

Instructions for use – Microreader II

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








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Instructions for use (IFU) – Microreader II

Document version: V1.2, 2024-05-13

2 Symbols

	Attention! Important and safety-relevant information
	Manufacturer
	Please follow the instructions
	In-Vitro-Diagnostics
	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
	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 Microreader II is a photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in DPP and DDPP Lateral Flow Assays (LFAs) / rapid tests.

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

The measurement results are automatically stored in the reader’s memory allowing to save up to 7000 results. Every saved result includes a unique measurement ID, test name, lot number, distributor/manufacturer, date and time, Meta data along the actual result value. The measurement data can be extracted via Micro-USB using a commercial Micro-USB cable and the DataReader software. The device is powered by battery but can also be powered via USB.

The use of the device is subject to the provisions in the “Commissioning and 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 Microreader II 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, 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 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.

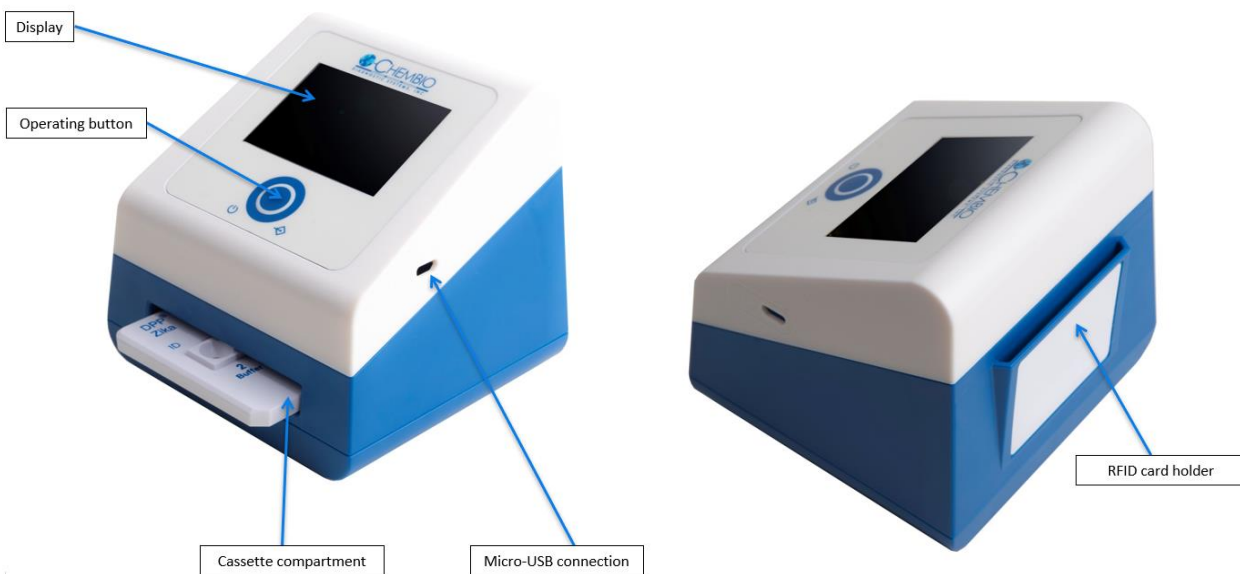
In order to establish a definitive diagnosis and initiate appropriate therapies, reference results shall always be included that were determined using recognized, comparable methods.

6 Scope of Delivery

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

- Reader incl. IFU
- Three batteries type AA
- Battery holder
- Brush for cleaning camera window
- Micro-USB data cable
- QC Set (optional)

7 Reader Overview



8 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:

Only use the provided brush for cleaning the clear plastic window of the camera.



Attention:

The QC set optionally 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.

9 Mains Operation

The device can be powered from an electrical outlet using a Micro-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.

10 Battery Operation

The device works with 3 AA batteries (alkaline cells). These are already inserted in the battery holder to be found in the Microreader II packaging.



Turn the reader upside down. Use your forefinger to open the maintenance and battery hatch.



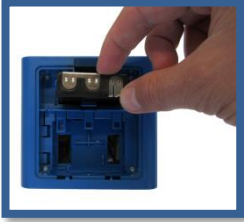
Open the hatch and remove it from the reader.



The batter holder needs to be equipped with three AA batteries.



If no batteries are inserted in the holder or if the batteries need to be changed new batteries need to be placed in the holder. Follow the marks on the holder to ensure correct polarity ('+'- sign up, see Fig.). Add the batteries one by one.



After three AA batteries have been placed in the holder it needs to be reinserted into the reader. The holder only fits one way with the round corners pointing towards the back of the device. An anti-twist safeguard will protect a wrong insertion sidewise. If the holder seems to clamp within the slot please turn the adapter and try the insertion again. A “click” sound will appear when the adapter has been inserted completely and correctly.



While inserting batteries body grease attached to fingers should not come in contact with the batteries. Contamination can lead to a more rapid discharge of the batteries. Therefore gloves are recommended.

In case the device does not start after putting in new batteries please check the polarity and clean the batteries by using a dry cloth.

11 Measurement Modes

The device offers two options to perform a measurement.

11.1 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.

11.2 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.

12 Measurement Procedure

12.1 Off

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

12.2 Switch-on

To turn on the device, press the button briefly less than 1 sec. or insert a test cartridge. The display will turn on.



The cartridge slot is designed in such a way to prevent a wrong cassette insertion. Ensure that the cartridge slides in smoothly without applying too much pressure. Too much pressure might cause damages to the anti-twist safeguards.

12.2.1 Self-Test

The device performs a short system self-test to check memory and measurement-related internal functions.

12.3 Ready for Use – Main menu

After switching on the device, the display shows the following information.



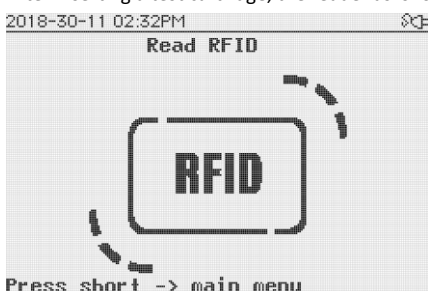
Three options are available:

- Insert a cartridge: this will lead to the start measurement screen
- Press short: this will lead to the RFID screen
- Press long: this will open a settings menu

Wait for 4 minutes and the reader will automatically switch off.

12.4 Measurement data via RFID

After inserting a test cartridge, the reader asks for the measurement information by showing RFID.

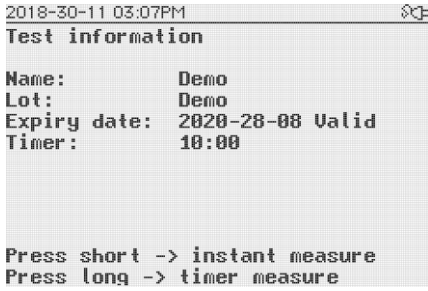


If the RFID tag is attached to the cartridge this screen will only show up for less than 1s and the measurement information screen will be displayed. If not, the reader will wait for four minutes before showing an error.

- short press: go back to main menu
- Wait for 4 minutes: the reader will turn off

12.5 Test information

After applying the RFID card either by holding it against the display or by sliding it into the RFID card holder located at the back of the device the reader will download the measurement method and will display the most important information on screen prior to starting the measurement.



This window will also be shown if a smart tag has been inserted.
 The window allows the following options:

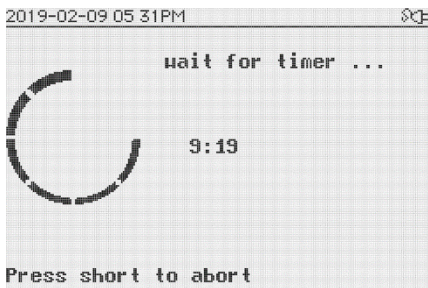
- Long press: to start a timer measurement
- Short press: to start an instant measurement
- Wait for 4 minutes: the reader will turn off

12.6 Measurement

Depending on the kind of measurement started either a timer will appear or the result screen will be shown right away.
 Start the measurement by briefly pressing the button.

12.6.1 Timing measurement

If a timer measurement has been started the countdown will be displayed according to the time setup in the configuration file.

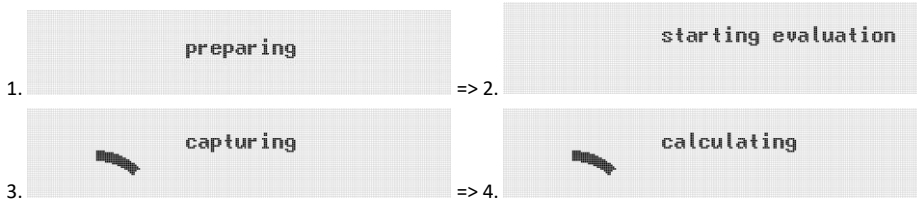


If the timer had ended the result will be displayed.

- Short press: aborts the measurement, goes back to main menu

12.6.2 Instant measurement

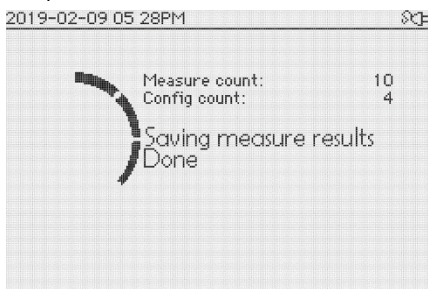
If an instant measurement has been started the measurement will be performed right away. The following steps will be shown on screen:



Depending on the setup of the measurement method a value or class is being calculated out of the measured test line value.

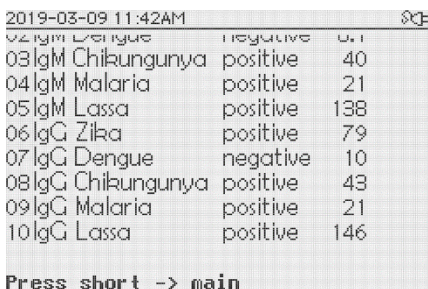
12.7 Saving Result

Every Microreader II will save the result automatically before showing it on the display. The memory of Microreader II is accessible within the reader.



12.8 Result

The measurement is done when the results are shown.



The result includes a result number, the result name, the class (if setup in the configuration file) and the measured value.

The result display can include information different than the ones shown in the example.

If the amount of results is more than ten the list will start to scroll from bottom to top. A new page is indicated by a line.

2019-03-09 11:49AM		
05 IgM Lassa	positive	138
06 IgG Zika	positive	79
07 IgG Dengue	negative	10
08 IgG Chikungunya	positive	43
09 IgG Malaria	positive	21
10 IgG Lassa	positive	146
<hr/>		
01 IgM Zika	positive	79
02 IgM Dengue	negative	R.1

Press short -> main

The reader allows the following options:

- Short press: go back to main menu
- Wait for 4 minutes: the reader will turn off



The reader will save every result. Furthermore, the reader offers a simple database to look up stored results.

12.9 Switch-off

Please note:

The reader will switch off automatically after 4 minutes. There is no active function to shut off the device.

13 Selection menu

Apart from the measurement functionality the reader offers a simple database to look up stored results. Furthermore the reader offers simple options to change the workflow of starting a measurement or to adjust the display contrast and brightness. All these features can be managed throughout the selection menu.

Open the selection menu by holding the button > 1s while the reader is “Ready for operation” mode.

2018-30-11 02:49PM	
Selection menu	
Back to main	
Show results	
Setup	

The reader allows the following options:

- Short press: navigate through the list of items
- Long press: select the tagged item
- Wait for 4 minutes: the reader will turn off

14 Stored results

The memory capacity allows the storage of up to 7000 results. Each of the results contains all OEM information, measured values, classes and information about the picture used by the reader to calculate the result value. Furthermore, each measurement result is branded with a unique test ID for allowing a better traceability.

The database can be found in the selection menu.

- Navigate to the selection menu
- Tag and select item “Show results”
- The reader will show a measurement list which contains all results stored

2019-03-09 11 33AM	
Measurement list	
Back to main	
2019-02-09 05:41PM ABC	
2019-02-09 05:28PM ABC	
2019-02-09 05:27PM ABC	
2019-02-09 05:25PM Zika MacUp	
2019-30-08 12:24AM ABC	
2019-30-08 12:24AM ABC	
2019-30-08 10:22AM ABC	
2019-30-08 10:22AM ABC	

The reader allows the following options:

- Short press: navigate through the list of items
- Long press: select the tagged item
- Wait for 4 minutes: the reader will turn off

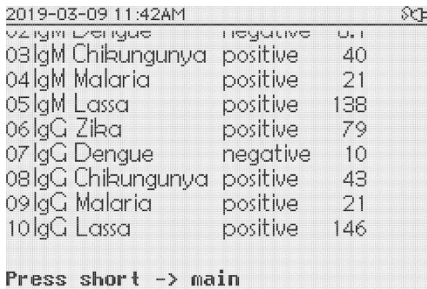
14.1 Result details

It is possible to look at the detailed information and result values of every entry in the measurement list.

The database can be found in the selection menu.

- Navigate to the result of interest
- Tag the item and select it by a long press of the button

The reader will now show the details of the selected result.



If the amount of single results exceeds 8 lines the display starts to scroll from bottom to top.

The reader allows the following options:

- Short press: go back to main menu
- Wait for 4 minutes: the reader will turn off

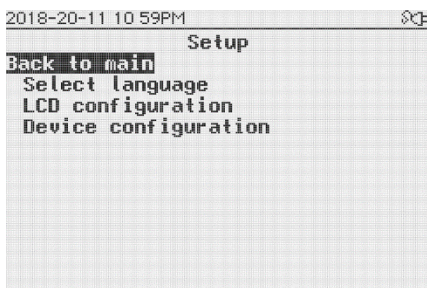
15 Setup

The reader allows adjusting the certain parameters and settings of the user interface such as:

- Language
- Display configuration
- Device configuration

The setup can be found in the selection menu.

- Navigate to the selection menu
- Tag and select item “Setup”



The reader allows the following options:

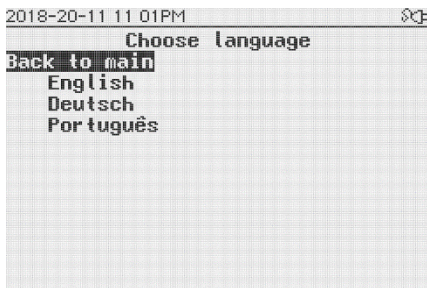
- Short press: navigate through the list of items
- Long press: select the tagged item
- Wait for 4 minutes: the reader will turn off

15.1 Setting menu language

The reader allows changing the menu language. The language menu can be found in the Setup menu which is part of the selection menu.

- Navigate to Setup in the selection menu
- Tag and select item “Select Language”

The reader will show the list “Choose language” which allows to choose the appropriate language.



The reader allows the following options:

- Short press: navigate through the list of items
- Long press: select the tagged item
- Wait for 4 minutes: the reader will turn off

After selecting the language of interest the reader will go back to the main menu and will use the language chosen.



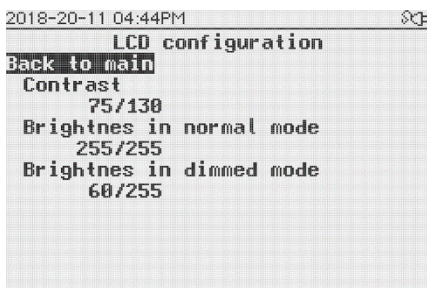
It is possible that additional languages have been added which are not shown in the screenshot above. This does not affect the workflow described in this paragraph.

15.2 Configure LCD screen

The reader allows changing the setting of the screen in order to provide a better contrast or adapt the display onto different surroundings.

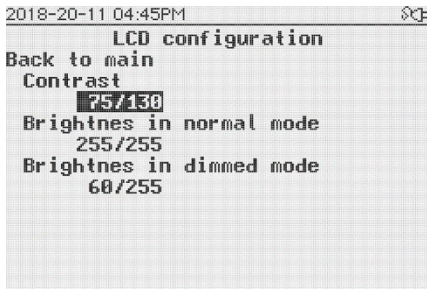
The setup can be found in the selection menu.

- Navigate to the selection menu
- Tag and select item “LCD configuration”



- Short press: navigate through the list of items
- Long press: select the tagged parameter

After the designated parameter has been tagged the cursor will jump onto the values which can be changed now.

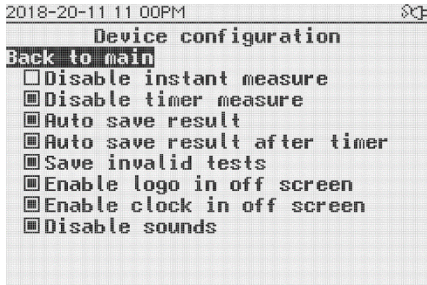


- Short press: change the parameter value
- Long press: confirm the new setting and go back to the item list

A second long press of the button will move the menu back to the main menu.

15.3 Device configuration

The reader offers changing the following options:



The reader allows the following options:

- Short press: navigate through the list of items
- Long press: select the tagged item and check or uncheck the item

15.3.1 Disable instant measure

If this option is activated the instant measurement mode will be disabled. The reader will only perform timing measurements. Once the measurement information has been read from an RFID tag the measurement will start automatically.

15.3.2 Disable timer measure

If this option is activated the timer measurement mode will be disabled. The reader will only perform instant measurements. Once the measurement information has been read from an RFID tag the measurement will start automatically.

15.3.3 Auto save result

If this option is activated all measurement results will be saved automatically. Once deactivated, the reader will not save any measurement results.

15.3.4 Auto save result after timer

If this option is activated while item 3.3 is deactivated, the reader will only save results from a timer measurement. This option becomes ineffective if item 3.3 is activated.

15.3.5 Save invalid tests

If this option is activated the reader will also save invalid results such as results where the control line was missing.

15.3.6 Enable logo in off screen

If this option is activated the company logo will be displayed while the reader is turned off.

15.3.7 Enable clock in off screen

If this option is activated date and time information will be displayed while the reader is turned off.

15.3.8 Disable sounds

This option activates and deactivates the buzzer of the reader. If this option is activated the reader will provide no audible feedback.

16 Data transfer

The device provides the possibility of data transfer to a PC, laptop or tablet. Therefore a Micro-USB cable and the Microreader II Data Reader software are required.

Please refer to the MR II DataReader software IFU for further details.

17 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 test cassette and an associated QC test configuration on an RFID tag (enclosed as an RFID card), in a light-proof packaging with a desiccant.

17.1 QC Test Measurement

To perform a QC test, please take the QC test cassette out of the packaging and insert it in the reader. Then press the button briefly, the text "RFID" 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.

18 Error Messages

18.1 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 0. If the expiry date has not yet passed, check the device-internal date, and correct it if necessary (see chapter 14).

18.2 Display: “FAIL”

The device could not find a C line.

Fix

Ensure that the test cassette is correctly inserted into the device (step 0). Then return to the “ON” state with a short press and repeat step 12.6. If the error occurs again, use a new test.

18.3 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.

19 Device Specifications

<i>Description:</i>	Reader for DPP and DDPP lateral flow assay / rapid tests
<i>User:</i>	Professional Use; Lab and POCT
<i>Test format:</i>	Test cassette DPP and DDPP
<i>Measurement:</i>	Device for quantification, semi-quantification, or qualification of test-line intensity – also adaptable for multiple test-line measurements
<i>Dimensions L x W x H:</i>	L x W x H: Approx. 3.9 x 3.9 x 4.2 in. (100 x 98 x 106 mm)
<i>Weight:</i>	267.6g (+69.4g when batteries are inserted)
<i>Operation:</i>	One button operation
<i>Display:</i>	240x160-pixel, monochrome LCD
<i>Storage capacity:</i>	7.000 test results
<i>Measurement period:</i>	Approx. 5 sec.
<i>Power supply:</i>	3 batteries AA (1,5 V/≈2 Ah), or Microreader II-Micro-USB cable also usable for data transfer to PC/laptop
<i>Wired Interface:</i>	Micro-USB B connector
<i>Configuration:</i>	Test specific configuration program; RFID technology
<i>Measuring field:</i>	2x FOV of Min. 0.2 in. (4 mm) width; Max. 0.7 in. (18 mm) length
<i>Lighting:</i>	2x Wavelength 525 nm
<i>Signaling device:</i>	Buzzer
<i>Operating conditions:</i>	Between 50°F (+10°C) and 95°F (+35°C); Between 20% and 85% humidity
<i>Transport / Storage conditions:</i>	Between -22°F (-30°C) and 176°F (+80°C); between +20% and 85% humidity
<i>Storage QC Set</i>	Storage with lightproof packaging Storage at room temperature (65°F..72°F / 18°C..22°C) Maximum relative humidity 40%
<i>Degree of protection:</i>	IP 20
<i>Color of housing:</i>	White top, blue bottom

20 Maintenance and Cleaning of the Window

The device is maintenance free. Before each measurement the two glass covers of the camera system should be checked for impurities. Therefore, remove the lid of the battery compartment. This will provide access to the bottom side of the camera. For cleaning use the green brush included in the cardboard box. Move the brush over the window with caution.

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.

21 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.

22 Disinfection Receipt

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

Device type: Microreader II

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

23 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.

24 Manufacturer's Information



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



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