

# Chapter 12



## Autoclave

<b>GMDN Code</b>	<b>35366</b>	<b>35366</b>	<b>35366</b>
<b>ECRI Code</b>	<b>13-746</b>	<b>16-141</b>	<b>16-142</b>
<b>Denomination</b>	<b>Sterilizing unit, steam</b>	<b>Sterilizing unit, bulk</b>	<b>Sterilizing unit, tabletop</b>

The autoclave is a piece of equipment used for sterilizing. The word sterilizing means the destruction or elimination of all forms of life (microbial, including spores) present in inanimate objects by means of physical, chemical or gaseous procedures. The word *sterilizer* comes from the Latin word *sterilis* which means not to bear fruit. This chapter will focus exclusively on autoclaves as these are greatly used in public health establishments, clinical and research laboratories. This type of equipment is also known as a sterilizer. Sterilization must be considered as a group of very important interrelated processes for carrying out health services, (sterilization of materials, culture medium, instruments) within rigorous conditions of asepsis. The processes associated in achieving sterile conditions of inanimate objects are the following:

1. Cleaning
2. Decontamination
3. Inspection
4. Preparation and packing
5. Sterilization
6. Storage
7. Delivery of materials

### PHOTOGRAPH OF AUTOCLAVE



Photo courtesy of SysTec GmbH

### PURPOSE OF THE AUTOCLAVE

The autoclave is equipment designed with the aim of reliably eliminating<sup>1</sup> microorganisms, which would otherwise be present on objects used in diagnostic activities, in treatment or surveillance in health institutions (hospitals, laboratories). It is also widely used in the food processing and pharmaceutical industries. In the laboratory, materials and objects are sterilized for the following purposes:

1. To prepare materials for bacteriological cell cultures (test tubes, pipettes, Petri dishes, etc.) in order to avoid their contamination.
2. Prepare elements used for taking samples. (All must be in sterile conditions: needles, tubes, containers).
3. Sterilize contaminated material.

Autoclaves are available in many sizes. The smallest are the table-top type and the largest are complex equipment that require a great amount of pre-installation for their operation. The volume of the sterilization chamber is taken as a reference and measured in cubic decimetres [dm<sup>3</sup>] or in litres [l] in order to measure the autoclave's size. Depending on how their operation is controlled, it is possible to find manual, semiautomatic or fully automatic models.

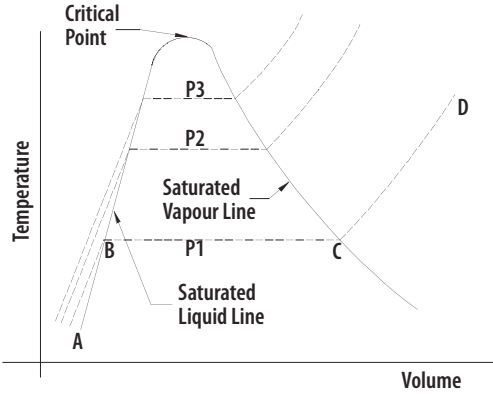
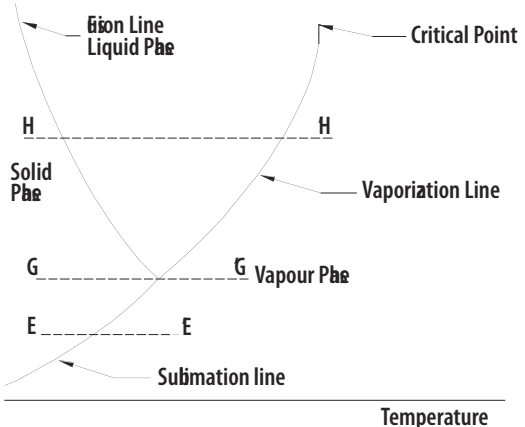
<sup>1</sup> The Food and Drug Administration (FDA) classifies sterility of an article based on statistical studies. An article is considered sterile if the probability of encountering it not sterile in a set of articles submitted to the same process of sterilization, is less than one in a million. This index is called Sterility Assurance Level (SAL) and describes the theoretic potential of microbial inactivation in a sterilization process.



**OPERATION PRINCIPLES**

Autoclaves work by taking advantage of the thermodynamic properties of water which can be considered as a pure substance. In normal conditions (at sea level and pressure of 1 atmosphere) water (in liquid phase) boils and is converted into vapour (gaseous phase) at a 100 °C. If the pressure is reduced, it boils at a lower temperature. If the pressure rises, it boils at a greater temperature. Through the control of water vapour pressure, the autoclave can, in its sealed chamber, reach temperatures higher than 100 °C; or inversely, by controlling the temperature, can achieve pressures greater than atmospheric pressure. The following graph demonstrates the behaviour of water depending on conditions of pressure and temperature.

Autoclaves use pressurized saturated vapour (with a quality greater than 98%) for transmitting thermal energy to elements that require sterilization. In general, this method is known by the terms *steam* or *moist heat sterilization*. This is the sterilization method mostly used due to its effectiveness, rapidity and low cost. However, not all materials can be sterilized with moist heat; for those elements that are affected by heat and humidity, alternative methods of sterilization have been developed. In the laboratory, in order to carry out sterilization processes, steam autoclaves as well as drying ovens using dry heat (without the presence of humidity) are used. See Chapter 13: *Drying ovens*.

Temperature / Volume Graphic	Pressure / Temperature Graphic
 <p>The graph plots Temperature on the y-axis and Volume on the x-axis. It shows two curves: the Saturated Liquid Line on the left and the Saturated Vapour Line on the right. A horizontal line at pressure P1 intersects the liquid line at point B and the vapour line at point C. A higher pressure P2 intersects the liquid line at point A and the vapour line at point D. A third pressure P3 is shown above P2. The Critical Point is marked at the top of the vapour line.</p>	 <p>The graph plots Pressure on the y-axis and Temperature on the x-axis. It shows three phase change lines: the Fusion Line (Solid to Liquid), the Vaporization Line (Liquid to Vapour), and the Sublimation line (Solid to Vapour). The intersection of all three lines is the Critical Point. Horizontal dashed lines represent constant pressure conditions: E-E (sublimation), G-G (vaporization), and H-H (fusion).</p>
<p>1. This graph shows two defined lines: the saturated liquid (to the left) and the saturated vapour (to the right) lines.</p>	<p>1. This graph shows the behaviour and relation between the solid, liquid and gaseous phases of water depending on the pressure and temperature conditions.</p>
<p>2. As the pressure increases, so does the temperature. (See lines P1, P2, P3) where: P3 &gt; P2 &gt; P1.</p>	<p>2. The sublimation lines show that at determined conditions, if heat is transferred to the solid phase, it can be converted directly into the vapour phase (section E-E), without going through the liquid phase.</p>
<p>3. To the left of the saturated liquid line, the water is in a liquid state (plot A-B). Upon heat transfer, the temperature of the liquid is raised from Temperature A to B.</p>	<p>3. The fusion line shows that at determined conditions, upon transferring heat to water, the solid phase is transformed into the liquid phase and, if more heat is added, it is transformed to the vapour phase (section H-H').</p>
<p>4. Between the line of saturated liquid and saturated vapour (section B-C) there is a mixture of the vapour and liquid phases, and the temperature remains constant. The closer it is to point C, the greater is the vapour's quality<sup>1</sup>.</p>	<p>4. The vaporization line shows at which temperature conditions the water in liquid phase is transformed into the vapour phase.</p>
<p>5. To the right of the saturated vapour line, all the water is in vapour phase (section C-D).</p>	<p>5. The point at which the three lines are intercepted is called the Triple Point. In such circumstances the three phases exist simultaneously in equilibrium.</p>

<sup>1</sup> Quality [X]. The relationship between total vapour mass and total mass (liquid mass plus vapour mass). Quality = 1: means that the vapour is saturated and that any increase in temperature will overheat the vapour.



**Cross-section diagram of the vapour autoclave**

Figure 32 shows the main components of the vapour system of an autoclave. For clarity, parts normally located around the autoclave (their precise location depends on the manufacturer), have been included on top and at the bottom of the autoclave diagram.

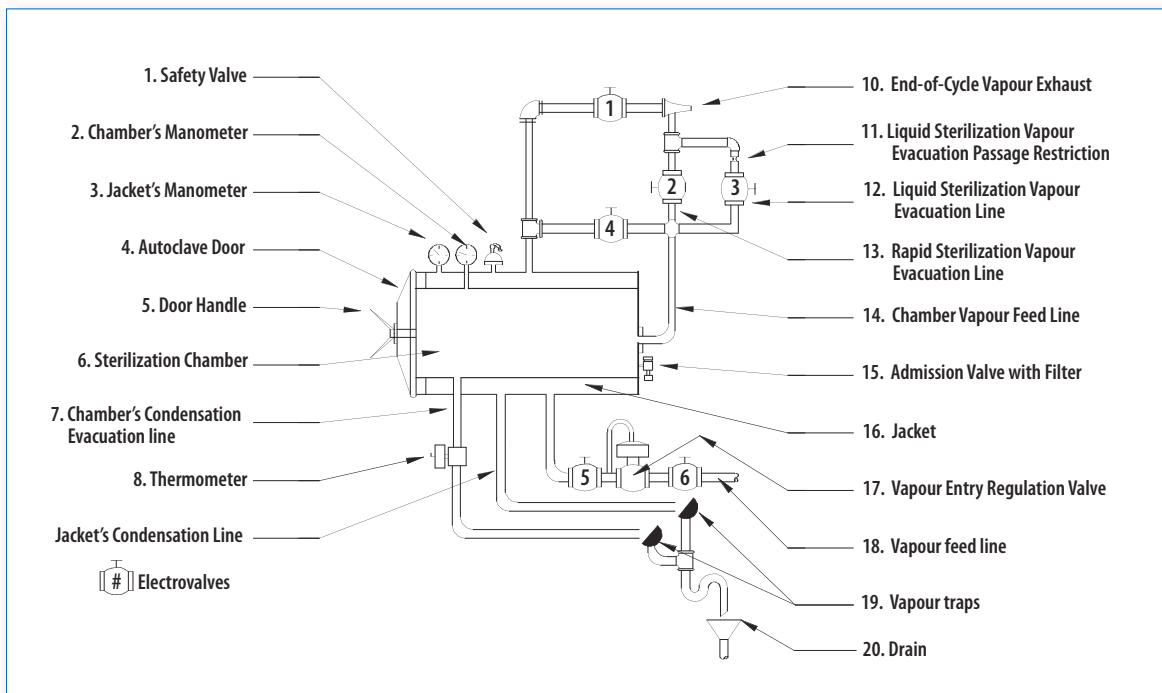
**Description of the components in the diagram**

A brief description of the most common elements of the vapour circuit of an autoclave is given next. The same number identifying each component is used in Figure 32 and its description below. Note that the configurations vary depending on each manufacturer's design.

1. **Safety valve.** A device that impedes the vapour pressure from rising above a determined value. The manufacturers install these in the sterilization chamber as well as in the jacket.
2. **Chamber manometer.** A mechanical device that indicates the vapour pressure in the sterilization chamber.
3. **Jacket manometer (pressure gauge).** A mechanical device that indicates the vapour pressure inside the autoclave's jacket.
4. **Autoclave door.** A device which allows the sterilization chamber to be isolated from the outside environment. It normally has safety devices that prevent it from opening when the chamber is pressurized. It also has seals for preventing vapour from leaving the chamber when the equipment is in operation. Autoclave doors can be manually or electromechanically operated.

5. **Door handle.** A device which in some equipment, allows the operator to open and close the door. The larger capacity equipment in general has motorized mechanisms for activating the door.
6. **Sterilization chamber.** The space where objects or materials to be sterilized are placed. When the door is closed, the chamber remains isolated from the exterior. When the sterilization process is in progress, it is filled and pressurized with vapour.
7. **Chamber condensation evacuation line.** A duct that allows the collecting of condensation formed in the sterilization chamber as a consequence of the heat transference processes between the vapour and objects being sterilized.
8. **Thermometer.** An instrument that indicates the temperature at which the sterilization processes in the autoclave chamber is done.
9. **The jacket's condensation evacuation line.** A duct that allows the extraction of condensation formed in the casing as a result of heat transference between the vapour and the jacket's walls.
10. **Vapour exit at the end of the cycle.** When a sterilization cycle is finished, vapour is extracted from the autoclave by controlled procedures.
11. **Vapour passage restriction for liquid sterilization cycle.** A mechanical device that restricts the passage of vapour during a liquid sterilization cycle to allow the temperature to decrease in a controlled manner and to prevent sterilized liquids from boiling.

**Figure 32. Vapour circuit of an autoclave**



12. **Vapour evacuation duct for sterilization of liquids.** A path followed by vapour when a liquid sterilization process is being conducted and which passes through the restriction described above.
13. **Vapour evacuation line during the rapid sterilization cycle.** A path that follows vapour when a rapid sterilization cycle is being carried out.
14. **Vapour feed line.** A conduct that feeds the autoclave with vapour. This line has controls and accessories that enable vapour to reach the autoclave at the conditions stipulated for the sterilization cycle.
15. **Air admission valve with filter.** A device that allows the entry of filtered air upon finishing the sterilization cycle. The valve homogenizes the pressure of the sterilization chamber to that of the atmosphere.
16. **Jacket.** A space located around the sterilization chamber in which vapour circulates. Its purpose is to transfer heat to the chamber and lessen the formation of condensation. It is connected to the chamber and to the drainage through lines controlled by electrovalves. Not all autoclaves have jackets. Some manufacturers substitute it by placing electrical resistors around the sterilization chamber.
17. **Vapour entry regulation valve.** It is a mechanical device which controls the pressure at which vapour enters the autoclave. Depending on the cycle selected, the pressure and the temperature will be different. The greater the pressure, the greater the temperature. The lesser pressure, the lesser the temperature.
18. **Vapour feed line.** A duct that brings vapour from the boiler or the vapour generator to the autoclave.
19. **Vapour trap.** A device designed to take maximum advantage of vapour's thermal energy. Its function is to prevent vapour from leaving the system. The trap only allows condensed liquid formed in the chamber, jacket and autoclave conducts to leave.
20. **Drain.** A collection line for the condensed liquid produced in the autoclave to exit.

Nowadays, autoclaves use microprocessor-controlled systems and each one of their valves and accessories work in accordance with pre-established programs stored in their memory. Operations remain recorded in a registering system, which allows the different stages of the sterilization to be checked. Each manufacturer has incorporated registering systems which are indispensable for quality control.

**Vapour production.** The vapour autoclaves use is generated in devices which transfer thermal energy to water using electrical energy or fossil combustible. These are called boilers or vapour generators and constitute a fundamental component of the autoclave. Depending on their size and the frequency of use, autoclaves have vapour feed systems that originate from a central system of boilers or from their own vapour generator. These generally function

with electrical resistors and come already incorporated into the equipment or are supplied as an accessory by the manufacturers.

### OPERATION OF THE AUTOCLAVE

The general operation of an autoclave is described next. Some procedures will vary according to the degree of automation incorporated into the equipment:

1. Verify that the registering system has forms and/or paper required for documenting the development of the sterilization cycle. Supply any missing element (ink, form, etc.).
2. Turn the autoclave ON.
3. Open the door of the autoclave. In large capacity autoclaves, this process is done electromechanically. It is often manual in medium and low capacity autoclaves.
4. Place the sterilization baskets or containers containing the previously prepared material (cleaned, washed, dried, classified and packaged) into the sterilization chamber, according to the manufacturers' recommended distribution instructions.
5. Close the door of the autoclave<sup>1</sup>.
6. Select the required sterilization cycle depending on the type of objects or materials to be sterilized<sup>2</sup>. In general, a labelled button corresponding to the cycle required is pressed and automatically initiates the programmed cycle. From this moment on, the process proceeds as indicated next<sup>3</sup>:
  - a) The pre-treatment phase is initiated. In this phase, short alternate cycles of emptying and injecting of vapour into the sterilization chamber are performed so that air is extracted from it and packets protecting the material are sterilized.
  - b) When the air has been removed, filling and pressurization of the sterilization chamber is initiated. At this time, the vapour enters into contact with objects to be sterilized and a process of heat transference is initiated between high temperature vapour and articles to be sterilized. Upon transferring thermal energy, a portion of vapour is converted into liquid water (condensed liquid) in the exterior layers of the material used for packing, simultaneously decreasing its volume in a significant way. More vapour can then enter the sterilization chamber, which penetrates even further inside the packages to be sterilized. Vapour eventually completely surrounds these and the pressure and temperature are established.

<sup>1</sup> Before loading the autoclave, the jacket is pressurized so that the interior of the chamber is hot to reduce the formation of condensed liquid at the beginning of the sterilization cycle.

<sup>2</sup> See the information on the sterilization cycles included further on.

<sup>3</sup> A typical cycle of a sterilizing autoclave, equipped with an exhaust system activated by an electro hydraulic pump is described.

- c) Once these conditions are attained, the countdown for completing the sterilization (depending on the type of objects or materials being processed) is initiated. The higher the temperature and pressure, the lesser the time required for sterilizing.
  - d) Once the programmed sterilization time has ended, post treatment process is initiated. This includes depressurization of the chamber normally done with the help of the exhaust and drying system using the supply of heat transferred from the jacket to the sterilization chamber. Upon decreasing the pressure, the required temperature for evaporating any liquid residue that may have formed on objects during depressurization is attained. A vacuum of 10 % of the atmospheric pressure is created and maintained steady for a period of time. When liquids are sterilized, no vacuum is created; rather, vapour extraction is controlled through a restrictive mechanism to prevent boiling inside the containers autoclaved.
  - e) Finally, controlled entry of air through valves with high efficiency filters will be allowed until the pressure in the sterilization chamber is equal to the atmospheric pressure. The sterilization cycle has ended.
7. Open the door of the autoclave.
  8. Unload the sterilized material.
  9. Close the door once the sterilized material is unloaded to conserve the heat in the sterilization chamber and facilitate the next sterilization cycle.
  10. Store the sterilized material appropriately.

**Note:** The sterilization cycles must be supervised and submitted to quality control procedures through the use of physical, chemical and biological type indicators for ensuring their effectiveness.

**Warning:** Not all objects can be sterilized with moist heat. Some require sterilization procedures at low temperature. Verify which procedure must be used according to the type of material to be sterilized.

### Sterilization cycles

The sterilization processes follow predefined cycles according to the type of load to be sterilized. There are different sterilization cycles for porous materials, surgical instruments, liquids or heat sensitive material. The main ones known as clinical sterilization cycles are carried out under the following conditions: 121 °C / 1.1 kg /cm<sup>2</sup> or 134 °C / 2.2 kg /cm<sup>2</sup>. Their main characteristics are featured in the table on the next page.

**Note:** The sterilization cycle times are adjusted to the altitude where the autoclave is located. Manufacturers supply compensation tables to be taken into account. In

general, the higher the altitude of the equipment's location, the longer the sterilization time will be.

### Quality Control

In order for a product to be considered sterilized, it is necessary to verify that all the stages of the sterilization process have been carried out correctly. To verify that these have been fulfilled, a series of tests have been developed to evaluate the characteristics of the process and its influence on the activity of microorganisms. Evaluations of the temperature, pressure, time, humidity and general equipment behaviour are carried out to certify that it complies with, and functions according to procedures that demonstrated its validity and reliability. There are also tests or indicators that allow the death of the microorganisms to be certified in order to guarantee the quality of the sterilization processes. Different categories of tests have been developed. Some are featured next:

1. **Sterilization process indicators.** These are designed for supervising the functioning of the autoclaves. They include instruments that control parameters like temperature, time and pressure (thermometers, manometers and chronometers) and register the development of the process. The registering systems of modern autoclaves (microprocessor) register all the parameters of the sterilization cycle and also halt the cycle in case some anomaly occurs. There is also the Bowie-Dick test in this category: it evaluates the efficiency of the exhaust pump using a test sheet which changes in colour uniformly if the process has been completed satisfactorily. If it is not the case, the colour of the sheet is uneven.
2. **Chemical indicators.** These are typical chemical tests changing colour or state when exposed to the different phases of the sterilization process. Chemical indicators allow the differentiation of articles submitted or exposed to a successful sterilization process from those that have not. Among the best known are the adhesive tapes or strips that go inside a component or on packages. The ISO N° 11140-1 standard describes categories of chemical indicators. One has to keep in mind that chemical indicators by themselves do not guarantee that the sterilization process complied with all the requirements: personnel who use these must receive precise training to allow them to determine if the result obtained is coherent with the evolution of the whole sterilization process.
3. **Biological indicators.** These are considered the best methods for controlling the quality of a sterilization process. They are made of live microorganisms which have a greater resistance to a determined sterilization process, or of chemical reagents which react in the presence of the specific proteins of this type of organism. In order to control the sterilization process by saturated vapour, (hydrogen peroxide) or formaldehyde, spores

Cycle no.	Materials	Temp. °C	Pressure kg/cm <sup>2</sup>	Typical graph <sup>1</sup>
1	<ul style="list-style-type: none"> <li>• Porous loads</li> <li>• Textiles</li> <li>• Wrapped instruments</li> <li>• Tubes</li> </ul>	135	2.2	
2	<ul style="list-style-type: none"> <li>• Open instruments</li> <li>• Utensils</li> <li>• Glassware</li> <li>• Open containers</li> </ul>	135	2.2	
3	<ul style="list-style-type: none"> <li>• Heat sensitive materials</li> <li>• Rubber</li> <li>• Plastic</li> </ul>	121	1.1	
4	<ul style="list-style-type: none"> <li>• Liquids in open or semi-closed containers. (*)</li> </ul>	121	1.1	<p>121°C, 20 min Time</p>
Convention	<p>A: Pre-treatment. Alternate cycles of injection / vacuum of vapour. Pre-treatment. (Processes 1, 2, 3).</p> <p>Process 4: Sterilization.</p> <p>C: Post-treatment (Process 5: vacuum and drying).</p> <p>D: Internal and external pressures completely mixed.</p> <p><b>Note:</b> The liquid process does not have vacuum after sterilization. The cooling is natural.</p>			

<sup>1</sup> The graphs included correspond to an autoclave with an emptying pump, Getinge brand GE-660 autoclave.  
 (\*) Times depend on the volume of the load. There is no vacuum during cooling.



of *Bacillus stearotherophilus* are generally used. To control sterilization by dry heat (a process that drying ovens perform) and by ethylene oxide, spores of the *Niger* variety of *Bacillus subtilis* are used. The spore indicator is placed in the sterilizing load. After the process, it is incubated, analyzed and it is determined if the cycle meets with the sterilization requirements. Generally a change of colour is observed. These tests are standardized and manufacturers indicate how to use them and interpret the results. Biological indicators by themselves do not guarantee that the sterilization cycle complies with all the requirements. The only way to do this is by controlling all the sterilization cycle's parameters.

**Frequency of the quality control processes**

A table summarizing the suggested frequency with regard to the use of quality control indicators in the sterilization processes is shown next.

Type of indicator	Frequency of use
Process	In each sterilization cycle.
Chemical	In each package.
Biological	Weekly, in all the sterilization equipment; in the packets that contain implants.

**INSTALLATION REQUIREMENTS**

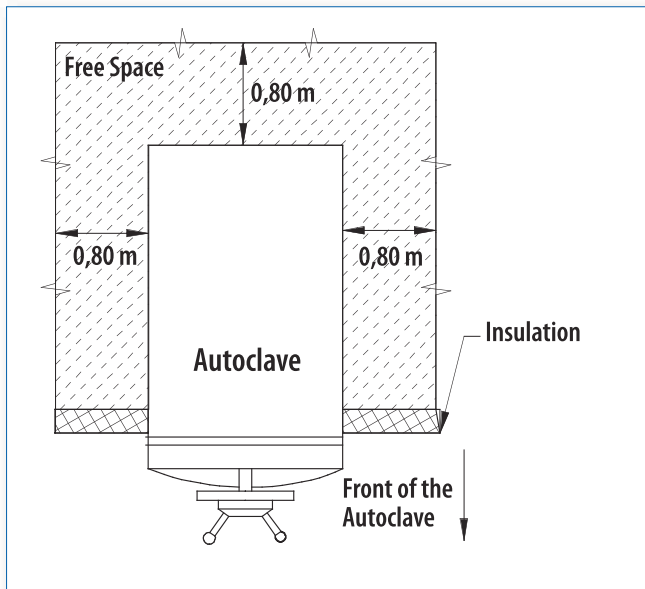
To be able to function, autoclaves require the following services:

1. A well ventilated area for removing heat and humidity generated while in operation. It also requires free space around the back and sides, to accommodate technical

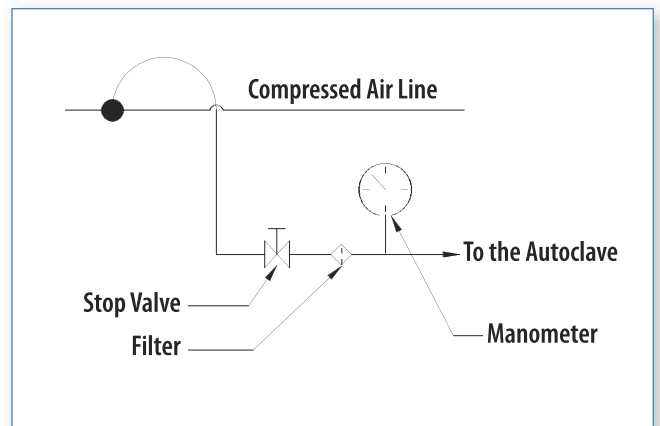
servicing. This space should be at least 0.8 m. Depending on the design of the autoclave, complementary infrastructure must be anticipated so that it can operate satisfactorily. The diagram in Figure 33 explains the space required around the autoclave. The temperature in the immediate vicinity of the equipment may increase to more than 70 °C when it is in operation. The floor should be well levelled and constructed with materials resistant to humidity and heat.

2. An electrical outlet in proportion to the equipment's consumption. If the autoclave is autonomous, meaning that it has its own vapour generator, the electrical connection must be studied in detail as the required power could be significantly higher. Typical power demands are 21, 38, 48 kW and higher, for the vapour generator to function. The connection must be equipped with required safety and protection elements. The typical voltages required for autoclaves are 220 V, 60 Hz, or 380 V, 60 Hz triphase.
3. Water connection proportional to the equipment's consumption in volume and pressure: the larger the equipment, the greater the consumption. The water which the autoclave consumes must have received required treatments for eliminating solids in suspension as these may negatively affect the functioning of the electrovalves as well as that of the electro hydraulic devices.
4. Some sterilizers require compressed air, as their controls are managed by pneumatic pressure. In general, the required pressure varies from  $5 \times 10^5$  to  $9.9 \times 10^5$  Pa. The following diagram shows the minimum installation requirements (cut-off valve, filter and manometer).
5. A drainage system designed for collecting hot water.
6. A vapour connection. If the autoclave does not have its own vapour generator, it must be fed from the institution's vapour generating system (machine room, boiler). The supply installation must meet the necessary

**Figure 33.** Space required for autoclave



**Figure 34.** Compressed air connection



requirements: a cut-off valve, filter, manometer as well as an appropriate installation for collecting the condensed liquid with a filter and vapour trap, as indicated in the

Figure 35. Vapour connection

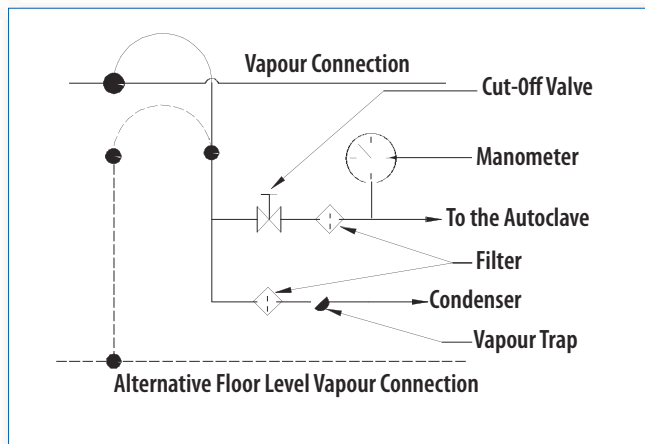


Figure 35.

- The autoclave must be operated exclusively by personnel specially trained and qualified in these types of processes.

### ROUTINE MAINTENANCE

The autoclave is equipment which demands supervision and continuous preventive maintenance due to its multiple components and systems. Maintenance is focused on the basic routines that can be performed by the operators. In order to carry out detailed maintenance, the instructions described in the manufacturer's service manuals must be followed.

#### Daily verifications

Before initiating the sterilization processes, the following verifications will have to be carried out:

- Place a new form on the registration device in order to document the development of the sterilization cycle.
- Ensure that the cycle-recording pen or that the printing module of the autoclave has ink and recording paper.
- Ensure that the cold water, compressed air and vapour supply valves are open.
- Activate the switch that triggers the autoclave's jacket heating. Upon activating this control, vapour is allowed to enter the sterilization chamber's jacket. When vapour enters the sterilization chamber, the heating process begins. To avoid heat loss, keep the autoclave's door closed until it is time to add the load for sterilization.
- Verify that the pressure from the vapour supply line is at least 2.5 bar.
- Test the condition of manometers and thermometers.
- Ensure that there are no vapour leaks in any of the systems functioning in the autoclave.
- Clean the front of the autoclave, controls, indicators and

handles with a damp cloth.

#### Weekly maintenance

##### **Responsible: The equipment operator**

- Clean the sterilization chamber drainage filter. Remove any residue retained inside.
- Clean the inside of the sterilization chamber using cleaning products that do not contain chlorine. Clean the guides used for placing the baskets as well.
- Clean with an acetified solution, if solutions with chlorine are being sterilized. The chlorine causes corrosion even on stainless steel implants. Next, wash with plenty of water.
- Clean the external rust-proof surfaces with a mild detergent. A solvent like ethylene chloride can be used, avoiding touching any surface with painted coverings, markings or plastic coverings.
- In autoclaves with manually activated doors, verify that these mechanisms are well adjusted and that their operation is smooth.
- Drain the vapour generator (if the equipment has one). To do this, open a valve located on the lower part of the generator which allows its contents to be drained. Generally this is done at the end of weekly activities. Follow the manufacturer's recommendations.
- Never use steel wool for cleaning the inside of the sterilization chamber.
- Check adequate functioning using a biological or chemical indicator. To check the temperature, use chemical test strips checking time and temperature of exposure sold for this purpose.

#### Quarterly maintenance

##### **Responsible: The autoclave technician**

- Check that the manometers function as expected.
- Activate the safety valves manually to verify that they are operating well. Use a large screwdriver to move the activation lever normally located in the upper part of the valve. Make sure that the face and body of the operator are not in the vapour's path. Once the valve is activated, ensure that there are no vapour leaks. If there are any leaks, the valve must be activated again until it is well sealed.

**Warning:** If vapour leaks are not eliminated, this will deteriorate the seal rapidly and the whole safety valve system will have to be replaced.

- Lubricate the door's gasket. Use the lubricant and the procedure recommended by the equipment's manufacturer. Some manufacturers recommend the following procedure:
  - Remove the gasket. To do this, it is necessary to dismount from the groove, loosening the retention mechanisms (screws and plates).



- b) Clean the gasket and the groove with alcohol so that there is no foreign material to affect the seal. The surface of the gasket must stay smooth and clean.
  - c) Apply the lubricant recommended by the manufacturer to the body of the gasket until it is completely protected. Many autoclave manufacturers use graphite lubricant resistant to high temperatures.
  - d) Reinstall the gasket. In rectangular chamber autoclaves, this is normally installed placing the gasket in the middle of one of the assembly groove's sides and adjusting the remaining portion towards the sides, until it is well adjusted inside the groove. The same procedure is repeated for each remaining side. In round chamber autoclaves, the gasket assembly begins on the upper part and is adjusted progressively into the groove without pulling it, until the whole gasket is installed. Next, assembly elements are adjusted.
4. Verify that the seals of the safety valves are in good condition.
  5. Clean the points of the registration pen system with water or alcohol and restore the ink levels. Generally, the pressure is registered with red ink and the temperature with green.
  6. Clean the inside of the vapour generator (for equipment with this accessory). For the vapour generator, the cleaning procedure involves carrying out the following activities:
    - a) Disconnect the electrical supply to the equipment.
    - b) Discharge the vapour pressure and wait for the equipment to reach room temperature.

- c) Remove the front cover of the generator.
- d) Disconnect the electrical terminals of the heating resistors (immersion).
- e) Remove the screws that secure the front plate where the heating resistances are installed and dismount the front plate.
- f) Check the gasket and substitute it if necessary.
- g) Remove dirt accumulated on the surface of the heating resistors. Use products recommended<sup>1</sup>.
- h) Re-assemble in the reverse order.

Figure 36 shows the vapour generator and its components.

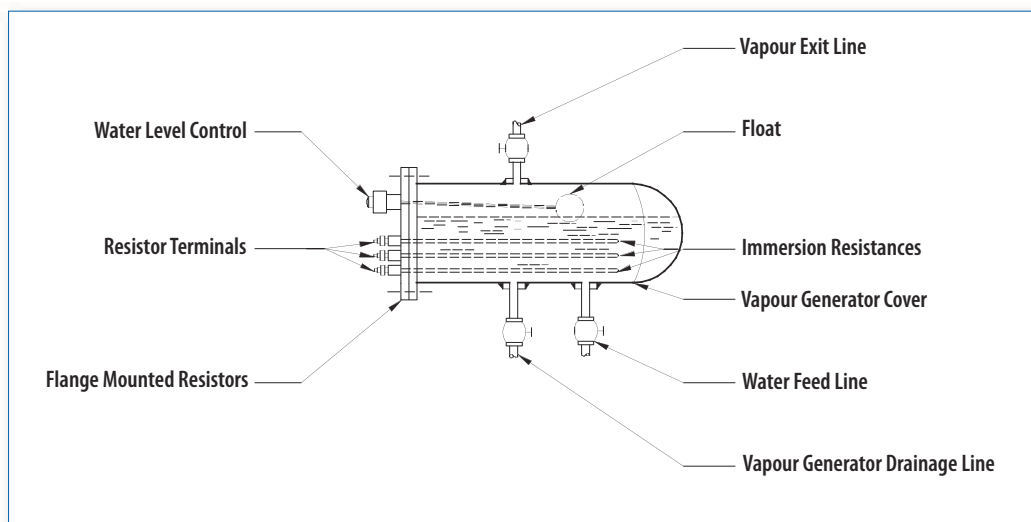
**Annual maintenance**

**Responsible: The autoclave technician**

1. Clean all the filters.
2. Test and adjust the water level of feed tank so that it is within 20 mm of the maximum level.
3. Verify and adjust the tension of diaphragm valves' springs.
4. Dismount, clean and adjust the safety valves.
5. Change the air filter.
6. Conduct a general sterilization process testing in detail the pressure, temperature, required times for completing each phase of the cycle, state of the process' signal lamps and functioning of the registration system. Verify that it is functioning within tolerances defined by the manufacturer.
7. Perform the quarterly routines.

<sup>1</sup> Incrustations are seen when the water used by the vapour generator has not received adequate treatment.

**Figure 36. Vapour generator**



## MAINTENANCE OF SPECIALIZED COMPONENTS

Included next are some specialized routines requiring a service technician and applicable to equipment components. Given that autoclaves have multiple designs, routines stipulated here are only applicable to certain equipment models.

### Maintenance of solenoid valves

1. Verify the sound made by the bobbins or solenoids (*humming*). Excessive noise is a warning of overheating due to abnormally high electric currents through the solenoid. Current alternates rise when the impedance [Z] of the circuit decreases. This occurs when the solenoid is not adequately surrounded by a closed iron cover. An air gap in the magnetic circuit can be caused by dirt which prevents the protective cover from reaching its final position when the solenoid is energized. Carefully clean the housing of the bobbin and its nucleus so that the piston's movement is not impeded by filth.
2. Replace the O-rings between the solenoid and the body of the valve once these have been disassembled.
3. Before any disassembly, verify how the solenoid valve is installed. Some possess clear installation indications but others lack such information.
4. When dismantling a servo-assisted solenoid valve, control the position of the orifices that put it in contact with the work environment, so as to be able to re-assemble the valve.

## Cleaning of the vapour filter

**Warning:** Before disassembling the vapour filter, dissipate the vapour pressure in the system.

1. Lift the cover.
2. Remove the mesh.
3. Clean carefully.
4. Reinstall the mesh.
5. Replace the cover.

Here are some of the most common problems. Given the diversity of brands, models and available technology, it is advisable that users follow instructions from the user manual for the autoclave used.

TROUBLESHOOTING TABLE			
PROBLEM	PROBABLE CAUSE	SOLUTION	
The sterilization indicator did not indicate the successful end of the sterilization cycle.	The sterilization chamber is incorrectly loaded or over-loaded.	Check the load distribution and the load quantity. Adjust according to the manufacturer's recommendations.	
	The vapour trap is defective.	Check the vapour trap. Repair or substitute it.	
	The sterilization time is insufficient.	Check the sterilization time. Adjust to the cycle type.	
	The autoclave does not reach the temperature and sterilization pressure selected.		Check the temperature selection. Check the vapour pressure corresponding to the selected cycle.
			Check for possible vapour leaks in the door (gasket) or in the passage control devices.
	There is insufficient vapour penetration.	Reduce the quantity of packets to be sterilized; this allows a better vapour flow.	
	The pre-treatment is inadequate. Too much air has remained inside the chamber.	Seek the assistance of a specialized service technician to check the exhaust system.	
The biological indicator is inappropriate for the cycle conducted.	Check the user specifications of the biological indicator. Repeat the sterilization cycle.		
The sterilization cycle is interrupted without any apparent reason.	Inadequate vapour, water or air pressure. As a result, the regulation and servo-assisted control devices are not activated.	Check vapour, water and air feed pressures. Adjust the regulation systems.	
The sterilized material comes out damp.	The vapour trap is defective.	Check/clean the vapour trap. Substitute the trap.	
	The sterilization chamber drainage is blocked.	Check the drainage system. Clean.	
	The autoclave is overloaded.	Reduce the load quantity in the chamber. Repeat the sterilization cycle.	
	The autoclave is not levelled.	Level the autoclave.	
The biological indicator is positive.	The biological indicator was incorrectly selected.	Use a biological indicator of another lot or manufacturer. Carefully register the parameters.	
Vapour pressure too low.	The door's gasket is defective.	Check the gasket; replace it.	
	The internal vapour leaks into another autoclave component.	Check the traps, electrovalves etc.	
There is excessive vapour pressure.	The autoclave is overloaded with textile material.	Reduce the autoclave's load.	
	Autoclave is not calibrated.	Calibrate the autoclave.	

## BASIC DEFINITIONS

**Asepsis.** A set of procedures necessary to eliminate microorganisms.

**Atmosphere.** An old unit of pressure equivalent to 101 325 Pa (Pascals) or to 14.69 pounds per square inch.

**Bar.** A unit of pressure equivalent to  $10^5$  Pa (Pascals).

**Cleaning.** Mechanical removal of all foreign material located on the surface of inanimate objects; in general, it implies the use of clean water combined with a detergent. It is a basic procedure performed before submitting the objects to their respective sterilization processes. Cleaning can be done manually or by using automatic methods. It must be understood that it is not a procedure destroying microorganisms, but only decreasing their quantity.

**Decontamination.** A procedure to decrease the quantity of microorganisms of an object or substance so that its use or/and manipulation is safe. For example, objects used in patient care procedures in possible contact with fluids, bodily substances or organic materials require decontamination or even sterilization (see definition below).

**Disinfection.** A process that uses physical or chemical means to destroy any form of life in a vegetative state from inanimate objects (excluding spores).

**Inspection.** A visual evaluation of washed articles, with the purpose of finding defects or dirt that may interfere with the sterilization processes. It is a process of great importance which may be done using a magnifying glass to discern minute details.

**Jacket.** Enclosed space around the sterilization chamber through which vapour circulates. Its function is to transfer heat to the sterilization chamber in the pre-treatment stages (air removal) and post treatment (drying of the sterilized material).

**Moist heat.** A sterilization method that eliminates microorganisms by denaturation of the proteins which is accelerated by the presence of water vapour (steam).

**Pascal (Pa).** A unit of pressure from the International system, which corresponds to the force of a Newton (N) that acts on a (1) square meter:

$$\text{Pa} = \frac{1\text{N}}{\text{m}^2}$$

**Quality.** Thermodynamic property identified in general with the letter [X] and defined as the relationship existing between the vapour mass and the total mass of the substance under saturated conditions.

**Servo-assisted valves.** Solenoid-type valves that depend on the surrounding pressure to close or open. In general, these have membranes with small openings through which the working medium is supplied.

**Solenoid valves.** Electromagnetic control devices used in multiple applications also known as electrovalves. The position of a piston is controlled by a bobbin which is energized or at rest. The piston permits or impedes the passage of a fluid inside of a determined circuit. They are used in hydraulic, pneumatic, vapour and vacuum systems. Manufacturers have developed a great number of designs for specialized applications.

**Sterilization.** A set of actions by means of which all forms of life are destroyed (including spores) on inanimate objects using physical, chemical and gaseous procedures.

**Sterilization chamber.** The area where objects requiring sterilization are placed. When the sterilization process is being carried out, the chamber is filled with pressurized vapour, reaching temperatures directly related to the selected pressures. During the sterilization cycle, it is sealed by a door by a safeguarding system which can only be opened once the sterilization process has been completed and the internal pressure has reached that of the atmosphere.

**Sterilization indicator.** A chemical or biological indicator that allows checking if an object or material has been submitted to a sterilization process successfully. The most commonly known are the thermosensitive tape (it changes colour when the determined temperature conditions are reached) and *B. stearothermophilus* spores.

**Vapour trap.** A device designed to restrict the passage of vapour and allow the passage of condensed liquid.