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Metrodata TiNet 2.5 Compliant

8.110.8353 Instructions for Use

08.08.2003 / dö

What's new in TiNet 2.5 SR1?

General

- TiNet 2.5 can be installed in one of the two following versions:
  - **TiNet 2.5**
    Basic version of TiNet. Except for some new devices (see below), this version is identical to TiNet 2.4 and will be described in the **8.110.8243 "TiNet 2.4/2.5" Instructions for Use**.
  - **TiNet 2.5 Compliant**
    Extended version of TiNet, which can be configured and run in order to comply with 21 CFR Part 11. In this program version, password protection, user administration, electronic signatures, Audit Trail, and method and determination administration in a database are integrated. The new and different features of this version compared to TiNet 2.5 are described in these Instructions for Use.
- You can always use methods and data created by older TiNet versions.

Devices

- The 794, 795, 798, and 799 Titrinos can be fully controlled by TiNet.
- The 831 KF Coulometer can be fully controlled by TiNet.
- The 778, 789 and 824 Sample Changers can be fully controlled by TiNet (details see Online-Help).

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Contents

1. Overview

1.1 Overview of TiNet 2.5 Compliant

1.1.1 Purpose of program

The name "TiNet" is derived from **Ti**tration **Net**work. TiNet 2.5 Compliant is a comprehensive program package for titrations. It offers the following possibilities:

- Several Titrinos, KF Coulometers, Sample Changers, Dosimats and Conductometers can be used in a single method.
- IF conditions, messages and requests can be incorporated in the method sequence.
- The layout of reports can be designed.

For the performance of the determinations, you use the main window. Here, you control and monitor all important data.

- You can enter sample data manually or via a connected balance.
- Sample data can also be entered for future use in (different) sample data memories (silos).
- You are shown the status of the sample processing.
- Live Titration curves are displayed.
- You can also perform several determinations at different wet workstations simultaneously (parallel titrations).

TiNet 2.5 Compliant can be installed, configured and used in order to comply to the requirements for using electronic documentation and signatures according to 21 CFR Part 11. For this purpose, the program contains password protection, user administration, electronic signatures, Audit Trail and administration of methods and results in databases.

1.1.2 Program parts

Instead of the TiNet panel of previous program versions, TiNet 2.5 Compliant comprises a new main window for performance of determinations. From this main window, the other independent program parts can be called up:

TiNet 2.5 Compliant
Main window of TiNet. Here you handle your daily work: You start titrations and enter sample data (see *section 5.1*).

TiNet 2.5 – Configuration
Here you register the connected devices, as well as manage common variables and calibration data (see *section 2*).

TiNet 2.5 – Methods
Here you edit new or existing draft methods (see *section 4*).

Method administration
Here you organize method versions in the method database according to 21 CFR 11 (see *section 4.3*).

Results
Here you can view and print the original results stored in the result database according to 21 CFR 11 (see *section 6.3*).

TiNet 2.5 – Results
The titration results are also stored (not according to 21 CFR 11) in the so-called "TiNet database". Here, you can display, sort, view and recalculate your data (see *section 6.2*).

1.1.3 Program sub-directories

The installation program copies the files from the installation CD to the drive and directory you specify and creates the following sub-directories:

..\Bin	Includes all files needed for the program package.
..\Data	Default directory for method, result and Audit Trail databases.
..\Database	Default directory for the TiNet database of the program part "Results".
..\Doc	Includes several PDF documents concerning TiNet.
..\Export	Default directory for data exported.
..\Methods	Default directory for draft methods.
..\Methods\Standard	Includes the TiNet standard methods.
..\Results	Default directory for the raw results generated during the course of the methods.
..\Silo	Default directory for silo memories.
..\Tmp	Default directory for PDF report files.

1.1.4 General information

Help

You can use the <F1> key to request context-sensitive help for the current topic anywhere in the program.

Magenta texts — always identify the dialog point in the corresponding window. In some cases, the color is also used to highlight important information.

Green texts — You can click on these texts to branch to other Help topics.

You will always find these two buttons in the toolbar of the program parts. If you press <?>, the list of contents of Help appears for the corresponding program part. With <↖?> you obtain direct help on the individual (menu) items. Click the button. The pointer is now shown as a ?. Move this pointer to the point on which you require help.

Backup

You should back up your data at regular intervals using a long time archiving system.

Select the following sub-directories for backup:

- **Data** (method, result and Audit Trail databases)
- **Database** (TiNet database)
- **Methods** (draft methods)
- **Results** (raw results which have not yet been read into the database)
- **Silo** (sample data memories)
- **Tmp** (PDF files)

1.2 Program installation

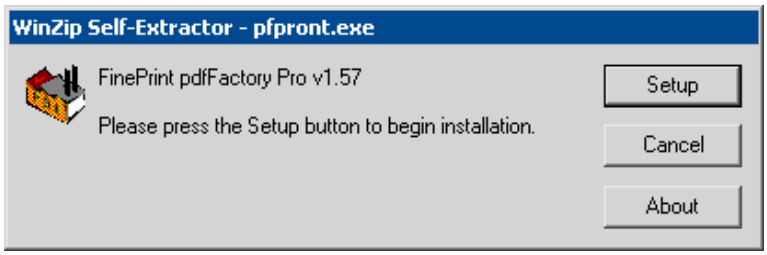
1.2.1 System requirements

Computer	recommended Pentium processor
Operating system	Windows 98/Me, Windows NT 4.0, Windows 2000 (recommended), Windows XP
Disk space	Program: min. 30 MB on hard disk Data: min. 150 MB
RAM	recommended 32 MB
ComPorts	1 free COM port per connected device
LPT	1 free LPT per connected Sample Changer with 664 Control Unit

1.2.2 Installation of TiNet 2.5 Compliant

Note: Start directly with **Step 5**, if you do not want to generate and print PDF reports.

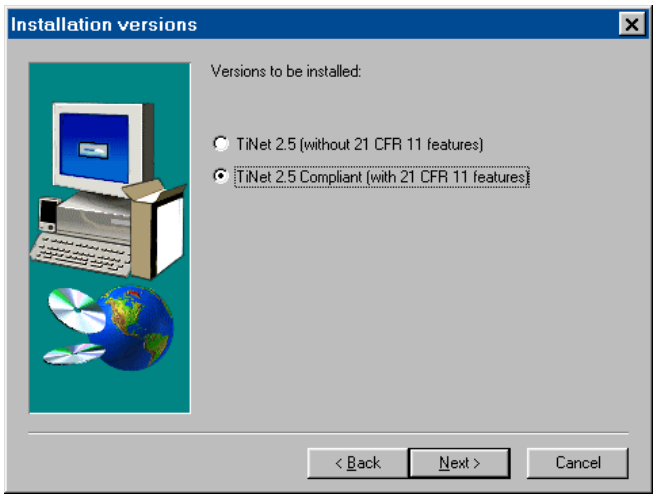
1. If the Adobe Acrobat Reader program is not already installed on the computer, open the **Acro5/English** directory for Adobe Acrobat Reader installation on the installation CD and start the ***.exe** file.
2. After completion of the installation, open Acrobat Reader, accept the contract, open a PDF file, print it, and close Acrobat Reader.
3. Open the **PDFFact/English** directory for Fineprint PDFFactory Pro printer driver installation on the installation CD. According to your operating system, open the **95_98_ME** or **NT2000XP** directory and start the ***.exe** file.



4. Click on **<Setup>** and confirm the installation procedure with **<Yes>**.

   Important: The installed printer driver "FinePrint pdfFactory Pro" is a shareware version with all functions, which creates a message on each report. If you like to print reports without this message, the full version of "PDF Factory Pro" must be purchased. You will find ordering information on **www.fineprint.com/company/resellers.html**.

5. Install TiNet 2.5 from the installation CD and proceed according to the installation wizard until the window **Installation versions** appears.



6. Select the option **TiNet 2.5 Compliant (with 21 CFR 11 features)** and click on **Next>**.
7. Select the installation directory and click on **Next>**. The "TiNet 2.5 Compliant" program will be installed.
8. Click on **Finish>** to complete the installation.
9. Open the TiNet 2.5 Compliant program. The **Login** window appears (see *section 7.1.1*).
10. Enter "**Admin**" for **User name** and "**TiNet2**" for **Password**. Click on **<OK>**.
11. Select **Extra/Options/Print options** to open the **Print options** window (see *section 3.4.2*).
12. In the **Print options for TiNet reports** box, enable the **Special printer** option and select the **FinePrint pdfFactory Pro** printer driver.
13. Select the directory to which PDF reports will be saved. There must be no '**.**' (dot) in the whole path!
14. Select a **Delay** for the PDF creation. It is not recommended to select shorter times than 45 sec. Note that this is the minimum method duration time (add a WAIT block to the method if the duration time is shorter than this delay)!
15. Enable or disable the option for immediate printing of PDF reports. This requires the installation of Adobe Acrobat Reader (see Step 1).
16. Click on **<OK>** to close the **Print options** window and close the program.
17. Create a new method containing a WAIT block (waiting time 60 s), a CALC block (with a calculation formula "RS = SmplSize") and a REPORT block (text field, "Print immediately" activated).
18. Start the method.
19. If you are working with a NTFS file system, make sure that all Windows users have read and write privileges for all subdirectories of the program directory, for the method directory, for all export directories defined in the program and for C:\ and the two files **WIN.INI** and **TINET2.INI** in the Windows directory.

20. Make sure that all Windows users have read and write privileges for the following registry keys and subkeys (use **REGEDT32.EXE** to view and modify the permissions):
    a. **HKEY_CURRENT_USER\Software\FinePrint Software\pdfFactory**
    b. **HKEY_LOCAL_MACHINE\Software\Classes\Tinet2**
    c. **HKEY_LOCAL_MACHINE\Software\Metrohm\TiNetCom**
    d. **HKEY_LOCAL_MACHINE\Software\Adobe**
    f. **HKEY_LOCAL_MACHINE\Software\PDFReport** (only displayed after first PDF printout)
    g. **HKEY_CLASSES_ROOT** (write privileges)
21. Restart the computer.
22. Please send us your registration card as soon as possible so that we can register you as an official user of TiNet. Only registered users will get updated program versions at a special price.

1.2.3 Installation of the Dongle

The 6.2145.000 or 6.2145.060 Dongle is part of the scope of delivery of the **full program versions**. Set this Dongle on LPT-Port 1 or 2 (if possible on the LPT Port where you connected the printer, not on the Sample Changer Port). The printer cable is set onto the Dongle. Starting TiNet, the Dongle will be checked.

If you set the dongle onto a different LPT after installing TiNet, proceed as follows:

- Close TiNet.
- Start the **iniedit.exe** program in the Bin directory of TiNet.
- Select the **Miscellaneous** tab and click on **<Apply>**.

If you make an **update of an older version of TiNet**, first set the dongle on the LPT (see above) before you start TiNet. Do not click the option "4COM card" during the installation.

A **demonstration version** can be used for 100 days. After this 100 days you may continue to use the program, but you cannot start any determination. You can upgrade your demonstration version at any time if you set a 6.2145.000 or 6.2145.060 Dongle on the LPT Port of your computer.

Note: The use of TiNet 2.5 Compliant without dongle as **demo version** is not recommended.

1.2.4 Deinstallation of TiNet

After uninstalling TiNet you will get a dialog with the button **<Detail>**. Here you will find a list of directories which could not be deleted.

2. Connection of devices and configuration

2.1 Connection of devices

You will find detailed information on connecting devices and adding additional interfaces in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 2*.

2.2 Configuration

You will find detailed information on the lists of devices, calibration data and common variables in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 5*.

2.3 Special settings

You will find detailed information on the special settings which can be set by the INIEDIT.EXE program in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 9*.

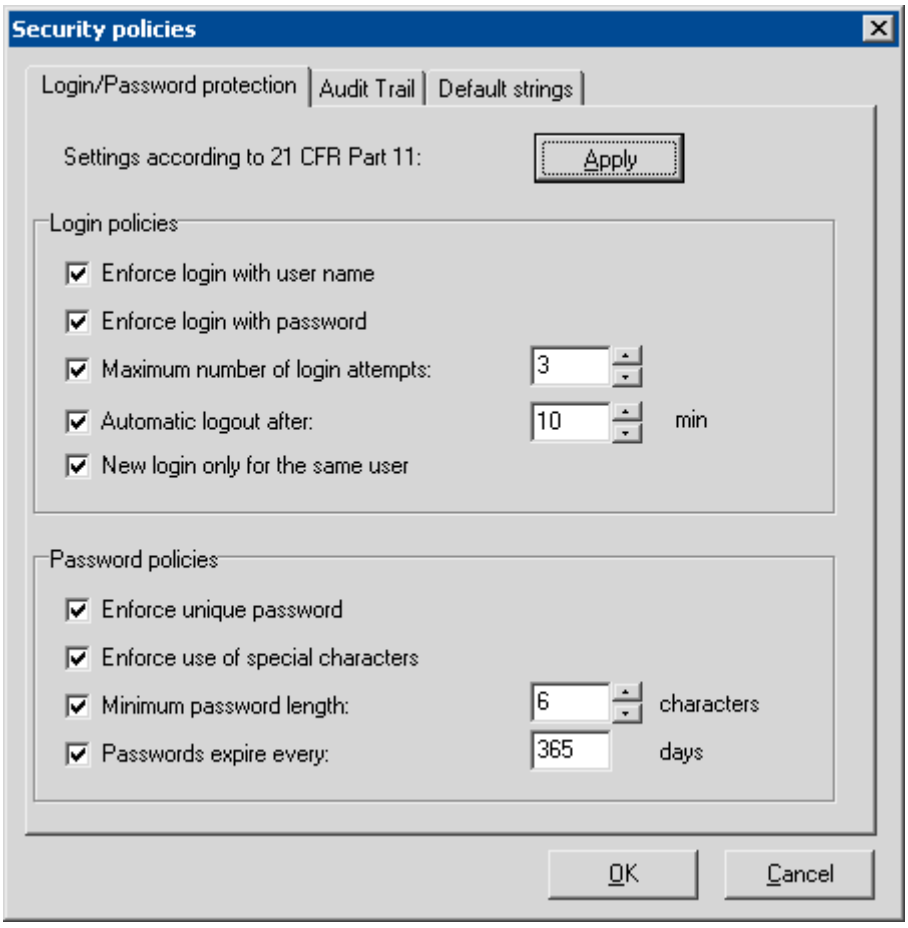
3. Program settings

3.1 Security policies

TiNet 2.5 Compliant, Extra, Security policies

This menu item opens the **Security policies** window for definition of login options, password protection, Audit Trail, electronic signatures and default strings.

3.1.1 Options for Login/Password protection



Settings according to 21 CFR 11:

<Apply> sets all login and password options to default settings according to 21 CFR Part 11.

Login policies

Enforce login with user name ([on], off)

If this option is enabled, every user must enter her/his user name in the **Login** window at every program start. If this option is disabled, no login is required. The following login and password policies are meaningless and will be set to inactive (gray).

Enforce login with password ([on], off)

If this option is enabled, every user must enter user name and password in the **Login** window at every program start. If this option is disabled, no login is required. The following login and password policies are meaningless and will be set to inactive (gray).

Maximum number of login attempts ([on], off); 2...[3]...6)

If this option is enabled, a user is set to "**inactive**" as soon as the maximum number of login attempts is exceeded. The counter for login attempts is set to zero for all users at every new start of the program.

Automatic logout after ([on], off); 1...[10]...60 min)

If this option is enabled, the user is logged out automatically if no operating function via mouse or keyboard is done during the defined delay time.

New login only for the same user ([on], off)

If this option is enabled, only the same user can login after automatic logout. In any case, user with administrator privileges can always login.

Password

Enforce unique password ([on], off)

If this option is enabled, passwords must be unique. Expired passwords are treated like active passwords, so every password can only be used once.

Enforce use of special characters ([on], off)

If this option is enabled, a password must contain at least one special character.

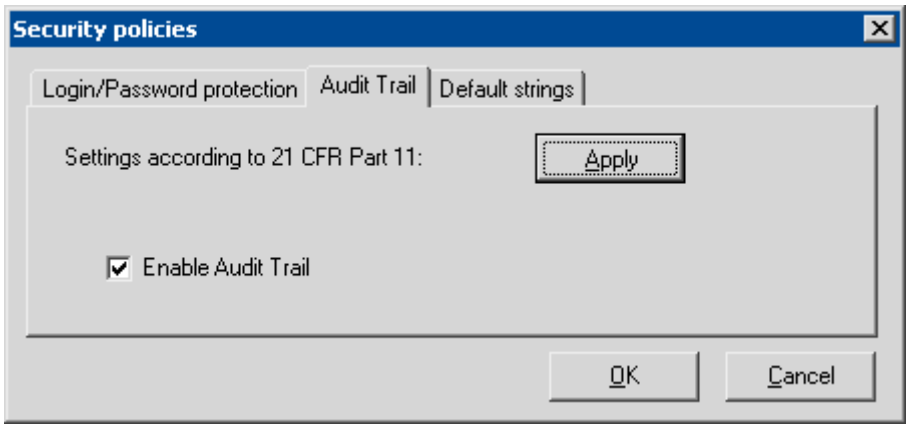
Minimum password length ([on], off; 1...[6]...40 characters)

If this option is enabled, the password must have the set number of characters.

Passwords expire every ([on], off; 1...[365]...999 days)

If this option is enabled, a new password must be entered after the expiration time.

3.1.2 Audit Trail settings



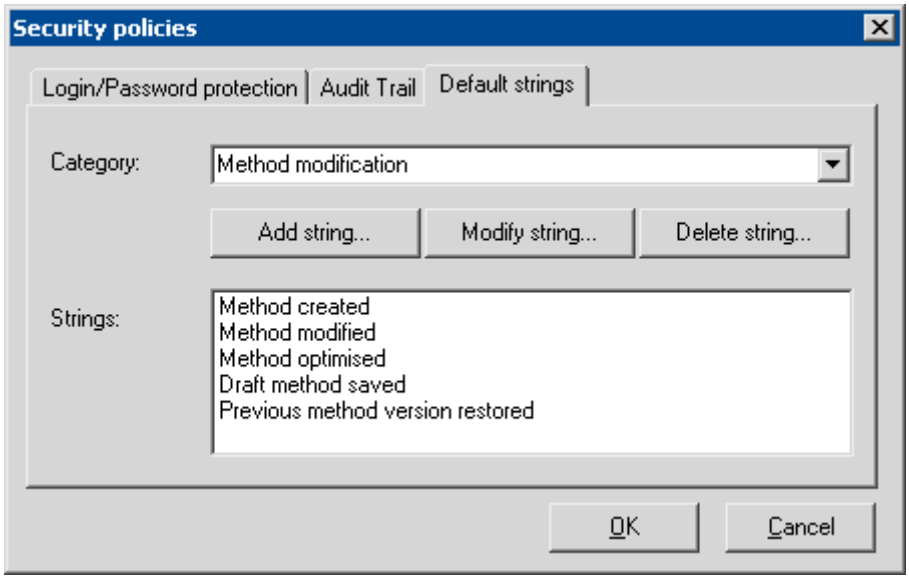
Settings according to 21 CFR Part 11:

<Apply> sets all Audit Trail options to default settings according to 21 CFR Part 11.

Enable Audit Trail ([on], off)

If this option is enabled, all program actions defined as Audit Trail actions are registered automatically in the Audit Trail database.

3.1.3 Define default strings



Category: Selection of the category, for which default strings can be defined.

Add new default string. The window for entering default strings is opened.

Modify string...

Modify selected string. The window for edition of default strings is opened.

Delete string...

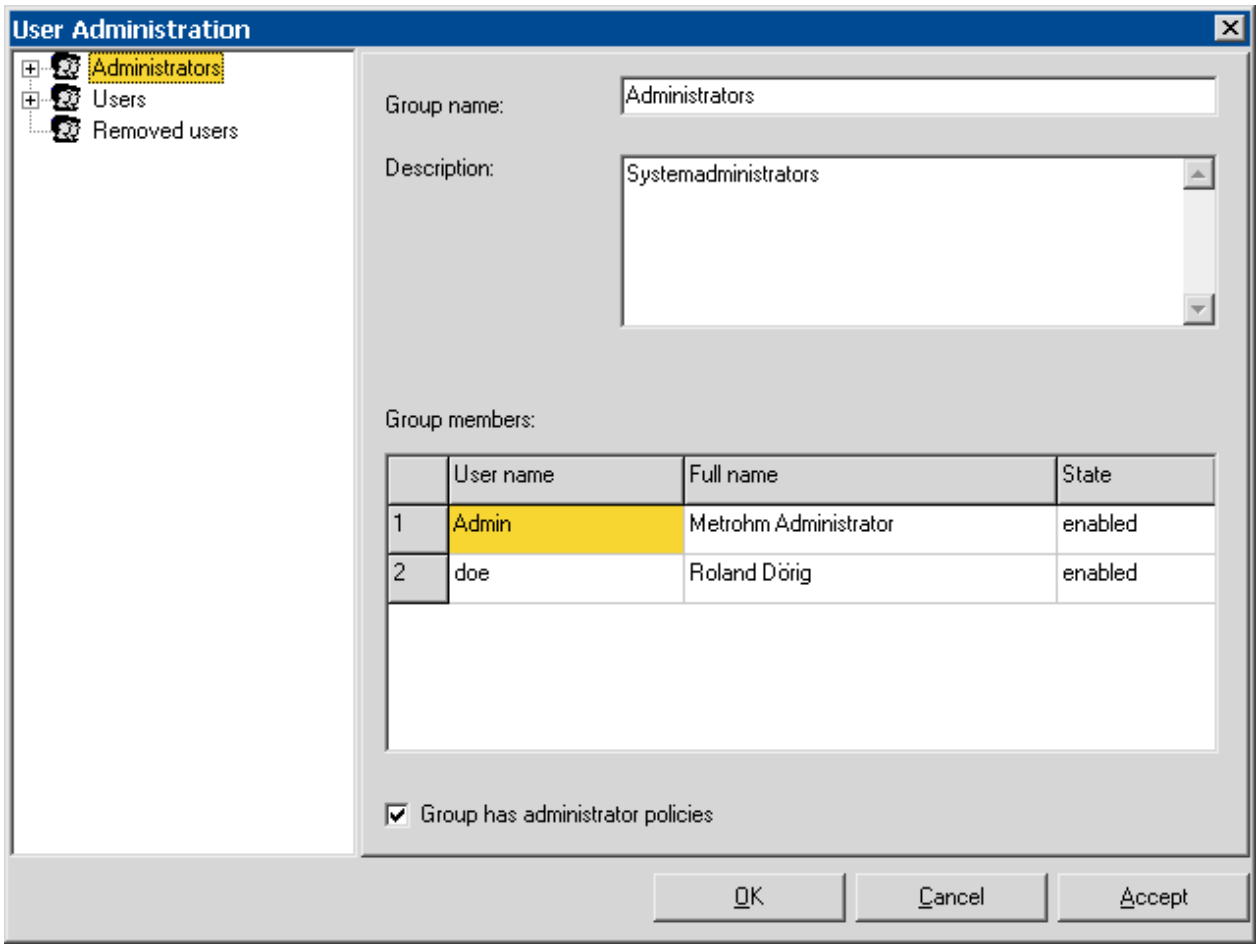
Delete selected string.

3.2 User administration

TiNet 2.5 Compliant, Extra, User administration

This menu item opens the **User administration** window for administration of user groups and users and their access rights and signature policies.

3.2.1 User groups



If a user group is selected in the left part of the **User administration** window, details on this user group and a table with all group members (**User name**, **Full name** und **State**) are shown in the right part.

Group name:

Name of the user group. This name must be unique. The name

can also be edited by clicking the group name field in the explorer part.

Description:
Description of the user group.

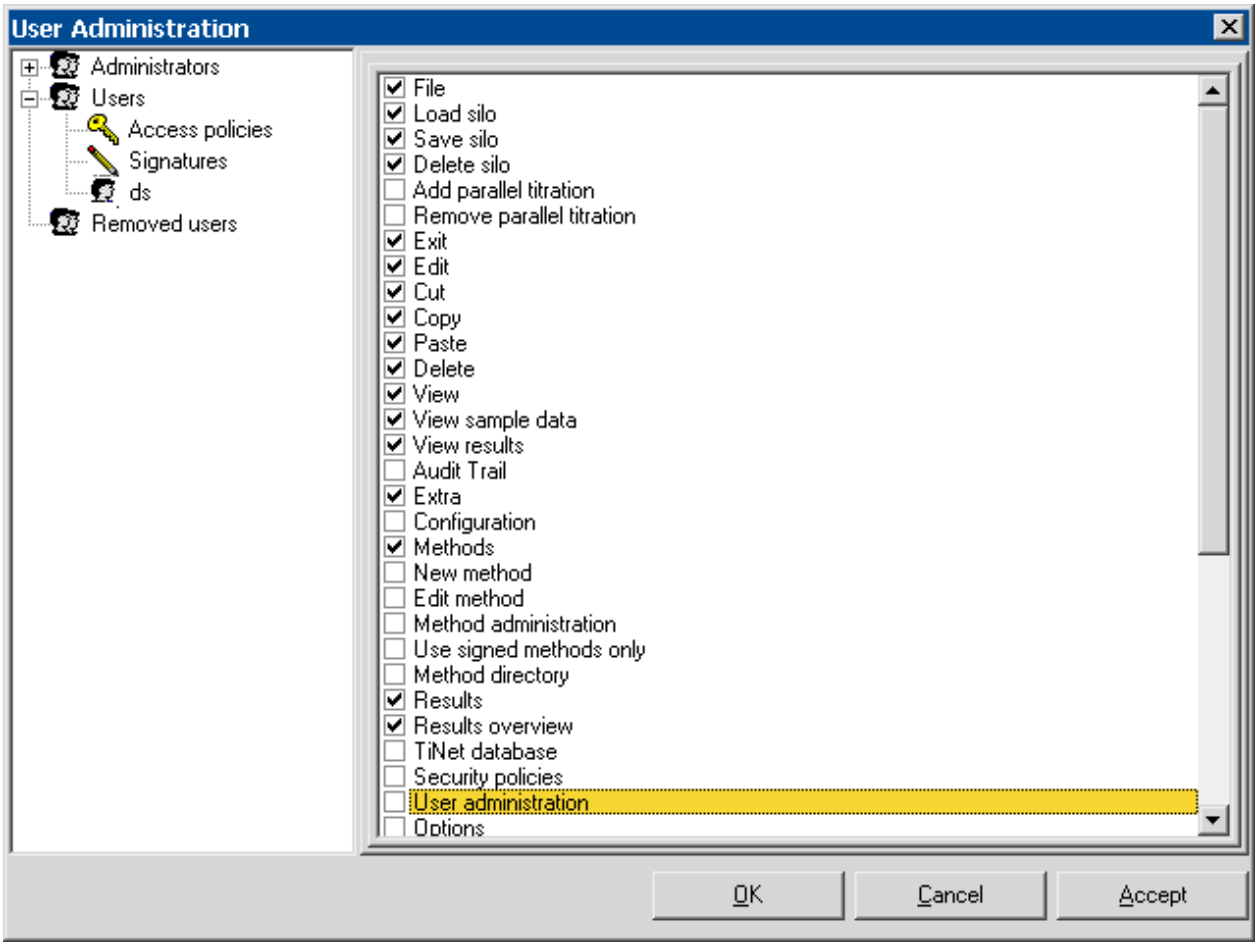
Group has administrator policies
If this option is enabled, the user group has administrator policies. This option must be enabled for at least one group.

After clicking the group name field in the explorer part with the right mouse key, user groups can be created and deleted:

New group
Create new user group.

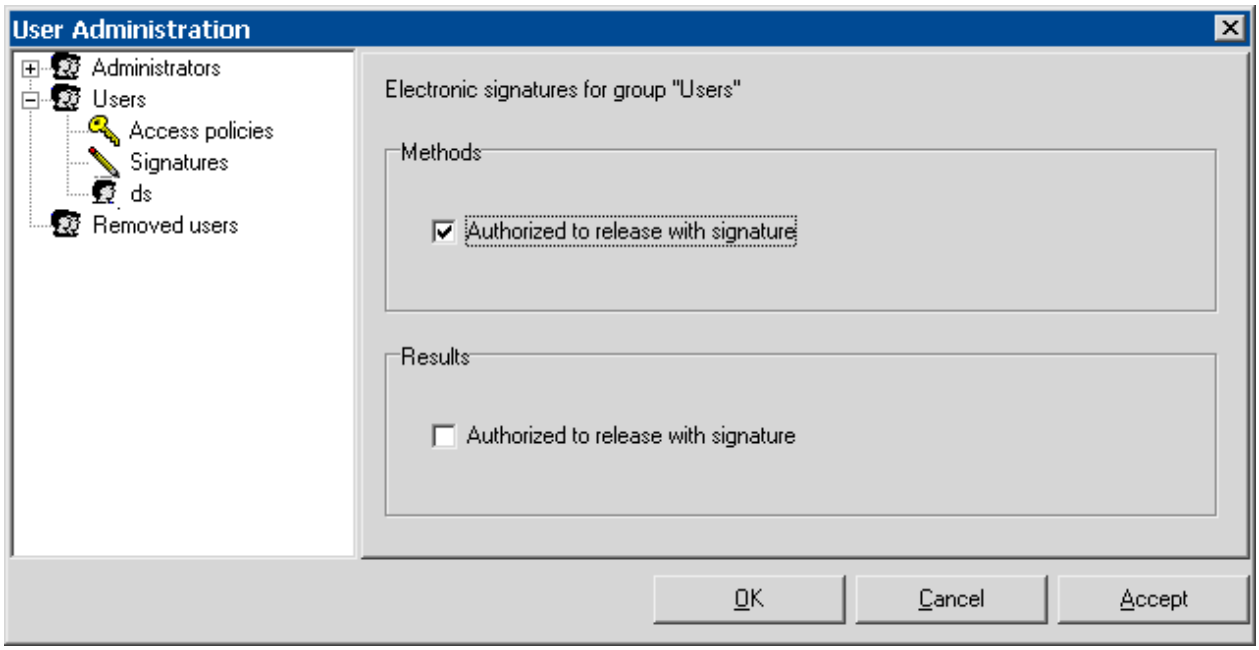
Delete group
Delete selected user group. The group can only be deleted if it has no users any more.

3.2.2 Access policies



If the **Access policies** element is selected in the left part of the **User administration** window, access policies for this user group are shown in the right part and can be modified. Every menu item of the TiNet 2.5 Compliant main window can be enabled or disabled.

3.2.3 Electronic signatures

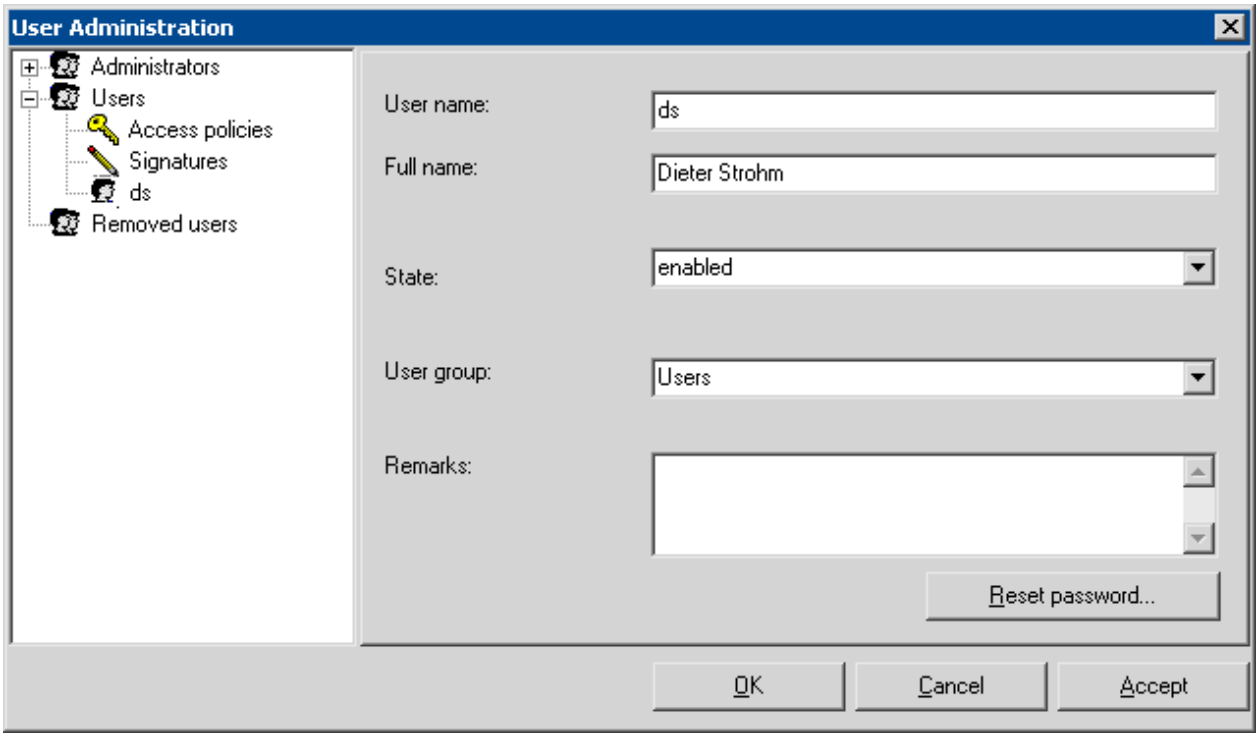


If the **Signatures** element is selected in the left part of the **User administration** window, the authorization for signature of methods and results for this user group are shown in the right part and can be modified.

Authorized to release with signature

If this option is enabled, user of this user group are allowed to sign methods or results.

3.2.4 Users



If a user from a user group is selected in the left part of the **User administration** window, details on this user are shown in the right part.

User name:
Short name of the user which must be entered for **User name** in the **Login** window. This name will be enclosed in the report.

Full name: Full name of the user with possibility for additional information (e.g. title, address, etc.).

State: Current user state (**active**, **inactive**, **removed**). The administrator is allowed to change the user state.

User group:
Current user group. The administrator is allowed to change the group for the user. If this is done, the user icons are automatically transferred to the new group.

Remarks: Possibility to enter additional user information.

<Reset password>
Possibility to reset the password for the user to the original start password (identical to the **User name**), which must be changed immediately at first login.

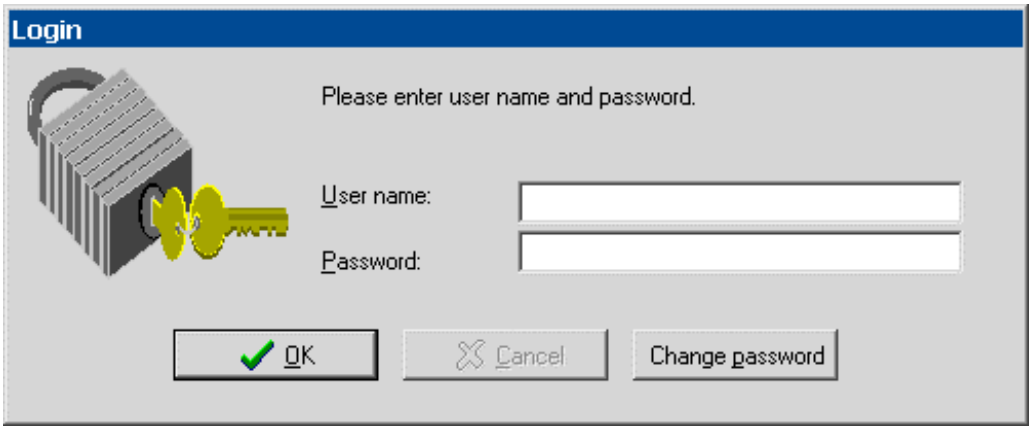
After clicking into the explorer part with the right mouse key, users can be created and deleted:

New user Add new user to user group.

Delete user
Delete selected user from the user group and transfer to the **Removed users** group.

3.3 Login/Logout

3.3.1 Login

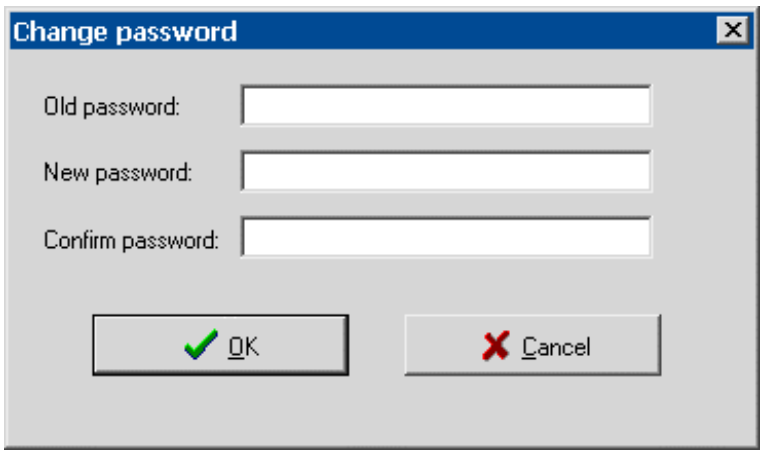


If password protection is enabled on the **Security policies** tab, the **Login** window appears at every new start of TiNet or after Logout. In this window, you have to login by entering user name and password.

User name
Enter your user name (capitals are ignored).

Password Enter your password (capitals must be identical!). At first login, the **Password** is identical to the **User name**, but it must be changed immediately.

Click this button to change your password.



Old password:
Enter your old password.

New password:
Enter the new password.

Confirm password:
Confirm the new password.

3.3.2 Logout

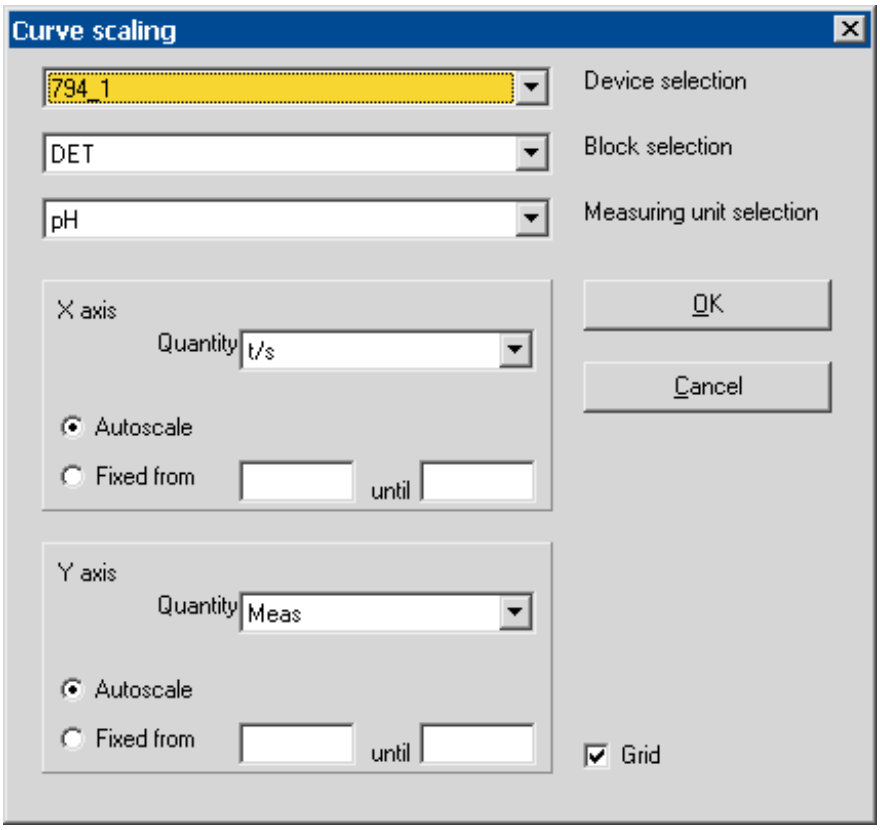
By clicking this button the current user is logged out. At the same time, the **Login** window for login of a new user appears on the screen.

3.4 Options

3.4.1 Curve settings

TiNet 2.5 Compliant, Extra, Options, Curve settings

This menu item opens the **Curve settings** window. You can define here how to display live titration curves on the device tabs in the main window.



Device selection

Selection of the device for which the curve settings will apply.

Block selection

Selection of the block (e.g. **MET**, **DET**) which the curve settings will apply.

Measuring unit selection

Selection of the measuring unit (e.g. **pH**, **U**) for which the curve settings will apply.

X axis

Quantity

Selection of the quantity which will be displayed on the X axis: Volume (**V/ml**), Time (**t/s**), Measured value (**Meas**), **ERC** (only for DET titrations; first derivative multiplied with a logarithmic factor), **Meas & ERC** (both curves), **Temp** (Temperature in °C).

Autoscale

Automatic scaling.

Fixed from...until

Fixed scaling.

Y axis identical to X axis.

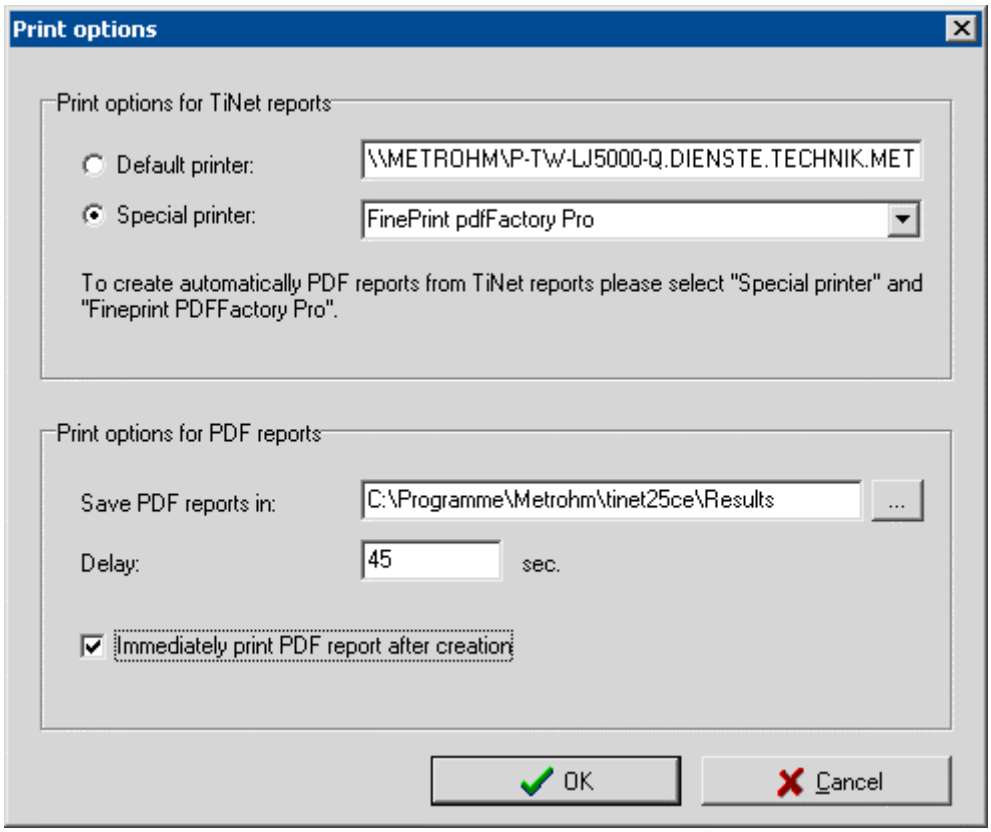
Grid Display of grid lines.

3.4.2 Print options

TiNet 2.5 Compliant, Extra, Options, Print options

This menu item opens the **Print options** window for report output settings.

Note: Reports are only created automatically in the method sequence if the **Print immediately** option in the **Report** block is enabled.



Print options for TiNet reports

Printer selection für TiNet report printing:

Default printer

Windows default printer (display only).

Special printer

Selection of a printer configured for Windows. In order to create automatically PDF reports from TiNet reports, the "**FinePrint pdfFactory Pro**" printer must be selected.

Print options for PDF reports

Save PDF reports in

Selection of the directory to save the automatically generated PDF reports.

Note: No point (.) is allowed in the whole directory path.

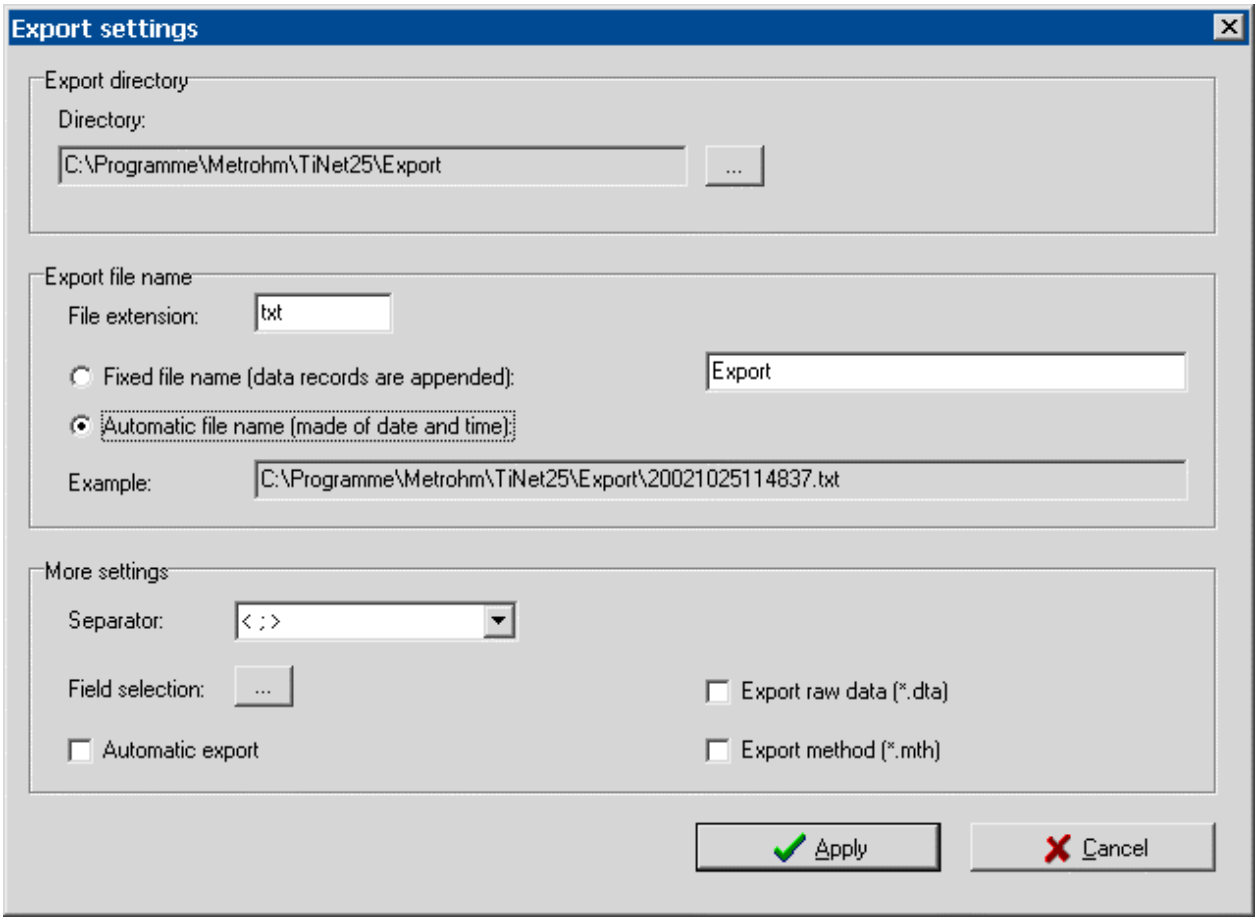
Delay Delay time for PDF report generation. It is recommended to set a minimum delay of 45 s.

Immediately print PDF reports after creation
If this option is enabled, the PDF reports are printed on the selected printer. If this option is disabled, the PDF reports are only saved.

3.4.3 Export settings

TiNet 2.5 Compliant, Extra, Options, Export settings

This menu item opens the **Export settings** window. You can define here how to export data from the result database.



Export directory

Directory
Selection of the directory to which data will be exported.

Export file name
Definitions for export file name.

File extension
File extension for export file.

Fixed file name (data records are appended)

If this option is enabled, the data of the selected determinations will be appended in one file. The name for this file can be entered in the field on the right side.

Automatic file name (made of date and time)

If this option is enabled, a separate file is created for each determination selected. The name for these files are generated automatically from date and time of the determination.

Example

Display of an example name with set parameters.

More settings

Separator

Selection of character for separation of field contents. Available characters: " ; " , ", " **TAB** " and " **SPACE**".

Field selection

Click on  to open the **Field selection** window. You can select here the fields of the result overview table which will be exported.

Automatic export

If this option is enabled, the data will be exported automatically at the time the determination data are saved in the result database.

Export raw data (*.dta)

If this option is enabled, the raw data of the selected determination will be saved in a *.dta file. The name of this file will be generated automatically from date and time of the determination.

Export method (*.mth)

If this option is enabled, the method used for the selected determination will be saved in a **'Method name'.mth** file.

3.4.4 System name

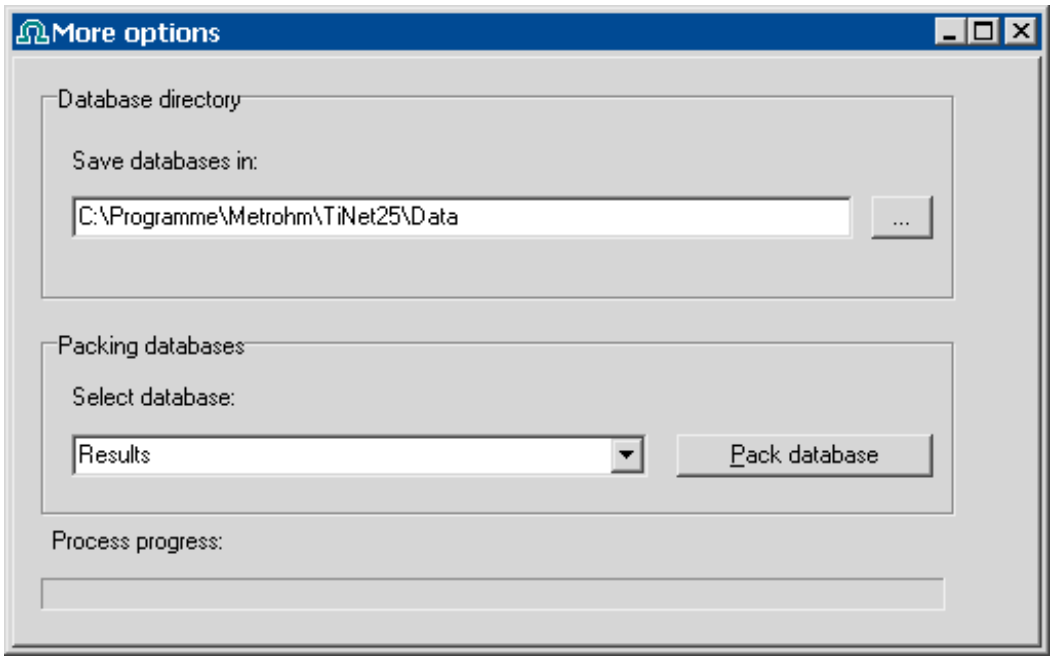
TiNet 2.5 Compliant, Extra, Options, System name

This menu item opens the **System name** window where the name to be entered as **System name** in the Audit Trail (see *section 7.5.1*) can be defined.

3.4.5 Database options

TiNet 2.5 Compliant, Extra, Options, Database options

This menu item opens the **More options** window. You can define here where to save method, result and Audit Trail database. It is also used to pack databases.



Database directory

Save databases in

Selection of the directory for saving method, result and Audit Trail databases.
Note: Make sure that every user has permanent read/write privileges for this directory!

Packing databases

Select database

Selection of the database to be packed.

<Pack database>

Start packing.

Process progress

Display of packing progress.

4. Methods

4.1 General information on methods

Two different types of methods are used in TiNet 2.5 Compliant: **Draft methods** and **Database methods**.

4.1.1 Draft methods

Draft methods are stored as files in the **Methods** directory. Only these methods can be edited in the **TiNet 2.5 – Methods** program part. If the **Use signed methods only** option is disabled, draft methods can also be used to perform determinations. In this case, the requirements for working according to 21 CFR Part 11 are not met.

You will find detailed information on edition of draft methods in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 6*.

Note:
Start and end sequences are ignored with TiNet 2.5 Compliant.

4.1.2 Database methods

Draft methods can be saved in the method database as **Database methods**. At every saving procedure, a new method version is created. The user must enter a comment for each method version. In order to use database methods they must be signed electronically and given a signature comment. In addition to this, the **Use signed methods only** option must be enabled. If you use database methods, the requirements for working according to 21 CFR Part 11 are met.

A method version of the method database must be copied as draft method before it can be edited. If already present, an existing draft method with the same name is overwritten. Once the method has been modified, it must be saved again in the method database as a new method version.

You will find detailed information on edition of draft methods in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 6*.

4.2 Draft methods

4.2.1 Create new method

TiNet 2.5 Compliant, Extra, Methods, New method

This menu item opens the **TiNet 2.5** / **Methods** program part, where a new method can be created.

You will find detailed information on edition of draft methods in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 6*.

4.2.2 Edit existing methods

TiNet 2.5 Compliant, Extra, Methods, Edit method

This menu item opens one of the draft methods available in the current method directory in the **TiNet 2.5 - Methods** program part.

Method administration, Draft methods, Edit method

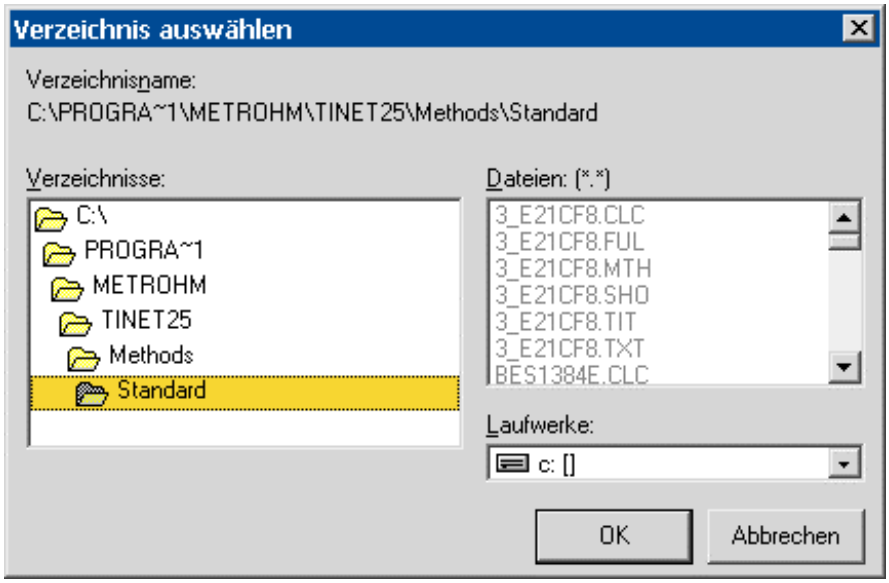
This context-sensitive menu item opens the selected draft method in the **TiNet 2.5 - Methods** program part.

You will find detailed information on edition of draft methods in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 6*.

4.2.3 Set method directory

TiNet 2.5 Compliant, Extra, Methods, Method directory

This menu item opens the **Select directory** window for selection of the directory for draft methods. You will find existing default methods in the **..\Methods\Standard** directory.

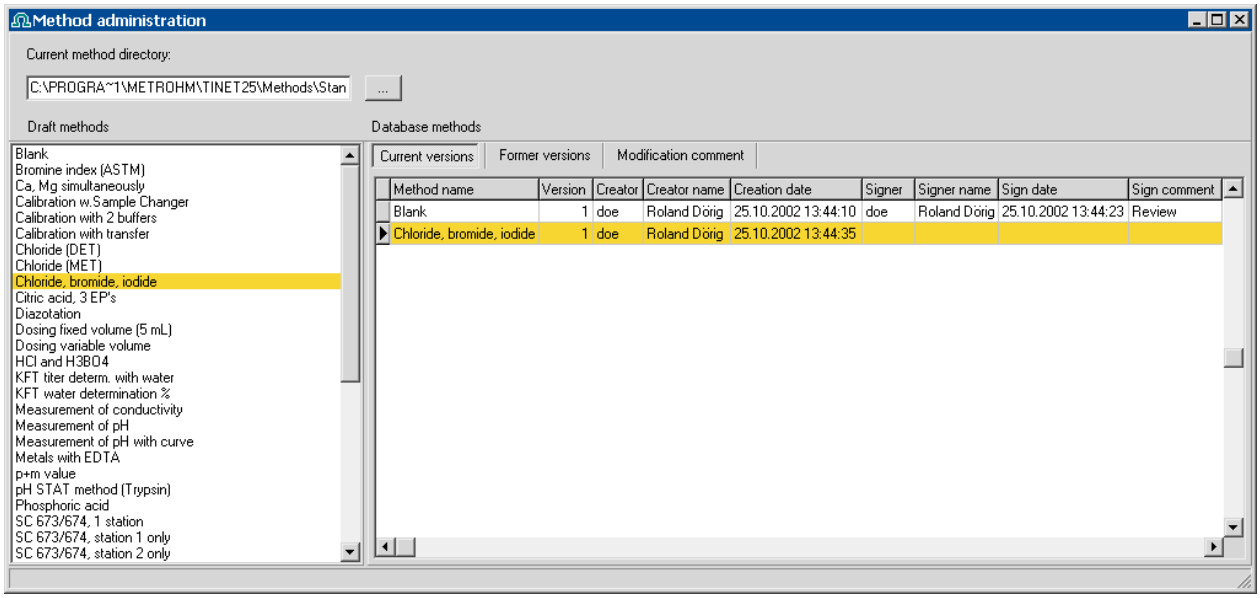


4.3 Database methods

4.3.1 Method administration

TiNet 2.5 Compliant, Extra, Methods, Method administration

This menu item opens the **Method administration** window for display of all draft methods and database methods with its versions.



Current method directory

Display of the current directory for draft methods. TiNet has more than 40 prepared default draft methods in the **..\Methods\Standard** directory.

Draft methods

Display of the draft methods available in the current methods directory. By clicking a draft method with the right mouse key the following functions can be triggered:

Save method in database (see *section 4.3.2*)

New method (see *section 4.2.1*)

Edit method (see *section 4.2.2*)

Database methods

Display of the methods in the method database. By clicking a database method with the right mouse key the following functions can be triggered:

Copy method to editor

The database method is copied as draft method into the method directory.

Show method

The database method is opened as draft method but cannot be edited.

Sign method (see *section 4.3.3*)

Export method (see *section 4.3.4*)

Method report (see *section 4.3.5*)

Delete method (see *section 4.3.6*)

Current versions

On this tab, the current versions of the available database methods are shown. The table on this tab has the following columns:

Method name
Name of database method.

Version
Version number of database method (stored as **Id8** for determinations).

Creator
User name of the user who saved the database method.

Creator name
Full name of the user who saved the database method.

Creation date
Date and time when the database method was saved.

Signer
User name of the last user who signed the database method.

Signer name
Full name of the last user who signed the database method.

Sign date
Date and time when the database method was signed.

Sign comment
Comment entered at signing the database method.

Former versions

On this tab, the former versions of the available database methods are shown. With the exception of the method name, which is shown above the table, the table has the same columns as the **Current versions** tab. In order to convert a former version to the current version, it must be copied first as draft method with **Copy method to editor** and then saved again as a new version in the method database with **Save method in database**.

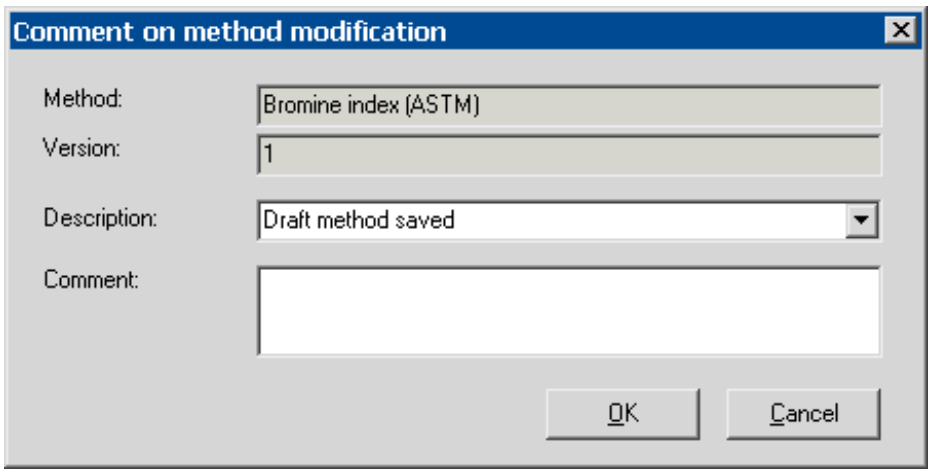
Modification comment

On this tab, the comment entered at saving of the database method is shown.

4.3.2 Save method in database

Method administration, Draft methods, Save method in database

Using this context-sensitive menu item, a draft method can be saved in the method database. Before the method is saved, the **Comment on method modification** window appears:



Method:
Method name (display only)

Version:
Automatically set version number (display only)

Description:
Selection of a default string or entry of a user-specific text.

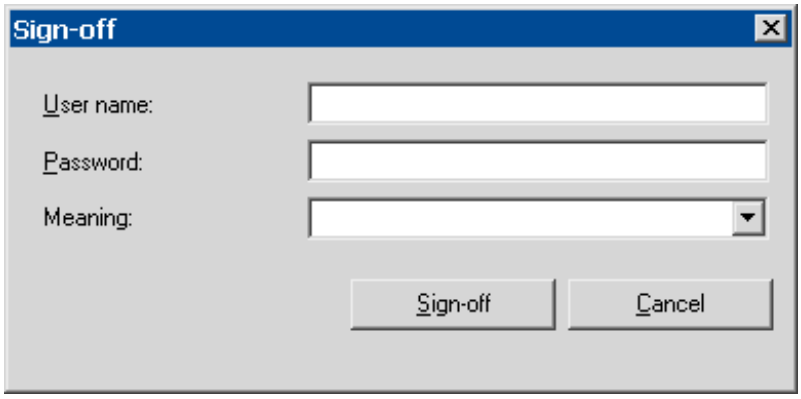
Comment:
User-specific comment for description of method modifications.

Afterwards, the method can be signed.

4.3.3 Sign method

Method administration, Database methods, Sign method

Using this context-sensitive menu item, a database method can be signed electronically. The **Sign-off** window appears, containing the following fields:



User name
Name of the user who wants to sign the method.

Password
Password of the user who wants to sign the method.

Meaning
User-specific comment to the signature.

By clicking on **<Sign-off>**, these data are saved in the method database. Signature data already present is always overwritten by the new signature data.

4.3.4 Export method

Method administration, Database methods, Export method

Using this context-sensitive menu item, a database method can be exported. The **Select directory** window appears for selection of the export directory. With **<OK>**, the method is saved as method file (***.mth**) and the application note as text file (***.txt**) in this directory.

Exported methods can be imported into a method database using the **Save method in database** menu item.

4.3.5 Method report

Method administration, Database methods, Method report

Using this context-sensitive menu item, a report of the selected database method is printed on the default printer. This report contains the following entries:

Method name:
Method name

Method version:
Version number of the method

Saved by:
Full name of the user who saved the method in the method database.

Saved on:
Date and time of saving the method.

Signed by:
Full name of the user who signed the database method.

Signed on:
Date and time of signing the method.

Sign comment:
Comment to signature.

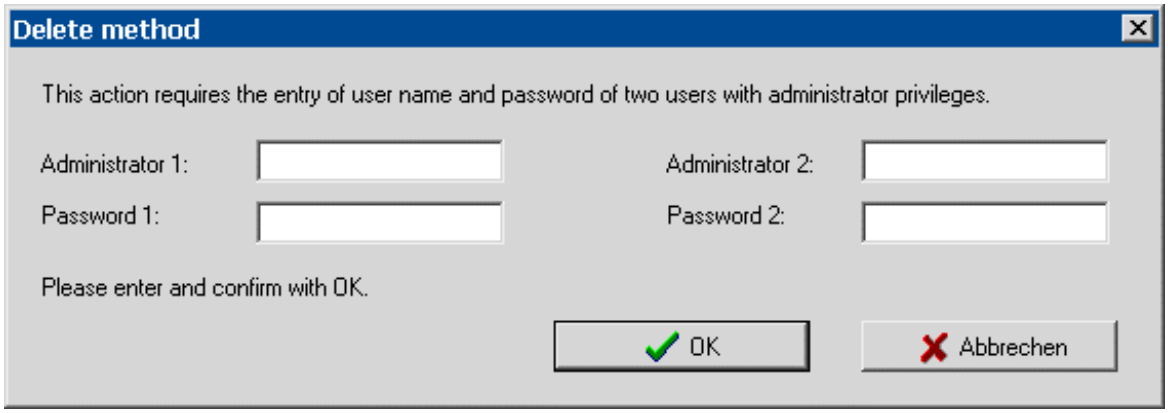
Report printed on:
Date and time of printing the report.

4.3.6 Delete method

Method administration, Database methods, Delete method

Using this context-sensitive menu item, the selected database method can be deleted.

After confirmation of the deleting action, the **Delete method** window opens, where two administrators must confirm the deletion by entering user name and password.



4.3.7 Use signed methods only

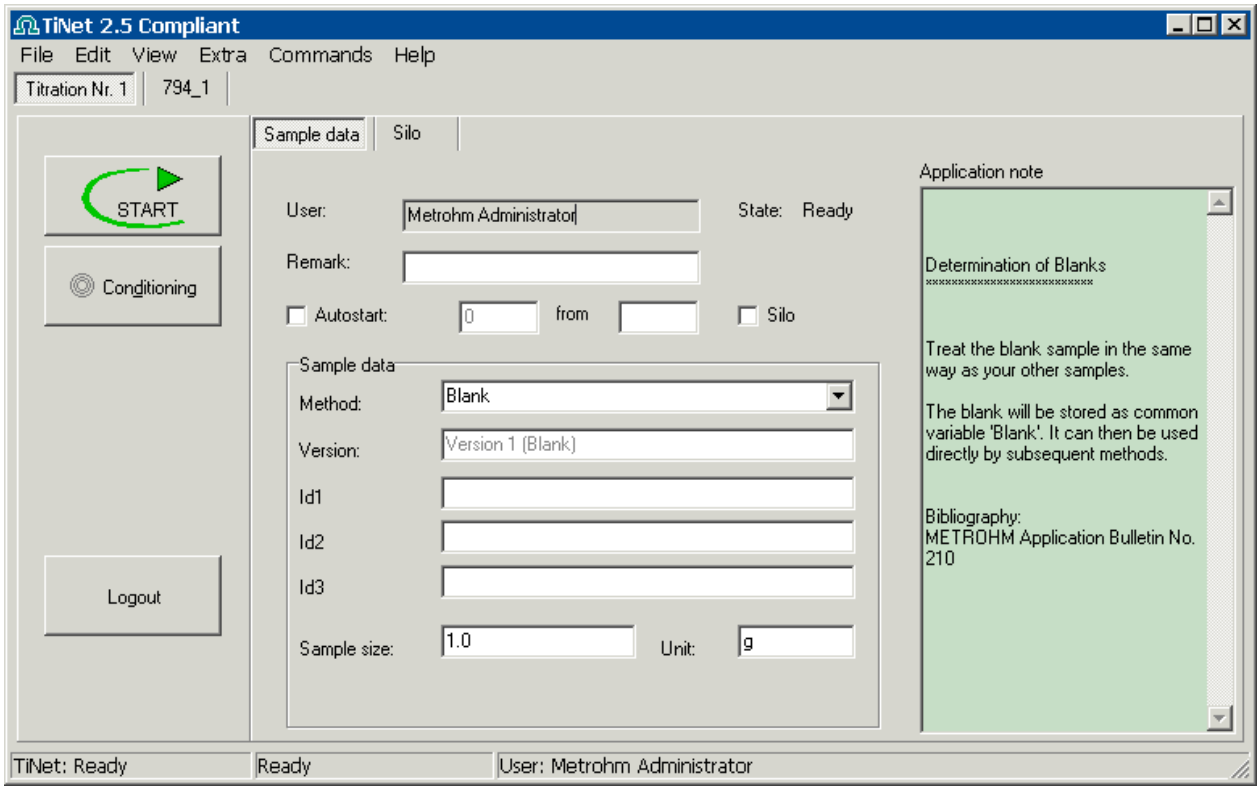
TiNet 2.5 Compliant, Extra, Methods, Use signed methods only

This option ensures that only signed database methods can be used to perform determinations. It must be enabled to to be compliant according to 21 CFR 11.

5. Titrations

5.1 Main window

5.1.1 Overview



The main window "TiNet 2.5 Compliant" is the working window where you can make the necessary entries for your determinations, enter sample data for single determinations and sample series, start and stop your methods, and show live titration curves using the following elements:

- Menu items (see *section 5.1.2*)
- Tab for sample data entry
- Tab for silo memory
- Buttons for titrations
- Display of application note
- Tabs for parallel titrations (see *section 5.2*)
- Tabs for live curves (see *section 5.X*)

5.1.2 Menu items

File	
Load silo	Opens an existing file with silo data (see *section 5.3.3*).
Save silo	Saves an open silo file under the same or a new name (see *section 5.3.3*).
Delete silo	Deletes a silo file (see *section 5.3.3*).
Add parallel titration	Adds a new tab with a parallel titration (see *section 5.5.1*).
Remove parallel titration	Removes the tab with the parallel titration added last (see *section 5.5.1*).
Exit	Exits the "TiNet 2.5 Compliant" program.
Edit	
Cut	Deletes data and transfers this data to the clipboard.
Copy	Copies data to the clipboard.
Paste	Inserts data from the clipboard.
Delete	Deletes data.
View	
View sample data	Define view of identifications **Id1...Id7** on the **Sample data** and **Silo** tabs (see *section 5.2.2*).
View results	Define view of results on the **Silo** tab (see *section 5.3.4*).
Audit Trail	Opens Audit Trail table (see *section 7.3.1*).
Extra	
Configuration	Opens the **TiNet 2.5 - Configuration** window (see *section 2.2*).
Methods	
New method	Opens a new empty method in the **TiNet 2.5 - Configuration** window (see *section 4.2.1*).
Edit method	Opens the selected method in the **TiNet 2.5 - Configuration** window (see *section 4.2.2*).
Method administration	Opens the **Method administration** window (see *section 4.3.1*).
Use signed methods only	Enable/Disable restricted use of signed database methods (see *section 4.3.7*).
Method directory	Select the directory of the methods for the method select lists (see *section 4.2.3*).
Results	
Results overview	Opens the **Results overview** window for display of determination data stored in the result database (see *section 6.3.1*).

TiNet database	Opens the **TiNet 2.5 - Results** program window for display and recalculation of determination data stored in the TiNet database (see *section 6.2*).
Security policies	Settings for login, password protection, Audit Trail, and default strings (see *section 3.1*).
User administration	Administration of user groups and users and their access policies (see *section 3.2*).
Options	
Curve settings	Options for display of live curves (see *section 3.4.1*).
Print options	Options for report printout (see *section 3.4.2*).
Export settings	Options for export of results (see *section 3.4.3*).
System name	Definition of the system name for Audit Trail (see *section 3.4.4*).
Database options	Options for method, result and Audit Trail databases (see *section 3.4.5*).

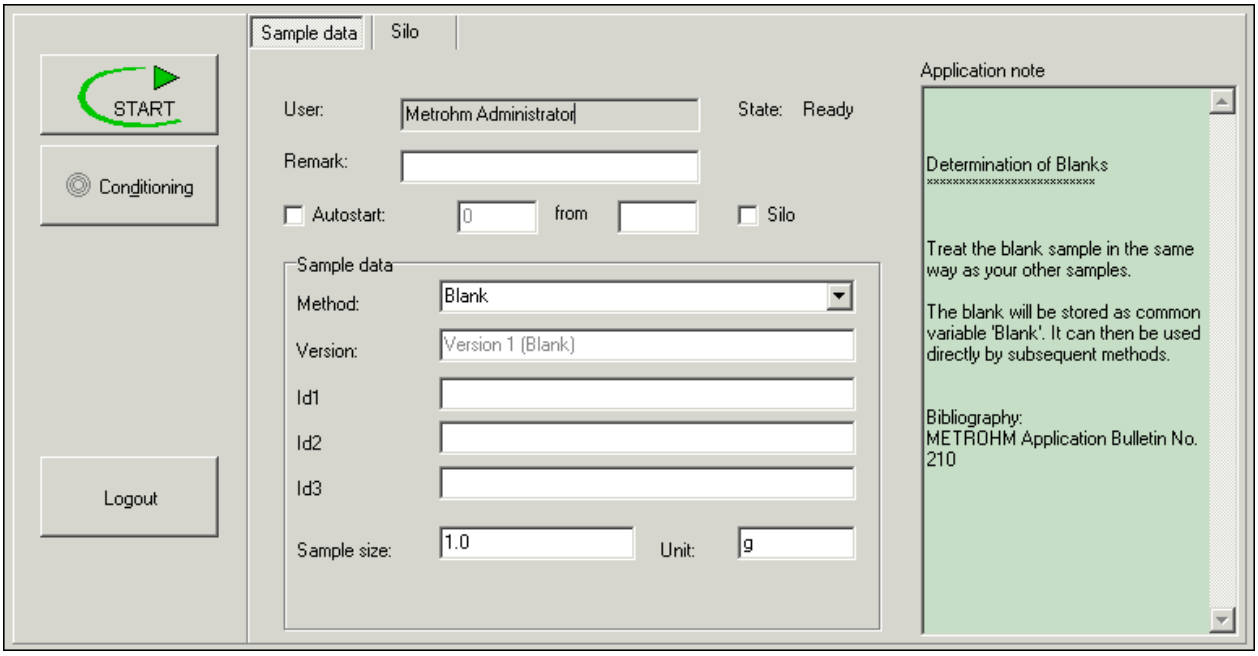
Commands	
Start	Starts the method (see *section 5.4.3*).
Stopp	Stops the method (see *section 5.4.3*).
Continue	Continue with the method after hold by "Wait/Message/Request" block (see *section 5.4.3*).
Conditioning	Starts conditioning (see *section 5.4.3*).
Clear statistics	Clears the current value of the statistics counter.
Clear autostart	Clears the current value of the auto start counter (see *section 5.2.2*).
Initialise devices	Initializes the connected devices.

Help	
Help contents	Shows the contents of the Help texts.
About	Shows the program version.

5.2 Sample data

5.2.1 Sample data entry

Every parallel titration has its own **Sample data #** tab in the main window for display and entry of sample data.



User Display of the logged-in user. The name will be printed out with the titration data and stored in the determination.

Remark Enter the remark regarding, e.g. the sample series. It will be printed out with the titration data and stored in the determination.

State Display of TiNet state.

Autostart Number of automatic, internal starts. Select this option for series determinations with a sample changer. The number on the left counts the starts already performed (current value counter), the total number of starts which must be performed is on the right (set counter). Enter the number of samples on the sample changer in the right counter.

The current value counter can be zeroed with the menu item **Commands, Clear autostart**. The counter is also set to 0 if you answer **yes** to the question **New series?**.

Auto start is interrupted when the option is disabled.

Silo Open silo memory for sample data (see *section 5.2.2*). If the **Silo** option is enabled, the sample data are transferred for each determination from the silo and displayed under **Sample data**. This option must be enabled in order to edit the silo memory.

Sample data

Here, you can enter sample data for single determinations and multiple determinations with autostart. These date will be printed out with the titration data and stored in the determination. If the **Silo** option is enabled, the fields can not be edited. During the method sequence, the current data from the silo memory are displayed in these fields.

Method

Selection of the method used to process the sample. The method is reloaded on every start.

Version

Display of method version number.

Id1...7 Identifications of the sample (up to 30 characters each).
You can define in the **View sample data** window (see *section 5.2.2*) the identifications which should be displayed. The identifications can be used in the method sequence as variables (e.g. for calculations or IF decisions).

Note:
Modifications of the identifications **ID1...7** made after the start of a determination are ignored for this determination. **ID8** is always used for saving the version number of the database method.

Sample size

Sample size (mass).
The sample size is available for calculations in the method as a variable.

Note:
If the **Sample size** is modified and confirmed with <Enter> after the start of a determination, the modified value will be used for this determination.

Unit Unit of the sample size.

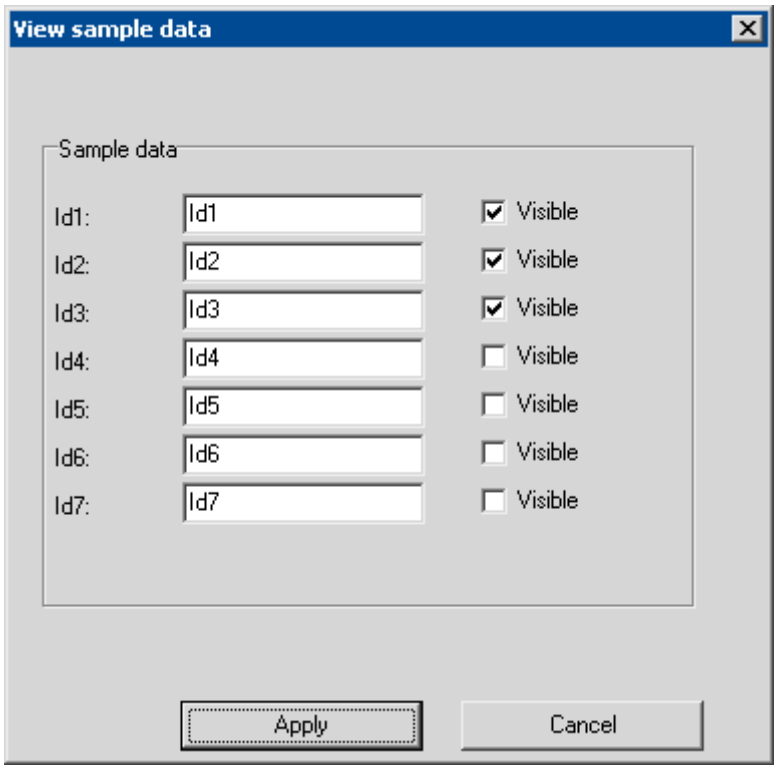
Application note

The application not of the current method loaded is displayed in the green field (if present). The application note can be created in the program part "Methods" (see *section 4.2.2*). It can be exported as a text file (***.txt**) and printed.

5.2.2 View for sample data

TiNet 2.5 Compliant, View, View sample data

This menu item opens the **View sample data** window. You can define here which identifications with which names will be displayed on the **Sample data** and **Silo** tabs in the main window.



Id1...Id7

Identifications which can be displayed (display only) .

(Designation)

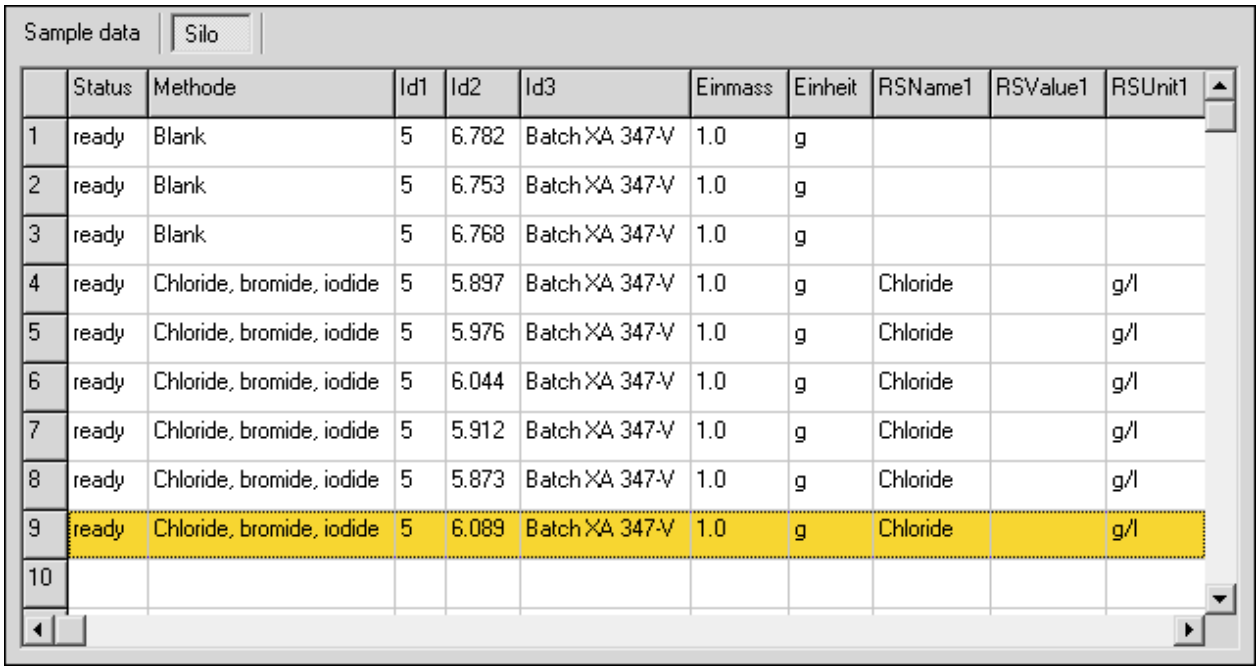
User-defined designations for identifications.

Visible Selection of the identifications to be displayed in the main window.

5.3 Silo memory

5.3.1 Display silo memory

Every parallel titration has its own silo memory, which is shown on the **Silo #** tab in the main window. The silo memory is used on one side for the display of the finished determinations and their results, and on the other side for entering sample data "for future use" (e.g. for sample series with a sample changer).



	Status	Methode	Id1	Id2	Id3	Einmass	Einheit	RSName1	RSValue1	RSUnit1
1	ready	Blank	5	6.782	Batch XA 347-V	1.0	g			
2	ready	Blank	5	6.753	Batch XA 347-V	1.0	g			
3	ready	Blank	5	6.768	Batch XA 347-V	1.0	g			
4	ready	Chloride, bromide, iodide	5	5.897	Batch XA 347-V	1.0	g	Chloride		g/l
5	ready	Chloride, bromide, iodide	5	5.976	Batch XA 347-V	1.0	g	Chloride		g/l
6	ready	Chloride, bromide, iodide	5	6.044	Batch XA 347-V	1.0	g	Chloride		g/l
7	ready	Chloride, bromide, iodide	5	5.912	Batch XA 347-V	1.0	g	Chloride		g/l
8	ready	Chloride, bromide, iodide	5	5.873	Batch XA 347-V	1.0	g	Chloride		g/l
9	ready	Chloride, bromide, iodide	5	6.089	Batch XA 347-V	1.0	g	Chloride		g/l
10										

The silo memory contains the **Status** column and the columns defined under **View sample data** (see *section 5.2.2*) and **View results** (see *section 5.3.4*).

Status Display of the determination status:

- **ready** The sample data are used for the next determinations.
- **running** The determination is running.
- **finished** The determination is finished, results have been entered.
- **aborted** The determination has been aborted.

For automatic processing of sample data from the silo memory for series determination, the **Silo** option on the **Sample data** tab must be enabled and the number of automatic starts must be entered in the **Autostart** field. In this case, the sample data are transferred from the silo memory at each new method start. The weighing data from a connected balance are written to the silo memory. The silo memory operates on the FIFO (first in, first out) principle: The lines are entered and processed in ascending order.

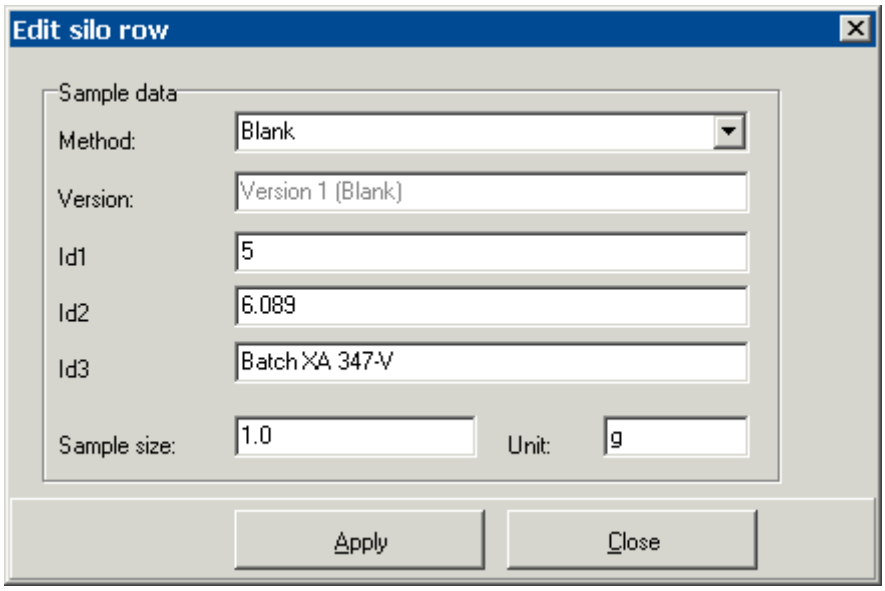
If the silo memory is enabled, the sample data can be edited using context-sensitive menu items (see *section 5.3.2*). The content of the silo memory can be saved, loaded or deleted (see *section 5.3.3*).

5.3.2 Edit silo memory

Edit silo row

(Silo memory), Edit silo row

To edit data of the silo memory, click into the silo memory using the right mouse key and select the **Edit silo row** menu item. The **Edit silo row** window is opened. If an empty silo row has been selected, the previously entered data are shown in this window.



Method Selection of the method to process the sample. The method is reloaded at every new start.

Version Display of method version.

Id1...7 Identifications of the sample (up to 30 characters each).
You can define in the **View sample data** window the identifications which should be displayed. In addition to this, identifications can be renamed.
The identifications can be used in the method sequence as Variables (e.g. for calculations or IF decisions).

Sample size
Sample size (mass).
The **sample size** is available for calculations in the method as a variable.

Unit Unit of the sample size..

<Apply> Use this button to transfer the sample data into the selected existing silo row or into a new empty silo row.

<Close> Use this button to close the **Edit silo row** window.

This context-sensitive menu item is only active if the **Silo** option is enabled on the **Sample data** tab.

Insert silo row

(Silo memory), Insert silo row

To insert a new silo row into the silo memory, select the desired row by clicking it using the left mouse key. Then click into this row using the right mouse key and select the **Insert silo row** menu item. The **Edit silo row** window is opened for entering data for the new row. With **<Apply>**, a new silo row containing these data is created above the selected silo row.

This context-sensitive menu item is only active if the **Silo** option is enabled on the **Sample data** tab.

Delete silo row

(Silo memory), Delete silo row

To delete a single silo row in the silo memory, select the desired row by clicking it using the left mouse key. Then click into this row using the right mouse key and select the **Delete silo row** menu item.

This context-sensitive menu item is only active if the **Silo** option is enabled on the **Sample data** tab.

Delete all silo rows

(Silo memory), Delete all silo rows

To delete all silo rows in the silo memory, click into the silo memory table using the right mouse key and select the **Delete all silo rows** menu item.

Enter new silo data

To enter data into a new, empty row of the silo memory, select the desired empty row by clicking it using the left mouse key. Then click into this row using the right mouse key and select the **Edit silo row** menu item. The **Edit silo row** window is opened for entering the desired sample data. With **<Apply>**, these data are filled into the first empty silo row. Afterwards, the **Edit silo row** window remains open for the entry of additional silo rows. With every click on **<Apply>**, a new silo row is filled.

Modify existing silo data

To modify data in an existing row of the silo memory, select the desired row by clicking it using the left mouse key. Then click into this row using the right mouse key and select the **Edit silo row** menu item. The **Edit silo row** window is opened for modifying the desired sample data. With **<Apply>**, these modified data are filled into the selected silo row. Afterwards, the **Edit silo row** window shows the data of the next silo row.

5.3.3 Load, save, and delete silo

Load silo

TiNet 2.5 Compliant, File, Load silo

This menu item opens the **Open** window for selection of the desired silo file ***.tso** to be loaded into the silo memory.

Save silo

TiNet 2.5 Compliant, File, Save silo

This menu item opens the **Save file as** window for saving the current silo memory with the desired file name.

Delete silo

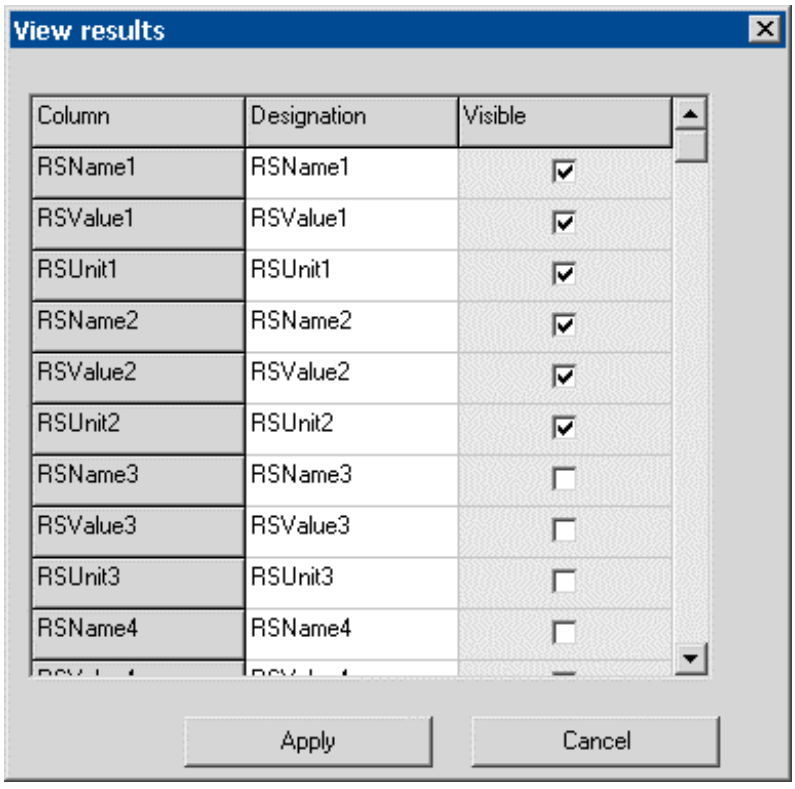
TiNet 2.5 Compliant, File, Delete silo

This menu item opens the **Delete silo** file window for selection of the desired silo file to be deleted.

5.3.4 View results

TiNet 2.5 Compliant, View, View results

This menu item opens the **View results** window. You can define here which results with which names will be displayed on the **Silo** tab in the main window.



RS1...10 Name
Result names which can be displayed (display only).

RS1...10 Value
Result values which can be displayed (display only).

RS1...10 Unit
Result units which can be displayed (display only).

Designation
User-defined designations for results.

Visible Selection of the results to be displayed in the silo.

5.4 Performing titrations

5.4.1 Preparing single determinations

Before starting single determinations, proceed as follows:

- Connect, switch on and initialize devices (see *section 2.1*).
- Start TiNet 2.5 Compliant.
- Disable the **Autostart** option on the **Sample data** tab (see *section 5.2.1*).
- Enter method and sample data on the **Sample data** tab (see *section 5.2.1*), or
- Enable the **Silo** option on the **Sample data** tab and enter method and sample data in the silo memory (see *section 5.3.1*)

5.4.2 Preparing sample series

Before starting single determinations, proceed as follows:

- Connect and initialize devices (see *section 2.1*).
- Enable the **Autostart** option on the **Sample data** and enter the number of samples (see *section 5.2.1*).
- Enter method and sample data on the **Sample data** tab (see *section 5.2.1*), or
- Enable the **Silo** option on the **Sample data** tab and enter method and sample data in the silo memory (see *section 5.3.1*)

5.4.3 Buttons for titrations

The individual buttons in the main window have the following meaning:

Starts the determination. The button is shown gray when it is not active.

Stops the determination. The button is shown gray when it is not active. Can also be used as an emergency stop. If a Titrino stops, TiNet must be stopped manually.

Continues with the determination after hold by "Wait/Message/Request" block. The button is shown gray when it is not active.

Start conditioning. The button is shown gray when it is not active.

5.4.4 Working with connected balance

Weighing data of a connected balance can be transferred.

The receipt of weighing data is confirmed by the PC with a beep.

Important: Depending on the work load of your PC, you should wait a few seconds between transmissions of the individual weighing data.

The balance is always assigned to the active parallel titration. If the **Silo** option is disabled, the weighing data are sent directly to the current sample data row. If the **Silo** option is enabled, they are sent to the silo.

5.4.5 Karl Fischer titrations

Start/Stop

Start conditioning with button **<Conditioning>**.

Wait for a stable drift and start the titration. The titration can only be started if "conditioning is ok". The titration start stops the conditioning; it is therefore important that there is not a great delay between the start and the beginning of the titration. After the PC method is terminated, the titration vessel is again conditioned.

This key stops the titration as well as the conditioning.

Prerequisites in the method

Conditioning has to be activated in the titration blocks of the method. Conditioning is possible for the following blocks:

- KFC (conditioning is always active)
- KFT
- SET
- Titrino method (conditioning is active in the Titrino method)

Notes

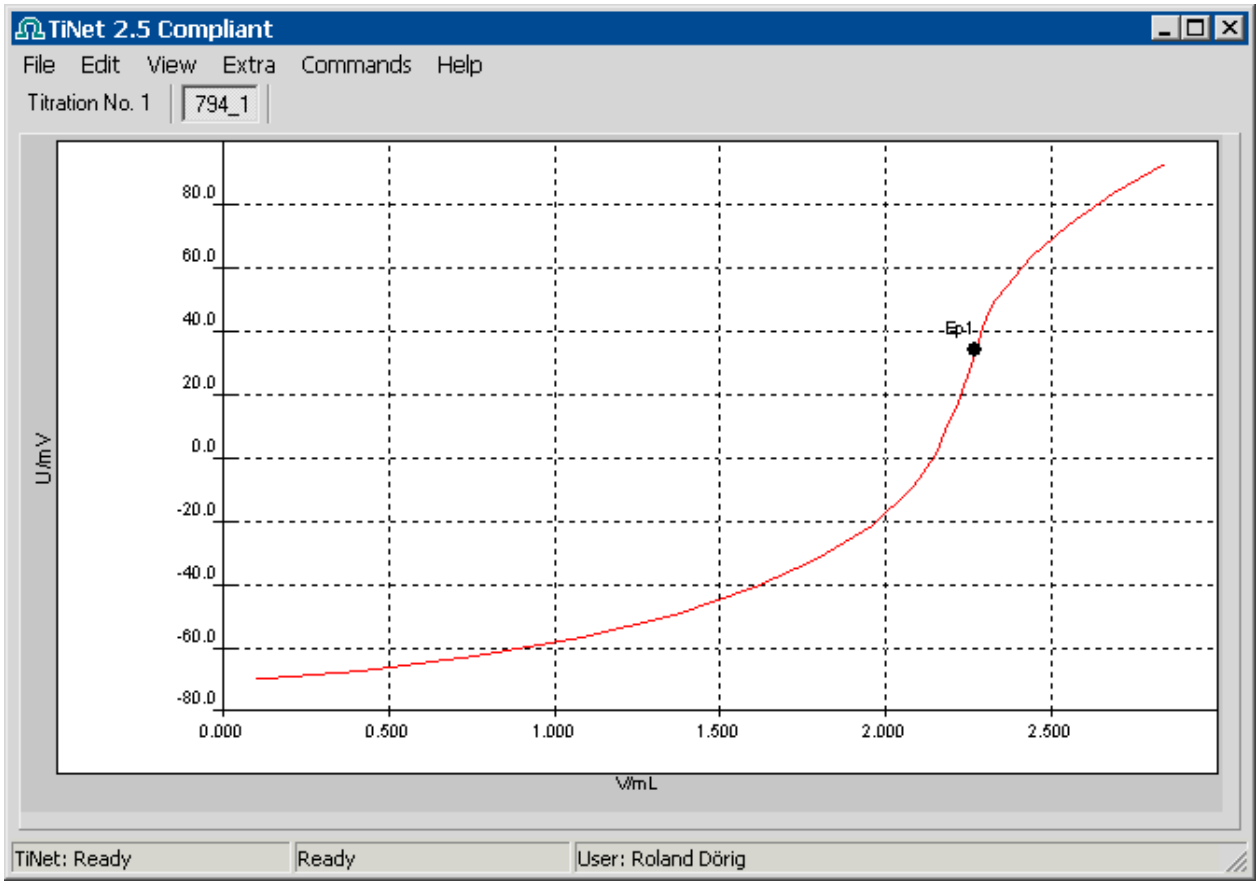
- Autostart starts only the titration. If you wish to condition, start conditioning (**<Conditioning>**) first.
- If the method contains an IF, the parameters used for conditioning are in the left (TRUE) branch.
- If the method contains several blocks with conditioning, the parameter of the first block are valid for conditioning.

Working with the 774 Oven Sample Processor

- After heating up the system, the first determination should always be discarded. You should therefore prepare one "blank" vial more than necessary.
- Start the series with key **<Start>** in TiNet: If the option conditioning for the Oven Sample Processor is active in the corresponding method, the sample changer goes to the conditioning vial, switches the gas flow on and waits until the temperature is reached. The titrator is conditioned at the same time.
- If the Oven and the titrator are conditioned, the titration series will be started with autostart.
- The stirrer is controlled by TiNet if you work with the 756/831 KF Coulometer or 751, 758, 784, 785 Titrino. For other titrators, please switch stirrer on manually.
- If you work off several series at different temperatures, we recommend to have an empty dummy method which sets the temperature between the series. This method should change the temperature and wait for its equilibration.
- If a method contains different temperatures for conditioning of the Oven Sample Processor, only the first is valid.
- If a method contains an IF block, the parameters of the left branch (TRUE) are used for conditioning.

5.4.6 Live titration curves

For every connected titration device, a tab with the name of this device is displayed in the main window. On these tabs, the live curves of running determinations will be displayed. The view of this curves can be defined with **TiNet 2.5 Compliant, Extra, Options, Curve settings** (see *section 3.4.1*).



5.4.7 Emergency stop

<Stop> immediately stops the run. Any calculations and report instructions after this sop point will not be carried out.

If you wish to stop only one titration, one measurement or any single device procedure, you can do this with the **<STOP>** key on the device itself.

5.5 Parallel titrations

5.5.1 Add parallel titration

File, Add parallel titration

Use this command if you wish to perform several titrations at the same time.

A new tab for the added parallel titration is opened. For a better overview, it is advisable to use the connected devices only in one parallel titration at the same time, e.g. Titrino 1 and Sample Changer are used in parallel titration 1; Titrino 2 in parallel titration 2.

The parallel titrations are independent of each other. The buttons **<Start>**, **<Stop>**, **<Continue>** are always effective for the visible parallel titration. All other commands under the menu item **Commands** also apply to this parallel titration.

Each parallel titration has an own silo memory. The commands under menu item **File** apply to the active silo memory.

Note:
If you are working with parallel titrations, you should not use methods generating PDF reports.

5.5.2 Remove parallel titration

File, Remove parallel titration

Use this command if you wish to remove the parallel titration added last.

The tab with the opened parallel titration is removed from the main window.

5.5.3 Rename parallel titration

Use the context-sensitive command **Rename** to change the default name **Titration No. #** on the tab. The **Name** window is displayed where the desired name can be entered and confirmed with **<OK>**.

6. Results

6.1 General information on determination data

TiNet 2.5 Compliant saves determination data in two different databases which are called **TiNet database** and **Result database**.

TiNet database

In the TiNet database, determination data are stored non-compliant to 21 CFR Part 11. Data can be displayed, sorted, and recalculated (see *section 6.2*).

Result database

In the Result database, determination data (including raw data file and method file) are stored in compliance to 21 CFR Part 11 and shown in the **Results overview** table (see *section 6.3*). Results can be electronically signed and PDF reports and result reports can be printed.

6.2 TiNet database

TiNet 2.5 Compliant, Extra, Results, TiNet database

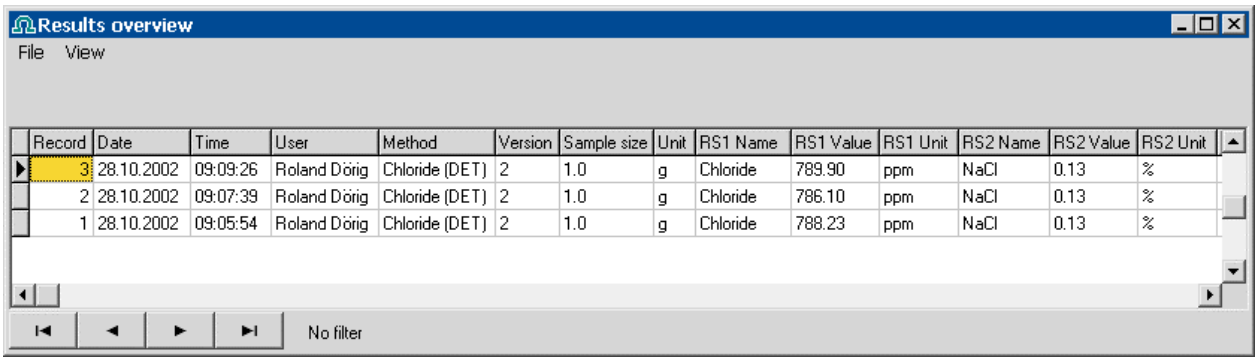
This menu item opens the **TiNet 2.5 – Results** window. Here, data of the TiNet database can be displayed, sorted, and recalculated. You will find detailed information on the TiNet database in the **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 8*.

6.3 Results overview

6.3.1 Display of results

TiNet 2.5 Compliant, Extra, Results, Results overview

This menu item opens the **Results overview** window for display of the determination data stored in the result database in a tabular form.



Each row of the results overview table contains data of a single determination. The determinations are sorted chronologically in descending order, e.g. the last determination performed is in the first row.

The columns of the results overview table are described in *section 6.3.2*.

Select determinations

A single determination can be selected by clicking into any field of the row using the left mouse key. The selected row is marked with the ▶ icon in the first column.

The navigation keys below the table can be used to select another determination:

|◀ Select first determination.

◀ Select previous determination.

▶ Select next determination.

▶| Select last determination.

Menu items

The **Results overview** table contains the following menu items:

File	
Show PDF report	Show PDF report of the selected determination in the Adobe Acrobat Reader program (see *section 6.3.3*).
Print result report	Print result report of the selected determination (see *section 6.3.4*).
Sign result	Electronically sign the results of the selected determination (see *section 6.3.5*).
Export result	Export the results of the selected determination (see *section 6.3.6*).
Delete result	Delete the results of the selected determination (see *section 6.3.7*).
Close	Close **Results overview** window.
View	
Column view	Define column view for the results overview table (see *section 6.3.8*).
Edit filter	Edit filter options for the **Results overview** table (see *section 6.3.9*).
Apply filter	Apply filter for the **Results overview** table (see *section 6.3.10*).

6.3.2 Columns of the results overview table

The following columns can be displayed in the results overview table (see also *section 6.3.6*):

Record Automatically generated, consecutive number for data sets.

Date Date when determination was started.

Time Time when determination was started.

User Name of the user who has started the determination.

Remark Remark entered on the **Sample data** tab.

Method Name of the method used to process the determination.

Version Version number of the method used.

Id1...Id7 Sample identifications.

Sample size
Sample size (mass).

Unit Unit of the sample size.

RS1...15 Name
Name for result 1...15

RS1...15 Value
Value for result 1...15

RS1...15 Unit
Unit for result 1...15

Signer User name of the last user who signed the determination.

Signer name
Full name of the last user who signed the determination.

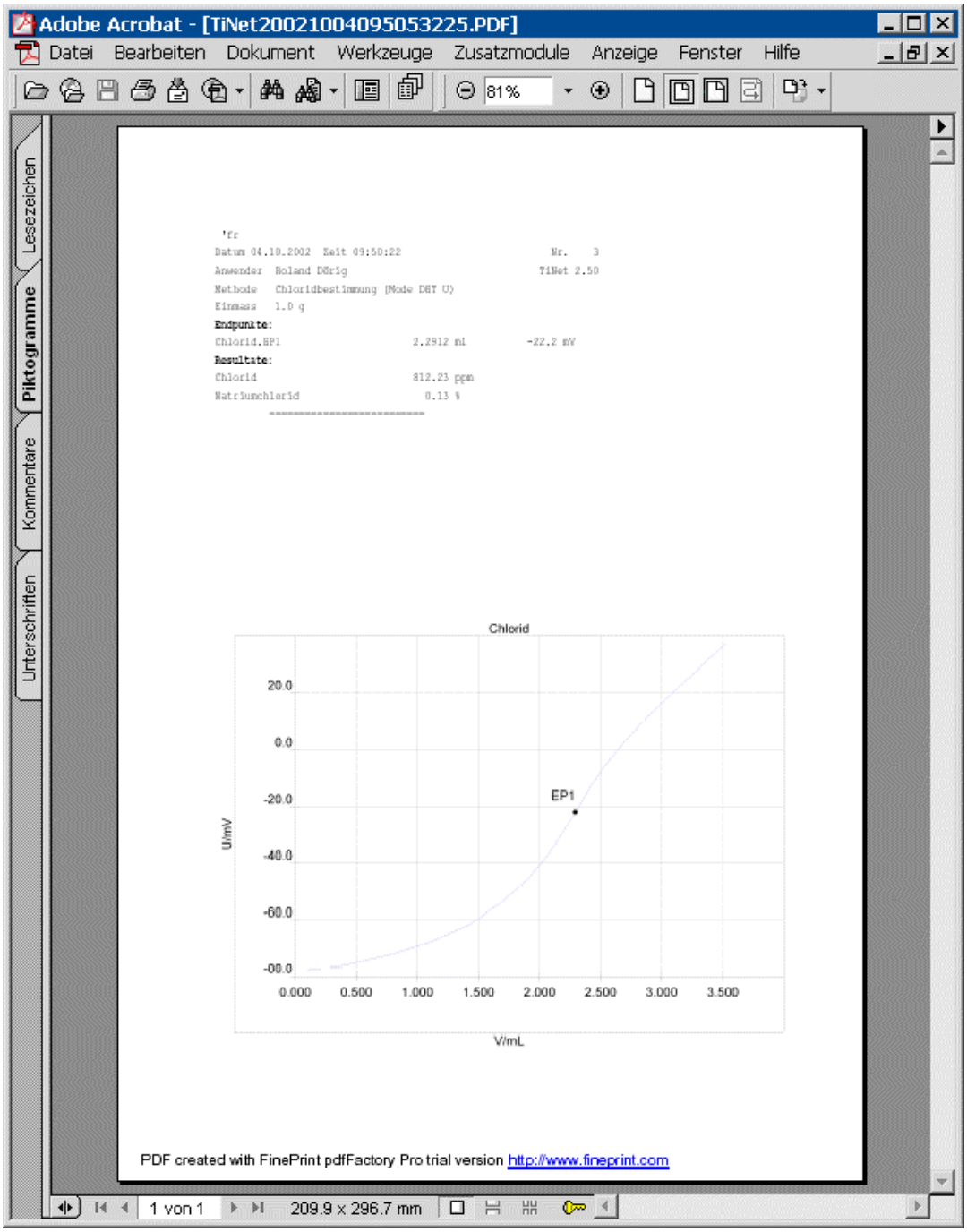
Sign date
Date and time when the determination was signed.

Sign comment
Comment entered at signing the determination.

6.3.3 Show PDF report

Results overview, File, Show PDF report

This menu item opens the PDF report of the selected determination with the Adobe Acrobat Reader, from which it can be printed to the desired printer.

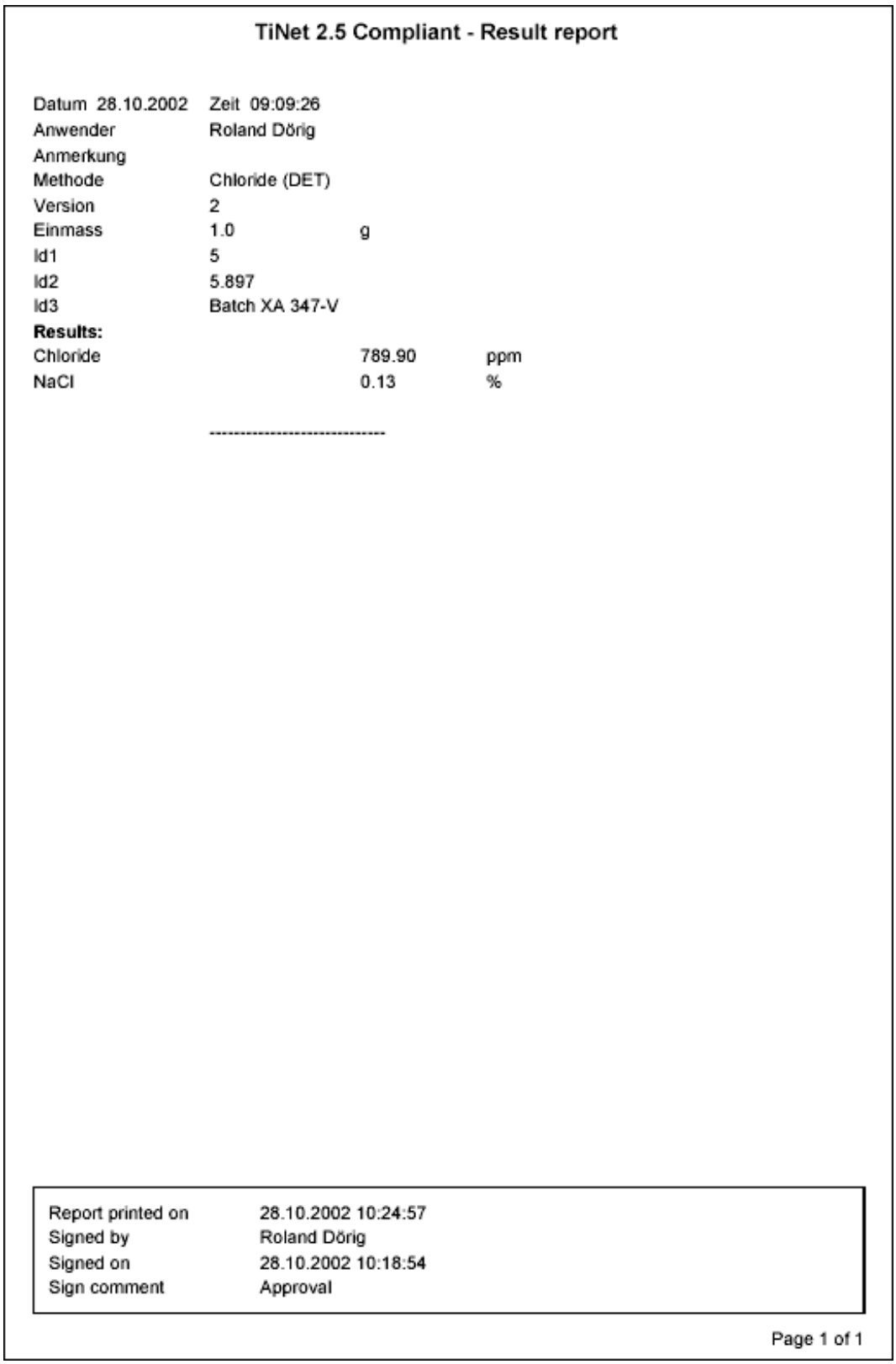


Note: PDF reports can only be displayed if they have been generated automatically at the end of the determinations. This happens only if the method contains a report block with the **Print immediately** option enabled, and if the **Print options** are set in order to create PDF reports (see *sections 1.1.2* and *3.4.2*).

6.3.4 Print result report

Results overview, File, Print result report

With this menu item, a result report of the selected determination is printed on the default printer.



TiNet 2.5 Compliant - Result report

Datum 28.10.2002	Zeit 09:09:26		
Anwender	Roland Dörig		
Anmerkung			
Methode	Chloride (DET)		
Version	2		
Einmass	1.0	g	
Id1	5		
Id2	5.897		
Id3	Batch XA 347-V		
Results:			
Chloride		789.90	ppm
NaCl		0.13	%

Report printed on	28.10.2002 10:24:57
Signed by	Roland Dörig
Signed on	28.10.2002 10:18:54
Sign comment	Approval

Page 1 of 1

This report contains the following entries (independent of the set column view):

Date: Date when determination was started.

Time: Time when determination was started.

User: Name of the user who has started the determination.

Remark: Remark entered on the **Sample data** tab.

Method: Method name.

Version: Version number of the method

Id1...Id7 Sample identifications (all identifications which are not empty are printed).

Sample size
Sample size (mass).

Unit Unit of the sample size.

Results Results (all results which are not empty are displayed)

Report printed on:
Date and time when the result report was printed.

Signed by:
Full name of the user who signed the results.

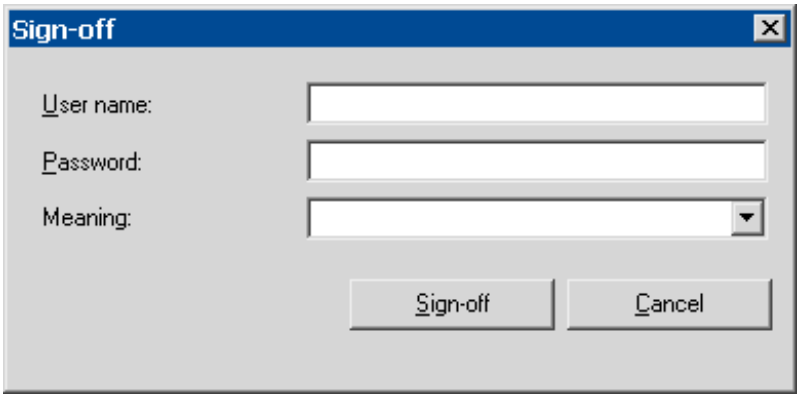
Signed on:
Date and time when the results were signed.

Sign comment:
Comment for the signature.

6.3.5 Sign result

Results overview, File, Sign result

With this menu item, the **Sign-off** window appears for applying electronic signatures on results of the selected determination (the old signature data is overwritten).



User name

Name of the user who wants to sign the results.

Password

Password of the user who wants to sign the results.

Meaning User-specific comment to the signature.

6.3.6 Export result

Results overview, File, Export result

With this menu item, the results of the selected determination are exported according to the set **Export settings** (see *section 3.4.3*).

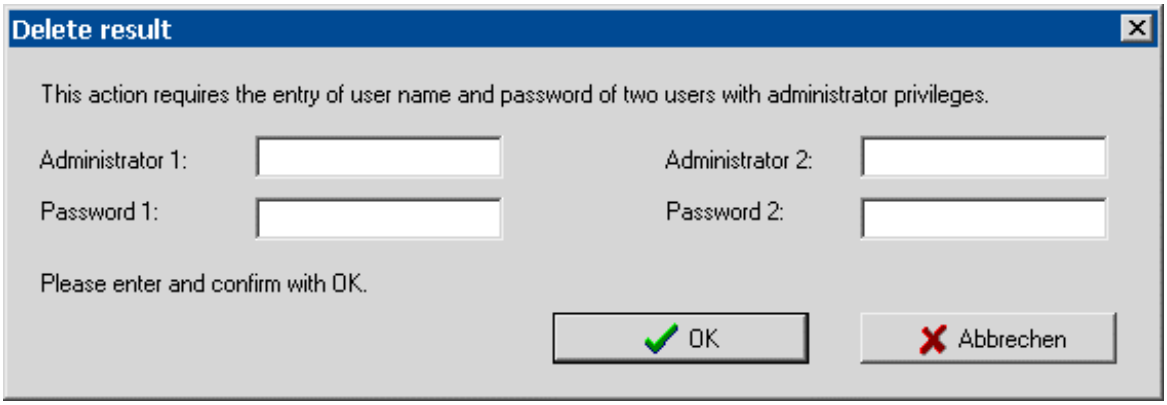
Import of results into the results database is impossible.

6.3.7 Delete result

Results overview, File, Delete result

With this menu item, the results of the selected determination can be deleted.

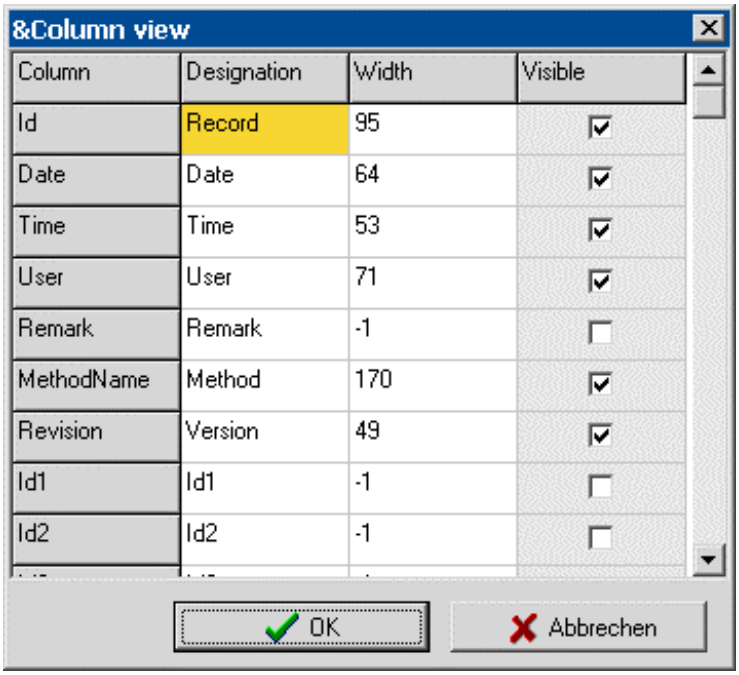
After confirmation of the deleting action, the **Delete result** window opens, where two administrators must confirm the deletion by entering user name and password.



6.3.8 Column view for results overview

Results overview, View, Column view

This menu item opens the **Column view** window for definition of the columns (display, name, width) to be displayed in the results overview.



Column Name of the parameter to be displayed as column (display only, meaning see *section 6.3.2*).

Designation
User-specific designations for columns.

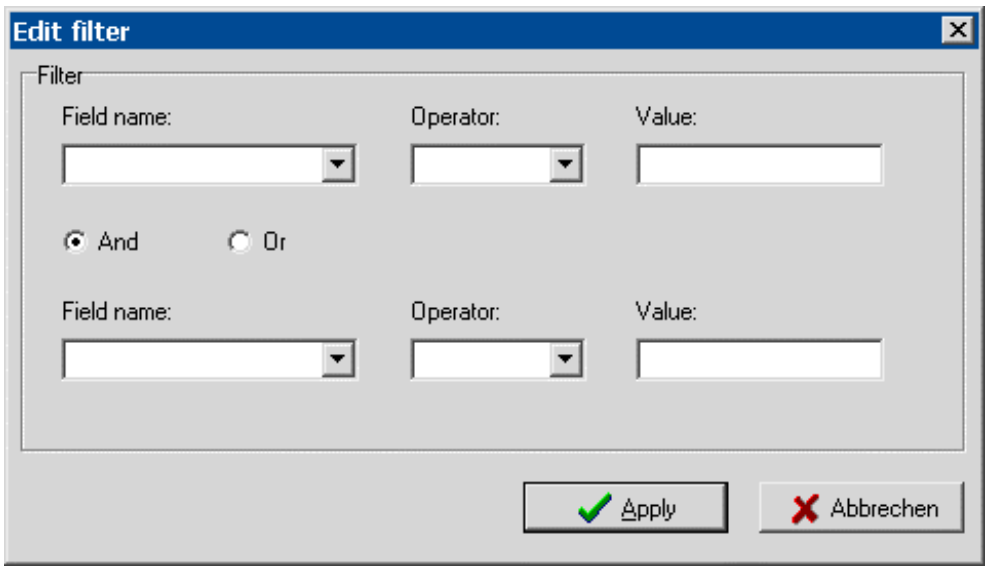
Width Column width in pixel. The column width can also be set in the results overview table by drag and drop of the column border using the left mouse key.

Visible Selection of columns to be displayed in the results overview table.

6.3.9 Edit filter for results

Results overview, View, Edit filter

This menu item opens the **Edit filter** window for definition of filter conditions to filter the results overview table.



Field name
Selection of the desired column for the filter condition.

Operator Selection of the operator for the filter condition (=, <>, <, >).

Value Value for the filter condition.

The two filter conditions can be combined either with **And** or with **Or**.

The filter is applied to the results overview table with **Results overview, View, Apply filter**.

6.3.10 Apply filter for results

Results overview, View, Apply filter

Apply the filter set with **Results overview, View, Edit filter** to the results overview table.

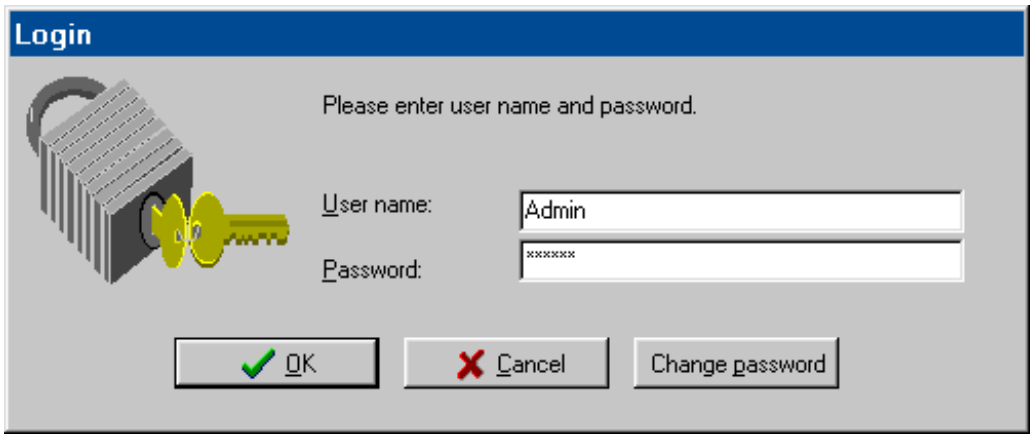
7. Working according to 21 CFR 11

In this section, you will find a detailed description how to work with "TiNet 2.5 Compliant" according to 21 CFR 11. In order to do this, the program must have been installed according to *section 1.2.2*.

7.1 Program settings

7.1.1 First login

1. Open the TiNet 2.5 Compliant program. The **Login** window appears.



2. Enter "**Admin**" for **User name** and "**TiNet2**" (pay attention to capitalization) for **Password**. Click on **<OK>**.

7.1.2 Security policies

1. Select **Extra/Security policies** to open the **Security policies** window (see *section 3.1*).
2. On the **Login/Password protection** tab, click on **<Apply>** to set the parameters according to 21 CFR 11 (see *section 3.1.1*). If desired, modify the maximum number of login attempts, the automatic logoff time, the minimum password length and the password expiration time.
3. On the **Audit Trail** tab, click on **<Apply>** to set the parameters according to 21 CFR 11 (see *section 3.1.2*).
4. On the **Default strings** tab, add, modify and delete the desired default strings for comments on method modifications and signatures.
5. Click on **<OK>** to close the **Security policies** window.

7.1.3 Addition of new administrators

1. Select **Extra**/**User administration** to open the **User administration** window (see *section 3.2*).
2. Using the right mouse key, click on the selected **Administrator** group and select the **New user** menu item.
3. Enter **User name**, **Full name** and **Remarks** for the new administrator and click on **<Accept>**.
4. Repeat this procedure (steps 2 and 3) to enter a second new user with administrator policies.
5. If desired, repeat this procedure (steps 2 and 3) to enter more users with administrator policies.
6. Click on **<OK>** to close the **User administration** window.
7. Click on **<Logout>**. The **Login** window opens (see *section 3.3.1*).
8. Enter the user name of one of the new administrator users into the **User name** field and the same user name into the **Password** field. Click on **<OK>**.
9. Confirm the message appearing in the **Information** window with **<OK>**. The **Change password** window appears.
10. Enter the user name into the **Old password** field and a new password into the **New password** field. Confirm this password by reentering it in the **Confirm password** field and click on **<OK>**.
11. Enter the new password in the **Login** window and click on **<OK>**.
12. Select **Extra**/**User administration** to open the **User administration** window.
13. Expand the **Administrator** branch in the left field of the window and select the **Admin** user.
14. Using the right mouse key, click on the selected **Admin** user and select the **Remove user** menu item.
15. Confirm the appearing message with **<OK>**. The **Admin** user will be removed from the **Administrator** group.

7.1.4 Addition of user groups and users

1. Using the right mouse key, click into the left field of the **User administration** window (see *section 3.2*) and select the **New group** menu item.
2. Enter the desired **Group name** and **Description** and click on **<Accept>** (see *section 3.2.1*).
3. Expand the new user group branch and click on **Access policies** (see *section 3.2.2*).
4. Disable the desired menu items, which should not be accessed by this user group, and click on **<Accept>**.
5. Click on **Signatures** (see *section 3.2.3*).
6. Enable or disable the electronic signature policy for methods and results for this group and click on **<Accept>**.
7. Using the right mouse key, click on the new user branch and select the **New user** menu item.
8. Enter **User name**, **Full name** and **Remarks** for the new user and click on **<Accept>**.
9. Repeat this procedure to enter all the desired user groups and users.
10. Click on **<OK>** to close the **User administration** window

7.1.5 Print options

1. Select **Extra**/**Options**/**Print options** to open the **Print options** window (see *section 3.4.2*).
2. In the **Print options for TiNet reports** box, enable the **Special printer** option and select the **FinePrint pdfFactory Pro** printer driver.
3. In the **Print options for PDF reports** box, select the printer to which PDF reports will be printed.
4. Select the directory to which PDF reports will be saved.
5. Enable or disable the option for immediate printing of PDF reports (Adobe Acrobat Reader must be installed).
6. Click on **<OK>** to close the **Print options** window.

7.2 Configuration of devices

1. Select **Extra**/**Configuration** to open the **TiNet 2.5 Configuration** window.
2. Configure all devices connected to the PC (see **8.110.8243 Instructions for Use "TiNet 2.4/2.5"**, *section 2*).
3. Close the **TiNet 2.5 Configuration** window.

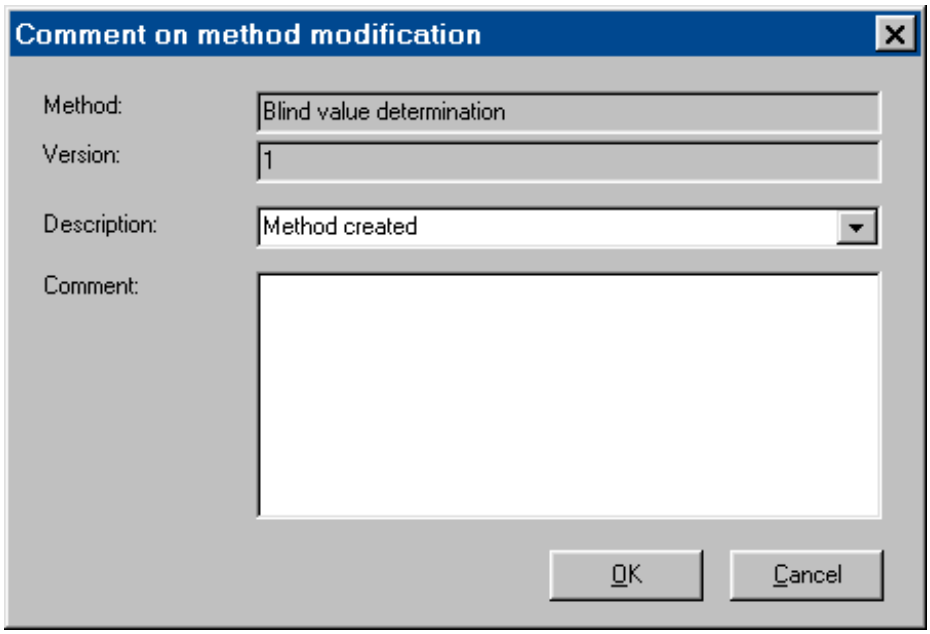
7.3 Methods

7.3.1 Create new draft methods

1. Select **Extra**/**Methods**/**New method** to open the **TiNet 2.5 Methods** window.
2. Create the new draft method (see **8.110.8243 Instructions "TiNet 2.4/2.5"**, *section 2*).
3. In order to generate automatically a PDF report, make sure that the **Print immediately** option is enabled in the report block. This report generation only works with one report block per method (others are ignored).
4. Save the new method in the desired directory.
5. Close the **TiNet 2.5 Methods** window.

7.3.2 Save methods in the method database

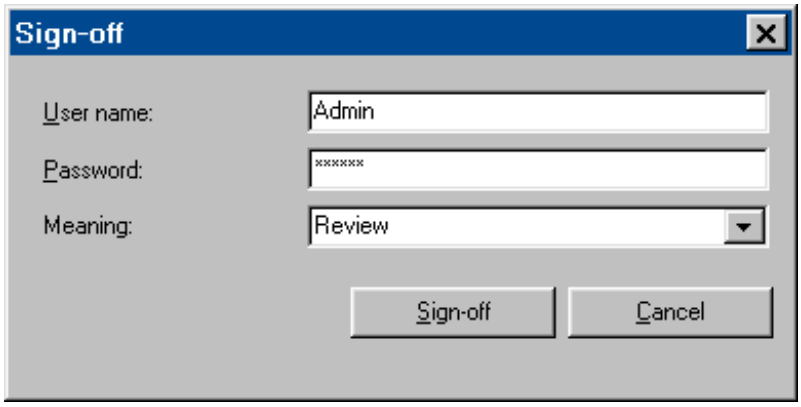
1. Select **Extra**/**Methods**/**Method administration** to open the **Method administration** window (see *section 4.3.1*).
2. Select the **Current method directory** from which you would copy draft methods into the method database.
3. Select the desired draft method, which should be saved as database method.
4. Using the right mouse key, select the **Save method in database** menu item. The **Comment on method modification** window appears.



5. Select a method description and enter a comment for the method. Click on **<OK>**.
6. You are asked if you want to sign the method. Click on **<Yes>** (details see *section 7.3.3*) or **<No>**.
7. Repeat this procedure for all draft methods you want to save in the method database.
8. Close the **Method administration** window.

7.3.3 Sign methods

1. Select **Extra/Methods/Method administration** to open the **Method administration** window (see *section 4.3.1*).
2. Select the desired database method, which should be signed.
3. Using the right mouse key, select the **Sign method** menu item. The **Sign-off** window appears.



4. Enter your user name and password and select or enter a sign comment. Click on **<Sign-off>** to sign the method. Afterwards, click on **<Sign-off>**.

5. If desired, print a method report including all method data stored in the method database by selecting the **Method report** menu item using the right mouse key.
6. Close the **Method administration** window.

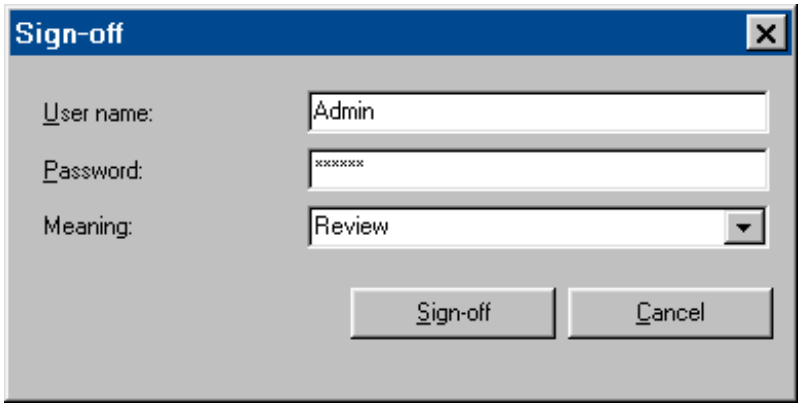
7.3.4 Restrict method selection

1. Enable the **Extra/Methods/Use signed methods only** option to make sure that only signed database methods can be selected in the **Method** field of the **Sample data** tab and for the silo.
2. To make sure that users cannot disable the **Use signed methods only** option, disable this menu item for the user group under **User administration/'Group'/Access policies/Menu items** (see *section 3.2.2*).

7.4 Results

7.4.1 Sign results

1. Select **Extra/Results/Results overview** to open the **Results overview** window (see *section 6.3*).
2. Select the desired result, which should be signed.
3. Using the right mouse key, select the **Sign-off result** menu item. The **Sign-off** window appears.



4. Enter your user name and password and select or enter a sign comment. Click on **<Sign-off>** to sign the result. Afterwards, click on **<Sign-off>**.
5. If desired, print a result report including all determination data stored in the result database by selecting the **Result report** menu item using the right mouse key.
6. Close the **Results overview** window.

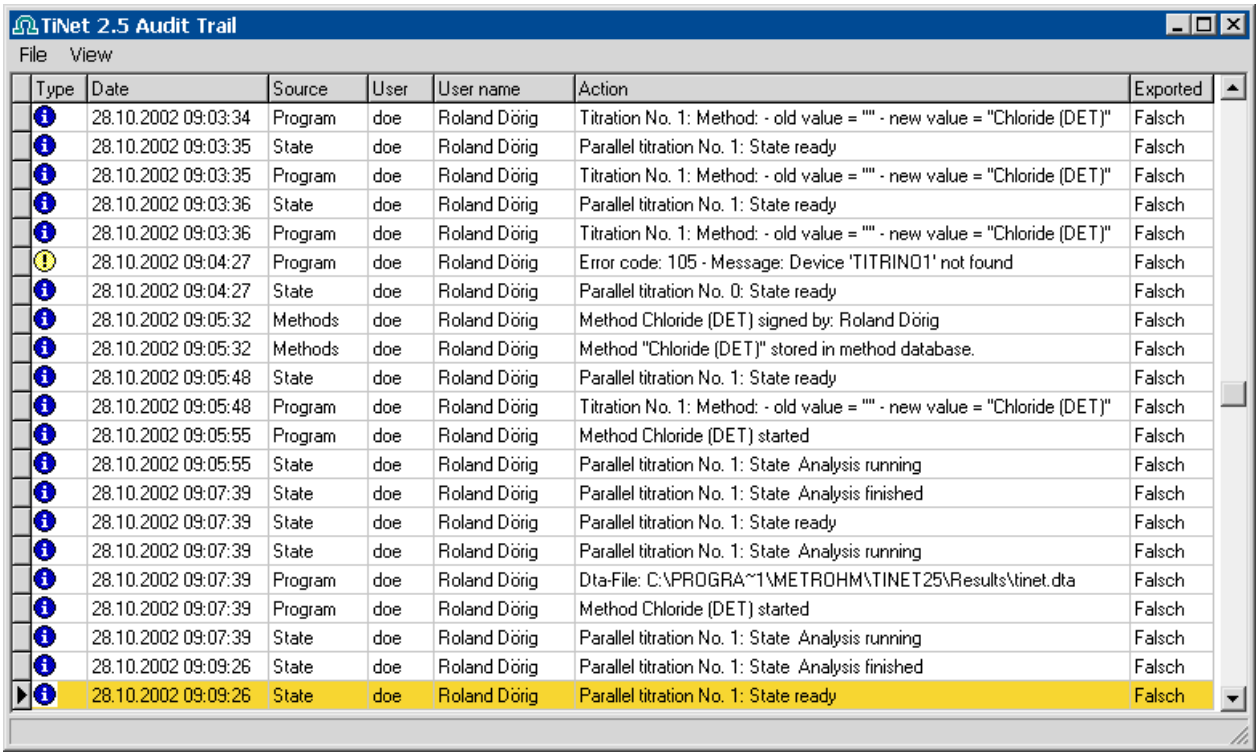
7.4.2 Show and print result reports

1. Select **Extra**/**Results**/**Results overview** to open the **Results overview** window (see *section 6.3*).
2. Select the desired result whose PDF report should be shown. Using the right mouse key, select the **Show PDF report** menu item. The Adobe Acrobat Reader program opens showing the PDF report of the selected determination. This report can be printed or copied to the desired directory.
3. Select the desired result whose result report should be printed. Using the right mouse key, select the **Print result report** menu item. The result report including all relevant data of the determination (including method name, method version and signature data) is printed on the selected printer. Using the Adobe Acrobat program (full version), it is possible to generate a PDF file of this report and save it in the desired directory.

7.5 Audit Trail

7.5.1 Display Audit Trail

TiNet 2.5 Compliant, View, Audit Trail



Type	Date	Source	User	User name	Action	Exported
i	28.10.2002 09:03:34	Program	doe	Roland Dörig	Titration No. 1: Method: - old value = "" - new value = "Chloride (DET)"	Falsch
i	28.10.2002 09:03:35	State	doe	Roland Dörig	Parallel titration No. 1: State ready	Falsch
i	28.10.2002 09:03:35	Program	doe	Roland Dörig	Titration No. 1: Method: - old value = "" - new value = "Chloride (DET)"	Falsch
i	28.10.2002 09:03:36	State	doe	Roland Dörig	Parallel titration No. 1: State ready	Falsch
i	28.10.2002 09:03:36	Program	doe	Roland Dörig	Titration No. 1: Method: - old value = "" - new value = "Chloride (DET)"	Falsch
!	28.10.2002 09:04:27	Program	doe	Roland Dörig	Error code: 105 - Message: Device 'TITRINO1' not found	Falsch
i	28.10.2002 09:04:27	State	doe	Roland Dörig	Parallel titration No. 0: State ready	Falsch
i	28.10.2002 09:05:32	Methods	doe	Roland Dörig	Method Chloride (DET) signed by: Roland Dörig	Falsch
i	28.10.2002 09:05:32	Methods	doe	Roland Dörig	Method "Chloride (DET)" stored in method database.	Falsch
i	28.10.2002 09:05:48	State	doe	Roland Dörig	Parallel titration No. 1: State ready	Falsch
i	28.10.2002 09:05:48	Program	doe	Roland Dörig	Titration No. 1: Method: - old value = "" - new value = "Chloride (DET)"	Falsch
i	28.10.2002 09:05:55	Program	doe	Roland Dörig	Method Chloride (DET) started	Falsch
i	28.10.2002 09:05:55	State	doe	Roland Dörig	Parallel titration No. 1: State Analysis running	Falsch
i	28.10.2002 09:07:39	State	doe	Roland Dörig	Parallel titration No. 1: State Analysis finished	Falsch
i	28.10.2002 09:07:39	State	doe	Roland Dörig	Parallel titration No. 1: State ready	Falsch
i	28.10.2002 09:07:39	State	doe	Roland Dörig	Parallel titration No. 1: State Analysis running	Falsch
i	28.10.2002 09:07:39	Program	doe	Roland Dörig	Dta-File: C:\PROGRA~1\METROHM\TINET25\Results\tinet.dta	Falsch
i	28.10.2002 09:07:39	Program	doe	Roland Dörig	Method Chloride (DET) started	Falsch
i	28.10.2002 09:07:39	State	doe	Roland Dörig	Parallel titration No. 1: State Analysis running	Falsch
i	28.10.2002 09:09:26	State	doe	Roland Dörig	Parallel titration No. 1: State Analysis finished	Falsch
i	28.10.2002 09:09:26	State	doe	Roland Dörig	Parallel titration No. 1: State ready	Falsch

This menu item opens the **Audit Trail** window where all program actions defined as Audit Trail actions are displayed. The Audit Trail table contains the following columns:

Type Icon for characterization of the Audit Trail action:

- Information for correct action.
- Warning for special action.
- Error or malfunction.

Date Date and time of the Audit Trail action.

Time zone
Time zone of the Audit Trail action.

Source Display of the source program part of the Audit Trail action.

User Short name of the logged-in user.

User name
Full name of the logged-in user.

Action Details of the Audit Trail action.

System name
System name defined with **Extra, Options, System name**.

Exported Display, if the Audit Trail action has already been exported or not.

The **Audit Trail** window contains the following menu items:

Audit Trail, File, Find date…
In the **Date** window, the desired date can be selected.

Audit Trail, File, Export
Export Audit Trail actions.

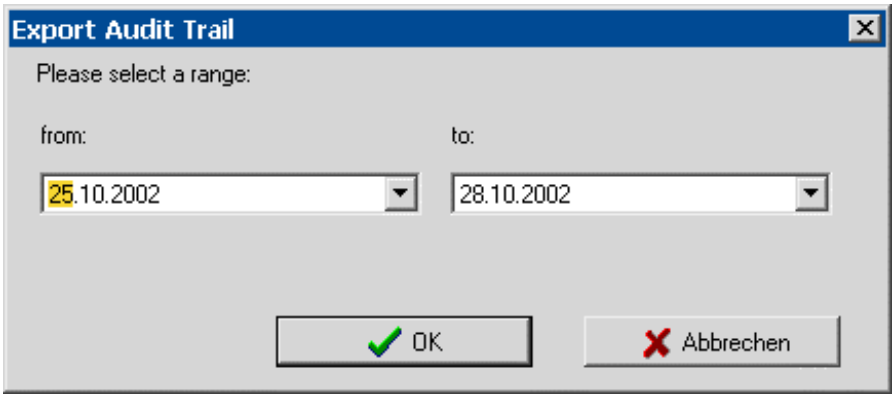
Audit Trail, File, Delete
Delete Audit Trail actions.

Audit Trail, View, Column view
Define the column view of the Audit Trail table.

7.5.2 Export Audit Trail

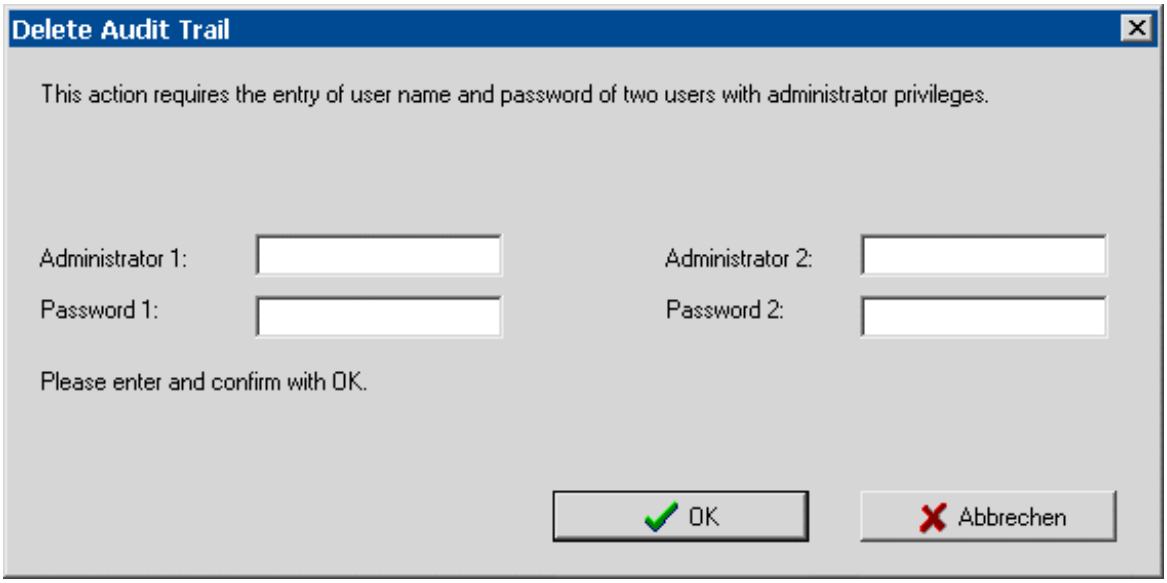
Audit Trail, File, Export

This menu item opens the **Export Audit Trail** window for selection of the range for export of Audit Trail actions. Afterwards, file name and directory for saving the export file (***.txt**) must be entered.



7.5.3 Delete Audit Trail

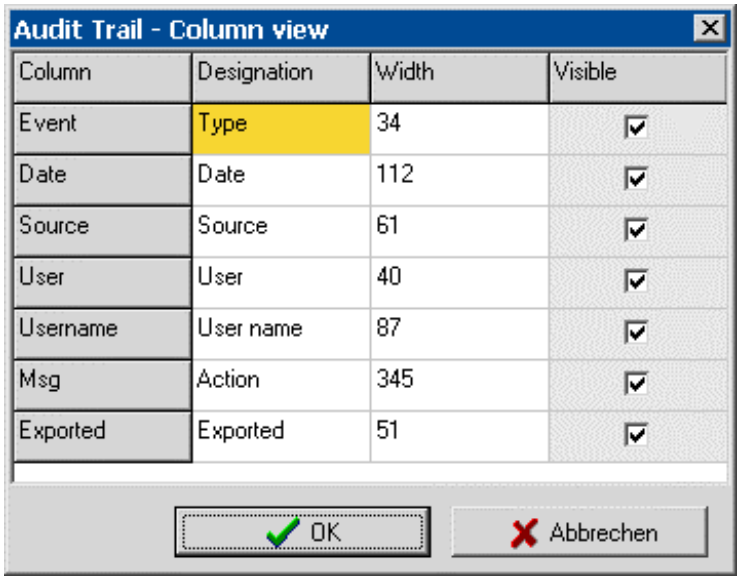
Audit Trail, File, Delete



With this menu item, the **Delete Audit Trail** window opens, where two administrators must confirm the deletion by entering user name and password. Afterwards, the **Export Audit Trail** window for selection of the range for export of the Audit Trail actions, which are exported prior to the deletion.

7.5.4 Column view for Audit Trail

Audit Trail, View, Column view



This menu item opens the **Column view** window for definition of the columns (display, name, width) to be displayed in the Audit Trail table. The following columns can be edited:

Column Name of the parameter to be displayed as column (display only).

Designation
User-specific designations for columns.

Width Column width in pixel. The column width can also be set in the Audit Trail table by drag and drop of the column border using the left mouse key.

Visible Selection of columns to be displayed in the Audit Trail table.

8. Appendix

8.1 Software license

The use of the Software is subject to this License Agreement between you and Metrohm AG. With the offer, you have received this License Agreement and taken note of it. You have already accepted this License Agreement upon the placement of your order with Metrohm AG or one of its distributors or upon confirmation of the order by Metrohm or one of its distributors. At the very latest, you agree to be bound by the terms of this License Agreement when you start using the Software.

1. Metrohm grants you the non-transferable and non-exclusive right to use this Software in connection with Metrohm analysis devices.
2. The copyright to the Software is retained by Metrohm or a licensor of Metrohm. You are not permitted to alter or remove any notes regarding confidential handling, indications of title or indications of copyright. You are not permitted to sell the Software, lease it to or otherwise pass it on to third parties, except in conjunction with its use with analysis devices of the Metrohm Group and if the third party expressly agrees to the terms of this License Agreement. It is not permitted to change or copy the Software in its entirety or in part. It is only permissible to make one copy for backup purposes.
3. The license fee for the above use is included in the sales price of the analysis device. If the software is supplied separately, the fee is billed along with the Software. If for any reason the sales price or the license fee is not paid in full by the due date, the right to use the Software lapses and Metrohm is entitled to demand the return of the Software or its deletion from your system.
4. Metrohm warrants that the Software is suitable for the indicated use with analysis devices of the Metrohm Group if properly operated and that the Software is properly stored on the data carrier. If this is not the case, you are entitled to demand that Metrohm and/or its distributor provide you with a new flawless Software in exchange for handing in the Software you have complained about. This warranty applies to initial operators of the Software only.
5. Metrohm and its distributor disclaim all other warranties and liability. In particular, Metrohm and its distributor assume no liability for third-party damage or consequential damage, loss of data, lost profits, interruption of business, etc.
6. This Agreement applies until it is terminated. You can terminate this Agreement by destroying the Software and every copy of it. The Agreement is also deemed terminated if you violate any of its terms, in which case you are also obligated to destroy the Software and every

copy of it, whereby Metrohm is also entitled to explicitly demand this of you.

7. Any changes and amendments to this Agreement must be rendered in writing to attain validity. This stipulation requiring written form also applies to a change in this provision. If parts of this Agreement prove to be null and void or legally ineffective now or in the future, the remainder of the Agreement continues to apply. The Agreement must then be interpreted and applied so that the intended purpose of the ineffective section is nevertheless achieved to the greatest extent possible.
8. Venue: Any disputes arising from this Agreement shall be decided by the courts at the location of the registered office of Metrohm AG. Metrohm is also entitled to demand that the venue be the location of the defendant's registered office.

8.2 Declaration of conformity – Software validation

The software "Metrodata TiNet 2.5 Compliant" was developed in accordance with the requirements of the ISO 9001 quality system regarding the design, testing and servicing of Metrodata software. The relevant procedures are described in the document "Project procedure for creating Metrodata software" which is available at your Metrohm agency on request.

The software was validated with respect to functionality, analytical performance and accuracy of results. The technical specifications and software functions are described in the Instructions for Use.

Herisau, July 1, 2003

Dr. J. Frank
Vice President
Head of R&D

Ch. Buchmann
Vice President
Head of Production
Responsible for Quality Assurance

8.3 Accessories

8.3.1 Standard equipment

TiNet 2.5 for n devices 6.6012.140
including
Dongle 6.2145.000

TiNet 2.5 for 2 devices 6.6012.540
including
Dongle 6.2145.060

Both versions are supplied with the following documents:

Registration card 8.110.8167
Compliance White Paper for TiNet 2.5 Compliant (English) 8.110.8343
Instructions for Use TiNet 2.4/2.5 (German) 8.110.8241
Instructions for Use TiNet 2.4/2.5 (English) 8.110.8243
Instructions for Use TiNet 2.5 Compliant (German) 8.110.8351
Instructions for Use TiNet 2.5 Compliant (English) 8.110.8353

8.3.2 Options

Cables and adapters

Cable Metrohm device - PC:
- Metrohm device 25-pin – PC 25-pin 6.2125.060
- Metrohm device 9-pin – PC 25-pin 6.2125.110
- Metrohm device 25-pin – PC 9-pin 6.2125.110
- Metrohm device 9-pin – PC 9-pin 6.2134.040

Adapter for 25-pin ⇒ 9-pin plug 6.2125.010

Cable PC-Balance
- Sartorius-PC, 25-pin 6.2125.070
- Sartorius-PC, 9-pin 6.2134.060
- Mettler AM, PM, AT - PC, 25-pin 6.2146.020
- Mettler AM, PM, AT - PC, 9-pin ..... 6.2146.020+6.2125.010
- Mettler AE (Opt.011) - PC, 25-pin 6.2125.020
- Mettler AE (Opt.011) - PC, 9-pin ..... 6.2125.020+6.2125.010
- Mettler PG - PC, 25-pin 6.2125.130
- Mettler PG - PC, 9-pin 6.2134.110
- Mettler AB, AG, PR - PC, 25-pin ..... Mettler Interface LC-RS25
- Mettler AB, AG, PR - PC, 9-pin ..... Mettler Interface LC-RS9
- AND - PC, 25-pin 6.2125.020
- AND - PC, 9-pin ..... 6.2125.020+6.2125.010
- Precisa - PC, 25-pin 6.2125.080
- Precisa - PC, 25-pin ..... 6.2125.080+6.2125.010

Cable PC (25-pin)-Dosimat 6.2124.050
Adapter for the connection of <u>one</u> electrode to 2 Titrinos 6.2103.100

Interfaces for PC

USB Port Server (4 serial interfaces, 9-pin) 2.145.0320
Multiport DIGI PCI (8 serial interfaces, 25-pin) 2.145.0230

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