



## INTRODUCTION

Early endoscope leak detection is an important step to infection prevention and to lowering the risk of cross-contamination. Early leak detection can also reduce endoscope repairs by identifying leaks when repairs are minor and less costly. Undetected leaks result in endoscope fluid invasion which increases repair costs. Using a leak detection system with proven accuracy and documented test results, ensures consistent, and reliable leak testing, and drives compliance with endoscope leak test protocols.

The Veriscan® automated endoscope leak detection system utilizes highly sensitive, innovative leak sensing technology for extremely accurate identification of endoscope leaks. Current manual leak detection methods are estimated to be ~65% accurate and lack measurable precision by relying on subjective visual observation for endoscope leak identification. The Veriscan system performs a dry endoscope leak test which is 99% accurate and based upon pressure measurement and decay; not fluid immersion which could further damage and contaminate a leaky endoscope.

This paper presents test data on the accuracy of the Veriscan leak detection system. All Veriscan testing was performed on Olympus®, Pentax® and Fujinon® brand endoscopes, and was documented by Medivator's R&D Department. Veriscan accurately identified 99% of all endoscope leak and no leak conditions, as confirmed in three separate Veriscan Leak Test Studies.



---

## LEAK TEST ACCURACY STUDY METHODS

### 1. Veriscan Accuracy Study using the Screening Test.

**Under QP 202073**, 360 tests were conducted on 35 different endoscopes for a leak or no leak condition. The endoscopes tested included a range of Olympus®, Pentax® and Fujinon models. All non-ultrasound endoscopes tested had an internal volume <750 ml, and all ultrasound endoscopes tested had an internal volume >750 ml. All testing was conducted under ambient room temperature and humidity conditions using the Veriscan parameter setting of 0.005 PSI under the Screening Test.

During the study, the endoscopes were tested in a non-leaking and in a simulated leak state. An endoscope leak was simulated by adding a 0.0004 inch orifice to a Veriscan hookup. All endoscope leaks were manually leak tested to confirm the results. All Veriscan printouts and manual leak test results were retained for documentation purposes. Pressure and humidity measurements from Veriscan were recorded using a data recorder.

### 2. Veriscan Accuracy Study using the Standard Test.

**Under QP 202172**, 108 tests were conducted on six different endoscopes for a leak or no leak condition. The endoscopes tested included a range of Olympus, Pentax and Fujinon models, and all had an internal volume between 350 – 650 ml. All testing was conducted in the Medivators R&D Laboratory under elevated temperature conditions to simulate actual use conditions, and used the Veriscan parameter setting of 0.028 PSI under the Standard Test.

This test simulated actual facility endoscope testing procedures and subsequent cool down, followed by a Veriscan leak test. Testing was accomplished by placing 95% of the insertion end into a 37°C temperature controlled water bath (to simulate body temperature) for 20 minutes. In parallel to the water bath, heat energy was introduced into the endoscope by attaching it to an Olympus CLV light source. Upon removing the endoscope from the heat source, the insertion tip was placed into a 500 ml beaker of water for flushing the suction/biopsy channel. This channel was flushed for 30 seconds followed by 10 to 20 seconds of water aspiration. Four minutes of cool down was maintained from the time the endoscope was disconnected from the light source and flushed, to the time the Veriscan leak test was initiated.

The endoscopes were leak tested in a non-leaking and a simulated leak state. An endoscope leak was simulated by adding a 0.0008 inch orifice to a Veriscan hookup. All Veriscan printouts and manual leak test results were retained for documentation purposes.

### 3. Veriscan Accuracy Study using Screening Test and Standard Test.

**Under QP 202234**, 70 screening tests and 1,076 actual in-use tests were conducted on a facility's endoscopes for a leak or no leak condition. The endoscopes tested were a range of Olympus models which are used by the endoscopy facility on a routine basis. Endoscope screening testing was performed using three (3) different Veriscan units which all used the 0.005 PSI parameter setting under the Screening Test. The actual in-use testing was performed using two (2) different Veriscan units which all used the 0.028 PSI parameter setting under the Standard Test.

Endoscope screening was performed using the Screening Test under ambient room temperature and humidity conditions. Endoscope in-use leak testing was conducted using the Standard Test under actual elevated environmental use-conditions immediately following a patient endoscopy procedure. All tests were conducted in an endoscopy facility and by the facility's staff.



The Veriscan evaluation was performed in two phases; a screening phase and an in-use phase. The screening phase was intended to determine if any of the facility's inventoried endoscopes contained leaks. The in-use testing phase was intended to allow the facility's staff to evaluate the Veriscan during a normal endoscope reprocessing environmental use. All Veriscan printouts and leak test results were retained for documentation purposes.

## RESULTS OF LEAK TEST ACCURACY STUDIES

### 1. Veriscan Accuracy Study using the Screening Test.

**Under QP 202073**, three hundred and sixty (360) leak tests were conducted on thirty-five (35) different endoscopes consisting of nineteen (19) Olympus, seven (7) Fujinon, and nine (9) Pentax endoscopes. Of these thirty-five (35) endoscopes, twelve (12) endoscopes failed the Veriscan leak test and were manually tested and verified to have leaks. The remaining twenty-three (23) endoscopes tested were verified to be leak free.

**Test Results for Non-leaking Endoscopes:** One hundred and fourteen (114) leak tests were performed on endoscopes not having a simulated leak. Veriscan accurately identified all one hundred and fourteen (114) as non-leaking endoscopes. One hundred and fourteen (114) leak tests were also performed on endoscopes having a simulated leak. Veriscan accurately identified one hundred and eight (108) as leaking endoscopes. The six (6) inaccurate leak test results (did not detect a leak) all occurred when testing the Pentax EG-3870UTK Ultrasound endoscope.

**Test Results for Leaking Endoscopes:** Sixty-six (66) leak tests were performed on endoscopes having a true and confirmed endoscope leak, which was not a simulated leak. Veriscan accurately identified all sixty-six (66) as leaking endoscopes. Sixty-six (66) leak tests were also performed on endoscopes having a simulated leak. Veriscan accurately identified all sixty-six (66) as leaking endoscopes.

**Final Report Summary:** In total there were three hundred and sixty (360) leak tests performed during the study. Veriscan accurately identified the endoscope condition (leaking or not leaking) in three hundred and fifty-four (354) leak tests or 98.3% of the time. The six (6) leak test where Veriscan did not detect a simulated leak all occurred when testing a large volume endoscope, a Pentax EG-3870UTK ultrasound endoscope, having an internal volume >750 ml. While Veriscan should be used to leak test all endoscopes, a fluid immersion test should also be performed when leak testing large volume ultrasound endoscopes using Veriscan's Constant Air capability.

The data collected demonstrated that Veriscan's leak test accuracy decreases slightly when testing a large volume endoscopes having an internal volume >750 ml. The data collected also demonstrated that Veriscan's leak test accuracy increased to 100% when testing endoscopes having an internal volume <750 ml (excluding ultrasound endoscopes).



### Conclusion:

- The study demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0004 inch in size using the 0.005 PSI parameter setting under the Screening Test.
- Veriscan accurately identified the leak/no leak condition in all 360 endoscope leak tests 98.3% of the time (including large volume ultrasound endoscopes).
- Veriscan accurately identified the leak/no leak condition in all 354 endoscope leak tests 100% of the time (excluding ultrasound endoscopes). It is not the intention of Medivators to claim 100% Veriscan leak detection accuracy, but rather a 99% accuracy claim on endoscopes having an internal volume <750 ml (excluding ultrasound endoscopes).

## 2. Veriscan Accuracy Study using the Standard Test

**Under QP 202172**, one-hundred and eight (108) leak tests were conducted on six (6) different endoscopes consisting of three (3) Olympus, two (2) Fujinon, and one (1) Pentax endoscope. All six (6) endoscopes were verified to be leak free at the onset of the study.

**Test Results for Non-leaking Endoscopes:** Fifty-four (54) leak tests (nine tests for each endoscope) were performed on endoscopes not having a simulated leak. The Veriscan unit accurately identified all fifty-four (54) as non-leaking endoscopes.

**Test Results for Leaking Endoscopes:** Fifty-four (54) leak tests (nine tests for each endoscope) were performed on endoscopes not having a simulated leak. The Veriscan unit accurately identified all fifty-four (54) as leaking endoscopes.

**Final Report Summary:** In total there were one hundred and eight (108) leak tests performed during the study. Veriscan accurately identified the endoscope condition (leaking or not leaking) in all one hundred and eight (108) endoscope leak tests, 100% of the time.

### Conclusion:

- The study demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0008 inch in size using the 0.028 PSI parameter setting under the Standard Test.
- Veriscan accurately identified the leak/no leak condition of all 108 endoscope leak tests 100% of the time.
- It is not the intention of Medivators to claim 100% Veriscan leak detection accuracy, but rather a 99% accuracy claim on endoscopes having an internal volume between 350 – 650 mls and leak tested within four (4) minutes of removal from the patient.



### 3. Veriscan Accuracy Study using Screening Test and Standard Test.

Under QP 202234, 70 screening tests and 1,076 actual in-use tests were conducted on a facility's endoscopes for a leak or no leak condition, on a range of Olympus models used on a routine basis by an endoscopy facility.

**Test Results for Phase 1, Screening Test:** The facility's inventory of endoscopes was tested with three (3) Veriscan leak test system using the "Screening Test" setting (L diff max = 0.005 PSI). The screening phase was intended to determine if any endoscopes within the facility's inventory contained leaks. All endoscopes tested during the screening phase were at a stable temperature.

Seventy (70) endoscopes were tested. Fifty-four (54) endoscopes passed and sixteen (16) endoscopes leaked. During the screening test, there was no opportunity to verify the endoscope leaks; however, the two endoscopes that produced high leak test scores were later verified to have a leak using a submersion test by the facility's staff.

**Test Results for Phase 2, In-use Test:** During the in-use test, two (2) Veriscan leak test units were used by the facility's staff in the "Standard Test" setting (L diff max = 0.028 PSI. This setting was used as part of the facility's normal endoscope reprocessing process over a sixteen (16) day period. Upon completion, the Veriscan cycle logs were down-loaded to a computer using Veriscan's Data Management Software with a total cycle log summary as follows:

Number of leak tests cycles run = 1,076  
Number of endoscope passes = 1,069 (99.3%)  
Number of endoscope failures = 7 (0.7%)  
Number of endoscope gross failures (from above listed failures) = 6 (0.6%)  
Number of passes during first test (<150 seconds) = 1,056 (98.1%)  
Average leak test cycle time = 88 seconds

Of the seven (7) endoscope failures, six (6) were recorded as gross failures. The one (1) failure that was not a gross failure was one of the two (2) endoscopes previously identified as having a leak during the screening test. For each of the six (6) gross leak failures identified during the in-use testing, the endoscopes were immediately retested using the Veriscan leak tester. After retesting, five (5) endoscopes passed and one (1) endoscope failed. Of the five (5) endoscopes that passed after the second leak test, two (2) were not connected properly to the Veriscan system, one (1) had uncharacteristically high pressure, and two (2) had a leak in the hook-up or water-tight leak test cap. Of the one (1) endoscope that failed after the second leak test, it never reached the correct test pressure level which indicates a gross leak.

**Final Report Summary:** During the Phase 1 Screening Test, a total of seventy (70) endoscopes were tested. Veriscan accurately identified the endoscope condition (leaking or not leaking) in fifty-six (56) endoscopes which included the fifty-four (54) endoscopes that passed and the two (2) endoscopes that were confirmed as having a leak by the facility's staff, 100% of the time. During the screening test, there was no opportunity to verify the endoscope leak condition in the other fourteen (14) endoscopes which were identified to have a leak by the facility's staff. The data collected during the Phase 1 Screening Test demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0004 inch in size using Veriscan's Screening Test and the 0.005 PSI parameter setting .



During the Phase 2 In-use Test portion of the study, a total of one thousand and seventy-six (1,076) trials were performed. Veriscan accurately identified the endoscope condition (leaking or not leaking) in all one thousand and seventy-six (1,076) endoscopes, 100% of the time. The data collected during the Phase 2, In-use Test demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0008 inch in size using Veriscan's Standard Test and the 0.028 PSI parameter setting.

#### **Conclusion:**

- The study demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0004 inch in size using the 0.005 PSI parameter setting under the Screening test.
- The study demonstrated Veriscan's accuracy at detecting endoscope leaks as small as 0.0008 inch in size using the 0.028 PSI parameter setting under the Standard test.
- During actual facility use on patient-used endoscopes, Veriscan accurately detected the leak/no leak condition on all 1,076 endoscopes leak tested, 100% of the time.
- It is not the intention of Medivators to claim 100% Veriscan leak detection accuracy, but rather a 99% accuracy claim on endoscope leak detection.

## **DISCUSSION OF RESULTS**

When considering the choice of an endoscope leak detection method, the user should choose a reliable method with proven ability, demonstrated accuracy, and documented results. Manual leak detection methods rely solely on human intervention to identify a leak which lacks precision and does not provide documented leak test results. With increased attention on process compliance and patient safety, risk must always be minimized and as new leak test technology is introduced to the market, it must be considered and evaluated thoroughly. Consistent and reliable endoscope leak testing ensures compliance with leak test protocols and lowers the risk of cross-contamination due to undetected leaks. Early detection of endoscope leaks also allows cost containment on endoscope repairs by identifying leaks when repairs are minor and less expensive.

The leak studies cited demonstrate Veriscan's performance and extreme accuracy in identifying very small endoscope leaks.

- Veriscan will accurately detect endoscope leaks as small as 0.0004 inch in the Screening Test using the 0.005 PSI parameter setting. A leak of this size (1/10<sup>th</sup> the diameter of a human hair) is extremely difficult to detect by manual leak test methods and is visually equivalent to one very small bubble every 10 – 20 seconds.
- Veriscan will also accurately detect endoscope leaks as small as 0.0008 inch in the Standard Test using the 0.028 PSI parameter setting. A leak of this size (1/3<sup>rd</sup> the diameter of a human hair) is visually equivalent to a very small but continuous stream of bubbles.



---

Veriscan consistently and accurately identified 99% of all endoscope leak and no leak conditions, as confirmed by three separate Veriscan Leak Test Studies. The Veriscan system also uses a precision dry endoscope leak test, not fluid immersion which could further damage a leaky endoscope and more importantly, put patients at risk of cross-contamination.

The Veriscan system is compatible with all Olympus®, Pentax®, Storz® and Fujinon® brand flexible, immersible endoscopes, and complies with the endoscope manufacturer's specifications for endoscope leak testing. The use of the Veriscan automated endoscope leak detection system enhances reprocessing room efficiency and standardizes the leak testing process, while providing unsurpassed leak detection accuracy.

A copy of this product bulletin is available on the Medivators website at [www.minntech.com/medivators](http://www.minntech.com/medivators) by selecting "Medivators Reprocessing Systems" followed by "Resource Center." If you have any questions regarding this Product Bulletin, please contact Medivators Customer Support at 1-800-444-4729.