WORLD CONGRESS OF STERILIZATION
COMBINED MEETING
WFHSS / AIOS

Small Steam Sterilizers
BS EN 1360:2004
L Kingston. Registered Authorised Person {Sterilizers}
Member of :-

- **BSI - CH198** – Sterilization
- **CEN - TC 102 wg 2/3** – Steam Sterilizers
- **ISO - TC 198 wg 3** – Moist Heat Sterilization.
- **EPL/66 Safety of Measuring, Control and Laboratory Equipment.**
- **BSI LBI 35- 1**
SCOPE OF THE PRESENTATION FOR THE CHANGES WITHIN BS EN 1360

➢ To provide a brief introduction to the update requirements and changes.

➢ To introduce the current standard focusing on what is the requirement of small steam sterilizer:

➢ Definition Small steam sterilizer:-Size one which is unable to accommodate sterilization module and has a chamber volume less than 60 litres

Note One Sterilization module =300mmx 300mm x600mm
SCOPE OF THE PRESENTATION
FOR THE CHANGES WITHIN BS EN 1360

- Sterilization cycle type:- classification of the process based on performance

- Solid:- product not made from porous materials no recesses which present a greater or equal challenge than a hollow load (B)

- Hollow load A :- single ended open space ratio of length to diameter of cavity greater than 1 less or equal 750 (1 ≤ L/D ≤ 750) or (L ≤ 1 500mm) or (2 ≤ L/D ≤ 1 500) (L ≤ 3000mm) which is not a hollow load (B)
REVIEW OF THE CHANGES WITHIN BS EN 1360

- **Hollow load B**: single ended open space ratio of length to diameter of cavity greater than 1 less or equal to 5 \((1 \leq L/D \leq 5)\) Where diameter greater than or equal to 5mm \((D \geq 5\text{mm})\) or double ended where ratio length / diameter greater than equal to 2 less than 10 \((2 \leq L/D \leq 10)\) or \((D \geq 5\text{mm})\)

- **Temperature measurement reference position**: identified by manufacture condition in useable space of chamber
BS EN 1360– Structure

SMALL STEAM STERILIZER
TYPE REQUIREMENTS

Type
All wrapped or non wrapped products

Type
All non wrapped Solid products

Type
All wrapped or non wrapped products

Type
All non wrapped Solid products

Type
All wrapped or non wrapped products
BS EN 1360– Structure

SMALL STEAM STERILIZER
TYPES WITHIN S LOADS IN TYPE TESTS

**S1**
Type
All wrapped or non wrapped products

- Type S1
  - Hollow Load A&B
  - Dryness Solid Load

**S2**
Type
All non wrapped Solid products

- Type S2
  - Dryness, Porous Load & Solid products

**S3**
Type
All wrapped or non wrapped products

- Type S3
  - Specific Medical Devices
Operational Services
Points to be aware of:

- **Water Supply Steam Generation.**
- Designed to function with water free of contaminants
- Cause no harm to sterilizer or the sterilizer load
Operational Services
Points to be aware of:

- **Water Used other than for Steam Generation.**
  - Potable quality
  - Range specified manufacturer, including 15°C
  - Cooling Purposes
  - Vacuum systems
  - Total hardness value $0.7\text{mmol/l} \leq 2.0\text{mmol/l}$
Operational Services

Points to be aware of:

- Water reservoir if fitted
- Pipe work shall be fitted with valve or other device automatic to allow draining by operator reservoir and pipework
- Manufacturers design shall facilitate cleaning filling and inspection
- Indicate sufficient water for operating cycle or shall not be capable of starting cycle
- Designed to prevent back siphoning to chamber
### BS EN 1360 PROCESS PERFORMANCE DATA

**Values Type testing**

<table>
<thead>
<tr>
<th>1 of 2 Sheets Type Tests</th>
<th>Sterilization Process Cycle Types</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td><strong>Dynamic chamber pressure</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Air leakage</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Empty chamber</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Solid load</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Small Porous items</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Small porous loads</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Full porous load</strong></td>
<td>YES</td>
</tr>
</tbody>
</table>
**BS EN 1360 PROCESS PERFORMANCE DATA**

**Values Type testing**

<table>
<thead>
<tr>
<th>2 of 2 Sheets Type Tests</th>
<th>Sterilization Process Cycle Types</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td><strong>Hollow load B</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Hollow load A</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Multiple wrapping</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Dryness solid load</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Dryness porous load</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Residual air</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Specific medical devices</strong></td>
<td></td>
</tr>
</tbody>
</table>

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### BS EN 1360 PROCESS DATA

**limiting values to be recorded**

<table>
<thead>
<tr>
<th>Start</th>
<th>Time for vacuum pulse</th>
<th>Time for pressure pulse</th>
<th>Sterilization start time</th>
<th>Holding time</th>
<th>Sterilization end time</th>
<th>Drying start time</th>
<th>Drying end time</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

- **Pressure Scale**: 0kPa to 400kPa
- **Temperature Range**: 50°C to 150°C

- **Sample each channel**
- **At least every 2.5sec**
- **Accuracy**
  - Better than ±5kPa
- **Accuracy**
  - Better than ±1%

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**Sterilizers which have no vacuum phase**

Pressure Scale 100kPa to 400kPa
BS 1360 Sterilizers Process Evaluation System

If fitted
1. Compare with validated cycle any change pressure or temperature time period that change occurs
2. Change beyond programme limits

Shall cause an indicate Fault
If fitted

1. Compare two independent temperature sensors sterilizer temperature instrument chamber and recorder; or

1. Capable comparing theoretical steam temperature with chamber during the holding period

Shall cause an indicate

Fault
BS 1360 Sterilizers Process System

Time – Temperature relationships:- STERILIZATION

<table>
<thead>
<tr>
<th>Sterilization Temperature °C</th>
<th>Minimum Holding Time Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>121°C</td>
<td>15 Min</td>
</tr>
<tr>
<td>126°C</td>
<td>10 Min</td>
</tr>
<tr>
<td>134°C</td>
<td>3 Min</td>
</tr>
<tr>
<td>143°C</td>
<td>1 Min</td>
</tr>
</tbody>
</table>
**BS 1360 Sterilizers Process System**

**Time – Temperature relationships:- Equilibration**

<table>
<thead>
<tr>
<th>Temperature °C</th>
<th>Equilibration Time Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>121° 126° 134° 143°</td>
<td>15 seconds</td>
</tr>
<tr>
<td>&gt;1K/min &lt; 8K/min</td>
<td>Not exceeding 30 seconds is acceptable</td>
</tr>
</tbody>
</table>

*If ?*
BS 1360 Sterilizers Process System

**Time – Temperature relationships:- Equilibration**

<table>
<thead>
<tr>
<th>Temperature °C</th>
<th>Equilibration Time Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>121° 126° 134° 143°</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Theoretical steam Temperature 10K heating stage Less than 8K/min But greater than 1K/min</td>
<td>During last 10K of heating stage chamber and load do not differ by more than 2K</td>
</tr>
</tbody>
</table>
BS 1360 Sterilizers Process Cycle

DATA AND LIMITING VALUES TO BE RECORDED

START TIME

HIGHEST & LOWEST VALUES PRESSURE TEMPERATURE

AMBIENT PRESSURE

TOP OF PULSE TIME

HOLDING TIME

START DRYING

END TIME

134°C

TIME SECONDS

-1BAR

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TYPE B cycle

- Fractionated vacuum
- Plateau
- Drying

ECO-B

- 20 min
- 15 min

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BS 1360 Sterilizers Testing System

Air Leakage Test

Requirement: Shall not cause rate pressure rise to exceed 0.13kPa/min{1.3mbar/min} when tested.

\[ \frac{\Delta p}{\Delta t} = \frac{p_3 - p_2}{10} \]

Ambient atmospheric pressure

Time in seconds

0 300sec 600sec 21
# BS 13060 STERILIZER Leak Test Reports

## W&H Sterilization Lisa 517 08-0066 00.12.02.00.12

**Horsham WSCPDS**

### Cycle: VACUUM TEST

### Number: 00196

<table>
<thead>
<tr>
<th>Date</th>
<th>03/04/08 14:50:13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Time</td>
</tr>
<tr>
<td>Start</td>
<td>00:00</td>
</tr>
<tr>
<td>P1</td>
<td>02:02</td>
</tr>
<tr>
<td>P2</td>
<td>07:02</td>
</tr>
</tbody>
</table>

### A390 VACUUM TEST P3

<table>
<thead>
<tr>
<th>Number: 00196</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: 03/04/08 15:06:30</td>
</tr>
</tbody>
</table>

- **P Chamber**: -0.842 bar
- **T Chamber int.**: 45.16 °C
- **T Chamber ext.**: 58.58 °C
- **T Steam gen.**: 48.56 °C

| Date: 03/04/08 15:07:42 |

**Test failed**

**Trk.**: C2138C200196

## Failure

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## W&H Sterilization Lisa 517 08-0066 00.12.02.00.12

**Horsham WSCPDS**

### Cycle: VACUUM TEST

### Number: 00197

<table>
<thead>
<tr>
<th>Date</th>
<th>03/04/08 15:11:22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Time</td>
</tr>
<tr>
<td>Start</td>
<td>00:00</td>
</tr>
<tr>
<td>P1</td>
<td>01:58</td>
</tr>
<tr>
<td>P2</td>
<td>06:58</td>
</tr>
<tr>
<td>P3</td>
<td>16:58</td>
</tr>
<tr>
<td>END</td>
<td>18:15</td>
</tr>
</tbody>
</table>

| Date: 03/04/08 15:29:37 |

**Test passed**

**Trk.**: C2138C200197

## Success

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**PASS**

---

**FAIL**
### ATTAINMENT STERILIZATION CONDITIONS

<table>
<thead>
<tr>
<th>Requirement:</th>
<th>All temperatures measured in useable space and load</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>are not lower than the sterilizer selected temperature</td>
</tr>
<tr>
<td></td>
<td>Are not more than 4K above sterilization temperature selected</td>
</tr>
<tr>
<td></td>
<td>Do not differ from each other by more than 2K</td>
</tr>
</tbody>
</table>
BS 1360 Sterilizers Performance

TYPE TEST PROCEDURE

Test equipment requirements

- One external pressure sensor
- Sensors connect to chamber
- Type tests shall be repeated Twice (three tests in all)
- Thermometric measurement
  - Eight sensors shall be used
BS 1360 Sterilizers Testing
Process Cycle

Process Challenge Device & Chemical Indicator system for Hollow Load A

**Key**
1 Capsule
2 Sealing
3 Indicator system
4 Connector
5 Open end
6 Tube
BS 1360 Sterilizers Steam Testing

- Steam pressure kPa (bar) Bore mm ± 0.02
  - up to 400 (3) 0.8
  - up to 500 (4) 0.6
  - up to 800 (7) 0.4

Bulkhead fitting

Dimensions in millimetres
Exact position of the capillary tube inlet to sample from the sterilizer chamber has been found to vary in position for collection of sample.

For measurement of non-condensable gases
BS 1360 Sterilizers Steam Testing

Steam Service supply main steam

- **Steam pressure kPa (bar) Bore mm ± 0,02 up to 400 (3) 0,8 up to 500 (4) 0,6 up to 800 (7) 0,4**
BS 1360 Sterilizers Steam Testing

Steam Service supply main steam

- Apparatus
- for sampling
- Steam
- Condensate
- for chemical analysis
**BS 1360 Sterilizers**

**Definition hollow space A**

**Not hollow**

*Objects which are not hollow*
*Within standard cavity to diameter less than 1*

**Hollow A objects**
*Cavity with length to diameter greater than 1 and greater than 5 for all objects*
BS 1360 Sterilizers
Definition hollow space $B$

Hollow $B$ objects

Ratio of the length of cavity to diameter greater than 1 and less than than 5 for both objects

Example 8mm x 15mm
BS EN 1360 Porous load

WORKS / INSTALLATION TEST

Small load textiles  cotton sheets
450mm x 300mm

Reduced test pack

Small porous load test single wrapped

Thermal Sensors x positions

Volume of more than 54 litres
Diameter of at least 35 cm
BS EN 1360 Porous load

TYPE TEST

Small load textiles cotton sheets
450mm x 300mm

Small porous load test
single wrapped

Reduced test pack

Volume of more than 54 litres
Diameter of at least 35 cm

Thermal Sensors x positions

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SMALL STERILIZERS

Moist Heat Sterilization

The future may be a combined standard applicable to all moist heat sterilizers

- EN 13060
- EN 285
- In accordance with the Vienna agreement
The Vienna Agreement

- An agreement made between CEN and ISO to ensure harmonisation of standards published by the two organisations.
Thank you

Question

JUNE 2008

Time