Daily and Periodic Tests for Washer-Disinfectors and Sterilizers: Regulations, Technical and Operational Characteristics, and Updates on Electronic Bowie Dick Tests

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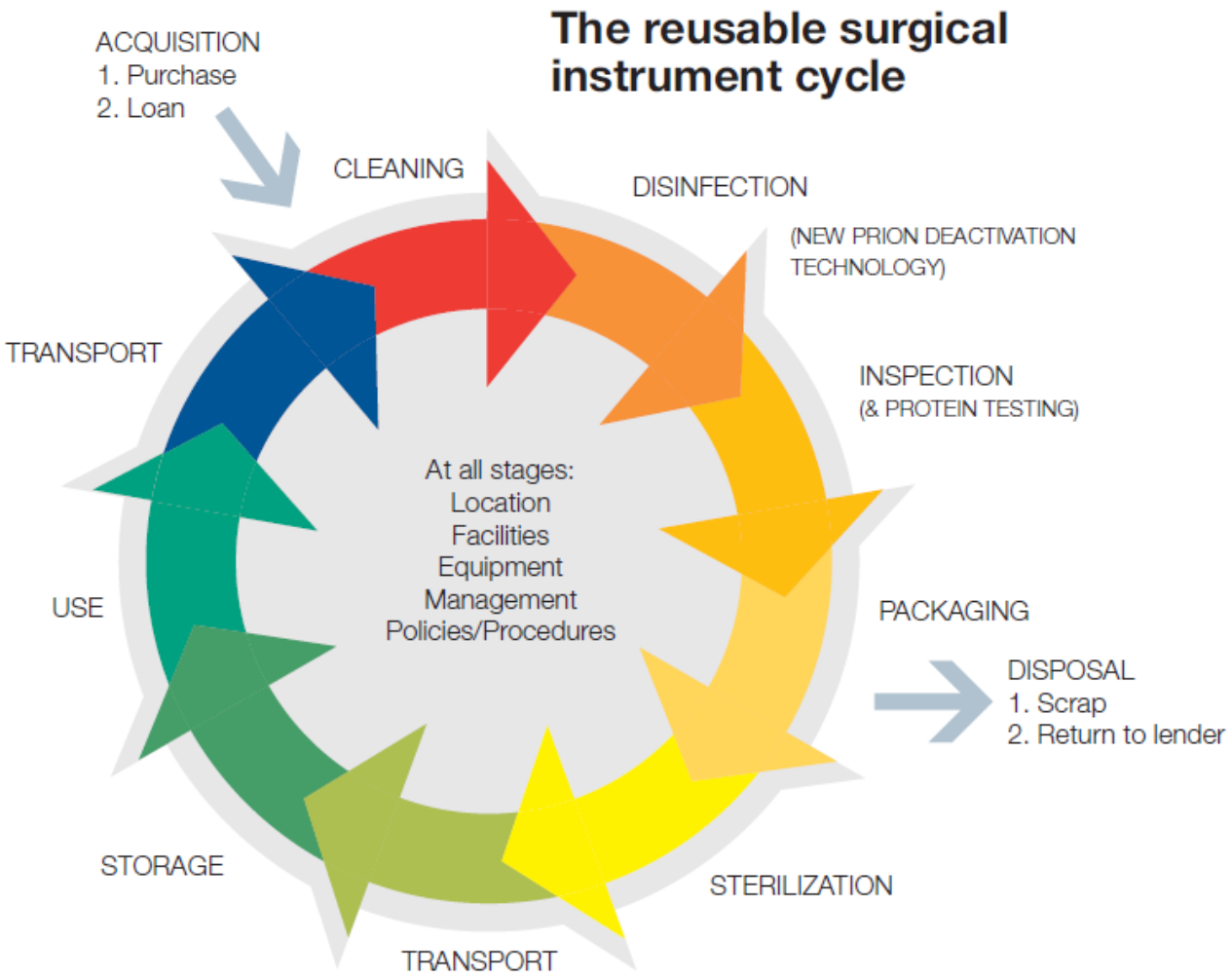
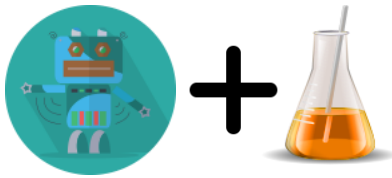
The Reusable Surgical Instrument Cycle

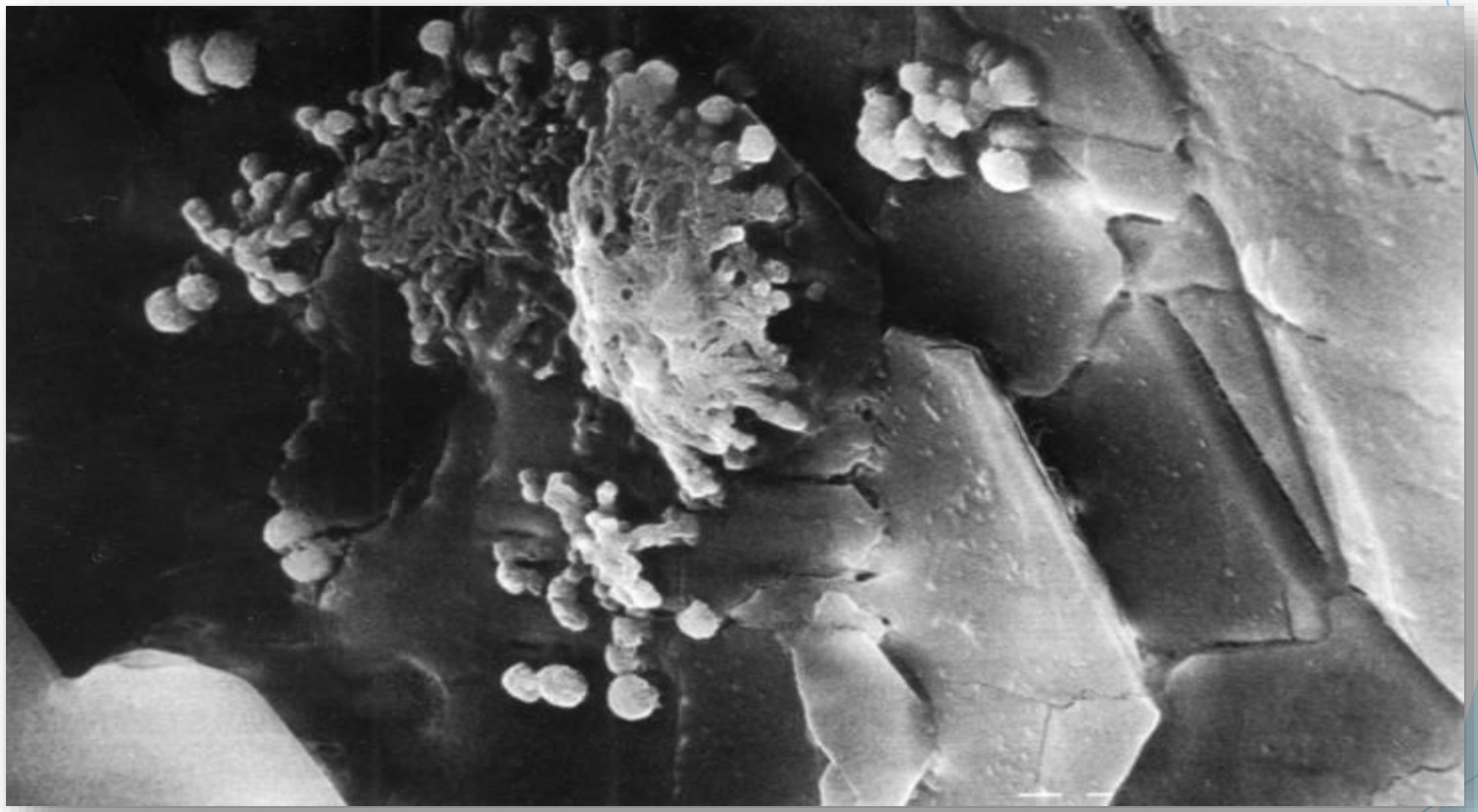


Cleaning & Washing

- Cleaning can be described as the process of removing undesirable soiling from a device to the extent necessary for its further processing and its intended subsequent use
- This may be achieved by
  - mechanical means
  - chemical means
- or preferably a combination of both

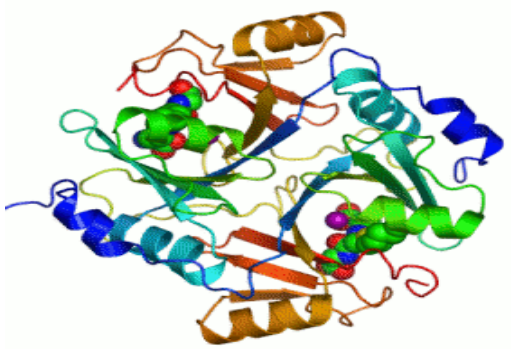


Soiling



Proteins

- Proteins are used as a primary measure of cleaning for two reasons:
- Difficulty in removing
- TSEs
  - Transmissible spongiform encephalopathies
    - CJD
    - BSE
    - Scrapie
    - GSS (Gerstmann-Straussler-Scheinker Disease)
    - Kuru



UK and vCJD

- In the UK (since 2016) 178 deaths from vCJD
- Peak year was 2000
  - Numbers fallen progressively; no cases in 2014-2015, 1 case in 2016
- Small number of vCJD cases may have been transmitted by blood transfusion
- No known cases of vCJD being transmitted by surgical instruments or endoscopes
- Sporadic/familial CJD has been transmitted by instruments used in brain surgery

UK Advisory Committee on Dangerous Pathogens (ACDP)

- The ACDP TSE – 5µg or less of protein in situ on the side of any instrument tested; lower level for high risk tissues

How Do We Validate Cleaning?

- Variables of cleaning processes
  - time
  - temperature
  - chemical action
  - mechanical action
- But we can’t validate each variable independently

Use of Test Soils

- Used as a periodic validation test
- The only way to determine cleaning efficacy
- How do we demonstrate consistency (reproducibility) of test soils
  - individual soil variation?
  - application rate?
  - instrument load?

Should we monitor every cycle?

- UK HTM 01-01 specifies use of a daily process challenge device (PCD)
- This device is also used in each load

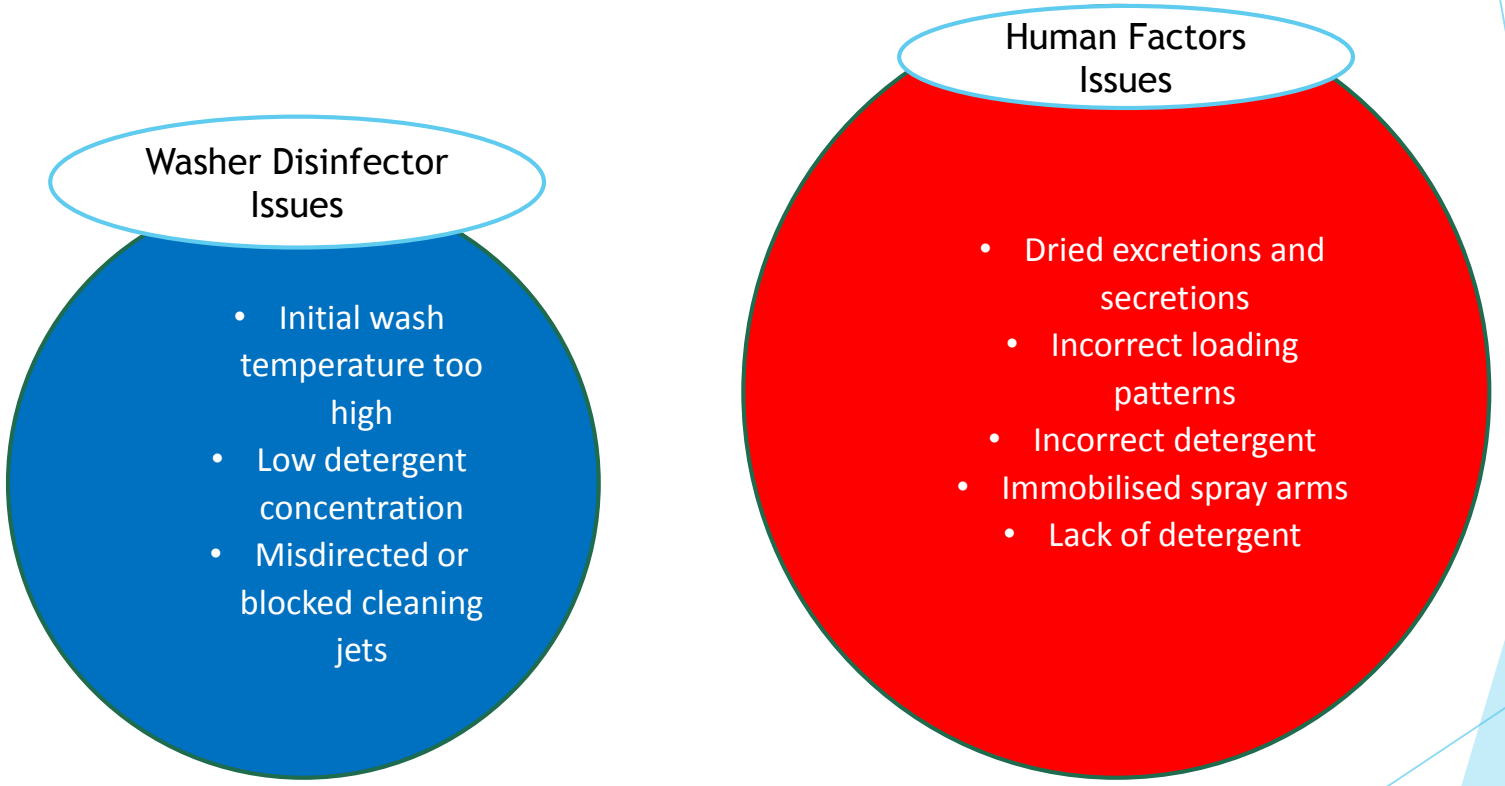
being monitored and actions are being taken based on these results. SSDs should include:

- daily testing using process challenge devices* (along with the standard periodic tests);
- quarterly residual protein testing (see paragraphs 2.271–2.277 in HTM 01-01 Part D –'Validation and verification'). See also Appendix B in this document for example sampling rates.

Understanding the Process -The Washer-Disinfector

- Process works by a combination of mechanical and chemical action
  - Both are critical to successful cleaning
- Temperature is an important factor
  - High temperatures improve removal of lipids and carbohydrates, and improve chemical action of detergents
  - High temperatures also denature proteins

Possible Causes of Cleaning Failure



‘Artificial’ Test Soils

- Advantages
  - No blood products
  - Porcine-free
  - Easy to mix
  - Easy to use (brush)
  - Non toxic
  - Easy storage
  - Performs as Edinburgh soil
  - Consistent formulation / performance

- Disadvantages
  - Time consuming
  - Not used on every load

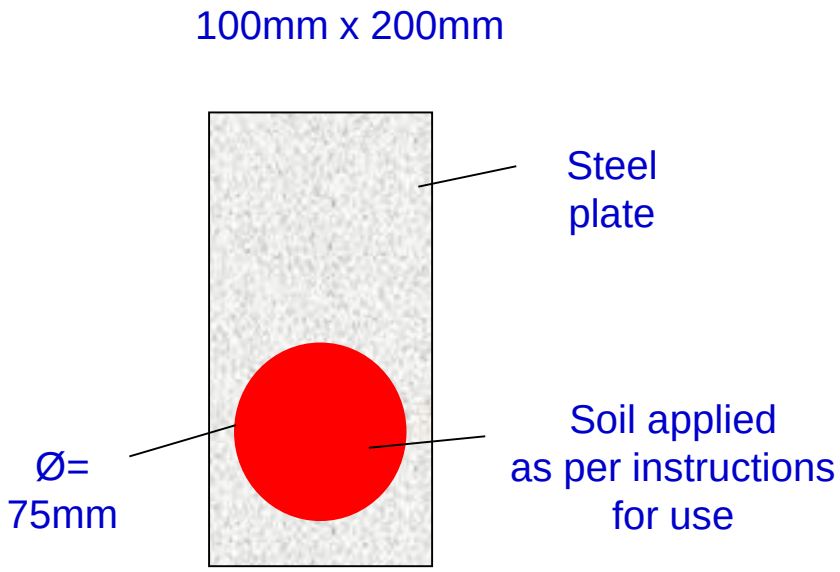
ISO/TS 15883 - 5

- ISO standard for washer disinfectors
- Part 5 published in 2005 as TS
- Contains formulations for test soils designed to be used for cleaning efficacy validation

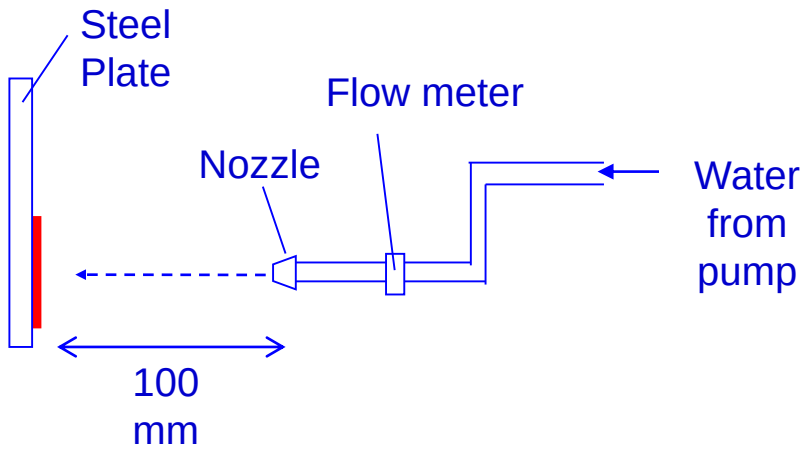
Cleaning Indicators vs. ISO/TS 15883-5 Test Soils

- A comparison of the test soils specified in ISO/TS 15883-5 soils in the following conditions:
  - Chemical-only action
  - Mechanical-only action
  - Combination of both chemical and mechanical action

Stainless Steel Test Plate

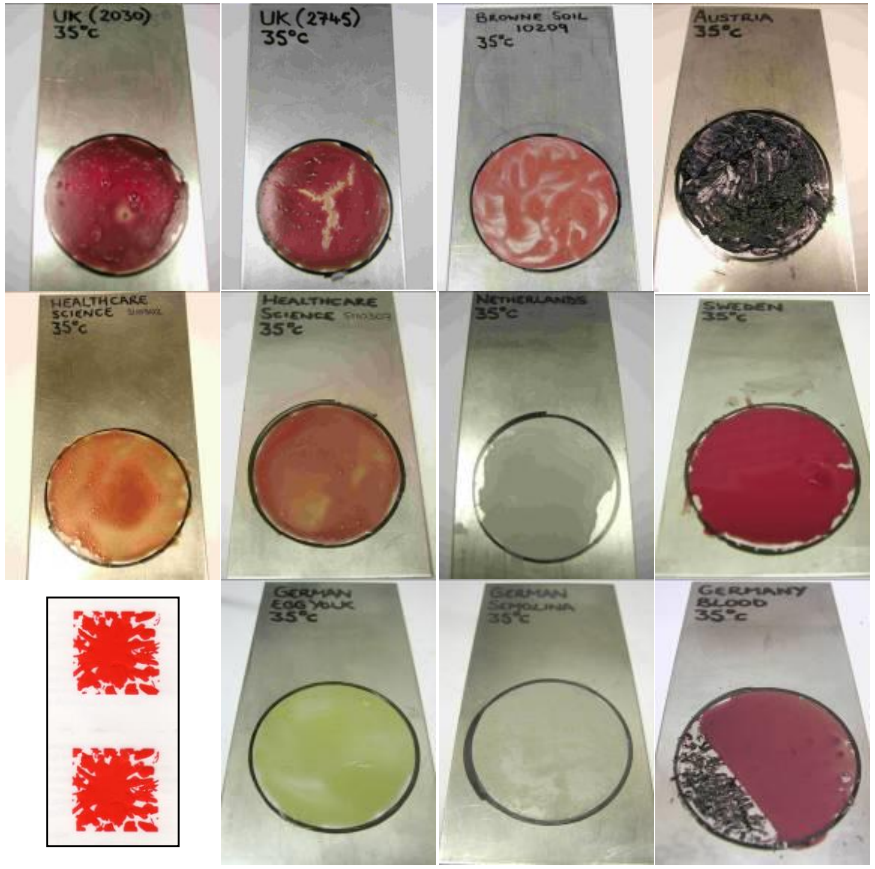


Mechanical-only Test

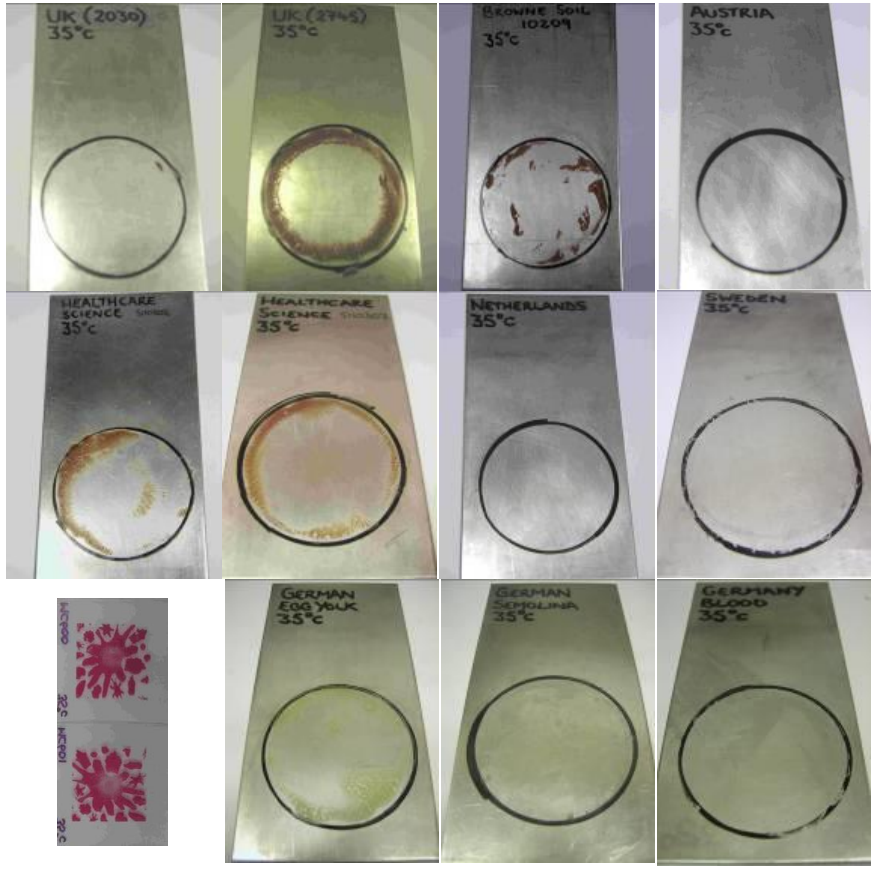


Detergent-only Test

35°C – No Detergent
Before Test



35˚C – No Detergent
After Test



Relevant Standards/Guidance

HTM 01-01 Part D	• Washer Disinfectors • Recently revised
HTM 01-06	• Endoscopy • Recently revised
EN ISO 15883	• Washer disinfectors

UNI EN ISO 15883-1

- ISO 15883-1 defines minimum values for disinfection by moist heat using A0 concept

$$A_0 = \sum 10^{\left[(T-80)/z\right]} \times \Delta t$$

- A0 is the A value when Z=10°C
- t= time in seconds
- T= temperature in °C

ISO 15883-5 Alert Limits (draft)

- Protein < 6.4 µg/cm2
- TOC (total organic carbon) < 12 µg/cm2
- Carbohydrate < 1.8 µg/cm2
- Haemoglobin < 2.2 µg/cm2
- ATP < 22 femtomoles/cm2

- Proposal to reduce (action) limits further by :
  - Protein <3 µg/cm2
  - Haemoglobin <1 µg/cm2

Protein Detection

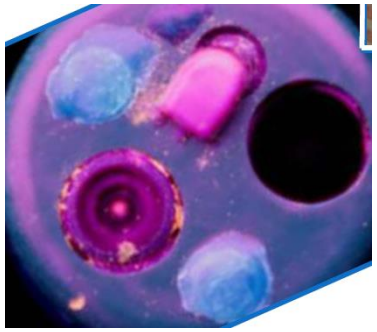
- Ninhydrin specified for protein detection in HTM 2030 and EN ISO 15883

- HTM 01-01 now specifies maximum protein residue of 5µg per instrument side

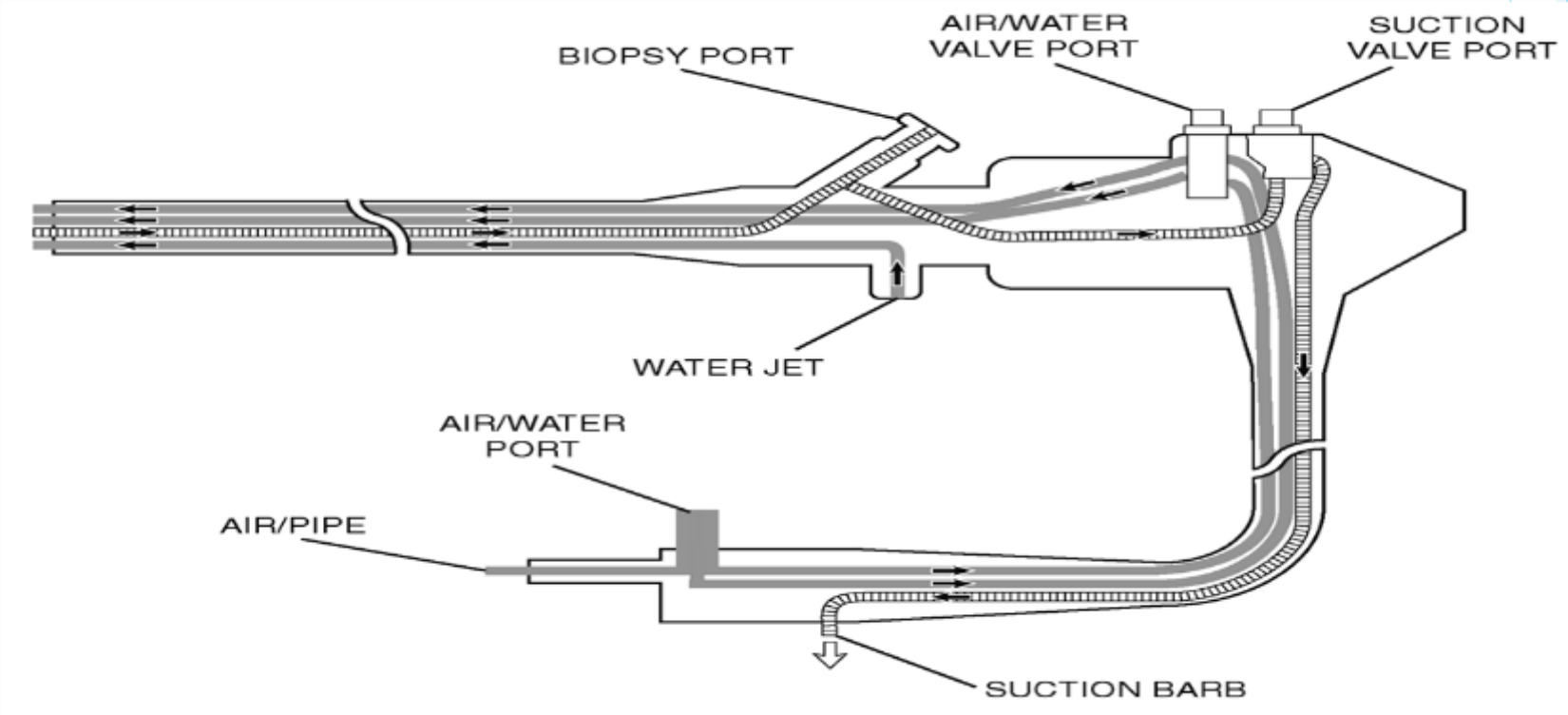
Protein Detection

- Validated detection to 1µg of protein
- 10 second read time
- No incubation

Endoscopes – an Unique Challenge?



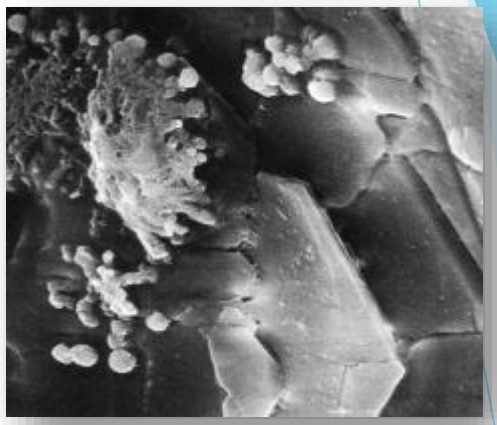
‘Typical’ Endoscope?



Duodenoscopes in US

Endoscope Soiling

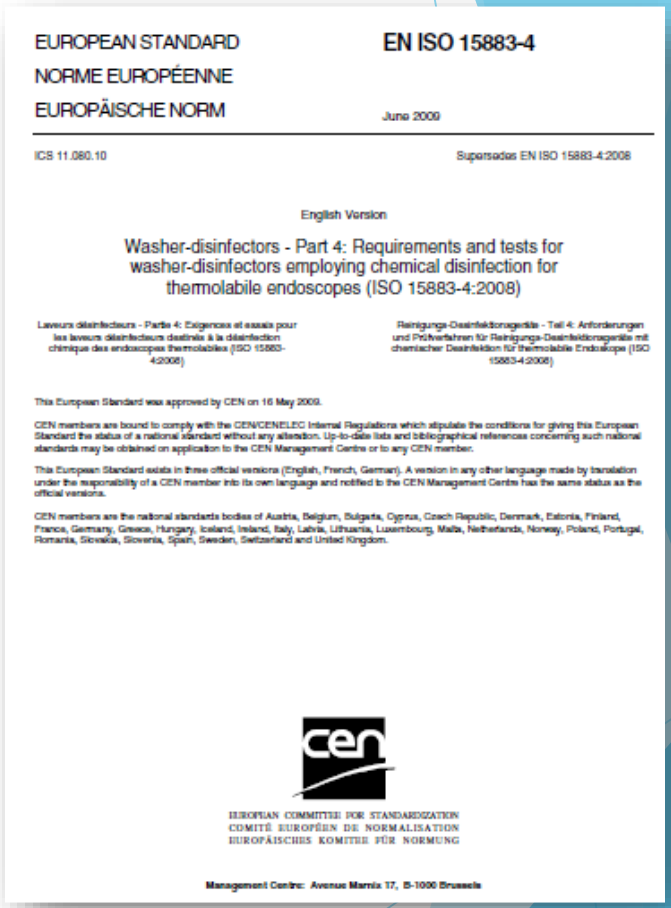
- Contamination on and within endoscopes is likely to consist of:
  - Microorganisms
  - Carbohydrates
  - Proteins
  - Lipids



- Proteins will be denatured if the initial rinse temperature is too high
  - Denatured proteins are extremely difficult to remove
- Lipids require higher temperatures to aid dissolution

ISO 15883-4

- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
- 6.6 Channels non-obstruction test
- 6.11 Tests of cleaning efficacy



EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15883-4

June 2009

ICS 11.080.10

Supersedes EN ISO 15883-4:2008

English Version

Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)

Laveurs désinfecteurs - Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles (ISO 15883-4:2008)

Reinigungs-Desinfektionsgeräte - Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (ISO 15883-4:2008)

This European Standard was approved by CEN on 16 May 2009.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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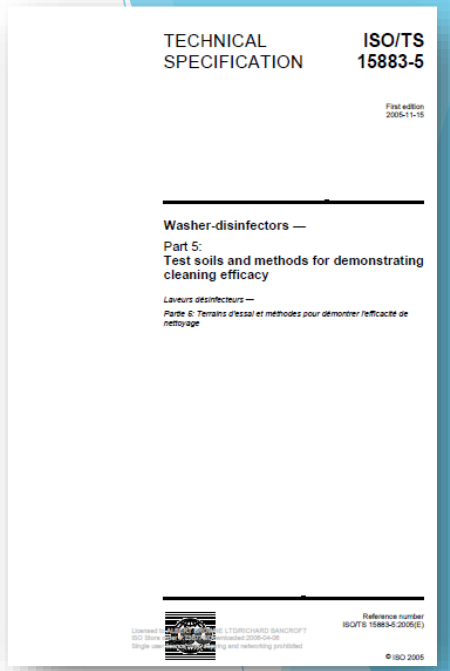
ISO/TS 15883-5

- Annex R
- A surrogate device for investigation of cleaning and disinfection constructed from two 1,5 m lengths of polytetrafluoroethylene (PTFE) tube with inner diameter of 2 mm and one 1,5 m length of PTFE tube having an inner diameter of 1 mm; bound together with adhesive tape


TECHNICAL SPECIFICATION

ISO/TS 15883-5

First edition 2005-11-15

Washer-disinfectors —

Part 5:
Test soils and methods for demonstrating cleaning efficacy

Laveurs désinfecteurs —

Partie 5: Terrains d'essai et méthodes pour démontrer l'efficacité de nettoyage

Reference number ISO/TS 15883-5:2005(E)

© ISO 2005

Steam Sterilization

Problems with Steam

- We must achieve 134 °C for a minimum period of time at ALL PARTS of the load
- This temperature and time must be in the presence of STEAM
  - sealed hollow devices
  - porous loads - AIR

Sporicidal Activity in Steam and Air

- Steam at 134 °C is capable of destroying 1 million spores in under 1 minute
- Dry heat at 160 °C will take 1 hour

ISO 17665-1

- ISO 17665-1 – Sterilization of healthcare products – validation and routine control of moist heat sterilization products
- Requirement to perform steam penetration test (Bowie Dick Test) at the commencement of every day
- Test should conform to UNI EN ISO 11140-4

Leak Rate Test

- Test used to assess chamber integrity/leaks in a large steam sterilizer
- Chamber integrity test
- Specified in UNI EN 285
- Supplements, but not replaces, the Bowie Dick Test

Electronic Bowie Dick Tests

- Electronic Bowie Dick Tests do not use chemical indicators to provide the result
- Cannot meet the requirements of UNI EN ISO 11140-4

Zentral CENTRAL SERVICE
STERILISATION

Reprint from
2011; 19 (3): 174–184

F. Benoit, D. Merger, R.J. Hermsen, J.P.C.M. van Doornmalen: A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4

Official journal of the
German Society for Sterile Supply
(DGSV e. V.)

mhp
Verlag GmbH

Central Service 3/2011

A comparison of four commercially available electronic steam penetration tests according to ISO 11140 part 4

*F. Benoit[1], D. Merger[1], R.J. Hermsen[2], J.P.C.M. van Doornmalen[2]**

Conclusion

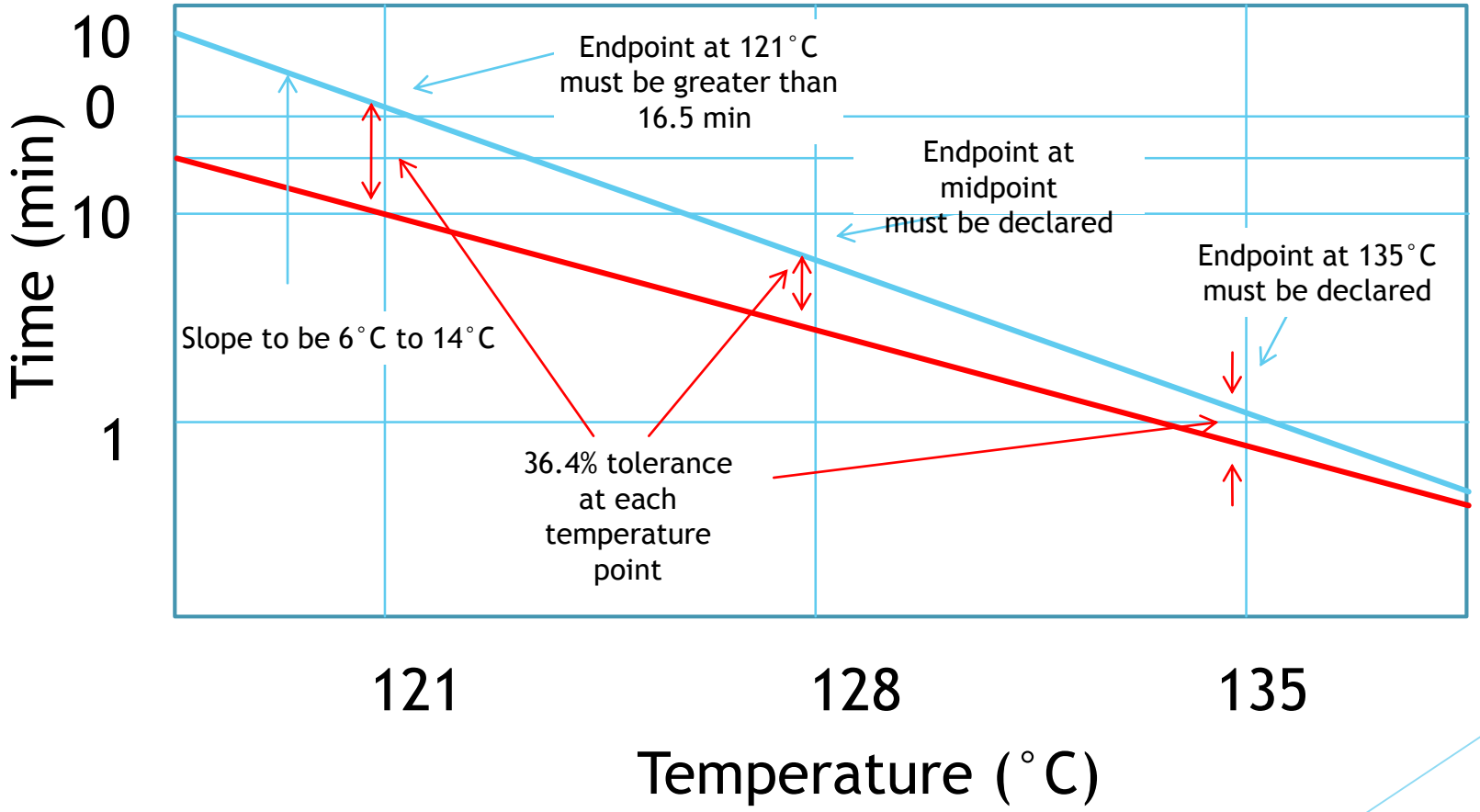
From the four devices tested only one device meets the performance requirements of the steam penetration ISO 11140 part 4. This is the only device that does detect NCGs which clearly shows that measurements of temperature and pressure only are insufficient to adequately detect fail conditions as specified in the standard for steam penetration. It can therefore be concluded that to fulfil the performance requirements for steam penetration tests with an electronic test device detection of NCGs is a necessity.

chemical indicators – ISO 11140-1

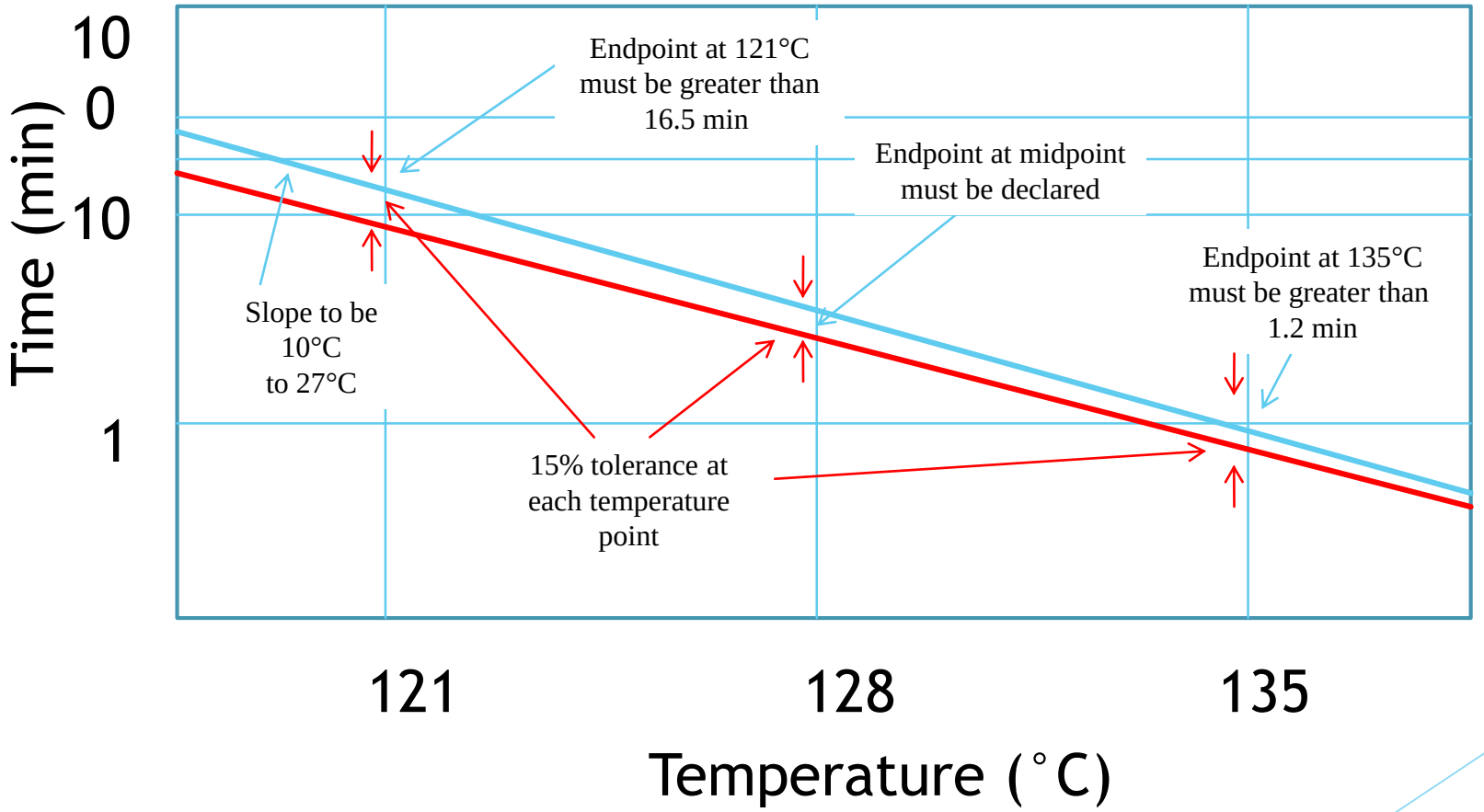
Chemical Indicators

- ~~Class~~ **Type 1 indicators (process indicators)** are used to differentiate processed and non-processed items
- ~~Class~~ **Type 2 (Bowie Dick indicators)** are used to assess steam penetration of the sterilizer cycle
- ~~Class~~ **Type 5 indicators** perform similarly to the performance of an ISO 11138 biological indicator
- ~~Class~~ **Type 6 indicators** give assurance that the set sterilization parameters have been achieved

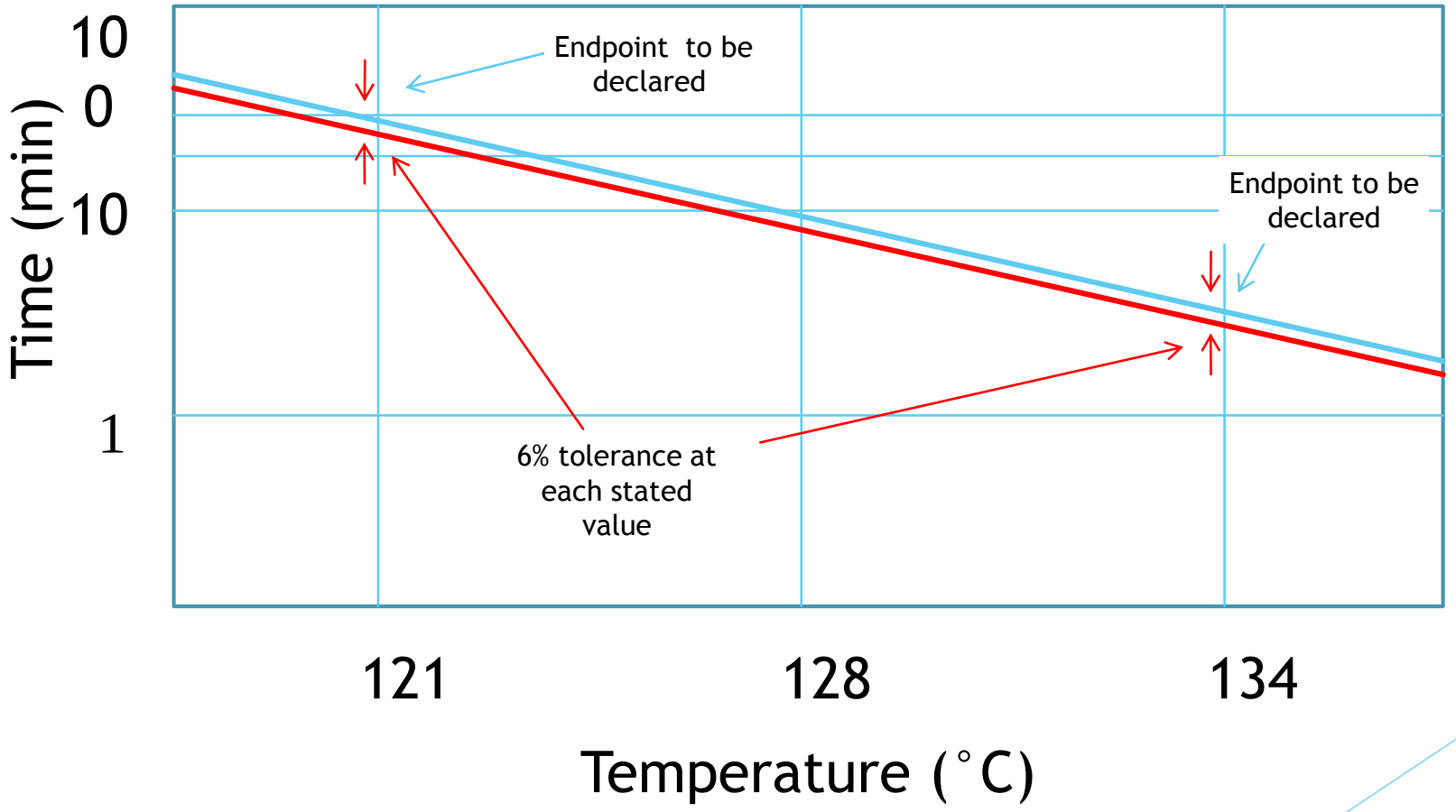
Previous Class 5 Performance- ISO 11140-1:2005



Current Type 5 Performance- ISO 11140-1:2014



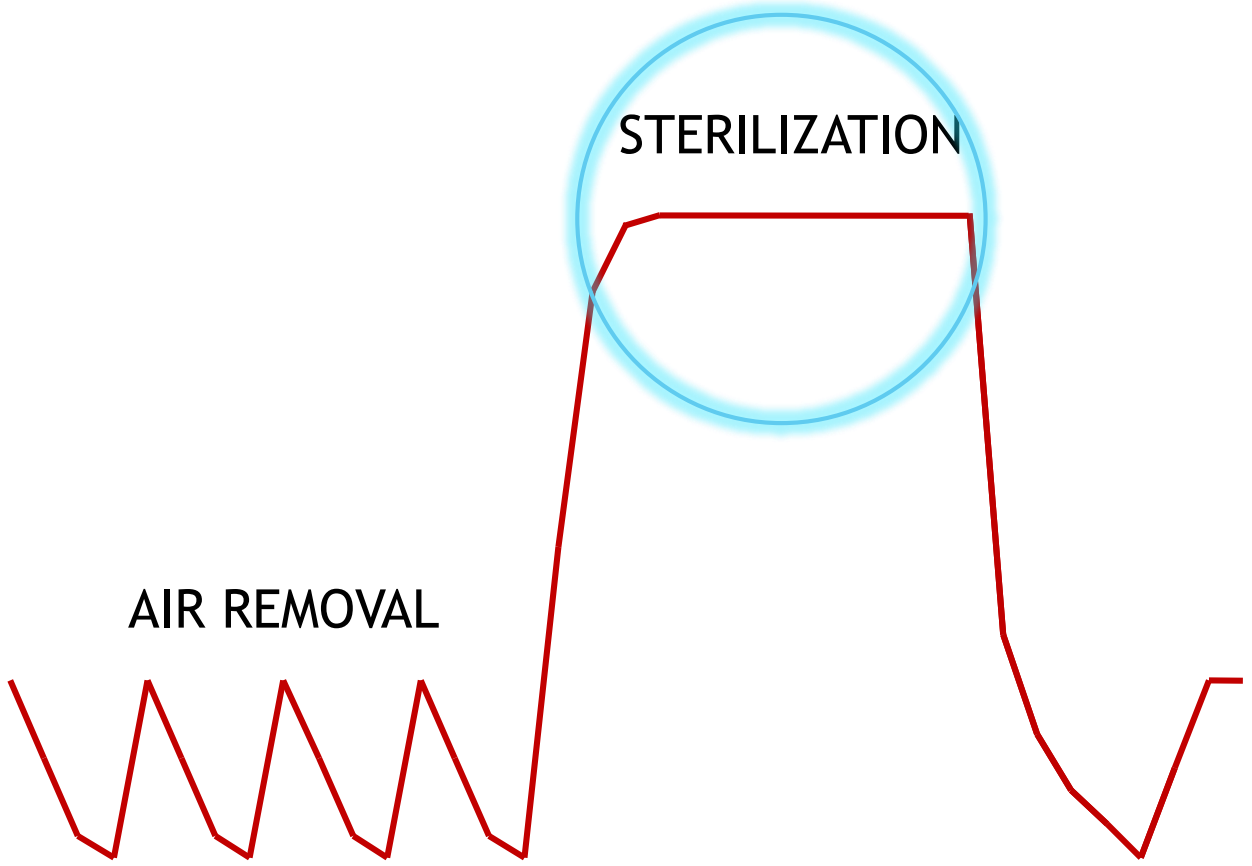
Type 6 Performance



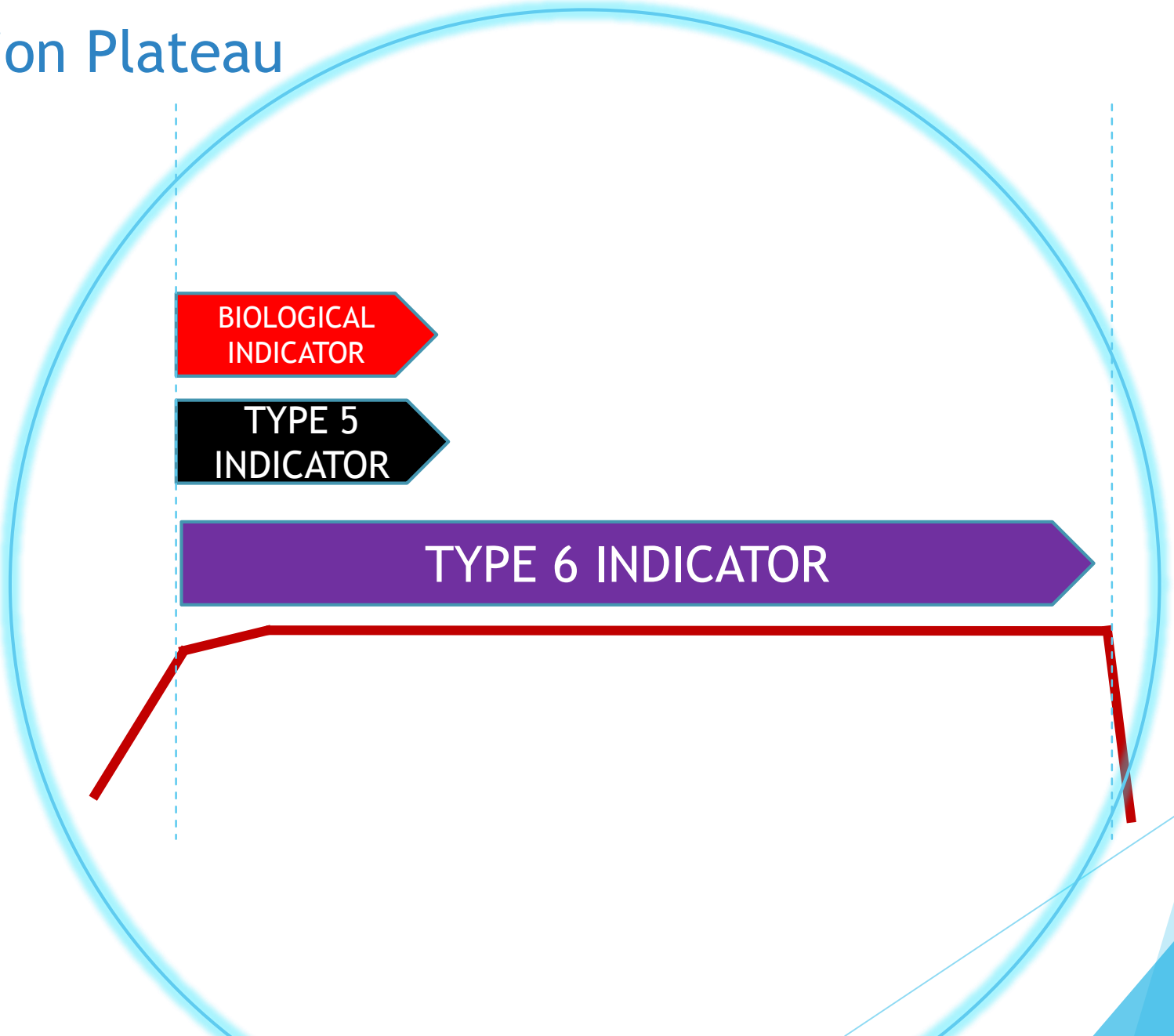
Type 5 versus Type 6

- **Type 5** has endpoint at
  - 121°C of ≥ 16.5 min
  - 134°C of ≥ 1.2 min
- **Type 5 indicators** are correlated to the performance of biological indicators, and are not cycle specific
- **Type 6 indicators** are matched to the cycle parameters that are actually used e.g. 134°C for 3.5 minutes, 134°C for 4 minutes, 134°C for 5.3 minutes, 134°C for 7 minutes

Sterilizer Cycle



Sterilization Plateau



conclusions

Monitoring

- Washer-Disinfector should be tested every cycle or every day
  - Cleaning indicator and test soils
    - ISO/TS 15883-5
- Sterilizer should be tested at the start of every day
  - Bowie Dick Test
    - UNI EN ISO 11140-4
- Each load must be monitored
  - Type 5 or Type 6 Chemical Indicator
    - UNI EN ISO 11140-1
- Both types of process monitoring is critical

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