The Bowie and Dick Type Test

Does size and penetration really matter?

Presented by
Terry McAuley
Sterilisation and Infection Control Consultant
Discuss the purpose of the Bowie Dick type test

Examine the applicable European Norms (EN) & International Standards Organisation (ISO) standards that refer to Bowie-Dick type tests

Outline the basic requirements in the EN & ISO standards that can be used to evaluate claims of test conformance

Explain the correct method for performance, interpretation and documentation of the Bowie-Dick type test
It’s a matter of physical chemistry…..

- A Bowie-Dick is a physical test uses a chemical indicator to demonstrate that steam penetration has been adequate by showing a uniform colour change in the indicator
  - In order for the indicator to change colour a chemical reaction must occur at certain temperatures in the presence of moisture
  - By default, a satisfactory result translates into an assumption that air removal was adequate
Size matters

- **Required for the test:**
  - Huckaback towels (36” x 24” ) folded to give 8 thicknesses of cloth
    - 25-29 were required to create a stack of the right height
  - Two 12” strips of autoclave tape placed in the form of a cross on a 10” x 8” sheet of unglazed paper
    - These sheets could be inserted at various levels throughout the stack, although one sheet in the centre of the pack was acceptable
  - Huckaback towels in a 10”-11” high stack were then placed in a rectangular dressing casket, cardboard box or were wrapped in fabric

- Bowie et al (1963)
Fig. 1—General arrangement of original test, showing towels and tape before sterilisation.

Fig. 2—*a*, satisfactory run (uniform colour change); *b*, unsatisfactory run (colour change incomplete at centre).
“This test is essentially a test of steam penetration, not of time-at-temperature”

“A satisfactory test will indicate rapid steam penetration, adequate air removal and freedom from significant air leaks.”

“A uniform colour change may be obtained without adequate initial air removal if the holding time is artificially extended”

– Beyond 3 ½ minutes@ 134ºC

– Bowie et al (1963)
“In some sterilisers (where steam is admitted during vacuum phases) penetration will occur and the load temperature will rise before the end of the prevacuum period. In such sterilisers a satisfactory result indicates adequate steam penetration but does not necessarily confirm a suitable degree of air tightness … therefore an air leakage test may be needed in addition.”

– Bowie et al (1963)
Change is inevitable....

- That was then...
  - Single deep vacuum phase +/- conditioning
  - Majority of items processed were porous in nature
  - Surgical instruments mostly constructed of metal
  - Very few multi-part or cannulated devices

- This is now...
  - Superatmospheric, transatmospheric or subatmospheric pulsing
  - Majority of items processed are non-porous
  - Surgical instruments constructed of a variety of materials
  - Large percentage of multi-part and long-lumened devices
Is the Bowie & Dick test still relevant?

- What do you think?
What do we need to check for?

- Chamber integrity – to ensure no air leakage is present at any stage of the sterilisation cycle
- Ability of the vacuum pump to eliminate air from the chamber and load
- Steam quality
Performance Testing of Steam Sterilisers

- **Air Leakage Test**
  - Establishes that no air leakage will occur during vacuum stages of the sterilisation cycle

- **Leak rate tests** are now an automatic test cycle on most modern sterilisers
Performance Testing of Steam Sterilisers

- **Air detectors**
  - Commonly fitted to most modern sterilisers
  - Samples the conditions present in the steriliser chamber after the air removal stage and during steam admission, in every cycle
  - Is set to cause the cycle to abort if temperature differences $\geq 2^0\text{C}$ are detected
Performance Testing of Steam Sterilisers

- Air removal and steam penetration test
  - Establishes efficacy of vacuum system and can give an indication of steam quality – i.e. presence of non-condensable gases

- Commercially available alternatives to the original Bowie & Dick test are in widespread use
What Standards are there that refer to B&D tests?

LOTS!!!!!!!
Which Standards?

- EN 867-3:1997
- EN 867-4:2001
- ISO 15882:2003
- prEN ISO/FDIS 17665-1
- ISO/CD 17665-2
- ISO 11140 Parts 1-5

Just to name the most relevant few............
ISO 11140 Sterilisation of Health Care Products – Chemical indicators

- All of these documents are currently under review.....
  - ISO 11140 -3 2000 – Part 3 Class 2 indicators for steam penetration test sheets
  - ISO 11140 -4 2001 – Part 4 Class 2 indicators for steam penetration test packs
  - ISO 11140 -5 2000 – Part 5 Class 2 indicators for air removal test sheets and packs
ISO/DIS 11140-3

- Specifications only for test indicator sheets that are to be used in conjunction with a standard test pack as described in EN 285
  - (Equivalent to original BD pack)
- This Standard specifies the performance of the indicator, but not that of the test pack itself
ISO/DIS 11140-4
- Specifies the performance of the indicator system in combination with the test load with which it is intended to be used
  - May be single or multi-use with a new indicator each time of use
- Intended to indicate that steam penetration has been inadequate in the case of a number of different causes for fault cycles
- Does not include test methods to establish the suitability of the indicators for use in sterilisers that do not use a vacuum stage for air removal
ISO/DIS 11140-5

- Specifies the requirements for an indicator and alternative test system used to evaluate the effectiveness of air removal during the prevacuum phase of prevacuum steam sterilisation cycles or during the pulsing stage of positive pulsing cycles.
- Failure of the test could be due to retention of air, an air leak or non-condensable gases during the air removal stage.
# Summary of the differences

(ISO 15882)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test pack density</strong></td>
<td>0.42 kg/dm³</td>
<td>0.42 kg/dm³</td>
<td>0.20 kg/dm³</td>
</tr>
<tr>
<td><strong>Test pack size</strong></td>
<td>220 mm × 300 mm × 250 mm</td>
<td>220 mm × 300 mm × 250 mm</td>
<td>250 mm × 300 mm × 250 mm - 280 mm</td>
</tr>
<tr>
<td><strong>Criteria for pass condition</strong></td>
<td>Temp in pack not more than 0.5 °C lower than drain throughout plateau.</td>
<td>Temp in pack not more than 1 °C lower than set operating temperature measured in drain.</td>
<td>Temp in pack not more than 0.5 °C lower than drain throughout plateau.</td>
</tr>
<tr>
<td><strong>Criteria for fail condition</strong></td>
<td>Temperature in pack between 2 °C to 3 °C lower than drain temperature at the beginning of plateau.</td>
<td>Temperature in pack between 2 °C to 7 °C lower than the drain at the start of the holding stage and between 2 °C to 4 °C at the start of, and not more than 1 °C at the end of, the plateau stage.</td>
<td>2 °C difference between drain and centre of pack 1 min before end of 3.5 min 134 °C cycle</td>
</tr>
<tr>
<td><strong>Pack Size</strong></td>
<td>7kg pack</td>
<td>7kg pack</td>
<td>4kg pack</td>
</tr>
</tbody>
</table>
Fail condition per 11140-5 (inadequate air removal)

Fail conditions per 11140-4 (Range of Causes)

Fail condition per 11140-3 (Original Bowie & Dick result)
Which test is right for my steriliser?

- What air removal system does your steriliser have?
  - Subatmospheric
    - Pulses occur all below atmospheric conditions
  - Transatmospheric
    - Pulses occur above and below atmospheric conditions
  - Superatmospheric
    - Initial vacuum pulses followed by superatmospheric pulses

- Check both the steriliser and BD test manufacturer’s recommendations
What are you using the Bowie and Dick test to do?

- Check only for adequate air removal?
  - Select a test compliant with ISO 11140-5

- Check for both air removal and steam penetration?
  - Select a test sheet compliant with ISO11140-3

- Check for both air removal, steam penetration and possible failures due to other causes
  - Select a test compliant with ISO11140-4
What to look for in a test...

- Conformance to the applicable EN or ISO Standards
  - Independent certification of conformance in preference to self certification
  - Clear instructions on how to store, handle, use and interpret the test
  - Information on the reliability in maintaining end point change
What to look for in a test..

- The indicator sheet
  - Reagent must cover $\geq 30\%$ of the sheet with no more than 20mm gap between areas of reagent
  - The pattern must enable clear interpretation of the colour change
  - The edges must be able to be compared with the centre and be of A4 size (ISO 11140-3 only)
  - The dye must be non-toxic and non-transferable
  - The indicator itself or the pre-assembled pack must allow writing to be made on it
Clear colour change

Unprocessed

Processed (Pass)
Edges can be compared to the centre

Processed
(Examples of Failures)
Writing can be made on the pack or the test sheet.
How to perform the test

- Empty chamber except for chamber furniture and the test itself

- Locate the test in the geometric centre of the horizontal plane of the usable chamber space between 100-200mm from the chamber base (EN 285)
  - This may or may not be over the chamber drain
This is NOT how to use a BD type test!
How to perform the test

- The sterilising stage of the cycle must be no longer than 3 ½ minutes
  - Many sterilisers now incorporate a pre-set air removal and steam penetration test cycle
  - Drying times should not be extended
How to interpret the result

- Standard Procedure to be followed
- All staff trained to interpret the result according to manufacturer’s instructions
- Flat surface and clear overhead lighting
- Compare edges to centre
Record Keeping

- There is no specified guidance with respect to the length of time to keep a chemical indicator result, even a BD indicator.
  - ISO 15882 states that users may record the outcome or result of the indicator, or choose to retain it for varying periods of time according to local requirements.
In conclusion...

- “We hope that others will use it, perhaps in conjunction with more refined methods, to examine sterilisers...and in doing so,...they will collect much needed information about the current status of sterilisers...”

  – Bowie et al (1963)
References and Further Reading

References and Further Reading

- **EN 285** *Large steam sterilisers*
- **EN 867-5:2001** *Non-biological systems for use in sterilisers. Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small steam sterilisers Type B and Type S.*
References and Further Reading


References and Further Reading

- ISO 11140 -1 2005 *Sterilisation of Health Care Products – Chemical indicators – Part 1 General Requirements*
  - ISO 11140 -3 2000 – *Sterilisation of Health Care Products – Chemical indicators – Part 3 Class 2 indicators for steam penetration test sheets*

- ISO 11140 -4 2001 – *Sterilisation of Health Care Products – Chemical indicators – Part 4 Class 2 indicators for steam penetration test packs*

- ISO 11140 -5 2000 – *Sterilisation of Health Care Products – Chemical indicators – Part 5 Class 2 indicators for air removal test sheets and packs*
**References and Further Reading**

- **ISO 15882:2003 Sterilisation of Health Care Products – Chemical indicators – Guidance for selection, use and interpretation of results**
- **ISO 15882 (draft 2005) Sterilisation of health care products – Chemical indicators – Guidance for the selection, use and interpretation of results.**
References and Further Reading

- ISO/DIS 17665-1 *Sterilisation of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices*


- AS 1410 – 2003 *Sterilisers-Steam-Prevacuum*