8. DISINFECTION AND STERILISATION OF MEDICAL SUPPLIES AND EQUIPMENT

a. INTRODUCTION

Disinfection is a process whereby micro-organisms are destroyed to a level which is safe for some purposes but not for others. Heat-resistant spores will not be destroyed.

Sterilisation is a process whereby all micro-organisms, including heat-resistant bacterial spores, are removed or destroyed.

Which equipment should be disinfected? Which should be sterilised?

Disinfection is recommended for equipment that is not intended for piercing the skin, or touching open wounds. Disinfected equipment may safely be in contact with the intact skin and mucous membranes of the body. Equipment which is to be disinfected includes items such as linen, bedpans, crockery, instruments, tongue depressors, etc.

Sterilisation is recommended for all items penetrating the skin or which will be in contact with broken skin and mucous membranes or entering otherwise sterile body areas. This includes equipment such as surgical instruments, implants, dressings, gowns, catheters, wound irrigation fluids, syringes, needles and other items which may pierce the skin or be in contact with open wounds.

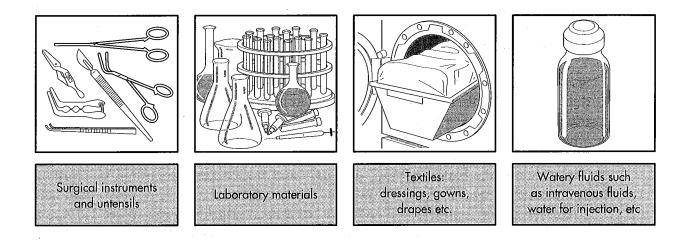


Figure 21: Materials which can be sterilised by autoclaving

Importance of cleaning before disinfection and sterilisation

Before disinfection and/or sterilisation it is essential that all equipment is thoroughly cleaned in order to remove all blood, tissue and other dirt. Cleaning will drastically reduce the number of micro-organisms on the items and thus will ensure an acceptably low level of contamination before disinfection or sterilisation.

Cleaning of instruments and materials may well be the most dangerous work in the sterilisation department: the risk of accidents is highest during this work. Do the cleaning in a deep sink or basin to avoid splashing. Use appropriate protective clothing: wear an apron, strong rubber gloves and a face mask.

Disinfection by boiling in water

The most common equipment for disinfection is the boiling water bath disinfector. They are also called boiling water 'sterilisers'; however, they do not sterilise. They should be referred to as 'disinfection equipment'. That is, they do not kill heat-resistant bacterial spores. Instruments can be disinfected by boiling in water (100°C) for at least 10 minutes (this applies to sea level, and does not include the warming-up time).

Sterilisation by exposure to high temperature steam

In health care the most common method of sterilisation is by pressurised, high temperature steam. This is the preferred method of sterilisation used by health care professionals worldwide, including the World Health Organisation (WHO), because it is a rapid, simple and effective process. As it does not use any chemicals, it is safer and more environmentally friendly; it is also more cost-effective than other methods.

The machine used in most hospitals to sterilise equipment is the steam autoclave, which basically consists of a pressure vessel in which steam is created under high pressure and temperature. For proper sterilisation it is essential that all surfaces of the load are directly exposed to the steam at a sufficiently high temperature for a sufficiently long time.

A well designed and well operated autoclave creates these sterilisation conditions during each sterilisation cycle: in modern, automatic sterilisers, a steriliser control programme regulates these conditions. If a hand-operated autoclave is used, the manufacturer's instructions should be followed strictly.

The relationship between time, pressure and temperature in order to sterilise equipment using steam is shown in Figures 22 and 23. The most common combinations for temperature and time used for sterilising in steam are 121°C for 17.5 minutes and 134°C for 3 minutes. The time during which the load is exposed to the steam at the sterilisation temperature is referred to as the **sterilisation time**.

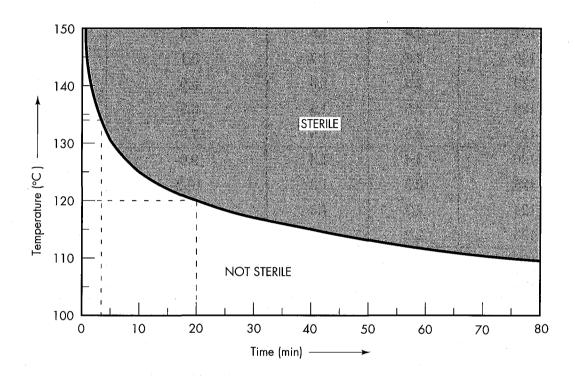


Figure 22: Thermal death curve for steam. The line indicates the minimum sterilisation time at any given temperature. If materials are exposed to steam at a temperature and time which is in the shaded part of the diagram they will be sterile. Example: When an instrument is exposed to steam at a temperature of 120 °C it will be sterile after 20 minutes. If you use a manually operated autoclave, refer to Figure 23 for the recommended sterilisation time at various temperatures.

		Gauge	Sterilisation time		
Sterilisation	Absolute	Pressure	Minimum time	When using	
Temperature	Pressure	(sea level)	(Automatic timing)	manual timing	
[°C]	[Bar _{abs}]	[Bar _g]	[Minutes]	[Minutes]	
136	3.2	2.2	2.3	10	
135	3.1	2.1	2.6	10	
134	3.0	2,0	3.0	10	
133	3.0	2.0	3.4	10	
132	2.9	1.9	4.0	10	
131	2.8	1.8	4.5	10	
130	2.7	1.7	5.1	10	
129	2.6	1.6	5.9	10	
128	2.5	1.5	6.8	10	
127	2.5	1.5	7.8	10	
126	2.4	1.4	9.0	15	
125	2.3	1.3	10.2	15	
124	2.3	1.3	11.6	15	
123	2.2	1.2	13.3	15	
122	2.1	1.1	15.3	20	
121	2.0	1.0	17.5	20	
120	2.0	1.0	20.0	25	
119	1.9	0.9	22.9	25	
118	1.9	0.9	26.2	30	
117	1.8	0.8	30.0	35	
116	1.7	0.7	34.4	40	
115	1.7	0.7	39.5	45	
114	1.6	0.6	45.1	50	
113	1.6	0.6	51.6	55	
112	1.5	0.5	59.1	60	
111	1.5	0.5	67.7	70	
110	1.4	0.4	77.5	80	

Figure 23: Combinations of temperature and time required for sterilisation by steam. The most commonly used temperatures are 121°C and 134°C (in the shaded rows). If a hand-operated autoclave is used, use the sterilisation time indicated in the far right-hand column (labelled 'When using manual timing'). The time indicated in this column includes an extra safety margin in order to compensate for the inaccuracies of manual timing. All the values apply at sea level. When you are situated at higher altitudes, refer to Figure 24. For explanations of 'absolute pressure' and 'gauge pressure' refer to the shaded box on page 79.

Because of the high temperature needed for sterilisation in steam, not all equipment is suitable for autoclaving. Take great care when deciding which items to sterilise, as some could be badly damaged by the high temperature of the steam. Certain plastics in particular are very sensitive to heat and cannot be sterilised in steam; however, items made of nylon, Teflon (PTFE) and silicone rubber can safely be autoclaved.

Rubber goods can also be sterilised in steam. However rubber is affected by the heat and will become brittle after a while. Rubber goods should preferably be autoclaved at lower temperatures, e.g. 121°C.

If in doubt refer to the manufacturer's instructions for the materials to be sterilised; or test a single item by autoclaving it and observing the result.

Influence of altitude on cycles for disinfection and sterilisation

The atmospheric pressure depends on the altitude above sea level: it decreases as altitude increases. The temperature at which water boils also decreases with the altitude. You must therefore make adjustments in the cycle for disinfection. If an autoclave has a pressure control valve or other pressure control system, the cycle for sterilisation has to be adjusted for the altitude at which you are working. Refer to Figure 24.

			Disiní	ection	Sterilisation		
					Sea-level setting		
			in boiling water		121°C/	127°C/	134°C/
	Atmospheric	Pressure			1 Bar _g	1.5 Bar _g	2 Bar _g
Altitude	pressure	reduction	Temp	Time	Temp	Temp	Temp
[m]	[Bar _{abs}]	[Bar]	[°C]	[Min]	[°C]	[°C]	[°C]
0	1.0	0.0	100	10	121	127	134
1,000	0.9	0.1	96	10	118	126	132
2,000	0.8	0.2	93	10	117	125	131
3,000	0.7	0.3	90	20	115	124	130
4,000	0.6	0.4	86	20	114	124	129
5,000	0.5	0.5	83	30	112	121	128
6,000	0.5	0.5	79	45	111	120	127
7,000	0.4	0.6	76	60	110	119	127
	[m] 0 1,000 2,000 3,000 4,000 5,000 6,000	Altitude pressure [m] [Bar _{abs}] 0 1.0 1,000 0.9 2,000 0.8 3,000 0.7 4,000 0.6 5,000 0.5 6,000 0.5	Altitude pressure reduction [m] [Bar _{abs}] [Bar] 0 1.0 0.0 1,000 0.9 0.1 2,000 0.8 0.2 3,000 0.7 0.3 4,000 0.6 0.4 5,000 0.5 0.5 6,000 0.5 0.5	Atmospheric Pressure water Altitude pressure reduction Temp [m] [Bar _{abs}] [Bar] [°C] 0 1.0 0.0 100 1,000 0.9 0.1 96 2,000 0.8 0.2 93 3,000 0.7 0.3 90 4,000 0.6 0.4 86 5,000 0.5 0.5 83 6,000 0.5 0.5 79	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

Figure 24: Altitude considerations for disinfection and sterilisation

Disinfection in boiling water at higher altitudes

- choose the row with the altitude at which you are working
- in the columns headed 'Disinfection', you can read the boiling temperature of water at that altitude and the required boiling time

Sterilisation at higher altitudes

When you are at significantly higher altitudes you either have to increase the (relative) sterilisation pressure in order to get the same temperature of steam, or extend the sterilisation time.

Increasing sterilisation pressure

If the pressure of your autoclave can be adjusted, you should increase the relative operating pressure by the amount of pressure reduction caused by the altitude. By doing so the temperature which will be reached will be the same as it would be at sea level. Using Figure 24:

- select the row with the altitude at which you are operating the autoclave
- read the pressure reduction associated with the altitude. Increase the sterilisation pressure by this value
- run a sterilisation cycle and check that the required temperature is indeed reached
- the sterilisation time should be the time needed at that temperature (Figure 23)

For example: if your autoclave has been set by the manufacturer at $121^{\circ}\text{C}/1$ Barg for use at sea level, and you are at 2000m, you should increase the pressure by 0.2 Barg to 1.2 Barg. Use the time as stated in Figure 23 for sterilisation at 121°C : 25 minutes.

Extending sterilisation time

If you cannot change the operating pressure you should extend the sterilisation time when working at higher altitudes. Using Figure 24:

- select the altitude at which you are operating the autoclave
- select the column with the sterilisation pressure at sea-level setting which is closest to that of your steriliser
- read the temperature which will be reached
- in Figure 23 you will find the sterilisation time required for that temperature

For example: the pressure control for your autoclave is set for sterilising at $121^{\circ}\text{C}/1$ Bar_g at sea level. You are working at 2000 metres. The table indicates that the temperature will be 117°C . In Figure 23 you will find that the required sterilisation time for that temperature is 35 minutes.

Absolute pressure and gauge pressure

In daily life, when talking about pressure in vessels, we mean an applied pressure which differs from the atmospheric pressure. Pressure gauges indicate this difference in pressure between the vessel they are connected to and the surrounding atmosphere. This pressure difference is referred to as 'gauge pressure'. For these pressures the suffix $_g$ is used. See Figures 23 and 24. The unit for pressure is Pa or kPa (1 kPa = 1000 Pa). Also the unit Bar is used: 1 Bar = 100 kPa.

In scientific applications, the pressure in vessels is usually compared to the situation in space, where there is no pressure at all (an absolute vacuum). The pressure compared to vacuum is called the 'absolute pressure'. For indicating absolute pressures the suffix $_{\rm abs}$ is used. At sea level the pressure of the atmosphere is approximately $100~{\rm kPa_{abs}}$ or $1~{\rm Bar}$.

In autoclave documentation the gauge pressure is usually stated. However sometimes also the value of absolute pressure is used.

Readings of pressure gauges at higher altitudes

At higher altitudes, the pressure gauge of an autoclave will indicate the same pressures as when at sea level. This is because the pressure controller is set for a pressure difference between the vessel and the atmosphere and the gauge indicates this pressure difference. This difference is the same at all altitudes. However with the same setting of the pressure control of the autoclave, at higher altitudes the absolute pressure in the vessel will be lower and thus the temperature that will be reached during sterilisation is lower. Refer to Figure 24.

Keeping goods sterile: packaging

As soon as goods are taken out of the steriliser, they will be contaminated again by particles in the air. Therefore it is necessary that the items to be sterilised are packaged properly prior to sterilisation. The packaging should allow steam to penetrate to the items inside but should prevent access by micro-organisms after sterilisation. Packaging materials can be sterilising containers, sheets of certain fabrics, paper and non-wovens and pouches made of paper or so called laminate pouches. The design of drums and containers to be used depends on the sterilisation process.

Schimmelbusch drums are used in some hospitals as a method of packaging. They are metal drums which have holes in their sides which can be opened and closed with a metal band. Before sterilisation, the holes are opened and the drum is put into the autoclave. After sterilisation, the drum is taken out of the autoclave and the holes closed by shifting the metal band. Research has shown however that these Schimmelbusch drums are not a suitable method of packaging because air remains trapped inside.

When only using cotton sheets as a packaging material, the goods should be used immediately. For more information about sterilisation packing materials, refer to the book *Sterilisation of Medical Supplies* listed in the Bibliography.