



Programming Libero PDF Logger® using **SmartStart Pack&Go**

Customer Information

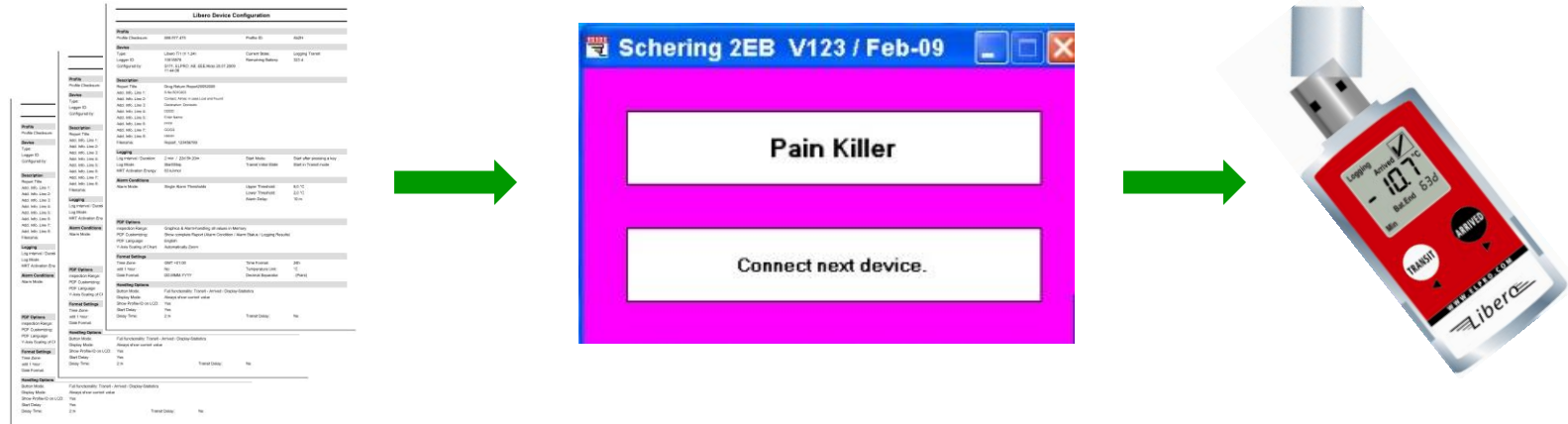
What is SmartStart Pack&Go?

It is a process for fast and error-free programming of Libero PDF Loggers.
Running a Libero Pack&Go will display a window with title, in a predefined color.
As soon as a Libero is plugged into a USB either in OFF or Conf mode it will be configured within one second.

This functionality is included in the Libero Configuration Utility from version 1.7.1 onwards, downloadable free of charge from www.pdf-datalogger.com

Before preparing a Pack&Go, all configuration parameters per profile have to be defined and released.
Then, the profile information can be compiled into a Pack&Go.exe program. This includes all required settings for one or several configurations.

With Pack&Go, there are no external links needed to apply a profile to the Libero, anywhere in a global system.



All the existing functionalities of Libero and SmartStart are supported.

Preconfigured or user-programmed Libero PDF Logger?

A) Use a preconfigured Libero



Preconfigured

User-programmed



Press START

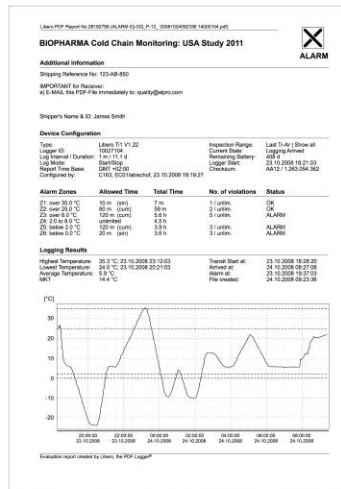


Use it in a temperature-controlled shipment

B) User programmable by SmartStart Pack&Go

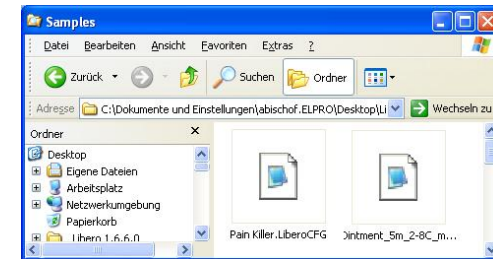
Step 1: Define all Settings with Libero Configuration Utility

- Title text
- Additional Text (8x80 Chr.)
- Log Interval
- Alarms:
 - Single: 2 Limits
 - Multiple: 5 Ranges
- Additional Settings
 - Start Mode
 - Inspection Range
 - Profile Info



Step 2: Save this Configurations as Files on the PC

Example: Painkiller Profile. LiberoCFG



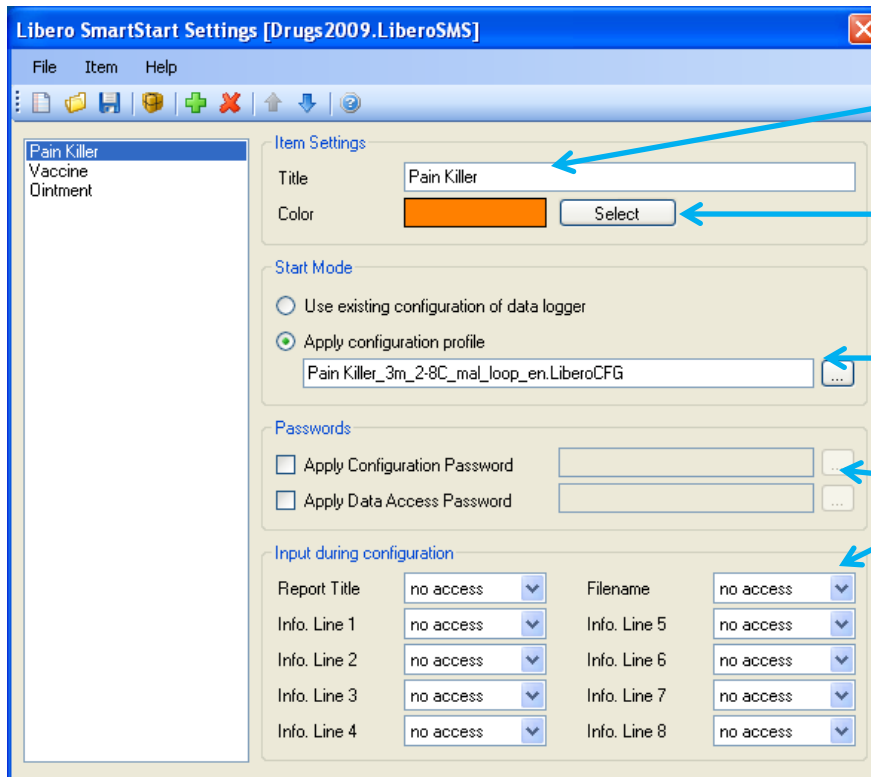
Create as many profile as needed

Combine profiles and prepare SmartStart Settings

Step 3: Create a SmartStart Setting

Go to:
Liberio Configuration Utility → Tools → SmartStart Settings

In a SmartStart settings file one can combine a number of Liberio profiles under one name tag.



Enter a project or product name

Select a Color

Link the corresponding configuration profile

Optional:

- Passwords to protect Logger & PDF file
- User Entries required

Add as many Profile items as required

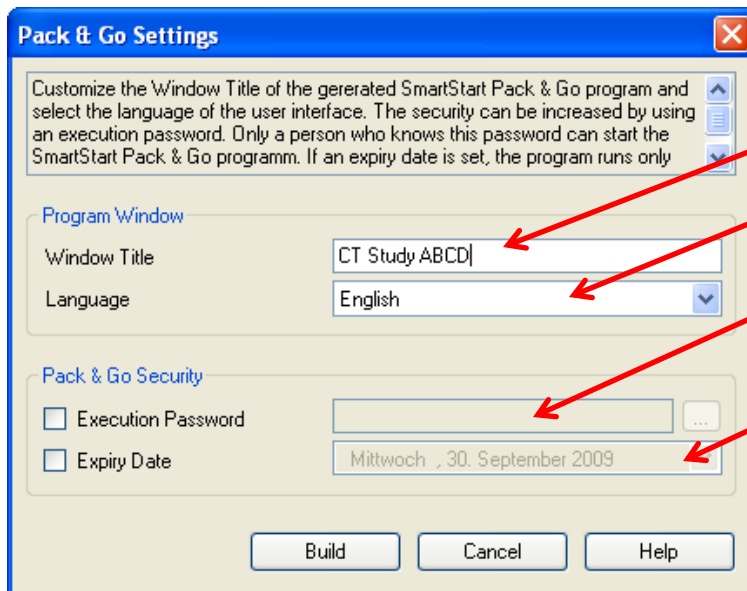
Save these settings on the PC

Make it ready for use:

Step 4: Create a Pack&Go (P&G)



Create or open a SmartStart settings file first (Step 3) then use Pack&Go Icon to start the P&G creation.

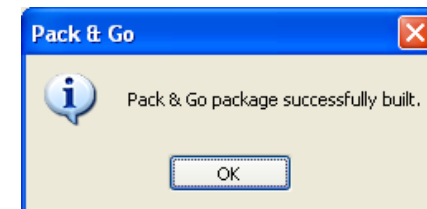


Enter a project title which will appear on top of the Window

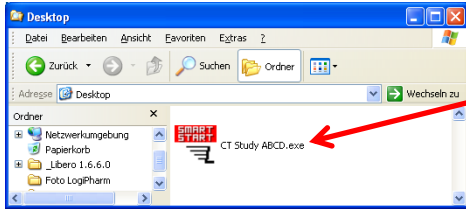
Optional:

- Language for the P&G user
- P&G password to prevent unauthorized use
- P&G expiry date this P&G can only be used until the defined date

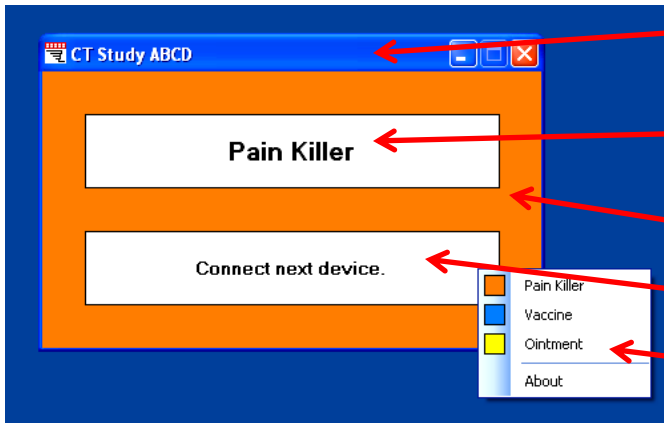
"Build" will now create an executable SmartStart file including all required configuration information.
Save this file to a server or deploy over the Web.



Run the Pack&Go*.exe File



- Start Libero Pack&Go application ABCD.exe
- directly on the PC
- from any server location
- directly from a WEB or FTP or File server
- execute directly from the Internet



- "Title" may include a specific name
Example: "Schering 2EB V123 / Feb-09"
- "Name" may specify the active Profile of a Product or a Clinical Study
- Color code and name of active profile
- Command Window
- Right Mouse will open a selection Window



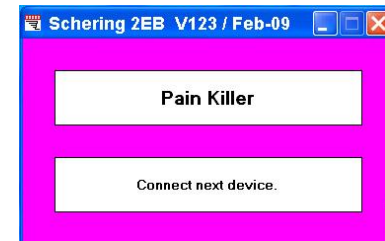
Use a switched off Libero or bring Libero in CONF mode (simultaneously press both buttons)
Plug Libero into USB, in one second, the Libero is programmed.

Deploy over a Network or a Web Server

Place the actual valid ABCD.exe file to a Web Server.
Have the access rights defined by the Administrator of the WebServer
Initial Work at the CRO, once: Install Libero USB Driver and .NET Framework

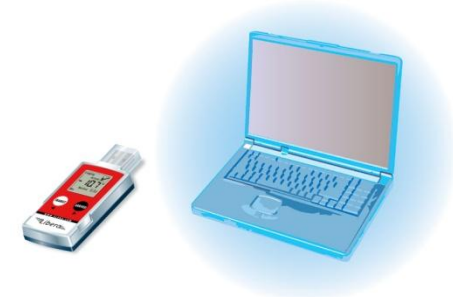
To Use:

- a) *Select URL: <http://user-remote> ABCDSmartStart
Select: ABCD.exe and run this application
SmartStart Window will appear on PC screen*
- b) *Start working directly (Single Profile)
or select a configuration to be used for this application.*
- c) *Configure the required number of Libero PDF Loggers*



If SmartStart ABCD.exe is run directly from a FTP location, an authorized person from QA could update it at any time with a new version.

Automatically, all users would just access this new version.



Additional considerations: Password and Expiry

In order to have a high security and keep user and versions under control, the following additional features are be built in and selectable:

Password:

A Pack&Go Password can be given to the file. Only a person who knows this can run the program and Smart a Libero PDF-Logger

Expiry Date:

A Pack&Go expiry date can be added to the file. Then the program will only run until this date.

Example: 05 Oct. 2009

Name Tag of Program Window:

A Title showing owner, content or version. This will appear on the screen

Example: Schering 2EB V123 / Feb 09

Name of .EXE file:

The actual File Name. Example: Schering 2EB.exe

Initial Work needed to use SmartStart Pack&Go on a PC:

Install the Libero USB device driver for each USB port used: Plus a Libero in OFF or in CONF mode into the USB. Install the driver (Included in the free configuration utility or downloadable)

If not yet on this PC: Install the Microsoft .NET Framework. It is included in the free configuration utility or downloadable. **(Admin rights required for both)**

Requirement for Configuration Utility, SmartStart and PDF Reader

- **System requirements for Configuration Utility, SmartStart and PDF Reader**

- Windows 2000 SP4, XP or Vista
- Pentium 1.5GHz
- Memory: 512 MB RAM
- Free hard disk space: 50 MB
- Monitor 800 x 600 Pixel

- **System requirements to run a SmartStart Pack&Go.Exe**

- Windows 2000 SP4, XP or Vista
- .Net Framework (Dot Net) of Microsoft
- Libero Device Driver installed on each used USB port (ElproLibero.inf)

The driver and the .Net Framework is included in the Libero Configuration Utility and will automatically be deployed during software installation. www.pdf-logger.com

- **PDF Reading Software**

We recommend to use Adobe Reader, (Minimum Version 4).

Do not use Adobe Acrobat or any other PDF Writer program. When saving a Libero PDF file with any of these programs by "save" or "save as", the file format will be manipulated, not complying any longer with 21CFR11.

Access of the Raw Data included in the Libero PDF file:

- The raw data can be imported and evaluated with the elproLOG ANALYZE Software



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