



# **Alfa-Scan Reader**

**R101**

## **User Manual**

Published February 18, 2009

## **IMPORTANT SAFETY INSTRUCTIONS**

**DANGER** – Misuse of electrical equipment can cause burns, fire, electrocution and other hazards.

Basic safety precautions should always be taken, including those listed below. Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

### **READ THIS BEFORE USE**

- 1) Check that the voltage setting matches the supply voltage.
- 2) Unplug the reader immediately after use.
- 3) The reader should not be immersed in liquid or come in contact with liquid. Unplug the reader before touching it if it becomes wet.
- 4) Use the reader only for the purposes described in the instructions for use.
- 5) Use only the accessories that are supplied or recommended by the manufacturer.
- 6) Discontinue or avoid use if the reader is not working properly or if it has suffered any damage. Examples include:
  - Damage to the flexible supply cord or the plug
  - Damage caused by dropping the reader
  - Damage caused by the reader coming into contact with water or other liquids
- 7) Do not let the reader or its flexible cord come in contact with surfaces which are too hot to touch.
- 8) Do not block air openings or place reader on a soft surface which might block them. Air openings must be kept free of lint, hair, fluff, etc.
- 9) Do not place anything on top of the reader.
- 10) Do not use the reader where aerosol sprays are being used or where oxygen is being administered.
- 11) Do not use the reader outdoors.

### **KEEP THESE INSTRUCTIONS IN A SAFE PLACE**

## Introduction

The Alfa-Scan Reader provides a detection platform for rapid test applications. The Alfa-Scan Reader distinguishes color changes resulting from various biochemical reactions, and analyzes the reactions to provide a quantitative clinical diagnosis. The main diagnostic analyses are for diseases, cardiac markers, drugs and fertility tests.

## Software User Manual

### 1. EXECUTE the Alfa-Scan Reader Application.

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

(B) Execute the analysis program [ALFA R101 v1.2.2].

(Some computers require more time to recognize USB devices. If the program asks you to plug in the reader after you have already executed Step (A), wait a few minutes and execute the program again.)

The main screen is shown below:

ALFA R101 (v1.2.2)

**ALFA**  
SCIENTIFIC DESIGNS, INC.

# R101 Chromogenic Reader

Patient ID  Product ID  Test Date 2/18/2009

Patient Name  Operator  Test Time   5 min  00:00

Analysis Patient Management System Setting


Item					
Cutoff(ng/ml)					
Intensity					
Ref Int					
Test / Control					

## 2. BEFORE ANALYSIS

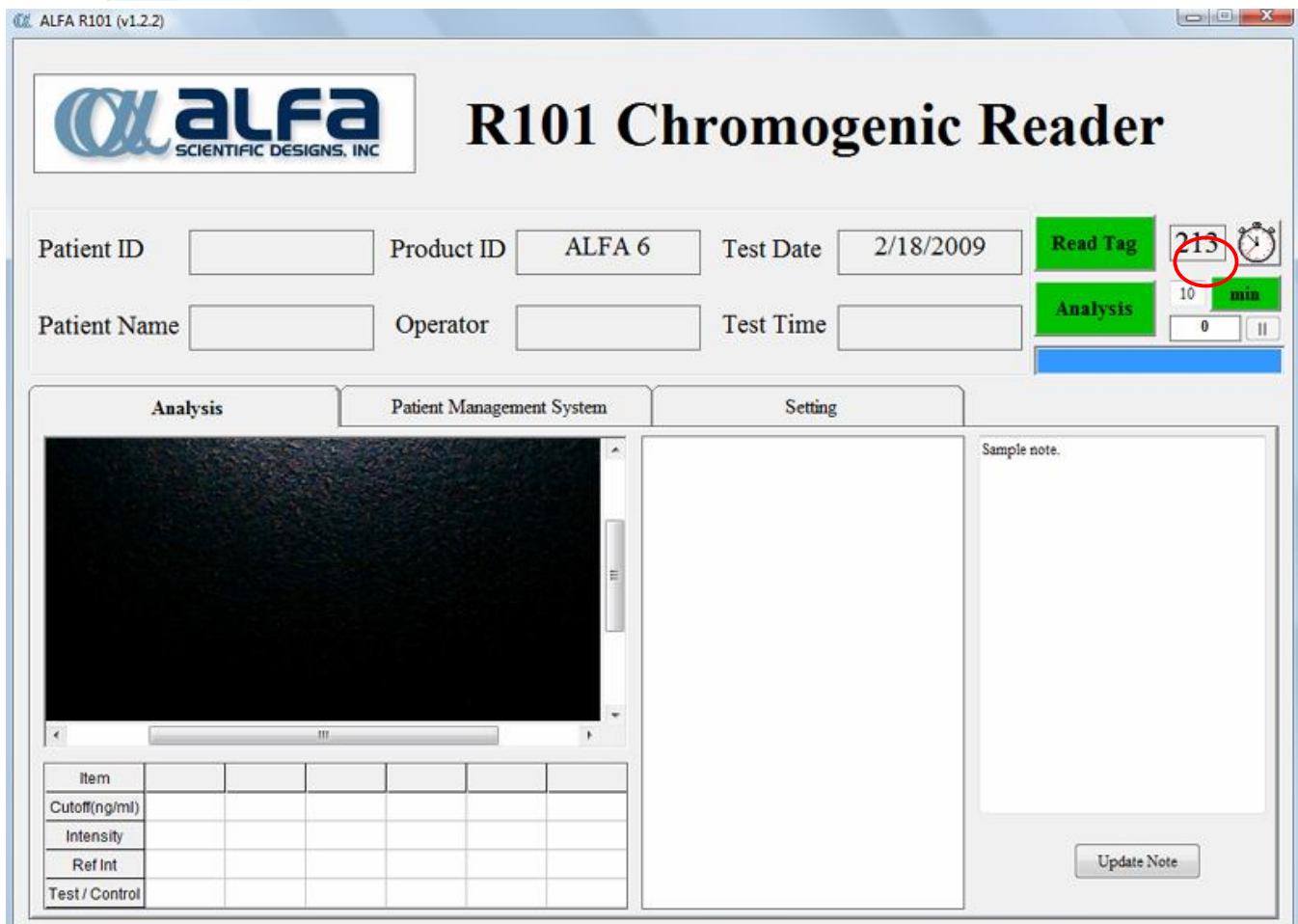
Before analysis, several parameters need to be loaded from the RFID calibration tag included with the test kit.

(A) Insert the RFID tag into the RFID slot of the Alfa-Scan reader.

(B) Press . The reader will automatically load the following:

- Product ID: The type of test.
- Product Lot#: The manufacturer lot number.
- Expiration Date: The expiration date of the test.
- 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 computer's clock. (It will update automatically when  is pressed).
- Remaining tests: (circled below) The number of tests available according to your license. To protect the integrity of records, each test you purchase can only be read once.




(C) The  button will illuminate once the reader is ready for use.




ALFA R101 (v1.2.2)

**ALFA**  
SCIENTIFIC DESIGNS, INC.

# R101 Chromogenic Reader

Patient ID  Product ID  Test Date    


Patient Name  Operator  Test Time  

Analysis Patient Management System Setting

Sample note.


Item					
Cutoff(ng/ml)					
Intensity					
Ref Int					
Test / Control					

(D) RFID tags should only be used with tests shipped in the same kit box. If you switch to another kit box, it is imperative that you change the RFID tag as well. Remove the RFID tag from the RFID slot and insert the tag from the test kit you intend to use. Note: Using the wrong RFID tag may result in invalid or incorrect test results.

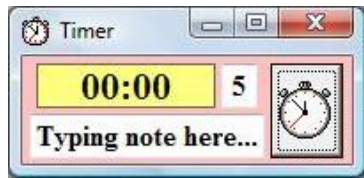
(E) It is not necessary to remove the RFID tag or press  again if running tests from the same box.


(F) It is strongly recommended to calibrate the reader before any testing. To calibrate the reader, please refer to the SETTING section (5(c)).

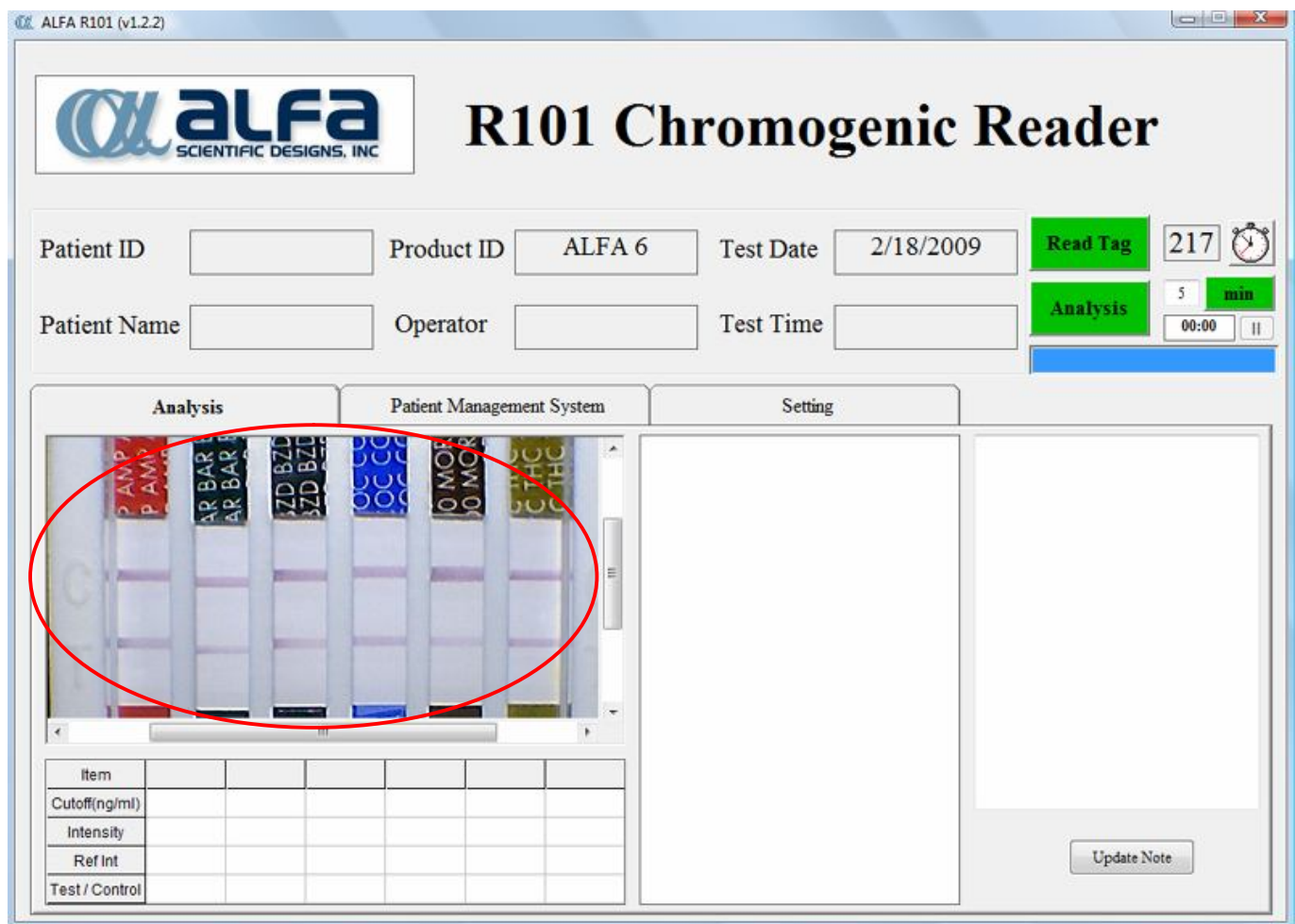
### 3. ANALYSIS (Analysis tab)

- (A) At this point you may open the test kit and follow the directions for use.
- (B) Once the test has been initiated, wait several minutes until the read time described in the instructions provided with the test kit. Pressing  activates a timer that can assist you.

While you can run as many tests as you want at the same time, some time must be allocated for the reader to analyze the results. The read time can also be changed from this screen, and a short note may be added, if desired.



- (C) Once the read time has elapsed, insert the test into its corresponding tray adapter. Press the button on the front of the reader to open the reading tray of the Alfa-Scan reader, place the adapter into the tray and close it. A live image will appear in the left-hand preview window of the program (see below). Press  to read results.



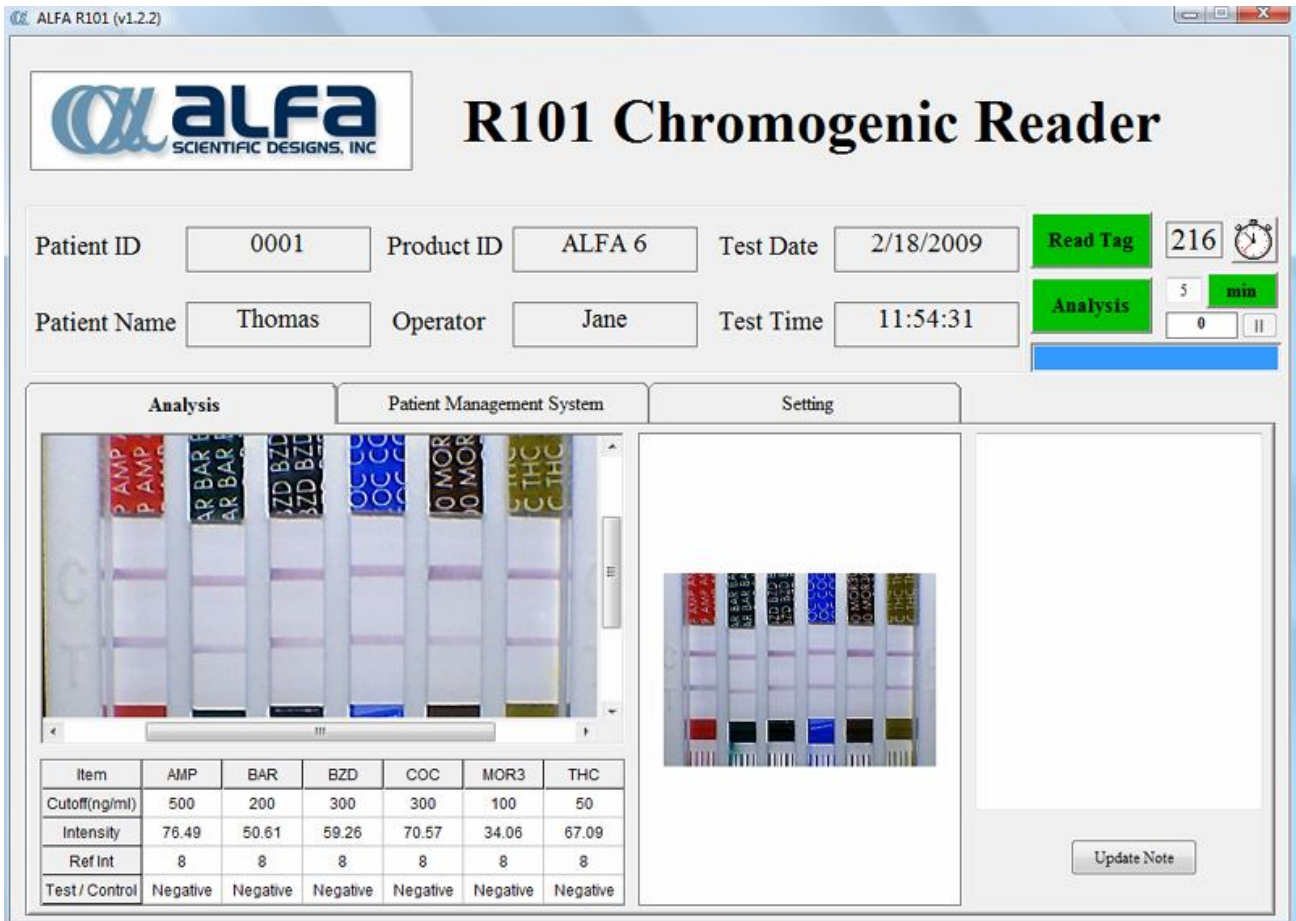
(D) A new window will appear, where you can enter additional information:

- 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 executing the test.

(E) Names and IDs can be entered using the input boxes, or selected from a user-defined list from the dropdown menu. If a name will be used again later, you may press  to add the name to the menu. You can also remove names from the menu by pressing . All names in the list can be cleared by pressing .

(F) After entering the patient and operator data, press  to continue. The number of remaining tests on the license will then be decremented. If you need to change the patient or operator data at this point, press  to return to the previous step.

(G) When  is pressed, the program will automatically begin analysis using the parameters provided by the RFID tag. These parameters include the type of test, number of parameters (for multi-analyte tests), cut off values, etc. In the lower left corner, the results will be displayed while the captured image is shown in the lower center area. Negative, Positive or Invalid results will be shown in the result table.



(H) Alternatively, the reader can also be programmed to automatically run an analysis after a preset time. The time (in minutes) can be entered in the input box:



The test can then be initiated and inserted into the reader. Pressing  will start the timer. In this mode, when the timer reaches zero the reader will automatically perform an analysis. Pressing  will stop the timer and initiate an analysis immediately.

(I) Notes can be added in the lower-right hand window, if desired. To save notes in the result database, press . You can also modify these notes at a later time from the "Patient Management System Page" (see SAVING FILES, Section 6).

#### 4. REPORTING (Patient Management System tab)


(A) Results can be reviewed from the Patient Management System tab. The latest test result is added to the last row and the count incremented. The session is then saved automatically under the same filename (see SAVING FILES, Section 6).


The screenshot displays the ALFA R101 Chromogenic Reader software interface. At the top left is the ALFA Scientific Designs, Inc. logo. The main title is "R101 Chromogenic Reader". Below the title are input fields for Patient ID (0002), Product ID (ALFA 6), Test Date (2/18/2009), Patient Name (Richard), Operator (Jane), and Test Time (11:55:44). There are also buttons for "Read Tag" (showing 213) and "Analysis" (showing 10 min). A navigation bar at the bottom of the top section has three tabs: "Analysis", "Patient Management System" (which is selected), and "Setting".

The "Patient Management System" tab contains a table of test results. The table has columns for Patient ID, Test Date, and various analytes (AMP, BAR, BZD, COC, MOR3, THC). The fourth row is highlighted in blue, showing Patient ID 0002, Test Date 11:55:44, and analyte results: AMP 77.59, BAR 49.51, BZD 60.51, COC 70.53, MOR3 34.45, and THC 65.06. To the left of the table is a search and filter section with a "Counts" box showing the number 4. To the right of the table are several buttons: "Output Folder", "Save As", "Modify", "Excel", "Open Data", "Delete Row", "Create New Library", "Print Charts", "Print Tables", and "Print Selected".


	0002	2/18/2009	AMP	BAR	BZD	COC	MOR3	THC
	Richard	11:55:44	77.59	49.51	60.51	70.53	34.45	65.06
Search	1	0001	Thomas	Jane	2/18/2009			
	2	0002	Richard	Jane	2/18/2009			
	3	0003	Harold	Jane	2/18/2009			
	4	0002	Richard	Jane	2/18/2009			

(B) Print Charts / Print Selected:


Pressing  will print all results in the current session. This printout will include a copy of the test image, a graph displaying the relative intensities, and the data in tabular format.

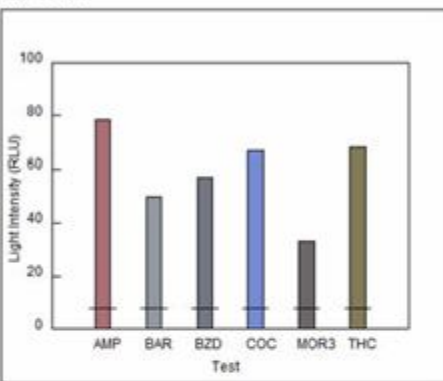
Clicking an entry and pressing  will print only the selected results. Users can hold CTRL while clicking to select multiple entries, or SHIFT while clicking to select a range.

**Sample Output (Print Charts)**



**Test Report**

(1) Test Image 

(2) Graph 

(3) Results

Product ID	ALFA 6	Product Lot#	DEMO	Exp Date	2009/12/31	
Patient ID	0001	Operator	Jane	Test Date	2/18/2009	
Patient Name	Thomas			Test Time	11:05:05	
Item	AMP	BAR	BZD	COC	MOR3	THC
Cutoff(ng/ml)	500	200	300	300	100	50
Intensity	78.28	49.88	57.2	67.1	32.95	68.1
Ref Int	8	8	8	8	8	8
Test / Control	Negative	Negative	Negative	Negative	Negative	Negative


Patient Signature : \_\_\_\_\_ Operator Signature : \_\_\_\_\_

2/6/2009 3:19:26 PM , Calibration PASS For research and investigational use. 2/18/2009 11:09:16

(C) Print Tables:

When  is pressed, all results in the current session will be printed in tabular format only, with no test images or graphs.

**Sample Output (Print Tables)**



**Test Report**

Product ID	ALFA 6	Product Lot#	DEMO	Exp Date	2009/12/31	
Patient ID	0001	Operator	Jane	Test Date	2/18/2009	
Patient Name	Thomas			Test Time	11:05:05	
Item	AMP	BAR	BZD	COC	MOR3	THC
Cutoff(ng/ml)	500	200	300	300	100	50
Intensity	78.28	49.88	57.2	67.1	32.95	68.1
Ref Int	8	8	8	8	8	8
Test / Control	Negative	Negative	Negative	Negative	Negative	Negative

2/6/2009 3:19:26 PM , Calibration PASS

Product ID	ALFA 6	Product Lot#	DEMO	Exp Date	2009/12/31	
Patient ID	0002	Operator	Jane	Test Date	2/18/2009	
Patient Name	Richard			Test Time	11:07:21	
Item	AMP	BAR	BZD	COC	MOR3	THC
Cutoff(ng/ml)	500	200	300	300	100	50
Intensity	78.99	51.24	58.93	68.08	34.14	69.42
Ref Int	8	8	8	8	8	8
Test / Control	Negative	Negative	Negative	Negative	Negative	Negative

2/6/2009 3:19:26 PM , Calibration PASS

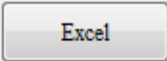
  

Product ID	ALFA 6	Product Lot#	DEMO	Exp Date	2009/12/31	
Patient ID	0003	Operator	Jane	Test Date	2/18/2009	
Patient Name	Harold			Test Time	11:07:53	
Item	AMP	BAR	BZD	COC	MOR3	THC
Cutoff(ng/ml)	500	200	300	300	100	50
Intensity	79.51	50.29	58.05	67.04	33.69	69.55
Ref Int	8	8	8	8	8	8
Test / Control	Negative	Negative	Negative	Negative	Negative	Negative


2/6/2009 3:19:26 PM , Calibration PASS

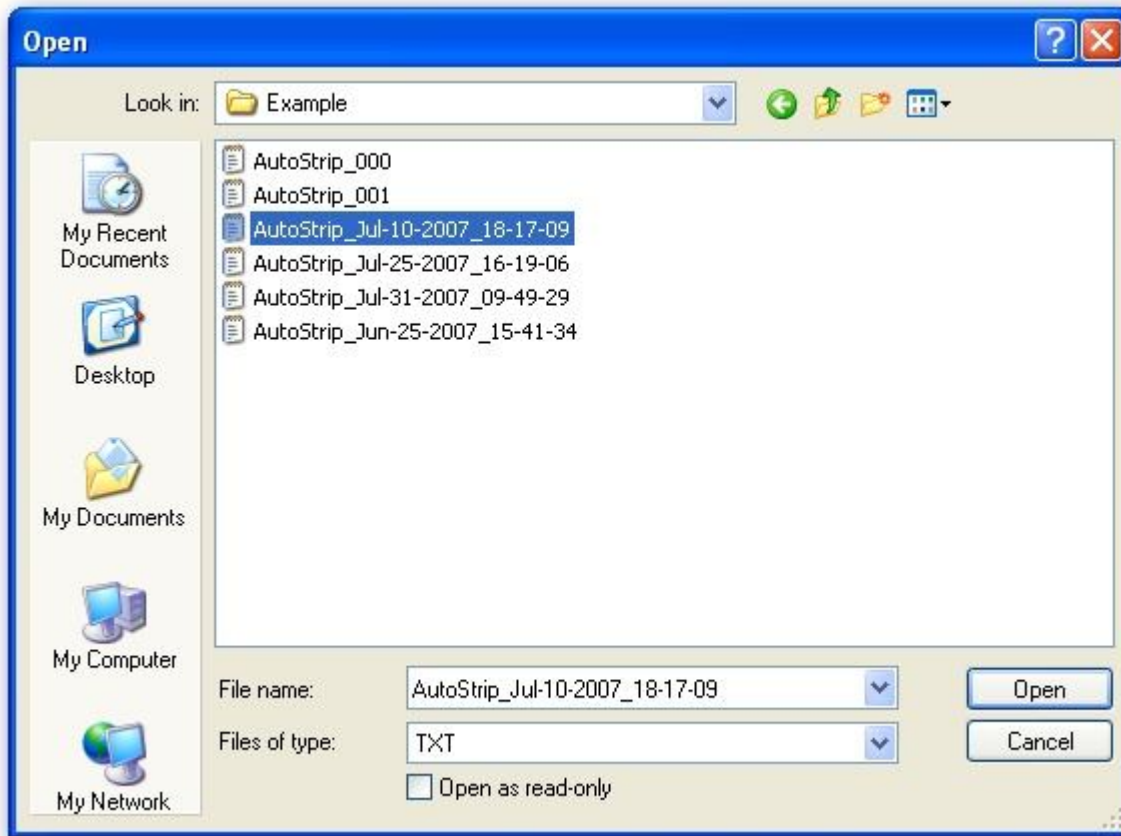
For research and investigational use. 2/18/2009 11:11:02

(D) Excel:

Pressing  will create and open a spreadsheet of the current session's data in Microsoft Excel.

(E) Open Data:

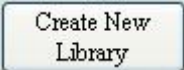
Press  and select a saved file to review results from previous sessions.



(F) Delete Row:

Pressing  will delete highlighted data from the current session.

(G) Create New Library:

Pressing  will delete all the data in the current session and create a new session in a new file.

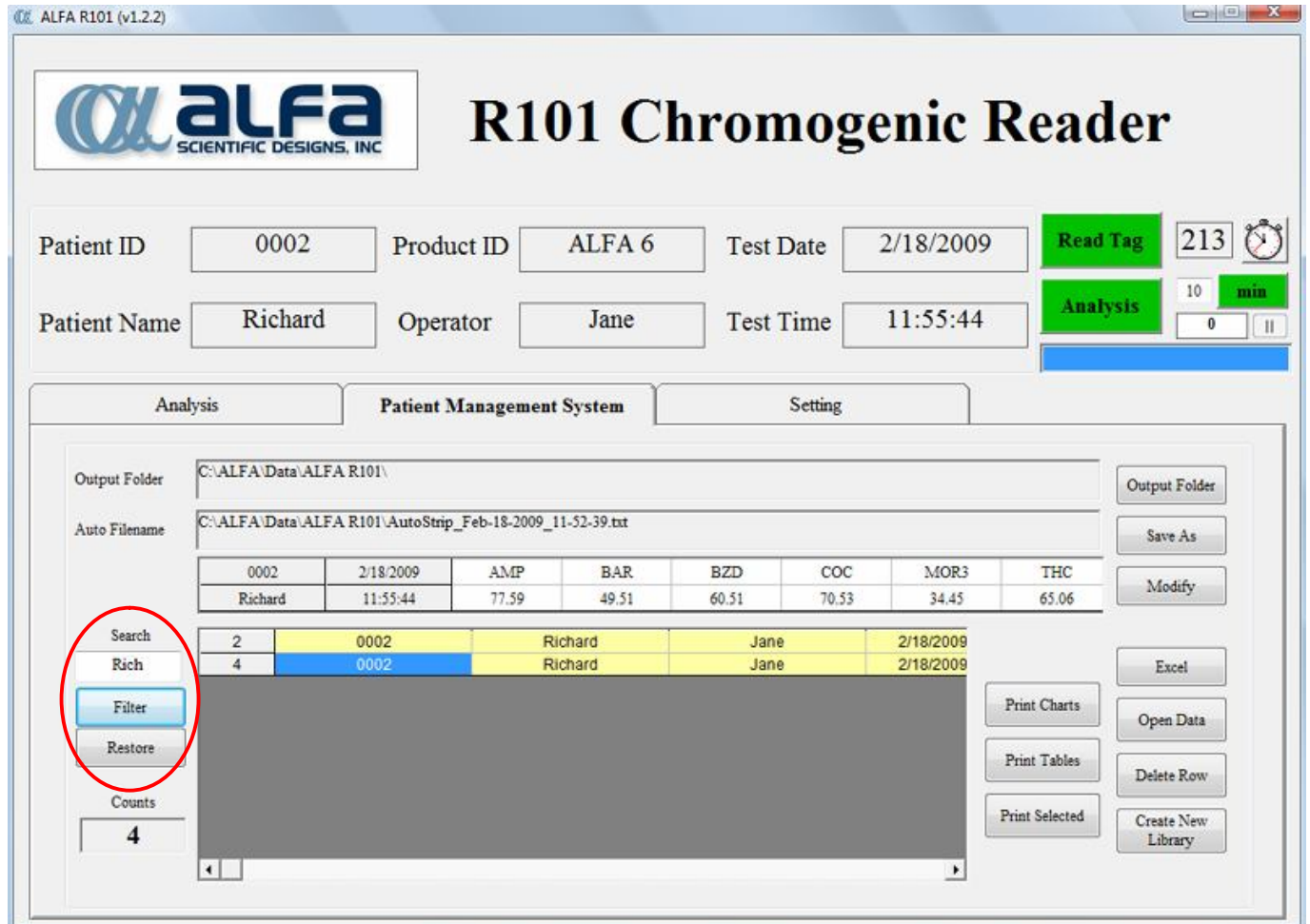
(H) Searching Data:

From the Patient Management System tab, you can choose to display only specific records. Type the specific characters you want to search for in the search box and press



. The program will display all records that match the search terms. To restore all

results, press



The search function can be applied to any field, including the Patient Name, Operator Name, Test Date, etc.

(I) To exit the program or to view other results press



## 5. CONFIGURATION (Setting tab)

The program is pre-configured to ensure best results with the reader when shipped. Changing the settings is not recommended.

ALFA R101 (v1.2.2)

**ALFA**  
SCIENTIFIC DESIGNS, INC.

# R101 Chromogenic Reader

Patient ID: 0002    Product ID: ALFA 6    Test Date: 2/18/2009    Read Tag: 213

Patient Name: Richard    Operator: Jane    Test Time: 11:55:44    Analysis: 10 min

**Setting**

Device Setting:  
Language: English  
HiCam USB 2.0 PCam S  
Camera Source

Positive / Negative Type:  
 Drug-Multiple  
 Drug-Single  
 Saliva  
Gray Calibration    Restore Factory Calibration

Calibration History:  
2/6/2009 3:19:26 PM, Calibration PASS  
2/6/2009 3:06:00 PM, Calibration PASS  
1/28/2009 8:17:43 AM, Calibration PASS  
1/22/2009 12:17:17 PM, Calibration PASS  
1/20/2009 9:54:26 AM, Calibration PASS  
1/9/2009 11:20:37 AM, Calibration PASS  
1/9/2009 11:16:03 AM, Calibration PASS  
1/9/2009 11:11:44 AM, Calibration PASS  
1/8/2009 3:09:28 PM, Calibration PASS  
1/8/2009 3:06:13 PM, Calibration PASS


Cassette Setting:  
Tag Status: OK  
Product ID: ALFA 6  
Items per Cassette: 6

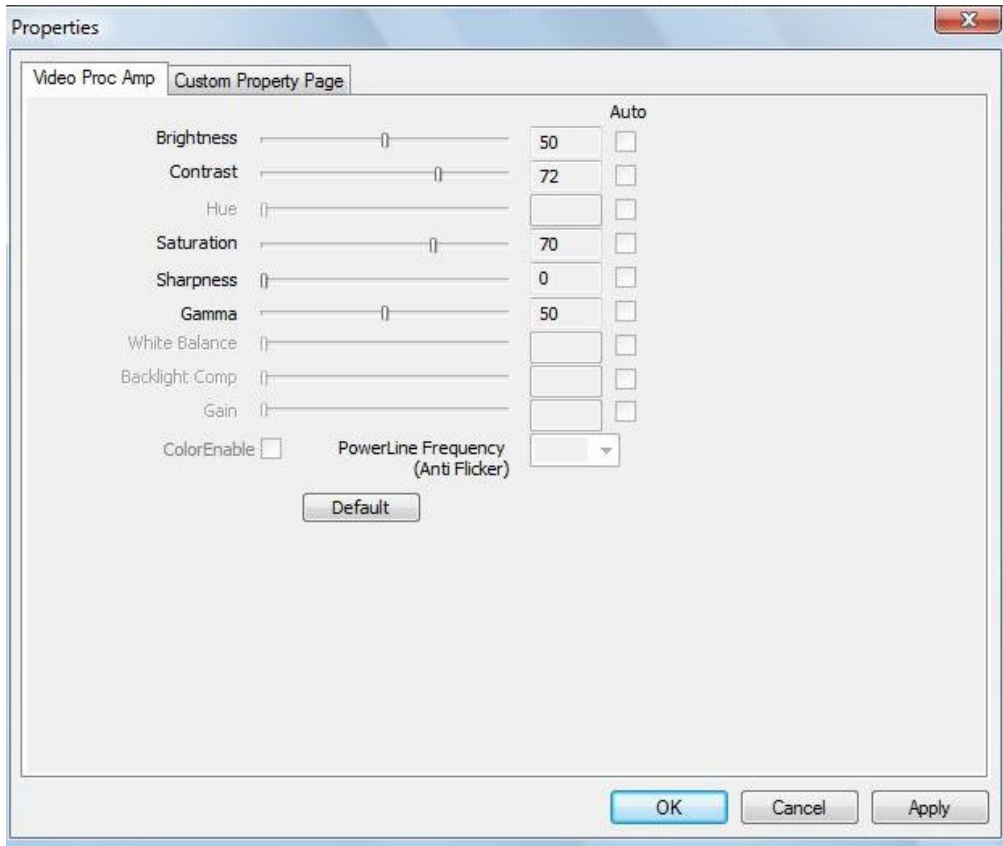
Item	Test	Cutoff(ng/ml)	Ref Int
1	AMP	500	8
2	BAR	200	8
3	BZD	300	8
4	COC	300	8
5	MOR3	100	8
6	THC	50	8

### (A) Positive/Negative Type :

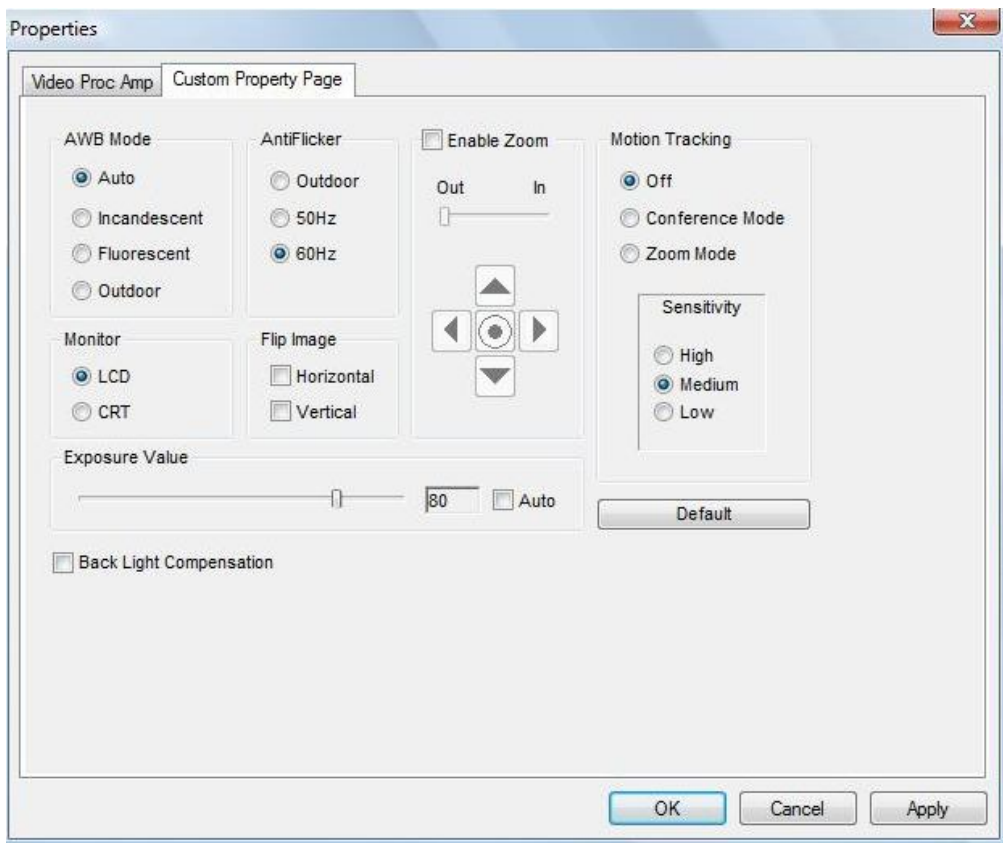
The mode of result interpretation is specific for each product. For some tests, a line in the T line region is a positive result. For others, a line in the C line region is a negative result. The result type is set by the RFID tag, and cannot be manually changed.

### (B) Camera Source :

To configure the camera, press . The default camera setting is [i-Spy PC Cam] or [HiCam USB 2.0 PCam S]. It is recommended to keep the original setting. Changing any of the camera properties is strongly discouraged. If you need to change any settings, please consult your supplier.



In some countries, where the power supply frequency is 50Hz, you may find it necessary to adjust the PowerLine Frequency (Anti-Flicker) to 50Hz (the default is 60Hz) to eliminate flickering on the display.



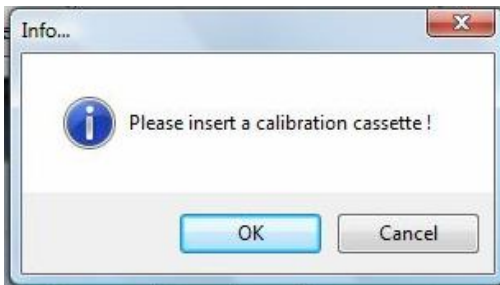
(C) Language :

You can choose a different language from the dropdown menu box. Once you choose a language, all of the text in the program will be changed. However, please note that if you elect to load data from a previously saved database, these data will be displayed in their original language.

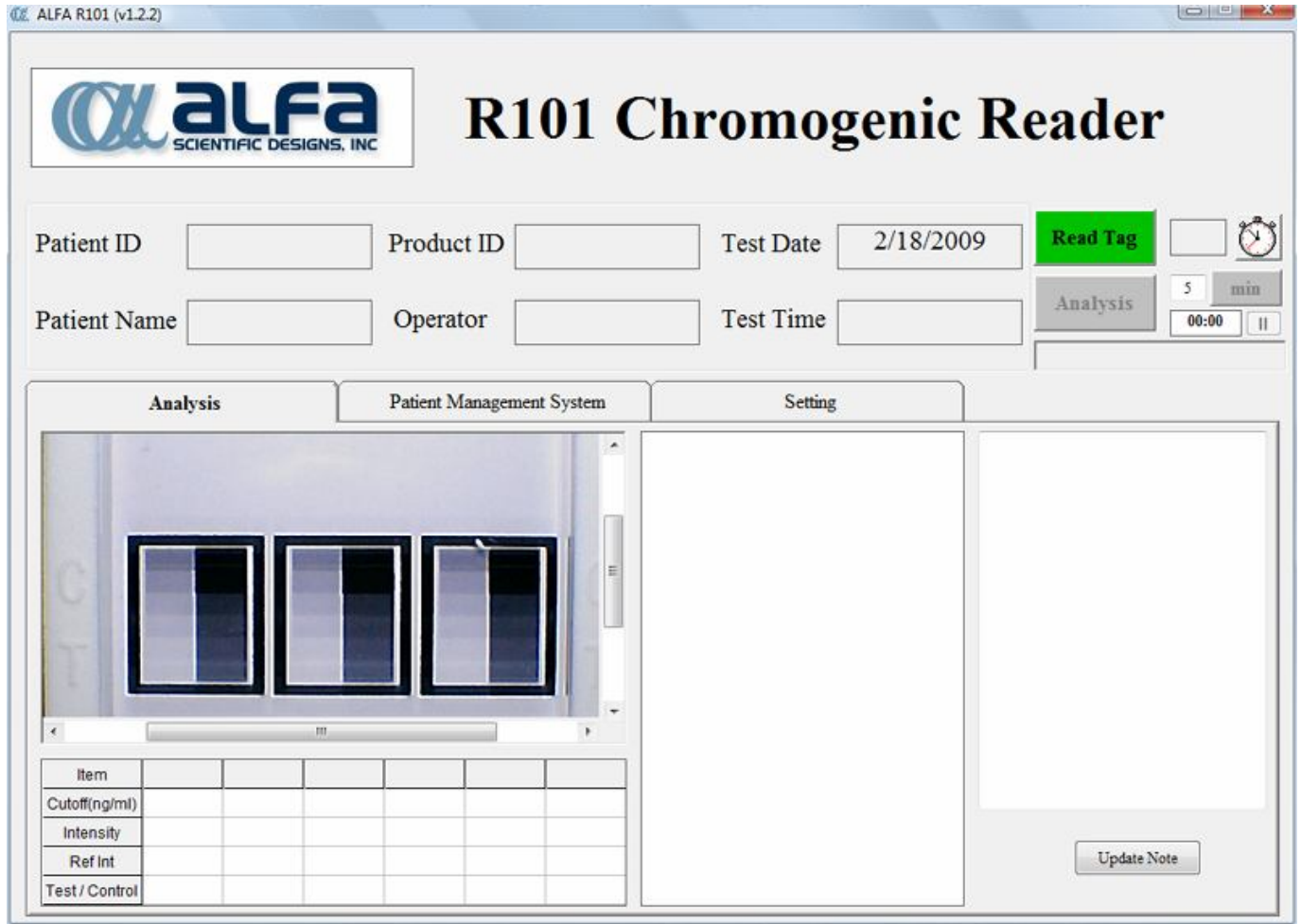
(D) Gray Calibration :

For best results, it is suggested that you calibrate the reader as soon as you run the program. You may also calibrate the reader again whenever necessary. To calibrate the reader:

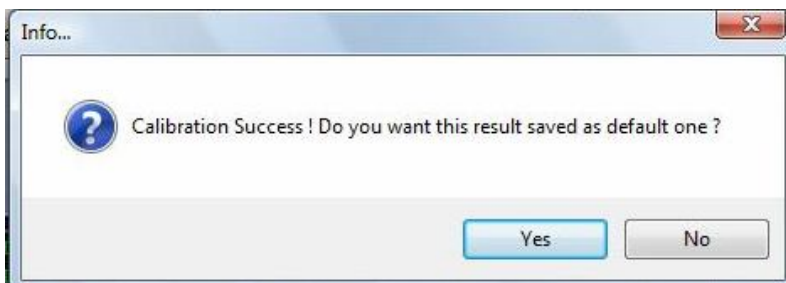
- Press 



- Insert the calibration cassette (included with the reader package) in the front slot of the reader. Press  to continue, or press  to abort the calibration process. From the Analysis tab you can verify if the calibration cassette is in position.



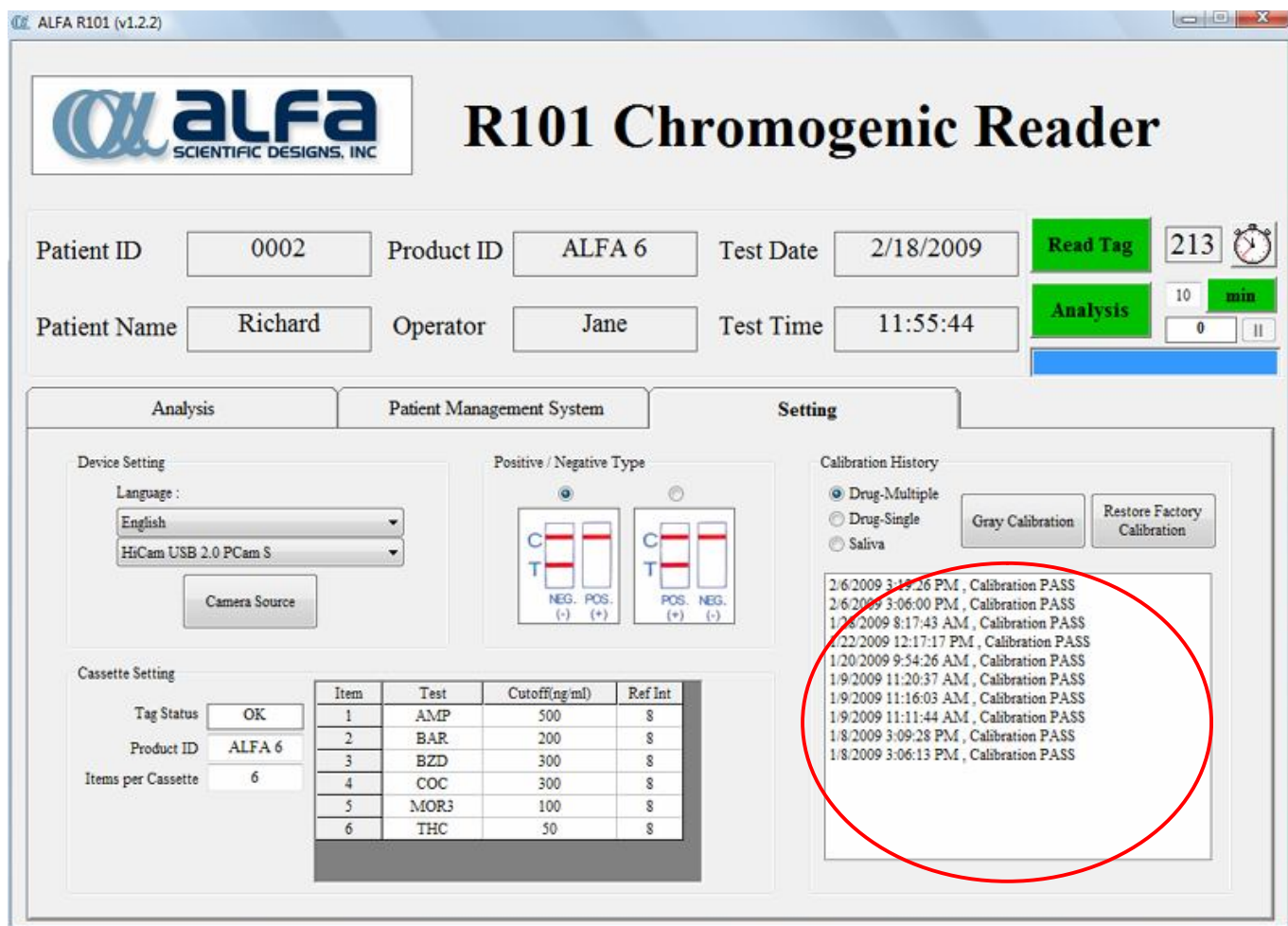
- Once calibrated, the new calibration curve will be used until the program is turned off. To save the new calibration curve and overwrite the old curve, press . If you do not want to use the new calibration curve in the future, press  and the old calibration curve will be used the next time the program is run.



- Please note that once you press , the calibration history will be recorded and the current calibration date will be shown in following reports.

(E) Calibration History :

Whenever the reader is calibrated, the reader will analyze the calibration cassette. If the gray scale values meet the calibration requirements, the reader passes the test. Calibration failure may be due to a defective calibration cassette or a problem with the camera. In this case, please contact your vendor for further technical assistance. All results are automatically recorded in the Calibration History window (see below).



(F) Restore Factory Calibration :

If you accidentally calibrate the reader or if the calibration results appear questionable, the original factory settings can be restored by pressing **Restore Factory Calibration** and pressing **Yes** when asked to confirm.



(G) Cassette Setting:

Cassette variables are displayed on this page. These variables include the product information from the RFID tag used to correctly analyze the strip. Always double check this information before testing.

- Tag Status: When an RFID tag is successfully read, this field will read OK. If an error is encountered while reading the RFID tag, this field will read NG.
- Product ID: The product ID of the test.
- Items per Cassette: Number of parameters per cassette.

(H) Press  to exit the program.

## 6. SAVING FILES

After each analysis, results are automatically saved. If desired, you may change the filename from the Patient Management System tab.

The screenshot shows the ALFA R101 Chromogenic Reader software interface. The window title is "ALFA R101 (v1.2.2)". The main header displays the ALFA Scientific Designs, Inc. logo and the text "R101 Chromogenic Reader".

At the top, there are input fields for Patient ID (0002), Product ID (ALFA 6), Test Date (2/18/2009), Patient Name (Richard), Operator (Jane), and Test Time (11:55:44). To the right, there are buttons for "Read Tag" (displaying 213) and "Analysis" (displaying 10 min).

The interface has three tabs: "Analysis", "Patient Management System" (which is selected), and "Setting".

Under the "Patient Management System" tab, there are fields for "Output Folder" (C:\ALFA\Data\ALFA R101\), "Auto Filename" (C:\ALFA\Data\ALFA R101\AutoStrip\_Feb-18-2009\_11-52-39.txt), and a "Counts" display showing "4".

There are two data tables. The first table shows test results for Patient ID 0002:

	2/18/2009	AMP	BAR	BZD	COC	MOR3	THC
Richard	11:55:44	77.59	49.51	60.51	70.53	34.45	65.06

The second table shows a list of patients:

		Thomas	Jane	2/18/2009
1	0001			
2	0002	Richard	Jane	2/18/2009
3	0003	Harold	Jane	2/18/2009
4	0002	Richard	Jane	2/18/2009

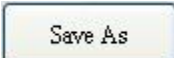
On the right side of the interface, there are several buttons: "Output Folder", "Save As", "Modify", "Excel", "Print Charts", "Print Tables", "Print Selected", "Open Data", "Delete Row", and "Create New Library".

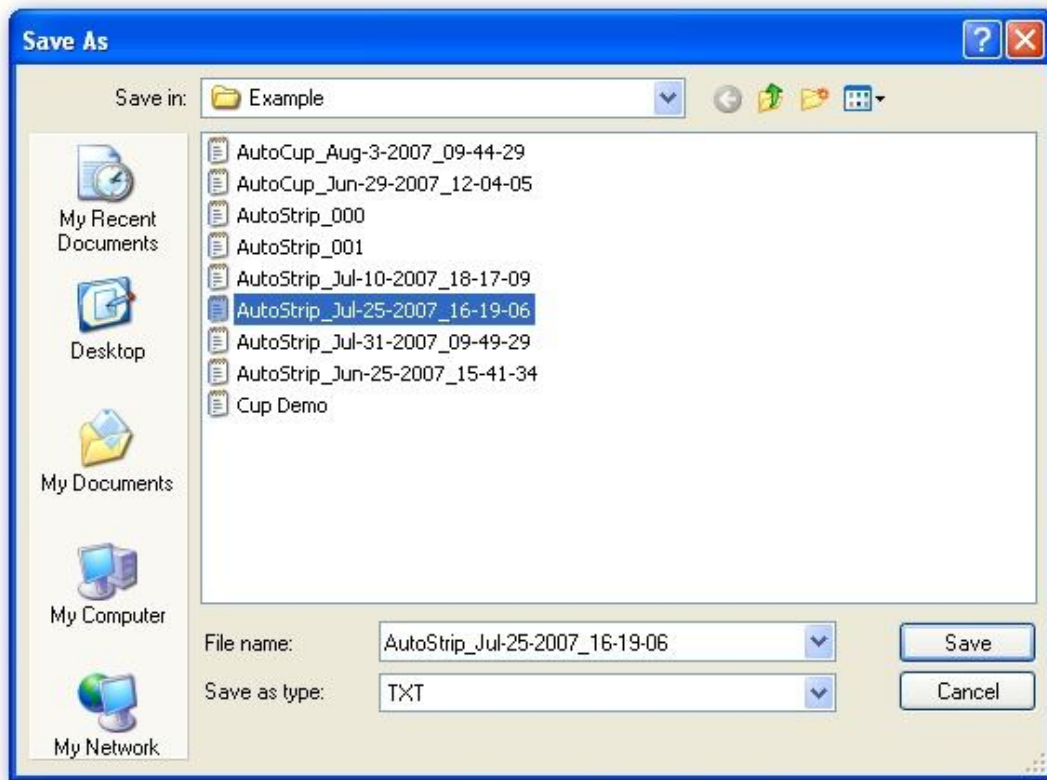
(A) File Path:

The default output folder is the \ALFA\Data\ALFA R101 directory on your primary drive. To change the output folder, press . Following test results will be saved into this folder unless the output folder is changed again.

(B) File Name:

Once the first test in a session is done, the system will automatically generate a saved file. Reflecting the time of the first analysis in the session, the file name will be “AutoStrip\_Month-Day-Year\_hh-mm-ss” in text (.TXT) format. All results from a session are saved in the same file. A picture for each result will also be saved automatically; the corresponding file name is listed in the report file.

To save a copy of a test result, press . New results will still be saved to the original file, and not the new copy.



(C) Modify patient information:

Changing patient information is not recommended. However, if it is necessary to change patient information, press  to change the patient ID and/or patient name. From

this screen, notes can also be added or modified. Press  to continue, or

to discard changes.

The image shows a software dialog box titled "Modify". It has a light green background and a blue title bar with a pencil icon. The dialog contains four input fields: "Patient ID" with the value "0002", "Patient Name" with the value "Richard", "Operator" with the value "Jane", and "Note" with the value "Sample note.". At the bottom of the dialog, there are two buttons: "Next" and "Cancel".