can be created and exciting recipes can be edited in the recipe menu with the use of a recipe editor. Also recipe can be deleted in this menu.
Due to the possibility to add a maximum of 60 recipe steps, the recipes described in chapter "Description of the sterilization process" can be created.
The recipes are saved in a MS SQL-database on the Panel PC and therefore an almost unlimited amount of recipes can be saved. The appearance of the recipe editor is process-dependent when

multiple processes are implemented e.g. filter sterilization to accommodate process-dependent settings.
Recipes must have a unique name for identification.
Umlaut (mutated vowel), special- or empty characters are not allowed.
All changes in recipes can be commented and are trailed (recipe audit trail). A recipe that has been edited can't be overwritten and has to be saved with another recipe name.
The original recipe is not deleted.

The following functions can be done:

- Create recipe — Create a new recipe
- Edit recipe — Edit an exciting recipe
- Print recipe audit trail — Print a recipe change protocol on the Windows standard printer.
- Print recipe — Print a recipe on the Windows standard printer.
- Release recipe — Only released recipe can be loaded into the PLC and started
- Unrelease recipe — Only unreleased recipe can be edited.

5.4.3 Service

The following functions can be done:

- Release numbers — Display of the software release numbers and project information.
- Administrator menu — Settings for the WinCC user-management. Configure Simatic Logon and the Windows Policy Editor can be opened.
- I/O Test — Display of the analog and digital in- and outputs and the possibility to test all digital outputs (actuators like valves, lights, etc.).
- Windows Explorer — The Windows explorer is opened (to make a backup on a USB-stick, etc.)
- Close WinCC Runtime — The WinCC Runtime is closed

5.4.4 Shut down computer

The visualization is closed down and the computer is turned off automatically.

5.4.5 Cleaning function

A menu is opened where unwanted actions can be avoided during the cleaning procedure of the touch screen.

5.4.6 Screenshot

A screenshot can be made of the visualization. The screenshot is automatically printed on the Windows standard printer.

5.5 Visualization options of PC

5.5.1 Bilingual visualization with Latin alphabet

All menus, screens, displays, entries as well as the batch protocol are programmed bilingually. The language can be changed by pressing a button on the visualization.

The language of the audit trail protocol, graph print outs and external applications like Simatic Logon (Event log viewer) are created in the main language, only.

Definition language:

- Main language: French
- Second language: English

5.6 Shut down

The sterilizer can be switched off with the key-switch “CONTROL POWER ON/OFF” when the visualization can been shut down completely. Then the main power can be switched off.

6 SAFETY

Definition “Safe state”:
- All digital outputs are disconnected.
- All motors are stopped and all valves are deactivated (to initial state)
- The visualization and the inputs of the PLC remain active

6.1 Alarm messages with PC

All alarms are generated in to PLC and send to the visualization. The alarms are displayed on the visualization and sorted according time of occurrence.

There are two alarms groups:
- Alarms that can be acknowledged simultaneously (only on the visualization)
- Alarms that has to be acknowledged separately (e.g. power failure, emergency stop)

Alarms are display until they are deactivated and/or acknowledged by an operator)

Alarm indication:
- Visualization
- Acoustic signal on the loading side

Alarms are displayed on the visualization as follows: Number / Status / Alarm text

The alarm text consist of a tag number of the component in question (when applicable) and a small description of the malfunction

The alarms are numbered with 1 to 3-digits without leading zeros (e.g. 1, 10 or 100)

The alarms marked indicated as follows:
- A new alarm is activated and has not been acknowledged[color representation: red]
- A alarm that not active anymore and has not been acknowledged[color representation: blue]
- A still active alarm that has been acknowledged[color representation: green]

Additionally the alarms are saved in the log-term archive. The last 1000 alarms are archived. The alarm archive can be display on the visualization.

6.2 Safety interlocks of the types ADV-F and SDT as two-door model with gas-tight design

All safety interlocks of the door are engineered according to the TÜV type examination certificate No.: PED B 19004B. Named place: TÜV Bayern SZA

The doors can only be operated when the sterilizer is in the status Standby, Ready for operation of Program end. A software interlock prevent that both doors can be open(ed) simultaneously.

Additionally hardwired interlocks are implemented via safety relays which can not be deactivated by a user:
- The compressed air supply of the utility valves is interrupted by a pneumatic switch when one of the doors is open. Therefore the utility valves to the chamber are closed and no utility can enter the chamber. This function is activated until both doors are completely closed.
- Two chamber pressure switches and a software interlock prevents that one of the doors is opened when the chamber is pressurized. The door can be opened when the chamber pressure is < 0,15 bar(g)

- A safety thermostat permits only the door opening when the temperature is lower than 80°C.

  WARNING:
  The temperature must be measured from inside the product. A plausibility check (editable in the recipe) alarm will be activated, when the sensor is not place in the load.

- Each door is equipped with a safety-bar to detect obstacles during the closing movement. The door opens immediately when an obstacle is detected.
- The door sealing pressure balance system (chamber pressure is lead to the door sealing) is activated when the compressed air supply pressure is too low and the door sealing pressure can't be maintained. Two (one on each side working independently) "B-valves" (normally open) are used to maintain door sealing pressure even in case of a power failure or when the emergency stop is activated.

These interlocks are active in all processes and can't be deactivated.
Safety valves: see chapter "Chamber" and "Internal heat exchanger" (when applicable). All rotating parts are touch protected.

6.3 Emergency stop

The sterilizer is equipped with (a) emergency stop button(s).
See the chapter "Visualization and operating instruments" for the location and amount of emergency stop buttons.
Emergency button(s) with a key-switch (to unlock) and a protection guard to prevent unwanted activation of the emergency stop button are used.
Deactivation of the emergency stop is not possible without a key.
The sterilizer is brought into a "Safe state" when the emergency button is pressed.

Acknowledge the emergency stop:
- Acknowledge the acoustic alarm
- Unlock the emergency stop button (key required)
- Press the "E-STOP ACKN." button
- Acknowledge the alarm (on the loading side visualization)

The cycle is continued at the point of interruption when the emergency stop has been acknowledged successfully. Self start without acknowledging the alarm is not possible!
The signal and indication instruments remain active during a emergency stop.

6.4 Utility monitoring with alarming for piping class PC01 and PC03

Pressure gauges are mounted on all utility piping to read out the actual utility pressure.
Pressure switches are mounted on utility piping with piping class PC01, pressure sensors are mounted on utility piping with piping class PC03.
An alarm is shown on the visualization when a utility pressure is lower than a pre-set value.
A utility failure has no direct effect on the cycle. Follow-up alarms can occur caused by a utility alarm (sterilization under temperature, step time limit exceeded, etc) and therefore can have indirectly an effect on the product.
The cycle is continued (with no follow-up alarms) when the utility pressure is restored. The follow-up alarms that may occurred have to be handled separately (alarm dependent).

6.5 Power failure with integrated UPS and PC

The sterilizer is brought in a safe-state when a power failure occurs.

The build in (in the switch cabinet) UPS powers the next components:
- o Visualization
- o Control system plus the digital & analog inputs.

The cycle is continued at the point of interruption when the power is restored. Self start without acknowledging the alarm is not possible!
Programs, setting, parameters, etc will not be lost during a power failure.

The PC is closed down automatically when the UPS reaches a critical condition (pre-set time).

The PLC remains in a safe-state when the power is restored till the PC is manually started and all alarms are acknowledged. The cycle is continued at the point of interruption.

6.6 Breakdown of process relevant sensors for the type SDT

The sterilizer is brought in a safe-state when both chamber pressure sensors break down and the cycle must be advanced manually.

Temperature sensor failure:

Vacuum mode	Reaction
o Drain temperature sensor defective	Element 1: -Display of the alarm; -The recipe steps heating and sterilizing are aborted; -No data recording for the batch protocol (when implemented); Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown
o One or all load temperature sensors defective	Element 1: -Display of the alarm(s); Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown
o Safety thermostat temperature sensor defective	Element 1: -No display of the temperature inside the switch cabinet; Element 2: -Display of the alarm
o All load temperature sensors (element 1) and the safety thermostat temperature sensor (element 2) defective	-Display of the alarms and no display of the temperature inside the switch cabinet; -No data recording on the recorder (when implemented) Remark: no alarm message shown Display of the safety thermostat alarm
o Chamber temperature sensor defective	Element 1: -Display of the alarm; Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown

Liquid mode	Reaction
o Drain temperature sensor defective	Element 1: -Display of the alarm; Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown
o One load temperature sensor defective	Element 1: -Display of the alarm; -the unit is controlled by the remaining sensors Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown
o All load temperature sensors defective	Element(s) 1: -Display of the alarms; -The recipe steps heating and sterilizing are aborted and the next recipe step is started; the safety temperature sensor takes over the function of the load temperature sensors in the cooling step -No data recording for the batch protocol (when implemented); Element(s) 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown
o Safety thermostat temperature sensor defective	Element 1: -Opening the door at program end is not possible for safety reasons Element 2: -Display of the alarm
o Both load temperature sensors (element 1) and the safety thermostat temperature sensor (element 2) defective	-Display of the alarms; -The recipe steps heating and sterilizing are aborted and the next recipe step is started; a safety cooling time (45min) is started in the cooling step; the chamber pressure is regulated to a pre-set value of 2,0 bar; the door(s) can't be opened when the sterilizer is in Program end because of safety reasons
o Chamber temperature sensor defective	Element 1: -Display of the alarms; -The recipe steps heating and sterilizing are aborted and the next recipe step is started; a safety cooling time (45min) is started in the cooling step; the chamber pressure is regulated to a pre-set value of 2,0 bar; the door(s) can't be opened when the sterilizer is in Program end because of safety reasons Element 2: -No data recording on the recorder (when implemented) Remark: no alarm message shown

6.7 Process failure – Under- respectively Over-temperature for the types ADV-F and SDT

The reaction of the sterilizer is set in the recipe parameters when a under temperature alarm occurs in the sterilizing step:

- o Stop: The time is paused till the sterilization temperature is recovered.
- o Reset: The time is reset and starts again when the sterilization temperature is recovered.
- o Abort: The sterilization step is aborted
- o None: No reaction, only a alarm is shown on the visualization

The reaction of the sterilizer is set in the recipe parameters when a over temperature alarm occurs in the sterilizing step:

- o Abort: The sterilization step is aborted
- o None: No reaction, only a alarm is shown on the visualization

Temperature sensor used to trigger an Under- respectively Over-temperature:

Vacuum mode: Drain temperature sensor
Liquid mode: Load temperature sensor

For every recipe step a limit time can be set. An alarm is set when this time is exceeded. The reaction of the sterilizer is set in the recipe parameters. This reaction is only active in the steps heating and sterilizing

During heating and sterilizing:

- o Abort: The sterilization step is aborted
- o None: No reaction, only a alarm is shown on the visualization

In all other recipe steps:

- o None: No reaction, only a alarm is shown on the visualization

6.8 Step over button (abort program) for the type ADV with cooling, ADV-F and SDT

An authorized operator can step over recipe steps till Program end is reached with the use of a key-switch when a failure occurred during a cycle.
Only safety relevant recipe steps (e.g. cooling) can't be stepped over.
The recipe step filter cooling can't be step over when a automatic filter sterilization is implemented (see chapter "Automatic inline filter sterilization")

6.9 Access protection PC

The requirements of the user-management according to 21 CFR Part 11 is adhered to.
The programming, parameterization and operating the visualization is access protected. Several access levels are available where users can be assigned to. The user-management can be set locally on the Touch Panel PC or via a network server and is based on the Windows user-management. Creating and activating new operators can only be done by administrators. The operators can log in to the visualization by entering the user-name and password according to the user-management. The input of the password is encrypted (********).The logged in user is automatically logged out after a pre-set time that's been set by the administrator. The user is forced to change his password after a pre-set time (set by the administrator). Access to the system is blocked as long as the user didn't change his password. This is not applicable for the administrator him-self. The old password must be entered and the new password must be entered and repeated when the user is changing his password. Passwords are (when the user changed his password) not visible for the administrator.

The user can be assigned to different user-groups with different authorities. A maximum of 99 user-groups are possible. Every function of menu can be set or reset for every user-group. Users can be assigned to one of the groups by the administrator. Every menu is password protected.

The next password-levels are defined:

Level	User-group	User-group description
1	WinCC_User	The user is authorized to access the menus for a normal operating of the sterilizer
2	WinCC_Validation	This user has the same authorization as the Operator and is also authorized to edit recipes and parameters, release and unrelease recipes and re-print protocols
3	WinCC_Service	This user is authorized to access the menus for a normal operating of the sterilizer and is also authorized to enter the Service menu and the submenus (shut down WinCC runtime is not possible)
4	Administrators	System generated user-group No restrictions (administrator rights)

The authorizations can be on menus, buttons and individual input fields. All log-in and log-out actions are recorded by the audit-trial with time indication and can be seen and exported with the Simatic Logon Eventlog Viewer.

6.10 Backup Restore / Disaster Recovery of the visualization PC

Fundamental disaster recovery procedure:

- PLC: Upload the application software with the use of a laptop or a memory card.
- Touch Panel PC: The disaster recovery procedure is part of the documentation

A detailed description is part of the documentation

7 Data acquisition – Protocols of the visualization PC with local or network printer)

7.1 General requirements

The control system protocols all relevant process values like:

- Measured values, analog values
- Actual set points
- Actual limit values (over- and under-temperature, limit times)
- Alarms
- Audit Trail data

The relevant data (e.g. analog values of the sensors) are handled by the CPU of the control system and send to the visualization in pre-defined intervals. The data is displayed and stored in the Touch panel PC. The protocols are automatically printed or can be manually printed when cycle has ended. The memory capacity of the Touch Panel PC is sufficient to save all protocols for at least 10 years. The electronic data can't be edited or manipulated due to the database storage (MS SQL - Database)

7.2 SQL requests through the network

Requests on the SQL database as far as the PC is included in Elaiapharm's network.
The installation of the database security is configured in order to connect to Elaiapharms AD-server using the normal windows-domain-logon; username and password when logging on to the database.

7.3 Printer protocol

7.3.1 Batch protocol

Parts of the protocols:

- o Batch protocol: Start data, process and batch data and stop data (evaluation)
- o Graph protocol: Temperature and pressure values displayed in a graph.

The protocols that are printed out automatically after a cycle can be selected in the recipe parameters when the recipe is created. An interval of the data logging on the protocols can selected (10sec, 30sec, 1min or 5min). The data is saved in a MS SQL - Database can be re-printed afterwards.

Layout of the protocols: SBM Standard protocol

Example:

Start data: Page 1

(Title)

ev. Logo **Batch Protocol Steri xx** **Page x/y**

(Header)

Program name	:	e.g. Test 1	Title block text 1	:	xxxxxxxxxx
Recipe name	:	e.g. Testname 1	Title block text 2	:	xxxxxxxxxx
Start time	:	YYYY-MM-DD hh:mm:ss	Title block text 3	:	xxxxxxxxxx
Operator at cycle start	:	e.g. Operator 1	Comment field 1	:	xxxxxxxxxx
			Comment field 2	:	xxxxxxxxxx
Title block field 2	:	xxxxxxxxxx	Comment field 3	:	xxxxxxxxxx

---

(Recipe Info)

Recipe name	:	e.g. Testname 1		
Mode	:	e.g. ADV, SWS, SDR, VT, FLT		
Created by	:	e.g. Pharmazeut 1	Date/Time: YYYY-MM-DD hh:mm:ss	
Released by	:	e.g. Pharmazeut 2	Date/Time: YYYY-MM-DD hh:mm:ss	

(Recipe data) The recipe data is displayed here in a tabular format

(Recipe parameter) The recipe parameters are displayed here in a tabular format

Run record:

(Title)

ev. Logo Batch Protocol Steri xx Page x/y

(Header)

Program name	:	e.g. Test 1	Title block text 1	:	xxxxxxxxxx
Recipe name	:	e.g. Testname 1	Title block text 2	:	xxxxxxxxxx
Start time	:	YYYY-MM-DD hh:mm:ss	Title block text 3	:	xxxxxxxxxx
Operator at cycle start	:	e.g. Operator 1	Comment field 1	:	xxxxxxxxxx
			Comment field 2	:	xxxxxxxxxx
Title block field 2	:	xxxxxxxxxx	Comment field 3	:	xxxxxxxxxx

(Run record)

Time HH:MM:SS	Analog value 1 [Unit]	Analog value 2 [Unit]	Analog value 3 [Unit]	Analog value x [Unit]
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	--- Step change ---(2nd Recipe step)			
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Value	Value	Value	Value
hh:mm:ss	Program end			

Stop data:

(Title)

ev. Logo Batch Protocol Steri xx Page x/y

(Header)

Program name	:	e.g. Test 1	Title block text 1	:	xxxxxxxxxx
Recipe name	:	e.g. Testname 1	Title block text 2	:	xxxxxxxxxx
Start time	:	YYYY-MM-DD hh:mm:ss	Title block text 3	:	xxxxxxxxxx
Operator at cycle start	:	e.g. Operator 1	Comment field 1	:	xxxxxxxxxx
			Comment field 2	:	xxxxxxxxxx
Title block field 2	:	xxxxxxxxxx	Comment field 3	:	xxxxxxxxxx

(Analyses)

Start time	:	YYYY-MM-DD hh:mm:ss	Operator at cycle start	: e.g. Operator 1
End time	:	YYYY-MM-DD hh:mm:ss	Operator at cycle end	: e.g. Operator 1
Batch time	:	Hh:mm:ss		

Sterilization phase :	Min. Temp. Value	Max. Temp. Value	Min. F0 Value	Max. F0 Value

Amount of failures : x

Date / Time	Status	Number	Text	User
YYYY-MM-DD hh:mm:ss	e.g.: +	e.g.: 001	e.g.: Emergency stop	Operator 1

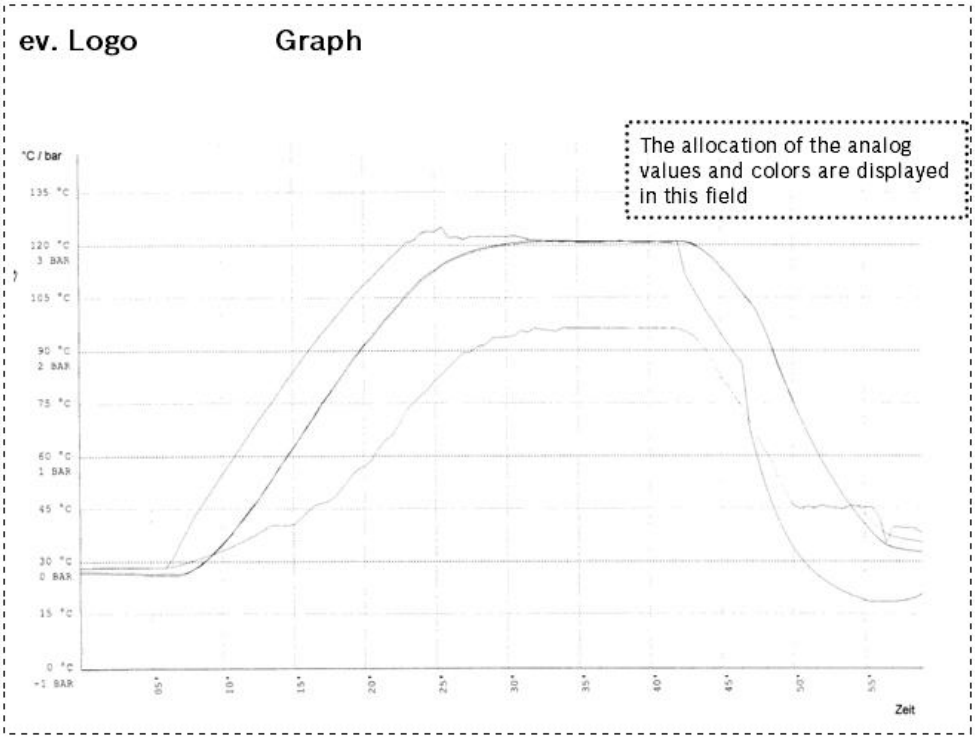
Evaluation : Sterilization successful ! (or not successful !)

Date _____ Signature _____

Graph:

(Title)

(Graph)



7.3.2 Recipe protocol

Recipe and parameters can be printed.

Layout of the protocols: SBM Standard protocol

Example:

(Title)

(Recipe Info)

(Recipe data)

(Recipe parameter)

ev. Logo **Recipe Protocol** **Page x/y**

Recipe name	:	e.g. Testname 1	
Mode	:	e.g. ADV, SWS, SDR, VT, FLT	
Created by	:	e.g. Pharmazeut 1	Date/Time: YYYY-MM-DD hh:mm:ss
Released by	:	e.g. Pharmazeut 2	Date/Time: YYYY-MM-DD hh:mm:ss

The recipe data is displayed here in a tabular format

The recipe parameters are displayed here in a tabular format

7.3.3 Audit Trail - User-actions

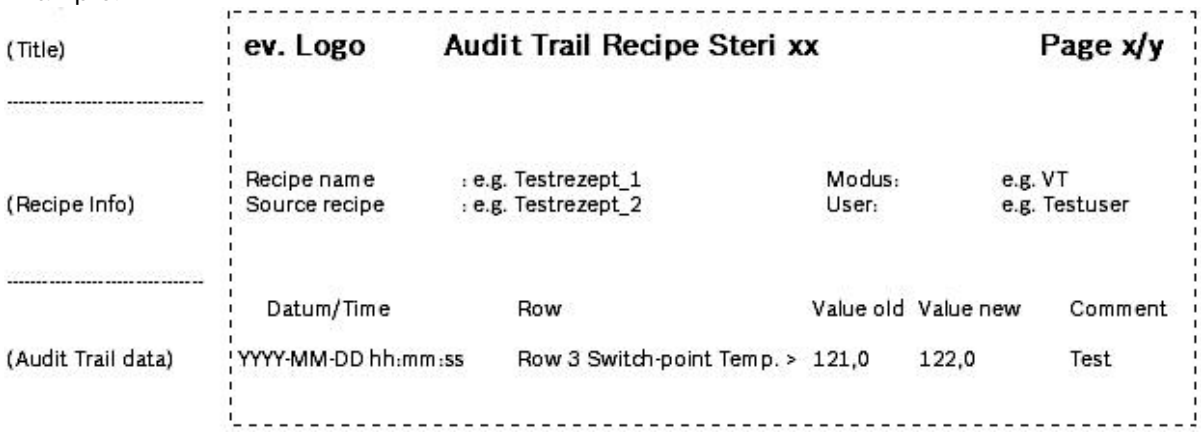
A user-action is an action done by the user (e.g. pressing a software button or starting a cycle, etc)
The following user actions are logged by Audit Trail:

- WinCC runtime is started, WinCC runtime ended, shut down PC
- Lon-in button pressed, batch protocol re-printed, Audit Trail printed
- Recipe loaded, cycle started, step over button used (cycle aborted)
- I/O Test menu opened, administrator menu opened, recipe menu opened
- Recipe created, recipe edited, recipe released, recipe unreleased

The data is saved in a MS SQL - Database can be re-printed afterwards.

Layout of the protocols: SBM Standard protocol

Example:



7.3.4 Audit Trail - Recipe and parameter change protocol

Changes made in already existing recipes are logged by Audit Trail

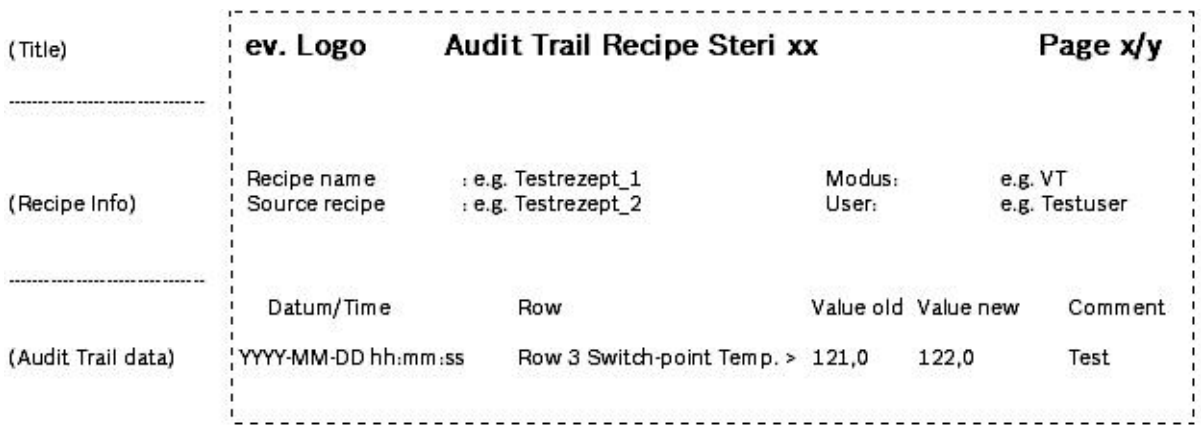
The following data are logged by Audit Trail:

- Date / Time, User, old parameter value, new parameter value, comment
- Old recipe name / New recipe name

The data is saved in a MS SQL - Database can be re-printed afterwards.

Layout of the protocols: SBM Standard protocol

Example:



7.3.5 Audit Trail of the user-management

The users and user-groups are set according to the SBM Standard with the use of Windows Security and is taken over (only the user-groups) in WinCC with Siemens add-on Simatic Logon. The authorizations of the user-groups are defined in WinCC on the Touch Panel PC. Authorizations (user-group dependent) as well as users and user-groups can be handled locally on the PC or via the customer network.

Access protection to the visualization is realized with the use of the Simatic Logon Software. The access protection is based on the working of the Windows operating system. The user logs in and out at the application via the Simatic Logon Service.

The following events are logged with Simatic Logon Eventlog Viewer:

- Successful log-in, failed log-in, authentication of the user
- Log-out by the user, automatic Log-out, password change

The logged events can be seen with the use of the SIMATIC Logon Eventlog Viewer. SIMATIC Logon Eventlog Viewer can be opened in the production menu in sub-menu “Reports”. The Audit trail data can be displayed with the Eventlog Viewer. The data can be exported as an XML, SCV or a PDF format and saved on a desired location by pressing the export button. These files can be opened and edited (e.g. Excel) if required.

8 Documentation

8.1 Basis Documentation

- Declaration of CE-Conformity
  Confirms, that the machine is engineered with the corresponding EU-guidelines.
- Important notices *
  Defines Target-groups, explains the meaning of the safety and warning symbols, operating position, statements of the emissions and scrapping and disposal
- Basic Safety Information *
  Statements about warranty and liability, intended use, obligations of the plant operator as well as safety information's
- Transport, Installation and Connections
  Information about delivery, transport, assembly, connection, storage and conservation
- Description of the Machine / Plant
  General design specification
- Operation + HMI - User manual *
  Machine operation, shut-down the machine, start-up the machine, operating the instruments, loading, select recipes, start recipes, program end, unloading, alarms, detailed descriptions of the menus with the aid of print-screens: operating the sterilizer, menus, menu structure, creating recipes, selecting recipes, start recipes, recipe and parameter input possibilities.
- Trouble shooting
  Alarms and interlocks. Alarm description, alarm number, alarm text, technical info, SBM classification, GMP-critical, safety relevant and message (only for documentation reasons, no impact on the control system), reaction and trouble shooting are to find in the Alarms and interlocks document.
- Change of Size / Product
  Describes the action to be taken if the product changes (e.g. product size /volume)
- Maintenance *
  Statements of maintenance work divided in daily, weekly monthly, quarterly, semi-annual and annual + more information's.
- Media and Interface List
  A list of requirements of utility supply consumption, connection, required pressure, etc.
- Spare Part Recommended
- Wear Parts Recommended

Note:
Documents marked with * will be distributed in national language of the country, where the sterilizer is installed.

8.2 Technical documentation

8.2.1 Equipment documentation

- P & I Diagram (Pipe work- and Instrumentation- Diagram) including Part list, including Pneumatic diagram (graphical/symbolical piping and instrumentation diagram according to DIN EN ISO 10628 + DIN19227. Not scaled, no indication of the actual piping construction)
- Layout drawing
- Documentation Main Components
  All necessary documents of the authorities of the pressure vessel "Sterilization chamber" according to the guidelines to be used (97/23/EG or ASME, see chapter "Standards").
  Including Material certificates of the pressure vessel chamber.
  Including Roughness measurement of the inside of the pressure vessel chamber

- Valves, and accessories-, MCR-, Motor- and EMCR-List
  Cross reference list to the with component datasheet with component indication
- Documentation of Valves and accessories-, MCR-, Motor- and EMCR-components.
  Datasheets / detailed documentation of the components

8.2.2 Process automation with SDS, HDS and FS at FAT

- Software Design Specification
  The SDS for the PLC and the visualization defines the functionality of the visualization and control system
  Contents of the SDS:
- SDS Software Configuration:
  Description of the PLC and the visualization
  Description of the electrical components
  Description of the Profibus configuration
  Classification of the software according to GAMP
- SDS Recipe parameter
  Description of the recipe step limits of each used recipe step
  Description of the switch-point limits of each used recipe step
  Description of each recipe parameter limit of each used sterilization mode
- SDS Audit Trail description (when implemented):
  Description of the Audit Trail function according to CFR 21 Part 11
- → Scope of services: preparation of the documents before FAT

- Hardware Design Specification
  The HDS defines the hardware components of the visualization and control system.
  - Content:
    - General information
    - Description of the used components
    - Description of the Profibus network
- → Scope of services: preparation of the documents before FAT

- Main components control cabinet and control system
  Datasheets / detailed documentation of the components (e.g. Siemens S7, CPU, visualization components)

- Functional Specification
  This document defines the electrical equipment and the functionality of the sterilizer.
  - Content:
    - General information
    - Description of the sterilization process
    - Mechanical equipment
    - Electrical equipment
    - System functions
    - Safety
    - Data acquisition and Protocols
    - Documentation
    - Scope of services
    - List of abbreviations and technical terms
    - Attachments
- → Scope of services: preparation of the documents before FAT

- Main components control cabinet and control system
  Datasheets / detailed documentation of the components (e.g. Siemens S7, CPU, visualization components)

- Wiring diagram (see chapter “Wiring diagram”)
- Program sequence / Technology
  Description of the projected recipe steps
  A description of the projected recipe steps and the used formulas in the PLC.
  Tabular display of the valve positions in the implemented recipe steps including Legend
- Configuration lists / Parameters of the hardware components and field devices
  The settings of the electrical hardware components as well as intelligent configurable field devices are documented.
- System access / User accounts
  The factory-set system access authorities based on the menu structure
- Disaster recovery plan
  Describes the software recovery procedure after a system crash

8.2.3 Manufacturing documentation

- Manufacturer’s certificates
  - ISO9001 certificate
  - HP0 License
  - Type exanimation certificate
  - Quality system according 97/23/EG (when applicable)
- Calibration certificates of used testing equipment (reference measuring equipment)
- Declaration of compliance and inspection certificates: see chapter “Declaration of compliance / Inspection certificates”
- Certificates calibrated instrumentation (SBM - Calibration certificates)
- Lubricants
  Conformity declarations of lubricants in contact with Pharmaceutical-relevant surfaces from the lubricant manufacturer according to NSF H1 (FDA)
  Not included: FDA Conformity declarations of lubricants used in e.g. geared motors.
- Certificates of safety relevant components
  - Safety valve - Certificate of safety valve settings
  - List of pressure equipment (97/23/EG) – (when applicable)
    SBM assessment of the complete assembly sterilizer according to 97/23/EG (when applicable)
- Welding documentation: see chapter “Option welding documentation and material certificates”
- Borescope inspection of the utility piping leading to the chamber: see chapter “Option Borescope inspection for the media piping leading to the chamber”
- X-ray test: see chapter “Option X-ray test”

8.2.4 Declaration of compliance and Inspection certificates

8.2.4.1 Material certificates for piping and components with product contact according to EN10204-3.1

- Material certificates: contains inspection certificates of the pure media parts according to EN10204-3.1
  When available, inspection certificates according to EN10204-3.1, when no 3.1 certificate is available, certificates according EN10204-2.2 are provided after consultation with the customer. (the material certificates of the chamber are included in the chamber documentation and to find in chapter “Technical documentation”.)
- For fittings
  Inspection certificates according to EN10204-3.1 for fitting (e.g. valves) in the pure media piping leading to the chamber. (no reference between components and material certificates)
  Manufacturer FDA conformity declaration according to CFR 21, part 177 (Nr. 2600 for EPDM,

Nr. 1560 for PTFE) for elastomer components in contact with the product
(elastomer components are not marked with a heat-number, no reference between components and material certificates)

- For MCR- and EMCR-components
  Inspection certificates according to EN10204-3.1 for pure media MCR- and EMCR-components (no reference between components and material certificates)
  Manufacturer FDA conformity declaration according to CFR 21, part 177 (Nr. 2600 for EPDM, Nr. 1560 for PTFE) for elastomer components in contact with the product
  (elastomer components are not marked with a heat-number, no reference between components and material certificates)
- For piping and piping gaskets
  Inspection certificates according to EN10204-3.1 for piping (e.g. piping, bends) and fittings (e.g. flanges) in pure media piping leading to the chamber.
  (no reference between components and material certificates)
  Manufacturer FDA conformity declaration according to CFR 21, part 177 (Nr. 2600 for EPDM, Nr. 1560 for PTFE) for used gasket for fittings in the pure media piping
  (gasket are not marked with a heat-number, no reference between components and material certificates)

8.2.5 Option Welding documentation and material certificates

8.2.5.1 No welding documentation and material certificates

No welding documentation and material certificates are requested for this project.

8.2.6 Option borescope inspection for the media piping leading to the chamber

8.2.6.1 No borescope inspection for the media piping leading to the chamber

No borescope inspection for the media piping is requested for this project.

8.2.7 Option X-ray test

8.2.7.1 No X-ray test

No X-ray test is requested for this project.

8.2.8 Wiring diagram

The wiring diagram is created with the EPLAN P8 develop platform and is build-up as follows:

- Cover patch
- Technical data / global information’s
- Table of contents
- Wiring diagram
- Switch cabinet layout drawing
- Part list
- Project structure

8.3 Standard acceptance and Qualification documentation

8.3.1 Traceability Matrix

The goal of the RTM is to give the documented evidence, that the customer requirements (URS) are implemented and tested in the different qualification phases.
The matrix is used for the transparent tracing of the user requirements to the SBM specification (DS, FS) and the qualification documentation (IQ/OQ).
The traceability is documented in table form.
Scope of activities:

- Preparation of the traceability matrix 1 as reference to the SBM specification (GDS, FS)
- Submitting of the traceability matrix 1 to the customer for release
- Preparation of the traceability matrix 2 as reference to the SBM qualification documents (IQ/OQ)
- Submitting of the traceability matrix 2 to the customer for release

Remark:
The user requirements must be available in a workable format (MS Word, MS Excel).

8.3.2 Documentation for the factory acceptance test (FAT)

Preparation of the FAT protocol and test forms with the following tests:

- Check of the document inventory
- Check of the instrument and piping inventory
- Check of the layout
- Check of the loading and unloading procedure
- Check of the chamber door function
- Program verification - 1 test run for each mode

The FAT protocol and test forms are according to the GMP regulations, contents the test philosophy, a detailed test plan and the acceptance criteria.
These documents are delivered timely to the customer for informational purposes.
Not included: Additional tests.

8.3.3 Documentation for the site acceptance test (SAT)

Preparation of the SAT protocol and test forms with the following tests:

- Check if the open points list of the FAT are closed
- Check of the correct assembly on-site
- Program verification - 1 test run for each mode

The FAT protocol and test forms are according to the GMP regulations, contents the test philosophy, a detailed test plan and the acceptance criteria.
These documents are delivered timely to the customer for informational purposes.
Not included: Additional tests.

8.3.4 Qualification documentation (IQ/OQ)

Preparation of the IQ/OQ protocols and test forms with the following tests:

- IQ – Check of the document inventory
- IQ – Check of the instrument and piping inventory
- IQ – Check of the media connections
- IQ – Check of the layout
- IQ – Check of the main and safety part
- IQ – Software inventory
- IQ – MSR Instrument list / Check of the instrument calibration
- IQ – Check of completeness of PC installation
- OQ – Check of the digital and analog in- and outputs
- OQ – Check of the alarms
- OQ – Check of the chamber door function
- OQ – Check of the reaction of the equipment by breakdown of the pressure transmitter
- OQ – Check of the reaction of the equipment by breakdown of the temperature sensors
- OQ – Check of the step over button function
- OQ – Check of the temperature distribution in the empty chamber – 1 Recipe / 3 repetitions for each mode
- OQ – Program verification - 1 test run for each mode

The IQ/OQ protocols and test forms are according to the GMP regulations, contents the test philosophy, a detailed test plan and the acceptance criteria.
These documents are delivered timely to the customer for informational purposes.
Not included: Additional tests.

9 SCOPE OF SERVICES

9.1 Quality check before delivery

9.1.1 Quality management system

The from Lloyd´s Register Quality Assurance certified (according to EN ISO 9001: 2008) quality management system contains information about the SBM quality philosophy and the extent.

9.1.2 Standard GMP Risk analysis

The purpose of the standard FMEA risk analysis is to evaluate the assessment of potentially GMP risks and the initiation of preventive measures to reduce the risk concerning product quality and product safety. The risk analysis is preformed directly after the planning phase, which means that eventually necessary modifications can be done without much expense.
Scope of activities:

- Preparation activities by an qualification engineer
- Executing of the risk analysis with SBM experts from the process- and the electrical engineering department under guidance of a qualification engineer
- Preparation of a final risk analysis report
- Handing over the final risk analysis report to the customers for informational purposes.

The risk analysis evaluation is exclusively done by SBM.

9.1.3 Design Qualification with FS and Traceability Matrix

The technical specification and the relevant drawings are tested during a design qualification. The comparison of the relevant standards, the customer requirements and the planned execution is pictured and documented. The following design qualification documents are handed over to the customers for informational purposes:

- Design Specification
- Functional Specification
- Traceability Matrix
- Media and Interface List
- P&I Diagram
- Installation plan

9.1.4 Internal factory acceptance test

The pressure equipment is accepted by the TÜV following the requirements described in chapter “Standards”. The internal test takes place within the manufacturer attendant tests according to the SBM standard[SOP Nr. F.00.001.xx] and consists of:

- Mechanical tests
- Electrical tests
- Pre-calibration
- Commissioning test
- Test of function and performance as far as practicable possible

9.1.5 Standard factory acceptance test (FAT)

The factory acceptance test is executed to test the sterilizer before delivery. The test done is described in chapter “Documentation of the factory acceptance test (FAT)“. The execution is done by trained SBM personnel in the presence of the customer. Deviations are documented in a deviation report list. The FAT protocol is handed over to the customers for approval and release of the FAT result.
The duration of the test phase is limited to 1,5 days

9.1.6 Delivery, installation and assembly without support

The following points must be performed on-site:
- The base must be installed according to the installation plan
- The required utilities are available according to the installation plan and the Media and Interface List
- The on-site utilities are connected

The requirement for assembly start is a well-swept building area. Delays and interruptions by the customer are documented and are charged separately.

9.1.7 Bringing in by customer under supervision of SBM

The unloading, bringing in and the positioning of the sterilizer chamber is done by the customer under supervision of the SBM assembly and commissioning technicians. On-site deviations must be corrected prior to assembly begin. SBM is not responsible for damage resulting from the deviations. Any additional expenses for SBM (e.g. waiting times), which are caused by the deviations are charged separately.

9.1.8 Assembly by SBM with help of the customer

The mechanical assembly respectively the electrical cabling and wiring is done by the SBM assembly technicians with partial help of the customer personnel.

9.1.9 Commissioning

The sterilizer is commissioned directly after the assembly and connection works are completed. The required utilities must be present and connected.

9.2 Quality check after delivery

9.2.1 SBM Commissioning test

The commissioning test is executed within the assembly accompanying tests according to the SBM-standard and contains:
- System setup / configuration
- Input / output tests
- Setting the control parameters and valves settings
- Calibration (the necessary equipment is to be provided by the customer)
- Program verification in a empty chamber for each mode

9.2.2 Standard Site acceptance test (SAT)

The purpose of the SAT is to validate the sterilizer. The tests executed during the SAT are described in chapter “Documentation of the site acceptance test (SAT)”. The test is executed by trained SBM personnel under supervision of the customer. Deviations are documented in a deviation list.
The SAT protocol is handed over to the customer for approval of the SAT results and release of the sterilizer for qualification.
The duration of the test phase is limited to 1 day

9.2.3 Customer training – machine instructions

This training for operation and maintenance personnel will be performed during commissioning by the SBM technician directly at the sterilizer. The duration of the training is defined with 1 day (8 hours). The execution of the training will be documented with a participation confirmation. The training language is English.
Personal training material for every participant is not included in this project.

9.2.4 Standard Qualification for the types ADV-F and SDT

This GMP-conform qualification is a documented evidence that the installed sterilizer is conform with the required design specifications. The qualification documentation can be used for inspections by third parties. The tests are described in chapter “Qualification documentation (IQ/OQ)”. The execution of the qualification is done on the finished on-site assembled sterilizer by trained SBM personnel under supervision of the customer. The test results are GMP-conform documented in the IQ/OQ test forms and summarized in the test overview in the IQ and OQ protocols. The qualification contains GMP-conform deviation reports and deviation procedures. The qualification protocols are handed over to the customer for approval of the SAT results and release of the sterilizer for qualification.
The duration of the test phase is limited to 7 days

10 List of abbreviations and technical terms

CSV	Comma Separated Value
DS	Design specification
F_0	A F_0-Value of 1 is the heat penetration of 121,1 °C in one minute (saturated steam conditions)
FAT	Factory Acceptance Test
FDA	Food and Drugs Administration
FS	Functional Specification
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
HDS	Hardware design specification
I/O	Input / Output
IQ	Installation Qualification
MIL	Media and Interface List
MCR technology	Measurement, control and regulation technology
OP	Operator Panel
OQ	Operation Qualification
P&I Diagram	Piping and instrumentation diagram
SAT	Site Acceptance Test
SBM	Schöller Bleckmann Medizintechnik
SDS	Software design specification
SOP	Standard Operating Procedure (work instruction)
PLC	Programmable logic controller

11 Attachments

Attachment 1	Key data standard ADV/ADV-F/SDT

11.1 Attachment 1: Key data standard ADV/ADV-F/SDT

ADV																
TYPE	**Usable Space**			**Chamber dimensions**			**Cart Dimensions**			**Tray Dimensions**		**Exterior measurements**			**Net weight**	**Weight during pressure test**
	Height	Width	Depth	Height	Width	Depth	Width	Depth	Height	Width	Length	Height	Width	Depth		
06.06.06	600	600	600	700	700	650	600	600	600	600	550	2100	2300	1150	1400	1700
06.06.09	600	600	900	700	700	950	600	600	900	600	850	2100	2300	1450	1600	2100
06.06.12	600	600	1200	700	700	1250	600	600	1200	600	1150	2100	2300	1750	1800	2400
09.06.09	900	600	900	1000	700	950	900	600	900	900	850	2100	2300	1450	1700	2400
09.06.12	900	600	1200	1000	700	1250	900	600	1200	900	1150	2100	2300	1750	1900	2800
09.09.09	900	900	900	1000	1000	950	900	900	900	900	850	2100	2900	1450	2100	3100
09.09.12	900	900	1200	1000	1000	1250	900	900	1200	900	1150	2100	2900	1750	2300	3600
09.09.18	900	900	1800	1000	1000	1850	900	900	900	900	850	2100	2900	2350	2900	4800
12.09.12	**1200**	**900**	**1200**	**1300**	**1000**	**1250**	**1200**	**900**	**1200**	**1200**	**1150**	**2300**	**2900**	**1850**	**3000**	**4600**
12.09.18	1200	900	1800	1300	1000	1850	1200	900	900	1200	850	2300	2900	2450	3200	5600
12.09.24	1200	900	2400	1300	1000	2450	1200	900	1200	1200	1150	2300	2900	3050	3800	7000
12.12.12	1200	1200	1200	1300	1300	1250	1200	1200	1200	1200	1110	2300	3500	1850	3100	5200