Assessment for virus-decontaminating / virus-inactivating processing of bedpans and urine bottles in the Flusher disinfectors Ninjo FD1600 and Ninjo FD1610 from Arjo

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Introduction

Flusher Disinfectors / Bedpan washers are mainly used in patient care and therefore in a hygienically particularly sensitive area.

In order to ensure the safety of staff and patients from an unwanted contamination with microorganisms or viruses from faeces, the devices and processes used must have a comprehensive decontamination and disinfection performance, in addition to the efficient cleaning of the items to be washed.

The technique used for processing generally works at temperatures of more than 40 °C and is therefore comparable to a chemo-thermal processing procedure. However, for the assessment of processes tested in this way, it is not decisive to control individual process steps, but the efficiency of the entire processing procedure, only.

Experimental Investigation

The devices to be assessed were two Flusher Disinfectors **Ninjo FD1600** and **Ninjo FD1610** from Arjo.

Testing and proof of virus efficacy were carried out based on EN 17111 (2018)[1]. The test soil, consists of bovine serum albumin, mucin and corn starch (RAMS), was carried out in accordance with the European Standard EN ISO 15883-5, 2005[3], but performed with Murine Norovirus. The design of the complete test protocol in the machine itself was carried out in accordance with the European Standard EN ISO 15883-3, 2009[2].

For the investigation, the Flusher disinfector was loaded according to the specifications of EN 15883-3 with bedpans, urine bottles and virus-contaminated germ carriers. In addition, virus-contaminated germ carriers were also fixed on the inner wall of the machine chambers.

The items to be washed were then treated according to the standard cleaning and disinfection program P5 which includes the following processing steps:

- Rinse with cold water
- Rinsing with mixed cold / hot water
- Rinse with hot water
- Rinse with hot water and Arjo Flusher Detergent
- Rinse with hot water
- Disinfection at 91 °C / 60 seconds contact time
- Cooling and Flusher rinse

At the end of the procedure, the carriers were recovered, eluted and the elution fluid was then titrated for residual virus on RAW 264.7 Cells. The investigation was carried out using three independent test approaches for FD1600 and one approach for FD1610. Virus-contaminated germ carriers that were not subjected to the treatment process served as controls.

In addition to the contaminated test specimens, a test carrier with the test soil only but without a virus suspension was included in each treatment process in order to check the cytotoxicity of process residues and other influences. Finally, the last rinse water was also examined for the presence of the test virus.

The tests were carried out in the HygCen test laboratory in Schwerin, Germany which is accredited for these kind of investigations, and are documented under the test numbers SN 33281-I and SN 33746 in the test facility.

The tested machines FD1600 and FD1610 are identical in their construction and work with the same machine standard program. Only the material of the machine chamber is different. The FD1600 has a heat-resistant plastic chamber, while the FD1610 has a stainless steel flushing chamber. The study was reproduced three times using the FD1600. An additional investigation in the FD1610 with only one test run served as a control to confirm the inert influence of the chamber material for both machines.

Results

At an application titre of $10^{4,63}$ $TCID_{50}$ (first test run) and $10^{4,75}$ Tissue Culture Infectious $Dosage_{50}$ (TCID) of Norovirus per germ carrier (second and third test run), no residual test virus could be detected after undergoing the complete treatment cycle in all three test runs. In addition, no test virus could be found in the rinse water at the end of the process either and a titre reduction, significantly more than 4 log steps could therefore be documented by the overall process.

Furthermore, the eluate of the carriers for checking cytotoxic effects did not show any cytotoxic effects. Thus cytotoxicity was less than 0.50 lg $TCID_{50}$.

Summary and Evaluation

Based on the previously described experimental investigations about the decontamination and disinfection of Norovirus in the Flusher Disinfectors Ninjo FD1600 and Ninjo FD1610 from Arjo, and in compliance with the disinfection parameters of 91 °C / 60 seconds a comprehensive decontamination and disinfection efficacy can be certified. When the standard processing procedure is carried out a titre reduction of more than 4 log steps can be expected.

Conclusion

The Flusher Disinfectors Ninjo FD1610 and Ninjo FD1600 from Arjo have achieve a comprehensive virus-effective decontamination and disinfection effect against norovirus. When the program P5 is carried out and the disinfection parameters of 91 °C / 60 seconds contact time are used, **this effectiveness can also be expected against common human pathogenic viruses of the intestinal tract under the same conditions as for rotaviruses, adenoviruses or coronaviruses.**

Since Ninjo FD1610 and FD1615 are identical in construction of the chamber and technical parts related to the cleaning and disinfection process, it can be assumed that virucidal efficacy applies to all Ninjo models.

References

1. **European Standard EN 17111:** Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2).
2. **EN ISO 15883-3:** Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers, as of 2009.
3. **ISO/TS 15883-5:** Test soils and methods for demonstrating cleaning efficacy, as of 2005.

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