# readwell Touch

# **ELISA Plate Analyser**

# **User Manual**

**Version - 3.308** 



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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, etc. 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 fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

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

# 1.3. Disposal instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

### 1.4. Contacts:

## Manufacturer:

ROBONIK (INDIA) PVT LTD A-374, TTC, MIDC Industrial Area, MAHAPE, NAVI MUMBAI - 400 710 INDIA

Tel: +91-22-67829700, Fax: +91-22-67829701

Email: sales@robonikindia.com Website: www.robonikindia.com

#### **European Authorized Representative**

Obelis s.a 34, Av. de Tervuren, bte 44 B-1040 Brussels, BELGIUM

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## GENERAL SAFETY WARNINGS

# 2.1. Danger - warnings symbols:



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



This is a symbol of 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 makes use of chemical reagents and other dangerous (Corrosive, irritant, or harmful) CHEMICAL SUBSTANCES, which can cause damage to people or materials. When this label is found, pay attention to the manufacturer's recommendations.



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 heeded



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



This symbol indicates a Protective Earth or Ground terminal.

### 2.2. Use of the Instrument:

- ➤ The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules, by qualified personnel.
- > This manual contains instructions for operation by qualified personel.
- ➤ 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).
- ➤ A qualified technician is entitled to maintain and fix the instrument, according to the instructions given, using the original spare parts. Maintain room temperature and Humidity as specified in the manual.
- > The instrument has to be used as described in this manual. If it is not use the protection provided by the instrument may be impaired.
- > Alterations to the instrument are prohibited. The user is liable for any improper modification to the instrument, and for the deriving consequences.
- > Should the instrument need extraordinary maintenance, contact MANUFACTURER service or authorized service center. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance.
- > This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.



- <u>Warning</u>: 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."
- 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 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 as well as a round bottom well 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 volts). 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 detailed results available on screen.

Following are the other special features of **readwell TOUCH**:

- Option of Lamp saving mode.
- Selection of both primary and secondary filters.
- o Latest technology with battery back up for 250 tests with QC, more than 2500 result.
- o Robust in built 52-column thermal printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- o Alphanumeric Patients ID entry.
- o Editing of saved tests.
- Human machine user interface: Touch panel, Keypad
- o Multi-standard curve up to 12 standard calibrations with one blank optional.
- Access to test by touch of key.
- o Capability to connect to 80-column printer for direct report printout.
- o Blank is optional.
- Setting of the Date and Time.
- o Capable of storing, deleting and recalling tests.
- o Multiple calibrator modes.
- o Selection of duplicates for both calibrators and samples.
- o Extensive software for cut off mode.
- Selection of Positive, Equivocal, Negative cut-off.
- Several pre-programmed calculation modes help to facilitate data processing of enzyme immunoassays. These are menu driven modes for simple and error free operations.
  - ✓ ABSORBANCE MODE.
  - ✓ CUT-OFF MODE.
  - ✓ MULTISTANDARD MODE.
  - ✓ SINGLE STANDARD MODE.
  - ✓ % ABSORBANCE MODE.
  - ✓ UPTAKE
  - ✓ KINETIC

# 3.3. Technical Specification of readwell TOUCH

Human Machine Interface	TOUCH PANEL / KEYPAD
Linear measurement range	0.000 to 3.500 Absorbance Units (A).
Photometric Accuracy	± 2% or 0.007 whichever is higher, from 0 to 1.5 A
	± 3% from 1.5 A to 3.5 A
Drift	<0.005 A/hr
Photometric Linearity	2.5 A
Optical measurement	8 Channel
Filters	
Type of filter	Narrow band Interference
Wave Length	405nm, 450nm, 492nm, 630nm, & Four Optional
Half Bandwidth	10nm ± 2nm
Selection	Automatic by Stepper Motor.
Light Source	Tungsten halogen lamp, 20 Watts
Display	6" Graphics LCD, Negative Blue, STN
Curve Plotting	Graphical Representation on Printer
Plate Carrier Movement	Precisely through the stepper motor
Printer	Built in Thermal Printer 52 columns
Memory	Battery back up for 250 tests and more than 2500
······································	results.
Analysis Mode	Absorbance (Normal & Differential)
	Cut - off
	Multi - Standard
	% Absorbance
	Single Standard
	Uptake
	Kinetic
Connectivity / RS232 Serial Port/USB	9600 baud, 8 data, 1 stop, no parity bits / USB
Power	
Wattage	75 Watts
Voltage	115 - 230 Volts ± 10%, 50 / 60 Hz.
Operation Position	On horizontal flat, rigid and vibration free surface
Operating Conditions	
Temperature	From + 18° C to 35° C
Relative Humidity	Up to 80%
Storage Conditions	
Temperature	From - 10 <sup>o</sup> C to 40 <sup>o</sup> C
Relative Humidity	Up to 80%
Enclosure	ABS Fire Retardant
C! /\	ADS FIFE RELATIONIL
Size (cm)	36 x 36 x 22 (lxbxh)

# 4. PACKING, TRANSPORT AND STORAGE

## 4.1. General Warnings:

Instrument has to be decontaminated before packing for transportation.

# 4.2. Packing:

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

To pack the instrument follows the instructions below:

- Decontaminate the instrument as explained on decontamination chapter of this manual
- 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)
- Mark the package 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 -  $10^{\circ}$ C and  $40^{\circ}$ C.

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## 5. INSTRUMENT DESCRIPTION

# 5.1. Instrument Working Principle:

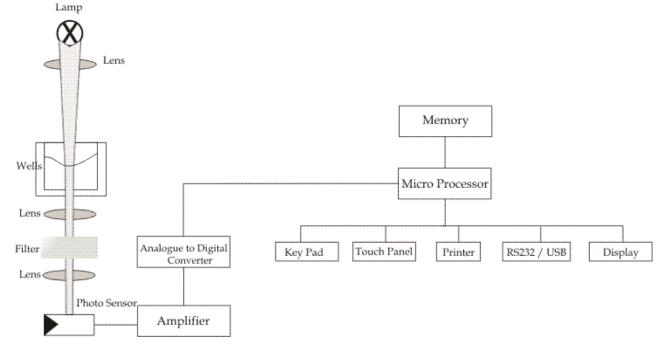
- Switch on and program the instrument.
- Place the plate firmly onto the carriage.
- Start the test, the plate will be conveyed inside and strip is placed precisely below the optical path. The measurement is carried out step by step.
- At the end of the cycle the results can be printed or user can save 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.

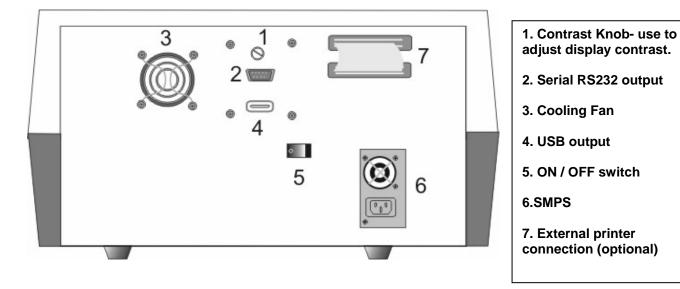


# 5.2. Perspective view

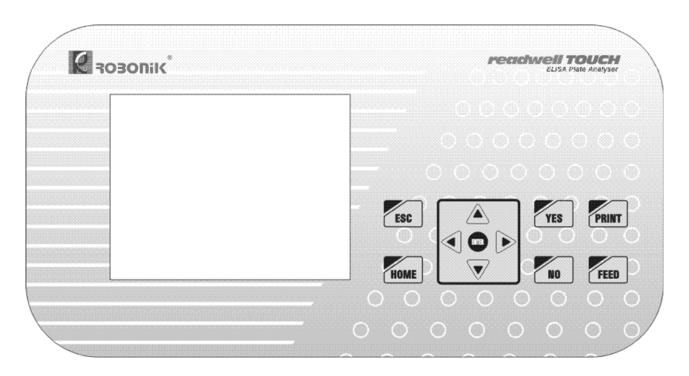
## Front View:



# 5.3. Rear View:



# 5.4. 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 to forward the paper in thermal printer by one print line.
- ▲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 to bring plate carrier at home position. Home key function is disabled.

## 6. INSTALLATION PROCEDURE AND VERIFICATION CRITERIA

# 6.1. Unpacking Instructions:

Check accessories as per packing list.

Kindly store all packing 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 it from direct sunshine.

# 6.3. Power Supply Requirements:

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA, and UL marked.

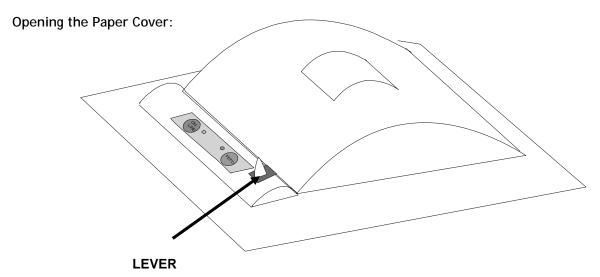
115 - 230 Volts ± 10%, 50-60 Hz

# 6.4. Protective Grounding:

Warning: Please make sure that electrical power source is properly grounded.

## 6.5. Printer:

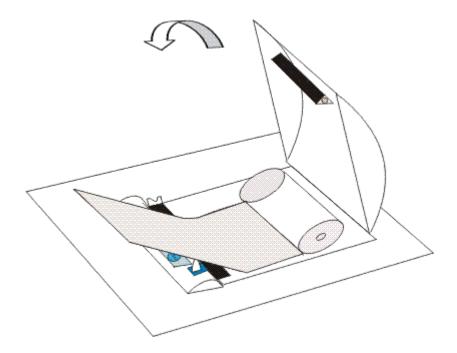
Readwell touch, ELISA Analyser is equipped with a built in 52 columns easy load thermal printer. Procedure to load the paper is as follows:



- 1) Slide the LEVER towards back of the printer to open lock of the PAPER COVER
- 2) Lightly push up on the front of the paper cover (marked) with your thumb and rotate it towards the back of the printer.

Closing the paper cover:

Close the paper cover and push down on it to lock it into place till you get locking sound.



- 1) Open the paper cover.
- 2) Remove the paper roller from the slot and place the paper roll over it as shown.
- 3) Place back the paper roller with paper into the slot provided and close the paper cover as described before.
- 4) Keep pressing 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 about to finish, red lines appear on both sides of the paper.

# 6.6. Start up Instructions:

1. Switch on the instrument.

2. The instrument initializes all the parameters internally, and carries out a power on self-test and then displays the following screens, and a message will get display "Please wait system initializing."

#### readwell TOUCH

Robonik (India) Pvt. Ltd., Plot No. A-374, TTC, MIDC Mahape Navi Mumbai – 400 710. Maharashtra, (INDIA)

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The instrument will print the model name "READWELL TOUCH", VERSION NUMBER, CLINIC NAME CURRENT DATE WITH TIME.

READWELL	Date	
Clinic name	MENU	
	ct Test	SEL
1. HBSAG	6. HIV	PRNT
2. HCV	7. IGM	NEXT
3. T3	8. T4	PREV
4. TSH		
5. HIV		DEL

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.

"DEL": Deletes the selected test.

If the number of tests is more than 10, "NEXT "and "PREV can be used for browsing through the list pages

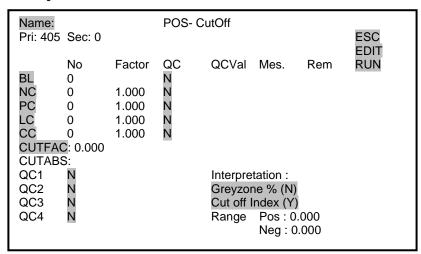
"PRINT": For printing the test screen.

"MENU" used to select Main menu screen.

## 6.7. Touch Panel Check.

**readwell TOUCH** provides a *Touch sensitive LCD panel* and a *KEYPAD* for easy user interface. The Menus are displayed; the text of the parameter forms the TOUCH ZONE.

Touch screen Layout



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, and rest of the "Touch Zone" is deactivated.

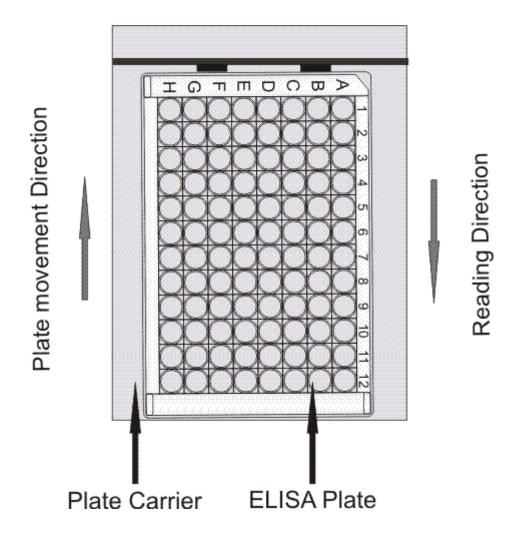
For Example: - To activate the selection.

- To enter the primary filter value, 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 onscreen 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.

# 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 the 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:

Control and sample pipetting procedure in case of cut off:

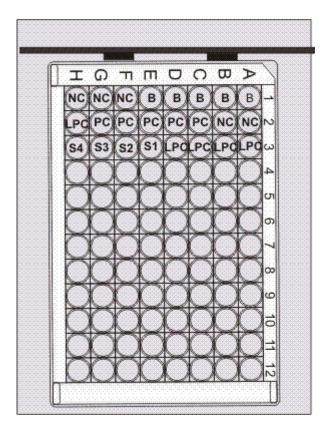
Maximum number of Blanks = 5

Maximum number of Controls:

- 1. Negative Control = 05
- 2. Positive Control = 05
- 3. Cut of control = 05
- 4. Low Positive Control =05

Total number of 20 controls can be run in any combination.

Pipetting sequence should be as shown below,



# 6.10. Readings Check:

Checking of readings should be done through controls reading, that should be 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.)

## 7. PRECAUTIONS



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



Always check for proper grounding, before installation. Never operate the instrument with ground wire removed.

- 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.
- Use a clean plate and follow the instructions for blanking and standardizing. Do not read any wells containing bubbles or dust particles.
- 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.
- Monitoring of the printed values or displayed values during operation may help detect an error in the making.
- Check the linearity and calibration of the instrument regularly against some standard reference.
- 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.



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

# 8. PROGRAMMING MODES

# 8.1. Absorbance Mode:

In this mode instrument gives you the only absorbances of all wells of plates which contains controls / calibrators and samples.

Programming a new test:

## 1. Select "Test Operation"

1 Test Operations	ESC
2 Technical Diagnosis	
3 Utilities	
4 View Plate	
5 Serial Communication	

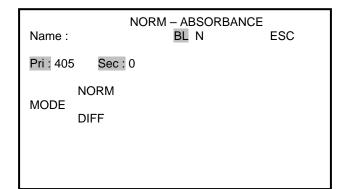
### 2. Select "Add New Test"

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

## 3. Select mode of operation "Absorbance" in "Add new test"

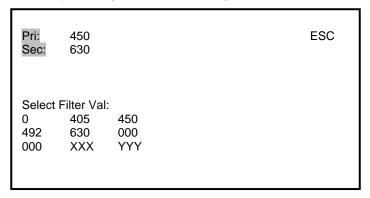
Se 1> Absorbance	lect Test Mode 0	
2> Single Standard	0	
3> Cut off	0	
4> Multi Standard	0	
5> Percent Absorbance	0	
6> Uptake	0	
7> Kinetic	0	

## 4. Enter Test Name

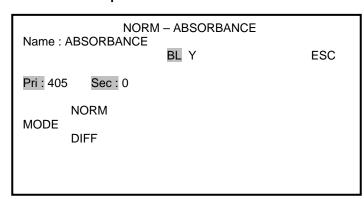


NI-				NO	RM -	- AB	SORE	BANCE		
iva	me:	AB	S 45	0						
A I Q Y 3	B J R Z 4	K	L T -		F N V -8		H P X 2 0		ENTER CLEAR	

5. Select primary and secondary filter

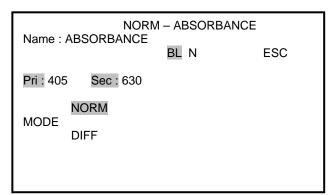


6. If Blank is required select "BL".

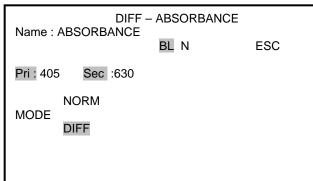


If you select "BL Y", it will read first well of first strip 'A1' as a blank and subtract the absorbance of blank well from all other well's absorbance.

- 7. In absorbance mode there are two modes of operations
  - a) Normal Absorbance Mode: Instrument gives the absorbance of each and every well. Select touch zone "NORM".
  - b) 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".
- 1) In Normal Mode



2) In Differential Mode



## 9 Example Print-out obtained From **readwell TOUCH**

### NORM-ABSORBANCE

Name :	HCV										
			BL	Ν							
Pri : 45 HCV, 2 A	0 1/07/08,	Sec : 6	30								
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.

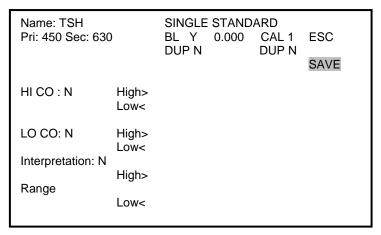
# 8.2. Single Standard

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 0.0.

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 absorbances 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.



(Entry of all the parameter is similar to Multi standard mode (Please refer Multistandard 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 mean of the negative controls and the mean of the positive control, Cut-off controls, and Low positive is also calculated.

# **Programming a New Test:**

1. 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	

2. Select mode of operation "Cut-Off" in "Add new test"

	Select Test Mode	
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	

3. Entry of test name Select touch Zone "Name:"

Name: Pri: 450	) Sec: 0		POS- C	CutOff			ESC
BL NC PC LC CC CUTFA	No 0 0 0 0 0 0 C: 0.000	1.000 1.000 1.000 1.000	QC N N N N	QCVal	Mes.	Rem	SAVE
QC1 QC2 QC3 QC4	N N N N			•	etation : ne % (N) Index (Y) Pos : 0 Neg : 0	.000	

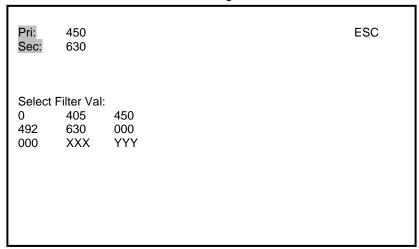
After selecting the touching the Name Zone, Alphanumerical characters will come in the screen as shown below. Enter the name of the test by selecting the individual characters one by one. After selecting all the characters select Enter option in touch screen for confirmation of test Name.

Naı	me:	НВ	HBSAG		POS- CutOff			
A I Q Y 3	B J R Z 4	CKS, 5	D L T - 6	E M U + 7	F N V -8	G O W 1 9	H P X 2 0	ENTER CLEAR

4. Selection of Primary and secondary filters. Select zone "Pri:" on the touch screen

	Name: HBSAG Pri: 450 Sec: 630				POS- CutOff		
BL NC PC LC CC CUTFA	No 0 0 0 0 0 AC: 0.000	1.000 1.000 1.000 1.000	QC N N N N	QCVal	Mes.	Rem	SAVE
QC1 QC2 QC3 QC4	N N			•	etation : ne % (N) Index (Y Pos : 0 Neg : 0	) .000	

After selecting the "Pri:" zone below screen will appear in the display. Select the filter required by selecting the filter from Select filter value region.



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

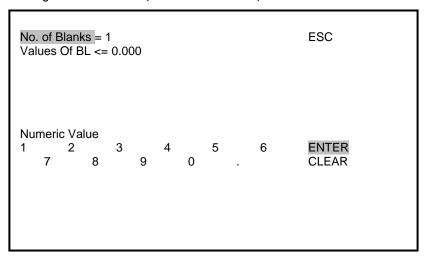
	Name: HBSAG Pri: 450 Sec: 630				POS- CutOff		
BL NC PC LC CC CUTFA	No 0 0 0 0 0 .C: 0.000	1.000 1.000 1.000 1.000	QC N N N N N	QCVal	Mes.	Rem	SAVE
QC1 QC2 QC3 QC4	N N N N			-	e % (N)	.000	

6. Entry of Blank and Blank QC values

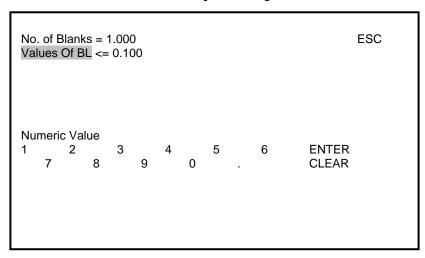
Select "BL" to enter blank details. (Blank has to be always put in first wells if selected)

	HBSAG 0 Sec: 6			POS- C	POS- CutOff		
BL NC PC LC CC CUTFA	No 0 0 0 0 0 AC: 0.000	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal 0.000 0.000 0.000	Mes. 0.000 0.000 0.000	Rem	SAVE
QC1 QC2 QC3 QC4	N N N N			•	etation : ne % (N) Index (Y) Pos : 0 Neg : 0	.000	

7. After selecting "BL", below screen will come in the display, enter total number of blanks by selecting No. of Blanks. (Maximum 5 blank).



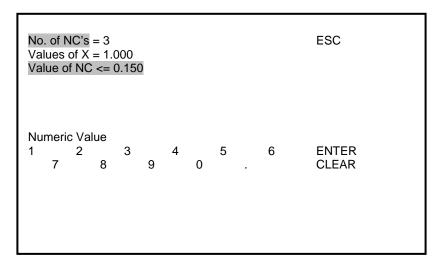
8. Enter the QC value of the blank by selecting the touch Zone "Values of BL <="



9. Entry of Negative control and its QC values Select touch Zone "NC".

	HBSAG Sec: 6	30		POS- CutOff	ESC
BL NC PC LC CC CUTFA	No 1 0 0 0 0 0 AC: 0.000	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal Mes. Rem 0.100	SAVE
QC1 QC2 QC3 QC4	N N N N N			Interpretation : Greyzone % (N) Cut off Index (Y) Range Pos : 0.000 Neg : 0.000	

10. Enter no of Negative control 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".



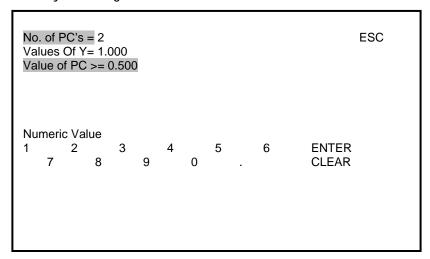
11. After the entry of no of NCs Select ESC. The below screen will come in the display.

	HBSAG 0 Sec: 6			POS- CutC	POS- CutOff		
BL NC PC LC CC CUTFA	No 1 3 0 0 0 0 AC: 0.000	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal M 0.100 0.150	es. Rem	SAVE	
QC1 QC2 QC3 QC4	N N N N			0	% (N)		

- 12. Entry of positive Controls (PC).
  - Select touch Zone "PC".

	: HBSAG 50 Sec: 6			POS- CutOff ESC
	No 1 3 0 0 0 7AC: 0.00	1.000 1.000 1.000 1.000 0	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150
QC1 QC2 QC3 QC4	N N N N N			Interpretation : Greyzone % (N) Cut off Index (Y) Range Pos : 0.000 Neg : 0.000

13. After selecting PC below screen will come in 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".



14. After entering the details of PCs escape from the screen by selecting "ESC". Below screen will come on the display.

	HBSAG 0 Sec: 6			POS- CutOff ESC	
BL NC PC LC CC CUTF/	No 1 3 2 0 0 AC: 0.000	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150 0.500	
QC1 QC2 QC3 QC4	N N N N			Interpretation : Greyzone % (N) Cut off Index (Y) Range Pos : 0.000 Neg : 0.000	

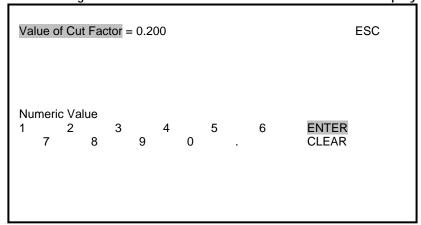
{NOTE: Same way you can enter values for LC (lower positive controls) and CC (Cot of controls).}

- 15. Entry of Cut off Factor:
  - Select touch Zone "CUT FAC"

	HBSAG 0 Sec: 6			POS- CutOff	ESC
BL NC PC LC CC CUTF/	No 1 3 2 0 0 C: 0.000	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal Mes. F 0.100 0.150 0.500	Rem SAVE
QC1 QC2 QC3 QC4	N N N N			Interpretation: Greyzone % (N) Cut off Index (Y) Range Pos: 0.00 Neg: 0.00	

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After selecting the "CUTFAC" below screen will come in the display.



- 16. Entry of Cut off absorbance equation:
  - Select touch Zone "CUTABS"

	HBSAG 0 Sec: 6	30		POS- CutOff	ESC	
BL NC PC LC CC CUTFA	No 1 3 2 0 0 AC: 0.200	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal Mes. 0.100 0.150 0.500	Rem	SAVE
QC1 QC2 QC3 QC4	N N N N			Interpretation : Greyzone % (N Cut off Index (N Range Pos : Neg :	Ϋ́)	

After selecting the "CUTABS" below screen will come in the display. Enter the equation as given in the reagent manual.

```
Here, NC = Mean of NCs * Factor X,
PC = Mean of PCs * Factor Y,
LC = Mean of LCs * Factor W,
CC = Mean of CCs * Factor Z,
CF = Cut off factor,
Sqrt = square root,
Lg = LOG, ALg = Anti LOG,
Ln = Natural LOG, Aln = Anti Natural LOG,
Abs. = any absolute value.
```

For Example,

- A) For equation  $\underline{\text{CUT OFF ABS}} = (0.45 * \text{NC}) + (0.35 * \text{PC}) + 0.10$ , the formulae can be enter 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 select from the screen).
- 2.In second method the formulae can be enter as  $\underline{\text{CUT ABS}} = \underline{\text{NC}} + \underline{\text{PC}} + \underline{\text{CF}}$ . (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 mention above.

B) If  $\underline{\text{'CUTOFF ABS'}} = (NC + PC) / 6$ . This can be entered as it is CUTABS = (NC + PC) / 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.
```

17. QC1, QC2, QC3 & QC4. can be used for any QC Checking of the test provided in reagent manual. For example some kit manufacture 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 become 'Y', as shown in screen below. By selecting touch zone 'QC1' you enter QC equation.

Name: Pri: 450		-		POS- C	POS- CutOff			
F11. 450	J Sec.	030					ESC	
BL NC PC LC CC	No 1 3 2 0 0	1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal 0.100 0.150 0.500	Mes.	Rem	SAVE	
			(0 35 <sup>3</sup>	* PC) + 0.1	0			
QC1 > QC2 QC3 QC4		.5 .10)	(3.30	İnterpre Greyzoi	tation : ne % (N) Index (Y	) ).000		

Enter equation of QC and value of QC check, Select touch zone 'QC1 Value' and 'QC1 equat'.

```
Enter QC Value and Equation:
QC1 Value: 0.500
QC1 Equat:

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

```
Enter QC Value and Equation:
                                          ESC
QC1 Value: 0.000
QC1 Equat
QC Equat: PC - NC
NC
       PC
               LC
                       CC
                               SA
                                          ENTER
                               %
                                          CLEAR
               3
1
        2
                       4
                               5
7
                       0
        8
               9
                               ALn
                                       Abs
Sqrt
       Log
               ALog
                       Ln
```

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

#### \*NOTE:

- 1) On screen it is mention that "QC1 > Y", it is not necessary in any reagent manual they always mention QC value should be greater than some constant value. There may be chance that they will mention QC value should be less than some constant value. In such a case you can change the symbol from "QC1 > Y" to "QC1 < Y", only by selecting a symbol of comparison.
- 2) 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.)

## 18. Interpretation of samples:

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

## 18.1. Interpretation by GREYZONE percentage:

Select touch zone 'Greyzone % (N)',

	HBSAG 0 Sec: 6			POS- CutOff ESC
	No 1 3 2 0 0 AC: 0.200	1.000 1.000 1.000 1.000 0	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150 0.500
00.7	N N N N			Interpretation : Greyzone % (N) Cut off Index (Y) Range Pos : 0.000 Neg : 0.000

Enter Greyzone percentage value.

Enter % Value : % Value = 10.00				ESC
Numeric Value 1 2 3 7 8	9	5 0 .	6	ENTER CLEAR

If you enter 'Greyzone' percentage '10.00', instrument will show you the same as shown in screen. It makes the 'Cutoff Index Range' option 'NO'. This means when you are using a 'Greyzone' option the 'Cut off Index Range' option will not work.

Name:	CPC Sec: 6	20		POS- CutOff ESC
P11. 450	J Sec. 6	30		ESC
BL NC PC LC CC CUTFA	No 1 3 2 0 0 0 AC: 0.200	1.000 1.000 1.000 1.000 1.000	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150 0.500
QC1 > QC2 QC3 QC4		PC + CF 00		Interpretation : Greyzone % (Y) 10.00 Cut off Index (N) Range

In case of 'Greyzone', it gives the 'Positive' remarks to sample absorbance greater than greyzone area of cutoff absorbance and a 'Negative' remarks to sample absorbances less than greyzone area of cutoff absorbance. The sample absorbances lying in greyzone area get remarks 'Equivocal' = 'EQ'.

(\*NOTE: If you do not select any option for interpretation of sample results, the instrument will take 'Cutoff Absorbance' as a reference. It will give 'Positive' remark to sample absorbance greater than cutoff and 'Negative' to sample absorbance less than cutoff.)

## 18.2. Interpretation by 'Cutoff Index Range":

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

Name: Pri: 45	CPC 0 Sec: 6	630		POS- CutOff ESC
	No 1 3 2 0 0 AC: 0.200	-	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150 0.500
	SS: NC 4 Y 0.5 N N N	+ PC + CF 500		Interpretation : Greyzone % (N) Cut off Index (Y) Range Pos : 0.000 Neg : 0.000

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.)

RESULT RANGE: POSITIVE >= 1.000 NEGATIVE <= 0.900  ESC								
Nume 1 7	eric Value 2 8	e 3 9	4 0	5 .	6	ENTER CLEAR		

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'.

Name		20		POS- CutOff
Pri: 45	60 Sec: 6	30		ESC
	No 1 3 2 0 0 AC: 0.200	Factor  1.000 1.000 1.000 1.000 0 - PC + CF	QC Y Y Y N N	QCVal Mes. Rem SAVE 0.100 0.150 0.500
	> Y 0.5 N N N			Interpretation: Greyzone % (N) Cut off Index (Y) Range Pos: 1.000 Neg: 0.900

For example:

If you enter POS >= 1.0 and NEG <=0.9.

Then, the sample will 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.

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

Name: HBSAG Pri: 450 Sec: 630			POS-C	ESC		
	No 1 3 2 0 0 0 C: 0.200		QC Y Y Y N N	QCVal Me 0.100 0.150 0.500	es. Rem	SAVE
	Y 0.50 N N N			Interpretatio Greyzone % Cut off Inde Range	6 (Y) 10.00	

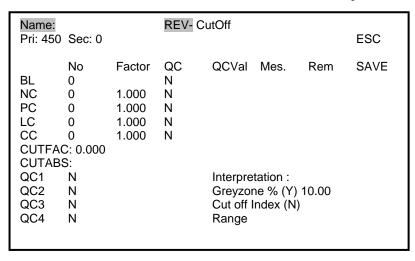
## 10 Example Print-out obtained From **readwell TOUCH**

POS-CutOff

Name : HCV Pri : 450 Sec : 630 NO Factor QC					QCVal N	Aeas.						
	BL NC PC LC CC	1 2 2 0	0.000 0.100 1.000 1.000	Y Y N N	0.100 0.150 0.500	0.000 0.000						
	CUTFAC: 0.100 CUTABS: .1*PC+CF QC1 N Interpretation: QC2 N Greyzone%(Y) QC3 N Cutoff Index (N				10.0							
	QC4	N	Range									
	HCV, 2	1/07/08										
	A W1 B	W2 S4	W3 S12	W4 S20	W5 S28	W6 S36	W7 S44	W8 S52	W9 S60	W10 S68	W11 S76	W12 S84
	0.002 0.000	OPD13 0.147 1.302 POS	OPD21 0.091 0.803 NEG	OPD29 0.011 0.099 NEG	OPD37 0.083 0.737 NEG	OPD45 0.127 1.122 POS	OPD53 0.362 3.201 POS	OPD61 0.072 0.636 NEG	OPD69 0.400 3.533 POS	OPD77 1.454 12.84 POS	OPD85 0.743 6.564 POS	OPD93 0.222 1.959 POS
	B W1 NC	W2 S5 OPD14		W4 S21 OPD30	W5 S29 OPD38	W6 S37 OPD46	W7 S45 OPD54	W8 S53 OPD62				W12 S85 OPD94
	0.062 0.000	0.145 1.278 POS	0.382 3.372 POS	2.535 22.39 POS	0.116 1.024 EQ	1.470 12.99 POS	2.573 22.73 POS	0.115 1.011 EQ	2.515 22.22 POS	0.747 6.597 POS	0.748 6.608 POS	0.003 0.025 NEG
	C W1 NC	W2 S6 OPD15		W4 S22 OPD31	W5 S30 OPD39	W6 S38 OPD47	W7 S46 OPD55	W8 S54 OPD63				W12 S86 OPD95
	0.040 0.000	2.573 22.72 POS	0.129 1.136 POS	0.159 1.405 POS	0.133 1.177 POS	0.217 1.917 POS	0.077 0.677 NEG	0.091 0.804 NEG	1.584 13.99 POS	1.557 13.75 POS	0.502 4.434 POS	2.638 23.30 POS
	D W1 PC	W2 S7 OPD16	W3 S15 OPD24	W4 S23 OPD32	W5 S31 OPD40	W6 S39 OPD48	W7 S47 OPD56	W8 S55 OPD64	W9 S63 OPD72	W10 S71 OPD80	W11 S79 OPD88	W12 S87 OPD96
	0.080	0.157 1.389 POS	2.630 23.23 POS	0.141 1.246 POS	2.642 23.33 POS	0.058 0.516 NEG	0.155 1.370 POS	0.159 1.403 POS	1.515 13.38 POS	0.071 0.628 NEG	0.423 3.732 POS	0.209 1.850 POS
	E W1 PC	W2 S8 OPD17	W3 S16 OPD25	W4 S24 OPD33	W5 S32 OPD41	W6 S40 OPD49	W7 S48 OPD57	W8 S56 OPD65	W9 S64 OPD73	W10 S72 OPD81	W11 S80 OPD89	W12 S88 OPD97
	2.562 0.000	0.172 1.517 POS	0.198 1.751 POS	0.061 0.536 NEG	0.182 1.612 POS	0.165 1.457 POS	2.656 23.46 POS	0.156 1.377 POS	0.080 0.705 NEG	2.616 23.11 POS	0.259 2.291 POS	0.224 1.978 POS
	F W1 S1 OPD10 2.626 23.19 POS	W2 S9 OPD18 2.612 23.07 POS	W3 S17 OPD26 0.055 0.483 NEG	W4 S25 OPD34 0.116 1.023 EQ	W5 S33 OPD42 2.649 23.40 POS	W6 S41 OPD50 0.188 1.660 POS	W7 S49 OPD58 0.176 1.553 POS	W8 S57 OPD66 0.052 0.460 NEG	W9 S65 OPD74 2.638 23.30 POS	W10 S73 OPD82 0.855 7.548 POS	W11 S81 OPD90 0.899 7.942 POS	W12 S89 OPD98 0.419 3.699 POS
	G W1 S2 OPD11 0.049 0.429 NEG H	W2 S10 OPD19 0.140 1.234 POS	W3 S18 OPD27 2.595 22.92 POS	W4 S26 OPD35 0.138 1.215 POS	W5 S34 OPD43 0.142 1.252 POS	W6 S42 OPD51 0.117 1.035 EQ	W7 S50 OPD59 2.611 23.06 POS	W8 S58 OPD67 0.076 0.672 NEG	W9 S66 OPD75 0.081 0.717 NEG	W10 S74 OPD83 0.050 0.441 NEG	W11 S82 OPD91 0.403 3.564 POS	W12 S90 OPD99 2.579 22.78 POS
	W1 S3 OPD12 0.061 0.538 NEG	W2 S11 OPD20 0.109 0.964 EQ	W3 S19 OPD28 0.002 0.018 NEG	W4 S27 OPD36 0.071 0.631 NEG	W5 S35 OPD44 0.076 0.670 NEG	W6 S43 OPD52 0.131 1.157 POS	W7 S51 OPD60 0.109 0.960 EQ	W8 S59 OPD68 0.101 1.896 NEG	W9 S67 OPD76 0.082 0.721 NEG	W10 S75 OPD84 2.560 22.61 POS	W11 S83 OPD92 0.399 3.527 POS	W12 S91 OPD100 0.015 0.132 NEG

#### 8.4. Reverse Cut Off Mode

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



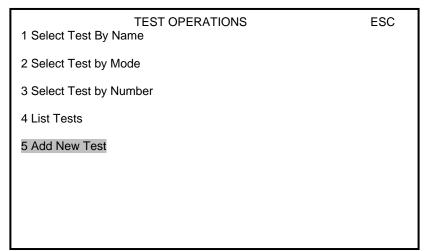
In reverse Cut Off mode, programming of test is same as Positive Cut off mode; only QC check conditions for blanks and controls get reversed. And in 'INTERPRETATION' sample absorbance which are lesser than cut off absorbance gets remarked POSITIVE and sample absorbance higher than cut off absorbance gets remarked NEGATIVE, this exactly opposite to normal POSITIVE Cut Off mode. Same way it does the interpretation in case you select 'Cutoff Index Range'.

#### 8.5. Multi Standards 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:

1. Select Main Menu/Test Operation/Add new test



2. Select Touch Zone "Multi Standard".

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

> After selecting the Multistandard mode below screen will come in the display

Name:		MULTISTAN		500
Pri: 405 Sec: 0		BL N DUP N	CAL 2 DUP N	ESC
Graph: LINEAR	2			SAVE
Y vs X : ABS vs	CONC			
HI CO : N	High> Low<			
LO CO: N	High> Low<			
Interpretation: N				
Range	High>			
	Low<			

### 3. Entry of Test Name:

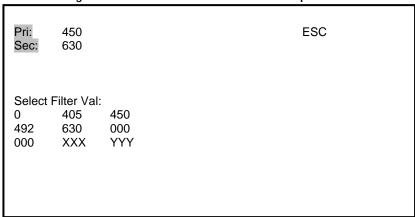
- > Test Name can be entered by Selecting Touch Zone "Name:".
- > Procedure for entering the test name is same as that of cut off mode. Refer Test Name entry in Cut off mode for further details.

- 4. Selection of Primary and secondary filters
  - Select Touch Zone "Pri:"

Name: TSH Pri: 405 Sec: 0		MULTISTANDA BL N DUP N	RD CAL 2 DUP N	ESC SAVE
Graph: LINEAF Y vs X: ABS vs				SAVE
HI CO : N	High> Low<			
LO CO: N Interpretation: N	High> Low<			
Range	High>			
	Low<			

After selecting the Zone "Pri:" below screen will come in the display

> Select the filters as per details given in the reagent manual by selecting the filter number given in the "Select Filter value:" option.



- 5. Selection of Blank
  - Select Touch Zone "BL".

Name: Pri: 405 Sec: 0	В	MULTISTANDAR BL N DUP N	D CAL 2 DUP N	ESC
Graph: LINEAR Y vs X: ABS vs 0	CONC			SAVE
	High> Low<			
	High> Low<			
Range	High> Low<			

Instrument will display the message "Blank required Yes/No". At the bottom of the Screen as shown below, select yes if blank is required

Name: Pri: 405 Sec: 0		MULTISTANDA BL N DUP N	ARD CAL 2 DUP N	ESC
Graph: LINEAR Y vs X: ABS vs				SAVE
HI CO : N	High> Low<			
LO CO: N Interpretation: N	High> Low<			
Range	High>			
	Low<	YES		
Blank Required 1	?	NO		

- 6. Entry of Standard Concentration:
  - Select touch Zone "CAL" to enter Number of calibrators and its concentration.

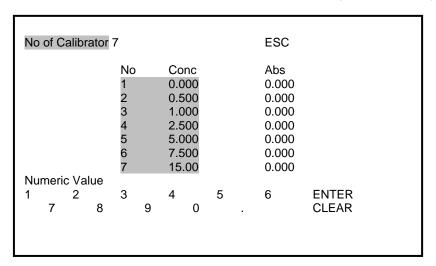
Name: Pri: 405 Sec: 0		MULTISTANDAF BL N 0.000 DUP N	ESC
Graph: LINEAR Y vs X: ABS vs			SAVE
HI CO : N	High> Low<		
LO CO: N	High> Low<		
Interpretation: N Range	High>		
	Low<		

- > After selecting "CAL" below screen will come in the display.
- > Select Touch Zone "No. Of Calibrators". Numerals will display on the bottom of the screen
- > Select the number of calibrators (User can select min 2 and Maxim 12 standard in this mode)

No Of Calibrator	2	ESC	
	No 1	Conc 0.000	Abs 0.000
	2	0.000	0.000
Numeric Value 1 2 7 8	3 9	4 5 .	6 ENTER CLEAR

#### Concentration Entry:

- > After entering the number of calibrators. Concentration and absorbance column will come in 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: The concentration value should be either ascending or descending order.)



Programming Screen after Entry of standards.

Name: TSH Pri: 450 Sec: 630	MULTISTANDARD BLY 0.000 CAL7 ESC	
Graph: LINEAR	DUP N DUP N SAVE	
Y vs X : ABS vs C0		
HI CO : N F	> <	
LO CO: N H	> <	
Interpretation: N Range H	>	
L	<	

- 7. Selection of Duplicate Blank and calibrators
- A) For Duplicate Blank:
  - > To select the duplicate blank select touch zone "DUP" below the "BLN"

Name: Pri: 405 Sec: 0		MULTIS BL Y DUP N	TANDAF 0.000	RD CAL 7 DUP N	ESC
Graph: LINEAF Y vs X: ABS vs					SAVE
HI CO : N	High> Low<				
LO CO: N	High> Low<				
Interpretation: N					
Range	High>				
	Low<				

> After selecting "DUP" instrument will display message "Duplicate Blank Yes/No" as shown below. Select "Yes" for Duplication of Blank.

Name: Pri: 405 Sec: 0		MULTIS BL Y DUP N	TANDAF 0.000	 ESC SAVE
Graph: LINEAF Y vs X: ABS vs				SAVE
HI CO : N	High> Low<			
LO CO: N Interpretation: N	High> Low<			
Range	High>			
Dunlingto Blanks	Low<	YES		
Duplicate Blank?		NO		

B) For Duplicate Calibrators:

> To select <u>Duplicate Calibrator select Touch Zone "DUP" below the "CAL 7"</u>

Name: Pri: 405 Sec: 0		MULTIS BL Y DUP Y	TANDAR 0.000	RD CAL 7 DUP N	ESC
Graph: LINEAR Y vs X: ABS vs					SAVE
HI CO : N	High> Low<				
LO CO: N	High> Low<				
Interpretation: N Range	High>				
	Low<				

> After selecting "DUP" instrument will display message "Duplicate Calibrator Yes/No" as shown below. Select "Yes" for Duplication of calibrator.

Name: Pri: 405 Sec: 0		MULTIS BL Y DUP Y	TANDAF 0.000	RD CAL 7 DUP N	ESC
Graph: LINEAF Y vs X: ABS vs					SAVE
HI CO : N	High> Low<				
LO CO: N Interpretation: N	High> Low<				
Range	High>				
	Low<	YES			
Duplicate Calibra	ator?	NO			

> Screen after standard entry & selection of duplicate - Blank & Calibrators.

Name: Pri: 405 Sec: 0		MULTIS BL Y DUP Y	TANDAR 0.000	RD CAL 7 DUP Y	ESC
Graph: LINEAR Y vs X: ABS vs CONC					SAVE
HI CO : N	High> Low<				
LO CO: N Interpretation: N	High> Low<				
Range	High> Low<				

8) Linear mode and Point to Point mode

There are two types of graphs in Multistandard

- 1) Linear (LINEAR)
- 2) Point to Point (PT TO PT)

There are five types of scales for X and Y axis

- 1) LOGABS vs CONC (X-axis = Concentration v/s Y-axis = LOG of ABS.)
- 2) ABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = Absorbance)
- 3) LOGITABS VS LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOGIT of Absorbance)
- 4) ABS vs CONC (X-axis = Concentration v/s Y-axis = Absorbance)
- 5) LOGABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOG of absorbance)

#### A) Selection of Graph

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

Name: **MULTISTANDARD** Pri: 405 Sec: 0 BLN CAL2 **ESC** DUP N DUP N SAVE Graph: LINEAR Y vs X: ABS vs CONC HI CO: N Low< LO CO: N High> Low< Interpretation: N Range High> Low<

A) Linear mode graph type:

- ➤ After Selecting the "Graph" below screen will come in the display
- Select Graph type as Linear
- Select scale as per the details given in the reagent manual.

Graph: LINEAR Y vs X: ABS vs CONC **ESC** 

TYPE SCALE

LINEAR LOGABS vs CONC

ABS vs LOGCONC

PT TO PT LOGITABS vs LOGCONC

ABS vs CONC

LOGABS vs LOGCONC

B) Point to Point Graph Type

Select touch zone "PT to PT" abs scale of graph 'ABS vs. CONC'

PT TO PT **ESC** Graph Type: Y vs X: ABS vs CONC

**TYPE SCALE** 

LINEAR LOGABS vs CONC

ABS vs LOGCONC

LOGITABS vs LOGCONC PT TO PT

ABS vs CONC

LOGABS vs LOGCONC

Select the scale type touching the required zone.

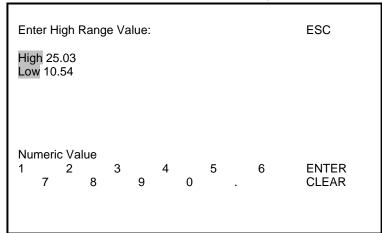
Name: Pri: 405 Sec: 0		MULTISTANDA BL N DUP N	ARD CAL 2 DUP N	ESC
Graph: PT TO PT Y vs X: ABS vs CONC				SAVE
HI CO : N	High> Low<			
LO CO: N Interpretation: N	High> Low<			
Range	High> Low<			

#### 9. Selection of Controls

A) For High control select zone 'HI CO: N' It will ask "High Control Required? Yes / No". Select 'YES' and then enter range of control "HIGH" and "LOW".

Name: Pri: 405 Sec: 0		MULTISTAND BL N DUP N	ARD CAL 2 DUP N	ESC SAVE
Graph: LINEAR Y vs X: ABS vs				
HI CO : N	High> Low<			
LO CO: N	High> Low<			
Interpretation: N Range	High>			
	Low<	YES		
High Control Rec	quired?	NO		

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



Name: **MULTISTANDARD** Pri: 405 Sec: 0 **ESC** BL N CAL 2 DUP N DUP N SAVE Graph: LINEAR Y vs X: ABS vs CONC HI CO: N High>25.03 Low<10.54 LO CO: N High> Low< Interpretation: N Range High> Low<

B) For Low control select zone 'LO CO: N' It will ask "Low Control Required? Yes / No". Select 'YES'

MULTISTANDARD Name: Pri: 405 Sec: 0 **ESC** BL N CAL 2 DUP N DUP N SAVE Graph: LINEAR Y vs X: ABS vs CONC HI CO: N High>25.03 Low<10.54 LO CO: N High> Low< Interpretation: N Range High> Low< YES Low Control Required? NO

> Enter the range 'High' and 'Low' as per the reagent manual.

High> 16.61 ESC

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

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### 10. Normal Range selection for interpretation of samples:

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

MULTISTANDARD Name: Pri: 0 Sec: 0 BL N CAL 2 **ESC** DUP N DUP N SAVE Graph: LINEAR Y vs X: ABS vs CONC HI CO: N High>25.03 Low<10.54 LO CO: N High>16.61 Low<5.45 Interpretation: N Range High> Low<

> Enter Normal Range for positive and negative samples.

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

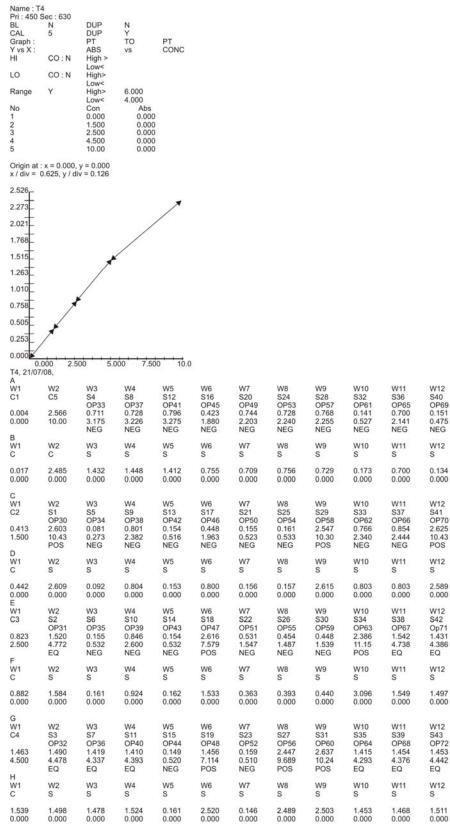
> After entering all the parameter save the test by selecting "SAVE" option.

Name: TSH **MULTISTANDARD** Pri: 450 Sec: 630 BL Y 0.000 CAL 7 **ESC** DUP N DUP N SAVE Graph: LINEAR Y vs. X: ABS vs CONC High>25.03 HI CO: N Low<10.54 LO CO: N High>16.61 Low<5.45 Interpretation: Y Range High> 15.25 Low< 9.46

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

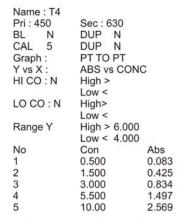
#### 11 Example Print-out obtained From **readwell TOUCH**

MULTI STDS

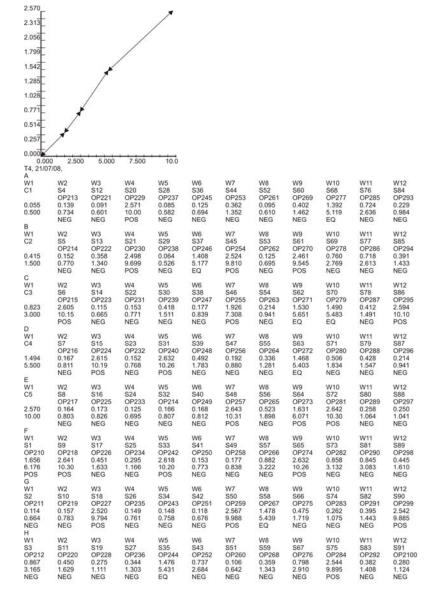


#### 12 Example Print-out obtained From **readwell TOUCH**

#### **MULTI STDS**



Origin at : x = 0.000, y = 0.000x/div = 0.625, y/div = 0.128



## 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.

Name: TSH % ABSORBANCE Pri: 450 Sec: 630 BL Y 0.000 CAL 1 **ESC** DUP N DUP N SAVE HI CO: N High> Low< LO CO: N High> Low< Interpretation: N Range High> Low<

## 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 0.0. 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 == Calibrator Absorbance \* Calibrator Concentration

#### **Sample Absorbance**

Name: TSH Pri: 450 Sec: 630		UPTAKE BL Y 0.000 DUP N	CAL 1 DUP N	ESC SAVE
HI CO: N	High> Low<			
LO CO: N Interpretation: N Range	High> Low<			
	Low<			

> Please refer single standard for parameter entry.

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# 8.8. Kinetic mode of Operation:

To create a new test in "KINETIC" mode.

KINETIC
Name: KINETIC
ESC
Pri: 405 Sec: 0
SAVE
Read Time: 1 min.
Read Period: 15 sec.

"Read Time" is total read period of whole test. You need to enter it only in minutes.

"Read Period" is time interval between two readings. You must enter it in seconds. The instrument will automatically calculate the number of readings.

Select primary and secondary filters, give a name to test and save it.

#### To run the kinetic test.

		KINETIC	
Name : KINETIC	MINETIO	ESC	
Pri: 405 Sec: 0			EDIT
Read Time :	1	min.	RUN
Read Period :	15	sec.	PRINT

Select "RUN" to start. The following screen will appear.

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.

	KINETIC 5 Sec		KINETI	С			
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		
la Diata	. I oodod		YES				
is Plate	Loaded		NO				
	DDI. :-	MATRIX	OENE	DI ATE !	OAD NEVT		
ESC	PRINT	MATRIX	SEND	PLATE L	OAD NEXT		

	KINETIC	000	KINETIC			
Pri : 40 D/M 1	5 Sec: D/M 2	D/M 3	D/M 4	D/M 5	D/M 6	
D/M	D/M	D/M	D/M	D/M	D/M	
7	8	9	10	11	12	
	_		YES			
Is Plate	Remove	d	NO			
ESC	PRINT	MATRIX	SEND PLATE LOAD NEXT			

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

		BANCE : 630	_	RBANCE	
   		D/M 3 0.010	0.000		
0.030 D/M 7 0.020  	0.056 D/M 8 0.002	0.075 D/M 9 0.010	D/M 10	D/M	12
0.030 ESC		0.075 MATRIX		0.068 PLATE	

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...

```
W1
      W2
             W3
                   W4
                          W5
                                W6
0.200  0.100  1.200  0.300  2.600  0.900.. these are initial absorbances.
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
             W3
                          W5
      W2
                   W4
                                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..
```

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

<sup>&</sup>quot;LOAD NEXT" uses to get the absorbance of next plate.

#### 13 Example Print-out obtained From **readwell TOUCH**

#### KINETIC

Name : KINETIC 1

 Pri : 405
 Sec : 630

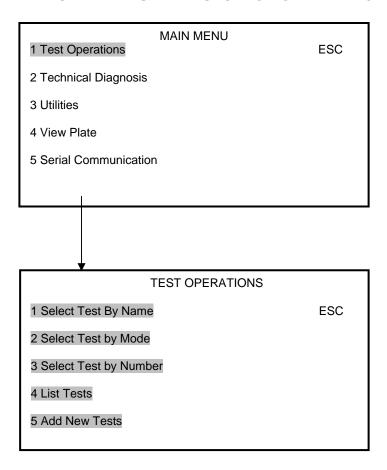
 Read Timer
 5 min

 Read Period
 60 sec

KINETIC 1, 12/9/09, 16:28:27,

	, , . , . , .	05, 10.20.									
A											
W1 0.303	W2 0.373	W3 0.249	W4 0.270	W5 0.306	W6 0.294	W7 0.251	W8 0.242	W9 0.234	W10 0.258	W11 0.251	W12 0.242
0.000	-0.002	-0.004	-0.006	0.002	-0.012	-0.005	-0.009	0.000	-0.008	0.002	0.000
0.000	-0.002	-0.004	-0.006	0.002	-0.012	-0.005	-0.009	0.000	-0.008	0.002	0.000
В	0.002	-0.001	-0.000	0.002	-0.012	-0.003	-0.003	0.000	-0.000	0.002	0.000
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.250	0.225	0.272	0.378	0.233	0.287	0.278	0.260	0.253	0.220	0.270	0.275
-0.002	0.002	0.005	0.000	0.001	-0.003	0.000	-0.014	-0.001	0.000	-0.001	0.000
-0.002	0.002	0.005	0.000	0.001	-0.003	0.000	-0.014	-0.001	0.000	-0.001	0.000
C	0.002	0.003	0.000	0.001	-0.003	0.000	-0.014	-0.001	0.000	-0.001	0.000
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.243	0.217	0.195	0.203	0.254	0.209	0.244	0.206	0.338	0.280	0.295	0.251
0.243	-0.004	-0.000	0.203	-0.000	-0.001	0.244	-0.004	-0.004	-0.011	-0.001	0.251
0.002	-0.004	-0.000	0.002	-0.000	-0.001	0.000	-0.004	-0.004	-0.011	-0.001	0.004
D.002	-0.004	-0.000	0.002	-0.000	-0.001	0.000	-0.004	-0.004	-0.011	-0.001	0.004
	TAPE	3409	347.4	****	w	14.07	1470	TATO	1474.0	1474.4	was
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.232	0.248	0.235	0.197	0.168	0.235	0.331	0.242	0.187	0.273	0.292	0.213
0.001	0.005	-0.003	-0.007	0.001	0.005	-0.001	-0.005	0.006	-0.002	-0.003	0.000
E	1477	*****	****	****	****	****	*****	*****	****	****	*****
W1	W2	W3	W4 0.221	W5 0.233	W6	W7	W8	W9	W10	W11 0.210	W12
0.258	0.215	0.224			0.240	0.173	0.203	0.195	0.199		0.172
0.001	0.000	0.001	-0.001	-0.005	0.004	-0.001	-0.002	0.002	0.002	0.002	0.002
0.001	0.000	0.001	-0.001	-0.005	0.004	-0.001	-0.002	0.002	0.002	0.002	0.002
F	1470	1400	****	7.47P	W6	24700	1410	1400	1414.0	11144	3474.0
W1	W2	W3	W4	W5		W7	W8	W9	W10	W11	W12
0.258	0.189	0.249	0.241	0.236	0.266	0.289	0.312	0.226	0.357	0.273	0.190
0.000	-0.002	-0.002	0.001	0.001	0.000	0.007	0.004	0.005	-0.000	0.006	-0.003
0.000	-0.002	-0.002	0.001	0.001	0.000	0.007	0.004	0.005	-0.000	0.006	-0.003
G	TARR	3400	147.4	****	****	TA155	*****	1410	14/4 0	1474.4	11140
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.251	0.239	0.257	0.235	0.306	0.240	0.288	0.195	0.202	0.244	0.241	0.204
0.001	0.001	0.001	0.001	012	0.000	0.016	-0.001	0.000	0.002	-0.000	0.000
0.001	0.001	0.001	0.001	0.012	0.000	0.016	-0.001	0.000	0.002	-0.000	0.000
H	*****	3400	147.4	****	****	****	*****	1410	1474.0	1414.4	X1140
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.259	0.241	0.213	0.253	0.258	0.221	0.235	0.218	0.258	0.251	0.242	0.221
0.003	-0.003	-0.000	-0.003	-0.001	0.001	-0.002	-0.000	-0.000	-0.001	0.002	-0.001
0.003	-0.003	-0.000	-0.003	-0.001	0.001	-0.002	-0.000	-0.000	-0.001	0.002	-0.001

## 9. RECALLING AND RUNNING OF STORED TEST/PROGRAMS



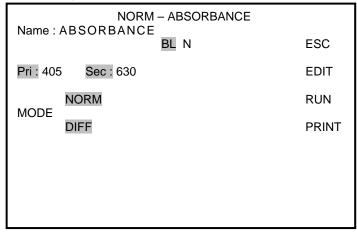
Test can be recall by Name, Mode, Number or by List test.

\* The entire saved test are available on first screen, tests can be selected from this screen also.

READWELL TOUCH ABCDEFGHIJKLM	01/01/08
Select Test 1 HBSAG	MENU SEL
2 TSH	PRNT NXT PREV
3.ABSORBANCE	DEL

## 9.1. Absorbance Mode:

Select the test by "SEL" option.



> Below screen will appear on the display after selecting the Run display

The instrument will ask "Is Plate Loaded? YES / NO" Press Yes. Instrument will read the absorbances using mechanical plate movement. After completion of reading it will ask

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

	ABSOR 5 Sec		NORM BL		ORBANCE
ABS 1	ABS 2	ABS 3	ABS 4	ABS 5	ABS 6
ABS 7	ABS 8	ABS 9	ABS 10	ABS 11	ABS 12
Is Plate	Loaded		YES		
lo i late	Louded		NO		
ESC	PRINTMATRIX		SEND	PLATE I	LOAD NEXT

Name: ABSORBANCE Pri : 405 Sec : 630			NORM – ABSORBANCE BL N			
ABS 1	ABS 2	ABS 3	ABS 4	ABS 5	ABS 6	
ABS 7	ABS 8	ABS 9	ABS 10	ABS 11	ABS 12	
le Plate	Pomove	nd.	YES			
Is Plate Removed			NO			
ESC	PRINT	MATRIX	SEND PLATE LOAD NEXT			

Details of absorbances of all well in table format for each strip will display in the screen as shown below.

Name: ABSORBANCE Pri : 405 Sec : 630			_	– ABSOI N	RBANCE
ABS 1 0.125   	ABS 2 0.250	ABS 3 0.350	4	5	ABS 6 0.650
0.125	0.250	0.350	0.450	0.550	0.650
ABS 7 0.125   	ABS 8 0.250	ABS 9 0.350	ABS 10 0.450	11	12
0.125 ESC	0.250 PRINTI	0.350 MATRIX	0.450 SEND	0.550 PLATE	0.650 LOAD NEXT

In this operation if you keep BLANK YES The first well of first strip will be consider as blank and instrument will gives the absorbances 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 send to computer using either USB or SERIAL RS232.

"LOAD NEXT" uses to get the absorbance of next plate.

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

Name: Pri : 40	ABSORE	BANCE : 630	NORM BL N	– ABSO	RBANCE
ABS 1	ABS 2 0.100 0.200 0.300 0.400 0.500 0.600 0.700 0.800	ABS 3	ABS 4 0.900 1.000 1.100 1.200 1.300 1.400 1.500 1.600	ABS 5	ABS 6 1.700 1.800 1.900 2.000 2.100 2.200 2.300 2.400
ABS 7	ABS 8 0.100 0.200 0.300 0.400 0.500 0.600 0.700 0.800	ABS 9	ABS 10 0.900 1.000 1.100 1.200 1.300 1.400 1.500 1.600	ABS 11	ABS 12 1.700 1.800 1.900 2.000 2.100 2.200 2.300 2.400
ESC	PRINT	MATRIX	SEND I	PLATE	LOAD NEXT

It is showing the absorbances 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 0.200 0.100 1.200 0.300 2.600 0.900..

0.000 0.100 0.000 0.900 0.000 1.700..

В

W1 W2 W3 W4 W5 W6 0.300 0.100 1.200 0.200 2.600 0.800..

0.000 0.200 0.000 1.000 0.000 1.800..

### 9.2. Cut off Mode:

Name: HBSAG Pri: 450 Sec: 63	80	POS- C	POS- Cut Off				
No BL 1 NC 3 PC 2 LC 0 CC 0 CUTFAC: 0.200 CUTABS: (0.45 QC1 > Y QC2 N QC3 N QC4 N	1.000 1.000 1.000 1.000 1.000 * NC) + (	Interpre Greyzo Cut off	•	000	Rem	SAVE	

1) You can run this test by selecting RUN option. "PRINT" is used to print the details of test parameters.

A screen will come as follows,

```
Name: HBSAG
                      POS- Cut Off
Pri: 450 Sec: 630
                                                      ESC
No. of Samples: 0
                                                      RUN
DUP N
               SIMUL
                                                      PID
                5
                    6
                        7
                           8
                                     10
                                          11
                                                12
В
NC
NC
NC
PC
PC
```

2) It shows the 12 strips horizontal with 8 wells vertical with blanks and controls loaded in first strip. You enter no. of samples by selecting that option and enter no. of samples, you want to load. In case of 10 samples.

	Name: HBSAG POS- Cut Off Pri: 450 Sec: 630								
No. of Sam DUP N	No. of Samples : 10 DUP N SIMUL								
1 2 3 B S3 NC S4 NC S5 NC S6 PC S7 PC S8 S1 S9 S2 S10	3 4	5 6	7	8	9	10	11	12	

3) After entering No. of samples, press RUN. The plate-loading tray will come out and a message will appear "Is plate loaded? YES / NO".

```
Name: HBSAG
                      POS- Cut Off
Pri: 450 Sec: 630
                                                   ESC
                                                   RUN
No. of Samples: 10
DUP N
              SIMUL
                                                   PID
   2
                5
                    6
                        7
                            8
                               9
                                     10
                                          11
                                               12
В
    S3
NC
   S4
NC
   S5
NC S6
PC S7
PC S8
S1
   S9
S2
   S10
                      YES
Is Plate Loaded
                      NO
```

4) Here you load the plate in the direction that controls should go in first. And press "YES". The instrument will read the controls and samples, and then it will bring the tray out. This time a message will come "Is plate removed? YES / NO". You remove the tray and press YES.

Name: HBSAG Pri: 450 Sec: 630	ESC	
No. of Samples : 10 DUP N SIMUL	RUN PID	
1 2 3 4 5 B S3 NC S4 NC S5 NC S6 PC S7 PC S8 S1 S9 S2 S10	6 7 8 9 10 11 12	
Is Plate Removed	YES	
13 Flate Removed	NO	

5) After pressing YES, result screen will come, where you will get the measured values of mean blank, mean of all controls, cut off absorbance.

Name: HBSAG Pri: 450 Sec: 630			POS- C	Cut Off		ESC	
BL NC PC	No 1 3 2	Factor 1.000 0.100	QC Y Y Y	QCVal 0.100 0.150 0.500	Mes. 0.050 0.098 2.658	Rem	ACCEPT TEST PRINT
LC CC	0 0 AC: 0.200	1.000 1.000	N N CUTAE	3S: 0.563			Display
QC1 2 QC3	.560	QC2 QC4					LOAD NEXT
Range	% 10.00						

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6) To check the results of samples, select option 'Display value:', you will get the details as shown below,

Name: HBS		ESC							
	Pri: 450 Sec: 630 BL 1 Range PERCENTAGE % 10.00 Pos: 0.330								
CUT ABS=	0.300		:0.270			PREV			
NO SAM A1 B B1 NC 	1P ABS 0.050	AVG 0.050	CONC	REM	PID				
F1 S1 G1 S2	0.200 1.854	0.200 1.854	0.254 7.245	NEG POS	HIV-1 HIV-2				
PRINT RESULTS	SAV RES	E ULTS	NT RIX	PLATE OPT.					

7) By selecting 'ACCEPT TEST' option you can save this test with the details of controls absorbance. So next time it is possible to you to run the same test without loading controls. Means using previous stored values of controls, you can find the results of new samples.

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

Or you can get 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 parameter in print matrix for a single well.

ROW IDENTIFICATION
WELL NUMBER
WELL ID OR SAMPLE NUMBER
PATIENT IDENTIFICATION
WELL ABSORBANCE
SAMPLE CONCENTRATION
INTERPRETATION / REMARKS

A,B, C,D,.....
W1, W2, W3, W4....
BL, NC, PC, OR S1, S2, S3, ....
RAMESH, VIKAS, etc.
0.050, 0.098, 0.085, ...
0.738, 0.689, 2.578,...
POS or NEG or EQ

#### 9.2. A. Invalid Assay in Cut Off Mode:

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

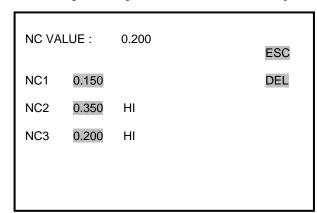
Name: HBSAG Pri: 450 Sec: 630			POS- (	POS- Cut Off			ESC		
BL NC PC LC CC CUTFA	No 1 3 2 0 0 .C: 0.200	1.000 0.100 1.000 1.000	QC Y Y Y N N CUTAE	QCVal 0.100 0.150 0.500	Meas. 0.105 0.200 0.456	Rem HI HI LO	ACCEPT TEST PRINT Display		
QC1 2 QC3 <u>Invalic</u>	.560 HI <u>I Assay</u>	QC2 QC4					VALUE: LOAD NEXT		

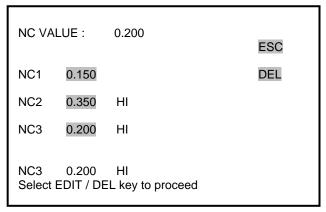
(NOTE: The absorbance of controls should not go above 3.500. If it goes more than 3.50, it will show you the remark 'HI' for that control. In such a case edit the control absorbance.)

In such a case, you can easily delete an individual control, so that the mean of remaining controls will satisfy the QC condition of that control as per reagent manual.

To select any control for deleting, you select touch zone shown in above screen. When you select any particular control for deleting (suppose you have selected Negative Control (NC)),

Here you will get a following screen, which will show you, which control is not satisfying the QC condition with 'HI' or 'LO' remark. You can delete that particular control. When you select that control, a message will get display "Select EDIT / DEL key to proceed", here select 'DEL' key. After deleting that control, the absorbance of that control will become zero and the average of controls will also get changed. Then select 'ESC' key to come back.





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

\*NOTE: 1) In test with blank, if blank do not satisfies the QC condition first make the blank absorbance valid, and then if necessary valid the control absorbances. This is because, the absorbance of blank affect the absorbance of all controls and samples.

\*NOTE: 2) It is recommended that, for a test with single Blank and single control, if absorbance not satisfies QC condition or if located all controls of any single type (means all NC controls or all PC controls) not satisfy the QC condition, the test will become totally invalid. It is not possible to make it VALID TEST and you must load the new controls.)

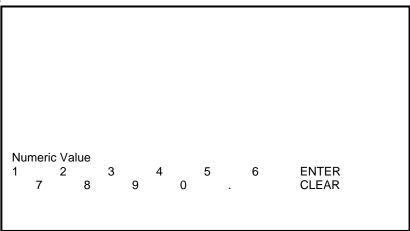
## 9.3. Multi Standard Mode:

Name: TSH Pri: 450 Sec: 63	MULTISTANDARD 0 BL Y 0.000 CAL 7 DUP N DUP N	ESC
		EDIT
Graph: LINEAR Y vs X: ABS vs		RUN
HI CO : N	High>25.03 Low<10.54	PRINT
LO CO: N	High>16.61 Low<5.45	
Interpretation: Y	115-h 45-05	
Range	High> 15.25	
To change value	Low< 9.46 es press EDIT	

1) You can run this test by selecting RUN option. A screen will come

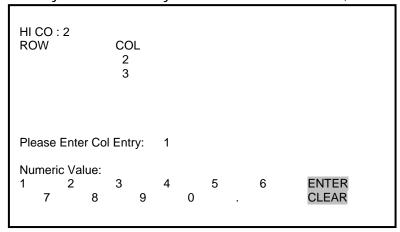
```
Name: TSH
                     MULTISTANDARD
Pri: 450 Sec: 630
                                                 ESC
No. of samples: 0
                                                 RUN
DUP N SIMUL
                                                 PID
1
    2 3 4
                5
                    6 7
                            8 9
                                    10
                                         11
                                             12
В
C1
C2
C3
C4
C5
C6
C7
HI CO: 0
COL
ROW
```

2) To enter total no. of HI controls you want to load in plate select "HI CO:" option and enter numeric value



3) If you select no. of HI controls TWO.

Then you have to locate the position of HI controls by selecting column number and row number. For column number entry select "COL" key and enter columns number,



For row entry select "ROW" key 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
```

4) You locate controls from first well of 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 3, row B for second HI control then the location of HI control will be display on screen. As shown in screen below.

```
Name: TSH
                      MULTISTANDARD
Pri: 450 Sec: 630
                                                    ESC
                                                    RUN
No. of samples: 0
DUP N
              SIMUL
                                                    PID
     2
                         7
                              8
                                  9
                                      10
                                           11
                                                 12
1
                 5
                     6
В
    HC
        HC
C1
C2
C3
C4
C5
C6
C7
HI CO: 2
COL
ROW
```

5) Now you select no. of samples you want to run. If you have 12 samples. Then the screen will appear

```
Name: TSH
                     MULTISTANDARD
Pri: 450 Sec: 630
                                                  ESC
No. of samples: 12
                                                  RUN
DUP N
              SIMUL
                                                  PID
            4 5
         3
                       7
                            8
                                9
                                    10
                                         11
                                              12
 1
    2
                    6
В
        S8
    HC
C1
    S1
        HC
C2
    S2
        S9
C3
    S3
        S10
C4
    S4
        S11
C5
   S5
        S12
C6
   S6
C7
   S7
HI CO: 2
COL
ROW
```

#### 6) THEN YOU PRESS 'RUN' TO START THE READING OPERATION.

The tray will come out. A message will come "Is Plate loaded YES / NO".

Here you load the tray in a direction that calibrators should go in first, and press YES.

The instrument will read the absorbance of calibrators and samples.

After reading a message will come "Is plate removed? YES / NO". You remove the tray and press YES. The Tray holder will go inside and a screen will come which gives details of all calibrators, samples and controls.

	e: TSH	630	_	_TI STAN / CAL	ESC		
Pri: 450 Sec: 630 Range High > 16.61 HI CO: High >			:				NXT
	CO : High		Low				PREV
NO A1	SAMP B	ABS 0.050	AVG 0.050	CONC	REM	PID	SAVE
B1 C1	C1 C2	0.070 0.257	0.070	0.000 2.500			RESULT
	02	0.237	0.237	2.500			
 	0.4			0.400	NEO	T011.4	
F1 G1	S1 S2	0.200 1.854	0.200 1.854	2.100 9.845	NEG POS	TSH-1 TSH-2	
LOA NXT			PLATE OPT.	VIE\ GRA	N NPH:	ACCEPT TEST	PRINT RESULTS

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

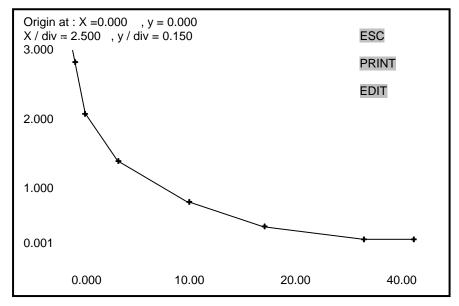
Or you can get the print in matrix format, by selecting option 'PRINT MATRIX'.

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

ROW IDENTIFICATION
WELL NUMBER
WELL ID OR SAMPLE NUMBER
PATIENT IDENTIFICATION
WELL ABSORBANCE
SAMPLE CONCENTRATION
INTERPRETATION / REMARKS

A, B, C, D,..... W1, W2, W3, W4... B, C1, C2, C3, OR S1, S2, S3,.. RAMESH, VIKAS, etc. 0.050, 0.098, 0.085, ... 0.738, 0.689, 2.578... POS, NEG, EQ,

7) By selecting option 'View Graph:' key, you can get graph on screen, with all the details of X-axis and Y-axis. You can get the graph print by selecting 'PRINT' option.



By selecting 'ACCEPT TEST' option you can save this test with the details of calibrator absorbance. So next time it is possible to you to run the same test without loading calibrators. Means using previous stored graph, you can find the results of new samples.

(\* NOTE: If you do not want to run the calibrators every time, please select "ACCEPT TEST" option to save graph, whenever you run the test with calibrators. So that it is possible for you to run the test without calibrators, using previously stored graph.)

#### 9.3. A. Invalid assay in Multi standard Mode:

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

	e: TSH I50 Sec:	630	MUL	_TI STAN BL Y	7	ESC	
Rang	ge High	> 16.61		< 10.30	NXT		
	O: High O:High		Low	< 0.000 <			
NO	SAMP	ABS	AVG	CONC	REM	PID	PREV
A1	B	0.050	0.050	CONC	KEIVI	PID	SAVE
B1	C1	0.070	0.070	0.000			RESULT
C1	C2	0.257	0.257	2.500			
Inva	lid Assa	y					
LOAI NXT			PLATE OPT.	VIE\ GR <i>A</i>	N APH:	ACCEPT TEST	PRINT RESULTS

In such a case "EDIT" option available in GRAPH screen. If you select EDIT, the following screen will appear

CAL 1	2.562	ESC	CAL 1 2.562	ESC
CAL 2	1.865		CAL 2 1.865	
CAL 3	2.050		CAL 3 2.050	
CAL 4	1.054		CAL 4 1.054	
CAL 5	0.648		CAL 5 0.648	
CAL 6	0.356		CAL 6 0.356	
CAL 7	0.045		CAL 7 0.045	
			Numeric Value: 1 2 3 4 5 7 8 9 0	6 ENTER . CLEAR

You can easily select any particular calibrator by touching that touch zone and edit the absorbance of that. After editing the calibrator's absorbance select "ESC". A message will come "PLEASE WAIT..." and you will get the modified graph.

(\*NOTE: SAME PROCEDURE YOU CAN USE TO CREATE AND RUN THE TEST IN ALL OTHER MODES, LIKE SINGLE STANDARD, % ABSORBANCE AND UPTAKE.)

## 10. RERUNNING ACCEPTED TESTS / PROGRAMS

We know "ACCEPT TEST" option is used to store the data of controls or calibrators (refer chapter 9.2 (7), page-59 and 9.3 (7), page-64). After running any test first time with controls or calibrators, you select 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.

#### 1) In "CUT OFF" Mode:

	HBSAG ) Sec: 60	30	POS- (	Cut Off	ESC		
BL NC PC	No 1 3 2	Factor 1.000 0.100	QC Y Y Y	QCVal 0.100 0.150 0.500	Mes. 0.050 0.098 2.658	Rem	ACCEPT TEST PRINT
LC CC CUTFA	0 0 AC: 0.200	1.000 1.000	N N CUTAE	3S: 0.563			Display VALUE:
QC1 2 QC3	2.560	QC2 QC4					LOAD NEXT
Range	% 10.00						

#### 2) In "Multi standard" Mode:

Name:	: TSH 50 Sec: 6	30	MUL BL Y	TI STAN			ESC
Range HI CO	e High > D : High > D : High >	> 16.61 >	Low	< 10.30 < 0.000	,		NXT
	Ü				DEM	DID	PREV
		ABS 0.050	AVG 0.050	CONC	REM	PID	SAVE
1	C1 C2	0.070 0.257	0.070 0.257	0.000 2.500			RESULT
1	_	0.200 1.854	0.200 1.854	2.100 9.845	NEG POS	TSH-1 TSH-2	
LOAD NXT	PRINT MATR		PLATE OPT.	VIEV GRA		ACCEPT TEST	PRINT RESULTS

When you want to run such a accepted test, after selecting 'RUN' option in test detail screen, In "CUT OFF" mode:

	me: H 450	_	_		F	OS-	Cut (	Off				ESC
	No. of Samples : 0 DUP N SIMUL											
1 2 3 4 5 6 7 8 9 10 11 12												
Loa	YES Load Blank?											
					N	Ю						

This time, it will not load the blank and controls directly. It will ask "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 / graph of controls select 'NO', so that you can run only samples to get their results without loading control and calibrators. If you want to load only 'Blank', select "Load Blank? YES" and "Load Controls? NO".

Name: HBSAG Pri: 450 Sec: 630	POS- Cut Off	ESC									
No. of Samples : 0 DUP N SIMUL											
1 2 3 4	l 12										
Load Controls?											
	Load Controls?										

### 2) In Multi Standard / Single Standard / % Absorbance / Uptake Mode:

	me: H 450		G : 630		F	OS-	Cut C	Off				ESC
No. of Samples : 0 DUP N SIMUL												
1 2 3 4 5 6 7 8 9 10 11 12												
YES Load Calibrators?												
					N	Ю						

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

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".

### 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 instrument takes the average of it this is 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.

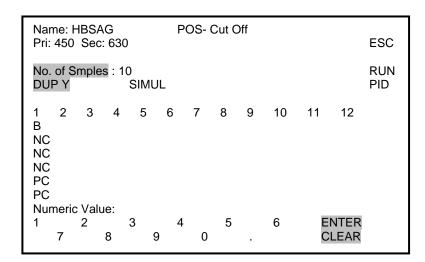
```
Name: HBSAG
                       POS- Cut Off
                                                      ESC
Pri: 450 Sec: 630
No. of Smples: 0
                                                      RUN
DUP N
               SIMUL
                                                      PID
    2
        3
            4
                 5
                     6
                         7
                              8
                                  9
                                      10
                                            11
                                                 12
1
В
NC
NC
NC
PC
PC
```

```
Name: HBSAG
                       POS- Cut Off
Pri: 450 Sec: 630
                                                       ESC
No. of Smples: 0
                                                       RUN
DUP N
               SIMUL
                                                       PID
                 5
                      6
                          7
                              8
                                       10
                                             11
                                                  12
В
NC
NC
NČ
PC
PC
Numeric Value:
                                               ENTER
1
       2
               3
                       4
                               5
                                       6
            8
                   9
                           0
                                               CLEAR
```

	Name: HBSAG POS- Cut Off Pri: 450 Sec: 630												ESC
	No. of Smples : 10 DUP N SIMUL										RUN PID		
N N F F	3 NC NC NC PC PC	2 S3 S4 S5 S6 S7 S8 S9 S10		4	5	6	7	8	9	10	11	12	

If you want to load duplicate samples select "DUP" key, it will changed from 'N' to 'Y'. After this, enter number of samples by selecting "No. of Samples".

```
Name: HBSAG
                      POS- Cut Off
Pri: 450 Sec: 630
                                                    ESC
                                                    RUN
No. of Smples: 0
DUP Y
               SIMUL
                                                    PID
                5
                        7
                    6
                            8
                                9
                                     10
                                                12
                                          11
В
NC
NC
NC
PC
PC
```

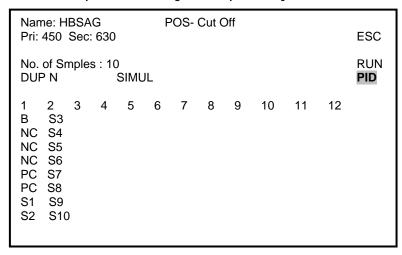


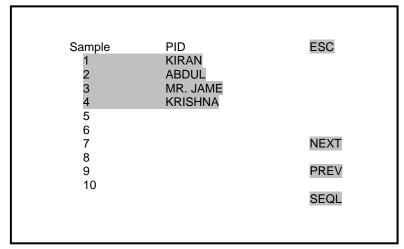
```
POS- Cut Off
Name: HBSAG
Pri: 450 Sec: 630
                                                  ESC
No. of Smples: 10
                                                  RUN
DUP Y
              SIMUL
                                                  PID
       3
           4
               5
                    6
                       7
                               9
                                    10
                                              12
                            8
                                         11
   S2 S6 S10
В
NC S2 S6 S10
NC S3 S7
NC
   S3 S7
PC
   S4 S8
PC
   S4 S8
S1
   S5 S9
S1
    S5 S9
```

(\* Same way you load the samples and Sample Duplicates in all other modes)

### 12. PATIENT IDENTITY / SAMPLE IDENTITY ENTRY

12.1. To enter a patient ID for all samples there is option provided in loading screen shown as "PID". After entering number of samples either single or duplicate, you select "PID".





One by one you can enter name of each patient. The character length of PID is only 7 characters. "NEXT" and "PREV"-previous use to go to next screen in many numbers of samples.

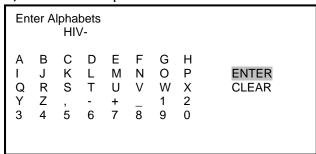
#### 12.2. Sequential Patient ID Entry: -

This one by one entry will take more time, so we have provided one more option to enter patient lds. This option is "SEQL"-sequential entry. Suppose you are loading around 80 numbers of samples for HIV test. You marked all this samples as a one batch of 80 starting from HIV-1 to HIV-80.

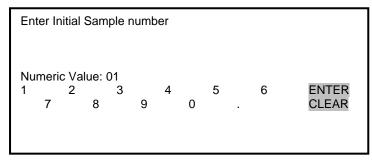
If you select "PID" option for patient ID entry, the instrument will ask the following, "Delete Previous PIDs, Yes / No". If you select NO, it will directly load the previously entered PIDs for sample and if you say YES, it will delete the previous PIDs. Here you have to enter new PIDs.

After selecting 'NO', select "SEQL" option to enter different sequential PIDs. Follow the steps as follows,

A) Enter Initial Alphabets. Maximum 4 characters



B) Enter Initial well Number. This is starting well location of that particular batch.



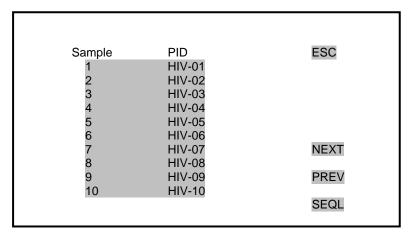
C) Enter last well Number. This is last well location of that particular batch.

Enter last s	ample nu	mbei	ſ				
Numeric Va 1 2 7	lue: 01 3 8	9	4	0	5	6	ENTER CLEAR

D) Enter initial PID Number. This is starting number of that particular batch, maximum 3 digits.

Enter in	itial PID	number					
Numerio 1 7	c Value: 2 8	01 3 9	4	0	5	6	ENTER CLEAR

The final screen will appear which will display the sequential IDs of patient samples, for the well location that you have selected.



Suppose you have totally 70 nos. of samples from three different batch which you are loading in single plate. For first batch the PID are from HIV 1 to HIV 30, for second batch PIDs are from HIV 51 to HIV 75 and the third batch has PIDs from HIV 91 to HIV 105.

To enter these PIDs, you have to enter sequential entries three times, use following steps

- 12.3. Select 'SEQL', Enter alphabet 'HIV'. Enter initial well number '1' and the last well number '30', after this enter initial PID number '1'. It will load PIDs for first 30 samples from HIV 1 to HIV 30.
- 12.4. To enter next sequence again select 'SEQL', enter alphabet 'HIV'. Enter initial well number '31' and last well number '55'. After this enter initial PID number '51'. It will load PIDs for next 25 samples from HIV 51 to HIV 75.
- 12.5. To enter next sequence again select 'SEQL', enter alphabet 'HIV'. Enter initial well number '56' and last well number '70'. After this enter initial PID number '91'. It will load PIDs for next 15 samples from HIV 91 to HIV 105.

In this way you can select any sequence for any well locations.

(\*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 stored results.

### A) In cut Off mode:

Name: HBSAG POS- Cut Off **ESC** Pri: 450 Sec: 630 BL 1 Range PERCENTAGE % 10.00 NXT SAMP ABS AVG CONC PID **PREV** NO REM 0.050 0.050 Α1 В В1 NC --SAVE **PLATE PRINT PRINT** RESULTS OPT. **RESULTS MATRIX** 

B) In Multi standard or any calibrator mode:

Name: TSH Pri: 450 Sec: 630	MULTI STANDARD	BLY CAL7	ESC
Range High > 16.61 HI CO: High >	Low < 10.30 Low < 0.000		NXT
LO CO : High >	Low <		PREV
NO SAMP ABS A1 B 0.050 B1 C1 0.070 C1 C2 0.257	AVG CONC REM 0.050 0.070 0.000 0.257 2.500	PID	SAVE RESULT
	PLATE VIEW OPT. GRAPH:	ACCEPT TEST	PRINT RESULTS

If you select "PLATE OPT.", you will get two options. Select "SAVE PLATE DATA", which will save the entire plate information along with the control/calibrator information. You can save maximum TEN plates data.

"SEND PLATE DATA" is used to send the data from instrument to computer through USB or serial RS232 connection.

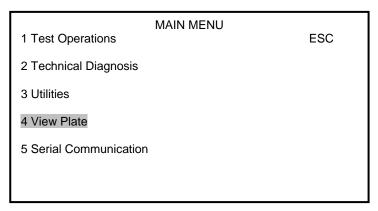
If you select "SAVE RESULT" option it will directly saves information of samples only except controls/ calibrators, with test name, patient ID and date.

1. SAVE PLATE DATA

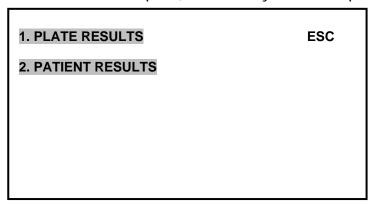
2. SEND PLATE DATA

## 14. VIEW STORED DATA

You can view the stored plate or stored results, by option "View Plate" available in "MAIN MENU".



When you will select the "View Plate" option, it will show you the two options,



1. "PLATE RESULTS" will show you the details of stored plate (last 10 plate) with date, Test name and mode of operation in descending order from last to first. You can select any test; the instrument will show you the full plate information along with controls/ calibrators in table format.

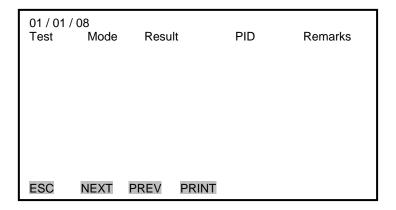
NO 4 3 2	DATE 02/01/08 01/01/08 30/12/07 28/12/07	TEST HBSAG TSH HIV HIV	MODE C M C	ESC SEL	HBSA CUT NO	ABS= ( SAI		ABS	AVG	RES	REM	02/01/08 PID
					ESC	NEXT	PREV	' PRI	NTMATR	RIX SEN	IDDATA	PRINT

Print Matrix will print the details of entire plate in matrix format as explain earlier. "Print" will print only the data displayed on screen.

"Send data" is used to send the data from instrument to computer through USB or serial RS232 connection.

2. "PATIENT RESULTS" 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. You will get the Test name, Mode of test operation, result of sample, PID and Remark. The instrument has a memory to stored 2500 sample results.

This option not shows the information of controls or calibrators.



<sup>&</sup>quot;PRINT" is used to print the details as available on display screen.

(\*NOTE: When memory gets full or remains very less memory it will display a message, "Memory Left for \_\_\_ samples First Samples Deleted")

The instrument automatically deletes required number of samples stored very first and saved the new samples at that location.

<sup>&</sup>quot;NEXT" and "PREV" option is used to go to next page of sample details and come back to previous page.

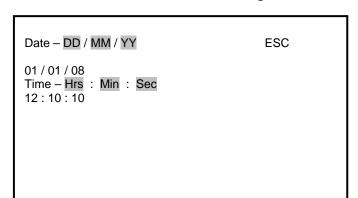
## 15. UTILITIES

In utilities we have seven different functions.

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

UTILITIES	Version (RBNK-3.308)	
1. Date and Time		Esc
2. Program Filter	I	
3. Printer On / Of	f : ON	
4. Enter Clinic Na	ame	
5. Shaker		
6. Calibrator		
7. Communicatio	on Settings: USB	
8. CV Diagnostic	OFF	

# 15.1. Date and Time Setting



Set current Date and Time by Selecting DD, MM, YY and Hrs, Min, Sec.

# 15.2. Printer On / Off setting

UTILITIES Version (RBNK-3.308)

1. Date and Time Esc

2. Program Filter.

3. Printer On / Off : ON

4. Enter Clinic Name

5. Shaker

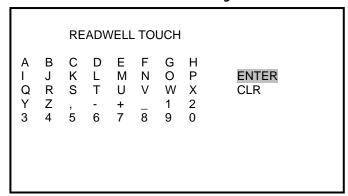
6. Calibrator

7. Communication Settings: USB

8. CV Diagnostic OFF

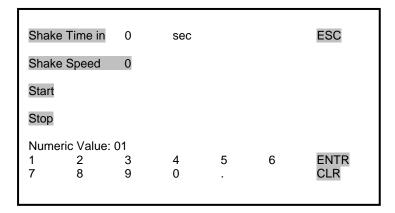
It is used to turn PRINTER On and OFF. If you do not want to use printer, you can keep it OFF by selecting this key.

# 15.3. Clinic Name Entry.



Type your Clinic Name here and select "ENTER". The character length is M\maximum 19 characters.

## 15.4. Plate Shaking Mode (Shaker)



Here a total shake time can be put in seconds.

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

After entering shake time and shake speed, select Start option. When you will select Start, the tray will come out and on screen you will get a message "Is plate loaded? -- Yes / No". This time you load the ELISA plate and select option YES.

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 shaking gets over, the system will bring the tray out and display a message "Is plate removed? Yes / No". You remove the tray and press Yes, to end the process.

# 15.5. Communication Settings:

UTILITIES	Version (RBNK-3.308)	
1. Date and T	ime	Esc
2. Program F	ilter.	
3. Printer On	/ Off : ON	
4. Enter Clini	c Name	
5. Shaker		
6. Calibrator		
7. Communio	cation Settings: USB	
8. CV Diagno	stic OFF	

UTILITIES	Version (RBNK-3.308)	
1. Date and Time	Esc	
2. Program Filter	:	
3. Printer On / Of	f : ON	
4. Enter Clinic Na	ame	
5. Shaker		
6. Calibrator		
7. Communication	on Settings: Serial	
8. CV Diagnostic	OFF	

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.

We provide one application which support to this communication between instrument and computer. This application receives data either by USB setting or by Serial setting.

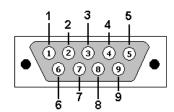
(\* The options 6. Calibrator is not for user. Do not select this utility and change settings in that. If you change any numerical values in this utility, your instrument calibration will get changed and it will not work satisfactory. This calibrator is used for the mechanical alignment of instrument. If you changed it, the mechanical alignment of instrument will get disturbed. So, Please do not go to this utility and change any setting.)

(\* The option 8. CV Diagnostic OFF is not for user. This is for factory use only.)

# 16. SERIAL COMMUNICATION

The instrument is equipped with an RS232 serial port.

RS232 DB9 (EiA/TIA 574)



READWELL TOUCH
Clinic Name or Serial Number
MAIN MENU

Date

- 1. Test Operations
- 2. Technical Diagnosis
- 3. Utilities
- 4. View Plate
- 5. Serial communications

SERIAL COMM.	ЛМ. ESC	
1. Send Results		

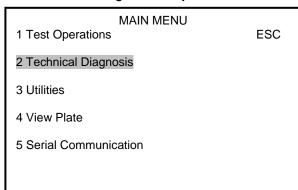
SERIAL COMM. 1. Send Results		ESC
Results	YES NO	

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## 17. TECHNICAL DIAGNOSIS

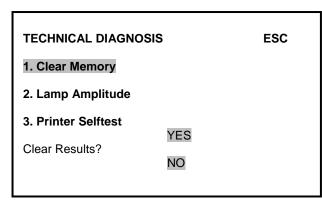
Technical Diagnosis is present in "Main Menu".



TECHNICAL DIAGNOSIS	ESC
1. Clear Memory	
2. Lamp Amplitude	
3. Printer Self test	

## 17.1. Clear Memory:

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



When you select this option, the instrument will first ask, "Clear Results? YES / NO". If you select "YES" it will start clearing only saved patient results and saved plates, stored in instrument memory, and shows message "Clearing Memory ...".

This option does not clear the

This option does not clear the programmed test saved in instrument memory.

After clearing the memory or If you select option "NO" here, it will moves forward to ask next question.

This time instrument will ask,

"Clear Test Records? YES / NO". If you select "YES" it will start clearing all programmed test saved in instrument memory, and shows message "Clearing Memory ..."

# 17.2. Lamp Amplitude.

This option is used to check the Lamp Amplitude of filters used in instrument. It shows the gain of each channel filter in table format. The range of amplitude is from 600.00 to 2450.00. If this amplitude goes below 600.00 for any channel, you will get a message "Amp -Low" for that particular channel and if it goes more than 2490.00, it will show you the over range voltage figure 2500.00 which is also not good because that is saturation level.

We have perfectly set these gains of filters within a required range. When you select this option, the lamps will turns ON, tray holder plate will come out and instrument will start showing amplitudes (gains) of all filters one by one.

Filter: 405			ESC
CH1	CH2	CH3	CH4
1800.0	2200.0	1900.0	2300.0
1800.0	2200.0	1900.0	2300.0
CH1	CH2	CH3	CH4
1950.0	2100.0	2240.0	1860.0
1950.0	2100.0	2240.0	1860.0

## 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.

# 18. TROUBLE SHOOTING

MESSAGES	CAUSE /CORRECTIVE ACTION
1) Printer disabled Disable Printer YES / NO?	Refer 6.5 "Thermal printer". 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 factory engineer.
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 checks 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
3) Invalid Assay	has reduced or intensity of lamp of that channel has become poor, so contact factory engineer.  In Cut Off and Multi standard mode if controls and standard are not proper 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.
5) "Check USB Application on Computer Do you want to continue? YES / NO"	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 select 'USB' communication, on computer and select 'YES' key to transfer data.  To avoid this message, connect proper data cable, select the same communication medium (USB or Serial), on computer data receiving application, which you have selected on instrument 'Communication Setting'.
6) Filter Movement Error!!!	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 tray. These two sensors are mounted on bottom of the mechanism. One detects the home position and second 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.
7) Plate Movement Error!!!	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 carrier. These two sensors are mounted on top of the mechanism. One detects the home position and second 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.

#### **General Considerations** 19.3.

- 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
Address —	Position
Dept	
Tel:	
Country	Fax:
Post Code	
Model No	Serial No
Accessories Returne <u>d</u>	
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 If YES, please specify	*YES/NO
b) Other Biohazard If YES, Please specify	*YES/NO