

Instructions for Use for

magellan

Basic Guide

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WARNING

CAREFULLY READ AND FOLLOW THE INSTRUCTIONS PROVIDED IN THIS MANUAL BEFORE OPERATING THE INSTRUMENT.

Notice

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We would appreciate any comments on this publication.



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Declaration for EC Certificate

Provided upon request.

magellan Intended Use

See 1.1 Area of Application.

About this Manual

magellan is a universal data reduction package used to analyze data generated from microplate assays. It is designed for professional use only.

This manual instructs how to:

- Install the software
- Operate the software

Remark on Screenshots

The version number displayed in screenshots may not always be the one of the currently released version. Screenshots are replaced only if content related to application has changed.



Warnings, Cautions and Notes

The following types of notices are used in this publication; they highlight important information or warn the user of a potentially dangerous situation:



Note Gives helpful information.



CAUTION INDICATES A POSSIBILITY OF INSTRUMENT DAMAGE OR DATA LOSS IF INSTRUCTIONS ARE NOT FOLLOWED.



WARNING

INDICATES THE POSSIBILITY OF SEVERE PERSONAL INJURY, LOSS OF LIFE OR EQUIPMENT DAMAGE IF THE INSTRUCTIONS ARE NOT FOLLOWED.



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1. Introduction

1.1 Area of Application

magellan is universal reader control and data reduction software for analyzing data generated from microplate tests using Tecan measuring devices. magellan is available in two versions:

- magellan Tracker and
- magellan Standard.

magellan Standard software is intended for endpoint, kinetic and multilabel assays in pharmaceutical, biotechnological and life science industry, for research use, for food analysis and veterinary applications.

magellan Tracker offers all functionality to become compliant with the FDA Regulation 21 CFR part 11 and with the European In vitro diagnostic directive 98/79/EC.



Note

It is important to note that the proper installation of the instrument and the magellan software alone will not ensure compliance with laws and requirements. Corresponding policies concerning processes and standard operating procedures, including validation and quality control, must also be established.

magellan Tracker is designed for use with the operating systems and Microsoft Office versions specified in chapter 1.4.3 System Requirements. If additional programs are installed, functionality in accordance with IVD for Europe and FDA Regulations cannot be guaranteed.



Note

magellan is designed to be used with one computer; it is not intended to be integrated into a network.

1.2 Intended Use of magellan

magellan Standard software is a reader control and data reduction software for analyzing data generated from microplates using a Tecan absorbance, fluorescence, luminescence and/ or AlphaScreen/ AlphaLISA microplate reader. The software is intended for endpoint, kinetic, multilabel, fluorescence lifetime, and spectral scanning assays.

magellan software is intended for professional use according to the software specifications described in the manual (Instructions for Use for **magellan**).

magellan Tracker software offers all functionality for compliance with the FDA regulation 21 CFR part 11 for electronic records and signatures in addition to the functionality of **magellan** Standard. **magellan** Tracker software is also intended for in vitro diagnostic use in Europe according to the In vitro diagnostic directive 98/79/EC as an accessory together with a Tecan SUNRISE or INFINITE F50 absorbance reader. **magellan** cannot be used for agglutination assays.



1.3 User Profile

1.3.1 Professional User - Administrator Level

The administrator is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

The administrator has extensive skills and is able to instruct the end user or the routine user in assay protocols in connection with a Tecan product within the bounds of the intended use.

Computer application skills and good English skills are required.

1.3.2 End User or Routine User

The end user or routine user is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

Computer application skills and good language skills for the respective national language at the installation site and English are required.



Note

Training dates, their duration and frequency are available at your customer support.

Address and telephone number can be found in these Instructions for Use and in the web: http://www.tecan.com/customersupport

1.4 Specifications

1.4.1 System Requirements

The following requirements have to be met for using magellan:

| | Minimum | Recommended |
|----|---|-------------------|
| PC | Windows XP (32-bit): Windows compatible PC with a Pentium compatible processor running at 1 GHz | 2 GHz (Dual Core) |
| | Windows Vista (32 bit): Windows compatible PC with a Pentium compatible processor running at 1,5 GHz | 2 GHz (Dual Core) |
| | Windows 7 (32- or 64-bit): Windows compatible PC with a Pentium compatible processor running at 1 GHz | 2 GHz (Dual Core) |
| | Windows 8 (32- or 64-bit): Windows compatible PC with a Pentium compatible processor running at 1 GHz | 2 GHz (Dual Core) |





| Operating | Windows XP (32-bit) – SP3 | Windows 7 (64-bit) – SP1 |
|---------------|---|--------------------------|
| System | Edition: Professional | Edition: Professional |
| | Windows Vista (32-bit) – SP2 | |
| | Editions: Business, Enterprise, Ultimate | |
| | | |
| | Windows 7 (32-bit) – SP1 | |
| | Windows 7 (64-bit) - SP1 | |
| | Editions: Professional, Ultimate, | |
| | Enterprise | |
| | Windows8 (32-bit) | |
| | Windows8 (64-bit) | |
| | Editions: Pro, Enterprise | |
| | RT NOT supported! | |
| Memory | Windows XP: | |
| | 512 MB RAM | 1 GB RAM |
| | Windows Vista (32-bit): | |
| | 1 GB RAM | 2 GB RAM |
| | | |
| | Windows 7 (32-bit): | |
| | 1 GB RAM | 2 GB RAM |
| | Windows 7 (64-bit): | |
| | 2 GB RAM | 4 GB RAM |
| | Windows 8 (32-bit): | |
| | 1 GB RAM | 2 GB RAM |
| | Windows 8 (64-bit): | |
| | 2 GB RAM | 4 GB RAM |
| Space | 1 GB | 2 GB |
| Requirements | | |
| Monitor | Super VGA Graphics | |
| Resolution | 1024 x 600 | 1280 x 1024 |
| Color Depth | 256 | |
| Mouse | Microsoft mouse or compatible pointing device | |
| Communication | 1 x USB 2.0 | 2 x USB 2.0 |
| | | 1 x RS232 (Serial) |
| Devices | 1 x CD-ROM drive | |
| | Windows Vista: | |
| | DirectX 9 graphics and 128 MB of | |
| | graphics memory plus WDDM support | |
| | συμμοτι | |



1. Introduction

| | Windows 7: DirectX 9 graphics device with WDDM 1.0 or higher driver Windows 8: DirectX 9 graphics device with WDDM driver | |
|----------------------|--|--|
| .NET | Microsoft .NET Framework 3.5: In Windows versions prior to Windows 8, the required .NET version is installed automatically alongside any existing versions. In Windows 8, the user will be prompted to install the required .NET framework (2.0 or 3.5), if it is not already present. | |
| Windows Installer | 3.1 If this version is not present, the install/upgrade program will install it. | |
| Microsoft Excel | 2002 2003 2007 2010 | |
| | Only 32-bit editions supported! Starter editions NOT supported! | |

1.4.2 Reader Compatibility

The following Tecan readers can be used with **magellan**:

| Instrument Types Measurement Mode | |
|-----------------------------------|--|
| DNA Expert | Fluorescence / Absorbance / Luminescence |
| GENios | Fluorescence / Absorbance / Luminescence |
| GENios FL | Fluorescence |
| GENios Plus | Fluorescence / Absorbance / Luminescence |
| GENios Pro | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| SPECTRAFluor | Fluorescence / Absorbance |
| SPECTRAFluor Plus | Fluorescence / Absorbance / Luminescence |
| SAFIRE | Fluorescence / Absorbance |
| SAFIRE ² | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| SUNRISE | Absorbance |
| ULTRA Evolution | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization / FLT |





| ULTRA | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
|------------------------------------|---|
| ULTRA 384 | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| Infinite M200 Infinite M200 PRO | Fluorescence / Absorbance / Luminescence |
| Infinite F200 | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| Infinite F200 PRO | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization / AlphaScreen/AlphaLISA |
| Infinite F500 | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| Infinite M1000 | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization |
| Infinite M1000 PRO | Fluorescence / Absorbance / Luminescence / Fluorescence Polarization / AlphaScreen/AlphaLISA |
| Infinite F50 | Absorbance |
| | |



Note

The Connect stacker can be used together with Tecan instruments in order to measure batches of plates. Please refer to the Instruction for Use for the Connect stacker for more information.



1.5 Software Installation Procedure

1.5.1 Automatic Software Setup Program

magellan is installed by an automatic software setup program. All necessary components are installed automatically.

Start **Tecan.exe** (within the root folder of your installation media) to begin the installation procedure (in case Auto Start from that media is disabled on your system):

- In the first InstallShield Wizard window the components, which are required prior to installing Magellan are shown. Click Install to continue. Windows 8: If the required .NET Framework is not present (2.0 or 3.5), the user is prompted to start the installation. Select Install this feature (an internet connection is required). If the installation is skipped by the user, the Magallan installation will not be successful.
- A **Welcome Window** appears with information about the software and the installation process. Click **Next** to continue.
- The next window displays the License Agreement. Read the License Agreement and click I agree to accept it and continue.
- The Customer Information window appears next. If you have already
 purchased the software, enter now your serial number and click Next. If
 you do not yet have a serial number, click Next as well to continue the
 setup. You can register later (see chapter 2.6 Licensing magellan).
- The **Destination Folder** window appears next. The default installation path is displayed. Click **Browse** to change the default destination path, if desired. Click **Next** to continue.
- The Language Selection window appears next. Choose your preferred language.
- In the Use For Regulated Environments window, select magellan Standard or magellan Tracker, depending on which version you have ordered, to install the software. Click Next to continue.
- The setup program is now ready for installation. Click Next to start installation.
- Click **Finish** to end installation and to close the setup program.

The software can be started via the Windows **Start** menu by selecting Magellan. (In Windows 8: Select the appropriate **Magellan App** from the main screen).

The setup program automatically detects a previous installation of **magellan**. The old version has to be de-installed before being able to install a new Magellan version. The de-installation can be performed automatically by using the installation wizard (see also chapter 1.5.3 Automatic Software Removal).



Note

It is very important that the person who installs the software has administrator rights on the computer.



Note

If an older version of magellan is to be installed, the currently installed version has to be completely de-installed before the older version can be installed from scratch.



1.5.2 Installation Qualification – IQ

Check successful installation of **magellan** with the automatic installation qualification program:

Start *MagellanIQ.exe* from the default installation path specified in the setup program (typically C:\Program Files\Tecan\Magellan) or from the Windows Start menu: Start > Programs > Tecan > MagellanIQ.

Click **Check** to start the installation qualification. All installed components should have status **OK**. Please contact your local dealer if any potential problem is reported.

You can leave the installation qualification program by clicking Cancel or Exit.



Note

The installation qualification should be repeated each time magellan is installed or updated to a newer version.

1.5.3 Automatic Software Removal

The **magellan** software can be removed using the standard Windows uninstall routine:

- Close magellan
- Select Add/Remove Programs from the Settings Control Panel in the Windows Start menu.
- Select the magellan icon and click Remove.

In the removal procedure you will be asked whether or not shared components should be removed. If **Yes** is selected, **magellan** will be completely uninstalled and other Tecan programs such as XFluor, HS Control Manager or Gemini will no longer work. Leaving these components installed will not harm your system. If you are not sure what to do, we suggest to not remove the shared components. After clicking **Yes** or **No**, the **magellan** software is uninstalled.



Note

When removing all shared components, the user administration data is also removed. Some Tecan programs, for example EVOware, will not work anymore and must be re-installed.



2. Start Working with magellan

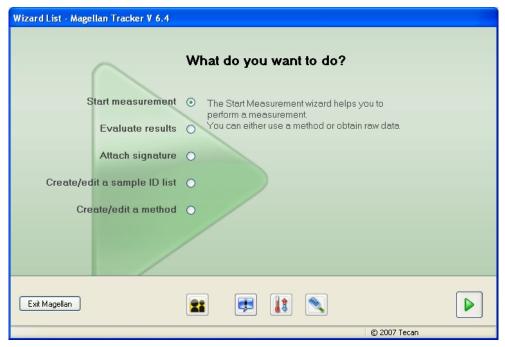
The main type of the user interface in magellan is the wizard.

Standard **magellan** wizards represent workflow modules, which are step-by-step guides for performing complex procedures.

Occasionally, menus are available in the heading bar. The **Menu** offers a conventional way of using the software: the relevant menu item is selected from the main menus. All subsequent actions are started instantly, or a dialog box is displayed where further selections or entries can be made.

2.1 User Interface – Wizard List

After launching magellan, the Wizard List appears:



Each wizard can be started either by double-clicking or by selecting it and clicking the **Next** button.



Start Measurement Wizard

The **Start Measurement wizard** includes the following options:

- Obtain Raw Data is used to generate raw data quickly and easily by setting the required measurement parameters and starting a measurement.
- Run Strip Lavout is used to collect strips from different methods, combine the strips to one method and run this method.
- Use Predefined Method is used to perform measurements based on previously defined methods.
- Start Favorite is used to select one of the most frequently used methods from the list of numbered icons.

For a detailed description, refer to chapter 6 Start Measurement Wizard.

After the measurement is finished a workspace file is created.

Evaluate Results Wizard

The **Evaluate Results wizard** is used to view the raw data and to evaluate the results. The evaluation parameters can be viewed and data can be re-evaluated.

For a detailed description, refer to chapter 7 Evaluate Results Wizard.

Attach Signature Wizard

The Attach Signature wizard is used to sign method and workspace files. This feature is only available with magellan Tracker.

For a detailed description, refer to chapter 8 Attach Signature Wizard.

Create/Edit a Sample ID List Wizard

The Create/Edit a Sample ID list wizard is used to create new and to edit existing sample ID lists.

For a detailed description, refer to chapter 5 Create/Edit a Sample ID List Wizard.

Create/Edit a Method Wizard

The Create/edit a method wizard is used to define or edit methods.

For detailed description, refer to chapter 4 Create/Edit a Method Wizard.

Icons



lcon: Change Current User

If the user administration is active (refer to chapter 11.4 User Administration (magellan Tracker) and to chapter 11.5 User Administration (magellan Standard)) click this icon to log out the current user and to login a new user.

With magellan Standard, user administration is optional. With magellan Tracker user administration is obligatory.





Icon: Miscellaneous

Click on the **Miscellaneous** icon to select the following options:

| | Instrument control | | Options |
|---|--------------------|----|---------------------|
| | File handling | 22 | User administration |
| m | About magellan | | |

- **Instrument control** provides quick access to several instrument functions, to service and setup options. See chapter 3 Instrument Control & Settings.
- **File handling** is used to move files to an archive location, to convert files from or to another **magellan** version and to import raw data from an ASCII-file. See chapter 11.2 File Handling.
- **Options** is used to customize certain default settings as path of generated files, clipboard and Excel copy options, the plate view and miscellaneous wizard, startup, language and password settings. See chapter 11.3 Options.
- **User administration** is used to add or disable users and to set or modify user rights. See chapter 11.4 User Administration (magellan Tracker), respectively chapter 11.5 User Administration (magellan Standard).
- About magellan provides license information and details on the currently installed version and components. Registration can be requested starting the Register wizard (see chapter 2.4.4 Licensing magellan).

Close the Miscellaneous window to go back to the wizard list.



Icon: Temperature control

Use this icon to set the target temperature for the connected instrument. For a detailed description, refer to chapter 3.1.2 Temperature Control... .



Icon: Move plate

Use this icon to move the plate carrier in or out of the instrument.



2.2 Components & Terms – Basic Logic of magellan

2.2.1 File Types Used with magellan

The following file types are used with magellan.

By default, all file types associated with **magellan** are stored in subdirectories in the appropriate directory:

...\All Users\Documents\Tecan\Magellan

The subdirectories are displayed in the table below:

| Type of File | File Extension | Directory magellan |
|------------------|----------------|--------------------|
| Workspace | .wsp | \magellan\wsp |
| Method | .mth | \magellan\mth |
| Sample ID List | .smp | \magellan\smp |
| Export Files | .asc | \magellan\asc |
| Standard Curve | .std | \magellan\wsp |
| Plate Definition | .pdf / pdfx | \Reader\pdf |
| | | \Reader\pdfx |

For a detailed description on methods, sample ID lists, workspaces and standard curves, refer to the chapters 4 Create/Edit a Method Wizard, 5.2.3 Import a Sample ID List and 7 Evaluate Results Wizard.



Note

The difference between plate definition files with .pdf extension and .pdfx extension is that Infinite Series instruments use the .pdfx format files, whereas all other Tecan instruments use .pdf files.



Note

The menus and toolbars available vary depending on the type of file currently opened.

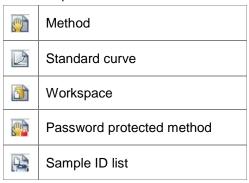


2.2.2 Folder Handling

In **magellan**, it is possible to create a user-specific folder structure for saving files (methods, workspaces, standard curves and sample ID lists) in any folder of the Windows Explorer. New folders can be created by right-clicking and selecting **New folder** from the context sensitive menu. Files and folders can be moved/cut/copied in the same manner as in Windows Explorer.

File Type Symbols

magellan uses the following symbols for methods, workspaces, standard curves and sample ID lists in the file view window:



magellan Standard

Default paths for saving newly created files can be set via: **Wizard list** main page → **Miscellaneous** button → **Options** button → **Paths** tab.

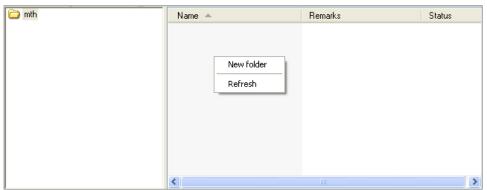
Users can create new folders in any folder of the Windows Explorer during the saving process.

In the **Save** window, the folder, specified by the default path of the file, is opened automatically, whenever a new file is created. If an already existing file is modified, the path to the current location of the file will be opened. However, it is possible to save files in any folder of the Windows Explorer or in a newly created folder.

magellan Tracker

magellan users with administration rights can set the default paths for saving newly created files via: Wizard list main page → Miscellaneous button → Options button → Paths. These default paths are valid for all users.

Users can create new subfolders only in the folder specified by the default path during the saving process.





In the **Save** window, the folder, specified by the default path of the file, is opened automatically, whenever a new file is created. If an already existing file is modified, the path to the current location of the file will be opened. However, it is only possible to save files in the default folder, or in an existing or newly created subfolder within this folder.

2.2.3 Standard Elements

Each wizard displays sequentially a number of windows, in which all necessary information, settings and data entry possibilities are provided.

Standard Elements of a magellan Wizard

For navigation from one window to another there are several buttons at the bottom of the wizard page:

| Back button | The Back button is used to navigate back to the previous window within a wizard. |
|---------------|---|
| Next button | The Next button is used to navigate forward to the next window within a wizard. |
| Finish button | The Finish button is used to navigate forward to the save window of the wizard. |
| Save button | The Save button is only found in the last window of a wizard and replaces the Next button. It is used to close the wizard and save all changes or to start a process. |
| Cancel button | The Cancel button is used to close a wizard without saving any changes to settings or documents. |
| Help button | The Help button opens the help window. |

Standard Elements of Microsoft Windows

| OK button | This button confirms settings, applies and saves changes accordingly and closes the dialog box. |
|------------------|---|
| Cancel button | This button closes the dialog box without saving any changes to settings or documents. |
| Help button | Click the Help button to open the magellan online help. |

Status Bar Information

The status bar displays the following information:

- Current command info
- User name of the currently logged in user.
- Name of connected instrument. For example: Sunrise
- Method: measurement mode and unit. For example: Absorbance [OD]
- Workspace: date and time of measurement. For example: 27.11.2002 14:13:03
 - Number of selected wells. For example: 3 well(s) selected
- Keyboard status information: activity of the keyboard toggles: CAP (caps lock), NUM (Numeric block lock), SCRL (Scroll lock)
- Instrument connection state icon



2.2.4 The Help Button

Click the **Help** button or press 'F1' to open the **magellan** online help.

2.2.5 The Welcome Dialog Box

Each wizard starts with a **Welcome** dialog box, which gives a short introductory description of the procedure to be performed.

Clear the **Show welcome page** check box to suppress welcome pages when starting wizards in the future.

2.2.6 Shortcuts List

| SHIFT+B | Back button |
|------------------------|--|
| SHIFT+N | Next button |
| ESC | Cancel button |
| ENTER | Next or Finish button, if active window |
| F1 | Help menu |
| CTRL+C or CTRL+INSERT | Сору |
| CTRL+V or SHIFT+INSERT | Paste |
| CTRL+X | Cut |
| CTRL+Y | Redo |
| CTRL+Z | Undo |
| DEL | Delete content of active well (edit sample ID, edit formula) |
| CTRL+SHIFT | Show formula of selected well when transformation result is viewed (Evaluate Results wizard) |



2.3 Starting magellan

2.3.1 Starting Standard Version

Perform the following steps to start magellan:

- 1. Make sure that an instrument is connected or that **Demo mode** is *allowed*.
- 2. In the Windows **Start** menu, select the **Tecan** program group and click the **magellan** icon.
- magellan starts.



Note

magellan can be run with an instrument connected or in a demo mode, simulating an instrument. If you want to connect to an instrument (see chapter 2.4 Connecting an Instrument), switch the instrument on before starting magellan.



Note

Before starting to work with magellan, we suggest reading the document Notice Anomalies magellan for any malfunctions in the application.

2.3.2 Starting Tracker Version



Note

When using magellan Tracker, the user administration system must be customized by a designated administrator, who is responsible for the setup of user accounts and for the assignment of user rights. The Administrator must always be trained by Tecan or a Tecan authorized organization.

Logging in for the First Time with magellan Tracker

When **magellan Tracker** is started for the first time, a dialog box appears, informing the user that a **User Administrator** must be created first. Click **OK** and the **Create Administrator** dialog box appears.

Complete the text fields and click \mathbf{OK} to save the settings. At least one user administrator must be created.



Caution

If the User Administrator password is forgotten, User Administration settings cannot be changed and magellan must be completely reinstalled.

We recommend to create at least two User Administrators.

For all further user definitions of the user administration (e. g. user rights), refer to chapter 11.4 User Administration (magellan Tracker) and chapter 11.5 User Administration (magellan Standard).



Password

Initial Password (magellan Tracker only)

When a user logs in for the first time, the password assigned by the administrator has to be changed.

After entering the **User name** and **Password** and clicking **OK**, the message "Your initial password is only valid once. You have to change the password!" appears. Click **OK**; the **Change Password** window forces the user to enter a new password.

Password Expiration (magellan Tracker only)

When the password expires, the user will be prompted to enter a new password. See chapter 11.4.4 User Administration Options.

Login

Once user administration has been activated, the **Login** dialog box will appear each time **magellan** starts.



The **Login** dialog box contains the following elements:

| Username text box | Enter your UserID |
|-------------------|----------------------------|
| Password text box | Enter your Password |

Click the GO button to enter or the Cancel button to terminate magellan.

Application Locked

If the application has not been in use for the specified maximum of time (user defined only in **magellan** Tracker) it will be locked. The password must be entered to unlock the application.



2.4 Connecting an Instrument

2.4.1 Instrument Connected

Connect the instrument to your computer as described in the instructions for use for the instrument and switch on the instrument before starting **magellan**.

First Start of magellan

The first time **magellan** is started, the **Setup Port** dialog box appears:



| Instrument | Select the connected instrument from the drop down list or select Find any . |
|--------------|---|
| Port | Select the appropriate COM port from the drop down list or select Find any and Click OK . |
| Stacker Port | If a Tecan Connect stacker is used together with the instrument, select the connecting port from the drop down list or select Find any . If no stacker is used select None for the stacker port. |

Change Instrument

Click the **miscellaneous** icon in the wizard list and **instrument control** in the miscellaneous list. Select **Change instrument** from **Setup & Service** to connect an instrument or to change the currently connected instrument.

Demo Mode

If **no instrument** is connected, select the instrument to be simulated from the drop down list in the **Instrument** group box and select **Demo mode** in the **Port** group box and Click **OK**. **magellan** is now in demo mode.

Demo mode allowed (in the Options dialog) is selected by default.

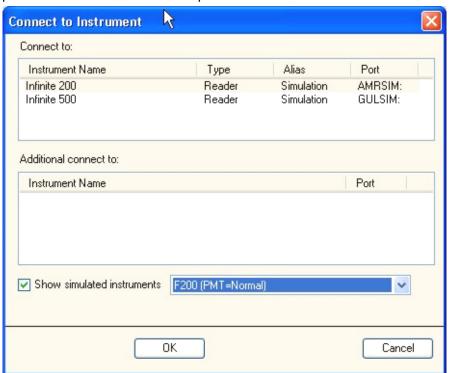
In demo mode it is possible to perform all functions except running actual measurements.



2.4.2 Connecting an Instrument of the Infinite Series

Select **Infinite Series** in the **Instrument** group box in the **Setup Port** dialog box. Click **OK** to display the **Connect to Instrument** dialog box, select the instrument and click **OK**.

For demo mode select the **Show simulated instruments** checkbox and the preferred instrument from the drop down list and click OK.



2.4.3 Connecting a Stacker

The Tecan **Connect** stacker can be used additionally. Refer to chapter **Batch Processing** in the Instructions for Use for **magellan** for further information.



2.4.4 Licensing magellan



Note

magellan can be used unregistered for 30 single days of work. If magellan is not registered after this period, the save and print options will be disabled.

The licensing of **magellan** is performed with the **Register magellan** wizard. If **magellan** has not been registered, this wizard will launch automatically each time the program is started.

The **Register magellan** wizard can also be opened over the **miscellaneous** icon in the wizard list starting page. (**miscellaneous** \rightarrow **About magellan** \rightarrow **Register**).

In order to register magellan, a Magellan serial number, the hardware (PC) unit identification number (HUID) and a license number are required.

For licensing magellan there are two possibilities:

1. The software has been purchased. Together with the software the serial number is delivered.

After the serial number has been entered in the register **magellan** dialog box, fill out the registration form to start the license number request. The completed registration form is sent together with the individual HUID to Tecan Austria. The HUID number is generated by the software and is inserted into the registration form automatically. It is related to Windows given system drive number.

After receiving the license number you have to start the registration wizard again and enter it. The **Register magellan** wizard confirms the license number and summarizes the user information. Click the **Finish** button to complete the registration procedure. **magellan**'s functions will then remain fully available to the user.

2. The software was delivered as a demo version together with the instrument. A registration is possible afterwards (No serial number is delivered).

To purchase **magellan** and to receive a serial number, select the option **Order magellan to obtain a valid license** and proceed with the registration procedure as described above. Refer to the Instructions for Use for **magellan** for further information.



Note

It is very important that the person who registers the software also has administrator rights for the operating system on the computer.



3. Instrument Control & Settings

Click the **Instrument Control** button in the *Wizard List* dialog box and the **Instrument Control** dialog box appears.

Depending on the instrument connected, different instrument and setup & service options are enabled or disabled.

3.1 Instrument Options

3.1.1 Movements...

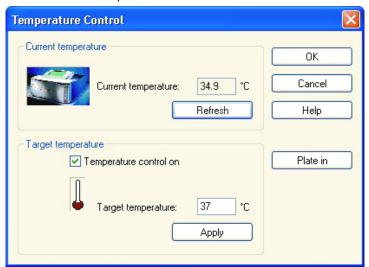
This opens the **Movements** dialog box, in which it is possible to control the movements of the plate carrier, filter slides, dichroic mirrors and cuvettes.

3.1.2 Temperature Control...

Only available for instruments equipped with temperature control.

This option allows the user to establish the temperature inside the reader.

This dialog is also accessible via the **Start Measurement** dialog box before starting a measurement. (See chapter 6.6 Start Measurement with a Predefined or Favorite Method).



Current temperature

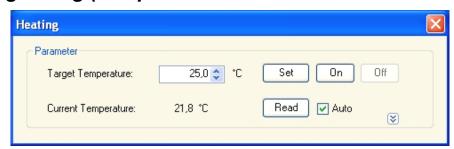
The current temperature is displayed in the corresponding field. Click the **Refresh** button to update the current temperature.

Target temperature

To start or stop the temperature control, select or clear the check box and enter the target temperature. Click **Apply** to send the temperature to the instrument and finally **OK** to close the dialog box.



3.1.3 Heating Dialog (Temp Control for Infinite Series Readers)



Target temperature

This command is used to set the target temperature of the instrument manually. Select or enter the Target temperature and click Set.

Click On/Off to start/stop instrument heating.

Current
Click the Read button to display the current temperature of the instrument or click the Auto check box to have it read automatically. Click Off to stop heating.

Click the down button, , to display the heating graph and click the up button, , to collapse. Click the close button, , to exit the Heating dialog box.

For detailed information on *Lamp/Laser Control*, *Injector Control* and *Dispense please refer to* the respective Instructions for Use of the connected instrument.

3.2 Setup & Service Options

3.2.1 Change Instrument...

In the **Setup & Service** box, click **Change instrument...** to open the **Setup Port** dialog box.

This option allows connecting **magellan** to an instrument. See chapter 2.4 Connecting an Instrument for further details.



Note

If you connect another instrument to your computer or if you modify the interface parameters, you must always select this menu option. The settings will be automatically used the next time the software is launched.

3.2.2 Define Filter Slides...

Standard and custom filter slides can be defined.

3.2.3 Insert Transport Lock...

Instrument feature (see the corresponding Instructions for Use for more information).



3.2.4 Optimize Z-Position

Only applicable for instruments with z-positioning option.

This option can be used to find the optimum Z-position of the plate transport in relation to the measuring head for the specific instruments.

3.2.5 Plate Geometry Editor...

Use the **Plate geometry editor** to create plate geometry files for not listed plates in order to use them with **magellan** or to validate existing plate geometry files.

Refer to the Instructions for Use for **magellan** for further information on the Plate Geometry Editor.

3.3 Log Files

During working with **magellan** log files are created. The communication between the software and the instrument and the communication between components of the software are stored in these log files.

They can be found in the following paths:

- magellan Log files (communication between single components of magellan):
 - C:\Documents and Settings\AllUsers\Documents\Tecan\LogFiles
- Collection of necessary Log files
 Log files can be saved as zip archive by selecting the Save Logfiles...
 button in the File handling dialog (Miscellaneous → File Handling). The
 zip archive can now be named and saved in a defined directory. In case of
 any magellan measurement or status error(s), this archive contains all well
 data, status (e.g. overflow, lamp low) or calculation error(s) and can be
 easily sent to Expertline-at@tecan.com for support request. For further
 information please refer to chapter 11.2 File Handling Save Log Files.
- Infinite Series Log files (communication between magellan and Infinite series instrument):
 - C:\Documents and Settings\All
 Users\Documents\Tecan\LogFiles\Magellan\V x.y
- Rdr.OLE Log files (communication between magellan and Rdr.ole Instrument) by default:
 - C:\Documents and Settings\CurrentUser\Local Settings\Temp



4. Create/Edit a Method Wizard

4.1 Introduction

The Create/Edit a Method wizard is used to

- Create or edit methods.
- Set measurement and evaluation parameters,
- Define the plate layout,
- Select the format of the printed report and
- Set the automated data handling parameters.

Workflow Summary

Click **Continue** on the welcome page of the **Create/Edit a Method** wizard. In the next window, select

- Create new if you want to define a new method or
- Edit if you want to modify an existing method.

In the **Define Measurement Parameters** window, measurement parameters can be set. Click **Define Evaluation** to define the plate layout, evaluation parameters, print out and automated data handling parameters. At the end of the wizard the new or modified method is saved as .mth file.



Note

For a step-by-step description of how to create a method, refer to the Instructions for Use for magellan.

File Selection Page

In the wizard list, click **Create/Edit a method** button. Click **Next** on the welcome page of the **Create/Edit a method** wizard and the **File Selection** page with the following elements appears:

| Create new button | Select Create New button to create a new method. |
|----------------------|--|
| Edit button | The Edit button must be selected to edit an existing method. |
| Show combo box | In the Show combo box a file filter can be defined in order to get only those methods in the list, which fulfill the selected criteria: • All files • Files from this instrument • My files: This option is available if the user administration is enabled (always enabled in magellan Tracker). • Signed files: only available for magellan Tracker • Example files: only available if they have been installed. |
| Filename list | Select the method to be edited from the Filename list. A Remarks field next to every file name contains - if entered - a short description of the method. All methods available in the standard method directory will be displayed (see chapter 11.3 Options). |
| Print Preview button | Click the Print Preview button to open the Print Preview dialog <i>box</i> , where a preview of the settings of the selected method is displayed and a printout can be started. |





Note

If the proper instrument for the selected file is not connected, the Instrument Mismatch dialog box appears. The dialog offers two options:

- · Connect to the proper instrument
- Convert the measurement parameters to those compatible with the connected instrument. - This option is not available if the measurement mode is not supported by the connected instrument, for example, a Sunrise does not support Fluorescence measurements.

It is highly recommended to review the measurement parameters.

4.2 Define the Measurement Parameters

In the **Measurement Parameters** window it is possible to set all required parameters for the measurement, including measurement mode, wavelengths, read mode, temperature, etc. depending on the type of instrument connected. Refer to the Instructions for Use for **magellan** for further information on how to **Define the Measurements Parameters**.

When connected to an Infinite instrument, refer to the Instructions for Use for i-control for further details on defining measurement parameters.



Note

The available parameters to be defined depend on the instrument connected.



4.3 Define Evaluation

4.3.1 The Create/Edit Method Overview Window

In the **Define Evaluation** window the user defines the plate layout, transformations and calculations, selects the format of the printed report and sets the automated date handling parameters.



Toolbar

On top of the window a **Toolbar** is displayed with the most common functions depending on the currently selected options:

| Undo button | Click Undo to undo a previous action. |
|--------------------------|---|
| Redo button | Click Redo to redo an action that was undone. |
| Select all unused button | Plate Layout mode only: All unused wells of the plate are marked. |
| Zoom to 10% button | This will set the plate layout view to 10%. |
| Zoom to 100% button | This will set the plate layout view to 100%. |
| Zoom mode button | Use the Zoom mode button to zoom into the marked area. If activated, the user can select an area to zoom in by clicking and dragging a frame over the desired layout area. Click the right mouse button to zoom out to 100% display. |



Plate Layout Window

In the central area of the window the **Plate Layout Window** displays a schematically layout of a microplate.

When creating a new method select the wells for the measurement. A mouse click selects an individual well. Unselected wells will remain gray.

For the defined layout, the identifiers, transformations and formulas selected in the **Control Bar** are displayed in the corresponding wells (see **Control Bar of Create/Edit Method** below).

By right-clicking on a well on the plate layout, a **context-sensitive** menu for the marked wells is displayed. Refer to the Instructions for Use for **magellan** for further details

Control Bar of Create/Edit Method Tab

The **Control Bar** on the left of the screen provides a number of options, which should be executed in the suggested sequence. Depending on the kind of measurement and the connected reader type, some of the options may not be available and therefore are hidden.

When selecting an item in the control bar the corresponding dialog or plate view is displayed in the **Plate Layout window** pane on the right side of the screen.

All available options will be marked with a checkmark, once they have been defined. For any kind of transformation the transformation name is displayed.

The Control bar - Create/edit method tab contains the following elements:

| Method layout group | Plate layout item The Plate layout window is opened, displaying the plate layout and the Well assignment dialog box. Conc., Dil., and Refvalues item The Concentration/Dilution/Reference definition dialog box is opened, displaying the dilution, concentration or reference value of each well. The standard concentrations can be established as well as the dilution factors and the reference values. An Autofill function | |
|----------------------------|---|--|
| | provides easy assignment of concentrations in case of distinctive mathematical relations of the concentrations between the individual wells. | |
| Precalculation | Polarization data reduction for fluorescence polarization measurements Spectra data reduction for wavelength scans Cuvette data reduction for combined plate and cuvette measurements | |
| Transformed data group | Add new transformation item The Plate layout window is opened, displaying the plate layout and the Transformations dialog input field. | |
| Kinetic group | Kinetic data reduction item The Kinetics Calculation Parameters window is opened. The evaluation of the kinetics measurement data can be defined. | |
| Kinetics transformation | Add new kinetic transformation item The Plate layout window is opened, displaying the plate layout and the Transformations dialog input field (only kinetic input data can be selected). | |



| Concentrations group | Standard curve item The Standard Curve window is opened to set the parameters for the calculation of concentrations and the graphical display of the standard curve of the evaluated data. |
|---|--|
| Concentration transformation data group | Add new concentration transformation item The Plate layout window is opened, displaying the plate layout and the Concentration Transformations dialog input field (only concentrations can be selected as input data). |
| Evaluate data group | Cutoff definition item QC validation item The Define Cutoff window is opened. In this dialog box the limits for a qualitative evaluation (screening) can be defined. The Define QC Validation window is opened. It is used to verify the validity of a test. |
| Data handling group | Data export item Printed report item Automated data handling item |
| Miscellaneous group | User prompts item Number format item Method notes item The Define User Prompts window enables the assignment of data (keywords, comments or prompts) to each measurement, which can then be incorporated into a printout. The Number format window allows the user to define the number format for the displayed raw data or transformed data. In the Method notes it is possible to enter a description of the method. |

By right-clicking on any transformation, kinetic transformation and concentration transformation on the control bar, a **context-sensitive menu** for the marked transformation is displayed. Refer to the Instructions for Use for **magellan** for further information.

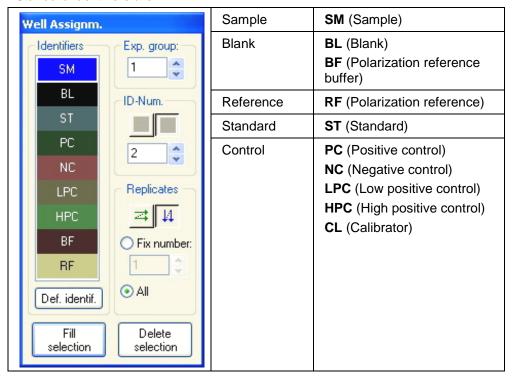
4.3.2 Method Layout: How to Define a Plate Layout

In the **Control bar** expand **Method layout** and select **Plate layout**. The **Plate view** and the **Well Assignment** dialog box are displayed.

To each well in the analysis plate an identifier can be assigned. On this basis the plate layout should be defined, (i.e. a well that is to be viewed as being a positive control, would be allocated a different identifier from that of a well that is to be viewed as being a negative control).



Standard identifiers are:



Assign an Identifier to the Required Well

In the **Well Assignment** dialog box, well identification and layout definition can be carried out. This box provides also a number of automated ID assignment capabilities, which is an essential tool for high density plates.

The desired settings have to be made in the **Well Assignment** dialog box. Generally, the wells can be selected by clicking the individual well or dragging the mouse over the required wells. For all other selection ways, refer to the Instructions for Use for **magellan**.

Following ways are possible to assign the selected identifier to the wells:

- Double-click when making the selection of the well
- Select the wells on the microplate and then click the Fill selection button (or click the right mouse button and select Fill selection in the context-sensitive menu) on the Well Assignment dialog box
- Select the wells on the microplate and then double click the identifier in the identifier list box of the well assignment dialog.

After assigning the definitions the display in the modified wells will change.

Example of a labeled well:

| SM1_4 | 1 st line: sample, experimental group number of 1, sample ID number of 4. |
|-------|--|
| 1/14 | 2 nd line: number of replicate is 1, total number of replicates is 14. |
| x-BL1 | 3 rd line: primary empty – filled with the transformation formula or a concentration, dilution or reference value if defined, e.g. reduce the value of this well (x) by the mean of the blanks. |



| The Well assignment dialog box contains the following elements: | |
|---|--|
| Identifiers group box | Select identifiers from the drop down list to mark the wells. Click the Define Identif button to define additional identifiers. |
| Exp. group selection field | If the plate is made up of more than one test, i.e. more than one experimental group, define the Experiment group to which the wells belong to. |
| ID-Num. group box | The ID Number is used to assign the same ID to replicates that belong together. The ID Number is only available for samples and standards. ID-Num. selection field The ID-Num option allows the user to mark those replicates that are associated with the same ID. This can be used if the replicates have been assigned to different areas of the plate. Arrow buttons The ID will be calculated automatically. If a number of wells is marked, the direction in which the IDs are assigned to the wells (vertically, horizontally) can be established using the arrow buttons. |
| Replicates group box | Determines the number of replicates for the selected identifier type: Fix number option button Only enabled for standards and samples where IDs can be used. This number defines how many replicates are intended for this identifier. All option button All selected wells are defined as replicates of one identifier. If an existing ID number for the samples and standards is chosen, the selected wells are then added as replicates to the existing replicates. With all other identifier types the selected wells are added as replicates to the existing replicates. Two Arrow buttons define the direction of counting up the replicate number. |
| Fill section button | If an area of the plate has been marked, it can be filled with the respective identifiers. The IDs and the color of the identifiers will be displayed on the plate layout. |
| Delete section button | Click Delete or press DEL to delete the IDs and color identifiers of the selected wells and leave them blank. |
| Define identifier button | Click Def. identif. if a new identifier is to be defined or if an existing identifier is to be edited (see Define a New Identifier) |

Assign Alias to the Required Well

To assign alias designations for defined well names, click the right mouse button in the required well, select **Set/Remove Alias...** and choose an alternative identifier name in the drop down list. The alias is marked with an asterisk * and has same experimental group, ID number and replicate number as the primarily defined well. This feature is used, if e.g. the 0-Standard is also used as Negative control.

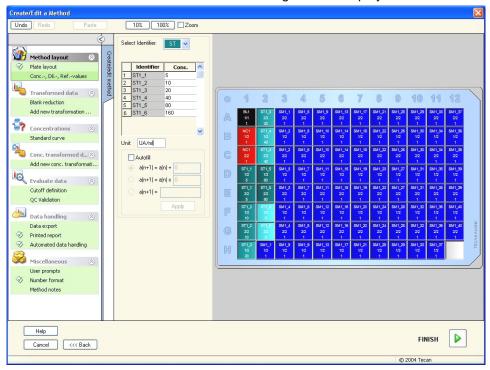


Define a New Identifier

Refer to the Instructions for Use for **magellan** for information on how to **Define a New Identifier**.

4.3.3 Method Layout: Conc., Dil. and Ref. Values

In the **Control bar** expand **Method layout** and select **Conc./Dil./Ref.-values**. The **Plate View** and the **Select Identifier** dialog box are displayed.



The **Concentration/Dilution/Reference** window contains the following elements:

| Select Identifier drop down list | The values are co-related within the individual well types; this field provides all wells currently included in the measurement. Select an identifier to edit the corresponding dilution or concentration factors. All wells, which match the selected well type identifier, are listed. |
|---|---|
| Exp. group selection field | Select the respective experimental group. If there is only one experimental group, the field cannot be edited. |
| Table with Identifier and Concentration/ Dilution columns | This table displays all wells in the Identifier column, which match the selected identifier (as from the Select Identifier list). The corresponding dilutions, concentrations or reference values are inserted and listed in the Dilution/Concentration/Reference column. E.g. entering a dilution factor of 2 means that the sample has been diluted by half. The calculated concentration will therefore be multiplied by 2. |
| Unit text field | The displayed concentration unit can be determined. |
| Autofill check box | The Autofill function provides the calculation of the corresponding concentrations or dilution factors according to available types of series. |



| Option buttons for the mathematical concentration calculation | If the Autofill check box has been selected, the following options are available: Arithmetic series: a (n+1) = a (n) + Geometric series: a (n+1) = a (n) x User defined series a(n+1) = Example: Each subsequent concentration should contain twice + 0.5 of the previous concentration: Formula 1: a(n+1) = 2 * n + 0.5 |
|--|---|
| Apply button | The Apply button applies the selected mathematical concentration calculation to the wells as displayed in the table with Identifier and Concentration/ Dilution columns. |
| Dilution series group box | Calculate ICx check box Displays a dilution graph of the sample and automatically calculates the ICx values. This requires samples with at least 4 replicates and at least 4 different dilutions defined*. |
| | Input Data drop down list Select from the drop down list the input data. |
| | Calculation Condition text field The intercept will be calculated with the entered percentage of the maximum value respectively maximum value minus minimum value*. |
| | ICx name text field Data can be selected for ICx calculation. The name is filled in automatically based on the calculation condition. |
| | Set 0% value to Intensity 0* Min. intensity of dilution series* |

^{*}For further details please refer to the Instructions for Use for **magellan** for information on **ICxCalculation**.

Dilution can be edited directly in the plate layout window by right mouse clicking in one or more selected wells. In this way, it is possible to assign different dilution values to replicates.

4.3.4 Precalculation: Polarization Data Reduction

This option is only available for Fluorescence Polarization (FP) measurements.

Expand **Precalculation** in the control bar and select **Polarization Data Reduction**.

The appropriate entries for fluorescence polarization measurements must be made under the **G-factor** and **Sample blank reduction** group boxes of the **Polarization Settings** dialog box.

Refer to the Instructions for Use for magellan for further information.

4.3.5 Precalculation: Spectra Data Reduction

This option is only available for measurements containing a two-dimensional scan (absorbance scan, excitation scan, emission scan).

Expand **Precalculation** in the control bar and select **Spectra Data Reduction**.

Spectra data reduction allows to perform a spectra blank reduction and to extract specific data, e.g. intensities, from the scan.

Refer to the Instructions for Use for **magellan** for further information.



4.3.6 Precalculation: Cuvette Data Reduction

If you are using an **Infinite M200** with **Cuvette option** you can define methods with a combination of plate and cuvette measurements. Using the Precalculation - cuvette data reduction dialog it is possible to define formulas to get single values from a scan or a kinetic measurement. Refer to the Instructions for Use for **magellan** for further information.

4.3.7 Transformed Data: Add New Transformation

In the control bar expand **Transformed data**. All defined transformations are displayed in the control bar.

To define a new transformation select the well(s) for which the transformation is to be applied and click **Add new transformation...** .

The default name should be changed immediately in the edit box. The name can be inserted or changed also later, clicking **Rename Transformation** from the context-sensitive menu.



Note

The transformation name has to be in Latin characters in order to make the transformation available as additional input data for further transformations with multiple input data.



Note

The name of a transformation is used to represent the result of the calculations and will also be used when the values are displayed in the specific data output menus. Calculated values of the transformations are also available as input data for further evaluations.

A typical example of a transformation is the reduction of the empty value (blank) from all wells.



Note

If a blank is set in the Plate Layout, the formula to calculate the blank reduction is offered in the combo box: x-BL1.

The symbol x refers to the current value within a well. BL1 is the average value of the blank well(s).



If a multilabel measurement with two labels is defined, different formulas to reduce the multilabel data are offered in the combo box.



'Label1'!x/'Label2'!x ... predefined ratio calculation
'Label2'!x/'Label1'!x ... predefined ratio calculation
'Label1'!x-'Label2'!x ... predefined difference calculation
'Label2'!x-'Label1'!x ... predefined difference calculation
('Lable1'!x-'Label1'!BL1)/('Label2'!x-'Label2'!BL1) ... predefined ratio
caculation with blank reduction
('Lable2'!x-'Label2'!BL1)/('Label1'!x-'Label1'!BL1) ... predefined ratio
caculation with blank reduction





Note

If the read mode is set to absorbance, the formula to calculate the transmission is offered in the combo box: 1/10^x.

Refer to the Instructions for Use for magellan for further information.

Define Constants

Use the **Define Constants** dialog box to define the constant values of a method. These constants can be used wherever a formula can be entered.

Click the **OK** button to save the edited parameters.

The **Define Constants** dialog box contains the following elements:

Constants list

In each row, a constant can be defined. The rows are divided into 4 columns:

Name

Enter an appropriate identifier name for the constant, for example: a code or an abbreviation. Only letters can be used.

Value

In the **Value** text field a numerical value must be allocated to the constant.

Comment

Enter a short comment to the constant.

• Req. ("required")

The **Req.** check box indicates, that a measurement can only be launched on receipt or confirmation of the value for the constant.



4.3.8 Kinetic: Kinetic Data Reduction

In the control bar expand Kinetic and select Kinetic data reduction.

The dialog box is structured in tabs: **Slopes**, **Onsets**, **Min./Max./Area**, **Available output data**, **Enzyme kinetics**. The unit of the values is displayed according to the selected measurement mode (for example: OD for absorbance).



Note

Unusable data (e.g. overflow values) are ignored for kinetic data calculation.

Slopes Tab

This tab allows the user to establish the evaluation of the kinetic curve's slope:

| Input data drop down list | Select the input data to be processed. |
|------------------------------|---|
| Calculation drop down list | Select the calculation method, linear or quadratic (refer to chapter 13 Calculations). |
| Mean slope check box | The start and end time can be typed into the provided text fields, otherwise the whole kinetic is analyzed. |
| | Time/Points option buttons: If Time is selected the start and end time is entered in hours, minutes and seconds. If Points is selected the start and end point for the analysis is given through the entered kinetic cycle number. |
| | Start field: The start time (in hours, minutes and seconds) or cycle number must be entered here. |
| | End field: The end time (in hours, minutes and seconds) or cycle number must be entered here. |
| Maximum slope check box | The start and end time can be typed into the provided text fields, otherwise the whole kinetic is analyzed. |
| | Time/Points option buttons: If Time is selected the start and end time is entered in hours, minutes and seconds. If Points is selected the start and end point for the analysis is given through the entered kinetic cycle number. |
| | Start field: The start time (in hours, minutes and seconds) or cycle number has to be entered here. |
| | End field: The end time (in hours, minutes and seconds) or cycle number has to be entered here. |
| | Points text field: Select for how many points the maximum slope calculation is performed. |

Refer to the Instructions for Use for **magellan** for further description of **mean** and **maximum slope** function.



Onsets Tab

Use the **Onsets** tab to determine the time to reach a certain data point:

| Input data drop down list | Select the input data to be processed. |
|------------------------------|---|
| Time to onset check box | If the Time to onset check box is selected, an absolute value for the onset can be entered in the following text field. |
| | Text field: An absolute value for the onset must be entered. |
| | Basis mean of the first n points option button and text field: If selected, enter the desired number of points. |
| | Basis option button and text field: If selected, an absolute value for the basis must be entered in the adjacent text field. |
| Time to onset % check box | If the Time to onset % check box is selected, a percentage value for the onset can be entered in the following text field. |
| | Text field: A percentage value for the onset must be entered. |
| | Basis mean of the first n points option button and text field: If selected, the desired number of points can be entered. |
| | Basis option button and text field: If selected, an absolute value for the basis must be entered in the adjacent text field. |

The result data made available through this method includes the basis value, the time taken to reach the basis value, the time taken to reach the sum of basis and onset value, and the difference of these two time spans (Time Basis to Onset).

With increasing kinetic measurement values the onset value is to be defined as a positive number, with decreasing values the onset value is to be defined as a negative number.

Min./Max./Area Tab

Use this tab to define the evaluation of the minimum and maximum values contained in the curve and to define the calculation of the area under the kinetic curve:

| Input data drop down list | Select the input data to be processed. |
|------------------------------|---|
| Mean minimum value check box | Select to open the Points text field where the fixed number of points has to be entered for the minimum value. An even curve will then be generated using these points and the lowest value contained in the curve determined. |
| Mean maximum value check box | Select to open the Points text field where the fixed number of points must be entered for the maximum value. An even curve will then be generated using these points and the highest value contained in the curve determined. |
| Area check box | The start and end time can be typed into the provided text fields, otherwise the whole kinetic is analyzed. |



| Time/Points option buttons: If Time is selected the start and end time is entered in hours, minutes and seconds. If Points is selected the start and end point for the analysis is given through the entered kinetic cycle number. |
|---|
| Start field: The start time (in hours, minutes and seconds) or cycle number has to be entered here. |
| End field: The end time (in hours, minutes and seconds) or cycle number has to be entered here. |

Averages are taken from the number of points starting from the first kinetic measurement value and stepping through one by one until the last kinetic measurement point is included in the average calculation. The minimum/maximum value is determined from these averages.

The result data made available through this method includes minimum/maximum value and the time span from the first measurement to the minimum/maximum value in seconds.

Available Data Tab

A list of the results is displayed in the **Available output data** tab:

| Data field | The data field lists values as selected in the previous tabs of the Kinetic Calculation Parameters dialog box. |
|------------|--|
| | This data field is for pure display of the listed output data only and provides no edit functions. |

Enzyme Kinetics Tab

Use this tab to establish the evaluation of enzyme kinetics according to the model of Michaelis and Menten:

| Input data drop down list | Select the input data to be processed. |
|---------------------------------|---|
| Calculate Km and Vmax check box | Decide whether to calculate Km and Vmax selecting the corresponding check box. |
| Calculation type group box | The calculation type can be selected as: Hanes (concentration versus concentration/input data) Eadie-Hofstee (input data/concentration versus input data) Lineweaver-Burk(1/input data versus 1/concentration) |

The result data made available through this method includes Km and Vmax for Enzyme kinetic graph of each experimental group.

Unlike the results of the other kinetic calculations, these results are displayed in the **Graph: Enzyme Kinetics** dialog box.

This tab is only available if standards are on the plate and either transformations or slope calculations are defined.



4.3.9 Kinetics Transformations: Add New Kinetics Transformations

In the **Kinetic transformations** dialog box a transformation formula can be defined, which is used for transforming kinetic input data individually for every well.

In the **Kinetic transformations** dialog box further calculations can be performed on kinetic input data.

The window elements are similar to the **Transformation** input. Refer to chapter 4.3.7 Transformed Data: Add New Transformation for further information.

4.3.10 Concentrations: Standard Curve

Use this option to set up standard curves for quantitative tests.

The standard curve dialog box contains various settings concerning the analysis type, the axes and the display of the standard curve. The editable fields and elements are grouped in 5 different tabs.

Data Tab

This tab stipulates some basic settings like the input data source.

| Exp. group spin control | If several tests are to be performed on one plate the Experiment group must be selected. If the plate contains only one test, then the spin control will not be displayed. For each experiment group the input data can be defined individually. |
|---|--|
| Input data drop down list | Select the Input data to be used for the standard curve. Select measurement data or any available transformation results. |
| Standards from layout option button | Calculate the standard curve from the standards on the layout. |
| Standards from ext. file option button | If the selected experimental group contains no standards, a standard curve can be loaded from a .std file. The Select button must be clicked to select the file. |
| Standards from exp. group option button | If the selected experimental group contains no standards, a standard curve from another experimental group can be used. |
| No standard curve option button | If the selected experimental group contains no standards, it can be decided to calculate no concentrations for this experimental group (in this case set per default). |
| Additional Concentrations button | Click the Additional Concentrations button to open the Calculate Additional Concentration dialog box. Select additional sets of input data, which are to be used to calculate concentrations based on the current standard curve. |



4. Create/Edit a Method Wizard

The Calculate Additional Concentrations dialog box contains the following elements:

| Input data drop down list | Select the input data for calculation of additional concentrations. |
|------------------------------|--|
| Selected data list | The list contains the input data names for calculation of additional concentrations. |
| Add button | Click the Add button to add the currently selected input data in the Input data drop down list to the Selected data list. |
| Remove button | Click the Remove button to remove the currently selected data from the Selected data list. |

Analysis Type Tab

Use this tab to select the analysis type. Please refer to Instructions for Use for **magellan** for a detailed description of the **Analysis Type Tab**.

Intercepts Tab

Use this tab to calculate concentrations for selected Y values based on the standard curve. Refer to Instructions for Use for **magellan** for further details of the **Intercepts Tab**.

Axis Tab

Use this tab to define the appearance of the axes. Refer to Instructions for Use for **magellan** for further details of the **Axis Tab**.

Graph Tab

Use this tab to define the appearance of the graph. Please refer to Instructions for Use for **magellan** for further details of the **Graph Tab**.

4.3.11 Concentrations Transformations: Add New Concentration Transformations

In the **Concentration transformations** dialog box a concentration formula can be defined, which is used for transforming concentration input data individually for every well.

In the **Concentration transformations** dialog box further calculations can be performed on concentration input data.

The window elements are similar to the **Transformation** input. Refer to chapter 4.3.7 Transformed Data: Add New Transformation for further information.



4.3.12 Evaluate Data: Cutoff Definition

Use this option to categorize either raw data or calculated data on threshold limits. Threshold limits can be defined as fixed numeric values or formulas.

Use the **Cutoff Definition** window to define the cutoff ranges and to assign colors and names to cutoff results.

The **Cutoff Definition** window contains the following elements:

| Input data drop down list | Select the input data which is to be used in the evaluation. |
|------------------------------|---|
| Exp. group selection list | In case the plate contains more than one test, the relevant experimental group to which the cutoff should apply must be selected. If the plate contains only one test, then only one group will be available and the field is not visible. |

In the **Cutoff** list, up to ten cutoff ranges can be defined. The limits for each range can be entered.

The highest limit value must be entered on top of the list. The next lower will be placed beyond and so on. A displayed Low-High arrow shows the level. The limit values itself belong to the upper ranges (greater and equal condition).

| 9 | , |
|---------------------------------|---|
| Colors buttons | A color can be allocated to the individual result levels. When displaying the results these colors will be incorporated, representing the qualitative results. |
| Labels text fields | The result indicators for every value range must be named, for example: positive (pos), negative (neg), intermediate (?), |
| Limits text fields | The limits can be entered as a constant value or as a formula. Formulas can be entered directly into a field or via the Formula input fields. A maximum of up to nine limits may be defined. |
| Formula input group box | Formulas to be entered into the Limits field can be composed by using the variables, operators and functions below. Refer to chapter 13.2 How to Write a Formula for further details. • Variables drop down list All available variables are displayed. • button Click this button to open the Define constants dialog box. • Operators drop down list All available operators are displayed. • Functions drop down list Available functions can be selected. |
| Competitive Test check box | Competitive tests allocate a positive result to low values and a negative result to high values. In the evaluation, the limits will run from top to bottom and the corresponding results symbol will be allocated when a value is found to be equal to or less than the limit. In view of this, the Low-High arrow will be reversed. |
| Cutoff results selection button | Click the Cutoff results selection button to open the Cutoff Results Selection dialog box. |



Cutoff Results Selection

Use this window to select whether a qualitative result for a certain identifier type is shown or not.

The Cutoff Results Selection contains the following elements:

Cutoff display selection tree structure

All defined identifier names are shown in a tree structure, grouped by identifier types. Each identifier is associated with a check box.

Selecting or clearing the check box of an identifier name indicates, whether the qualitative results of the according wells will be shown or not. After evaluation, only cutoff results for the selected identifier types are displayed.

4.3.13 Evaluate Data: QC Validation

Validations are used to check the validity of a test. If the defined criteria are not met, an error message will be displayed after the measurement run and no cutoff results will be displayed. (Except the user has the right to *continue evaluation when error* – see chapter 11.6 User Rights

Upon selecting the correct input data, the desired formulas are to be entered in the **Validation Conditions** list field. A formula editor supports the user in the creation of the corresponding mathematical formulas.

Example:

If the validation criteria are defined as follows:

NC1>0 and NC1<0.1

the evaluation will check whether the negative control can be found within the given range. If this is not the case an error message will appear.

The **Define QC Validations** dialog box contains the following elements:

| Input data drop down list | Select the relevant data, to which the validation must apply. For example: Raw data, etc. |
|-------------------------------------|--|
| Exp group selection field | If the plate contains more than one test, the relevant experimental group to which the validation should apply must be selected. If the plate contains only one test, then only one group will be available. |
| Validation group selection field | Use Validation groups to define validation criteria for the same experimental group with different input data. |
| Validation Conditions list field | This one-dimensional list will be filled with the formulas and logical equations, which define the Validation Conditions . These logical equations will generate a logical result. The program will examine the input data using this equation and, if the validation criteria are met, will return a result of TRUE. If the criteria did not meet, a result of FALSE and an error message will be displayed. |



| Formula input | Parts of the formulas to be entered into the Validation |
|---------------|---|
| group box | Conditions field can be selected from the following drop down lists: |
| | Variables drop down list All available variables displayed. |
| | button Click this button to open the Define constants dialog |

box.

- Operators drop down list All available operators are displayed.
- Functions drop down list
 Using the given palette, available functions can be chosen.

Refer to chapter 13.2 How to Write a Formula for further details.

Plate to Plate QC

Use this option to define a long-term QC validation (refer to chapter 7.4.2 Toolbar Menu: File/ Plate to Plate QC):

| Input data drop down list | Select the relevant data, to which the validation must be applied, from the drop down list. |
|---------------------------------------|---|
| Control check boxes | Select the type of control from the drop down list, then enter the expected mean and standard deviation. A scroll bar appears next to the dialog controls to define more than 4 QC controls. |
| | |
| Workspaces to be evaluated options | Select the appropriate filter to define which workspaces should be evaluated. |

4.3.14 Data Handling: Data Export

Data to be exported into an ASCII or Excel file can be selected using this dialog box:

| Available data list | A list of all available data is displayed, depending on the method definition. |
|-----------------------------------|--|
| ← and → buttons | Data for exporting can be selected simply with drag and drop or by clicking the data in the Available data window and then the arrow pointing towards the Selected data window. Data can be deselected by operating the reverse procedure. |
| Up and Down buttons | The order of the selected data can be changed by selecting an item and pressing the button Up to move it up or Down to move it down |
| Selected data list | This list shows all selected data, which has been transferred from the Available data field list. |
| Export options button | Click this button to open the Export Options dialog box. |

The actual exporting of data only occurs using automated data handling (see 4.3.16 Data Handling: Automated Data Handling).



Export Options

Please refer to Instructions for Use for magellan for all the details of the Export Options.

Export of Multiple Reads per Well Data

Please refer to Instructions for Use for **magellan** for all the details of the **Export Options**.

Export to ASCII File

The **Export to ASCII File** dialog box contains the following elements:

| The Export to Ason | The dialog box contains the following elements. |
|------------------------------------|--|
| Decimal character group box | The decimal character may be a point or a comma: Point (x.xx) option button Comma (x,xx) option button |
| Delimiter group box | This option sets a delimiter to separate the individual values within the data in the lines of an ASCII file: |
| | Tabulator option button Default option, using tabulators as delimiters. |
| | Other symbol option button If selected, a user-defined delimiter character can be entered. |
| Path group box | This option sets the path where the ASCII file will be stored: |
| | Export default path option button |
| | Use path option button: Select any path where the ASCII file shall be stored |
| Encoding group | Select the export code: |
| box | ANSI: For ANSI compatible characters. |
| | Unicode: For characters that cannot be exported with ANSI code (e.g. Chinese, Cyrillic). |
| Set as default button | The settings can be logged as a default for future use. |
| Restore default button | The settings can be reset to the previously defined default. |



Caution

A suitable export delimiter must be selected. The export delimiter and decimal character should not be the same. TAB is set as the default delimiter, but another symbol can be selected.



Export to Excel

The **Export to Excel** dialog box contains the following elements:

| The Export to Excel dialog box contains the following elements. | | |
|---|---|--|
| Target group box | The option buttons define where to position the transferred data within Excel. This option is also valid for automatic Excel export. • New workbook option button | |
| | Transferred data will be stored in the first worksheet of a new workbook. A new file will always be created, no matter if Excel is started or not. | |
| | New worksheet option button Transferred data will be put into a new worksheet within an open, active Excel workbook. If Excel is not open, when selecting this option, it will be started and a new workbook created, including the requested data into the first worksheet. | |
| | Insert into worksheet at cell option button and cell coordinates text field The first value of the transferred data will be placed into the cell indicated (default is cell A1) of an open, active Excel worksheet. If Excel is not open when selecting this option, it will be started and a new workbook will be created, inserting the requested data into the first worksheet at the defined cell. | |
| | Append to current worksheet option button This option will append the data to the current worksheet. If Excel is not open when selecting this option, it will be started and a new workbook will be created, inserting the requested data into the first worksheet. | |
| | Use Insert into Template to export data into a predefined Excel template. Path and name of the Excel template must be entered, clicking the button. The corresponding cell position must be indicated. | |
| Set as default button | The settings can be logged as a default for future use. | |
| Restore default button | The settings can be reset to the previously defined default. | |

4.3.15 Data Handling: Printed Report

The **Printed report** dialog box provides formatting features for hardcopy printouts to customize the contents and the appearance of the printout.

The settings for the reports are grouped in four tabs, which represent certain formatting areas:

- 1. Data Selection tab
- 2. Page Setup tab
- 3. Header tab
- 4. Footer tab

Please refer to Instructions for Use for **magellan** for further descriptions of the single **Tabs**.



4.3.16 Data Handling: Automated Data Handling

After a measurement some actions can be started automatically.

Select these actions and they are executed chronologically in the following order:

- If the **load sample ID list** check box is selected, a sample ID list is automatically loaded.
- If the **save workspace** check box is selected (always selected in **magellan** Tracker), the created workspace is automatically saved.
- If the **export to ASCII file** check box is selected, the data selected for export are automatically exported to an ASCII file.
- If the export to ASTM file check box is selected, after running the method, the data selected for export is automatically exported in ASTM format and can be further used in compatible Laboratory Information Systems (LIS).
- If the export to Sample Tracking check box is selected, after running the method, the data selected for export is automatically exported to the Sample Tracking system. For more information please refer to the corresponding manual for Sample Tracking.
- If the **export to Excel** check box is selected, the data selected for export are automatically exported to Excel.
- If the **print** check box is selected, the data selected for the printed report are automatically printed on the default printer.
- If the view results after measurement check box is selected, the measurement data and the calculated data are displayed for reviewing.

More - Load Sample ID List

The More (Load Sample ID List) dialog box contains the following elements:

| Filename group box | Select the filename of the sample ID list to be loaded: Same filename as workspace option button Filename option button: Enter a filename in the text field. |
|--------------------|--|
| Path group box | Select the path where the sample ID list is stored: Sample ID list default path option button Use path option button: Select any path. |
| Format group box | Select the format of the sample ID list to be loaded (see chapter 5.2.3 Import a Sample ID List for details): Autodetect from the list of supported formats option button Custom file format option button: Click the File format button to open the Custom Format dialog box. |



Note

If an only partly filled sample ID list is loaded automatically, all unused samples are automatically deleted from the layout.

If a final control (e.g. in well H12) has been defined within the layout, this control is automatically moved to the well after the last used sample well.



Note

Automatically loaded sample ID lists should contain only IDs for samples and must not contain IDs for non-samples (controls, standards etc.).



More - Workspace Name

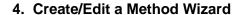
Selecting **Save workspace – More** the **Workspace Name** dialog box with the following elements appears:

| Format group box | One of the offered option buttons has to be selected for defining the default workspace name. The name can consist of the date, counter or a certain set of letters. Another possibility is to combine the date with a choice of letters. Counters used together with the date are reset daily otherwise the counter is incremented with each measurement: Date (DDMMYYYY) + Counter option button Date (YYYYMMDD) + Counter option button Total Counter option button Use available barcode option button |
|------------------------|--|
| Prefix text field | The entered text is added at the beginning of the workspace name as defined above. |
| Example text field | The Example text field shows an example of the current selection. |
| Set as default button | The settings can be logged as a default for future use. |
| Restore default button | The settings can be reset to the previously defined default. |

More - Export to LIS

The More (Export to LIS) dialog box contains the following elements:

| , , , , , , , , , , , , , , , , , , , | , |
|---------------------------------------|---|
| ASTM delimiter definition group box | Define the ASTM delimiters : |
| | • Field delimiter: Enter a sign for separating fields (by default) |
| | • Repeat delimiter: Enter a sign for repeat (\ by default) |
| | Component delimiter: Enter a sign for separating components (^ by default). |
| | • Escape character: Enter a sign for escape (& by default). |
| Sender ID group box | Define the Sender ID settings that are to be displayed in the header of an ASTM file: |
| | • Sender ID text field: Empty by default. If defined, e.g. Infinite 200, the name is displayed in the header of the ASTM file (e.g. H \^& Infinite 200^Magellan V6.55^Standard). |
| | • Append app. name: If selected, application name, i.e. magellan, is exported in the header of the ASTM file (e.g. Magellan V6.55). |
| | Append app. version: If selected, the magellan version number is exported in the header of the ASTM file (e.g. Standard or Tracker). |





| LIS assay name group box | Select the LIS assay name to be displayed in the test order record and result record of the ASTM file: • Use method name: name of the method used for the measurement. • Use name text field: define a new name to be displayed. Example: ELISA Test order record: O 1 Sample ID ^^ELISA Date and |
|-----------------------------|--|
| | time of measurement Result record: R 1 ^^^ ELISA^results |
| Encoding group box | Select the export code: • ANSI: For ANSI compatible characters. • Unicode: For characters that cannot be exported with ANSI code (e.g. Chinese, Cyrillic). |
| Path group box | Define the path for the ASTM export: Export default path: the export is performed to the folder defined in Miscellaneous. Use path text field: define a new export path. |
| Set as default button | Using this option, the settings can be logged as a default for future use. |
| Restore default button | Using this option, the settings can be reset to the previously defined default. |

For an ASTM Export - Example File please refer to the Instructions for Use for **magellan**.

More - View Results

The More (View Results) dialog box contains the following elements:

| Plate view group box | Select the data to be displayed in the plate view: 1st line in well (fixed) drop down list: Select a name from the available data names. 2nd line in well (fixed) drop down list: Select a name from the available data names. 3rd line in well (first selection) drop down list: Select a name from the available data names. In contrast to the first two lines this selection is only applied for the first time. Whenever another data to be viewed in the plate view is selected in the control bar, this data is displayed in the 3rd line. The first two lines remain unchanged. The 1st and 2nd line can be omitted by selecting not used, which makes the plate view more easily readable. |
|-------------------------|--|
| Text box group box | Select a name from the available data names. This selection is only applied for the first time. Whenever another data to be viewed in the textbox is selected in the control bar, this data is displayed in the text box. |

For detailed information on *User Prompts*, *Number Format* and *Method Notes* please refer to the Instructions for Use for **magellan**.



Saving the Method

Click Finish save the method via the Save as window, which contains the following elements:

| Filename field | Enter or modify the method's file name. |
|-------------------------------|---|
| File remarks field | Add some comments to the file name, which will be displayed for example in the Open file dialog boxes. |
| Audit trail comment field | Add some comment, which will be stored in the audit trail (only available for magellan Tracker). |
| Organize favorites button | Click this button to open the Organize favorites dialog box. See 6.5 Start Favorite for further information. |
| Run this method now check box | Select this check box to start the method immediately after finishing this wizard. |

The modified document can be saved under its current file name or under a different name.

Click Save&Finish to save the method and close the Create/Edit a Method wizard.

Additional buttons in magellan Tracker:

Audit trail... button Click this button to open the **Audit trail** dialog box where the user, the date, the executed action and a comment are displayed. A print preview of the workspace, the method and the sample ID list of the current and all previous versions can be displayed clicking the appropriate buttons. Additionally it is possible to save a previous version of the method under another name. Audit Trail Action | 1 Administrator (Admin) | 18.10.2005 15:57:39 | Created (.wsp Modified) | Administrator (Admin) | 18.10.2005 16:29:24 | Modified (.wsp Modified) | Modifie Workspace... Method..

Signature... button

Click this button to open the **Signature** dialog box, where user, date, action and comment are displayed.

This button is only available when the file has been signed using the Attach Signature wizard. See chapter 8 Attach Signature Wizard for further details.

Method password

field

When entering a password for a method, this method will be password protected and cannot be modified until the correct password is entered. See detailed description below.



4.4.1 Password Protection of Methods

Protect Method with a Password

Users who have the right to create and to edit methods can protect methods by assigning them a password.

Per default, **Administrators** and **Application Specialists** possess the required rights.

When a new method is created, the password protection can be set in the **Save** as tab of the **Create/edit a method wizard**. Enter the name of the method, type the password in the **Method password edit field** (right bottom corner of the dialog) and click **Finish**.

Confirm the password in the displayed **Method password dialog box** and click **OK**. The method is saved with the password protection.

Already saved, but not password protected methods can be protected by opening the method and setting the password in the **Save as tab** as described above.

Edit Password Protected Methods

For opening a password protected method enter the correct method password. The method is opened in **Edit mode**. It is possible to edit and save the method.

If **Read only** is selected, the method is opened in read only mode. It is still possible to edit the method, but it is not possible to save the changes.

Change the Password of a Password Protected Method

In order to change the password of a password protected method, open the method in **Edit mode** (password entry required) and enter a new password in the **Method password edit field** of the **Save as tab**. Click **Finish**.

Confirm the password in the successive **Method password dialog box** and click **OK**.

4.5 Multiplate Methods

When connected to a Tecan instrument from the Infinite series or to a Safire² instrument, **multiplate methods** can be defined using **magellan**, version 6.0 or higher.

When connected to an instrument from the Infinite series, the number of plates to be measured can be set in the measurement parameters editor, during method definition (see the Instructions for Use for i-control). When connected to a Safire² instrument, the option can be selected from the Create/ Edit a Method wizard page.

Refer to Instructions for Use for **magellan** for further details on **Multiplate Methods**.



5. Create/Edit a Sample ID List Wizard

5.1 Introduction

The **Create/edit a sample ID list** wizard is used to create new sample lists or to edit existing sample lists.

Workflow Summary

Start the **Create/edit a sample ID list** wizard. After a welcome page, the **File selection** page appears. Select one of the options: **Create new** sample ID list or **Edit** an existing sample ID list and save the ID list using the **Save as** page.

5.2 Create/Edit a Sample ID List

The File Selection window contains the following elements:

| a) Create new option button | A new sample ID list can be created. |
|-----------------------------|---|
| b) Edit option button | An existing sample ID list can be modified. |
| Show combo box | The files are displayed according to the chosen selection: All files My files: This option is available if the user administration is enabled (always enabled in magellan Tracker) |
| Filename list | The sample ID list to be edited has to be selected. A Remarks field next to every file name contains - if entered - a short description of the sample ID list. All sample ID lists available in the standard sample ID list directory, which fulfill the filter criteria selected in the show combo box, will be displayed. |
| Print Preview button | A preview of the selected sample ID list is displayed and a printout can be started. |



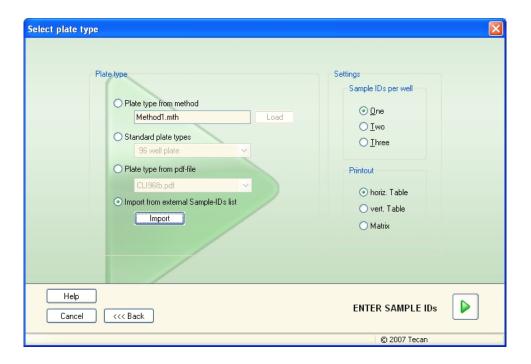
5.2.1 Create New Sample ID List

In the **Select Plate Type** window the number of sample IDs per well and the used plate type can be selected. The **Import from external sample ID list** option allows to browse for different types of sample ID files and to import them into **magellan**.



Note

Some sample ID lists may contain additional information such as concentrations and dilutions which may affect evaluation of the measurement data.



The **Select plate type** dialog box contains the following elements:

| Settings | |
|------------------------------------|---|
| Sample IDs per well option buttons | Enter the number of sample IDs required per well (a maximum of three can be entered). |
| Printout option buttons | Define the layout for printing the sample ID list. |



Plate type option buttons

Four option buttons define the plate type to be selected:

· Plate type from method

Select a method to load the plate layout. Click **Load** to browse for existing method files. The WindowsTM **Open** dialog box appears. Select the desired file and click **Open**.

Standard plate type

Standard geometry plate types can be selected to define the plate format.

When activated, a standard geometry plate type can be chosen from an associated drop down list.

· Plate type from pdf-file

A predefined .pdf file (or .pdfx file for infinite series instruments) can be used to define the plate format. Plates that are not listed can be created using the **Plate geometry editor** option, which is a software application accessible via **magellan**. For more information refer to chapter 3.2.5 Plate Geometry Editor....

When activated, a predefined *.pdf* file can be chosen from an associated drop down list.

Import from external Sample ID list An external file type can be selected for import as sample ID list. See chapter 5.2.3 Import a Sample ID List

The **Enter sample IDs** button is only enabled if the required settings have been defined (method has been loaded, standard plate type or pdf-file has been selected).

5.2.2 Import/Edit a Sample ID List

After the selection of the plate type, the **Import/edit a sample ID list** plate window is displayed:

- Toolbar with Settings, Edit, Autofill, Delete, Undo/Redo, Print format, Print preview and Zooming buttons
- Plate view with a schematically layout of a microplate.
- Sample ID list (when **Plate type from method** has been selected)
- Dialog to insert sample IDs (when **Standard plate type** has been selected)

If a new sample ID list is to be created no sample IDs are assigned to the wells. A well can be selected by clicking in the well.

All required sample IDs have to be entered either manually or using the buttons in the tool bar or can be read by the handheld barcode scanner for sample IDs. The sample IDs can be defined and edited in the defined microplate type. Up to three sample IDs can be entered in each well. Sample IDs can be moved or copied.

When a method has been selected, on the left side a *List of all Samples from the plate layout* is displayed. Only samples without replicates are shown in the list. The sample IDs can be entered either in the list or on the plate. All changes are shown immediately.

Toolbar Buttons

Refer to the Instructions for Use for **magellan**.



Context-Sensitive Menu of the Plate Layout

By right-clicking on a well on the plate layout, a context-sensitive menu for the marked wells is displayed. Refer to the Instructions for Use for **magellan** for further details on the **Context-Sensitive Menu of the Plate Layout.**

Edit well...

The **Edit Well** dialog box can be accessed via the context-sensitive menu or the tool bar button.

Sample IDs for all wells on a microplate can be defined. Refer to the Instructions for Use for magellan for further details of **Edit well...**.

Autofill Selection

The **Autofill Selection** dialog box can be accessed via the context-sensitive menu or the tool bar button.

This dialog box allows the user to fill the selected wells with sample IDs automatically.

Select the whole plate or parts of the plate and enter the desired sample IDs and increment settings for the marked wells in the **Autofill Selection** dialog box. Click **OK** to close the dialog box and to fill the selected wells with the defined sample IDs. In each well up to 3 sample IDs can be entered. Therefore, the list contains three **Sample ID** text fields and an **Autoincrement** check box, a **Start index** text field and a **Vertical** check box associated to each of them.

The **Autofill Selection** dialog box contains the following elements:

| Use ID check box | The Use ID check box can only be accessed, if the identical number of sample ID were selected. The checkmark determines if the autoincrement function is applied to the selected sample ID. |
|----------------------------|---|
| Sample ID text fields | Sample IDs for the marked well can be entered in the Sample ID text fields. The sample IDs can contain letters, numbers or a combination of letters and numbers. |
| Autoincrement check box | The Autoincrement check box must be selected, if the sample IDs for the wells are to be numbered automatically (incremented by 1). |
| Start index text field | The Start index text field is only editable, if the Autoincrement check box is selected. The starter value for the automated incrementing of the sample ID has to be entered. |
| Vertical check box | The Vertical check box can only be accessed, if the Autoincrement check box is selected. If this check box is selected, the sample IDs will be entered and numbered in vertical direction. If it is cleared, the sample IDs will be entered and numbered in horizontal direction. |



Well Summary

The Well Summary dialog box can be accessed via the context-sensitive menu.

This dialog box delivers an overview of all defined Sample IDs and the Sample ID list related settings of a selected well. Refer to the Instructions for Use for **magellan** for further details of **Well Summary**.

Paste in ASCII-Format

The **Paste in ASCII-Format** function can be accessed via the context-sensitive menu.

This function pastes the contents of selected data in ASCII format from the clipboard into **magellan**. Refer to the Instructions for Use for **magellan** for further details of **Paste in ASCII-Format**.

5.2.3 Import a Sample ID List

Sample ID lists that have been created using other programs, or sample ID lists that have been defined using other forms of analytical equipment have to be imported into **magellan** before being used.



Important

Some sample ID lists may contain additional information such as concentrations and dilutions which may affect evaluation of the measurement data.

Click **Import** button in the **Sample ID list settings** dialog box to browse for existing external sample ID files. The Windows TM **Open** dialog box appears.

The window offers a list of **File names** that match the selected **File type**. The **File type** can be chosen from an associated drop down list.

The following external file types are supported:

- Easy-Files .esy
- Tecan-files .tpl
- DD1-Files .dd1
- Hamilton-Files .pro
- APL-Files .apl
- Gemini-Files .csv
- Custom Format Files .txt

Select the requested file to be imported and click the **Open** button. The WindowsTM **Open** dialog box is closed and the file is loaded.

Confirming the **Sample ID List Setting** dialog box with **Next** will open the **Import/Edit a Sample ID List** plate window with the sample IDs displayed.

The **Import** button can also be accessed via the **Insert Sample ID List** dialog box, which is available in the **Start Measurement** window (**Insert** button) and **Evaluate Results** plate view (**Edit** toolbar menu).

Please refer to Instructions for Use for **magellan** for further information on **Sample ID File Types**.







Caution

Make sure that the correct ID list has been selected, otherwise the results will be assigned to another list.



Note

When importing .tpl, .dd1, or custom format sample ID lists, additional information that modifies the evaluation definitions can be included.



Note

When importing sample ID lists with dilutions, the dilution must not be more than 1:1e+12 (magellan Standard and magellan Tracker).

Saving the Sample ID List 5.2.4

Click Next in the Import/Edit a Sample ID List window and the Save as window appears, in which the created or modified sample ID list can be saved:

| Filename field | This field is intended for entering or modifying the file name of the sample ID list (.smp). |
|---------------------------------|--|
| File remarks field | The File remarks field allows adding some comments to the file, which will be displayed for example in the Open File dialog boxes. |
| Audit trail comment field | The Audit trail comment field allows adding some comments, which will be stored in the audit trail (only available for magellan Tracker). |
| Audit trail button | Displays the audit trail of the sample ID list (only available in magellan Tracker). See 4.4 Saving the Method - Audit trail for further information. |

The Save&Finish button is only enabled when a document has been modified. The modified document can be saved under its current file name or under a different name.

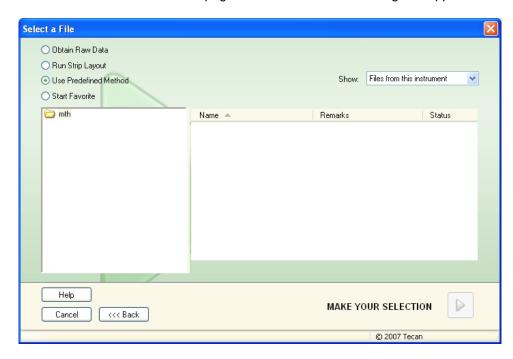
Click Save&Finish to save the sample ID list and close the Create/Edit a Sample ID List wizard.



6. Start Measurement Wizard

6.1 Introduction

In the **Wizard List** window, click **Start Measurement** to open the wizard. Click **Continue** on the welcome page and the **Select a file** dialog box appears:



| Obtain Raw Data | Is used to generate raw data quickly by setting the required measurement parameters. |
|--------------------------|---|
| Run Strip Layout | Enables the user to create one strip method from different methods and to run this combined method. |
| Use Predefined Method | Is used to perform measurements based on already defined methods. |
| Start Favorite | Is used to select one of the most frequently used methods from the list of numbered icons. |



6.2 Obtain Raw Data

Select **Obtain Raw Data** and click **Next** to open the **Measurement Parameter** dialog box.

In the **Measurement Parameter** dialog box, the following options are available:

| Endpoint measurement | Use this button to perform a single measurement. |
|------------------------|--|
| Kinetic measurement | For multiple measurements within a specified time interval this type of measurement is used. |
| Measurement parameters | Click this button to define the parameters in the Measurement Parameters dialog box. |

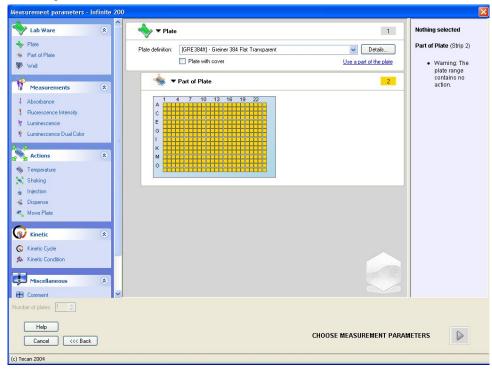


WARNING

IT IS STRONGLY RECOMMENDED TO CHECK ALL OF THE MEASUREMENT PARAMETERS (EVEN PARAMETERS NOT USED IN THE CURRENT MEASUREMENT), BECAUSE PARAMETERS FROM THE PREVIOUS MEASUREMENT METHOD WILL STILL BE SET.

6.2.1 Obtain Raw Data with the Infinite Instrument

When an Infinite instrument is connected the following window appears after selecting **Obtain Raw Data**:



Define the measurement parameters following the list on the left side.

Click **Choose Measurement Parameters** to finish the definition. Refer to the **i-control** instructions for use for further information.

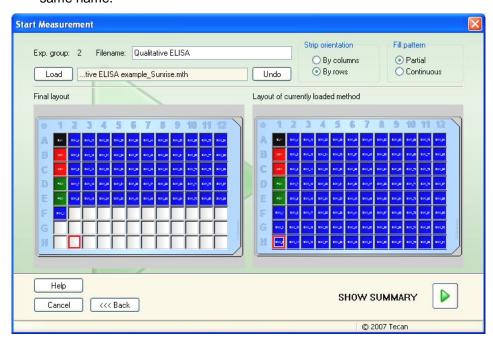


6.3 Run Strip Layout

The **Strip Method...** option allows the user to create one method composed of strips from different methods containing different parameters and to run this combined method.

The methods involved must be defined with:

- exactly the same measurement parameters
- transformations, concentration and kinetic transformations must have the same name.



The **Strip Method Definition** dialog box contains the following elements:

| Exp. group field | This field displays the experimental group number that is assigned to the next inserted strip method. |
|-----------------------------------|--|
| Load button | Click the Load button to open a file selection dialog box where all available method files are displayed. Select the required single strip method from the file list and click Open . |
| File name text field | This field displays the name of the currently selected method file. |
| Text field | In this field the complete path of the method file name is displayed. |
| Undo button | This option cancels the last strip method insertion. |
| Strip orientation option buttons | Determine how the strips are to be allocated to the plate. |
| Fill pattern option buttons | This option allows the user to decide between allocating every new strip to a new row or column (Partial) or allocating it to the next available well in the plate (Continuous). |
| Final layout graphical display | The graphical display shows the layout of the composition of strip methods. The way, in which wells are transferred from the Layout of currently loaded method area to the Final layout area, depends on the settings of the option buttons Strip orientation and Fill pattern . |



Layout of currently loaded method graphical display

The graphical display shows the layout of the currently loaded method. Double-clicking on the last available well will add the strip method at this position to the plate. This will be displayed in the **Final layout** area on the left side. Replicates, which are not selected, are automatically added.

This step can be repeated by loading another strip method.

6.4 Use Predefined Method

Click Use Predefined Method and select a method from the Filename list.

The available methods are displayed according to the selection of the **Show** drop down list, i.e. **All files, Files from this instrument, My files, Signed files** or **Last selected methods**.

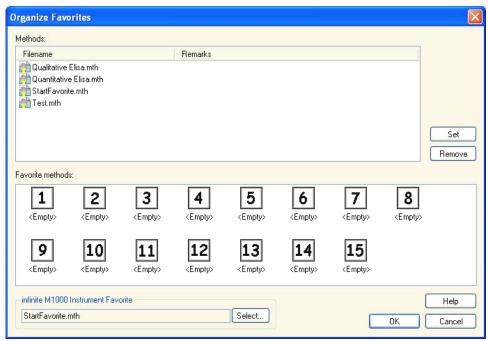
6.5 Start Favorite

Click **Start Favorites** to select a method, previously defined as so called favorite, frequently used method, from the list of numbered icons.

Click Organize favorites to add to or remove methods from the favorites list.

Organize Favorites

Method files can be dragged from the **Method** list onto one of the 15 icons in the **Favorite** list to save it as a favorite.



The Organize Favorites dialog box contains the following elements:

| Methods list | Lists all available methods. The filename and corresponding remarks - if entered - are displayed. |
|-------------------|---|
| Set button | After selecting a method from the Methods Filename list and selecting a method icon, click Set to add the selected method to the Favorites . |
| Remove button | Select a method icon and click Remove to delete a method from the Favorites . |



| Infinite |
|-----------|
| M1000/ |
| M1000 Pro |
| Instrumen |
| Favorite |
| group box |

With the Infinite M1000/M1000 Pro instrument, it is possible to start a measurement run with a favorite method directly via the instrument's **Start** button.

To define a favorite method click the **Select...** button and select a method. This method will remain the favorite one as long as another method is selected.

6.6 Start Measurement with a Predefined or Favorite Method

Click **Make your selection** respectively **Show Summary** in the **Select a file** dialog box to open the **Start Measurement** dialog box. Before the instrument starts to measure, the user has to (if defined) answer the report prompts and/or to confirm or change the constants.

Edit Prompts Dialog

If user prompts were specified in the method, the **Edit user prompts** dialog box is displayed:

| Prompt Answer list | At each text field of this list any text prompt can be entered. |
|--------------------|---|
| Req. check box | A Required check box next to every Prompt Answer text field determines that the measurement can only be started when a text has been entered. |

Click **Continue** to close the user prompts dialog; the **Start Measurement** window appears. If set in the method, the **Edit Constants** dialog appears.

Edit Constants Dialog

The **Edit Constants** dialog box appears only, if the required flag is set for at least one constant in the selected method.

| Constants list | At each text field of this list the value of the constant or the comment can be modified. |
|----------------|---|
| Req. check box | A Required check box next to every Constant value text field determines that this constant value needs to be confirmed. Do this by continuing to the next page. |

If the method constants have been modified, the new values can be automatically transferred and saved into the corresponding method. Click **Modify constants in Method** to modify the current method with the new defined constants. Please note that this dialog is available only for **Magellan** users with the user right **Edit methods**.

Click **Continue** to close the constants dialog; the **Start Measurement** window appears.





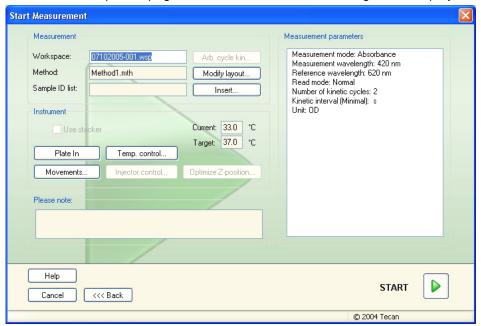
Note

Using magellan Tracker or magellan Standard with User administration, a default magellan Operator (refer to the chapters 11.6 User Rights and 11.5.3 Change User) can edit only the required constants. The constants without required flag set are displayed gray and cannot be edited.

A default magellan Administrator can edit also constants without required flag set.

For a default magellan Application Specialist it depends on the method he runs. Using an unsigned method he is allowed to edit constant with and without required flag. Using a signed method he can edit only the required constants

After these two optional pages the **Start Measurement** dialog box is displayed:



Measurement group box

Workspace text field: The default workspace filename as defined in **Automated Data Handling** is displayed. The filename of this workspace can be renamed.

Arb. cycle kin. ... button: This button is available if a kinetic measurement is performed. Click this button to display the **Arbitrary Cycle Kinetic** dialog box. In this dialog box the measurement can be split up into several submeasurements with a different number of measurement cycles and interval times. Each of these sub-measurements can be started at any time, for example: the workspace can be saved and the measurement can be continued on another day.



Note

This option is not available for Infinite Series instruments.



| | Method text field: The filename of the previously selected method is displayed. |
|-------------------------|--|
| | Modify layout button: Depending on the user rights, the plate layout can be modified. Click the Modify layoutbutton to open the Modify Layout dialog box. The user can move controls and remove samples, change the concentration or change the measurement parameters. The changes are stored only in the workspace and not in the previously selected method. This button is not available when Obtain Raw Data has been selected and after inserting a sample ID list. |
| | Sample ID List text field: The filename of the currently loaded sample ID list is displayed |
| | Insert button: see also below. Click this button to open the Insert Sample ID List dialog box. After selection of a sample ID list file the Sample ID List with Plate Layout Preview dialog appears in which the user has to confirm the selection. |
| Instrument group box | Use stacker: This option is available whenever the Connect stacker is used together with the instrument. Refer to the Connect Instructions for Use for further information. The workspaces will be stored with default workspace names. After all plates have been measured only the first workspace is open. Use File Open or the Evaluate Results wizard to open the other workspaces. It is not possible to use the stacker when performing kinetic measurements. |
| | Plate In/Out button: Click to move the plate carrier. This button changes its text depending on the position of the plate carrier. |



Note

When Use stacker is selected while using magellan, make sure that the overall runtime does not exceed the time set in the Auto Lock option (see chapter 11.4.4 User Administration Options/ Login Options).

When magellan is locked, the stacker run will stop even if the measurements are not finished.

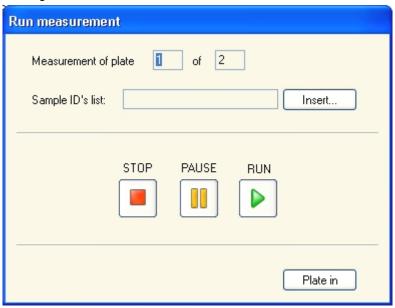
| Movements button: Further movements of the instrument can be invoked (filter slide, mirror carriage and so on.) |
|---|
| Optimize Z-Position button: The user can optimize the z-position of the reader. |
| Injector control : Refer to the respective instrument's instructions for use. |
| Current Temperature text field: The current temperature of the instrument is displayed. |
| Target Temperature text field: The target temperature, set in the Temperature Control dialog box, is displayed. |
| Temperature Control button: Click this button to open the Temperature Control dialog box. See chapter 3.1.2 Temperature Control |



| Measurement parameters group box | In a text field all configured measurement parameters are listed and can be double-checked. |
|----------------------------------|--|
| Please note group box | Important information is displayed. Read this information and start appropriate actions before running the method. |

A warning is displayed if the layout is defined for wells that will not be measured. Click **Start** to start the measurement.

If you run a multiplate method, the **Run Measurement** dialog box appears after clicking **Start**.



It contains the following elements:

| Measurement of plate | Displays the number of the currently processed plate. |
|----------------------|---|
| Sample ID List | Insert the appropriate sample ID list for the selected plate. Sample ID lists have to be inserted plate by plate. |



Note

Only sample ID lists created in magellan can be inserted. Import of other formats is not supported.

| RUN | Click this button to start the measurement. |
|-------|---|
| PAUSE | The Evaluate Results wizard is reached when clicking Pause ; further plates can be appended later. |
| STOP | The Evaluate Results wizard is reached when clicking Stop ; no further plates can be added. |

After the measurement is completed, the **Results** dialog box appears, in which all results and calculations can be viewed. See chapter 7 Evaluate Results Wizard for more information.



Insert Sample ID List

The **Insert Sample ID List** option is used to load a previously defined sample ID list file into a workspace:

| Filename field | The list displays all available sample ID list files (.smp). Select a sample ID list by clicking a filename. | |
|----------------|--|--|
| Remarks field | Available comments and remarks will be displayed. | |
| Import button | Click to open a standard Windows Open dialog box. External files can be imported. Refer to chapter 5.2.3 Import a Sample ID List for further information. | |

Select the desired sample ID list from the **Filename** field and click **OK** to view the sample ID list in the **Sample ID List with Plate Layout Preview** window. This dialog box displays the sample ID list together with the defined plate layout. If the method and the sample ID list have different plate formats, then an error message is displayed.

Refer to Instructions for Use for magellan for further information.

6.7 Measurement Status

The **Measurement Status** dialog box is shown during the measurement performance of the instrument and contains the following elements:

| Status text field | The text field is updated during the measurement and contains a measurement status information. | |
|-------------------------------|---|--|
| Display in wells group box | Select the mode of representation of data in the wells: Values: The measured value is displayed in the well. If more than one value is measured (for example: polarization measurement) all values are displayed in one well. | |
| | Graph : The option is enabled if a kinetic graph can be displayed. The graph is shown as soon as more than one value is available. | |
| Pause button | To pause a kinetic measurement run at the next possible moment, click the Pause button. In the Pausing Kinetic dialog click the Plate out / Plate in button to move the plate transport out of or into the instrument. Click the Continue button to go on with the kinetic run. | |
| | Pausing Kinetic Kinetic run is pausing Press button 'Continue' to continue kinetic run. Plate out CONTINUE | |
| Break button | Click this button to break the measurement at the next possible time point. | |





| Plate View display | The Plate View display shows a schematic display of the microplate. According to the Display in wells option the contents of the wells are customized. The wells are updated as fast as the instrument delivers data. When injection or dispensing is performed, the currently used well is automatically highlighted in a different color. |
|-----------------------------|--|
| Cycle text field | If a kinetic measurement is performed, the Cycle text field displays the current cycle number and the maximum number of kinetic cycles. |
| Graph display | If a kinetic or multilabel measurement is performed, the kinetic or multilabel graph of the currently selected well is displayed in a larger size at the right side of the Measurement Status dialog box. |
| Previous cycle group box | As long as the transmission of the data of the current cycle was not started the Raw data and the Temperature text fields contain the value and the temperature of the previous measured cycle of the currently selected well, respectively. |
| Time group box | The Elapsed time text field displays the time span since the start of the measurement. |
| | The Exp. run time text field displays the time span expected for the whole measurement. |

Scaling of the y-axis in the graph is possible by selecting either **Auto select** range or **Select range** (MIN/MAX).



Note

It is possible to select multiple wells on the plate to view the selected kinetic curves in a graph. When performing kinetic measurements, the retrieved data is saved automatically every 30 min in the magellan log file directory (refer to chapter 3.3 Log Files).



7. Evaluate Results Wizard

7.1 Introduction

The **Evaluate Results wizard** is designed to help the user analyze measurement results. Raw data, evaluation data and evaluation parameters can be viewed and data can be re-evaluated.

Workflow Summary

Start the **Evaluate Results wizard** and select an existing workspace for evaluation (**Select a File** dialog box)

Click **Make your selection** to open the **Results** dialog box, in which the results can be viewed or printed (**Evaluate Results** tab) and if necessary, the used method modified (**Edit Method** tab).

Click **Finish** and use the **Save** dialog box to save a workspace file which contains method definitions, instrument data and sample ID list if configured.

Evaluated data are not stored in the workspace but recalculated every time the workspace is opened.

7.2 Select a File

The **Select a File** dialog box contains the following elements:

| Filename list | The Filename list contains the list of all files (and their remarks) within the standard workspace directory. |
|----------------|--|
| Show combo box | In the Show combo box, the displayed list of files can be modified according to the selection: |
| | All files |
| | Files from this instrument |
| | My files: This option is available if the user administration is enabled (always enabled in magellan Tracker). |
| | Signed files: only available for magellan Tracker. |
| | Custom definitions are possible by clicking the button; see File Selection Criteria below. |
| | Example files: only available if they have been installed. |



7.2.1 File Selection Criteria



Click the button to open the File Selection Criteria dialog box.

Select one of the options under **Workspace Criteria** or enter characters in the **Containing** text field which must appear in the **Filename**. A time filter can be applied by selecting one of the options under **Workspace file created/modified** or enter a number in the **Last ... days** field. Click **OK** to save the settings.

Select the workspace file to be evaluated from the **Filename** list and click **Make** your selection.

Note

If the proper instrument for the selected file is not connected, the Instrument Mismatch dialog box appears.

The dialog offers two options:

- Connect to the proper instrument
- Convert the measurement parameters to the connected instrument.

This option is not available if the measurement mode is not supported by the connected instrument, for example: a Sunrise does not support fluorescence measurements.

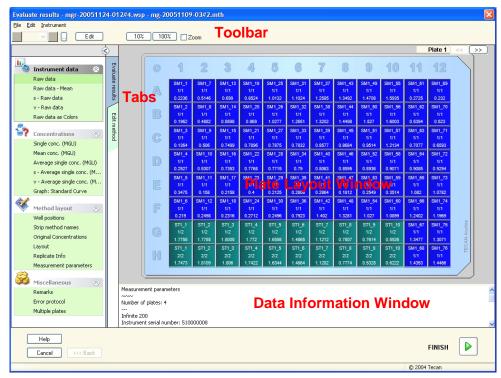




7.3 The Workspace Overview Window

The **Workspace Overview** window displays all available data of the currently selected workspace.

If the currently working user has the appropriate **magellan** rights, it is also possible to make some changes in the method by clicking on the **Edit Method** tab and perform a recalculation of the measured data.



Control Bar

The Workspace Overview is composed of the following elements:

- Plate Layout window: selected data for each well is displayed in the plate layout. If a multiplate workspace is opened, a "counter" for switching between the different plates is displayed in the right upper corner.
- **Toolbar**: for editing, zooming, switching between kinetic cycles and viewing the summary of one selected well.
- Data Information window: data which cannot be assigned to a single well is displayed in the text box window (for example: measurement parameters, cutoff definition, result statistic, etc.).
- **Control Bar** of **Evaluate Results** *tab:* all available data set names are displayed. Selecting a data set will either display the data in the plate layout or display the data in the *Data Information* window.
- **Control Bar** of **Edit Method** *tab*: the settings and parameters of the loaded method are displayed.

The size of the latter three windows can be changed by using the splitter bars that separate the windows.

Please refer to Instructions for Use for **magellan** for the further description of the **Workspace Overview Window**.



7.4 Evaluate Results Tab

All available data set names are displayed in the *Available Data* control bar. There are several different viewing options:

- Selected data that presents a value for each well is displayed in the plate layout window. It can be viewed as values or in pseudo-colors together with a colors scale.
- Kinetic data can be viewed as a small graph in each well.
- Selected data that presents a data collection which cannot be assigned to a single well is displayed in the data information window (f.e. QC-Validation criteria).
- If a graph (standard curve, kinetics, enzyme kinetics, dilution series, multilabel, spectra) is selected, the **Graph** dialog box appears.

If a measurement sequence consisting of individual independent measurements has been executed, the results of each measurement are displayed upon selection of the relevant measurement number from a drop down list in the toolbar (f.e. kinetic cycles in a kinetic run).

If necessary, the measurement results can be modified by clicking the **Edit** button. Manipulated data is marked with a ~ sign.



WARNING

THIS FUNCTION IS FOR RESEARCH USE ONLY AND MUST NEVER BE USED FOR DIAGNOSTIC TESTS.

In each well of the plate layout, three lines of data can be displayed. Depending on which criteria selected in the control panel in the left window, different values are displayed.

7.4.1 Menus

| File | ASCII File Export |
|------------|---------------------------------|
| | ASTM File Export (LIS) |
| | Sample Tracking Export |
| | Excel Export |
| | Method Export |
| | Print |
| | Print Preview |
| | Printer Setup |
| | Printout Font |
| | Plate to Plate QC |
| Edit | Copy to Excel |
| | Copy to ASCII Format |
| | Paste from ASCII Format |
| | Insert Sample ID List |
| | Recalculate with another Method |
| Instrument | Movements |
| | Temperature Control |
| | Optimize Z-Position |
| | Injector Control |
| | Start Measurement |
| | |



7.4.2 Toolbar Menu: File

ASCII File Export

Click ASCII File Export to export data as ASCII (.asc) files.

Before export procedure, the data must be selected in the **Data Export** dialog box via **Edit method tab** \rightarrow **Data handling** \rightarrow **Data export**.

Select the folder, where the exported data shall be stored. Enter a file name (.asc).

Upon clicking **Save** in the **Save as** dialog box, the data sets specified in the **Data Export** dialog box will be saved as an ASCII file.

ASTM File Export (LIS)

In the **File** menu, click **ASTM File Export** to export data to in ASTM format to compatible Laboratory Information Systems.

Select the data to be exported from the **Data Export** dialog box via **Edit method** tab \rightarrow **Data handling** \rightarrow **Data export**.

Sample Tracking Export

In the **File** menu, click **Sample Tracking Export** to export data to the Sample Tracking system

Select the data to be exported from the **Data Export** dialog box via **Edit method** $tab \rightarrow Data \ handling \rightarrow Data \ export$.

Excel Export

Click Excel Export to export data to Excel.

Select the data to be exported from the **Data Export** dialog box via **Edit method** $tab \rightarrow Data \ handling \rightarrow Data \ export$.

Method Export

Click **Method Export** to export a method.

Select the folder to save the method and enter the desired file name. Additionally some comments can be added in the **Remarks** text field.

Print

In the **File** menu, click **Print...** or press **SHIFT-P** to print the data as defined with the **Printed Report** setup from the method. The standard Windows **Print** dialog box is opened, where the printer, page range and number of copies can be selected.

Print Preview

Click **Print Preview....**to see exactly how a print-out will appear without actually having to print the document.

Refer to Instructions for Use for **magellan** for further information on **Print Preview** elements.

Printer Setup

Click **Printer Setup...**. to change the current printer or modify the printer settings. The standard Windows **Print Setup** dialog box appears. Select printer, paper size and orientation of printout.

Printout Font

Click **Printout Font...** to select a specific font, font style, font size, font color etc. for future printouts.



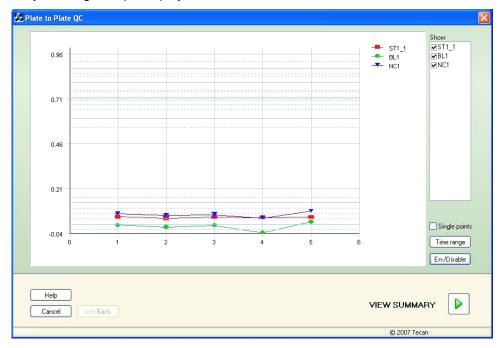
These settings will have no effect on the screen display. Large fonts should be avoided to prevent errors or misrepresentation of data.

Plate to Plate QC

When **Plate to Plate QC** is configured in the method definition, **magellan** compares the currently observed mean value of a control against the mean and standard deviation previously defined for this method. (Refer to chapter 4 Create/Edit a Method Wizard).

Levy-Jennings-Graph

Click **Plate to Plate QC** and the *Levy-Jennings-Graph* window appears. The Levy-Jennings-Graph displays the trend of the control values.



On the y-axes, the data values (raw data, concentrations, etc.) as set in the method definition are applied on the time scale of days (x- axes).

The control values are displayed together with the mean value and the distance lines of the standard deviations (1s, 2s, 3s).

When the cursor is placed on a measurement point, a tool-tip shows additional information (workspace name, etc.). Use the check boxes of the single elements of the **Show** list to select various controls to be displayed.

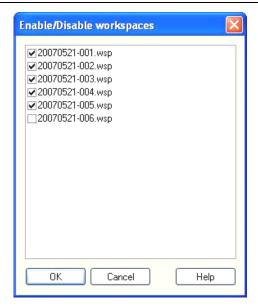
Time Range

Click **Time range** to evaluate workspaces within a defined time range.

Select Workspaces

Click **En-/Disable** to enable or disable certain workspaces for evaluation.





Data Sheet

Click View summary to open the Data sheet dialog box:

| Workspace column | A list of the evaluated workspace files. On the left hand side of the workspace name, a green checkmark indicates fulfillment, a red cross indicates failure of the Westgard [®] rule evaluation (see Instructions for Use for magellan for further information on Westgards Rules). |
|-----------------------------------|--|
| Control column | The different controls are listed. |
| Value column | The mean value of each control is displayed. |
| Westgard® rule evaluation columns | The individual Westgard [®] rules are evaluated with OK for a not violated control rule or x for a violated control rule. |
| Comments field | Comments to the evaluation can be entered. |
| Print Preview button | Print preview with the Levy-Jennings graph, Westgard rules check and comments. |

7.4.3 Toolbar Menu: Edit

The **Edit** menu contains the following selections:

Copy to Excel

The **Copy to Excel** command allows the user to export data directly into an MS Excel worksheet.

Copy in ASCII-Format

Select **Copy in ASCII format** to copy the data, which is contained in the selected wells of the plate layout, to the clipboard.

This function allows transferring the well data to other software applications.



Paste from ASCII-Format

The contents of selected data will be pasted from the clipboard using the ASCII data format. The function allows the transferring of data from other software applications (for example: Excel) into the wells.

Refer to Instructions for Use for magellan for further information on Copy to Excel, Copy in ASCII-Format and Paste from ASCII-Format.

Insert Sample ID list

For detailed information see 6.6 Start Measurement - Insert Sample ID List.

Recalculate with another Method

A recalculation based on the settings of a newly selected method will be performed.

If an error occurs during recalculation, the procedure will be stopped.

Click this option to open the **File Open** dialog box. In an additional **Remarks** field, a text description of the file - if entered - will be displayed (available only in **magellan** Tracker). The method must be selected by either double-clicking the method file or by selecting the method file and clicking the **Open** button.

After selecting the method, the **Calculating...** dialog box is displayed. This dialog box is for display only and contains no elements for editing. It closes after the calculation is finished.

7.4.4 Toolbar Menu: Instrument

For detailed information on **Movements**, **Temperature Control**, **Optimize Z-Posotion** and **Injector Control** see chapter 3.1.1 Instrument Options.

Start Measurement

Using this option the measurement run can be started again with the currently loaded method and current data will be overwritten if **YES** is selected in the **magellan** dialog box.

In case of an incomplete kinetic run, cycles can be added (not available for Infinite Series instruments).

For detailed information see 6.6 Start Measurement with a Predefined or Favorite Method.

7.4.5 Plate Layout Window

The data, which is to be displayed within a well when opening a workspace file, can be set when defining the method (Automated data handling → view results after measurement → More...).

In each single well, three lines are visible; the following data is displayed as default:

1st line: layout

2nd line: replicate info

3rd line: in the third line, according to the data selected, the conventions described in the following chapter are used (cf. 7.4.6 Special Characters).

7.4.6 Special Characters

| "None" | No data is displayed. |
|-----------|--|
| "~" tilde | A tilde is appended for the manipulated value of a well (simulated, edited); for example: 0.354~ |



| "()" parenthesis | Parenthesis are applied for the masked value of a well; for example: (0.354) |
|---|--|
| "!" exclamation mark | An exclamation mark is appended for the eliminated value of a well; for example: !0.354 |
| "#" hash | Concentration values are marked with a '#' when the calculated concentration lies outside of the range of the standard curve that means the concentration value has been extrapolated. For example: #13.75 |
| " * " asterisk | An asterisk marks values that have been measured using the "Use gain regulation" option, which corrects (=lowers) the gain. |
| Corresponding error message is displayed | The average value of a well is unusable (for example: lamp low, divide by zero, negative logarithm). |
| No color, third line is empty | No formula is applied to the well or Replicate well if "average s" or "v calculation" or No cutoff result. |
| Data of first replicate is masked or eliminated | Average value is derived without using the masked data but the average value is displayed in the well of the first replicate |
| "< MIN" | The calculated concentration lies beneath the lowest standard. |
| "MItPt" | Multiple points; a unique concentration cannot be calculated. |
| "> MAX" | The calculated concentration lies above the highest standard. |
| "NoCalc" | Input data is not found or calculation error; calculation is not possible |
| | |

Shortcuts

When viewing transformed data, press CTRL-SHIFT to display the defined formula in the second line as long as the key is pressed.

7.4.7 Control Bar: Instrument Data

The user can select raw data, spectrum data, etc. and their statistics according to the performed measurement.

7.4.8 Control Bar: Reduced Data

The user can select reduced data, e.g. difference data, polarization, etc. according to the performed measurement.

7.4.9 Control Bar: Transformed Data

The user can select the required transformation to display the calculated results including their statistics, colored display, etc.



7.4.10 Control Bar: Kinetic Parameters

The user can view the kinetic evaluation parameters such as Mean/Max slope, Time Onset, etc. according to the measurement definition.



Note

Unusable data (e.g. overflow values) are ignored for kinetic data calculation.

Define Kinetic Data Reduction Well Specifically

Please refer to Instructions for Use for magellan.

7.4.11 Control Bar: Concentrations

Select single concentration, mean or average single concentration to view the results, calculated according to the standard curve:

- Single conc. (Unit)
 Concentration of individual replicate.
- Mean conc. (Unit)
 The mean value of replicates is used for calculation of concentration. If replicates with different dilutions are defined, the mean concentration will not be available.
- Average single conc. (Unit)
 For each replicate the concentration is calculated. Then the concentrations are averaged.
- Additional concentrations (single, mean and average concentration) if available.
- Graph: Standard Curve
 Click this option to open the Graph: Standard Curve dialog box
- Intercepts
- Values for concentration transformations if defined
- IC 50, r-IC 50, Graph: dilution series

Graph: Standard Curve Dialog and Graph: Dilution Series Dialog

The **Graph: Standard Curve Dialog** has its own menu to save the standard curve, change the analysis type or compare a number of curves. The graph can also be exported as a bitmap and incorporated into documents of other software applications. For further information on **Graph: Standard Curve Dialog** and **Graph: Dilution Series Dialog** refer to the Instructions for Use for **magellan**.



7.4.12 Control Bar: Qualitative Results

The cutoff definition shows an overview of the currently used cutoff ranges and the used cutoff limits.

In the data information window on the bottom of the screen, the list of cutoff definitions is displayed (experimental groups, input data, cutoff ranges, etc.).

The user can view the cutoff results.

- Cutoff definition
 Ranges and limits of the ranges
- Cutoff results
 Cutoff result for each well
- Cutoff statistic
 Statistics of the number of hits for each range

7.4.13 Control Bar: Sample IDs

The user can view the sample ID list data.

7.4.14 Control Bar: Method Layout

The user can view the method layout, i.e. well positions, layout, replicate info, measurement parameters, etc.

7.4.15 Control Bar: QC Validation

The list of validations contains the experimental groups, the input data for each validation group, the validation formulas and their results (TRUE or FALSE).

If the result is TRUE, it indicates that the validation criteria were met for this specific plate, whereas FALSE represents an invalid result for the whole plate.

7.4.16 Control Bar: Miscellaneous

The error protocol logs all errors that occur during the run of a method. Errors can occur during a measurement or during the calculation. Review the error protocol before using data and results.

7.4.17 Color Scale Box

If values contained within the analysis plate are presented in different colors, the **Color scale** dialog box is displayed. The colors allow for a fast overview of the measurement results of the individual wells. The colors, as they are used, depend on the settings defined in the color scheme.

7.4.18 Context-Sensitive Menu of a Well

By right-clicking on a well on the plate layout – when having selected the tab **Edit Method** –, a context-sensitive menu is displayed. Refer to Instructions for Use for **magellan** for further information.



7.5 Edit Method Tab

Click this tab to change to the currently used method and its settings. Every modification of the method results in a re-calculation of all data when changing back to the Evaluate Results tab. These changes can be saved in the workspace, however, will not be applied to the originally inserted method file itself. See chapter 4 Create/Edit a Method Wizard for further information

The Edit method tab is displayed only if the currently working user has the appropriate rights (chapter 11.6 User Rights).

7.6 Saving the Evaluated Results

Click **Next** on the **Results** dialog box to reach the **Save in** dialog box:

| Save in group box | Filename text field: a default name for the file will appear, but can be changed if desired. |
|-------------------------------|--|
| | File remarks text field: enter remarks if necessary. |
| Audit trail comment group box | Audit trail comment text field: enter comments to the audit trail as necessary (only available for magellan Tracker). |
| Save button: | Saves the workspace file |
| Export | Click this button to open the Export dialog |
| Audit Trail button: | Use to view the Audit Trail of the file (only available for magellan Tracker). Refer to chapter 4.4 Saving the Method – Audit trail for further information. |
| Signatures button: | Use to view the signatures attached to this file (only available for magellan Tracker). Refer to chapter 4.4 Saving the Method for further information. |
| Sign this workspace now | Select Sign this workspace now to open the Attach Signature wizard (only available for magellan Tracker). |

Click the **FINISH** button to close the **Evaluate Results** wizard. In case of unsaved changes the user is asked to perform the saving.

Click the **Save** button for saving the data without closing the wizard.



8. Attach Signature Wizard

8.1 Introduction

Several signatures can be applied to one record and are always included in the printed report. Signed records can only be modified by users with the appropriate rights. It is possible to fully control the use of methods by allowing users to run only signed methods. Only **Method** and **Workspace** files can be signed.



Note This wizard is only available with magellan Tracker.

Click Attach signature to start the Attach signature wizard.

After the welcome dialog box, the **Select a File** dialog box appears. Select a **Method** or **Workspace** file for signing.

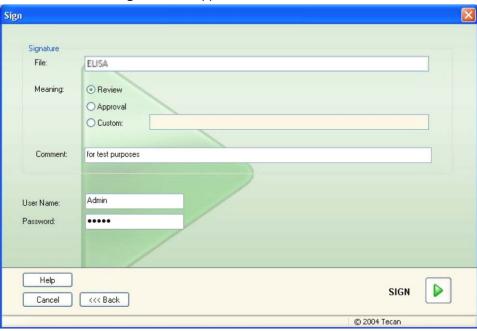
Show combo box

In the **Show** combo box the displayed list of files can be modified according to the selection. Possible selections are:

- All files
- Unsigned files
- Signed files

8.2 Sign a File

Click Next and the Sign window appears:





8. Attach Signature Wizard

| Review | Can only be signed by a user with the appropriate rights. |
|----------|---|
| Approval | Can only be applied by a user with the appropriate rights for records with an already existing review signature. Review and approval cannot be signed by the same user. No changes may be made to the file between review and approval. |
| Custom | Enter a custom signature meaning in the text field. |

The default user settings only allow administrators to attach signatures to reviews and approvals and to modify signed files.

Comments can be added in the Comment text box.

In the **User Name** text field, the user name of the currently logged in user must be entered. In the **Password** text field, the password of the currently logged in user must be entered.

Click **Finish** to confirm the entered information and sign the record.



Note

Depending on the standard operating procedures of the company using this software, this signature may be viewed as legally binding. Therefore it is very important that the users keep their passwords secret.



9. Batch Processing

magellan supports batch processing with the Tecan **Connect** stacker and supported Tecan readers.

Refer to the Instructions for Use for **magellan** for further information on **Batch Processing**.

10. Gas Control Module (GCM)

The **magellan** software supports the usage of the **Gas Control Module (GCM)** Enhanced together with Infinite200 Pro readers. Refer to the corresponding Instructions for Use.



11. Miscellaneous Icon

Click the **miscellaneous** icon in the wizard window and select between the following actions/ definitions:



11.1 Instrument Control

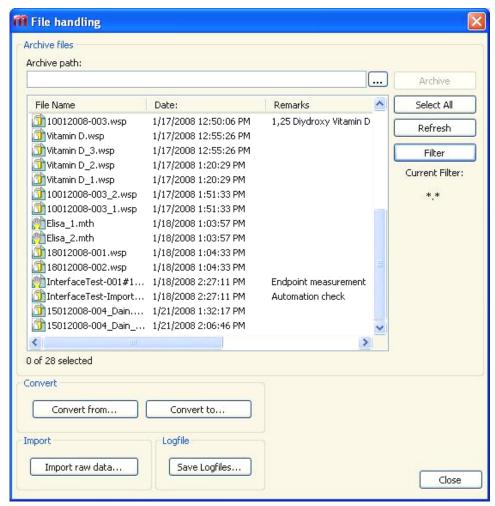
See chapter 3 Instrument Control & Settings.

11.2 File Handling

11.2.1 Archive Files

The **Archive Files** group box gives an overview and complete control of file backup. It lists all the files (workspaces, methods, sample ID lists or temporary files) saved by **magellan**.





The files for backup have to be selected from the File Name list.

Click **Archive** to move all selected files to the specified backup directory in the appropriate subfolders.

When files have the attribute **read-only**, a warning box appears before the files are deleted.

The **Archive Files** group box contains the following elements:

| Archive path | Define the archive path. Click the browse button to change the path. |
|-----------------------|--|
| File Name list | Lists all files saved by magellan filtered by the options entered via the Filter button. |
| Archive button | Click Archive to move all files selected in the File Name list to the backup directory (cut-and-paste function). |
| Select All button | Click Select All to select all files displayed in the File Name list. |
| Refresh button | Click the Refresh button to cancel the current Filter option and to refresh the file list. |
| Filter button | This button is used to display only specific files, or files with a certain string in their file names: |
| | A question mark ? can be applied as a wildcard for one single character. |
| | An asterisk * can be applied as a wildcard for no or many characters. |



11.2.2 Import Raw Data

By using the **ASCII File Import** function the user can process ASCII data files in **magellan** which already contain measurement data and additional transformations. Some data format definitions must be performed in advance to guarantee correct data retrieval. For example, the individual data must be separated from the data list by specified separators.

Further options which must be specified are: Plate format, number of measurements, measurement interval, and type of data order, orientation and physical unit of the values.

Data import fails if the ASCII file does not contain as many entries as specified by the plate format.

Once the required options have been defined, select the desired file from the *files* selection field and retrieve the file data by clicking the **Open** button.

The **Open** dialog box is a standard Windows 'open file' dialog box with file navigation elements, a text field for entering a file name and a drop down list for the selection of a file type (*.asc).

Additionally, the **Open** dialog box contains the following elements for setting ASCII-Options:

| Format option button | It defines the expected data format Table or Matrix |
|-------------------------------|--|
| Separator group box | It defines which character is used for the separation of the data fields of the list or matrix: Tabulator if Tabulator is selected. Any other character entered in the Other text-field. |
| Orientation option button | It defines the orientation of the data, i.e. either horizontal or vertical. |
| Measurement Param | eters |
| Info | The box shows the following parameters: Plate format Data unit Number of measurements Measurement interval |
| Measurement Parameters button | Select the measurement type, the plate type, kinetic cycle number and interval. |



11.2.3 Convert To

The Convert Documents – Convert to dialog box enables the user to convert magellan files from the current magellan version to files for previous magellan versions.



Note

This option is available only when the current user has local administrator rights for the Windows system.



Important

After conversion, methods must be validated, because the content of the converted files may differ slightly from the original file (e.g. contents of printed report, etc.)

The **Convert Documents** dialog box contains the following elements:

| Document type group box | Select the document type for conversion |
|------------------------------------|---|
| Select all button | Click this button to select all displayed files in the file list |
| Filename list | All files available for conversion are displayed. Click a file to select it for conversion. By holding the Shift-key, multiple file selections are possible. |
| Source path edit field | The Source path edit field contains the path where the files to be converted are stored. Click the button on the right of the text field to change the path. |
| Destination path edit field | The Destination path edit field contains the path where the converted files are stored. Click the button on the right of the text field to change the path. |
| Convert document(s) button | Click this button to start conversion. |
| Version drop down menu | Select from the drop down menu the version of magellan the files shall be converted to. |
| Progress bar | This bar shows the progress of the conversion. |



WARNING

THE FILES MAY CONTAIN FEATURES THAT ARE NOT COMPATIBLE WITH THE SELECTED FORMAT. THESE FEATURES ARE THEN UNAVAILABLE.



11.2.4 Convert From

The **Convert Documents – Convert from** dialog box allows to convert **magellan** files from previous versions to the current file format. Standard **magellan** files can also be converted to **magellan** Tracker files.



Note

Files for conversion are displayed only if magellan is connected with the instrument (measurement or demo mode) for which the files were generated.



Note

Files from magellan versions earlier than 4.0 must be converted in order to be used.



Note

Files from magellan Standard must be converted in order to be used with magellan Tracker.



Important

After conversion, methods must be validated, because the content of the converted files may differ slightly from the original file (e.g. contents of printed report, etc.)

The **Convert Documents** dialog box contains two tabs.

The **magellan** 2.x/**magellan** 3.x tab contains the following elements:

| Document type group box | Select the document type for conversion, e.g. a method |
|---|--|
| Customize new method specific options group box | Several global options – in magellan versions lower than V4.0 – are now method specific. In order to set this options correctly in the method and workspace files, use one of the export buttons or the Workspace name button. |
| Select all button | Click this button to select all displayed files in the file list |
| File name list | All files available for conversion are displayed. Click a file to select it for conversion. By holding the Shift-key, multiple file selections are possible. Note! Only workspaces and methods created with the currently connected instrument are displayed. |
| Source path edit field | The Source path edit field contains the path where the files to be converted are stored. Click the button on the right of the text field to change the path. |
| Destination path edit field | The Destination path edit field contains the path where the converted files are stored. Click the button on the right of the text field to change the path. magellan Tracker: this path cannot be modified. |
| Convert document(s) button | Click this button to start conversion. |
| Progress bar | This bar shows the progress of the conversion. |





WARNING

TESTS DO NOT CONTAIN MEASUREMENT PARAMETERS. WHEN CONVERTING A TEST TO A METHOD THE MEASUREMENT PARAMETERS HAVE TO BE DEFINED. MAKE SURE THE MEASUREMENT PARAMTERS FIT TO THE SELECTED TEST.

The **magellan** 4.x / 5.x tab—available only with **magellan** Tracker—contains the same window elements as the previously described tab, except that the following options are not necessary:

• Document type test: Tests are not available with **magellan** 4.x / 5.x. Customize new method specific options: These options are already customized in **magellan** 4.x / 5.x files.

11.2.5 Save LogFiles

All log files can be saved as zip archive by clicking the **Save Logfiles...** button. The zip archive can now be named and saved in a defined directory. In case of any measurement or status error during performance of **magellan**, this archive contains well data, status (e.g. overflow, lamp low) or calculation error(s) and can be easily sent to Expertline-at@tecan.com for support request.



11.3 Options

Several selections and adjustments which are valid throughout the complete menus and wizards of **magellan** are defined in the **Options** dialog box. If **magellan** user administration is activated, several settings are user dependent. The **Options** dialog box is divided into individual tabs:

- · Paths tab
- Copy tab
- Plate View tab
- Miscellaneous tab

The requested options have to be entered in the corresponding tabs. Click **OK** to save the changes and to close the dialog box.

User dependent options (every user can modify the options for his convenience) are:

- Default paths (only in magellan Standard)
- Copy to clipboard and Excel options
- Plate view
- Skip welcome page
- Start with wizard list or favorites page
- Move plate in after startup

The following user dependent options cannot be set in the options dialog box:

- Selected Printer
- Printout orientation.
- Printout paper size and source.
- Printout font and color.
- Default identifier types.
- Jumping direction for sample ID input.
- Import raw data settings.
- Default for Export options, Export to ASCII file, Export to Excel, and Workspace Name.
- Use stacker
- Graph dialog box size

The following options can only be modified by a user with the appropriate right. These options are then valid for all users:

- Language
- Demo mode allowed
- Suppress 'not monotone' warning for standard curve
- Favorites
- Accepted HUIDs



Note

In magellan Standard the data path can be set by the user, in magellan Tracker the data path is a general setting, valid for all users.

Refer to the Instructions for Use for **magellan** for all further information on the **Options** dialog group.



11.4 User Administration (magellan Tracker)

There are three types of administrators mentioned in this publication:

System Administrator is responsible for any changes made to the computer's operating system.

The **Administrator** is responsible for user rights in the **magellan** software.

magellan Administrator has access to all features of the **magellan** software, but cannot change user rights.

magellan offers password protection to prevent misuse of the software and to restrict access to parts of the software based on user rights.

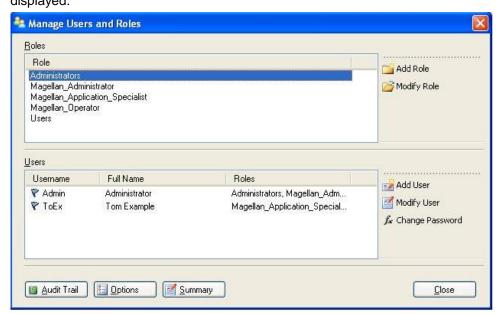


Caution

To prevent the misuse of user rights and falsification of data, it is recommended that the User Administrator does not have magellan rights (i.e. does not belong to a magellan User Group).

Ideally, the User Administrator should belong to the IT department.

Select miscellaneous in the wizard window and click the User administration icon. The Manage Users and Roles dialog box is displayed:



Users and roles can be added and modified, user rights can be defined. The **Manage Users and Roles** dialog box contains the following elements:

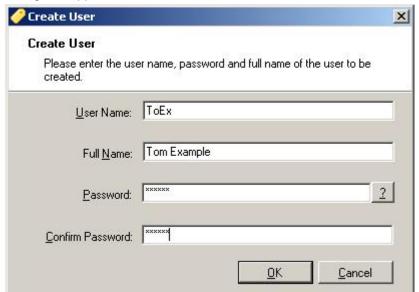
| Roles | The Roles list shows all existing user groups (user levels). |
|-------------|---|
| Add Role | A new group with corresponding rights can be created. |
| Modify Role | Rights of an existing group can be modified |
| Users | The user list shows all existing users and which group they are member of. |
| Add User | A new user can be created. |
| Modify User | Full name, user level (group) or password of an existing user can be changed. |



| Lock User | A user account can be enabled / disabled. The button is visible only if a user name is selected. |
|-------------|--|
| Audit Trail | All modifications of the user administration database (e.g. creation of groups/users, change of rights, change of options,) are recorded in the user management audit trail written by the user management server. |
| Options | General login, password or email options can be modified |
| Summary | A detailed description of all existing users and user groups as plain text |

11.4.1 Add/Modify User (magellan Tracker)

Click **Add User** in the *Manage Users and Roles* dialog box and the *Create User* dialog box appears:



The *Create User* dialog box contains the following elements:

| User Name | A unique user name has to be entered when a new user is created. This name cannot be modified afterwards. |
|-----------|---|
| Full Name | Enter the full name of the user. This can be changed later. |
| Password | Enter the initial password. The password must be changed at the next login. |



Click OK and the *Modify User* dialog box appears:



The *Modify User* dialog box contains the following elements:

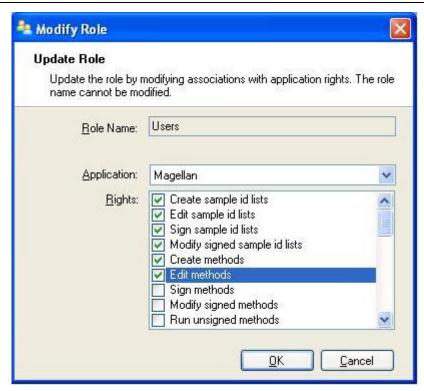
| Full Name | Enter the full name of the user |
|--------------------|--|
| Roles | Select from one of the existing user groups. The rights associated with that group are assigned to the user. |
| Change picture | User's picture can be added or changed. |
| Delete picture | Delete the user's picture. |
| Change Password | A new user's password can be defined. Note that the administrator needs not to provide the old password. |

To modify a user, click **Modify User** in the *Manage Users and Roles* dialog box. In the *Modify User* dialog box proceed as described above.

11.4.2 Add/Modify Role

Click **Add Role** in the *Manage Users and Roles* dialog box and the *Create New Role* dialog box appears. Define a unique **Role Name**. Note that this name cannot be modified afterwards. Close the *Add Role* dialog box by clicking **OK**. Open the *Modify Role* dialog box:



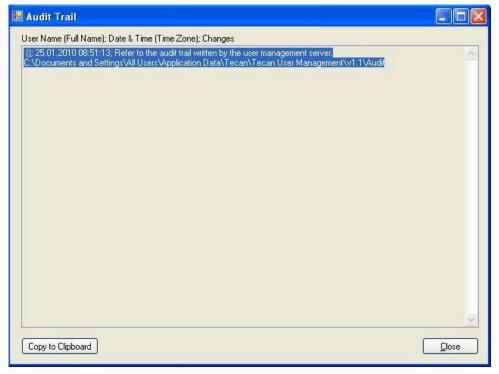


The *Modify Role* dialog box contains the following elements:

| Role Name | The role name is defined in the Add Role dialog box. |
|-------------|--|
| Application | Tecan software component, i.e. Magellan. |
| Rights | The role represents a specific user level and corresponding user rights can be selected. |

11.4.3 User Administration Audit Trail

Click **Audit Trail** in the *Manage Users and Roles* dialog box and the *Audit Trail* dialog box appears:





All modifications of the user administration database are recorded in the user management audit trail written by the user management server.

User Rights

There are three different security levels of user rights, the highest level of which is *Magellan Administrator*, who has access to all program functions. The *Application Specialist* and *Operator* levels are increasingly limited.

magellan Standard: The default rights are assigned as stated below.

magellan Tracker: Each right can be assigned or withdrawn by an Administrator and by default are assigned as stated below. The default set of rights is based on a typical laboratory environment.



Caution

Administrators have the responsibility to make sure that the settings (and any modifications) match the laboratory environment defined by the user SOPs (standard operating procedures) and comply with applicable laws.



Note

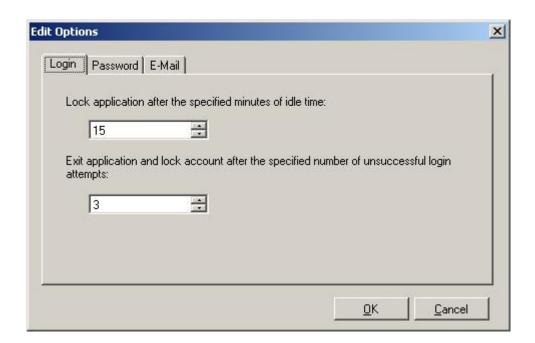
For clinical diagnostic applications, the operating authority must validate all methods to ensure the safety of the results. A method is considered validated when signed by the operating authority. The operating authority is fully responsible for any results obtained.



11.4.4 User Administration Options

Click **Options** in the *Manage Users and Roles* dialog box and the *Edit Options* dialog box appears.

Login Options



Lock of application after a specified time (1 min – 36500 h). To unlock the application the user has to reenter the password.

Unsuccessful After a number of consecutive unsuccessful logins (1 – 100), the user account is locked and optionally an alert email is sent to the system administrator.

If the user account of a user administrator has been locked due to unsuccessful logins, this account remains locked for an idle time of 45 minutes. After this waiting time the account is unlocked and can be used again.





Caution

If the User Administrator password is forgotten, User Administration settings cannot be changed. In that case please uninstall Magellan first and perform a new installation afterwards (see chapter 1.5 Software Installation Procedure).

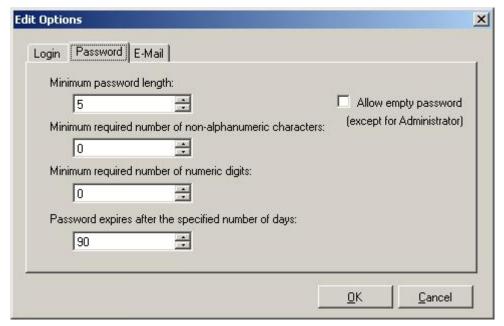




Note

When uninstalling magellan, NO existing magellan files will get lost. All previous files can be found in a backup folder generated during the new installation procedure.

Password Options



Passwords have to contain a specific minimum number of characters. Passwords can be defined to contain non-alphanumeric characters and/or numeric digits. Password cannot be reused.

Minimum password length:

Specify the required number of characters.

Minimum required number of non-alphanumeric characters:

Specify the required number of non-alphanumeric characters.

Minimum required number of numeric digits:

Specify the required number of numeric digits.

Password expires after the specified number if of days:

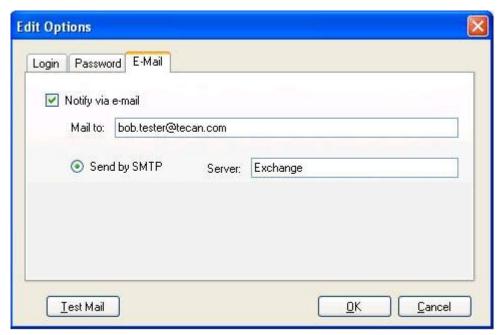
User passwords expire after a configurable number of days. The user must then choose another password. Specify the required number of days (range: 1 to 36500 days).

Allow empty password:

Select this checkbox if it is allowed to have an empty password for a user except for the administrator.



Email Options



An administrator can be notified in case of potential security attacks (a user account has been locked because a number of unsuccessful logins).

An email can be sent to the entered email address:

• **SMTP server**: the IP address of the SMTP server has to be entered (f.e. SEUATEXCH01.eu.tecan.net)

Click **Test Mail** to send a test mail to verify that the settings are correct.



Note

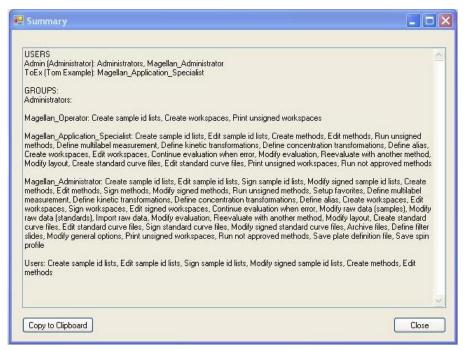
The notification via e-mail requires an SMTP server without authentication.

11.4.5 User Administration Summary

A detailed description of all existing users and user groups as plain text can be obtained by clicking **Summary** in the *Manage Users and Roles* dialog box.



11. Miscellaneous Icon

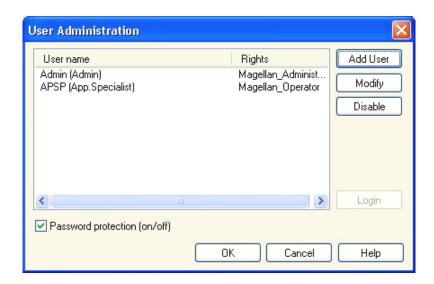


The text can be copied to a word processing program for printing.



11.5 User Administration (magellan Standard)

The **magellan** software offers protection against misuse of the software or access to the software from unauthorized users by providing a password protection facility.



User profiles can be defined at three different security levels. The highest level of security within the software is that of the **magellan Administrator**. This level gives access to all of the program's functions and data editing facilities. For **Application Specialist** and **Operator** level, options are increasingly restricted.

Only the **User Administrator** has the ability to enable or disable the software's password protection, define new users or delete old users. If the users are logged in under their user name, the system will only give access to options according to their user rights definition.

The **User administration** dialog box contains the following elements:

| Login button | The Login dialog box is displayed. A user can log in with his user name. |
|--|--|
| User list | All currently setup users with their User name and Rights are displayed within this list. Any user to be edited or deleted can be selected here. |
| Add User button | The Add User button opens the User Rights dialog box, in which a password, name, and user ID can be entered to define a new user. |
| Modify button | The Modify button opens the User Rights dialog box for modifying the selected user in the user list. |
| Disable button | The Disable button will disable the selected user in the current user list. |
| Password protection (on/off) check box | This check box enables to switch on/off the software's password protection facility. If enabled, the Login dialog box will be displayed upon starting magellan . |



11.5.1 Add/Modify User (magellan Standard)

This dialog allows adding or editing of users and assigning them to a User group. For the rights of different user groups see chapter 11.6 User Rights .

The User Rights dialog box contains the following elements:

| User name text field | Enter the full name of the user – as it shall be displayed |
|-----------------------------|---|
| UserID text field | Define the user ID that the user has to enter for login |
| User rights option buttons | Define the level of access to the software's facilities available for the user: |
| | Operator |
| | Application Specialist |
| | Administrator |
| Password text field | Define the user password (at least 5 characters) |
| Confirm password text field | Re-enter the password. For security concerns, in this field, the password characters are displayed as symbol. |

Click the **OK** button to save and close the dialog box.

Click the **Cancel** button to close the dialog box without saving the entered settings.



Note

If no users have been defined at all and the user administration shall be used, an administrator has to be defined first. Therefore, upon clicking the Login button, a short message is displayed. After that, the User Rights dialog box is displayed for entering the user information of the administrator (see chapter 2.3 Starting magellan/Login).

11.5.2 Login

This button is only enabled if user administration is activated but **Password protection** was not selected. Therefore at startup the **Login** dialog was not displayed. In order to activate the password protected user administration, click the **Login** button.

11.5.3 Change User

To change the active user, click the **Change user** icon in the wizard window. The **Login** dialog box is displayed.



11.6 User Rights

There are three different security levels of user rights, the highest level of which is *Administrator*, who has access to all program functions. The *Application Specialist* and *Operator* levels are increasingly limited.

magellan Standard: The default rights are assigned as stated below.

magellan Tracker: Each right can be assigned or withdrawn by a User Administrator and by default are assigned as stated below. The default set of rights is based on a typical laboratory environment.



Caution

User Administrators have the responsibility to make sure that the settings (and any modifications) match the laboratory environment defined by the user SOPs (standard operating procedures) and comply with applicable laws.



Note

For clinical diagnostic applications, the operating authority must validate all methods to ensure the safety of the results. A method is considered validated when signed by the operating authority. The operating authority is fully responsible for any results obtained.

The user rights are summarized in the table below and valid for both **magellan** versions, i.e. **magellan Tracker** and **magellan Standard**, unless otherwise stated:

| User Rights | magellan Administrator | magellan Application Specialist | magellan Operator |
|--|---------------------------|---------------------------------------|----------------------|
| Sample ID List | | | |
| Create sample ID lists | | | |
| Create a new sample ID list or save an existing one with a new name. | Yes | Yes | Yes |
| Edit sample ID lists | | | |
| Edit an existing sample ID list and save it with the same name. | Yes | Yes | No |
| Sign sample ID lists* | gn sample ID lists* | | |
| Sign an existing sample ID list for review/approval. | Reserved for future use. | | |
| Modify signed sample ID lists* | | | |
| Edit or change sample IDs in a signed sample ID list. | Reserved for future use. | | |
| Method | | | |
| Create methods | | | |
| Create a new method or save an existing one with a new name. | Yes | Yes | No |



11. Miscellaneous Icon

| Heer Dimbte | magellan Administrator | magellan Application | magellan |
|--|---------------------------|-------------------------|-----------------------------------|
| User Rights | Administrator | Specialist | Operator |
| Edit methods | | | |
| Edit an existing method and save it with the same name. | Yes | Yes | No |
| Sign methods* | | | |
| Sign an existing method for review/approval. | Yes | No | No |
| Modify signed methods* | | | |
| Edit a signed method and save it with the same name. | Yes | No | No |
| Run unsigned methods* | | | |
| Run methods that haven't been signed. | | | |
| Note: Each signature (review, approval, | | | |
| custom) allows operators to run those methods! | Yes | Yes | No |
| | 162 | 1 62 | INU |
| Setup favorites | Ves | Na | NI. |
| Add/Remove methods from the favorite list. | Yes | No | No |
| Define multilabel measurement | | | |
| Define methods using multilabel measurements. | Yes | Yes | No |
| Define kinetic transformations | | | |
| Define methods using kinetic transformations. | Yes | Yes | No |
| Define concentration transformations | | | |
| Define methods using concentration transformations. | Yes | Yes | No |
| Define alias | | | |
| Define methods using aliases for identifiers. | Yes | Yes | No |
| Workspace | | | ı |
| Create workspaces | | | |
| Perform a measurement and save the | | | |
| workspace with a new name – or – save an | V. | Mar. | V. |
| existing workspace with a new name. | Yes | Yes | Yes |
| Edit workspaces | | | |
| Edit an existing workspace and save it with the same name. | Yes | Yes | No |
| | 1 69 | 1 53 | INU |
| Sign workspaces* | | | |
| Sign an existing workspace for review/approval. | Yes | No | No |
| Edit signed workspaces* | . 55 | | 1.13 |
| Edit a signed workspace and save it with the | | | |
| same name. | Yes | No | No |
| Continue evaluation when error | | | |
| Continue calculation after errors have | | | |
| occurred | Yes | Yes | No ¹ /Yes ² |
| Modify raw data (samples) | | | |
| Edit or mask measurement data of samples. | Yes | No | No |



| User Rights | magellan Administrator | magellan Application Specialist | magellan Operator |
|---|---------------------------|---------------------------------------|----------------------|
| Modify raw data (standards) | | | |
| Edit or mask measurement data of standards, controls, blanks. | Yes | No | No |
| Import raw data | | | |
| Import raw data from ASCII file in an existing workspace. | Yes | No | No |
| Modify evaluation | | | |
| Change evaluation (method) settings in an existing workspace. | Yes | Yes | No |
| Reevaluate with another method | | | |
| Reevaluate an existing workspace with another method. | Yes | Yes | No |
| Modify layout | | | |
| Change measurement parameters, concentration and layout before starting a measurement. | Yes | Yes | No |
| | 103 | 103 | 140 |
| Standard curve | | | |
| Create standard curve files | | | |
| Create a new standard curve and save it with a new name. | Yes | Yes | No |
| Edit standard curve files | | | |
| Edit an existing standard curve and save it with the same name | Yes | Yes | No |
| Sign standard curve files* | | | |
| Sign an existing standard curve for review/approval. | Reserved for future use. | | |
| Modify signed standard curve files* | | | |
| Edit and change settings in a signed standard curve file. | Reserved for future use. | | |
| General | | | |
| Archive files | | | |
| Move files to an archive location | Yes | No | No |
| Set default paths** | | | |
| Set individual paths for saving workspace, method, sample ID list, export and bitmap files. | Yes | Yes | Yes |
| Define filter slides | | | |
| Change the filter definition of the instrument | Yes | No | No |
| Modify general options | | | |
| Select language, suppress not monotone warning, allow demo mode. | Yes | No | No |
| Print unsigned workspaces* | | | |
| The results of an unsigned workspace can be printed. | Yes | Yes | Yes |
| - | | | |



11. Miscellaneous Icon

| User Rights | magellan Administrator | magellan Application Specialist | magellan Operator |
|---|---------------------------|---------------------------------------|----------------------|
| Run not approved methods* | | | |
| Reviewed methods can be used for a measurement run. | Yes | Yes | No |
| Note: This right can be used in combination with the right <i>Run unsigned methods</i> to allow the user to run already reviewed, but still not approved methods. | | | |
| Reader Server | | | |
| Save plate definition files | | | |
| Create or edit plate definition files. | Yes | No ¹ /Yes ² | No |
| Save spin profile | | | |
| Create or edit spin profile files. | Yes | No | No |

^{*} user rights available in magellan Tracker only

11.7 About magellan

Select **About magellan** to display the copyright information and software disclaimer:

In the **About magellan** dialog box, information about the currently installed version of the **magellan** software, the version numbers of the components (tab **components**), and the program license of the user are displayed (tab **license**).

Register Wizard

For further details on the **Register magellan Wizard**, please refer to the Instructions for Use for **magellan**.

^{**} user rights available in magellan Standard only

¹ magellan *Tracker*

² magellan Standard



12. Additional Features for magellan Tracker

12.1 User Administration

In **magellan** Tracker a user administration is obligatory. Refer to chapter 11.4 User Administration (magellan Tracker) for further details.

12.1.1 Audit Trail

To become compliant with the **FDA Regulation 21 CFR part 11** every step done in **magellan** Tracker is documented. In the **Audit Trail** all modifications concerning the following data are listed:

- a method file
- a workspace file
- a Sample ID list
- a standard curve file
- the user administration database or
- options and default settings.

Each entry consists of the user (name and full name), date and time of change, whether the file was created or modified, and any audit trail comments.

Audit Trail of Methods, Workspaces, Sample ID lists

You can view the Audit trail using the **Audit trail** button at the save page of the wizards.

Audit Trail of a Standard Curve

Standard curves can be saved and afterwards be used for evaluation of data from another workspace. For the feature to load a standard curve from external file refer to chapter 4.3.10 Concentrations: Standard Curve of the Create/Edit a Method Wizard. For opening a previously saved standard curve in the standard curve graph refer to chapter 7.4.11 Control Bar: Concentrations.

To view the audit trail of the loaded standard curve select **Audit trail** from the **View** menu in Standard Curve Graph dialog box.

Audit Trail of the User Administration Database

To view the Audit trail of the User Administration Database select **Miscellaneous** icon in the **Wizard List** starting page and click **User Administration**.

Audit Trail of Options and Default Settings

To view the Audit trail of all options and default settings select **miscellaneous** icon in the **Wizard List** starting page and click **Options**. In the **Miscellaneous** tab the **Audit trail** button can then be selected.



12.2 File Handling

The measured data is always saved directly after the measurement.

12.2.1 Saving a File

A file, created and saved in **magellan** Tracker, is indicated with a "#" sign in its file name. The added "#" sign can only be seen in the appropriate subdirectory of **magellan**.

Example

method#1.mth

workspace#1.wsp

sampleIDlist#1.smp

12.2.2 Changing a Method or Workspace File

Every time a method or workspace file is modified and saved, the number behind the "#" in the file name is automatically increased (e.g.: first version of a workspace: name#1.wsp; edit and save the new version to get name#2.wsp; After the next change name#3.wsp is created...). All versions of a file are listed in the appropriated subdirectories of **magellan**.



Note

When transferring Tracker files it is necessary to transfer all versions of the file.

12.2.3 Opening a File

Only the last saved version of a file is available in the wizards of create/edit a method, create/edit a sample ID list, evaluate results and start measurement.

To view a previous version of a file, open the **Audit trail** in the saving page of the file, select the preferred version of the file by clicking once on the number and click **Save previous version as...** button. Rename the file and add some file remarks or Audit trail comments and open the file with the **Create/Edit a Method** wizard.



Note

If you want to compare a method with its previous versions a printout must be made, because two print preview windows cannot be opened simultaneously.



12.2.4 Opening a File Created on Another PC – Add HUIDs

In the licensing process of magellan, three numbers are involved:

- Serial number of the software
- HUID (Hardware Unit Identification Number) and
- License number (refer to chapter 2.4.4 Licensing magellan).

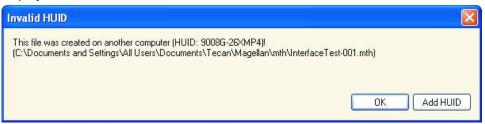
The HUID of a Personal Computer is configured during **magellan** registration and all files created and saved on this PC are linked to this special HUID.

If there is the need to work with **magellan** Tracker files, which were created on another PC, the HUID of this other PC must be accepted.

When a user with the right to **Modify general options** tries to open a document (sample ID list, method, workspace) from another PC, i.e. with a different HUID number, the user is automatically asked to add that number to the list of known HUID numbers. If the button **Accept HUID** is clicked, the HUID number will be added to the list and the document will be opened without further interactions.

Hence this HUID number is always accepted.

To view the list of accepted HUID numbers of other PCs click **Miscellaneous** icon in the wizard list starting page → **Options** → **Miscellaneous** tab. Click the **Add HUID** button and the dialog box with the other PCs HUID numbers is displayed.





13. Calculations

13.1 Evaluate Results – Calculation Procedure

Depending on the settings the calculation follows the procedure below:

- 1. Precalculation
 - 1.1 G-Factor calculation, polarization calculation (blank reduction, intensity, total intensity and anisotropy calculation)
 - 1.2 Cuvette data reduction
 - 1.3 Spectra calculation
- 2. Check if data and evaluation settings fit together
- 3. Raw data statistic calculation
- 4. Transformation calculation
- 5. Kinetic parameter calculation
- 6. Kinetic transformation calculation
- 7. Concentration calculation
- 8. Concentration transformation calculation
- 9. Cutoff range determination
- 10. QC Validation
- 11. Statistic calculation

The procedure is repeated if

- QC Validation eliminated values using the eliminate functions.
- Interpolation parameters in the transformations are required.

Equal values for transformations in kinetic and multilabel measurements will be suppressed.

For calculations with different dilutions the Mean concentrations will be discarded. In case the evaluation procedure is aborted through errors, results calculated until that point can be displayed.

In case some values are found to be FALSE, the following **Occurred Errors** dialog box will appear:

| Message text field | The error message and a short explanation is displayed in a text field. |
|---------------------|---|
| Save as file button | Click the Save as file button and the error protocol can be stored in an ASCII file. |

In case the curve fit failed, depending on the user right, a question is displayed, where the user can decide to change the Analysis Type settings. After changes the evaluation procedure will be started from beginning.

In case the validation failed, depending on the user right, an error message box is displayed or a question message box is displayed, where the user can decide to continue the calculation anyway. If the calculation is aborted, cutoff results cannot be accessed. However, on a printout a validation failed message will be included.



| In case values or se | In case values or settings have been changed, a message box will appear. | | |
|----------------------|--|--|--|
| Message | The instrument values have been changed. Do you want to re-start the result calculation? | | |
| Yes button | Click the Yes button to re-calculate the evaluation values. | | |
| No button | Click the No button to close the message. No recalculation will be performed. | | |

13.1.1 Statistics

Refer to the Instructions for Use for **magellan** for detailed information on **Statistics**.

For detailed information on *Polarization Data Reduction* and *Spectra Data Reduction* please refer to the Instructions for Use for **magellan**.

13.2 How to Write a Formula

13.2.1 Introduction

A variety of formulas are necessary for the calculations, the cutoff requirements and the validation. These formulas resemble the syntax of BASIC commands.

All values are calculated in double precision although they are displayed depending on the desired number format.

13.2.2 Formula Variables

All of the previously defined abbreviations for the identifiers contained within the analysis plate can be employed as variables in calculations.

For example:

PC1, SM1_1, BL1...Average values

PC1_1, SM1_1_1, BL1_1...Individual values, individual replicates



Note

The program differentiates between lower and upper case letters when dealing with these labels.

It is also possible to work with the well coordinates.

For example: A2, B3, H12



Note

Well coordinates must always be written using upper case letters.



Note

The symbol x refers to the current value within a well. For example: x-BL1...subtracts the empty value (blank) from the current value.



Note

The different cycles for kinetic measurements can be accessed by indices [], where "0" indicates the first cycle.



For example:

SM1_1[0]... Average value of sample 1 of the first cycle

x[1]... value of current well of the second cycle

x[i] ... value of the current well and the current cycle

Serial Kinetic Subtraction – Calculation of Difference between Kinetic Cycles

Calculations over kinetic data can be defined by using the iteration variable 'i' in formulas. For instance a numerical derivative of a kinetic curve can be performed using the formula x[i]-x[i-1], which subtracts each kinetic cycle by the previous. But use of that formula would automatically lead to an error for cycle number 1. Therefore, set the formula if(i>0) then(x[i]-x[i-1]) else ignore() in the transformation edit field to prevent the subtraction of the first cycle.

The use of constants in formulas is identical to all other variables, the only difference being that a constant can contain characters (f.e. alpha, dilution).

There are two predefined accessors.

concX ...

returns the concentration of the standard of the current well dilX ...

returns the dilution of the sample or control of the current well



Note

If more than one set of input data shall be used for calculations, select the appropriate data from the available data drop down list, activated in transformation edit fields of the Create/edit a method tab (refer to chapter 4.3.7 Transformed Data: Add New Transformation and chapter 7.4.9 Control Bar: Transformed Data).



Note

Using one of the mathematical functions described in the following chapters, an "intellisense" help is activated to support correct writing of special formulas.

Formula Operators

| Operator | Description |
|----------|--|
| + | Plus |
| - | Minus |
| * | Multiplication |
| 1 | Division |
| ^ | To the power of the exponent The symbol used to represent the expression "to the power of" is '^'. This character can be obtained by pressing the SHIFT key together with the number 6 key (but not on the numerical keypad.) Example: x^3 The value of the well will be increased to the power of three. |



| Operator | Description |
|----------|--------------------------|
| < | Less than |
| <= | Less than or equal to |
| > | Greater than |
| >= | Greater than or equal to |
| == | Equals |
| != | Is not equal to |
| = | Assigned to |



Note

The difference between equals (\Longrightarrow) and assign to (\Longrightarrow). For example: If ($x \Longrightarrow 0.000$), then x = 1.000 (If the current value of x is equal to 0 then set the value of x to 1)

13.2.3 Formula Functions

The expressions "and" and "or" can be incorporated into the same equation through the use of logic functions. The result from a logical equation will be either TRUE or FALSE and is therefore a Boolean value. The individual equations must be enclosed in brackets.

Logical Expressions

and

In equations of this nature, the result will be TRUE if both expressions are found to apply, otherwise a result of FALSE will be given. Example:

Where the value held by the well is 0.3

$$(x>0.0)$$
 and $(x<1) = TRUE$

$$(x>0.0)$$
 and $(x<0.1) = FALSE$

or

In equations of this nature, at least one of the expressions involved must be found to apply in order that a result of TRUE can be given.

Example: where the value held by the well is 0.3

$$(x>0.0)$$
 or $(x<0.1) = TRUE$

$$(x>0.4)$$
 or $(x<0.1) = FALSE$

if(...) then(...) else(...)

The following expressions are used in the program and, as an example, can be written in the following manner:

if (statement) then Term A else Term B

The statement:

The statement must be either true or false and written in brackets. If the statement is arrived at by means of logical operators (and/or), then the whole expression must be written here and enclosed in brackets.

Terms A and B:



If the statement is true, Term A will apply and if the statement is false Term B will apply.

It is not always necessary to include the else expression. If it is not present in the equation, no response will be given in the event of a false result.

The "if(...) then(...) else(...)" expression can also be used with Boolean terms for QC Validation.

Example:

Check whether the value of a well lies within a defined range. If the result is yes, the well will be represented by the value 0.0, if the result is no, the value 1 will be used.

if ((x>-0.005)) and (x<0.0)) then (0.0) else (1.0)

13.2.4 Basic Functions

abs(argument)

This function gives the absolute sum of the argument.

Therefore (-1*x) where x<0 and (x) where x>=0.

Example:

abs(-1) = 1

abs(1) = 1

exp(argument)

This function raises the Euler (e) value to the power of the argument.

Example: $\exp(1) = e^1 = 2.718$

frac(argument)

This function separates out the fraction section of argument.

frac(): delivers the fraction section of a decimal value.

Example: frac(1.7) = 0.7

int(argument)

This function separates out the integer sections of argument.

int(): delivers the integer section of a decimal value.

Example: int (1.7) = 1

Log(argument)

log(arg1;arg2)

This function takes the logarithm of arg2 to the base of arg1.

Example:

The well holds a value of 100.

log(x;10)

The result here will be 0.5.

In(argument)

This function takes the natural logarithm of argument.

Example: ln(10) = 2,303

Ig(argument)

This function takes the logarithm to base 10 of argument.

Example: lg(10) = 1



round(argument)

This function rounds argument to an integer value.

Example:

To round 12.579 to two decimal places use the following formula:

round(12.579*100)/100

The result is 12.58.

sqr(argument)

This function raises argument to the power of 2

Example: sqr(3) = 9

sqrt(argument)

This function takes the square root of argument

Example: sqrt(9) = 3

13.2.5 Statistical Functions



Note

Use single and not average or mean data as input data for transformations with statistical functions.

avg(argument) and mean(argument)

This function calculates the average value of argument. The argument must be an identifier.

Example:

avg(SM1)

The average of all the samples in the first experimental group will be formed. Furthermore, the replicates of a value can be averaged:

avg(ST1_1)

Averages all replicates of the first standard.

median(argument)

This function determines the median of argument. The argument must be an identifier. The individual replicates are ordered in terms of size and the median determined by taking the middle value in the order. If the number of values is an even number, the average of the two middle values will be determined.

Example:

Median (NC1)

Assume NC1_1=0.1, NC1_2=0.05, NC1_3=0.04

The median value of these negative controls will be determined as follows.

The order of the values gives:

0.04 0.05 0.1

The median is therefore 0.05.



medianPlate()

The median of the whole plate can be determined using this function. The individual values are ordered in terms of size and the median determined by taking the middle value in the order. If the number of values is an even number, the average of the two middle values will be determined.

Example:

medianPlate()

Assume BL1=1, NC1=2, PC1=3, SM1_1=4, SM1_2=5 and no other wells defined. The median of the whole plate is 3.

max(argument) and min(argument)

This function calculates the minimum/maximum of argument. The argument must be an identifier.

Example:

max(SM1)

The maximum of all the samples in the first experimental group will be formed. min(ST1_1)

Determines the minimum of the individual replicates of the first standard.

maxAvg(argument) and minAvg(argument)

This function gives the maximum/minimum average value of argument. The argument must be an identifier.

Example:

minAvg(SM1)

If a number of results are found for SM1, only the minimum average will be given.

PointwiseCV(argument)

The average point wise coefficient of variation (CV) is determined. The result can be used to validate the standard curve. The argument must be an identifier.

Example:

PointwiseCV(ST1)

Assume

ST1_1_1=0.54 ST1_1_2=0.52 cv=2.668 ST1_2_1=0.72 ST1_2_2=0.77 cv=4.746 ST1_3_1=1.08 ST1_3_2=0.99 cv=6.148

The result of pointwiseCV is the average of the CV of ST1_1, ST1_2 and ST1_3 and is 4.5209.

Sum(argument)

This function calculates the sum of argument.

Example:

sum(SM1)

The sum of all the samples in the first experimental group will be formed.

sum(ST1_1)

Determines the sum of the replicates of the first standard.

stddev(argument)

This function calculates the standard deviation of argument. The argument must be an identifier.



Example:

stddev(NC1)

The standard deviation of the negative control in the first experimental group will be formed.

13.2.6 Elimination Functions

The elimination functions will be employed in the validation. In this way the user can make sure that the measurement values lie within a valid interval and delete any rogue values.

Three differing elimination functions can be employed when defining the validity intervals. The identifier that is to be influenced by the function is always the first parameter required when defining the elimination criteria.

All three elimination functions produce a logical result. TRUE is given when there are enough valid measurement values available and FALSE is given when less than the requirement are valid.

Invalid measurement values will be labeled with an exclamation mark.

eliminate (arg1; arg2; arg3; arg4)

The validation interval will be defined using a defined value.

This function eliminates values that lie outside of the validation range defined in arg2.

arg1: Identifier name (NC1,PC1).

arg2: Value used to represent the range, dependent upon arg4.

arg3: Number of valid, individual values that must be available in order that an average can be generated. If too few values are available following the elimination, a result of FALSE will be given.



Note For arg3:

a value of "2" or higher has to be defined. "1" is not accepted.

arg4: Represents the selection of whether testing will use the range average-arg2 to average+arg2 (argument of 1) or it will be checked whether the individual values lie below average+arg2 (argument of 0). In this case (argument of 0) there is no lower limit.

The elimination function here determines the average of arg1. The value with the highest absolute deviation to the average value is then checked to ensure that it lies within the range according to arg4. Is the value lying outside of this range it will be viewed as being invalid. In this case the average calculation will begin again, excluding the previously discovered invalid value, and continue in this manner until no more rogue values can be found.

A result of TRUE will be delivered when enough valid individual values are available.

Example:

eliminate(NC1;0.15;2;0)

The average value will be generated for the negative controls. It will then be seen whether the individual negative controls lie above NC1+0.15. (There is no lower limit). If this is the case, the rogue value(s) will be eliminated as described above. If on completion, at least 2 individual values are valid, a result of TRUE will be returned; otherwise a result of FALSE will be given.



eliminatePerc (arg1; arg2; arg3; arg4)

The validation interval will be defined using a percentage of the average value.

This function eliminates values as described for function eliminate. The validation range is defined using a percentage (arg2) of the identifier.

Example:

eliminatePerc(NC1;10;2;1)

Individual values will be invalid if they deviate to an extent of more than 10% below or above the average. On completion, a minimum of 2 individual values must be valid in order that the negative controls are declared as being valid.

eliminateRange (arg1; arg2; arg3; arg4)

This function eliminates values that lie outside of the validation range defined by arguments 2 and 3.

arg1: Identifier name (NC1,PC1)

arg2: Lower limit of the selected range

arg3: Upper limit of the selected range

arg4: The number of valid, individual values that must be to proceed. If too few values are available following the elimination, a result of FALSE will be given.

A result of TRUE will be delivered when enough valid individual values are available.

Example:

eliminateRange(NC1; 0.0; 0.1; 2)

The individual values for the negative controls must fall within the range of 0.0 and 0.1 in order to be valid. To achieve a result of TRUE, at least 2 of the values must be viewed as being valid.

eliminateCV (arg1; arg2; arg3)

This function eliminates replicates until the CV of the remaining replicates is lower than the given CV (arg2). The replicates are eliminated step by step, beginning with the value with the highest difference to the mean value.

arg1: Identifier name

arg2: Limit of accepted CV value

arg3: The number of valid, individual values that have to be left to deliver a positive result. If too few values are available following the elimination, a result of FALSE will be given.

A result of TRUE will be delivered when enough valid individual values are available.

Example:

eliminateCV(NC1; 15; 3)

The calculated CV of the individual values of the negative control shall be below 15%. After the elimination, at least 3 replicates must be left to get TRUE as result.

countDeleted(arg1; arg2)

This function checks if there are enough valid values available and returns TRUE or FALSE.

arg1: The identifier, whose quantity is to be checked.

arg2: The lowest number of replicates that must be available.

Example:

countDeleted(NC1; 2)



This function works in conjunction with the Eliminate functions in equations:

The Validation contains the following line:

if (NC1>0.5) then eliminateRange(NC1; 0; 0.5; 2)

If the average of the negative control lies above 0.5, then all replicates that lie outside of the range should be omitted.

This elimination will be processed once. If values for elimination are found, a new calculation will follow making sure that the average lies under 0.5 and a result of TRUE will be given.

At this point it is not yet certain that the necessary number of replicates is available. This is then determined using the countDeleted function within an else statement:

if (NC1>0.5) then eliminateRange(NC1; 0; 0.5; 2) else countDeleted(NC1; 2)

The equation process (of the second run following the elimination) uses the else statement. The countDeleted function then checks, whether the given identifier in arg1 is available in the quantity specified in arg2. If this is the case a result of TRUE will be given, if not FALSE.

Step by step example eliminate respectively eliminatePerc

The only difference between eliminate and eliminatePerc is the way for calculating the limits for the valid range (see above). The calculation sequence is the same for both functions. For the step by step description, eliminate is used.

eliminate(NC1;0.15;2;0)

Individual values:
$$NC1 1 = 0.217$$

NC1_2 = 0.439
$$\overline{NC1} = 0.288$$

$$NC1_3 = 0.208$$

Step 1: The individual values are sorted by their distance to the average.

| $ NC1_1 - \overline{NC1} $ | 0.217-0.288 | 0.071 | | NC1_2 (0.439) |
|-----------------------------|-------------|-------|----------|---------------|
| <i>NC</i> 1_2 – <i>NC</i> 1 | 0.439-0.288 | 0.151 | → | NC1_3 (0.208) |
| $ NC1_3 - \overline{NC1} $ | 0.208-0.288 | 80.0 | | NC1_1 (0.217) |

Step 2: Calculation of upper limit: 0.288+0.15 = 0.438

Step 3: first comparison:

0.439 > 0.438 and therefore out of the valid range \rightarrow Step 4: value of NC1_2 is eliminated and the average and the limit are recalculated.

Step 4: New avg =
$$(0.217+0.208)/2 = 0.2125$$

New limit = $0.2125+0.15 = 0.3625$

Step 5: second comparison:

0.208 <= 0.3625 → valid

 $0.217 \le 0.3625 \rightarrow \text{valid}$

Result:



The replicate NC1_2 doesn't fit into the given range and therefore has been eliminated.

Function returns TRUE because there are still two replicates left.

Note: In each calculation cycle (Step 1 to Step 4), only one replicate is deleted (the replicate with the highest distance to the average). The cycle is repeated until no replicate is deleted during the comparison step within the cycle.

13.2.7 Other Functions

ignore()

This function omits the values of chosen wells so they will not be incorporated into the calculations. Ignored values are displayed with a leading '!' and handled like eliminated values.

Example:

if(x<0.9*SM1_1) then ignore()

isInvalid()

This function gives a Boolean value, whether values within the well are valid or not. Invalid values for example can be caused by overflow values of the reader.

Example:

if(isInvalid()) then x=3.0

If the well contains an invalid value, the value 3.0 will be assigned. In this way, further calculations are possible, in spite of such values.

calcAlways(argument)

This function enables to calculate formulas on wells independent of the state of the value. argument can be any valid formula. The formula will be calculated even if the value is masked or invalid. This function can be used to calculate results that do not depend on the value of the used well.

Example:

calcAlways(A)

The value of parameter A of the standard curve formula is returned.

concX

This function can be used in concentration transformations. The result of *concX* is the original concentration of the well and can therefore only be used in wells with standards as identifier.

Example:

x – concX gives the difference between the calculated and the original concentration of the well.



13.2.8 Spectra Functions

smooth(numPts)

Smoothes with the given number of points.

minimum()

Delivers the minimum as data pair (wavelength, intensity).

maximum()

Delivers the maximum as data pair (wavelength, intensity).

normalize(wl)

Normalizes by using the intensity at the given wavelength.

peak(threshold;wlStart;wlEnd;peakIndex:percLimit)

Delivers the peak as data set (intensity, wavelength, width, area). Peaks lower than the threshold will not be found.

Peak search is done in the given wavelength range.

peakIndex = $-1 \rightarrow$ returns max. peak peakIndex = $-2 \rightarrow$ returns min. peak

peakIndex = 0, 1, 2, ... \rightarrow returns peak at the given index

percLimit is a percentage used for calculating width and area.

numPeaks(threshold;wlStart;wlEnd)

Delivers the number of peaks found in the given wavelength range. Peaks lower than the threshold will not be found.

derive(degree)

Calculates the derivate of the given degree. Valid degrees are 1 and 2; e.g. derive(2).

intensity(function)

Delivers the intensity of either a data pair or a peak; e.g. intensity(minimum()).

wavelength(function)

Delivers the wavelength of either a data pair or a peak; e.g. wavelength(maximum())

width(function)

Delivers the width of a peak; e.g. width(peak0.5;450;650;-1;50)).

area(function)

Delivers the area of a peak; e.g. area(peak0.5;450;650;-1;50)).



13.2.9 Examples

Transformations

Transformations modify the current value of the well. The result must always be a numerical value.

Blank reduction:

x-BL1

The empty value (blank) will be deducted from the current value of the well.

Blanking of a kinetic run:

x-x[0]

The value of first point of the kinetic is used as blank and will be deduced from the values of all kinetic cycles.



Note

The index "0" represents the first measurement of a kinetic run.

Ratio:

x/PC1 * 100

Calculates the ratio between a sample and a control in percentages.

DNA/Protein ratio:

'Label1'!x/'Label2'!x

In order to calculate the DNA/protein ratio, a multilabel measurement must be defined. The first measurement uses a wavelength of 260 nm, the second measurement uses a wavelength of 280 nm.

Conditional result:

If (x<0.0) then 0 else x

If the value of the well is less than 0, it will be represented by 0, otherwise it remains unchanged.

Cutoff

The cutoff dictates the limits to be applied when evaluating. The result must always be a numerical value.

Label: POS Limit: NC1*1.15

Label: ??

Limit: NC1*0.85

Label: -

The result is positive (POS) when the absorbance is more than 15% above the average of the negative controls and negative (-) when it is more than 15% below the average. A result is declared as open (??) if it lies between these two values.



QC Validation

The validation serves to examine the validity of the test. The result must always be a logical statement, TRUE or FALSE.

(BL1>-0.005) and (BL1<0.120)

If the average value of the empty value falls within the range of -0.005 to 0.12, a result of TRUE will be declared.

eliminateRange(NC1;-0,005;0.12;2)

If a minimum of two negative controls fall within the range of -0.005 to 0.12, a result of TRUE will be declared.

abs(PC1-NC1)>0.25

The distance between the averages of positive controls and the negative controls must be greater than 0.25. If this is the case, a result of TRUE will be declared.

For detailed information on *Standard Curve Analysis* and *Dilution Series* please refer to the Instructions for Use for **magellan**.



14. Glossary of Terms

| Term | Definition |
|------------------------------------|--|
| Anisotropy | Data calculated with polarization measurements |
| Average single conc. (???) | Concentration calculated by averaging the single concentrations |
| Basis ??? | Kinetic Parameter: Basis OD/RFU/RLU value of the onset calculation |
| Basis ??? % | Kinetic Parameter: Basis value of the onset calculation in % |
| Blank Reduction – parallel | Reduced data calculated with polarization measurements |
| Blank Reduction – perpendicular | Reduced data calculated with polarization measurements |
| Clipboard | The clipboard is the medium by which programs under Windows exchange data with each other. Data can be selected in one Windows application by cutting or copying it to the clipboard and then added into another application by pasting it from the clipboard. |
| Correlation coeff. | Correlation coefficient, indicates the strength and direction of a linear relationship between two random variables. |
| Cutoff limit | The cutoff limit enables the user to define the limits between two conditions (for example: positive or intermediate). These criteria are used in the evaluation of the results. |
| Cutoff results | Name of the cutoff range the value lies in as defined under cutoff definition |
| Cutoff definition | Definition of all cutoff ranges and calculated limits |
| Dilution factors | Defined dilution factors of the samples and controls. A dilution factor of 2 represents a 1:2 dilution. |
| Dilution series | A sample with replicates in different dilutions. |
| G-Factor | The G-factor is a instrument constant used in calculations of polarization measurements. In order to determine the G-factor a calibration measurement has to be performed. |
| Goodness of fit | 1 minus average relative square deviations of the base points from the curve |
| Graph | Graphs can be displayed for kinetic measurements, enzyme kinetics, multilabel measurements, dilution series or standard curves. |



14. Glossary of Terms

| Term | Definition |
|---------------------------|--|
| Hidden | Displayed if well data is hidden when printing |
| HUID | Hardware Unit Identification Number |
| IC 50 | The dilution/concentration which results in 50% of the maximum response |
| Intensity – parallel | Reduced data calculated with polarization measurements |
| Intensity – perpendicular | Reduced data calculated with polarization measurements |
| Invalid | Value is invalid, no calculation possible |
| Graph: Kinetic | Graph of kinetic measurements |
| Lamp low | No values from measurement because of absorbance instrument error. |
| Layout, Plate Layout | Defines where samples or controls are placed on the microplate |
| Max. slope ???/hr | Kinetic Parameter: Maximum slopes of the kinetic curves per hour |
| Max. slope ???/min | Kinetic Parameter: Maximum slopes of the kinetic curves per minute |
| Max. slope ???/sec | Kinetic Parameter: Maximum slopes of the kinetic curves per second |
| Maximum ??? | Kinetic Parameter: Maximum value of the kinetic curves |
| Mean slope ???/hr | Kinetic Parameter: Average slopes of the kinetics curves per hour |
| Mean slope ???/min | Kinetic Parameter: Average slopes of the kinetics curves per minute |
| Mean slope ???/sec | Kinetic Parameter: Average slopes of the kinetics curves per second |
| Mean. conc (???) | Concentration calculated from the mean of the replicates of the input data |
| Measurement data | Dual wavelength absorbance measurement: Data measured using the measurement filter |
| Measurement parameters | Defines measurement mode, wavelength, plate size, shaking, etc. |
| Measurement type | The measurement type can be endpoint measurement, kinetic measurement, multilabel measurement or well-kinetic measurement. |
| Method | Methods contain of the measurement parameters and the evaluation definition. Running a method leads to a workspace that contains the measured and calculated data. |



| Term | Definition |
|--|---|
| Minimum ??? | Kinetic Parameter: Minimum value of the kinetic curves |
| Multiple Reads per Well Measurement | A variety of readers have the ability to run a number of measurements within the same well. The average of the individual values will be determined for use in the evaluation and, if required, chosen values can be masked from the calculations of the mean value. |
| MultPt | The standard curve is not monotone and delivers more than one concentration at the given input data. |
| NoCalc | No value returned from the calculation. |
| Original Concentrations | Concentrations of the standard curve defined in the method. |
| Overflow | Overflow occurred during measurement in this well |
| Pipetting status | If a sample ID list is imported from a pipetting software, the pipetting status can be displayed. |
| QC Validation | The QC validation criteria are defined in the method and stipulate whether a measurement is valid or invalid. The criteria can, for example, indicate if the measurement values lie too far apart from each other, or if they deviate too far from an expected value. The program automatically warns the user if the criteria are not met. |
| Strip Method Names | File names of the strip methods (useful for export of strip method results) |
| Polarization | Data calculated with polarization measurements |
| Raw data | Data measured by the instrument. |
| Reference data | Dual wavelength absorbance measurement: Data measured using the reference filter |
| Results statistics | Summary of the number of values in the different cutoff ranges |
| RFU – parallel | Data measured with polarization measurements |
| RFU – perpendicular | Data measured with polarization measurements |
| Sample ID List | Sample IDs are assigned to each well on the basis that the associated probe can be identified. The IDs are usually barcodes imported from sample ID lists stored by a pipetting software. |
| Sample IDs | IDs of the samples |
| Single. conc (???) | Concentration calculated from the input data of each replicate |



14. Glossary of Terms

| Term | Definition | | |
|---------------------------|--|--|--|
| Test | In previous versions a test contained the evaluation settings but not the measurement parameters. Tests are not longer supported in magellan and are replaced by the more powerful methods. | | |
| Time Basis ??? | Kinetic Parameter: Time until the basis value is reached | | |
| Time Basis ??? % | Kinetic Parameter: Time until the basis value % is reached | | |
| Time Basis to Onset ??? | Kinetic Parameter: Time between basis value and onset value | | |
| Time Basis to Onset ??? % | Kinetic Parameter: Time between the basis and the onset value % | | |
| Time max. slope sec | Kinetic Parameter: Kinetic Parameter: Time point of the maximum slope | | |
| Time maximum ??? | Kinetic Parameter: Time until the maximum is reached | | |
| Time minimum ??? | Kinetic Parameter: Time until the minimum is reached | | |
| Time Onset ??? | Kinetic Parameter: Time until the defined onset value is reached | | |
| Time Onset ??? % | Kinetic Parameter: Time until the defined onset in % is reached | | |
| Time points | Time stamps of the single measurements of a kinetic measurement | | |
| Total Intensity | Data calculated with polarization measurements | | |
| Unavailable | Requested data is not available | | |
| Unused | No data measured, no layout defined in this well | | |
| User Prompts | User Prompts are references that are setup in the method. They are displayed before the measurement and the user has to add text to them. This text will then be incorporated in a printout. | | |
| Validation criteria | Summary of validation condition results | | |
| Well position | Name of the well, for example: A1, A2, | | |
| Workspace | All available data within the program can be found in the Workspace, for example the measurement data, the print definition and the method definition. The Workspace is used for loading methods and running measurements. | | |
| · I | Precedes values that have been eliminated during calculation | | |
| # | Precedes concentration values that have been calculated using extrapolation and lie outside the range of the standard curve | | |



| Term | Definition |
|--|---|
| () | Parenthesis surround values that have been masked |
| * | An asterisk marks values that have been measured using the "Use gain regulation" option, which corrects (=lowers) the gain. |
| ??? - Mean | Calculated averages (for example: Raw data – Mean) |
| ??? – Standard deviation s - ??? | Calculated standard deviations (for example: Raw data – Standard deviation or s – Raw data) |
| ??? – Variation coefficient v - ??? | Calculated variation coefficients (for example: Raw data – Variation coefficient or v – Raw data) |
| ~ | Added to values that have been edited or simulated |
| <min< th=""><th>Calculated concentration is lower than minimum</th></min<> | Calculated concentration is lower than minimum |
| >Max | Calculated concentration exceeds maximum |
| <blank></blank> | Printed report: Insert empty matrix or table printout |
| <page break=""></page> | Printed report: Print next item on the next page |
| <separator></separator> | Printed report: Print line between two items |
| x | Symbol x refers to the current value within a well |
| concX | Symbol concX refers to the concentration of the standard in the current well. |
| dilX | Symbol dilX refers to the dilution of the sample or control in the current well. |
| '???'! | Available data set if more than one set of input data shall be used for calculations |
| [] | Indices access the different cycles of a kinetic measurement whereas [0] indicates the first cycle |
| * | The asterisk marks identifiers that have been set as aliases. |



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