

Flexible endoscope reprocessing: Focus on correcting key weaknesses



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Winnipeg, Manitoba, CANADA

Hosted by Jim Gauthier

www.webbertraining.com

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Disclosures: Dr. Michelle J. Alfa

Consulting services: Healthmark, Olympus, 3M, Nanosonics

Royalties: University of Manitoba for patent license to Healthmark

Sponsored Speaker: 3M, Olympus

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All publications mentioned are listed at the end of the presentation

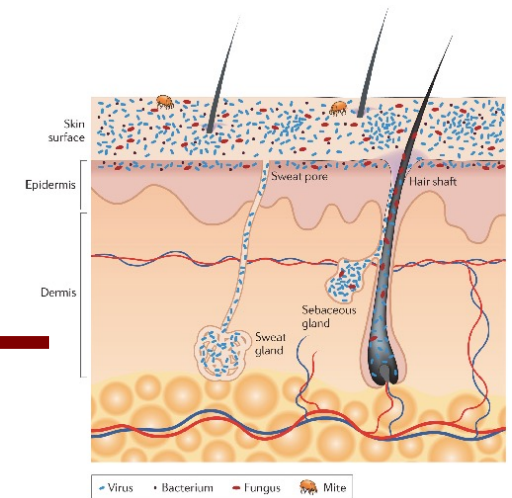
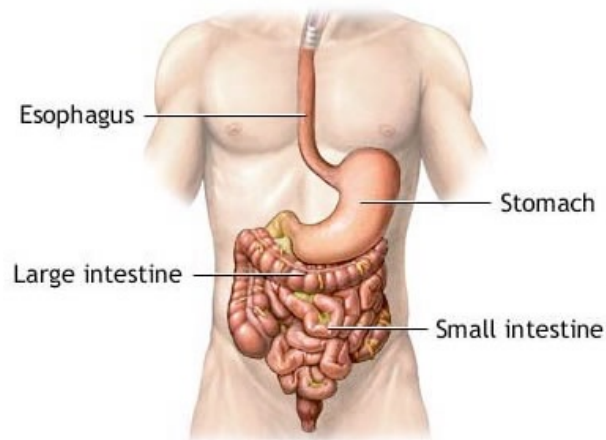
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OBJECTIVES:

- *Current data on contamination of patient-ready endoscopes*
- *Identify key weaknesses in current reprocessing protocols*
- *Recommend what can be done to address key weaknesses*

Patient Infections related to Contaminated Medical Devices

Endogenous: Infections due to patient's own organisms



Exogenous: Infection resulting from contaminated medical device



Endoscope Contamination: Patient Infection vs Carrier

Duodenoscope *NDM-E.coli* Outbreak 2014 [Illinois, USA]

98 exposed patients:

- Transmission was 36.8%
 - 9.2% developed infection
 - 27.6% became gastrointestinal carriers

Carriers:

1. Long term colonization [years]
2. Transmit MDRO to others
3. Subsequent antibiotic exposure selects for MDRO

Epstein L et al New Delhi Metallo B-Lactamase producing carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes JAMA 2014;312:1447-55

Ureteroscope *P. aeruginosa* MDRO Outbreak 2019 [London, England]

Culture of 40 exposed patients:

- 13/40 (32.5%) developed infection [Urinary tract infections/urosepsis]

Kumarage J et al Transmission of multi-drug resistant *P. aeruginosa* between two flexible ureteroscopes and an outbreak of urinary tract infection: the fragility of endoscope decontamination. J Hosp Infect 2019;102:89-94

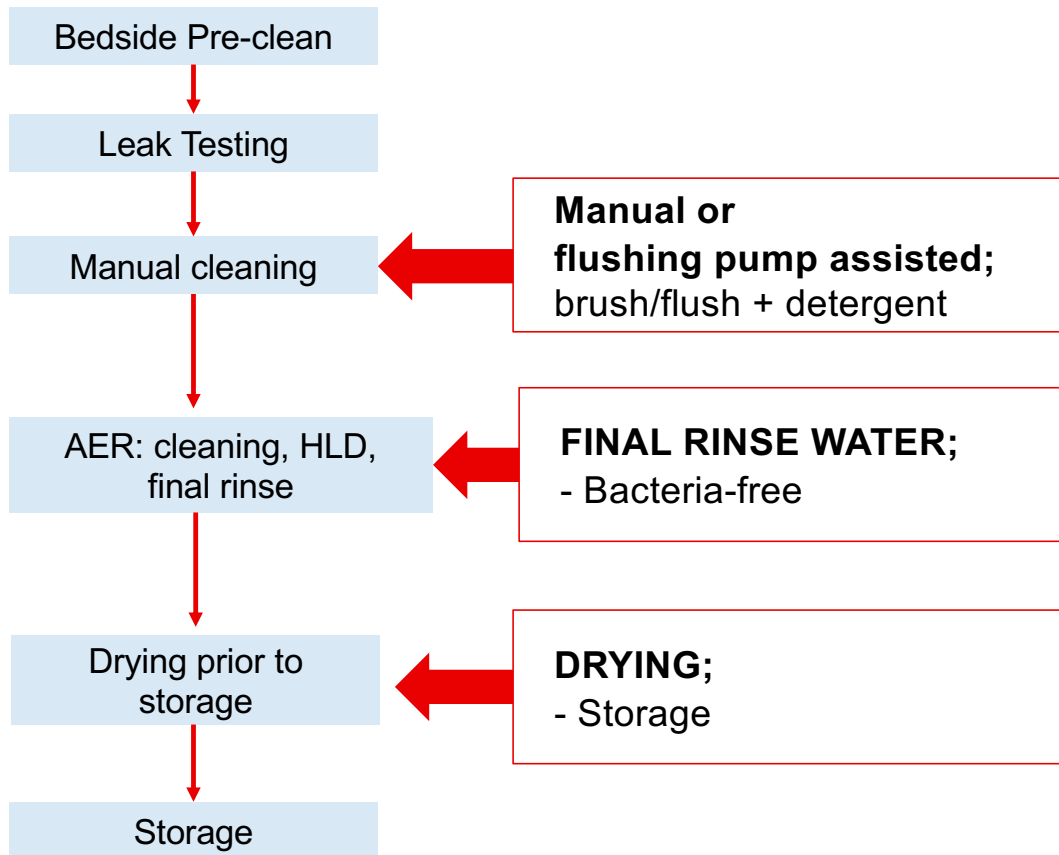
Extent of cross-contamination of patients from GI endoscopy: World-wide Problem



• Upper GI endoscopy • Duodenoscopy and ERCP • Colonoscopy and sigmoidoscopy

Deb A et al Gastrointestinal Endoscopy-Associated Infections: Update on an Emerging Issue. Digestive Diseases and Sciences (2022) 67:1718–1732

Endoscope Reprocessing System



- Reprocessing is a **SYSTEM** with sequential stages
- Breaches in any one stage can result in persistence of microbes and organic matter in the patient-ready endoscopes

What is the Non-outbreak prevalence?

FDA mandated 522 Post-market clinical study

HIGH CONCERN ORGANISMS:

Gram negative bacilli:

Escherichia coli, *Klebsiella pneumoniae*, other Enterobacteriaceae, *Pseudomonas aeruginosa*,

Gram positives:

Staphylococcus aureus, *Beta-hemolytic Streptococcus*,
Enterococcus spp.,

Yeasts

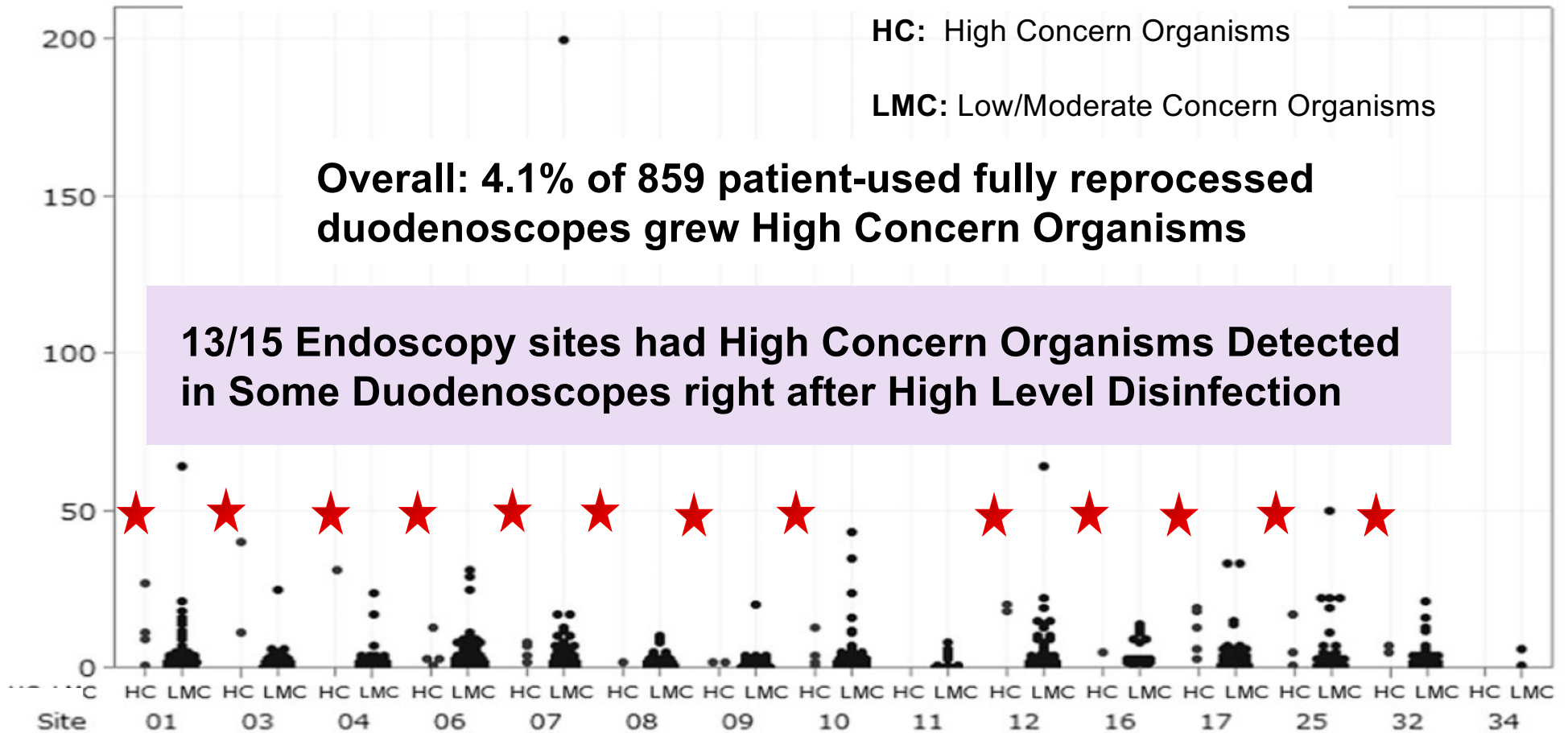
Olympus TJF-Q180V Duodenoscope

HC: High Concern Organisms

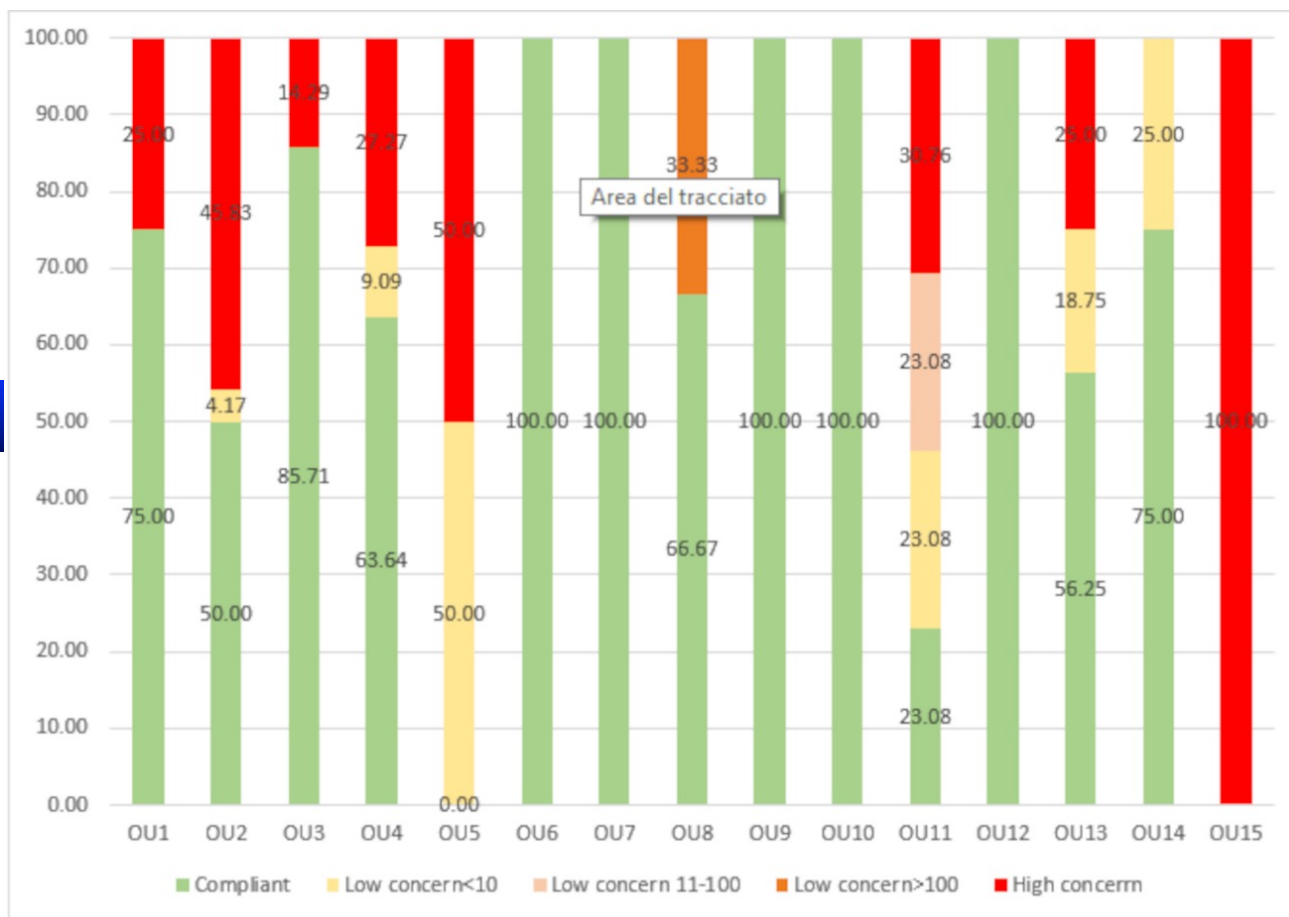
LMC: Low/Moderate Concern Organisms

Overall: 4.1% of 859 patient-used fully reprocessed duodenoscopes grew High Concern Organisms

13/15 Endoscopy sites had High Concern Organisms Detected in Some Duodenoscopes right after High Level Disinfection



Italian Clinical study: Non-outbreak situation



8 of 15 sites had some High Concern organisms (Red bars)

7 of 15 sites had no High Concern Organisms

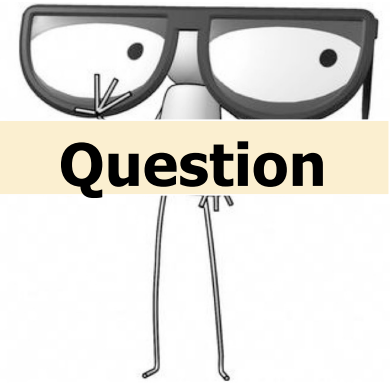
Casini B. et. al. Microbiological surveillance post-reprocessing of flexible endoscopes used in digestive endoscopy: a national study. Journal of Hospital Infection, [https:// doi.org/10.1016/j.jhin.2022.09.024](https://doi.org/10.1016/j.jhin.2022.09.024)

UPMC Presbyterian Gastrointestinal Endoscopy service
University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

Duodenoscope Type	Reprocessing Method	Frequency of Pathogenic Bacteria (Positive/Total Cultured)	%
Duodenoscope or linear echoendoscope	dHLD	4/47	8.5
Duodenoscope or linear echoendoscope	HLD-ETO	2/80	2.5

Ayres A et. al. Endoscopic retrograde cholangiopancreatography and endoscopic ultrasound endoscope reprocessing: Variables impacting contamination risk. *Infection Control & Hospital Epidemiology* 2023; 44:1485–1489 doi:10.1017/ice.2022.319

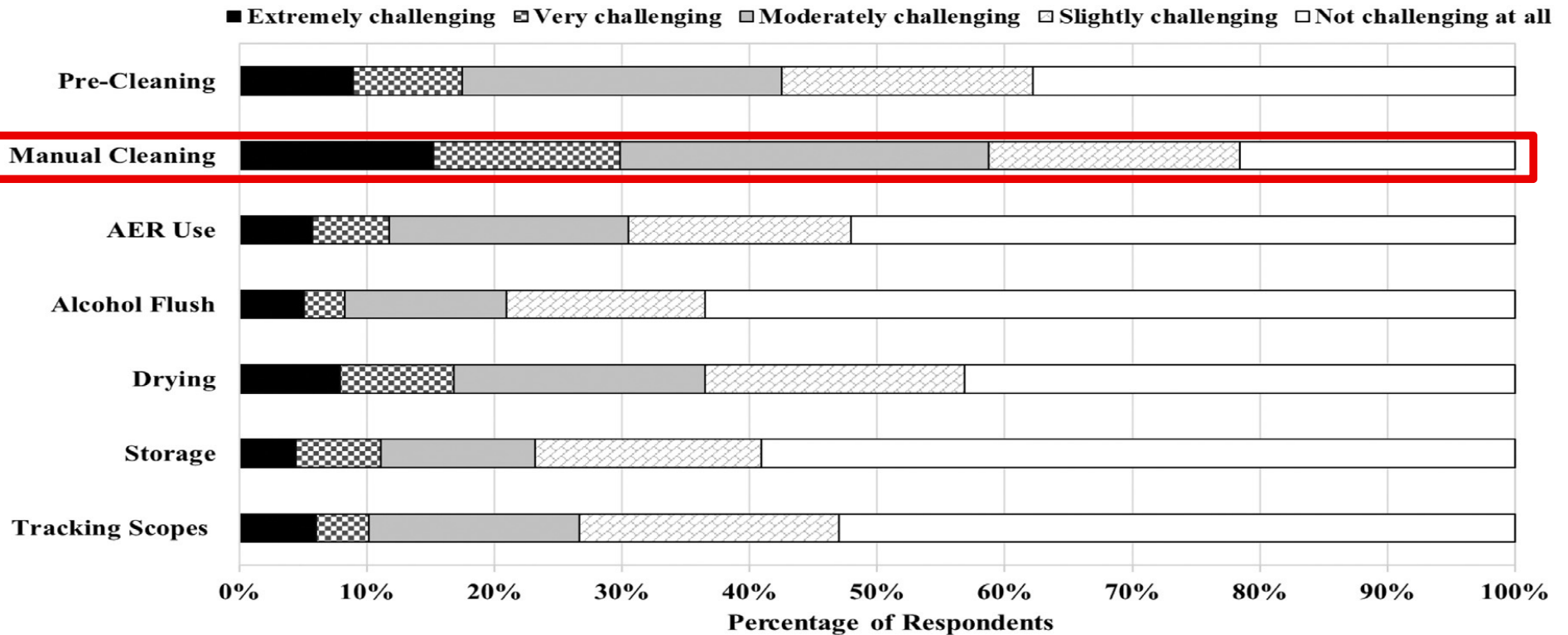
Underlying Causes of Persistent Endoscope Contamination?



Key “weak link 1”: Inadequate Cleaning

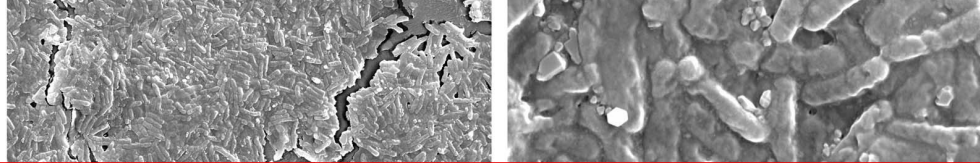
ADEQUATE CLEANING OF ALL ENDOSCOPE CHANNELS:
Should Remove/Reduce:

- ORGANIC RESIDUES
- MICROORGANISMS
- BIOFILM ACCUMULATION

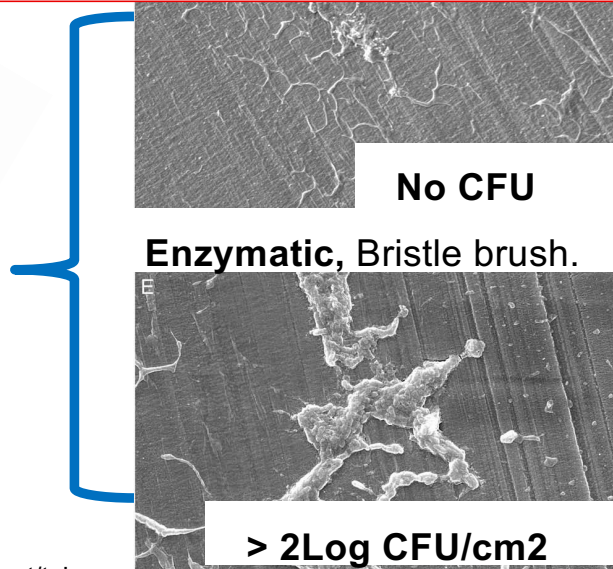


“70% of survey respondents felt pressure to work quickly and 17% of the respondents routinely skipped endoscope IFU steps due to time pressure.”

Alfa M et al Simulated-Use Polytetrafluorethylene Biofilm Model: Repeated Rounds of Complete Reprocessing Lead to Accumulation of Organic Debris and Viable Bacteria. ICHE 2017 DOI: 10.1017/ice.2017.215



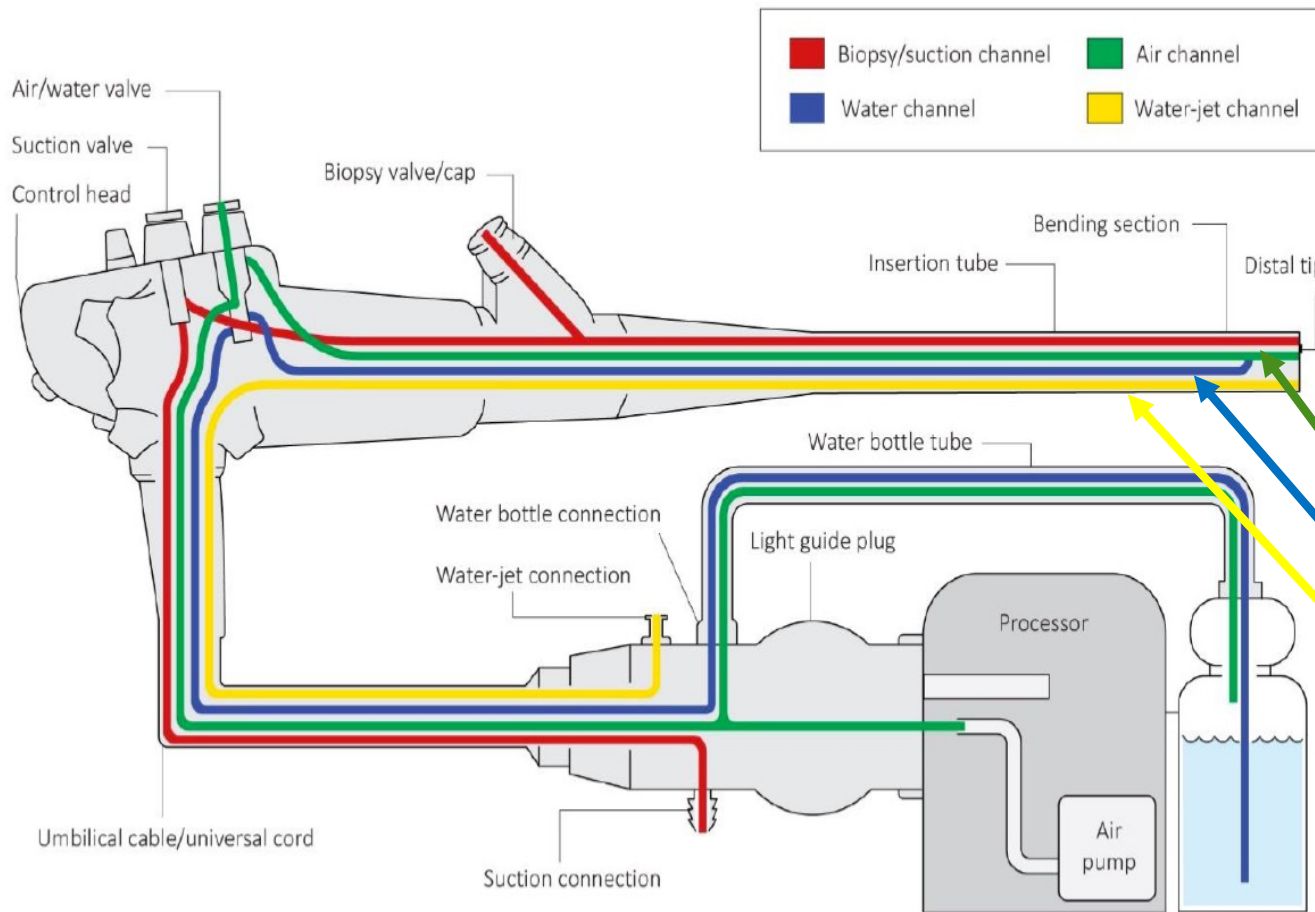
SURFACE FRICTION IS CRUCIAL FOR CLEANING



Bristle brush Image from:
<https://www.hmark.com/product/tube-brushes-for-cleaning-lumens/>

Non-enzymatic, Bristle brush.

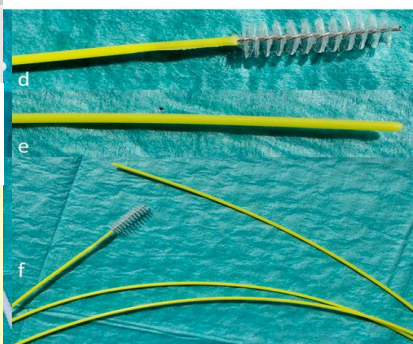
Figure 3. Schematic of an endoscope



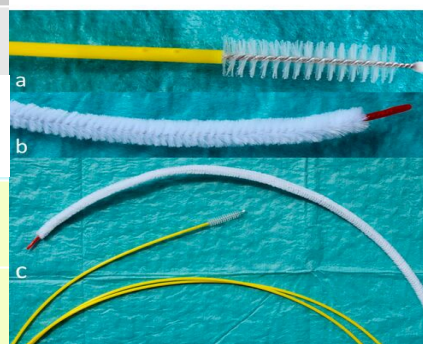
Narrow channels lack of friction:
No brush used for cleaning: flushing detergent only.

Clinical Study: Impact of Improved Friction in Biopsy/Suction channel cleaning on Duodenoscope contamination

Channel	Bristle Brush Cleaning High concern Organisms	Push-pull brush Cleaning High concern Organisms
	N = 176	N = 81
Overall	45.5%	17.3%
Biopsy	29.0%	3.7%
Suction	30.1%	2.5%



Labels: d, e, f



Labels: a, b, c

NOTE: Bristle & Push-pull brush cannot be used for Air/Water channel cleaning

van der Ploeg K, et al. Effect of novel endoscope cleaning brush on duodenoscope contamination. *Endoscopy* 2023. doi: 10.1055/a-2193-4481.

Basic start: Document time for manual cleaning

[Ensure detergent manufacturer's contact time is achieved]



- **Alfa 2010: [Manual flushing]**
Clinical staff; Average; 5 to 6.5 mins for all bronchoscopes, gastroscopes, duodenoscopes
Research staff; 14 mins for bronchoscopes to 25 mins for duodenoscopes, ensuring Manufacturer's Instructions were followed
- **Schmitt 2018:**
Clinical staff; Average 16 mins for Gastroscopes

Ensure appropriate manual cleaning time BEFORE attempting to monitor cleaning efficacy using rapid test methods.

American
National
Standard

ANSI/AAMI
ST91:2021
Flexible and semi-rigid
endoscope processing in
health care facilities

Requires verification of manual cleaning for High Risk endoscopes

(duodenoscopes, bronchoscopes, ureteroscopes, cystoscopes)

Rapid cleaning monitoring tests:

Organic: Carbohydrate, protein, hemoglobin

ATP: patient secretions

Rapid cleaning verification methods:

After Manual Clean: Flush channels to collect samples

Organic residues: Color change; visual interpretation
Single or multiple organic markers



ATP: Level of ATP from hand-held detector; numeric



- RLU Cut-off varies by test kit used
- RLU's DO NOT indicate level of microbes [i.e. microbes can be present even if RLU < cutoff]
- RLU's detect; patient secretions, food etc.

Images from manufacturer's websites

Rapid cleaning verification methods:

After Manual Clean: Flush channels to collect samples

Organic residues: Color change; visual interpretation
Single or multiple organic markers



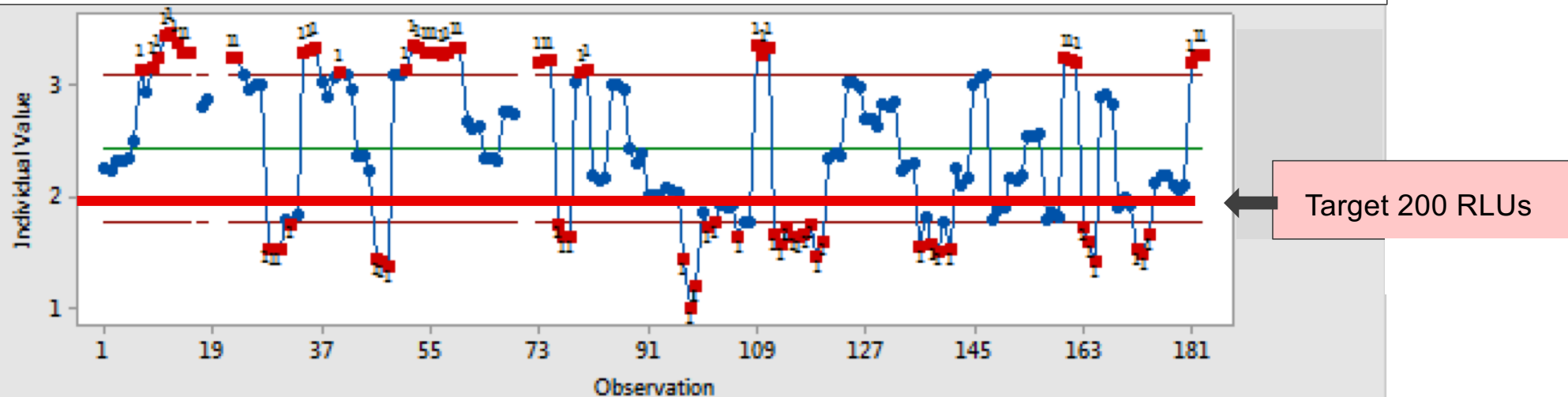
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Images from manufacturer's websites

GASTROSCOPES: POST MANUAL CLEANING ATP LEVELS



High ATP after Bedside clean → Failure after Manual Cleaning

Clinical Study: ATP Monitoring Manual Cleaning

**Sample:
Endoscope Channel 40 mL Flush
Umbilical to Distal end**

Pre-Clean

Post-Manual Clean

Gastrosopes (13)

All > 200 RLUs

All < 200 RLUs

Colonoscopes (15)

All > 200 RLUs

All < 200 RLUs

Duodenoscopes (2)

All > 200 RLUs

1 at 671 RLUs

Bronchoscopes (3)

All > 200 RLUs

All < 200 RLUs

Cystoscopes (5)

All > 200 RLUs

All < 200 RLUs

Chan et al Effectiveness of adenosine triphosphate to monitor manual cleaning and disinfection efficacy of flexible endoscopes in Hong Kong. JGH Open; 2023; doi:10.1002/jgh3.12863

Underlying Causes of Persistent Endoscope Contamination?



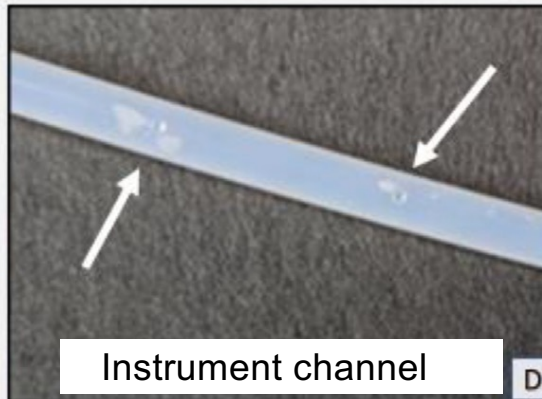
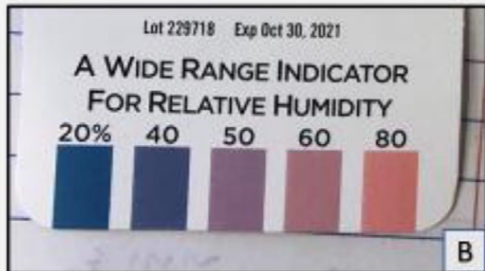
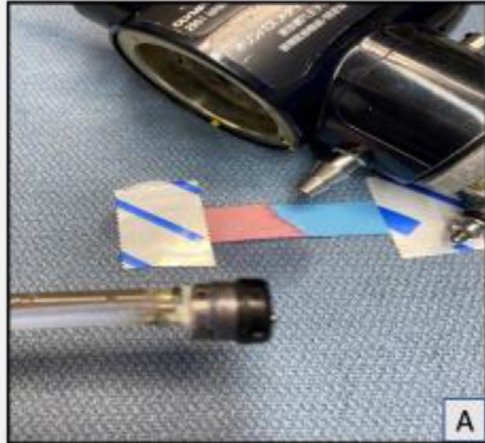
Key “weak link 2”: Inadequate Drying

ADEQUATE DRYING FOR ENDOSCOPE STORAGE:

Should prevent microbial replication

- AER: *drying is inadequate*
- NARROW CHANNELS: *hardest to dry*
- TRACE RESIDUAL MOISTURE: *microbial replication*

3 min AER Dry



Yassin M et al How effective are the alcohol flush and drying cycles of automated endoscope reprocessors? Stripped endoscope model. AJIC 2023;51:527-532

Moisture Retention in SE Models (≥ 1 visible drop, misting, or confluent fluid)

Air cycle	Channel	Stripped endoscope model		
		CF-HQ190L	PCF-H190DL	CF-Q160L
3-min	Biopsy/Suction	+	+	+
	Air/Water	+	+	+
10-mi	Biopsy/Suction	-	-	-
	Air/Water	+	+	+
3-min + 7-d hang dry	Biopsy/Suction	-	-	-
	Air/Water	+	+	+
10-min + 7-d hang dry	Biopsy/Suction	-	-	-
	Air/Water	+	+	+



A positive symbol represents the presence of visible water.

Yassin M et al How effective are the alcohol flush and drying cycles of automated endoscope reprocessors? Stripped endoscope model. AJIC 2023;51:527-532

How to Dry flexible endoscope channels?

1. Manual; Compressed air-gun:
Not Practical
2. Flushing Pump-assisted;
& Endoscope dolly



Ofstead et al Fluid retention in endoscopes a real world study. AJIC 2024
<https://doi.org/10.1016/j.ajic.2024.02.015>

3. Automated;
Channel-purge storage cabinet

GESA GENCA; Infection Prevention
and Control in Endoscopy 2021.
Gastroenterological Society of Australia



Images from Wassenberg website

Underlying Causes of Persistent Endoscope Contamination?

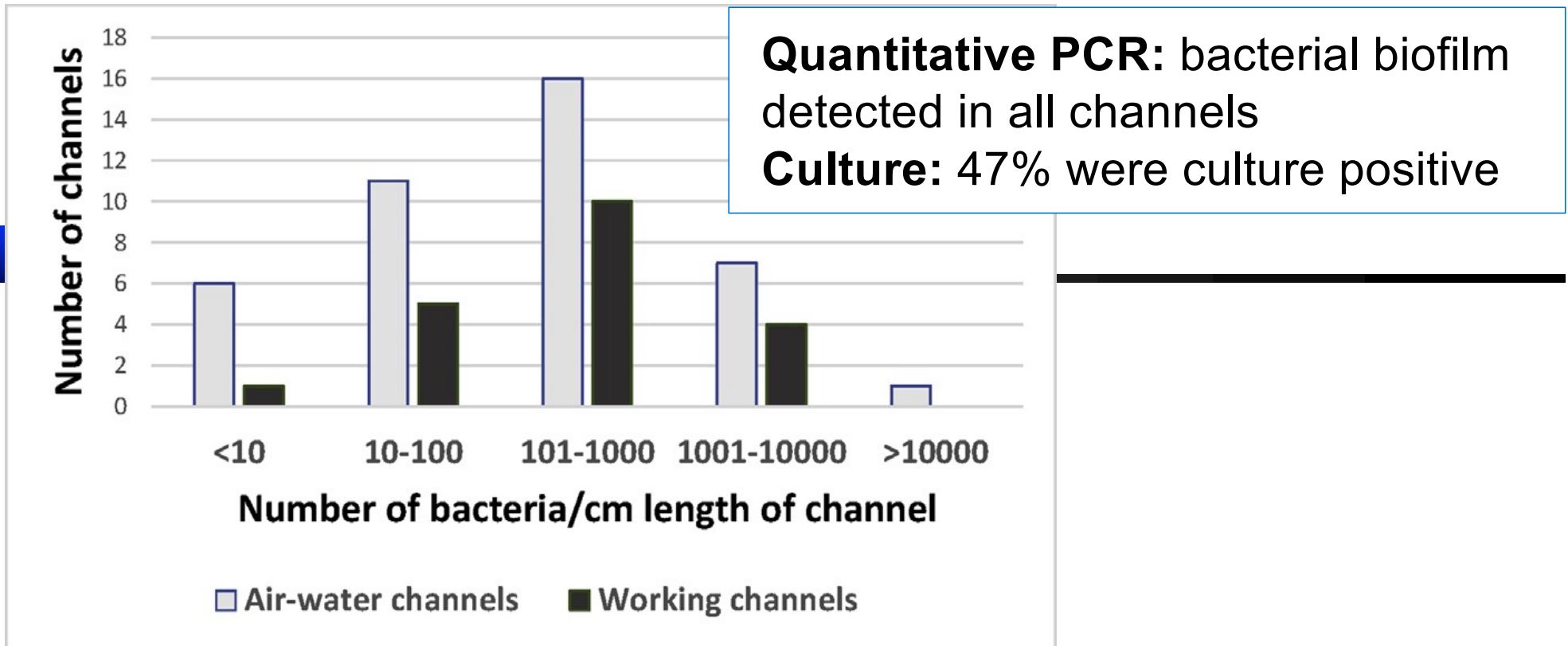


Key “weak link 3”: Build-up Biofilm

INADEQUATE CLEANING & DRYING LEAD TO ACCUMULATION OF ORGANIC RESIDUES AND MICROBE SURVIVAL

- **FRICITION:** *during cleaning is critical*
- **NARROW CHANNELS:** *Little/No friction*
- **REMOVAL OF BUILD-UP BIOFILM:** *almost impossible*

64 Gastroscope and Colonoscope channels evaluated



Johani K, et al., Determination of bacterial species present in biofilm contaminating the channels of clinical endoscopes, *Infection, Disease & Health* (2018), <https://doi.org/10.1016/j.idh.2018.06.003>


New approaches to biofilm removal are needed.

“Lumened endoscopes, especially gastrointestinal endoscopes, have the highest potential for biofilm formation in the lumen....”



“In fact, gastrointestinal endoscopes and bronchoscopes have been associated with far more outbreaks of infections (> 130 outbreaks) than any other reusable medical or surgical device in health care.”

Weber JD et. al. Biofilms on medical instruments and surfaces: Do they interfere with instrument reprocessing and surface disinfection. Am J Infect Control 2023;51:A114-A119. <https://doi.org/10.1016/j.ajic.2023.04.158>

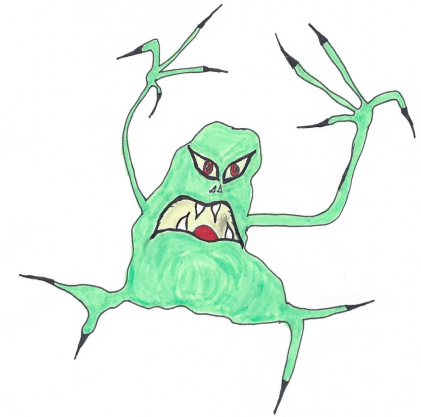


Quality Parameter:	AAMI ST91 2021	ISO 15883-4 2019
	User Verification:	Routine Testing:
Manual Cleaning	YES: All HR scopes, others periodically	NO

CONCLUSIONS:

➤ Endoscope Contamination:

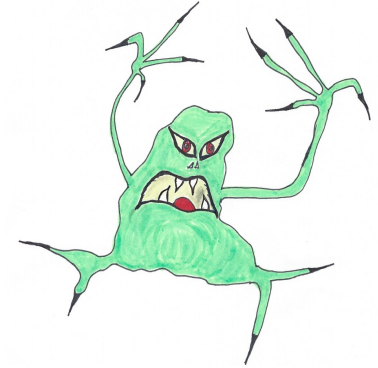
- Still a major problem
- **ACTION:** Audit/Monitor the Key Weak links



➤ Inadequate channel cleaning is a Weak Link:

- Audit manual cleaning; time study
- Monitor cleaning [ATP, Rapid Organic marker tests]

CONCLUSIONS:



➤ Inadequate drying of channels is a weak link:

- Audit channel drying; Cobalt chloride paper
- Air flushing pump; minimum 10 min drying
- Convert to channel-purge storage

No Monitoring means



**You don't know what you
don't know!**

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