QCR 6000R

QuikScreen Drug Cup Reader

User Manual

and

Installation Guide

Version 3.1.0

Published at July 13, 2007

Introduction

The QCR 6000R QuikScreen Drug Cup reader can distinguish the differences of colors from various biochemical reactions and analyze the reactants to provide quantitative clinical diagnosis. The main diagnostic analysis is for drug test. To summarize, this reader provides a detection platform for rapid test applications.

Software User Manual

1. EXECUTE QCR 6000R QuikScreen Drug Cup Reader Application

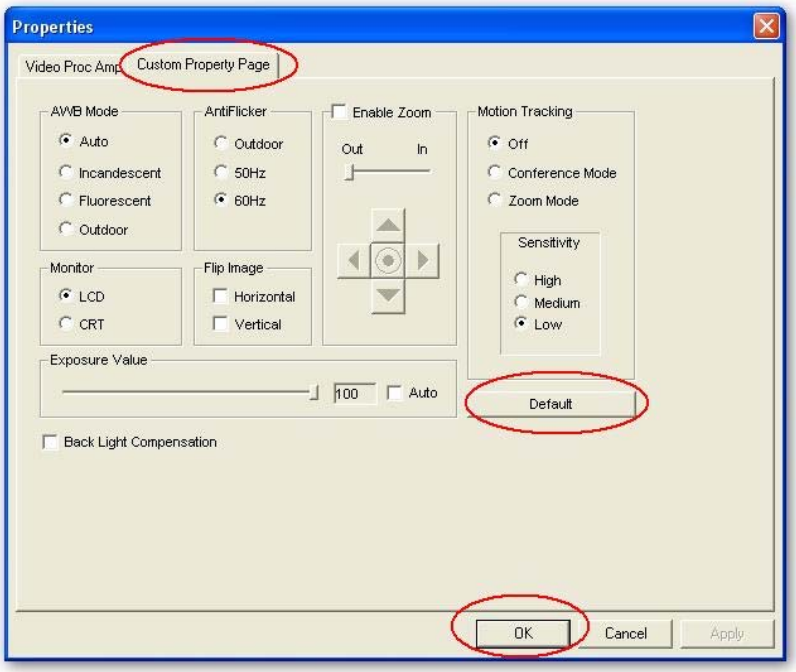
(A) Connect the USB cable from the reader to one of the computer's USB port.

(B) Plug in the power cord to the back of the reader.

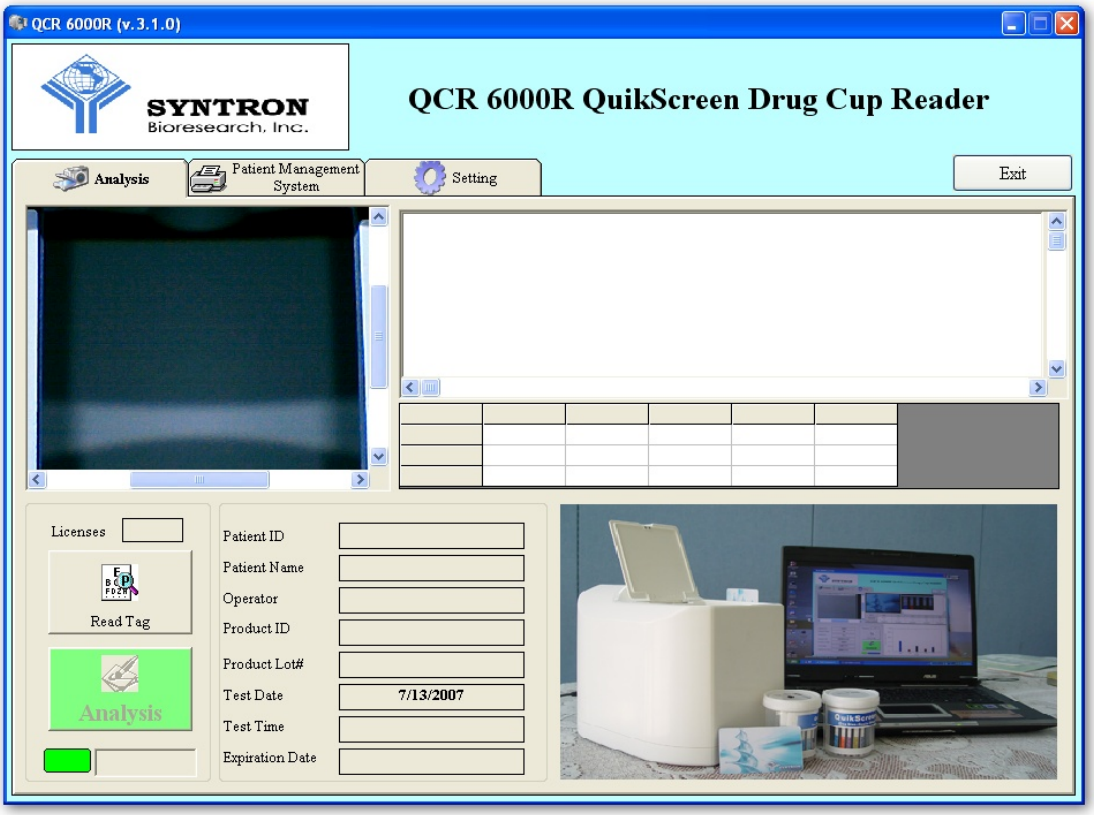
(C) EXECUTE the analysis software [QCR 6000R v.3.1.0.exe].

(Some computers require more time to recognize the USB devices, if the software asks you to plug in the Reader while you have really executed Steps (A) & (B), you may have to wait a little bit longer and then execute the software again)

(D) Please press Default on "Custom Property Page" and check the Auto option is not ticked, then press OK to continue.

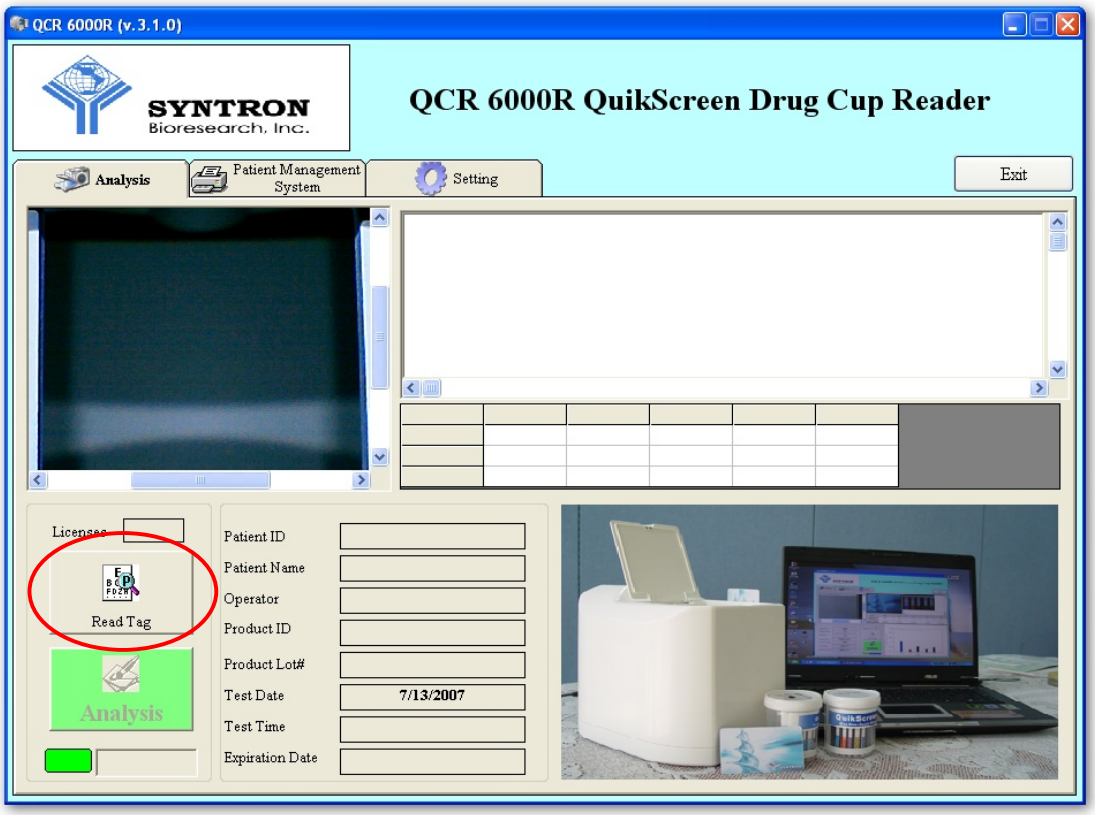


(E) You can now see the main frame of the software as shown below:



2. BEFORE ANALYSIS

Before analyze the cup, there are several parameters needed to be loaded from the RFID calibration Tag, which comes with the tests.



(A) INSERT the RFID Tag into the top RFID slot of the QCR 6000R Reader.

(B) Press

, the Reader will automatically loading:

- ***Product ID***: The kind of the test strip.
- ***Product Lot#***: The manufacturer lot number.
- ***Expiration Date***: The expiration date of the strip.

- ***Test Date***: The test date is generated automatically according to the clock of the computer.

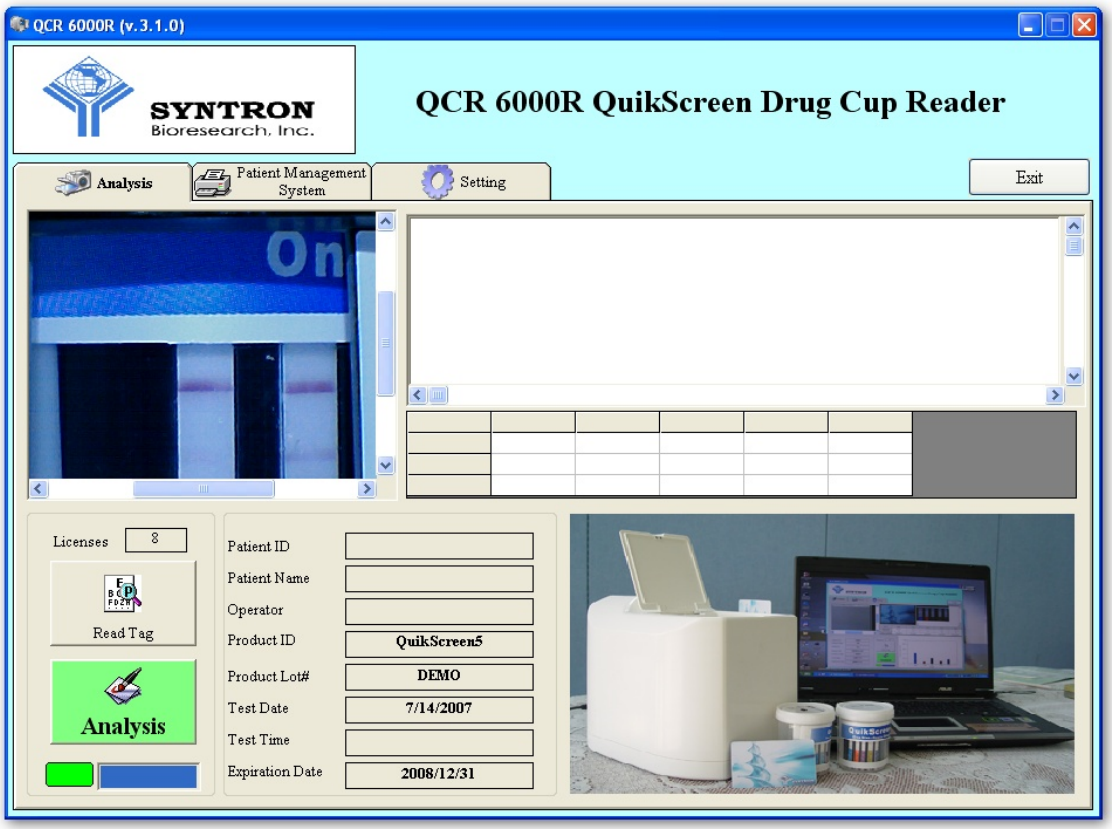
- ***Test Time***: The test time is generated automatically according to the clock of the computer (it will be updated automatically when the

button is pressed.)

- ***Licenses***: The tests remained to be done according to your purchasing. To make sure the record is not been changed, each test you bought is allowed to be read once only.

(C) The

button will lit on and the Reader is ready for use.



(D) Please be noted that RFID tag should only be used for the tests included inside the same box. If you use the test from different box, please change the RFID tag by simply remove it from the back slot. Using wrong RFID tag may result in wrong test result.

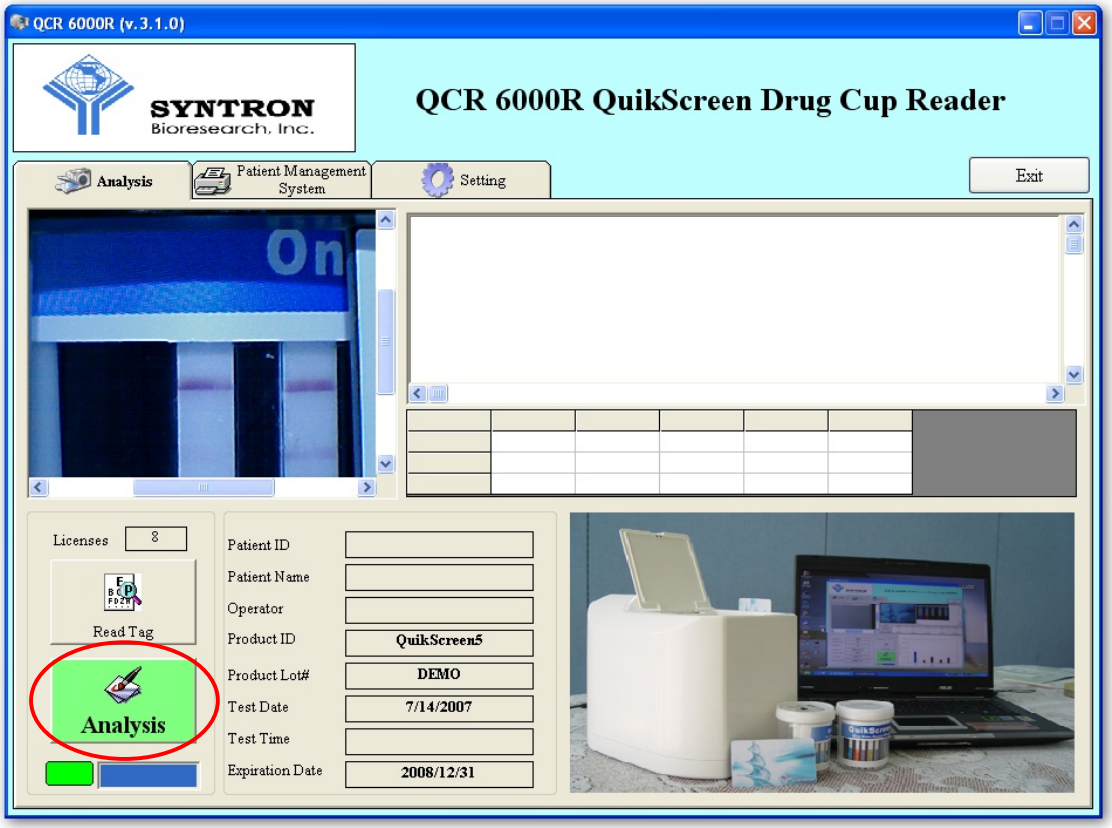
(E) You don't have to remove the RFID tag or press

again if you keep using the tests from the same box.

(F) It is strongly suggested that you calibrate the reader first before you do any test. To calibrate the reader, please refer to the SETTING section (5(c))

3. ANALYSIS (Analysis Page)

(A) Open the cover and put a cup into the hole of the QCR 6000R Reader, you may see the live image appeared on the upper left preview window.

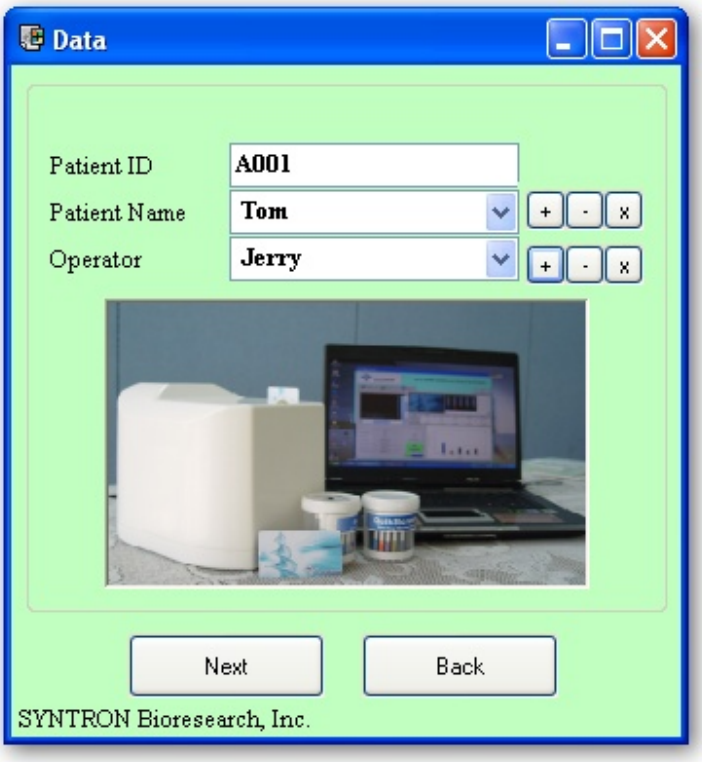


(B) Press

.

(C) A new window appears for you to type in manually:

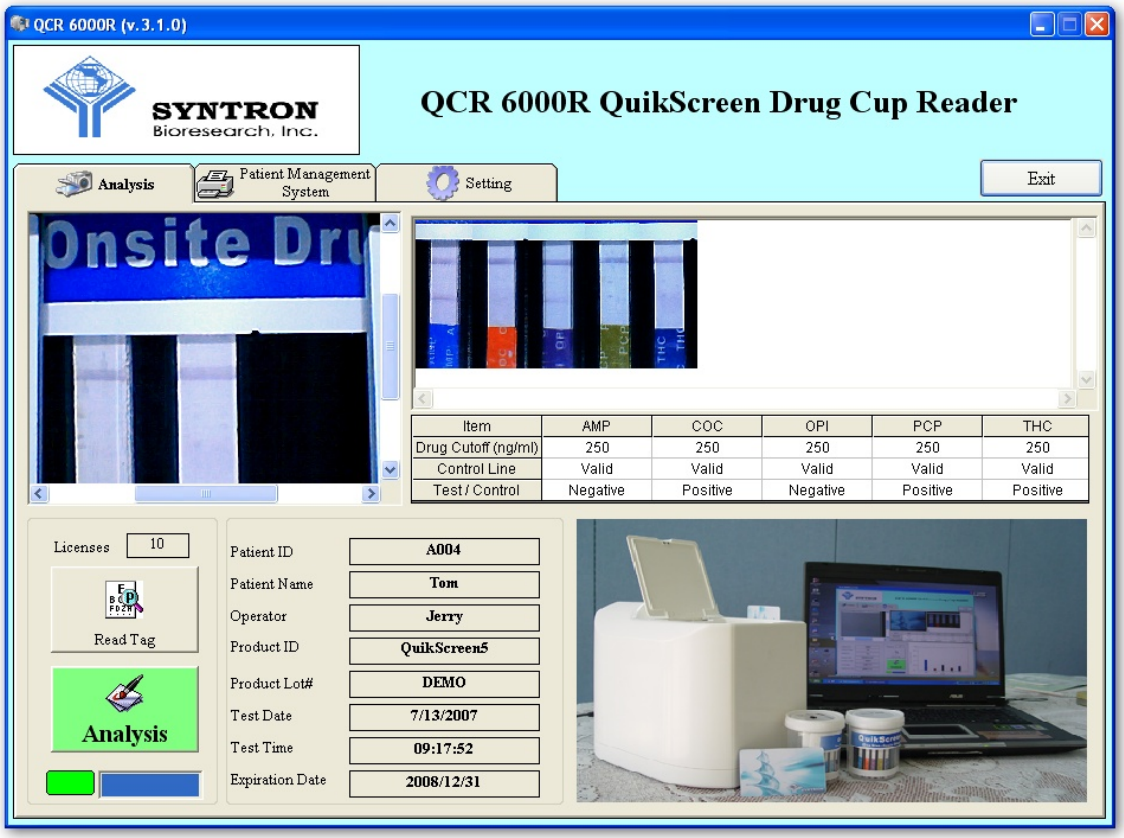
- ***Patient ID***: The ID number of the patient or sample source.
- ***Patient Name***: The name of the patient or sample source.
- ***Operator***: The name of the operator who is executing this test.



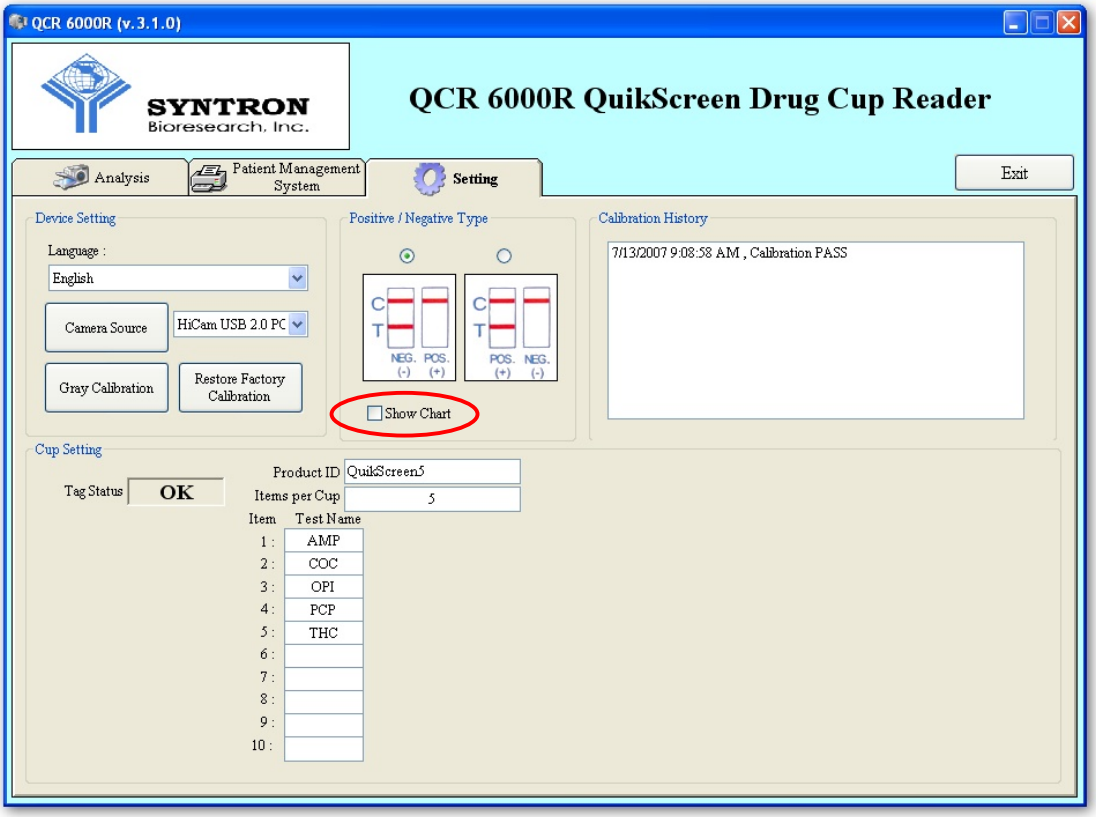
(D) You can type in the names and ID in the input boxes or you can select from previous data by clicking on the pull-down box. If you think you will use the inputted name again later, you may click on the + button to add the name into the database. You can also remove the name from the database by clicking on the - button. You can also remove all data from the database by clicking the x button.

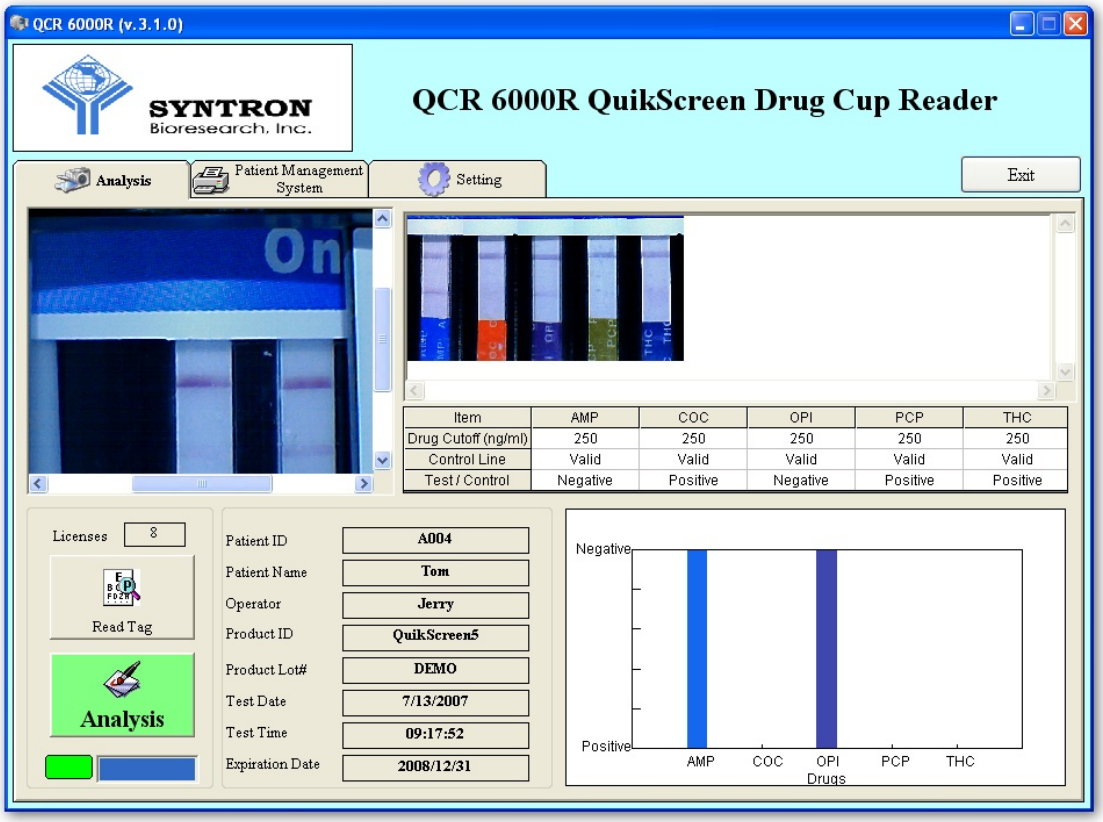
(E) If you are sure about the data you typed in, press Next to continue, the number to licenses will then be deducted one. If you are not sure about the data you typed in, please Back to return to previous step.

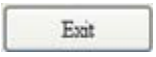
(F) When the Next button is pressed, the software will analyze automatically using the parameters provided by RFID tag, including the kinds of tests, numbers of tests, cut off values, etc. The analyzed result is shown in lower right corner while the captured image is shown in the lower center area. “Negative” or “Positive” results will be shown in the result table while the control lines are shown as “Valid” for valid testing or “Invalid” for invalid testing.



(G) If you want to show the results in bar chart format, go to the “Setting” page and check on the box, the “Positive” or “Negative” results will be shown in bar chart format as shown in next page. If you don’t want to see the results in bar chart format, just uncheck the “Show Chart” box.

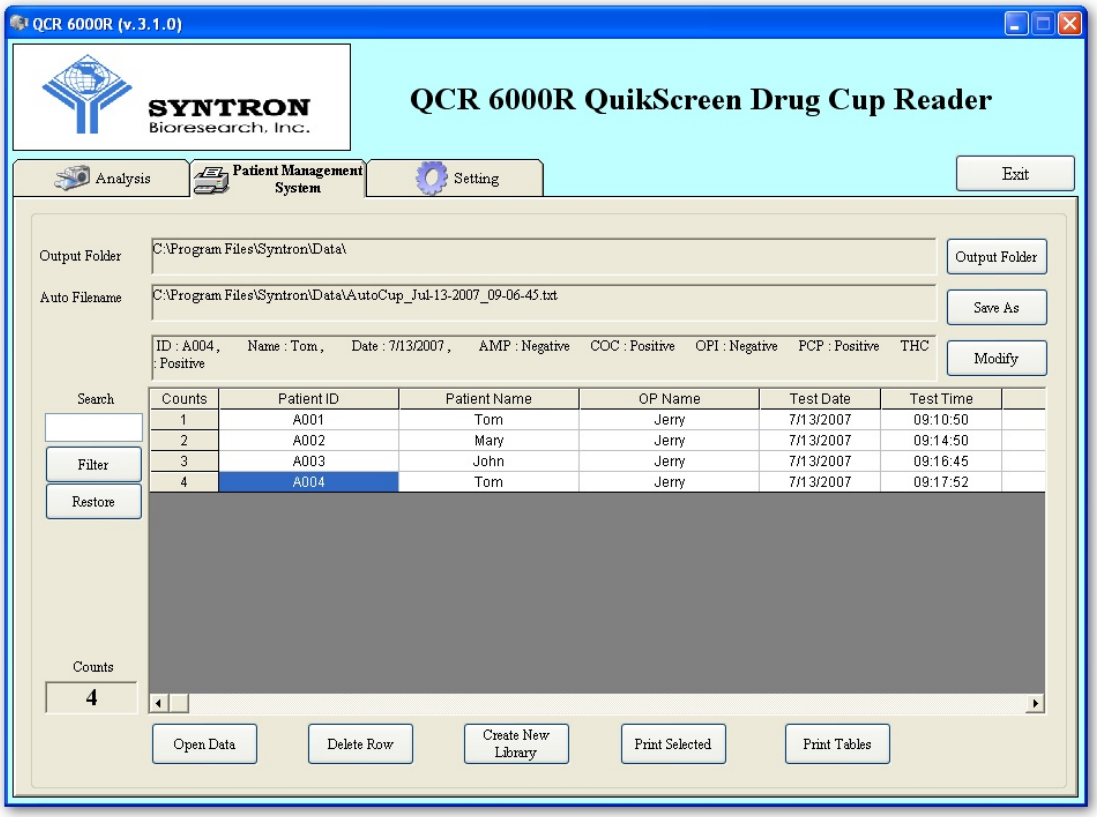




(H) Press  to exit the software

4. REPORTING (History Page)

(A) The test result can be seen on “Patient Management System” page. The new tested result is added to the row and given a new “count” to the batch, this batch is then saved automatically under the same filename (please see SAVING FILES section for more information).



(B) ***Print Selected***:

If there is only one result in a batch to be printed, you may use the

button.

SYNTRON
Bioresearch, Inc.

Test Report

(1) Results

Product ID	QuikScreen5	Product Lot#	DEMO	Exp Date	2008/12/31
Patient ID	A004			Test Date	7/13/2007
Patient Name	Tom			Operator	Jerry
Item	AMP	COC	OPI	PCP	THC
Test / Control	Negative	Positive	Negative	Positive	Positive

(2) Test Image

Patient Signature : _____ Operator Signature : _____

7/13/2007 9:08:58 AM , Calibration PASS 7/13/2007 09:20:46

(C) ***Print Tables***:

When [Print Tables] button is clicked, all tested in this batch will be printed. However, only tables are outputted.

SYNTRON Bioresearch, Inc.

Test Report

Product ID	QuikScreen5	Product Lot#	DEMO	Exp Date	2008/12/31
Patient ID	A001			Test Date	7/13/2007
Patient Name	Tom			Operator	Jerry
Item	AMP	COC	OPI	PCP	THC
Test / Control	Negative	Negative	Negative	Negative	Negative

7/13/2007 9:08:58 AM , Calibration PASS

Product ID	QuikScreen5	Product Lot#	DEMO	Exp Date	2008/12/31
Patient ID	A002			Test Date	7/13/2007
Patient Name	Mary			Operator	Jerry
Item	AMP	COC	OPI	PCP	THC
Test / Control	Negative	Negative	Negative	Negative	Negative

7/13/2007 9:08:58 AM , Calibration PASS

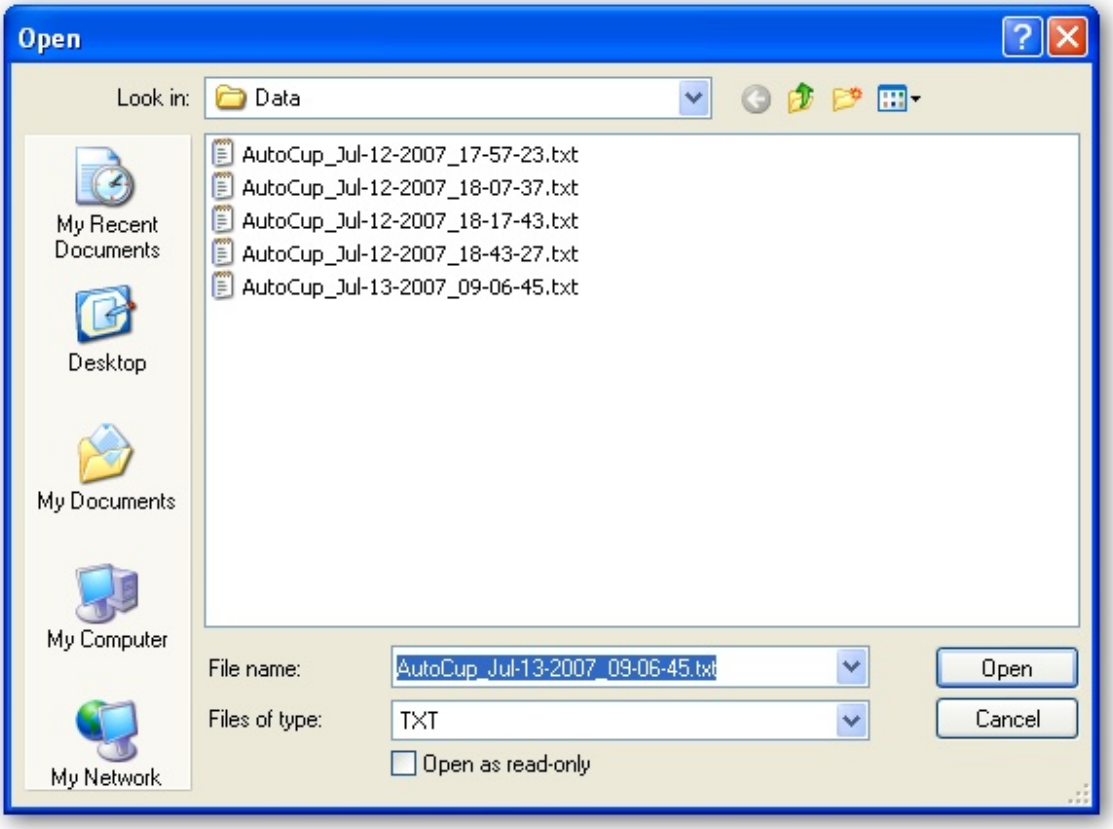
Product ID	QuikScreen5	Product Lot#	DEMO	Exp Date	2008/12/31
Patient ID	A003			Test Date	7/13/2007
Patient Name	John			Operator	Jerry
Item	AMP	COC	OPI	PCP	THC
Test / Control	Negative	Positive	Negative	Positive	Positive

7/13/2007 9:08:58 AM , Calibration PASS

7/13/2007 09:21:38

(D) ***Open Data***:

You may open and check previous batch results by simply clicking the Open Data button and choose any previous saved files:



(E) ***Delete Row***:

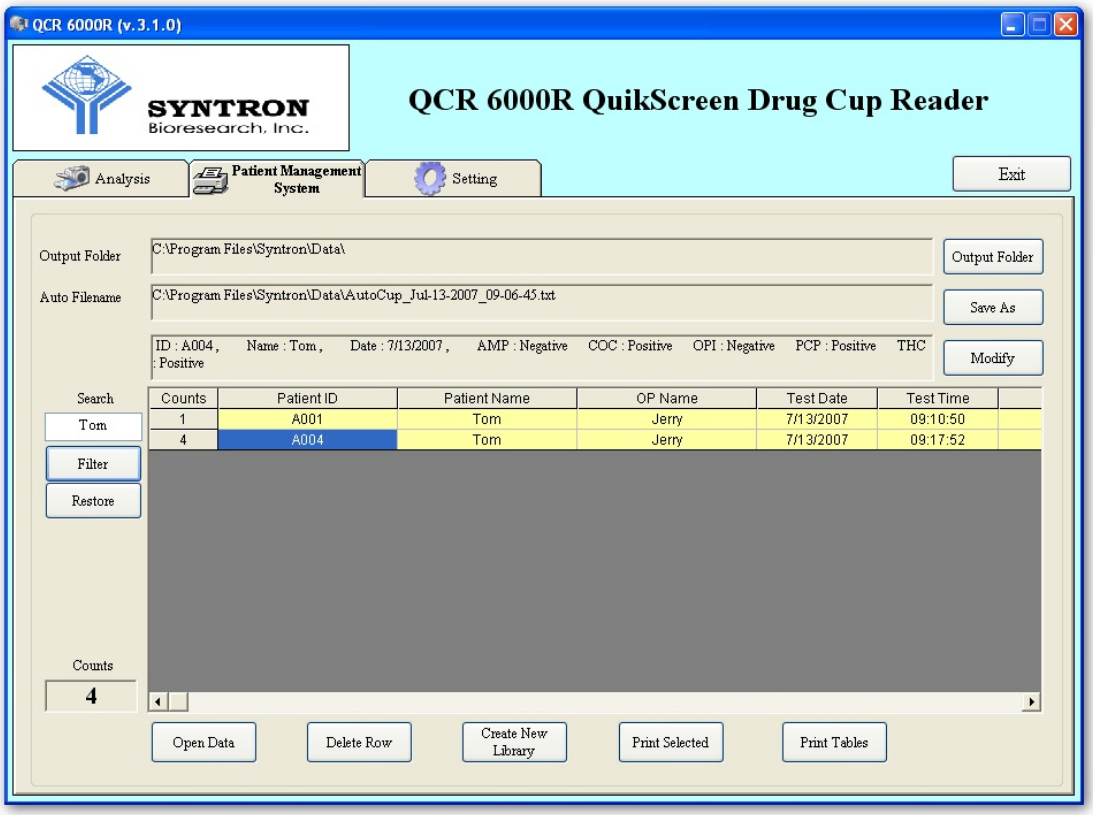
You can delete a selected single experimental data by clicking Delete Row button. The highlighted data will be deleted from the batch.

(F) ***Create New Library***:

You can delete all dada in the batch and create a new batch (as well as a new file) by clicking Create New Library button.

(G) ***Searching Specific Characters in File System***:

You can choose to display some specific data only in the “Patient Management System” page. To do so, just type in the specific characters you want to search in the “Search Box” and click on the Filter button. The search system will look into the data base (in the Filename shown) and display them as shown below. To restore all results (in the Filename shown), just clicking Restore button.



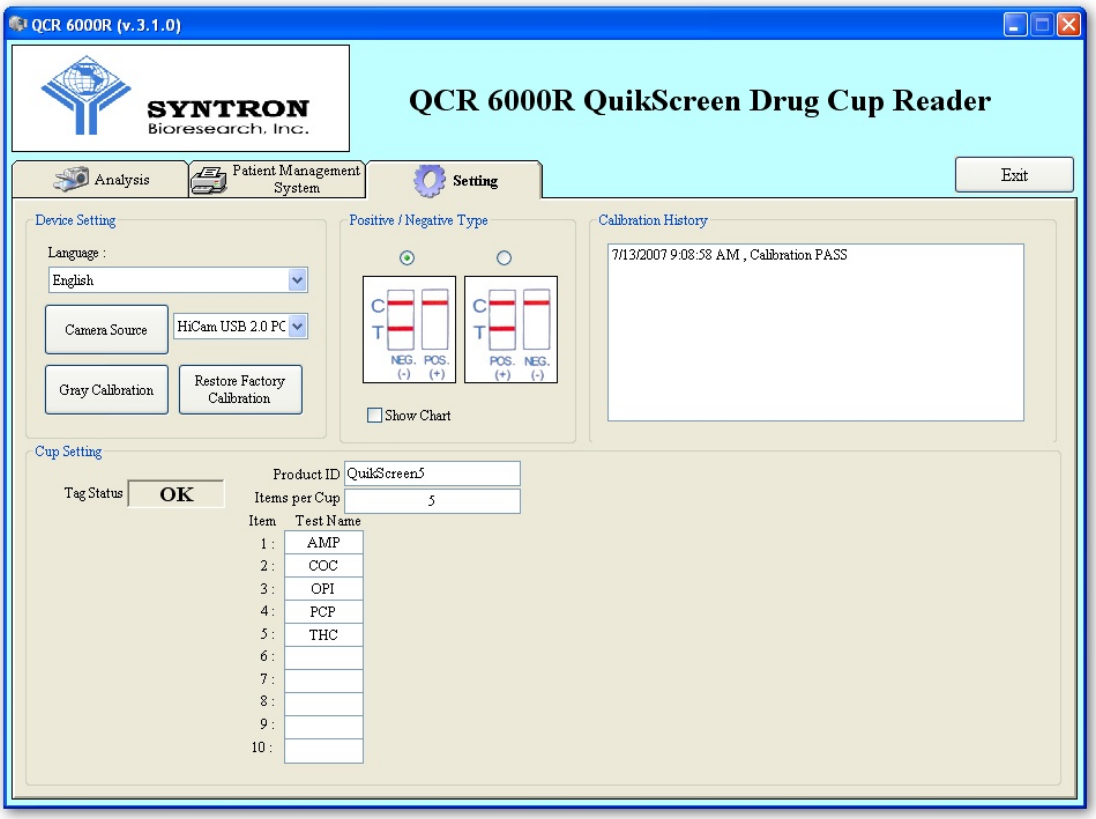
Please be noted that the searching not only applies to the “Patient Name,” it can also applies to the “Operator Name,” “Test Date,” and all characters saved in the database.

(H) Press

to exit the software

5. CONFIGURING (Setting Page)

The software is pre-adjusted for best condition with the hardware when shipped, it is not recommended to make any adjustment.

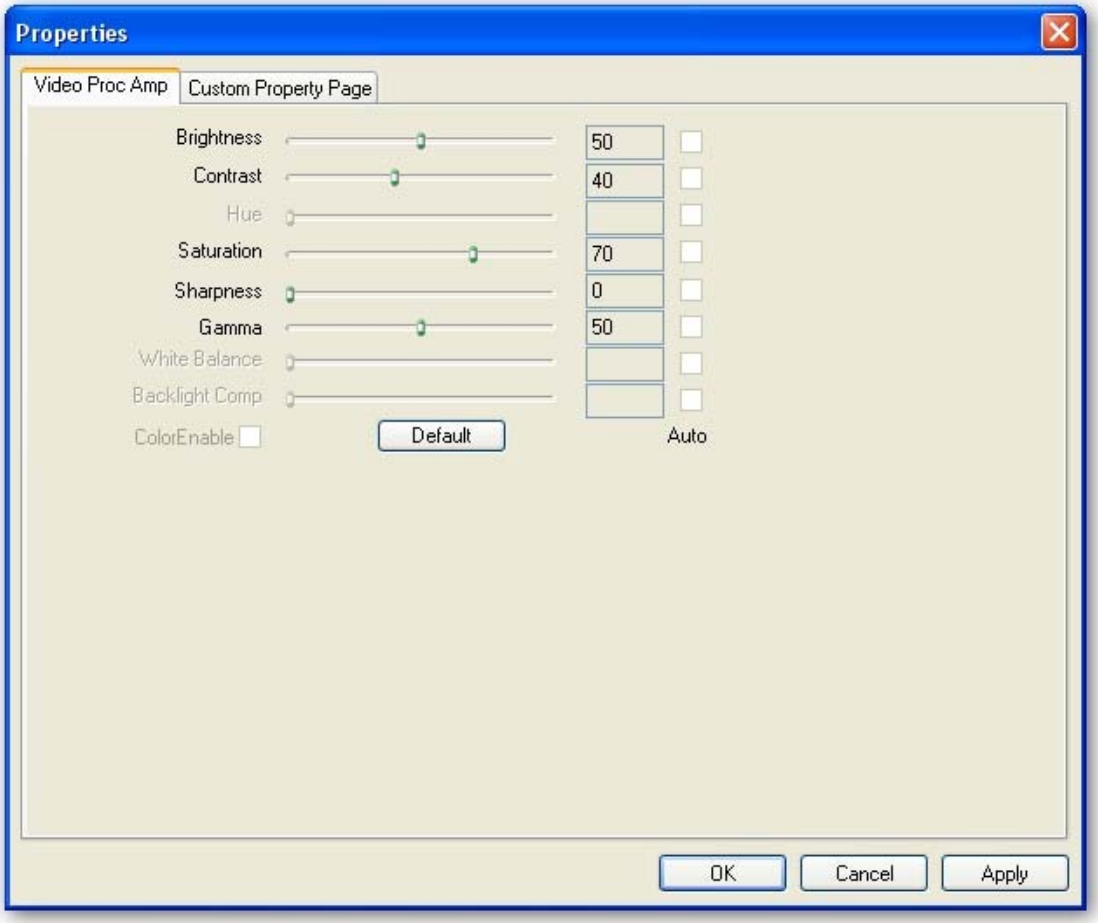


(A) ***Positive/Negative Type*** :

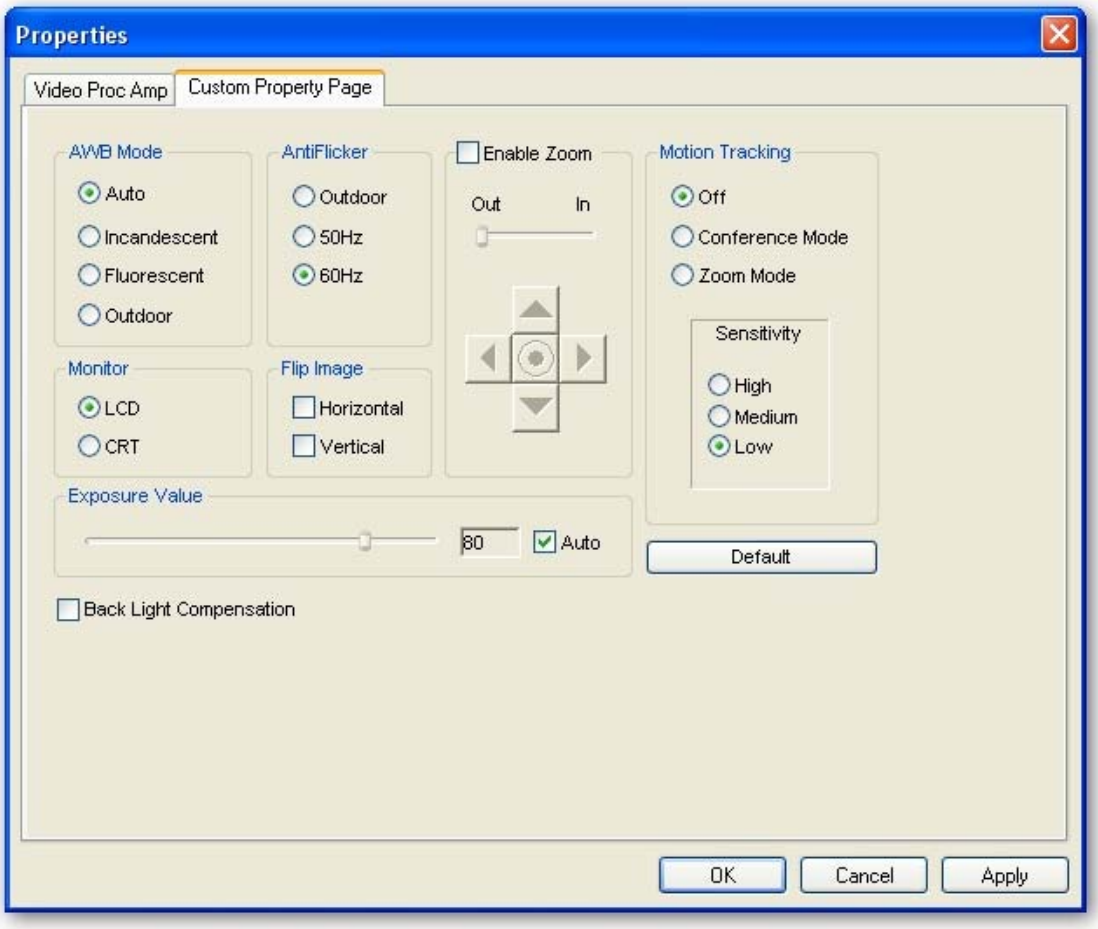
It is according to the kind of the test. In some kind of tests, a line shown on the T line position is treated as positive, and vice versa. It is preset inside the RFID tag.

(B) ***Camera Source*** :

Click the Camera Source button to set up the camera, the default camera is [i-Spy PC Cam] or [HiCam USB 2.0 PCam S], it is also suggested to use the original setting. It is strongly suggested not to change any camera properties, if you need to change any coefficient, please consult with your supplier.



In some countries using 50Hz as the power supply frequency, it may be necessary to adjust the AntiFlicker into 50Hz (default is 60Hz) if you see the flickering in the display.

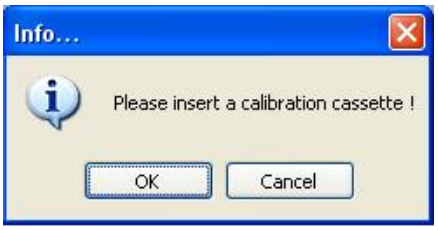


(C) ***Gray Calibration*** :

It is suggested that you calibrate the reader immediately when you execute this software to get the best result out of the product. You may also calibrate the reader again during the operation when you think it is necessary. To calibrate the reader:

(i) Press the

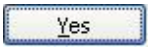
button.

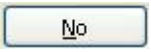


(ii) Insert the calibration cassette (included with the reader package) into the front slot of the reader. Press

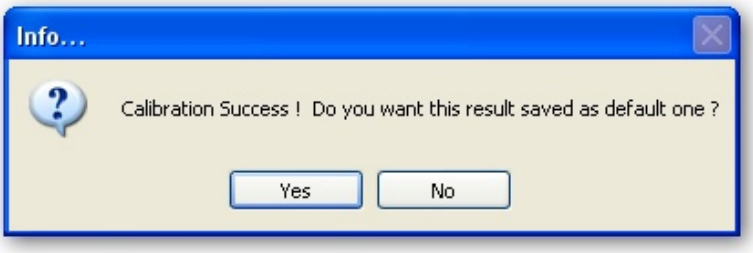
to continue, or press

to abort the calibration.

(iii) Once calibrated, the new calibration curve will be used before the software is turned off. If you want to save this new calibration curve and overwrite the old calibration curve, press the 

button. If you just want to use this new calibration curve, press 

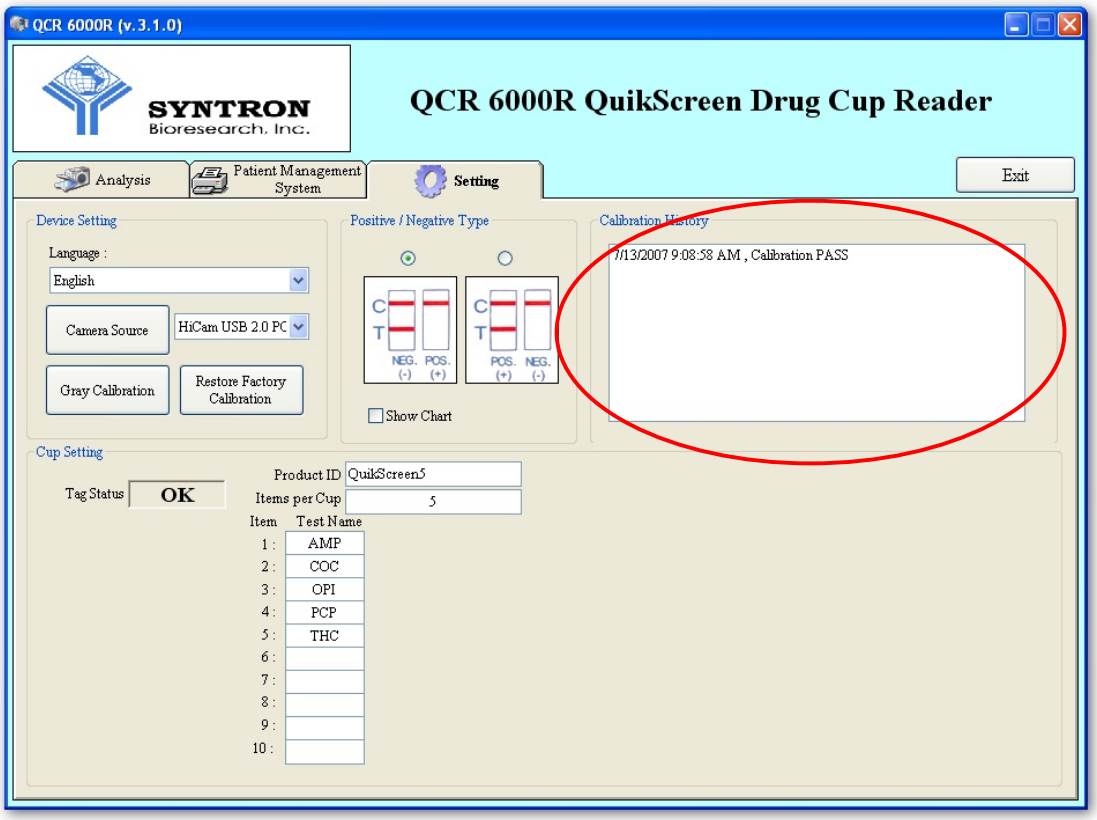
button and the old calibration curve will still be used next time when you turn on the software (noted that the new curve is used before you turn off the software).



(iv) Please note that once you click [Yes] button, the calibration history will be recorded and the recent calibration date will be shown in your future report. (same date shown in the “Last Calibration” box)

(D) ***Calibration History*** :

Whenever the Reader is calibrated, the system will check the calibration cassette with the built in camera. If the gray scale values meet the calibration requirement, the system passes the test. Otherwise, if the calibration fails, it may due to the camera of stain on your calibration cassette. Please contact your vender for further assistance. All tested results are automatically recorded in the Calibration History window as sown in next page.



(E) ***Restore Factory Calibration*** :

If you calibrate the reader by accident or you are not sure about the calibration result, you can always restore the original factory setting by pressing the Restore Factory Calibration button. Press Yes button if you are sure.

(F) ***Tag Status*** :

When RFID tag is correctly read, the “OK” sign will be shown, otherwise, the “NG” sign will be shown for error reading RFID tag.

(G) ***The Cassette Variables***:

Some cassette variables are seen in this page, these variables contain the product information recorded in the RFID tag to correctly analyze the strip. Check the information to confirm whether this is the right test you are going to analyze.

■***Product ID***: The product ID for the test strip.

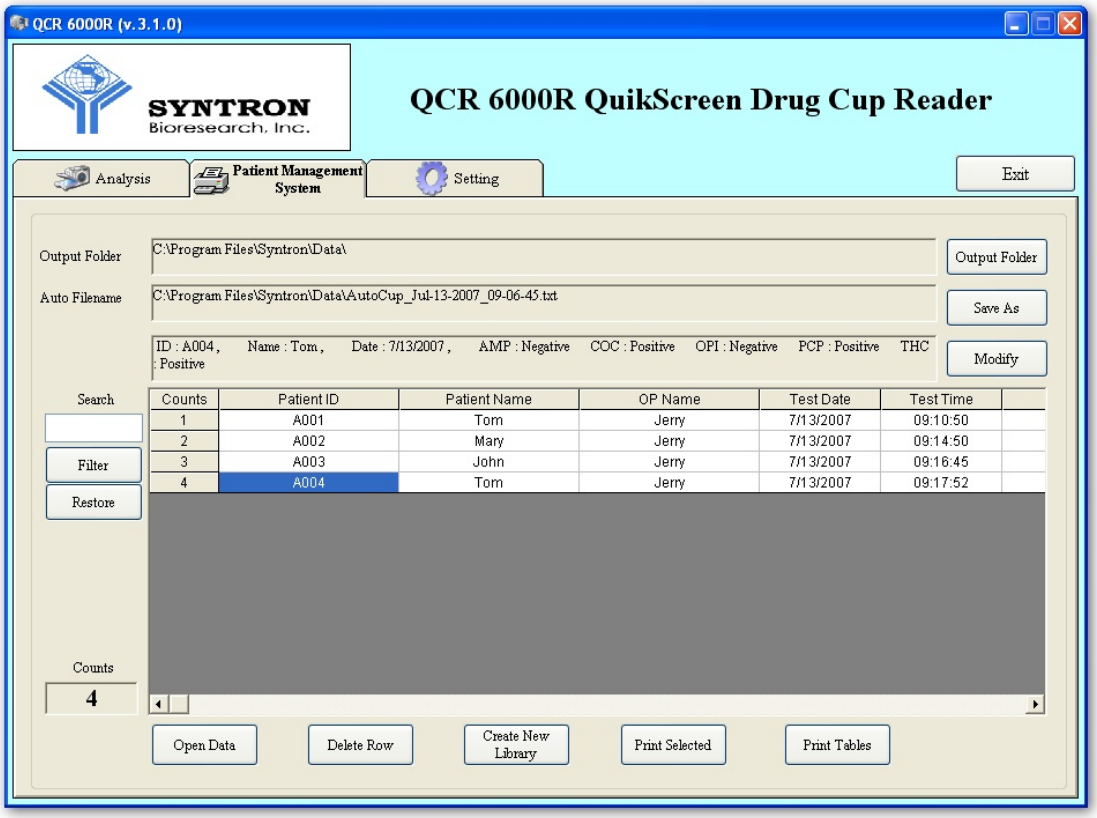
■***Items per Cassette***: Numbers of tests per cassette.

■***Test Name***: Name of the test.

(H) Press Exit to exit the software

6. SAVING FILES

The analysis results are automatically saved once tests were done, however, you may choose to change the filename.



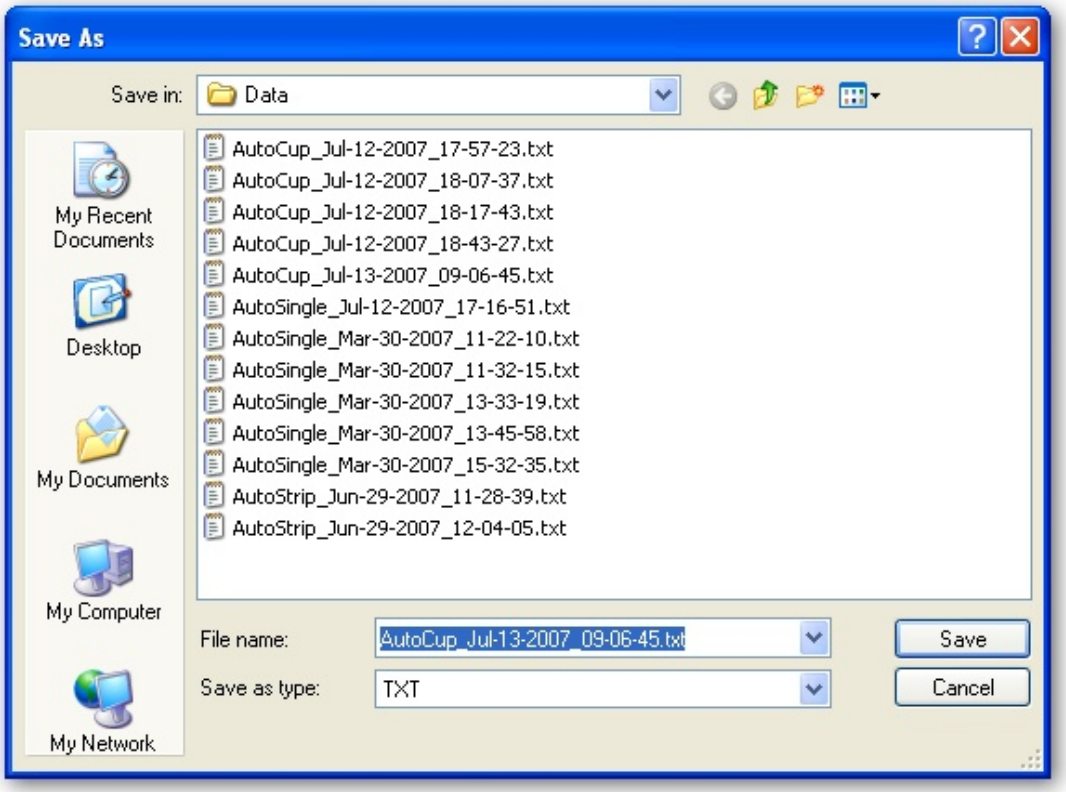
(A) ***The File Path***:

The default output folder is set to "C:\Program Files\Syntron\Data." User can click on the Output Folder button to select a new output folder.

(B) ***The File Name***:

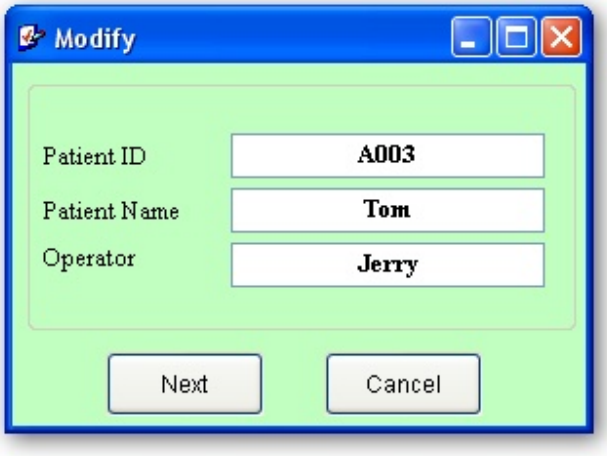
The system will automatically generate a saved file once the first test in a batch is done. The file name is “AutoStrip_Month-Day-Year_hh-mm-ss” to represent the time of first analysis done in this batch. The format for the file is with the suffix “.txt”. All tests in the same batch are saved under the same filename. If a new file batch is necessary, you can click on the “Reset” button or simply quit the software and re-execute the software again. A picture for each test will also be saved automatically according to the report file.

If you choose to save the file with different filename, click Save As button to change the filename:



(C) ***Modify the patient information***:

It is not suggested that you change the patient information. However, if it is to be changed, click on the Modify button to change the patient ID and/or patient name. Click Next to continue or please Cancel to abort the modification.



Software Installation Guide

1. Insert the INSTALLATION CD into the CD reader, the SETUP program will be automatically executed.

2. If the SETUP program is not automatically executed, please locate the Setup.exe in the root directory in the CD and execute it.

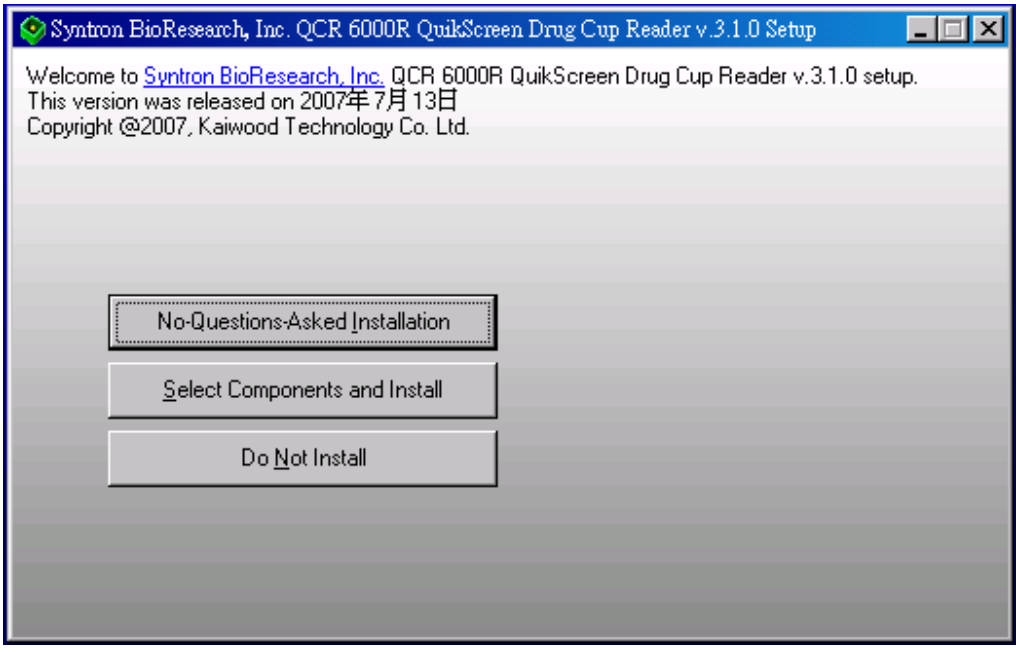
3. There are four software to be installed. First is the Camera and the second is QCR 6000R, the third one the Acrobat Reader and the last one is PDF Creator. The Setup program will automatically install the Camera and DCR 6000R software (except Acrobat Reader is for reading the PDF files and PDF Creator is just for printing out reports on the computer instead of hard copies, you can install the Acrobat Reader by locating the Acrobat Reader Folder and PDF Creator by locating the PDFCreator Folder in the program folder or in the CD).

4. Before install the Camera driver, DO NOT connect the reader to the computer (through the USB port), it connected, your computer may prompt you to search for the driver and cause the confusion.

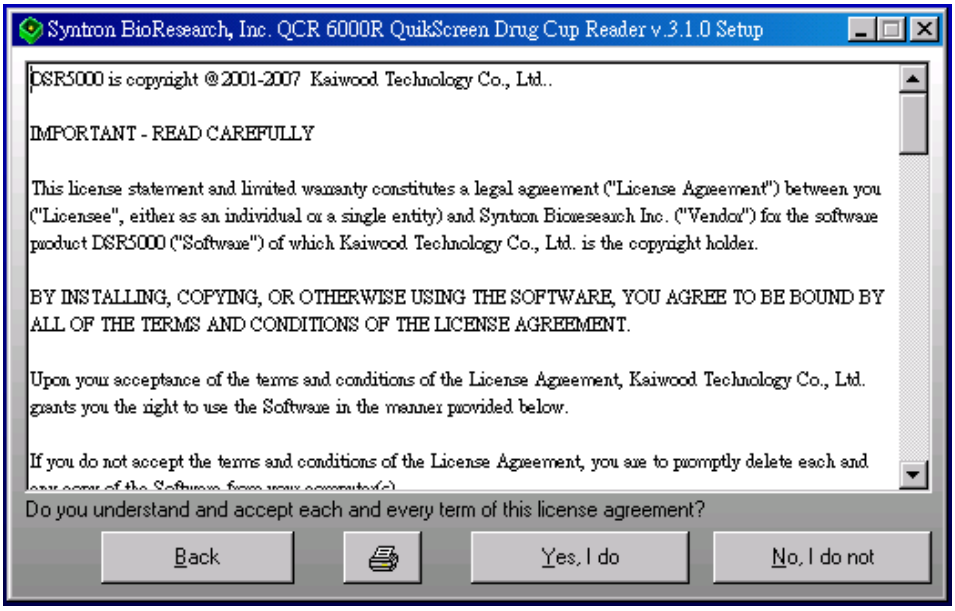
5. ***Installation the QCR 6000R***

(A) After inserting the CD, the Setup.exe program will automatically execute. You can find the Setup.exe in the root directory in the CD.

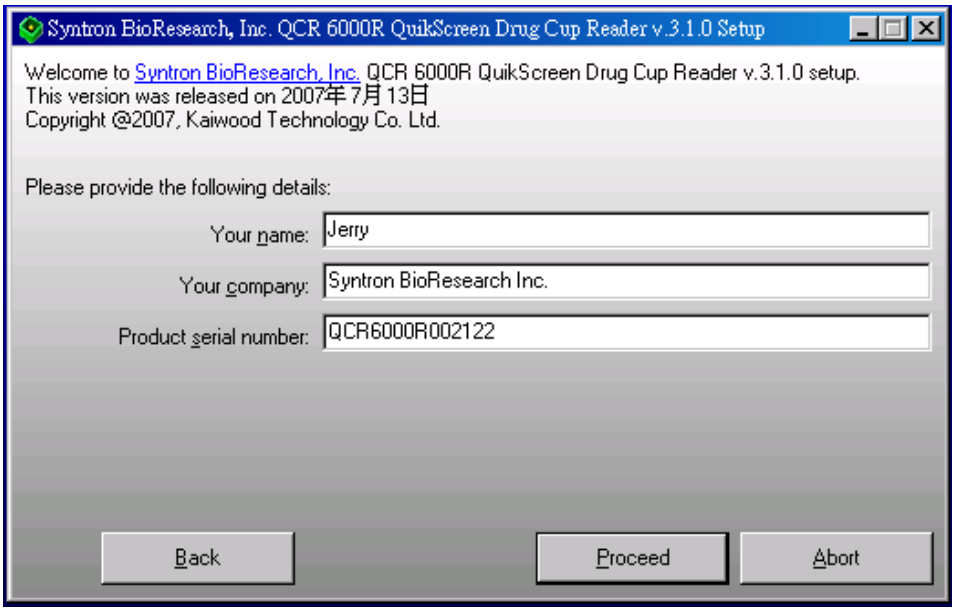
(B) You will see the following window, just simply click the No-Questions-Asked Installation button to continue. You may also choose to select the components to install (e.g. camera only) by clicking Select Components and Install to change the default installation folder, or quit by clicking the Do Not Install button.



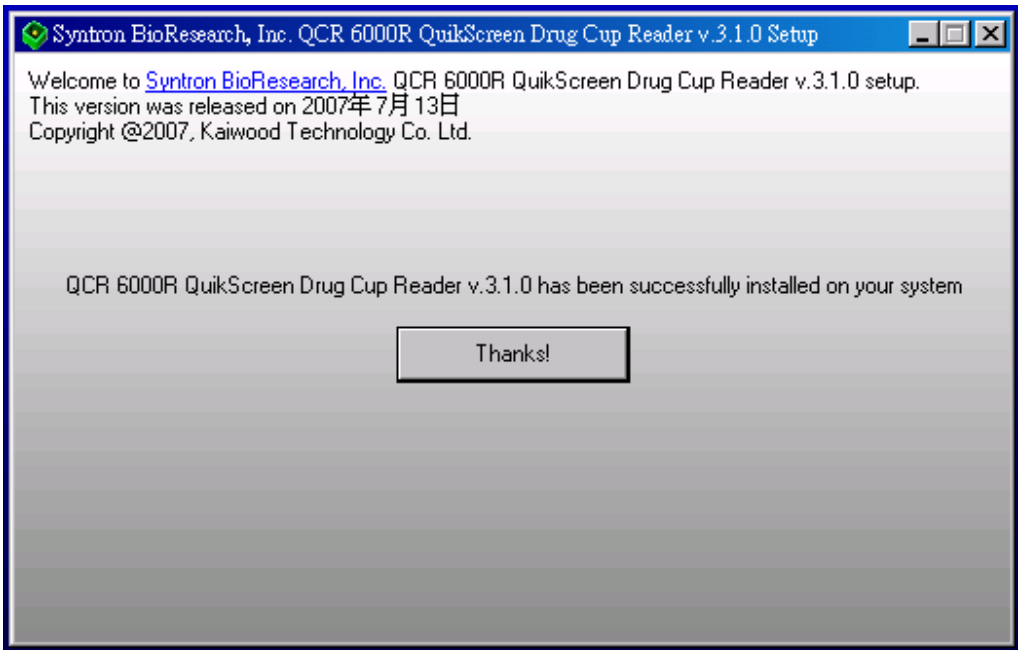
(C) When the No-Questions-Asked Installation is clicked, please accept the license agreement by clicking Yes, I do

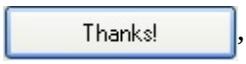


(D) The installation requires you to input your name, company, and the serial number which you can find at the back of your QCR 6000R Reader.



(E) After installing the main software, the window prompt:

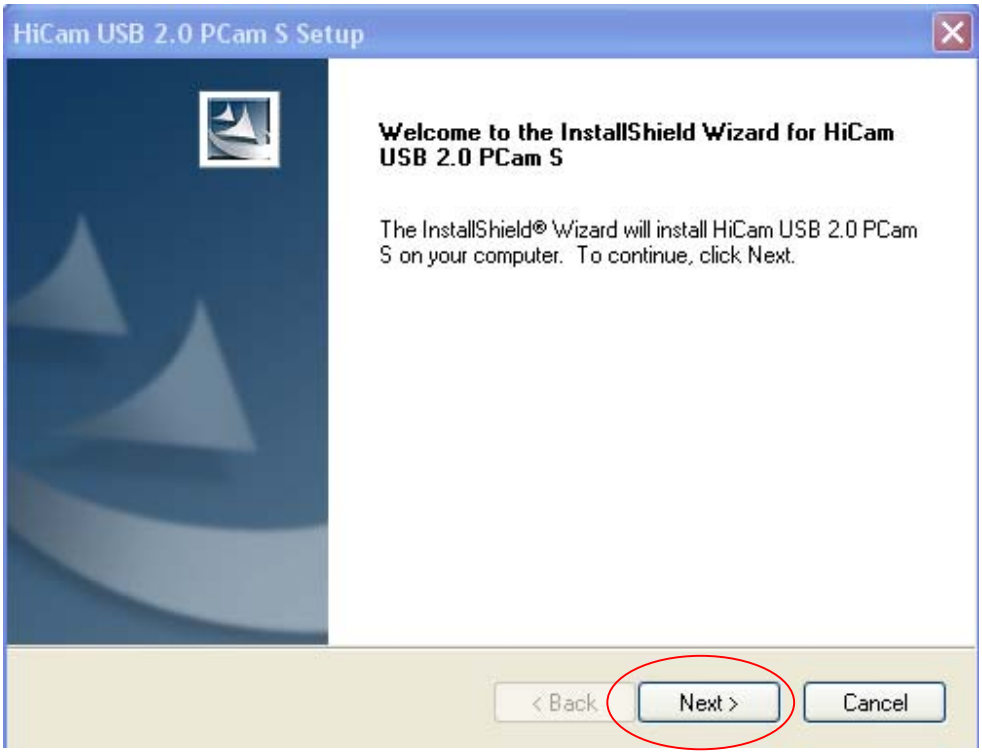


(F) When you click 

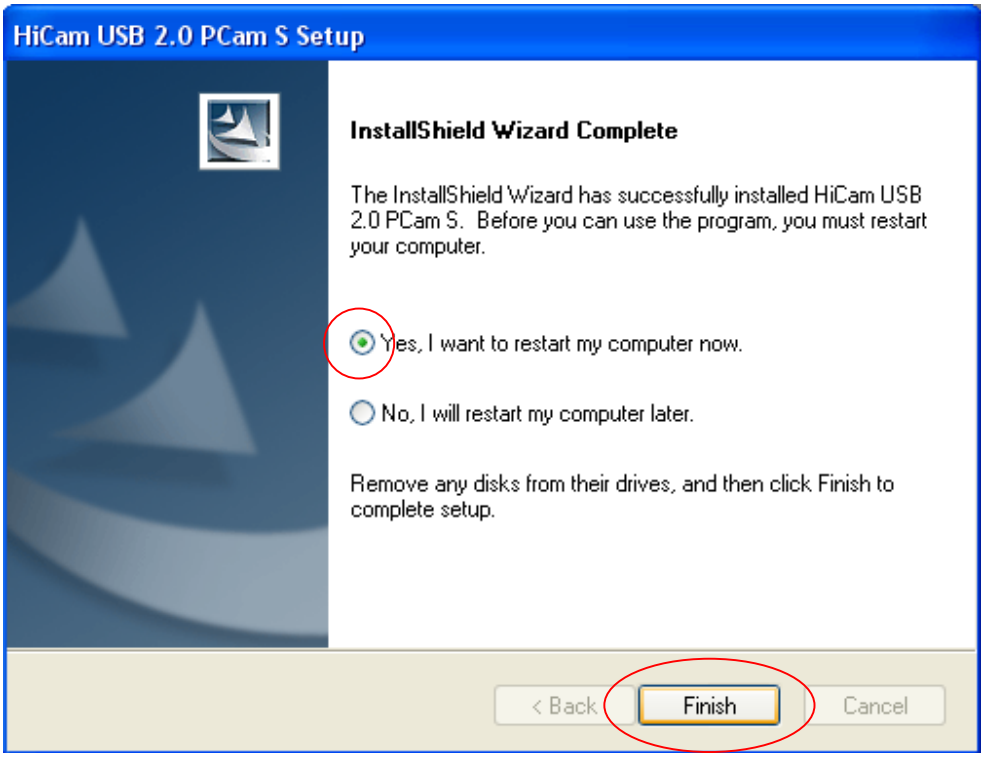
, the installation will automatically install the camera (Please see the Manually Install Camera Section)

6. ***Manually Install the Camera***

(A) Locate the Camera Folder in root\Camera. EXECUTE the Setup.exe program, you will see the following window, just simply click the Next > button as circled in RED to continue. If not, you may choose to quit by clicking the Cancel button.



(B) The program will then guide you through all processes. When done, click YES and press [Finish] button to restart your computer.

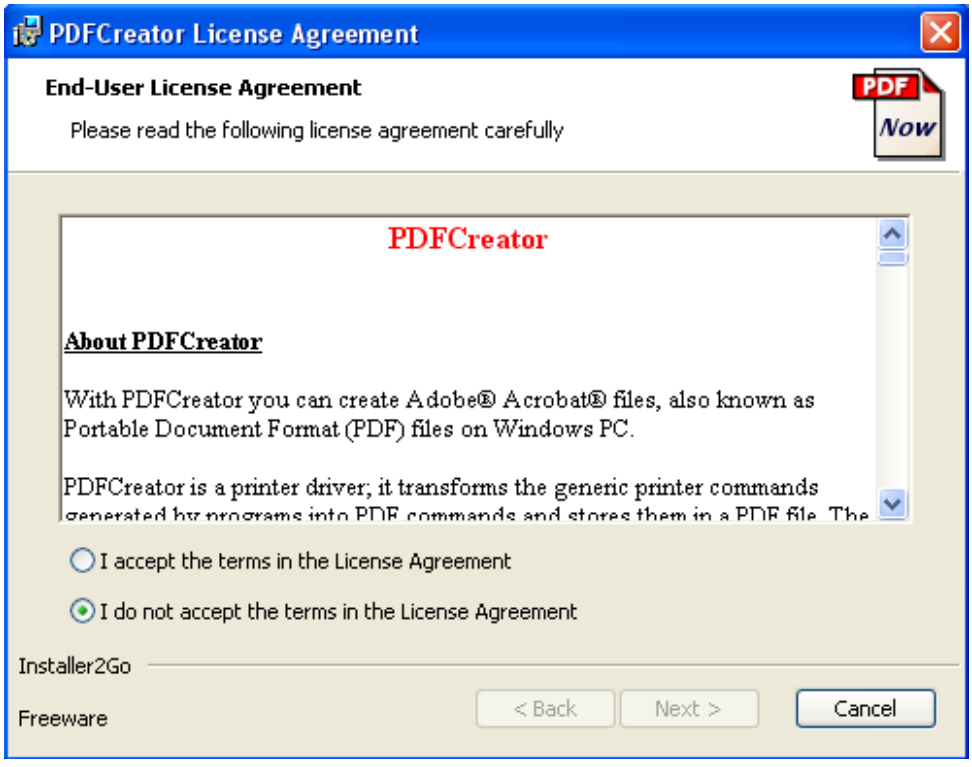


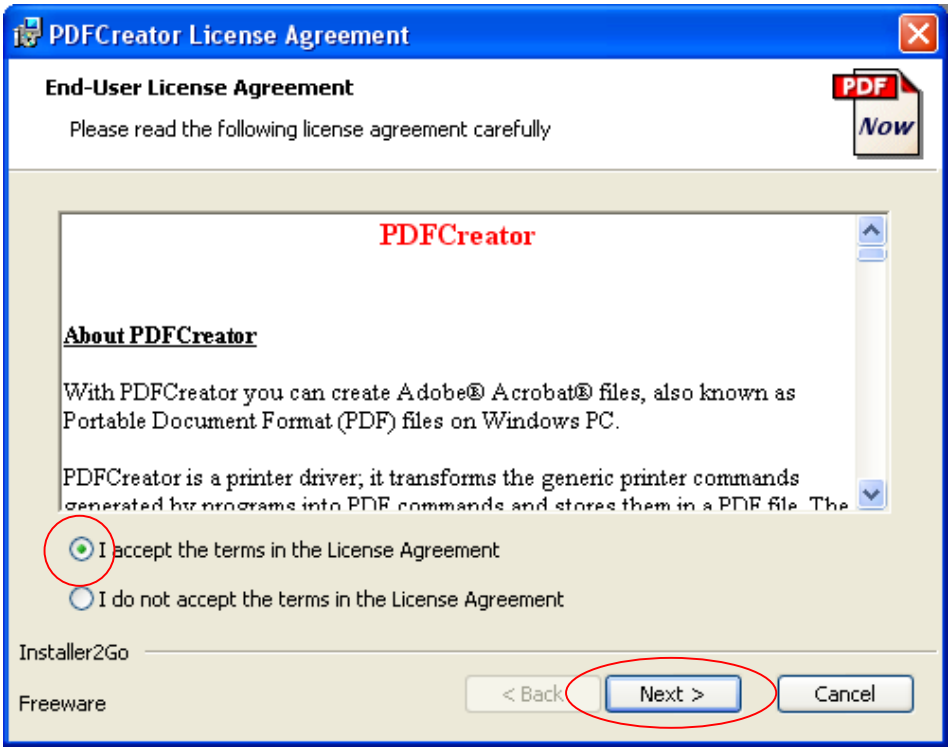
(C) If you have installed the camera before, it will prompt you whether you want to uninstall the camera. Just check NO.

7. ***Manually install the PDFCreator***

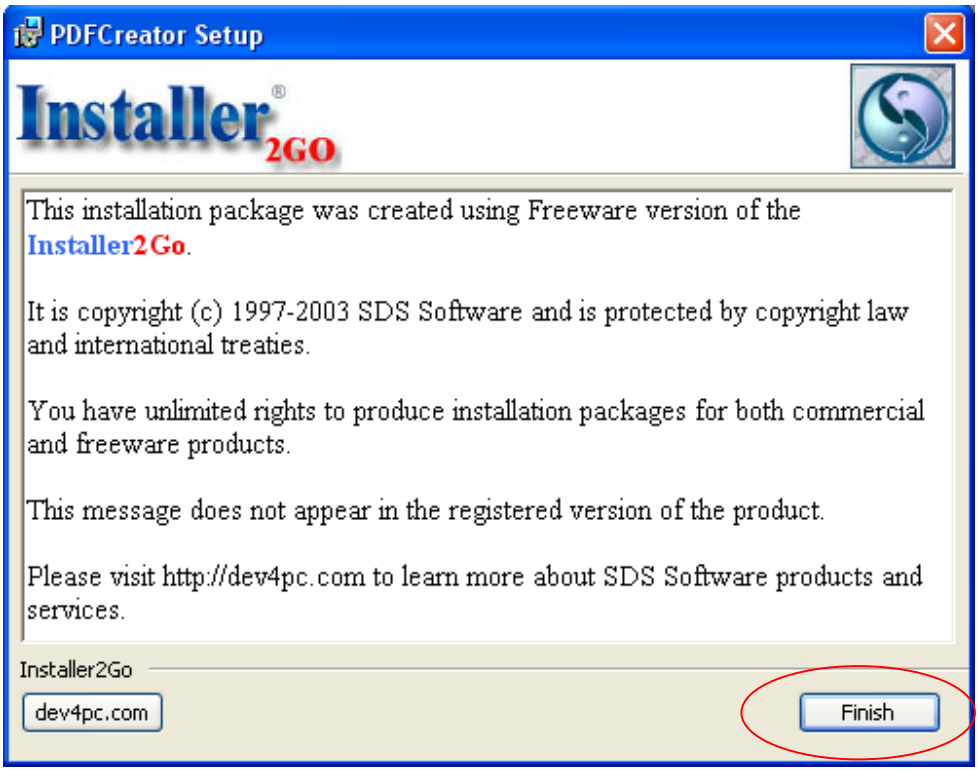
(Note that this is just an option, it should be installed only when you need to preview your report on your computer screen when there is no real printer installed, i.e. this software provides a preview function. The software PDFCreater is not supported by VISTA yet.)

(A) You can find the PDFCreater.msi in root\PDFCreator directory. After executing it, you will see the following window, check on [I accept] and then the Next > button will pop out, press Next > to continue. You may choose to quit by clicking the Cancel button.




PDFCreator License Agreement
End-User License Agreement
Please read the following license agreement carefully
PDF Now
PDFCreator
About PDFCreator
With PDFCreator you can create Adobe® Acrobat® files, also known as Portable Document Format (PDF) files on Windows PC.
PDFCreator is a printer driver; it transforms the generic printer commands
I accept the terms in the License Agreement
I do not accept the terms in the License Agreement
Installer2Go
Freeware
< Back
Next >
Cancel

(B) The program will then guide you through all processes. When done, press [Finish] button to exit



8. Uninstall

To uninstall the software, you may have to uninstall the QCR 6000R software and Camera separately.

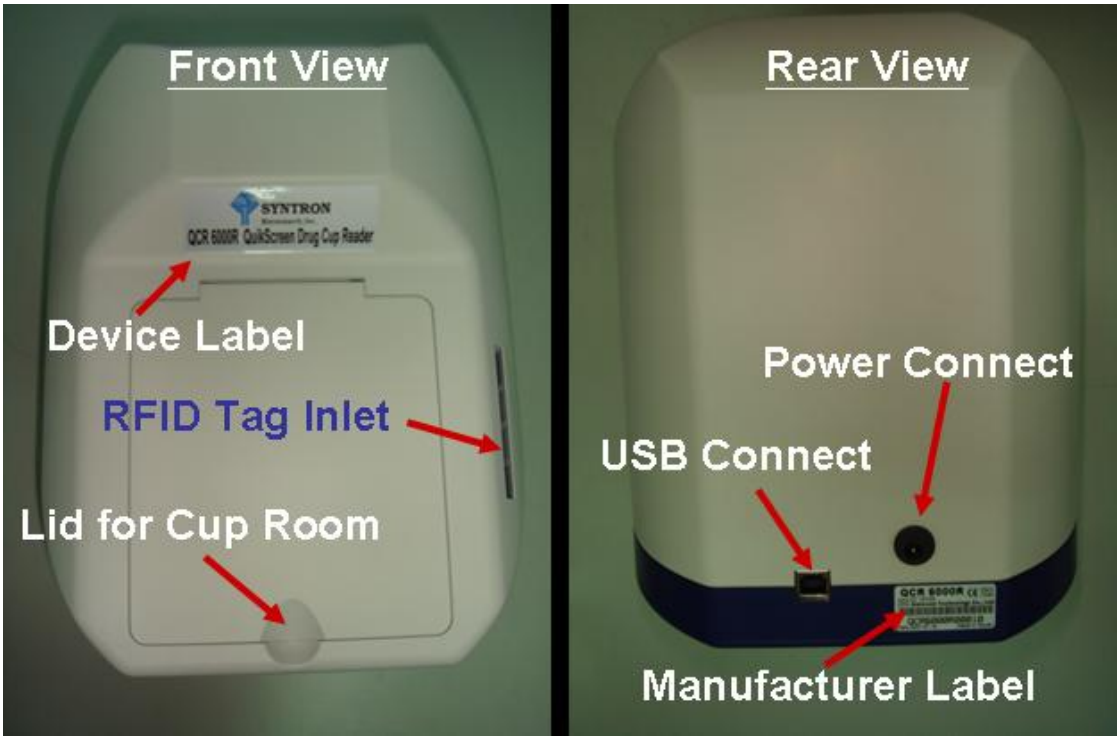
(A) EXECUTE the “Remove QCR 6000R QuikScreen Drug Cup Reader” in SYTRON folder (in Startup Menu / All Programs), the software will automatically uninstall the QCR 6000R software.

(B) EXECUTE the “Uninstall” in USB 2.0 Camera folder (in Startup Menu / All Programs), the software will automatically uninstall the camera software.

Hardware Specification

- Detector: CMOS Sensor
- Dynamic Range: 8 bit
- Transfer: USB 2.0 Plug-and-Play
- Format: Drug Cup
- Power: USB Port with 500mA Power Supply and 12V 1A Power Supply
- Computer requirement:
  - OS: Windows 2000 or XP (Vista is working, but not fully supported yet)
  - USB 2.0 port
  - Windows resolution: 1024 x 768 (above)
  - RAM: 512MB or better
  - It is suggested to execute the software individually, not with other software running simultaneously.
- Environment:
  - Indoor Use
  - Attitude: 2000m
  - Operation Temperature: 5 ℃ ~ 40 ℃
  - Humidity: Maximum 80%RH at 31℃ decreasing to 50%RH at 40℃
  - Away from high radio frequency interference (such as base station, etc.)
  - Pollution Degree: 2
- Maintenance:
  - Keep the device outlook clean by using soft towel. It is not necessary to clean inside.
  - In case of calibration error or any problems, please contact Syntron BioResearch Inc. (www.syntron.net) for nearest service provider.

- Labels:



- Company: Syntron BioResearch Inc.

  2774 Loker Avenue West, Carlsbad, CA 92008, USA
  www.syntron.net

- Manufacturer: Kaiwood Technology Co., Ltd..

  5F, No12, Ln31, Sec1 Huondung Rd., Hsinshi Township,
  Southern Taiwan Science Park,
  Tainan County 741, Taiwan
  www.kaiwood.com.tw

Patterns

- Optical Optimization Method
  - Taiwan, 196357
  - China, 215732

- CCD-Based Biochip Reader
  - Taiwan, I 226437
  - USA, 7173707
  - China, 03156851.3 (Pending)

- Cylindrical Reagent Chip Reader (USA)
  - Taiwan, 095114871 (Pending)
  - USA, 11/542259 (Pending)
  - China, 200610078019.3 (Pending)

- Image Detection Method for Diagnostic Plates
  - Taiwan, 096112275 (Pending)
  - China, 200710106122.9 (Pending)

Certification

- CE
  - Report No: 06-07-MAS-040
  - The equipment is IVD medical equipment
- FDA
  - Product Code: JJQ
  - Device Class: 1
  - Owner/Operator Number: 9096712
  - Date of Listing: 01/03/07
  - Reference:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm?&ID=103087
- FC
  - ID No: VGG-KWCHR001
- ISO13485
  - Certificate No: GB06169533
- ISO9001:2000
  - Certificate No: GB06169534
- GMP
  - Medicine No: 0960312056
  - Manufacture No: Medical Device First 001887

FCC Notices

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Change or modification not expressly approved by the party responsible for compliance could void the user’s authority to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, theuser is encouraged to try to correct the interference by one or more of the following measures:
--Reorient or relocate the receiving antenna.
--Increase the separation between the equipment and receiver.
--Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
--Consult the dealer or an experienced radio/TV technician for help.

CAUTION:
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

RF exposure warning:
The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment. The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.