

Regulatory requirements

- FDA and cGMP compliant
- Compliant with GAMP 5, CFR 21 Part 11, EU GMP Annex 1 and Annex 11
- ISO:9001 certified
- MK can help you to meet the Annex 1 leak testing requirements with minimum impact to your production schedule:
Integrity testing of the barrier systems, (...) performed minimum at the beginning and end of each batch is possible in an easy and fast way
- Easy integration into existing GITS® 4 software

Your solution to meet EU GMP Annex 1 changes

- Customizable to your port size
- 100% Made in Germany
- Easy cleaning, H₂O₂/VHP treatment
- Complete qualification service
- Usable as stand-alone or fully integrated barrier system



Fully automatic Transfer System Tester

MK TST Alpha / Beta

Your solution to meet EU GMP
Annex 1 requirements



Contact us

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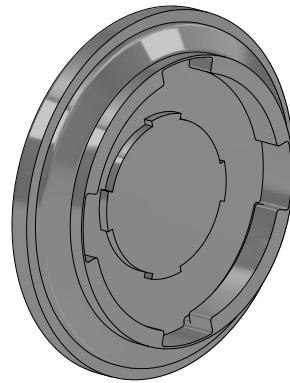
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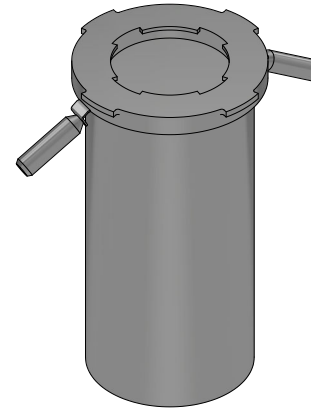


Easy to use

1 TST Alpha Port

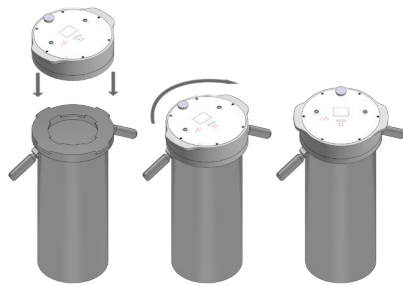


Alpha Port

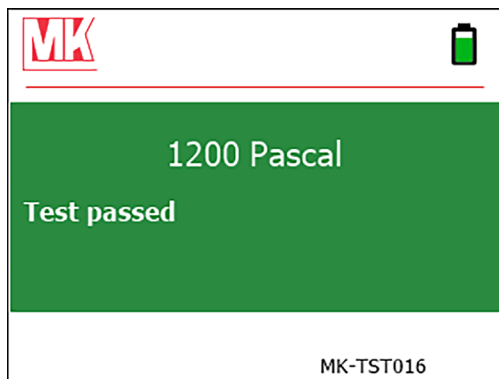


Beta Container

2 TST Beta Container



3 Start measurement



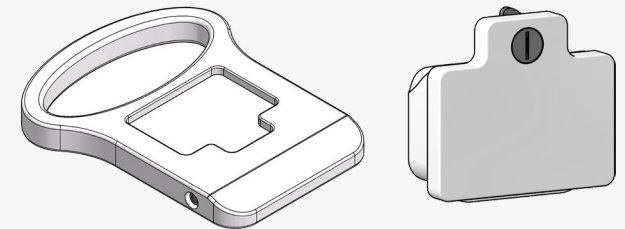
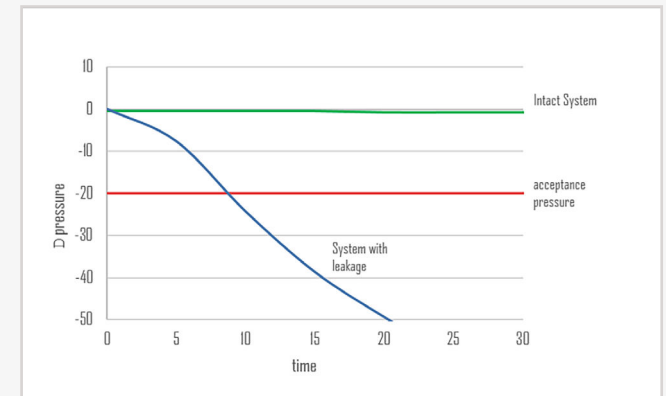
Features

- Integrated in your existing GITS® 4 system
- Integrated WLAN functionality and optional RFID recognition
- Administration of recipe parameters and users
- Creation of PDF measurement reports
- Integration into product life cycle tracking via GLCS® software
- MES and SCADA integration possible

Accessories and services

- Specific test parameters
- Qualification services (IQ, OQ, PQ and more)
- Service and maintenance
- WLAN site survey and planning

Parameter development



- Inductive battery (incl.) and charging station