ZENTRAL STERILISATION 5

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The Relevance of the Bowie and Dick Test in Hospital Sterilisation

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Steam sterilisers are routinely subjected to a series of tests. Typically this includes an annual performance qualification (including temperature measurements in an empty steriliser chamber and in the Bowie and Dick test pack), weekly air leakage test, daily Bowie and Dick test and chemical indicators per batch.

Years ago this series of tests was particularly useful. The sterilisers were manually controlled or were fitted with mechanical semi-automatic controllers, which lacked the necessary reliability. Failure of valves and seals occurred frequently. Steam supply for the sterilisers was seldom dedicated. Sterilisers were simply hooked up to the main steam supply and interference from concurrent operated autoclaves or other applications, such as the kitchen or heating, were taken for granted.

Equipment and procedures have evolved and time has come to ask whether the classic Bowie and Dick test is still necessary or even useful.

Is the Bowie and Dick test a mandatory test?

The general opinion in the field is that the Bowie and Dick test is a mandatory test; the daily execution of the test cannot be questioned. The obligation to perform the Bowie and Dick test on a daily basis can however only come from national or regional legislation. In the Netherlands the "Decree on sterilisation of medical devices in hospitals" (1) requires that the hospital shall use adequate equipment to sterilise the medical devices. The performance of the equipment shall be verified on a regular basis. The necessary test methods are not specified in the decree, but the Dutch Health Care Inspectorate expects hospitals to perform a daily steam penetration test which is a representative challenge to the sterilisation process (2).

Practical test procedures are given in standards and guidelines. The European standard EN554 on validation and routine monitoring requires a daily steam penetration test where saturated steam is used and the efficacy of the process depends on air removal. The draft ISO standard ISO/CD17665, superseding EN554, requires a steam penetration test to be carried out at specified intervals. The nature of the steam penetration test is not specified in either document. It may be a test based on a textile test pack e.g. Bowie and Dick test or tubular device e.g. a test helix. These requirements for a steam penetration test are historically interpreted as an obligation to perform the Bowie and Dick test.

The Bowie and Dick test is prescribed in the type test procedure for steam sterilisers that are build in compliance with EN285. The Bowie and Dick test pack as specified in EN285 is often considered to be "the most difficult to sterilise object". If the steriliser is capable of providing sufficient steam penetration into this test pack one tends to assume that the steriliser is capable of sterilising all types of loads and items. The design of the sterilisation cycles operated in Dutch hospitals is for the larger part based on the achievement of steam penetration in this "worst case" standard textile test pack. Contra indications are given in literature and national guidance documents.

a. The specifications of the most difficult to sterilise textile pack seem to depend on the steriliser chamber size. CEN TC102 has re-defined the "standard" test pack for steam sterilisers with a chamber volume of 1 standard unit. A pack, smaller than the standard Bowie and Dick test pack, seems to be more of a challenge for the smaller models of large steam sterilisers (3).

b. To test whether steam penetration in hollow devices is sufficient the draft European standard for small steam sterilisers (prEN13060:2003) requires the standard helix test (EN867-5) to be performed.

c. Recommendations to conduct the helix test are found in guidance documents for healthcare from Germany (4), the Netherlands (5) and the UK (6).

d. A published study from Gömann (7) shows that the Bowie and Dick test is less of a challenge than the standard helix test (EN867-5).

The purpose of the Bowie and Dick test

The introduction section of the European standard for the chemical indicators to be used in the Bowie and Dick test, EN867-3, clearly explains the purpose of the Bowie and Dick test. "The Bowie and Dick test was conceived as a test for successful air removal from high vacuum porous load sterilisers (8). A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due either to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, are cir-

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cumstances which can lead to a failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilisation.

A failure of the Bowie and Dick test is not conclusive proof that the fault in the steriliser is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure. The Bowie and Dick test is a performance test for steam sterilisers for wrapped goods and porous loads. As such it is performed during the demonstration of conformance of steam sterilisers to EN285 and as a routine test of performance in EN554. The method of carrying out the test is described in EN285.

A test pack for the Bowie and Dick test consists of two components:

a. a small standardised test load and

b. a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described (8), utilised Huckaback Towels as the material for the test load. The test as described in EN285 uses cotton sheets for this purpose."

The three underlined sterilisation problems that may lead to failure of the Bowie and Dick test may have been of major concern at the time the test method was conceived. With the advancement of the steriliser technology the usefulness of the Bowie and Dick test in relation to these problems can be commented on.

Inefficient air removal

The efficacy of the air removal in a vacuum steriliser depends on the values for the pressure of the vacuum and steam pulses during the air removal stage. Once the optimum values for these parameters are programmed into the automatic controller of the steriliser, it is unlikely that these values will change spontaneously. Failure of the vacuum system will show on the process records and might even lead to a fault condition and consequent termination of the process. For modern vacuum steam sterilisers the added value of a daily indicator test to detect failure of the air removal stage of the process is limited.

Air leakage

In the Netherlands the air leakage test is usually performed once a week, in line with the national recommendations. Apparently the occurrence of air leakage is considered a small risk. Air leakage is easily detected by direct measurement. The method described in EN285 measures the air leakage into the vacuumed steriliser chamber by the pressure increase during a defined time interval. This test is suitable for automation. A number of steriliser manufacturers provide the means for an automated air leakage test that is commenced before the start of the working day. There is no need for a steam penetration test to detect an air leakage into the steriliser chamber.

Non-condensable gases in the steam

In the Netherlands the presence of non-condensable gases in the steam used for sterilisation is an undervalued problem. None of the Dutch hospitals measures the amount of non-condensable gases as described in EN 285. Apparently there is no concern about the amount of non-condensable gases in the steam for sterilisation. However, non-condensable gases in steam may impair steam penetration into the load, regardless of the source of the non-condensable gases. Non-condensable gases may also cause excessive superheat in the steriliser chamber. A problem that is often the cause of rejection of the steriliser during validation and that leads to modifications of the sterilisation process, e.g. slowing down of the heating stage to prevent temperature overshoot. The chances of detecting non-condensable gases with a daily indicator test are limited. Non-condensable gases from the feed water of the boiler are released as a bolus of gas (9). Taking into account that the Bowie and Dick test is usually performed at the start of the working day and does not necessarily coincide with the peak in steam demand in the hospital and therefore the need for boiler feed water and consequent release of non-condensable gases, it is mere "luck" that the Bowie and Dick test indicates a bolus of gas in the steam supply. When there is serious concern for non-condensable gases a daily indicator test is not suitable to indicate possible problems. The amount of non-condensable gases should be monitored frequently at different moments during the working day. Preferably a system is installed that continuously measures the amount of non-condensable gases in the steam supply to the steriliser chamber (9). Other systems may be equally suitable, e.g. an air detector as described in the UK HTM 2010 documents.

The original intentions of the Bowie and Dick test have little relevance for modern steam sterilisers. Problems such as failure of the air removal system and air leakage can be detected by the fault indication system of the steriliser or by review of the process records. The presence of non-condensable gases in steam is a concern but it is unlikely that this particular problem will be detected by a daily steam penetration test. Continuous or batch wise monitoring is preferred.

The following section describes a number of the different steam penetration tests that are available at the moment. The possible application for the batch monitoring of the sterilisation process is considered for each test.

Steam penetration tests

A system for the steam penetration test consists of two components.

1. An indicator to show the presence of the sterilant at the specified conditions of temperature, relative humidity and time, necessary to give an acceptable sterilisation cycle. For steam sterilisation the indicator may either be a well chosen biological indicator (10), a chemical indicator or an electronic device to measure temperature, pressure and time.

2. A barrier that prevents direct access of the sterilant to the indicator. For steam sterilisation the barrier comes in the form of a device; a process challenge device (PCD). PCD's can be divided into two major groups; the porous load PCD's and the hollow load PCD's. The standard test pack used in the Bowie and Dick test is the classic example of a porous load PCD. Hollow load PCD's are widely used for the testing of ETO and low temperature steam and formaldehyde sterilisers.

The construction of the process challenge device and the performance of the indicator are designed to ensure that penetration of steam in the load within the steriliser will provide adequate assurance

that steam penetration will occur in routine loads. The process challenge device simulates the worst case of conditions for attainment of the specified sterilisation conditions within the items to be sterilised. It challenges the sterilisation process by representing the worst case conditions for the sterilising agent to penetrate. The design of the process challenge device depends on the characteristics of the goods to be sterilised, the packaging and the sterilisation process.

a. Alternatives to the Bowie and Dick test (Disposable test packs).

Since cotton sheets are not available in the CSD, because these are no longer used for surgical drapes, daily testing in hospitals is performed with disposable test packs. Only for the operational qualification and performance qualification the textile pack according to EN285 is used. It is then usually provided by the subcontractor performing these qualifications. These alternative tests are often viewed on as disposable paper test packs that will give the same response to faults in the sterilisation process as the standard Bowie and Dick test. However, the introduction section of the European standard on alternatives for the Bowie and Dick test (EN867-4) refutes this. "Indicators intended as an alternative to the Bowie and Dick Test use different materials for the test load and employ indicator systems specifically formulated for use with the defined test load. This standard specifies the performance of the indicator system in combination with the test load with which it is intended to be used. The test load may be presented with the indicator system already incorporated and intended for single-use or may be intended for multiple-use with a new indicator system to be inserted prior to each use. The indicator for which the performance is specified in the European standard is intended to indicate that steam penetration has been inadequate. The performance of the indicator should be equivalent, but not necessarily identical, to the performance obtained in a Bowie and Dick test as described in EN285. Equivalence should be regarded as providing a similar response to steam penetration with any differences being predictable and such that the necessary level of assurance of satisfactory steam penetration is provided. An indicator meeting this specification is not intended to identify which of the potential causes of poor steam penetration was responsible for the failure indicated by the test."

In the test section of the standard, information is given that indicates that the performance of alternative tests may vary from steriliser to steriliser and that the performance of alternative tests from different sources may not be comparable in every situation. Equivalence of the alternative test to the Bowie and Dick test is established by running three sterilisation cycles with different design of the air removal stage under fault condition. The fault condition is set and verified by thermometric measurements in the standard Bowie and Dick test pack. By injection of air into the steriliser chamber at critical moments during the sterilisation process a temperature depression of 2 °C in the centre of the test pack is created. This fault shall be indicated by the alternative for the Bowie and Dick test. The tests under fault condition shall be performed in a steriliser with a chamber volume of not less than 250 litres and not more than 750 litres.

This procedure may result in problems that may become apparent during the use of alternative tests:

a. The volume restrictions for the test steriliser imply that the alternative test may not give an equivalent reaction to the standard Bowie and Dick test when it is used in a steam steriliser with a smaller or a larger chamber volume.

b. There may be an inter laboratory variation. The aforementioned variation in chamber sizes and also the state of the textile from which the Bowie and Dick test pack is assembled. The sheets get compressed and shrink during use (8). After time more sheets are necessary to get the dimensions of the test pack within specification.

c. Alternatives for the Bowie and Dick test from a variety of sources, all fulfilling the requirements in EN867-4 may not necessarily be suitable for a particular steriliser. Variations in the testing systems employed by the different test laboratories may lead to different sensitivities of the test. Experience has shown that a steriliser fails the Bowie and Dick test when a disposable pack from manufacturer A was used, while no problem occurred when a test pack from manufacturer B was used. Both manufacturers claimed that the product was in compliance with EN867-4.

Neither the Bowie and Dick test, nor the alternative tests are considered to be suitable for batch wise monitoring of the sterilisation process.

b. Helix test

The helix test consists of a hollow load PCD, made from a tube, closed at one end with an indicator receptacle in which a chemical indicator, a biological indicator or temperature probe is placed. The tube is coiled up into a helix.

The internal volume of the tube and the internal volume of the indicator receptacle must be carefully matched to one another. At the end of the air removal phase the volume of air that remains in the tube and the indicator receptacle must well fit into the indicator receptacle when the sterilisation pressure is reached. Moreover, the amount of residual air must be small enough so that it can mix with the incoming steam and not prevent the attainment of conditions under which the indicator will pass. When the volume of the indicator receptacle is relative large more air must be retained in the tube before the indicator will show a fail. At a smaller ratio the efficacy of the air removal must be higher and the test will be harder to pass. Standard EN 867-5 specifies that the volume of the indicator receptacle (with indicator in place) shall be 6% of the volume of the tube.

The helix test does not only indicate insufficient air removal but is also sensitive to non condensable gases in the steam.

Since the heat capacity of the test is small it will not hinder the sterilisation process, which makes it, in combination with the correct indicator (reaction time and temperature set to the sterilisation time and temperature) an ideal candidate for a batch wise test.

The German Society for Hospital Hygiene (DGKH) recommends the use of a helix test in every sterilisation cycle (4).

c. Rubber load test

The rubber load test described in EN 285 is used to test the ability of the steam steriliser to sterilise natural rubber tubes. A piece of

natural rubber tubing comprises three inoculated carriers complying with prEN 866-3 (consisting of a carrier of glass tubing) inserted as spigots to rejoin the piece of tubing to a nominal length of 1500 mm. One inoculated carrier shall be located in the middle of the tubing and one approximately 200 mm from each end of the tubing.

This test is not designed as a steam penetration test for hollow devices in general. The problems with the sterilisation of natural rubber lie in the fact that rubber gases out at elevated temperature. The gases released by the material may inhibit steam penetration in the tube. The process challenge device is clearly chosen to mimic devices made from natural rubber.

With carefully selected biological indicators (D-value and number of microorganisms) the test items could be used for batch monitoring of steam penetration, when rubber materials are routinely sterilised. However, the use of biological indicators make it necessary to keep the sterilised products in quarantine until the incubation period is completed.

d. Electronic test systems

The 3M Electronic Test System is an electronic sterilisation monitoring tool based on physical measurement of the process variables temperature, pressure and time. The temperature is measured on the outside of the device and on two locations inside a cavity. The cavity functions effectively as a hollow load PCD. From the collected data the built-in electronics can calculate whether steam penetration in the cavity is sufficient.

According to the manufacturer the ETS is designed to provide an electronic means of conducting the daily steam penetration test as required by EN554. The manufacturer designed the system to provide additional features such as steam penetration test equivalent to EN285 pack, leak rate test, lethality calculation for pharmaceutical applications and calibration checks.

The added value of a number of these features is limited as they can equally be performed by using the data from the measuring systems of the steriliser in a graphical representation or by putting the data through a calculation program.

As an alternative for the Bowie and Dick test it suffers from the same disadvantages. Strong points are the combination of the electronic sensors, the PCD and the built-in electronics to provide a clear go/no-go indication at the end of the cycle. Misinterpretation of the test result is prevented.

The system is not designed for batch-wise monitoring of the sterilisation process.

e. Wireless datalogger

Wireless dataloggers (from numerous manufacturers) give an electronic record of the signals from one or more temperature sensors and a pressure sensor. When the temperature measurement is limited to the free chamber space, process faults, such as the occurrence of non condensable gases, will only be detected when the fault is large enough to give a temperature depression outside the normal range.

Without a process challenge device, dataloggers are not suitable as a steam penetration test. In that case it will only give a means to verify the reading of the instruments of the steriliser.

To be useful as a process monitoring system it should be combined with a process challenge device, to collect and enhance the effect of the non-condensable gases, but the application may be limited by the diameter of the temperature probe. E.g. EN 285 prescribes that the diameter of the temperature probe that is used to measure the temperature inside the standard test pack shall not exceed 2 mm. Therefore wireless dataloggers that are provided with a temperature probe with a larger diameter than 2 mm shall not be used in combination with a porous load PCD.

Wireless data loggers may be suitable for batch wise monitoring when combined with a suitable process challenge device.

Relevance of the Bowie and Dick test in hospital sterilisation

Steam penetration tests may serve a purpose in the routine testing of steam sterilisers. Especially to detect an excess of non-condensable gases in the steriliser chamber during the heat-up and sterilisation phase of the process. Steam penetration tests that can be performed within each batch are preferred as they provide this information for each sterilisation cycle and may aid in the procedure for parametric release of the steriliser load.

A well designed steam penetration test will also function as a worst case model for the steriliser loads and as a long-term reference test. The type of steam penetration test must therefore be well chosen. The PCD must mimic the real loads that are sterilised. The results from a steam penetration test using a porous load pcd may not be relevant for the sterilisation of hollow devices and vice versa (7).

The use of the Bowie and Dick test in steam sterilisers that are not used for the sterilisation of textile packs with saturated steam, cannot be recommended. Published studies (3, 7) indicate that the standard Bowie and Dick test pack is not in all cases the most difficult to sterilise load. For the smaller types of large sterilisers, a smaller test pack seems to be more appropriate. Textile packs do not provide a good model for hollow devices. Air removal from hollow devices primarily depends on the efficacy of the vacuum system, where textile packs can be sterilised when the air removal is based on gravity displacement alone (11). The same argument can be given against the use of alternatives to Bowie and Dick test (disposable test packs). In addition these alternatives may not be expected to give an identical response to process conditions as the standard Bowie and Dick test. The ability to detect process faults seems to depend on specifications of the sterilisation cycle, in terms of speed of air removal, heat up times, overall process time etc. A fault indicated by disposable test packs from one brand may not be indicated by the test packs from an other brand.

Helixes provide a model for hollow devices and that they can be tuned to give an optimum correlation to the steriliser loads.

The indicator receptacle can be adapted for the use of biological indicators or chemical indicators. The volume ratio between the indicator receptacle and the tube must however be noted. Contrary to the European and international standards a number of national guidelines explicitly advise to use a steam penetration test with a hollow load PCD rather than the Bowie and Dick test.

In 2000 the Dutch Health Care Inspectorate expressed her concern about the lack of consideration given by the Dutch

hospitals to the relevance of the daily steam penetration test (2). The fact that textile is no longer sterilised makes the use of the textile standard test pack for the Bowie and Dick test (or paper pack alternatives) obsolete. Certainly the Bowie and Dick test pack shall not be used as the reference worst case load in the design of the sterilisation cycle, unless it is demonstrated that sterilisation of this test pack is more difficult to achieve than the sterilisation of routine loads and that the nature of the test pack is relevant for the routine loads.

Since the publication of the report by the Dutch Health Care Inspectorate some hospitals have performed the helix test; all with negative results. To determine whether these observations are purely coincidental or that the Dutch sterilisation cycles are by design not adequate for the sterilisation of hollow medical devices the inspectorate has asked the RIVM to visit 20 hospitals and perform the standard helix test on site. The tests will be performed both as the daily test using the Bowie and Dick test cycle (where available) and as a batch test. The test protocol is available in English from the authors. The results of the study are expected by the first quarter of 2004 and will be offered to this journal in due time. ✻

References

1. Besluit van 6 mei 1983 (Stb. 281), houdende de regelen met betrekking tot in ziekenhuizen gesteriliseerde medische hulpmiddelen (Besluit gesteriliseerde medische hulpmiddelen in ziekenhuizen)(in Dutch).
2. Inspectie voor de Gezondheidszorg, Den Haag, Validatiestatus sterilisatoren voor medische hulpmiddelen in de Nederlandse ziekenhuizen. December 2000 (in Dutch).
3. Meurer et al.: Critical size of test pack for steam sterilisers with chamber volume of 80 litres. Zentr Steril 2000; 8 (5): 278–288.
4. German Society for Hospital Hygiene (DGKH): Recommendations for validation and routine monitoring of sterilisation processes with moist heat for medical devices. Zentr Steril 1998; 6(1): 30–46.
5. Richtlijnen steriliseren en Steriliteit; R6103a Validatie van stoomsterilisatieprocessen voor medische hulpmiddelen (in Dutch).
6. MDA Guidance on the purchase, operation and maintenance of vacuum benchtop steam sterilisers, DB 2000/05 (NI).
7. Gömann et al.: Air removal from porous and hollow goods using different steam sterilisation processes, Zentr Steril 2001; 9 (3): 177–186.
8. Bowie J.H. et al.: The Bowie and Dick autoclave tape test. Lancet I, 1963: 586–587.
9. Kirk B.: Non-condensable gases (NCG) in the steam supply of a steriliser. Zentr Steril 2000; 9 (5): 317–334.
10. Pflug I. J., Evans K. D.: Carrying out biological qualification, the control operation of moist-heat (steam sterilisation) processes for producing sterile pharmaceuticals and medical devices. PDA Journal of Pharmaceutical Science & Technology 2000: 54 (2): 117–135.
11. van Drongelen A.W., de Bruijn A.C.P., Huys J.F.M.M., Muis B.: Optimisation of the Process for a Manually-Operated Jacketed Steam Steriliser. Zentr Steril 2002; 10 (6): 373–384.