

## General Information

1. **Date of Audit:**
  2. **Facility Name & Address:**
  3. **Staff Present During Audit:**
  4. **What services at this location require instrument reprocessing?:**
  5. **Are instruments transported from another location for reprocessing? (Yes/No)**
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## Inventory of Instruments & Endoscopes

6. **What single-use instruments are used?:**
  7. **What reusable instruments are used? (Record item numbers)**
  8. **What endoscopes are being used? (Record item numbers)**
  9. **Are ultrasound probes (TEE, transvaginal) reprocessed at this site? (Yes/No)**
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## Point of Use Treatment

10. **What product is used for pre-treatment?:**
  11. **Where does pre-treatment take place? (Exam room/Reprocessing area)**
  12. **Is PPE used during pre-treatment? (Yes/No)**
  13. **Are instruments placed in an open position for pre-treatment? (Yes/No)**
  14. **Are transport containers:**
    - **Puncture-proof, leak-resistant, equipped with a lid, and labeled as biohazardous? (Yes/No)**
  15. **Are endoscopes transported in a compliant manner? (Yes/No)**
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## Environmental Considerations

16. **Is the decontamination area separate from the clean assembly/sterilization area? (Yes/No)**
17. **Is there at least 4 feet of separation between dirty and clean work areas? (Yes/No)**
18. **Is the decontamination area negative pressure? (Yes/No)**
19. **Does the air in the decontamination area exhaust directly outdoors? (Yes/No)**
20. **Is the clean assembly and sterilization area positive pressure? (Yes/No)**

21. **Is the temperature in the decontamination area maintained at 72-78°F? (Yes/No/Not Monitored)**
  22. **Is the humidity in the clean workroom less than 60%? (Yes/No)**
  23. **Are dedicated handwashing sinks available in the decontamination area? (Yes/No)**
  24. **Is an eyewash station available in the decontamination or HLD area? (Yes/No)**
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### **Manual Cleaning Process**

25. **Are endoscopes cleaned within 1 hour after use? (Yes/No)**
  26. **Is appropriate PPE (gowns, gloves, eye protection) available and used for cleaning? (Yes/No)**
  27. **How many sinks are available for cleaning?:**
  28. **Are sinks appropriately sized for reprocessing? (Yes/No)**
  29. **Are endoscopes leak tested after each use according to MIFU? (Yes/No)**
  30. **What enzymatic detergent is used?:**
  31. **How is detergent dilution measured and verified?:**
  32. **Is detergent temperature monitored and within range? (Yes/No)**
  33. **Is critical water used for the final rinse? (Yes/No)**
  34. **Are cleaning brushes appropriately sized and single-use items disposed of after use? (Yes/No)**
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### **Packaging & Sterilization**

35. **Does the site autoclave instruments? (Yes/No)**
  36. **How are instruments packaged for sterilization? (Rigid containers, Blue wrap, Peel pouches)**
  37. **Are chemical indicators used in all packages? (Yes/No)**
  38. **Are sterilized items labeled correctly and stored in a clean, controlled environment? (Yes/No)**
  39. **Is the autoclave monitored with biological indicators (BI)? (Yes/No)**
  40. **How often is BI testing performed?:**
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### **High-Level Disinfection (HLD)**

41. **What solution is used for HLD?:**
42. **Is PPE donned for HLD per manufacturer's instructions? (Yes/No)**

- 43. **Is a spill kit available for HLD chemicals?** (Yes/No)
  - 44. **Is the disinfectant temperature and exposure time monitored?** (Yes/No)
  - 45. **Are test strips marked with open/expiration dates and quality control documented?** (Yes/No)
  - 46. **Are endoscopes rinsed with critical water after HLD?** (Yes/No)
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#### **Endoscope Drying, Storage, and Transport**

- 47. **How are endoscopes dried after HLD?:**
  - 48. **Are reprocessed endoscopes labeled with reprocessing date, technician ID, and storage time?** (Yes/No)
  - 49. **Where are endoscopes stored?:**
  - 50. **Is the storage cabinet cleaned and documented weekly or per IFU?** (Yes/No)
  - 51. **Does staff handle reprocessed endoscopes with gloves?** (Yes/No)
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#### **Competency & Documentation**

- 52. **Is competency documentation available for all staff performing reprocessing?** (Yes/No)
- 53. **When was the last competency assessment completed?:**
- 54. **Who conducts competency assessments?:**
- 55. **Are all reprocessing records complete and available for review?** (Yes/No)