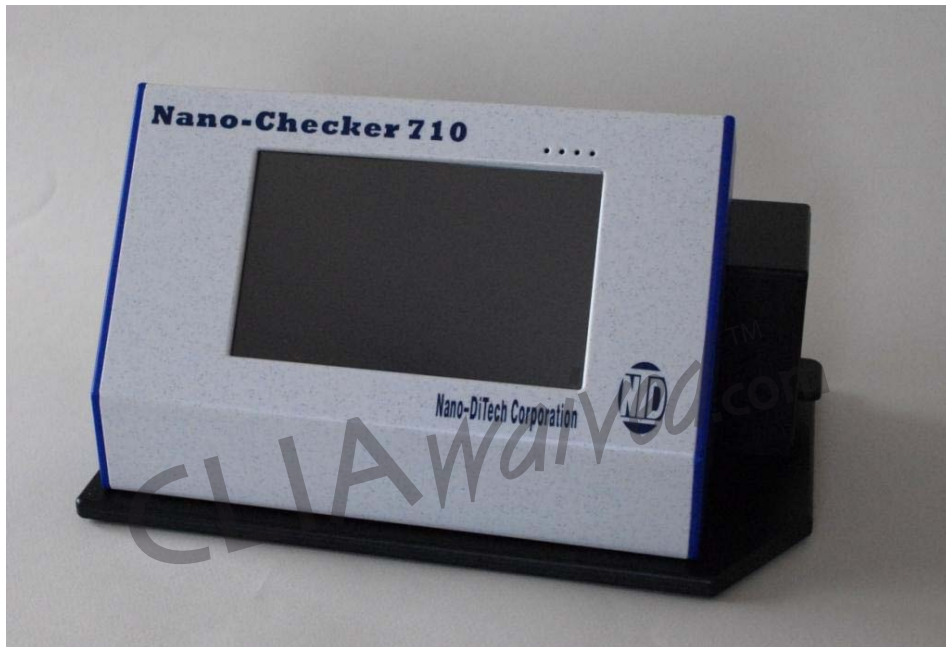


# **USER MANUAL**

## **FOR**

# **Nano-Checker 710**



**THE PIONEER AND CONSISTENT INNOVATOR**  
**FOR *IN VITRO* DIAGNOSTICS**

- **Read before initial operation**
- **Any questions call our technical support line:**

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**This manual complies with the Norm DIN EN 591.  
Intended only for use by qualified personnel**

**Manual Version 0708-RR-0185-03**

**April - 2009**

## PURPOSE

The NANO-CHECKER 710 is an instrument that evaluates the reflection or optical density, of a biochemical reaction compared to the environmental background of the measurement sample.

## PERFORMANCE FEATURES

The NANO-CHECKER 710 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.

## OUTPUT OF ANALYTICAL DATA

Measurement values of the NANO-CHECKER 710 are correlated linearly to the reflected density measurements of the control function.

Optical densities are converted to the value of analyte concentration. Figure 1 shows a signal slope generated by the NANO-CHECKER 710. The measurement of the reflected density allows calculating the concentration of analyte in the tested specimen based on the predetermined slope.

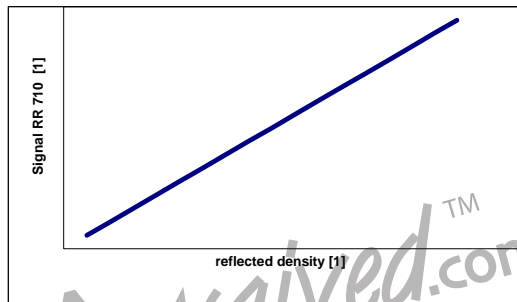


Figure 1

## SCOPE OF USE

During the testing routine, the standard approved AMI tests are selected for reading (See section 8; Adding a test). The tests **cover** the product and scope of use of the NANO-CHECKER 710 provided by the manufacturer.

## USER LIMITATIONS

*The NANO-CHECKER 710 should only be used for measurements and evaluation of tests manufactured by the original equipment supplier. The manufacturer and distributor disclaims all warranties expressed or implied, if a user attempts to use the NANO-CHECKER 710 to record the results of a test not covered under "Scope of Use". Furthermore, the manufacturer and/or distributor shall not be held liable for any damages, including but not limited to incidental, consequential or special damages, arising out of the user attempting to use the NANO-CHECKER 710 to record the results of a test not covered under "Scope of Use".*

## PRECAUTIONS

Correct capture and results of the tests are only possible when the test used has been handled according to the package insert.

## 2 EQUIPMENT SUPPLIED

---

### CONTENTS

- 1 NANO-CHECKER 710 instrument
- Instruction Manual
- Brief Instructions

**Note:** *Should any piece of equipment be missing or damaged contact your local distributor.*

### IMPORTANT!

- Read this manual prior to first use.
- Follow the instructions.
- **The software is factory installed and the NANO-CHECKER 710 is ready to use when it is delivered.**
- **Use touch screen, pen and/or mouse.**
- Distributor and manufacturer are not responsible for any damage occurring due to misuse or improper handling of software or hardware. disclaims all warranties, express or implied, including any implied warranty of merchantability or fitness for a particular purpose, and the limit of 's liability on account of any breach of any express warranty under this agreement will be limited to replacement of the product, or the purchase price of the product, as will determine. Without limiting the foregoing, shall not be liable for incidental, special or consequential damages arising out of any product defect, failure to include all components listed, or any breach of warranty.
- See the license provisions for further details (page 30).
- If you have any questions concerning handling of software or hardware, contact or your distributor by phone, fax or e-mail:

### 3 TECHNICAL SPECIFICATIONS

#### Storage • Settings

---

**INTERNATIONAL & EUROPEAN NORM:**

International Norm: This system can be used according to the conditions of FCC Part 15 B, CISPR 11 and CISPR 22.

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

**DIMENSIONS:**

16.5 x 32.3 x 17.5 cm (H x W x L)

**WEIGHT:**

2.25 kg

**PHYSICAL DATA:**

DC 12 V / 5 A

**POWER CONSUMPTION:**

Maximum 60 Watt

**ENVIRONMENTAL STORAGE/ OPERATING TEMPERATURE:**

Storage temperature should not be under 32°F (0°C) and not over 122°F (40°C).

Operating temperature of the instrument should not be under 50°F (10°C) and not over 104°F (40°C).

The instrument should not be exposed to direct sunlight.

**BASIC SETTINGS**

The factory-installed basic settings are factory installed.

- The NANO-CHECKER 710 software is factory-installed
- Operating system Windows XP or Vista
- Hard disk space 40 GB
- Touch Screen

**PRECAUTION!**

**The NANO-CHECKER 710 is a touch screen instrument.**

**Please do not use any sharp objects to touch the screen!**

## 4 INTEGRATED PC

---

### SWITCHING ON AND OFF

- The on/off button is on the rear right side of the NANO-CHECKER 710.
- In order to switch the NANO-CHECKER 710 on or off – press the silver button on the back side of the NANO-CHECKER 710 shortly.



### HANDLING

You will find a stick for touching the screen in the carton.

There are four USB ports built in the NANO-CHECKER 710 so that you can connect printer, keyboard a.s.o.



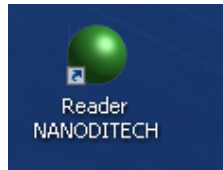
### POWER SUPPLY

Plug the power outlet into the socket.



**Having pressed the silver button for switching on the NANO-CHECKER 710, wait a few seconds.  
The Reader software boots up automatically.**

Start the software by clicking on the green ball.



### USER ADMINISTRATION

The Nano-Checker 710 offers a user administration option.

Each user has the option and flexibility to choose program functions that are allocated to individual users.

### USER LOGIN

After program start:

- Type in *user name*.
- Type in *password*.
- Click **Continue**

SET UP ► CHANGE ► ADVANCED ► USER ACCOUNT ► MODIFY USER ACCOUNT



proceed with login by using

**Continue**

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

**Note:** When the program is first started the administrator login password “**admin**” will be automatically assigned. (*Type admin in lower case letters.*)

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

**Note:** Password is case sensitive

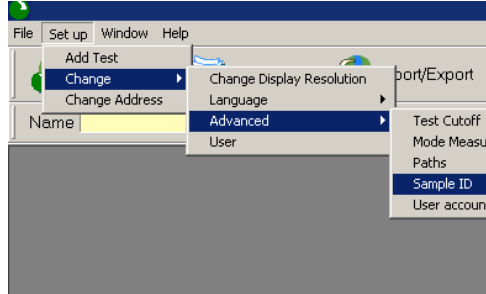
## 5 USER ADMINISTRATION

### USER PROFILES

In the program module **user administration** you can **add, modify, and delete** a user account quickly and easily.

In the program:

SET UP ▶ CHANGE ▶ ADVANCED ▶ USER ACCOUNT



### USER ACCOUNT

known with **Name** and

**Active** Status (YES/NO) see below

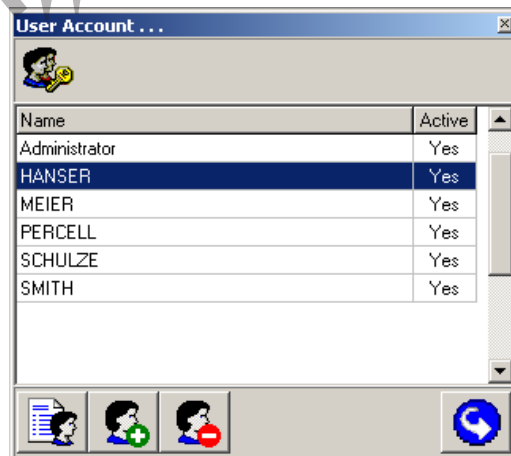
### USER STATUS

- **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

### ICONS

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



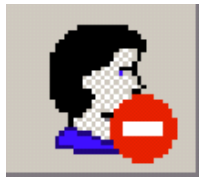
#### Modify User Account

Changes the functions of a user profile.



#### Add User Account

Adds a new user profile.



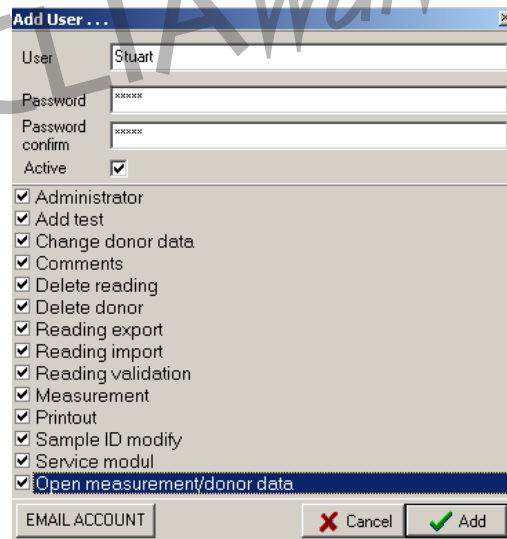
#### Delete User Account

Deletes an old user profile.



#### Close User Account

Leaves the user administration.



ADD USER ...

User Stuart

Password xxxxxx

Password confirm xxxxxx

Active

- Administrator
- Add test
- Change donor data
- Comments
- Delete reading
- Delete donor
- Reading export
- Reading import
- Reading validation
- Measurement
- Printout
- Sample ID modify
- Service modul
- Open measurement/donor data

EMAIL ACCOUNT

If Add User or Modify User is activated, then a **window for changing the user profile** appears.

## 5 USER ADMINISTRATION

OPTIONS	DESCRIPTIONS
<i>User</i>	Name of the user Allowed characters: A ... Z, a ... z, 0 ... 9
<i>Password</i>	Type in password Allowed characters: A ... Z, a ... z, 0 ... 9
<i>Password confirm</i>	Type in password Allowed characters: 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 of the user administration. The user profile <i>ADMINISTRATOR</i> <u>cannot</u> be deleted.
<i>Add test</i>	Adds a new test by using the key number <i>In the program:</i> <b>SET UP ▶ ADD TEST</b>
<i>Change donor data</i>	Changes the donor data or other data base information.
<i>Comments</i>	Adds comments to the single measurements.
<i>Delete reading/donor</i>	Deletes single measurements and/or donor data.
<i>Import/export data</i>	Can import or export single measurements.
<i>E-mail capabilities</i>	Results may be transmitted via electronic mail or interfaced with a network.
<i>Results management</i>	Sending or archiving of results in Excel format
<i>Reading validation</i>	Can validate single measurements.
<i>Measurement</i>	Can perform reading/measurement of donor samples.
<i>Printout</i>	Prints out the measurement results.
<i>Sample ID modify</i>	Changes the sample ID numbers.
<i>Open measurement/donor data</i>	Archived data can be opened and retrieved from the data bank.

## 6 MENU BAR

MAIN MENU	SUB MENU	DESCRIPTION
•File• ▶ ▶ ▶ ▶ ▶	New reading	Creates a new reading for an existing donor
	Load donor	Loads a donor and previous readings
	Import / Export	Allows data transfer between NANO-CHECKER 710s, local drive or a network
	Print	Allows preview of a printout and the option to print.
	Exit	Closes the program
•Set up• ▶ ▶ ▶	Add test	Adds a new test using the key number
	Change	▶ LANGUAGE <b>ENGLISH / SPANISH / GERMAN</b> ▶ Select ▶ ADVANCED ▶ <i>Menu for technical support</i>
	Change address	Edits the information of the laboratory performing the test
•Window• ▶ ▶ ▶ ▶	Cascade	Cascades all open windows
	Tile	Tiles all open windows
	Close all windows	Closes all open windows
	Show reading list	Shows all open windows
•E-mail• ▶ ▶ ▶ ▶ ▶	Modify account	E-mail account
	Set up	POP3 settings: active incoming mail server SMTP settings: , active outgoing mail server
	Sending results	Sends results by e-mail
	Message editor	Offers the option to add additional recipients. Sends the message automatically from the screen.
	Receive e-mail	Opens the NANO-CHECKER 710 software, e-mail and attachments. Opens results
•Help• ▶ ▶	Technical support	Shows the contact details for technical support for help with the NANO-CHECKER 710 software
	About	Shows copyright information

## 7 ADDING A NEW TEST

- **SYSTEM KEY**

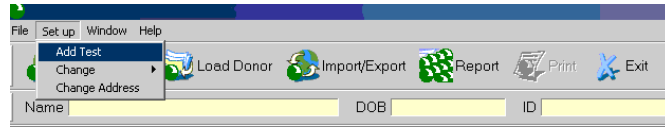
Each test strip holder and NANO-CHECKER 710 has its own system-key.

- **NEW TEST**

*In the program:*

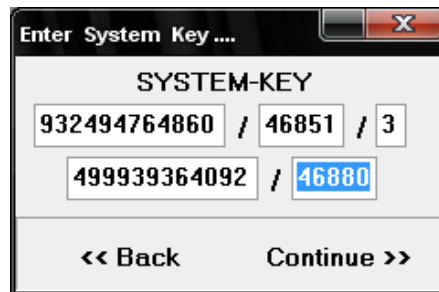
**MENU BAR**

**SET UP ▶ ADD TEST**



*In the program:*

- The field to enter the system-key appears.
- Enter the new system-key number if you are using a different NANO-CHECKER 710 or another test strip holder.

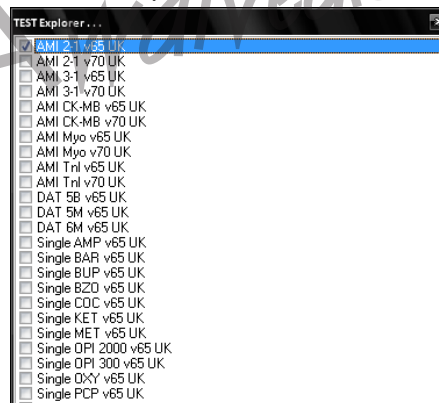


- Click **CONTINUE**

*In the program:*

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

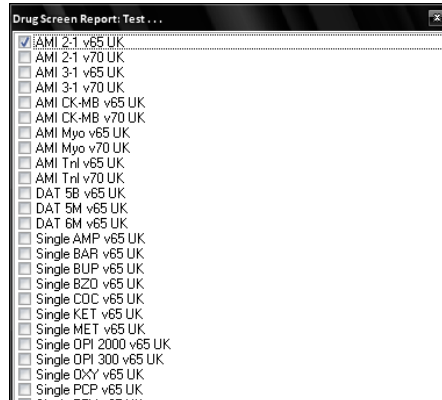
- Click individual tests or panels to be utilized.
- To select all tests click **Select All**
- To unselect all selected tests click **Unselect All**
- To convert all selected tests into non selected tests or convert all not selected tests into selected ones click **Select Inverse** ODER
- Click **continue**



- The installation may take a few moments.

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

- Click **OK**



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## 8 ADDING A DONOR

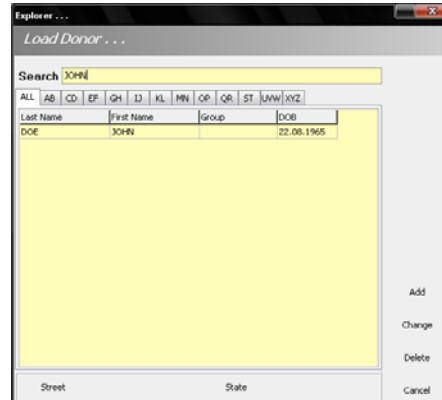
### ADDING A DONOR

In the program:

#### MENU BAR

NEW READING

- Click **ADD** to confirm



### TYPE IN THE DONOR'S DATA

- Type the donor's data into the form.
- Click **OK**
- Now you can perform a reading on this donor.
- To edit the data of an existing donor click **Load donor / change** and type in the new data.

Address  
Create Donor Data

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_  
DOB: \_\_\_\_\_ Gender: \_\_\_\_\_  
DOB: MM.YYYY

Street: \_\_\_\_\_  email active  
City: \_\_\_\_\_ TO: \_\_\_\_\_  
State: \_\_\_\_\_ CC: \_\_\_\_\_  
ZIP: \_\_\_\_\_ BCC: \_\_\_\_\_  
Country: \_\_\_\_\_  
Group: \_\_\_\_\_  
ID: \_\_\_\_\_

OK Cancel

## 9 PREPARING A MEASUREMENT

---

1. Insert the test cassette into the holder of the NANO-CHECKER 710.



2. Ensure the cassette is face up and inserted correctly as well as pressed down into the holder completely.

*Do not touch the surface of the test*



3. Push the test holder into the NANO-CHECKER 710. The test holder must be inserted exactly and evenly into the NANO-CHECKER 710. Make sure that the test holder is completely closed.

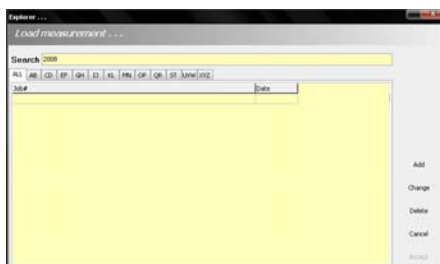


## 10 PERFORMING A MEASUREMENT

### SELECT DONOR

*In the program:*

**MENU BAR**  
▼  
**NEW READING**



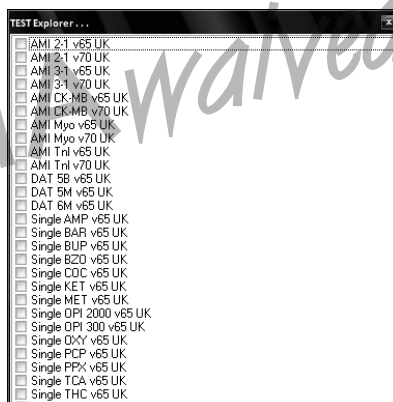
- Select a donor.
- Click **ACCEPT**

You may use the “search option” to find the donor when entering the first types of their name or date of a saved measurement in the input window.

### SELECT TEST

*In the program:*

- Select a TEST.
- Click **CONTINUE**





## 10 PERFORMING A MEASUREMENT

### CAMERA PREVIEW

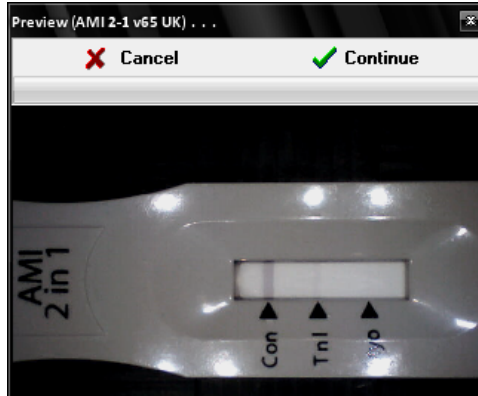
*In the program:*

Accept the picture with

- **CONTINUE**

or disregard with

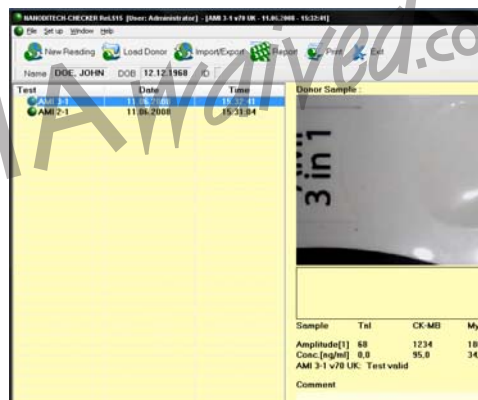
- **CANCEL**



### PICTURE ACCEPTANCE

The results appear on the screen after a few moments.

- Analyzed test strip
- Densitometric evaluation
- Calculated values

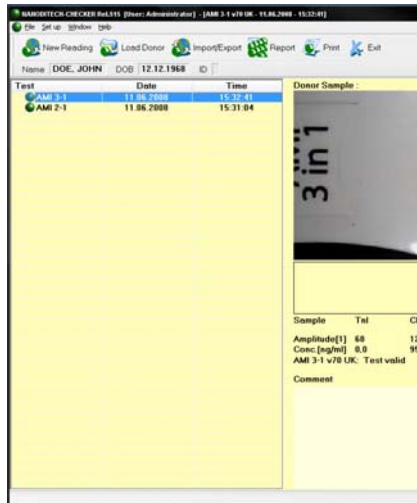




## CURRENT MEASUREMENT

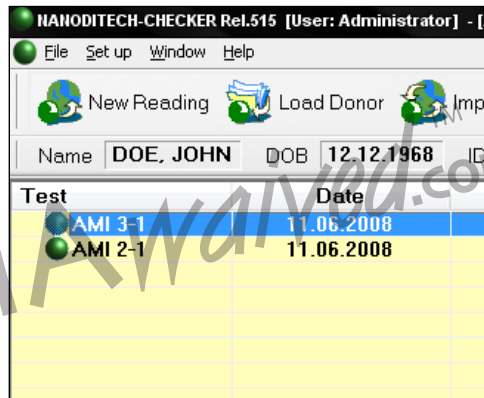
After the measurement the software shows:

- Results of Tests
- Test Evaluation



## PRIOR MEASUREMENT

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



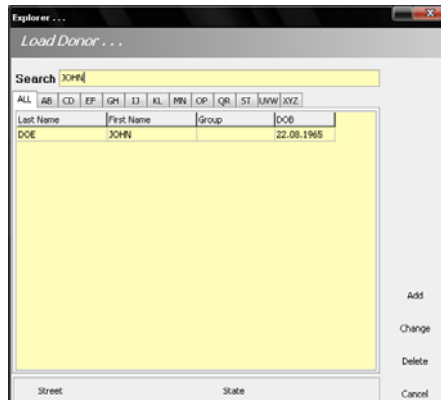
## DELETING A DONOR

In the program:

### MENU BAR

#### NEW READING

- Select the donor to be deleted.
- Click **DELETE**

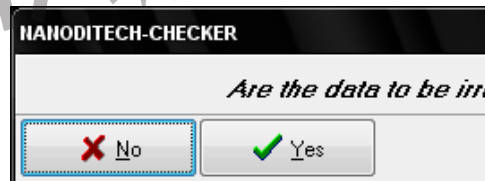


You may use the “search option” to find the donor when entering the first types of their name or date of a saved measurement in the input window.

## CONFIRMATION

- The selected donor data will be deleted permanently and cannot be recovered.
- Click **YES** to confirm

**Note:** The donor data and test results are no longer available.



- Click **No** to cancel

## 12 DELETING A READING

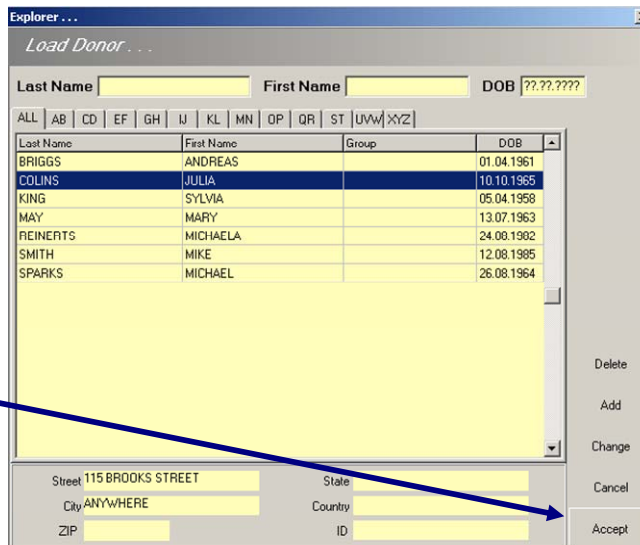
### LOAD A DONOR

In the program:

#### MENU BAR

#### LOAD DONOR

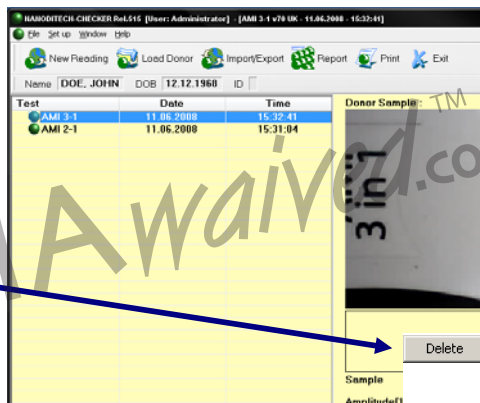
- Select the donor.
- Click **ACCEPT**



### DELETING READINGS

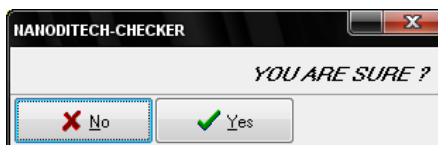
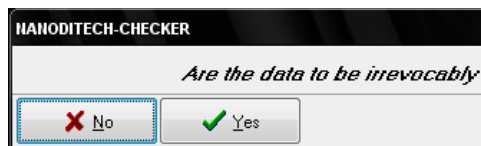
Load the reading to be deleted

- Right click on the result area.
- Click **DELETE**



### CONFIRMATION

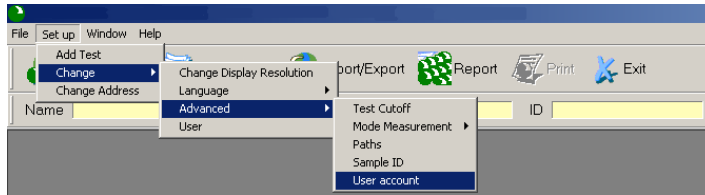
- The selected reading will be permanently deleted.
- Click **YES** to confirm the data is no longer available.
- Click **No** to cancel



## SET UP USER ACCOUNT

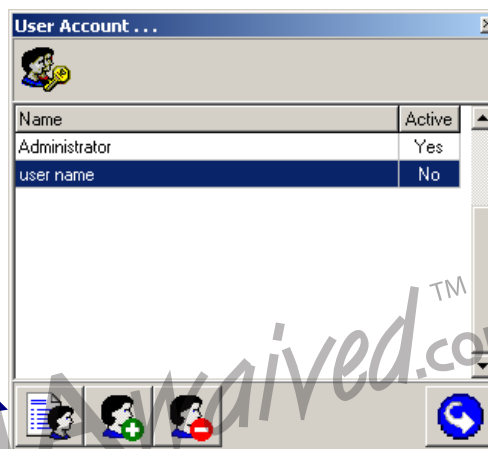
In the program:

- SET UP
- ▼
- CHANGE
- ▼
- ADVANCED
- ▼
- USER ACCOUNT



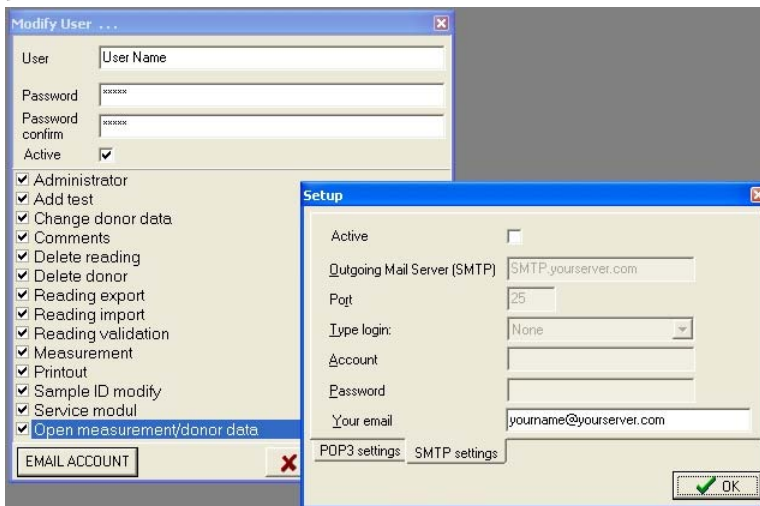
## USER ACCOUNT

- Select the user
- Modify the User Account



## MODIFY ACCOUNT

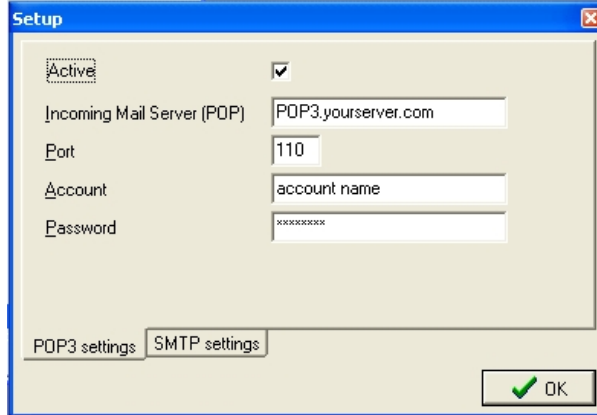
- Type in Password
- Type in Password confirm
- Click on **E-MAIL ACCOUNT** and the set up menu will come up
- In the set up menu select **POP3** settings followed by **SMTP** settings and add your e-mail information
- Click on **OK** to confirm
- Click on **MODIFY**



# 13 IMPORT / EXPORT OF DATA

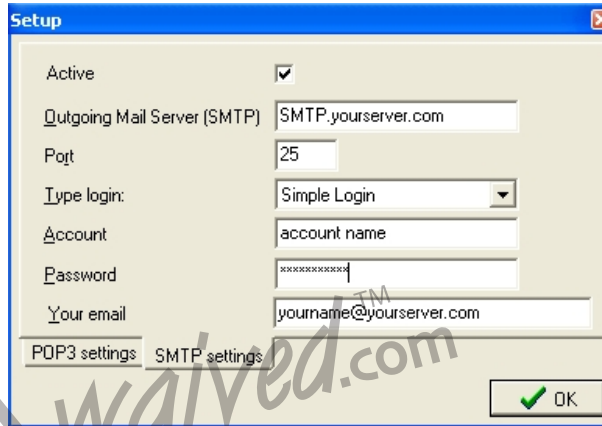
## SET UP: POP3

- Active – check box
- Incoming Mail Server – enter your incoming mail server
- Account – type in account name
- Password – type in password
- Click on **OK** to confirm



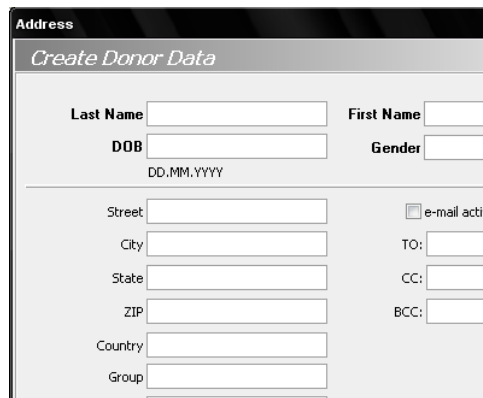
## SET UP: SMTP Settings

- Active – check box
- Outgoing Mail Server – enter your outgoing mail server
- Port – enter 25
- Type login – select Simple Login
- Account – type in account name
- Password – type in password
- Add your e-mail information
- Click on **OK** to confirm



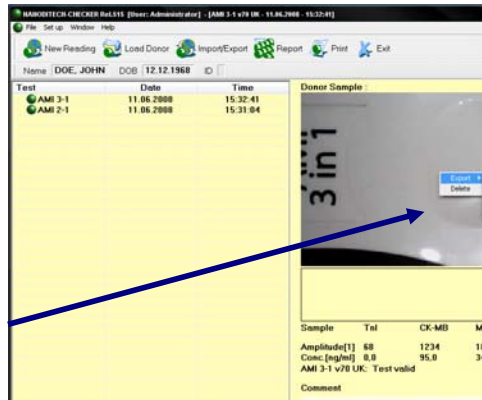
## DONOR

- Click on **LOAD DONOR**
- Click on **ADD/CHANGE DATA**
- Enter/ Add recipient e-mail address(es) in TO, CC and BCC



### SENDING RESULTS

- Right click mouse anywhere on the screen
- Click on **SEND TO....**
- Select **E-MAIL**
- Click on how the data is to be transmitted **ASCII / Excel / PDF/ Reader**

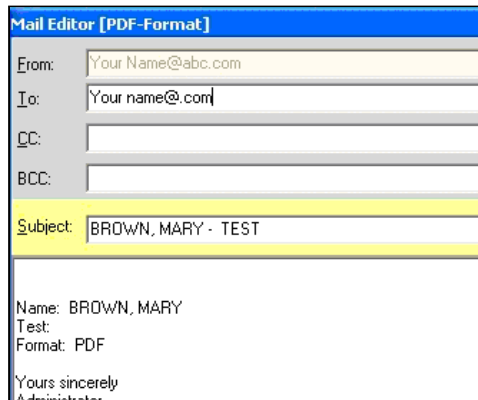


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## 13 IMPORT/EXPORT OF DATA

### MESSAGE EDITOR

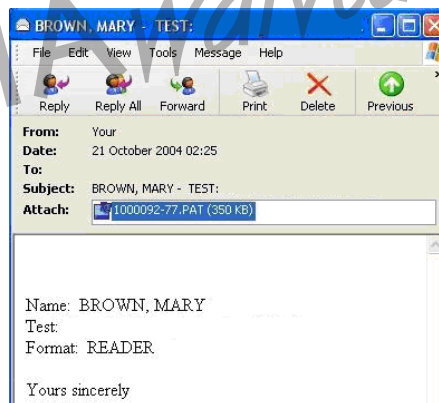
- Type in recipient(s)
- Type in your message
- Click on **SEND** to send the message
- Sends the message automatically from the screen



### RECEIVING E-MAIL

- Open the NANO-CHECKER 710 Software
- Open e-mail
- If the attachment is a PDF or Excel file, double click to open the file

If the attachment is a PAT file, click and drag the file into the NANO-CHECKER 710 program. The results will open.





## 13 IMPORT/EXPORT OF DATA

### DATA TRANSFER

- All donor data, including saved results, can be exported or imported to and from any destination on the local drive or onto a network.
- Results can be exchanged between different NANO-CHECKER 710 systems.

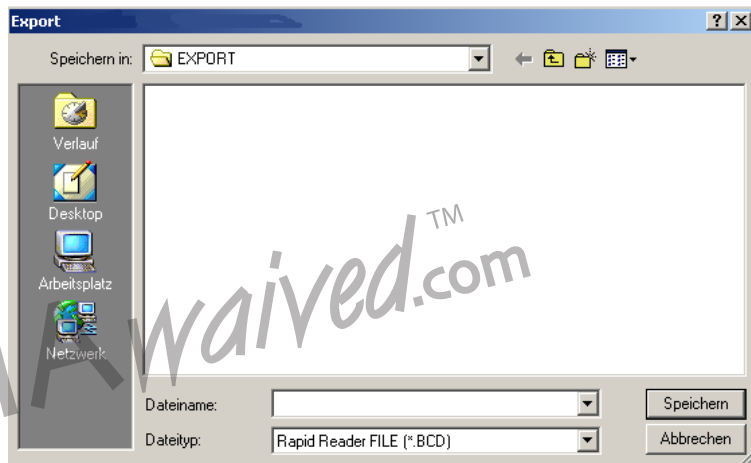
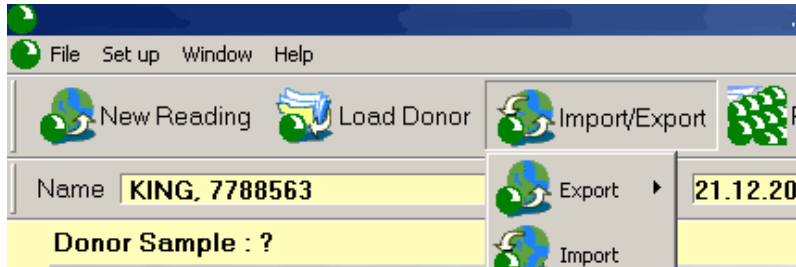
### DATA TRANSFER

*In the program:*

#### MENU BAR

IMPORT / EXPORT

- ▶ Select directory
- ▶ Enter file name
- ▶ Click on **SAVE** to save the file



# 13 IMPORT/EXPORT OF DATA

## RESULTS MANAGEMENT

Users can record donor information (donor name, DOB, test used, test results). All data is stored in Microsoft® Excel allowing review, analysis and charting of data.

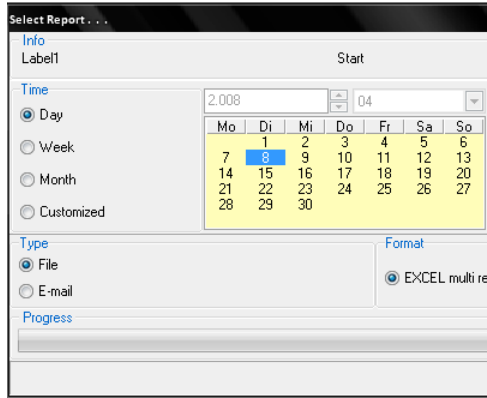
*In the program:*

### MENU BAR

#### REPORT

- Select report – today, week, month, customized
- Select report type – file, e-mail
- Click on **CONTINUE**

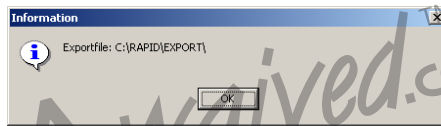
If the selected report type is File, this will be automatically saved in C:\Rapid\Export



## DATA BACKUP

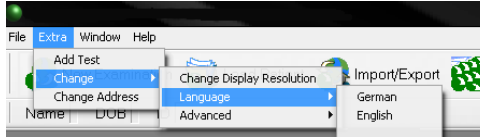
### IMPORTANT!

It is recommended that all data is backed up on a regular basis to an external storage system e.g. CD, CDRW, DVD, External Hard Drive, USB stick etc.



## SETTINGS

The SET UP option allows you to determine several settings (see page 13).



## ADDRESS

The address of the location performing the testing is entered. This address will appear at the top of all reports.

Street	7 Clarke Drive
City	Cranbury
State	NJ
ZIP	08512
Country	USA
Tel	609-409-0700
FAX	609-409-0722
Website	www.nanoditech.com
e-mail	info@nanoditech.com
Cost Center Number	

Optional information regarding QC/QA may be added here.

Reader ID refers to the serial number of the NANO-CHECKER 710.

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# 15 PRINTING AN ASSAY REPORT

## PREVIEW / PRINTOUT

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

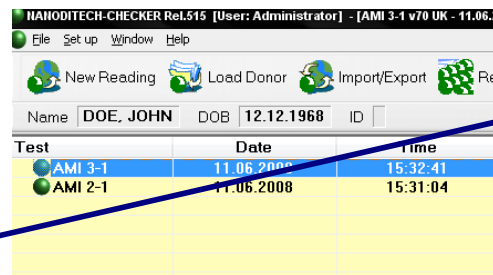
### PREVIEW

In the program:

- The result is shown in the window

#### USING THE ICON

**PRINT** ▶ **PREVIEW**



Test	Date	Time
AMI 3-1	11.06.2008	15:32:41
AMI 2-1	11.06.2008	15:31:04

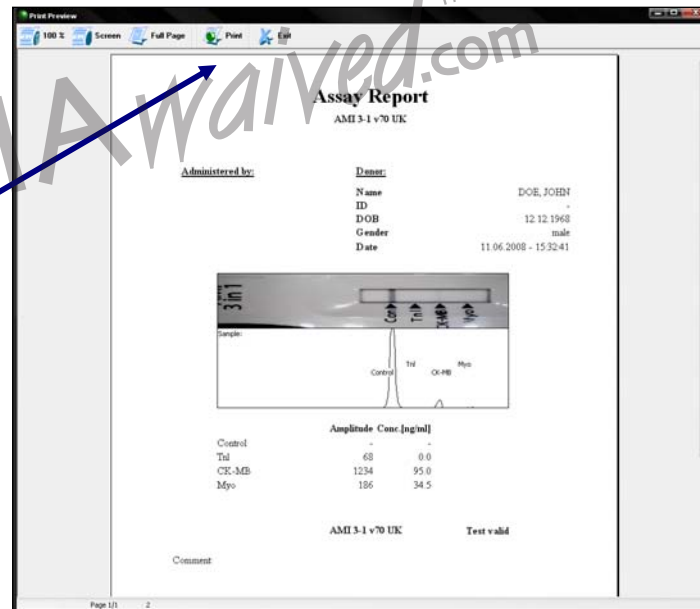
### Printout

In the program:

- The printout is shown in the window

#### USING THE ICON

**PRINT** ▶ **PRINTOUT**



## 16 TROUBLE SHOOTING

Symptom	Problem	Help
<b>Message: Target and source equal when importing</b>	An attempt to import a file that is already on the PC	<ul style="list-style-type: none"><li>▪ The file is already on the PC</li></ul>
<b>Image of test strip seems off centre or slope</b>	The test cassette was not inserted accurately	<ul style="list-style-type: none"><li>▪ Insert the test strip / cassette properly into the holder</li><li>▪ Retry the reading</li></ul>
<b>Image of test strip seems very light or overexposed</b>	The holder was not inserted entirely	<ul style="list-style-type: none"><li>▪ Insert holder completely</li><li>▪ Retry the reading</li></ul>
<b>Evaluation of the result is not possible.</b>	The wrong test cassette or the wrong test was selected	<ul style="list-style-type: none"><li>▪ Insert correct test from the test list</li><li>▪ Select the correct test to be read</li><li>▪ Retry the reading</li></ul>
<b>There is no visible light inside the NANO-CHECKER 710 device</b>	Lack of power	<ul style="list-style-type: none"><li>▪ Check the connection between the NANO-CHECKER 710 and power outlet.</li></ul>

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- |                                     |  |   |
|-------------------------------------|--|---|
| <b>Cleaning of NANO-CHECKER 710</b> | <ul style="list-style-type: none"><li>• Wipe the case by using ordinary laboratory detergents (disinfectant) or alcohol.</li></ul>               | <ul style="list-style-type: none"><li>• Do not use acid agents or solvents.</li><li>• Use scratch-free wipes.</li></ul> |
| <b>Cleaning of test holder</b>      | <ul style="list-style-type: none"><li>• Wipe the entire test holder by using ordinary laboratory detergents (disinfectant) or alcohol.</li></ul> | <ul style="list-style-type: none"><li>• Do not use acid agents or solvents.</li><li>• Use scratch-free wipes.</li></ul> |

Nano-Checker 710 was calibrated by manufacture before shipping to customer. However all customer should check the calibration status using calibration cards provided with Reader when install the reader and periodically (recommend at least once per month). The measurement protocol is follows

- 1, Check the serial number of the calibration card (Printed on the pouch and backside of device) and Reader (Printed on the back side of monitor). Numbers should be matched with each other.
- 2, Open the calibration card pouch and take out the card from the pouch, place the card device into the cassette holder of Nano-Checker 710.
3. Measure 5 times for each card following the user manual and record the reading value on the calibration recording sheet.
4. Analysis the reading result following as the recording book, the calculated average value should be in the range of acceptable deviation described on the calibration card and provided QC record.
5. If the average value is out of range of acceptable deviation, restart the reader and repeat step 2 and 4. Still the value is not acceptable, contact your local customer service agent or the manufacturer.

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For more information please contact CLIAwaived<sup>TM</sup> Inc. at:

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