If something looks clean, is it really clean?
Cleaning validations for reusable medical devices
OVERVIEW
Tips & Tricks
Device → use → Clean
Device → use → Clean
How do you validated your cleaning procedure?
How do you validated your cleaning procedure?
Device → Soil → Clean → evaluate
Device → Soil → Clean → evaluate
KNOW YOUR DEVICE

Surface area’s
KNOW YOUR DEVICE

Surface area’s

Disassembly
KNOW YOUR DEVICE

Surface area’s

Disassembly

Simulated use
KNOW YOUR DEVICE

Surface area’s

Disassembly

ISO 17664 / AAMI TIR 12
Family grouping

Simulated use
KNOW YOUR DEVICE

Disassembly

Surface area’s

ISO 17664 / AAMI TIR 12
Family grouping

Simulated use
Device → Soil → Clean → evaluate
“OTHER THAN LEAVING THE LID OFF THE BLENDER, I THINK MY FIRST SMOOTHIE WENT RATHER WELL!”
SOIL COMPONENTS
ISO 15883-5 / ASTM F3208
SOIL COMPONENTS
ISO 15883-5 / ASTM F3208

CONTAMINATION

DRY TIME IS CRUCIAL
Manual
- Soaking
- Brushing
- Flushing
- ....

Mechanical
- Ultrasonic cleaners
Washer-disinfector
- Pre-wash
- Washing
- Neutralization
- Rinsing
- Thermal disinfection
- Final rinsing
- drying
A validated method of manual cleaning and at least one cycle of automated cleaning in a washer/disinfector must be validated.
Evaluate your cleaning procedure

how to wash your dishes

1. place in hot, soapy water
2. tell yourself it needs to soak
3. go watch tv

pleated-jeans
Evaluate your cleaning procedure

How to wash your dishes:

1. Place in hot, soapy water
2. Tell yourself it needs to soak
3. Go watch TV

Tip!
## Cleaning Procedures

<table>
<thead>
<tr>
<th>IFU</th>
<th>Validation Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare detergent per manufacturer recommendations (5 mL/L; 10 mL/L; 15 mL/L)</td>
<td>Prepare detergent using (5 mL/L)</td>
</tr>
<tr>
<td>Soak the device in detergent for 2-5 minutes</td>
<td>Soak the device in detergent for not more than 2 minutes</td>
</tr>
<tr>
<td>Flush the lumen with 60 mL of prepared detergent</td>
<td>Flush the lumen with 55 mL of prepared detergent</td>
</tr>
<tr>
<td>Clean the devices in an enzymatic detergent at 45 ± 5°C</td>
<td>Clean the devices in an enzymatic detergent at 40°C</td>
</tr>
</tbody>
</table>
Selection of detergents
Selection of detergents

Chemical properties

Compatiblity

AVAILABLE NOW

AVAILABILITY

EU vs US

Tip!
Device → Soil → Clean → evaluate
Level 1

Level 2

Level 3
VISUAL INSPECTION
VISUAL INSPECTION
Level 1: visual inspection
EVALUATION

CLEANED DEVICE

Extraction Solvents

Extraction conditions

ANALYSES OF THE EXTRACTS
EVALUATION

CLEANED DEVICE

Extraction conditions

Extraction Solvents

ANALYSES OF THE EXTRACTS
Extraction methods

- Sonication
- Manual Shaking
- Orbital Shaking
- Flushing (lumen)
- Swabbing
- ...

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Extraction methods

- Sonication
- Manual Shaking
- Orbital Shaking
- Flushing (lumen)
- Swabbing
- ...

DETERMINE EXTRACTION EFFICIENCY
EVALUATION

CLEANED DEVICE

Extraction conditions

Extraction Solvents

ANALYSES OF THE EXTRACTS
- Hemoglobin
- Protein
- Carbohydrates
- Total organic carbon
- Bioload reduction
- Endotoxin
Select at least 2 parameters!

- Hemoglobin
- Protein
- Carbohydrates
- Total organic carbon
- Bioload reduction (only in EU)
- Endotoxin
These acceptance criteria are for flexible endoscopes that contact mucosal surfaces.
CONTROLS

Positive device control

Soiled

Uncleaned

Extraction efficiency

Negative device control

unsoiled

Cleaned

Test control
Level 1: visual inspection

Level 2: analytical endpoints
Detergent residues
Level 1: visual inspection

Level 2: analytical endpoints

Level 3: Cytotoxicity test
Things to consider!
Ageing of the device
Ageing of the device
BIOCOMPATIBILITY

Can this be affected by cleaning and detergent residues?
THE GAP
- Ageing of material
- Type of detergent
- Processing steps of the device
  - Sterilization
  - Cleaning?
- ...
Level 1: visual inspection

Level 2: analytical endpoints

Level 3: Cytotoxicity test
Lifecycle of a device
Summary!
Device → use → Clean
Device → Soil → Clean → evaluate
thank you!

Tip! lvanderkelen@nelsonlabs.com