

Operations Manual for the Glove Leak Test Apparatus (GLTA)




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1.0 Introduction


The Glove Leak Test Apparatus or GLTA is a device used to pressurize a glove with compressed air. After pressurization (*typically to around 15 – 20 inches of water column which equates to approximately 3500 – 5000 Pascals*), the glove is inserted into a vessel containing water. Bubbles flowing from the surface of the glove denotes a leak. The GLTA identifies the exact location of the leak. Based on validation data, the GLTA has the capability of detecting an approximate 10 micrometer diameter hole in the glove.

2.0 Safety

- 2.1 The GLTA weighs approximately 7 lbs. Use caution when carrying unit. A cart is recommended for general transport.
- 2.2 Use safety glasses when using the GLTA because the procedure involves the use of compressed air.

3.0 Material Specifics

- 3.1 Glove Leak Test Apparatus (GLTA)
 - 3.1.1 Material: AISI 316L stainless steel.
 - 3.1.2 All welds continuous. Ground and polished throughout.
 - 3.1.3 Electropolished and passivated.
 - 3.1.4 Proprietary design.
- 3.2 Industrial Quick-Disconnect Female Socket with Threaded NPTF Male End
 - 3.2.1 Material: AISI 303 stainless steel.
 - 3.2.2 Seal: Buna-N rubber.
 - 3.2.3 Socket locking type: push to connect.
 - 3.2.4 Size: 1/4" coupling size, 1/4" pipe thread.
- 3.3 Industrial Quick-Disconnect Male Plug with Barbed Male End
 - 3.3.1 Material: AISI 303 stainless steel.
 - 3.3.2 Straight-through, non-valved, open-flow.
 - 3.3.3 Size: 1/4" coupling size, 1/4" hose internal diameter.

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3.4 Tubing/Hose

3.4.1 Material: High-temperature silicone rubber.

3.4.2 Size: ¼" internal diameter, ½" outer diameter, ⅛" wall.

3.5 O-Rings

3.5.1 Material: Silicone rubber.

3.5.2 Size: 0.210" wall, 3.725" internal diameter, 4.145" outer diameter.

3.5.3 Size: 0.210" wall, 3.600" internal diameter, 4.020" outer diameter.

3.6 Pressure Gauge



It is recommended to calibrate the Pressure Gauge once on-site.

3.6.1 Measurement pressure range: 0 – 30 inches of water.

3.6.2 Accuracy: ± 1% full scale.

3.6.3 Case material: AISI 304 stainless steel.

3.6.4 Lens material: glass.

3.6.5 Connection material: brass.

3.6.6 Hose barb adapter material: AISI 304 stainless steel.

3.6.7 Hose barb adapter size: ¼" pipe thread, ¼" hose internal diameter.

4.0 Required Utilities


4.1 Compressed air.

NOTE: *If a compressed air source is not available, this portable oil-free electric pump is recommended:*

<https://www.mcmaster.com/#4176k11/=16I0739>

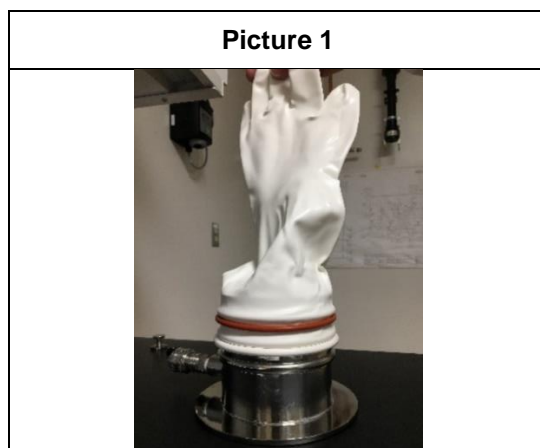
4.2 Sink or suitable vessel containing water.

5.0 Glove Leak Test Procedure

 The Glove Leak Test Apparatus (GLTA) weighs approximately 7 lbs. Use caution when carrying unit. A cart is recommended for general transport.

 Use safety glasses when using the GLTA because the procedure involves the use of compressed air.

- 5.1 Place the GLTA on a flat surface.
- 5.2 Stretch the cuff end of the glove around the GLTA. Place the integrated O-Ring of the glove in the groove closest to the base of the GLTA. See **Picture 1**.

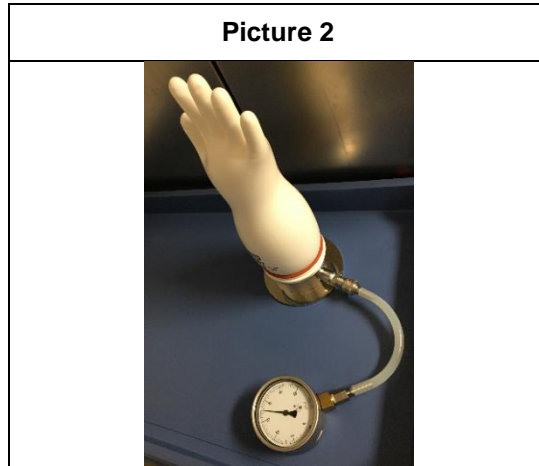


- 5.3 Apply at least one O-Ring around the cuff of the glove to secure the glove in place to the GLTA. Place O-Ring(s) in the groove closest to the top of the GLTA. See **Picture 1**.
- 5.4 Connect the open end of the \approx 5-foot piece of tubing to a pressure supply port. Connect the other end of the tubing to the GLTA via the quick-disconnect fitting. Using a gradual supply of air, pressurize the glove until firm when pressed and/or approximately between 15 and 20 inches of water column pressure.


NOTE: Depending on the diameter of the integrated O-Ring of the glove or the tightness of the added O-Ring(s), it is possible that the glove may slip from the groove closest to the base to the groove closest to the top of the GLTA when pressurized. This is normal.

- 5.5 Disconnect the \approx 5-foot piece of tubing from the GLTA via the quick-disconnect fitting. Connect the Pressure Gauge to the GLTA via the quick-disconnect fitting as indicated in **Picture 2**. Confirm the pressure within the GLTA is between 15 and 20 inches of water column pressure. If it is not repeat Step 5.4, or relieve some pressure from the GLTA by performing Step 5.11.

Picture 2




- 5.6 Disconnect the Pressure Gauge from the GLTA via the quick-disconnect fitting.

 DO NOT submerge the pressure gauge in water.

- 5.7 Transport the GLTA to a suitable container filled with water.
- 5.8 Submerge the glove into the water and observe for the presence of bubbles in the water. Rotate the glove in the water so that all surfaces of the glove can easily be viewed. Bubbles flowing from the surface of the glove denotes a leak. Discard the glove if it has a leak. Document results in the form entitled, "Glove Leak Testing Form".

NOTE: *Bubbles flowing from the back of the glove (near the integrated O-Ring of the glove) do not constitute a leak in the glove. In such case, try applying pressure to the added O-Ring(s) in the groove by pressing on the O-Rings with your hands or use O-Rings with a slightly smaller diameter.*

- 5.9 Dry the glove and GLTA using low-particulate wipe(s).
- 5.10 Clean the glove using low-particulate wipe(s) saturated with 70% isopropyl alcohol.
- 5.11 When leak testing of the glove is complete, remove pressure from within the GLTA. This can be done by connecting the \approx 5-foot piece of tubing via the quick-disconnect fitting on the GLTA and then disconnecting the other end of the tubing from the pressure supply port.
- 5.12 Remove the O-Ring(s) and the glove from the GLTA.
- 5.13 If the glove is a new glove, identify the glove in accordance with the form entitled, "Glove Tracking Log".
- 5.14 Re-install the glove per the form entitled, "Glove Tracking Form".

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- 5.15 Document results in forms entitled, “Glove Leak Testing Form” and “Glove Tracking Form”.
- 5.16 When all testing is completed, empty the water into a sink. Store Glove Leak Test GLTA and all accessories in a suitable area or cabinet so these items will not be damaged or dropped.

6.0 Maximum Frequency of Glove Leak Testing

- 6.1 Monthly
25 - 35 days (30 +/- 5 days) after previous testing entry (under routine conditions).

NOTE: *This procedure should also performed after three (3) successive isolator pressure leak test failures that automatically run prior to the isolator’s decontamination cycle.*

7.0 General Cleaning

- 7.1 This method includes the general cleaning procedure for the Glove Leak Test Apparatus, Quick-Disconnect Fittings, Tubing, O-Rings, and the Pressure Gauge.
 - 7.1.1 Clean items/components using low-particulate wipe(s) saturated with 70% isopropyl alcohol. Allow to dry.

8.0 General Troubleshooting

- 8.1 Refer to this Operations Manual.
- 8.2 Please feel free to contact Ardien Consulting Services if there are any technical questions related to the content of this document or the Glove Leak Test Apparatus.
- 8.3 Contact Ardien Consulting Services.
 - 8.3.1 Name: Rick Nieskes
 - 8.3.2 Email: rick@ardienconsulting.com
 - 8.3.3 Telephone: 262-548-9748
 - 8.3.4 Cell: 262-853-9748

Glove Leak Testing Form

Specified	Observations	Performed By: Initials / Date
Glove tested	<input type="checkbox"/> Existing Glove <input type="checkbox"/> New Glove	
Glove Code (see the form entitled, "Glove Tracking Form"). If applicable, otherwise enter "New" in the Observations column.		
No leaks detected? If no leaks detected, circle "Pass". If leak(s) detected, circle "Fail". If leak(s) detected, discard glove, and repeat testing with a replacement glove.	Pass / Fail	
Location of leaks, if applicable. Otherwise enter "N/A" in the Observations column		
Glove acceptable for use? If no leaks detected, circle "Pass". If leaks detected, circle "Fail".	Pass / Fail	

After completing this form, complete the form entitled, "Glove Tracking Form".

<p>Comments:</p>

<p>Reviewed By (Initials / Date):</p>	
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Glove Tracking Form

Glove Code ¹	New or Existing Glove? (New, Ex)	Leak Test Acceptable? (Y, N) ²	Number of Times the Glove Has Been Re-Installed in the Isolator? (0, 1, 2, etc., D) ³	Performed By: Initials / Date

Y = Yes, **N** = No, **D** = Discarded, **New** = New Glove, **Ex** = Existing Glove

¹: On a flat surface of the glove, write the Glove Code using a fine tip marker. Glove Code = “DDMMYY”- GP”##“, where “DDMMYY” is the date the new glove was installed (e.g. 01SEP17 or 01Sep17) and the “GP##” is the Glove Port Number (e.g. GP01). Initial and date after the Glove Code was written. Install the glove in the identified glove port.

²: If the glove leak test failed, discard the glove, and write in “**N**” for this column, and “**D**” for the remaining columns.

³: When a NEW glove is installed, record “**0**” in this column. A glove may be removed, leak tested and re-installed repeatedly for up to 90 days, if no leaks in the glove have been detected. After 90 days have elapsed, discard the glove.

Comments:

Reviewed By (Initials / Date):	
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