



# Software Validation Test Suite:

## SoftMax® Pro Data Acquisition & Analysis Software – GxP Edition

Our SoftMax Pro GxP Software Validation Test Suite provides the most comprehensive documentation available to validate GxP functionality that ensures data integrity and compliance to FDA 21 CFR Part 11 and EudraLex Annex 11 and Annex 15. Each step in the process will be carefully planned and executed.

### Key benefits

- Minimize downtime - leave the validation to us and focus on your research
- Gain access to a pre-service consultation led by our Professional Services team
- Get comprehensive software validation testing by our certified Field Service Engineer (FSE)
- Streamline the IQ and OQ validation activities to one day with our automated service tools
- Receive a complete data package of audit-ready documents after completion of all tests:
  - Electronically signed, digitized copy of SoftMax Pro GxP validation document [IQ, PQ]
  - Automated OQ: Results template with select screenshots at each test case
  - Copy of the FSE Training Certificate

### Validation Test Suite

Whether you decide to validate for yourself or purchase our software validation services, our Validation Test Suite provides step-by-step instructions with complete and accurate “soft copies” of required IQ/OQ/PQ records can be printed to document activities for your regulated environment.

Visit Spectranet, our Customer Portal for the current version of the SoftMax Pro Software Validation Test Suite.

- **Installation Qualification [IQ]** worksheets contain instructions for installing the SoftMax Pro GxP Software Suite in stand-alone (single PC) or single server (multi PC) environments
- **Operational Qualification [OQ]** worksheets contain a comprehensive suite of functional testing of all configurable permissions in the GxP Admin Portal and their behavior in SoftMax Pro GxP Software
- **Performance Qualification [PQ]** worksheets contain a suite of performance tests for connectivity, curve fitting, and graphing interpolation using sample data sets in SoftMax Pro GxP Software

#### Contact Us

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Check our website for a current listing of worldwide distributors.

#### Regional Offices

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United Kingdom	+44.118.944.8000	Japan	+81.3.6362.9109
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