

Section: UTMB On-line Documentation	01.05 - Policy
Subject: Healthcare Epidemiology Policies and Procedures	
Topic: 01.05 Cleaning, Sterilization, High-Level Disinfection and Storage of Patient Care Devices and Other Items	4.11.14 Revised 1981 - Author

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01.05 Cleaning, Sterilization, High-Level Disinfection and Storage of Patient Care Devices and Other Items

Purpose	To provide clean and sterile supplies for patient care. To define the responsibility for cleaning, disinfecting, sterilization and storage of patient care instruments and other patient care items.
Audience	All those in the UTMB Health System who clean, disinfect, sterilize or store patient care instruments and other healthcare items.
Policy	All patient care devices and other items will be cleaned, reprocessed and stored according to these policies.
General Recommendations	<p>All objects to be disinfected or sterilized should first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue. Dedicated, non-handwashing sinks shall be used for this purpose.</p> <ul style="list-style-type: none"> • All items used in patient care shall be kept clean and in proper working condition. • All medical instruments and other items used for patient care must be cleaned and disinfected or sterilized before use on another patient. • A hospital grade disinfectant approved by the Department of Healthcare Epidemiology must be used to disinfect medical instruments and other healthcare items.
Electrical Safety	<ul style="list-style-type: none"> • Excessive moisture on electrical components can cause damage to certain instruments. Disinfectants and cleaners sprayed directly onto electrical devices may cause them to short circuit. This can also happen with excessively wet cleaning cloths. Manufacturers frequently recommend against certain types of cleaning such as steam cleaning, pressure washing, ultrasound, ethylene oxide gas, radiation, and immersion. • Please refer to the manufacturer's instructions for use of the appropriate type of disinfectant and the best method of cleaning and sterilizing each piece of medical instrumentation. (Or contact Environmental Services [EVS] at phone x. 24040, Clinical Equipment Services [CES] at x.76143 or Healthcare Epidemiology [HCE] x. 23192 if you need additional guidance on medical device cleaning technique.)

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Personnel Guidelines

- All personnel who work in Decontamination must wear PPE (personal protective equipment). Gloves, liquid-resistant gown, eye protection and a surgical mask if risk of splash or aerosols is present.
- Reusable general purpose utility gloves (i.e. rubber household gloves) and goggles or face shields should be cleaned at least daily.
- All head and facial hair (except eyebrows and eyelashes should be completely covered with a surgical type hair covering, (i.e. disposable bouffant) when packaging medical devices or equipment for sterilization.
- Jewelry and wristwatches should not be worn in Decontamination, Prep and Packaging, or Sterilization areas. PPE should be worn whenever the service person is working on or in-servicing equipment that might be contaminated or whenever the service person is in doubt about the safety of a piece of equipment.
- Before leaving the Decontamination area, PPE should be removed taking care not to contaminate skin or clothing followed by thorough hand washing.

Classification of Patient Care Items

Critical Items

- Critical medical devices that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before each use (refer to methods of sterilization and disinfection in this policy and manufacturer’s instructions for use [MFG’s IFU] for medical devices being sterilized).

Semi-critical Items

- Devices that come in contact with mucous membranes or skin that is not intact should be free of all microorganisms except for bacterial spores and are called semicritical medical devices. Intact mucous membranes are generally resistant to infection by common bacterial spores but susceptible to other organisms such as tubercle bacilli and viruses. Respiratory and anesthesia devices, endoscopes, diaphragm fitting rings and vaginal speculums are included in this category. Semicritical items require high-level disinfection using chemical disinfectants.

Non-critical Items

- Medical devices that come in contact with intact skin, but not mucous membranes only need cleaning or low-level disinfection.
- Disinfection is a process that eliminates pathogenic microorganisms on inanimate objects with the exception of bacterial spores. Chemical germicides used for disinfection should be registered with the Environmental Protection Agency (EPA). The following agents will be acceptable for disinfection provided that the manufacturer’s recommendations are followed.

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Classification of Patient Care Items (cont.)

- Ethyl or isopropyl alcohol (70%-90%)
- Quaternary ammonium germicidal detergent solution
- For routine cleaning of most noncritical items, a quaternary ammonium germicidal detergent is available. Most of the noncritical items can be cleaned with this product between patients and when soiled.

Return of Equipment to CES

- Equipment belonging to CES will be returned from the patient care area to CES when the patient is discharged.
- The CES technician will perform hand hygiene, don gloves and do a surface clean of the equipment prior to transport.
- After the surface is cleaned, the CES technician will remove the gloves and perform hand hygiene. Then the equipment may be transported to the department.

Decontamination and Transporting

- Cleaning and decontamination should begin as soon as possible after use as blood and body fluids can cause pitting of instruments and if left to dry can be difficult to remove. Surgery should pre-clean instruments to remove gross soil immediately after use.
- When transport to the decontamination area is going to be delayed, soiled instruments should be moistened with a wet towel or enzymatic solution.
- Transporting instruments from surgery to the Decontamination area should be done in containers that prevent damage and/or spillage; such as, bins with lids, impermeable bags, enclosed or covered carts, and closed rigid sterilization containers. Do not transport instruments in terry cloth towels, pillow cases or any material that will allow leakage.
- Decontamination and packaging should not be performed in patient care areas.
- Non-Critical items (i.e. beds, monitoring equipment, IV poles, etc.) may be cleaned in an area designated for dirty equipment or in non-patient care areas.

Cleaning and Other Decontamination Processes

- Once in sterile processing, the instruments will be inspected. If there are grossly soiled instruments, the Sterile Processing Manager will be notified, the tray will be tracked, and the OR team responsible for pre-cleaning instruments will be reported to the Charge Nurse.
- All instruments that are grossly soiled will be soaked in water with enzymatic solution (follow MFG's IFU for appropriate soaking time) and thoroughly brushed.
- If the instruments have a channel (cannulated), the channel must be irrigated with enzyme cleaner diluted according to MFG's IFU and brushed until all visible body fluids are removed.
- Instruments must be disassembled and with hinges opened and sprayed with

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an enzymatic solution.

- Each cannulated instrument, if needed, will be connected to an irrigation hose with the appropriate sizing and placed in the ultrasonic washer with an enzymatic solution. The cycle will run at 140 degrees F, for 8 minutes. All channels will then be brushed and flushed until fluid runs clear. The procedure will be repeated if needed.
- The instruments will be placed in the Washer/Disinfector for final cleaning (refer to Manufacturer's [MFG's] validated Instructions for Use [IFU] for the specific Washer/Disinfector) prior to proceeding to Prep and Pack for inspection and assembly before sterilization. If any instruments remain soiled, they will be returned to the decontamination area for the cleaning process to be repeated.
- Multi-part instruments should be disassembled for decontamination unless the instrument MFG has provided validated IFU to the contrary.
- When decontaminating each medical device, follow the MFG's validated IFU.
- When manually cleaning, wash below the water line surface to reduce aerosols.
- Abrasive cleaning compounds (scouring pads) or metal brushes should not be used unless specified in the device MFG's IFU.
- Brushes and other cleaning supplies, if reusable, should be decontaminated after each use.
- Mechanical cleaners should be used whenever possible and are available, (i.e. ultrasonic cleaners, utensil washers, washer-sanitizers, washer-disinfectors and cart washers).
- Ultrasonic cleaners should only be used for fine cleaning to remove soil from joints, crevices, lumens and other difficult to clean areas. The cleaning solution should be changed before it becomes heavily soiled and all items thoroughly rinsed afterwards to remove loose debris and residual detergent.
- Regardless of manual or mechanical cleaning, use warm water (do not exceed 140°F/60°C. Use appropriate detergent.
- Rinse all instruments thoroughly to remove loose debris and detergent residue using tap or treated water as indicated by the device MFG's IFU.

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Packaging
Supplies to be
Sterilized

- Hair covering should be worn in the packaging area.
- Inspect each instrument for cleanliness and function.
- If soil is observed on any instrument, personnel should return the dirty instrument to Decontamination and then wash their hands. Never clean a dirty instrument on the clean side as this is an OSHA violation.
- Instruments should be sorted by size and type, without dumping (turning trays over) or clumping (grabbing hands full of instruments)
- Multi-part instruments should be disassembled for sterilization unless the instrument manufacturer has provided validated IFU to the contrary.
- Instruments in disrepair should be tagged or labeled and taken out of service until repaired.
- Stylets or plugs should be removed from instruments with lumens, such as catheters, needles and tubing. For gravity displacement steam sterilizers, such devices may need to be flushed with distilled or deionized water before they are packaged.
- The weight of an instrument tray should not exceed 25 pounds, including the containment devices, wrapper and/or rigid sterilization container.
- Follow the validated drying times provided by the device MFG's IFU.
- Do not place count sheets inside trays unless validated for safety.
- Packaging must withstand the physical conditions of the sterilization process chosen for the device.
- Packaging must allow for adequate air removal.
- Packaging must be easily penetrated by the sterilant.
- Packaging must allow adequate removal of the sterilant.
- Packaging must be a reliable barrier to dust particles that carry microorganisms.
- It must be possible to seal the packaging in such a way that tampering will be evident.
- Packaging must adapt to the size and shape of the item to be packaged.
- Packaging must resist tearing and puncturing under ordinary conditions of use.

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- Packaging must protect the package contents from physical damage.
- Packaging must allow aseptic removal of the contents.
- Use peel pouches for small, lightweight instruments and place on edge in the sterilizer.
- Double pouching may be acceptable. Confirm that your pouch supplier has validated double pouching.
- Place inside pouch paper to align (match) with the outside pouch paper.
- Do not fold inside pouch.
- Do not use peel pouches made of paper/plastic inside wrapped trays or rigid containers.
- Verify that tape used to secure wrapped items is latex-free for staff or patients who are latex sensitive.
- Newly purchased rigid containers should be cleaned and disinfected per the MFG's validated IFU before initial use and after each sterilization cycle.
- Inspect rigid containers. Verify that gaskets are free of breaks, cracks, or cuts, filters are held in place securely, locks secure the lid, tamper evident valves function properly and move freely, and that rivets or screws are secure and there is no damage or signs of corrosion.
- Confirm which sterilization process and cycles for which your rigid sterilization container system may not be validated.
- For those departments who package their own items, physical barriers should separate the decontamination area from the packing area.
- Refer to AAMI ST79 for guidelines for Packaging

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Guides for Sterilization

- Sterilization is the elimination or destruction of all forms of microbial life. Sterilization may be accomplished in any of the following ways:
 - Stream sterilization
 - Hydrogen peroxide gas plasma sterilization (Sterrad)
 - Peracetic Acid sterilization (Steris)
- Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable.
- Steam is recommended as the sterilization process of choice whenever possible.
 - Always load steam sterilizers with light items on top and heavier items on the bottom.
 - Peel pouches, linen packs and solid bottom instrument trays or basins, should be placed on edge to facilitate sterilization and drying.
 - Instrument sets with wire or mesh bottoms should be placed flat.
 - *Note: It is important not to overload the sterilizer as this can cause wet packs and/or sterilization failure.*
 - Steam sterilizers are available with different modes, such as; Gravity displacement or Dynamic air removal (prevacuum or steam flush pressure pulse).
 - Depending on the instruments processed, one or more of these modes can be used with cycle exposure time, dry time, and temperature validated and listed in the device MFG's IFU. See Table 1 for minimum cycle times for dynamic air removal steam sterilization cycles.
 - Some complex devices may require much longer cycle times. Always consult the instrument MFG's IFU to confirm the sterilizer mode and cycle parameters. If these parameters cannot be met, do not process the instrument as sterility cannot be assured.

Guides for Cooling After Steam Sterilization

- When removing processed loads from a sterilizer, it is important to place the items in a holding area with minimal traffic. Do not place items near air vents or fans as air currents can cause condensate to form. Items should remain on the sterilizer cart until adequately cooled. For steam processed items, a minimum of 30 minutes is recommended, although heavier trays will take longer. The room temperature at which sterilized items cool should be 78°F/26°C. Inexpensive temperature laser pens can be used to verify pack temperature prior to handling. All personnel should be trained to minimize handling of sterile items. All packages should be visually inspected for tears and wetness with dropped items returned to Decontamination for reprocessing. Items that are torn, damaged or wet should be considered contaminated and not used.

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Immediate-Use
Steam
Sterilization

- Immediate-Use Steam Sterilization (IUSS), formerly known as flash sterilization, should only be used in carefully selected clinical situations (i.e. instrument needed for case falls on the floor and no replacement instrument is available.) IUSS should not be used due to inadequate inventory.
- Immediate implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants.
- The following process must be used for each item that is sterilized for immediate use.
 - The item must be thoroughly cleaned including the lumen, if present, so that it is free of all foreign substances.
 - The item must be sterilized in a container that permits penetration of steam and which can be used to safely transfer the sterilized item to the operating room
 - Each load must be monitored by physical/chemical indicators.
 - The item must be sterilized at an exposure time and temperature that reliably kills microorganisms. (See table 1.)
 - Personnel must be formally trained for immediate use sterilization.
 - A record must be kept on every item subjected to immediate use sterilization.
 - Item sterilized
 - Patient’s name and UH#
 - Results of physical/chemical indicators
 - Sterilizer parameters (time, temperature)
- A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.
- Immediate-use sterilization should NOT be performed on the following devices:
 - Implants, except in a documented emergency situation when no other option is available
 - Post procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders. Please see AAMI ST79, to Annexes C for Processing CJD-contaminated patient care equipment and environmental surfaces.
 - Devices or loads that have not been validated with the specific cycle employed.
 - See Table 2 for immediate use (formerly flash) sterilization cycle times.

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Table 1 – Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying Times
Wrapped instruments	4 minutes		20-30 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5-20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
Unwrapped nonporous items (e.g., instruments)	3 minutes	3 minutes	NA
Unwrapped non porous and porous items in mixed load	4 minutes	3 minutes	NA

Gas Plasma Sterilization

- Gas plasma sterilization (radio frequencies are used to create hydrogen peroxide vapor) (Sterrad).
Gas plasma is an acceptable method for sterilization. It requires no aeration time and the end products are not toxic. It cannot be used with cellulose or linen and cannot be used for instruments with very small lumens.

Labeling Packages for Sterilization

- Packages must be labeled correctly and completely. The contents of packages must be identified before the packages are opened.
- The label information should include:
 - Date of cycle
 - Identification of the sterilizer and cycle
 - Description of the contents if not visible
 - Technician’s initials
- For tape-secured packages that are hand-labeled, felt-tip, indelible-ink markers may be used to record the necessary information on the tape. Do not write on the wrapper material. Indelible-ink is necessary so that the marking will not run or fade. Felt-tip indelible-ink markers (Sharpie 13601) may also be used on pouches. For paper/plastic pouches, the label must be on the clear/plastic side. Writing on the paper side may damage the material, and the ink may bleed through and contaminate the package contents.
- All packages must be labeled prior to sterilization.

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Sterilization
Process
Monitoring
Recommendations

- Every sterilization load should:
 - Be physically-monitored for time, temperature, and pressure. Before items are removed from the sterilizer, check printout to verify that all cycle parameters were met and initial the printout.
 - Contain an External and an Internal Chemical Indicator (CI), except for packages that allow visual inspection of an internal indicator such as those with paper-plastic packaging.
- External CIs should be placed on the outside of the packaging material. They may be used as a form of closure for the package such as indicator tape. If the external CI does not demonstrate or show that the package has been in the autoclave, it should be reported to the manager/director of the Sterile Processing Department with the load control number.
See Actions for Sterilization Process Failure below.
- An internal CI should be placed in the center of the package in the center of the tray when sterilizing. If the internal CI does not indicate that the item has been sterilized, it should be reported with the load control number to the Manager/Director of the Sterile Processing Department.
- Bowie-Dick-type indicators for routine sterilizer testing (dynamic-air-removal sterilizers only) should be run, within a PCD, each day, in an empty sterilizer before the first processed load. Bowie-Dick-type indicators for sterilizer qualifications testing (dynamic-air-removal sterilizers only) should be run within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; the test should be run three times consecutively in an empty chamber after Biological Indicator (BI) tests.
See Actions for Sterilization Process Failure below.
- Process Challenge Devices (PCDs) (BI challenge test packs) formerly known as test packs shall be used during initial installation testing of steam sterilizers and dynamic air-removal sterilizers and after any major repairs of the sterilizer. A BI PCD using *Geobacillus stearothermophilus* shall be used routinely **once each day** on all steam sterilizers (i.e., gravity-displacement, pre-vacuum). Each load containing implantable devices shall be biologically monitored and the implantable device shall be quarantined until the results of the BI test are available.
- A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. A PCD may be a user assembled challenge test pack or test tray or a commercially available, disposable, preassembled challenge test pack.
- The PCD is placed in the portion of the sterilizer where it is most difficult to sterilize items. For steam sterilizers, the “cold point” is usually on the bottom shelf of the sterilizer, directly above the chamber drain. Hydrogen peroxide plasma sterilizers use *Bacillus subtilis* as a BI. Peracetic Acid sterilization uses *Geobacillus stearothermophilus* as a BI. See Sterile Processing policy for

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perioperative nursing: Monitoring of the Sterilization Process.

- Release criteria for implants
 - Place a BI and a Class 5 integrating CI in each load containing an implant.
 - The latter indicators should be placed in the load in the appropriate location as described above.
 - Place an external CI on and an internal CI in each package.
 - Monitor each load physically (time, temperature, pressure)
 - Quarantine each implant until the BI is negative
 - Release loads only if the criteria for release are present.
- For each sterilization cycle, the following information should be recorded and maintained.
 - lot number
 - contents of load
 - exposure time and temperature if not on a recording chart
 - operator identification
 - results of BI testing
 - results of CI and the BI challenge test pack,
 - results of Bowie-Dick testing
 - any reports of inconclusive or nonresponsive CIs in the load
 - If cause of failure is not immediately identified, the following shall take place (use flow chart to help determine problem (Figure)).
- When any internal or external CIs fail to indicate sterilization or positive BI results (other than viability controls)the following steps must be taken::
 - Pull the load printout sheet, inspect printout for appropriate time and temperature parameters
 - If parameters were not met, retest the sterilizer with BI with the next load
 - Hold both loads pending results of 2nd BI
 - If 2nd BI test positive, tag the sterilizer as “out of service” and immediately report by phone or messenger to the appropriate supervisor. This notification shall be followed by a written report
 - See Appendix 1 for failed run report at the end of this document
- If the biological indicator is of the type that can be cultured it shall be sent to the microbiology laboratory for presumptive identification of the microorganism present on the positive biological indicator test.
- The Program Manager of Sterile Processing with representation from the Physical Plant Department or qualified contract personnel shall attempt to determine the cause of sterilization failure and arrange for corrective action.
- After the cause of the sterilization failure is determined and corrected, the

Actions for
Sterilization
Process Failure

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sterilizer in question shall be immediately rechallenged with a biological indicator PCD. Until the results of retesting are satisfactory, the performance of the sterilizer shall be considered to be in question.

- Sterilization failure shall be substantiated by laboratory confirmed positive biological indicator tests, verification of proper testing techniques by personnel, and confirmation by Physical Plant or qualified contract personnel that a mechanical failure did occur. At this time, materials processed in that sterilization cycle since the last negative biological indicator shall be considered non-sterile. These items shall be retrieved, if possible, and reprocessed.
- Any other information that may be useful in determining whether the report is valid or is questionable due to human error shall be documented.

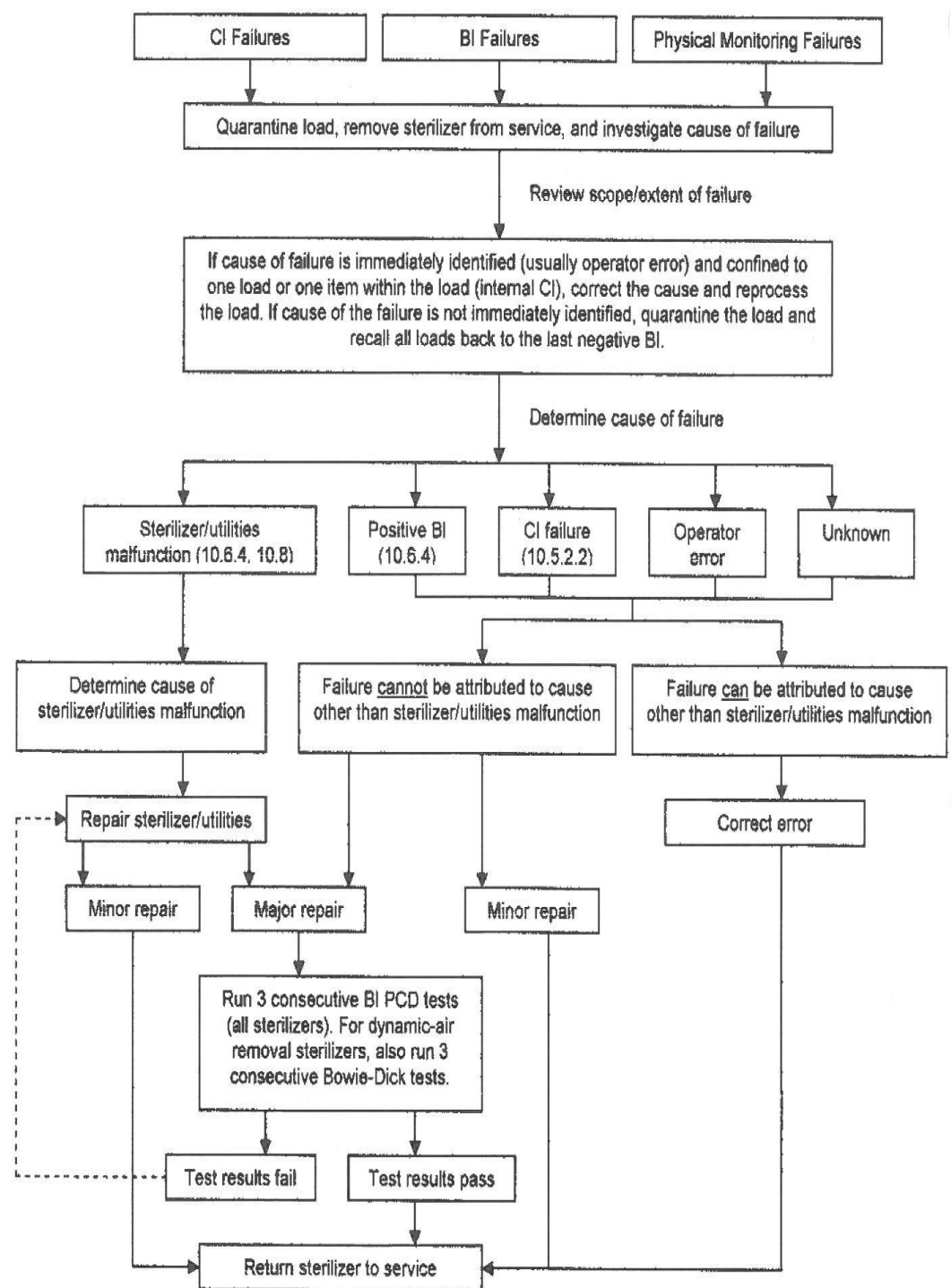


Figure – Decision tree for conducting investigations of steam sterilization process failures

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Special Considerations for Table-Top Steam Sterilizers

- A table-top steam sterilizer is defined by the Association for the Advancement of Medical Instrumentation (AAMI) as a “compact steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user.”
- Each day the sterilizer is used, check to make sure there is enough water in the sterilizer reservoir for the number of loads to be processed.
- Table-top steam sterilizers must have recording devices to monitor and provide a read out for time, temperature and pressures during the time that a sterilizer is in operation, i.e. sterilizing a load.
- Keep clear when the M9/M11 door is ready to be opened.
- Do not attempt to open the M9/M11 door until steam dissipates.
- Allow instruments to cool on tray/shelf inside the sterilizer.
- **Chemical Indicators (CI)**
 - An internal CI must be placed within each package, tray or rigid container system to be sterilized. The CI should be a Class 5 integrating indicator. The CI should be placed in the area of the package, tray or container system considered to be least accessible to steam penetration.
 - The CI result for each run should always be recorded
 - External CIs (Exposure Control) identify processed medical devices from unprocessed medical devices at a glance. These indicators should be placed on the outside of each package unless the internal chemical indicator is visible, e.g. peel pouches.
- **Biological Indicators (BI)**
 - BIs are the only indicators that directly measure the lethality of the process.
 - A BI must be used every day the sterilizer is in use.
- Choose the appropriate BI for each type of sterilization mode or cycle that will be used. See the BI/CI log at the end of this document for more information (Appendix 2).
- BIs shall be handled and used according to the manufacturer’s instructions and in accordance with the type of sterilizer being monitored.
- BIs that are positive shall be discarded as medical waste.

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- Place the BI in the area of the load determined to create the greatest challenge to air removal and sterilant penetration and in the coldest area of the sterilizer chamber as determined by the sterilizer manufacturer.
 - After the sterilizer cycle, incubate the BI test and control vials (Note: the control vial must be from the same lot # as the processed BI). Label the control for the BI with a “C” and date. Read and record the results.
 - Record the results for the BI.
 - Release the load if the monitoring results are correct.
- Process Challenge Devices (PCDs) containing a BI, formerly known as BI challenge test packs, shall be used during initial installation of table-top sterilizers and after any major repairs of table-top sterilizers (See Table 3). PCD containing a BI using *Geobacillus stearothermophilus* shall be used **weekly** on gravity-displaced steam sterilizers. Each load containing implantable devices shall be biologically monitored and the implantable device shall be quarantined until the results of the biological indicator test are available.
- A PCD shall be constructed according to the type of sterilization cycle selected. A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. For table-top sterilizers there are no commercially available PCDs. They must be user assembled.
- The PCD is placed in the portion of the sterilizer where it is most difficult to sterilize items. For steam sterilizers, the “cold point” is usually on the bottom shelf of the sterilizer, directly above the chamber drain.
- Label each item or pack with a “lot control identifier” to be used in the event of a recall, to trace problems such as wet packs to their source and to facilitate proper stock rotation.
 - The “lot control identifier” should include the sterilizer number, the cycle number and the date of sterilization.
- Records on cycle parameters must be kept for each sterilization cycle.
 - lot number
 - contents of load
 - exposure time and temperature if not on a recording chart
 - operator identification
 - results of BI testing
 - results of CI and the BI challenge test pack
 - any reports of inconclusive or nonresponsive CIs in the load
 - Refer to actions for sterilization process failures on Figure 1 if CI or BI fail, and the reason for failure cannot be determined.
 - If the operator can determine the reason for failure, correct problem and reprocess instruments.

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**Table 2:
Immediate Use Sterilization**

Type of Sterilizer	Load Configuration	Temperature, Time
Gravity displacement	Nonporous items only (metal, no lumens)	132°C, 3m
	Nonporous and porous (rubber, plastic, lumens)	132°C, 10m
Prevacuum	Nonporous items only	132°C, 3m
	Nonporous and porous	132°C, 4m

Maintenance for M-9-M-11 Table-Top Sterilizers

- See Table 4 for maintenance requirements.

Table-Top Qualification Testing

- Qualification testing should be completed after installation, relocation, malfunction, major repairs and sterilization process failures.
- Qualification testing is accomplished by 3 consecutive cycles in a fully loaded chamber with a PCD containing a BI (the PCD may also contain a CI).
- Document results of qualification testing on biological indicator log. (Appendix 2)

TABLE 3: BI PCDs for Qualification and Routine Sterilizer Efficacy Testing of Table-Top Steam Sterilizers

Program/Load	Temperature	Time*	BI PCD (Challenge or Test Pack)
Unwrapped instruments on a tray or glassware	270°F-274°F (132°C-135°C)	≥ 3 min	BI in unwrapped instrument tray or glassware
Wrapped trays of instruments, instruments in peel pouches	270°F-274°F (132°C-135°C)	≥ 5 min	Bi in wrapped tray or peel pouch and include porous items if applicable
Packs, wrapped	250°F (121°C)	≥ 30 min	BI in wrapped pack that is representative of the load, include porous items if appropriate
Liquids	250°F (121°C)	≥ 15 min	BI suspended above a test container of the liquid

**Check with the medical device or sterilizer manufacturer for correct times for the items being processed.*

Guidelines for High-Level Disinfection

- For those departments that perform high-level disinfection with chemicals, the area for reprocessing should be separated from the area where items are stored. If only two sinks other than the handwashing sink are available, one should be designated “clean” and the other “dirty”.

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- Disinfectants used for high level disinfection include **Cidex[®] glutaraldehyde 2.4% and Cidex[®] ortho-phthalaldehyde (OPA)**. The former product has been largely replaced by Cidex[®] OPA. OPA does not irritate the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor and requires no activation. It will stain proteins grey and must be thoroughly rinsed to prevent discoloration of the patient's skin and inflammation of mucous membranes.
- Cidex[®] OPA solution should be stored in its original sealed container at controlled room temperature 15-30°C (59-86°F) in a well-ventilated, low traffic area. The expiration date of the Cidex[®] OPA solution is found on the original container as received from the manufacturer. Once opened the unused portion of the solution may be stored in the original container for up to **75 days** until used. Calculate 75 days from when the original container was opened and record this date on the bottle. Verify that the expiration date on the original container is longer than 75 days.
- Reprocessing should be performed away from patient care areas, and the area should be well-ventilated. The area must have sufficient air changes to prevent build up of vapor. Healthcare workers who process instruments in Cidex[®] OPA or Cidex[®] glutaraldehyde must wear PPE including face shield, fluid-resistant gown and gloves. If latex gloves are used, don 2 pair of gloves. A single pair of gloves may be used if made from 100% synthetic copolymer, nitrile rubber or butyl rubber.
- Noxious levels of glutaraldehyde vapor are determined by detection badges worn by personnel working in the area. OPA requires no monitoring badges. Monitoring for concentrations of glutaraldehyde vapor is overseen by the Department of Environmental Health and Safety.
- The bucket and tray systems used for OPA disinfection must be made from polypropylene, acrylonitrile-butadiene-styrene, polyethylene, glass-filled polypropylene and/or polycarbonate plastics.
- Prior to placement of instruments into the disinfectant solution, they must be thoroughly cleaned with a suitable detergent by brushing the surfaces to remove all blood, body fluids, tissue and any other foreign matter. Hinged instruments must be opened to permit thorough removal of all organic material. Lumens in instruments must be thoroughly brushed and irrigated until clean.
- The soaking bucket or tray containing Glutaraldehyde 2.4% or OPA solution must be labeled with name of the solution, date of first use, and date of expiration. The instruments must be fully immersed, hinged instruments opened, instrument lumens filled with disinfectant and the cover closed. High-level disinfection requires a **45 minute** soak time for glutaraldehyde and **12 minutes** for OPA.
- Glutaraldehyde 2.4% and OPA solutions must be monitored with a chemical test strip and results documented each time the solution is used.
- See Attachments for Soaking & Monitoring Instructions.

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- Urology Instruments
- OPA must not be used to process any urological instruments used to treat patients with a history of bladder cancer.
 - Cidex[®] glutaraldehyde should be used to process urological instruments intended for use in patients with a history of bladder cancer.
 - However, woven Filiforms and Followers must be soaked in Cidex[®] OPA. They may NOT be soaked in Cidex[®] glutaraldehyde.
 - Transducers used for puncture or intraoperative procedures.
 - These procedures are classified by the CDC and the RKI as critical. Ideally, they require transducers and reusable puncture attachments to be cleaned immediately and then sterilized.
 - If a device cannot withstand being sterilized, the FDA in the USA and the RKI in Germany recognize that disinfection (in the USA, high-level disinfection) and the use of a sterile gel and a sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for ultrasound transducers (4, 6). All puncture attachments must be steam-sterilized (autoclaved) before use unless they are supplied sterile.

- Storage and Transportation of Patient Care Medical Devices and Other Patient Care Items After Sterilization or High Level Disinfection
- Sterile Items
- Sterile items should be stored in a manner that will reduce the potential for contamination.
 - Room temperature should be approximately 24°C (75°F).
 - The room(s) should have at least 4 air exchanges per hour.
 - Humidity should be controlled so that it does not exceed 70%.
 - Traffic should be controlled and access limited to those individuals who have been trained in the proper handling of sterile items.
 - Sterile items should be stored in a manner that will permit adequate air circulation and permit thorough cleaning of the storage space. Items should be stored at least 8 to 10 inches above the floor, 18 inches below the ceiling and at least 2 inches from outside walls.
 - Items should be positioned to prevent crushing, compression, bending or puncture.
 - Sterile items should not be stored next to or under sinks or under exposed water or sewer pipes.
 - Sterile supplies should not be stored on floors, window sills or in areas other than designated shelving, counters or carts.
 - Outside shipping containers, (corrugated cardboard cartons) should not be used as containers in sterile storage areas.
 - The shelf life of packaged sterile items is event-related. Sterile items in storage should be rotated based on “first in, first out”. Sterile packages should be carefully inspected to identify any damage to the integrity of the packaging materials before the items are used.

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High Level Disinfected Items

- Endoscopes
 - After high level disinfection, the channels in endoscopes should be rinsed with alcohol (minimum of 70%) and dried with compressed air.
 - Processed endoscopes should be stored by hanging them in the vertical position in a clean area, preferably in a cabinet.
- Other items should be placed in clean packages or wrapped in clean cloth wraps and stored on a clean shelf or in a clean drawer.

Off-Site
Transportation of
Sterile Items

Off-site transportation from SPD on the UTMB campus to the hospital/clinics will be carried out using closed containers, and closed containers will be used for items being returned to SPD.

References

1. Rutala WA, Weber DJ. Selection and Use of Disinfectants in Healthcare, In Mayhall, CG, Ed. Hospital Epidemiology & Infection Control. Fourth Edition, Lippincott Williams and Wilkins, 2012.
2. Association for the Advancement of Medical Instrumentation. Quality Control 2010;10:97-136.
3. Young M. Quality control of table-top steam sterilizers. Managing Infection Control 2007;82-97.

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Table 4

Autoclave Maintenance M9 & M11

REQUIREMENTS:

Daily:

Page 25 of Manuf. Installation & Operation Guide.

For midmark modles, instructions are available at www.midmark.com or 1-800-MIDMARK

Plseas initial box on Process Monitor Documentation for Table-top

Gravity Filled Steam Steralizers Log indicating that daily cleaning was completed.

- 1 Clean exterior surfaces
- 2 Clean sterilizer door gasket
- 3 Drain water from resevoir daily if using MILK to lubercate instruments.

Note: this only needs to be done daily if clinic is using MILK to lubricate instruments daily as part of their reprocessing procedure. The weekly draining of reservoir as part of Speed-Clean remains the same see below under weekly maintenance.

Weekly:

Document date of performance below

Page 26 of Manuf. Installation & Operation Guide or Quick Reference Guide

- 1 Drain water from reservoir using drain tube located on front of unit.
- 2 Clean trays, door gasket, metal surfaces and inside of chamber with Speed-Clean and distilled water
- 3 Inspect door gasket for damage that could prevent proper sealing.
- 3 Refill reservoir with distilled water.

Weekly Cleaning Date:

Monthly:

Document date of performance below.

Page 26, 27 & 28 of Manuf. Installation & Operation Guide or Quick Reference Guide

- 1 Run Speed-Clean per instructions in Installation & Operation Guide
 - 2 Remove door gasket, dam gasket and gasket ring. Clean with Speed-Clean and distilled water
 - 2 Clean Fill/Vent and Air Filter Screens
- Wipe out the inside of chamber using care not to damage the heating element, steam
- 3 temperature probe or level sensor probe
 - 4 Perform Pressure Relief Valve Check

Monthly Cleaning Date:

Appendix 2



Process Monitor Documentation for Table-top Gravity Filled Steam Sterilizers
3M Attest Biological Indicator Documentation and Chemical Indicator Documentation

- 1) Run CI with each package. CI must be used on the outside and on the inside of all items in the load, unless the internal CI is visible.
- 2) Test one Sterilized and one Non-Sterilized biological indicator each day sterilizer is in use according to manufacturer's insert.
- 3) Clean the steam sterilizer according to manufacturer's instructions.
- 4) FAX THE STEAM STERILIZER BIOLOGICAL INDICATOR RECORD LOG TO HCE (FAX 772-2337) OR SCAN VIA COPIER TO mmguigne@utmb.edu EACH MONTH even if the machine was not in use. Please document when the steam sterilizer was not in use on the log. (i.e. 10/10 through 10/14 or 10/10, 10/11 and 10/12)
- 5) Please indicate on Log which sterilizer was used (i.e. #1, #2, with labels on the sterilizers to match).

Clinic Name: _____

NOTE: IF TEST FAILS, REPEAT USING NEW INDICATORS. IF TEST FAILS ON REPEAT, QUARANTINE ALL DEVICES, STERILIZED THE DAY OF THE FAILED RUN. Notify CES and HCE immediately. Complete & fax a "Failed Run" form.

Preprogrammed Sterilization Cycle Name	Run Date	Load #	Sterilizer	Load Contents	Chemical Indicator Lot #	Biological Indicator A tests™ 1262 (48hr visual color readout M&M 40132) for 250°F/121°C & 270°F/132°C					Daily clean-wipe out
						Date/Time In Initials	Date/Time Out Initials	BI Indicator Lot No.	Sterilized Indicator		
					Result	Brown strip on label? (Y/N)	Purple Soln? (Y/N)	Rose strip on label? (Y/N)	Yellow Soln? (Y/N)	Read by (Initials)	
Load Information New M9 & M11 (came out July 2003) Pouch Cycle 270°C for 5 minutes Old M9 & M11 (manufactured through June 2003) Pouch Cycle 270°C for 15 minutes New and Old M9 & M11 Wrapped Cycle 250°C for 30 minutes					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						
					Accept						
					Reject						

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QUALITY CONTROL PROCEDURE FOR CIDEX® OPA TEST STRIPS

Processing Steps:	Check (✓)	Comments/follow-up
STORAGE AND USE OF OPA TEST STRIPS		
CIDEX® OPA TEST STRIPS must be discarded 90 days after the bottle is opened <u>or</u> on the expiration date of the bottle, whichever comes first.		
The test strip bottle must not be left open for more than 30 minutes.		
Keep the bottle tightly closed after removing the test strip.		
Do not refrigerate or freeze the bottle of test strips		
Protect the strips from heat, light and moisture		
PREPARATION OF CONTROL SOLUTIONS		
Use full strength CIDEX® OPA Solution as a positive control.		
To prepare a negative control, dilute 1 part CIDEX® OPA Solution with 1 part of water.		
TESTING PROCEDURE		
Submerge 3 test strips in each freshly prepared solution for 1 second each.		
Remove.		
The 3 strips dipped in full strength positive control solution should exhibit a complete purple color on the indicating pad at 90 seconds.		
The 3 strips dipped in the diluted negative control solution should either remain completely blue or exhibit an incomplete color change to purple at 90 seconds.		
Refer to the color chart on the test strip bottle for interpretation of results.		
TESTING FREQUENCY		
The testing of positive and negative controls should be performed on each newly opened bottle of CIDEX® OPA Solution Test Strips.		
Testing of freshly prepared positive and negative controls should be performed when test strips are improperly stored or handled.		
UNSATISFACTORY QC TEST PERFORMANCE		
If the results obtained from using positive and negative controls indicate the test strip is not functioning properly, discard strips.		
DO NOT USE STRIPS.		

Surveyor's Name: _____

Survey Date: _____

Surveyed HCW's Initials: _____

Surveyed Area: _____

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CIDEX® OPA TEST STRIPS QUALITY CONTROL LOG

Location/Department: _____

Purpose: Document performing quality control of the Cidex® OPA Quality Control strips when a new bottle of strips is opened.

Definitions:

- ^a **Expiration date** is printed on the label by the manufacturer
- ^b **Discard date** is calculated by adding 90 days to the open date of the strips
- ^c **Quality control** means both positive and negative controls are performed each time a new bottle of QC strips is opened.

Procedure to Prepare the Positive & Negative Controls: POSITIVE Control - use full strength, activated Cidex® OPA (30 ml); NEGATIVE Control is one part activated Cidex® OPA (15 ml) and one part water (15 ml). Timing is critical. Insert **3** strips into each of the two control solutions for **(1) second**. Remove excess solution by standing up the strips. Read results in exactly ninety **(90) seconds**.

Controls Results: To "PASS" on the positive controls, the dipped QC strip(s) must turn **purple**; if any blue appears on indicating pad apart from the top line, the solution did not pass ("FAILS"); to "PASS" on the negative controls, the strip color is blue or blue/purple.

***Corrective Action Key:** use the following key to denote action if either control did not pass:

- D:** Cidex® OPA Solution Test Strips discarded today because test failed;
- D1:** Cidex® OPA Solution Test Strips discarded today because bottle was left open;
- D2:** Cidex® OPA Solution Test Strips discarded today because bottle was not dated when opened.

Test Date Year _____	Cidex® OPA Solution Lot# and Manufacturer ^a Expiration Date	Cidex® OPA Strips Lot# and Manufacturer ^a Expiration Date	Cidex® OPA Strips: Date Opened and Calculated ^b Discard Date	^c Positive Quality Controls All 3 results:(Pass/Fail) Pass = only purple color	^c Negative Quality Controls All 3 results:(Pass/Fail) Pass = Blue or blue/purple	Print Employee Name performing Quality Controls	*Corrective Action Key (use reverse side for comments)
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				

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**PROTOCOL FOR HIGH-LEVEL DISINFECTION
CIDEX® OPA**

Processing Steps:	Check (✓)	Comments/follow-up
CIDEX® OPA CONTAINER		
Label with chemical name (if not official Cidex container).		
Cover fluid at all times.		
MSDS sheets for Cidex® OPA should be easily accessible.		
Label container with expiration date and initial each time the chemical is changed.		
Cidex® OPA must be discarded at 14 days even if the OPA Test Strips indicate that there is a minimally effective concentration (MEC) in the Cidex® OPA solution.		
TEST STRIPS		
Date bottle of test strips when opened (expiration at 90 days or the expiration date on the bottle of test strips, whichever comes first).		
Cidex® OPA must be tested EACH TIME when medical instruments are reprocessed.		
Dip test strip into solution for 1 second . Do not shake strip after removal. Remove excess solution from the pad by standing the strip upright on a paper towel.		
Read the results of the chemical reaction 90 seconds after the test strip has been removed from the solution. The entire indicating pad must be completely purple to pass the test indicating an effective concentration of the solution. Compare this color reaction to the color chart on the side of the test strip bottle. If any blue appears on the indicating pad apart from the top line, this is a failure, verifying the solution is below the MEC and should be discarded.		
Document the results of the test strip.		
If the color of the test strip matches the "fail" panel on the color chart: <ul style="list-style-type: none"> ▶ Check the test strips expiration date. If the test strips are out of date, discard and retest with new strips. ▶ If test strips are in-date, discard solution, rinse out container, and refill with fresh solution. Retest new solution and document test results. 		
SOAKING IN CIDEX® OPA		
Cidex® OPA is a high-level disinfectant. Do not soak instruments in Cidex® OPA prior to steam or plasma gas sterilization		
Do not soak single-use disposables. They must be discarded after use		
All instruments that cut or biopsy must be sterilized (do not soak in Cidex® OPA).		
Instruments that are soaked in Cidex® OPA must be pre-washed in soap and water prior to high-level disinfection. ALL particulate matter must be removed (brushes and enzyme cleaners are available for this process)		
Instruments must be TOTALLY SUBMERGED in the solution. All lumens must be filled and air pockets eliminated.		
Instruments must soak for 12 MINUTES using a timer at room temperature.		
After removal of instruments from the Cidex® OPA solution, they must be rinsed in 2 gallons of *filtered tap water. The devices must be submerged for at least one minute. All lumens must be irrigated with at least 100 ml of water. After the initial rinse, the water must be used for no other purpose and discarded. This rinse process will be repeated with 2 gallons of fresh *filtered tap water 2 more times for a total of three (3) rinses.		

* 0.2µ filter

Surveyor's Name: _____ Survey Date: _____

Surveyed HCW's Initials: _____ Surveyed Area: _____

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CIDEX® OPA Working Solution QUALITY CONTROL LOG

Location/ Dept: _____

Note: Use backside of log for any Corrective Action taken (eg working solution temperature out-of-range), or comments. Don't forget to date and initial!

Working Solution Quality Test Date Year _____	Probe and/or Scope # and Patient MRN #	Cidex® OPA Gallon Bottle Manufacturer's Label Lot# and Exp Date	Cidex® OPA Gallon Bottle Open Date and +75 days Date (75 days = 2.5 months)	Cidex® OPA Working Solution (WS) Container Start Date	Cidex® OPA Working Solution (WS) Expiration Date (Never use WS past 14 days from start date)	Test Strips Lot# Open date and + 90 days Date (90 days = 3 months)	Cidex® OPA Working Solution (before each use) Strip Test Results (Circle correct response)	Cidex® OPA Working Solution Temp Acceptable ≥ 20°C (68°F)	Tested By (Print Name)
	# MRN:	Lot# Exp. Date=	Open gal= + 75 days=			Lot # Open date= + 90 days=	Pass Fail		
	# MRN:	Lot# Exp. Date=	Open gal= + 75 days=			Lot # Open date= + 90 days=	Pass Fail		
	# MRN:	Lot# Exp. Date=	Open gal= + 75 days=			Lot # Open date= + 90 days=	Pass Fail		
	# MRN:	Lot# Exp. Date=	Open gal= + 75 days=			Lot # Open date= + 90 days=	Pass Fail		

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QUALITY CONTROL PROCEDURE FOR CIDEX® GLUTARALDEHYDE TEST STRIPS

Processing Steps:	Check (✓)	Comments/follow-up
STORAGE AND USE OF CIDEX® GLUTARALDEHYDE TEST STRIPS		
Cidex® Glutaraldehyde Test Strips must be discarded 90 days after the bottle is opened or on the expiration date of the bottle, whichever comes first.		
The test strip bottle must not be left open for more than 30 minutes.		
Keep the bottle tightly closed after removing the test strip.		
Do not refrigerate or freeze the bottle of test strips		
Protect the strips from heat, light and moisture		
PREPARATION OF CONTROL SOLUTIONS		
Use full strength Cidex® Glutaraldehyde solution as a positive control.		
To prepare a negative control, dilute 1 part Cidex® Glutaraldehyde solution with 1 part of water.		
TESTING PROCEDURE		
Submerge 3 test strips in each freshly prepared solution for 3 seconds each.		
Remove.		
The 3 strips dipped in full strength positive control solution should exhibit a complete purple color on the indicating pad at 75 seconds .		
The 3 strips dipped in the diluted negative control solution should either remain completely blue or exhibit an incomplete color change to purple at 75 seconds .		
Refer to the color chart on the test strip bottle for interpretation of results.		
TESTING FREQUENCY		
The testing of positive and negative controls should be performed on each newly opened bottle of Cidex® Glutaraldehyde solution Test Strips.		
Testing of freshly prepared positive and negative controls should be performed only with test strips that have been properly stored or handled.		
UNSATISFACTORY QC TEST PERFORMANCE		
If the results obtained from using positive and negative controls indicate the test strips are not functioning properly, discard the strips.		
Obtain a new bottle of test strips and repeat the test with positive and negative controls.		

Surveyor's Name: _____ **Survey Date:** _____

Surveyed HCW's Initials: _____ **Surveyed Area:** _____

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CIDEX® GLUTARALDEHYDE TEST STRIPS QUALITY CONTROL LOG

Location/Department: _____

Purpose: Document performing quality control of the Cidex® Glutaraldehyde Quality Control strips when a new bottle of strips is opened.

Definitions:

- ^a **Expiration date** is printed on the label by the manufacturer
- ^b **Discard date** is calculated by adding 90 days to the open date of the strips
- ^c **Quality control** means both positive and negative controls are performed each time a new bottle of QC strips is opened.

Procedure to Prepare the Positive & Negative Controls: POSITIVE Control - use full strength, activated Cidex® Glutaraldehyde (30 ml); NEGATIVE Control is one part activated Cidex® Glutaraldehyde (15 ml) and one part water (15 ml). Timing is critical. Insert **3** strips into each of the two control solutions for **3 seconds**. Remove excess solution by standing up the strips. Read results in exactly seventy-five (**75**) seconds.

Controls Results: To "PASS" on the positive controls, the dipped QC strip(s) must turn **purple**; if any blue appears on indicating pad apart from the top line, the solution did not pass ("FAILS"); to "PASS" on the negative controls, the strip color should either remain completely orange or exhibit an incomplete color change to purple at **75 seconds**.

***Corrective Action Key:** use the following key to denote action if either control did not pass:

- D:** Cidex® Glutaraldehyde Solution Test Strips discarded today because test failed;
- D1:** Cidex® Glutaraldehyde Solution Test Strips discarded today because bottle was left open;
- D2:** Cidex® Glutaraldehyde Solution Test Strips discarded today because bottle was not dated when opened.

Test Date Year _____	Cidex® Glutaraldehyde Solution Lot# and Manufacturer ^a Expiration Date	Cidex® Glutaraldehyde Strips Lot# and Manufacturer ^a Expiration Date	Cidex® Glutaraldehyde Strips: Date Opened and calculated ^b Discard Date	^c Positive Quality Controls All 3 results:(Pass/Fail) Pass = only purple	^c Negative Quality Controls All 3 results:(Pass/Fail) Pass = orange or incomplete change to purple	Print Employee Name performing Quality Controls	*Corrective Action Key (use reverse side for comments)
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				
	Lot	Lot	Opened				
	Exp:	Exp	Discard				

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**PROTOCOL FOR HIGH-LEVEL DISINFECTION
CIDEX® GLUTARALDEHYDE**

Processing Steps:	Check (✓)	Comments/follow-up
CIDEX® GLUTARALDEHYDE CONTAINER		
Label with chemical name.		
Cover fluid at all times.		
MSDS sheets for Cidex® Glutaraldehyde should be easily accessible.		
Label container with activation date and expiration date and initial each time the chemical is changed. Cidex Glutaraldehyde must be discarded at 14 days even if the Cidex Glutaraldehyde test strips indicate that there is a minimally effective concentration (MEC) in the Cidex Glutaraldehyde solution.		
TEST STRIPS		
Date bottle of test strips when opened (expiration at 90 days or the expiration date on the bottle of test strips, whichever comes first).		
Cidex® Glutaraldehyde must be tested EACH TIME when medical instruments are reprocessed.		
Dip test strip into solution for 3 seconds . Do not shake strip after removal.		
Read the results of the chemical reaction 75 seconds after the test strip has been removed from the solution. Compare this color reaction to the color chart on the side of the test strip bottle.		
Document the results of the test strip.		
If the color of the test strip matches the "fail" panel on the color chart: <ul style="list-style-type: none"> ▶ Check the test strips expiration date. If the test strips are out of date, discard and retest with new strips. ▶ If test strips are in-date, discard solution, rinse out container, and refill with fresh solution. Retest new solution and document test results. 		
SOAKING IN CIDEX® GLUTARALDEHYDE		
Cidex® Glutaraldehyde is a high-level disinfectant. Do not soak instruments in Cidex® prior to steam or plasma gas sterilization		
Do not soak single-use disposables. They must be discarded after use		
All instruments that cut or biopsy must be sterilized (do not soak in CIDEX).		
Instruments that are soaked in Cidex® Glutaraldehyde must be pre-washed in soap and water prior to high-level disinfection. ALL particulate matter must be removed (brushes and enzyme cleaners are available for this process)		
Instruments must be TOTALLY SUBMERGED in the solution.		
Instruments must soak for 45 MINUTES using a timer.		
After removal of instruments from the Cidex® Glutaraldehyde solution, they must be rinsed in 2 gallons of *filtered tap water. The devices must be submerged for at least one minute. All lumens must be irrigated with at least 100 ml of water. After the initial rinse, the water must be used for no other purpose and discarded. This rinse process will be repeated with 2 gallons of fresh *filtered tap water 2 more times for a total of three (3) rinses.		

* 0.2µ filter

Surveyor's Name: _____ Survey Date: _____

Surveyed HCW's Initials: _____ Surveyed Area: _____

High-Level Disinfection (CIDEX OPA)



1. Date and initial the **CIDEX OPA** bottle when opened. Expiration date is **75 days** after bottle is opened.
2. Label **CIDEX OPA** pour-over containers with expiration date and initials. Expiration date is **14 days** after pouring into **CIDEX OPA** container.
3. Check **CIDEX OPA** solution before each use with a CIDEX OPA Test Strip dipped into the solution for **1 second**.
4. Read the test strip in **90 seconds**. (If solution fails by test strip, identify problem and take corrective action.)
5. Record the result of the test strip.

6. Don **PPE** before starting cleaning process:

- **Gloves**
- **Fluid resistant gown**
- **Mask**
- **Eyewear (goggles or face shield)**



**12
MINUTES**

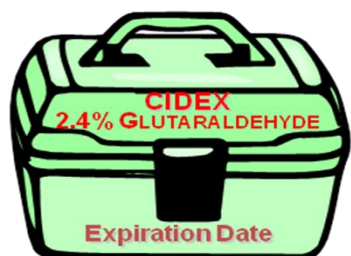


7. Prewash instruments with enzymatic cleaner before placing in the **CIDEX OPA** bath. Instruments must be **TOTALLY SUBMERGED** and all lumens filled with disinfectant.
8. Soak the instruments for **12 MINUTES** using a timer.
9. Rinse well **3 times** with a minimum of **2 gallons of 0.2µ filtered water** (or sterile water) each time and then air dry.

NOTE: Single use disposables must not be reprocessed. Instruments that cut or biopsy must be sterilized.

DEPARTMENT OF HEALTHCARE EPIDEMIOLOGY

High-Level Disinfection (CIDEX) 2.4% Glutaraldehyde



1. Date and initial the CIDEX 2.4% Glutaraldehyde bottle when activated. Expiration date is **14 days** after activation.
2. Label CIDEX 2.4% Glutaraldehyde pour-over containers with expiration date and initials. Expiration date is **14 days** after activation.
3. Check CIDEX 2.4% Glutaraldehyde for effectiveness before each use with a CIDEX Test Strip dipped into the solution for **3 seconds**.
4. Read the test strip in **75 seconds**. (If solution fails by test strip, identify problem and take corrective action.)
5. Record the result of the test strip.
6. Don **PPE** before starting cleaning process:
 - ▶ Gloves
 - ▶ Fluid resistant gown
 - ▶ Mask
 - ▶ Eyewear (goggles or face shield)



**45
MINUTES**



7. Prewash instruments with enzymatic cleaner before placing in the CIDEX 2.4% Glutaraldehyde bath. Instruments must be **TOTALLY SUBMERGED** and all lumens filled with disinfectant.
8. Soak the instruments for **45 MINUTES** using a timer.
9. Rinse well **3 times** with a minimum of **2 gals of 0.2µ filtered water** (or sterile water) each time and then air dry.

NOTE: Single use disposables must not be reprocessed.
Instruments that cut or biopsy must be sterilized.

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