

Cleaning:

Recent advances in products and processes and Real-time monitoring



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Overview:

- ***Medical Device Cleaning:
Current Issues & Advances***
 - ***Manufacturer validated protocols***
 - ***Cleaning mechanics***
 - ***Cleaning agents***
- ***Real-time monitoring***
 - ***Manufacturer/Research tests***
 - ***Rapid User testing***
- ***Conclusions***



Manufacturer validated cleaning protocols

- Lack of validated manufacturer's cleaning instructions for some devices:
 - "Clean as per usual hospital protocol"
 - "Clean the tips by aspirating distilled water through the tip to clear any debris from within the tip and prevent plugging of the suction port."
- No indication whether disassembly is required
- No indication whether sonication is needed or could damage device

New Developments:

Manufacturer's Instructions:

- AAMI ST81 and EN ISO 17664 Guidance documents now require medical device manufacturers provide at least one manual and one automated validated cleaning protocol
- **USERS:** refuse to order/pay for medical device until validated cleaning protocol provided by manufacturer



Cleaning Mechanics: Automated versus Manual

Automated preferred

(equipment must be maintained properly)

- **Automated Endoscope Reprocessors (AERs)**
 - cleaning cycles
(many do not have FDA clearance for cleaning claims)
 - channel separators; flow monitoring (ISO 15883-4)
- **Narrow lumen cleaners**
 - ultrasonic combined with detergent and fluid flow
 - self-decontamination (thermal or other)**
- **Washer/Disinfectors**
 - validated for respiratory equipment; replace pasteurizers
(spray vs immersion)



And What About the Water Quality???!??!

- AAMI working on a “Water Quality” Guidance document for users
- ISO 15883-1; Viable count of final rinse water and/or other methods that are equivalent (e.g. ATP method)



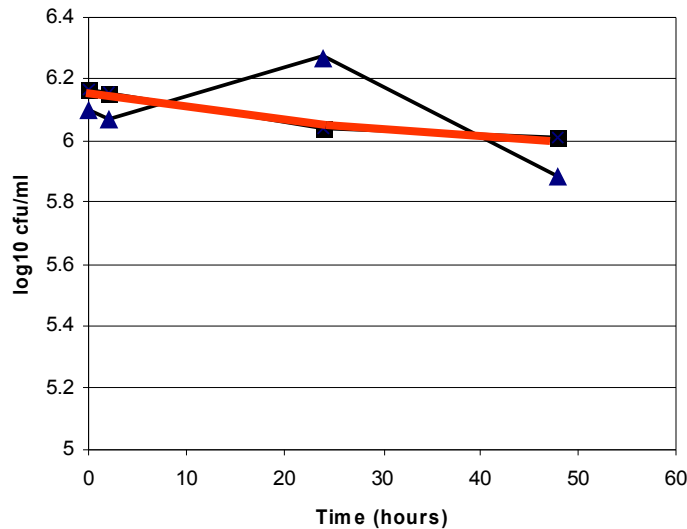
Cleaning Agents:

- Chemical detergents:
Alkaline, Acid, Neutral
- Enzymatic detergents:
 - single or multi-enzyme
 - contact time
 - protein solution (rinsing important)
- Accelerated Hydrogen Peroxide agents

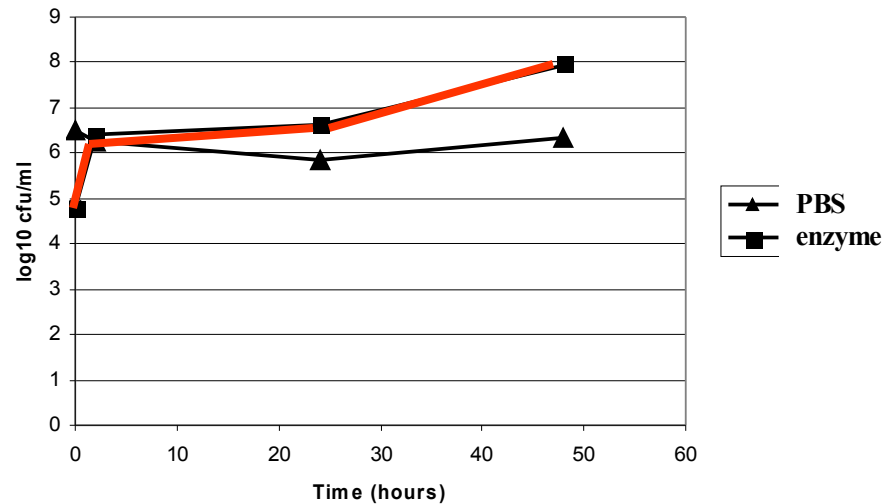
The ***specific formulation*** determines efficacy; cannot compare across class of agents (e.g. not all enzymatic detergents are equally effective)

Survival of bacteria in enzymatic detergent

Enterococcus faecalis

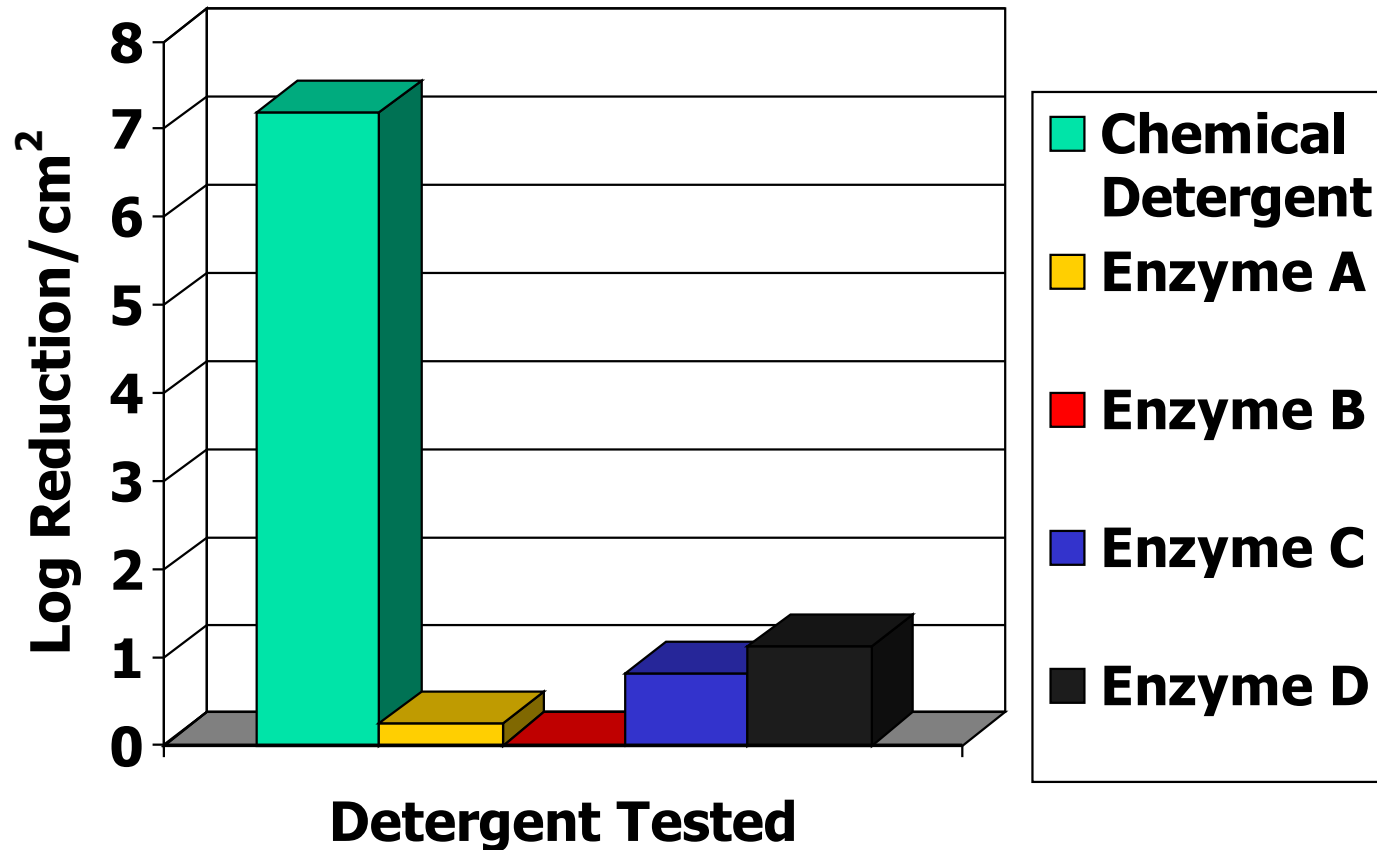


Pseudomonas aeruginosa



Soaking overnight at room temperature in enzymatic detergent will lead to biofilm formation!!

Enzymatic Detergent: Biofilm removal

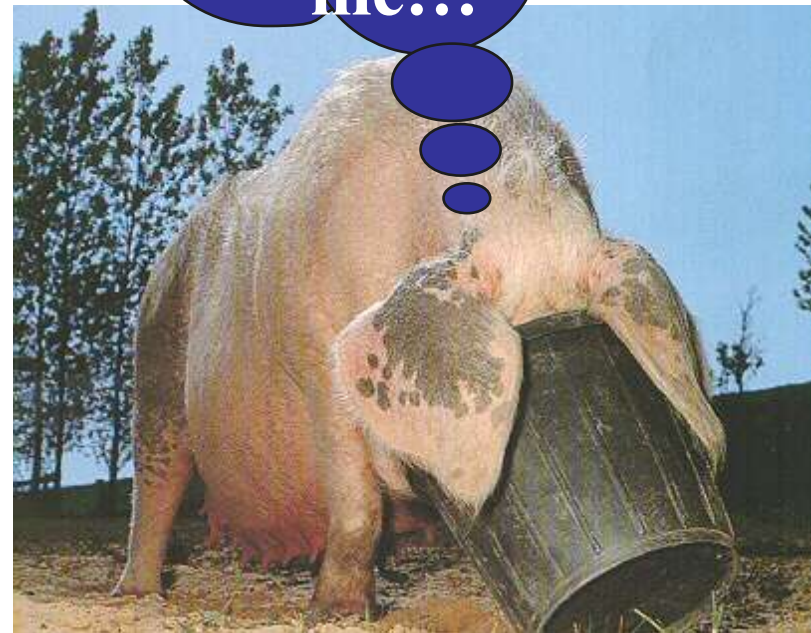


Vickery et al Am J Infect Control 2004;32:170-6.

Medical Device Cleaning; Real-time monitoring

- Monitor Washer function
- Monitor medical devices post-cleaning

**It Looks
Clean
Enough to
me!!!**



Recent Advance: Guidelines encouraging rapid user test methods

- **CEN/ISO (15883-5):** working toward standardizing soils and test methods for users
- **AAMI:** guideline for manufacturer's
 - recommending manufacturers provide rapid tests for users to verify in-use cleaning efficacy

How Clean is Clean Enough!!??

What parameter to monitor?

Guidelines: "Visibly Clean"

Literature parameter benchmarks:

Stainless steel instruments: Protein

- OPA method: 0.01 $\mu\text{g}/\text{device}$; (Verjat 1999)
- Ninhydrin method: 2.5 $\mu\text{g}/\text{swab}$; (deBruin 2002)
- Biuret method: 5.5 $\mu\text{g}/\text{cm}^2$; (Kruger 1997)
- Hemoglobin strips: ? Limit of detection (Fengler)

Flexible endoscope biopsy channel: (Alfa et al 2002)

- Protein; < 6.4 $\mu\text{g}/\text{cm}^2$
- Carbohydrate; < 1.8 $\mu\text{g}/\text{cm}^2$
- Hemoglobin; < 2.2 $\mu\text{g}/\text{cm}^2$

WHAT IS REALISTIC FOR IN-USE TESTING???

New Developments: Test Soil



- ISO 15883-5: Multiple test soils:
- de Bruin (2005): compared soils and identified a universal standardized test soil for users (only for alkaline detergent cleaning in hot water)
 - visual assessment of cleaning
 - Washer monitoring; no correlation with in-use benchmarks
 - recommended German egg yolk test soil

Research/Manufacturer's

Device cleaning test methods:

Device immersed, or lumen filled with reagent

- **Bradford's reagent:** detects protein by turning blue
- **TMB reagent:** detects hemoglobin by turning green:
- **Radioactive tracers:** labeled protein; if not removed, detected as residual radioactivity inside medical device



**Specialized radioisotope
imaging equipment**



SYPRO Ruby Test for Protein on Medical devices

- Sensitive dye that stains any protein; detected using special epi-fluorescent microscope
- Surface testing of residual protein on medical devices after cleaning; LD of 85pg/mm²
- Not clear what would be an acceptable level of residual dye (ie. cutoff for residual protein)
- A good research tool but not readily adaptable to in-use testing for users

Washer Monitoring; in-hospital use

- **TOSI:** Protein/fibrin (PEREG, GmbH) QA device for washers; visual inspection post-cleaning.
- **Test soil:** colored paste brushed onto devices, test carriers, or inside washer on walls; visual inspection post-cleaning (e.g. Browne's soil, Danish soil).
- **Lumen Test:**
 - Soil/stained/fixed inside tubing; clean then visualize
 - Biofilm; after cleaning, stain or do viable count to determine if biofilm removed

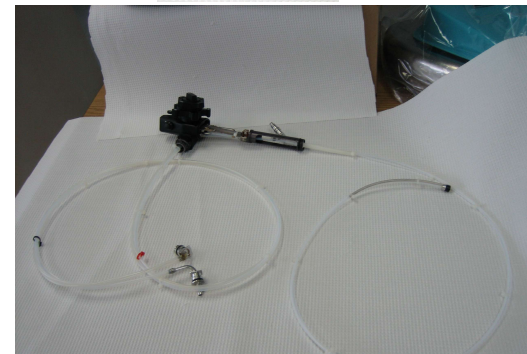
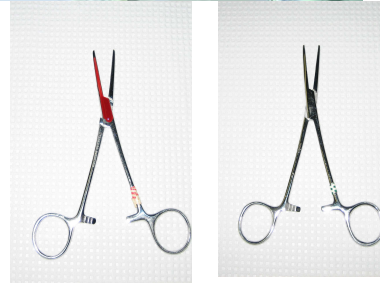
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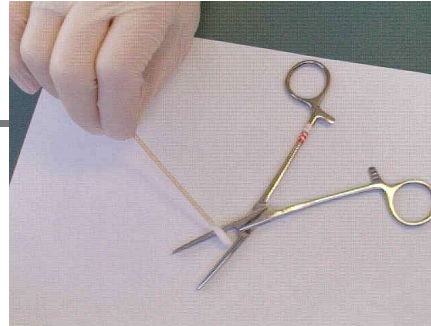


Commercially
available



Orzechowski et al Zentr Steril 2003;11:165-178
Zuhlsdorf et al J Hosp Infect 2004;56:305-11
Vickery et al Am J Infect Control 2004;32:170-6.

Rapid User Tests: for in-hospital cleaning assessment



- **Biuret reaction ($5.5 \mu\text{g}/\text{cm}^2$):**
Protein (Kruger 1997);
swab device → assess colour
development.

- **Protec Swab test (unknown LD):**
Protein or ATP (Biotrace) swab can
be tested. (commercially available)

Commercially
available

- **Ninhydrin Swab test ($2.5 \mu\text{g}/\text{swab}$):**
Protein: ISO/CEN method evaluated
for users; swab method (deBruin
2002)

Surface testing only, not applicable to lumens

REMEMBER:

Rinse well after Cleaning

Enzymatic detergents are proteins

and if not properly rinsed off can be detected by rapid user cleaning tests that detect protein!!



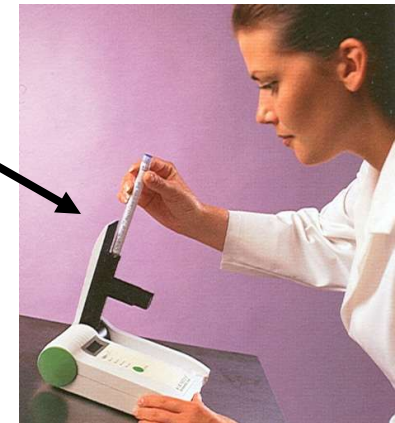
ATP: Flexible Endoscopes

(Obee et al Am J Infect Control 2005;33:202-206)

- ATP is “energy source” in living cells (e.g. eukaryotes; human cells) and prokaryotes; bacterial cells)
- Rapid test methods for swab & fluid samples from flexible scopes (surfaces and lumens)
- Cutoff for adequate cleaning?
 - 500 RLU/sample suggested
- Organic material alone; no ATP (fecal protein, carbohydrate etc)



sample



RLU (relative light units) measured

ATP: Real-time Monitoring

(from: Obee et al 2005)	ATP RLU/sample (% above 500 RLU)	
Site sampled: (surface; swab, channel; brush)	Unit A (N = 25)	Unit B (N = 38)
Scope: Biopsy channel (post-clean, pre-disinfection)	683 (16%)	1389 (45%)
Scope: Biopsy channel (post-clean, post-disinfection)	82 (4%)	67 (0%)
Scope: Exterior, tip (post-clean, post-disinfection)	1387 (44%)	353 (16%)
Endoscopy room: Video equipment switches	5322 (92%)	401 (13%)



Value of Cleaning Verification tests for users

- **Washing Machine tests:**
 - **confirm proper function (QA)**
- **Medical device tests:**
 - **confirm that cleaning protocol used in-hospital is effective**
 - **confirm staff training and document competency over time**



SUMMARY:

- ***Medical Device Cleaning:
Current Issues & Advances***
 - ***Manufacturer validated protocols***
 - ***Cleaning mechanics***
 - ***Cleaning agents***
- ***Real-time monitoring by users:***
 - ***Washer efficacy*****
 - ***Cleanliness of medical devices***