

## 21 CFR Part 11 Compliance Module (4Y, 5Y, CY10)





The drawings, photos and graphics used are for illustrative purposes only.

21 CFR

## **Overview**

The 21 CFR Part 11 Compliance Module is a solution especially useful for those users who are obliged to conform to provisions of 21 CFR Part 11 and EU GMP Part 4, Annex 11 regulations. These two documents determine the rules for using electronic records and signatures. Data protection is guaranteed by: advanced password settings, control of logging correctness, various permission levels, data management access, backup, electronic signature, time-defined automatic logout, modification record to Audit Trail file.

The module includes "Audit Trail". Audit Trail is a kind of a log where all modifications of balance settings, changes in database records and user activity are recorded. Audit Trail, for example, keeps record of previous and new modifications in databases and informs by whom and when they were introduced. This log allows the administrator to track and find out who logged in, when, who signed a document or who used invalid password. The Audit Trail Reader freeware allows users, upon connection with a balance, to display Audit Trail log and manage it by generating reports of various formats: pdf, xls, csv, html.

## **Compatible with (Additional Fee)**

XA 5Y.M.A.P Microbalance for pipettes calibration MYA 5Y.P Microbalance for pipettes calibration AK-5/100.STENT Automatic Balance for Stents UMA 5Y.F Automatic Weighing System UMA Automatic Mass Comparator APP 5Y.KO Manual Mass Comparator Density measurement MYA 5Y Microbalance MA 5Y Moisture Analyzer 5Y.PM Precision balance MYA 5Y.F Microbalance for Filters XA 5Y.M.A Microbalance CY10 Scales for PGC PUE CY10 Weighing Terminal CY10 Multifunctional Scale XA 5Y.A Analytical Balance WAY 5Y.KO Manual Mass Comparator **Robotic Mass Comparators** UYA 5Y Ultra-Microbalance MA 5Y.IC Moisture Analyzer AS 5Y Analytical Balance AK-4 Automatic Mass Comparator PS 5Y Balances for PGC AKM-2 Automatic Mass Comparator CY10 Precision balance

Analytical Balance for Filters XA 5Y.F

XA 5Y Analytical Balance Manual susceptometers - Magnetization 5Y.PM.KB Manual Mass Comparator HRP 5Y.KO Mass Comparator PS 5Y Precision Balance Automatic Vacuum Mass Comparators PMV 5Y Moisture Analyzer Automatic susceptometers - Magnetization XA 5Y.KO Manual Mass Comparator HRP 5Y.KB Mass Comparator XA 5Y.M Microbalance RMC F Robotic Weighing System RB F Robotic Weighing System UYA 5Y.KO Manual Mass Comparator UYA 5Y.F Ultra-Microbalance for Filters Nano-Comparator NANO.AK-4.500.5Y XA 5Y.M.A.S Microbalance for stents weighing AK-6 5Y.F Automatic Weighing System