EVALUATION OF THE CLEANING EFFECTIVENESS OF REVITAL-OX® 2X CONCENTRATE ENZYMATIC DETERGENT ON FLEXIBLE ENDOSCOPES IN A SIMULATED MANUAL USE STUDY

PURPOSE

Revital-Ox 2X Concentrate Enzymatic Detergent is designed to be a low foaming, free rinsing, biodegradable and neutral pH enzymatic detergent. It is recommended for use in cleaning flexible endoscopes and accessories where blood, protein, mucous and lipids form hard to remove soils. Laboratory experiments were conducted to assess the cleaning effectiveness of Revital-Ox 2X Concentrate Enzymatic Detergent in removing soils from endoscopes using a simulated manual use study.

METHODS

Materials

Four flexible endoscopes were tested in this study:

- Fujinon® Colonoscope 1 EC-530 HL
- Pentax® Gastroscope 2 EG-1580K
- Olympus® Bronchoscope 3 BF-3C30
- Pentax® Duodenoscope ED-2900

Representative artificial soils were applied to the surfaces of control handles and distal ends and to channels of the flexible endoscopes. These soils were allowed to dry on the endoscope surfaces for greater than 60 minutes at room temperature prior to manual cleaning.

Manual Cleaning

Manual cleaning was performed by qualified personnel following the endoscope manufacturer’s recommendations and national guidelines governing best practices. Manual cleaning trials of the four endoscopes were done in triplicate.

Determination of Cleaning Effectiveness

Residual soil samples were collected from each test site using swabbing or flushing with deionized water. The effectiveness of cleaning was evaluated by quantification of the cleaning markers, protein and total organic carbon (TOC), that indicated the level of artificial soil detected in the samples recovered from each endoscope. The residual soil samples were recorded and converted to µg/cm².

Evaluation Methods for Markers

Protein quantification was evaluated using a fluorometric assay using fluorescamine. The endpoint for protein was < 6.4 µg/cm². Total organic carbon was determined using a Sievers/GE TOC analyzer. The endpoint for TOC was <12 µg/cm².

RESULTS

Figures 1 and 2 depict the remaining protein and TOC on the surfaces and channels of the tested bronchoscope and gastroscope respectively after manual cleaning with Revital-Ox 2X Concentrate Enzymatic Detergent. The results displayed are an average from three cleaning trials. The remaining protein levels on test areas are all well below the maximum acceptable level of < 6.4 µg/cm² on both endoscopes. The TOC levels on all test areas of both endoscopes are also well below the maximum acceptable level of < 12 µg/cm².

1. Fujinon® is a registered trademark of Fujifilm Corporation.
2. Pentax® is a registered trademark of Pentax Corporation.
3. Olympus® is a registered trademark of Olympus Corporation.
Figures 3 and 4 display the results of the remaining protein and TOC on the surfaces and channels of the tested colonoscope and duodenoscope respectively after manual cleaning with Revital-Ox 2X Concentrate Enzymatic Detergent. The results displayed are an average from three cleaning trials. The remaining protein levels on test areas are all well below the maximum acceptable level of < 6.4 µg/cm² on both endoscopes. The TOC levels on all test areas of both endoscopes are also well below the maximum acceptable level of < 12 µg/cm².
Figure 3. Quantitation of Protein and TOC Remaining On Fujinon Colonoscope EC-530 HL After Manual Cleaning

Figure 4. Quantitation of Protein and TOC Remaining on Pentax Duodenoscope ED-2900 After Manual Cleaning
CONCLUSION

The results demonstrated that Revital-Ox 2X Concentrate Enzymatic Detergent effectively removed the soils from the surfaces and channels of the endoscopes in this manual cleaning simulated use study. The average residual soil levels after manual cleaning were well below the established endpoints for protein and TOC.

REFERENCES