Chemical indicators and test devices
Benchmarking sterilisation processes
Regulatory landscape

- National Law
- Directive / Regulation
- Guidelines
- Standards
Directive
Regulation

Law

Guideline

Standard
Relevant standards

1. Classification of chemical indicators
   - DIN EN ISO 11140-1
   - DIN EN ISO 11140-3
   - DIN EN ISO 11140-4
   - DIN EN ISO 11140-5
   - EN ISO 867-5

2. Guideline for selection, application und interpretation
   - DIN EN ISO 15882

3. Test equipment
   - DIN EN ISO 18472
     (formerly 11140-2)
Air removal and steam penetration

ISO 11140-1 Type 2
- ISO 11140-4: Bowie-Dick-Test
- EN 867-5: Batch Monitoring

Pressure

Steam exposure (temperature and time)

ISO 11140-1 Type 1 to Type 6 (except Type 2)

Drying
Use of chemical indicators

- As **indicator strips** to make distinction between processed and non-processed items, and as „internal“ indicators inside of packages.
- As indicators to be used inside of **test devices** for the monitoring of steam penetration.
Indicator strips

- easy-to-handle (e.g. 3cm x 8cm)
- blank space for e.g. date and signature

in sterilisation wraps  in pouches  in containers
Indicator strips

- exposure time
- saturated steam
- temperature

Indicator types (formerly classes) according to ISO 11140-1:2014

- type 4: 25%
- type 5: 15%
- type 6: 6%
## Indicator strips

<table>
<thead>
<tr>
<th>Type 5 indicators</th>
<th>Type 6 indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>High precision</td>
<td>Highest precision</td>
</tr>
<tr>
<td>Stated values resulting from the behavior of biological indicators at 121°C and 134°C (steam).</td>
<td>Manufacturer prescribes any applicable stated values. The use of indicators is restricted to the use according to stated values of the manufacturer.</td>
</tr>
</tbody>
</table>

Use of type 5 may have some advantage if one indicator is used in various cycles. However, using specific type 6 indicators will bring highest accuracy.
Indicator strips

Reference colour

3.5 min 5.3 min
Indicator strips: test equipment

Front side

Rear side
Indicator strips: test equipment

Water supply according to the requirements of EN 285

Steam quality according to requirements of 1140-4: appendix J
Bowie-Dick-Test and Batch Monitoring System

- Porous load
- Helix
- Bowie-Dick
- Batch monitoring
Test device: Bowie-Dick-Test

- identical serial number on the test device as well as on the box filled with indicator strips
- intended use within 250 sterilisation cycles
- no maintenance of seals e.g.
- best possible safety over the full life-cycle
Assessment of Bowie-Dick-Tests

Sub atmospheric cycles
Pass-cycle
Fail-cycle modified air removal
Fail-cycle air injection
Fail-cycle leakage

Trans atmospheric cycles
Pass-cycle
Fail cycle modified air removal

Super atmospheric cycles
Pass-cycle
Fail-cycle air injection

Tolerance window of product
Test device: Batch Monitoring System

• independent standard within DIN EN ISO 11140 series is not yet existing

• therefore, standard EN 867-5 is still the reference, defining a helix test device to be used for type testing of sterilisers

• test steriliser is used for testing

• reproducibility is the product´s key feature
Test devices: spezification of batch monitoring

- **Maximum capability of process**
  - Device according to state of the art
  - Optimum conditions

- **Regular capability of process**
  (with respect to usual deviations from optimum)

- **Required capability of process**
  depending on specific load
Test device: test equipment

- thermocouples
- cotton towel pack (7 kg)
Test devices: test steriliser

Test steriliser according to DIN EN ISO 11140-4: appendix J

Steam for test purpose according to DIN EN ISO 11140-4: appendix J
Test devices: test equipment

- Equipment for simulation of leakage
- Equipment for air injection
- High precision valves to hit pressure set-points accurately
Summary

Indicator Strips:
- ISO 11140-1
- Monitoring of parameters in sterilisation phase
- Classification according to precision (type 4, type 5, type 6)
- Development and quality assurance with a BIER-vessel

Test devices
- ISO 11140-4 (Bowie-Dick-Test) and EN 867-5 (batch monitoring)
- Indicators type 2 according to 11140-1
- Monitoring of air removal and steam penetration
- Development and quality assurance with a test steriliser
Thank you for your attention!

What can we do for you?

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