

CUSTOMER:

REFERENCE:

GLT SYSTEM – GLOVE LEAK TESTER

PRODUCT SPECIFICATION

The glove of an isolator constitutes the weakest link in the containment barrier. GLT system allows “in situ” glove testing without breaking the sterility and thereby stopping the use of the isolator.

APPLICATION

The GLT system is stand-alone mobile system used to test isolator gloves. Simple to operate (approximately 6 minutes to test one glove), the equipment is capable of detecting a glove perforation not visible to the naked eye (can detect 40 µm diameter pin hole).

The standard equipment is designed for use with Getinge-La Calhène glove cuff ring system (type RAC 100).

KEY FEATURES

- A polyester housing
- Test chamber
- Control system:
- Automatic PLC control (Siemens)

QUALITY STATEMENT

Confidence in the Getinge Group is the most important quality criteria. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for continued competitive and successful enterprise.



STANDARDS & CODES

The GLT system complies with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards.

Electrical requirement

- Directive n° 89/336/EEC amended 92/31/EEC
- Directive n° 73/23/EEC

Automation regulations

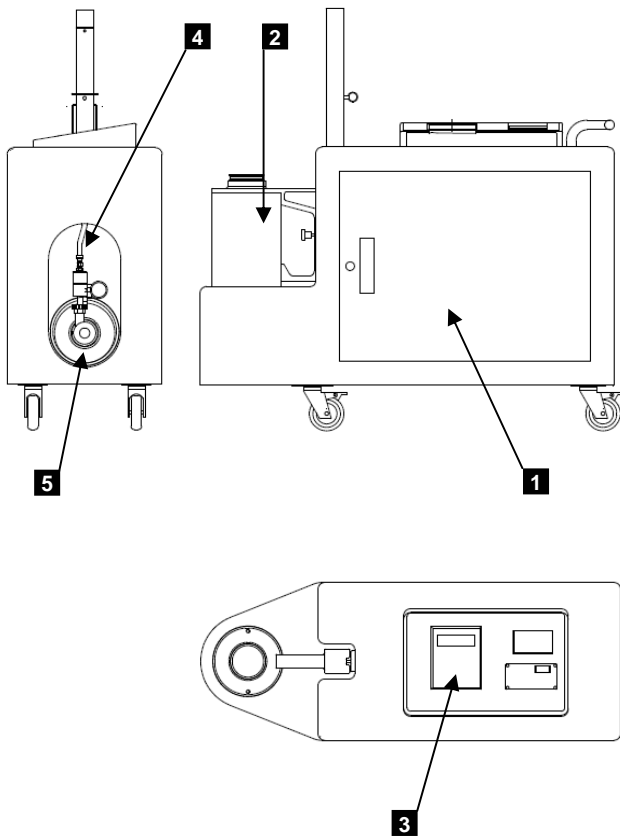
- GAMP4 procedures (optional), current guidelines are followed in all our documentation and validation support materials.
- 21CFR Part 11 capable in accordance to the PLC capabilities

DESCRIPTION

PRODUCT DESCRIPTION

The GLT system is composed of 5 parts:

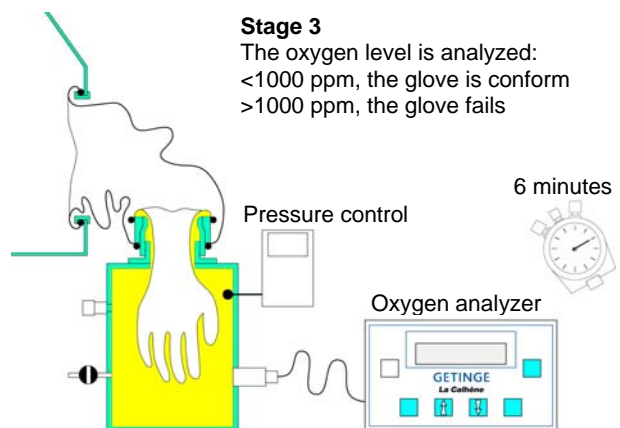
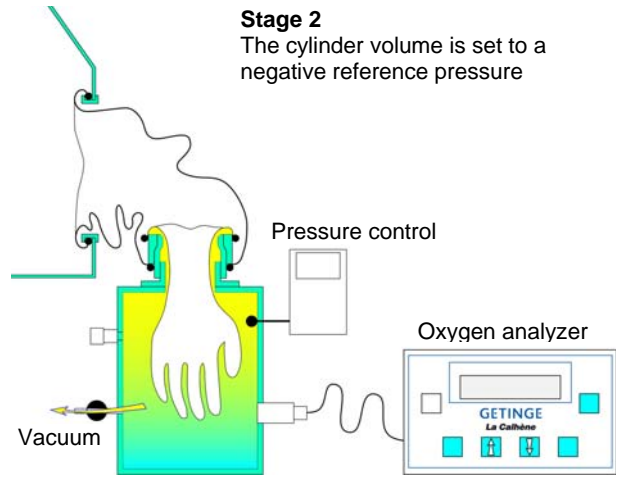
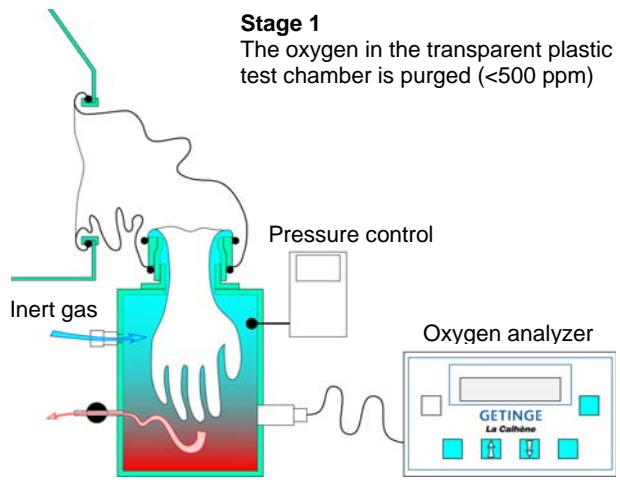
- Housing **1**
- Test chamber **2**
- Control system **3**
- Connector for inert gas **4**
- Bottle housing **5**



PRINCIPLE OF OPERATION

Analysis of content inert gas

- The glove is inserted into a test chamber to the cuff level, providing a closed volume purged with inert gas
- After purging, the volume is reduced to a negative reference pressure and the oxygen level analysed
- The duration of the test is approximately 6 minutes (not including the start up cycle)



BASIC DESIGN FEATURES

Design features and material definition conform to the specification listed below, unless specifically mentioned as optional.

Housing

The housing is made of in polyester, mounted on four casters with brakes

Test chamber

The test chamber is made of in transparent plastic (with an orifice for the glove cuff ring) monted on a adjustable mast. The test chamber has a handle for easier handling, and a locking pin used to hold the test chamber in working position on the mast. A mast extension is included for use to test gloves located at a height of over 720 mm.

Control system

The operator/machine interface is done via the printer and the PLC control console

The control console comprises:

- Alphanumeric keyboard to enter requested values or information
- Function keyboard to navigate between the different menus
- Display screen

The printer is used to print the alarms, the recipe and the phase reports



Connector for inert gas

A coupling allows to connect of the GLT system to an external inert gas source.

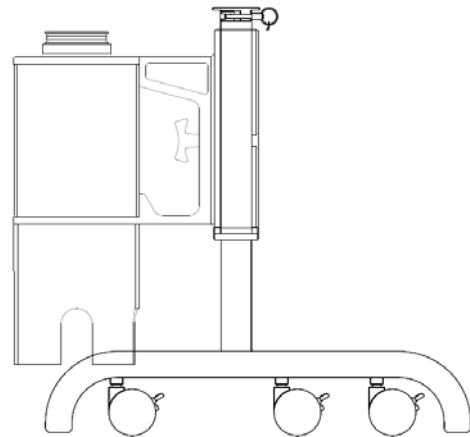
Bottle housing

A housing optional allows an inert gas bottle to be installed inside the unit. The housing includes a lock with a pin to hold the bottle in place.

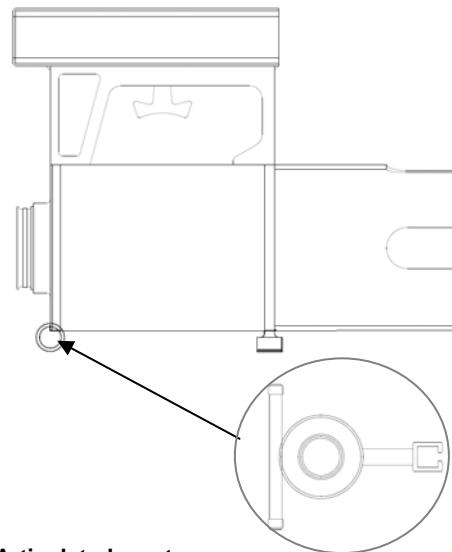
PROCESS FEATURES AND OPTIONS

For testing gloves with limited accessibility, there are 3 options to mount the test chamber, with the possibility to add a 4 meters flexible pipe.

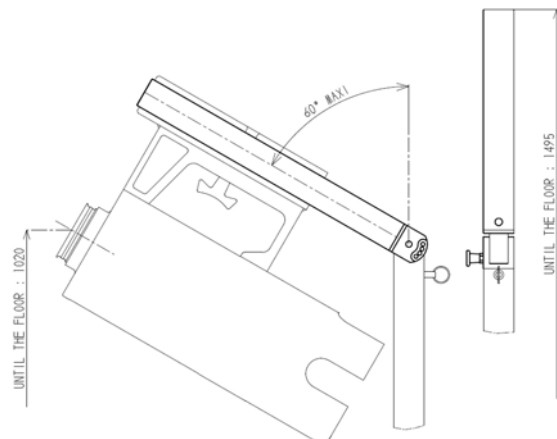
Mobile trolley



Horizontal support



Articulated mast

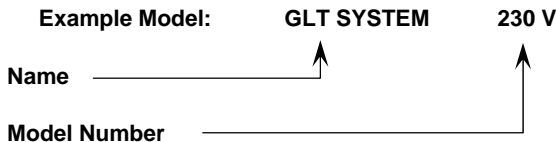


ORDERING

ORDERING

Description

Use the description below, with the dimension table to select the appropriate model.



- GLT SYSTEM 230 V
- GLT SYSTEM 115 V

DIMENSIONS (Detail see page 6)

OPTION LIST

Testing gloves with limited accessibility

- Mobile trolley
- Horizontal support
- Articulated mast
- Flexible pipe (4 meters)

On-board inert gas bottle

- Nitrogen U bottle (oxygen contents < 5 ppm)

Calibration

- Kit calibration

SERVICES

The GLT system is inspected before shipment. This operation is carried out by our Inspection Quality Department following the inspection plan. The inspection plan describes the manufacturing process and inspection. It gives the input and output data of the different phases of the product manufacturing and inspection. Inspections sheets are signed by the Inspection Quality Department.

Option:

FAT validation protocol (Factory Acceptance Test), written according to GETINGE-La Calhène format and test procedure. The protocol is sent to the customer before test execution.

Documentation

Standard:

- English language
- French language
- Assembly drawing(s) and parts list(s)
- Electrical file(s)
- Technical documents (component data sheet)

- User manual(s)
- Inspection
- Certificates (material certificate main parts and the calibration certificates of the equipment used during the test)
- Acceptance reports

Option list:

- Other language:
- Factory Acceptance Testing (include the standard documentation in place of the inspection notes)
- Software package
- Detail Design Specification (DDS)
- Software validation package

PACKING AND OPTIONS

Packaging identification

- Item reference
- Quantity
- Assembly

Packing method

- The GLT system will be packed according to the agreed method of shipment

Storage conditions

- storage temperature (16°C and 24°C)

SHIPPING AND OPTIONS

- Shipping by air
- Shipping by sea
- Shipping by road (distribution service)
- Shipping by road (direct carriage)

INSTALLATIONS

Limits of use / specification

- Test time for one glove
6 minutes on average
- Start-up time (preheating)
For 230 V: about 3 minutes
For 115 V: about 9 minutes
- Endurance
Unit with bottle option: about 35 cycles
- Power consumption
Nitrogen or inert gas: 60 liters / cycles
- GLT system protection index:
IP 30
- GLT system weight:
Without inert gas bottle: 72kg
With on-board inert gas bottle: 88kg

Environment

GLT System must not be installed in non explosion-proof environments

- Ambient temperature range:
16°C to 24°C
- Relative humidity
25 to 85% non condensing

Electrical

- Power supply:
AC 207 to 244 V, 50 to 60 Hz.
AC 103.5 to 122 V, 50 to 60 Hz
- Power consumption
805 VA max
- Compatible earthing system:
IT, TT, TN.
- Breaking capacity:
IT earthing system: 3 kA
TT / TN earthing system: 20 kA.
- Testing voltage (*standard test*):
As per NFC 20 030
Classification of II excess-voltage, degree of pollution 2.
- Electrical safety device:
As per NFC 20 030
- Electromagnetic compatibility:
EN 50081-2
EN 50082-2

GLOSSARY

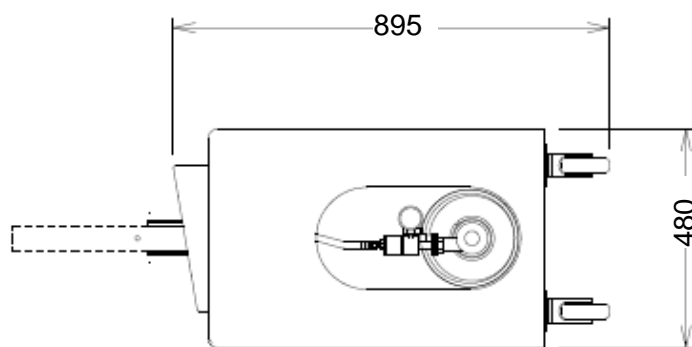
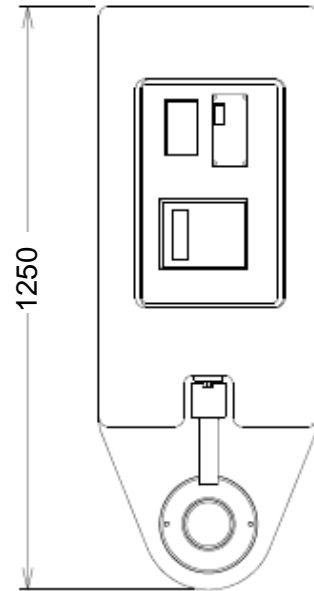
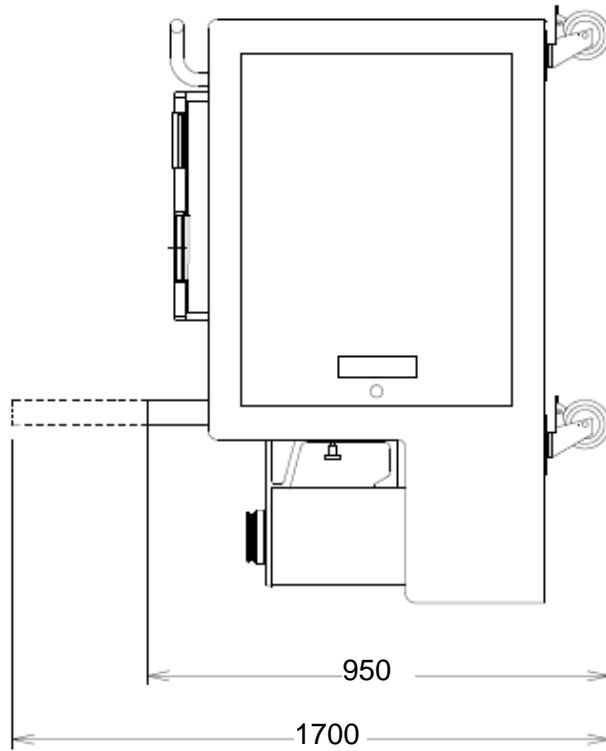
GAMP: Good Automated Manufacturing Practice

PPM: Parts per million

GETINGE

La Calhène

DIMENSIONS (diagrams)





GLT SYSTEM – FP 300 – rev October - 2008

Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

La Calhène

Getinge-La Calhène
1 rue du Comté de Donegal, F-41102 Vendôme, France
Tél.: +33 [0] 254 734 747
Fax: +33 [0] 254 734 748
www.lacalhene.com

GETINGE

THE GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. Equipment, services and technologies are supplied under the brands **ARJO** for patient hygiene, patient handling and wound care, **GETINGE** for infection control and prevention within healthcare and life science and **MAQUET** for surgical workplaces, cardiopulmonary and critical care.