Mitigating Risks of Processing Reusable Medical Devices in Ambulatory Care Settings

AORN-Healthmark
ASC Instrument Reprocessing Webinar
10-07-2021

JOHN WHELAN BSN, RN

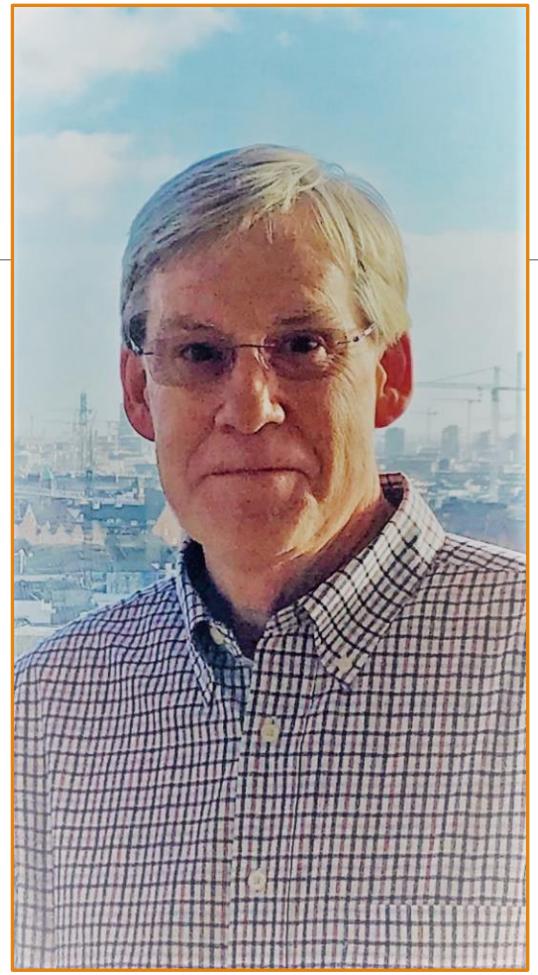
CLINICAL EDUCATION SPECIALIST

HEALTHMARK INDUSTRIES

JWHELAN@HMARK.COM

Continuing Education Provider

Sponsored by



John Whelan BSN, RN
jwhelan@hmark.com

- Clinical Educator for Healthmark Industries.

- Healthcare career - More than 40 years.
  - 20 years in Endoscopy.
  - 4 years system role – overseeing HLD and endoscope processing for health system. Launch of the Centralized Endoscope Reprocessing Department on the main medical campus.

- Memberships:
  - SGNA, ASGE, APIC, AORN, AAMI.

Disclosures

I am an employee of Healthmark Industries Fraser, Michigan USA – a manufacturer and distributor of medical products to healthcare facilities and healthcare professionals.

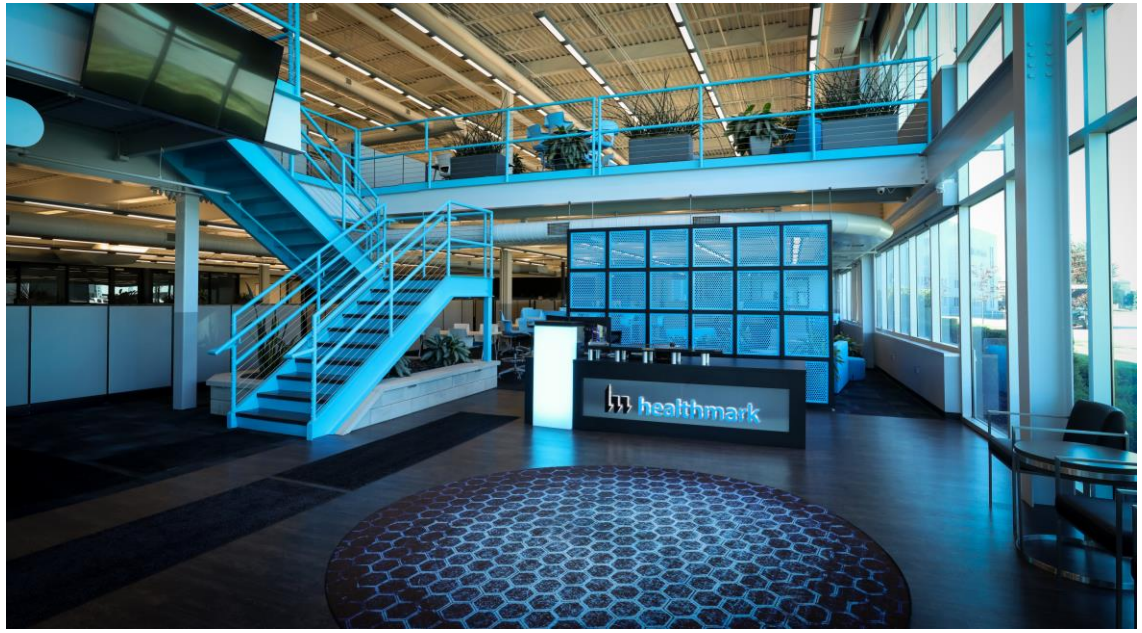
All opinions are those of the presenter.

This presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

Healthmark Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.



Objectives

Discuss the processes and practices for reusable device processing that put ambulatory clinical sites – and their patients - at risk.

Review the applicable best practice standards and guidelines for device processing.

Identify key strategies for identification and mitigation of related risks.

Objectives

Discuss the processes and practices for reusable device processing that put ambulatory clinical sites – and their patients - at risk.

Review the applicable best practice standards and guidelines for device processing.

Identify key strategies for identification and mitigation of related risks.

Common Amb. Care sites - not all inclusive

Allergy
Cardiology
Emergency
Endoscopy (GI/Pulmonary)
Family Medicine
OB/GYN & Women's Health
Ophthalmology
Oral Surgery
Otolaryngology
Pulmonary
Radiation Oncology
Sleep Labs
Speech Pathology
Surgery Clinics
Urology and Urology Oncology

Potential Amb. Care sites with local HLD/sterilization – and common reusable devices requiring processing

- not all inclusive

Allergy – endoscopes

Cardiology – pneumotachs

Emergency – endoscopes, laryngoscope blades

Endoscopy (GI/Pulmonary) – endoscopes, dilators, manometry probes

Family Medicine – vag. specs, endocavitary US probes, fitting diaphragms

OB/GYN & Women's' Health - vag. specs, endocavitary US probes, fitting diaphragms, endoscopes

Ophthalmology - tonometers

Oral Surgery - endoscopes

Otolaryngology – endoscopes

Pulmonary – endoscopes, laryngoscope blades, trachs

Radiation Oncology – endoscopes, rectal bx probes

Sleep Labs – sleep masks/appliances

Speech Pathology - endoscopes

Surgery Clinics – endoscopes, anoscopes, dilators

Urology and Urology Oncology - endoscopes, rectal bx probes, endocavitary US probes

ECRI Institute
https://www.ecri.org/

ECRI

SPECIAL REPORT

Top 10 Patient Safety Concerns 2020

Executive Brief

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively. This annual top 10 list helps organizations identify looming patient safety challenges and offers suggestions and resources for addressing them.

The List for 2020

1. Missed and Delayed Diagnoses
2. Maternal Health across the Continuum
3. Early Recognition of Behavioral Health Needs
4. Responding to and Learning from Device Problems
5. Device Cleaning, Disinfection, and Sterilization
6. Standardizing Safety across the System
7. Patient Matching in the Electronic Health Record
8. Antimicrobial Stewardship
9. Overrides of Automated Dispensing Cabinets
10. Fragmentation across Care Settings

©2020 ECRI. May be disseminated for internal educational purposes solely at the subscribing site.
For broader use of these copyrighted materials, please contact ECRI to obtain proper permission.

ECRI Institute
https://www.ecri.org/

ECRI

SPECIAL REPORT

Top 10 Patient Safety Concerns 2020

Executive Brief

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively. This annual top 10 list helps organizations identify looming patient safety challenges and offers suggestions and resources for addressing them.

The List for 2020

1. Missed and Delayed Diagnoses
2. Maternal Health across the Continuum
3. Early Recognition of Behavioral Health Needs
4. Responding to and Learning from Device Problems
5. Device Cleaning, Disinfection, and Sterilization
6. Standardizing Safety across the System
7. Patient Matching in the Electronic Health Record
8. Antimicrobial Stewardship
9. Overrides of Automated Dispensing Cabinets
10. Fragmentation across Care Settings

©2020 ECRI. May be disseminated for internal educational purposes solely at the subscribing site.
For broader use of these copyrighted materials, please contact ECRI to obtain proper permission.

#4 - Responding to and Learning from Device Problems –

- Create a plan for device-related incidents, towards better response, and limiting reoccurrence.

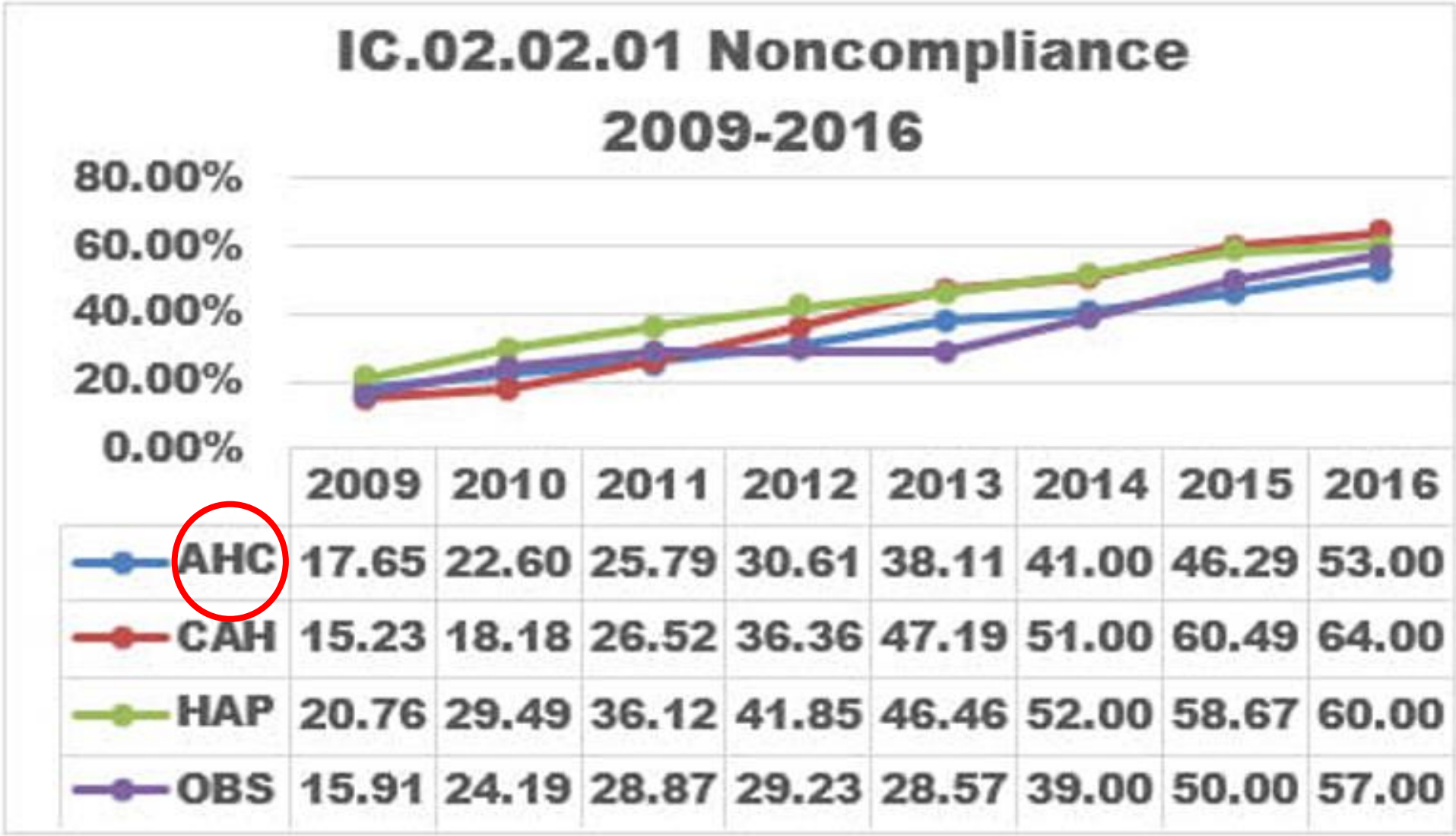
#5 - Device Cleaning, Disinfection, and Sterilization -

- "… productivity pressures; lack of access to current manufacturer instructions…lack of necessary supplies; communication breakdowns… and a lack of universal training and certification requirements."

#6 - Standardizing Safety across the System –

- "Cultures of safety" need to be reproduced and maintained through all healthcare systems - large and small.

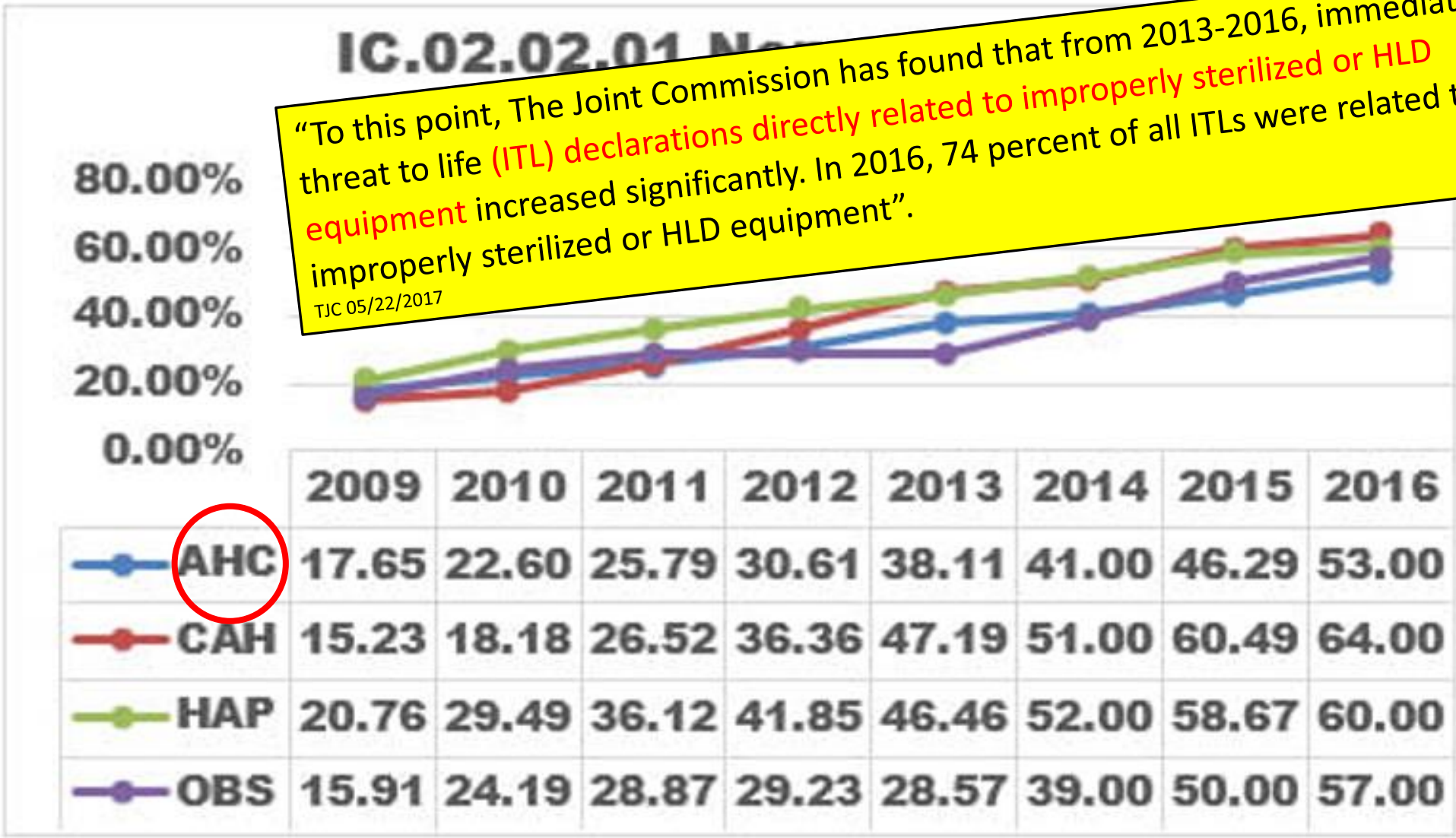
TJC noncompliance rate by program



	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

The Joint Commission. Quick Safety 33: *Improperly sterilized or HLD equipment – a growing problem*. May 22, 2017. Retrieved from URL https://www.jcrinc.com/search/#q=high%20level%20disinfection&first=10&t=_Tab_All&sort=relevancy&f:_SitesOrganizations=[Joint%20Commission%20Resources,The%20Joint%20Commission] Accessed 09-08-2020.

TJC noncompliance rate by program



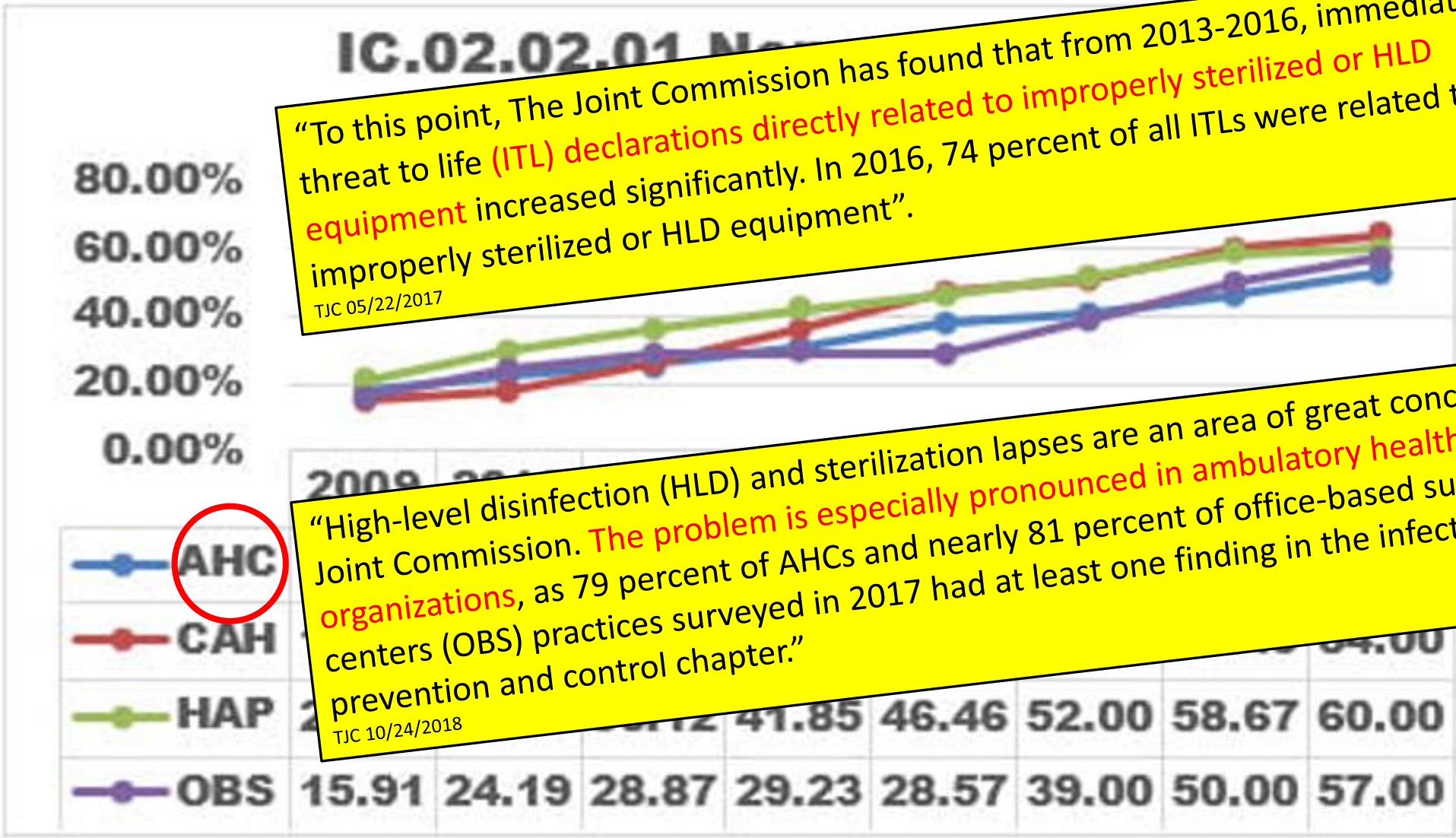
"To this point, The Joint Commission has found that from 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly. In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment".

TJC 05/22/2017

	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

The Joint Commission. Quick Safety 33: *Improperly sterilized or HLD equipment – a growing problem*. May 22, 2017. Retrieved from URL https://www.jcrinc.com/search/#q=high%20level%20disinfection&first=10&t=_Tab_All&sort=relevancy&f:_SitesOrganizations=[Joint%20Commission%20Resources,The%20Joint%20Commission] Accessed 09-08-2020.

TJC noncompliance rate by program



"To this point, The Joint Commission has found that from 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly. In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment".

TJC 05/22/2017

"High-level disinfection (HLD) and sterilization lapses are an area of great concern for The Joint Commission. The problem is especially pronounced in ambulatory health care (AHC) organizations, as 79 percent of AHCs and nearly 81 percent of office-based surgery centers (OBS) practices surveyed in 2017 had at least one finding in the infection prevention and control chapter."

TJC 10/24/2018

The Joint Commission. Quick Safety 33: *Improperly sterilized or HLD equipment – a growing problem*. May 22, 2017. Retrieved from URL https://www.jcrinc.com/search/#q=high%20level%20disinfection&first=10&t=_Tab_All&sort=relevancy&f:_SitesOrganizations=[Joint%20Commission%20Resources,The%20Joint%20Commission] Accessed 09-08-2020.

Joint Commission Online

May 12, 2021

Accreditation and Certification

Top 5 most challenging requirements for 2020

The Joint Commission collects data on organizations' compliance with standards, National Patient Safety Goals (NPSGs), and Accreditation and Certification Participation Requirements to identify trends and focus education on challenging requirements.

The table below identifies the Top 5 Joint Commission requirements identified most frequently as "not compliant" during surveys and reviews from Jan. 1 through Dec. 31, 2020. Fewer surveys were conducted in 2020 because of the coronavirus pandemic. However, Joint Commission surveyors were able to identify Requirements for Improvement (RFIs) in key areas for improvement.

For more information, see the May issue of *Perspectives* or the Standards Frequently Asked Questions. (Contact: Standards Interpretation Group, 630-792-5900 or online question form)

In this issue

Rank	Standard	Element of performance
	Ambulatory Health Care	
1	IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies.	EP 2
2	IC.02.01.01: The organization implements infection prevention and control activities.	EP 2
3	MM.01.01.03: The organization safely manages high-alert and hazardous medications.	EP 2
4	EC.02.05.01: The organization manages risks associated with its utility systems.	EP 7
5	MM.01.02.01: The organization addresses the safe use of look-alike/sound-alike	EP2

https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/joint-commission-online/may-12-2021/top-5-most-challenging-requirements-for-2020/

Frequently scored noncompliance – IC.02.02.01

- 2016
- 2017
- 2018
- 2019
- 2020

This Photo by Unknown Author is licensed under CC BY-NC-ND

Joint Commission Online

May 12, 2021

Accreditation and Certification

Top 5 most challenging requirements for 2020

The Joint Commission collects data on organizations' compliance with standards, National Patient Safety Goals (NPSGs), and Accreditation and Certification Participation Requirements to identify trends and focus education on challenging requirements.

The table below identifies the Top 5 Joint Commission requirements identified most frequently as "not compliant" during surveys and reviews from Jan. 1 through Dec. 31, 2020. Fewer surveys were conducted in 2020 because of the coronavirus pandemic. However, Joint Commission surveyors were able to identify Requirements for Improvement (RFIs) in key areas for improvement.

For more information, see the May issue of *Perspectives* or the Standards Frequently Asked Questions. (Contact: Standards Interpretation Group, 630-792-5900 or online question form)

In this issue

Rank	Standard	Element of performance
	Ambulatory Health Care	
1	IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies.	EP 2
2	IC.02.01.01: The organization implements infection prevention and control activities.	EP 2
3	MM.01.01.03: The organization safely manages high-alert and hazardous medications.	EP 2
4	EC.02.05.01: The organization manages risks associated with its utility systems.	EP 7
5	MM.01.02.01: The organization addresses the safe use of look-alike/sound-alike	EP2

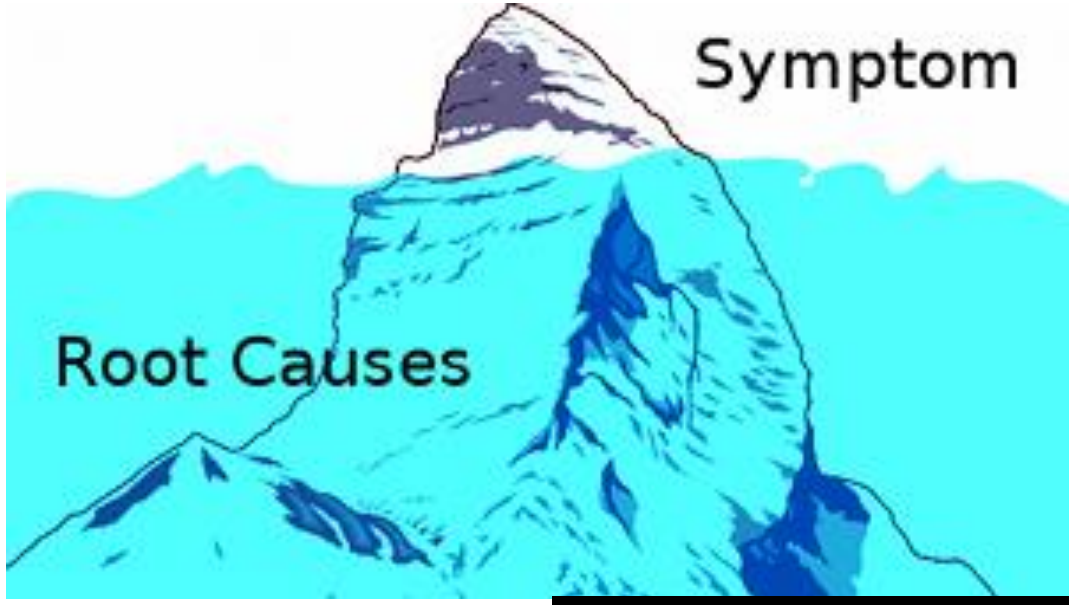
https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/joint-commission-online/may-12-2021/top-5-most-challenging-requirements-for-2020/

Common system risks

- Multiple sites performing High-level Disinfection (HLD)/sterilization
- Multiple staff/job families with varied experience/training
  - Instr. Sterilizers, MAs/Techs, Therapists, Nurses, Physicians.
- Multiple devices
  - Endoscopes, speculums, probes, trachs, tonometers, dilators, sterile instruments, etc.
- Multiple processes
  - Glutaraldehyde, OPA, H202, Trophon, steam autoclave, etc.
- Never an institutional expectation for approval to use HLD/sterilization processes.

COMMON ROOT CAUSES

- Processes in place but not followed
  - No precleaning.
  - Disinfectant test strip bottle not dated correctly.
  - Incorrect product used for pre-soak.
  - Inappropriate storage.
- Lack of clarity/understanding re: standards
  - Cleaning brushes
  - Drying time after surface disinfection
  - Biohazard labelling
  - Double peel pack with inner pouch folded over
  - Storage of HLD items in proximity to reprocessing
  - Outside shipping containers in clean storage areas
- Misalignment of policies with manufacturers' Instructions For Use (IFU) and/or standards
  - Enzymatic detergent dilution

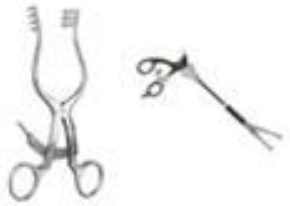


This Photo by Unknown Author is licensed under CC BY-NC-ND

Where do we start with what isn’t happening, and what should be happening?

Where do we start with what isn't happening, and what should be happening?

SPAULDING CLASIFICATION for reprocessing reusable medical devices

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

Where do we start with what isn't happening, and what should be happening?

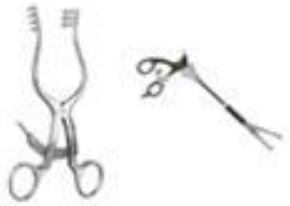
INTACT SKIN –

Cleaning <u>and</u> minimum of low-level disinfection.

Example devices: BP cuffs, stethoscopes

Example methods: **surface disinfectant wipes**

SPAULDING CLASIFICATION for reprocessing reusable medical devices

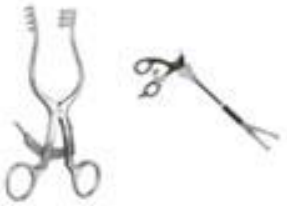
Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

Where do we start with what isn't happening, and what should be happening?

INTACT SKIN –
- Cleaning and minimum of low-level disinfection.
- Example devices: BP cuffs, stethoscopes
- Example methods: **surface disinfectant wipes**

MUCOUS MEMBRANES or NON-INTACT SKIN –
- Cleaning and minimum of high-level disinfection.
- Example devices: vaginal specula, vaginal US probes, scopes
- Example methods: **glutaraldehyde, OPA**

SPAULDING CLASIFICATION for reprocessing reusable medical devices

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

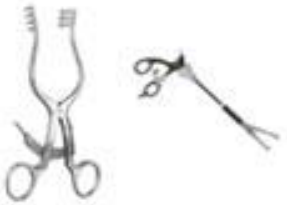
Where do we start with what isn't happening, and what should be happening?

INTACT SKIN –
- Cleaning and minimum of low-level disinfection.
- Example devices: BP cuffs, stethoscopes
- Example methods: **surface disinfectant wipes**

MUCOUS MEMBRANES or NON-INTACT SKIN –
- Cleaning and minimum of high-level disinfection.
- Example devices: vaginal specula, vaginal US probes, scopes
- Example methods: **glutaraldehyde, OPA**

STERILE AREAS OF THE BODY –
- Cleaning and sterilization.
- Example devices: sterile packaged instruments
- Example methods: **steam autoclave**

SPAULDING CLASIFICATION for reprocessing reusable medical devices

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

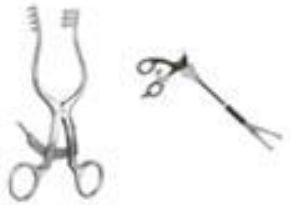
Where do we start with what isn't happening, and what should be happening?

INTACT SKIN –
Cleaning and minimum of low-level disinfection.
Example devices: BP cuffs, stethoscopes
Example methods: **surface disinfectant wipes**

MUCOUS MEMBRANES or NON-INTACT SKIN –
Cleaning and minimum of high-level disinfection.
Example devices: vaginal specula, vaginal US probes, scopes
Example methods: **glutaraldehyde, OPA**

STERILE AREAS OF THE BODY –
Cleaning and sterilization.
Example devices: sterile packaged instruments
Example methods: **steam autoclave**

SPAULDING CLASIFICATION for reprocessing reusable medical devices

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

Basic steps for any reusable medical device that requires HLD/sterilization processing

01	02	03	04	05	06	07	08	09
Point of use treatment/ precleaning	Soiled transport	Manual/ automated cleaning then rinse	Post-cleaning inspection - includes cleaning verification	Packaging (sterilization)	HLD or sterilization	Post HLD rinsing and drying	Clean transport	Storage

POINT OF USE TREATMENT/PRECLEANING

- At point of use – exam/procedure room.
- May be simple – e.g. wiping gross residual off a vag. spec.
- May be more complicated – e.g. flushing channels for a cystoscope.
- May involve prepackaged kits – e.g. with enzymatic deterrent.
- For surgical instruments, often involves foaming sprays.

SOILED TRANSPORT

- Containment – commonly solid, leakproof, puncture resistant containers or transport carts
- Prevent cross contamination and damage to device
- Appropriate size transport container
- Labeling as contaminated (biohazard), NOT patient ready
- Needs to meet OSHA hazardous transport guidelines
- For offsite transport, need to meet D.O.T., state, local regulations.

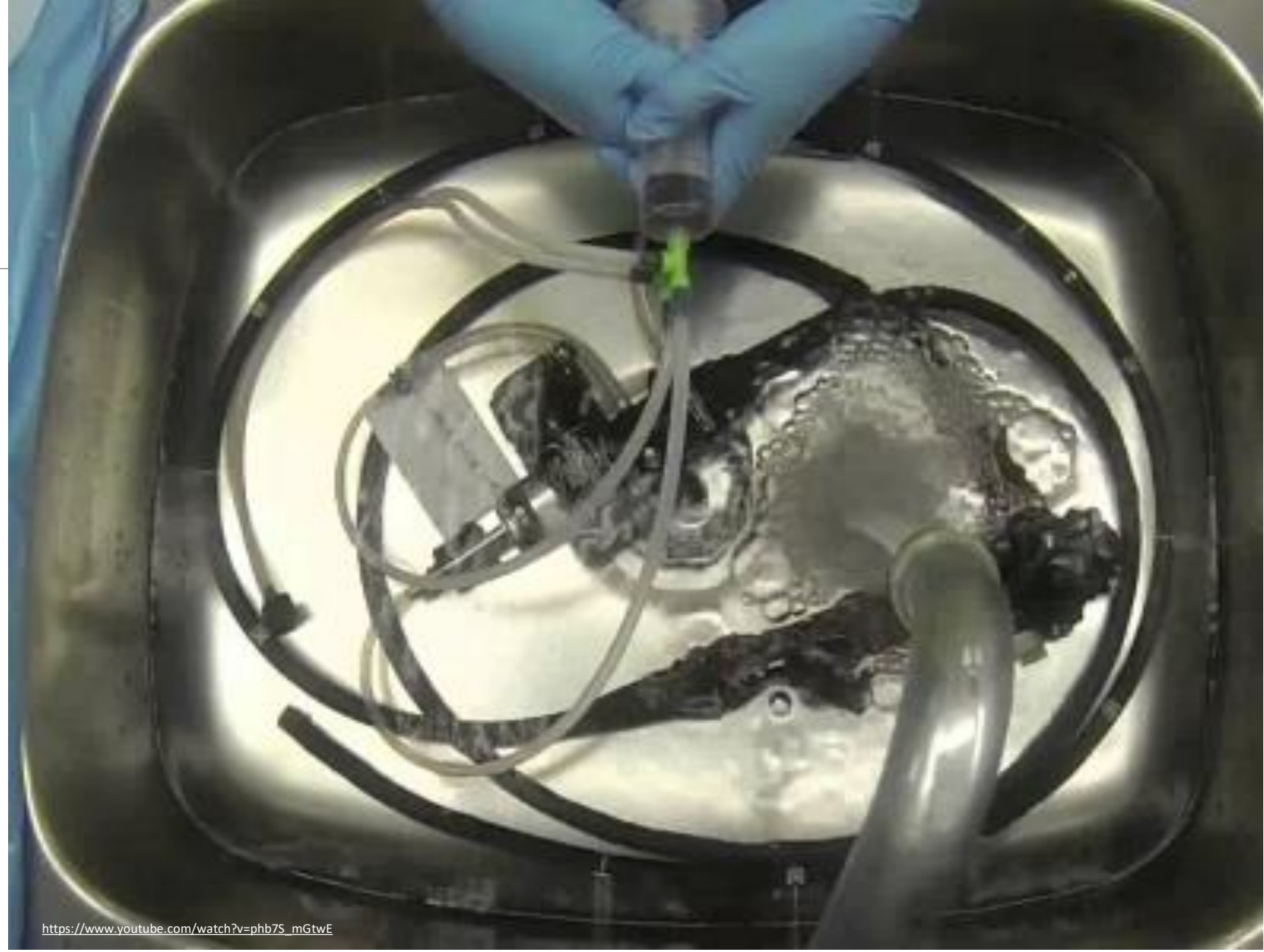
IMPORTANCE OF CLEANING

CLEANING:

- The removal of all soil and organic material.
- Must precede disinfection/sterilization.

○SOIL that remains:

- May interfere with the ability of the disinfection/sterilization process to effectively destroy microorganisms; and
- May contribute to biofilm



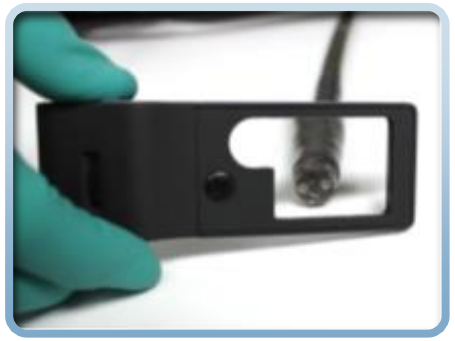
MANUAL/AUTOMATED CLEANING THEN RINSE

- Appropriate brushes – made for cleaning medical devices.
- Negative pressure air flow – DOORS REMAIN SHUT.
- Dirty-to-clean workflow.

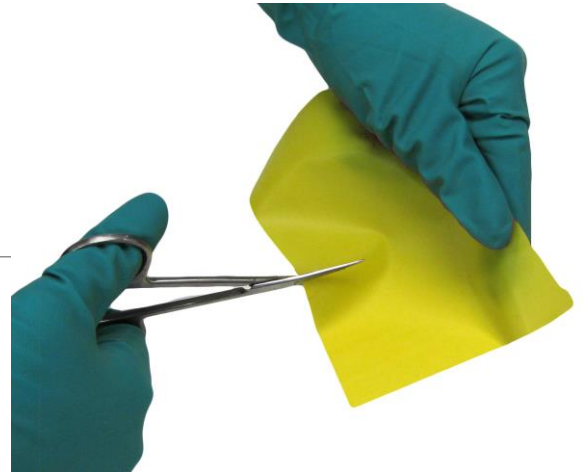
POST CLEANING INSPECTION – incl. cleaning verification

- Minimally gross visual inspection.
- BEST PRACTICE - enhanced visual inspection (lighted magnification).
  - Allows items to be returned for additional cleaning if needed.
  - Allows damaged items to be removed from service.

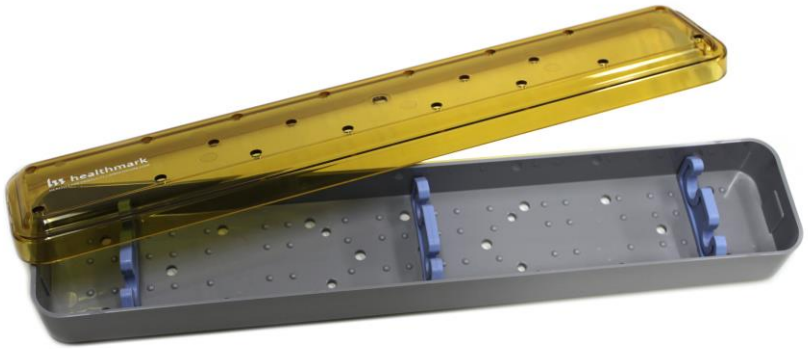
- Cleaning verification tests: Protein, Carbohydrate, Hemoglobin, ATP.



PREP and PACKAGING (sterilization)



- Inspection (cleanliness, damage)
- Functionality testing – e.g. scissors sharp, insulation testing.
- Contents correct - compared with count sheets.
- Proper packaging to facilitate complete and effective sterilization – so all surfaces exposed
- Commonly seen in Amb Care. – peel pouches and trays.
- Chemical indicator strip inside peel packs
- External indicator tape for blue wrapped items.



HLD or STERILIZATION

HLD

- Minimum processing for semi-critical devices (per Spaulding's, if sterilization available and compatible, should be used).
- Manual or automated liquid chemical exposure.
- Process monitoring: soak time, minimum effective concentration, temperature.
- Complete rinsing critical.

STERILIZATION

- Tabletop steam sterilizer (AKA autoclave) - common to Amb. Care
- Not all devices can withstand steam sterilization (e.g. flexible endoscopes).
- Physical, chemical and biological indicators.
- Complete documentation of sterilization cycle.

POST-HLD RINSING AND DRYING

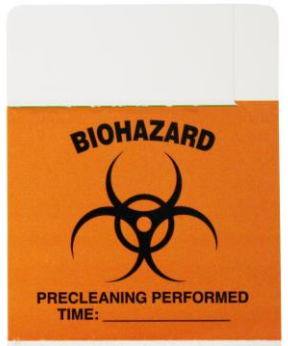
- PPE used for cleaning was removed and hand hygiene took place.
- Complete rinsing – as per mfr. IFUs.
- Pay attention to IFU re: quality of rinse water.
- Drying area and beyond is dedicated clean space.
- Post-HLD visual cues.

CLEAN/STERILE TRANSPORT

- Containment intended to protect device and minimize chance of contamination
- Trays and carts
- Avoid excessive handling
- Anything dropping to the floor is considered contaminated

STORAGE

- POSITIVE pressure space – doors remains closed.
- Clean, protected (e.g. endoscope storage cabinets).
- Temperature/humidity controlled.
- Not randomly kept amongst equipment. and office supplies.
- No food or drink.
- Visual cues.



Objectives

Discuss the processes and practices for reusable device processing that put ambulatory clinical sites – and their patients - at risk.

Review the applicable best practice standards and guidelines for device processing.

Identify key strategies for identification and mitigation of related risks.

What are expected cleaning and disinfection/sterilization practices based on?

1. Manufacturer’s Instructions For Use (**IFU**)
2. National guidelines and standards
3. Institutional policies

Manufacturer's Instructions for Use (IFU)

KEY EXPECTATIONS:

- Have IFUs readily available
- Know the IFUs
- Follow the IFUs

REMEMBER THIS REFERS TO:

- IFUs for devices being processed
- IFUs for automated processing equipment
- IFUs for chemistries

OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)
- Sterilization tray (WA05991A, sold separately)*1
- Single use channel cleaning brush (BW-201B, sold separately)
- Single use channel-opening cleaning brush (MAJ-1339, sold separately)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

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

OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)
- Sterilization tray (WA05991A, sold separately)*1
- Single use channel cleaning brush (BW-201B, sold separately)
- Single use channel-opening cleaning brush (MAJ-1339, sold separately)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

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

User Manual

English

Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers

PHILIPS

OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)
- Sterilization tray (WA05991A, sold separately)*1
- Single use channel cleaning brush (BW-201B, sold separately)
- Single use channel-opening cleaning brush (MAJ-1339, sold separately)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

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

User Manual

English

Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers

PHILIPS

Integra® Miltex®

Pessary Fitting Set

Directions for Use/English

INTEGRA

REF LOT Rx ONLY NOT MADE WITH NATURAL RUBBER LATEX

Description

The Pessary Fitting Set is to help determine the proper style and size of pessary for each patient. It includes six popular Ring pessaries and an embossed cross-reference chart to use in selecting the appropriate pessary.

Indications for Use

The Pessary Fitting Set is designed for the physician to determine the proper size and type of pessary for the patient before prescription is written.

Contraindications

Pessary Fitting Set is contraindicated in patients with acute genital tract infections, pelvic infections, or non-compliant patients.

Precautions

Pessary Fitting Set is not designed for at home patient use. The Pessary Fitting Set is supplied non-sterile.

Cleaning and Sterilization Instructions

1. Cleaning: submerge in enzymatic cleaner for 20 minutes. Remove from enzymatic cleaner and rinse thoroughly with demineralized water. Allow to dry completely prior to sterilization.

   Disinfecting: use high level disinfecting solution. Be sure to review and follow manufacturer of the disinfection solution's instructions for use.

2. Recommended Sterilization Parameters:

Sterilizer	Exposure Temperature	Exposure Time
Pre-Vacuum	132°C (270°F)	4 minutes
Gravity Steam	121°C (250°F)	30 minutes
Gravity Steam	132°C – 135°C (270°F – 275°F)	10 minutes

Returned Goods Policy

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Integra. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

Product Information Disclosure

INTEGRA AND ITS SUBSIDIARIES ("INTEGRA") AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT INTEGRA'S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

OLYMPUS

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPER
cover, for operation information.

USA: CAUTION: Federal law restricts this device to s

WelchAllyn

Rechargeable laryngoscope handles

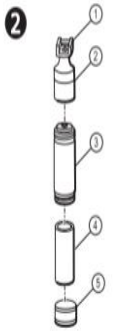
Directions for use

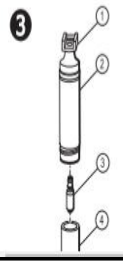
727432

℞ ONLY

DIR 80022393 Ver. A
© 2017 Welch Allyn, Inc.

REF This manual applies to 901087 instrument handle.





English

Intended use

The rechargeable laryngoscope handle is an accessory used with compatible rigid laryngoscope blades which are used to examine and visualize a patient's airway and aid placement of a tracheal tube.

About this document

These directions for use apply to Welch Allyn reusable rechargeable laryngoscope handles: 60713, 60835 (2.5V & 3.5V fiber optic) and 60710 & 60720 (2.5V standard).

Welch Allyn reusable rechargeable fiber optic laryngoscope handles (60713 & 60835) may be used with Welch Allyn fiber optic laryngoscope blades MacIntosh 690BX, English MacIntosh 692LX, and Miller 680BX.

Welch Allyn reusable rechargeable standard laryngoscope handles (60710 & 60720) may be used with Welch Allyn standard laryngoscope blades MacIntosh 690AX, English MacIntosh 692AX, and Miller 680AX and 68470 (standard).

Warnings

WARNING: Welch Allyn reusable rechargeable laryngoscope handles must be reprocessed after each use.

WARNING: The reprocessing procedure and the equipment and materials described must be followed and conducted by persons trained and familiar with medical device reprocessing.

WARNING: Consult cleaning and disinfecting agent manufacturer instructions for their proper preparation and use.

WARNING: Repeated reprocessing may degrade elements of the handle. Follow inspection procedures to assure damage has not occurred to the handle.

WARNING: High level disinfection and/or sterilization are not achieved by these methods.

WARNING: Lamps, if left illuminated, could generate sufficient heat to cause burns.

WARNING: Discard any component that shows evidence of damage or deterioration.

WARNING: Do not modify this equipment. Any modification of this equipment may lead to patient injury. Any modification of this equipment voids the product warranty.

WARNING: Personnel shall follow their facility policies and procedures and wear appropriate personal protective equipment when handling potentially contaminated equipment.

WARNING: Laryngoscope equipment is not suitable for use in intense magnetic fields

Cautions

CAUTION: Failure to follow these instructions may cause damage to this handle.

CAUTION: Do not immerse/soak handle, damage to handle may occur.

CAUTION: Only use lamp specified. Failure to follow these instructions may cause damage or poor performance of the handle.

CAUTION: If the device will be unused for several months or longer, remove the batteries prior to storing the device.

Reprocessing instructions

These reprocessing instructions refer to procedures for cleaning and intermediate level disinfection. Rechargeable laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

- Cleaning and intermediate level disinfection

Welch Allyn has validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation and routine monitoring of the user's actual process.

Cleaning and intermediate level disinfection instructions

Point of use

1. Separate blade assembly from handle and place handle into suitable containment for subsequent reprocessing. See Figure 1. Do not place handle with sharp devices.
2. Prevent the handle from drying (i.e. wrap/cover in moist germicidal wipe).

Preparation for decontamination

1. Select an appropriate quaternary ammonium isopropanol based germicidal cleaning wipe labeled suitable for use on healthcare equipment and capable of intermediate level disinfection. Reference EPA-registered disinfectants: http://www.epa.gov/oppad001/chemregindex.htm. Outside of the U.S., please consult applicable regulatory body for equivalent quaternary ammonium isopropanol germicidal cleaner.
2. For 60710 & 60720 standard handle, unscrew bottom cap (5) of handle counterclockwise, remove battery (4) and separate handle (2 and 3). See Figure 2.
   For 60713 & 60835 fiber optic handles; unscrew bottom cap (5) of handle counterclockwise, remove battery (4) and lamp cartridge (3). See Figure 3.
3. Set battery aside.

Initial cleaning and disinfection

1. Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of handle parts, bottom cap (and lamp cartridge for 60713 & 60835).
2. If necessary, brush with a dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil.
3. After all visible soil is removed, re-wipe to wet all surfaces and allow adequate contact time for disinfection as directed by the germicidal wipe manufacturer.

CAUTION: Only use quaternary ammonium isopropanol based germicidal wipes.

Drying

User Manual

English

nd Cleaning
trasound
ansducers

PHILIPS

Integra® Miltex®

Pessary Fitting Set

Directions for Use/English

INTEGRA

REF LOT ℞ ONLY NOT MADE WITH NATURAL RUBBER LATEX

Description

The Pessary Fitting Set is to help determine the proper style and size of pessary for each patient. It includes six popular Ring pessaries and an embossed cross-reference chart to use in selecting the appropriate pessary.

Indications for Use

The Pessary Fitting Set is designed for the physician to determine the proper size and type of pessary for the patient before prescription is written.

Contraindications

Pessary Fitting Set is contraindicated in patients with acute genital tract infections, pelvic infections, or non-compliant patients.

Precautions

Pessary Fitting Set is not designed for at home patient use. The Pessary Fitting Set is supplied non-sterile.

Cleaning and Sterilization Instructions

1. Cleaning: submerge in enzymatic cleaner for 20 minutes. Remove from enzymatic cleaner and rinse thoroughly with demineralized water. Allow to dry completely prior to sterilization.

   Disinfecting: use high level disinfecting solution. Be sure to review and follow manufacturer of the disinfection solution's instructions for use.
2. Recommended Sterilization Parameters:

Sterilizer	Exposure Temperature	Exposure Time
Pre-Vacuum	132°C (270°F)	4 minutes
Gravity Steam	121°C (250°F)	30 minutes
Gravity Steam	132°C ~ 135°C (270°F ~ 275°F)	10 minutes

Returned Goods Policy

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Integra. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

Product Information Disclosure

INTEGRA AND ITS SUBSIDIARIES ("INTEGRA") AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT INTEGRA'S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

OLYMPUS

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPER
cover, for operation information.

USA: CAUTION: Federal law restricts this device to s

WelchAllyn

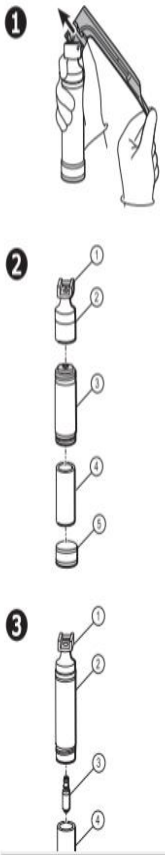
Rechargeable laryngoscope handles

Directions for use

72743 2 Rx ONLY

DIR 80022393 Ver. A
© 2017 Welch Allyn, Inc.

REF This manual applies to 901087 instrument handle.



English

Intended use

The rechargeable laryngoscope handle is an accessory used with compatible rigid laryngoscope blades which are used to examine and visualize a patient's airway and aid placement of a tracheal tube.

About this document

These directions for use apply to Welch Allyn reusable rechargeable laryngoscope handles: 60713, 60835 (2.5V & 3.5V fiber optic) and 60710 & 60720 (2.5V standard).

Welch Allyn reusable rechargeable fiber optic laryngoscope handles (60713 & 60835) may be used with Welch Allyn fiber optic laryngoscope blades MacIntosh 690BX, English MacIntosh 692LX, and Miller 680BX.

Welch Allyn reusable rechargeable standard laryngoscope handles (60710 & 60720) may be used with Welch Allyn standard laryngoscope blades MacIntosh 690AX, English MacIntosh 692AX, and Miller 680AX and 68470 (standard).

⚠ Warnings

WARNING: Welch Allyn reusable rechargeable laryngoscope handles must be reprocessed after each use.

WARNING: The reprocessing procedure and the equipment and materials described must be followed and conducted by persons trained and familiar with medical device reprocessing.

WARNING: Consult cleaning and disinfecting agent manufacturer instructions for their proper preparation and use.

WARNING: Repeated reprocessing may degrade elements of the handle. Follow inspection procedures to assure damage has not occurred to the handle.

WARNING: High level disinfection and/or sterilization are not achieved by these methods.

WARNING: Lamps, if left illuminated, could generate sufficient heat to cause burns.

WARNING: Discard any component that shows evidence of damage or deterioration.

WARNING: Do not modify this equipment. Any modification of this equipment may lead to patient injury. Any modification of this equipment voids the product warranty.

WARNING: Personnel shall follow their facility policies and procedures and wear appropriate personal protective equipment when handling potentially contaminated equipment.

WARNING: Laryngoscope equipment is not suitable for use in intense magnetic fields

⚠ Cautions

CAUTION: Failure to follow these instructions may cause damage to this handle.

CAUTION: Do not immerse/soak handle, damage to handle may occur.

CAUTION: Only use lamp specified. Failure to follow these instructions may cause damage or poor performance of the handle.

CAUTION: If the device will be unused for several months or longer, remove the batteries prior to storing the device.

Reprocessing instructions

These reprocessing instructions refer to procedures for cleaning and intermediate level disinfection. Rechargeable laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

- Cleaning and intermediate level disinfection

Welch Allyn has validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation and routine monitoring of the user's actual process.

Cleaning and intermediate level disinfection instructions

Point of use

1. Separate blade assembly from handle and place handle into suitable containment for subsequent reprocessing. See Figure 1. Do not place handle with sharp devices.
2. Prevent the handle from drying (i.e. wrap/cover in moist germicidal wipe).

Preparation for decontamination

1. Select an appropriate quaternary ammonium isopropanol based germicidal cleaning wipe labeled suitable for use on healthcare equipment and capable of intermediate level disinfection. Reference EPA-registered disinfectants: http://www.epa.gov/oppad001/chemregindex.htm. Outside of the U.S., please consult applicable regulatory body for equivalent quaternary ammonium isopropanol germicidal cleaner.
2. For 60710 & 60720 standard handle, unscrew bottom cap (5) of handle counterclockwise, remove battery (4) and separate handle (2 and 3). See Figure 2.
   For 60713 & 60835 fiber optic handles; unscrew bottom cap (5) of handle counterclockwise, remove battery (4) and lamp cartridge (3). See Figure 3.
3. Set battery aside.

Initial cleaning and disinfection

1. Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of handle parts, bottom cap (and lamp cartridge for 60713 & 60835).
2. If necessary, brush with a dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil.
3. After all visible soil is removed, re-wipe to wet all surfaces and allow adequate contact time for disinfection as directed by the germicidal wipe manufacturer.

⚠ **CAUTION**: Only use quaternary ammonium isopropanol based germicidal wipes.

Drying

storz
Ophthalmic Instruments

BAUSCH+LOMB
Instruments
Ear, Nose, Throat & Plastic Surgery

en

REPROCESSING INSTRUCTIONS FOR NON-POWERED INSTRUMENTS

GENERAL COMMENTS

The following are instrument care instructions for all reusable medical devices supplied by Bausch + Lomb, unless different instructions are supplied with the device.

The following instructions have been validated by Bausch + Lomb as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the facility to achieve the desired results. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilization processes require validation at the point of use. their effectiveness will depend on many factors and it is only possible to provide general guidance on proper device cleaning and sterilization.

Products unless stated otherwise are supplied from Bausch + Lomb in a non-sterile state and are not to be used without being cleaned, disinfected and sterilized.

These instructions are intended for use only by persons with the required knowledge and training.

Cleaning and Disinfecting Processing Equipment should be qualified and validated to ensure suitability for its intended purpose.

WARNINGS

- Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage the instrument.
- Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.
- Do not process powered instruments in an ultrasonic cleaner.
- Do not process single use instruments.
- Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Do not use this procedure for diamond knives.

LIMITATIONS ON REPROCESSING

Reprocessing according to the instructions provided below should not adversely affect the functionality of instruments. The useful life of the instrument is determined by wear and damage during use.

INSTRUCTIONS

Point of Use

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
- The instrument should be kept moist to prevent soil from drying on the instrument.

WARNING: Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage the instrument.

WARNING: Single use instruments should not be reprocessed.

Containment and Transport

- The instruments should be reprocessed as soon as possible.
- The instruments should be placed in a suitable container to protect personnel from contamination during transport to the decontamination area.

Preparation for Decontamination and Cleaning

Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to your institution's policies.

Automated Cleaning and Thermal Disinfection

WARNING: Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.

1. Follow the instructions of the washer manufacturer.
2. Use only neutral pH cleaning solutions.
3. If gross soiling is evident on the instrument manual pre-cleaning with a neutral pH cleaning solution may be necessary.
4. Ensure that any hinged instruments are open and that instruments with lumens can drain effectively. Where the washer has provisions for lumen adaptors these should be employed for lumened instruments.
5. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
6. Process the instrument according to the conditions indicated below. The cleaning times and conditions may be adjusted based on the amount of soiling present on the instrument. The following conditions were validated using a neutral pH detergent (Getinge Neutrawash) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

Phase	Time	Temperature

7. The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident. Follow the instructions of the manufacturer for the cleaning and draining of the ultrasonic bath.
8. Repeat steps 4-6 as necessary if visible soil remains on the instrument.
9. Rinse the instrument by holding it under warm (27°C – 49°C/80°F – 117°F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.
10. If the instrument has lumens the lumens should be flushed using a syringe filled with 50cc of warm distilled or deionized water using a stopcock as follows:
    a. Place syringe tip into a beaker of warm (30°C – 40°C/86°F – 104°F) distilled or deionized water and fill to the 50cc mark.
    b. Connect the end of the syringe to the center stopcock fitting.
    c. Rotate the stopcock lever to the male luer fitting (irrigation) or to the female luer fitting (aspiration) to allow fluid flow to the appropriate luer fitting.
    d. Connect the stopcock to the appropriate luer connector on the instrument.
    e. Push on the syringe plunger to force fluid through the lumen into another beaker for proper disposal. Do not draw flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe/stopcock from the instrument.
    f. Repeat steps A-E at least three times, for each lumen.
    g. Fill the syringe with 50cc of air, reattach the stopcock, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.
    NOTE: The CX7120 Universal Maintenance Kit contains a syringe and stopcock suitable for cleaning instrument lumens.
11. Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.
12. Immerse the instrument in second clean basin containing fresh deionized or distilled water and soak for at least three minutes.
13. Perform a final rinse of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

Disinfection

Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction Bausch + Lomb does not recommend the use of liquid chemical disinfectants or sterilants with instruments. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfector.

Drying

Carefully dry the instrument with a lint free surgical wipe or blow the instrument dry with micro filtered forced air.

Maintenance, Inspection and Testing

Following cleaning inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended.

Packaging

Package the instrument in a suitable sterilization pouch or instrument tray.

Sterilization

Unless otherwise indicated in the Directions for Use provided with the specific instrument, instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods:

- Pre-vacuum High Temperature Autoclave: 274°F (134°C) for 3 minute, wrapped.
  NOTE: As per ANSI/AAMI ST79:2010 and A1:2010 270°F (132°C) for 4 minutes and 275°F (135°C) for 3 minutes are acceptable minimum cycle times for dynamic-air-removal steam sterilization cycles.
- Standard Gravity Autoclave: 250°F/15.2 psi (121°C/104.8kPa [1.048 bar]) for 30 minutes, wrapped.
- High Speed (Flash) Autoclave: 270°F/27.1 psi (132°C/186.8kPa [1.868 bar]) for 10 minutes, unwrapped, but covered.
- High Vacuum (Pre-vacuum) Autoclave: 274°F/30.0 psi (134°C/206.8kPa [2.068 bar]) for 3 minutes.

WARNING: Instruments processed in a wrapped instrument tray should be placed within the tray in a manner that allows steam to contact all surfaces of the instrument. Do not pile instruments on top of each other as this may block steam penetration and condensate drainage. Do not overload the tray. Heavily loaded instrument trays should be processed by high temperature pre-vacuum steam sterilization.

WARNING: Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.

WARNING: Single use instruments should not be reprocessed.

The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

Storage

Following sterilization processing packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies.

ADDITIONAL INFORMATION

INTEGRA

LATEX
NOT MADE WITH NATURAL RUBBER LATEX

and size of pessary for each patient. It includes six
art to use in selecting the appropriate pessary.

rmine the proper size and type of pessary for the

genital tract infections, pelvic infections, or

The Pessary Fitting Set is supplied non-sterile.

s. Remove from enzymatic cleaner and rinse
pletely prior to sterilization.
re to review and follow manufacturer of the

posure Time
minutes
minutes
minutes

ufacturer's seals intact to be accepted for
product defect. Determination of a product
d for replacement if they have been in the

ACTURER EXCLUDE ALL WARRANTIES, EXCEPT
EXPRESSED OR IMPLIED, INCLUDING BUT NOT
LITY OR FITNESS FOR A PARTICULAR PURPOSE.
FOR ANY INCIDENTAL OR CONSEQUENTIAL
RISING FROM USE OF THIS PRODUCT. NEITHER
ANY PERSON TO ASSUME FOR THEM ANY
CONNECTION WITH THESE PRODUCTS.

OLYMPUS

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Forceps/irrigation plug (isolated type) (MAJ-891)

*1 This product may not be available in some areas.

Refer to the endoscope's companion manual, the "OPER
cover, for operation information.

USA: CAUTION: Federal law restricts this device to s

Welch Allyn

Rechargeable laryngoscope handles
Directions for use

727432

R_x ONLY

DIR 80022393 Ver. A
© 2017 Welch Allyn, Inc.

REF This manual applies to 901087 instrument handle.

1

2

3

ResMed

AirFit™ F30i

R_x Only

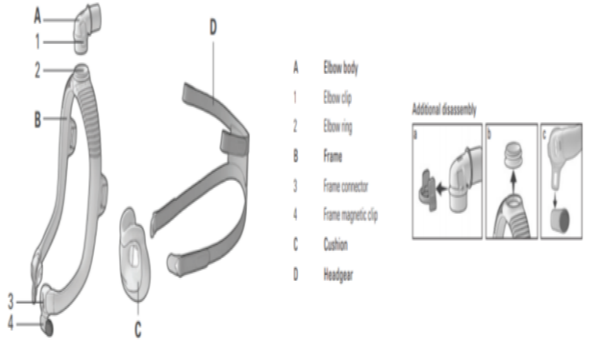
Clinical use only

Disinfection guide

This guide is intended for multi-patient re-use of the AirFit™ F30i full face mask in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. The processor is responsible for ensuring that reprocessing is completed in accordance with ResMed's validated procedures.

Mask component[1]	Cleaning - Mild alkaline, anionic detergent eg, Alconox Thermal Disinfection 160°F (75°C) for 30 minutes OR 194-199°F (90-93°C) for 1 to 10 minutes	Validated number of cycles
• Cushion	✓	30
• Frame / frame magnetic clips	✓	30
• Elbow body / elbow clip / elbow ring	✓	30
• Headgear[2]	✓	30
• Soft wraps[3]	-	-

[1]May not be available in all regions. For full details regarding the correct use of this mask, please refer to the User Guide. For a list of available replacement parts, check the Product Guide on ResMed.com.
[2]Headgear includes headgear magnetic clips.
[3]Not intended for multi-patient re-use.



A Elbow body
1 Elbow clip
2 Elbow ring
B Frame
3 Frame connector
4 Frame magnetic clip
C Cushion
D Headgear

BAUSCH+LOMB

Instruments

Ear, Nose, Throat & Plastic Surgery

7. The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident. Follow the instructions of the manufacturer for the cleaning and draining of the ultrasonic bath.
8. Repeat steps 4-6 as necessary if visible soil remains on the instrument.
9. Rinse the instrument by holding it under warm (27°C – 41°C/80°F – 105°F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.
10. If the instrument has lumens the lumens should be flushed using a syringe filled with 50cc of warm distilled or deionized water using a stopcock as follows:
    a. Place syringe tip into a beaker of warm (30°C – 40°C/86°F – 104°F) distilled or deionized water and fill to the 50cc mark.
    b. Connect the end of the syringe to the center stopcock fitting.
    c. Rotate the stopcock lever to the male luer fitting (irrigation) or to the female luer fitting (aspiration) to allow fluid flow to the appropriate luer fitting.
    d. Connect the stopcock to the appropriate luer connector on the instrument.
    e. Push on the syringe plunger to force fluid through the lumen into another beaker for proper disposal. Do not draw flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe/stopcock from the instrument.
    f. Repeat steps A-E at least three times, for each lumen.
    g. Fill the syringe with 50cc of air, reattach the stopcock, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.
    NOTE: The CX7120 Universal Maintenance Kit contains a syringe and stopcock suitable for cleaning instrument lumens.
11. Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.
12. Immerse the instrument in second clean basin containing fresh deionized or distilled water and soak for at least three minutes.
13. Perform a final rinse of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

Disinfection

Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction Bausch + Lomb does not recommend the use of liquid chemical disinfectants or sterilants with instruments. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfector.

Drying

Carefully dry the instrument with a lint free surgical wipe or blow the instrument dry with micro filtered forced air.

Maintenance, Inspection and Testing

Following cleaning inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended.

Packaging

Package the instrument in a suitable sterilization pouch or instrument tray.

Sterilization

Unless otherwise indicated in the Directions for Use provided with the specific instrument, instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods:

- Pre-vacuum High Temperature Autoclave: 274°F (134°C) for 3 minutes, wrapped.
  NOTE: As per ANSI/AAMI ST79:2010 and A1:2010 270°F (132°C) for 4 minutes and 275°F (135°C) for 3 minutes are acceptable minimum cycle times for dynamic-air-removal steam sterilization cycles.
- Standard Gravity Autoclave: 250°F/15.2 psi (121°C/104.8kPa [1.048 bar]) for 30 minutes, wrapped.
- High Speed (Flash) Autoclave: 270°F/27.1 psi (132°C/186.8kPa [1.868 bar]) for 10 minutes, unwrapped, but covered.
- High Vacuum (Pre-vacuum) Autoclave: 274°F/30.0 psi (134°C/206.8kPa [2.068 bar]) for 3 minutes.

WARNING: Instruments processed in a wrapped instrument tray should be placed within the tray in a manner that allows steam to contact all surfaces of the instrument. Do not pile instruments on top of each other as this may block steam penetration and condensate drainage. Do not overload the tray. Heavily loaded instrument trays should be processed by high temperature pre-vacuum steam sterilization.

WARNING: Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.

WARNING: Single use instruments should not be reprocessed.

The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

Storage

Following sterilization processing packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies.

ADDITIONAL INFORMATION

INTEGRA

LATEX
NOT MADE WITH NATURAL RUBBER LATEX

and size of pessary for each patient. It includes six
art to use in selecting the appropriate pessary.

rmine the proper size and type of pessary for the

genital tract infections, pelvic infections, or

The Pessary Fitting Set is supplied non-sterile.

s. Remove from enzymatic cleaner and rinse
pletely prior to sterilization.
re to review and follow manufacturer of the

posure Time
minutes
minutes
minutes

ufacturer's seals intact to be accepted for
product defect. Determination of a product
d for replacement if they have been in the

ACTURER EXCLUDE ALL WARRANTIES, EXCEPT
EXPRESSED OR IMPLIED, INCLUDING BUT NOT
LITY OR FITNESS FOR A PARTICULAR PURPOSE.
FOR ANY INCIDENTAL OR CONSEQUENTIAL
RISING FROM USE OF THIS PRODUCT. NEITHER
ANY PERSON TO ASSUME FOR THEM ANY
CONNECTION WITH THESE PRODUCTS.

Regulations/Standards/Guidelines

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory

- Standards
  - Requirements and specifications to ensure consistency and fit for purpose
  - Voluntary, but can become mandatory

- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation

Examples from governmental standards and guidelines

- OSHA
  - 1910.1030 - Bloodborne pathogens
  - 1910.1200 - Hazard Communication
- EPA
  - Emissions Standards for Hospital Ethylene Oxide Sterilizers
  - Chemical disposal requirements
- CDC
  - Guidelines for disinfection and sterilization
  - Essential elements for processing flexible endoscopes
- FDA
  - Reprocessing reusable medical devices
  - Factors affecting quality of reprocessing
  - FDA cleared sterilants and high-level disinfectants

SAMPLE FDA RECOMMENDATIONS

- Follow manufacturer's IFUs.
- Adhere to professional reprocessing guidelines.
- Comprehensive QC program.
- Required documentation.
- Competencies.
- Quality monitors.

Organization	Standard/Guideline
AAMI	• ST79 – Steam sterilization and sterility assurance • ST90 – Quality management systems • ST91 – Endoscope reprocessing • Technical Information Reports (TIR)
ASGE	• Multisociety guideline on reprocessing flexible GI endoscopes
SGNA	• Reprocessing of Flexible Gastrointestinal Endoscopes • Infection Prevention in the Gastroenterology Setting • Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles • Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting
AORN	• Cleaning and care of surgical instruments • Guideline for HLD • Flexible endoscope processing
AIUM	• Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as well as Safe Handling and Use of Ultrasound Coupling Gel
AAO	• Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments
AUA	• Joint AUA/SUNA White Paper on Reprocessing of Flexible Cystoscopes

Common reference points

All the major contributors support in principal

- Quality improvement
- Quality assurance
- Monitoring of processes

Clinically relevant & evidence-based practices

Peer reviewed literature

Other articles and research.

Manufacturer’s IFUs

QC highlights within guidelines

Recommendations for:

- Certifications and training frequency for staff performing reprocessing
- Process monitoring:
  - the manual cleaning process
  - automated cleaning processes
  - water quality
  - temperature of detergents and disinfectant solutions
- Traceability
- Risk Assessments
- Documentation and quality assurance parameters

This is, and has been, a dynamic process – stay connected and up-to-date

Joint Commission Online

Aug. 12, 2020

Quality and safety

Sentinel event statistics released for first half of 2020

Sentinel events reported from Jan. 1, 2020 through June 30, 2020	
Category	**Sentinel Events reported**
Care management events	165
Surgical or invasive procedure events	131
Unassigned	46
Suicide	41
Protection events	38
Environment events	12
Product or device events	4

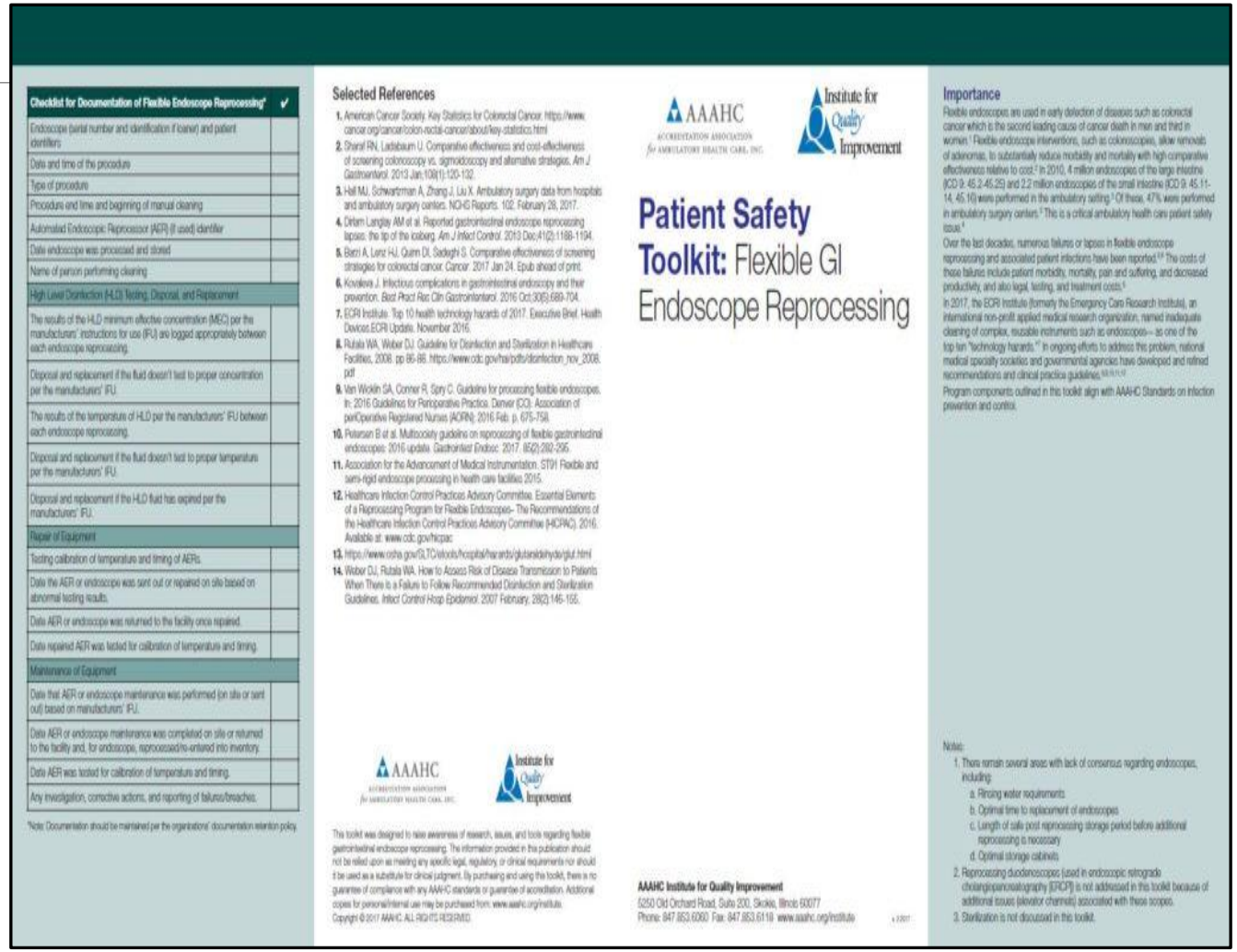
Through the first six months of 2020, The Joint Commission reviewed a total of 437 sentinel events. The majority — 372 or 85% — were voluntarily self-reported by an accredited or certified organization.

In accordance with the Sentinel Event Policy, and as required by Leadership (LD) Standard LD.03.09.01, accredited organizations must review all sentinel events and implement risk reduction strategies to prevent recurrence.

In this issue

Less than an estimated 2% of all sentinel events are reported to The Joint Commission. Of these, 60% (9,422 of 15,770 events) have been self-reported since 2005. Therefore, these data are not an epidemiologic data set, and no conclusions should be drawn about the actual relative frequency of events or trends in events over time. The most frequently reported types of sentinel events reported from Jan. 1 through June 30 were from the following categories:

- Care management
- Surgical or invasive procedures
- Unassigned events at the time of the report
- Suicide
- Protection events
- Environment events
- Product or device



Checklist for Documentation of Flexible Endoscope Reprocessing*	✓
Endoscope (serial number and identification if loaner) and patient identifiers	
Date and time of the procedure	
Type of procedure	
Procedure end time and beginning of manual cleaning	
Automated Endoscopic Reprocessor (AER) (if used) identifier	
Date endoscope was processed and stored	
Name of person performing cleaning	
High Level Disinfection (HLD) Testing, Disposal, and Replacement	
The results of the HLD minimum effective concentration (MEC) per the manufacturers' instructions for use (IFU) are logged appropriately between each endoscope reprocessing.	
Disposal and replacement if the fluid doesn't test to proper concentration per the manufacturers' IFU.	
The results of the temperature of HLD per the manufacturers' IFU between each endoscope reprocessing.	
Disposal and replacement if the fluid doesn't test to proper temperature per the manufacturers' IFU.	
Disposal and replacement if the HLD fluid has expired per the manufacturers' IFU.	
Repair of Equipment	
Testing calibration of temperature and timing of AERs.	
Date the AER or endoscope was sent out or repaired on site based on abnormal testing results.	
Date AER or endoscope was returned to the facility once repaired.	
Date repaired AER was tested for calibration of temperature and timing.	
Maintenance of Equipment	
Date that AER or endoscope maintenance was performed (on site or sent out) based on manufacturers' IFU.	
Date AER or endoscope maintenance was completed on site or returned to the facility and, for endoscope, reprocessed/re-entered into inventory.	
Date AER was tested for calibration of temperature and timing.	
Any investigation, corrective actions, and reporting of failures/breaches.	

*Note: Documentation should be maintained per the organizations' documentation retention policy.

Selected References

1. American Cancer Society. Key Statistics for Colorectal Cancer. https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html
2. Sharaf RN, Ladabaum U. Comparative effectiveness and cost-effectiveness of screening colonoscopy vs. sigmoidoscopy and alternative strategies. Am J Gastroenterol. 2013 Jan;108(1):120-132.
3. Hall MJ, Schwartzman A, Zhang J, Liu X. Ambulatory surgery data from hospitals and ambulatory surgery centers: NCHS Reports. 102. February 28, 2017.
4. Ditter Langley AM et al. Reported gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. Am J Infect Control. 2013 Dec;41(2):1188-1194.
5. Bercı A, Lenz HJ, Quinn DI, Sadeghi S. Comparative effectiveness of screening strategies for colorectal cancer. Cancer. 2017 Jan 24. Epub ahead of print.
6. Kovalева J. Infectious complications in gastrointestinal endoscopy and their prevention. Best Pract Res Clin Gastroenterol. 2016 Oct;30(5):689-704.
7. ECRI Institute. Top 10 health technology hazards of 2017. Executive Brief. Health Devices ECRI Update. November 2016.
8. Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. pp 86-88. https://www.cdc.gov/hai/pdfs/disinfection_nov_2008.pdf
9. Van Wicklin SA, Conner R, Spry C. Guideline for processing flexible endoscopes. In: 2016 Guidelines for Perioperative Practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2016 Feb. p. 675-758.
10. Petersen B et al. Multisociety guideline on reprocessing of flexible gastrointestinal endoscopes: 2016 update. Gastrointest Endosc. 2017. 85(2):282-295.
11. Association for the Advancement of Medical Instrumentation. ST91 Flexible and semi-rigid endoscope processing in health care facilities 2015.
12. Healthcare Infection Control Practices Advisory Committee. Essential Elements of a Reprocessing Program for Flexible Endoscopes- The Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC). 2016. Available at: www.cdc.gov/hicpac
13. https://www.osha.gov/SLTC/etools/hospital/hazards/glutaraldehyde/glut.html
14. Weber DJ, Rutala WA. How to Assess Risk of Disease Transmission to Patients When There is a Failure to Follow Recommended Disinfection and Sterilization Guidelines. Infect Control Hosp Epidemiol. 2007 February; 28(2):146-155.

AAAHC ACCREDITATION ASSOCIATION for AMBULATORY HEALTH CARE, INC.

Institute for Quality Improvement

Patient Safety Toolkit: Flexible GI Endoscope Reprocessing

This toolkit was designed to raise awareness of research, issues, and tools regarding flexible gastrointestinal endoscope reprocessing. The information provided in this publication should not be relied upon as meeting any specific legal, regulatory, or clinical requirements nor should it be used as a substitute for clinical judgment. By purchasing and using this toolkit, there is no guarantee of compliance with any AAAHC standards or guarantee of accreditation. Additional copies for personal/internal use may be purchased from: www.aaahc.org/institute.

Copyright © 2017 AAAHC. ALL RIGHTS RESERVED.

AAAHC Institute for Quality Improvement

5250 Old Orchard Road, Suite 200, Skokie, Illinois 60077

Phone: 847.853.6060 Fax: 847.853.6118 www.aaahc.org/institute

Importance

Flexible endoscopes are used in early detection of diseases such as colorectal cancer which is the second leading cause of cancer death in men and third in women.[1] Flexible endoscope interventions, such as colonoscopies, allow removals of adenomas, to substantially reduce morbidity and mortality with high comparative effectiveness relative to cost.[2] In 2010, 4 million endoscopies of the large intestine (ICD 9: 45.2-45.25) and 2.2 million endoscopies of the small intestine (ICD 9: 45.11-14, 45.16) were performed in this ambulatory setting.[3] Of these, 47% were performed in ambulatory surgery centers.[3] This is a critical ambulatory health care patient safety issue.[4]

Over the last decades, numerous failures or lapses in flexible endoscope reprocessing and associated patient infections have been reported.[5-8] The costs of these failures include patient morbidity, mortality, pain and suffering, and decreased productivity, and also legal, testing, and treatment costs.[9]

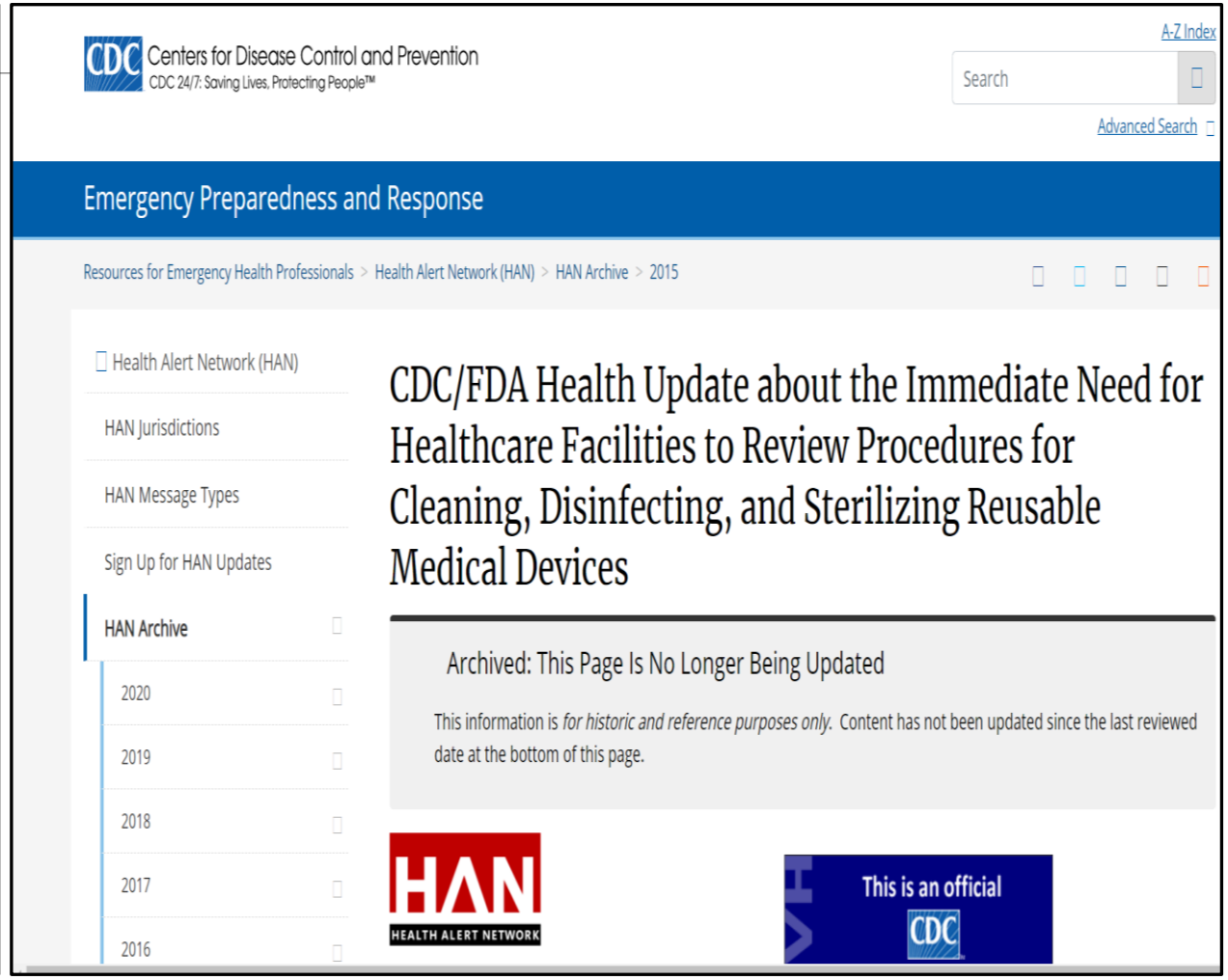
In 2017, the ECRI Institute (formerly the Emergency Care Research Institute), an international non-profit applied medical research organization, named inadequate cleaning of complex, reusable instruments such as endoscopes— as one of the top ten "technology hazards."[7] In ongoing efforts to address this problem, national medical specialty societies and governmental agencies have developed and refined recommendations and clinical practice guidelines.[8,9,10,11]

Program components outlined in this toolkit align with AAAHC Standards on infection prevention and control.

Notes:

1. There remain several areas with lack of consensus regarding endoscopes, including:
   a. Rinsing water requirements
   b. Optimal time to replacement of endoscopes
   c. Length of safe post reprocessing storage period before additional reprocessing is necessary
   d. Optimal storage cabinets
2. Reprocessing duodenoscopes (used in endoscopic retrograde cholangiopancreatography [ERCP]) is not addressed in this toolkit because of additional issues (elevator channels) associated with these scopes.
3. Sterilization is not discussed in this toolkit.

This is, and has been, a dynamic process – stay connected and up-to-date



Objectives

Discuss the processes and practices for reusable device processing that put ambulatory clinical sites – and their patients - at risk.

Review the applicable best practice standards and guidelines for device processing.

Identify key strategies for identification and mitigation of related risks.

SYSTEM RISKS/CHALLENGES:

This Photo by Unknown Author is licensed under CC BY-SA-NC

- Lack of standardization
- Multiple sites performing HLD/sterilization
- Multiple staff/job families with varied experience/training
- Multiple devices
- Multiple processes
- Variable training/education
- Never an institutional expectation for approval to use HLD/sterilization processes.

SYSTEM RISKS/CHALLENGES:

- Lack of standardization
- Multiple sites performing HLD/sterilization
- Multiple staff/job families with varied experience/training
- Multiple devices
- Multiple processes
- Variable training/education
- Never an institutional expectation for approval to use HLD/sterilization processes.

This Photo by Unknown Author is licensed under CC BY-SA

RESULTING POOR OUTCOMES:

- Inconsistent practices.
- High risk when reprocessing performed incorrectly.
- Misses & near misses.
- Poor accreditation survey results.

Disciplined Approach

1. Assemble Multidisciplinary Stakeholder Team
2. Agree on Guidelines and Recommendations
3. Develop Gap Analysis, Audit Tool, and Timelines
4. Examine Current State of Affairs
5. Conduct Mock Tracer, Gap/Risk Analyses
6. Present and Analyze Results
7. Prioritize Issues
8. Change/modify practices where needed
9. Follow up Improvement Plans
10. Evaluate Actions
11. Conduct Regular Risk Assessments, Mock Tracers, Gap/Risk Analyses

This Photo by Unknown Author is licensed under CC BY-SA0

This Photo by Unknown Author is licensed under CC BY-NC-ND

Multidisciplinary critical evaluation -

- IP, Processing, Clinicians, Safety, Quality/Risk Management, Facilities, Accreditation, Amb. Care Administration, Supply Chain
- “Get on the same page”/resolve conflicts
- Prioritize change

This Photo by Unknown Author is licensed under CC BY

Current state –

- Survey; but GO SEE - what is happening compared to what should be happening

Goals

This Photo by Unknown Author is licensed under CC BY

- ✓CREATE SYSTEM-WIDE EXPECTATIONS
  - Consider system oversight roles
  - Periodic internal reviews
  - Administration support
- ✓STANDARDIZATION OF PROCESSES
- ✓CONSOLIDATION WHERE POSSIBLE
- ✓ONGOING SITE REVIEWS
- ✓ONGOING EDUCATION
- ✓FORMAL PATHS FOR REVIEW, DECISION MAKING, CRITICAL RESPONSE
  - Link to existing formal committees: IP, Safety, Quality. Amb. Care

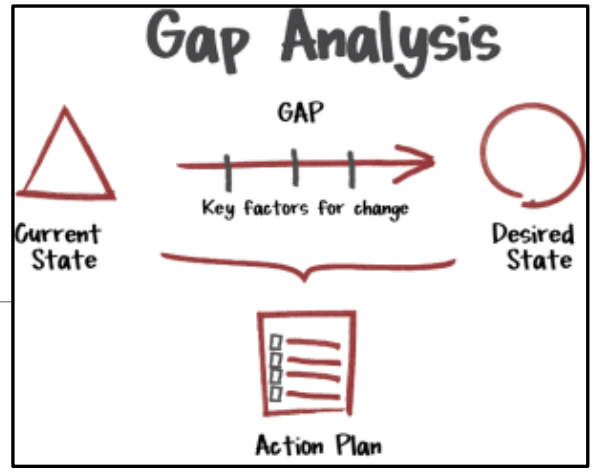
Example - resolving conflicts and agreeing on guidelines and IFUs

Processing consideration	SGNA	AAMI ST91	AORN	Multisociety Guideline
Storage interval after which flexible endoscopes must be processed before use (“hang time”)	7 days	Perform risk assessment	Perform risk assessment	Perform risk assessment
Cleaning verification	Pre-established interval	Weekly, preferably daily	With each reprocessing cycle	Monitor as part of quality program

Resolving conflicts and agreeing on guidelines and IFUs

- Review current guidelines for reprocessing flexible endoscopes – wherever they are clinically used.
- Have the latest version of guidelines available.
- Review supplemental FDA guidance – safety communications.
- Resolve conflicts if not in harmony!
- When evidence is lacking, expert opinion, independent guidelines, or standards for accreditation may differ.
- Always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance.
- Accrediting bodies will typically survey for performance in accordance with this guidance.

Develop Gap Analysis Audit Tool and Timelines



This Photo by Unknown Author is licensed under CC BY-ND

Can use or modify available templates.

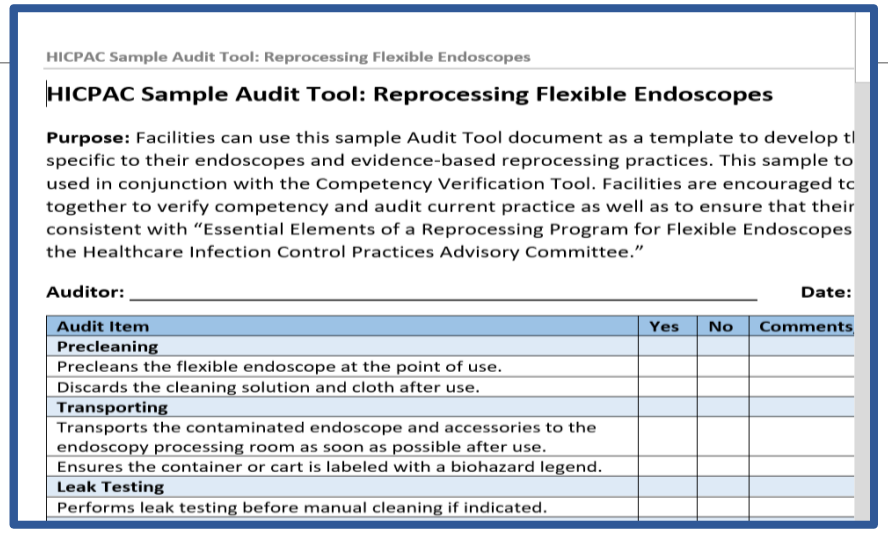
Needs to pointedly be reflective of institution's written policies/procedures.

"Basics" address P & P and assessment of:

- Reprocessing steps
- Reprocessing staff
- Reprocessing equipment and supplies
- Reprocessing OEM IFU readily available and followed
- Adequate physical space and HVAC
- Appropriate endoscope storage
- Documentation
- Traceability
- AER validation
- Frequency of Gap Analysis

This Photo by Unknown Author is licensed under CC BY

Consider converting existing Guidelines/Recommendations/Audits into your own Yes/No Document



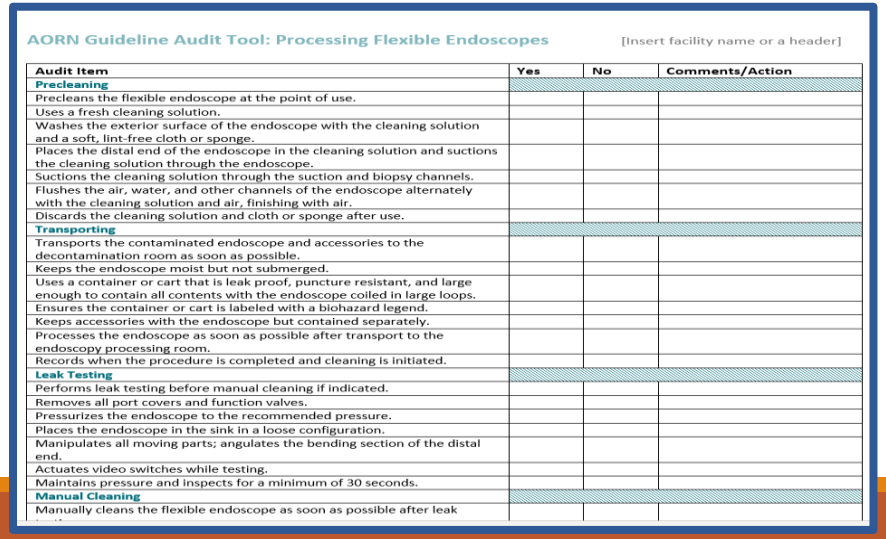
HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Audit Tool document as a template to develop tl specific to their endoscopes and evidence-based reprocessing practices. This sample to used in conjunction with the Competency Verification Tool. Facilities are encouraged tc together to verify competency and audit current practice as well as to ensure that their consistent with "Essential Elements of a Reprocessing Program for Flexible Endoscopes the Healthcare Infection Control Practices Advisory Committee."

Auditor: _____ **Date:**

Audit Item	Yes	No	Comments
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			

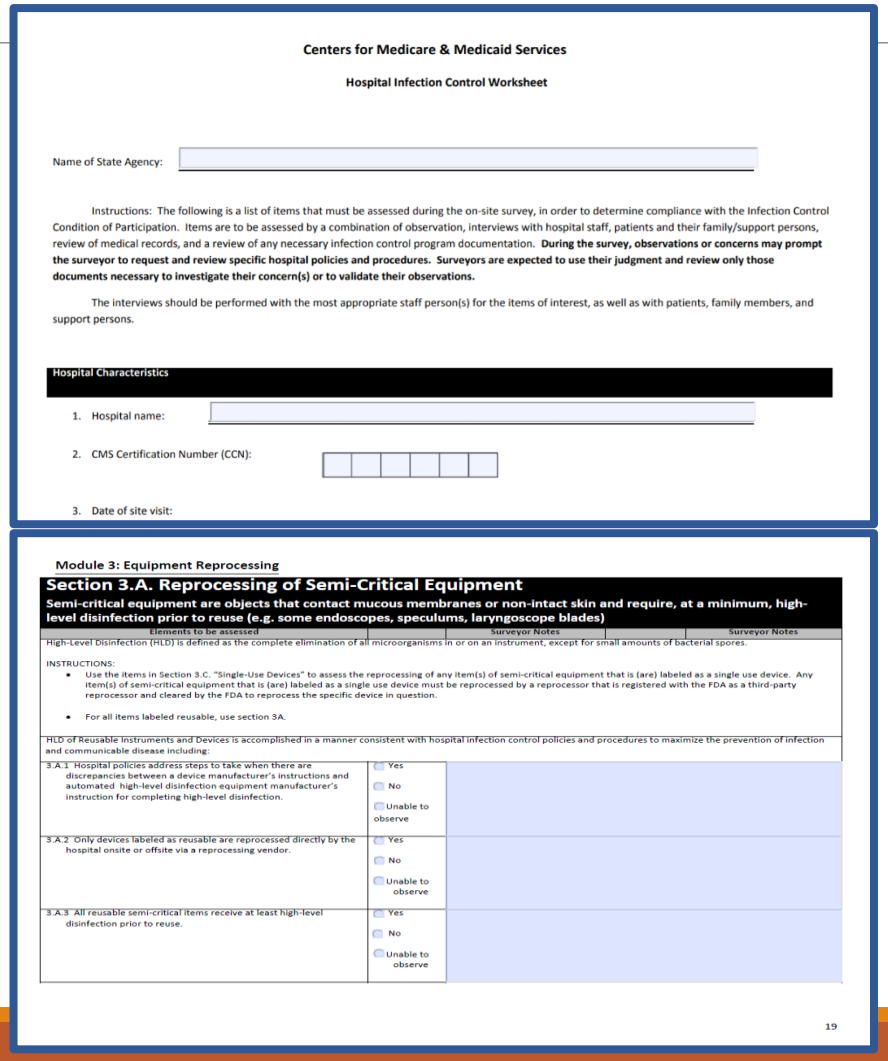


AORN Guideline Audit Tool: Processing Flexible Endoscopes [Insert facility name or a header]

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Uses a fresh cleaning solution.			
Washes the exterior surface of the endoscope with the cleaning solution and a soft, lint-free cloth or sponge.			
Places the distal end of the endoscope in the cleaning solution and suctions the cleaning solution through the endoscope.			
Suctions the cleaning solution through the suction and biopsy channels.			
Flushes the air, water, and other channels of the endoscope alternately with the cleaning solution and air, finishing with air.			
Discards the cleaning solution and cloth or sponge after use.			
Transporting			
Transports the contaminated endoscope and accessories to the decontamination room as soon as possible.			
Keeps the endoscope moist but not submerged.			
Uses a container or cart that is leak proof, puncture resistant, and large enough to contain all contents with the endoscope coiled in large loops.			
Ensures the container or cart is labeled with a biohazard legend.			
Keeps accessories with the endoscope but contained separately.			
Processes the endoscope as soon as possible after transport to the endoscopy processing room.			
Records when the procedure is completed and cleaning is initiated.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			
Removes all port covers and function valves.			
Pressurizes the endoscope to the recommended pressure.			
Places the endoscope in the sink in a loose configuration.			
Manipulates all moving parts; angulates the bending section of the distal end.			
Actuates video switches while testing.			
Maintains pressure and inspects for a minimum of 30 seconds.			
Manual Cleaning			
Manually cleans the flexible endoscope as soon as possible after leak			

Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC
https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html
Page last reviewed: December 27, 2018.

Consider converting existing Guidelines/Recommendations/Audits into your own Yes/No Document



Centers for Medicare & Medicaid Services

Hospital Infection Control Worksheet

Name of State Agency:

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the Infection Control Condition of Participation. Items are to be assessed by a combination of observation, interviews with hospital staff, patients and their family/support persons, review of medical records, and a review of any necessary infection control program documentation. **During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.**

The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

Hospital Characteristics

1. Hospital name:
2. CMS Certification Number (CCN):
3. Date of site visit:

Module 3: Equipment Reprocessing

Section 3.A. Reprocessing of Semi-Critical Equipment

Semi-critical equipment are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (e.g. some endoscopes, speculums, laryngoscope blades)

Elements to be assessed		Surveyor Notes
High-Level Disinfection (HLD) is defined as the complete elimination of all microorganisms in or on an instrument, except for small amounts of bacterial spores. INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of semi-critical equipment that is (are) labeled as a single use device. Any item(s) of semi-critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • For all items labeled reusable, use section 3A.		
HLD of Reusable Instruments and Devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including:		
3.A.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and automated high-level disinfection equipment manufacturer's instruction for completing high-level disinfection.	☐ Yes ☐ No ☐ Unable to observe	
3.A.2 Only devices labeled as reusable are reprocessed directly by the hospital onsite or offsite via a reprocessing vendor.	☐ Yes ☐ No ☐ Unable to observe	
3.A.3 All reusable semi-critical items receive at least high-level disinfection prior to reuse.	☐ Yes ☐ No ☐ Unable to observe	

19

CMS.gov
Centers for Medicare & Medicaid Services

CMS Hospital Infection Control Worksheet – https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf

Examine Current State of Affairs

Who? What? When? Where?

Inventory information:

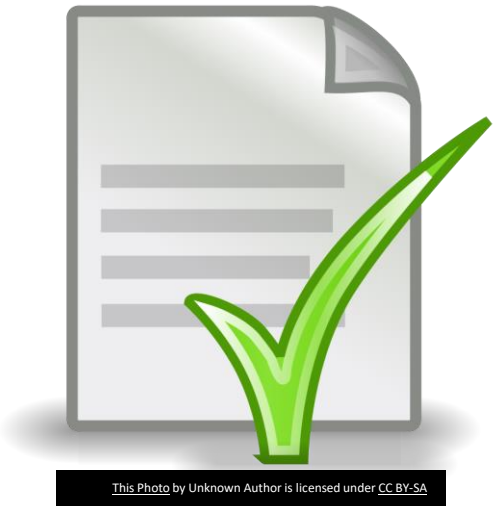
- Endoscope make and model.
- Clinical site using.
- Number of procedures performed.
- Location of OEM IFUs.
- Location for reprocessing.
- Equipment used for HLD and / or sterilization.
- Endoscope inventory tracking: in-use versus out for repair versus “retired”.

Current: P & P, Competency records, Guidelines and Reference documents.

Conducting Mock Tracers / Gap Analyses

Have	Hit	Identify	Ensure
Have multiple disciplines tour together.	Hit all areas that use flexible endoscopes. • Common: GI Endo., ORs, Respiratory, ICU, ED, Anesthesia, Urology, ENT, OB/GYN	Identify deficiencies in practice as compared to policies.	Ensure compliance with all current federal and local regulatory requirements, as well as applicable accrediting organizations.

Processing related documentation



Training and competencies

- Frequency of renewal clear.

Processing logs

- Can be electronic or paper
- Any gaps are red flags

PMs/maintenance/repairs

- Devices (e.g. scopes
- Equipment

Management of records

- Reference HR - Staff Performance & Competency documentation policy
  - Processing log sheets:
  - Patient to device tracking (endoscopes, probes)
  - Often an accreditation survey cycle – e.g. 3 years
- Reprocessing completion and quality assurance validation
  - Demonstrate a track record of performance.
  - Example - 12 months

Disciplined Approach

1. Assemble Multidisciplinary Stakeholder Team
2. Agree on Guidelines and Recommendations
3. Develop Gap Analysis, Audit Tool, and Timelines
4. Examine Current State of Affairs
5. Conduct Mock Tracer, Gap/Risk Analyses
6. Present and Analyze Results
7. Prioritize Issues
8. Change/modify practices where needed
9. Follow up Improvement Plans
10. Evaluate Actions
11. Conduct Regular Risk Assessments, Mock Tracers, Gap/Risk Analyses

This Photo by Unknown Author is licensed under CC BY-SA0

This Photo by Unknown Author is licensed under CC BY-NC-ND

https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/joint-commission-online/aug-25-2021/new-risk-assessment-guide-available-from-jcr/

Home > Resources > News & Multimedia > Newsletters > Joint Commission Online > Aug 25 2021 >
New risk assessment guide available from JCR

New risk assessment guide available from JCR

Risk assessment — or the potential to cause harm — is an ongoing concern for health care organizations.

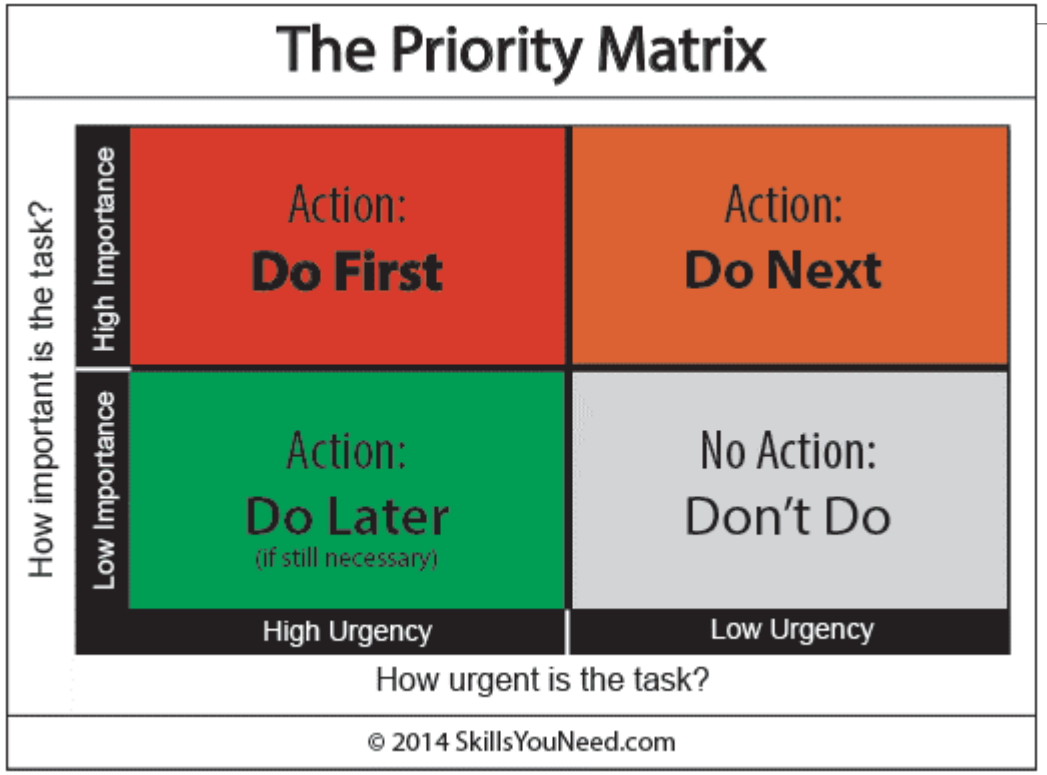
In response, Joint Commission Resources developed *The Joint Commission Guide to Risk Assessment*, a brand-new book to help all types of health care organizations create and implement effective risk assessments that support safe, quality care and ongoing performance improvement.

The book features:

- Sample risk assessments for each Joint Commission standard or element of performance that specifically requires a risk assessment
- Tools, tracers, checklists, and sample policies to help with the assessment process

TJC Online 08-25-21

- "Sample risk assessments for each Joint Commission standard or element of performance that specifically requires a risk assessment."
- "Tools, tracers, checklists, and sample policies to help with the assessment process"



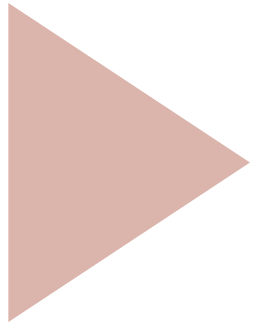
This Photo by Unknown Author is licensed under CC BY-NC-ND

- Present and Analyze Results
  - Need ongoing relationship with and support of administration!
- Prioritize Issues
  - Can't/shouldn't do it all at once.

- Change/modify practices where needed
  - On the spot
  - Through policies
  - Through education
- Follow up Improvement Plans
  - Don’t assume changes are sustained.

This Photo by Unknown Author is licensed under CC BY-SA-NC

Evaluate Actions



Conduct Regular Risk Assessments, Mock Tracers, Gap/Risk Analyses

This Photo by Unknown Author is licensed under CC BY-ND

AAMI ST90

Processing of health care products - Quality management systems for reprocessing

- This standard specifies the minimum requirements for a quality management system that can be used by healthcare organizations that process medical devices.

- It was developed to help healthcare professionals more effectively, efficiently, and consistently reprocess reusable medical devices in order to prevent infections, pyrogenic reactions, or other adverse events.

The path forward

healthmark

Mitigating Risks of Processing Reusable Medical Devices in Ambulatory Care Settings

jwhelan@hmark.com

Healthmark Industries Co., Inc.

18600 Malyn Blvd.

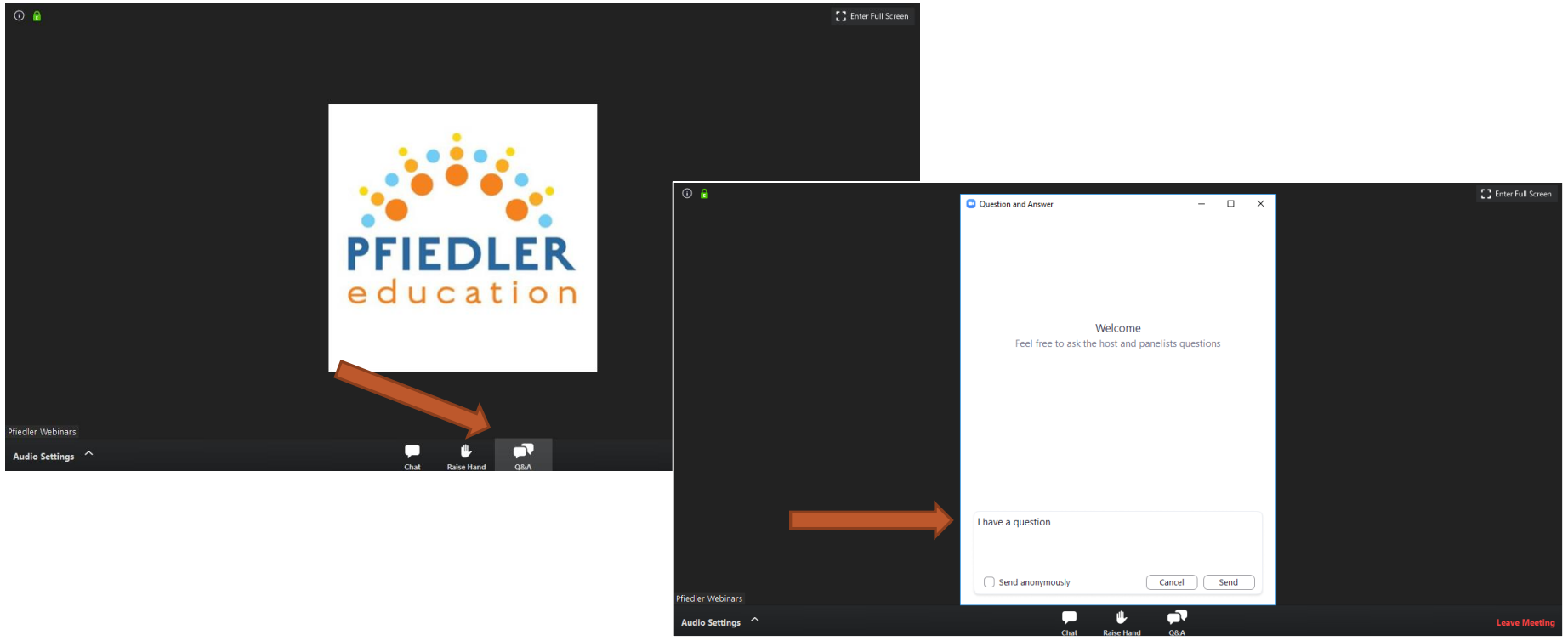
Fraser, Michigan 48026

800.521.6224

www.hmark.com

Healthmark@hmark.com

Audience Q&A


Enter Full Screen
PFIEDLER education
Pfiedler Webinars
Audio Settings
Chat
Raise Hand
Q&A
Question and Answer
Welcome
Feel free to ask the host and panelists questions
I have a question
Send anonymously
Cancel
Send
Pfiedler Webinars
Audio Settings
Chat
Raise Hand
Q&A
Leave Meeting

Questions?

Thank you for attending this continuing education presentation

Tomorrow, you will receive an email with a link for claiming continuing education credits

Contact pfiedlermeetings@pfiedler.com for any questions regarding continuing education credits