



**Operating manual**  
**+ Additional functions + Instructions**

For *Apo-Ident* NIR analyser

Based on version 1.3





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## Quick Reference User Guide

### 1. Starting the software

Start the *QuickStep Apo-Ident* software by double-clicking the icon which is on the desktop.

The *Apo-Ident* user interface will open.

**Note:** In case of low internal instrument temperature a warm-up phase will start automatically. Please wait until the operating temperature of at least 20°C is reached. Once the respective message has disappeared, the system is ready to start the measurement.



### 2. Select configuration profile

The first step is to choose your user profile under **Configuration profile**.

**Note:** In order to learn how to create a configuration profile, refer to page 8 of our detailed manual.

### 3. Select substance class and substance

Under **Substance selection** first select the class to be examined, e.g. APIs & excipients, solid.

Then enter the English name of the substance. Alternatively, enter the Latin name (if existing) in the line below.

**Note:** After entering the first letters the software will provide suggestions. Select the correct substance from the list.

Class:	APIs & excipients, solid
Name:	Tetraca
Latin:	<div> <div>Tetracaine base</div> <div>Tetracaine hydrochloride</div> </div>

### 4. Different measurement procedures for solid and liquid substances

#### 4.1 APIs & excipients solid, narcotic substances solid and drugs

##### Start measurement

Firstly, place your **sample container with the substance** (filling height 2-4mm) and the **distance ring** on the measuring window. Start the measuring process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) directly on top of the instrument.

**Note:** Some substances can also be identified using a lower quantity of the substance. You can find the corresponding process in our detailed manual on page 13.

Start measurement



##### Referencing

After the first measurement after switching on the *Apo-Ident*, the external reference standards are requested to be put onto the measurement window for measurement: Black and white reference (Zenith).

**Note:** Please make sure to use always the distance ring. The measurement of the references will have to be repeated upon request by the software from time to time. Please follow the instructions of the software.

Black reference



White reference (Zenith)



## Quick Reference User Guide

### 4.2 APIs & excipients, liquid/semi-solid

#### Transflectance reference

Start with the transflectance reference without the liquid/semi-solid. Put the transflectance insert with the little feet facing the bottom into an empty sample container. Following this, place the container with the transflectance insert on the measuring window of the *Apo-Ident* instrument. Start the transflectance reference by clicking on the green button.



**Important:** Both, the transflectance reference as well as the liquid/semi-solid have to be measured with the same transflectance insert and sample container. Otherwise this may result in non-identification.

**Note:** Having the initial transflectance reference successfully completed, the measurement of substances has to commence within a time frame of five minutes. Otherwise the transflectance insert measurement must be repeated.

#### Referencing

After the transflectance reference, the external reference standards are requested to be put onto the measurement window for measurement.

Please pay attention to the instructions in chapter 4.1.

#### Start measurement

Place your sample container with the substance, the transflectance insert and the distance ring on the measuring window. Start the measuring process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) directly on top of the instrument.

**Note:** Ensure that you press the transflectance insert down properly with its feet downwards in the sample container so that no air pockets are visible.

Class:	APIs & excipients, liquid/semi-solid (with analysis certificate)
Name:	Dexpanthenol
Latin:	Dexpanthenolum

Transflectance reference  Please use the same transflectance insert for the following sample measurement.

Transflectance insert



Result	Name:	Base cream DAC
	NIRS Result:	Match
	Value:	99.9% (Limits 98% to 100%)
	Validation:	Available

Operator name:	Smith
Manufacturer/Supplier:	Sample supplier
Use-by date:	November 2016
Batch number:	1234567
PPN:	
Additional tests:	(empty)
Comment:	
Test number:	10

Create report




### 5. Result presentation

After few seconds the instrument will show whether the substance has been identified or not.

**Note:** In case of non-identification please see the additional information. Please check or repeat the measurement.

### 6. Data for the report

Following successful measurement, enter all the compulsory fields for the measurement information. If required, the fields **<Additional tests>** and **<Comment>** can be entered.

As long as this symbol  is visible, additional input data is missing and the analytical report cannot be generated.

### 7. Create report

The measurement report may now be saved, shown as a PDF and printed if required.

**Note:** Irrespective of which of the four functions are selected, the measurement data and result will be saved automatically. Additionally, a label can be printed via a label printer (small printer icon).

## 1. First steps

### 1.1. Safety instructions

Please read the complete safety instructions carefully before using the *Apo-Ident* system.

- Make sure that the input voltage matches the specification on the rating label.
- Avoid using the instrument in high temperatures and high humidity or dusty and aggressive environments.
- The installation location should be well ventilated and the instrument should not be placed in direct sunlight. Install the instrument on a nonflammable, flat surface that does not transfer vibrations to instrument.
- Do not use if the power cord or plug is damaged or the wall socket is loose in any way. If the power cable is defective or shows faults, please replace it with a new one. Working with a defective cable can be hazardous as the instrument works with 230 Volts.
- Please ensure that no liquids or other materials get into the instrument. In the event of material ingress please disconnect the instrument from the electrical supply and contact customer services.
- Do not open the instrument by yourself.
- Do not operate the instrument in an explosive or flammable environment.
- *Apo-Ident* is frequently used for identification of dangerous substances. Only trained and qualified staff should operate the system. If unsure please contact the laboratory manager or the responsible person.

### 1.2. Software installation

- Insert the provided USB stick in your PC.
- Double click on the file QuickStep\_\*.exe and accept the license terms and conditions. Follow the setup instructions as directed by the software.
- Double click on the file named IdentModul\_\*.exe and accept the license terms and conditions. Follow the setup instructions as directed by the software.
- Following a successful installation of the software a certificate will be produced that may be saved or printed as part of your quality system.

### 1.3. Connecting the analytical instrument

*Apo-Ident* requires a power supply and a PC/Laptop with installed *Apo-Ident* software.

Please follow these steps:

- Insert the power supply cable in the socket at the back of the instrument (left side) and connect to an earthed socket of 230 Volts power supply. (The analytical instrument can also work with other power supply systems with earthed connection of 100V - 230 V and 50/60 Hz.)
- Connect *Apo-Ident* with the USB cable provided to a convenient USB port on the computer. The *Apo-Ident* USB port is at the back right-hand side of the unit.
- Switch on the instrument. The power switch is at the back left-hand side of the unit.
  - The indicator light on the top front panel will now show red indicating the system is live.

*Apo-Ident* is now ready to use.

## 1. First steps

### 1.4. Starting the software

Start the *Apo-Ident* software by double-clicking the icon which is on the desktop.

The *Apo-Ident* user interface will open.

**Note:** In case of low internal instrument temperature a warmup phase will start automatically. Please wait until the operating temperature of at least 20°C is reached. Once the respective message has disappeared, the system is ready to start the measurement.

### 1.5. Creating configuration profiles

When starting the program the *Apo-Ident* preferences will open automatically because only one standard profile is deposited. Principally you can proceed first measurements. **However, important information of your pharmacy will be missing on the test report.** Click on the „+“ symbol on the right side.

Enter the name of your pharmacy or department as the profile name and confirm with **<OK>**.

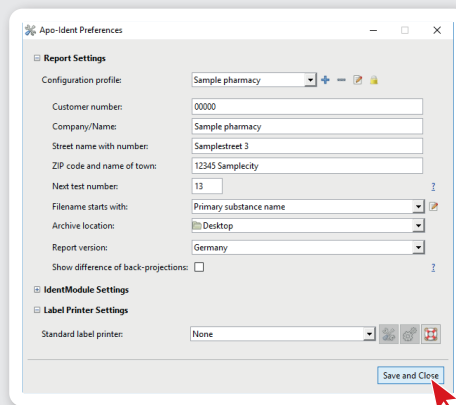
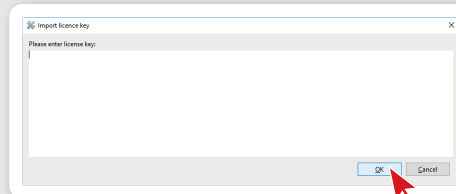
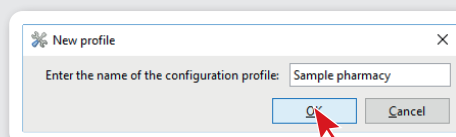
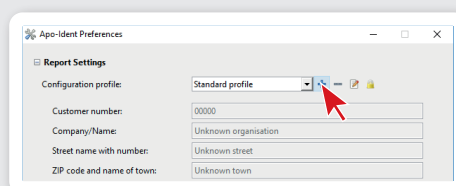
You are requested to enter a license key in the next window. **Please refer to the *Apo-Ident* customer service for support** when creating and completing your profile.

Moreover, you can determine the following:

- How the filename of the test report created by *Apo-Ident* begins → **section 1.6**
- Where the file of the test reports is located → **section 1.7**
- Language or form of the test report (according to corresponding legal procedures or requirements) → **section 1.8**
- Settings for label printing → **section 1.10**

Once you have modified the settings click on **<Save and Close>**. Your user profile is now saved and available for sample analysis.

**Note:** You can assign various user profiles with this function, e.g. when the identification tests are carried out in different franchised pharmacies. Please note that according to the license agreement the *Apo-Ident* shall be used in a maximum of four pharmacies.





## 1. First steps

### 1.6. Selection of naming structure in archive folder

Select the classification for every substance, in order to save the substance name in archives in its particular form. By default, the primary substance name is stored.

Click on the icon with the pen next to **<Filename starts with>**, to adjust settings for the currently selected user profile.

Individually set for every substance category, whether the file name of the test protocol for the primary substance shall be defined in English or in Latin. This setting is only applied for the currently selected user profile. Please consider that the latin name is not available for all substances in the database.

**Note:** You can always modify the name format in the menu bar by selecting **<Preferences>**.

### 1.7. Selection of an individualised archive location of test reports

For every user profile you must select an individual **<Archive location>** for test reports inside settings for problem free archiving.

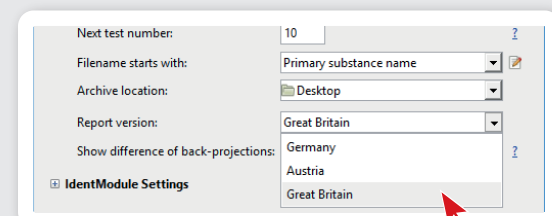
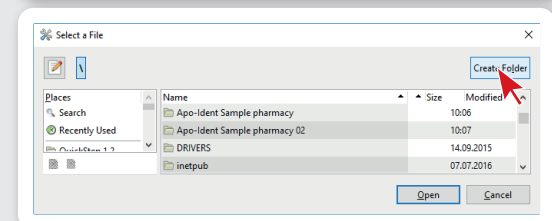
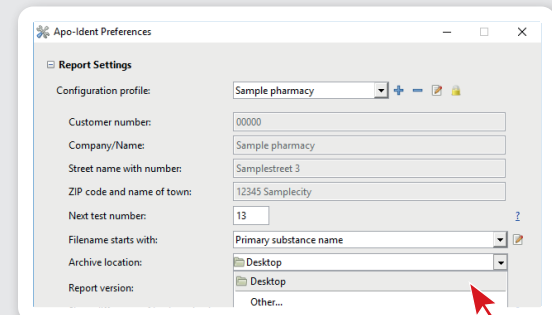
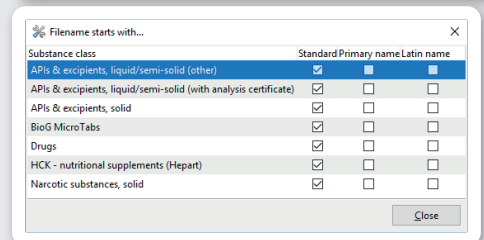
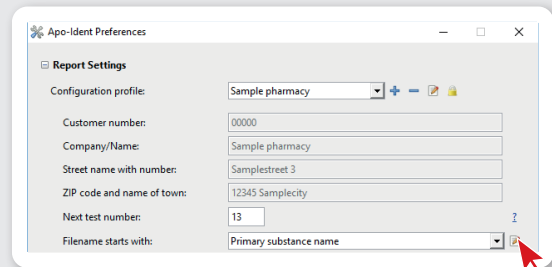
**Note:** As of Version 1.3, the archive is created on the desktop by default.

If you want to create a new archive folder, select **<Archive location>** and then **<Other>**. Another window opens in which you can allocate your individual archive location or create a new folder.

### 1.8. Language and form of the test report

Click right on the arrow next to **<Report version>** and choose language or form of the test report. This setting will only be used for the currently chosen user profile.

This setting affects the test report header as well as the label printout and the ranking display in the PDF.



## 1. First steps

Prior to beginning the measurement, the selected profile may always be chosen in the upper part of the user interface under **Configuration profile**. Please ensure the correct user profile is selected prior to a measurement. Changing the user profile after a measurement results in the data being discarded and so the sample measurement must be repeated.

### 1.9. Settings for label printers

**Brother QL 560 and QL 570 with fanfold paper DK-22205**

#### Installation of driver software

In Windows 10, the drivers are automatically installed after plugging in and turning on the printer.

**Note:** For Windows 7 and Windows 8.1, please install the device drivers prior to switching on the label printer. They can be found on the USB stick also delivered, under useful.

#### Apo-Ident software settings

From **Label printer settings**, select **<Standard label printer>** your printer (Brother QL 560 or QL 570) from the list.

Then select the following\* settings:

- Page size: 62mm
- Orientation: check rotate 0°

#### Advanced Layout Settings:

- Label width / mm: 62,0
- Label height / mm: 35,0
- X-offset / mm: 0,0
- Y-offset / mm: 0,0
- Scale factor: 1,00

\* These figures refer to the use of the continuous label roll type DK-22205.

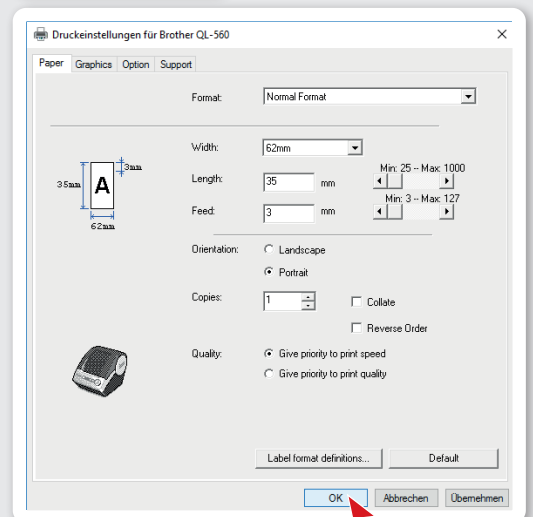
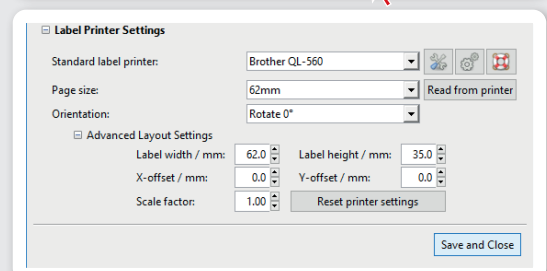
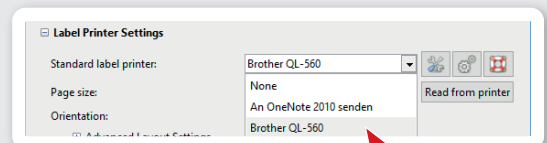
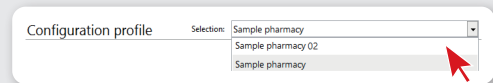
Click the **<tool-icon>** on the right side of the list „Open printer settings“. Change the following settings in the open dialog box:

- Format: Normal Format
- Width: 62mm
- Length: 35,0
- Feed: 3
- Orientation: Portrait

Click on **<Apply>** and confirm with **<OK>**. You are now back to the Apo-Ident software settings.

**Note:** Before you save your settings, you may do a test print. In order to do that, click the middle button next to the description of the chosen printer.

Apply with **<Save and Close>** if your test print was successful. If the test print failed then please contact customer service.



## 1. First steps

### Brother QL 560 and QL 570 with single labels DK-11201

#### Installation of driver software

In Windows 10, the drivers are automatically installed after plugging in and turning on the printer.

**Note:** For Windows 7 and Windows 8.1, please install the device drivers prior to switching on the label printer. They can be found on the USB stick also delivered, under useful.

#### Apo-Ident software settings

From **Label printer settings**, select **<Standard label printer>** your printer (Brother QL 560 or QL 570) from the list.

Then select the following\* settings:

- Page size: 29mm x 90mm
- Orientation: rotate 90° clockwise

#### Advanced Layout Settings:

- Label width / mm: 29,0
- Label height / mm: 89,9
- X-offset / mm: 0,0
- Y-offset / mm: 0,0
- Scale factor: 1,00

\* These figures refer to the use of the single label type DK-11201.

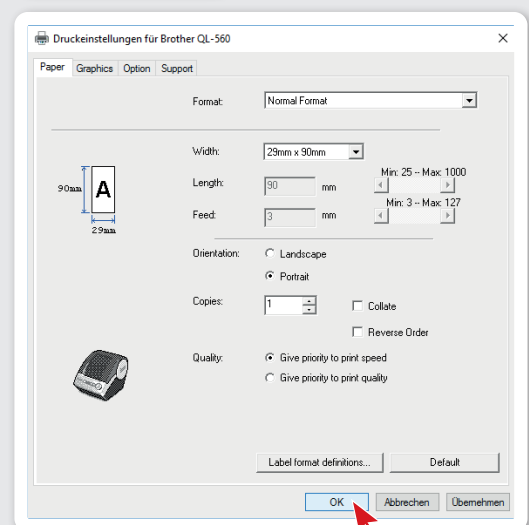
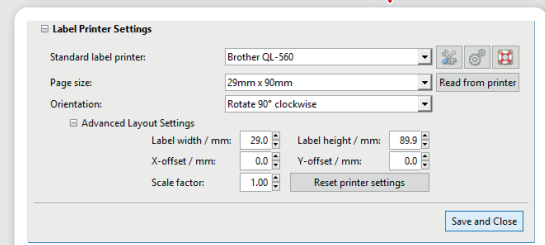
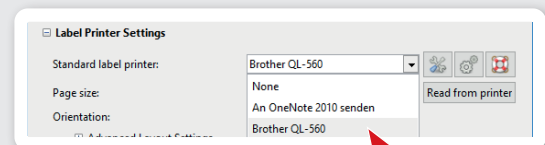
Click the **<tool-icon>** on the right side of the list „Open printer settings“. Change the following settings in the open dialog box:

- Format: Normal Format
- Width: 29mm x 90mm
- Length: 89,9
- Feed: 3
- Orientation: Portrait

Click on **<Apply>** and confirm with **<OK>**. You are now back to the Apo-Ident software settings.

**Note:** Before you save your settings, you may do a test print. In order to do that, click the middle button next to the description of the chosen printer.

Apply with **<Save and Close>** if your test print was successful. If the test print failed then please contact customer service.



## 2. Measurement operation

### 2.1. APIs & excipients solid, narcotic substances solid and drugs, which can be clearly identified with Apo-Ident

Select the category to be examined under **Substance selection**, e.g. „APIs & excipients, solid“.

Then enter the English name of the substance. Alternatively, enter the Latin name (if existing) in the line below.

**Note:** After entering the first letters the software will provide suggestions. Select the correct substance from the list.

The substance is distinctly identifiable if there is a **green button** in front of the name. If the button is yellow or red, please continue reading under section 2.3 or 2.4.

#### Start measurement

Firstly, place your **sample container with the substance** (filling height 2-4mm) and the **distance ring** on the measuring window. Start the measuring process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) directly on top of the instrument.

**Note:** Some substances can also be identified using a lower quantity of the substance. You can find the corresponding process in the box on the next page.

#### Referencing


After the first measurement after switching on the Apo-Ident, the external reference standards are requested to be put onto the measurement window for measurement: Black and white reference (Zenith).

**Note:** Please make sure to use always the distance ring. The measurement of the references will have to be repeated upon request by the software from time to time. Please follow the instructions of the software.

After few seconds the instrument will show whether the substance has been identified or not.

**Note:** In case of non-identification please see the additional information. Please check or repeat the measurement.

Following successful measurement, enter all the compulsory fields for the measurement information. If required, the fields **<Additional tests>** and **<Comment>** can be entered.

As long as this symbol  is visible, additional input data is missing and the analytical report cannot be generated.

The measurement report may now be saved, shown as a PDF and printed if required.

**Note:** Irrespective of which of the four functions are selected, the measurement data and result will be saved automatically. Additionally, a label can be printed via a label printer (small printer icon).

Class:	APIs & excipients, solid
Name:	Tetrac
Latin:	<div><div></div>Tetracaine base</div> <div><div></div>Tetracaine hydrochloride</div>

Start measurement



Black reference



White reference (Zenith)



Result

Name: **Sodium citrate**  
[NIRS Result:](#) **Match**  
[Value:](#) **99.9%** (Limits 98% to 100%)  
[Validation:](#) Available

Operator name:	Smith
Manufacturer/Supplier:	Sample supplier
<a href="#">Use-by date:</a>	November 2016
Batch number:	1234567
PPN:	
<a href="#">Additional tests:</a>	(empty)
Comment:	
Test number:	10

Create report



## 2. Measurement operation

### Measurement with sample insert for small amounts of substances

Some substances in the **classes APIs & excipients solid, narcotic substances solid and drugs** can also be identified using a lower quantity of the substance. Here, you need the **sample insert** and its **white reference for the sample insert** which is required for referencing.

An overview of all substances which may be measured with the sample insert, may be found under **<Help> - <Subscribed substances with sample insert>**.

Select the category to be examined under **Substance selection** „APIs & excipients, solid“.

Then enter the English name of the substance. Alternatively, enter the Latin name (if existing) in the line below.

If you have selected a corresponding substance, the checkbox **<Use sample insert>** appears on the right-hand side when you **start measurement**. Add a tick when using the sample insert.

**Note:** After entering the first letters the software will provide suggestions. The sample should be filled to a height of about 4mm in the sample insert.

Firstly, place your **sample container with the sample insert** and **substance** with the **distance ring** on the measurement window. Start the measuring process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) directly on top of the instrument.

After the first measurement after switching on the *Apo-Ident*, the external reference standards are requested to be put onto the measurement window for measurement. Please use the black reference and the **correct white reference for the sample insert**, otherwise non-identification results.

**Note:** The measurement of the references will have to be repeated upon request by the software from time to time.

After few seconds the instrument will show whether the substance has been identified or not. Following this, proceed as usual.



Substance selection	Class: APIs & excipients, solid	
	Name: Betamethasone valerate	
	Latin: Betamethasoni valeras	
Transflectance reference	<input checked="" type="checkbox"/>	
Start measurement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Use sample insert



## 2. Measurement operation

### 2.2. APIs & excipients, liquid/semi-solid, which can be clearly identified with *Apo-Ident*

#### Transflectance reference

Start with the transflectance reference without the liquid/semi-solid. Put the transflectance insert with the little feet facing the bottom into an empty sample container. Following this, place the container with the transflectance insert on the measuring window of the *Apo-Ident* instrument. Start the transflectance reference by clicking on the green button.

**Important:** Both, the transflectance reference as well as the liquid/semi-solid have to be measured with the same transflectance insert and sample container. Otherwise this may result in non-identification.

**Note:** Having the initial transflectance reference successfully completed, the measurement of substances has to commence within a time frame of five minutes. Otherwise the transflectance insert measurement must be repeated.

#### Referencing

After the transflectance reference, the external reference standards are requested to be put onto the measurement window for measurement.

Please pay attention to the instructions in chapter 2.1.

#### Start measurement


Place your sample container with the substance, the transflectance insert and the distance ring on the measuring window. Start the measuring process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) directly on top of the instrument.

**Note:** Ensure that you press the transflectance insert down properly with its feet downwards in the sample container so that no air pockets are visible.

After few seconds the instrument will show whether the substance has been identified or not.

**Note:** In case of non-identification please see the additional information. Please check or repeat the measurement.

Following successful measurement, enter all the compulsory fields for the measurement information. If required, the fields **<Additional tests>** and **<Comment>** can be entered.

As long as this symbol  is visible, additional input data is missing and the analytical report cannot be generated.

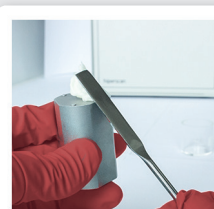
The measurement report may now be saved, shown as a PDF and printed if required.

**Note:** Irrespective of which of the four functions are selected, the measurement data and result will be saved automatically. Additionally, a label can be printed via a label printer (small printer icon).

Class:	APIs & excipients, liquid/semi-solid (with analysis certificate)
Name:	Dexpanthenol
Latin:	Dexpanthenolum

Transflectance reference  Please use the same transflectance insert for the following sample measurement.

Transflectance insert



Name: **Base cream DAC**  
Result: **NIRS Result: Match**  
Value: **99.9%** (Limits 98% to 100%)  
Validation: Available

Operator name:	Smith
Manufacturer/Supplier:	Sample supplier
Use-by date:	November 2016
Batch number:	1234567
PPH:	
Additional tests:	(empty)
Comment:	
Test number:	10

Create report





## 2. Measurement operation

### 2.3. Particularities for substances with indeterminate test results

Substances which are not clearly identified with *Apo-Ident* will be indicated by a yellow icon in front of the substance name.

For further information click on the icon .

Click **<Show as PDF>** if you want to print this information.

For exact identification, an additional test (or tests) may be required. The method and the result may be entered directly in the software (under **<Additional tests>**) or handwritten on the test report. The final result information should be completed in the appropriate fields.

Substance selection

Class:	APIs & excipients, liquid/semi-solid (with analysis certificate)
Name:	Cool
Latin:	<input type="radio"/> Cooling cream DAB <input type="radio"/> Cooling cream DAB 6 (stabilised, contains rose oil)







**Substance not conclusively distinguishable**

The selected substance 'Cooling cream DAB 6 (stabilised, contains rose oil)' is not conclusively distinguishable by near-infrared spectroscopy (Apo-Ident) from following substances:

Substance name	Latin name
Cooling cream DAB	Unguentum leniens

Apo-Ident combines these substances in the classification 'Cooling cream / Cooling cream with rose oil'. In order to get a conclusive test result, additional tests are necessary to distinguish within this classification.

[Show as PDF](#) [Close](#)

Configuration profile	Selection: Sample pharmacy
Substance selection	Class: APIs & excipients, liquid/semi-solid (with analysis certificate) Name: Cooling cream DAB 6 (stabilised, contains rose oil) Latin: Unguentum leniens DAB 6
Transflectance reference	
Start measurement	 Please use the same transflectance insert for the reference and sample measurement.
Result	Name: Cooling cream / Cooling cream with rose oil <a href="#">NIRS Result:</a> Match (Additional Tests required) <a href="#">Value:</a> 99.5% (Limits 98% to 100%) <a href="#">Validation:</a> Available
Report details	Operator name: Smith Manufacturer/Supplier: Sample supplier <a href="#">Use-by date:</a> October 2016 Batch number: 1234567 PPN: <a href="#">Additional tests:</a> (empty) Comment: Test number: 10
Create report	    <a href="#">Show group as PDF</a>

The method and the result of the measurement should be entered in the software under **<Additional tests>**.

If the additional test results are available you may confirm if the substance is positively identified by clicking the check box ☒ **<Identified>**.

**Additional Tests (Method and Result)**

Yellowish white paste, odour slightly like rose oil

Final result: ☒ Identified ☐ Discard

[Approve](#) [Discard](#)

## 2. Measurement operation

The text entry and the final result will be displayed in the report.

### Result NIRS:

**The sample has been identified as a substance within the group Cooling cream / Cooling cream with rose oil\*.**

Value: 99.5% (limits 98.0% to 100%)

All other substances of the database have been excluded on the basis of the NIR spectrum. The test result is only conclusive with additional tests which differentiates within the group.

*\* Cooling cream DAB 6 (stabilised, contains rose oil); Cooling cream DAB*

Additional tests:  
(Method and result)

Yellowy white paste, odour slightly like rose oil

### Conclusion:

Cooling cream DAB 6 (stabilised, contains rose oil) has been clearly identified.

Approved by:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date/Signature

### Handwritten entry of additional testing results on printed report

If the additional testing will be carried out at a later time, the final result has to be checked on the printed test result when completed. The checkbox ☒ **<Identified>** must **not** be clicked in the software.

### Result NIRS:

**The sample has been identified as a substance within the group Cooling cream / Cooling cream with rose oil\*.**

Value: 99.5% (limits 98.0% to 100%)

All other substances of the database have been excluded on the basis of the NIR spectrum. The test result is only conclusive with additional tests which differentiates within the group.

*\* Cooling cream DAB 6 (stabilised, contains rose oil); Cooling cream DAB*

Additional tests:  
(Method and result)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### Conclusion:

Cooling cream DAB 6 (stabilised, contains rose oil) has been clearly identified.

☐ Yes    ☐ No

Approved by:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date/Signature



## 2. Measurement operation

### 2.4. Particularities for substances which are not identified with *Apo-Ident*

Substances which cannot be identified with *Apo-Ident*, e.g. because they do not have a sufficient signature in the NIR, will be clearly indicated in red after the substance name is entered. A message box with additional information will also be displayed.

For identification of this substance a different test method is required.

However the *Apo-Ident* software can provide you with the test report. Just click **<OK>**.

The method and the result may be entered directly in the software (under **<Tests>**) or handwritten on the test report. The final result information should be completed in the appropriate fields.

Substance selection

Class: APis & excipients, solid

Name: selen

Latin: Natrii selenas

Class: APis & excipients, solid

Name: Sodium selenate

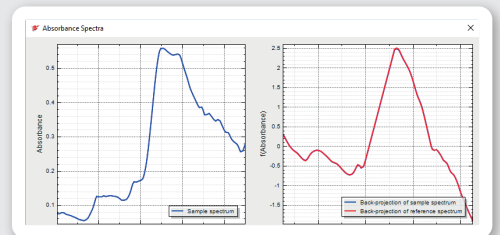
Latin: Natrii selenas

Substance 'Sodium selenate' cannot be identified by Apo-Ident. Please use another identification method.

You can create a protocol anyway. Please complete the required fields for this substance.

Otherwise please select another substance.

**OK**



### Test report for identity verification of raw substances

**Sample pharmacy**  
Samplestreet 3, 12345 Samplecity

06/10/2016

Tested substance: Sodium selenate  
Natrii selenas

Batch number: 123

Manufacturer/Supplier: Sample supplier

Use-by date: October 2016

Test number: 11

Operator name: Smith

Report file: Sodium\_sel\_\_123\_\_2016-10-06\_15-04-42.pdf

Comment:

Tests:  
(Method and result)

**Conclusion:** Sodium selenate has been clearly identified.

☐ Yes ☐ No

Approved by:

Name

Date/Signature

### 3. Additional functions

#### 3.1. Consistency percentage and control input

The confidence limits for identification are displayed after the reported value. If the measured spectrum is outside of the limits the substance will not be identified and designated as „No match“

By clicking on the hyperlink **<NIRS Result>** you may view the measured spectrum.

#### 3.2. Display of the difference between the sample and the reference

If required, you are able to view the difference between the spectrum of the sample and the reference in the displayed graphs (this is only possible for positive substance identification). Please note that only the right-hand graph will display the difference spectrum for ease of interpretation.

Under **<Preferences>** check **<Show difference of back-projections>** to have the line displayed in the report. The button **<Save and Close>** completes the input.

#### 3.3. Search function (query) for substance, expiration date or custom criteria

This feature lets you review test reports or labels and print them.

Click the button **<Query>** in the menu bar.

The search window depicted on the right will open.

Adjust the user/configuration profile on top for the search query if necessary. For example, in the tab **<Substance>**, enter the name of the substance for which you want to find the test reports. Click **<Execute>**. All test reports containing the entered search text will be shown.

In order to search for the expiration date, click on the tab **<Use-by Date/Shelf Life>** and enter the data needed.

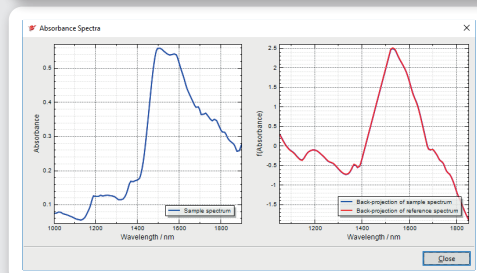
After running the query you may choose the relevant substance in the result window and view information about the measurement or report. Additionally, you may print the test report or label again.

Name: **Glucose monohydrate**

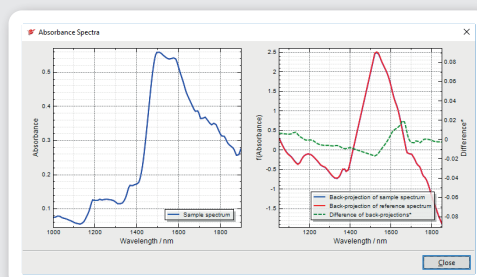
Result **NIRS Result** **Match**

Value: **99.9%** (Limits 98% to 100%)

Validation: Available



Graph without display of difference



Graph with display of difference

Archive Query

Configuration profile: Sample pharmacy

Substance Use-by Date/Shelf Life Advanced

Search for substance with given name, test number or PPN.

Substance name, test number or PPN:

Execute

Primary Name: Latin Name/Manufacturer/Supplier Batch Number Test number PPN Timestamp/Use-by Date/Shelf Life

Information Show Report Print Report Print Label

Save Copy to ... Close

Archive Query

Configuration profile: Sample pharmacy

Substance Use-by Date/Shelf Life Advanced

Search for substances with use-by date/shelf life in the time period

from October 2016 to October 2016

Execute 2 matches found.

Primary Name	Latin Name	Manufacturer/Supplier Batch Number	Test number	PPN
Cooling cream DAB 6 (stabilised, contains rose oil)	Unguentum Ictericum DAB 6	Sample supplier	1234567	10
Sodium selenate	Natrii selenas	Sample supplier	123	11

Information Show Report Print Report Print Label

Save Copy to ... Close

### 3. Additional functions

Under the tab **<Advanced>** you are able to define your own search criteria. You may also search for the operator, supplier or a batch number.

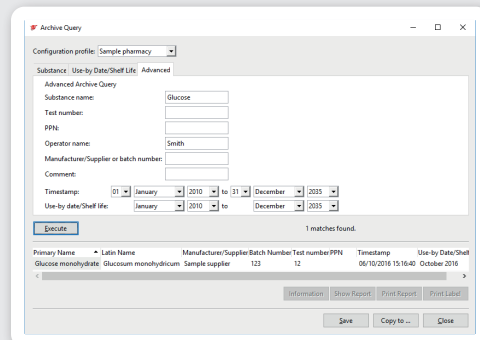
In the query **<Timestamp>** you are, for example, able to request all measurements starting from the 01-01-2016.

#### Export of query results in CSV format

Results of the query may be saved in CSV format by clicking **<Save>**. You may open these in a CSV compatible program (like MS Excel) to either print the list or continue using it.

#### Copy data to customised locations (e.g. onto a USB flash drive)

If you want to copy the found data to a custom location, please click the **<Copy to...>** button and select the desired location. All data pertinent to the search criteria will be copied.

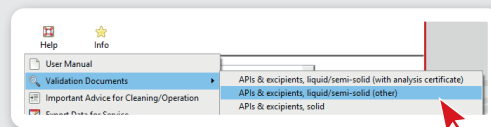


#### 3.4. Display of validation documents

Click on **<Help>** in the menu bar on top.

Now choose the relevant document.

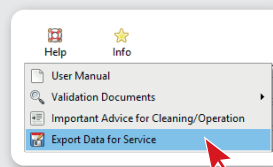
After a successful measurement, you may open the validation document of the presently identified substance directly via the *Apo-Ident* interface. To open the document, click on **<Validation>** in the result area.



#### 3.5. Export data (e.g. for Apo-Ident customer service)

To send your test reports or to save for the purpose of data backup, click on **<Help>** in the menu bar on top.

Choose **<Export Data for Service>** and continue as described in section 3.6



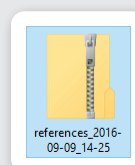
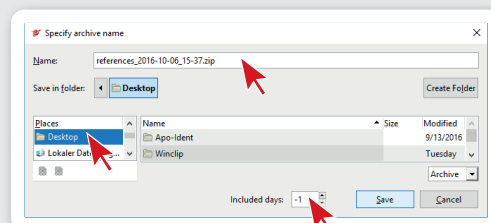
#### 3.6. Custom selection of the number of measuring days for saving or sending data

This feature lets you save your spectra compressed in a ZIP file. You may set how many measurement days you want to summarise and send or save in the following way. Only whole days are possible for this feature:

- -1 = all days
- 1 = 1 day
- 2 = 2 days
- and so on

Click **<Save>**. Afterwards, the according archive file will be displayed on your desktop. Of course, you may choose another location as well.

This file is now available for forwarding by email if required.



### 3. Additional functions

#### 3.7. Details of identification (ranking)

*Apo-Ident* compares the measured spectrum with the other samples saved in the spectral reference library. A maximum of 20 results of the highest consistency may be displayed in the ranking table. In order to view the ranking table, please click the hyperlink **<Value>** in the result section of the user interface.

A table will then be displayed which provides all the identification criteria. If you select the button **<Show as PDF>**, you will get the displayed table in PDF format and you may print and file it together with the test report.

At the first position (rank 1) the reference substance with the **highest consistency with the sample** will be displayed. If the criteria for the identification of the substance are met, it will be displayed in **green**.

Thereafter, the nearest reference substances follow in **red**. These are not directly considered in the evaluation of the measured spectrum of the sample. Please note that the name in the ranked list (classification) may differ from the substance name for substances which are summarised in groups. The group name will then be displayed (e.g. "triglycerides").

This figure supports the confirmability and validation of the identification results by the user.

You can find an explanation of the particular terms on the next page.

Name: **Glucose monohydrate**

Result

NIRS Result: **Match**

Value: **99.9%** (Limits 98% to 100%)

Validation: Available

Identification details							
Ranking	Classification	Sample ID	Significance	Confidence	Correlation	Distance	Value
1	Glucose monohydrate	20031	0.9992	0.9992	0.9999	2.7	99.92%
2	Potassium tartrate hemihydrate	20999	0.9558	0.9076	0.9955	22.3	0.00%
3	Potassium tartrate hemihydrate	21440	0.9373	0.8063	0.9964	26.2	0.00%
4	Lactose monohydrate	20029	0.9309	0.9238	0.9905	30.3	0.00%
5	Levothyroxine sodium	21820SI	0.8920	0.7375	0.4612	41.5	0.00%
6	Borax	20179	0.8762	0.6258	0.8753	51.5	0.00%
7	Arginine	20391	0.8716	0.7486	0.8530	46.8	0.00%
8	Allantoin	20079	0.8561	0.5706	0.7040	63.1	0.00%
9	Levothyroxine sodium	21708	0.8496	0.4669	0.5237	68.3	0.00%
10	Aciclovir	21677	0.8481	0.8602	0.9089	33.0	0.00%
11	Levothyroxine sodium	21708SI	0.8421	0.1656	0.4582	73.1	0.00%
12	Calcium orotate dihydrate	20418	0.8417	0.2483	0.9431	74.8	0.00%
13	D-(-)-Mannose	21035	0.8379	0.3894	0.9617	75.4	0.00%
14	Potassium sodium tartrate tetrahydrate	20782	0.8349	0.2741	0.9798	75.2	0.00%
15	Glucose, anhydrous	20982	0.8280	0.4188	0.9749	57.1	0.00%
16	Tannin	20018	0.8279	0.2466	0.9345	85.7	0.00%
17	Starch	20181	0.8264	0.2812	0.9077	70.9	0.00%
18	Potassium sodium tartrate tetrahydrate	21801	0.8252	0.2044	0.9795	81.0	0.00%
19	Magnesium orotate dihydrate	20429	0.8236	0.0260	0.8795	95.5	0.00%
20	Morphine sulfate	21184SI	0.8220	0.3040	0.1360	100.9	0.00%

## 4. Explanation of Terms

Name	Explanation	Valuation
<b>Ranking</b>	Determined degree of consistency of the measurement compared against the reference samples deposited in the database	
<b>Classification</b>	Substance or substance group clearly distinguishable by <i>Apo-Ident</i> ; A substance group represents several substances which are not distinguishable by <i>Apo-Ident</i> but are available for measurement (e.g. "triglycerides"). For a clear identification further tests are generally necessary	Indication green = identified red = not identified
<b>Sample ID</b>	Identification number of reference samples given by <i>HiperScan GmbH</i> to the spectra of substances which define the basis of the <i>Apo-Ident</i> library; Detailed information for all reference samples may be taken from the validation documentation	
<b>Significance</b>	Measure for the distance of the measurement result regarding to the mean value of the reference measurements of a sample or classification	The greater the value (maximum 1), the closer the spectrum of the sample lies to stored reference values.
<b>Confidence</b>	Outlier evaluation	The higher the value (maximum 1) the nearer the measured spectrum of the sample fits to the stored reference spectra.
<b>Correlation</b>	Statistical measure for the similarity between the back-projection of the mean of the stored reference spectra and the back-projection of the measured spectrum of the sample.	The higher the value (maximum 1) the greater the correlation of the back-projection.
<b>Distance</b>	Distance measure between the mean of the stored spectra of a reference sample and the measured spectrum as a function of the principal component space (Mahalanobis distance)	The smaller the value, the closer is the spectrum of the sample to the stored reference values.
<b>Value</b>	Uses the minimum of significance, confidence and correlation. Any rank after rank 1 forces evaluation to zero.	The greater the value (maximum 100 %), the closer the sample is to the stored reference values. The defined minimum value for an identification is 98 %.
<b>Specificity</b> (only for substance class of PhytoComm)	The specificity of a classification is the true negativ rate. Only if all false samples are rejected, specificity is 100 %.	
<b>Recognition rate</b> (only for substance class of PhytoComm)	This is the true positiv rate. It defines the amount of correctly classified spectra in the validation run.	

## 5. Important note

### 5.1. Correct filling of sample container

#### *Transflectance reference measurement*

Please be careful that the sample container is placed inside the **black distance ring**. Place the transflectance insert with the little feet facing the bottom into a clean, empty sample container. Then place the sample container with the transflectance insert onto the measurement window of the *Apo-Ident* instrument.



**Important:** The initial transflectance reference as well as measuring liquids/semi-solids must be performed with the same transflectance insert and sample container. Otherwise this may result in non-identification.

**semi-solids:** after the transflectance reference measurement, remove the transflectance insert from sample container and hold it in hands with little feet pointing upwards. Using a narrow spatula, take a pea sized sample of the substance to measured and place it on the top of the transflectance insert (as shown).

Place the sample container over the transflectance insert and rotate to evenly distribute the sample over the surface. Firmly press the insert so that **all three feet** may be seen touching the bottom of the container. Please make sure that there are **no air pockets** under the transflectance insert.

**liquids:** after the transflectance reference measurement remove the transflectance insert from the sample container. Pour a little liquid in the container so that its **base is completely covered**. Place the transflectance insert with feet pointing downwards in the sample container. A small amount of the liquid sample should be visible between the transflectance insert and the sample container sides. Inspect the container to make sure there are **no trapped air bubbles** in the measurement area.



## 5. Important note

### 5.2. Cleaning/operation of sample container, transfectance insert and sample insert

#### Sample container

##### Cleaning:

- After every measurement clean the sample container first with tissue paper. This is especially recommended after the measurement of ointments and emulsion.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry it with a lint-free cloth.
- Before using a sample container, rinse with 70 % isopropyl alcohol and dry it with a tissue paper.

***Before measurement, please take care that the bottom of the container is clean and free from contamination.***

***No water marks should be visible.***

#### Transfectance insert

##### Instructions for use:

Scratches between the transfectance insert feet or strong colour change can influence the identification process. Therefore please handle the transfectance insert carefully.

- Never clean the transfectance insert with a scourer, spatulas or other abrasive materials.
- The transfectance insert is not suitable for cleaning in a dishwasher.

##### Cleaning:

- Clean the transfectance insert after measurement with a tissue paper.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry with a lint-free cloth.
- Before using the transfectance insert, rinse with 70 % isopropyl alcohol and dry it with a tissue paper.

#### Sample insert for the measurement of small samples

##### Cleaning:

- After a measurement using the sample insert, gently tap the sample container to release powder residues.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry with a lint-free cloth.
- Before using the sample insert rinse with 70 % isopropyl alcohol and let it dry.

#### Measurement window

Please make sure that the measurement window of the *Apo-Ident* instrument is always clean and free from contamination. We recommend a lint free cloth soaked in 70 % isopropyl alcohol for cleaning purposes.

If you use the sample container to prepare a pharmaceutical product please ensure that all surfaces that come into contact with the substance is free from any microbial contamination.

## 6. Technical data and disposal

### 6.1. Technical data

Analytical method	Near-infrared spectroscopy
Measuring time	< 15 seconds
Spectral range	1,000 - 1,900 nm
Spectral resolution	10 nm
Wavelength accuracy	$\pm 1$ nm
Wavelength reproducibility	$\pm 0.3$ nm
Automatic recalibration/ equipment check	integrated wavelength and white standard
Operating temperature	15 - 35 °C
Dimensions	232 x 210 x 282 mm
Weight	5.2 kg
Interface	USB, Typ B
Operating voltage	100 - 240 V~/50/60 Hz/60 W
Software	<i>QuickStep Apo-Ident</i>
System requirements	<ul style="list-style-type: none"><li>• PC with Windows Vista, Windows 7 (except Starter version), Windows 8, Windows 10, Linux</li><li>• min. 1 GB RAM</li><li>• min. 1.6 GHz Pentium</li><li>• 0.5 GB disk space</li></ul>



The instrument complies with the following EG-Standards:

- EMC Directive 2014/30/EU
- Low voltage directive 2014/35/EU
- RoHS Directive 2011/65/EU

### 6.2. Disposal



According to European WEEE standards, the electrical and electronics instruments are not allowed to be disposed of in domestic waste. Recycling or disposing would be carried out because incorrect disposal can sustainably damage the health and environment, created by toxic and dangerous components.

Please do not hesitate to contact us if you have any further questions.



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