KREO HMI TUTORIAL
FDA – CFR21

Tutorial dedicated to the development of an application FDA cfr21 part 11 compliant

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Introduction

This document provides a brief description of FDA CFR21 part 11 and the procedures in order to develop a KREO HMI application compliant with this regulation.

The purpose is to have the legal equivalence of electronic documents (digital records and electronic signature) compared to traditional paper ones.

In order to be compliant with the CFR21 Part 11 standard, it is necessary to ensure that the recorded data always refer to the operator (Electronic Signature) and, in addition, specific policies are implemented that make it impossible to modify the electronical recorded data.

The regulation

FDA (Food and Drug Administration) is the U.S. agency responsible for controlling and regulating production processes in the food, pharmaceutical, and chemical industries.
It is not only American companies that are subject to its control, but all those that operate in the US and export there.

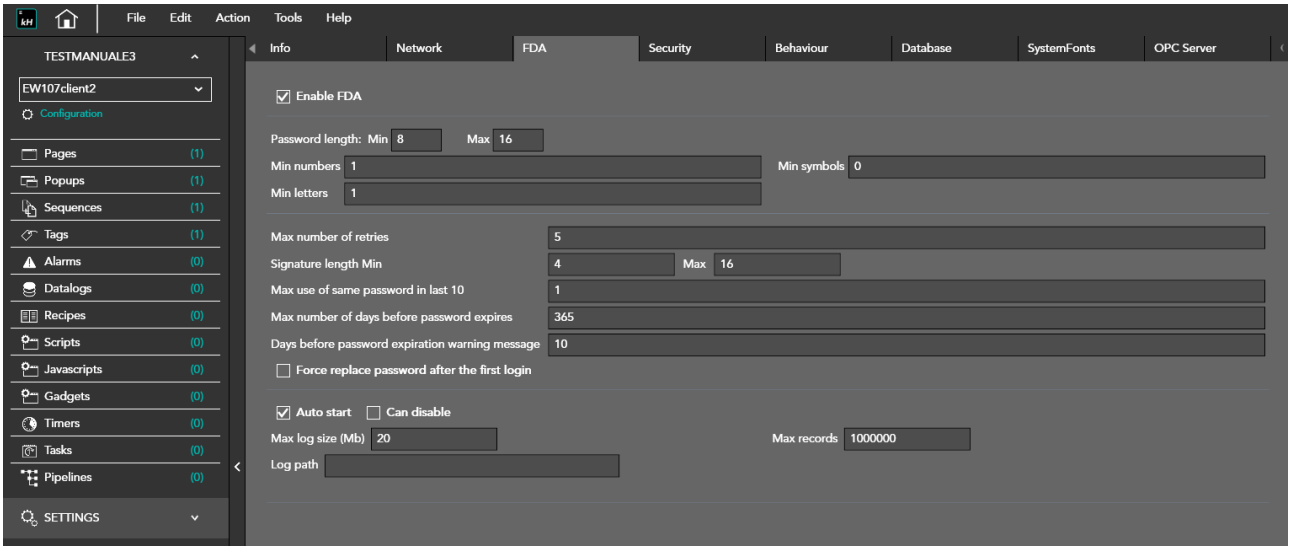
CFR 21 is a regulation issued by the FDA in 1997 in collaboration with the U.S. government regarding the use of technology in specific manufacturing process procedures.Part 11 is divided into two main sections:

- Electronic Archives
- Electronic Signatures

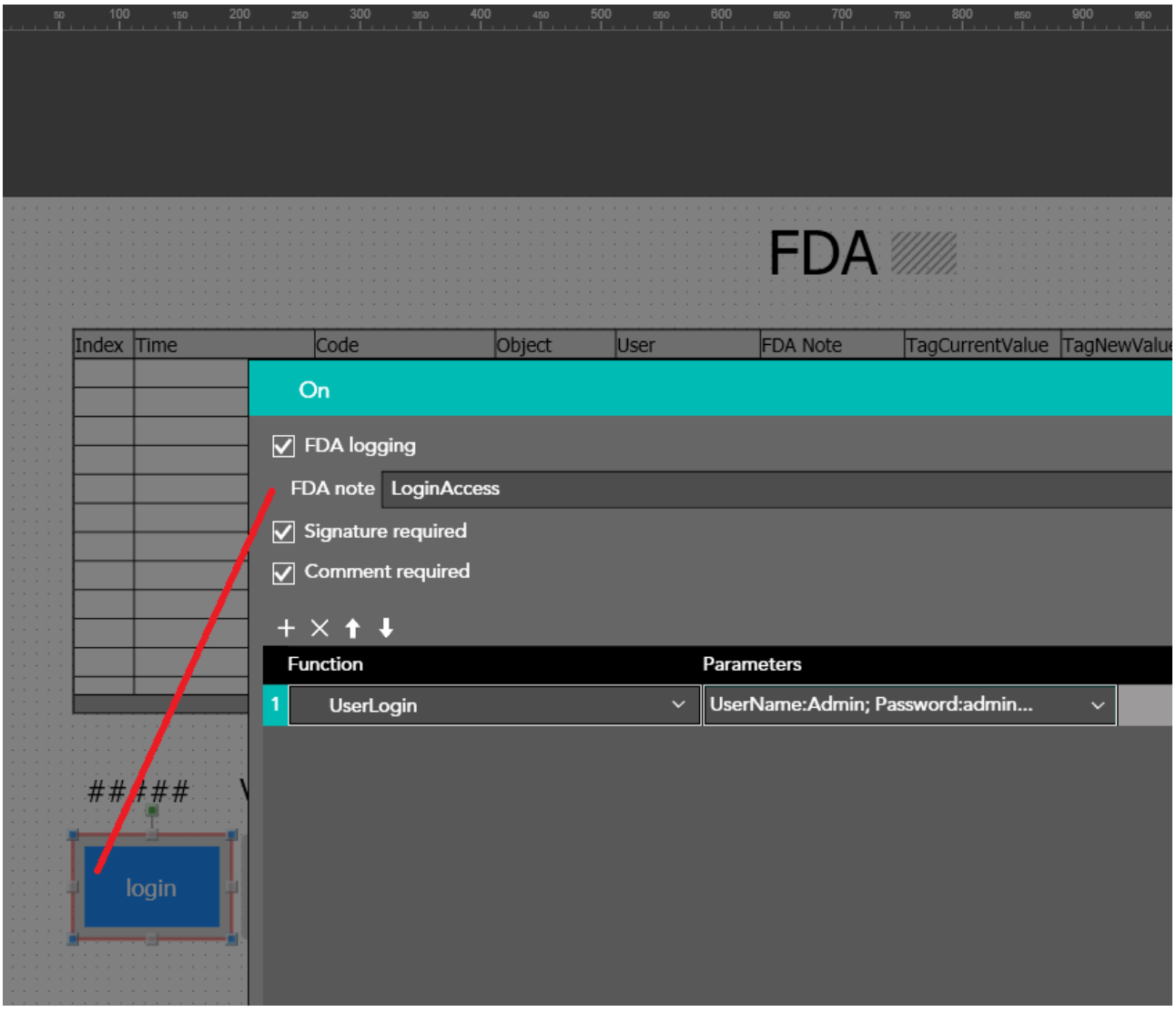
CFR 21 Part 11 regulates the way in which data stored in electronic support is handled and the related security issues.
The objective of CFR 21 Part 11 is therefore to verify that all procedures adopted in the process comply with the requirements.
CFR 21 Part 11 of the FDA is also a guarantee tool for companies such as ESA SPA,which want to offer their customers high and consistent quality and safety standards in their products.

How to do:

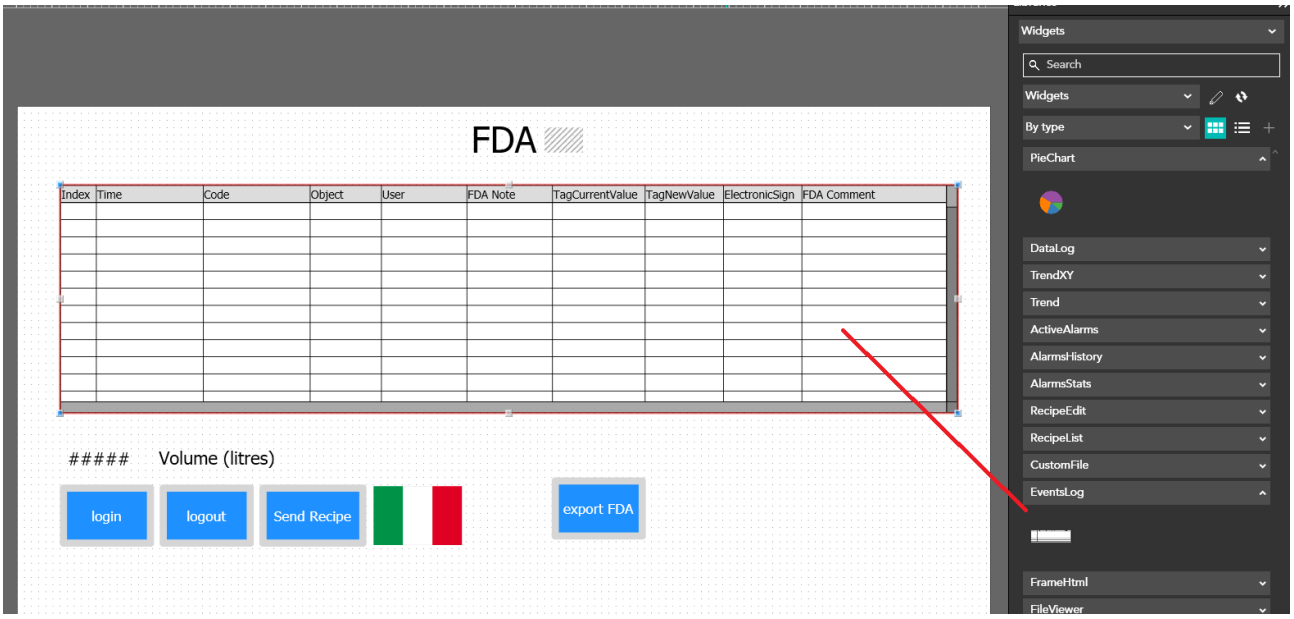
1) In order to enable the FDA functionalities it is necessary to open the Configuration – FDA section, select the Enable option and then insert the general settings:



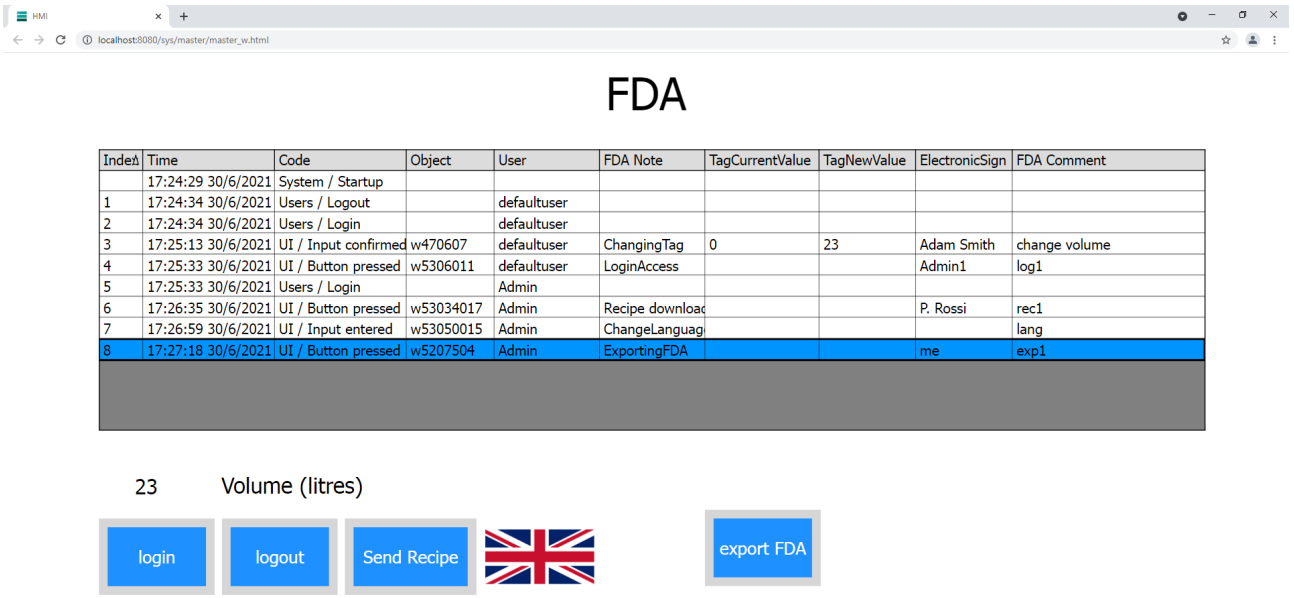
2) Create the project pages and enable or not enable FDA functionality on the different project objects. In each configurable function of the objects you will have the below options:
    - enabling FDA tracking
    - additional notes
    - signature/comment required at RUNTIME by interacting with the object itself



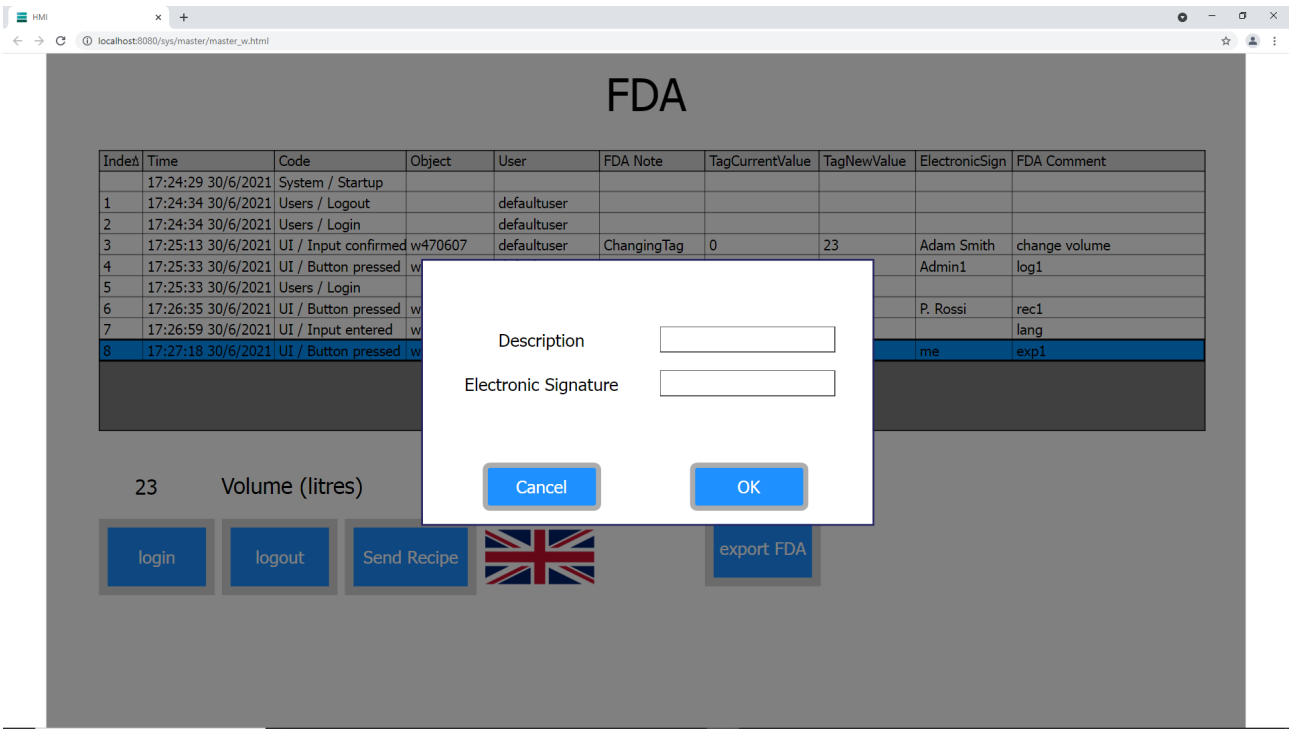
All these options are available on the function settings of each project object and the visualization can be enabled in the dedicated system widget named Events Log. (see the below image)



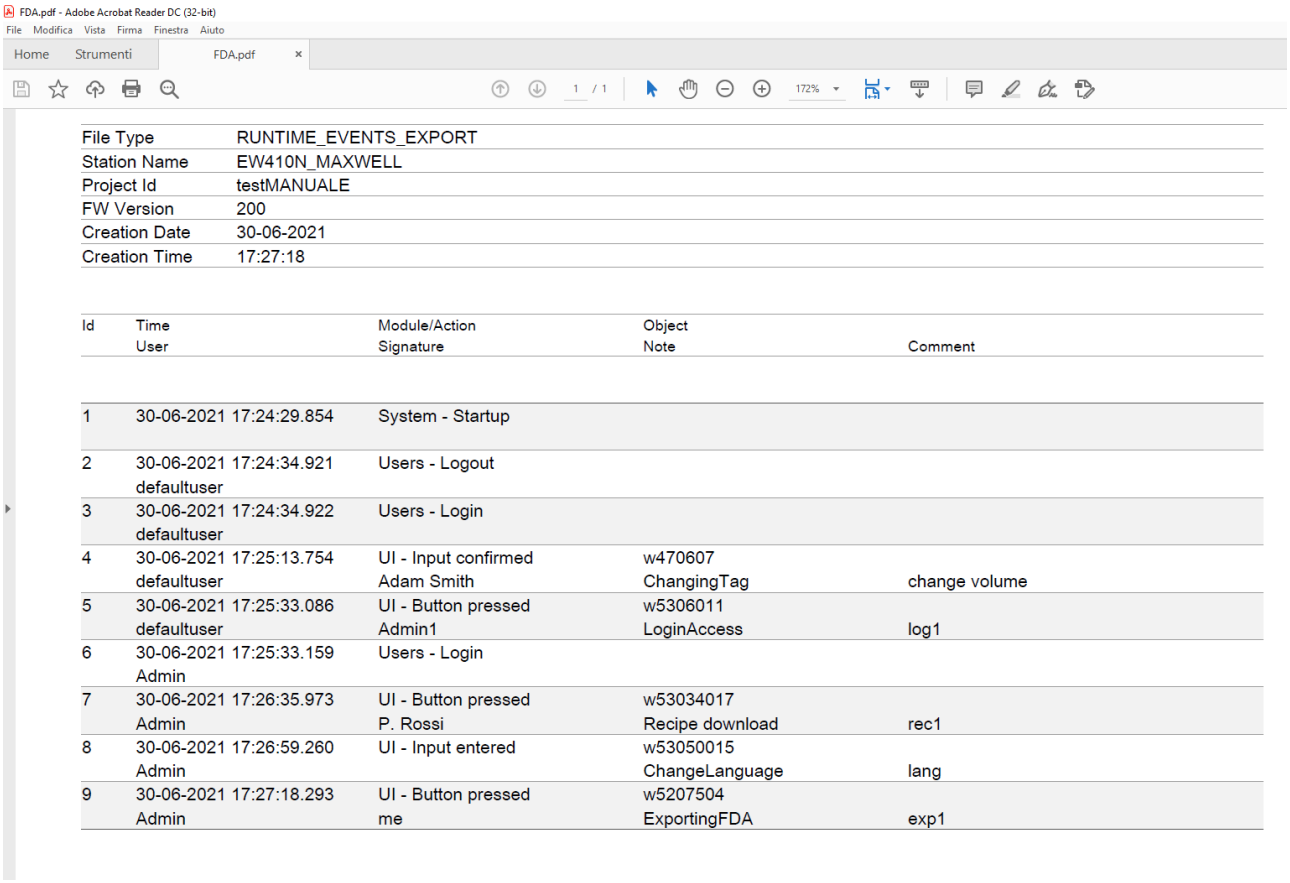
3) Now considering a typica RUNTIME page, the interaction with the different objects to be FDA recorded (numeric field, login, logout, recipe download, language change,...) will be displayed the log below:



4) At each click on the field/key/image object you will get the input request for description and signature (if enabled in the project events):



5) The same log can be exported in PDF / CSV format through the function: FDATracingExport. Below is an example of the result:


FDA.pdf - Adobe Acrobat Reader DC (32-bit)

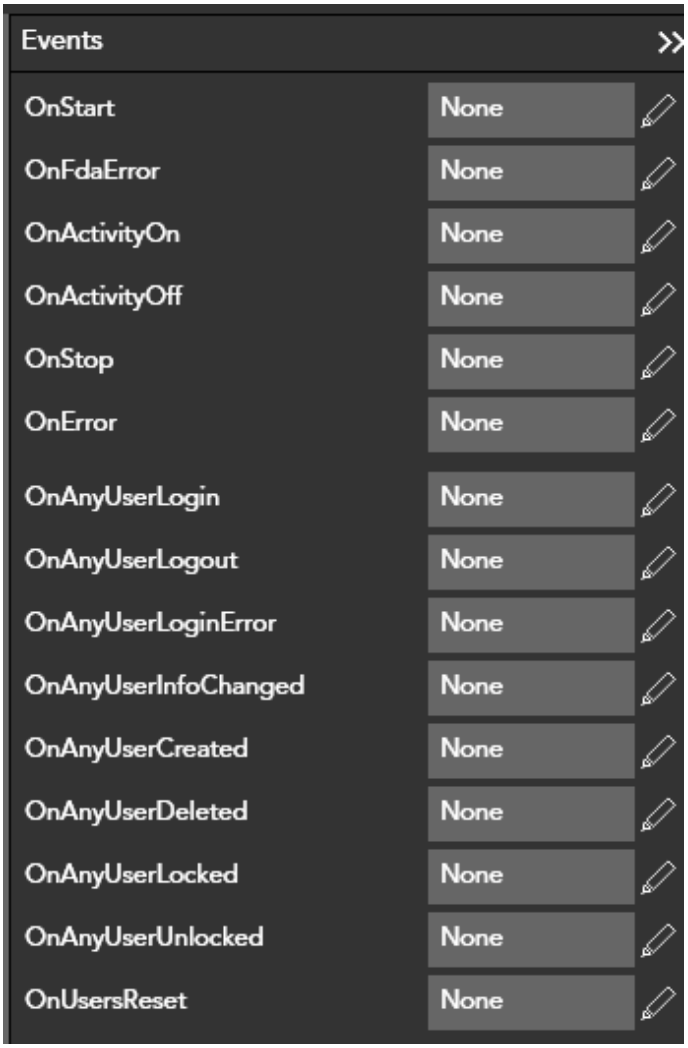
File Modifica Vista Firma Finestra Aiuto

Home Strumenti FDA.pdf

File Type	RUNTIME_EVENTS_EXPORT
Station Name	EW410N_MAXWELL
Project Id	testMANUALE
FW Version	200
Creation Date	30-06-2021
Creation Time	17:27:18

Id	Time User	Module/Action Signature	Object Note	Comment
1	30-06-2021 17:24:29.854	System - Startup		
2	30-06-2021 17:24:34.921 defaultuser	Users - Logout		
3	30-06-2021 17:24:34.922 defaultuser	Users - Login		
4	30-06-2021 17:25:13.754 defaultuser	UI - Input confirmed Adam Smith	w470607 ChangingTag	change volume
5	30-06-2021 17:25:33.086 defaultuser	UI - Button pressed Admin1	w5306011 LoginAccess	log1
6	30-06-2021 17:25:33.159 Admin	Users - Login		
7	30-06-2021 17:26:35.973 Admin	UI - Button pressed P. Rossi	w53034017 Recipe download	rec1
8	30-06-2021 17:26:59.260 Admin	UI - Input entered	w53050015 ChangeLanguage	lang
9	30-06-2021 17:27:18.293 Admin	UI - Button pressed me	w5207504 ExportingFDA	exp1

The FDA events:



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