

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 distribution.

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 hardware are moved to a new platform
- when the OQ or TLog21 program versions are updated

Checklist

Item	Date	Checked
Package identification	____/____/____	<input type="checkbox"/>
Data system and calibration	____/____/____	<input type="checkbox"/>
Installation	____/____/____	<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 release	____/____/____	<input type="checkbox"/>
Data view	____/____/____	<input type="checkbox"/>
Release	____/____/____	<input type="checkbox"/>
Release	____/____/____	<input type="checkbox"/>
Audit trail	____/____/____	<input type="checkbox"/>

