TOTAL SOLUTION FOR ENDOSCOPE REPROCESSING

A NEED FOR A COMPLETE PROCESS

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PATHOGEN TRANSMISSION RELATED TO ENDOSCOPE
**WHAT IS THE CONTAMINATION RISK?**

Rates of bacteremia and infectious complications associated with upper endoscopic procedures


<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mean Rate of Bacteremia</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGD + biopsy</td>
<td>4.1%</td>
</tr>
<tr>
<td>Esophageal dilatation</td>
<td>22.8%</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>4.4%</td>
</tr>
<tr>
<td>ERCP + sphincterotomy</td>
<td>6.4% (nonobstructed ducts)</td>
</tr>
<tr>
<td></td>
<td>18.0% (obstructed ducts)</td>
</tr>
</tbody>
</table>
# Endoscope Contamination

What can be found in an endoscope after use?

Michelle J. Alfa. *AJIC*, 27, 5, octobre 99, 392-401

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Hemoglobin (µg)</th>
<th>Proteins (µg)</th>
<th>Endotoxines (UE)</th>
<th>Carbohydrates (µg)</th>
<th>Bacteria log(nb.UF C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoscope</td>
<td>610</td>
<td>1290</td>
<td>1054</td>
<td>35</td>
<td>6.76</td>
</tr>
<tr>
<td>Duodenoscope</td>
<td>300</td>
<td>1680</td>
<td>499</td>
<td>151</td>
<td>6.84</td>
</tr>
<tr>
<td>Coloscope</td>
<td>1240</td>
<td>7110</td>
<td>174997</td>
<td>990</td>
<td>8.46</td>
</tr>
<tr>
<td>Mean</td>
<td>717</td>
<td>3360</td>
<td>58840</td>
<td>393</td>
<td>7.35</td>
</tr>
</tbody>
</table>
## Source of Contamination of Digestive Endoscopes

**Douglas B. Nelson, 2003**

<table>
<thead>
<tr>
<th>Source of Contamination</th>
<th>Percentage</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic endoscope reprocessor</td>
<td>39%</td>
<td>153</td>
</tr>
<tr>
<td>Inadequate disinfectant</td>
<td>29%</td>
<td>115</td>
</tr>
<tr>
<td>Improper drying (alcohol)</td>
<td>14.5%</td>
<td>57</td>
</tr>
<tr>
<td>Water bottle</td>
<td>4.3%</td>
<td>17</td>
</tr>
<tr>
<td>No treatment of the elevator channel</td>
<td>4.1%</td>
<td>16</td>
</tr>
<tr>
<td>Biopsy forceps</td>
<td>3.8%</td>
<td>15</td>
</tr>
<tr>
<td>No disinfection</td>
<td>1.5%</td>
<td>6</td>
</tr>
<tr>
<td>No treatment of the air/water channel</td>
<td>1.3%</td>
<td>5</td>
</tr>
<tr>
<td>Unknown</td>
<td>2%</td>
<td>8</td>
</tr>
</tbody>
</table>
## MICROORGANISMS

### SPACH 1993

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>GI endoscopy (n=163)</th>
<th>Bronchoscopy (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudomonas sp.</em></td>
<td>57 %</td>
<td>27,5 %</td>
</tr>
<tr>
<td><em>Salmonella sp.</em></td>
<td>23,3 %</td>
<td>-</td>
</tr>
<tr>
<td><em>Mycobacterium sp.</em></td>
<td>-</td>
<td>45 %</td>
</tr>
<tr>
<td><em>Staphylococcus sp.</em></td>
<td>5,5 %</td>
<td>-</td>
</tr>
<tr>
<td><em>Helicobacter pylori</em></td>
<td>2,5 %</td>
<td>-</td>
</tr>
<tr>
<td><em>Streptococcus sp.</em></td>
<td>2,5 %</td>
<td>-</td>
</tr>
<tr>
<td>Hépatitis B</td>
<td>1,8 %</td>
<td>-</td>
</tr>
<tr>
<td>Others</td>
<td>7,4 %</td>
<td>27,5 %</td>
</tr>
</tbody>
</table>
ENDOSCOPE REPROCESSING PROCEDURE

TRANSPORTATION → STORAGE → CLEANING-
DISINFECTION → PRE-TREATMENT → RINSING → DISINFECTION → RINSING → DRYING → TRANSPORTATION
WHAT ARE THE CRITICAL POINTS?

All parameters which may influence the quality of the process:
- Water quality,
- Chemicals used (detergent, disinfectant),
- Nurse training (Respect of currently accepted guidelines),
- Equipment quality (automatic or semi-automatic endoscope reprocessors).
- Endoscope and endoscope accessories (biopsy forceps, valves, water bottle,...)
- The drying and storage,
- ...

The goal is to control the critical parameters to prevent any drift.
WHAT AN ENDSOCPE IS?

PENTAX VSB 3440 enteroscope
PENTAX EG3630R echoendoscope
THE PRE-TREATMENT

Immediately after use (to limit proteins fixation), endoscopes have to be submitted to a pre-treatment including:

✓ wiping of endoscope external parts,
✓ aspiration of the biopsy/suction channel,
✓ forced insufflation of air and water channels,
✓ Leak testing.

Endoscopes shall be then submitted to a complete cleaning stage (manual reprocessing) or to an immersion in a detergent solution for channels irrigation and brushing (automatic reprocessing).

The objective of this pre-treatment is to facilitate the following stages by:

→ reducing bacterial contamination,
→ removing organic and inorganic soils (interfering substances),
→ limiting drying and fixation of the soil to avoid infectivity stabilization.
HOW TO REPROCESS AN ENDOSCOPE?

MANUAL REPROCESSING

- Non reproducible procedure (no respect of guidelines)
- Time and personnel consuming (1 person for up to 40-50 minutes)
- Required trained nurses (endoscope channels irrigation)
- Chemical exposure of personnel
- Incomplete traceability

SEMI-AUTOMATIC REPROCESSING
WHAT TO LOOK FOR IN AN ISO-15883 COMPLIANT DETERGENT

According to ISO 15883-4:2008 clause 6.11 the cleaning efficacy of the washing stage of an AER shall be tested first (type testing) using the biofilm test pieces as specified in ISO/TS 15883-5:2005, Annex F incorporated into a surrogate device.

For operational qualification cleaning tests shall be performed with one, or more, of the appropriate test soils by the method given in ISO/TS 15883-5:2005 (user choice, local regulation).

In addition, test loads composed of sufficient representative types (make, model) of device(s) that the WD is intended to process shall be used for type tests and operational testing.
OVERVIEW ON DISINFECTANTS

- **Glutaraldehyde based solutions**: widespread use in health-care facilities, excellent biocidal properties; active in the presence of organic matter (20% bovine serum), noncorrosive but toxic, unstable and are strong fixative agents (prions concern).

- **OPA**: excellent biocidal properties (superior mycobactericidal activity to glutaraldehyde), less potent cross-linking agent, excellent material compatibility, stable, less toxic but it stains proteins gray and presents a poor sporidical activity.

- **Peracetic acid based solutions**: rapidly active against all microorganisms, lack harmful decomposition products, enhance removal of organic material, and leave no residue. They remain effective in the presence of organic matter and are sporidical even at low temperatures but they are considered unstable when diluted and corrosive for some metals.
HARMONIZED STANDARDS FOR AER

Horizontal standard
EN ISO 15883-1 General requirements and tests.

Vertical standards:
- EN ISO 15883-2 washer-disinfectors for surgical instruments
  Published 02/2007
- EN ISO 15883-3 washer-disinfectors for human waste containers
  Published 02/2007
- EN ISO 15883-4 washer-disinfectors for flexible endoscopes
  Published 04/2008
- EN ISO TS 15883-5 Test soils for cleaning tests
  Published 10/2006
- EN ISO TS 15883-6 Small instrument WD Draft
WHAT ARE THE KEY POINTS/REQUIREMENTS OF ISO 15883-4:2008?
ISO 15883-4:2008

Scope and field of application

This part of draft EN ISO 15883 specifies the particular requirements, including performance for washer-disinfectors that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

The method, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring an re-validation, periodically and after essential repairs are also specified.
ENDOSCOPE WASHER-DISINFECTOR

Reproducible reprocessing procedure

Each device, including any device channels and/or cavities, are submitted to a complete cycle including:

a) leak testing (where appropriate);
b) cleaning (which may include several stages);
c) rinsing (when appropriate);
d) disinfection;
e) final rinsing;
f) purging of rinse water;
g) drying (when appropriate).
A self-disinfection cycle is provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs or testing (see also ISO15883-4:2008, 4.8.1).

The self-disinfection cycle ensure that a WD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. (see also ISO15883-4:2008, 4.8.5).
ENDOSCOPE WASHER-DISINFECTOR

Process verification / Traceability

The endoscope washer disinfecter is equipped with a multi-channel recorder, with sensors and signal processing independent from the controller, to record the process variables which were determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes (ISO 15883-1:2006, 5.11.4 c and ISO 15883-4:2008, 5.6).

If the values of the cycle variables are outside the limits specified by the manufacturer the automatic controller indicates and records that a fault has occurred;
Device channel irrigation system

During at least part of each of the cleaning, disinfection and rinsing phases, the device channel irrigation system ensures that the various process fluids flow through each of the internal channels and/or cavities of the devices that are required to be cleaned and disinfected (ISO 15883-4:2008: 5.2.1.1).
Before reprocessing endoscopes shall be transported in a dedicated container to prevent contamination of the environment.

After reprocessing, endoscopes shall be transported in a manner that preserves the cleanliness and disinfection status of the endoscope.

To prevent endoscopes damaging during transport and handling.
ENDOSCOPE STORAGE

What the risk is?

"Further potential vehicles of infection are inadequately designed or improperly maintained automatic endoscope reprocessors, the use of substandard disinfectant, or inadequate drying and/or storage of endoscopes"  BSG 2003

"Bacterial colonization during overnight storage of endoscopes has been linked to patient infection and death.\textit{Spach DH} 1993, \textit{Streulens MJ} 1993, Allen JI
ENDOSCOPE STORAGE

CIRCULAIRE DHOS/E2/DGS/SD5C/2003/N°591 du 17/12/2003
French guidelines for manual reprocessing of endoscopes

If the endoscope is not used immediately, it is recommended to dry it with medical grade air.”

Endoscopes should be stored in a clean, dry an dedicated area away from any source of microbial contamination.

When the endoscope has been stored for 12 hours or more, a disinfection (intermediary level or high level disinfection according to the endoscope considered) have to be performed before the first use of this endoscope."
# ENDOSCOPE STORAGE

**Lawrence F. Muscarella, Am J Gastroenterol 2006;101:2147–2154**

Table 1. The Positions, as Expressed in Published Guidelines, of Several Organizations Regarding Drying Flexible Endoscopes Using 70% Alcohol Followed by Forced or Compressed Air

<table>
<thead>
<tr>
<th></th>
<th>Between-Patient Procedures</th>
<th>Before Storage</th>
<th>After High-Level Disinfection, a Tap-Water Rinse</th>
<th>After &quot;Liquid Sterilization,&quot; a Sterile-Water Rinse</th>
<th>Reprocessing the endoscope before the first patient of the day</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCP, AAB (60)</td>
<td>Unclear</td>
<td>Recommended</td>
<td>UNCLEAR</td>
<td>Not recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>AORN (1,4,37,40)</td>
<td>Not recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>APIC (6,38)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>ASGE (57)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>ASTM (11)</td>
<td>Not applicable</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>BSG (17)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>CSGNA (9)</td>
<td>Not recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>ESGE (12)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommend*</td>
<td>Recommended</td>
</tr>
<tr>
<td>FDA-CDC (10,28,41,44,50–52,59)</td>
<td>Clear</td>
<td>To be “considered”</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Recommended</td>
</tr>
<tr>
<td>FSDE (14)</td>
<td>Unclear</td>
<td>To be “considered”</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>GSA (16)</td>
<td>Not recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>MACID (15)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Multi-society Guideline (5,58)</td>
<td>Clear</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Muscarella (33,35)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Queensland Government (Australia) (13)</td>
<td>Clear</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
<tr>
<td>SGNA (7,8,35)</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Not applicable</td>
<td>Not recommended</td>
</tr>
</tbody>
</table>

*Only if an automated endoscope reprocessor (AER) is used.

1. In small units or isolated areas where neither water filtration nor regular bacteriological water monitoring is practical, then alcohol flushing and air drying between each case is recommended for routine endoscopy and colonoscopy.

2. This multi-society guideline will be updated in the near future to be in agreement with SGNA’s guidelines (personal communication with lead author, 05-03-06).

3. Recommended, especially for duodenoscopes.

4. Only recommended if surveillance cultures of the endoscope are taken in the morning before the first patient and bacterial overgrowth is identified.

5. Only under a few circumstances is drying the endoscope before the first patient of the day recommended (34).

6. AORN = Association of periOperative Registered Nurses; ASGE = American Society for Gastrointestinal Endoscopy; APIC = Association for Professionals in Infection Control and Epidemiology; SGNA = Society of Gastroenterology Nurses and Associates; CSGNA = Canadian Society of Gastroenterology Nurses and Associates; ASTM = American Society for Testing and Materials; ESGE = European Society of Gastrointestinal Endoscopy; FSDE = French Society of Digestive Endoscopy; MACID = Manitoba Advisory Committee on Infectious Disease; GSA = Gastroenterological Society of Australia; CDC = Centers for Disease Control and Prevention; FDA = Food and Drug Administration; BSG = British Society of Gastroenterology.
The storage cabinets are designed to provide drying of the endoscope, including the endoscope channels, and a controlled environment for storage of the dried endoscope(s).

The cabinet is not intended to provide any cleaning or disinfection function but is intended to ensure that there is no deterioration in microbial quality of the processed endoscope.

Extension of storage times before submitting them to a new reprocessing procedure.
To improve the final quality of endocopes all stages of the reprocessing procedure need to be considered and quality controls including endoscope sampling and performance qualification shall be implemented.