

New Developments in Reprocessing Critical and Semicritical Items

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Disclosure: Advanced Sterilization Products and Clorox

Disinfection and Sterilization

- New Developments in Reprocessing Critical and Semicritical Items
 - New sterilization technologies and HLDs
 - Reprocessing semicritical items: endoscopes (new AERs); endocavitary probes; prostate biopsy probes; tonometers; laryngoscopes; infrared coagulation

Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected depended on the object's intended use.

CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be **sterile**.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (**high-level disinfection [HLD]**) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require **low-level disinfection** (or non-germicidal detergent).

Sterilization of "Critical Objects"

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Peracetic acid (0.2%)-chemical sterilization
Ozone
Vaporized hydrogen peroxide
Steam formaldehyde

Ozone

- Advantages
 - Used for moisture and heat-sensitive items
 - Ozone generated from oxygen and water (oxidizing)
 - No aeration because no toxic by-products
 - FDA cleared for metal and plastic surgical instruments, including some instruments with lumens
- Disadvantages
 - Sterilization chamber small, 4ft³
 - Limited use (material compatibility/penetrability/organic material resistance?) and limited microbicidal efficacy data

V-PRO™1, Vaporized Hydrogen Peroxide

- Advantages
 - Safe for the environment and health care worker; it leaves no toxic residuals
 - Fast - cycle time is 55 min and no aeration necessary
 - Used for heat and moisture sensitive items (metal and nonmetal devices)
- Disadvantages
 - Sterilization chamber is small, about 4.8ft³
 - Medical devices restrictions based on lumen internal diameter and length-see manufacturer's recommendations, e.g., SS lumen 1mm diameter, 125mm length
 - Not used for liquid, linens, powders, or any cellulose materials
 - Requires synthetic packaging (polypropylene)
 - Limited use and limited comparative microbicidal efficacy data

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Semicritical Devices

Semicritical Items

- Endoscopes
- Laryngoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings
- Infrared coagulation devices

Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning

High Level Disinfection of "Semicritical Objects"

Exposure Time \geq 12 m-30m (US), 20°C

Germicide	Concentration
Glutaraldehyde	\geq 2.0%
Ortho-phthalaldehyde (12 m)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified



Resert™ XL HLD

- High Level Disinfectant
- 2% hydrogen peroxide
 - pH stabilizers
 - Chelating agents
 - Corrosion inhibitors
- Efficacy (claims need verification)
 - Sporicidal, virucidal, bactericidal, tuberculocidal, fungicidal
- HLD: 8 mins at 20°C
- Odorless, non-staining, ready-to-use
- No special shipping or venting requirements
- Manual or automated applications
- 12-month shelf life, 14 days reuse
- Material compatibility/organic material resistance?



*The Accelerated Hydrogen Peroxide technology and logo are the property of Virox Technologies, Inc. Modified from G McDonnell. AJIC 2006:34:571

Endoscopes

GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/ 10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
 - >300 infections transmitted
 - 70% agents *Salmonella sp.* and *P. aeruginosa*
 - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
 - 90 infections transmitted
 - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Spach DH et al Ann Intern Med 1993; 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

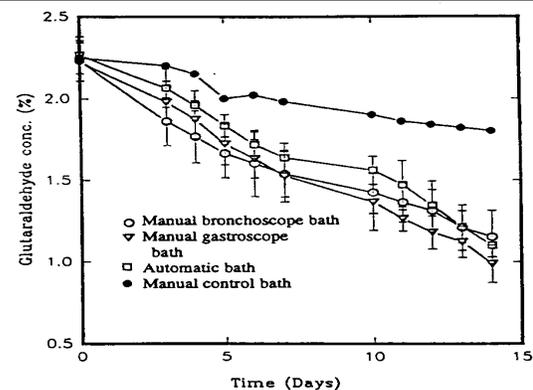
Endoscope Reprocessing, Worldwide

- Worldwide, endoscopy reprocessing varies greatly
 - India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)
 - Brazil, "a high standard ...occur only exceptionally"
 - Western Europe, $\geq 30\%$ did not adequately disinfect
 - Japan, found "exceedingly poor" disinfection protocols
 - US, 25% of endoscopes revealed >100,000 bacteria

Schembre DB. Gastroint Endoscopy 2000;10:215

ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerscope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination



Minimum Effective Concentration Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5% (OPA 0.3%)
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used. Check solution each day of use (or more frequently) using the appropriate indicator. Surveyor may require compliance with manufacturer's recommendations.
- Record results

ENDOSCOPE SAFETY

- Ensure protocols equivalent to guidelines from professional organizations (APIC, SGNA, ASGE, CDC)
- Are the staff who reprocess the endoscope specifically trained in that job?
- Are the staff competency tested at least annually?
- Conduct IC rounds to ensure compliance with policy
- Perform microbiologic testing of the endoscope or rinse water-no recommendation (unresolved issue)

C. difficile spores

Disinfectants and Antiseptics

C. difficile spores at 10 and 20 min, Rutala et al, 2006

- ~4 log₁₀ reduction (3 *C. difficile* strains including BI-9)
 - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50, ~1,200 ppm)
 - Clorox Clean-up, ~1,910 ppm chlorine
 - Tilex, ~25,000 ppm chlorine
 - Steris 20 sterilant, 0.2% peracetic acid
 - Cidex, 2.4% glutaraldehyde
 - Cidex-OPA, 0.55% OPA
 - Wavicide, 2.65% glutaraldehyde
 - Aldahol, 3.4% glutaraldehyde and 26% alcohol

Errors in designing and reprocessing
semicritical items continue and place
patients at risk of infection

Automatic Endoscope Reprocessors (AERs)

- Manual cleaning of endoscopes is prone to error.
- AER Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water
- AER Disadvantages: failure of AERs linked to outbreaks, does not eliminate precleaning, does not monitor HLD concentration
- Problems: incompatible AER (side-viewing duodenoscope); biofilm buildup; contaminated AER; inadequate channel connectors; used wrong set-up or connector MMWR 1999;48:557
- Must ensure exposure of internal surfaces with HLD/sterilant

EVOTECH w/Cleaning Claim



- Product Definition:
 - Integrated double-bay AER
 - Eliminates manual cleaning
 - Uses New High-Level Disinfectant (HLD) with IP protection
 - Single-shot HLD
 - Automated testing of endoscope channels and minimum effective concentration of HLD
 - Incorporates additional features (LAN, LCD display)

Reliance™ EPS Endoscope Processing System



Reliance™ DG



Endoscope Processing Support



Klenzyme®, CIP® 200



Reliance™ PI

Automatic Endoscope Reprocessors

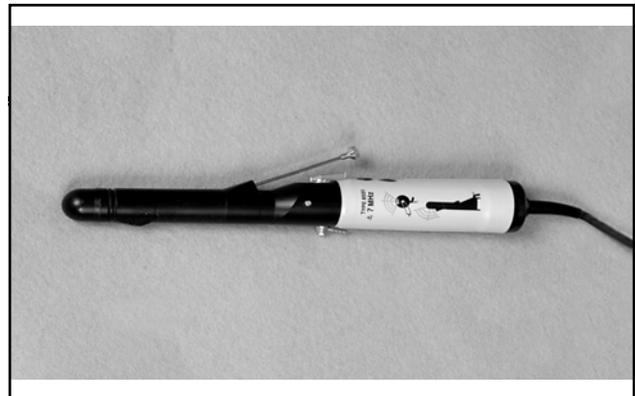
- EvoTech-integrates cleaning (FDA-cleared claim) and disinfection. Automated cleaning comparable to manual cleaning. All residual data for cleaning of the internal channels as well as external insertion tube surfaces were below the limit of $8.5\mu\text{g}/\text{cm}^2$.
- Reliance-requires a minimal number of connections to the endoscope channels and uses a control boot (housing apparatus that creates pressure differentials to ensure connectorless fluid flow through all channels that are accessible through the endoscope's control handle channel ports). Data demonstrate that the soil and microbial removal effected by Reliance washing phase was equivalent to that achieved by optimal manual cleaning. Alfa, Olson, DeGagne. AJIC 2006;34:561.

Endocavitary Probes

- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed

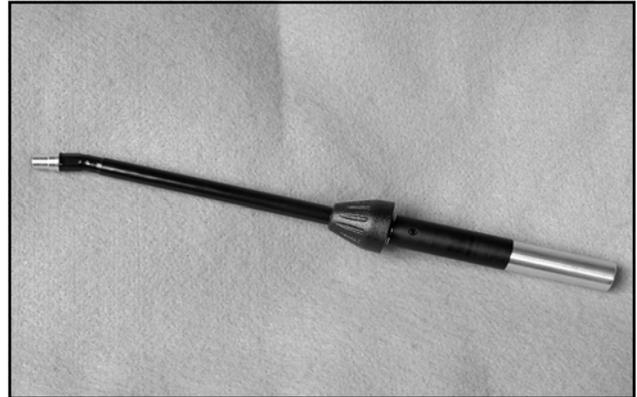
Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate of perforations before use (0%, 25%, 65% perforations from three suppliers)
- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)



Prostate Biopsy Probe

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated (10^6 - 10^7 *P.aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place
- Conclusion: HLD achieved when unassembled but not when assembled



Infrared Coagulation (IRC)

- IRC is a widely used method for treating hemorrhoids. The procedure involves applying infrared light to compress and seal hemorrhoid veins.
- The manufacture sells a sterile disposable sheath and states removing and soaking lightguides between procedures is no longer required.
- The manufacturer also states that the lightguide is damaged by immersion in a disinfectant (as the lightguide is not sealed at the end and disinfectant gets between the quartz glass and the covering)

Infrared Coagulation (IRC)

- CDC guideline recommends immersion for reprocessing endocavitary probes with covers because integrity of the cover is compromised
- Since the lightguide cannot be immersed we investigated an alternative procedure
 - Wipe the probe for 2 minutes with 1:10 bleach (5000 ppm)
 - Wipe probe with sterile water and let air dry

Infrared Coagulation Testing

(Rutala, Gergen, Weber, Unpublished results, 2006)

Test Organism	Inoculum	Log ₁₀ Reduction (%)
<i>Mycobacterium terrae</i>	7.8×10^6	6.9

Wiping the non-immersible IRC probe for 2 min with 5000 ppm chlorine was effective in removing/inactivating microorganisms from the instruments



Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536

- Limited guidelines for reprocessing laryngoscope's blades and handles
- Many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades-Steris, handle [without batteries]-Sterrad)

Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis



Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips.

CDC. MMWR 1985; 34:533.

CDC, 1985

- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
 - 5,000 chlorine (~1:10 household bleach)
 - 3% hydrogen peroxide
 - 70% ethyl alcohol
 - 70% isopropyl alcohol

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective $-2 \log_{10}$ reduction
 - Bactoshield (4% CHG)
 - Vesphene (phenolic)
 - 70% isopropyl alcohol
 - 3% hydrogen peroxide
 - TBQ (0.06% QUAT)
 - Novaplus (10% povidone iodine)
 - Soft 'N Sure (0.5% triclosan)
 - Acute-Kare (1% chloroxylenol)
 - Sterilox (218 and 695 ppm chlorine)
 - Dettol (4.8% chloroxylenol)
 - Accel TB (0.5% accelerated hydrogen peroxide)
 - Microcyn (~80 ppm chlorine)

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- ~4 \log_{10} reduction
 - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
 - Clorox Clean-up, ~1,910 ppm chlorine
 - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
 - Steris 20 sterilant, 0.35% peracetic acid
 - Ethanol, 70%
 - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
 - Cidex, 2.4% glutaraldehyde
 - Cidex-OPA, 0.55% OPA
 - Wavicide, 2.65% glutaraldehyde

CDC Guidelines

- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
 - 5,000 chlorine
 - 3% hydrogen peroxide
 - 70% ethyl alcohol
 - 70% isopropyl alcohol
- CDC, 2008. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

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Thank you