Manual

RapiRead™
CUBE READER

SPARK™
MOBILE | DIAGNOSTICS

CE

IVD

Legal references

Trademark rights

Copyright information

Manual RapiRead™ CUBE Reader
Document version: V1.4, 03/2016

Contents

Symbols used in the manual and on the Cube

	Attention! Very important and safety relevant information
	Manufacturer's instructions
	Please follow the description
	*In-Vitro*-Diagnostics
 2004-06	Date of manufacture (year & month)
	Serial number
	Don't dispose in general trash. By disposal of device please refer to country specific rules and laws
REF	Catalog Number
IP20	Protection class of electronic equipment
	CE-symbol

Scope of application and safety instructions

Thank you for choosing an innovative product by Sparklabs Diagnotics India LLP. The RapiRead™ CUBE Reader is for in vitro diagnostic use, intended for professional use. The device is a mobile measuring device for the qualitative and quantitative evaluation of Sparklabs Diagnotics India LLP lateral flow IVD tests. The performance characteristic of the RapiRead™ CUBE Reader are established in combination with the Sparklabs Diagnotics India LLP lateral flow IVD test "Spar-D Quantitative Vitamin D Test" are described in the instruction for use (REF 1155Q-25 / 1155Q-10). The test specific data is transferred wirelessly by radio-frequency identification (RFID) before each measurement. Please check before each measurement if the batch number of the test matches the one printed on the RFID tag.

In case different shaped cassette types will be used always ensure using the correct cassette adapter with this particular test cassette. A wrong cassette adaptor can affect the measurement result.
The measurement data can be stored internally. Every saved result includes a unique measurement ID, test name, lot number, distributor/manufacturer, and date and time. The measurement data can be extracted via USB using a special USB cable and the Cube Data Reader software. The device is powered by battery but can also be powered via USB.

The use of the monitoring device is only allowed by following the instructions stated in chapter "Commissioning and safety instructions". The RapiRead™ CUBE Reader can be used as a mobile handheld device or as a desktop measuring device remotely controlled via USB cable and the free-to-use Cube Data Reader software.

The device and cassette adaptor can get contaminated by any test specific residues. In this case a cleaning with a disinfectant solution and protective equipment which does not affect the housing or the cassette adaptor has to be conducted (e.g. *Mikrozid® AF Liquid* or similar products).

Liability Exclusion

The devices are produced, calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. However several test-specific configurations are made by third companies (test manufacturer) and provided via RFID card for running the tests on the RapiRead™ CUBE Reader. For this reason, the device manufacturer is not liable for the correctness of test-specific measurement results for tests that have been installed on the device by a third company.
As a basic principle, results determined with the device should not be the sole base of a medical diagnosis. They should always be compared to reference values obtained from approved, comparable methods before a final diagnosis is made and a resulting therapy is initiated.

Scope of delivery

Every RapiRead™ CUBE Reader comes with three batteries, type CR2032 and a lid for the battery compartment.

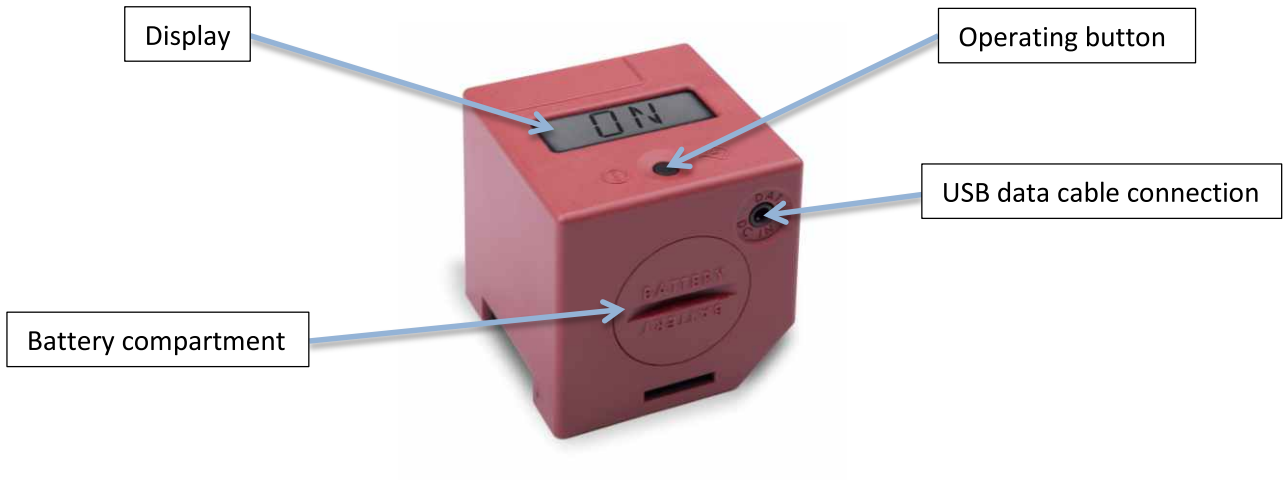
Depending on the shape of the test cassette each RapiRead™ CUBE Reader also includes a specific cassette adaptor.

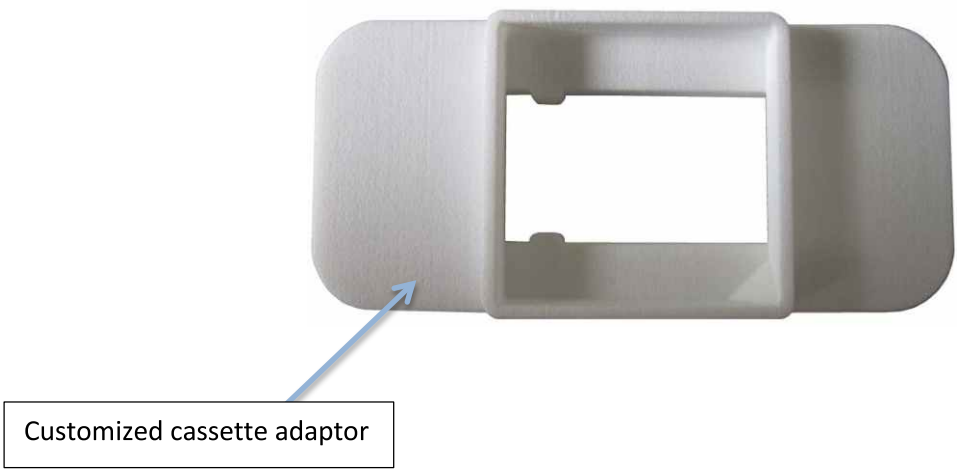
Depending on the order an RFID card and a USB cable can be included.

Depending on the reader configuration a QC set consisting of QC cassette and RFID card with QC configuration can be included.

On customer request a printed manual can be enclosed.

Device Specifications





Commissioning and safety instructions

Prior to commissioning, please read the instruction manual carefully.

Attention: The device is designed for use on a straight and horizontal surface area. During the measurement it should not be moved and not be exposed to any bright light (e.g. sunlight).

Attention: Always ensure that the RapiRead™ CUBE Reader is attached correctly and tight to the cassette adaptor. A wrong or improper attachment can lead to faulty results.

Attention: Protect the device from any liquids. Be aware that a direct contact to any liquid can damage the RapiRead™ CUBE Reader. Damages caused by liquids can be irreparably.

Attention: The device shall not be opened. Otherwise the warranty of the manufacturer is terminated.

Attention: At proper usage, there are no biological hazards coming from the device. However, when not handled properly, contamination due to biological dangerous material is possible. Safety measures of the device can become ineffective at improper usage.
Therefore please follow the instructions in this manual in any case!

Attention: Concerning test disposal of cassettes containing hazardous or infectious material, please follow the instructions of the test manufacturer.

Attention: Metal surfaces can influence the RFID scanner. Always place the RFID tag on top of the housing/display to ensure best readability of the configuration information.

Battery insertion

The device works with 3 lithium batteries (button cells) called CR2032. These have to be removed from the packaging and inserted into the battery compartment of the device. Turn the battery cover with a smooth-edged coin counter clockwise until it stops.
Turn the device slightly down, so that the battery cover can be removed. Place the three button cell batteries with correct polarity ('+'- sign up, see Fig.) into the tray one by one. Thereafter, the battery cover has to be pressed slightly with a coin and turned clockwise until it stops.
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 or plastic tweezers 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.




After turning on the device for the first time or changing the batteries, date and time need to be set. Please refer to chapter “Setting date and time”.

Measurement Modes

The device offers the following options for the test measurement:

a) Immediate measurement

For this type of measurement the test-specific incubation time must be monitored by the user. The user will decide when to apply the test to the Cube. If the user is not monitoring the incubation time correctly, the measurement results can be wrong.
When applying the test to the Cube the measurement starts immediately after pressing the button. The result will be displayed and can be stored in the internal memory.

b) Timer measurement

This type of measurement follows a test-specifically configured incubation period, e.g. 10 minutes. The incubation time is implemented in the configuration file and will be automatically started if chosen by the user. At the end of the incubation period the measurement starts and displays the result. The timer measurement procedure can be stopped by pressing the control button. The user has to ensure to start the measurement after the lateral flow test has been activated, waiting too long will affect the incubation time and thus the result.

The actual procedure of measuring will be described in the following chapter.

Measurement Procedure

Note: Items indicated with a * symbol are optional and may not apply to all RapiRead™ CUBE Reader devices.

1. Off

The device is turned off, the display is empty.

2. Turn-on

To turn on the device, press the button briefly less than 1 sec.

2.1 Display Test

After activation all display segments flash at once to check the display functionality.

Attention: If you notice single non-functioning segments the reader should not be used for measurements because result data may be displayed incorrectly. Please contact your supplier for a replacement in this case.

2.2 Self-test

After the display flash the reader runs a self-test to check internal functions important for the measurement process and memory integrity. During the self-test 'WAIT' is displayed.

2.3 Setting date and time

In case the reader was without power supply (via batteries or cable connection) for longer than 1 minute, the reader will show date and time after the self-test. Please refer to the chapter "Setting date and time". After setting date and time the reader will restart; proceed to point 2.1.

*2.4 Remaining Tests - Cube expiry **

In case your reader has the option activated to expire after a certain amount of measurements, the number of remaining measurements will be displayed after the self-test.

*2.5 Remaining Tests - until QC test **

In case your reader has the option activated that a QC test is required after a certain amount of measurements, the number of remaining tests until the next QC test is displayed next.

*2.6 Last saved result **

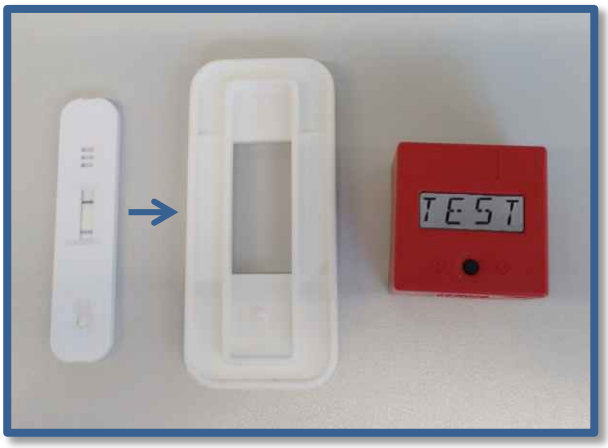
In case your reader has the option activated to show the last saved result, the next information presented on the display will be the last saved result. Press the button briefly less than 1 sec to acknowledge and the reader will show 'ON' to indicate readiness for operation.

3. Ready for operation

The display shows 'ON' and the reader is ready for operation. The rapid test is now required.

4. Test insertion

Place the test into the cassette adaptor, depending on the type of adaptor you either have to put in the test from on top or from the bottom.



After the test is placed in the cassette adaptor the reader can be placed on top. The slanted reader corner and an according counterpart inside the adaptor help to find the correct position of the reader.

5. Measurement

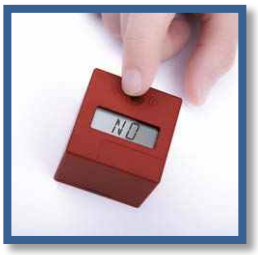
The reader is now ready to start a measurement.

5.1 Direct Measurement

Press the button briefly, the display will show 'RFID' or 'TEST', depending on your reader configuration; proceed to 6.1 or 6.2 accordingly.

5.2 Timer Measurement

If you want to start the measurement after a certain incubation time has passed, press the button longer than 1 sec. The display will show 'RFID' or 'TEST', depending on your reader configuration. Each timer measurement can be stopped by pressing the button during the measurement.



6. Test configuration data

There are different possibilities of test configuration data transmission depending on the reader configuration.

*6.1 Configuration data via RFID **

In case your reader has the option activated that test configurations are uploaded via RFID before the measurement, put the lot specific RFID card onto the top side of the device or hold the device against the RFID tag sticking on the test box until the configuration data has been uploaded (audible signal).

*6.2 Transfer of configuration from RFID to reader - temporal or permanent **

In case your reader has the additional RFID option activated that a configuration is transferred to the reader memory after being uploaded via RFID, the configuration is still available for further tests after the measurement.

There are two versions of the feature. The first version is a temporal saving of the configuration, i.e. in this case the configuration can be used for measurements until the cube turns off. When a configuration is available the reader shows 'RFID' and 'TEST' alternately instead of only 'RFID' at point 5. By pressing the button shortly the reader will use the stored configuration and proceed to point 7. If a new RFID card is placed on the reader instead, the new configuration will be uploaded

and will replace the old stored configuration. Then the reader proceeds to point 7. At turn-off the configuration is erased and a new RFID transmission is required after turn-on.

The second version of the feature is a permanent saving of the configuration after upload via RFID which is still stored after turn-off and can be used again after turn-on until it is replaced with a new RFID transmission.

Attention: The permanent version of the feature bears the risk that the currently stored configuration is unknown and a wrong test is measured with it which can lead to faulty results.

*6.3 Configuration data stored in reader **

In case your reader has the option activated that up to three test configurations are stored permanently in the reader memory and can be selected before each measurement, the reader will now show either 'TEST' if only one configuration is available. In this case proceed directly to point 7.

If more than one configuration is available in the reader memory the reader will show the tests available. A blinking display of the scrolling test name indicates the currently selected test. By pressing the button shortly the display changes to the second test name, another short press to the third, if available. As long as the display is blinking, the test is not definitely selected. To select the currently visible test, press and hold the button longer than 1 sec. The display stops blinking and the test name of the selected test scrolls through the display.

7. Test

After successful RFID transmission of the configuration or selecting the test to be run from the reader memory the display shows 'TEST'. Press and hold the button longer than 1 sec. to show test and lot specific information of the test to be run. Press the button shortly to return to 'TEST' and continue with the measurement process.

*7.1 Automatic measurement start **

In case your reader has the option activated that the measurement is started automatically after the test configuration has been uploaded via RFID, the reader does not show 'TEST' but automatically starts the measurement. In this case no lot specific information can be displayed.

8. Start measurement

Start the measurement by pressing the button shortly.

9. Run

The device measures and the display shows ‘RUN‘.

10. Result

After a few seconds the result is displayed.

Qualitative Result

Quantitative Result

11. Result saving

The reader has an internal memory to store up to 100 readings. If the internal memory is full and a new result shall be saved, the reader overwrites the first saved result. Every new saved result will overwrite the saved results in chronological order.

There are different possibilities concerning result saving on the reader depending on the reader configuration. If no saving is required or if data saving is deactivated on your reader, proceed to 11.4.

*11.1 Automatic saving **

In case your reader has the option activated to automatically save each result, all results will be saved after the measurement. The reader will not give a specific display message. Proceed to point 11.3.

*11.2 Manual saving **

In case your reader has the option of manual saving activated, press and hold the button longer than 1 sec. the measurement result will be stored, the display shows ‘SAVE’.

11.3 Return to ‘ON’ state

Press the button again to return to ‘ON’. Thereafter proceed to point 4 for a new measurement.

11.4 No saving

If no result storage is required, or if data saving is deactivated on your reader, briefly press the button less than 1 sec. to not store the result. ‘ON’ appears in the display; proceed to point 4 if a new measurement shall be started.

12. Turn-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 proceed to point 2.

Please note: There is no active function to shut off the device.

QC-Test

Your reader may have the option activated that a QC test is required at certain times. QC sets consisting of a special QC cassette and an according QC configuration on RFID card are provided for this purpose. There are several possible versions of the feature.

QC test daily

A QC test can be required once a day. At first start-up on a new day the reader will give an audible signal and show 'QC TEST REQUIRED'.

QC test after certain amount of measurements

A QC test can be required after a certain amount of measurements have been run. If this version is active the reader will show the remaining tests until a QC test is required after start-up. When the QC test is needed the reader will give an audible signal and show 'QC TEST REQUIRED'.

QC test after every measurement

A QC test can also be required after every measurement. In this case the reader will be able to run one measurement and will then give an audible signal and show 'QC TEST REQUIRED'.

No QC test

If the QC feature is not active, the reader will never ask for a QC test and measurements can always be run without limitation.

Attention:
If the QC feature is active and no QC test is run at the requested time the reader will be blocked and not be able to run a measurement until the QC test has been run.

When a QC test is required please take the provided QC set and insert the QC cassette into the cassette adaptor according to the point 'test insertion' of the measurement procedure and place the reader on top. Press the button shortly, 'RFID' will be displayed. Put the QC RFID card on top of the reader and wait until the QC configuration data has been uploaded (audible signal). Alternatively select the QC test from the reader memory. Press the button again shortly to start the QC test. The QC test result will be displayed afterwards.

Attention:
The result of the QC test may be 'PASS' or 'FAIL' (or similar depending on the QC configuration). The reader will be able to measure again after the QC test, even if the QC result was 'FAIL'. When a QC test fails the reader should not be used for measurements because results could be faulty. Please contact your supplier for a replacement in this case.

Error messages - Causes and Solutions

Display: ‘ERR’

The device could not read the information from the RFID card.

Elimination

Press the button briefly (<1 sec.), the display will show 'ON' and continue with point 4a or 4b. If the error occurs for several times, please contact your test manufacturer.

Display: ‘DATE‘

The expiry date of the test seems to be exceeded.

Elimination

The device checks the internally set time with the expiration date of the test.
Check the expiration date of the test. If this is actually exceeded, select a new test from another shipment which has not expired. Press the button briefly, the display will show 'ON' and repeat point 4a or 4b. If the expiration date is not exceeded, check the internally set time and date of the device and adjust it if necessary.

Display: 'FAIL'

The device could not find a C-line.

Elimination

Check if the test cassette is placed correctly below the cube and in the cassette adaptor (section: measurement procedure, point 7). Then press the button briefly (<1 sec.), the device shows 'ON' and repeat with 4a or 4b.
If the error will not disappear, select a new test and repeat the measurement procedure. Press the control button briefly (<1 sec.), the display will show 'ON' and continue with 4a or 4b.

No function

Despite pressing the button no information is visible on the screen.

Cause: The batteries may be discharged.

Elimination

Open the battery compartment and replace the 3 batteries by new ones as described in section 'Battery insertion'.
Should the device still not react after changing the batteries, please contact the manufacturer.

Setting date and time

Bring the device to position ‘ON’ according to step 1. Press the button shortly twice (<1 sec.). Year, date and time will appear on the display.

Press the button for about 1 sec., a flashing display appears with the first time specification, year. By repeated short (<1 sec.) pressing of the button, the displayed value can be changed. When reached the wanted value (e.g. year) press the button longer (>1 sec), the appointed value will be stored and the next time information will be presented. Repeat these steps to successively move to year, month, day, hour and minute. After setting the date and time information accordingly the device will display ‘OK’.

Press the button one more time, the reader will show ‘ON’ and is now ready for use. Repeat this process after every battery change.

Data transfer

The device provides the possibility of data transfer to a PC or laptop. Therefor a unique USB cable and the Cube Data Reader software are required.
This data package, consisting of USB cable and software can be purchased under item no: RR-USB.

Cube Expiry

Your reader may have the option activated that only a certain amount of measurements or a certain lifetime is allowed. After that the reader expires and can either be used at own risk, or the reader is blocked and cannot be used for measurements anymore. The following versions of the feature are possible.

Expiry at a certain date

When the reader expires at a certain date the reader can be used until that date. Afterwards the reader will display ‘EXPIRED’ at start-up and either be blocked completely or additionally display ‘USE AT OWN RISK’ depending on the reader configuration.

Expiry after certain amount of measurements

When the reader expires after a certain amount of measurements, the reader shows the remaining measurements at each start-up. It may also display a warning message when only a certain small amount of measurements is left. When the counter reaches zero the reader will display ‘EXPIRED’ at start-up and either be blocked completely or additionally display ‘USE AT OWN RISK’ depending on the reader configuration.

Expiry after certain lifetime

When the reader expires after a certain lifetime the internally defined lifetime will start at first activation of the reader. The reader can be used for the defined period of time and will expire when the time is up. Afterwards the reader will display ‘EXPIRED’ at start-up and either be blocked completely or additionally display ‘USE AT OWN RISK’ depending on the reader configuration.

Maintenance and cleaning of the window

The device is maintenance free. Before each measurement the glass on the bottom should be checked for impurities. For cleaning a commercial cloth together with a commercial cleaning fluid, e.g. for glasses products, is recommended.

The status of the batteries is being monitored. Replace the batteries when the battery symbol starts to blink. The batteries cannot be recharged and have to be properly disposed.

Transmittal of the device

In case of a defect it may be necessary to send the device back to the manufacturer. Due to contact with infectious material while using the device, disinfection is required to prevent infections or other contaminations.

For disinfection every surface of the device as well as the cassette adaptor need to be cleaned with a suitable disinfection solution. That solution should be approved for medical devices and should not affect the device housing material. The disinfection spray Mikrozid® AF Liquid for instance is a suitable solution. Comparable products can be used as well.

The customer has to give a receipt for the disinfection of the device. Therefor the form on the following page can be used. Then the device has to be sent to the manufacturer together with the signed form.

Please send the signed form with the shipping note so that it is directly available in the manufacturer's incoming goods department. The device case will not be opened until the disinfection receipt is on hand.

Attention: Please note that a transmitted device without a disinfection receipt cannot be accepted by the manufacturer and will be returned to the sender without being opened!

Disinfection Receipt

Attention: ***A transmitted device won't be accepted by the manufacturer without this receipt! It will be returned to the sender without being opened!***

Device type: RapiRead™ CUBE Reader
Reason for transmittal:

Customer/company:

Date of disinfection:
Disinfection operator:

The following device(s) was/were disinfected (Serial numbers):

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

☐ Cleaning of the cassette adaptor with paper tissue and disinfection solution suitable for medical devices
(for instance *Mikrozid® AF Liquid* or comparable product)

Place and date _____ Signature _____

Disposal of the device

As the device can be contaminated by any material it should be disinfected with appropriate safety equipment.
Dispose of the used device after removing the batteries in accordance with the applicable country-specific regulations.

Manufacturer's information

SPARK™
MOBILE | DIAGNOSTICS

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