B BRAUN
SHARING EXPERTISE

PRIME*Line*® PRO CLEANING VALIDATION

AESCULAP® STERILE CONTAINER

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PURPOSE

The purpose of the cleaning validation was to prove the cleaning efficacy of the PrimeLine Pro lid in an automated process.

TEST PROCESS

Whole blood as test soil was applied at the inside and outside of the completely assembled PrimeLine Pro lids with the filter covers. The contamination was kept deliberately high - in specific at narrow, curved and hollow designed areas of the samples. Once, the surface with the test soil had completely dried, the washing procedure was performed without any kind of manual pre-cleaning step. Thus, a real use condition in combination with a worst case scenario of cleaning according to the instructions for use was simulated.

AUTOMATED CLEANING:

Pre-rinse:	3 minutes of pre-rinse with tap water at <25°C
Cleaning:	10 minutes cleaning with demineralised water at 55°C, cleaner: B.BRAUN HELIMATIC CLEANER, neutral, pH neutral, 0,5% solution
Intermediate rinse:	1 minute rinsing with demineralised water at >10 C°

In addition, a protein test and haemoglobin test was performed.

CONCLUSION

At the end of the automated cleaning process, no test soil was detected visibly. A positive cleaning result well-suited for daily hospital use was achieved. The cleaning result complied to the full extent of the acceptance criteria based on

- EN ISO 15883-1 (2014-10)
- RKI Guideline (2012)[1]
- DGKH, DGSV, AKI (2014)
- AAMI TIR 30 (2011).

The result of the performed cleaning validates that the PrimeLine Pro lid became clean under real use condition in combination with a worst case scenario simulation of an automated cleaning process.

[1] Residue criteria for cleaning values for surgical instruments was applied

REFERENCE

The test was performed in accordance to following norms and standards:

- AAMI TIR 12 (2010): Designing, testing, and labelling reusable medical devices for reprocessing healthcare facilities: A Guide for Device Manufacturers.
- AAMI TIR 30 (2011): TIR 30 A compendium of processes, materials, last methods, acceptance criteria for cleaning reusable medical devices.
- AAMI ST-81 (2004): Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- DIN EN ISO 17664 (2004-07): Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- DIN EN ISO 15883-1 (2014-10): Washer/Disinfectors – Part 1: General requirements, terms and definitions and tests.
- TS/ISO 15883-5 (2006): Test soils and methods for demonstrating cleaning efficacy of washer and disinfectors.)
- Guideline of DGKH, DGSV and AKI for the validation and routine control of automated cleaning and disinfection process for thermostable medical devices and principles of device selection (2014).
- Guideline of DGKH, DGSV and AKI for the validation and routine control of manual cleaning and chemical disinfection process of medical devices (2013).
- RKI Guideline (2012) Hygiene requirements for the Reprocessing of Medical Devices, Robert-Koch Institute, Germany.
- FDA Guidance Document Reprocessing (2015): Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling. Guidance for Industry and Food and Drug Administration Staff.

AESCULAP® – a B. Braun brand

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