Model GIT-XA1

Model GIT-P2

Model GIT-P4

Glove Integrity Tester Models

Presented by:

Dynamic Design Pharma, Inc.

Mission Viejo, California USA

GIT- P4 – Four glove tester

GIT-P2 - Dual Glove Tester

GIT- XA1 - Single glove tester

GIT-XA1 and GIT-P4 Glove Testers

- TEST ENVIRONMENTS
- SYSTEMS DESCRIPTION
- OIT SCREENS AND PRINTING FUNCTIONS
- FEATURES
- PRINCIPLE OF OPERATION
- INTERFACE TO ISOLATOR SYSTEM
- IMPLEMENTATION NOTES
- DOCUMENTATION
- MODEL SELECTION

GIT-P4, GIT-P2 and GIT-XA1 Glove Testers

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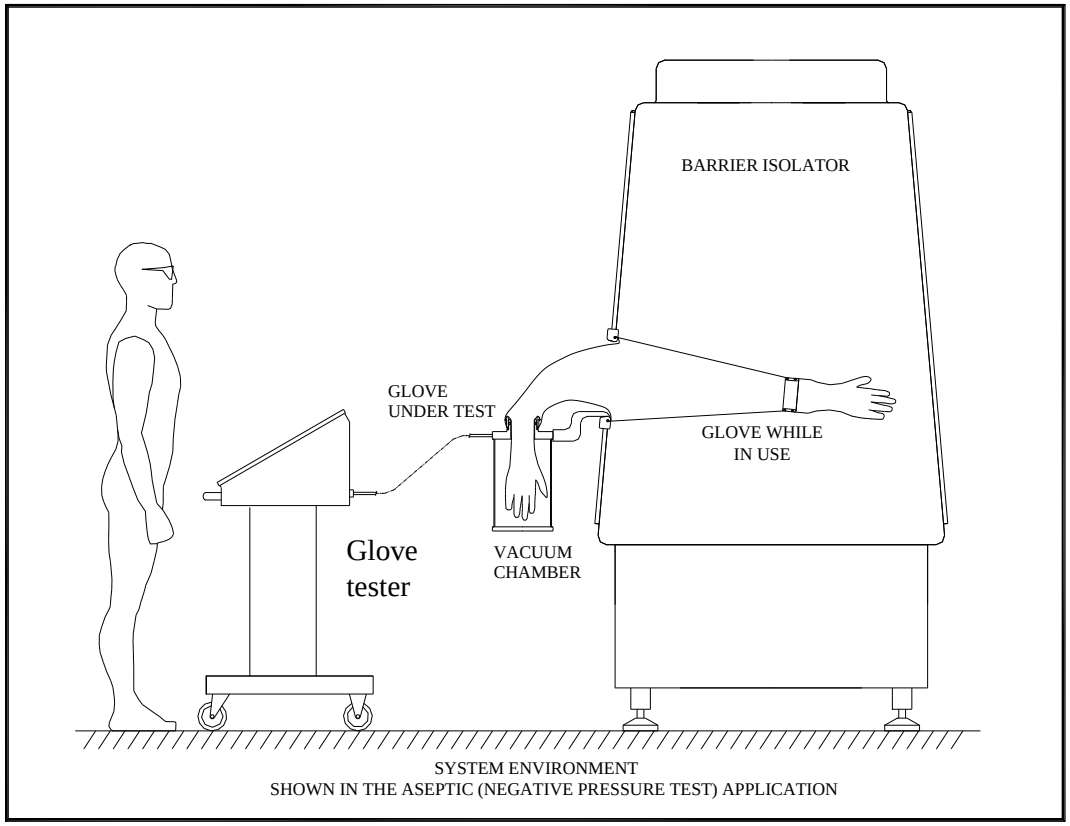
Negative Pressure Testing - Aseptic

Glove/Sleeve placed under vacuum from outside the isolator

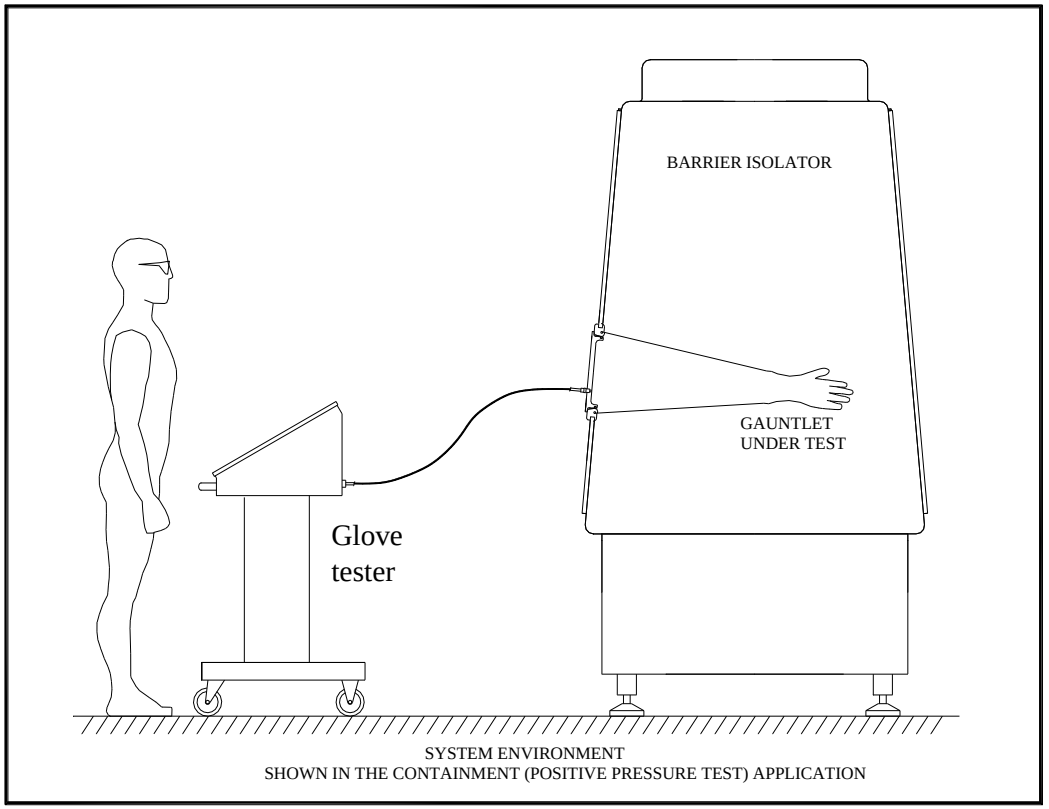
In the event of a leak being present in the test item, negative pressure outside the test item causes air flow **out** of the isolator system.



Positive Pressure Testing - Containment

Glove/Sleeve is pressurized from outside the isolator

In the event of a leak being present in the test item, positive pressure inside test item causes air flow **into** the isolator system.



SYSTEM ENVIRONMENT
SHOWN IN THE CONTAINMENT (POSITIVE PRESSURE TEST) APPLICATION

GIT-P4, GIT-P2 and GIT-XA1 Glove Testers

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GIT-P4

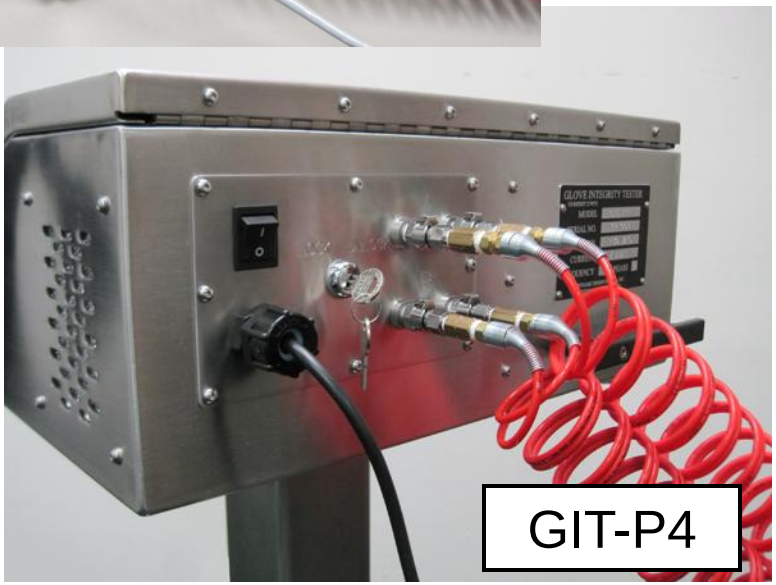
- ✓ Simultaneous test of four gloves
- ✓ Stainless Steel Control Console
- ✓ Maneuvering Handle
- ✓ Polyurethane Casters
- ✓ Touchscreen Control Panel
- ✓ Printer
- ✓ Size: 500W x 630L x 1000H

GIT-P2 / GIT-XA1

- ✓ Dual / Single glove test
- ✓ Stainless Steel Control Console
- ✓ Table Top design
- ✓ Touchscreen Control Panel
- ✓ Printer
- ✓ Size: 400W x 400L x 250H

Control Console Rear

GIT-P2
and
GIT-XA1



GIT-P4

- ✓ Power on/off switch
- ✓ Power cord and winding bracket
- ✓ Pneumatic tubing connections
- ✓ Parameters lock-out key switch
- ✓ ID tag

GIT-P4, GIT-P2 and GIT-XA1 Glove Testers

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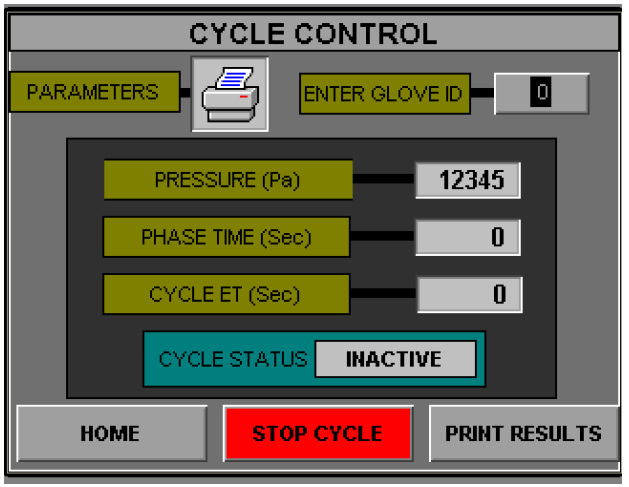
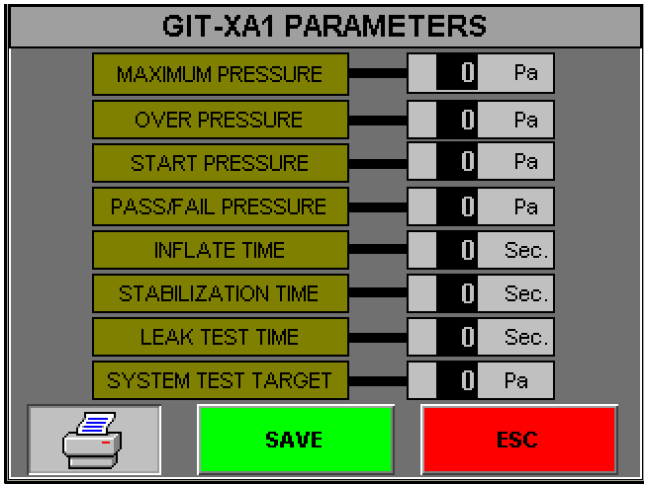
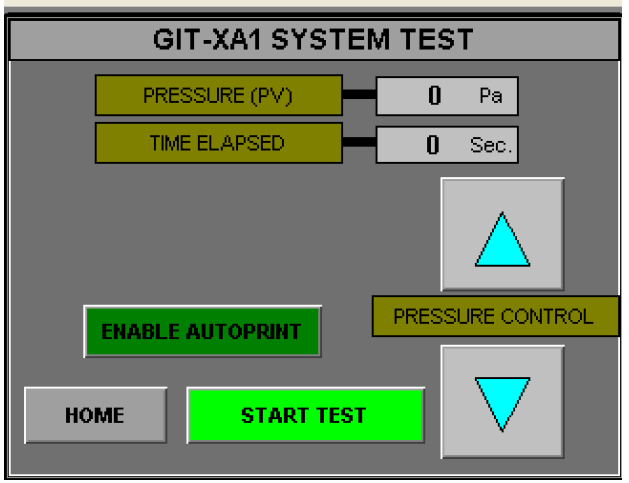
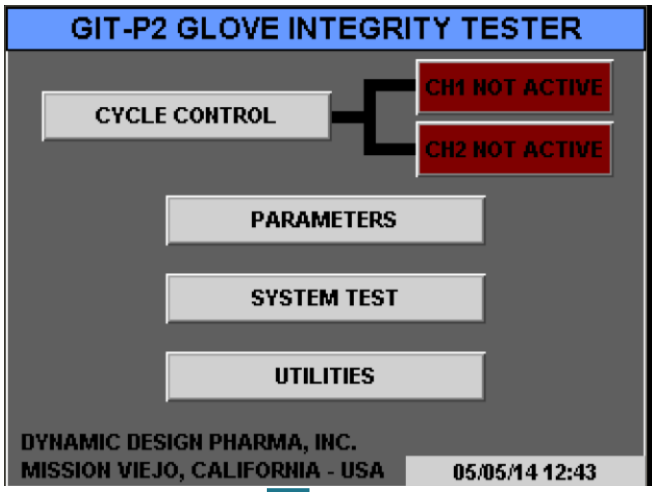
GIT-XA1 OIT Screens – Typical Navigation

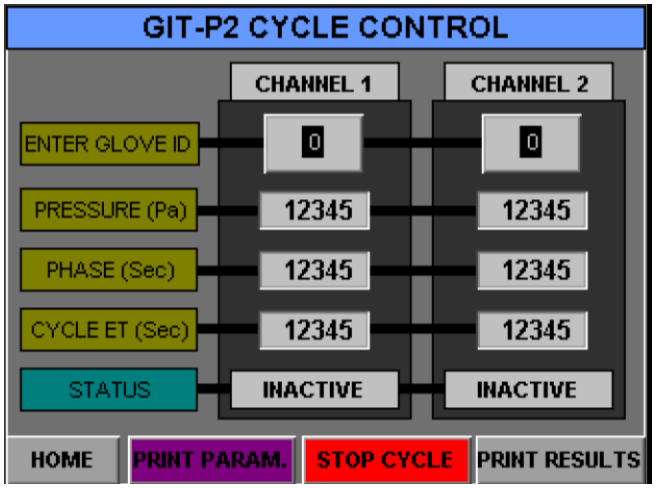


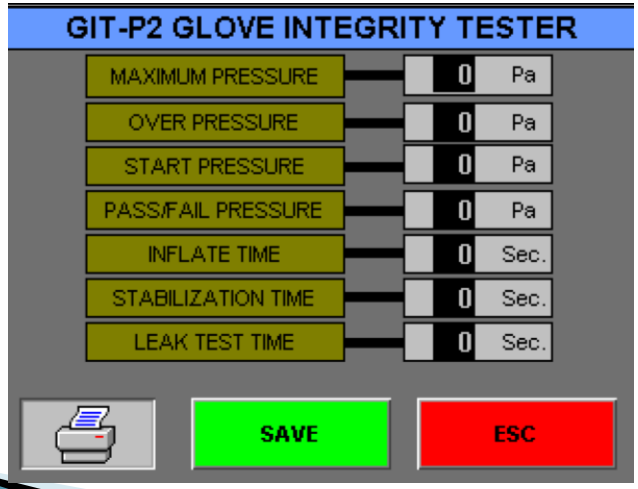


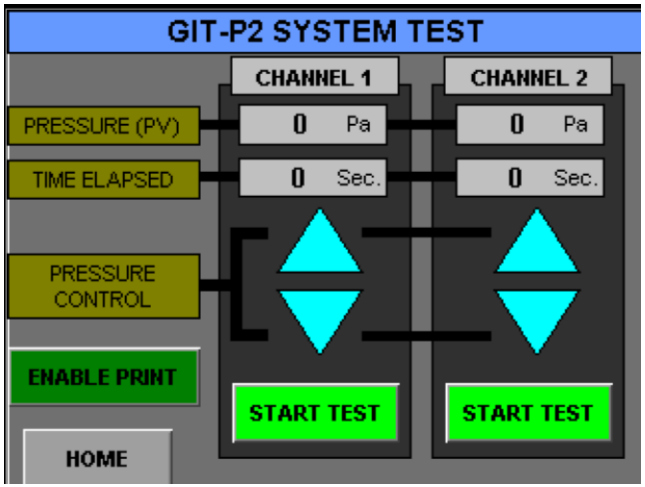


GIT-P2 OIT Screens – Typical Navigation









NOTE: GIT-P4 OIT screens are similar but with four channels

Printing Functions (typical)

Parameter report

- Date stamp
- Leak Test parameters

Leak Test Report

- Date Stamp
- Active Channel
- Pass/Fail Result
- Cycle Duration
- Pressure at end of test

System Test Report

- Active Channel
- Current Pressure
- Elapsed Time

NOTE: Continuous printing at fixed time interval

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Primary Features – All Models

- ✓ Programmable parameters
- ✓ Clear Pass/Fail test result feedback to the operator
- ✓ Numeric test result feedback
- ✓ Print out capability
- ✓ Positive or Negative pressure test (capability)
- ✓ System Test capability (parameters development)
- ✓ Cost effective
- ✓ Simple operation, validation, training and maintenance

Operation – All Models

STEP 1:
Operator installs the glove interface onto glove to be tested

STEP 2:
Operator starts the leak test cycle

STEP 3:
At the end of the leak test cycle, the operator reviews the results and initiates printing

STEP 4:
The system prints out the test results and the cycle concludes

NOTE: GIT-P4 and GIT-P2 operation is identical to the GIT-XA1 operation except for the added channel selection function

GIT-P4, GIT-P2 and GIT-XA1 Glove Testers

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Principle of Operation – All Models

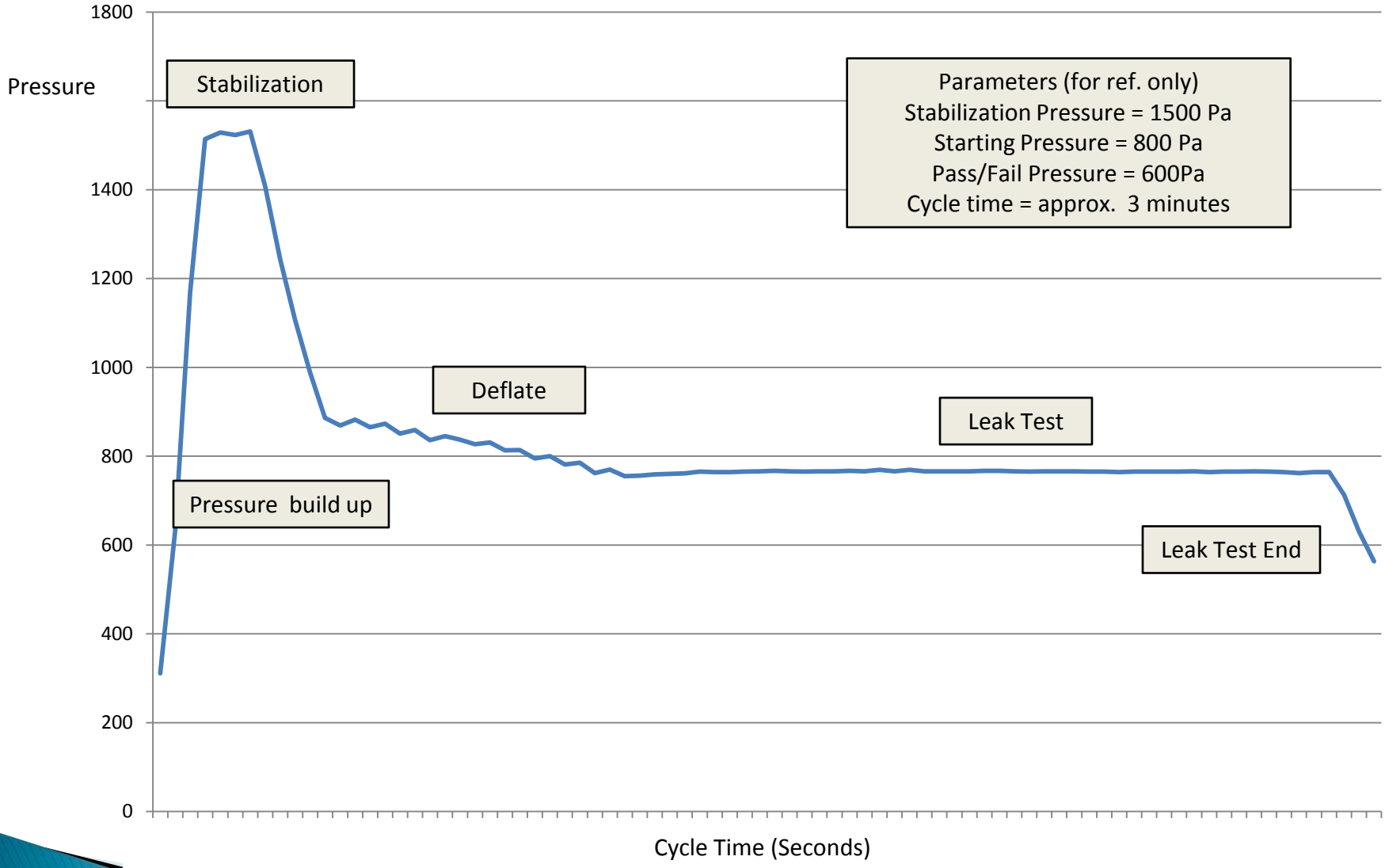
The system detects a leak in the glove under test by comparing the internal pressure of the glove to a pass/fail pressure threshold level after having been pressurized to a set level and held in a sealed condition for a given time duration.

This methodology of leak detection is called pressure decay.

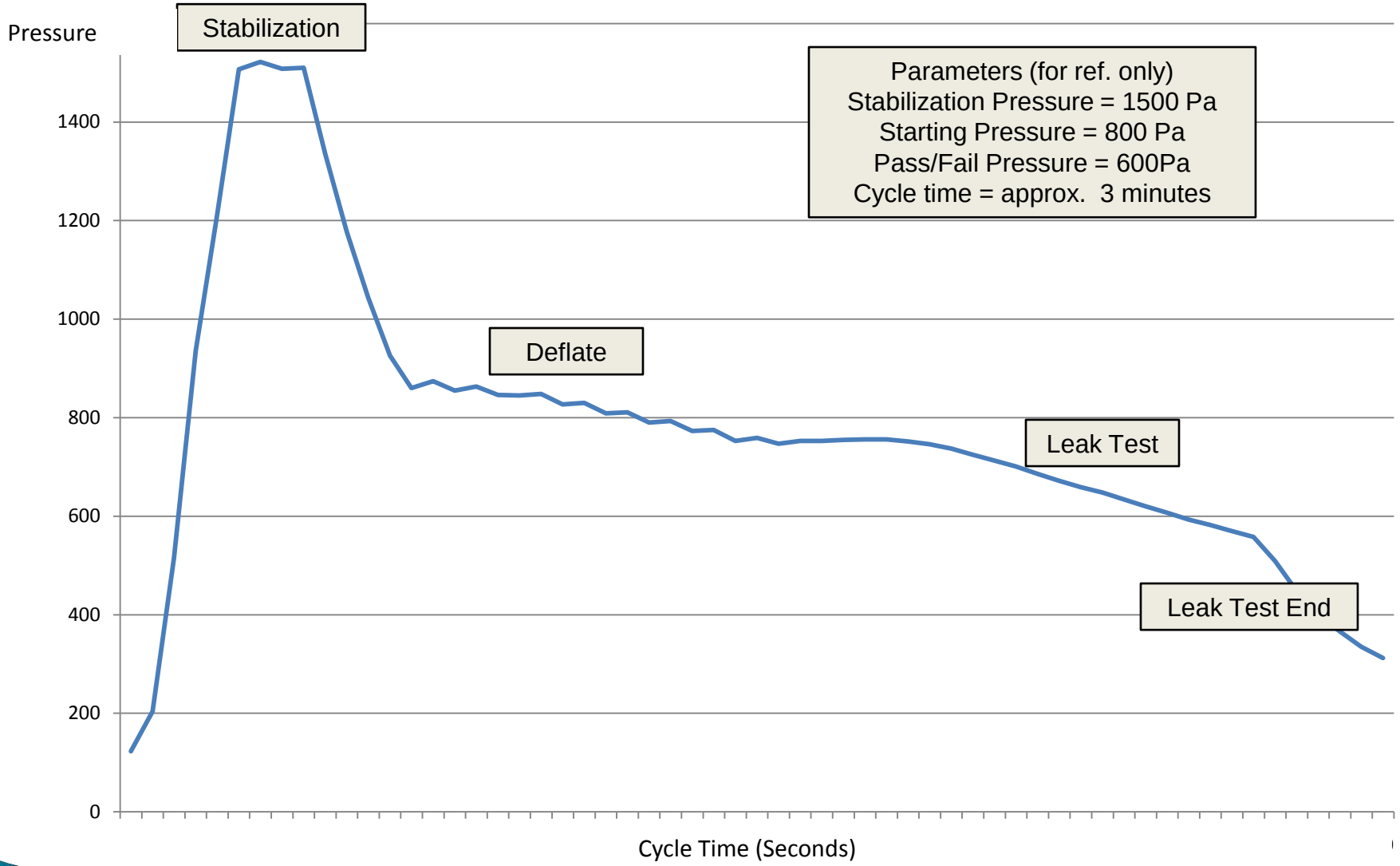
Phases of the Leak Test Cycle

INFLATE	Initial pressurization to set point value
STABILIZE	Maintain pressure at a set level for a programmed duration to allow glove material to stretch
DEFLATE	Allow pressure to drop to the leak test starting pressure level
LEAK TEST	Close off the opening to glove under test for the programmed time duration and monitor the internal pressure level.
LEAK TEST END	At the end of the Leak Test phase, the pressure internal to the glove under test is compared to the programmed Pass/Fail pressure level. The system then makes the leak test outcome decision and displays the result on the OIT

Leak Test Diagram (Passing Test - Glove)



Leak Test Diagram (Failing Test / Glove)



System Capability – Glove Testing

Positive or Negative pressure, glove only

Hole size detection capability = 100 um (0.004 inches) or larger

Parameters to achieve above capability (guideline only)

- Pressure Threshold = 1500 pa
- Inflate time: less than 10 seconds
- Stabilization = 60 seconds
- Leak test = 120 seconds

Certainty of detection with > 3 sigma confidence

Certainty of no false positives with > 3 sigma confidence

System Capability – Gauntlet Testing

Positive pressure

Hole size detection capability = 250 um (0.010 inches) or larger

Parameters to achieve above capability (guideline only)

- Pass/Fail Pressure = 600 pa
- Inflate time: 60 seconds (approx.)
- Stabilization = 120 seconds
- Leak test = 180 seconds

Certainty of detection with > 3 sigma confidence

Certainty of no false positives with > 3 sigma confidence

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Interface to the Isolator - Options

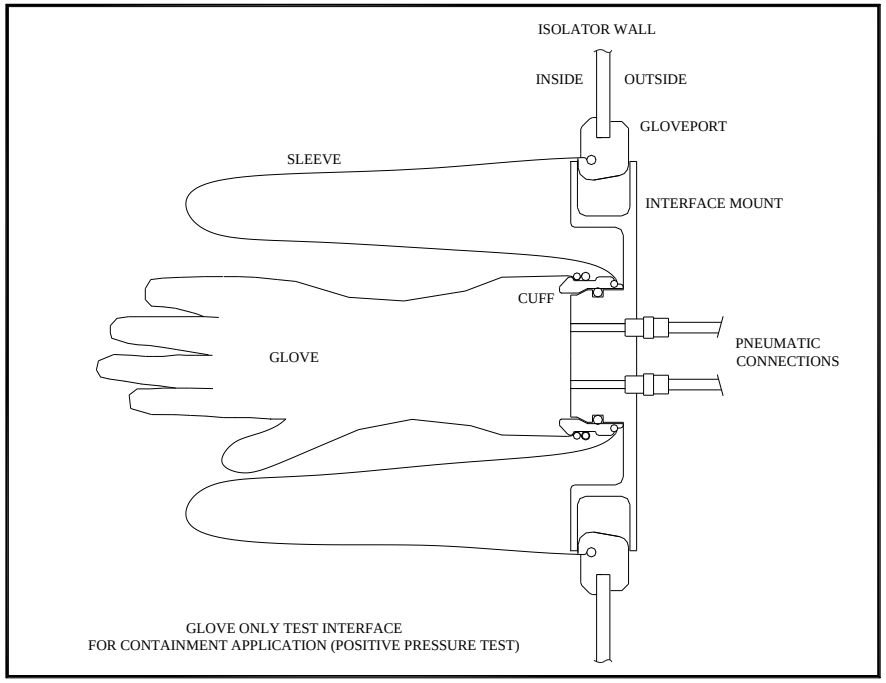
Containment Applications (Positive Pressure Testing)

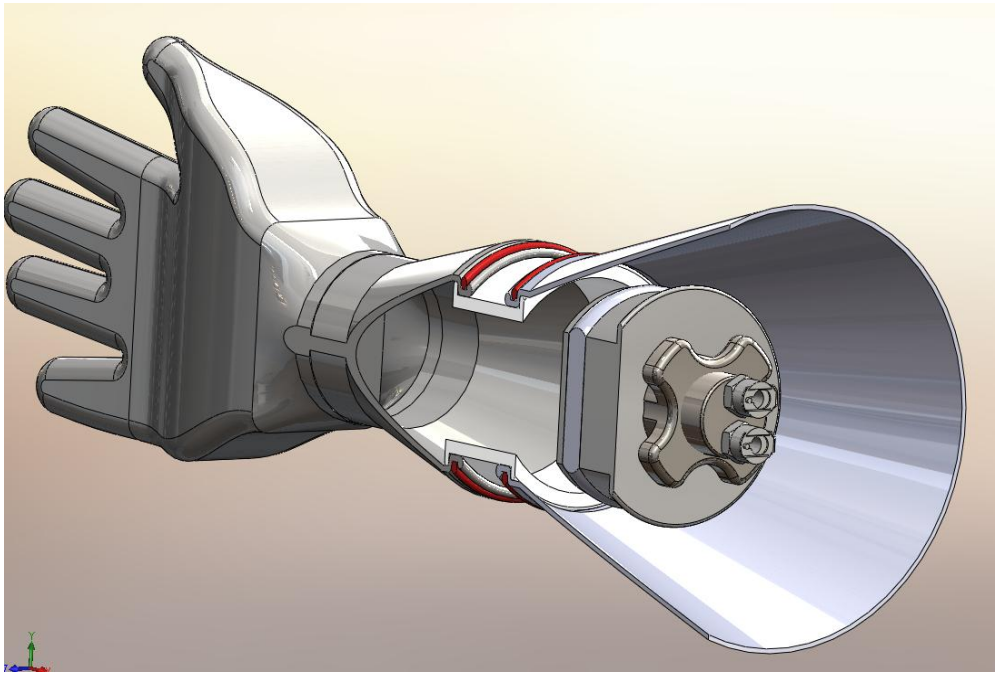
1. Glove Interface
2. Single Piece Gauntlet Interface

Aseptic Applications (Negative Pressure Testing)

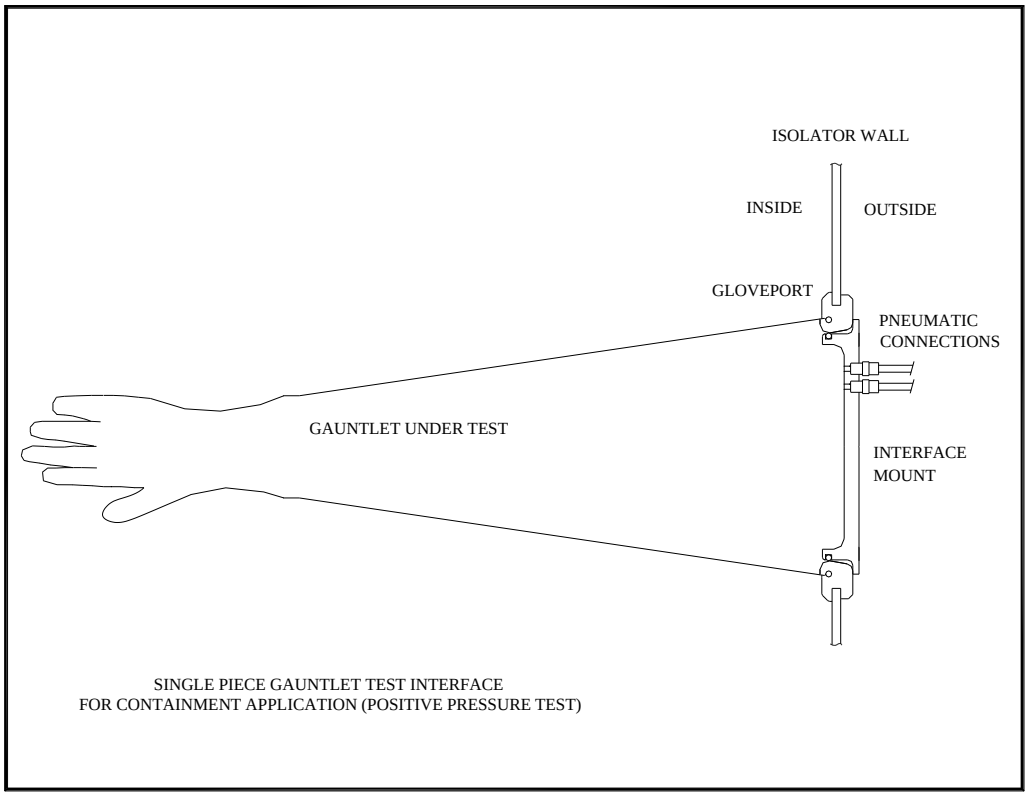
1. Glove Vacuum Chamber
2. Single Piece Gauntlet Vacuum Chamber

Glove Interface - Positive Pressure Testing



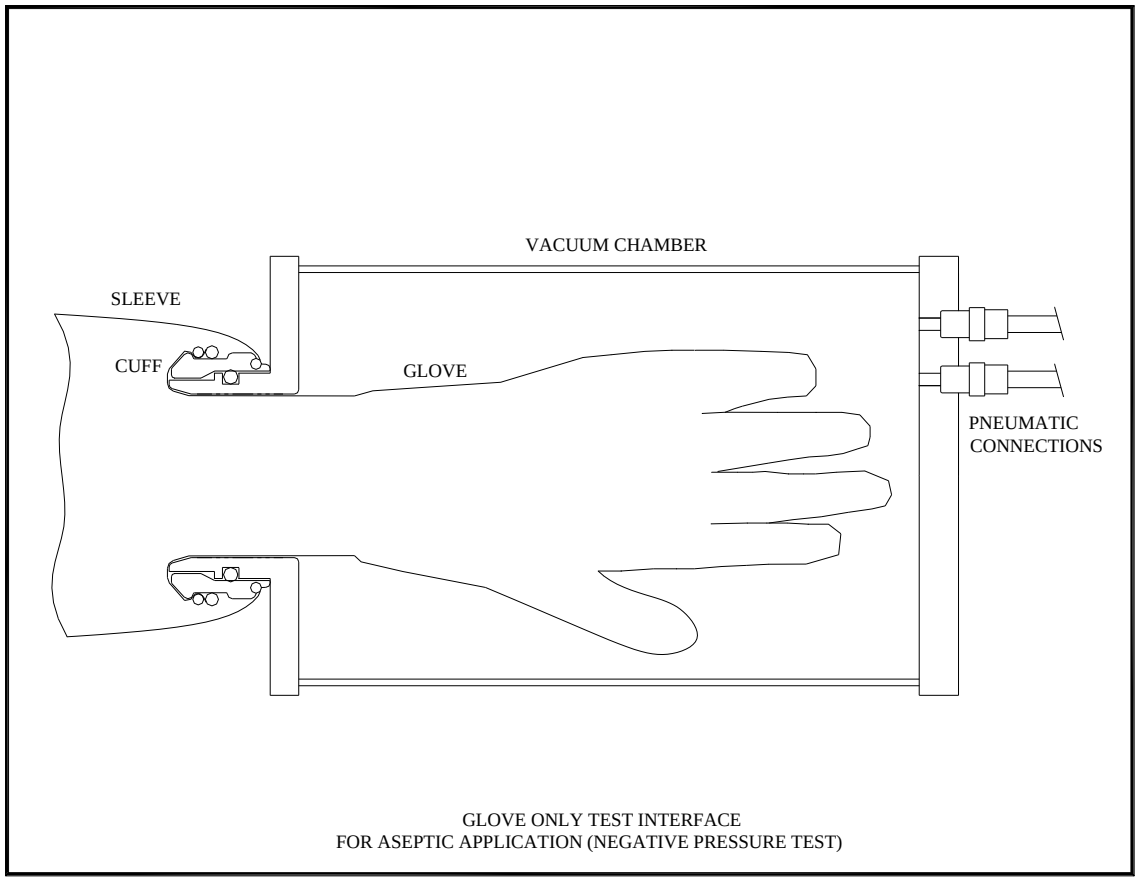


Gauntlet Interface - Positive Pressure Testing



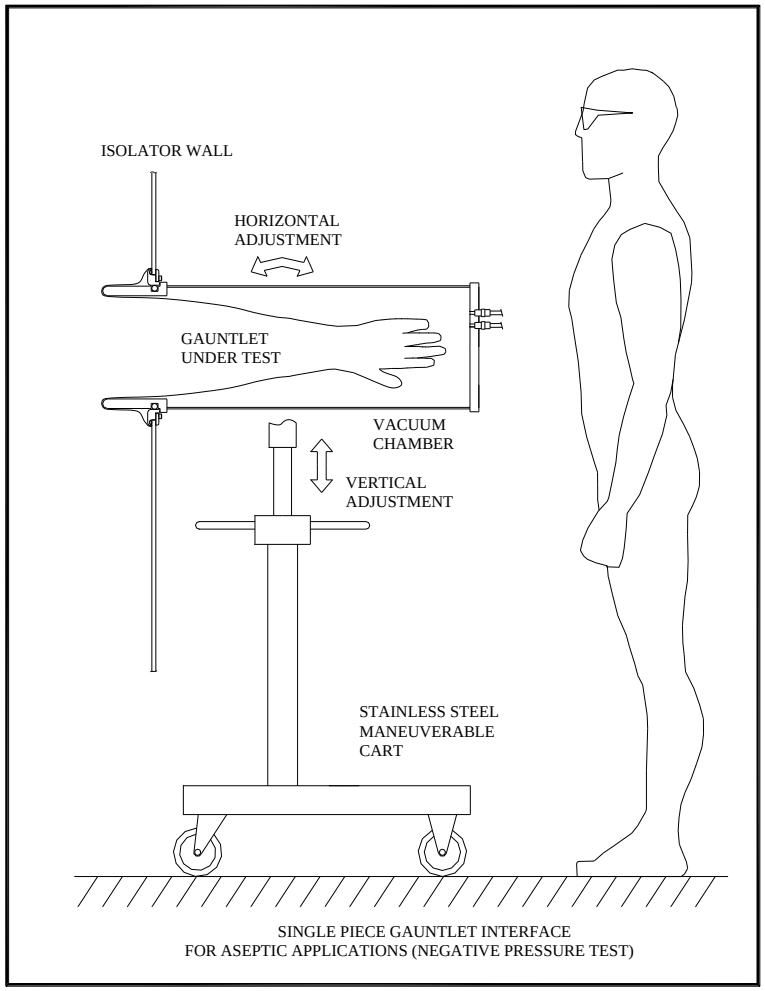
SINGLE PIECE GAUNTLET TEST INTERFACE
FOR CONTAINMENT APPLICATION (POSITIVE PRESSURE TEST)

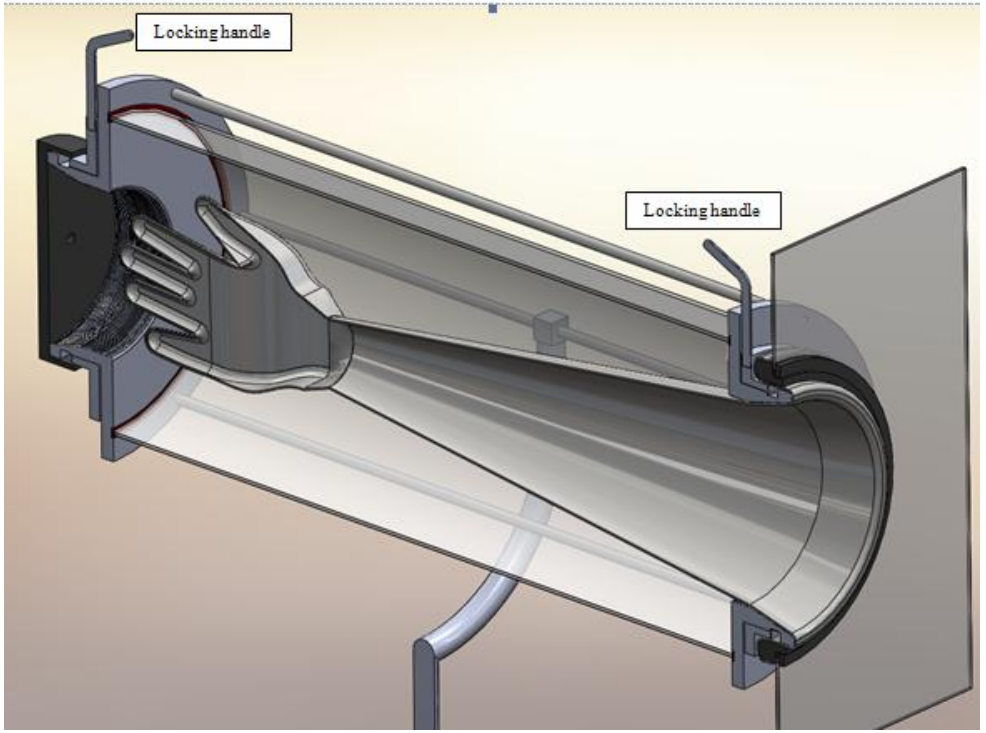
Glove Vacuum Chamber - Negative Pressure Testing



GLOVE ONLY TEST INTERFACE
FOR ASEPTIC APPLICATION (NEGATIVE PRESSURE TEST)

Gauntlet Vacuum Chamber – Negative Pressure Testing





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Parameters Development Guidelines

- Use the SYSTEM TEST function built into the system to develop a pressure profile with a known “good” glove
- Use the SYSTEM TEST Build a pressure profile with the same glove and a connected precision orifice (100um diameter)
- From profiles, select a time duration and test pressure values that yield the desired difference between a “Pass” and a “Fail” pressure values
- Repeat tests a number of times to determine level of confidence of repeated detection (sigma >3)
- Repeat tests with the same parameters and a “good” glove to determine the level of confidence of “no false positives” (sigma >3)

Validation Principle

- Obtain a glove known to be leak free (multiple gloves can be used as well)
- Run a minimum of 5 separate tests with and without the DDP supplied 100um/250um diameter test orifice connected
- All gloves tested without orifice must pass and use the end pressure values to calculate the passing level of confidence. Must be > 3 sigma
- All gloves tested with orifice connected must fail. Use the end pressure values to calculate the failing level of confidence. Must be > 3 sigma

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Documentation

The following documentation package is supplied with the system

- Instruction manual (operator and maintenance)
- Assembly and control drawing package
- System Specification
- Functional and Design Specification document
- Functional Test document (executed)
- Factory Acceptance Test (executed)
- IOQ Protocol (ready for execution)

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GIT-P4, GIT-P2 and GIT-XA1 Glove Testers

	GIT-P4	GIT-P2	GIT-XA1
Number of gloves simultaneously tested	4	2	1
Test methodology	Press. Decay	Press. Decay	Press. Decay
Number of gloves tested/hour (including set up)	80 (3)(5)	40 (3)(5)	15 (1)
Number of gauntlets tested/hour (including set up)	40 (4)(5)	20 (4)(5)	8 (1)
Recommended isolator size (# of gloves)	➢12	6-12	2-6

(1) This calculation assumes a gloveport interface installation time of 1 minute.

(2) All models require a single electrical power connection

(3) The above assumes a glove testing cycle time of 3 minutes

(4) The above assumes a gauntlet testing cycle time of 6 minutes

(5) This calculation assumes no gloveport interface installation time (continuous testing)

Summary

Clean room friendly, easy to operate and maintain

Capable of meeting hole size detection requirements

Can be validated using non-microbiological methods

Highly cost effective

Thank You

Dynamic Design Pharma