



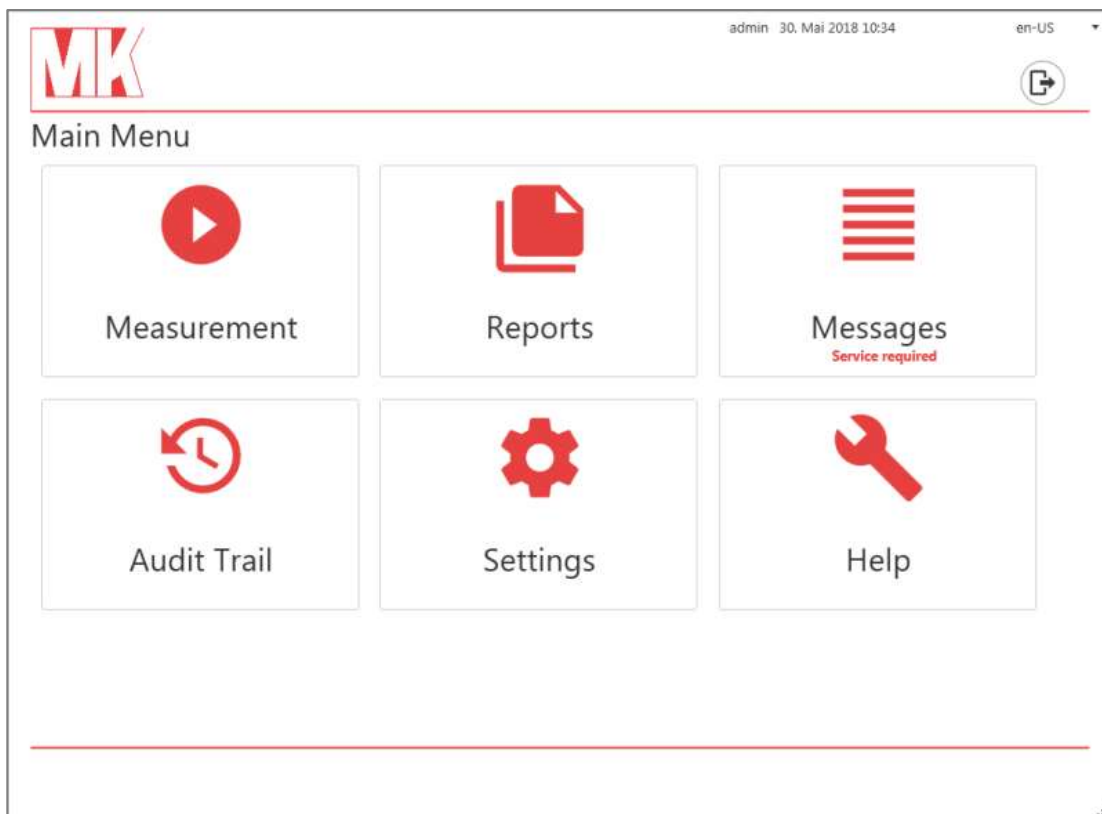
## General Features

The Glove Integrity Test System Software 4 (GITS®-software) by MK is the visual interface to control all testers. 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, CFR 21 Part 11 and EU Annex 11 conform simultaneously with the focus on **intuitive handling and ease of use** for operators and administrators. The clean interface the big tile buttons make the software very **touch friendly** and intuitive.

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

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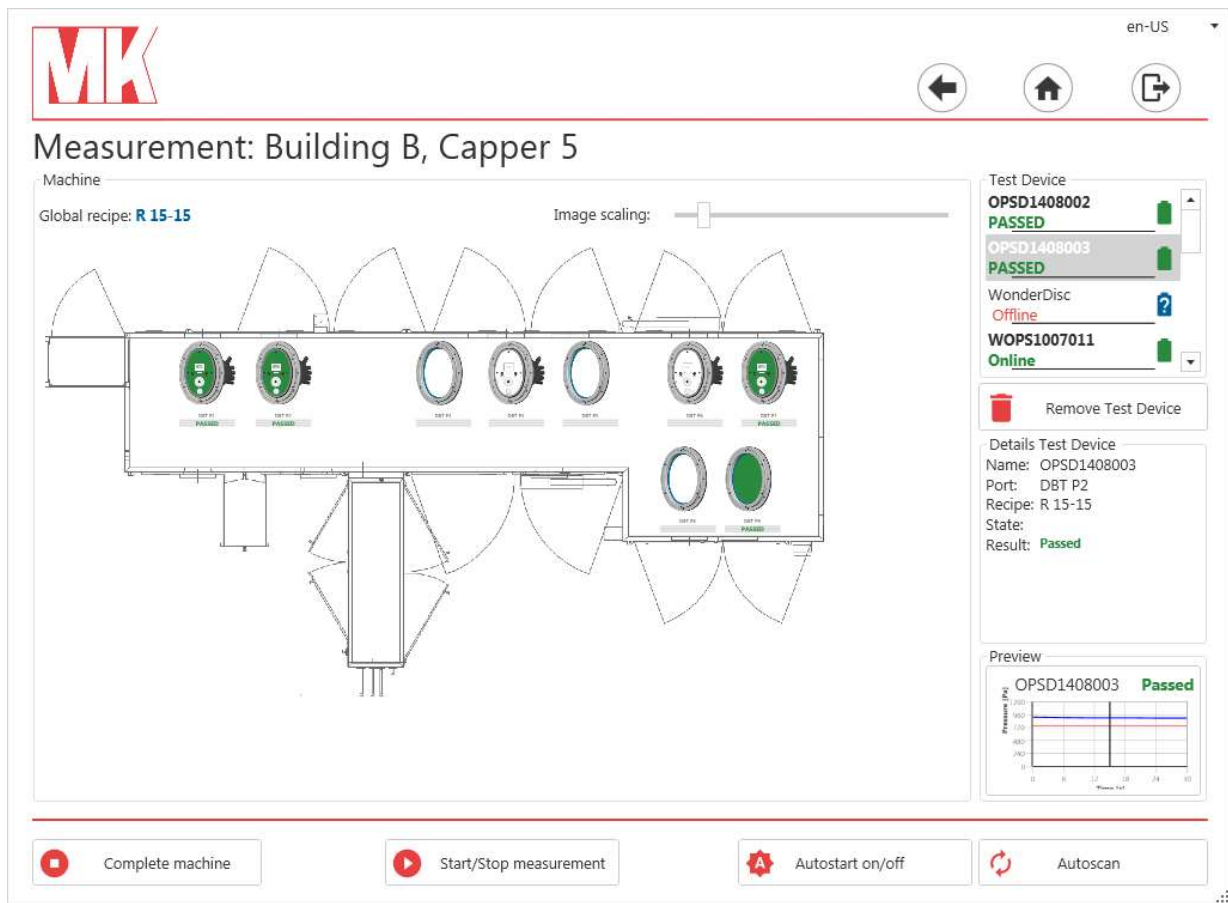


Our Glove Testing Devices will be connected by a Wi-Fi access point with our software. Another option is to integrate the GITS 4 Software into the customers network (Server Installation). So, the Glove Testing Devices can be connected and communicate with the software through the internal WIFI-network.

To customer request we can also integrate the GITS 4 Software into SCADA/MES with customized Interface.

### 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 View", showcasing your isolator/RABS with its ports and their current test status. Thus, giving a direct overview about the validation progress.

An additional benefit of RFID port detection is the option to **fully automate your machine test**. The implemented autostart feature detects inserted glove testers automatically and triggers the measurement with the parameters set-up for the machine by an administrator. 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 measurement can be completed automatically and the corresponding reports will be created. The operator has to take care about inserting the glove testers only.



Overview of available GITS®4 Versions and key differences:

Function	Essential	Professional	Enterprise
Intuitive User Interface; Desktop and Touch Friendly	✓	✓	✓
Visualisation of machine layouts	✗	✓*	✓*
Simultaneous and Parallel Measurement	✓	✓	✓
Absolute and Differential Pressure Decay Method <sup>!</sup>	✓	✓	✓
Easy Backup and Restore Management of all Data	✓	✓	✓
Automatic Calibration Validity Check of Glove Test Devices <sup>!</sup>	✓	✓	✓
Audittrail	✓	✓	✓
Compliant to GAMP5, CFR 21 Part 11, EU Annex 11	✓	✓	✓
Recipe Setup	✓	✓	✓
Recipe Assignment to Machines, Ports and Gloves <sup>!</sup>	✗	✓	✓
Automatic Creation of PDF Measurement Reports	✓	✓	✓
Individual Storage Path and File Name for PDF Reports <sup>!</sup>	✗	✓	✓
Customized PDF Reports	✗	✓*	✓*
RFID Port and Glove recognition <sup>!</sup>	✓	✓	✓
RFID Port and Glove identification and assignment <sup>!</sup> Including Automated Check of Machine Measurement Completion, Machine Summary Reports, and more.	✗	✓*	✓
Active Directory User Management	✗	✓*	✓
Individual User Roles / Individual User Right Management <sup>!</sup>	✗	✓*	✓
PDF/A support for all generated PDF files <sup>!</sup>	✗	✓*	✓
Raw Data Export (CSV/SQL/XML) <sup>!</sup>	✗	✓*	✓*
Simultaneous Multi-User Access <sup>!</sup>	✗	✓*	✓*
Custom Adaptation/Programming of Software-Features	✗	✓*	✓*
Integration in Customer Network / Server Installation	✗	✗	✓
SCADA / MES Integration with Customized Communication Interface	✗	✗	✓*
Maximum Number of Supported Glove Testing Devices	4	16	999+

<sup>!</sup> indicating unique features of MK / GITS Software

\* additional cost involved / optional additional function