

# USER MANUAL

# E-SPECTRO 2

DREAM

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# 1. Introduction

# 1.1. Manufacturer Information

Manufacturer	9	SHIN JIN MEDICS INC.
Manufacturer Address	Office: I	3301, 138, Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 10442, Korea
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# 1.2 Manual Preparation Date and Version

Date 2016-03-31 Manual Version 1.0

# 1.3 INTENDED USE

E-SPECTRO is used in Enzyme Immunization Diagnosis (EIA) to determine the presence or absence of certain disease in patient's specimen by measuring the qualitative/quantitative/semiquantitative result of the Microplate OD.



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## 2.1 Product Name

E-SPECTRO2 (Brand Name: DREAM)

## 2.2 Product Description

This product is used in Enzyme Immunization Diagnosis (EIA) in measuring the absorbance of the EIA microplate thus; evaluates antigen-antibody reaction of a specimen.

Qualitative, Quantitative and Semi-qualitative assays are provided, in quantitative assay Standard Curve Fitting is analyzed by utilizing a Graph Method such as Point to Point, Linear Regression, Cubic Spline, Smoothing Spline, Four Parameter Logistic, and Five Parameter Logistic. Total of 7 Band-pass Filter can be installed and with each individual filters, the OD value can be read up to 3.5.

Windows is used as an O.S (Operating System) thus; makes easy to connect with printer, mouse, keyboard and any other external devices and also, the wireless LAN supports an easy network interface with hospital devices.



# 2.3 Feature

No.	ltem	Description				
	Filter	405nm, 450nm, 620nm (Can be installed up to 7)				
	Light Source	20W Halogen Lamp				
	OD Range	0~3.5 (When wavelength 3 used, 9.0)				
	Reading Speed	10 Seconds per Plate				
Hardware	ADC	12 Bit(0~4096)				
	Supply Power	110~230 VAC, 50/60 Hz				
	Power consumption	250 Watt				
	Dimension	276(W) x 432(D) x 190(H) (mm)				
	Weight	10 Kg				
	USB Port	External 3 ports				
	Assay Type	1) Quantitative Test				
		2) Qualitative Test				
		3) Semi-Quantitative Test				
	Standard Curve	1) Point to Point				
Software		2) Linear Regression				
Soltware		3) Cubic Spline				
		4) Smoothing Spline				
		5) Four Parameter Logistic				
		6) Five Parameter Logistic				
	O.S.	Windows 10				
	Protocol QC	Included in Manager software				

# 2.4 External Design

# 2.4.1 Front View



NO.	Name	Description
1	LCD Monitor	Touch available by Table PC. Internally installed wireless LAN and Bluetooth function.
2	EJECT Button	Used to eject in and out the MICROPLATE TRAY. A LED functions once device is turned on.
3	MICROPLATE TRAY	When EJECT BUTTON is pressed, MICROPLATE TRAY is ejected and if pressed again, is inserted.

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# 2.4.2 Side View



NO.	Name	Description		
1	Main Power	Device main power		
		Power of PC		
		When PC OFF, press the button about 20 seconds		
2	PC Power	to supply the power.		
		In SLEEP Mode, press the PC power about 1		
		second then monitor screen appears		

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## 2.4.3 Back View



NO.	Name	Description
1	USB SOCKET	USB socket for external device connection
2	Power Connector	Power supply Jack

# 2.4.4 Component List

NO.	Quantity	Description			
1	1	E-SPECTRO2 main body			
2	1	Power adapter			
3	1	User Manual			
4	1	Q.C. Report			



# 3.1 Initializing



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#### Step1.

When main power switch is turned on the device automatically operates about 10 seconds for position correction.

#### Step2.

After the auto-operation of the device run the E-SPECTRO MANAGER to test the next 3 steps:

#### 1) Communication Line Connection Test

Connect the device once "Connecting" is displayed on the screen.

If an error message of "Connection Fail" appears, run the program in an Inactive mode then check if the Device Connection Port is correctly set in Configuration.

#### 2) Device Positioning Test

Operate the initialization when "Initializing Position" is displayed on the screen. If an error message of "Filter motor or sensor error" or "Plate motor or sensor error" appears, request for a Service (Mechanical problem in inner part of device).

#### 3) Background and Empty Well Brightness Accuracy Test

Inspect the validity by measuring the Background and Empty Well Brightness of each filters. Problem occurring during initialization, refer to 4.Trouble Shooting.

#### Step3.

If the auto-operation test is complete, Display the Main View of the program.

## 3.2 Main View



#### 1) Protocol

Used to create, delete, edit or read the protocol of each assay.

#### 2) Result

Used to check the result of assay performed.

#### 3) Configuration

It sets the Filter Information, Device Initial Position and its Network Interface.

# 3.3 Protocol

## 3.3.1 Protocol Main View

Total of 100 Protocols can be saved and the protocol which performs the Quantitative, Qualitative and Semi-quantitative assays can be created and read.

1 Afp	<sup>2</sup> ТЗ	<sup>3</sup> FT3	4	
				EDIT
5	U U	,	0	<b>a</b> [-0.0
9	10		12	СОРҮ
				SWAP
13	14	15	16	DELETE

Item	Description
Protocol Button	Item button of the protocol.
Read	Measures the Microplate with selected Protocol.
Edit	Edits the selected Protocol.
	Even after the protocol modification, the result of assay will not
	be affected.
Q.C.	Check the EE20, 50 and 80 of the result and the Q.C. result of
	the Control with the selected Protocol.
Сору	Copies the selected Protocol.
Swap	Changes the position of the selected Protocol with another
	Protocol.
Delete	Deletes the selected Protocol.
Virtual Data	Used to create a virtual data.



Click the empty Protocol Button > Edit to create new protocol. Following Dialog Box will appear. User can select the desired type of Protocol.



- 1) Quantitative Test
- 2) Qualitative Test
- 3) Semi Quantitative Test

# 3.3.3 Quantitative Test

				()			
					- /		
Filter			Standa	evruD br			
Main	405	~	Cui	ve Type	Point to Point	~	
Poforo	nco			X(Conc)	Linear	-	
Referen				V(OD)	Lineau	_	
Second	larv	~		T(UD)	Linear		
			Decin	nal Point	2 ~ 1	Jnit iu/ml	
Readent	Blank	~	No	Reagent	Replication	Conc/Range	
	Cinale	>>	1	S1	Single	0.00	X
	Single		2	S2	Single	1.00	
			3	S3	Single	1.80	Un
			4	54	Single	3.00	op
			5	S5	Single	4.00	Deven
			6	S6	Single	5.00	Down
							_
	-		_				

ltem	Description				
Protocol Name	Test Name				
Interface ID	ID used for the Interface, possible up to 2.				
Filter	<ul> <li>Filters are Main, Reference and Secondary. Set Wavelength from the Configuration is displayed.</li> <li>Set the wavelength upon testing. <ul> <li>Main Wavelength: Main measuring wavelength</li> <li>Reference Wavelength: Based on Background wavelength.</li> <li>Actual OD calculation = Main - Reference</li> <li>Secondary Wavelength: Used when the measured OD is 3.5 from the Main wavelength and desires to measure up to 9.0, This method is calculated by multiplying the computed factor value of Main and secondary wavelength OD ratio evaluation.</li> </ul> </li> </ul>				
Curve Type	Select the type of Standard Curve.         -       Point to Point         -       Regression         -       Cubic Spline         -       Smoothing Spline         -       Four Parameter Logistic         -       Five Parameter Logistic				



	Set the Scale of X-axis (Concentration).						
	Note: The selected Scale does not only change the Curve data						
	displayed but also it directly calculates the data by changing to its						
	For example. The concentration of \$1 and \$2 is 20 and 100 respectively.						
X(Concentration)	when Linear is set, it Fits the graph by using the value to 20 and 100.						
	When Log is set, graph is fitted by using the values of Log (20) and Log						
	(100).						
	Therefore, If the user wants to fit in the Log-Logit graph, it does not						
	display on the graph type rather user can use Regression Fitting after						
	setting the x-axis as Logit and y-axis as Log.						
Y(OD)	Set the Scale of Y-axis OD value.						
	Application for Scale is same as X-axis.						
	Set the decimal places to be displayed for the calculated concentration						
Decimal Point	If you want to use the decimal like 1.02, set to 2.						
	Can select the Unit.						
Unit	Can select the Unit. It does not participate in calculation but is simply used as Report						
Unit	Can select the Unit. It does not participate in calculation but is simply used as Report reference.						
Unit	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests						
Unit Reagent	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added.						
Unit Reagent	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range.						
Unit Reagent	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range.						
Unit Reagent Sample	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range. Set the number of sample test.						
Unit Reagent Sample	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range. Set the number of sample test. Enter the normal concentration value of the sample.						
Unit Reagent Sample Normal Range	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range. Set the number of sample test. Enter the normal concentration value of the sample. In case the sample results show above the set normal values, it displays						
Unit Reagent Sample Normal Range	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range. Set the number of sample test. Enter the normal concentration value of the sample. In case the sample results show above the set normal values, it displays an 'R' in the ERR items on result window.						
Unit Reagent Sample Normal Range Left Arrow Button	Can select the Unit. It does not participate in calculation but is simply used as Report reference. Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added. In case you want to change the concentration, edit the item by clicking the concentration of corresponding reagent from the Conc/Range. Set the number of sample test. Enter the normal concentration value of the sample. In case the sample results show above the set normal values, it displays an 'R' in the ERR items on result window. Returns to previous screen without saving.						

# 3.3.4 Qualitative Test

Protocol Ha	ama <mark>T3</mark>		Interfac	eID (1) (2)		SAVE
Filter			Formula	>= ~	N*3	Validation Check
Main	450	~			N: Negative P: Posi	tive
Referenc	e 620	~				
Secondar	<b>y</b> 405	~				
Reagent	Blank Single	~	>> <mark>Na</mark> 1 2	Reagent     Negative     Positive	ReplicationDuplicationDuplication	<b>x</b>
						Up
						Down
Sample	Single	~	⊠ Gray Zone(ind	dex) 0.000	0 ~ 0.200	

ltem	Description							
Protocol Name	Test Name							
Interface ID	ID used for the Interface, possible up to 2.							
Filter	<ul> <li>Filters are Main, Reference and Secondary. Set Wavelength from the Configuration is displayed.</li> <li>Set the wavelength upon testing. <ul> <li>Main Wavelength: Main measuring wavelength</li> <li>Reference Wavelength: Based on Background wavelength.</li> <li>Actual OD calculation = Main - Reference</li> <li>Secondary: Used when the measured OD is 3.5 from the Main wavelength and desires to measure up to 9.0.</li> <li>This method is calculated by multiplying the computed factor value of Main and secondary wavelength OD ratio evaluation.</li> </ul> </li> </ul>							
Formula	The part where you input the formula to be applied in qualitative test. For example, the standard for determining a positive value is greater than the Negative Control X 2 + Positive Control, enter as $>=N*2+P$ . Check the validation of the formula by clicking on Validation Check after entering the formula.							

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Reagent	Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added.
Sample	Set the number of sample test.
Gray Zone	<ul> <li>Select the zone of evaluation for negative/positive results which are not sure.</li> <li>Each OD value shall be based on the Index which is the Cutoff value.</li> <li>For example, if you want to set the Gray Zone as +/- 10% of the Cutoff, set to 0.9~1.1.</li> <li>Once set and measured, the result will be divided into Positive, Negative, and Gray Zone.</li> </ul>
Left Arrow Button	Returns to previous screen without saving.
Save	Saves the protocol and returns to previous screen.

# 3.3.5 Semi-Quantitative Test

Fretecel Rame	FT3		Interface	ID (1) (2)	45		
Main Reference	450 620	~	Formula	N*X N: Ne C1:Co	gative P: P introl1 C2:C	ositive X:Sample	Validation Check
Secondary		~	ι	Init i		Decimal Point	1 ~
Reagent Blan	k ~		No	Reagent	Replication	Control Range	x
Sing	le ~	>>	1 2	Negative Positive	Single Duplication		
							Up
							Down

ltem	Description							
Protocol Name	Test Name							
Interface ID	ID used for the Interface, possible up to 2.							
Filter	<ul> <li>Filters are Main, Reference and Secondary. Set Wavelength from the Configuration is displayed.</li> <li>Set the wavelength upon testing. <ul> <li>Main Wavelength: Main measuring wavelength</li> <li>Reference Wavelength: Based on Background wavelength.</li> <li>Actual OD calculation = Main - Reference</li> <li>Secondary: Used when the measured OD is 3.5 from the Main wavelength and desires to measure up to 9.0.</li> <li>This method is calculated by multiplying the computed factor value of Main and secondary wavelength OD ratio evaluation.</li> </ul> </li> </ul>							
Formula	The part where you input the formula to be applied in qualitative test. For example, the standard for determining a positive value is greater than the Negative Control X 2 + Positive Control, enter as $>=N*2+P$ . Check the validation of the formula by clicking on Validation Check after entering the formula.							

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Decimal Point	Set the decimal places to be displayed for the calculated concentration If you want to use the decimal like 1.02, set to 2.
Unit	Can select the Unit. It does not participate in calculation but is simply used as Report reference.
Reagent	Select the type of reagent you want to add, set the number of tests and when you press the arrow button reagent will be added.
Sample	Set the number of sample test.
Gray Zone	<ul> <li>Select the zone of evaluation for negative/positive results which are not sure.</li> <li>Each OD value shall be based on the Index which is the Cutoff value.</li> <li>For example, if you want to set the Gray Zone as +/- 10% of the Cutoff, set to 0.9~1.1.</li> <li>Once set and measured, the result will be divided into Positive, Negative, and Gray Zone.</li> </ul>
Left Arrow Button	Returns to previous screen without saving.
Save	Saves the protocol and returns to previous screen.

# 3.4 Reading

Step1. Select the protocol you want to Read and press Read button.



Step2. Enter the number of Well of the Reading. More than 1 Microplate (96 Wells) is possible for reading.





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Step3. The wavelength on reading will be displayed, and the result after is displayed as shown below. OD value can be edited on the result page by pressing the 'Next.'

Plate	e <b>1</b>	~	OD		~	Ca	alculate	ed OD	~							
	1	2	3	4	5	6	7	8	9	10	11	12	Backgr ound	Empty Well	NE	XT
A	NE 1.140	SMP3 1.150	SMP7 1.170													RINI
B	PO 1.520	SMP3 1.530	SMP7 1.540													
C	PO 1.890	SMP4 1.910	SMP8 1.920													
D	C1 2.270	SMP4 2.280	SMP8 2.300													
E	SMP1 2.650	SMP5 2.660														
F	SMP1 3.020	SMP5 3.040														
G	SMP2 0.400	SMP6 0.410														
Н	SMP2 0.780	SMP6 0.790														

No.	ltem	Description
1	Plate Number	If the Well is more than 96, select the number of Microplate you
-		want to display.
2	Display Item	Select between OD/ADC.
		Once you selected the OD,
		You can check the OD value by selecting its Calculated OD/Main
		Wavelength/Reference Wavelength/Secondary Wavelength.
		For Calculated OD:
		In case only Main Wavelength is selected, the result is the same
3	ОД Туре	as Main Wavelength.
		If Main and Reference Wavelength is selected, the result is
		calculated as Reference Wavelength.
		If all Main, Reference and Secondary Wavelength is selected, the
		result is calculated as Main-Reference wavelength for OD below
		2.0 and proportional secondary wavelength for OD above 2.0.

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# 3.5 Result Calculation

### 3.5.1 Main Screen for Result List

			20	15-11	-09			No	Test Tige	Protocol	Well	^	
Г							N	1	15:18:03	TEST1	100		RESULT
	K			Today	· · · · ·			2	15:19:00	Anti-HBs	96		
	Sun	Mon	Tue	Wed	Thu	Fri	Sat						
		_	_										PLATE
	1	2	3	4	5	6	7						
					. T	- <b>-</b>							
	8	9	10	11	12	13	14						DELETE
	15	16	17	18	19	20	21						
	22	23	24	25	26	27	28						
	29	30											
													4
													PREVIOUS
L												Ŧ	

Green circle is displayed on the dates of test performed (Calendar on left).

When corresponding date is clicked, list of tests performed on that day appears and the latest test is shown on the top of the list.

Test list shows the Name and Time of Test, and Number of measured Well.

Select and click Result to see the test results.

To check the OD value in a table form, press the Plate button.

If you want to delete the test result, press Delete button.

## 3.5.2 Quantitative Test Results



#### Step1. Reagent Measurement Result Modification and Standard Curve Fitting

Test Name
Time of test performed
Number of Well measured
Concentration unit
Wavelength (Main, Reference, and Secondary) used in measurement
Protocol ID used in transferring results to network
If Fitting success, graph will be displayed and if not, "Regression Fail" error will be displayed. If the Standard concentration continuously does not increase or decrease, it will absolutely be 'Regression Fail', in case of specific fitting method, the graph may or may not be drawn depending on its characteristics of the data.
· · · · · · · · · · · · · · · · · · ·



Curve Type	Can select the type of Standard Curve.
	Curve type is same as the items shown in the Protocol Edit.
X(Concentration)	Can assign the Linear and Log.
Y(OD)	Select the data Scale of Y-axis. Can assign the Linear, Log, and Logic. When Logit is used, 1 Standard cannot be calculated because the largest OD value from the data must be used as the denominator. In case of Logic, the linearity of the graph of inverse proportional graph (competitive immunoassay) is good therefore if LOG-LOG is frequently used in proportional graph, LOG-LOGIT is mainly used in inverse proportional graph.
ED20,ED50,ED80 (EC20,ED0,EC80)	Effective Concentration standing for Median Effective dose refers to the Maximum 20%, 50%, and 80% value from the result. This is displayed based on the concentration calculated by Max 20%, 50%, and 70% OD value in the Standard and on the right side, it represents the average of latest 100 tests as a reference. The validity of ED20, ED50, and ED80's Selected tests can be evaluated by comparing with previous data.
R-Square	This is based on measuring the difference between the graph and actual data (Standard) and does not always necessarily pass the Standard points for some Types of graph, in this case, the difference between calculated concentration of graph and the actual set concentration of Standard is evaluated. If the result is 1, means it passes all the Points of the graph and the closer result to 0, the difference of calculated graph and point can be seen. (For reference, Point to Point and Cubic Spline must pass the Standard Point in order for the result to be displayed as 1.) $\underbrace{5.000}_{1.00}$
	(Point to Point)

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#### Curve Type Smoothing Splin 5.000 (Conc) Linear Linear 2.500 0.987 R-Sa AVR.8 Current 1.300 ED20 1.61 0.74 0.500 ED50 3.02 1.71 4.00 ED80 3.75 3.11 1.00 3.00 Name OD1 OD2 OD3 CV(%) Mean OD Conc. Control Range Well Pos. Err **S1** 0.100 0.0% 0.100 0.00 1.A1 0.500 0.0% 0.500 1.00 1.B1 **S2 S**3 0.0% 1.300 1.C1 1.300 1.80 **S4** 2.500 0.0% 2.500 3.00 1.D1 **S**5 5.000 0.0% 5.000 4.00 1.E1 C1 3.500 0.0% 3.500 3.56 1.F1 0.0% 3,500 1.G1 C2 3.500 3.56 C3 3.500 0.0% 3.500 3.56 1.H1 (Smoothing Spline) Name OD1 OD2 OD3 CV(%) Mean OD Conc. Control Range Well Pos. Err **S1** 0.100 0.0% 0.100 0.00 1.A1 **S2** 0.0% 0.500 1.00 1.B1 0.500 **S**3 1.300 0.0% 1.300 1.80 1.C1 **S4** 2.500 0.0% 2.500 3.00 1.D1 5.000 1.E1 **S**5 0.0% 5.000 4.00 C1 3.500 0.0% 3.500 3.56 1.F1 C2 3.500 0.0% 3.500 3.56 1.G1 Reagent C3 3.500 0.0% 3.500 3.56 1.H1 Shows the result of Reagent, and as shown above the Type of Reagent, Measured OD, CV for greater than Duplication, Mean OD, Concentration, Control Range, Well Position (Plate No.), and ERR is displayed from the left. User can edit by clicking the OD1 value, and is immediately reflected to graph and calculation. Activated when Standard Curve Fitting is accepted, **Next Button** The data can be checked by pressing the Next Button. Used to change the protocol of the test, and if modified, the items will **Change Protocol** reflect only in the results and does not reflect on the original protocol Button setting. Modification method is the same as protocol edit in 4.3.2. Q.C Provides the statistics of ED,20,50,80 and Control.

### Step2. Sample Result

sai						Normal	Range	0.30	~	0.80		
No	Name	Barcode	OD1	OD2	OD3	CV(%)	Mean	Conc	Well Pos	Err	^	S S
SMP1			0.214	0.218		0.6%	0.216	0.34	1.A2~1.B2	~		
SMP2			0.601	0.579		1.2%	0.590	0.96	1.C2~1.D2	R		
SMP3			3.500	3.500		0.0%	3.500	3.56	1.E2~1.F2	R		
SMP4			3.500	3.500		0.0%	3.500	3.56	1.G2~1.H2	R		
SMP5			3.500	3.500		0.0%	3.500	3.56	1.A3~1.B3	R		
SMP6	1		3.500	3.500		0.0%	3.500	3.56	1.C3~1.D3	R		
SMP7			3.500	3.500		0.0%	3.500	3.56	1.E3~1.F3	R		
SMP8	1		3.500	3.500		0.0%	3.500	3.56	1.G3~1.H3	R		
SMP9			3.500	3.500		0.0%	3.500	3.56	1.A4~1.B4	R		
SMP10	Î		3.500	3.500		0.0%	3.500	3.56	1.C4~1.D4	R		
SMP11			3.500	3.500		0.0%	3.500	3.56	1.E4~1.F4	R		
SMP12	Î		3.318	3.500		1.8%	3.409	3.52	1.G4~1.H4	R		
SMP13			3.500	3.500		0.0%	3.500	3.56	1.A5~1.B5	R		
SMP14			3.500	3.500		0.0%	3.500	3.56	1.C5~1.D5	R		
SMP15			3.500	3.500		0.0%	3.500	3.56	1.E5~1.F5	R		
SMP16	1		3.500	3.500		0.0%	3.500	3.56	1.G5~1.H5	R		
SMP17			0.550	0.540		0.6%	0.545	0.89	1.A6~1.B6	R		
SMP18	1		0.535	0.535		0.0%	0.535	0.88	1.C6~1.D6	R		
SMP19			0.535	0.537		0.1%	0.536	0.88	1.E6~1.F6	R		
SMP20			0.533	0.537		0.2%	0.535	0.88	1.G6~1.H6	R		
SMP21			3.500	3.500		0.0%	3.500	3.56	1.A7~1.B7	R		
SMP22			3.500	3.500		0.0%	3.500	3.56	1.C7~1.D7	R		PREVIO
SMP23			3.500	3.500		0.0%	3.500	3.56	1.E7~1.F7	R		

ltem	Description
Protocol Name	Test Name
Name	Patient Name (Information received from Network Interface)
Barcode	Patient Registration No. (Information received from Network Interface)
OD1,OD2,OD3	Result
CV (%)	Greater than Duplication: CV of OD value
Mean	Mean of OD
Well Position	Microplate Well Position
ERR	If above the Normal Range, displayed as 'R'
Save	Saves the protocol and returns to previous screen
Print	If printer is installed, print with the default printer
Network	Sends the result by Network
Left Arrow Button	Returns to previous screen without saving
Normal Range	Normal Range set on the protocol

DREAM

# 3.5.3 Qualitative Result

Step1. Reagent Result Edit and Cut-off Calculation	

Proto	ocol Name		Т3			Filter	W.L.	No	Interface ID	NEXT
Test	Time	201	6-03-30	18:52:59		Reference	620	1	Incentice ID	
						Secondary	405	2		
Well	Count	15								
Form	ula	>=		N <sup>a</sup>	3					Change Protoc
Cut o	off	4.21	5 1	P/N RATIO	1.57	AVR.3	1.507			
Grav	Zone	0.00	) ~	0.200						d oc
-										
Control										
and a subscription	OD1	OD2	OD3	CV(%)	Mean OD	Result	Index	Well Pos.	Err	
Name		1 640		11.2	1.405			1.A1~1.B1		
Name Negative	1.170	1.040								
Name Negative Positive	1.170 2.020	2.400		5.7	2.210			1.C1~1.D1		
Name Negative Positive C1	1.170 2.020 2.770	2.400		5.7 0.0	2.210 2.770	Negative	0.657	1.C1~1.D1 1.E1		

ltem					D	escript	ion					
Protocol Name	Test Nar	ne										
Test Time	Time of	test p	erform	ed								
Well Count	Number	of W	ell mea	asured								
Formula	Cutoff Fo	Cutoff Formula										
Cut off	Processe	d as l	ndex=	1 by C	alculat	ed Cut o	off value					
P/N RATIO	Positive/ The Mea	Nega <sup>.</sup> In P/N	tive Ra I Ratio	tio use of Prc	ed for ( otocol i	Q.C. recently	performe	ed is sho	own on the	right.		
Gray Zone	Displaye Value is	d her basec	e wher I on th	n Gray e Inde	Zone s x	set in the	e protoco	bl				
	Control											
	Name	OD1	OD2	OD3	CV(%)	Mean OD	Result	Index	Well Pos.	Err		
	Negative	1.170	1.640		11.2	1.405			1.A1~1.B1			
	Positive	2.020	2.400		5.7	2.210	No. and the	0.057	1.C1~1.D1			
	<u>CI</u>	2.770			0.0	2.770	Negauve	0.037	1.01			
Reagent	Shows t Measure Control	he re d OE Range	sult of ), CV f e, Well	Reag or gre Positic	ent, an eater tl on (Plat	nd as sh han Dup te No.), a 101 yalu	nown ab blication, and ERR	ove the Mean is displa	e Type of F OD, Concer nyed from the	Reagent, ntration, he left.		
				icking				5 mmilet	latery rene			
	grapn ar	id cal	culatio	n.								

#### Step2. Sample Result

HBs	sAg											- SAVE
Smp No	Name	Barcode	OD1	OD2	OD3	CV(%)	Mean	Result	Index	Well Pos		
SMP1			0.232	0.828		37.5%	0.530	Positive	3.029	1.F1~1.G1		
SMP2			0.905	1.704		20.4%	1.304	Positive	7.451	1.H1~1.A2		
SMP3			1.895	2.434		8.3%	2.164	Positive	12.366	1.B2~1.C2		
SMP4			2.397	1.163		23.1%	1.780	Positive	10.171	1.D2~1.E2		1
SMP5			1.165	1.679		12.0%	1.422	Positive	8.126	1.F2~1.G2	Ξ	
SMP6			0.163	0.100		16.0%	0.132	Negative	0.754	1.H2~1.A3		
SMP7			0.506	0.322		14.8%	0.414	Positive	2.366	1.B3~1.C3		
SMP8			2.305	0.664		36.8%	1.485	Positive	8.486	1.D3~1.E3		
SMP9			0.000	0.120		66.7%	0.060	Negative	0.343	1.F3~1.G3		
SMP10			2.402	0.203		56.3%	1.303	Positive	7.446	1.H3~1.A4		
SMP11			0.920	2.241		27.9%	1.581	Positive	9.034	1.B4~1.C4		
SMP12			2.434	1.008		27.6%	1.721	Positive	9.834	1.D4~1.E4		
SMP13			1.516	0.286		45.5%	0.901	Positive	5.149	1.F4~1.G4		
SMP14			2.225	0.401		46.3%	1.313	Positive	7.503	1.H4~1.A5		
SMP15			1.488	0.144		54.9%	0.816	Positive	4.663	1.B5~1.C5		
SMP16			0.323	2.225		49.8%	1.274	Positive	7.280	1.D5~1.E5		
SMP17			0.042	2.447		64.4%	1.245	Positive	7.114	1.F5~1.G5		
SMP18			2.498	0.543		42.9%	1.520	Positive	8.686	1.H5~1.A6		
SMP19			0.629	0.678		2.5%	0.654	Positive	3.737	1.B6~1.C6		
SMP20			0.395	1.205		33.8%	0.800	Positive	4.571	1.D6~1.E6		
SMP21			0.182	1.845		54.7%	1.013	Positive	5.789	1.F6~1.G6		PREVIOUS
CHIDDO.			0.670	2 1 4 4		24 60/	1 411	ntet	0.000	1 116 1 47	-	

ltem	Description
Protocol Name	Test Name
Name	Patient Name (Information received from Network Interface)
Barcode	Patient Registration No. (Information received from Network Interface)
OD1,OD2,OD3	Result
CV (%)	Greater than Duplication: CV of OD value
Mean	Mean of OD
Result	Positive/Negative/Gray Zone
Well Position	Microplate Well Position
ERR	If above the Normal Range, displayed as 'R'
Save	Saves the protocol and returns to previous screen
Print	If printer is installed, print with the default printer
Network	Sends the result by Network
Left Arrow Button	Returns to previous screen without saving
Normal Range	Normal Range set on the protocol

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# 3.5.4 Semi-quantitative Result

FICLOC	oi Name		FI3			Filter P <mark>rimary</mark>	<b>w.L.</b> 450	No Inter	face ID	NE
Test Ti	me	2016-0	)3-30 19	:18:04		Secondary Reference	620	1		
Well Co	ount	20			ł			-		Chang
Formul	a	=		N*>	(					Criting
Unit		i	De	cimal Po	oint	1				
Norma	Range	-	~							
Contro Name	OD1	0D2	0D3	CV(%)	Mean OD	Conc.	Control Range	Well Pos	Frr ^	
Negative	1.140			0.0	1.140		conta or mange	1.A1		
	1.520	1.890		7.2	1.705			1.B1~1.C1		
Positive	2 270			0.0	2.270	2.6		1.D1		
Positive C1	2.270									

Step1. Reagent Result Edit and Cut-off Calculation

ltem					De	scripti	on				
Protocol Name	Test Nam	ne									
Test Time	Time of t	est pe	rforme	d							
Well Count	Number	of We	ll meas	ured							
Formula	Cutoff Fc	ormula									
Unit	Concentr	ation	unit								
Decimal Point	Decimal	places	to be	used i	n the c	oncentr	ation	calculation			
Normal Range	Normal F	Range	set on	the pr	otocol						
	Name	OD1	OD2	OD3	CV(%)	Mean OD	Conc.	Control Range	Well Pos.	Err	^
	Negative	1.140			0.0	1.140			1.A1		
	Positive	1.520	1.890		7.2	1.705			1.B1~1.C1		
	C1	2.270			0.0	2.270	2.6		1.D1		
Reagent											
5	Shows th	ne res	ult of	Reage	nt, and	d as sh	own a	above the T	ype of F	Reage	ent,
	Measure	d OD,	CV fo	r grea	ter tha	an Dupl	icatio	n, Mean OD	, Concei	ntrati	on,
	Control F	Range,	Well P	ositior	ı (Plate	No.), a	nd ER	R is displaye	d from th	ne lef	ft.

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User can edit by clicking the OD1 value, and is immediately reflected to
graph and calculation.

#### Step2. Sample Result

Smp No	Name	Barcode	OD1	OD2	OD3	CV(%)	Mean	Conc	Well Pos	Err	^	SAV
SMP1			2.7	3.0		3.5%	2.850	3.2	1.E1~1.F1			
SMP2			0.4	0.8		22.2%	0.600	0.7	1.G1~1.H1			
SMP3			1.1	1.5		10.3%	1.300	1.5	1.A2~1.B2			_
SMP4			1.9	2.3		6.3%	2.100	2.4	1.C2~1.D2			
SMP5			2.7	3.0		3.5%	2.850	3.2	1.E2~1.F2			
SMP6			0.4	0.8		22.2%	0.600	0.7	1.G2~1.H2			
SMP7			1.2	1.5		7.4%	1.350	1.5	1.A3~1.B3			
SMP8			1.9	2.3		6.3%	2.100	2.4	1.C3~1.D3			

ltem	Description					
Protocol Name	Test Name					
Name	Patient Name (Information received from Network Interface)					
Barcode	Patient Registration No. (Information received from Network Interface)					
OD1,OD2,OD3	Result					
CV (%)	Greater than Duplication: CV of OD value					
Mean	Mean of OD					
Well Position	Microplate Well Position					
ERR	If above the Normal Range, displayed as 'R'					
Save	Saves the protocol and returns to previous screen					
Print	If printer is installed, print with the default printer					
Network	Sends the result by Network					
Left Arrow Button	Returns to previous screen without saving					
Normal Range	Normal Range set on the protocol					

## 3.5.5 Display in PLATE Form

	1	2	3	4	5	6	7	8	9	10	11	12	Backgr ound	Empty Well
A	NE 1.140	SMP3 1.150	SMP7 1.170			10								
В	PO 1.520	SMP3 1.530	SMP7 1.540											
С	PO 1.890	SMP4 1.910	SMP8 1.920											
D	C1 2.270	SMP4 2.280	SMP8 2.300											
E	SMP1 2.650	SMP5 2.660												
F	SMP1 3.020	SMP5 3.040												
G	SMP2 0.400	SMP6 0.410												
н	SMP2 0.780	SMP6 0.790												

If you want to check the Plate Reading result by each wavelengths or simply need the OD value only, by using this feature you can see the Microplate OD value.

Item	Description					
Plate Number	Tested Plate Number					
Value Type	Can be selected between OD and ADC OD(Optical Density) =log10 ( Empty ADC/Target ADC )					
ОД Туре	Calculated OD : Primary Filter, Reference: If filter is set Primary-Reference Value displays If Secondary Filter applied the value applied with K- Factor is displayed Measured Wavelength : OD values for single wavelength is displayed					
NEXT	Can check the result					
Print	Print the current screen contents					
Left Arrow Button	Returns to previous screen without saving					

# 3.6 Protocol Q.C

sdf Data Count : 2		CTRL1		CTRL2		CTRL3		CTRL4		2016-03-01
		Mean	4.22	Mean	4.72	Mean	1.70	Mean		
		CV(%)	19.3%	CV(%)	28.0%	CV(%)	100.0% 1.70	CV(%)		2016-03-31
		SD	0.82	SD	1.33	SD		SD		
lo	Test Time	Conc.	SD Ratio	Conc.	SD Ratio	Conc.	SD Ratio	Conc.	SD Ratio	Y-AXIS
	20160329085727	3.40	-1.00	3.40	-1.00	3.40	1.00			• S.D.
<u>.</u>	20160321095142	5.03	1.00	6.05	1.00	0.00	-1.00			O Concentrati
	3 2.6								]	
	3 25 2 1.5								CONTROL1 CONTROL2 CONTROL3 CONTROL4	PRINT
8	3 25 2 15 1 0 0								CONTROL1 CONTROL2 CONTROL3 CONTROL4	
8	3 25 2 15 1 0.5 0.5								CONTROL1 CONTROL2 CONTROL4	PRINT
8	3 25 2 15 1 0.5 0 0.0 5								CONTROLI CONTROLS CONTROLS CONTROLS	PRINT
8	3 25 2 15 1 05 05 05 05 05 1 1 1 1 1 1 1 1 1 1								CONTROL1 CONTROL2 CONTROL3 CONTROL4	
8	3 25 2 15 1 05 05 05 05 05 05 05 05 05 05 05 05 05								CONTROL1 CONTROL2 CONTROL3 CONTROL4	

By using the statistic (ED20, ED50, ED80 and Control) function in quantitative assay, user can check the CV, SD, and Mean of the data on selected test date performed thus; allows to evaluate the stability of the reagents indirectly.

SD Ratio is shown in red for the tests above 2SD allowing the users to easily check.

The concentration and SD Ratio per Test Time is displayed and the statistic formula for each item are as follows:

$$\begin{split} &\text{SD} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(x_i-m)^2} \\ &\text{CV}(\%) = \text{SD}/m \\ &\text{SD RATIO} = (x_i-m)/\text{SD} \\ &\text{(n: Data Count, } x_i \text{ : Data Concentration, } m \text{ : Average of Concentration }) \end{split}$$

Item	Description
Select Date	Select the date you wish to QC.
Y-Axis	Select the data type to display on Y-axis. Select between OD Ratio and Concentration.
Print Button	QC results can be printed.
Excel	Saves the data file in form of CSV.
Left Arrow Button	Returns to previous screen without saving.

# 3.7 Configuration

evice	Connection Po	ort COM5	~				
Filter	Wave Length	Bright(0~255)	Edit	Interface			
1 2	405 450	220 120	Add	None			
3	620	40	Delete Up	• NETWORK F	ILE		
			Down	Result			
Init	Information	10		X Init Position F Init Position	9650 1500	(default : 9650) (default : 1500)	

ltem	Description									
Device Connection Port	Set the Serial Port connecting in between the device and computer. Serial Port can be checked in Control Panel -> Hardware and Sound -> Device Manager of the windows.									
Filter	Set the Band-pass Filter. Wavelength is not an actual value measured but can be assigned as the preference of the user, Brightness sets the brightness of the Halogen Lamp when measuring with its filter. We recommend to set the brightness to values more than 2500 in all sensors. However, the position of the set filter is important and when opening the device, the Filter Tray is located in front of the user's location.									
Initial Information	The initial data measured per filter during the program execution can be checked. Below 100 background values are recommended and an error occurs if 150 above thus; fail to measure. Sensor value of 2500-4000 is recommended for the brightness of Empty Well and if below 1500, an error will occur thus; fail to measure. $\boxed{\frac{Filter  Lamp Power}{100  Background \ 0  0  0  0  0  0  0  0  0  0$									



Empty Well Subtraction	Upon Well measurement, it does not only measure the OD value of the actual reagent inside but also the Transparent contained on Well is influenced. If Reference wavelength is generally used, the OD value is subtracted automatically so there would be no problem however, if you are to measure the OD value of materials inside by a single wavelength, must enter. Enter the difference ratio of the ADC measured without inserting a Well and ADC measured with an Empty Well for the entry value. For example, ADC without inserting a Well is 3500 and 3000 for Empty Well (3500-3000) (3500 = 0.1428 => Enter 14%
Interface	Select the Network File Path in receiving and sending the Worklist and result for Network Interface. For more details, refer to "Network Interface".
X Init Position	Set the initial point of Microplate Tray.
F Init Position	Set the initial point of Bandpass Filter Tray.
Save	Saves the modified result.

# 3.8 Network Interface

## 3.8.1 Receiving and Measuring Worklist

If the Network Interface is set in the configuration, the Worklist can be received and Result Data can be transferred by the server.

-20	21-40	41-60 61	-80 81-100	Interfa	ce	Quanty	Quali	Semi Virtual Data		
No	Prot. No	Prot. Name	Receive Time	SMP Cnt.	Well Cnt.	^ No	Sample Name	Barcode ^		10/10 <sup>-</sup>
1	1	Afp	20160331164312	96	198	1	test0	test0		
2	1	Afo	20160331164335	96	108	2	test1	test1		
-	1		20100331104333	50	150	3	test2	test2		DH
						4	test3	test3		
						5	test4	test4		
						6	test5	test5		
						7	test6	test6	<b>4</b> 1	
						8	test7	test7		
						9	test8	test8		
						10	test9	test9		
						11	test10	test10	C	OPY
						12	test11	test11		
						13	test12	test12		
						14	test13	test13	5	WAP
						15	test14	test14		
						16	test15	test15		
						17	test16	test16	DE	LETE
						18	test17	test17		
						19	test18	test18		
						20	test19	test19		
						21	test20	test20		
						22	test21	test21		
						23	test22	test22	The second se	EVIOUS_

When receiving a Worklist from the Server, click the Interface Tab of protocol from the initial menu to check the Worklist.

If you are to measure the Worklist, choose the Worklist you desire and click Read button on the Worklist box shown on the left.

And if you want to delete the Worklist, click the Delete button on the lower right of the screen. To send the result after testing, click Network interface button on the result screen.

## 3.8.2 Network Protocol

The Result/Worklist uses the same Protocol in data transmission and is composed of Packet Header + (Patient Record  $\times$  N) (N:Record number).

For example, to send 3 patient data,

Send together with Packet Header (Sample Count=3) + Patient1 Record + Patient2 Record + Patient3 Record.

NULL (0x00) entry is a default for the portion that are not filled inside.

#### 1) Packet Header

```
[ C Language ]
```

typedef struct

```
{
```

char[20] InterfaceId1 ;	// Interface ID1 defined in the protocol.
char[20] InterfaceId2 ;	// If other ID exists, Enter Interface ID 2 also.
	// E-SPECTRO Manager searches the protocol which match
	// with Interface ID1 and 2 and if any of the protocols match
	// appropriate protocol is selected.
char[5] SampleCount ;	// Enter the Sample No. in Text Format not Binary Format.
	// Number entered must match with Patient Record.
	// (Ex.) "15"
char [50] rsvd ;	// If not used as dummy field, enter NULL.
TInterfaceHeader :	

#### [ PASCAL ]

}

```
type TInterfaceHeader=packed record
InterfaceId1:array[0..19] of ansichar ;
InterfaceId2:array[0..19] of ansichar ;
SampleCount:array[0..4] of ansichar ;
rsvd :array[0..49] of ansichar ;
end;
```

[Eng, V1.0]



#### 2) Patient Record

Data must exist as much as the Sample Count set on the Packet Header.

#### [ C Language ]

typedef struct

{

char[50] Sa	ampleName;	// Patient Name
char[50] S	SampleBarcode	; // Patient Barcode No.
char[11]	OD ;	// Measured OD. Shows up to 3 decimal places.
char[15]	Result ;	// Result
		// Conc value sent for Quanti & Semi-quantitative
		// POSITIVE & NEGATIVE for Qualitative
char[10] in	idex ;	// Ratio of Cut-off value during Qualitative
char[50] rs	svd ;	// If not used as dummy field, enter NULL.

} TPatientRecord ;

#### [ PASCAL ]

type TInterfaceRecord=packed record

SampleName:array[0..49] of ansichar ; SampleBarcode:array[0..49] of ansichar ; OD :array[0..10] of AnsiChar ; Result:array[0..14] of ansichar ; index :array[0..9] of ansichar ; rsvd :array[0..49] of ansichar ;

end;

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# 4. Troubleshooting

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## 4.1 Trouble Shooting

#### 1) Connection Fail

(Indication/Causes) Device connection failed

(Management)

Step1. Check if the Serial Port (that connects with the device) is equipped in the Control Panel of Windows system.

If none, check the connection between the Computer and the Main Board.

You can easily check this by simply connecting of USB port with USB memory or a mouse.

If the connection is not accessed in WINDOWS, request a service maintenance because an error might have occurred with the Device and Main board connection.

Step2. Check whether the Device connection Port is well set in the Configuration.

#### 2) [ERROR] Connection Fail(No Response)

(Indication/Causes) Serial Port is opened however, Device connection failed. (Management) Same as the management of Connection Fail.

#### 3) [ERROR] Background is too high.

(Indication/Causes) In case the ADC value of a Background is above 150 from total / partial sensor. (Management)

Step1. Check if the same happens even after the device and program is started over.

If it normally works, the initial detection sensor point of the Plate and Filter Tray might have caused an error. If error frequently repeated, replace the Sensor.

Step2. Open the device and check the position of the Plate and Filter Tray.

During initialization the Halogen Lamp turns on to check the location and a light checks if the Plate Tray matches with the initial position of the entrance and light is projected at the center of first Filter of the Filter Tray.

If the position is not correct, adjust the X and F Initial Position from the Configuration.

#### 4) [ERROR] Bright variation is too high.

(Indication/Causes) In case the ADC value of Sensor (partially) is above the normal range which is from 1500 to 4000.

(Management)

- Step1. Same as Step1 of 3)
- Step2. Same as Step2 of 3)

Step3. Request a service maintenance due to an error in the optical cable.



#### 5) [ERROR] Row Max bright.

(Indication/Causes) The Maximum Lamp strength is increased up to 255 however, the light measured from the Sensor is below 1500.

(Management)

Step1. Same as Step1 of 3)

Step2. Same as Step2 of 3)

Step3. Due to dusts on top of the Band-pass Filter, clean the Filter by opening the device. Step4. Due to an expiration of a Halogen Lamp Life time, replace the Lamp.

#### 6) In case Crosstalk exists in the Sensor when measured with Q.C Plate

Step1. Same as Step1 of 3)Step2. Same as Step2 of 3)Step3. Check whether the Filter Cover is secured in place.

7) In case OD value differs a lot from the same line when measured with Q.C Plate Step1. Check if the Q.C. Plate is clean. Step2. Check whether the Filter Cover is secured in place.

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# 5. Safety Precaution

# 5.1 Transportation Safety

Special precaution is needed during device transportation because the accessories installed inside such as Band Pass Filter and Halogen Lamp are very much fragile.

- Since battery is used in supplying a power to the PC, turn off the power of the PC upon packing.
- Do not carry the device upside down.
- It is recommended to securely pack for protection.
- Be sure to transport without any objects on the top of the device.
- Attach a Fragile Mark on exterior packing box.
- Check if the Plate Tray is empty.

## 5.2 User Safety

#### **Installation Precaution**

- Install the device on a solid desk.
- Solid desk must be stable and do not expose in humid and high temperature areas.
- Install the device with a distance of 20 cm from the wall or surrounding devices.
- Do not expose to sunlight
- External Temperature: 15~28°C (Maintain the external temperature as low as possible because the accessories installed internally such as Halogen Lamp and Table PC is sensitive to exothermic reaction.)
- External Humidity: 20~80%

#### **Operation Precaution**

- Operate the device in an appropriate setting.
- Never put any foreign materials or human body parts inside the device during operated.
- Do not put heavy objects on the top of the product.
- Make sure to maintain a clean surrounding because a spill may occur inside the reader in case water is stained on the outside of a Microplate or device is operated with a plate full of reagents.

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# 6. Maintenance

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## 6.1 Maintenance

#### 1) Weekly maintenance

- Check the device using a Q.C. Plate.

#### 2) Monthly maintenance or A Quarter-year maintenance

- In case of frequent usage (at least once a day), clean monthly. On the other hand, open the device internally and clean the debris falling from the Microplate.
   At this time, be careful not to cut off the internal wiring.
- BACKUP the results in an external memory such as USB.

#### 3) Annual maintenance

Evaluate the reading accuracy of the equipment by a Certified Authority.