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Instructions for Use: Leak Tester Tester

Brand Name of Product	Leak Tester Tester
Generic Name of Product	Leak Tester Tester (LTT)
Product Code Number(s)	LTT4000, LTT-1001, LTT-1002, LTT-1003, LTT-1004
Intended Use	To test the pressure of air (pounds per square inch [psi or lb/in^2]) of a leak tester.
Range of Applications for Product	Testing pump and the connector functionality of leak testers.
Key Specifications of Product	The LTT4000 Includes one of each: • Olympus MU-1 leak tester- LTT-1001 • Olympus handheld leak testers, Olympus ALT-Pro- LTT-1002 • Pentax handheld leak testers- LTT-1003 • Karl Storz handheld leak testers- LTT-1004.

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

Instructions for Using Product	
Description of Use(s)	To verify the accuracy of air pressure provided by automated and handheld endoscope leakage testers.

Preparation for Use	• The LTT4000 has each of the following calibrations:
	  • Olympus MU-1 leak tester. **(Fig. 1)**.
	  • Olympus handheld leak testers. **(Fig. 2)**.
	  • Pentax handheld leak testers. **(Fig. 3)**.
	  • Karl Storz handheld leak testers. **(Fig. 4)**.
	• The unit of measure psi is identified on the gauge face of the handheld endoscope leak testers. **(Fig. 5)**.

Diagrams (drawings, pictures)

Fig. 1 Olympus MU-1 LTT-1001

Fig. 2 Olympus Handheld and MB-155 and ALT-PRO LTT-1002

Fig. 3 Pentax Handheld LTT-1003

Fig. 4 Karl Storz Handheld LTT-1004

Figure 5

Figure 6

Figure 7

Figure8

Figure 9

Figure 10

Figure 11 LTT-1002

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 pressure (not a zero), pull up on the blue cap atop of the gauge. **(Fig. 7)**. This process will open the vent plug and relieve the internal pressure changes in the gauge case. Malfunctioning gauges that do not return to zero need to be returned for evaluation.

Olympus MU-1

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

Olympus Alt-Pro

1. Install the MAJ-2009 leak test air tube into the tube connecter of the Alt-Pro. **(Fig. 9)**.
2. Connect the LTT-1002 to MAJ-2009 leak test air tube.
3. Set the Alt-Pro to *Manual* testing, then press *Start* to pressurize the LTT. **(Fig. 10)**.
4. The passing pressure range should be 2.9- to 4.1 psi (hold for at least 30 seconds).
    a. If the psi is not in this range, it is considered a failure.
    b. Do not use the MB-155. **(Fig. 11)**.
5. Repeat the above steps 1–4 on the alternate leak test air tube.

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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 pressurized position. **(Fig. 13)**.
3. Identify the measurement of pressure on the gauge face of the LTT and handheld leak tester. **(Fig. 14 and 15)**.
4. 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 **Chart 1**) based on the unit of measurement. **(Fig. 14 and 15)**.

Chart 1

Unit of Pressure	Conversion to LTT Green Zone
kPa: pressurize to 25 units	3.6 psi on test fixture
mmHg: pressurize to 160 units	3.0 psi on test fixture
lb/in^2 (psi): pressurize to 5 psi	5.0 psi on test fixture

***NOTE**: Test fixture gauge has an allowable variance of 0.24 psi.*

5. Record the pressure reading on your specific LTT gauge. The pressure should equal the psi measurements in Chart 1. (NOTE: They match green zone to pressure on the leak tester tester.)
6. Make sure the needle holds steady for one (1)-minute in the green zone.
7. If the needle falls slowly outside of the green zone during the one (1)-minute timeframe, your handheld tester is faulty and does not hold a pressure. *Do not use; replace.*
8. If the needle falls rapidly or pressure cannot be maintained during the one (1)-minute timeframe, the handheld tester *should not be used and must be replaced.*
9. Successful green zone pressure for one (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).
10. Disconnect the leak tester from the LTT.

Olympus MB-155 Leak Tester Cable (coiled)

1. Install the MB-155 leak tester into the socket of the MU-1. **(Fig. 16)**.
2. Connect the LTT to MB-155 leak tester. **(Fig. 16A)**.
3. Turn the power switch to the *on* position to pressurize the testing device.
4. The pressure range should be 2.9- to 4.1 psi (hold for at least 30 seconds).
    a. If the psi is not in this range, it is considered a fail.
    b. *Do not use and remove it from service***. (Fig. 17)**.
5. Turn the power switch off and remove LTT from the MU-1 leak testing device.
6. Detach the MB-155 from the LTT.

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<tr><td>Interpretation of Test Results</td><td>N/A</td></tr>
<tr><td>Contraindications of Test Results</td><td>N/A</td></tr>
<tr><td>Documentation</td><td>N/A</td></tr>
<tr><td>Special Warnings and Cautions</td><td>

- 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.
- Submerging, dropping, or mishandling LTT may damage the accuracy of the gauge.

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<tr><td>Disposal</td><td>N/A</td></tr>
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Reprocessing Instructions	
Point of Use	N/A

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