Automated Medical Instrument Washers:

are they cleaning properly?

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Disclosures:

- ***Sponsored to give invited presentations at various National and International conferences by;***
  STERIS, 3M, J&J, Healthmark, APIC, CACMID, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.

- ***The University of Manitoba has licensed Dr. Alfa's patent for Artificial Test Soil to Healthmark.***

- ***Opinion Leader Panel participation or Consulting Services for***: 3M, J&J, STERIS, Olympus, bioMerieux, Serim, Borden Ladner Gervais LLP, various Canadian Healthcare facilities.

- ***Research projects for:***
  3M, STERIS, J&J, Novaflux, Virox, Olympus, Medisafe, Case Medical, Province of Manitoba, Public Health Agency of Canada
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Objectives:

- **Reusable Medical Device Reprocessing:**
  - Regulation of medical device cleaning
  - Roles for Manufacturers and Users
- **Monitoring of Automated washers**:
  - Methods for monitoring
  - Guidelines: Frequency? Interpretation of data?
- **Data from clinical study**
  - are automated washers cleaning properly?
- **Summary**

Healthcare Cleaning Monitoring Issues:

- Reusable Medical Devices
  - automated washers
  - manual cleaning
- Shared patient equipment* (e.g. IV poles, commodes, etc)
- Environmental cleaning*

* ***PIDAC 2009 Best Practices for Environmental Cleaning for prevention and control of infections: In all health care settings***
http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_enviro_clean.pdf

Medical Device Reprocessing

- **Canada:**
  - ***Sale of medical devices*** is regulated nationally. New "Guide to Manufacturers" re: information they must provide for ALL reusable medical devices
  - ***Reprocessing of Medical Devices*** not regulated nationally or provincially

Website for Manufacturer's Guideline:
http:www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_reprocessing_im_ld_retraitement-eng.php

Website for Scientific Advisory Panel recommendations:
http:hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/reproc-retraite/saprmd_gcsmm_recom_2005-02-10_e.html

Medical Device Reprocessing

- **USA: Public FDA/AAMI Workshops:**

  [June & Oct, 2011 at FDA campus]

  - Draft guidance on labeling of reusable medical devices
  - Focus on requiring manufacturer's to validate cleaning nstructions

New FDA Website: www.fda.gov/reprocessingreusabledevices

Reprocessing of Reusable Medical Devices

- **Historical:**
  The focus of regulators and manufacturer's was previously on validation of disinfection or sterilization
- **Current:**
  The cleaning aspect of medical device reprocessing has become centre stage.

Reprocessing Staff:

Your voices are gradually being heard!

Pictures from Goggle Images; May 2011

Quality Process: Medical Device Reprocessing

Surgical instruments:

- ***Sterilization:***
  monitoring done (e.g. BIs & CIs)

- ***Cleaning (manual/automated):***
  no monitoring other than visual inspection

Who is responsible for What?

- **Manufacturers:**
  Validate that the automated washer does clean effectively

- **Healthcare Facilities:**
  Verify that using their on site staff and following the manufacturer's validated washer cycles, they can reliably clean reusable devices

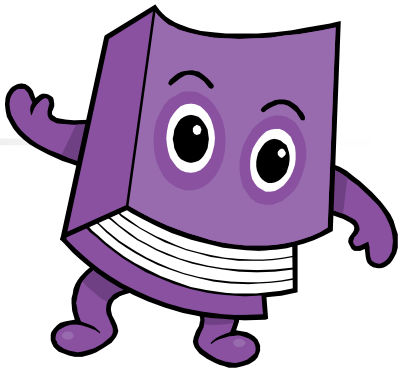
Pictures from Goggle Images; May 2011

Automated Medical Instrument Washers: Quality Program

- **Ensure Staff competency:**
  - initial training verification,
  - yearly competency assessment needed
- **Ensure ongoing adequacy of Automated washers:**
  - ***audit tools***:
    - washer cycle monitors

Guidelines: What do they say?

- Decontamination of reusable medical devices. CSA guideline Z314.8-08
- Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. Public Health Agency of Canada 2010
- Standards of Infection Control in Reprocessing of Flexible Gastrointestinal endoscopes SGNA 2011.
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice for Cleaning, Disinfection and Sterilization – In all Health Care Settings. April 30, 2006

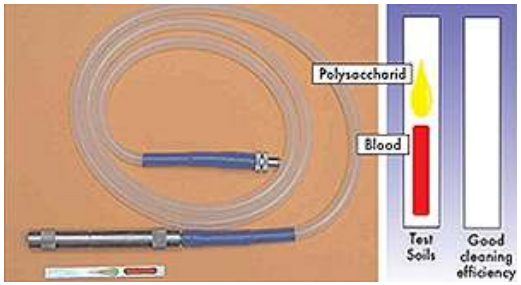


No specific recommendations for how to monitor cleaning

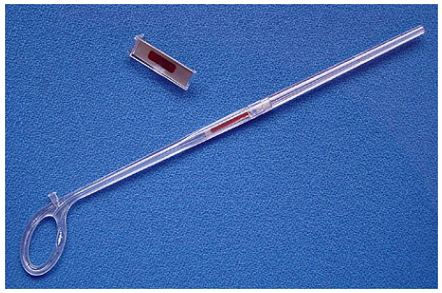
What commercial rapid monitors are available to assess cleaning efficacy of automated washers?

Endoscope Cleaning Monitors for Lumens: Automated Washers

HealthMark USA, Medisafe UK, Steris/Browne UK, SteriTec, USA



Flexi check: Endoscope lumen



Medisafe Lumen check: Laparoscopic device lumen

TOSI Lumchek

Steritec Wash-Checks

These monitors assess how effective the washer function is:
ISO committee working to standardize washer cleaning monitoring

These represent some examples it is NOT an all-inclusive list

Pictures from company websites

Published Data: Is there anything to worry about?

- Surgical instruments; residuals?
- Efficacy of automated washers?

STUDY: Automated Medical Instrument Washer

Surgical Tray set for "plastic surgery" procedures in Emergency Dept

reprocessed in Central Processing Dept using automated washer

- ***Enzymatic and alkaline detergent cleaning cycles***
- ***Deionized water used for final rinse***

Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Patient-used instruments: quantitate residuals pre and post cleaning

Curved Iris

Skin Hook

Needle driver

Curved Mosquito

Adson toothed fine

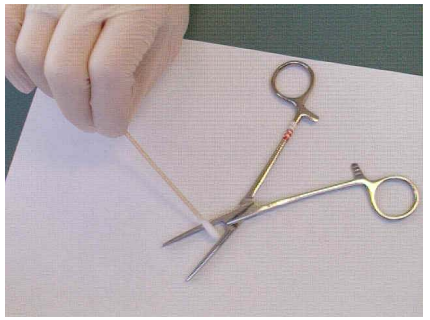
Pictures from company website

Each time the same five most commonly soiled instruments in the tray set were tested

Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Study Method:

- Total of 10 patient procedures evaluated
  - 5 patient-used before cleaning
  - 5 patient-used post-cleaning
- Surface area swabbed: 1cm^2
- Each sample assayed quantitatively for: Protein, Hemoglobin, Carbohydrate, LPS (i.e. endotoxin)



Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Residuals on Patient-used instruments post-cleaning: Automated washer

Plastics Tray **Instrument type:** **(visible soil after use)**	**Protein: (µg/cm^2)** **Average for 5 devices**		**Hemoglobin: (µg/cm^2)** **Average for 5 devices**	
	Before cleaning	***After cleaning***	***Before cleaning***	***After cleaning***
1. Curved Mosquito forcep **1/5 visibly soiled:** **(1 device; 1+)**	**7.04**	**0.18**	**0.00**	**0.00**
2. Fine Needle Driver **5/5 visibly soiled:** **(2 devices; 1+, 3 devices; 3+)**	**49.96**	**0.00**	**13.26**	**0.00**
3. Curved Iris Scissors **2/5 visibly soiled:** **(2 devices; 3+)**	**373.78**	**0.14**	**110.96**	**0.00**
4. Toothed Adson forcep (fine) **4/5 visibly soiled:** **(2 devices; 1+, 2 devices; 2+)**	**55.38**	**1.04**	**9.90**	**0.44**
5. Skin Hook **1/5 visibly soiled:** **(1 device; 1+)**	**3.36**	**3.16**	**0.36**	**0.12**
Average:	**97.90**	**0.90**	**26.90**	**0.11**

Residuals on Patient-used instruments post-cleaning: Automated washer

Plastics Tray Instrument type: (visible soil after use)	**Carbohydrate: (µg/cm²) Average for 5 devices (SD)***		**Endotoxin: (EU/cm²) Average for 5 devices (SD)**	
	Before cleaning	***After cleaning***	***Before cleaning***	***After cleaning***
1. Curved Mosquito forcep **1/5 visibly soiled:** **(1 device; 1+)**	**120.52**	**301.16**	**13.68**	**18245.32**
2. Fine Needle Driver **5/5 visibly soiled:** **(2 devices; 1+, 3 devices; 3+)**	**116.86**	**336.86**	**10.62**	**23667.74**
3. Curved Iris Scissors **2/5 visibly soiled:** **(2 devices; 3+)**	**146.68**	**352.10**	**32.40**	**20.42**
4. Toothed Adson forcep (fine) **4/5 visibly soiled:** **(2 devices; 1+, 2 devices; 2+)**	**169.40**	**138.76**	**23.44**	**13.14**
5. Skin Hook **1/5 visibly soiled:** **(1 device; 1+)**	**141.14**	**193.46**	**10.58**	**25373.88**
Average:	**138.92**	**264.47**	**18.14**	**13464.10**

Automated cleaning:

Instruments had higher
Carbohydrate and
Endotoxin levels
AFTER automated
cleaning!!

Conclusions from Study:

- Not all Washer cycles had this problem
  (84% of instruments had higher Carbohydrate and 60% had higher Carbohydrate & LPS residuals post cleaning vs pre-cleaning Avg level)
- Likely reflected inadequate water quality → ? Final rinse water
- ? Biofilm in lines/water holding tank?

Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Take Home Message: Residuals Post-cleaning

- Organic material remains on instrument
- Endotoxin (LPS); not destroyed by steam sterilization→ still causes inflammatory response
- Proteins etc are denatured by steam sterilization → but still remain antigenic

Frequency of Monitoring??

- ***Quality Assurance Program:***
  No Guideline recommendations for monitoring cleaning efficacy of Washers

- **<u>Site decision:</u>**
  - Establish site baseline by initial testing of all automated washers for a short period of time
  - Ongoing each washer tested minimally 1/week

Pictures from Google Images

SUMMARY:

- **Reusable Medical Device Reprocessing:**
  - Cleaning Validation (Manufacturers)
  - Cleaning Verification (Users)

- **Automated instrument washers**
  - Ensure they are cleaning properly
  - Ensure quality of water for final rinse

- **Monitoring of manual and automated cleaning**:
  - Guidelines needed: Frequency? Interpretation of data?

References

General Reprocessing

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- Red brochure*: Proper Maintenance of Instruments, 8ed.* http://www.a-k-i.org/englisch/lit.htm
- Spaulding EH. *Chemical disinfection of medical and surgical materials [Chapter 32].* In: Lawrence CA, Block SS, eds. Disinfection, sterilization and preservation. Philadelphia, PA: Lea & Febiger, 1968: 517–31
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- CDC (HICPAC) *Guideline for Disinfection and Sterilization in Healthcare Facilities 2008*
- ISO 15883-1:2006. *Washer–disinfectors, Part 1: General requirements, definitions and tests.*

References

Reprocessing Instructions & Methods

- AAMI TIR12:2004 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed*
- ANSI/AAMI ST81:2004 *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices*
- ANSI/AAMI ST79:2006 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

Cleaning

- AAMI TIR34:2008 *Water for reprocessing medical devices*
- AAMI TIR30:2003 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
- ISO/TS 15883-5:2005 *Washer-disinfectors — Part 5:Test soils and methods for demonstrating cleaning efficacy of washer–disinfectors*