IPA Product Review – Steps 7-11

Process Step	Guideline Overview		Current State	Cantel Solution
Drying & Storage	AAMI	Drying scopes and accessories is necessary before storage via forced air	Time:	Time:
	AORN	Channels must be purged with Instrument air or dried in a mechanical system		
	SGNA	Drying can take 30 minutes–4 hours depending on cabinet manufacturer, 7 day hang time recommended, horizontal storage OK for forced air cabinets		
	FDA	Incorporate final drying step into reprocessing protocol		
	CDC	Store endoscopes in manner that prevents recontamination, protect from damage, ensure dry		
	AAMI	Protected from recontamination, impervious barrier system/container	Time:	Time:
	AORN	Transported with clean latex gloves in a manner that protects from contamination		
Transport to Procedure	SGNA	Transport in closed, puncture-resistant container that prevents contamination		
	FDA	No guidance		
	CDC	In compliance with manufacturer's IFU		
Valves	AAMI	Single-use disposable valves should be considered	Time:	Time:
	AORN	Single-use valves may be used		
	SGNA	Reusable accessories/valves must be visually inspected, life cycle maintained, documentation of HLD/Sterilization and cross referenced to patients		
	FDA	Must be tracked, some designs are prone to harbor debris—thoroughly dissemble to clean		
	CDC	Disconnect and disassemble where possible, steam sterilize if possible		
	AAMI	Reusable water bottles should be cleaned and HLD once per day at minimum	Time:	Time:
	AORN	Same as AAMI, and single-use devices should be used if available	MALUSI	
Water Bottles/ Tubing	SGNA	Manually clean, HLD or sterilize once per day, thoroughly dry prior to storage, sterile water must be used in bottles, must have single use backflow prevention method	Time: RINTERNAL USE ONLY	
	FDA	Use single-use connectors that prevent the possible backflow of fluid		
	CDC	Cleaned and HLD once per day, no residual water should remain in bottle or tubing		
Documentation/ Tracking	AAMI	Document performance of all steps/tests including operator, time, date, outcome, serial number	Time:	Time:
	AORN	Patient Ready scopes should have a clearly marked identifier indicating they are ready for use		
	SGNA	Maintain documentation of reprocessing activities, accessories/valves should be marked as read for use, date of HLD, staff responsible, cross referenced to records to track patient, date and type of procedure	У	
	FDA	Recommends establishing a program to follow well-established guidelines		
	CDC	Tracking is essential in case in disinfection failure		

Notes:			



This document is not meant to offer medical, legal, regulatory, or compliance advice and is not intended to establish a standard of care. The guidelines listed above are for reference purposes only.



IPA Product Review – Steps 1-6

Facility:		Department: Facility Representative:	Cantel Rep:	
Process Step		Guideline Overview	Current State	Cantel Solution
Pre Treatment	AAMI	Should be done in procedure room with fresh cleaning solution	Time:	Time:
	AORN	Should be done at point of use with fresh solution		
	SGNA	Should be done in procedure room with detergent solution		
	FDA	Imperative that staff flush scopes with enzymatic cleaner—2009		
	CDC	Perform pre-cleaning immediately following scope usage		
Contaminated Transport	AAMI	Transport in closed container marked w/biohazard symbol	Time:	Time:
	AORN	ASAP to reprocessing room in closed, leakproof, and puncture-resistant container		
	SGNA	Transport in closed puncture resistant container, biohazard label, large enough to prevent overcoiling of the scope		
	FDA	No guidance		
	CDC	Transport in coordination with scope IFU		
Leak Test	AAMI	In reprocessing area as soon as it enters, adequate time should be given to perform test	Time:	Time:
	AORN	After every patient use, before manual cleaning and immersion in cleaning solution		
	SGNA	Done before immersion in cleaning solutions, follow manufacturer IFU, manual or automatic either wet or dry		
	FDA	Testing for leaks should be done		
	CDC	Perform leak test prior to manual cleaning per the manufacturer's IFU after each use	CE ONL'	
	AAMI	ASAP after passing leak test, Automated Flush—OK	Time:	Time:
	AORN	Endoscopes should be manually cleaned after leak testing according to the IFU	Time: NTERNAL USE ONLY	
Manual Wash	SGNA	Low-foaming detergents are recommended, cleaning is required regardless of AER	OK ,	
	FDA	Cleaning is separate process from disinfection, all debris/biofilm must be removed		
	CDC	Meticulous cleaning per the IFU and within the time frame of IFU		
	AAMI	Repeat brushing, flushing and rinsing if debris is present before HLD	Time:	Time:
	AORN	Visualization should occur after manual cleaning		
Visualization	SGNA	Is essential prior to HLD, use lighted magnification and a borescope if possible		
	FDA	No specific recommendation		
	CDC	No specific recommendation		
HLD	AAMI	Document solution, dates, operator, scope make/model, rinse and purge with alcohol and air	Time:	Time:
	AORN	If AER IFU directs HLD without manual cleaning facility may choose to follow IFU		
	SGNA	HLD is the standard for reprocessing, wear proper PPE, test and monitor for MEC		
	FDA	Properly train staff, thorough cleaning MUST be done first, HLD must contact all surfaces		
	CDC	Perform HLD to IFU, mechanically clean all reusable accessories		

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AAMI - Association for the Advancement of Medical Instrumentation

AORN - Association of periOperative Registered Nurses

SGNA - Society of Gastroenterology Nurses and Associates

FDA - Food and Drug Administration

CDC - Centers for Disease Control and Prevention

