Model GIT-S1

Glove Integrity Tester

Presented by:

Dynamic Design Pharma, Inc.

Carlsbad, California USA

GIT-S1
Single channel glove integrity tester

GIT-S1 Glove Tester

SYSTEMS DESCRIPTION

OIT SCREENS, SECURITY AND DATA OUTPUT

FEATURES

PRINCIPLE OF OPERATION

INTERFACE TO ISOLATOR SYSTEM

IMPLEMENTATION NOTES

DOCUMENTATION

MODEL SELECTION

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GIT-S1

- ✓ Single channel glove test

- ✓ Free standing, stainless steel console on casters

- ✓ Battery operated, minimum 10 cycles per charge

- ✓ Touchscreen Color Operator Interface Terminal (OIT)

- ✓ Wireless and USB port leak test and audit trail data download

- ✓ Gloveport interface holder for ease of transport and use

- ✓ CFR21 Part 11 compliant software

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

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GIT-S1 OIT Screens – Typical

GIT-S1 GLOVE INTEGRITY TESTER

- CYCLE CONTROL
- PARAMETERS
- MAINTENANCE
- UTILITIES
- SECURITY

USER NAME
USER FUNCTION
LOG IN
LOG OFF

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01-01-97 00:00   0

STORE
BITMAP
REMOTE

GIT-S1 CYCLE CONTROL

ACTIVE 0 CONFIRM
ENTER NEW RECIPE 0 CANCEL
0 ACTIVE

GLOVE ID

PRESSURE (Pa.) 0
PHASE TIME (Sec.) 0
CYCLE ET (Sec.) 0

CYCLE STATUS TIME...

USER NAME
USER FUNCTION
0

HOME   START CYCLE   OUTPUT RESULTS

PARAMETER RECIPE 1 THROUGH 5

	1	2	3	4	5
PO	0	0	0	0	0
PS	0	0	0	0	0
PP	0	0	0	0	0
TI	0	0	0	0	0
TS	0	0	0	0	0
TT	0	0	0	0	0
ID	GAUNT.	GAUNT.	GAUNT.	GAUNT.	GAUNT.

INFO ?   PRINT   SAVE   ESC

GIT-S1 UTILITIES   HOME

- ISOLATOR # ENTRY OFF
- SHORTENED TEST CYCLE OFF
- MEMORY STATS
- SYSTEM SET UP
- OUTPUT CONTROL
- DISABLED
- BARCODE TEACH
- PRINT BARCODES
- BARCODE READER

SET UP   CONTROL

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Security Functions

- ➢ Four login levels: Operator, Supervisor, Maintenance 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

- ➢ Maintenance has access to maintenance functions

- ➢ Administrator has access to all functions

- ➢ Electronic signature of each leak test record

Data Output Options

Data Output Options

➢ Remote printing via Ethernet (Optional)

➢ Data storage and retrieval via laptop

➢ Data storage and wireless retrieval

Note:

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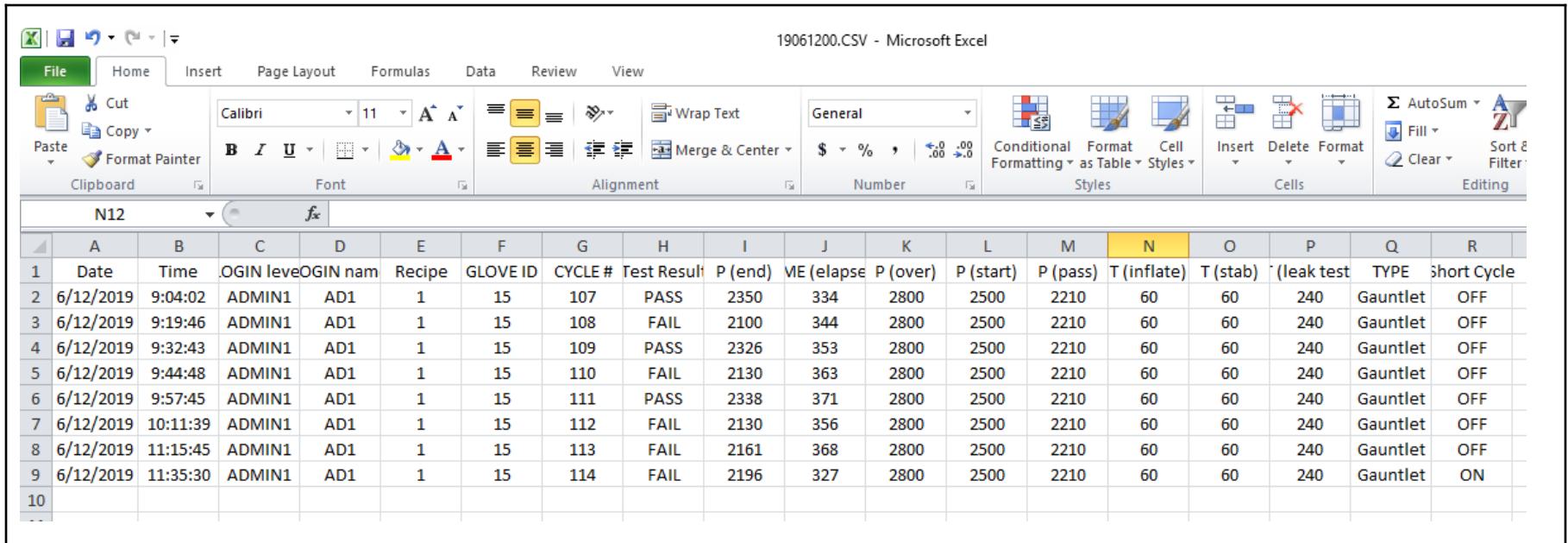
Leak Test Data

➢ Active Recipe

➢ Time/Date Stamp

➢ Login user info

➢ Active Channel

➢ Parameters

➢ Pass/Fail Result

➢ Cycle Duration

➢ Pressure at end of test

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

- A "teaching" functionality allows the programing of the barcode affixed on each gloveport and to the 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 pressure test (pressure decay methodology)
- ✓ Cost effective
- ✓ Barcode Reader functionality
- ✓ Simple operation, validation, training and maintenance
- ✓ Support structure for gloveport interface assemblies

Operation

<u>STEP 1</u>:
Operator installs the glove interface onto glove to be tested and scans the barcode

<u>STEP 2</u>:
Operator starts the leak test cycle

<u>STEP 3</u>:
At the end of the leak test cycle, the operator reviews the results and takes appropriate action. If the results are acceptable, the results are stored within the unit

<u>STEP 4</u>:
When all the test cycles have been run, the operator retrieves the tests results from the unit for archiving purposes

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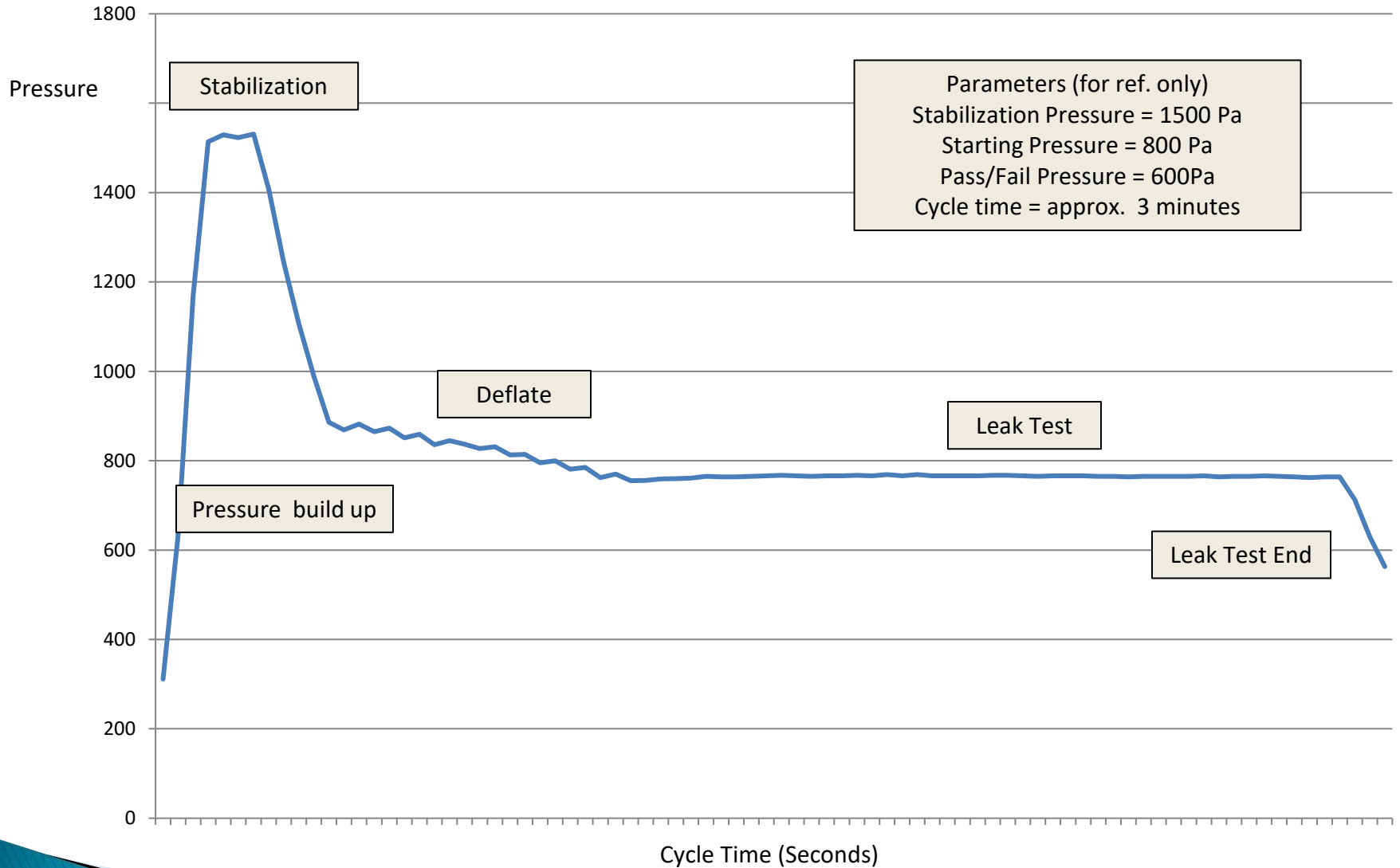
Principle of Operation

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.

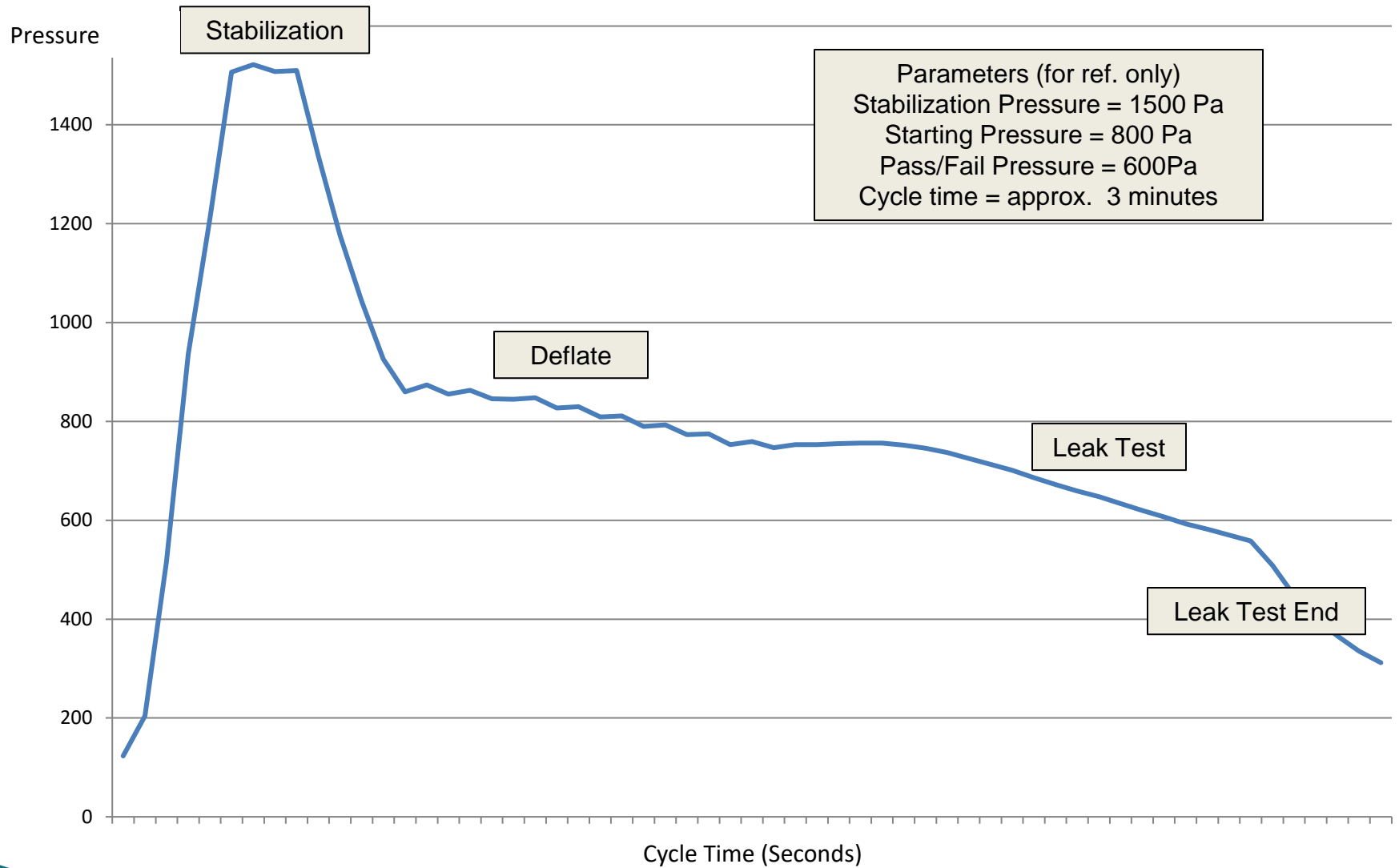This methodology of leak detection is called pressure decay.

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)

DDP
Dynamic Design Pharma

Pressure

Stabilization

Parameters (for ref. only)
Stabilization Pressure = 1500 Pa
Starting Pressure = 800 Pa
Pass/Fail Pressure = 600Pa
Cycle time = approx. 3 minutes

Deflate

Leak Test

Pressure build up

Leak Test End

Cycle Time (Seconds)

Leak Test Diagram (Failing Test / Glove)

Pressure

Stabilization

Parameters (for ref. only)
Stabilization Pressure = 1500 Pa
Starting Pressure = 800 Pa
Pass/Fail Pressure = 600Pa
Cycle time = approx. 3 minutes

Deflate

Leak Test

Leak Test End

Cycle Time (Seconds)

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System Capability – Glove Testing

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

Note: the above parameters are shown for reference only and are not representative of an actual system

System Capability – Gauntlet Testing

Hole size detection capability = 150 um (0.006 inches) or larger

Cycle time parameters to achieve above capability (guideline only)
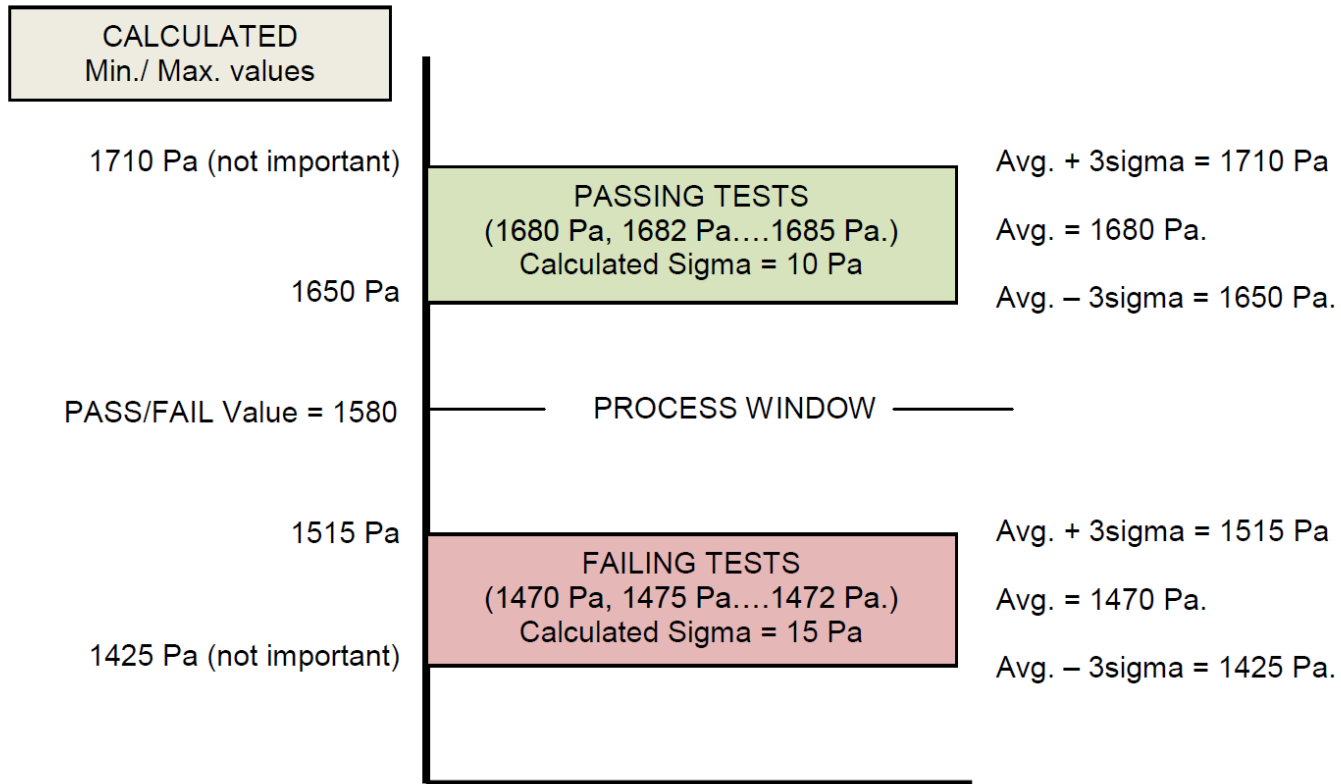
- Inflate time: 60 seconds (approx.)
- Stabilization = 120 seconds
- Leak test = 360 seconds

Certainty of detection with > 3 sigma confidence

Certainty of no false positives with > 3 sigma confidence

Note: the above parameters are shown for reference only and are not representative of an actual system

Process window determination

CALCULATED Min./ Max. values		
1710 Pa (not important)		Avg. + 3sigma = 1710 Pa
	PASSING TESTS (1680 Pa, 1682 Pa....1685 Pa.) Calculated Sigma = 10 Pa	Avg. = 1680 Pa.
1650 Pa		Avg. – 3sigma = 1650 Pa.
PASS/FAIL Value = 1580	PROCESS WINDOW	
1515 Pa		Avg. + 3sigma = 1515 Pa
	FAILING TESTS (1470 Pa, 1475 Pa....1472 Pa.) Calculated Sigma = 15 Pa	Avg. = 1470 Pa.
1425 Pa (not important)		Avg. – 3sigma = 1425 Pa.

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

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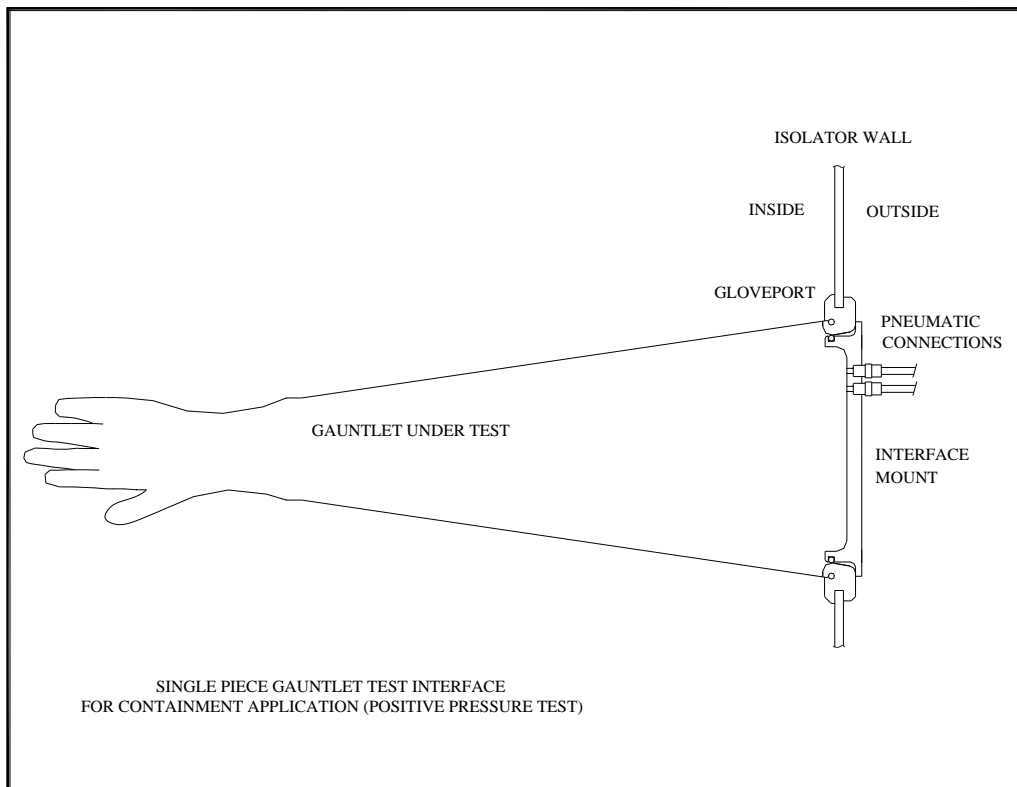**INTERFACE TO ISOLATOR SYSTEM**

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MODEL SELECTION

Gloveport Interface

1. Standard proven design

    1. Molded silicone seal that is compressed to seal against the gloveport

    2. 6 knobs that the operator tightens to create the proper seal

    3. Machined plastic plates

    4. Leak tight pneumatic connections

2. Customized geometry to fit the customer's gloveport system

Gauntlet Interface - Positive Pressure Testing

ISOLATOR WALL

INSIDE   OUTSIDE

GLOVEPORT

PNEUMATIC
CONNECTIONS

GAUNTLET UNDER TEST

INTERFACE
MOUNT

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

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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

- Factory Acceptance Test (executed)

- IOQ Protocol (ready for execution)

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All Dynamic Design Pharma's Glove Tester Models

	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-P2 and the GIT-P4 testers are not described in this presentation

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