The Joint Commission

< Back to Manual

Infection Prevention and Control (IC) (Office Based Surgery / Office-Based Surgery)

Use of Self-Contained High Level Disinfection Units for Semi-Critical Devices

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What are the Joint Commission recommendations regarding Gluteraldehyde User Station's (GUS), disinfection soak station's (or similar self-contained high level disinfection units which often use 0.55% ortho-phthalaldehyde) for disinfecting devices (such as vaginal probes and other endo-cavitiy probes) utilized in various settings (such as radiology, outpatient procedure rooms in hospital, and ambulatory care settings). Specifically, are there any specific requirements for ventilation, use and processing locations (shared or separate) and can the unit share space with a sterilizer?

This response is specific to the use of self-contained high level disinfection (HLD) units and does not apply to reprocessing of instruments, such as endoscopes, bronchoscopes or TEE probes. In addition, the Joint Commission does not endorse or promote any specific brand, product, process or device for performing HLD or sterilization. Such decisions are the responsibility of the organization's leadership, giving consideration to the scope of services provided, patient population served and accepted evidence-based guidelines, law and regulation.

Disinfection strategies vary widely for semi- critical devices (such as vaginal probes, endocavity probes). Based on the device and product(s) used for reprocessing, it would be expected that organizations follow the manufacturer's recommendations to ensure safe, effective use.

This response addresses the environment where Gluteraldehyde User Station's (GUS) disinfection soak stations (or similar self-contained high level disinfection units, such as those using 0.55% ortho-phthalaldehyde) are used. The primary intent is that the 'process' for cleaning and disinfection of probes is consistent with current evidence-based practices (that is recommended by AAMI, CDC, etc.) for such devices as well as following recommendations from the product's manufacturer for both the device used for reprocessing as well as the device being reprocessed.

The Joint Commission and OSHA require that health care facilities protect workers and patients from known risks. Since all high-level disinfectants by definition are toxic, and their fumes are known irritants, workers and patients need protection from exposure. Proper handling and use of high-level disinfectants falls under The Joint Commission's Environment of Care Standard 02.02.01 EP 9 which states "The organization minimizes risks associated with selecting, handling storing, transporting, using and disposing hazardous gases and vapors."

The Joint Commission Infection Control Standard IC.02.02.01 EP2 may be scored if the high level disinfectant is not being properly used, including improper efficacy testing, frequency for changing the solutions in the unit not following policy, or dilution ratio requirements not being followed.

The Joint Commission expects organizations to use evidence-based national guidelines, such as the ANSI/ AAMI ST58:2013 "Chemical Sterilization and High-level Disinfection in Health Care Facilities". This document includes the following requirements:

- Chemical sterilants should be used in an area that is properly ventilated.
- When general room ventilation is not adequate, a self-contained, freestanding system* or a local exhaust hood should be installed to capture chemical vapor during processing.
- When an outside exhaust system is not available, a ductless fume hood* can be used to deliver vapor to a filter system that chemically inactivates the vapor; then clean, filtered air is returned to the room.
- Filters for these systems should be replaced in accordance with the manufacturer's recommendations.
- *A ductless fume hood is simply a freestanding system that captures the toxic fumes and vapors and returns clean air to the room. Other names for ductless fume hoods are vapor control systems and disinfection soak stations.

Practitioners should consult the labels of proprietary products for specific instructions. They should also consult instrument manufacturers regarding compatibility of these agents with probes. Many of the chemical disinfectants are potentially toxic and many require adequate precautions such as proper ventilation, personal protective devices (gloves, face/eye protection, etc.) and thorough rinsing before reuse of the probe.Specific questions pertaining to device cleaning and the self contained high level disinfection units:

1. What is the normal sequence of operations regarding device processing, including room environments?

   - After the patient is removed from the room the device is either processed in the room or removed from the room in a covered container and brought to a separate room where the GUS (Gluteraldehyde User Station) disinfection soak station (or similar self-contained high level disinfection unit, such as those using 0.55% ortho-phthalaldehyde) is located. The processing procedure does not determine the pressure differentials of the room (i.e. negative pressure), but the pressure differentials are established by The Facility Guidelines Institute (FGI) 2010 Guidelines for Design & Construction of Health Care Facilities and the identified use of the room. For example, a soiled utility room is required to be maintained under negative pressure, whether or not the GUS is in the room. A clean utility room is required to be maintained under positive pressure, whether or not the GUS is in the room.
   - The cleaning and disinfecting process should follow national guidelines (such as CDC guidelines) where staff should wear appropriate Personal Protective Equipment (PPE) and follow manufacturers' recommendations to process the device.
   - Store the device in a manner that will protect from damage or contamination and that is consistent with national guidelines and manufacturers' recommendations such as hanging vertically in a cabinet and storing in a clean environment

2. Is it acceptable to rinse the probes under tap water after Cidex disinfection OR should sterile water be used?

   - There is no current recommendation to use sterile or filtered water rather than tap water for rinsing semi -critical equipment that contact mucous membranes. The Joint Commission would expect the organization to conduct a risk assessment to determine the quality of their rinse media.

< Back to Manual