

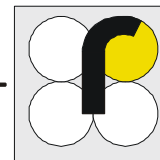
USER MANUAL FOR

RIDA[®]

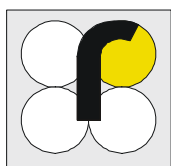
X-Screen



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



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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.

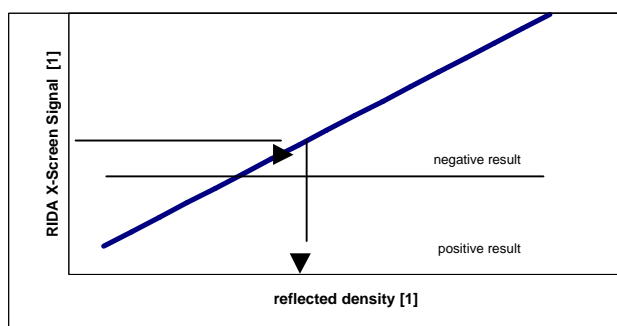
Performance features

The RIDA[®] 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[®] 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[®] 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[®] 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.

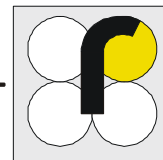
Safety instructions and cautions

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.

**Packing list**

- 1 "RIDA[®] 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 30).
- **Do not connect the RIDA[®] X-Screen reader device to the PC before having installed the software completely.**

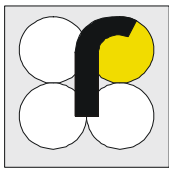
If you have any questions concerning handling of soft- or hardware, please contact R-Biopharm AG or your distributor by phone, fax or email:

Telephone	+ 49(0) 61 51 81 02 – 0
Telefax	+ 49(0) 61 51 81 02 – 20
e-mail	info@r-biopharm.de
Order	orders@r-biopharm.de

Address	R-Biopharm AG
	Landwehrstrasse 54
	64293 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 470a.



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.

Basic settings: The factory-made basic settings are conducted by the set up routine and can be verified in the manual, chapter: control sample - quality control.

Measures of installation: The instrument should not be exposed to direct and permanent radiation of sun or light. Please pay attention for the operating and storage temperature.

Please follow the installation instructions.

System requirements

- Operating system Win ME / Win2000 / Windows XP
Win NT / Win 98 / 98 SE is **not** supported
- min. 64 MB RAM
- min. Intel P 233
- min. 300 MB of free hard disk space
- min. CD-ROM drive/quadspeed
- min. VGA Display Card 800*600 resolution, 24 bit color depths
- Free USB port

Installation

- First keep the RIDA[®] X-Screen **disconnected**.
- Put the enclosed RIDA[®] 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.

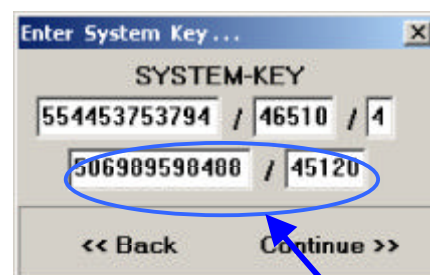
The system key has to be entered during the installation routine.

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

In case no second part-key-number is available,
please enter:
999999999999 / 99999.

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



second part-key-number



SOFTWARE INSTALLATION • SYSTEM CHECK I

- The installation program tests all essential points of the installed components in the computer.
- The RIDA[®] X-Screen Instrument and the software need specified system requirements.
- At the completion of the system check the results of the individual test will be presented according to the following picture

System Check		
Operation system	Windows 98 Ver. 4.10.1998	Test ok
Processor	Intel Pentium	Test ok
Processor(s) #	1	Test ok
RAM (min. 64 MB)	368 MB	Test ok
Graphic resolution	>= 800x600	Test ok
Graphic depth	>= 24 Bit	Test ok
Graphic resolution (current)	1280 x 1024	Test ok
Colors (current)	32 bit	Test ok
Harddisk space (free)	> 300 MB	Test ok
Printer (default)	EPSON AL-C1000 Advanced on LPT1:	Test ok
Software		installed
Camera Driver	Version Kodak/Logitech	Logitech
Printer (default)	Acrobat PDFWriter on LPT1:	-
	Acrobat Distiller on C:\WINDOWS\All Users\Desktop	-
	EPSON AL-C1000 Advanced on LPT1:	-

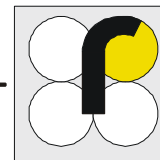
Continue >>
<< Cancel
Print

- If one or more components are found to be unacceptable the button **Continue** >> will not be released (grey). In this case some defined basic conditions are not fulfilled. Below you can find the individual test functions and the corresponding error handling.

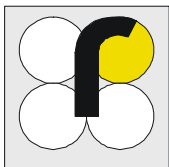
Test function	Minimum requirement	Error handling
Operating system	Windows ME Windows 2000 Windows XP	Windows 3.1 / Windows 95 are detected: The computer is not adapted for the installation of the software. <i>Error correction</i> : Installation of an appropriate operating system (before this data should be stored on external media)
Processor(s) (Processor / CPU-type)	Intel P 233 AMD K6 300 or better	Processor 386/486 or other ones will be detected: The speed of the CPU is not appropriate to install the software. <i>Error correction</i> : a newer / faster processor should be used.
Processor(s) #	Min. 1	

4 SYSTEM REQUIREMENTS

SOFTWARE INSTALLATION •
SYSTEM CHECK II



Test function	Minimum requirement	Error handling
RAM	Min. 64 MB	Less than 64 MB memory have been found. The physical memory (RAM) should be extended up to minimum 64 MB. <i>We recommend: 128 MB or more</i>
Graphic resolution Graphic depth	Min. 800 x 600 Pixel 24 bit	No resolution found regarding 800 x 600 Pixel. The graphic card is not sufficient for this program. The resolution is not adequate regarding the number of colours. <i>Error correction:</i> Change the actual graphic card and use a card with a resolution of minimum 800 x 600 with a colour depth of 24 bits.
Graphic resolution current Colours current	The actual settings do not correspond to the required values but will be supported by the graphic card.	Please refer to the manual on page 24 " Monitor resolution ".
Hard disk (free)	Min. 300 MB	The hard disk space (free) is less than 300 MB. Delete files which are not required from the hard disk.
Printer (default)	Printer installed. A printer is installed and connected to a port. This printer will be used as an output unit for the software.	No printer installed. It is strongly recommended to install a printer for the printout of the results.
Printer (installed)	List of the installed printers.	



User administration

The RIDA[®] 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:

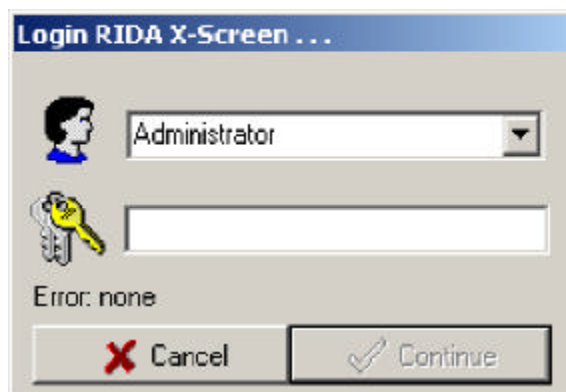
- type in *user name*.
- type in *password*.

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

Recommendation: Choose a new password after the first program starts.

In the program (see picture next page)

EXTRA ► CHANGE ► ADVANCED ► USERACCOUNT ► MODIFYUSERACCOUNT



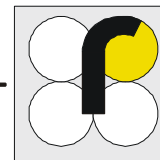
proceed login by using

Continue

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

5 USER ADMINISTRATION

USER PROFILES

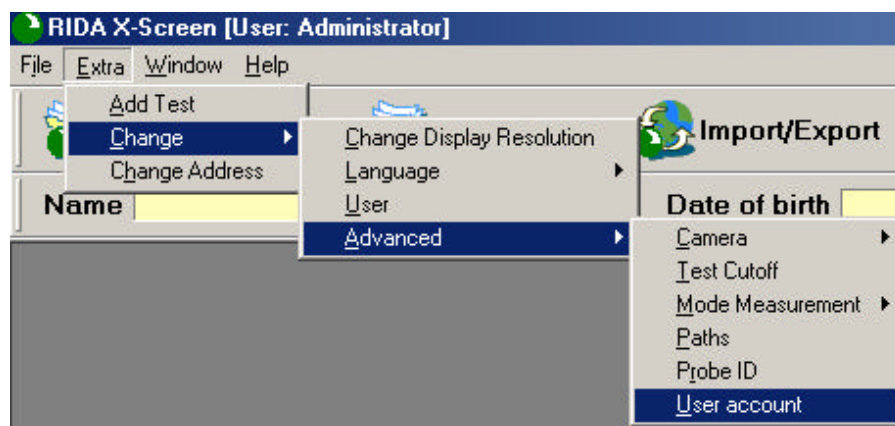


User profiles

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

In the program:

EXTRA ► CHANGE ► ADVANCED ► USERACCOUNT

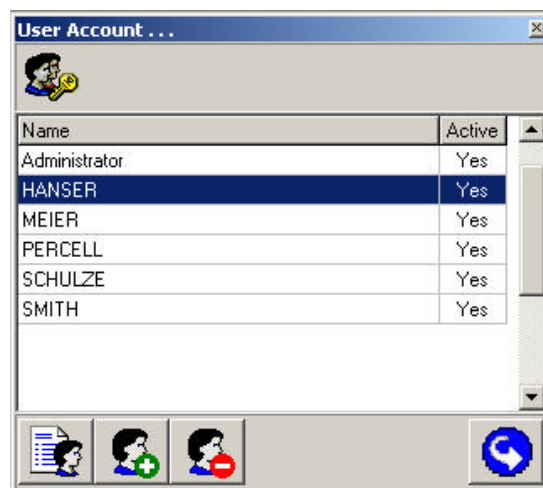


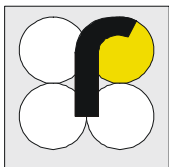
Survey

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.





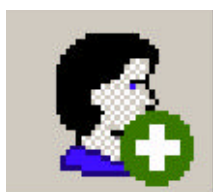
Icons

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



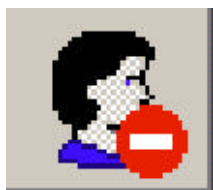
Modify User Account

Changing the functions of an user profile.



Add User Account

Adding a new user profile.



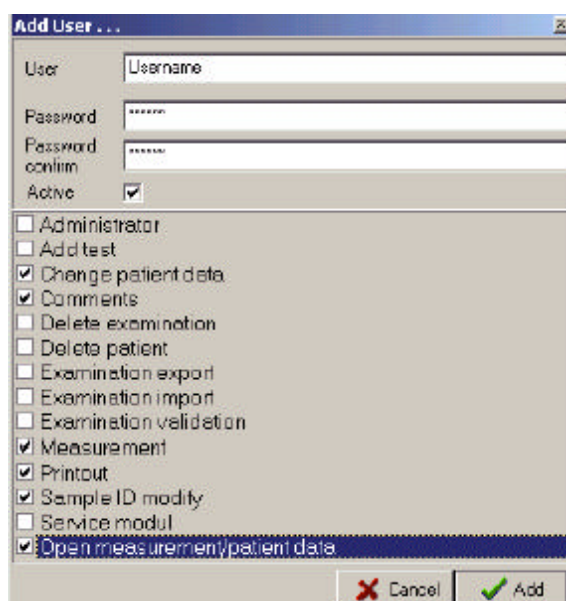
Delete User Account

Deleting an old user profile.



Close User Account

Leaving the user administration.



if

Add User

or

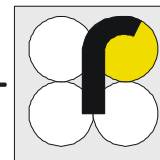
Modify User

is activated, a

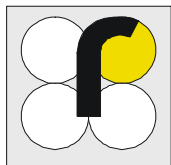
**window
for changing
the user profile**
appears.

5 USER ADMINISTRATION

USER PROFILE • OPTIONS



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

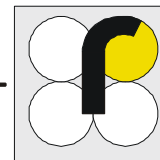


MAIN MENU	SUB MENU	DESCRIPTION
File	▶ New examination	Creates a new examination for an existing patient
	▶ Load patient	Loads a patient and its existing examinations
	▶ Import / Export	Allows data transfer between RIDA [®] X-Screen-Readers
	▶ Print	Allows preview of a printout
	▶ Exit	Closes the program

Extra	▶ Add test	Adds a new test using the key number
	▶ Change	▶ CHANGE DISPLAY RESOLUTION RESOLUTION ▶ Changes the graphic resolution ▶ LANGUAGE ENGLISH / GERMAN ▶ 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	▶ Technical support	Shows the address of the technical support concerning help about the RIDA [®] X-Screen software
	▶ About	Shows copyright information



- **System-Key**

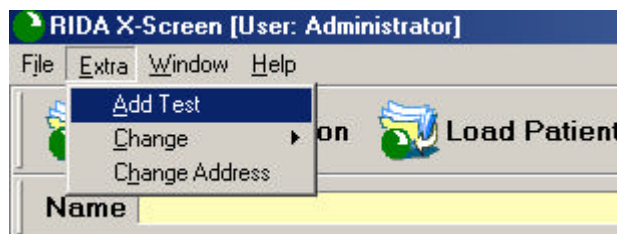
Each test strip holder and RIDA[®] X-Screen has got its own system-key. This key already has been entered while installing.

- **New Test**

In the program:

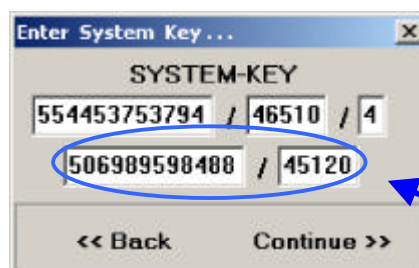
MENU BAR

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[®] X-Screen or another test strip holder.



second part-key number

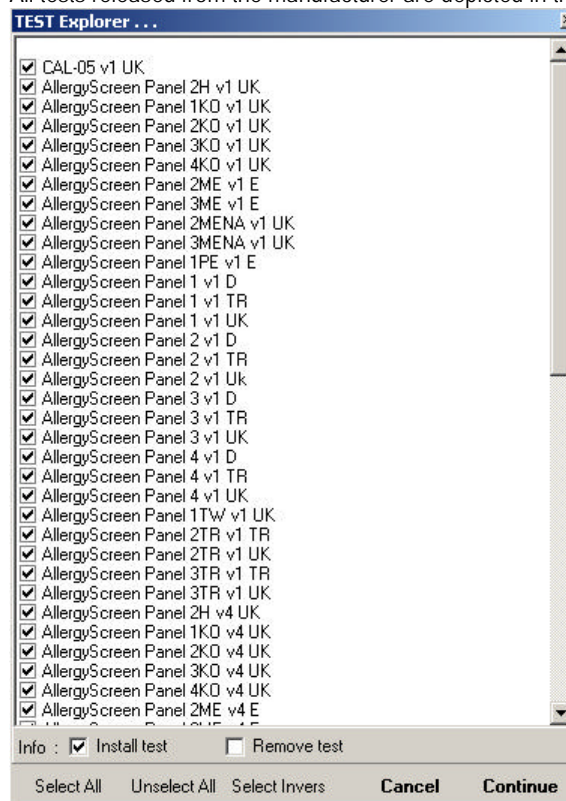
In case no second part- key number is available, please enter:
999999999999 / 99999

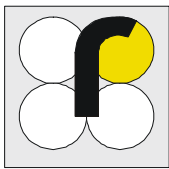
- Use **CONTINUE**

In the program:

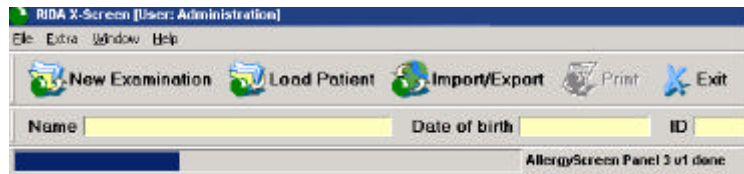
- By clicking on **Select all**, you can select all tests.
- By clicking on **Unselect all** you can call off all selected tests.
- By clicking on **Select invers** you can convert all selected tests into not selected tests or convert all not selected tests into selected ones.
- Use **CONTINUE**

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

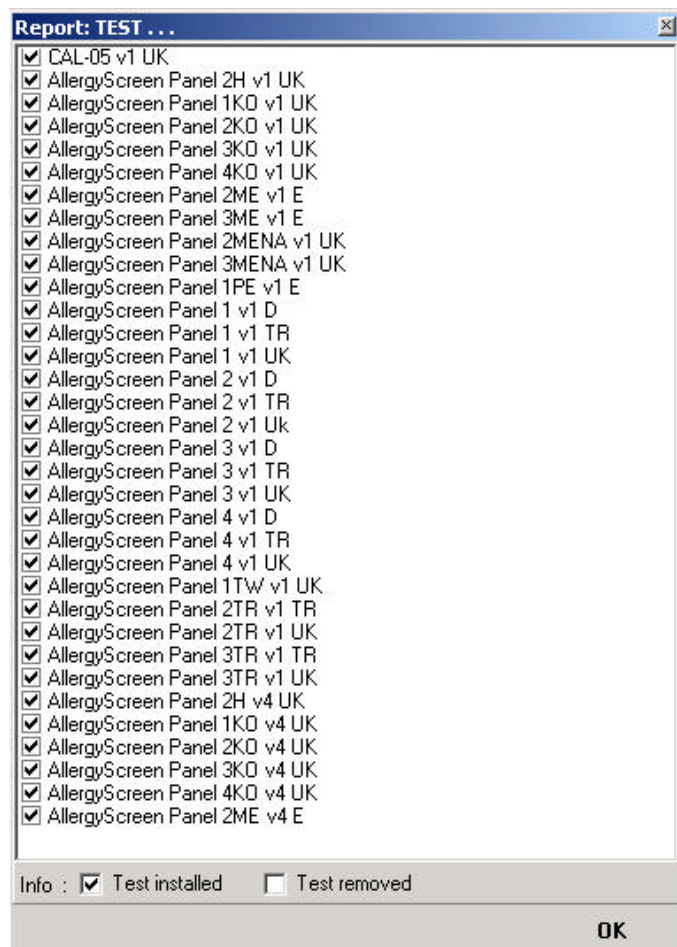




- The blue running bar and the test text inform about the installation process of the tests
- The installation may take a few seconds

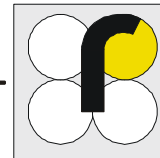


- After completion of the installation a test report is depicted for all installed tests.
- Use **OK**



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

Linkone	Firstname	Group	Date of birth
ABEL	BERND	ALL	15.10.58
ALFRED	BEN	METH	11.12.71
ANTON	RAINER	BAR	15.07.64
ATLAS	JUDITH	BZO	15.12.72
BECKER	WILU	MTD	12.09.86
BENIGER	CHRISTA	BZO	21.06.02
BODENBACH	SVEN	MOR	12.10.75
CALISATION	GAL	CAL	01.10.02
DMIC	SENEH	THC	12.07.72
DUPPER	TORSTEN	AMP	01.12.72
EBERT	NICOLE	COC	15.12.72
FUHS	LILLI	BAR	26.03.02
GOLDBACH	TINA	MOR	26.03.02
HUPERT	KLAUS	COC	26.03.02
INERIS	SIMONE	MTD	26.03.02
KARIN	KUNAST	LH	26.03.02

Street: LINSTRASSE 4 State: BERLIN
City: BERLIN Country: DEUTSCHLAND
Zip: 10788 ID: 19956-14540

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.

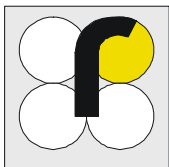
First Name: JOHN Name: SMITH
Date Of Birth: 19.02.1966 Sex: MALE
Patient ID: 451245 Group:
Street: MAIN STREET 14
City: UPTOWN ZIP: 78457
State:
Country:
OK Cancel

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.

Working list: LAB-04-04-2003
Type of Test: AllergyScreen Panel 1 v3 D.TST
Lot#: K030325
Sample ID: 12345-6789
Date: 04.04.2003
Cancel OK



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:

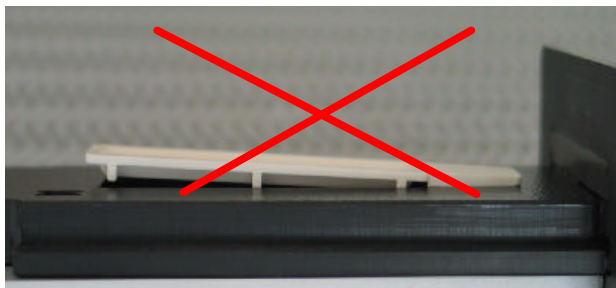
Please pay attention to a correct insert of the test strip into the test strip holder.

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



The test strip holder has to be pushed in exactly into the RIDA[®] X-Screen. Please take care for a complete closing of the test strip holder.

Correct

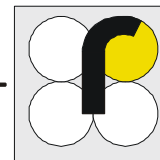


False



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

Lastname	Firstname	Group	Date of birth
ABEL	BERND	ALL	15.10.59
ALFRED	BEN	METH	11.12.71
ANTON	RAINER	BAR	15.07.64
ATLAS	JUDITH	BZO	15.12.72
BECKER	WILLI	MTD	12.03.85
BERGER	CHRISTA	BZO	21.06.02
BODENBACH	SVEN	MOR	12.10.75
CALIBATION	CAL	CAL	01.10.02
OMIC	SEHEN	THC	12.07.72
DÜRRE	TORSTEN	AMP	01.12.72
EBERT	NICOLE	COC	15.12.72
FUHS	LILU	BAR	26.03.02
GOLDBACH	TINA	MOR	26.03.02
HUPERT	KLAUS	COC	26.03.02
INERS	SWONE	MTD	26.03.02
KARN	KONAST	UH	26.03.02

Street: LINSTRASSE 4 State: BERLIN
City: BERLIN Country: DEUTSCHLAND
ZIP: 10789 ID: 19096-145640

Buttons: Delete, Add, Change, Cancel, Accept

Select test

In the program:

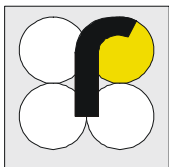
- Select a test
- Use **ACCEPT**

Test	Name
7004004	AllergyScreen Panel 1 v4 D
7004004	AllergyScreen Panel 1 v4 TR
7004004	AllergyScreen Panel 1 v4 UK
7039004	AllergyScreen Panel 1KD v4 UK
7021004	AllergyScreen Panel 1PE v4 E
7005004	AllergyScreen Panel 2 v4 D
7005004	AllergyScreen Panel 2 v4 TR
7005004	AllergyScreen Panel 2 v4 UK
7036004	AllergyScreen Panel 2H v4 UK
7041004	AllergyScreen Panel 2KD v4 UK
7023004	AllergyScreen Panel 2ME v4 E
7025004	AllergyScreen Panel 2MENA v4 UK
7047004	AllergyScreen Panel 2TR v4 TR
7047004	AllergyScreen Panel 2TR v4 UK
7006004	AllergyScreen Panel 3 v4 D
7006004	AllergyScreen Panel 3 v4 TR
7006004	AllergyScreen Panel 3 v4 UK
7042004	AllergyScreen Panel 3KD v4 UK
7024004	AllergyScreen Panel 3ME v4 E
7026004	AllergyScreen Panel 3MENA v4 UK
7048004	AllergyScreen Panel 3TR v4 TR

Buttons: << Cancel, Accept >>

Camera contact

The RIDA[®] X-Screen software starts the camera.
This procedure takes a few seconds.



Camera preview

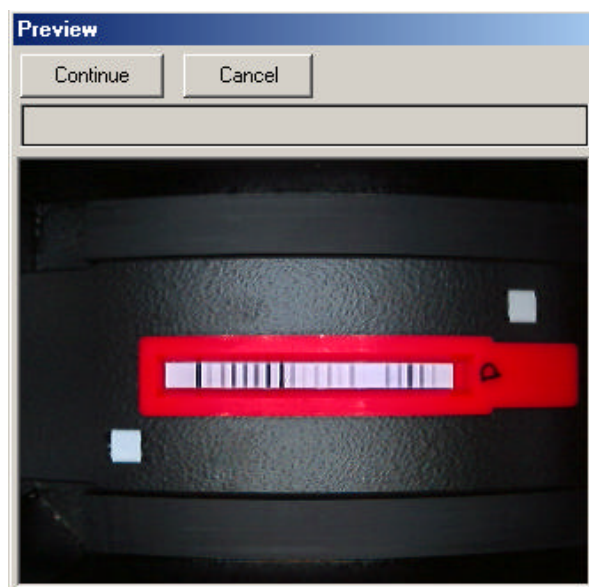
In the program:

Adopt the picture with

- **CONTINUE**

or break off with

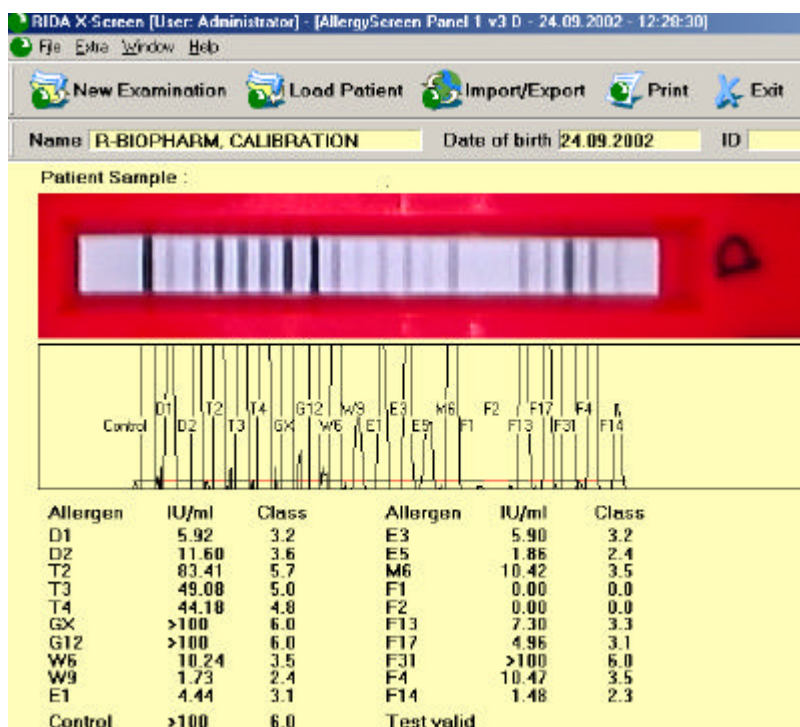
- **CANCEL**



Picture adoption

The results appear on the screen after a few seconds

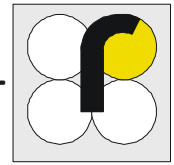
- analysed test strip / cassette
- densitometry evaluation
- calculated values



10 MEASUREMENT AND EVALUATION

MEASUREMENT DATA •

CURRENT OR PRIOR MEASUREMENTS



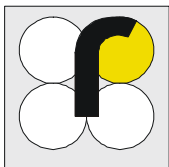
Measurement data

Prior measurement

- Examinations, which were saved or archived, can be recalled by clicking the entry in the exam. list
▶ [clicking on exam.list](#)

The screenshot shows a software window with a title bar and a menu bar. Below the menu bar, there is a section with an 'ID' input field and a 'Show Exam.list' button. To the left of the table is a vertical bar with a red section. The table itself has three columns: 'Test', 'Date', and 'Time'. The first row is highlighted with a green circle next to the 'Test' entry 'AS P1 v3'. The subsequent rows are highlighted in yellow.

Test	Date	Time
AS P1 v3	02.10.2002	12:17:51
AS P1 v3	01.10.2002	14:24:31
CAL-05 v 1	01.10.2002	14:21:38
CAL-05 v 1	01.10.2002	14:20:31
AS P1 v3	01.10.2002	14:10:54
CAL-05 v 1	01.10.2002	14:07:32
CAL-05 v 1	01.10.2002	14:05:22
CAL-05 v 1	01.10.2002	14:03:59
CAL-05 v 1	01.10.2002	14:02:38
CAL-05 v 1	01.10.2002	14:01:40
CAL-05 v 1	01.10.2002	13:54:26



Deleting a patient

In the program:

MENU BAR

NEW EXAMINATION

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

Lastname	Firstname	Group	Date of birth
BAKER	NORMA		10.03.1954
SMITH	JOHN		13.02.1953

Confirmation

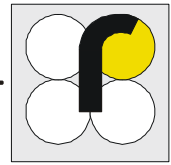
- The chosen patient's data will be deleted irrevocably.
- Use **YES**
- Now the patient's data are no longer available.

Are the data of the patient to be irrevocably deleted?

☐ No ☒ Yes

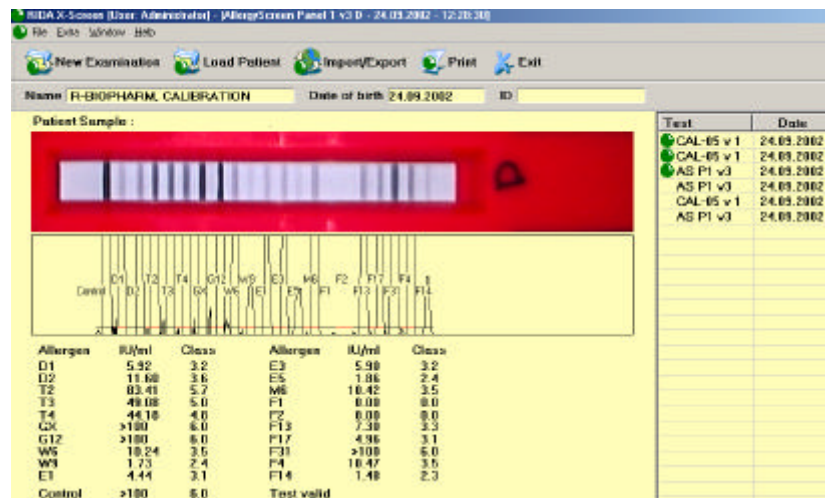
12 DELETING AN EXAMINATION

DELETING SINGLE MEASUREMENTS



Load patient

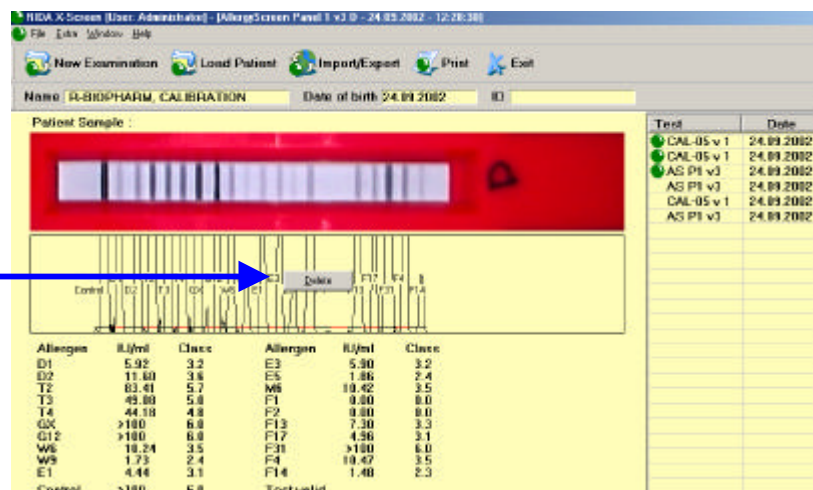
- Measurements, which were saved or archived, can be recalled by clicking the entry in the exam. list.



Deleting measurement data

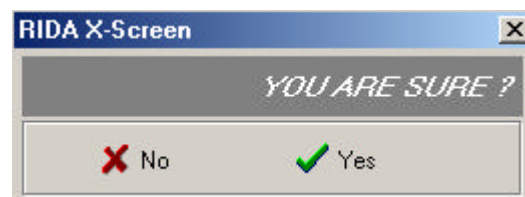
load the measurement, which is going to be deleted

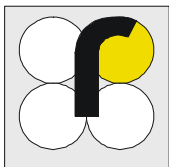
- Click on the result domain with the right mouse button
- The button **DELETE** appears:
- Click on delete



Confirmation

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





Data transfer

Data transfer

In the program:

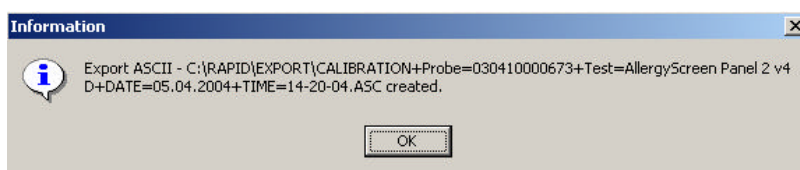
MENU BAR

IMPORT / EXPORT

Select either ASCII or Reader

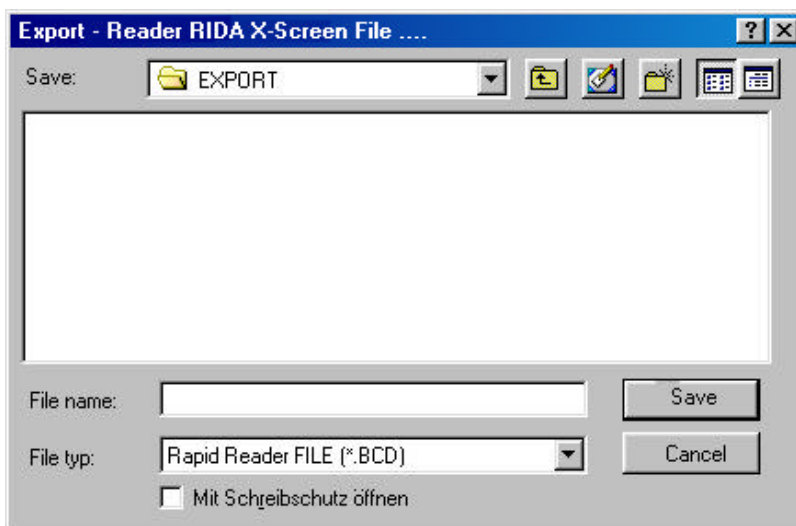
When having selected ASCII export is generated automatically.
Confirm by clicking on **OK**

- You can import and export the examination data of any patient to and from any destination on the local drive or on your network.
- So you can exchange the results of the measurements between different RIDA[®] X-Screen Reader systems.



When having selected READER:

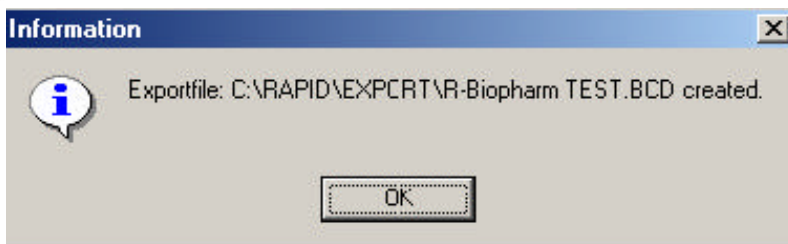
- Choose directory
- Enter file name
- Save file



Saving data

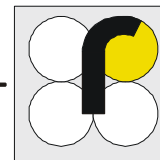
IMPORTANT !

- 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[®] X-Screen USERS.
Data can be shown at the receiver's places by clicking on import.



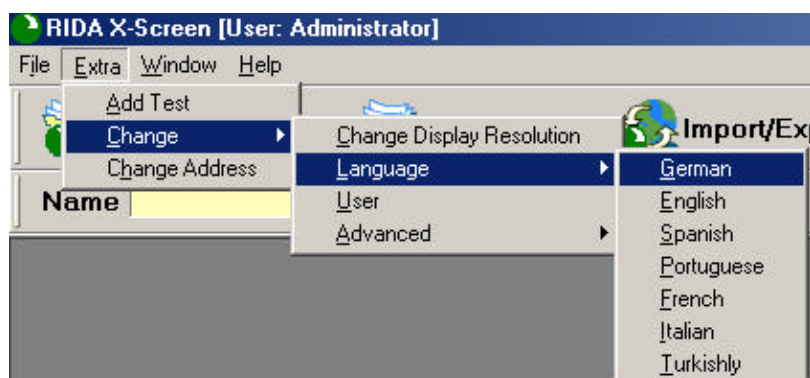
14 EXTRAS

SETTINGS • GRAPHIC MODUS •
ADDRESS



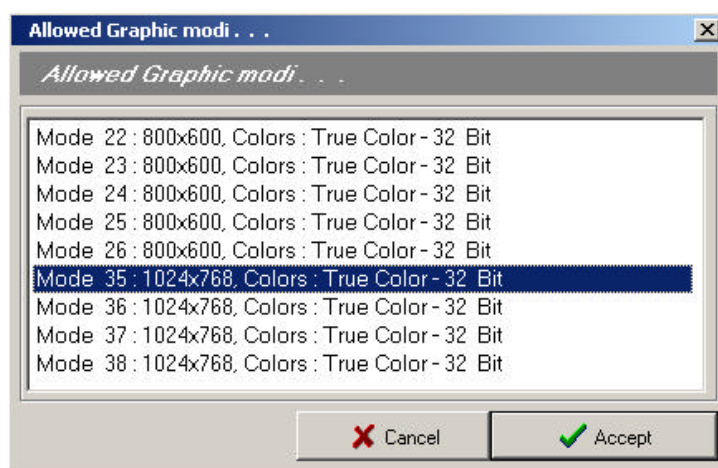
Settings

The EXTRA option allows you to alter several settings.



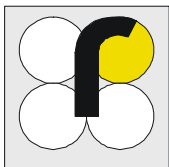
Monitor resolution

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.



Preview / printout

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

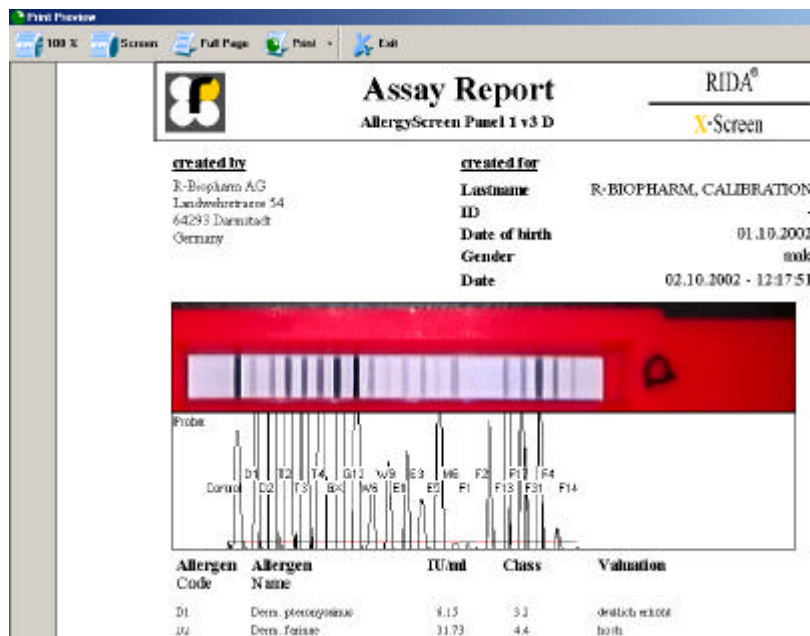
Preview

In the program:

- The result is shown in the window

USING THE ICON

PRINT ► PREVIEW



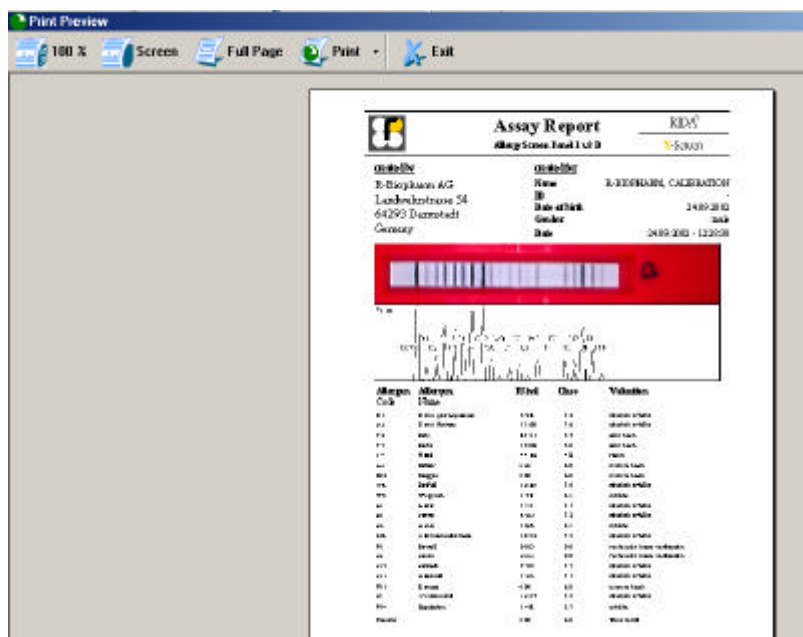
Printout

In the program:

- The printout is shown in the window

USING THE ICON

PRINT ► PRINTOUT



Control sample

The control sample is provided by the manufacturer for examination of the performance features of the RIDA[®] 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.

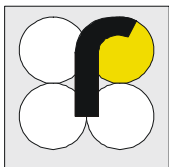
See page 28 record of measurements of the control sample.

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** ► **ADDTTEST**

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



Measuring range and interpretation

The measurement below is an example:

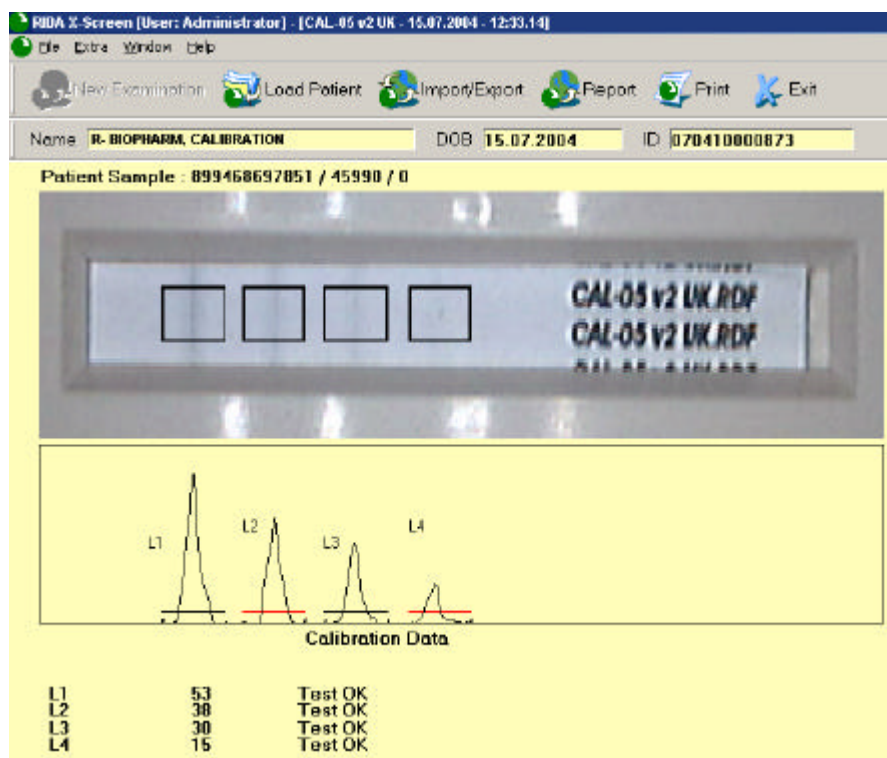
Line 1 (L1)	▶	Test passed / test failed
Line 2 (L2)	▶	Test passed / test failed
Line 3 (L3)	▶	Test passed / test failed
Line 4 (L4)	▶	Test passed / test failed

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



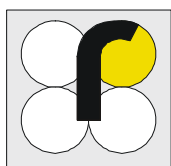
Handling (control sample)

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

[illegible]



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[®] 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.

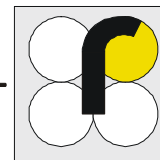
Procedure

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 2v4UK

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[®] X-Screen. The mean value should show a max. deviation of +/- 0.2 classes from the preset value on the certificate.

Evaluation of the control panel RIDA X-screen									
Date: _____									
Laboratory: _____									
Serial No. X-Screen: _____									
	Measurement 1	Measurement 2	Measurement 3	Measurement 4	Measurement 5	Mean value	preset value	deviation	result
D1									
D2									
T2									
T3									
T4									
T7									
GX									
G12									
W6									
W9									
E1									
E3									
E5									
E6									
EB4									
EB2									
M1									
M2									
M3									
M6									



Storage of the camera-specific control panel

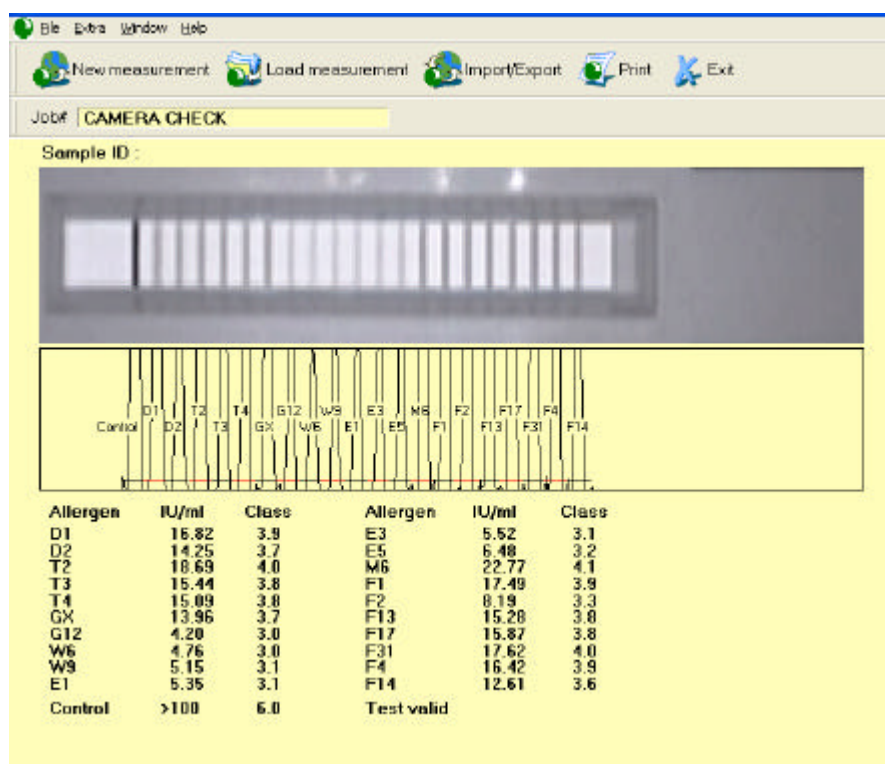
The control panel must be protected against:

- light
- humidity
- fingerprints

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

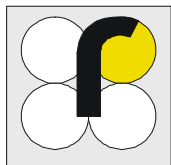
Example

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.



Symptom	Problem	Help
Message: target and source equal when importing	You tried to import a file that is already on the PC	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● Insert holder completely ● Retry the examination
Assessment is completely impossible	The wrong test strip / cassette or the wrong test was selected	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● Check the connection between the RIDA[®] X-Screen and the USB Port
Installation under Windows 2000 is not possible	Lacking administrator rights	<ul style="list-style-type: none"> ● You need to log in as administrator to be allowed to install

Maintenance

Standard maintenance is not designated for the **RIDA[®] X-Screen**. In case of trouble or defective control samples, please contact:

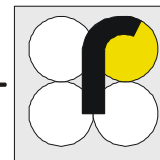
R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0

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.



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.

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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“.
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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.
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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 licensee 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, Landwehrstrasse 54, 64293 Darmstadt.