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

Damien TALON, Axèle REBERGA
Pharmacy-Sterilization Department
Hospital Bichat, AP-HP Paris, France
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 STF
  - 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
  - small stainless steel plate
  - transparent plastic holder

- TOSI acceptable (= pass) (scale: 0 to 1)
  - fibrin layer remains

- TOSI N/a (= fail) (scale: 2 to 5)
  - fibrin layer remains + proteins residue

**Test Details:**
- 20 mg of standardized soil test
- Small stainless steel plate
- Transparent plastic holder

**Results:**
- TOSI acceptable: fibrin layer remains
- TOSI N/a: fibrin layer remains + proteins residue
(Tosi®) Interpretation Guide

Cleaning Efficiency Scale

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visually Clean</td>
<td>Minor Fibrin Residue</td>
<td>Fibrin Layer Remains</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Hemoglobin Residue</td>
<td>Most of Fibrin Layer and Some Hemoglobin</td>
<td>Test soil as unused</td>
</tr>
</tbody>
</table>

Interpretation Guide

- **0**: Visually Clean
- **1**: Minor Fibrin Residue
- **2**: Fibrin Layer Remains
- **3**: Minor Hemoglobin Residue
- **4**: Most of Fibrin Layer and Some Hemoglobin
- **5**: Major lack of cleaning

http://www.healthmark.info/proformance.html
Materials: cleaning efficacy tests

- **Load Check Indicator Strip (STF)**
  - 2 proteins + lipids + polysaccharides
  - Load Check Holder
  - 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

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

Artificial microbiological soil test (IRM)
- Bacillus subtilis
Microbiological tests: Methods

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

Initial number of colonies

WD assay

Reduction Factor (RF) = \textbf{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

<table>
<thead>
<tr>
<th></th>
<th>Preliminary experiment (repeated 3 times)</th>
<th>Microbiological experiment (repeated 5 times)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>- 1 TOSI</td>
<td>- 1 TOSI</td>
</tr>
<tr>
<td></td>
<td>- 2 Kochers (soil test)</td>
<td>- 1 microbiological test</td>
</tr>
<tr>
<td>2</td>
<td>- 1 TOSI</td>
<td>- 1 TOSI</td>
</tr>
<tr>
<td></td>
<td>- 1 Kocher (soil test)</td>
<td>- 1 microbiological test</td>
</tr>
<tr>
<td></td>
<td>- 1 temperature sensor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CleanvaC (Sterigest)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 1 STF</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>- 1 TOSI</td>
<td>- 1 TOSI</td>
</tr>
<tr>
<td></td>
<td>- 2 Kochers (soil test)</td>
<td>- 1 microbiological test</td>
</tr>
</tbody>
</table>
### Materials: WD Standardized cycles

<table>
<thead>
<tr>
<th>Step</th>
<th>Parameters</th>
<th>Quality of water*</th>
</tr>
</thead>
<tbody>
<tr>
<td>cold pre-wash</td>
<td>1 min 30, 20°C</td>
<td>Demineralized water</td>
</tr>
<tr>
<td>cleaning</td>
<td>Variation of T (°C), t (sec), C (%)</td>
<td>For alkaline detergent</td>
</tr>
<tr>
<td>neutralization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rinsing</td>
<td>5 min, 20°C</td>
<td>Osmosis water</td>
</tr>
<tr>
<td>thermal disinfection</td>
<td>5 min, 90°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cycle was interrupted before this step for microbiological assays</td>
</tr>
</tbody>
</table>

* Daily controlled: pH, TH (< 5), conductivity (< 30 μS/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

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

TOSI + STF = N/a

TOSI + STF acceptable
Alkaline detergent

**Conclusion**: optimized parameters

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

* Manufacturer recommendations

Soil test Kocher clamps = failed
Enzymatic detergent

<table>
<thead>
<tr>
<th>Detergent concentration</th>
<th>Temperature of cleaning</th>
<th>Cleaning time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 %</td>
<td>40°C</td>
<td>10 min</td>
</tr>
<tr>
<td></td>
<td>15 min</td>
<td></td>
</tr>
<tr>
<td>0.7 %</td>
<td>45°C</td>
<td>10 min</td>
</tr>
<tr>
<td></td>
<td>15 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>45°C</td>
<td>15 min</td>
</tr>
</tbody>
</table>

Results

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<tr>
<th>Preliminary experiment (n=3)</th>
<th>Microbiological experiment (n=5)</th>
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<tbody>
<tr>
<td>- 15 Tosi N/a</td>
<td>N/e</td>
</tr>
<tr>
<td>- 3 STF N/a</td>
<td></td>
</tr>
<tr>
<td>- 15 Tosi acceptable</td>
<td>Evaluated</td>
</tr>
<tr>
<td>- 3 STF acceptable</td>
<td></td>
</tr>
<tr>
<td>- 15 Tosi acceptable</td>
<td>N/e</td>
</tr>
<tr>
<td>- 3 STF N/a</td>
<td></td>
</tr>
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</table>

* Manufacturer recommendations

Conclusion: optimized parameters

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

Soil test Kocher clamps = failed
**Neutral detergent**

**Cleaning time** | **Temperature of cleaning** | **Detergent concentration**
--- | --- | ---
5 min | 65°C | 0.3%  
0.5%  
0.7%  
10 min | 65°C | 0.7%  
* Manufacturer recommendations

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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

  \[ \text{RF blank test control} = \text{RF detergent} = 5.0 \log_{10} \]

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

  \[ \text{RF blank test control} = \text{RF detergent} = 5.0 \log_{10} \]

- 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
Feel free to contact us:

anne.jacolot@avc.aphp.fr

damien.talon@bch.aphp.fr