

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 Operation Qualification is performed after the installation of the TLog21 & Spine System using the Operation Qualification Protocol. Refer to the purchase order and user confirmation for system identification.
The OQ demonstrates that the TLog21 & Spine System is functioning according to its specification. The Operation Qualification tests should be performed:
- when upon receipt of TLog21 & Spine System
- when software and its functions are revised for a new version
- when the OQ or PQ program versions are updated

Checklist	Test	Case	Checked
Package identification			<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 programming up			<input type="checkbox"/>
Setup			<input type="checkbox"/>
System configuration			<input type="checkbox"/>
Power location			<input type="checkbox"/>
Profile location			<input type="checkbox"/>
Display location			<input type="checkbox"/>
Device location			<input type="checkbox"/>
Display location			<input type="checkbox"/>
Display location			<input type="checkbox"/>
Data network			<input type="checkbox"/>
Data view			<input type="checkbox"/>
Device			<input type="checkbox"/>
Printer			<input type="checkbox"/>
Audit trail			<input type="checkbox"/>

