# Validation of TOSI®Test Object Surgical Instruments for the Monitoring of the Cleaning Efficiency of Washer-Disinfectors

Martin Pfeifer, Waldkraiburg, Federal Republic of Germany

**Summary**

Validation as the proof of intended use is of major importance for any test monitors for all type of Medical Devices. The following describes the validation of the newly introduced TOSI® test objects as a useful monitor for the control of the cleaning efficiency relative to blood and blood components in washer-disinfectors. The results show correlation of the TOSI® test soil to human blood as well as easy reading and safe interpretation of results through visual inspection of the test objects while compared to a chemical test method. All data proof the achievement of the requested design goals of TOSI®.

**Key words:** Cleaning efficiency; Reprocessing of instruments; Test objects; Test soil; Validation; Washer-disinfector;

## Introduction

Literature gives a lot of definitions for the term "Validation" starting with the proof of principle of a certain method all way down to the documentation of a process which results in a product with defined and guaranteed quality. There is no doubt about the importance of the proof of principle of a certain technique, however the proof of sense of a product only correlates with the defined quality of such product. As an example, fast food products definitely have a defined quality even though people may have a different opinion about such quality.

As a general definition "Validation" shall be explained as the proof that a certain process fulfils the requirements for its intended use. As a first step this intended use has to be defined either by general public interest or through legal regulations. In next steps the intended use of such process shall be defined precisely including all necessary testing procedures and an answer has to be given in respect to the process' capability to meeting the requested requirements.

In the specific case of the development of a monitor for the detection of the cleaning efficiency in washer-disinfectors the following goals had to be achieved: There is general public interest that CSSD provides surgical instruments which are free from any residuals which may cause harm to patients, personnel or any third party, and there is the European Medical Device Directive and its corresponding regulations of each member state like the German Medical Device Law (MPG) and the German Medical Device Operator Regulations (MPBetreibV). The latter was published in June 1998 and went into effect immediately without any transition period. The regulations require that the function of each washer-disinfector has to be tested and reconfirmed prior to use. Future regulations, norms and directives will take care about most of the quality requirements of Medical Devices and its monitors.

## Materials and methods

### 1. General requirements

There are a lot of different washer-disinfectors available on the market place. They are equipped with a number of different programmes consisting of rinsing steps with cold water, cleaning steps followed by rinsing again, disinfection, rinsing, instrument care steps and drying.
The variety of materials to be reprocessed includes different types of surgical instruments, plastic parts and even glassware. Soils may be multivariable as well. Aside of blood and blood components, there are i.e. residuals of ointment or stool. It is clear that such variety of cleaning-disinfection programs, materials and soils requires more than the validation of just one process.

This is also the case for the validation of a useful monitor for the control of the cleaning efficiency. TOSI® Test Object Surgical Instruments was designed for the monitoring of the cleaning efficiency when reprocessing blood-contaminated surgical instruments in washer-disinfectors. Blood is by far the most frequent contaminant on surgical instruments and is considered to be of high hygienic relevance. In addition blood coagulation and high concentration of proteins result in complex chemical reactions, which may severely impact the whole reprocessing. Additional test objects and test soils are under development to cover materials and soils other than blood on surgical instruments.

The designated intended use of TOSI® is the monitoring of the cleaning efficiency relative to blood. Critical parameters for the blood removal during cleaning in a washer-disinfector are mechanical parameters like water pressure, distribution of water or ultrasonic, but also chemical parameters like the pH-value and the water quality as well as the cleaning temperature.

This “simple” job of just rinsing away blood from instruments may be superposed by conditions which are specific for blood proteins like:

- water solubility of proteins
- denaturation effects
- hydrolysis
- mechanical detaching

Any change of a critical cleaning parameters may impact this sensitive interplay resulting in insufficient cleaning. Some examples are changes of cleaning chemistry or its dosage, of cleaning temperature or time, or any mechanical disturbances as caused by a blocked spray system.

In order to control all relevant parameters TOSI® combines the features of a test soil correlated to human blood with a specially designed test object. The blood cleaning efficiency is shown visually immediately after the end of cycle.

### 2. Suitability Test

The first question to be answered concerns the cleaning efficiency of a washing cycle. What causes good, incomplete or inferior results and how are they detected? A known high cleaning efficiency may be reached with alkaline detergents at a high cleanjng temperature. Assuming along enough cleaning cycie time combined with reliable mechanical performance of the machine there should be efficient cleaning of the reprocessed instruments, and TOSI® should confirm the result. Insufficient results may be caused by any handling mistake or by an invalid process.
Two protocols were used for suitability testing: In one protocol the first rinsing cycle was conducted at a temperature higher than the denaturation temperature of blood proteins with the result of a partial hardening of proteins which could not be dissolved

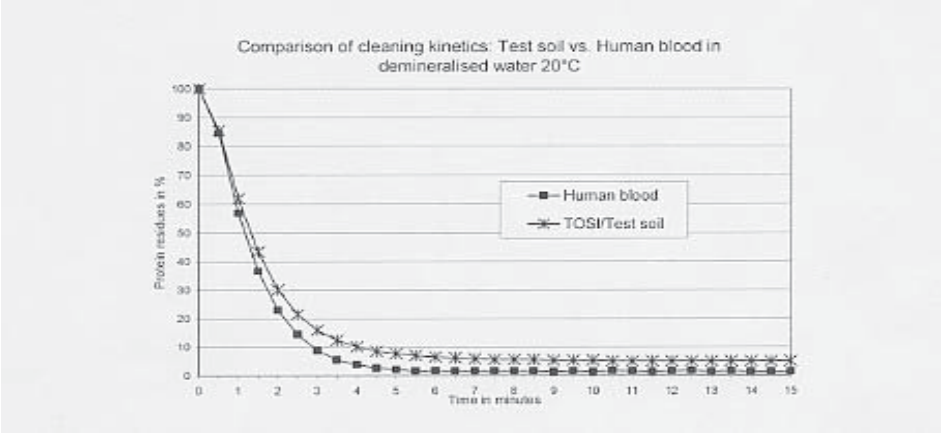
during the following cleaning cycle. In another protocol an alkaline detergent was used at a too low temperature and was therefore unable to decompose the fibrin fibres.

In addition the general detaching capabilities of blood and the TOSI® test soil were compared to confirm TOSI®'s correlation with human blood.

**Results**

**1. Correlation with blood**

Washer-disinfectors are no useful tool for such study as the spray systems and the resulting distribution of water do not generate homogenous and reproducible cleaning conditions inside the machine. A dipping process in a suitable basin with demineralised water is a much better and more reproducible tool to test the correlation of the TOSI® test soil with human blood. Measuring the amount of detached substances online will result in the cleaning kinetics of the test soil and human blood which may than be compared. Fig. 1 shows the correlation between the standardised test soil and human blood in demineralised water at room temperature.




*Comparison of cleaning kinetics: Test soil vs. Human blood in demineralised water 20°C*

*Time in minutes*

Fig. 1: Comparison of cleaning kinetics: Test soil vs. Human blood in demineralised water

This correlation study indicates another important conclusion concerning the composition of blood. It is clearly visible that most of the blood proteins are water soluble while only relatively little residuals of water insoluble fibrin fibres remain on the test object. But it also says that a 100% cleaning efficiency may not be achieved with water only, therefore the aid of mechanical cleaning parameters is needed.

The standardised TOSI®test soil simulates this phenomenon. Corresponding fibrin fibres forming coagulation factors are used in the test soil at a level which is somewhat higher than in coagulated human blood to represent worst case scenario conditions.

## 2. Reading of Cleaning Efficiency

In addition to the dipping protocol for correlation testing the TOSI® test soil was also examined in a special testing washer-disinfector under various test conditions. All test were conducted in 6 replicates with 3 test objects per run.

**Test A:** Mistake in initial rinsing protocol caused by too high temperature resulting in denaturation of blood proteins. This trial was simulated by cleaning in demineralised water at 65°C for 10 minutes.
**Result:** The test soil remained more or less completely on the test object.

**Test B:** Cleaning with low efficiency caused by mistake in temperature selection. This trial was simulated in a cleaning programme with 0.5% alkaline detergent in demineralised water at 30°C for 10 minutes.
**Result:** Fibrin residuals are easily detectable.

**Test C:** Efficient cleaning with protein hydrolysis. This trial was simulated in a cleaning programme with 0.5% alkaline detergent in demineralised water at 80°C for 10 minutes.
**Result:** All test objects show optimal result with no residuals left.

In addition to the visual inspection of the TOSI® test objects the remaining residuals were dissolved in sodium hydroxide and chemically measured in the UV-region of the light spectrum.

Fig. 2 shows the amount of proteins measured with the chemical sodium hydroxide hydrolysis before and after each trial. The graphic shows the average of each of the 18 tests obtained in each trial.

*Chemical evaluation by hydrolysis*

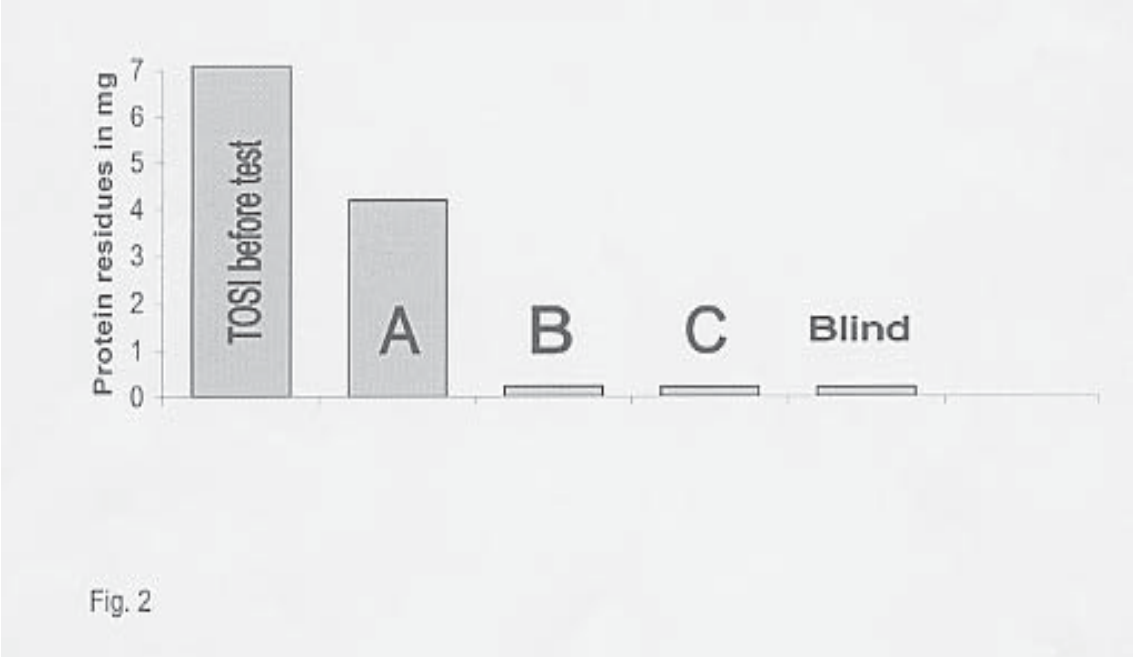



Fig. 2

Fig. 3 shows photographs of the results of the optical evaluation of the test results. Note: In order to allow for best picture quality the plastic clips of the test objects were removed.

For visual inspection a schedule of 6 (from 0 to 5) is recommended, where 0 stands for an optically clean result while 5 stands for test soil still completely available. Table1 shows the results of the Tests A, B and C and its classification according to schedule 0-5.

Important note: Within tests all 18-test objects showed the same reading.

| | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| A | | | | | | X |
| B | | | X | | | |
| C | X | | | | | |

Tab. 1

A comparison of the chemical evaluation with the simple visual inspection shows very good correlation. Therefore visual inspection of test objects is considered to be a valuable detection system, mainly knowing that protein residuals may be visually detected at low jug-levels already. The more complicated chemical determination has the disadvantage that smaller amount of proteins like shown in trial B may interfere with high background measures caused by residuals of the cleaning detergent.

**Discussion**

The TOSI® test soils correlates with human blood and is therefore a safe monitor to control the complex cleaning process of blood contaminated surgical instruments. Handling mistakes or parametric conditions causing insufficient cleaning of blood contaminations are detected safely.

TOSI® is not intended to be a monitor to detect mistakes which may happen during disinfection, instrument care and drying. Generally TOSI® is intended to monitor the cleaning efficiency of the total process, therefore mistakes may add up or a very strong process parameter may balance a weaker process parameter.

At current TOSI® test objects are intended for the control of the cleaning efficiency during the reprocessing of blood contaminated standard surgical instruments. Other test objects for the monitoring of the cleaning efficiency of complex instruments (i.e. MIS-instruments) and other soils are under development.

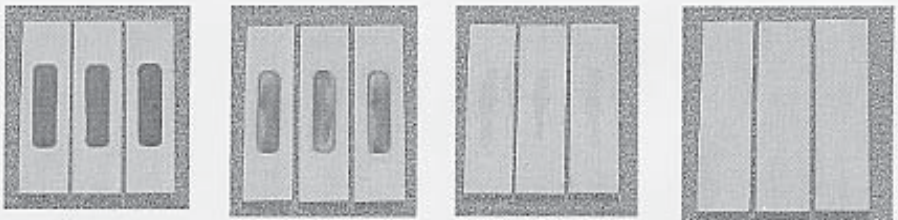



Fig. 3