readwell Touch

ELISA Plate Analyzer

User Manual

Version: RBK 3.500A



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Version No. : RBK 3.500A Effective Date: Mar, 2014

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1. GENERAL INFORMATION

1.1. Warranty Information

Each Instrument is completely tested and guaranteed for twelve months from delivery The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use and maintenance in compliance with the instructions given in this manual.

ROBONIK will, at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any travel and man-hour expenses will be charged extra.

In case of tenders warranty would be as per tender terms and conditions.

1.2. Technical Service

ROBONIK is always accessible to the customers for any kind of information about installation, use, maintenance and others. When asking for service, please refer to this manual and report the data reported on the identification label (serial number).

Only qualified technicians are entitled to repair instruments. The user should carry out ordinary maintenance.

The technical service of ROBONIK or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts only, is always available for extraordinary maintenance (repair), under a yearly maintenance contract or on specific demand.

1.3. Contacts

Manufacturer:

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2. GENERAL SAFETY WARNINGS

2.1.Danger - warnings symbols:

The following symbols are used to inform the user of the safety rules.



This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.



This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.



This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.



This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.



This symbol indicates a portion, which is particularly important, and should be studied carefully.



This symbol indicates a Protective Earth or Ground terminal.

General Symbols



Symbol for "Manufacturer"



Symbol for "IN VITRO DIAGNOSTIC MEDICAL DEVICE"



Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

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2.2. Use of the Instrument

1. The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules by qualified personnel.

- 2. This manual contains instructions for operation performed by qualified personnel.
- 3. A qualified user has to make sure that environmental condition is suitable, the installation is correct, the use and maintenance are proper according to the general safety rules as well as to the particular precautions described in the manual. (However, he is not entitled to repair the instrument)
- 4. A qualified technician is entitled to maintain and repair the instrument using the original spare parts according to the given instructions.
- 5. Maintain room temperature and humidity as specified in the manual.
- 6. If the instrument is not used as described in the manual, the protection provided by the instrument may be impaired.
- 7. Alterations to the instrument are prohibited. The user is liable for any improper modification to the instrument, and for the deriving consequences.
- 8. Contact the MANUFACTURER service or authorized service center in case the instrument need extraordinary maintenance. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance.
- 9. This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.



- 10. **Warning**: This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."
- 11. An advisory that the electromagnetic environment should be evaluated prior to operation of the device.



Warning: Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

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3. INTRODUCTION

3.1. Description

readwell TOUCH is a user friendly micro plate Analyser. It is compact & lightweight. It is designed to measure and interpret enzyme immunoassay results, both monochromatically and bichromatically. It is intended for in vitro diagnostic use.

3.2. Special Features

The **readwell TOUCH** can accommodate a flat bottom as well as a round configuration. The carriage is designed in a way that the plate automatically moves smoothly and positions itself accurately in the optical measurement path. Readings are taken continuously. The average value is calculated and results are presented according to the option selected.

The **readwell TOUCH** operates on a WIDE voltage (90-270 volt). This eliminates the need for an external voltage stabilizer.

The **readwell TOUCH** has a special provision, which allows it to be used even when a printer is not available. Readings can be conveniently noted down manually.

The other special features of **readwell TOUCH** are as follows:

- Option of Lamp saving mode.
- Selection of both primary and secondary filters.
- Latest technology with battery backup for 250 tests, and more than 2500 results.
- Robust built in 52-column thermal printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- Alphanumeric Patients ID entry.
- Editing of saved tests.
- Human machine user interface: Touch panel, Keypad
- Multi-standard curve up to 12 standard calibrations with one blank optional.
- Access to test by touch of key.
- Capability to connect to 80-column printer for direct report printout.
- Blank is optional.
- Setting of the Date and Time.
- Capable of storing, deleting and recalling tests.
- Multiple calibrator modes.
- Selection of duplicates for both calibrators and samples.
- Extensive software for Cut Off mode.
- Selection of Positive, Equivocal, Negative cut-off.

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 Several pre-programmed calculation modes will help to facilitate data processing of enzyme immunoassays. These are menu driven modes for simple and error free operations.

- ✓ ABSORBANCE MODE
- ✓ SINGLE STANDARD MODE
- ✓ CUT-OFF MODE
- ✓ MULTISTANDARD MODE
- ✓ % ABSORBANCE MODE
- ✓ UPTAKE
- ✓ KINETIC

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3.3. Technical Specification of readwell TOUCH:

Drift	Human Machine Interface	TOUCH PANEL / KEYPAD
# 2% or 0.007 whichever is higher, from 0 to 1.5 A ± 3% from 1.5 A to 3.0 A **O005 A/hr** **Co005 A/hr** **Deptical measurement** **Section** **Deptical measurement** **Section** **Proposed Filter** **Wave Length** **Intersammely = 560, and YYY (editable)* **Intersammely =		
Photometric Linearity 2.5 A Deptical measurement 8 Channel Filters Pype of filter Narrow band Interference 405nm, 450nm, 492nm, 630nm, with two optional filters namely – 560, and YYY (editable) Half Bandwidth 10nm ± 2nm Automatic by Stepper Motor Light Source Tungsten halogen lamp, 20 Watts 6" Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphical Representation on Printer Plate Carrier Movement Precisely through the stepper motor Printer Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage 75 Watts Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From 10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (1xbxh)	Photometric Accuracy	_
Deptical measurement 8 Channel 9 Chann, 450nm, 492nm, 630nm, with two optional filters namely – 560, and YYY (editable) 10 Channel Stepper Motor 10 Channels (Channels of Graphical Lept, 20 Watts of Graphical Lept, 20 Watts of Graphical Representation on Printer 8 Channel Printer S2 Columns 8 Channel 9 Channel Printer S2 Columns 9 Channel Printer S2 Channel Printer S2 Columns 9 Channel Printer S2 Ch	Drift	<0.005 A/hr
Filters Type of filter Wave Length Half Bandwidth Half Bandwidth Half Bandwidth Filters namely - 560, and YYY (editable) Hom ± 2nm Automatic by Stepper Motor Light Source Display Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphical Representation on Printer Printer Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / R\$232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (kbxh)	Photometric Linearity	2.5 A
Pye of filter Wave Length Half Bandwidth Half Bandwidth Selection Light Source Display Curve Plotting Plate Carrier Movement Printer Built in Thermal Printer 52 columns Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage Typeration Position Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Enclosure ABS Fire Retardant Size (cm) Signe Standard Cut-off Cut-of	Optical measurement	8 Channel
Half Bandwidth Selection Automatic by Stepper Motor Light Source Display Graphica LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphical Representation on Printer Plate Carrier Movement Printer Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Deparation Position On horizontal flat, rigid and vibration free surface Deparating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Encolosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Filters Type of filter Wave Length	405nm, 450nm, 492nm, 630nm, with two optional
Light Source Display G* Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphical Representation on Printer Plate Carrier Movement Precisely through the stepper motor Printer Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Deparating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Half Bandwidth	
Curve Plotting 6" Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots Graphical Representation on Printer Plate Carrier Movement Precisely through the stepper motor Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Selection	Automatic by Stepper Motor
Printer Built in Thermal Printer 52 columns Memory Battery backup supporting 2500 open channels 64 KB Non Volatile RAM Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Light Source Display Curve Plotting	6" Graphics LCD, Negative, Blue Transmissive, STN 320 x 240 dots
Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Poop Book Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz On horizontal flat, rigid and vibration free surface Up to 80% From -10°C to 40°C Up to 80% ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Plate Carrier Movement	Precisely through the stepper motor
Analysis Mode Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% ABS Fire Retardant Size (cm) ABS Fire Retardant Size (cm) Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic On parity bits / USB On parity bits / USB On parity bits / USB Temperature Rigid and vibration free surface From + 18°C to 35°C Up to 80% ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Printer	Built in Thermal Printer 52 columns
Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic Connectivity / RS232 Serial Port / USB Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Memory	
Power Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Analysis Mode	Single Standard Cut-off Multi-Standard % Absorbance Uptake
Wattage Voltage 75 Watts 115-230 Volt ± 10%, 50/60 Hz Operation Position On horizontal flat, rigid and vibration free surface Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Connectivity / RS232 Serial Port / USB	9600 baud, 8 data, 1 stop, no parity bits / USB
Operating Conditions Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Power Wattage Voltage	
Temperature Relative Humidity From + 18°C to 35°C Up to 80% Storage Conditions Temperature Relative Humidity From -10°C to 40°C Up to 80% Enclosure ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Operation Position	On horizontal flat, rigid and vibration free surface
Temperature Relative Humidity Up to 80% ABS Fire Retardant Size (cm) 36 x 36 x 22 (lxbxh)	Operating Conditions Temperature Relative Humidity	
Size (cm) 36 x 36 x 22 (lxbxh)	Storage Conditions Temperature Relative Humidity	
30 N 30 N 22 (MOMI)	Enclosure	ABS Fire Retardant
Weight (Approx.) 10 Kg	Size (cm)	36 x 36 x 22 (lxbxh)
	Weight (Approx.)	10 Kg

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4. PACKAGING, TRANSPORT AND STORAGE

4.1. General Warnings

Instrument has to be decontaminated before packing for transportation.

4.2. Packaging

Packaging is needed whenever the instrument is to be transported or shipped by courier or other purposes.

To pack the instrument the following instructions has to be followed:

- 1. Decontaminate the instrument as explained on decontamination chapter of this manual.
- 2. Put the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of Safety clearance certificate (copy of Safety clearance certificate is attached at the end of this manual)
- 3. Mark the packaging with address, instrument identification and warning labels

4.3. Instrument Transportation

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of Instrument

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

Relative humidity has to be less than 85%, and temperature between -10°C and 40°C.

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5. INSTRUMENT DESCRIPTION

5.1. Instrument Working Principle:

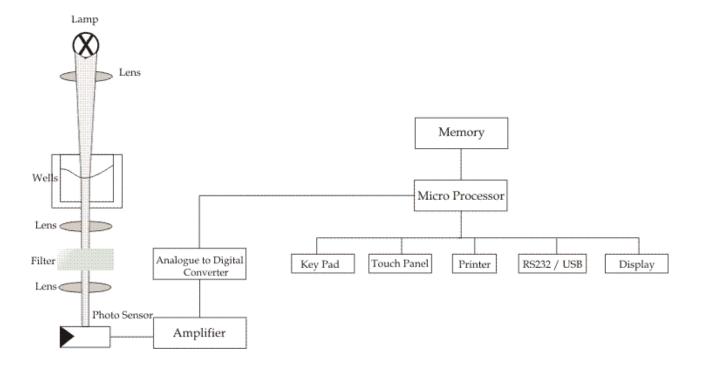
- Switch on and program the instrument.
- Place the plate firmly onto the carriage.
- Start the test, the plate will be conveyed inside and strip is placed precisely below the optical path. The measurement is carried out step by step.
- At the end of the cycle the results can be printed or user can save the plate data
- Results are also available at the RS232 Serial Port / USB Port.

On starting the test, the plate will be conveyed into the instrument.

Plate is moved in step by step by a well-controlled mechanism & each well is positioned precisely below the optical path. Optical density of each well is measured as explained below. Based on selected programming mode, sophisticated algorithms are used for analyzing the measured value & presenting the same on the printer, display & RS232 Serial Port / USB Port for computer Interface.

The following diagram represents the main functional elements of the instrument:

White light produced by the lamps is focused into a beam by the lens & passes through the sample. Part of the light is absorbed by the sample & the remaining light is transmitted. It is filtered by interference filters & focused onto the photodiodes. The photodiode converts the received light in to an electrical signal which is in-turn transformed into digital form, from which the microprocessor calculates the absorbance, taking in account of the blank & bichromatic selection.



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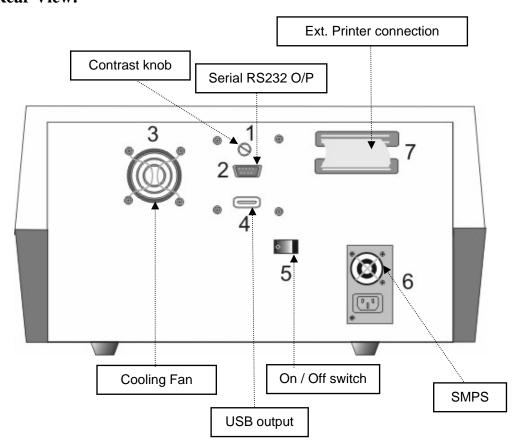
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5.2. Perspective View

5.2.1. Front View:



5.2.2. Rear View:

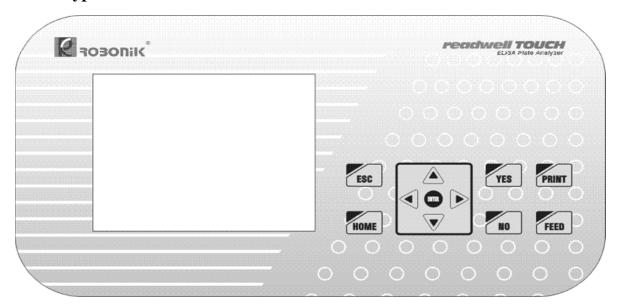


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- 1) Contrast Knob-use to adjust display contrast
- 2) Serial RS232 output
- 3) Cooling Fan
- 4) USB output
- 5) ON/OFF switch
- 6) SMPS
- 7) External printer connection

5.3. Keypad



- 1) 'YES' key is used to select any 'YES' option on screen directly.
- 2) 'NO' key is used to select any 'NO' option on screen directly.
- 3) 'PRINT' key is used to get a printout of current screen displayed.
- 4) 'FEED' key is used for directly accessing the RUN screen of the selected test.
- 5) Navigation keys are used to select any option available on current screen.
- 6) 'ENTER' key is used to run any option selected by navigation keys.
- 7) 'ESC' key is used for escaping from any screen.
- **8)** 'HOME' key is used for directly accessing the shaking mode (ie. SHAKER) (refer 15.5 for more details on SHAKER)

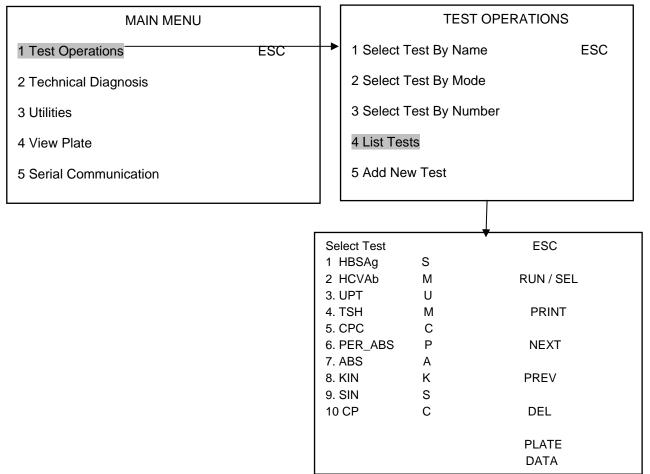
(Note: Functions based on HOME & FEED keys operates only when it is in List Test screen or the first screen after initializing)

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readwell TOUC Clinic name / S		01/03/14 MENU
1. HBSAg	6. PER_ABS	RUN / SEL
2. HCVAb	7. CRP	PRINT
3. UPT	8. KIN	NEXT
4. TSH	9. SIN	PREV
5. CPC	10. CP	DEL
		PLATE DATA

User can select "List Test" screen as shown below-



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Select "FEED" button present on the keypad. It will display following screen for selecting the particular test. In this way user can directly run the selected test by just entering the valid test no.

Select Test		ESC		Name:	ABS	NORM	I – ABSO	RBANCE	
1 HBSAg	S			Pri : 45	50 Sec	: 0	ВІ	L N	
2 HCVAb	М	RUN / SEL		ABS	ABS	ABS	ABS	ABS	ABS
3. UPT	U			١.,	•				•
4. TSH	M	PRINT		1	2	3	4	5	6
5. CPC	С								
6. PER_ABS	Р	NEXT							
7. ABS	Α		├	1					
8. KIN	K	PREV		1 , 50	450	400	450	450	450
9. SIN	S			ABS	ABS	ABS	ABS	ABS	ABS
10 CP	С	DEL		7	8	9	10	11	12
Numeric Valu	e: 7								
1 2 3 4	5 6	ENTER		ls Plate	e Loaded	?		YES	/ NO
7 8 9 0		CLEAR							

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6. INSTALLATION PROCEDURE & VERIFICATION CRITERIA

6.1. Unpacking Instructions

Check accessories as per packing list.

Kindly store all packaging materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the Instrument

The instrument has to be placed on a level bench.

Room temperature has to be between 10 to 35°C with a relative humidity below 85%.

Protect the instrument from direct sunshine.

6.3. Power Supply Requirements

Plug the instrument into a power source by the locally available approved plug in cable. Power cord should be CE, CSA, and UL marked.

 $115 - 230 \text{ Volt} \pm 10\%, 50-60 \text{ Hz}$



6.4. Protective Grounding

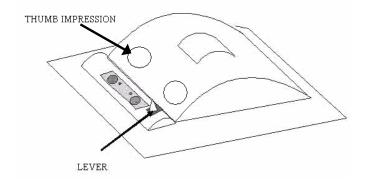
Please make sure that electrical power source is properly grounded.

6.5. Printer

"READWELL TOUCH", an ELISA Analyser is equipped with a built in 52 columns easy load Thermal printer. Procedure to load the paper is as follows:

Opening the Paper Cover:

Slide the LEVER towards back of the printer to open lock of the Paper Cover.



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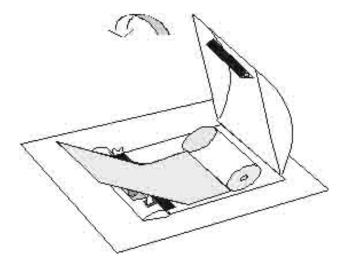
Closing the Paper Cover + replacement of paper roller:

Open the Paper Flap.

Remove the paper roller from the slot.

Now place the Thermal side of the paper roll at the top into the slot provided and then close the paper flap in the direction as shown in the following figure, till you get the locking sound. Use Thumb impressions to push the cover .

Press the paper feed switch until the paper feeds straight and smoothly.



HINT:

When the paper is set correctly and when the closing of the paper cover is proper the FEED LED will not glow.

It keeps on flashing when the data is being printed.

When the paper is almost finished, red lines appear on both sides of the paper.

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6.6. Start up Instructions

Switch on the instrument.

The instrument initializes all the parameters internally and carries out a power on self-test During Initializing it displays the string: "Please wait system initializing."

It will display the ADDRESS screen after completing the initialization.

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MAHAPE, NAVI MUMBAI – 400 710

INDIA

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The instrument will print the model name "readwell TOUCH", Version number, Clinic Name, current Date with Time.

readwell TOUCH Clinic name / Seria		01/03/14	MENU
Select T 1. HBSAg	est 6. PER_ABS		RUN / SEL
2. HCVAb	7. ABS		PRINT
3. UPT	8. KIN		NEXT
4. TSH	9. SIN		PREV
5. CPC	10. CP		DEL
			PLATE DATA

User can select a saved test by first touching the required "Test Name" on the screen and then touch the "SEL" option to carry out further operation on the test.

"RUN" option is used to directly run the selected test.

"DEL": Deletes the selected test.

If the numbers of tests are more than 10, "NEXT" and "PREV" options can be used for browsing through the list pages.

"PRINT": For printing the test screen.

MENU" used to select Main menu screen.

"PLATE DATA" this option helps the user to view the Plate Results easily by selecting this option present on the screen.

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6.7. Touch Panel Check

READWELL TOUCH provides a *Touch sensitive LCD panel* and a *KEYPAD* for easy user interface.

The Menus are displayed and the text of the parameter forms the TOUCH ZONE.

Touch screen Layout

Name:		POS- CutOff	ESC
Pri: 405	Sec: 0		SAVE
No F	actor QC	QCVal Mes. Rem	
BL 0	N		
NC 0 1.	.000 N		
PC 0 1.	.000 N		
LC 0 1.	.000 N		
CC 0 1.	.000 N		
CUTFAC:	0.000		
CUTABS:			
QC1	N	Interpretation:	
QC2	N	Greyzone % (N)	
QC3	N	Cut off Index (Y)	
QC4	N	Range Pos: 0.000	
		Neg: 0.000	

Above is the generic representation of a Test Screen. The Highlighted zones are TOUCH ZONES, which are active. On touching the "Touch Zone" of a parameter, a sub menu/menu is displayed or the requested action is carried out. The rest of the "Touch Zone" is deactivated.

For Example: To activate the selection

Enter the primary filter value to touch any point in the shaded area "Pri" on the LCD screen.

On proper selection the analyser responds with blinking of the parameter text and also the TOUCH ZONE and a submenu is displayed.

To enter Test Name: Touching the "Name" touch zone provides an alphanumeric screen.

Enter the Test name by touching the Touch zone of that variable. The selected value blinks and is displayed next to the parameter.

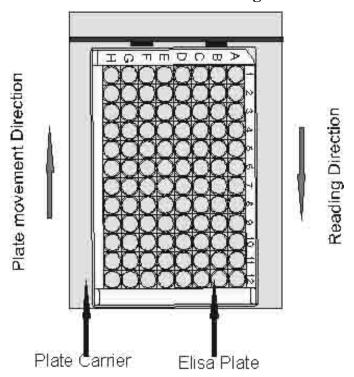
Selection Indicator

Selected on screen item is shown in a shaded background. When the screen first displays, the default selection is shown. Pressing a selection either highlights that item or activates it.

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6.8. Micro Titer Plate Carriage



The instrument is provided with a micro titer plate carriage to move the micro titer plate inside. This carriage is driven by stepper motor with timing belt. It places each well of plate exactly below the optical path of each channel. The plate carrier is moved by a well controlled stepper motor drive.

6.9. Plate Loading & Pipetting Procedure

Controls and Sample pipetting procedure in case of CUT OFF:

Maximum number of Blanks = 5

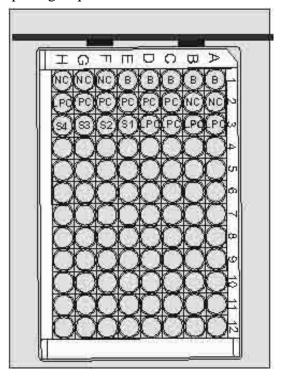
Maximum number of Controls:

- 1. Negative Control = 05
- 2. Positive Control = 05
- 3. Low Positive Control = 05

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Pipetting sequence should be as shown below.



6.10. Readings Check

Checking of readings should be done through controls reading within range specified in data sheet of controls (care should be taken while preparing and pipetting controls and reagents, reagent and control expiry dates need to be checked).

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7. PRECAUTIONS



1.Do not use any sharp objects on the Touch Screen. Always use the STYLUS provided to operate the touch panel.



- 2.Always check for proper grounding before installation. Never operate the instrument when ground wire is removed.
 - 3. Do not attempt to open the instrument and make repairs without proper technical training. Do not allow unauthorized persons to operate or repair the instrument.
 - 4. Use a clean plate and follow the instructions for blanking and standardizing. Do not read any wells containing bubbles or dust particles.
 - 5. The volume of sample, calibrators and blanks should be identical for correct readings. The absorbance is proportionate to the path length. Pipetting should also be proper.
 - 6. Monitoring of the printed values or displayed values during operation may help detect an error. Check the linearity and calibration of the instrument regularly against some standard reference.
 - 7. Check the micro wells before use. They should be scratch-free. The micro well track in the **READWELL TOUCH** has been designed in such a way that the micro wells are totally protected from scratches.



- 8. Recheck the reading of high OD (above 2A).
- 9. Place Plate carefully on the tray.
- 10. Ensure that the main power switch is in OFF position before connecting.
- 11. Plug the instrument to the AC mains. Confirm proper grounding for trouble free operation.
- 12. Connect the printer only when the instrument is OFF.

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8. PROGRAMMING MODES

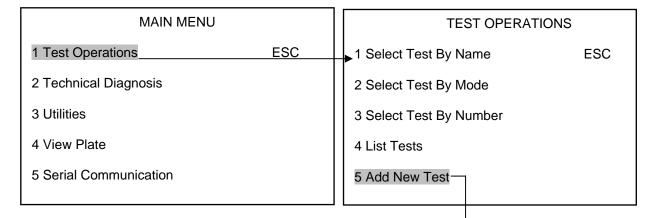
8.1. Absorbance Mode

In this mode the instrument gives only absorbance values of all wells of the respective plate.

Programming a New Test:

A. Select "Test Operation"

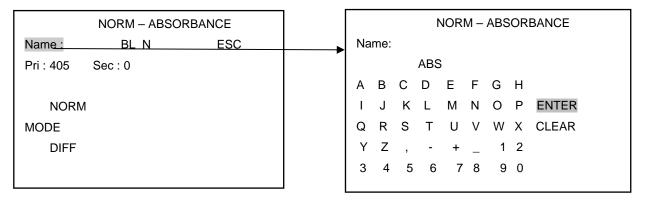
B. Select "Add New Test"



C. Select mode of operation "Absorbance" in "Add New Test"

Select Test Mode		ESC
1> Absorbance	0	
2> Single Standard	0	•
3> Cut off	0	
4> Multi Standard	0	
5> Percent Absorbance	0	
6> Uptake	0	
7> Kinetic	0	

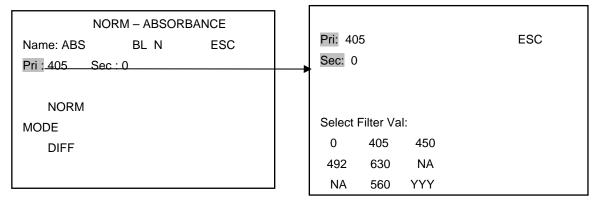
D. Enter "Test Name"



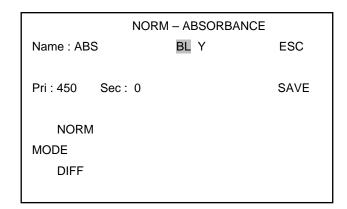
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E. Select primary and secondary filter



F. If blank is required select "BL"



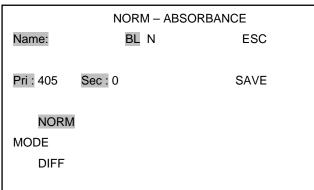
If you select "BL Y", it will read first well first strip 'A1' as a blank and subtract the absorbance of blank well from all other well's absorbance.

G. In absorbance mode there are two modes of operations

Normal Absorbance Mode: Instrument gives the absorbance of each and every well. Select touch zone "NORM".

Differential Absorbance Mode: Instrument shows the difference of absorbance between odd number wells and even number wells. For Example,- Strip 1- Strip 2, Strip 3 - Strip 4, Strip 5 - Strip 6. For this Mode select touch zone "DIFF".

In Normal Mode



In Differential Mode

	DIFF – ABS	SORBANCE
Name:		ESC
Pri : 405	Sec : 0	SAVE
NORM	И	
MODE		
DIFF		

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8.2. Single Standard

In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.000

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law. The absorbance are read at user selected wavelengths. If Blank is selected, instrument will automatically blank on the first well and subtract its absorbance from each subsequent well. The second well is treated as the calibrator/standard well. The third well is also treated as calibrator/standard well if the calibrator/standard is in duplicate.

CALCULATION:

Sample Concentration = (Calibrator concentration / Calibrator Abs.) x Sample Abs

Name: SIN_STD SINGLE STANDARD				
Pri: 450 Sec: 0	BL Y 0.000	CAL 1	ESC	
	DUP N	DUP N	SAVE	
HI CO : N High>	Low<			
LO CO: N High>	Low<			
'	High> Low<			

Entry of all the parameters is similar to Multi standard mode (Please refer Multi standard for entry of parameters)

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8.3. Cut Off Mode

In this mode Cut-Off point is determined for interpretation of specimens as per formula given in the reagent manual. The negative controls are read followed by the positive controls, Cut-off control, low positive control. Blanking on the first well is optional. The instrument calculates the average of the negative controls and the average of the positive control, Cut-off controls and Low positives are also calculated.

Programming a New Test:

A. Select "Add New Test"

TEST OPERATIONS	ESC	
1 Select Test By Name		
2 Select Test By Mode		
3 Select Test By Number		
4 List Tests		
5 Add New Test		

B. Select mode of operation "Cut-Off" in "Add New Test"

Select Test Mode	e ESC	
1> Absorbance	0	
2> Single Standard	0	
3> Cut off	0	
4> Multi Standard	0	
5> Percent Absorbance	0	
6> Uptake	0	
7> Kinetic	0	

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C. Entry of test name

Select touch Zone "Name:"

Name			POS- Cu	utOff		
Pri: 40	5 Sec: 0					ESC
N	o Factor	QC	QCVal	Mes.	Rem	SAVE
BL 0		N				
NC 0	1.000	N				
PC 0	1.000	N				
LC 0	1.000	N				
CC 0	1.000	N				
CUTF	AC: 0.000					
CUTA	BS:					
QC1	N		Interpreta	ation :		
QC2	N		Greyzon	e % (N)		
QC3	N		Cut off Ir	ndex (Y)		
QC4	N		Range	Pos : 0.	000	
				Neg : 0.	000	

Alphanumerical characters will appears on the screen as shown below after touching "Name" on the screen. Enter the name of the test by selecting the individual characters one by one. After selecting all the characters select Enter option in touch screen for confirmation of test Name.

Na	Name: POS- CutOff							
	HBSAG							
A	В	С	D	Ε	F	G	Н	
ı	J	K	L	М	N	0	Р	ENTER
Q	R	S	Т	U	٧	W	Χ	CLEAR
Y	Z	,	-	+	_	1	2	
3	4	5	6	7	8	9	0	

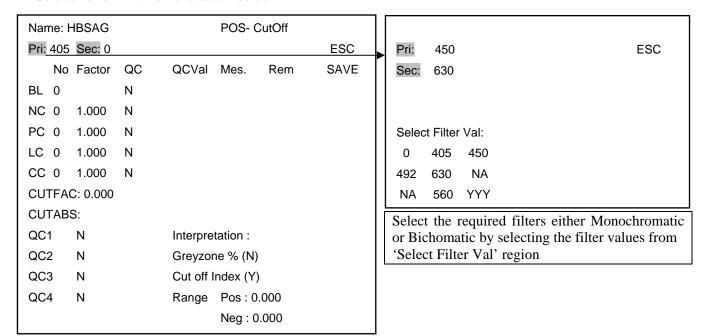
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D. Selection of Primary and secondary filters.

Select zone "Pri:" on the touch screen



E. According to the reagent manual, change Blank, NCs, PCs to 'YES' for QC check.

Name: HE	BSAG		POS- C	utOff	
Pri: 450	Sec: 630				ESC
No F	actor QC	QCVal	Mes.	Rem	SAVE
BL 0	N				
NC 0 1	1.000 N				
PC 0 1	1.000 N				
LC 0 1	1.000 N				
CC 0 1	1.000 N				
CUTFAC:	0.000				
CUTABS:					
QC1 N	٧	Interpre	tation:		
QC2 N	N	Greyzo	ne % (N)		
QC3 N	N	Cut off	ndex (Y)		
QC4 N	٧	Range	Pos : 0.	000	
			Neg:0	.000	

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F. Entry of Blank and Blank QC values

Select "BL" to enter blank details.

Nam	ne: I	HBSAG		POS-	CutOff		
Pri: 4	450	Sec: 63	30				ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	0		Υ	0.000	0.000		
NC	0	1.000	Υ	0.000	0.000		
PC	0	1.000	Υ	0.000	0.000		
LC	0	1.000	N				
СС	0	1.000	N				
СП	FA	C: 0.000					
СП	AB	S:					
QC1		N		Interpre	tation:		
QC2	2	N		Greyzo	ne % (N)		
QC3	3	N		Cut off	Index (Y))	
QC4	1	N		Range	Pos:0	.000	
					Neg:0	.000	

G. After selecting "BL", enter total number of blanks by selecting No. of Blanks. (Maximum 5 blank).

H. Enter the QC value of the blank by selecting the touch Zone "Values of BL <="

```
No. of Blanks = 1 ESC

Values Of BL <= 0.000

Numeric Value: 0.100
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR
```

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I. Entry of Negative control and its QC values

Select touch Zone "NC"

```
Name: HBSAG
                             POS- CutOff
Pri: 450 Sec: 630
                                              ESC
   No Factor QC
                     QCVal Mes.
                                              SAVE
                                    Rem
BL 1
              Υ
                     0.100
NC 0
      1.000
              Υ
PC 0
       1.000
LC 0
      1.000
              Ν
CC 0 1.000
              Ν
CUTFAC: 0.000
CUTABS:
QC1
       Ν
              Interpretation:
QC2
       Ν
              Greyzone % (N)
QC3
       Ν
              Cut off Index (Y)
QC4
              Range Pos: 0.000
                     Neg: 0.000
```

J. Enter Number of Negative controls by selecting touch Zone "No. of NC's" (maximum 5 Negative Controls). Enter the QC value of the Negative Control by selecting the touch Zone "Value of NC" and enter the value of X given in the reagent manual by selecting Zone "Values Of X".

```
No. of NC's = 3 ESC

Values Of X = 1.000

Value of NC <= 0.150

Numeric Value

1 2 3 4 5 6 ENTER

7 8 9 0 . CLEAR
```

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K. After the entry of "No. of NC's", select ESC. The below screen will appear on the display.

Nam	ne: H	HBSAG		POS- C	utOff		
Pri:	450	Sec: 63	0				ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Υ	0.100			
NC	3	1.000	Υ	0.150			
PC	0	1.000	Υ				
LC	0	1.000	N				
СС	0	1.000	N				
CUI	ΓFΑ	C: 0.000					
CUI	ГАВ	S:					
QC1	l	N		Interpre	tation:		
QC2	2	N		Greyzoi	ne % (N)		
QC3	3	N		Cut off I	Index (Y)		
QC4	1	N		Range	Pos : 0.	000	
					Neg:0	.000	

L. Entry of Positive Controls (PC).

Select touch Zone "PC".

Name: I	HBSAG		POS- CutOff
Pri: 450	Sec: 63	0	ESC
No	Factor	QC	QCVal Mes. Rem SAVE
BL 1		Υ	0.100
NC 3	1.000	Υ	0.150
PC 0	1.000	Υ	
LC 0	1.000	N	
CC 0	1.000	N	
CUTFA	C: 0.000		
CUTAB	S:		
QC1	N		Interpretation:
QC2	N		Greyzone % (N)
QC3	N		Cut off Index (Y)
QC4	N		Range Pos: 0.000
			Neg : 0.000

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M. After selecting "No. of PC's", the screen below will appear on the display. Enter number of Positive Controls by Selecting Zone "No. of PC's" (Maximum 5). Enter the QC value of the Positive Control by selecting the touch Zone "Value of PC >=" and enter the value of Y given in the reagent manual by selecting Zone "Values Of Y".

```
No. of PC's = 2 ESC

Values Of Y= 1.000

Value of PC >= 0.500

Numeric Value:

1 2 3 4 5 6 ENTER

7 8 9 0 . CLEAR
```

N. After entering the details of PCs, escape from the screen by selecting "ESC" option. Below screen will appear on the display:

Name	: HBSAG			POS- (CutOff	
Pri: 4	50 Sec: 63	30				ESC
N	lo Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Υ	0.100			
NC 3	1.000	Υ	0.150			
PC 2	1.000	Υ	0.500			
LC C	1.000	N				
CC C	1.000	N				
CUTF	AC: 0.000					
CUTA	ABS:					
QC1	N		Interpre	tation:		
QC2	N		Greyzor	ne % (N))	
QC3	N		Cut off I	ndex (Y)	
QC4	N		Range	Pos:0	.000	
				Neg:0	0.000	

NOTE: Same way you can enter values for LC (lower positive controls) and CC (Cut of Controls)

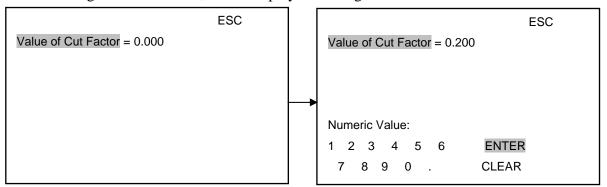
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O. Entry of CUT-OFF FACTOR:

Select touch Zone "CUT FAC" in order to enter the value for Cut Off Factor.

Name: I	HBSAG			POS- 0	CutOff	
Pri: 450	Sec: 63	0				ESC
No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Υ	0.100			
NC 3	1.000	Υ	0.150			
PC 2	1.000	Υ	0.500			
LC 0	1.000	N				
CC 0	1.000	N				
CUTFA	C: 0.000					
CUTAB	S:					
QC1	N		Interpre	tation:		
QC2	N		Greyzoi	ne % (N)		
QC3	N		Cut off I	Index (Y))	
QC4	N		Range	Pos: 0.	000	
				Neg: 0.	.000	

After selecting the "CUTFAC", it will display following screen.



Enter the Value for Cut Off Factor and select ESC option to come out to the test parameter screen.

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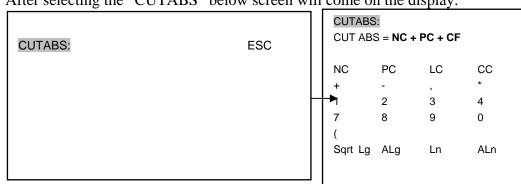
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P. Entry of Cut off absorbance equation:

Select touch Zone "CUTABS"

Name: I	HBSAG		POS- CutOff	
Pri: 450	Sec: 63	0		ESC
No	Factor	QC	QCVal Mes. Ren	n SAVE
BL 1		Υ	0.100	
NC 3	1.000	Υ	0.150	
PC 2	1.000	Υ	0.500	
LC 0	1.000	N		
CC 0	1.000	N		
CUTFA	C: 0.200			
CUTAB	S:			
QC1	N		Interpretation:	
QC2	N		Greyzone % (N)	
QC3	N		Cut off Index (Y)	
QC4	N		Range Pos: 0.000	
			Neg : 0.000	

After selecting the "CUTABS" below screen will come on the display.



For entering the CUTABS equation, user has to select CUTABS present on the screen.

Now enter the equation as given in the reagent manual or else select ESC option in order to come out of the CUTABS screen.

Whereas, NC = Mean of NCs * Factor X

Sqrt = Square root

PC = Mean of PCs * Factor Y

Lg = LOG

Aln = Anti Natural LOG

CF

%

5

Abs

ESC

6

)

ENTER CLEAR

LC = Mean of LCs * Factor W

Ln = Natural LOG

CC = Mean of CCs * Factor Z

Abs. = any absolute value

CF = Cut off Factor

ALg = Anti LOG

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For Example :

For equation <u>CUT OFF ABS</u> = (0.45 * NC) + (0.35 * PC) + 0.10, the formula can be entered in two ways.

1. Enter the values as it is i.e. $\underline{\text{CUTABS}} = (0.45*\text{NC}) + (0.35*\text{PC}) + 0.010$. Keep the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'. (Numbers, mathematical functions and symbols for NC, PC, CC, LPC can be selected from the screen).

OR

2. In second method the formula can be entered as $\underline{\text{CUT ABS}} = \text{NC} + \text{PC} + \text{CF}$. (Since the Value of X, Y, Z, W is entered in the QC option of NC, PC, CC, LPC and Cut off factor in the CUT FAC option, there is no need to enter the same data again). Means here Multiplication Factor for NC = X = 0.45

Multiplication factor for PC = Y = 0.35 and the value of cut of factor = CUT FAC = 0.100.

This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mentioned above.

If $\underline{\text{'CUTOFF ABS'}} = \underline{\text{(NC + PC)}} / \underline{6}$. This can be entered as it is CUTABS = $\underline{\text{(NC + PC)}} / \underline{6}$ by keeping the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'.

OR

As you know in mathematics (NC + PC) / 6 = (NC / 6) + (PC / 6) = (1/6) * NC + (1/6) * PC = (0.166 * NC) + (0.166 * PC),

So, you can enter same equation as CUT ABS = NC + PC, by entering

Multiplication Factor for NC = X = 0.166, multiplication factor for PC = Y = 0.166.

This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mention above.

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Q. QC1, QC2, QC3 & QC4. can be used for any QC Checking of the test provided in reagent manual.

For example some kit may give QC check equation like |PCx - NCx| > 0.500,

PC / NC > 15, etc. This equation can be entered by selecting these QC options. Select touch zone 'N'. It will change to 'Y', as shown in the below screen. Now select touch zone 'QC1' and enter QC equation.

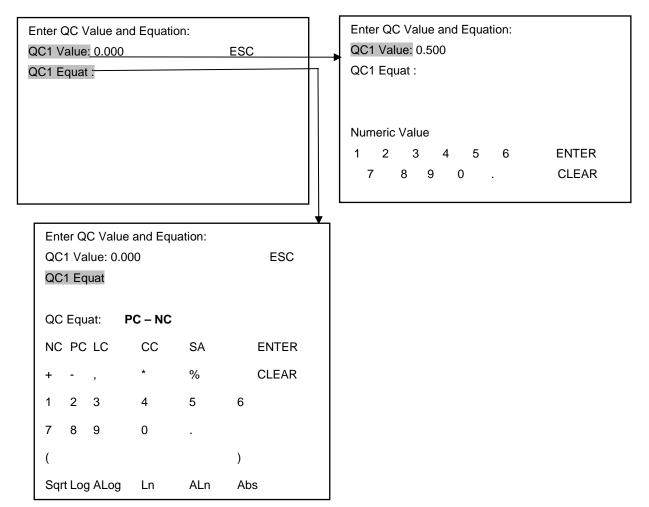
Name: HB	Name: HBSAG			utOff		
Pri: 450 S	Sec: 63	0				ESC
No F	actor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Υ	0.100			
NC 3 1	.000	Υ	0.150			
PC 2 1	.000	Υ	0.500			
LC 0 1	.000	N				
CC 0 1	.000	N				
CUTFAC:	0.200					
CUTABS:	NC + F	C + CF				
QC1 > Y	1		Interpret	tation:		
QC2 N	I		Greyzor	ne % (N)		
QC3 N	I		Cut off I	ndex (Y)		
QC4 N	I		Range	Pos : 0.0	000	
				Neg : 0.	000	

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Enter equation of QC and value of QC check by selecting touch zone 'QC1 Value' & 'QC1 equat'.



Same way you can enter QC equations for QC2, QC3 and QC4.

*NOTE:

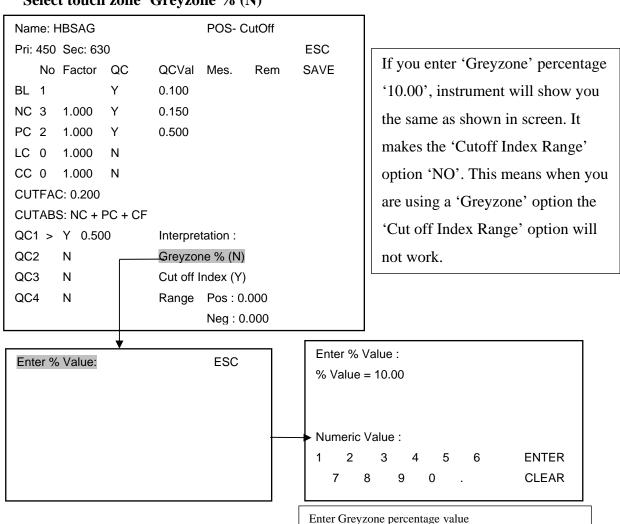
On screen it is mentioned that "QC1 > Y". In most of the reagent inserts it is mentioned that QC value should be greater than some constant value. Sometimes in the box insert it is mentioned that the value should be less than some constant value. In such case, you can change the symbol from "QC1 > Y" to "QC1 < Y", only by selecting a symbol of comparison.

If any QC check is selected to 'YES' option, the system will not save the test without entering the QC equation and QC check value of equation.

R. Interpretation of samples

Enter RANGE for interpretation of results either in percentage (Greyzone) or positive and negative values of INDEX, as a ratio of (Sample Abs. / Cutoff Abs.). If Cutoff Index range or Greyzone is not mentioned do not enter any values. Instrument will do the interpretation with references to the Cut off absorbance.

R.1. Interpretation by GREYZONE percentage Select touch zone 'Greyzone % (N)'



NOTE: If you don't select any option for interpretation of sample results, the instrument will take Cutoff Absorbance as a reference.

Select ESC option after entering Greyzone % value to

come out to the parameter screen.

It will give "Positive' remark to sample absorbance greater than cutoff and 'Negative' to sample absorbance less than cutoff.

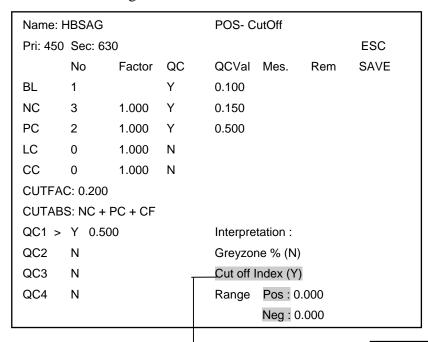
Name:	Name: HBSAG			utOff		
Pri: 450	Sec: 63	0				ESC
No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Υ	0.100			
NC 3	1.000	Υ	0.150			
PC 2	1.000	Υ	0.500			
LC 0	1.000	N				
CC 0	1.000	N				
CUTFA	C: 0.200					
CUTAB	S: NC +	PC + CF				
QC1 >	Y 0.50	00	Interpre	tation:		
QC2	N		Greyzor	ne % (Y)	10.00	
QC3	N		Cut off I	ndex (N)	
QC4	N		Range			

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R.2. Interpretation by 'Cutoff Index Range'

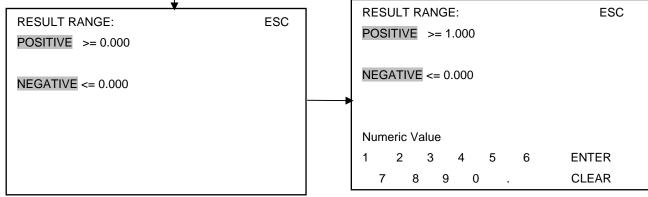
It is also provided to do the interpretation using 'Cutoff Index' by entering normal range for 'Positive' and 'Negative'.



Cut off Index is the ratio of Sample Absorbance / Cut off Absorbance.

When you select 'Cutoff Index'
-'Y', the 'Greyzone %' will
become 'NO', means inactive.

In 'Cutoff Index', provide the range for interpretation, the positive and negative value of ratio (Sample Abs. / Cutoff Abs.)



In case of 'Cutoff Index Range',

It gives the 'Positive' remarks to sample having index value, a ratio of ...

(Sample abs. / Cutoff Abs.) greater than or equal to entered 'POSITIVE' value and

it gives 'Negative' remarks to sample having index value, a ratio of

(Sample abs. / Cutoff Abs.) less than entered 'NEGATIVE' value.

The sample having index value in between 'POSITIVE' and 'NEGATIVE" range get remarks 'Equivocal' = 'EQ'.

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After entering the Interpretation values (ie. conditions for interpretation) the screen will be displayed as follows -

displayed as follow	<u> </u>	
Name: HBSAG	POS- CutOff	
Pri: 450 Sec: 630	ESC	
No Factor QC	QCVal Mes. Rem SAVE	
BL 1 Y	0.100	
NC 3 1.000 Y	0.150	
PC 2 1.000 Y	0.500	
LC 0 1.000 N		
CC 0 1.000 N		
CUTFAC: 0.200		
CUTABS: NC + PC + CF		
QC1 > Y 0.500	Interpretation:	
QC2 N	Greyzone % (N)	
QC3 N	Cut off Index (Y)	
QC4 N	Range Pos: 1.000	
	Neg: 0.900	

For example: If you enter POS >= 1.0 and NEG <=0.9. the sample will Then, get POSITIVE remarks having INDEX Value, (Sam. Abs./ Cutoff Abs.) >= 1.000. The sample will get NEGATIVE remarks having INDEX Value, (Sam. Abs./ Cutoff Abs.) <= 0.900. The sample will get EQUIVOCAL remarks having INDEX Value, (Sam. Abs./ Cutoff Abs.) in the range from 0.900 to 1.000.

S. To save the test after entering all the parameters, select 'SAVE' option.

Name: I	Name: HBSAG			ut Off		
Pri: 450	Sec: 63	0				ESC
No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Υ	0.100			
NC 3	1.000	Υ	0.150			
PC 2	1.000	Υ	0.500			
LC 0	1.000	N				
CC 0	1.000	N				
CUTFA	C: 0.200					
CUTAB	S: NC + I	PC + CF				
QC1 >	Y 0.50	0	Interpre	tation:		
QC2	N		Greyzor	ne % (Y)	10.00	
QC3	N		Cut off I	ndex (N)	
QC4	N		Range			

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8.4. Reverse Cut Off Mode

For Reverse Cut Off mode, select touch zone 'POS'- Cut Off key. It will change to REV- Cut Off.

Name:			REV- CutOff			
Pri: 40	5 Sec: 0					ESC
No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 0		N				
NC 0	1.000	N				
PC 0	1.000	N				
LC 0	1.000	N				
CC 0	1.000	N				
CUTFA	C: 0.000					
CUTAE	3S:					
QC1	N		Interpre	tation:		
QC2	N		Greyzoi	ne % (Y)	10.00	
QC3	N		Cut off I	ndex (N)	
QC4	N			Range		

In Reverse Cut Off Mode, programming of test is the same as Positive Cut off Mode. Only QC check conditions for blanks and controls get reversed. In the 'INTERPRETATION', sample absorbance, which is lesser than cut off absorbance, gets remarked POSITIVE. Sample absorbance higher than cut off absorbance, gets remarked NEGATIVE. This is exactly the opposite to normal POSITIVE Cut Off Mode. Same way in case you select 'Cutoff Index Range'.

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8.5. Multi Standard Mode:

In this mode the instrument accepts a maximum of 12 calibrators and calculates concentration based on the best-fit curve. Graph is printed with Absorbance on Y-axis and concentration on X-axis.

Programming a New Test:

A. Select Main Menu/Test Operation/Add New Test

TEST OPERATIONS

1 Select Test By Name

2 Select Test by Mode

3 Select Test by Number

4 List Tests

5 Add New Test

Select Test Mode

1 > Absorbance

2 > Single Standard

3 > Cut off

4 > Multi Standard

5 > Percent Absorbance

6 > Uptake

7 > Kinetic

B. Select Touch Zone "Multi Standard"

0

0

0

0

0

0

ESC

After selecting Multistandard mode it will display following screen -

Name:	ame: MULTISTANDARD					
Pri: 405 Sec: 0	BL N	CAL 2	ESC			
	DUP N	DUP N				
			SAVE			
HI CO : N Hig	h> Lov	V<				
LO CO: N Hig	gh> Lov	V<				
latamastic N. D	- LU-l					
Interpret'n: N R	ange High>	•				
Low<						
Graph: LINEAR						
Y vs X: ABS vs C	ONC					

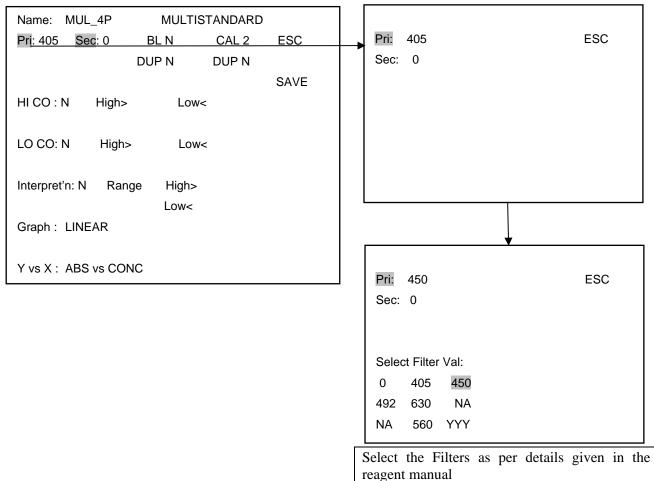
C. Entry of Test Name

Test Name can be entered by Selecting Touch Zone "Name:"

Procedure for entering the test name is same as that of the Cut Off mode. Refer Test Name entry in Cut off mode for further details.

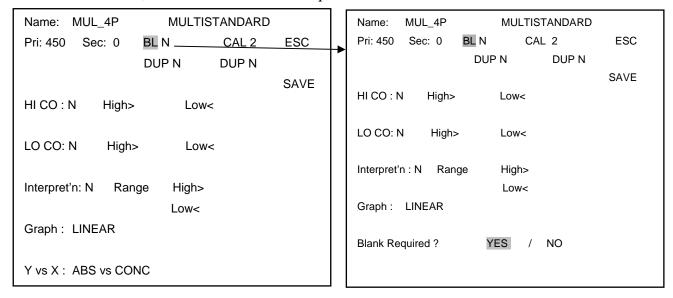
D. Selection of Primary and secondary filters

Select Touch Zone "Pri:"



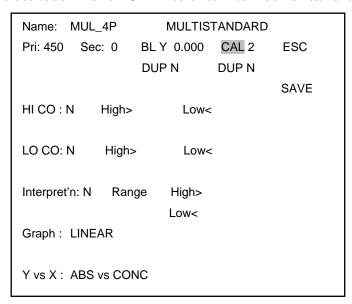
E. Selection of Blank

Select Touch Zone "BL". Instrument will display the message "Blank required Yes/No" at the bottom of the Screen, select "Yes" if blank is required.



F. Entry of Standard Concentration

Select touch Zone "CAL" to enter Number of calibrators and its concentration.

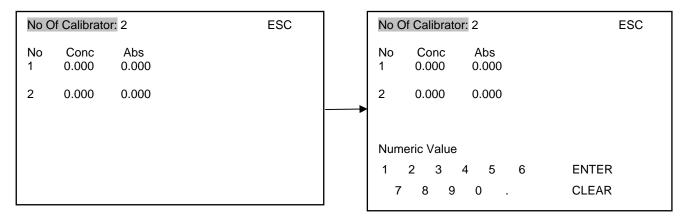


After selecting "CAL", it will display following screen:

Select Touch Zone "No. Of Calibrators". Numeric screen will be displayed at the bottom of the screen.

Select the number of calibrators (User can select min 2 and max. 12 standard in this mode).

Whereas in case of 4 Parameter, user can select min. 5 and max.12 calibrators.



Concentration Entry:

After entering the number of calibrators, concentration and absorbance column will come on the display as shown below.

To enter concentration values select 0.000 in Conc. column corresponding to the standard and enter the concentration value. e.g. for entering Concentration of standard 4 Select 0.000 in fourth row of Conc. Column and enter the concentration by selecting the numerals.

(Note: 1. The concentration values should be either in ascending or descending order.

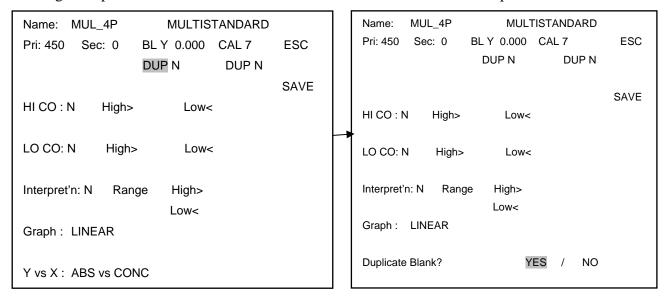
No	No Of Calibrator 7 ESC					
No	Conc	Abs	No	Conc	Abs	
1	0.000	0.000	7	10.00	0.000	
2	0.500	0.000				
3	1.000	0.000				
4	2.500	0.000				
5	5.000	0.000				
6	7.500	0.000				
Nur	meric Val	ue				
1	2 3	4 5	6	Εl	NTER	
	7 8	9 0	•	CL	EAR	

Screen after entry of calibration will be displayed as follows -

Name: MUL_4P **MULTISTANDARD** Pri: 450 Sec: 0 BL Y 0.000 CAL 7 **ESC** DUP N DUP N SAVE HI CO: N High> Low< LO CO: N High> Low< Interpret'n: N Range High> Low< Graph: LINEAR

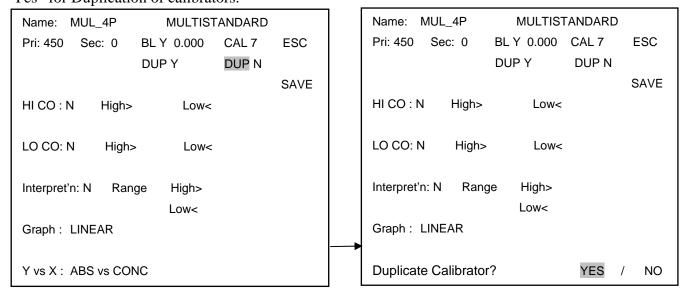
For Duplicate Blank:

Select touch zone "DUP" below the "BL Y" After selecting "DUP" instrument will display message "Duplicate Blank? Yes/ No" as shown below. Select "Yes" for Duplication of Blank.

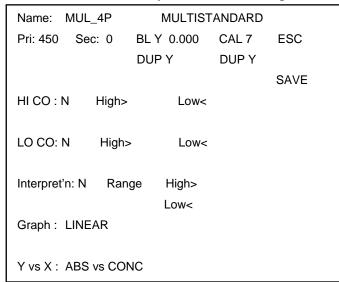


For Duplicate Calibrators:

To select Duplicate Calibrator select Touch Zone "DUP" below the "CAL 7". After selecting "DUP" instrument will display message "Duplicate Calibrator? Yes/No" as shown below. Select "Yes" for Duplication of calibrators.



Screen after standard entry & selection of duplicate – Blank & Calibrators.



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H. Graph type along with its scales:

There are three types of graphs in Multistandard. They are mentioned as follows -

- 1. Linear (LINEAR)
- 2. Point to Point (PT TO PT)
- 3. 4 Parameter

There are five types of scales for X and Y axis

LOGABS vs CONC (X-axis = Concentration v/s Y-axis = LOG of ABS.)

ABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = Absorbance)

LOGITABS VS LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOGIT of Absorbance)

ABS vs CONC (X-axis = Concentration v/s Y-axis = Absorbance)

LOGABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOG of absorbance)

Selection of Graph

Select Graph type as per the details given in the reagent manual by selecting Touch Zone "Graph".

Name: MUL_4P MULTISTANDARD						
BL Y 0.000	CAL 7	ESC				
DUP Y	DUP Y					
		SAVE				
Low<						
> Low<						
•						
Low<						
VC .						
	BL Y 0.000 DUP Y	BLY 0.000 CAL 7 DUPY DUPY Low< Low< High> Low<				

1. LINEAR Mode graph type:

After Selecting the "Graph" option present in the test parameter screen, it will display following screen.

Select Graph type as Linear and its Scale type as per the details given in the reagent manual.

Graph: LINEAR ESC

Y vs X: ABS vs LOGCONC

TYPE SCALE

LINEAR LOGABS vs CONC

ABS vs LOGCONC

PT TO PT LOGITABS vs LOGCONC

ABS vs CONC

4 PARAMETER LOGABS vs LOGCONC

2. POINT TO POINT Graph Type:

Select touch zone "PT to PT" and its scale type as 'LOGABS vs. CONC'. (as per the details given in the reagent manual)

Graph Type: PT TO PT ESC

Y vs X: ABS vs CONC

TYPE SCALE

LINEAR LOGABS vs CONC

ABS vs LOGCONC

PT TO PT LOGITABS vs LOGCONC

ABS vs CONC

4 PARAMETER LOGABS vs LOGCONC

3. 4 PARAMETER Graph Type:

Select touch zone "4 PARAMETER" and it will automatically selects it's **default** scale type as "ABS vs CONC".User have to remember this regarding 4-Parameter mode.

Graph Type: 4 PARAMETER ESC

Y vs X: ABS vs CONC

TYPE SCALE

LINEAR LOGABS vs CONC

ABS vs LOGCONC

PT TO PT LOGITABS vs LOGCONC

ABS vs CONC

4 PARAMETER LOGABS vs LOGCONC

Select the scale type touching the required zone.

Name: MUL_4P MULTISTANDARD

Pri: 450 Sec: 0 BL Y 0.000 CAL 7 ESC

DUP Y DUP Y

SAVE

HI CO: N High> Low<

LO CO: N High> Low<

Interpret'n: N Range High>

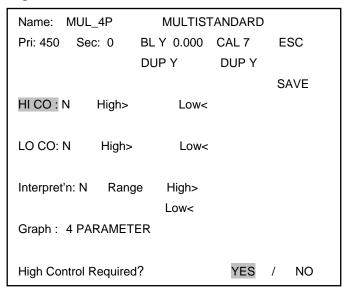
Low<

Graph: 4 PARAMETER

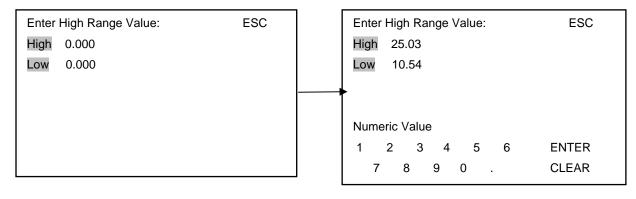
Y vs X: ABS vs CONC

I. Selection of Controls

For High control select touch zone 'HI CO: N' Following message appears: "High Control Required? Yes / No". Select 'YES' and then enter range of control "HIGH" and "LOW".



Enter range of control "HIGH" and "LOW" as per reagent manual.



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Similarly, for Low Control select touch zone 'LO CO: N' It will display the message "Low Control Required? Yes / No". Select 'YES' and then enter range of control "HIGH" and "LOW".

Name: MUL_4P MULTISTANDARD					
Pri: 450 Sec: 0	BL Y 0.000	CAL 7	ESC		
	DUP Y	DUP Y			
			SAVE		
HI CO : N High>	25.03 Low<	10.54			
LO CO: N High:	> Low<				
Interpret'n: N Ran	nge High>				
Graph: 4 PARAME					
Low Control Require	d?	YES	/ NO		

(Note: Entry of LO CO is similar to that of HI CO)

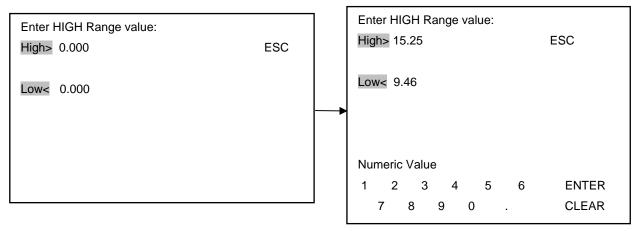
J. Normal Range selection for interpretation of samples:

For interpretation of specimen result (POSITIVE or NEGATIVE), enter normal range given in REAGENT MANUAL. Select "Interpretation: N". It will change to "Interpretation: Y". Then select "HIGH>" and "LOW<" to enter normal range.

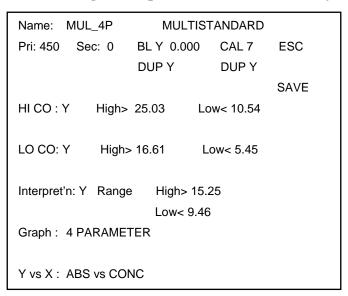
Name: MUL_4P	MULTIS	STANDARD			
Pri: 450 Sec: 0	BL Y 0.000	CAL 7	ESC		
	DUP Y	DUP Y			
			SAVE		
HI CO : Y High>	25.03	Low< 10.54			
LO CO: Y High>	16.61	Low< 5.45			
Interpret'n: Y Range High> 0.000 Low< 0.000 Graph: 4 PARAMETER					
·					
Y vs X: ABS vs CON	IC				

All the results whose concentration is coming above the High Range will be considered as positive and coming below the Low Range will be consider as negative. The results having concentration in between High and Low range will get remarks 'Equivocal' = 'EQ'.

Enter Normal Range for positive and negative samples.



After entering all the parameters save the test by selecting "SAVE" option.



(*Same way you can make a test for Single standard, % Absorbance and uptake)

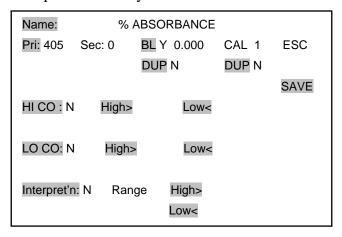
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8.6. Percentage Absorbance

The Percentage Absorbance Mode requires one calibrator (read singly or duplicate). In this mode, calibrator is considered to have a concentration of 100%. The absorbance's of unknown samples are read and compared to the calibrator absorbance, and reported as % concentration of calibrator. Refer 8.5 for parameter entry.

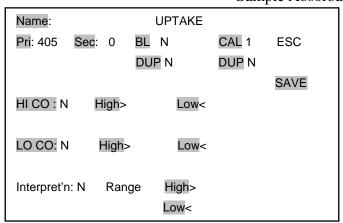


8.7. Uptake

In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.000

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law

Sample Concentration = <u>Calibrator Absorbance * Calibrator Concentration</u>

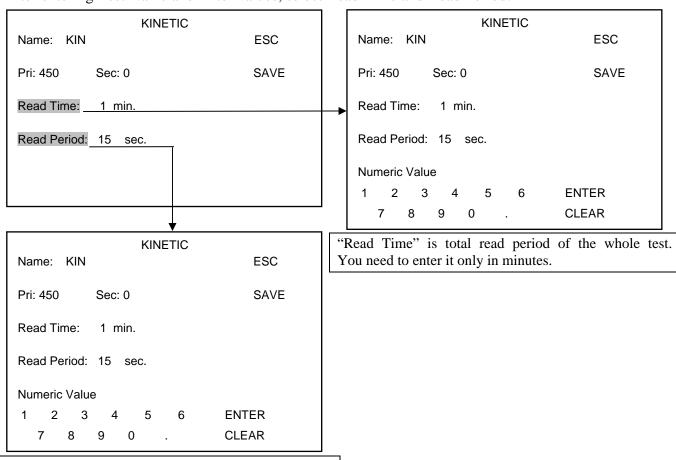


Sample Absorbance

Please refer 8.5 for parameter entry.

8.8. Kinetic

After entering Test Name and Filter values, select Read Time and Read Period.



"Read Period" is time interval between two readings. User must enter it in seconds.

Finally select the "Save" option in order to save the test in KINETIC mode

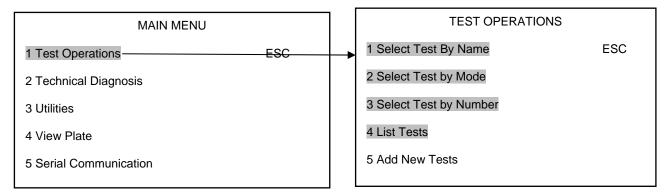
KINETIC	
Name: KIN	ESC
Pri: 450 Sec: 0	SAVE
Read Time: 1 min.	
Read Period: 15 sec.	

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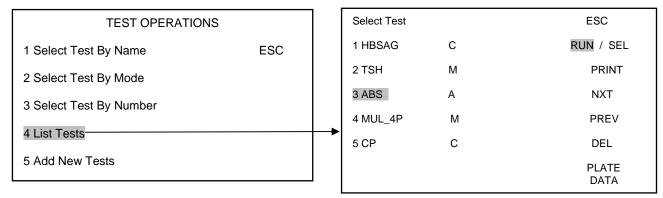
9. RECALLING AND RUNNING OF STORED TEST/PROGRAMS



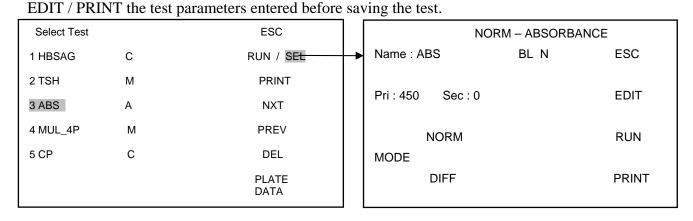
Test can be recalled by Name, Mode, Number or by List test.

The entire saved tests are available on the List Test or on the first screen after initialization.

User can directly RUN the test by selecting RUN option present on the screen.



Tests can be selected with the help of SEL option present on the Select Test screen in order to



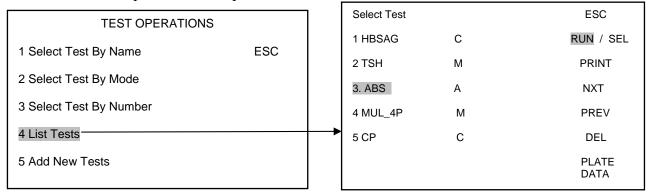
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9.1. Absorbance Mode:

Select the test and point to RUN option



On selecting RUN option it will display following screen.

The instrument will ask "Is Plate Loaded? YES / NO", select 'Yes'. Instrument will read the absorbance using mechanical plate movement. After completion of reading it will ask:

"Is Plate Removed? YES / NO". Remove the plate and Select 'YES'.

Name:	ABS	NORM – ABSORBANCE			
Pri : 45	50 Sec	: 0	BL	. N	
ABS	ABS	ABS	ABS	ABS	ABS
1	2	3	4	5	6
ABS	ABS	ABS	ABS	ABS	ABS
7	8	9	10	11	12
Is Plate	e Loaded	?		YES	/ NO

Name:	ABS	NORM	– ABSO	RBANCE		
Pri : 45	50 Sec	: 0	BL	. N		
ABS	ABS	ABS	ABS	ABS	ABS	
1	2	3	4	5	6	
ABS	ABS	ABS	ABS	ABS	ABS	
7	8	9	10	11	12	
Is Plate	e Remove	ed ?		YES	/	NO

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Details of absorbance of all wells in table format for each strip will be displayed on the screen as shown below.

Name:	ABS	NORM	– ABSOI	RBANCE	
Pri : 45	0 Sec	: 0	BL	N	
ABS	ABS	ABS	ABS	ABS	ABS
1	2	3	4	5	6
0.028	0.145	0.100	0.017	0.089	0.135
0.071	0.123	0.113	0.054	0.116	0.060
ABS	ABS	ABS	ABS	ABS	ABS
7	8	9	10	11	12
0.362	0.078	0.410	1.440	0.746	0.224
0.112	0.111	0.093	2.568	0.396	0.015
ESCPF	RINTMAT	RIX	SEND	PLATE	LOAD NEXT

In this operation if you keep BLANK YES

The first well of first strip will be considered as blank and instrument will give the absorbance of remaining all well with blank subtraction from original absorbance.

The "PRINT MATRIX" will print the details of entire plate with well identification and absorbance of that well, like.....

Α

W1 W2 W3 W4 W5 W6 0.125 0.250 0.350 0.450 0.550 0.650..

Using "SEND PLATE" plate data can be sent to computer using either USB or SERIAL RS232.

"LOAD NEXT" is used to load the Next Plate in order to get the absorbance of next plate

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Example Print-out of ABSORBANCE test obtained from READWELL TOUCH

After running the plate in Absorbance mode, user can take the print of the result in the form of Print matrix which will be printed as follows –

	NORM-ABSORBANCE										
Name :	ABS		BL	N							
Pri : 450 ABS, 21 A	0 1/07/08,	Sec : 0									
W1 0.028 B	W2 0.145	W3 0.100	W4 0.017	W5 0.089	W6 0.135	W7 0.362	W8 0.078	W9 0.410	W10 1.440	W11 0.746	W12 0.224
W1 0.058 C	W2 0.151	W3 0.386	W4 2.553	W5 0.111	W6 1.479	W7 2.593	W8 0.081	W9 2.517	W10 0.781	W11 0.730	W12 0.005
W1 0.065 D	W2 2.596	W3 0.135	W4 0.142	W5 0.141	W6 0.182	W7 0.108	W8 0.112	W9 1.585	W10 1.530	W11 0.405	W12 2.635
W1 0.072 E	W2 0.150	W3 2.630	W4 0.143	W5 2.650	W6 0.077	W7 0.159	W8 0.170	W9 1.504	W10 0.071	W11 0.426	W12 0.222
W1 2.541 F	W2 0.140	W3 0.149	W4 0.091	W5 0.166	W6 0.173	W7 2.653	W8 0.191	W9 0.097	W10 2.659	W11 0.252	W12 0.222
W1 2.614 G	W2 2.682	W3 0.185	W4 0.130	W5 2.648	W6 0.167	W7 0.176	W8 0.071	W9 2.686	W10 0.853	W11 0.907	W12 0.426
W1 0.056 H	W2 0.163	W3 2.571	W4 0.155	W5 0.147	W6 0.119	W7 2.618	W8 0.081	W9 0.085	W10 0.070	W11 0.407	W12 2.591
W1 0.071	W2 0.123	W3 0.113	W4 0.054	W5 0.116	W6 0.060	W7 0.112	W8 0.111	W9 0.093	W10 2.568	W11 0.396	W12 0.015.

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Differential Absorbance Mode: In differential absorbance mode the instrument will give the absorbance difference each set of "ODD" number strip and EVEN number strip.

405010	unce un	10101100	- Cach Sc	7 01 0	DD Hullioei su	-P
Name:	ABS	D	IFF- ABS	SORBAN	CE	
Pri : 45	50 Sec	: 0				
ABS	ABS	ABS	ABS	ABS	ABS	
1	2	3	4	5	6	
	0.900		1.700		0.900	
	0.200		1.000		1.800	
	0.300		1.100		1.900	
	0.400		1.200		2.000	
	0.500		1.300		2.100	
	0.600		1.400		2.200	
	0.700		1.500		2.300	
	0.800		1.600		2.400	
ABS	ABS	ABS	ABS	ABS	ABS	
7	8	9	10	11	12	
	0.100		0.900		1.700	
	0.200		1.000		1.800	
	0.300		1.100		1.900	
	0.400		1.200		2.000	
	0.500		1.300		2.100	
	0.600		1.400		2.200	
	0.700		1.500		2.300	
	0.800		1.600		2.400	
ESC	PRINTI	MATRIX	SEND I	PLATE	LOAD NEXT	

It is showing the absorbance only for even number strips. This absorbance values are actually differences between each well of strip 1 and well of strip 2. You can get the difference between set of 1-2, 3-4, 5-6, 7-8, 9-10 and 11-12. It is not possible to change this combination.

In "PRINT MATRIX", you will get the print of entire plate data with actual absorbance of each well and difference of absorbance between ODD well and EVEN well, like

Α											
W1	W2	W3	W4	W5	W6	W7	W8	W9 W	/10	W11	W12
0.300	0.279	0.524	0.497	0.816	0.499	0.082	0.474	0.651	0.331	0.394	0.562
0.000	0.021	0.000	0.028	0.000	0.316	0.000	-0.391	0.000	0.320	0.000	-0.168
В											
W1	W2	W3	W4	W5	W6	W7	W8	W9 W	/10	W11	W12
0.506	0.584	0.648	0.194	0.472	0.457	0.822	0.346	0.679	0.387	1.047	0.130
0.000	-0.077	0.000	0.453	0.000	0.015	0.000	0.476	0.000	0.292	0.000	0.918

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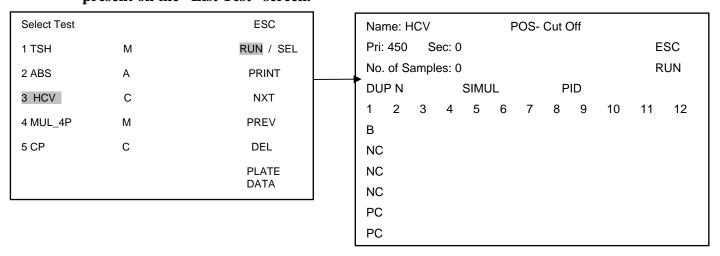
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9.2. Cut off Mode

After recalling the test saved in Cut-Off mode, it will display following screen. User can take the print of the test parameters by selecting "PRINT" option present on the screen. It will print all the details of the test parameters alongwith QC equations.

Name	: HCV		POS- C	Cut Off			
Pri: 45	io Sec	: 0				ESC	
	No	Factor	QC	QCVal	Mes.		EDIT
BL	1		Υ	0.100	0.000		RUN
NC	2	1.000	Υ	0.150	0.000		PRINT
PC	2	1.000	Υ	0.500	0.000		
LC	0	1.000	N				
CC	0	1.000	N				
CUTF	AC: 0.100)					
CUTA	BS: 0.1*F	PC+CF					
QC1	N		Interpre	etation:			
QC2	N		Greyzo	ne % (Y)	10.00		
QC3	N		Cut off	Index (N)			
QC4	Ν		Range				
To cha	ange valu	es press E	DIT				

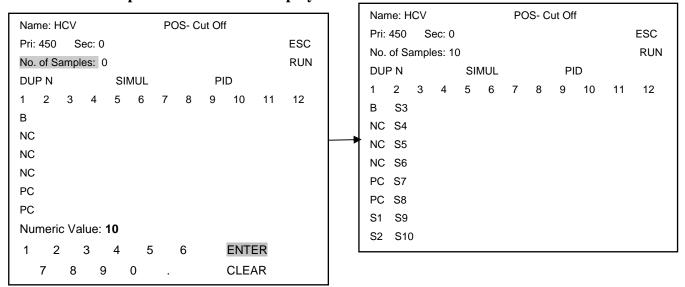
A) For running the test in CUTOFF mode select the particular test and point to RUN option present on the "List Test" screen.



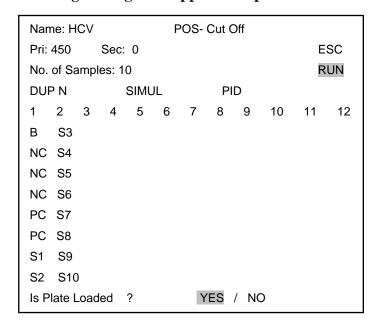
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B) It shows the 12 strips horizontal with 8 wells vertical with blanks and controls loaded in first strip. Select the 'No. of Samples' and enter the total Number of samples you want to load with the help of numeric screen displayed at the bottom of the screen.



C) After entering No. of samples, select RUN. The plate-loading tray will come out and the following message will appear: "Is plate loaded? YES / NO"



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D) Here the plate is loaded in the direction that controls should go in first. Select "YES". The instrument will read the controls and samples.

Following message appears: "Is plate removed? YES / NO". Remove the plate and select YES.

Nan	ne: H	CV			F	os-	Cut C	Off			
Pri:	450	S	ec: C)							ESC
No.	of Sa	ampl	es: 1	0							RUN
DUF	PΝ			SIML	JL		PID				
1	2	3	4	5	6	7	8	9	10	11	12
В	S3										
NC	S4										
NC	S5										
NC	S6										
PC	S7										
PC	S8										
S1	S9										
S2	S10)									
	Is P	late	Rem	oved	?			YES	5 /	N	0

E) After selecting YES, result screen will appear with the measured values of average blank, average of all controls and the cut off absorbance. To check the results of samples, select option 'Display value'

			ESC
QCVal	Mes.	Rem	ACCEPT
0.100	0.050		TEST
0.150	0.098		
0.500	2.658		PRINT
CUTABS	S: 0.563		Display
			VALUE
			LOAD
			NEXT
c).100).150).500	0.100 0.050 0.150 0.098	0.100 0.050 0.150 0.098 0.500 2.658

F) 'DISPLAY VALUE' option will display the result of all samples along with the controls selected.

Name: HC	V	POS	S- Cut Off		ESC
Pri: 450 S	ec: 0	BL	Υ		
Range F	PERCENTA	GE % 10	.00		NXT
		Pos	0.330		
CUT ABS=	0.300	Neg	: 0.270		PREV
NO SAI	MP ABS	AVG	INDEX	REM	PID
A1 B	0.050	0.050			
B1 NC					
G1 S1	0.200	0.200	0.254	NEG	PQR-1
H1 S2	1.854	1.854	7.245	POS	PQR-2
PRINT	SAV	Έ	PRI	NT	PLATE
RESULTS	RES	ULTS	MAT	RIX	OPT.

G) By selecting 'ACCEPT TEST' option you can save this test with the details of controls absorbance. Next time it is possible to run the same test without loading controls. This means that the previous stored values of controls can be used.

All the details are in table format, as per row and column shown on the screen. You can obtain the print of the same format by selecting option 'PRINT RESULTS'. To check the results of next samples, choose option 'NXT', and then print it in format as shown on the screen by option 'Print Results'

You can obtain the print in matrix format, by selecting option 'PRINT MATRIX'.

In matrix form you will get the print as per your tray/plate for all the wells. Instrument prints seven different parameters in print matrix for a single well.

ROW IDENTIFICATION

A, B, C,D,.....

WELL NUMBER

W1, W2, W3, W4....

WELL ID OR SAMPLE NUMBER

BL, NC, PC, OR S1, S2, S3,

PATIENT IDENTIFICATION

RAMESH, VIKAS, etc.

0.050, 0.098, 0.085, ...

SAMPLE CONCENTRATION

0.738, 0.689, 2.578,...

INTERPRETATION / REMARKS

POS or NEG or EQ

Example Print-out of POS-CUTOFF test obtained from READWELL TOUCH

	•				200						
					PO	S-CutOff					
Name : Pri : 450		Sec: 0									
	NO Fac	tor	QC	QCVal N	Aeas.						
BL NC	1 2	0.000	Y	0.100	0.000						
PC	2	0.100	Y	0.500	0.000						
CC CC	0	1.000	N								
CUTFAC	3 :	0.100									
CUTABS QC1	s: N	.1*PC+0									
QC2	N	Greyzor	ne%(Y)	10.0							
QC3	N	Cutoff Range	Index (N	1)							
QC4	N 1/07/08										
HCV, 2											
W1 B	W2 S4	W3 S12	W4 S20	W5 S28	W6 S36	W7 S44	W8 S52	W9 S60	W10 S68	W11 S76	W12 S84
050.00	OPD13	OPD21	OPD29	OPD37	OPD45	OPD53	OPD61	OPD69	OPD77	OPD85	OPD93
0.002	0.147 1.302	0.091	0.011	0.083	0.127 1.122	0.362 3.201	0.072 0.636	0.400 3.533	1.454 12.84	0.743 6.564	0.222 1.959
	POS	NEG	NEG	NEG	POS	POS	NEG	POS	POS	POS	POS
B W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S5 OPD14	S13 OPD22	S21 OPD30	S29 OPD38	S37 OPD46	S45 OPD54	S53 OPD62	S61 OPD70	S69 OPD78	S77 OPD86	S85 OPD94
0.062	0.145	0.382	2.535	0.116	1.470	2.573	0.115	2.515	0.747	0.748	0.003
0.000	1.278 POS	3.372 POS	22.39 POS	1.024 EQ	12.99 POS	22.73 POS	1.011 EQ	22.22 POS	6.597 POS	6.608 POS	0.025 NEG
400	103	103	100	Lu	103	103	Lu	103	103	103	NEG
C W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S6	S14	S22	S30	S38	S46	S54	S62	S70	S78	S86
0.040	OPD15 2.573	OPD23 0.129	OPD31 0.159	OPD39 0.133	OPD47 0.217	OPD55 0.077	OPD63 0.091	OPD71 1.584	OPD79 1.557	OPD87 0.502	OPD95 2.638
0.000	22.72	1.136	1.405	1.177	1.917	0.677	0.804	13.99	13.75	4.434	23.30
D	POS	POS	POS	POS	POS	NEG	NEG	POS	POS	POS	POS
W1 PC	W2 S7	W3 S15	W4 S23	W5 S31	W6 S39	W7 S47	W8 S55	W9 S63	W10 S71	W11 S79	W12 S87
	OPD16	OPD24	OPD32	OPD40	OPD48	OPD56	OPD64	OPD72	OPD80	OPD88	OPD96
0.080	0.157	2.630	0.141	2.642 23.33	0.058	0.155 1.370	0.159 1.403	1.515 13.38	0.071	0.423 3.732	0.209 1.850
	POS	POS	POS	POS	NEG	POS	POS	POS	NEG	POS	POS
E W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
PC	S8	S16	S24	S32	S40	S48	S56	S64	S72	S80	S88
2.562	OPD17 0.172	OPD25 0.198	OPD33 0.061	OPD41 0.182	OPD49 0.165	OPD57 2.656	OPD65 0.156	OPD73 0.080	OPD81 2.616	OPD89 0.259	OPD97 0.224
0.000	1.517 POS	1.751 POS	0.536 NEG	1.612 POS	1.457 POS	23.46 POS	1.377 POS	0.705 NEG	23.11 POS	2.291 POS	1.978 POS
F											
W1 S1	W2 S9	W3 S17	W4 S25	W5 S33	W6 S41	W7 S49	W8 S57	W9 S65	W10 S73	W11 S81	W12 S89
OPD10	OPD18	OPD26	OPD34	OPD42	OPD50	OPD58	OPD66	OPD74	OPD82	OPD90	OPD98
2.626 23.19	2.612 23.07	0.055	0.116	2.649 23.40	0.188 1.660	0.176 1.553	0.052 0.460	2.638	0.855 7.548	0.899 7.942	0.419 3.699
POS	POS	NEG	EQ	POS	POS	POS	NEG	POS	POS	POS	POS
G											
W1 S2	W2 S10	W3 S18	W4 S26	W5 S34	W6 S42	W7 S50	W8 S58	W9 S66	W10 S74	W11 S82	W12 S90
OPD11	OPD19	OPD27	OPD35	OPD43	OPD51	OPD59	OPD67	OPD75	OPD83	OPD91	OPD99
0.049 0.429	0.140	2.595	0.138	0.142	0.117	2.611	0.076	0.081	0.050	0.403	2.579
NEG	1.234 POS	22.92 POS	1.215 POS	1.252 POS	1.035 EQ	23.06 POS	0.672 NEG	0.717 NEG	0.441 NEG	3.564 POS	22.78 POS
H W1	W2	W3	W4	W5	W6	W7	w8	W9	W10	W11	W12
S3	S11	S19	S27	S35	S43	S51	S59	S67	S75	S83	S91
OPD12 0.061	OPD20 0.109	OPD28 0.002	OPD36 0.071	OPD44 0.076	OPD52 0.131	OPD60 0.109	OPD68 0.101	OPD76 0.082	OPD84 2.560	OPD92 0.399	OPD100 0.015
0.538	0.964	0.018	0.631	0.670	1.157	0.960	1.896	0.721	22.61	3.527	0.132
NEG	EQ	NEG	NEG	NEG	POS	EQ	NEG	NEG	POS	POS	NEG

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9.2. A. Invalid Assay in Cut Off Mode

If any individual control behaves incorrectly and it's absorbance is not satisfying the QC check value of that control, the following message appears: "Invalid Assay" and a remark "HI" or "LO" for that particular control. OR if the QC1, QC2, QC3 and QC4, which has an other QC condition of controls (like some reagent manual gives condition PC-NC > 0.2 or NC/PC > 0.5) the following message appears: "Invalid Assay" and a remark either 'HI' or 'LO' for that QC condition.

Name:	HBSAG		POS- C	POS- Cut Off			
Pri: 405	Sec: 0					ESC	
No	Factor	QC	QCVal	Meas.	Rem	ACCEPT	
BL 1		Υ	0.100	0.105	HI	TEST	
NC 3	1.000	Υ	0.150	0.200	HI		
PC 2	0.100	Υ	0.500	0.456	LO	PRINT	
LC 0	1.000	N					
CC 0	1.000	N					
CUTFA	C: 0.200		CUTAB	S: 0.563		DISPLAY	
						VALUE	
QC1 2.	.560 HI	QC2					
QC3		QC4				LOAD	
Invalid	<u>Assay</u>					NEXT	

(NOTE: The absorbance of controls should not go above 3.50. If it is > than 3.50, it will show the remark 'HI' for that control. In such a case edit the control absorbance.)

In such case, delete an individual control, so that the average of remaining controls will satisfy the QC condition of that control as per reagent manual.

To select any control for deleting, you must select the touch zone as shown in the above screen.

When you select any particular control for deleting (suppose you have selected Negative Control (NC), 'HI' or 'LO' remark appear on the screen.

"Select EDIT / DEL key to proceed". To delete the control select 'DEL'. After deleting that control, the absorbance of that control will become zero and the average of controls will also get changed. Select 'ESC' option to come back to the Result screen.

NC VALUE :	0.200	ESC
NC1 0.150		DEL
NC2 0.350	Н	
NC3 0.200	НІ	

When you go back, you will get the edited values for average of control with no remark for any control and no "Invalid Assay" message.

*NOTE:

Make the blank absorbance valid in case the absorbance doesn't meet the QC conditions.

If necessary valid the control absorbance because the absorbance of the blank affect the absorbance of all controls and samples.

It is recommended that, for a test with single blank and single control, if absorbance doesn't satisfy QC conditions or if all controls of any single type (means all NC controls or all PC controls) doesn't meet the QC, the test will become totally invalid. It is not possible to make the VALID TEST and new controls have to be loaded.

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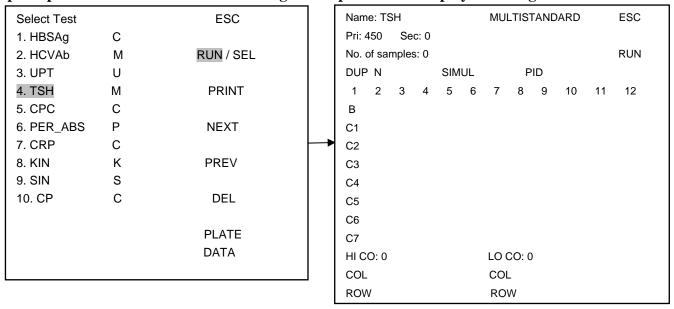
9.3. Multistandard:

After recalling the test in multistandard mode it will display following screen. Take the print of the test parameters if required and select "Run" option. Or else you can directly run the test from the List Test screen.

Multi Standard Mode

viaiti Standard 111								
Name: TSH	MULTIS							
Pri: 450 Sec: 0	BL Y 0.000	CAL 7	ESC					
	DUP N	DUP Y	EDIT					
			RUN					
HI CO: Y High>	25.03 Lo	w< 10.54	PRINT					
LO CO: Y High:	> 16.61 L	ow< 5.45						
Interpret'n: Y Range High> 15.25								
Low< 9.46								
Graph: 4 PARAMETER								
Y vs X: ABS vs CONC								
To change values press EDIT								

A) For running the test in MUL_STD mode select the particular test and point to RUN option present on the screen. On selecting RUN option it will display following screen.



B) To enter total No. of HI controls, select "HI CO:" option and enter numeric value.

Numeric Value										
1	2	3	3	4		5		6	ENTER	
7		8	9		0				CLEAR	

C) If you select No. of HI controls = 2, then you have to locate the position of HI controls by selecting column number and row number.

For column number entry select "COL" option and enter column number.

```
HI CO: 2
ROW COL
2
3

Please Enter Col Entry: 1
Numeric Value:
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR
```

For row entry select "ROW" option and enter row position.

```
HI CO: 2
ROW COL
A 2
B 3

Please Enter Row Entry: 1
Row Entry:
A B C D E F G H ENTER
CLEAR
```

Similarly, you can enter No. of LO Controls and locate its positions.

D) You can locate Controls from first well or after last calibrator to last well of strip 12 in any test.

Suppose you select column 2 & row A for first HI control and column 2, row B for second HI control then the location of HI control will be display on screen as shown below.

```
Name: TSH
                   MULTISTANDARD
Pri: 450
        Sec: 0
                                      ESC
                                      RUN
No. of samples: 0
DUP N
            SIMUL
                         PID
       3 4 5 6
1
    2
                     7 8 9 10
                                    11
                                          12
В
  HC
C1
   HC
C2
C3
C4
C5
C6
C7
HI CO: 2
COL
ROW
```

E) Select No. of samples you want to run. In case of 10 samples, it will load 10 samples as follows -

```
Name: TSH
                   MULTISTANDARD
Pri: 450
         Sec: 0
                                        ESC
No. of samples: 10
                                        RUN
DUP N
            SIMUL
                         PID
       3
              5 6
                     7
                         8 9
                                10
                                         12
В
   HC S5
C1 HC S6
C2 LC S7
C3 LC S8
C4 S1 S9
C5 S2 S10
C6 S3
C7
   S4
                   LO CO: 2
HI CO: 2
COL
                   COL
ROW
                   ROW
```

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F) Now Select RUN option so that readings can be taken in MULTI STANDARD mode.

The plate holder will come out and will display the message string- "Is Plate loaded YES / NO". The plate has to be loaded in such a way that the direction of the calibrators should go in first and then select 'YES'.

The instrument will read the absorbance of calibrators and samples. And finally display the string-"Is plate removed? YES / NO". Remove the plate and select 'YES'. The plate holder will go inside and following screen will be flashed on the display.

(Note: It takes maximum 6 min only in case of 4 parameter)

`					1	
Name:	MULTI	STANDA	Е	ESC		
Pri: Sec:	BL	CAI	_	1	TXV	
	DUP	DU	P	REV		
Range High	> Low <					
HI CO: High	>	Low <		S	AVE	
LO CO : High	>	Low <		RE	SULT	
NO SAMP	ABS	AVG	CONC	REM	PID	
Please Wait						
It may take ma	ximum 6 n	ninutes.				
LOAD PRINT			ACCEPT	PRINT		
_			TEST I			

After reading it will display all the details of calibrators, samples and controls on the screen as shown below-

```
Name: TSH
                       MULTI STANDARD
                                          ESC
Pri: 450 Sec: 0
                       BL Y
                                     CAL 7
                    DUP N
                                DUP N
                                                  NXT
Range High > 15.25
                       Low < 9.46
HI CO: High > 25.03
                       low < 10.54
LO CO: High > 16.61
                                               PREV
                       Low < 5.45
                        CONC REM
                                       PID
NO
    SAMP
           ABS
                  AVG
    В
            0.050
                  0.050
Α1
B1
    C1
            0.070
                  0.070
                         0.000
                                        RESULT
C1
    C2
            0.257
                  0.257
                         2.500
G1
     S1
           0.200
                  0.200
                         2.100
                                NEG TSH-1
                                      TSH-2
           1.854
                  1.854
                         9.845
                                 POS
H1
     S2
LOAD
       PRINT
                  PLATE
                          VIEW
                                   ACCEPT
                                                PRINT
NXT
       MATRIX
                  OPT.
                         GRAPH
                                    TEST
                                               RESULTS
```

All the details as per row and column are shown on the screen. The printout of the same format can be obtained by selecting 'PRINT RESULTS'. To check the results of next samples, select 'NXT' and print the format shown on screen by option 'Print Results'.

You can get the print in matrix format, by selecting 'PRINT MATRIX'.

In matrix form you will get the print as per your plate for all the wells. Instrument will print seven different parameters in print matrix for a single well as follows:

ROW IDENTIFICATION A,B, C,D,.....

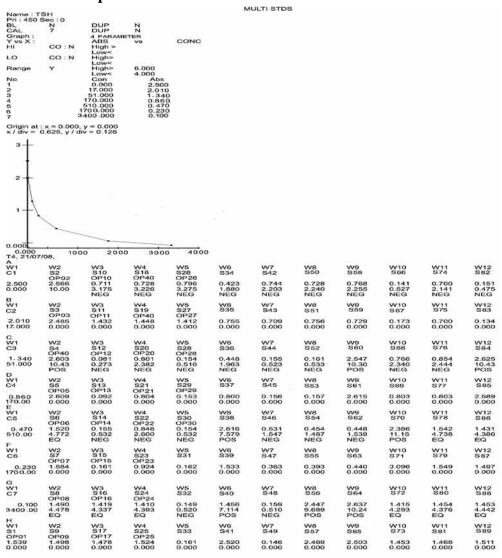
WELL NUMBER W1, W2, W3, W4...

WELL ID OR SAMPLE NUMBER B, C1, C2, C3, OR S1, S2, S3,...

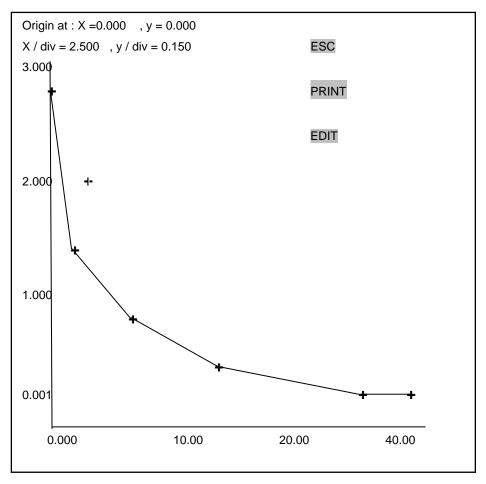
PATIENT IDENTIFICATION RAMESH, VIKAS, etc.
WELL ABSORBANCE 0.050, 0.098, 0.085, ...
SAMPLE CONCENTRATION 0.738, 0.689, 2.578...

INTERPRETATION / REMARKS POS, NEG, EQ,

Remember that Negative sign result is interpreted as zero both in printout as well as on screen. Example Print-out of MultiStandard test obtained from READWELL TOUCH



G) On selecting 'View Graph:', it displays the Graph screen with all the details of X-axis and Y-axis. Select 'PRINT' option to obtain the print out.



Select 'ACCEPT TEST' option to save this test with the details of calibrator absorbance. It is possible to run the same test without loading calibrators. The previous graph can be used for new samples.

(* **NOTE:** If you do not want to run the calibrators each time, please select "ACCEPT TEST" option to save graph, whenever you run the test with calibrators.)

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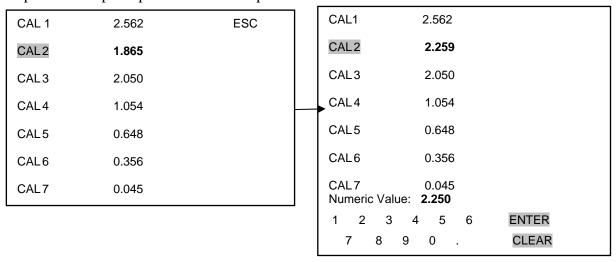
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9.3.A. Invalid assay in Multi standard Mode

In Multi standard, the absorbance of calibrators should be in increasing or decreasing from one calibrator to the next calibrator. If any calibrator/s behave(s) incorrectly you will obtain a message "Invalid Assay" at the bottom of the screen.

Name:	TSH		MUI	LTI STANI	DARD		ESC
Pri: 450	Sec: ()	BL \	Y CAL			
Range	High:	> 16.61	Low	< 10.30			NXT
н со	: High	>	Low	<i>'</i> <			
LO CO	: High :	>	Low	<i>!</i> <			PREV
NO	SAMP	ABS	AVG	CONC	REM	PID	
A1 E	3	0.050	0.050				SAVE
B1 (C1	0.070	0.070	0.000			RESULT
C1 C	2	0.257	0.257	2.500			
Invalid	Assay						
LOAD	PRIN [®]	T F	PLATE	VIEW	ACC	CEPT	PRINT
NXT	MATF	RIX (OPT.	GRAPH:	TE	ST	RESULTS

If Assay is Invalid then "Accept Test", "Save Results", "Print Matrix", "Save Plate" options are blocked. In such a case, select VIEW GRAPH option and change the ASSAY to VALID with the help of EDIT option present on the Graph screen.



You can easily select any particular calibrator by touching the particular touch zone and edit the absorbance of that. After editing the calibrator's absorbance select "ESC". A message will appear: "PLEASE WAIT..." and then the modified graph will appear on the screen.

If calibrator's value being edited in Multistandard mode then "*Mod..." string is displayed in the print.

9.4. Kinetic:

Select "RUN" to start to run the test in Kinetic mode.

	KINETIC								
Name : KIN	ESC								
Pri: 450 Sec: 0)		EDIT						
Read Time :	1	min.	RUN						
Read Period :	15	sec.	PRINT						

Or else you can directly run the test from the List Test screen by selecting RUN option present on the screen.

Select Test		ESC
1. HBSAg	С	
2. HCVAb	M	RUN / SEL
3. UPT	U	
4. TSH	M	PRINT
5. CPC	С	
6. PER_ABS	Р	NEXT
7. CRP	С	
8. KIN	K	PREV
9. SIN	S	
10. CP	С	DEL
		PLATE
		DATA

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The "D/M" means delta per minute of reaction. When test will over, instrument will show you the "D/M" values of reaction done in each well.

Name:	KIN		KINET	IC		
Pri : 45	0 Sec	: 0				
D/M	D/M	D/M	D/M	D/M	D/M	
1	2	3	4	5	6	
D/M 7	D/M 8	D/M 9	D/M 10	D/M 11	D/M 12	
Is Plate	e Loaded	?		YES	/ NO	

Name: K	(IN		KINETIO	2	
Pri : 450	Sec:				
D/M	D/M	D/M	D/M	D/M	D/M
1	2	3	4	5	6
D/M	D/M	D/M	D/M	D/M	D/M
7	8	9	10	11	12
Is Plate	Removed	? !		YES	/ NO

It is showing the "D/M" values for each and every well in table format.

Name:	KIN		KINETI	KINETIC				
Pri : 45	50 Sec	: 0						
D/M	D/M	D/M	D/M	D/M	D/M			
1	2	3	4	5	6			
0.020	0.002	0.010	0.035	0.056	0.001			
0.030	0.056	0.075	0.100	0.068	0.090			
D/M	D/M	D/M	D/M	D/M	D/M			
7	8	9	10	11	12			
0.020	0.002	0.010	0.0.35	0.056	0.001			
0.030	0.056	0.075	0.100	0.068	0.090			
ESC	PRINTM	IATRIX	SEND F	PLATE	LOAD NEXT			

In "PRINT MATRIX", you will get the print of entire plate data with initial absorbance of each sample, average delta values of each sample and "D/M" values of each well, like...

```
A
W1
       W2
              W3
                     W4
                             W5
                                    W6
0.200 0.100 1.200 0.300 2.600 0.900.. these are initial absorbance.
0.010 0.001 0.005 0.017 0.028 0.001.. these are average delta values.
0.020 0.002 0.010 0.035 0.056 0.001.. these are "D/M" values of each sample.
В
W1
       W2
              W3
                     W4
                             W5
                                    W6
0.300 0.100 1.200 0.200 2.600 0.800..
0.015 \ 0.028 \ 0.037 \ 0.050 \ 0.034 \ 0.045..
0.030 \ 0.056 \ 0.075 \ 0.100 \ 0.068 \ 0.090..
```

On selecting "SEND PLATE" option user can send the plate data to computer with the help of USB or SERIAL communication.

"LOAD NEXT" is used to load the next plate.

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• Example Print-out obtained from READWELL TOUCH

KINETIC

Pri : 450 Sec : 0

Read Time 1 min

Name: KIN_450

Read Period 15 sec KIN D, 21/07/08, W1 W2 W3 W4 W5 W6 W7 **W8** W9 W10 W11 W12 0.160 0.889 0.515 0.822 0.838 0.228 0.786 0.232 2.653 0.843 0.831 0.835 0.028 -0.004 -0.002 -0.008 -0.008 -0.003 0.005 0.008 -0.0040.002 0.020 0.017 В W2 W3 W5 W6 W7 **W8** W9 W10 W11 W12 W1 W4 0.793 0.139 1.493 0.832 0.805 2.577 1.502 1.511 0.861 0.233 0.813 0.226 0.061 0.004 -0.0020.020 0.026 0.023 0.011 0.030 -0.004 0.022 0.015 -0.012С W1 W2 W3 W4 W5 W6 W7 W8 W9 W10 W11 W12 0.502 0.252 2.592 2.700 0.168 0.878 0.278 0.523 0.236 0.867 2.720 0.963 0.042 0.001 0.004 0.011 0.014 0.014 0.029 0.037 0.005 0.030 0.009 0.018 D W1 W2 W3 W4 W5 W6 W7 W8 W9 W10 W11 W12 0.536 2.730 0.196 0.897 0.260 0.897 0.257 0.255 2.720 0.907 0.912 2.698 0.015 0.014 0.0270.013 0.035 0.0430.027 0.012 -0.0000.030 0.004 -0.016 W2 W7 W9 W1 W3 W4 W5 W6 **W8** W10 W11 W12 0.936 1.608 0.264 0.938 0.282 2.711 0.635 0.556 0.568 2.462 1.655 1.542 0.036 0.024 0.021 0.027 -0.005-0.008 -0.0060.005 0.009 0.021 0.007 0.014 W1 W7 W2 W3 W4 W5 W6 **W8** W9 W10 W11 W12 1.009 1.706 0.289 1.132 0.313 1.707 0.568 0.554 0.604 3.155 1.682 1.647 0.054 0.078 0.055 0.057 0.044 0.077 0.067 0.040 0.040 0.012 0.036 0.055 G W1 W2 W3 W4 W5 W6 W7 W8 W9 W10 W11 W12 1.559 1.565 1.448 1.485 0.225 1.523 0.239 2.547 2.715 1.490 1.542 1.532 0.027 0.021 0.026 0.027 0.022 0.033 0.031 0.012 0.022 0.027 0.054 0.013 W1 W2 W7 W3 W4 W5 W6 W8 W9 W10 W11 W12 1.618 1.595 1.581 1.615 0.250 2.646 0.274 2.564 2.616 1.598 1.576 1.613

(Note: Same Procedure can be used to create and run the test in all other modes, like Single Standard, % Absorbance & Uptake)

0.017

0.079

0.007

-0.020

0.050

0.022

0.003

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0.050

0.031

0.047

0.018

0.037

10. RERUNNING ACCEPTED TESTS / PROGRAMS

"ACCEPT TEST" option is used to store the data of controls or calibrators. After running any test first time with controls or calibrators, user can select the option "Accept Test" to save the data of controls or calibrators, so that next time when you want to load the same test, there is no need to load controls or calibrators in ELISA plate. You can use previously stored data. If user recall the test with saved parameters then "Using stored values" strings should appeared in the printout.

A) In "CUT OFF" Mode:

Name: H	HCV		POS- C	ut Off		
Pri: 450	Pri: 450 Sec: 0					ESC
No	Factor	QC	QCVal	Mes.	Rem	ACCEPT
BL 1		Υ	0.100	0.050		TEST
NC 3	1.000	Υ	0.150	0.098		
PC 2	0.100	Υ	0.500	2.658		PRINT
LC 0	1.000	N				
CC 0	1.000	N				
CUTFAC	C: 0.200		CUTABS	S: 0.563		Display
						VALUE
QC1 2.	560	QC2				
QC3		QC4				LOAD
						NEXT
Range %	% 10.00					

B) In "Multi standard" Mode:

Name: TSH	MULTI STANDARD	ESC
Pri: 450 Sec: 0	BLY CAL 7	
Range High > 16.61	Low < 10.30	NXT
HI CO: High >	Low < 0.000	
LO CO: High >	Low <	PREV
NO SAMP ABS	AVG CONC REM PID	
A1 B 0.050	0.050	SAVE
B1 C1 0.070	0.070 0.000	RESULT
C1 C2 0.257	0.257 2.500	
G1 S1 0.200	0.200 2.100 NEG TSH-1	
H1 S2 1.854	1.854 9.845 POS TSH-2	
LOAD PRINT	PLATE VIEW ACCEPT	PRINT
NXT MATRIX	OPT. GRAPH TEST	RESULTS

When you want to run such an accepted test, select that particular test for instant 'CUTOFF' mode and point to 'RUN' option present on the Select Test screen.

No. of Samples: 0									ESC RUN	
DUP N			SIML	JL		PIE)			
1 2	3	4	5	6	7	8	9	10	11	12
Loa	ıd Bl	ank?					YES	s /	NO	

```
Name: HCV
                   POS- Cut Off
Pri: 450 Sec: 0
                                         ESC
No. of Samples: 0
                                         RUN
DUP N
            SIMUL
                          PID
          4 5 6
1 2 3
                     7
                         8 9
                               10
                                   11
                                         12
Load Controls?
                           YES /
                                    NO
```

This time, the blank and controls will not be loaded directly and you will get the following questions: "Load Blank? YES / NO" and "Load Controls? YES / NO".

If you are running both, select 'YES', and if you want to use earlier stored data of controls select 'NO', so that you can run only samples to get their results without loading Blank and Controls.

If you want to load only 'Blank', select "Load Blank? YES" and

"Load Controls? NO".

In case if you are using previously Stored "Blank" and "Controls" then it will print following strings in the printout-

"Using Blank Stored value...." and "Using Controls Stored value..."

C) In Multi Standard / Single Standard / % Absorbance / Uptake Mode:

Γ	Name: TSH MUL						IULTI	STA	NDA	RD			
	Pri:	450	Se	ec: 0									ESC
	No. of Samples: 0												RUN
l	DUP N			SI	ИUL			PID					
	1	2	3	4	5	6	7	8	9	10	11	12	
	Loa	ad Bl	ank	?				Y	ES	/ 1	10		
L													

1	MU	JLTI S	ATAN	IDAR	D			
Pri: 450 Sec: 0 ES								
ples: 0						RU	N	
SIN	ИUL			PID				
4 5	6	7	8	9	10	11	12	
rators?				YE	s /	NO)	
	Sec: 0 ples: 0 SIN 4 5	Sec: 0 ples: 0 SIMUL 4 5 6	Sec: 0 ples: 0 SIMUL 4 5 6 7	Sec: 0 ples: 0 SIMUL 4 5 6 7 8	Sec: 0 ples: 0 SIMUL PID 4 5 6 7 8 9	Sec: 0 ples: 0	Sec: 0 ES ples: 0 RU SIMUL PID 4 5 6 7 8 9 10 11	

In Calibrator Mode, after asking "Load Blank? Yes / No" you will get the following question "Load Calibrators? Yes / No". If you are loading new calibrators and want the results of samples as per new graph select "Load Calibrators? YES".

Or else, If you are not loading new calibrators and want to use previously stored graph select "Load Calibrators? No".

If you want to load only 'Blank', select "Load Blank? YES" and "Load Calibrators? NO".

In case if you are using previously Stored "Blank" and "Calibrators" then it will print following strings in the printout-

"Using Blank Stored value...." and "Using Calibrator Stored value..."

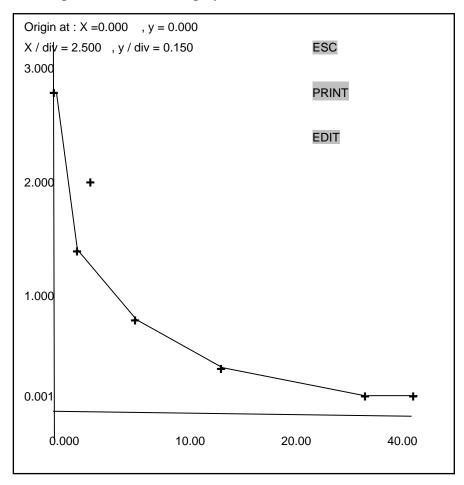
NOTE: User can view the Saved Graph from the Test parameter screen before re-running the same test.

Name: TSH MULTISTANDARD Pri: 450 Sec: 0 BL Y 0.000 CAL 7 ESC DUP Y DUP Y **EDIT** RUN HI CO: Y High> 25.03 Low< 10.54 **PRINT** LO CO: Y High> 16.61 Low< 5.45 Interpret'n: Y Range High> 15.25 Low< 9.46 Graph: 4 PARAMETER Y vs X: ABS vs CONC To change values press EDIT

On selecting GRAPH option, it will display following screen where user can select "PLOT" option in order to view the Valid GRAPH Screen.

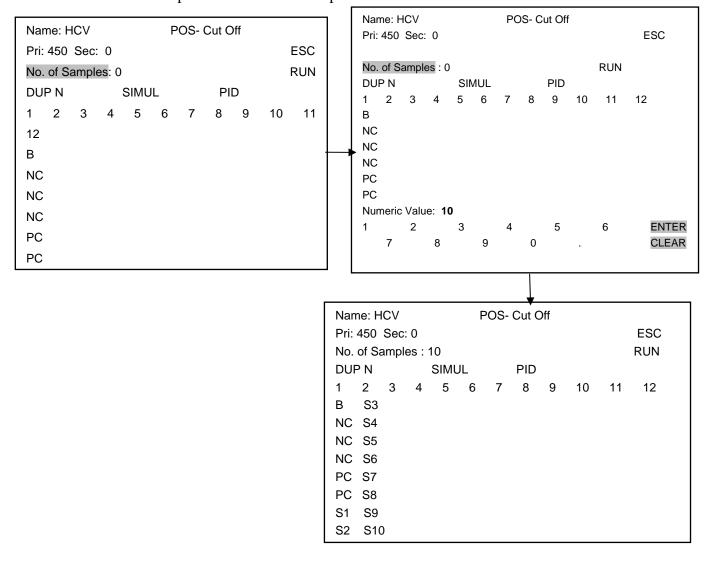
No	Conc A	Abs No	Conc	Abs
1	0.000	0.220		
2	10.00	0.454		
3	25.00	0.725		
4	50.00	1.026		
5	100.00	1.269		
6	150.00	1.850		
7	200.00	2.000		
ESC	C PRIN	T PLOT	1	

The Graph screen will be displayed as shown below-



11. SAMPLE AND SAMPLE DUPLICATE

While loading the samples you can load a single sample in single well or a single sample in adjacent two well and finally the instrument will take the average of it known as Sample Duplicate. The instrument will load the controls / calibrators automatically in any new test or not accepted test. You have to provide the number of samples. If you are loading single samples keep "DUP"-No. Select "No. of Samples:" to enter total samples.

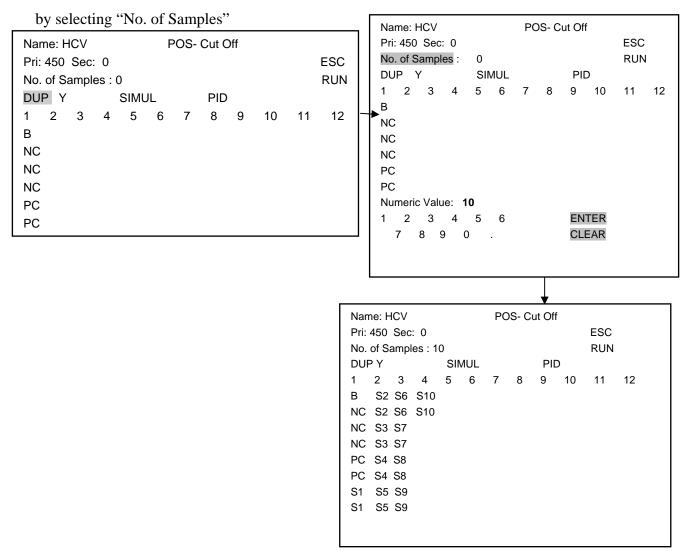


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If you want to load duplicate samples select "DUP" option and then enter the number of samples



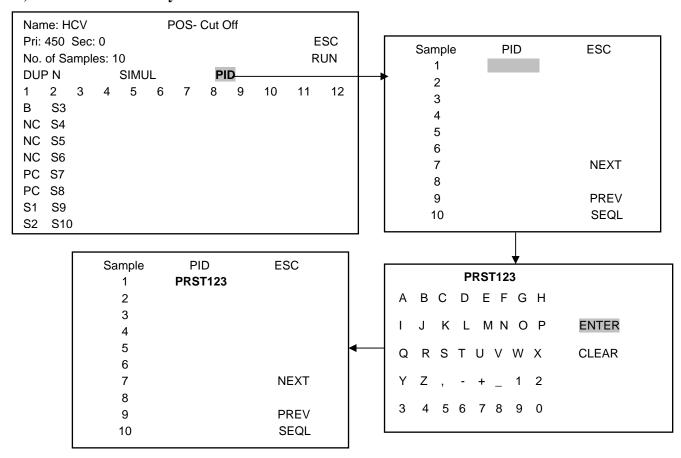
(* Similarly, user can load the samples and Sample Duplicates in all other modes)

12. PATIENT IDENTITY / SAMPLE IDENTITY ENTRY

To enter Patient ID for all samples there is an option provided in loading screen shown as "PID"

After entering number of samples either single or duplicate, select "PID".

A) Individual PID entry -



One by one you can enter name of each patient. The character length of PID is only 7 characters in the following combinations –

Since PID of the Patient is entered with the help of Alpha-numeric characters, the combination must be as mentioned below.

Alphabets	Numbers	
4	3	
3	4	
2	5	

For example -

1. In the first combination, user can enter PID with 4 Alphabets and 3 Numbers. That means, entered PID should be PQRS123

- 2. Similarly, for the second combination, user can enter PID with 3 Alphabets and 4 Numbers. And therefore, entered PID will be UTV1234
- 3. And for the third combination, user can enter PID with 2 Alphabets and 5 Numbers ie. PID will be displayed as RB12345
- 4. But one can't enter the PID with 1 Alphabet and 6 Numbers since its maximum numeric count is 65500.

(Note: The same combinations should be used during SEQUENTIAL entry also.)

B) Sequential Patient ID Entry

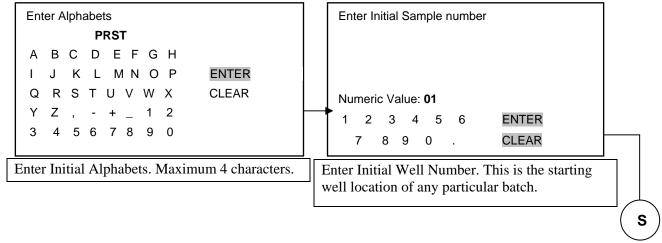
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This one by one entry will take more time, therefore one more option to enter Patient Ids is provided. This option is "SEQL" sequential entry.

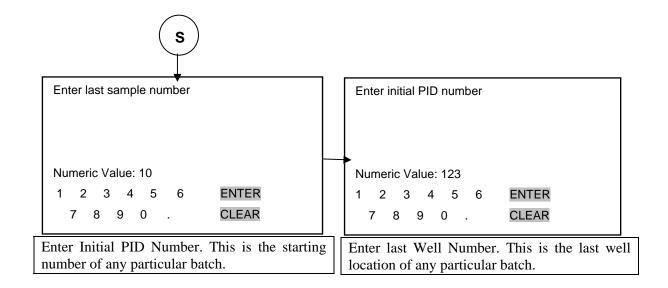
If you select "PID" option for patient ID entry, the following question appears on the screen:

"Delete Previous PIDs? Yes / No". If you select NO, it will directly load the previously entered PIDs for sample and if you select YES, it will delete the previous PIDs.

Now select 'SEQL', it will display Alphanumeric screen where user can enter different sequential PIDs. Follow the steps below-



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The final screen will appear which displays the sequential IDs of patient samples for the well location that is selected.

Sample	PID	ESC
1	PRST123	
2	PRST124	
3	PRST125	
4	PRST126	
5	PRST127	
6	PRST128	NEXT
7	PRST129	
8	PRST130	PREV
9	PRST131	
10	PRST132	SEQL

Go to the next and previous screen with the help of "NEXT" and "PREV" option present on the screen.

(*NOTE: The entered PID get stored in instrument memory, until you delete it by using option, "Delete previous PIDs? Yes / NO")

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13. SAVE PLATE AND SAVE RESULTS

In all modes of operation, there are two options provided to store results.

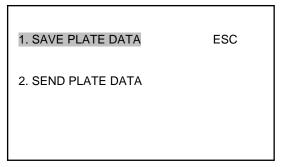
A) In Cut Off mode:

Name	Name: HCV POS			S- Cut Off			ESC
Pri: 4	Pri: 450 Sec: 0 BL			Υ			
Rang	je PERCE	ENTAGE	% 10.00)			NXT
NO	SAMP	ABS	AVG	CONC	REM	PID	PREV
A1	В	0.050	0.050				
B1	NC						
PRINT SAVE			PRI	NT	PLA ⁻	ΤΕ	
RESULTS RESULTS			МАТ	RIX	OPT		

B) In Multi standard or any calibrator mode:

Name: TSH	MULTI STANDARD	ESC
Pri: 450 Sec: 0	BLY CAL7	
Range High > 16.61	Low < 10.30	NXT
HI CO: High >	Low <	
LO CO : High >	Low <	PREV
NO SAMP ABS	AVG CONC REM F	PID
A1 B 0.050	0.050	SAVE
B1 C1 0.070	0.070 0.000	RESULT
C1 C2 0.257	0.257 2.500	
LOAD PRINT PL	ATE VIEW ACCEPT	PRINT
NXT MATRIX O	PT. GRAPH TEST	RESULTS

If "PLATE OPT." is selected, you will obtain two options.



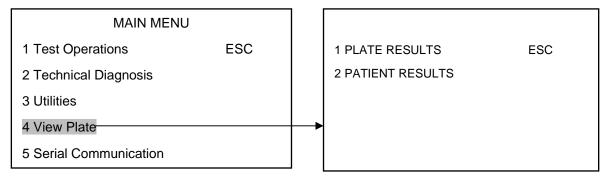
- 1. "SAVE PLATE DATA", it helps the user to save the entire plate information along with the control/calibrator information (maximum 10 plate data can be saved).
- 2. "SEND PLATE DATA" is used to send the data from instrument to computer through USB or serial RS232 connection.

If "SAVE RESULT" option is selected the information of samples only except controls/calibrators, with test name, patient ID and date will be saved.

"SAVE RESULTS" option is used to save the details related to samples.

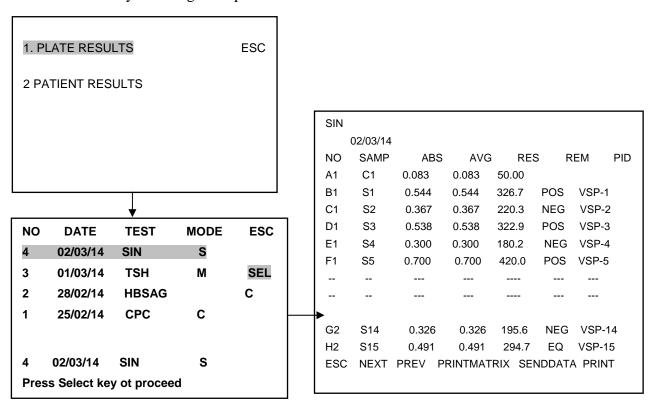
14. VIEW STORED DATA

The stored plate or stored results appear on the screen by selecting option "View Plate" in "MAIN MENU".



14.1. PLATE RESULT:

It displays the details of stored plate (last 10 plates) with date, test name and mode of operation in descending order. User can select any test to view its plate results by selecting this option.



[&]quot;Print Matrix" will print the details of entire plate in matrix format as explained earlier.

[&]quot;Print" will print only the data displayed on screen.

[&]quot;Send data" can be used to send the data from instrument to computer through USB or serial RS232 connection.

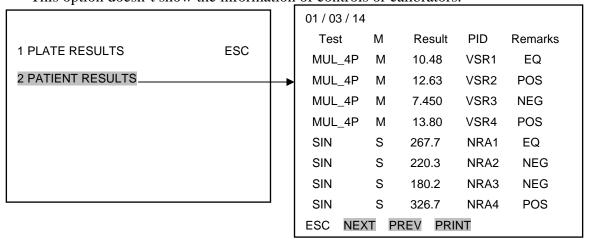
Note: User can directly view the details of Plate Results by accessing it through Plate Data option present on the Select Test screen.

Ton Present of		cicci i est sci ceiii
Select Test		ESC
1. HBSAg	С	
2. HCVAb	М	RUN / SEL
3. UPT	U	
4. TSH	М	PRINT
5. CPC	С	
6. PER_ABS	Р	NEXT
7. CRP	С	
8. KIN	K	PREV
9. SIN	S	
10. CP	С	DEL
		PLATE
		DATA

14.3. PATIENT RESULTS

It will show the details of all samples, saved in memory using option "SAVE RESULTS" in all different modes, as explain earlier. This option will display the data in table format as shown below. Test name, Mode of test operation, result of sample, PID and Remark will appear on the screen. The instrument has a memory to store 2500 sample results.

This option doesn't show the information of controls or calibrators.



[&]quot;PRINT" is used to print the details as available on the screen.

[&]quot;NEXT" and "PREV" options are used to browse through the pages so that one can view all the results one after the other.

NOTE:

1. When there is not enough memory the following message appears:

"Memory Left for samples- First Samples Deleted"

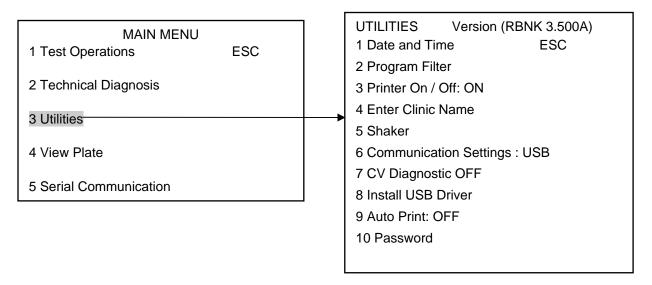
The instrument automatically deletes a number of samples that are stored in the beginning and then save the new samples at that location.

2. If a test is being deleted or edited then previously stored results of that particular test are displayed with their test mode as "X". But test name retained as it is.

01 / 03 / 14						
Test	М	Result	PID	Remarks		
MUL_4P	X	10.48	VSR1	EQ		
MUL_4P	X	12.63	VSR2	POS		
MUL_4P	X	7.450	VSR3	NEG		
MUL_4P	X	13.80	VSR4	POS		
SIN	S	267.7	NRA1	EQ		
SIN	S	220.3	NRA2	NEG		
SIN	S	180.2	NRA3	NEG		
SIN	S	326.7	NRA4	POS		
ESC NE	(T F	REV PRI	NT			

15. UTILITIES

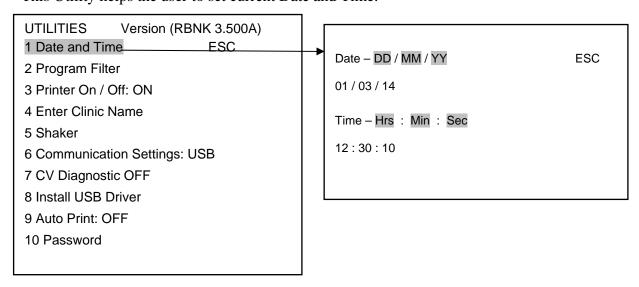
UTILITIES consists of 10 different functions which can be viewed as follows-



15.1. Date & Time Setting

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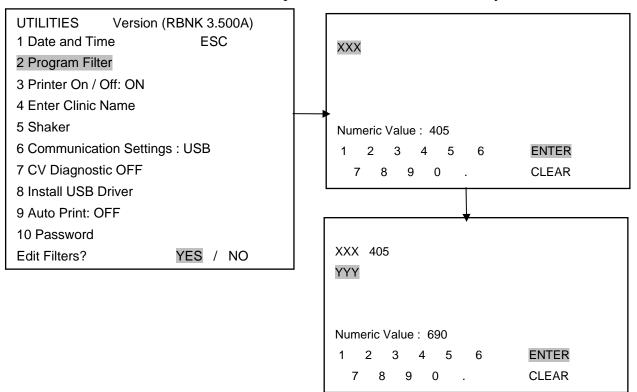
This Utility helps the user to set current Date and Time.



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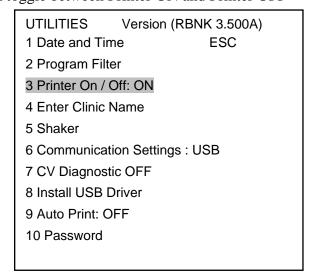
15.2. Program Filter

It consists of two editable filters and thus helps the user to edit the filters if any.



15.3. Printer On / Off setting:

Its a toggle between Printer ON and Printer OFF



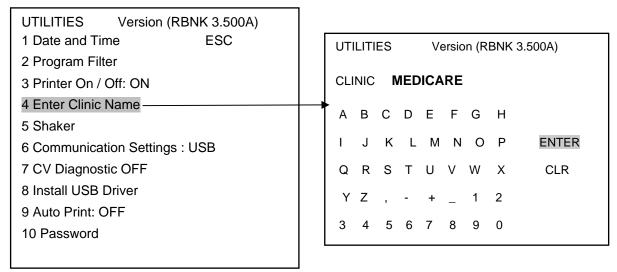
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15.4. Enter Clinic Name:

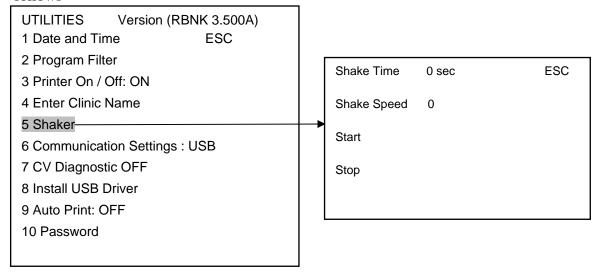
Enter your Clinic Name and select "ENTER". The character length is maximum 19 characters.



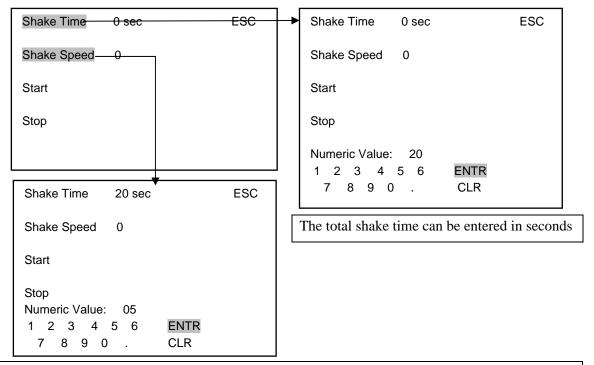
15.5. Shaker (Plate Shaking Mode)

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Shaker is used for shaking the plate before running any test. The Shaker screen is displayed as follows –



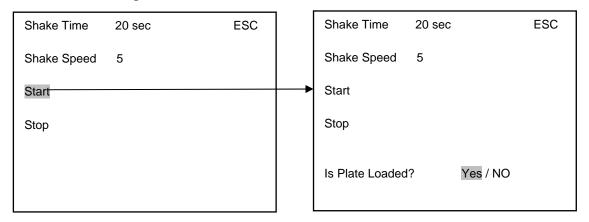
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Regarding the "Shake Speed", there are 10 types of speeds. You can choose any speed by entering numbers from 1 to 10. The shaking speed increases as the number increases.

	Respective
Speed	RPM
1	200
2	210
3	220
4	230
5	240
6	250
7	260
8	270
9	280
10	290

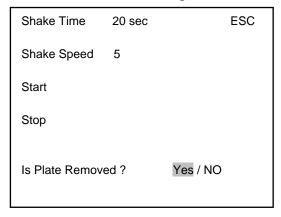
After entering shake time and shake speed, select Start option. When "Start" is selected, the tray will come out and on the screen you will obtain a message "Is plate loaded? Yes / No". Load the plate and select YES option.



After selecting 'YES' the tray will go inside and instrument will do the shaking of plate for the given time period with selected speed.

When the shaking is finished, the plate holder will come out and display a message-

"Is plate removed? Yes / No". Remove the plate and select 'YES' to end the process.



Similarly, to stop the Shaking process in between select "STOP" option present on the screen. After selecting STOP option it will display the message string – 'Is Plate Removed? YES / NO'. Select NO to terminate the ongoing process.

Note: 'HOME' key is also used for directly accessing the shaking mode (ie. SHAKER)

15.6. Communication Settings:

It is a toggle between USB and SERIAL communication. User can either switch to USB or Serial communication by connecting their respective cables.

UTILITIES Version (RBNK 3.500A)

1 Date and Time ESC

2 Program Filter

3 Printer On / Off: ON

4 Enter Clinic Name

5 Shaker

6 Communication Settings : USB

7 CV Diagnostic OFF

8 Install USB Driver

9 Auto Print: OFF

10 Password

UTILITIES Version (RBNK 3.500A)

1 Date and Time ESC

2 Program Filter

3 Printer On / Off: ON

4 Enter Clinic Name

5 Shaker

6 Communication Settings : SERIAL

7 CV Diagnostic OFF

8 Install USB Driver

9 Auto Print: OFF

10 Password

This setting is very important, whenever you want to transfer data from instrument to computer. You can transfer data either using USB or by Serial RS232 cable.

NOTE: The option 7. "CV Diagnostic OFF" is not for users. It is for factory use only. 15.8. Install USB Driver:

This option present in the Utilities helps the user to install the USB Drivers in their respective computers. Remember that before installing the USB drivers you must first switch on to the USB communication settings.

UTILITIES Version (RBNK 3.500A) UTILITIES Version (RBNK 3.500A) 1 Date and Time **ESC** 1 Date and Time **ESC** 2 Program Filter 2 Program Filter 3 Printer On / Off: ON 3 Printer On / Off: ON 4 Enter Clinic Name 4 Enter Clinic Name 5 Shaker 5 Shaker 6 Communication Settings: USB 6 Communication Settings: USB 7 CV Diagnostic OFF 7 CV Diagnostic OFF 8 Install USB Driver-8 Install USB Driver 9 Auto Print: OFF 9 Auto Print: OFF 10 Password 10 Password Install USB Drivers? YES / NO

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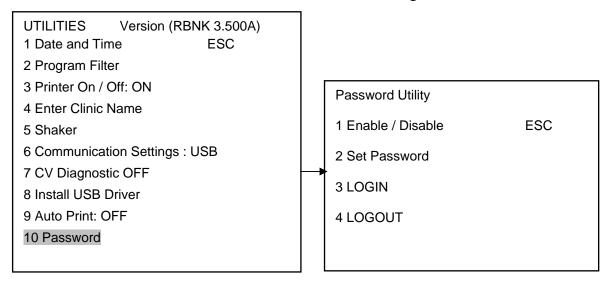
15.9. Auto Print: ON

It is a toggle key between Auto Print: ON and Auto Print: OFF.

After completing the running process it automatically takes the print of the result and its graph if any in order to maintain the record of the plate run in the form of hard copy. Auto Print is active in all modes excluding ABS mode. For Auto Print, user must set the printer ON otherwise it will display the error string "Disable printer YES / NO?"

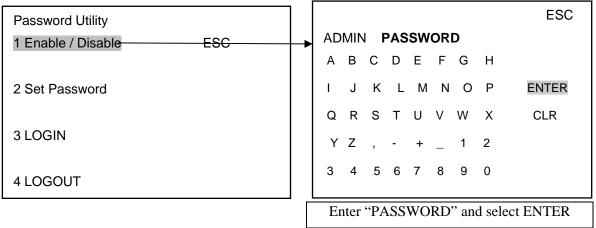
15.10. PASSWORD:

Select Password option in order to Set the Password so that one can't ADD, EDIT, DELETE and SEND / RECEIVE Test records without entering the valid Password.



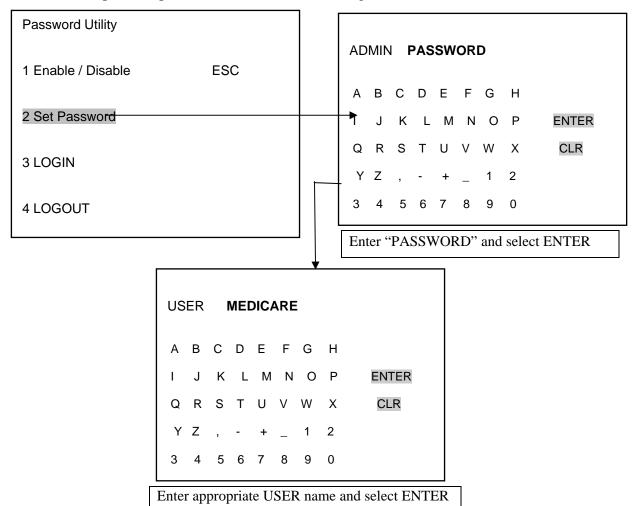
15.10.1. ENABLE / DISABLE:

Enable / Disable helps the user to set the Password or Remove the Password from the Password Utility. Enter Password with the help Alphanumeric screen which is displayed after selecting Enable / Disable option.



15.10.2. SET PASSWORD:

This option helps to set the PASSWORD along with the USER name.



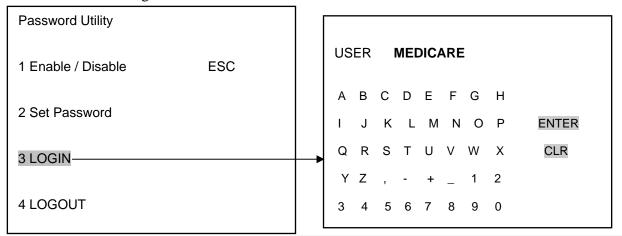
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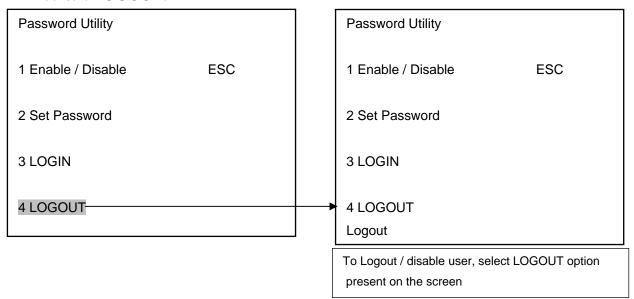
15.10.3. LOGIN:

After entering the Password user needs to select LOGIN.



To Login/ enable user, enter the USER name and select ENTER

15.10.4. LOGOUT:



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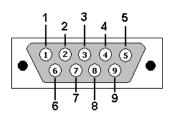
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16. SERIAL COMMUNICATION

The instrument is equipped with an RS232 serial port for PC configuration ie. User-computer interface. A cable is available to link the instrument to PC.

RS232 DB9 (EiA/TIA 574)



Communication will only start when both ends detect the presence of an active terminal or device.

RS232 port settings in a windows Operating system.

PORT SETTINGS

Bits per second: 9600

Data Bits : 8

Parity None : None

Stop Bits : 1

Flow control : None

There is an option present on the Main menu screen named as SERIAL Communication which is used for transferring data from instrument to the computer and also from

instrument to instrument.

	1	
MAIN MENU	ESC	
1. Test Operations		
2. Technical Diagnosis		
3. Utilities		
4. View Plate		
5. Serial communications		

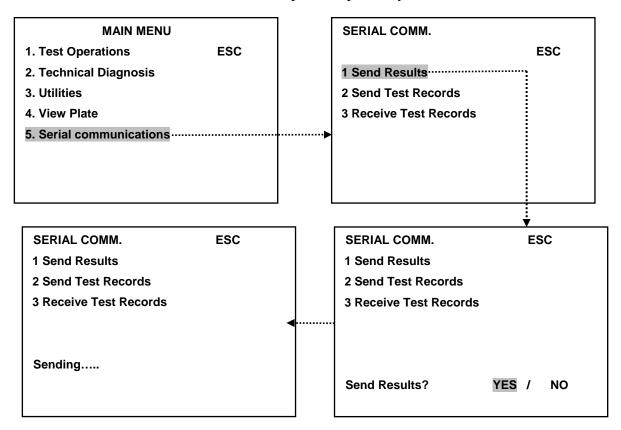
16.1. Send Results:

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SEND RESULTS helps the user to transfer all the Results stored in the instrument to the computer via Serial Communication.

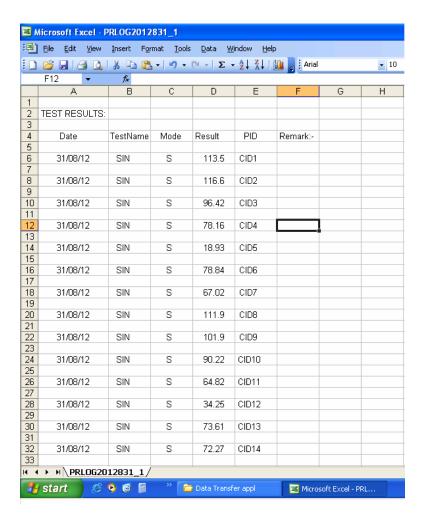
Results can be send either through USB or SERIAL communication.

Before Sending the Results check whether the Serial cable / USB cable is connected to both the ends of the instrument and the computer respectively.



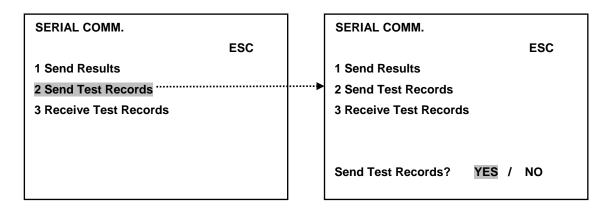
These Results are send through Application which are created in ".csv" format, Convert the corresponding format to Excel file which is created as shown below –

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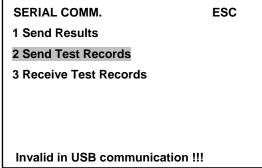


16.2. Send Test Records:

This option helps the user to send the Test Records created in one instrument to another instrument serially with the help of serial cable. And therefore one has to select serial communication in Utilities.

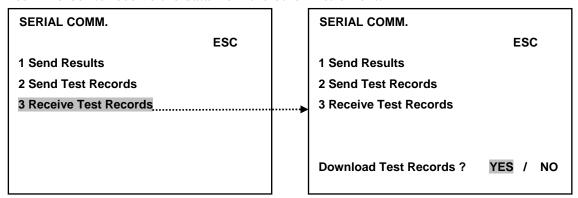


Suppose by default if Serial Communication is set to USB then it will display following screen with msg string.



16.3. Receive Test Records:

This option is used for receiving the Test Records from one instrument to another. On selecting "Receive Test Records"; it will display the string – Download Test Records? Yes / No. Select "Yes" in order to receive the data from the other instrument.



Note: 1. User must first restart the instrument before sending the data from one instrument to another.

- 2. Remember that while transferring Test Records from one instrument to another one must first select "Receive Test Records" and then select
 - "Send Test Records" in order to send the data from one instrument to another.

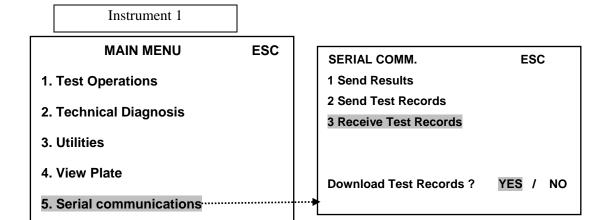
For instance, let us take an example which will show how the Test Records are transferred from instrument to instrument.

Let "Instrument 1" resemble the screen of the Instrument which will receive the Test Records from other instrument. And "Instrument 2" resemble the screen of the Instrument which will send the Test Records to other instrument.

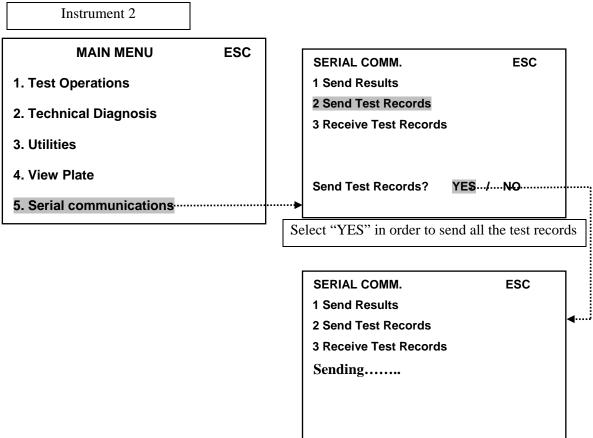
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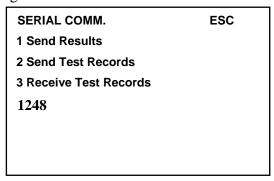
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Now for Sending Test Records switch on to Instrument 2.



And similarly, Instrument 1 will display the following screen which denotes that the instrument is downloading the Test Records.



After completing the process of transferring the data, one must restart both the instrument and check for the data transferred between the instruments

In this way, one can transfer Test Records from instrument to instrument.

3. User can Send and Receive the Test Records only through serial cable and therefore one has to set the **Serial Communication: SERIAL** in Utilities.

If Serial Communication is set to USB, then it will display following screen –

SERIAL COMM. ESC

1 Send Results
2 Send Test Records
3 Receive Test Records

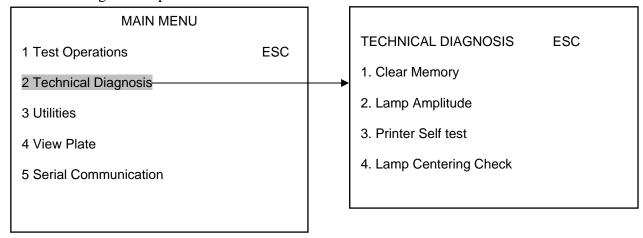
Invalid in USB communication !!!

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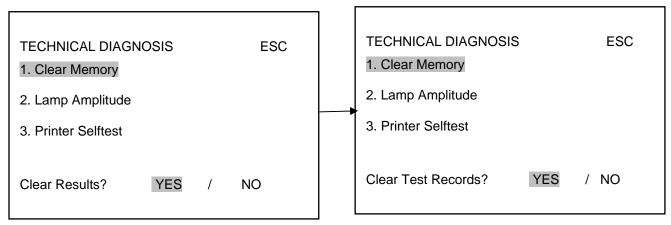
17. TECHNICAL DIAGNOSIS

Technical Diagnosis is present in "Main Menu".



17.1. Clear Memory

This option is used to clear entire saved Test Records and Patient Results along with saved plates. The "Test Records" are the different kind of programmed test that are made in different modes of operation and saved in instrument program memory.



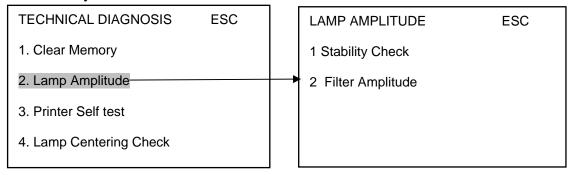
Select "Clear Memory", it will display the message string "Clear Results? Yes / No". Select "Yes" in order to clear the Results stored in the memory. This will only clear the Patient Results and Plate Results stored in the memory by displaying the message "Clearing Memory...." Similarly, another message string "Clear Test Records? Yes /No" will be displayed on the screen. These records are the Tests created in the particular modes. Select "Yes" to delete the Test Records stored in the memory.

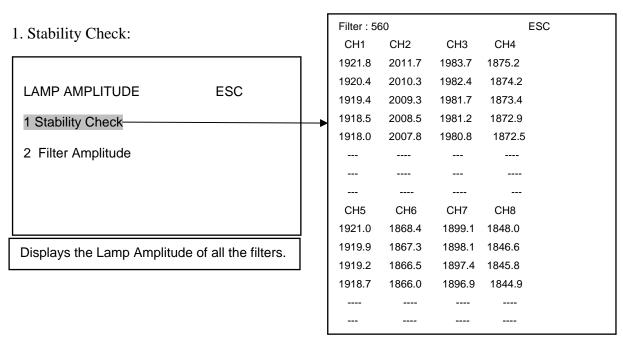
17.2. Lamp Amplitude

This option is used to check the light gain of filters used in the instrument. There are 8- channels used of same type. This option shows the gain of each channel filter in table format. In the

instrument the range of amplitude is from 600.00 to 2450.00. If the amplitude goes below 600.00 for any channel, the message "Amp –Low" will appear on the screen for that particular channel if the amplitude goes more than 2490.00, than the over range saturation voltage figure of 2500.00 will be passed.

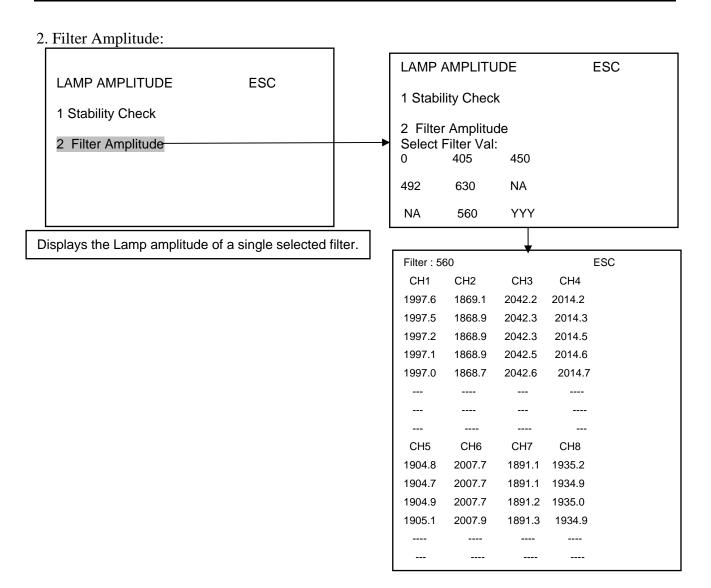
The gains of filters are set within a required range. When you select this option, the lamps will turn ON, tray holder plate will comes out and the instrument will start showing amplitudes (gains) of all filters one by one.





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17.3. Printer Self test

It is used to check the printing of thermal printer. Is it printing perfectly or not? When you select this, it will print first two lines of Technical Diagnosis Screen.

17.4. Lamp Centering Check:

NOTE: "Lamp Centering Check" is not for users. It is only for service purpose.

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18. Trouble Shooting

	CAUSE /CORRECTIVE ACTION
1) Printer disabled Disable Printer YES / NO?	You will get this message, if paper is not loaded properly or lever is not at correct position. Check all possibilities. Also check ON LINE and FEED LED glowing or not and when you switch 'ON' the instrument check paper is moving forward or not. If LEDs are not glowing and paper is not moving forward contact service angineer.
2) "Check Light Path!!! CH x" Where 'x' is any channel number X = 1/2/3/4/5/6/7/8	You can get this message in any mode of operation. Before reading absorbance, instrument is checking the filter reference voltages of all 8 channels. If filter voltage of any channel is less than minimum required voltage, it will display a message "Check Light Path!!! CH x". Here 'x' is channel numbers having reference voltage less than minimum required. For ex. If reference voltage of channel 3 is less the message will be displayed "Check Light Path!!! CH 3". It will indicate all channel numbers having less reference voltage, like "Check Light Path!!! CH 1 3 6" In such a case, there is a possibility of filter gain of that channel is reduced or intensity of lamp of that channel has become poor, so contact factory engineer.
3) Invalid Assay	If in the Cut Off and Multi standard mode the controls and standards are not ok then this error message will appear.
4) Memory Full	If Number of saved tests exceeds the memory limit of 250 tests then delete the unwanted tests and save the test.
	Using data receiving application on computer, 1) If you have not connected the data cable (USB or Serial) correctly, you will get this message. 2) If you have selected 'Communication Setting' (ref. 14.5), USB on instrument, and you have selected a

	'Serial' communication on computer data receiving
	application, you will get this message. In such a case
5) "Check USB Application on	select 'USB' communication, on computer and select
Computer	'YES' key to transfer data.
Do you want to continue?	To avoid this message, connect proper data cable, select
YES / NO"	the same communication medium (USB or Serial), on
	computer data receiving application, which you have
	selected on instrument 'Communication Setting'.
	Instrument will display this message, if there is problem
	with MOC sensor PCB or with filter tray stepper motor.
	The MOC sensors are used to detect the position of filter
6) Filter Movement Error!!!	tray. These two sensors are mounted on bottom of the
OR	mechanism. One detects the home position and second
Filter Index Error!!!	detects the each filter position of filter tray. In such a
	condition we need to check the connection to these sensor
	and also the connection of stepper motor, which is used to
	move filter tray.
	Instrument will display this message, if there is problem
	with MOC sensor PCB or with plate carrier stepper motor.
	The MOC sensors are used to detect the position of plate
7) Plate Movement Error!!!	carrier. These two sensors are mounted on top of the
OR	mechanism. One detects the home position and second
Plate Index Error!!!	detects the each strip position of plate carrier. In such a
	condition we need to check the connection to these sensor
	and also the connection of stepper motor, which is used to
	move plate carrier.

19. DECONTAMINATION

19.1. Decontamination Procedure

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method of decontaminating the instrument before packaging and shipment.

19.2. Purpose of Decontamination

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

19.3. General Considerations

- Any laboratory instrument that has been used for clinical analysis is considered a
 biohazard and should be decontaminated prior to handling. Intact skin is generally
 considered an effective barrier against infectious Organisms; however, small abrasions
 and cuts may not be always being visible. Prophylactic gloves must be worn when
 handling instruments that have not been decontaminated. Gloved hands should be
 considered contaminated at all times and must be kept away from eyes, mouth and nose
 at all times.
- Mucous membranes are considered prime entry routes for infectious agents. Wear eye
 protection and a surgical mask when there is a possibility of aerosols.
- Eating and drinking while decontaminating instruments is not advisable.

19.4. Procedure

- A solution of .5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.
- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution.
 Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.
- Reassemble the unit and discard the used gloves and towels.

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20. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your cooperation. Customer _____ Contact_____ Position_____ Dept Tel: _____ Fax:_____ Country __ Post Code Model No. Serial No. Accessories Returned Date of Purchase (if known) Complaint Has the equipment been exposed to any of the following: (*delete as applicable) a) Blood, body fluids, pathological specimens *YES/NO If YES, please specify_____ b) Other Biohazard *YES/NO If YES, Please specify