Status Active PolicyStat ID 19947051

Origination	04/2020
Last Approved	02/2026
Effective	02/2026
Last Revised	02/2026
Next Review	02/2029

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Policy Area	Infection Prevention
Applicability	UNC Medical Center

High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices (excluding ALL flexible endoscopes)

I. Description

This policy provides UNC Hospitals staff guidance for the cleaning and high-level disinfection (HLD) of semi-critical devices and instruments. High-level disinfectants are used in healthcare to chemically disinfect reusable medical and dental devices to prevent healthcare-associated infections among patients.

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 the reprocessing of flexible endoscopes. **For policy addressing ALL flexible endoscopes, please see the Infection Prevention policy: Endoscope.**

II. 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 instructions for use (MIFU); non-critical items require low-level disinfection as instructed by the item's MIFU.

In conjunction with MIFU, 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 MIFU.

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

B. Departmental Responsibilities

NOTE:	**When facing a conflict between the reusable medical device's MIFU and the accessory used for processing (e.g., detergent, disinfectant, sterilization container, sterilizer), the device drives the process; however, it is important to note that the healthcare facility is responsible for addressing the conflict by first contacting the technical services of the manufacturer of the medical device or accessory. The inquiry may be referred out to the FDA Division of Industry and Consumer Education (DICE) or the Manufacturer and User Facility Device Experience (MAUDE) database.**

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 MIFU and/or user's manuals for devices, equipment, and supplies.
    c. Oversee compliance with policy, procedure, and MIFU related to HLD reprocessing activities.
    d. Ensures all reprocessing equipment receives routine care, cleaning, and quality assurance testing in accordance with MIFU.
    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 staff 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 (e.g., paper logs, electronic logs) are retained for 5 years.

l. Ensures cleaning and disinfection of the reprocessing environment is performed daily and as needed with an EPA-registered disinfectant.

m. Ensure there is a spill response kit appropriate to the HLD chemicals used and that staff are trained in 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

- 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. Chlorine Dioxide (ClO_2) (Tristel)

b. Cidex OPA-C for (Evotech AER)

c. Cidex® ortho-phthalaldehyde (OPA)

d. Rapicide PA® (select automated endoscope reprocessors (AER))

e. Rapicide® glutaraldehyde (select AER only)

f. Revital-Ox Resert®

g. TD-5 (single-use, 2.65% glutaraldehyde) for the TD 100® AER

h. Trophon Sonex HL cartridges (proprietary disinfectant liquid with 35% hydrogen peroxide chemistry)

D. HLD Education and Competency

1. Education

    a. All staff who perform HLD activities (excluding Trophon operation and Tristel) are required to attend the initial HLD education as soon as possible after assignment of HLD responsibilities. Following the initial training, staff are required to complete the HLD refresher LMS module annually.

        - HLD training and on-the-job training are performed with a competent person.

    b. All staff who perform HLD activities using only the Trophon or only Tristel must complete product-specific training and on-the-job training with a competent person.

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. Staff must successfully demonstrate HLD processes.

        ii. Staff are observed performing HLD processes.

        iii. Successful demonstration of the HLD processes is documented by staff competent to perform HLD.

3. All staff performing HLD, Trophon, and/or Tristel must take an LMS module for color blindness prior to initial competency.

III. 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 MIFU.
    b. Lumens should be flushed/suctioned according to MIFU.
    c. Used devices and instruments should be kept moist per MIFU 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" are appropriate if no instruments with sharp edges are being transported.
3. PPE (Personal Protective Equipment)
    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 and Tristel reprocessing activities, only gloves 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. MIFU for decontamination must be followed for all instruments reprocessed.
    b. If clinical teams report or suspect 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 MIFU.
    e. If using an enzymatic dispensing system, it needs to be checked per the MIFU 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 staff.
    i. Ensure soak times as prescribed by detergent MIFU.
    j. Rinse decontaminated instruments thoroughly to remove organic material, paying special attention to lumens and/or hard-to-reach areas.
    k. If manual HLD will be undertaken on the instruments in the next step, 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 MIFU.
    b. Use techniques, including test strip management practices, timing, and frequency, according to MIFU 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. 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 MIFU.
        i. Soak times are according to MIFU.

ii. Reusable HLD chemicals are used for the length of days allowed per MIFU, 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 container, the label must contain:

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 must be completed according to HLD chemical MIFU.

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 MIFU.

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 (documented daily)

iii. Test strip lot number

iv. Date the test strips expire

v. Test strip quality control results (pass or fail) if required by MIFU

vi. Date the HLD chemical expires

vii. MEC results (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®

Trophons® 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 MIFU 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 examination 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. Tristel

Tristel ULT is a chlorine dioxide (ClO_2) foam designed specifically for the high-level disinfection of semi-critical medical devices used in ultrasound, such as transrectal and transvaginal probes, and general-purpose transducers.

1. Tristel will be used in accordance with the MIFU and user's manual.
2. It is important to separate clean and dirty processes to prevent cross-contamination.

D. 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 ultrasound probe cover or

sheath does not eliminate the need for HLD if the probe is used as a semi-critical device.

IV. Definitions - See Instrument Reprocessing Website

V. References

Shenoy ES, Weber DJ, McMullen K, et al. Multisociety guidance for sterilization and high-level disinfection. *Infection Control & Hospital Epidemiology*. 2025;46(6):561-583. doi:10.1017/ice.2025.41

VI. Responsible for Content

Infection Prevention Department

VII. 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

All Revision Dates

02/2026, 02/2023, 06/2022, 01/2022, 12/2020, 04/2020

Approval Signatures

Step Description	Approver	Date
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Applicability

UNC Medical Center