

# TitriSoft 3.0 - convincingly simple ...

# TitriSoft

The TitriSoft 3.0 titration software is the optimum solution for your titration tasks. The software can be used with Windows XP, Vista and 7 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.

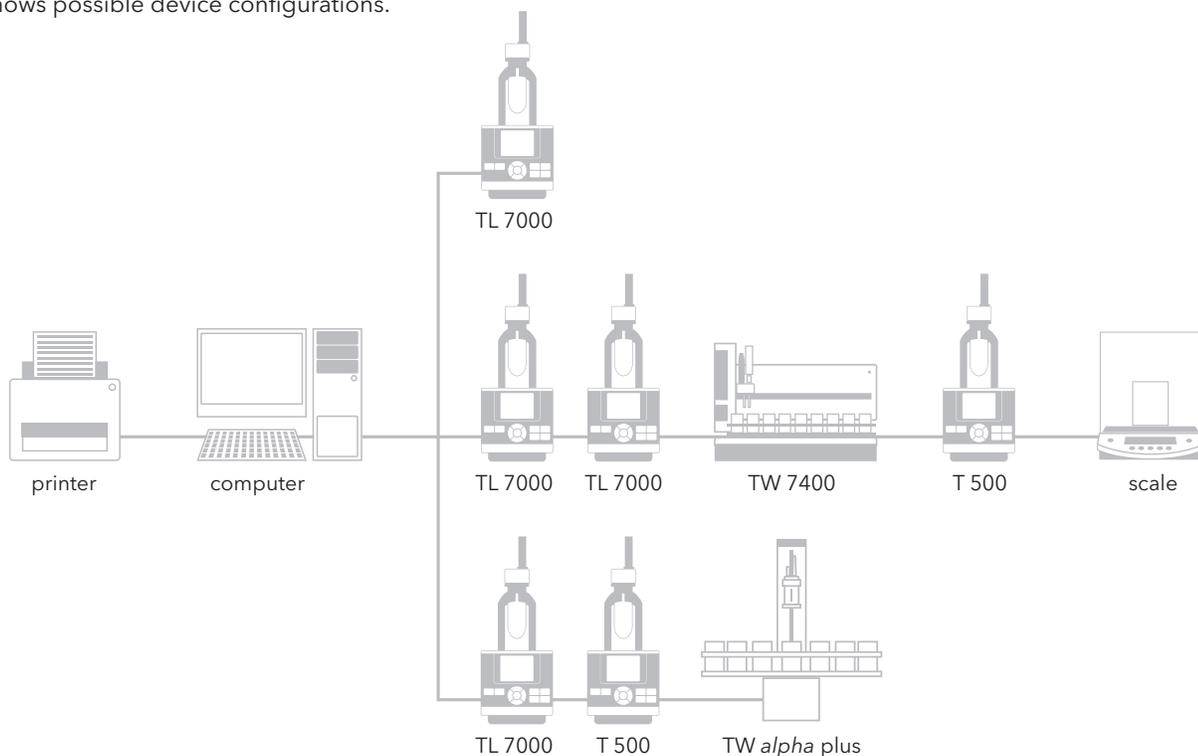
## Connection possibilities

Using TitriSoft 3.0 you can control the following devices from a PC:

- **Titration units** (TitroLine® 7000, 7500 KF, 7500 KF *trace* and TitroLine® *alpha plus*)
- **Sample changers** (TW *alpha plus*, TW 7400, TW *alpha* und TW 280)
- **Piston burettes** (TITRONIC® 500 and TITRONIC® *universal*, TITRONIC® 110/200 and TITRONIC® 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 the TitroLine® 7000 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. Of course, you can also use the software for dosing only.

The image below shows possible device configurations.



## System requirements

For optimal and fast working with the TitriSoft 3.0 software your system should be equipped as shown below:

**Interface:** a free USB or RS232-interface per configuration

**Computer:** Pentium D (Dual-Core) 2 GHz or higher

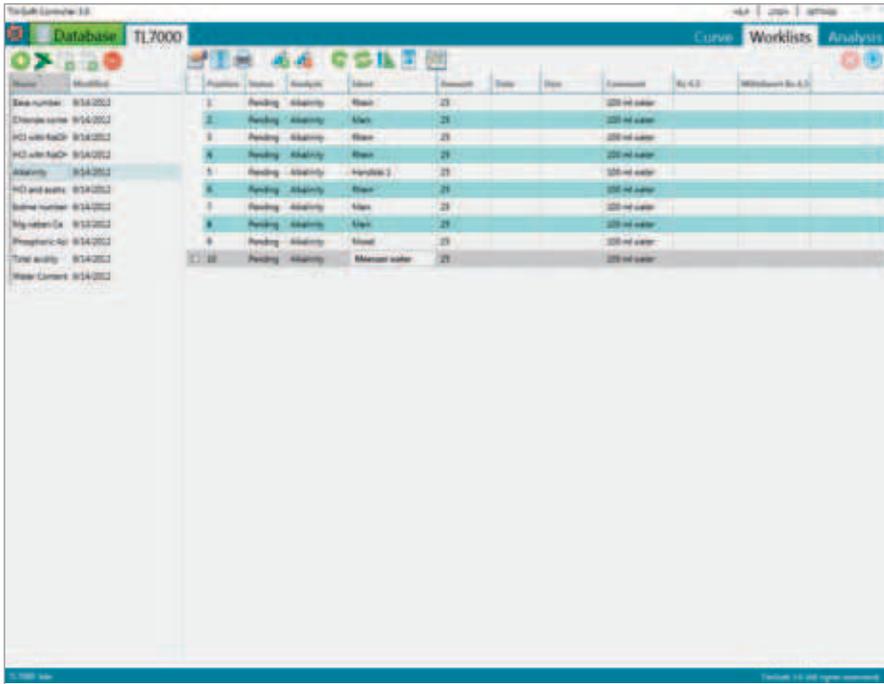
**Operating system:** Windows XP, Vista or 7

**RAM:** minimum 2 GB

**Hard disk:** minimum free storage volume 200 MB

**Graphics card:** minimum resolution 1280 x 1024

... strong benefits ...



Name	Method	Position	Status	Analysis	Unit	Amount	Date	Time	Comment	As 4.0	Method No. 4.0
Base number	014/2002	1	Pending	Ability	Blank	25			200 ml water		
Chloride content	014/2002	2	Pending	Ability	Blank	25			200 ml water		
Cl <sup>-</sup> with NaCl	014/2002	3	Pending	Ability	Blank	25			200 ml water		
Cl <sup>-</sup> with NaCl	014/2002	4	Pending	Ability	Blank	25			200 ml water		
Ability	014/2002	5	Pending	Ability	Standard 1	25			200 ml water		
Cl <sup>-</sup> with water	014/2002	6	Pending	Ability	Blank	25			200 ml water		
Base number	014/2002	7	Pending	Ability	Blank	25			200 ml water		
Hydrogen Ca	014/2002	8	Pending	Ability	Blank	25			200 ml water		
Phosphate in	014/2002	9	Pending	Ability	Blank	25			200 ml water		
Total acidity	014/2002	10	Pending	Ability	Blank	25			200 ml water		
Water Content	014/2002										

›Navigator‹, the main menu

The different software tasks are assigned to five different centers:

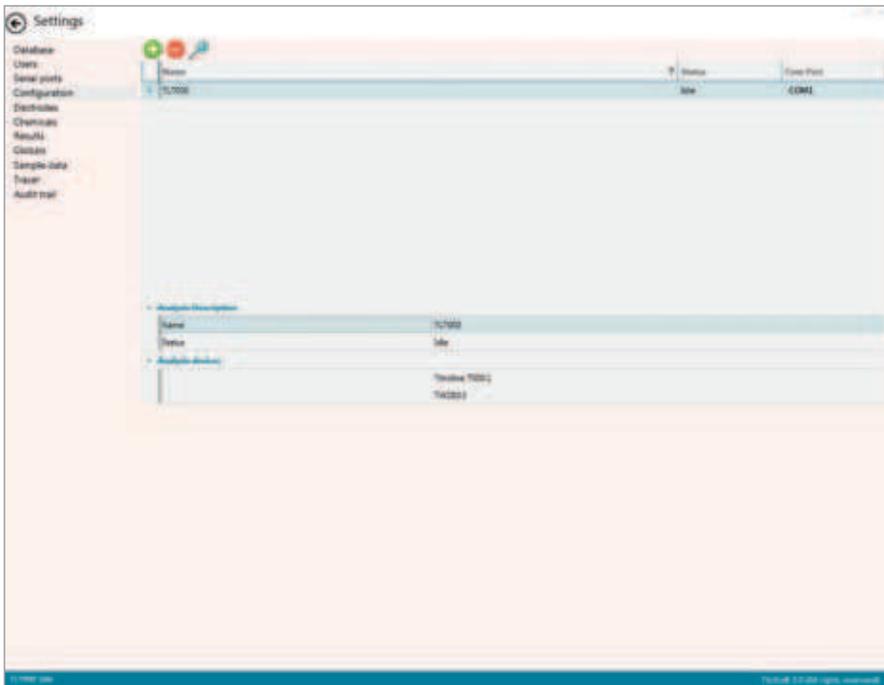
- Settings,
- Database,
- Analysis,
- Worklists
- Curve

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).

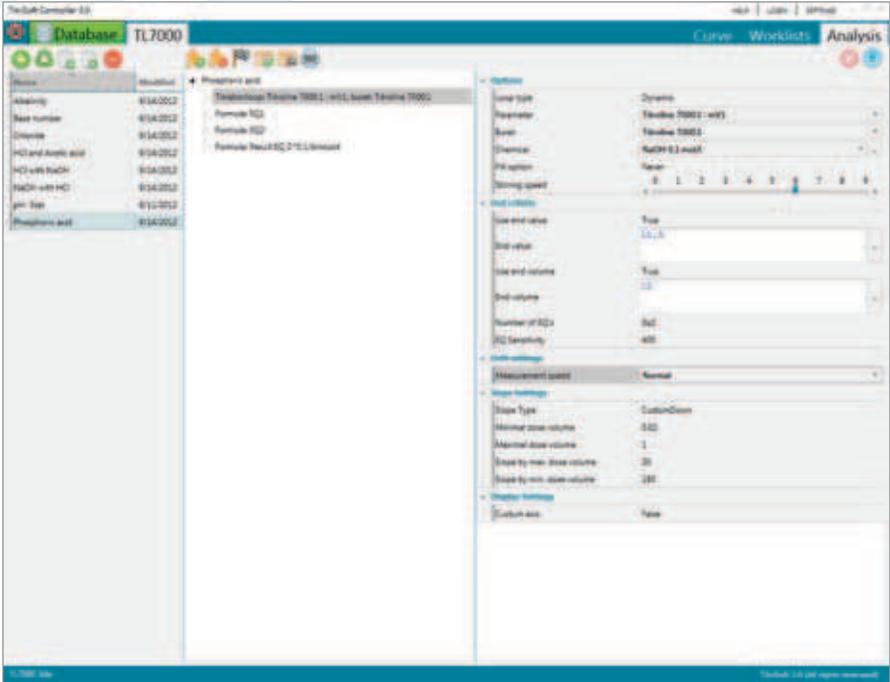
All TitriSoft users can be listed by their names. TitriSoft supports five user types. The Administrator has access to all configuration and software operation options. The "Administrator" has access to all configuration and software operation options. The "User" or "Advanced User" has the same rights as the Administrator but is not allowed to delete results, methods and worklists. Users are restricted to operation of the Titration Center which very much simplifies matters.



Name	Title	Code
Administrator	Administrator	1
User	User	2
Advanced User	Advanced User	3

... clearly structured ...

3.0



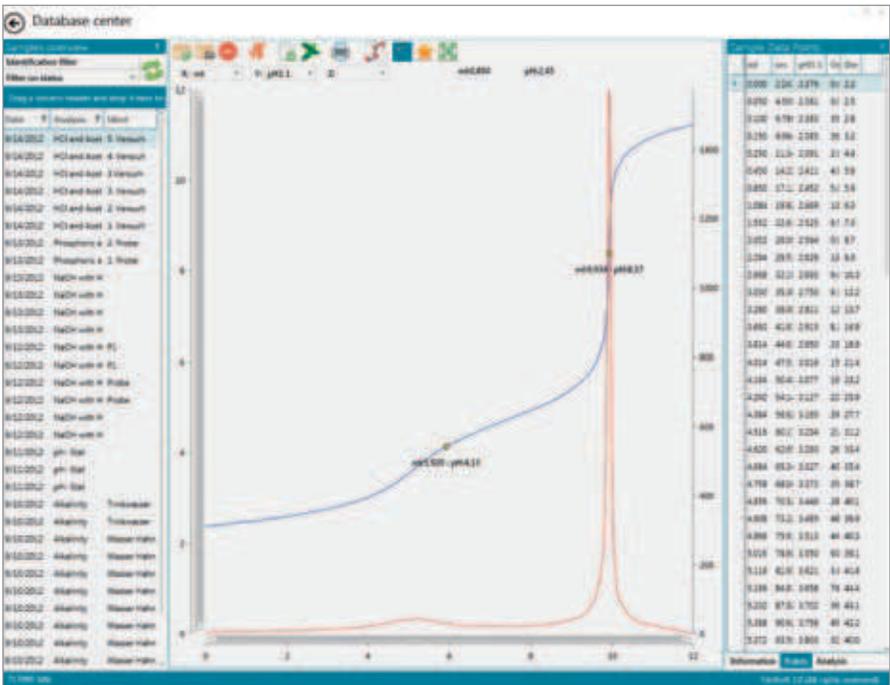
›Analysis, your method center

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 database

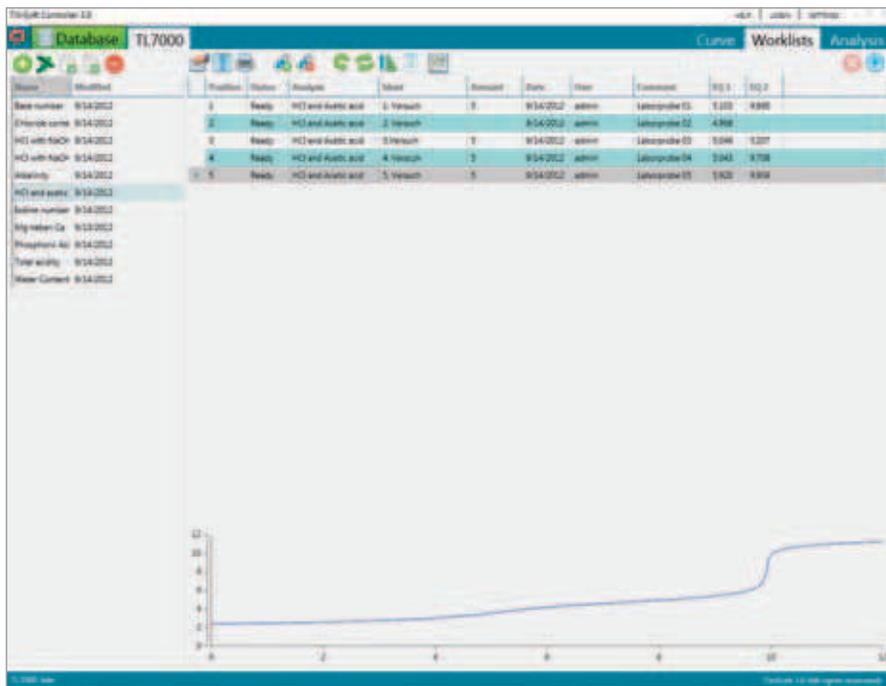
Titration curves, results, measured values and used methods of all titrations are stored in the database. These data can be selected by sample name, date, user and method and loaded in a few seconds.

Information on titrations performed can be displayed in the form of a diagram, results list or measured value list. You can optimize stored titration information in accordance with your requirements, e.g. add and store subsequent calculations or analyze titration curves and print it out together. Additionally, an export of the data to Excel and ASCII is also available.



Ti

## ... highly productive: TitrSoft 3.0



### ›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 print-outs 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.

titriSoft

# TitriSoft 3.0 P – simply reliable ...

In this case, the “P” stands for “pharmaceutical”. The TitriSoft 3.0 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. Food and Drug Administration 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

For optimal and fast working with the TitriSoft 3.0 software your system should be equipped as shown below:

**Interface:** a free USB or RS232-interface per configuration

**Computer:** Pentium D (Dual-Core) 2 GHz or higher

**Operating system:** Windows XP, Vista or 7

**RAM:** minimum 2 GB

**Hard disk:**  
minimum free storage volume 200 MB

**Graphics card:**  
minimum resolution 1280 x 1024

## Comparison between TitriSoft 3.0 and 3.0 P

Functions	TitriSoft 3.0	TitriSoft 3.0 P
Electronic Record		■
Electronic Signature		■
Audit Trail		■
Controlled Access		■
Copies of Records		■
Manual with forms for SOPs, IQ, OQ, PQ and validation reports		■
Straightforward procedure	■	■
All types of titrations	■	■
Comfortable worklists	■	■
Online titration curves	■	■
Clear documentation	■	■
Perfect titration control by PC	■	■

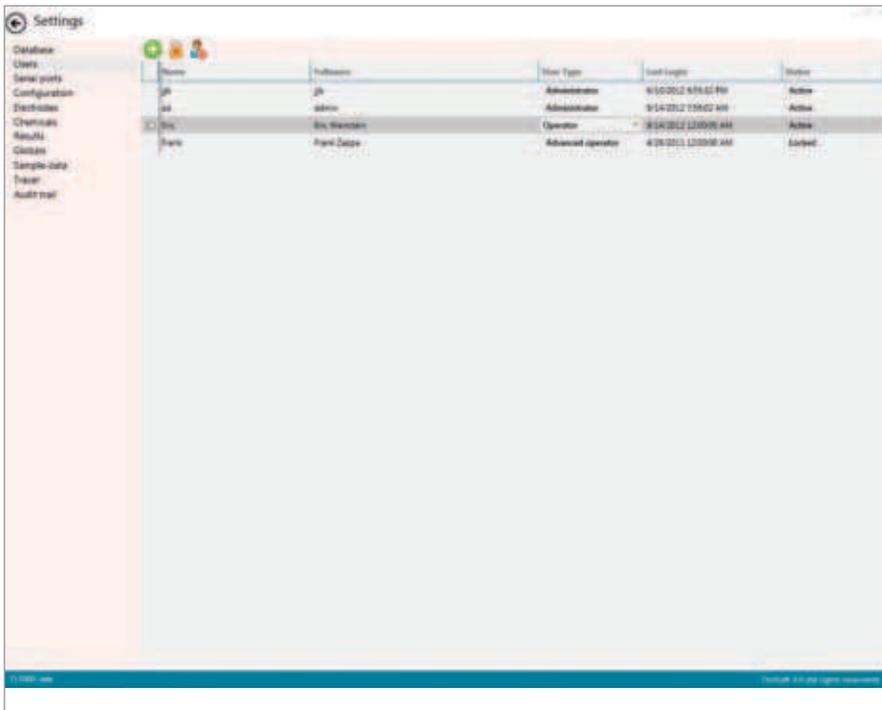
TitriSoft

## 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 3.0 P has 5 different access levels: The "Operator" level does only allow 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. He even has the permission to delete records, but only after a copy of the database has been generated.

# 3.0 P



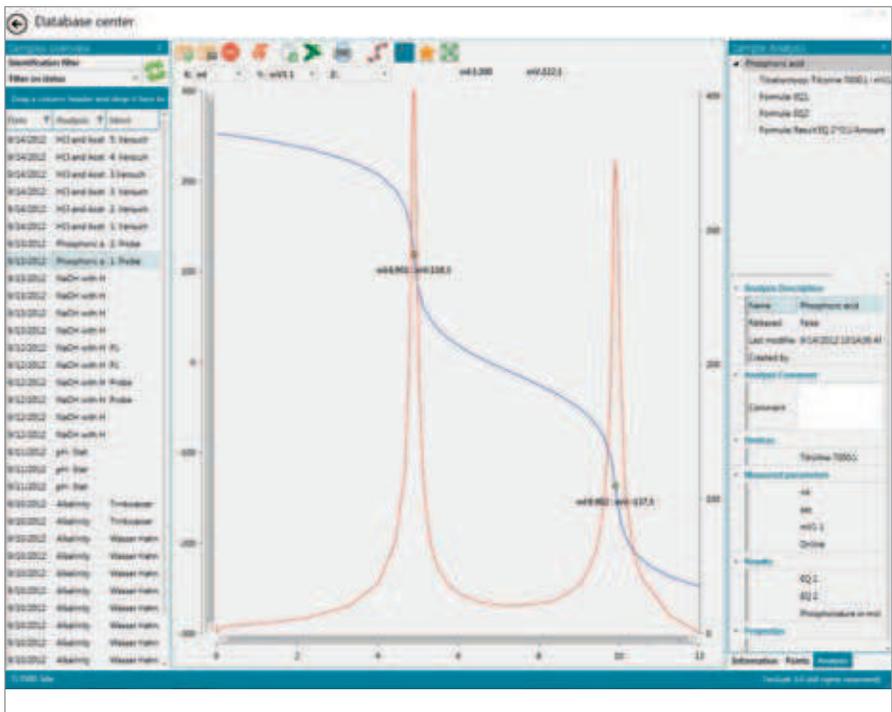
The screenshot shows the 'Settings' window in TitriSoft 3.0 P. On the left is a navigation menu with options: Database, Users, Device profile, Configuration, Electrodes, Chemicals, Results, Classes, Sample data, Paper, and Audit trail. The main area displays a table of users with the following data:

Name	Fullname	User Type	Last Login	Status
jk	jk	Administrator	9/10/2012 8:14:02 AM	Active
jk	admin	Administrator	9/14/2012 11:50:02 AM	Active
jk	jk	Operator	9/14/2012 11:50:00 AM	Active
jk	Frank Depp	Advanced operator	4/28/2011 12:00:00 AM	Locked

ID	Date	Action	Description
1547	8/7/2012 11:40:28 AM	Application	UpdateFlow 40
1548	8/7/2012 11:40:28 AM	Application	UserLogout 40
1549	8/7/2012 11:40:28 AM	Application	UpdateFlow 40
1550	8/7/2012 11:40:28 AM	Application	UserLogoutFailed 40
1551	8/7/2012 11:41:25 AM	Application	UpdateFlow 40
1552	8/7/2012 11:41:25 AM	Application	UserLogoutFailed 40
1553	8/7/2012 11:41:25 AM	Application	UpdateFlow 40
1554	8/7/2012 11:41:25 AM	Application	UserLogout 40
1555	8/7/2012 11:41:29 AM	Application	UpdateFlow 40
1556	8/7/2012 11:41:29 AM	Application	UserLogout 40
1557	8/7/2012 11:41:31 AM	Application	UpdateFlow 40
1558	8/7/2012 11:41:31 AM	Application	UserLogout 40
1559	8/7/2012 11:41:34 AM	Application	UpdateFlow 40
1560	8/7/2012 11:41:34 AM	Application	UserLogout 40
1561	8/7/2012 11:41:37 AM	Application	UpdateFlow 20
1562	8/7/2012 11:41:37 AM	Application	UpdateFlow 40
1563	8/7/2012 11:41:44 AM	Application	UpdateFlow 40
1564	8/7/2012 11:41:44 AM	Application	UserLogout 40
1565	8/7/2012 11:41:47 AM	Application	UpdateFlow 40
1566	8/7/2012 11:41:47 AM	Application	UserLogout 40
1567	8/7/2012 11:41:47 AM	Method	ResultFlow HCl mit NaOH für und für
1568	8/7/2012 11:41:49 AM	Method	UpdateFlow HCl mit NaOH für und für
1569	8/7/2012 11:41:49 AM	Method	HCl mit NaOH für und für
1570	8/7/2012 11:41:49 AM	Analysis	UpdateFlow NaOH mit HCl vor abgelesen
1571	8/7/2012 11:41:49 AM	Analysis	ResultFlow HCl 1
1572	8/7/2012 11:41:49 AM	Analysis	UpdateFlow HCl 1
1573	8/7/2012 11:41:49 AM	Analysis	ResultFlow HCl 2
1574	8/7/2012 11:41:49 AM	Analysis	UpdateFlow HCl 2
1575	8/7/2012 11:41:49 AM	Analysis	ResultFlow HCl 3
1576	8/7/2012 11:41:49 AM	Analysis	UpdateFlow HCl 3
1577	8/7/2012 11:41:49 AM	Analysis	ResultFlow HCl 4
1578	8/7/2012 11:41:49 AM	Application	UpdateFlow 40

### Audit Trail

The 21 CFR Part 11 prescribes that creating methods, modifying passwords or saving results, generates an entry in the Audit Trail. TitriSoft 3.0 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 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.

