Model GIT-P2

Model GIT-P4

Glove Integrity Tester Models

Presented by:

Dynamic Design Pharma, Inc.

Carlsbad, California USA

GIT-P2 – Dual Channel glove tester

GIT- P4 – Four channel glove tester`

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

- TEST ENVIRONMENTS
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- OIT SCREENS, SECURITY AND DATA OUTPUT
- FEATURES
- PRINCIPLE OF OPERATION
- INTERFACE TO ISOLATOR SYSTEM
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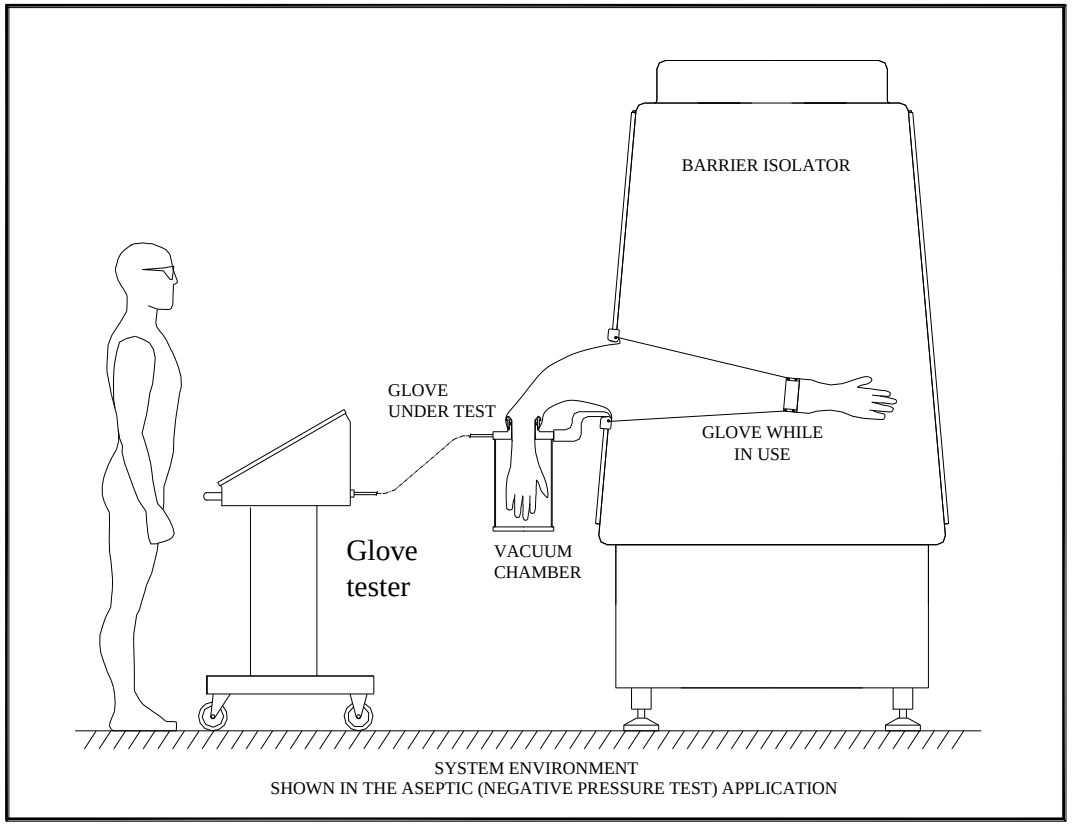
Negative Pressure Testing - Aseptic

Glove/Sleeve placed under vacuum from outside the isolator

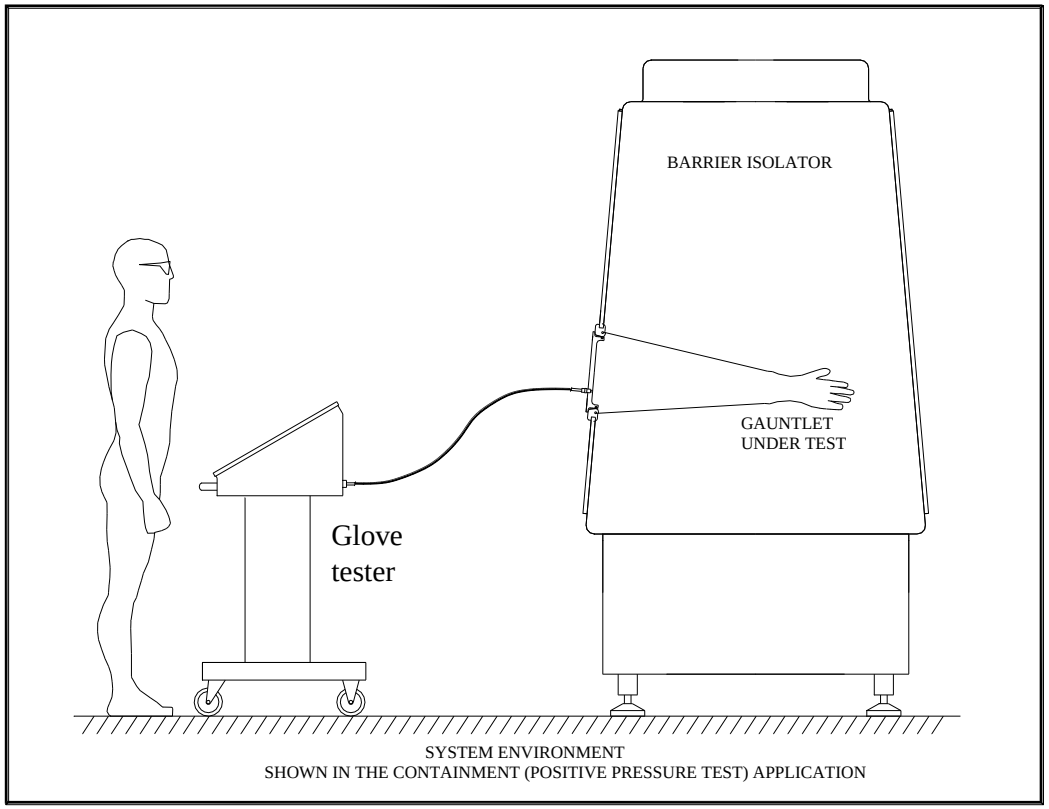
In the event of a leak being present in the test item, negative pressure outside the test item causes air flow **out** of the isolator system.



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

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DDP
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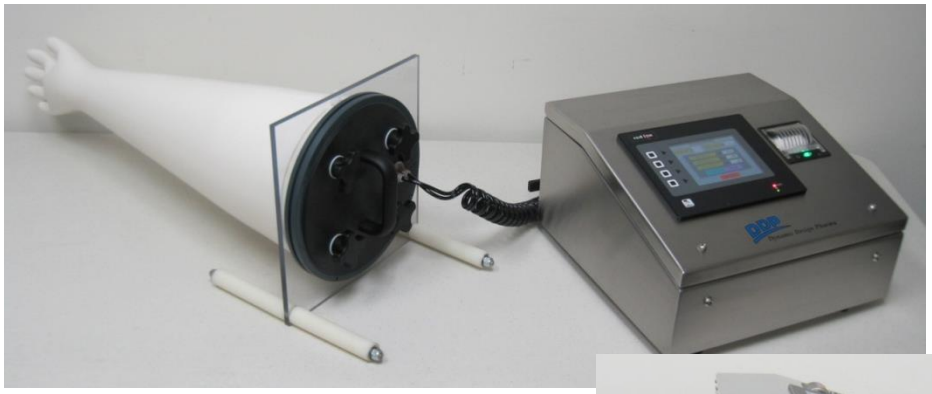
GIT-P4

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



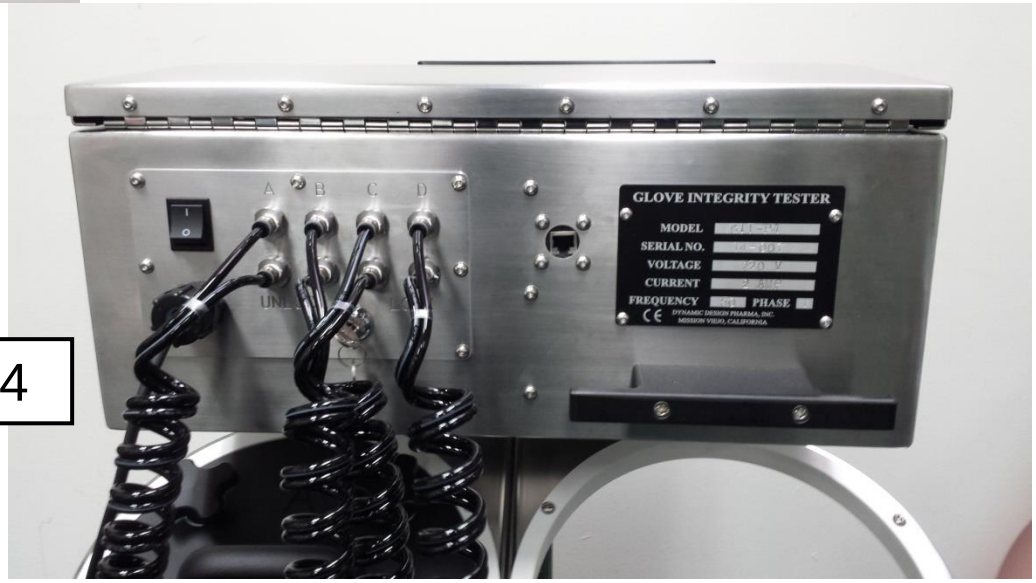
GIT-P2

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

Control Console Rear

GIT-P2

- ✓ Power on/off switch
- ✓ Power cord and winding bracket
- ✓ Pneumatic tubing connections
- ✓ Ethernet port
- ✓ USB connector
- ✓ ID tag



GIT-P4

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

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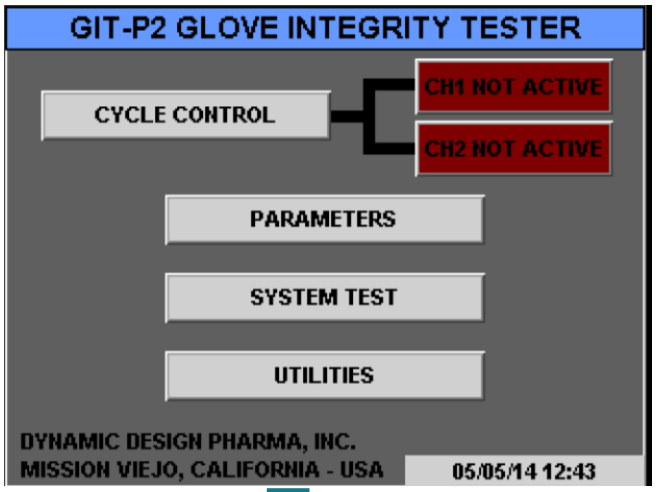
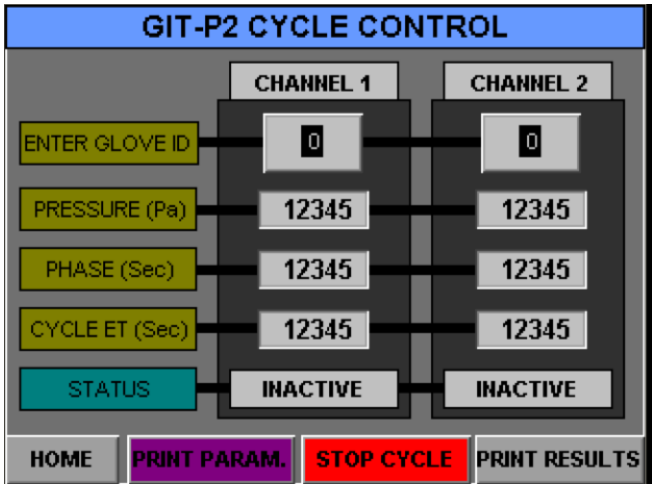
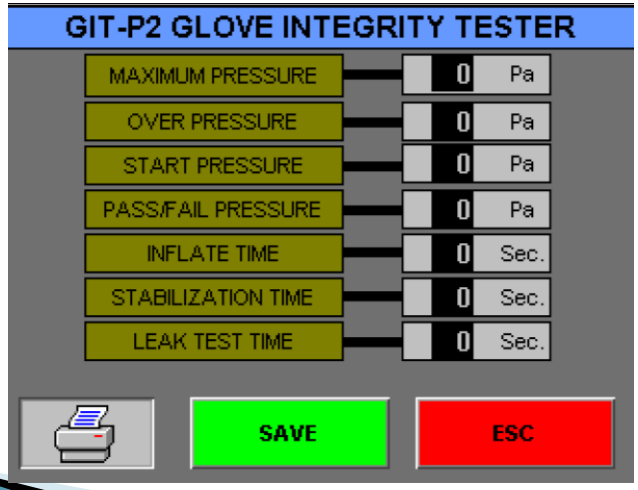
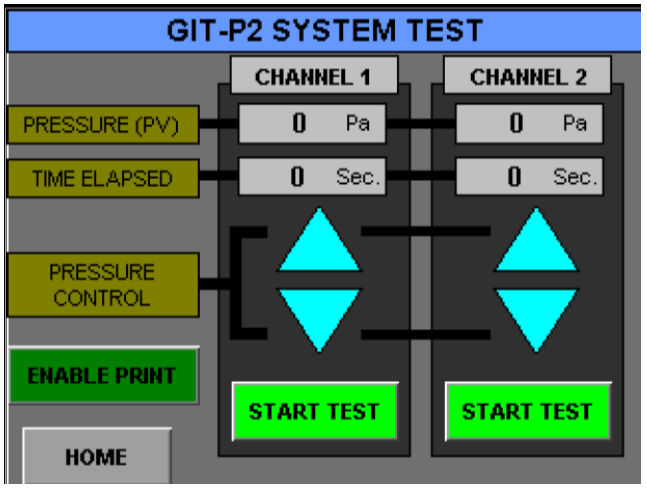
GIT-P2 OIT Screens – Typical Navigation

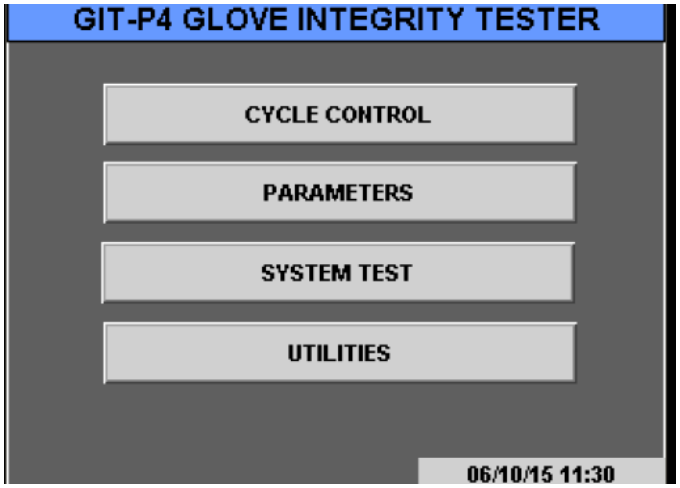


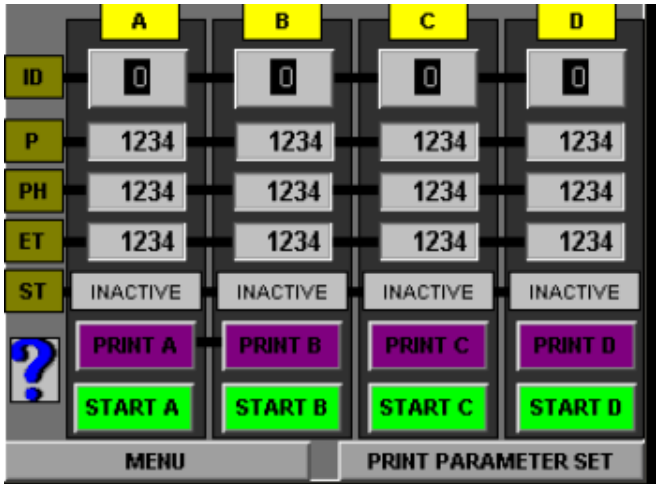


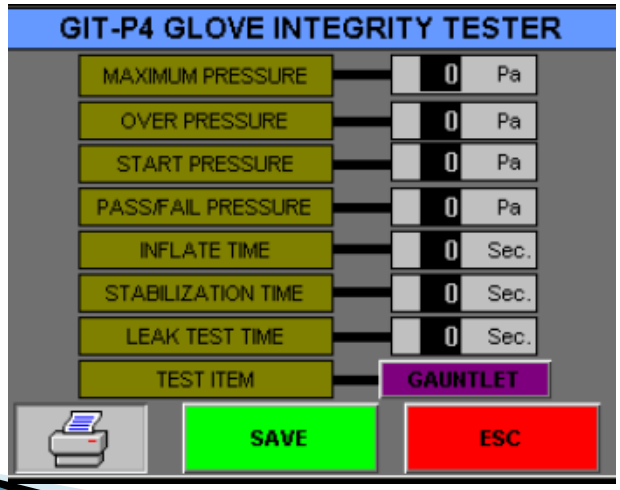


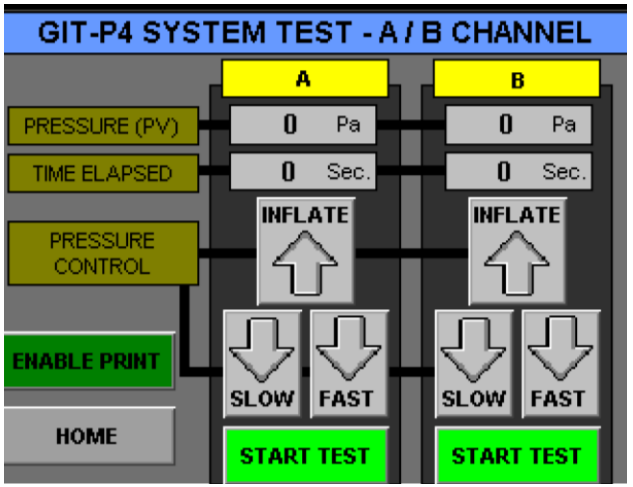


GIT-P4 OIT Screens – Typical Navigation









Security Functions

- Three login levels: Operator, Supervisor and Administrator
- Individual real name assignment
- Individual Password assignment
- Automatic logout
- Login information part of the Leak Test record
- Operator has access to Leak Test functions only
- Supervisor has access to Leak test functions, Parameters Management and Utilities
- Administrator has access to all functions
- Electronic signature of each leak test record

Data Output Options

Data Output Options

- Local printing at thermal printer
- Remote printing via Ethernet
- Data storage and retrieval via laptop
- Data storage and wireless retrieval

Leak Test Data

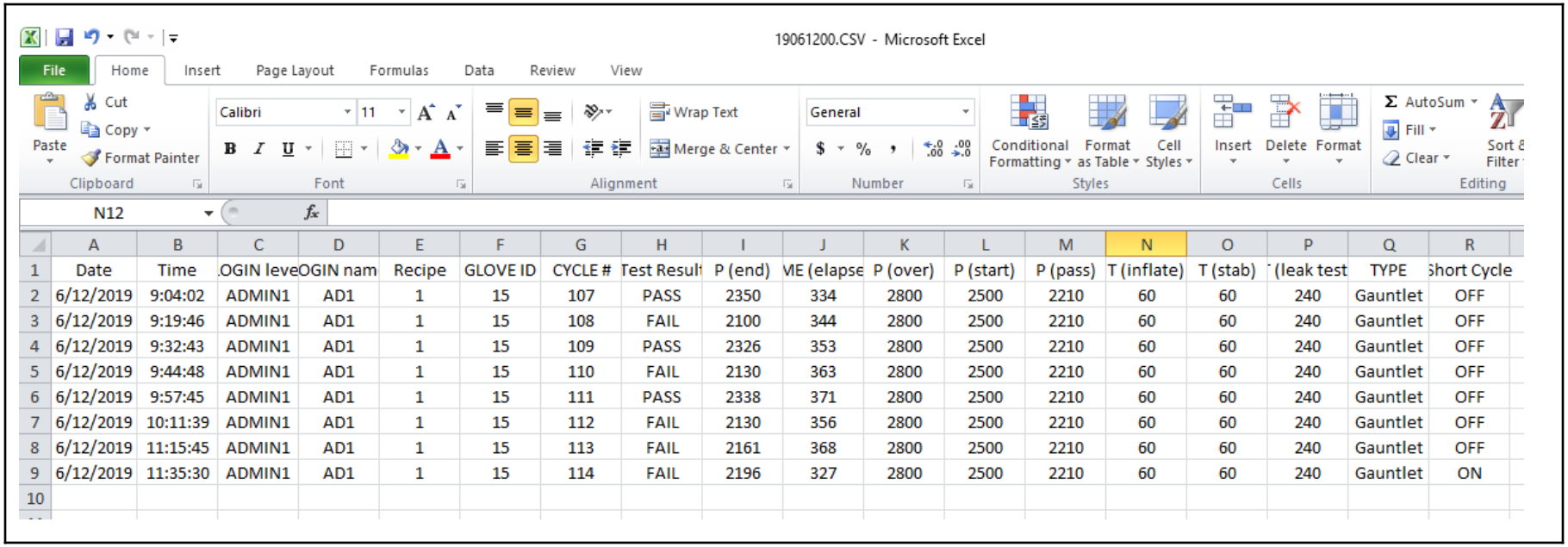
- Active Recipe
- Time/Date Stamp
- Login user info
- Active Channel
- Parameters
- Pass/Fail Result
- Cycle Duration
- Pressure at end of test

Note:

Data output is in a .CSV file format that can be easily opened using an Excel spreadsheet

Wireless Data Transmission – All models

- DDP's glove testers feature a wireless router that allows the password protected read-only download of the leak test data to a remote computer.
- Each day's leak test data is automatically stored within a unique data file that is then downloaded for visualization and archiving.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Date	Time	OGIN leve	OGIN nam	Recipe	GLOVE ID	CYCLE #	Test Result	P (end)	ME (elapse	P (over)	P (start)	P (pass)	T (inflate)	T (stab)	(leak test	TYPE	Short Cycle
2	6/12/2019	9:04:02	ADMIN1	AD1	1	15	107	PASS	2350	334	2800	2500	2210	60	60	240	Gauntlet	OFF
3	6/12/2019	9:19:46	ADMIN1	AD1	1	15	108	FAIL	2100	344	2800	2500	2210	60	60	240	Gauntlet	OFF
4	6/12/2019	9:32:43	ADMIN1	AD1	1	15	109	PASS	2326	353	2800	2500	2210	60	60	240	Gauntlet	OFF
5	6/12/2019	9:44:48	ADMIN1	AD1	1	15	110	FAIL	2130	363	2800	2500	2210	60	60	240	Gauntlet	OFF
6	6/12/2019	9:57:45	ADMIN1	AD1	1	15	111	PASS	2338	371	2800	2500	2210	60	60	240	Gauntlet	OFF
7	6/12/2019	10:11:39	ADMIN1	AD1	1	15	112	FAIL	2130	356	2800	2500	2210	60	60	240	Gauntlet	OFF
8	6/12/2019	11:15:45	ADMIN1	AD1	1	15	113	FAIL	2161	368	2800	2500	2210	60	60	240	Gauntlet	OFF
9	6/12/2019	11:35:30	ADMIN1	AD1	1	15	114	FAIL	2196	327	2800	2500	2210	60	60	240	Gauntlet	ON
10																		

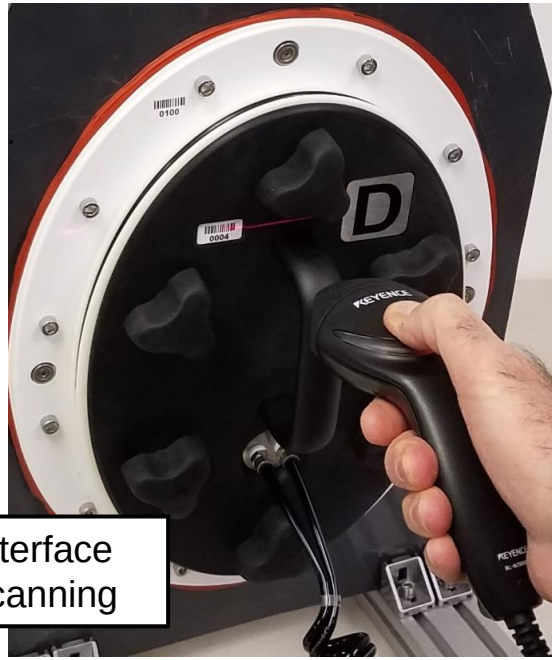
Note:

Data output is in a .CSV file format that can be easily opened using an Excel spreadsheet

Barcode Reader Functionality – All models

- DDP's glove testers feature a barcode reader that assures accuracy of the gloveport identification and eliminates the possibility of operator mistakes
- In multi-channel systems, the barcode reader also identifies the appropriate channel (A, B, C or D) by scanning the barcode located on the interface
- A "teaching" functionality allows the programing of the barcode affixed on each gloveport and each interface.

Gloveport Scanning



Interface Scanning

Note: Scanning of both the gloveport and the interface and automatically checking the validity of both scans assures the elimination of operator mistakes

GIT-P4 and GIT-P2 Glove Testers

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Primary Features – All Models

- ✓ Programmable parameters
- ✓ Clear Pass/Fail test result feedback to the operator
- ✓ Numeric test result feedback
- ✓ Data Output capability
- ✓ Security login
- ✓ Positive or Negative pressure test (capability)
- ✓ Cost effective
- ✓ Barcode Reader functionality
- ✓ Simple operation, validation, training and maintenance
- ✓ Support structure for gloveport interface assemblies

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

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

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Principle of Operation – All Models

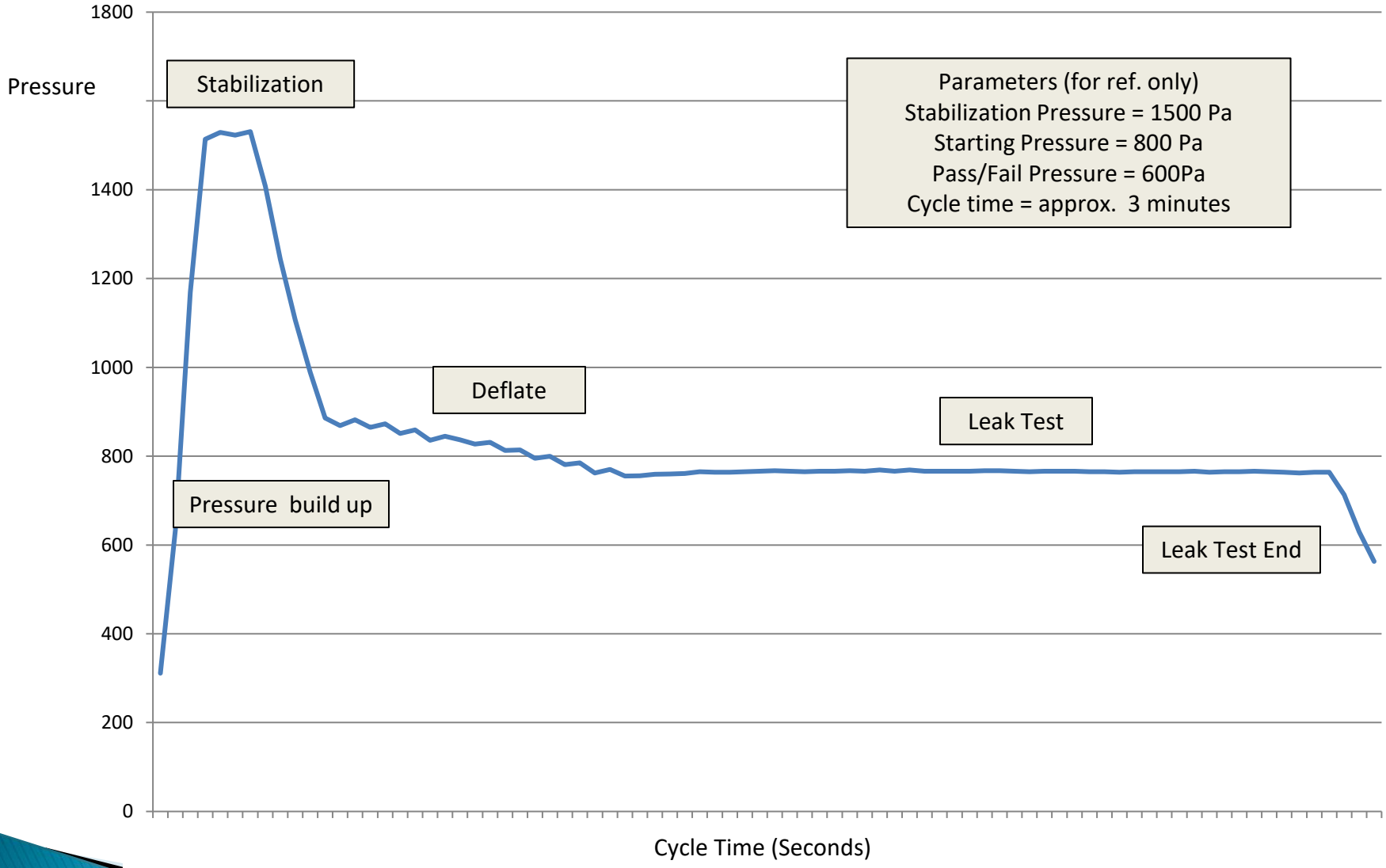
The system detects a leak in the glove under test by comparing the internal pressure of the glove to a pass/fail pressure threshold level after having been pressurized to a set level and held in a sealed condition for a given time duration.

This methodology of leak detection is called pressure decay.

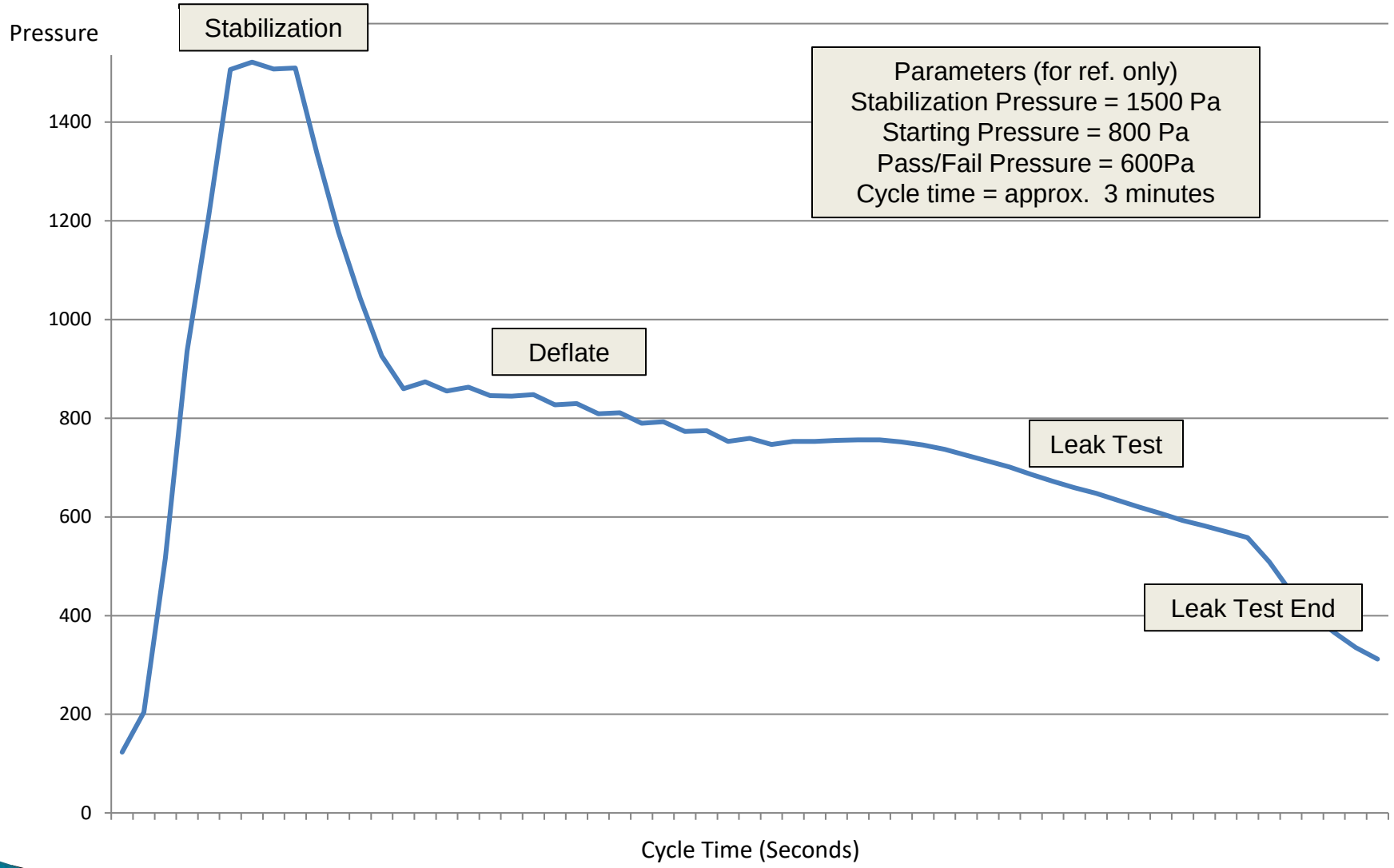
Phases of the Leak Test Cycle

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 = 150 um (0.006 inches) or larger

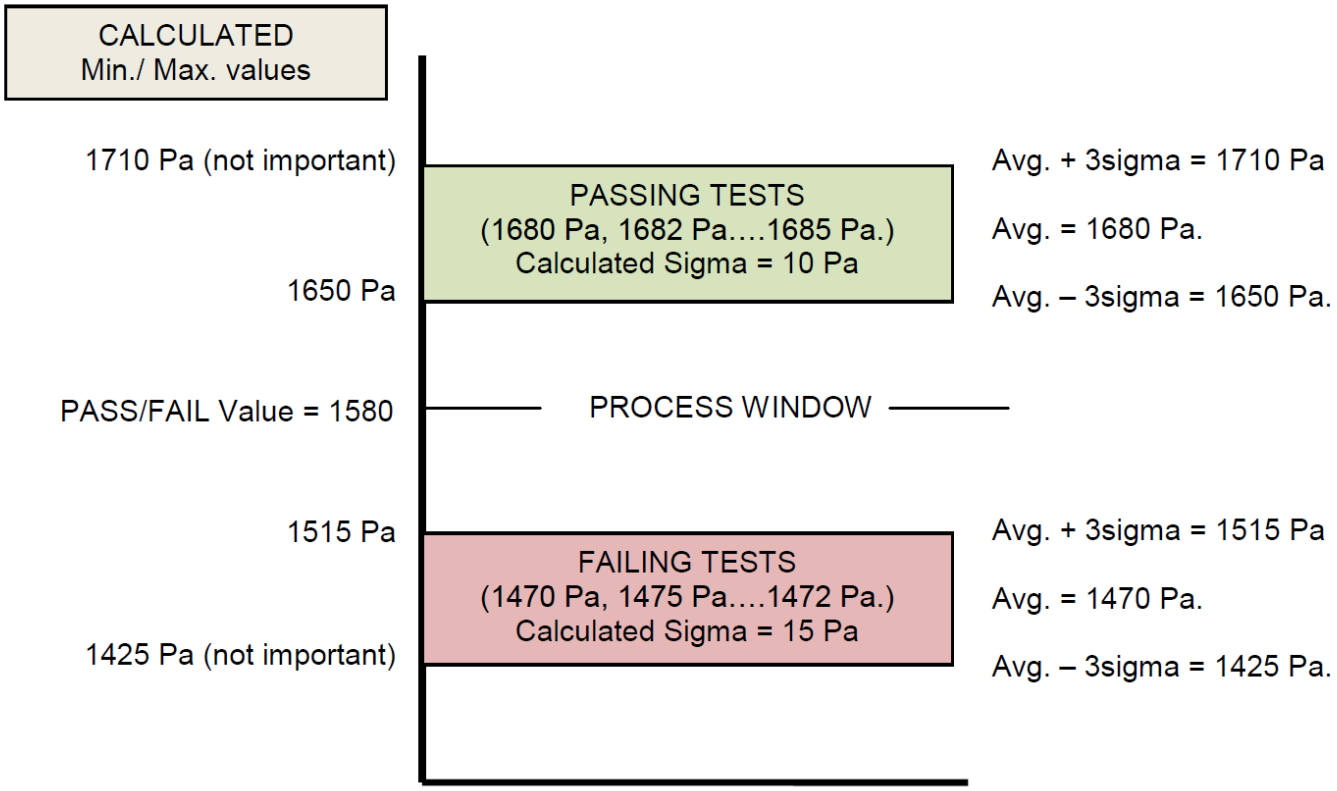
Cycle time parameters to achieve above capability (guideline only)

- 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

Process window determination



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Interface to the Isolator - Options

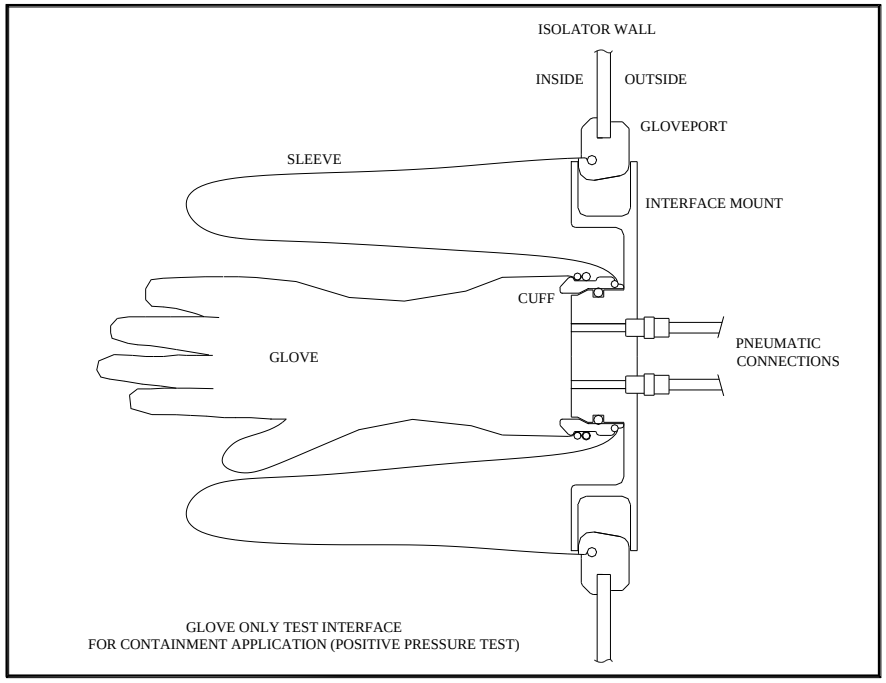
Containment Applications (Positive Pressure Testing)

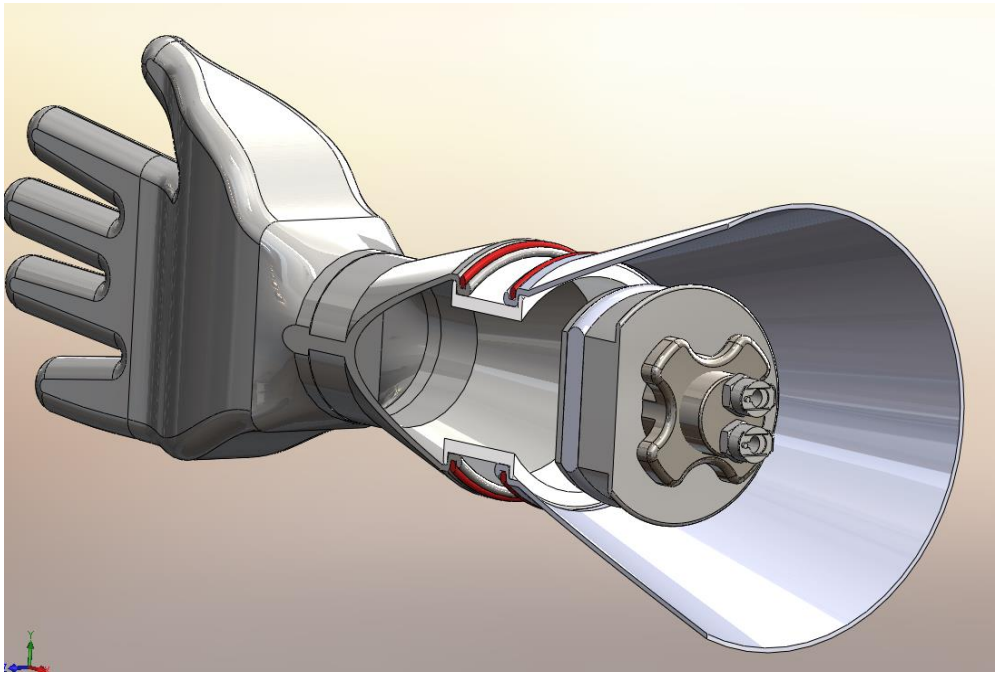
1. Glove Interface
2. Single Piece Gauntlet Interface

Aseptic Applications (Negative Pressure Testing)

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

Glove Interface - Positive Pressure Testing





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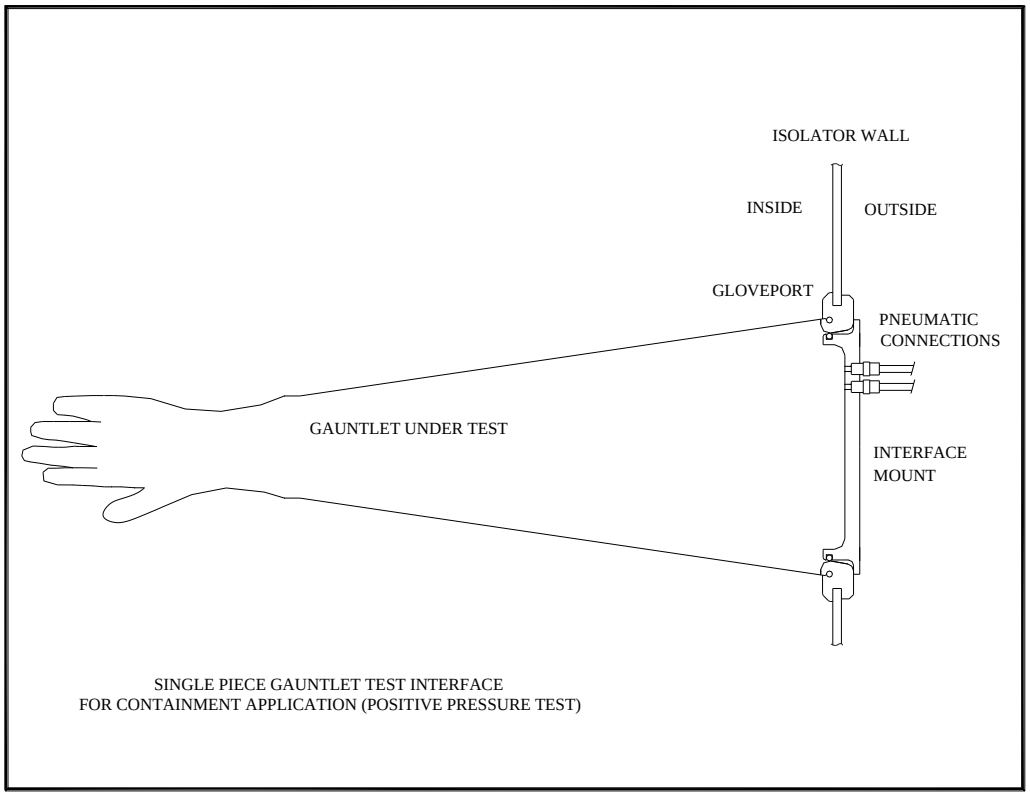
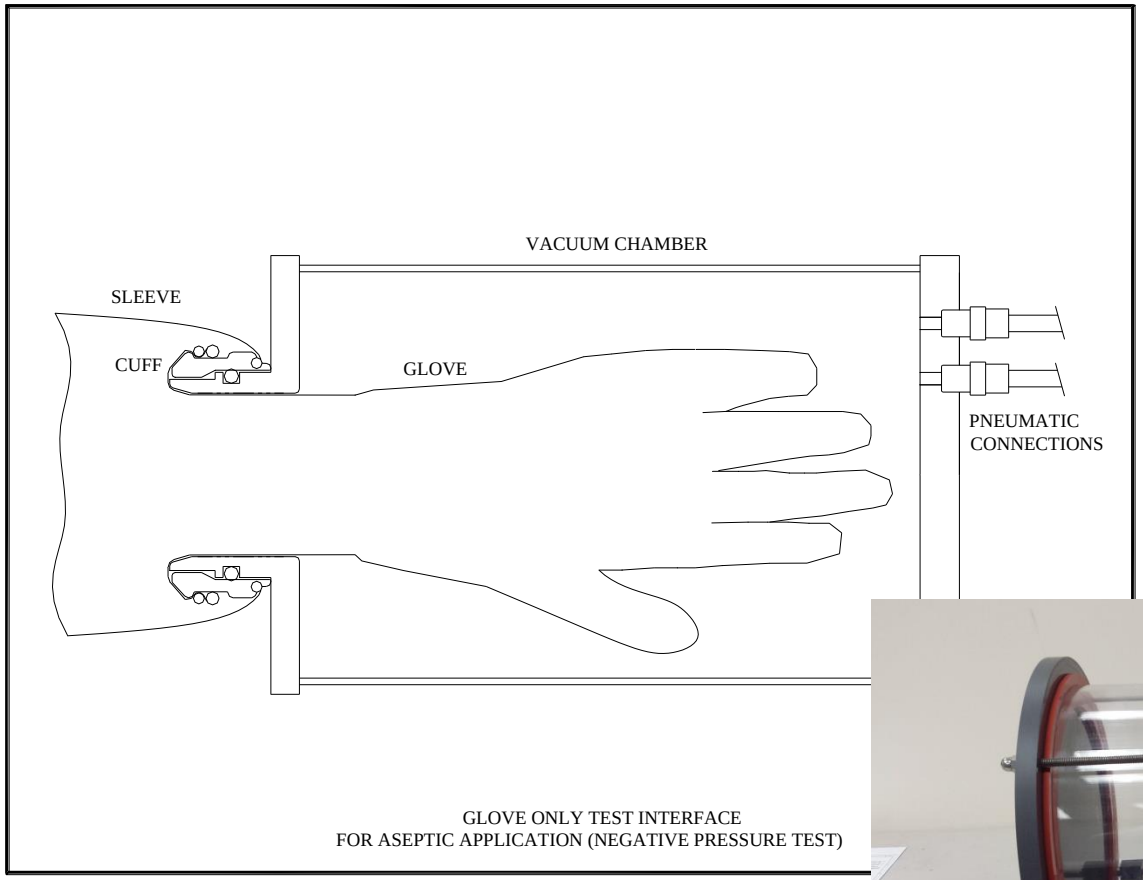
Gauntlet Interface - Positive Pressure Testing

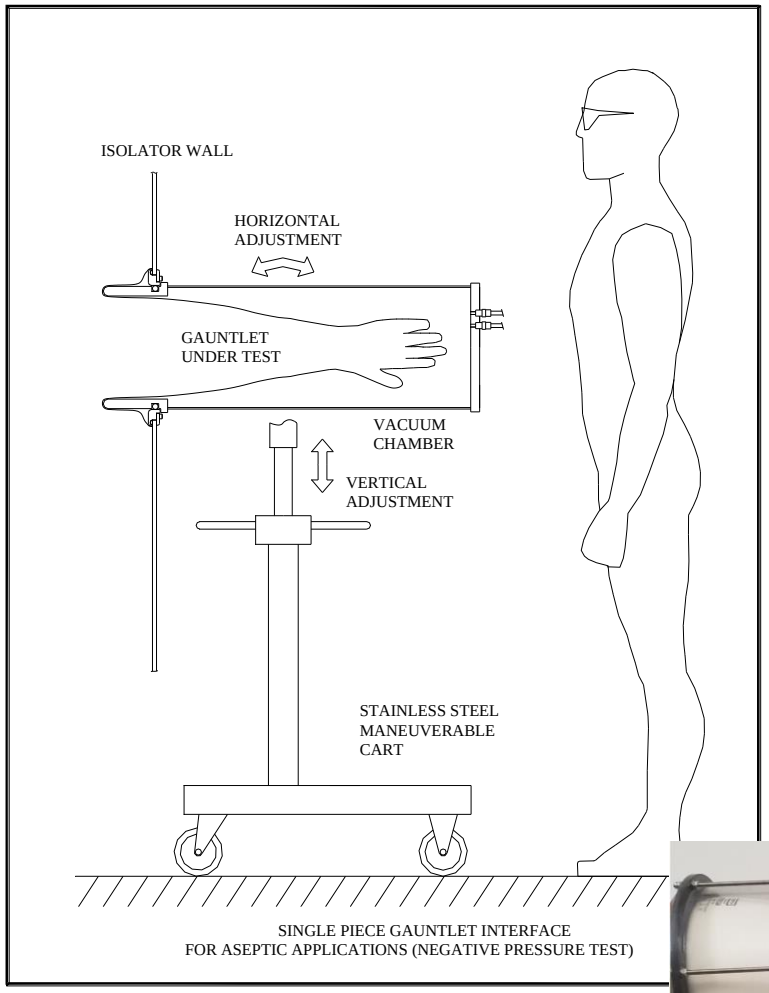


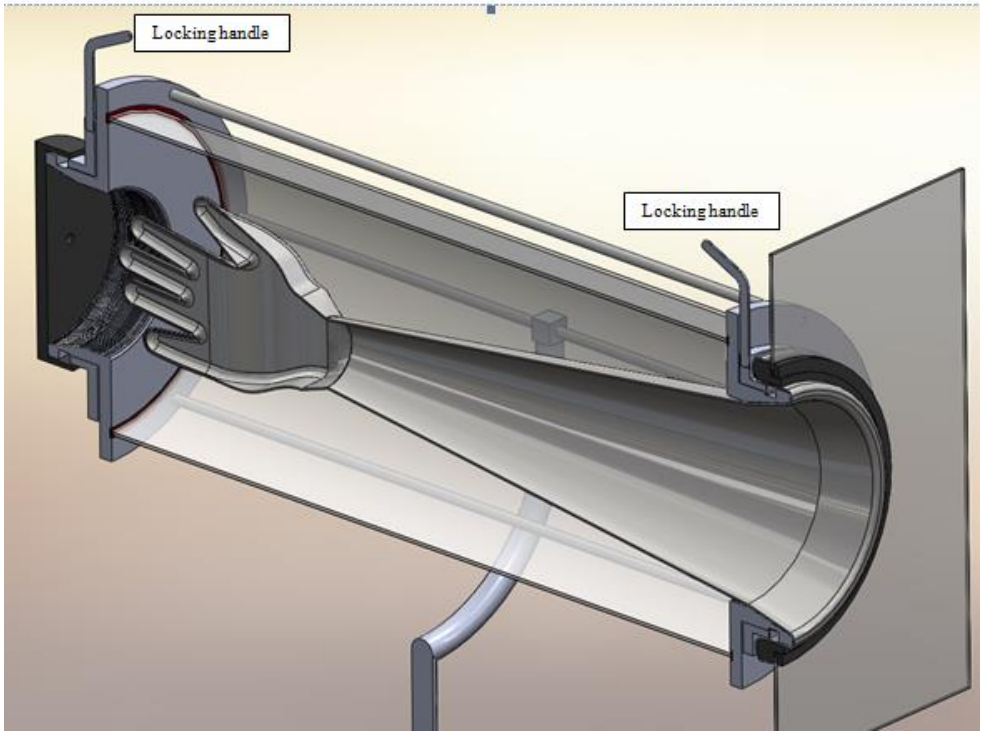
SINGLE PIECE GAUNTLET TEST INTERFACE
FOR CONTAINMENT APPLICATION (POSITIVE PRESSURE TEST)

Glove Vacuum Chamber - Negative Pressure Testing



Gauntlet Vacuum Chamber – Negative Pressure Testing





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Validation Principle

- Obtain a glove known to be leak free (multiple gloves can be used as well)
- Run a minimum of 10 separate tests with and without the DDP supplied test orifice connected
- Determine whether an acceptable process window is present

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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-S1 Glove Testers

	GIT-P4	GIT-P2	GIT-S1
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)

(6) The GIT-S1 tester is not described in this presentation

DDP
Dynamic Design Pharma

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

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