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The Use of Test Soils & Surrogate Devices to Validate Endoscope & Surgical Instrument Decontamination

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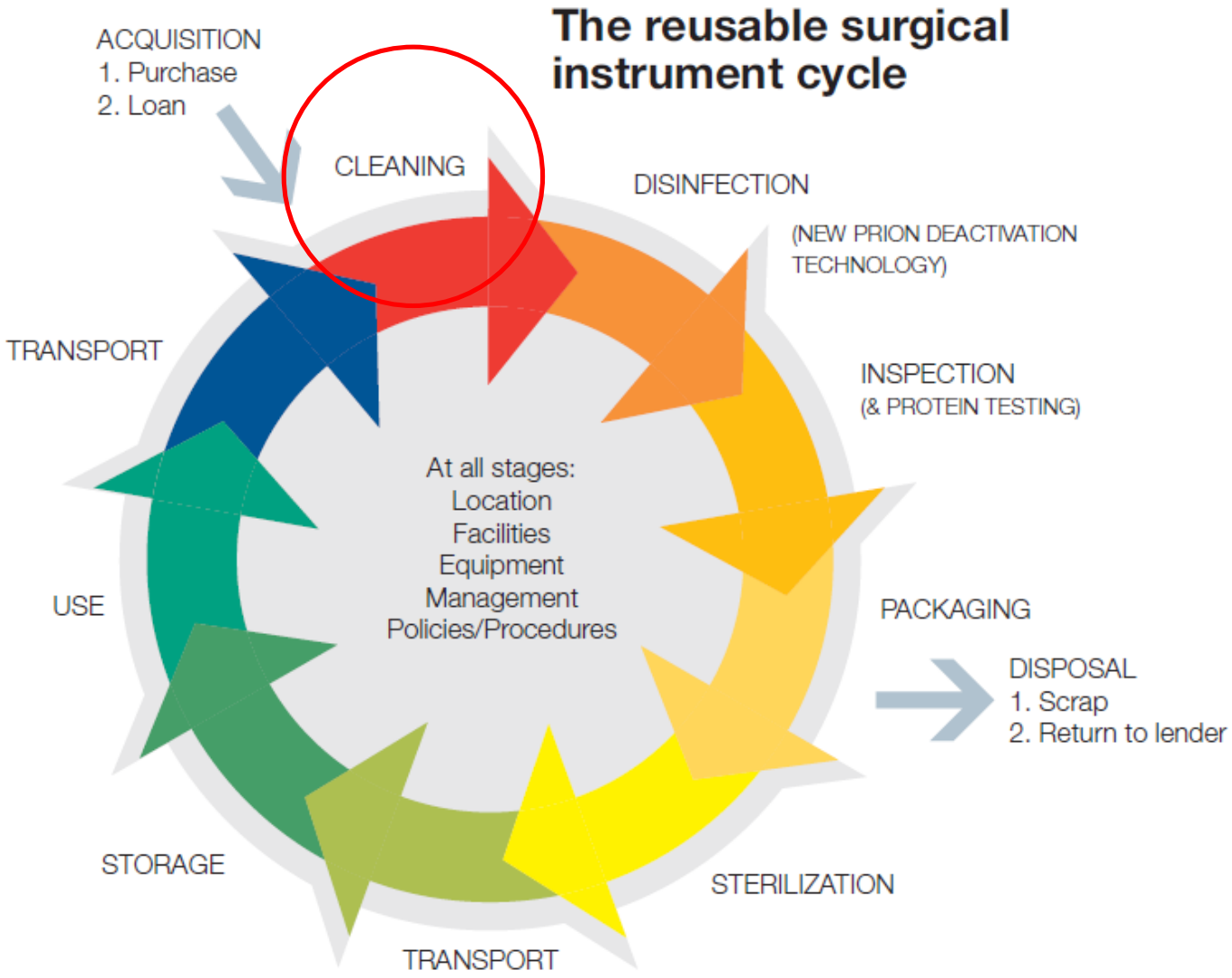
Cleaning is the first step in reusable device processing



UK HTM 01-01 part A

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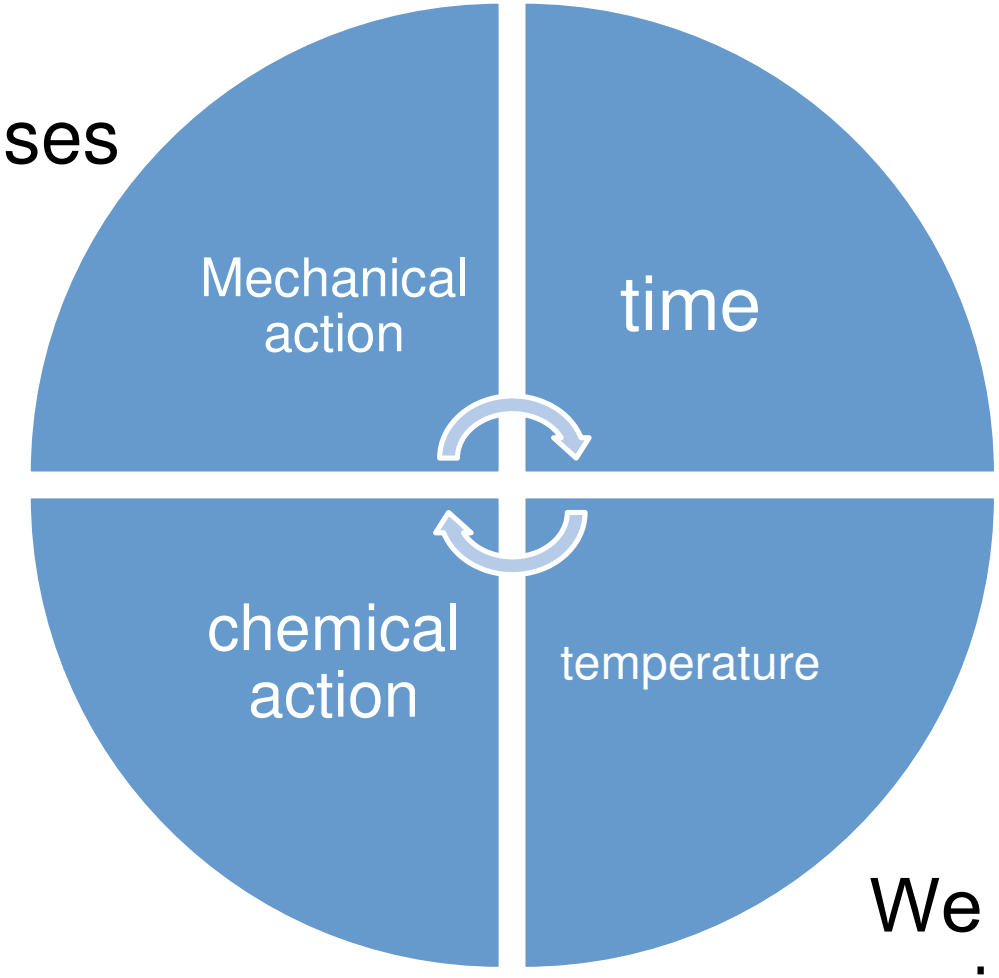
Validation of cleaning

If an instrument is already clean prior to processing in a washer-disinfector, we can't assess the result of the process

Soiling with a defined test soil allows quantification of that process

How do we achieve cleaning?

Variables of cleaning processes

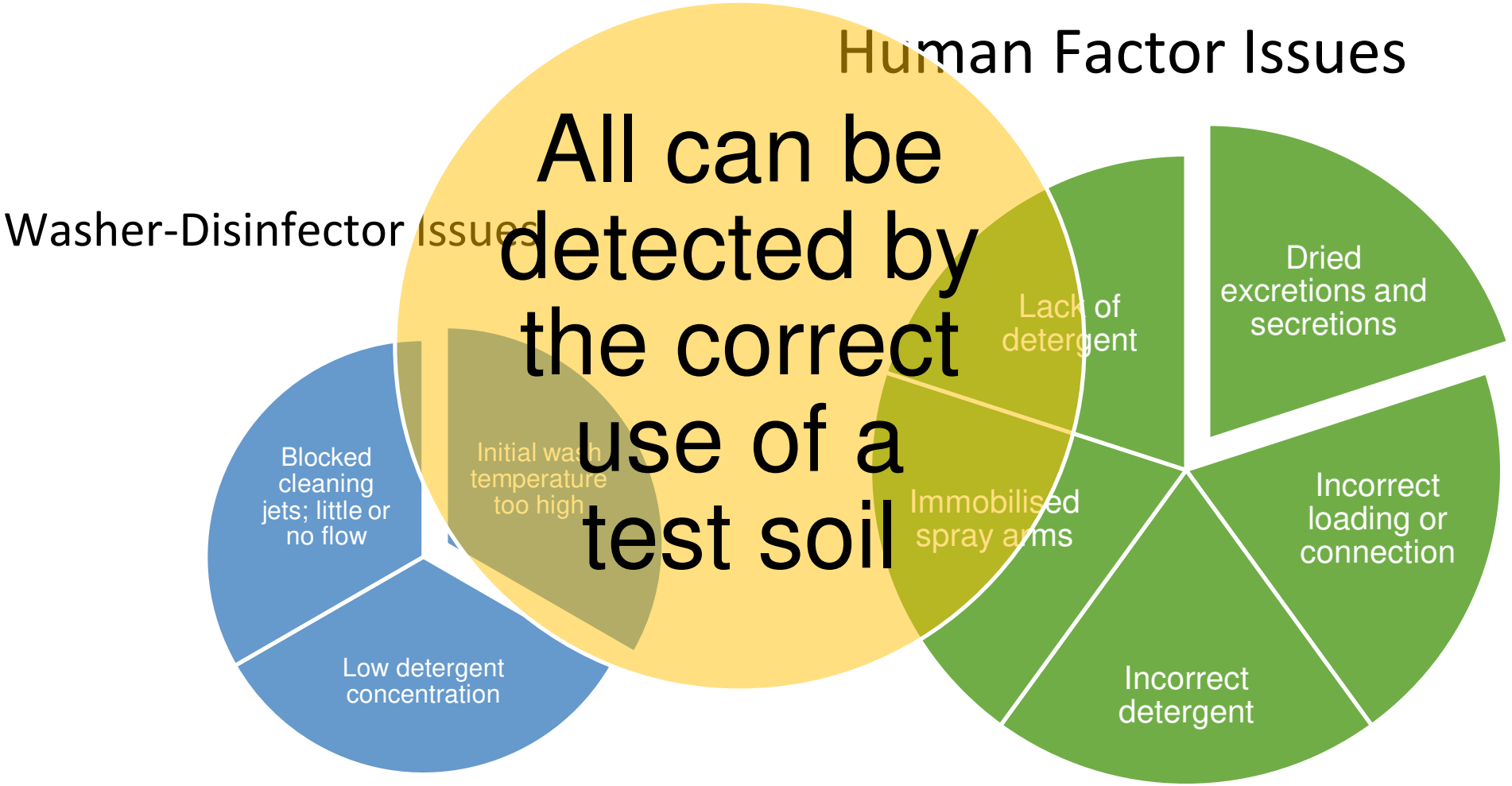


Sinner Circle*

We don't validate each variable independently

*Herbert Sinner, 1959

Possible causes of cleaning failure



Test soils

- Used as a periodic validation test
- The only way to assess overall cleaning efficacy
- How do we determine which test soil?

The ISO compendium of test soils - ISO/TS 15883 - 5

Published in 2005

Contains formulations for test soils designed to be used for cleaning efficacy validation

What do the formulations have in common?

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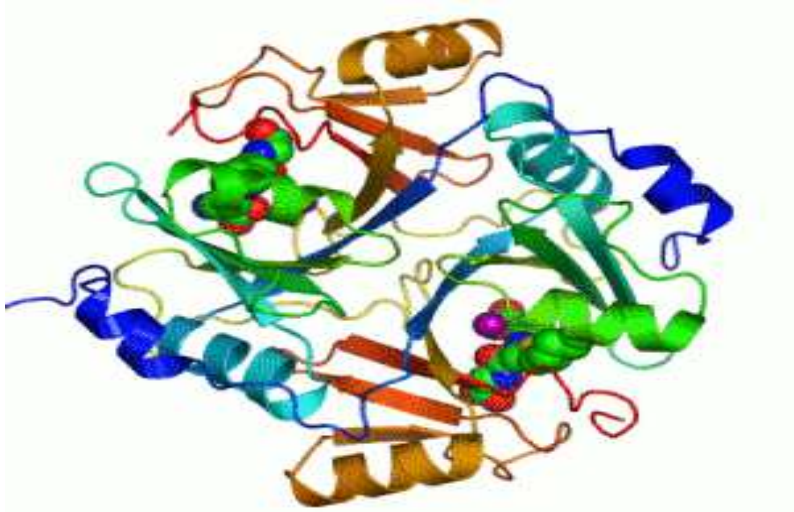
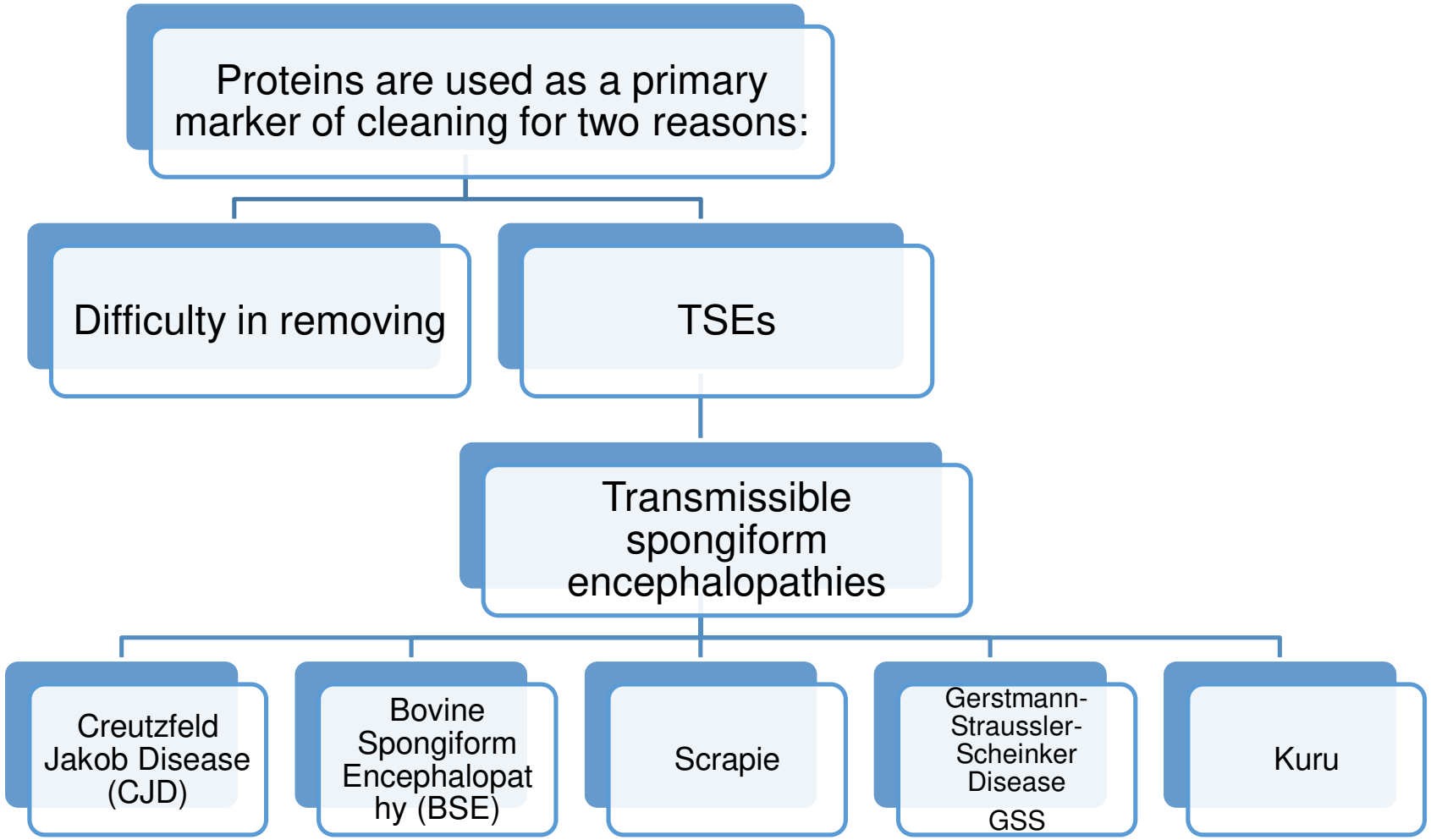
Protein!



Protein-based soils

- Clinical soils usually proteinaceous in nature
- Mimic typical soiling from surgical procedures
- Test soils e.g. ISO/TS 15883-5 create worst-case soiling on reusable medical devices

Proteins



This presentation is not intended to suggest suitability of a cleaning process in cleaning devices that might have been exposed to prions, the causative agent in transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease (CJD)

UK and vCJD

178 deaths from vCJD in UK (to date)

Peak year was 2000

- Numbers fallen;
- no cases in 2014, 2015, 2017, 2018, 2019 (as of 7th October 2019)
- 1 case in 2016

Small number of vCJD cases transmitted by blood transfusion

No known cases of vCJD transmitted by surgical instruments or endoscopes

Sporadic / familial CJD transmitted by instruments used in brain surgery

But still many cases of CJD (all forms) in the UK…

Year	Total Cases
2016	125
2017	134
2018	150
2019	95

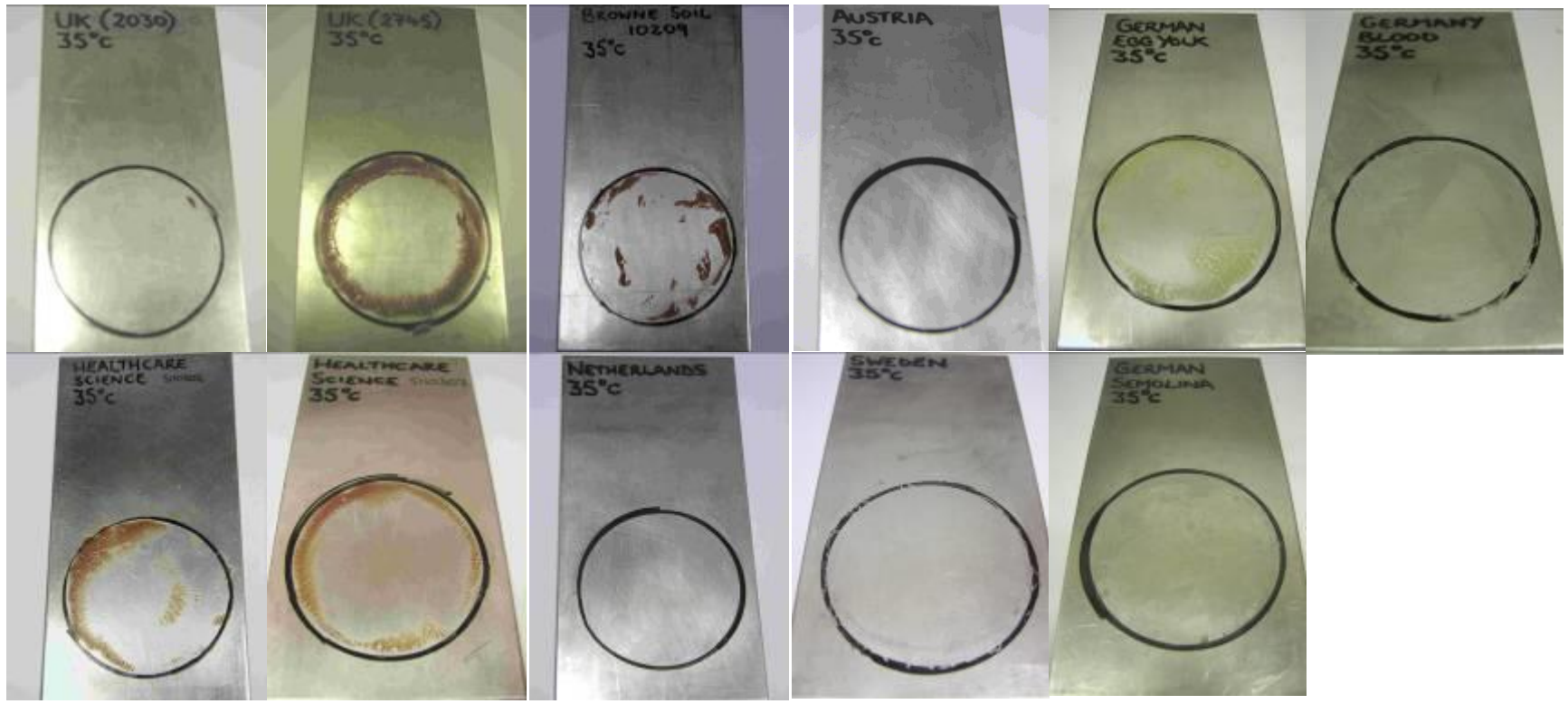
https://www.cjd.ed.ac.uk/sites/default/files/figs.pdf 7th October 2019

Current ISO/TS 15883-5:2005 test soils

Austria	Nigrosin, oatmeal, egg, dehydrated potato flakes, water
Germany	Blood, egg yolk, semolina, butter, sugar, milk powder
Netherlands	Bovine albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1
Sweden	Citrated cattle blood coagulated with calcium chloride
UK	Defibrinated horse blood, egg yolk, dehydrated hog mucin

ISO/TS 15883-5:2005 soils on stainless steel plates

After testing - 35°C, water



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Revision of ISO 15883-5

ISO began work years ago to revise the requirements for test soils

Revision focused on apparatus and test method to define test soil parameters - rather than a formulation

The test soil should be defined based on its properties - not on its formulation

ISO/DIS 15883-5

DIS indicates the standard's status as a Draft International Standard

- prEN is the equivalent CEN state

Use of any test soil - as long as its use is justified as clinically relevant

Use of analytes as markers of cleaning

Which analytes are important?

- Recognition that multiple analytes may be important (depending on clinical relevance)
- Recognition of the supremacy of protein as the most important analyte

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Key terms and definitions – ISO/DIS 15883-5

action level

value from monitoring that necessitates immediate intervention

- note - this is the maximum value of analyte not to be exceeded

alert level

value from monitoring providing early warning of deviation from specified conditions

- note - this is the target value of analyte

analyte

chemical substance that is the subject of chemical analysis

clean

visually free of soil and below specified levels of analytes

ISO/DIS 15883-5:2019

Action levels:

• Protein	6.4 **µg**/cm²
• TOC (total organic carbon)	12 µg/cm²
• Carbohydrate	1.8 µg/cm²
• Haemoglobin	2.2 µg/cm²
• Endotoxin	20 EU/device
• ATP	22 femtomoles/cm²

Alert levels :

• Protein	3 **µg**/cm²
• TOC (total organic carbon)	6 µg/cm²
• Carbohydrate	0.9 µg/cm²
• Haemoglobin	1 µg/cm²
• Endotoxin	2.2 EU/cm²
• ATP	10 femtomoles/cm²

The new test soil paradigm according to ISO/DIS 15883-5

Choice of test soil shall be justified, including method of application

The test soil shall conform to the protein test method performance criteria

Test soil shall include at least the concentration of analyte(s) representative of tissues/fluids

Conditioning (drying) must consider:

- Transport & dwell time from point of use to reprocessing
- Ambient temperature
- Ambient humidity

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Test soil examples (ISO/DIS 15883-5 Annex A)

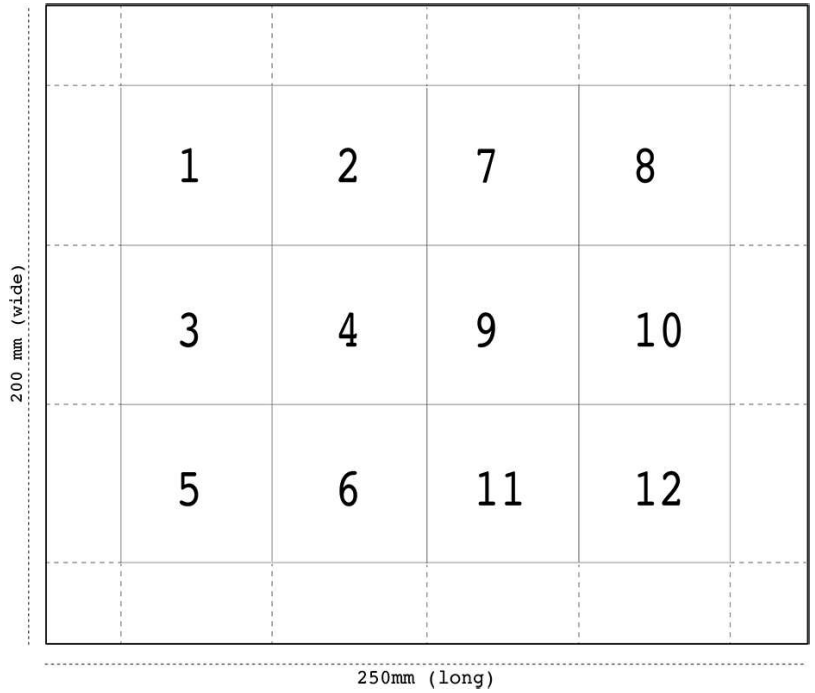
Test soils	Application	Main Composition
Heparinized blood	General surgery	Blood, heparin, protamine sulphate
Citrated blood	General surgery	Blood, sodium citrate, calcium chloride
2-component blood	General surgery	Bovine albumin, haemoglobin, fibrinogen + thrombin
Edinburgh soil	General surgery, orthopaedic; upper respiratory	Blood, egg yolk, hog mucin
Artificial test soil	Gastrointestinal	RPMI 1640, bovine serum, bovine oxgall, blood
Blood test soil	General surgery	Bovine albumin, haemoglobin, sodium alginate, calcium chloride
Biofilm test soil	Endoscopy	Pseudomonas aeruginosa grown in situ on trypticase soy agar
RAMS	Toileting	Bovine albumin, mucin, maize starch

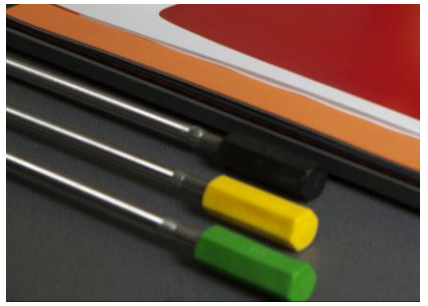
Device considerations

- lumens
- valves
- crevices
- hinges and joints
- rough and irregular surfaces
- material composition, including porosity
- junctions and dead ends

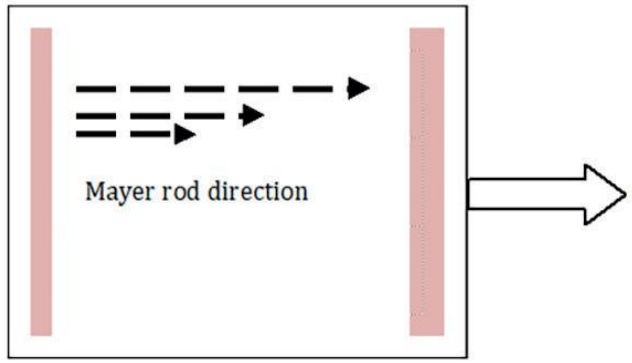
ISO/DIS 15883-5 test piece preparation

Stainless steel coated with heparinised blood

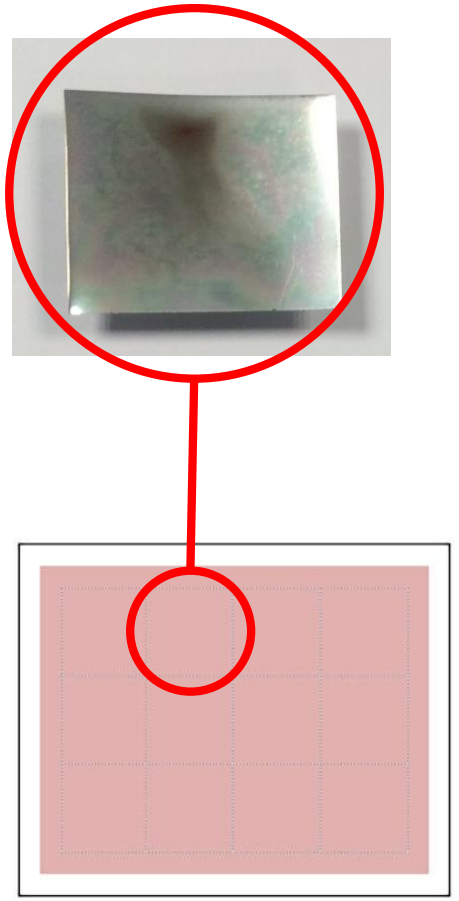




RK Print Coat Instruments



50 mm x 50 mm test pieces



Laboratory apparatus

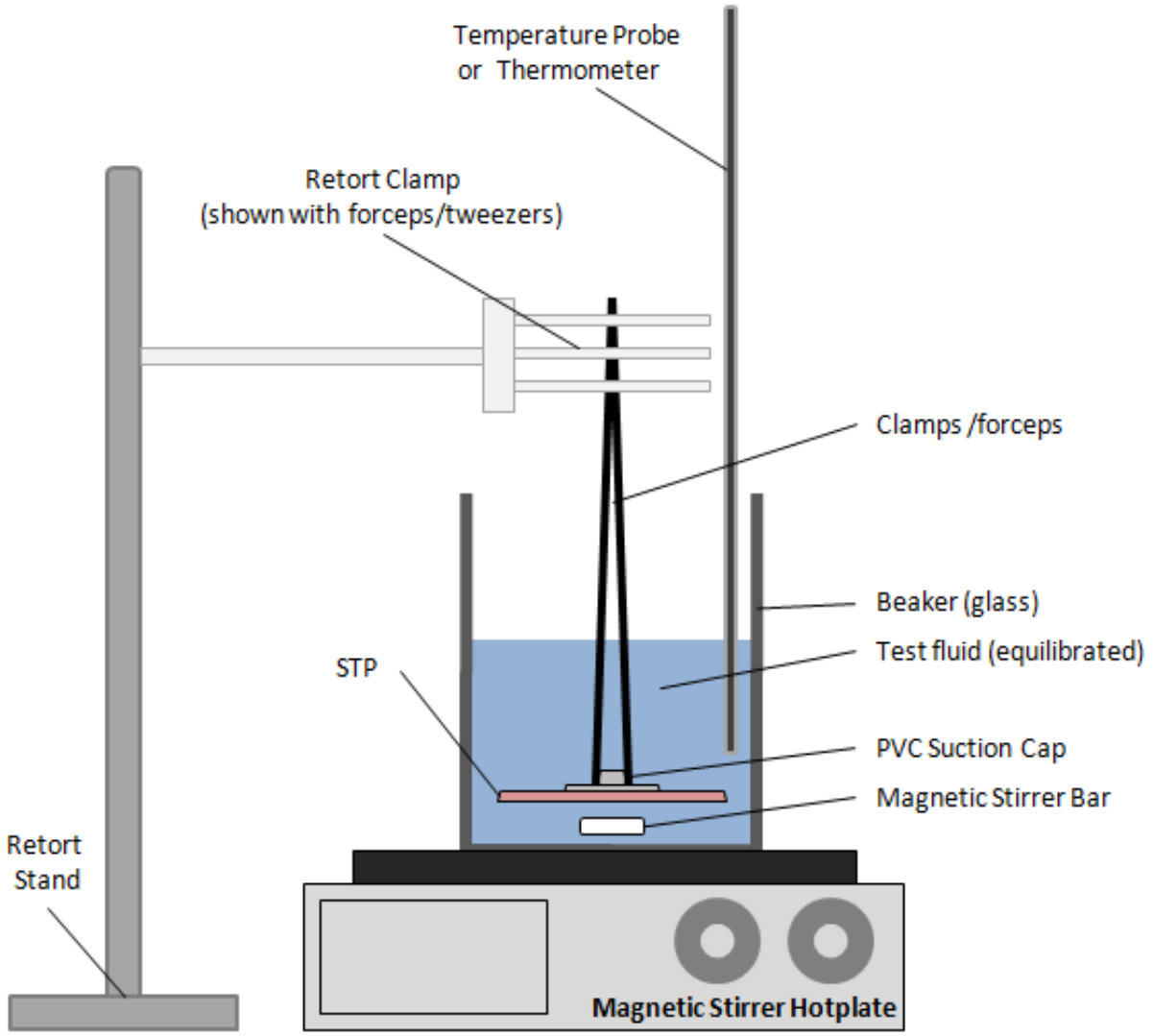
Removal of test soil over time

+

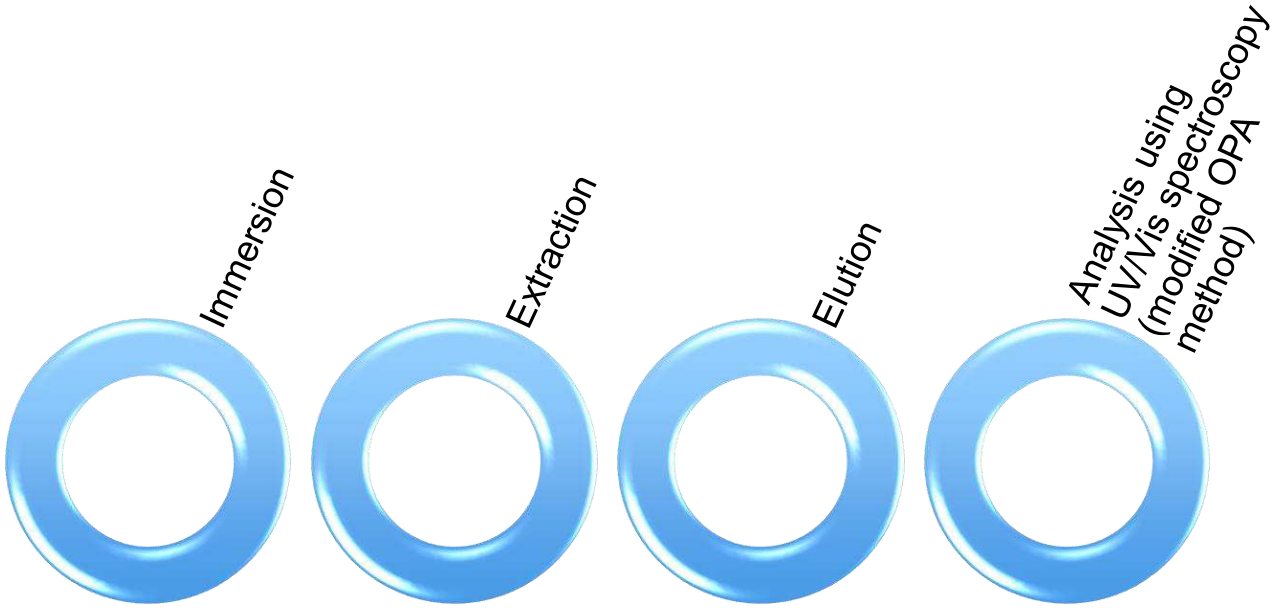
Defined test conditions

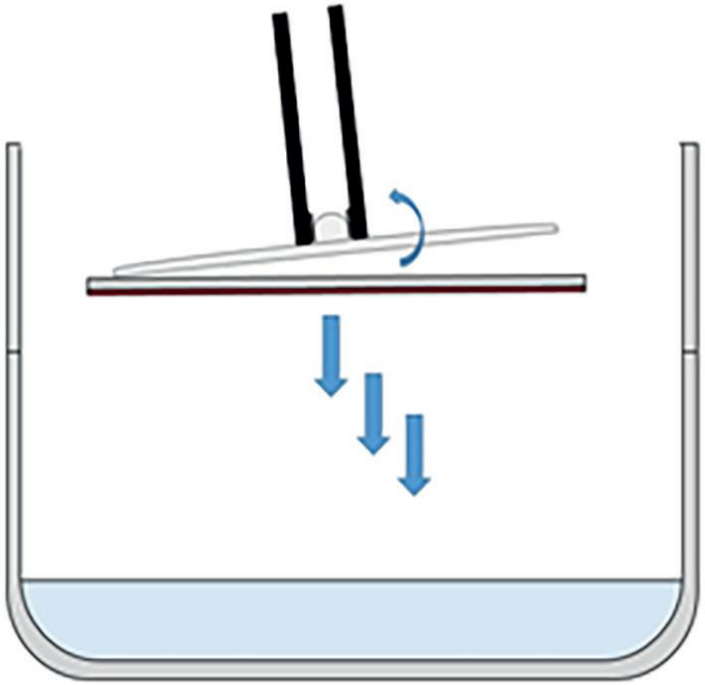
→

Assess residual protein



Test piece method





ISO/DIS 15883-5:2019 protein acceptance limits

Requirements		
Test condition	Time	Residual soil remaining
Water, 25 °C	30 secs	≥12% protein remaining
Water, 25 °C	90 secs	≥2% protein remaining
Water, 75 °C	30 secs	≥12% protein remaining
Water, 75 °C	90 secs	≥6% protein remaining

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Process Challenge Devices (PCDs)

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EN ISO 15883 series

Part 1: General requirements, terms and definitions and tests

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Part 5: Test soils and methods for demonstrating cleaning efficacy [Technical specification]

Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

EN ISO 15883 series

- Most important parts of standard for reusable medical devices are:

- Part 1 (General)
- Part 2 (Surgical Instrument – thermal disinfection)
- Part 4 (Endoscopes – chemical disinfection)
- Part 5 (Test soils)

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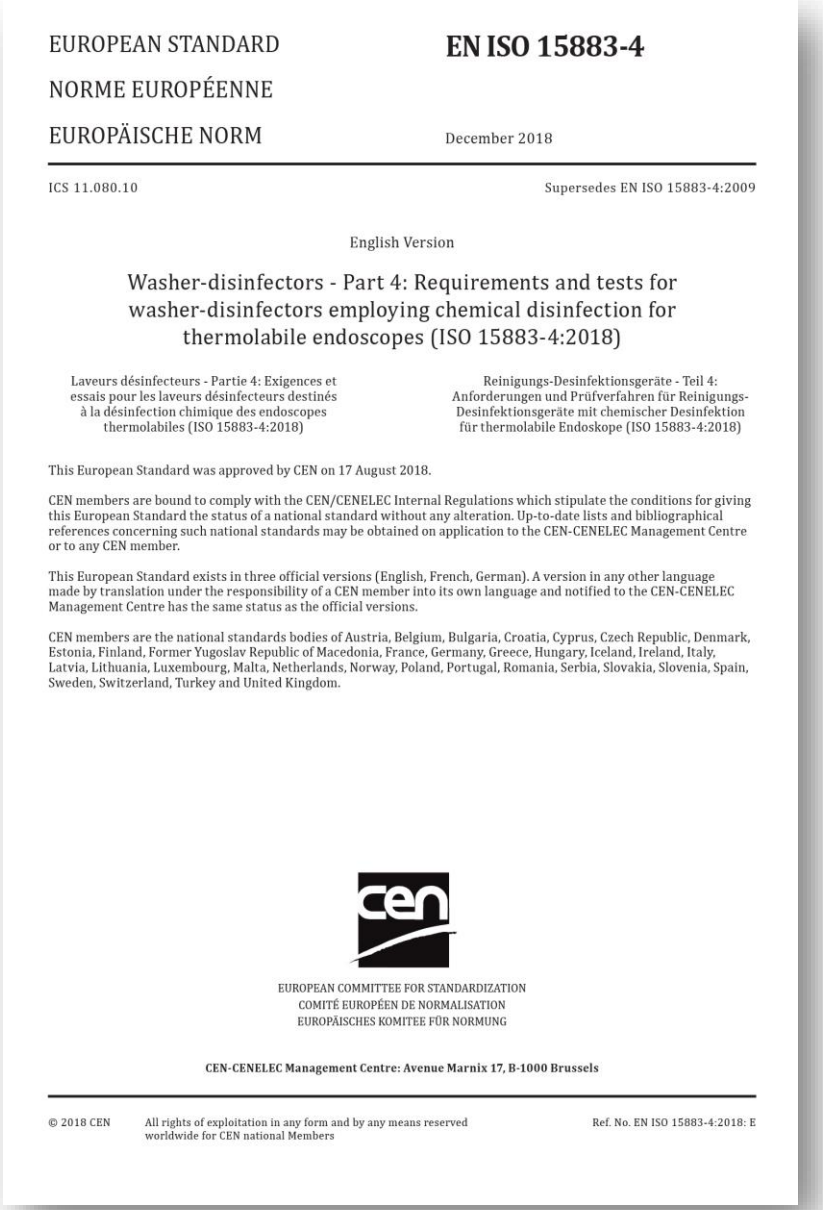
Revision of EN ISO 15883-4

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Revision of EN ISO 15883-4 published December 2018

Changes to type testing of washer-disinfectors & processes

- E.g. Use of a range of endoscope surrogate devices (annex H)



EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15883-4

December 2018

ICS 11.080.10

Supersedes EN ISO 15883-4:2009

English Version

Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)

Laveurs désinfecteurs - Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles (ISO 15883-4:2018)

Reinigungs-Desinfektionsgeräte - Teil 4: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit chemischer Desinfektion für thermolabile Endoskope (ISO 15883-4:2018)

This European Standard was approved by CEN on 17 August 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 15883-4:2018: E

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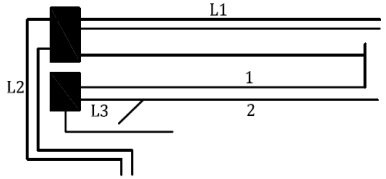
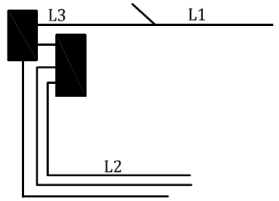
Endoscope Type Test Groups

Diagrams of endoscopes that cannot be divided into endoscope blocks due to interconnections between water/air and biopsy/suction channels or combinations with balloon channels	Specification
 **Key** 1: balloon channel 2: biopsy/suction channel L1: air/water channel to distal end L2: valve to connector L3: suction channel to valve	Ultrasound endoscope Air channel and water channel: — Ø 0,8 mm ≤ d ≤ Ø 1,2 mm Biopsy/suction channel: — Ø 1,2 mm ≤ d ≤ Ø 2,5 mm Balloon channel: — Ø 0,8 mm ≤ d ≤ Ø 1,2 mm Channel lengths: — 1 200 mm < L1 < 2 200 mm — 1 400 mm < L2 < 2 000 mm — L3 < 200 mm
 **Key** L1: biopsy port to distal end L2: valve to connector L3: suction channel to valve	Paediatric GI endoscope Air channel, water channel, biopsy, suction: — Ø 1,2 mm ≤ d ≤ Ø 2,5 mm Channel lengths: — 1 200 mm < L1 < 2 200 mm — 1 400 mm < L2 < 2 000 mm — L3 < 200 mm

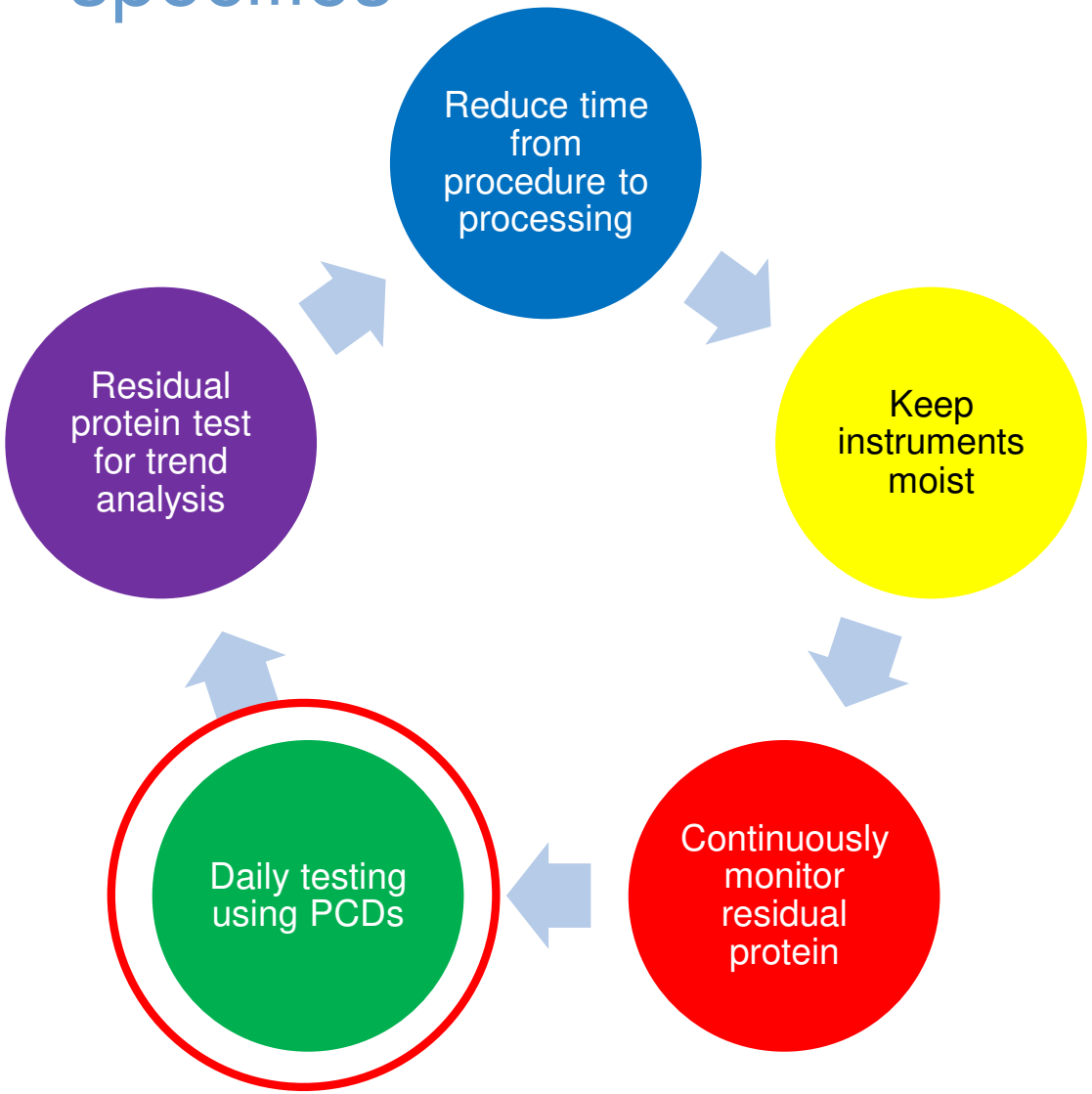
Process Challenge Devices

- Enables verification of specific minimum performance
  - Establishes a ‘line in the sand’

Benefits of PCDs

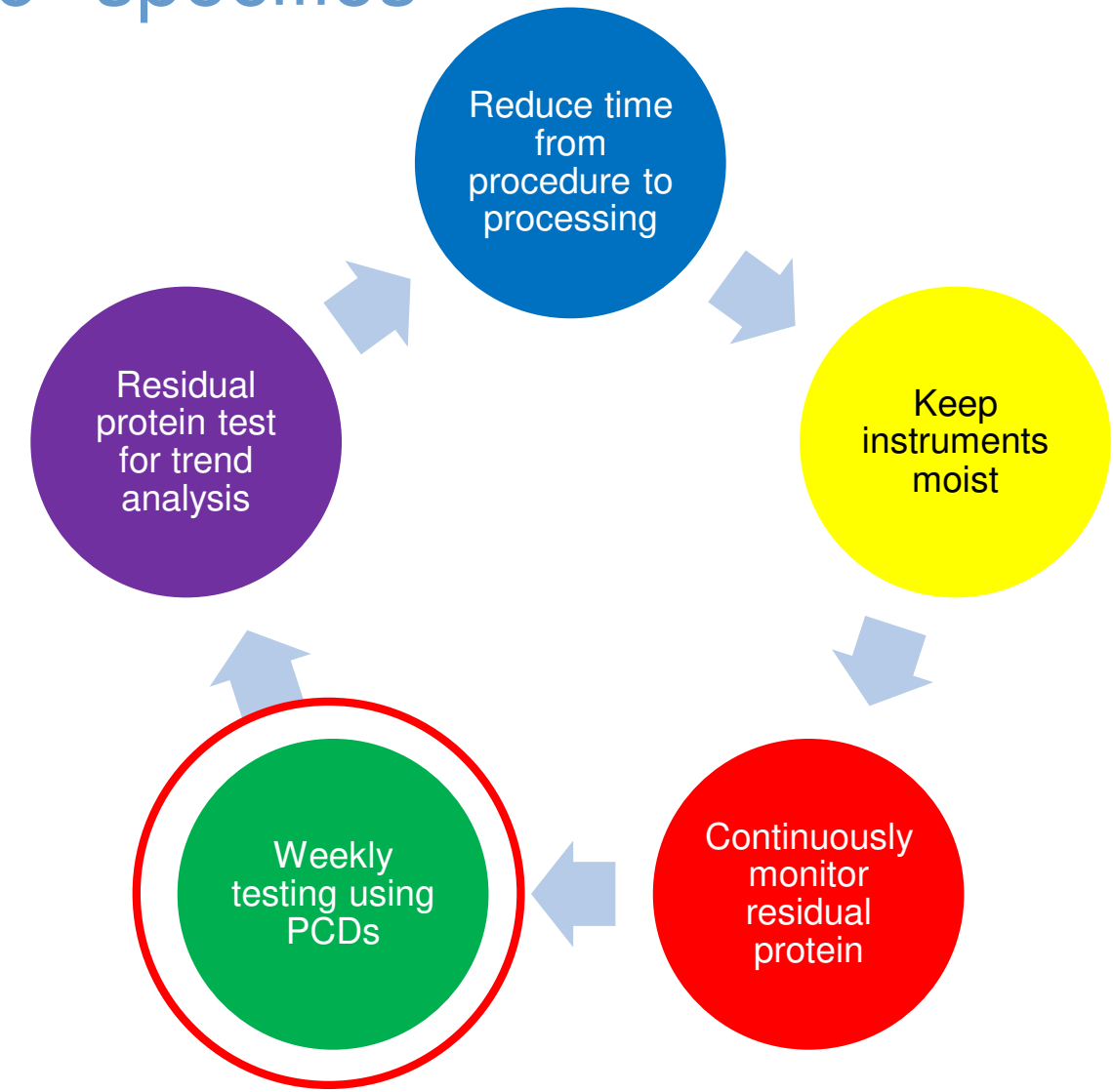
- Can be used as a daily (periodic) test, as well as during validation
- Ensures performance of washer-disinfector and its services
  - Water quality
  - Detergent
- Ensures performance of washer-disinfector in a similar way to the daily test of steam penetration (Bowie Dick test)

UK HTM 01-01* specifies



*HTM 01-01 Executive Summary

UK HTM 01-06* specifies



*HTM 01-06 Executive Summary

Conclusion

- A consistent method for quantifying the performance of test soils has been devised
- ISO/DIS 15883-5 is not yet a published standard, but has passed both CEN and ISO formal enquiry ballots (October 2019)
- ISO/DIS 15883-5 is a significant step towards defined test soil performance
  - May also be useful in the definition of clean, at least from a washer-disinfector process perspective
- Next steps:
  - ISO have almost 700 comments to review in December 2019

References & further reading

- ISO/DIS 15883-5:2019 Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
- ISO 15883-1:2006 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
- ISO 15883-2:2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- ISO/TS 15883-5:2005 Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
- UK HTM 01-01 Decontamination of Surgical Instruments
- UK HTM 01-06 Management and Decontamination of Flexible Endoscopes

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Thank You!