R-Biopharm AG

RIDA®CUBE SCAN

User Manual

R-Biopharm – for the safety of your analysis.

Symbols & Abbreviations

The following symbols and abbreviations are used in the product labeling and instructions for the Eurolyser laboratory photometer.

Symbol / Abbreviation	Explanation
CE	Conformity marking according to the directive 2004/108/EC of the European Parliament and of the European Council
REF	Catalogue number / Order number
LOT	Lot number
SN	Serial number
	Bluetooth
	Connection
	Power Supply / Device Readiness
	Use by
	Temperature limitations
	Relative humidity limitations
	Manufacturer
	Production date
STERILE	Sterile
	Warnings and precautions, see accompanying documents
	Operator's action
	Refer to the user’s manual and follow the instructions
	Do not dispose with household waste
ERS TC	ERS Testing Cartridge

LED	Light Emitting Diode
PC	Personal Computer
ID	Identification
HIS / LIS	Hospital Information System / Laboratory Information System
AC	Alternating Current
DC	Direct Current
RFID	Radio Frequency Identification

Table 1: Product Labelling and User Manual Symbols

Table of contents

Introduction

Intended use of the RIDA®CUBE SCAN Laboratory Photometer

The RIDA®CUBE SCAN Analyser consisting of the RIDA®CUBE SCAN Instrument laboratory photometer and the RIDA®CUBE SCAN Tablet PC is intended as a general purpose laboratory instrument for the quantitative determination of Food & Feed wet chemistry parameters.

The RIDA®CUBE SCAN Instrument is highly compact and is designed as a point of care measuring Instrument for R-Biopharm. It is easy to use and provides quick, reliable and accurate results.

About this user manual

This user manual will guide you through the installation, operation and maintenance of your RIDA®CUBE SCAN Instrument. The user manual also explains how the photometer works, describes the quality assurance system and assists you in troubleshooting any errors or problems. When not used according to the user manual the CUBE Instrument may be influenced or damaged.

We recommend that you familiarize yourself with these instructions before operating the RIDA®CUBE SCAN Instrument. Some of the information in this user manual is marked with following symbols:

Operator's action

Warnings and precautions; see accompanying documents

Refer to the user manual or test kit package insert and follow the given instructions

Inspecting the package contents

When unpacking the RIDA®CUBE SCAN Analyser, check the contents against the list below and examine the components for signs of shipping damage (see illustration on the following page).

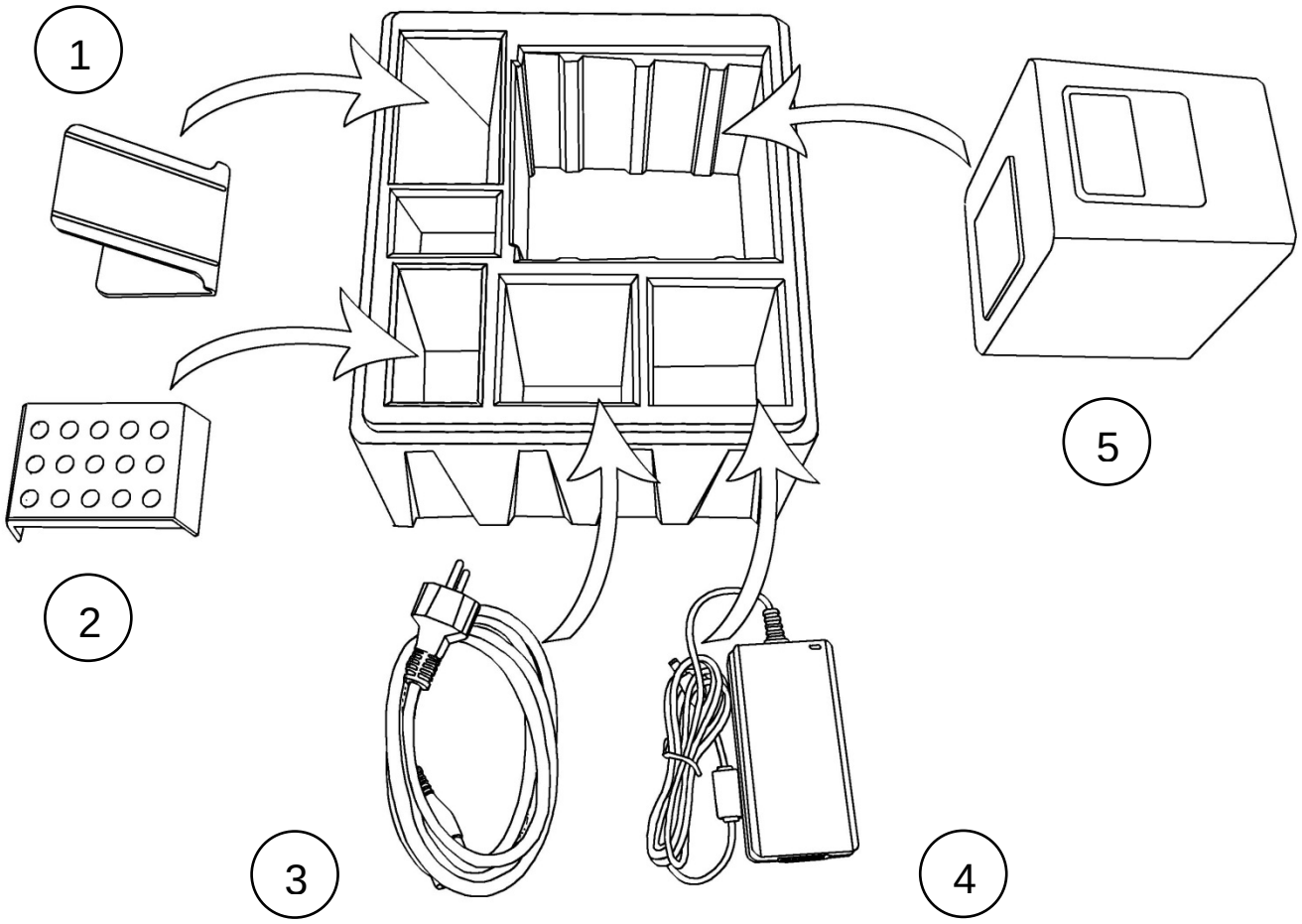
The RIDA®CUBE SCAN package contains:

- the RIDA®CUBE SCAN Instrument
- a main adapter
- a power cable
- this user Manual (on a CD)
- the Quick Reference
- a Test-Kit Rack
- a Tablet Stand

If any part of the package is missing or damaged, please report this to your supplier immediately.
It is recommended to keep the original packaging, in case the Instrument ever needs to be transported.

CUBE packaging

In case of returning the CUBE Instrument to the manufacturer and/or before transporting the Instrument, please repack the CUBE Instrument contents in the original packaging according to the following illustration:



1. Tablet Stand
2. Test-Kit Rack
3. Power Cable
4. Main Adapter
5. RIDA®CUBE SCAN Instrument

Note: In case of a necessary return of the Instrument to the manufacturer or before transport please repack the RIDA®CUBE SCAN Instrument contents in the original packaging according to the illustration above! Moreover, please remember to reinsert the white transport lock into the RIDA®CUBE SCAN Instrument door before repacking (see following page)!

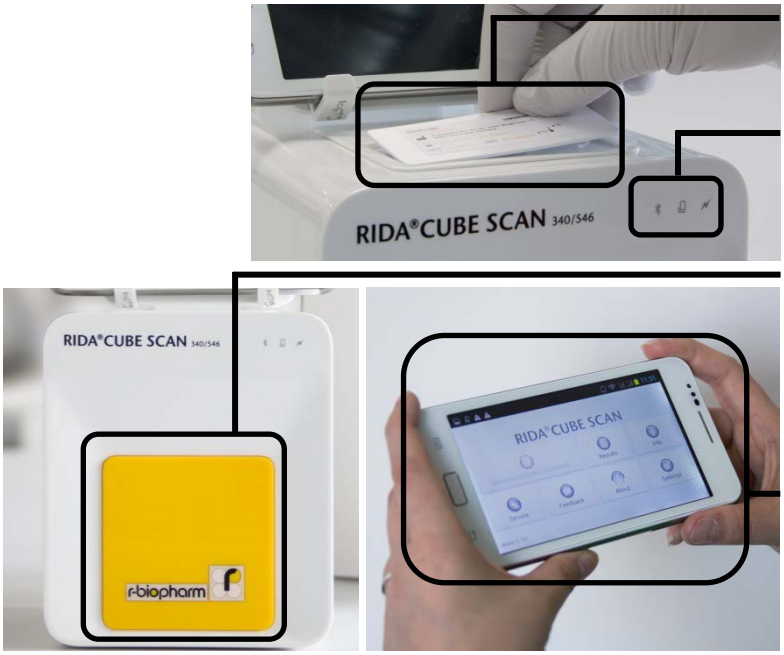
Note: The RIDA®CUBE SCAN Tablet PC is delivered in a separate package and must be returned in this if necessary.

WARNING: Wrong packing and/or the use of inappropriate packaging can cause severe damage to the Instrument! These damages won't be covered under warranty.

System description

Description of the RIDA®CUBE SCAN Analyser

This section introduces the general characteristics of the RIDA®CUBE SCAN Instrument and Tablet PC.



RFID Card Pit The RFID card is placed here

Indicator Lights There are 3 LEDs on the front of the Instrument. For a detailed description refer to page 9

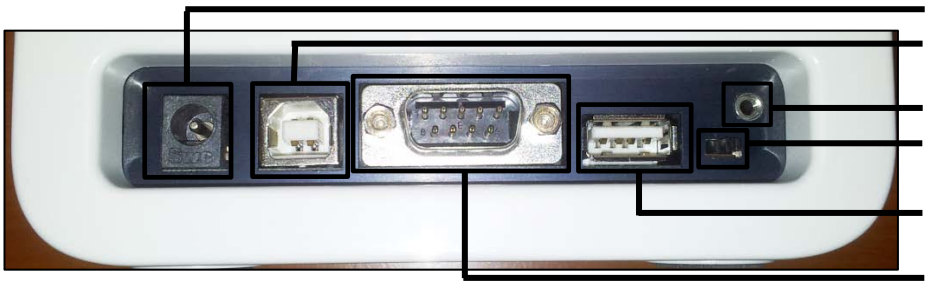
Door Test cartridges are inserted and then removed here.

Note: do not attempt to open door manually!

Tablet PC The Tablet PC is the main user interface to operate the Instrument & process the results

CUBE Instrument Interfaces

RIDA®CUBE SCAN Instrument Interfaces



Power supply
USB Socket for connecting a PC (for data transfer)
Tablet PC-Lock eyelet
Bluetooth on/off switch (left: Bluetooth OFF)
USB Port for connecting a Tablet PC
RS 232 socket for connecting a printer, a barcode reader or a PC (for data transfer)

- **Do not use liquid cleaners on the Instrument or Tablet PC! Use a lint-free, slightly damp cloth only!**
- **Do not attempt to open the door manually**

Indicator lights

RIDA®CUBE SCAN front

LEDs on the RIDA®CUBE SCAN Instrument

This green LED indicates the readiness of the photometer
Flashing: the Instrument is warming up and testing cannot be started yet (*Note*: this takes approximately 10 min.)
Constantly lit: the Instrument is warmed up and ready for use
Off: the Instrument is not plugged in

This blue LED indicates a connection to a Tablet PC
Constantly lit: a connection with a Tablet PC is established
Off: the Tablet PC is not connected

This blue LED indicates a Bluetooth connection to Tablet PC
Constantly lit: a connection with a Tablet PC is established
Flashing: Bluetooth is activated on the photometer but no Tablet PC is connected via Bluetooth
Off: Bluetooth is switched off

Note: The Bluetooth connection is operational with Tablet PCs with serial numbers Tb##### or higher. To keep the Tablet PC constantly powered it is recommended to use the USB cable connection.

How to handle the RIDA®CUBE SCAN Laboratory Photometer

The RIDA®CUBE SCAN Instrument is operated solely by means of the Tablet PC. All the basic operating steps are displayed as symbols. An overview of these symbols can be found in Table 1 (p. 3) and Table 2 (p. 11). To activate a symbol tap it with a finger.

In order to perform a test, the RFID card enclosed in the test kit must first be placed on the Instrument. This card contains all the data needed to perform the tests. No analysis can be started without the RFID test card!

The door opens automatically once a test is initiated by pressing the  button. After entering all the requested data on the Tablet PC and inserting the test cartridge into the slot, close the door and the testing procedure begins automatically. After the analysis is completed, the door opens automatically and the test cartridge is to be removed.

The door prevents ambient light, dust, dirt and humidity from entering the Instrument during the testing process and when the Instrument is not in use.

Please make sure the door is closed whenever the Instrument is not in use.

How the RIDA®CUBE SCAN Laboratory Photometer works

The Instrument is equipped with an RFID card-reader module. RFID cards are necessary for performing any testing procedures. They are included in the test kits and contain all the specific steps for the various tests, the lot data, as well as the calibration data. The Instrument performs the tests automatically according to that data. Numerous types of tests can be selected and performed automatically.

The sample and the reagent are automatically mixed within the Instrument. The photometer unit performs the analysis with a light diode. The absorption of light rays is measured during this process and the measured value is then converted into the test result using mathematical methods. The result is displayed on the Tablet PC. Optionally, results can be exported to an external computer or an HIS/LIS and can also be printed out using an external printer.

After the test process the door opens automatically and the test cartridge can be removed and discarded. After confirming the result on the Tablet PC and closing the door on the insturment the system is ready to perform the next analysis.

Manufacturer calibration

The RIDA®CUBE SCAN Instrument is manufactured according to the highest quality standards in order to yield safe and accurate testing results. Every Instrument is inspected and calibrated during the manufacturing process, using the EU-stipulated reference methods.

Pictogramms / Button Symbols

Tablet PC symbols and their functions

Tapping one of these symbols on the Tablet PC activates the described function.

Symbol	Name	Function
	RIDA®CUBE SCAN App Icon	Starts the RIDA®CUBE SCAN app
	Browser	Opens the Web Browser on the Tablet PC
	Android Settings	Opens the Android settings menu
	Return arrow	Cancels an input OR return to the previous screen or menu
	Return to main menu	Returns directly to the main menu
	Measurement	Opens the menu for test data entries
	Results	Opens the result list screen
	CUBE Settings	Opens the Configuration menu
	Edit	Opens an entry or value so it can be edited
	Confirm	Confirms the input
	Abort to main menu	Cancels an action and returns to the main menu
	Start analysis	Starts the test process
	Print	Opens the print / export / mail dialogue
	Filter	Opens the Filter Options
	Transmit	Opens the Export dialogue
	Chart	Displays the photometric data curve of a test result
	Page forward	Displays the next page
	Page backward	Displays the previous page
	Recycle bin	Opens the delete dialogue
	Synchronize	Synchronises result(s) and Instrument status with the servers for technical support

Table 2: CUBE Tablet PC symbols

Getting started

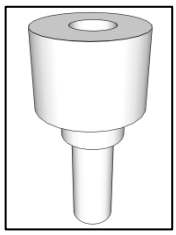
The proper placement of the RIDA®CUBE SCAN Laboratory Photometer

Place the Instrument on a dry, clean, stable and level surface. Make sure the Instrument has at least 10 cm of table surface and clearance on each side and that the Instrument can be easily disconnected from the power source. Allow the Instrument to acclimate to the ambient room temperature before operating it.

The Instrument can be damaged by:

- **Condensing humidity and water**
- **Heat and large temperature fluctuations**
- **Direct sunlight**
- **Vibrations (e.g. from centrifuges and dishwashers)**
- **Electromagnetic radiation**
- **Electrostatic discharge**

Transport lock

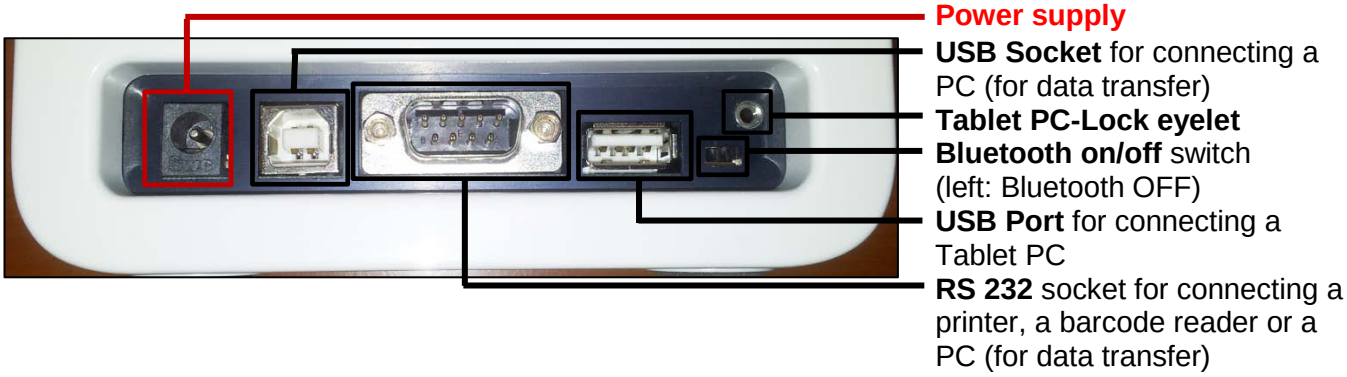


Upon first use the white transport lock is to be removed from the door of the Instrument.

Note: keep both the transport lock and the original packaging. In case of a defect the Instrument is to be returned in the original packaging (see p. 7) with the transport lock installed to prevent any damage during transportation!

Connecting the power supply

RIDA®CUBE SCAN Instrument Interfaces



- Connect the power cable to the power supply unit.
- Insert the plug from the power supply unit into the power socket on the back of the Instrument
- Plug the power cable into the wall socket.

Always connect to the proper supply voltage. The power supply voltage must comply with the regulations cited in the technical specifications on page 31. Ensure a properly installed electrical grounding. The Instrument is to be operated only using the power supply unit provided.

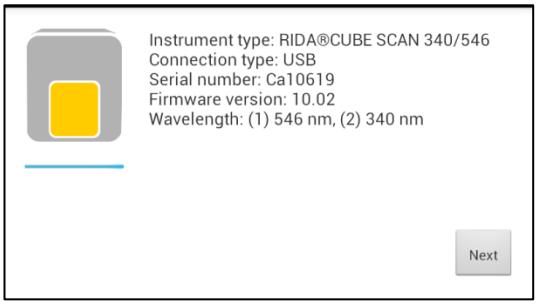
The Tablet PC

The RIDA®CUBE SCAN Instrument is operated with a Tablet PC.
Connect the Tablet PC to the USB port of the plugged-in Instrument and then turn on the Tablet PC.

An independent Tablet PC manual is delivered with the Tablet PC. It describes in detail the operating of the Tablet PC, how to manage settings and the establishing of a Bluetooth or USB connection between the RIDA®CUBE SCAN and the Tablet PC.

Starting & Operating the Tablet PC

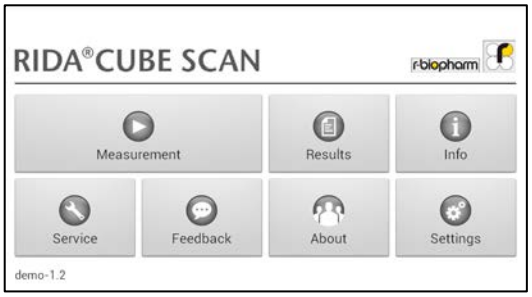
1. Connection Screen



The connection screen appears upon connecting the Tablet PC with the RIDA®CUBE SCAN Instrument.

Tap *Next* to continue.

2. Main Menu

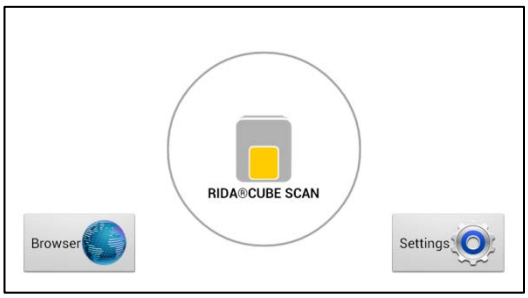


The RIDA®CUBE SCAN app starts and the main menu appears.

Note: while the RIDA®CUBE SCAN Instrument is warming up (indicated by the flashing green LED on the front) the “Measurement” Button is grey and inactive.

The RIDA®CUBE SCAN Launcher

RIDA®CUBE SCAN Launcher



When the Tablet PC is not connected to the Instrument or by pressing the Home Button the RIDA®CUBE SCAN Launcher appears:

Tapping *Browser* opens the Android web browser

Tapping *RIDA®CUBE SCAN* starts the RIDA®CUBE SCAN app

Tapping *Settings* opens the Android settings menu

Note: If the standard Android Desktop appears instead, switch the Tablet PC off, back on, select “RIDA®CUBE SCAN Launcher” and confirm by tapping “Always”.

Changing the language of the RIDA®CUBE SCAN application

The language of the application is automatically set according to the language of the operating system of the Tablet. It can be changed by pressing the home button on the Tablet PC (the launcher appears), then pressing 

to open the settings. Swipe down and select *Language and input* in the category "Personal". Tap *Language* and choose a language. Press the home button to return to the launcher.

Note: the RIDA®CUBE SCAN application supports several languages. If you choose a language in the system settings that is not supported by the RIDA®CUBE SCAN app English will be used.

How to switch the RIDA®CUBE SCAN Laboratory Photometer ON

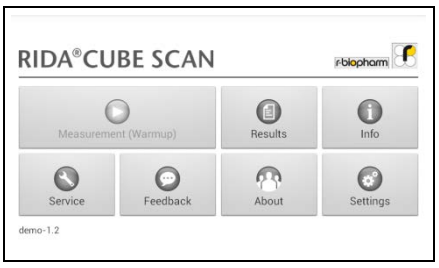
The Instrument is switched on by plugging the power cable into the socket. This launches the Instrument's automatic start-up and warm-up processes. Please wait for these to be completed (approximately 10 minutes).

When operating the Instrument:

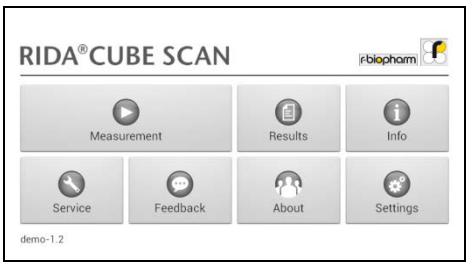
- **The door protects the analysis system from dust, dirt and humidity. Empty the door's cartridge chamber after every analysis and keep it closed when the Instrument is not in use.**
- **The door opens automatically. Do not attempt to open the door manually!**
- **If an error message appears during an analysis, please consult the "Troubleshooting" section on page 29.**

The automatic start-up and warm-up processes

1. Warm-up menu



2. Main Menu



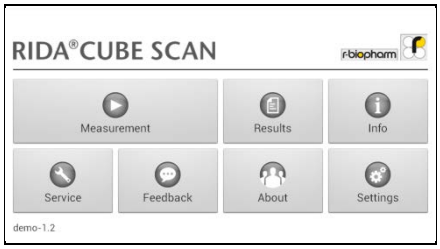
The automatic start-up procedure (indicated by the flashing green LED) starts as soon as the Instrument is connected to the power supply. The Instrument is warmed up to its proper working temperature in approximately 10 - 15 minutes.

As soon as the initialization of the optical unit is completed, the  button turns from b/w to color and reacts to tapping. The Instrument is now operational.

Configuring the RIDA®CUBE SCAN

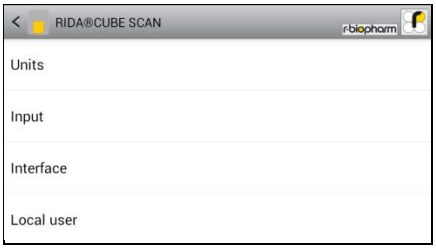
You can configure your RIDA®CUBE SCAN laboratory photometer according to your needs before using it. To access the configuration menu follow these steps:

1. Start-up menu



Tap  to open the Settings menu.

2. Settings menu



Tap the setting you want to configure. Swipe down to view all available options.

All following descriptions are examples. The configuration of the RIDA®CUBE SCAN Instrument models may vary depending on the tests used.

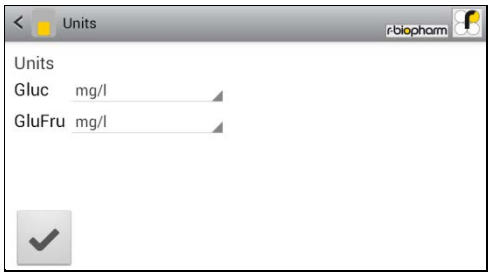
Note: **The normal values, units and sample types for a test can only be displayed if the respective test RFID card has been placed on the Instrument and read.**

Setting units

1. Configuration menu

Tap *Units* to open the Unit selection menu.

2. Unit selection menu



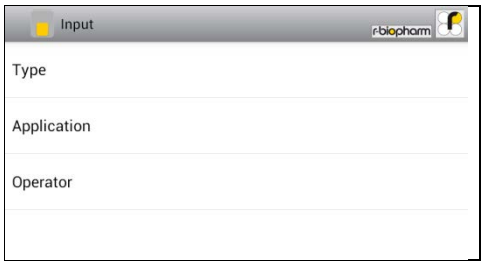
Tap and select a unit in the appearing drop-down menu. Confirm the change(s) with  .

Configuring inputs (Input, Application, Operator)

1. Configuration menu

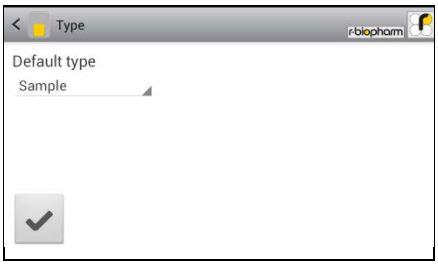
Tap *Input* to open the input menu.

2. Input menu



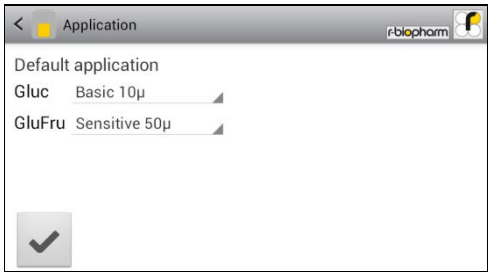
Tap a parameter and the respective menu will open.
The following descriptions are provided in the order of the parameters in the Input menu.

3.1 Default type menu



Tapping opens a drop down menu. Select which gender is to be used as the standard default. *Last used* means that the gender last used will always be selected.

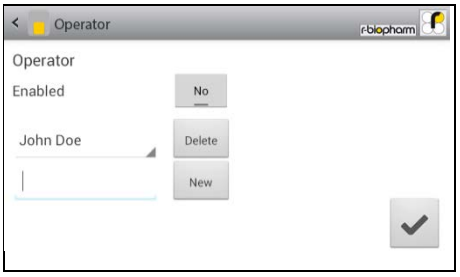
3.2 Application menu



Tap and a drop down menu opens, select which type of sample should be selected by default. *Last used* means the sample type last used will be selected. Confirm with .

Press to cancel.

3.3 Operator menu



Enable the operator mode by tapping the button.
To create a new operator, type the name in the box and then tap New.
To delete an operator, tap and select a name in the drop down menu, then tap Delete.

Configuring interfaces

1. Configuration menu

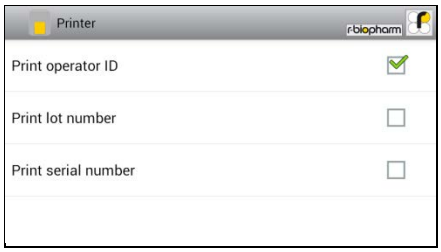
Tap *Interface* in the Configuration menu. The Interface menu appears.

2. Interface menu

Tap an interface to configure and the respective configuration menu appears.

The following descriptions are in the order of the interfaces in the Interface menu.

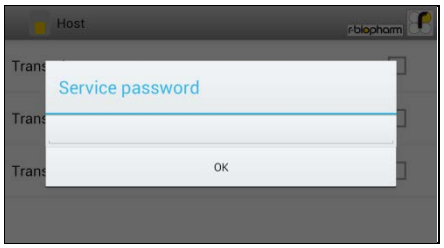
3.1 Printer configuration menu



Tap a checkbox next to an option to select or de-select it.

Note: the screenshot above is for demonstration purposes only. By default all boxes are unchecked.

3.2a Host configuration password screen



The service password is required to change interface host options. Tapping on the input field opens the Tablet PC keyboard and the password can be typed.

If you do not know the Service Password please contact your dealer.

3.2b Host configuration menu

After pressing OK on the password screen, the host configuration menu opens.
Tap a checkbox next to an option to select or de-select it.

Note: the screenshot above is for demonstration purposes only. By default all boxes are unchecked.

Optional Equipment

Barcode scanner or PC

The following optional devices (not included in the standard delivery package) can be connected to the Instrument:

- An external barcode scanner
- A PC – for the transfer of test data into a HIS or laboratory software

⚠ **Connect optional equipment only when the Instrument is switched off. Please note that attaching optional equipment (e.g. a printer) can increase the amount of leakage current. All optional equipment must be connected before such leakage current can be measured.**

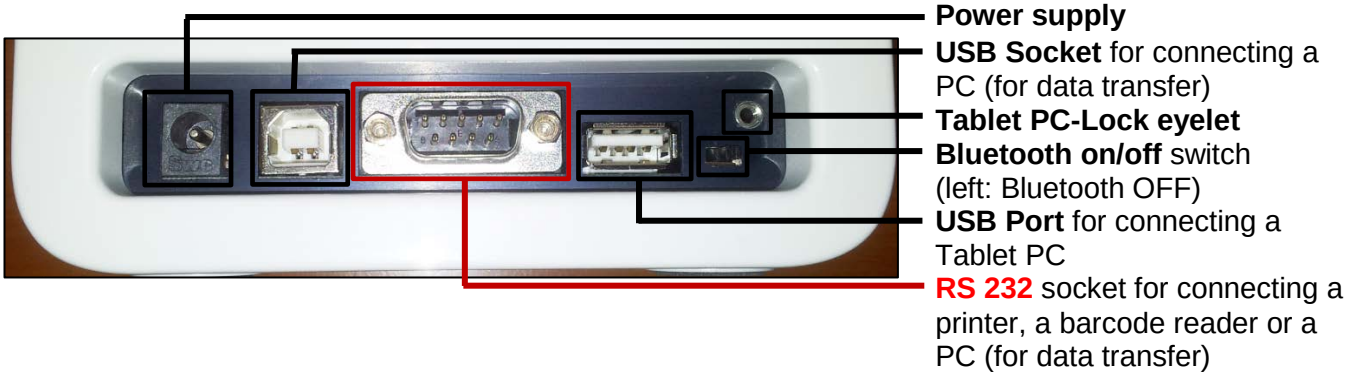
⚠ **If the Instrument is not used according to the instruction manual, then the provided levels of safety will be lowered.**

Connecting a barcode scanner

To install the Datalogic Touch 65 barcode reader (Order number: SZ0400) please connect the RS232 cable to the RS232 socket at the Instrument (see illustration below). Always connect the power supply to the barcode scanner correctly before using it.

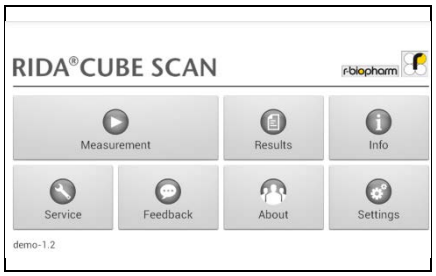
The barcode reader can handle barcodes up to 16 digits.

RIDA®CUBE SCAN Instrument Interfaces



Using a barcode scanner to scan patient ID and/or operator information

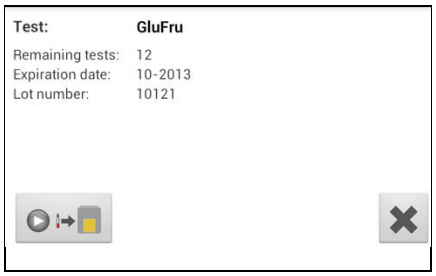
1. Main menu



Start a test by tapping  .

Make sure that a RFID card is placed on the CUBE Instrument.

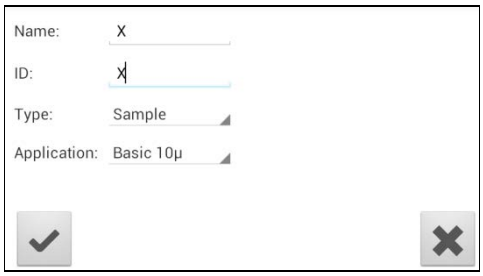
2.Test screen



The RIDA®CUBE SCAN displays the type of test and number of tests remaining on the RFID card.

Tap  to proceed to the input menu or  to exit to the main menu.

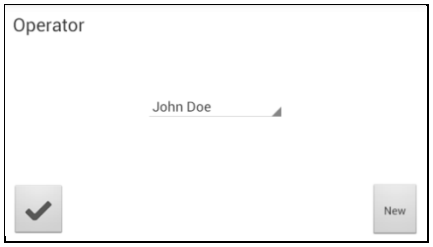
3.Input menu



Scan sample information with the barcode scanner. It will automatically be set as “ID” value.

Tap  to confirm the input or  to exit to the main menu.

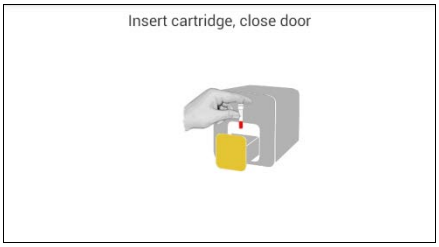
4. Select operator screen*[1]



On this screen an operator can now be selected by scanning the operator barcode and tapping  to continue.

If new information is scanned (i.e. the operator has not been created in the operator menu yet) a new operator will be created automatically.

5. Insert cartridge and close door



The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

***[1]** *This screen only appears if the operator input has been enabled (see 3.4 on page 16)!*

How to wake the CUBE Analyser up or switch it OFF

When the Tablet PC displays the main menu, the “power safe” function dims the screen. Pressing the Lock Switch will re-illuminate the display to its customary level of brightness.
It is not necessary to switch the Instrument off every day. Switching the Instrument off completely can only be done by disconnecting it from the power supply.

Test Procedures

Overview of the testing and measuring procedures

Allow the test cartridge to reach room temperature before use. If the RIDA®CUBE SCAN Instrument has been disconnected from the power supply, plug it in soon enough for it to be at the proper operating temperature when it is needed.

To analyse a patient sample:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare a test cartridge and a patient sample according to the instructions on the test kit insert
- Enter the required patient data.
- Insert the test cartridge into the Instrument and start the analysis.
- The result will be displayed on the Tablet PC.
- The result will be saved in the Tablet PC's memory.
- If desired, export the result to an (optional) external computer or send it via email (see p. 24)

How to run a control test:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare the control serum according to the instructions on the control package insert.
- Enter the lot number instead of the patient data.
- Prepare the test just like a patient sample and start the analysis.
- The result is displayed on the Tablet PC.
- Record the result according to your laboratory's quality guidelines.
- The result will be saved in the Instrument's memory – just like a patient's results.
- If desired, export the result(s) to an (optional) external computer or send it via email (see p. 24)
- Verify that the result lies within the mandatory limits for the control material (according to the control material's package insert).

Be sure to follow the detailed instructions for the analysis processes that are provided in the following sections and to comply with the information provided on the package insert enclosed with each testing kit.

When operating the RIDA®CUBE SCAN Analyser:

- **Use only your fingertips to operate the Tablet PC! Do not use pens or any other objects that may scratch or damage the screen.**

- **If an error message appears on the screen, please consult the "Troubleshooting" section on page 29.**
- **The door protects the analysis system from dust, dirt and humidity. Empty the door's cartridge chamber after every analysis and keep it closed when the Instrument is not in use.**
- **The door opens automatically. Do not attempt to open the door manually!**

When handling a test cartridge:

- **Do not use test cartridges after their expiration date, or when the test cartridges have not been stored in accordance with the regulations**
- **Do not use the test cartridge if the packaging is damaged or if fluids have leaked.**
- **The test cartridge must reach room temperature (20 - 28°C; 68 - 82.5 °F) before use**
- **Use gloves when handling and disposing the test cartridges, patient samples and sample collection equipment, because they pose a potential biohazard**

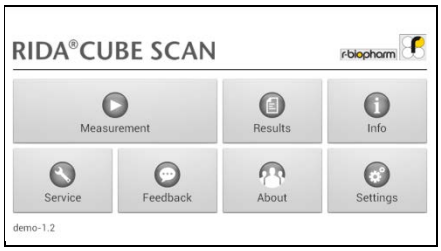
- Please refer to package insert provided with each test kit suitable for use with the RIDA®CUBE SCAN Instrument and follow all instructions regarding:
  - The proper temperature a cartridge must have before a test is performed
  - The exact amount of the sample volume
  - The regulations for the proper storage of the test cartridges

Analysing a sample

1. RFID card placement

Take the provided RFID card out of the test kit package and place it on the RFID card pit on top of the Instrument.

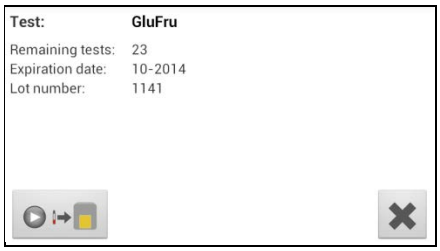
2. Main menu



Tap  in the main menu to start a measurement.

The RIDA®CUBE SCAN Instrument automatically reads the RFID card and the Test Menu appears.

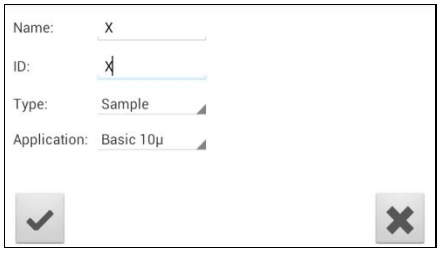
3.Test screen



The RIDA®CUBE SCAN displays the type of test and number of tests remaining on the RFID card.

Tap  to proceed.
Tap  to return to the main menu.

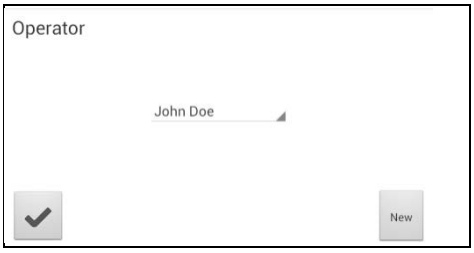
4.Input menu



Tap the desired input field (e.g. “Name”), the Tablet PC keyboard appears. Enter the information and confirm with “Done”.
Next, tap  and select an entry from the drop down-menu.

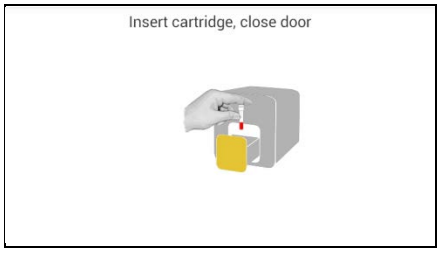
Tap  to confirm the input or  to return to the main menu.

5. Select operator screen*[1]



All saved operators will be shown in the drop down list. Tap  and select an operator or tap  to create a new operator (see. 3.4 on p. 16 for details).
Tap  to confirm the input.
Note: when testing for the first time, you will be prompted to create an operator.
Tap  to open the operator menu (see 3.4 on p. 16 for details).

6. Insert cartridge and close door

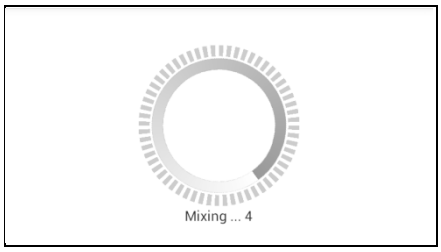


The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

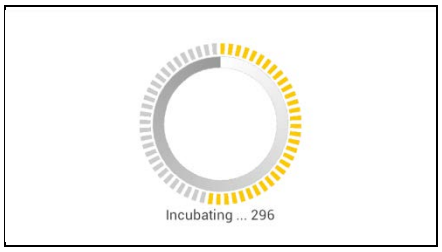
***[1]** *This screen only appears if the operator input as enabled (see 3.4 on page 16)!*

The Instrument displays the following information during the testing process (varies by test type):

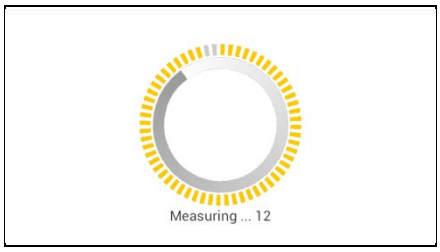
Mixing



Incubating



Measuring

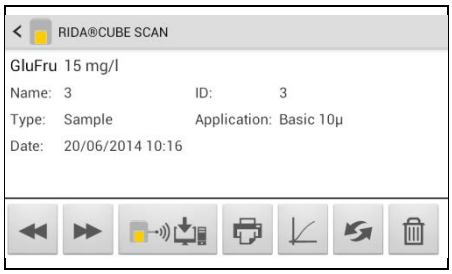


- **Be sure to handle the test cartridge according to the instructions on the package insert**
- **Be sure the test cartridge is properly sealed before inserting it into the Instrument**
- **Be sure the test cartridge is fully inserted into the proper opening in the Instrument**
- **Use ONLY manufacturer-approved test cartridges! Otherwise serious damage to the RIDA®CUBE SCAN photometer and/or inaccurate test results may occur**
- **Do not attempt to open the door manually!**

Viewing and processing test results

After processing a test, the result screen appears on the Tablet PC:

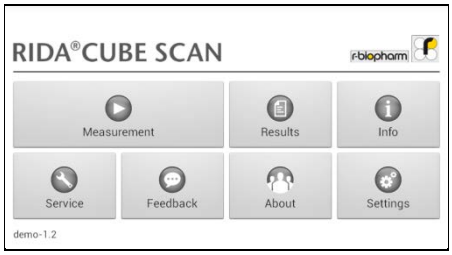
1. Result Screen



The test result is displayed on the Tablet PC. Use ◀◀ and ▶▶ to scroll back and forth within the results. Tap to export to a HIS/LIS or PC or send as Email.
Tap to print.
Tap to open the photometric data curve.
Tap to delete the result.
Tap to exit to the main menu.

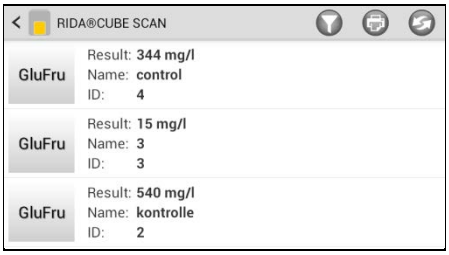
All test results are stored on the Tablet PC. They can be accessed as follows:

1. Main Menu



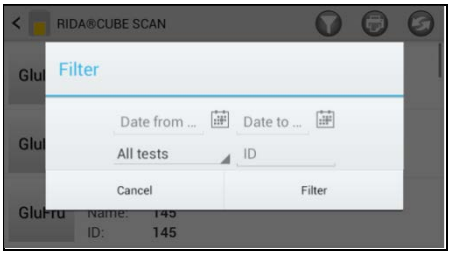
Tap in the main menu to open the Result List.

2. Result List Screen



The stored results can be browsed by swiping up and down.
Tap a result to open the result screen (see above), to return to the result list from a result screen press the *Return Arrow*
Tap to open the filter options
Tap to print, mail or export.

2.1 Filter Options



Results can be filtered by date, test type and Sample ID.
Tap Date from ... to set the desired start date, Date to ... to set the desired end date.
Tap All tests to select a test type in the drop down menu (e.g. PT)
Tap Patient ID ... to filter by patient ID

Whenever the transmission of the operator ID, lot number and serial number is activated in the appropriate settings menu (see p. 17) the according data will be transferred to the printer or host system automatically and will appear on the printouts and/or the computer or host system.

Quality control

A quality control program should be performed on a regular basis to verify the RIDA®CUBE SCAN Instrument is working properly and providing reliable results. Data integrity can only be assured when controls and GCLP practices are used routinely. The frequency of performing QC differs from laboratory to laboratory; please comply with your national quality control regulations.

Choosing quality control (QC) materials

The authorized manufacturers of the RIDA®CUBE SCAN test cartridges also supply control materials. These control kits contain control materials, which allow you to assess the measuring accuracy of the Instrument.

Ensure the measuring methods are compatible with the RIDA®CUBE SCAN Instrument before using QC kits from other suppliers.

The measuring methods are listed on the test cartridge's package insert.

Handling the QC control materials

Please refer to the package insert provided with each control kit for detailed instructions on storage and handling of control materials.

Follow the instructions in the "Analysing a sample" sections (starting on p. 22) on how to properly perform a control test. The measured values must be within the range of target values specified on the control vial label or in the control package insert. If the control results fall within the specified range, the testing of patient samples may begin.

If one or more controls tested are outside the specified control range:

- Verify that the control materials have been stored according to the directions and that the expiration date has not passed
- Verify that the handling and testing procedures were performed according to the directions on the package insert
- Repeat the control test, using a new control from the same lot

If one or more control results are still outside the specified range:

- Perform a test using a control from a new lot.

If all instructions have been followed but control results are still not within range please contact your local R-Biopharm supplier for assistance before proceeding on testing any new samples.

Frequency of QC testing

Control testing is recommended when:

- a new shipment of test kits is about to be used.
- a new lot is about to be used.
- if it’s possible that the test cartridges have not been properly stored.
- if an unexpected patient result is obtained.
- when new personnel is being trained to use the equipment .
- if local regulations require more frequent control testing than described above, then the number of control tests performed must comply with these regulations.

Cleaning instructions

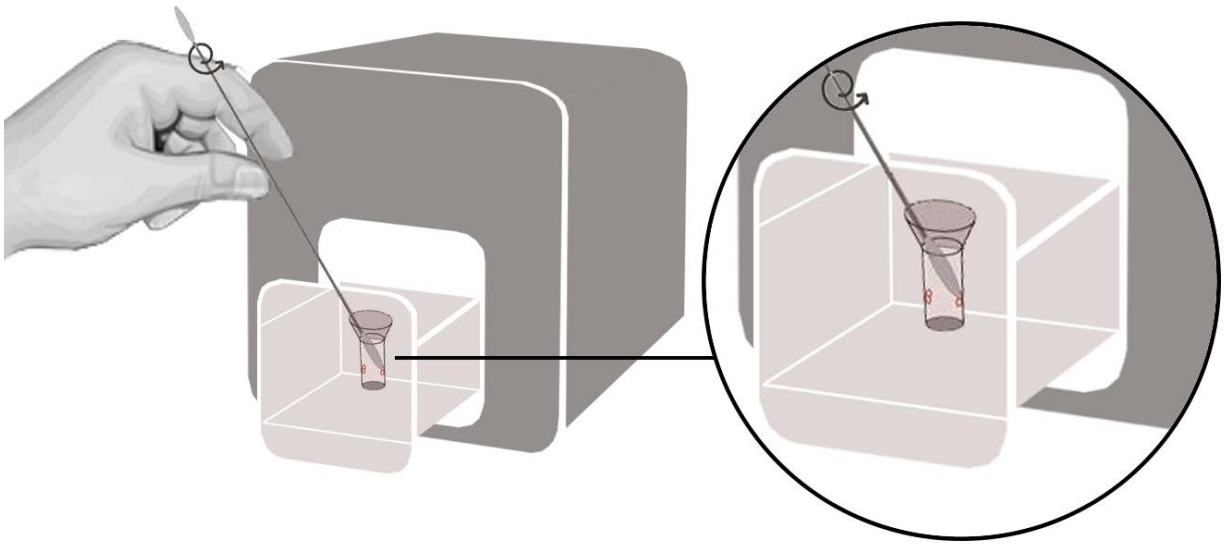
Cleaning the touch display of the Tablet PC

Clean the touch display of the Tablet PC with a clean, lint-free cloth moistened with water.

Do not use any other liquid except water when cleaning the Tablet PC!
To avoid damage do not spill too much water on the Tablet PC!

Cleaning the Door & Cartridge Area

Clean the door with a clean, lint-free cloth moistened with isopropyl alcohol. Wipe down the surface.
The cartridge area may be cleaned with a cotton swab moistened with isopropyl alcohol.



Cleaning the Exterior

Do not clean the surface of the Tablet PC with isopropyl alcohol!

The surface of the RIDA®CUBE SCAN Instrument should be cleaned with a clean, lint-free cloth only moistened with isopropyl alcohol. Wipe down the exposed surfaces.

External interface description

Serial Interface

Interface signals

Pin	Signal
1	
2	TxD
3	RxD
4	
5	GND
6	
7	
8	
9	

Interface parameters

Parameter	Value
Baud rate	9600
Data bits	8
Parity	None
Stop bits	1

Data format

Data is transmitted in blocks of data sets.
One data set contains the data from one analysis.
Data sets consist of data fields.
A data field consists of an identifier (7 characters) and its respective value or text.
Data fields are concluded with one carriage return and line feed.
Data sets are concluded with three carriage returns and line feeds.

Data Fields

Identifier	Format	Example	Remarks
Name:	Text	Name: John Doe	
ID:	Text	ID: 1234	
Type:	Sample/Control	Type: Sample	
Applic:	Basic5µ/Sensitiv100µ/...	Applic:Basic10µ	Optional
Testname:	Value and unit	GluFru:103 mg/l	
Calculatedname:	Value and unit	XY: 100 mmol/l	Optional
Time:	hh:mm	Time: 14:44	
Date:	dd-mm-yyyy	Date: 08-02-2007	
Operat:	Text	Operat:Max Muster	Optional
Lot No:	Value	Lot No:4111	Optional
Ser No:	Value	Ser No:Ca10001	Optional

USB Interface

The USB interface emulates the serial interface.

Error information and troubleshooting

Error messages and possible causes

Error message	Cause	Correction
Invalid card	A wrong, defective or expired RFID card; A defective RFID module;	Use a new test kit. Contact your dealer.
Tests expired	The test cartridge has passed its expiration date.	Use a cartridge from a new test kit that has not expired.
Door blocked	The test cartridge is blocking the door because the cartridge has not been inserted completely or the cuvette has not been capped firmly enough.	Reposition the test cartridge or tighten the cap on the cuvette.
Wrong cap | Missing cap | Missing cartridge	The wrong cap is being used or the cap is missing or the cartridge is missing or an already used cartridge is inserted.	Use the correct cartridge and cap.
Bolt blocked	The test cartridge blocks the bolt because the wrong cap is being used.	Use the correct cartridge and cap.
Measurement overflow	The photometric measurement value lies outside the measuring range (e.g. a cold cartridge has been used).	Repeat the test using a new cartridge.
Blank error	The photometric measurement value is outside the measuring range (without the cartridge).	Repeat the test after restarting the Instrument.
Temperature error	The temperature is outside the range.	Repeat the test after restarting the Instrument.
Wrong sampletype?	The wrong sample type has possibly been selected.	Select the correct sample type.
Linearity error	The reaction of kinetic test is not linear (e.g. if a cold cartridge has been used, if wrong sampletype was set, if wrong samplevolume was used or if a cartridge with integrated capillary was not used correctly).	Repeat the test using a new sample and a new cartridge.
Mix error	Instrument fails to perform test due to possible hardware error.	Please contact your local dealer.
Sample volume error	The provided sample volume is not correct (e.g. pipetting error).	Repeat the test using a new cartridge with correct sample volume.
Cartridge temperature error	The cartridges' temperature is too low for a proper test.	Repeat the test and refer to the package inserts for proper cartridge use.

Service information

If the problem persists after the corrective actions are taken, contact your local RIDA®CUBE SCAN Instrument dealer for technical assistance.

Before asking for assistance, please have the following information ready:

- the serial number of your RIDA®CUBE SCAN Instrument
- the test type
- the test lot number
- the control lot number
- the control results obtained so far
- a description of the problem, including any of the RIDA®CUBE SCAN error messages

Technical specifications

RIDA®CUBE SCAN Instrument

Photometer resolution	0.0001 ABS
Reproducibility	<1.5% CV at 1 OD
Linearity	0.1000 – 3.0000 OD better than +/- 1.5% and +/- 0.01 OD
Temperature control	Electrical temperature control of the photometer unit to 37°C +- 2°C
Fuse	2.5 A, self-healing
Dimensions	160 x 135 x 145 mm (H x W x D)
Weight	2.2 kg (unpackaged)
Communications interface	RS232, USB, Bluetooth
Tolerance conditions:	Work space: 20 - 28°C; relative humidity: 10 – 85%
	Transport/Storage: 0 - 50°C; relative humidity: 5 – 85%
Work surface:	A dry, clean, level surface. Avoid direct sunlight.
Power usage:	12V DC, 2A

Power supply

Manufacturer	Globtek
Type	GTM21097-5012
Mains adapter	A separate AC to DC mains adapter with double insulation
Input	90-264V AC, 47-63 Hz
Output	12V DC, 4.17A
Power usage	Max. 30 VA

Options

Thermo printer	Seiko DPU-414
Interface	Serial
Mains adapter	100-240 VAC
Barcode reader (scanner)	Datalogic Touch65
Reading area	63 mm
Max. resolution	0.10 mm (4 mils)
Mains adapter	100-240 VAC

Declaration of conformity

The RIDA®CUBE SCAN Analyser consisting of the RIDA®CUBE SCAN Instrument and the RIDA®CUBE SCAN Tablet PC is in conformity with the directive **2004/108/EC** of the European Parliament and the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

The standards

"**EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices**",

"**IEC 61010-1:2001 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements**",

"**IEC 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**",

and the standards referenced below were taken in consideration:

EN 55011:2009 Class B;

EN 61000-4-2:2009;

EN 61000-4-3:2009;

EN 61000-4-4:2009;

EN 61000-4-5:2009;

EN 61000-4-6:2009;

EN 61000-4-11:2009;

EN 61326-1:2006-05-01;

ISO 14971:2007-10-01.

Shut down and waste management

Before shutting down the RIDA®CUBE SCAN Instrument for the purpose of a repair or disposal it is necessary to ensure that there is no cartridge left within the RIDA®CUBE SCAN Instrument. For the purpose of delivering the RIDA®CUBE SCAN Instrument it is also required to protect the photometer with its original delivered packaging and packaging inserts (see page 7).

For proper waste management according to the directive 2002/96/EG please contact your local dealer. Used cartridges need to be disposed with laboratory waste and according to the corresponding regulations.

Manufacturer information

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