Simulated-Use Testing: Flexible Endoscope

Objective
To characterize the cleaning efficacy of flexible endoscopes utilizing Artificial Test Soil (ATS).

Inoculation
The target device is an Olympus colonoscope model CF101 type 1 (or similar device). To characterize the cleaning efficacy, the colonoscope is inoculated into the biopsy port by injecting 10mLs of ATS, containing $10^8$ cfu/mL of various challenge organisms. The excess soil is drained from the distal end of the scope. The scope is held at room temperature for 30 minutes. This soiled, dried scope is then sampled before and after complete or suboptimal manual cleaning.

Optimal Cleaning
Complete cleaning is performed by first ensuring that the cleaning cap to cover the electrical connections is in place. A small brush dipped in enzymatic detergent is used to brush the cap, suction, air/water and biopsy ports. A piece of gauze is dipped in the enzymatic detergent and then used to wipe down the control head, the umbilical cord and finally the insertion tube. The all-channel irrigator is attached and the scope is rinsed by flushing 100mLs of reverse osmosis (RO) water through the channels. The scope attached to the all-channel irrigator is then immersed in a basin containing 8 liters of enzymatic detergent diluted per manufacturer's instructions. The scope is rinsed with the detergent by using the all-channel irrigator to flush 100mLs through the channels, and then allowed to soak for 2 minutes. The all-channel irrigator is removed and while submerged, an appropriately sized double-ended endoscope channel brush is passed twice through all the channels including: suction port to umbilical end, suction port to distal end and biopsy port to distal end. The all-channel irrigator is reattached and used to flush another 100mLs of enzymatic detergent through the channels. The scope is immersed for a further 3 minutes at room temperature (total enzymatic detergent contact time of 5 minutes). The scope is removed from the enzymatic solution and the all-channel irrigator is used to flush air to ensure that all enzyme solution is drained from the scope. The scope is then transferred to a basin containing 8L of RO water and 1 L of RO water is sucked through the scope. The scope is then removed from the basin and while still attached to the vacuum source all excess fluid is sucked out.

Suboptimal Cleaning:
Incomplete cleaning consists of using a non-immersion method and omitting the brushing steps in the cleaning protocol. After soiling, a 20cc sterile syringe is used to flush 20mLs of tap water through the biopsy port. Using a second 20cc syringe, 20mLs of enzymatic solution is flushed through the biopsy port. Finally, 40mLs of tap water is flushed through the biopsy port.
**Positive control** (*soiled, unclean*):
Samples are collected immediately after the 30 minute dry stage.

**Negative Control** (*unsoiled, unclean*):
Baseline testing is performed by sampling the channel prior to soiling.