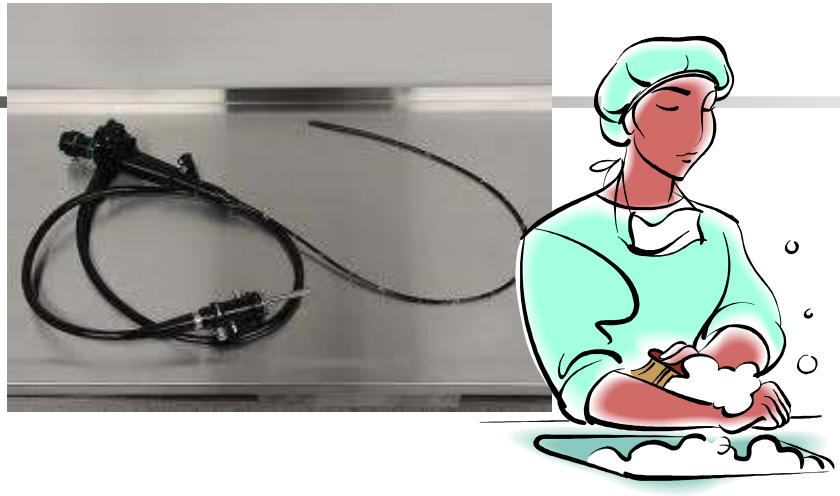
Flexible Endoscopes:

The "A,B,C's" of Monitoring Manual Cleaning Efficacy!



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Disclosure:

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.

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Objectives:

- **Quality Process: Flexible Endoscopes**
  Monitoring of manual cleaning
  - Sample collection
  - Test Methods: ATP, Organic residuals, Bioburden?
  - Validation of methods
- **Summary**

Recent Endoscope reprocessing Issues in Canada and the USA:

"500 Vancouver Island patients warned of possible infection from dirty endoscopes"

"Vancouver Patients Warned About Potential Infectious Exposure from Endoscopy Procedure"

- 500 Vancouver patients were alerted to potential exposure of blood-born virus infections due to improperly reprocessed endoscopes (April 2010)
- Approximately 10,000 former Veterans Affairs patients in Georgia, Tennessee, and Florida warned of potential exposure to infections (Feb. 2009)
- The VA said the problems were caused by human error in the cleaning and operation of endoscopic equipment

Older Flexible Endoscopes pose greatest problems

"..the number of times an individual endoscope was contaminated was directly proportional to the number of occasions that the instrument was used."

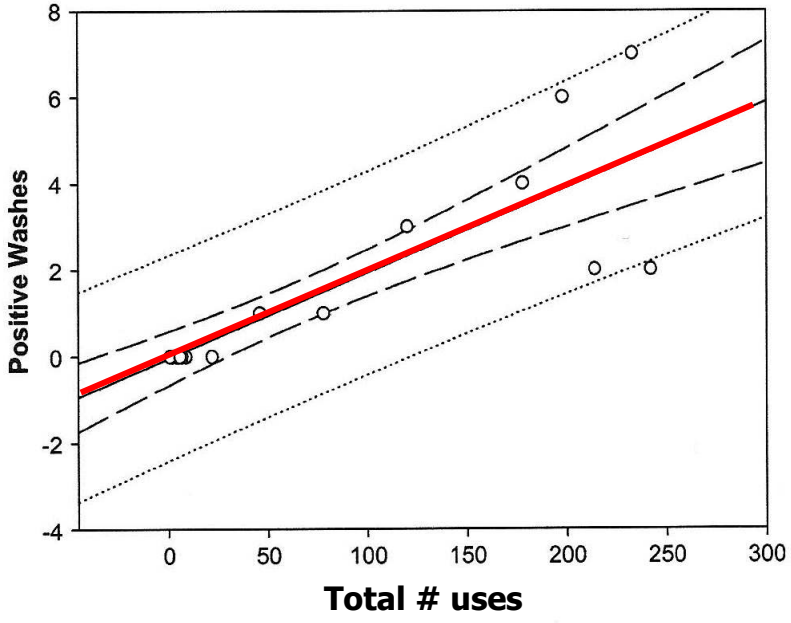


Fig 1. Linear regression analysis for gastroscopes, showing 99% and 95% confidence levels and prediction of contamination incidence numbers against total washes collected per gastroscope.

Bisset et al Am J Infect Control 2006;34:274-80

What are the issues?

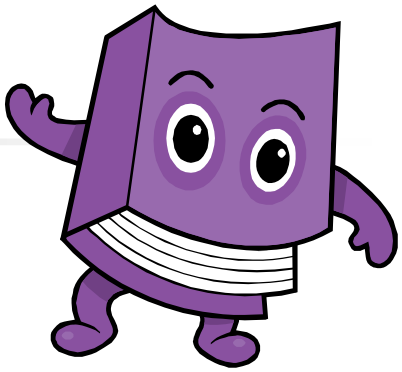
- Endoscopes stored wet → biofilm
- Design flaws
- Human errors in reprocessing
- Automated Endoscope Reprocessor errors

Visual inspection is inadequate:
you cannot see inside the channels
that range from 2mm – 4.2mm

Infection Prevention and Control Guideline for Flexible GI endoscopes and Bronchoscopes. Public Health Agency of Canada 2010

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 Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings. April 30, 2006



No specific recommendations for how to monitor manual cleaning

Validation of Manual Cleaning Monitors

Endoscope Channel Sample

Channel Chek: Healthmark

Carbohydrate, protein, hemoglobin

Clean-trace: 3M

Detects ATP

Tests assess how well the manual cleaning is being done by staff

Pictures from company websites

Manufacturer Validation of Manual Cleaning Monitors for Flexible Endoscopes

- ***Which channels to monitor***?
- ***How should channel sample be collected:***
  - realistic in busy clinic
  - volume, type of liquid used for sampling
- ***Limit of detection of method***
  - relate to benchmarks to be achieved

Channel-Chek PrototypeTest:

protein, blood, carbohydrate

- How to collect Sample?
- Benchmark for Clean?
- In hospital clinics is it feasible?

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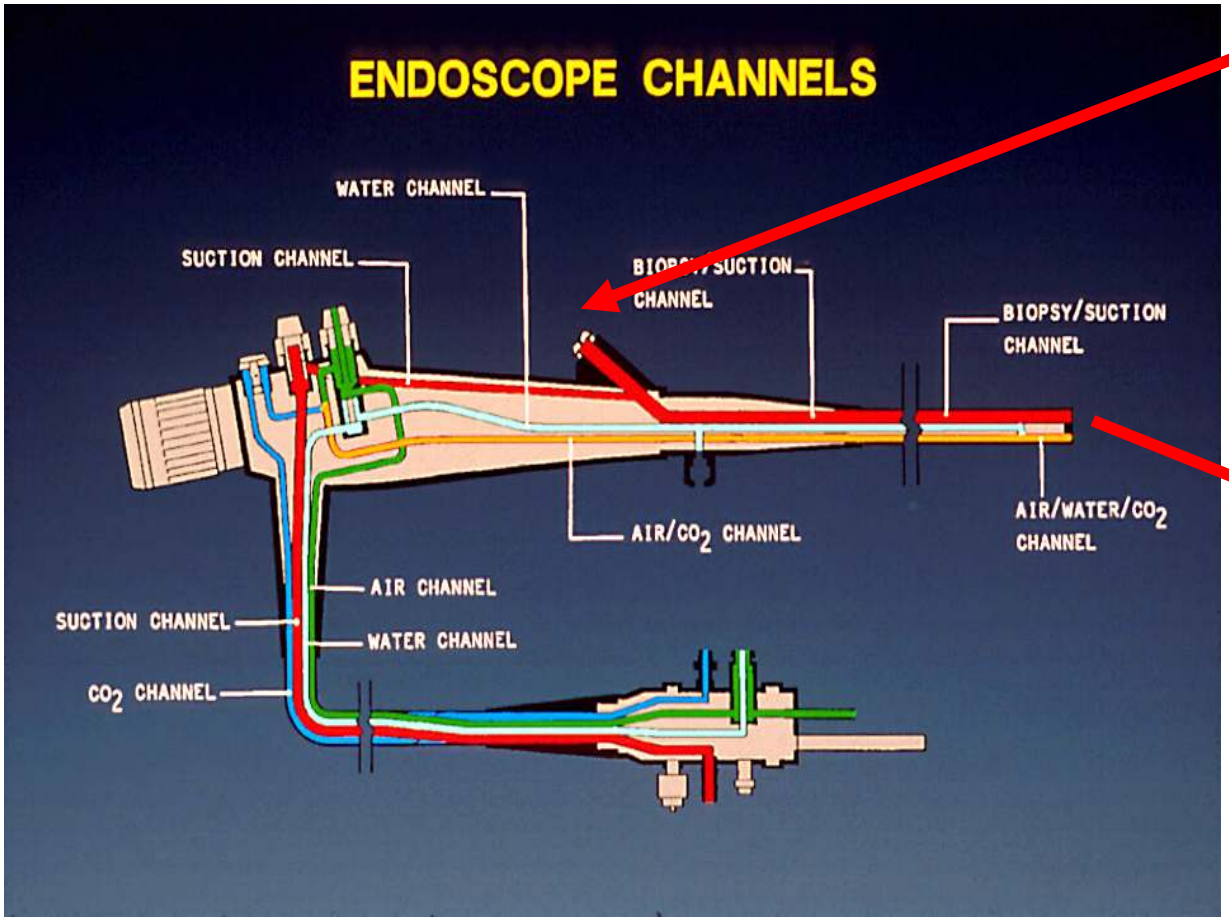
Endoscope Channel: sample collection

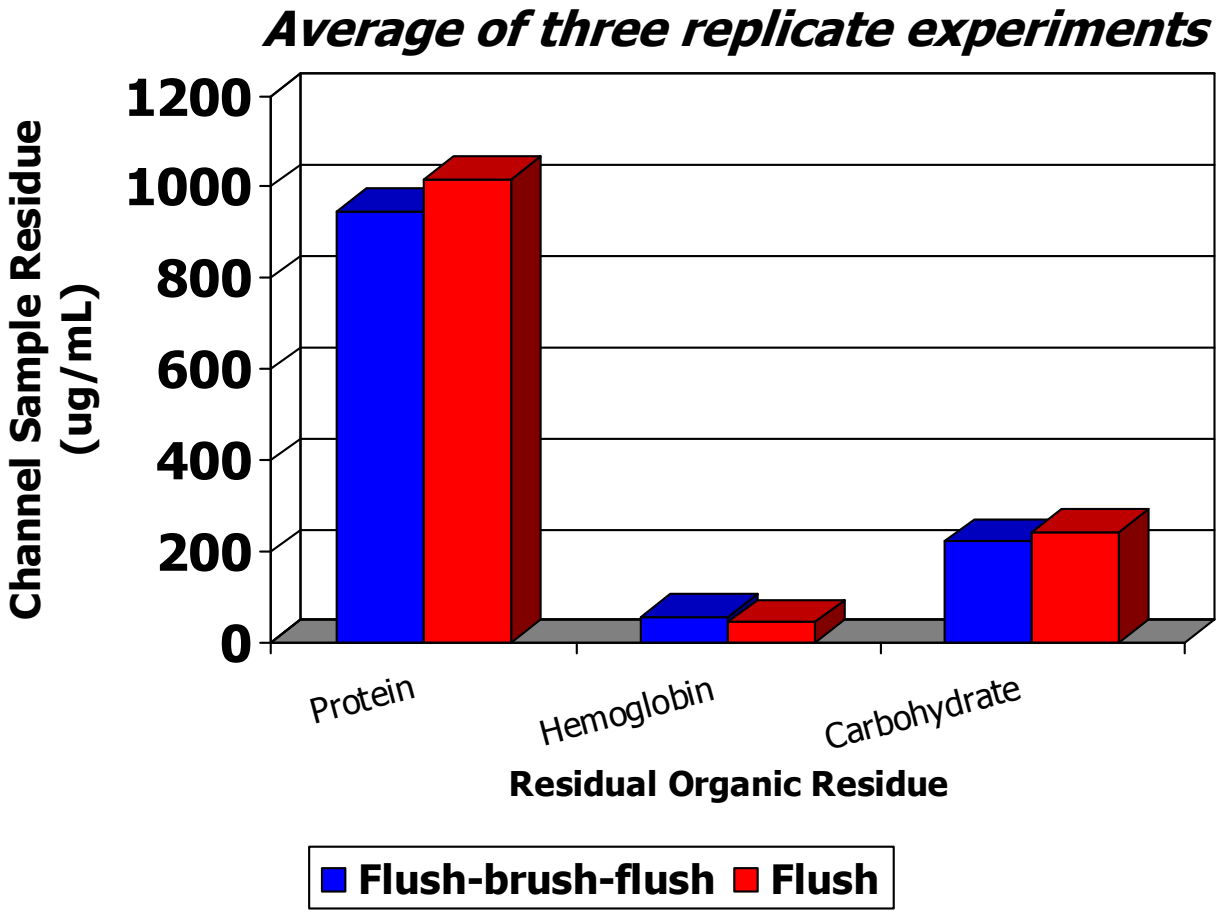


10 mL sterile RO water flushed into biopsy port

10 mL sample collected

Flush-brush-Flush Vs: Flush for Endoscope Sample collection

Suction Biopsy Channel



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Validation of Rapid Organic Test Strips using Research studies

- ***All pads negative*** complies with benchmarks:
  < 6.4 ug/cm^2 protein,
  < 500 ug/cm^2 carbohydrate
  < .25 ug/cm^2 hemoglobin
- ***Result interpretation:***
  If ANY of the 3 pads flags as positive → re-clean entire scope and retest S/B channel

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Channel-Chek PrototypeTest:

Canadian Multi-centre testing

- Prototype kits sent to 44 clinics from 23 Healthcare facilities;
  1499 scopes tested
- Sample: S/B → distal end using 10 ml sterile RO water
- Staff surveyed regarding test method

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Trans-Canada Survey: patient-ready flexible endoscopes

	No:	Pos:	Carbohydrate	Protein	Blood
Gastroscope	**543**	**50 (9.2%)**	**0**	**3**	**47**
Colonoscope	**463**	**32 (6.9%)**	**5**	**2**	**25**
Bronchoscope	**251**	**10 (4%)**	**0**	**0**	**10**
ERCP scope	**57**	**7 (12.3%)**	**0**	**0**	**7**
[Elevator wire]	**21**	**4 (19.1%)**	**0**	**0**	**4**
Sigmoidoscope	**91**	**2 (2.2%)**	**0**	**0**	**2**

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Reprocessing Staff Questionnaire: Trans-Canada Survey

How important is it to confirm adequate cleaning of flexible endoscope channels?	4.86
Should test be done some scopes each day?	4.16
Should test be regular part of QA in endoscopy area?	4.47
Ease of ENTIRE Rapid test?	4.64
Is time of test (90 sec) realistic for endoscopy area test?	3.98

(1: lowest/worst…… 5: highest/best)

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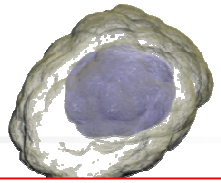
ATP monitoring of Endoscope Channel Cleaning



Human White cell

Bacteria

- ATP is present in ***living*** cells: both human and bacterial cells
- ATP measured by assay that detects "relative light units" or RLUs

Low level of RLUs

High level of RLUs

Pictures from Google Images

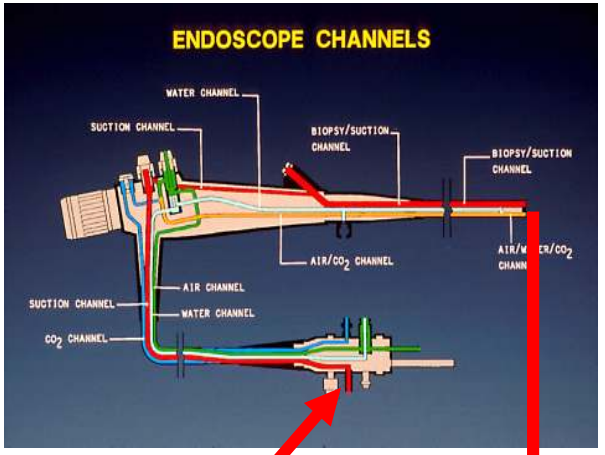
ATP Assay

- ATP does not have a linear correlation with microbial numbers
  [~10^3 cfu/mL to be detected]
- Various manufacturer's kits have different limits of detection for bacteria
  [Aiken et al ICHE 2001]
- Reflects total human cellular and bacterial cellular residuals
- Disinfectants inactivate ATP

Pictures from Google Images

ATP: Simulated-use testing

- Artificial Test Soil
  (containing 10^6 cfu/mL *Pseudomonas aeruginosa, Enterococcus faecalis)*
- All channels inoculated, held 1 Hr at RT
- Flush method used to sample all channels

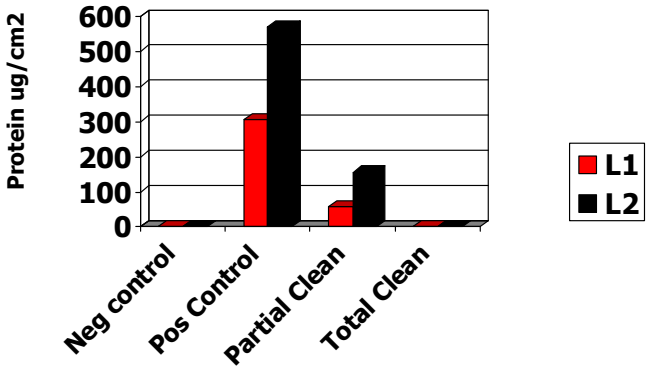


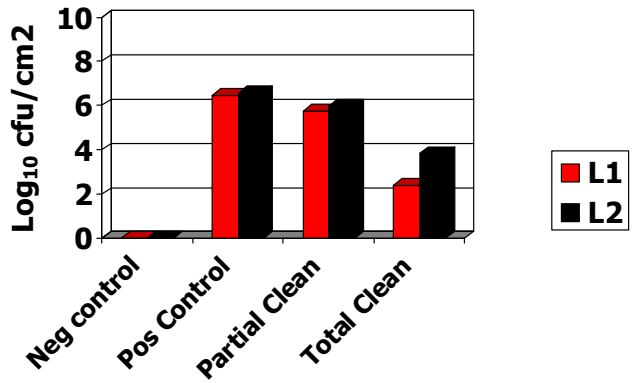
20 mLs sterile RO water

Channel sample collected

Simulated-use Evaluation

Duodenoscope: triplicate testing

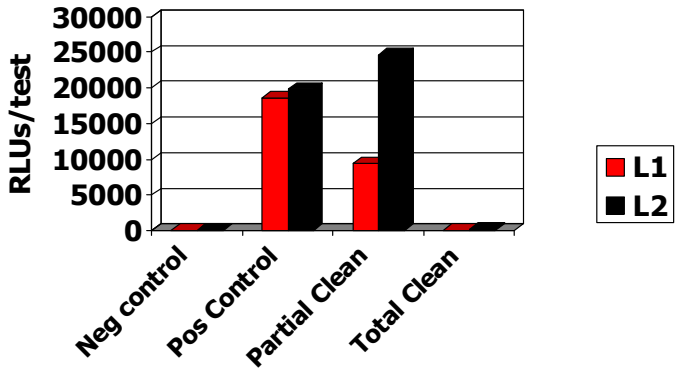




CLEAN Benchmarks:

Protein: < 6.4 ug/cm^2

Bioburden: < 4 Log_{10}/cm^2



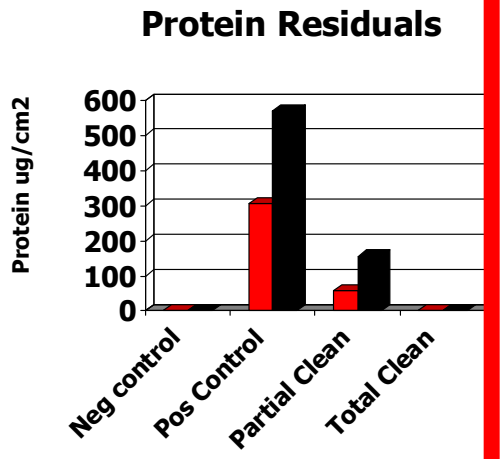
Sterile RO water to collect sample

L1: Suction/biopsy channel (40 mL)

L2: Air/water channel (20 mL)

Simulated-use Evaluation

Duodenoscope: triplicate testing



Protein:
- **Total clean: range 0.06 – 0.46 ug/cm²**
- **Partial clean: range 45 – 356 ug/cm²**

Bioburden:
- **Total clean: range 2 – 3 Log_{10}/cm^2**
- **Partial clean: range 5 – 6 Log_{10}/cm^2**

ATP:
- **Total clean: range 16 – 183 RLUs**
- **Partial clean: range 8,000 – 46,000 RLUs**

CLEAN Benchmarks:

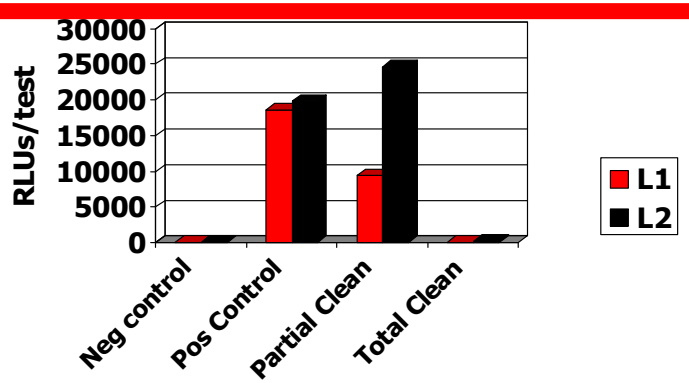
Protein: < 6.4 ug/cm²

Bioburden: < 4 Log_{10}/cm^2

Sterile RO water to collect sample

L1: Suction/biopsy channel (40 mL)

L2: Air/water channel (20 mL)



ATP Clinical Study: One hospital
Benchmark for clean < 200 RLUs

30 colonoscopes and 30 duodenoscopes post manual cleaning

1. ***Duodenoscopes more difficult to clean than Colonoscopes***

2. ***Duodenoscopes Post manual cleaning:***

Surface 1:	10% > 200 RLUs	(all < 750 RLUs)
Suction/Biopsy channel:	0% > 200 RLUs	
Air/water channel:	0% > 200 RLUs	
Elevator G-wire channel:	20% > 200 RLUs	(all < 700 RLUs)

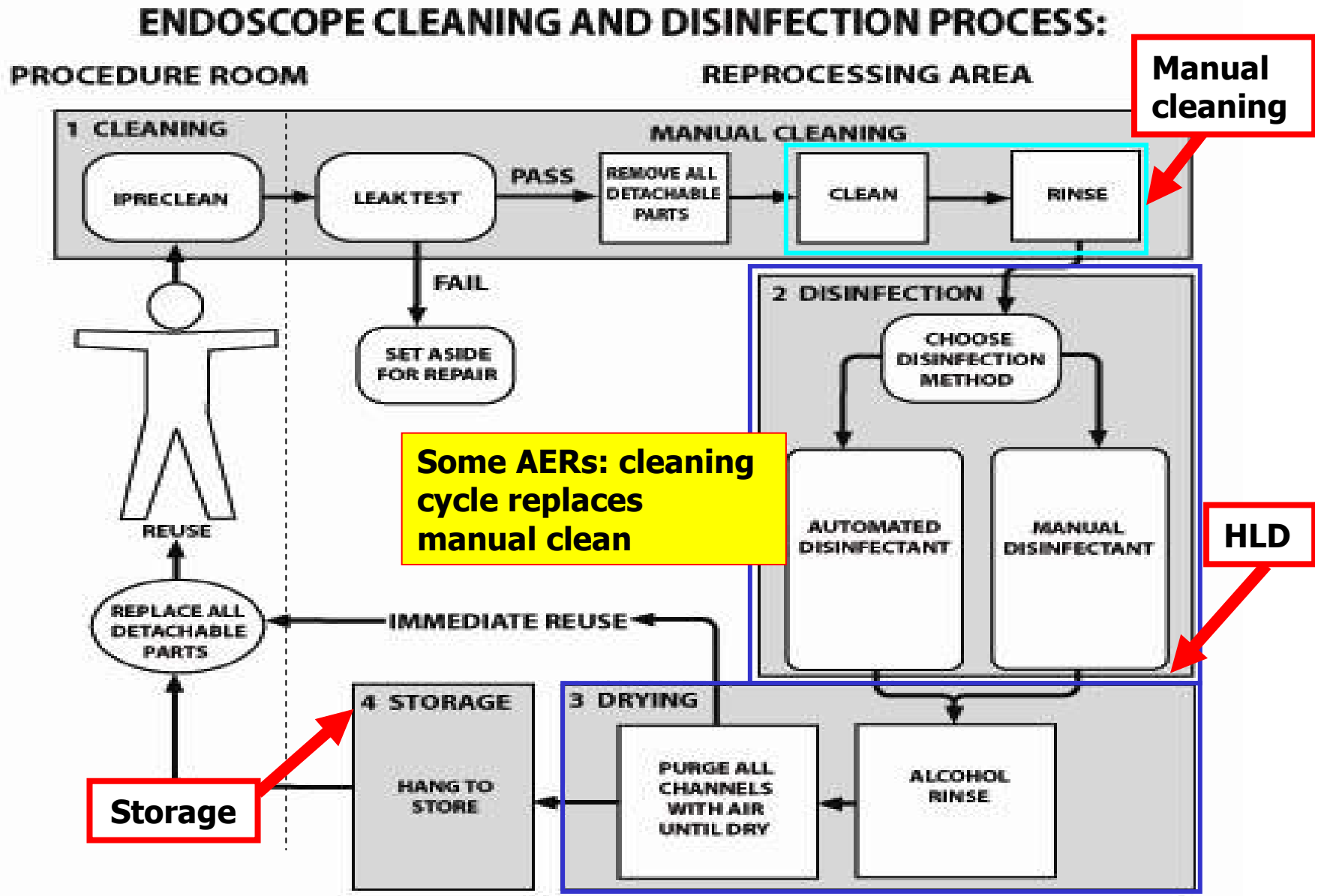
Manuscripts submitted to American Journal of Infection Control

Summary: ATP Assay Validation

- **Each manufacturer** needs to validate benchmark RLU that correlates with adequate manual cleaning
- **ATP Assay (3M):** < 200 RLUs ensures entire channel meets benchmarks
  (i.e. < 6.4 ug/cm^2 & < 4 Log_{10} cfu/cm^2)
- **ATP Assay:**
  - not applicable after HLD

Pictures from Clip-Art

Monitoring Cleaning at What stage?



When to Monitor Cleaning??

Quality Assurance Program: Staff

- ***New staff:*** QA for training adequacy
  [all channels for each scope type]
- ***New endoscopes***: QA for training adequacy
  [all channels for each scope type]
- ***Ongoing (yearly):*** QA for maintenance of staff competency
  [all channels for each scope type]

Pictures from Google Images

Frequency of Monitoring??

Quality Assurance Program: Endoscopes

- ***Site Verification***:
  - Establish reproducible baseline by testing all scopes all channels for a short period of time
- ***Ongoing Monitoring:***
  - Each scope used tested ~1/week
  - Problem persists in S/B channel → test all channels

Pictures from Google Images

SUMMARY:

- **Quality Process: Flexible endoscopes**
  - Monitor cleaning process, not just disinfection stage

- **Ongoing Rapid Monitoring of manual cleaning**:
  - Select a Validated test method: ATP, Organic residuals
  - Users to Verify site can reliably meet validated cutoffs
  - Ensure test used at the correct stage of reprocessing

- **Guidelines:**
  - What frequency of testing?

References

General Reprocessing

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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.*

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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*
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- ANSI/AAMI ST79:2006 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

Cleaning

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