

Two 21CFR Part 11 Solutions

Labs want a solution that is secure and meets regulatory requirements.
IT wants solutions that satisfy network security requirements.

The Challenge in today's Pharma Labs



Data integrity, cybersecurity, and regulatory compliance are more critical than ever.

Labs must meet:

- 21 CFR Part 11
- EU Annex 11
- ALCOA+
- GAMP 5

Hidden Risk: Open Source Operating Systems



Many instruments still run unmanaged embedded Linux OS that IT cannot secure.

Risks Include:

- No patch management
- No antivirus, malware
- Hacking vulnerabilities
- No Active Directory
- Open Source
- Network vulnerabilities

What GLP Labs Really Need



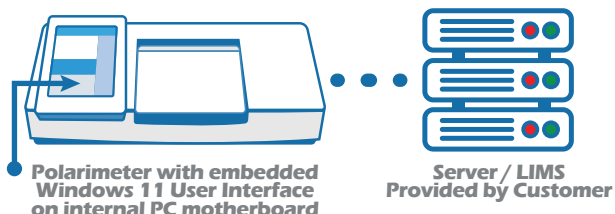
A secure, automated, reviewable data workflow with:

- Centralized authentication
- Audit trails
- Metadata integrity
- Network storage
- LIMS/ELN connectivity

Rudolph's Dual-Architecture Solutions

Solution 1

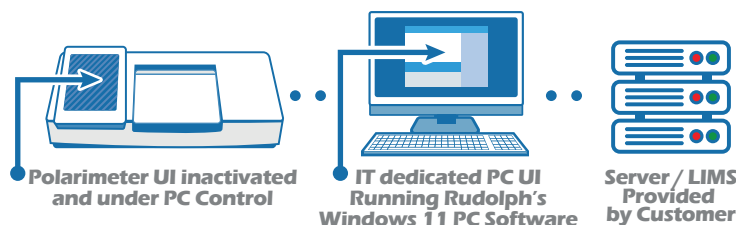
Benefits of Windows 11 Embedded Operation



- Incorporated User Interface
- Local audit trails
- Secure offline workflows
- Save and Sort Metadata Locally and on Server
- Save Metadata to Server for LIMS collection and storage

Solution 2

Benefits of IT Supplied PC Instrument controlled by dedicated PC with OS Windows 11



The PC provides:

- Active Directory Passwords
- Patch management
- Antivirus software
- Encryption
- Centralized storage

Benefits for Your Lab & Your IT Team

For Compliance



- Strengthens CFR Part 11 & ALCOA+
- Improves audit readiness
- Creates reviewable, traceable records

For IT Security



- SIEM/SOC monitoring
- VLAN segmentation
- Firewall integration
- Encrypted connections

For Operations



- Automated backups
- VLAN segmentation
- LIMS/ELN integration
- Multi-instrument workflows