BS EN ISO 15883-5:2021
Incorporating corrigendum January 2022

BSI Standards Publication

Washer-disinfectors

Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 15883-5:2021. It is identical to ISO 15883-5:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Maximum residual protein on reusable medical devices after processing

UK Department of Health's Health Technical Memorandum 01-01 gives guidance that specifies after cleaning and disinfection, reusable surgical instruments and other medical devices should have an upper limit of acceptable protein contamination of 5 micrograms BSA equivalent per instrument side (5µg/side)[1].

This British Standard, BS EN ISO 15883-5, specifies that after cleaning and disinfection, reusable surgical instruments and other medical devices should have a protein level lower than 6.4 micrograms per square centimetre (6.4 µg/cm^2). ISO have defined protein per unit area in order to fix the requirement independent of instrument size.

As the size of reusable surgical instruments varies, there is a discrepancy between the UK HTM 01-01 requirements and the BS EN ISO 15883-5 requirements.

In consequence, UK sterile service managers could have conflicting requirements between UK guidance (HTM 01-01) and BS EN ISO 15883-5 for residual protein levels, depending upon the size of the reusable surgical instrument.

Surgical instruments used for high-risk procedures such as neurosurgery are typically smaller in size. Smaller surgical instruments could significantly exceed the ISO requirements, yet still meet UK guidance requirements. Conversely, larger surgical instruments could significantly exceed the UK guidance requirements for residual protein, yet still meet the ISO requirements.

EN ISO 15883-5 is listed in the European Commission's Standardisation Request for harmonisation to Regulation (EU) 2017/745 (MDR); EN ISO 15883-5 is not listed in the UK designated standards notice 0034/21 of 1st January 2021, however other parts of the EN ISO 15883 series are listed, and ISO 15883-5 is an essential part for demonstrating conformity to the other parts.

Therefore, taking into account HTM 01-01's requirements and BS EN ISO 15883-5 requirements, the UK committee recommends that UK sterile service managers adopt the following requirements:

For any reusable surgical instrument, the levels of residual protein should be as low as possible. After processing, there should be:

i) no more than 5 µg of protein on the side of any instrument tested, and

ii) no more than 6.4 µg/cm^2 on any part of the instrument tested.