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- steam sterilisation process
- non-condensable gases (NCGs)
- process challenge device (PCD)

ZENTRAL STERILISATION 1

Effects of Non-Condensable Gases (NCGs) on Steam Sterilisation Processes

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Introduction

The dangers posed by non-condensable gases (NCGs) in steam sterilisation processes have long been underestimated. Biological indicators, or the best chemical indicators on the market, do not signal the presence of a NCG content of up to 10% in a sterilisation process so long as there is mixing of steam and NCGs in the sterilisation chamber.

Already back in 1963, Bowie and Dick (1) demonstrated that steam/NCG mixtures could prove dangerous if steam resulting from condensation is being consumed on the sterile supplies and the NCGs enclosed in this steam are able to accumulate present in the form of closed packages.

If the NCGs are unable to mix again with steam within closed packages containing instruments, in porous laundry packages or within lumened devices, these quantities of gas will accumulate and prevent steam penetration into these areas, thus also preventing the build-up of heat and entry of water which are prerequisites for successful sterilisation.

Relatively large volumes of steam are consumed in sterilisation processes for heating (sterilisation) supplies (approx. 300 – 400 l per 10 kg materials under normal conditions). Conversely, the steam decreases its volume by a factor of 1,000 on condensing to water. This means that one litter of steam produces around one 1 ml water. The exact ratio will be determined by the pressure/temperature conditions.

If a package contains 10 kg of supplies that are to be heated by means of condensation and the steam were to contain only 1% NCGs, this would result in around 4 litres NCGs accumulating in this package, and large sections of the package would not be sterilised.

Therefore European Standard EN 285 regulating steam sterilisation processes for the health sector has set a very small limit for the quantity of NCGs in steam with which sterilisers should still be operated. The presence of 35 ml NCGs in 1 litre steam-condensate is given in the standard as 3.5%. But these specifications apply for a

NCG-condensate mixture. In reality the mixture is present in the gas phase with a somewhat 1,000-fold greater steam volume compared with the condensate volume, hence the actual percentage in the gas phase must be around 1,000-fold less, and may reach a maximum level of around 0.003%. As borne out in practice, this is a realistic value, which if exceeded will lead to quantifiable problems.

Task Definition

There are various reasons why NCGs occur:

1. Inadequate air removal from the sterilisation chamber before steam entry.

2. Leaks. In modern sterilisers a vacuum is generated to remove air. Leaks in door seals, valves or screw fittings, which can also occur briefly because of dirt or lost labels, allow air to enter. Therefore modern sterilisers are equipped with a leak-test programme that, however, is run at most once daily before commencing operations.

3. Leaky door seals. Modern sterilisers are fitted with slide doors closed by means of pneumatically actuated door seals. A pressure level that is essentially higher than the operating pressure prevailing within the sterilisation chamber must be built up behind the seals. Compressed air can escape into the steriliser chamber if the seals have leaks. Often, it is not possible to detect this problem by running a leak test first because this is carried out with an internal pressure value that is 2-3 bar lower and hence the test differential pressure is much greater than that prevailing during the actual sterilisation process.

To curtail this risk many steriliser manufacturers therefore use steam instead of air. The use of steam means that the service life of the door seals is shortened and that, accordingly, the maintenance intervals are also shorter.

4. Steam Pipes and steam generators become filled with air or NCGs if they are not used over a period of time. Before using the sterilisation system again, steam generators and pipes must first be rinsed out with steam. In the hospital setting this rinsing task is performed mainly by running an empty load to heat the steriliser. The ensuing Bowie-Dick test is then run to check that air has been successfully removed from the pipes. If the BD test is negative on the first attempt, the next attempt will generally be successful Therefore a BD test programme of e.g. 134 °C, 3.5 min is generally stipulated for large sterilisers.

Small sterilisers with an integrated steam generator face less risk because they are not hampered by long pipelines. Hence the recently published standard

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regulating small sterilisers,

EN 13060, does not stipulate a BD test for small sterilisers.

5. The most critical source of problems is NCGs that are carried into the sterilisation process with the steam. These NCGs are formed during steam generation because of:

– Air dissolved in the water that is expelled when the water is heated. In the case of raw water containing iron and manganese, air is often introduced into external water-processing systems to precipitate these metals as oxides. What remains then is water with a high content of dissolved air.
– Hydrogen carbonate salts dissolved in the feedwater which when heated disintegrate to carbonate salts (limescale) and give off carbon dioxide (CO_2) as a NCG.

Therefore feedwater processing is of paramount importance in steam generation. The water should be demineralised and degassed before being fed into the steam generator.

While more than 90% of dissolved salts are removed from the raw water by means of reverse osmosis (RO) desalination systems, gases such as CO_2 and air pass quantitatively through the RO membranes. The latter are thus not sufficient for feedwater processing, so for this reason mixed-bed ion exchangers still have to be used to remove at least the CO_2 but not the dissolved air.

The best way to remove NCGs is to preconnenct a degassing facility that heats the water to 90 – 100°C before it is fed into the steam generator. No thermal energy is lost here because the water continues being heated later.

Therefore the presence of any NCGs in the steam plays a critical role in sterilisation process since with each episode of discontinued feeding of water into the steam generator, a NCG peak is formed in the steam a short time later. Hence the NCG concentration in the steam is not constant over time, rather NCG peaks occur after feeding water into the steam generator. In a hospital setting where a central steam supply facility with a high steam consumption rate, e.g. for the kitchen or laundry, is used such peaks occur only at certain times.

The method outlined in standard EN 285 can be used to measure (2) NCGs.

For a long time now discussions have focused on what NCG concentrations pose a danger to the steam sterilisation process. Here there is no absolute answer as this will depend greatly on the loading pattern. Minimal loads in a large steriliser are more critical because any residual quantities of NCGs in the steriliser will be fully taken up by the minimal load, whereas the same residual quantity of NCGs is better distributed in a full load, and is thus less critical for the individual load (small load effect = SLE). The SLE is manifested only in the case of those causes listed above in Points 1 – 4. This does not apply if NCGs are present in the steam (Point 5).

The dangers posed by the NCG concentrations in the steam vary greatly for the different sterile supplies:

1 NCGs are not at all critical for open trays with solid, unwrapped instruments because convection provides for mixing of the NCG with the steam. Hence such a load can also be reliably sterilised in sterilisers using gravitational or flow methods.

2 High NCG concentrations are always critical for trays containing wrapped solid instruments irrespective of the porosity of the packaging. This is because no convection takes place and the amount of NCGs accumulating within the packaging as a result of steam condensation will not be distributed. The NCGs can escape only by means of slow diffusion through the packaging. This is explains why longer sterilisation times are selected for processes with poor air removal: to remove the air rather than to kill the microbes. But a longer sterilisation time is not effective for voluminous porous items and lumened (hollow) devices under such conditions.

3 As the volume of a package increases, porous articles such as laundry packages, surgical towels or swabs impede convection. For a long time it was believed that it was large porous packages that were the main cause of problems in sterilisation processes. Therefore even today European standard EN 285 uses a 7-kg laundry package as a BD test package to simulate a worst-case scenario for air removal and steam penetration test. From standard tests described in the test standard EN 867-4 one notes that this laundry package signals errors in the steam sterilisation process when the quantity of NCGs reaches approx. 150 – 250 ml.

4 Narrow-lumened (hollow) devices such as minimally invasive surgical (MIS) instruments, catheters and tubes have very small lumens depending on their design, and these lumens are also heated by steam. If NCGs are present they will also be carried into such lumens and have no means of mixing once again with the steam through convection. A tube with a 2 mm internal diameter and 1 m length has an interval volume of only 3.14 ml. If 10 cm of this internal volume is occupied by NCGs, the remaining volume will only be 0.31 ml. This demonstrates how even NCG quantities of well below 1 ml can be absolutely critical for lumened devices.

A study conducted by Prof. von Eiff of University of Münster in hospitals in North Rhine Westphalia and Lower Saxony revealed that, in particular, 40% of hollow instruments released for use were not sterile (4). One reason for such problems is that the classic biological and/or well-integrated chemical indicators can attest to the sterility of supplies only at those locations at which they are positioned. But in general these indicators cannot be placed at those sites within the instrument which are most difficult to access, hence the established practice of using such indicators is not suitable for providing insights into the sterility of lumened devices.

Implications for Validation and Routine Monitoring

Various publications (2) have revealed the standard BD test is not able to detect NCG quantities below 50 ml. These NCG quantities are too high by a factor of 100 as far as lumened devices are concerned. European standard EN 867-5 describes a hollow device system "Hollow A" that is capable of detecting NCG quantities of well below 1 ml. This is a tube model with a 1.5 m PTFE tube with an internal diameter of 2 mm and a PTFE terminal capsule with

an internal volume of approx. 0.3 ml which is able to accommodate a biological or chemical indicator for detection of NCGs. This capsule is able to detect NCG volumes of less than 0.1 ml.

If one compares the results of the standard BD test package with those of the helix PCD (2) one notes that air removal programmes of less depth but with a greater number of repeated air-removal cycles show a positive result for air removal in the BD test but a negative result for the helix PCD (2). This proves that the standard BD test is unable to demonstrate that air is reliably removed from hollow devices with a small internal diameter.

Likewise, the use of thermoelectric measurements, in particular, in metal instruments with a small internal diameter gives incorrect results because the minute, residual quantities of air within it are quickly heated by the metal walls, which are good conductors of heat, thus ensuring that the internal temperature will soon reach that of the outside temperature regardless of whether NCGs or steam are present in the hollow device. Since thermocouples are not able to distinguish between NCGs and steam, thermoelectric measurements are not suitable in principle for narrow lumened metal hollow devices.

Measurement of the pressure-temperature profile is now a standard practice both for validation and routine monitoring. Based on Dalton's Law, the partial pressures of all gases are added together in an enclosed space to give a total pressure value. If saturated steam is present, a partial pressure value must be assigned to each temperature (steam-pressure table). If NCGs are present in the steam the pressure must therefore be higher than in pure steam. But NCG concentrations well below 1 % can be dangerous. The associated partial pressure is thus max 1-2 mbar. The test pressure-display instruments are, unfortunately, not able to record these minimal changes in pressure. Hence recording the pressure-temperature curves gives no insights into critical NCG concentrations. This has also been borne out by the measurements carried out by B. Kirk (4).

To measure the critical NCG quantities for hollow devices there is at present no technical means other than to use a suitable process challenge device (PCD) able to measure the minute NCG quantities. Their sensitivity must be adapted to the loading pattern. The "Hollow A" PCD described in EN 867-5 is representative of a large portion of the instruments currently used in the health sector, but not of all supplies undergoing sterilisation. When validating steam sterilisation processes it must be ensured that the PCDs employed present a greater challenge to steam penetration than do the intricate devices contained in a load.

Since the NCG concentrations change for each load, if hollow devices are being sterilised, hollow PCDs should also be used instead of the porous BD test to furnish proof of the effectiveness of the process, not only on commencing operations but also for all loads.

In the revised draft to European Standard EN 285 for large sterilisers for the health sector, which had been in force for 10 years, The European Standardisation Commission has included, in addition to the BD test system, the Hollow A test from European standard EN 867-5 for the type test in order to ensure that the respective steriliser type can sterilise the intricate devices currently used in the health sector. ❊

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