

# **EXPERT Plus**

# **Microplate Reader**

# **Operating manual**



Biochrom Ltd 22 Cambridge Science Park Cambridge UK CB4 0FJ

Tel.: +44/1223 423723 E-Mail: <u>asys-sales@biochrom.co.uk</u>

# **Operators Manual Expert Plus**

# Table of content

EXPERT	Plus	1
Table of	content	. 2
Chapter 1		4
Introdu	ction and Specification	. 4
1.1	Introduction and Intended use.	
1.2	Specification	
Chapter 2	1	
Installa	ion	.7
2.1	Introduction	. 7
2.2	Unpacking and Inspection	. 7
2.2	1 Unpacking Procedure	. 7
2.3	Power Requirements	. 8
2.4	Environmental Requirements	. 8
2.5	Warning and precautions	. 8
2.6	Safety symbols	. 9
2.7	Instrument Installation Procedure	10
СНАРТЕ	R 3	11
Theory	of operation	
3.1	Introduction	
3.2	Main components	
3.3	Optical system	
3.4	Description of the Digital Light Control	
3.4		
3.4	2 Measurement	12
CHAPTE	R 4	13
Operati	on and programming	13
4.1	Basic operation	
4	4.1.1 Description of the main menu options	
4.2	Method definition	
4	4.2.1 Method Definition: Filters	15
4	4.2.2 Method Definition: Layout	16
4	4.2.3 Method Definition: Samples	17
4	4.2.4       Method Definition: Standards	18
4	4.2.5       Method Definition: Kinetics	19
4	4.2.6Method Definition: Calculations	20
4	4.2.7         Method Definition: Factors	20
4	4.28 Elimination	
	4.2.8Method Definition: Transformation	22
4	4.2.9Method Definition: Thresholds (Cut-off)	
	4.2.10     Method Definition: Validation	
	4.2.11     Method Definition: Printout	
	4.2.12     Saving Method Definition	
4.3	Running a method	
4.4	Recalling a plate	
4.5	Setup	
4.5		
4.5	2 Filters	29

4.	.5.3 Date / Time	
4.	.5.4 Contrast	
4.	.5.5 Language	
Chapter	5	
Conne	ect Plus software	
5.0	Uploading and downloading plate data results and assay protocols	
5.1	Method download, upload, saving and sorting	
	5.1.1 Arrange methods	
	5.1.2 Descriptions of keys	
	5.1.3 Loading methods to 'Arrange methods'	
	5.1.4 Uploading the methods	
	5.1.5 Special Functions	
5.2	1	
	5.2.1 Arrange Plates	
	5.2.2 Load Plates	
	5.2.3 View Plate data	
	5.2.4 Save Plate data to file	
5.3	5.2.5 Upload data to Instrument Special functions of the Connect Plus software	
5.5	5.3.1 Language	
	5.3.2 Printing specials and Data capture	
	5.3.3 View a created Bitmap	
	5.3.4 Create Plate data for simulation	
	5.3.5 Exporting Plate data results	
Chanter	<i>6</i>	
-		
6.1	ng your data	
6.1 6.2	How to print directly from the instrument How to print your data from your PC	
6.2 6.3	Printout example	
	-	
-	7	
	enance	
7.1	Introduction	
7.2	Cleaning and checking the outer surface of the Instrument	
	Liquid Spills	
7.2	Regular cleaning	
7.3	Changing the Fuses Changing or adding a Filter	
7.4	.4.1 Cleaning an interference filter	
7.5	Instrument Disinfection	
	.5.1 Disinfecting Procedure	
7.6	End of lifetime - waste disposal	
	8	
-		
Perfor	mance verification	

# Chapter 1

## Introduction and Specification

#### 1.1 Introduction and Intended use.

The 'Expert Plus' is a microprocessor controlled 8-channel microplate reader designed to measure the optical density of liquids in the wells of 96-well microplates. It has been designed to meet the 98/79/EC directive of the EU for In-Vitro Diagnostic Devices.

It combines a large, graphics display with easy to use on-board software, making it ideal for use in any laboratory performing ELISA and other colorimetric microplate assays. It has both exciting styling and design that place it at the forefront of its class. It can perform single and dual end point measurements at any two wavelengths between 400 and 800nm (340 and 800 nm for Expert Plus UV). Quantitative, qualitative and Kinetics assays can be easily defined and stored in the non-volatile memory. The method definitions can be also performed by means of the delivered PC-based simulation program. Up to 100 sets of measured data can be stored and recalled for later evaluation.

## 1.2 Specification

TTT 1 (1		
Wavelength range:	400 - 800 nm (Expert Plus),	
	340 - 800 nm (Expert Plus UV)	
Filters:	405, 450, 492 and 620 nm (Expert Plus)	
	340, 405, 492 and 620 nm (Expert Plus UV)	
	supplied as standard, up to six filters possible	
Photometric method:	Multi channel, optical system with self	
	calibration and digital light control	
Light source:	Tungsten Halogen, expected life time 10 million	
	readings	
Photodetector:	Multiple silicon photodiodes	
Resolution:	0.001 OD	
Measurement range:	0.000 – 4.000 OD	
Accuracy:	+/- 1.0% (0 - 2.5 OD)	
Repeatability:	+/- 0.5% (0 - 2.5 OD)	
Reading speed:	Single wavelength: 5 secs	
Shaking:	Choice of 4 modes	
Plate format:	96-wells, flat, round and V-bottom	
Digital output:	RS-232 bi-directional and Centronics parallel	
Display:	Graphical LCD display 240 x 128 dots with	
	backlighting	
Keyboard:	23-key membrane keypad with tactile feedback	
Method storage:	120 methods	
Plate data storage:	100 plates can be stored on-board	
Dimensions and	43 x 27 x 24 cm (W x D x H), 12 kg	
weight:	· · · -	
Power requirements:	90 – 250 V ~, 47 – 63 Hz (autosensing), 80VA	
Operating temperature:	+ 10 to +35 °C	
Operating humidity:	0 to 80 % (non condensing)	
Storage temperature:	-25 to 50°C	
Storage humidity:	< 95% (non-condensing)	

## 1.3 Accessories

Expert Plus Reader with 4 Filters, power cord, RS-232 cable, Connect Plus and DigiRead software Order number:G020150
Expert Plus UV Reader with 4 Filters, power cord, RS-232 cable, Connect Plus and DigiRead software Order number:G020151
Software options:
Kim software Screening /Curve-fit
Accessories:
Spare lamp:B020007Spare lamp Expert Plus UVB020009Interference filter 340nmB010075Interference filter 405nmB010060Interference filter 450nmB010061Interference filter 450nmB010062Interference filter 550nmB010063Interference filter 620nmB010064Interference filter 690nmB010066
Other wavelengths on request

# Chapter 2

# Installation

### 2.1 Introduction

This chapter contains the necessary information for installing the instrument and the software. The installation procedures involve unpacking, power requirements, environmental requirements, interfacing and software installation.

#### 2.2 Unpacking and Inspection

The instrument is shipped in one carton that includes:

Instrument, Power cord, Computer connection cable, Printer connection cable, Software on CD Instruction manual (This manual)

#### 2.2.1 Unpacking Procedure

- 1. Visually inspect, the container for damage, before opening it. *Report any damage immediately to the delivering carrier.*
- 2. Place the carton in an upright position and open it.
- 3. Lift the instrument out of the carton and place it on a flat surface, free from dust, vibration and away from direct sunlight.
- 4. Open the plate cover and visually inspect the instrument for loose, bent or broken parts. *Report any damage immediately.*
- 5. Compare the instrument's serial number, attached on the rear panel of the instrument, against the serial number of the instrument, on the delivery (shipping) note.
- 6. Check the instrument accessories against the delivery (shipping) note.
- 7. Please save all packing materials, as they maybe required for later transportation.

### 2.3 Power Requirements

The instrument has an autosensing power supply, which operates in the voltage range from 90V to 250 V AC.

Check the voltage specifications on the rear panel of the Instrument.

#### WARNING:

For safe operation of the equipment it is mandatory that it is connected to a wall socket equipped with a ground (earth) connector.

For instructions how to change fuses please refer to chapter 7 of this manual.

### 2.4 Environmental Requirements

The instrument should be placed on an even surface that is free from dust, solvents and acidic vapors.

Vibration and direct sunlight must be avoided, to ensure correct results.

Before the instrument is installed and switched on, it should be left to stand for at least 2 hours, so there is no possibility of condensation causing a malfunction.

### 2.5 Warning and precautions

If inflammable, toxic or biologically hazardous substances are used when operating the equipment, please observe the instructions and precautions enclosed with such substance.

Never spill fluids in or on the equipment.

Wash your hands thoroughly after handling test fluids.

If equipment has been in contact with hazardous substances, it must be disinfected prior to shipment in accordance with the effective provisions.

Voltages dangerous to human life are present in this device. Do not remove any cover.

Ensure that only fuses with the rated current and of the specified type are used for replacement.

Do not touch the plate during movement of the plate transport (risk of injury).

Authorized service personnel should service the instrument only.

Do not expose the instrument to environmental condition outside the one described in the specifications. The system performance may be adversely affected if the instrument is operated outside the temperature range  $10 - 35^{\circ}$ C.

Use the equipment only in the intended manner and as specified by the manufacturer, otherwise the protection provided by the equipment may be impaired.

## 2.6 Safety symbols

The following safety symbols may be found in several locations on the instrument. Only persons who fully understand the safety precautions and recognize shock hazards should operate this instrument.

~	Alternating current
IVD	In Vitro Diagnostic Device
	Protective ground terminal
	ON
$\bigcirc$	OFF
$\underline{\land}$	Caution, see enclosed document



The symbol on the product indicates that this product shall not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment.

### 2.7 Instrument Installation Procedure

The following procedures detail the necessary steps to be followed when installing the Instrument.

When the requirements above have been met, the instrument is installed using the following procedure:

- 1. Place the instrument into the required position Ensure, that the distance between the back panel of the instrument and the wall is at least 10 cm.
- 2. Remove any packing and transport lock material from the instrument.
- 3. Plug the printer connection cable with the 25-pin connector into the respective printer port (parallel port) on the computer. Connect the other side with the 36-pin connector to the printer.
- 4. Ensure the instrument's mains power switch in the back panel of the instrument is in the OFF position.
- 5. Insert the power cable into the mains power socket in the back panel of the instrument.
- 6. Use the interface cable if a connection to the PC is desired. The interfacing cable is connected into the 9-pin serial interface socket in the back panel of the instrument.

Plug the other side of the interface cable into a free serial interface socket of the computer. If the connector of the computer is a 25-pin type, use a 9 to 25-pin adapter.

7. Turn the instrument on. After the instrument has finished the initialization please perform a calibration as described in paragraph 4.5.2.

# **CHAPTER 3**

# Theory of operation

### 3.1 Introduction

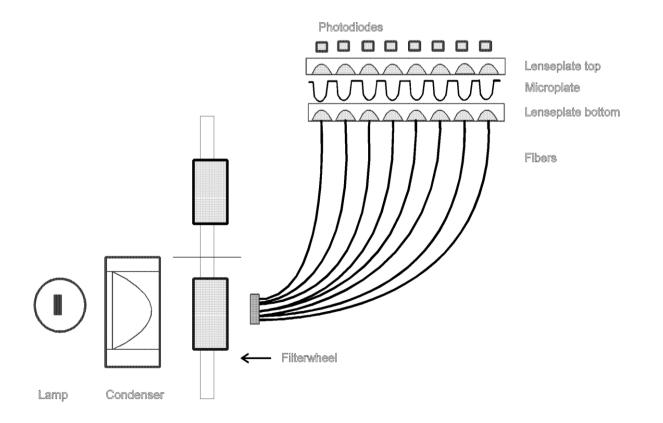
This chapter gives the description of the main components, the optical system and describes the digital light control.

#### 3.2 Main components

The main components of the reader are the CPU board, the preamplifier board with the photodiodes, the plate transport mechanism, the light source, the filterwheel and the power supply unit.

#### 3.3 Optical system

The optical system consists of the lamp, the condenser lens, the interference filters on the six position filter wheel, the fiber bundle, a focusing lens for each of the eight measurement channels and eight silicon photodetectors with a focusing lens in front of each detector.



## 3.4 Description of the Digital Light Control

The CPU of the Expert Plus reader can control the lamp intensity by means of a 16-bit Digital-Analog converter in combination with the lamp powersupply. At any time the microcontroller "knows" the status of the light control, so that measurement errors caused by undetected light control problems are prevented.

#### 3.4.1 Calibration run

The calibration run is initiated any time a filter wavelength is to be changed or by specific request of the user. During the calibration run the lamp intensity for each wavelength is adjusted to a value that guaranties optimum measurement conditions and highest resolution.

#### 3.4.2 Measurement

After the initial calibration run, the required light intensity for each wavelength is known by the system, this means that for any subsequent measurements the light intensity is set to the stored value and only a check is to be done.

Now the output for each of the eight channels, known as the 100% values, is stored and the plate transport starts moving. Several measurements are taken in the center of each well. After the measurement is finished, the absorbance is calculated under consideration of the 100% values and the so-called 'zero-measurement'. The results are then transmitted to the controlling PC.

This digital light control system prevents any drift out of the optimum operating range, known to current analogue light control systems. The digital light control makes it possible to detect a lamp failure before the lamp has reached the end of its lifetime.

Another important feature is the active filter detection. If light intensity for a wavelength is different to the value in the memory, an error message will be displayed. Any wrong inserted or defective filter will cause therefore an error message.

# **CHAPTER 4**

# Operation and programming

### 4.1 Basic operation

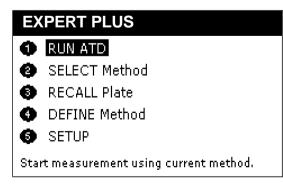
The 240 x 128 pixel high resolution, graphical, liquid crystal display provides the user with set up parameters and experimental results and the keypad is a hard wearing, spill-proof membrane. Navigating around the menu structure is simple:

- Press the corresponding number on the keypad to enter the user mode choices or numeric data
- Press the soft key on the keypad directly below the corresponding option on the display (F1, F2, F3 and F4) to select that option
- Use the four **↓** ▲ **↓** cursor keys to navigate around the options when the prompts appear
- Use the enter key to move forward to the next display page
- Use the ESC key as an escape mechanism to go back
- Incorrect entries can be removed using the **{** key

The keypad can be locked to prevent unauthorized access. (default PIN is 1505). Service engineers can access service functions from here by entry of a specific PIN

Text entry, when required or appropriate, is also easy and described when its use first appears.

The main menu screen is displayed on start up. This and all the other displays are divided into three main sections:



- the top line which shows the current topic
- the main section which serves to present the entry parameters
- the bottom line that indicates the description of the soft-keys.

In some cases, especially when a graphical content is shown, the top and / or the bottom line are not shown.

### 4.1.1 Description of the main menu options

Run	This option starts a measurement with the last used or defined	
	method.	
Select Method	This option selects a pre-defined or previously stored method to	
	use	
Recall Plate data	This option recalls previously stored measurement data.	
Define Method	This option enables a new method to be defined ( <b>Method</b>	
	<b>Definition</b> ), either from the beginning or by modification of a	
	previously stored or default method	
Setup	This option enables the basic plate reader parameters, such as	
	printer driver and filter set up/calibration, to be set up.	

## 4.2 Method definition

Me	Method Definition		
<b>O</b>	START new Method		
0	SELECT a Method and Edit		
0	DELETE a Method		
Ø	Explain more		
Choose this if no similar method exists.			

The method definition submenu offers three choices. The first one is to define a new method; the second is mainly intended to edit an existing method that can then replace the original method or stored using a new name. The third option is to delete an existing method.

To start a method definition chose either 1 or 2 from the menu. The procedure is identical for both options.

#### 4.2.1 Method Definition: Filters

• Measurement

Use the  $\checkmark$  keys to select the filter to be used for measurement.

• Reference

Use the  $\checkmark$  keys to select the filter to be used as a reference; use "none" for no filter. The reference value, usually 620nm, is subtracted from the measured value to correct for imperfections etc. on the plastic microplate; these can have a great effect on low OD measurements.

• Shake

Press F2 if plate shaking is required before measurement; this is often used if working with cells so they do not settle on bottom of well. Enter the shaking time required in seconds and the degree of shaking. The options are slow / medium / fast / very fast and a combination of speed and travel distance. Press F4 to accept the entries.

• Kinetics

Press F4 if kinetics is required. Enter the interval time (time between readings) and the number of measurements. The total process time is calculated and indicated on the screen. The minimum interval time is 10 seconds and the maximum number of measurements is 100.

Note: Up to 100 plate data results can be stored in the instruments memory. If during the kinetic measurement the maximum capacity is reached the new results will overwrite the results stored first. When previous measured data should be kept please save these data with the Connect Plus program. Press F4 to accept the entries.

Press enter to move to the next method definition box.

#### 4.2.2 Method Definition: Layout

(for controls and standards)

• Options

Press F3 to define default directions (horizontal or vertical) for replicates of controls and for samples. Move the  $\checkmark$  symbol to the desired option with the up / down arrow keys and select the option by pressing either the left or right arrow key. Press F4 to accept the entries.

• Choose well definition

Press F1 '--->' to select the well type required from the options listed at the bottom of the display box. With the exception of BK and ST the terms are just names and whatever you want them to be, they are not "tied". For example, LP and HP can be used to substitute for terms T1 and T2 defined in a specific test kit. The terms can be used in calculations defined later in the method definition.

Method Definition: Layout			
Locations E01	of ST4:	E02;	
Туре:	BK PC NC	LP HP CC	) QC <mark>ST</mark>
>	ST4	Options	Place

BK	Blank	The absorbance of the blank value(s) is <b>automatically</b> subtracted from the absorbance of the other wells.
NC	Negative Control	Use for qualitative / screening tests
PC	Positive Control	Use for qualitative / screening tests
LP	Low Positive	Use to see if results are outside pre-defined limits
HP	High Positive	Use to see if results are outside pre-defined limits
CO	Control	Use as required
QC	Quality Control	Use as required
ST	Standards	Use for quantitative determinations; a maximum of 16 standards can be used

• Placement

Press F4 to place the required well type at the location shown on the display. Enter replicates by repeat pressing of F4 as appropriate. By alternating between F1 and F4 it is possible to build up the plate as required. You can come back to edit the layout if required. Use the arrow keys to move around the plate layout. Above the plate illustration the current position and well type is shown.

• Standards

When ST (standards) is selected, 'ST1' option appears as F2. After placing these on the layout, press F2 to get ST2. A total of 16 standards, with replicates, can be built up in this way. When doing standards, note that the concentrations are entered later on.

Press enter to move to the next method definition box.

#### 4.2.3 Method Definition: Samples

Sample can be placed either individually by moving the cursor to the desired location, alternatively all wells not already used can be filled with samples. Replicate samples can be used in combination with single samples when desired; there is no limit on the replicate number.

• Options

Press F3 to define default directions (horizontal or vertical) for replicates of samples and for different samples. Move the  $\checkmark$  symbol to the desired option with the up / down arrow keys and select the option by pressing either the left or right arrow key. Press F4 to accept the entries.

• Place Samples

Place the first sample (SM1) and replicates using F4, the press F1 to get SM2. Use F4 to place the second sample, and repeat as necessary. Replicates of samples can be placed in any free location; it is not necessary that the wells are adjacent.

• Fill All

To reproduce the first sample pattern for all samples: Sample 1 has to be defined. The Function 'Fill All' (F2) will fill the plate accordingly as set in 'Options'.

To erase all already defined sample positions press the Backspace ( $\leftarrow$ ) for a few seconds.

Press enter to move to the next method definition box

#### 4.2.4 Method Definition: Standards

In case standards have been defined in the layout section, the calibration screen appears.

Use this option to enter the values of the standards, the units for the concentration and to choose the curve-fit method (model).

Method Definition: Standards				
	Concentrations Units			
2	448	ng/ml		
3	1792	Model		
4	7168	4-Parameter		
5	28672	Lin/Log		
6	1.1469e+005			
Q	Quick			

The concentrations for the standards should be entered first. The screen offers as many entry fields as standards have been defined.

In case the standards are in linear serial dilution, the Quick key (F1) offers a quick way of entering the concentrations.

Generate Concentrations			
Start value:	112		
Divide Multiply			
by:	4		

Units can be defined using the alphanumeric routine.

Now select the analysis model for the standard curve. The options are Linear regression, Parabolic, Cubic, Point to Point (linear interpolation), Spline and 4-parameter.

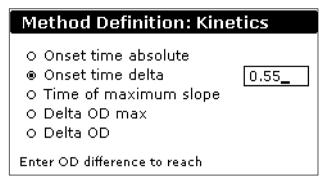
Finally select the y- and x-axis format required for presentation of the results; linear/linear, log/linear, linear/log, log/log.

Press enter to move to the next method definition box.

#### 4.2.5 Method Definition: Kinetics

In case a Kinetic measurement has been defined, the Kinetics calculation definition window will appear after the layout has been set up. The calculated results for these kinetics options are normally used as the basis for quantitative, qualitative or combined sample evaluation.

Five kinetic calculation options are available and described below:



#### <u>Onset time absolute</u>

This option calculates the time required to reache the Absorbance value specified in the input field, for each well. A linear regression is used to interpolate the time between the kinetic measurement points.

#### Onset time delta

The option calculates the time required for the Absorbance difference between that of the first measurement and that specified in the input field to be reached, for each well. A linear regression is used to interpolate the time between the kinetic measurement points.

#### Time of maximum slope

This option calculates the time at which the maximum slope is reached. A linear regression is performed for every three consecutive readings over the whole measurement time. The center point in time of the regression with the steepest slope is the time the maximum slope.

#### Delta OD max.

This function calculates the absorbance change, normalized to a minute; for the three readings at the maximum slope.

#### D<u>elta OD</u>

The absorbance change, normalized to a minute, over the whole measurement time is calculated.

• Note: If non of these kinetic options is chosen, the raw absorbance data for each well at the specified time intervals can be printed out.

#### 4.2.6 Method Definition: Calculations

In case kinetics is not activated, the Calculation window will appear after the layout has been set up.

Method Definition: Calculations		
□ Factors ⊲⊳		
🛛 Elimination		
🛛 Transformation		
🛛 Thresholds		
🛛 Validation		
Test specific constants.		

Use the left / right keys to select the option required, and up / down keys to move onto the next.

Press enter to move to the next method definition screen. Depending on the selected options different screens will be shown.

Note: In case controls are used in replicates they must be referred as avg(xx), otherwise they are not recognized in a formula (xx should be replaced by the name of the control).

#### 4.2.7 Method Definition: Factors

Use this option to enter a constant specific to a particular test, for example to compensate for batch variations if biological materials are being used as part of the assay kit. Thus if the material is less biologically active than it should be, the manufacturer will specify the use of a factor or factors to normalize results to what they should be.

These factors can be used in any further calculation step, e.g. in the transformation formulas.

Press enter to move to the next method definition screen

#### 4.28 Elimination

This option allows to define conditions for the automatic elimination of individual controls which do not meet the set criteria. Two different controls can be evaluated.

The selection field *Ctrl:* shows the selected control types, the left / right cursor keys are used to scroll through the available ones. Only control types which are defined in the layout are shown.

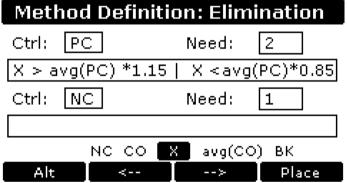
The field *Need* is used to enter the number of controls which should be left after the elimination process. When this condition is not met, the test is declared invalid.

The next entry field is used to enter the condition for the elimination. For example these individual positive controls should be eliminated which are deviating more than 15 % from the mean value. The condition is entered as following:

X > avg(PC) \*1.15 | X < avg(PC) \*0.85

X represents any single well of the positive control well, the '|' stands for a logical or.

The formula can be read as: If as single positive control is higher than 115 % of the mean value of the positive control or if a single positive control is lower than 85 % of the mean value then eliminate the respective single positive control.



When the cursor is in the entry field the function keys are active and allow to select different options. There are three groups of elements that can be selected by pressing the F1 (Alt) key. The first group contains controls (single and average) and the factors, the second one operators like +, -, /, etc. and the third one all available mathematical and logical functions.

Use F2 and F3 to select the desired element and F4 to place it.

#### 4.2.8 Method Definition: Transformation

Method Definition: Transform
Formula will be applied to each well. X stands for original well value.
Y=
((X-avg(CO))/(avg(QC)-avg(CO)))*1
avg(HP) avg(CO) avg(QC) QC
Alt <> Place

Use this option to define a calculation equation to be applied to each well. All typical mathematical functions are available ( + /- , sqr, abs, log, log10,  $x^2$ , etc.) and Pow (power of x).

There are three groups of elements that can be selected by pressing the F1 (Alt) key. The first group contains controls (single and average) and the factors, the second one operators like +, -, /, etc. and the third one all available mathematical and logical functions.

Use F2 and F3 to select the desired element and F4 to place it

# Note: If a Blank (BK) is defined it will be automatically subtracted from the absorbencies of all other wells.

Example: An index (in per cent), based on the absorbance of the CO control should be calculated for each well (Absorbance of the CO control = 100 %).

The formula should be entered as follows: (X\*100) / avg(CO)

Press enter to move to the next method definition screen.

#### 4.2.9 Method Definition: Thresholds (Cut-off)

Use this option to define the threshold limits for a qualitative result. Up to three different classes (ranges) are possible. The label for the classes can be user defined. For **n** thresholds you have n+1 quantitative labels.

Cut-off limits can be defined for the measured absorbance values (OD.), kinetic values, transformed values or concentration values, depending on the test protocol.

To define the threshold(s) proceed as follows:

Select the data source first. The options are 'Val' (absorbance or kinetic data), 'Trf' (transformed data) or 'Conc' (concentration). Next enter the label for the upper limit in the top left edit field. This can be a text like 'Positive' or a symbol like '+'. Now enter the threshold condition for the upper limit. This

can be a value or an equation. After the condition for the upper limit has been entered,

labels for other classes and corresponding conditions can be entered.

The threshold limits work as follows:

```
Label 1

Threshold A

Label 2

Threshold B

Label 3

If X > A \rightarrow Label 1

If X <=A and X > B \rightarrow Label 2

If X <=B \rightarrow Label 3
```

```
(X ... Value of well)
```

The example below shows the setup for a typical Elisa assay. Here a sample is considered positive if the absorbance value is above (mean Positive control - Negative control) / 2. In addition it is specified that samples that are +/-10% of the cut-off are considered as equivocal.

Method Definition: Thresholds								
Pos	Data	source:	Val					
	╡ [((ª	vg(PC)-N	C)/2)*1.1					
equivoc	╡ [((a	((avg(PC)-NC)/2)*0.9						
-			_					
=<>/* <b>[]</b> - <b>]</b> + abc								
Up/Lo	<	h,->-	<b>I</b> Place					

Press enter to move to the next method definition box

#### 4.2.10 Method Definition: Validation

Use this option to apply parameters to ensure that the test is valid within the requirements stated by the assay test protocol. If these conditions are not met, the result of the test is considered not valid. This is indicated on the printout.

Validation criteria can be defined for the measured absorbance values or kinetic values (Val), transformed values (Trf) as defined in Transformation or concentration values (Conc), depending on the test protocol.

To define a validation condition chose the data source first. Then enter the first condition. At the bottom of the screen you can see various options like avg(PC), Fct1, etc. Use the function keys F2 and F3 to select the desired option and press F4 to place the selected option. 'Alt' (F1-key) toggles between well types, mathematical operators and mathematical functions.

To connect 2 or more conditions of the same data source use the '&' sign. If you use '&' between two conditions BOTH must be fulfilled in order for the measurement to be valid.

Use >= for  $\geq$  and <= for  $\leq$ .

Example:

For an Elisa assay the following criteria must be fulfilled:

- The absorbance of the Standard 1 must be < 0.2.
- The absorbance of the Standard 2 must be higher than that of the Negative Control.
- The absorbance of the Standard 2 must be lower than that of the Low Positive Control.
- The High Positive Control must be > 250 IU/ml.
- The Negative Control must be < 40 IU/ml.

Method Definition: Validation
Data source 1: Val
Cond.1: ST1<0.2&ST2>NC&ST1 <lp< td=""></lp<>
Data source 2: Conc
Cond.2: HP>250&NC<40

Press enter to move to the next method definition box

#### 4.2.11 Method Definition: Printout

Use this option to select the content of the printout. You can select one, several or all options. Only options relevant to the assay that has been defined / selected are displayed; the image below shows all options that are possible (if kinetics has been selected, the option for Absorbances is replaced by Kinetic values).

Method Definition: Printout					
⊠ Layout ⊠ Absorbances □ Averages □ Transformed □ Concentrations	<ul> <li>□ Thresholds</li> <li>□ STD Curve</li> <li>□ Kinetic Curves</li> <li>□ Statistics</li> </ul>				
Location of controls a	ind samples.				

If replicates have been used, the average value can be printed out.

Press enter to move to the next method definition box

#### 4.2.12 Saving Method Definition

The complete method has now been defined and should be saved in the non-volatile memory. There are three options how the new methods should be stored.

The new method can be appended to the list of already existing methods by scrolling down the list and pressing the **Append** (F4) key.

It is also possible to store the new method at any position in the list by scrolling to the desired position for the new method. Press now the **Insert** (F4) key, the new method will be inserted before the current selected position.

In case an existing method should be replaced by the new one , scroll to the method to be replaced and press the **Replace** (F3) key.

Enter the method name using the alphanumeric function and press enter. This new method is then placed as the default method for the next measurement.

## 4.3 Running a method

This can either be done immediately after defining a method (press 1) or by recalling an existing method (press 2, select using  $\checkmark \checkmark$  and F4). The plate carrier will move out now, allowing loading the microplate.

Each plate requires a unique ID. This ID is used to identify the plate on the printout and the measured data for later recall.

In case an ID already used is entered, the screen will show a warning, asking if the previous measured data with the same ID should be overwritten.

The maximum number of samples for the chosen method is displayed below the plate ID. When less than the maximum number of samples should be processed, the number of existing samples can be entered. This will avoid that empty well positions show unwanted results.

Press the F3 key to select the post run option from three choices: **Printer –** Use if a printer is connected (results are sent out via both the parallel and serial data ports)

**Serial** – Use if PC connected to send results through the serial port. **None** – Use if neither printer nor PC are connected. Results are stored in the memory and can be recalled later using the Recall Plate Data option. This can speed up the measurement of a batch of plates significantly.

When the plate ID has been entered press the RUN or the ENTER key to start the measurement. During reading the screen shows a status message. A soft-key labeled 'STOP' is the only key active during reading and subsequent printing. Up to 100 plate data results can be stored in memory; after this is full, the new results overwrite the first results. To avoid this, results can be downloaded to PC for archiving.

## 4.4 Recalling a plate

Previously run assays are stored using the unique plate ID. The Recall menu can be called from the main menu by pressing key 3 and the ID.

R	CAL	Plate		
		Select a	plate	
Pla	234	test2		
	4	2562		
Με	3	225.4		
	44	2567		÷
	7	222.4		
۷o	234	testnew		
Se	earch		Cancel	Select

The screen shows a list of stored plates. The left column indicates the plate ID, the center column shows the method used for the measurement.

A plate can be chosen using the up / down arrow keys or with the help of the search function. The search function is especially useful in case of many stored plates.

After a plate has been chosen press either F4 or the Enter key to load the data from the memory.

RECALL Plate Data							
Plate ID: 34 Method: Toxoplasma IgG 3pt							
You may use original or another method.							
Other	Show	Print OD	Process				

Now the desired processing can be chosen. The options are:

**Other** – use a different method. Available methods are displayed (see earlier).

**Show –** show the plate data

**Print OD –** print the OD values obtained for the plate. No calculations are carried out

**Process** – process the data with the chosen method; calculations to display slope (if appropriate) and print out obtained (if selected originally)

**Note:** It is the sole responsibility of the user to make sure that the chosen method gives useful results. The program cannot determine if the selected method makes sense with the existing data.

When the measured OD values should be printed press the key F3 (Raw). No calculations will be performed with this option.

To show the measured OD values on the screen of the reader press F2 (Show).

RECALL Plate Data							
Plate ID:	34	B02:SM4					
Method:	Toxoplasma	•+•					
Absorbanc	e						
0.162							
Use arrow keys to navigate through wells							

The new screen shows the plate ID, the original method and the absorbance (OD. value) of the selected position. On the right side of the screen there is a representation of a microplate. You can move across the plate with the cursor keys to select a particular well. At top of the plate representation the actual well location and the well designation is indicated.

### 4.5 Setup

#### 4.5.1 Printer

Use this option to define which printer is connected to the plate reader. You can chose from a wide list of printer models.

Many different printers can be used with generic type drivers. Consult the printer manual in case your printer is not listed, to find out the nearest compatible type.

Use the up / down arrow keys to highlight the printer required and press enter to confirm your selection. Depending on the printer type some options like paper size may be shown. Use the function keys to select the required option and press the OK key to confirm the selection.

#### 4.5.2 Filters

The Filter submenu serves to review the installed filters, inform the system about new or removed filters and to perform a calibration. To remove a filter from the list enter 0 (zero) for the wavelength and press F3 (Curr). To add a filter enter the wavelength of the newly installed filter in the respective edit field corresponding to the position on the filterwheel and press F3.

Any new installed filter must be calibrated to save the wavelength information.

It is strongly recommended that all filters be calibrated before the instrument is used the first time.

For a technical description of the calibration process please refer to chapter 3.

#### 4.5.3 Date / Time

Use this menu option to change the date and time with  $\uparrow$  and the keypad. A choice of AM, PM or 24 hour clock is available.

#### 4.5.4 Contrast

Use this option to change the contrast of the liquid crystal display using the F1 and F2 keys.

#### 4.5.5 Language

Use  $\checkmark$  to select the language that is used on the displays and printouts.

# Chapter 5

# **Connect Plus software**

# 5.0 Uploading and downloading plate data results and assay protocols

The ability to download plate data results means that such results can be permanently archived in addition to having a print out or download to spreadsheet. New assay protocols can be uploaded into the instrument easily, meaning that they can be prepared away from the laboratory. Note also that when the instrument's storage capacity of 120 methods and 100 plate results is full, these can be downloaded for archiving and removed from the instrument to make space for new ones.

The procedures for doing this are easily achieved using the Connect Plus software on the CD supplied with the instrument.

**IMPORTANT:** Uploading methods or plates to the instrument from the PC will override all methods or all plates currently stored in the reader memory. To avoid loosing any information you have to load the methods/plate data down to the computer (as described in 5.1.3.1 and 5.2.2.1 Download from the Instrument) before and upload them with the new method/data back to the instrument.

## 5.1 Method download, upload, saving and sorting

Connect the reader and the computer with the serial cable supplied. Locate the folder 'Connect Plus' on the Reader CD and double click on the file sim.exe to start the software. Before the software can be used the first time the COM port (serial port) on the computer to which the reader is connected must be selected.

Open the Files menu in the top left corner of the Connect Plus window and select Serial communication.



Select the correct COM port (serial port) and press the OK key to save the setting.

#### 5.1.1 Arrange methods

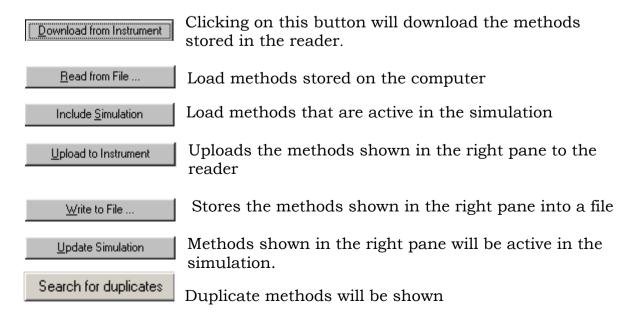
From the Files menu select 'Arrange methods'. A new window like the one below will appear.

Arrange methods	×
Method Definition Sources	Method Definition Targets
Download from Instrument	Upload to Instrument
<u>R</u> ead from File	<u></u> write to File
Include Simulation	Update Simulation
	-> <
Select All Unselect Delete	Select All Unselect Delete
Search for duplicates	Close Search for duplicates

The arrange methods mode is used to update, store and archive method definitions. All methods may be stored to a file. They may also be rearranged to a customer designed order.

The Connect Plus simulation program can be updated with existing methods from the reader in order to modify and store them. New defined methods – from a file or the simulation mode – may easily be uploaded to the instrument.

#### 5.1.2 Descriptions of keys



#### 5.1.3 Loading methods to 'Arrange methods'

In order to load methods to the left pane they can be imported from different sources.

5.1.3.1 Download from the Instrument

All methods stored in the instrument can be uploaded to the computer: Click on the button 'Download from Instrument'. A pop-up window will appear which shows the download progress. After the download is finished the methods are shown in the left pane.

5.1.3.2 Read from file

Click on the button 'Read from file'. A pop-up window will appear where \*.kmt files may the selected. After pressing 'Open' all methods stored in the selected file should be shown in the left pane.

5.1.3.3 Loading methods from the Simulation

By pressing the bottom 'Include Simulation' all methods defined in the simulation are loaded to the left pane.

Note: Some basic methods as well as demo data are available on the CD-ROM. Load the file named 'Demo' to use these methods on the simulation. A description how to load the demo plate data can be found on the next page.

#### 5.1.4 Uploading the methods

Before you can upload the methods to the different targets you have to copy them into the right pane. Therefore you have to select them and click on the bottom  $\rightarrow$ .

Note: If you intend to load the methods up to the reader in a certain order, you have to arrange them, as you desire at this time.

5.1.4.1 Upload to the Instruments

If the bottom is 'Upload to Instrument' is pressed *all* methods in the right pane – no matter if they are selected or not - are loaded to the instrument

**Note:** Uploading methods will override all methods currently stored in the reader memory. To avoid loosing any methods you have to load them up to the computer before (as described in 5.1.3.1 Download from the Instrument).

#### 5.1.4.2 Write to File

All methods from the right pane can be saved to a single file by clicking 'Write to File'.

5.1.4.3 Update Simulation

To update the simulation with new methods from the right pane use the 'Update to Simulation' bottom. The new methods are added to the already existing methods in the simulation.

#### 5.1.5 Special Functions

For your convenience the menu contains the options 'Select All' and 'Unselect'.

In case one or more methods should not be saved they can be selected by a mouse click and deleted.

### 5. 2 Plate data upload and download

For plate up- and download choose 'Arrange plates' from the file menu.

#### 5.2.1 Arrange Plates

In this menu you are able load plate data to the computer in order to save it or load it into a spreadsheet. The plate data can also be processed using a suitable method and the result can be shown on the screen like on a printout. You can even upload plate data back to the instrument.

Arrange plates	;					×				
	Source	s			$\square$ Selection only					
	<u>D</u> ownlo	ad			Upload					
	<u>R</u> ead file	e			<u>W</u> rite file					
001. S: 5. 002. S: 4. 003. S: 3. 004. S: 2. 005. S: 1. 006. S: ep 007. S: ep 008. S: ep 010. S: ep 011. S: ep 011. S: ep 013. S: ep 014. S: ep 014. S: ep	234 234 234 234 4 3 44 7 234 99 8888 4556 5 89	04.06.03 04.06.03 04.06.03 04.06.03 04.06.03 13.02.03 13.02.03 13.02.03 13.02.03 13.02.03 27.01.03 27.01.03 27.01.03 27.01.03 27.01.03	22:48 22:48 22:48 22:48 22:48 22:42 22:11 22:09 21:05 16:55 23:27 23:26 21:41 21:35 21:34	test2 test2 test2 test2 22567 2225.4 22567 222.4 testnew 222-5 222-5 222-5 222-5 222-5						
	Select All Unselect Delete									

The plate window is showing the following information (from left to the right)

- Sequential number of plates, the newest plate has the number 001
- Code for the data source. S = simulation, R = reader, Fx = file.
- ep indicates End-point measurement, incremental numbers (1. 2. ..) showing the individual measurements of kinetic readings.
- Plate ID
- Data and time of data generation
- Method name

For your convenience the menu contains the options 'Select All' and 'Unselect'.

#### 5.2.2 Load Plates

You may either load plate data from the instrument or from a file.

5.2.2.1 Download from the Instrument

All plates stored in the instrument can be uploaded to the computer: Click on the button 'Download from Instrument'. A pop-up window will appear which shows the download progress. After the download is finished the plates are shown in the list below.

5.2.2.2 Read from file

Click on the button 'Read from file'. A pop-up window will appear where \*.kpl files may the selected. After pressing 'Open' all plates stored in the selected file are listed in the window below.

#### 5.2.3 View Plate data

Double-click on a plate to see measured data and other details: a plate data window opens up.

Plate data												×
7 📕 F	late ID 2	25		Kinetic(5)		Method n	ame Kl	N				
	ate 20.0	07.03	Time 13	:47	Filter(s)	620 nm						
1	2	3	4	5	6	7	8	9	10	11	12	
A 0.080	0.080	0.073	0.080	0.068	0.064	0.069	1.740	0.652	1.591	0.067	0.069	1
B 0.072	0.071	0.078	0.074	0.076	0.065	0.073	1.672	0.780	1.419	0.070	0.070	
C 0.072	0.075	0.074	0.083	0.086	0.075	0.064	1.706	0.840	1.319	0.070	0.065	1
D 0.065	0.063	0.060	0.068	0.071	0.082	0.071	1.850	1.056	1.147	0.065	0.070	
E 0.067	0.070	0.073	0.067	0.068	0.074	0.072	1.700	0.574	1.553	0.066	0.065	
F 0.074	0.076	0.082	0.076	0.066	0.069	0.069	1.684	0.555	1.551	0.081	0.074	1
G 0.073	0.079	0.078	0.076	0.069	0.068	0.065	1.722	0.661	1.484	0.085	0.072	
Н 0.220	0.067	0.074	0.064	0.069	0.061	0.059	1.717	0.654	1.548	0.072	0.077	
									ОК		Cancel	

You may scroll through all plates loaded into the menu by using the scroll bottoms in the left upper corner.

#### 5.2.4 Save Plate data to file

Select plate data to be saved to a file and click on 'Write to File'. A pop-up window will appear where you may save all selected plates to a \*.kpl file.

#### 5.2.5 Upload data to Instrument

You are also able to load plate data to the reader. Select the plates you would like to upload and press 'Upload to Instrument'.

<u>Note:</u> Uploading plates will override all plate currently stored in the reader memory. To avoid loosing any plate data you have to load them up to the computer (as described in 5.2.2.1 Download from the Instrument) before.

#### 5.3 Special functions of the Connect Plus software

#### 5.3.1 Language

You may choose from different languages for the Connect Plus software.

Open the 'Special' menu in the top left corner of the Connect Plus window and select 'Simulate language': a 'Language' window appears. Choose a language from the pull down menu and press 'OK'. The software will be set to the chosen language.

#### 5.3.2 Printing specials and Data capture

Connect plus offers you different options for what to do with your data: you can capture the data to a file (vrsim.prn), print it or create a bitmap of a printing preview. You may also save your data as vrsimser.txt or direct it to a com port.

This is - of course – only possible in the simulation software. Instead of printing the data directly after a measurement you may choose form different options available in the simulation software.

Open 'Special' in the top left corner of the Connect Plus window and select 'Printing options...'. The 'Printing simulation' window has two parts: a parallel and a serial printing simulation.

Parallel printing simulation

- You may choose to save your data in a file as vrsim.prn.
- You can print the data with your standard windows printer. Select 'Direct to parallel port' and choose the parallel port your printer is connected from the pull down menu.
- The third option is to create a bitmap with your data. A bitmap showing a printing preview opens up.

Serial printing simulation

• You may capture your data to a text file (vrsimser.txt) which can be used to import data in other software programs like Microsoft Excel. Please refer to 5.3.5 for further details

• The second option is to direct the data to a com port. This option might be useful to send data to a different PC.

Choose an option for serial and parallel printing. Confirm your choice by pressing 'OK'. The program is now set to your convenience. After the next measurement the data will be processed (printed, save to file, etc.) as set in Printing options.

#### 5.3.3 View a created Bitmap

Use the 'View BMP' option from the menu 'Special' to view a previously created bitmap (simulated printout).

#### 5.3.4 Create Plate data for simulation

You are able to create plate data for simulation purposes. This data will be used for simulated measurements.

Open the 'Special' menu in the top left corner of the Connect Plus window and select 'Edit plate data'. A 'Plate data' window appears which shows a microplate matrix.

You can navigate through the wells with the 'Tab'-key to the right and with the combination of 'Tab' and 'Shift' to the left. Use the Up- and Down- Keys (  $\uparrow$ ,  $\downarrow$ ).to move across the rows. To enter a value select the respective well and type in the desired value.

#### 5.3.5 Exporting Plate data results

Plate data results can be exported to other software programs with Connect Plus. Load the plate data to the program as described above. Set the serial printing simulation in 'printing options' to 'capture to file' (vrsimser.txt). Recall the plate data results and press 'F3 – Print OD' if you need the raw data only or 'F4 - Process' to get the processed data. Either way the data of this plate is now stored in vrsimser.txt in the folder in which the simulation software is installed.

To import the data to other programs please follow the instructions from the specific software.

Importing to Microsoft EXCEL (or similar Windows software):

Open EXCEL, click on 'File ' and choose 'Open...'. Open the folder which contains the file vrsimser.txt , select it and press 'Open'. Follow the instructions on the screen to import the plate data correctly to Excel.

# Chapter 6

# Printing your data

#### 6.1 How to print directly from the instrument

The EXPERT Plus has the great feature that you are able to print your data directly from the instrument - without connecting it to a computer. You may choose from a wide range of printers.

See 4.5.1 Printer

It is easy: at the end of each measurement your processed data is automatically printed.

You can also print all stored plate data. Just choose 'Recall Plate data' from the main menu and select the data you would like to print. You may either print the absorption values (F3) or the processed data (F4).

### 6.2 How to print your data from your PC

If you don't have a printer connected to the instrument you can print the data with the printer connected to your computer. All data from the instrument can be uploaded to your computer with Connect Plus. You are able to print all data stored in Connect Plus. All it takes are a few steps:

- Measure the plate with a method of your choice. If no printer is connected you have to choose 'Non' for output.
- Choose 'Recall Plate data' if you wish to view your data on the screen. See 4.5. You can also see which method has been used with your plate.
- Connection to your PC: Make sure the EXPERT Plus is connected to your computer as described above.
- Open the Connect Plus software and make sure the right method for your plate date is available. If the method is not stored on the computer you have to download it from the reader and update the simulation with the method first. Please refer to 5.1.1 Arrange methods.
- Next download the plate data from the instrument to your PC. Please refer to 5. 2 Plate data upload and download.
- Before the next step set your printer in printing options: Select 'Special' and 'Printing options...'. Choose 'Direct to parallel port' and the parallel port to which your standard Windows printer is connected. Confirm with OK.
- Now choose 'RECALL Plate data' from the main menu of the simulation software. Select the plate you would like to print and press 'enter' or 'select'. You may either just print the OD values only (F3) or the processed data (F4).

### 6.3 Printout example

The example on the next page shows a typical printout of a screening test with most the calculation options selected.

The header lines are showing the plate ID, the used method, the measurement date and time and the filter(s) used for the measurement.

The next line indicates if the test is valid or not. In case of an invalid test the condition not met will be indicated too.

The line after can be used to record lot numbers and expiration date of the reagent kit as well as the operators name.

The legend line indicates the content and order of the results in the plate matrix. The line after the legend shows the threshold limits.

It is followed by the measured and calculated data in a plate matrix format. This is followed by statistical information about the controls as well as information about the validity of the assay.

#### Plate ID: 34

Method : ENA-6 SCREEN Measurement Date : 29.08.04 19:52 Measurement Filters : 405/620 nm Test is valid. Exp.Date: Lot no.:

Operator:

Legend: Layout / Absorbance / Transformation / Thresholds Threshold limits (Trf): "POS" 1.09 "EQ" 0.9 "NEG"

	1	2	3	4	5	6	7	8	9	10	11	12
	BK	SM3	SM11	SM19	SM27	SM35	SM43	SM51	SM59	SM67	SM75	SM83
	0.000	0.905	0.418	0.555	0.797	0.436	0.094	0.192	-0.040	-0.040	-0.040	-0.040
Α	0	2.922	1.35	1.792	2.574	1.408	0.3036	0.62	-0.1292	-0.1292	-0.1292	-0.1292
		POS	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
	NC	SM4	SM12	SM20	SM28	SM36	SM44	SM52	SM60	SM68	SM76	SM84
	0.084	1.194	0.224	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
В	0.2713	3.856	0.7234	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	NEG	POS	NEG									
	C0	SM5	SM13	SM21	SM29	SM37	SM45	SM53	SM61	SM69	SM77	SM85
	0.306	0.553	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
С	0.9882	1.786	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	EQ	POS	NEG									
	C0	SM6	SM14	SM22	SM30	SM38	SM46	SM54	SM62	SM70	SM78	SM86
	0.314	0.685	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
D	1.014	2.212	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	EQ	POS	NEG									
	C0	SM7	SM15	SM23	SM31	SM39	SM47	SM55	SM63	SM71	SM79	SM87
	0.309	0.633	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
Е	0.9978	2.044	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	EQ	POS	NEG									
	PC	SM8	SM16	SM24	SM32	SM40	SM48	SM56	SM64	SM72	SM80	SM88
	1.083	0.256	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
F	3.497	0.8267	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	POS	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
	SM1	SM9	SM17	SM25	SM33	SM41	SM49	SM57	SM65	SM73	SM81	SM89
	0.234	0.081	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
G	0.7557	0.2616	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
	SM2	SM10	SM18	SM26	SM34	SM42	SM50	SM58	SM66	SM74	SM82	SM90
	0.538	0.654	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040	-0.040
Н	1.737	2.112	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292	-0.1292
	POS	POS	NEG									

#### Control Statistics

Туре	Average	Std.Dev	CV (%)	Count	Deleted	Minimum	Maximum
BK	0.04			1	0	0.04	0.04
PC	1.083			1	0	1.083	1.083
NC	0.084			1	0	0.084	0.084
CO	0.3097	0.00404	1.31	3	0	0.306	0.314

Validation Criteria

Data Source	Holds	Validity Condition
Val	Yes	avg(CO)>=0.10
Trf	Yes	NC<=0.8&PC>=1.1

Page 1

Results

# Chapter 7

# Maintenance

### 7.1 Introduction

This chapter gives the instructions on how to maintain, clean and disinfect the Expert Plus.

# 7.2 Cleaning and checking the outer surface of the Instrument

This instrument is a precision instrument and requires regular cleaning to ensure the continued precision.

#### Liquid Spills

If any liquid is spilled in the instrument, it should be IMMEDIATELY removed so that the liquid does not run in to the Optical System and causes a loss of accuracy.

#### Regular cleaning

The housing of the instrument should be cleaned regularly with a mild household-cleaning agent.

Warning: Do not use aggressive solutions

If any damage of the cover is seen, refrain from using the instrument and contact the service department.

## 7.3 Changing the Fuses

The following steps must be performed to replace the fuse, which is located above the power cable connection, in the rear panel of the instrument.

#### WARNING

Before replacing fuses, disconnect the power cord. To avoid risk of fire, replace fuses only with same type and rating

- 1. Switch off the instrument and unplug the power cord.
- 2. Open the plastic cover of the fuse compartment, by inserting a screwdriver into the slot at the left side of the cover and pushing the cover out.
- 3. Pull the fuse holder away from the instrument.
- 4. Replace the fuses only with the same type and rating.Ensure that the fuses have the correct rating: **3.15 A TH250VAC**
- 5. Replace the fuse holder.
- 6. Reconnect the power cord and switch the instrument on

## 7.4 Changing or adding a Filter

The instrument is supplied with a filter wheel that contains up to 6 changeable filters.

To replace or add one or more of these filters, please perform the following procedure:

- 1. Switch off the instrument.
- 2. Open the filter compartment cover plate at the right side of the instrument.
- 3. Rotate the filter wheel, until the required filter or filter position is at the front.

The filter position one is marked with a yellow sticker. Filter position two is located below the filter one.

- 4. In case a filter should be replaced, pull the filter out of the filter wheel.
- 5. Carefully insert the 'new' filter in to the filter wheel.

#### CAUTION:

Carefully hold the filter only by the edges to avoid any fingerprints on the filters.

- 6. Close the filter compartment cover.
- 7. Switch the instrument on.
- 8. After changing a filter, a calibration run is required. Please see 4.5.2 in this manual.

#### 7.4.1 Cleaning an interference filter

If an interference filter is dirty it needs to be cleaned. For the cleaning procedure you need low-lint cotton-tipped swabs and a lens cleaning solution or reagent-grade isopropyl alcohol. First blow off dust and dirt with pressurized gas. Apply a few drops of the cleaner on both sides of the filter and wipe-off the dirt with the cotton swabs. Allow the cleaner to evaporate and then visually check the filter surface for streaks or spots. If there are any repeat the procedure.

When streaks or spots are visible which cannot be removed by the procedure as described above most probably they are inside the filter. In such a case the filter must be replaced.

Note: Interference filters do have a limited lifetime of a few years, depending on the humidity and ambient temperature. Under tropical conditions a filter may get unusable within less than two years.

## 7.5 Instrument Disinfection

All parts of the instrument that come into contact with patient sera or positive controls must be treated as potentially infectious.

It is very important that the instrument is thoroughly disinfected before it is removed from the Laboratory or any servicing is performed on it.

#### 7.5.1 Disinfecting Procedure

If the laboratory has no specific disinfecting procedure, the following procedure should be used to disinfect the instrument.

- The instrument should be disinfected using a suitable disinfecting solution.
  - 1. Disconnect the instrument from the mains power supply.
  - 2. Disconnect the instrument from the computer.
  - 3. Carefully wipe all the outside surfaces of the instrument and the plate support area with a wad of cotton wool that has been soaked in the disinfecting solution.

#### Ensure that disposable gloves are worn.

- 4. Place the instrument in to a large plastic bag.
- 5. Place a wad of cotton wool that has been soaked in the disinfecting solution in to the plastic bag.
  - Ensure that the wad is not touching the instrument.
- 6. Close and seal the plastic bag.
- 7. Leave the instrument to stand in the plastic bag for at least 24 hours.
- 8. After the standing time, remove the instrument from the plastic bag and wipe all the outside surfaces of the instrument and the plate support area with a wad of cotton wool, which has been soaked in a 50% Alcohol solution.
- 9. Repeat the disinfecting procedure on any accessories that are also being moved or returned.

#### 7.6 End of lifetime - waste disposal

Please follow all national legal requirements for the disposal of the instrument at the end of its lifetime.

# Chapter 8

# Performance verification

To check the performance of the Expert Plus reader we recommend to use the QC-plate with the QC-software.

The QC- plate checks the mechanical alignment of both the plate transport and the optical path and tests the accuracy and precision.

The QC-plate consists of a precise milled aluminum body in the dimensions of a standard microplate and three neutral density glass filters. In contrast to other neutral density filters the sensitive coated area is protected by another glass layer, avoiding the known problems with scratches and degradation caused by frequent cleaning.

The neutral density filters covering all of the eight measurement channels.

For instructions how to use the QC-plate and - software see the manual which comes with the QC-plate.

In case the QC-plate is not available ask your supplier to check the instrument.

It is recommended to check the instrument once every year.