INTRODUCTION TO CLEANING INDICATORS

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INTRODUCTION TO EN15883.

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Introduction to EN15883

What is the content of this validation norm for WD's

- Part 1: General requirements, terms and definitions and tests
- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo labile endoscopes
- Part 5: Test soils and methods for demonstrating cleaning efficacy [Technical Specification]

Introduction to EN15883

Part 1 - 6.10 Test of cleaning efficacy

- **6.10.1 General**
- During tests of cleaning efficacy, the cycle shall be run without a disinfection stage.
- The drying stage may also be omitted if this is necessary to facilitate the detection of residual contamination or test soil.

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Part 1: General requirements, terms and definitions and tests

- This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.
- It specifies performance requirements for cleaning and disinfection as well as for the accessories which may be required to achieve the necessary performance.
- The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.
- Guidance on a routine test program is given in Annex A.

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Part 1: General requirements, terms and definitions and tests

- **6.10.2 Cleaning efficacy test 1**
- **6.10.2.1 General**
- The tests for cleaning efficacy shall be carried out using the appropriate test method(s) and test soil(s) as described in ISO/TS 15883-5 by taking into consideration the corresponding category of load. (See also References [24] to [39].)
- The attention of users is drawn to local regulations that can require the use of particular test soils and test methods.
- The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.
- The test soil used for the load, chamber wall and load carriers may not be the same. Where different test soils are used the rationale for the choice of test soil should be documented.

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Part 1: General requirements, terms and definitions and tests

- **6.10.2 Cleaning efficacy test 1**
- **6.10.2.2 Procedure**
- Contaminate the test load, chamber walls and load carrier with the test soil as described in the relevant test method of ISO/TS 15883-5.
- Operate a normal wash cycle for the load type under test.
- After completion of the wash cycle, examine the test load, chamber walls and load carrier for the presence of residual test soil using the method described in the relevant test method of ISO/TS 15883-5.
- **6.10.2.3 Results**
- The test result shall be regarded as satisfactory if it meets the criteria given in the relevant test method of ISO/TS 15883-5.

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Introduction to EN15883

Part 1: General requirements, terms and definitions and tests

- **6.10.3 Cleaning efficacy test 2**
- **6.10.3.1 General**
- This test is undertaken following satisfactory completion of cleaning efficacy test 1 and the thermometric tests (see 6.8). The WD shall be tested using actual loads contaminated by normal use, specified by the user as being representative of loads that it is intended to process.
- **6.10.3.2 Procedure**
- Operate no less than three cycles using actual loads contaminated by normal use of the type that it is intended to process.
- Visually assess the cleanliness of the processed items**.**

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Video on visual clean
https://www.youtube.com/watch?v=QAT0TC8lTs0

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Part 1: General requirements, terms and definitions and tests

- **6.10.3 Cleaning efficacy test 2**
- When the items are visually clean, one of the methods given in Annex C shall be used to detect the presence of residual protein contamination.
- When other methods will be used routinely for assessing the acceptability of items processed through the WD, the test method to be used shall be agreed between the user and the manufacturer.
- **6.10.3.3 Results**
- Report the composition of the test load, the method(s) used to assess the cleanliness of the load and whether all parts of the load were found to be free from residual contamination by the test method used.

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Part 5: Test soils and methods for demonstrating cleaning efficacy

Table A.1 — Summary of test programmes for WDs

Validation **User**

Brief description of test	Requirements clause	Test clause	Type test	Works test	Operational qualification	Performance qualification	Routine test
1 Cleaning efficacy							
1.1 Chamber	4.2.1.1	6.10.2	X	B	X	B	B
1.2 Load carrier	5.1.10	6.10.2	X	B	X	B	B
1.3 Load **Reference load**	4.2.1.1	6.10.2	X	B	X	B	X(Q)
Real load user defined		6.10.3 (visual)	B	B	B	X	X(D)
		6.10.3 (Annex C)			O	X	O

X recommended

B not recommended

O optional test which can be requested by the purchaser or user

v verification of calibration at the value(s) of interest for the particular instrument e.g. the disinfection temperature

Q quarterly test interval, W weekly test interval, D daily test interval;

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Part 5: Test soils and methods for demonstrating cleaning efficacy

Table 1 — Summary of test soils including their allocation to the type of load

Load type	Country code[a]	Reference in Bibliography	Constituents of soil	Annex in this Technical Specification
Surgical instruments (including rigid endoscopes)	AT	[34]	Heparinzed sheep blood coagulated with protamine	Annex A
	DE	[32], [33]	Sheep blood, *E. faecium*[b] Egg yolk, *E. faecium*[b] Semolina, butter, sugar, milk powder, *E. faecium*[b]	Annex G
	DE	[41], [42], [43]	Tetramethylbenzidine, hydrogen peroxide solution, bovine haemoglobin	Annex J
	NL	[39]	Bovine serum albumin fraction 5, porcine gastric mucin type 3, bovine fibrinogen fraction 1, bovine thrombin	Annex K
	SE	[24]	Citrated cattle blood coagulated with calcium chloride	Annex M
	UK	[28], [30]	Defibrinated horse/sheep blood, egg yolk, dehydrated hog mucin	Annex N
	US	[31] [47]	Protein/organic soil (user preference), *B. atrophaeus* endospores Albumin, haemoglobin, fibrinogen, thrombin	Annex S

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What about other countries?

What does local recommendation say?

- **Belgium has a recommendation of the “Hoge gezondheidsraad”**
- **Controle na reiniging en ontsmetting**
  - Bij een visuele controle onmiddellijk na het reinigen en ontsmetten moet nagekeken worden of er geen residuen van chemische producten of vuilresten achtergebleven zijn.
  - Bij een periodieke controle kan gebruik gemaakt worden van allerhande hulpmiddelen zoals testplaatjes, swap testen of een bevuilingstest. Het zijn hulpmiddelen die op een eenvoudige wijze snel aangeven dat de beoogde kwaliteit al dan niet bereikt werd.

Er is geen vermelding wat de resultaten van die bijkomende testen moeten zijn

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HOW CAN A CLEANING VALIDATION BE DONE ACC EN15883?

As an example; this is how the Austrian validation is done.

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How to prepare instruments according EN15883-5

A.7.1 Ordinary surgical instruments

- Allow the blood to equilibrate to room temperature before use. Clean and dry the test instruments thoroughly. Apply the test soil to joints and corrugate surfaces of the instruments at ambient temperature using a paintbrush. Take care that the blood is used within approximately 10 min (in any case before complete coagulation).
- The total amount of the test soil should be about 0,05 % of the amount of water for the cleaning phase in the tank of the WD (e.g. 20 l water; 10 ml blood).

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How to prepare instruments according EN15883-5

- Place 20 pieces of the soiled instruments horizontally and at random on each of the trays. All instruments shall be prepared and arranged on the tray within 30 min. Leave the instruments on the tray to dry at ambient temperature and humidity for approximately 30 min. Then take each of the instruments and check them for excessive test soil (e.g. coagulated test soil spots W 5 mm in diameter on the surface of the instruments) which shall be removed by means of an absorbent pad. Then place the instruments upside down on another tray and leave them to dry for at least 30 min but not more than 60 min.

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How to prepare instruments according EN15883-5

A.8 Test method

A.8.1 Ordinary surgical instruments

- Load the WD with the test instruments on their tray and start the WD with a full load. Run the cleaning cycle of the “surgical instrument” program in accordance with the manufacturer’s instructions.
- Immediately after the cleaning cycle, interrupt the program and unload the WD.

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How to evaluate instruments according EN15883-5

A.9 Results

- **A.9.1 Ordinary surgical instruments**
- **A.9.1.1 Detection of residual soil**

- After cleaning in the WD, examine the instruments visually. Examine every single instrument by opening and closing box locks and joints. Record the number of clean (no remains of blood visible to the naked eye at normal light with any optical corrections required for normal visual acuity) and not clean instruments.
- Calculate the ratio of the test pieces with residual soil to the originally soiled instruments. Express the result in percent.

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How to evaluate instruments according EN15883-5

A.9 Results

- **A.9.1 Ordinary surgical instruments**
- **A.9.1.2 Acceptance criteria**

- The cleaning efficacy of the WD shall be regarded as satisfactory if
  - at least 95 % of all test pieces show no visible residue of the test soil,
  - the amount of protein on the instruments is below the detection level or within the limits of the acceptance criteria given by the manufacturer of the test as applicable (see also ISO 15883-1:2005, Annex C)

Acc EN15883 = <100µg/instrument
New guideline for automated washing of instruments (2014) = <80ug/instrument

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Conclusion

- Validation is setting the standard of the washer disinfector
- A WD has a certain cleaning efficacy that must be meassured on soiled instruments before using cleaning indicators
- Only after validation a cleaning indicator should be used to compare the performance of the WD vs the initial validation.
- Therefore there is no pass or fail!

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Conclusion

- All commercial cleaning indicators actually on the market contain artificial blood and do not comply to EN15883 and have to be considered as a cleaning “indicator”
- Therefore no validations acc EN15883 shall be done with only commercial cleaning indicators, they can only be used as an indication and can not be the reason to reject a validation
- A reference load for validation should be defined (even when doing a routine check)
- There are more factors then only chemicals that are influencing the final cleaning result
- Position of the indicators should always be positioned on the same place and in the same direction. Be realistic in your expectations

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FACTS THAT INFLUENCES THE CLEANING RESULT

Facts the influence the cleaning result

- Conclusion if the cleaning indicators fail you can influence the cleaning result by:
  - Change water type or mix
  - Change water quality
  - Change cleaning temperature
    - Can vary from 45’C to 60’C
    - When > temperature; test Alu and other soft metals
  - Change dosing moment
    - Can be from the beginning or can be as of 35’C
  - Change cycle time
  - Check the (over) load
  - Change the product/dosing

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Check list to optimize cleaning result

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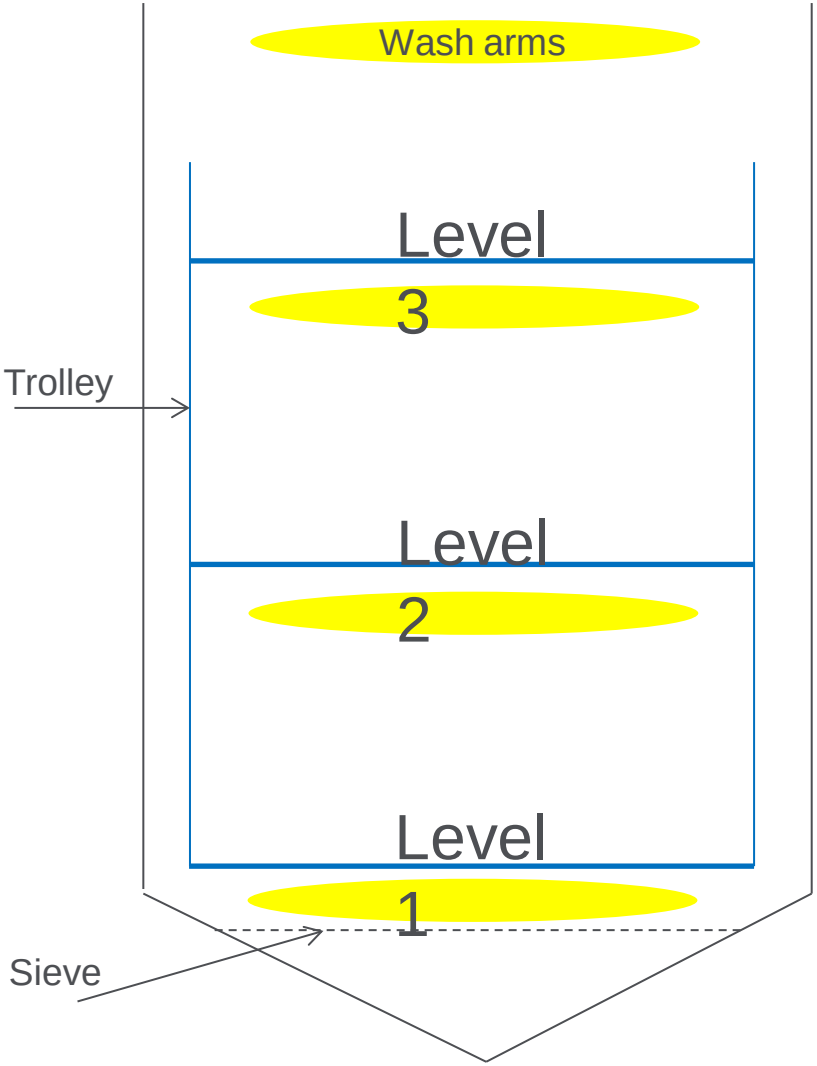
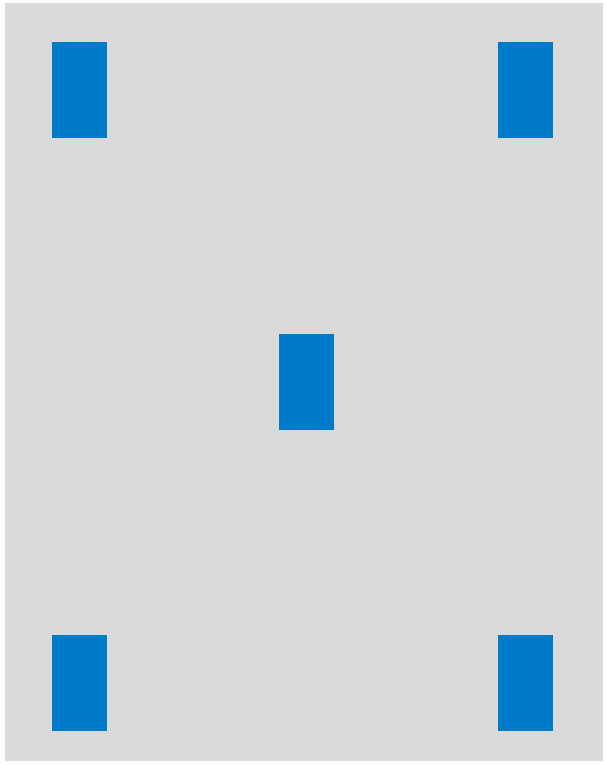
Facts the influence the cleaning result

Video's: https://www.youtube.com/watch?v=3OdCT2VbHa4
https://www.youtube.com/watch?v=1BhlRIRnW_s

Facts when using cleaning indicators





A cleaning indiator should always be positioned on the same place and with the same load.
Put 5 indicators on each level of your trolley.
If you have a worse result than the initial audit, please check water quality, cleaning pressure and correct product dosing!

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Facts when using cleaning indicators

- As mechanical power is one of the most influential factors for you cleaning result it is recommended to use a pressure data logger.
- This gives you the ability to compare different machines on the market and therefore also their cleaning efficacy
- It’s also useful to use “3M Clean Trace Protein test”

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WHAT ARE THE MOST FREQUENT USED CLEANING INDICATORS ON THE MARKET?

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Different cleaning indicators

Some topics to consider

- Does the customer want to have a cleaning indicator that is 100% clean?
- How hard to clean should a cleaning indicator be?
  - Easy, medium or hard to clean?
- It’s a fact that cleaning indicators react mainly on alkalinity and temperature

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Cleaning indicators on the market

Some topics to consider

- What is important when using a cleaning indicator?
  - It is an indicator, it doesn't have to be 100% clean but the result should be comparable with the initial test
  - Same load for each test cycle
  - Same position of the cleaning indicator
  - Same process cycle vs previous test

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Cleaning indicators on the market

TOSI test

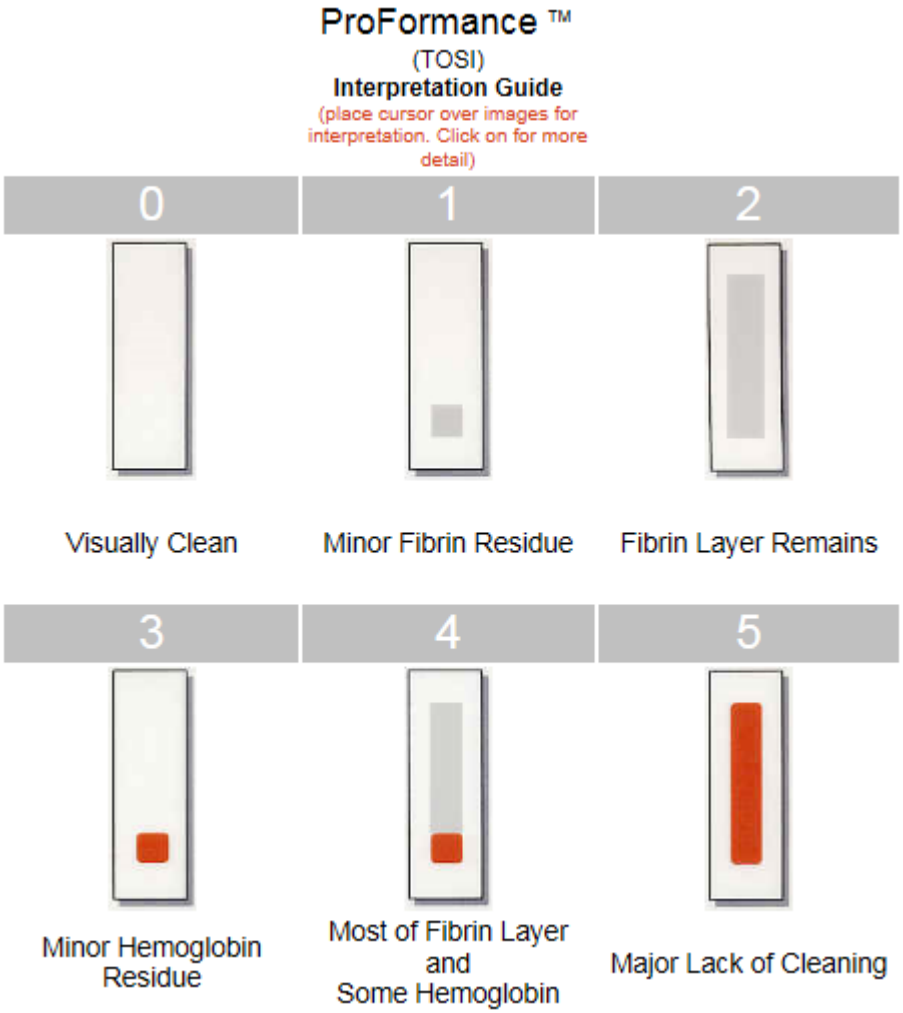
Cleaning indicators on the market

TOSI test

- Consists of 3 components:
  - Test Soil
    - Is chemically engineered to mimic the properties of human blood
  - Stainless steel plate
    - Is scratched or grooved to replicate the uneven surface of an instrument
  - Transparent plastic holder
    - Is a holder in an angle providing a gradually more difficult cleaning test from one end to the other.
    - Transparency allows the visual evaluation of the cleaning efficacy

Cleaning indicators on the market

TOSI test



Cleaning indicators on the market

TOSI test

Minor Fibrin Residue

Mechanical spray activity is good, try improving chemical activity by increasing enzyme hold time, raising temp. or raising pH.

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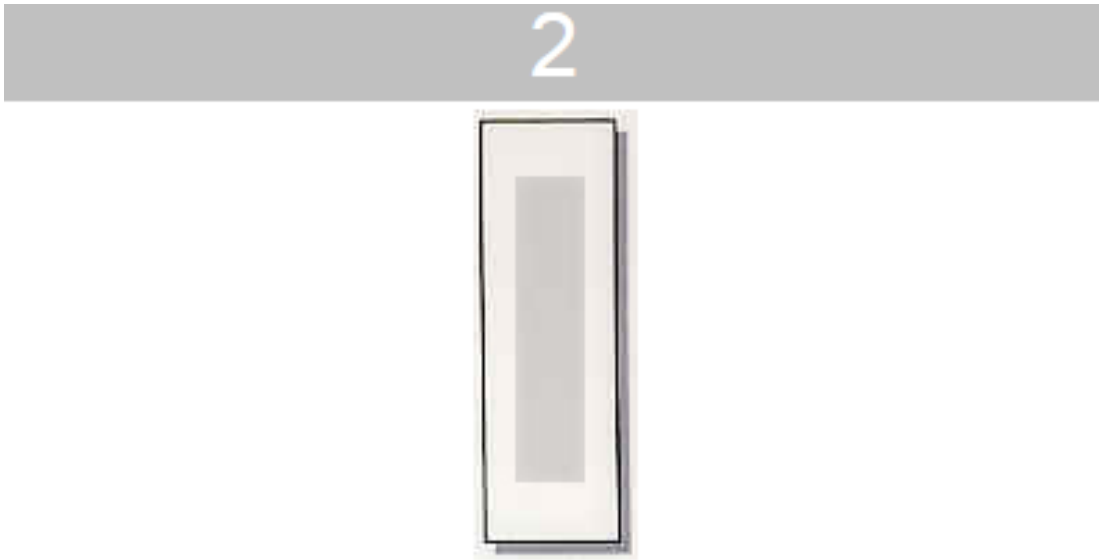
Cleaning indicators on the market

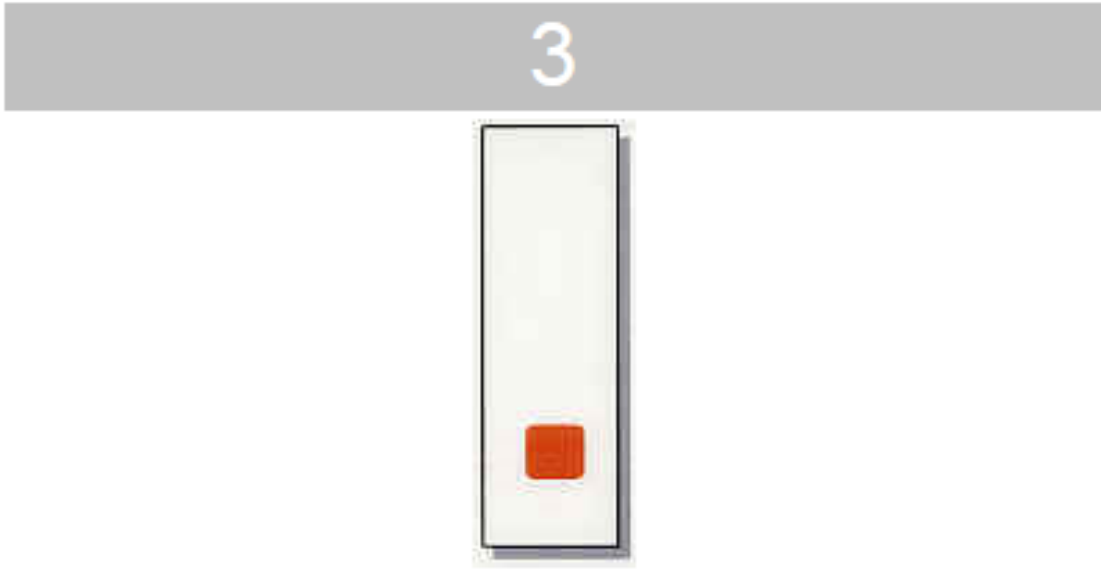
TOSI test



Fibrin Layer Remains
Chemical activity is poor, check for lack of enzyme cleaner and/or lack of high pH detergent.

Cleaning indicators on the market

TOSI test



Minor Hemoglobin Residue

Chemical activity is good but some obstruction to spray action. Check for overloading or blocked spray arms

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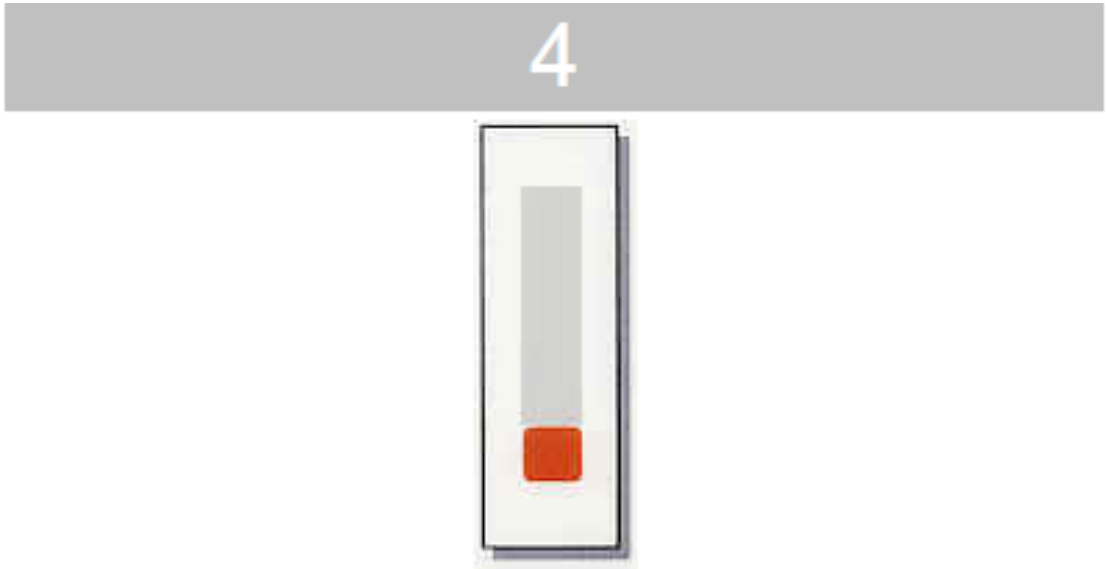
Cleaning indicators on the market

TOSI test



Most of Fibrin Layer and Some Hemoglobin

Poor chemical activity and some spray obstruction

Cleaning indicators on the market

TOSI test

5

Major Lack of Cleaning

Very little activity from both chemical and spray action. Major blockage or cold rinse may be too hot

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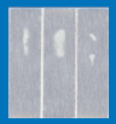
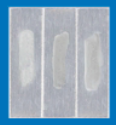
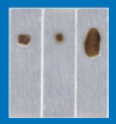
TOSI test

TOSI®-Troubleshooting Guide: What to do in case of…

TOSI Test Results	Rating	Description	Possible Reasons for TOSI Test Results	Immediate corrective action (to be conducted by CSSD personnel)	Proposal for optimisation of relevant process parameters (typically requires Service Engineer)
	0	**Optimum Result** Test soil is completely dissolved, no test soil residuals are left	Optimum result	not necessary	not necessary
	1	**Negative Result 1** TOSI is completely rinsed = no water soluble proteins visible, but small amount of fibrin residuals remain	a) Incorrectly positioned or blocked TOSI b) Cleaning time too short c) Temperature not optimal d) Dosage of detergent too low	a) Repeat test protocol with small load b) Investigate cleaning time c) Investigate cleaning temperature d) Check dosage/concentration of detergent	a) Consider other possible reasons b) Adjust cleaning time to type of detergent or extend time c) Adjust cleaning temperature to type of detergent d) Increase dosage
	2	**Negative Result 2** TOSI is completely rinsed = no water soluble proteins visible, but most or all of the fibrin layer remains	a) Incorrectly positioned or blocked TOSI b) Overloading/incorrect loading c) Cleaning time too short d) Temperature not optimal e) Dosage of detergent too low f) Insufficient detergent efficiency	a) Repeat test protocol with small load b) Repeat test protocol with correct load c) Investigate cleaning time d) Investigate cleaning temperature e) Check dosage/reservoir of detergent f) Check storage conditions and expiry date of detergent	a) Consider other possible reasons b) Consider other possible reasons c) Adjust cleaning time to type of detergent or extend time d) Adjust cleaning temperature to type of detergent e) Increase dosage or refill/replace reservoir f) Replace incorrectly stored or expired detergent
	3	**Negative Result 3** TOSI is incompletely rinsed = small residuals of the water soluble (red) proteins are visible. None or only a small amount of the fibrin layer remains visible	a) Incorrectly positioned or blocked TOSI b) Overloading/incorrect loading c) Non-uniform water distribution d) Blocked spray system e) Blocked filter f) Insufficient water pressure g) Foaming residuals left over from pre-cleaning or ultrasonic bath	a) Repeat test protocol with small load b) Repeat test protocol with correct load c) Check load + installation of spray system d) Check movement of spray arms and clean e) Check filter f) Refer to Service Engineer g) Rinse instruments more carefully after pre-cleaning or ultrasonic treatment	a) Consider other possible reasons b) Consider other possible reasons c) Install spray system correctly or replace by suitable one d) Replace defective spray arms if necessary e) Replace filter if necessary f) Check/increase water pressure, check function of pump g) Not applicable
	4	**Negative Result 4** TOSI is completely rinsed = significant residuals of water soluble (red) proteins are visible. In addition, most or all of the fibrin layer remains	a)-g) same as rating 3 but more distinct h) Defective pump i) Loss of pressure or other defect j) Incorrect temperatre for detergent k) Failure of chemistry in use	a)-g) same as rating 3 h) Refer to Service Engineer i) Check spray-arm and rack connection j) Investigate cleaning temperature k) Check tube connections/reservoir/storage conditions/expiration date of detergent	a)-g) same as rating 3 h) Replace pump i) Repair leaks and/or replace defective spare parts j) Select and set appropriate parameters for detergent in use k) Reconnect tubing/refill or replace reservoir/replace incorrectly stored or expired detergent
	5	**Negative Result 5** TOSI – test soil is largely or completely unaffected	a)-k) same as rating 4 l) No cold pre-rinsing step in place or pre-rinsing too hot m) Complete breakdown of the washer and/or the chemistry	a)-k) same as rating 4 l) Investigate pre-rinsing temperature and/or availability of a pre-rinsing step m) It is strongly recommended not to use the washer/disinfector until problems have been identified and resolved	a)-k) same as rating 4 l) Reduce pre-rinsing temperature below 40°C or install cold pre-rinsing cycle m) Investigate carefully all relevant cleaning parameters and make necessary corrections

Recommended Cleaning Parameters (please refer also to specifications of manufacturer)

Type of detergent	Concentration	Cleaning Time	Temperature
Alkaline detergent pH-Value ≥ 11,5	5 g/litre	5 min	> 60°C
Neutral detergent with Enzymes	10 g/litre	10 min	45°C
Neutral detergent without Enzymes	7-10 g/litre	10 min	45° - 60°C

Important note

In case of unsatisfactory test results these results should be confirmed by rerunning the test program with a smaller load. In case of confirmation of the initial test results it is recommended to investigate potential reasons for the failure. In case the cause of a failure cannot be resolved by the CSSD staff the technical service of the machine or detergent manufacturer should be contacted.

It is not recommended to change any installed parameters if such modification is restricted to the technical service of the supplier! Violation may result in a loss of warranty!

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TOSI test https://www.youtube.com/watch?v=-b5sv6PGw0M
https://www.youtube.com/watch?v=2MDcR7PFSb8

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Verify All Clean Test Washer Indicator

The VERIFY All Clean Test Washer Indicator - a consistent, reproducible method to routinely check the performance of your automated washing process.

PDF

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Verify All Clean Test Washer Indicator

Features and benefits

- **No blood products** - Safe-to-handle, safe-to-place in your washer/disinfector, no toxic residuals on instruments
- **Consistent formulation** - Reproducible testing, time after time
- **Bright red test soil formula** - Easy-to-see, easy-to-interpret
- **Stainless steel holder** - corrosion and abrasion resistant
- **Mesh design holder** - Mimics typical surfaces to present a realistic challenge
- **Lot number on end of strip** - provides traceability

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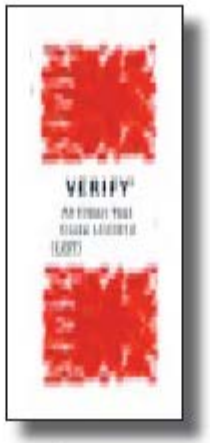
Verify All Clean Test Washer Indicator

1 Materials

All Clean Test Washer Indicator Holder



All Clean Test Washer Indicator

Automated Washer/ Disinfector

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Verify All Clean Test Washer Indicator

2 Procedures

Make sure the holder is clean and dry. Insert indicator into holder.

Centrally place the holder with indicator into a wire basket. Orientation of the holder should be placed with one of the soil stains flat (facing down) on the wire basket and the other soil stain oriented vertically. (see image above)

To establish a control, place empty basket with holder into a rack for processing at the beginning of each day. Level of rack and/or number of racks used to be determined by customer.

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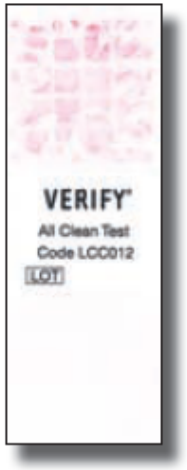
Verify All Clean Test Washer Indicator

3 Results

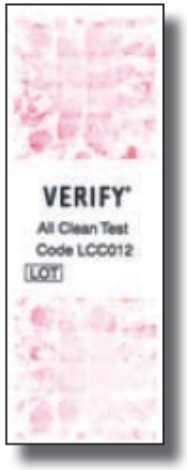
After running a complete cycle, remove the device from the tray or basket and carefully remove the VERIFY All Clean Test Indicator from the holder. Inspect the indicator for evidence of soil by placing the plastic film against a white background. Compare the results against the samples below to determine the cause of action. If the indicator remains visible to the naked eye - the result is a FAIL.

Unused



Impingement Related Failure

1) Incorrect positioning of indicator
2) Blocked spray arms
3) Lack of water pressure
4) Overloading of rack



Chemistry Related Failure

1) Incorrect positioning of indicator
2) Enzyme and/or wash phase is too short
3) Temperature parameters are not correct
4) Chemistry injection rates are not correct

Pass

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Wash-Checks Steritec

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Wash-Checks Steritec

- Designed to monitor the wash/detergent system effectiveness with a consistent monitor on a routine basis.
- If insufficient time, temperature, detergent concentration, spray arm function or enzyme soak occurs, a red residue remains
- Test soil is designed to parallel the removal of blood and tissue from surgical instruments
- No actual blood components from any source are contained in the test soil
- Low cost monitor promotes routine use

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Wash-Checks Steritec

- We recommend monitoring each shelf of every washer each day for a machine release and using a minimum of one Wash-Check monitor per load when the washer has proven effective
- Use with reusable Wash-Checks holder (WC 102), that acts as a hinged instrument measuring impingement
- Third party testing has proven Wash-Checks to be the most reliable and effective wash monitor on the market
  (Austrian Association of Sterile Supply)

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Wash-Checks Steritec

INTERPRETATION

Unexposed
The red spot will disappear when proper washing conditions have been met

Pass
Detergent Chemistry: Good
Impingement: Good

Fail
Detergent Chemistry: Medium
Impingement: Good

Fail
Detergent Chemistry: Weak
Impingement: Good

Fail
Detergent Chemistry: Medium
Impingement: Weak

Fail
Detergent Chemistry: Weak
Impingement: Good

Wash family common failures:

- Inadequate water spray/impingement
- Clogged spray arms
- Overloading
- Instrument shadowing
- Inadeqate detergent dosing
- Improper detergent dosing
- Faulty peristaltic pumps
- Poor water quality

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Wash-Checks Steritec
https://www.youtube.com/watch?v=yUExWAKTVRI

Technology + People = Knowledge

THANK YOU FOR YOUR ATTENTION

Video link

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