

Status **Active** PolicyStat ID **13066957**



Origination 04/2020  
Last Approved 02/2023  
Effective 02/2023  
Last Revised 02/2023  
Next Review 02/2026

Owner Sherie Goldbach:  
Project Coordinator  
Policy Area Infection Prevention  
Applicability UNC Medical Center

## High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices

### I. Description

This policy provides UNC Medical Center health care personnel (HCP) guidance for the cleaning and high-level disinfection (HLD) of semi-critical devices and instrument.

Non-critical and critical devices and instruments are not addressed in this policy. Please see the Infection Prevention policies: [Sterilization of Reusable Patient Care Items](#), [Cleaning and Disinfection of Non-Critical Items](#), and [Environmental Services](#).

This policy does not address reprocessing of flexible endoscopes. For policy addressing ALL flexible endoscopes, please see the Infection Prevention policy: [Endoscope](#).

### II. Rationale

HLD is the required reprocessing procedure to render many reusable semi-critical items safe for all patients and to reduce the risk of cross-transmission. High-level disinfectants (HLD) are used in healthcare to chemically disinfect reusable, medical, and dental devices to prevent healthcare-associated infections among patients.

### III. Policy

#### A. Spaulding Classification Scheme

The Spaulding classification scheme is a rational approach to disinfection and sterilization of reusable patient care equipment and/or devices. Based on the degree of infection risk involved in the use of items, the scheme divides reusable patient care items into three distinct categories: 1)

critical; 2) semi-critical; and 3) non-critical. Critical items require sterilization; semi-critical items require at least high-level disinfection unless sterilization is feasible and in alignment with the item's manufacturer's IFU; non-critical items require low level disinfection as instructed by the item's manufacturer's IFU.

In conjunction with manufacturer's IFU, refer to the Spaulding classification scheme to determine the level of reprocessing required. Please contact Infection Prevention for questions related to the Spaulding scheme and/or manufacturer IFU.

Critical Items: require sterilization	Enter/contact normally sterile tissue or the vascular system. Examples include but not limited to surgical instruments, certain catheters, implants, laparoscopes, arthroscopes.
Semi-critical Items: require at least high-level disinfection	Contact intact mucous membranes or non-intact skin. Examples include but not limited to some endoscopes, endocavitary probes, diaphragm fitting rings, laryngeal blades.
Non-critical Items: require low-level disinfection	Contact intact skin but not mucous membranes. Examples include but not limited to bed pans, blood pressure cuffs, and stethoscopes.

## B. Departmental Responsibilities

### 1. Reprocessing Department Directors, Managers, and/or Designees

- a. Ensures reprocessing activities, including cleaning, decontamination, inspection, and HLD is performed by competent and qualified personnel.
- b. Ensures access to manufacturer's IFU and/or user's manuals for devices, equipment, and supplies.
- c. Oversee compliance with policy, procedure, and IFU related to HLD reprocessing activities.
- d. Ensures all reprocessing equipment receives routine care, cleaning, and quality assurance testing in accordance with manufacturer's IFU.
- e. Verifies education, training, and competency activities are completed upon hire and annually, including Hazard Communications training for chemicals used.
- f. Ensures education and training are updated when new devices, equipment, and/or products are introduced.
- g. Ensures that breaches in reprocessing activities are reported to Infection Prevention and other appropriate leadership and investigated. A SAFE report must be completed.
- h. Ensures HCP working in reprocessing areas have appropriate protection (i.e., personal protective equipment).

- i. Ensures reprocessing department procedures are reviewed on a regular basis and as needed. Collaborate with appropriate stakeholders, including Infection Prevention, prior to any changes and before implementing new procedures.
- j. Trials and/or purchases of reusable items or equipment used for HLD are done in collaboration with Infection Prevention.
- k. Documentation records (paper logs, electronic logs, etc.) are retained for 5 years.
- l. Ensures cleaning and disinfection of reprocessing environment is performed daily and as needed with an EPA-registered disinfectant.
- m. Ensures there is a spill response kit appropriate to the HLD chemicals used and that staff are trained on spill response procedures.

## 2. Infection Prevention Department

- a. Investigates reports of inadequate HLD and addresses findings with appropriate stakeholders promptly.
- b. Maintains records of all HLD locations including HLD chemicals and equipment. Communicates list to Environmental Health and Safety and Plant Engineering.
- c. Provides consultation to clinical units and reprocessing departments for decision-making regarding cleaning, decontamination, HLD, documentation, and relevant tracking of reusable semi-critical items.
- d. Conducts routine rounds using a designated HLD tracer tool to evaluate reprocessing environments and activities. Reports findings to leadership and collaboratively addresses areas of concern to ensure safe and effective reprocessing principles.

## C. HLD Chemicals

1. Only HLD chemicals that have been approved by the Infection Prevention department may be used. See the Infection Prevention Instrument Reprocessing website for the advantages and disadvantages of each. The current approved HLD chemicals:
  - a. Cidex® ortho-phthalaldehyde (OPA)
  - b. Revital-Ox Resert®
  - c. Rapicide PA® (select automated endoscope reprocessors (AER))
  - d. Rapicide® glutaraldehyde (selecte AER only)
  - e. TD-5 (single-use, 2.65% glutaraldehyde) for the TD 100® AER

- f. Cidex OPA-C for (Evotech AER)
- g. Trophon sonex hl cartridges (proprietary disinfectant liquid with 35% hydrogen peroxide chemistry)

## D. HLD Education and Competency

### 1. Education

- a. All health care personnel (HCP) who perform HLD activities (excluding Trophon operation) are required to attend the initial HLD education as soon as possible after assignment of HLD responsibilities. Following the initial training, HCP are required to complete the HLD refresher LMS module annually.
  - HLD training and on-the-job training is performed with a competent person.
- b. All HCP who perform HLD activities using only the Trophon must complete Nanosonics Academy online Trophon training and on-the-job training with a competent person.

**NOTE: HCP only using Trophon as a means for HLD are not required to attend the initial refresher. Trophon competency is still required. HCP are required to complete the appropriate online Trophon module annually.**

### 2. Competency

- a. Includes demonstration, observation, and documentation of HLD process.
- b. Please see the Infection Prevention's [Instrument Reprocessing website](#) for the most current competency form for the HLD and Trophon processes.
- c. Competency is required upon hire and annually
  - i. Each HCP must successfully demonstrate HLD processes.
  - ii. Each HCP is observed performing HLD processes.
  - iii. Successful demonstration of the HLD processes is documented by HCP competent to perform HLD.

- 3. All HCP performing HLD and Trophon operators must take an LMS module for color blindness prior to initial competency.

## IV. Procedure

### A. Components of HLD Device/Instrument Reprocessing

#### 1. Point of Use Treatment

- a. At point of use, devices/instruments should be wiped to remove gross debris and/or blood following the manufacturer's IFU.
- b. Lumens should be flushed/suctioned according to manufacturer's IFU.
- c. Used devices and instruments should be kept moist per manufacturer's IFU until they are transported to the decontamination area (i.e., central processing department, clinic instrument reprocessing room).

#### 2. Transport of used, contaminated patient care devices/instruments:

- a. Transport used devices and instruments in a leak-resistant container marked "biohazard".
- b. Type of transport containers include, but are not limited to:
  - i. Bins/containers with lids.
  - ii. Carts should be enclosed or covered.
  - iii. Impermeable bags marked "biohazard" is appropriate if no instruments with sharp edges are being transported.

#### 3. PPE

- a. Wear appropriate PPE for all decontamination and high-level disinfection processes per chemical Safety Data Sheet requirements. PPE includes:
  - i. Fluid-resistant gown
  - ii. 12" (or longer) extended cuff nitrile gloves
  - iii. ANSI approved face shield for Splash and Droplet Protection
  - iv. ANSI approved safety glasses or chemical goggles
  - v. Environmental Health and Safety can assist in identifying appropriate PPE
  - vi. For Trophon reprocessing activities only gloves alone are required.
- b. Observers present in the instrument reprocessing rooms, should don full PPE if there is a potential for splash from decontamination or manual HLD.

- c. Remove PPE and perform hand hygiene before leaving the decontamination area

#### 4. Decontamination

- a. Manufacturer's IFU for decontamination must be followed for all instruments reprocessed.
- b. If clinical teams reports or suspects damage, the device or instrument should be removed from service, tagged "Damaged - Do Not Use", placed in a container marked biohazard, and notify leadership.
- c. Visually inspect all parts of devices/instruments for damage prior to decontamination.
- d. Measure, mix, label, dispense, and discard detergent solutions appropriately and according to manufacturer's IFU.
- e. If using an enzymatic dispensing system, it needs to be checked per the manufacturer's IFU to validate it is dispensing the correct amount.
- f. Single use brushes are preferred. Single use brushes are discarded after each use.
- g. Reusable brushes must be reprocessed after each use. Discard when worn or damaged.
- h. All brushing is performed under water to decrease the risk of splash exposure to HCP.
  - i. Ensure soak times as prescribed by detergent manufacturer's IFU.
  - j. Rinse decontaminated instruments thoroughly to remove organic material, paying special attention to lumens and/or hard-to-reach areas.
  - k. If manual HLD, dry devices/instruments thoroughly to avoid dilution of HLD chemicals.

#### 5. HLD Quality Control and Minimum Effective Concentration (MEC)

- a. Perform quality control checks using test strips and/or other manufacturer's testing materials according to manufacturer's IFU.
- b. Use techniques, including test strip management practices, timing, and frequency, according to manufacturer's IFU for the product(s) in use.
- c. Keep test strip containers completely closed at all times. Exposure to air can cause MEC test strip failures.
- d. Test strip bottles/vials must have opened and expiration dates clearly marked with an indelible felt-tipped pen. A written expiration date cannot

exceed a manufacturer's stamped expiration date.

## 6. High-level Disinfect

- a. Measure, mix, and use HLD chemicals according to manufacturer's IFU.
  - i. Soak times are according to manufacturer's IFU.
  - ii. Reusable HLD chemicals are used for the length of days allowed per manufacturer's IFU, if testing indicates the chemical meets the MEC.
- b. Contain solutions in an appropriate and compatible container and keep covered at all times.
- c. If using a secondary containers, it must be labeled:
  - i. Product name
  - ii. Hazard information (from the SDS)
  - iii. Open and expiration dates of chemicals

## 7. Final Rinses and Drying

- a. After appropriate soak time in a manual soak station, thorough and complete rinsing with tap water according to HLD chemical manufacturer IFU.
  - i. Do not reuse rinse water.
  - ii. Ensure that channels and/or lumens are adequately flushed with clean water.
- b. Ensure channels and/or lumens are flushed with 70% ethyl or isopropyl alcohol.
  - Follow alcohol flush with medical-grade forced air (instrument air) until completely dry, per the manufacturer IFU.

## 8. Documentation

- a. Use the HLD log appropriate to the HLD chemical or an approved documentation system (i.e., Censitrac). Please consult with Infection Prevention to determine what is required for your area.
- b. Keep only the current logs, (i.e., current month) within the reprocessing area. Retain all documentation for 5 years.
- c. Documentation (i.e., logs) must include the following elements:
  - i. Test/reprocessing date

- ii. HLD chemical temperature daily
- iii. Test strip lot number
- iv. Date test strips expire
- v. Test strip quality control pass or fail if required by manufacturer's IFU
- vi. Date HLD chemical expires
- vii. MEC pass or fail for every reprocessing occurrence

#### 9. Storage

- a. High-level disinfected items shall be stored in a manner that prevents recontamination (e.g., in a clean drawer covered with a clean probe cover, etc.). Consult with Infection Prevention for appropriate methods.
- b. Ideally, high-level disinfected items should not be stored in the instrument reprocessing room.

## B. Trophons<sup>®</sup>

Trophons<sup>®</sup> are automated high-level disinfectors used to HLD vaginal and rectal probes. The Trophon uses an FDA-approved hydrogen-peroxide high-level disinfectant. The Trophon does not emit any vapors, allowing point of care (POC) high-level disinfection.

1. The Trophon will be operated in accordance with the manufacturer's IFU and user's manual to include proper dating of cartridges and chemical indicators, correct storage of these items, and prescribed periodic maintenance.
2. It is important to separate clean and dirty processes to prevent cross-contamination.
  - Trophons may be placed in examinations rooms. Cross contamination can be prevented by clear designation of clean and dirty zones and processes.
3. High-level disinfected probes shall be covered with a clean pouch or probe cover with the Trophon label which documents the HLD cycle affixed.
4. Please see the Infection Prevention's [Instrument Reprocessing website](#) for the current Trophon log and competency form.

## C. Ultrasound Endocavitary Probes

1. When used on intact skin (e.g., central line puncture site, needle biopsy), the probe is considered a noncritical device and low-level disinfection with an EPA-registered disinfectant is adequate. Refer to the product manufacturer for the recommended cleaning product.



2. When used on non-intact skin or mucous membranes, the probe is considered a semi-critical device, the Infection Prevention policy: High-Level Disinfection - Manual Reprocessing of Reusable Semi-Critical Devices shall be followed. The use of an US probe cover or sheath does not preclude HLD.

## V. Definitions - See [Instrument Reprocessing Website](#)

## VI. References

Flexible and semi-rigid endoscope processing in health care facilities; Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST91: 2021.

CDC guideline for disinfection and sterilization in health-care facilities; Rutala WA, Weber DJ, and Healthcare Infection Control Advisory Committee (HICPAC). 2008. Update 2019

Multisociety guideline on reprocessing flexible GI endoscopes and accessories 2021

High-level Disinfection and Sterilization BoosterPak, 2015, The Joint Commission.

Ambulatory Surgical Center Infection Control Survey Worksheet, Center for Medicare and Medicaid Services, 2015.

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes, 2016. Retrieved 12/03/2022

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes, 2016. Retrieved 12/06/2022

## VII. Responsible for Content

Infection Prevention Department

## VIII. Related Policies

[Environmental Health and Safety Policy: Hazard Communication Program](#)

[Infection Prevention Policy: Cleaning and Disinfection of Non-Critical Items](#)

[Infection Prevention Policy: Endoscope](#)

[Infection Prevention Policy: Environmental Services](#)

[Infection Prevention Policy: Sterilization of Reusable Patient Care Items](#)

## Approval Signatures

Step Description

Approver

Date

Policy Stat Administrator	Kimberly Novak-Jones: Nurse Educator	02/2023
	Thomas Ivester: CMO/VP Medical Affairs	02/2023
	Emily Vavalle: Dir Epidemiology	02/2023
	Sherie Goldbach: Project Coordinator	01/2023

COPY