

Experion™ Security Edition Software Setup Guide

(Catalog Number 700-7052)

Introduction

Experion Security Edition software provides a secure environment for the maintenance, verification, and tracking of all electronic records generated by Experion software. Security Edition software offers tools for compliance with US FDA 21 CFR Part 11 regulations. Features include:

- Authorization system to provide secure user login and allow different levels of access for authorized users.
- Audit trail table to track daily use of the system
- Password protection and auto lock function to maintain database and file integrity
- Electronic signatures for easy record keeping and tracking
- Report generation for quick viewing and archiving of multiple run parameters, data, audit trail, and electronic signatures

The installation qualification and operational qualification (IQ/OQ) validation kit is included with the Security Edition package. The IQ/OQ protocols test the critical functions of the system to verify and validate the system to the specified functionality. Installation qualification should be performed when the system is moved to a new location, when the software is upgraded, and when the computer that runs the electrophoresis station is changed or modified. Operational qualification should be run on a regular basis.

- Ensure reliability and consistency of analysis results
- Allow automation with incorporated procedures in Experion software (version 2.0+)
- Perform routine instrument maintenance and validation procedures

User Access

When security mode is enabled, only an authorized and authenticated user (created within Experion software) can access the software. Each user is associated with one of five different access levels.

Each access level can be configured to allow or deny access to different features and functions of Experion software.

Hardware protection key (Dongle)

Experion Security Edition software is controlled by a specially coded hardware protection key (HPK), or dongle. This key can be connected to any available USB port and must be in position before launching the software. If the Experion software does not detect this key at launch, then it will run in standard mode instead of security mode.

Install Software

Follow the installation instructions printed on the CD booklet or the Quick Installation Guide (included with the Experion electrophoresis station package). For more information, consult the software help section.

Note: To install Experion software, the Microsoft Windows user must have administrative privileges.

Launch Application for the First Time

Once the application is installed and the HPK (dongle) is connected to a USB port, launch the application for the first time by following the steps for your operating system.

Windows XP

Use the following procedure to launch the application for the first time:

1. Log into Windows operating system with a Windows Administrator account.
 - Double-click the Experion icon located on the desktop to start
 - When the Experion Login Form appears, enter the following:
 - o Experion Login User Name – user must be a Windows Administrator and will automatically be assigned the role of an Experion Administrator
 - o Password – Experion*System. Password is case sensitive

Windows Vista

User Account Control (UAC) Turned On

Use the following procedure to launch the application for the first time:

1. Log into Windows operating system with a Windows Administrator account.
 - Double-click on the Experion desktop icon to start
 - Click 'Continue' when the UAC permission dialog box appears
 - When the Experion Login Form appears, enter the following:
 - o Experion Login User Name – user must be a Windows Administrator and will automatically be assigned the role of an Experion Administrator
 - o Password – Experion*System. Password is case sensitive

User Account Control (UAC) Turned Off

Follow the 'Launch Application' steps for Windows XP.

Launching Application for Adding Users

- Log into the Windows operating system with a Windows Administrator account.
- Launch Experion using the procedure for XP or Vista respectively
- Log into Experion with Experion Administrator Account
- Click on the Create New User button
- Select the available user from the User Name DropDown ComboBox
- Complete the requested information
- Click on Save

Launching Application for Normal Usage

Subsequent launching of the application minimally requires a standard Windows User account which has been added as a valid Experion User Account.

Note 1: English language versions of default Windows contain a default Windows Login name of Administrator. The Experion system supports using this name ('Administrator') to log into Experion. The initial password is Experion*System.

Note 2: User names and passwords are case sensitive. Passwords must contain both capital and lowercase letters and a symbol.

Note 3: Once you have entered the application, you should change your Experion Administrator login and signature passwords from the default values.

This can be performed by selecting the Security menu to access the security-specific functions: "User and System Administration..."

The default signature password for the initial Experion software Administrator is: Experion*System*Sig.