

Instructions for use – Cube Reader (Cavity)

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Instructions for use (IFU) - Cube Reader

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2 Symbole

	Attention! Important and safety-relevant information
	Manufacturer
	Please follow the instructions
	In-Vitro-Diagnostics
 2004-06	Time of manufacture (year & month)
	Serial number
	Do not dispose in general trash. Please refer to country-specific rules and laws when disposing if the device
REF	Part number
IP20	Protection class of electronic equipment
	CE symbol
Var.A	Variant info of device configuration (Factory setting of device functionality as described in this manual)
	Distributor
	Importer
CH REP	Swiss authorized representative

	For near patient testing (POCT)
	Not for self-testing
	Transport and storage between -30 °C and 80 °C

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 Cube Reader is a photometer for qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests.

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

The measurement results can be saved internally. In addition to its own measurement ID (identification number of the measurement), each measurement result contains the test name, lot number, the test manufacturer name, as well as the date and time of the measurement. The measurement results can be read out via a special USB cable using the Cube DataReader software. The device is battery-operated, but can also be powered via the USB cable.

The use of the device is subject to the provisions in the "Start-up & safety instructions" chapter. The reader can be used as a portable handheld device or as a stationary measuring device. It can also be operated remotely using a Cube Reader-specific USB cable and the free Cube DataReader software.

The device can be contaminated by test-specific residues. In this case, it must be cleaned with appropriate protective measures using a disinfectant that does not attack the housing of the device (e.g. Mikrozid® AF Liquid or comparable products).

5 Liability Exclusion

The devices are manufactured under strict quality controls, calibrated and thoroughly tested before delivery to ensure a high level of quality. The test-specific configurations are created by third-party companies (test manufacturers/dealers) and made available on the device using an RFID card for test execution. The manufacturer of the device is therefore not liable for the accuracy of test-specific measurement results from tests installed on this device by third-party companies. The RFID cards are included with the associated tests and, like these, may be lot-specific.



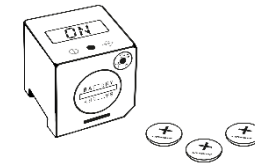
Results obtained from the device shall never be used as the sole basis for making a diagnosis.

In order to establish a definitive diagnosis and initiate appropriate therapies, reference results shall always be included that were determined using recognized, comparable methods.

6 Scope of Delivery

Each reader is delivered in a box with the following contents:

- Reader
- Three CR2032 batteries (optional)
- Reader-specific USB data cable (optional)
- USB Stick with Cube DataReader Software (optional)
- QC-Set (optional)



7 Commissioning and Safety Instructions

Please read the manual carefully before use.



Attention:

Any serious incident that has occurred in relation to the device 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 device must not be opened. Opening the device voids any warranty on the part of the manufacturer.



Attention:

Protect the device from liquids. Any direct contact with liquids can cause irreparable damage.



Attention:

When used correctly, the device does not pose a biological hazard.

However, careless handling can contaminate the device with hazardous biological materials. Safety measures of the device can lose their function through incorrect use.

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



Attention:

The device is intended for use on a flat and level surface. It should not be moved during the measurement and should be protected from strong lighting, such as direct sunlight.



Attention:

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



Attention:

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

8 Mains Operation

The device can be powered from an electrical outlet using the Reader-specific USB cable and a standard USB power adapter.

The permanent power supply ensures uninterrupted operation and secure storage.

If the device is operated with batteries, there is a risk that a measurement process or result storage process will not be completed if the battery level is low.

9 Battery Operation

The device can also be operated with three lithium batteries of the type CR2032 (button cells). When the device is delivered, these may be inserted in the device and secured with an insulating strip / pull tab. In this case, pull out the pull tab to activate battery operation of the device.

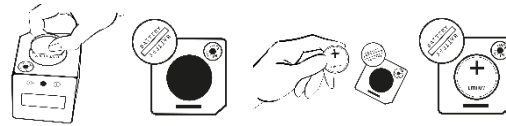
To reinsert batteries, open the battery compartment cover by turning it counterclockwise with a coin as far as it will go.

Tilt the device so that the lid can be removed. Place the three button cells in the correct orientation (with the “+” sign facing up, as shown) one at a time into the compartment.

Then place the cover back into the battery compartment while applying slight pressure and turn it clockwise with a coin until it stops.

Avoid getting the batteries dirty, for example with greasy fingers. Even slight soiling can lead to faster discharge of the batteries. It is recommended to wear gloves or use plastic tweezers.

If the device does not start after inserting the new batteries, check the correct polarity of the batteries and clean them with a dry cloth.



After the device is started up for the first time, the date and time must be set. You can find details on this in the “Date and Time” chapter.

10 Measurement Modes

The device offers two options to perform 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 decide when the test is read out by the reader. 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. 15 minutes, the reader carries out the measurement automatically and shows the result on the display. The timer measurement can be canceled at any time by pressing the operating button. The user is responsible for triggering 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 process are described in the following chapter.

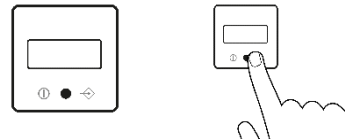
11 Measurement Procedure

11.1 Off

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

11.2 Switch-on

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



11.2.1 Display Test

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



Attention: If one or more of the segments do not light up, the device should not be used for measurements as results may

not be presented correctly. Please contact your distributor immediately to exchange the defective device.

11.2.2 Self-Test

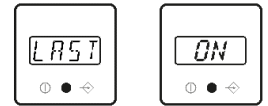
After the display test, the device performs a short self-test to check memory and measurement-related internal functions.

11.2.3 Checking Date and Time

If the measuring device has been disconnected from the power supply for longer than one minute (via batteries or cable), the device will display the date and time after the self-test has been completed. In this case, please follow the descriptions in the chapter “Date and Time”. After setting, the device will restart automatically.

11.2.4 Last saved Result

If your device has the option to display the last saved result, this will now be shown on the display. Confirm the result by briefly pressing the button (<1 sec.). The device will then display “ON” and is ready for use.

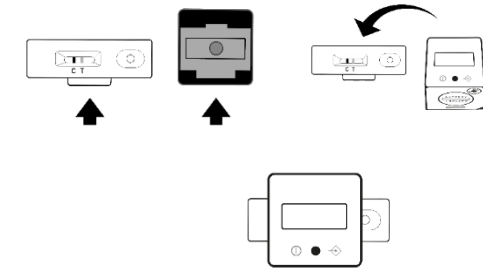


11.3 Ready for Use

“ON” appears on the display and the device is ready for use. Next, the lateral flow rapid test is needed.

11.4 Test Insertion

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

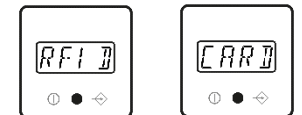


11.5 Measurement

The device 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 the length of the button press.

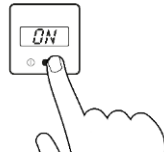
11.5.1 Direct Measurement

Briefly press the button (<1 sec.) to start a direct measurement; the display will now show “RFID” or “CARD”. Then continue with point 11.6.



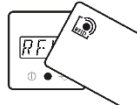
11.5.2 Timer Measurement

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 now shows “RFID” or “CARD”. Timer measurements can be canceled during the measurement by pressing the button.



11.6 Test Configuration Data

Place the test-specific RFID card included in the test kit on the top of the device or hold the device against the surface labeled “RFID”. Wait for an audio signal to confirm 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.

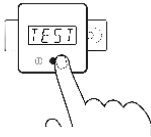
11.7.1 Show Test- & Lot-specific Information

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.



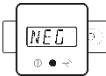
11.9 Run

The display now shows “RUN” and the measurement is carried out.



11.10 Result

After a few seconds, the result will be displayed.



11.11 Saving Result

The device's internal memory 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. Each further saving leads to a corresponding chronological overwriting. All measurement results are automatically stored in the internal memory. No specific message appears on the display and you can proceed to step 11.11.1.

11.11.1 Return to 'ON' state

After briefly pressing the button, “ON” appears again on the display. You can now continue with step 11.3 again.

11.12 Switch-off

If the device is switched on and will not be activated for about 50 sec., the device automatically shuts down. If a new measurement shall be started, start again at step 11.2.

Please note:

There is no active function to shut off the device.

12 QC Test with QC set

A basic check of the device function is ensured by the integrated self-test 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 concrete 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 tag (integrated in the adapter or enclosed as an RFID card), in a light-proof packaging with a desiccant.

12.1 QC Test Measurement

To perform a QC test, please take the QC adapter out of the packaging and place the reader on top according to step 11.4 “Test Insertion”. Then press the button briefly, the text “RFID” or “CARD” should appear on the display. Hold the corresponding RFID card with the QC configuration on the device 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 device 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 devices.



Attention:

The QC set must be stored under special conditions: light-proof packaging, temperature 18 - 22°C, maximum humidity 40%. The packaging provided with a desiccant guarantees these conditions.

13 Error Messages

13.1 Display: “ERR”

The device could not read the RFID card correctly.

Fix

Confirm by briefly pressing the button, the display now shows “ON” again. Proceed to step 11.5 again. If the error occurs repeatedly, please contact your distributor.



13.2 Display: “DATE”

The expiration date of the test has passed.

Fix



The device 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 is indeed expired. After briefly pressing the button, “ON” appears on the display and you can continue with step 11.4. If the expiry date has not yet passed, check the device-internal date, and correct it if necessary (see chapter 14).

13.3 Display: “FAIL”

The device could not find a C line.

Fix

Ensure that the test cassette is correctly inserted into the device (step 11.4). Then return to the “ON” state with a short press and repeat step 11.5. If the error occurs again, use a new test.



13.4 No Function

Despite pressing the button, no information appears on the display.

Possible cause: Discharged batteries

Fix

Open the battery compartment and replace the discharged batteries with new ones as described in section 9 “Battery Operation”.

If the device still does not respond with new batteries, please contact the distributor.



14 Date and Time

Set the device to “ON” state via step 11.2. 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:

- Keep the button pressed for >1 sec. => entry flashes (editing mode active)
- Press button briefly for <1 second => change of the flashing value
- Keep the button pressed for >1 second => the currently flashing value is saved
- Next entry flashes, etc.

After each confirmation by pressing the button for a long time, the next entry is 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 saying “OK”.

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



15 Data Transfer

The device offers the possibility of transferring data to a PC or laptop. This requires a Cube Reader specific USB cable and the Cube DataReader software.

This package consisting of cable and software (USB stick) may be included in the scope of delivery. To install and use the software, follow the instructions in the software manual, which can also be found on the USB stick.

16 Device Specifications

Description:	Reader for standard lateral flow assays
User:	Professional Use; Lab and POCT
Test format:	Test cassette or test strip
Measurement:	Device for quantification, semi-quantification, or qualification of test-line intensity – also adaptable for multiple test-line measurements
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:	3 batteries CR2032 (3 V/230 mAh) or Cube Reader specific power cord (optional article) also usable for data transfer to PC/laptop
Interface:	4 pole – 0.1 in. (2,5 mm) jack plug for power supply and USB 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 50°F (+10°C) and 95°F (+35°C); Between 20% and 85% humidity
Transport / Storage conditions:	Between -22°F (-30°C) and 176°F (+80°C); Between 20% and 85% humidity
Storage QC Set	Storage with lightproof packaging Storage at room temperature (65°F..72°F / 18°C..22°C) Maximum relative humidity 40%
Degree of protection:	IP 20
Color of housing:	Customizable

17 Maintenance and Cleaning of the Window

The device does not require regular maintenance. Before each measurement, the bottom of the glass window should be checked for dirt. A

commercially available textile cloth suitable for glass and a cleaning agent are recommended for cleaning of the window.

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

The battery voltage is continuously monitored. Replace the batteries as soon as the battery icon starts flashing. Never recharge empty batteries and ensure that they are disposed of properly.

18 Returning the Reader

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

Due to potential contamination with infectious material during use, disinfection is required prior to return.

For complete disinfection, all 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 device. Suitable for this are, for example, *Mikrozyd® AF Liquid* or comparable products.

The template on the following page can be used as proof of the disinfection of the device. Please enclose the disinfection slip with the delivery papers.

19 Disinfection Receipt

Attention: A reader sent in cannot be accepted without a signed disinfection receipt and will be returned unopened!

Device type: Cube Reader

Reason for transmittal:

Customer/company:

Date of disinfection:

Disinfection operator:

Serial numbers of disinfected devices:

The following disinfecting measures were executed on the above-mentioned devices: (please checkmark):

Cleaning of every surface of the device with paper tissue and disinfection solution suitable for laboratory devices
(for instance *Mikrozyd® AF Liquid* or comparable product)

Place and date

Signature

20 Disposal of the device

Since the device is exposed to potential contamination during use, it must be properly disinfected using suitable protective equipment.

Then dispose of the device separately from the batteries in accordance with the respective country-specific regulations.

Alternatively, you can send the device back to your distributor or directly to the manufacturer for disposal. Please note the specifications in chapter 18 for the return.

21 Manufacturer's Information



BIOSYNEX TECHNOLOGIES GmbH
12489 Berlin, Germany
Schwarzschildstraße 1
CDGInfo@chembio.com
www.chembiogermany.de
www.biosynex-technologies.de



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