



steriCLIN[®]

Chemical indicators and test devices

Benchmarking sterilisation processes

Regulatory landscape

National Law

Directive / Regulation

Guidelines

Standards



Directive
Regulation



Law



Guideline



Standard



ROBERT KOCH INSTITUT



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)



DIN EN ISO
11140-1

DIN EN ISO
11140-3

DIN EN ISO
11140-4

DIN EN ISO
11140-5

EN ISO
867-5

type 1

type 2

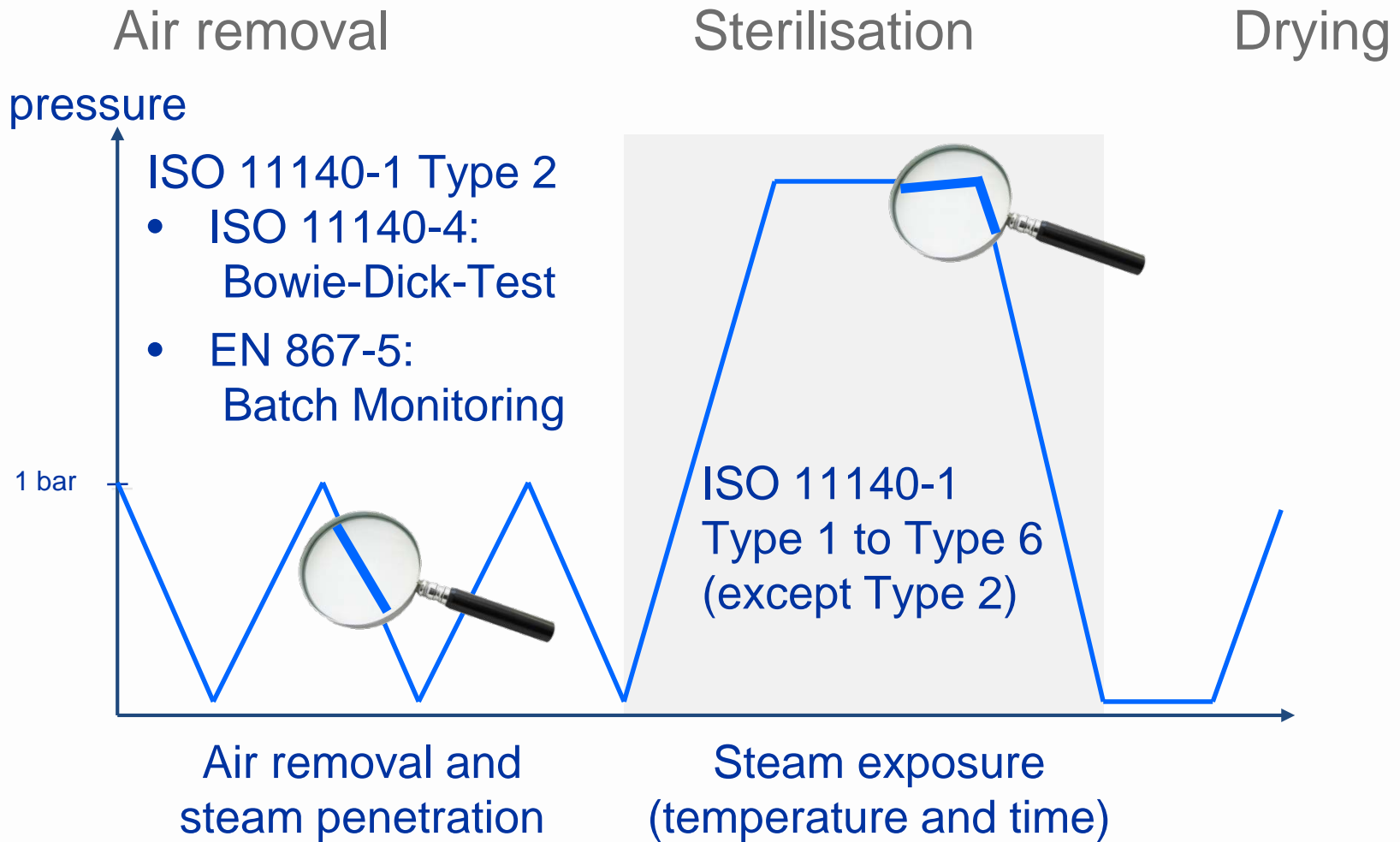
type 3

type 4

type 5

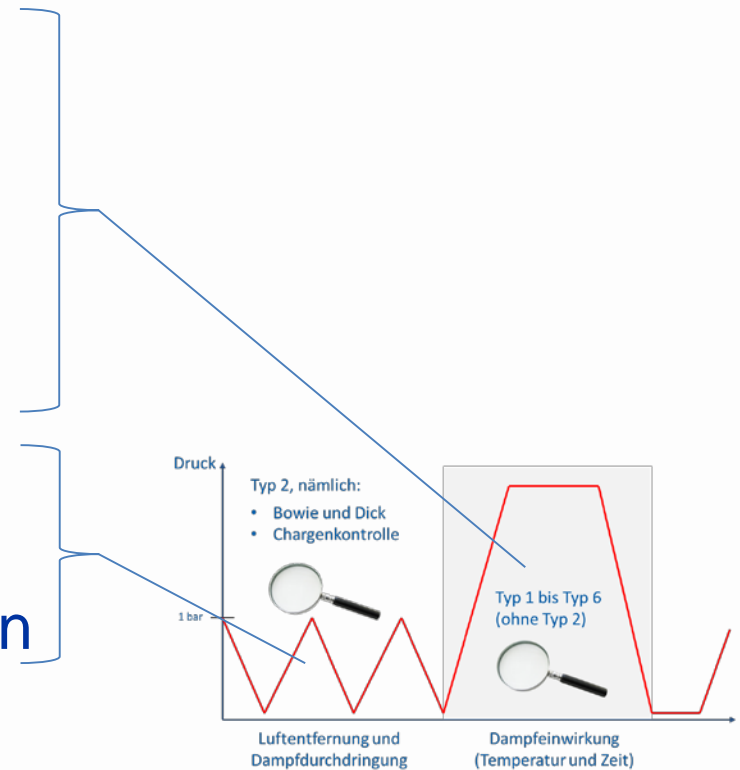
type 6



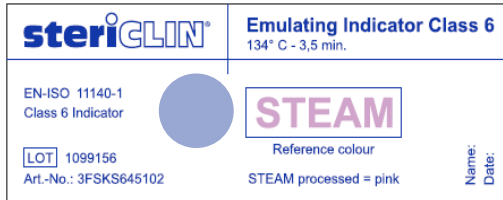


Use of chemical indicators

- 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



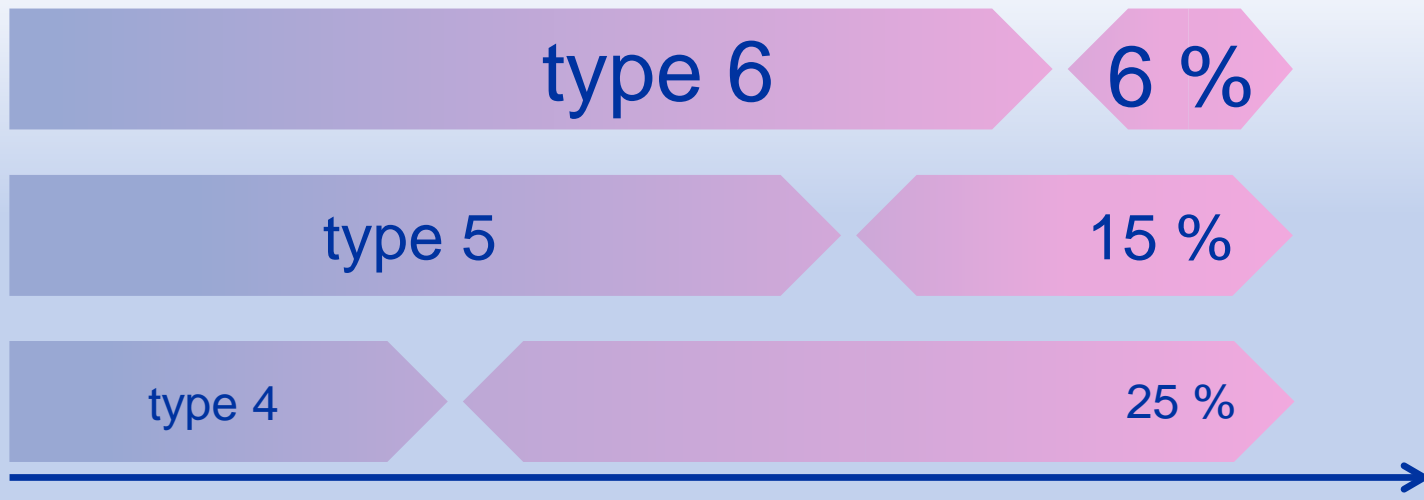
in pouches



in containers

Indicator strips

- exposure time
- saturated steam
- temperature



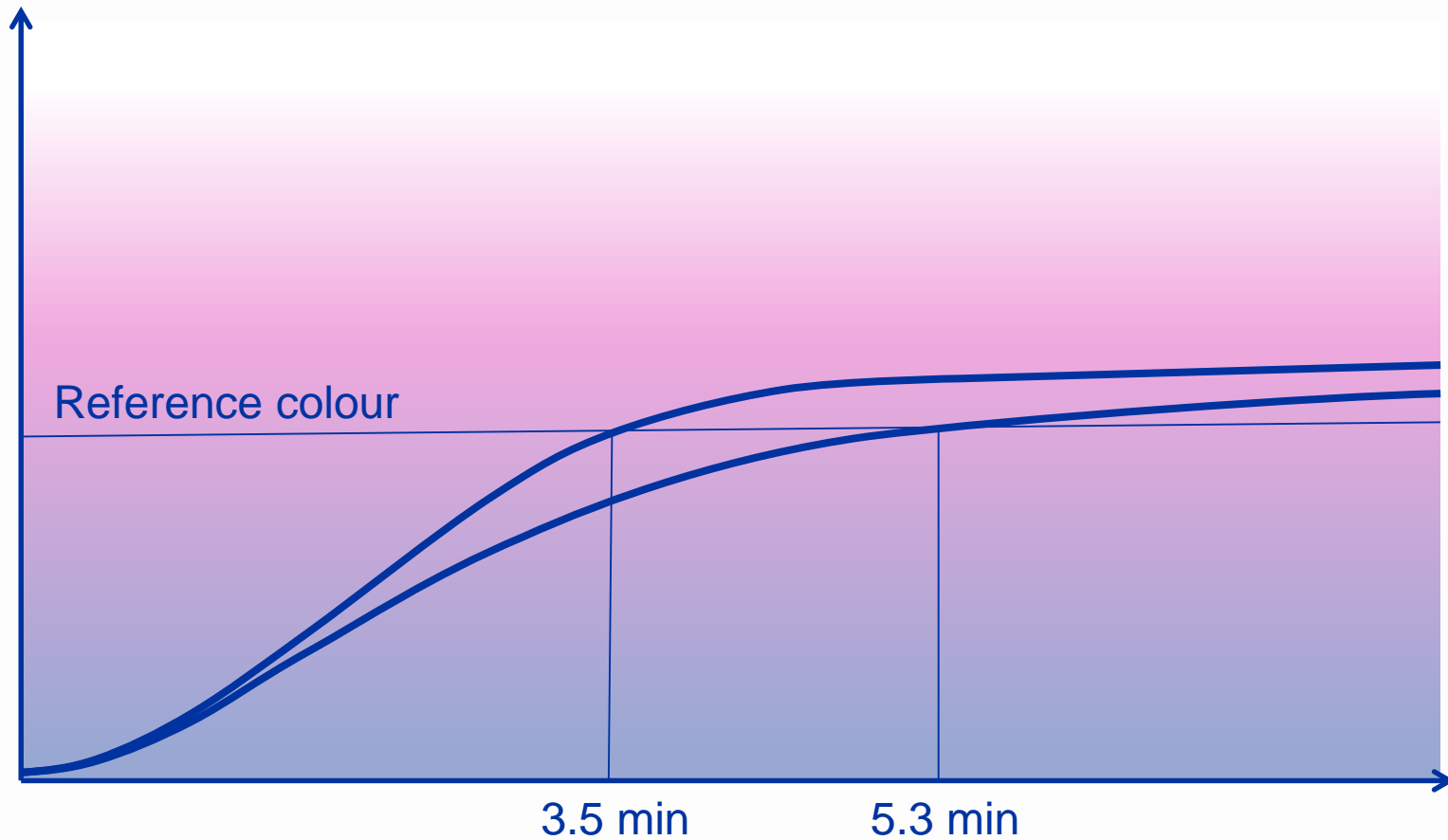
Indicator types (formerly classes) according to ISO 11140-1:2014

Indicator strips

Type 5 indicators	Type 6 indicators
<p data-bbox="137 582 546 644">High precision</p> <p data-bbox="137 719 803 961">Stated values resulting from the behavior of biological indicators at 121°C and 134°C (steam).</p>	<p data-bbox="1029 582 1522 644">Highest precision</p> <p data-bbox="1029 719 1818 1018">Manufacturer prescribes any applicable stated values. The use of indicators is restricted to the use according to stated values of the manufacturer.</p>

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



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



SN 00003

- 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

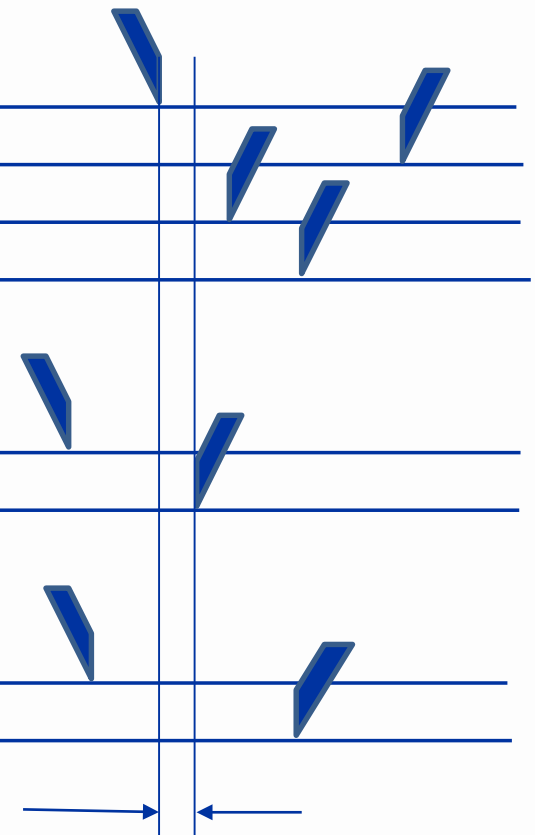
Pass-cycle

Fail cycle modified air removal

Super atmospheric cycles

Pass-cycle

Fail-cycle air injection



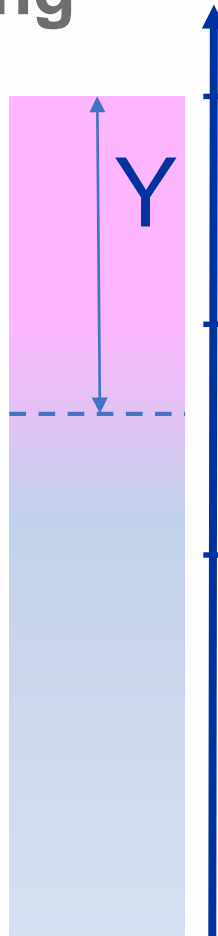
Tolerance window of product

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: specification of batch monitoring



Maximum capability of process

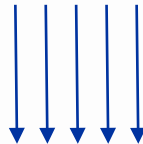
- Device according to state of the art
- Optimum conditions

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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