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Your Vision, Our Future

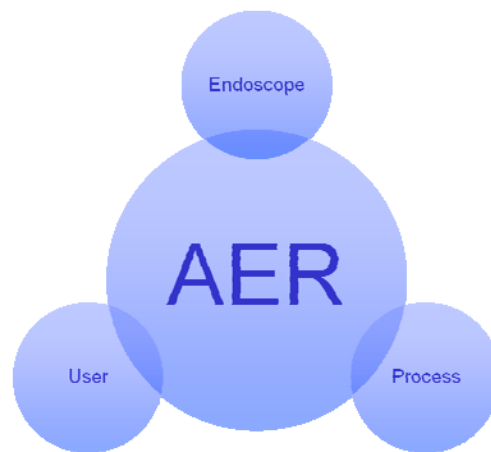
# Validation Strategy for an Automated Endoscope Reprocessor

November 16, 2010  
Bradley Catalone

## AER Validation Strategy

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### System Approach



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### AER Validation Strategy

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- AER
  - ▶ Scope-specific connectors
  - ▶ Requires prior manual cleaning
- User
  - ▶ High turnover
  - ▶ Resource and time constraints
- Endoscope
  - ▶ Complex, multiple designs, new models consistently introduced
- Process
  - ▶ Multiple steps
  - ▶ Manual cleaning
  - ▶ Device-specific adapters

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### Validation Objectives

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- Reduce manual steps
- Eliminate scope-specific adapters during manual cleaning
- Eliminate manual channel flushing
- Improve other cumbersome or unnecessary steps (eliminate bedside flush with detergent, reduce manual flush volumes, etc.)
  - ✓ Reduces variability
  - ✓ Less user dependent
  - ✓ Improves compliance with instructions

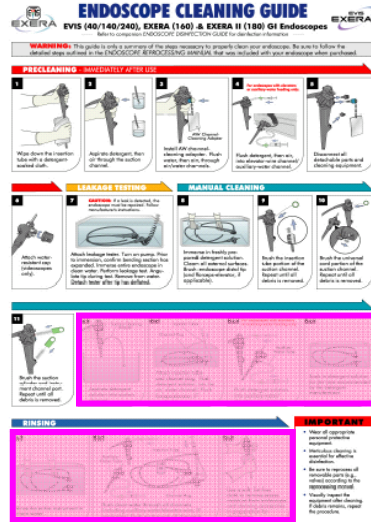


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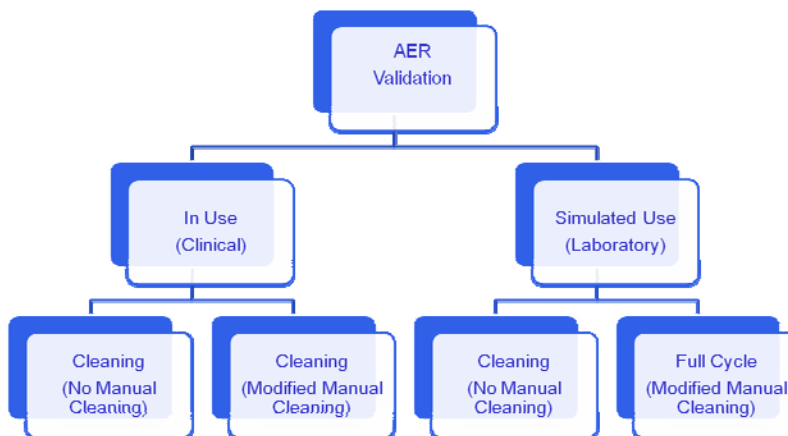
## Modified Cleaning

- AER automates channel flushing
  - External surface cleaning and channel brushing required
- ✓ Reduces manual steps
  - ✓ Reduces labor
  - ✓ Improves efficiency
  - ✓ Improves compliance
  - ✓ Improves consistency



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## AER Validation Design



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## AER Validation Strategy

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### Simulated Use Testing

- Worst case for identified variables related to process efficacy
- Specific user-dependent steps not performed for testing

### In Use (Clinical) Testing

- Validate efficacy in clinical environment according to AER IFUs
- Repeat validation eliminating specific user-dependent steps

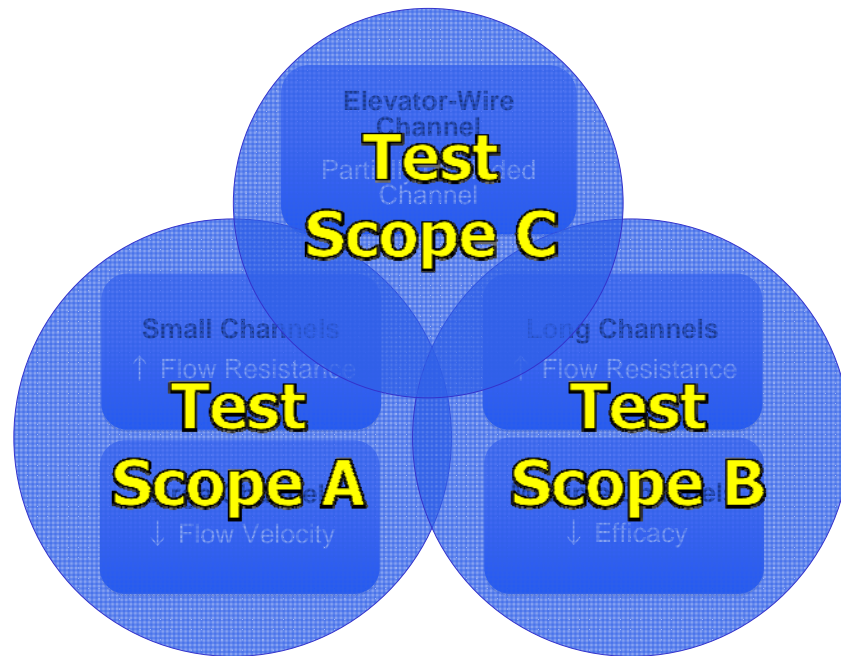
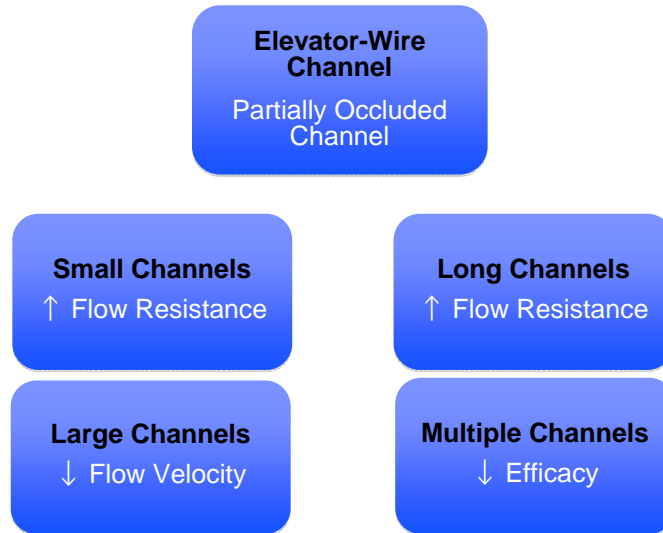
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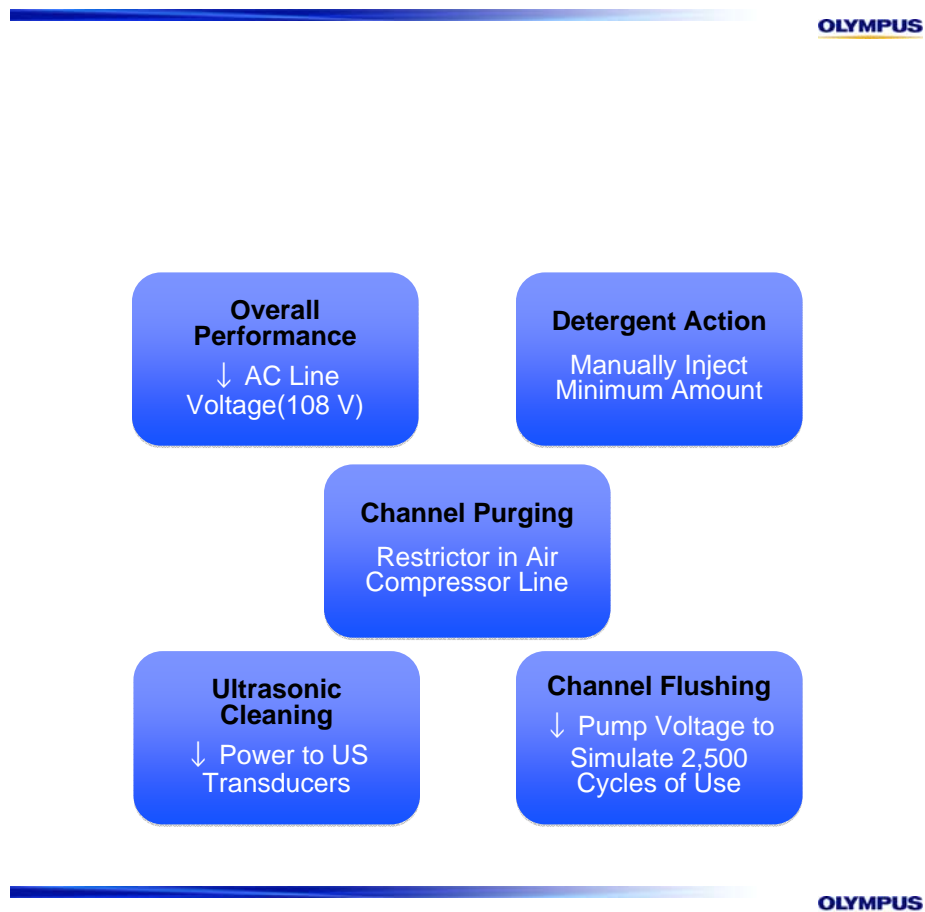
**Panel of Test Endoscopes  
to represent all  
Olympus Endoscope  
Models**

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# Worst-Case Conditions for the AER





**Worst-Case  
Conditions for the  
AER**

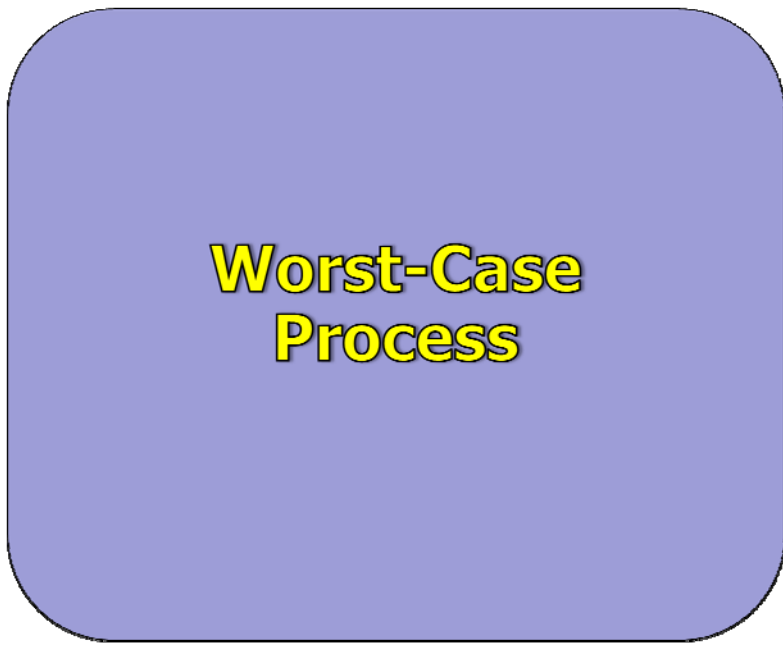
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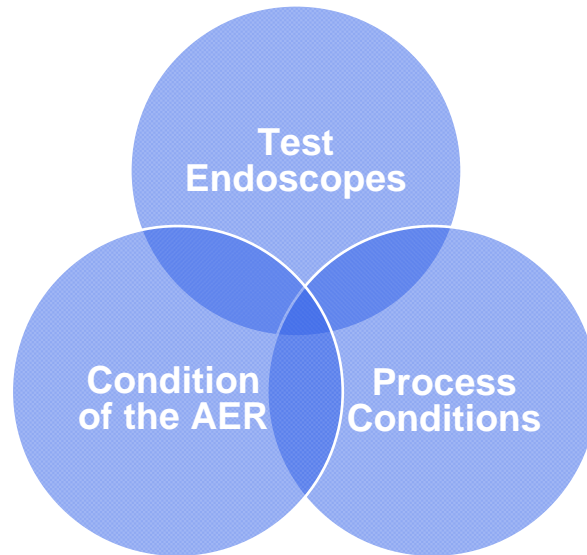
**Worst-Case Conditions  
for the Process**

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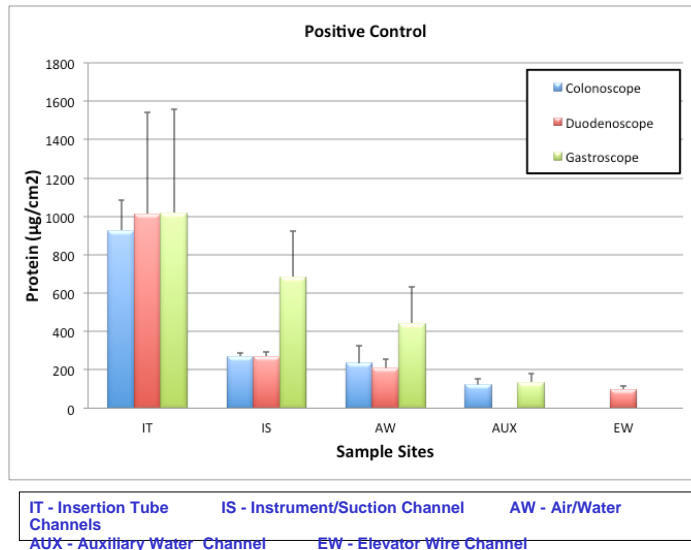


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		Simulated Use	Simulated Use	Clinical Use	Clinical Use
AER	Soil	ATS	ATS	Patient	Patient
	Pre-Clean				
	Manual Clean				
	Clean				
	Rinse				
	HLD				
	Rinse				
	Alcohol				

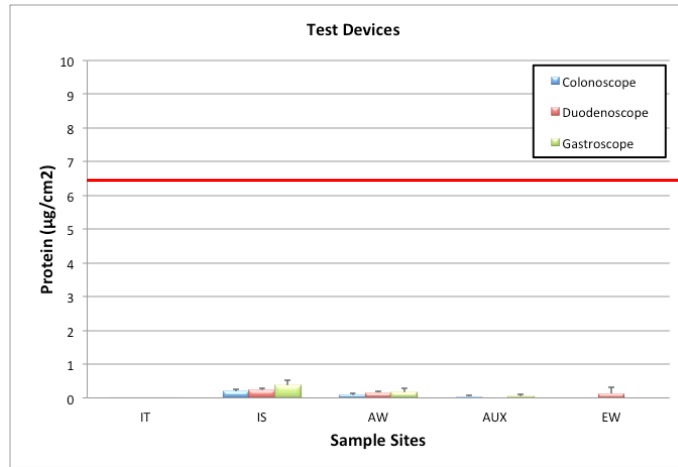
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## Simulated Use Cleaning



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## Simulated Use Cleaning

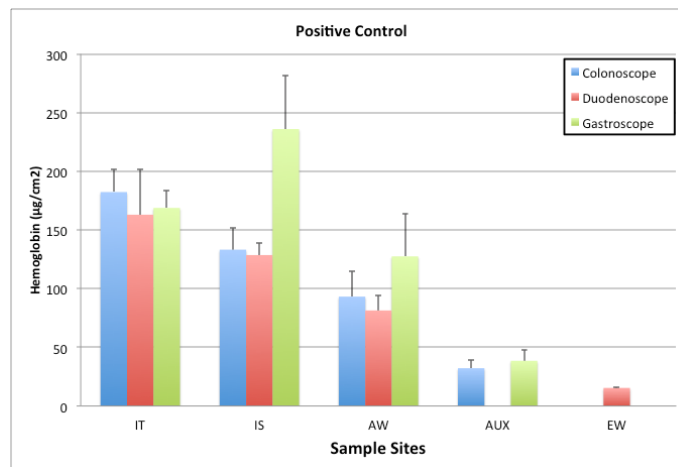


6.4 µg/cm<sup>2</sup>

IT - Insertion Tube Channels    IS - Instrument/Suction Channel    AW - Air/Water Channel  
AUX - Auxiliary Water Channel    EW - Elevator Wire Channel

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## Simulated Use Cleaning



Test Devices  
• < LOD

IT - Insertion Tube Channels    IS - Instrument/Suction Channel    AW - Air/Water Channel  
AUX - Auxiliary Water Channel    EW - Elevator Wire Channel

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## In Use - Cleaning



- **Endpoints**
  - **Protein:** < 6.4 µg/cm<sup>2</sup>
  - **Bioburden:** < 4 Log<sub>10</sub> CFU/cm<sup>2</sup>
- **15 Endoscopes, 65 Samples**
- **Bronchoscope, Colonoscopes, Duodenoscopes**
- **Results**

	Protein (µg/cm <sup>2</sup> )	Bioburden (Log <sub>10</sub> CFU/cm <sup>2</sup> )
Bronchoscopes	<LOD – 0.55	0 - 0.016
Colonoscopes	<LOD – 0.60	0 - 0.005
Duodenoscopes	<LOD – 0.62	0 - 0.050

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## In Use - Cleaning

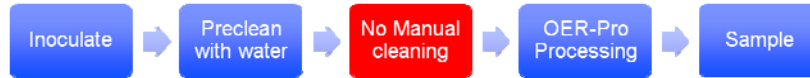


- **Endpoints**
  - **Protein:** < 6.4 µg/cm<sup>2</sup>
  - **Hemoglobin:** < 1.8 µg/cm<sup>2</sup>
- **14 endoscopes, 62 samples**
- **Bronchoscope, Colonoscopes, Duodenoscopes**
- **Results**

	Protein (µg/cm <sup>2</sup> )	Hemoglobin (µg/cm <sup>2</sup> )
Bronchoscopes	<LOD – 1.39	<LOD
Colonoscopes	<LOD – 4.33	<LOD
Duodenoscopes	<LOD – 0.88	<LOD

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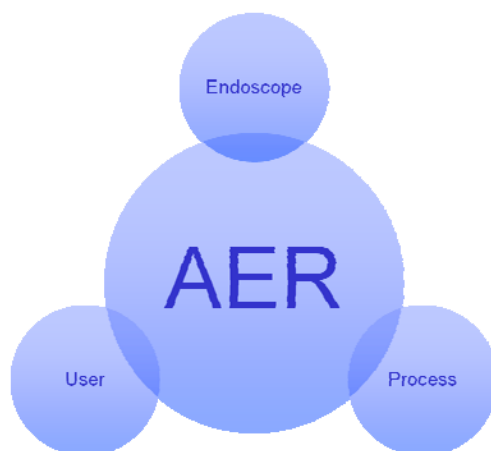
## Simulated Use Full Cycle Testing



- **Endpoints**
  - **Protein:** < 6.4 µg/cm<sup>2</sup>
  - **Bioburden:** ≥ 6 Log<sub>10</sub> reduction in *M. terrae*
- **13 endoscopes, 65 samples**  
**Gastroscope, Colonoscope, Duodenoscope and Ultrasound Endoscope**
- **Results**
  - **All samples < 6.4 µg/cm<sup>2</sup> residual protein**
  - **62 of 65 samples ≥ 6 Log<sub>10</sub> reduction in *M. terrae***
  - **3 samples > 5.9 Log<sub>10</sub> reduction – sample volume limitation**

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## Summary



- Covers all Olympus endoscopes
- Reduced dependence on scope-specific adapters
- Reduced burden on user
- Simplified instructions
- ✓ Effective endoscope reprocessing

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# Workshop on Medical Device Cleanliness: How Clean is Clean Enough?

Sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices

