

Protocolli IQ/OQ/PQ per TSLog21



I documenti relativi ai protocolli di qualifica per installazione, funzionamento e prestazioni sono disponibili per i sistemi Tecnosoft compatibili con la normativa FDA 21 CFR Part 11, Annex 11 e GAMP.

I documenti sono personalizzati per ogni cliente e possono essere compilati direttamente dall'utente. In alternativa è possibile chiedere a Tecnosoft di eseguire la qualifica.

Operational qualification
The Operation Qualification is performed after the installation of the TSLog21 & Spine System and the Installation Qualification Protocol. Refer to the software user and user administrator for system distribution.
The OQ demonstrates that the TSLog21 & Spine System is functioning according to its specification. The Operation Qualification tests should be performed:
- when new version of TSLog21 & Spine System
- when software and hardware are moved to a new platform
- when the OQ or PQ program version are updated

Checklist	Test	Case	Checked
Package installation	Test Case	Case	<input type="checkbox"/>
Data system and calibration	Test Case	Case	<input type="checkbox"/>
Calibration	Test Case	Case	<input type="checkbox"/>
System requirements	Test Case	Case	<input type="checkbox"/>
Software requirements	Test Case	Case	<input type="checkbox"/>
TSLog21 program version up	Test Case	Case	<input type="checkbox"/>
Setup	Test Case	Case	<input type="checkbox"/>
System configuration	Test Case	Case	<input type="checkbox"/>
Access operation	Test Case	Case	<input type="checkbox"/>
Profile operation	Test Case	Case	<input type="checkbox"/>
Display operation	Test Case	Case	<input type="checkbox"/>
Device operation	Test Case	Case	<input type="checkbox"/>
Output operation	Test Case	Case	<input type="checkbox"/>
Data retrieval	Test Case	Case	<input type="checkbox"/>
Data view	Test Case	Case	<input type="checkbox"/>
Device	Test Case	Case	<input type="checkbox"/>
Printer	Test Case	Case	<input type="checkbox"/>
Audit trail	Test Case	Case	<input type="checkbox"/>

