Importance of Dry Storage to prevent biofilm formation

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Sponsored Educational Speaker: Olympus, 3M

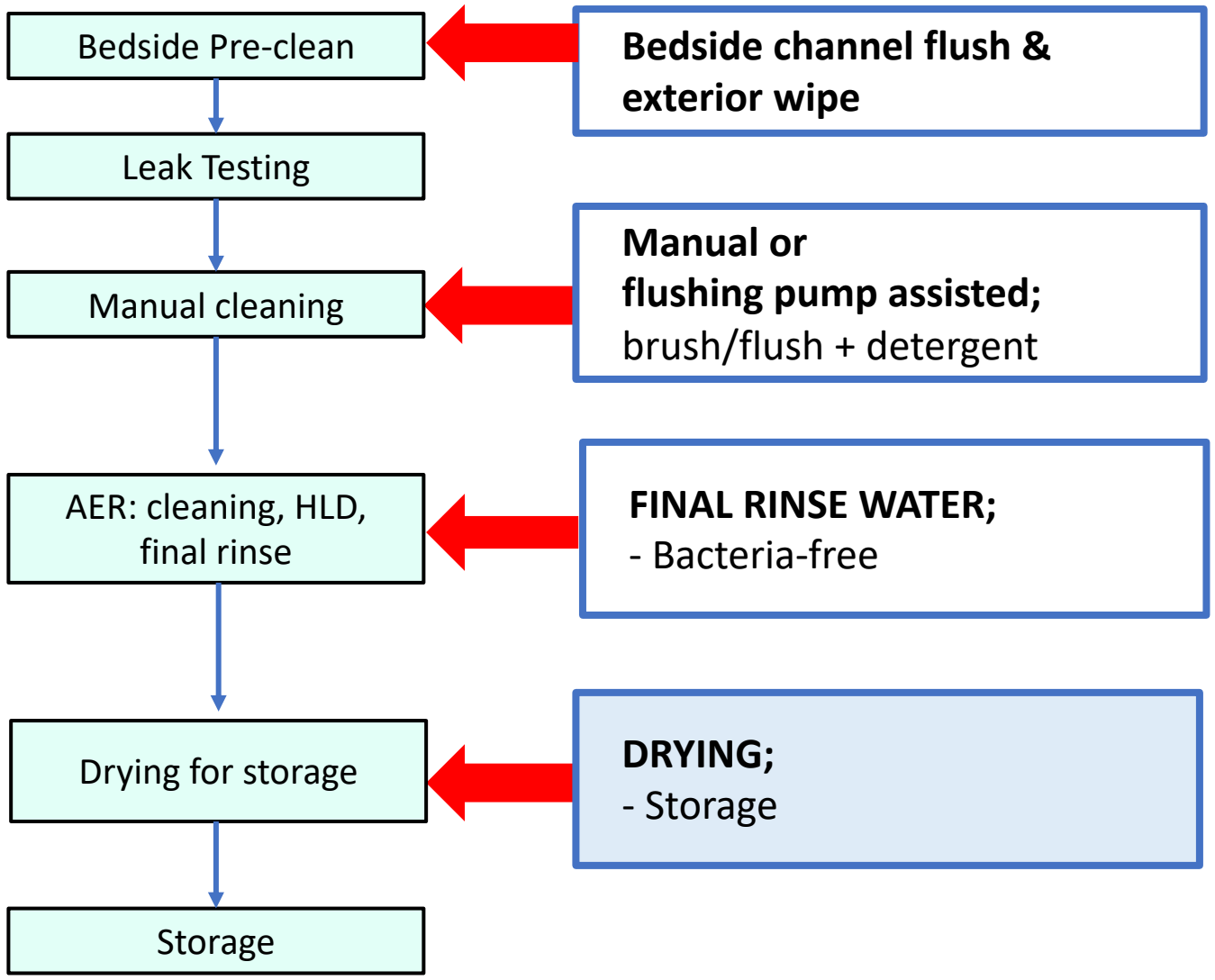
The information presented today is based on published data and my opinion and is independent of any company to whom I provide consulting services.

All publications mentioned are listed at the end of the presentation

OBJECTIVES:

- *Identify key weaknesses in current reprocessing protocols*
- *Focus on the impact of inadequate drying on endoscope contamination*

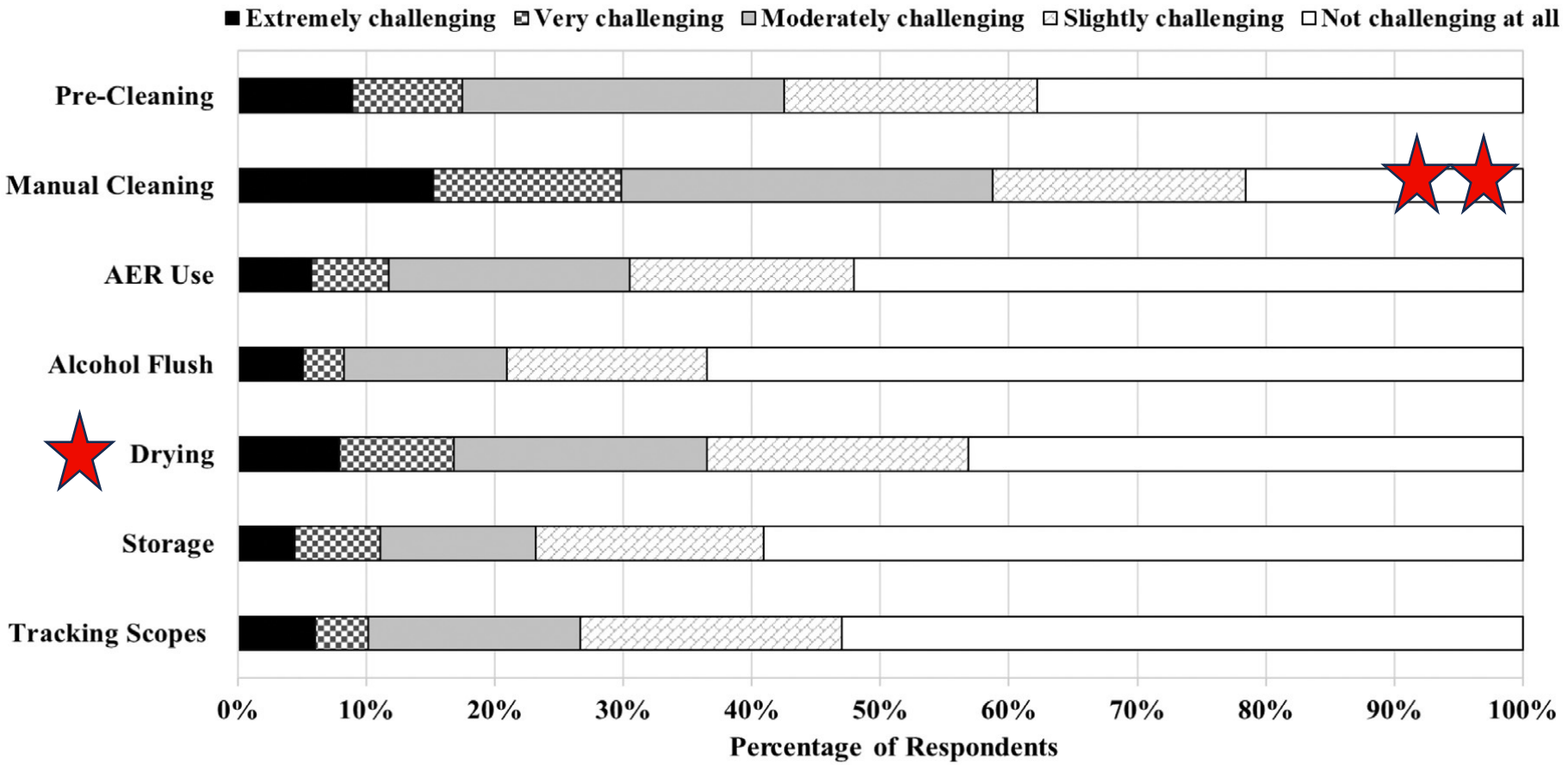
Endoscope Reprocessing System



- 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 Leading → Biofilm formation

WHAT STAGES IN REPROCESSING ARE DIFFICULT FOR STAFF?



"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

Evidence of Microbial Replication during Storage of Clinically used, Fully Reprocessed Duodenoscopes

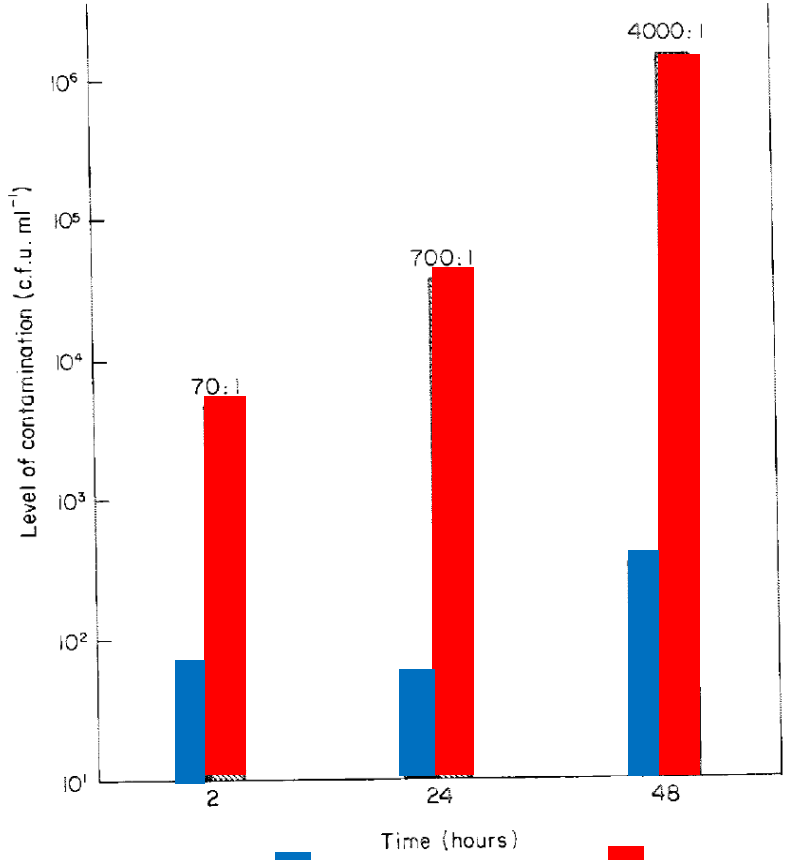


Figure 1. Level of contamination. , Gram-positive bacteria; , Gram-negative bacteria.

Contamination of duodenoscopes

Table II. *Bacterial concentration of contaminated ERCP scopes*

Organism	Concentration of bacteria*		
	2 hours	24 hours	48 hours
Gram-positive:			
Coagulase-negative staphylococcus	$5{\cdot}5 \times 10^1$	$1{\cdot}0 \times 10^4$	$1{\cdot}0 \times 10^3$
Diphtheroids	0	$1{\cdot}35 \times 10^2$	$1{\cdot}0 \times 10^1$
Micrococcus sp.	0	$1{\cdot}0 \times 10^1$	$1{\cdot}0 \times 10^1$
Gram-negative:			
Acinetobacter sp.	$4{\cdot}48 \times 10^3$	$2{\cdot}35 \times 10^2$	$3{\cdot}3 \times 10^6$
Pseudomonas aeruginosa	0	$3{\cdot}05 \times 10^3$	$1{\cdot}15 \times 10^6$
Proteus sp.	0	0	$1{\cdot}0 \times 10^3$
Klebsiella sp.	0	$5{\cdot}16 \times 10^4$	0
Enterobacter sp.	0	0	$2{\cdot}5 \times 10^6$
Fungi:			
Aspergillus sp.	0	0	$1{\cdot}0 \times 10^1$
Candida albicans	$5{\cdot}0 \times 10^1$	$1{\cdot}0 \times 10^1$	$1{\cdot}5 \times 10^2$

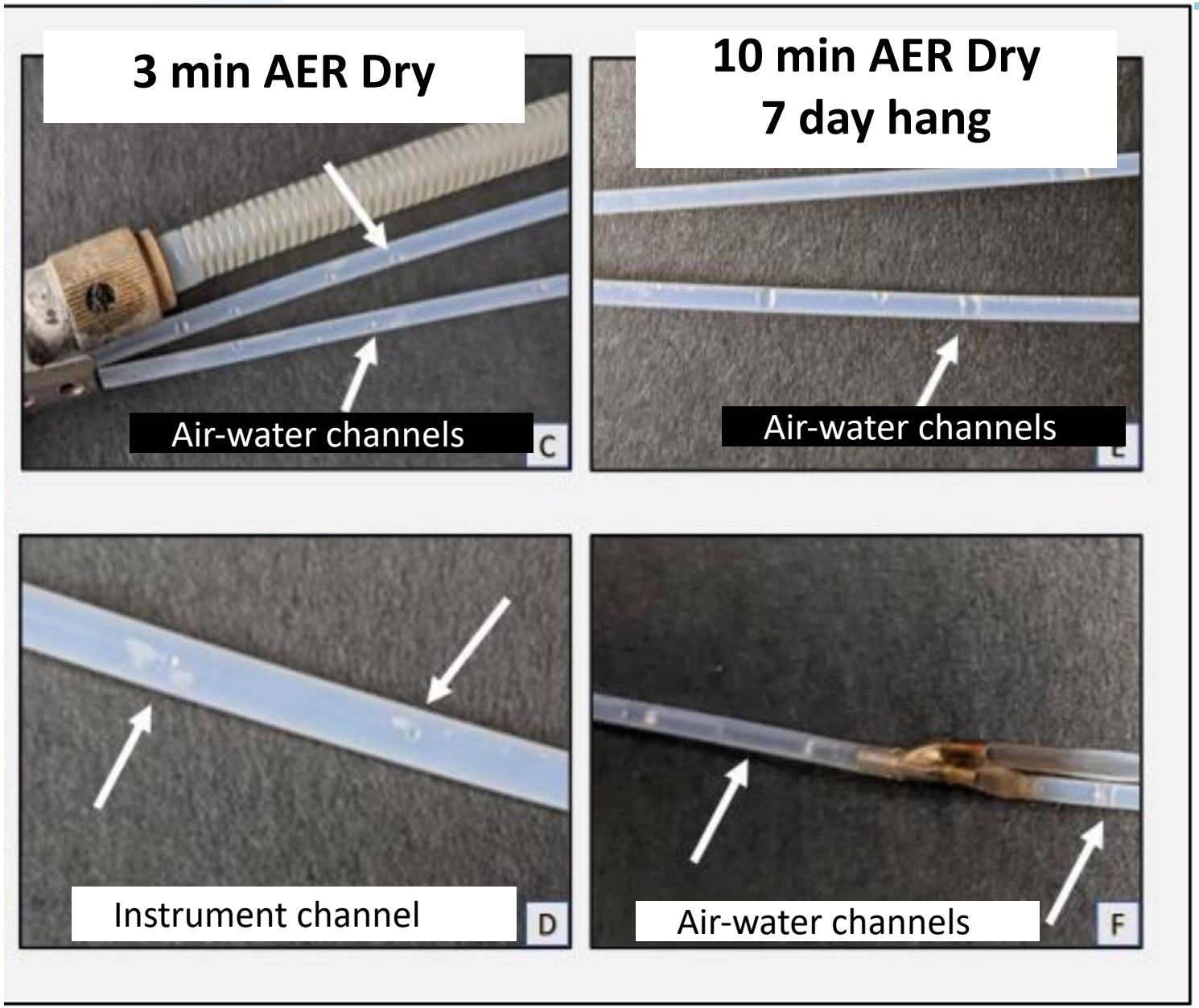
* Average bacterial concentration from all scopes that grew this organism.

Forced Air Drying for 10 mins: ***N=19***

No detectable microbes at 2, 24 or 48 Hrs

Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effects of drying. J Hosp Infect 1991;19:89-98

How Dry is an AER Channel Flush?



3 min Air flush in AER:

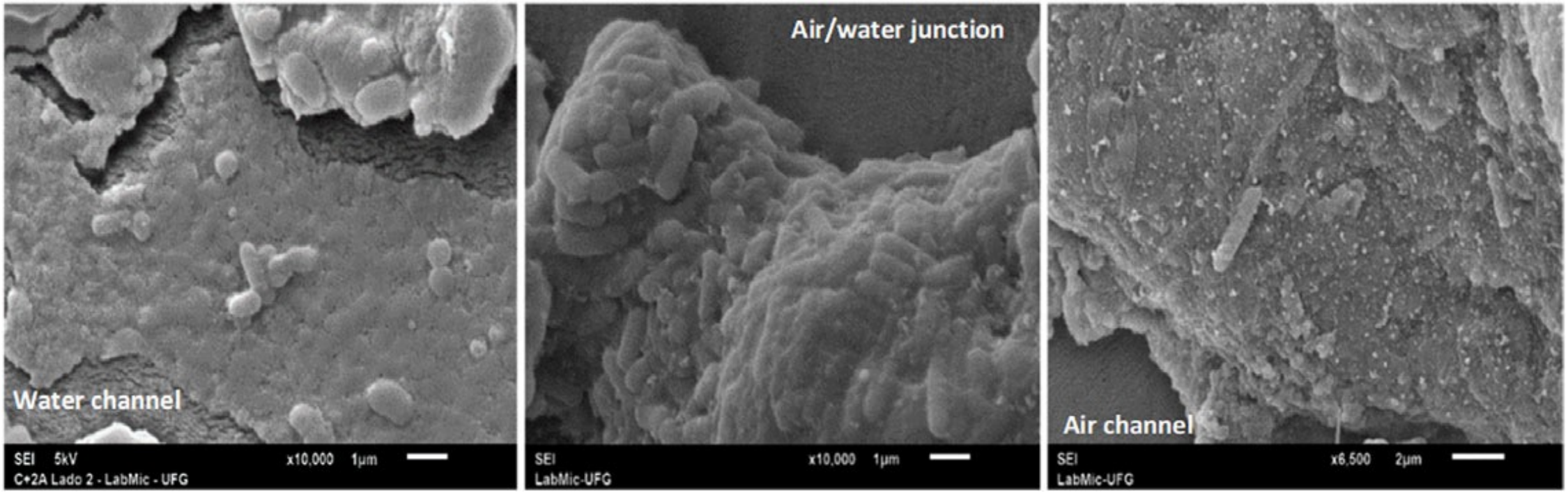
- Suction/Instrument Channel: **Not OK**
- Air/Water channel: **Not OK**

10 Min Air flush in AER <u>plus 7 day storage</u>:

- Suction/Instrument Channel: **OK**
- Air/Water channel: **Not OK**

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

Biofilm: Rapid accumulation in Patient – used Gastroscopes

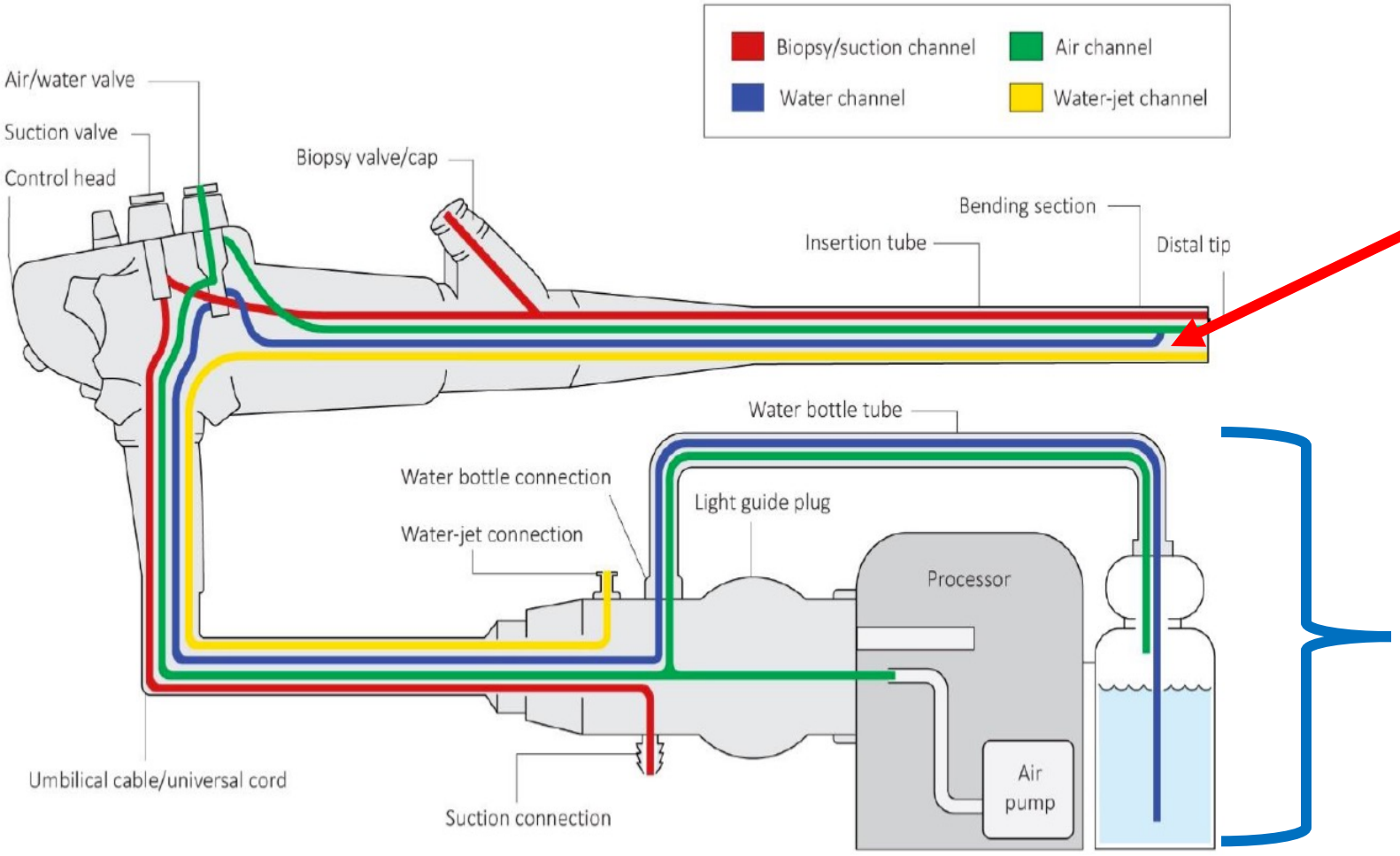


Biofilm in Air/Water channels of clinically used gastroscopes:

These narrow channels were replaced with new channels but they developed similar extensive biofilm within 30 days of clinical use that persisted for 60 days.

Primo MGB, et al. (2021). Biofilm accumulation in new flexible gastroscope channels in clinical use. Infection Control & Hospital Epidemiology, https://doi.org/10.1017/ice.2021.99

Figure 3. Schematic of an endoscope



Only Distal Air/water channels replaced.

Rapid recolonization from Umbilical portion of Air/Water channels

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

NON-OUTBREAK SETTING DUODENOSCOPES

Classification	High Concern Organisms	# of TJF-Q180V Duodenoscopes
Gastrointestinal	*Klebsiella spp.* *Enterococcus spp.* *Escherichia spp.* *Pantoea spp.* *Pluralibacter spp.*	4 2 2 1 1
Human-origin (other than GI)	*Staphylococcus aureus* *S. lugdenensis* *Candida spp.*	5 5 2
Environmental	*Acinetobacter spp.* *Candida spp.* *Erwinia bilingae* *Pseudomonas spp.* *Ralstonia spp.* *Roseomonas spp.* *Sphingomonas mucosissema*	4 1 1 1 1 1 1
Water-borne	*Brevundimonas spp.* *Massilia spp.* *Pseudomonas spp.*	3 2 2

High Concern Organisms (35/859; 4.1%)

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

NON-OUTBREAK SETTING DUODENOSCOPES

- ***Drying Cabinet for storage; 90 mins drying considered adequate***

Pentax ED34-i10T2 duodenoscopes	Reprocessing cycles	Duodenoscope use	Duodenoscope cultures	Positive duodenoscope culture results		
				MGO	Gut flora	Oral flora
A110077, n (%)	113 (8.7%)	101 (8.8%)	33 (10.8%)	3 (5.2%)	1 (2.3%)	2 (11.8%)
A110095, n (%)	273 (21.1%)	231 (20.1%)	40 (13.0%)	6 (10.3%)	4 (9.3%)	2 (11.8%)
A110096, n (%)	239 (18.4%)	218 (19%)	50 (16.3%)	8 (13.8%)	6 (14%)	2 (11.8%)
A110098, n (%)	176 (13.6%)	161 (14.%)	33 (10.7%)	2 (3.4%)	2 (4.7%)	0 (0%)
A110100, n (%)	201 (15.5%)	185 (16.1%)	48 (15.6%)	11 (19%)	8 (18.6%)	4 (23.5%)
A110280, n (%)	87 (6.7%)	76 (6.6%)	36 (11.7%)	1 (1.7%)	0 (0%)	1 (5.9%)
A110377, n (%)	98 (7.6%)	85 (7.4%)	32 (10.4%)	5 (8.6%)	2 (4.7%)	3 (17.6%)
A110409, n (%)	109 (8.4%)	93 (8.1%)	35 (11.4%)	22 (37.9%)	20 (46.5%)	3 (17.6%)
Total, n (%)	1296 (100%)	1150 (100%)	307 (100%)	58 (100%)	43 (100%)	17 (100%)

N, number; MGO, microorganisms of gut or oral origin

43/307 (14%) cultures grew Gut organisms

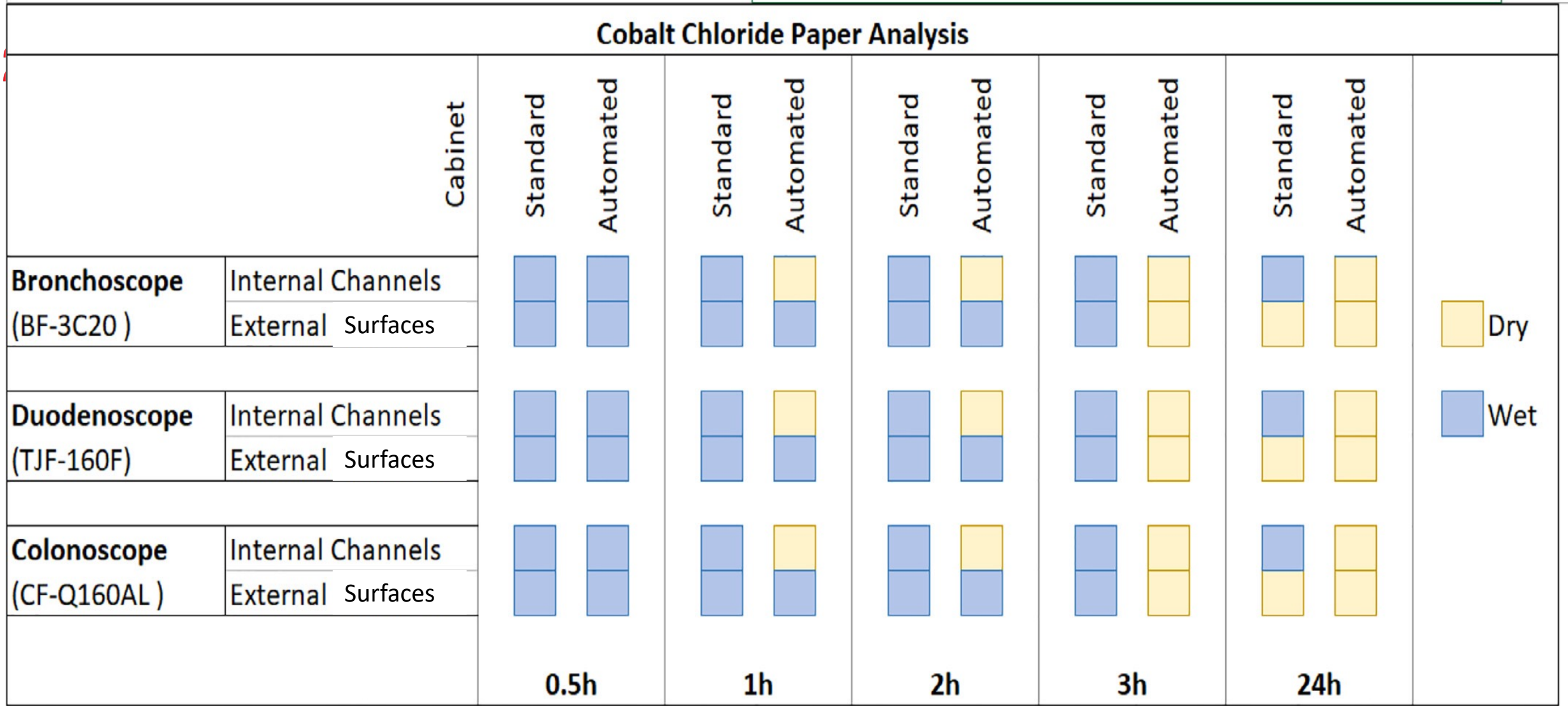
van der Ploeg K, et. al. Impact of Duodenoscope Reprocessing Factors on Duodenoscope Contamination: A Retrospective Observational Study, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2024.09.018

Cobalt Chloride test paper:

NEGATIVE

WATER DETECTED

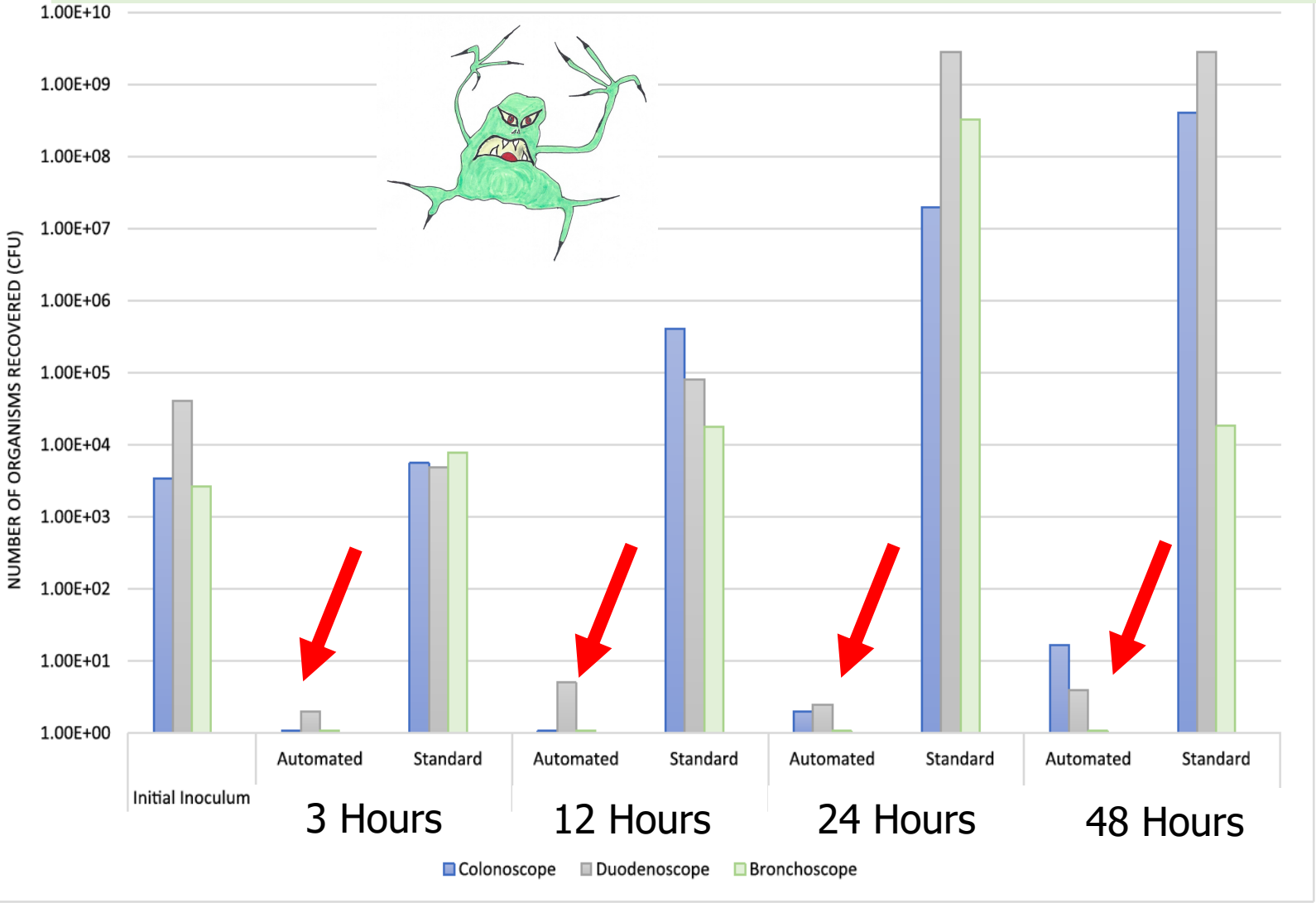
Cobalt Chloride Paper Analysis



Limit of Detection:	***Bronchoscope:*** 5 uL → Suction/Biopsy channel	***Duodenoscope:*** 250uL → Air/water channel 100uL → Suction/Biopsy channel	***Colonoscope:*** 100 uL → Air/water channel 150 uL → Suction/Biopsy channel

Perumpail et al. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet Am J Infect Control 2019 https://doi.org/10.1016/j.ajic.2019.02.016

AUTOMATED AIR FLOW IN ALL CHANNELS VERSUS STANDARD: NO AIR FLOW IN CHANNELS



1. **Low level of *P. aeruginosa* inoculated into instrument channel of Colonoscope, Duodenoscope & Bronchoscope**
2. **<u>After 31 days storage</u>;**
   - 0 CFU in Colonoscope & Bronchoscope
   - 1 CFU in Duodenoscope

Colonoscope

Duodenoscope

Bronchoscope

Perumpail et al. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet Am J Infect Control 2019 https://doi.org/10.1016/j.ajic.2019.02.016

Borescope of Instrument channel

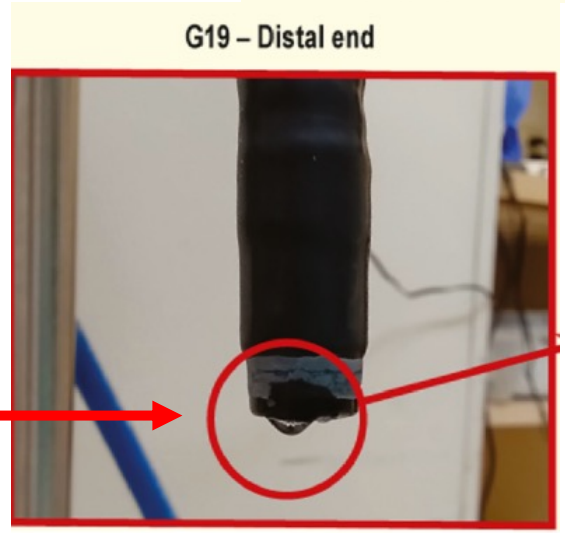
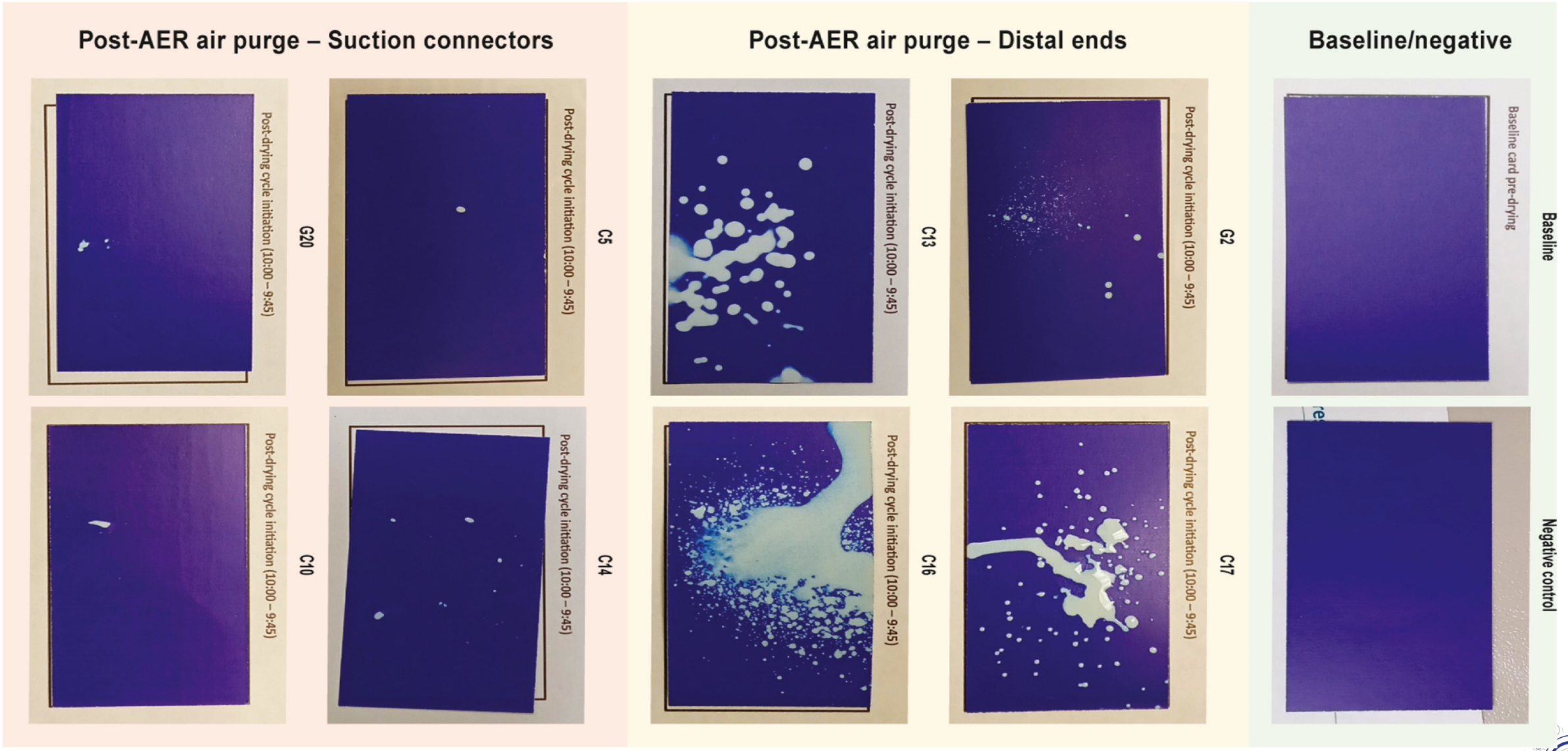


Fig. 1. Droplets observed after alcohol flush and 2 AER air purge cycles totaling 13 minutes forced air (photos collected during pre-study training session). AER, automated endoscope reprocessor.

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

COBALT CHLORIDE TESTING



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

	After AER 3 min air Purge		After 10 minute Forced Air Drying System (FADS) cycle	
	Gastroscope	**Colonoscope**	**Gastroscope**	**Colonoscope**
Cobalt Chloride testing Distal end	22/22 (100%)	20/20 (100%)	0/22 (0%)	0/20 (0%)
Visual Inspection Distal end	9/17 (52.9%)	5/13 (38.5%)	0/17 (0%)	0/13 (0%)
Borescope exam Suction/instrument channel	Not done	Not done	0/4 (0%)	0/6 (0%)

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

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 cabinets

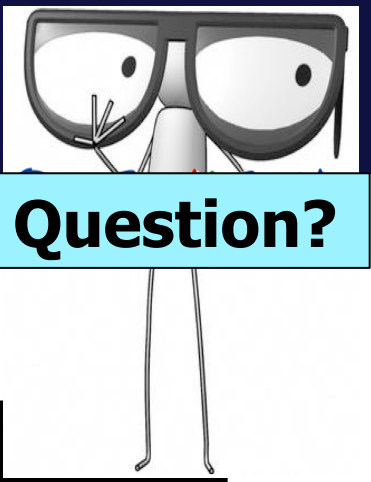
Image from STERIS website

Images from OLYMPUS website

How Long to Adequately Dry Flexible Endoscope channels??

1. **Manual Air-gun (channels & endoscope exterior): *Published data*[1]**
   - Staff must hold Air-gun and flush each channel for at least 10 mins:
     HIGH RISK that staff will be not comply as it very labour-intensive
2. **Pump assisted channel drying: *Published Data*[1,2,3]**
   - Various pump systems for channel drying: allows staff to do other tasks
     10 mins shown effective
3. **Drying Cabinet (channels & endoscope exterior): *Published Data*[1,4,5]**
   - Various commercial cabinets: allows staff to do other tasks
     90 mins to several hours

1. Bellenhoff Ulrike. Endoscope reprocessing: How to perform an adequate air drying? Endosc Int Open 2023;11:E440-E442.
2. Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effects of drying. J Hosp Infect1991;19:89-98
3. Ofstead et al Fluid retention in endoscopes a real world study. AJIC 2024 https://doi.org/10.1016/j.ajic.2024.02.015
4. Perumpail et al. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet Am J Infect Control 2019 https://doi.org/10.1016/j.ajic.2019.02.016
5. Van der Ploeg K. et. al. Impact of duodenoscope reprocessing factors on duodenoscope contamination: A retrospective observational study. J Hosp Infect https://doi.org/10.1016/j.jhin.2024.0.018

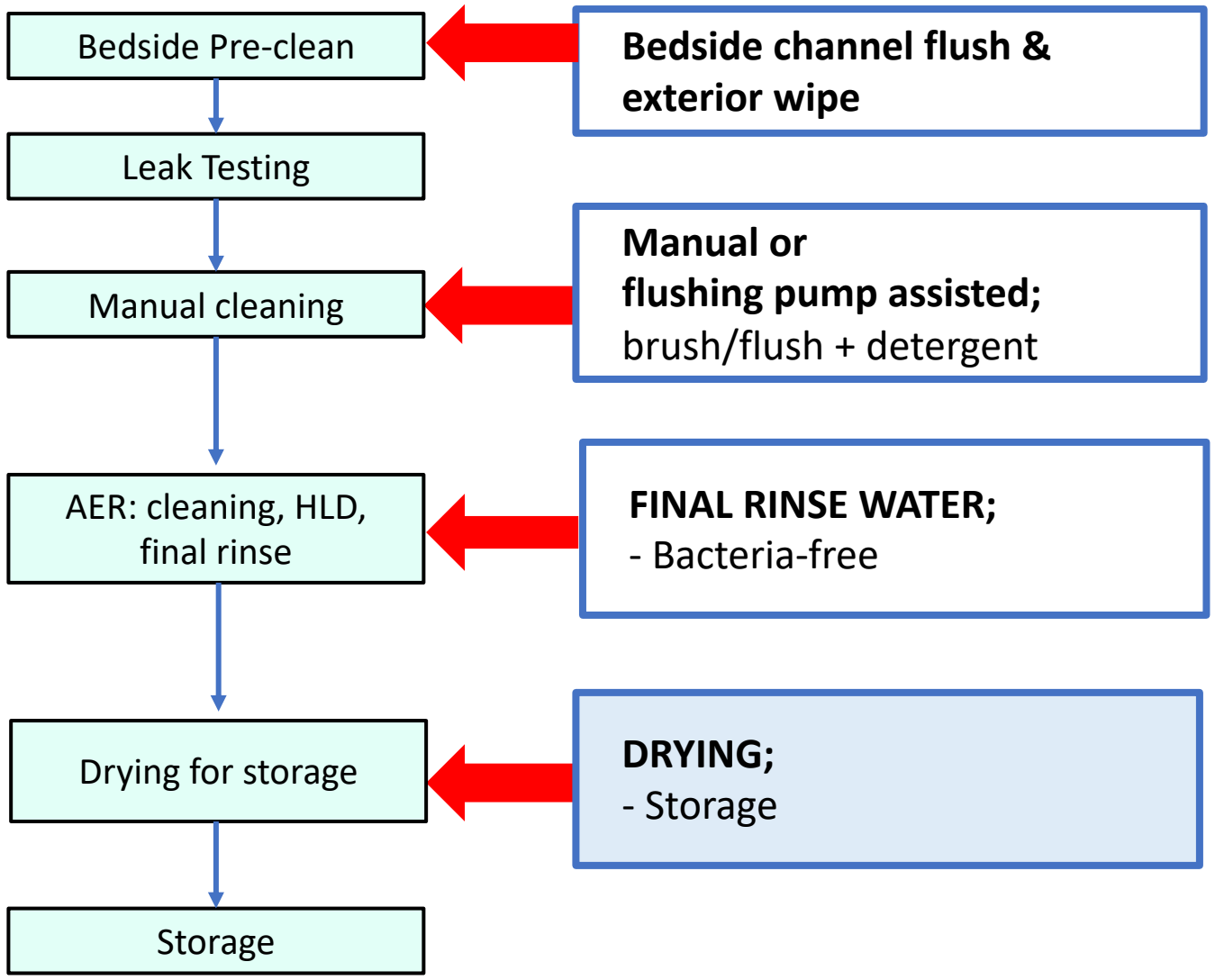


WHAT DO THE GUIDELINES SAY?

Quality Parameter:	AAMI ST91 2021	ISO 15883-4 2019 EN 16442:2015
	User Verification:	**Routine Testing:**
Drying of scope channels	**Optional:** (Cobalt Chloride) No frequency indicated	**YES:** (Cobalt Chloride) No frequency indicated

ANSI/AAMI ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities.
EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.
DIN EN ISO 15883-4 2019 Washer disinfectors – Part 4 Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. (section 6.8.4 Channel drying)

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 Leading → Biofilm formation

SUMMARY

How can we break the cycle of Biofilm formation??

- <u>Ensure adequate drying for storage:</u>

  - Cobalt chloride test to monitor residual moisture in channels
  - Compressor assisted drying (not manual air-gun drying)
  - Adopt Drying endoscope storage cabinets (i.e. all channels flushed)

- <u>Ensure all other stages of endoscope reprocessing are optimal</u>

Without monitoring; You don't know what you don't know!!