

IQ/OQ/PQ TLog21 Protocols



Installation, Operation and Performance Qualification Protocols documents are available for Tecnosoft systems compatible with the FDA 21 CFR Part 11, Annex 11 and GAMP regulation.

The documents are customised for each customer and can be filled directly by the user. Alternatively it is possible to ask Tecnosoft to perform the qualification.

Operational qualification

The Operational Qualification is performed after the installation of the TLog21 & Spine System and the Installation Qualification Protocol. Note to the customer order and order confirmation for system identification.

The OQ demonstrates that the TLog21 & Spine System is functioning according to its specification. The Operational Qualification tests should be performed:

- when upon receipt of TLog21 & Spine System
- when software and hardware are moved to a new platform
- when the OQ or TLog21 program version are updated

Checklist

Test	Date	Checked
Package for installation	_____	<input type="checkbox"/>
Data system and calibration	_____	<input type="checkbox"/>
Calibration	_____	<input type="checkbox"/>
System requirements	_____	<input type="checkbox"/>
Software requirements	_____	<input type="checkbox"/>
TLog21 implementation	_____	<input type="checkbox"/>
Log21	_____	<input type="checkbox"/>
System configuration	_____	<input type="checkbox"/>
System security	_____	<input type="checkbox"/>
Profile creation	_____	<input type="checkbox"/>
Device creation	_____	<input type="checkbox"/>
Device creation	_____	<input type="checkbox"/>
Device creation	_____	<input type="checkbox"/>
Device creation	_____	<input type="checkbox"/>
Data network	_____	<input type="checkbox"/>
Data rules	_____	<input type="checkbox"/>
Network	_____	<input type="checkbox"/>
Network	_____	<input type="checkbox"/>
Audit trail	_____	<input type="checkbox"/>

