On behalf of:

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Improvement of Handling Medical Waste in Healthcare Facilities in two Pilot Regions of the Russian Federation

# Disinfection and testing standards for steam based treatment technologies of infectious healthcare waste (Class B and C)

by:
ETLog Health Consulting GmbH
Kremmen, Germany
Authors: Dr. Ute Pieper, Jan-Gerd Kühling

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| AAM | Advancing Safety in Medical Technology |
| AC | Alternative Current |
| AISI | American Iron and Steel Institute |
| CE | Conformité Européenne |
| cfu | colony forming units |
| EN | European Norm |
| DC | Direct Current |
| ISO | International Organisation for Standardisation |
| PCD | Process Challenging Device |
| PT | Pressure Test |
| STATT | State and Territorial Association on Alternate Treatment Technologies |
| TDes | Triple Data Encryption Algorithm |
| TT | Temperature Test |

## Terms and Definitions

**Air removal**: removal of air from the chamber and waste load to facilitate steam penetration

**Biological Indicator**: microbiological test system providing a defined resistance to a specified decontamination process

**Calibration:** set of operation that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure of a reference material and the corresponding values realized by standards.

**Challenge /Reference load:** a typical waste load that reflects the maximum waste quantity that is intended to be processed and includes all the waste streams that the treatment device is authorized to treat

**Disinfect:** To render non-viable potential pathogens, but not necessarily all microbial forms to the level set out in these standards.

**General waste:** Waste that is generated from a health care facility and not from a medical procedure and therefore no infectious content in it.

**Hazard:** A substance, mixture or substances, process or situation that have the potential to cause harm to human health or adverse effect to the environment.

**Hazardous waste**: A waste that is considered to be of special risk to human health or environment and therefore needs special management.

**Healthcare waste**: Waste that is generated during the diagnosis, treatment or immunization of human beings or animals, in bio-medical research and in the production or testing of biological products.

**Holding time:** period which the temperatures at the reference measurement point and at all points within the load are continuously within the disinfection temperature band.

**Infectious waste**: All kind of waste that may transmit viral, bacterial, fungal or parasitic diseases to human beings and animals

**Installation qualification (IQ):** process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications

**Operation qualification (OQ):** process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance to its operation procedures

**Performance qualification (PQ):** process to demonstrate that the disinfection process is capable of achieving a predetermined decontamination assurance level for the subject load on a repeatable basis.

**Pressure vessel:** vessel comprising the chamber, jacket (if fitted), door and components that are in permanent connection with the treatment chamber.

**Saturated steam**: water vapour in a state of equilibrium between condensation and evaporation

**Segregation:** Any activity that separates waste materials for processing.

**Spore strip:** a sealed strip containing bacterial spores at the specific concentration

**Validation:** A documented procedure for obtaining, recording and interpreting data required to show that a disinfection process will consistently comply with predetermined specifications

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# 1 Approval of steam disinfection technologies

Potential infectious waste and infectious waste can be treated by incineration and alternative technologies like the treatment by steam. In accordance to the Basel Convention steam treatment by autoclaving is listed as the preferred method for the treatment of infectious healthcare waste.

For the protection of human health against communicable diseases the treatment of infectious and potential infectious waste (waste Classes B and C) should only be conducted by steam based methods which have been tested on efficacy and harmlessness to health and environment. The approved methods should be published in an official register.

This document outlines the necessary testing requirements for steam treatment technologies to proof the effectiveness to disinfect infectious waste.

In the annex exemplary methods and technologies are introduced which are approved and registered by the German Robert Koch Institute and which therefore can be purchased and used by health provider for the treatment of infectious waste.

## 1.1 Selection Criteria

The use of specific technical methods on waste disinfection must take the different microbiological efficiency capacity into account. This disinfection efficiency of technical methods is structured into 4 areas:

A: Suitable to kill vegetative bacteria, including mycobacteria, such as fungi, including fungal spores,
B: suitable for the inactivation of viruses,
C: suitable to kill spores of anthrax,
D: suitable to kill spores of gas gangrene and tetanus.

This document describes the selection and testing methodology of steam treatment technologies which are effective for the areas A, B and C.

Inclusion of a treatment method into the register of approved technologies can only be accomplished if the process is sufficiently effective and have no unacceptable effects on human health and the environment. The effectiveness testing is conducted based on expert opinion in accordance with default methods and / or own investigations in accordance with the relevant national and international norms and Standards.

## 1.2 Steam disinfection methods

The testing methods which are described in this document are focused on the disinfection of contaminated waste. It has to be ensured that it is possible to evacuate the air from the waste completely. Furthermore the mentioned treatment times are calculated from the time at which all waste is moistened with steam and the defined treatment temperature has been reached.

Disinfection of porous materials such as waste requires **fractional vacuum process**, which is characterized by:

(1) Removal of air from the chamber and waste by repeated evacuation of air alternating with inflow of saturated steam,
(2) Disinfection with saturated steam, and if needed drying of the disinfected waste by evacuation.

To carry out this process steam is required, which is largely free from air or other gases (see DIN EN 285). The disinfection chamber must be vacuum tight.

**Requirements for the disinfection of waste by steam disinfection:**

a) The waste containers must not be hermetically closed during the treatment in the disinfection chamber. Heat resistance waste bags or containers with sufficient steam inlets can be used.
b) If the waste bags are tied up they must be permeable for steam or are rupturing during the process.
c) Hermetically sealed packaging is not allowed, unless they contain water or aqueous solutions. However, the amount of liquid per treatment cycle must be levelled in that amount, that the equilibration time is sufficient to heat the entire volume to the defined disinfection temperature.
d) The cooling time must be aligned on the type of waste. In particular, the waste structure and the volume of liquid are to be considered.
e) Taking a disinfection temperature of 105 °C, at least 30 minutes treatment time must be provided.
f) The exhaust air and the condensate must be treated.
g) The efficacy of the treatment process must be confirmed by an extraordinary "hollow" test load (chapter 2.2).

The disinfection equipment has to be loaded in accordance to the operation instructions and must be regularly serviced and maintained for proper operation.

# 2 Testing of steam based waste treatment technologies

The following information specifies general requirements and the relevant test for steam treatment systems for the disinfection of infectious healthcare waste. The information provided are not applicable for steam treatment plants designed to be used for the sterilization of medical products, pharmaceutical products and equipment.

The information is only partly applicable for treatment processes requiring pre-shredding, as the tests have to conduct for all steps during the process and are not stable enough to be shredded.

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. The international norms for the validation of sterilization procedures are technically the same as for disinfection procedures except of the different level of deactivation of the microbes. Therefore the following reference documents are base of this standard:

- ISO 17665-1:2006 [1]: "*Sterilization of health care products — Moist heat — Part 1":* The requirements for the development, validation and routine control of a sterilization process for medical devices are provided. It specifies a number of methods and procedures that can be used to monitor sterilization processes. The equipment required will normally be commercially available.
- ISO/TS 17665-2 [2]: Guidance on the application of ISO 17665-1 provides guidance for validation and routine control of moist heat sterilization processes for medical devices.
- EN 285 [3]: "*Sterilization — Steam sterilizers — Large sterilizers"* provides detailed information about the tests and performance requirements.
- EN 13060 [4].: "Small steam sterilizers" provides tests and performance requirements for small sterilizers.
- ANSI/AAM ST79:2006 [5]: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- DIN 58949-3 [6]: description of types of test, test loads, test apparatus and biological indicators, extent of testing as well as procedure and expression of results (German language).

## 2.1 General technical requirements

In the following, the main technical requirements for steam treatment technologies are outlined:

### Technical loading requirements

Steam treatment plants should be built in a way that the loading of the waste can be carried out without entering the chamber. The treatment plant should be equipped with suitable loading carts, to ensure that the waste bags or packaging is not toughing the autoclave walls for effective steam flow.

### Pressure vessel requirements and materials

Materials in contact with steam should resist attack from steam and condensate; should not cause deterioration of the quality of the steam and should not release any substances known to be toxic in such quantities that could create a health or environmental hazard. When selecting materials, the possible corrosive influence of the goods to be sterilized within the sterilizer chamber, the existence of corrosion promoting substances in the sterilizing steam or cooling

agents, the possibility of forming corrosion resistant layers at surfaces and environmental aspects (e. g. migration of substances and scrapping at end of life) should be considered.

The pressure vessel should be normally manufactured from stainless steel and should be approved for the planned working temperature and pressure. All materials for piping and supply should be chosen under special observation against corrosion.

### Control of the treatment process

The steering of the treatment process should be fully automatically, a manual control should not be possible. The control should however allow the step-by-step processing by an authorized person. An intervention with a stroke switch should be only possible in serial-circuit processing with a key-switch. During the stroking the automatic process must be switched of and it should not interfere with any functions relevant for safety.

### Test connections for test instruments and thermoelements

The treatment plant should be equipped with at least one connection for test instruments and one connection for passing cords to the temperature sensors. The test connection for instruments should be fitted to the sterilizer chamber or in a pipe which is in direct connection with the sterilizer chamber (excluding vacuum line). The test connection should be provided with a cap, marked PT (pressure test) and sealed with either an O-ring-seal or a flat seal.

For the test connection for thermoelements, a straight connecting sleeve should be provided at a point of easy access in order to pass at least six flexible cords to the temperature sensors. The connecting sleeve with its O-ring-seal or flat seal should be closed with a cap, and a temperature proof and mechanically resistant soft packing. The cap should be marked with the letters TT (temperature test).

### Treatment chamber (Pressure Vessel)

The door of the treatment chamber should be possible to open after carrying out a successful treatment cycle. If the depth of the pressure vessel will be larger than 1 m (or larger than 0,65 $m^3$), a device must be available to avoid accidental closing of the door. Entering the treatment chamber of large autoclaves, the closure device must be enabled.

The pressure vessel should be heat insulation, the maximum outer surface temperature of the insulation should guarantee that a temperature of 40°C within the machine room will not be exceeded, the heat passage resistance of the insulation material should be at least 2,86 $m^2$ K/W. The insulation of the doors should be designed in a way that during the process, at a room temperature of 23°C the outer surface temperature will not exceed 55°C.

Pressure vessels in treatment plants applying a vacuum should be pressure tight to allow that during vacuum-testing the rising of the pressure (at a start pressure of below 80 mbar) will be lower than 1 mbar/min. Vacuum test should be only carried out if the vessel is empty, dry, and if the temperature is +/- 20 K of the outside temperature. After evacuation down to 80 mbar all valves have to be closed and the vacuum pump must be switched of. After compensation time of 5 minutes the test time of 10 minutes should start.

### Conduit and fittings

Conduits for steam or water with a temperature of >60°C must be equipped with insulation material. Based on a heat conductivity of 0,035 W/mK, the thickness of the insulation material should be 2/3 of the diameter of the pipe. Conduits for pressurized air and condensate should be equipped with dirt catchers. Adjustment and safety valves should be designed according to local safety standards.

### Display, steering and measurement instruments

All instruments and indicating devices should be located in a position where they can be readily viewed by the operator under normal operation of the sterilizer and should be identified as to their function.

The treatment plant should be equipped at least with the following instruments:

a) treatment chamber temperature indicating instrument;
b) treatment chamber temperature recorder;
c) treatment chamber pressure indicating instrument;
d) treatment chamber pressure recorder;
e) jacket pressure indicating instrument (if the sterilizer is fitted with a jacket);
f) steam pressure gauge (if a steam generator is incorporated into a sterilizer panelling)

Also, the plant should be provided with at least the following indicating devices:

a) visual display indicating "door locked";
b) visual display indicating "in progress";
c) visual display indicating "cycle complete";
d) visual display indicating "fault";
e) indication of the operating cycle selected;
f) operating cycle counter;
g) operating cycle stage indication.

### Pressure steering and gauge instruments

The steam supply pipe, the pressure vessel and the steam jacket should be equipped with a pressure gauge. For the control process, absolute pressure regulators should be used. The treatment chamber pressure indicating instrument should be graduated in kilopascals or bars, have a scale which includes the range 0 kPa to 400 kPa or - 1 bar to 3 bar with a zero reading at absolute vacuum or ambient pressure respectively and have an accuracy of at least ± 1,6 % over the scale range 0 kPa to 400 kPa (- 1 bar to 3 bar). They should be adjusted to an accuracy of at least ± 5 kPa (± 0,05 bar) at the operating pressure and have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range.

Steering instruments and heat gauge for the process temperature: At least two independent temperature sensors should be provided. The measurement range should be 20°C – 160°C. The temperature sensor should have a response time T< 5 s when tested in water and should have an accuracy of at least ± 1 % over the scale range. It should be adjusted to an accuracy of at least ± 0,5 °C at the treatment temperature and have an ambient temperature error compensation not exceeding 0,04 K/K.

The recorder should be independent such that the measuring chain as well as value data processing and printed values are separate from the automatic controller. Records should include the limiting values for all cycle variables throughout the operating cycle. The printing of data should be sufficient to ensure that any deviation outside permitted tolerances can be identified. The recorder should produce a record which should be readable when stored in defined conditions for a period of not less than 10 years.

### Process temperature and holding time

The treatment temperature band should have the lower limit defined by the treatment temperature and an upper limit of + 4 K. Throughout the holding time (period for which the temperatures at the reference measurement point and the load are held within the sterilization temperature band) the temperature measured at the reference measurement point of the

sterilizer chamber should not be lower than 105°C (TDes 0+4) for 30 minutes. If sterilization is required a temperature of 121°C (TDes 0+4) with a treatment time of 20 minutes or 134°C (TDes 0+4) with a treatment time of 10 minutes should be used.

### Vacuum system

If a vacuum system should be used, the vacuum system should have in the pressure range of 900 mbar to 55 mbar an average suction power V (in $m^3/h$) of: 0,033 * Volume of the pressure vessel (in 0,1$m^3$). It must guarantee that the necessary vacuum for the system can be reached. Between vacuum system and pressure vessel a valve must be existent to avoid the back-sucking of air/water/steam. Temperature of cooling water after usage must be below 65°C.

The prescribed absolute pressures during vacuum phases have to be met with a maximum deviation of +10 mbar and during the intermediate blast of steam with a maximum deviation of -10 mbar.

### Cooling system

The treatment plant should be equipped with a cooling down device for the waste after treatment, normally via applying a post-vacuum. The cooling time depends on the kind of waste to be treated and should be not less than 10 minutes. The temperature of the waste should be not higher than 80°C after finishing the cooling down process.

### Exhaust air and condensate

Exhaust air which is erases from the chamber filled with untreated waste should be treated by membrane filters as it might contain pathogens. The filter should be placed between pressure vessel and the next component, it should be built in a way that a disinfection of the filter should be possible in a built-in condition e.g. for the change of filters and for the periodical cleaning to avoid germs grow. The filters must be heat resistant, steam resistant and hydrophobic and pressure resistant for the pressure difference. Only validate membrane filter with a validation of 0,01 μm in gaseous substances and 0,2 μm for liquids should be allowed. Condensate from the process should be thermal treated before disposal.

### Noise control

The sound created by the treatment plant should not exceed 80 dB(A) in the treatment area.

### Process steering

To ensure the treatment effectiveness, it must be ensured that the physical target values for the different process steps are reached. The defined treatment time should only start after the necessary temperature is reached and will be kept during the entire treatment time. For vacuum systems, additionally the necessary pressure must be reached, for steam injection systems the target value for the steam amount must be reached. The momentary status of the treatment cycle must be visual displayed. In case of an interruption of the process, the entire process has to start again. It should be only possible to open the door if the safety for the operator can be guaranteed.

### Feed water supply

In general the feed water specifications of the manufacturer are to be followed. If not information are available the contaminants in the feed water supplied to a steam generator should not exceed the parameters shown in the table below. If these parameters cannot be reached, an additional feed water treatment will be necessary:

*Table 1: Suggested maximum values of contaminants in feed water and condensate*

| Determinant | Feed water |
|---|---|
| Evaporation residue | < 10 mg/l |
| Silicium oxide, $SiO_2$ | < 1 mg/l |
| Iron | < 0,2 mg/l |
| Cadmium | < 0,005 mg/l |
| Lead | < 0,05 mg/l |
| Rest of heavy metals except iron, cadmium, lead | < 0,1 mg/l |
| Chloride (Cl') | < 2 mg/l |
| Phosphate ($P_2O_5$) | < 0,5 mg/l |
| Conductivity (at 20 °C) | < 15 µs/cm |
| pH value (degree of acidity) | 5 to 7,5 |
| Appearance: | colourless clean without sediment |
| Hardness (Σ Ions of alkaline earth) | < 0,02 mmol/l |

*Source: EN 285:2006 – Table B1 [3]*

The feed water inlet should be designed to prevent back-syphoning into the feed water system.

### Steam quality

Generally, the treatment plant should be designed to operate with a steam supply which is provided with a condensate trap within 2 m of the connection to the plant. The treatment plant should be designed to operate with saturated steam containing up to 3,5 % V/V of non-condensable gases. It should be designed to operate with saturated steam with a dryness value down to 0,90 when tested. When the supplied steam is expanded to atmospheric pressure the superheat should not exceed 25 K for a treatment temperature of 134 °C when tested. The plant should be designed to operate with a pressure fluctuation not exceeding ± 10 % of the nominal gauge pressure measured at the inlet to the final pressure reduction value.

The level of non-condensable gases contained in the steam should not prevent the attainment of sterilization conditions in any part of the treatment plants load. The concentration of non-condensable gases changes considerably. A peak which occurs for a few seconds can however be sufficient to cause a fault during sterilization.

A continuous supply of saturated steam is required for steam treatment. Excess moisture carried in suspension can cause damp loads, while too little cannot prevent the steam from becoming superheated during expansion into the treatment chamber. The accurate measurement of the percentage of moisture content in the steam is difficult and the traditional methods where constant steam flow is required are not suitable for sterilizers.

Superheated steam may result in insufficient treatment of waste. The amount of moisture in suspension with steam supplied from the service supply must be sufficient to prevent that the steam is becoming superheated during expansion into the treatment chamber.

### Compressed air supply

For the pneumatic system, compressed air is necessary. The sterilizer should be designed to operate with a compressed air supply at a pressure of 500 kPa to 700 kPa (5 bar to 7 bar), free of liquid water, filtered to 25 μm and free from oil droplets greater than 2 μm.

**Accompanying documents**

Following accompanying documents should be supplied with the treatment system:

a) Operation instructions (including process description;
b) Loading and maintenance procedures;
c) Short-form of operation and loading procedures;
d) Circuit and pneumatic plan, technical data sheet, pressure vessel certificate.

## 2.2 Testing methodology

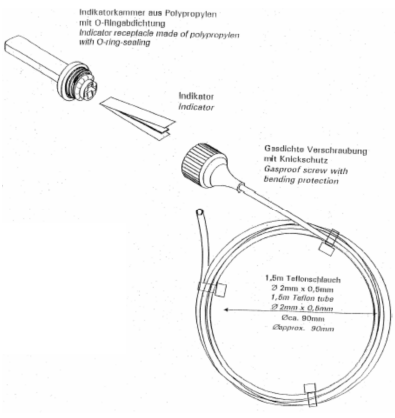
### 2.2.1 General aspects relevant for testing

Sterilization and disinfection refer to microbial inactivation and are used by manufacturers of infectious waste treatment plants to describe the capabilities of their technologies. Sterilization is the complete destruction of all forms of microbial life; some references accept a 99,9999 % reduction in the microbial population as "sterilization." Disinfection is the reduction of microbial contamination, especially the diminution of disease-causing microorganisms or pathogens by 99,99 %.

Internationally, today four levels of treatment are accepted. Most institutions and organization recommend that alternative technologies meet at least the criteria for Level III disinfection which is equivalent to the inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 Log10 reduction or greater; and inactivation of G. stearothermophilus spores and B. atrophaeus spores at a 4 Log10 reduction or greater. A 4 log10 kill is equal to a 99,99% reduction or a one-ten thousandth (0,0001) survival probability [7].

For the validation, testing of "reference loads" should be carried out. The reference loads should comprise a variety of materials, the composition of which should reflect that of the waste material to be treated.

*Figure 1: Lumen test equipment 1,5 m Teflon tube; 2 mm inner diameter*




In the test, only packing material for the test load should be used which later on will also be used for the waste packing. Measuring implements (biological indicators and thermoelements) should be distributed at critical points throughout the test load in a representative manner.

Test loads should include the simulation of porous materials. Containers can for example be filled with horizontal layers of cellulose arranged as uniformly as possible. In order to simulate of lumens or hollow objects like intravenous tubs in the waste, test carriers should be packed in the requisite containers and placed in the treatment chamber (Figure 2 [8]).

*Source: EN EN867-5*

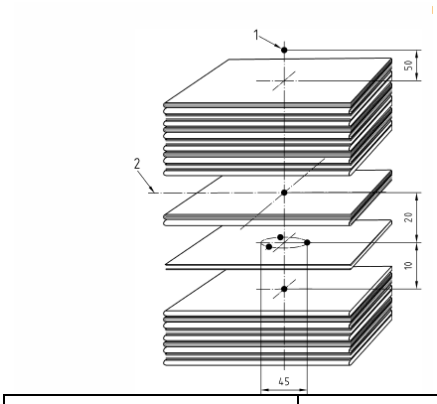
The tests are conducted without adding any additional padding and liquid products. The treatment of liquids should be conducted in a different test. Liquids can be simulated by plastic bottles filled with 0,5 l of water. Thermoelements should be inserted in the liquid to monitor its temperature.

### Standard tests loads

Reproducibility within acceptable limits should be checked using a minimum of three replicate cycles for the first validation of an autoclave [2]. For the following re-qualifications one test cycle is sufficient. For contained product processes, the test load and its location in the autoclave chamber should be as proposed for routine production. Heating, exposure and cooling profiles within the autoclave chamber should be checked at least in positions adjacent to the containers as identified in operational qualification to attain the shortest and longest exposure. The profiles should then be checked within the reference product placed in these locations in a test load and loading configuration according to the proposed production load. If process parameters change during subsequent development, microbiological effectiveness and the limits on exposure for the existing waste kinds should be verified.

For the test, so called standard test packs are used to check that, at the levels at which the process variables are set, rapid and even penetration of steam into the pack is attained. The standard test pack is a reusable item that may be used for testing continuously. The test pack should be composed of plain cotton sheets, each sheet should be bleached white and have an approximate size of 900 mm x 1200 mm. The number of threads per centimetre in the warp should be (30 ± 6) and the number of threads per centimetre in the weft should be (27 ± 5). The sheets should be washed when new and when soiled and should not be subjected to any fabric conditioning agent. The sheets should be folded to a nominal size of 220 mm x 300 mm and then stacked to a nominal height of 250 mm. After compressing by hand the pack should be wrapped in similar fabric and then secured with tape not exceeding 25 mm in width. The total weight of the pack should be (7 ± 0,7) kg.

*Figure 2: Standard test load (packs)*




| | |
|---|---|
| *1 = position of sensors* | *2 = centre layer* |
| *Dimensions in mm* | |

*Source: EN 285:2006*

### 2.2.2 Parameters to be tested

For the testing of steam based waste treatment plants, in total five different parameters should be tested:

**Pressure Test**

Pressure should be measured by means of an absolute pressure gauge with and indication or, if possible, recording imprecision of no more than +/- 6 mbar. This pressure gauge should be adequately protected by over temperature and overpressure protection devices.

**Air leakage Test**

The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level which will inhibit the penetration of steam into the sterilizer load. The rising of the pressure (at a start pressure of below 80 mbar) during the test should be lower than 1 mbar/min (See also technical requirements).

**Air removal Test**

To ensure a safe waste treatment by steam, it must be ensured that all air is removed out of the treatment chamber. The Bowie and Dick test was conceived as a test for successful air removal for sterilizers so called high vacuum porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack.

**Temperature Test**

The thermoelements used should be fitted with wires equipped with sturdy, heat resistant insulation sheathing. The Thermoelements should be placed at all critical points within the test load, one extra thermoelement being placed at the most unfavourable location within the treatment chamber but outside of the test load. There should be facilities for automatic test data recording. Temperature data should be precise to within +/- 1K.

It is recommended to use thermoelements equipped with sensors made of either copper/copper-nickel or nickel-chromium-nickel having a maximum diameter of 1 mm inclusive insulation. The recorder used should be a temperature compensated dotted line recorder with a minimum of six input ports and a range of between 20-150°C, a usable width of 100 mm, a dot interval length of 1 s whenever possible and a paper feed rate of 240 mm/h minimum.

**Microbiological inactivation**

Microbial inactivation is more appropriately expressed as a probability function, measured as reductions by factors of 10 in survival probability of a microbial population. Suspensions of resistant bacterial endospores are typically used as biological indicators: Bacillus stearothermophilus to test thermal inactivation. The test generally entails adding the biological indicator to the test loads, running the load through the process, and collecting the biological indicator organisms after processing. The microorganism suspensions are plated to quantify microbial recovery.

The first test run is done without microbial inactivation (e.g., no heat, no chemical disinfectant, no irradiation) to establish control conditions. The second run is done under normal operating conditions. Microbial populations are measured in colony forming units (cfu) per gram of waste solids. Calculations are then made to determine microbial inactivation in terms of the logarithms of the number of viable test microorganisms in accordance to the standards (Chapter 2.2.1).

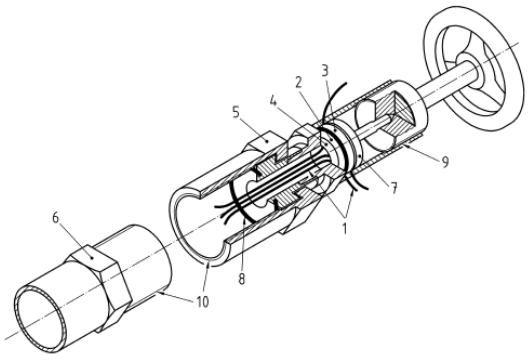
### 2.2.3 Thermoelectric tests

The above outlined temperature tests are conducted by thermoelectric tests. Thermometric use accurate measuring equipment to monitor temperatures and pressures independently of the instruments fitted to the autoclave. The tests are conducted in a preheated chamber. These tests provide the assurance that the temperature requirements for decontaminating are met.

1) Thermometric tests for a small load are designed for autoclaves with an active air removal system they demonstrate that the autoclave is capable of removing air from a small load in which air from a near-empty chamber has been retained.
2) Thermometric tests for full load are designed to show that decontamination conditions are present in a test load of specified maximum mass and of sufficient size to fill the usable chamber space.

Thermoelectric tests should be conducted with thermo elements or thermocouples. The thermocouples are connected to computerized multichannel recording systems that can record and print temperature data. For validation purposes, type T thermocouples are recommended because they are stable throughout a wide temperature range. For testing a solid waste autoclave for both small and full load test at least 6 thermo elements should be taken. Thermocouples should not be placed in the chamber through the door gasket because they can be easily damaged when loading or unloading the chamber, which can also create a leak that will affect the normal working conditions of the autoclave. One should place the thermocouples in the autoclave chamber by means of a feed-through assembly connected to a suitable port. After purchasing a new autoclave, this port must be documented.

*Figure 3: Example of a method used to introduce temperature sensors into the autoclave chamber*




| | |
|---|---|
| *1 temperature sensor wire* | *7 metal thrust spigot* |
| *2 silicon rubber washer* | *8 O-ring* |
| *3+4 metal thrust washer* | *9 castellated to permit entry of loads* |
| *5 metal body* | *10 pipe thread* |
| *6 adopter* | |

*Sources: EN 285:2006 [3] and [9]*

### 2.2.4 Microbiological Testing

A microbiological indicator contains live spores in a defined concentration. If the treatment process is sufficient to kill the spores in the indicator, it can be assumed that the pathogens in the waste are eliminated. After treatment the spores have to be incubated and after the indicated time the colour of the probe will change – the evaluation (incubation) can be done by an accredited lab. Biological indicators used in validation testing must:

- Inactivate *G. stearothermophilus* spores using disinfection temperatures of more than 120 C [10]
- Be located in a small and full load of the defined standard test load and
- Be placed in the parts of the load that have been identified as being the most difficult to treat (see annex).

The microbiological testing of solid waste is conducted in two steps: small and full load. For each test at least 10 biological indicators should be used. The tests are described in the chapter "Thermoelectric testing". The location of the indicators in the test pack is shown in Annex. Microbiological and thermoelectric tests can be conducted at the same time. The use of a blind probe and a detailed documentation is necessary.

The following table provides an overview about the number of sensors / indicators for the thermoelectric and biologic test are needed.

*Table 2 Number of thermoelectric elements and biological indicators for different tests*

| | Number of Thermoelectric elements | Number of biological indictors |
|---|---|---|
| Full load | 7 | 10 |
| Small load | 7 | 10 |
| Liquid test | Depending on the used chamber volume | Optional |
| Hollow load test (PCD) | 5 | - |

## 2.3 Tests to be conducted

For an effective validation of infectious waste treatment plants, the carrying out of four different tests is recommended.

### 2.3.1 Type and safety tests (Pre-validation Tests)

The purpose of the type test or homologation test is to determine what operating data are to be used in the operation of a specific type of treatment system. It also serves to determine exactly what kind of waste may be treated by the process in question, what loading and/or packaging regulations should be followed, and where critical levels for measurements to be carried out in the future lie. Another purpose of type testing is to check conformance with general requirements, particularly with regard to malfunctions and the innocuousness of waste water and exhaust air. Type test should be performed only on application by the manufacturers. After the successful completion of such a test an application can be made to be recognized as approved treatment technology.

A prerequisite for validation of an autoclave is that the autoclave manufacturer must provide the operator with certain types of specifications and information.

Before delivery of the autoclave and with a view to its installation, the autoclave manufacturer should provide the purchaser with the following information:

- installation instructions, including the overall dimensions and overall mass of the autoclave, the floor loading at each support when the autoclave pressure vessel is filled with water, the clearance required for access and the masses of the principal heavy components;

- type of electricity supply, e.g. DC or AC, single or three phase, voltage and frequency including minimum and maximum values and maximum continuous power in kilowatts or Mlovolt amperes;
- the maximum flow and usage rate and the maximum and minimum supply pressure for steam;
- the minimum and maximum pressure and flow at minimum pressure, volume used per cycle for water and feed water;
- the minimum and maximum pressure and flow at minimum pressure for compressed air;
- the total heat in watts transmitted to the surrounding air when the autoclave is operated in an ambient temperature of (23 ± 2) °C in still air;
- the mean and peak sound power levels generated by the autoclave, expressed as an A-weighted sound power level;
- the type of doors and information on the necessary space required for the movement of the door(s);
- the acceptable range of steam supply pressures;
- the approximate location of the reference measurement point of the autoclave chamber;
- the maximum flow of water and condensed steam to the drain;
- the maximum hardness value, the range of pH and the conductivity of the feed water.

The scope of test should include the microbiological test (with biological indicators) as well as the physical test (temperature distribution and pressure). The test should be carried out in empty, under partial and under full load. Biological indicators should be used to determine the limits of process efficiency. Containers filled with porous materials should be fitted with no less than 10 bio-indicators preferably placed in critical locations. The container, in turn, should itself be placed in a critical location with the disinfection chamber.

In “lumen” and “liquid” test, at least five of the test carriers used should be equipped with biological indicators, in quantitative tests three biological indicators suffice as a rule. Tests should be repeated no less than twice. Tests of processes not belonging to the fractionated-vacuum category should be repeated four times.

Type test records should show what exposure time has been determined experimentally. Furthermore, such reports should contain descriptions of critical locations and critical batches.

### 2.3.2 Commissioning tests (Installation qualification)

The inspection and testing of treatment plants on site serves the purpose of demonstrating that a particular treatment plant is capable of conforming to the relevant general requirements, provided there is no deviation from the operating instructions. The operating data determined in the course of homologating testing should be applied to the operation of the unit on site, which necessitates proper loading and a proper supply of expendables. This test may be commissioned either by the manufacturer or the supplier of the unit.

For the test, as a minimum one test involving a test batch of lumens should be conducted. The test should involve no less than five test carriers fitted with bio-indicators. The batch in the treatment chamber should be one of the critical batches identified in the homologation test or, alternatively, a full load. Furthermore, these tests should involve measurement of all physical parameters.

### 2.3.3 Periodic Tests (Operation Qualification)

Periodic performance tests should be conducted on site at intervals of no more than six months. Their purpose is to demonstrate that the disinfection performance of the treatment plant is good and that it causes no infection hazard, provided there is no deviation from the operating instructions and a proper supply of expendables is at hand. Test involving biological indicators should be conducted as for a commissioning test. In addition, once per year the physical parameters should be measured.

### 2.3.4 Unscheduled Tests (Performance Qualification

Unscheduled Tests should be conducted whenever there has been a change in the type, quantity, or packaging of the waste material being treated, whenever there is cause to suspect that the efficiency of the treatment plant has been impaired, or whenever repairs have been affected by which said efficiency might have been impaired. In that case, same test as used for the commissioning test should be conducted. All tests being carried out should be documented. At a minimum, test records should show the following:

- Type, brand, manufacturing date and location of the tested treatment plant
- type of test conducted,
- a description of procedure involved
- type and weight of the load together with a description of the containers used
- Location of the biological indicators and thermoelements
- Process parameters measurement
- The results of the test, inclusive of the biological indicator resistance test.

Reports should show the makes of biological indicators use as well as their batch numbers, expiration dates and, if necessary, package types.

### 2.3.5 Regular performance verification (routine testing)

During normal operation, a regular verification of the performance has to be carried out and the regular tests have to be performed. All tests are used to prove that the parameters needed for proper decontamination have been achieved during the treatment process. For fractionated vacuum steam treatment plants the following test are recommended:

- Visual check
- Interpretation of physical factors (pressure, time, temperature)
- Bowie and Dick test (Air removal test) every morning before starting the waste treatment
- Hollow load test (PCD/helix) – Chemical test for each treatment cycle.

## 2.4 Testing summary

In general different testing levels for qualification of treatment device can be distinguished:

1. Pre-validation requirements
2. Validation including:
   a) Installation qualification,
   b) Operation qualification and
   c) Performance qualification.
3. Routine testing, which includes frequent monitoring and testing of the equipment.

*Table 3: Overview about the tests needed for the validation and testing procedure*

| Testing level | Qualification tests | Frequencies | Responsibility |
|---|---|---|---|
| Pre-validation tests (Chapter 2.3.1) | Type and safety tests | Before delivery | Manufacturer |
| Installation qualification (Chapter 2.3.2) | Water and steam quality | Once a year | Purchaser |
| | Correct delivery | Once after installation | Purchaser |
| | Correct Installation | Once after installation | Purchaser |
| | Complete Documentation | Once after installation | Purchaser |
| | Process description | Once after installation | Purchaser |
| | Process parameter and tolerances | Once after installation | Purchaser |
| Operation qualification (Chapter 2.3.3) | Calibration of pressure and temperature measurement systems | Once a year | Qualified technician / service company |
| | Air leakage test | Once after installation | Purchaser |
| | Air removal test (Bowie and Dick Test) | Once after installation | Purchaser |
| | Microbiological Tests | Every 6 month | Purchaser / Qualified company |
| | Thermoelectric Tests | Once after installation: 3 time test processes in a row | Qualified service company |
| Performance qualification (Chapter 2.3.4) | Thermoelectric tests | Requalification once a year: 1 test cycle | Qualified service company |
| | Microbiological Test | First time: 3 time test processes in a row and after that once a year: 1 test cycle | Qualified service company |
| | Interpretation of physical factors (pressure, time, temperature) | Once a year | Qualified service company |
| Routine tests (Chapter 2.3.5) | Visual check | Daily | Operator |
| | Interpretation of physical factors (pressure, time, temperature) | Every cycle | Operator |
| | Hollow load test (PCD) | Every cycle | Operator |
| | Bowie and Dick test | Daily before operation | Operator |

NOTE: The Installation and Operation Qualification phases can be instituted separately or simultaneously.

# 3 Test report

The final stage of the validation program requires the documentation of all acquired data. The qualification–validation report summarizes the overall results of validation. It includes the calibration certificates for calibrating instrumentation, calibration records, and methods for calibrating the measuring instruments, gauges, and recorders as well as the accuracy verification data of thermocouples. The validation report is not complete unless it contains evidence checks for the availability of an instrument. Logbook, the standard operating procedures (SOPs) used with the autoclave, procedures for preventive and unscheduled maintenance, and recalibration programs. The validation report also should include the user's training records.

The qualification–validation report must include the drawings of all loads tested. The location of the thermocouples/sensors and biological indicators must be specified in each drawing. Any specification deviations that were encountered during validation activities and the procedures that followed their discovery should be reviewed.

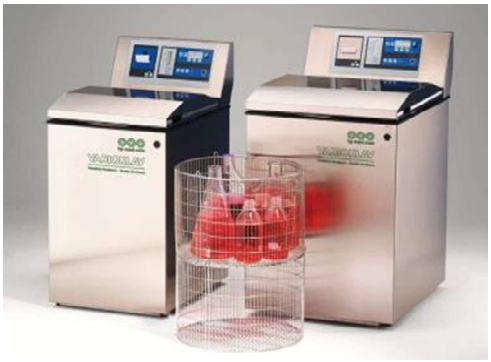
After the validation activities are completed, all data and documents that were accumulated must be revised, approved, and certified by both the owner of the autoclave and the contractor in cases when the validation was performed with third parties or by the manufacturer.

# 4 Annex

## 4.1 Examples of German listed treatment technologies

### 4.1.1 HP –Medizintechnik GmbH

**VARIOKLAV Steamsterilzer S and T**



*Key Information*

Approved by RKI since: 29.08.2006

Available types:
- 75 and 135 liter floor and table-top models

Number of plants installed since 2000:
- 8000

Number of plants installed last 5 years:
- 3000

**Reference installations:**
All over the world except USA from 1993 till

Short description:

**XVARIOKLA 135 S**
Floor model, for usual laboratory use
135 liter chamber, D/L 500/700 mm,
7,5 kW, 3N/400V/16A power-coated
Chamber of sterilization: Pressure 5,0 bar and 100% vacuum
Steam generator: abs. pressure 5,5 bar
Safety circuit and safety related equipment are accredited for this range of high pressure and temperature and are already integrated in the model acceptable temperature 160°C (accreditation by TÜV SÜD Industrie Service GmbH)

**Including:**
- fractionated pre-vacuum module

For hard-to de-aerate solid and porous materials, particularly blown bottles and waste in bags, elective single pre-vacuum or fractionated circle, number of pressure-changes and depth of vacuum adjustable, powerful watering vacuum pump, reachable final vacuum 70 mbar after drying with vacuum and stainless steel wall heating for all solid and porous materials including sterile air ventilation.

- FA Module

With condensate exhaust filtration sterilization, emission-free, thermal detector in filter body integrated, with simultaneously sterilization of filter body, filter and condensate, dead-spot free drain valve for secure sterilization of dangerous materials, from the protection class/security level L1 (S1) is recommended, from L2 (S2) is required

- XGLP batch printer, integrated,

For direct documentation of process data, or confirmation of secure sterilization, recording the chronological sequence of the chamber-temperature, medium temperature, pressure of the chamber and process data.

Contact:

HP Medizintechnik
Bruckmannring 19
85764 Oberschleißheim
Germany
Tel: +4989306664750

Contact partner: Angelika Brunner
Email: angelika.brunner@hp-med.com

## 4.1.2 F. & M. Lautenschläger GmbH & Co. KG

### LaboCERT

*Key Information*

Approved by RKI since: 2003

Available types: LaboCERT

Number of plants installed since 2000: > 40

Number of plants installed last 5 years: > 25

**Reference installations:**
1. LaboCERT, University Duisburg-Essen, Campus Essen, 2011)
2. LaboCERT, Heinrich Heine University Düsseldorf, ZKF, 2011
3. LaboCERT, University Clinic of Bonn, Institute of Virology, 2012
4. LaboCERT, University of Saarland, Department of Physiology, 2014

Short description:

LaboCERT – a customized solution for hospital and aboratory waste treatment. The Lautenschläger LaboCERT is a modern and highly efficient high pressure steam sterilizer working with a fractionated vacuum process which is designed to treat solid and liquid wastes at disinfection/sterilization temperatures of 121°C and 134°C.
Steam and moist heat deactivate micro-organisms very efficiently. To allow heat and moisture reaching all parts of the load, the LaboCERT operates with a powerful vacuum system to remove air from the sterilization chamber and to replace it by high pressure steam. The steam heats the inner and outer surfaces of the load and condenses on the load. After a temperature holding period of 15 min for solid waste and 45 min for liquid waste, respectively, the steam is withdrawn from the chamber and replaced by clean air again.
The autoclave is equipped with special safety devices to prevent contaminated air and condensate leaving the sterilization chamber. A vacuum air sterile filter system and a condensate sterilization module guarantee that waste water and exhaust air are free of potentially dangerous micro-organisms. A wide range of additional technical features, especially for liquid waste sterilization, protects the user and the environment. According to the individual application and the individual requirements, a customized solution in terms of the required safety level and the necessary treatment capacity can be chosen from a modular construction system.

Ecological and Economical advantages:

- Integrated heat recovery systems and innovative process technology for a minimum energy and cooling water demand
- Preventive maintenance only once a year – a patented inflatable door seal system, durable and accurate instrumentation and low-wear components permit long service intervals and lowest maintenance costs
- Highest design standards acc. to European regulations and high-class materials guarantee a perfect reliability and the highest possible life expectancy
- Perfect handling, easy operation by an interactive graphical user interface and a very low sound level for optimum usability and operator convenience

Contact:

F. & M. Lautenschläger GmbH & Co. KG
Zum Engelshof 1-5
50996 Köln, Germany
Tel.: 0221 35017 0

Contact partner: Dr. Markus Meurer
Email: info@lautenschlaeger.net

### 4.1.3 Metaka GmbH

## MEDISTER HF-Waste decontamination


*Key Information*

Approved by RKI since: 1996
Available types: MEDISTER 10 / 20 / 60 / 160
Treatment capacity (from – to kg/h): 4-25
Number of plants installed since 2000: ~400
Number of plants installed last 5 years: ~ 200
**Reference installations:**
1. 2x MEDISTER 160; Sozialmedizinisches Zentrum Süd Vienna; 2012 and 2014
2. 4x MEDISTER 160; FSCC PHOI n.a. Dmitry Rogachev, Moscow; 2011
3. 1x MEDISTER 60; Central Clinical Hospital Nr.1 of Russian Railways, Moscow; 2009

Short description:

The METEKA Hygiene and Infection Prevention System is more than only decontamination of infectious health care waste, because of ...
... the "on-site" collection of health care waste using the puncture-proof MEDITAINER containers, avoiding contact by hand with the container at the same time.
... the transportation of infectious health care waste inside the MEDITAINER container to the MEDISTER HF-decontamination device using the MEDITRANS transport trolley.
... the "on-site" treatment of the infectious waste in the same reusable MEDITAINER waste container which is also used for collection and transportation.
The front-loading system of the MEDISTER devices allows safe and ergonomic loading and unloading of the MEDITAINER containers. In the MEDISTER devices, microwaves produce heat inside the moist waste. The special entry of the HF-energy into the treatment chamber ensures uniform heating of the waste material – even if the waste composition is inhomogeneous. The energy transfer is contact-free; it heats up only the moist waste but not the housing. The decontaminated waste can be regionally disposed of like ordinary household waste.

Ecological and Economical advantages:

- Infection prevention
- Easy, convenient and safe operation and handling
- Maximum treatment reliability
- Easy and Quick Installation
- Low energy consumption
- Reuse of the MEDITAINER waste containers
- No chemicals needed = protection of man and environment
- No air pollution – no air emissions in the exhaust air
- Reduction of the "carbon footprint" compared to other systems
- Possible traceability of the waste stream
- Certified system / legal security
- More than 25 years hands-on experience in the field of decontamination of infectious waste

Contact:

METEKA GmbH
Viktor-Kaplan-Straße 7
8750 Judenburg, Austria
Tel:+43 (0) 3572 / 85166

Contact partner: Mag. Roland Katschnig
Email: info@meteka.com

### 4.1.4 WEBECO / Matachana

## Waste Management / Steam Sterilizer

***Key Information***

Approved by RKI since: 31.08.2006
Available types: EC140/EC240, S-1004I-E1/E2, EC160/EC260, S-1006I-E1/E2
Treatment capacity (from 30 to 70 kg/h)
Number of plants installed since 2000: 9 in Germany
Number of plants installed last 5 years:
- 7 in Germany

**Reference installations:**
-Charité, Universitätsmedizin Berlin, -Centrum für Regenerative Therapien (BCRT)
-Robert-Koch-Institut, Berlin
-Landeslabor Schleswig-Holstein, Neumünster

### Short description:

EC/S1000 Webeco/Matachana sterilizers are designed for the purpose of inactivating and sterilizing infectious waste generated in hospitals making them sterile and therefore similar to ordinary urban waste. They are equipped with vacuum system, ergonomic touch screen, dual PLC and industrial microcomputer, pneumatic and vertical sliding doors, AISI 316L stainless steel chamber, jacket and steam pipes and built-in steam generator.
They work by fractionated vacuum and sterilization programs at a temperature of 134 °C, with the following features specifically designed for this purpose:

- Treatment of fluids evacuated from the chamber at the beginning of the process and when the load has not yet been sterilized. These fluids can be of a liquid nature (condensed) or gases (air) and can carry micro-organisms that are prone to being contaminating. For this reason, they are treated with a special system that guarantees they are sterile before being dumped through the general drainpipe and to the environment.
- Program parameters such as sterilization time and temperature are according to process approved by RKI.

### Ecological and Economical advantages:

- Production process certified according to ISO14001 and ISO9001.
- Treatment of fluids evacuated from the chamber at the beginning of the process and when the load has not yet been sterilized.
- System intended to avoid obstruction (saturation) of the L3 filter during sterilization process resulting in cycle span optimization.
- Equipped with a safety setup, thus in case of process failure, the condensates as well as all other fluids remain hermetically retained inside the chamber.
- Vacuum system by means of ejector (Venturi system) with recirculation pump and water economizer set, effective, silent operation and low maintenance.
- Independent water tank equipped with heat recovery coil from jacket condensates, which heats up the water intended for steam production leading to energy savings.
- Process monitoring and recording by independent industrial microcomputer.
- Access ports for introducing validation probes for pressure and temperature.
- Compliance with the most recent regulations in the European Community. The sterilizers have been designed according to the European standard EN13445:2009 and European Directive 97/23/EC. They are marked with the number CE0053, the corresponding number notified by ATISAE Organism.

### Contact:

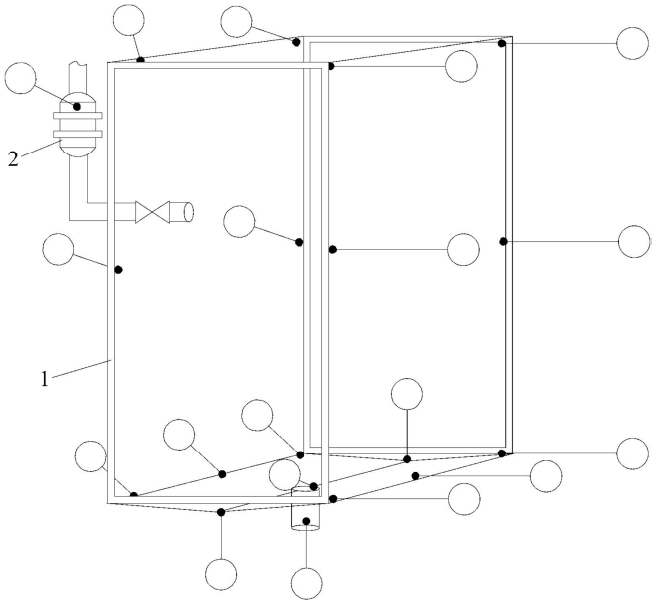
WEBECO GmbH & Co.KG
An der Trave 14,
23923 Selmsdorf, Germany
Tel: 0049 (451) 28072-0

Contact partner: Thomas Kuehne
Email: thomas.kuehne@webeco.de

## 4.2 Thermoelectric and microbiological loads

The following exemplary loads and test indicator distribution is taken from the German Norm DIN 58949-3: “Disinfection - Steam disinfection apparatus - Part 3: Efficiency testing”

### 4.2.1 Example for the application of temperature profile (positions of temperature sensors in an autoclaving chamber)

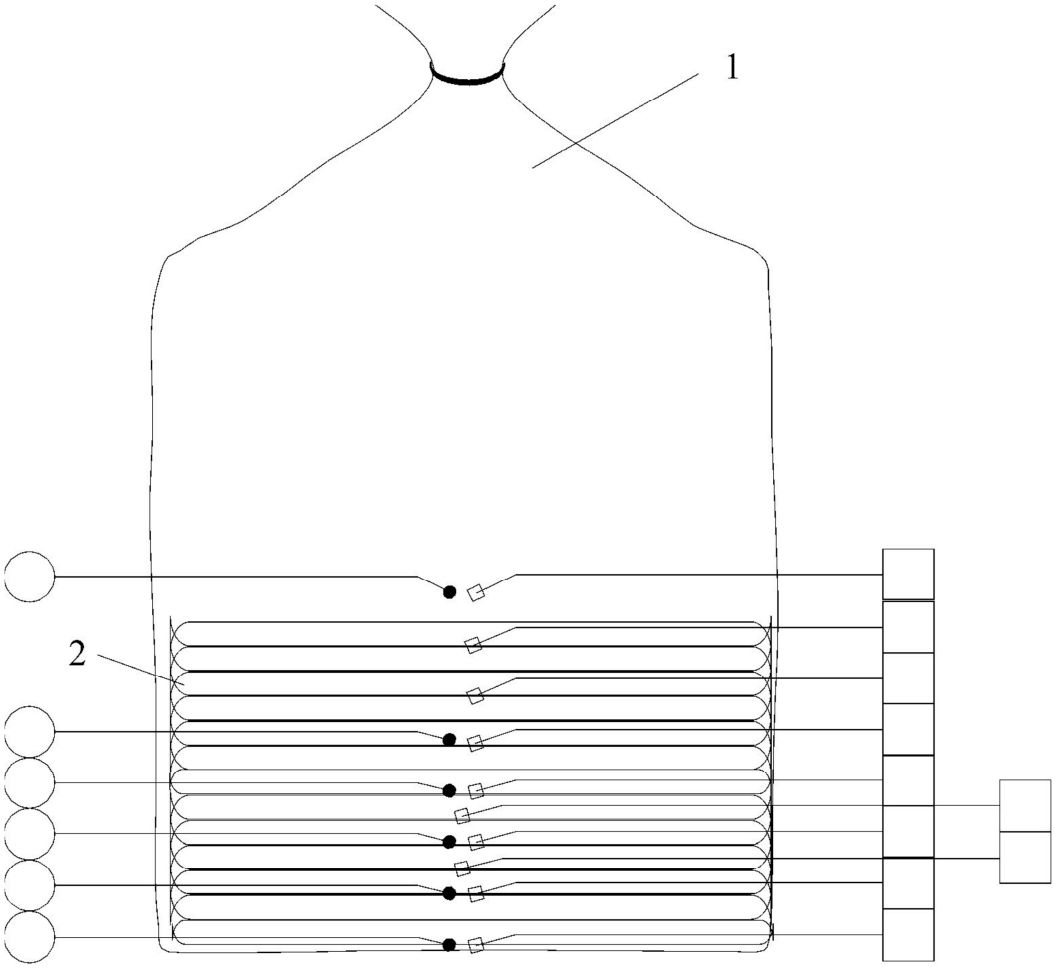



1 Autoclave chamber
2 Air filter

| | |
|---|---|
| ● | Thermo elements (the numbers can be put and described) |

Source: DIN 58949-3

### 4.2.2 Example for the distribution of thermo elements and biological indictors in a waste bag for the small load test

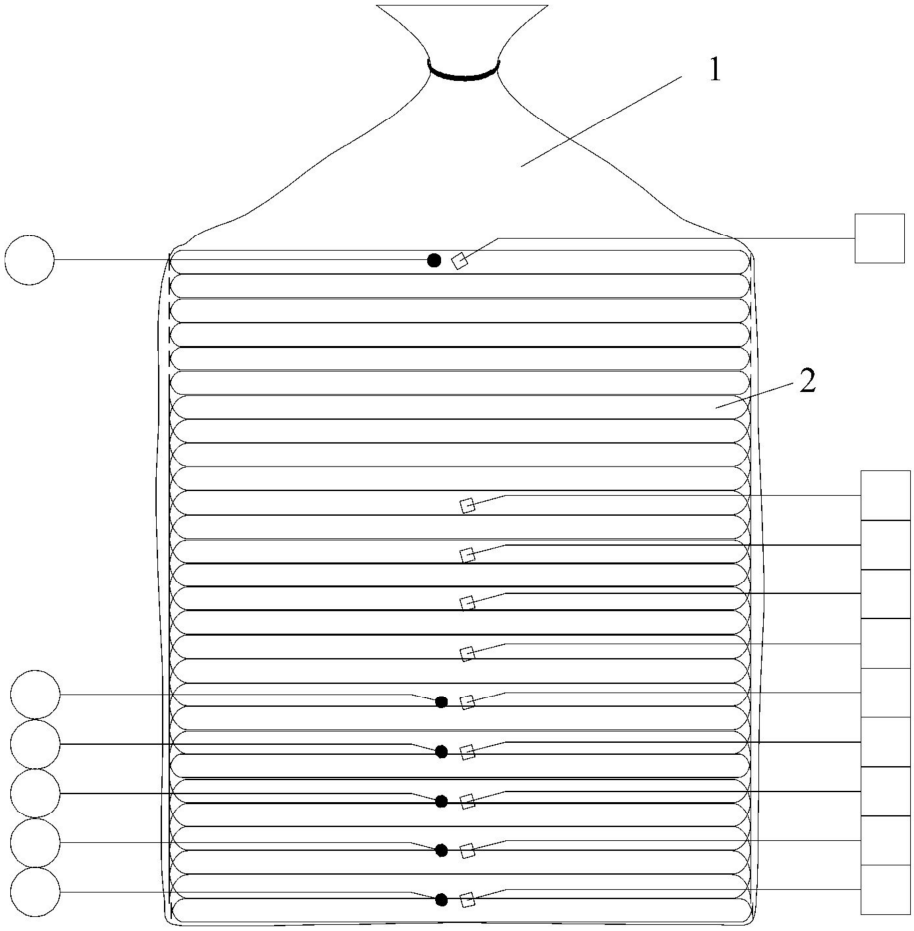



1 waste bag (waste container)
2 test pack (solid material to be disinfected)

| | |
|---|---|
| ■ | Biologic indicators (the numbers can be put and described) |
| ● | Thermo elements (the numbers can be put and described) |

NOTE: One Thermo element is located outside of the bag in the chamber (not shown)
Source: DIN 58949-3

### 4.2.3 Example for the distribution of thermo elements and biological indictors in a waste bag for the full load test

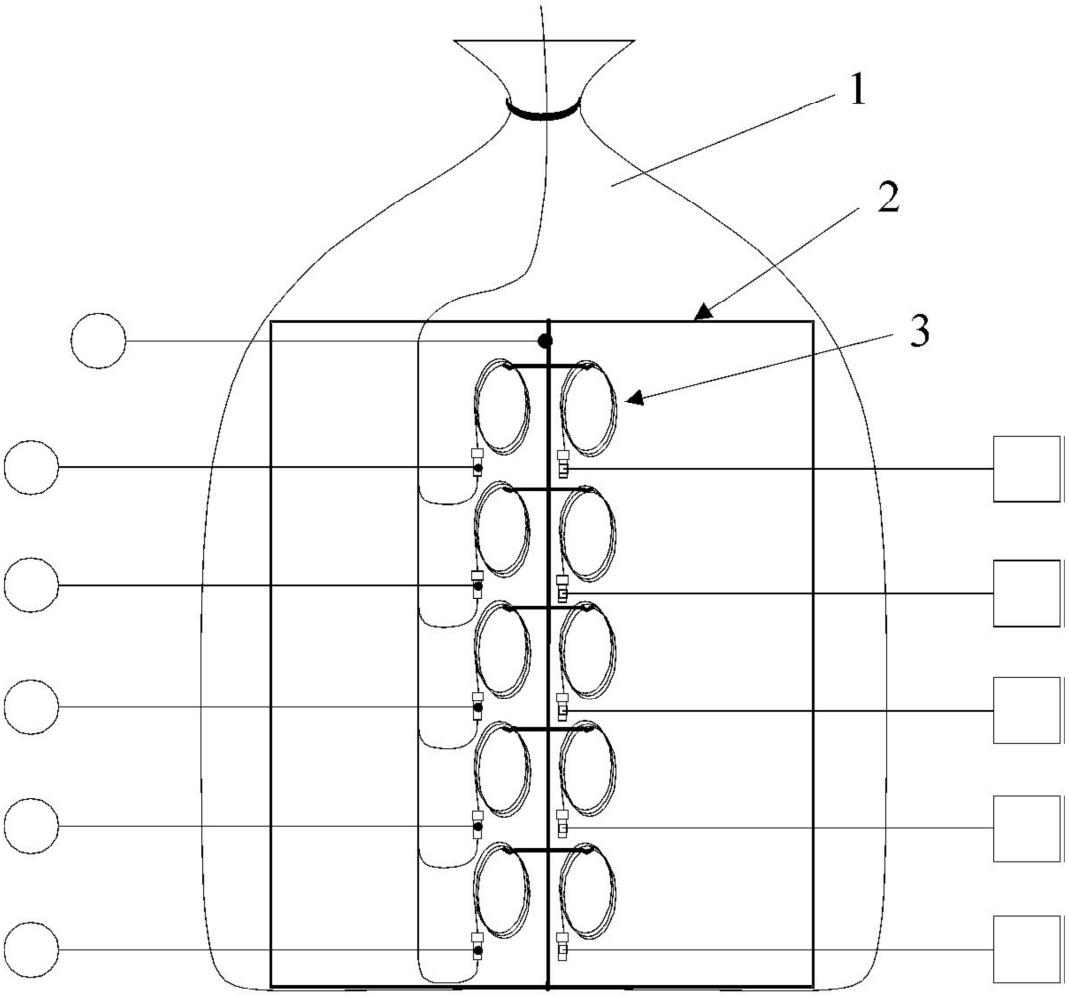



1 waste bag
2 test pack

| | |
|---|---|
| | Biologic indicators (10) |
| | Thermo elements (6) |

NOTE: One Thermo element is located outside of the bag in the chamber (not shown)
Source: DIN 58949-3

### 4.2.4 Example for the distribution of PCD with thermo elements and biological indictors in an empty waste bag

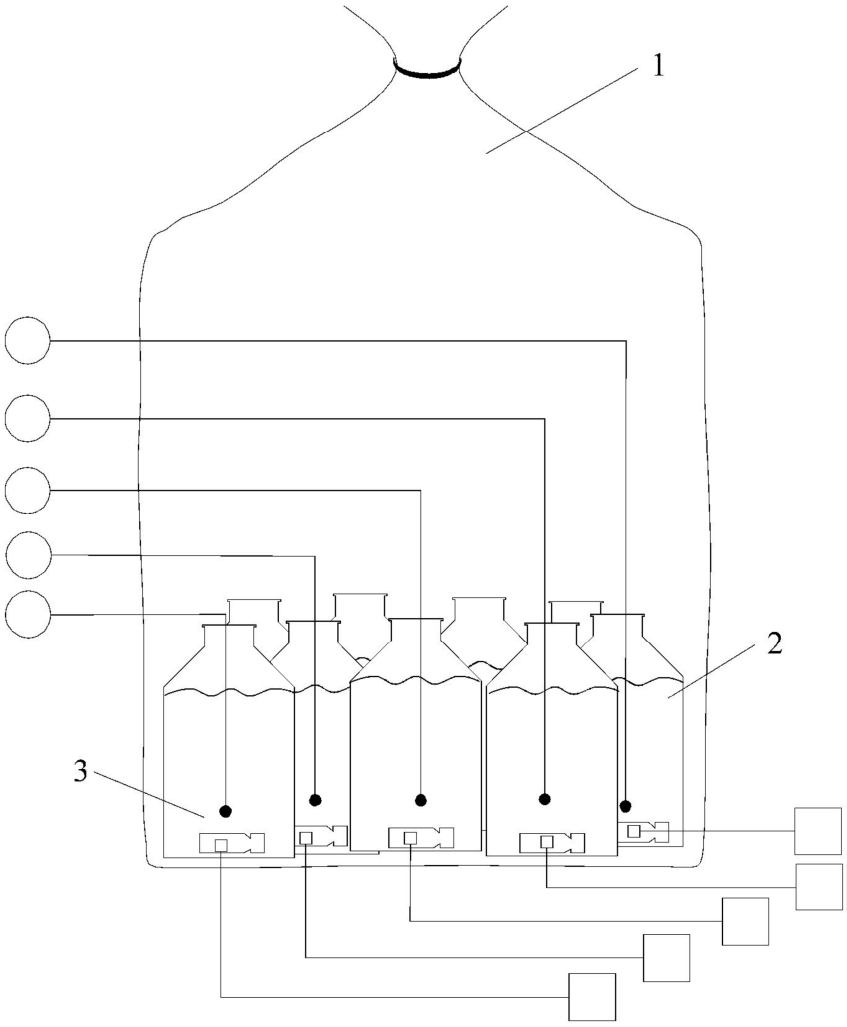



1 waste bag
2 test rack
3 PCD for Hollow load test

| | |
|---|---|
| ■ | Biologic indicators (5) |
| ● | Thermo elements (5) |

NOTE: One Thermo element is located outside of the bag in the chamber (not shown).
Source: DIN 58949-3

### 4.2.5 Example for the load for the testing of liquids in an empty waste bag




1 waste bag (waste container)
2 >= 500 ml liquid (water)
3 location of biological indicators and thermo elements

| | |
|---|---|
| | Biologic indicators (5) |
| | Thermo elements (5) |

NOTE: The volume of the used liquid should reach at least 1/10 of the chamber volume.
NOTE: One Thermo element is located outside of the bag in the chamber (not shown).

Source: DIN 58949-3

## 4.3 Routine monitoring checklist

| No | Inspection locations | Activity | Who | When |
|---|---|---|---|---|
| 1 | Chambers walls<br>Door seals<br>Operating media | Visual control for cleanness, operational readiness | operator | Daily before operation |
| 2 | De-aeration<br>Steam penetration | Perform BD test | operator | Every day before operation |
| 3 | Chamber – treatment cycle | PCD Test | operator | Every treatment cycle |
| 5 | Chamber floor<br>Lint sieve in the drain spout<br>Steam generator | Cleaning, inspection desalination | operator | Weekly and if necessary |
| 6 | Printer<br>Emergency stop switch<br>Water level indicator steam generator<br>Safety contact bar | Testing of operational readiness,<br>Function test | Operator / technician | Weekly and if necessary |
| 7 | Safety valves for chamber<br>Preheating jacket and steam generator | Lift off | Operator / technician | Every 3 month |
| 8 | Filters and sieves in the piping system | cleaning, examination | Operator / technician | Every 3 month and if necessary |
| 9 | Door guides, locking bolts | Grease, function test | | Every 3 month and if necessary |
| 10 | Complete autoclave | Inspection, maintenance, safety technical inspection | Manufacture service | Semiannual and if necessary |
| 11 | Ventilation filters<br>Sieves valves | Change, clean, inspect | Manufacture service | Yearly and if necessary |
| 12 | Complete autoclave | Function test<br>calibration | Manufacture service or external specialist | Yearly and if necessary |
| 13 | Complete autoclave | Effectiveness test,<br>Performance evaluation (validation) | External specialist | Yearly and if necessary |
| 14 | Chamber door | Change seal | technician | Yearly and if necessary |
| 15 | Complete autoclave | Major overhaul | Manufacturer service | Every 5 years |
| 16 | Pressure vessel | Inspection for proper function, Inner examination and strength test | External specialist | Accordance to specification of inspection authority |

# 5 References & Further reading

[1] ISO 17665-1:2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

[2] ISO/TS 17665-2:2009: Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1

[3] EN 285:2006: Sterilization — Steam sterilizers — Large sterilizers

[4] EN 13060:2004: Small steam sterilizers

[5] ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

[6] DIN 58949-3:2012: Disinfection - Steam disinfection apparatus - Part 3: Efficiency testing,

[7] STATT-1994 (State and Territorial Association on Alternate Treatment Technologies): Environmental Protection Agency (EPA), Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies, USA, http://www.epa.gov/osw/nonhaz/industrial/medical/publications.htm

[8] EN 867-5:2001: Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S; German version

[9] DIN ISO 228 (DIN 259):2003: Whitworth Parallel Pipe Thread

[10] ISO 11138-3:2006: Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

**Further Reading**

- ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*
- ISO/TS 11139:2006, *Sterilization of healthcare products — Vocabulary*
- ISO 11737-1:2006, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*
- ISO 11737-2:2006, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
- ISO 14161: *Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results*
- IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*
- EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*
- EN 867-5, *Non-biological systems for use in sterilizers — Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*
- BOWIE, J.H., KELSEY, J.C. and THOMPSON, G.R. *The Bowie and Dick autoclave test*, Lancet, pp. 586-587, 1963

- ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*
- ISO 11140-3, *Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*
- ISO 11140-4, *Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*
- ISO 11140-5, *Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*
- ISO 3746, Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane