

John Leahy
37096 Blue Bill Drive
Selbyville, DE 19975

January 12, 2016

CERTIFIED - RETURN RECEIPT

Siobahn S. Bradley, Attorney, Disclosure Unit
U.S Office of Special Counsel
1730 M Street, NW. Suite 300
Washington, DC 20036

Re.: OSC File No. DI-15-0563

Dear Attorney Bradley:

This is in reply to yours of the 29th ult., with which you conveyed a copy of a supplementary report from the Department of Veterans Affairs (VA) in response to allegations I made related to the above referenced matter. You offered me the opportunity to read the VA's supplementary report and to respond with written comment. Essentially my comment is that the new VA report refutes nothing in my initial comment of October 30, 2015, and I stand by every word that I have written. The bottom line is that the VA purchased sophisticated equipment and failed to read and follow clear manufacturer-supplied instructions-for-use, and thus employed that equipment in a manner which created a clear risk to public health and safety for veteran patients for a span of thirteen years in support of more than 52,000 patient appointments. Given DNA-confirmed research about the spread of disease by leaking endoscopes, it is a statistical certainty that veterans were made ill by the VA's careless practices. **I respectfully ask that exposed veterans be honestly notified and offered follow up testing.** Let's consider the VA's new responses question by question, item by item.

Question 1

The first question was whether leak testing is part of the manufacturers reprocessing guidelines. The VA responds with two sentences:

“Leak testing is a preventative measure to ensure major damage does not occur to the endoscope. Any fluid ingress into the optical bundle of the fiberscope or video scope will cause major damage, resulting in high-cost repairs.”

Aside from ignoring the human element of patient cross-infection, the VA's answer ignores the actual question. The question is whether leak testing is a required part of effective endoscope cleaning. Leak testing is a crucial and absolutely required step to effective disinfection of all flexible endoscopes. As evidence, see Attachment 1, which is a 2009 Olympus memorandum laying out the basic steps of leak testing for both standard and delayed reprocessing. In this memorandum, leak testing is basic-step-number-two for all disinfection. Also as evidence, see

Attachment 2, which is the cover, copyright notice, and 3 selected pages from the 1997 Olympus manual for reprocessing all Olympus flexible non-lumen endoscopes. This manual states, *“The medical literature reports incidents of patient cross contamination resulting from improper cleaning, disinfection, or sterilization....organic material...could reduce the efficacy of disinfection or sterilization.”* The manual then goes on to specify leak testing as one of the necessary steps to effective disinfection.

Question 2

The OSC questioned the VA’s assertion that leaks in endoscopes could be detected by visual inspection, without performing leak testing. In response, the VA describes at length how carefully physicians examine endoscopes before they use them. The VA then doubles down on its assertion that,

“With a thorough visual inspection of the endoscope, observed abnormalities... can be detected and scopes removed from service.”

The VA’s assertion is not remotely defensible. As evidence, see my Attachment 3. This is a series of 2008 email exchanges involving me, the Clinical Director of the VAMC’s Sterile Processing Department (SPD), an infection control nurse, the Director of Infection Control, and my supervisor. This is where I report that I had recently found one ENF-GP scope that failed leak testing, and now, of 7 more tested, 3 had failed. Here’s the thing: All 4 of the leaking endoscopes had been in very frequent use, and had therefore each been inspected by physicians more than once a day. For an unknown number of days, weeks, or months the physicians had failed to detect the leaks and had continued to use the scopes. This is proof enough that leaks cannot be detected without leak testing. Besides, if leak testing were not necessary, it would not be counted as a fundamental step of effective disinfection by every single endoscope manufacturer.

(By the way, in the Attachment 3 email exchanges, the Clinical Director of Sterile Processing acknowledges for the first time (8/25/2008) that leak testing should have been performed in the past, and this is conveyed to the Director of Infection Control. It is doubtful, therefore, that other departments besides ENT were leak testing as required. The 52,000 ENT Clinic encounters are probably just the tip of a very large iceberg, as I discussed with the VA’s current inspection team.)

Question 2A

The OSC asked the VA to respond to the danger to public health and safety posed by leaking endoscopes being used on many patients over an extended period of time before the leak is detected. In answer, the VA merely doubles down on its assertion that

“During reprocessing with the use of High Level Disinfectant, cleaning and disinfecting fluids have access to the same areas of the leak as do biological materials, thereby killing bacteria and viruses.”

This VA's assertion can be proven false in so many ways, from so many reliable sources, that I hardly know where to begin! The basic facts are that (1) holes in endoscope insertion tubes usually may NOT be noticed, or even seen, with the naked eye, (2) damage to fiberoptics from small fluid invasions may be minimal and may take long periods of time to develop, during which time the endoscope may be used on a succession of many patients, (3) because of the rubbery nature of the insertion tubes, some leaks are positional, not constant, so that the Cidex OPA disinfectant may not have the same access as the infected biomaterial, and (4) even if the Cidex OPA follows the biomaterial inside the insertion tube may prevent the Cidex OPA from killing microorganisms. In support of #4, please see Attachment 4, the CIDEX OPA manufacturer's instructions for use which states clearly that the presence of residual materials "will decrease the effectiveness of the germicide." Also refer back to Attachment 2, the Olympus disinfection manual, which states that the presence of organic material "could reduce the efficacy of disinfection." Additionally, refer to Attachment 5, a journal article co-authored by Bradley Catalone, PhD, the Senior Manager of Infection Control for the Medical Systems Group of Olympus America. Dr. Catalone writes that, "Patient biomaterial provides a nutrient source that will promote the growth of microorganisms. Also when this biomaterial is not removed immediately after a procedure, it will dry and harden. The surface of the hardened material functions as a barrier that prevents the penetration of disinfecting and sterilizing agents that kill microorganisms. In addition, patient biomaterial may inactivate disinfectants." So the VA's Office of the Medical Inspector is clinging to an assertion which is obviously false..

Question 3

"The whistleblower asserts that Cidex OPA, the disinfectant used to [disinfect] the endoscopes, is well-known to be potentially ineffective in the presence of biomaterials. In addition, because some holes may be positional, and not constant, the Cidex OPA may not travel the same path as the biomaterial through the scopes. Please address these concerns in the context of the report finding that the cleaning process would inactivate biohazardous materials (page iii)."

Again, the VA ignores the OSC's question by stating that Cidex OPA is the best choice of disinfection agents. There are a number of very good agents to disinfect endoscopes, and whether Cidex OPA is best choice is entirely beside the question and beyond the scope of this inquiry. The crucial fact is that, whatever agent you use, you have to use it in accordance with the agent's manufacturer's instructions (Attachment 4) and the endoscope's manufacturer's instructions for disinfection (Attachment 2).

Question 4

Question 4 confronts the VA with its false assertion that I told the VA inspectors that pre-2008 that is before I came to the ENT Clinic, disinfection procedures were just fine except for the question of leak testing. The OSC produced my email to the VA inspectors detailing 10 pre-2008/2007 deficiencies dating back to at least 1995.

In response, the VA now lays out 10 answers to my 10 assertions. In these 10 answers, the VA seems to double down on its verbose but hollow assertion that pre-2008 endoscope disinfection procedures were just fine. The answers are labeled 4a through 4j. Let's take them one at a time.

Question 4a

Assertion: Before 2007 there were no timers for timing for timing Cidex OPA soak times, or disinfectant soak times, or Cidex OPA test strip times – all key components of disinfection.

VA's answer: Timers are not necessary, as any clock may be used.

However: The VAMC's Quality Management Coordinator's 2007 internal memo attached to my last letter as Attachment CC found that there was no clock in the room, and called that a disinfection deficit. Furthermore, it is obvious that multiple basins containing both Cidex OPA (12 minute soak) and enzymatic detergent (at that time a 15 minute soak) the timing for each basin is different and requires a separate timer. A single wristwatch would simply not do the job. That is why one of the first things I did when I came to the ENT Clinic in 2008 was to go out to Target and buy 4 kitchen timers for each of the 4 basins. (The time and red tape to buy 4 timers through the VAMC was insurmountable. The ENT Chief was later kind enough to reimburse me out of her own money.)

Question 4b

Assertion: Before 2007, there were no written Standard Operating Procedures (SOP) to control disinfection procedures.

VA's answer: VA medical facilities were not required [by the VA] to have SOP's until 2009. Prior to 2009, they were supposed to be following manufacturers' disinfection guidelines.

However: If the VA had been following manufacturers' guidelines, there would be no problem here. That's the crux of my complaint.

Question 4c

Assertion: Before 2007 there was a lack of a wall clock for timing Cidex test strip quality checks.

VA's answer: "VA was told by the whistleblower that he used his watch as no wall clock was present."

However: I came to the ENT Clinic in 2008. Why would I tell the inspectors that I used my wrist watch to time the 90-second test strip exposure time when I have already established that a wall clock was placed in the room in 2007 for this very purpose?

Question 4d

Assertion: Before 2008, MAJ-210 biopsy port covers were routinely but erroneously used on the PEF Type V transnasal esophagovideoscope.

VA answer: “The scopes are non-channeled flexible endoscopes. The MAJ-210 water resistant cap is included in the accessories provided with the sale of the ultrasonic endoscope. The MAJ-210 may also be purchased as a disposable single use item. The cap allows the endoscope to be safely immersed in solution. The site visit team was neither shown nor sent documents indicating that the PEF Type V endoscope was sent each time to the vendor after use due for processing failure based on no MAJ-210 cap.”

However: Amazingly, every sentence of the VA’s answer is factually incorrect. The PEF-Type V endoscope is, indeed, a channeled endoscope. In fact, the PEF Type V is unusual among channeled endoscopes in that it has two channels that require disinfection instead of the usual one. It has an insertion tube channel and a universal cord channel. This unusual configuration requires special disinfection procedures. That is why the Olympus instructions are 85 pages long and why you must have either an SOP or Olympus manual to get it right. (The ENT Clinic had neither.) The MAJ-210 biopsy port cover is strictly a single use item, and is cleverly designed to self destruct after a single use. The MAJ-210 biopsy port cover is NOT included with a new PEF Type V endoscope. In fact, page 19 of the Olympus PEF Type V instructions (Attachment 6) explicitly warns that the MAJ-210 cover must never be used with the PEF Type V endoscope or it will cause leakage. (That’s my point, by the way.) The MAJ-210 does not allow the PEF Type V endoscope to be immersed in solution. It has nothing to do with that! Since the universal cord is permanently attached, the PEF Type V endoscope is fully submersible without the use of a waterproof cap, and the biopsy port cover serves a different, unrelated purpose.

Question 4e

Assertion: Before 2008, there was no suction equipment in the room to support the required steps for disinfecting the channeled (PEF Type V) endoscope.

VA answer: Maybe they used syringes.

However: The PEF Type V endoscope is relatively large and complex and disinfection requires both syringes and suction equipment. For example, see Attachment 7, which is page 69 of the PEF Type V manual. It is just one example but page 69 show a disinfection step which requires suction equipment.

Question 4f

Assertion: Before 2008 there was no leak testing equipment on site.

VA answer: The Washington DC VAMC reports that no infections were linked to the cleaning and processing of non-channeled endoscopes during the period in question.

However: The likelihood of adverse health effects to veterans is overwhelmingly serious. Suffice it to say that if one improperly disinfected endoscope can infect 9 patients in a two-and-a-half week period (as documented by my last letter, with supporting attachment) then the ramifications of 52,000-plus

patient appointments conducted with improperly disinfected endoscopes are obvious. For a knowledgeable person to believe that veterans were not cross contaminated with disease in such circumstances would be tantamount to adult believing in the Tooth Fairy.

In an APICE study, Lawrence Muscarella, Ph.D. warned that “[Flexible laryngoscopes] have been reported to be contaminated with blood, body fluids, organic debris, and potentially pathogenic microorganisms during routine clinical use. **Failure to reprocess properly a flexible laryngoscope may, therefore, result in patient-to-patient disease transmission**” *Helicobacter pylori*, *pseudomonas aeruginosa*, *enterobacteriaceae*, *mycobacterium tuberculosis*, fungi, Hepatitis B, *bacillus sp.*, *seratia marcescens*, fungus, and *legionella pneumophila* have all been documented to be transmitted by upper endoscopy endoscopes according to the Public Health Agency of Canada. That Agency goes on to postulate that even CJD may be transmitted if the tonsils are traumatized by endoscope insertion, and Olympus endoscope manuals also warn of possible CJD (prion) transmission. There is concern that HIV may be transmitted. Common sense tells us that if an organism is present in blood, lymph or sputum, then it can be transmitted by being trapped inside an endoscope which has a hole in it! If you admit that, then transmittable diseases would include the common cold, flu, HPV (which is associated with 30 % to 60% of all tracheolaryngeal cancers), and HIV. The 2011 Multisociety Guideline on Reprocessing Flexible GI Endoscopes remarks, “A Taiwanese case of *Acinetobacter* prosthetic valve endocarditis after polymicrobial bacteremia was, in the absence of other apparent sources, attributed to upper endoscopy performed 11 days earlier for esophagitis with associated esophageal ulceration.... Several occurrences of hepatitis C virus transmission have been associated with breaches in accepted endoscope reprocessing protocols. **Most recently, lapses in the use of appropriate tubing with attached 1-way valves and lapses in reprocessing of the tubing used to attach water pumps to endoscope irrigation channels have been recognized in numerous centers around the United States, including several Veterans Administration hospitals.**”

Question 4g

Assertion: Before 2008 there was a lack of suction equipment to support required disinfection procedures.

VA answer: “The endoscopes being used were nonchanneled and therefore did not require suctioning.”

However: I think we’ve covered this already. The PEF Type V has multiple channels and requires suction equipment for disinfection.

Question 4h

Assertion: Before 2008 there was a lack of temperature testing for Cidex OPA.

VA Answer: “Part of this period Cidex testing strips were recalled by the manufacturer due to ‘performance failure complaints, moisture ingress into the bottles was causing failure and variability in results.’”

However: I don't understand the connection between the assertion and the VA's answer. Cidex OPA's effectiveness is temperature dependent and the temperature of the Cidex must therefore be monitored regularly.

Question 4i

Assertion: Before 2008 there was a lack of bioburden testing after disinfection of the PEF Type V endoscope.

VA answer: Bioburden testing was not recognized as a requirement at the time.

However: Bioburden testing would have been prudent and is now required

Question 4j

Assertion: Before 2008, the ENT Clinic had no MAJ-1219 cleaning adapter which is required for PEF Type V endoscope reprocessing

VA answer: "According to the Washington DC VAMC reports, there had been no infections linked to the cleaning and processing of nonchanneled endoscopes during the period in question."

However: Again, the VA does not address the question of whether or not the ENT Clinic possessed the MAJ-1219 cleaning adapter required to disinfect the PEF-Type V. Additionally, the VA is mistaken in implying that the PEF Type V is a nonchanneled endoscope. The PEF Type V is not a nonchanneled endoscope. It has 2 channels and the MAJ-1219 is required for disinfecting them, as evidenced by Attachment 8, the Olympus list of required reprocessing equipment for the PEF Type V endoscope.

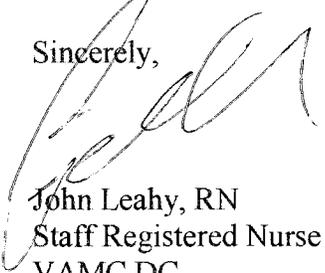
In the face of overwhelming evidence of a danger to veterans' health, the VA investigators have dismissed the human impact of infection risk due to failure to leak test, stating that the true purpose of leak testing is to prevent damage to the expensive endoscopes!! The inspectors have falsely stated that I told them that reprocessing was within standard-of-practice except for the matter of leak testing prior to 2008. They have ignored the fact that in 2007 and prior, **endoscope disinfection was deficient in every way imaginable – even worse than I have reported because crucial disinfection requirements of ancillary endoscope equipment such as water bottles, gas adapters, and air pump components were not even contemplated by pre-2008 procedures** .(This is evidenced by Attachment 8, the email wherein the Infection Control nurse transmits to the prior ENT nurse the "new and improved," committee-written SOP for lumened and non-lumen flexible and rigid endoscopes. **This SOP completely ignores leak testing and everything else I have mentioned, but also this written SOP and all parties concerned were entirely oblivious to the separate and distinct manufacturers' user manuals and disinfection requirements of ancillary equipment, around which other VA scandals have centered.**.) Furthermore – and this is important – the inspectors failed to follow the rabbit down the rabbit hole when they discovered things during their investigation. For example, they

seem to have ignored my assertion that I have seen flexible endoscopes in the Medical Center as recently as 2015 which are not documented in the Medical Center's Equipment Inventory List and have no record of use or disinfection or even if they have been leak tested to date. (See Attachment EE of my last letter.) As another example, when I was meeting with the VA inspection team looking at an inventory record of an endoscope, they, themselves, noticed and remarked that the scope was 10-years past its scheduled 2005 retirement (and replacement) date. In response, I told them that there were a number of other currently deployed ENT endoscopes that were years past their scheduled retirement dates. As a matter of fact, the PEF Type V endoscope that we have been writing about is another good example of an endoscope that is long past its scheduled retirement date. When they were purchased, all of the ENT Clinic's endoscopes were assigned retirement dates 10 years in the future. The PEF Type V arrived in 1993 as a component of its stroboscopy equipment tower. Biomed declared that particular equipment tower obsolete around 2009 and refused to authorize further repairs or even maintenance. Therefore, after years of tireless lobbying by me, a replacement equipment tower, including a new, replacement channeled TNE videoscope (Pentax model EE-1580K, s/n A110308) arrived during the first half of 2011. The old equipment tower was junked – except for the PEF Type V scope, which is still in use to this very day. It is 13 years past its scheduled retirement date! Its replacement endoscope has been stored, undeployed, in its shipping container since early 2011!! My management would not allow me to deploy the replacement scope, even though I had carefully written a disinfection procedure (SOP) for it and submitted it for management approval. I was instructed by my supervisor to keep new scope stored undeployed in its case while the obsolete scope has continued to be used. I asked but was never given an explanation why. **The point, however, is that the disinfection problem was every bit as bad as I have reported – or worse.**

I respectfully assert that veterans deserve better. Any patient would deserve better, but veterans especially have sacrificed so much to serve their country! It is statistically certain that veterans were made ill by VA deficits. If through VA's disregard or incompetence veterans may have become sick, or remain sick, or even if they died of infectious disease of unknown source – all exposed veterans (or their surviving families) deserve to be honored with full and honest disclosure, and to be offered follow up testing. I respectfully request that involved veterans be so notified. That seems to me like a no-brainer. It is right and just and morally necessary.

Thank you.

Sincerely,



John Leahy, RN
Staff Registered Nurse
VAMC DC



Handwritten signature
①

July 21, 2009

RE: Delayed Reprocessing of Olympus Flexible Endoscopes

Dear Health Care Practitioner:

This letter is in response to your recent inquiry regarding delayed reprocessing of Olympus flexible endoscopes.

The standard Olympus procedure for reprocessing flexible endoscopes is labeled for and intended to be performed without time delays. Continuous reprocessing through the steps indicated in the Olympus endoscope manual ensures that patient fluids and debris do not begin to dry and harden on the endoscope external surfaces and within the endoscope channels.

If reprocessing has been delayed after endoscope precleaning, resulting in patient fluid or debris drying onto the surface of the endoscope, the standard reprocessing procedure may not be effective. In this case, the endoscope should be reprocessed according to the instructions provided in the endoscope manual for "Presoak for Excessive Bleeding and/or Delayed Reprocessing". This procedure has been included in most flexible endoscope manuals and should be performed as an additional reprocessing step after precleaning and leakage testing, but prior to Manual Cleaning.

Standard Reprocessing Procedure

1. Precleaning
2. Leakage Testing
3. Manual Cleaning
4. Disinfection or Sterilization

Delayed Reprocessing Procedure

1. Precleaning
2. Leakage Testing
3. **Presoak for Delayed Reprocessing**
4. Manual Cleaning
5. Disinfection or Sterilization

Olympus has performed cleaning validation studies that include a one-hour delay between precleaning and manual cleaning. Precleaning should always be performed at bedside immediately after the patient procedure according to the instructions provided in the endoscope manual. Following precleaning, the endoscope should be transported to the decontamination area to undergo leakage testing, manual cleaning, and terminal high-level disinfection or sterilization. In the event that manual cleaning of the endoscope is delayed for more than one-hour from the time precleaning is completed or patient fluid/material has dried onto the endoscope surfaces, the endoscope should be reprocessed according to the instructions in the endoscope manual for "Presoak for Excessive Bleeding and/or Delayed Reprocessing."

OLYMPUS AMERICA INC. 3500 Corporate Parkway P.O. Box 610 Center Valley, PA 18034-0610 Telephone: (484) 896-5000 www.olympusamerica.com	OLYMPUS CANADA INC. 151 Telson Road Markham, Ontario L3R 1E7 Canada Telephone: (800) 387-0437 www.olympuscanada.com
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WARNING

The procedure described in "Presoak for Excessive Bleeding and/or Delayed Reprocessing" is not intended for routine reprocessing. Since the endoscope is soaked for an extended period of time during this procedure, it should be utilized only when necessary. Routine, prolonged soaking of flexible endoscopes may result in damage to the instrument.

If you have any additional questions, please contact your local Olympus sales representative, the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 ext 703026 (Canada).

Thank you.

Sincerely,

Bradley J. Catalone, Ph.D.
Director of Clinical Affairs

OLYMPUS AMERICA INC.
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610
Telephone: (484) 896-5000
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Markham, Ontario L3R 1E7
Canada
Telephone: (800) 387-0437
www.olympuscanada.com

INSTRUCTIONS

OLYMPUS BF/ENF/LF

(Endoscopes Without Channel)

1997 version

This instruction manual is for the Broncho, Rhino-laryngo and Tracheal Intubation videoscope/fiberscope models without channel.

Refer to the endoscope's companion manual, BF, ENF, LF OPERATION MANUAL for inspection and operation information.

USA: CAUTION : Federal law restricts this device to sale by or on the order of a physician.

Chapter 1 General Policy

1.1 Instructions

- This instruction manual is for the Broncho, Rhino-laryngo and Tracheal Intubation videoscope/fiberscope models without channel.
- This manual describes the recommended procedures for cleaning and disinfecting or sterilizing this instrument.
- Thoroughly review the manuals of all equipment which will be used with this instrument and use the equipment as instructed.
- If you have any questions or comments about any information in this manual, or if a problem that cannot be solved occurs while you are using the instrument, contact Olympus.
- The medical literature reports incidents of patient cross contamination resulting from improper cleaning, disinfection or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.

A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.

- All individuals responsible for reprocessing should thoroughly understand:
 - your institution's reprocessing procedures
 - occupational health and safety regulations
 - national and local hospital guidelines and policies
 - the instructions in this manual
 - the mechanical aspects of endoscopic equipment
 - pertinent germicide labeling

1.2 Signal Words

The following signal words are used throughout this manual:

- | | |
|----------------|---|
| WARNING | Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. |
| CAUTION | Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage. |
| NOTE | Indicates additional helpful information. |

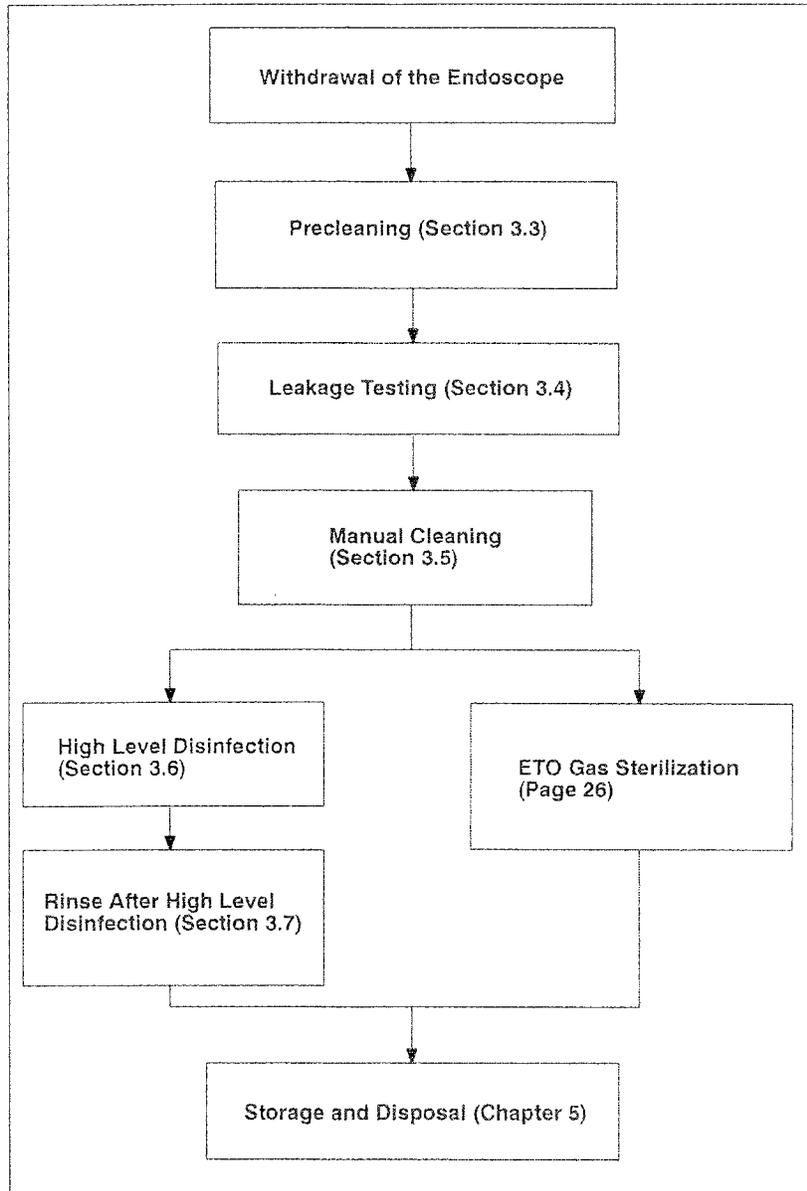
1.3 Precautions

- | | |
|----------------|---|
| WARNING | <ul style="list-style-type: none">• Failure to properly clean and high-level disinfect or sterilize endoscopic equipment after each examination can compromise patient safety. During use, the instrument normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the endoscope must undergo thorough manual cleaning followed by high-level disinfection or sterilization.• If the endoscope is not cleaned meticulously, effective disinfection (or sterilization) may not be possible. Clean the endoscope and accessories thoroughly before disinfection or sterilization to remove microorganisms or <u>organic material that could reduce the efficacy of disinfection or sterilization.</u> |
|----------------|---|

1997
version

3.2 Cleaning, Disinfection and Sterilization Procedures

Reprocessing Summary Chart





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John Leahy
3

From: Leahy, John C. <John.Leahy@va.gov>
Sent: 08/26/08 at 12:14 PM
To: Irmmler, Monica

Glad to distribute all the information I have. Here's what I have in electronic format. There is a general Olympus reprocessing manual for BF/ENF/LF non-lumen endoscopes. Section 1.3 of this one is worthy of note, as is Section 3.2. I also have a PEF Type V lumened scope manual which I am attaching. Also, an Olympus MU-1 Leak Tester manual. Also, a Welch Allyn RL-150 non lumen scope manual, which deals extensively about the need to leak test that scope. Unfortunately, our MU-1 leak tester does not fit the RL-150 endoscope. <<MU-1_Instruction Manual.pdf>> <<PeF-V_Instruction Manual.pdf>> <<Reprocess ENF_LF_Manual.pdf>> As for the <<usermanual_20070321_rl150[1].pdf>> Olympus ENF Type GP manual, I only have that in hard copy but I'm seeking an electronic copy & will forward it when I get it.

John Leahy
RN, BSN, MA
ENT Clinic

From: Irmmler, Monica
Sent: Monday, August 25, 2008 4:53 PM
To: Leahy, John C.
Subject: RE: Leak testing
John,

Can I get a copy of the instruction manuals on the scopes?
Thanks,

--Monica

From: Leahy, John C.
Sent: Monday, August 25, 2008 3:38 PM
To: Irmmler, Monica

Subject: RE: Leak testing
thanks

From: Irmmler, Monica
Sent: Monday, August 25, 2008 3:23 PM
To: Rampertaap, Shanta M.; Leahy, John C.; Malekzadeh, Sonya

Cc: Schultz, Maureen

Subject: FW: Leak testing

fyi

From: Clark, Arlene F

Sent: Monday, August 25, 2008 3:10 PM

To: Irmeler, Monica

Subject: RE: Leak testing

I called Olympus technical support. The rep. is correct. All scopes, lumen or not, need to be leak tested.

Arlene F. Clark, R.N.

Clinical Director, SPD

Office: (202)745-2267

-----Original Message-----

From: Irmeler, Monica

Sent: Monday, August 25, 2008 2:12 PM

To: Clark, Arlene F

Subject: FW: Leak testing

fyi

From: Leahy, John C.

Sent: Monday, August 25, 2008 8:32 AM

To: Rampertaap, Shanta M.; Malekzadeh, Sonya; Irmeler, Monica

Cc: Schultz, Maureen

Subject: Leak testing

In order to make certain that all of our flexible non-lumen Olympus scopes had been leak tested, I came to work early today and conducted a count of the scopes. We own a total of 11 ENF Type GP scopes. One is in Biomed repair for missing light guide adapter. One is in repair for having failed a leak test. There should have been 9 in the racks this morning. I collected only 7. Perhaps the residents arrived earlier than I and have 2 scopes in the OR – in any event, two ENF GP scopes are missing from my leak testing this morning. (Also, Dr. Malkzadeh, there is an additional light guide adapter not on a scope....)

Of the 7 ENF GP scopes leak tested this morning, 3 failed: #2806287, 2896289, and 2704599. The other 2 flexible Olympus non-lumen scopes were tested and passed. All scopes tested were marked with green tape so that we can identify the other 2 when they turn up. The 3 scopes that failed will be sent to Biomed for transit to Olympus. I believe that 2 of them are under warranty. This leaves 4 functioning ENF-GP scopes in our racks at the moment. I will try to get loaners from Olympus ASAP.

Cidex® OPA

ortho-phthalaldehyde Solution

high level disinfectant for semi-critical medical devices
Active Ingredient

ortho-phthalaldehyde	0.55%
Inert Ingredients	99.45%
Dipotassium hydrogen phosphate	
Potassium dihydrogen phosphate	
Benzotriazole	
Citric acid	
D&C Green Dye #2	
N-(hydroxyethyl)-ethylenediaminetetraacetic acid (HEDTA)	
Total	100.00%

Does not require activation before use.

INSTRUCTIONS FOR USE

Intended Use: CIDEX® OPA Solution is a high level disinfectant for processing heat sensitive reusable semi-critical medical devices, for which sterilization is not feasible, and when used according to the Directions for Use. CIDEX OPA Solution is intended for use in manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadiene-styrene (ABS), polyethylene, glass-filled polypropylene and/or polycarbonate plastics. CIDEX OPA Solution may also be used in automated endoscope reprocessors according to the manufacturer's instructions and should be monitored with CIDEX OPA Solution Test Strips. See DIRECTIONS FOR USE - Reusage for Disinfection.

The semi-critical medical devices reprocessed in CIDEX OPA Solution must first be cleaned according to a validated cleaning protocol or standard, such as the ASTM F 1518 "US Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Indications for Use: CIDEX OPA Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices, for which sterilization is not suitable, and when used according to the Directions for Use.

Manual Processing: High Level Disinfectant at a minimum of 20°C (68°F). CIDEX OPA Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX OPA Solution Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Automatic Endoscope Reprocessors that can be set to a minimum of 25°C: High Level Disinfectant at a minimum of 25°C (77°F). CIDEX OPA Solution is a high level disinfectant when used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C) according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX OPA Solution Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 14 days.

Note: If your AER cannot be set to a minimum of 25°C please follow the time and temperature stated in Indications for Use, Manual Processing.

Minimum Effective Concentration (MEC): 0.3%.

Reuse Period for Disinfection: CIDEX OPA Solution has demonstrated disinfection efficacy in the presence of 5% organic soil contamination and microbiological burden during reuse. CIDEX OPA Solution may be reused for up to a maximum of 14 days provided the required conditions of ortho-phthalaldehyde concentration and temperature exist based upon monitoring described in the Directions for Use. DO NOT rely solely on days in use. Concentration of this product during its reuse life must be verified by the CIDEX OPA Solution Test Strip prior to each use to determine that the concentration of ortho-phthalaldehyde is above the MEC of 0.3%. The product must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

General Information on Selection and Use of Germicides for Medical Disinfection: Choose a germicide with the level of antimicrobial activity that is appropriate for the reusable device. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical or semi-critical device.

Critical device: Presents a high risk of infection if not sterile. Routinely penetrates the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.

Semi-critical device: Makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

Second, determine if sterilization or high level disinfection is required.

Critical device (e.g., cardiac catheters, scalpels, surgical instruments): Sterilization is required.

Semi-critical reusable device (e.g., endoscopes): Sterilization is required whenever feasible; where not feasible, high level disinfection is the minimum acceptable process.

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

Microbicidal Activity: The following table indicates the spectrum of activity as demonstrated by testing of CIDEX OPA Solution using prescribed test methods.

MICROORGANISM	
VEGETATIVE ORGANISMS	
<i>Staphylococcus aureus</i>	
<i>Salmonella choleraesuis</i>	
<i>Pseudomonas aeruginosa</i>	
<i>Mycobacterium bovis</i>	
FUNGI	
<i>Trichophyton mentagrophytes</i>	
VIRUSES	
NON-ENVELOPED	
Poliovirus Type 1	
Rhinovirus Type 42	
Adenovirus Type 2	
Vaccinia (Wyeth)	
Coxsackievirus Type B-3	
ENVELOPED	
Coronavirus	
Cytomegalovirus	
Influenza Virus [Hong Kong]	
HIV-1	
Herpes simplex Types 1,2	

To qualify CIDEX OPA Solution as a high level disinfectant, the reused solution passed the AOAC Sporidical Activity Test in 32 hours at 20°C and in 32 hours at 25°C.

Material Compatibility: CIDEX OPA Solution has been tested and found to be compatible with the materials shown below.

METALS ¹	PLASTICS ²
Aluminum	Polymethylmethacrylate (Acrylic)
Anodized aluminum ³	Nylon
Brass	Polyethylene terephthalate (Polyester)
Carbon steel	Polystyrene
Chrome plated brass ²	Polyvinylchloride (PVC) ³
Chrome plated steel ²	Acrylonitrile/butadiene/styrene (ABS)
Copper	Polysulfone
Nickel plated brass ²	Polycarbonate ¹
Nickel silver alloy ²	Polyethylene
Stainless steel ¹	Polypropylene
Titanium	Acetal
Tungsten carbide ³	PTFE
Vanadium steel ¹	Polyamide

ELASTOMERS⁵
Polychloroprene (Neoprene)
Kraton G
Polyurethane
Silicone rubber²
Natural Rubber Latex

ADHESIVES⁶
Cyanacrylate⁵
EPO-TEK 301 Epoxy⁵
EPO-TEK 353 Epoxy

- Exposed to 31 days (744 hours) of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
- Shows signs of surface discoloration at 7 days or greater.
- Most grades tested show no effect. Others may exhibit slight discoloration at 7 days or greater. Stainless steel 440 shows rust at 14 days immersion.
- Treated with 500 cycles of CIDEX OPA Solution. Surface breakdown noted after 150 cycles (25 hour total contact).
- Exposed 7 days of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
- Some grades or applications exhibit discoloration.
- Some sonic welded parts may exhibit crazing.
- Some loss in shear strength but show no signs of severe degradation.

Olympus, Pentax, and Fujinon endoscopes are compatible with CIDEX OPA Solution.

If questions arise regarding the compatibility of a device with CIDEX OPA Solution, contact the device manufacturer.

Cleaning Agent Compatibility: CIDEX OPA Solution is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment (e.g., ENZOL[®] Enzymatic Detergent). Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.

CONTRAINDICATIONS

- CIDEX OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances CIDEX OPA Solution has been associated with anaplasia-like reactions in bladder cancer patients undergoing repeated cystoscopies.
- CIDEX OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX OPA Solution or any of its components.
- CIDEX OPA Solution should not be used to sterilize heat sensitive medical devices. When sterilization by a biologically monitorable process is not feasible, high level disinfection of rigid endoscopes is recommended by the Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC).

WARNINGS

- May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances. In the majority of these instances health care workers were not using the product in a well-ventilated room or not wearing proper personal protective equipment. (See PRECAUTIONS).
- Avoid contact with eyes, skin, or clothing. (See PRECAUTIONS - for important information on how to protect eyes, skin and clothing.) Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary staining. Repeated contact with skin may cause skin sensitization. In case of eye contact, immediately flush eyes with large quantities of water for at

least 15 minutes. Seek medical attention. In case of skin contact, immediately wash with water. Refer to the MSDS for additional information. Do not form sprays, mists or aerosols of this product.

- Avoid contamination of food. Ingestion may cause irritation or chemical burns of the mouth, throat, esophagus and stomach. If swallowed, DO NOT INDUCE VOMITING. Drink large quantities of water and call a physician immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.
- Avoid exposure to ortho-phthalaldehyde vapors, as they may be irritating to the respiratory tract and eyes. May cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and tightness, difficulty with breathing, wheezing, lightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, dry mouth or headache. May aggravate a pre-existing asthma or bronchitis condition. In case of adverse reactions from inhalation of vapor, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention.
- The use of CIDEX OPA Solution with semi-critical devices must be part of a validated rinsing procedure as provided by the device manufacturer. See DIRECTIONS FOR USE Rinsing instructions - for important information on rinsing.
- ALWAYS follow the Directions For Use Rinsing Instructions (Part B) and the SPECIAL INSTRUCTIONS for transesophageal echocardiography (TEE) probes in Part C EXACTLY or residues of CIDEX OPA Solution may remain on the device. Failure to follow rinsing instructions exactly has resulted in reports of chemical burns, irritation, and staining of the mouth, throat, esophagus and stomach.

PRECAUTIONS

Follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning soiled devices.

- When disinfecting devices, use gloves of appropriate type and length, eye protection and fluid-resistant gowns. When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g., after 12 minutes of exposure. For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves, or butyl rubber gloves may be used.
Note: Contact with CIDEX OPA Solution may stain exposed skin or clothing.
- Use CIDEX OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb ortho-phthalaldehyde from the air.
- Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination with soil or lubricants will decrease the effectiveness of the germicide.
- The user MUST adhere to the Directions for Use, as modification to the Directions for Use may affect the safety and effectiveness of the germicide.
- Do not use CIDEX OPA Solution on critical medical devices that are intended for use in a sterile area of the body (e.g. cataract surgical instruments).
- The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX OPA Solution.



7. The use of CIDEX OPA Solution in automated endoscope reprocessors must be part of a validated reprocessing procedure. The contact conditions must be 25°C for 5 minutes. (See note following the Indications for Use section).
8. Use CIDEX OPA Solution Test Strips to detect ortho-phthalaldehyde concentration before each cycle to detect the MEC. Follow the Directions For Use provided with the CIDEX OPA Solution Test Strips.

DIRECTIONS FOR USE

Cleaning/Decontamination: Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of semi-critical medical devices before reprocessing in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal.

Refer to the reusable device manufacturer's labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

Before immersion in CIDEX OPA Solution, thoroughly clean devices, including all lumens, using a cleaning protocol or standard, such as the ASTM F 1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Thoroughly rinse and rough dry all surfaces and lumens of cleaned devices.

Usage: NO ACTIVATION IS REQUIRED.

Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used.

Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

A. High Level Disinfection

1. **Manual Processing:** Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX OPA Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below.
2. **Automatic Endoscope Reprocessor that can be set to a minimum of 25°C** (See note following the Indications for Use section): High Level Disinfectant at a minimum of 25°C (77°F). For use in a legally marketed AER (that can be set to a minimum of 25°C) with a minimum immersion time of 5 minutes. As with all high level disinfectants, it is critical that temperature is monitored when using CIDEX OPA Solution in an AER at 25°C. See section D. 1 "Monitoring of Germicide."

B. Rinsing Instructions

1. RINSING PROCEDURE

- a) **Manual Processing:**
 - Following removal from CIDEX OPA Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g., 2 gallons) of water. Use sterile water unless potable water is acceptable. See Item 2 or 3 below.
 - Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.

- Manish all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX OPA Solution residues. Residues may cause serious side effects. SEE WARNINGS, THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.
- Refer to the reusable semi-critical medical device manufacturer's labeling for additional rinsing instructions.

b) Automated Processing:

- Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with this product.
- Ensure that the automated rinse cycle selected will thoroughly rinse the semi-critical medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer's recommendations.
- Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose.
- Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

2. STERILE WATER RINSE:

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

Devices intended for use in normally sterile areas of the body.

Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served).

When practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms.

3. POTABLE WATER RINSE:

For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms which may be present in potable water supplies.

Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

A device that is not completely dried is an ideal situation for rapid colonization of bacteria. As these waterborne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

- C. **Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing:** As with all devices, carefully follow all probe manufacturer recommendations such as use of a sterile protective sheath when performing TEE. Soaking for a minimum of 12 minutes in CIDEX OPA Solution is required for high level disinfection (HLD). Excessive soaking of the probes (e.g., longer than an hour) during HLD and/or not rinsing three times with a fresh quantity of water each time as described in Part B, may result in residual CIDEX OPA Solution remaining on the device, the use of which may cause staining, irritation or chemical burn of the mouth, throat, esophagus and stomach.

- D. **Reuse for Disinfection:** CIDEX OPA Solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The ortho-phthalaldehyde concentration of CIDEX OPA Solution during its use-life must be verified by the CIDEX OPA Solution Test Strips prior to each use, to determine that the MEC of 0.3% is present. CIDEX OPA Solution may be used and reused within the limitations indicated above for up to a maximum of 14 days. CIDEX OPA Solution must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

1. **MONITORING OF GERMICIDE:** During reuse, it is recommended that the CIDEX OPA Solution be tested with CIDEX OPA Solution Test Strips prior to each use. This is to ensure that the Minimum Effective Concentration (MEC) of ortho-phthalaldehyde is present.

During the usage of CIDEX OPA Solution as a high level disinfectant, it is recommended that a thermometer and timer be utilized to ensure that the optimum conditions are met.

Monitoring Temperature in Automatic Endoscope Reprocessor that can be set to a minimum of 25°C: As with all high level disinfectants, temperature monitoring is critical for use of CIDEX OPA Solution at a minimum of 25°C for 5 minutes in an AER. If you cannot monitor temperature appropriately in your machine, contact ASP at (888) 783-7723 for further instructions.

Visually inspect the solution during the reuse life for the presence of precipitates which may result from the use of hard water. Discard solution if precipitation occurs.

POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES: Disinfected reusable devices are either to be immediately used, or stored in a manner to minimize recontamination. Refer to the reusable device manufacturer's labeling for additional storage and/or handling instructions.

STORAGE CONDITIONS AND EXPIRATION DATE

1. 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.
2. Once opened, the unused portion of the solution may be stored in the original container for up to 75 days until used.

3. The expiration date of the CIDEX OPA Solution is found on the immediate container.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

For further hazard information please refer to the Material Safety Data Sheet. Emergency, safety, or technical information about CIDEX OPA Solution can be obtained from Advanced Sterilization Products at (888) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

USER TRAINING

The user should be adequately trained in the decontamination and disinfection of semi-critical medical devices and the handling of liquid chemical germicides. Additional information about CIDEX OPA Solution can be obtained by contacting your local Advanced Sterilization Products sales representative.

DISINFECTANT/CONTAINER DISPOSAL INFORMATION

Disinfectant Disposal: Check state and local disposal regulations. Glycine (free base) may be used as a neutralizer for CIDEX OPA Solution prior to disposal, if required. A minimum of 25 grams of glycine (free base) should be used to neutralize one gallon of CIDEX OPA Solution. The minimum recommended neutralization time is one hour. Discard residual solution into drain. Flush drain thoroughly with water.

Container Disposal: Do not reuse empty container. Rinse and dispose per hospital policy.

HOW SUPPLIED

Reorder	Description	Case Contains
20390	One Gallon (3.785L) Container	4 gals (4 x 3.785L)/case
20392	CIDEX OPA Solution Test Strips	60 strips/btl; 2 btl/case
20393	CIDEX OPA Solution Test Strips	15 strips/btl; 2 btl/case

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Reprocessing Flexible Endoscopes

Avoiding Reprocessing Errors Critical for Infection Prevention and Control

By Bradley Catalone, Ph.D., and George Koos

Flexible endoscopy procedures are now a routine part of patient diagnosis and treatment in hospitals and surgery centers in the United States. The demand for these safe and effective procedures continues to increase, with more than 15 million endoscopy procedures annually. Endoscopies are performed with sophisticated, reusable, flexible instruments that have specific requirements for cleaning, disinfection and sterilization. Because of this, adherence to recommended practices and guidelines for reprocessing is a critical component of infection control and reducing the risk of nosocomial infections.

Failure to follow established guidelines for reprocessing has resulted in the transmission of infectious agents causing serious patient injury and/or death.¹⁻³ Despite these incidents, concise manufacturer's reprocessing guidelines, and the development and publication of several recommended practice and guidance documents,⁴⁻⁸ appropriate cleaning, disinfection and/or sterilization of endoscopes continue to be a challenge for many facilities. This article presents some reprocessing

errors commonly identified in hospitals and surgery centers in the United States and discusses how these can be avoided.

Pre-cleaning

Pre-cleaning is an essential reprocessing step that removes patient biomaterial and microorganisms from the endoscope. Following an endoscopy, biomaterial from the patient is present on the insertion tube and within the internal channels of the endoscope. All channels must be cleaned, even if unused, due to fluid and debris entering these channels at the distal tip. Patient biomaterial provides a nutrient source that will promote the growth of potentially pathogenic microorganisms. Also, when this biomaterial is not removed immediately after a procedure, it will dry and harden. The surface of the hardened material functions as a barrier that prevents the penetration of disinfecting and sterilizing agents that kill microorganisms. In addition, patient biomaterial may inactivate disinfectants. The result is potentially infectious material still present on the endoscope or in the endoscope channels following reprocessing delays.

Instrument Care



A reprocessing delay may occur when a patient has both upper and lower procedures performed during the same visit. The endoscope from the first procedure is kept in the procedure room until the second procedure is completed. If pre-cleaning is not initiated within an hour, the endoscope should be

If pre-cleaning is not initiated within an hour, the endoscope should be soaked in an appropriate enzymatic detergent according to the manufacturer's recommendations, before continuing with mechanical cleaning and then terminal reprocessing. This process will allow for any dried debris to be loosened and ensure its removal during cleaning.

soaked in an appropriate enzymatic detergent according to the manufacturer's recommendations, before continuing with mechanical cleaning and then terminal reprocessing. This process will allow for any dried debris to be loosened and ensure its removal during cleaning.

Reprocessing delays may be encountered if staff must come in and perform emergency procedures at night or over the weekend, leaving the endoscope to be properly reprocessed by the regular staff on the next workday. Delays may also occur in busy departments, especially when cases run longer than expected. In the rush to get to the next procedure, the pre-cleaning is often abbreviated or the endoscope is set aside until the next case is finished. The pre-cleaning process is not a long procedure, but is an essential step in the cleaning process. Pre-cleaning should be performed every time according to manufacturer's instructions.

To avoid additional delays, the endoscope insertion tube should be wiped down and all of the channels flushed with detergent and/or water (as specified by manufacturer's instructions) as soon after the procedure as possible, preferably immediately.

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The mechanical action of wiping the endoscope, coupled with flushing all of the channels, removes biomaterial that harbors and provides nutrients for microorganisms. When delays in pre-cleaning do occur, additional reprocessing steps, which include an extended soak period, are required. Follow the manufacturer's instructions for delayed reprocessing of endoscopes.

Mechanical Cleaning

Guidelines from professional organizations consistently state that mechanical cleaning is critical for proper endoscope reprocessing. Mechanical cleaning is essential to reducing bioburden and preventing the risk of cross-contamination. Studies indicate that mechanical cleaning alone reduces bioburden by an average of 4 logs (99.99%).⁹⁻¹⁰ The Multi-society Guideline for Reprocessing Gastrointestinal Endoscopes⁵ identifies mechanical cleaning as "essential before manual or automated disinfection," and the guideline categorizes cleaning as a Class 1A recommendation, the strongest possible classification, stating: "strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies."

Mechanical cleaning is a multi-step process that involves accessories for brushing and flushing the endoscope channels and openings. The multitude of detergents, disinfectants, and accessories specific for each endoscope may lead to improper cleaning. Some common areas to focus on include the following:

□ Detergent Use

One of the most common errors during cleaning is improper dilution of the detergent. The "more is better" theory may work with some things in life, but detergents and liquid chemical germicides are not among them. The detergent is formulated to be effective at a specific dilution and temperature. Any deviation from the instructions for use may alter the effectiveness of the detergent, its ability to be properly rinsed, and possibly cause damage to the scope. As a result, the detergent should be used according to the manufacturer's instructions. Use of an enzymatic detergent is recommended to help breakdown and flush patient biomaterial from the scope.

According to all accepted reprocessing guidelines, enzymatic detergents are intended for single use. In general, detergents have little or no bacteriocidal activity. As a result, potentially infectious material will remain in the detergent following its use in endoscope cleaning. To prevent cross-contamination, dispose of the detergent after each use.

□ Submersion

A common reprocessing error is the failure to fully submerge the endoscope in detergent or disinfectant for the required length of time. Contact time is a critical component to the efficacy of any detergent or disinfectant, especially for the disinfectant. Do not guess; use a timer. Anything less than the recommended time will not produce a "patient-ready" endoscope. Anything substantially over the recommended time may lead to endoscope damage. If portions of the endoscope are not submerged for the required contact time during exposure to either the detergent or disinfectant, infectious material may remain on the endoscope following reprocessing.

The primary reasons for failure to fully submerge the endoscope are that the sink/basin is not large enough to accommodate the flexible endoscope, or not enough of the properly diluted detergent or disinfectant was added. The recommended sink/basin should be at least 16 inches by 16 inches by 8 inches. After placing the endoscope in the sink/basin, ensure that the scope is fully submerged. If not, add additional properly diluted detergent or disinfectant. If using an automated endoscope reprocessor, follow the manufacturer's instructions for loading the endoscope into the basin.

□ Channel Reprocessing and Cleaning Accessories

The validated cleaning adapters supplied by the manufacturer are critical for properly reprocessing the endoscope channels. Some scopes have additional or unique channels, such as an auxiliary water channel (forward water-jet) or elevator wire channel, which require reprocessing. All channels must be cleaned and disinfected even if they are not used during the procedure. By not utilizing the correct, validated connection, there is a high probability that many or all channels will not be adequately reprocessed. To ensure that all channels are adequately reprocessed, refer to the manufacturer's instruction manual for scope reprocessing and, if applicable, contact the automated endoscope reprocessor (AER) manufacturer for the proper cleaning accessories.

□ Channel Brushing

Channel brushes may seem like simple devices, but they are an important part of effective cleaning. For effective cleaning, the brush must contact the channel wall to produce mechanical abrasion of the surface, which results in the removal of biomaterial. Worn or damaged cleaning brushes may result in ineffective cleaning or channel damage. To avoid this, routinely inspect channel brushes for missing bristles, bends or kinks, and missing solder beads holding the twisted wires together. Also, keep an inventory of spare brushes in the event that one needs to be replaced. Reprocess and use the brush in accordance with the manufacturer's instructions.

□ Water Rinsing

Manual cleaning is completed with a thorough rinse of the endoscope with fresh water. There is a common misconception that rinsing after cleaning is not critical because the scope will subsequently be terminally reprocessed; however, residual detergent may react with and inhibit the disinfectant or sterilant solution. This reaction may also result in insertion tube staining or peeling. It is equally important to ensure that the disinfectant or sterilant solution is thoroughly rinsed from the scope following terminal reprocessing. Failure to thoroughly flush disinfectant or sterilant from the endoscope following reprocessing has resulted in adverse patient outcomes including chemical irritation of tissue and patient anaphylaxis.¹¹ Contact your equipment and/or disinfectant manufacturer to determine the rinse volume and total number of rinses required.

Disinfection/Sterilization

High-level disinfection or sterilization of endoscopes is listed as a requirement in all guidance documents, with high-level disinfection being the standard and minimum requirement.

□ Disinfectant/Sterilant Use

The Multi-society Guideline recommends that manual or automated reprocessing include use of “a high-level disinfectant/sterilant cleared by the FDA for high-level disinfection/sterilization.” All disinfectants and sterilants have expiration dating established by the manufacturer. For example, most glutaraldehyde solutions have both a shelf life printed on the container and a 14- or 28-day expiration following activation or first use. Expiration dating is based on the stability (expiration date and use life) of the product and minimum effective concentration (MEC) required to achieve the expected result of disinfection or sterilization. Reusable disinfectants and sterilants begin to degrade upon preparation. The addition of any debris or solution, such as water, will reduce the effective concentration. Therefore, it is recommended that the MEC be tested prior to each use according to the manufacturer’s instructions.

For many disinfectants and sterilants, the solution must be activated and the use period starts from the date of activation. A common misconception is that the addition of fresh disinfectant or sterilant to an existing solution will extend the duration of use or expiration of the older solution. This is incorrect, and mixing the two solutions will reduce the efficacy of the freshly prepared disinfectant or sterilant. Also, under no circumstances, including a passing MEC result, may the use period for a disinfectant/sterilant be extended beyond the manufacturer's recommendations. Facilities should maintain and routinely review MEC logs to ensure proper disinfectant/sterilant use.

Endoscopes should be stored in a clean, dry, and well-ventilated area to minimize the possibility of recontamination. Also, all valves and the water resistant cap should be removed during storage to facilitate drying.

□ Air Purge and Alcohol Flush

An air purge should be completed immediately following the water rinse. Residual water, depending upon the quality used to rinse the scope, may contain waterborne organisms. If sterile water is not used to rinse the scope, an additional alcohol purge followed by a forced air purge is required to thoroughly dry the scope and prevent recontamination. An alcohol flush is recommended to enhance drying whether or not sterile water is used during the final rinse.¹²

Storage

Endoscopes should be stored in a clean, dry, and well-ventilated area to minimize the possibility of recontamination. Also, all valves and the water resistant cap should be removed during storage to facilitate drying. During storage, many facilities use distal tip protectors, most of which are essentially sponges. These protectors will absorb moisture and may harbor microorganisms. To minimize the risk of recontamination, these protectors are typically designed for single-use only.

The benefits of flexible endoscopic procedures for the detection, prevention and treatment of many diseases, such as cancer, are well established. There is no doubt that these procedures have improved healthcare and diagnostic capabilities. As discussed, these procedures require the use of

sophisticated equipment. Flexible endoscopes can be cleaned, disinfected and/or sterilized efficiently and effectively when the manufacturer's guidelines are followed. If there are concerns about the current procedures performed at your facility, contact the manufacturer and review the current published guidelines. ✦

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6

3.3 Preparation and inspection of accessories

WARNING

Only single-use biopsy valve (MAJ-1218) is compatible with this endoscope. Single-use biopsy valve (MAJ-210) may allow debris to leak or drip from its slit.

Prepare cleaned and disinfected or sterilized the air/water valve (MAJ-1248) and suction valve (MAJ-1247) as described in Chapter 5, "General Policy" through Chapter 7, "Cleaning, Disinfection and Sterilization Procedures".

Inspection of the air/water and suction valves

1. Confirm that the holes of valves are not blocked (see Figures 3.3 and 3.4).
2. Confirm that the valves are not deformed or cracked (see Figures 3.3 and 3.4).
3. Check for excessive scratching or tears in the air/water valve's seals (see Figure 3.3).

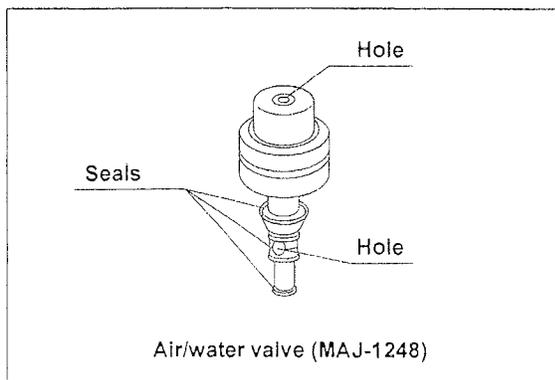


Figure 3.3

Aspirating detergent solution into the suction channels

1. Attach the suction cleaning adapter's port cap (MAJ-1219) to the instrument channel port (see Figures 7.15, 7.16).
2. Connect the suction tube from the suction pump to the suction connector on the light guide connector section of the endoscope. Turn the suction pump ON.
3. Immerse both the endoscope's distal end and the weighted end of the suction cleaning adapter in the detergent solution.
4. Cover the suction cylinder with your finger and aspirate the detergent solution for approximately 30 seconds.
5. Turn the suction pump OFF.
6. Disconnect the suction tube, and the suction cleaning adapter (MAJ-1219).
7. Reprocess the suction cleaning adaptor as described in Section 7.9, "Cleaning, disinfection and sterilization procedures for reusable parts and reprocessing equipment".

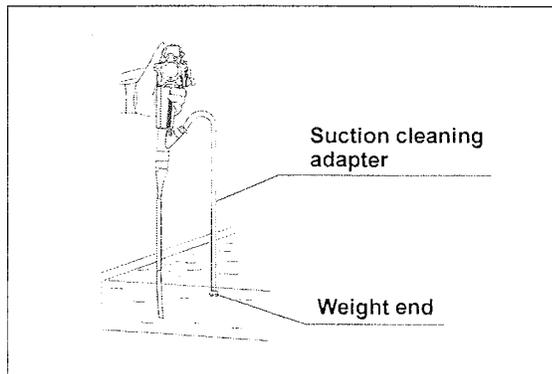


Figure 7.15

[Handwritten signature and a circled number '8']

Chapter 7 Cleaning, Disinfection and Sterilization Procedures

WARNING

ALL channels of the endoscope MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

7.1 Required reprocessing equipment

Preparation of the equipment

Prior to cleaning, disinfection or sterilization, prepare the equipment shown in Figure 7.1.

CAUTION

- Carefully clean and dry the electrical contacts of the video connector after performing the procedure described in Section 7.7, "Rinsing after high-level disinfection". Otherwise, equipment damage can result.
- Use basins which are at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
- For proper reprocessing results, do not coil the insertion tube or universal cord with a diameter of less than 40 cm.
- Do not coil the endoscope's insertion tube, universal cord or video cable with a diameter of less than 12 cm. The endoscope can be damaged if coiled too tightly.

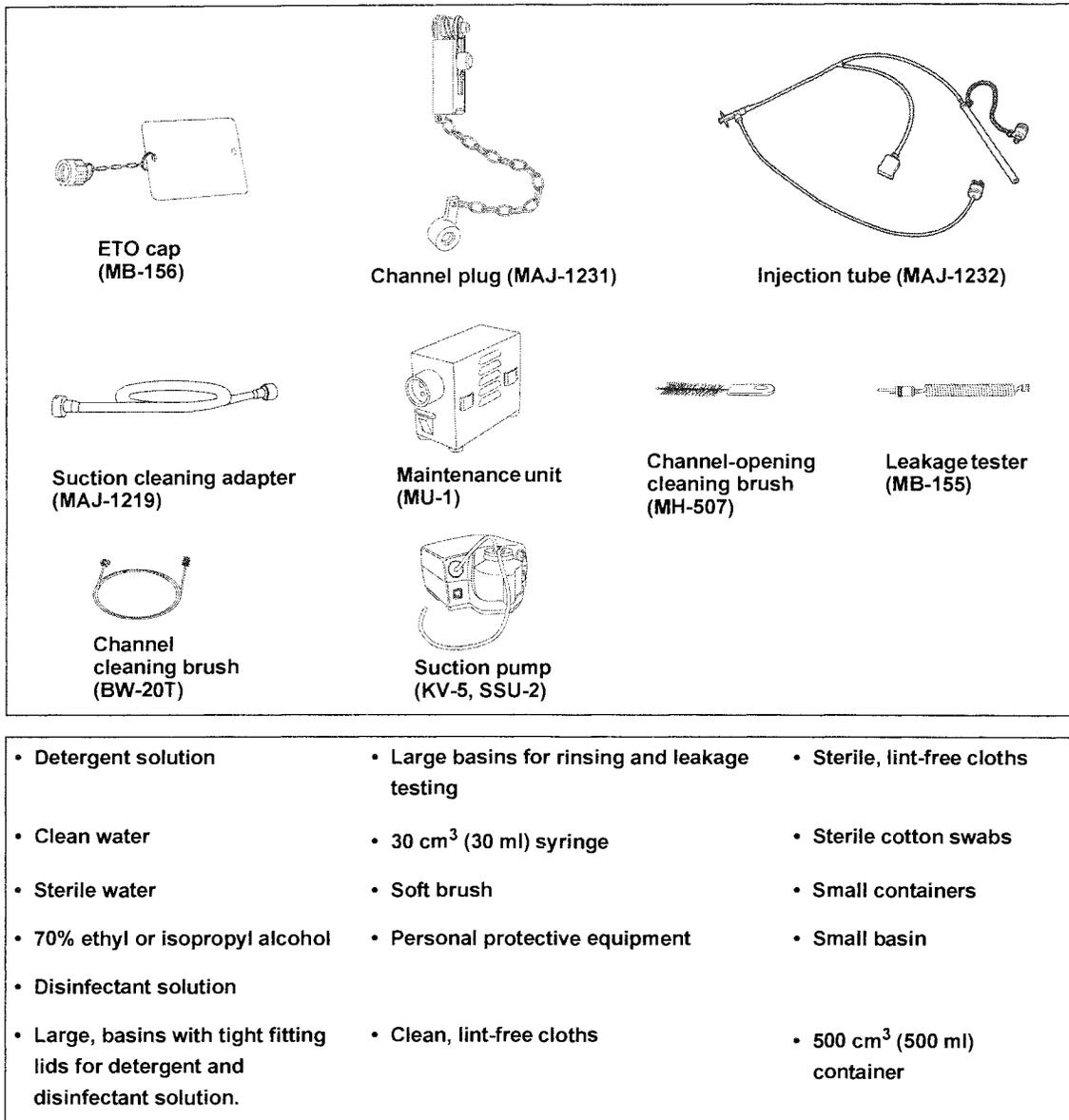


Figure 7.1



Adeleye, John A

From: Irmeler, Monica
Sent: Thursday, February 08, 2007 12:39 PM
To: Adeleye, John A
Subject: CIDEX Equip Disinfection

Department of Veterans Affairs Medical Center
50 Irving St., NW
Washington, DC 20422

Disinfection of Equipment Using Cidex OPA

Meticulous cleaning, following measures outlined below, must precede disinfection with Cidex OPA (*ortho-phthalaldehyde*).

Supplies Needed:

- Personal protective equipment (Nitrile gloves, mask, eye protection, impervious gown)
- Enzymatic cleaning solution and solution container
- Cidex OPA solution
- Cidex OPA test strips
- Large covered non-metal container for Cidex OPA
- Gauze sponge or soft, lint-free cloth
- Sterile water for rinsing
- Rinse basins
- Air and water channel cleaning adapters per manufacturers instructions (for lumined endoscopes)
- Timer
- Glycine for neutralizing Cidex OPA before discarding and for spills cleanup.

STEPS

RATIONALE

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| 1. Put on gloves, impervious gown, mask, and eye protection. | To prevent exposure to patient secretions and to caustic cleaning/germicide agents. Do not wear vinyl gloves. |
| 2. Set up work area in an approved workroom. | |

CLEANING

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| 3. Immediately after use, rinse equipment with water and wipe with gauze. | To prevent organic material from drying on equipment. |
| 4. Fill a basin with freshly made solution of water and a low sudsing enzymatic detergent compatible with the equipment. | Use fresh solution for each instrument to prevent cross contamination. |
| 5. Soak at least 15 minutes or until all organic | |

(9)

material is loosened.

- 6. Remove from enzymatic detergent solution, rinse with tap water, and thoroughly dry using lint-free gauze.

Drying is essential to prevent dilution of Cidex OPA solution.

- 7. See specific leak testing and cleaning guidelines for lumined endoscopes.

only for lumined endoscopes which requires need to leak test non lumined. also, for ENT clinic did not even leak testing equipment !!

DISINFECTION

- 8a. Read the directions for use on the bottle label and package insert, then pour Cidex OPA Solution into a CIDEX® Solution tray or appropriate container.

- 8b. Solution left in the bottle may be stored for up to 30 days.

- 9. Record the date that the solution was poured from the original container, and the date that it can no longer be reused (not to exceed 14 days).

Logbooks are available from Pharmacy.

- 10. Test Cidex OPA Solution prior to use with CIDEX® OPA Solution Test Strips. **When a new case of test strips is opened a quality control test must be done on the test strips. Perform the test as outlined at the end of this procedure.**

Verify the Minimum Effective Concentration (MEC) of *ortho*-phthalaldehyde is present.

- a. Date bottle of test strips when opened.
- b. Dip entire indicating pad of strip into Cidex OPA solution for 1 second and remove. Do not shake strip after removal.
- c. Remove excess solution by standing the strip upright on a paper towel.
- d. Read results after 90 seconds. Do not read past 2 minutes.
- e. Pad will be completely purple if solution is acceptable. If any blue appears on the pad apart from the top line, the solution is unacceptable and must be discarded.

Bottle of test strips is good for 90 days after the date opened.

- 11. Immerse clean, dry instruments completely in the Cidex OPA Solution.

Insure that all instruments are completely submerged, and fill any lumens with solution.

- 12. Cover the Cidex Solution tray securely and soak instruments for 12 minutes at room temperature.

High-level disinfection is accomplished in 12 minutes.

- 13. Following disinfection, rinse instruments

Sterile water is recommended for rinsing. See

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- | | |
|---|--|
| thoroughly, with sterile water, flushing all channels and lumens. | package insert for detailed directions. |
| 14. Repeat the rinse process twice, for a total of 3 rinses. Each rinse should use a fresh bottle of sterile water. | Each rinse should be a minimum of 1 minute in duration. Failure to rinse instruments according to recommendations may cause them to turn gray. |
| 15. Thoroughly dry the instruments. | See manufacturer's labeling for additional storage or handling instructions. |
| 16. Disinfected instruments should be used immediately, or stored in a manner to minimize recontamination. | Refer to manufacturer's labeling for additional storage or handling instructions. |
| 17. BEFORE DISCARDING Cidex OPA down drain, put 25 Gm of glycine per one gallon of Cidex OPA into solution and let it sit for 1 hour. | The glycine neutralizes the Cidex OPA before it is dumped into the sanitation stream. |
| 18. After dumping the neutralized Cidex OPA down the drain, run cold water for 5 minutes. | Copious flushing with water further dilutes the Cidex OPA. |
| 19. Discard Cidex OPA Solution after 14 days, even if the Test Strips indicate a concentration above the MEC. | Once neutralized, Cidex OPA Solution may be discarded down hospital drains in accordance with local regulations. |

Procedure for Performing Quality Control Test on New Case of Test Strips:

1. Preparation of Control Solutions
 - a. Verify that the labeled expiration date for the solution is appropriate.
 - b. Use the Cidex OPA solution for the positive control solution.
 - c. Prepare a negative control solution by diluting one part of full strength solution with one part of water. Label each control solution appropriately.
2. Testing Procedure
 - a. Following the directions for use, submerge three test strips in each of the above freshly prepared solutions for one second each.
 - b. Remove.
 - c. The 3 test strips dipped in the full strength positive control solution should exhibit a complete purple color on the indicating pad at 90 seconds.
 - d. The 3 strips dipped in the diluted negative control should either remain completely blue or change to purple when read at 90 seconds.
 - e. Refer to the color chart on the test strip bottle for interpretation of results.
3. Testing Frequency
 - a. Perform the positive and negative control test on a newly opened test strip bottle from each case of Cidex OPA solution.\
4. Unsatisfactory QC Test Performance
 - a. If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, return the case to the Pharmacy. **DO NOT USE THE STRIPS.**

Spills Clean up Procedure



Supplies Needed:

Safety glasses
Nitrile gloves
Mop and Bucket (readily available)

Sponges and towels
Plastic bag
Glycine freebase

For small spills:

1. Put on gloves
2. Sprinkle 25G of Glycine onto the spill
3. With mop, sponge or towel, blend Glycine into spill for 1-2 minutes to neutralize spill
4. Collect all neutralized liquid with the mop, sponge or towel
5. Flush liquid down drain with fresh water.
6. Place mop, sponge or towel into plastic bag and seal. If disposable, discard. If reusable, contact EMD.

For large spills contact the HAZMAT Officer (Safety Office)

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