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QUANTITATIVE MONITORING OF RESIDUAL PROTEIN IN CANNULATED MEDICAL DEVICES: Findings from a Multicenter Study

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ALTA COMPLEJIDAD EN RED Hospital El Cruce Dr. Néstor Carlos Kirchner

A multi-center study
Who are we?

Hospital Italiano de Buenos Aires is one of Argentina's leading healthcare institutions,acredited by JCI and renowned for its excellence in medical care, teaching, and research.

- Founded in 1853, it provides health services through advanced technology and a patient-centered approach.

- As a university hospital it carries out healthcare, teaching, research and development activities in the field of medicine.

A multi-center study
Who are we?

Favaloro Foundation University Hospital in Buenos Aires is a leading medical institution in Argentina, internationally recognized for its excellence in cardiovascular medicine, surgery, and research.

- Founded by Dr. René Favaloro in 1992, the hospital continues his legacy of combining advanced medical technology with strong ethical and humanistic values.
- -It offers comprehensive healthcare services, promotes cutting-edge biomedical research, and provides academic training through the Universidad Favaloro.

A multi-center study
Who are we?

El **Cruce High Complexity Hospital – Néstor Kirchner** is a public healthcare institution located in Buenos Aires Province, Argentina.

- Established in 2007, it was designed to provide high-complexity medical care to patients referred from regional hospitals.
- It is recognized for its advanced diagnostic and therapeutic technologies and strong focus on accessibility, equity, and innovation in public health.
- It also plays a key role in medical education, research, and collaboration with universities and national health programs.

Objectives

- ✓ To evaluate the performance of a protein detection system specifically designed for application within cannulated medical devices.
- ✓ To validate the system's reliability under conditions simulating real clinical reprocessing scenarios.
- ✓ To demonstrate the technical advantages of using a sensitive, non-destructive monitoring method capable of detecting clinically relevant levels of residual protein in lumens.
- ✓ To verify and improve the quality of the cleaning process in the hospitals participating in the study

Why test protein residues?

I. Proteins are present in alive or dead organisms

- ✓ E. coli and Staphylococcus aureus (about 2 million proteins).
- ✓ Smaller bacterias like Mycoplasma or Spirochetes (50,000 to 1 million).
- ✓ Eukaryotic cells contains much more proteins.

I. Proteins have many functions in organisms:

- ✓ Catalysing metabolic reactions.
- ✓ DNA replication.
- ✓ Providing structure to cells and organisms.
- ✓ Transporting molecules.

Why test protein residues?

III. Proteins are highly resistant to removal

They can denature, coagulate, and bind tightly to instrument surfaces when exposed to heat or drying, making them more challenging to eliminate than other types of soil.

III. Protein presence correlates with infection risk

Residual proteins may harbor or shield microorganisms, including prions, potentially compromising subsequent disinfection or sterilization steps.

III. Protein quantification is a sensitive and reliable marker of cleaning efficacy

Protein assays can detect very low concentrations (μg/cm²), providing objective evidence of cleaning performance that goes beyond visual inspection.

Regulations applied to endoscope reprocessing and protein monitoring

HTM 01-06:2016 (UK)
Protein threshold: use of trend analysis (no fixed µg/cm² limit

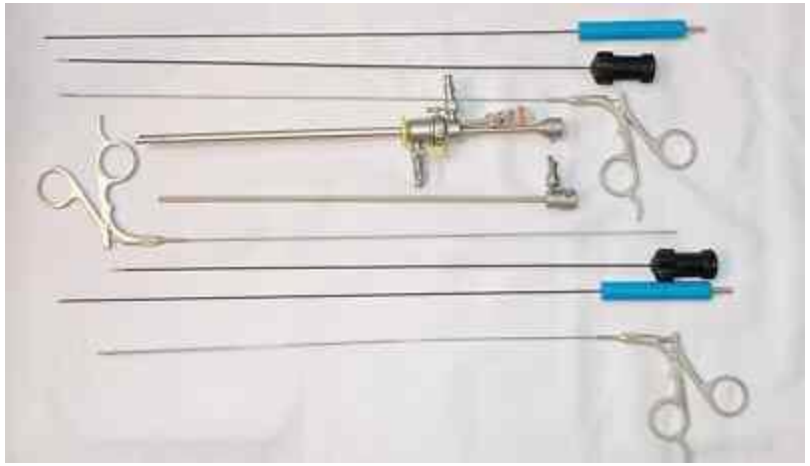
ISO 15883-5:2021 (Worldwide)
Protein threshold:
Alert level : 3 µg/cm²
Action level :6.4 µg/cm²

ANSI/AAMI ST91:2021 (USA)
Protein threshold: 6.4 µg/cm²
Frequency:
High-risk endoscopes (e.g., duodenoscopes): after each use

Materials and Methods

List of Instruments tested

- Cannula Pump (Two-section Pump Cannula)
- Hepatic Aspiration Cannula 2
- Laparoscopic Forceps Sheath
- Ureteroscope
- Cystoscope
- Bettochi
- De Bakey Suction Tube – 4 mm × 20 cm



Materials and Methods

List of Instruments tested

- Poole Suction Cannula
- Frazier Suction Tube (9 Fr -12 Fr)
- Fine Suction Cannula (Fergusson) Aesculap GF373R
- Suction Tube – 4 mm (12 Fr)
- Coronary Aspiration Cannula
- Neuro Aspiration Cannula
- Olsen Forceps for Cholangiography

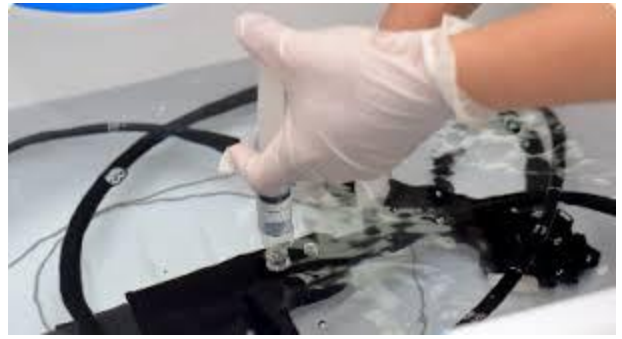
Materials and Methods

Protein detection system

- High-absorption swabs
  - ✓ Diameter: 1.7mm, 2mm, 2.7mm, 3mm
  - ✓ Long: 2.5 m
- Moisturizer (wetting solution)
- Autoreader
  - ✓ Quantifies up to 50 μg of protein
  - ✓ Resolution of 0.1 μg
  - ✓ Sensitivity of 0.3 μg

Methods - Washing Process

Manual Cleaning — Actions Performed



I. The detergent solution was prepared according to the manufacturer's specifications for dilution, temperature, and contact time.

I. The disassembled medical devices were fully immersed and brushed while submerged to avoid aerosolization of particles.

I. Soft-bristle brushes (for internal and/or external surfaces), sponges, water guns, spray nozzles, and similar tools were used.

I. For internal lumens channel, proper contact with the enzymatic detergent solution was ensured, using devices such as syringes to flush the internal channels and proper brushes.

Washing process - Summary

Manual Cleaning

Parameter	Italiano	Cruce	Favaloro
Detergent name	TRIDEX	CIDEZYME	ANIOSYME DLT PLUS
Detergent manufacturer	COVIDEX	ASP	LECTUS
Detergent concentration	2.5 mL/L	8 mL/L	5 mL/L
Temperature (°C)	40	40	30
Time (min)	5	5	5

Methods - Washing Process

Automatic Cleaning — Actions Performed

I. The cannulated devices were disassembled, separating all detachable parts before processing.

I. They were placed in the Steelco ultrasonic washer on dedicated lumen racks to ensure fluid flow through the channels.

I. The validated ultrasonic cycle was selected, using manufacturer-specified water temperature, enzymatic detergent dose, ultrasonic frequency, and duration.

I. The lumen irrigation system was activated to ensure continuous flushing of the internal channels during ultrasonication.

I. After the cycle completed, the devices were removed.

Washing process - Summary

Automatic Cleaning

Parameter	Value
Equipment	Steelco Ultrasonic Washer
Detergent	Cidezyme
Detergent concentration	10 mL/L
Washing temperature	40 °C
Washing time	10 min
Rinsing time	10 min

Methods – Testing Procedure

The experimental design was carried out using three washing replicates of the same instrument

I. The device was placed on a clean surface, and the swab that best fit the lumen of the cannulated instrument was selected.

I. The protein monitoring device was removed from its package ten minutes before use until it reached a temperature of 20–25 °C.

I. The swab (SWE) was removed, ensuring that the absorbent tip was not touched and moistened by immersing it for 5 seconds in the wetting solution.

I. The swab was inserted and passed through the internal channel of the endoscope or cannulated instrument in a single motion.

Methods - Testing Procedure

V. Scissors were used to cut the swab approximately 20 cm from the absorbent tip, without touching or damaging the absorbent portion.

V. The protein-monitoring device (PMD) was activated, and the swab was inserted into the PMD's reading cone until it was fully immersed in the solution.

V. The swab was gently kept in the solution for 10 seconds, then was taken away and the PMD was incubated into the auto-reader at 60 ± 2 °C during 4 min and the result (ug of protein) was recorded.

Results

Instrument	Type of Cleaning	Average µg Protein	Maximum µg Protein	Minimum µg Protein	A (cm²)	µg/cm² (Average)	µg/cm² (Maximum)
CANNULA PUMP (Two-section pump cannula)	Automatic	0,25	1,00	0,00	58,09	0,00	0,02
Hepatic Aspiration Cannula 2	Automatic	0,00	0,00	0,00	31,40	0,00	0,00
Laparoscopic Forceps Sheath	Automatic	0,43	1,30	0,00	40,19	0,01	0,03
Urethroscope	Manual	1,62	6,00	0,00	56,52	0,03	0,11
Cystoscope	Manual	0,67	4,00	0,00	68,77	0,01	0,06
Bettochi	Manual	2,82	6,00	0,00	47,10	0,06	0,13
De Bakey Suction Tube 4 mm 20 cm (Intermediate Pediatric 1)	Manual	0,00	0,00	0,00	25,12	0,00	0,00
Poole Suction Cannula (Cardio Pediatric 20–40)	Manual	0,00	0,00	0,00	13,82	0,00	0,00
FRAZIER Suction Tube (Plastic 2)	Manual	1,57	1,90	1,10	23,86	0,07	0,08
Poole Suction Cannula (Thoracic Cardio 1)	Manual	0,34	1,00	0,00	6,91	0,05	0,14
FRAZIER Suction Tube 9 Fr (Neuro 3 Light)	Manual	0,25	0,50	0,00	22,61	0,01	0,02
Fine Suction Cannula (FERGUSSON) AESCULAP GF373R (Hepatic Implant 1)	Manual	2,10	3,40	0,00	16,96	0,12	0,20
FRAZIER Suction Tube 9 Fr (Light Neuro 1)	Manual	0,00	0,00	0,00	16,96	0,00	0,00

Results

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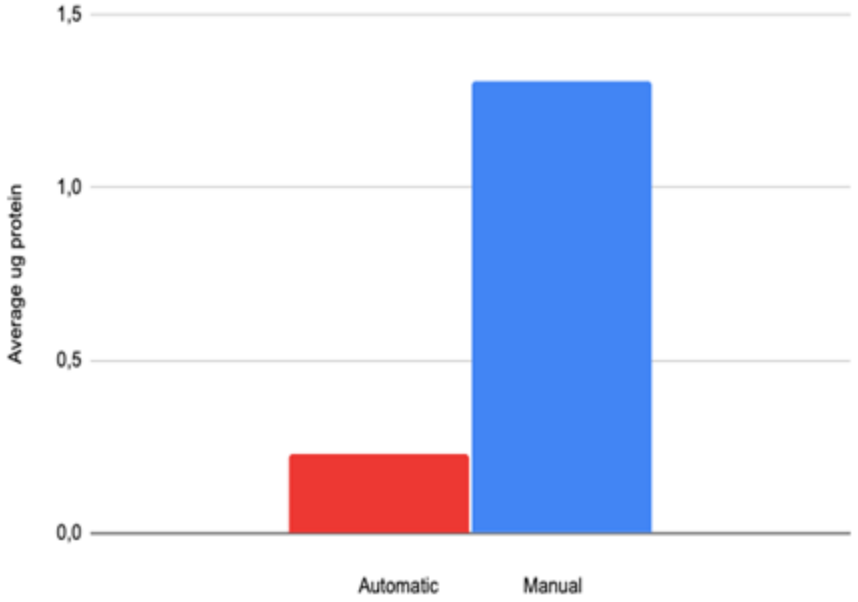
FRAZIER Suction Tube 9 Fr (Light Neuro 1)	Manual	0,00	0,00	0,00	16,96	0,00	0,00
FRAZIER Suction Tube 12 Fr (Light Neuro 1)	Manual	0,33	1,00	0,00	22,61	0,01	0,04
Suction Tube 4 mm (12 Fr) (Column Soft Parts 2)	Manual	2,87	3,40	2,20	20,10	0,14	0,17
FRAZIER Suction Tube 13 (Column Soft Parts)	Manual	2,10	6,30	0,00	24,30	0,09	0,26
Coronary Aspiration Cannula	Manual	1,26	2,60	0,00	37,68	0,03	0,07
Neuro Aspiration Cannula	Manual	1,40	1,70	1,00	7,54	0,19	0,23
OLSEN Forceps for Cholangiography	Manual	3,65	6,30	1,00	7,54	0,48	0,84

Results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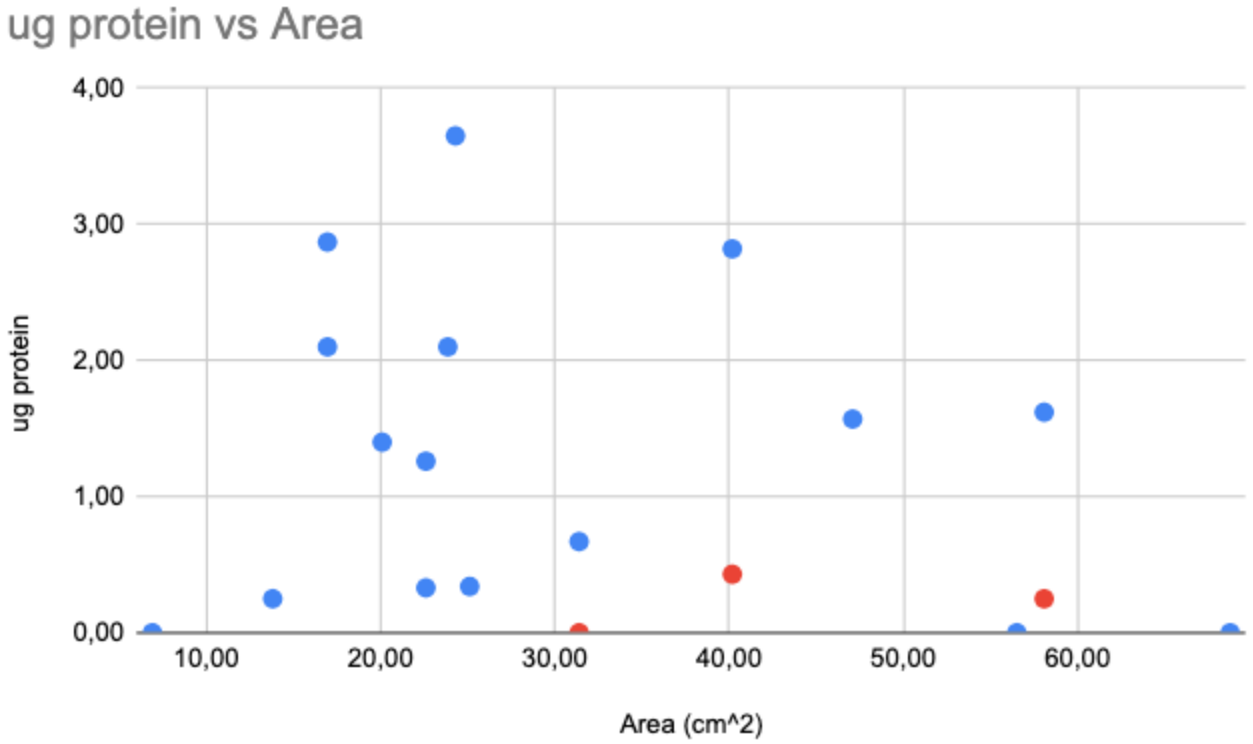
Average ug protein
Automatic
Manual


ug protein vs Area
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2,00
1,00
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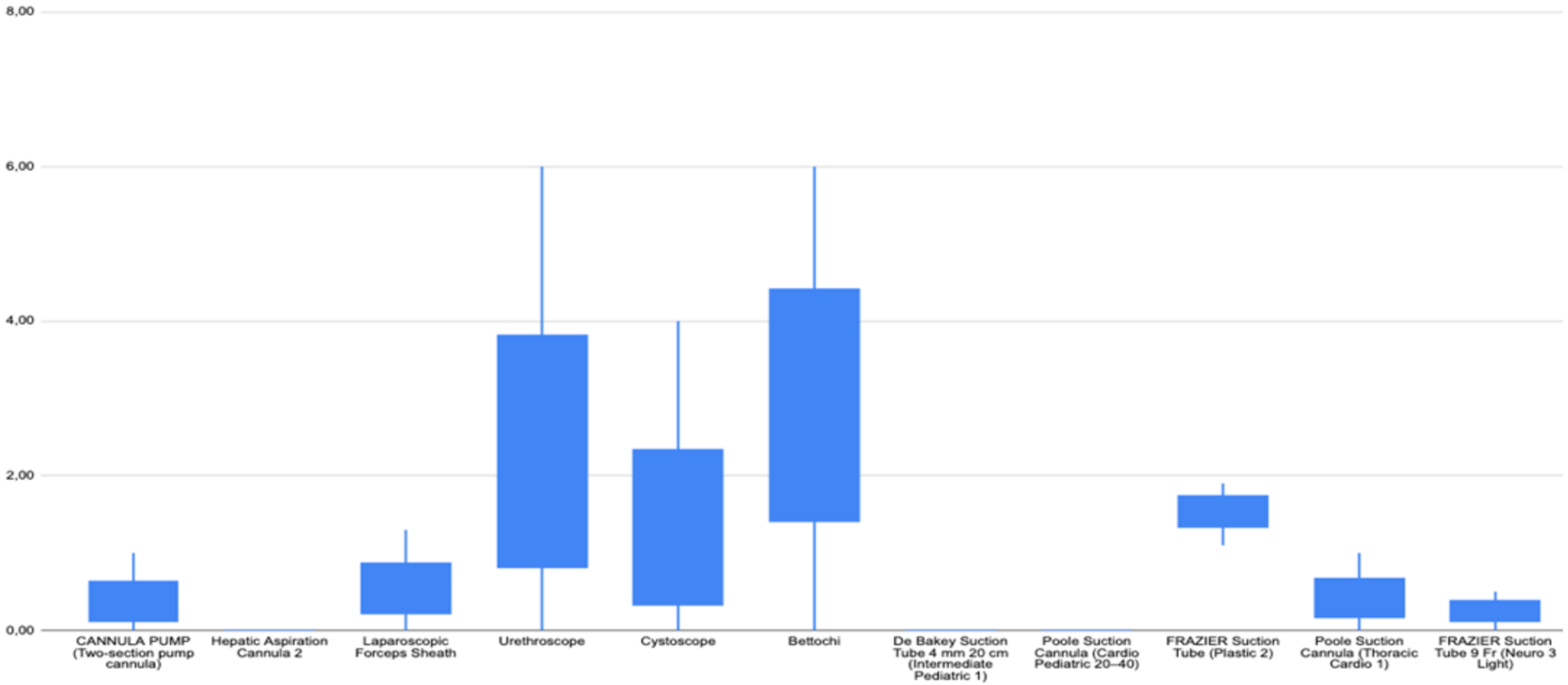
ug protein
10,00
20,00
30,00
40,00
50,00
60,00
Area (cm^2)

Results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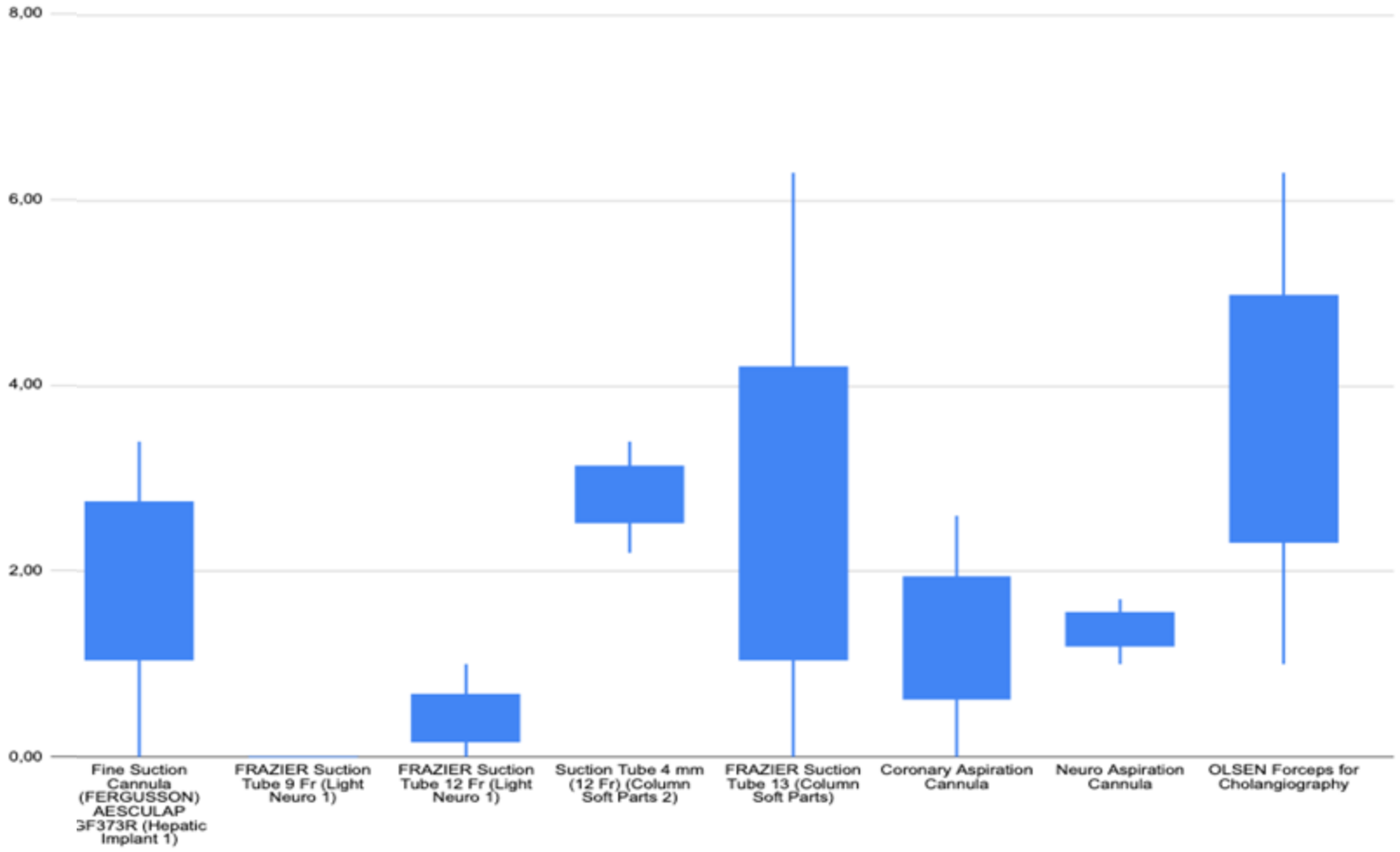
Results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FRAZIER Suction Tube 13 (Column Soft Parts)
Coronary Aspiration Cannula
Neuro Aspiration Cannula
OLSEN Forceps for Cholangiography

Results

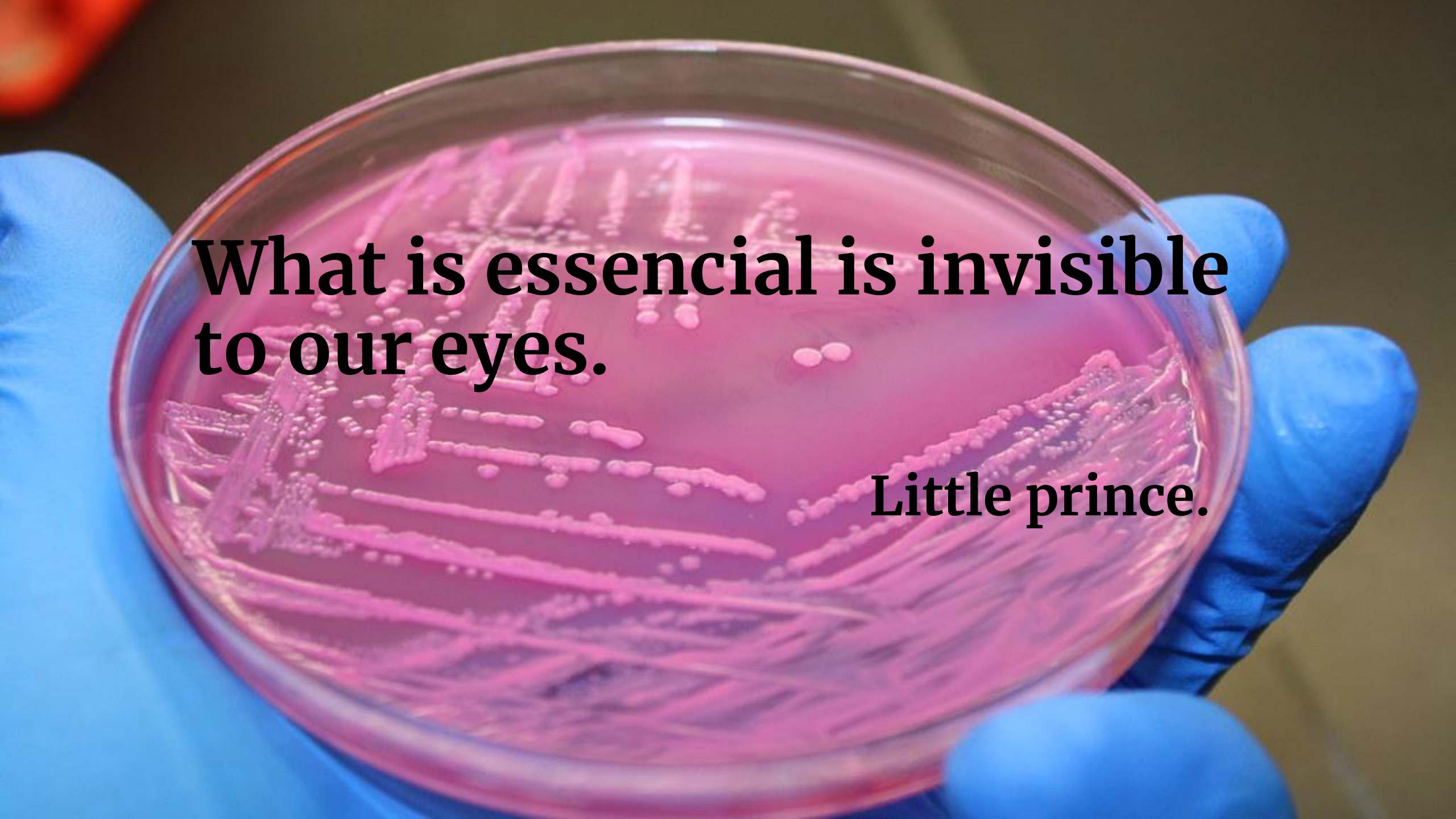
1. The Pro1 Endo system demonstrated high sensitivity, successfully detecting residual protein levels below the clinically significant threshold in most samples, confirming its suitability for post-cleaning verification of cannulated devices.

1. Manual cleaning processes showed variable results depending on the device type and internal geometry (diameter and length), indicating that lumen complexity significantly affects cleaning efficacy.

1. Devices with smaller internal diameters (<3 mm) tended to retain more protein residues, emphasizing the need for targeted cleaning validation in narrow-channel endoscopes and suction tubes.

1. Visual inspection alone was insufficient, as several instruments with undetectable soil visually still showed measurable protein levels — reinforcing the importance of quantitative biochemical monitoring.

1. Overall cleaning performance met acceptable limits, with most samples exhibiting protein residues below 6.4 µg/cm², supporting compliance with international recommendations for cleanliness verification in reprocessed medical devices.


What is essencial is invisible to our eyes.
Little prince.