

# **Performance Comparison of Wash-Checks and Tosi<sup>®</sup>, two commercially available Control Systems for Monitoring of the Cleaning Efficacy in Washer- Disinfectors in Daily Routine**

**Introductory note:** *This summary is solely an extract of a comparison study conducted by Reinfried Früh, Kronberg, Germany, in March of 2007 at CISA S.r.l., Pomezia, Italy. The complete study was accepted for publication in Krankenhaus-Hygiene + Infektionsverhütung (Krh.-Hyg. + Inf.verh.) and will be published in volume 4/07.*

## **Summary**

The purpose of this comparison study was to evaluate commercially available washer monitors for the control of the cleaning efficiency in washer-disinfectors under daily routine conditions. The systems compared in this study showed ease of use in the assembly for testing (where needed) as well as simple and accurate result interpretation when following the manufacturer instructions.

Test conditions were selected to identify the potential of these monitoring systems to allow for accurate reading of results in expected PASS conditions and also to detect any fault which may harm cleaning efficacy. Thus testing was conducted in commercially available routine washer-disinfectors using commercially available chemistry. A recommended test soil as outlined in EN ISO 15883 was used as a reference.

Test results revealed a very close correlation between Tosi, Wash-Checks and the reference material according to EN ISO 15883. Both products under investigation correlated very well with the expected result. This was confirmed by close correlation with the reference material used, even though the reference material did show some performance limitations relative to the selected cleaning parameters.

As a conclusion it may be summarized that Tosi and Wash-Checks proved their capabilities as useful tools for the monitoring of cleaning efficiency in washer-disinfectors in daily routine.

## **Introduction**

The monitoring of the efficiency of cleaning steps in reprocessing Medical Devices (MD) became of growing importance since Creutzfeldt-Jacob Disease and other infectious diseases caused by prions implemented a new level of infectivity in medicine. It is common understanding among hygiene experts around the world that efficient cleaning of MD prior to further treatment, including sterilization, is important to the proper functioning of MD and its safe usage with patients and personnel. New surgical techniques like minimal invasive surgeries (MIS) further increased the necessity of proper handling of each single reprocessing step including the washing and disinfection steps.

This has also generated demand for the implementation of proper control tools. The harmonised Norm EN ISO 15883 describes several alternative test soils identified to be useful for the monitoring of cleaning efficiency in washer-disinfectors. However, none of these options allow an easy and immediate read-out and interpretation in daily routine. Not surprisingly, industry was searching for such alternatives. In this study commercially available systems for the monitoring of the cleaning efficiency in washer-disinfectors were compared and correlated with one of the reference test soils recommended in EN ISO 15883.

This performance evaluation was conducted at CISA S.r.l., located in Pomezia, Italy, using freely programmable routine washer-disinfectors of the “Kappa 105 Range”. CISA is a leading manufacturer of sterilizers and washer-disinfectors in Europe. Commercially available alkaline and enzymatic detergents were used according to manufacturer’s specifications and dosage recommendations. In addition numerous process variables including the critical parameters temperature, time, detergent dosage, water pressure and mechanical defaults were investigated in order to simulate failure conditions and to evaluate the capabilities of commercially available washer monitors as well as the reference test soil to detecting any malfunction in the washer-disinfector.

## Materials and Methods

**Test apparatus:** Washer-disinfector, CISA, Model **Kappa 155**  
Manufacturer: CISA S.r.l., Via Pontina Km.28, I-00040 Pomezia (RM), Italy  
Chamber dimension: 630 x 680 x 840 mm, volume 355 litres  
Number of levels: 5  
Number of rotating spray arms: 6 (set-up to allow water supply from above and below each level)  
Load: standardized load consisting of a total of 10 trays (baskets) at a size of 48 x 25 x 5 cm each, two trays located on each level  
Two identical washer-disinfectors were used in side by side test, one connected to an alkaline cleaner, the other to an enzymatic cleaner.  
**Important note:** Cycles were interrupted after final cold rinsing and prior to the start of the disinfection mode.

**Detergents:**

**Alkaline cleaning cycles:**  
Cleaning: **neodisher® FA**, LOT 302016/0107, Exp.-D.: 01/2011  
pH (in demineralised water at 20°C) 2-4 ml/l: 11.4 – 11.9  
Manufacturer: Chemische Fabrik Dr. Weigert GmbH & Co,  
Mühlenhagen 85, D-20539 Hamburg, Germany  
Neutralisation: **neodisher® Z**, LOT 299981/0107, Exp.-D.: 01/2011; pH (in demineralised water at 20°C) 1-5 ml/l: 3.0 – 2.6  
Manufacturer: Chemische Fabrik Dr. Weigert GmbH & Co,  
Mühlenhagen 85, D-20539 Hamburg, Germany

**Enzymatic cleaning cycles:**  
**deconex® 23 NEUTRAZYM**, LOT 128395, Exp.-D.: 2008-11  
pH (in demineralised water at 20°C) 1% solution: approx. 8.8  
Manufacturer: Borer Chemie AG, Gewerbestr. 13, CH-4528  
Zuchwil, Switzerland

**Note:** Selection of reagents was based on CISA's current choice for its evaluation and testing purposes, corresponding reagents from other manufacturers may yield to same/similar results.

**Test material A:** TOSI<sup>®</sup>, LOT 700630, Exp.-D.: 04/2008; Manufacturer: Pereg GmbH, Porschestra. 12, D-84478 Waldkraiburg, Germany

**Test material B:** Wash-Checks, LOT 060802, Exp.-D. 08-2008 and LOT 061101, Exp.-D. 11-2008; Manufacturer: Steritec Products, Inc., Castle Rock, CO 80109, U.S.A.

**Reference mat.:** Test soil according to EN ISO 15883 made from heparinized Sheep Blood with Protamin applied to Crile arterial clamps; prepared by: iki - Institut für Krankenhaushygiene und Infektionskontrolle GbR, Siemensstr. 18, D-35394 Gießen, Germany; visual inspection and protein determination (modified Biuret-method, "Reagent Kit for Protein Determination for the Cleaning Control of Surgical Instruments", manufactured by E. Merck, Darmstadt, Germany, for Miele Professional, Miele & Cie. KG, Gütersloh, Germany), conducted by: iki - Institut für Krankenhaushygiene und Infektionskontrolle GbR, Siemensstr. 18, D-35394 Gießen, Germany (certified reference laboratory)

## Positioning of Monitors

One sample each of the test materials and one reference test were positioned in two different locations of the washer-disinfector. The locations had been identified to be critical spots during several pre-qualification runs. For this purpose initial tests were conducted by positioning the set of 3 test materials and reference in different corners on level 1, 2, 4 and 5 in the washer-disinfector. These pre-qualification runs indicated critical spots on level 1 (highest level, left corner, close to back-door) and level 5 (lowest level, right corner, close to front-door). These two locations were selected for the test profile. Test materials and reference were placed in the cycles together and run simultaneously. Test materials were positioned according to the corresponding manufacturer recommendations in their instructions for use. Within the test materials the relative positioning in the selected corners was rotated. The reference material was positioned horizontally close to the test materials.

## Time and Location of Evaluation

All tests were conducted in week 12 of year 2007 at the premises of CISA Company.

## Test Results

Reading and interpretation of the test materials were conducted according to the individual manufacturer's recommendations.

Consequently the readout of test material A (Tosi) was grouped in 6 classes 0-5 with only Level 0 (test soil is completely dissolved, no test soil residuals are left) being accepted as a good result according to the manufacturer's instructions. For details please refer to the manufacturer's instructions.

The readout of test material B (Wash-Checks) according to the instructions for use is classified in four levels with level 1 standing for complete rinsing of the test soil (optimum result), level 2 for very little residuals of the test soil (minor residuals, borderline acceptable result), level 3 for significant residuals of test soil at a major portion of the test field (poor result) and level 4 with no or only very little removal of the test soil (clear fail = critical result).

The readout of the reference material was made twofold one using visual inspection for any residuals and the second using an accepted protein determination method (modified Biuret-method, see Section Materials and Methods above). Due to known inaccuracies in the visual reading caused potentially by inorganic residuals the reference institute entrusted with the manufacturing and evaluation of the reference soil material considers the biochemical result as being the more valid evaluation. Biochemical determination was done semi-quantitative by the differentiation at levels of 0, 25, 50, 100 and higher than 100 micrograms per millilitre.

### Test Profiles Conducted and Results

**Note:** For interpretation guidance of test materials A plus B and the reference material please refer to Section "Readout of Results" above

#### A) Test cycles conducted with alkaline cleaning chemistry

Cycle profile: Cold rinsing, washing according to the cycle parameters specified in each experiment, neutralization, cold rinsing, process stopped prior to disinfection

A1) Cycle parameters: T = 60°C, t = 5 minutes, dosage 3 ml/l

(Note: dosage range recommended by detergent manufacturer: 2-4 ml/l)

Water quality: Demineralised water

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 1 fault	Level 1 fault
Test material B (Wash-Checks)	Residuals detected (2-3)	Poor result (level 3)
Reference mat. (EN ISO 15883)	0 µg/ml	75 µg/ml

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Conclusions: Insufficient cleaning, good correlation among the monitoring systems tested

A2) Cycle parameters: T = 60°C, t = 5 minutes, dosage 5 ml/l (increased dosage)

Water quality: Demineralised water

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 2 fault	Level 0 (pass)
Test material B (Wash-Checks)	Minor residuals (2)	Minor residuals (2)
Reference mat. (EN ISO 15883)	0 µg/ml	50 µg/ml (no vis. cont.)

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Conclusions: Improved cleaning vs. experiment A1 due to increased dosage, acceptably good correlation among the monitoring systems tested

A3) Cycle parameters: T = 60°C, t = 10 minutes, dosage 3 ml/l (increased time)  
Water quality: Demineralised water

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 4 fault	Level 0 (pass)
Test material B (Wash-Checks)	Minor residuals (2)	Optimum result (1)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

Conclusions: Significantly improved cleaning vs. experiment A1 due to increased cleaning time, Tosi with a surprisingly poor cleaning result in tray at machine level 1 (highest)

A4) Cycle parameters: T = 60°C, t = 10 minutes, dosage 5 ml/l (incr. time + dosage)  
Water quality: Demineralised water

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 1 fault	Level 0 (pass)
Test material B (Wash-Checks)	Minor residuals (2)	Minor residuals (2)
Reference mat. (EN ISO 15883)	25 µg/ml	50 µg/ml

Conclusions: Significantly improved cleaning vs. experiment A1 due to increased cleaning time and temperature, generally good among the monitoring systems tested

A5) Cycle parameters: T = 60°C, t = 10 minutes, dosage 7 ml/l (rec. cycle f. tub-water)  
Water quality: Tub water, 40 dH (very hard water)

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 0 (pass)	Level 0 (pass)
Test material B (Wash-Checks)	Minor residuals (2)	Optimum result (1)
Reference mat. (EN ISO 15883)	50 µg/ml	0 µg/ml

Conclusions: Good cleaning obtained with recommended cycle parameters for the quality of tub-water, generally acceptable correlation among the monitoring systems with some limitations and spreading of result at machine level 1 (highest)

A6) Cycle parameters: T = 60°C, t = 10 minutes, dosage 3 ml/l (reduced dosage)  
Water quality: Tub water, 40 dH (very hard water)

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 2 fault	Level 2 fault
Test material B (Wash-Checks)	Residuals detected (2-3)	Optimum result (1)
Reference mat. (EN ISO 15883)	75 µg/ml	0 µg/ml

Conclusions: Still acceptable cleaning obtained with reduced dosage (compare to cycles 3 and 6), with some limitations acceptable correlation among the monitoring systems

A7) Cycle parameters: T = 45°C, t = 10 minutes, dosage 7 ml/l (red. temperature)  
Water quality: Tub water, 40 dH (very hard water)

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 1 fault	Level 2 fault
Test material B (Wash-Checks)	Optimum result (1)	Minor residuals (2)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

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Conclusions: Still good cleaning obtained with reduced temperature, acceptable correlation among the monitoring systems

A8) Cycle parameters: T = 45°C, t = 10 minutes, dosage 5 ml/l (reduced T + dosage)  
Water quality: Tub water, 40 dH (very hard water)

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 4 fault	Level 4 fault
Test material B (Wash-Checks)	Clear fail result (4)	Clear fail result (4)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

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Conclusions: Poor cleaning confirmed by the test materials, reference material however did not show any biochemical result; correctness of reference material questioned

## **B) Test cycles conducted with enzymatic cleaning chemistry**

Cycle profile: Cold rinsing, washing according to the cycle parameters specified in each experiment, rinsing, process-stop prior to disinfection step.

B1) Cycle parameters: T = 45°C, t = 10 minutes, dosage 5 ml/l (rec. dosage)  
Water quality: Demineralised water

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 2 fault	Level 1 fault
Test material B (Wash-Checks)	Clear fail result (4)	Minor residuals (2)
Reference mat. (EN ISO 15883)	50 µg/ml	0 µg/ml

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Conclusions: Good cleaning obtained with recommended cycle parameters at low level; failures detected at highest level

B2) Cycle parameters: T = 45°C, t = 10 minutes, dosage 7 ml/l (increased dosage)  
Water quality: Demineralised water

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Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
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Test material A (Tosi)	Level 0 (pass)	Level 0 (pass)
Test material B (Wash-Checks)	Minor residuals (2)	Optimum result (1)
Reference mat. (EN ISO 15883)	50 µg/ml	0 µg/ml

Conclusions: Good cleaning obtained with recommended cycle parameters, but still detected soil residuals with reference material and some with Wash-Checks at machine level 1

**B3) Cycle parameters: T = 45°C, t = 10 minutes, dosage 10 ml/l (increased dosage)  
Water quality: Demineralised water**

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 0 (borderline pass)	Level 0 (pass)
Test material B (Wash-Checks)	Optimum result (1)	Optimum result (1)
Reference mat. (EN ISO 15883)	25 µg/ml	0 µg/ml

Conclusions: Good cleaning obtained with recommended cycle parameters, still detected minor soil residuals with reference material at high machine level 1

**B4) Cycle parameters: T = 60°C, t = 10 minutes, dosage 7 ml/l (incr. T + dosage)  
Water quality: Demineralised water**

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 0 (pass)	Level 0 (pass)
Test material B (Wash-Checks)	Optimum result (1)	Optimum result (1)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

Conclusions: Good cleaning obtained with increased temperature, very good correlation of the test materials incl. reference material

**B5) Cycle parameters: T = 75°C, t = 10 minutes, dosage 7 ml/l (further increased T)  
Water quality: Demineralised water**

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 1 fault	Level 0 (pass)
Test material B (Wash-Checks)	Optimum result (1)	Optimum result (1)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

Conclusions: Good cleaning obtained with high temperature cycle, very good correlation of Tosi, Wash-Checks and reference material

**B6) Cycle parameters: T = 45°C, t = 10 minutes, dosage 4 ml/l (reduced dosage)  
Water quality: Demineralised water**

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 1-2 fault	Level 1 fault
Test material B (Wash-Checks)	Minor residuals (2)	Optimum result (1)
Reference mat. (EN ISO 15883)	50 µg/ml	0 µg/ml

Conclusions: Acceptable cleaning obtained even at lowered dosage, very good correlation of the test materials and the reference material

B7) Cycle parameters: T = 45°C/t = 3 min + T = 60°C/t = 3 min, dosage 7 ml/l (2-step “high efficiency” profile recommended by detergent manufacturer)  
Water quality: Demineralised water

Monitoring System	Result Tray 1 (highest)	Result Tray 5 (lowest)
Test material A (Tosi)	Level 0 (pass)	Level 0 (pass)
Test material B (Wash-Checks)	Optimum result (1)	Optimum result (1)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

Conclusions: Optimum cleaning obtained with this 2-step profile recommended by the detergent manufacturer

**C) Test cycles conducted without cleaning detergents (water only)**

Cycle profile: Cold rinsing, washing according to the cycle parameters specified in each experiment, cold rinsing, process-stop prior to disinfection step.

C1) Cycle parameters: T = 60°C, t = 10 minutes, dosage 0 ml/l (no chemistry)  
Water quality: Tub water, 40 dH (very hard water)

Monitoring System	Result Tray 1 (highest)	Result Tray 5
Test material A (Tosi)	Level 4 fault	Level 2 fault
Test material B (Wash-Checks)	Clear fail result (4)	Clear fail result (4)
Reference mat. (EN ISO 15883)	100 µg/ml	> 100 µg/ml

Conclusions: Cycle without chemistry detected by all monitors, result with Tosi at machine level 5 is somewhat soft relative to the extend of the problem

C2) Cycle parameters: T = 75°C, t = 10 minutes, dosage 0 ml/l (no chemistry, high T)  
Water quality: Tub water, 40 dH (very hard water)

Monitoring System	Result Tray 1 (highest)	Result Tray 5
Test material A (Tosi)	Level 4 fault	Level 4 fault
Test material B (Wash-Checks)	Clear fail result (4)	Clear fail result (4)

Reference mat. (EN ISO 15883) > 100 µg/ml 0 µg/ml

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Conclusions: Cycle without chemistry detected by both commercial monitors even at higher temperature, negative result with the reference material at machine level 5 is to be considered a critical malfunction

#### D) Other failure cycles

Cycle profile: Cold rinsing, washing according to the cycle parameters specified in each experiment, neutralization, cold rinsing, process-stop prior to disinfection step.

D1) Cycle parameters: T = 60°C, t = 10 minutes, dosage 7 ml/l alkaline detergent (standard tub-water)

Water quality: Tub water, 40 dH (very hard water)

Spray arms below level 1 and 4 blocked, monitors positioned at level 1 and 4 = no water supply from below at level 1 and only indirect water supply at level 4

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Monitoring System	Result Tray 1 (highest)	Result Tray 4
Test material A (Tosi)	Level 4 fault	Level 3 fault
Test material B (Wash-Checks)	Clear fail result (4)	Clear fail result (4)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

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Conclusions: Mechanical problem clearly detected by both Tosi and Wash-Checks, not detected by reference material

D2) Cycle parameters: T = 60°C, t = 10 minutes, dosage 7 ml/l alkaline detergent

Water quality: Tub water, 40 dH (very hard water), other: reduced/low water level

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Monitoring System	Result Tray 1 (highest)	Result Tray 5
Test material A (Tosi)	Level 2 fault	Level 3 fault
Test material B (Wash-Checks)	Poor result (level 3)	Minor residuals (2)
Reference mat. (EN ISO 15883)	0 µg/ml	0 µg/ml

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Conclusions: Water supply problem partly detected by test materials, not by reference material.

Note: Limited value of experiment D2 due to difficulty to control water supply.

## Discussion of Results and Conclusions

The purpose of this comparison study was to evaluate the potential of commercially available washer monitors for the control of the cleaning efficacy in washer-disinfectors under daily routine conditions. Not only should an appropriate washer monitor detect any functioning and/or malfunctioning of the cleaning system, but also it must be easy to use and interpret. All three systems compared in this study showed ease of use in the assembly for testing (where needed) as well as simple and safe reading when following the manufacturer instructions and associated documents for result interpretation.

In order to demonstrate the capabilities of the monitors to detect FAIL and PASS conditions correctly test conditions were set up accordingly. Evaluations did include alkaline and enzymatic cleaning chemistry at recommended concentrations and test profiles but also at lower than suggested dosage, time and/or temperature as well as with parameters higher than recommended by the manufacturer. In addition experiments were generated without any cleaning chemistry and with reduced water pressure.

In the majority of the experiments there was correlation between the test materials used, the reference soil and the predicted outcome based upon the parameters set. As with most of biochemical systems some test results have been identified that do not compare with other testing tools and/or the theory.

In this evaluation the following observations were made which might be considered critical:

- Reference test soil according to EN 15883: Results obtained merely followed the expectations according to the parameter settings and relative to the results obtained with the majority of the test materials used in this study. However there have been several results not following to this logic, like in experiment A8) alkaline cleaner with reduced dosage at reduced temperature, in experiment C2) no chemistry, experiment (level 5 only), D1) blocked spray arms, and experiment D2) reduced water pressure respectively. In none of these cases was the reference material able to detect such a problem although theory would indicate the opposite. On the other hand theory was confirmed by the results obtained with the washer monitors investigated.
- Tosi monitors: Aside from the deviations described above for the reference soil (most likely caused by too easy cleaning of the reference soil) there is only little inaccuracy detected with Tosi monitors, like in cycle 4 with a high FAIL indication at the upper level while other alternatives show acceptable results. On the other hand there are some results indicating proper cleaning with Tosi while the reference material shows insufficient cleaning like in experiments A4, B2 and B3 respectively.
- Wash-Checks: There is very good correlation with theory, Tosi and the reference test soil in the majority of the experiments. All variables were within the range of one interpretation level or less. Relative comparison with the reference soil indicated a good fit for optimum verification of the cleaning capabilities of washer-disinfectors.

Overall test results proved very close correlation of Tosi and Wash-Checks with the reference material according to EN ISO 15883. They also correlate well with the expected result as set by the selection of parameters which was confirmed by good correlation with the reference material.

As a conclusion it may be summarized that Tosi and Wash-Checks proved their capabilities as a useful tool for the monitoring of the cleaning efficiency in washer-disinfectors in daily routine.