

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	install	install	<input type="checkbox"/>
Data system and calibration	install	install	<input type="checkbox"/>
Calibration	install	install	<input type="checkbox"/>
System requirements	install	install	<input type="checkbox"/>
Software requirements	install	install	<input type="checkbox"/>
TSLog21 programming up	install	install	<input type="checkbox"/>
Setup	install	install	<input type="checkbox"/>
System configuration	install	install	<input type="checkbox"/>
Access creation	install	install	<input type="checkbox"/>
Profile creation	install	install	<input type="checkbox"/>
Group creation	install	install	<input type="checkbox"/>
Device creation	install	install	<input type="checkbox"/>
Group creation	install	install	<input type="checkbox"/>
Data retrieval	install	install	<input type="checkbox"/>
Data view	install	install	<input type="checkbox"/>
Device	install	install	<input type="checkbox"/>
Printer	install	install	<input type="checkbox"/>
Audit trail	install	install	<input type="checkbox"/>

