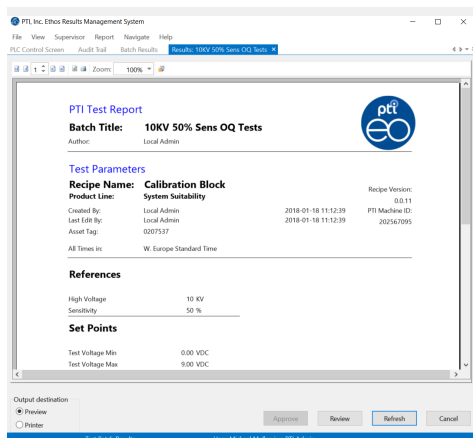# PTI ETHOS

21 CFR Part 11 Software Solution

PTI has developed a new standard for protecting, storing and presenting data generated from its line of non-destructive leak testers in the form of a software package called PTI Ethos.

PTI Ethos collects and protects the data in a Microsoft SQL server database while serving as a simple and convenient method of interacting with the leak tester, data reports and audit trails. Reports can be customized to suit our customer's needs more effectively to their internal standards. The user base is tied to the pre-existing customer managed Windows Active Directory for simplified password management and user access to PTI Ethos. The software also provides user-friendly tools to assign e-signatures to all data reports as either "Review" or "Approve" along with database search and sorting tools. All reports can have a copy printed or exported to PDF at the customer's discretion while the original master copies remain secure within the database.

Key Features

- Secured SQL Server Database stores all information
- Data stored in the database cannot be edited or deleted
- Row Check Sum performed on all data to check for database tampering
- Results are logged into database at the time of test completion
- Reports are customizable to customer needs
- Full audit trail and recipe history reports can be generated
- Database is sortable and searchable for simplified report retrieval
- Electronic signatures for "Review" and "Approve"
- Complete audit trail of PC software and tester alarms

Specifications

Function	PTI Standalone	PTI Ethos
External PC Required		✔
Password protected user interface	✔	✔
Support for Windows Active Directory		✔
Multi-level access to user key functions	✔	✔
User configured test recipes for customized test methods	✔	✔
User defined pass/fail criteria	✔	✔
Minimal operator training required	✔	✔
Measurements presented in human readable form	✔	✔
Data stored at time of measurement	✔	✔
Data stored in human readable form	✔	✔
Full audit trail of events		✔
Full recipe history of previous revisions		✔
All events date/time stamped		✔
Secure data viewer		✔
Electronic signatures for review and approve		✔
Searchable/sortable database of all reports		✔
PDF export functionality		✔
Secure transfer of all data from PLC to PC		✔
Full validation package available	✔	✔
21 CFR Part 11 compliant		✔

PC Technical Requirements

- CPU: I3 or higher
- Memory: 8GB RAM or higher
- Hard Drive: 250 GB or higher
- Network: 2x 1GB Ethernet Connection
- Operating System: Windows 7 or higher
- Processor 32 or 64bit
- Monitor Resolution: min 1024x768

FDA
21 CFR Part 11
Compliant