

Ingenix[®] Suite

GxP Compliance Module



Product Information

The GxP Compliance Module ensures laboratory operations meet Good Practice (GxP) regulations by centralizing compliance information with Device and System Audit Trails. The Device Audit Trail records detailed single device actions, while the System Audit Trail logs all compliance relevant activities from all balance devices.

Features include the full audit trail, four-eye principle, and electronic signatures. Advanced filtering based on time, users, device etc. to significantly reduce the time to find audit relevant events. It supports customizable compliance reports for reviews and submissions, offering insights into compliance processes. Real-time monitoring and reporting enable proactive compliance management.



Learn More:



Features	▪ Electronic signatures and four-eyes principle ▪ Full Audit Trail of Devices and the System ▪ Exporting of Audit Trail ▪ Filter for audit records by user, balance name, serial number, timestamp and more ▪ File Export/Saving Formats (PDF, XML) to enable archiving and ELN/LIMS integration
System Requirements	▪ Processor: 2 GHz or faster, 2-core ▪ Memory: 4 GB RAM ▪ Hard disk: 4 GB of available disk space ▪ Display: 1280 x 768 screen resolution (32-bit requires hardware acceleration for 4K and higher) ▪ Graphics: Graphics hardware acceleration requires DirectX 9 or later, with WDDM 2.0 or higher for Windows 10/128 MB graphics memory ▪ Operating system: Windows OS: Windows 10 / 11 ▪ .NET version: .NET6 and higher ▪ Server: MSSQL server 2019 or later
Product (Item No.)	Mandatory Modules: ▪ Ingenix® Suite Lab Balance Device Manager Module incl. 1 Balance License 1 Year License (DSX1PC01LWGFLM01) or 5 Year License (DSX5PC01LWGFLM01) Optional extras: ▪ Ingenix® Suite External Balance Calibration Module incl. 1 Balance License 1 Year License (DSX1PC01LWGEXC01) or 5 Year License (DSX5PC01LWGEXC01) ▪ Ingenix® Suite Pipette Check Module incl. 1 Balance License 1 Year License (DSX1PC01LH-FAC01) or 5 Year License (DSX5PC01LH-FAC01) ▪ Ingenix® Suite Balance License for Single Device 1 Year License (DSX1PC-LWGSBL-) or 5 Year License (DSX5PC-LWGSBL-) ▪ Ingenix® Suite Software Qualification Documents - Ingenix® Suite Software IQ Documents (DSX-PC01LWGSVM01) - Ingenix® Suite Lab Balance Device Manager Module OQ Document (DSX-PC01LWGFED01) - Ingenix® Suite External Balance Calibration Module OQ Document (DSX-PC01LWGSVM02) - Ingenix® Suite Pipette Check Module OQ Document (DSX-PC01LH-SVM01) - Ingenix® Suite Advanced Pipette Calibration Module OQ Document (DSX-PC01LWGSVM03) ▪ Ingenix® Suite Installation, Qualification & Training Service (DSX-PC01-GXP01)

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