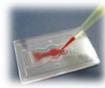
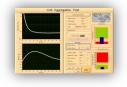
Hemorheometer RheoScan













Disposable type
(RheoScan-AnD 300)
USER'S MANUAL

RheoScan AnD-300 series

User's Manual

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RheoScan-AnD 300, User's Manual

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E.02.60 Date: May 2011 E.02.70 Date: Aug 2012



- 1. Do not disassemble the main body of RheoScan-AnD 300 system. Any disassemble may cause unexpected accidents including electric hazards. Moreover, the warranty (one year after delivery and inspection) may not be valid after disassemble.
- 2. Always ensure that the power supply input voltage match the voltage available in your location.
- 3. For operation environment, see chapter 6, "Specifications".
- 4. This machine is air-cooled so its surfaces become hot during operation. When installing it, leave spaces of more than 10 cm around it.
- 5. Never insert metallic objects into the air vents of the RheoScan-AnD 300 as this could result in electrical shock, personal injury and equipment damage.
- 6. Always set the main switch on the power supply unit to "O" (OFF) before connecting the power cord to the wall outlet.
- 7. Always ensure that the grounding terminal of the Rheoscan-D and that of the wall outlet are properly connected. The power cord should be connected to a grounded, 3-conductor power outlet.
- 8. To avoid potential shock hazard, make sure that the power cord is properly grounded.
- 9. Be sure to insert the test kit holder, the main switch to "O" (OFF) and unplug the power cord before moving.

Safety Symbols

The following symbols are found on the RheoScan-AnD 300. Study the meaning of the symbols and always use the equipment in the safest possible manner.

Symbol	Meaning	
\triangle	Caution	
I	ON (Power)	
	OFF (Power)	
(4)	Protective earth (Ground)	
·	Warning for laser radiation	

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1. Introduction

The RheoMeditech.,Inc. provides a new research tool named RheoScan-AnD 300 that is a simple and fast computer controlled instrument for users.

The RheoScan-AnD 300 system can measure cell deformability as well as cell aggregation with simple and easy operation and provide graphical charting of the results as well as archiving data. Hence the Rheoscan-D technology guarantees the exceptionally precise and user-independent results about the cell deformability.

The RheoScan-AnD 300 uses the micro-channel test kit to provide ease of use, fast performance and more safety in cell deformability/aggregation measurements. This model enables the user to determine cell deformability/aggregation of cells without washing or cleaning process after use.

The RheoScan-AnD 300 is an easy, compact, convenient and credible system to provide high quality results. The model RheoScan-AnD 300 is a "compact system" with high accuracy comparing with other conventional complex equipments.

2. Installation



RheoScan-AnD 300 System and Components

When you receive the RheoScan-AnD 300 system for the first time, you will find the following components in your package.

[Instrument part]

RheoScan-AnD300 main system

Power cord (1.5 m): 1 ea

USB cable: 2 ea

Fuse(spare): 5 ea

Brief manual & User's manual : 1 ea

Installation USB Memory: 1ea

[Consumable part]

Deformability Test Kit (RSD-K02): 1 Box (20 /box) - solutions

Aggregation- I Test Kit (RSD-K01): 1 Box (20 /box)

Aggregation-Ⅱ Test chip (RSA-C01): 1Box(20/box)

(This part does not apply to RheoScan-D 300)

NI VISION RUNTIME LICENSE: 1ea (written on the USB Memory body)

□ Operating System The RheoScan-AnD300 is controlled by a Window-compatible computer program (RheoScan-ACE) based on Windows-XP Professional and Window7 operating system
☐ Electric Power The RheoScan-AnD 300 is powered by 110/230 V~, 50-60Hz, 30W
$\hfill \square$ PVP solution In the RheoScan-D system, a medium solution (RSD-P01) is supplied, which is Poly Vinyl Pyrrolidone (PVP, MW = 360,000) dissolved in phosphate-buffered-saline solution. The solution osmolality is 300 mOsm/kg and its viscosity is in the range of 30 \sim 32 mPa-s at 37°C.
Test Kit The RheoScan-AnD Test Kit (RSD-K01 or RSD-K02) is a disposable test kit, which consists of a sample chamber, microchannel, waste sample chamber, and rubber cap. The Test Kit is made of transparent plastic, which is disposable after use. This disposablility make it possible for the RheoScan-AnD system to be used in clinical environment. The typical disposable kit loads the volume of 0.5 ml sample (for deformability, 6 μl of whole blood in 600 μl medium solution). The dimension of the microchannel is 4mm width and 40 mm length. The height of the microchannel ranges is $190{\sim}230~\mu m$. For each test kit, the channel height is specified on the test kit cover.
□ Test chip - (This part does not apply to RheoScan-D 300) The Test Chip (RSA-C01) is a disposable test kit, which consists of a sample chamber, micro-stirrer, microscopic observation window, and two inlets. The Test Chip is made of transparent plastic, which is disposable after use. This disposablility make it possible for the Rheoscan system to be used in clinical environment. The typical disposable kit loads the volume of 8 μl of whole

blood. The dimension of the test chamber is 4mm diameter and 0.3mm depth.

☐ Measurement technique

The principles of the technique used in the RheoScan-AnD 300 are the well-known methods. For deformability test, it adopts the laser-diffraction method, whereas for aggregation, it does light-transmission. Both methods implement in a small, highly advanced microfluidic rheometry combined with optical devices.

☐ Image acquisition and analysis

The light source is a red diode laser ($\lambda = 635$ nm). For deformability, the red light scattered by the cells in the sample is projected onto the screen and caputered by detector (CCD camera). Then image analysis program determines the elongation index (EI) to represent the cell difformability of the sample. For aggregation, the transmitted light is detected by photodiode and recorded over 120 s and analyzed for aggregation indices.

RheoScan-AnD 300



Power cord













User's manual



Installation USB Memory



Rheoscan-D Test Kit &chip

Medium Solution

Figure 2-1. The RheoScan-AnD 300 system configuration



Hardware Description

The front of the RheoScan-AnD-300 has the control button, LED lamp and test kit loading door. (Figure 2-2)

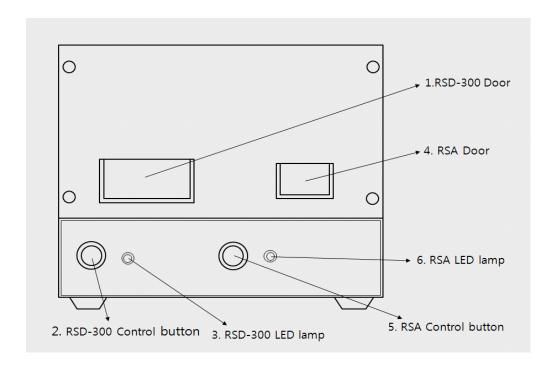


Figure 2-2. The front side of the RheoScan-AnD 300

- Door: There are two doors. The left hand side one is for measurement of deformability and critical shear stress. The right hand side door is for measurement of RBC aggregation such as AI and M.
- 2. LED lamp: Indicate either the Power-on when steady light-on or operationg mode when blinking.
- 3. Button: to run/start a test, push the button either button "300" or button "RSA".
 - Run/Start : Perform all testing procedures of automatic operation

The rear panel of the RheoScan-AnD 300 has the power switch, fuse box, power plug, USB camera port, and USB sreal port. (Figure 2-3)

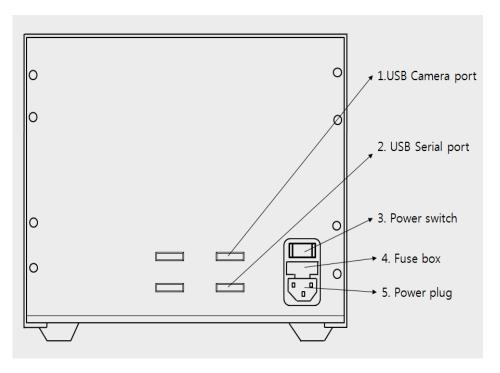


Figure 2-3. The rear side of the RheoScan-AnD 300

- ① USB Camera port
- 2 USB Serial port
- ③ Power switch: Main power on/off control.
- ④ Fuse box: Include a specified fuse in the box
- ⑤ Power plug: Connects the RheoScan-AnD 300 power cord to wall outlet



Connecting the Components

The following steps will guide you through the process of connecting the components.

- 1) First of all, connect the power cord to RheoScan-AnD-300 power socket, and plug the mains power cord into a wall outlet. The power cord should be connected to a grounded, 3-conductor power outlet.
- 2) Connect the USB cable to the USB serial port.
 - ** Configuration of port **
 - Connect the USB cable to the USB port on the rear panel and computer. Then, a USB drive program will be automatically installed on the computer. If the computer did not recognize the USB cable, please install the USB driver (as shown below) in the supplied "Installation USB Memory"



- 2. Install RheoScan-ACE-V2.1 on computer.
- 3. After installing RheoScan-ACE V2.1, the corresponding icon of RheoScan-ACE V2.1 would be generated. Execute the icon and click the "Configuration" button. Then, in the 'Port Configuration', the corresponding port would be automatically selected. If not, user has to select the correct port number.



4. Click the "Check Comm" button for checking whether the correct port was selected or not. If OK, the following message would be shown. If not, select another port number.

```
5. RSAnD-300 VER 1,1 2009-09-15
```

3) Connect USB Camera cable with the USB camera port on the rear panel.

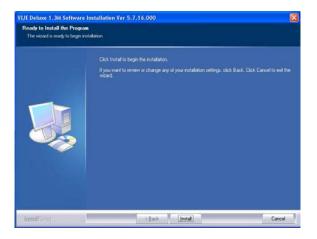
⚠Caution: Prior to connect USB camera to PC, the camera dirver program must be installed.



Installation of the Software

(1) Installation of Web-Camera Driver

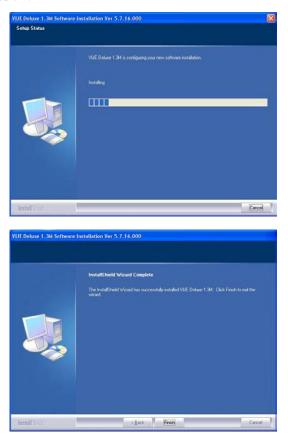
- 1) Make sure that RheoScan-AnD 300 system should not be connected with your PC before the installing the camera driver program.
- 2) Insert 'USB Memory' to the 'USB Port' of computer.
- 3) Run "*Camera driver setup.exe*" file to start the installation. Then you will see the below.



4) Click "Install" to continue. If the following window pops up, choose "continue anyway".



5) Then, the installation of camera dirver starts. Follow all the procedures and click "Finish".



6) RheoScanAnD- 300 with your PC using the USB cable, and "Add New Hardware Wizard" will show up.

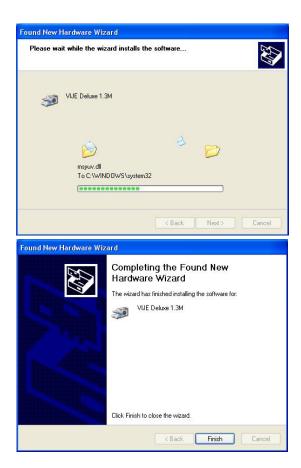


7) Select "Install the software automatically (Recommended)", then click "Next" button.

8) If the following window pops up, choose "continue anyway".



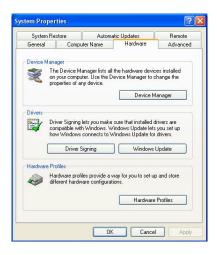
9) Then the hardware installation starts. Follow all the procedures and click "Finish".



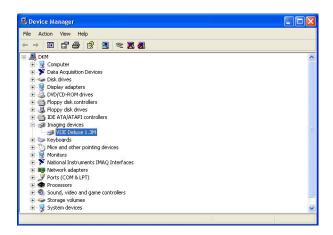
10) To make sure the installation is successful, click on *Start*, point to *Settings*, and open the *Control panel*. Then, double click the *System* icon.



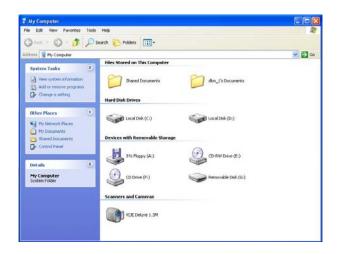
11) Click "Hardware", and open "Device manager" when the system properties window appears.



12) Double click "imaging Devices" to find "VIJE Deluxe 1.3M".



13) Then, click "My computer", the "VIJE Deluxe 1.3M" camera should also be listed there.



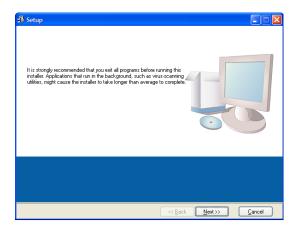
14) If you can find it, the camera is properly installed.

(2) Installation of Rheoscan-ACE V2.1

- 1) RheoscanACE-V2.1 needs support of Microsoft .NET Framework 1.1 or higher version, run "MS .NET Framwork 1.1 Package.exe" to install it firstly if it has not been installed on your computer.
- 2) Run "setup.exe" file. Initialization of installation starts. Then you will see the below.



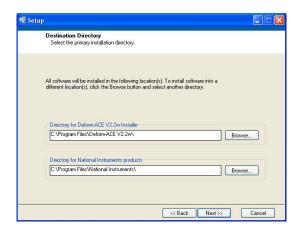
3) Click "Next" button to continue when you see the below.



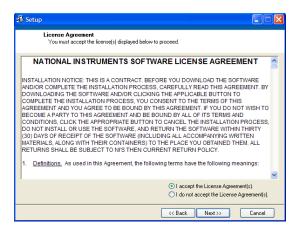
4) Then, RheoscanACE-V2.1 would be installed on the default directory (C:\ProgramFiles\RSAnD-300V2.1\).

Instead of the default directory, another directory can be used using "But a second content of the default directory, another directory can be used using "But a second content of the default directory, another directory can be used using "But a second content of the default directory, another directory can be used using "But a second content of the default directory, another directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using "But a second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second content of the default directory can be used using the second con

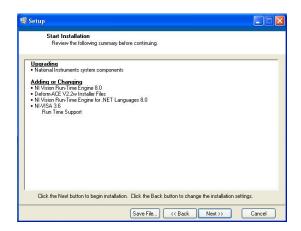
Instead of the default directory, another directory can be used using "*Browse*" button and select another one. Then, click "Next".



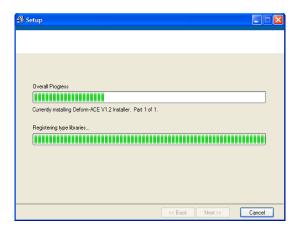
5) Choose "I accept License Agreement(s)" and click "next" button to continue.



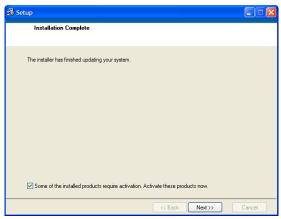
6) Click "next" button to start installation.



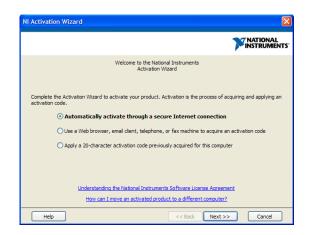
7) Then, installation starts. If you want to abort it, click "Cancel" button anytime.

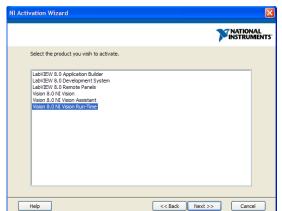


9) Click "Next" button to complete the installation process and start activation process of "NI Vision Runtime Engine". Activation process needs internet connection.



9) Choose "Automatically activate....." and click "Next" button to continue.





10) Then, select "Vision: NI Vision Run-Time". Click "Next" button to continue.

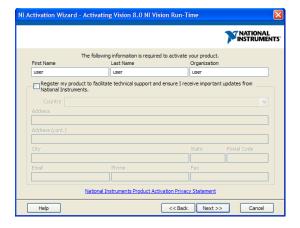
11) Input the provided serial number on the USB Memory. (in the Vision Development Module 2010 Runtime) Then, click "Next" button to continue.



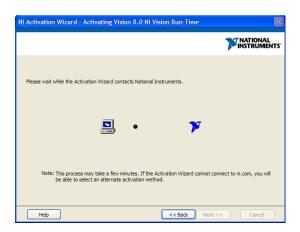
 \bigwedge

Note: Do not write anything in the blank.

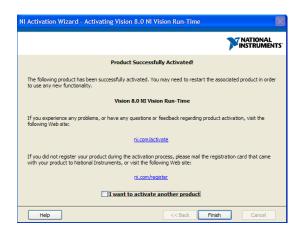
12) If you want, input your information here. Then, click "Next" button to continue.



13) Start activation process through internet connection.



14) The following window should appear after successful activation process.



- 15) Click "Finish" button in the previous step to complete installation.
- **16)** After successful installation and rebooting, an icon of "RheoscanACE-V2.1" will appear on your computer's desktop for your convenience.
- **△** Caution: Do not modify any contents in the installation folders if you are not sure.

3. Software Description



Introduction

Rheoscan-ACE V2.1 consist of three programs: Deform-ACE, Stress-ACE, and Aggrego-ACE. The detailed description of each program is as belows:

☐ Deform-ACE

Deform-ACE is a main program for RBC deformability test.

The main function is to operate the system with automatic measurement using Rheoscan-D Test Kit (RSD-K02).

To start Deform-ACE,

- 1. Click the icon of "RheoscanACE-V2.1"
- 2. Click "Deformability" button.

☐ Stress-ACE

Stress-ACE is a main program for RBC aggregation test- I

(**Threshold shear stress**). The main function is to operate the system with automatic measurement using Rheoscan-D Test Kit (RSD-K01).

To start Stress-ACE,

- 1. Click the icon of "RheoscanACE-V2.1"
- 2. Click "Aggregation-1" button.

☐ Aggrego-ACE (This part does not apply to RheoScan-D 300)

Aggrego-ACE is a main program for RBC aggregation test-2

 $(AI, t_{1/2}, M, Amp).$

To start Aggrego-ACE,

- 1. Click the icon of "RheoscanACE-V2.1"
- 2. Click "Aggregation-2" button.

The results of measurement are automatically saved in the user's specified directory. The measured data can be printed or transformed to a document report (PDF) file. Even though the acquired images are stored, they may be replaced by the following test.

3.2

Main Menu

Click "RheoscanACE-V2.1" icon and the main menu window would

be opened. Click the RheoScan logo would be connected. In the main menu window, there are five buttons as below:



Figure 3-1 Main menu

- Deformability
 Button for measuring RBC deformability
- 2) Aggregation- I

Button for measuring threshold shear stress for RBC aggregation.

- 3)Aggregation- Π (This part does not apply to RheoScan-D 300)
 Button for measuring RBC aggregation (AI, M, $t_{1/2}$, Amp, etc.).
- 4) Configuration

 Button for setting configurations (communication port, pressure constant, etc.)
- 5) Exit



1. RS232C

After installing RheoScan-ACE, configuration shoud be checked.

In the main window, click "Configuration" button. Then, the first page of configuration would appear as shown in Fig.3-2.



1) Port Configuration

For port number, user should find and specify suitable communication port number, which may be different on each computer.

Do not change the others (baud rate, data bits, stop bits and parity) if you are not sure.

2) Press. Senor Constant

Find the value written the rear panel of instrument.

User must input the correct values in the program when the program is newly installed or re-installed.

After input Port number and Press.sensor constant, click **SAVE** button.

Then click "Check Comm." button to check whether the right communication port was selected. If so, there would be some response in the blank box. If not, there would be no response.

2. Deformability configuration

This is for configuration for Deformability measurement program. As shown in Fig.3-3, user can check or set configurations such as camera view, sampling config, geometric dimension of microchannel, and result storage.

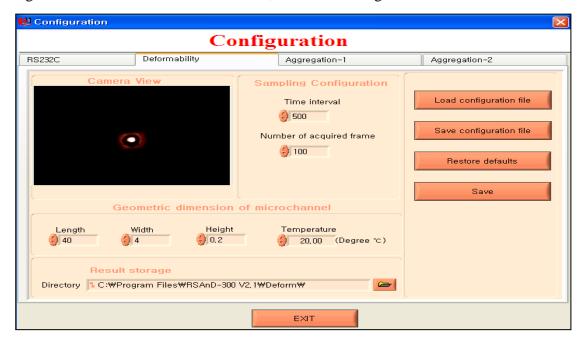


Figure 3-3 configuration funcion

1)CameraView

This enables to check the operation of camera and diode laser. There should be a red light image on the camera.

2) Sampling

User can determine the sampleing time interval as well as number of picture frames. .But, sampling interval time should greater than 500 ms (0.5 s).

3) Geometric dimension of microchannel

Each disposable Test Kit (RSD-K01 or RSD-K02) has unique value of channel depth. Thus, user must type in the correct value shown in the label of vinyl cover of each test kit. However, the length and width of the test channel are fixed as shown in the window as default values. Thus, do not change the default values if you are not sure.

Temperature is set at 20°C. User can change the temperature above room temperature.

4) Result Storage

User can specify a directory to store the test results. (After clicking the button, browse directories, select a directory, and click the button Select Cur Dir for setting. Then, the result file after each mesurement would be stored under the specified directory as the format of .txt file.



In order to retrieve the saved configuration, user can brwose the configuration files in the default directory and select the desired file. After loading a configuration file, all the configurations are set as specified in the loaded configuration file. The format of configuration file is *.cfg* and stored in

[C:\Programfiles\RSAnD-300V2.1\configuration\].



User can specify customized configurations and save them as a new file name. It would be better to save in the directory of

[C:\Programfiles\RSAnD-300V2.1\configuration\].



With this button, user can initialize the configurations with manufacturer's default values. After initializing the configurations, user must check and revise the "port configuration" and "press sensor constant".



Button to save and apply the altered configurations.



Button to exit to main menu.

3. Aggregation- I configuration

This window is for configuration of Aggregation-1 program. As shown in Fig.3-4, user can specify sampling configuration, geometric dimension of microchannel, temperature and result storage.

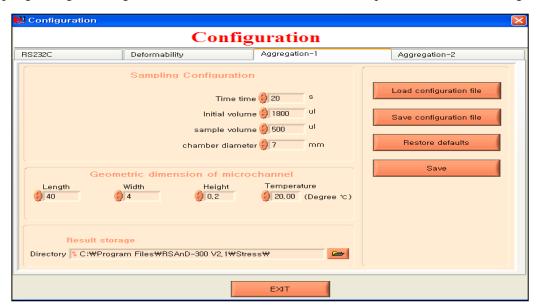


Figure 3-4 configuration funcion

1) Sampling

User can determine the sampleing time interval as well as number of picture frames. But, sampling interval time should greater than 500 ms (0.5 s).

Since the initial volume, sample volume and chamber diameter are fixed by manufacturer, user should not change these if you are not sure. User should load the precision amount of sampling volume (0.5 ml).

2) Geometric dimension of microchannel

Each disposable Test Kit (RSD-K01 or RSD-K02) has unique value of channel depth. Thus, user must type in the correct value shown in the label of vinyl cover of each test kit. However, the length and width of the test channel are fixed as shown in the window as default values. Thus, do not change the default values if you are not sure.

Temperature is set at 20°C. User can change the temperature above room temperature.

3) Result Storage

User can specify a directory to store the test results. (After clicking the button, browse directories, select a directory, and click the button Select Cur Dir for setting. Then, the result file after each mesurement would be stored under the specified directory as the format of .txt file.

4. Aggregation-Ⅱ config (This part does not apply to RheoScan-D 300)

This is configuration window for "Aggregation-2" program. As shown in Fig.3-5, user can specify test time, result storage, rotation time, rotation speed, etc.

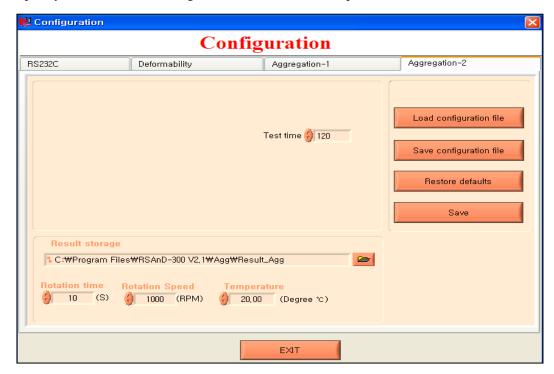


Figure 3-5 configration funcion

1) Test time

User can specify test time. The default value is 120 s.

2) Result Storage

User can specify the directory to save the test results. (With clicking button, browse directories and select a directory. Then, click the button Select Cur Dir.). Then, the result file after each mesurement would be stored under the specified directory as the format of .txt file.

3) Rotation time

User can change the motor-operation time. The default value is 10 seconds.

4) Rotation speed

User can change the rotational speed of motor. The default value is 1000 rpm.

5) Temperature

User can change the temperature above room temperature. The default temperature is 20°C.



Measurement Function

1. Deformability measurement mode

This is an initial window to measure RBC deformability after specifying configuration. In the main menu, clicking "Deformability" button, the window as shown in Fig 3-6 would appear.

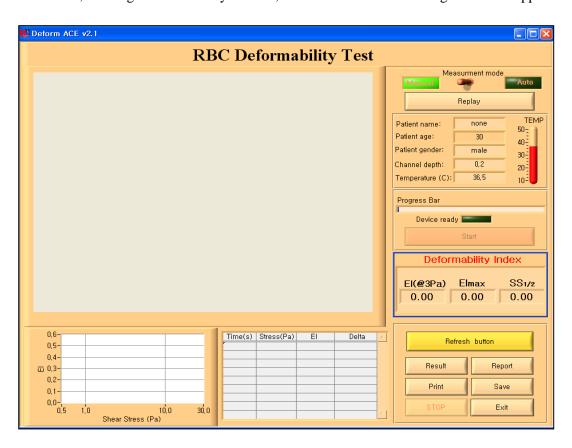
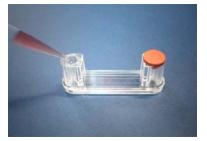


Figure 3-6 Measurement

1) Preparing blood sample in test kit

With precision pipette, load $6\mu l$ of whole blood (with EDTA) into the provided PVP solution tube, mix and load the mixed liquid into the test kit.

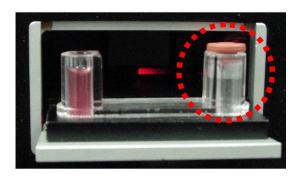




2) Loading test kit

Then, load the test kit in the RheoScanD-300. The test kit should be laoded in the device as shown below. The **rubber cap-side** should be on the **right-hand side**.

Left-hand side

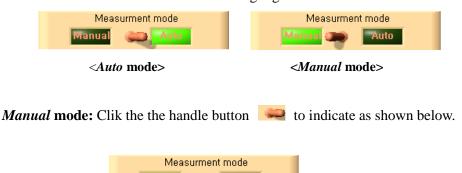


right-hand side

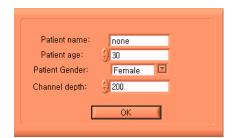
3) Measurement mode

There are two measurement modes, Manual mode(default mode) and Auto mode.

User can click the knob button in the upper right corner panel and select measurement mode. The selected mode will be indicated with bright green color.



In this *Manual* mode, the measurement does not start, even though the control button in the RheoScanD-300 is pressed. If user presses the control button in *Manual* mode, then the following window automatically pops up and asks to type "Patient Name" and others.



After typing, click the OK button. If the typed information is correct, then click the red "Start" button to start the measurement.

(During measurement, the "Start" button is disabled.)

The *Manual* mode is designed for clinical use for handling many patients, which result file should be named uniquely. Each result file is to be saved as patient-named file.

△Caution: Since the <u>Manual mode</u> is the <u>default</u> mode, all information below will be given based on the <u>Manual mode</u>, unless otherwise specified.

Auto mode: This is the default mode. Click the knob button as below.



Auto mode

In this *Auto* mode, the measurement starts automatically when the control button of the front panel in the RheoScanD-300 is pressed.

(In the case of Auto mode, start button is always disabled.)

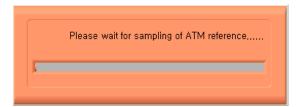


After completing a test, the diffraction images and the corresponding graph would be repayed and replotted, respectively. Click the "Replay" button.

5) Sampling of Reference Pressure

This function is to measure the reference pressure in terms of voltage. Before each measurement, the pop-up window as below comes out and measures the atmospheric pressure for a few seconds.

To make the function properly, do not operate anything till the following window pops out.



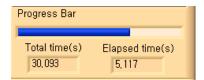
\triangle Caution:

For *auto* mode, the result file will be automatically named after string of 'patient name' and number orderly like Brown000, Brown001, and so on. Without specifying the patient name, the result file name will be test000, test001 and so on.

For *Manual* mode, however, user must input patient name each measurement. If not, for multi-measurements, the previous result file will be overwritten by the next measurement file or the result file can not be saved properly.

6) Progress bar

This progress bar indicates the progression status in the whole course of measurement. So, user can visually see the progressing status of the measurement. After completing measuremen, the duration spent for measurement and image processing will be shown in the indicator, respectively as below.



7) Image window

Image window is employed to display the images (diffraction patterns) captured by the CCD camera and the frame grabber.

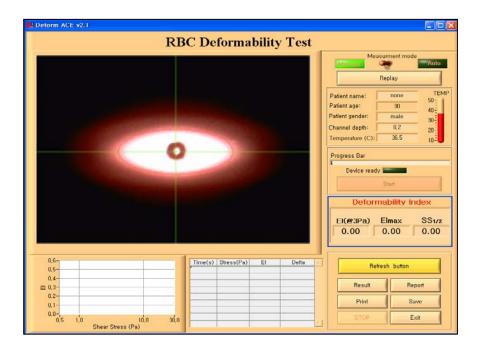
When the control button is pressed with loading the RheoScan-D Test Kit (RSD-K02) having the blood sample, the diffraction patterns appear in the image window.



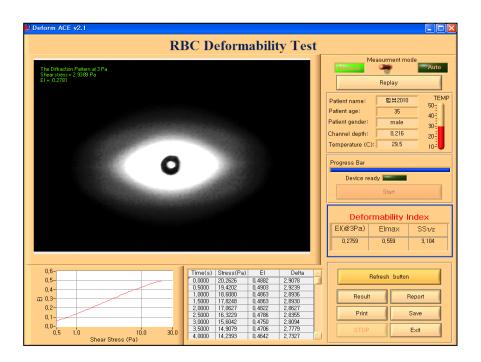
The diffraction images are to be stored in the directory of <installation directory>\image\... automatically.

Then, the images undergo the image-processing to determine the lengths of vertical and horizontal axes, respectively, as shown in the below.

The red closed curve is the ellipse-fitting edge of corresponding diffraction pattern. The two green orthogonal lines denote the vertical and horizontal axes, respectively.



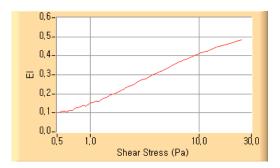
After measuremet, a diffraction image measured at (or near) 3Pa would be shown on window and the calculated results such as EI(Elongation Index), EI_{max} , and $SS_{1/2}$.



8) Results

a) Deformability curve

After measurement, user can find a graph of relationship between Elongation Index (EI) and Shear Stress.

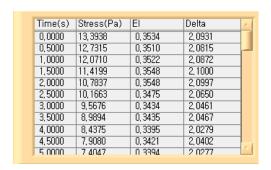


b) Result table

Result table lists the detail data including time, stress, elongation index (*EI*) and Delta (δ).

EI is the Elongation Index, defined as the (A-B)/(A+B), where A and B are the lengths of major and minor axes, respectively.

Delta(δ) is the length ratio of major axis to minor axis of the fitting ellipse (A/B).



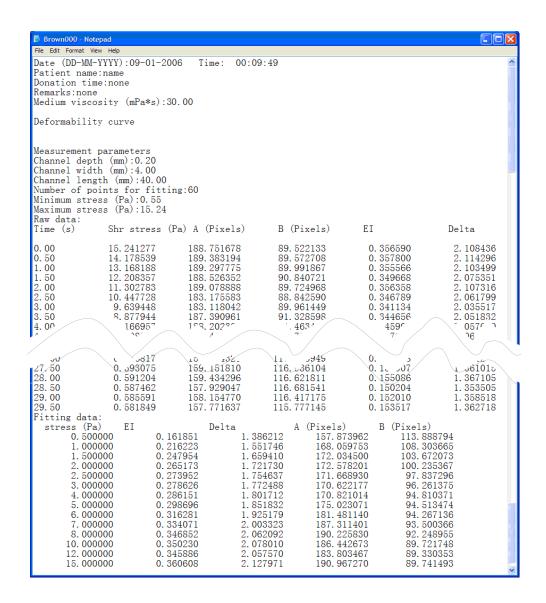
c) Deformability Index

EI, EImax and SS1/2 are deformability indices. The EI value at 3 Pa is selected as a representative deformability value for easy comparison between samples along various shear stresses.

Deformability Index				
EI(@3Pa)	El max	SS 1/2		
0,2808	0,554	3,046		

d) Result file

The result file would be saved in a format of *.txt* in the specified directory [c:/ program file/ RSAnD-300V2.1/ Deform/ Result_Deform/]. In the result file, various informations including date, patient name, measured data and curve-fittied data.



10) Refresh button

Even though "Reference Press." value can be renewed automatically before each test, user can click button to refresh the "Reference Press." value manually to get the latest value before new test.

11) Result and Report buttons

With Result button and Report button, user can check the raw data and print-version data, respectively.



12) Print button

Click Print button to print report of measurement. After clicking, the following window comes out.



A Caution: This function needs support of *Microsoft Word 2000* or higher versions.

a) Print button

Click the "Print" button to print report using a default printer. For some printer, the following window may come out after clicking "Print" button, please click "Yes" to continue. Sample of measurement report is attached on next page.



Tip: User can print a report as PDF file. This function should be supported by a virtual printer of Adobe[®] PDF as default printer.

b) Cancel button

Click it to close the print report window without printing.

13) Save button

After test, click save button save the test data, which would be stored in a specified directory such as [c:/ program file / RSAnD-300V2.1/ Deform /Report_Deform/].

RBC DEFORMABILITY ANALYSIS

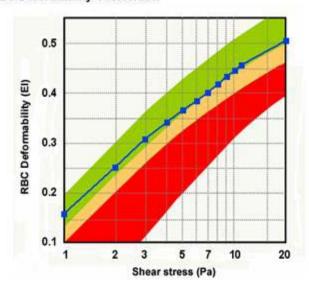
RheoScan-D



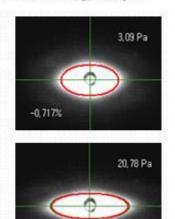
Name/ID	Patient name					
Date	2007-06-07	Time:	11:12:52			
Age	30		Gender	Male		



RBC Deformability Test Result



Diffraction Image Analysis



Comparison Analysis

Shear stress (Pa)	1.0	3.0	7.0	10	20
Measured El	0.158	0.307	0.401	0.445	0.504
Standard El	0.155	0.305	0.415	0.455	0.510
Percentage (%)	2.223	0.684	-3,386	-2.127	-1.092

Result Analysis

-3,210%

The measured RBC deformability (EI) is 0.307, which is in **normal** range and **0.68%** compared to healthy control.

Graphical Analysis



Research Data

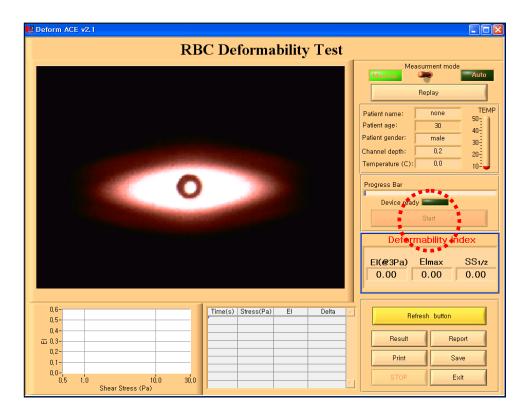
Channel depth (mm):0.194 ATM reference (V):2.5000 Time for 3Pa (s):9.50 Minimum stress (Pa):0.05 Maximum stress (Pa):20.78

14) Stop for emergency

This button is prepared for user to stop measurement during test.

If user clicks the button, RBC Deformability test and RBC Deformability test will stop. Then, the test kit loader of RBC Deformability will be ejected.

In order to restart after using "Stop" button, push the control button (named "300" in the fron panel. Then, the test kit loader would go into machine and click "Start".



15) Exit measurement

Click the "Exit" button to finish measurement mode. Then, the measment window is closed with withdrawing the test kit loader of RBC Deformability test

3.6 Exit

Click button on the main menu to exit RBC Deformability test.

⚠ Caution: After measurement, user should remove the used test kit from the loader. To conduct another measurement, user should load the new Test Kit on the loader and press the "Control button". Then, the automatic measurement will be conducted as explained above.

2. Aggregation - I Measurement Mode

After checking the configuration, user can click the "Aggregation-2" button in the main menu to measure critical shear stress for RBC aggregation.

Then, a measurement window would be popped out as shown in Fig 3-7.

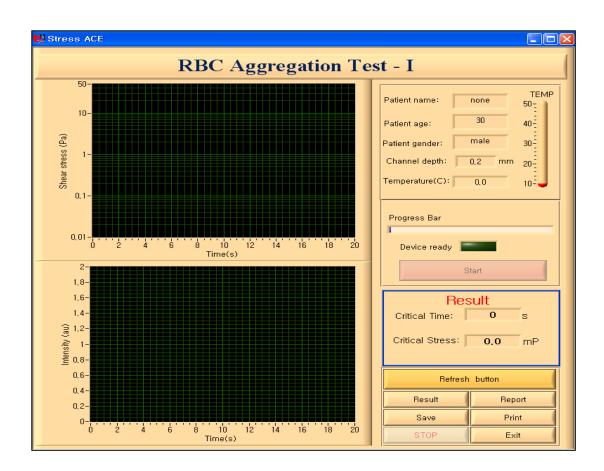


Figure 3-7 Critical shear stress Measurement

1) Sample preparation in a Test Kit

Fill the 0.5 ml of sample (whole blood with EDTA) in the test kit using precisio pipette.

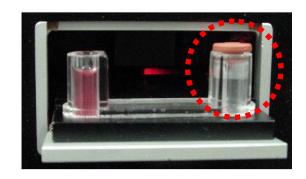




2) Loading test kit

Then, load the test kit in the RheoScan-D 300. The test kit should be laoded in the device as shown below. The **rubber cap-side** should be on the **right-hand side**.

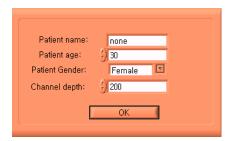
Left-hand side



right-hand side

3) Measurement mode

The measurement does not start, even though the control button in the RheoScan-AnD 300 is pressed. If user presses the control button, then the following window automatically pops up and asks to type "Patient Name, age and sex", and "Channel depth".



After typing, click the OK button or push "Enter key". Then test would be automatically started.

4) Sampling of Reference Pressure

This function is to measure the reference pressure in terms of voltage. Before each measurement, the pop-up window as below comes out and measures the atmospheric pressure for a few seconds.



5) Progress bar

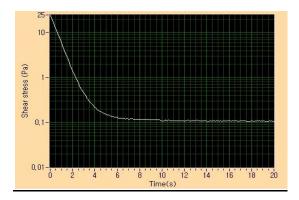
This progress bar indicates the progression status in the whole course of measurement. So, user can visually see the progressing status of the measurement. After completing measuremen, the duration spent for measurement and image processing will be shown in the indicator, respectively as below.



7) Results

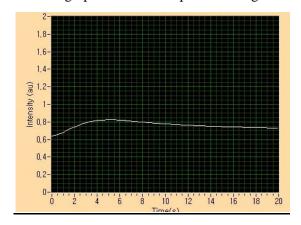
a) Shear stress vs. time curve

After measurement, user can find a graph of relationship between Wall Shear Stress vs. time.



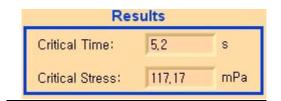
b) Light Intensity vs. time

User can also find a graph of relationship between light intensity vs. time.



c) Threshold values

During a progressive shear-stress decreasing procedure, disaggregation of RBCs stops and re-aggregation starts at certain point, this is called threshold point. Threshold point can be described as threshold-time and –shear stress.



d) Result file

The result file would be saved in the format of *.txt* in the specified directory such as [c:/ program file/RSAnD-300V2.1 /Stress /Result_Stress /]. Typical result file is as follows:

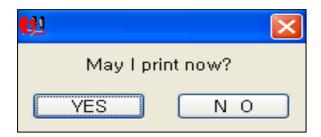
🕽 미국-1 - 메모상 파일(F) 편집(E) 서식(Q) 보기(\underline{V}) 도움말(\underline{H}) Date (YYYY-MM-DD):2009-03-14 Time: 13:28:42 Patient name: 미국-1 Patient gender: Female Patient age: 30 Channel depth(mm): 0.227 ATM reference(V): 0.0439 Minimum stress(Pa): 0.10 Maximum stress(Pa): 25.54 Results: Critical time(s): 5.20 Critical stress(mPa): 117.17 Raw data: Time (s) Stress (Pa) Intensity (au) Real Stress (Pa) 0.00000 0.63904 25.71538 25.54418 0.10000 21.65931 0.64217 21.79399 0.20000 18.88206 0.64476 18.99212 0.30000 16.50273 0.64789 16.59261 0.40000 14.39826 0.65132 14.47094 0.50000 12.52351 0.65529 12.58137 0.60000 10.87029 0.65903 10.91544 0.70000 9.41398 0.66345 9.44822 0.80000 8.14227 0.66826 8.16718 0.90000 7.03055 0.67253 7.04745 1.00000 6.06651 0.67749 6.07658 1.10000 5.23785 0.68375 5.24213 1.20000 4.51584 0.69206 4.51514 1.30000 3.90871 0.70061 3.90385 1.40000 0.70755 3.37541 3.36694 1.50000 2.92005 0.71487 2.90852 1.60000 2.53444 0.72060 2.52033 1.70000 2.19805 0.72594 2.18171 1.80000 1.91089 0.73105 1.89265 1.90000 1.66475 0.73547 1.64489 2.00000 1.45554 0.74097 1.43430 2.10000 1.27914 0.74623 1.25674 2.20000 1.12325 0.75188 1.09984 2.30000 0.98788 0.75691 0.96358 2.40000 0.87301 0.76218 0.84797 2.50000 0.75300 0.77866 0.76714 2 60000 0 60251 A 7794A 0 66620

8) Refresh button

Even though "Reference Press." value can be renewed automatically before each test, user can click button to refresh the "Reference Press." value manually to get the latest value before new test.

9) Print button

At Aggregation Test-1 this, print function is not available. However, the result file, can be saved in the specified folder and printed the saved document.



a) YES Print button

Click the "Print" button to print report using a default printer. For some printer, the following window may come out after clicking "Print" button, please click "Yes" to continue. Sample of measurement report is attached on next page.



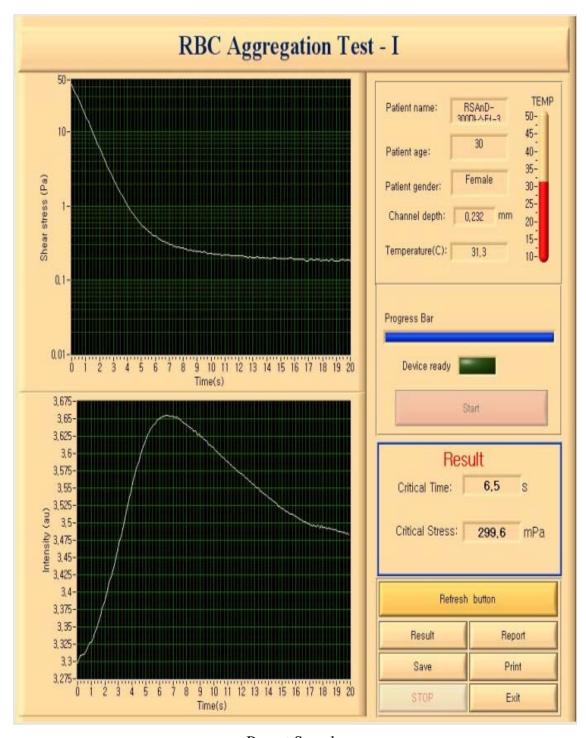
Tip: User can print a report as PDF file. This function should be supported by a virtual printer of Adobe[®] PDF as default printer.

b) N 0 Cancel button

Click it to close the print report window without printing.

10) Save button

After measurement, click the save button and the rest result file would be saved in the specified directory such as [c:/ program file/RSAnD-300V2.1 /Stress/Report_Stress/].



< Report Sample >

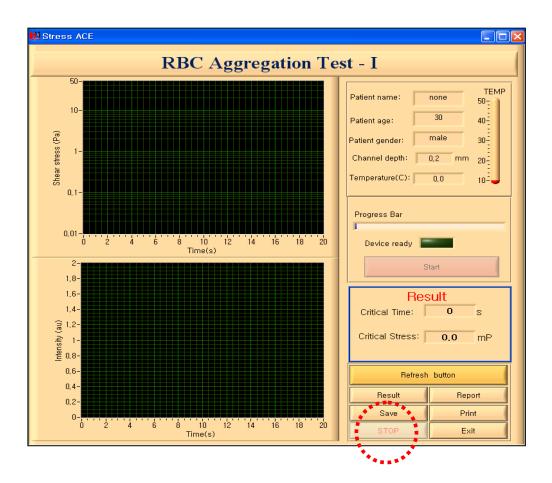
11) Stop for emergency

This button is prepared for user to stop measurement during test.

If user clicks the button, RheoScan-D 300 and Rheoscan-A will stop.

Then, the test kit loader of Rheoscan-D 300 will be ejected.

In order to restart measurement after using "Stop" button, push the control button (named "300" in the front panel). Then, it would be ready to next test.



12) Exit measurement

Click the "Exit" button to finish measurement mode.

⚠ Caution: After measurement, user should remove the used test kit from the loader. To conduct another measurement, user should load the new Test Kit on the loader and press the "Control button". Then, the automatic measurement will be conducted as explained above.

3. Aggregation-■ Measurement Mode-(This part does not apply to RheoScan-D 300)

After checking the configuration, user can click the "Aggregation-2" button in the main menu to measure critical shear stress for RBC aggregation.

Then, a measurement window would be popped out as shown in Fig 3-8.

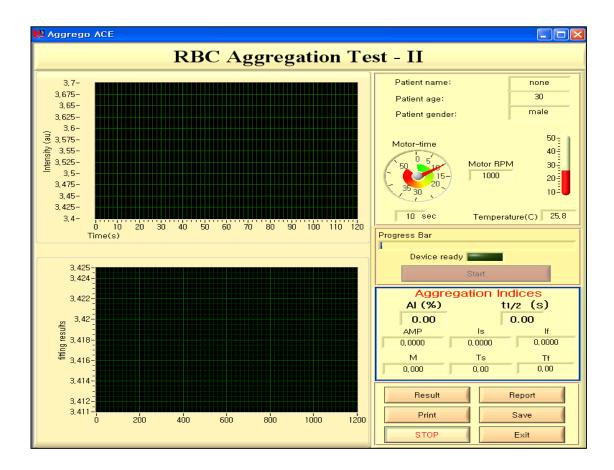
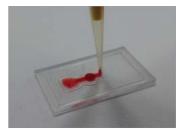


Figure 3-8 Measurement

1) Filling blood sample in test chip

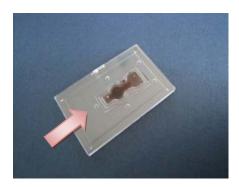
Using a precision pipette, load blood sample of $8\mu l$ (whole blood with EDTA) into test chip as shown in below figure.





2) Loading test chip

Load the test chip in the test chip loader of RheoScan-AnD-300 as shown in figure. Note that the direction of loading test kit must be checked as shown in below figure.

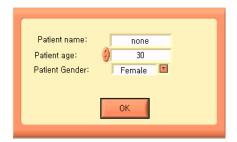




3) Measurement mode

Push the control button (named as "RSA") and the test chip would go into machine. Then, a new window would be popped out as below.

Type the patient name, age, and gender.



Then, click "OK" or push "Enter key". Then, click "Start" button or push "Enter key".

4) Progress bar

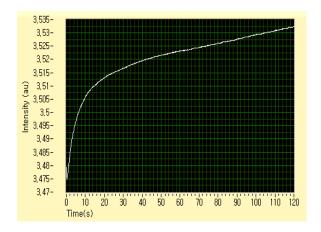
This progress bar indicates the progression status in the whole course of measurement. So, user can visually see the progressing status of the measurement. After completing measuremen, the duration spent for measurement and image processing will be shown in the indicator, respectively as below.



5) Results

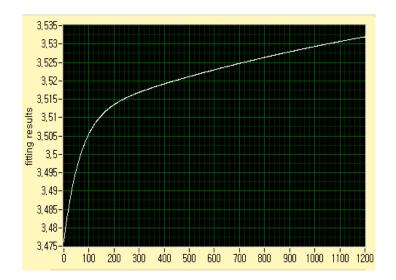
a) Intencity vs. time curve

During measurement, user can see the Light intensity versus time curve (s acalled Syllectogram" as time foes on up to 120 seconds.



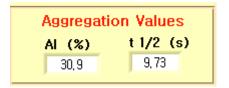
b) Fitting result

After measurement, the fitted curve for light intensity vs. time would be shown in the below graph window.



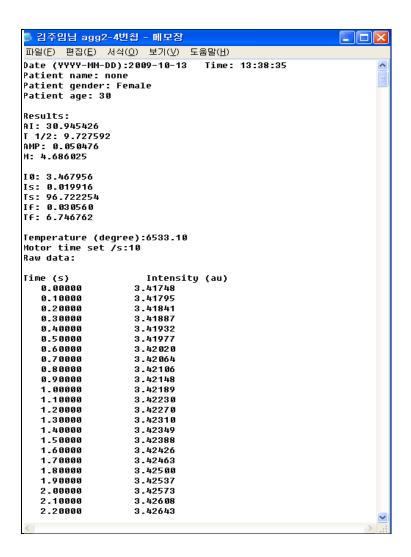
c) Aggregation Indices

After curve-fitting, several aggregation indices would be calculated and shown in the window. Typical indices are AI, $t_{1/2}$, M, Amp, t_s , t_f , etc.



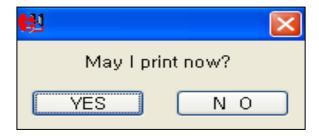
d) Result file

The result file would be saved in the format of .txt by clicking save button in the specified directory such as [c:/ program file/RSAnD-300V2.1 /Agg /Result_Agg].



7) Print button

At Aggregation Test-Ⅱ, print function is not available. However, the result file can be saved in the specified folder and printed the saved document.



a) YES Print button

Click the "Print" button to print report using a default printer. For some printer, the following window may come out after clicking "Print" button, please click "Yes" to continue. Sample of measurement report is attached on next page.



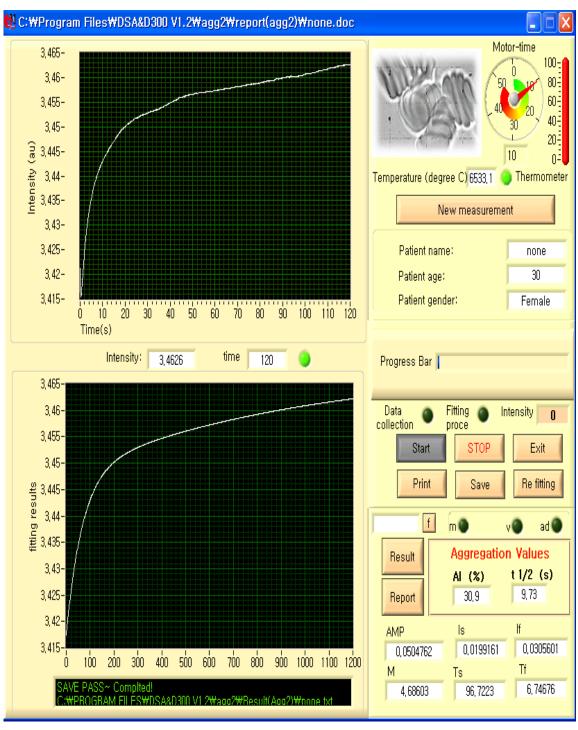
Tip: User can print a report as PDF file. This function should be supported by a virtual printer of Adobe[®] PDF as default printer.

b) N O Cancel button

Click it to close the print report window without printing.

8) Save button

After measurement, cluck the save button to save the tested results. Then, the result filee would be saved in the the specified directory such as "[c:/ program file/RSAnD-300V2.1 /Agg /Report_Agg /].



< Report Sample >

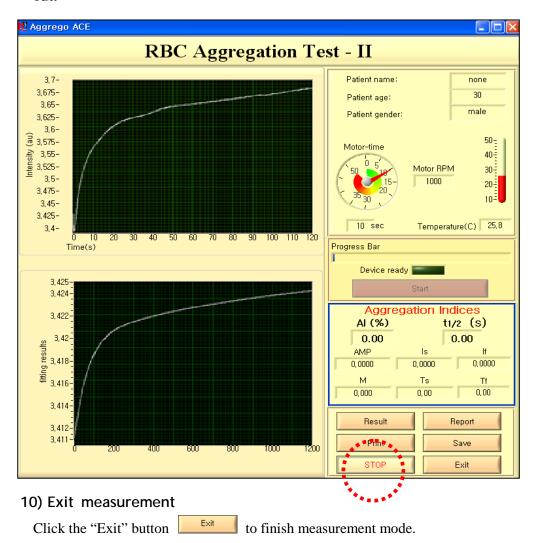
9) Stop for emergency

Stop button is for emergency stop during measurement.

If this button is clecled, Aggregation-Ⅱ program would be inactive and the

operation of RheoScan-AnD 300 would be stopped and the test chip loader would come out.

In order to restart the machine after using "Stop" button, push the control button (named "RSA" in the front panel), then a new window would be poped out.



⚠ Caution: After measurement, user should remove the used test kit from the loader. To conduct another measurement, user should load the new Test Kit on the loader and press the "Control button". Then, the automatic measurement will be conducted as explained above.

4. Getting Started

4.1

Introduction

The RheoScan-AnD 300 is an ektacytometer using laser-diffraction technique with a microfluidic disposable channel.

The essential feature of the RheoScan-AnD 300 is the continuous measurement of cell deformability while shear stress is decreasing. The instantaneous shear stress and the corresponding diffraction image are recorded in a computer data file.

Another feature is the use of the disposable test kit, which eliminate the washing process after use in the conventional ektacytometry.

For use at point-of-care, the RheoScan-AnD 300 is fully automated and one-touch operation leads to a complete test within 50~120 seconds.

RheoScan-AnD 300 experiment needs the following items.

Deformability

Blood: 6 µl

Medium Solution (RSD-P01): 0.6 ml Rheoscan-D Test Kit (RSD-K02): 1 ea

Mixing tube: 1ea

Pipette and tips (1~50 µl and 0.01~1 ml)

Aggregation-I

Blood: 0.5ml

Rheoscan-D Test Kit (RSD-K01): 1 ea

Pipette and tips (0.01~1 ml)

Aggregation ☐ (This part does not apply to RheoScan-D 300)

Blood: 8µl

Rheoscan-A Test chip (RSA-C01): 1 ea

Pipette and tips (1~50 μl)



Preparation of sample

Preparion of Blood sample

- 1) Draw the venous blood sample from antecubital vein into a K2 EDTA containing Vacutainer.
- 2) Shake the bottle gently for several seconds with hand or shaker.

1) Deformability

- 1) Prepare 0.6 ml of the medium solution in the mixing tube.
- 2) Aspirate $6 \mu l$ from the Vacutainer and inject it to the mixing tube.
- 3) Shake the mixing tube gently with hand for several times.
- 4) Check visually if the blood sample is completely mixed with the medium solution.
- 5) Aspirate the mixture (0.5 ml) using a pipet tip (blue one) and dispense it into the Rheoscan-D Test Kit (RSD-K01).

2) Aggregation- I

- 1) Aspirate 0.5 ml from the Vacutainer and inject it to the test kit (RSD-K01).
- 2) When dispensing the blood in the test kit, any bubble should not be generated.

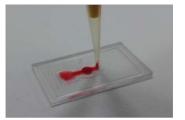




3) Aggregation- Π (This part does not apply to RheoScan-D 300)

- 1) Load 8µl of blood into a test chip (RSA-C01)
- 2) With loading blood into a test chip, any bubble should not be captured in the test chip.





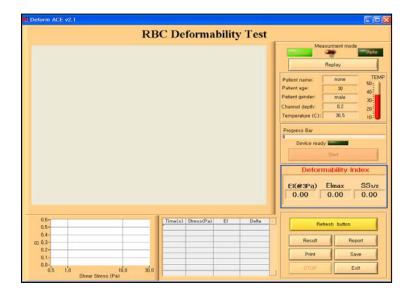


Operation for Deformability Test

- 1) Connect RheoScan-AnD 300 power cable, USB cable and USB camera cable.
- Tun on the power switch located on the rear panel.
 (Then, the Test Kit loader (left side) would be automatically ejected.)
- 3) Click the icon of RheoscanACE-V2.1.



- 4) For configuration of communication port, refer to the page 8.(User should select the correct port for communication between PC an instrument)
- 5) For the pressure constant, type the correct value written panel on the instrumnet.
 - 6) Click "Deformability" for deformability measurement.

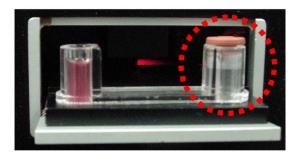


- 7) If necessary, change the measurement mode by clicking the knob (You may skip this step if you want to use *Manual mode*, which is default.)
- 8) Load a test kit (RSD-K01/02) on the test kit loader.

⚠Caution:

- The Rheoscan-D Test Kit should be placed as shown below.
- The rubber capped chamber must be righthand side.
- The blood sample should be in the left chamber.
- The right chamber should be empty.
- The rubber cap should be tightly inserted into the chamber.
- The microchannel surface should be free of any finger print or foreign material.

Left-hand side



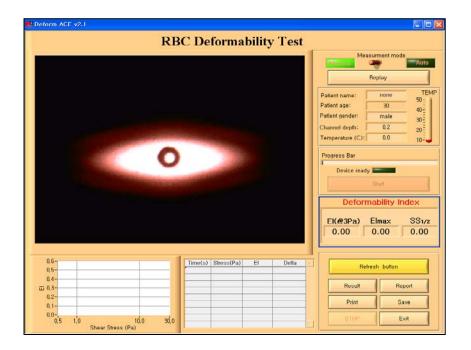
right-hand side

Caution: Before measurement, you must check whether the right chamber of the test kit is empty. If blood sample may be in the right chamber of the test kit, it may be aspirated into the system, which causes serious problems in the RheoScan-D300 system.

9) Push the control button (named "300" located in the front panel of RheoScan-AnD 300). Then, test kit would automatically go in and the below window would pop out.



- ⚠ Caution: If the test kit loader would come out, then wait 5 seconds and push the control button, again. This would happen when the machine is busy due to changing measurement mode.
- 9) Input the information of the loaded blood sample in the pop-up window. Click "OK" button, then reference pressure will be sampled automatically again, and a progress bar will pop out. You should wait until the pop-up window disappears.
- 10) Click "Start" button on the screen when "Device ready" LED lights up, and then following series of operation will be automatically conducted.
 - -The diffraction images display as the shear stress decreases with time.
 - -The image analysis is conducted while cleaning process (not displayed) is on going.
 - -The result table and graph will be displayed with representive deformability value.
 - -The Test kit will be automatically ejected while RheoScan-AnD 300 completes cleaning process.



⚠ Caution: While image analysis is in the middle of processing, Rheocan-AnD 300 may also be in cleaning process. The cleaning process may take for about 10 seconds, followed by automatic ejection of test kit. Please do not operate RheoScan-AnD 300 until cleaning process is over.

11) Check the measured indices such as EI @ 3 Pa, maximum EI (EI $_{max}$), and half shear stress (SS1/2).

Deformability Index				
El(@3Pa) El max SS 1/3				
0,2808	0,554	3,046		

- 12) Remove the Test Kit from the loader.
- 13) If necessary, click the "Print" button to print report, and click "Save" button to save the report file.
- 14) Repeat step 7 to 13 if user wants to continue measurement. (For **reproducibility test** with the same kit, repeat step 8 to 11.)
- 15) Click *Exit* button on the measurement window if you want finsh measurement.
- 16) Click *Exit* button on the main menu of Deform-ACE to exit.
 To insert the loader, press control button on the front panel for 2 seconds
- 17) Turn-off the main power-switch in the rear panel if the RheoScan-D300 is not going to use within 30 min. This will save the lifetime of the laser in the RheoScan-D300.

Caution: Before turning off the main power-switch, be sure to insert the test kit loader. Remove any test kit on the loader and press the control button. Then, you may turn-off the main power switch.

Definition of Cell Deformability

Cell deformability is representaed in terms of the elongation index defined as following.

Elongation Index (EI) =
$$\frac{A - B}{A + B}$$

EI : The elongation index of the cells

A : The length of major axis in the ellipsoidal diffraction image

B : The length of minor axis in the ellipsoidal diffraction image

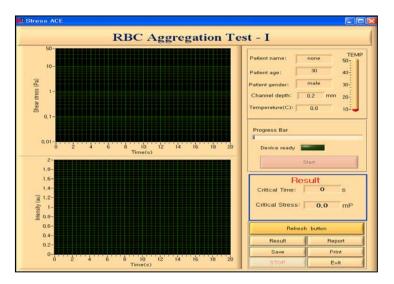


Operation for Aggregation-1 Test

- 1) Connect RheoScan-AnD 300 power cable, USB cable and USB camera cable.
- 2) Tun on the power switch located on the rear panel.(Then, the Test Kit loader (left side) would be automatically ejected.)
- 3) Click the icon of RheoscanACE-V2.1.



- 4) If necessary, select *Configuration* and adjust the confiuraions. (You should ensure the correct configuration of serial port, at least)
- 5) Click "Aggregation-1"

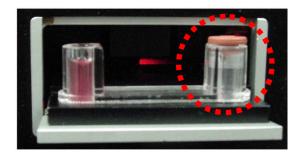


 $\boldsymbol{6}$) Place the Rheoscan-D Test Kit (RSD-K01) onto the loader.

riangleCaution:

The Rheoscan-D Test Kit should be placed as shown below.

- The rubber capped chamber must be righthand side.
- The blood sample should be in the left chamber.
- The right chamber should be empty.
- The rubber cap should be tightly inserted into the chamber.

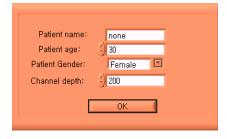


Left-hand side

right-hand side

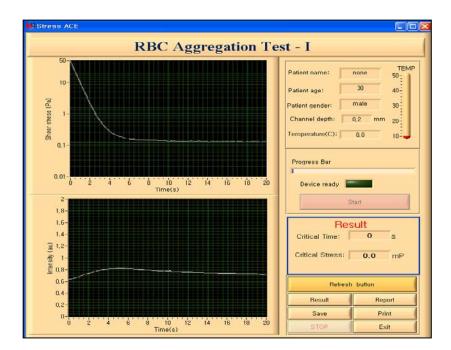
Caution: Before measurement, you must check whether the right chamber of the test kit is empty. If blood sample may be in the right chamber of the test kit, it may be aspirated into the system, which causes serious problems in the Rheoscan-D300 system.

7) Push the control button (named "300" located in the front panel of RheoScan-AnD 300). Then, the test kit loader would go into machine and a new window would pop out as below.

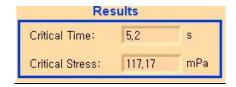


8) Type in the suitable information in the pop-up window. Click "OK" button, then reference pressure will be sampled automatically again, and a progress bar will pop out. Then following series of operation will be automatically conducted.

- -In the left upper window, the the shear stress would decreases with time.
- -In the left bottom window, the light intensity vs time curve (syllectogram) would bi displayed.
- -The test results (critical time, critical shear stress) would be displayed in the right table and graph.
- -The Test kit will be automatically ejected while Rheoscan-AnD300 completes cleaning process.



- ⚠ Caution: While image analysis is in the middle of processing, Rheocan-AnD300_may also be in cleaning process. The cleaning process may take for about 10seconds, followed by automatic ejection of test kit. Please do not operate Rheoscan-AnD300 until cleaning process is over.
- 10) Check the "Results" which are the main result indices for "Critical Time" and "Critical Stress"



- 11) Remove the Test Kit from the loader.
- 12) If necessary, click the "Save" button to save the report file.
- 13) Repeat step 6 to 11 if user wants to continue measurement. (For **repeatability test** with the same kit, repeat step 7 to 10)
- 14) Click *Exit* button on the measurement window if you want finsh measurement.
- 15) Click *Exit* button on the main menu of Aggregation-1 to exit.
 User can press control button on the front panel of Rheoscan-D300 for 2 seconds to insert the loader.
- 16) Turn-off the main power-switch in the rear panel if the RheoScan-AnD300 is not going to use within 30 min. This will save the lifetime of the laser in the RheoScan-D300.

Caution: Before turning off the main power-switch, be sure to insert the test kit loader. Remove any test kit on the loader and press the control button. Then, you may turn-off the main power switch.

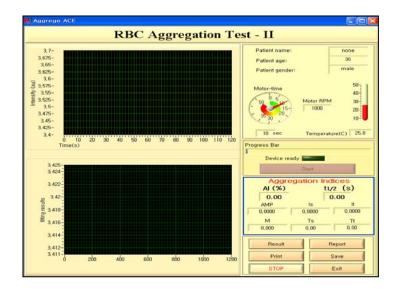


Operation Aggregation-II Test (This part does not apply to RheoScan-D 300)

- 1) Connect RheoScan-AnD 300 power cable, USB cable and USB camera cable.
- Tun on the power switch located on the rear panel.(Then, the Test Kit loader (left side) would be automatically ejected.)
- 3) Click the icon of RheoscanACE-V2.1.



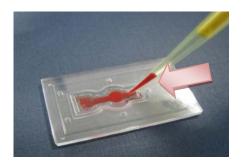
- 4) If necessary, select *Configuration* and adjust the confiuraions. (You should ensure the correct configuration of serial port, at least)
- 5) Click the button "*Aggregation-1*" to get in measurement mode. (Then, the test chip loader would be ejected from the machine.)

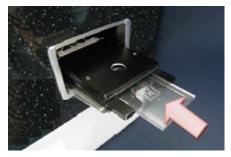


6) Load a test chip (RSA-C01) onto test kit loader.

Notes:

- Fill blood into test chip via inlet hole using pipette.
- Load precise amount of blood into a test chip.
- Note that there should not be any air bubble in a test chip.
- The tetst chip must be loaded in the correct direction as shown in below figure.



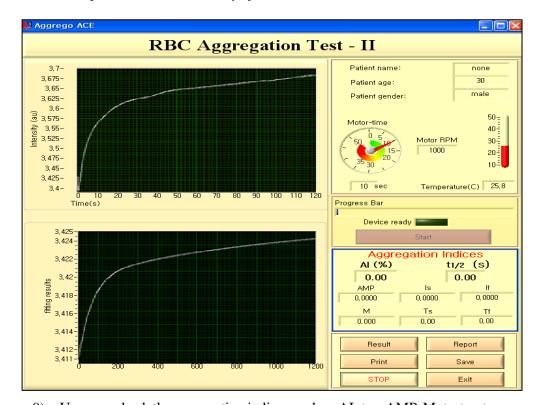


- ⚠ Caution: Prior to test, check whether the circular chamber in a test chip is contaminated or not. If so, cleanse the area with soft textile.
 - 7) Push the control button (names "RSA" located in front panel of RheoScan-AnD 300). Then, the testchip would be automatically go into machine and a new window would pop up.



8) Type in required information and click OK button or push "Enter key". Then, type in the suitable information and click OK button. The the following steps would be automatically started.

- ⇒ In the left upper window, the intensity (raw data) would increases with time.
- ⇒ In the left bottom window, the curve-fitted intensity vs time (syllectogram) would be displayed
- \Rightarrow The test results (AI, $t_{1/2}$, AMP, M, t_s , t_f , etc.) would be displayed in the right table.
- ⇒ The test chip would be automatically ejected after measurement.



- 9) User can check the aggregation indices such as AI, $t_{1/2}$, AMP, M, t_s , t_f , etc
- 10) Remove the test chip in the test loader.
- 11) If necessary, click the "Save" button to save the report file.
- 12) Repeat step 6 to 11 if user wants to continue measurement. (For **repeatability test** with the same kit, repeat step 7 to 10)
- 13) Click *Exit* button on the measurement window if you want finsh measurement.
- 14) User can press control button on the front panel of RheocanAnD-300_for 2 seconds to insert the loader.

5. Troubleshooting Guide

△ Caution: Don't take off all the seals on Rheoscan-AnD300 device. If not, notice that we would not give customers any post-sales services even though it's under warranty (one year after delivery and inspection).

5.1

Software Part

- 1) Software does not properly work when Rheoscan-AnD300 is ready (the LED lamp is on).
 - > Check the connection of your serial cable
 - Check the configuration of serial port.
 - Close and restart the Rheoscan-ACE.
 - ➤ If this problem can not be fixed, please reinstall Rheoscan-ACE.
 - ➤ When this problem repeats, contact the customer service.
- 2) No image on the Measurement window
 - > Check the connection of USB cable.
 - ➤ Check whether the camera is installed properly.
 - Check the laser diode of RheoScan-AnD300 with opening the loader door.
- 3) Can not finish the measurement by clicking *Exit* button on the Measurement window.
 - It may happen when you click the *Stop* button for immediate stop.
 - Click button of the Measurement window to exit.
- 4) During operation, power is accidentally turned off. What should be done?
 - Exit Rheoscan-ACE.
 - Turn on Rheoscan-AnD300 system and start Rheoscan-ACE again.
- 5) During operation, PC is accidentally turned off. What should be done?
 - ➤ Press the "Control" button to eject the test kit loader.
 - > Remove the test kit.
 - > Turn on PC and start RheoScan-ACE.

Caution: If you can not fix the trouble, contact customer service (info@rheoscan.com).



Hardware Part

- 1) Rheoscan-AnD 300 is not turned on.
 - Check whether the power cable is properly connected to wall outlet and power socket.
 - Check whether the main power switch is turned-on on the rear panel of the Rheoscan-AnD 300.
 - > Check the fuse in the fuse box in the rear panel.
 - ➤ When Rheoscan-AnD 300 is turned on, the LED lamp will be on.
- 2) No action after inserting the Test Kit
 - Push the "Control" button and check the followings:
 - a) Rubber cap is tightly sealed.
 - b) Test kit is properly loaded in the right position.
 - ➤ Then, press the "Control button" to insert the Test Kit.
- 3) Test Kit is ejected without measurement
 - Check if there is any blood sample in the waste sample (right hand side) chamber.
 - Remove the test kit and load a new Test Kit.
 - ➤ Then, press the "Control" button to insert the new Test Kit.
- 4) Shear stress does not decrease with time
 - ➤ This may occur when the sample is aspirated into the system and block the air-way. When this problem happens, please contact the customer service center. Do not operate the system without solving this problem.
- 5) By accident, sample was aspirated through the needle
 - Please contact the customer service.
- 6) The main-power is turned off without inserting the test kit loader.
 - > Turn on the power and remove the test kit
 - > Push the "Control" button.
 - > Then, turn-off the power switch.

(Caution: If you can not fix the trouble, please contact the customer service.

6. Technical Specifications

• Hardware

Laser : 635 nm

Camera : VIJE Deluxe 1.3M

• Software

OS : Windows XP and Window7

Program : Rheoscan-ACE

Demension

$$285(L) \times 330(W) \times 255(H) \text{ mm}$$

• Net Weight

15 kg

• Power

• Environment Condition

$$5^{\circ}C \leq T \leq 40^{\circ}C$$

 $rH \le 80 \%$

Altitude $\leq 2000 \text{ m}$

• Loading Volume

0.5 ml of the mixture is recommended for the Test Kit.

• Measuring Time

120 sec (Aggregation-2) - (This part does not apply to RheoScan-D 300)

• Measurement Range

Accessories

Power cord: 1.5 m

USB Serial cable: 1m *2

• Related products

Test Kit: Disposable test kit (**RSD-K01**, 20unit /box)

Disposable test kit with medium tube (RSD-K02, 20unit

/box)-solution

Disposable test chip (**RSA-C01**, 20unit/box)

- (This part does not apply to RheoScan-D 300)

Number	Symbol	Publication	Description
101	Background colour - yellow; symbol and outline - black.	ISO 7000 – 0659	Biohazard
102	LOT	EN 980, subclause 4	Batch code

Removal of equipment from use for repair or disposal

Instructions shall be provided for the RESPONSIBLE BODY for eliminating or reducing HAZARDS involved in removal from use, transportation or disposal. These instructions shall include requirements for minimizing biohazards.

Ordering Information

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