

Deleterious health consequences for patients from failures in reprocessing flexible endoscopes

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New Horizon in Infection Prevention and Control
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6th International Infection Control Unit Conference of TBRI
Cairo, 24th – 26th November 2014

Contents

- Bioburden
- Statements
- Published transmissions/infections
- Requirements
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Bioburden

Mouth

10^6 - 10^9 bacteria / mL saliva

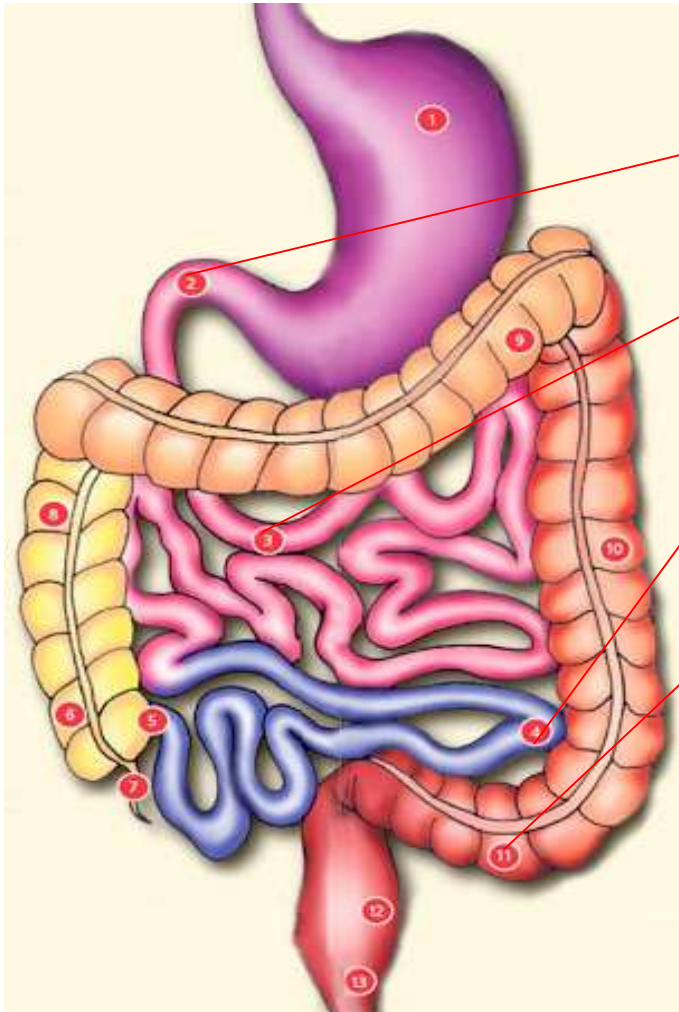


* 1174 taxon, 68%
thereof not cultivable
(Moter 2011)

- Mouth *
- Streptococcus
- Lactobacillus
- Fusobacteria
- Veillonella
- Corynebacteria
- Neisseria
- Actinomyces
- Mycoplasma
- Spirochaetaceae
- Bacteroides

Bioburden

Digestive system



Bacteria (cfu/mL)

- Duodenum: $10 - 10^3$
- Upper small intestine: $10^3 - 10^5$
- Lower small intestine: $10^4 - 10^8$
- Large intestine: $10^{10} - 10^{11}$

Bioburden After use

	Gastroscope (n = 5)	Colonoscope (n = 5)
	\log_{10} CFU	\log_{10} CFU
Outer surface	3.4 – 4.5	4.5 – 7.0
Air channel	2.8 – 5.2	6.2 – 7.8
Water channel	2.3 – 3.5	2.4 – 7.0
Suction channel	4.4 – 7.3	4.0 – 9.0

Vesley et al., Gastroenterology Nursing (1999)

EN ISO 15883 Part 4 (2008)

4 Performance requirements 4.1 General

- **4.1.3** After the complete process in the WD
.....shall be designed to achieve this condition
recognising **the high level of bacterial contamination that
may exist [26], [27] and [28].**.....

The WD manufacturer shall **demonstrate** this capability
during type testing for all the types of endoscope that
the WD is designed to process.



Process shall ensure a **9 log₁₀** reduction

The Human Microbiome Project

- “The gastrointestinal tract
 - 6.5 meters long
 - contains up to 100 trillion (10^{12}) microbes
 - representing 1,000 different species
 - **the majority of such microbes can't be cultured in the lab “**

Bioburden

Intestine

- Informations
 - 100 x more microbial genes than human genes
 - 2.000 to 3.000 species
- Species differ between intestine and faeces

Virus bioburden

After use

- Hepatitis B virus DNA-positive samples (17 patients)
 - 30 % (!!) suction / accessory channels
titers of 7×10^4 to 1×10^6 copies/channel
 - negative after reprocessing
 - 6 % water channels and 18 % air channels
 - titers of 6×10^3 to 3×10^4 and 3×10^3 copies/channel
 - negative after reprocessing

Contamination with hepatitis B virus DNA in gastrointestinal endoscope channels: risk of infection on reuse after on-site cleaning, Ishino et al., Endoscopy (2005)

Blood donation in Germany

Novelle 2005, last change in August 2011

- 2.2 **Refusal of blood donation**
 - 2.2.2.2 Because of the risk of being infected
 - **After endoscopy: Deferral of 4 months**

Novelle 2005, letzte Änderung vom 12. August 2011; Richtlinien zur Gewinnung von Blut u. Blutbestandteilen und zur Anwendung von Blutprodukten-aufgestellt von der Bundesärztekammer im Einvernehmen mit dem Paul-Ehrlich-Institut

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Statement

- However, ascertainment of infection resulting from endoscopy may be generally **under-recognized** as infections with blood-borne viruses can be **subclinical**, leading to an underestimate of the actual number of infections.

“Gastrointestinal endoscopy decontamination failure and the risk of transmission of blood-borne viruses: a review.”

Morris et al., Journal Hospital Infection (2006)

Statement

- It is our experience that the number of incidents that are published or reported in the press **represent a small fraction of the disinfection instrument reprocessing failure incidents** that result in patient notification.

“How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines”

Rutala and Weber; Infect Control Hosp Epidemiol 28 (2007)

Statement

- Bacterial transmission from endoscopes to patients **tends to be incidently identified** when unusual species or a microorganism with an uncommon resistance profile is involved.

„Endoscope disinfection and ist pittfalls – requirement for retrograde surveillancce cultures.“

Buss et al., Endoscopy (2008)

Statement

- Contaminated endoscopes have been linked to **more outbreaks** of healthcare-associated infections than **any other medical device**.

„Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation“

Ofstead et al., Gastroenterology Nursing (2010)

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Outbreak

Pseudomonas aeruginosa

Juni – July 2007 (Atlanta)

- 54 bronchoscopies; 3 bronchoscopes
 - 20 patients examined with same bronchoscope
 - 11 positive with identical strain (+ index patient February)
 - 10 treated with antibiotics
 - 3 patients died (for it??)
- Reprocessing practices were appropriate
 - Precleaning, leak test, HLD, postinfection rinsing, drying
- Defects of the bronchoscope
 - Forceps channel tube was kinked
 - Bending section sheath cover was damaged
 - Bending section assembly required replacement
 - Insertion tube was pinched
 - Light guide tube coating cracked and peeling

Outbreak

Burkholderia cepacia

- Positive samples for *Burkholderia cepacia*
 - 3 patients on 3 consecutive days (bronchoalveolar lavages)
 - 8 of 10 bronchoscopes
 - WD (MediVator)
 - Surface of the chamber
 - Rinse water
- Negative Samples for *Burkholderia cepacia*
 - Feed water (reverse osmosis)
- Cause
 - 0,2 µm bacteria-retentive filter was missing

Rosengarten et al, Infect Control Hosp Epidemiol 31: 769-771 (2010)

Outbreak multidrug-resistant *Pseudomonas aeruginosa*

- Microbiological surveillance testing
 - Therapeutic endoscopes: once a month
 - Diagnostic endoscopes: once every 3 month
- 36 patients underwent ERCP with the same endoscope
 - 3 patients with sepsis: same strain
 - Patient 1: high fever after 6 days
 - Patient 2: high fever after 6 weeks
 - Patient 3: no details given
- After HLD and sterilization with ETO still present
- Channels undamaged but **biofilm**

Kovaleva et al., Endoscopy (2009)

Outbreak

multidrug-resistant *Klebsiella pneumoniae*

Multidrug-resistant *K. pneumoniae*

- December 2008 to August 2009 (ERCP of 253 patients)
 - 8 bloodstream infections
 - 4 biliary tract infections
 - 4 patients with faecal carriage
- Saline-flushing of the operating, suction, and air/water channels
 - No bacterial growth
- After brushing with a Tween 80-lecithin-based solution
 - *K. pneumoniae*, *P. aeruginosa*, *M. morganii*

Aumeran et al., Endoscopy 2010

Reprocessing failures resulting in patient notification

Place, year	Instrument involved	Persons exposed (n)
Sacramento, CA, 2002	Endoscope	750
Toronto, ON, 2003	Endoscope	146
Seattle, WA, 2004	Endoscope	600
Sacramento, CA, 2004	Endoscope	1.331
San Francisco, CA, 2004	Endoscope	2.000
Long Island, NY, 2004	Endoscope	177
Charleston, NC, 2004	Endoscope	1.383
Pittsburgh, PA, 2005	Endoscope	200
Leesboruf, VA, 2005	Endoscope	144
San Diego, CA, 2006	Endoscope	300

Rutala und Weber, Infect Control Hosp Epidemiol 28 (2007)

Outbreak

- Review of data 01.2005 to 06.2012 (US)
 - Only 1 case published in a peer-reviewed journal
 - 21 media reports (US)
 - 6 governmental reports (US)
 - Duration: 10 days to 5 years
 - Patients: 1 to 9.000

Dirlam et al; AJIC 41 (2013)

05. Januar 2014



Largest outbreak of dangerous bacteria in U.S. tied to Park Ridge hospital

BY TINA SFONDELES Staff Reporter January 5, 2014 5:10PM

“A large number of patients have been identified, a large number of transmissions — total of 44 — and 39 of those were found in the Chicago area. It’s the largest outbreak that we’ve seen in the U.S. of this bacteria ever,” said Alex Kallen, an infectious diseases doctor who served as the supervisor of the CDC investigation.

Notes from the Field

New Delhi Metallo- β -Lactamase-Producing
Escherichia coli Associated with Endoscopic
Retrograde Cholangiopancreatography —
Illinois, 2013

to the outbreak strain by PFGE. Retrospective review and direct observation of endoscope reprocessing did not identify lapses in protocol. Previous studies have shown an association between ERCP endoscopes and transmission of multidrug-resistant bacteria; the design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection (2,3).

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Requirements

- Medical Device Directive (1994)
- Regulations governing the Installation, Operation and Use of Medical Devices (1998)
- Requirements on Hygiene during reprocessing Medical Devices (Robert Koch-Institute) (2001, 2006, 2012)
- EN ISO 15883-4: washer-disinfectors (2008)
- Guideline for the Validation of automatic cleaning and disinfecting Processes to reprocess flexible Endoscopes (done by five Societies) (2011)
- Agreement to control Quality for Coloscopy (Compulsory Health Insurance Doctors) (2002)

Regulations governing the Installation, Operation and Use of Medical Devices

Verordnung über das Errichten,
Betreiben und Anwenden von Medizinprodukten
(Medizinprodukte-Betreiberverordnung – MPBetreibV)*

vom 29. Juni **1998** (BGBl I S. 1762), in der Fassung der Bekanntmachung
vom 29. August 2002 (BGBl I S. 3396);
zuletzt geändert am **25. Juli 2014** (BGBl. I S. 1227)

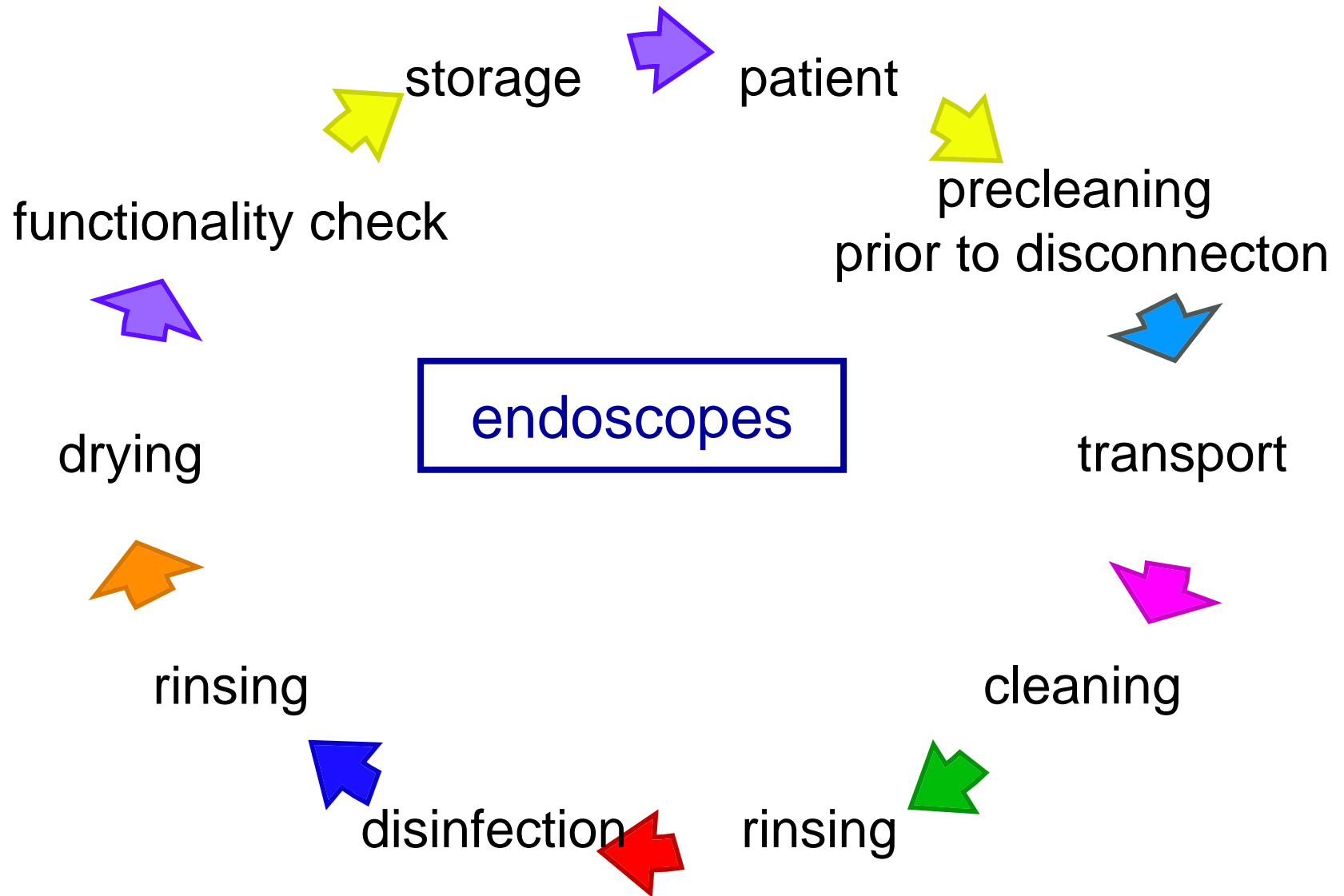
§ 4 Maintenance (MPBetreibV)

- (2) ... reprocessing ... of medical devices
... by **validated methods**...

Requirements

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Reprocessing



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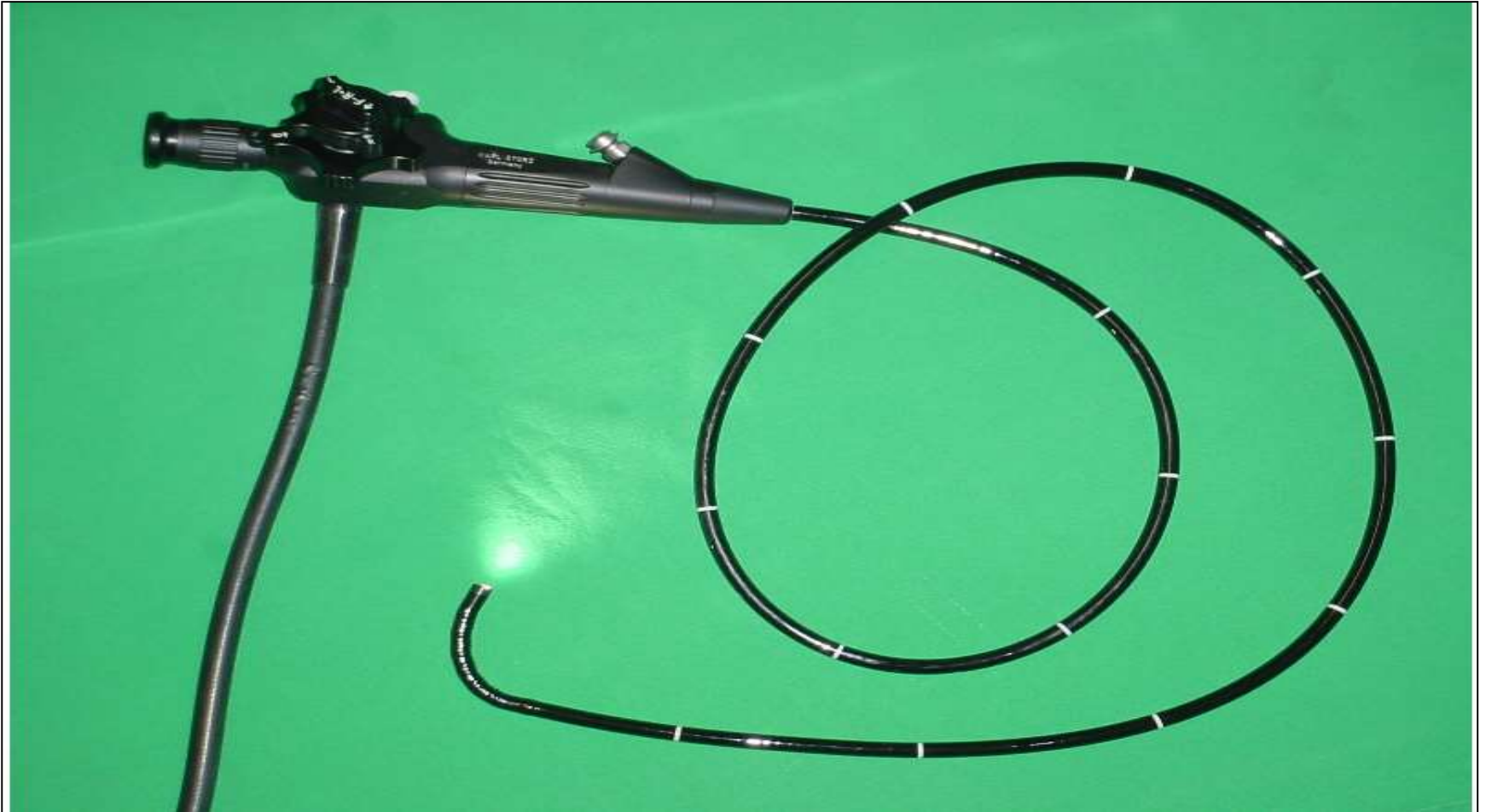
Requirement Endoscope-channels

	Robert Koch- Institut	Validation Guideline of Societies	Coloscopes
E. coli, Enterobacteriaceae Enterococci	0 / 20 mL		0 / ???
P. aeruginosa, Pseudomonas ssp., Non-fermentative bacilli	0 / 20 mL		0 / ???
S. aureus and other NI	0 / 20 mL		0 / ???
Viridans Streptococci (e.g. bronchoscopes, ERCP)	0 / 20 mL		0 / ???
CFU/channel	≤ 20 / 20 mL		≤ 10 / 1 mL (200 / 20 mL)

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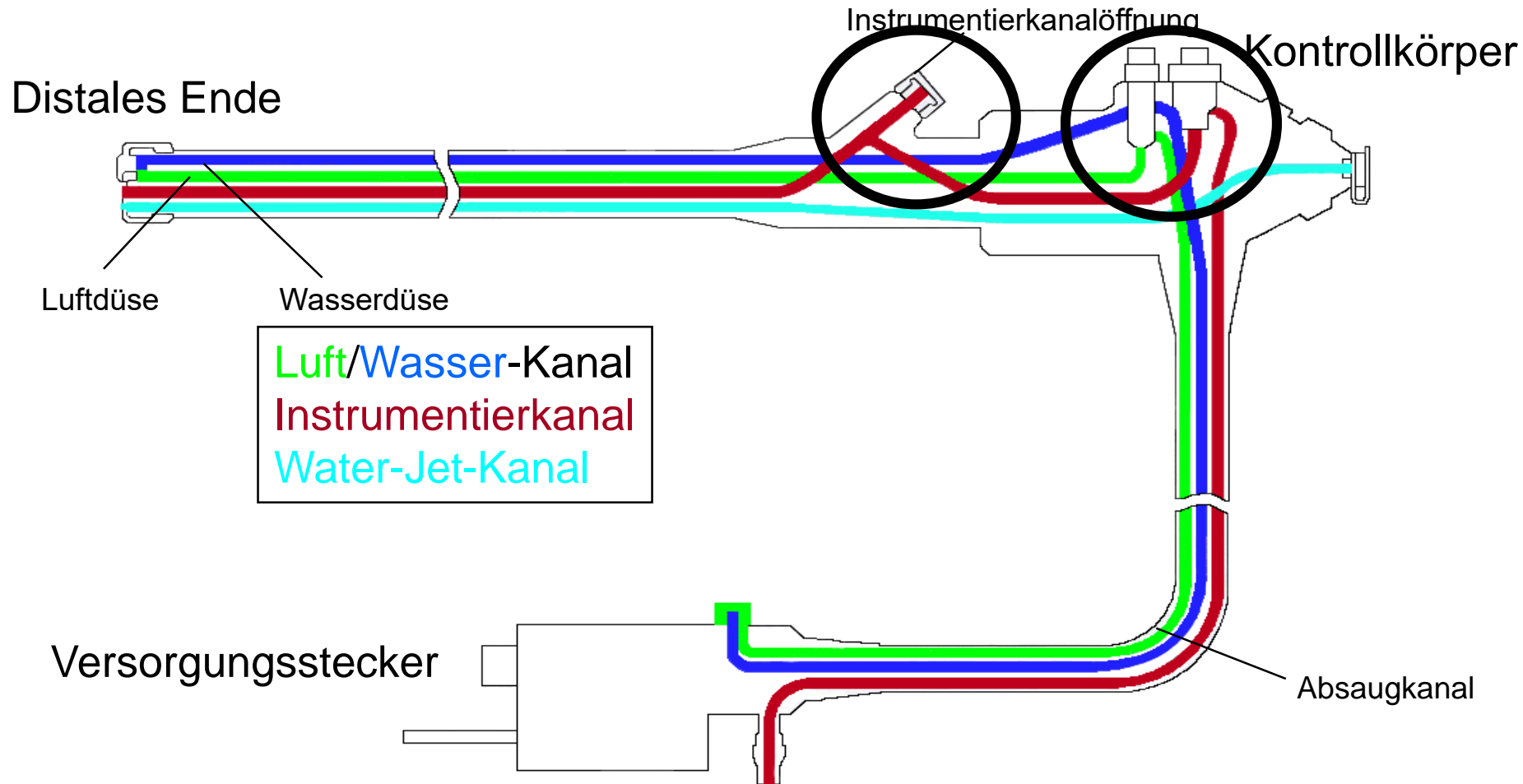
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Flexible endoscope










Reprocessing

Channel system of an endoscope



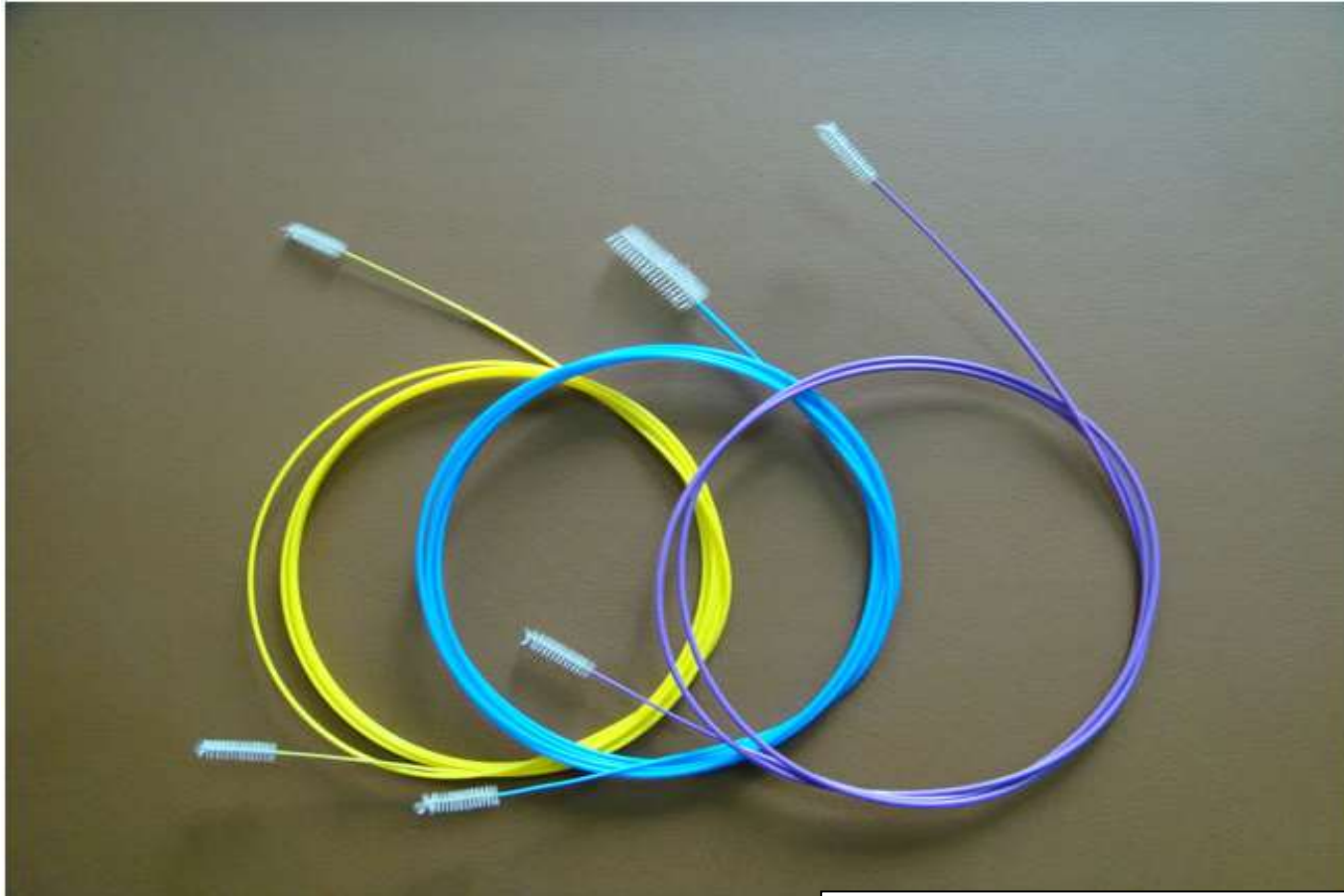
Diameter of channels, not complete

	Air	\varnothing 0.7 mm
	Water	\varnothing 0.7 mm
	Biopsy	\varnothing 4.2 mm
	Suction	\varnothing 4.2 mm
	CO₂	\varnothing 0.7 mm
	Water jet	\varnothing 0.7 mm
	Surface	\varnothing 0.15 mm

Cleaning Matching brushes

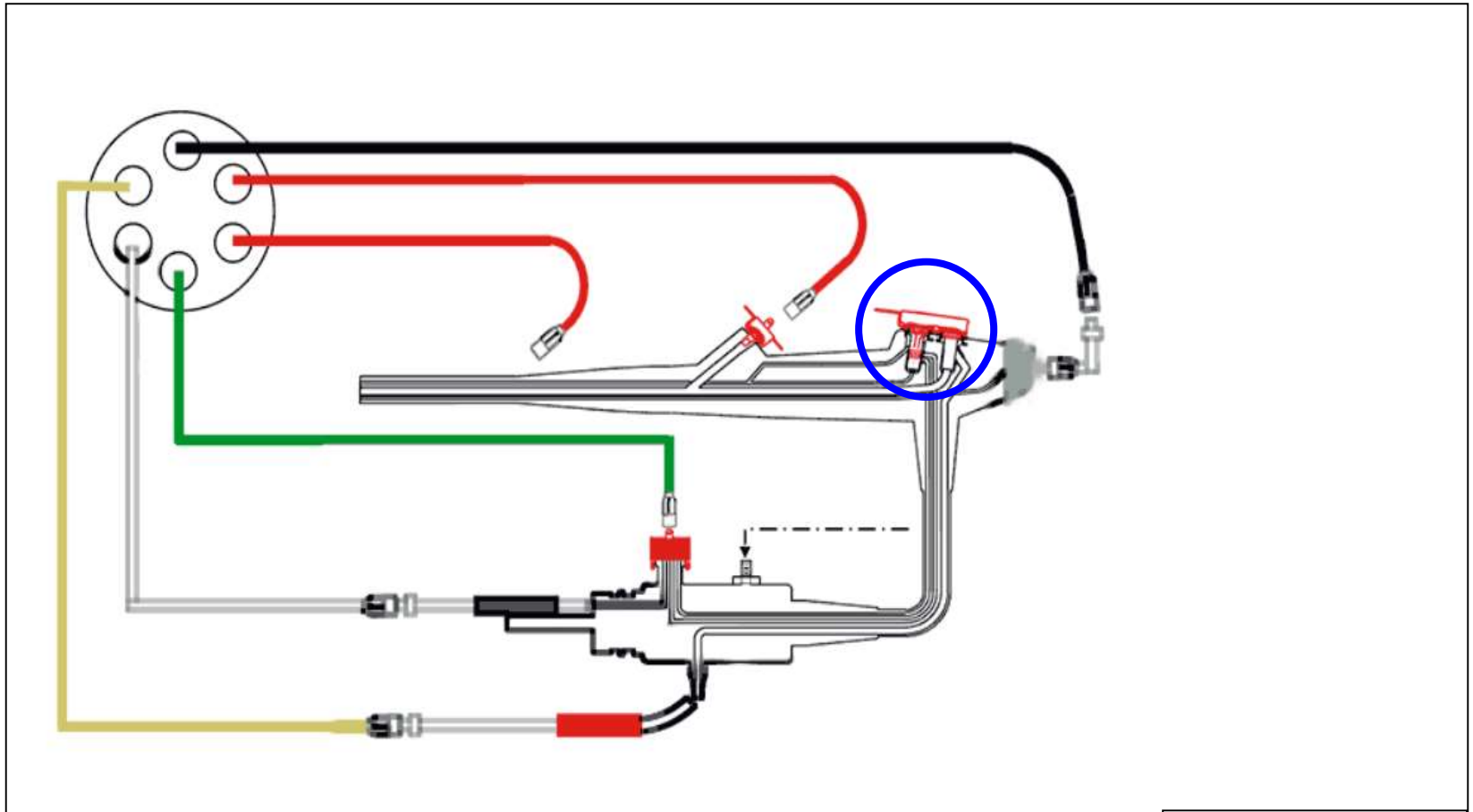


Cleaning Matching brushes



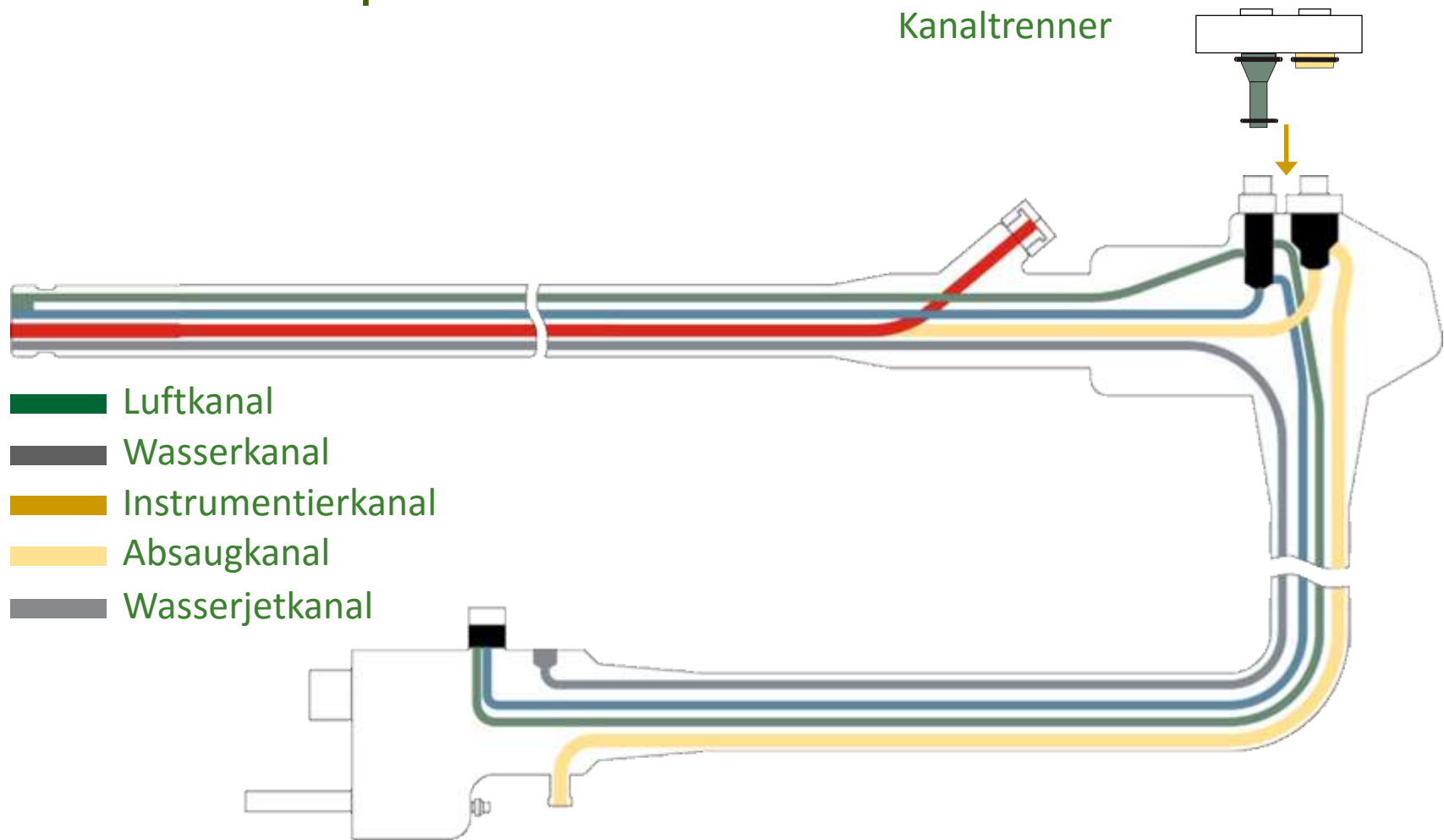
www.videoscopeparts.com

Reprocessing Channel separation



WWW.bht.de

Reprocessing Channel separation



Grafik: PENTAX Medical

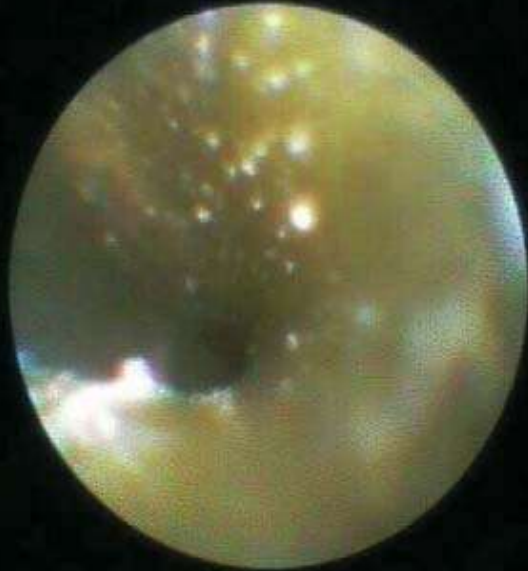
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Despite requirements

- A couple of published failures in reprocessing

Process validated?



Rests of tissue

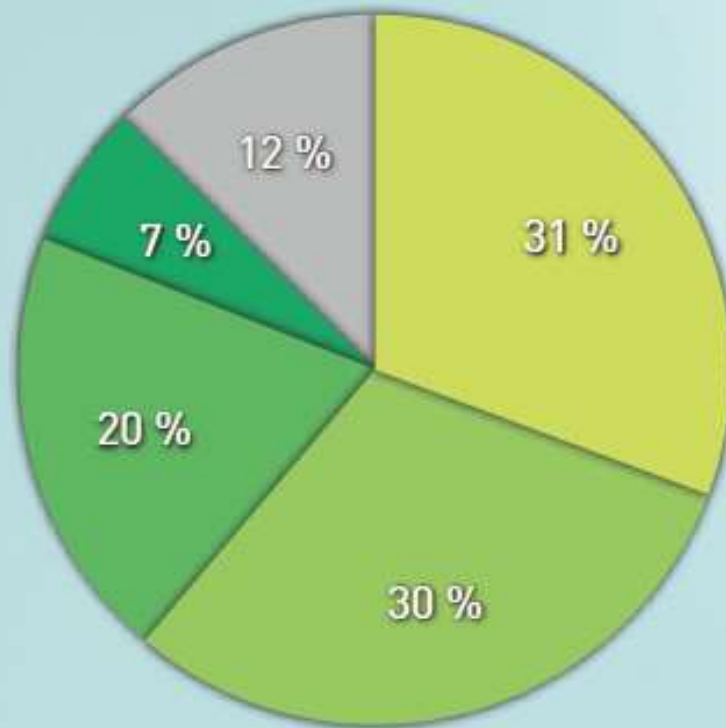


Rests of blood

Silent risks and hidden dangers in endoscopy: what to do?
Hermann et al., Acta Endosc (2008)

Prozess validated?

2010: 100 of 389 endoscopes rejected [11,25%]



- Gastroscopie
- Koloskope
- Bronchoskope
- ERCP-Geräte
- Keine Angabe

beanstandet:
100 Geräte = 11,25%

Quelle: eigene Ergebnisse; Auswertung durch Dr. Gabriele Porsch



Process validated??

- *K. pneumoniae*; Berlin I OXA-48
 - Duodenoscope: „imperfect“ disinfection?
 - 2 infections
 - 5 colonisations

- *K. pneumoniae*; Berlin II OXA-48
 - Bronchoscope: washer-disinfector/cleaning?
 - 2 infections
 - 3 colonisations

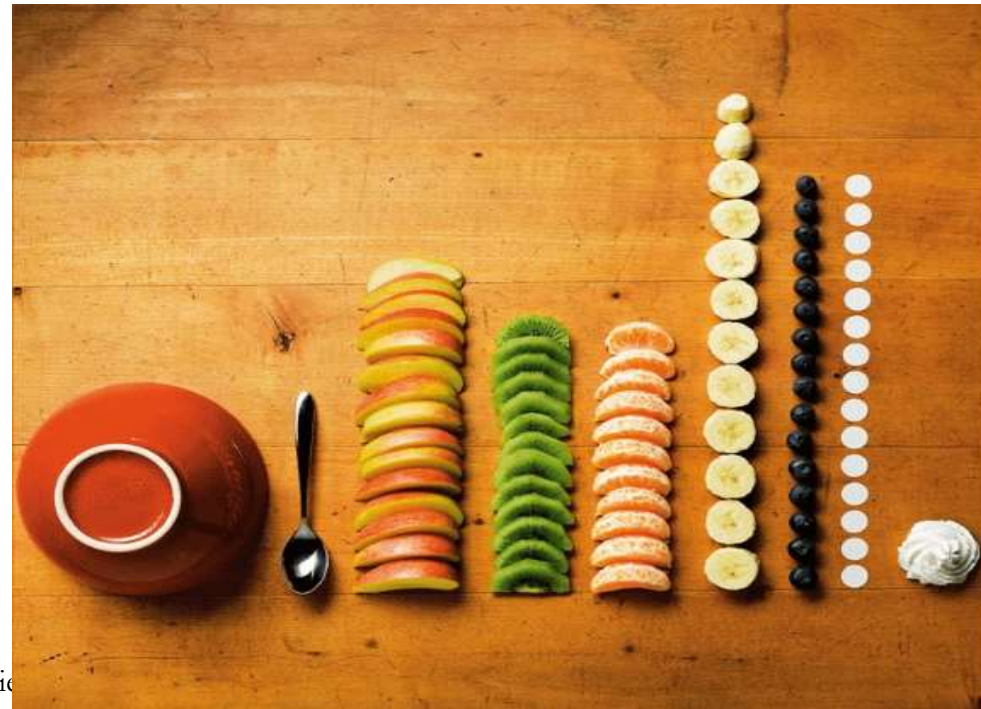
Gastmeier and Vonberg; Infection (2014); Geffers et. al 2014 (poster)

Prozess validated?



Thanks to Jakob Fisch

- Validated process implies
 - Always to be sure of your outcome



Bugs are always on the go!!!



Central Service (ZentralSterilisation) 18; 113-117 (2010)

- *Will be part of "Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes", which is being currently drafted*

- *German Society of Hospital Hygiene (DGKH)*
- *German Society of Endoscopy Assistant Personnel (DEGEA)*
- *German Society of Sterile Supply (DGSV)*
- *German Society for Digestive and Metabolic Diseases (DGVS)*
- *Working Group Instrument Preparation (AKI)*
- *Working Group of Washer-Disinfector Manufacturers (AK RDG)*
- *Endoscope manufacturers*

Sampling plan for routine: frequency

2.1 Frequency

- Each endoscope should be subjected to hygienic and microbiological inspection at least once per year.
- During routine inspection of endoscopes at least one endoscope from each endoscope family used in the unit must be inspected. If different methods of reprocessing (automatic and/or manual) are used in the unit, it must be ensured that both reprocessing methods are included.
- Depending on the frequency of use, quality of reprocessing and on the endoscope family the intervals for routine inspections shall be defined during **risk analysis**.

Sampling plan for routine: frequency

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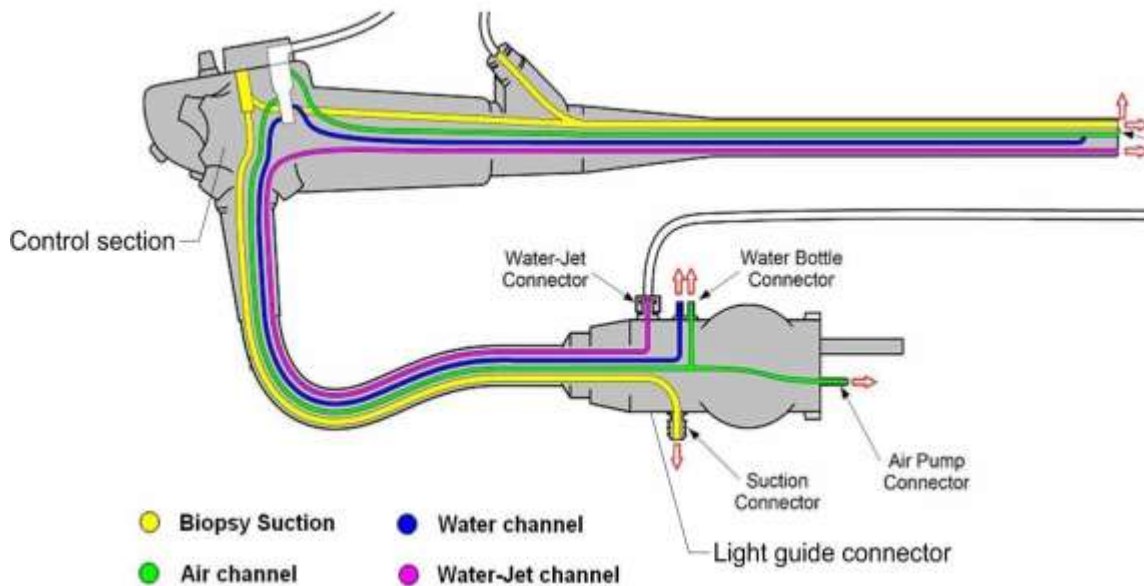
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Sampling plan for routine: sample types

- Liquid samples
 - Rinse samples
 - from each channel that can be purged
 - *Note: If the "sponge method" or a similar method is used additionally, it must be ensured that the sponge (sterilised!) or a similar object cannot be left behind in the channel*



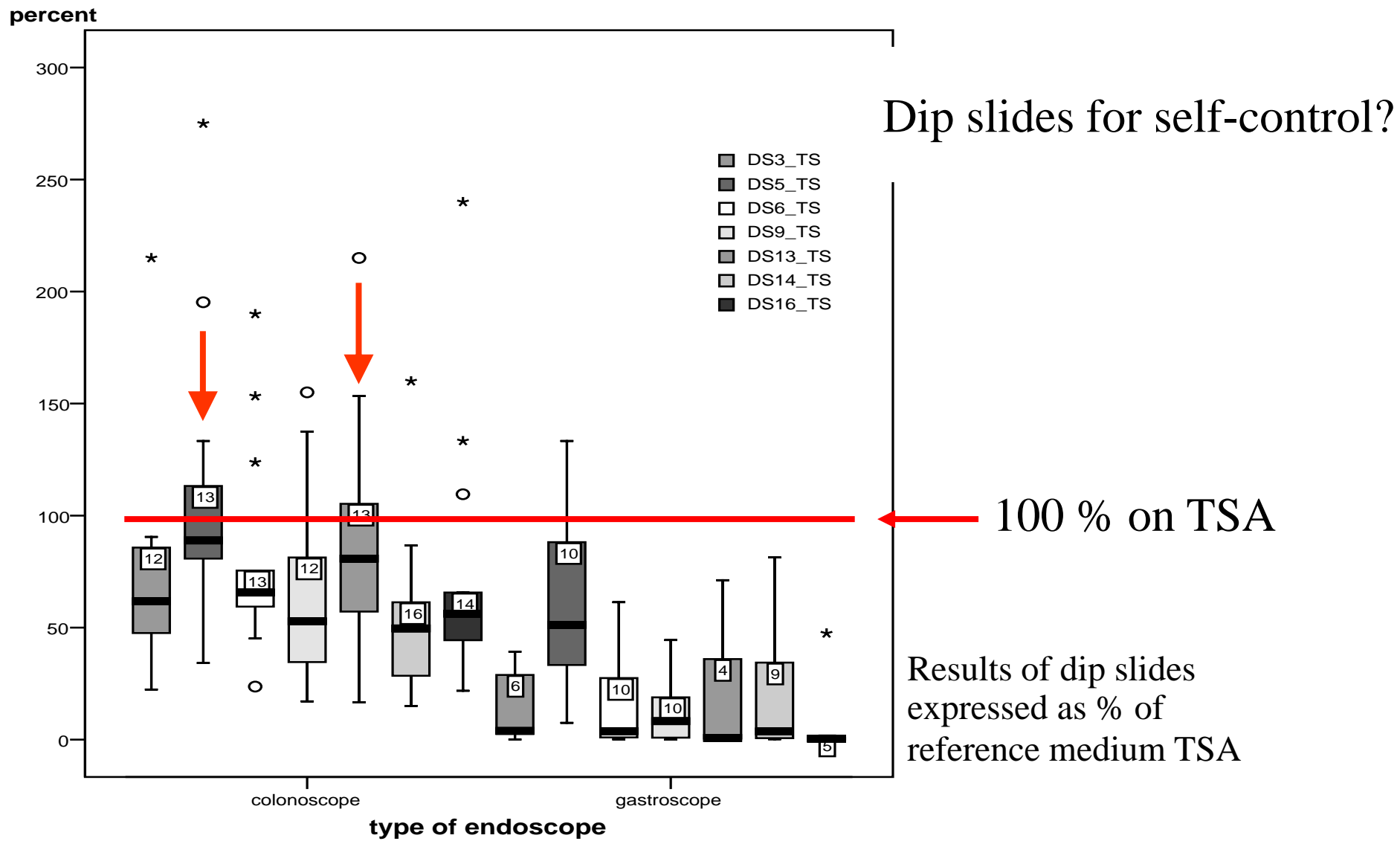
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 - Water samples
 - from the water bottle

Sampling plan for routine: test methods

- *Note: The pour plate method is not recommended because it impedes growth of aerobic bacteria such as e.g. Pseudomonas aeruginosa*
- *Dip slides must be suitable to detect **1 cfu/ml***





Kircheis, Kampf, Gerstenberger, Martiny, HygMed (2007)

Ringversuch zur Prüfung der Reinigungsleistung von Reinigungs-Desinfektionsgeräten für thermolabile Endoskope mittels eines Schlauchmodells mit Proteinnachweis

Biering, Beilenhoff, Heintz; ZentrSteril 2013

Zu Anhang 8 RDG-E

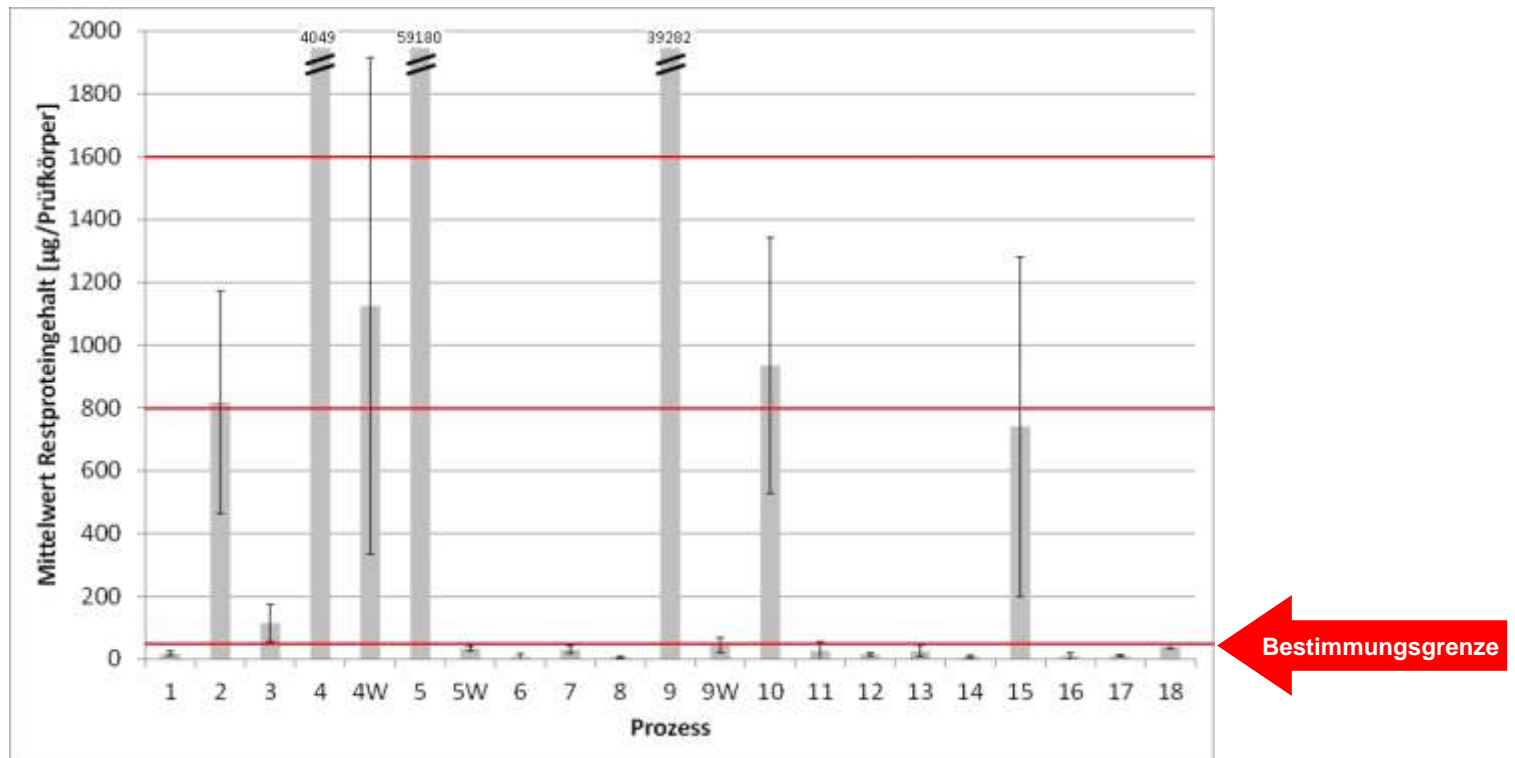


Abb. 1: Mittlere Restproteinmenge pro Verfahren in µg Protein/Prüfkörper und die Standardabweichung der pro Verfahren eingesetzten Prüfkörper (n= 6)