Endoscopes are complex medical devices that require strict adherence to manufacturer instructions and professional guidelines. However, few quality control tools currently exist for verifying the bioburden before manual cleaning. Some have reported the presence of carbohydrates, protein, and hemoglobin within the lumen of patient-used endoscopes. Therefore, ChannelCheck test strips can be utilized within healthcare facilities to verify that their manual cleaning process has been performed properly. This will help to ensure their subsequent high-level disinfection or sterilization of the endoscopes has properly occurred.

ChannelCheck test strips would also be an effective tool for users to verify and validate their cleaning process as recommended in AAMI TIR 122. This would be an important part of an Infection Control program as users would be able to record the results of the test strips, allowing for a robust Quality System.

The use of ChannelCheck 3-in-1 test strips would be an excellent training tool for new employees, as well as a competency-testing and auditing tool. ChannelCheck test strips provide a uniform scale with a simple-to-use test which verifies that adequate cleaning has been achieved.

**ABSTRACT**

Endoscopes are complex medical devices that require strict adherence to manufacturer instructions and professional guidelines. However, few quality control tools currently exist for verifying the bioburden before manual cleaning. A field study was conducted at 10 clinical facilities using 79 patient-used endoscopes prior to and after manual cleaning. The results of the study indicated that none of the endoscopes tested positive for residual carbohydrate, protein, or hemoglobin after manual cleaning in a clinical environment. Patient safety is a major concern for all medical facilities. One approach to improving patient safety is the use of monitoring tools that verify proper device cleaning. Flexible endoscopes are complex devices that are cleaned primarily using a manual process that is both labor-intensive and prone to error. Visual inspection alone is inadequate to ensure proper cleaning, and the presence of multiple internal lumens that are highly contaminated during patient use emphasize the need for an objective method to verify endoscope cleaning.

**RESULTS**

A total of 79 Olympus endoscopes were sampled using the collection procedure. Table 1 demonstrates the number and type of each endoscope sampled. The results indicated that none of the endoscopes tested positive for residual carbohydrate, protein, or hemoglobin after manual cleaning in a clinical environment.

**DISCUSSION**

ChannelCheck test strips test for three common organic soils at once: protein, carbohydrate, and hemoglobin. An additional study was conducted to determine the detection limits for each residual type. The lower detection limits of each type were 10 ng/mL for protein, 100 µg/mL for carbohydrate, and 0.25 µg/mL for hemoglobin. Two studies conducted by HealthMark Industries have demonstrated the recovery efficiency of each residual type using 100 mL sterile water for lumen flushing. The study verified that a 100 mL flush is a adequate volume of water for utilization of the ChannelCheck test strip.

An additional study was conducted to determine the detection limits for each residual type. The lower detection limits of each type were 10 ng/mL for protein, 100 µg/mL for carbohydrate, and 0.25 µg/mL for hemoglobin. When the limits of detection were exceeded, ChannelCheck test strips test for three common organic soils at once: protein, carbohydrate, and hemoglobin.

**OLYMPUS SURVEY RESULTS**

A survey was conducted by Olympus to evaluate end-user responses to the product. Responses of 8 end-users to a survey regarding use of ChannelCheck 3-in-1 test strips are listed below.

**REFERENCES**
