Product Information
Glove Testing System WiFi
• Simultaneous and parallel measurement of 35+ gloves controlled by GITS® software allows for timesaving glove integrity testing

• Reliable in-situ testing without jeopardizing glove integrity by glove removal or manipulation

• 100% mobility lightweight and completely wireless glove testing system

• Customizable to your requirements in size and shape, even in form factor and material

• Port and glove detection integrated RFID technology enables automatic machine validation and glove lifecycle tracking

• Superior hole detection of holes smaller than 100 µm while maintaining short measurement times

• Fast glove integrity verification typically commencing from 8 - 15 minutes total test time, depending on glove material

• Easy cleaning and sterilization glove tester build with minimal grooves and edges

Long operating time for repetitive measurements to validate your entire isolator/RABS without troubles

Electronically controlled clamping and sealing of glove port with pneumatic inflated rubber seal

Status-related information Pressure gauge, battery status, measurement information and results shown on digital display

Simplicity of operation intuitive two button interface

Automatic glove filling no additional air supply needed with automatic glove filling pump

alternatively:

Manual initial glove filling external pressure allocation through handle with integrated air filler valve

Cleanroom suitable IP64 certification and easily replaceable 0.3 µm filter for air intake

Slim and ergonomic design thin casing of only 2.5 cm for manual initial filling and 5 cm with automatic glove filling
Simultaneous and parallel measurement

The Glove Testing System WiFi is a software-assisted glove testing system enabling you to test your gloves fast and efficiently. With this system you can test all gloves in your isolator/RABS simultaneously and regain valuable production time of your plants. The flexibility of the system even allows to run multiple test batches in parallel, allowing you to begin testing as soon as the first glove tester is prepared and thus further reducing overall testing time.

For more information on automated parallel testing please see: GITS®-Software Feature Information – General Features; page 7

Port and glove detection

Integrated RFID technology allows to reliably identify tagged glove ports, thus automatically recognizing the current measurement position of a glove tester in your isolator/RABS. In combination with automated software features this extension allows to validate your machine easy, fast and 100% reliable.

With our worldwide unique glove recognition, chipped gloves are identified by the GITS®-software allowing for glove lifecycle tracking, as well as long-term tracing and analysis to proactively learn which gloves need to be replaced before a breach in glove integrity occurred.

For more information on automated software features and glove lifecycle tracking please see: GITS®-Software Feature Information – Advantages of automatic port and/or glove detection through RFID technology; page 7/8

Reliable in-situ testing

In contrast to the downsides of glove integrity tests through visual inspection, water leakage tests or diffusional test with chemicals, our glove tester utilizes the pressure drop test which eliminates drawbacks and unifies all benefits. This testing method is a highly reproducible, human-independent way to test the glove integrity without inducing contamination and minimizing wear and tear of the glove. It allows to test each glove in-situ inhibiting a probable glove integrity breach due to glove removal, manipulation or during re-assembly.

100% mobility

Our system is built for the highest degree of mobility. The lightweight glove testers equipped with WiFi communication to transmit all data to the corresponding computer, whether it is placed right next to the device or in any other room within the same WiFi network. If the glove testers are equipped with the automatic glove filling pump not even a temporary pressure connection is necessary. Even if glove testers with manual initial glove filling were chosen, the system offers complete mobility by use of our portable pharma pump for glove inflation.
Superior hole detection

Though our glove testers are feature packed the most important part, the detection of holes, stays our priority. Through constant research and development we offer superior hole detection capabilities of holes even below 100 µm (if the glove material properties permit it) while maintaining short measurement times.

Fast glove integrity verification

Concurrently to superior hole detection our research and development aims for fast glove integrity verification enabling to check for these small holes in 8 - 15 minutes total test time and even faster for bigger holes for most glove materials.

Easy Cleaning and Sterilization

With the need to regularly clean and sterilize in mind we developed a glove tester design with minimal grooves and edges. The flat front with shallow buttons, the cover printing from inside and the round handle all represent this philosophy trying to simplify the cleaning without compromising the functionality.
Customizable to your requirements

The deep vertical range of manufacture at MK Versuchsanlagen allows to customize our glove tester in almost every imaginable aspect. For construction of a glove tester we check for special requirements with the customer first. Subsequently the geometry of the port is acquired and mathematically modelled for construction. Thereafter construction of molding components for manufacturing of the seals, CNC cutting of main parts and crafting of smaller components is carried out parallel to the assembly of electronic components, leading to the joining of the single parts for the finished glove tester. Since all is done at MK Versuchsanlagen we are proud to offer you the following solutions and options for your glove tester requirements:

- Customizable in size
- Customizable shape, i.e. round, oval or flat-oval

• Manufactured from PVC or POM. Other materials, i.e. conductive polyethylene, usually available on customer request
• Port sealing from inside or outside
• Individualized constructions for specific requirements, i.e. small port sizes of 150 mm diameter

For further questions to any required individualization of glove testers please contact us.
Status-related information

To guide the operator through each measurement the digital display shows status-related information. On screen messages notify about what to do next or which procedure is currently carried out by the glove tester. After completion of the glove integrity test the result is displayed until the device is removed by the operator. Therefore the operator always has all information directly available without the need to check the computer.

Simplicity of operation

A user friendly interface with only two buttons was chosen to make the handling as easy as possible. The almost fully automatic execution of glove testing combined with status-related information on the digital display allow the glove tester to be operated intuitively.

Automatic glove filling

To fully simplify the task of glove testing and eliminate the time-consuming work of manually allocating pressure a dedicated pump for fast, automatic glove filling is built into our devices. Thus removing the need for a pressure terminal and the hassle to manually carry out the initial glove filling. If nevertheless desired we also offer an option with an integrated air filler valve for manual initial filling.

Cleanroom suitable

For usage in cleanrooms we make sure that our glove testers are protected against ingress of dust as well as against splashing of water. Hence, our glove testers are certified by IP64 protection class utilizing easily replaceable 0.3 µm air filters for air intake.

Long operating time

Even after several measurements you do not have to worry about battery depletion. The external battery of our glove testers offers extended operating time for standard glove integrity tests. For constant heavy-duty usage of a glove tester without intermediate charging, the external battery can be exchanged in seconds allowing to continue the work without interruption. On customer request we also offer a battery integrated into the glove tester with an external charging connector.

Electronically controlled clamping and sealing of glove port

An EPDM-rubber seal is pneumatically inflated by the integrated pump to fix the glove testers into the glove port and securely seal it. To ensure a proper sealing, the pressure is constantly monitored and inflation is adjusted when necessary.
General Features

The Glove Integrity Test System software (GITS®-software) by MK is the visual interface to control all WiFi glove testers with one computer. Multiple devices can be measured simultaneously and even several parallel measurements with different glove integrity test parameters are possible.

We developed the software GAMP 5 and EU Annex 11 conform simultaneously with the focus on intuitive handling and ease of use for operators and administrators. For operators the available options are reduced to the functions needed for glove testing while administrators receive full control over the settings. To simplify the administration the software supports active directory for the user management and features a recipe management to define different glove integrity test parameters.

After completion of a measurement and optional filling of comment fields, the software can automatically create the measurement reports electronically or with automatized printing. To comply with internal company standards the reporting can be customized to your requirements and needs due to a separated report engine. The generated electronic and paper reports are trustworthy, reliable and immutable, complying with 21 CFR Part 11 of the Code of Federal Regulations.

Advantages of automatic port and/or glove detection through RFID technology

With the optional RFID technology for the glove testers and the GITS®-software, the full potential of this system can be harvested. The automatic recognition of ports allows the software to detect the position of each inserted glove tester and therefore actively control and check the carried out measurements. As a consequence the software fully controls the validation of your isolator/RABS and prevents human errors such as the accidental skipping of a port.
To simplify the glove integrity testing for operators we introduced “Machine Validation View”, showcasing your isolator/RABS with its ports and their current test status. Thus giving a direct overview about the validation progress.

![Machine Validation View in GITS®-software (part of a RABS)](image)

An additional benefit of RFID port detection is the option to fully automate your machine validation. The implemented autostart feature detects inserted glove testers automatically and triggers the measurement with the preselected parameters. The software controls the inflation of the gloves to the appointed pressure and performs the measurement. The port detection allows the software to automatically allocate a measurement and, if desired, subsequently finalize it after completion. As soon as every measurement was successfully finalized your isolator/RABS can be validated automatically and the corresponding reports will be created. The operator has to take care about inserting the glove testers only.

The RFID glove detection enables to track and analyze the complete lifecycle of a glove. By easy to use RFID scanners the storage supply of gloves, executed sterilization of gloves and glove age can be tracked. With this information the GITS®-software for example can automatically warn operators or halt execution if sterilization was not executed or if the glove age has exceed a maximum value. Concurrently minimum stock level is monitored.

Glove and port detection information combined complete the lifecycle tracking and allow for full traceability of a glove's testing results including its position in a isolator/RABS. With an independent analysis software this data can be utilized to perform statistical analysis of measurements relating to a port and/or glove, thus giving the opportunity to recognize possible failure of gloves in advance and determine critical positions for glove damage in your isolator/RABS.

Software customization and integration

On customer demand our in-house IT department can modify the software to your needs or assist with the integration in your existing systems, for instance the addition of customer specialized features, or active control and lock functions of an attached isolator/RABS if scheduled glove tests are due.
MK Versuchsanlagen is strongly committed to customer satisfaction and doesn't stop support with the selling of a product. To ensure proper functionality of the glove testing system over its lifetime, MK Versuchsanlagen is proud to offer the following services to its customers:

Custom glove integrity test parameters

Our research and development team constantly performs measurements with different glove types and hole sizes to further improve the already superior detection capabilities, reduce measurement times and find means to make measuring even easier and more efficient. Thus we have a broad knowledge, backed up with our database, of suitable testing parameters. If desired we assist you with defining the right parameters for your needs or we develop parameters for gloves we have not used before.

WiFi site survey and WiFi planning:

Advantages of WiFi based glove testing systems only pay off if a stable signal is established between the glove tester and the access point/s. To ensure proper communication MK Versuchsanlagen offers to perform a WiFi site survey measuring signal strength, interference, ping loss and more for defined access point positions to find a suitable position.

For more complex facilities MK Versuchsanlagen offers to carry out the entire WiFi planning and installation with multiple access points to guarantee seamless communication across the entire isolator/RABS.

Example analysis of a WiFi site survey. Schematic view with access point position (left) overlapped with measured WiFi signal (right)

Qualification Services

To create all necessary documentation and to perform the qualification required by FDA regulations can be a very time-consuming and costly effort. Depending on your desires MK can simplify these tasks and reduce your efforts to a minimum by either assisting you with the documentation and qualification or by conducting the work altogether for you.

Our offered services include project adjusted documentation (FDS, SDS, HDS, IQ and OQ) and SAT (including IQ and OQ). Since MK Versuchsanlagen is certified under ISO 9001 demanding high standards for quality management a FAT is offered on customer demands only.
Service and Maintenance

While a calibration check can be performed by customers with our dedicated examination socket and a calibrated device, we go beyond with our service and maintenance contracts. On customers’ choice we arrange half-yearly or yearly maintenance of the glove testing device in our service labs in Mücke or on-site at the customer’s location. Maintenance of the glove testing devices includes:

- As found calibration
- Replacement of wearing parts
- Adjustment and as left calibration
- Calibration certificates and documentation

With regular maintenance we minimize measurement problems due to needed adjustments or due to possible malfunction of wearing parts. Thus we enable customers to reliably test regularly during their daily or weekly routines enhancing productivity and safety.

Extended services are custom tailored to your needs. Whether you might need instant replacement of damaged devices or a entire replacement system during maintenance, we can arrange the right service agreement package for you.

Ask for our other brochures on equipment and other glove testing devices.