USER MANUAL FOR

RIDA®

X-Screen





- Urgently to be read before initial operation
 - Observe safety instructions

DESCRIPTION OF CONTENTS



	Page
General	3
Equipment supplied • Remarks	4
Technical specifications • Storage • Settings	5
System requirements • software installation	6
User administration • program start • user login	9
User administration • user profiles	10
User administration • user profiles • icons	11
User administration • user profiles • options	12
Menu bar • Program options	13
Adding a new test	14
Adding a new patient • opening • changing patient 's data	16
Performing an examination • prepare measurement	17
Performing an examination • new examination •	18
opening/changing patient´s data	
Performing an examination • camera preview • picture adoption	19
Measurement and Evaluation • measurement data • current or	20
prior measurements	
Deleting a patient • deleting patient 's data	21
Deleting an examination • deleting single measurements	22
Import / Export of examinations • data transfer • saving data	23
Extras • settings • graphic modus • address	24
Printing out an examination • print preview • printout	25
Control sample • quality control	26
Control sample • quality control • record	28
Control panel • quality control	29
Control panel • quality control • record	30
Troubleshooting • Maintenance	31
Licence conditions	32
	Equipment supplied • Remarks Technical specifications • Storage • Settings System requirements • software installation User administration • program start • user login User administration • user profiles User administration • user profiles • icons User administration • user profiles • options Menu bar • Program options Adding a new test Adding a new patient • opening • changing patient 's data Performing an examination • prepare measurement Performing an examination • new examination • opening/changing patient 's data Performing an examination • camera preview • picture adoption Measurement and Evaluation • measurement data • current or prior measurements Deleting a patient • deleting patient 's data Deleting an examination • deleting single measurements Import / Export of examinations • data transfer • saving data Extras • settings • graphic modus • address Printing out an examination • print preview • printout Control sample • quality control Control sample • quality control Control panel • quality control Control panel • quality control Troubleshooting • Maintenance



Purpose

The RIDA® X-Screen is an instrument that evaluates the reflection or optical density of a biochemical reaction compared to the environmental background of the measured sample.

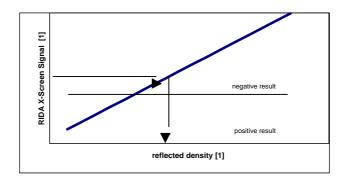
Performance features

The RIDA $^{\rm O}$ X-Screen can detect optical density signals of 0,25 % or greater. When there is an optical density of 5 %, reproducibility of 0,2 % optical density can be achieved.

The performance of the $RIDA^{\circ}$ X-Screen is heavily dependent on the computer used, however it is possible to read a test every 30 seconds. In order to achieve this optimum performance level it is recommended to use the computer specified.

Output of analytical data

Measurement values of the RIDA^O X-Screen are correlated linearly to the reflected density measurements of the control function. Optical densities are divided into several segments. The figure shows a high signal generated by the RIDA^O X-Screen. The measurement of the reflected density allows the interpretation of a negative test result.



Scope of use

During the set up routine, different tests, released by the manufacturer, are transferred on the personal computer. These tests cover the product and scope of use of the Reader provided by the manufacturer.

Application not recommended by the manufacturer

This instrument only should be used for measurements and evaluation of tests, released by the manufacturer. The manufacturer excludes warranty when other tests are used.

Safety instructions and cautions

Correct capture and treatment of the tests only is possible when the test used has been handled according to its instruction sheet.

Especially one should care for time limits and sample quantity, as these factors have a great influence on the measurement results.

Action in case of emergency

In case of samples taken of patient cases of emergency these samples can be examined at every time by interrupting the routine work and performing the examination according to the instruction sheet.

2 EQUIPMENT SUPPLIED - REMARKS



Packing list

- 1 "RIDA^Ò X-Screen" Reader instrument
- 1 Test strip holder
- 1 CD-ROM with "RIDA" X-Screen Reader software
- 1 control sample
- 1 control panel
- Manual
- Brief instructions

Advice: Should any piece of equipment be missing or damaged, please contact your distributor.

IMPORTANT!

- Please read this manual entirely prior to first use.
- Follow the instruction closely.
- R-Biopharm AG is not responsible for any damage occurring due to misuse or wrong handling of soft- and hardware.
- See the license agreements for further details (page 32).
- Do not connect the RIDA^o X-Screen reader device to the PC before having installed the software completely.

If you have any questions concerning handling of soft- or hardware, please contact R-Biopharm AG or your distributor by phone, fax or email:

Telephone + 49(0) 61 51 81 02 - 0

Telefax + 49(0) 61 51 81 02 - 40

e-mail info@r-biopharm.de

Order orders@r-biopharm.de

Address R-Biopharm AG

An der Neuen Bergstraße 17

64297 Darmstadt

Germany

This manual has been edited conscientiously and complies with the Standard DIN EN 591.

This user manual is effective from date of software version 490g.

Manual Version 0401-RR-0009-07

2009-05-06



3 TECHNICAL SPECIFICATIONS

STORAGE • SETTINGS

This system can be applied according to the conditions of EN 61326: 1997 + A 1:1998 (Class: B) for emission and absorption.

Dimensions: 262 x 110 x 200 mm³ (H x W x L)

Weight: 1,7 kg

Physical data: 5 V / 0,5 Ampere

Consumption: maximally 2,5 Watt

Storage and operating temperature:

Storage temperature should not be under 0 degree and not over 50 degree Celsius.

Location or rather operating temperature of the instrument should not be under 10 degree and not over 40 degree Celsius.

The factory-made basic settings are conducted by the set up **Basic settings:**

routine and can be verified in the manual, chapter: control sample

- quality control.

The instrument should not be exposed to direct and permanent **Measures of** installation:

radiation of sun or light. Please pay attention for the operating

and storage temperature.

Please follow the installation instructions.

4 SYSTEM REQUIREMENTS SOFTWARE INSTALLATION



System requirements

- Operating system Windows XP, Windows Vista 32 Bit Win NT / Win 98/98 SE, Win ME are **not** supported
- Windows XP 512 MB, Vista Vista 1 GB
- Celeron, Pentium IV or better
- Hard disk space: 850 MB
- CD-ROM: 24x speed or better
- Display resolution: min 1024x768 / 16 bit color or better
- 1 free USB port



4 SYSTEM REQUIREMENTS

SOFTWARE INSTALLATION • SYSTEM CHECK I

Installation

- First keep the RIDA X-Screen disconnected.
- Put the enclosed RIDA^O X-Screen program CD in your CD drive.
- If your system supports Autorun, the setup program will launch itself.
- If not:
 - go to START/RUN
 - type in X:\install (X = letter of your CD path)
 - then press ENTER

System-Key

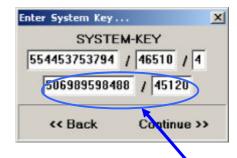
Each test strip holder has its own system key, which has to be kept well.

The system key has to be entered during the installation routine.

Remark: The system key is stipulated on the outer packing (carton) of the RIDA X-Screen as well as on the bottom side of the test strip holder.

• Enter licence number

- Use **CONTINUE**
- Follow the instructions.



second part-key-number

SYSTEM REQUIREMENTS

SOFTWARE INSTALLATION • SYSTEM CHECK II



System check

The installation program tests all essential points of the installed components in the computer. The RAPID READER has special system requirements.

Minimum roquiromonto	Freez bandling
•	Error handling
Windows XP Windows Vista 32 Bit	Windows 3.1 / 95 / 98 / 98SE /ME are detected:
	The computer is not adapted for the installation of the software.
	Error correction: Installation of an appropriate operating system (any existing data should be stored on external media)
Intel Pentium IV or better Celeron	Processor 386/486 or higher has been detected:
	The speed of the CPU is not appropriate to install the software.
	Error correction: a newer / faster processor should be used.
Minimum 1	
Windows XP Min. 512 MB Windows Vist – Min. 1 GB	Less than 512 MB memory has been found. The physical memory (RAM) should be increased to minimum 512 MB. 512 MB or more recommended.
	Resolution 1024x768 Pixel not found. The graphic card is not sufficient for this program. The resolution is not adequate.
16 bit or more	Error correction: Change the current graphic card and use a card with a resolution of minimum 1024 x 768 with a color depth of 16 bits or more.
The current settings do not correspond to the required values but will be supported by the graphic card.	Refer to the manual "Monitor Resolution"
Minimum 850 MB	The hard disk space (free) is less than 850 MB.
	Delete files that are not required from the hard drive or increase the size of the hard drive.
Drinter installed A printer	(Data should be stored on external media).
is installed and connected to a port. This printer wil be used as an output unit	No printer installed. It is strongly recommended to install a printer for the printout of the results.
List of the installed printers.	
	Intel Pentium IV or better Celeron Minimum 1 Windows XP Min. 512 MB Windows Vist – Min. 1 GB Minimum 1024 x 768 Pixel 16 bit or more The current settings do not correspond to the required values but will be supported by the graphic card. Minimum 850 MB Printer installed. A printer is installed and connected to a port. This printer will be used as an output unit for the software. List of the installed

8



5 USER ADMINISTRATION PROGRAM START • USFR LOGIN

User administration The RIDA^O X-Screen offers a comfortable user administration.

Therewith every user can choose and equip program functions and program options individually and flexibly.

User login

After program start:

- type in user name.
- type in password.

Advice: At the first program start the administrator login with the password **admin** (please type in admin in lower case letters.)

Recommendation: Choose a <u>new</u> password after the first program starts.

In the program (see picture next page)

EXTRA ▶ CHANGE ▶ ADVANCED ▶ USER ACCOUNT ▶ MODIFY USER ACCOUNT



proceed login by using

Continue

The program starts by using the correct password and the settings, which were defined by the user.

USER PROFILES

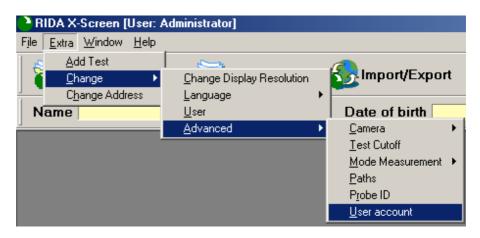


User profiles

With the program module *user administration* you can *add*, *modify* or *delete* an user account quickly and easily.

In the program:

EXTRA ▶ CHANGE ▶ ADVANCED ▶ USER ACCOUNT



Survey

Already established user profiles will be shown with *name* and Status *active* (YES/NO) *see below*

User status

• Active status: YES

The user is able to start the program.

• Active status: NO

The user is not able to start the program.



5 USER ADMINISTRATION USER PROFILE • ICONS

Icons

The options of the user administration are accessible by using the following 4 icons.



Modify User Account

Changing the functions of an user profile.



Add User Account

Adding a new user profile.



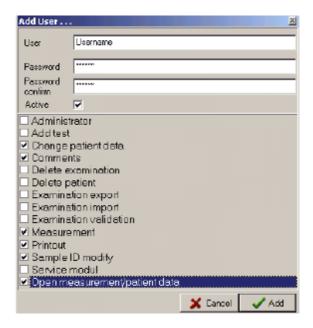
Delete User Account

Deleting an old user profile.



Close User Account

Leaving the user administration.



or

Modify User

is activated, a

window for changing the user profile appears.

5 USER ADMINISTRATION

USER PROFILE • OPTIONS



OPTIONS	DESCRIPTIONS			
User	Name of the user Allowed signs: A Z, a z, 0 9			
Password	Type in password Allowed signs: A Z, a z, 0 9			
Password confirm	Type in password Allowed signs: A Z, a z, 0 9			
Active	✓ = the user is able to start the program			
Administrator	Only the program administrator can use all program functions inclusive the user administration. The user profile ADMINISTRATOR can not be deleted.			
Add test	Adds a new test by using the key number In the program: EXTRA ▶ ADD TEST			
Change patient's data	Changes the patient's data or other data base information.			
Comments	Adds comments to the single measurements.			
Delete examination / patient	Deletes single measurements and/or patient's data.			
Examination import / export	Can import or export single measurements.			
Examination validation	Can validate single measurements.			
Measurement	Can perform examination/measurement of patient samples.			
Printout	Prints out the measurement results.			
Sample ID modify	Changes the sample ID numbers.			
Service module	Can change the internal program settings.			
Open measurement / patient's data	Archived data can be opened and regarded from the data bank.			



MAIN MENU	MAIN MENU SUB MENU		DESCRIPTION				
File	•	New examination	Creates a new examination for an existing patient				
	•	Load patient	Loads a patient and its existing examinations				
	•	Import / Export	Allows data transfer between RIDA X-Screen-Readers				
	•	Print	Allows preview of a printout				
	•	Exit	Closes the program				

Extra	•	Add test	Adds a new test using the key number		
	•	Change	► CHANGE DISPLAY RESOLUTION **RESOLUTION** Changes the graphic resolution**		
			► LANGUAGE <i>ENGLISH / GERMAN</i> ► Selects		
	•	Change address	Edits the data of the performing laboratory		

Window >	Cascade	Cascades all open windows		
•	Tile	Tiles all open windows		
•	Close all windows	Closes all open windows		
•	Show exam. list	Shows all open windows		
•	Hide exam. list	Hides the examination list		

Help	•		Shows the address of the technical support concerning help about the RIDA ^o X-Screen software
	•	About	Shows copyright information

7 ADDING A NEW TEST



System-Key

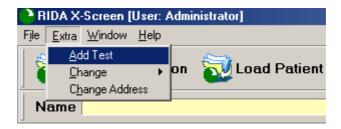
Each test strip holder and RIDA® X-Screen has got its own system-key. This key already has been entered while installing.

New Test

In the program:

MENU BAR

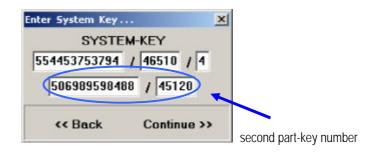
EXTRA → ADD TEST



In the program:

- The system-key as well as the number entered while installing appear.
- Please enter the new system-key number in case you want to use another RIDA^O X- Screen or another test strip holder.

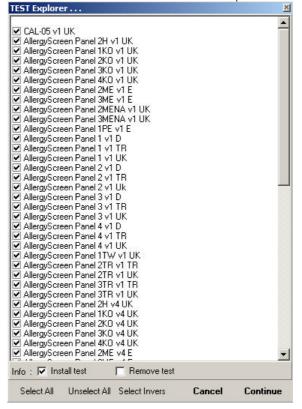
• Use **CONTINUE**



In the program:

- By clicking on Select all , you can select all tests.
- By clicking on Unselect all you can call off all selected tests.
- By clicking on Select invers you can convert all selected tests into not selected tests or convert all not selected tests into selected ones.
- Use CONTINUE

All tests released from the manufacturer are depicted in the Test Explorer.





Date of birth

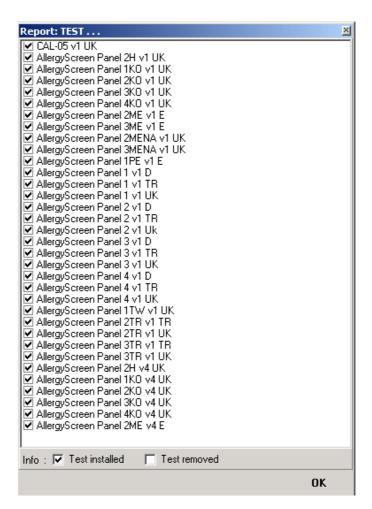
Exit

ID

AllergyScreen Panel 3 v1 done



- The blue running bar and the test text inform about the installation process of the tests
- The installation may take a few seconds
- After completion of the installation a test report is depicted for all installed tests.
- Use OK



New Examination 🔂 Load Patient 🧞 Import/Export 🕡 Print

RIDA X-Screen [User: Administration



8 ADDING A NEW PATIENT

OPENING • CHANGING PATIENT'S DATA



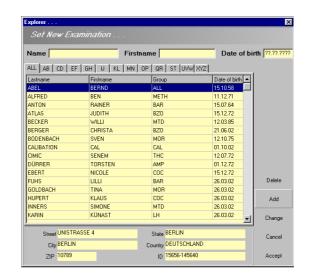
Adding a patient

In the program:

MENU BAR

NEW EXAMINATION

• click on ADD to confirm

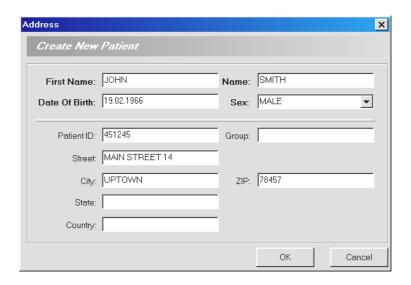


Practice mode

Type in the patient's data

- Type in the patient's data into the form
- click on OK
- Now you can perform an examination with this patient.
- To edit the data of an existing patient click

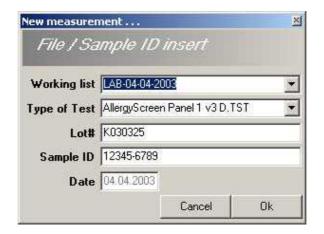
Load patient / change and type in the new data.



Laboratory mode

Type in the laboratory's data

- Type in the laboratory's data into the form
- click on OK
- Now you can perform an examination with these laboratory's data.







9 PERFORMING AN EXAMINATION

PREPARE MEASUREMENT

Patient's data

Make sure that the patient's data are acquired in the database.

Prepare measurement

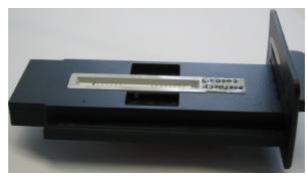
After the end of the reaction time (also see: test conduction), please insert the test strip into the holder of the RIDA X-Screen.

Remark:

Please pay attention to a correct insert of the test strip into the test strip holder.

Please put in the test strip into the depression the way it fits evenly, exactly and appropriately. Pay attention not to touch the surface of the membrane.

Correct



False



Correct

The test strip holder has to be pushed in exactly into the $RIDA^{\hat{O}}$ X-Screen. Please take care for a complete closing of the test strip holder.



False



9 PERFORMING AN EXAMINATION

NEW EXAMINATION • OPENING/CHANGING PATIENT'S DATA



Choose patient

In the program:

MENU BAR

NEW EXAMINATION

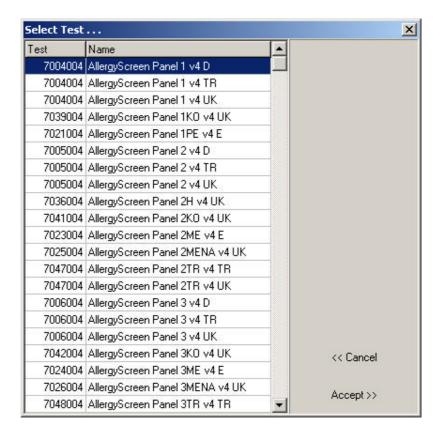
- Choose a patient
- Click on **ACCEPT** to continue



Select test

In the program:

- Select a test
- Use **ACCEPT**



Camera contact

The RIDA X-Screen software starts the camera.

This procedure takes a few seconds.



9 PERFORMING AN EXAMINATION

CAMERA PREVIEW • PICTURE ADOPTION

Camera preview

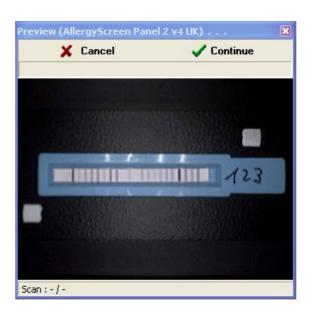
In the program:

Adopt the picture with

CONTINUE

or break off with

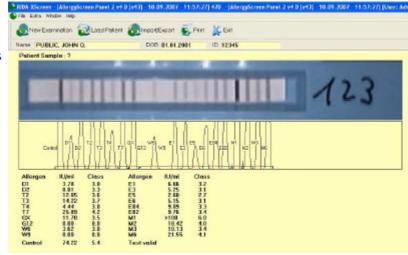
CANCEL



Picture adoption

The results appear on the screen after a few seconds

- analysed test strip / cassette
- densitometry evaluation
- calculated values



10 MEASUREMENT AND EVALUATION

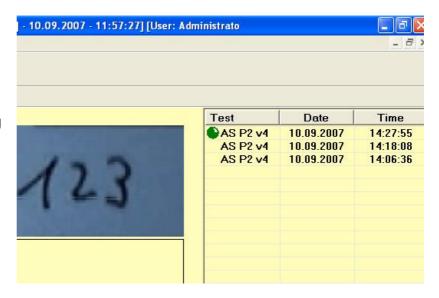
MEASUREMENT DATA • CURRENT OR PRIOR MEASUREMENTS



Measurement data

Prior measurement

- Examinations, which were saved or archived, can be recalled by clicking the entry in the exam. list
 - clicking on exam.list







11 DELETING A PATIENT DELETING PATIENT'S DATA

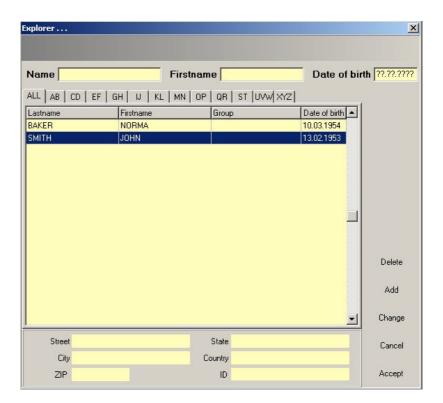
Deleting a patient

In the program:

MENU BAR

NEW EXAMINATION

- Choose the patient, who is going to be deleted.
- Use **DELETE**



Confirmation

- The chosen patient's data will be deleted irrevocably.
- Use **YES**
- Now the patient's data are no longer available.



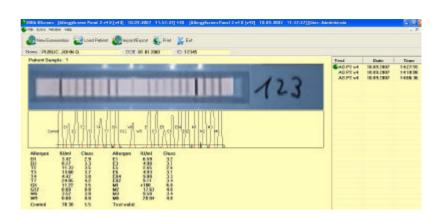
12 DELETING AN EXAMINATION

DELETING SINGLE MEASUREMENTS



Load patient

 Measurements, which were saved or archived, can be recalled by clicking the entry in the exam. list.



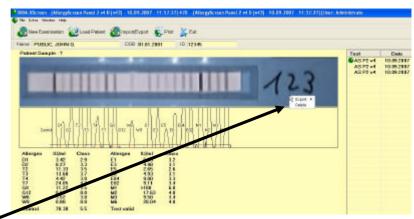
Deleting measurement data

load the measurement, which is going to be deleted

- Click on the result domain with the right mouse button
- The button

Export ?
Delete
appears:

Click on delete



Confirmation

- The measurement data chosen will be deleted irrevocably.
- Use **YES**
- Now the measurement data are no longer available.





22



13 IMPORT/EXPORT OF EXAMINATIONS

DATA TRANSFER • SAVING DATA

Data transfer

network. So you can exchange the results of the measurements

• So you can exchange the results of the measurements between different RIDA^O X-Screen Reader systems.

You can import and export the examination data of any patient

to and from any destination on the local drive or on your





Data transfer

In the program:

MENU BAR

IMPORT / EXPORT

Select either ASCII or Reader

When having selected ASCII export is generated automatically.

Confirm by clicking on OK

When having selected READER:

- Choose directory
- Enter file name
- Save file

Saving data

IMPORTANT!

- It is recommended to run backups of the acquired data on an external storage system on a regular basis.
- The file might be sent to all RIDA^o X-Screen users.
 Data can be shown at the receiver's places by clicking on import.





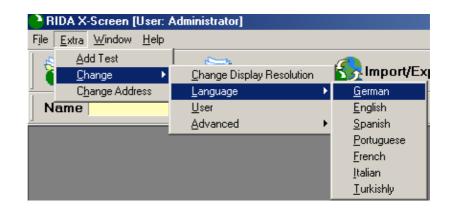


SETTINGS • GRAPHIC MODUS • ADDRESS



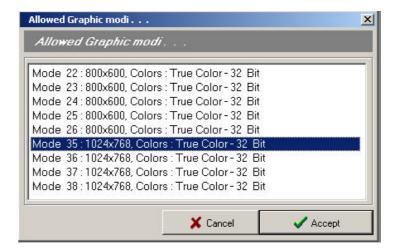
Settings

The EXTRA option allows you to alter several settings.



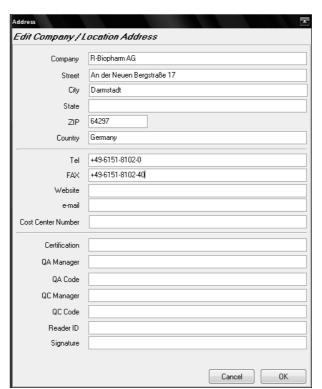
Monitor resolution

You can change the resolution of your monitor for maximum comfort.



Address

You can edit the address of the location at which the examination is performed.







15 PRINTING OUT AN EXAMINATION

PRINT PREVIEW • PRINTOUT

Preview / printout

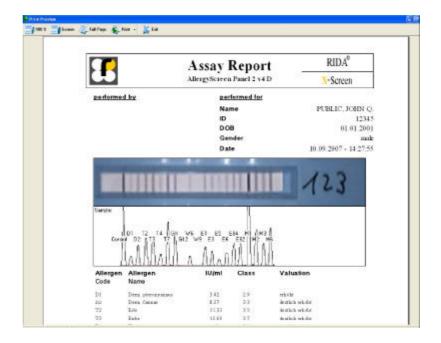
Preview

In the program:

 The result is shown in the window USING THE ICON



You can activate the **preview** and **printout** by using the icon **Print** in the respective window.

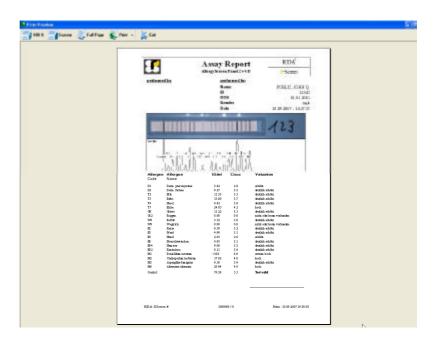


Printout

In the program:

 The printout is shown in the window USING THE ICON





16 CONTROL SAMPLE

QUALITY CONTROL



Control sample

The control sample is provided by the manufacturer for examination of the performance features of the RIDA^o X-Screen.

By using the control sample troubles during the measurement of patient samples might be detected and/or quality control can be carried out.

Caution

In case there has not been conducted a documented continuous examination by using the control sample, the manufacturer excludes every warranty for the measurement values.

Frequency of measurements by using the control sample should correspond to the location and safeguard a closed control of the system. These measurements should be entered into a separate table and a printout of the measurement values of the control sample should be archived.

See page 28 record of measurements of the control sample.

Performing control measurement

Control measurement is carried out by using the test CAL 05 v2 UK.RDF and is already preinstalled together with all other tests.

Please go to ▶ MENUTASK ▶ EXTRAS ▶ ADD TEST

And proceed according to chapter 7 "adding a new test" and carry out measurement according to chapter 9 "performing an examination"

26

16 CONTROL SAMPLE QUALITY CONTROL



Measuring range and interpretation

The measurement below is an example:

Line 1 (L1) Test passed / test failed

Line 2 (L2) Test passed / test failed

Line 3 (L3) Test passed / test failed

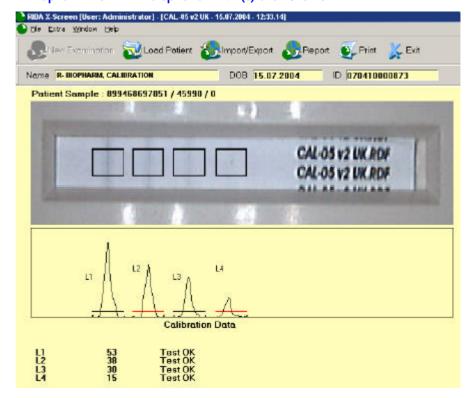
Line 4 (L4) Test passed / test failed

When "test failed" is stated in one or more lines (L1 to L4) the result is out of specification.

Contact your technical support or distributor:

R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0

Control sample



Handling (control sample)

Note:

- The control sample should be stored at room temperature in a dark and dry place in the original package.
- Record the date opened on the package.
- However, after the first measurement the control sample should not be used longer than 6 months.
- Do not use control card beyond the expiration date printed on the package.
- You can obtain new control samples from your distributor:
 R-Biopharm AG
 Telephone ++ 49 (0) 6151 8102-0

16 CONTROL SAMPLE

QUALITY CONTROL • RECORD



Date	User Abbrev./signature	Printout generated?	Result	Further proceeding when "test failed"
		Yes/No	ok/failed	



17 CONTROL PANEL QUALITY CONTROL

Control Panel

The control panel is provided by the manufacturer and serves to verify the measuring intervals and the light value of the corresponding camera.

The determination of the additional control panel is to be operated only in case that the camera is not working properly or you are requested by R-Biopharm.

Caution

Please perform the determination of the control panel as described below before sending an inquiry or complaint about the RIDA^o X-Screen to the manufacturer. Without the data of the control panel a complaint cannot be accepted.

See " Procedure" below.

Content

Within each camera box you will find additionally to the RIDA® X-Screen camera and the cal-strip (showing 4 greyish bands) a camera-specific control panel (showing 21 greyish bands). The camera and the control panel share the same serial number.

Therefore, the control panel must be used in combination with the corresponding camera only.

Procedure

The control panel should be measured with the corresponding camera for the below mentioned rdf-calibration file in five independent measurements.

Please use rdf-file: Panel 2vxx.UK

For each single measurement the trough must be removed and replaced in the camera again. After this, the mean value for each line has to be calculated and afterwards compared with the preset value as shown in the certificate of the RIDA $^{\circledR}$ X-Screen. The mean value should show a max. deviation of +/- 0.3 classes from the preset value on the certificate.

	Evaluation of the control panel RIDA X-screen								
Date):								
Labo	oratory:								
	al No. X-Scr	een:							
	Measurement 1	Measurement 2	Measurement 3	Measurement 4	Measurement 5	Mean value	preset value	deviation	yes/no
D1				ė.	5				
D2									
T2									
T3									i.
T4						-			. 3
17		is.	X	is.	is.	Α	18		
GX									
G12		7	2	2	9	/	1/2		8
W6									100
W9									
E1									
E3	10								
E5									
E6			8	8	8	3	15		8 8
E84	4								
E82			/				· ·		0
M1									120
M2									
M3		2		2	2	<u></u>			
M6	9								

17 CONTROL PANEL

OUALITY CONTROL • RECORD



Storage of the camera-specific control panel

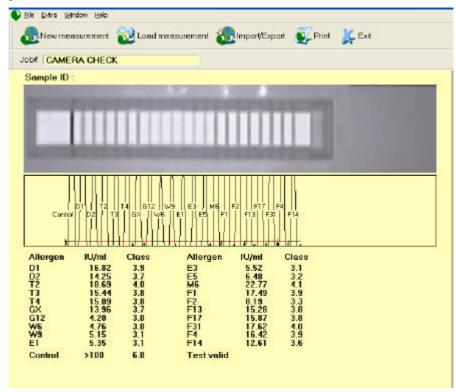
The control panel must be protected against:

- light
- humidity
- fingerprints

Please don't touch the surface of the membrane and store it in the included aluminium bag with silica gel.

Example

The following picture shows one measurement of a control panel:



After five independent measurements the calculated mean value for each line can be compared with the given class value in the certificate of the RIDA® X-Screen.

In case the mean value does not meet the specifications mentioned on the camera-specific certificate, please contact your local distributor.



18 TROUBLE SHOOTING MAINTENANCE

Symptom	Problem	Help
Message: target and source equal when importing	You tried to import a file that is already on the PC	The file is already on the PC
Image of test strip / cassette seems off center or slope	The test strip / cassette wasn't inserted accurately	 Insert the test strip / cassette properly into the holder Retry the examination
Image of test strip / cassette seems very light or overexposed	The holder wasn't inserted entirely	Insert holder completelyRetry the examination
Assessment is completely impossible	The wrong test strip / cassette or the wrong test was selected	 Insert correct test to the test list Select the correct test for examination Retry the examination
There is no visible light inside the RIDA® X-Screen device	Lack of power	Check the connection between the RIDA ^o X-Screen and the USB Port
Installation under Windows 2000 is not possible	Lacking administrator rights	You need to log in as administrator to be allowed to install

Maintenance

Standard maintenance is not designated for the $RIDA^O$ X-Screen. In case of trouble or defective control samples, please contact:

R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0

Cleaning of case

- Wipe the case by using ordinary laboratory detergents (disinfectant).
- Do not use acid agents or solvents.
- Please use scratch-free wipes.

Cleaning of test strip holder:

- Wipe and wipe out the test strip holder and depressions by using ordinary laboratory detergents (disinfectant).
- Do not use acid agents or solvents .
- Please use scratch-free wipes.

19 LICENCE CONDITIONS



License Agreement

PREFACE

The following conditions for your use of the RIDA X-Screen READER SOFTWARE apply to end-users ("licensee").

By opening the sealed data carrier package you agree to the following licence agreement. Please, read this agreement carefully.

If you do not agree to the conditions mentioned below you are not allowed to open the sealed data carrier package. In this case **do not open the package** and return it immediately as well as all other parts of the purchased product (including all written documents or material, hardware components and packing) to the place you bought it from.

Conditions of Contract

- 1) Subject of contract:
 - Subject of this contract are the following components: the computer program recorded on a data carrier (CD), the user manual, related hardware components and written material. These components are referred to as "software".
 - R-BIOPHARM AG explicitly states that based on today's technology it is not possible to issue a software in such a way that it is free of mistakes in all applications or combinations possible. The product can thus be described as a software which can generally be used as per its description and the corresponding user manual.
- 2) Scope of use
 - R-BIOPHARM AG grants a single, non-exclusive and personal right to use the enclosed copy of software on <u>one computer</u> and to use it only at <u>one work station</u> ("**license**"). A licensee is allowed to record the software in corporeal form from one computer to another (i.e. recorded on a data carrier) provided that it will be used only on one single computer at any time. Parallel use on two or more computers is strictly forbidden.
- 3) Special conditions
 - Without previous written approval from R-BIOPHARM AG the licensee shall not surrender the software to a third party or allow access to it nor shall he send the software via net or other data transmission channels to another computer. It is also forbidden to copy, alter, translate, redevelop, decompile, disassemble or develop derived products, neither software nor written material, without prior approval from R-BIOPHARM AG.
- 4) Ownership of rights
 - By purchasing this product you are given the sole ownership of the corporeal data carrier which the software is recorded on. A right of ownership of the software itself is not included. R-BIOPHARM AG has all rights reserved, e.g. rights of publication, copy, handling, adaptation and utilization.
- and utilization.
 5) Duplication
 - Software and written documentation are copyright protected. As far as the software is not provided with a copy protection you are allowed to generate one single copy for security purposes only. You are obliged to install the R-BIOPHARM AG copyright mark on the disk and include it. Neither the notice of copyright nor the registration number shall be removed. It is explicitly forbidden to copy the software and written material, neither entirely nor partially, in its original or altered format, in a mixed version with another software or in a version combined with another software.
- 6) Transfer of right of use
 - The right of use of the software may only be transferred to a third party with the prior written approval by R-BIOPHARM AG and only under the conditions of the terms of this contract. Giving away for free, leasing, renting out or lending are explicitly forbidden.
- 7) Duration of contract
 - The contract shall last for an unspecified period of time. The licensee's right to use the software automatically expires without notice if he breaks one of the conditions mentioned in this contract. The licensee shall destroy the original CD as well as all copies of the software including software versions which have been altered plus all documents upon termination of the right of use.
- 8) Compensation for damages due to break of contract
 - R-BIOPHARM AG will make you liable for all damages resulting from copyright infringements which arise from breaking any condition of this contract.
- 9) Alterations and updates
 - R-BIOPHARM AG is allowed to create updates at its own discretion. R-BIOPHARM AG is not obliged to provide such updates to licensees who did not pay the update fee.
- 10) Warranty and liability
 - R-BIOPHARM AG grants to the original license that at the time of providing the data carrier which the software is recorded on and the respective hardware all components work faultlessly under normal operating conditions and with standard maintenance. If a data carrier (CD) or hardware should be defective within the warranty period of 24 months the buyer may ask for a replacement. He shall return the CD, the respective hardware, any spare copy and written material as well as provide a copy of the corresponding invoice or receipt.
 - Should a defect arise as per this sentence 10 which cannot be solved by replacing components within a reasonable period of time the buyer is entitled to ask for a reduction in price or cancellation of the contract.
 - R-BIOPHARM AG does not grant entirely faultless software due to the reasons mentioned in sentence 1 of this contract. R-BIOPHARM AG does not warrant that the software entirely meets the purpose and request of the buyer himself or works without problems when it is combined with other software programmes chosen by the buyer.
 - The buyer himself is responsible for the correct choice and combination of products, the results of the use of software as well as the results he intends to achieve or gets. The same applies to the written material accompanying the software.
 - In case the basic software is not usable due to reasons mentioned in sentence 1 the buyer may cancel the contract. The same applies to R-BIOPHARM AG if production of a usable software as per sentence 1 is not possible within an adequate expenditure range.
 - R-BIOPHARM AG is not responsible for damages unless a damage is the result of intention or negligence by R-BIOPHARM AG. Liability for gross negligence is excluded towards businessmen. The liability regarding assured characteristics remains untouched. Liability for non-insured subsequent damages is also excluded.
- 11) Place of Jurisdiction
 - German law only applies to this contract. The place of jurisdiction is Darmstadt/Germany.
 - Concerning questions regarding these licence conditions, please contact: R-BIOPHARM AG AG, Neue Bergstr. 17, 64297 Darmstadt.