► GITS®4 Software compliant with GAMP 5, CFR 21 Part 11 and EU Annex 11

► FDA and cGMP compliant

► ISO:9001 certified

► MK can help you to meet the Annex 1 glove leak testing requirements with minimum impact to your production schedules:

Integrity testing of the barrier systems, and leak testing of the glove system (…) performed minimum at the beginning and end of each batch is possible in an easy and fast way

To make your glove testing process easier and faster and for more information contact us:

MK Versuchsanlagen und Laborbedarf e.K.

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35325 Muecke-Merlau
Germany

sales@mk-versuchsanlagen.de
☎ +49 6400 – 9576030
www.mk-versuchsanlagen.de

Scan me

Full Automatic Glove Tester

MK Glove Test Device Generation 3

Your solution to meet EU GMP Annex 1 changes!

- FDA and cGMP compliant
- Customizable to your port size
- 100% Made in Germany
- Easy cleaning, H_2O_2/VHP fumigable
- Complete qualification service
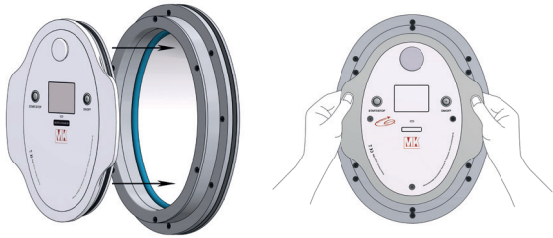- Usable as stand-alone or fully integrated system

Easy to Use

1 Insert Glove Tester

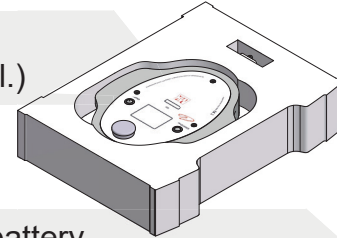## 2 Turn on Glove Tester

MK

xx   Pascal

Insert device into a port.
Then press Start.

xxxxxxxxxxxxxxx

3 Start measurement

MK

xx   Pascal

Inflating glove
Filling to xxx Pascal

xxxxxxxxxxxxxxx

Features

Total test time
- 8 – 15 Minutes (depending on glove material and port size)

MK Glove Integrity Test System - GITS®
- Traceability of glove testing
- Port and glove recognition with integrated RFID technology
- Automatic machine validation and generated reports

MK Glove Life Cycle System - GLCS®
- Monitoring of glove aging process
- Recognize glove failure in advance
- Glove life cycle tracking, from inventory to sterilization, through testing to replacement

Measurement: Demo Machine B   (started: 04. Feb 2020 12:02:26)

Accessories and Services

Transportcase for smooth delivery (incl.)
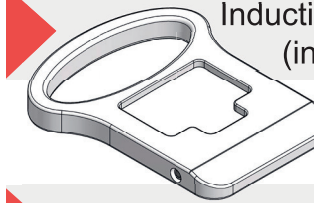
Inductive battery (incl.) and charging station

Specific glove test parameters

Service trolley for up to 18 test devices with included charging stations
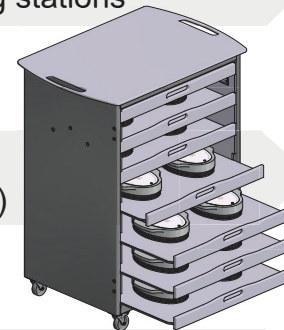
Qualification services (IQ, OQ, PQ and more)
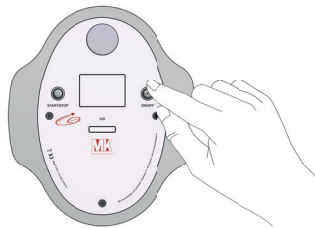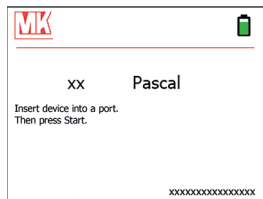
Service and maintenance

WLAN site survey and planning