Equipment Packet: Autoclave

UMDNS #: 13746

Date of Creation: September 16, 2015

Creator: Engineering World Health EWH

Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of autoclaves.

Part I: External from the Packet:

1. **Introduction to Autoclaves** (PowerPoint)

Part II: Included in this Packet:

1. Introduction to Autoclaves

Featured in this Section:

Malkin, Robert. Medical Instrumentation in the Developing World. Engineering World Health, 2006.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Wikipedia. “Sterilization (Microbiology).” *Wikipedia*, p. 1-12. Retrieved from: https://en.wikipedia.org/wiki/Sterilization_(microbiology)

Brief Introduction to Autoclaves

User Care of Medical Equipment – First line maintenance for end users

Chapter 4.2 Autoclaves and Sterilizers

Function

Sterilization is the killing of microorganisms that could harm patients. It can be done by heat (steam, air, flame or boiling) or by chemical means. Autoclaves use high pressure steam and sterilizers use boiling water mixed with chemicals to achieve this. Materials are placed inside the unit for a carefully specified length of time. Autoclaves achieve better sterilization than boiling water sterilizers. Autoclaves can be small table top designs (e.g. dental departments), portable upright units (e.g. small clinics) or large fixed systems.

How it works

Heat is delivered to water either by electricity or flame. This generates high temperature within the chamber. The autoclave also contains high pressure when in use, hence the need for pressure control valves and safety valves. Users must be careful to check how long items need to be kept at the temperature reached.

Sterilization (microbiology)

Sterilization (or **sterilisation**, see spelling differences) refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, spore forms, etc.) from a surface, equipment, article of food or medication, or biological culture medium.[1] [2] Sterilization does not, however, remove prions. Sterilization can be achieved through application of heat, chemicals, irradiation, high pressure or filtration.

Applications

Foods

The first application of sterilization by Nicolas Appert was thorough cooking to affect the partial heat sterilization of foods and water. Cultures that practice heat sterilization of food and water have longer life expectancy and lower rates of disability. Canning of foods by heat sterilization was an extension of the same principle. Ingestion of contaminated food and water remains a leading cause of illness and death in the developing world, particularly for children.

Medicine and surgery

In general, surgical instruments and medications that enter an already sterile part of the body (such as the blood, or beneath the skin) must have a high sterility assurance level. Examples of such instruments include scalpels, hypodermic needles and artificial pacemakers. This is also essential in the manufacture of parenteral pharmaceuticals.

Heat sterilization of medical instruments is known to have been used in Ancient Rome, but it mostly disappeared throughout the Middle Ages resulting in significant increases in disability and death following surgical procedures.

Preparation of injectable medications and intravenous solutions for fluid replacement therapy requires not only a high sterility assurance level, but well-designed containers to prevent entry of adventitious agents after initial sterilization.

Compare sterilisation to sanitization which reduces the number of viable organisms to an acceptable level. An example of the latter is Pasteurization.

Heat sterilization

Steam sterilization utensils

Front-loading autoclaves

A widely-used method for heat sterilization is the autoclave, sometimes called a converter. Autoclaves commonly use steam heated to 121–134 °C (250–273 °F). To achieve sterility, a holding time of at least 15 minutes at 121 °C (250 °F) or 3 minutes at 134 °C (273 °F) is required. Additional sterilizing time is usually required for liquids and instruments packed in layers of cloth, as they may take longer to reach the required temperature (unnecessary in

machines that grind the contents prior to sterilization). Following sterilization, liquids in a pressurized autoclave must be cooled slowly to avoid boiling over when the pressure is released. Modern converters operate around this problem by gradually depressing the sterilization chamber and allowing liquids to evaporate under a negative pressure, while cooling the contents.

Proper autoclave treatment will inactivate all fungi, bacteria, viruses and also bacterial spores, which can be quite resistant. It will not necessarily eliminate all prions.

For prion elimination, various recommendations state 121–132 °C (250–270 °F) for 60 minutes or 134 °C (273 °F) for at least 18 minutes. The prion that causes the disease scrapie (strain 263K) is inactivated relatively quickly by such sterilization procedures; however, other strains of scrapie, as well as strains of CJD and BSE are more resistant. Using mice as test animals, one experiment showed that heating BSE positive brain tissue at 134–138 °C (273–280 °F) for 18 minutes resulted in only a 2.5 log decrease in prion infectivity. (The initial BSE concentration in the tissue was relatively low). For a significant margin of safety, cleaning should reduce infectivity by 4 logs, and the sterilization method should reduce it a further 5 logs.

To ensure the autoclaving process was able to cause sterilization, most autoclaves have meters and charts that record or display pertinent information such as temperature and pressure as a function of time. Indicator tape is often placed on packages of products prior to autoclaving. A chemical in the tape will change color when the appropriate conditions have been met. Some types of packaging have built-in indicators on them.

Biological indicators ("bioindicators") can also be used to independently confirm autoclave performance. Simple bioindicator devices are commercially available based on microbial spores. Most contain spores of the heat resistant microbe *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*), among the toughest organisms for an autoclave to destroy. Typically these devices have a self-contained liquid growth medium and a growth indicator. After autoclaving an internal glass ampule is shattered, releasing the spores into the growth medium. The vial is then incubated (typically at 56 °C (133 °F)) for 24 hours. If the autoclave destroyed the spores, the medium will remain its original color. If autoclaving was unsuccessful the *B. sterothermophilus* will metabolize during incubation, causing a color change during the incubation.

For effective sterilization, steam needs to penetrate the autoclave load uniformly, so an autoclave must not be overcrowded, and the lids of bottles and containers must be left ajar. Alternatively steam penetration can be achieved by shredding the waste in some Autoclave models that also render the end product unrecognizable(www.hydroclave.com). During the initial heating of the chamber, residual air must be removed. Indicators should be placed in the most difficult places for the steam to reach to ensure that steam actually penetrates there.

For autoclaving, as for all disinfection or sterilization methods, cleaning is critical. Extraneous biological matter or grime may shield organisms from the property intended to kill them, whether it physical or chemical. Cleaning can also remove a large number of organisms. Proper cleaning can be achieved by physical scrubbing. This should be done with detergent and warm water to get the best results. Cleaning instruments or utensils with organic matter, cool water must be used because warm or hot water may cause organic debris to coagulate. Treatment with ultrasound or pulsed air can also be used to remove debris.

Food

Although imperfect, cooking and canning are the most common applications of heat sterilization. Boiling water kills the vegetative stage of all common microbes. Roasting meat until it is well done typically completely sterilizes the surface. Since the surface is also the part of food most likely to be contaminated by microbes, roasting usually prevents food poisoning. Note that the common methods of cooking food **do not** sterilize food - they simply reduce the number of disease-causing micro-organisms to a level that is not dangerous for people with normal digestive and immune systems.

Pressure cooking is analogous to autoclaving and when performed correctly renders food sterile. However, some foods are notoriously difficult to sterilize with home canning equipment, so expert recommendations should be followed for home processing to avoid food poisoning.

Food utensils

Dishwashers often only use hot tap water or heat the water to between 49 and 60 °C (120 and 140 °F), and thus provide temperatures that could promote bacterial growth. That is to say, they do not effectively sterilize utensils. Some dishwashers do actually heat water up to 74 °C (165 °F) or higher; those often are specifically described as having sterilization modes of some sort, but this is not a substitute for autoclaving.

Note that dishwashers remove food traces from the utensils by a combination of mechanical action (the action of water hitting the plates and cutlery) and the action of detergents and enzymes on fats and proteins. This removal of food particles thus removes one of the factors required for bacterial growth (food), it clearly explains why items with cracks and crevices should either be washed by hand or disposed of: if the water cannot get to the area needing cleaning, the warm, moist, dark conditions in the dishwasher can actually promote bacterial growth.

Bathing

Bathing and washing are not hot enough to sterilize bacteria without scalding the skin. Most hot tap water is between 43 and 49 °C (109 and 120 °F), though some people set theirs as high as 55 °C (131 °F). Humans begin to find water painful at 41 to 42 °C (106 to 108 °F), which to many bacteria is just starting to get warm *enough* for them to grow quickly; they will grow faster, rather than be killed at temperatures up to 55 °C (131 °F) or more.

Other methods

Other heat methods include flaming, incineration, boiling, tindalization, and using dry heat.

Flaming is done to loops and straight-wires in microbiology labs. Leaving the loop in the flame of a Bunsen burner or alcohol lamp until it glows red ensures that any infectious agent gets inactivated. This is commonly used for small metal or glass objects, but not for large objects (see Incineration below). However, during the initial heating infectious material may be "sprayed" from the wire surface before it is killed, contaminating nearby surfaces and objects. Therefore, special heaters have been developed that surround the inoculating loop with a heated cage, ensuring that such sprayed material does not further contaminate the area. Another problem is that gas flames may leave residues on the object, e.g. carbon, if the object is not heated enough.

A variation on flaming is to dip the object in 70% ethanol (or a higher concentration) and merely touch the object briefly to the Bunsen burner flame, but not hold it in the gas flame. The ethanol will ignite and burn off in a few seconds. 70% ethanol kills many, but not all, bacteria and viruses, and has the advantage that it leaves less residue than a gas flame. This method works well for the glass "hockey stick"-shaped bacteria spreaders.

Incineration will also burn any organism to ash. It is used to sanitize medical and other biohazardous waste before it is discarded with non-hazardous waste.

Boiling in water for fifteen minutes will kill most vegetative bacteria and inactivate viruses, but boiling is ineffective against prions and many bacterial and fungal spores; therefore boiling is unsuitable for sterilization. However, since boiling does kill most vegetative microbes and viruses, it is useful for reducing viable levels if no better method is available. Boiling is a simple process, and is an option available to most people, requiring only water, enough heat, and a container that can withstand the heat; however, boiling can be hazardous and cumbersome.

Tindalization[3] **/Tyndallization**[4] named after John Tyndall is a lengthy process designed to reduce the level of activity of sporulating bacteria that are left by a simple boiling water method. The process involves boiling for a period (typically 20 minutes) at atmospheric pressure, cooling, incubating for a day, boiling, cooling, incubating for a day, boiling, cooling, incubating for a day, and finally boiling again. The three incubation periods are to allow

heat-resistant spores surviving the previous boiling period to germinate to form the heat-sensitive vegetative (growing) stage, which can be killed by the next boiling step. This is effective because many spores are stimulated to grow by the heat shock. The procedure only works for media that can support bacterial growth - it will not sterilize plain water. Tindalization/tyndallization is ineffective against prions.

Dry heat can be used to sterilize items, but as the heat takes much longer to be transferred to the organism, both the time and the temperature must usually be increased, unless forced ventilation of the hot air is used. The standard setting for a hot air oven is at least two hours at 160 °C (320 °F). A rapid method heats air to 190 °C (374 °F) for 6 minutes for unwrapped objects and 12 minutes for wrapped objects.[5] [6] Dry heat has the advantage that it can be used on powders and other heat-stable items that are adversely affected by steam (for instance, it does not cause rusting of steel objects).

Dry heat sterilisator

Prions can be inactivated by immersion in sodium hydroxide (NaOH 0.09N) for two hours plus one hour autoclaving (121 °C/250 °F). Several investigators have shown complete (>7.4 logs) inactivation with this combined treatment. However, sodium hydroxide may corrode surgical instruments, especially at the elevated temperatures of the autoclave.

Glass bead sterilizer, once a common sterilization method employed in dental offices as well as biologic laboratories,[7] is not approved by the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to be used as inter-patients sterilizer since 1997.[8] Still it is popular in European as well as Israeli dental practice although there are no current evidence-based guidelines for using this sterilizer.[7]

Chemical sterilization

Chemicals are also used for sterilization. Although heating provides the most reliable way to rid objects of all transmissible agents, it is not always appropriate, because it will damage heat-sensitive materials such as biological materials, fiber optics, electronics, and many plastics. Low temperature gas sterilizers function by exposing the articles to be sterilized to high concentrations (typically 5 - 10% v/v) of very reactive gases (alkylating agents such as ethylene oxide, and oxidizing agents such as hydrogen peroxide and ozone). Liquid sterilants and high disinfectants typically include oxidizing agents such as hydrogen peroxide and peracetic acid and aldehydes such as glutaraldehyde and more recently o-phthalaldehyde. While the use of gas and liquid chemical sterilants/high level disinfectants avoids the problem of heat damage, users must ensure that article to be sterilized is chemically compatible with the sterilant being used. The manufacturer of the article can provide specific information regarding compatible sterilants. In addition, the use of chemical sterilants poses new challenges for workplace safety. The chemicals used as sterilants are designed to destroy a wide range of pathogens and typically the same properties that make them good sterilants makes them harmful to humans. Employers have a duty to ensure a safe work environment (Occupational Safety and Health Act of 1970, section 5 for United States) and work practices, engineering controls and monitoring should be employed appropriately.

Chemiclav

Ethylene Oxide

Ethylene oxide (EO or EtO) gas is commonly used to sterilize objects sensitive to temperatures greater than 60 °C such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/L for at least three hours. Ethylene oxide penetrates well, moving through paper, cloth, and some plastic films and is highly effective. Ethylene oxide sterilizers are used to process sensitive instruments which cannot be adequately sterilized by other methods. EtO can kill all known viruses, bacteria and fungi, including bacterial spores and is satisfactory for most medical materials, even with repeated use. However, it is highly flammable, and requires a longer time to sterilize than any heat treatment. The process also requires a period of post-sterilization aeration to remove toxic residues. Ethylene oxide is the most common sterilization method, used for over 70% of total sterilizations, and for 50% of all disposable medical devices.

The two most important ethylene oxide sterilization methods are: (1) the gas chamber method and (2) the micro-dose method. To benefit from economies of scale, EtO has traditionally been delivered by flooding a large chamber with a combination of EtO and other gases used as dilutants (usually CFCs or carbon dioxide). This method has drawbacks inherent to the use of large amounts of sterilant being released into a large space, including air contamination produced by CFCs and/or large amounts of EtO residuals, flammability and storage issues calling for special handling and storage, operator exposure risk and training costs

Ethylene oxide is still widely used by medical device manufacturers for larger scale sterilization (e.g. by the pallet), but while still used, EtO is becoming less popular in hospitals. Since Eto is explosive from its lower explosive limit of 3% all the way to 100%, EtO was traditionally supplied with an inert carrier gas such as a CFC or halogenated hydrocarbon. The use of CFCs as the carrier gas was banned because of concerns of ozone depletion [9] and halogenated hydrocarbons are being replaced by so-called 100% EtO systems because of the much greater cost of the blends. In hospitals, most EtO sterilizers use single use cartridges (e.g. 3M's Steri-Vac line[10], or Steris Corporation's Stericert sterilizers[11]) because of the convenience and ease of use compared to the former plumbed gas cylinders of EtO blends. Another 100% method is the so-called micro-dose sterilization method, developed in the late 1950s, using a specially designed bag to eliminate the need to flood a larger chamber with EtO. This method is also known as gas diffusion sterilization, or bag sterilization. This method minimizes the use of gas.[12]

Another reason for the decrease in use of EtO are the well known health effects. In addition to being a primary irritant, EtO is now classified by the IARC as a known human carcinogen.[13] The US OSHA has set the permissible exposure limit (PEL) at 1 ppm calculated as an eight hour time weighted average (TWA) [29 CFR 1910.1047] and 5 ppm as a 15 minute TWA. The NIOSH Immediately dangerous to life and health limit for EtO is 800 ppm.[14] The odor threshold is around 500 ppm[15] and so EtO is imperceptible until concentrations well above the OSHA PEL. Therefore, OSHA recommends that some kind of continuous gas monitoring system be used to protect workers using EtO for sterilization.[16] While the hazards of EtO are generally well known, it should be noted that all chemical sterilants are designed to kill a broad spectrum of organisms, by exposing them to high concentrations of reactive chemicals. Therefore, it is no surprise that all the common chemical gas sterilants are toxic and adequate protective measures must be taken to protect workers using these materials.

Spore testing

Bacillus subtilis, a very resistant organism, is used as a rapid biological indicator for EO sterilizers. If sterilization fails, incubation at 37 °C causes a fluorescent change within four hours, which is read by an auto-reader. After 96 hours, a visible color change occurs. Fluorescence is emitted if a particular (EO resistant) enzyme is present, which means that spores are still active. The color change indicates a pH shift due to bacterial metabolism. The rapid results mean that the objects treated can be quarantined until the test results are available.

Ozone

Ozone is used in industrial settings to sterilize water and air, as well as a disinfectant for surfaces. It has the benefit of being able to oxidize most organic matter. On the other hand, it is a toxic and unstable gas that must be produced on-site, so it is not practical to use in many settings.

Ozone offers many advantages as a sterilant gas; ozone is a very efficient sterilant because of its strong oxidizing properties (E = 2.076 vs SHE, CRC Handbook of Chemistry and Physics, 76th Ed, 1995-1996) capable of destroying a wide range of pathogens, including prions[17] without the need for handling hazardous chemicals since the ozone is generated within the sterilizer from medical grade oxygen. In 2005 a Canadian company called TSO3 Inc[18] received FDA clearance to sell an ozone sterilizer for use in healthcare. The high reactivity of ozone means that waste ozone can be destroyed by passing over a simple catalyst that reverts it back to oxygen and also means that the cycle time is relatively short (about 4.5 hours for TSO3's model 125L). The downside of using ozone is that the gas is very reactive and very hazardous. The NIOSH immediately dangerous to life and health limit for ozone is 5 ppm, much 160 times smaller than the 800 ppm IDLH for ethylene oxide.Documentation for Immediately Dangerous to Life or Health Concentrations (IDLH): NIOSH Chemical Listing and Documentation of Revised IDLH Values (as of 3/1/95) [19] and OSHA has set the PEL for ozone at 0.1 ppm calculated as an eight hour time weighted average (29 CFR 1910.1000, Table Z-1). The Canadian Center for Occupation Health and Safety provides an excellent summary of the health effects of exposure to ozone.[20] The sterilant gas manufacturers include many safety features in their products but prudent practice is to provide continuous monitoring to below the OSHA PEL to provide a rapid warning in the even of a leak and monitors for determining workplace exposure to ozone are commercially available.

Bleach

Chlorine bleach is another accepted liquid sterilizing agent. Household bleach consists of 5.25% sodium hypochlorite. It is usually diluted to 1/10 immediately before use; however to kill *Mycobacterium tuberculosis* it should be diluted only 1/5, and 1/2.5 (1 part bleach and 1.5 parts water) to inactivate prions. The dilution factor must take into account the volume of any liquid waste that it is being used to sterilize.[21] Bleach will kill many organisms immediately, but for full sterilization it should be allowed to react for 20 minutes. Bleach will kill many, but not all spores. It is also highly corrosive.

Bleach decomposes over time when exposed to air, so fresh solutions should be made daily.[22]

Glutaraldehyde and Formaldehyde

Glutaraldehyde and formaldehyde solutions (also used as fixatives) are accepted liquid sterilizing agents, provided that the immersion time is sufficiently long. To kill all spores in a clear liquid can take up to 12 hours with glutaraldehyde and even longer with formaldehyde. The presence of solid particles may lengthen the required period or render the treatment ineffective. Sterilization of blocks of tissue can take much longer, due to the time required for the fixative to penetrate. Glutaraldehyde and formaldehyde are volatile, and toxic by both skin contact and inhalation. Glutaraldehyde has a short shelf life (<2 weeks), and is expensive. Formaldehyde is less expensive and has a much longer shelf life if some methanol is added to inhibit polymerization to paraformaldehyde, but is much more volatile. Formaldehyde is also used as a gaseous sterilizing agent; in this case, it is prepared on-site by depolymerization of solid paraformaldehyde. Many vaccines, such as the original Salk polio vaccine, are sterilized with formaldehyde.

Phthalaldehyde

Ortho-phthalaldehyde (OPA) is a chemical sterilizing agent that received Food and Drug Administration (FDA) clearance in late 1999. Typically used in a 0.55% solution, OPA shows better myco-bactericidal activity than glutaraldehyde. It also is effective against glutaraldehyde-resistant spores. OPA has superior stability, is less volatile, and does not irritate skin or eyes, and it acts more quickly than glutaraldehyde. On the other hand, it is more expensive, and will stain proteins (including skin) gray in color.

Hydrogen Peroxide

Hydrogen peroxide is another chemical sterilizing agent. It is relatively non-toxic when diluted to low concentrations, such as the familiar 3% retail solutions although hydrogen peroxide is a dangerous oxidizer at high concentrations (> 10% w/w). Hydrogen peroxide is strong oxidant and these oxidizing properties allow it to destroy a wide range of pathogens and it is used to sterilize heat or temperature sensitive articles such as rigid endoscopes. In medical sterilization hydrogen peroxide is used at higher concentrations, ranging from around 35% up to 90%. The biggest advantage of hydrogen peroxide as a sterilant is the short cycle time. Whereas the cycle time for ethylene oxide (discussed above) may be 10 to 15 hours, the use of very high concentrations of hydrogen peroxide allows much shorter cycle times. Some hydrogen peroxide modern sterilizers, such as the Sterrad NX have a cycle time as short as 28 minutes.

Hydrogen peroxide sterilizers have their drawbacks. Since hydrogen peroxide is a strong oxidant, there are material compatibility issues and users should consult the manufacturer of the article to be sterilized to ensure that it is compatible with this method of sterilization. Paper products cannot be sterilized in the Sterrad system because of a process called cellulostics, in which the hydrogen peroxide would be completely absorbed by the paper product. The penetrating ability of hydrogen peroxide is not as good as ethylene oxide and so there are limitations on the length and diameter of lumens that can be effectively sterilized and guidance is available from the sterilizer manufacturers.

While hydrogen peroxide offers significant advantages in terms of throughput, as with all sterilant gases, sterility is achieved through the use of high concentrations of reactive gases. Hydrogen peroxide is primary irritant and the contact of the liquid solution with skin will cause bleaching or ulceration depending on the concentration and contact time. The vapor is also hazardous with the target organs being the eyes and respiratory system. Even short term exposures can be hazardous and NIOSH has set the Immediately Dangerous to Life and Health Level (IDLH) at 75 ppm.[14] less than one tenth the IDLH for ethylene oxide (800 ppm). Prolonged exposure to even low ppm concentrations can cause permanent lung damage and consequently OSHA has set the permissible exposure limit to 1.0 ppm, calculated as an 8 hour time weighted average (29 CFR 1910.1000 Table Z-1). Employers thus have a legal duty to ensure that their personnel are not exposed to concentrations exceeding this PEL. Even though the sterilizer manufacturers go to great lengths to make their products safe through careful design and incorporation of many safety features, workplace exposures of hydrogen peroxide from gas sterilizers are documented in the FDA MAUDE database.[23] When using any type of gas sterilizer, prudent work practices will include good ventilation (10 air exchanges per hour), a continuous gas monitor for hydrogen peroxide as well as good work practices and training. Further information about the health effects of hydrogen peroxide and good work practices is available from OSHA[24] and the ATSDR.[25]

Hydrogen peroxide can also be mixed with formic acid as needed in the Endoclens device for sterilization of endoscopes. This device has two independent asynchronous bays, and cleans (in warm detergent with pulsed air), sterilizes and dries endoscopes automatically in 30 minutes. Studies with synthetic soil with bacterial spores showed the effectiveness of this device.

Dry sterilization process

Dry sterilization process (DSP) uses hydrogen peroxide at a concentration of 30-35% under low pressure conditions. This process achieves bacterial reduction of 10^{-6}...10^{-8}. The complete process cycle time is just 6 seconds, and the surface temperature is increased only 10-15 °C (18 to 27 °F). Originally designed for the sterilization of plastic bottles in the beverage industry, because of the high germ reduction and the slight temperature increase the dry sterilization process is also useful for medical and pharmaceutical applications.

Peracetic acid

Peracetic acid (0.2%) is used to sterilize instruments in the Steris system.

Prions

Prions are highly resistant to chemical sterilization. Treatment with aldehydes (e.g., formaldehyde) have actually been shown to increase prion resistance. Hydrogen peroxide (3%) for one hour was shown to be ineffective, providing less than 3 logs (10^{-3}) reduction in contamination. Iodine, formaldehyde, glutaraldehyde and peracetic acid also fail this test (one hour treatment). Only chlorine, a phenolic compound, guanidinium thiocyanate, and sodium hydroxide (NaOH) reduce prion levels by more than 4 logs. Chlorine and NaOH are the most consistent agents for prions. Chlorine is too corrosive to use on certain objects. Sodium hydroxide has had many studies showing its effectiveness.

Silver

Silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi, typical for heavy metals like lead or mercury, but without the high toxicity to humans that is normally associated with these other metals. Its germicidal effects kill many microbial organisms *in vitro*, but testing and standardization of silver products is yet difficult.[26]

Hippocrates, the father of modern medicine, wrote that silver had beneficial healing and anti-disease properties, and the Phoenicians used to store water, wine, and vinegar in silver bottles to prevent spoiling. In the early 1900s people would put silver dollars in milk bottles to prolong the milk's freshness.[27] The exact process of silver's germicidal effect is still not well understood. One of the explanations is the oligodynamic effect, which accounts for the effect on microorganisms but not on viruses.

Silver compounds were used to prevent infection in World War I before the advent of antibiotics. Silver nitrate solution was a standard of care but was largely replaced by silver sulfadiazine cream (SSD Cream),[28] which was generally the "standard of care" for the antibacterial and antibiotic treatment of serious burns until the late 1990s.[29] Now, other options, such as silver-coated dressings (activated silver dressings), are used in addition to SSD cream. However, the evidence for the use of such silver-treated dressings is mixed and although the evidence on if they are effective is promising, it is marred by the poor quality of the trials used to assess these products.[30] Consequently a major systematic review by the Cochrane Collaboration found insufficient evidence to recommend the use of silver-treated dressings to treat infected wounds.[30]

The widespread use of silver went out of fashion with the development of antibiotics. However, recently there has been renewed interest in silver as a broad-spectrum antimicrobial. In particular, silver is being used with alginate, a naturally occurring biopolymer derived from seaweed, in a range of products designed to prevent infections as part of wound management procedures, particularly applicable to burn victims.[31] In 2007, AGC Flat Glass Europe introduced the first antibacterial glass to fight hospital-caught infection: it is covered with a thin layer of silver.[32] In addition, Samsung has introduced washing machines with a final rinse containing silver ions to provide several days of antibacterial protection in the clothes.[33] Kohler has introduced a line of toilet seats that have silver ions embedded to kill germs. A company called Thomson Research Associates has begun treating products with Ultra Fresh, an anti-microbial technology involving "proprietary nano-technology to produce the ultra-fine silver particles

essential to ease of application and long-term protection."[34] The U.S. Food and Drug Administration (FDA) has recently approved an endotracheal breathing tube with a fine coat of silver for use in mechanical ventilation, after studies found it reduced the risk of ventilator-associated pneumonia.[35]

It has long been known that antibacterial action of silver is enhanced by the presence of an electric field. Applying a few volts of electricity across silver electrodes drastically enhances the rate that bacteria in solution are killed. It was found recently that the antibacterial action of silver electrodes is greatly improved if the electrodes are covered with silver nanorods.[36] Note that enhanced antibacterial properties of nanoparticles compared to bulk material is not limited to silver, but has also been demonstrated on other materials such as ZnO[37]

Radiation Sterilization

Methods of sterilization exist using radiation such as electron beams, X-rays, gamma rays, or subatomic particles.[38]

- Gamma rays are very penetrating and are commonly used for sterilization of disposable medical equipment, such as syringes, needles, cannulas and IV sets. Gamma radiation requires bulky shielding for the safety of the operators; they also require storage of a radioisotope (usually Cobalt-60), which continuously emits gamma rays (it cannot be turned off, and therefore always presents a hazard in the area of the facility).
- Electron beam processing is also commonly used for medical device sterilization. Electron beams use an on-off technology and provide a much higher dosing rate than gamma or x-rays. Due to the higher dose rate, less exposure time is needed and thereby any potential degradation to polymers is reduced. A limitation is that electron beams are less penetrating than either gamma or x-rays.
- X-rays, High-energy X-rays (bremsstrahlung) are a form of ionizing energy allowing to irradiate large packages and pallet loads of medical devices. Their penetration is sufficient to treat multiple pallet loads of low-density packages with very good dose uniformity ratios. X-ray sterilization is an electricity based process not requiring chemical nor radio-active material. High energy and high power X-rays are generated by an X-ray machine that can be turned off for servicing and when not in use.
- Ultraviolet light irradiation (UV, from a germicidal lamp) is useful only for sterilization of surfaces and some transparent objects. Many objects that are transparent to visible light absorb UV. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets between uses, but is ineffective in shaded areas, including areas under dirt (which may become polymerized after prolonged irradiation, so that it is very difficult to remove). It also damages many plastics, such as polystyrene foam.
- Subatomic particles may be more or less penetrating, and may be generated by a radioisotope or a device, depending upon the type of particle.

Irradiation with X-rays or gamma rays does not make materials radioactive. Irradiation with particles may make materials radioactive, depending upon the type of particles and their energy, and the type of target material: neutrons and very high-energy particles can make materials radioactive, but have good penetration, whereas lower energy particles (other than neutrons) cannot make materials radioactive, but have poorer penetration.

Irradiation is used by the United States Postal Service to sterilize mail in the Washington, DC area. Some foods (e.g. spices, ground meats) are irradiated for sterilization (see food irradiation).

Sterile filtration

Clear liquids that would be damaged by heat, irradiation or chemical sterilization can be sterilized by mechanical filtration. This method is commonly used for sensitive pharmaceuticals and protein solutions in biological research. A filter with pore size 0.2 μm will effectively remove bacteria. If viruses must also be removed, a much smaller pore size around 20 nm is needed. Solutions filter slowly through membranes with smaller pore diameters. Prions are not removed by filtration. The filtration equipment and the filters themselves may be purchased as pre-sterilized disposable units in sealed packaging, or must be sterilized by the user, generally by autoclaving at a temperature that

does not damage the fragile filter membranes. To ensure sterility, the filtration system must be tested to ensure that the membranes have not been punctured prior to or during use.

To ensure the best results, pharmaceutical sterile filtration is performed in a room with highly filtered air (HEPA filtration) or in a laminar flow cabinet or "flowbox", a device which produces a laminar stream of HEPA filtered air.

See also

- Asepsis
- Antibacterial soap
- Contamination control
- Electron irradiation
- Pasteurization

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External links

- Chemical Disinfection [41]
- Sterilizer Cleaning and Maintenance [42]
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"

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Operation and Use of Autoclaves

3.7 Autoclaves

3.7.1 Use and Principles of Operation

An autoclave is a device used to sterilize medical instruments and equipment. It uses steam and pressure in the absence of air to assure sterile conditions. The small, table-top autoclave uses heat to boil water into steam. The steam continues heating and the pressure continues to increase. Bacteria cannot survive in these conditions. However, not all viruses and spores are killed. Exposing materials to a single heat cycle is somewhat effective, but sterilizing them 3 times over a period of 3 days will kill most vegetative spores.

Inside and outside of a small, electric autoclave.

Most hospitals have electric, steam autoclaves, but you will also find an autoclave like the "All American" distributed by UNICEF. It uses an open fire as its source of heat.

The small open fire autoclave is still common in the developing world.

An autoclave is a fairly simple instrument to operate but could be dangerous if operated improperly. It is important to wait until the chamber is completely depressurized before opening! If it is opened under pressure, large quantities of steam could escape causing severe burns! Most modern hospitals have automated autoclaves. These devices go through the steps of operation without intervention. If the machine is not going through its steps correctly, there is little that can be done to change the sequence of steps.

Manual machines, such as the All American, must be operated correctly to insure sterilization. The automated machines follow the same steps, though automatically.

Start by making sure that the water reservoir is filled to proper level with distilled water or filtered rain water. Well water will, in time, leave a scaly deposit on the instruments and autoclave. An indicator strip should be used with each pack being sterilized. However, in the developing world, this practice is not followed. Place the instruments into the chamber and close lid securely. Open the air outlet valve. Automated machines may use several cycles of vacuum to remove the air. The manual machines depend on the steam to push the air out of the chamber.

Now, the machine is ready to begin its cycle. Turn on or light the heating element. During this part of the cycle, the manual machine is evacuating the air. Therefore, it is important to wait until there is a steady stream of steam exiting from the autoclave. If the air release valve is

spitting and sputtering, it should remain open. Air left in the chamber will lead to cold spots, and poor sterilization.

When the air is completely evacuated from the machine, either by vacuum in the automated machines or by steam in the manual machines, the air outlet valve must be closed. The steam pressure will begin to rise. At this point, it is sufficient to monitor the temperature and time to insure sterilization. Do not open the chamber or valves, as the pressure of the escaping steam can be dangerous.

The sterilization cycle and sometimes the cool-down cycle can be timed. The proper time and temperature is shown below for unwrapped surgical instruments. Allow 30 minutes more at the holding temperature and pressure if the instruments are wrapped.

Sterilizing Temperature (C)	Appropriate pressure (kPa)	Appropriate pressure (psi)	Minimum holding time (min)	Overall time (min)
115	75	11	30	50
122	115	17	15	40
128	150	22	10	30
136	225	33	3	20

After the specified holding time, the sterilization cycle is complete. Turn the heating element off completely. Now the cool-down cycle begins. The progress of cool-down can be followed by time, temperature, or simply by dropping water on the outside of the vessel. If it boils off, the vessel is still too hot. When cool down is complete, the chamber can be opened. If a sterilization tape was used, check to see that it is completely black.

3.7.2 Common Problems

There are a number of different types of problems you may encounter. However, the manual autoclave is a very reliable instrument. It rarely fails when properly operated and maintained.

The most common problem in the developing world is a buildup of a scale due to the use of non-distilled water in the sterilization cycle. The scale can usually be scraped off the machine and simply thrown away. On manual machines, the scale may cause the air release valve and the over-pressure relief valve to be clogged. Both of these systems are difficult to scrape clean. If they can be removed from the machine and forced or left open, then simply soaking them for several days in pure distilled water should dissolve any deposits. It may be best to run a few dozen cycles with distilled water, where the air release valve is intentionally left open (steam will escape through the valve the entire cycle). This will help to dissolve any remaining the scale. If the relief valve cannot be opened and cleaned, it is best to replace this component.

Automated machines with scale build up may also see clogs in the vacuum lines and associated valves. If the machine is still operable, the best procedure may be to remove any visible build up, then run many cycles with pure distilled water until the remaining scale dissolves. If the valves have become blocked, remove them all and clean them all (not just the clogged one). If only one is clogged, it is certain that the others are close.

The second most common problem for autoclaves in the developing world is clogging of filters due to the use of dirty water, such as non-filtered rain water. This primarily plagues the automated autoclaves which often have inlet filters between the water storage and the main vessel. Some of these filters can be removed and back-flushed (run water backwards through the filter) to clean and restore them. Be sure to clean the tank of any particles that have settled to the bottom. In other cases, the filter must be replaced.

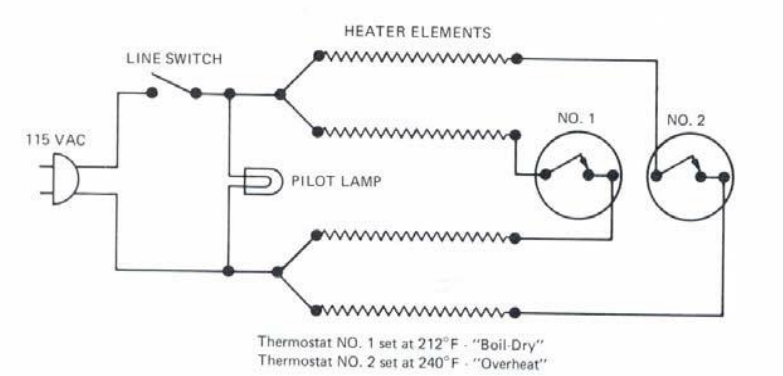
If you hear a hissing noise, then there is a leak in the pressure vessel or valve. Try to isolate the problem by looking for steam escaping and by using your ear. If the problem is a valve, it will probably be necessary to replace the valve. If the problem is the vessel, it is impossible to fix and the autoclave should be discarded. The seal on the vessel is also a common source of leaks. Check to see that there are no obstructions (dirt, or scale build up) along the seal. In some cases, the seal can be reground, but often, replacing the seal is required.

Some machines use a plastic or rubber seal. For these machines, run your fingernail into the seal. It should be pliable. If the seal is hard, or worse cracked, then it must be replaced. In larger cities, you may be able to find an automobile repair shop that can cut you a replacement gasket. Silicone sealant can be used to seal cracks in door gaskets until a replacement gasket can be located and installed.

If the seals are working and there are no leaks or clogs, the manual autoclave should work. The automatic autoclave may still not reach the proper temperature. The cause may be the thermostat or the heating element. In the most sophisticated autoclaves, the controller can be suspected.

If there is no heat generated, it could be the heating element or the thermostats. The typical heating element consists of two coils of nickel-chrome resistance wire, each of which has approximately 14 ohms of resistance. If the resistance across a coil is significantly higher, it is probably broken. These heaters are paralleled and the combination is placed in series with the on/off switch and one or both of the thermostats. Nicrome wire is common and can usually be found in the developing world. Match the resistance and length as closely as possible.

Circuit of a simple, electric autoclave.



There are often two thermostats. One is a boil-dry safety thermostat connected in series with one of the elements and set to open at 212 degrees F. This will reduce the violence of boiling once 212 is reached. The second thermostat, often called the overheat relay, is set to turn off the electricity going to the nicrome elements when the temperature is excessive, usually meaning that the water has boiled away. Both thermostats for this instrument are usually of the bimetallic-switch type. They rarely degrade themselves, but the device which holds them in place often deteriorates.

3.7.3 Suggested Testing

Autoclaves are like centrifuges in that there is a safety issue associated with their use. The device can injure the operator or leave the equipment undetectably contaminated. Therefore, some testing should be performed before releasing the device for use.

Before releasing an autoclave back to the floor, check the gaskets and check for scaling. You can prevent future clogging by removing any scale or dirt now. If the gasket for the vessel breaks, it

may leak steam, which can be dangerous. If the autoclave has an interlock that prevents opening during a cycle, check this again for safety.

If possible, check the temperature inside the vessel during sterilization. Most US hospital users put test strips with each sterilization pack. These strips verify that the temperature reached the required level for the required time and that humidity was present. However, in the developing world, these test strips are rarely used. It is nevertheless, possible to test the autoclave.

A complete test of an autoclave includes a Bowie-Dick test (to see that all the air was being removed) and either a temperature or a pressure test to see if the temperature and pressure reached the needed levels (since PV=nRT, and the chamber is only filled with steam, it is not necessary to measure both temperature and pressure). The time of the sterilization cycle can be measured with a watch. The Bowie-Dick test for air removal can be approximated by placing a standard Time-Temperature test strip on a sheet of paper in the center of a stack of 100% cotton towels and placed in a metal dressing can. The dressing can is placed in a warmed pre vac sterilizer and a short cycle is run using the tape on the cotton towels as a check. If there is any air left in the sterilizer chamber, then it would be trapped in the towels. Because the air would not allow the steam to touch the tape, the color change would not be uniform around the strip. In order to pass the test, the entire tape must change colors, not just the edges. This procedure will test both the temperature and the air removal process.

If test strips are not available, then it is not possible to reliably test the autoclave for both air removal and temperature/pressure. You will have to settle for a pressure measurement. At the present time, there is no reusable alternative to the test strips readily available in the developing world.

Check the safety valve on the vessel. If it is dirty or corroded, attempt to replace it. If you cannot replace it, it is possible to test the safety valve by bypassing the overheat limit switch. This should only be attempted by experienced technicians wearing proper safety gear. Furthermore, you can only test the safety valve on autoclaves with working pressure gages. The safety valve is factory set to open at 30 psi. To test this valve, short out the thermostat with a clip lead, operate the autoclave as in starting a normal cycle. Be ready to pull the plug from the wall very quickly, should the safety valve fail and the pressure rise above 31 psi. If the safety valve fails to operate at this upper limit, it must be replaced. If you cannot find a replacement, discuss the danger with the administration. Although not having a safety valve is a severe danger to the operator, not having an autoclave is a severe danger to the patients.

2. Autoclave Schematics and Diagrams

Featured in this Section:

Discover Biotech. “Physical Means of Microbial Control.” Retrieved from: http://www.discoverbiotech.com/wiki/-/wiki/Main/Physical+Methods+of+Microbial+Control

Figure 1: Physical Means of Microbial Control

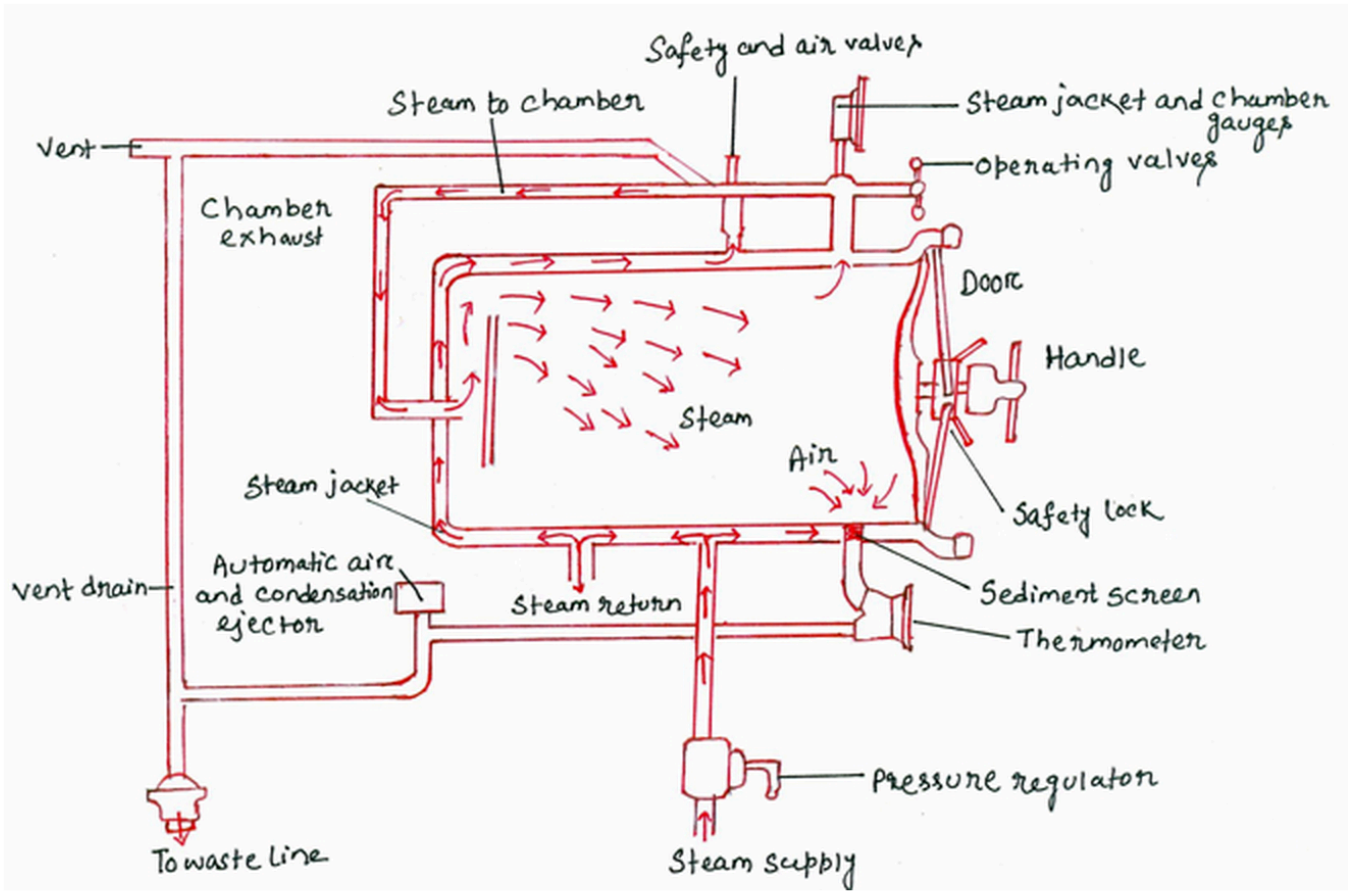


Figure 3: Cross sectional view of an autoclave

"Physical Methods of Microbial Control:
Image courtesy of: http://www.discoverbiotech.com/

3. Preventative Maintenance

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Autoclave Preventative Maintenance.” From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

EWH. “Descaling to Remove Mineral Buildup.” *Engineering World Health.*

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

WHO. “Quality Control For Autoclaves.” From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.

Descaling to Remove Mineral Buildup

Knowledge Domain: Plumbing
Unit: Blockages
Skill: Descaling

Tools and Parts Required:

1) **Vinegar**
2) **Autoclave, sterilizer, or hot water pot with mineral buildup**
3) **Nylon scouring pad (optional)**
4) **Mineral free (distilled) water**

Introduction

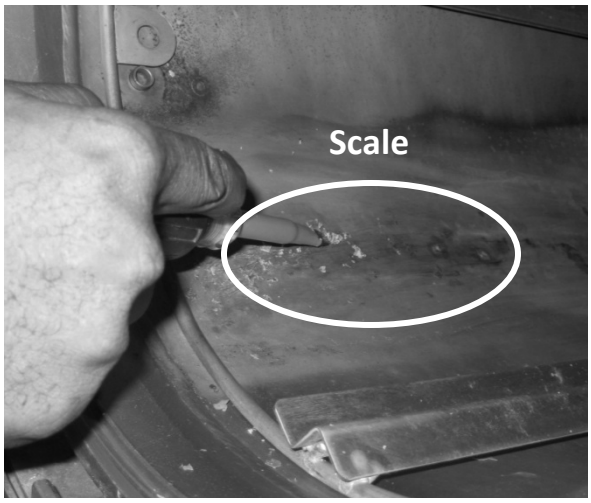
Equipment that uses water may accumulate mineral buildup. Minerals are corrosive to stainless steel. Mineral buildup will reduce the efficiency and lifespan of the equipment. Regular removal of mineral buildup will extend the life of the equipment. Mineral buildup can also prevent adequate sterilization.

Example

Below is a picture of an autoclave with mineral buildup (sometimes called scale).

Identification and Diagnosis

Scale is an accumulation of minerals such as calcium on the surface of a device. Scale is different from rust (see BTA skill on “cleaning rust”). Thick scale can sometimes be scraped off. Scale can be white or gray. Contaminants determine the color of the scale. Scale may appear as flakes as shown below. Some scale may look like a thin film covering surfaces that have been exposed to water.



Procedure

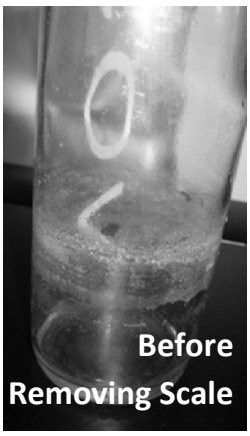
Before working on any medical equipment, ensure that the device has been disconnected from electricity.

Autoclaves become very hot during use. Avoid burns by ensuring the machine is not hot before touching any surfaces.

Begin by scraping any excess scale or contaminants. Use a cloth to wipe off loose contaminants and dirt. A plastic scouring pad can be used for more vigorous scrubbing.

Usually, you will need a solvent to remove scale. Some manufacturers suggest specific products for cleaning sterilizers and autoclaves. A mild acid such as vinegar or lemon juice is a good substitute.

Below is a picture of glass bottle with mineral buildup. Vinegar was used to remove the scale.



Soaking with Vinegar

For optimal performance, sterilizers and autoclaves should be cleaned once a week.

Mix the descaling solvent according to the manufacturer's directions. When using lemon juice or vinegar, use 1 part vinegar and 1 part mineral free (distilled) water.

Drain water from the reservoir of the autoclave. Fill with descaling solvent. Run a complete sterilization cycle. When descaling a single container, let the solvent sit for at least 30 minutes. Do not attempt to sterilize any equipment while descaling.

After the descaling is complete, drain the solvent. Rinse the system with mineral free water for at least 15 minutes. Do not sterilize any equipment until all solvent has been removed.

Sometimes a mild solvent is not strong enough to remove scale. In some cases you must use muriatic acid (also known as hydrochloric acid), a very strong acid. Always wear gloves and eye protection when using muriatic acid. Dilute muriatic acid with 1 part acid to 20 parts water. Pour the acid carefully into water to avoid splashes. Apply the solution to the scale. Bubbles indicate that the solution is strong enough. Run water over the area to rinse thoroughly after cleaning. Do not allow acid to come into contact with skin or eyes.

Detergents containing chlorine are corrosive to steel. Do not use detergents containing chlorine to remove scale.

Exercise

Removing scale requires the presence of scale. During your hospital visits, your instructor may point out an autoclave or sterilizer with mineral buildup. You may have the chance to remove the scale.

Check hot water pots and kettles for mineral buildup. Use the described procedure to remove the scale.

Your instructor must verify your work before you continue.

Preventative Maintenance and Calibration

Use mineral free water to prevent build up of scale.

Acids can be dangerous to the skin. Always use protective gloves and work in a well ventilated area.

Always calibrate every medical device before returning it to use.

EQUIPMENT

Autoclave Preventative Maintenance

Preventive Maintenance

- After each use: Clean the inside of the autoclave and around valve and vents
  - Empty all water from chamber and thoroughly dry
  - Wipe off metal-to-metal seal with clean towel to remove build-up
- Make sure valves are not clogged
  - Periodically clean control valve with hot, soapy water
- Check air exhaust tube by flushing water through it to make sure it is not blocked.
- Descale the chamber: most effective to use detergent meant for lime scale removal. Vinegar diluted with distilled water can also be used.
- Check for signs of wear and damage. Ensure sufficient seal around lid:
  - For a metal-to-metal seal, lubrication of the seal must be maintained
  - For a gasket seal, the seal must be pliable. If it is cracked or dry, then it should be replaced
- Valve safety check: Test the safety pop-off any time there is pressure built up in the sterilizer. Test the valve below the operating pressure with the use of a screwdriver to pop the pressure relief valve. Make sure your hand is away; otherwise the steam can cause burns.

Cooper, Justin and Alex Dahinten for EWH. "Autoclave Preventative Maintenance." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Autoclave Preventative Maintenance Table

User Care of Medical Equipment – First line maintenance for end users

User Care Checklist – Autoclaves / Sterilizers

Daily	
Cleaning	✓ Remove any dust / dirt with damp cloth and dry off ✓ Remove water and waste matter from inside
Visual checks	✓ Check all screws, connectors and parts are tightly fitted ✓ Check all moving parts move freely, all holes are unblocked
Function checks	✓ Use troubleshooting guide if problems occur

Weekly	
Cleaning	✓ Unplug, clean inside and outside with damp cloth and dry off ✓ Remove gasket, clean with a damp cloth and replace
Visual checks	✓ Scrape off any small deposits of limescale ✓ Send for repair if heating element covered with limescale ✓ If plug, cable or socket are damaged, replace
Function checks	✓ When next used, check pressure / temperature gauges rise ✓ When next used, check there are no leaks

Every six months
Biomedical Technician check required

Quality Control for Autoclaves

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^2 or 134 °C / 2.2 kg /cm^2. Their main characteristics are featured in the table on the next page.

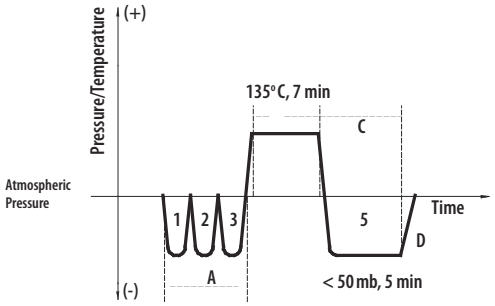
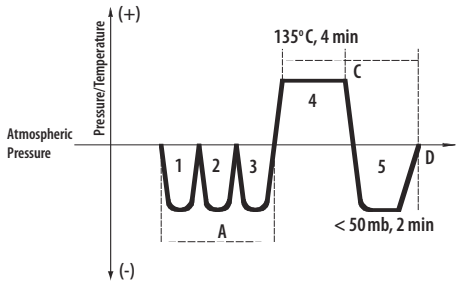
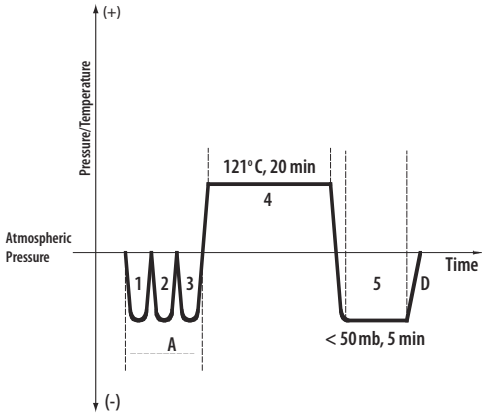
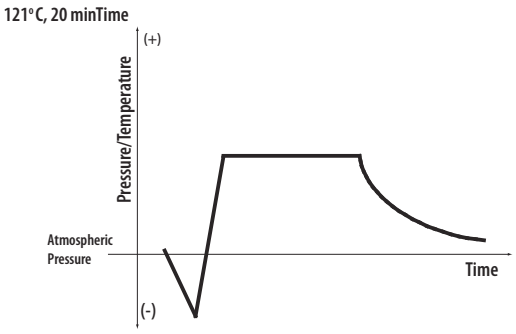
Note: The sterilization cycle times are adjusted to the altitude where the autoclave is located. Manufacturers supply compensation tables to be taken into account. In general, the higher the altitude of the equipment's location, the longer the sterilization time will be.

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 Nº 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 wl have a greater resistance to a determined steriliza process, or of chemical reagents which react in 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

WHO. "Quality Control For Autoclaves." From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.

Cycle no.	Materials	Temp. ˚C	Pressure kg/cm²	Typical graph[1]
1	• Porous loads • Textiles • Wrapped instruments • Tubes	135	2.2	
2	• Open instruments • Utensils • Glassware • Open containers	135	2.2	**Text** 
3	• Heat sensitive materials • Rubber • Plastic	121	1.1	
4	• Liquids in open or semi-closed containers.(*)	121	1.1	
Convention	A: Pre-treatment. Alternate cycles of injection / vacuum of vapour. Pre-treatment. (Processes 1, 2, 3).			
	Process 4: Sterilization.			
	C: Post-treatment (Process 5: vacuum and drying).			
	D: Internal and external pressures completely mixed.			
	Note: The liquid process does not have vacuum after sterilization. The cooling is natural.			

[1] 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.

86 **WHO. "Quality Control For Autoclaves." From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.**

of *Bacillus stearothermophilus* 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 $5x10^5$ to $9.9x10^5$ 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

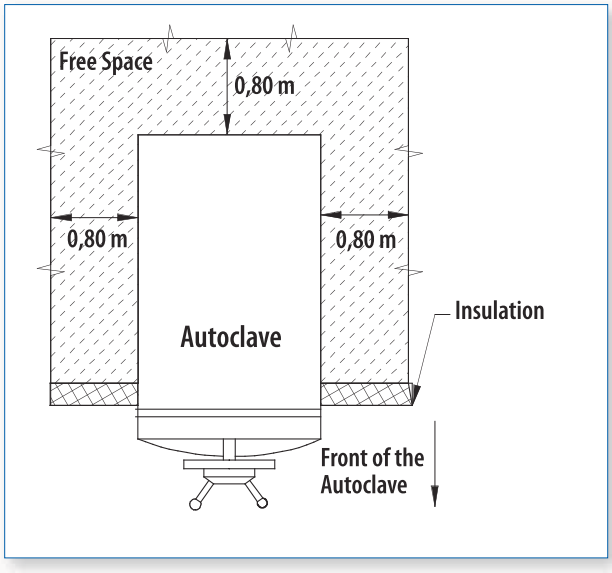
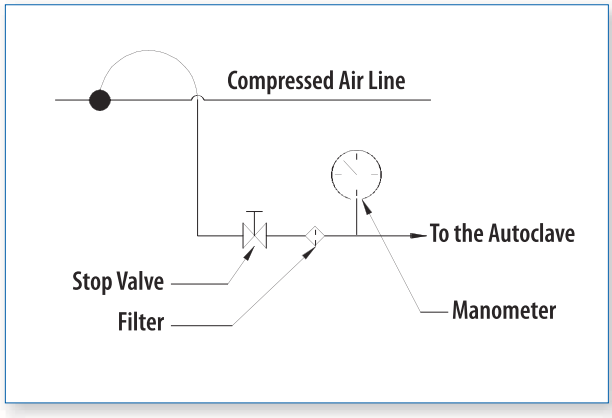


Figure 34. Compressed air connection



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

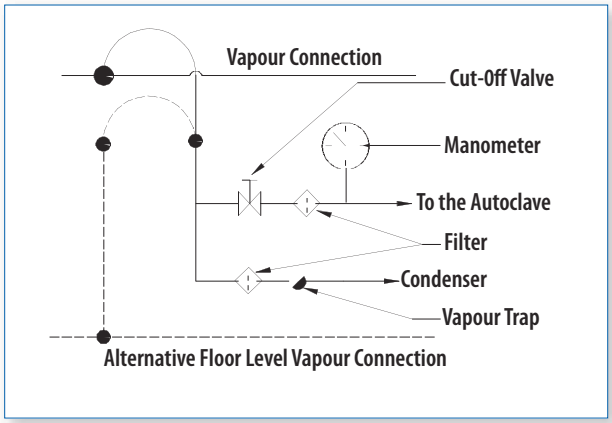


Figure 35.

6. 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:

1. Place a new form on the registration device in order to document the development of the sterilization cycle.
2. Ensure that the cycle-recording pen or that the printing module of the autoclave has ink and recording paper.
3. Ensure that the cold water, compressed air and vapour supply valves are open.
4. 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.
5. Verify that the pressure from the vapour supply line is at least 2.5 bar.
6. Test the condition of manometers and thermometers.
7. Ensure that there are no vapour leaks in any of the systems functioning in the autoclave.
8. Clean the front of the autoclave, controls, indicators and handles with a damp cloth.

Weekly maintenance

Responsible: The equipment operator

1. Clean the sterilization chamber drainage filter. Remove any residue retained inside.
2. 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.
3. 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.
4. 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.
5. In autoclaves with manually activated doors, verify that these mechanisms are well adjusted and that their operation is smooth.
6. 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.
7. Never use steel wool for cleaning the inside of the sterilization chamber.
8. 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

1. Check that the manometers function as expected.
2. 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.

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

WHO. "Quality Control For Autoclaves." From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.

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[1].
   h) Re-assemble in the reverse order.

Figure 36 shows the vapour generator and its components.

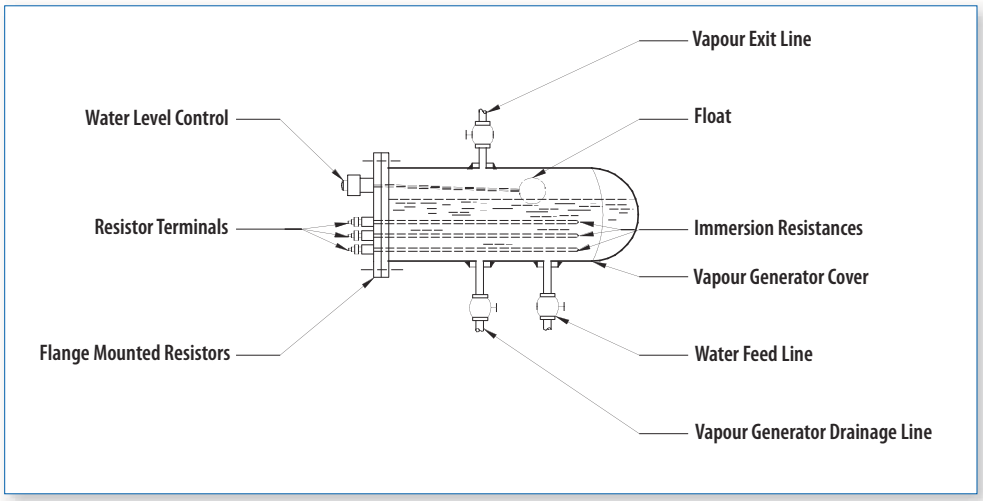
Annual maintenance

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.

[1] Incrustations are seen when the water used by the vapour generator has not received adequate treatment.

Figure 36. Vapour generator



WHO. "Quality Control For Autoclaves." From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.

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 dismounting 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.

WHO. "Quality Control For Autoclaves." From the publication: Laboratory Equipment Maintenance Manual, WHO: 2008.

4. Troubleshooting and Repair

Featured in this Section:

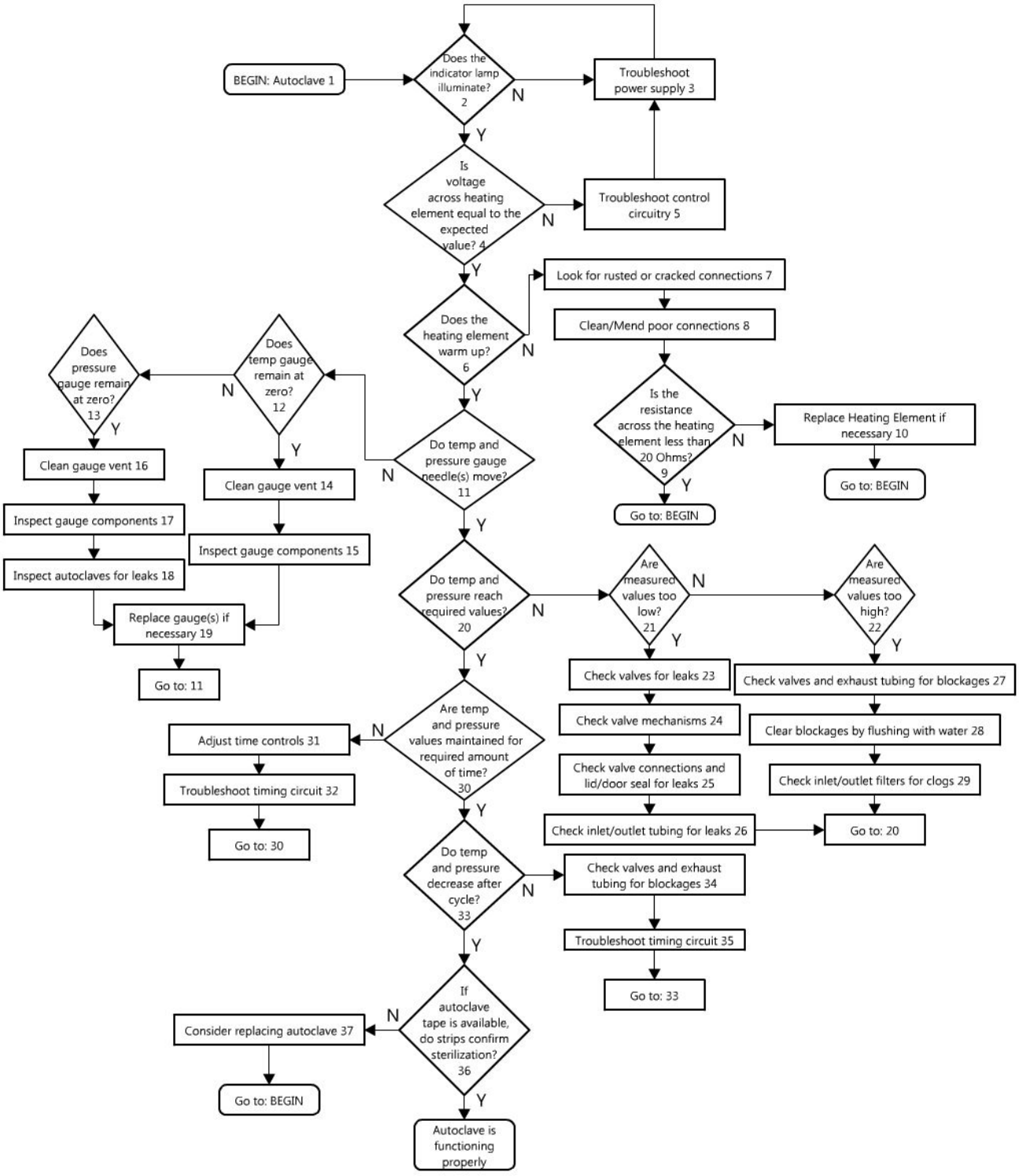
Cooper, Justin and Alex Dahinten for EWH. “Autoclave Troubleshooting Flowchart.” From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, (2013).

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Autoclave Troubleshooting and Repair Flowchart

Autoclave Troubleshooting Flowchart

Flowchart



Cooper, Justin and Alex Dahinten for EWH. "Autoclave Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, (2013).

Description

#	Text Box	Comments
1	Begin: Autoclave	Start the diagnostic process for a work order on an autoclave
2	Does the indicator lamp illuminate?	Provide appropriate power supply to the autoclave and observe indication that the device turns on
3	Troubleshoot power supply	If the device is connected to power but does not turn on, there is a problem with the power supply. This could be a problem with the wiring or connections within the device. See BTA skills on Power Supply
4	Is voltage across heating element equal to the expected value?	Use a multimeter to test the wires leading to the heating element to determine if it is receiving the expected voltage (wall voltage)
5	Troubleshoot control circuitry	If the device is receiving power but improper voltage is reaching the heating element, there is likely a problem with the control circuit. Ensure that all settings are what they should be for normal autoclave function
6	Does the heating element warm up?	Attach autoclave to power with lid open and observe whether the heating element begins to get hotter
7	Look for rusted or cracked connections	Examine connections involved with the heating element to determine whether they are adequate for proper functionality
8	Clean/Mend poor connections	See BTA skills on Connections
9	Is the resistance across the heating element less than 20 Ohms?	Use a multimeter across the heating element to determine its total resistance
10	Replace heating element if necessary	If the resistance across the heating element is greater than 20 Ohms, it needs to be replaced. To replace the wire within the element, nichrome wire must be used. See BTA skills on Heating Element
11	Do temp and pressure gauge needle(s) move?	While autoclave runs cycle, observe motion of temperature and pressure gauge(s). There must be displayed values for BOTH parameters to advance from this step
12	Does temperature gauge remain at zero?	Determine if value of zero is given for temperature despite temperature increase
13	Does pressure gauge remain at zero?	Determine if value of zero is given for pressure when pressure is expected to have increased

14	Clean gauge vent	If the gauge works but does not move during autoclave cycle, then the vent leading to the gauge input may be blocked. Flush vent with distilled water to remove blockage. CAUTION: do not submerge gauge in water. See BTA skills on Blockage
15	Inspect gauge components	If the cycle runs but the needle in the gauge doesn't move, there is a problem with the gauge. Remove gauge from autoclave and examine interior. Gently manipulate the gauge to mimic response to rising temperature and pressure within the device. If the needle can be made to move easily and smoothly, then the gauge components are functional
16	Clean gauge vent	If the gauge works but does not move during autoclave cycle, then the vent leading to the gauge input may be blocked. Flush vent with distilled water to remove blockage. CAUTION: do not submerge gauge in water. See BTA skills on Blockage
17	Inspect gauge components	If the cycle runs but the needle in the gauge doesn't move, there is a problem with the gauge. Remove gauge from autoclave and examine interior. Gently manipulate the gauge to mimic response to rising temperature and pressure within the device. If the needle can be made to move easily and smoothly, then the gauge components are functional
18	Inspect autoclave for leaks	Examine all parts of autoclave to find any leaks. Visually inspect for steam escaping from autoclave. See BTA skills on Leaking
19	Replace gauge(s) is necessary	If the gauge needle cannot be made to move as described in #15 and #17, then the gauge is likely broken and may need to be replaced
20	Do temperature and pressure reach required values?	Verify that interior of autoclave reaches temperature and pressure values required to achieve sterilization Common temperature values: 121˚C for 15 minutes, 134˚C for 3 minutes
21	Are measured values too low?	Determine if the autoclave reaches temperature and pressure values below those required for sterilization by reading the gauge values.
22	Are measured values too high?	Determine if the autoclave reaches temperature and pressure values above those required for sterilization by reading the gauge values.
23	Check valves for leaks	Visually inspect closed valves throughout cycle. If air escapes closed valve, then there is a leak in the valve that must be mended. See BTA skills on Leaking
24	Check valve mechanisms	Check functionality of valve components by ensuring that they are able to open and close smoothly
25	Check valve connections and lid/door seal for leaks	Examine points at which valves connect to autoclave to ensure that they are adequately sealed If autoclave door/lid has a metal-to-metal seal, lubricate seal

		If autoclave door/lid has a gasket seal, determine adequacy of gasket. If gasket is dry or cracked, it needs to be replaced See BTA skills on Seals
26	Check inlet/outlet tubing for leaks	Visually examine autoclave tubing for leaks. See BTA skills on Leaking
27	Check valves and exhaust tubing for blockages	Open valves and ensure that air can pass through them. Also verify that exhaust tubing is unobstructed. See BTA skills on Blockages
28	Clear blockages by flushing with water	If any blockages are found, flush the blocked components with distilled water to remove blockages. See BTA skills on Blockage
29	Check inlet/outlet filters for clogs	Examine autoclave filters for clogs. If clogs are found, clean or replace filter(s). See BTA skills on Filters
30	Are temperature and pressure values maintained for required amount of time?	Determine if the sterilization temperature and pressure values are maintained for enough time to sterilize autoclave contents
31	Adjust time controls	Ensure that time is on correct setting Common times: 121˚C for 15 minutes, 134˚C for 3 minutes
32	Troubleshoot timing circuit	If settings are correct, but autoclave does not maintain required temperature and pressure values for proper duration, there is a problem with the circuit controlling the timing of the cycle. Examine this circuit for broken or damaged connections and components. See BTA skills on Electrical Simple
33	Do temperature and pressure decrease after cycle?	Ensure that the temperature and pressure within the autoclave decrease after the completion of the sterilization cycle by observing the decrease in the measured values displayed on the device
34	Check valves and exhaust tubing for blockages	Note steam escape from open valves to ensure that they are not blocked If temperature and pressure values do not decrease after the completion of the autoclave cycle, it could be due to a blocked exhaust tube. See BTA skills on Blockages
35	Troubleshoot timing circuit	If settings are correct, but autoclave does not maintain required temperature and pressure values for proper duration, there is a problem with the circuit controlling the timing of the cycle. Examine this circuit for broken or damaged connections and components. See BTA skills on Electrical Simple
36	If autoclave tape is available, do strips confirm	Run test cycle with autoclave test tape to verify that sterilization is achieved. If tape is not available, biological indicators can also be used for

	sterilization?	sterilization.
37	Consider replacing autoclave	Autoclave may be beyond repair. Discontinue autoclave use or refer to specialist

Note about autoclave tape:

- Autoclave tape is an adhesive used to indicate whether a specific temperature and pressure have been reached
- Strips of this tape are applied to items before they are placed into the autoclave
- The tape has diagonal markings that will change color when the target temperature and pressure are achieved
- If the tape markings are still their original color after going through the autoclave cycle, then the autoclave did not reach the temperature and pressure required for sterilization
- Biological indicators can be used to monitor the sterilization of an autoclave, by testing its capability to kill microorganisms. Only *Bacillus stearothermophilus* spores can be used to monitor the effectiveness of steam autoclaves.
- A biological indicator system consists of the growth medium with spores and indicator dye. After autoclaving the indicator, it has to be incubated at 56°C for up to three days. Any signs of turbidity (indicating growth) indicate the autoclave did not function properly.

Autoclave Troubleshooting Table

User Care of Medical Equipment – First line maintenance for end users

Troubleshooting – Autoclaves and Sterilizers

	Fault	Possible Cause	Solution
1.	Equipment is not heating	No power at mains socket	Check power switch is on. Replace fuse with correct voltage and current rating if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
		Electrical cable fault	Try cable on another piece of equipment. Contact electrician for repair if required.
		Damaged heating element	Send to electrician if broken or covered in limescale (see picture below). Remove small amounts of limescale by light scraping and long soaking in distilled water.
2.	Pressure rises above the marked level	Blocked valve	Clean the pressure regulating valve, safety valve. Pressure vessel may be over filled. Retest autoclave under pressure with water only.
3.	Steam is constantly escaping	Poor seal	Clean leaky valve and hole, replace if defective. Clean leaking seal or gasket, replace if broken.
4.	Electrical shocks	Wiring fault	Refer to electrician

Limescale on heating element

5. Resources for More Information

Featured in this Section:

DHT Laboratory, “Sealing Autoclave Doors.” From the publication: *Biomedical Technician Assistant (BTA) Skills*. Developing World Healthcare Technology Laboratory: Duke University, 2011.

Fear, D. and Skeet, M. “Autoclaves.” From the publication: *Care and Safe Use of Medical Equipment.* VSO Books, 1995.

National Biosafety and Biocontainment Training Program, National Institute of Health, and Dartmouth College. “Autoclave Safety: The Proper Use of an Autoclave to Decontaminate Biohazardous Waste.” May 11, 2011. Retrieved from: https://www.youtube.com/watch?v=T901F2W7wks

Resources for More Information:

Internal Resources at library.ewh.org: For more information about autoclaves, please see this resource in the BMET Library!

1. DHT Laboratory, "Sealing Autoclave Doors." From the publication: *Biomedical Technician Assistant (BTA) Skills*. Developing World Healthcare Technology Laboratory: Duke University, 2011.

2. Fear, D. and Skeet, M. "Autoclaves." From the publication: *Care and Safe Use of edical Equipment.* VSO Books, 1995.

External Resources:

2. Autoclave Safety Videos:
These videos created by the National Biosafety and Biocontainment Training program and Dartmouth University explain how to **safely operate** an autoclave. This video demonstrates the path of energy through an autoclave, labels autoclave parts, and provides safety tips. This video is available in eight languages.

"Autoclave Safety: The Proper Use of an Autoclave to Decontaminate Biohazardous Waste."
National Biosafety and Biocontainment Training Program, National Institute of Health, and Dartmouth College. Posted May 11, 2011.

1. **Autoclave Safety (English):** https://www.youtube.com/watch?v=T901F2W7wks
2. **Autoclave Safety (Chinese):** https://www.youtube.com/watch?v=jTrAFZwK7r0
3. **Autoclave Safety (Arabic):** https://www.youtube.com/watch?v=-FMZ_bDDj4o
4. **Autoclave Safety (French):** https://www.youtube.com/watch?v=8o-OgmozIzY&list=PL7BADC53DB62439F4&index=12
5. **Autoclave Safety (Russian):** https://www.youtube.com/watch?v=fbVzDNker_0&list=PL7BADC53DB62439F4&index=10
6. **Autoclave Safety (Spanish):** https://www.youtube.com/watch?v=Mj264Iz6Hrs&list=PL7BADC53DB62439F4&index=5

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