

Standard Operating Procedure

Endoscopy Quality Assurance Protocol

Date: February 2014

☒ VUH	☒ Children's	VMG	VMG Off-site locations	VPH	VUSN	VUSM
Team Members Performing:						
☐ All faculty & staff	☐ Faculty & staff providing direct patient care or contact	☐ MD	☐ RN	☐ LPN	☒ Other: All staff performing endoscope reprocessing.	
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Applicable to: Perioperative Services

Team Members Performing: Endo Staff & OR Staff

I) Purpose:

To provide guidance to assist personnel in performing quality assurance check points with the use of manufacturer recommendations on care and handling of endoscopic instrumentation & equipment.

II) Procedure:

Define quality assurance process using these outlining topics:

- A. Leak Testing
- B. Optics/Image Quality
- C. Angulation (if applicable)
- D. External Components
- E. Repair/Maintenance

Endo Staff Responsibilities

A. Leakage Testing

1. All endoscopes are disassembled and leak tested in the reprocessing area.

2. Appropriate leak testing equipment and process must be used per endoscope manufacturer recommendation.
3. Appropriate leak testing includes, but is not limited to, the following steps:
 - a. Wear appropriate personal protective equipment (PPE).
 - b. Fill basin or sink with clean water for leakage testing.
 - c. Connect the leakage tester connector to the output socket and verify that the endoscope is pressurized.
 - d. Immerse the endoscope in the water as per manufacturer's recommendations and observe for 30 seconds, visually inspect for potential leaks.
 - e. Leakage in either the covering or one or more of the internal channels can be determined by the presence of air bubbles when air pressure is applied to the inside of the insertion tube.
 - f. Manipulate the angulation knobs and video switches to check for potential leaks.
 - g. Remove the endoscope from the water and allow the endoscope to depressurize
 - h. Disconnect the leakage tester from the water resistant cap. Do not remove the water resistant cap.
 - i. Dry the leakage tester connector cap.
4. When using a leak test system that does not require water ("dry test"), the leak test should be completed before submersion in water or cleaning solution.
5. Leaks in either the covering or one or more of the inside channels can be determined by a drop in pressure after inflation, by the inability to inflate the inside of the insertion tube, or visible bubbles when submerged.
6. In the event of a failed leak test (i.e. leakage is noted), reprocessing is stopped, the endoscope is considered damaged, and the device is handled as described below.

B. Optics/Image Quality

1. Rigid Endoscopes

- A. Handle rigid telescope by holding eyepiece only. Do not hold shaft of rigid scope.
- B. Using a loupe or other visual examination tool against a printed text at a distance 1 to 1.5 inches with lettering to inspect image is consistent from edge to edge.
- C. If image is not clear wipe down distal tip with alcohol.
- D. Evaluate image damage:
 - i. Scope dust may be visible. This looks like pepper and is from rod lenses rubbing, spacers rubbing or sterilization.
 - ii. Broken or chipped rod lenses. This will look like a half moon shape appearance, or curved glass shape like that of a broken window.
 - iii. Completely black image. Meaning all lens are broken.
- E. Any damage to endoscopic instrumentation and equipment (rigid & flexible/fiberoptic endoscopes) needs to be removed from service and sent out for repair. Process outlined in Section 5 of Endoscopy quality assurance protocol.

2. Fiberoptic/Flexible Endoscopes

- A. Handle flexible endoscope by holding shaft and distal tip. Do not let distal tip hang.
- B. View image under well lite lighting or attach light cable to a light source to provide additional lighting for quality testing of image.
- C. Using a loupe or other visual examination tool (video check) against a printed text at a distance 1 to 1.5 inches with lettering to inspect image is consistent from edge to edge.
- D. If image is not clear wipe down distal tip with alcohol.
- E. Evaluate image Damage:
 - White fibers=Good Fibers
 - Gray fibers=Damaged Fibers
 - Black fibers=Broken Fibers

- Pepper spots throughout the visual exam. 8 or more black specks endoscope needs to be removed from service and sent out for repair. These are broken fibers.
 - Look for clarity, stains, or flickering (in Olympus flexible endoscopes). If image results in poor clarity, stains or flickering this is an indication of damage.
3. Any damage to endoscopic instrumentation and equipment (rigid & flexible/fiberoptic endoscopes) needs to be removed from service and sent out for repair. Process outlined in Section 5 of Endoscopy quality assurance protocol.

C. Angulation

1. Applies to flexible endoscope or semi-rigid. Endoscope with a bending rubber.
 - a. Refer to manufacture recommendation for angulation of each model type endoscope.
2. Any damage to endoscopic instrumentation and equipment (rigid & flexible/fiberoptic endoscopes) needs to be removed from service and sent out for repair. Process outlined in Section 5 of Endoscopy quality assurance protocol.

D. External Components (Visual Examination)

1. Rigid Endoscopes
 - a. Eyepiece, Light Post & Block assembly
 - A. Look for excessive wear & inspect proximal window.
 - B. Inspect for missing parts or loose components.
 - C. Remove light adaptor and inspect light fibers.
 - b. Shaft & Distal Lens Assembly
 - A. Review shaft and light post looking for any dents, or any wear and tear damages. Include bending of shaft from visual inspection.
 - B. Examine distal lens for any cracks, burred edges, missing optical elements, & laser solder.

2. Fiberoptic/Flexible Endoscopes

- A. Storz Flexible endoscopes
 - i. Eyepiece:
 - Look for excessive wear, inspect proximal window.
 - ii. Handle:
 - Deflect leveler in both directions focus on distal end/tip. Movement should be smooth not gritty.
 - Look for black fiber areas making sure there are no more than ¼ black fibers on light post.
 - Working port should be clear of debris.
 - iii. Passive Shaft:
 - Examine shaft for any dents and/or creases and make sure the shaft is free of any defects.
 - iv. Bending Section/Active Deflection Segment:
 - Examine for dent or creases, structural integrity (such as thermal damage or puncture).
 - v. Distal End/Tip:
 - Visual examine the tip for thermal damage.
 - Joined areas are intact and present (i.e. adhesives).
- B. Olympus Flexible Endoscopes
 - i. Light Guide Connector
 - Visual exam of air pipe, light guide, suction connector, air supply connector, water supply connector, electrical contacts, suction connector, electrical connector, venting connector, and water resistant cap (if applicable).
 - 1. Check for loose/missing parts, chemical damage and/or cracking.
 - ii. Light Guide Tube
 - Visual check for chemical damage, dents, tears and loose connections.
 - iii. Control Body/Video Remote Switches
 - Visual exam of up/down angulation control knob & lock, right/left angulation control

knob & lock, grip section, air/water cylinder, suction cylinder, auxiliary water inlet, video control buttons, instrument channel port, and boot.

1. Check for loose/missing parts, chemical damage, cracking, and tears.
- iv. Insertion Tubes
 - Check for chemical damage, buckling, dents or tears.
 - v. Bending Section/Distal End/Tip
 - Bending section- check for chemical damage, buckling, dents or tears.
 - Distal tip/end- check glue bands, “C” cover has black cap, lens are not cracked.
 - Any damage to endoscopic instrumentation and equipment (rigid & flexible/fiberoptic endoscopes) needs to be removed from service and sent out for repair. Process outlined in Section 5 of Endoscopy quality assurance protocol.

E. Repair/Maintenance

1. Please notify department supervisor, lead or coordinator before sending endoscopic instrument or equipment out for repair.
2. Complete repair form indicating where damage is located, pan name, serial number & part number for reference.

Supervisor, Lead & Repair Coordinator Responsibilities:

a. Sending out Repairs:

- i. Departmental supervisor or lead tech will evaluate endoscopic instrumentation or equipment to confirm damage.
 1. Notify Repair Coordinator to schedule repair/maintenance service required.
- ii. Coordinator will complete the endoscope repair log, filling in all fields and will send instrumentation or equipment out for repair.

b. Checking in Repairs:

- i. Repair Coordinator will check endoscopic instrumentation or equipment in from repair.
 1. Notify departmental supervisor or lead tech to complete quality control form.
- ii. Departmental supervisor or lead tech will complete quality control form to perform evaluation on endoscopic instrumentation or equipment coming back from repair and ensure all endoscopes pass each required standard.
 1. If endoscopic instrument or equipment is replaced with new serial number that is to be logged on the repair log and added to Censitrac as a new item.
 - a. Item that is being replaced with new serial number will need to be removed from inventory in Censitrac.
- iii. Departmental supervisor or lead tech may work in partnership with designated surgeon to evaluate endoscopic instrument or equipment coming back from repair.
 1. This will be required when there is serious concern for a specific model endoscope.
 - a. When there are consistent breakages of endoscopes this will be required for supervisors or lead techs.

References:

Vanderbilt University Medical Center Standard Operating Procedures "Endoscope and Accessory Reprocessing"

Olympus Endoscope Field Audit Form & Karl Storz Rigid Telescope Inspection Guide