HONG KONG ASIAWORLD-EXPO 亞洲國際博覽館

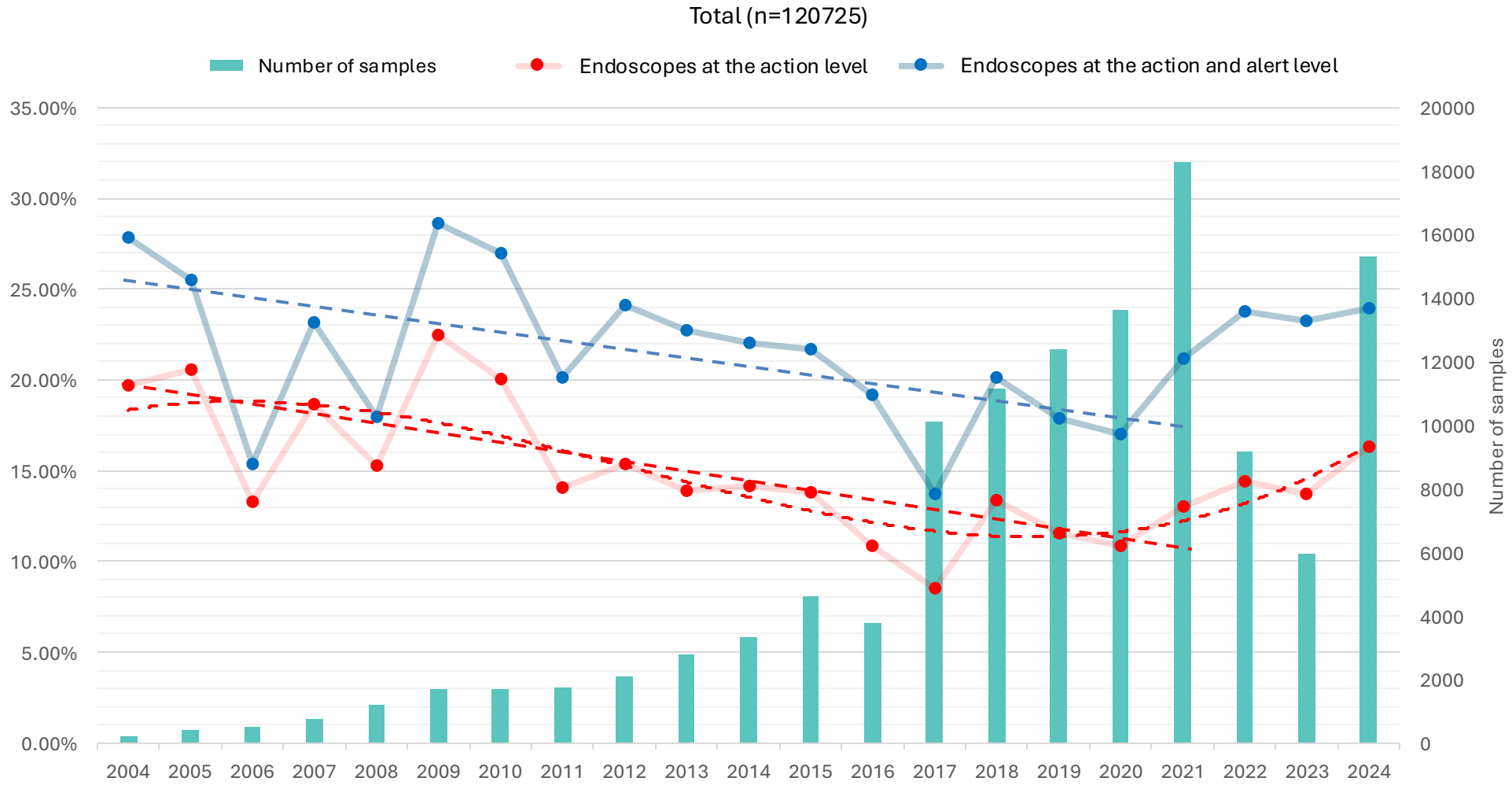
3RD TO 6TH DECEMBER 2025

World Federation for Hospital Sterilisation Sciences

TOWARDS A NEW HARMONIZED METHOD FOR ENDOSCOPE SAMPLING AND CULTURING

PINEAU Lionel
EUROFINS

EVOLUTION OF THE MICROBIOLOGICAL QUALITY OF ENDOSCOPES IN FRANCE



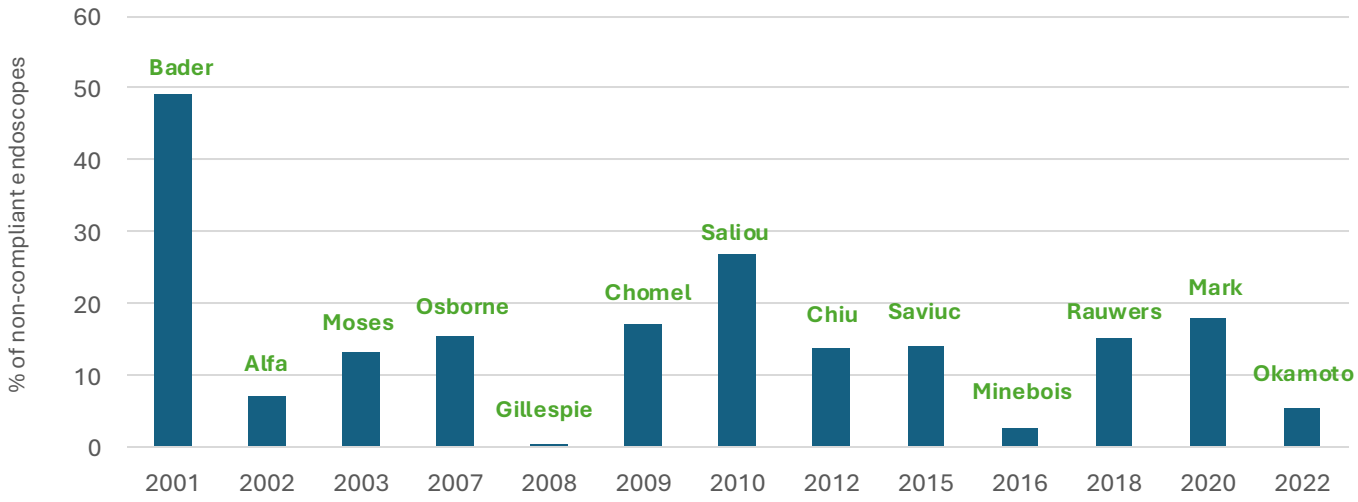

Endoscope reprocessing: Retrospective analysis of 90,311 samples

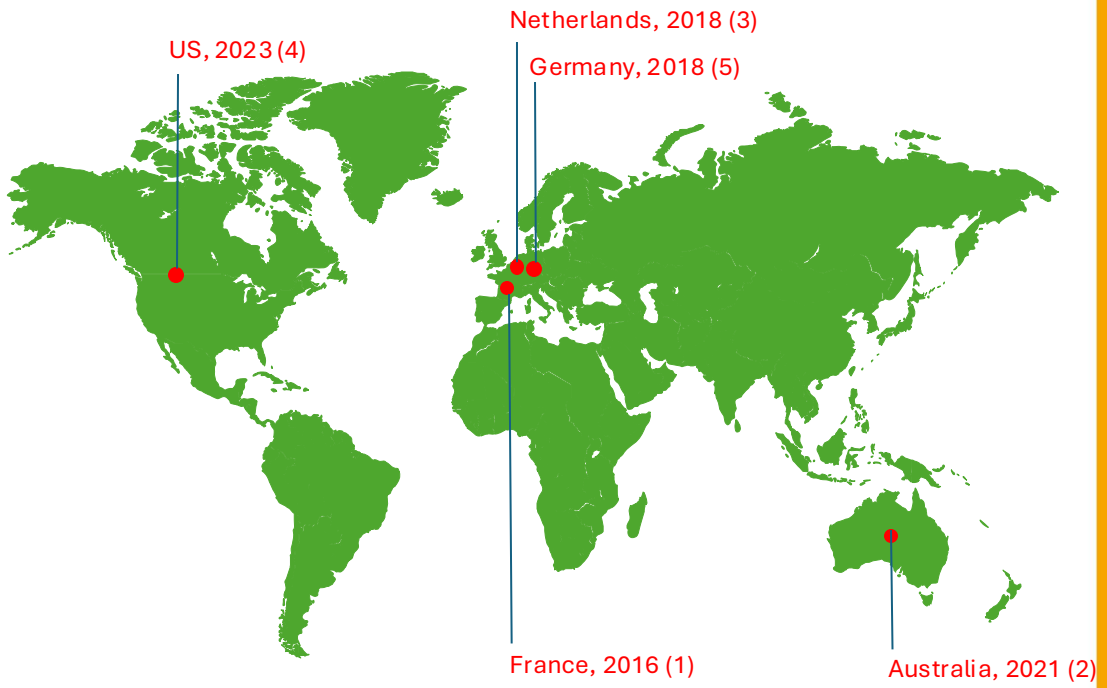
OPEN ACCESS

Pineau L. Endoscope reprocessing: Retrospective analysis of 90,311 samples. Endosc Int Open 2023; 11: E247–E257

ENDOSCOPE SAMPLING AND CULTURING

- The implementation of an endoscope sampling and culturing program is essential to **assess regularly** the adequacy of endoscope reprocessing.
- They have been proposed by many authorities and professional associations (as a **quality indicator**) Studies published in the literature indicate that the non-compliance rate of ready to use endoscopes varies from 0.4% to 49.0 %.





(1) Instruction n° DGOS/PF2/DGS/VSS1/2016/220 du 4 juillet 2016 relative au traitement des endoscopes souples thermosensibles à canaux au sein des lieux de soins.
(2) Gastroenterological Society of Australia (GESA). Infection prevention and control in endoscopy 2021.
(3) Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD). Professional standard handbook. Flexible endoscopes cleaning and disinfection. 2016.
(4) FDA/CDC/ASM. Duodenoscope Surveillance Sampling and Culturing Protocols. 2018.
(5) Hygiene Requirements for the Reprocessing of Medical Devices. Bundesgesundheitsbl 2012 · 55:1244–1310.

EXTRACTION EFFICACY OF ENDOSCOPE SAMPLING/CULTURING METHODS

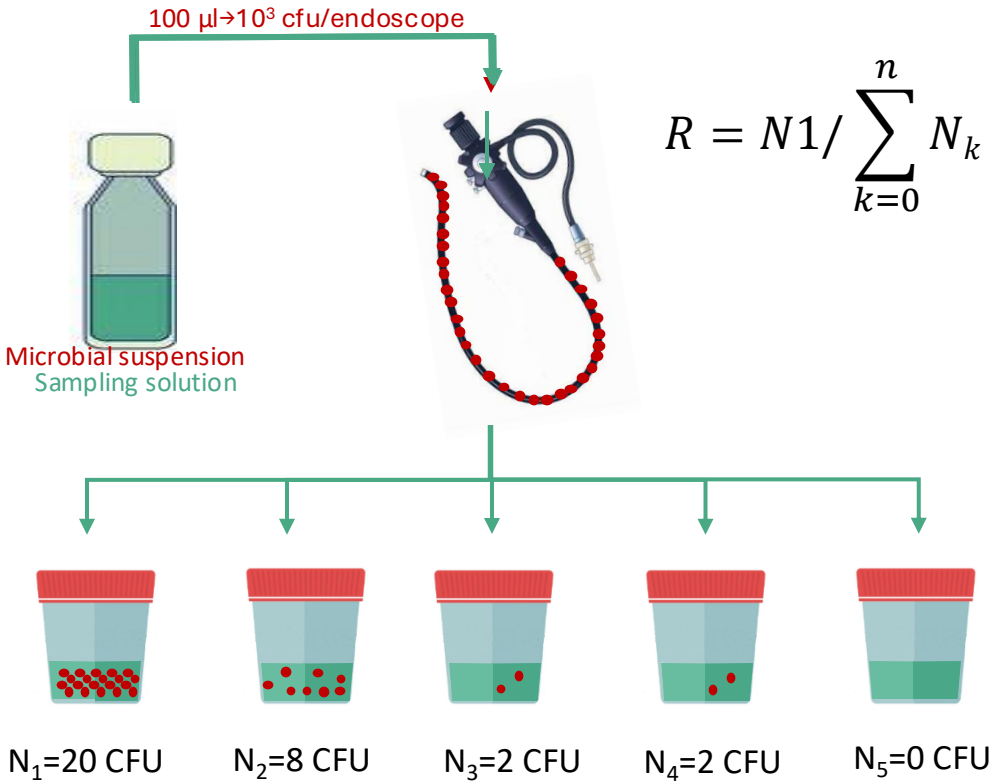
Objective

- Compare the efficacy of six duodenoscope sampling and culturing methods by means of extraction efficacy comparison.

Principle

- 5 sampling methods are compared: Germany, Netherland, France, Australia and US (FDA),
- 1 endoscope : 1 duodenoscope (TJF-Q180V),
- 3 microbial strains: *E.coli*, *S. aureus* and *P. aeruginosa*,
- 3 microbial concentrations are tested : 10 CFU/scope, 100 CFU/scope and 1000 CFU/scope,
- 2 transportation times: 1 and 24 hours,
- 6 assays are performed per conditions i.e. 6 x 2 x 3 x 3 = 108 assays per sampling method,
- Repetitive recovery method described in ISO 11737-1: 2018.

Method



L. Pineau, M. Alfa, C. Radix, Endoscope sampling and culturing methods, Journal of Hospital Infection, Volume 149, 2024, Pages 36-45, ISSN 0195-6701, https://doi.org/10.1016/j.jhin.2024.03.017.

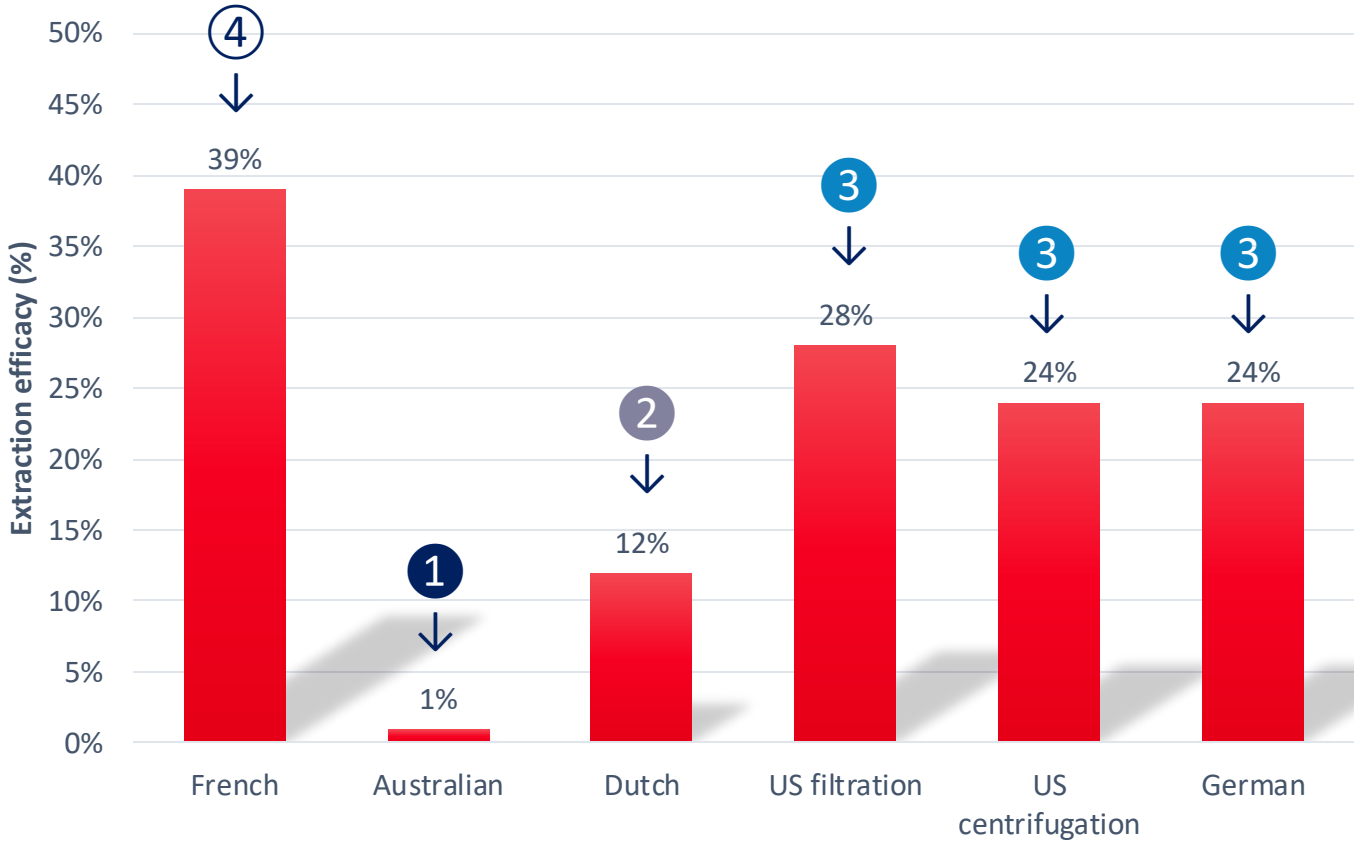
SAMPLING/CULTURING METHODS

METHOD		FRENCH	AUSTRIAN	DUTCH	US		GERMAN
Sample sites	Instrument channel	Y (FSF[a]) [2]	Y (FB[c]) [1]	Y (FSBF[e]) [2]	Y (FBF[b]) [2]		Y (F) [2]
	Suction/instrument channel	Y (FSF) [3]	Y (F[d]) [3]	Y (FSBF) [3]	N		Y (F) [3]
	Air/water channel	Y (FSF) [4]	Y (F[d]) [2]	Y (FSF) [4]	N		Y (F) [4]
	Elevator recess (distal end) with brush or swab	Y [1]	N	Y [1]	Y (1]		Y [1]
Sampling solution		NDP + thio	Sterile water	NaCl 0.9%	Sterile water		NaCl 0.9%
Addition of neutralizer to extracted sample		No (NDP + thio used for sampling)	No	No	Y (NDP + thio)		Y (NDP + thio) two time concentrated
Sample volume (sampling solution + neutralizer)		100 mL (distal end) + 130 mL (channels)	30 mL	60 mL	82 mL		3 x 50 mL
Friction for Instrument channel (bristle brush)		N	Y	Y	Y		N
Number of samples		2 (all channels pooled &distal end)	1 (all channels pooled)	2 (all channels pooled & distal end)	1 (Instrument channel & distal end pooled)		4 (All channels separately & distal end)
Culture method		Filtration	Centrifugation	Filtration	Filtration	Centrifugation	Filtration
Total volume used for sample extraction		230 mL	30 mL	60 mL	82 mL	82 mL	3 x 50 mL
Total sample volume analyzed		230 mL	0.2 mL	60 mL	82 mL	82 mL	3 x 50 mL
% of sample volume analyzed		100%	6.6%	100%	100%	100%	100%
Culture medium		Trypticase soy agar (TSA)	Blood + MacConkey agar	R2A Agar	Blood agar	Blood agar	Blood agar
Incubation time		5 days	5 days	3 days	3 days	3 days	2 days
Incubation temperature		30°C	35°C then 28°C	35°C	35°C to 37°C	35°C to 37°C	36°C
Result expression according to source		CFU/endoscope	CFU/mL	CFU/20 mL	CFU/endoscope	CFU/endoscope	CFU/channe

(a) FSF: Flush-Suction-Flush, (b): FBF: Flush-Brush-Flush, (c): FB: Flush-Brush, (d) F: Flush, (e): FSBF: Flush-Suction-Brush-Flush. Y: Yes, N: No, NDP + thio: Neutralizing Pharmacopeia Diluent plus thiosulfate. [x]: figures in square brackets define the chronology in which channels/sites were sampled.

EXTRACTION EFFICACY OF ENDOSCOPE SAMPLING/CULTURING METHODS

Mean extraction efficacy (R)



$$R = N1 / \sum_{k=0}^{n} N_k$$

1. No neutralizer used and only 6.6% of the solution injected was analysed.
2. No neutralizer used.
3. Addition of neutralizer after sampling.
4. Sampling with neutralizer solution.

A NEED FOR A STANDARD

Objectives

Provides requirements and provides guidance for sampling and methods of analysis for detection of microbial contamination of reusable thermolabile flexible endoscopes and endoscope valves that have completed processing, and which are ready for clinical use in another patient.
Provides implementation guidance on actions to consider when microbiological contamination is detected in a processed reusable flexible endoscope or endoscope valve.

2024-07-26

2024-07-26

ISO/NP 25224

Sterilization of health care products — Sampling and culturing for reusable, thermolabile flexible endoscopes

ISO/TC 198/WG17

SAMPLING CONDITIONS

Event related sampling

- Sampling should be conducted as follows but not limited to:
  - a) routinely in predefined intervals;
  - b) within 72 hours of receipt of new or loaned scopes or return from repair/maintenance;
  - c) during an identified outbreak situation;
  - d) for performance qualification purposes of endoscope washer-disinfectors and endoscope storage cabinets.
  - e) When a particular endoscope is identified as high risk

Sampling time points

- Sampling may shall be performed at the following time points:
  - a) immediately after reprocessing the endoscope (Performance qualification);
  - b) at a sufficient interval before the next procedure; or
  - c) after an appropriate storage period (Routine sampling).

SAMPLING FREQUENCY

- For endoscopes with one or more channels, routine sampling shall be performed as follows:

  a) at least on one endoscope representative of each endoscope product family using the same endoscope connector sets (see ISO 15883-4:2018 Table C.1, foot note a) according to ISO 15883-4:2018 Annex I every three months;

  b) on each individual endoscope at least once a year.

  NOTE 1 The frequency, the number of endoscopes and the number of endoscopes per product family to be sampled can be increased or reduced according to healthcare facility risk assessment or local regulation(s).

  NOTE 2 To ensure a reliable and repeatable process, all endoscopes should be tested periodically and not at the same time.

- For endoscopes without channels, sampling frequency shall be based on an assessment of the risk of contamination either in use or during storage.
- For performance qualification performed on endoscope washer-disinfectors or endoscope storage cabinets, one representative of each endoscope product family using the same endoscope connector sets (see ISO 15883-4:2018 Table C.1, foot note a) shall be sampled at least once a year in accordance with facility internal risk assessment.

SAMPLING MEDIA

Liquid sampling media

- The liquid sampling media shall be either
  1. isotonic [e.g. peptone water, phosphate buffer or 0,9 % NaCl (see ISO 11737-1)] and contain a neutralizer to neutralize any disinfectant residues remaining in the endoscope channels or on the endoscope surfaces or
  2. an isotonic solution without neutralizer. In such cases, the sample collected shall be mixed immediately, with the same volume of pre-dosed neutralizer.

Volume of sampling solution

- The minimum volume of sampling solution to be injected shall be as follows:
  - 50 ml for suction and biopsy channels;
  - 30 ml for air and water channels;
  - 10 to 30 ml for auxiliary all other channels.

  NOTE The volume of solution injected per channel is intended to be at least 2 times the volume of the channel.

Sampling method

- Endoscope channels shall be sampled using a sampling media. Endoscope channel samples may be collected separately or pooled. For routine testing, a pooled collection of samples of all endoscope channels is recommended.

TURBULENT FLOW

HHS Public Access
Author manuscript
J Microbiol Methods. Author manuscript; available in PMC 2021 January 01.

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J Microbiol Methods. 2020 January ; 168: 105782. doi:10.1016/j.mimet.2019.105782.

Turbulent Fluid Flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters

Seo Yean Sohn[1], Michelle J. Alfa[2], Richard Lai[1], Yacoob Tabani[1], Mohamed E. Labib[1]
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[2]Dept of Medical Microbiology, University of Manitoba, Winnipeg, Manitoba, Canada

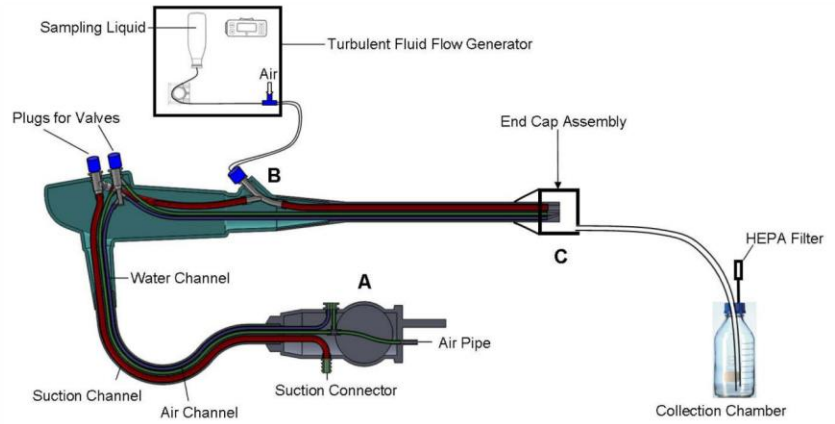
Abstract

Overview: Effective sample extraction from endoscope channels is crucial for monitoring manual cleaning adequacy as well as for ensuring optimal sensitivity for culture after disinfection. The objective of this study was to compare the efficacy of Turbulent Fluid Flow (TFF) to Flush (F) or Flush-Brush-Flush (FBF) methods.

Materials & Methods: *Pseudomonas aeruginosa* and *Enterococcus faecalis* in artificial test soil-2015 (ATS2015) were used as bacterial markers while protein and carbohydrate were the organic markers for biofilm formed inside 3.2-mm and 1.37-mm polytetrafluoroethylene (PTFE) channels. TFF was generated using compressed air and sterile water to provide friction for sample extraction. Extraction for biofilm coated PTFE channels as well as for colonoscope channels perfused with ATS2015 containing 10^8 CFU/mL *P. aeruginosa*, *E. faecalis* and *Candida albicans* was determined using TFF compared to FBF and F.

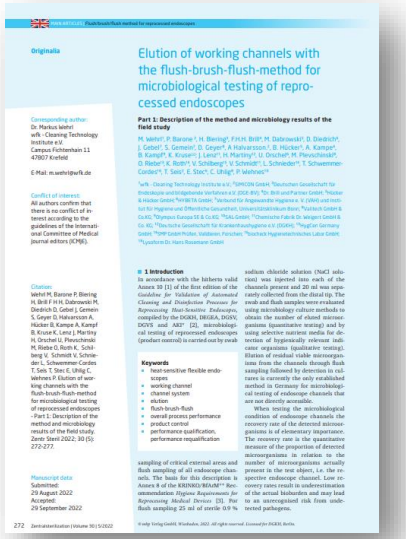
Results: The extraction ratio for *P. aeruginosa* and *E. faecalis* from biofilm extracted by TFF compared to the positive control was significantly better than F for 1.37-mm channels (≥ 0.94 for both bacteria by TFF versus 0.49 to 0.72 by F for *P. aeruginosa* and *E. faecalis*, respectively) but not significantly different between TFF and FBF for 3.2-mm channels. F was also ineffective for extraction of protein and carbohydrate from 1.37-mm channels. Extraction efficacy by TFF from inoculated colonoscope channels was >98% for all test markers.

Conclusions: The novel TFF method for extraction of samples from colonoscope channels is a more effective method than the existing FBF and F methods.



"The novel TFF method for extraction of samples from colonoscope channels is a ore effective method than the existing FBF and F methods"

Sohn S Y, Alfa M J, Lai R, Tabani Y, Labib M E Turbulent Fluid Flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters J Microbiol Methods. 2020 January ; 168: 105782



Originalia

Elution of working channels with the flush-brush-flush-method for microbiological testing of reprocessed endoscopes

Part 1: Description of the method and microbiology results of the field study

M. Wehrl[1], P. Barone[2], H. Biering[3], F.H.H. Brill[4], M. Dabrowski[5], D. Diedrich[6], J. Gebel[7], S. Gemein[8], D. Geyer[9], A. Halvarsson[10], B. Hücker[11], A. Kampe[12], B. Kampf[13], K. Krusen[14], J. Lenz[15], H. Martiny[16], U. Orschel[17], M. Plevschinski[18], D. Rieber[19], K. Roth[20], V. Schilberg[21], V. Schmidt[22], L. Schneider[23], T. Schwemmer-Cordes[24], T. Seis[25], E. Stoc[26], C. Uhlig[27], P. Wehnes[28]

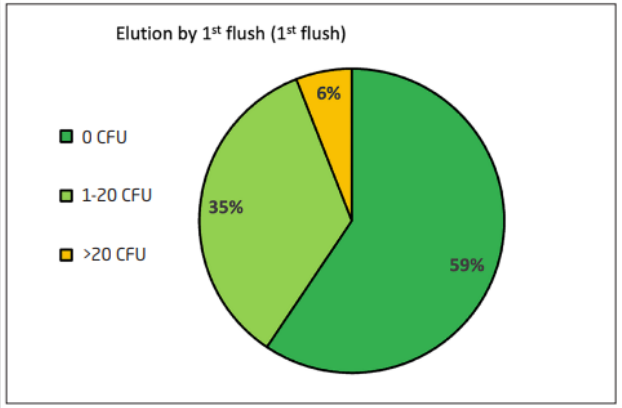
1 Introduction

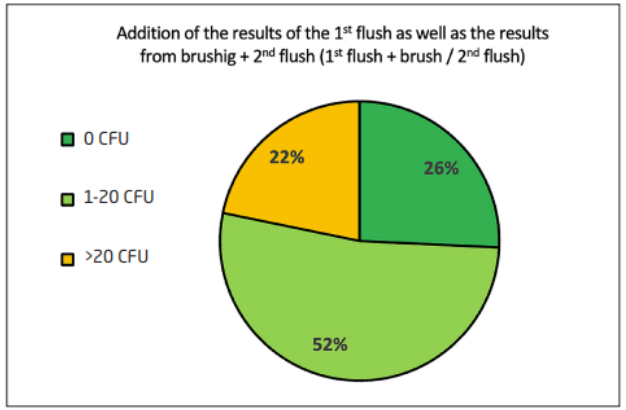
In accordance with the hitherto valid Annex 10 (1) of the first edition of the *Guideline for Validation of Automated Cleaning and Disinfection Processes for Reprocessing Heat-Sensitive Endoscopes*, compiled by the DGKH, DEGEA, DGSV, DGVS and AKI[2] [2], microbiological testing of reprocessed endoscopes (product control) is carried out by swab sampling of critical external areas and flush sampling of all endoscope channels. The basis for this description is Annex 8 of the KRINKO/BfArM[3] Recommendation *Hygiene Requirements for Reprocessing Medical Devices* [3]. For flush sampling 25 ml of sterile 0.9 % sodium chloride solution (NaCl solution) was injected into each of the channels present and 20 ml was separately collected from the distal tip. The swab and flush samples were evaluated using microbiology culture methods to obtain the number of eluted microorganisms (quantitative testing) and by using selective nutrient media for detection of hygienically relevant indicator organisms (qualitative testing). Elution of residual viable microorganisms from the channels through flush sampling followed by detection in cultures is currently the only established method in Germany for microbiological testing of endoscope channels that are not directly accessible.

When testing the microbiological condition of endoscope channels the recovery rate of the detected microorganisms is of elementary importance. The recovery rate is the quantitative measure of the proportion of detected microorganisms in relation to the number of microorganisms actually present in the test object, i.e. the respective endoscope channel. Low recovery rates result in underestimation of the actual bioburden and may lead to an unrecognised risk from undetected pathogens.

Keywords
- heat-sensitive flexible endoscopes
- working channel
- channel system
- elution
- flush-brush-flush
- overall process performance
- product control
- performance qualification, performance requalification

Manuscript data
Submitted: 29 August 2022
Accepted: 29 September 2022





Percentage distribution of the n = 101 results obtained for the total colony count for the two test methods, divided into the categories 0 CFU, 1 – 20 CFU and > 20 CFU per working channel.

"The results obtained demonstrate that the microorganism recovery rate can be sharply increased by using an endoscope cleaning brush, followed by a 2nd flush".

M. Wehrl et al. Elution of working channels with the flush-brush-flush-method for microbiological testing of reprocessed endoscopes2022. Zentralsterilization, Volume 30, 2772-277

SAMPLING METHOD

Sampling method

- Whenever required (e.g. low recovery or high correction factor), the method used to sample shall include friction for all brushable channels (e.g. flush-brush-flush method) to enhance recovery of contamination.

  For all other channels, the flush or flush-suction-flush method can be used.

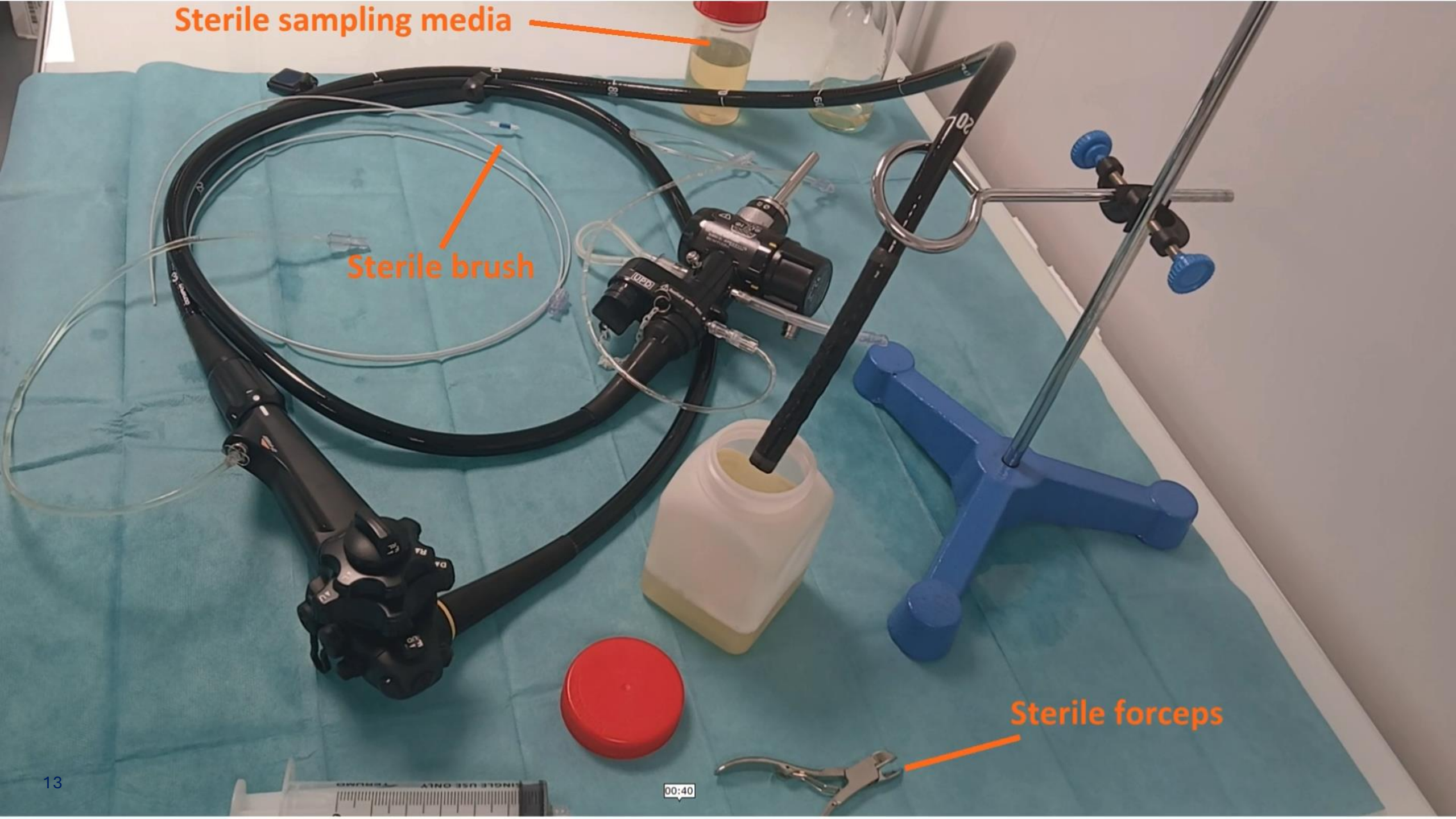
  NOTE 1 Literature describes anterograde or retrograde flushing directions for sampling.

  NOTE 2 The flush-suction-flush method can be done by a back-and-forth movement of the syringe piston during sampling.

Sampling brushes

- Sampling brushes should be sterile.
- The size of the brushes shall be appropriate for the diameter and length of the channels/areas or surfaces to be sampled and shall comply with the specification in the endoscope manufacturer's instructions for use.
- All tools used in association with these brushes (e.g. scissors used to cut off brush head after passing it through the channel) shall be sterile.

[5] Buss A., Been M., Borgers R. et al. Endoscope disinfection and its pitfalls - requirement for retrograde surveillance cultures. Endoscopy. 2008, 40(04) pp 327–332
[8] Wehrl M. et al. Elution of working channels with the flush-brush-flush method for microbiological testing or reprocessed endoscopes – Part 1: Description of the method and microbiological results if the field study. Zentr Steri. 2022, 30(5) pp 272-277


Sterile sampling media
Sterile brush
Sterile forceps

RECOVERY CORRECTION FACTOR

- The sampling method shall be validated (i.e. validation by inoculated product or repetitive recovery) for its ability to recover the bacteria present within endoscope channels, on the endoscope surfaces or on endoscope valves. A minimum of 3 samples (devices) shall be used to determine the recovery correction factor.
- The recovery correction factor shall be defined and considered for the expression of the results.
- Results shall be expressed as the total number of viable bacteria per endoscope or valve (X) taking into account the recovery correction factor (RCF) using Formula (1) (see ISO 11737-1).

$$X = \frac{Y}{RCF_1} + \frac{X}{RCF_2}$$ Where (Formula 1)

X is the corrected number of microorganisms per endoscope (or valve);

Y is the number of microorganisms enumerated in total volume of sampling solution used to sample channel(s) (or valve);

RCF1 is the recovery correction factor for the method used to sample channels (or valve);

Z is the number of microorganisms enumerated in the total volume of sampling solution used to sample external surfaces;

RCF2 is the recovery correction factor for the method used to sample external surfaces.

DUODENOSCOPES

Outbreaks of multidrug-resistant pathogens associated with duodenoscope


United States Senate
HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE
Patty Murray, Ranking Member

Preventable Tragedies:
Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients

Minority Staff Report

January 13, 2016

Investigation Olympus TJF-Q180V Scope

following detected contamination after cleaning and disinfection

(Internal title: Report Investigation Scope G-206)

Reporting, Conclusions and Recommendation

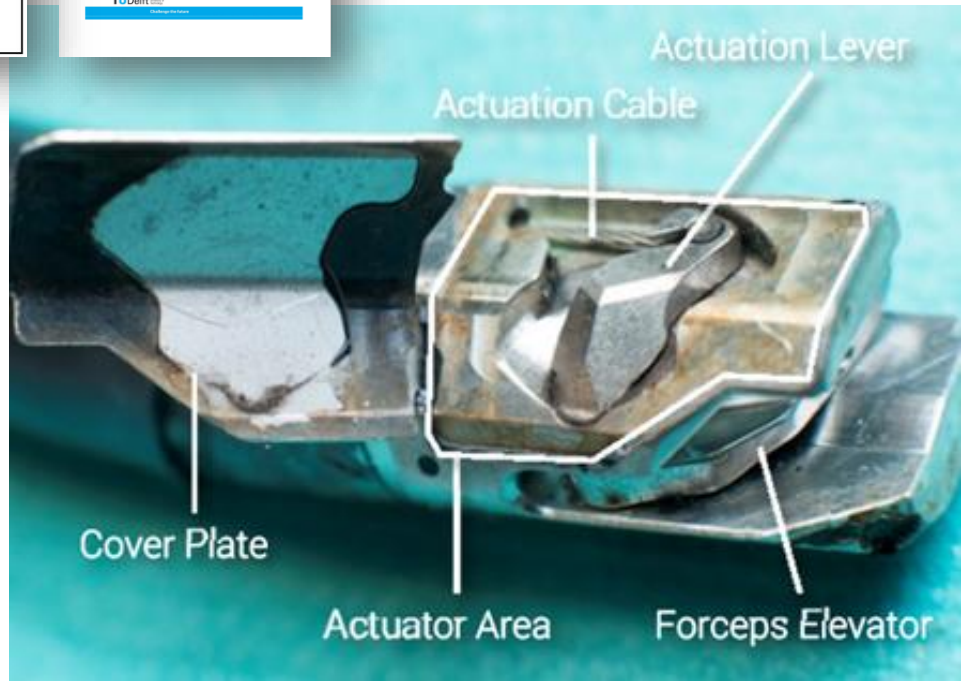
May 15, 2012

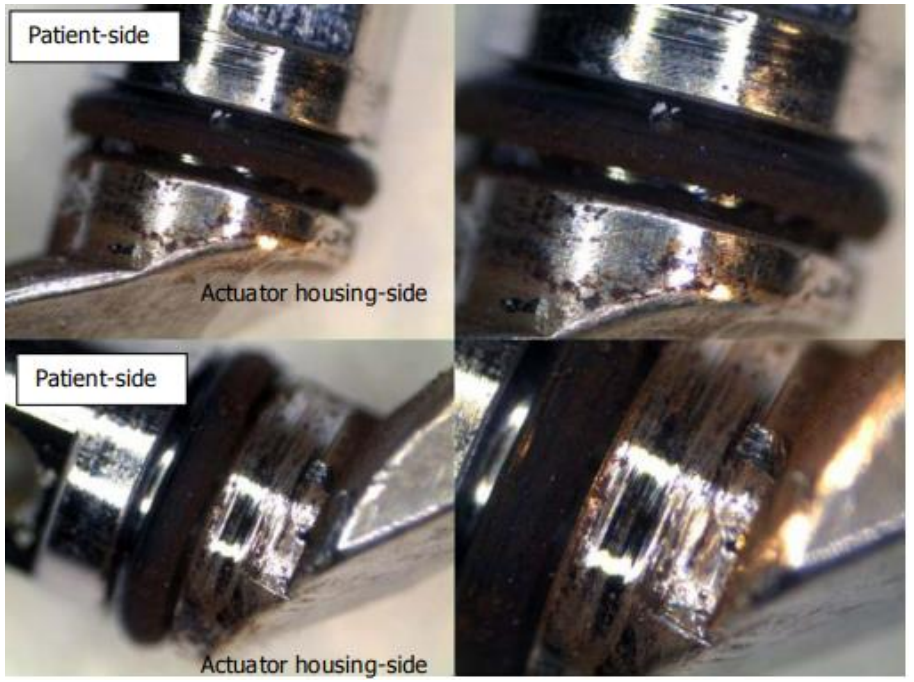
Dr. Ir. Arjo Loeve

Delft University of Technology

"It goes without saying that the sealing, actuator area and O-ring require direct and serious attention in all existing and future scopes similar to Scope G-206."

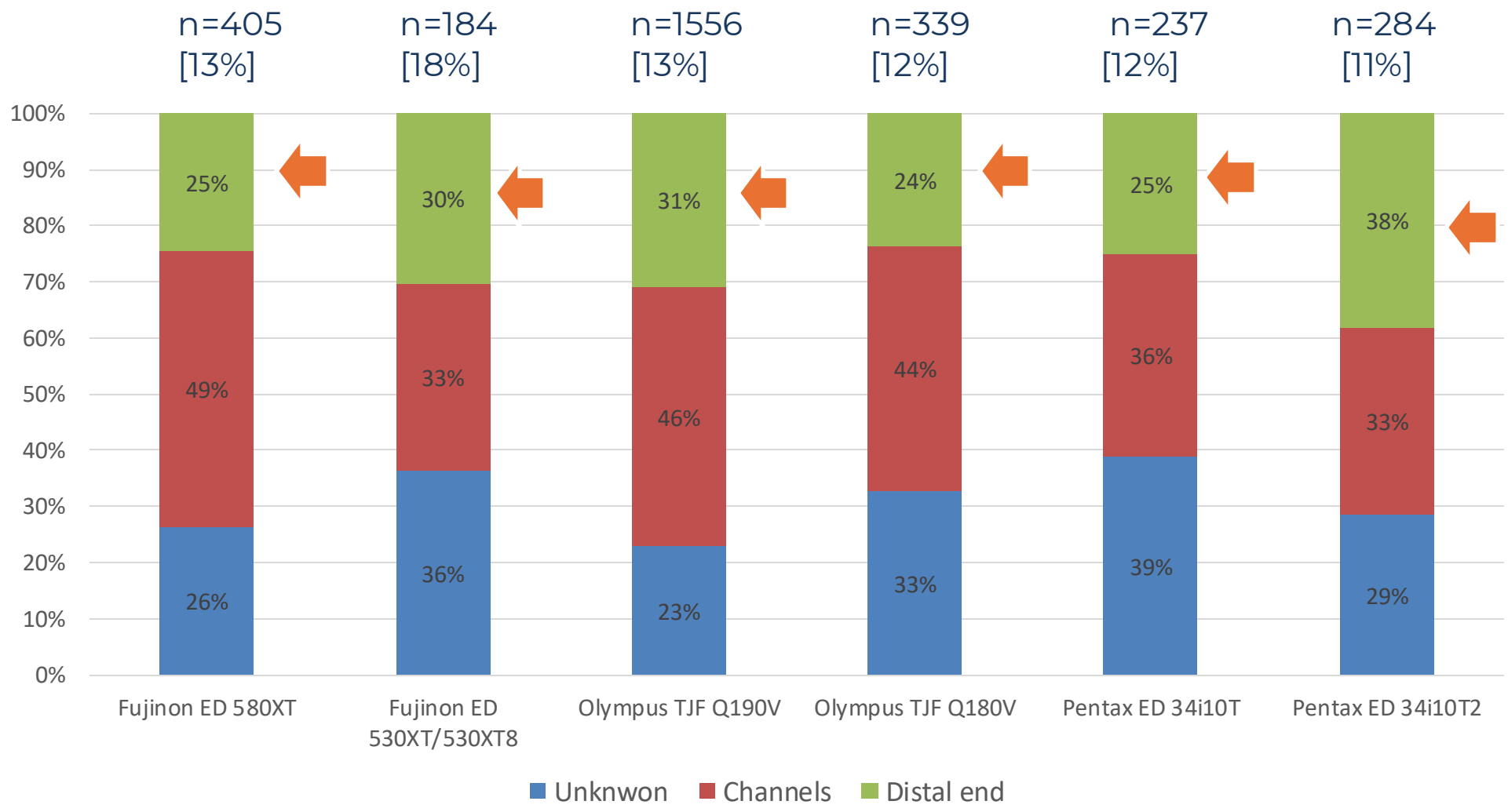
Dr. Ir. Arjo Loeve, Delft University of Technology, "Investigation Olympus TJF-Q180V scope: Following detected contamination after cleaning and disinfection" (May 15, 2012)





Murray, Patty. Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients. s. d. https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf

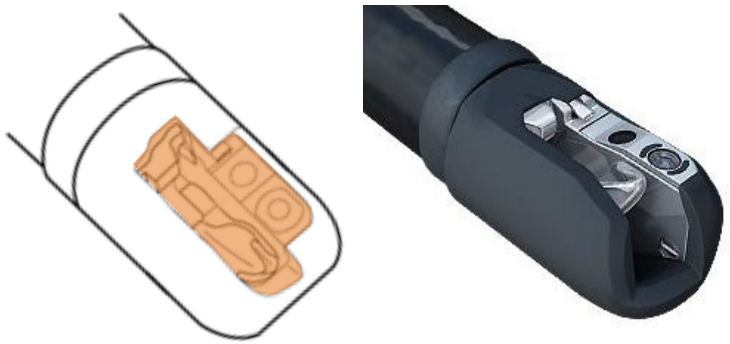
DUODENOSCOPE CONTAMINATION (2019-2024)



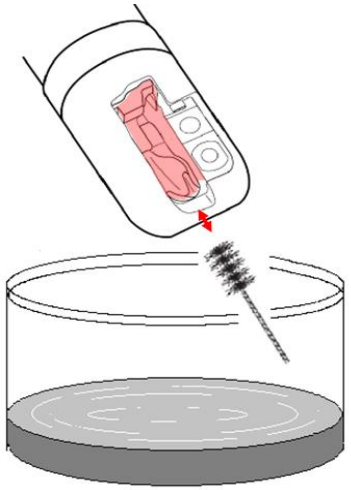
COMPLEX EXTERNAL GEOMETRIES

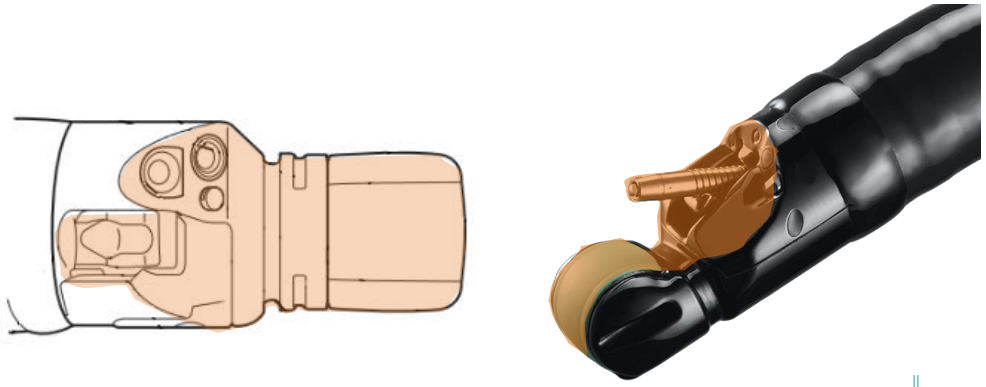
- The sampling of complex geometries such as distal end of duodenoscopes or ultrasound endoscopes shall be done by brushing and flushing with sampling solution or brushing and immersion in sampling solution. This may require actioning of mobile parts such as elevators during the sampling process.

  NOTE Other critical surfaces (e.g. balloon fixation, valve cylinders, control knob) can be sampled based on risk assessment.



Duodenoscopes





Linear echoendoscope

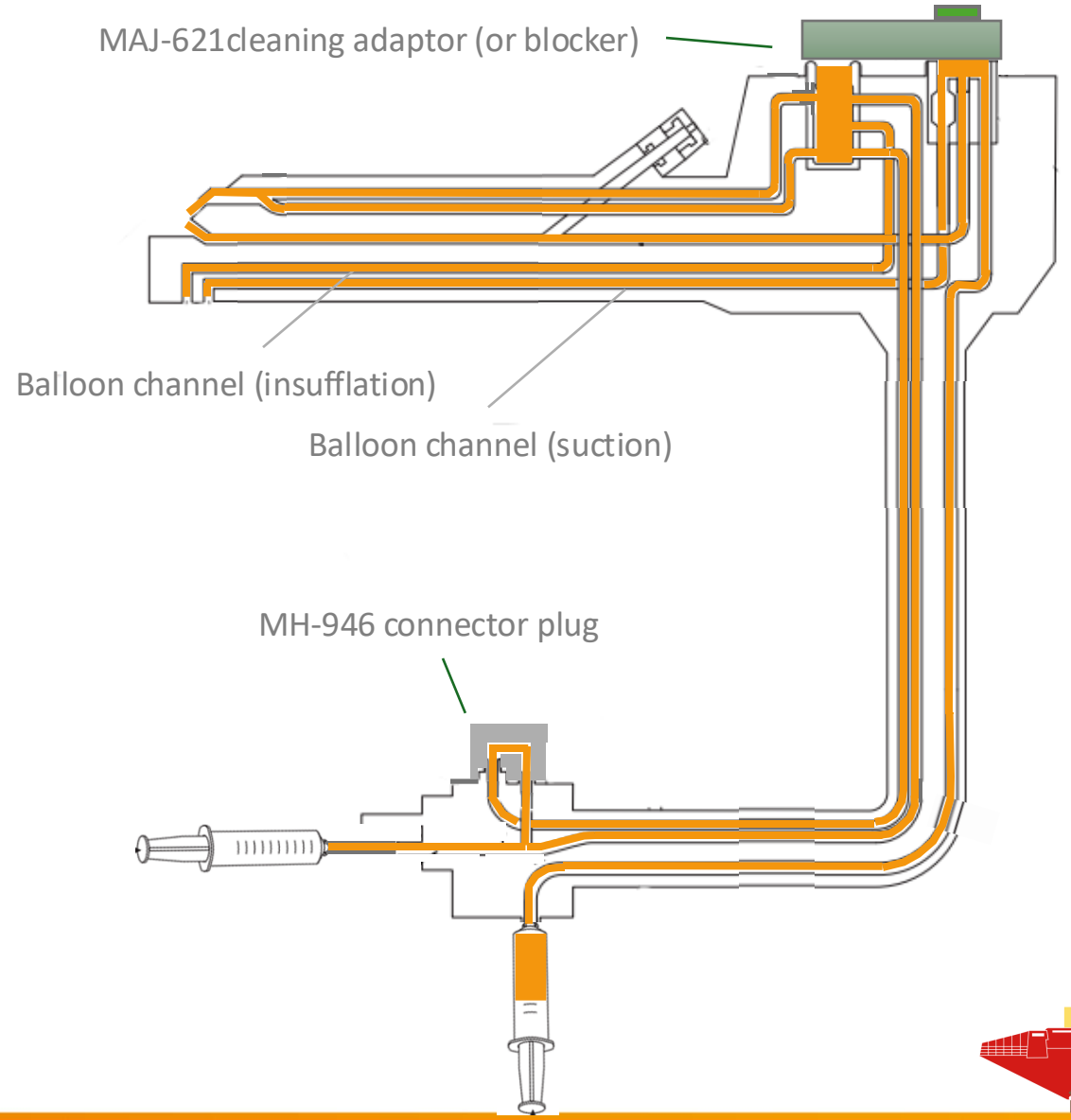
ULTRASOUND ENDOSCOPES

Olympus GF-UE190

- Use of the MAJ-621 cleaning adaptor (or blocker) and MH-946 connector plug.

⚠ No possibility to ensure that the balloon channel (suction part) has been properly sampled.

⚠ No possibility to ensure that the balloon channel (insufflation part) has been properly sampled.

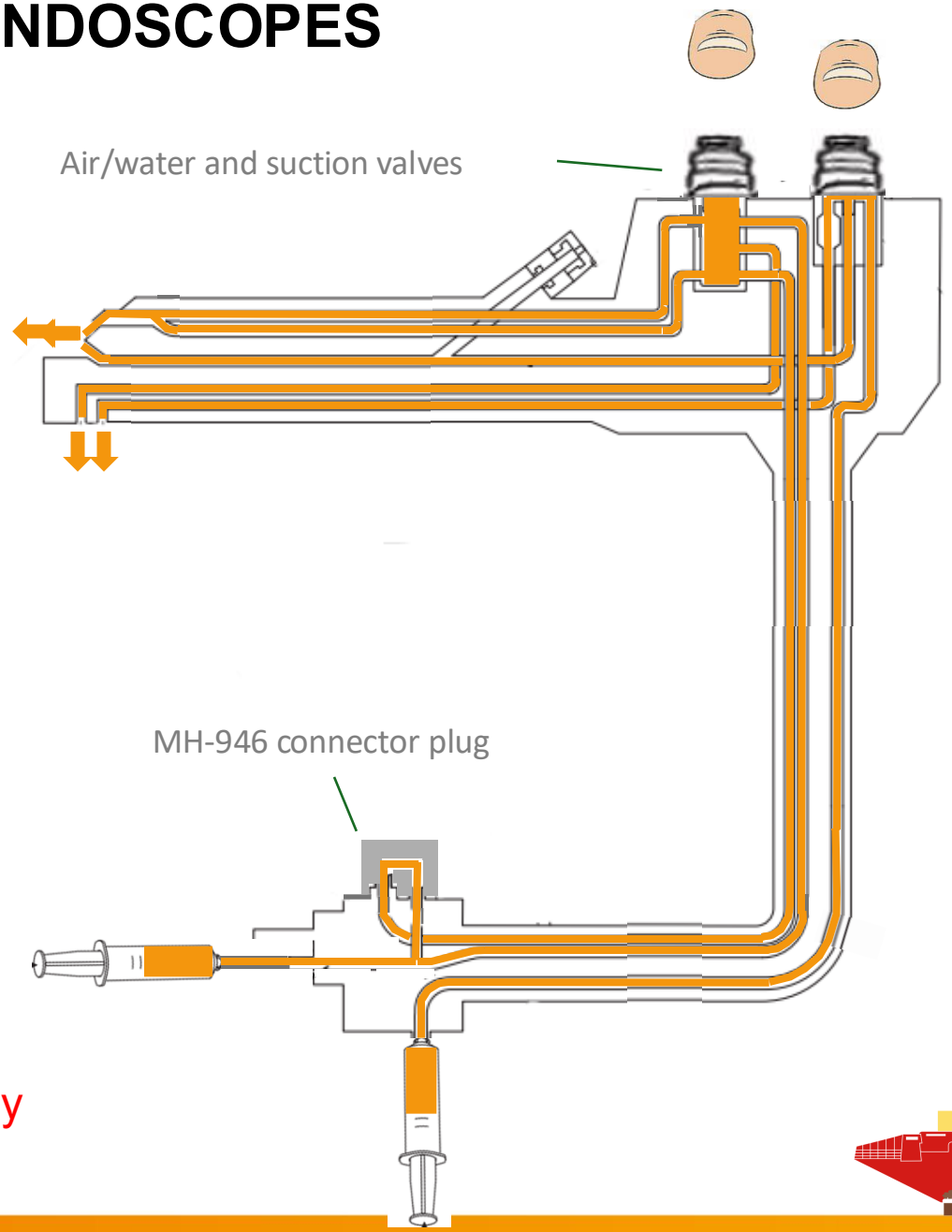


ULTRASOUND ENDOSCOPES

Olympus GF-UE190

Sampling with air/water and suction valves and MH-946 connector plug.

- Depress the suction valve to the first level for suction/instrument channel sampling,
- Depress the suction valve to the second level for balloon channel sampling (suction),
- Obstruction of the A/W valve hole for air channel sampling,
- Depress the A/W valve to the first level for water channel sampling,
- Depress the A/W valve to the second level for balloon channel (insufflation) sampling,



⚠ Air/water and suction valves may contaminate the sample.

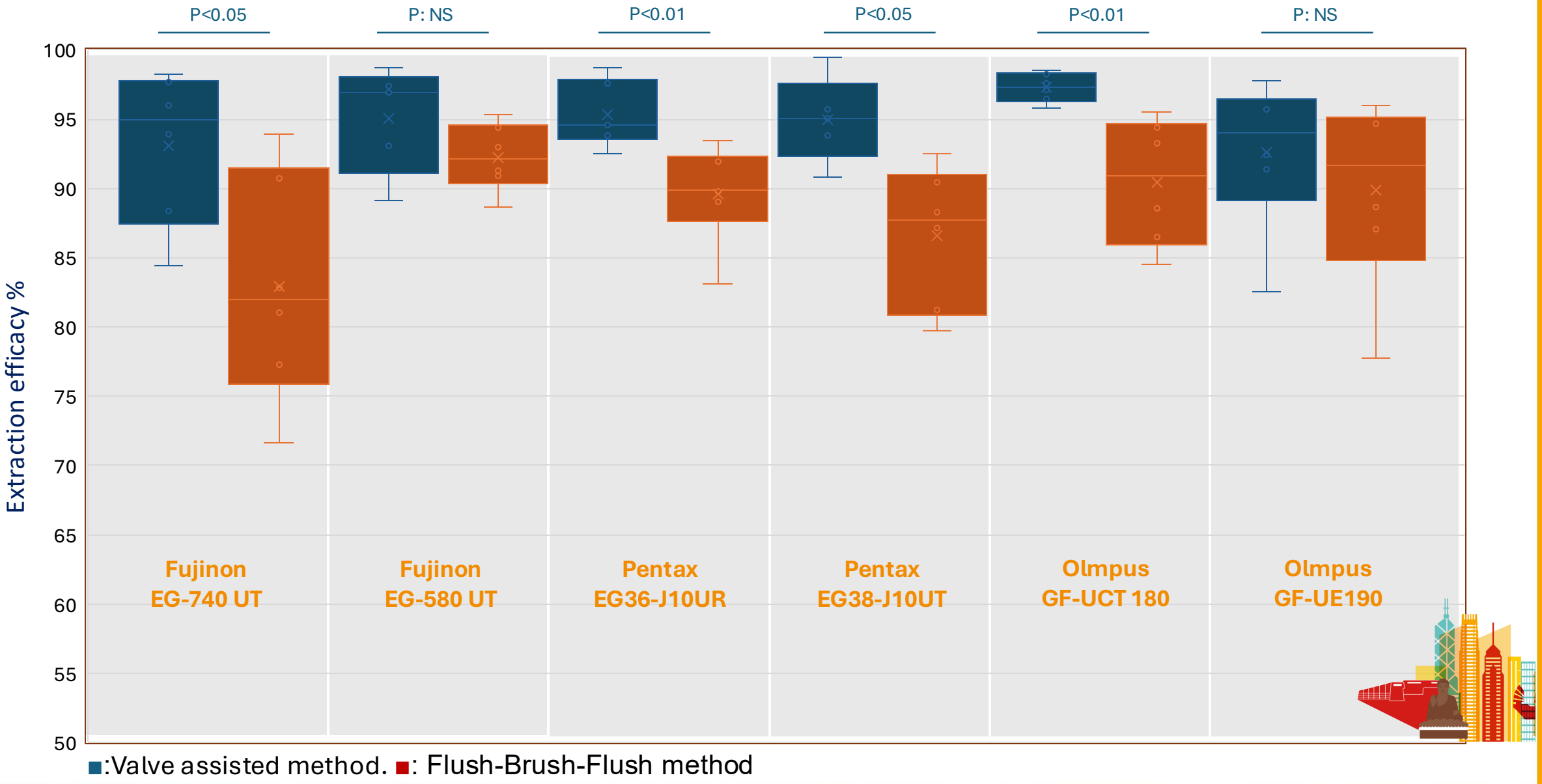
COMPARISON OF THE EFFICACY OF TWO SAMPLING METHODS ON ULTRASOUND ENDOSCOPES

Objectives

- The aim of this study is to determine the efficacy of two sampling methods for ultrasound endoscopes (“valved-assisted” (VA) method and “flush-brush-flush” method (FBF)).

Principle

- Endoscopes are manually reprocessed according to the endoscope manufacturer instruction for use (IFU) and are artificially contaminated with a microbial suspension (containing *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*) prepared in 0,5% NaCl solution.
- After 30 minutes of incubation endoscopes are sampled 5 successive times using the sampling protocols tested. Samples are maintained at 5°C for 1 hour (transportation time) and the number of microorganisms present in each sample is determined using the method recommended in the corresponding tested protocol. The bioburden recovery efficiency of each sampling protocol is calculated as described in ISO 11737-1:2018.
- 6 endoscopes were tested: Fujinon EG-740UT, Fujinon EG-580UT, Pentax EG36-J10UR, Pentax EG38J10UT, Olympus GF-UCT180, Olympus GF-UE190.

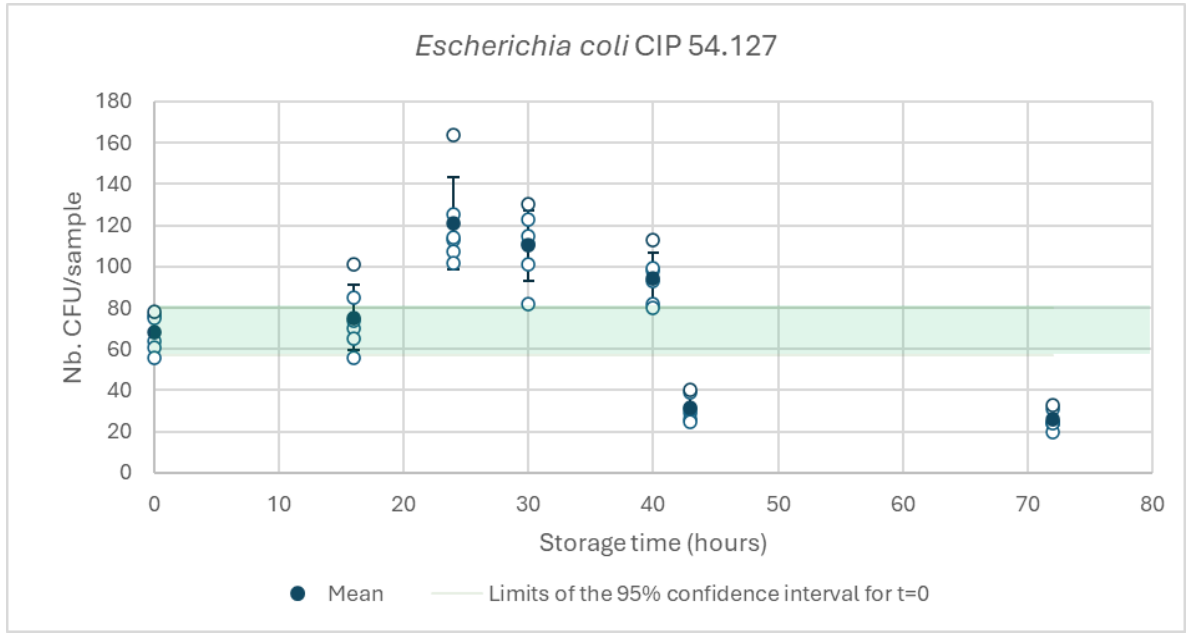

P<0.05
P: NS
P<0.01
P<0.05
P<0.01
P: NS
Extraction efficacy %
100
95
90
85
80
75
70
65
60
55
50
Fujinon EG-740 UT
Fujinon EG-580 UT
Pentax EG36-J10UR
Pentax EG38-J10UT
Olmpus GF-UCT 180
Olmpus GF-UE190
■:Valve assisted method. ■: Flush-Brush-Flush method

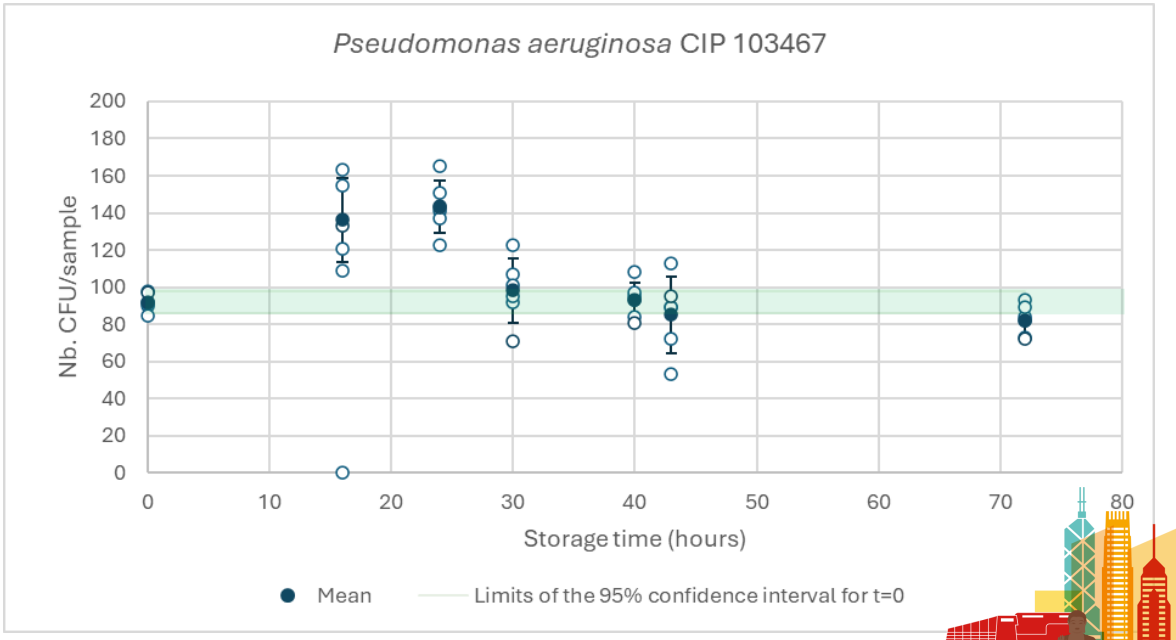
TRANSPORTATION CONDITIONS

- The sample shall be maintained at 5 °C +/-3 °C and shall be cultured as soon as possible, ideally within 24 hours and up to 48 hours.

  NOTE Extended times can interfere with the accuracy of the culturing method.

- Validation shall be performed if an alternative sampling solution is used, or if culturing and incubation is delayed by an extended transportation time.





CULTURING METHOD

- Several methods for sample analysis are described in literature such as filtration [1][2] or centrifugation (see Annex B, GENSA 2025)
- The preferred method for analysis shall be filtration with a maximum pore size of 0,45 µm .
- An alternative method of analysis can be used provided it is validated, has been demonstrated to be suitable for its intended purpose and is not inferior to the method of analysis specified in this document.

NOTE The filtration method has been shown to result in higher recovery rates than other culturing methods, i.e. centrifugation [3].

Incubation conditions

- Non-selective media such as Plate count agar (PCA), R2A, blood agar or Tryptone soy agar (TSA) shall be used for the determination of the total number of viable, aerobic bacteria in the sample.
- The plate shall be incubated at 30 °C – 35 °C for three days followed by two days at 20 °C – 25 °C.

[1] ALFA M., SINGH H. Contaminated flexible endoscopes: Review of impact of channel sampling methods on culture results and recommendations for root-cause analysis. Infect Control Hosp Epidemiol. 2022, 43(5) pp 623-638

[2] PINEAU L., ALFA M., RADIX C. Endoscope sampling and culturing methods. J Hosp Infect. 2024, 149 pp 36-45

[3] EL BOUJNOUNI H., NAIT BALLA K., BELKADI B., RAHOUTI M. Comparison between the recovery rate of three concentration protocols of water samples intended for analysis by Molecular Biology: Membrane filtration, filtration on gauze pad and centrifugation. Saudi J Biol Sci. 2022, 29(3) pp 1592-1597. doi: 10.1016/j.sjbs.2021.11.004. Epub 2021 Nov 11. PMID: 35280573; PMCID: PMC8913413.

INTERPRETATION CRITERIA

	Number of viable bacteria (CFU) per endoscope (or valve)			
	<1	**1-19**	**20 - 100**	**>100**
Total aerobic flora [a]			Alert level	Action level
Indicator organisms		Action level	Action level	Action level
(a) Local regulations can specify different values for Total aerobic flora count.				

Indicator organisms

- Indicator organisms are microorganisms associated with infections in the area of the body where the endoscope is used. When selecting appropriate indicator organisms, they should at least cover the following microorganisms:
  - *Enterobacterales*;
  - *Pseudomonas aeruginosa* and other *pseudomonadaceae*;
  - *Acinetobacter sp.*;
  - ß-hemolytic streptococci;
  - atypical mycobacteria (based on the intended use of the endoscope);
  - yeast (based on the intended use of the endoscope);
  - fungi (based on the intended use of the endoscope).

CONCLUSION

Standardizing microbiological sampling and testing protocols is essential for ensuring consistent, reliable, and clinically meaningful results.

The adoption of evidence-based guidelines promotes harmonized practices across healthcare settings, strengthens quality control, facilitates inter-laboratory compatibility, enhances data sharing and increases patient safety.

Thank you...