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Medical devices as reservoirs of healthcare associated infection and prevention strategies

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Transmission of healthcare associated infections

- Hands

- Contaminated medical devices

- Contaminated items, which are close to the patient (nursing utensils, blood pressure cuff, stethoscope, mobile phones, keyboards, doorhandles, sanitary equipment)

- Beds, furniture, floors

- Pharmaceuticals, food

- Air

Transmission of healthcare associated infections

- Contaminated medical devices
  - **Surgical devices**
    - **inadequate processing**
    - **contamination following sterilization (handling, open presentation in the OR)**
  - **Endoscopic devices**
    - **inadequate processing**
  - **Items touching mucuous membranes**
    - **inadequate processing**

The role of cleaning for processing of invasive devices

- Effective and reliable sterilization/disinfection requires a high level of cleanliness
- Cleanliness is difficult to define and to assess
- Visual inspection is not always reliable and sometimes impossible (hollow devices)
- Validation of cleaning processes is often confined to (SDS-soluble) residual proteins
- threshold values (X µg SDS-soluble protein per device) are disputable

Requirements for medical device processing: evidence-based or following best practice?

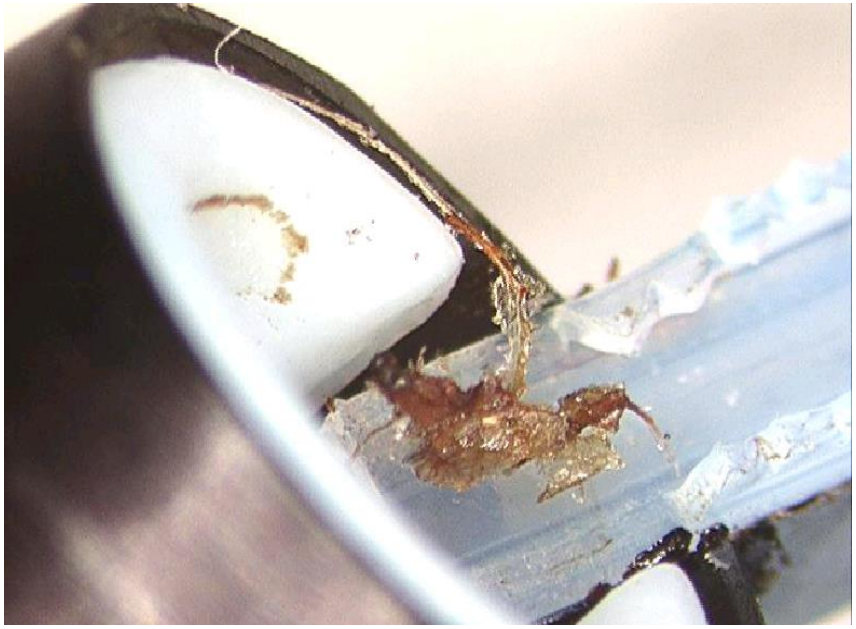
According to legal practice in Germany, processing of medical devices is a sector which can be “fully controlled”.

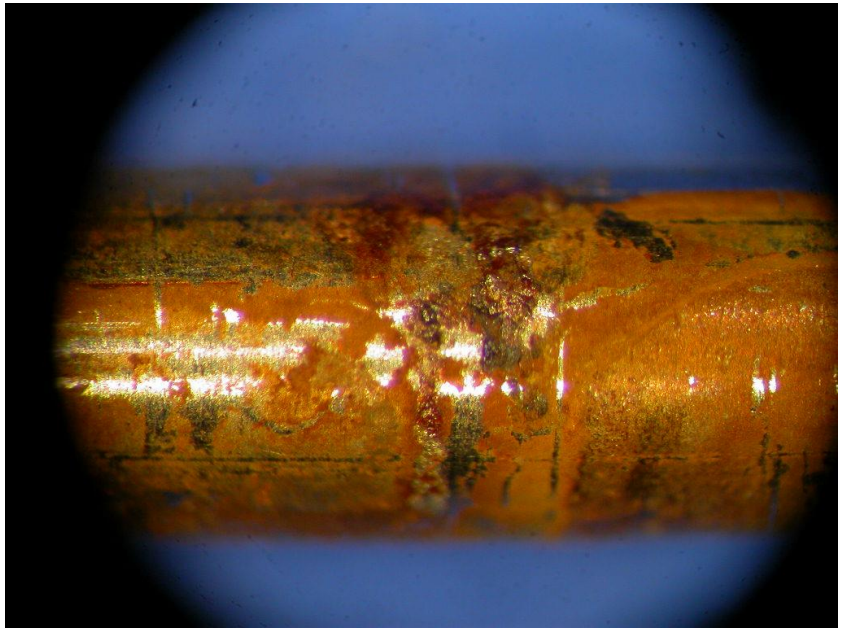
Healthcare institutions are therefore bound to apply procedures, which represent the state of the art, irrespective whether these are based on hard epidemiological data or not.

Medical devices as reservoirs of healthcare associated infection

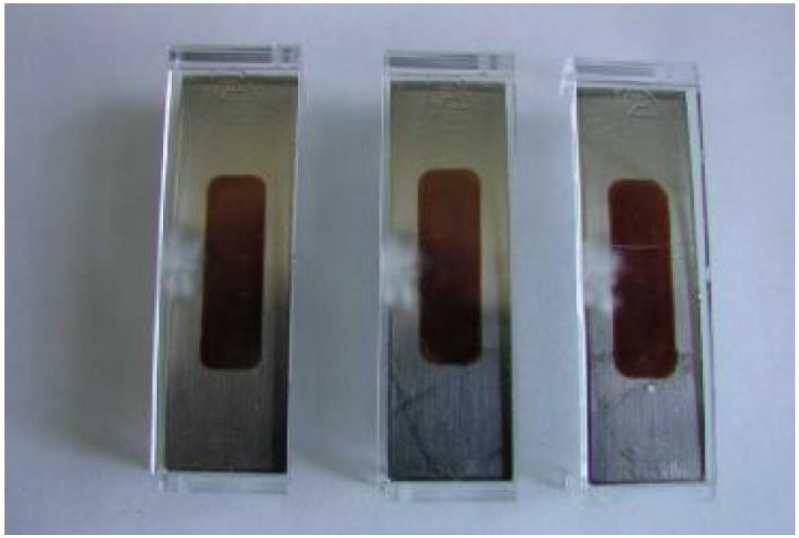
- Surgical instruments
- Flexible endoscopes
- Ultrasonic transducers

Testing the cleaning effect: visual inspection





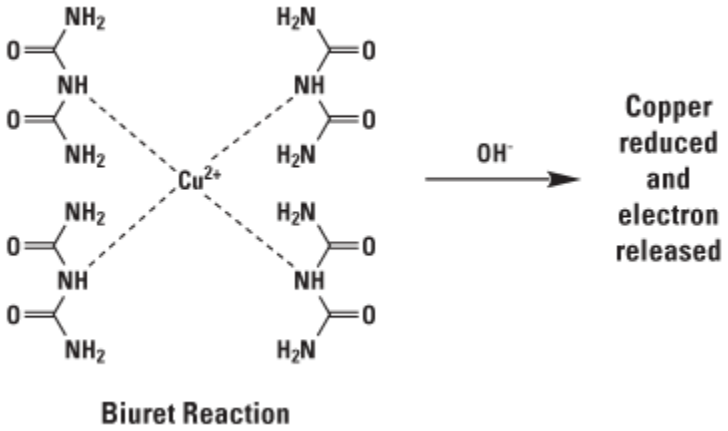
Testing the cleaning effect: carriers with test soil



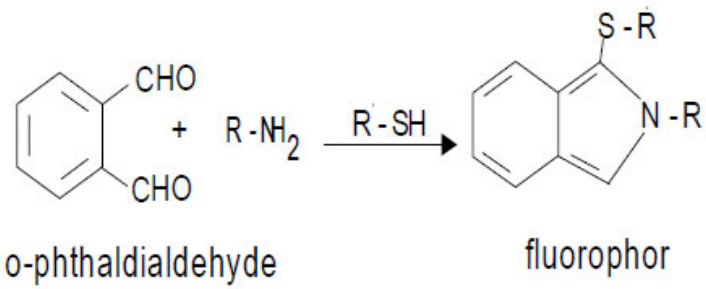
before treatment

after treatment in a WD: alkaline cleaner

Testing the cleaning effect: Biuret/BCA and OPA-test



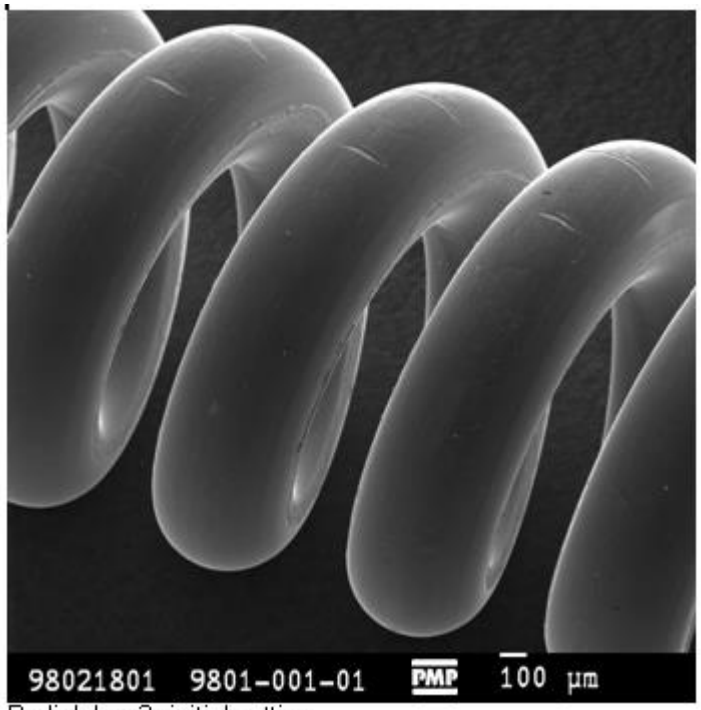
Biuret Reaction



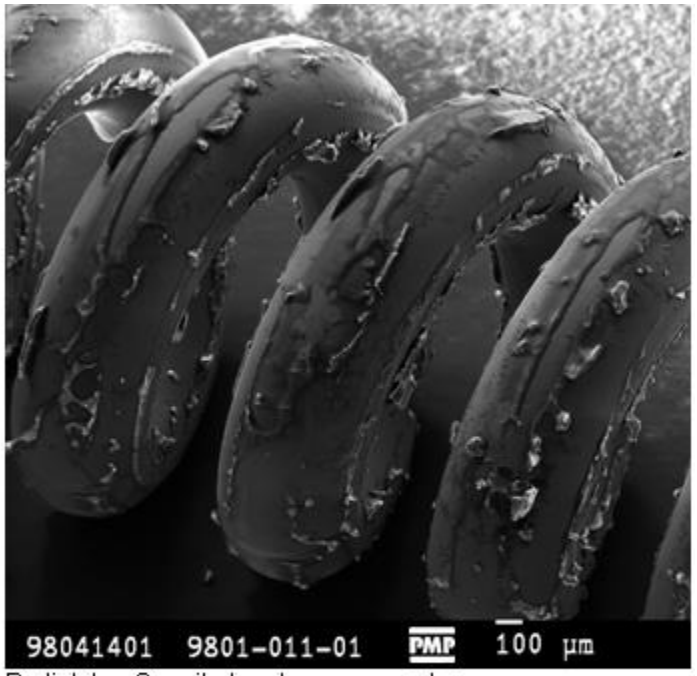
o-phthaldialdehyde fluorophor

Figure 1. Reaction of OPA and primary amino groups. *o-Phthaldialdehyde, in the presence of reduced sulfhydryl groups, reacts with the primary amino groups found in terminal amino acids and the e-amino group of lysine to form fluorescent moieties.*

Testing the cleaning effect: electron scanning microscopy (1)

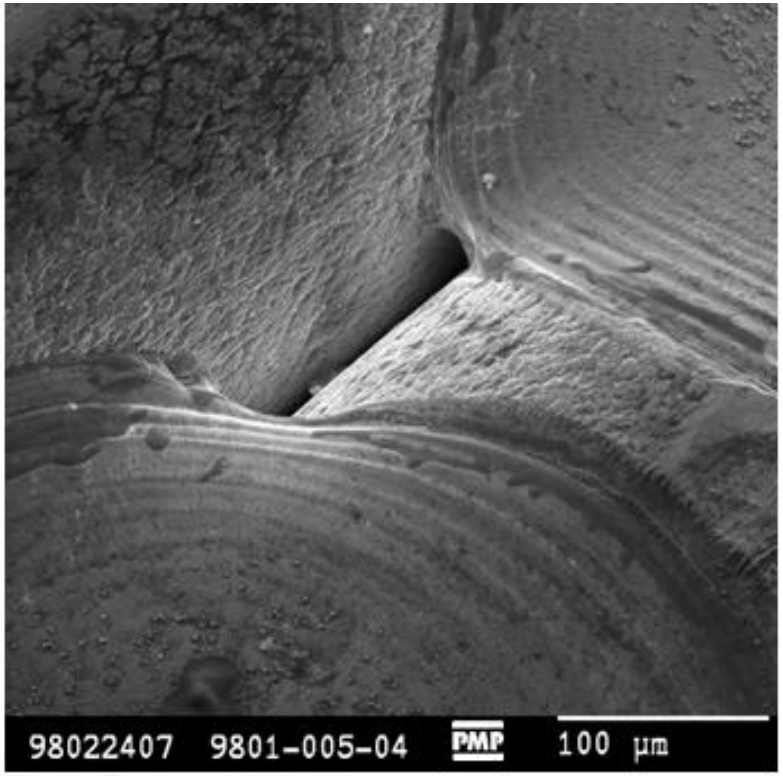


Radial Jaw 3, initial setting
Location: coil spring, 10 mm above the tip

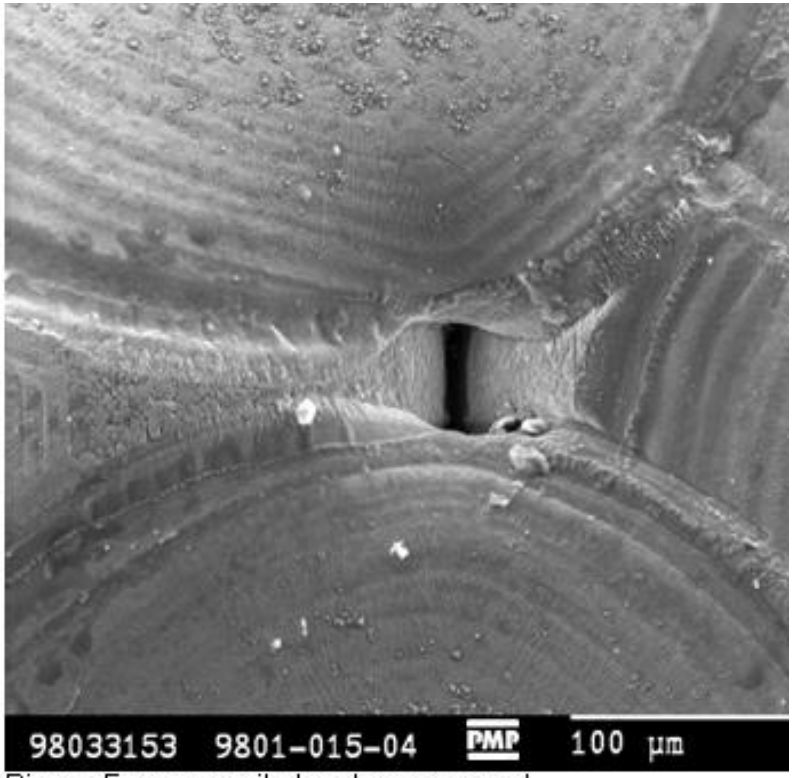


Radial Jaw 3, soiled and reprocessed
Location: coil spring, 10 mm above the tip
Coated with contamination

Testing the cleaning effect: electron scanning microscopy (2)



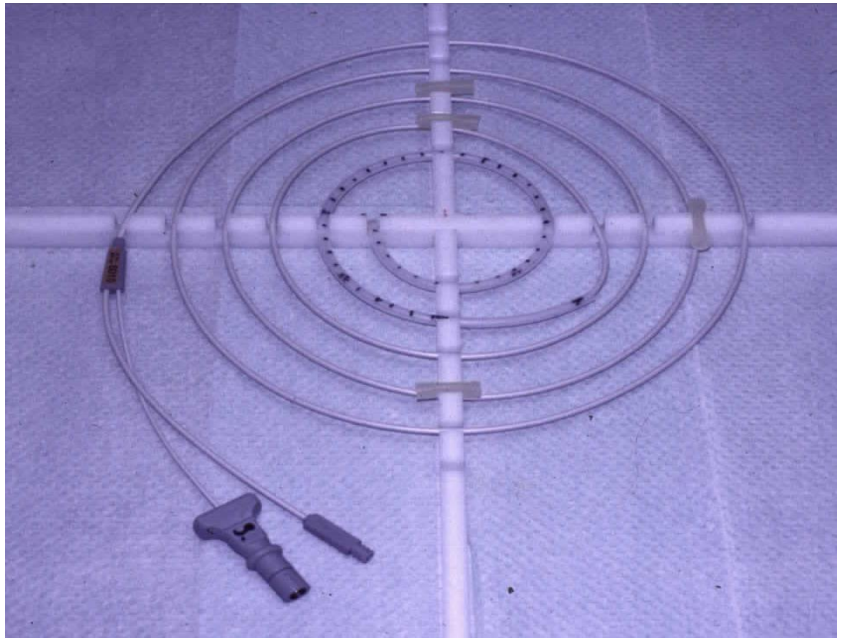
Biopsy Forceps, initial setting
Location: coil spring, welding area, 200 mm above the tip



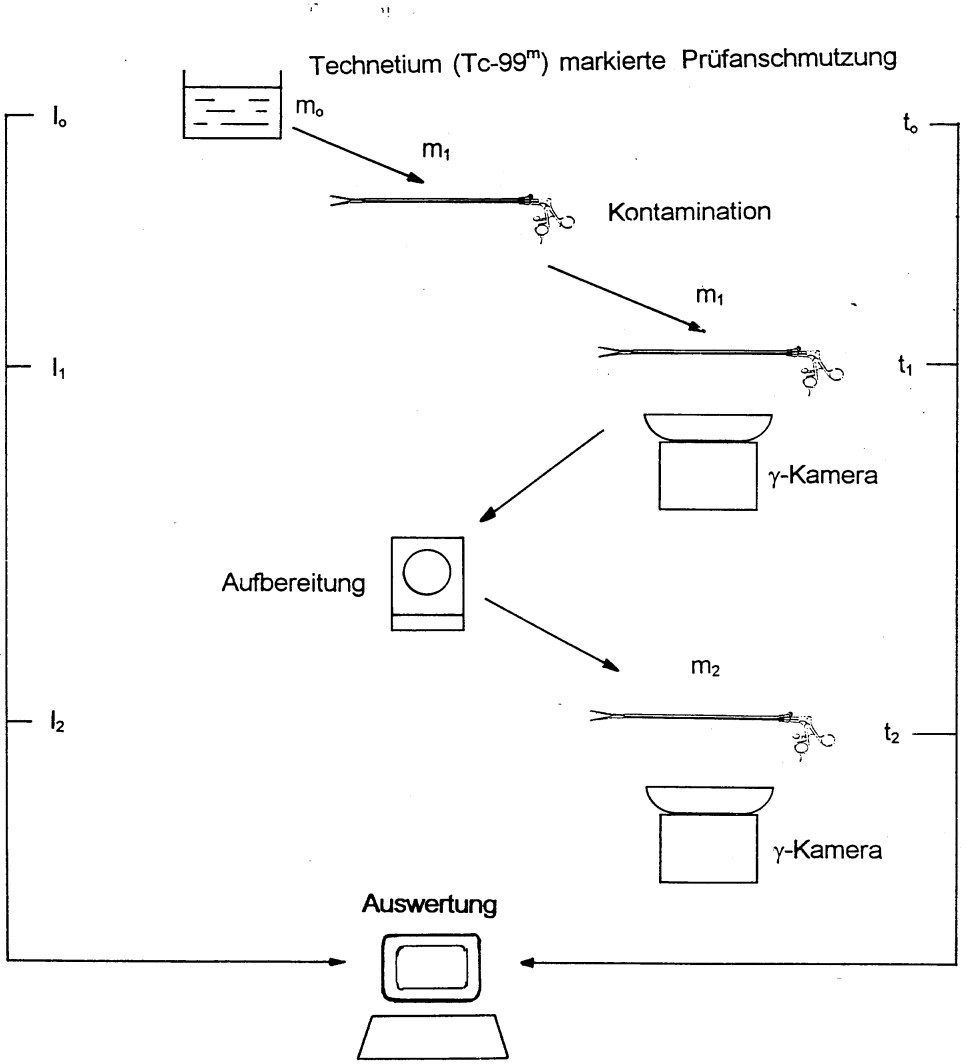
Biopsy Forceps, soiled and reprocessed
Location: coil spring, welding area, 200 mm above the tip

SEM_015.DOC

Testing the cleaning effect: radionuclide method (RNM)

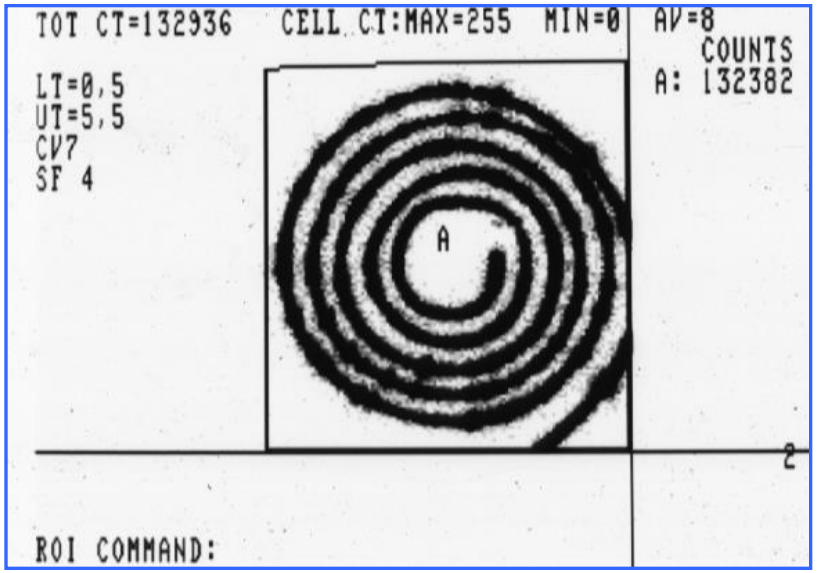


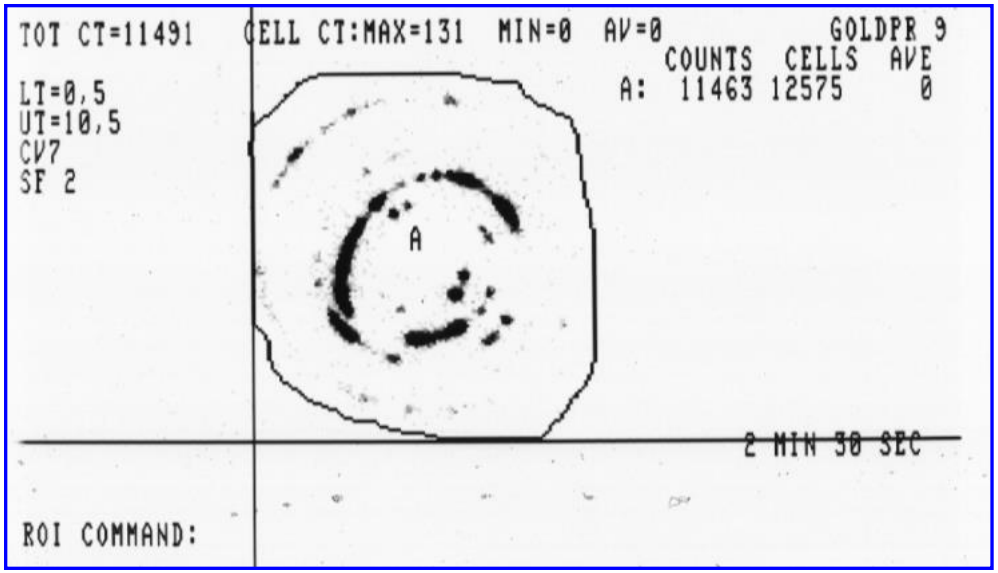
Radionuclide Method (RNM) (1)



- Radioactive labelling of human blood with Tc 99^m
- Contamination of the device
- Determination of radioactivity of the device (gamma-camera)
- Reprocessing of the device
- Determination of residual radioactivity
- Analysis: level and distribution of activity

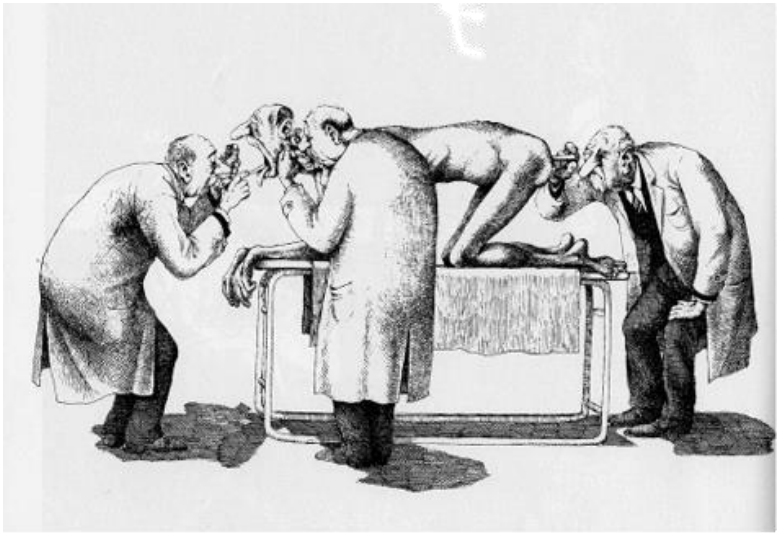
Radionuclide Method (RNM): results (1)





Radionuclide Method (RNM): results (2)

Endoscopy-associated infections: routes of transmission

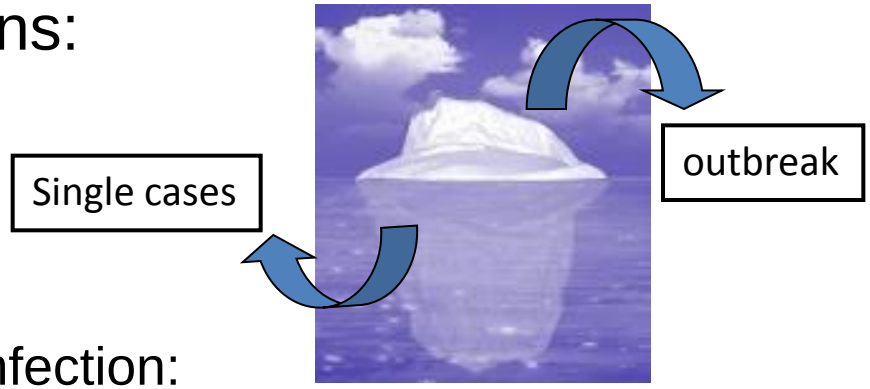


Endogenous infections (patient‘s flora):
injury during instrumentation and carry-over of resident flora

Exogenous infection:

cross infection (patient → patient):	device processing
environmental (water, washer disinfector):	device processing
cross infection (patient → staff):	device processing, factors not related to endoscopy

Endoscopy-associated infections: incidence



Estimated rate of endoscpy-associated infection:
1/1.8 million procedures

Kimmey MB et al. Gastrointest Endosc 1993; 39: 885-888

"However, the true rate of transmission during endoscopy may go unrecognized because of technically inadequate surveillance, no surveillance at all, low frequency, or the absence of clinical symptoms."

Kovaleva J et al. Endoscopy 2009; 41:913-916

:

Lessons from outbreaks associated with bronchoscopy

Leers	1980	*M. tuberculosis*	disinfection with PVP-iodine
Nelson	1983	*M. tuberculosis*	disinfection with PVP-iodone/70% ethanol
Pappas	1983	*M. chelonei*	damaged suction channels
Wheeler	1989	*M. tuberculosis*	contaminated valve
Agerton	1997	*M. tuberculosis MDR*	ineffective disinfection
Blanc	1997	*P. aeruginosa*	contaminated washer disinfector
Michele	1997	*M. tuberculosis*	ineffective disinfection
Kramer	2001	*P. aeruginosa*	disinfection using 0.04 % glutaraldehyde
Sorin	2001	*P. aeruginosa*	connectors not suitable

Weber DJ, Rutala WA. Infect Control Hosp Epidemiol 2001; 22: 403-408

Rate of bacteremia following endoscopic procedures

sigmoidoscopy	0.5 %
colonoscopy	2.2 %
gastro-duodenoscopy	4.2 %
ERCP	11 %
esophagus dilatation	22.8 %

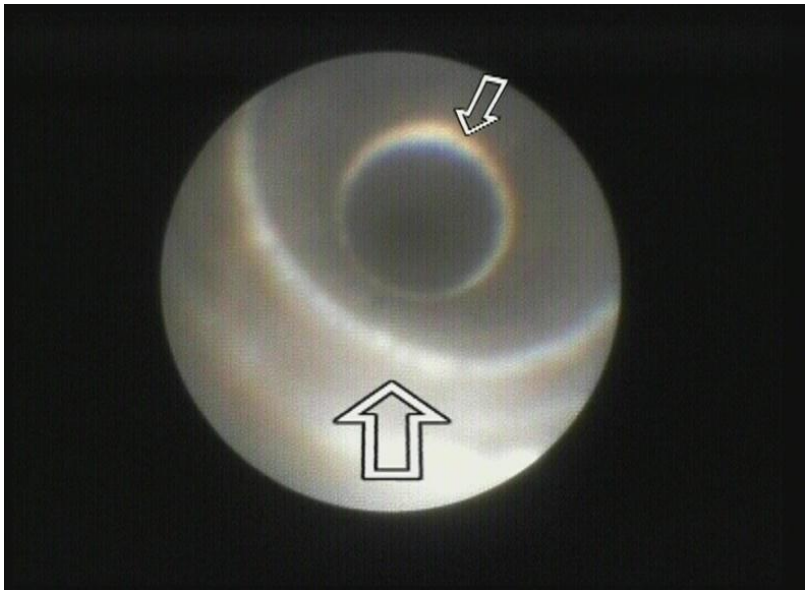
Nelson DB. J Lab Clin Med 2003; 141: 159-67

Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy

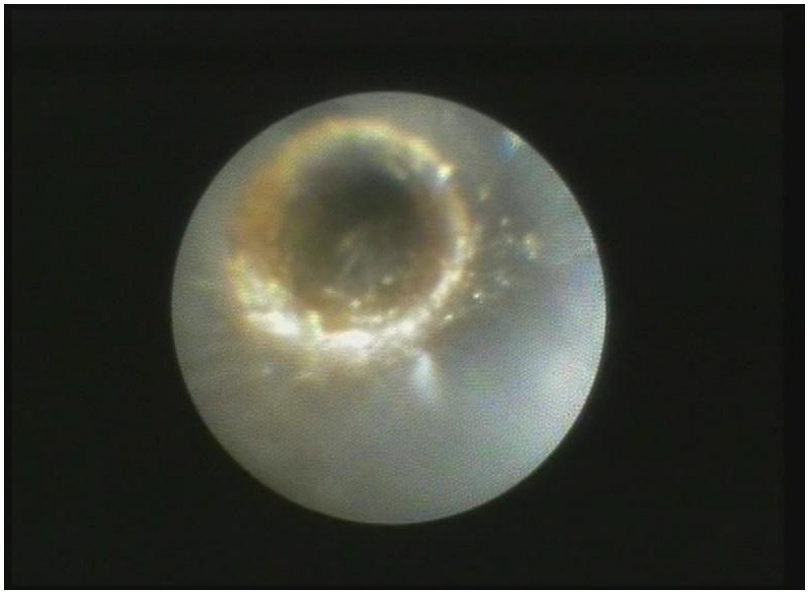
type of procedure	no. of publications	no. of contaminated patients	no. of infected patients
upper GI	19	168	56
sigmoidoscopy/ colonoscopy	5	14	6
ERCP	23	152	99
bronchoscopy	51	742	96

Kovaleva J et al. Clin Microbiol Rev 2013, 26: 231-254

Wear and tear:
alteration of the surface during clinical use



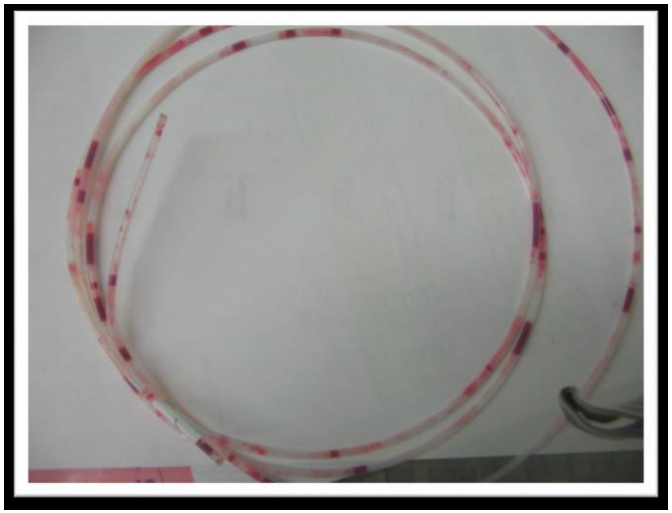
New gastroscope, unused:
smooth surface of the biopsy channel

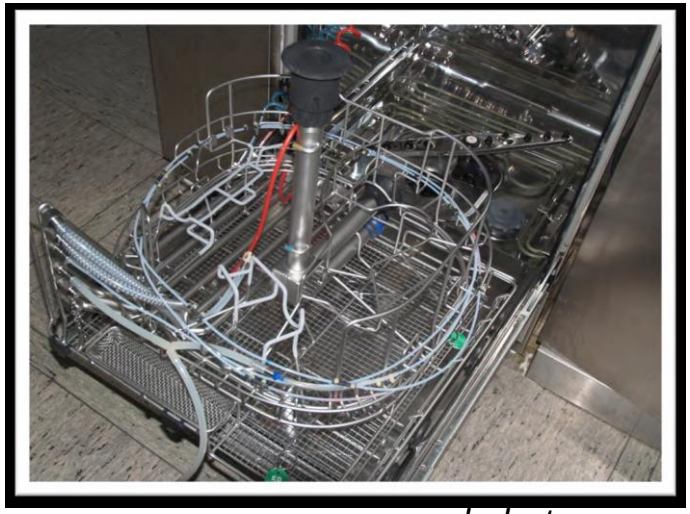


Used gastroscope: debris adhering
to brush marks

Prevention of endoscopy-associated infections: best practice

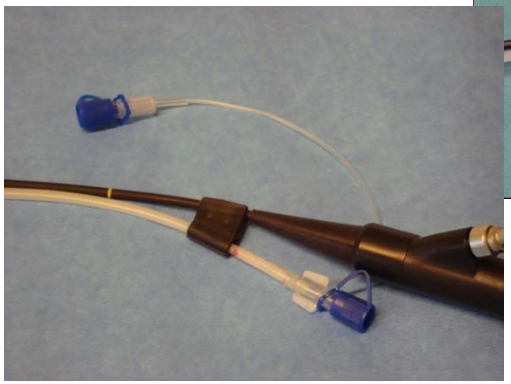
- Meticulous and careful manual pre-cleaning with lumen-fitting single use brushes (occupational safety!)
- Decontamination using a washer disinfector:
  - process validated according to EN ISO 15883, including single channel connection with control of the flow-rate
  - periodical evaluation of the cleaning and disinfection efficacy
  - routine monitoring of significant cycle parameters (temperature, concentration of the disinfectant, flow-rate, time)





www.hybeta.com

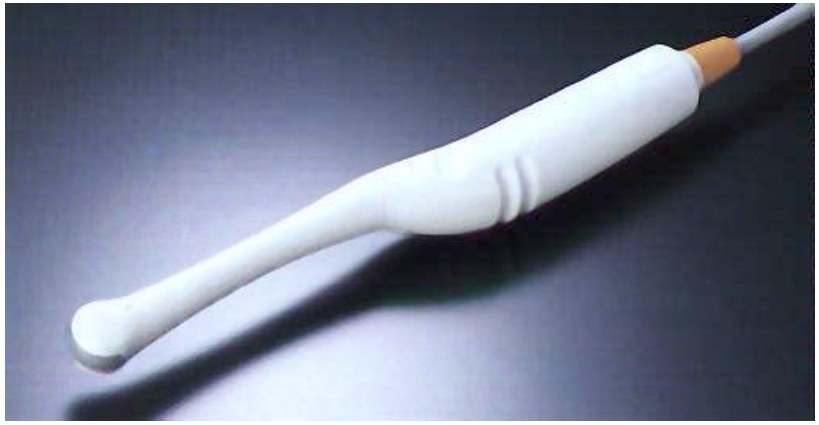
Next generation technology?



Detachable, single use channels

Heeg P, Herrmann IF. Ann N Y Acad Sci 2011;1232: 365-368

Processing of endocavity ultrasound transducers (probes) - an underestimated problem



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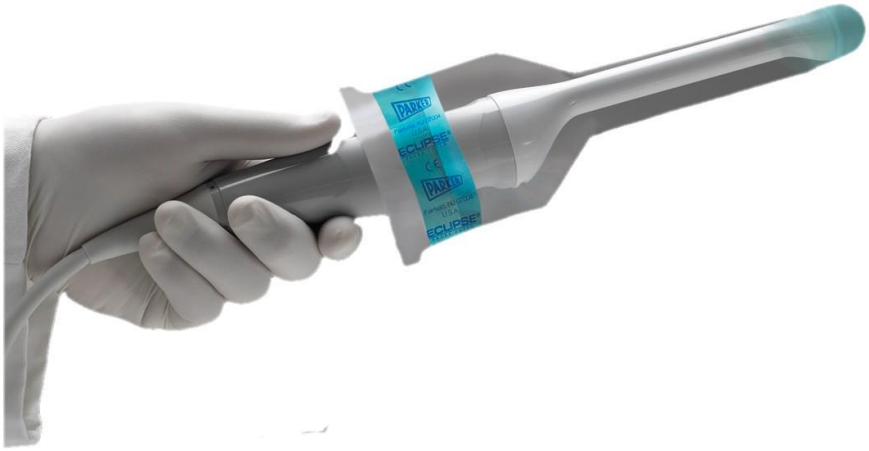


blog.pcimedical.com

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2010, VOL. 31, NO. 2

ORIGINAL ARTICLE

Evaluation of Ultraviolet C for Disinfection of Endocavitary Ultrasound Transducers Persistently Contaminated despite Probe Covers

Guillaume Kac, MD; Isabelle Podglajen, PhD; Ali Si-Mohamed, MD; Aurelia Rodi; Christine Grataloup, MD; Guy Meyer, MD

Bacterial contamination after removal of the cover from endovaginal/endorectal probes (n=440):

3.4% (CI 95%: 2.0 - 5.6)

Viral contamination (EBV, CMV, HPV) (n=336):

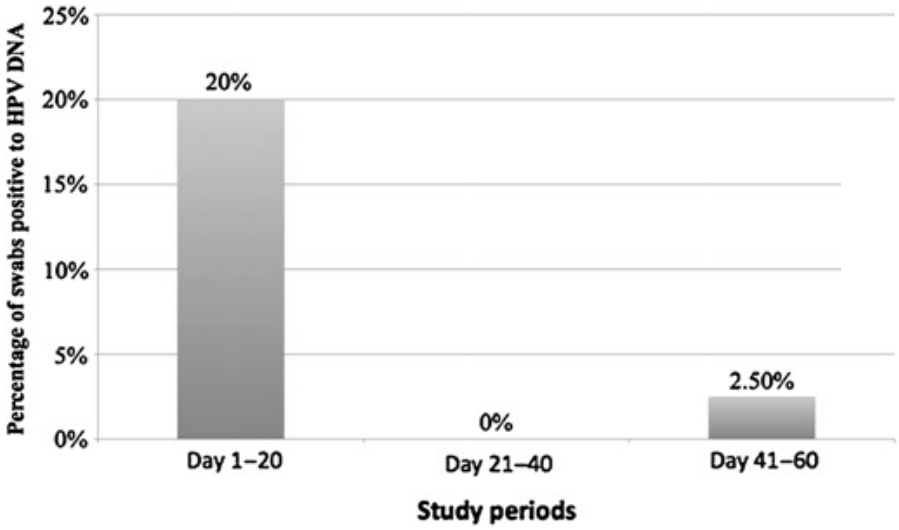
1.5% (CI 95%: 0.5 - 3.5)

EMJ Online First, published on July 3, 2012 as 10.1136/emermed-2012-201407

Original article

Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department

Shuk Ting Christine Ma,[1] A C Yeung,[2] Paul Kay Sheung Chan,[2] Colin A Graham[1]



- contamination rate 7.5%
- disinfection using a quat-based spray
- disinfection process not standardized

Detection of HPV-DNA (n=120)

Journal of Hospital Infection xxx (2012) 1–8

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Review

Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis

S. Leroy*

Epidemiology of Emerging Diseases Unit, Institut Pasteur, Paris, France

Bacterial contamination (nosocomial pathogens) of endovaginal probes following low level-disinfection (4 studies, n=596):

12.9% (CI 95%: 1.7 - 24.3)

Viral contamination (HPV, HSV, CMV) (2 studies, n=408):

covers: **19.4%** (CI 95%: 13.7 - 24.0)

probes: **1%** (0.0 - 10.0)

Journal of Hospital Infection xxx (2012) 1–8

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Review

Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis

S. Leroy*

Epidemiology of Emerging Diseases Unit, Institut Pasteur, Paris, France

Conclusions:

There appears to be a risk of transmitting bacterial or viral infections via endovaginal/rectal ultrasound transducers, and the present meta-analysis provides an estimate of this risk. Further research with sophisticated modelling is warranted to quantify the risk.

OPEN ACCESS Freely available online

PLOS ONE

High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?

Jean-sebastien Casalegno[1]*, Karine Le Bail Carval[2], Daniel Eibach[1,3], Marie-Laure Valdeyron[4], Gery Lamblin[2], Hervé Jacquemoud[5], Georges Mellier[2], Bruno Lina[1], Pascal Gaucherand[2], Patrice Mathevet[2], Yahia Mekki[1]*

PLoS ONE 2012; 7 (10): e48137

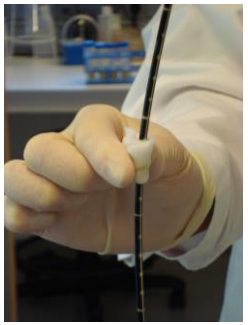
After low level-disinfection (n=217): 3% HR-HPV

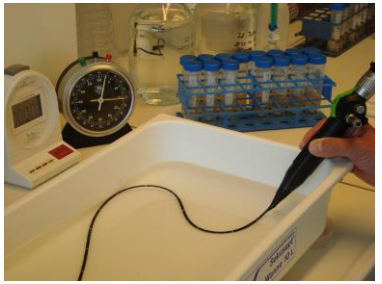
Before examination of the patient: 2.7% (1.9% HR-HPV)

Conclusion:
… We recommend the stringent use of high-level disinfectants, such as glutaraldehyde or hydrogen peroxide solutions.

Wipe or wash?

Comparison of different disinfection procedures for contaminated flexible esophagoscopes



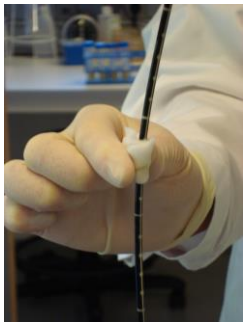


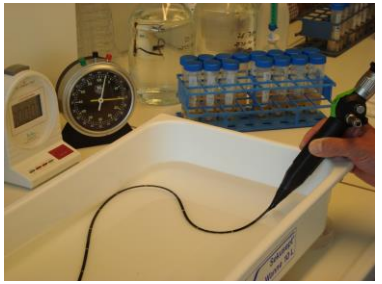
	wiping with sterile gauze pad, 30 sec	**immersion, 30 sec**
2-propanol, 70%	3.14 (1.99 - 5.13)	> 7.13 - > 7.52
cationic detergent	2.87 (1.62 - 3.63)	

Heeg P, Herrmann IF. OESO-Conference, Boston 2010

Wipe or wash?

Comparison of different disinfection procedures for contaminated flexible esophagoscopes





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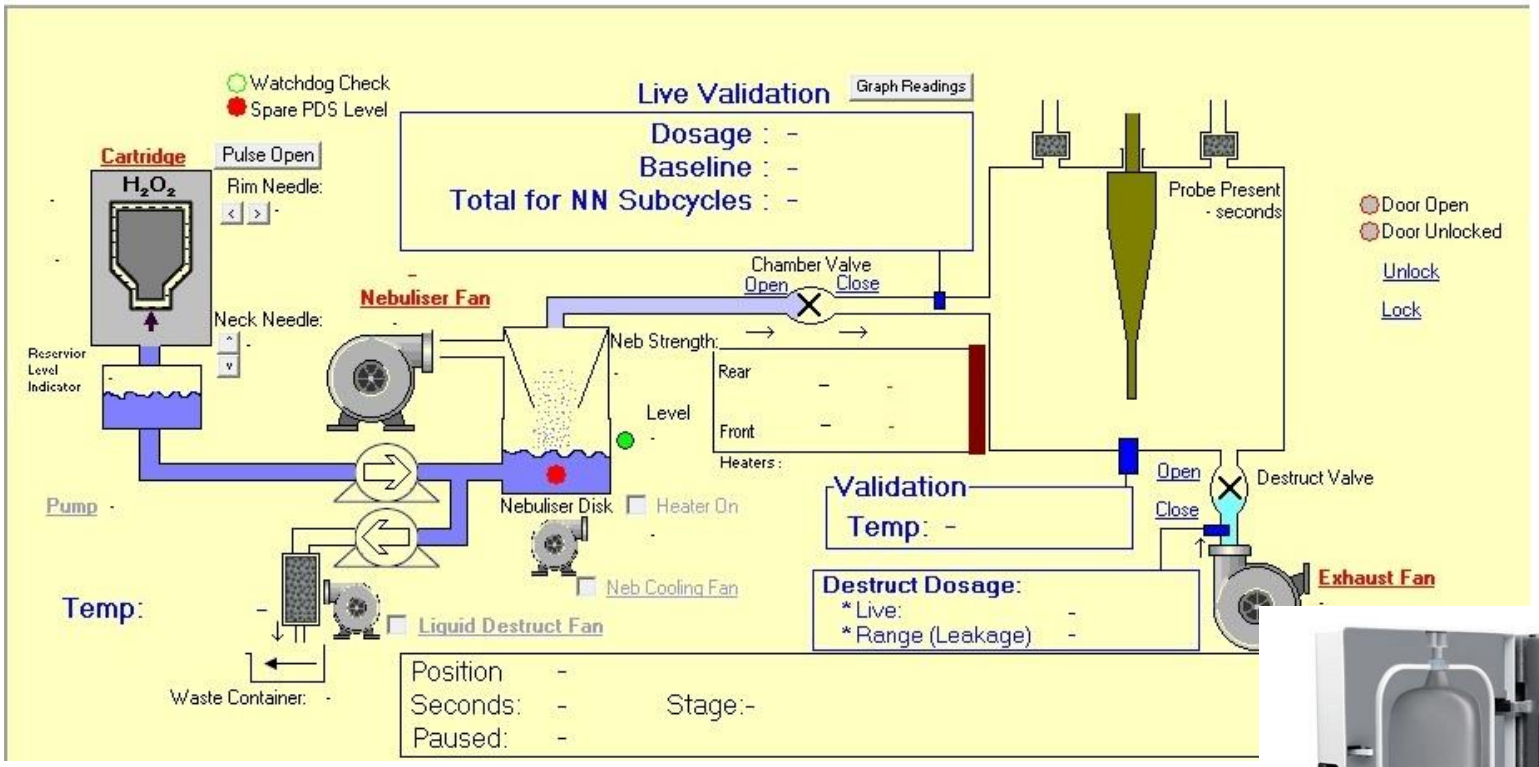
Study conditions!

Heeg P, Herrmann IF. OESO-Conference, Boston 2010

Disinfection chamber using hydrogen peroxide aerosol



nanosonics.com.au

Testing the Trophon EPR

Testing Center	Method	Organism	Result
AMS Laboratories AUS	AOAC 996.04	*C. sporogenes* *B. subtilis*	> 6 log > 7 log
AMS Biotech Germande FR SMP, Tuebingen, GER	AOAC 996.04 EN 14561	*G. stearotherm.* *S. aureus* *P. aeruginosa* *E. hirae* *M. terrae* *M. avium* *C. albicans* *A. niger*	> 6 log > 6 log > 6 log > 7 log > 7 log > 5 log > 5 log > 4.7 log
AMS Mikrolab, Bremen GER	AOAC 996.04 EN 14561	poliovirus	4.0 log
AMS	AOAC 996.04 EN 14561	poliovirus	> 4.3 log
AMS	AOAC 996.04 EN 14561	herpes virus Type I	> 4.3 log
Mikrolab	DVV-guideline	vaccinia virus strain Elstree adenovirus type 5 SV 40 strain 777	4.0 log

Prevention of medical device-associated infections: lessons to be learned

- ☆ education including practical training for the staff
- ☆ validated processing using washer disinfectors with particular attention to cleaning
- ☆ if WD are not available: manual processing strictly adhering to standard operation protocols
- ☆ safe storage and appropriate presentation of the devices on the site of use
- ☆ regular monitoring of processes and handling by the staff
- ☆ surveillance of device associated infections despite their supposed low incidence

Conclusion

Infections associated with the use of medical devices are:

possible,

rare,

for the most part preventable.