Product Bulletin

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Date: **January 7, 2013**

RE: SSD/DSD Leak Test System Synopsis and Operation

Leak Test System Synopsis

The automated leak test system for the SSD-102, DSD EDGE and DSD-201 has been designed to complement and enhance the endoscope reprocessing procedure.

- Medivators' leak tester system will:
- Detect a major leak in an endoscope and stop the cycle before fluid ingression could damage the endoscope.
- Ensure that endoscopes with minor leaks are not damaged by fluid ingression during an automated reprocessing cycle.
- Provide a save method of decontaminating endoscopes with minor leaks before they are returned for maintenance. (It is a requirement with minor leaks before they are returned for maintenance. (It is a requirement of servicing facilities that endoscopes are reprocessed before being returned for maintenance or overhaul.)

In use, the leak tester will inflate the endoscope to 160 mmHg at the start of each reprocessing cycle. This takes approximately 20 seconds and the pressure within the endoscope is then monitored for a further 20 seconds. If the pressure decreases to below 50 mmHg during this time (as would result from a leak of a diameter ≥ 0.01"), the SSD/DSD will alarm and the cycle will be aborted. If the pressure is maintained above 50 mmHg, the reprocessing cycle will start. The pressure is than monitored for the duration of the cycle and, provided that the pressure does not fall below 50 mmHg, the system will maintain pressure in the endoscope to stop the ingress of fluid, but will alarm at the end of the cycle signifying a leak ≤ 0.01".

The system is designed to detect leaks as small as 0.010" over a 30 second period, but will, in reality detect even smaller leaks over a longer total reprocessing time. Although the system is very sensitive, it is possible that operators may visually detect a very small leak during the reprocessing cycle that the leak test system will not. A stream of very small bubbles from a 'inhole' leak in a submerged endoscope is quite easily seen. The position of the endoscope within the AER can affect leak detection because bend radii can mask leaks b 'closing' off the suspect area.

Regardless of which reprocessing method is used (manual or automatic), endoscope manufacturers' instructions recommend that manual leak testing should be performed as soon as possible after the endoscope is removed from the patient and manual cleaning should not commence until the endoscope has passed the leak test. Because most fluid contamination of endoscopes takes place during the manual cleaning procedure, as well as during the patient examination, manual leak testing performed prior to manual cleaning continues to be the definitive method of leak detection in any endoscope.

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Product Bulletin

Leak Tester Operation

Use the following procedure to leak test and endoscope. Leak test adaptors are available for Pentax, Olympus, Fujinon and Stroz endoscopes

1. Install the water proof caps (if scope is equipped) and leak test adaptors on the endoscope following the endoscope manufacturer's instructions.
2. Load the endoscope into the reprocessor.
   - Connect the leak tester hook-up between the endoscope and the basin outlet.
3. Select the desired disinfection cycle. Press the START button on the reprocessor control panel.
4. The endoscope inflates for 20 seconds to 160 mmHg (3 psi) and is monitored for another 20 seconds. If the pressure decreases below the 50mmHg (1 psi) reading within this period, the warning LED on the reprocessor controls panel blinks, the system activates an alarm and the message "Sheath Fail" is displayed. Press the STOP button to end the cycle. The cycle is then aborted.
   - Verify the leak tester connectors are connected properly.
   - Verify the water proof cap is securely attached (if equipped)
5. Try starting the cycle once the scope is inspected. If the "Sheath Fail" message reappears, press the STOP button, remove the scope and inspect the scope and manual leak test.
6. If the scope passes the initial leak test at the beginning of the cycle, pressure is maintained during the disinfection cycle to detect small leaks and prevent fluid ingression. If a small leak is detected the reprocessor will continue to cycle, then alert the operator of any detected leaks at the end of the cycle,
   - Should the unit detect a small leak during the cycle, it will alarm "Sheath Fail" at the end of the cycle. Press STOP to clear the message, the unit will then compete the cycle.
   - Verify the leak tester connectors are connected properly.
   - Verify the water proof cap is securely attached (if equipped).
   - Rerun scope after inspection.
7. If the reprocessor does not detect a leak, the cycle will complete without an error message.
   - On the print out will be a notation "Sheath Test" in one of the first lines. See figure 1 .This indicates the leak test unit is activated and the scope has been tested. If this message is not present, the leak detection unit may be deactivated. Contact Medivators Technical service for assistance in activating the leak tester.

Product Bulletin

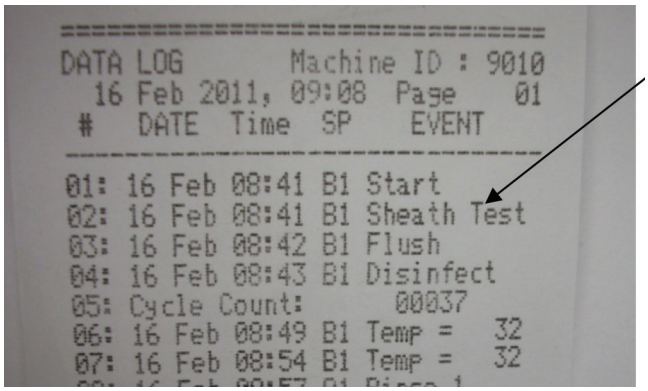

Figure 1

Caution! The leak tester adaptor must be disconnected and removed from the basin when not in use to avoid potential fluid ingression.

Note: Inspect the leak tester connector O-ring daily. Apply a light coating of silicon oil that has been approved by the endoscope manufacturer weekly to this O-ring, Lubrication will reduce O-ring wear and allow a better seal. See figure 2.

Figure 2

A copy of this product bulletin is available on the MEDIVATORS website located at www.medivators.com, under "Document" section. For additoinal information please contact MEDIVATORS Customer Support at 1-800-444-4729.