

Validation of the TOSI-FlexiCheck system

Summary of cleaning test results
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1. Introduction

Validation is defined as the proof that a certain process fulfils the requirements for its intended use. The intended use of the TOSI-FlexiCheck system is to monitor automated cleaning procedures for flexible endoscopes and give information regarding its ability to remove blood and Polysaccharides. The validation procedure will therefore check the ability of TOSI-FlexiCheck to indicate efficient or inefficient cleaning conditions.

2. material and methods

Test object holder: 1 meter silicon tube with stainless steel capsula and luer-lock connector (FlexiCheck).

Test object: Stainless steel stripe with 2 spots of standardised test soil, one polysaccharide mixture and one protein soil correlating to human blood (TOSI-FlexiCheck).

Test conditions: Cleaning parameters, detergent and water quality as mentioned in table 1 and table 2. Flow through FlexiCheck: 500ml/min.

3. Results

Table 1

Test results for efficient cleaning conditions (cleaning-time/-temperature/-chemistry)

time	Temp.	detergent	Water quality	Test result
10 min	45°C	enzymatic	demin.-water	Completely clean

time	Temp.	Detergent	Water quality	Test result
10 min	30°C	alkaline	demin.-water	Completely clean

Table 2

Test results for inefficient cleaning conditions (cleaning-time/-temperature/-chemistry). The problematic parameters are marked in red

time	Temp.	detergent	Water quality	Test result
5min	45°C	neutral	demin.-water	Fibrin residue

time	Temp.	detergent	Water quality	Test result
3 min	30°C	enzymatic	demin.-water	Fibrin residue

time	Temp.	detergent	Water quality	Test result
10 min	45°C	enzymatic	hard water (20°dH)	Polysaccharide residue

time	Temp.	detergent	Water quality	Test result
10 min	45°C	acidic	demin.-water	Polysaccharide residue

time	Temp.	detergent	Water quality	Test result
10 min	70°C	neutral	demin.-water	red protein residue

time	Temp.	detergent	Water quality	Test result
10 min	30°C	1%Glutaraldehyde	demin.-water	red protein residue

4. Discussion

The results in table 1 indicates a good cleaning efficiency by a completely clean TOSI-FlexiCheck (positive result). Problematic cleaning conditions are indicated by residues left on the test objects (negative result). Next to the positive/negative result of TOSI-FlexiCheck additional information are given by the 2 different test soils for troubleshooting and optimisation of cleaning procedures. The validation criteria for the TOSI-FlexiCheck system are therefore met and the system is able to monitor the cleaning efficiency of automated flexible endoscope washers with single channel irrigation system.