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Steam quality:
The last unknown in steam sterilization

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Steam quality may be the last uncontrolled variable in hospital steam sterilization. Steam sterilizers generally produce sterile product reliably, but there are times when things go awry for no obvious reason…

The definition of steam quality is the measureable aspects of steam used for sterilization. These include the usual measures such as temperature and pressure, and the relationship between the two. Steam quality also includes other aspects of steam that are almost never measured in North America. Deviations from established ranges of these aspects of the steam can result in wet, damaged, or unsterile loads.

When good steam goes bad…

Some of the effects of poor steam quality are:

- Wet packs
- Damaged loads and instruments
- Sterilization indicator failures and sterility failures
- Staining and corrosion of instruments and containers

Each of these has a specific cause. The degree of the problem can be measured, and the situation can be remedied. The good news is that all sterilizers cleared by the FDA for use in a healthcare facility can deliver good quality steam to the load and provide

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sterile, dry, and intact sterilization loads. The bad news is that any of them can experience any of these problems, and the cause is not always something that the end user can predict or determine.

It goes without saying that a sterilizer must be maintained properly to ensure proper, reliable operation. This includes preventative maintenance, calibration, and performance verification as described in AAMI ST79, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities." If a sterilizer is out of calibration, has leaks, or is otherwise not working in its normal manner, poor steam quality may be a result of those problems rather than the cause of difficulties. For this discussion, we assume that the sterilizer is in good repair. If it is not, needed maintenance should be done before steam quality is tested or blamed for difficulties.

Symptoms of steam quality problems

The four primary failures of steam quality are listed above. All of them can cause unsterile loads and/or damage instruments. The cost of repair of a laparoscope or similar device is upwards of $1,000 per incident. The financial and potential human cost of a recall of an unsterile load is greater.

The causes of each of these failures are discussed in detail below.

Wet packs

A wet load can be caused by a number of things, one of which is wet steam. Steam is composed of vaporized water, and steam delivered to a sterilizer should have essentially no liquid water in it. Sterilizers are designed for use with saturated steam and this is typically specified on the sterilizer manufacturer's installation drawings. Steam suitable for sterilization is defined in the European standards (EN 285, HTM2010) as having a dryness value of greater than 0.9 for non-metallic loads, and greater than 0.95 for metallic loads as delivered to the sterilizer chamber. The steam dryness value is simply the fraction of dry steam in the sample measured, with 0.9 dryness corresponding to 10% liquid water and 0.95 dryness corresponding to 5% liquid water. If the steam dryness value is too low, wet loads can occur.

Steam dryness is calculated by measuring the temperature change in a known amount of water and the mass of steam that was required to cause that temperature change. Ideally, the temperature rise would be exactly what would result if the energy in perfectly saturated steam was delivered to the water to heat it. This would result in a dryness value of 1.0. Normally, the dryness value is less than 1.0, as there are thermal losses in any piping system, and a sterilizer is no exception. Because the dryness value at the entry point to the sterilizer chamber can be quite a bit lower than the dryness value of the steam delivered to the sterilizer, measurements of steam dryness should be made at the entry point or by sampling the steam in the chamber.

Wet steam can be the result of engineering issues. These can be:

- Bad/missing/inadequate insulation in the sterilizer, allowing energy loss and condensation,
- Low sections of piping between the boiler and the sterilizer, allowing condensate to pool and be picked up by steam flowing across the condensate
- Too great a pressure drop across a regulator or between the jacket and chamber, which causes the "extra" water in the steam at the higher pressure to fall out as condensate,
- No/clogged steam filters, either letting condensate pass if no

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filter, or causing a pressure drop that causes condensate to fall out,
- No/clogged steam traps/separators, in either case, condensate in the steam line is not removed,
- Steam trap/filter too far from the sterilizer, allowing condensate to be generated between the trap or filter and the sterilizer,
- Constriction in the flow path from the boiler to the sterilizer, which can also cause a pressure drop and condensate.

Other causes of wet steam

Other causes of wet loads can be that they are too dense; that is, too much weight in too small a volume. The AAMI standard for sterilization containers has a limit of 25 pounds in a container, with no specification of density. The European standard for containers, EN 868-8, has a limit of 10 kg (22.4 lbs.) in a "standard sterilization volume[1]" of 30 cm x 30 cm x 60 cm, about 1.9 cu. ft. This is a density of 11.75 lb./cu. ft. Our experience is that if a container's density is less than this, there should be no problem with load wetness, assuming that the steam is suitably dry to begin with.

Damaged loads

Damage to loads can take place in two ways. There can be thermal damage, and there can be staining and/or corrosion of the instruments and packaging materials.

Thermal damage

You might ask how thermal damage can occur if the instruments are sterilized at temperatures prescribed in the item's DFU. The answer is that the steam could be superheated.

Superheat is the situation of having more energy in the steam than the steam temperature would lead you to expect. Conversely, superheat is also a situation in which the temperature of the steam is higher than the saturation temperature for its actual water content. It can result from the following sources:

- Jacket temperature/pressure too high
- Steam pressure/temperature too high entering the sterilizer
- Steam flowing through a small orifice between its source and the chamber causing a large pressure reduction.

Any of these can cause there to be too much energy in the steam for its pressure, temperature and water content. If this energy is released in the load, damage can occur to instruments as their temperature rises above the recommended processing temperature. The temperature shown on the sterilizer controls is generally not sensitive to superheat, as it is measured in the drain of the sterilizer chamber, and superheat will have been dissipated into the load, chamber wall, or door and backhead before it reaches the drain.

Sterilization indicators and sterility failures

A load run with any of the three steam quality problem listed above may have failed sterilization indicators and also may be unsterile. For superheat, non-condensable gases, and wet steam, too little energy is delivered to the load, since steam that is too dry (superheat), too wet (wet steam), or contains non-condensable gases, has less energy available than saturated steam to inactivate microorganisms. Non-condensable gases can also cause air

pockets in the load where steam does not penetrate, meaning that local islands of unsterility may exist in the load. Because these are localized, if an indicator is not in the "island", you could never know that an area is unsterile.

Staining and corrosion

Both of these have similar causes; something other than water in the steam. These may be impurities like steam piping treatments, rust in the facility steam pipes or in the sterilizer jacket or plumbing. If the problem is caused by piping anticorrosion treatments, the solution is to cut the treatments back or eliminate them. Anticorrosion treatments are especially problematic with stainless steel sterilizer jackets and chamber, which tend to pass the treatments on to the load. Older, tool steel sterilizers are more likely to chemically bind the treatments before they reach the chamber, since these sterilizers, like steel piping, have corrosion in the jacket that eats up the treatments before they can get to the load.

Chemical analysis of condensed steam can tell you what is doing the staining, and analysis of supplied steam and steam collected from the sterilizer chamber can tell you if it is problem with the source or with the sterilizer plumbing or jacket.

Solutions?

Each of these quantities can be measured and solutions found. The first step is to measure, even if there are no problems. This should be done at initial installation, or at or around preventative maintenance to establish a baseline for the system. Measurements made when there are no problems can also tell you if your sterilizer is close to having a problem.

If there is a problem, all relevant quantities should be measured. Persons experienced in steam quality analysis can usually make cost-effective suggestions to fix the problems, and of course measure to see if the problem is, in fact, fixed.

Case studies

Wet Packs

A hospital had no problems for a number of years. The facilities boiler was replaced and wet packs began to occur irregularly. Wet packs became a regular occurrence as time went by. The problem was observed in each of three steam sterilizers in SPD, all of which were from the same manufacturer but were of different models and of ages ranging from 6 to 14 years. The problem was also seen in four additional sterilizers in the OR suite. The boiler pressure was held at 125 psi, and reduced to 65 psi prior to being delivered to the sterilizers. Each sterilizer had a steam filter on its steam feed and the delivery plumbing was of proper design, with adequate steam traps. In other words, the hospital had an optimal, well-designed steam system and its delivery to the sterilizers was done "by the book". Furthermore, the manufacturer's service technician carried out a complete preventative maintenance and evaluation and found the machines to be in good working order.

Using steam quality measurements of steam dryness at the delivery point of steam to the sterilizer and at the entry point of steam into the sterilizer chamber, it was found that "perfect" steam, with a dryness value of at least 0.97 was being delivered to the sterilizers. At the same time, the steam entering the chamber had a dryness value of 0.84, that is, was very wet, with 16% liquid water content.

This problem was solved by adding additional insulation to the sterilizer plumbing and decreasing the steam pressure being delivered to the sterilizer. The insulation ensured that steam would not condense before delivery to the chamber and the pressure reduction decreased the amount of pressure reduction that was required of the sterilizer was less than two to one for a 270ºF cycle. This is a "magic number" in ensuring good steam quality.

It was also concluded that the absence of the problem for all the years before the new boiler was installed and its appearance after the installation was due to an IMPROVEMENT in delivered steam quality, i.e., that the old boiler was delivering superheated steam with lower moisture content, so wet packs did not occur. The new boiler, on the other hand, was doing a very good job. So good, it seems, that it created the problem of wet packs.

Non-condensable gases

A hospital had a total of seven steam sterilizers that were well maintained and fed from house steam. The steam system design was well done, with proper steam trapping and filtering on the steam lines. No visible leaks were found in the piping. Yet two of the sterilizers were found to have high non-condensable gas levels; one, a 30 cu. ft. unit, with >7% and one, a 3.9 cu ft. unit, with >13% non-condensable gas content. What was more mystifying was that the unit with >7% non-condensable gas content was directly adjacent to an identical sterilizer fed from the same steam line with 0.09% non-condensable gases. What was most distressing for the 3.9 cu. ft. unit was that it was used for flash cycles in the OR. This level of NCG's could preclude sterilization, although there had been no difficulty with the indicators.

The 30 cu. ft. unit suffered from two problems. One was that its steam filter housing's gasket was leaking. This was repaired, but with no effect on the non-condensable gas measurement. The steam trap on the steam filter was found to be in good working order. Further examination showed that the jacket steam trap of the unit had missed preventative maintenance and that there were cracks in some fittings in the steam plumbing. These can aspirate air into the steam. Once the trap was rebuilt and the fittings replaced, the unit joined its neighboring unit in the sub 1% range of non-condensable gases.

The 3.9 cu. ft. unit was found to have a different defect in the steam trap for incoming steam from the building steam lines. The drain valve from the trap was turned off, making it an expensive addition to the plumbing that had no effect on the steam quality. This valve was opened. However, there were still inconsistent readings. Prevacuum cycles were well within specification. Gravity cycles were not. It was determined that the port for reading the steam quality was the problem. This port was about 1" above the feed to the sterilizer chamber, on the far side of the chamber port from the steam supply line, which was a convenient location for installing it, but not useful for reading the actual steam quality. We all have heard that steam and air don't mix. This particular measurement proves it. With the trap turned on and the port issue dealt with, the average non-condensable gas level dropped to 0.13%, an exemplary number.

This last situation begs the question as to whether pure flash cycles, with gravity displacement should be used, or whether "express" cycles with one or two prevacuum pulses are preferred. Since the amount of time needed for the additional

evacuation and pulse or pulses of an express cycle is not long, if you must flash, and you really shouldn't, flashing with an express cycle is by far the better choice, as it will help the steam penetrate the item, which is what should be happening.

Almost all steam sterilization failures may be attributed to poor steam quality, as long as packaging and loading are carried out properly and the equipment is well maintained. Analysis of these failures is not straightforward for the hospital, and can only be done using specialized equipment. The practices presented in this article will help avoid steam-quality related problems, but do not substitute for actual analysis of the steam quality parameters. Although the US does not have any requirements for steam quality analysis, if you don't know why it isn't working, and steam quality was never checked, now may be the time. HPN

Definitions of steam quality parameters and effects of their deviations from accepted values

Parameter	Definition	Failure Mode
Steam Dryness	The measure of the water content of steam. Acceptable values are ³0.9 (<10% water) for non-metal loads and >0.95 (<5% water) for metal loads.	Wet steam can cause an unsterile load in two ways: • Insufficient energy delivered to the load to sterilize. • "wet packs", making the sterile barrier material surrounding the load less of a barrier and compromising sterility assurance.
Superheat	A situation in which the temperature of the steam is higher than the saturation temperature for its actual water content. (This is the opposite of wet steam)	Superheat has two potential effect: • Unsterile loads due to insufficient energy being delivered to the load, since the steam is too dry. • Damage to the load if the superheat is generated where the temperature reached by the load is higher than its materials can withstand.
Non-condensable gases	A measure of air or other gases entrained in the steam. Expressed as a percentage by volume of gas in the steam.	High non-condensable gas content can cause an unsterile load in two ways • Insufficient energy delivered to the load to sterilize. Gases do not deliver the same latent heat energy as steam. • Pockets of gas can form that provide "islands" of unsterility. Unless the indicator is in such an island, their

		presence will go undetected.

[1] The standard sterilization volume is the basic building block of European sterilizer chamber sizes.

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