6.1　TitriSoft 3.3 –
convincingly simple with strong benefits

The TitriSoft 3.3 titration software is the optimum solution for your titration tasks. The software can be used with Windows 7,8.1 and 10 and supports your daily work procedures during sample preparation, titration and evaluation of the results. The software has been developed to be clear, logical and user-friendly.

Connection possibilities

Using TitriSoft 3.3 you can control the following devices from a PC:

- **Titrators** TitroLine® (7000, 7750, 7500 KF, 7500 KF *trace* and *alpha* plus)

- **Sample changers** (TW *alpha* plus, TW 7400, TW alpha und TW 280)

- **Piston burettes** TITRONIC® (300, 500 and *universal*, 110/200 and 110 plus)

- **Balances**

You can connect the titration hardware to any of your PC's available USB-A or serial interfaces. Each of the interfaces allows different combinations of devices (configurations). To automate a titration procedure the software may be used to control, for example, a TitroLine® 7800 in connection with the TW *alpha* plus sample changer. For more complex titration tasks with sample preparation you can dose with piston burettes followed by titration with a TitroLine® 7000, 7750 or 7800. Of course, you can also use the software for dosing with piston burettes only.

The image below shows possible device configurations.
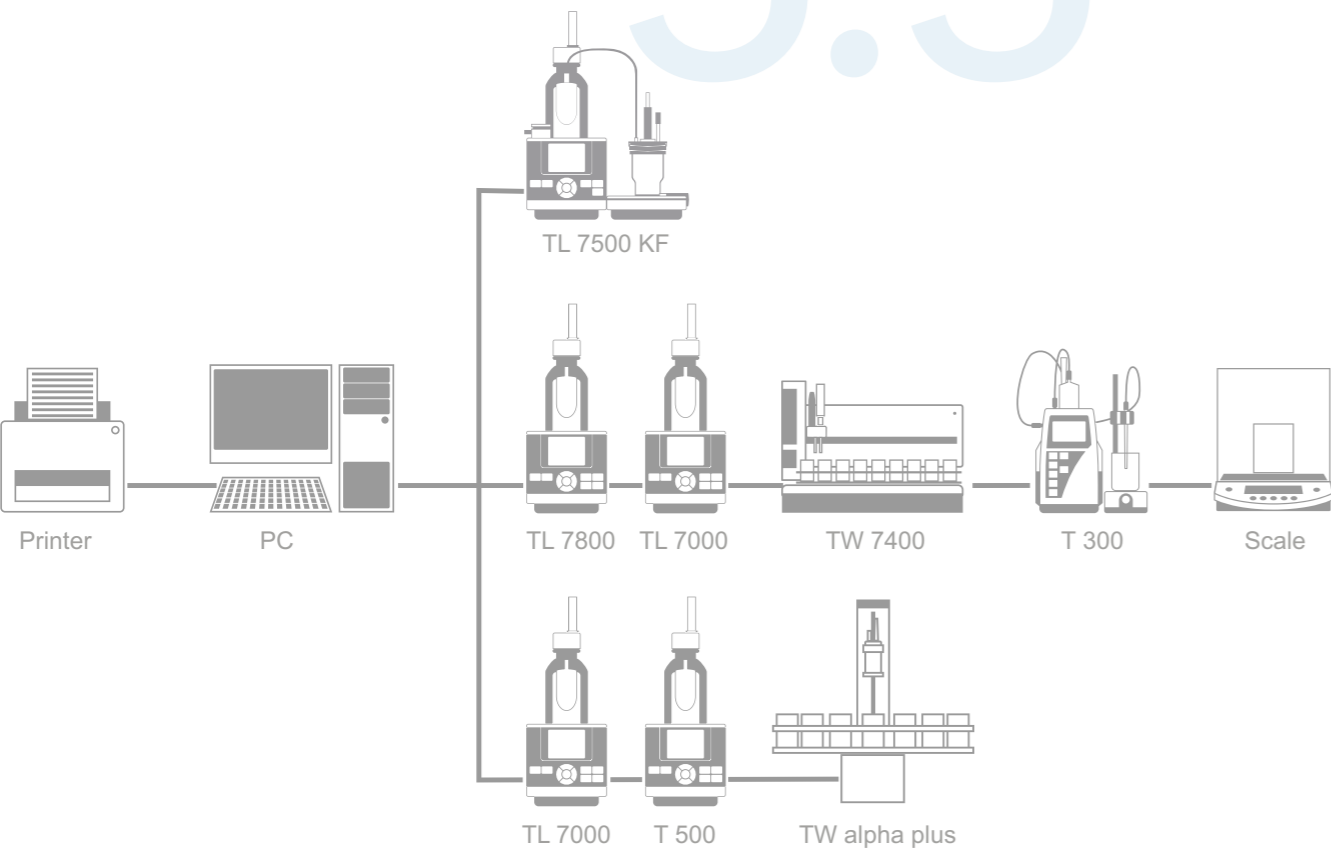
System requirements

For optimal and fast working with the TitriSoft 3.3 software your system should be equipped as shown below:

Interface: a free USB or RS232-interface per configuration

Computer: Pentium (Dual-Core) 2 GHz or higher (I3 or higher recommended)

Operating system: Windows 7, 8.1 or 10 (32/64 bit)

RAM: minimum 2 GB (4 GB or more recommended)

Hard disk:
minimum free storage volume 200 MB

Graphics card:
minimum resolution 1280 x 1024 recommended 1920 x 1200
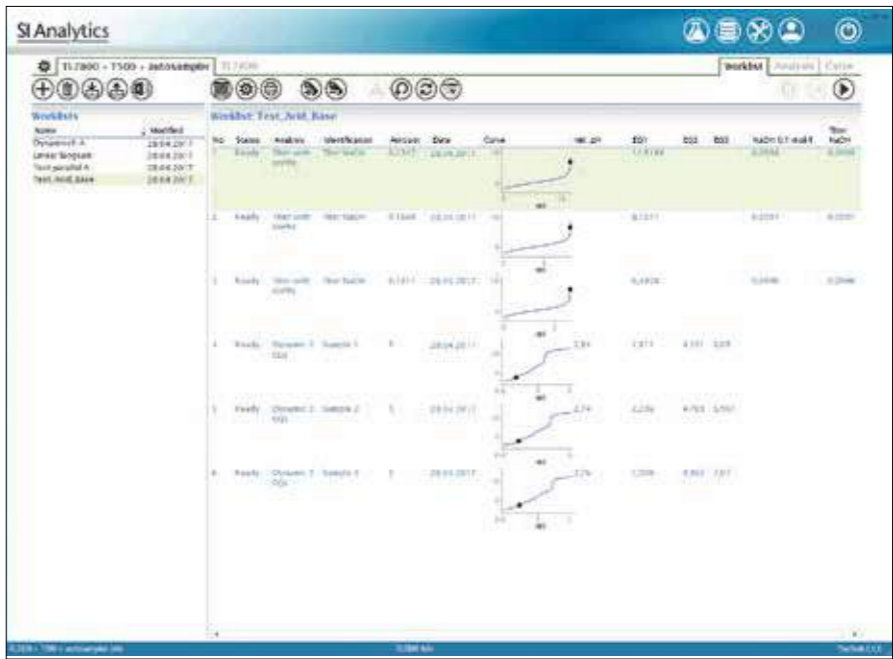
›Titration Center‹, the main menu

The different software tasks are assigned to five different centers:

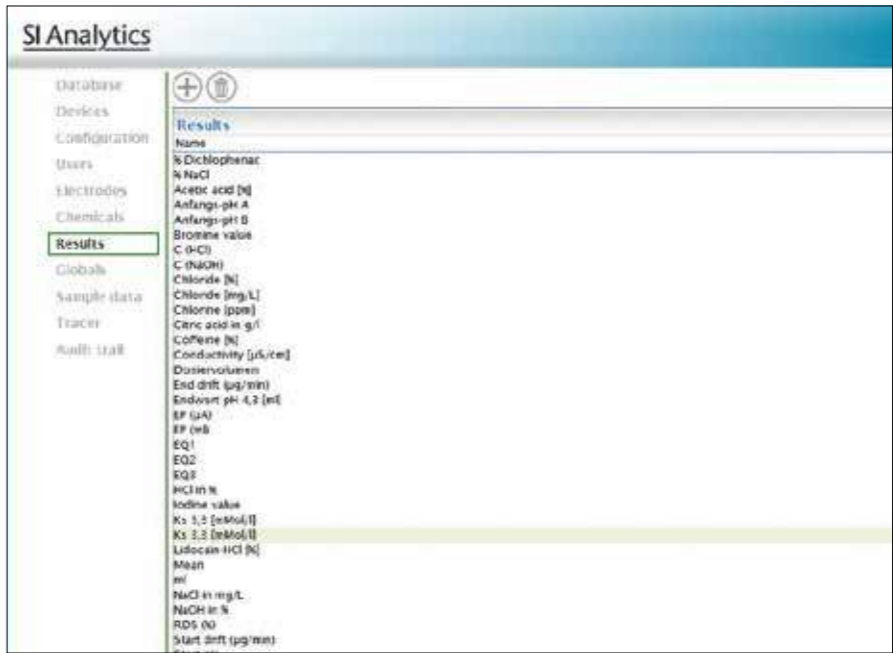- Settings
- Database
- Analysis
- Worklists
- Curve

Each of these centers can be chosen at the menu bar.

›Settings‹, the system configuration

In the system configuration, the software is set up for operation prior to running the first application, i.e. a configuration is set up with the connected hardware. The configuration of the attached hardware is automatically detected in a hardware scan. Each of these hardware configurations allows any number of "methods" and "work lists". Different configurations can work in parallel (see Connection Possibilities).
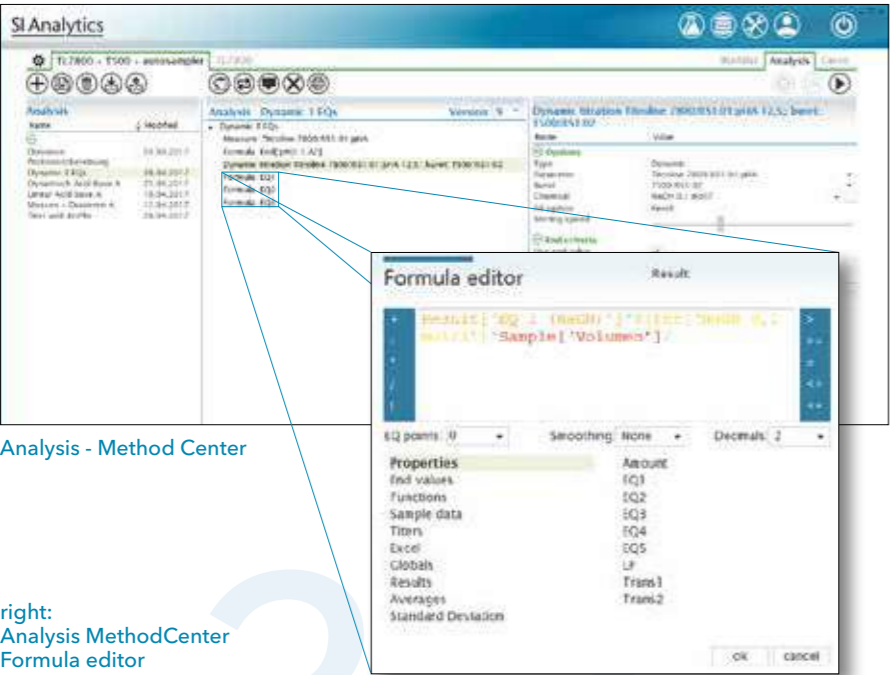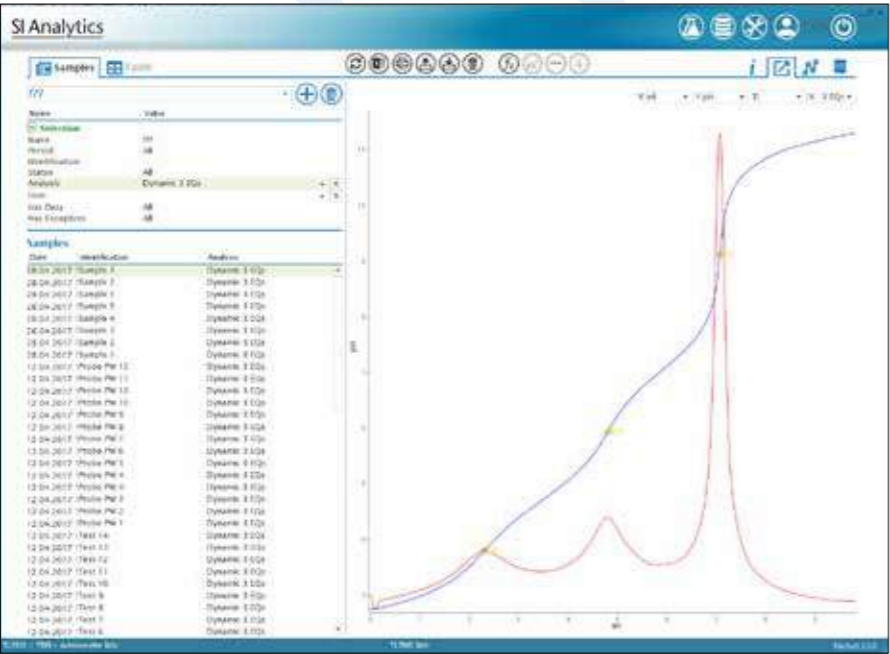

Titrations Center

System Configuration

Printer　　PC　　TL 7800　TL 7000　TW 7400　　T 300　　Scale

TL 7500 KF

TL 7000　T 500　TW alpha plus

Software

TitriSoft 3.3

Analysis - Method Center

right:
Analysis MethodCenter
Formula editor

Database Center - Sample view

›Analysis‹, your Method Center

This is where you set up and save your titration methods. Even complex methods can be installed with a few mouse clicks. Adjustment of the titration parameters is facilitated by the use of symbolic slide controls. Functions such as waiting time, IF loops, repetition, dosings and measurements in addition to the titration parameters and calculation formulas provide virtually unlimited options for method procedures.

›Database‹, your Data Storage

Titration curves, results, measured values and used methods of all titrations are stored in the database. These data can be selected by sample name, date, user and method and loaded in a few seconds.

You can display the information of the performed titrations as a graphic, result or measured value listing. Each stored titration can be subsequently optimized according to your needs, For example, you can add, save, and print subsequent calculations with the curve. A subsequent data export in ASCII or Excel format is possible at any time. In the TitriSoft 3.3 new filter functions have been added. Individual filters can be set by date, user, method, and the selected records are then listed as table form. These results lists can also be exported in Excel format, printed or saved as a PDF file.

## ›Worklists‹, your clearly structured workplace

›Worklists‹ is the place where you carry out your daily jobs, i.e. select methods, enter sample names and origin weighed-in quantities, start the work list and display (and print if desired) the results at the end of a titration. The work list shows the individual samples with the associated methods and their characteristics such as sample name, number, status, date, time, results and events and other freely configurable sample data, e.g. density.

During the process you can follow the titration under „curve" or directly via the worklist. You can, however, simply allow the samples to be processed in the background and use the PC for other tasks or start an additional titration with another configuration in parallel.

When working with the TW *alpha* plus and TW 7400 sample changer, you can adjust various settings such as skip empty items, rinse and waiting options.

Documentation, which is in accordance with GLP and ISO 9000 directives, can be produced in a number of different forms; tables, lists, curves or individual printouts with curves. In addition results can be saved in ASCII or CSV format, external documentation programs may be accessed and results transferred directly, e.g. into a LIMS.

Database Center - Tab. view
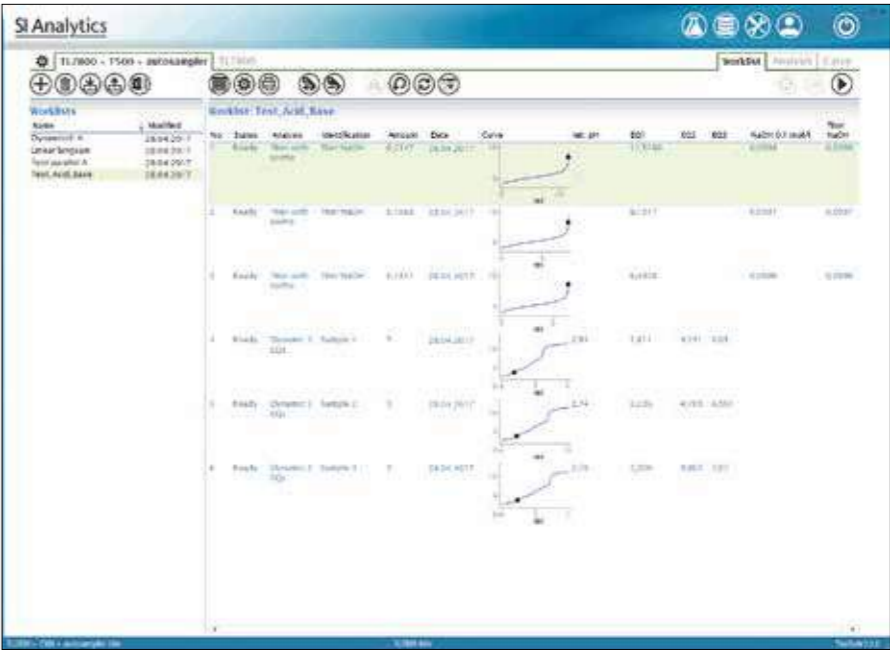
Titrations Center - Worklists

Software

6.2 TitriSoft 3.3 P – simply reliable …

In this case, the "P" stands for "pharmaceutical". "The TitriSoft 3.3 P fully meets all requirements of the FDA 21 CFR Part 11 regulation regarding „Electronic Records", „Electronic Signature" and „Audit Trail".

The FDA (i. e. **F**ood and **D**rug **A**dministration of the USA) 21 CFR Part 11 regulations describe how to deal with electronically stored data ("Electronic Records") and how to prepare electronic signatures ("Electronic Signature"). These regulations are binding for all companies offering medical, pharmaceutical or food products and services in the USA.

System requirements

The computer system requirements for TitriSoft 3.3 P are identical with those of the standard version.

Controlled Access

The controlled access guarantees that only authorized individuals have access to the software functions, according to your company's security policy and the FDA requirements.

TitriSoft 3.3 P has 5 different access levels: The "Operator" level only allows you to carry out the routine titrations, whereas the "Advanced User" level is entitled to approve the methods. The highest level, the "Administrator" may set up the users and assign them the user rights. The Administrator even has the permission to delete records, but only after a copy of the database has been generated. This is performed automatically.
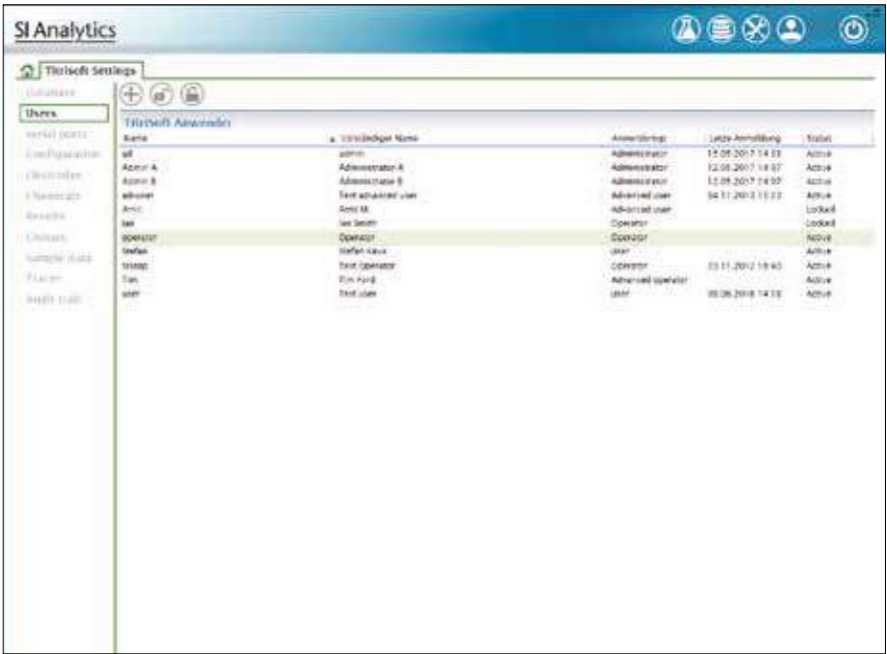
User administration
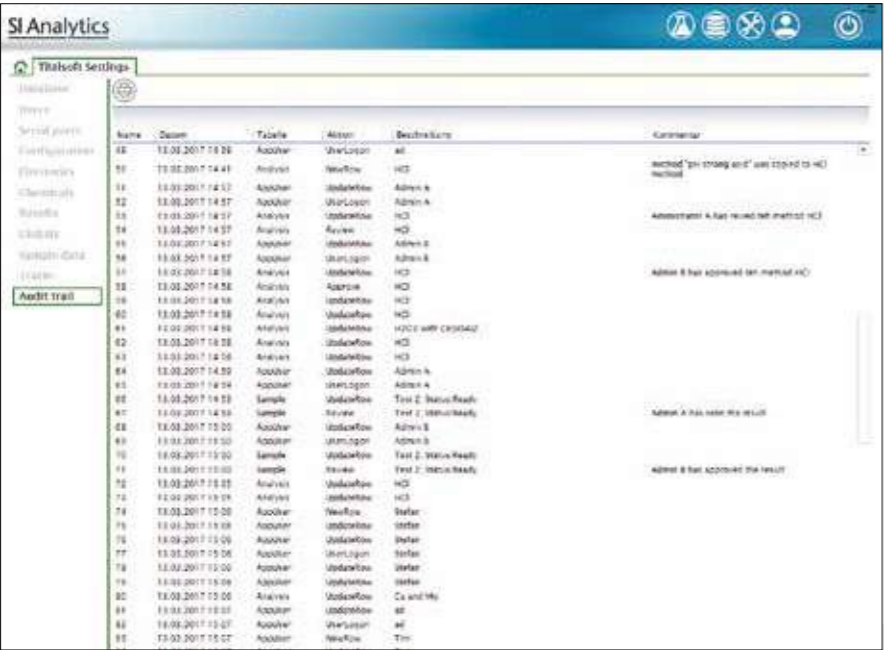
Comparison between TitriSoft 3.3 and 3.3 P

Functions	TitriSoft 3.3	TitriSoft 3.3 P
Electronic records	■	■
Electronic Signatures	–	■
Audit Trail	–	■
Controlled Access	■	■
Copies of Records	■	■
Straightforward procedure	■	■
All types of titrations	■	■
Comfortable worklists	■	■
Online titration curves	■	■
Clear documentation	■	■
Perfect titration control by PC	■	■
Parallel titration (with multiple configurations, also with a TL 7800 and a piston burette (please refer to page 55))	■	■

User level	Operator	Advanced Operator	User	Advanced User	Administrator
Starting worklists	■	■	■	■	■
Changing worklist settings	–	–	■	■	■
Delete worklists	–	–	–	■	■
Data base, export results again / recalculating	–	■	■	■	■
Generate methods	–	–	■	■	■
Delete methods	–	–	■ 1), 2)	■ 1), 2)	■ 1), 2)
Global system configuration	–	–	–	■	■
System configuration, generate and delete users	–	–	–	–	■

1) A method may only be deleted if no titration / measurement has been carried out yet.
2) For Pharmaversion only: If a method or result has been released, it may not be deleted. The administrator may delete results. But a copy of the database is automatically created before the delete process.

6.3 Ordering Information TitriSoft 3.3 /3.3 P

Type No.	Order No.	Description
TZ 3071	285220717	Titration software TitriSoft 3.3 for all TitroLine® 7XXX titrators and piston burettes TITRONIC® 300/500
TZ 3072	285220727	Titration software TitriSoft like Version 3.3, but 21 CFR, part 11 compliant version

Software

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SI Analytics
a xylem brand
Xylem Analytics Germany Sales GmbH & Co. KG, SI Analytics
Hattenbergstr. 10 · 55122 Mainz · Germany · Tel: +49 6131 665111 · Fax: +49 6131 665001 · Info.si-analytics@xyleminc.com
www.si-analytics.com

SI Analytics
a xylem brand
Xylem Analytics Germany Sales GmbH & Co. KG, SI Analytics
Hattenbergstr. 10 · 55122 Mainz · Germany · Tel: +49 6131 665111 · Fax: +49 6131 665001 · Info.si-analytics@xyleminc.com
www.si-analytics.com
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TitriSoft 3.3 P

Audit Trail

The 21 CFR Part 11 prescribes that creating methods, modifying passwords or saving results, generates an entry in the Audit Trail. TitriSoft 3.3 P automatically generates an entry in the Audit Trail table as soon as an access to the database has taken place. The local time and the GMT are automatically stored together with this entry in the Audit Trail. Each entry also asks for a comment. The Audit trail or parts of it can be printed out, or a "human" readable digital copy of it, e.g. a PDF file can be generated.

Electronic Records

The 21 CFR Part 11 prescribes how to safeguard and store the generated results over time. Besides regularly making backup copies of the complete database, is it possible to generate readable digital copies of the results, methods, worklists, the Audit Trail, the user administration and the configuration(s). For that purpose, a PDF writer is already integrated in the software. The purchase of expensive third-party software for generating PDF files is not necessary.

Of course the database is password protected against unauthorized access.

Electronic records

Electronic Signature

Digital analysis results have to be as reliable as classical, manually checked results with a handwritten signature. A digital signature, which is as safe as a handwritten one, can be placed to approve all electronic records. The approver has to enter the name and an additional password. The electronic signature is stored together with the signer's function, the reason of signing and the date and time.
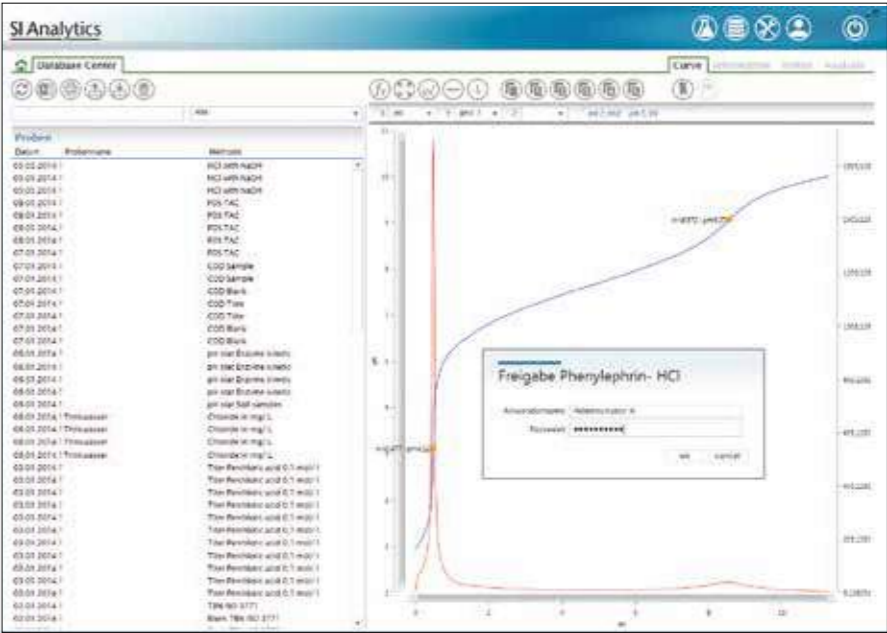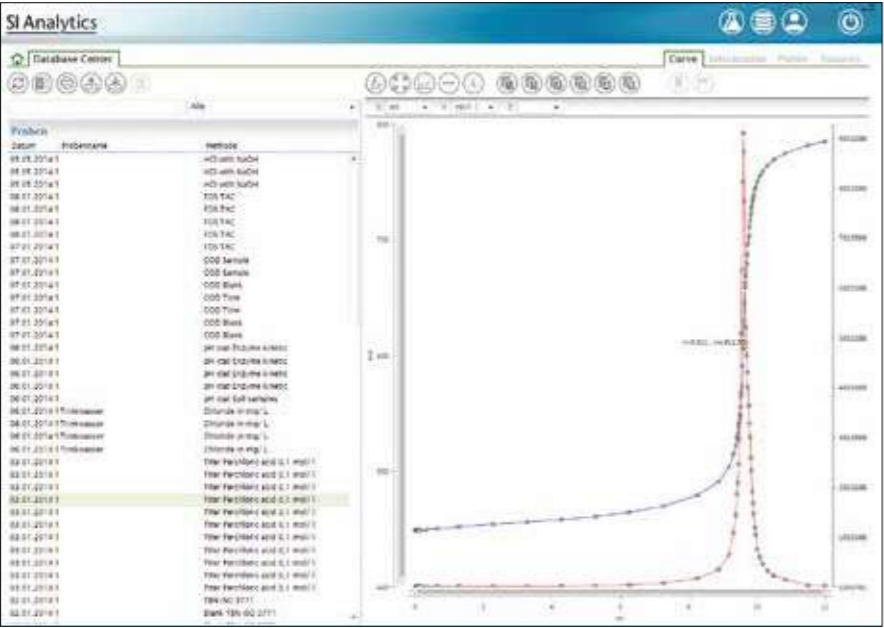

Electronic SIgnature

6.4 "Parallel" titration with TitroLine® 7800 and TitriSoft 3.3/3.3 P

In combination with the new TitriSoft 3.3 / 3.3 P, TitroLine ® 7800 and a piston burette TITRONIC ®300 / 500 can be used to perform a so - called „parallel" titration. This means you only need one titrator and one piston burette to carry out two titrations simultaneously, in parallel.

Typical example:

A TitroLine ® 7800 and a sample changer are used to carry out titrations in a configuration of acid base. The pH electrode is connected to the measuring input A. At the same time, a titration of chloride is carried out with a second configuration. The silver electrode is connected to the input B. The titration is carried out with a TITRONIC ® 500 piston burette.
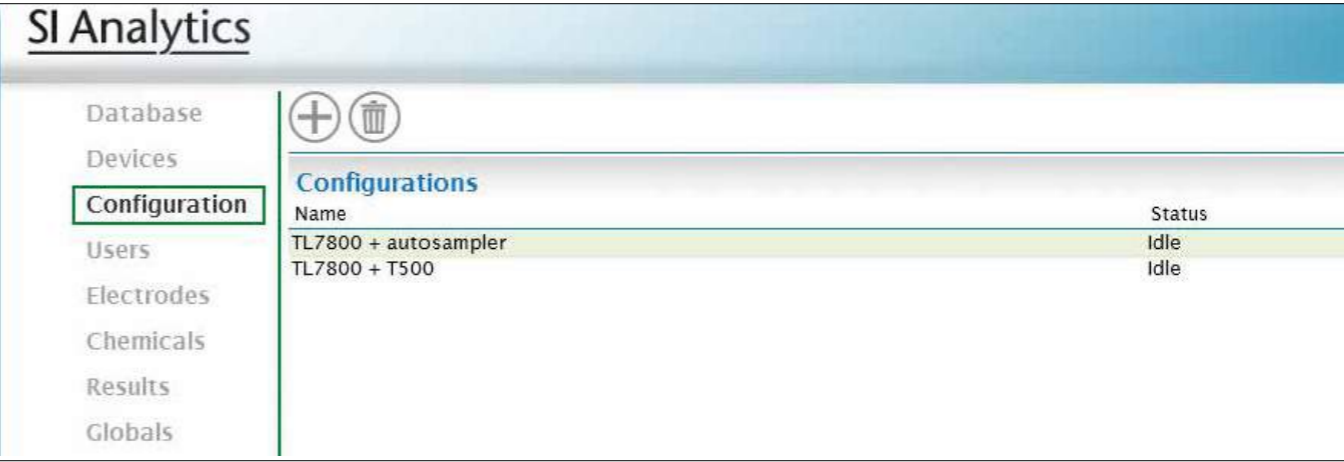

Parallel titration

Software