A Paradigm Shift in Endoscope Reprocessing
Improving the Standard of Care

Assessing Current Practices

Current practices favor turnover speed and low cost over quality control. Visual Inspection + High Level Disinfection = High throughput Cleaning Monitoring + EO Sterilization = Higher Level of Patient Safety

Facts: Cleaning Process Monitoring

- Assesses cleaning efficacy by detecting residual organic soil
- Rapid indicator provides quantitative results for Pass/Fail determination
- Generates data for trending and analysis within a Quality Control system

Facts: Ethylene Oxide (EO) Sterilization

- “Overkill” safety margin + multi-component quality control monitoring system
- EPA mitigation measures implemented in 2010
- Modern sterilizers engineered for safety
- EO sterilization validated by endoscope manufacturers and listed in IFUs
- Documented excellent materials compatibility (most polymers, metals, and ceramics/glasses) – no evidence of damage to endoscopes
- Used in health care settings, medical device, government, and other industries for 50+ years

Flexible Endoscope Manual Cleaning Efficacy

Study used multiple markers (ATP, protein and visual inspection) to evaluate contamination before and after manual cleaning. Results: “Multiple components were sampled during 37 encounters with 12 unique endoscopes. Although there was no visible residue on any endoscopes after manual cleaning, 82% had at least 1 positive rapid indicator test.”

Operator Safety Data: Ethylene Oxide Sterilization in Health Care Facilities

Mean exposure levels for operators decline, remaining significantly below OSHA occupational limit (1.0 ppm over 8 hours, TWA), based on personal breathing zone and area monitoring data.

Operator Safety Data: EO Exposure Limits

<table>
<thead>
<tr>
<th>Statistic</th>
<th>1979 to 1987 (ppm)*</th>
<th>1988 to 2007 (ppm)*</th>
<th>2012 (ppm)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arithmetic Mean</td>
<td>2.44 ± 24</td>
<td>0.49 ± 2</td>
<td>0.1218</td>
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<tr>
<td>50th Percentile</td>
<td>0.029</td>
<td>0.026</td>
<td>0.0731</td>
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<tr>
<td>75th Percentile</td>
<td>0.17</td>
<td>0.21</td>
<td>0.135</td>
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<td>90th Percentile</td>
<td>0.83</td>
<td>0.83</td>
<td>0.16</td>
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<tr>
<td>Maximum</td>
<td>312</td>
<td>22</td>
<td>10.1</td>
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<tr>
<td>Number of Observations</td>
<td>171</td>
<td>343</td>
<td>647</td>
</tr>
</tbody>
</table>

* Data from OSHA IMIS database as presented in EPA EO Final Work Plan (EPA-HQ-OPP-2013-0244-0017)
** Data from use of passive EO monitors in health care facilities across 33 states and Puerto Rico

EO sterilizers today are engineered for safe use and facilities have implemented practices to improve safety (e.g., area monitoring, operator training). Positive milestones for safety:

- 2008: U.S. EPA EO Reregistration eligibility decision (RED) requires risk mitigation measures in healthcare facilities, including in-chamber aeration
- 2010-2014: U.S. EPA Clean Air Act phase-out of HCFC-based products, including mixed gas HCFC/EO sterilant, eliminates positive pressure cycles and large volume EO tanks
- 2015: Introduction of completely updated 100% EO Sterilizer