

## Instructions for Use: Leak Tester Tester

<b>Brand Name of Product</b>	Leak Tester Tester
<b>Generic Name of Product</b>	Leak Tester Tester (LTT)
<b>Product Code Number(s)</b>	LTT4000, LTT-1001, LTT-1002, LTT-1003, LTT-1004
<b>Intended Use</b>	To test the pressure of air (pounds per square inch [psi or lb/in <sup>2</sup> ]) of a leak tester.
<b>Range of Applications for Product</b>	Testing pump and the connector functionality of leak testers.
<b>Key Specifications of Product</b>	<p>The LTT4000 Includes one of each:</p> <ul style="list-style-type: none"> <li>• Olympus MU-1 leak tester- LTT-1001</li> <li>• Olympus handheld leak testers- LTT-1002</li> <li>• Pentax handheld leak testers- LTT-1003</li> <li>• Karl Storz handheld leak testers- LTT-1004.</li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	Store the LTTs to prevent damage to the venting ports and factory calibrated gauge.
<b>Packaging Contents</b>	N/A
<b>Shelf Life</b>	N/A

Instructions for Using Product	
<b>Description of Use(s)</b>	To verify the accuracy of air pressure provided by automated and handheld endoscope leakage testers.
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>• The LTT4000 has each of the following calibrations: <ul style="list-style-type: none"> <li>• Olympus MU-1 leak tester. <b>(Fig. 1).</b></li> <li>• Olympus handheld leak testers. <b>(Fig. 2).</b></li> <li>• Pentax handheld leak testers. <b>(Fig. 3).</b></li> <li>• Karl Storz handheld leak testers. <b>(Fig. 4).</b></li> </ul> </li> <li>• The unit of measure psi is identified on the gauge face of the handheld endoscope leak testers. <b>(Fig. 5).</b></li> </ul>

Diagrams (drawings, pictures)



**Fig. 1 Olympus MU-1 & ALT-Pro LTT-1001**



**Fig. 2 Olympus Handheld LTT-1002**



**Fig. 3 Pentax Handheld LTT-1003**



**Fig. 4 Karl Storz Handheld LTT-1004**



**Figure 5**



**Figure 6**



**Figure 7**



Figure 8

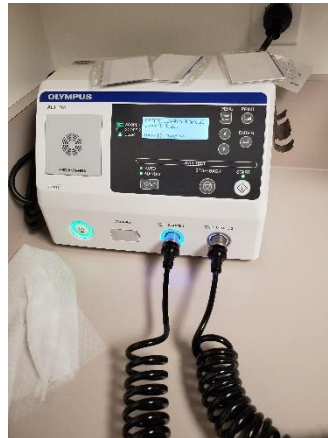


Figure 9



Figure 10



Figure 11



Figure 12



Figure 13



Figure 14



Figure 15

### Olympus MB-155 Leak Tester



Figure 16



Figure 16A



Figure 17

### Steps for Use of Product

#### Gauge Inspection Before Use

**NOTE:** Step 1 is performed for all gauges before they are used (inspection of the gauge).

1. Inspect LTT for damage (to include verifying the pressure gauge reads zero prior to use). (Fig. 6).
2. If the gauge is showing it has pressure (not a zero), pull up on the blue cap atop of the gauge. (Fig. 7). This process will open the vent plug and will relieve the internal pressure changes in the gauge case. If any of the gauges do not return to zero, the gauge is malfunctioning and should be returned for evaluation.

#### Olympus MU-1

3. Install the LTT into the socket of the MU-1 (Fig. 8).
4. Turn power switch to the on position to pressurize the LTT.
5. Record the pressure reading on the test figure gauge. The pressure should not be 4.0 psi or below (hold for at least 30 seconds), which is considered failure and the MU-1 *should not be used*.
6. Turn power switch off and remove LTT from the automated leak testing device.

#### Olympus Alt-Pro

1. Install the MAJ-2009 leak test air tube into the tube connector of the Alt-Pro. (Fig. 9).
2. Connect the test fixture to MB-155 leak test air tube.
3. Set the Alt-Pro to *Manual* testing, then press *Start* to pressurize the LTT. (Fig. 10).
4. The pressure range should be 2.9- to 4.1 psi (hold for at least 30 seconds). If the psi is not in this range, which is considered fail, do not use the MB-155. (Fig. 11).

#### Handheld Leak Tester: Pentax, Olympus, and Karl Storz

1. Attach handheld leak tester to the appropriate LTT. (Fig. 12).
2. Place handheld leak tester in the pressurize position. (Fig. 13).

	<ol style="list-style-type: none"> <li>Identify the measurement of pressure on the gauge face of the LTT and handheld leak tester. <b>(Fig. 14 and 15).</b></li> <li>Pump the inflation bulb of the handheld gauge until the needle holds steady in the correct pressure zone (the green zone). The LTT pressure gauge should match the unit of measurement on the handheld leak tester (see <b>Chart 1</b>) based on the unit of measurement <b>(Fig. 14 and 15).</b></li> </ol> <p style="text-align: center;"><b>Chart 1</b></p> <table border="1"> <thead> <tr> <th>Unit of Pressure</th><th>Conversion to LTT Green Zone</th></tr> </thead> <tbody> <tr> <td><b>kPa:</b> pressurize to 25 units</td><td>3.6 psi on test fixture</td></tr> <tr> <td><b>mmHg:</b> pressurize to 160 units</td><td>3.0 psi on test fixture</td></tr> <tr> <td><b>lb/in<sup>2</sup> (psi):</b> pressurize to 5 psi</td><td>5.0 psi on test fixture</td></tr> </tbody> </table> <p style="text-align: center;"><i>NOTE: Test fixture gauge has an allowable variance of 0.24 psi.</i></p> <ol style="list-style-type: none"> <li>Record the pressure reading on your specific LTT gauge. The pressure should equal the psi measurements in Chart 1 (they match green zone to pressure on the leak tester tester).</li> <li>Make sure the needle holds steady for (1) one-minute in the green zone.</li> <li>If the needle falls slowly outside of the green zone during the 1-minute timeframe, your handheld tester is faulty and does not hold a pressure. <i>Do not use and replace.</i></li> <li>If the needle falls rapidly or pressure cannot be maintained during the 1-minute timeframe, the handheld tester <i>should not be used and must be replaced.</i></li> <li>Successful green zone pressure for 1-minute means your handheld tester is acceptable for testing an endoscope. Release the pressure on the handheld leakage tester and allow 10 seconds to completely depressurize the LTT (test fixture).</li> <li>Disconnect the leak tester from the LTT.</li> </ol> <p><b>Olympus MB-155 Leak Tester Cable (coiled)</b></p> <ol style="list-style-type: none"> <li>Install the MB-155 leak tester into the socket of the MU-1. <b>(Fig. 16).</b></li> <li>Connect the LTT to MB-155 leak tester. <b>(Fig. 16A).</b></li> <li>Turn the power switch to the on position to pressurize the testing device.</li> <li>The pressure range should be 2.9- to 4.1 psi (hold for at least 30 seconds). If the psi is not in this range, which is considered fail, <i>do not use and remove it from service. (Fig. 17).</i></li> <li>Turn the power switch off and remove LTT from the MU-1 leak testing device.</li> <li>Detach the MB-155 from the LTT.</li> </ol>	Unit of Pressure	Conversion to LTT Green Zone	<b>kPa:</b> pressurize to 25 units	3.6 psi on test fixture	<b>mmHg:</b> pressurize to 160 units	3.0 psi on test fixture	<b>lb/in<sup>2</sup> (psi):</b> pressurize to 5 psi	5.0 psi on test fixture
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<b>Interpretation of Test Results</b>	N/A								
<b>Contraindications of Test Results</b>	N/A								
<b>Documentation</b>	N/A								
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>If the gauge becomes inadvertently submerged in fluid or the Leak Tester Tester (LTT) is dropped, the LTT should be returned to validate proper calibration.</li> <li>Submerging, dropping, or mishandling LTT may damage the accuracy of the gauge.</li> </ul>								
<b>Disposal</b>	N/A								

Reprocessing Instructions	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	Wipe with an IPA wipe.

<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	Each unit should be returned to Healthmark annually for recalibration.
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	Store the LTTs to prevent damage to the venting ports and factory calibrated gauge.
<b>Additional Information</b>	N/A
<b>Related Healthmark Products</b>	N/A
<b>Other Product Support Documents</b>	ProSys™ Brochure, ProSys™ Price List
<b>Reference Documents</b>	ISO 8600-7
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com