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## Technical Bulletin

October 6, 2015

### The Getinge Assured SafeStep Quality Assurance System

### Updated Recommended Pass/Fail Criteria for Scopes and Surgical Instruments.

Based on a new research study, the manufacturer is updating the Pass/Fail threshold for The Getinge Assured SafeStep Quality Assurance System, previously set at 45 and under for a passing result, to 100 and under for endoscopes and surgical instruments. This change is the result of data collected from a new study, *Simulated-Use Validation for a Sponge ATP Method for Determining the Adequacy of Manual Endoscope Channel Cleaning*.\*

This change will be implemented on all our technical data including the Directions for Use as we move through our current inventory. Please contact us or visit our website [www.getinge.com](http://www.getinge.com) for updated documentation and directions for changing the thresholds on your ATP device.

Application	Recommended Pass/Fail Criteria	
	Pass (RLU)	Fail (RLU)
<b>Endoscopes and Surgical Instruments</b>	0-100	101 and over
<b>Sterile Processing - General</b> (all non critical surfaces in procedure rooms, restrooms, waiting rooms, etc.; for testing counters, bedrails, blood pressure cuffs, toilets, faucets, hand rails, beds, computers, I.V. poles, etc.)	0-45	46 and over

The Getinge Assured SafeStep Quality Assurance System is a quick and reliable verification method for testing surgical instruments, flexible endoscopes and surfaces with results in as little as 15 seconds. Please contact Getinge for more information on quality assurance testing using our SafeStep device.

**It is recommended that ATP testing be done immediately after cleaning (prior to High Level Disinfection or Sterilization).**

**Please note:** Testing after High Level Disinfection is an option for periodic testing. The procedure and frequency of this step would be determined at the discretion of the individual facility.

\*The study, which was performed by a third party research lab, has been submitted for publication.