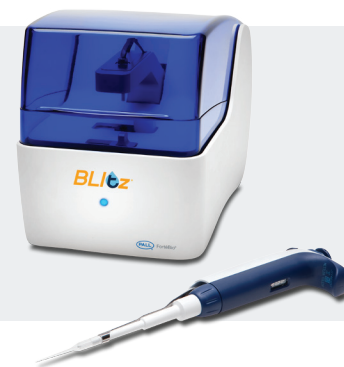


Qualification and Compliance Tools for the BLItz® System

Enabling Protein Detection and Analysis in Regulated Environments

KEY FEATURES

- Verification of proper system installation
- Confirmation of instrument performance
- Software tools for 21 CFR Part 11 compliance
- Extended service and support



OVERVIEW

Affordably priced and easy to use, the BLItz system is enabling label-free detection and analysis across protein manufacturing, purification, and processing workflows. To support requirements for customers working in regulated environments, Pall ForteBio offers additional tools to qualify BLItz systems and to protect the integrity of acquired data.

INSTRUMENT QUALIFICATION

The IQOQ Validation Manual and Testing Kit provides a step-by-step procedure for the Installation Qualification (IQ) and Operation Qualification (OQ) of the BLItz system.

The IQ procedure documents the proper and safe installation of the instrument, while the OQ confirms the system is operating to factory specifications.

In addition to the detailed manual for users to follow, the kit includes software analysis templates that automatically calculate pass/fail results and all the reagents and biosensors needed to perform the necessary assays.

BLITZ PRO CFR SOFTWARE

For GLP and GMP laboratories implementing 21 CFR Part 11 or other guidances for electronic record keeping, BLItz Pro CFR software builds additional security and traceability over the standard BLItz Pro software.

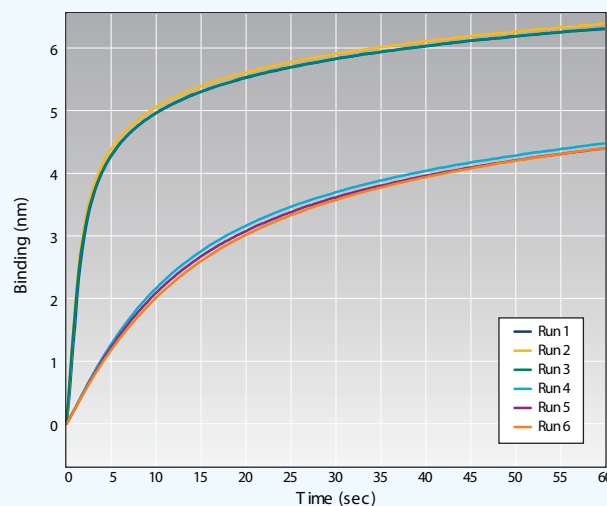
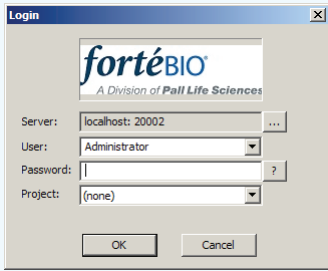


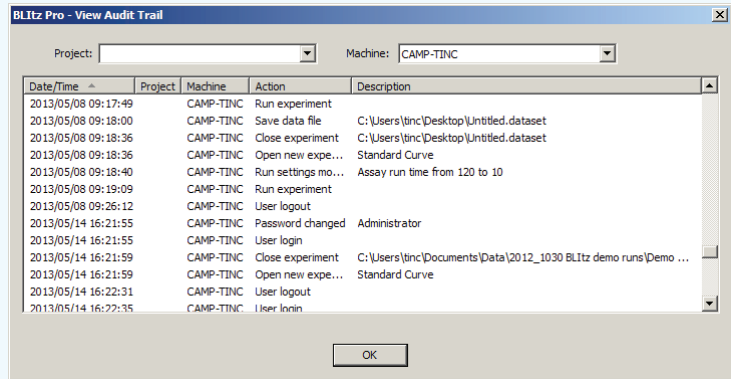
FIGURE 1: BLItz system IQOQ verifies that the instrument was properly installed and is operating consistently to factory specifications.

While maintaining the simple user interface approach, BLItz Pro CFR software:

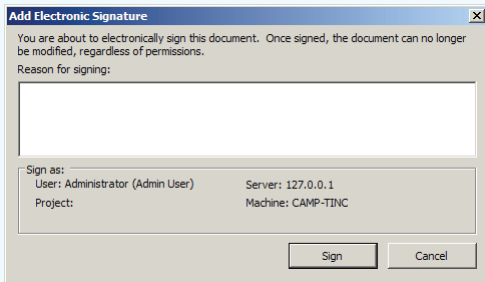
- Requires a secure login to access the system,
- Assigns permissions based on designated users,
- Tracks changes to data files in an audit trail,
- Supports electronic signatures.



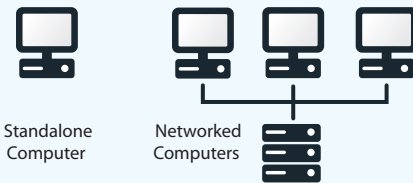
Secure logins to the software assign user privileges.



User actions are captured in an audit trail to provide traceability.



Data files support electronic signatures to record reviews and approvals.



The flexible ForteBio GxP Server allows administration on a single PC or over a network.

FIGURE 2: Enhanced features available in the BLITz Pro CFR software.

BLITz Pro CFR software includes ForteBio GxP Server software for use on a single computer or implementation in a networked environment.

Minimum Computer Requirements for BLITz Pro Software

- 32-bit or 64-bit Windows® XP or Windows 7
- Monitor resolution of at least 1,024 x 768
- 1 USB 2.0 port
- 2.5 GHz Dual Core CPU
- 2 GB RAM

ADDITIONAL SERVICES

Pall ForteBio offers additional services to protect your investment in the BLITz system and optimize your use of the system.

- Extend the warranty coverage of the BLITz instrument for peace of mind that any repairs* will be covered by our depot service, and the instrument returned to use quickly.
- On-site applications work by a Pall ForteBio field applications scientist can fulfill system training requirements and help speed assay development and troubleshooting.

ORDERING INFORMATION

Part No.	UOM	Description
41-0162	Each	BLITz System IQ/OQ Manual and Testing Kit
50-5045	Each	BLITz Pro CFR Software. Includes ForteBio GxP Server and 4 seat licenses
50-5046	Each	BLITz Pro CFR Software additional seat license
98-0007	Each	Depot Service Contract (one year)
30-6009	Each	On-Site Application Work

Notes:

The IQOQ Kit and CFR Software products are intended as tools to support regulatory compliance and do not ensure compliance in and of themselves.

The BLITz system and BLITz Pro CFR software are intended for research use only and not for use in diagnostic procedures.

*Exclusions from warranty coverage include damage resulting from unauthorized modifications or repair, accidents, and improper use or storage.