New methods to monitor steam penetration into complex medical devices (MD) using Medical Device Simulators (MDS) and Batch Monitoring Systems (BMS)

International Annual Meeting and Scientific Workshop – Sterilization and Disinfection

Opatija, March 27, 2009

Agenda

1. Consequences of non-condensable gases (NCG) in steam sterilization processes
2. Limitations of traditional biological and chemical indicators
3. Type tests to prove sterilizer specifications
4. Traditional batch monitoring testing the sterilizer
5. Concept of MDS and BMS
6. Using MDS and BMS
Services: Design, Validation and Monitoring of dry heat, steam, ethylenoxide, formaldehyde and hydrogen peroxide sterilization processes

Production and distribution of: Sterilization monitoring and documentation materials
Biological and chemical indicators with process challenge device (PCD) systems
Documentation labels

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Steam consumption

Steam

Steam condensation

Load

textile / non-woven pack / container

about 350 – 400 l/10 kg load
Bowie-Dick Test Sheet for Steam-Sterilization

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam sterilization</td>
<td>4/23</td>
<td>10/2008</td>
</tr>
</tbody>
</table>

**Test Procedure:**

1. Place the test tube in a 3.5% NaCl solution.
2. Boil for 15 minutes.
3. Observe for any signs of leakage.

**Results:**

- Tube No. 1: No leakage
- Tube No. 2: No leakage
- Tube No. 3: No leakage

**Conclusion:** The test was successful, indicating that the steam sterilization process was effective.
Vergleich
original Bowie-Dick-Testpaket mit Testblatt
gegen
GKE-Steri-Record Teststreifen
im gleichen Sterilisationsprozeß

Sterilisator: MMM
Innenvolumen 1m³
Bowie-Dick-Testprogramm
3,5 Min., 134°C
mit 3-fachem Vorvakuum
Leck: Lufteluß 2 Sek. nach dem letzten Vorvakuumzyklus durch das Belüftungsventil

GKE-Steri-Record Teststreifen mit Messingprüfkörper und unterschiedlicher Schlauchlänge
Schlauchlänge
1,5 m 3 m 4,5 m
Temperature and time parameters to achieve overkill for the steam sterilization process according to EN 554

<table>
<thead>
<tr>
<th>Temperature [°C]</th>
<th>Sterilization time [min]*</th>
<th>Equilibration time [min]**</th>
<th>( F_{0 , 121°C} ) [min]</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>121</td>
<td>15</td>
<td>&lt;0,5</td>
<td>15</td>
<td>Those conditions are only valid in presence of steam but not in presence of dry heat.</td>
</tr>
<tr>
<td>134</td>
<td>3</td>
<td>&lt;0,5</td>
<td>ca. 60</td>
<td></td>
</tr>
</tbody>
</table>

Dry heat and superheated steam sterilization process (incl. non-polar solvents and oils)

<table>
<thead>
<tr>
<th>Temperature [°C]</th>
<th>Sterilization time [min]*</th>
<th>Equilibration time [min]</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>160</td>
<td>120</td>
<td>10 – 50</td>
<td>The temperature-come-up-time changes depending on the heat capacity of the goods and the insulation of the pack.</td>
</tr>
<tr>
<td>180</td>
<td>30</td>
<td>10 - 30</td>
<td></td>
</tr>
</tbody>
</table>

* Sterilization time after reaching the temperature of the goods on the surface and in hollows
** If complete air removal is achieved
Comparison of separations of non-condensable gases (NCG) in porous loads and hollow instruments

Steam
NCG
Condensate

200 - 300 ml critical
0,2 - 0,3 ml critical

Ratio of the critical NCG amounts:
porous : hollow ≈ 1.000 : 1
Potential risks during a fractionated vacuum steam sterilization process

1. Unsatisfactory air removal during the fractionated vacuum cycle (remaining air in the sterilization chamber)

2. Leakages on door seals, valves and other devices (air returns into the chamber after the last vacuum cycle)

3. Air transfer through the door seal, if the sealing is pneumatically actuated (if steam is used to pressurize, the sealing problem does not occur)

4. Non-condensable gases are introduced together with steam (malfunction which is usually undetected during the sterilization cycle) After sterilizer and eventually steam generator are switched off, non-condensable gases develop in the pipes between steam generator and sterilizer and in the steam generator, and get into the sterilizer after starting again.
## Non-condensable gases (NCG) in steam

<table>
<thead>
<tr>
<th>Type of gas</th>
<th>Origin</th>
<th>Effect</th>
<th>Elimination</th>
</tr>
</thead>
<tbody>
<tr>
<td>air</td>
<td>dissolved air in water (ca. 25 ml air per 1 l water)</td>
<td>The produced amount of air depends on the supply of injected water in the steam vessel. (air peaks after water injection)</td>
<td>Degasing of the injected water by heating up to 90°C – 105°C before injecting into the steam vessel</td>
</tr>
<tr>
<td>carbon dioxide CO₂</td>
<td>water containing hydrogen-carbonates</td>
<td>During the heating process, CO₂ and carbonate salt (white covering) are formed Ca(HCO₃)₂ → CaCO₃↓ + CO₂↑ + H₂O (NCG peaks depending on the amount of water injection)</td>
<td>Degasing or de-mineralization by Ion-exchange or possibly together with Reversed Osmosis (RO) RO alone is not sufficient !</td>
</tr>
<tr>
<td>hydrogen H₂</td>
<td>corrosion of metals</td>
<td>permanent small amounts of NCG and of flying rust in iron pipes (seldom)</td>
<td>Adjust pH-value &gt; 7 in buffer solutions Remove chloride and other chelate complexing agents from feeding water</td>
</tr>
<tr>
<td>Superheated steam</td>
<td>pressure reduction in steam pipes</td>
<td>The superheated steam is unable to condensate until it is reaching its condensation point.</td>
<td>Install cooling line after pressure reduction. Don’t dry porous goods with dry heat before the sterilization. Conditioning in normal humidity is required or moisten the goods before sterilization</td>
</tr>
</tbody>
</table>

Dissolved air in water:

- Air: 
  - Origin: ca. 80% N₂, 20% O₂
  - Effect: The produced amount of air depends on the supply of injected water in the steam vessel. (air peaks after water injection)
  - Elimination: Degasing of the injected water by heating up to 90°C – 105°C before injecting into the steam vessel

In steam boilers and steam pipes before start-up:

- Air: 
  - Origin: ca. 80% N₂, 20% O₂
  - Effect: When not in operation steam boilers and steam pipes fill up with air
  - Elimination: During start-up steam pipes need to be purged by a warm-up cycle to remove the air.

Water containing hydrogen-carbonates:

- CO₂: 
  - Water containing hydrogen-carbonates
  - Effect: During the heating process, CO₂ and carbonate salt (white covering) are formed Ca(HCO₃)₂ → CaCO₃↓ + CO₂↑ + H₂O (NCG peaks depending on the amount of water injection)
  - Elimination: Degasing or de-mineralization by Ion-exchange or possibly together with Reversed Osmosis (RO) RO alone is not sufficient !

Hydratization of porous goods (heat generation by taking up water):

- Effect: The superheated steam is unable to condensate until it is reaching its condensation point.
  - Elimination: Install cooling line after pressure reduction. Don’t dry porous goods with dry heat before the sterilization. Conditioning in normal humidity is required or moisten the goods before sterilization
Limitations of biological and chemical indicators at different positions in steam sterilization cycles

- Biological and chemical indicators can only test the kill ability of steam (temperature vs. time), test of non-condensable gases in the chamber is not possible.
- Inside of the pack indicators can test if there is steam penetration to the surface of the instrument.
- The indicator can check the surface of a hollow device but cannot check steam penetration inside of the instrument.
- Process indicator, provides only logistic information, that the pack has passed the process, no sterility monitoring.
Analysis of non-condensable gases (NCG) in steam pipes

% NCG

Time

Injection of feeding water

11/23  gke-GmbH  Dr. U. Kaiser  10/2008
Influence of time if non-condensable gases (NCG) entering the steam sterilization process cause a risk

NCG are taken out with following vacuum cycles and are not critical for sterilization performance.

NCG being introduced during the warm-up-phase travel almost quantitatively into the packs of the loads and may harm the efficacy of sterilization processes depending on the type of load and the amount of NCG.

NCG enter the chamber during the sterilization plateau period and are also not critical for the sterilization efficacy since the packs do not absorb steam anymore and therefore also no NCG.
Different types of the Bowie-Dick-Test
Comparison Europe - USA

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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Standard for test</td>
</tr>
</tbody>
</table>
| Europe  | EN 285, part 17   | 25 x 35 x 20 | 7 kg ± 2%   | EN 867-4 = EN-ISO 11140-4 | Steam penetration test         | - Air removal
- Leaks
- Non-condensable gases |
|         |                   |           |             |                                | ISO 11140-5 | Air removal test | - Air removal |
| USA     | AAMI              | ca. 24 x 35 x 29 | 4 kg ± 200g (± 5%) | 132°C, 3 min | ISO 11140-5 | Air removal test | - Air removal |

The American test package has approximately 1/2 of the weight of the European test package and is therefore less sensitive in testing the air removal and steam penetration.
Helix-PCD® according to EN 867-5 Hollow A for validation and batch monitoring
Air removal – steam penetration of:

- Sterilizer capability
- Type Test
- Load configuration necessity
- Batch Monitoring System (BMS)

Increased air removal – steam penetration

EU Sterilizer, EN 285
EU BD-Test pack, 7 kg (Type test)
USA Sterilizer
AAMI-BD-Test pack, 4 kg (Type test)
Solid Load
Porous Load
Hollow Load
Batch Monitoring System (BMS) for Load 1
Solid Load
Porous Load
Hollow Load
Batch Monitoring System (BMS) for Load 2

Load Configuration 1
Hollow load test

Load Configuration 2
Commissioning + Performance Qualification = Validation of a process.

After validation the process is secured using a type test for routine monitoring to check the sterilizer.

Routine monitoring with a batch monitoring system (BMS) that is validated against a defined load, without a performance test of the sterilizer.
# Process Challenge Devices (PCDs) for different applications

<table>
<thead>
<tr>
<th>Reference</th>
<th>is simulated by</th>
<th>Process Challenge Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device</td>
<td>Medical Device</td>
<td>Medical Device Simulator</td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="MD" alt="Medical Device Simulator" /></td>
</tr>
<tr>
<td>Batch</td>
<td>Defined Load Configuration</td>
<td><img src="BMS" alt="Batch Monitoring System" /></td>
</tr>
<tr>
<td></td>
<td>MD</td>
<td><img src="MD" alt="MD" /></td>
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<tr>
<td></td>
<td>MD</td>
<td><img src="MD" alt="MD" /></td>
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</tbody>
</table>

**Defined Load Configuration**

**Batch Monitoring System**
Test method to check if a Medical Device Simulator (MDS) or Batch Monitoring System (BMS) is equivalent to a Medical Device (MD) or load.

- **Process**
  - **MDS or BMS**
    - no growth
      - sterile = "Pass"
        - **Downgrade process**
      - growth
        - unsterile = "Fail"
        - **Reference instrument (MD) or load**
          - growth
            - unsterile = "Fail"
          - no growth
            - sterile = "Pass"
            - MDS acceptable
    - growth
      - unsterile = "Fail"
      - **Upgrade process**
Class 2 indicators for type tests, MDS\(^1\) and BMS\(^2\)

MDS or BMS test-system are used to monitor sterility of a medical instrument or load in sterilization processes:

\[
\text{Process} \quad \text{Challenge} + \text{Indicator system} = \text{Indicator Device}
\]

An indicator is an object in its final form in which it is intended to be used.
(Definition in EN-ISO 11140-1 for class 2 indicators)

\(^1\) MDS = Medical Device Simulator
\(^2\) BMS = Batch Monitoring System
Use of a batch monitoring system (BMS)

The process challenge device (PCD) is designed to simulate a full load (BMS) and can monitor penetration into hollow devices as long as it is more difficult to penetrate than instruments in packs.

Process indicator, provides only logistic information, that the pack has passed the process, no sterility monitoring.
Historical monitoring concept:

Checking steam penetration specifications of a sterilizer with a type test
- large sterilizers EN 285 with the 7 kg BD-Test pack
- small sterilizers EN 13060 type B with helix test (EN 867-5)

Assumption:
If the sterilizer works according to the specifications, all goods come out sterile.

This concept is wrong:
Depending on the penetration requirements of the load the steam penetration may be sufficient, correct or not sufficient.

Suggested monitoring concept:

Defining the steam penetration requirements of a load by designing a batch monitoring system (BMS) checking the steam penetration requirements of the load

If the BMS is validated according to the load, the necessary steam penetration is checked, independent from the specification of the sterilizer.

The sterilizer does not require defined standard specifications but must work reproducible and must pass the BMS.

Depending on the requirements of the load configuration alternatively inexpensive sterilizers like type N or S or sterilizers or sterilizers according EN 285 may be used or sterilizers with higher penetration characteristics may be required.