

Table of Contents

Access to the Digital Tools in This Book	vi
Introduction	1
Related Joint Commission and JCI Standards.....	1
Compliance Obstacles	2
Implications of an ITHS finding	2
Full-year 2022 compliance data	2
Reprocessing Challenges	3
Why This Book?	3
Hierarchical approach to developing reprocessing policies and procedures	4
Audiences for This Book	5
How This Book Is Organized	5
About the Editors.....	6
References.....	6

Tool to Try

- Tool I-1. Most Frequently Cited Higher-Risk EPs for Four Joint Commission Accreditation Programs

Chapter 1. Reprocessing Basics: The Spaulding Classification System, Single-Use Devices, and Manufacturer Instructions	9
Determine Whether a Device Can Be Reprocessed	11
Items labeled as single-use devices (SUDs) and expired devices	11
Manufacturer Reprocessing Instructions	13
Potential IFUs discrepancies	14
Further caveats regarding IFUs	14
Resolving Issues with Reprocessing Instructions	15
Using Evidence-Based Guidelines.....	15
Resources to Tap.....	16
References.....	16

Tools to Try

- Tool 1-1. Hierarchy Application—Medical Device Reprocessing Policy Development and Review Checklist
- Tool 1-2. Checklist for Evaluating Steps in Medical Device Reprocessing

Chapter 2. High-Level Disinfection of Semi-Critical Devices: An Ongoing Challenge	21
HLD Challenges	22
General overview of HLD steps	23
Common problems and remedies	23
Safety Considerations When Working with High-Level Disinfectants	24
PPE and Safety Data Sheets	24
Spill containment and eyewash stations.....	24
Ventilation.....	24

HIGH-LEVEL DISINFECTION OF ENDOSCOPES	25
Flexible Endoscopes: Difficulties in Cleaning and Disinfection.....	25
Causes of outbreaks related to flexible endoscopes.....	25
<i>Minimum</i> level of reprocessing.....	26
Endoscope Inventory.....	27
Step-by-Step HLD Process for Flexible Endoscopes	27
Step 1. Treatment at the point of care	28
Step 2. Containment and transportation to the decontamination area.....	28
Step 3. Inspection for surface integrity and leak testing	29
Step 4. Cleaning.....	29
Automated Endoscope Reprocessing Considerations.....	30
Step 5. Rinsing and drying	33
Step 6. Visual inspection	34
Step 7. High-level disinfection (manual or automated)	34
Preparation and Use of HLD Products.....	34
Step 8. Rinsing endoscopes after high-level disinfection	37
Step 9. Drying endoscopes after rinsing	37
Step 10. Endoscope storage	37
 HIGH-LEVEL DISINFECTION OF ENDOCAVITY AND SURFACE ULTRASOUND TRANSDUCERS	 38
Endocavity and Surface Ultrasound Transducers Used as Semi-Critical Devices.....	38
Use of transducer sheath does not change HLD need	38
Surface ultrasound considerations	39
Reprocessing Endocavity and Surface Ultrasound Devices Intended to Be Used on Mucous Membranes or Nonintact Skin	39
Step 1. Treatment at the point of care	39
Step 2. Containment and transportation to the decontamination area.....	40
Step 3. Manual cleaning and rinsing.....	41
Step 4. Visual inspection for surface integrity	41
Step 5. High-level disinfection (manual or automated).....	41
Step 6 (if applicable). Electrical leak testing of transesophageal echocardiography probes.....	41
Step 7. Drying of semi-critical ultrasound transducers	42
Step 8. Storage of semi-critical ultrasound transducers.....	42
Documentation	43
 FURTHER CONSIDERATIONS	 43
Ongoing Challenges	43
Staff Competency.....	43
References.....	44

Tools to Try

- Tool 2-1. Sample Endoscope Inventory Form
- Tool 2-2. Sample Endoscope Audit Tool
- Tool 2-3. Endoscope Reprocessing Assessment Checklist
- Tool 2-4. HLD Reprocessing Mock Tracer Questions

Chapter 3. Sterilization	49
Devices That Must Be Sterilized or Are Often Sterilized	49
Sterilization of Semi-Critical Devices	50
OVERVIEW OF KEY STEPS IN STERILIZATION PROCESS	52
Step 1. Point-of-Use Treatment	52
Step 2. Preparing Dirty Instruments for Transport.....	53
Step 3. Transport to Decontamination Area.....	54
Step 4. Cleaning and Decontamination.....	54
Disassembly.....	55
Manual or automated cleaning process.....	55
Cleaning supplies and equipment.....	55
Rinsing.....	55
Drying.....	55
Step 5. Inspection	55
Lubrication.....	56
Step 6. Packaging	56
Process controls used with packaging—chemical indicators.....	57
Process controls used with packaging—labels.....	58
Step 7. Sterilization	58
Steam sterilization cycles	58
Process controls used to monitor exposure to the sterilization process—chemical indicators	59
Process controls used to monitor sterilization equipment function—chemical indicators.....	60
Biological indicators.....	60
Physical indicators	62
Immediate Use Steam Sterilization.....	62
Final Step. Confirm Ready for Use	62
COMMON STERILIZATION PROBLEMS CITED BY SURVEYORS	63
Improperly Sized Peel Pouches	63
Easy Identification of Sterile Status	63
Key Risks of Sterilization Failures	64
Sterilant can't reach all surfaces.....	64
Failure of cleaning and sterilizing equipment	64
Sample Protocol for Investigating Exposure Risk Due to Sterilization Failure.....	64
Maintaining Sterilizers	65
Maintenance records.....	65
Supplementing Applicable Regulations and IFUs	65
References.....	65
Tools to Try	
• Tool 3-1. Sterilization-Related Mock Tracer Questions	
• Tool 3-2. Sterilization Packaging Audit Tool	
• Tool 3-3. Examples of Load Records	
Glossary	67
Index	71