



## Operating manual

for Apo-Ident NIR analyser  
based on version 2.3



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## 1. Starting the software

Start the 'QuickStep Apo-Ident' software by double-clicking on the desktop icon. This will open the Apo-Ident user interface.

**Note:** If the device's internal temperature is too low, a warm-up phase will start automatically. Once a temperature of at least 20°C has been reached, the system will be ready to start.

## 2. Selecting the configuration profile

Choose your stored pharmacy under **Configuration profile**, if you have more than one configuration profile.

**Note:** Our detailed instructions on page 7 explain how to create a configuration profile.

## 3. Selecting the substance

Under **Substance selection**, enter the name of the raw material due to be tested in the search field, e.g. Sodium citrate.

The name of the substance, the Latin name and the classifier that will process the spectrum will be shown.

**Note:** The software will start providing suggestions once you enter the first letter. Select the correct substance from these suggestions

**Help:** If the NIR analysis can provide an unambiguous result for the selected substance, the search field will turn green. All information on colour-coding is available on page 11.

## 4. Measuring by substance category

### 4.1. APIs & excipients (solid) and narcotic substances (solid)

#### Starting the measurement

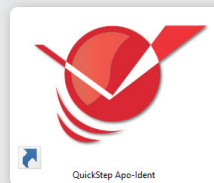
First place your **sample cup containing the substance** (fill height 2 - 4 mm) and the **adapter ring** onto the measurement point. Start the measurement process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) on the top of the device.

**Note:** Some substances can also be identified using smaller quantities. The relevant procedure can be found in our detailed instructions on page 12.

#### Referencing

After the first substance measurement, you will be asked to place the reference standards onto the measurement point. Follow the software's instructions and place first the black reference, then the white reference, on the measurement point.

**Note:** Please always use the black adapter ring. The software will request the reference measurement after approx. 100 min.



Substance selection

|             |                          |
|-------------|--------------------------|
| Search:     | Sodium citrate           |
| Classifier: | APIs & excipients, solid |
| Name:       | Sodium citrate           |
| Latin:      | Natrii citras            |

Start measurement  Apply the sample cup with the selected substance.



black reference



white reference



## 4.2. APIs & excipients (semisolid/liquid)

### Transflectance reference measurement

Start with the transflectance reference measurement. Place the clean **transflectance insert** feet-down into a clean, **empty sample cup**. Using the **adapter ring**, place the cup, with the transflectance insert, onto the Apo-Ident device's measurement point. Start the **transflectance reference measurement** by clicking the green button.

**Important:** Both the transflectance reference measurement and the liquid/ointment measurement must be conducted using the same transflectance insert and sample cup, otherwise identification may not be possible.

**Note:** Once the transflectance reference measurement has been successfully completed, start the substance measurement within 5 minutes. If no measurement is taken during this period, the transflectance reference measurement must be repeated.

### Referencing

After the transflectance reference measurement has been carried out, you will be asked to place the supplied reference standards onto the measurement point.

Please follow the referencing instructions under 4.1 of the Quick Reference User Guide.

### Starting the measurement

Place your **sample cup containing the substance**, the **transflectance insert** and the **adapter ring** onto the measurement point. Start the measurement process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) on the top of the device.

**Note:** Make sure you press the transflectance insert feet-down onto the bottom of the sample cup properly so that no air bubbles are visible.

## 5. Result

After a few seconds, the device will show you whether the substance has been identified.

**Note:** In the event of a negative result, please read the further information on non-identification. Check/repeat your measurement process accordingly.

## 6. Report details

Following successful measurement, complete all mandatory fields in the **Report details** section. The fields **Correction factor weighing**, **Comment** and **Additional tests** may be completed if necessary.

If you see a warning sign ⚠ in any of the input fields, it means input is still missing and the report cannot yet be created.

## 7. Creating the report

You can now save the measurement result, view the test report as a PDF file, or print it out.

**Note:** Once you select one of the icons, the measurement result will be saved automatically. You may also print out a label using your label printer (small printer symbol).

Transflectance insert



Transflectance reference

Apply the transflectance insert to an empty sample cup. Please use the same transflectance insert and sample cup for the following measurement.



Result

Name: **Sodium citrate**  
 NIRS Result: **Match**  
 Value: **99,9%** (Limits 98% to 100%)  
 Validation: Available

Report details

Operator name:   
 Manufacturer/Supplier:   
 Batch number:   
 PPN:   
 Use-by date:  2025  
 Corr. factor weighed portion:   
 Comment:   
 Additional tests:   
 Test number:

Create report



### 1.1. Safety instructions

Please read the safety instructions carefully.

- Make sure the input voltage matches the voltage shown on the type plate.
- Environmental factors such as high temperatures and high air humidity should be avoided just as much as dust, dirt and aggressive gases.
- The installation site should be well aerated and not exposed to direct sunlight. Set the device up on a flat, non-flammable surface that does not transmit any vibrations.
- If the power cord is defective or damaged, please immediately replace it with a new one. Using a defective cord can be extremely hazardous, as the device operates at 230 V~.
- Make sure no materials or liquids get into the device. If they do, immediately unplug the device and contact the manufacturer.
- Do not open the device.
- Do not use the device in explosive or easily flammable environments.
- Apo-Ident is often used to identify hazardous substances. This type of work should only be performed by qualified staff. If you are not totally sure, contact your supervisor or an expert.

### 1.2. Software installation

- Connect the provided USB stick to your computer.
- Drag the 'Apo-Ident' folder to your desktop and open the 'Current software' folder contained inside it. Start the installation process by double-clicking QuickStep\_\*.exe. Read and accept the licensing conditions, and follow the setup assistant.
- Then double-click the IdentModul\_\*.exe file. Read and accept the licensing conditions, and follow the setup assistant.
- If the installation is successful, you will then be shown an update certificate. Save this in the 'Apo-Ident/Update certificates' folder, stating the version or the date.

### 1.3. Connecting the analytical instrument

Apo-Ident needs a power connection and computer/laptop (see p. 24 for system requirements) installed with Apo-Ident software.

Follow these steps:

- Insert the power cord into the socket on the back of the device and connect it to a 230-V earthed socket. (The analytical instrument also operates on any other conventional earthed power supply from 100 V to 240 V~ and 50/60 Hz.)
- Connect Apo-Ident to a USB port on the computer/laptop using the USB cable provided. The Apo-Ident's USB port is located on the back of the device.
- Turn on the device. The power switch is also on the back.
- The indicator light on the top front panel will be red, signalling that Apo-Ident is now ready to use.
- Once you have selected a substance, the light will turn green, and you can start measuring.

### 1.4. Starting the software

Start the 'QuickStep Apo-Ident' software by double-clicking the desktop icon. This will open the Apo-Ident user interface.

**Note:** If the device's internal temperature is too low, a warm-up phase will start automatically. Once a temperature of at least 20°C has been reached, the system will be ready to start.

### 1.5. Apo-Ident settings

When the program starts for the first time, the settings will automatically be displayed. A demo profile used for presentations is set as the default. **With this demo profile you won't be able to create any valid test reports.**

#### 1.5.1. Test-report settings

**Configuration profile** > Click on the „+“ symbol on the right of the configuration profile to create your own profile.

Enter your pharmacy's name as your profile name, and confirm by pressing **<OK>**.

This will open another window asking you to enter your licence key.

**Note:** If you are using Apo-Ident in more than one pharmacy, you will need an individual licence key and an individual configuration profile for every pharmacy.

For new customers, the licence key is entered by our sales staff upon delivery.

Thereafter, you will find it on the desktop as a PDF under 'Licence documents' in the 'Apo-Ident' folder or on the USB stick provided.

You will need your licence key again in the following cases:

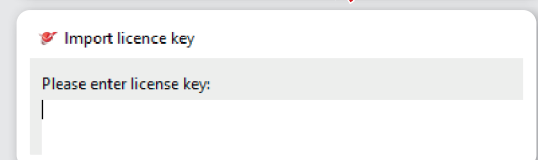
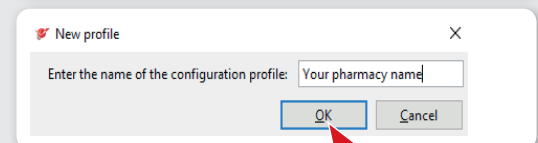
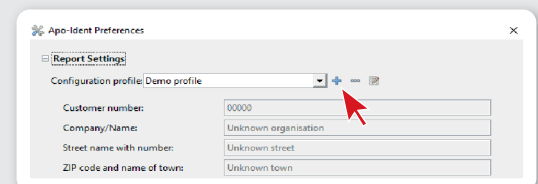
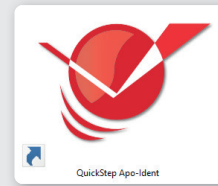
- New installations
- A change of computer

Existing customers will have received their licence key from us by e-mail. Copy the licence key from the PDF file and enter it.

**Note:** Existing customers from before 06/2017 will not have received a licence key with their Apo-Ident delivery. We can provide this to you upon request via e-mail at [kundenservice@apo-ident.de](mailto:kundenservice@apo-ident.de).

Confirm this by clicking **<OK>**. This will store your address data for the test report in your profile.

**Note:** If your pharmacy name or address changes, a new key will have to be requested.





**File name starts with** > This is where you can select whether the 'Primary substance name' (English) or 'Latin substance name', if available, is to be used in the test-report file name.

**Archive location** > If one profile has been created, the software automatically saves the archive (test reports) on the desktop at: *Desktop/Apo-Ident/Archiv/Profile\_Name1*

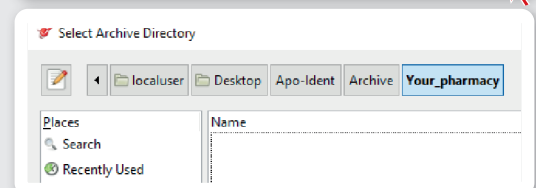
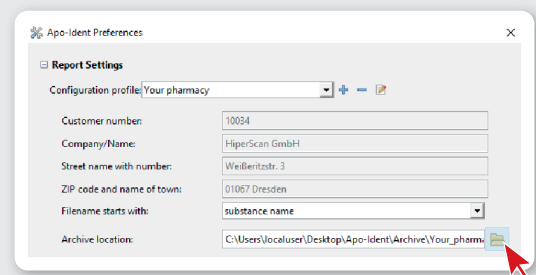
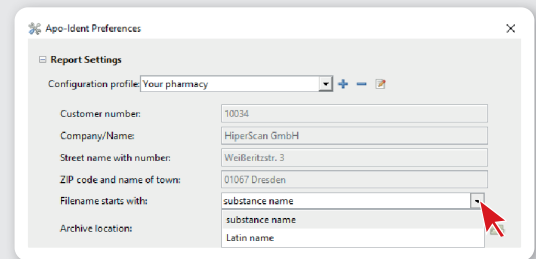
If a second profile has been created, the software also automatically saves the second archive at: *Desktop/Apo-Ident/Archiv/Profile\_Name2*

This prevents multiple profiles from being saved in the same archive, and safeguards against errors when retrieving archives.

**Note:** During initial installation by our sales staff, the 'Apo-Ident' folder structure will be created for you. The archive is integrated into this. If you wish to set a different storage location, move the entire 'Apo-Ident' folder from your desktop to the new location beforehand. This new location could be a local drive or a network drive on your computer. You can change the archive directory by clicking the folder icon in the settings. On the left, select the relevant drive in the 'Select archive directory' window that appears, and on the right the folder to which you wish to move the 'Apo-Ident' folder. Your changes will be applied when you close the settings. The 'Archive' button in the menu bar enables you to check whether the new path has been implemented.

**Report version** > Use this function to select the language/format of the test report for the selected profile. The setting applies to the report heading, printed label and rankings list (PDF).

**Note:** If you realise that the report version needs to be changed after the report has been checked and saved, make the necessary changes under Settings and re-save the report. This avoids you having to repeat the measurement.



## 1.5.2. Ident-Modul settings

Leave the settings with their defaults (ID: 'Local Ident module').

## 1.5.3. Label-printer settings

### Installing driver software

First install the drivers, which can be found under Useful/Brother drivers on the USB stick supplied. Select your model and launch the D\_SETUP.exe application. Follow the installation instructions. Alternatively, the latest drivers can also be found online in the [Brother Solution Centre](#).

### Setting up the Apo-Ident software

Once you have successfully installed the drivers, you can select your printer from the list of **Standard label printers** (Brother QL-700 or older models) under **Label printer settings**.

### Settings with continuous DK-22205

Select the following settings:

- Page size: 62 mm
- Orientation: 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

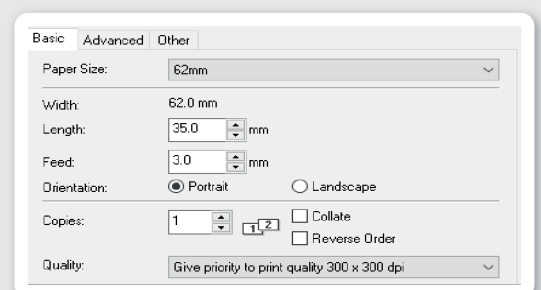
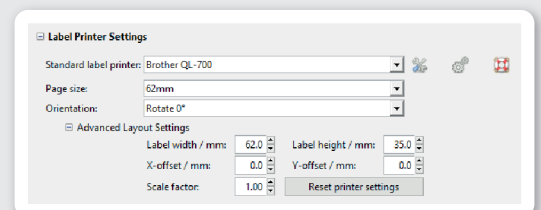
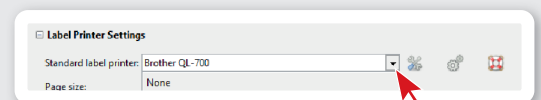
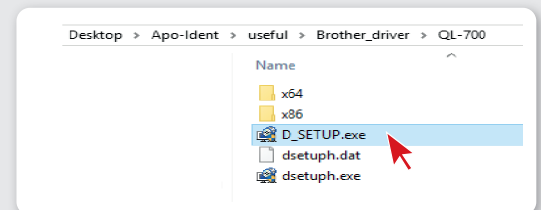
Click the 'Open printer settings' **tool icon** on the left. Enter the following data in the dialogue box that appears:

- Paper size: 62 mm
- Length: 35.0
- Feed: 3.0
- Orientation: Portrait
- Quality: Give priority to print quality 300 x 300 dpi

First click **<Apply>** and confirm by clicking **<OK>**. This will take you back to the Apo-Ident software settings.

**Note:** You can check your settings by starting a test print. To do so, click the 'Print test label' icon in the middle.

If your test print was successful, click **<Close>**. Your settings will now be applied and saved.





## Settings with single labels DK-11201

Select the following settings:

- Page size: 29 mm x 90 mm
- 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

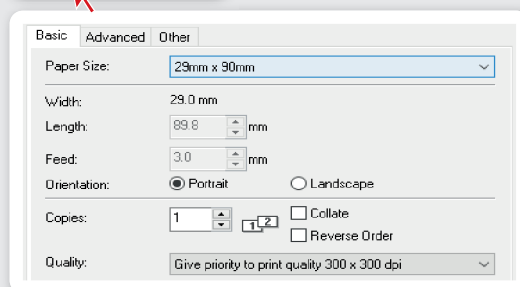
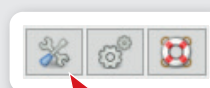
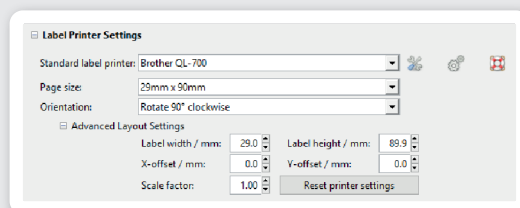
Click the 'Open printer settings' **tool icon** on the left. Enter the following data in the dialogue box that appears:

- Paper size: 29 mm x 90 mm
- Orientation: Portrait
- Quality: Give priority to print quality 300 x 300 dpi

First click **<Apply>** and confirm by clicking **<OK>**. This will take you back to the Apo-Ident software settings.

**Note:** You can check your settings by starting a test print. To do so, click the 'Print test label' icon in the middle.

If your test print was successful, click **<Close>**. Your settings will now be applied and saved.



## 2. Measurement

Enter the raw material due to be tested in the search field **Substance selection**. The search field will recognise both English and Latin substance names.

**Notes:** The software will start providing suggestions once you enter the first letter. Please select the correct substance from these suggestions.

**Green dot:** NIR-analysis can confirm the identity of this substance with an unambiguous result → **Section 2.1. / 2.2.**

**Yellow dot:** A yellow dot next to the name means only an ambiguous test result can be achieved for the substance, i.e. the identity is limited to few options, but more than one. After entering the substance, the search field turns yellow → **Section 2.3.**

**Red dot:** The substance cannot be identified using Apo-Ident. But these substances are pre-set in order to document the results of other tests in the test report. After entering the substance, the search field turns red. → **Section 2.4.**

**Grey dot:** You can generate substances yourself in the substance management area to create a test report for user-defined substances and document other test results. These substances cannot be identified by Apo-Ident. After entering the substance, the search field turns grey. → **Section 2.5.**

### 2.1. APIs & excipients (solid) and narcotic substances (solids) clearly identifiable using Apo-Ident

#### Starting the measurement

First place your **sample cup containing the substance** with the **adapter ring** onto the measurement point. Start the measurement process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) on the top of the device.

**Advice: 'Filling sample cups (solid substance) correctly'**  
Pour around 2 - 4 mm of the test substance into the sample cup. Make sure the bottom of the cup is covered evenly. The transfectance insert is not used for solid substances.

**Note:** Some substances can also be identified using smaller quantities. See Section 2.1.1. for instructions.

Substance selection

Search: Sodium citrate  
Classifier: APIs & excipients, solid  
Name: Sodium citrate  
Latin: Natrii citras

Substance selection

Search: Cooling cream DAB  
Classifier: APIs & excipients, liquid/semi-solid (with analysis certificate)  
Name: Cooling cream DAB  
Latin: Unguentum leniens

Substance selection

Search: Phosphoric acid 25%  
Classifier: Userdefined Substances  
Name: Phosphoric acid 25%  
Latin: Acidum phosphoricum 25 %

Substance selection

Search: Aerosil  
Classifier: Userdefined Substances  
Name: Aerosil  
Latin: n/a

Start measurement  Apply the sample cup with the selected substance.

## Referencing

After the first substance measurement, you will be asked to place the reference standards onto the measurement point. Follow the software's instructions and place first the black reference, then the white reference, on the measurement point.

**Note:** Please always use the black adapter ring. The software will request the reference measurement after approx. 100 min.


## Result

After a few seconds, the device will show you whether the substance has been identified.

**Note:** In the event of a negative result, please read the further information on non-identification. Check/repeat your measurement process accordingly.

## Report details

Following successful measurement, complete all mandatory fields in the **Report details** section. The fields **Correction factor weighing**, **Comment** and **Additional tests** may be completed if necessary.

If you see a warning sign  in any of the input fields, it means input is still missing and the report cannot yet be created.

## Create report

You can now save the measurement result, view the test report as a PDF file, or print it out.

**Note:** Once you select one of the icons, the measurement result will be saved automatically. You may also print out a label using your label printer (small printer symbol).

### 2.1.1. Measurement using sample insert for small substance quantities

Some substances in the **APIs & excipients (solid)** and **Narcotic substances (solids)** categories can also be identified using smaller quantities. This requires a **sample insert** and the associated **white reference for sample insert**, which is mandatory for referencing.

An overview of all substances which can be measured using the sample insert can be found under **<Help – Subscribed substances with sample insert>**.

Enter the substance due to be tested with the sample insert in the search field. Under **Starting the measurement**, the **Use sample insert** checkbox appears on the right-hand side. Tick the box if you are using the sample insert.


First place your **sample cup containing the sample insert** and **substance**, as well as the **adapter ring**, onto the measurement point. Start the measurement process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) on the top of the device.





|        |              |                                   |
|--------|--------------|-----------------------------------|
| Result | Name:        | <b>Sodium citrate</b>             |
|        | NIRS Result: | <b>Match</b>                      |
|        | Value:       | <b>99.9%</b> (Limits 98% to 100%) |
|        | Validation:  | Available                         |

|                |                               |               |
|----------------|-------------------------------|---------------|
| Report details | Operator name:                | Smith         |
|                | Manufacturer/Supplier:        | Caelo         |
|                | Batch number:                 | 23456         |
|                | PPN:                          | 1234567       |
|                | Use-by date:                  | December 2025 |
|                | Corr. factor weighed portion: |               |
|                | Comment:                      | (empty)       |
|                | Test number:                  | 190110084743  |

Create report



|                          |   |
|--------------------------|---|
| Search:                  | Urea  |
| Classifier:              | APIs & excipients, solid  |
| Name:                    | Urea  |
| Latin:                   | Carbamidum  |
| Transferrance reference: |    |
| Start measurement:       |  Apply the sample cup with the selected substance. <input checked="" type="checkbox"/> Use Sample Insert |



## Advice: 'Filling sample cups (solid substance) correctly'

The sample should be poured into the sample insert to a height of approx. 4 mm.

## Referencing

After the first substance measurement, you will be asked to place the references onto the measurement point. Please use the black reference and corresponding **white reference for sample insert**, as it will otherwise not be feasible to identify the substance

**Note:** The software will automatically re-request reference measurements after approx. 100 min.

After a few seconds, the device will show you whether or not the substance has been identified. Then proceed as per usual.

## 2.2. APIs & excipients (semisolid/liquid) clearly identifiable using Apo-Ident

### Transflectance reference measurement

Start with the transflectance reference measurement. Place the clean **transflectance insert** feet-down into a clean, **empty sample cup**. Using the **adapter ring**, place the cup, with the transflectance insert, onto the Apo-Ident device's measurement point. Start the **transflectance reference measurement** by clicking the green button.

**Important:** Both the transflectance reference measurement and the liquid/ointment measurement must be conducted using the same transflectance insert and sample cup, otherwise identification may not be possible.

**Note:** Once the transflectance reference measurement has been successfully completed, start the substance measurement within 5 minutes. If no measurement is taken during this period, the transflectance reference measurement must be repeated.

## Referencing

After the transflectance reference measurement has been taken, you will be asked to place the supplied reference standards onto the measurement point.

Please following the referencing instructions under 2.1 for this.



Transflectance reference



Apply the transflectance insert to an empty sample cup. Please use the same transflectance insert and sample cup for the following measurement.

## Starting the measurement

Place your **sample cup containing the substance**, the **transflectance insert** and the **adapter ring** onto the measurement point. Start the measurement process by clicking the green button next to **Start measurement** or by pressing the measurement button (green light) on the top of the device.

### **Advice: 'Filling sample cups (semi-solid substance) correctly'**

Once the transfectance reference measurement is complete, remove the transfectance insert from the sample cup and hold it up from its feet. Use a thin spatula to take about a hazelnut-size amount of the substance and scrape it on one of the transfectance insert's straight edges.

Place the empty sample cup over it, and spread the substance over the entire area. To finish, press the insert into the substance until all three of its feet visibly touch the bottom of the cup. Make sure there are no air bubbles under the transfectance insert.

### **Advice 'Filling sample cups (liquid substance) correctly'**

Once the transfectance reference measurement is complete, remove the transfectance insert from the sample cup. Pour a bit of liquid into the cup so that the bottom is fully covered. Place the transfectance insert feet-down into the sample cup. A part of the substance should visibly rise up between the sample cup and transfectance insert. Hold the glass up and make sure there are no air bubbles under the transfectance insert.


## Result

After a few seconds, the device will show you whether the substance has been identified.

**Note:** *In the event of a negative result, please read the further information on non-identification. Check/repeat your measurement process accordingly.*

## Report details

Following successful measurement, complete all mandatory fields in the **Report details** section. The fields **Correction factor weighing**, **Comment** and **Additional tests** may be completed if necessary.

If you see a warning sign  in any of the input fields, it means input is still missing and the report cannot yet be created.

## Create report

You can now save the measurement result, view the test report as a PDF file, or print it out.

**Note:** *Once you select one of the icons, the measurement result will be saved automatically. You may also print out a label using your label printer (small printer symbol).*




|   |  |
|---|--|
| Name: <b>Ethanol 70% pure / denatured</b>                 |  |
| Result  | <b>Match</b>   |
| Value:  | <b>99.1%</b> (Limits 98% to 100%)  |
| Validations:  | Available  |
| Operator name: <input type="text" value="Smith"/>         |  |
| Manufacturer/Supplier: <input type="text" value="23456"/> |  |
| Batch number: <input type="text" value="1234567"/>        |  |
| PPN: <input type="text" value="1234567"/>                 |  |
| Report details  | Use-by date: <input type="text" value="December"/> <input type="text" value="2025"/> |
| Corr. factor weighed portion: <input type="text"/>        |  |
| Comment: <input type="text"/>                             |  |
| Additional tests: <input type="text" value="(empty)"/>    |  |
| Test number: <input type="text" value="190110105409"/>    |  |

Create report



### 2.3. How to deal with substance that lead to ambiguous test results?

There are groups of substances with similar NIR-spectra, so NIR-analysis cannot safely discriminate between them. Such substances are marked with a yellow dot in front of the substance name. In this case Apo-Ident can only confirm that the substance under test is one of the substances in the list. Additional test may lead to a unique/unambiguous test result.


Click on the warning sign  to the right of the selected substance for more information.

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

### Starting the measurement

Proceed as normal with your measurement (see Section 2.1. or 2.2.)

Following successful measurement, complete all mandatory fields in the **Report details** section. The fields **Correction factor weighing**, **Comment** and **Additional tests** may be completed if necessary.

If you see a warning sign  in any of the input fields, it means input is still missing and the report cannot yet be created.

### Using the software to document additional tests

An additional test and test results can be entered in the software using the **Additional test** function.

If the result of the additional test is available at the time of measurement, this may be documented by clicking the **<Identified>** checkbox. Your data will be applied by clicking **<OK>**.

The text input and final result will then appear directly in the test report.

### Manually entering results onto the printed report


If the additional test is performed later on, methods and the final test result will be manually noted on the printed test report afterwards. Do **not** tick **<Identified>** checkbox in this case.

Substance selection

Search:

Classifier: APIs & excipients, liquid/semi-solid (with analysis certificate)

Name: Cooling cream DAB

Latin: Unguentum leniens 

Name: **Cooling cream / Cooling cream with rose oil**

NIRS Result: **Match (Additional Tests required)**

Value: **99.5%** (Limits 98% to 100%)

Validation: Available

Report details

Operator name:

Manufacturer/Supplier:

Batch number:

PPN:

Use-by date:

Corr. factor weighed portion:


Comment:

Additional tests:

Test number:

Additional tests (Method and Result)

Yellowish white paste, odour slightly like rose oil

Final result: ☐ Identified 

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

Complementary tests: (Method and results) Yellowish white paste, odour slightly like rose oil

Conclusion: Cooling cream DAB has been clearly identified.  
> Attach test certificate here or on the following page <



## 2.4. Particularities for substances not identifiable using Apo-Ident

**Not identifiable:** Substances which cannot be identified using Apo-Ident, e.g. because they do not have a sufficient signature in the NIR, are highlighted immediately after the name has been (partially) entered (a red dot appears next to the name. After entry, the search field turns red and an information window appears).

Identifying this substance requires a different test method.

But the Apo-Ident software enables reports to be created without a measurement. To do this, click **<OK>** and complete the mandatory information on the substance.

**Note:** The method and result can be entered directly in the software (under **Identity tests**) or manually onto the report. This requires entering details of the final result.

### Entering the identity test using the software

The identity test method and test result may be entered in the software via the **Identity tests** function.

If the result of the identity check is already available at the time the report is created, it may be documented by clicking the **<Identified>** checkbox. Your data will be applied by clicking **<OK>**.

The text input and final result will then appear directly in the test report (see also Section 2.3.).

### Manually entering the result on the printed report

If the Identity test is performed later on, the method and final test result has to be manually noted on the printed test report afterwards. Do **not** tick **<Identified>** checkbox in this case.

Substance selection

Search: **Phosphoric acid 25%**

Classifier: Userdefined Substances

Name: Phosphoric acid 25%

Latin: Acidum phosphoricum 25 %

Search: **Phosphoric acid 25%**

Classifier: Userdefined Substances

Name: Phosphoric acid 25%

Latin: Acidum phosphoricum 25 %

You have chosen a substance of the Classifier 'Userdefined Substances'. In this mode you can create a protocol without NIR measurement. Please fill in the mandatory input fields for this substance.

**OK**

Result

Name: **Phosphoric acid 25%**

NIRS Result: **Not NIR-active**

Value: **n/a**

Validation: Not available

Report details

Operator name: Smith

Manufacturer/Supplier: Caelo

Batch number: 23456

PPN: 1234567

Use-by date: December 2025

Corr. factor weighed portion: |

Comment: (empty)

Identity tests: (empty)

Test number: 190111115511

Identity tests:  
(Method and results)

Conclusion: Phosphoric acid 25% has been clearly identified.  
☐ Yes ☐ No

> Attach test certificate here or on the following page <

Approved by: \_\_\_\_\_

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

## 2.5. Substance Management

The Substance Management function is a new feature in the Apo-Ident software. It enables you to manage or create additional substances for which you can still create reports, despite them not being testable via NIR. You can also define which additional substances are available for selection as part of the classic identity check.

You will find the **<Substance Management>** function in the menu bar at the top.

The Additional Substances window will open. The Substance Management **must** be individually adjusted for each configuration profile.

### Predefined additional substances

Substances not identifiable using Apo-Ident, but which are often requested, are predefined by default. The Apo-Ident software can create a report without a NIR measurement using all selected substances (see Section 2.4.).

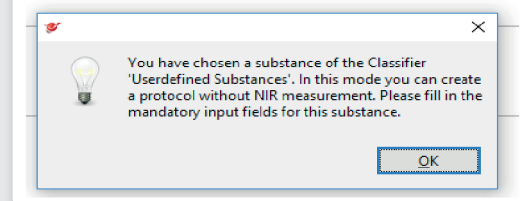
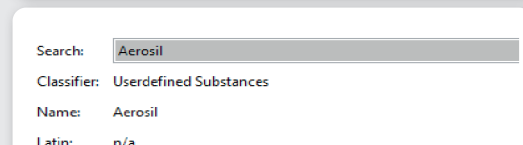
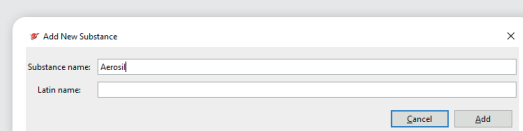
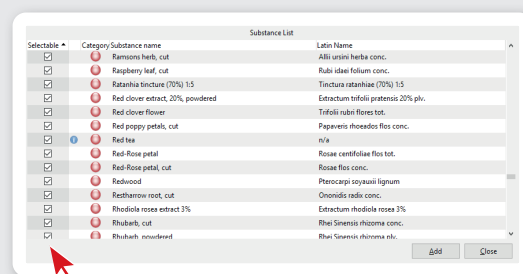
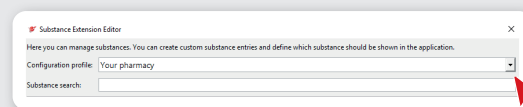
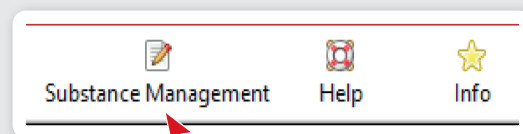
If a substance is not required in order to create the report, it may be deselected by unticking the box. The box can be re-ticked as soon as the substance is required again.

The blue info circle next to the tick shows alternative English and Latin substance names.

### Self-defined additional substances

The **<Add>** function enables you to create new substances for which you wish to create test reports. The substance name must be specified; the Latin name is optional. Re-clicking **<Add>** displays the newly created substance in the substance list with a grey dot. Close the window via **<OK>**.

A report can now be created for the self-defined substance even without a measurement (Method as per Section 2.4.)



### 2.6. Cleaning/Using sample cups, transfectance inserts and sample inserts

#### Sample cups

- After measuring, pre-clean the sample cups with a paper towel. This is particularly advisable after measuring ointment and emulsions
- Clean with detergent, warm water and a soft cloth
- Then rinse the sample cups with clean water, and rub dry with a lint-free cloth
- Before using the sample cups, disinfect them with isopropyl alcohol 70%, and dry with a disposable paper towel

**Before measuring, particularly check that the bottom of the cup is clean and not greasy. No water marks should be visible.**

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.

#### Transflectance insert

Scratches between the insert feet or severe discolouration can affect the identification process, so please treat the transflectance insert with care.

- Never clean the insert with scourers, spatulas or other aids
- Do not put it in dishwashers!
- Roughly wipe the transflectance insert down with a paper towel
- Clean it with detergent, warm water and a soft cloth
- Then rinse the insert with purified water, and rub dry with a lint-free cloth
- Before using the transflectance insert, disinfect it with isopropyl alcohol 70%, and dry with a disposable paper towel, in case you do not dispose the sample

#### Sample insert for measuring small substance quantities

- After measuring, lightly tap the sample cup to rid the sample insert of any residual powder
- Clean it using detergent, warm water and a soft cloth
- Then rinse the sample insert with clean water, and rub dry with a lint-free cloth
- Before using the sample insert, clean it with isopropyl alcohol 70%, and leave to dry, if you are going to retain the sample

#### Measurement point / Sample window

Please ensure the Apo-Ident device's measurement point (sample window) is kept clean. We recommend cleaning it with a cloth soaked in isopropyl alcohol 70%.

### 3.1. Consistency percentage + threshold value

The consistency between the sample spectrum and the stored reference spectrum is shown as a percentage. The permitted assessment range is shown after this. If the sample spectrum is below the threshold, the substance could not be identified ('**No match**').

Clicking **NIRS result** will show the spectrum measured.

### 3.2. Display showing the difference between the reference and sample spectrum

If necessary, you can display the difference between sample and reference spectrum in the test report graph (only possible for spectra of samples which could be identified). Please note that the right-hand scale is used for the difference line to ensure the differences are clearly visible.

Under Settings, tick the **<Show difference in back-projections>** option to display the line in the report. The input is applied by pressing the **<Close>** button.

### 3.3. Search function (query) by substance, expiration date or other criteria

This function enables you to re-display or reprint older reports or labels.

To do this, click **Query** in the menu bar. This opens the archive query.

Adjust the configuration profile at the top for the search query if necessary. Under the **Substance** tab, enter the name of the substance (or test number/PPN) whose test reports you wish to search for. Click **<Execute>**. This will show all test reports matching the search criteria.

To search by expiration date, click the **Use-by Date/Shelf Life** tab and enter the relevant data.

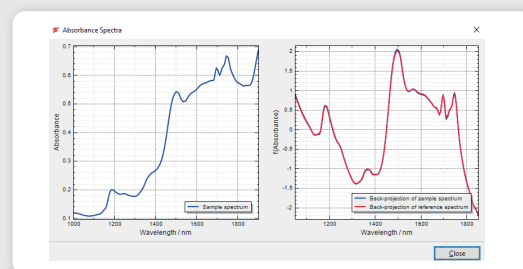
After performing the query, you can select the relevant substance in the results window and view information on the measurement/report.

You can also search by user, supplier or a batch number under the **Advanced** tab.

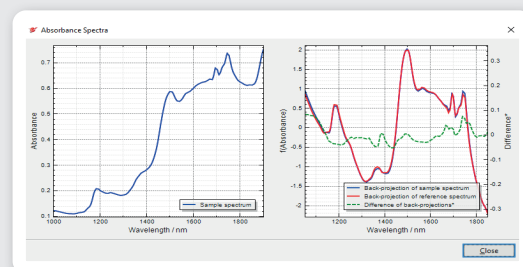
And you can use the **Timestamp** query to request all measurements from 1/1/2010, for example.

Result

Name: **Sodium citrate**  
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: Your 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: Your pharmacy

Substance Use-by Date/Shelf Life: Advanced

Advanced Archive Query

Substance name:

Test number:

PPN:

Operator name:

Manufacturer/Supplier or batch number:

Comment:

Timestamp: 01 January 2010 to 31 December 2025

Use-by date/Shelf life: January 2010 to December 2025

Execute

3 matches found.

| Primary Name        | Latin Name               | Manufacturer/Supplier | Batch Number | Test number  | PPN     | Timestamp           | Use-by Date/Shelf Life |
|---------------------|--------------------------|-----------------------|--------------|--------------|---------|---------------------|------------------------|
| Sodium citrate      | Natrii citras            | Celco                 | 23456        | 190111133137 | 1234567 | 11/01/2019 13:31:37 | December 2025          |
| Phosphoric acid 25% | Acidum phosphoricum 25 % | Celco                 | 23456        | 190111133137 | 1234567 | 11/01/2019 11:55:11 | December 2025          |

### Exporting query results in CSV Format

The query results can be stored in CSV format by clicking **<Save>**. Open this in a suitable program (e.g. MS Excel) to print or re-use the list.

### Copying files to individual saving locations (e.g. on a USB stick)

If you wish to copy the selected files to a specific location, please click the **<Copy to...>** button and select the desired storage location. All data meeting the search criteria will be copied.

### 3.4. Display validation documents

Click on **<Help>**, **<Validation Documents>** in the menu bar at the top.

Select the relevant validation document.

After successfully completing the measurement, you can also retrieve the validation document for the tested substance directly via the Apo-Ident interface. To do this, click **Validation** in the results area.

### 3.5. Data backup

To send your measurement reports to the Apo-Ident customer service or save them for data backup, click on **<Help>** in the menu bar at the top and select **<Data Backup>**.

You can now choose whether you wish to perform a **<Backup>** or export data for our **<Customer service>**.

If you wish to change computers or perform a new installation, we recommend backing up your data (export incl. log files, licence key, profile).

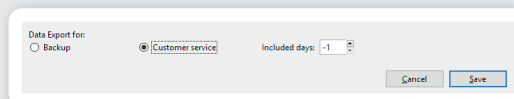
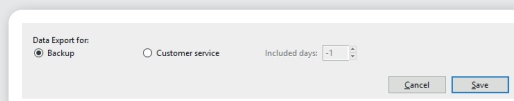
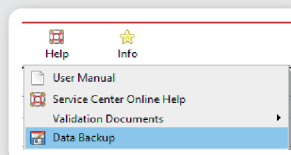
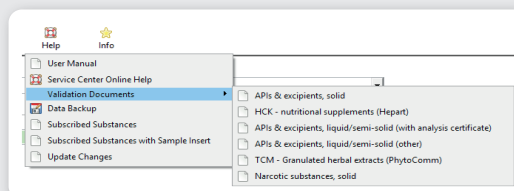
By clicking **<Save>**, the relevant information will be saved in a Zip archive on the desktop by default.

If you export the data for the customer service, your spectra will be compressed and saved in a ZIP file. You can set how many measurement days you wish to include into the archive and send or save as follows:

- -1 = all days
- 0 = only log files
- 1 = 1 day
- 2 = 2 days
- etc.

By clicking **<Save>**, the relevant information will be saved in a Zip archive on the desktop by default. You can now send it to us using our uploader <https://hiperscan-download.de/upload>.

| Primary Name        | Latin Name               | Manufacturer/Supplier | Batch Number | Test number  | PPN     | Timestamp           | Use-by Date/ Shelf Life |
|---------------------|--------------------------|-----------------------|--------------|--------------|---------|---------------------|-------------------------|
| Sodium citrate      | Natrii citras            | Celco                 | 23456        | 190111133157 | 1334567 | 11/01/2019 15:31:57 | December 2025           |
| Phosphoric acid 25% | Acidum phosphoricum 25 % | Celco                 | 23456        | 190111133157 | 1334567 | 11/01/2019 15:31:57 | December 2025           |



### 3.6. Identification details (rankings)

Apo-Ident compares the measured spectrum with all samples stored in the reference database. 20 results with the highest match will be shown in the rankings list. To display the rankings, click on **Value** in the **Result** section.

This will show the identification details. Selecting the **<Show as PDF>** button will export the displayed table in PDF format, and enable you to print and store it together with the report.

Position 1 (#1 rank) shows the reference sample displaying the **highest match with the sample**. If the criteria for identifying the substance have been met, this will be shown in **green**.

The nearest reference samples are marked in **red**, and are not directly taken into account when rating the measured sample spectrum. For substances combined in groups, please be aware that the name listed in the ranking (classification) may differ from the substance name. The group name will be shown in this case (e.g. 'Triglycerides').

This view enables the user to understand and assess the identification result.

The list shows the calculated statistical results of the analysed sample spectrum for the next 20 reference samples. The individual terms are explained on page 23.

Result

Name: **Sodium citrate**

NIRS Result: **Match**

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

Validat Available

Identification details

| Ranking | Classification                         | Sample ID | Significance | Confidence | Correlation | Distance | Value  |
|---------|--|-----------|--------------|------------|-------------|----------|--------|
| 1       | Sodium citrate                         | 20662     | 0.9995       | 0.9998     | 0.9997      | 3.7      | 99.95% |
| 2       | Sodium citrate                         | 22859     | 0.9720       | 0.9791     | 0.9898      | 30.2     | 0.00%  |
| 3       | Gentamicin sulfate                     | 21081     | 0.8642       | 0.7533     | 0.9128      | 129.5    | 0.00%  |
| 4       | Gentamicin sulfate                     | 22804     | 0.8507       | 0.5621     | 0.9087      | 168.5    | 0.00%  |
| 5       | Gentamicin sulfate                     | 22857     | 0.8500       | 0.6552     | 0.9231      | 171.3    | 0.00%  |
| 6       | Betamethasone dipropionate, micronized | 212505    | 0.8461       | 0.4352     | 0.5787      | 188.9    | 0.00%  |
| 7       | Clobetasol propionate                  | 227245    | 0.8413       | 0.2396     | 0.5532      | 219.4    | 0.00%  |
| 8       | Clobetasol propionate                  | 227145    | 0.8402       | 0.2302     | 0.5613      | 228.3    | 0.00%  |
| 9       | Betamethasone dipropionate, micronized | 223729    | 0.8401       | 0.2162     | 0.5739      | 229.6    | 0.00%  |
| 10      | Clobetasol propionate                  | 218029    | 0.8399       | 0.3269     | 0.5469      | 231.3    | 0.00%  |
| 11      | Gentamicin sulfate                     | 20661     | 0.8398       | 0.3629     | 0.9109      | 232.1    | 0.00%  |
| 12      | Betamethasone dipropionate, micronized | 213653    | 0.8366       | 0.0292     | 0.5754      | 265.6    | 0.00%  |
| 13      | Betamethasone dipropionate, micronized | 20930     | 0.8359       | 0.4408     | 0.5744      | 275.9    | 0.00%  |
| 14      | Clobetasol propionate                  | 218951    | 0.8358       | 0.0994     | 0.5404      | 276.5    | 0.00%  |
| 15      | Betamethasone dipropionate, micronized | 217165    | 0.8357       | 0.0482     | 0.5779      | 279.0    | 0.00%  |
| 16      | Clobetasol propionate                  | 21092     | 0.8349       | 0.2882     | 0.5576      | 290.8    | 0.00%  |
| 17      | Betamethasone dipropionate, micronized | 228985    | 0.8337       | 0.0070     | 0.5717      | 313.9    | 0.00%  |
| 18      | Betamethasone dipropionate, anhydrous  | 21046     | 0.8336       | 0.0048     | 0.5581      | 314.3    | 0.00%  |
| 19      | Betamethasone dipropionate, anhydrous  | 219779    | 0.8324       | 0.0000     | 0.5618      | 341.7    | 0.00%  |
| 20      | Betamethasone dipropionate, anhydrous  | 228951    | 0.8324       | 0.0000     | 0.5572      | 342.7    | 0.00%  |

Help Show as PDF Close

### 3.7. Help

The software's **<Help>** menu item offers you different support methods for safely using Apo-Ident.

**Operating Manual** > The detailed operating instructions for the Apo-Ident analysis device.

**Service Centre Online Help** > You will be redirected to the Apo-Ident Service Centre. This requires Internet access. There you will find the latest instructions, substance lists and software. You can also download information material and order forms, and retrieve previous validation documents and the open-source code.

**Validation Documents** > The validation documents are each divided into substance categories. You can retrieve the entire document here, or jump straight to the validation report for the respective raw material after each measurement → **Section 3.4**.

**Data backup** > see **Section 3.5**.

Help Info

- Operating Manual
- Service Centre Online Help
  - Validation Documents
- Data Backup
  - Additional Tests
- Subscribed Substances
- Subscribed Substances with Sample Insert
- Update Changes



**Subscribed substances** > This is where you will find an overview of the substances that can be measured using Apo-Ident.

**Subscribed substances with sample insert** > This is where you will find an overview of the substances that can also be measured in small quantities by using the sample insert.

**Update changes** > The latest update changes will be shown.

### 3.8. Info

This is where you can obtain information on the installed versions, organise a team-viewer session under **<Start Online Support>** or view the **<Certificate>** for installed software updates.

## 4. Definitions

| Term  | Explanation  | Assesment   |
|---|--|---|
| <b>Rank</b>   | Calculated ranking of consistency (match) between the measurement and the reference samples stored in the database   |   |
| <b>Classification</b>   | Substance or substance group <b>clearly</b> distinguishable using Apo-Ident; a substance group represents multiple substances not clearly separable using Apo-Ident, but which are available for the measurement (e.g. 'triglycerides'). | Classifications are marked yellow (non-unique result)   |
| <b>Sample-ID</b>  | HiperScan GmbH identification number assigned to reference samples whose spectra are used to build the Apo-Ident reference database. Detailed information on all reference samples can be found in the validation documentation.         |   |
| <b>Significance</b>   | Measure of the distance between the measurement result and the mean value of sample/classification reference measurements.   | The higher the value (maximum 1), the closer the measured sample spectrum is to the stored reference values.  |
| <b>Confidence</b>   | Outlier evaluation   | The higher the value (maximum 1), the better the measured sample spectrum's fit in the distribution of the stored reference values.                 |
| <b>Correlation</b>  | A statistical measure of the similarity between the back-projection of the stored reference spectra mean value and the back-projection of the measured sample spectrum.  | The higher the value (maximum 1), the higher the correlation of the back-projections.   |
| <b>Distance</b>   | A measure of distance between the mean value of a reference sample stored and the measured spectrum as a function of the principal component space (Mahalanobis distance).   | The smaller the value, the closer the sample spectrum is to the stored reference values.  |
| <b>Rating</b>   | The overall rating (regarding the aforementioned criteria) of the measured spectrum, as shown (or would be shown) on the screen and in the report.   | The higher the value (maximum 100 %), the closer the sample is to the stored reference values. The defined minimum value for identification is 98%. |
| <b>Specificity</b><br>(only for the PhytoComm substance group)      | The specificity of a classification is the true negative rate. It denotes the percentage of the spectra truly classified as non-identified during the validation.  |   |
| <b>Recognition rate</b><br>(only for the PhytoComm substance group) | This is the true positive rate. It denotes the percentage of the spectra truly classified as identified during the validation.   |   |

### 5. Technical data and disposal

#### 5.1. Technical data

|   |  |
|---|--|
| Analysis method                         | Near-infrared spectroscopy   |
| Measuring time                          | < 15 seconds   |
| Spectral range                          | 1000 - 1900 nm   |
| Spectral resolution                     | 10 nm  |
| Wavelength accuracy                     | ± 1 nm   |
| Wavelength reproducibility              | ± 0,3 nm   |
| Automatic recalibration/equipment check | Integrated wavelength and white standard   |
| Operating temperature                   | 15 - 35 °C   |
| Dimensions                              | 185 x 192 x 220 mm   |
| Weight                                  | 2,95 kg  |
| Interface                               | 1 x USB 1.1 Typ B Slave<br>to be added with aiLink: <ul style="list-style-type: none"><li>• 2 x USB 2.0 Typ A Host</li><li>• 2 x USB 3.0 Typ A Host</li><li>• Wifi 2,4GHz IEEE 802.11ac</li><li>• 1 x Gigabit Ethernet</li><li>• 1 x HDMI2.0 Typ A bis 4k/30Hz</li></ul> |
| Operating voltage                       | 100 - 240 V~ /50/60 Hz/60 W  |
| Software                                | QuickStep Apo-Ident  |
| System requirements                     | <ul style="list-style-type: none"><li>• PC with Windows 10</li><li>• min. 1 GB RAM</li><li>• min. 1,6 GHz Pentium</li><li>• 0,5 GB disk space</li></ul>  |



The device complies with the following EC regulations

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

#### 5.2. Disposal



In accordance with the European Directive, electric and electronic devices should not be disposed of as household waste. Their components need to be recycled or disposed of separately, as toxic and hazardous components may cause long-term damage to health and the environment if not disposed of correctly.



According to the WEEE directive 2012/19/EU (in Germany ElektroG), you are obliged to appropriately dispose of electrical and electronic devices at the end of their life. If you have not implemented any such process at your company, HiperScan GmbH as manufacturer, will recall the device.

HiperScan hopes you enjoy using Apo-Ident!  
We will be glad to assist if you have any questions.

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