Original operating instructions

Near-Infrared Spectrometer Apo-Ident 2.x

Contents

Icon	Ref. n. ISO7010	Meaning
	M001	General mandatory action sign
	M002	Refer to instruction manual
	M005	Connect an earth terminal to the ground
	W001	General warning sign
	W012	Electrical hazard
	W017	Hot surface
	W027	Optical radiation
	P075	Do not stare at light source

	Familiarize yourself with the operating manual before using the instrument
	Connect the instruments power supply to an outlet with a protective earth connector
	The DSUB-9 connector is intended solely for connection to manufacturer supplied accessories. The port provides a SELV voltage (Safety Extra Low Voltage) in accordance with IEC/EN 61010
	The DSUB-9 connector is not a serial port. Do not connect any cable or accessory not approved by the manufacturer of the instrument, as this may damage both connected devices
	The protective functions of the device, such as overvoltage protection and short-circuit protection, may be compromised if the device is used in a manner not intended by the manufacturer (e.g., through the use of unauthorized components or improper installation). Always follow the provided operating manual to ensure the full protection of the device
	Check the instrument for obvious damage before each use and disconnect it from the mains if it is damaged. Do not use the instrument again until the damage has been repaired / the fault has been rectified
	When testing or analyzing hazardous and harmful substances, ensure compliance with all applicable health and safety regulations. Ensure that you take all necessary protective measures, including the use of suitable personal protective equipment (such as gloves, safety goggles, respiratory protection, etc.). The user is solely responsible for taking the necessary safety precautions
	The instrument may only be set up in areas where the measuring instrument itself or its surfaces do not come into direct contact with the substances to be tested, their vapors, aerosols or particles. Ensure that the location of the instrument complies with the safety precautions specified in the MSD, in particular with regard to ventilation, distance from sources of danger and required protective equipment
	The samples must be destroyed at the end of the test and may not be processed in any other way
	Do not operate the instrument in a potentially explosive environment
	Do not operate the instrument unattended
	Only use the instrument with the original power supply unit supplied in conjunction with the enclosed mains connection cable
	The instrument must be connected to the power supply unit in a dry environment; ensure that all connections are free from moisture and contaminants

	If the power supply housing or cable insulation is damaged, disconnect the instrument from the mains and replace the damaged components before continuing to use it.
	Do not open the housing, the instrument does not contain any user-serviceable parts, do not operate the instrument with missing or incorrectly fitted housing parts
	Do not open the housing, there are heat sources and hot touchable surfaces inside the instrument
	Do not open the housing, there are intense point light sources inside the instrument
	Do not look directly into the light source

Purpose of This Document

These operating instructions are intended to help you use the Apo-Ident 2.x.

Here you will find important information on the following topics:

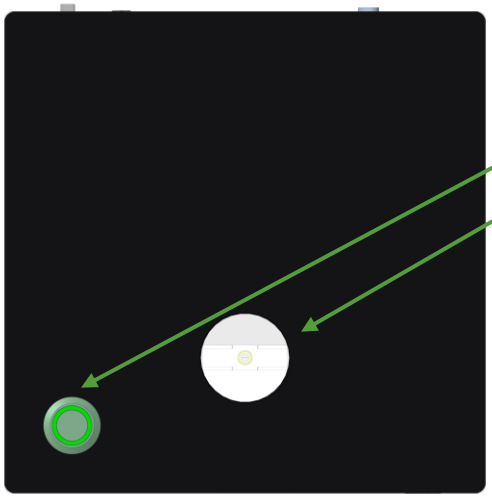
- General information
- Setting up the instrument
- Commissioning
- Mounting accessories
- Cleaning / Maintenance
- Ordering information for accessories and spare parts
- Instrument specification

The Apo-Ident 2.1 is a near-infrared spectrometer primarily used for the identification of drugs and excipients. The instrument can be used to analyze solid, semi-solid and liquid samples. The test is carried out in diffuse reflection for solids and in transflectance for semi-solid and liquid samples.

The Apo-Ident 2.x is a desktop instrument for laboratory use and is only designed for installation in areas where the measuring instrument itself including its surfaces do not come into direct contact with the substances to be tested.

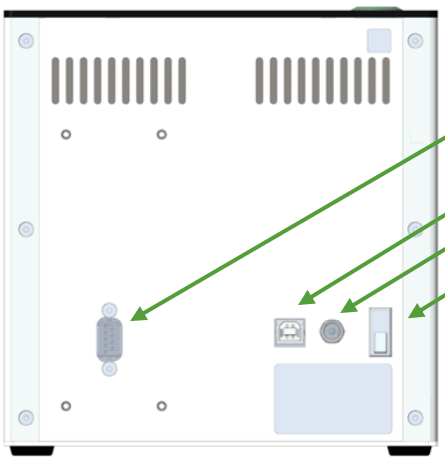
Overview of instrument interfaces and operating elements

View from above:



- Illuminated push-button
- Measurement area/ sample window

View from behind:



- D-SUB9 socket for connecting accessories
- USB-B socket
- Power supply connection
- On/off switch

Accessories overview

Adapter ring

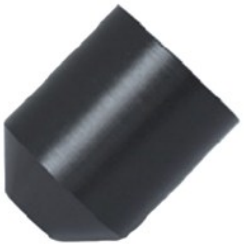
Black reference

White reference

White reference for sample insert (for small sample quantities)

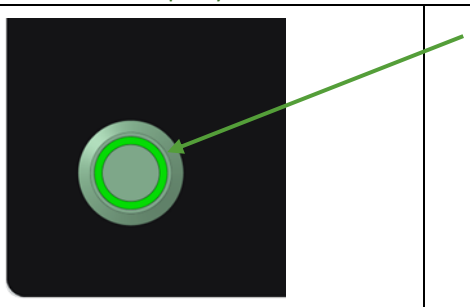
Transflectance insert

Sample insert



Sample cup

Overview of status display

	• The input button has an illuminated ring • The ring lights up in the colors green or red

Status display of the button

- Button lights up red continuously - **READY**:
  The instrument is ready to take measurements
- Button lights up green continuously - **start measurement**:
  The instrument is ready and awaits user interaction to take a measurement, pressing the green illuminated button starts the analysis
- Button flashes red - **ERROR**:
  An error has occurred while using the instrument, detailed information can be found in the error dialog of the software

Setting up the instrument

The dimensions of the instrument itself are 185mm x 192mm x 220mm (width x height x depth).

- Place the instrument upright on its feet on a flat, firm surface
- Make sure that there is at least 150 mm of free space behind the instrument for laying the connection cables
- Ensure that there is at least 100 mm of free space to the left and right of the instrument and that the ventilation openings on the underside of the instrument and the rear of the housing are unobstructed
- Position the instrument so that you can easily see and reach all controls at all times, including the on/off switch on the back of the instrument

The Apo-Ident 2.x is generally used in conjunction with a PC, please note the additional space required at the installation site

Also account for the space required for samples and sample containers depending on the test task and test volume

Observe the ergonomic requirements for setting up workstations to ensure fatigue-free use of the instrument

The instrument is intended for indoor use only, make sure that the ambient conditions of the installation location are within the technical instrument specification

Only set up the instrument in areas where the measuring instrument itself including its surfaces do not come into direct contact with the substances to be tested

Do not place the instrument on inclined surfaces

Do not install the instrument in potentially explosive atmospheres

Do not expose the instrument to strong vibrations during operation, as this can reduce the service life of the light source and the mechanical components

When selecting the installation location, observe the requirements of the safety data sheet for the substances to be measured

Choose an environment with as little dust as possible and prevent unnecessary dust exposure, especially around the ventilation opening, to avoid buildup inside of the instrument

Connecting the instrument


Make sure that the instrument is connected in a dry environment


Do not operate the power supply unit in a damp environment


Before connecting, check all plug connections for possible contamination, foreign objects or moisture


Connect the power supply unit to a protective earth conductor via the mains connection cable


Ensure that all connecting cables are free from mechanical stress


Only use the original power supply unit supplied in conjunction with the enclosed mains connection cable


Ensure good ventilation and place the power supply unit at least 100 mm away from other heat sources


Always pull the mains adapter out of the socket at the plug, never by the cable

1. Make sure that the power supply unit is disconnected from the mains and the on/off switch on the instrument is in the off position ("Off" or "◯")
2. Hold the connector plug and instrument firmly, push the plug into the power supply connection as far as it will go
3. Insert the USB-B plug into the connection socket as far as it will go
4. Connect the USB-A plug of the cable to the PC running the software
5. Once all cables are connected to the instrument, the power supply unit can be connected to the mains and the instrument can be switched on using the on/off switch, the switch position is marked "On" or "I"


To disconnect from the mains, set the on/off switch on the instrument to the off position ("Off" " or "◯") and proceed in reverse order


If the instrument is not to be used for a longer period of time, please disconnect the mains adapter from the socket

Visually check the instrument, power supply unit and accessories for damage each time before switching it on

Observe the applicable health and safety requirements when testing / analyzing hazardous or harmful substances!
If necessary, use the necessary personal protective equipment

Do not test / analyze substances with a temperature above 80°C, samples that are too hot can damage the adapter ring, also observe any applicable safety regulations and wear personal protective equipment

This is only a quick guide to give you a brief insight into the general function of the instrument. Further measurement methods are described in the user manual of the software

Before using the Apo-Ident 2.x, users should also familiarize themselves with the user manual for the software, where they will find detailed and further information on installing and using the instrument

Preparation

Prepare the following materials for the sample analysis:

- Apo-Ident 2.x
- PC/laptop with the "QuickStep Apo-Ident"
- Adapter ring
- Sample cup
- Black and white reference
- Sample to be analyzed

Connect the Apo-Ident 2.x to the PC / laptop using the USB cable and switch the instrument on.

If the internal instrument temperature is too low, a warm-up program is started automatically. Once the temperature inside the instrument has reached at least 20°C, the system is ready to start

Start "Quickstep Apo-Ident" and select the configuration profile

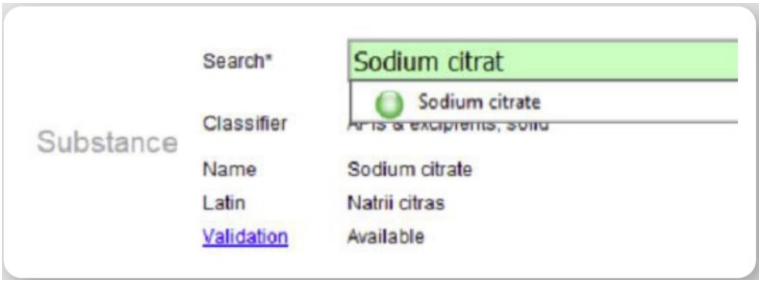
- Starting **Quickstep Apo-Ident** → Double-click on the desktop icon

- Under **configuration profile** → , select your stored pharmacy if you have stored several configuration profiles

You can find out how to create a configuration profile in the detailed operating instructions for the software

Selection of the substance

- Under **"Substance"** enter the name of the substance to be tested in the search field, e.g. sodium citrate. The classifier, in this case "APIs & excipients, solid", the name of the substance and the Latin name are now displayed



The software displays suggestions as soon as you enter the first few letters. You can select the right substance from the suggestions

If the substance can be identified with certainty, the search field turns green. All information on the color coding can be found in the detailed operating instructions for the user software

Measurement

Sample preparation

Depending on the sample, follow any specific instructions for sample preparation

Regardless of the sample, the following must be ensured for a successful analysis:

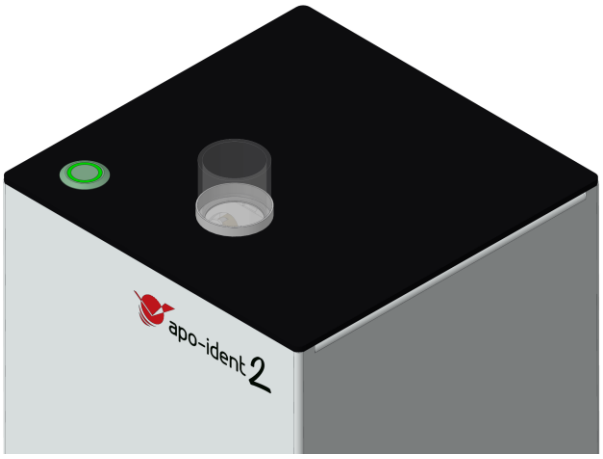
Use clean sample cup, for cleaning instructions - see section "Cleaning sample cup"

Sufficient sample quantity - the sample must completely cover the bottom of the sample vessel; a filling height of approx. 4 mm should be achieved

Some substances can also be identified with a smaller amount of substance. The corresponding procedure can be found in the detailed operating instructions for the user software

Ensure sufficient sample homogeneity, avoid air bubbles or air inclusions in the sample

- Place the sample cup with the substance and the adapter ring on the measuring point



Start the measurement

- Now start the measurement process by clicking on the blue button next to **"Measurement"** or by pressing the green illuminated button

Referencing

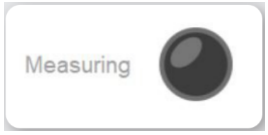
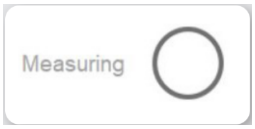
- After the first substance measurement, you will be prompted to set up and measure the reference standards. Follow the software instructions and first place the black reference and then the white reference on the measuring point

Always use the adapter ring for referencing

The measurement of the references is requested again by the software after approximately 60 minutes

- Start the respective reference measurement by clicking on the black or white button next to **"Measurement"**

Output of the result

- After a few seconds, the instrument will show you whether the substance has been identified

If the result is negative, please check the information on non-identification. Check or repeat your measurement process accordingly

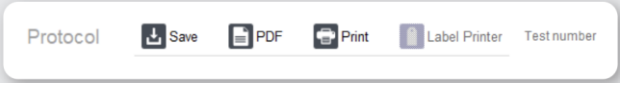
Measurement data

- After successful measurement, fill in all mandatory fields (marked with *) next to the Sample item and the user
- The fields PPN, weighing correction factor, Comment and Additional tests can be filled in if required

Please note that the log can only be created once all mandatory fields have been completed

Creating the protocol

- You can now save the measurement process, display the test report as a PDF file or print it out



Regardless of which function you select, the measurement process is always saved

You can also print out your test label on your label printer

Maintenance by the user


Visually check the instrument, power supply unit and accessories for damage each time before switching it on


Do not open the instrument, it does not contain any user-serviceable parts


If there is obvious damage or in case of doubt, do not operate the instrument


Only use spare parts and accessories supplied or approved for use by the original manufacturer


Send the instrument to HiperScan GmbH for maintenance or repair or arrange an on-site appointment with a local service partner. To arrange a maintenance or repair appointment, please contact customer support

Maintenance recommendation

To ensure reliable instrument operation, it is recommended that a performance check is carried out at least every 2 years by HiperScan GmbH or a service partner.

As part of the ÜDL, your instrument is tested for accuracy and reproducibility, and the internal components are checked for wear and tear and readjusted if necessary.

The ÜDL includes checking the following parameters, among others:

- Photometric linearity
- Photometric reproducibility
- Wavelength accuracy
- Wavelength reproducibility
- Checking the light source

Cleaning


Switch off the instrument and disconnect the power supply before cleaning the instrument


Do not use compressed air for cleaning


Observe the safety regulations when handling flammable cleaning agents


The following cleaning instructions ensure that the instrument functions properly. Please also observe any industry-specific requirements for hygiene and cleanliness of the instrument, accessories and working environment

Cleaning the instrument housing

We recommend using a damp, soft, lint-free cloth to clean the instrument housing. The following cleaning agents and disinfectants can be used:

- Lukewarm water in combination with standard dish soap
- Ethanol 70%, undenatured or denatured
- Isopropanol 70%

While cleaning, ensure that all interfaces and plug connections on the rear of the housing are kept free of moisture

Cleaning the measuring window

Please ensure that the glass surface is always clean and free from dirt or foreign objects.

Always handle the glass surface with care, as it is the optical interface to the sample.

Use a generously moistened, soft cloth to remove coarse soiling. Particularly in the case of any abrasive soiling caused by powder or dust, this should not be removed with a dry cloth to avoid scratching the glass surface.

The following agents can be used as cleaning agents or for disinfection:

- Lukewarm water in combination with standard dish soap
- Ethanol 70%, undenatured or denatured
- Isopropanol 70%

For very heavy and greasy soiling, pre-cleaning with lukewarm water and dish soap is recommended

It is recommended to use 70% undenatured ethanol, as denaturants do not always evaporate without leaving residues

The top of the housing is designed in such a way that the inside of the instrument is protected against the ingress of liquids to a damaging extent; if you see standing liquids on the instrument or the measuring point, wipe them up with soft, absorbent cloth

If the measuring point is heavily scratched, this can negatively affect the measurement, contact customer service to replace the cover glass

Cleaning adapter ring and sample insert

We recommend using a moistened, soft, lint-free cloth to clean the adapter ring. The following cleaning agents and disinfectants can be used:

- Lukewarm water in combination with standard dish soap
- Ethanol 70%, undenatured or denatured
- Isopropanol 70%

Cleaning sample cup

- After each measurement, first clean the sample cup with a lint-free cloth
- The sample cup is then cleaned with lukewarm water and washing-up liquid
- Then rinse the sample cup with deionized water and dry it with a lint-free cloth
- Before use, rinse the sample cup with 70% isopropyl alcohol and dry with a lint-free cloth

Before measuring, make sure that the base of the sample cup is clean and free from contamination and rinsing residue

Do not clean the sample cup in the dishwasher, the cleaning agents can permanently damage the surface

Cleaning transflectance insert

Always handle the transflectance insert with care, scratches between the insert feet or severe discoloration can affect the identification.

- Carefully wipe the transflectance insert with a paper towel after use
- The transflectance insert is then cleaned with lukewarm water and dish soap using a soft lint-free cloth
- Then rinse the transflectance insert with deionized water and dry it with a lint-free cloth
- Rinse the transflectance insert with 70% isopropyl alcohol before use, then rub dry with a lint-free disposable cloth

Never clean the transflectance insert with pot scrapers, spatulas or other abrasive tools

Do not clean the transflectance insert in the dishwasher, the cleaning agents can permanently damage the surface

Cleaning the power supply unit

Disconnect the mains plug from the socket before cleaning, do not pull the cable

When cleaning, do not bring the power supply unit into direct contact with liquid cleaning agents or cleaning sprays

Make sure that all plug connections remain free of moisture and foreign objects during cleaning

Clean the power supply unit with a slightly damp, lint-free cloth. The following cleaning agents or disinfectants can be used:

- Lukewarm water in combination with standard dishwashing detergent
- Ethanol 70%, undenatured or denatured
- Isopropanol 70%

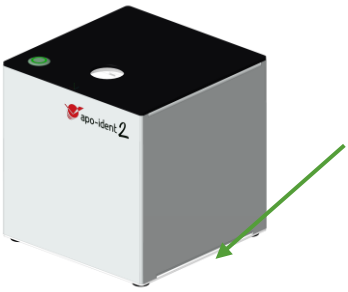
Dry any moisture residue with a lint-free cloth before reusing the power supply unit.

Transportation

We recommend using the original transport case for safe transportation of the instrument. If the instrument is to be shipped, the original outer packaging is recommended. Both products are specially designed for the instrument and offer optimum protection for your measuring instrument. The ordering information for both items can be found in the "Ordering information, accessories and spare parts" section.

Handling

If you want to lift the instrument to carry it, first switch it off using the on/off switch. Remove any attached accessories, for example the adapter ring from the top of the instrument, disconnect all cable connections and hold the instrument securely with both hands from the underside. To do this, reach under the side of the instrument between the housing feet.



- Reach under the instrument from both sides to lift it

Switch off the instrument before moving it

Storage

If you are not using the instrument for a longer period of time, disconnect the mains adapter from the socket

We recommend storage in the original transport case or outer packaging for transportation. The ordering information for both items can be found in the "Accessories and spare parts ordering information" section

Store the instrument in a dry, clean and dust-free environment, observe the information on ambient conditions for storage in the "Technical data" section

Error image	Troubleshooting
If the on/off switch is in the "On" position and the button on the Apo-Ident 2.x is not illuminated	• Check that all plug connections on the Apo-Ident 2.x and on the power supply unit are secure; if in doubt, disconnect the plug connections and reconnect them  • Do not carry out any repair work on the power supply unit, contact customer service and disconnect any defective instruments from the mains supply
The button of the Apo-Ident 2.x lights up after switching on, but the instrument is not recognized by the computer	• Check that the USB cable is securely connected to the Apo-Ident 2.x and the PC • Make sure that the instrument drivers are installed and working properly • Install any pending operating system updates and restart your PC • Switch the Apo-Ident 2.x off and on again using the on/off switch on the back of the instrument
The Apo-Ident 2.x does not start directly into the user software but into a warm-up program	• Ensure that the ambient temperature is within the permissible operating temperature • If the instrument has been stored or transported at very low temperatures, it takes a while for the instrument temperature to adjust to the ambient temperature; the instrument starts measuring operation from an internal instrument temperature of 20°C • If the internal instrument temperature is below 20°C, the Apo-Ident 2.x starts a warm-up program to reach the internal instrument temperature more quickly

Do not dispose of the instrument in household waste at the end of its service life after decommissioning

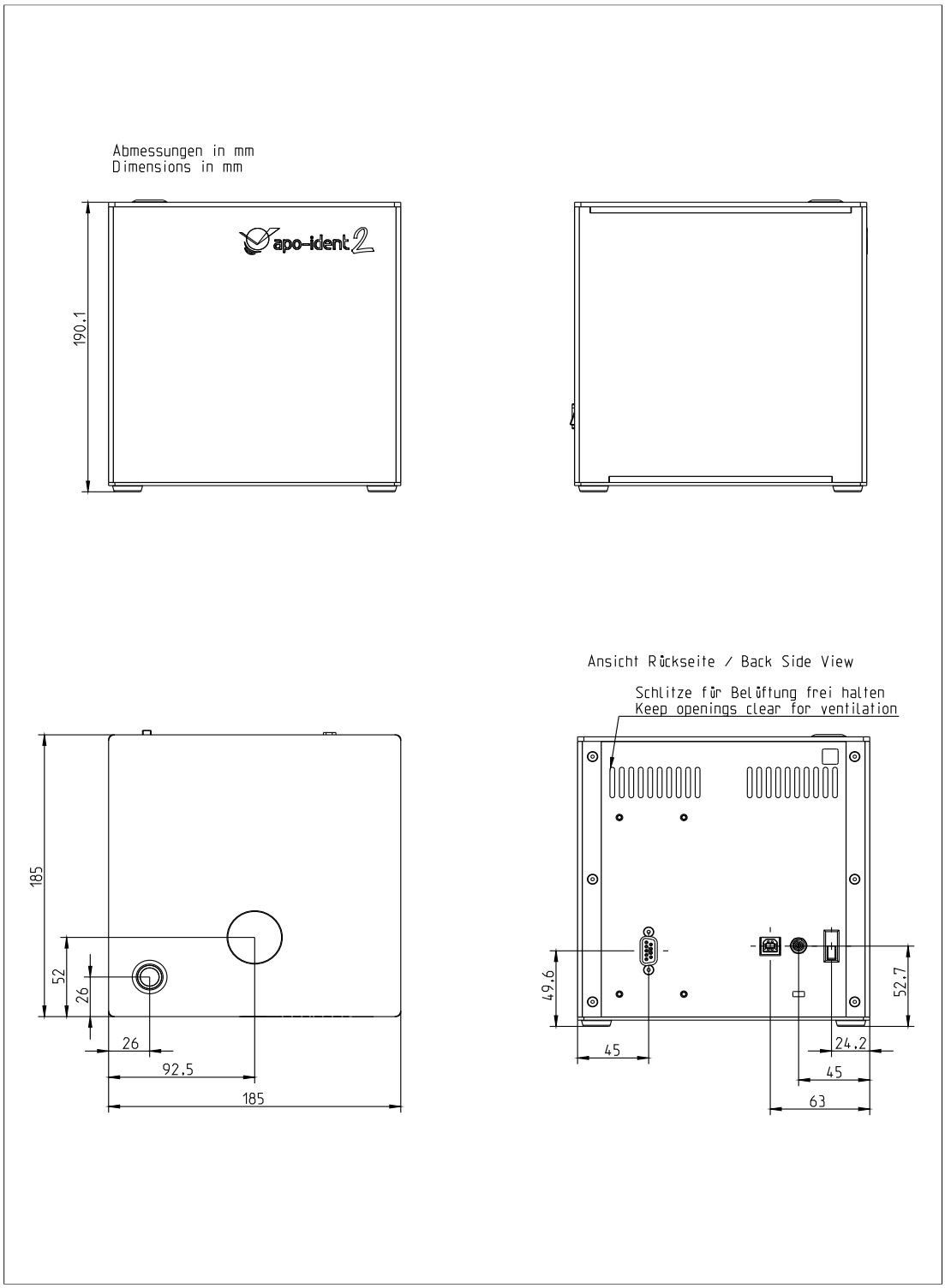
According to the European WEEE Directive, electrical and electronic instruments may not be disposed of with household waste. Their components must be recycled or disposed of separately, as toxic and hazardous components can cause lasting damage to health and the environment if disposed of improperly.

According to the German Electrical and Electronic Equipment Act (ElektroG), you are obliged to dispose of electrical and electronic equipment properly at the end of its service life. If you have not implemented a procedure for this in your company, HiperScan GmbH as the manufacturer will accept the instrument for disposal.

If you are located outside the EU, please contact local authorities or waste disposal companies for information on specific requirements and collection points for the proper disposal of electronic instruments.

Naming	Order number
Apo-Ident 2.x power supply unit	100-000136
IEC connection cable 1.8m	100-000009
USB cable Apo-Ident	100-000053
Transflectance insert	920-000003
Reference standards set	920-000049
White reference	920-000046
White reference sample insert	920-000007
Black reference	920-000047
Sample insert for small amounts of substance	920-000008
Sample cup	920-000002
Adapter ring	920-000004
Transport case	920-000010
Transport packaging	-

spectral range:	1000 - 1900 nm
Spectral resolution:	10nm (over the entire spectral range)
Stray light:	< 0,2%
Measuring time:	<15s per scan
Detector:	InGaAs single detector, uncooled
Wavelength accuracy:	± 1 nm (over the entire spectral range)
Wavelength reproducibility:	± 0.3 nm (over the entire spectral range)
Photometric reproducibility:	± 0.15 % (over the entire spectral range)
Photometric non-linearity (max / RMS):	< 2 % / < 1,5 %
Light source:	Tungsten-halogen light source
Integrated references:	White and wavelength standard
Ambient temperature range for storage:	-20 °C to 60 °C
Ambient temperature range during Operation:	5 to 35°C
Relative humidity in storage / operation:	≤ 80% (non-condensing)
Permissible altitude for operation:	≤ 2000 m ASL
Required degree of cleanliness:	Pollution degree 2 (DIN EN ISO 61010)
IP degree of protection Enclosure:	Comparable to IP20
Shockproof housing:	IK08
Input voltage instrument:	12 VDC
Input current instrument:	3,35 A
Maximum power consumption instrument:	40 W
Input voltage mains adapter:	100 - 240 VAC ± 10%, 50-60Hz
Protection class mains adapter:	Protection class 1
Protection class instrument:	Protection class 3
Interfaces on the instrument:	USB type B, D-SUB9 (manufacturer-specific assignment)
Emission sound pressure level:	<70dB(A)
Dimensions (WxHxD):	185x192x220mm³ (without plug connector)
Weight:	2.95 kg (without attachments)


Abmessungen in mm
Dimensions in mm
190.1
Ansicht Rückseite / Back Side View
Schlitze für Belüftung frei halten
Keep openings clear for ventilation
185
52
26
26
92.5
185
49.6
45
52.7
24.2
45
63

EC Declaration of Conformity

HiperScan GmbH hereby declares that the product ***Apo-Ident 2.x*** complies with the basic safety, health and environmental protection requirements of the EC directives listed below due to its design and construction in the version marketed by us.

WEEE Directive 2012/19/EU

RoHS Directive 2011/65/EU

Radio Equipment Directive 2014/53/EU

DIN EN 6231-1:2008	Limitations of human exposure to electromagnetic fields (0 Hz to 300 GHz)
DIN EN 300328-1:2019	Wideband transmission systems Data transmission equipment operating in the 2,4 GHz band
DIN EN 301489-1:2019	Electromagnetic compatibility (EMC) - Standard for radio equipment

EMC Directive 2014/30/EC

Applied harmonized standards Emitted interference:

DIN EN 61326 -1:2022-11	Electrical equipment for measurement, control and use - EMC requirements
DIN EN 61000-3-2:2019	Limit values for harmonic currents class A
DIN EN 61000-3-3:2013	Limitation of voltage changes, Voltage fluctuations and flicker in public Low-voltage supply networks
DIN EN 55011:2022-05	Industrial, scientific and medical equipment Equipment - Radio disturbance, Group 1, Class B

Applied harmonized standards Immunity:

DIN EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements
DIN EN 61000-4-11:2020	Immunity to voltage dips, Short-term interruptions and voltage fluctuations
DIN EN 61000-4-2:2009	Immunity to the discharge of static electricity
DIN EN 61000-4-3:2020	Testing of immunity to radio frequency electromagnetic fields
DIN EN 61000-4-4:2013	Immunity to fast transient electrical electrical disturbances/burst
DIN EN 61000-4-5:2014	Immunity to surge voltages/surge
DIN EN 61000-4-6:2014	Immunity to conducted disturbances, induced by high-frequency fields

Low Voltage Directive 2014/35/EC

EN 61010-1:2020-03	Safety requirements for electrical equipment for measurement, control and laboratory use control and laboratory equipment

Machinery Directive 2006/42/EC

DIN EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk Reduction Risk assessment and risk reduction

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Register entry

Entry in the commercial register.

Register court: Dresden

Register number: HRB 24683

Value added tax

Value added tax identification number in accordance with §27a UStG:

DE249 64 89 83

Waste of Electrical and Electronic Equipment

WEEE reg. no. DE 36177179