

AAMI ST108 Reference Sheet

1. Water Quality Categories:
 - a. **Utility Water**- mainly used for **flushing, washing, and intermediate rinsing** (e.g., rinsing between cleaning and disinfection)
 - b. **Critical Water**- mainly used for the **final rinse after high-level disinfection** and/or for the **final rinse for critical devices prior to sterilization**
 - c. **Steam**
2. Applicable Departments:
 - a. Medical device processing can occur in different areas throughout a health care facility.
 - i. typical area- **Sterile Processing**
 - ii. **Surgery** - may perform sterilization processes
 - iii. **Endoscopy**- performs high-level disinfection on their endoscopes
 - iv. **Physician and dental clinics**- perform sterilization processes
 - v. **Cardiac lab**- high-level disinfection of probes
3. Applicable devices:
 - a. **Critical devices**- instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or into other normally sterile areas of the body, and products with sterile fluid pathways.
 - i. Examples- surgical instruments, needles, cardiac catheters, implants, gastrointestinal sphincterotomes, biopsy forceps, rigid endoscopes used for minimally invasive surgery, inner surface components of extracorporeal blood-flow devices such as heart-lung machines, blood oxygenators, and the blood compartments of hemodialyzers.
 - ii. Water quality- **final rinse should be with Critical Water**
 - b. **Semi-critical devices**- instruments or objects that contact intact mucosal membranes or non-intact skin of the patient during use but do not usually penetrate the blood barrier or other normally sterile areas of the body.
 - i. Examples- noninvasive, flexible endoscopes, endotracheal and aspirator tubes, laryngoscopes, respiratory therapy equipment, and vaginal specula.
 1. Water quality- **sterilized**, if possible; **final rinse should be with Critical Water**
 - a. if sterilization is not feasible, the device should be subjected, at a minimum, to a **high-level disinfection** process
 - c. **Non-critical devices**- instruments or objects that usually contact only the intact skin of the patient.
 - i. Examples- bedpans, reusable anesthesia masks, blood pressure cuffs, most neurologic and cardiac diagnostic electrodes, and certain surfaces of radiological imaging (e.g., x-ray machines)
 - ii. Water quality- **Utility Water** is usually acceptable for all processing stages
4. Automated Cleaning Steps
 - a. **Pre-cleaning stage**- utility water
 - b. **Wash stage**- utility water, unless otherwise indicated by the medical device or cleaning agent manufacturer's written IFU

- c. **Post-cleaning rinse stage-** utility water, unless otherwise indicated by the medical device or cleaning agent manufacturer's written IFU
 - d. **Disinfection stage-** utility or critical used
 - i. Chemical disinfection should use water based on disinfectant manufacturer's written IFU for time, temperature, and any other conditions specified
 - ii. Thermal disinfection should use critical water
 - e. **Final rinse stages-** critical water used most often
 - 1. AERs- may be Utility or Critical Water according to the AER manufacturer's written IFU
5. Manual Cleaning Steps
- a. **Cleaning-** utility water used
 - b. **Rinsing-** utility water used
 - c. **Final Rinsing-** critical water used
6. Other equipment
- a. **Ultrasonic cleaners-** utility water, unless otherwise indicated by the ultrasonic or medical device manufacturer's written IFU
 - b. **Respiratory equipment-** pasteurization for semi-critical devices, thermal disinfection in washer–disinfectors for non-critical devices, provided that adequate temperature conditions are achieved; utility water for devices that will not be packaged but will be thermally disinfected or pasteurized

Referenced from AAMI ST108. For specific guidance, please refer to original Standard published by Association for the Advancement of Medical Instrumentation (AAMI) in 2023.