

Best Practices for High Level Disinfection – Part II

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There are many high level disinfectants on the market today. This module will discuss some of the more popular ones.

Glutaraldehydes – are high level disinfectants (HLD) for immersible items. There are acid and alkaline preparations. Some examples of glutaraldehyde-based products include Rapicide, Cidex and Aldahol. As with all HLD, the solution must make contact with all surfaces of the device. Thorough pre-cleaning is essential; all soils must be removed and rinsed off so the disinfection process can be effective.

This category of HLDs is mainly used for flexible and rigid scopes. However, they might also be used for laryngoscope blades that have been validated for HLD using the chemical. These products are generally, non-corrosive to plastic, metal and lensed instruments.

They require activation with a buffering agent which gets added to solution in the container. The buffering agent is a powder that gets mixed with the solution inside the container. Once activated, the product is good for 14-28 days depending on the formulation used.



The recommended soak time is 10- 45 min depending on the product. However, it is critical that you follow the specific manufacturer's instructions for use including any recommended temperature required.

In the High Level Disinfection Part I module, you learned that the use life of the product is affected by soils, temperature and in-use dilution. In a 2% solution glutaraldehydes are effective against all vegetative bacteria, viruses, TB and fungi. They can be toxic, and requires thorough rinsing to remove all residues which can cause sloughing of the patient's tissue. The quality of rinse water issue-can re-contaminate device. Consult with your Infection Prevention nurse regarding the water quality for rinsing.

Some general guidelines for use of glutaraldehyde solutions follow.

- Mix them according to manufacturer's instructions.
- Document on the solution container, the date the solution was made and when it expires.
- After soaking, thorough rinsing with sterile water recommended to prevent re-contamination (if need to present sterile otherwise utility [potable] water). NOTE: The quantity and quality of water must be followed for the specific disinfectant used.
- After high level disinfection, protect the device from re-contamination until used.
- Always use glutaraldehydes in a well-ventilated, restricted area.
- For safety, there are personnel monitoring devices and neutralization pads available.

Neutralization Pads – These devices are specifically designed to both absorb and neutralize small spills. They have a plastic backing for extra protection. The pad is placed under and around soaking basins. The pad eliminates the need to use towels which can expose personnel to fumes.

QA Testing of Test Strips – Read the package insert to determine if your test strip manufacturer recommends quality control testing of the test strips whenever a new bottle is opened. When a new bottle is opened, you should date the bottle when opened and note the expiration date (this is based on the manufacturer's instructions). If quality control testing of the test strips is recommended, always follow the test strip manufacturer's testing instructions. Quality control testing of the strips should be documented on a separate form from the Minimum Effective Concentration (MEC) testing discussed in Module I.

Personal Protective Equipment (PPE) - PPE should include eye shields, fluid resistant mask (to prevent splashes onto mucous membranes of the face), butyl rubber gloves (no vinyl or neoprene gloves), and a polyethylene gown (plastic) with long sleeves. You should consult with the Safety Data Sheet and the manufacturer's instructions for use to verify the recommended PPE for the product you are using.

Safety – Once in use, the solution should always be stored covered. There is an OSHA Ceiling limit for glutaraldehyde exposure of 0.2ppm. The American Congress of Governmental and Industrial Hygienists (ACGIH) recommend a level of 0.05 ppm. In the absence of an OSHA standard, OSHA defers to the ACGIH level of 0.05 ppm. Therefore, when testing for glutaraldehyde levels of staff, the level should be 0.05 ppm. This means at no time can the level exceed 0.05 ppm. The levels should be determined

annually with a glutaraldehyde meter (this is the most accurate reading). A spill plan is needed. Consult with the Safety Data Sheet for the recommended neutralization agent.

Understand that disposal of the solution is the number one cause of exposure for users (dumping down drain). When disposing, the solution should be diluted with copious amounts of running water. Follow the manufacturer's instructions for disposal. Dispose of the disinfectant containers per the label instructions.

There are many formulations of glutaraldehyde in use today such as:

- Cidex®
- Aldahol®
- Rapicide™
- Banicide Advanced®
- Sporidicin®
- Cetylcode-G®
- Procide-D®
- Omnicide™
- Metricide®
- Wavicide-01®

Some of these formulations are only validated for use in automated endoscope reprocessors (AERs). There are additional formulations; all are listed on the FDA website.

Ortho-phthalaldehyde (0.55%) Cidex OPA is a non-glutaraldehyde product. It is non-toxic. The chemical requires a 12 minute soak time for **manual** high level disinfection at MINIMUM of 68°F (20°C). Due to its non-toxicity, no employee monitoring for exposure is required. However, the chemical stains protein (e.g. skin, soils). Therefore, it must be used as directed. Approximately .5% of bladder cancer patients have a sensitivity to Cidex OPA, so its use on devices for these patients is not recommended.

Since there is a specific temperature required for the disinfectant to be effective, a thermometer is needed to monitor and document the temperature of the solution, before and during use (see photo below). If the minimum temperature is not reached, the disinfection process can be ineffective. Therefore the temperature should be documented. (See documentation later on in this Inservice). The manufacturer has guidance on how to heat up solution if minimum temperature cannot be achieved. A heat-up Pad or similar device may be needed in order to achieve the recommended temperature for Cidex OPA. Contact the manufacturer for more information on heating up the solution.



Thermometer in Cidex OPA container to monitor temperature

Rinsing – the disinfectant must be rinsed off thoroughly. Follow the manufacturer’s instructions for use for the quantity and quality of water and how many rinses are recommended. The rinse water should not be reused. Each rinse should be with fresh water. Rinsing should take place in a clean container not in a handwash or decontamination.

Cidex OPA has a 14 day use life meaning it can be used for up to 14 days once it is placed in a container. However, since the product does not have to be activated, you do not have to use the entire container at once. Any portion of the disinfectant you do not pour out, can remain in the original bottle for 75 days.

Always use the product in a well ventilated area. PPE is needed, but no special PPE is required.

In the event of a spill, refer to the Safety Data Sheet for the recommended neutralization agent. There are several products on the market that are recommended. The Spill Kit should be readily available in the area where the disinfectant is used and you should know where the spill kit is located.

Cidex OPA has a 5 minute high level disinfection claim but ONLY when it is used in an automated endoscope re-processor that can elevate the temperature of the solution. The 5-minute claim DOES NOT apply to Cidex OPA when it is used manually.

Trophon – is a relatively new product for high level disinfection of ultrasound probes ONLY. Only validated probes should be placed in the Trophon® EPR. Trophon achieves HLD of ultrasound probes (including shaft and handle) in 7 minutes. The probe must be pre-cleaned first. The system uses the sterilant - NanoNebulant Concentration 35%; Sonex-HL (USA/CAN)† Volume – 80 ml. It has a shelf life of 2 years. The chemical is concentrated hydrogen peroxide which provides high level disinfection of the shaft and the handle of the probe. This system has been validated to inactivate human papillomavirus.

Each cycle requires a chemical indicator. The indicator, before processing is a red/amber color which changes to a yellow color if the process was successful. At the end of the cycle, confirm successful high-level disinfection by comparing the chemical indicator disk to the color assessment chart.

There is an optional printer available which permits documentation of the cycle information.



Inside of a Trophon Unit

The Trophon EPR is **NOT** intended to reprocess single use devices nor to pre-clean ultrasound probes.

The chemical cartridges will last for approximately one month from date of installing.

Ultrasound probes are extremely delicate. They must be loaded correctly inside the unit to prevent damage to the tip of the probe. Incorrect positioning of the probe inside the unit may result in:

- High level disinfection will not be achieved during the Trophon EPR disinfection cycle.
- Excessive disinfectant residuals remaining on the probe surface.
- Damage to the probe.

Laryngoscope Handles and Blades - must be cleaned, HLD or sterilized according to the blade and the method of cleaning, disinfection or sterilization can vary with the manufacturer so it is important to confirm this information and not to assume.

If the handle or blade can be high level disinfected, you must protect the device from re-contamination after HLD. One suggestion is to place the blade or handle in a zip lock bag. Affix a label such as “HIGH LEVEL DISINFECTED” or “CLEAN NOT STERILE” affixed over the top of the bag.

Documentation of the HLD Process

Regardless of the method or chemical, for each HLD cycle, the following information should be recorded and maintained:

- the assigned lot number, AER, or soaking container identification and cycle number;
- the specific contents of the load, including quantity, department, and a description of the items;
- the patient’s name and medical record number, if available (for flexible scopes);
- the procedure, physician, and—if applicable -serial number or other identification of the item (required for all flexible scopes);
 - the shelf-life date, if applicable, the lot number, and the date that the original container of HLD was opened;

- the use-life of the open container;
- the date that the product was activated or diluted;
- the date that the activated, diluted, or ready-to-use solution was poured into a secondary container and the reuse-life of the solution;
- the exposure time and temperature, if not provided on the physical monitors;
- the date and time of cycle;
- the time, temperature, and—if applicable—chemical concentration of the exposure phase of the high-level disinfection cycle;
- the name or initials of the operator;
- the results of MRC or MEC testing, if applicable;
- any reports of low MRC or MEC testing results and action taken.

The high level disinfection records should be retained with the other sterilization records. The record retention time should be based upon the advice of your facility's attorney.

Make sure competencies for all personnel using chemicals are performed initially and annually. Retain these with your other education records.

Summary - Effective chemical disinfection requires:

- thorough pre-cleaning of the device
- proper mixing of the chemical
- proper concentration/temperature of the disinfectant
- proper documentation of the process
- proper PPE
- proper ventilation/location

REFERENCES:

AAMI, ANSI/AAMI - ST58:2013: Chemical sterilization and high-level disinfection in health care facilities.

The Basics of Sterile Processing textbook, 6th edition, Sterile Processing University, LLC.

QUIZ: HIGH LEVEL DISINFECTION - PART II

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/2017/hld2_quiz.html

Good Luck!