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

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Sponsored Speaker: 3M, Olympus

The information presented today is based on published data and my opinion and is independent of any company to whom I provide consulting services.

All publications mentioned are listed at the end of the presentation

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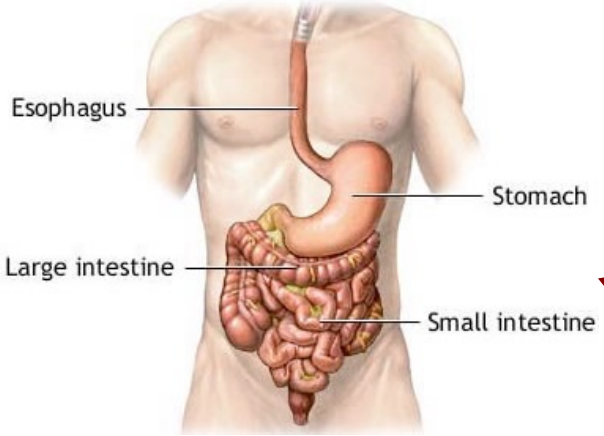
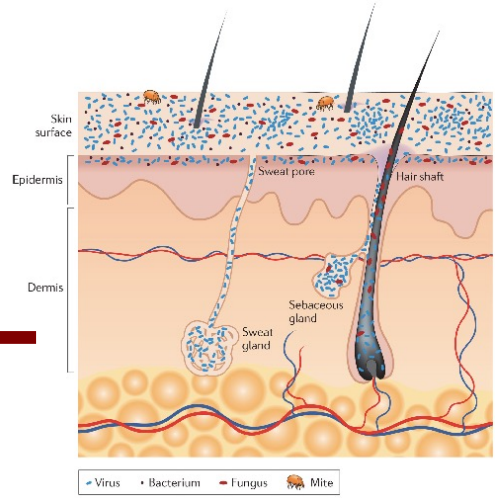
OBJECTIVES:

- *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 wiith exposure to duodenoscopes JAMA 2014;312:1447-55

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

Culture of 40 exposed patients:

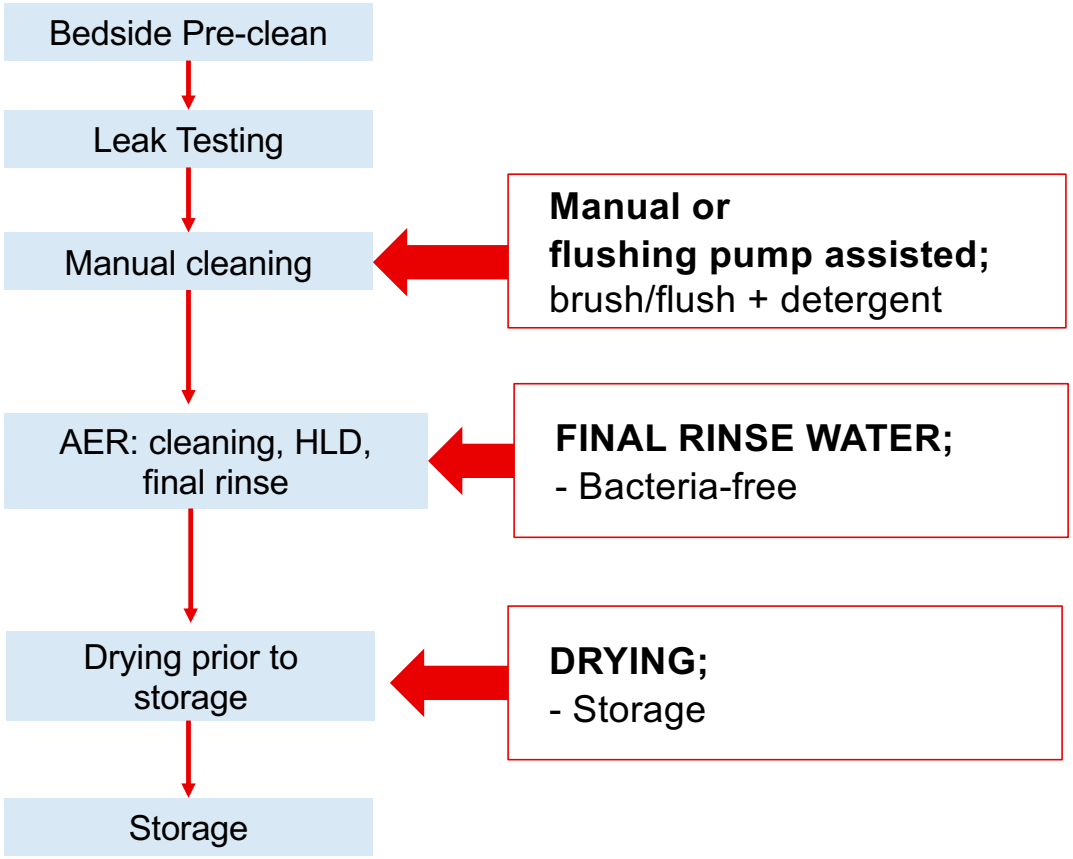
- 13/40 (32.5%) developed infection [Urinary tract infections/urosepsis]

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

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?

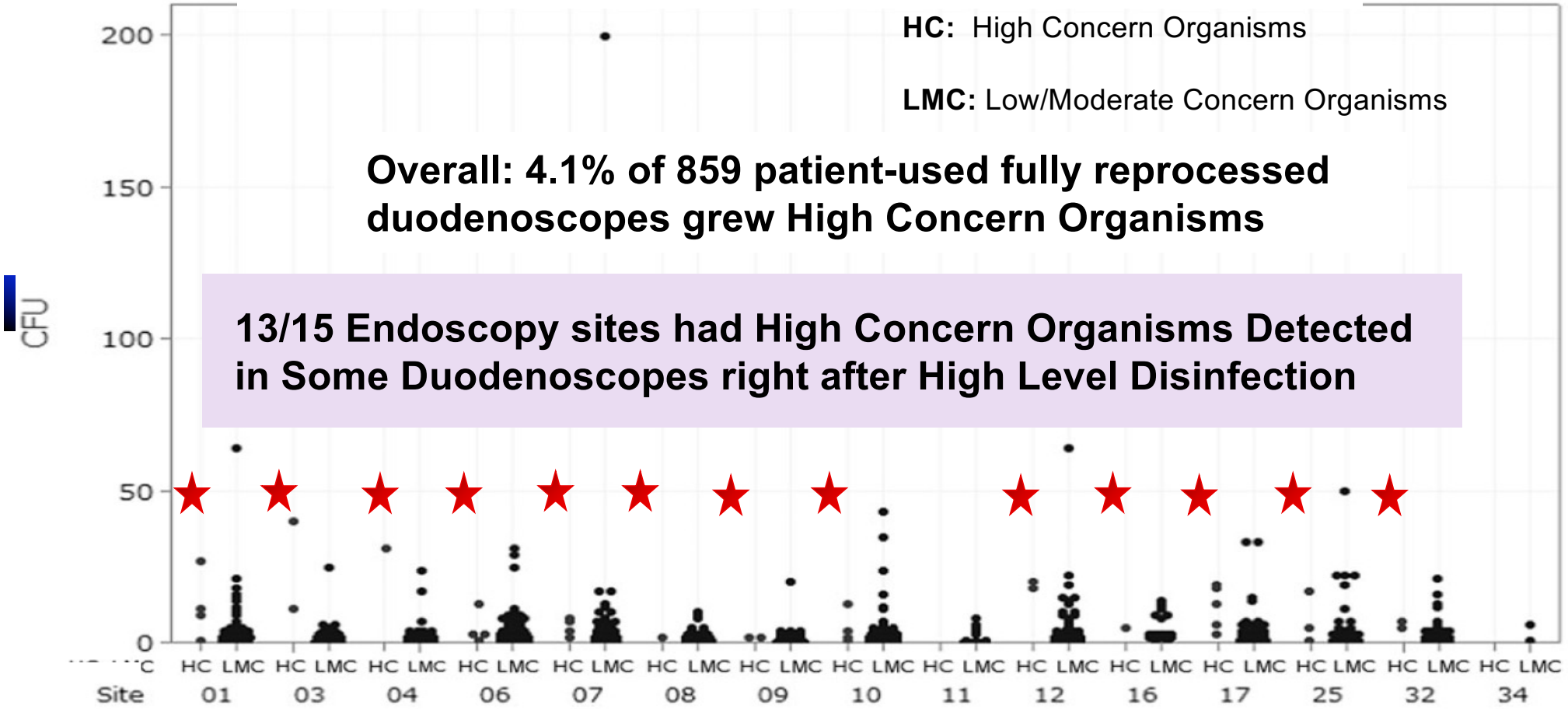
FDA mandated 522 Post-market clinical study

HIGH CONCERN ORGANISMS:

Gram negative bacilli:
Escherichia coli, Klebsiella pneumoniae, other Enterobacteriaceae, *Pseudomonas aeruginosa*,
Gram positives:
Staphylococcus aureus, Beta-hemolytic Streptococcus, Enterococcus spp.,
Yeasts

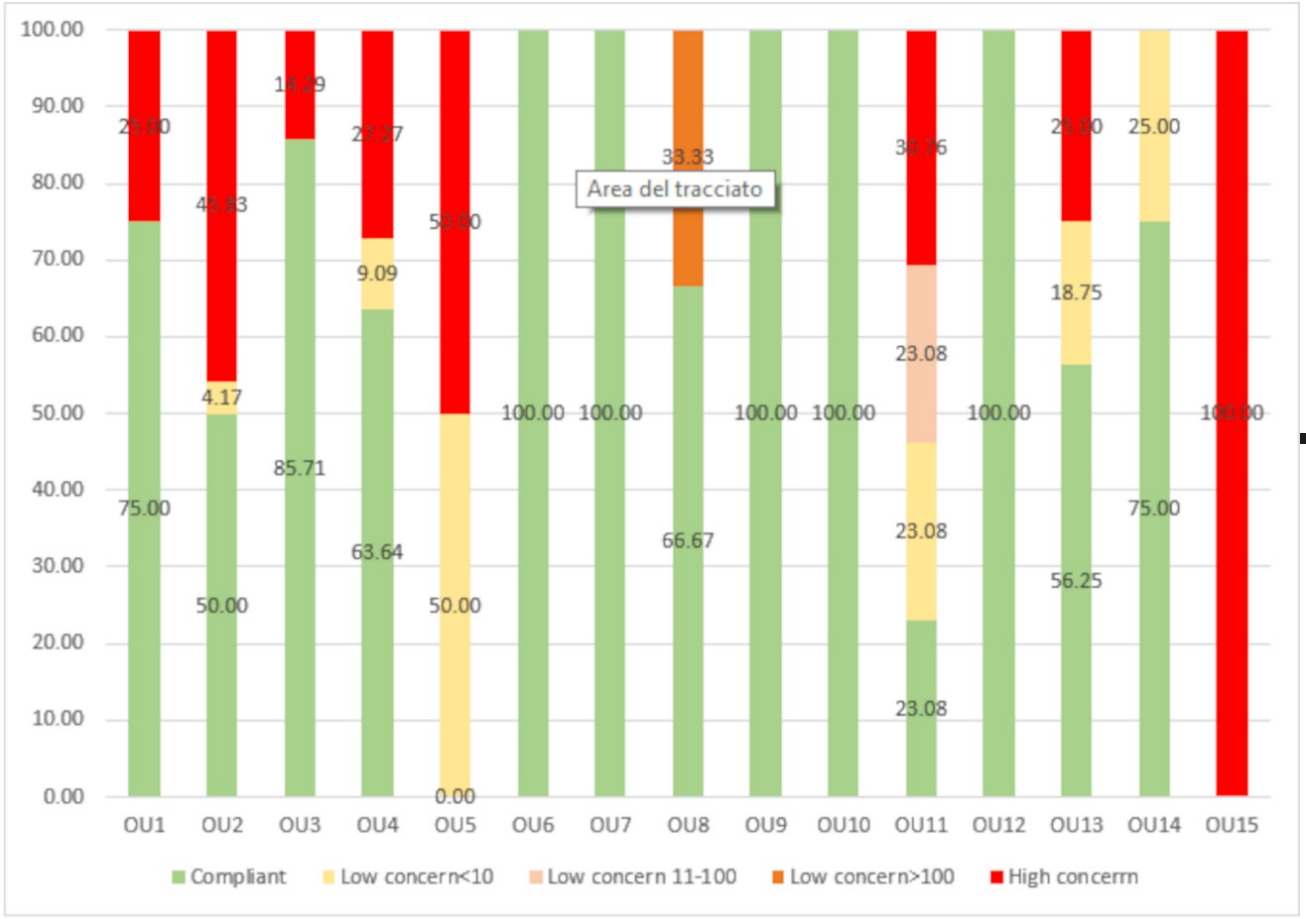
Duodenoscope Surveillance Sampling & Culturing FDA/CDC/ASM 2018. https://www.fda.gov/media/111081/download

Olympus TJF-Q180V Duodenoscope



Okamoto N, et al. A prospective, multicenter, clinical study of duodenoscope contamination after reprocessing. ICHE 2022 https://doi.org/10.1017/ice.2021.525

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

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

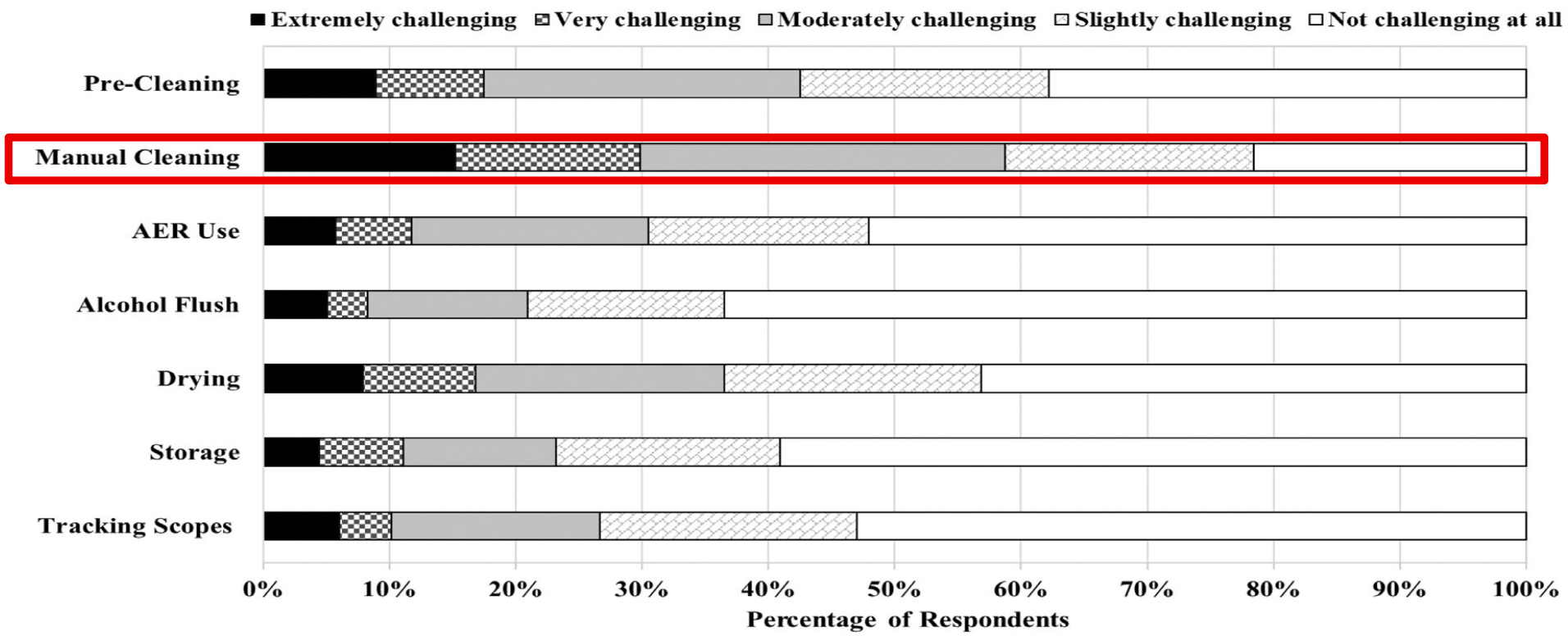
Ayres A et. al. Endoscopic retrograde cholangiopancreatography and endoscopic ultrasound endoscope reprocessing: Variables impacting contamination risk. Infection Control & Hospital Epidemiology 2023; 44:1485–1489 doi:10.1017/ice.2022.319

Underlying Causes of Persistent Endoscope Contamination?

Key "weak link 1": Inadequate Cleaning

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

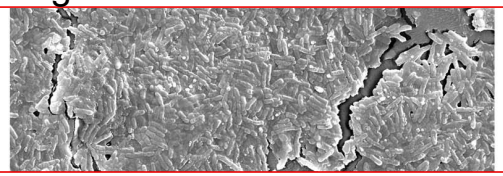
- ORGANIC RESIDUES
- MICROORGANISMS
- BIOFILM ACCUMULATION

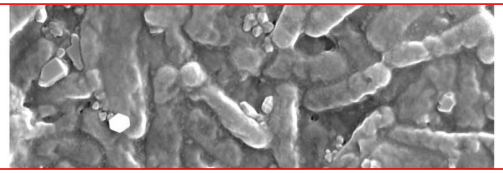


"*70% of survey respondents felt pressure to work quickly and 17% of the respondents routinely skipped endoscope IFU steps due to time pressure*."

Sivek A et al Healthcare worker feedback on duodenoscope reprocessing workflow and ergonomics. AJIC 2022 https://doi.org/10.1016/j.ajic.2022.01.012

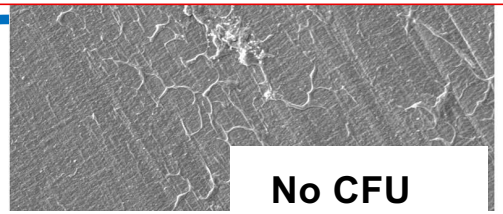
Alfa M et al Simulated-Use Polytetrafluorethylene Biofilm Model: Repeated Rounds of Complete Reprocessing Lead to Accumulation of Organic Debris and Viable Bacteria.ICHE 2017 DOI: 10.1017/ice.2017.215



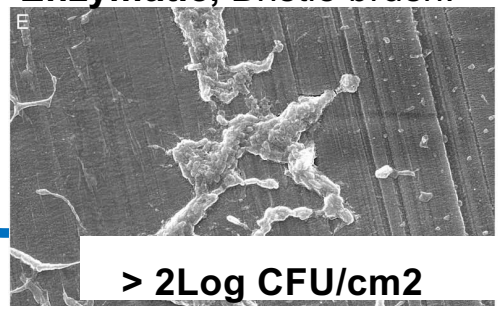


SURFACE FRICTION IS CRUCIAL FOR CLEANING

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

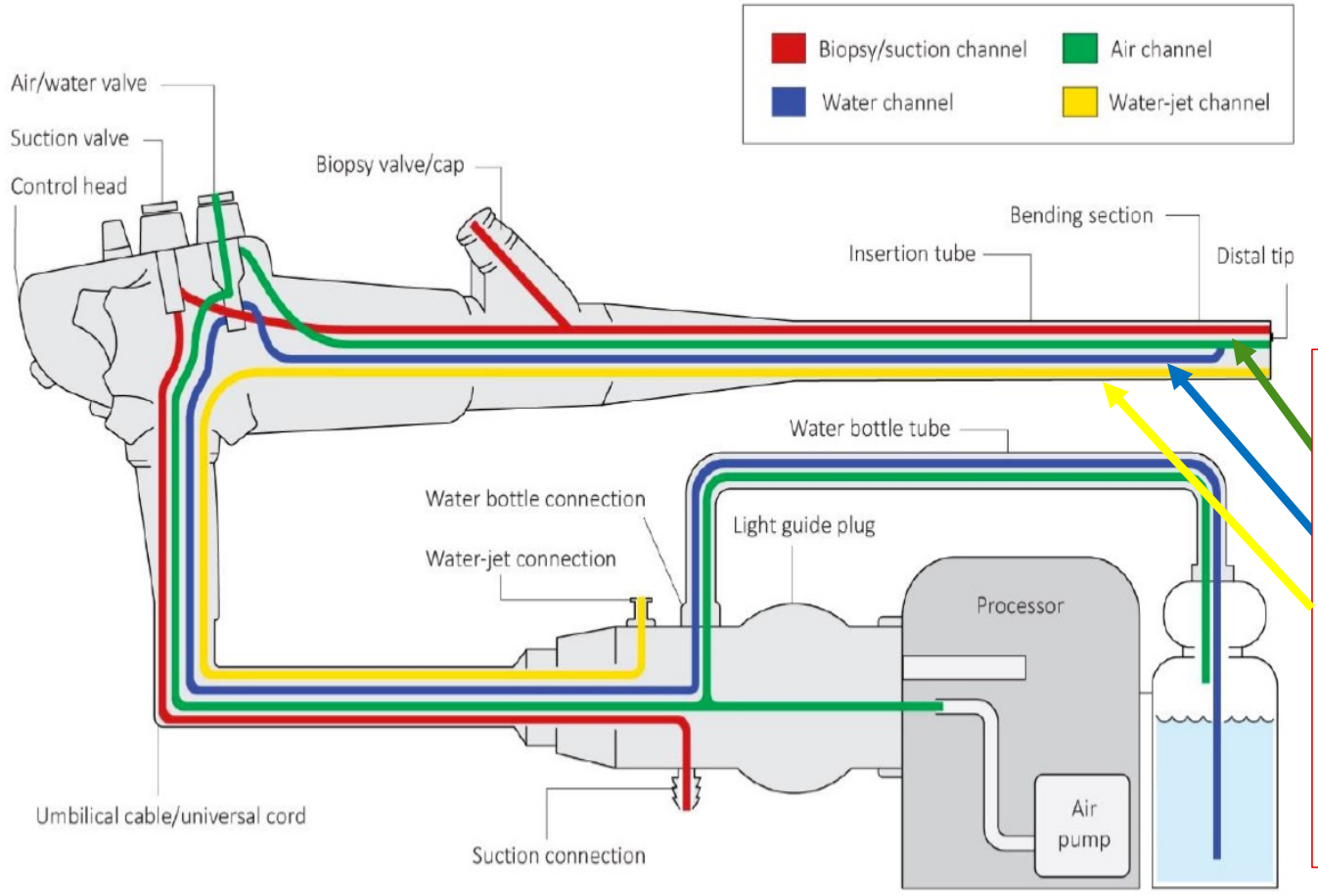


Enzymatic, Bristle brush.



Non-enzymatic, Bristle brush.

Figure 3. Schematic of an endoscope

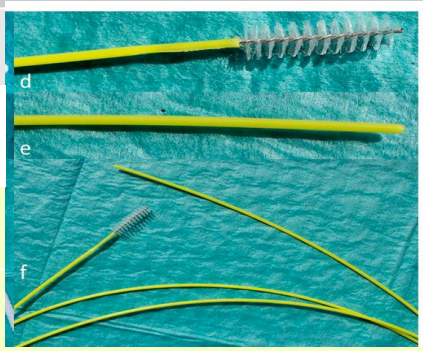


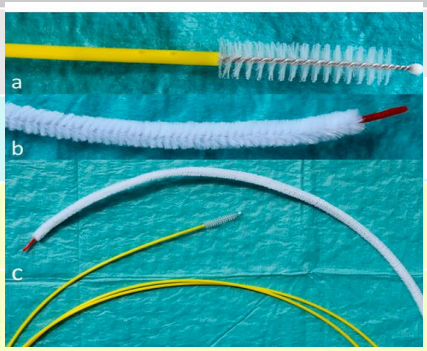
Narrow channels lack of friction:
No brush used for cleaning: flushing detergent only.

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

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%
		2.5%
Biopsy	29.0%	3.7%
Suction	30.1%	2.5%





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.

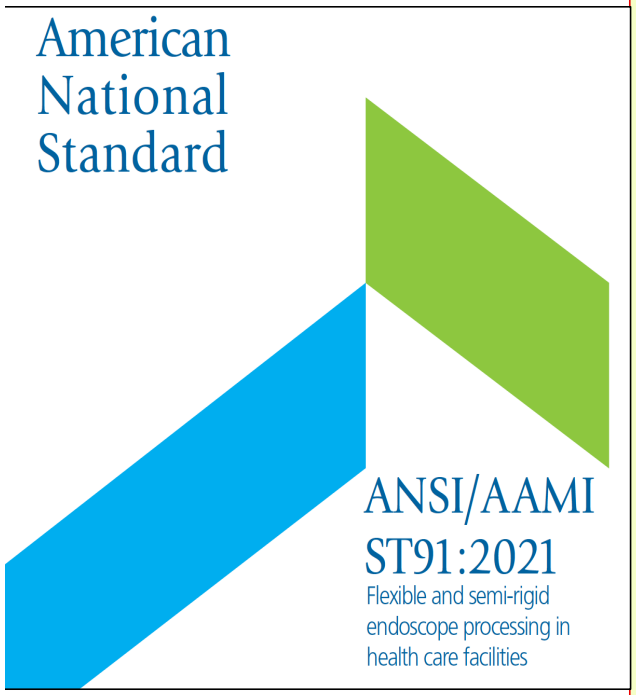
Basic start: Document time for manual cleaning

[Ensure detergent manufacturer's contact time is achieved]

- **<u>Alfa 2010: [Manual flushing]</u>**
  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
- **<u>Schmitt 2018:</u>**
  Clinical staff; Average 16 mins for Gastroscopes

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

Alfa MJ et al Evotech endoscope cleaner and reprocessor(ECR) simulated-use and clinical-use evaluation of cleaning efficacy BMC Infectious Diseases 2010, 10:200
Schmitt et al Evaluation of ATP test for cleaning assessment of gastroscopes and the effect on workload in a busy endoscopy center. AJIC 2018;46:1110-1114.



<u>Requires</u> verification of manual cleaning for High Risk endoscopes

(duodenoscopes, bronchoscopes, ureteroscopes, cystoscopes)

<u>Rapid cleaning monitoring tests</u>:

<u>Organic</u>: Carbohydrate, protein, hemoglobin

<u>ATP</u>: patient secretions

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

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**
- **RLUs DO NOT indicate level of microbes**
  [i.e. microbes can be present even if RLU < cutoff]
- **RLUs detect; patient secretions, food etc.**

Images from manufacturer's websites

Rapid cleaning verification methods:

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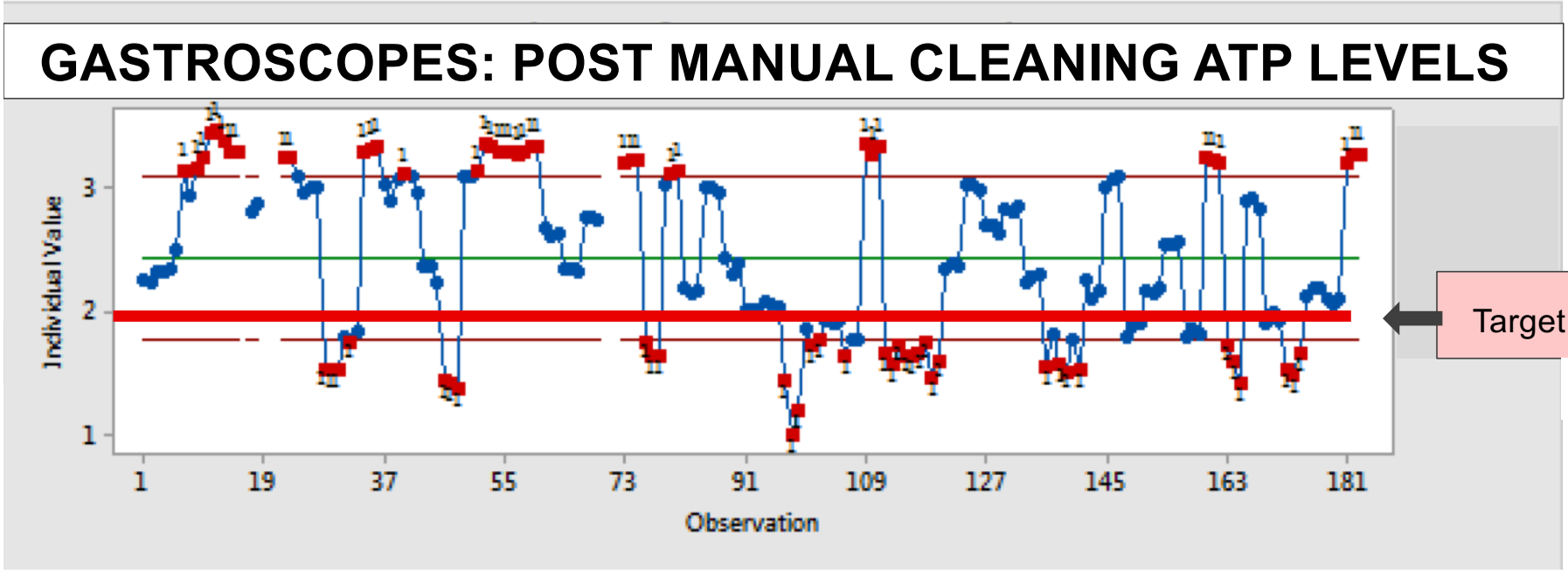
Images from manufacturer's websites

GASTROSCOPES: POST MANUAL CLEANING ATP LEVELS



Target 200 RLUs

High ATP after Bedside clean → Failure after Manual Cleaning

Parohl et al GMS Hygiene and Infection Control 2017;12:2196-5226

Clinical Study: ATP Monitoring Manual Cleaning

	Sample: Endoscope Channel 40 mL Flush Umbilical to Distal end	
	Pre-Clean	**Post-Manual Clean**
Gastroscopes (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

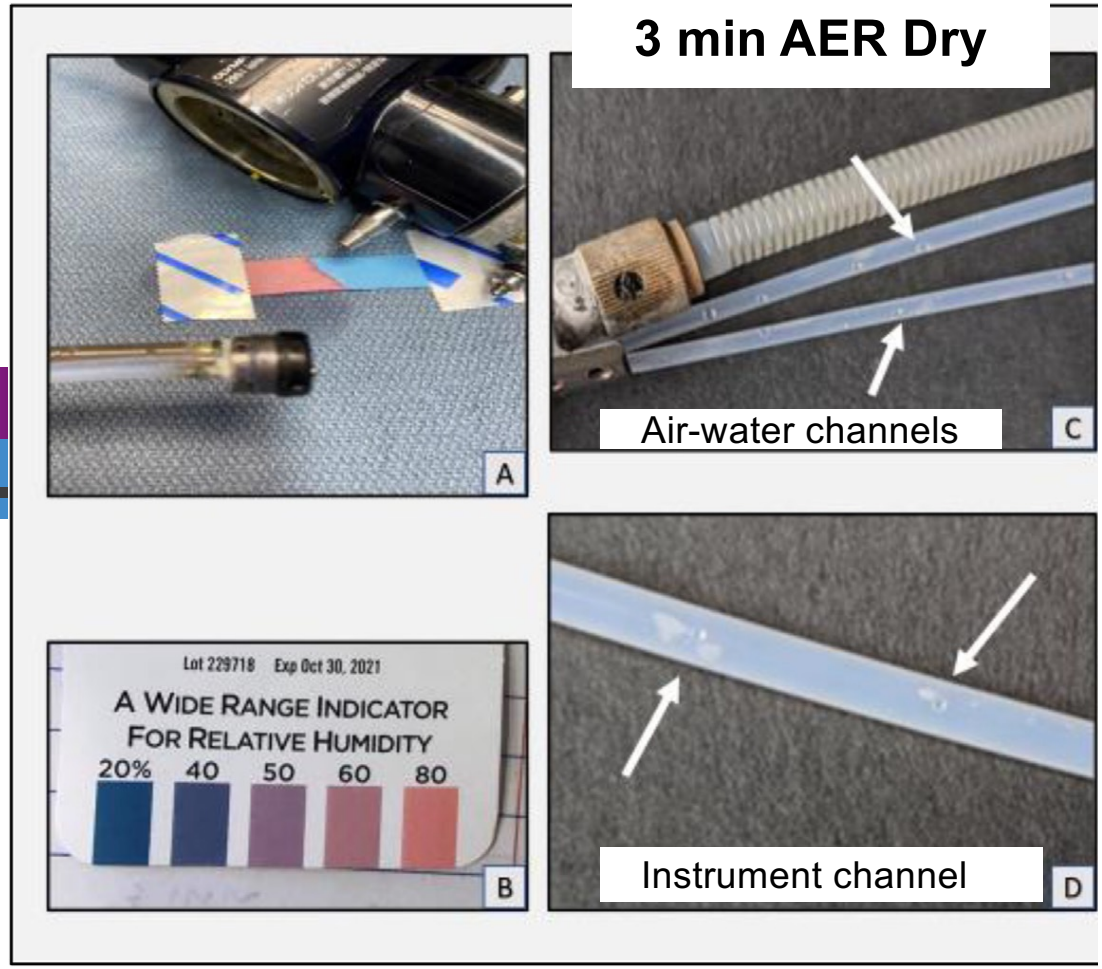
Chan et al Effectiveness of adenosine triphosphate to monitor manual cleaning and disinfection efficacy of flexible endoscopes in Hong Kong. JGH Open; 2023; doi:10.1002/jgh3.12863

Underlying Causes of Persistent Endoscope Contamination?

Key "weak link 2": Inadequate Drying

<u>ADEQUATE DRYING FOR ENDOSCOPE STORAGE:</u>
Should prevent microbial replication

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



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	+	+	+

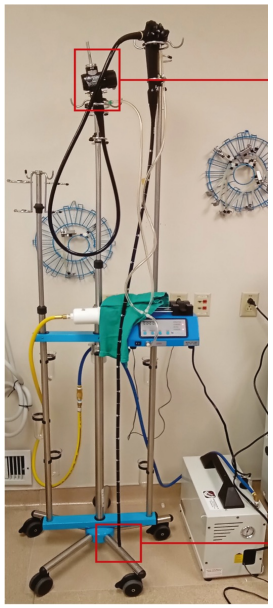
A positive symbol represents the presence of visible water.

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: <u>Not Practical</u>

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

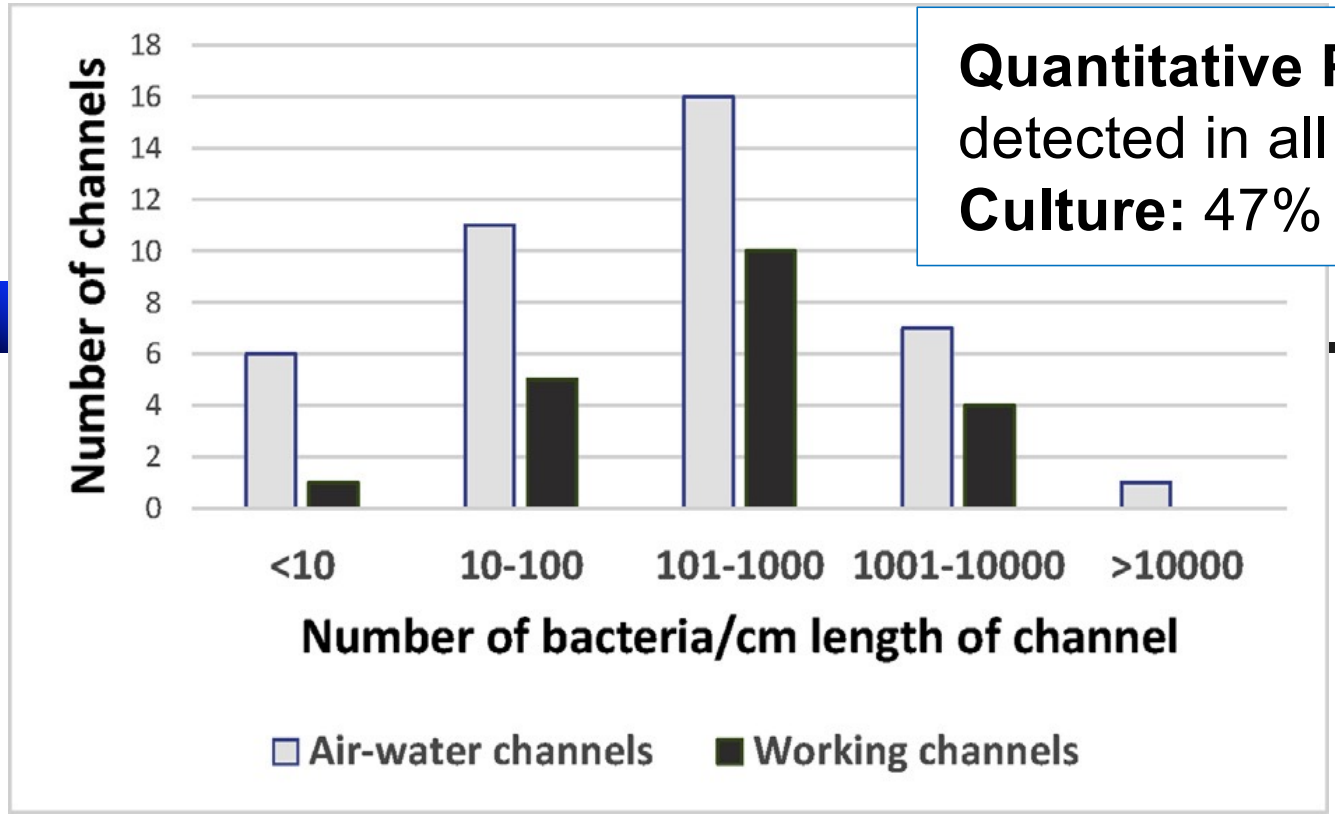
Underlying Causes of Persistent Endoscope Contamination?

Key "weak link 3": Build-up Biofilm

<u>INADEQUATE CLEANING & DRYING LEAD TO ACCUMULATION OF ORGANIC RESIDUES AND MICROBE SURVIVAL</u>

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

64 Gastroscope and Colonoscope channels evaluated



Quantitative PCR: bacterial biofilm detected in all channels
Culture: 47% were culture positive

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.

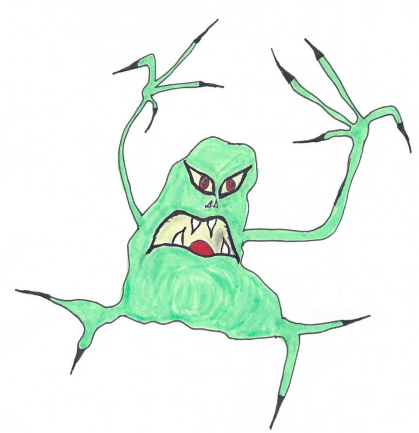
"Lumened endoscopes, especially gastrointestinal endoscopes, have the highest potential for biofilm formation in the lumen….

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**
AER Cleaning	**YES:** Can be done	**YES**: quarterly
AER final rinse water	**YES:** periodically	**YES:** quarterly
Drying of scope channels	**Optional:** (Cobalt Chloride)	**YES:** frequency? (Cobalt Chloride)
Culture reprocessed scopes	**Optional:** Instrument channel (FDA/CDC/ASM)	**YES:** quarterly; ? Sample collection method

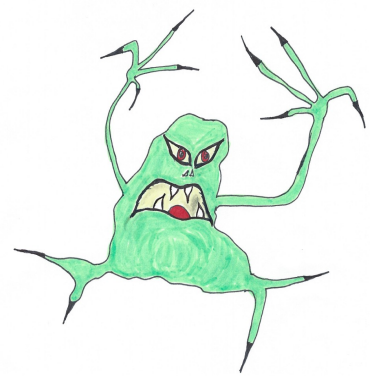
CONCLUSIONS:



- **<u>Endoscope Contamination:</u>**
  - Still a major problem
  - **ACTION:** Audit/Monitor the Key Weak links

- **<u>Inadequate channel cleaning is a Weak Link:</u>**
  - Audit manual cleaning; time study
  - Monitor cleaning [ATP, Rapid Organic marker tests]

CONCLUSIONS:



- **<u>Inadequate drying of channels is a weak link:</u>**
  - 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!

REFERENCES:

1. Epstein L et al New Delhi Metallo B-Lactamase producing carbapenem-resistant Escherichia coli associated wiith exposure to duodenoscopes JAMA 2014;312:1447-55
2. 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
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15. 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
16. 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
17. GESA GENCA; Infection Prevention and Control in Endoscopy 2021. Gastroenterological Society of Australia
18. Ofstead et al Fluid retention in endoscopes a real world study. AJIC 2024 https://doi.org/10.1016/j.ajic.2024.02.015
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20. 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

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May 21, 2024	*(European Teleclass)* **MATERIAL COMPATIBILITY FALLING THROUGH THE CRACKS?** Speaker: **Jake Jennings**, Materials Science Lead, Research and Development, GAMMA
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