



# HangTimeKit™

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## BACKGROUND

Endoscopes are widely used for diagnostic and therapeutic procedures. An endoscope can be used anywhere from 300 to 1,200 times a year (*Alfa, M.J., Healthcare Purchasing News, June 2003*). Due to the complex design of scopes, any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms in the suction channels (*Alfa, M.J., et al. 2006 American Journal of Infection Control, 34(9), 561-570*). If microorganisms survive the steps of endoscope reprocessing, it could potentially lead to subsequent patient infection. Nosocomial outbreaks linked to endoscopes contaminated with gram-negative bacteria have been frequently reported (*Muscarella L.F., Infect Control Hosp Epidemiol. 2002 May; 23(5):285-9*). Gram negative bacteria replicate more easily in the presence of moisture, and have been implicated in endoscope associated infections more frequently than have Gram positive bacteria (*Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effect of drying. J Hosp Infect 1991;19:89-98*).

Many flexible endoscopes are routinely used and hardly remain idle for a couple of days. However, there are other specialty endoscopes or their backup equipment that is used less frequently (*Catalone, B.J. et al, Healthcare Purchasing News, Nov 2010*). AORN guidelines recommend that endoscopes be reprocessed before use, if not used for more than five days (*Perioperative Standards and Recommended Practices, AORN, 2009*). SGNA recommends that stored endoscopes be hanged vertically, with the distal tip hanging freely in a clean, well ventilated, dust-free area. Good ventilation in the storage area encourages continued air drying of the scopes, and prevents moisture build-up, thereby discouraging any microbial contamination (*SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal 2008*). These guidelines further recommend that the endoscope's valves and other detachable components be removed in storage, to prevent the scope's internal channels from retaining water, which could then become contaminated with microorganisms. In practice however, it is observed that many scopes are not hanged properly and the storage conditions are not monitored large number of times. The last reprocessing date is also not marked many times. Failure to adhere to the guidelines leads to

an increased risk of survival and growth of microorganisms inside the endoscope channels. A survey of stored flexible endoscopes found that 23.9% of samples taken from devices' channels had  $>10^5$  cfu/channel (*Kaczmarek RG, Moore RM, Jr., McCrohan J, et al. Multi-state investigation of the actual disinfection/sterilization of endoscopes in health care facilities. Am J Med 1992;92:257-61*). Periodic surveillance of stored endoscopes at specific intervals thus plays a significant role in increasing efficiency, saving time and reducing future costs (*Muscarella, L.F., The Q-Net Monthly, Feb. 2001*).

There was a need to have a system that clearly identifies when each endoscope was last reprocessed, as well as to detect microbial growth inside the lumens of scopes stored for multiple days. This led to the conception of the HangTimeKit™ (HTK). The kit comprises a tag that is labeled with the last processing date of each individual scope and a test that detects the presence of gram negative bacteria inside the scope that might have grown during storage.

## DIRECT TEST OF ENDOSCOPE CHANNELS

Channels from 19 endoscopes were obtained from an endoscopy clinic. These scopes were processed after use and were hanging in storage for at least 2 days over the weekend. The scopes were not labeled with their last processing date and hence their exact time in storage was not available. The suction channels were tested for *E. coli*, *Salmonella* and fecal coliforms (all gram negative bacteria). Out of these 19 channels, 3 tested positive for *E. coli*, 4 tested positive for *Salmonella*, and 9 tested positive for fecal coliforms. Later, 21 more channels from processed scopes in storage were obtained from the clinic and tested for gram negative bacteria. All these channels tested negative. These results confirmed the need for an efficient, rapid test kit to determine how safe the endoscopes in storage really are.

## WORKING PRINCIPLE OF THE HANGTIMEKIT

The HangTimeKit™ detects gram negative bacteria like *E. coli*, *Salmonella*, *Helicobacter pylori*, *Serratia marcescens*, *Pseudomonas aeruginosa*, *Legionella*, associated with patient infection after endoscopic procedures. The gram negative bacteria also act as indicators for bacterial contamination in endoscopes and reduce the risk of false positives associated with the gram positive bacteria occurring normally as skin flora like *Staphylococcus epidermidis*, *Streptococcus salivarius*. The HangTimeKit™ works by detecting an enzyme mechanism

typical to the gram negative bacteria. The test utilizes a fluorogenic substrate which, when hydrolyzed by a specific enzyme present in gram negative bacteria, produces fluorescence that is then read by the fluorometer. The reading correlates to the amount of the bacterial enzyme present, which in turn relates directly to the number of gram negative bacterial cells present.

## **LABELLING THE ENDOSCOPES**

The HangTimeKit™ includes HTKLabels that are a first step in knowing when the scopes were last reprocessed. Each label is imprinted with the 12 months and with the numbers 1-31, representing the days of the month. Circle the month and day when the scope is reprocessed and wrap the tag with the self-looping design on the head of the scope. This will aid in clearly distinguishing the clean processed scopes from the unprocessed ones, as well as serve as a quality control tool to alert the healthcare technician as when to reprocess the scope if stored for long.

## **COLLECTING AND TESTING PROCEDURE FOR GRAM NEGATIVE BACTERIA**

To ensure that a scope in storage is still safe to use, the following set of instructions check for gram negative bacteria that might have grown in the channels of the scope during storage.

1. Pick a scope that has been in storage to be tested.
2. Using at least a 20ml syringe, fill with 5ml of sterile-DI water and 15ml of air.
3. Flush the channel (lumen, like a biopsy port) with the sterile-DI water followed by the air that is still in the syringe.
4. Recapture water in the provided zip-lock bag.
5. With the provided sterile pipette, draw up 1 ml of water into the pipette.
6. Add two drops (50µL) of the supplied HangTimeKit™ Reagent to the supplied cuvette (test vial).
7. From the pipette, fill the supplied cuvette to the fill line with the recaptured water (water sample, approx 150µL).
8. Close the lid of the cuvette.
9. Gently squeeze the bottom of the vial two to three times to mix the reagent with the sample water.

10. Holding test vial upright, shake to remove bubbles from the solution (bubbles will interfere with the reading of the fluorescence and may produce inaccurate test results).
11. Turn on the fluorometer.
12. Remove the black cap from the fluorometer.
13. Place the cuvette in the fluorometer, with the pointed end lined up with the indicator line near the fluorometer test chamber.
14. Replace the black cap on the fluorometer.
15. Push the “Measure” button on the touch screen.
16. Push the “BLANK” button on the touch screen. This zeroes out any background fluorescence.
17. Push the “Measure” button on the touch screen for initial reading. (This helps to eliminate any auto fluorescence or fluorescent artifacts that may occur) Push the ‘Measure’ button again in 10-15 seconds.
18. Wait 10 minutes.
19. After 10 minutes the fluorometer will automatically take a reading.
20. Any number above “0” is a positive result and indicates contamination. This further requires reprocessing (all the steps: cleaning and high level disinfection, alcohol flush and air purge).
21. Record the results. If the result is negative, the scope needs to be alcohol flushed and air dried according to manufacturer’s guidelines, before being put back in storage.
22. Turn off the machine and restart before running a new sample. (If the machine is not turned off and on between samples, the values may be incorrect).
23. Dispose of the used pipette and zip lock sample bag in an approved biohazard container.

## DISCUSSION

It is a good practice to label clean, processed endoscope channels in storage with their last processing date as well as test them for microbial growth, in order to confirm their safety before reuse. The HTK is tailored specifically for these purposes and adopts a unique biochemical test to detect gram negative bacteria. The rinse sampling method of the HTK however, does not guarantee that every microorganism in the difficult to access areas inside the endoscope is dislodged after the rinse and may thus rarely yield a false-negative result.

When the results of the HTK do indicate a contamination, the channel is very likely to be contaminated.

Thus the importance of random periodic endoscope sampling cannot be undermined when keeping patient safety in mind. The need for endoscope sampling is especially pronounced if the facility has recently adopted a new cleaning or disinfection protocol, if there is a recent nosocomial outbreak that needs to be investigated or if a perfect quality assurance program is not in place in the facility. Endoscopes in storage also need to be checked if they are observed to be wet, if their distal tip is touching the ground, if the valves had not been removed, or if they are stored in an AER or the carrying case (*Muscarella, L.F., The Q-Net Monthly, Dec. 2009*). The innovative HangTimeKit™ caters perfectly to these concerns and comes at a time when the awareness of these issues is on a steep rise.

## REFERENCES

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