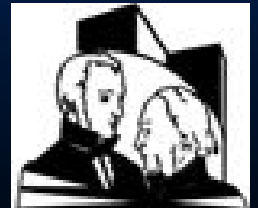


European Sterilization Congress 18th - 20th may 2006,
N f S and E f H S S - Lillehammer

Experience of soil tests used in two French hospitals : detergent validation

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Sterilization activity

■ University hospital Bichat

- 1000 beds
- 22 operating theaters (Orthopedic, Thoracic-Vascular, Digestive, Gynecology, Urology, ORL, Cardiology)
- Consultations, hospitalizations

■ Sterilization activity

- 27 operators + 3 supervisors
- Responsibility : pharmacist
- 5 washer-disinfector + 4 autoclaves
- Sterilization / year : 29 000 containers + 210 000 pouches and sheets

2005 : new detergents call for tenders

- Performance of 6 alkaline detergents with the manufacturer's cleaning parameters.
 - Washer-disinfector (WD) pr EN/ISO 15883-1: with a standardized full instrument-load (27 liters),
 - 5 experimentations with 3 Soil tests TOSI[®] (Amcor-SPS) + 1 STF load check + soil tests (Browne).
 - estimation of spray shadowing with 5 temperature sensors,

Conclusion:

- temperature (cleaning + disinfection) was in accordance with WD parameters,
- spray shadowing +++ corners of the upper part of the WD,
- STF + Soil test easier to remove than TOSI,
- choice of the better detergent.
- optimization of the cleaning parameters of manufacturers

Introduction

Objective: Optimization of the cleaning performance of 3 different detergents not yet commercialized (neutral, enzymatic, alkaline).

■ Variation of 3 parameters

- Temperature, cleaning time, concentration of detergent

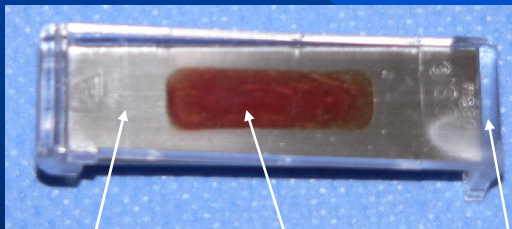
■ 4 soil tests have been used

- TOSI[®]
- Soil Test, Load Check Indicator Strip STE
- Artificial test soil EN/ISO TS 15883-5:2004 (annex G) with microbiological contamination (IRM)

Materials : cleaning efficacy tests

- Tosi® → 95% water soluble proteins + 5% water insoluble fibrin

Unused test



20 mg of standardized soil test

transparent plastic holder

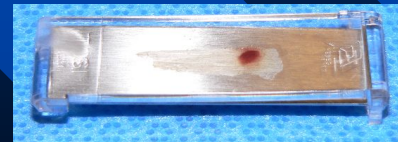
small stainless steel plate



TOSI acceptable
(= pass)
(scale : 0 to 1)



fibrin layer remains



fibrin layer remains
+ proteins residue

TOSI N/a
(= fail)
(scale : 2 to 5)

(Tosi®) Interpretation Guide

cleaning efficiency scale

0



Visually Clean

1



Minor Fibrin Residue

2



Fibrin Layer Remains

Poor chemical activity

3



Minor Hemoglobin Residue

Good chemical, poor mechanical activity

4



Most of Fibrin Layer and Some Hemoglobin

poor chemical and mechanical activity

5



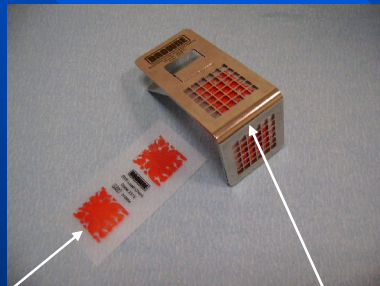
Test soil as unused

major lack of cleaning

Materials : cleaning efficacy tests

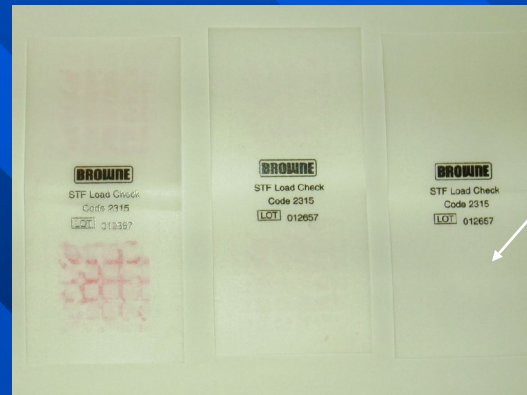
■ Load Check Indicator Strip (STF)

➔ 2 proteins + lipids + polysaccharides



Load Check Holder

Unused test



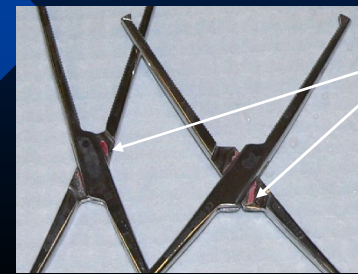
Transparent
= acceptable
(= pass)

Red to pink = N/a (= fail)

■ Soil Test[®] (drying period > 12 h)



5 Kochers
forceps

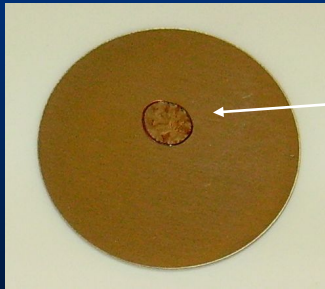


Traces
(hinge)
= N/a

Materials : Microbiological tests

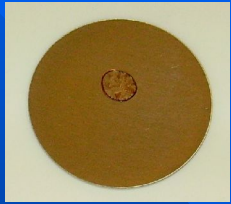
■ Artificial microbiological soil test (IRM)

- Soil tests : EN ISO/TS 15583-5:2004, Annex G
- *Bacillus subtilis*

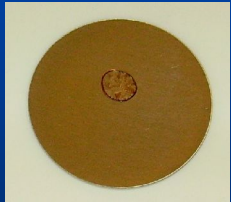


- Defibrinated sheep blood + *Bacillus subtilis* var *niger* CIP 77.18 (10^7 CFU / mL)
- Aliquots of 50 μ L
- Drying cabinet 1h30, 45°C

Microbiological tests : Methods

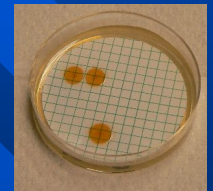


Initial number of colonies



WD assay

Rinsing with 100 mL water + 0.5% Tween 80
Filtration 100 mL
Agar-Agar Bacillus
Incubation 35°C 48h



Reduction
Factor (RF)

=

Mean \log_{10}

$\left[\frac{\text{Initial number of colonies}}{\text{number of colony after WD's assay}} \right]$

Materials : Washer-disinfector

LANCER HOSPITALIA 10.4 D

- standardized full instrument-load
- position of the tests



	Preliminary experiment (repeated 3 times)	Microbiological experiment (repeated 5 times)
1	- 1 TOSI - 2 Kochers (soil test)	- 1 TOSI - 1 microbiological test
2	- 1 TOSI - 1 Kocher (soil test) - 1 temperature sensor CleanvaC (Sterigest) - 1 STF	- 1 TOSI - 1 microbiological test - 1 temperature sensor CleanvaC (Sterigest)
3	- 1 TOSI - 2 Kochers (soil test)	- 1 TOSI - 1 microbiological test

Materials : WD Standardized cycles

	Parameters	Quality of water*
cold pre-wash	1 min 30, 20°C	Deminer- alized water
cleaning	Variation of T (°C), t (sec), C (%)	
neutralization	For alkaline detergent	
rinsing	5 min, 20°C	
thermal disinfection	5 min, 90°C	Osmosis water
	Cycle was interrupted before this step for microbiological assays	

* Daily controlled : pH, TH (< 5), conductivity (< 30 μ S/cm)

Materials : Detergents

Manufacturers : IRM + AMCOR-SPS

■ Alkaline DE 05/024-26

- Potassic mineral complexant
- biodegradable sequestrants (no ETDA)
- pH = 13-14, diluted 0.7% pH = 11.7

■ Enzymatic DE 5/028

- Monoenzymatic (protease) stabilized (4-formyl-phenyl-boronic acid)
- Non ionic tensio-activ
- pH = 9-10, diluted 1% pH = 8.6

■ Neutral DE 05/024-12 (midly alkaline detergent solution)

- Tensio-active anionic (hydrotrope) and no ionic, biodegradable sequestrant (no ETDA)
- pH = 10.4-11.4, diluted 0.5% pH = 10.7

Methods

■ Variation of 3 parameters

- Thermal = cleaning temperature,
- Mechanical = cleaning time,
- Chemical = detergent concentration

■ Blank test control

- Water instead of detergent
 - 5 tests 65°C, 5 min cleaning
 - 5 tests 45°C, 10 min cleaning

TOSI + STF = N/a



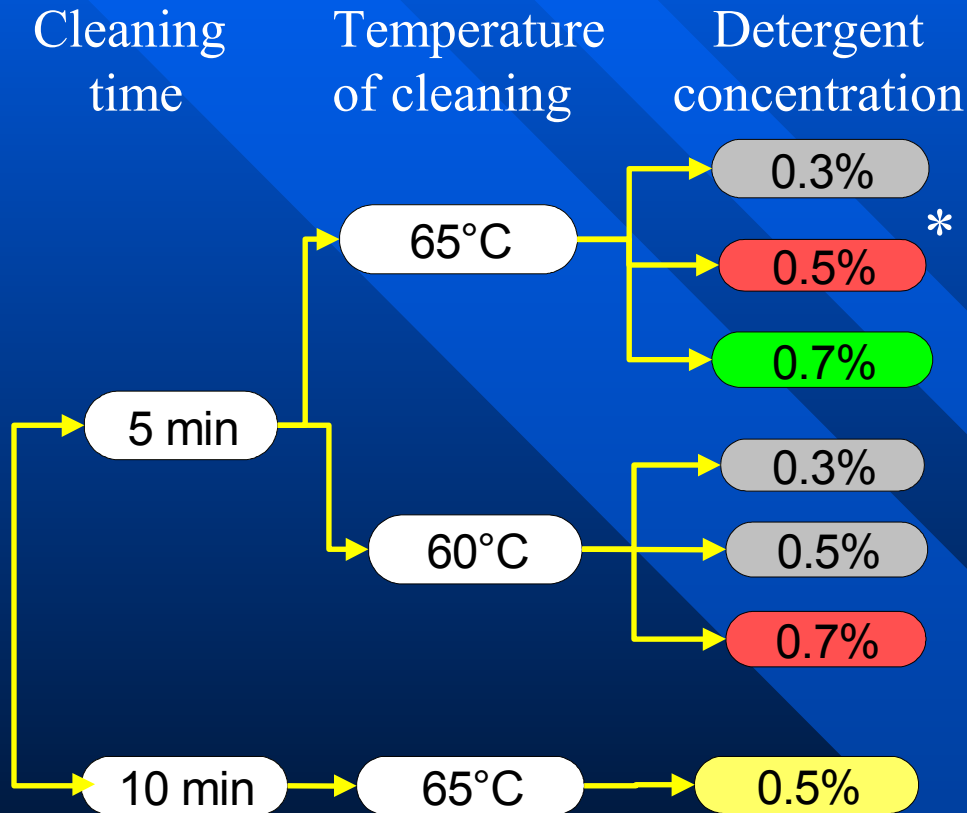
■ Positive control

- The better detergent tested in 2005 :
5 tests : 3 min cleaning, 70°C, Concentration = 0.6%

TOSI + STF acceptable



Alkaline detergent



* Manufacturer recommendations

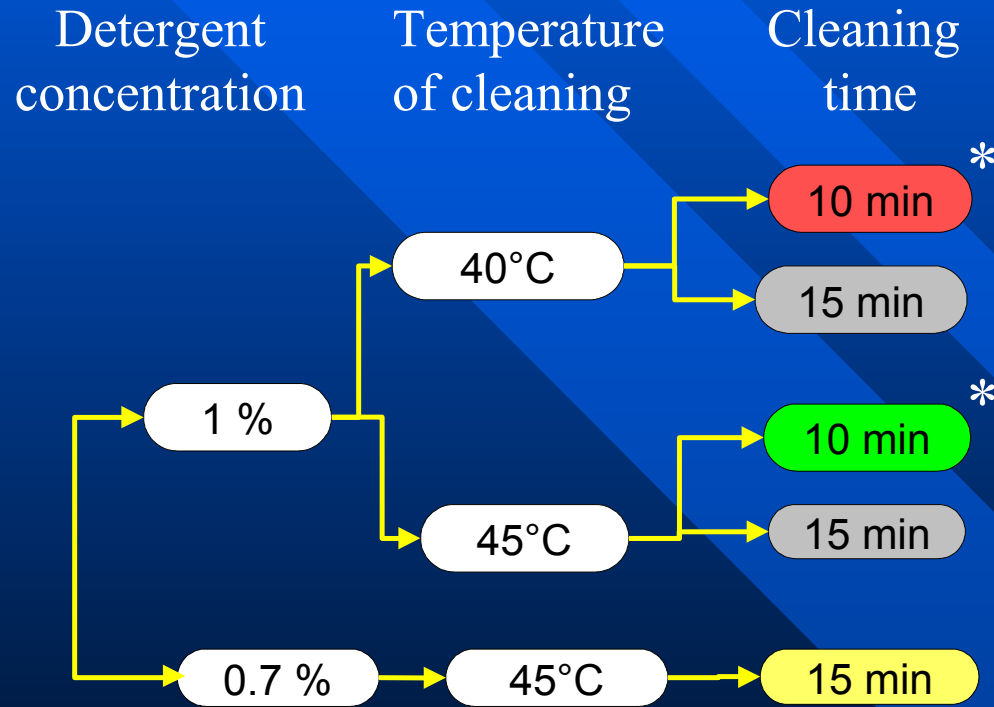
Results	
Preliminary experiment (n=3)	Microbiological experiment (n=5)
-	-
- 15 Tosi N/a - 3 STF N/a	N/e
- 15 Tosi acceptable - 3 STF acceptable	Evaluate
-	-
-	-
- 15 Tosi N/a - 3 STF N/a	N/e
- 15 Tosi acceptable - 3 STF acceptable	N/e

Soil test Kocher clamps = failed

Conclusion : optimized parameters

5 min / 65°C / 0.7% → manufacturer choice

Enzymatic detergent



* Manufacturer recommendations

Results	
Preliminary experiment (n=3)	Microbiological experiment (n=5)
- 15 Tosi N/a - 3 STF N/a	N/e
-	-
- 15 Tosi acceptable - 3 STF acceptable	Evaluated
-	-
- 15 Tosi acceptable - 3 STF N/a	N/e

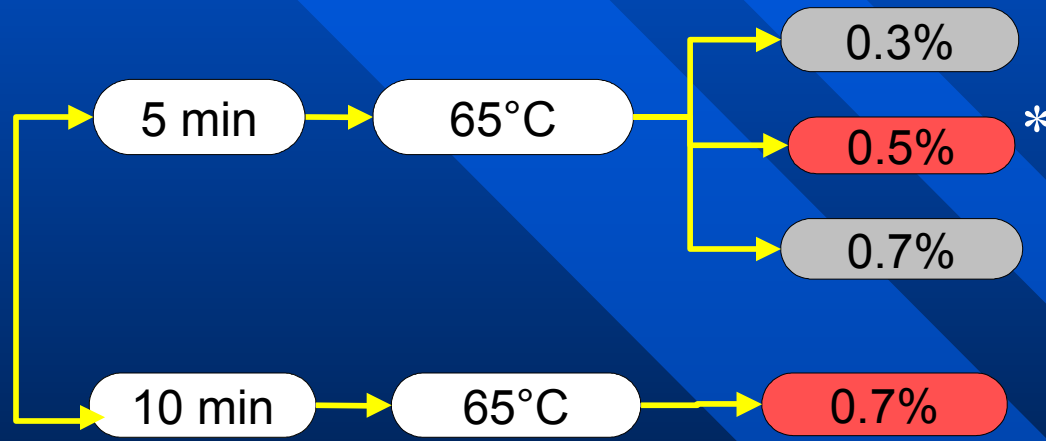
Soil test Kocher clamps = failed

Conclusion : optimized parameters

➔ 10 min / 45°C / 1% : manufacturer choice

Neutral detergent

Cleaning time Temperature of cleaning Detergent concentration



Results	
Preliminary experiment (n=3)	Microbiological experiment (n=5)
-	
- 15 Tosi N/a - 3 STF N/a	N/e
-	
- 15 Tosi N/a - 3 STF N/a	N/e

* Manufacturer recommendations

Soil test Kocher clamps = failed

Conclusion : optimized parameters not found

→ microbiological experiments not effected

Microbiological experiments : Results

■ Neutral detergent → not effected

■ Alkaline detergent

- Concentration (blank test control = 0, detergent = 0.7%)
- Cleaning time = 5 min, Temperature = 65°C

RF blank test control = RF detergent = $5.0 \log_{10}$

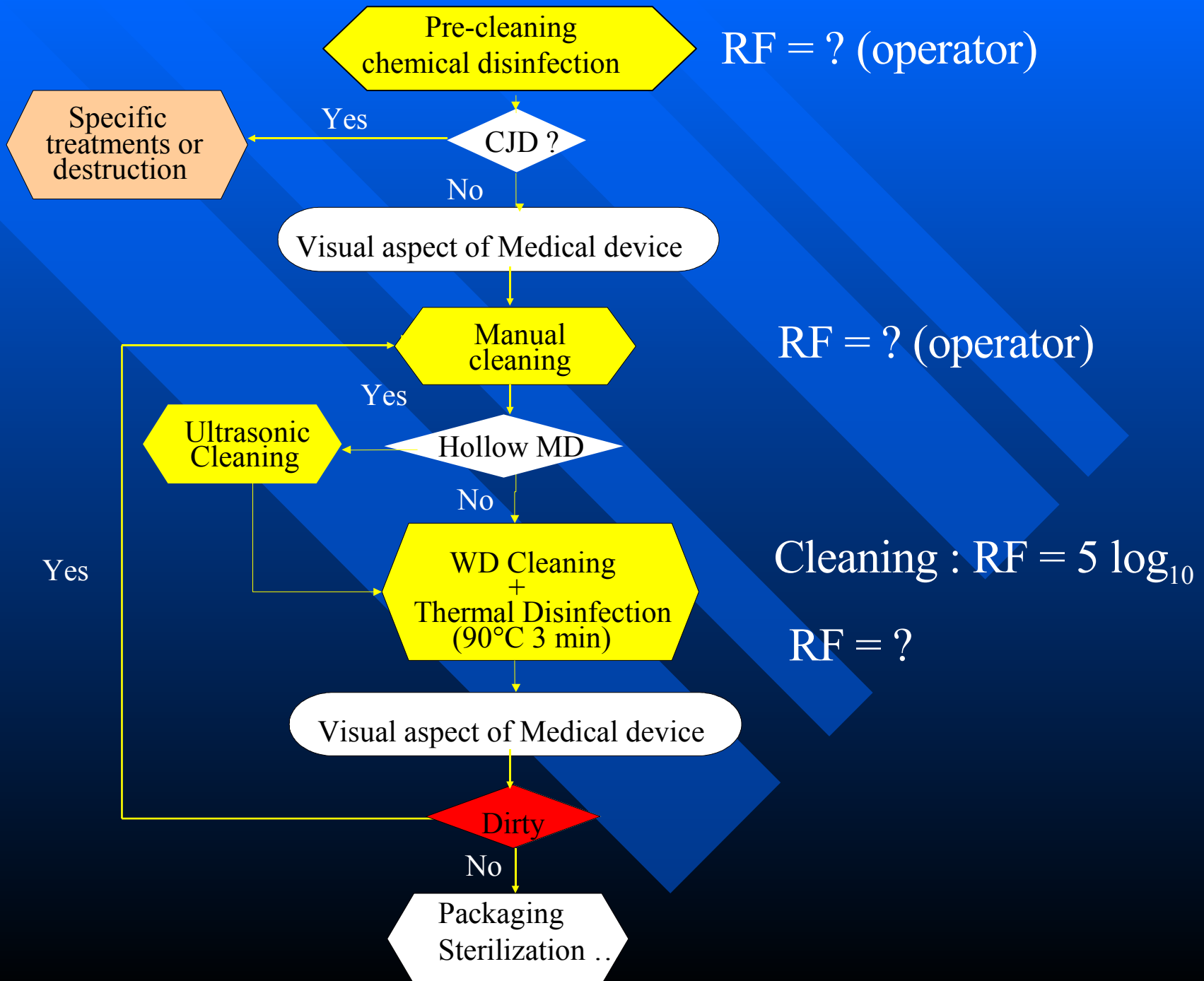
■ Enzymatic detergent

- Concentration (blank test control = 0, detergent = 1 %)
- Cleaning time = 10 min, Temperature = 45°C

RF blank test control = RF detergent = $5.0 \log_{10}$



- no conclusion for the detergent chemical efficacy with this test
- RF = $5.0 \log_{10}$ obtained by WD (mechanical + Temperature)



Cleaning performance

■ Plethora of parameters

- Chemical aspects : Detergent (concentration, time, temperature)
 - Easier to prove *in Vitro*
 - In our study : only with TOSI and STF tests
- WD : mechanical (pump pressure, spray system) + temperature + steps of the cycle (pre-wash, cleaning time, thermal disinfection)
- Water quality
- The load : generating +/- spray shadowing
- Medical device (hollow instrumentation)



Choice of detergent : difficult to prove cleaning efficacy
Validate : WD + detergent + tests + water quality

Use of the cleaning efficacy tests

■ Validation : qualification + re-qualification

– Soils tests

- Commercialized Soils tests (Soil test, STF, Tosi, ...)
- Standard EN ISO/TS 15883-5 (13 different : annex A to S)
 - ✓ Microbiological
 - ✓ Radionuclide

– Residual semi-quantitative tests

- blood (Hemo-check)
- protein (Biuret method, ninhydrine) :
- bacterium (ATP luminometry)



Evaluation of the performance WD + detergent
and validation of a cleaning process for a Medical Device

Use of the cleaning efficacy tests

■ Routine conditions (Bichat Hospital)

- TOSI or STF
 - Position in the WD
 - Frequency (each cycle ?, once a day ?, ...)
 - Test failed → what action ?
 - Refusal of the load ?
 - Check the WD, detergent level, water quality, position of the test in the load
- Temperature sensor (1 x / month)
- Visual inspection of medical devices (each cycle)



Detection of modifications of usual parameters

Conclusion

- It is well known that nothing can be rendered sterile unless it is clean,
- The efficiency of the cleaning of a medical instrument in a washer-disinfector is always a result of the combination of the chemical and mechanical capabilities of the system used,
- Our standards are only informing us about the need for cleaning efficiency but not telling us exactly how to do it.



Works need to be done to create standardized parameters
Proofs of cleaning efficiency need to be validate



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