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

WX-001-0133



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

## 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