

# 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



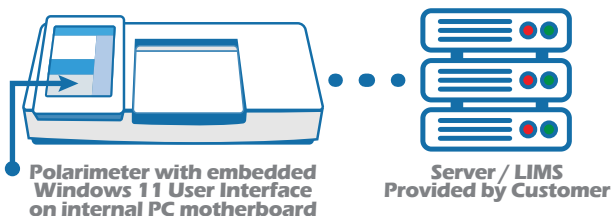
A secure, automated, reviewable data workflow with:

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

## Rudolph's Dual-Architecture Solutions

### Solution 1

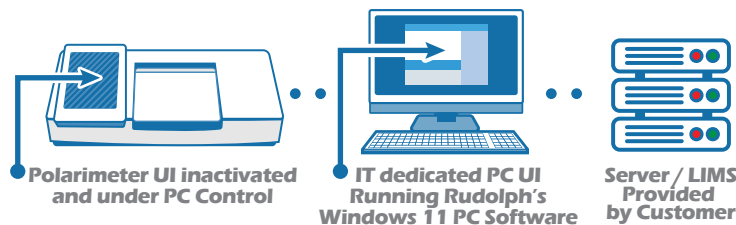
#### Benefits of Windows 11 Embedded Operation



- 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