Instructions for use – CubePlus

1 Legal References

Instructions for use (IFU) – CubePlus
Document version: V1.2, 2025-06-18

2 Symbols

	Attention! Important and safety-relevant information
	Manufacturer
	Please follow the instructions
	In-Vitro Medical Device
 2004-06	Date of manufacture (year & month)
	Serial number
	Do not dispose of in general waste. Please refer to country-specific rules and laws when disposing of the reader
REF	Part number
IP20	Protection class of electronic equipment
	CE symbol
Var.A	Variant info of reader configuration (Factory setting of reader functionality as described in this manual)
	Distributor
	Importer
	Swiss authorized representative
	For near patient testing (POCT)
	Not for self-testing
	Transport and storage between -30 °C and +80 °C / -22°F and +176°F

3 Intended Purpose

Photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests for in-vitro diagnostics. In particular, its function is to provide diagnostic assistance in connection with specific LFA tests, sample material for these tests can be any body fluids and extracts.

The evidence of a specific disorder, condition, or risk factor of interest depends on the test defined by the manufacturer of the assay reagents, who brings this test into the photometer via use of an RFID card. The manufacturer of the assay reagents also determines the related target population.

The application is solely performed manually by professional users. The photometer itself is not a companion diagnostic device.

4 Scope and general Information

Thank you for choosing this product.

The CubePlus is a photometric reading device, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests.

The respective test-specific data is transmitted wirelessly before the measurement using an RFID (Radio Frequency Identification) card. Before each measurement, please ensure that the lot number of the test matches on the number on the RFID tag.

The measurement results can be stored internally. They can be transferred to a PC by USB or to a smart device using Bluetooth. The reader contains a rechargeable battery, but can also be powered via a USB-C cable.

The use of the reader is subject to the provisions laid out in the “Commissioning and Safety Instructions” chapter. The reader can be used as a portable handheld reader or as a stationary measuring device.

The reader is at risk of contamination through test-specific residues. In such cases, it must be cleaned following appropriate protective measures using a disinfectant that does not damage the housing of the reader (e.g. Mikrozid® AF Liquid or comparable products).

5 Liability Exclusion

This product has been manufactured under strict quality controls, calibrated, and thoroughly tested before delivery, so that a high level of quality can be ensured. The test-specific configurations are created by third-party companies (test manufacturers/distributors) and made available on the reader using an RFID card for test execution. The manufacturer of the reader is therefore not liable for the accuracy of test-specific measurement results from tests used with this reader by third-party companies.

The RFID cards are included with the corresponding tests and, like the tests, may be lot specific.

Results obtained using the reader are not to be used as the sole basis for making a diagnosis.

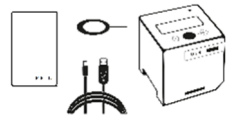
To establish a definitive diagnosis and initiate appropriate treatment, reference results that were determined using recognized, comparable methods should always be included.

6 Scope of Delivery

Variant CubePlus Flat:

- Reader incl. IFU
- Test adapter for measurement
- USB-C cable
- Reset pin
- USB power unit (optional)
- USB stick with CubePlus DataReader Software (optional)
- QC set (optional)

Variant CubePlus Cavity:



- Reader incl. IFU
- USB-C cable
- Reset pin
- USB power unit (optional)
- USB stick with CubePlus DataReader Software (optional)
- QC set (optional)

7 Commissioning and Safety Instructions

Please read the IFU carefully before use.

Attention: Any serious incident that has occurred in relation to the reader must be reported to the manufacturer, the distributor and the competent authority of the Member State where the user and/or patient is established.

Attention: The reader must not be opened. Opening the reader will void any manufacturer's warranty.

Attention: Protect the reader from liquids. Any direct contact with liquids can cause irreparable damage.

Attention: The reader contains a rechargeable lithium-ion battery. The battery should be charged before using. To do so, the reader must be connected via the USB-C cable to a USB power supply unit (optionally included in the delivery) and connected to the mains.

Attention: When charging, please use the provided power supply unit and cable, or similar standard products with the same technical specification as indicated on the components; The safety of the reader cannot be guaranteed otherwise.

Attention: When used correctly, the reader does not pose a biological hazard. However, careless handling can contaminate the reader with hazardous biological materials. The reader’s safety measures can lose their function through incorrect use.

Therefore, please always follow the instructions listed in this manual!

Attention: Please follow the test manufacturer's instructions for the disposal of cassettes containing harmful or infectious biological material.

Attention: The reader is intended for use on a flat and level surface. The reader should only be used within the specified operating conditions. It should not be moved during the measurement and should be protected from strong lighting, such as direct sunlight. When positioning the

reader in the workplace, please make sure that disconnecting from the mains is not prevented by any obstacles.

Attention: Metallic surfaces can affect the RFID card and Bluetooth receiver. Always hold the RFID card directly over the housing / display of the reader to ensure the best possible transfer of the configuration data.

Attention: The electromagnetic environment should be evaluated before operating the reader.
The reader should not be used near sources of strong electromagnetic radiation (e.g. e.g. deliberately unshielded high-frequency sources) as these may interfere with proper operation.

Attention: If the reader is stored for long periods and is not in use, it should be checked and switched on regularly (at least every three months) to check the charge level of the battery and charged if necessary to avoid deep discharge.

Attention: The QC set included in the scope of delivery must be stored under special conditions: light-proof packaging, temperature +18 to +22°C, maximum humidity 40%. The packaging provided with desiccant guarantees these conditions.

8 Battery and charging instructions

The reader is powered by a lithium-ion battery. The current charge level of the battery is only displayed to the user when the charge level is low by a battery symbol on the display.

The battery can be charged through the USB-C port at the front of the reader via USB-C cable, which can be connected to the mains with a standard USB power unit (may be included in the scope of delivery).

The reader can continue to be used normally whilst charging. When positioning the reader in the workplace, please make sure that disconnecting from the mains is not prevented by any obstacles.

9 Mains Operation

When the battery needs charging, the indicator light on the top right of the reader will flash red. The indicator light will remain a solid red while the device is connected and charging via cable.

The device will automatically turn off if the battery level is too low and the cable is unplugged.

10 Measurement Modes

The reader offers two options for performing a measurement.

10.1 Direct Measurement

With this type of measurement, the test-specific incubation time must be monitored by the user. The user must follow the test's instructions for use to determine the correct reading time. Failure to adhere to the exact incubation time can lead to erroneous results.

The measurement starts immediately after pressing the button on the reader. The result is shown on the display and can be saved internally.

10.2 Timer Measurement

With this type of measurement, the test-specific incubation time is firmly defined and already stored in the configuration file. The timer for the incubation is started manually by the user. After the timer has expired, e.g. after 15 minutes, the reader carries out the measurement automatically and displays the result on the screen. The timer measurement can be canceled at any time by pressing the operating button. The user is responsible for starting the timer immediately after applying the sample to the test cassette. Waiting too long increases the incubation time and can affect the measurement result.

Details of the measurement procedure are described in the following chapter.

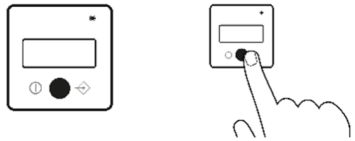
11 Measurement Procedure

11.1 Off

The reader is switched off, nothing is shown on the display.

11.2 Switch-on

Briefly press the button (<1 second) to switch on the reader.



11.2.1 Display Test

During start-up, all components of the display light up briefly to check their functionality.

Attention: If one or more of the components do not light up, the reader should not be used for measurements, as results may not be presented correctly. Please contact your distributor immediately to exchange the defective reader.

11.2.2 Self-Test

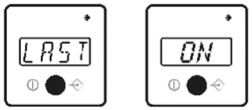
After the display test, the reader performs a short self-test to check memory and measurement-related internal functions.

11.2.3 Checking Date and Time

If the reader has been disconnected from the power supply for longer than one minute (via battery or cable), it will display the date and time after the self-test has been completed. In this case, please follow the instructions in the chapter "Date and Time". After setting the date and time, the reader will restart automatically.

11.2.4 Last saved Result

If your reader has the option to display the last saved result, this will now be displayed onscreen. Confirm the result by briefly pressing the button (<1 sec.). The reader will then display "ON" and is ready for use.



11.3 Ready for Use

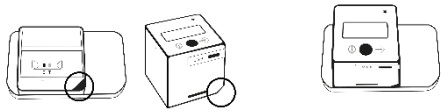
"ON" appears on the display screen and the reader is ready for use. The lateral flow rapid test is needed next.

11.4 Test Insertion

Variant CubePlus Flat:

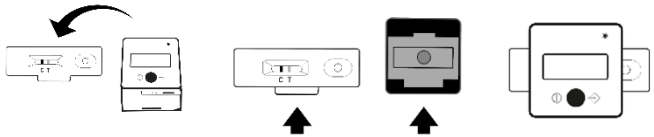
Place the test cassette into the appropriate adapter, inserting it from either the top or bottom depending on the type of adapter used.

After inserting the cassette into the adapter, place the reader on top of the adapter. The elevation in one of the corners of the adapter surface is used to position the reader correctly.



Variant CubePlus Cavity:

Place the cube reader on the test cassette according to the specified shape contour and bring it into its final position by pressing it lightly. The bottom of the cube reader and cassette should align.

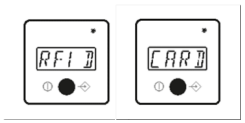


11.5 Start Measurement

The reader is now ready to start the measurement. Either an immediate measurement or a timer measurement can be started. Which type of measurement is started can be determined by preshow long the button is pressed for.

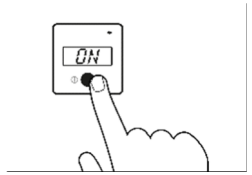
11.5.1 Direct Measurement

Briefly press the button (<1 sec.) to start an immediate measurement; the display will now show "RFID". Then continue with the next step.



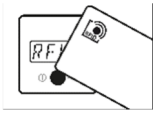
11.5.2 Timer Measurement

Press and hold the button longer (>1 sec.) if you want to start a timer measurement, i.e. if you want the measurement to start automatically after a fixed incubation time. Depending on the configuration, the display screen now shows "RFID". Timer measurements can be canceled during the measurement by pressing the button.



11.6 Test Configuration Data

Place the test-specific RFID card on the top of the reader or hold the reader against the surface labeled "RFID". Wait for an audio signal to confirm the loading of the configuration file.



11.7 Test

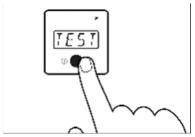
After a successful transfer or selection of the test configuration, "TEST" is now shown on the display screen.

11.7.1 Show Test- & Lot-specific Information

Optionally, you can press and hold the button for >1 sec to display test and lot specific information. With a short press of the button, you can return to the "TEST" display and continue with the measurement.

11.8 Start Measurement

Start the measurement by briefly pressing the button.



11.9 Run

The display screen now shows "RUN" and the measurement is carried out.

11.10 Results

After a few seconds, the result will be displayed.

11.11 Saving Results

The internal memory of the reader allows several hundred results to be saved. If the internal memory is already full when a new measurement result is stored, the oldest result will be overwritten. Any further storage will overwrite the results in chronological order.

All measurement results are automatically saved in the internal memory. No specific message appears on the display.

11.11.1 Return to 'ON' state

After briefly pressing the button, "ON" appears again on the display screen. You can now start a new measurement if required.

11.12 Switch-off

If the reader is switched on and will not be activated for at least 60 sec., the reader automatically shuts down. Restart the reader if a new measurement is to be carried out.

Please note:

There is no active function to shut down the reader. The reader cannot restart immediately after shutdown. Wait for 3 seconds before restarting the reader after it has shut down.

12 Status LED

The reader provides optical information about its status via LED.

Modes of LED lighting:

- Flashing blue: Waiting for Bluetooth connection
- Steady blue: Bluetooth connected
- Flashing red: Battery low
- Steady red: Connected by cable / recharging

The red and blue light can be activated simultaneously. This does not affect the status indication of each color.

13 Bluetooth

The reader provides Bluetooth connectivity following Bluetooth standard 5.0 and higher.

Bluetooth will be activated when the reader is switched on. The reader will check for Bluetooth devices every 10 seconds. Once a Bluetooth device has been connected, the status LED will change to a steady blue.

14 QC Test with QC set

A basic check of the reader function is ensured by the integrated self-test system during the switch-on process. In addition, a QC test can be carried out independently at any time with the help of a QC set, in which the correct function is checked by a full measurement of a test tool. The QC set required for this may be included in the scope of delivery or can be purchased if required. The QC set consists of a QC adapter and an associated QC test configuration on an RFID card (integrated in the adapter or enclosed as an RFID card), in a light-proof packaging with a desiccant.

14.1 QC Test Measurement

To perform a QC test, please take the QC adapter out of the packaging and place the reader on top of it according to step "Test insertion". Then press the button briefly and the text "RFID" should appear on the display screen. Hold the corresponding RFID card with the QC configuration on the reader and wait until the transmission of the configuration file is confirmed by an audio signal. The result is immediately displayed as "PASS/OK" or "FAIL".

⚠ Attention:

The QC test can pass (e.g. "PASS/OK") or fail (e.g. "FAIL"). If the test is not passed, the reader should not be used under any circumstances, as the measurement results could be incorrect. In this case, please contact your distributor for the replacement of defective readers.

⚠ Attention:

The QC set must be stored under special conditions: light-proof packaging, temperatures between 18 - 22°C, maximum humidity of 40%. The packaging provided with desiccant guarantees the light and humidity conditions.

15 Error Messages

15.1 Display: "ERR"

The reader could not read the RFID card correctly.

Fix

Confirm by briefly pressing the button, the display screen will now show "ON". Try to start the measurement process again. If the error occurs repeatedly, please contact your distributor.

15.2 Display: "DATE"

The expiration date of the test has passed.

Fix

The reader compares the internal date with the expiration date of the test.

Check the expiration date of the test and use a new one if it has indeed expired. After briefly pressing the button, "ON" will appear on the display screen and you can restart the measurement. If the expiry date has not yet passed, check the reader's internal date, and correct it if necessary ("Date and Time").

15.3 Display: "FAIL"

The reader could not find a C line.

Fix

Ensure that the test cassette is correctly inserted into the reader ("Test insertion"). Then return to the "ON" state with a short press and start the measurement again. If the error occurs again, use a new test.

15.4 No Function

Despite pressing the button, no information appears on the display screen.
Possible cause: Empty battery

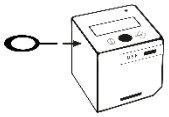
Fix

Insert the USB-C cable and try to start the reader again.

If the reader still does not respond, please contact the distributor.

16 Reset

In case the reader software freezes it is possible to restart the reader using the reset pin which can be found in the packaging. Insert the reset pin spike into the proper opening located on the upper left side of the reader.



Pressing the reset button will switch off the reader. Continue with step "Switch-on" to start the reader.

17 Date and Time

Turn the reader on via the step "Switch-on". Briefly press the button twice (<1 sec.) to call up the date and time display.

To change the current year, month, day, hour, and minute settings, do the following:

- Press and hold the button for >1 sec.
  ⇨ entry flashes (editing mode active)
- Press the button briefly for <1 second
  ⇨ flashing value can be edited
- Keep the button pressed for >1 second
  ⇨ the currently flashing value is saved
- Next entry flashes, etc.

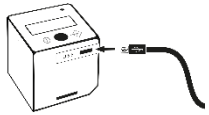
After each confirmation made by pressing and holding the button, the next entry will be displayed flashing. Repeat the process until you have set the year, month, day, and hour and minute to the current value.

The update of all values will then be confirmed with the display message "OK".

By briefly pressing the button again (<1 sec.), you can return to the "ON" state, the reader is now ready for measurements again. If necessary, repeat this process after replacing the battery.

18 Data Transfer

The reader offers the possibility of transferring data to a PC, laptop, or smart device. The data transfer can be done by USB or Bluetooth.



For Windows operating systems, the CubePlus DataReader software is required. The software may be included in the scope of delivery. The connection is made via USB-C cable.

Once the reader is connected by cable, the operating system will install the required driver automatically.

19 Maintenance and Cleaning of the Window

The reader does not require regular maintenance. Before each measurement, the bottom of the glass window should be checked for dirt, visible lint or marks on the glass. A commercially available textile cloth suitable for use on glass and with a cleaning agent is recommended for cleaning the window.

A disinfectant suitable for laboratory equipment can be used to clean the surface of the housing, e.g. *Mikrozid® AF Liquid* or comparable products.

20 Returning the Reader

In the event of a defect, it may be necessary to return the reader to the distributor. In such a case, first contact your distributor for further coordination.

Due to possible contamination with potentially infectious material during use, it is required that the reader is disinfected prior to return.

For complete disinfection, all parts must be cleaned with a suitable agent. The disinfectant should be suitable and approved for laboratory devices and should not affect the housing material of the reader. Suitable for this are, for example, *Mikrozid® AF Liquid* or comparable products.

The template in the following chapter can be used as proof of the disinfection of the reader.

Please send the reader back properly packaged, ideally in the original cardboard box and enclose the disinfection receipt with the delivery papers.

21 Disinfection Receipt

Attention: Returned readers cannot be accepted without a signed disinfection receipt and will be returned unopened!

Reader type: CubePlus

Reason for return:

Customer/company:

Date of disinfection:

Disinfection operator:

Serial numbers of disinfected readers:

The following disinfecting measures were carried on the aforementioned readers: (please tick):

☐ Cleaning of every surface of the reader with paper tissue and disinfection solution suitable for laboratory devices

(for instance, *Mikrozid® AF Liquid* or comparable product)

Place and Date _____ Signature _____

22 Disposal of the reader

Since the reader is exposed to potential contamination during use, it must be properly disinfected using suitable agents.

Then dispose of the reader separately from the battery in accordance with your country's specific regulations.

To remove the battery safely, please contact the manufacturer for instructions. Alternatively, you can send the reader back to your distributor or directly to the manufacturer for disposal. Please note the specifications laid out in chapter "Returning the Reader".

23 Reader Specifications

Description:	Reader for lateral flow assay tests / rapid tests
User:	Professional Use; Lab and POCT
Test format:	Test cassette or test strip
Application:	Reader for quantification, semi-quantification, or qualification of test-line intensity; adaptable for tests with multiple test lines
Dimensions L x W x H:	Approx. 1.6 x 1.6 x 1.6 in. (41 x 41 x 40 mm)
Weight:	Approx. 1.4 oz (40 g)
Operation:	One button operation
Display:	14-segment LCD
Storage capacity:	Several hundred test results
Measurement period:	Approx. 3 sec.
Power supply:	USB-C cable; rechargeable lithium-ion battery
Interface:	USB-C, Bluetooth 5.0, also usable for data transfer to PC/laptop
Configuration:	Specific configuration program; RFID technology
Measuring field:	Min. 0.2 in. (4 mm) width; max. 0.7 in. (18 mm) length
Lighting:	Wavelength 525 nm
Signaling device:	Buzzer
Operating conditions:	Between +10°C (+50°F) and +35°C (+95°F); Between 20% and 85% relative humidity
Transport / Storage conditions:	Between -30°C (-22°F) and +80°C (+176°F); Between 20% and 85% relative humidity
Storage QC Set	Storage with lightproof packaging Storage at room temperature (+18°C .. +22°C / +65°F .. +72°F) Maximum relative humidity 40%
Degree of protection:	IP 20
Color of housing:	Customizable

24 Manufacturer's Information

opTricon GmbH
12489 Berlin, Germany
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Info@optricon.de
www.optricon.de

CE

For support when using the product in combination with specific tests, please contact the distributor first.