

DIFFERENCE BETWEEN POROUS AND HOLLOW MONITORING

IN STEAM STERILISERS

Key words :

(MDS)

(SAL)

Monitoring

Instruments(MIS)

Batch Monitoring (BMS)

Bowie Dick Test

Medical Device Simulator

Sterility Assurance Level

Steam Sterilisation

Non condensable gases

Minimal Invasive

Bill Davis

What do we mean when we refer to “Porous” monitoring and “Hollow” monitoring?

Sterilising technicians are always asking this question, and it is, in its answer very simple. However, because of its simplicity, it becomes extremely difficult for people to get their heads around this question in order to reach a conclusion and also to determine a defined answer.

What do we mean when we refer to porous goods?

Any material of linen or textile construction is essentially porous. The level of porosity is determined by the volume of fibres versus the volume of air inside the textile/linen sheet. Additives such as polypropylene may be added to the basic textile to give it greater strength and durability. This type of material was used extensively throughout hospitals in Australia and New Zealand, and were, and still are, to a lesser degree, used in today's hospital environment. Principally they are used in operating theatres as drapes, gowns, wraps and in feeder packs and the need to ensure their sterility was therefore very important as they were used to create and maintain a sterile "field" in the operating theatre.

Hollows are defined in EN ISO 130601 as being hollow if the instruments depth is greater than its diameter. So bowl sets, dishes and trays are not classified as hollows.

The method of sterilising in these bygone days was to use a Downward or Gravity Displacement steriliser that utilised a Super Atmospheric cycle that operated in positive and over pressure only. Air removal was achieved by incoming steam which displaced the air inside the chamber and hopefully, the load, by the gravity displacement of the air inside the chamber. Steam is heavier than air, and the whole concept of sterilising was based on this factor.

However, because of the problem associated with steam penetration of textile packs in a gravity displacement cycle, the need to develop a system for monitoring the inside of these packs to ensure that steam penetration, condensation and the correct temperature for sterilising had been achieved, resulted in the development and introduction of chemical indicators. These chemical indicators ensured that the conditions inside the pack/load was the same as the conditions in the chamber free space outside the textile packs inside the steriliser.

The chemical indicator in turn was then sited by the staff in the operating theatre when the pack was opened and gave the theatre staff an assurance that the pack had been through a successful sterilising process². These chemical indicators inside each pack do not indicate that the packs used were, or are sterile. Today, chemical indicators inside packs are still perceived by some members of the operating theatre staff as proof that the goods inside the pack, including hollow instruments are sterile.² This is a complete misunderstanding and, a successful chemical indicator that shows a pass, is only giving the information on the outside of the hollow instrument and not the conditions on the inside of the instrument. To achieve this would require a chemical indicator to be placed inside the instrument as a worst case scenario.

In addition to chemical indicators, biological indicators were also used in every load/cycle to assist in the monitoring of each load. The number of biological indicators used in each cycle depended on the size of the steriliser chamber. The biological indicators were placed in every quadrant of the steriliser chamber to monitor the variables of the downward displacement process which could, and did have many variations of temperature throughout the chamber. On completion of the sterilising cycle, the biological indicators were removed and incubated for 48 hours to determine whether the destruction of the *Geo. Stearothermophilus* to a Sterility Assurance Level (SAL) of 10^{-6} had been successfully achieved. If the incubation of the biological indicator was successful, then the load was deemed as sterile. However, because some packs were required urgently in the operating theatre, packs were often released before the results of the incubation of the biological indicators were known. So, because of this lengthy time factor required before the results are known, the use of biological indicators for routine monitoring is not recommended. Never the less, in emergency situations, the chemical indicators inside each pack were then used to justify the use of the pack in these emergency situations.

The use of biological indicators in a sterilising cycle only represents the conditions outside the packs and not inside the packs. This information may result in false positives and is very dangerous to use as a Sterility Assurance Level (SAL) The old belief of homogenous conditions inside the load cannot be justified anymore.

Performance Qualification (PQ) during validation in these gravity displacement sterilisers included heat distribution programmes using thermocouples both inside and outside textile/linen packs, as the textile/linen packs required a tremendous amount of energy to achieve the required temperature inside each pack. This was heavily influenced by the high heat capacity of the textile/linen in each pack. The density of the linen is also influenced by the warp and weft of each piece of linen inside each pack

Today these gravity displacement sterilisers are being replaced by vacuum assisted sterilising cycles commonly referred to as “pre – vacuum sterilisers,” where air removal is effected mechanically by the use of a vacuum pump. There are different types of “pre – vacuum” cycles on the market, with varying air removal efficacies and the term “pre – vacuum steriliser” does not give any information about the steriliser’s performance or indeed its efficacy. The change in air removal characteristics in these sterilisers requires a totally different way of monitoring air removal and steam penetration in each cycle.

To ensure the functionality of pre-vacuum sterilisers, Dr’s Bowie, Dick, Thompson and Kelsey³ developed what is now referred to as the Bowie Dick test. It was based on a linen bundle that weighed 7kg +/- 10% and utilised an A4 sheet of paper. On this sheet of paper was placed autoclave tape in the shape of a St Andrews cross. If, on completion of the cycle, any residual air remained inside the pack, it would form a bubble in the centre of the cross which

would then have prevented the colour change on the tape to take place. This would have indicated a failed cycle.

Very simple, but for its time, very effective.

In recent years we have seen the development and introduction of commercially produced porous Bowie Dick test packs for use in pre-vacuum sterilisers. This type of test is still in use today. However, with the advent of Minimal Invasive Surgery (MIS) we are experiencing the development of extremely complex instruments. These demand far more sensitive monitoring and steriliser testing to ensure that the correct Sterility Assurance Level (SAL) is achieved in each and every cycle. Moreover, textile linen and drapes are being replaced and superseded by non woven materials for use in operating theatres, therefore the need for porous monitoring in pre – vacuum sterilisers is being eroded and reduced.

During a surgical procedure, textiles or linen are not used inside the patient with the exception of laparotomy sponges, which are commercially produced and sterilised by gamma irradiation or ethylene oxide processes.

Linen may not be used inside patients but hollow instruments most certainly are!

Class 5 and class 6 chemical indicators manufactured according to EN ISO 11140, provide the same results as a biological indicator. Subsequently, they are used extensively as a means of monitoring, however, they are ineffective as a means of monitoring complex instruments used in Minimal Invasive Surgery (MIS), even though they may be the correct indicators for the process. This is due to the fact that chemical indicators can only give information about the conditions of the sterilising parameters in the position that they are placed inside each pack or tray set. They cannot monitor the conditions and sterilising parameters inside any hollow or lumened instrument inside a pack, and are therefore ineffective for this purpose.

Commercially produced porous Bowie Dick tests can only recognise residual air between 50 and 200ml and are testing the functionality of the steriliser, not the sterility of the load. The steriliser software that produces the printout is also unable to recognise small amounts of residual below these levels and, given that requires only 0.31ml of air to fill a Trocar 10cm long by 3mm in diameter, the functionality test that the porous Bowie Dick test represents, plus the steriliser printout, reduces the capabilities of the sterilisers ability to monitor these miniscule amounts of air at start up or whenever the Bowie Dick test is carried out. This doesn't really challenge the steriliser's ability to effect air removal and steam penetration on the inside of blind ended and complex hollow instruments.

The only method of monitoring these complex hollow instruments is to simulate them inside a pack or bundle inside a steriliser using a Medical Device Simulator (MDS). Air removal and steam penetration monitoring of complex instruments cannot be achieved or recognised by air detectors, nor indeed the software that produces the printout at the end of each cycle, as both systems can only monitor the conditions in the free space (unused space) of the steriliser chamber.

The inner volume of air inside a lumen is determined by multiplying its length by its diameter. The greater the volume of air inside a lumen, the more difficult the removal of this air becomes, this in turn reduces the levels of condensate that can be formed on the inside surfaces of the instrument because the trapped air is preventing steam penetration of the instrument⁴. Hot water created by the steam condensing on the inner and out surfaces of everything in the load is the medium that actually sterilises the load, (and not the steam itself as many people believe) so steam penetration is absolutely critical for the sterilising of any hollow instrument.

To effectively monitor air removal from inside complex and hollow instruments requires the use of a Process Challenge Device (PCD) in every load/cycle that represents the worst case scenario in each and every load. This is called a Batch Monitoring System (BMS⁵). If we use the scenario of the Trocar 10cm long by 3mm in diameter and it has 0.31ml of trapped air inside the Trocar, then steam cannot penetrate the instrument and subsequently, the instrument would not be sterile and the Batch Monitoring System (BMS) would fail the cycle. However, a chemical indicator under the same conditions would record a successful cycle and give the staff in the operating theatres a non sterile instrument to be used on a patient. The Batch Monitoring System (BMS) should be capable of monitoring the load configuration and still have a safety margin over and above the load configuration established during the Performance Qualification (PQ).

In conclusion.

Using chemical or biological indicators to monitor complex and hollow instruments and lumens in a sterilising process cannot give an accurate indication of the Sterility Assurance Level (SAL) inside these hollow instruments and/or devices.

Chemical and biological indicators represent old technology and can only identify the time/steam/temperature parameters of the process and not the air removal and steam penetration parameters required to sterilise the inside of hollow instruments.

To effectively achieve the correct Sterility assurance Level (SAL) inside these hollow devices requires the use of a Process Challenge Device (PCD) in every batch/load determined by a Batch Monitoring System (BMS)

Referenced documents :

1. EN ISO 13060 “Small Steam Sterilisers”
2. ACORN standards 2006 (5.1 – 5.2 – 5.3)
3. Bowie, Dick, Kelsey, Thompson “The Bowie Dick Autoclave Tape Test” The Lancet 1963.
4. Gorman – Kaiser “ Air removal from hollow devices in the steam process” 1998
5. Robert Koch Institute (RKI) 10 – 1- 2006

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Essential Vocabulary for Today's World

BLAMESTORMING: Sitting around in a group, discussing why a deadline was missed or a project failed, and who was responsible.

SEAGULL MANAGER: A manager, who flies in, makes a lot of noise, craps on everything, and then leaves.

ASSMOSIS: The process by which some people seem to absorb success and advancement by kissing up to the boss rather than working hard

SALMON DAY: The experience of spending an entire day swimming upstream only to get screwed and die in the end.

CUBE FARM: An office filled with cubicles.

PRAIRIE DOGGING: When someone yells or drops something loudly in a cube farm, and people's heads pop up over the walls to see what's going on.

MOUSE POTATO: The on-line, wired generation's answer to the couch potato.

SITCOMs: Single Income, Two Children, Oppressive Mortgage. What Yuppies get into when they have children and one of them stops working to stay home with the kids.

STRESS PUPPY: A person who seems to thrive on being stressed out and whiny.

SWIPEOUT: An ATM or credit card that has been rendered useless because magnetic strip is worn away from extensive use.

XEROX SUBSIDY: Euphemism for swiping free photocopies from one's workplace.

IRRITAINMENT: Entertainment and media spectacles that are annoying but you find yourself unable to stop watching them.

PERCUSSIVE MAINTENANCE: The fine art of whacking the crap out of an electronic device to get it to work again.

ADMINISPHERE: The rarefied organizational layers beginning just above the rank and file. Decisions that fall from the adminisphere are often profoundly inappropriate or irrelevant to the problems they were designed to solve.

404: Someone who's clueless. From the World Wide Web error Message "404 Not Found," meaning that the requested site could not be located.

GENERICA: Features of the American landscape that are exactly the same no matter where one is, such as fast food joints, strip malls, and subdivisions.

OHNOSECOND: That minuscule fraction of time in which you realize that you've just made a **BIG** mistake. (Like after hitting send on an email by mistake).

WOOFS: Well-Off Older Folks.

Standards Talk

The website for accessing all standards, national and international, is;

<http://www.standards.co.nz>

There are monthly updates available on this website so you can keep up to date with changes. The complete address is;

<http://www.standards.co.nz:81/news-and-seminars/standards+update/>

Well it has been a quiet 3 months on the health standards development front and there is no amendments, drafts or new policies to update you on. Remember you are able to view what is happening with standards at any time by visiting the sites above.

Managers Forum

The first managers forum for 2007 was held in March. The second is on May 18th but this edition is going to print before then so will feed back on it and the August one in the next magazine.

The March meeting was again well attended. The meeting has been described as enjoyable and relaxed. What better way to network and share information. What was achieved?

Final discussion was held in relation to documents that are being formulated for national use. These were the Quality Audit Tool, Loan Instrument Guidelines and CJD Guidelines. All have been forwarded to the Ministry of Health for final comment. After this feedback the documents will be published in the Supplyline and also made available on the NZSSA website.

Steriliser Validation Guidelines are under development and final discussion is hoped to be held for these at the August forum.

These documents being formulated for national use are an initiative of members of the National Sterile Services Association Executive. The reason they are being brought to the forums is to get a good cross section of national input into their development.

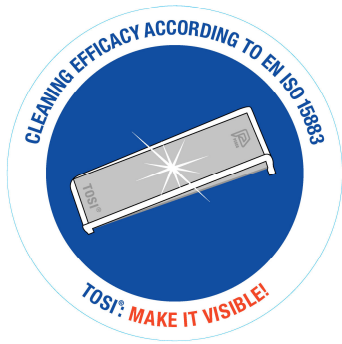
The remainder of the meeting was taken up with a lively general discussion around questions posed by the attendees.

These forums are for the managers or person with the decision making role in the Sterile Services environments throughout New Zealand. Your input and attendance is valued so we look forward to seeing you at future forums. The remaining dates for 2007 are;

August 17th at Wellington Airport

November 14th at War Memorial Conference Centre, Hastings

For further information please contact Alison Stewart, Wellington Hospital,
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Experiences gained with Test Object Surgical Instruments (TOSI®) and LumCheck

For operating our sterilisers we are told by the standards how to achieve sterility and also how to test for this performance, but what about our washer disinfectors!

The standards for washer-disinfectors do tell us that we need to remove all soils to achieve completely clean instruments but no detail is provided on how this should be achieved. Since cleaning is somehow more complicated than sterilizing (due to all different parameters involved); hospitals around the world do often have problems to achieve good cleaning efficiency. At least when it comes to the cleaning results the standards do tell us that we need visually clean instruments and we need to test the cleaning efficiency of the washer.

Testing of the cleaning efficiency of a washer-disinfectant is only one part of the story. The other is what to do in case of unsatisfactory results? The first question is: What is an unsatisfactory result?

Here the standards are pretty clear! Cleaning is the complete removal of soil and the result of the soil tests need to be a visually clean surface! This is nothing new for us since we are all used to reject instruments which are not visually clean after the cleaning process.

But once again it is not very clear how to we should do this job!

The first concerning questions are:

Is visual inspection enough?

Do I need to do some complicated chemical tests?

Which of the test soils do I have to use?

Some of them are neither standardized nor do they correlate to the soil we encounter on our instruments.

This is where we have gone a step further by producing a test method in accordance with the standards, not only producing it, but also supplying all

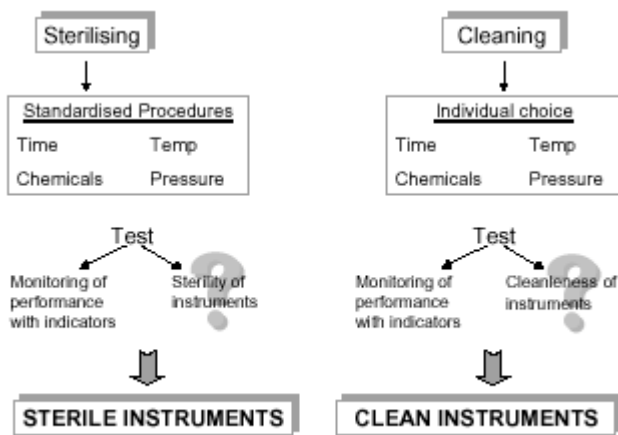
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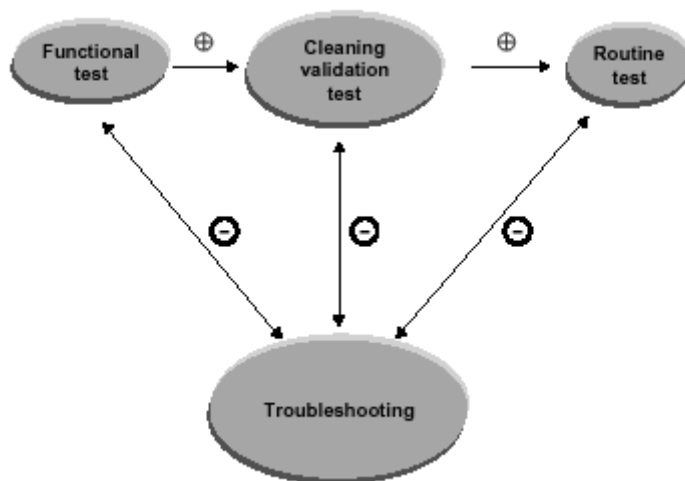
information about the parameters needed to achieve good results! Being a step ahead is what we call **moving forward!!!**

The PEREG clean monitoring product line is already well established and the **TOSI®** is used world-wide to check the normal cleaning efficiency of washer-disinfectors for standard instruments.

Therefore moving forward - How does the TOSI® work with the standards?



The current standards for washer disinfectors are only outlined in brief therefore implementing the detailed process, up to the best practice, is in the best interest of the end user and manufacturer to perform the routine validation tests. These tests include a daily, weekly protein residue test, a quarterly soil test and finally an annual revalidation to ensure the machine is still functioning within the original tested parameters. Validation is the manufacturer's scientific evidence that the equipment performs to its claimed specification and to current standards/guidelines.



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For quality assurance and safety, we need to monitor the performance of all equipment. Without recording the results it is like the test was never done. Washer-disinfectors should be tested on a routine base but this can only be done after it is made sure that all parameters are OK and the function is secured.

TOSI® is a tool developed to enable a user friendly routine, standardised, and reproducible test of the cleaning efficiency of the cleaning process in line with the standards recommendation.

How to solve cleaning problems in hospitals

Needed by standards for safety	TOSI
Standardised and reproducible	<input checked="" type="checkbox"/>
Correlation to situation in practise	<input checked="" type="checkbox"/>
Visual Check	<input checked="" type="checkbox"/>
Quantitative result	possible

How to solve cleaning problems in hospitals

To work according to the standards the **TOSI®** needs to be completely clean and in case of any visible residues there is an obvious need to optimize the process.

For the actual process of trouble-shooting and optimization we need to split the efficiency of a washer into the chemical and the mechanical part of the process. The chemical efficiency inside the wash-chamber is more or less the same in all places due to a good distribution of detergent concentration and temperature. The real ability to dissolve insoluble proteins like fibrin can vary between strongly, for alkaline detergents (only at high temperatures), and none existing, for neutral detergents without enzymes!

Un-fortunately all types of detergents are used in hospitals since there is no concrete information yet from the standards when it comes to which parameters should be used. The distribution of the mechanical efficiency inside the wash-chamber is a completely different story! The spray systems will supply water jets, directly hitting only certain areas inside the washer but not all. We therefore have higher and lower areas of mechanical efficiency and some-times areas where there is no efficiency at all!

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Of course on such blind spots even the best detergent will not work due to the missing contact with the instrument. This is also the reason why we can have different **TOSI®** results after a test with a larger number of **TOSI®**'s placed in the same washer in different spots. This will indicate problems with the mechanical efficiency.

CSSD's do not only handle standard instruments but operating techniques are becoming more complicated, to simulate the cleaning test of a worst-case scenario Pereg have developed the **TOSI®-Gold** correlating to denaturalized proteins.

More and more MIS instruments are being used, therefore the **TOSI®-LumCheck & FlexiCheck** system was launched to assist in the monitoring of the cleaning of cannulated instruments. Pereg suggests two possible uses for the **LumCheck & FlexiCheck** depending if cannulated instruments are reprocessed in washer-disinfectors or in an ultrasonic bath with an irrigation system. With respect to ultra-sonic baths, the **SonoCheck test device** is also a first step into the field of parametric measurement of ultrasonic energy.

For any queries or questions on the Pereg range of test monitoring devices please contact Mercer Medical.

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