

Flexible Endoscope Hand-Held, Manual Leak Tester IFU



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To prevent costly fluid invasion it is crucial to leak test flexible scopes after EVERY use, and PRIOR to cleaning, high-level disinfection / sterilization, or immersing in any type of fluid.

Whether using a hand-held leak tester, as outlined here, or an automated leak tester, the premise is to manually or mechanically put air into the scope. If there is a breach, or a leak in the scope, the air that is pumped in will “escape” from the leak point. Below are steps to perform a manual testing using our **FLEXIBLE ENDOSCOPE HAND-HELD LEAK TESTER**. With this device you can **DRY TEST** (leaks will cause the needle on the pressure gauge to drop), or pin point the location of the leak with a **WET TEST** (when scope is immersed you will be able to observe “bubbles from escaping air at the leak point).

△ CAUTION: Improper leak testing can cause fluid invasion. Please refer to the steps outlined here for proper leak testing techniques. Consult the manufacturer or your repair provider for additional information. Always review OEM instruction manuals for your device.

COMPONENT / TERMINOLOGY & ASSEMBLY

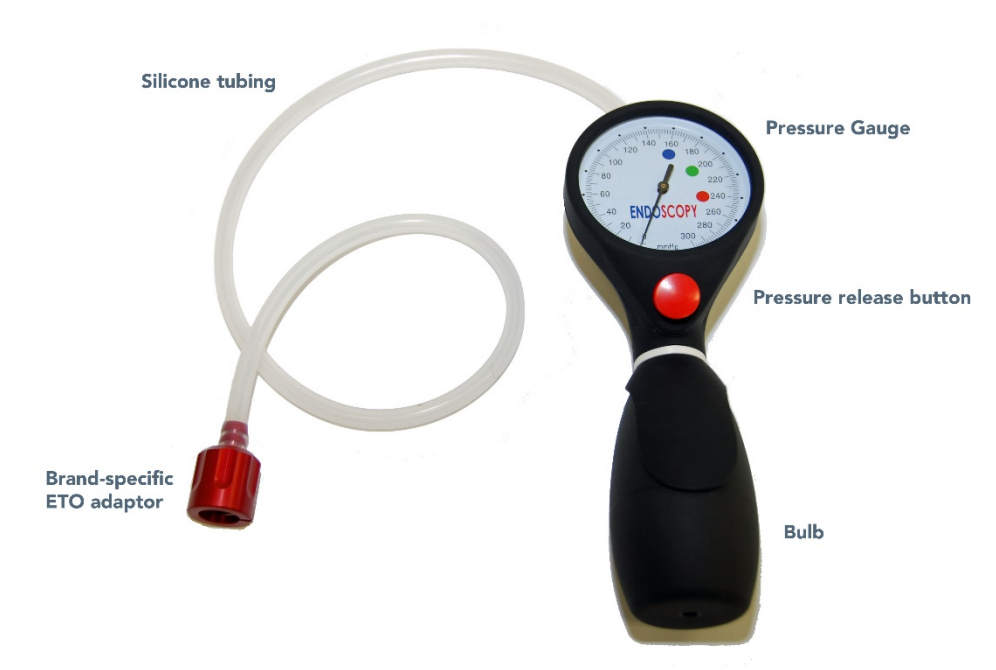


Figure 1 Components / Terminology



Figure 1 Select brand-specific adaptor (Olympus, Pentax, Fujinon shown here)



Figure 3 Insert barb from selected fitting into silicone tubing



Figure 3B Assembly complete

DRY TEST

1. To assemble (if not already installed), select appropriate adaptor and insert barb into silicone tubing as shown Fig 3 and 3B.
2. Visually inspect the scope for obvious tears, holes, or other damage. Verify that the light guide prong is tight.
3. Remove all valves from the scope (air/water, biopsy and suction valves)
4. Attach the water-resistant cap (on video scopes)
5. Attach the leak tester fitting to the ETO connector on the scope or water cap.
 - △ Each brand of endoscope requires a specific adaptor. They are not interchangeable. Ensure you are using the proper fitting for your scope. Available adaptors include Olympus, Pentax, Fujinon, Wolf, Storz and Stryker.
6. Manually pressurize the scope by pumping the bulb on the hand-held leak tester until the needle on the gauge reaches the “green” dot at 200 mmHg. You will notice the bending rubber will inflate slightly. Do not overinflate or pressure past the “red” stop dot.
7. Watch the needle on the gauge. It should remain in its original position. Should the needle drop (either rapidly; indicating a large leak, or very slowly; indicating a small leak) the scope has failed the leak test.
8. To expose small pin hole leaks in the bending rubber and leaks in the angulation controls, angulate the tip of the scope in every direction by rotating the angulation control knobs/level, while continuing to observe the needle.
9. Manipulate the video switch buttons to be sure there are no leaks in the rubber cover
10. A leak test of about 2-3 minutes should allow enough time to reveal small leaks.
11. If the needle remains in its original position throughout the test the scope has “passed” the dry test.
12. If you are only dry testing, press the red “pressure release button” on the hand-held tester to allow pressure to release from the scope.
 - △ **If you are continuing with a WET TEST, DO NOT release the pressure from the scope and continue to step 7 of the wet test.**
13. Verify that the scope is deflated by looking at the bending rubber. The needle on the gauge should be back to zero.
14. Disconnect the leak tester from the ETO valve



△ **Normal reprocessing cannot be performed if a leak is detected. Consult the manufacturer guidelines to modify the reprocessing routine if a leak is discovered.**

WET TEST

- △ Do NOT immerse scopes that have large tears or holes as fluid invasion may result
- △ Do NOT immerse scopes that will not hold pressure as fluid invasion may result
- △ Do NOT immerse scopes in water before pressurizing
- △ Bubbles in the water that indicate a leak may be very small so you must look closely
- △ **CRITICAL: If you notice the needle dropping on the pressure gauge during the test, you will need to continue to pump the bulb on the leak tester throughout the leak test procedure so that air pressure will keep fluid from entering the scope. Pressure IN pushes fluid OUT!**

Note: Steps 1-7 are the same as the dry test.

1. To assemble (if not already installed), select appropriate adaptor and insert barb into silicone tubing as shown Fig 3 and 3B.
2. Visually inspect the scope for obvious tears, holes, or other damage. Verify that the light guide prong is tight.
3. Remove all valves from the scope (air/water, biopsy and suction valves)
4. Attach the water-resistant cap (on video scopes)
5. Attach the leak tester fitting to the ETO connector on the scope or water cap.
 - △ Each brand of endoscope requires a specific adaptor. They are not interchangeable. Ensure you are using the proper fitting for your scope. Available adaptors include Olympus, Pentax, Fujinon, Wolf, Storz and Stryker.
6. Manually pressurize the scope by pumping the bulb on the hand-held leak tester until the needle on the gauge reaches the “green” dot at 200 mmHg. You will notice the bending rubber will inflate slightly. Do not overinflate or pressure past the “red” stop dot.
7. Watch the needle on the gauge. It should remain in its original position. Should the needle drop (either rapidly; indicating a large leak, or very slowly; indicating a small leak) the scope has failed the leak test.
8. With the scope pressurized, immerse the bending section only into water as this is the most common place for leaks to occur. Using the angulation control, deflect the tip in all directions to open small pin holes in the bending sheath. Leaks are indicated by a continuous stream of bubbles in the water.
9. With the scope pressurized, now immerse the entire scope.
 - △ **CRITICAL: Remember to continue to manually inflate the scope by pumping the bulb throughout the test if required to maintain positive pressurization!**
 - △ When you first immerse the scope, a few air bubbles may escape from the internal channels. You can purge this air by flushing the channels with water.
10. Now observe the scope in the water and look for continuous streams of bubbles which indicate a leak. Bubbles may be large and obvious, or very small. Closely evaluate the common areas below:
 - Bending Rubber (Pin holes, tears, deteriorating glue joints)
 - Angulation Control Knobs (o-rings can deteriorate causing leaks) You can turn, but do not press down on knobs while immersed.
 - Internal channels (leaks in channel are indicated by bubbles coming out of biopsy port, distal biopsy channel, air/water channel and suction ports)
 - Check distal tip, body of scope and light guide connector
 - Insertion Tube & Light Guide tube (buckles, holes, bites, or crush marks can leak)

- Covers on video switches (manipulate cover to expose small pin holes)
11. Leak test for 2-3 minutes to all small leaks to develop
 12. Remove the scope from the water and drain
 13. Press or turn the pressure release valve on the hand-held tester to release pressure
 14. Make sure to remove from water before releasing pressure!
 15. Verify that the scope is de-pressurized by looking at the bending rubber
 16. Disconnect the leak tester from the ETO valve. NEVER do this under water.

△ Normal reprocessing cannot be performed if there is a leak in the scope. Consult manufacturer guidelines to modify the reprocessing routine if a leak is detected. OEM manuals should be reviewed for leak testing instructions for particular devices.