Original Article

Experience Report: Feasibility and practical relevance of a supplementary AER type test based on a new publication by the Type Test Working Group on behalf of the author group of the German Guideline for Validation of AER Processes

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Abstract

With the adoption of DIN EN ISO 15883-1, - 4 and- 5 [1, 2, 3], the requirements for automated endoscope reprocessors (AERs), also known as endoscope washer/disinfectors (EWDs), are now defined. The AER type test is the responsibility of the AER manufacturer. It is the basis for assessment of the risks posed by automated reprocessing of thermolalbile (heat-sensitive) endoscopes and serves as proof that the AER complies with the requirements of DIN EN ISO 15883 [1, 2, 3]. The type test gives the operator the assurance that all relevant product characteristics specified by the AER manufacturer have been confirmed through testing and that the AER meets the requirements of the Medical Devices Act [4].

Keywords
- endoscope reprocessing
- AER
- validation
- type test

At the time of compiling the *German Guideline for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Thermolabile Endoscopes* [5] , it was noted that in the DIN EN ISO 15883 [1, 2, 3] series of standards the requirements for qualification testing of one process chemical in a particular AER had not been clearly described.

In January 2010 a working group, the *Type Test Working Group*, was set up to precisely define these requirements and foster a uniform understanding of the key issues involved. The content of the mandate assigned to the Type Test Working Group was developed by the author group of the German Guideline for Validation of AERs [5]. Following intensive work, the Type Test Working Group published its findings in April 2017 [6]. With the publication "Scope and performance of type test of washer/disinfectors used to reprocess thermolabile endoscopes as per standard series EN ISO 15883", tests and evidence are now defined for incorporation as a supplement to the type test.

Introduction

Based on the publication [6] by the Type Test Working Group, the cleaning, disinfection and overall process performance of a manual and an automated detergent in combination with an undercounter AER unit was tested as a supplementary type test. Otherwise, the hitherto AER programme structure used was retained.

Preconditions

Various preconditions had to be met for the test. These were as follows:

- Selection and procurement of the AER: This should as far as possible have high market penetration.
- Selection of suitable flexible endoscopes for the cleaning tests and for investigation of the AER overall process performance using real-life instruments: The flexible endoscopes were intended to conjure a

worst case scenario for the test and cover a broad spectrum of the various types of channels. The decision was made in favour of an Olympus BF-P40 bronchoscope with a working length of 600 mm and channel of 2 mm Ø as well as an Olympus CF-2T160L colonoscope with a working length of 1.630 mm and a 3.2 mm Ø and a 3.7 mm Ø working channel. The bronchoscope was representative of a short endoscope, with a narrow channel. The study by M. Alfa [9] from Canada had demonstrated that endoscopes of these dimensions were particularly difficult to clean. The 2-channel colonoscope was representative of an endoscope with a large volume and complex channel system. It has two working channels and an additional irrigation channel. These two endoscopes were functional endoscopes that had already been used but it was not possible to ascertain the number of procedures performed with each endoscope. Since the endoscopes had already been used it is assumed that the Teflon working channels will have been roughened, thus making cleaning more difficult and conjuring a worst-case scenario.

Description of the tests and reprocessing parameters

The *wfk-Institut für Angewandte Forschung e.V* (Institute for Applied Research)., Krefeld, was commissioned to conduct the tests. The scope of testing was based on publication [5] and comprised:

- Investigation of the cleaning performance: 2000 mm PTFE tubes, Ø 2 mm [7]
- investigation of the cleaning performance: 2000 mm PTFE tubes, Ø 1 mm [2, 3]
- Investigation of the cleaning performance using real-life instruments [2, 3]: Olympus BF-P40 and CF-2T160L
- Investigation of the overall process performance: 2000 mm PTFE tubes, Ø 2 mm [8]
- Investigation of the overall process performance: 2000 mm PTFE tubes, Ø 1 mm [2, 3]
- Investigation of the overall process performance with real-life instruments [2, 3]: Olympus BF-P40 and CF-2T160L
- Investigation of the disinfection performance: 2000 mm PTFE tubes, Ø 2 mm with Mycobacterium terrae, in conformance with ISO 15883-4 (Chapter l 6.6.2) Annex B [2, 3]
- Investigation of the disinfection performance: 2000 mm PTFE tubes, Ø 1 mm with Mycobacterium terrae, in conformance with ISO 15883-4 (Chapter 6.6.2) Annex B [2, 3]

Testing was conducted in parts of "standard" AER programme 1. The entire "standard" programme sequence used to reprocess flexible endoscopes is illustrated in Diagram 1 above.

The following programme steps (see table 1) were used to investigate the cleaning, disinfection and overall process performance in the AER. Differences in the programme sequence are due to the test specifications. The second rinse was omitted since that was only needed to measure the tolerable residues of process chemicals.

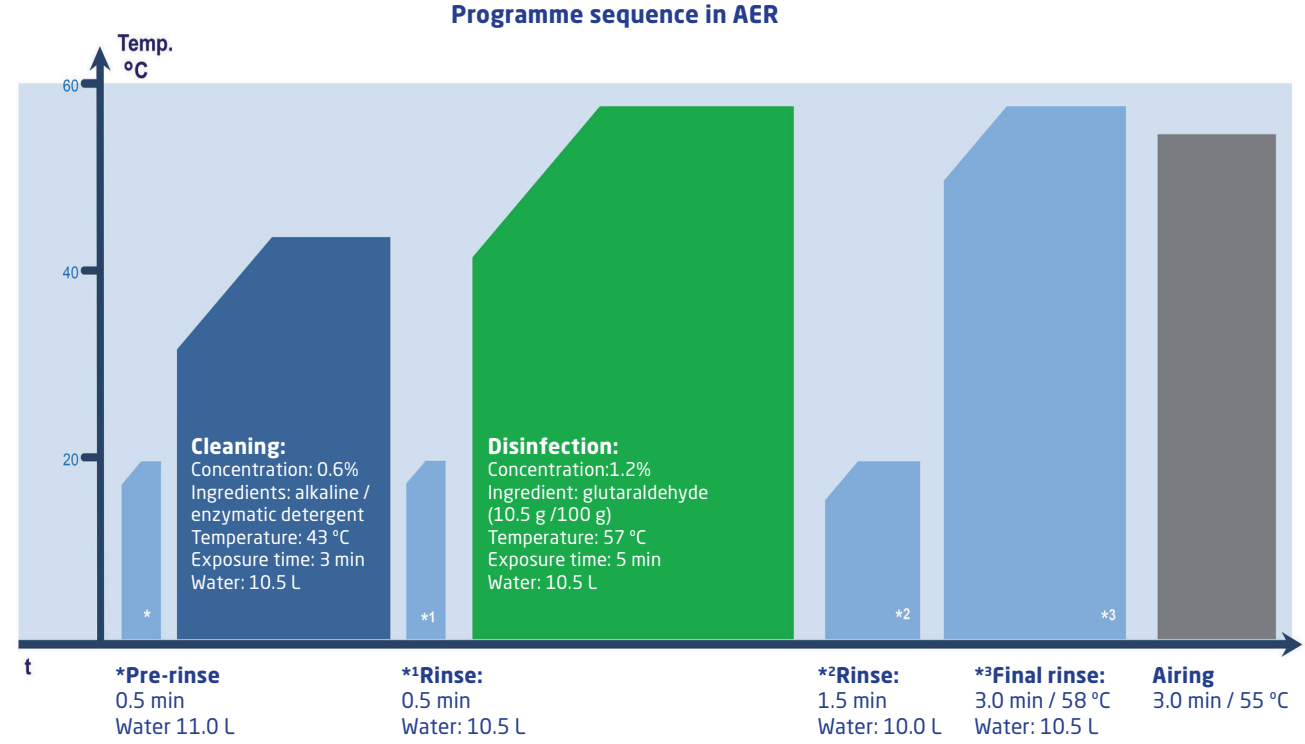

Figure 1: Programme sequence in AER

Summary of the test results

Tests were carried out in triplicate using softened water (<0.18 mmol/l). The cleaning and overall process performance was tested with process challenge devices (PCDs) (2.000 mm PTFE tubes with a diameter of 1 mm and 2 mm; for each test run two PCDs of each diameter) and with two real-life instruments from the manufacturer Olympus: bronchoscope BF-P40 and colonoscope CF-2T160L. The disinfection performance was tested with PCDs based on ISO 15883-4 (Chapter 6.6.2) Annex B.

Cleaning performance

The 2 mm diameter PCDs were contaminated with heparinised sheep blood as per Annex 8 of the *Guideline for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Thermolabile Endoscopes* [5]. The 1 mm diameter PCDs and the real-life instruments were contaminated with heparinised sheep blood and the test organism *Enterococcus faecium* ATCC 6057 as per DIN ISO/TS 15883-5 Annex I. The bronchoscope was precleaned manually with a flexible brush before being subjected to the automated reprocessing process.

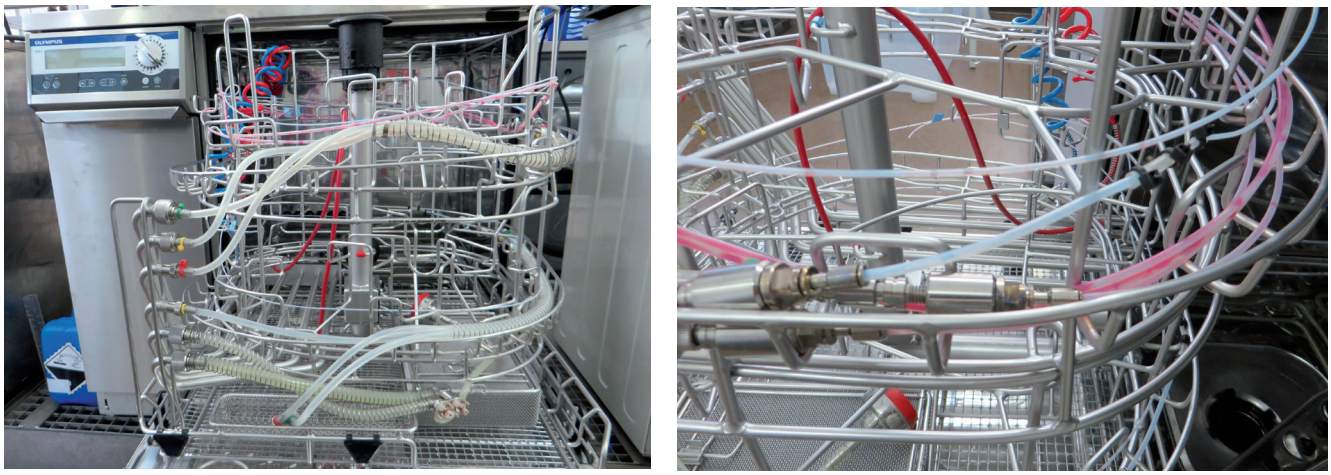

Image 1: AER with connected 2000 mm PTFE tubes, Ø 2 mm and Ø 1 mm

Table 1: Programme steps used to investigate the cleaning, disinfection and overall process performance in the AER

Programme step	Time [min]	Water consumption [L]	Temp. [°C]	Detergent/disinfectant	Dosage of chemicals [%]
Test programme for assessment of the cleaning performance					
Precleaning	0.5	11	23	-	-
Cleaning	3	10.5	43	Detergent (alkalis / enzymes / surfactants)	0.6
First rinse	0.5	10.5	-	-	-
Test programme for assessment of the overall process performance					
Precleaning	0.5	11	23	-	-
Cleaning	3	10.5	43	Detergent (alkalis / enzymes / surfactants)	0.6
First rinse	0.5	10.5	-	-	-
Disinfection	5	10.5	57	Glutaraldehyde (10.5g in 100g concentrate)	1.2
Second rinse	1.5	10	-	-	-
Test programme for assessment of the disinfection performance					
Disinfection	5	10.5	57	Glutaraldehyde (10.5g in 100g concentrate)	1.2
Second rinse	1.5	10	-	-	-

The cleaning performance test results are summarized in table 2 below.

A successful cleaning performance was demonstrated for the reprocessing process tested for the 2 mm PCDs in accordance with the requirements of Annex 8 [5], stipulating that the residual protein content on the PCDs should not exceed 100 μg.

In addition, the reprocessing process tested also met the requirements addressed to the cleaning performance as per DIN ISO/TS 15883-5 Annex I, stipulating a ≥ 4-log level reduction in the microbial count on the PCDs and real-life instruments tested.

Overall process performance

The 2 mm diameter PCDs were contaminated with heparinised sheep blood as per Annex 9 [5]. The 1 mm diameter PCDs and the real-life instruments were contaminated with heparinised sheep blood and the test organism *Enterococcus faecium* ATCC 6057 as per DIN ISO/TS 15883-5 Annex I. The real-life instruments were precleaned manually with a flexible brush before being subjected to the automated reprocessing process.

The overall process performance test results are summarized in table 3 below.

The automated reprocessing process tested met the requirements addressed to the overall process performance as per Annex 9 [5] and as per DIN ISO/TS 15883-5 Annex I, stipulating a ≥ 9-log level reduction in the microbial count on the PCDs and real-life instruments tested.

Disinfection performance

For the disinfection performance the disinfection and second rinse process steps of "standard" programme 1 were investigated in the AER. The test soil consisted of the test organism *Mycobacterium terrae* ATCC 15755 in conformance with ISO 15883-4 (Chapter 6.6.2) Annex B. Following the automated reprocessing process, a 5.11–6.33 $\log_{10}$ level reduction in the microbial count was demonstrated.

The automated reprocessing process tested met the requirements addressed to the disinfection performance as per ISO 15883-4 (6.6.2) Annex B, stipulating ≥ 5 log level reduction in the bacterial spores of the test organism *M. terrae* ATCC 15755 on the PCDs.

Table 2: Cleaning performance test results

PCD	Residual protein content [µg/PCD]	Residual protein content acceptance value [µg/PCD] as per Annex 87
2 mm	31 – 89	≤ 100
PCD	Reduction factor [$\log_{10}$ (cfu/PCD]	Reduction factor limit value [$\log_{10}$ (cfu/PCD)] as per DINISO/TS 15883-5 Annex I
1 mm	4.58 – 5.56	≥ 4
Real-life instrument	Reduction factor [$\log_{10}$ (cfu/channel)]	Reduction factor limit value [$\log_{10}$ (cfu/PCD)] as per DINISO/TS 15883-5 Annex I
Bronchoscope (BF)	5.30 – 5.98	≥ 4
Colonoscope channel A (CF-A)	5.08 – 5.13	
Colonoscope channel B (CF-B)	4.96 – 5.39	

cfu: colony forming unit

Table 3: Overall process performance test results

PCD	Reduction factor [$\log_{10}$(cfu/PCD]	Reduction factor limit value [$\log_{10}$(cfu/PCD)] as per Annex 9[8]
2 mm	9.31 – 9.87	≥ 9
PCD	Reduction factor [$\log_{10}$(cfu/PCD]	Reduction factor limit value [$\log_{10}$(cfu/PCD)] as per DINISO/TS 15883-5 Annex I
1 mm	>9.07 – >9.19	≥ 9
Real-life instrument	Reduction factor [$\log_{10}$(cfu/channel)]	Reduction factor limit value [$\log_{10}$(cfu/PCD)] as per DINISO/TS 15883-5 Annex I
Bronchoscope (BF)	>9.07 – >9.18	≥ 9
Colonoscope channel A (CF-A)	>9.82 – >10.02	
Colonoscope channel B (CF-B)	>9.52 – >9.84	

cfu: colony forming unit

Summary

Publication [6] addressing the scope of the supplementary AER type test served as the first guide of its kind in Europe to set out the scope and procedural approach for supplementary tests. The scope of the tests described comprised automated cleaning tests, investigation of the overall process performance and investigation of the automated disinfection efficacy for 1 mm and 2 mm PTFE tubes measuring 2.000 mm in length. The test sequence also entailed investigation of real-life instruments.

The test results demonstrated that the highly effective detergent with the specified ingredients achieved very good cleaning results even for short exposure times of only three minutes. In combination with the automated aldehyde-based disinfectant (10.5g glutaraldehyde in 100g concentrate), the stipulated reductions in the bacterial (spore) count for the overall process as well as in the mycobacterial count in the disinfection step were fully achieved.

Publication [6], which was compiled on behalf of the working group responsible for formulating the *German Guideline for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Thermolabile Endoscopes*, can be implemented in everyday practice and gives operators/users the assurance that the process chemicals used by them in the AER will achieve the specified cleaning and disinfection performance for both the test model and real-life instruments.

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