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| 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 (i.e., pounds per square inch [psi or lb/in ²]) of a leak tester. |
| Range of Applications for Product | Testing the pump and connector functionality of leak testers. |
| Key Specifications of Product | <p>The LTT4000 includes one of each Leak Tester Tester (LTT):</p> <ul style="list-style-type: none"> • LTT-1001- Olympus® MU-1 pump: > 4.0 psi • LTT-1002- Pressure must be between 2.9–4.1 psi for the following: <ul style="list-style-type: none"> ○ Olympus® handheld leak tester connections ○ Olympus® ALT-Pro. • LTT-1003- PENTAX® handheld leak tester connections: > 5.0 psi • LTT-1004- KARL STORZ® handheld leak tester connections: > 3.0 psi. |

| 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 | <p>LTT Gauge Inspection Before Use (NOTE: This is to be performed for all LTT gauges before they are used.)</p> <ol style="list-style-type: none"> 1. Inspect LTT for damage (includes verifying the pressure gauge reads zero prior to use). (Fig. 6). 2. If the gauge is showing pressure (not at zero), pull up on the blue cap atop the gauge. (Fig. 7). <ol style="list-style-type: none"> a. This process will open the vent plug and relieve the internal pressure changes in the gauge case. b. Malfunctioning gauges that do not tare to zero require returning for evaluation. |
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Diagrams (drawings, pictures)



Olympus® MU-1 LTT-1001
Figure 1



**Olympus® Handheld and MB-155 &
ALT-PRO LTT-1002**
Figure 2



PENTAX® Handheld LTT-1003
Figure 3



KARL STORZ® Handheld LTT-1004
Figure 4



Figure 5



Figure 6



Figure 7



Figure 8



Figure 9



Figure 10



Olympus® ALT-PRO LTT-1002
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

NOTE: The unit of measure (e.g., psi or mmHg) is identified on the gauge face of handheld endoscope leak testers. (Fig. 5).

Olympus® MU-1

1. Install the LTT into the socket of the MU-1. (Fig. 8).
2. Turn the power switch to the *On* position to pressurize the LTT.
3. Record the pressure reading on the test figure gauge.
 - a. *Passing:* Pressure should be above > 4.0 psi to be passing.
 - b. *Not Passing:* Pressure should **not** be ≤ 4.0 psi or below (hold for at least 30 seconds), which is considered a failure. In this case the MU-1 *should not be used*.
4. Turn off the power switch and remove LTT from the MU-1.
5. Record the pressure reading from the LTT gauge.

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 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, and the leak test air tube should be replaced.
 - b. Repeat the above steps 1–4 on the alternate leak test air tube.
5. Record the pressure reading from the LTT gauge.

Handheld Leak Testers:

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

| | <div>3. Pump the handheld leak tester’s inflation bulb until the needle holds steady in the correct pressure zone. The LTT pressure gauge should correlate to the unit of measurement on the handheld leak tester (see Chart 1 for conversions). (Figs. 14 and 15).</div> <div><div>Chart 1</div><table><tr><th>Unit of Pressure</th><th>Pressurize to</th><th>Correlation to LTT Gauge</th></tr><tr><td>kPa</td><td>25 units</td><td>3.6 psi on test fixture</td></tr><tr><td>mmHg</td><td>160 units</td><td>3.0 psi on test fixture</td></tr><tr><td>lb/in² (psi)</td><td>3 psi</td><td>3.0 psi on test fixture</td></tr></table><div>NOTE: Test fixture gauge has an allowable variance of 0.24 psi.</div></div> <div>4. Ensure the needle holds steady for one (1) minute.<div>a. If the needle falls or pressure cannot be maintained during the 1-minute timeframe, your handheld tester is faulty and does not hold a pressure.</div><div>b. Do not use; replace.</div><div>c. Maintaining pressure for 1 minute means your handheld tester is acceptable for testing an endoscope.</div></div> <div>5. Release the pressure on the handheld leakage tester and allow 10 seconds to completely depressurize the LTT (test fixture).</div> <div>6. Disconnect the leak tester from the LTT.</div> <div>7. Record the pressure reading from the LTT gauge.</div> <div>Olympus® MB-155 Leak Tester Cable (coiled)<div>1. Install the MB-155 cable into the socket of the MU-1. (Fig. 16).</div><div>2. Connect the LTT-1002 to MB-155 leak tester cable. (Fig. 16A).</div><div>3. Turn the power switch to the On position to pressurize the testing device.</div><div>4. The pressure range should be 2.9- to 4.1 psi (hold for at least 30 seconds). (Fig. 17).<div>a. If the psi is not in this range, it is considered a failure.</div><div>b. Do not use and remove it from service.</div></div><div>5. Turn the power switch Off.</div><div>6. Depressurize the connection at the pump and remove LTT from MB-155.</div><div>7. Record the pressure reading from the LTT gauge.</div></div> | Unit of Pressure | Pressurize to | Correlation to LTT Gauge | kPa | 25 units | 3.6 psi on test fixture | mmHg | 160 units | 3.0 psi on test fixture | lb/in ² (psi) | 3 psi | 3.0 psi on test fixture |
|-----------------------------------|--|--------------------------|---------------|--------------------------|-----|----------|-------------------------|------|-----------|-------------------------|--------------------------|-------|-------------------------|
| Unit of Pressure | Pressurize to | Correlation to LTT Gauge | | | | | | | | | | | |
| kPa | 25 units | 3.6 psi on test fixture | | | | | | | | | | | |
| mmHg | 160 units | 3.0 psi on test fixture | | | | | | | | | | | |
| lb/in ² (psi) | 3 psi | 3.0 psi on test fixture | | | | | | | | | | | |
| Interpretation of Test Results | N/A | | | | | | | | | | | | |
| Contraindications of Test Results | N/A | | | | | | | | | | | | |
| Documentation | N/A | | | | | | | | | | | | |
| Special Warnings and Cautions | <div><div><div>• If the gauge becomes inadvertently submerged in fluid or if the LTT is dropped, then the LTT should be returned to validate proper calibration.</div><div>• Submerging, dropping, or mishandling LTT may damage the accuracy of the gauge.</div></div></div> | | | | | | | | | | | | |
| Disposal | N/A | | | | | | | | | | | | |

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

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| Cleaning – Automated | N/A |
| Disinfection | N/A |
| Drying | N/A |
| Maintenance, Inspection, and Testing | Each LTT 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. |
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| Additional Information | N/A |
| Related Healthmark Products | N/A |
| Other Product Support Documents | ProSys™ Brochure |
| Reference Documents | ISO 8600-7 |
| Customer Service Contact | Healthmark, A Getinge company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com |